













# **Normal Breathing**



Inhalation:

- Ribcage expands, diaphragm descends
- Pleura move together with negative pressure between them
- Air comes into lungs due to atmospheric pressure exceeding pleural pressure, pressure in lungs is atmospheric pressure
- The anatomy of the peripheral lung changes before the air reaches the alveoli
- Elastic recoil causes exhalation







# **History of NPV**









# Why we changed from NPV to PPV

Large bulky negative pressure ventilators (NPVs) up to 3m long & 300kg in weight were replaced by smaller positive pressure ventilators (PPVs)

- The transition to PPV was driven by convenience, easier nursing care and space saving rather than superiority of technique
- PPVs have dominated subsequent development of respiratory support in critical care but their limitations have long been recognised
  - Ventilator-associated lung injury (including pneumonia related complications VAP)
  - Reduced cardiac output by increasing resistance to venous return
  - Invasive ventilation requires paralysis, deep sedation and intubation











# **Methods of Positive Pressure Ventilation**

- Face mask ventilators Non-invasive method using a mask that fits over the nose and mouth. Typically used to oxygen therapy when SPO2 is low. A common mode is CPAP.
- Manual resuscitator bags A simple bladder type device that the HCP squeezes to pump air into the patient's lungs. Can be attached to a facemask or ETT. Typically used for short transition or transportation periods.
- **Mechanical ventilators** An invasive method which takes over the breathing process for someone that cannot breathe on their own. The patient sedated, is intubated (an ETT or Laryngeal Mask in the throat). Then the ventilator regulates the pressure, temperature, and oxygen levels of the air that is pumped into the patient's lungs. Also used for patients who have surgery under general. For long term ventilation the patient will also have a nasal gastric tube to supply 'food'.













# **Potential Problems with PPV**

- Atelectasis, which occurs when the lungs do not expand fully, reducing the amount of oxygen that enters the bloodstream.
- Aspiration, or breathing foreign substances into the airways (e.g., saliva).
- Lung damage, which can happen as a result of high air pressure or high oxygen levels.
- Pulmonary Edema, which occurs when fluid builds up inside the air sacs in the lungs.
- Pneumothorax, which involves air leaking from the lungs into the space just outside of them, causing pain, shortness of breath, and in some cases lung collapse.
- Infections, which can include sinus infections and ventilator associated pneumonia (VAP).
- Airway obstruction due to occlusion of the ETT.
- Long-term trachea or vocal cord damage as a result of intubation.
- Blood clots or bed sores as a result of lying in one position for long periods.
- Cognitive effects associated with the use of sedative drugs.









**How Exovent Overcomes PPV Problems** 

# PPV

Interface with body (trachea/face/nose)

Oral hygiene management challenges

Infection (lung & oral)

Lung injury

Pneumothorax

Heart compressed

Sedation and neurological sequelae

#### **Exovent-PA**

No tight facemask or tube

Able to clean teeth

Lower risk of infection

Lower risk of lung injury

Very low risk of pneumothorax

Heart not compressed

Sedation not required







# **NPV Effectiveness**

Reported paralytic polio cases and deaths in the United States since 1910

The reported figures include both wild- and vaccine derived type polio indications that occurred indigenously and as imported cases









# **NPV Effectiveness**



- a) As the amount of CNEP is increased, tidal volume remains stable under patient control, but the FRC increases reflecting increased thoracic volume at greater negative pressures.
- b) In NPV the tidal volume is increased due to the difference between the baseline pressure (NEEP) and the inspiration pressure (Total).







# **NPV Effectiveness**

1998 Clinical Trial: Negative pressure ventilation vs conventional mechanical ventilation in the treatment of acute respiratory failure in COPD patients

52 patients with COPD and severe infection of the lungs were split into 2 similar groups. The first group was treated with the usual treatment of invasive PPV (controls) and the second with an iron lung (cases).



Fig. 1. – Total duration of ventilation (median) in the two groups of patients treated with negative pressure ventilation (cases) and conventional positive pressure ventilation (controls), \*: p<0.02, significant difference between groups.

Results:

- The effectiveness of matching was 91%.
- Mortality rate was 23% for cases and 27% for controls (NS), five cases needed endotracheal intubation, four of whom subsequently died.
- The duration of ventilation in survivors was significantly lower in cases than in controls, with a median of 16 hours (range 2-111 hrs) for NPV versus 96 hours (range 12-336 hrs) for PPV.







## **Exovent-PA Images**





Storage configuration

**Pre-patient test configuration** 









Patient on bed



Lower lid











Arm port accesses



Effective, comfortable seals



Medical line ports



**User interface** 







**User Interface** 









# **Plan to Resuscitate NPV**

		2025				2026				2027				2028			
	Qtr	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Controller																	
Verification & Validation																	
Pre-Market Clinical Inv'																	
Regulatory Approval											$\diamond$	Maj	y-27				
Post-Market Clinical Inv'																	

Simplified Gantt - does not show Health Economics / Usability / PPIE

- Mechanical design is mature. Completion of Control system (Q1 2025) enables verification and validation.
- Healthy Volunteer, then Mild/Moderate COPD First in Human pre-market clinical investigations will provide evidence of clinical safety.
- Notified/Approved body regulatory approval for CE & UKCA marking is a 12-month process. Device available for market (mid-2027).
- Post market clinical investigations will provide evidence of benefits:
  - Exacerbation of COPD at UHS & UCLH (2026/27).
  - Acute Hypoxemic Respiratory Failure (AHRF) 2028 onwards.







# **Illustrious Healthcare Solutions**

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