



Reservoirs of Pathogens: The Microbial Risks of Respiratory Medical Devices

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Introductions



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CORRESPONDENCE

The benefit of taking a control sample when performing bronchoalveolar lavage

Contamination of bronchoscopes is well described.¹⁻³ However, while cleaning and disinfecting bronchoscopes are clearly described in standardisation documents,¹⁻³ the performance of a control sample prior to bronchoscopy is not sug-

from that found in the index case. The patient was pyrexial and coughing within 24 h of the procedure. The symptoms gradually resolved over 6 weeks, while on broad-spectrum antibiotic cover.

Our case suggests potential benefits of performing a simple 'control lavage'. First, a contaminated bronchoscope will result in 'false-positive' BAL results. The control BAL sample is the only way to detect this error and avoid inappropriate treatment. Second, the BAL culture results may be 'true-positives', with the pathogen flushed into the patient's airways during lavage. This is an iatrogenic infection and

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Competing interests None declared.

Patient consent Obtained.

Provenance and peer review Not commissioned;



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CASE REPORT

Open Access



A case of failed eradication of cystic fibrosis-related sinus colonisation by *Pseudomonas aeruginosa*

Barry Linnane^{1,2,3}, Linda Kears^{1,3}, Nuala H. O'Connell^{1,2}, John Fenton^{1,2}, Miranda G. Kiernan¹ and Colum P. Dunne^{1*}



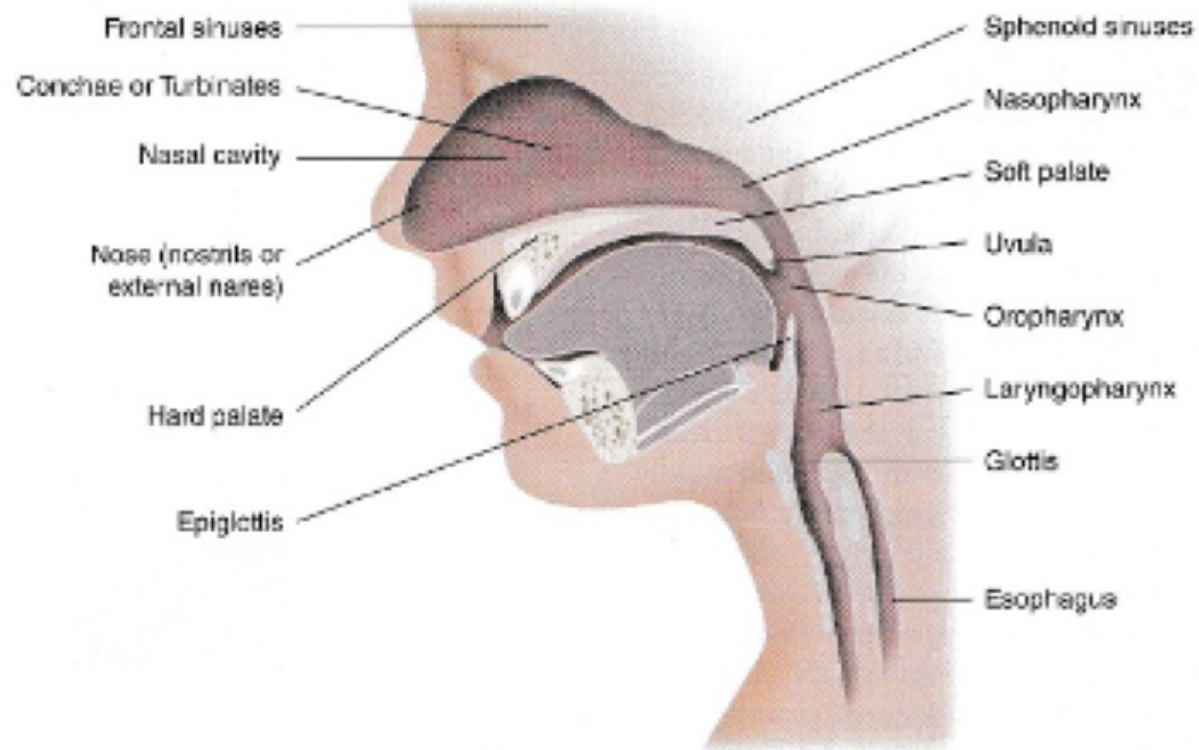


Figure 7: Anatomy of the upper airways (Hess et al., 2007)



Power et al. *BMC Pulmonary Medicine* (2016) 16:57
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BMC Pulmonary Medicine

CASE REPORT

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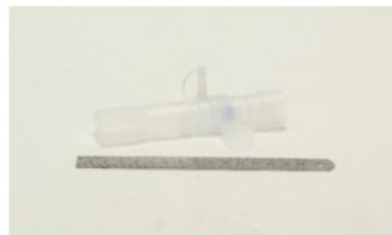
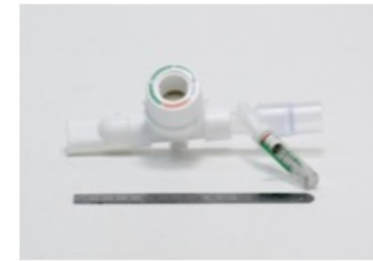


The first reported case of *Burkholderia contaminans* in patients with cystic fibrosis in Ireland: from the Sargasso Sea to Irish Children

Rachel F. Power^{1,2}, Barry Linnane^{1,2}, Ruth Martin², Noelle Power², Peig Harnett², Brian Casserly^{1,2}, Nuala H. O'Connell^{1,2} and Colum P. Dunne^{1*}

Objectives

- Respiratory medical devices are ubiquitous, used in both clinical and domestic settings globally.
 - Many are simple in design and may comprise a single part, others are complex with many parts.
 - Often, these devices are multi-use and require cleaning regularly if they are to remain hygienic.
- Discuss:
- What microbes are present on medical devices as they arrive from the manufacturer, if they are sterile or simply low microbial burden.
 - Scenarios/ cases that illustrate how such devices, in cystic fibrosis or COPD settings, may become colonised with potential pathogens.
 - How and why cleaning may not happen or may not be effective including involvement of water source at home and in hospitals; and an example of a novel device to overcome this problem.



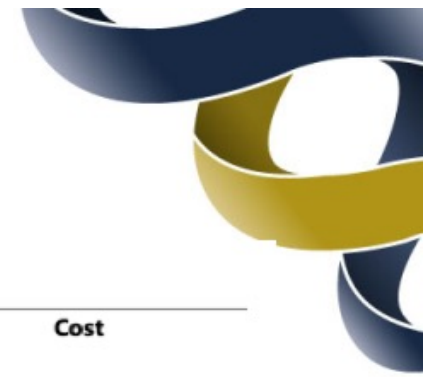


Table 1: Considerations when choosing airway clearance technique (Adapted from Dean and Frownfelter 2014)

Airway clearance Technique	Age	Assistance Needed	Equipment Needed	Suitable during acute exacerbation	Concurrent aerosol	Precautions	Cost
Postural Drainage. Percussion. Vibration/Shaking.	All ages	Yes	Positioning aids; Percussor/vibrator; Devices for infants	Yes	Only while upright or side-lying	May need to modify positions; repetitive motion injuries	Expensive when performed by care giver over long-term
Active Cycle of Breathing.	From 3-4 years	Until 8-10 years	Positioning aids; Percussor/vibrator;	Yes	Only while upright or side-lying	Precautions for head-down positions	Inexpensive when performed independently
Autogenic Drainage.	From 12 years	No	None	Possibly	No	Takes time to learn	No cost
High Frequency Chest Wall Oscillation.	From 2-3 years	For young children	Air pulse generator & appropriately sized vest	Yes	Yes	Any indwelling catheters or devices in chest area	Very expensive
Intermittent Positive Ventilation	Adolescents & adults	While in hospital	Home or hospital unit	May not be well tolerated	Yes	Titrate for comfort and visible chest movement	Moderately expensive
Acoustic Airway Clearance.	All ages	For children	Acoustic generator & transducer	Possibly	Yes	Further study needed	Very expensive
Exercise	All ages	For young children	Variable	No	Premedicate before exercise	Exercise induced bronchospasm; oxygen desaturation	Dependent on activity
(Oscillating) Positive Expiratory Pressure	All ages	For young children	(O)PEP device	Yes	Yes (device dependent)	Potential for pneumothorax; hyperventilation	Low to moderate dependant on device

Some Example Products

24 Current PEP/OPEP devices on the market.

Current identified PEP devices

Name	Manufacturer
1. TheraPEP [†]	Smiths Medical ASD
1. Threshold [†]	Respironics Respiratory Drug Delivery Ltd.
1. PEP/RMT [†]	Wellspect Healthcare
1. Pari PEP [†]	PARI GmbH
1. Ezi-PEP [†]	Armstrong Medical
1. Resistex [†]	Mercury Medical

Current identified OPEP devices

Name	Manufacturer
1. Aerobika [†]	Trudell Medical
1. Quake	Thayer Medical
1. RC Cornet	R. Cegla GmbH & Co. KG
1. Acapella [†]	Smiths Medical ASD
1. Pari-O-PEP	PARI GmbH
1. Flutter	VarioRaw SA
1. Lung Flute	Medical Acoustics
1. Shaker Classic	Powerbreath International Ltd.
1. Shaker Deluxe	Powerbreath International Ltd.
1. Shaker Plus	Powerbreath International Ltd.
1. Aerosure	Actegy Ltd.
1. vPEP [†]	D. R. Burton Healthcare Products LLC
1. PocketPEP ^{**}	D. R. Burton Healthcare Products LLC
1. iPEP ^{**}	D. R. Burton Healthcare Products LLC
1. Clean My Lungs	Air Physio
1. VibraPEP	Curaplex

*** Denotes devices in pre-production at time of writing*



Oscillating Positive Expiratory Pressure Therapy May Be Performed Poorly by Children With Cystic Fibrosis

Kevin J O’Sullivan, Louise Collins, Deirdre McGrath, Barry Linnane, Leonard O’Sullivan, and Colum P Dunne

BACKGROUND: Oscillating positive expiratory pressure devices aid removal of excess secretions and reduce gas trapping in patients with hypersecretory pulmonary diseases, for example, cystic fibrosis. Oscillating positive expiratory pressure works when the patient exhales actively against a fixed resistor, which generates mean intrapulmonary pressures of 10–20 cm H₂O with rapid fluctuations of at least 1 cm H₂O from the mean. In this study, we evaluated the performance of oscillating positive expiratory pressure therapy by pediatric subjects with cystic fibrosis to determine adherence to target therapeutic pressures. **METHODS:** Twenty-one pediatric subjects were recruited. Each had a history of using an oscillating positive expiratory pressure device twice daily and had received standardized training and instructions from the same specialist physiotherapist. Performance was evaluated by using a flow and pressure sensor placed in-line between the participant’s mouth and the device. The participants performed expirations as per their normal routine. **RESULTS:** None of the participants achieved target therapeutic pressure ranges during expiration. The mean ± SD pressure generated was 16.2 ± 6.8 cm H₂O, whereas mean ± SD flow was 31.3 ± 8.9 L/min. The mean ± SD expiration length was 2.5 ± 1.4 s. **CONCLUSIONS:** Despite standardized instruction, the results demonstrated considerable variation among the participants and overall poor technique during use. Outcomes of this study indicated that airway clearance effects of oscillating positive expiratory pressure were compromised due to poor technique. *Key words:* oscillating positive expiratory pressure therapy; cystic fibrosis; hypersecretion; airway clearance; pediatric. [Respir Care 2019;64(4):398–405. © 2019 Daedalus Enterprises]

Introduction

The purported benefits of airway clearance were first described in *The Lancet* in 1901.¹ In healthy individuals,

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mucus is removed from the lungs by the mucociliary system, but, in pathological conditions, such as cystic fibrosis (CF), bronchiectasis, productive COPD, and asthma, there is mucus hypersecretion coupled with thickening of the bronchial mucus.² Air-flow restrictions caused by retained secretions increase the work of breathing, create ventilation-perfusion mismatch, and can reduce gas exchange.³ In respiratory mucus hypersecretion, there is submucosal gland hypertrophy and goblet cell hyperplasia, and an increase in mucin synthesis. There also is decreased mucociliary transport, mucus plugging, and atelectasis in the small airways.³

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Figure 20: Author (KJOS) demonstrating the flow and pressure sensor positioned in-line with the OPEP device with anti-viral filter

Oscillating Positive Expiratory Pressure Therapy May Be Performed Poorly by Children With Cystic Fibrosis

Kevin J O'Sullivan, Louise Collins, Deirdre McGrath, Barry Linnane, Leonard O'Sullivan, and Colum P Dunne

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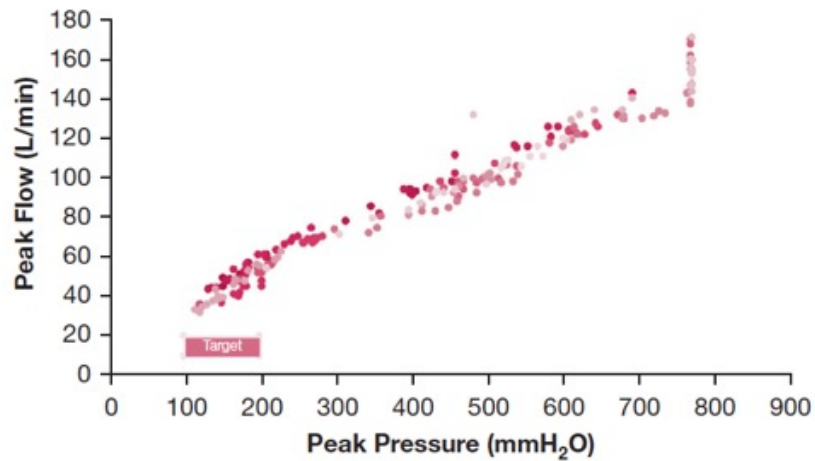


Figure 1 – Scatter plot of peak flow and pressure for all expirations. Target therapeutic range of 10 to 20 cmH₂O, at a flow rate of 10 to 20 L/min is shown in the shaded box.

[154 # 1 **CHEST** JULY 2018]

According to the literature, the effective range of PEP/OPEP is at pressures of 10-20cmH₂O at a flow rate of 10-20 L/min. In this table, the flow was kept as close as possible to 20 L/min for comparison (excl. the lung flute).

- The frequency is a source of debate: some authors argue that ~15Hz is appropriate to match the beat of the cilia in the respiratory system, while others argue that higher frequencies result in better shearing of the mucus and has a higher impact on viscosity.
- The amplitude (or level of oscillation) is deemed to be clinically relevant at 1cmH₂O.
- The higher the mean pressure achieved during exhalation, the more airways will be splinted open.

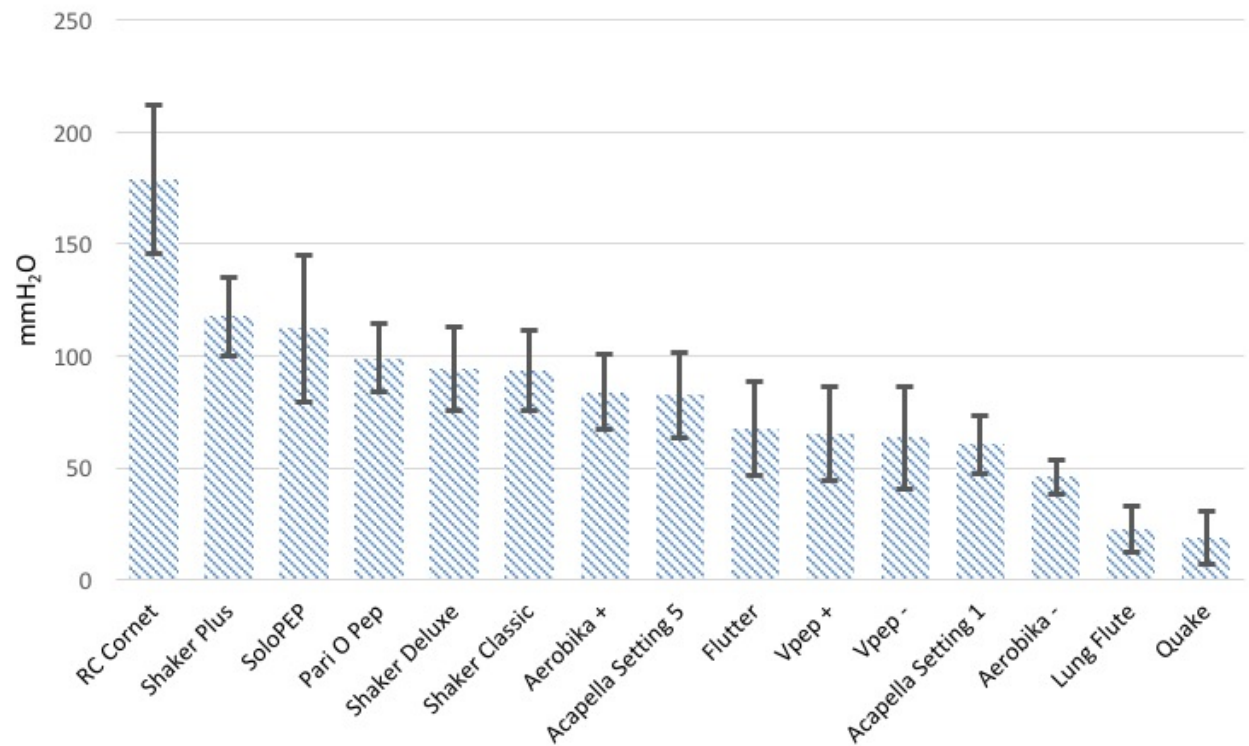
Mechanical characteristics of predicate OPEP devices

Device	\bar{x} Flow l/min [SD]	\bar{x} Pressure mmH ₂ O [SD]	Frequency Hz	Amplitude mmH ₂ O
SoloPEP	19.55 [0.22]	112.16 [17.56]	26	32.84
Acapella Setting 1	15.59 [0.62]	60.34 [8.97]	9	12.97
Acapella Setting 5	19.72 [1.05]	82.42 [13.39]	11	18.96
Aerobika -	20.81 [0.45]	46.12 [4.94]	9	7.59
Aerobika +	21.03 [0.61]	83.85 [12.24]	14	16.99
Flutter	26.55 [2.71]	67.68 [14.49]	8	21.07
Vpep -	23.98 [1.39]	63.53 [16.16]	12	22.79
Vpep +	24.55 [1.49]	65.15 [18.22]	13	21.07
RC Cornet	20.20 [0.50]	178.91 [17.98]	19	33.27
Quake	17.99 [0.31]	18.85 [8.92]	22*	12.06
Lung Flute	148.89 ^y [2.85]	22.57 [6.08]	44**	10.25
Pari O Pep	20.52 [0.74]	98.96 [10.49]	10	15.24
Shaker Classic	18.77 [1.61]	93.55 [12.31]	10	18.08
Shaker Deluxe	23.46 [1.77]	94.10 [12.37]	9	18.64
Shaker Plus	23.36 [1.40]	117.55 [12.07]	9	17.51

* Frequency is dependent on handle speed. ** Approximate rate. ^y Wont function at low flow

- The blue bars represent mean pressure, with the black error bars showing the amplitude of oscillation (in mmH₂O).
- SoloPEP is positioned favourably, particularly given it is a disposable device.
- The RC cornet has been identified as the best mechanically performing device based on pressure generated at a given flow, however the user experience is poor (the sound during use is similar to a whoopee-cushion).

Mean Pressure and Amplitude





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Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin



Letters to the Editor

Medical devices for cystic fibrosis care may be portable reservoirs of potential pathogens



Conflict of interest statement
None declared.

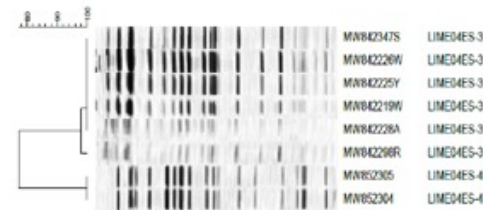
Funding sources
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Clinical Observation and Need Arising

- Discolouration of TheraPEP™ Tubing (non-cleanable component)
- Isolation of *S. maltophilia* reported by Prof. Linnane and Prof. Dunne¹
- Need originated as “What would be ideal is a disposable device...”



Bacterial isolates from the paediatric clinics of University Hospital Limerick could be confirmed as identical, for example MW852305 and MW852304 at the bottom of the figure (Unpublished data)



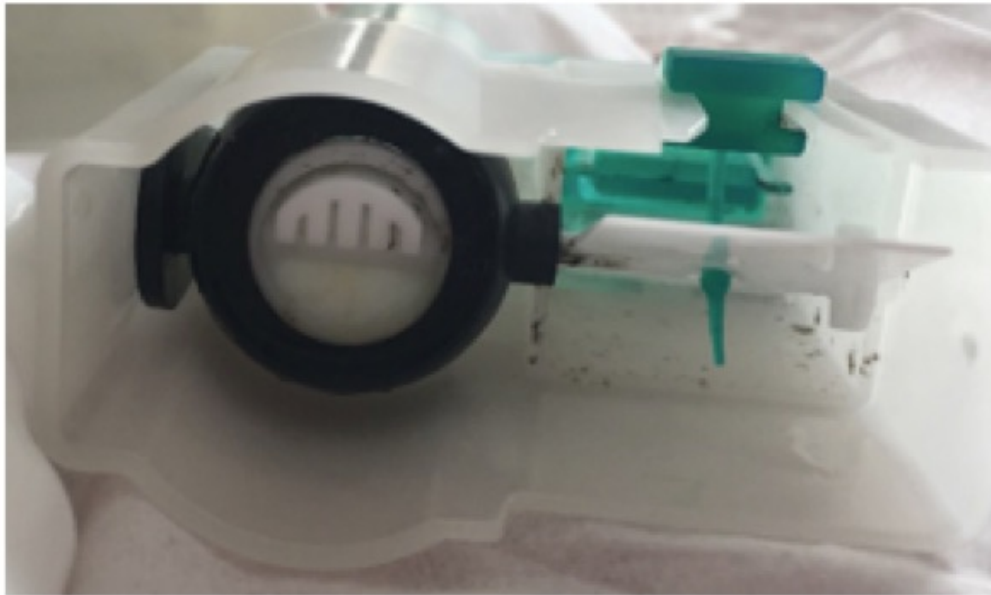
1. Linnane, B., Collins, L., Bussmann, N., O'Connell, N. H. and Dunne, C. P. (2017) 'Medical devices for cystic fibrosis care may be portable reservoirs of potential pathogens', *Journal of hospital infection*, 96(4), 397-398.

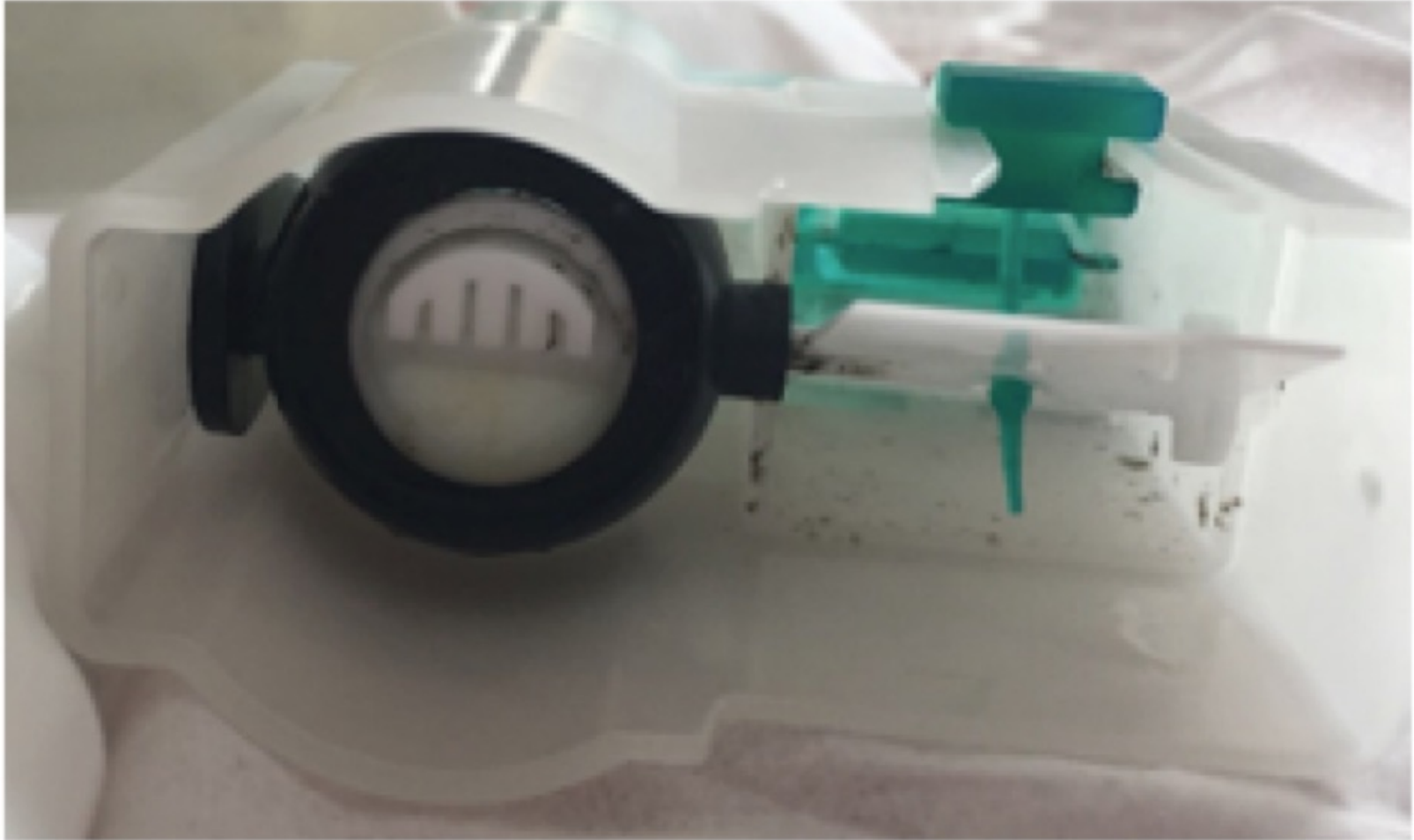


: Silicone tubing (arrow) where *S. maltophilia* was detected in a TheraPEP device (Smiths Medical, USA)

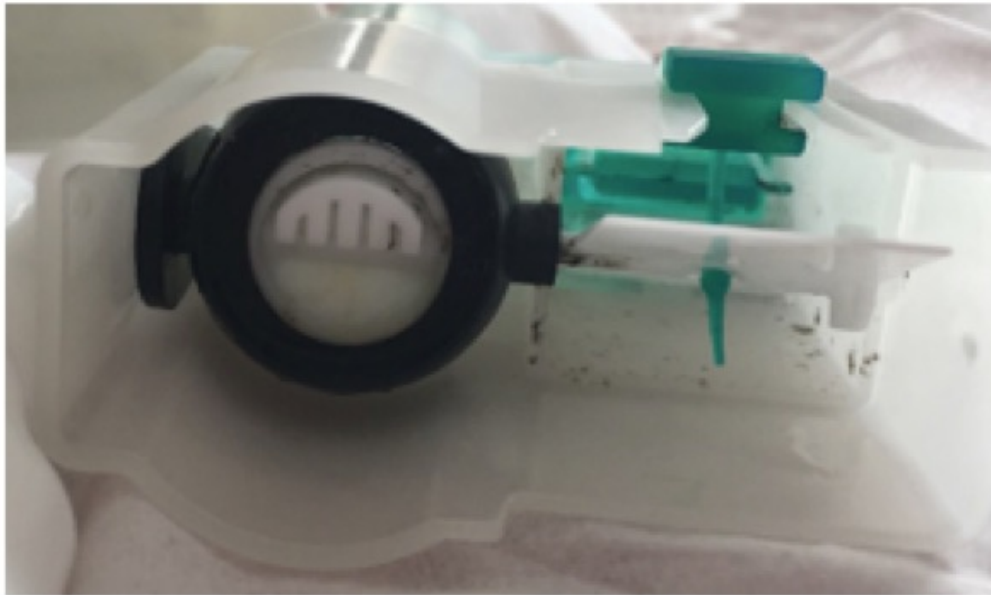


Figure 13: An Aerobika® device disassembled into all 10 individual components









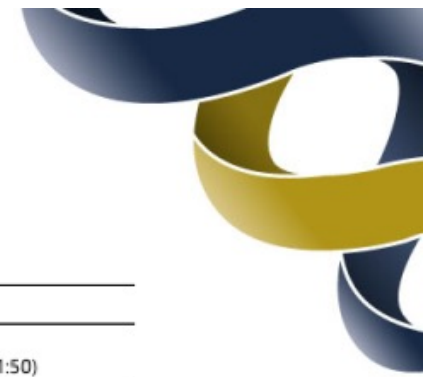


Table 4: Manufacturers cleaning guidelines

Name	Cleaning frequency	Cleaning method
<u>Aerobika</u>	Based on healthcare providers advice	Soap and water, dishwasher. Electronic steam steriliser, boiling, microwave steam bag, ISO alcohol (70%), Hydrogen Peroxide (3%), Bleach (1:50)
<u>Quake</u>	Once a week or more often as needed	Hand wash in soapy water, dishwasher, boil
<u>RC Cornet</u>	Twice weekly	Dishwasher, Vaporiser, steam cleaner, boil. Speciality microwave bag
<u>TheraPEP</u>	Regularly or after every use	Warm soapy water, Disinfect: Alcohol – 5 minutes twice daily, rinse with sterile water (boiled for 5 minutes). Peroxide – 3% for 30 minutes, rinse with sterile water. Bleach – 1:50 for 30 minutes, rinse with sterile water. Vinegar – 2:3 vinegar to distilled water, rinse with sterile water
<u>Acapella</u>	Regularly, or after every use	Clean with detergent before sterilising Boil up to twice daily for five minutes Autoclaving – Up to 136° for up to 30 cycles Dishwasher – top shelf Alcohol – soak in 70% isopropanol twice daily for 5 minutes
<u>Threshold</u>	Wash after each use	Wash in warm soapy water Rinse well and shake excess water
<u>PEP/RMT</u>	When needed – After every use (mouthpiece only)	Washing machine, boiling, chemicals, autoclave (121°C or 134°C)
<u>Pari PEP</u>	Clean after each use and disinfect at least once a day	Wash in warm soapy water for 5 minutes Boil for 5 minutes Baby bottle steriliser for 6 minutes min
<u>Pari-O-PEP</u>	Cleaned after every use and disinfected at least once a day	Warm soapy water for 5 minutes, rinse with warm water Boil for 5 minutes Baby bottle steriliser for 6 minutes min
<u>Flutter</u>	If you want, every time you use it, more vigorously every second day	Rinse with running water Was in mild soap or detergent
<u>Lung Flute</u>	Wash every two weeks (when replacing reed)	Warm soapy water, dry well.
<u>Shaker Classic</u>	Each use, once a week thoroughly	Wash with soapy water after each use, once a week use approved cleansing tablets
<u>Shaker Deluxe</u>	Each use, once a week thoroughly	Wash with soapy water after each use, once a week use approved cleansing tablets
<u>Shaker Plus</u>	Each use, once a week thoroughly	Wash with soapy water after each use, once a week use approved cleansing tablets
<u>Exi-PEP</u>	Once a week	Soapy water (max 50°C)
<u>Aerosure</u>	Rinse after every use, disinfect after every use for CF etc.	Remove mouthpiece, turn on, rinse under 40°C water. Use a mild disinfectant after every use for CF, shake and leave to dry.

Manufacturer cleaning recommendations vs best practice



- Inefficient cleaning and disinfection of PEP devices may pose a health risk to patients
- No consensus best practice standard for these regimens
- Cleaning is defined as the physical removal of foreign material, such as microbes, dirt, and impurities from surfaces and objects, normally accomplished using water with detergents or enzymatic products, while the purpose of disinfection is to kill microbes on objects, usually achieved through chemical or thermal means (Rutala and Weber 2008).
- Despite recommendations from the US Centres for Disease Control and Prevention (CDC) that PEP devices undergo 'high-level disinfection' (Tablan et al. 2004b), there are no official policy guidelines for cleaning or disinfecting PEP devices.

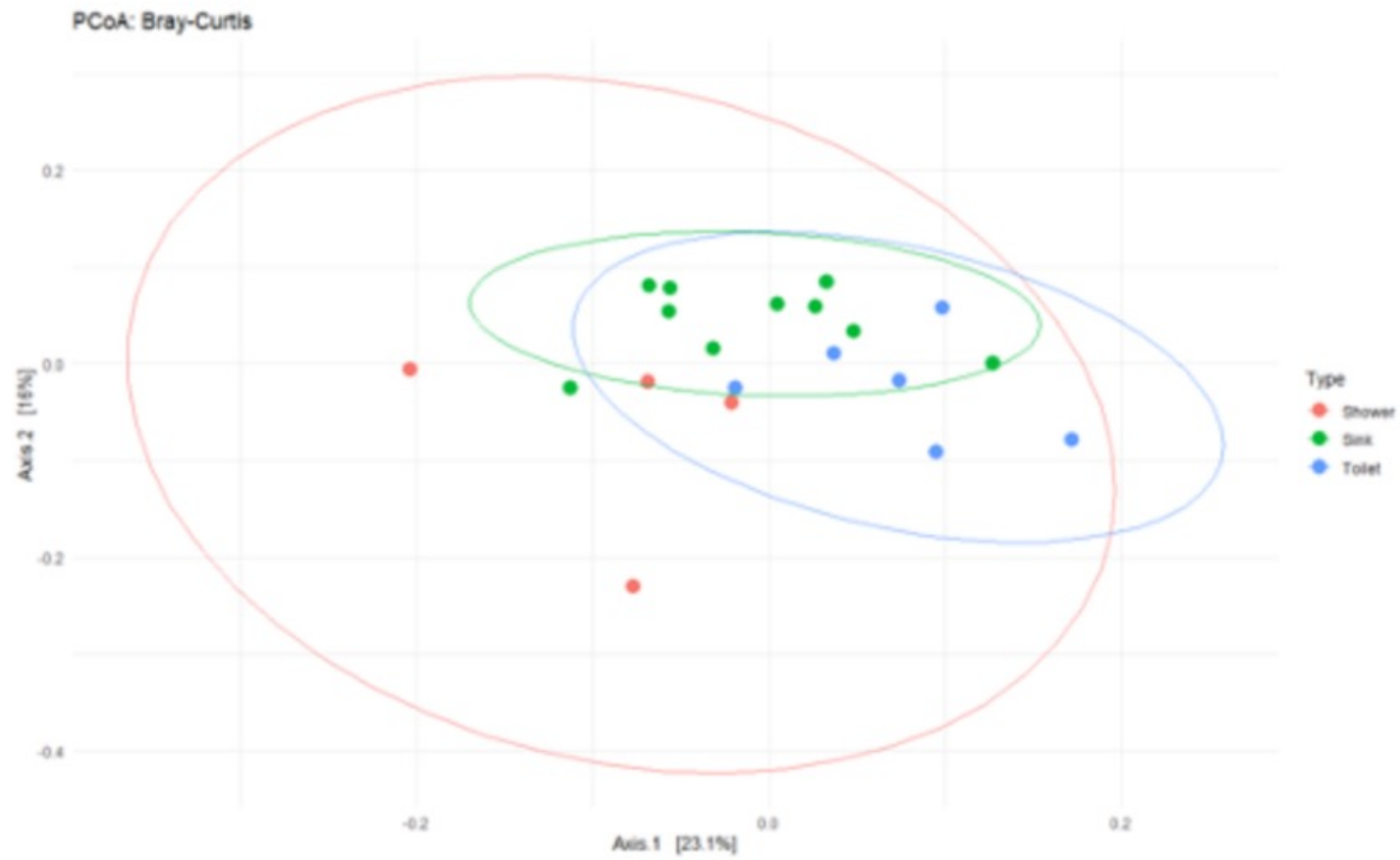
Manufacturer cleaning recommendations vs best practice

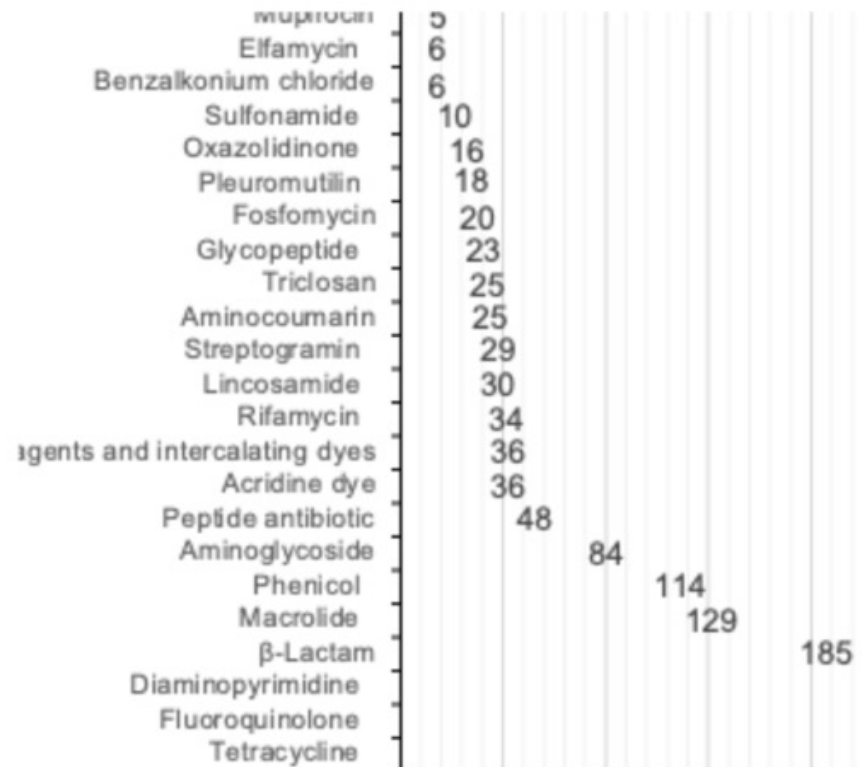


The Cystic Fibrosis Foundation (CFF) has endorsed guidelines for cleaning and disinfection of aerosol therapeutic devices (nebulizers) (O'Malley 2009, Saiman et al. 2014).

However, manufacturers' recommendations for cleaning and disinfecting PEP devices can differ from those for nebulizers (Manor et al. 2017, Linnane et al. 2017), and can vary greatly between devices (O'Malley 2015).

Specifically, it has been noted that some PEP device manufacturers recommend performing a final rinse of their device with tap water, even though this has been proposed as a source of *Stenotrophomonas maltophilia* detected in a PEP device used by a CF patient (Linnane et al. 2017).







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Assessment of the microbial load of airway clearance devices used by a cohort of children with cystic fibrosis

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M.G. Kiernan^c, D. McGrath^c, K.J. O'Sullivan^{c,e}, L. O'Sullivan^e, C.P. Dunne^{c,*}

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^e Rapid Innovation Unit – Confirm Centre for Smart Manufacturing, School of Design & Health Research Institute, University of Limerick, Limerick, Ireland



Table 15: Results of usage, cleaning, and storage habits of current OPEP devices

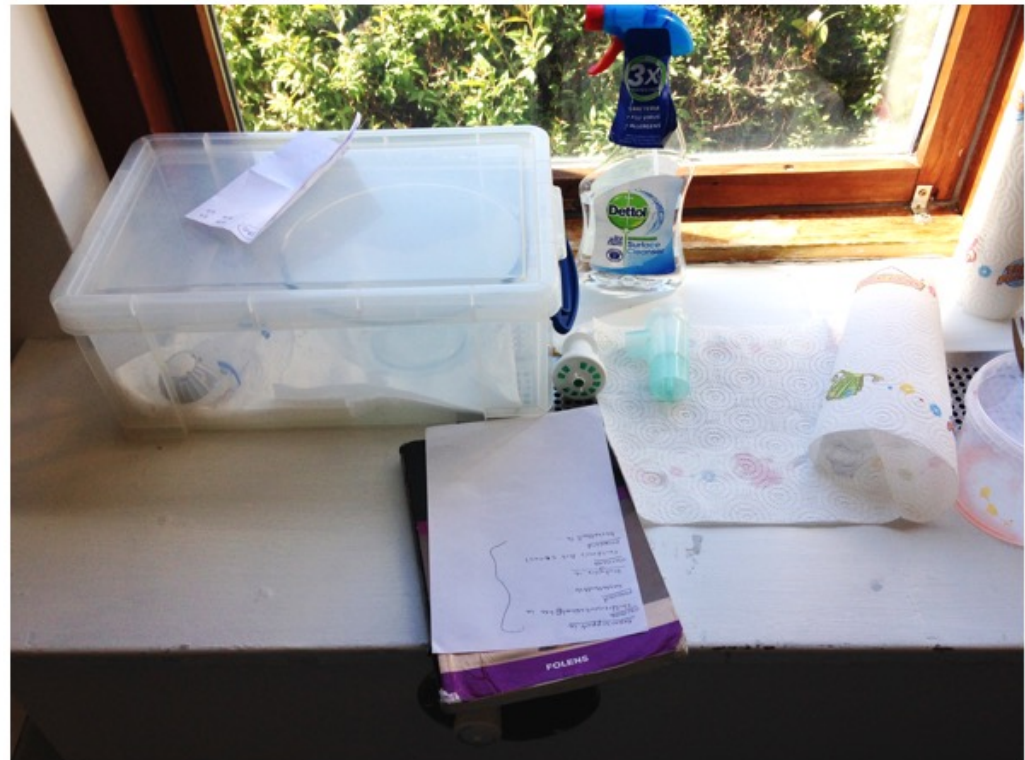
Frequency of Use	%	Duration of Use	%
occasional (only when unwell)	11	Less than 5 minutes	6
infrequent (2-3 times per week)	14	5 to 10 minutes	47
once a day	25	More than 10 minutes	25
twice a day	44	Number of breaths performed	22
three or more times per day	6		
Cleaning Frequency	%	Methods of Cleaning	%
After each use	53	Hand wash	50
Daily	17	Steriliser	15
Every second day	6	Handwash + steriliser	32
Twice a week	5	Dishwasher	3
Weekly	11		
Bi-weekly	3		
Not at all	5		
Duration of Cleaning	%	Storage Habits	%
Less than 5 minutes	15	Open un-protected (countertop/windowsill)	24
5 to 10 minutes	21	Open protected (cupboard/drawer)	18
10 to 15 minutes	22	Sealed container (plastic box/bag)	46
15 to 20 minutes	15	Non-sealed container (soft case)	12
More than 20 minutes	27		

User Snapshot

This picture was captured in May 2018 while on site in UHL. The patient is a 17 Yr. Male with CF. As he was facing a prolonged admission, he had brought his regular “equipment” with him.

- Plastic storage crate
- Pyrex Bowl
- Kitchen Towel
- Antibacterial Spray
- PEP/OPEP Device (x2)
- Nebuliser.

The patient spends over 1 Hr. daily cleaning and maintain PEP & Nebuliser devices.





To the best of our knowledge, only one previous published study had investigated the potential for bacteria to colonise PEP devices (Manor et al. 2017).

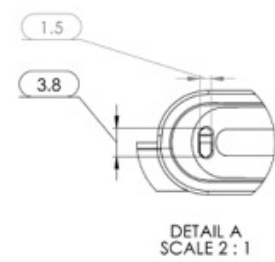
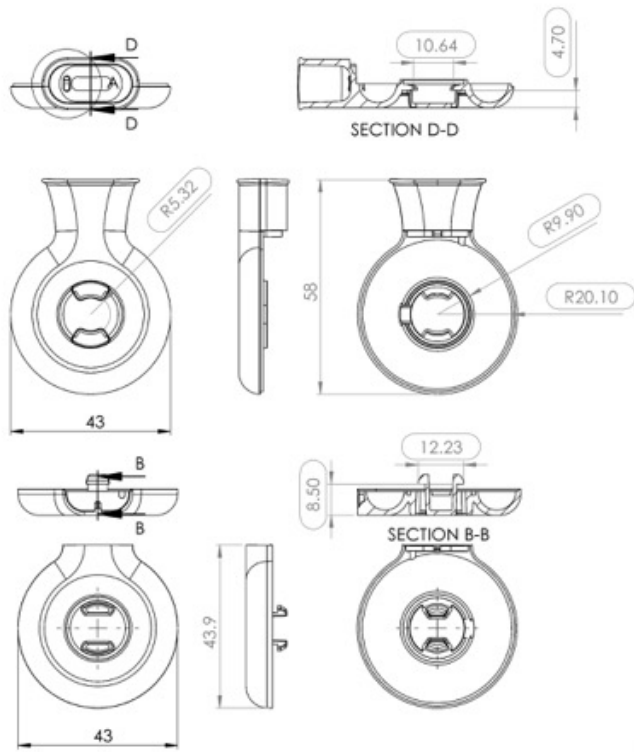
- Most devices are not sterile, unless the packaging says so!!!
- New unused Aerobika (n=2), TheraPep (n=2) and other (n=1) devices were analysed to determine the presence of bacteria. *Staphylococcus epidermis* was cultured from the PBS used to flush the inside of an Aerobika® device, while *Bacillus mojavensis* (typically soil-borne) was detected on the inside of the packaging from a TheraPep® device.



Table 10: Bacteria cultured from used devices of patients with cystic fibrosis.

Bacteria	Devices				P-value** (Chi ² test)
	Total (n=19)	Aerobika (n=14)	TheraPep (n=4)	Other* (n=1)	
	n (%)	n (%)	n (%)	n (%)	
Number of devices bacteria were cultured from.	19 (100%)	14 (100%)	4 (100%)	1 (100%)	
<i>Bacillus</i> species	12 (63%)	10 (71%)	2 (50%)	NC***	0.298
<i>Coagulase negative staphylococci</i>	8 (42%)	6 (43%)	1 (25%)	1 (100%)	0.395
<i>Curtobacterium flaccumfaciens</i>	1 (5%)	1 (7%)	NC	NC	0.828
<i>Kocuria rosea</i>	1 (5%)	1 (7%)	NC	NC	0.828
<i>Micrococcus</i> species	9 (47%)	2 (14%)	2 (50%)	1 (100%)	0.539
<i>Moraxella</i> species (not <i>catarrhalis</i>)	1 (5%)	1 (7%)	NC	NC	0.828
<i>Paenibacillus gluconolyticus</i>	2 (11%)	2 (7%)	NC	NC	0.671
<i>Proteus</i> species	1 (5%)	1 (14%)	NC	NC	0.828
<i>Pseudomonas koreensis</i>	1 (5%)	NC**	1 (25%)	NC	0.138
<i>Stenotrophomonas maltophilia</i>	5 (26%)	4 (29%)	1 (25%)	NC	0.820
* A device from amongst a wide market selection, excluding <i>Aerobika</i> and <i>TheraPep</i> . ** P-value refers to result of statistical tests (Chi ² test) comparing abundance of species cultured from various devices. NC = not cultured.					





Solopep SP_SLT_30_10.2_Rev1



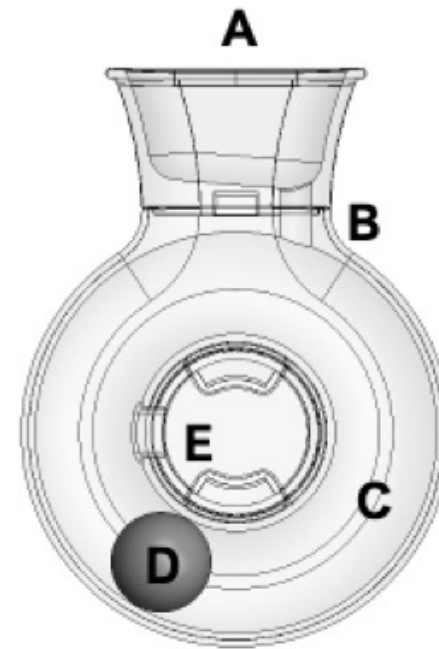
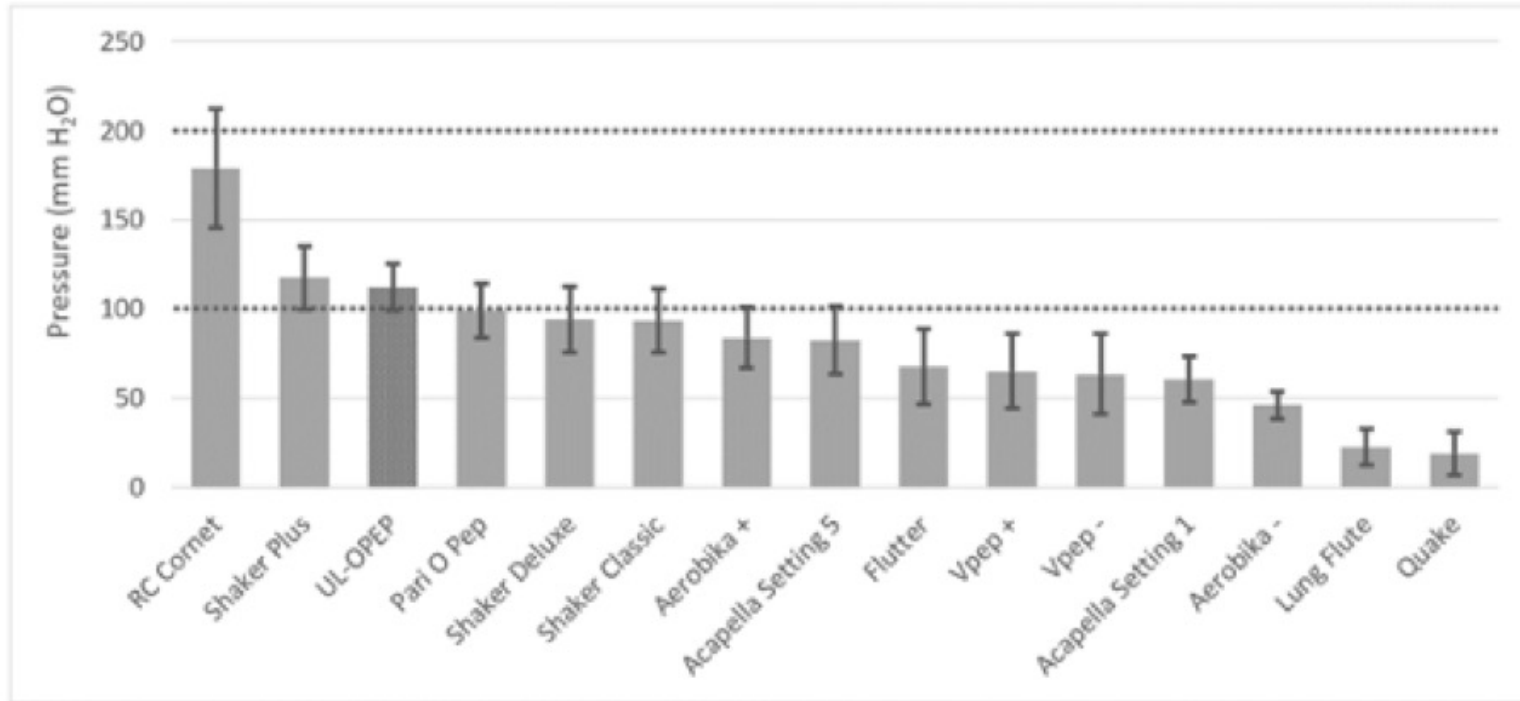




Table 12: Comparison of the UL-OPEP to commercial OPEP devices.

Device	\bar{x} Flow L/min [SD]	\bar{x} Pressure cmH ₂ O [SD]	Frequency Hz	Amplitude cmH ₂ O
UL-OPEP	18.82 [1.52]	14.86 [1.75]	26	1.28
Acapella Setting 1	19.21 [7.77]	6.03 [0.89]	9	1.29
Acapella Setting 5	19.79 [10.2]	8.24 [1.33]	11	1.89
Aerobika -	20.83 [4.55]	4.61 [0.49]	9	0.75
Aerobika +	21.03 [13.09]	8.38 [1.22]	14	1.69
Flutter	26.33 [13.14]	6.76 [1.44]	8	2.10
Vpep -	23.96 [11.53]	6.35 [1.61]	12	2.27
Vpep +	24.86 [11.53]	6.51 [1.82]	13	2.10
RC Cornet	20.20 [9.5]	17.89 [1.79]	19	3.32
Quake	17.99 [4.32]	1.88 [0.89]	22*	1.20
Lung Flute	148.89 [†] [6.28]	2.25 [0.60]	44**	1.02
Pari O Pep	20.52 [12.02]	9.89 [1.04]	10	1.52
Shaker Classic	18.93 [13.47]	9.35 [1.23]	10	1.80
Shaker Deluxe	23.46 [13.76]	9.41 [1.23]	9	1.86
Shaker Plus	23.36 [14.8]	11.75 [1.20]	9	1.75

* Frequency is dependent on handle speed. ** Approximate rate. [†] Does not function at low flow





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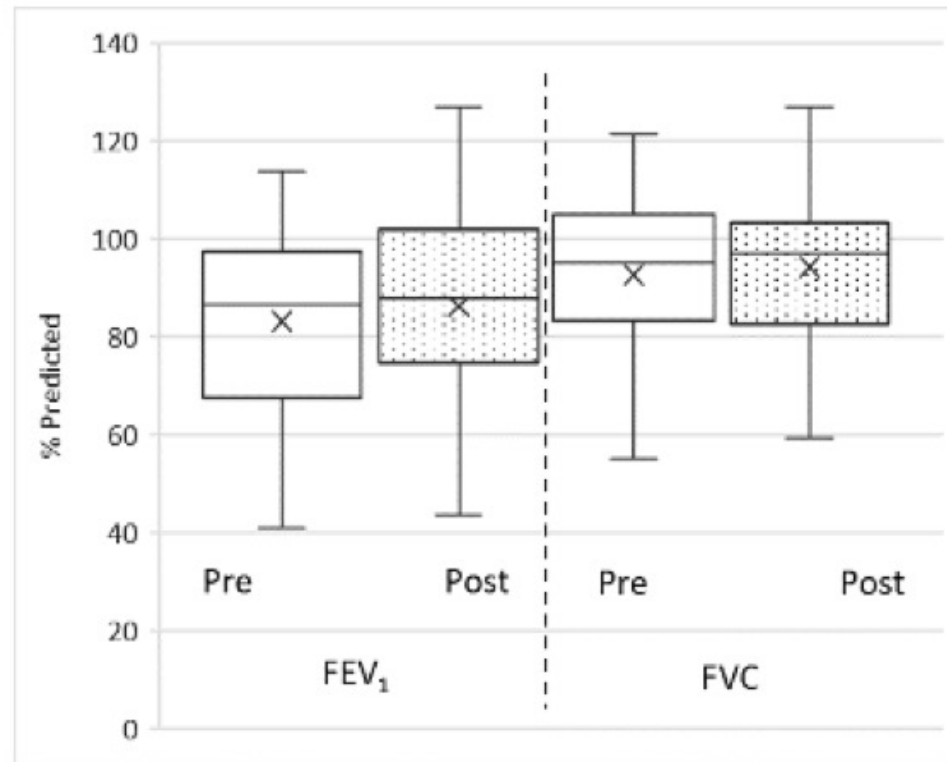


A short-term evaluation of a prototype disposable Oscillating Positive Expiratory Pressure (OPEP) device in a cohort of children with cystic fibrosis

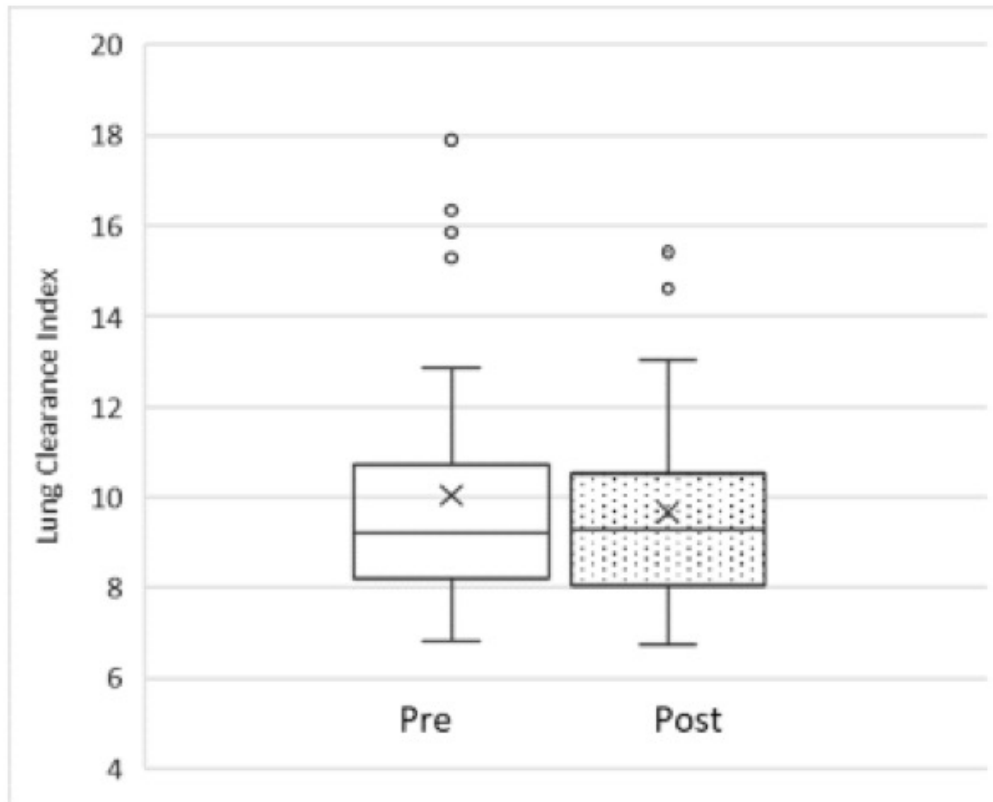
Kevin J. O'Sullivan^{1,2}, Valerie Power¹, Barry Linnane^{2,3,4}, Deirdre McGrath^{2,3}, Magdalena Mulligan^{2,5}, Rebecca White⁵, Leonard W. O'Sullivan¹ and Colum P. Dunne^{2*}



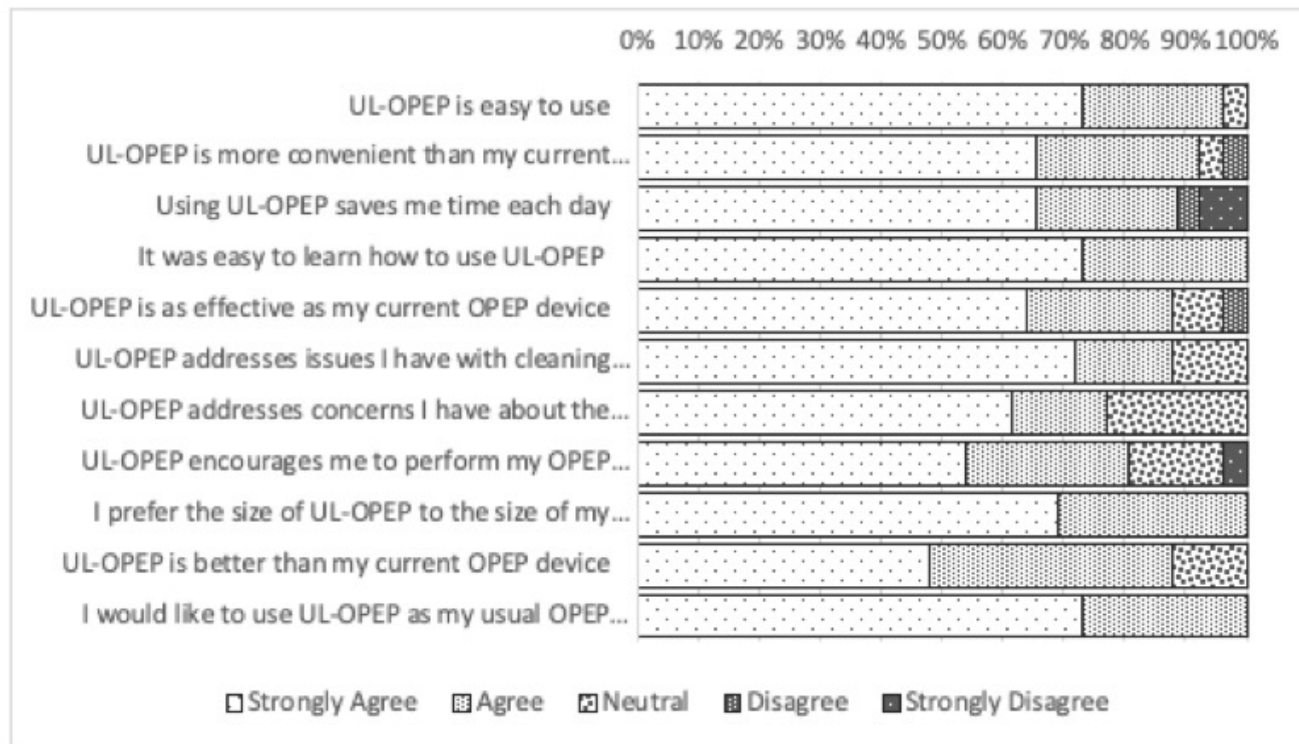
Figure 27: UL-OPEP Device



: FEV₁ and FVC (% predicted) pre and post study. Box-whisker plot shows mean (x), median (horizontal line), and interquartile ranges.



➤ Lung Clearance Index values pre and post study. Box-whisker plot shows mean (x), median (horizontal line), interquartile ranges, and outliers (circles).





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An initial evaluation of the safety of a disposable oscillating positive expiratory pressure device in patients with chronic obstructive pulmonary disease: a short-term pilot study

Kevin J. O'Sullivan¹, Valerie Power¹, Barry Linnane^{2,3,4,5}, Deirdre McGrath^{2,3}, Hilda Fogarty², Martina Ryan⁶, Rebecca White³, Conor Noonan⁶, Eithne Mulloy⁶, Leonard W. O'Sullivan¹ and Colum P. Dunne^{2*}



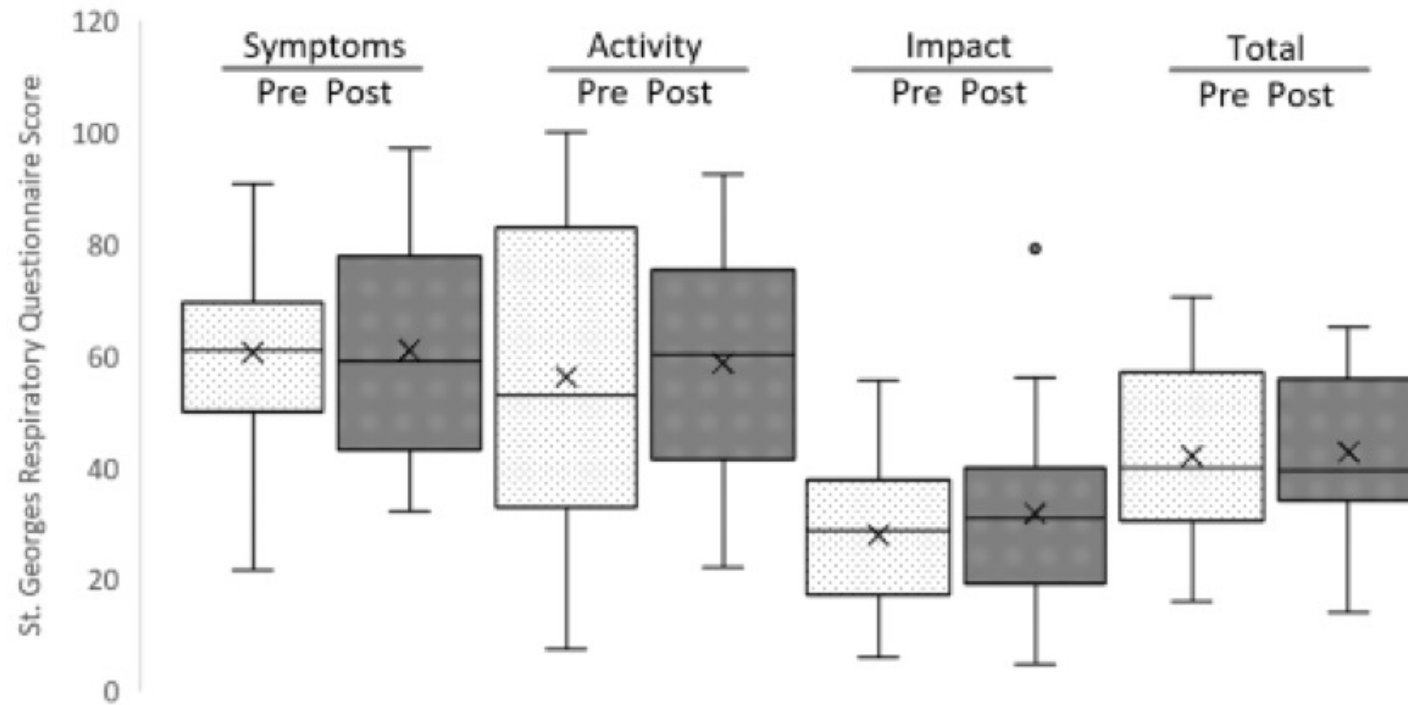


Figure 38: SGRQ scores pre- and post-study. Box-whisker plot shows mean (x), median (horizontal line), interquartile range (box), and minimum/maximum (whiskers).

Messages to take home:

- Not all respiratory devices are sterile.
- Many are used incorrectly.
- Some need regular cleaning and / or disinfection.
- Often that does not happen.
- There are few agreed rules for cleaning and disinfection.
- Use of domestic or hospital sink water can be problematic.
- AMR can be linked to wastewater.
- There are opportunities for single use, simplified respiratory devices.
- These can reduce risk of infection.
- They can be very effective and a good option for some patients.

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