

Licensing Opportunity

Above Cuff Vocalisation (ACV) Device

Summary

- An Above Cuff Vocalisation (ACV) device (pictured right) has been developed and tested by national NHS tracheostomy experts, to allow patients with a tracheostomy to speak.
- Clinical trials show that the device is safe, produces an effective voice, reduces patient anxiety and has beneficial effects for secretion management, swallowing and coughing.
- Manchester University NHS Foundation Trust (MFT) is looking for a company to take a licence to manufacture and sell the product.

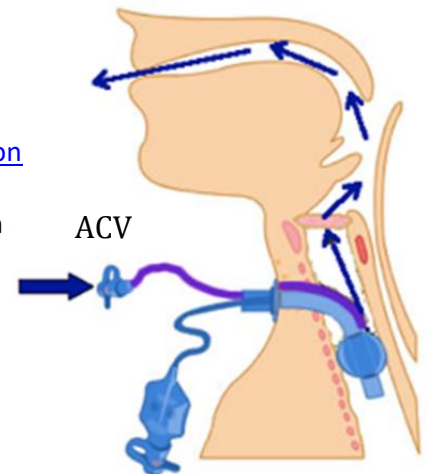


Background

- Patients with a new tracheostomy are usually unable to speak: the tracheostomy tube cuff prevents air from flowing through their larynx (voice box).
- This impacts communication with clinicians, friends and family, which can impede recovery and cause anxiety, especially during recovery from critical illness in ICU.
- Lack of use of the larynx makes swallowing, coughing, talking and liberation from the ventilator more difficult, and the patient's recovery process takes longer.
- Above Cuff Vocalisation (ACV) allows patients to speak by delivering airflow above the cuff, and out through the upper airway, even whilst the tracheostomy cuff is inflated – [watch this video](#).
- Standard ACV uses pipeline medical gas at 4 bar pressure. This approach has **no safety features**. There is a **risk of serious complications** such as **subcutaneous emphysema** and **death** if the tube is slightly dislodged.

Above Cuff Vocalisation device

- In 2018, a £595k National Institute of Health Research (NIHR) Invention for Innovation (i4i) grant was awarded to [Manchester University NHS Foundation Trust \(MFT\)](#) to create and test a new ACV device with safety features. The device is independent of lung ventilation and delivers ACV only in expiration (to mimic normal speech). The project concludes in December 2024.
- Co-developed with patients, clinicians, academics and engineers.
- The device is at **Technology Readiness Level (TRL) 6**: technology model or prototype demonstration in a relevant environment.
- Click the link for SEACTV in action: [SEA CTV: Our Innovation on Vimeo](#)



Device testing

- Initial laboratory and isolated animal-part testing determined optimum parameters for safe and effective ACV (e.g. flow rate, pressure, humidity, temperature and safety features).
- The device has undergone clinical investigation in a randomized-controlled trial at MFT testing safety, tolerability, effectiveness and the impact on the patient journey (including healthcare economic analysis). Data collection completed in December 2024.
- MFT is an internationally renowned tertiary NHS teaching hospital, which is very active in research & innovation. MFT has five large adult intensive care units available to conduct further trials, [an active ICU research team](#) with an [international reputation for airway research](#), strong collaborative links throughout the [Association of Northwest Intensive Care Units](#), and a strong track record in securing grant funding for further evaluation.
- The Trust's reputation is enhanced with the recent [NIHR Manchester HealthTech Research Centre](#).

Key team members

Name	Positions	Organisation
Professor Brendan McGrath	<ul style="list-style-type: none"> • Consultant in Anaesthesia and Intensive Care Medicine • NHS England National Clinical Advisor for Tracheostomy • Chair of the UK National Tracheostomy Safety Project 	Manchester University NHS Foundation Trust
Professor Sarah Wallace, OBE	<ul style="list-style-type: none"> • Consultant Speech and Language Therapist • Expert Advisor Royal College of Speech & Language Therapists • Speech and Language Therapy Lead for National Tracheostomy Safety Project 	Manchester University NHS Foundation Trust
Dr Rasool Erfani	<ul style="list-style-type: none"> • Senior Lecturer in Mechanical Engineering 	Manchester Metropolitan University
Patrick Hall	<ul style="list-style-type: none"> • Managing Director of an independent design agency • Product designer specializing in HealthTech 	Designing Science
Professor Shaheen Hamdy	<ul style="list-style-type: none"> • Professor of Medicine (Neurogastroenterology) • Founder of Phagenesis (medical device company providing dysphagia therapy) 	University of Manchester/Northern Care Alliance
Professor Paul Dark	<ul style="list-style-type: none"> • Professor of Critical Care Medicine • NIHR Senior Investigator • NIHR National Deputy Medical Director 	University of Manchester/Northern Care Alliance
NTSP PPIE Group	<ul style="list-style-type: none"> • Diverse group of current and former patients, families, carers • Relevant healthcare staff with an interest in tracheostomy 	National Tracheostomy Safety Project

Advantages

Enables effective speech	No competing products on the market
'Blows' secretions out of airway (which improves recovery and stimulates laryngeal rehabilitation)	Development team are international experts in caring for patients with tracheostomy
Beneficial physiological effects (e.g. spontaneous coughing and swallowing)	Potential to gain additional NIHR funding for further development and evaluation
Could be integrated into a ventilator or be a standalone product	Manchester University NHS Foundation Trust is one of the largest NHS organisations in the UK and has extensive research and innovation expertise

Market size

Around 20,000 new tracheostomies are inserted in the UK annually, with around two-thirds in ICU patients and the rest in head and neck surgical practice. An estimated 200,000 people in the US receive tracheostomies every year.

Commercial opportunity

We are seeking a commercial partner experienced in the development, manufacture and sale of medical devices (respiratory/intensive care units). A licence arrangement and/or a collaborative development project, which may include further clinical trials at MFT and/or elsewhere, are both possibilities.

Contact details

Dr Joanne Thomas
Programme Manager – Innovation and Intellectual Property
 Innovation Team, Manchester University NHS Foundation Trust
 Citylabs 1.0, Nelson Street, Manchester, M13 9NQ, UK
innovation@mft.nhs.uk **+44 (0)161 276 6965**

