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## Training in Multiple Breath Washout testing for respiratory physiotherapists

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1 **Debate article**

2 Title: Training in Multiple Breath Washout testing for respiratory physiotherapists

3

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6

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11

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25 **Debate article**

26 Title: Training in Multiple Breath Washout testing for respiratory physiotherapists

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29 Introduction: The development of multiple breath washout (MBW) testing in respiratory  
30 disease highlights the need for increased awareness amongst respiratory physiotherapists and  
31 a potential opportunity for professional development in the use of an important outcome  
32 measure for clinical trials.

33 Objectives: To rationalise how MBW may be a useful assessment tool for respiratory  
34 physiotherapists and to describe a local MBW training and certification programme for  
35 physiotherapists.

36 Results: The respiratory Multi-Disciplinary Team in the Belfast Health and Social Care Trust  
37 (BHSCT) identified a need for MBW testing to be available to facilitate clinical research and  
38 assessment. A 2 day training programme consisting of pre-reading preparation, self-directed  
39 learning, theory presentations, practical demonstrations and hands-on practice was developed  
40 and delivered. All participants underwent a certification process.

41 Conclusion: We have demonstrated the successful training and certification of clinical and  
42 research physiotherapists and encourage other respiratory physiotherapists to consider MBW  
43 test training.

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## 48 **Contribution of paper**

49 • This paper highlights the need for increased awareness amongst respiratory  
50 physiotherapists and a potential opportunity for professional development in the use of  
51 an important outcome measure for clinical trials.

52 • This paper demonstrates that respiratory physiotherapists can obtain training and  
53 certification in MBW testing

54

## 55 **Keywords**

56 Respiratory physiotherapy; multiple breath washout testing; lung clearance index; training;  
57 eLearning.

58

## 59 **Introduction**

60 In recent years, there has been a resurgence of interest in multiple breath washout (MBW)  
61 testing in respiratory disease. This method has the advantage of improved sensitivity in the  
62 detection of early airways disease compared to spirometry and has improved feasibility across  
63 a wider age range, requiring only relaxed tidal breathing. Studies in Cystic Fibrosis (CF) have  
64 shown that measures of MBW detect early lung disease, relate to measures of spirometry and  
65 health related quality of life and are responsive to mucolytic therapies (1-7). Consequently,  
66 parameters of MBW have been recommended as outcome measures in clinical trials in CF (8)  
67 and have already been used in landmark CF trials (9,10). Research into MBW in other  
68 respiratory conditions have also demonstrated that it could be a useful tool to detect disease  
69 and measure treatment response (11-14). FEV<sub>1</sub> is a key outcome measure in CF and is currently

70 the only Food and Drug Administration (FDA) approved surrogate outcome measure for use  
71 in clinical trials (15). It is also the most commonly used and reported measure of lung function  
72 in other lung diseases such as COPD (16). However, FEV<sub>1</sub> has physiological limitations; it  
73 primarily reflects the larger airways rather than the more peripheral, smaller airways which  
74 make up the majority of the surface area of the lung and where early processes occur (17).  
75 Furthermore in CF, the slow rate of decline in FEV<sub>1</sub> evident as a result of improved standards  
76 of care (18), limit its sensitivity to detect change in clinical status and response to treatment.  
77 Spirometry can only be reliably carried out in individuals aged >6 years as it requires ability to  
78 take instruction and co-operation. There is a clear need for an alternative measurement of lung  
79 function. As research has established that MBW is a valid and reliable measure of ventilation  
80 distribution which correlates with lung disease severity (8), it has become established as a  
81 secondary outcome in clinical trials and may also have a place in regular clinical monitoring in  
82 CF. Moreover, MBW could potentially inform physiotherapy assessment and the evaluation of  
83 new treatments.

84 Unlike spirometry, MBW is not part of undergraduate training programmes and there  
85 are few training programmes outside specialist research centers. Therefore, in order to facilitate  
86 the translation of MBW into clinical care there is a need for effective training. We propose  
87 that training respiratory physiotherapists to perform MBW could be advantageous in the  
88 management of respiratory patients.

89

## 90 **Objectives**

91 The objectives of this article are to

92 1. Rationalise how MBW may be a useful assessment tool for respiratory physiotherapists.

93 2. Describe a local MBW training and certification programme for physiotherapists.

94 3. Highlight available MBW training resources.

95

96 *MBW testing*

97 In respiratory disease, airway narrowing from mucus obstruction, inflammation and structural  
98 airway damage can cause uneven ventilation distribution and the degree of disease severity can  
99 be assessed using MBW. Lung Clearance Index (LCI) is the most commonly reported measure  
100 of the MBW test and represents the number of functional residual capacity (FRC) volume  
101 turnovers required to “washout” the tracer gas during testing. Individuals with uneven  
102 ventilation distribution use a greater number of turnovers to washout the tracer gas and  
103 therefore will have a higher (more abnormal) LCI. Although MBW tests have been available  
104 for many years, research and clinical interest has increased recently due to the availability of  
105 more sophisticated and user friendly equipment. The MBW test can be performed either with  
106 inhalation of an inert tracer gas such as sulphur hexafluoride (SF<sub>6</sub>) or helium (He), or by using  
107 100% oxygen (O<sub>2</sub>) to wash out resident nitrogen (N<sub>2</sub>). When using SF<sub>6</sub> or He, the gas is first  
108 washed into the lungs and then washed out. When using N<sub>2</sub> washout, 100% O<sub>2</sub> is delivered until  
109 N<sub>2</sub> is washed out. The European Respiratory Society/American Thoracic Society (ERS/ATS)  
110 consensus statement for inert gas washout measurements (19) provides evidence based  
111 guidelines on equipment specifications, test performance and analysis of results and is a key  
112 reference document for sites planning the set-up and delivery of MBW testing. Some key points  
113 about MBW from the inert gas washout measurements consensus statement (19) and an  
114 evidence review for LCI (8) are summarized in Table 1.

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118 Table 1: MBW key points

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- MBW tests assess the efficiency of ventilation distribution (19)
- LCI is the most commonly reported MBW index in current paediatric and adult literature (19)
- LCI is the number of functional residual capacity (FRC) lung volume turnovers required to reduce tracer gas concentration to a fraction of its starting concentration (19)
- End of washout is historically defined as 1/40<sup>th</sup> of the starting tracer gas concentration (19)
- MBW testing requires only tidal breathing and stability of resting lung volumes throughout the washout is critical (19)
- LCI is reported as the mean (SD) of 3 technically acceptable and repeatable washout tests (19)
- In a healthy person, upper limits of normal for LCI between 7.0 – 7.5 have been reported (2,30)
- A complete MBW testing session (3 tests) typically lasts between 20 - 40 minutes (2,31)
- The minimum clinically important difference in LCI has yet to be defined but treatment effects of 1.0-2.2 lung turnovers have been reported (3,9,32,33)
- LCI is dependent on body size and appropriate reference equations are essential for accurate interpretation of results (34)
- Results are specific to equipment and therefore are not comparable across different systems (e.g. system using SF<sub>6</sub> vs. system using N<sub>2</sub> as tracer gas)

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There are key areas where LCI demonstrates potential clinical utility. Firstly, LCI can detect early lung disease, potentially informing clinical decisions on treatment and management plans earlier in the disease trajectory. It has been shown to detect early lung disease in children and adults and is more sensitive than measures of spirometry (FEV<sub>1</sub>) in both CF and bronchiectasis (2,5,11). Indices from the MBW test have also been shown to be sensitive to lung disease in asthma (13), COPD (14) and alpha-1-antitrypsin deficiency (20).

138           Importantly, LCI relates to other meaningful clinical endpoints and patient centered  
139 outcomes, which confirms its validity as a useful measure. In CF, LCI has been shown to relate  
140 to health related quality of life as measured by a validated questionnaire, and to predict  
141 pulmonary exacerbations (4,21). In both CF and bronchiectasis, LCI relates to measures of  
142 high resolution computed tomography (HRCT) chest imaging (11). LCI has been shown to be  
143 responsive to the disease modulating therapy, ivacaftor, in CF (9). LCI, but not FEV<sub>1</sub>%  
144 predicted, was also responsive to mucoactive therapies including inhaled hypertonic saline (3)  
145 and DNase in CF (7). The responsiveness of LCI highlights that it could have a potential role  
146 in the assessment of therapies and in the long term monitoring in patients.

147           A small number of studies have been carried out to investigate the short term effect of  
148 airways clearance interventions on LCI in both CF and bronchiectasis. In CF, one study  
149 demonstrated a significant reduction (improvement) in LCI following treatment with Non-  
150 Invasive Ventilation compared to Positive Expiratory Pressure mask in 32 patients with CF  
151 (22). Measures of gas mixing efficiency from a single-breath gas washout test also improved  
152 significantly after airway clearance in 25 children with CF (23). The majority of studies show  
153 no change or a variable change (increase and decrease) in LCI (12,24-26). This highlights that  
154 airways clearance techniques cause alterations in gas mixing which are greater than those who  
155 do not undergo airway clearance. One theory suggested is that airway clearance may open up  
156 previously “blocked off” areas caused by mucus plugging, or relieve areas of atelectasis,  
157 opening up poorly ventilated areas, thereby causing a rise (worsening) in LCI. Further studies  
158 of the medium to long-term effect of airways clearance techniques on LCI and other MBW test  
159 outcomes would be beneficial in informing physiotherapists whether there is a place for MBW



160 testing in assessing airways clearance. The challenge with airways clearance trials remains that  
161 there is no consensus on the best index to use to measure effect (27).

162 As MBW testing demonstrates utility across a range of respiratory diseases, both  
163 clinical and clinical trial sites are exploring the acquisition of equipment and training in order  
164 to embed this outcome measure in trials and to offer this test as part of their assessment. This  
165 highlights a development opportunity for respiratory physiotherapists.

166

### 167 *The role of respiratory physiotherapists*

168 Respiratory physiotherapists are directly involved in conducting and interpreting lung function  
169 tests and the key role of the physiotherapist in evaluating response to inhaled therapies, airways  
170 clearance therapies and physical activity has been highlighted in CF (28). Physiotherapists are  
171 ideally placed to build on their existing knowledge and expertise in acquiring the skill of MBW  
172 testing, which could potentially be utilized as part of their patient's assessment. Respiratory  
173 physiotherapists form an integral part of the multidisciplinary team and are involved in the  
174 assessment of patients' respiratory status within the context of outpatient appointments, annual  
175 assessments as well as inpatient admissions. MBW testing falls under the Chartered Society of  
176 Physiotherapy (CSP) scope of practice of physiotherapy in the UK, defined as "any activity  
177 undertaken by an individual physiotherapist that may be situated within the four pillars of  
178 physiotherapy practice where the individual is educated, trained and competent to perform that  
179 activity" (CSP, 2008) and therefore is covered under professional liability insurance. As MBW  
180 testing has its roots in clinical research, conduct of the technique has historically been the remit  
181 of the researcher. Implementing research practices into clinical practice is challenging and  
182 requires the collaboration and commitment of the academic researchers, clinicians, managers

183 and patients. Increasing awareness and knowledge of new assessments, skills required and the  
184 wider practical implications are recognised aspects of successful integration of change to  
185 practice (29). A key feature of all clinical practice including physiotherapy practice, is the  
186 capacity to respond and evolve to changes in healthcare. A focus on providing the training  
187 opportunities to support physiotherapists to be competent at embedding new techniques within  
188 their clinical practice will facilitate the translation of research into practice. To enable the  
189 successful integration into clinical practice, appropriate training in the technical aspects of set  
190 up, conducting the test, and interpretation and quality assurance of results is essential (19).  
191 Through our experience of delivering a training programme, we have demonstrated how both  
192 clinical and research physiotherapists can successfully complete training and certification in  
193 this skill for use in research and clinical practice.

194

#### 195 *Training programme*

196 The respiratory Multi-Disciplinary Team in Belfast Health and Social Care Trust (BHSCT)  
197 identified a need for MBW testing to be available to facilitate clinical research and clinical  
198 assessment. In response to this, a 2 day programme was developed and delivered by a Queen's  
199 University Belfast PhD researcher (physiotherapist KON) trained in using the modified  
200 Innocor™ device (by an external expert in the equipment, Dr Alex Horsley, University of  
201 Manchester). The programme consisted of pre-reading preparation, self-directed learning, a  
202 presentation on theory, practical demonstrations and practice. Thereafter to be certified,  
203 participants completed 10 tests after the 2 day programme which were then assessed for  
204 technical validity and repeatability. The trainer was available for trouble shooting on  
205 calibration and testing during the certification process. Table 2 details the programme content

206 and layout and the certification procedure. Appendix 1 details the programme in full. All  
 207 content was based on the device Standard Operators Procedure (used with permission)  
 208 “Multiple breath washout test using modified Innocor™ device SOP; UK Cystic Fibrosis Gene  
 209 Therapy Consortium; September 2010, Dr. Nick Bell” and on guidance from external expert  
 210 Dr Alex Horsley, University of Manchester. A knowledge (6 multiple choice questions) and  
 211 confidence (Likert visual analogue scales rating setting up the equipment, conducting and  
 212 interpreting the test) questionnaire was completed by participants before the programme and  
 213 after submission of certification tests (appendix 2). Participants were also asked to make  
 214 suggestions for improvement of the programme.

215

216 Table 2: Programme content and layout

Preparation:  Key references and protocols for pre-reading.
Day 1:  Background to MBW. Overview of references and Standard Operating Procedure. Familiarisation with equipment components, on-screen menus and consumables. Overview and practice of calibrations. Patient preparation for testing.
Day 2:  Explanation and demonstration of phases of testing: Washin phase, beginning of washout, washout phase. Practice testing with volunteer and quality control of readings. Log keeping, cleaning of equipment and infection control. Accessing and downloading tests.
Certification procedure:

Trouble shooting on calibration and testing.

Collection of 10 tests.

9/10 technically acceptable tests required for certification.

If <9/10 tests valid, submission of additional 5 tests.

217

218 The programme was delivered on 2 occasions to a total of 10 participants (5 clinical researchers  
219 [3 physiotherapists, 1 nurse, 1 clinical physiologist] and 5 clinical physiotherapists) based in  
220 BHST. All 10 participants completed the 2 day programme. However 2/10 participants  
221 (clinical physiotherapists) did not complete the certification procedure (no time due to clinical  
222 caseload). The remaining 8 participants successfully completed the certification procedure. Six  
223 participants completed the knowledge and confidence assessment before and after the  
224 programme and certification (2 participants did not complete the certification and 2 completed  
225 the programme before the knowledge and confidence questionnaire was introduced). For these  
226 6 participants, knowledge improved from 61% at baseline to 100% post programme.  
227 Confidence improved from 3% at baseline to 76% post programme; however 2 participants  
228 highlighted that they still were not very confident in interpreting MBW results. Suggestions for  
229 improvement included the development of eLearning material, the inclusion of content on N<sub>2</sub>  
230 washout devices and information on the interpretation and analysis of MBW results.

231 Experience from this programme demonstrates how both clinical and research  
232 physiotherapists can successfully complete a training and certification programme in MBW  
233 testing. As 2 clinical staff members were unable to complete certification due to time  
234 constraints it highlights that agreement and ongoing support from management is required to  
235 ring fence time to organise and complete certification readings.

236 *Resources for MBW training*

237 For those wishing to pursue training in MBW testing, the ERS/ATS inert gas washout  
238 consensus statement provides a comprehensive outline on all aspects of equipment  
239 specifications, test performance and analysis (19). As MBW testing involves practical and  
240 technical skills, face-to-face training for “hands-on” experience is considered optimal. During  
241 the equipment installation process manufacturers usually provide training according to their  
242 standard operating procedure. Additional training is required to obtain certification to a  
243 research quality standard and there are UK sites who provide training, certification and an over-  
244 reading service (quality checking and final result verification of MBW data) as well as a point  
245 of contact for re-fresher training and troubleshooting. (Royal Brompton and Harefield Hospital,  
246 London and BHSCT).

247 MBW testing is a developing area and is technically challenging to perform. Therefore,  
248 regular practice with quality control checks is essential to ensure that confidence and  
249 competence with use of the equipment is maintained. Re-fresher training is important if time  
250 has elapsed since original training or last use. As MBW is primarily a research tool at present,  
251 it is possible that the operator may become deskilled if using the method infrequently or only  
252 during a specific clinical trial. eLearning tools are one method that reinforce face-to-face  
253 learning and support re-fresher training remotely. Some eLearning resources have been  
254 developed by commercial companies using MBW testing, however access is restricted to sites  
255 participating in the clinical trial. An eLearning tool developed at Queen’s University Belfast  
256 ([www.MBWtraining.com](http://www.MBWtraining.com)), is open access and provides comprehensive information on MBW  
257 testing using a variety of learning mediums including slideshow presentations, animations and  
258 a step by step library of videos demonstrating set-up and testing. The tool also includes a self-

259 assessment component, a social networking interface and teaching team contact details for on-  
260 going support. In addition to reinforcement of face-to-face learning, this eLearning tool aims  
261 to facilitate ongoing and re-fresher training and act as a point of contact for troubleshooting  
262 and quality assurance issues. This blended learning approach (face-to-face programme  
263 supported by eLearning) aims to provide an effective and accessible form of MBW training to  
264 sites.

265

## 266 **Conclusions**

267 MBW to measure LCI is emerging as a promising outcome measure with potential for  
268 integration into routine clinical management of patients with CF and growing potential for use  
269 in bronchiectasis, asthma and COPD. In order for integration into clinical practice to be  
270 successful, training of the appropriate personnel in the technical aspects of set up, conducting  
271 the test, interpretation and quality assurance of results is essential. We propose that respiratory  
272 physiotherapists are ideally placed to undergo such training and become qualified to perform  
273 the MBW technique in response to expansions in service delivery. We have demonstrated the  
274 successful training and certification of clinical and research physiotherapists and encourage  
275 other respiratory physiotherapists to explore the area of MBW test training.

276

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402

## **Appendix 1: Training Programme: Multiple Breath Washout Test using Modified Innocor™ device: Queen's University Belfast & Belfast Health and Social Care Trust**

### PROGRAMME

Multiple Breath Washout (MBW) Test using Modified Innocor™ device: Queen's University Belfast & Belfast Health and Social Care Trust

Author: **Katherine O'Neill, Prof. Judy Bradley, Prof. Stuart Elborn.**

### INSTRUCTIONAL GOALS

At the end of this course, you will:

- Understand the principals underpinning MBW testing.
- Be able to independently prepare the Innocor™ device and the testing room for procedure.
- Be able to independently set up device and perform all calibration procedures as per SOP
- Be able to maintain the set up to standard as per infection control guidelines in the SOP.
- Know how to complete and maintain the Innocor™ Usage log and the MBW Procedure and Analysis Washout Sheets.
- Know how to adequately explain and prepare patient for procedure.
- Be able to successfully conduct MBW test on adults as per SOP.
- Be able to recognize technically inadequate tests that may warrant an additional test.
- Be able to export the test tracings from the Innocor™ device in preparation for analysis.

## NEEDS AND RESOURCES

### **Required Background**

To successfully complete this course, you must;

- Read the key references
  - Robinson, P.D., Goldman, M.D. & Gustafsson, P.M. 2009, "Inert gas washout: theoretical background and clinical utility in respiratory disease", *Respiration*, vol. 78, no. 3, pp. 339-355.
  - Horsley, A. 2009, "Lung clearance index in the assessment of airways disease", *Respiratory medicine*, vol. 103, no. 6, pp. 793-799
- Read the SOP
  - Multiple breath washout test using modified Innocor™ device SOP; Nick Bell; Clinical Research Fellow; UK Cystic Fibrosis Gene Therapy Consortium; 20th September 2010.

### **Required Equipment**

To commence and successfully complete this course, you will need

- Innocor™ in place with adaptations made as per SOP (see page appendix C SOP)
- Supply of SF<sub>6</sub> gas (NB: Wall bracket or cylinder trolley for size L cylinder required; flow head/regulator for size L cylinder required (ordered through BOC part number 850820) (see page 5 SOP)

- Room set up for procedure (see page 5 SOP)
- Flow past circuit and patient interface consumables in stock (see page 19 SOP)

### **Required Materials**

To successfully complete this course, you will need;

- Multiple breath washout test using modified Innocor™ device SOP; Nick Bell; Clinical Research Fellow; UK Cystic Fibrosis Gene Therapy Consortium; 20th September 2010.
- MBW Procedure and Analysis Washout Sheets
- Multiple Breath Washout Test using the Modified Innocor™ device ; LCI operator Qualification Assessment Form; Oct 2011
- Innocor™ Instructions for Use Manual

## COURSE CONTENT

### TRAINING ITEMS

1. Overview of references and SOP.
2. Checklist of all equipment and consumables in place
3. Set up room, equipment and patient interface
4. Familiarisation with equipment
  - a) Innocor™
  - b) Innocor™ menus
  - c) Patient interface
  - d) Flow past circuit
  - e) Gas cylinder
  - f) Room set up
5. Practice with set up and calibration
  - a) Flow meter linearization
  - b) Flow meter calibration
  - c) Flow gas delay calibration
6. Preparing and explaining procedure to patients
7. Concepts of washin; disconnection and washout (as per SOP).
8. Observe a test \*Volunteer needed\*
9. Supervised practice with patients / volunteers \*Volunteer(s) needed\*

- a) Including keeping the log and note keeping during the test.
- b) Troubleshooting: Awareness of reasons for invalid tests (technician related and patient related) and how to avoid.

10. Infection control procedures

- a) Patient interface
- b) Room

11. Accessing and downloading tracings; sending tracings to analyzer.

12. Information obtained post analysis.

Certification procedure (completed independent post programme)

Trouble shooting on calibration and testing.

Collection of 10 tests.

9/10 technically acceptable tests required for certification.

If <9/10 tests valid, submission of additional 5 tests



Appendix 2: Knowledge and Confidence Assessment Questionnaire\_ Multiple Breath Washout  
Test using Modified Innocor™ device\_ Queen's University Belfast & Belfast Health and Social  
Care Trust\_ Katherine O'Neill\_ March 2013

**Knowledge assessment questionnaire**

**Multiple choice questions- Please choose one**

**1. LCI is derived from**

- a) Single breath washout test
- b) Multiple breath washout test
- c) Body plethysmography test
- d) Diffusion capacity test

**2. LCI is a measure of**

- a) Airflow
- b) Perfusion
- c) Inflammation
- d) Gas mixing efficiency

**3. The upper limit of normal for LCI is**

- a) 10
- b) 5.5
- c) 7.5
- d) 15.5

**4. LCI is calculated as**

- a) The number of lung turnovers required to washout a tracer gas
- b) The concentration of tracer gas at functional residual capacity

- c) The mean concentration of CO<sub>2</sub> at end tidal volume
- d) The number of lung regions ventilated

**5. LCI is a measure most sensitive to**

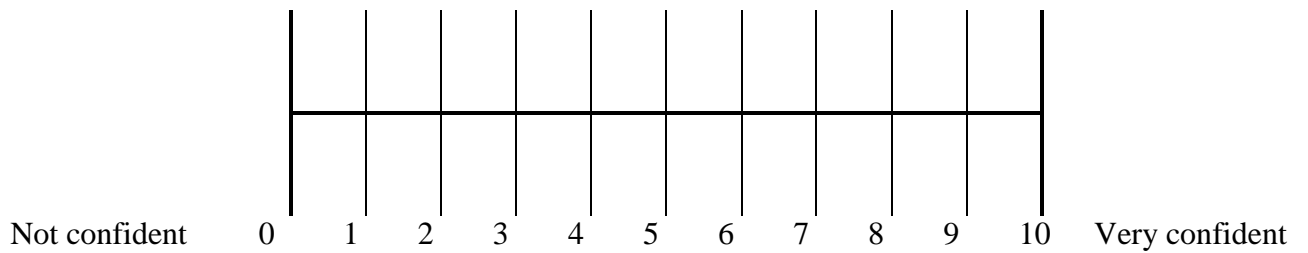
- a) Large airways dysfunction
- b) Small airways dysfunction
- c) SpO<sub>2</sub> levels
- d) Airways inflammation

**6. LCI is a measure which is most informative in**

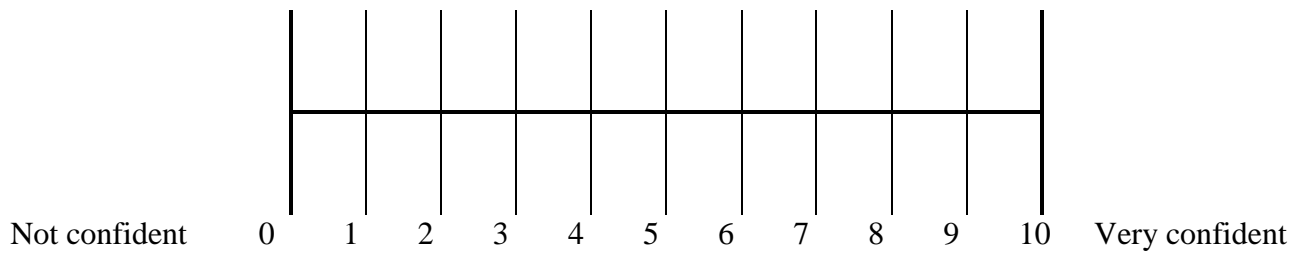
- a) Patients with advanced disease
- b) Patients awaiting transplant
- c) Healthy individuals
- d) Children and patients with mild disease

**Please answer the following questions which relate to your confidence in MBW procedure to obtain LCI**

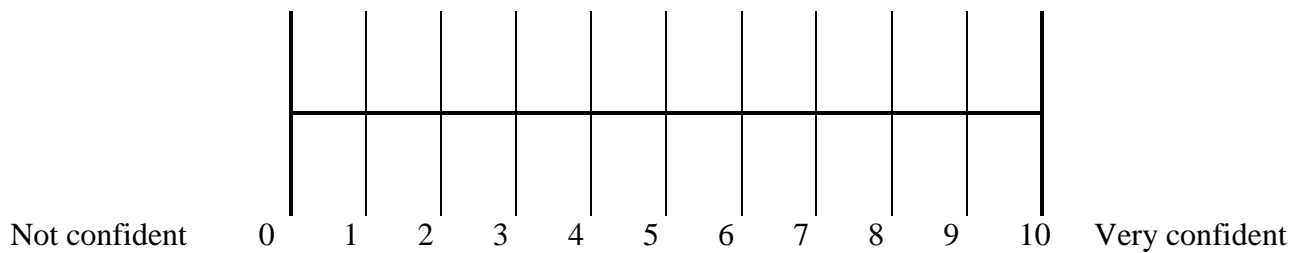
Rate your confidence performing **calibration procedures for MBW testing** before starting the training programme



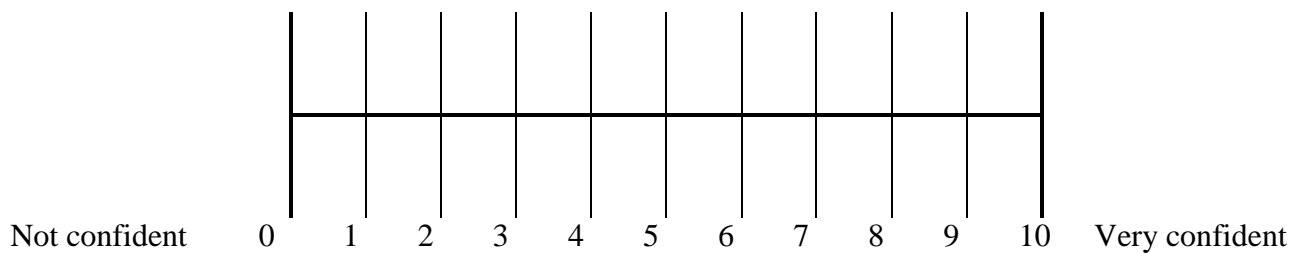
Rate your confidence performing **calibration procedures for MBW testing** on completion of the training programme



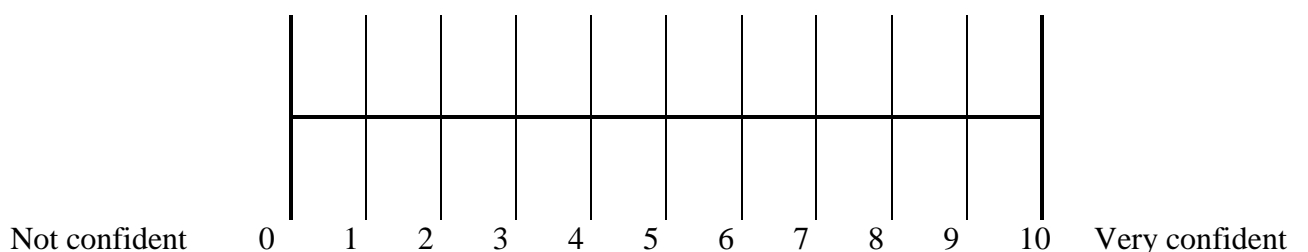
Rate your confidence using **equipment to perform MBW test** before starting the training programme



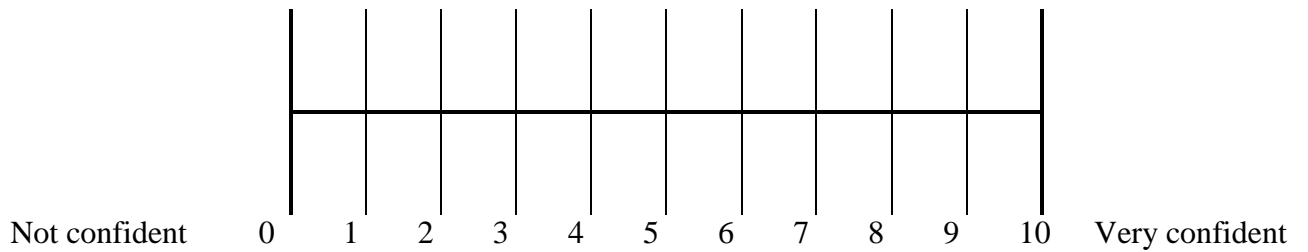
Rate your confidence using **equipment to perform MBW test** on completion of the training programme



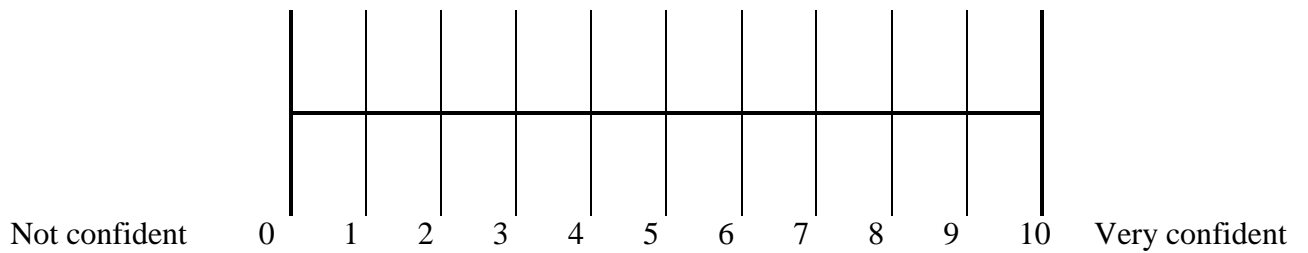
Rate your confidence on **interpreting the LCI result from the results sheet** before starting the training programme



Rate your confidence **interpreting the LCI result from the results sheet** on completion of the training programme



Rate your confidence on **maintenance of the MBW equipment** before starting the training programme



Rate your confidence **maintenance of the MBW equipment** on completion of the training programme

