ERS Annual Congress Barcelona
7 - 11 September 2013

Postgraduate Course 16
Spirometry knowledge and basic skills (part 1 of the European spirometry training programme)

Saturday, 7 September 2013
14:00 - 17:30

Room: 1.1 (CC1)

ERS Spirometry Training Programme

This document provides a step-by-step guide for those who wish to fully complete the European Spirometry training programme Part 1 and Part 2.

PART 1 and the ONLINE KNOWLEDGE TEST

Step 1: Attend the postgraduate course and educational skills workshop

Step 2: Online test

Each participant will receive a link to the online knowledge test after attending the postgraduate course and workshop. Participants will be expected to complete the online MCQ test within 4 weeks of attending the course and will have a total of 3 attempts to complete the test. All participants will be given access to the ERS spirometry website. On this website, participants will have access to content for each of the 8 modules, as well as access to an online knowledge test in English.

Step 3: ERS certificate: Part 1 of the ERS spirometry driving licence

On successful completion of the test, participants can generate an online certificate to confirm that they have passed the knowledge test and have been awarded Part 1 (theory only) certificate of the ERS spirometry driving licence.

ERS SPIROMETRY WORKBOOK

All participants must fully complete the ERS spirometry workbook before attending Part 2 of the European Spirometry training programme.

PART 2 PRACTICAL TRAINING AND ASSESSMENT

Participants will be required to attend Part 2 of the training programme, which will be held in Barcelona, 7 March 2014. This one course will cover modules in knowledge and competence in spirometry measurement. Details on how to register will be distributed in October.

Those who successfully pass the practical assessment and ERS workbook will be awarded Part 2 of the ERS Spirometry Driving Licence, knowledge and competence in spirometry measurement.

Postgraduate Course and Educational Skills Workshop
Spirometry knowledge and basic skills (European spirometry training programme)

Aims: *The aim of Part I Spirometry Knowledge and Skills is to ensure that participants acquire the knowledge and basic skills in spirometry best practice. The training programme is designed to cover the theory required to pass the Level I knowledge test and equip participants with the skills needed to perform spirometric tests and successfully complete a Spirometry workbook, including spirometry assignments, calibration logs, and a portfolio of spirometry tests.*
For more information on the European Spirometry Training Programme programme please visit http://hermes.ersnet.org/spirometry

HERMES LINKS ADULT: *D.1 Pulmonary function testing*

Target audience: *Respiratory therapists, nurses, respiratory physicians, general practitioners, trainees, medical assistants.*

Chairs: *I. Steenbruggen (Zwolle, The Netherlands), B.G. Cooper (Birmingham, United Kingdom)*

Anatomy, physiology and pathophysiology required for spirometry: short summary

Prof. Dr. Jorg Daniel Leuppi
Department of Internal Medicine
University Hospital Basel
Petersgraben 4
4031Basel
Switzerland
jleuppi@uhbs.ch

Summary
This module addresses the mechanics of tidal and maximal forced breathing, the limits of deep in and expiration, the different types of airway obstruction and the structure of airways and lung parenchyma. Spirographic examples will be used to introduce the differences between obstructive lung diseases (asthma and COPD) and restrictive lung diseases. A solid basic knowledge of respiratory anatomy will allow a deeper understanding of normal respiratory physiology and the situations where this is perturbed (i.e. respiratory pathology).

ESDL PART 1

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All you need to know is in:

SERIES "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING"
Edited by V. Brusasco, R. Crapo and G. Viegi

Miller, M. R., R. Crapo, et al. (2005). "General considerations for lung function testing." Eur Respir J **26**(1): 153-161.

Miller, M. R., J. Hankinson, et al. (2005). "Standardisation of spirometry." Eur Respir J 26(2): 319-338.

Pellegrino, R., G. Viegi, et al. (2005). "Interpretative strategies for lung function tests." Eur Respir J **26**(5): 948-968.

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Lucky the French have a translation in:

Traduction française des recommandations ATS-ERS 2005 pour les explorations fonctionnelles respiratoires . Volume 24, Issue 3, Part 2, Pages 4-160 (March 2007) Revue des maladies respiratoires.

Série du groupe de travail ATS/ERS : « standardisation des explorations fonctionnelles respiratoires » Coordonnée par V. Brusasco, R. Crapo et G. Viegi

Standardisation de la spirométrie

M.R. Miller, J. Hankinson, V. Brusasco, F. Burgo, R. Casaburi, A. Coates, R. Crapo, P. Enright, C.P.M. Van Der Grinten, P. Gustafsson, R. Jensen, D.C. Johnson, N. MacIntyre, R. McKay, D. Navajas, O.F. Pedersen, R. Pellegrino, G. Viegi, J. Wanger

Revised 23 March 2006. Accepted 6 April 2006. Available online 30 October 2007.

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And lucky Dutch also have a translation:

Vertaling Richtlijnen ATS/ERS

In beheer van de NVLA zijn uit de serie "TASKFORCE ATS/ERS: STANDAARDISATIE VAN LONGFUNCTIEONDERZOEK" in het Nederlands vertaald:

Free download available at:
www.nvla.nl

ESDL PART 1

MODULE 1

RESPIRATORY PHYSIOLOGY, ANATOMY AND PATHOLOGY

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Aims

- mechanics of tidal and maximal forced breathing
- limits of deep in- and expiration
- several types of airway obstruction
- structure of airways and lung parenchyma

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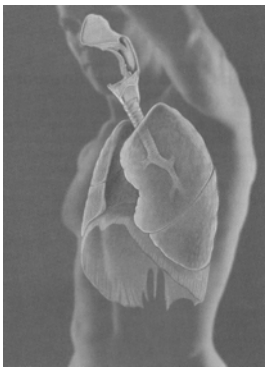
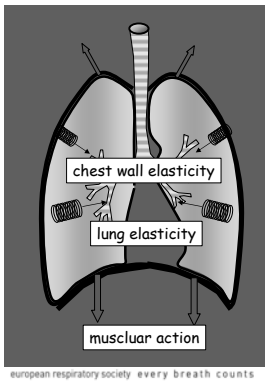
Lungs and chest case





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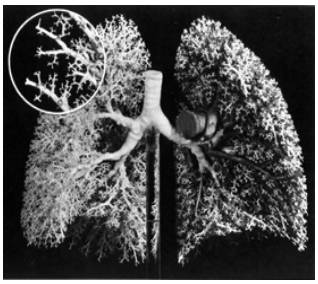
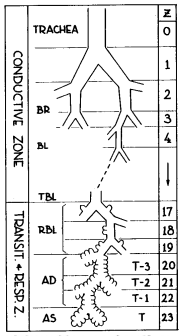
Lungs



Weibel 1984



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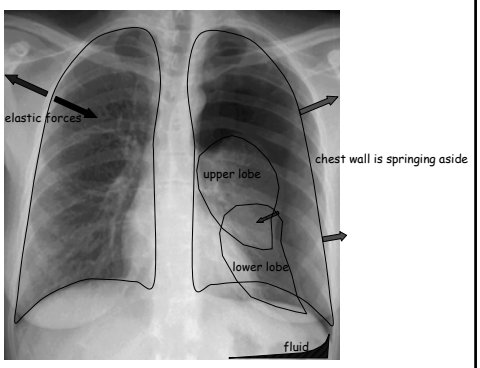
Collapse of the left lung



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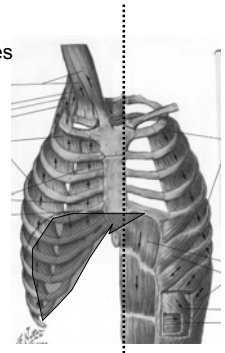
Muscles of respiration

inspiratory muscles

neck musculature

external intercostal

diaphragm



expiratory muscles

internal intercostal

abdominal musculature

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Maximal deep inspiration

sternocleidomastoideus
scalenis

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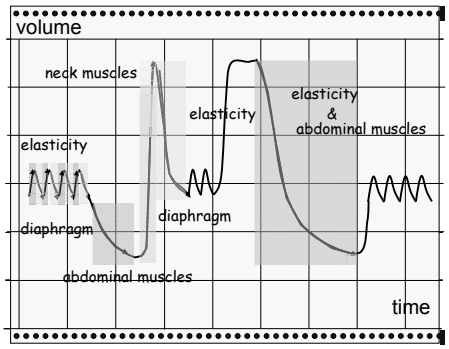
Mechanics during spirometry



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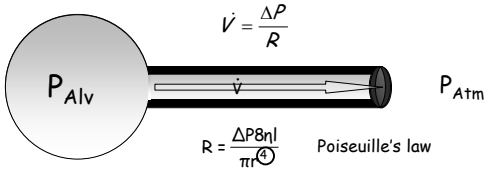
Airflow

$$\dot{V} = \frac{\Delta P}{R}$$



$$R = \frac{\Delta P 8 \eta l}{\pi r^4}$$ Poiseuille's law

airflow is dependent on:

- alveolar pressure
  - muscular strength
  - elasticity
- resistance
  - airway collapse
  - airway obstruction

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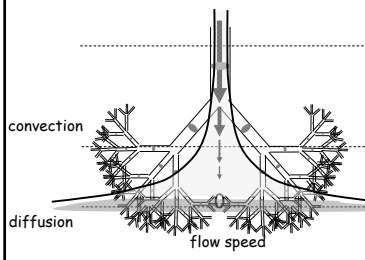
Trumpet of funnel model

sum of the transverse areas of each branching generation



generation	amount	cross-section	total area
trachea			
0	1	3 cm^2	3 cm^2
segmental bronchi			
3	20	0,15 cm^2	6 cm^2
respiratory bronchioli			
18	2.10^5	0,00195 cm^2	390 cm^2

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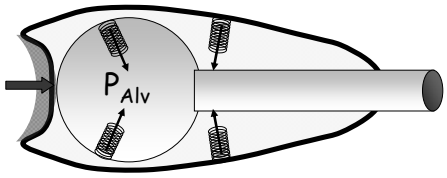
Alveolar and intrathoracic pressure



$$P_{alv} = P_{cw} + P_{musc} + P_{lung}$$
$$P_{int.th} = P_{cw} + P_{musc}$$

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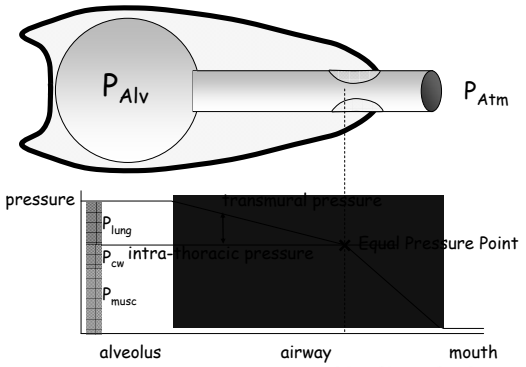
Expiratory airway collapse



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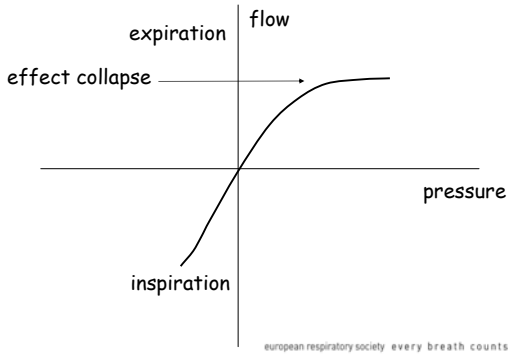
ISO volume flow-pressure (50% VC)



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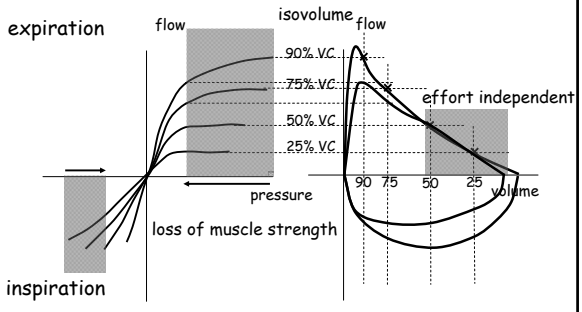
Reconstruction F -V curve



flow-pressure curve flow-volume curve

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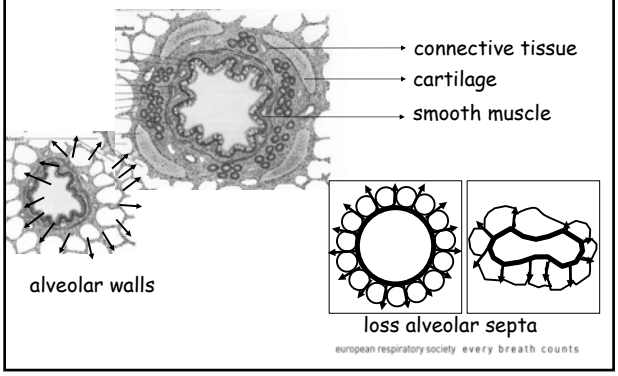
Airways and lung parenchyma



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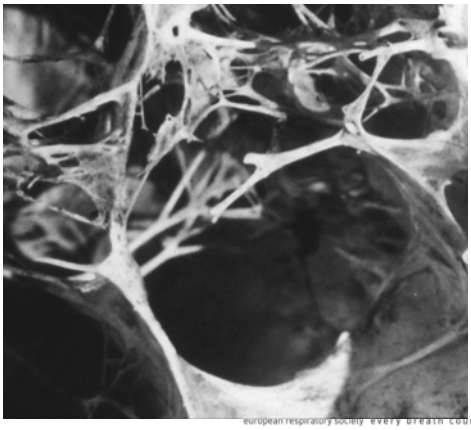

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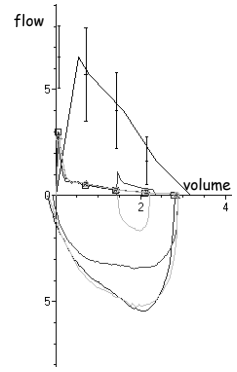
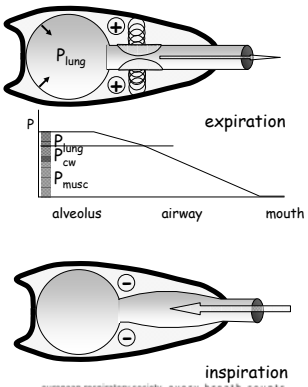
Airway mechanics in lung emphysema



F-V curve in lung emphysema



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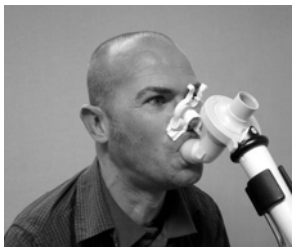
The limits of breathing

maximal inspiration



maximal expiration

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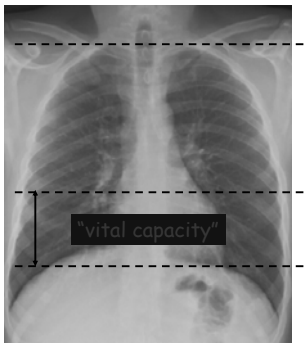
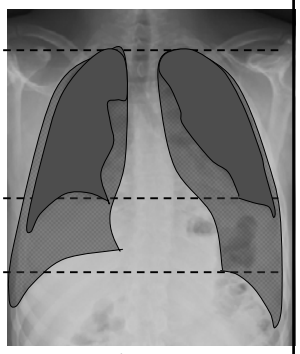
Maximal movements of the chest



maximal inspiration
TLC-niveau



maximal expiration
RV-niveau

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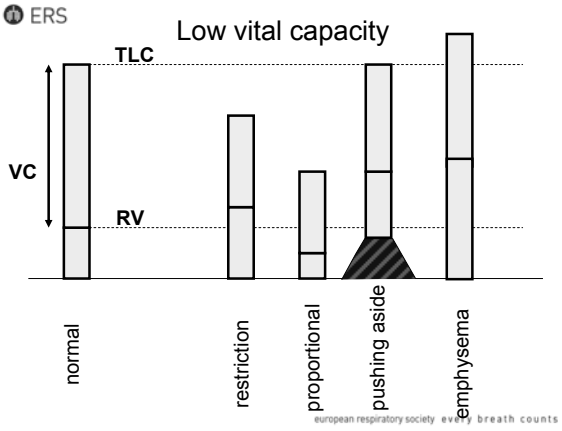
Low vital capacity



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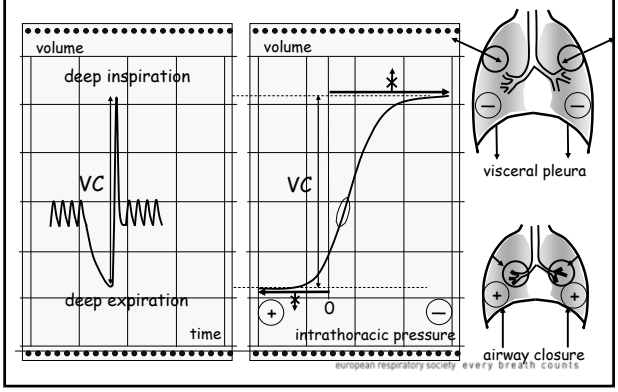
Limits of the vital capacity



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Respiratory pathology

Main categories of obstructive disease:

- Asthma
- COPD
  - Chronic bronchitis
  - Emphysema

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Asthma

- Airway inflammation with variable airway obstruction and abnormal airway responsiveness to a variety of stimuli.
- Often reversible airway obstruction – spontaneously or induced by treatment

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COPD

- Chronic Obstructive Pulmonary Disease (COPD) is characterised by airflow obstruction.
- The airflow obstruction is usually progressive and is not fully reversible
- Predominantly caused by smoking

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Obstruction

- Reduction of maximal airflow from the lung in relation to the maximal volume. It implies airway narrowing during exhalation and is defined by a reduced FEV1/(F)VC ratio
- Appears in asthma and COPD

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Restriction

- Maximum achievable lung volume has diminished. This implies a reduction in TLC

  Due to e.g.:

  – surgical removal of part of the lung
  – lung fibrosis
- Normal FEV1/(F)VC ratio

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Want to know more?

- About respiratory mechanics:
  Respiratory_mechanics_Caen.ppt
- About PEF and respiratory mechanics:
  Peak expiratory flow (ESDL).ppt
- About Forced expiratory flow and respiratory mechanics:
  Forced expiration (ESDL).ppt

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Definitions of spirometric values: short summary

Prof. Dr. Jorg Daniel Leuppi
Department of Internal Medicine
University Hospital Basel
Petersgraben 4
4031Basel
Switzerland
jleuppi@uhbs.ch

Summary
This module examines the definitions and calculations of spirometric indices. Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The primary signal measured in spirometry may be volume or flow. The test effort can be presented as a 'flow-volume loop' or as a 'volume-time curve`. The features of these two presentations of spirometric data will be highlighted as well as the measurements which can be derived from them. Methods for correction of spirometric data for patient factors (such as slow starting) or environmental factors (such as ambient temperature) will also be taught.

ESDL PART 1

MODULE 2

DEFINITIONS AND CALCULATIONS
OF SPIROMETRIC INDICES

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Aim of presentation is

- Overall – to improve your knowledge of definitions used routinely when carrying out spirometry testing, and to be able to identify where these measures are made.

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Aim of presentation is

- Also – to be able to know the differences between terms and to apply these terms when analysing test results.

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Background

- Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The primary signal measured in spirometry may be volume or flow.
- The test effort can be presented as a 'FLOW-VOLUME LOOP' or as a 'VOLUME-TIME CURVE'.

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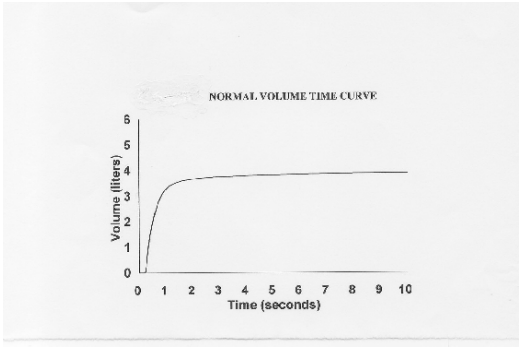
Volume time curve



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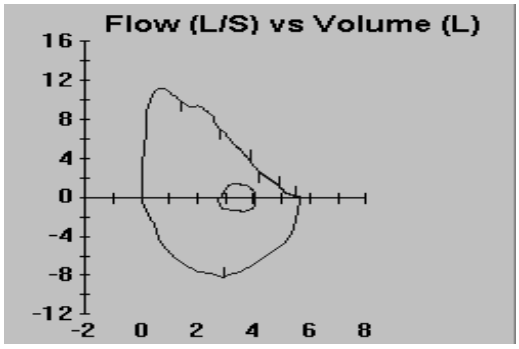
Flow volume loop



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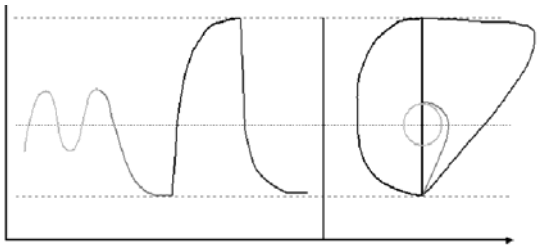
Volume – Time – Curve
Flow – Volume – Curve



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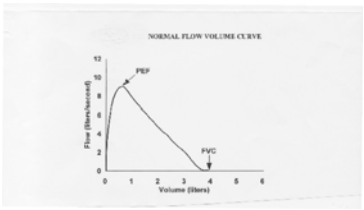
Expiratory limb of flow volume curve



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The main definitions

- VC – Vital Capacity –
  the maximal volume of air exhaled steadily from full inspiration to maximal expiration (not time dependent).

  The air in the lung between residual volume and total lung capacity.

  This is expressed in litres at BTPS (body temperature, and ambient pressure, saturated with water vapour).

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The main definitions

- FVC – FORCED VITAL CAPACITY the maximal volume of air exhaled with maximally forced effort from a maximal inspiration (expressed in litres at BTPS).

A slow or unforced VC or inspiratory vital capacity (IVC) manoeuvre may provide a larger and more appropriate denominator for calculation of the $FEV_1/VC\%$.

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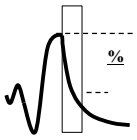
The main definitions

- FEV1 – FORCED EXPIRATORY VOLUME IN ONE SECOND
  the maximal volume of air exhaled in the first second of a forced expiration from a position of full inspiration (expressed in litres at BTPS).



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The main definitions

- FEV1/FVC
  Forced Expiratory Volume in 1 second divided by the Forced Vital Capacity (or FEV1 ratio). The percentage of the FVC that the patient can forcefully exhale in the first second of the FVC manoeuvre.

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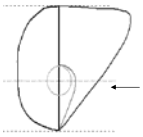
The main definitions

- P.E.F. – Peak Expiratory Flow
  the highest flow achieved from a maximum forced expiratory manoeuvre started without hesitation from a position of maximal inspiration. Can be expressed in litres per second, or litres per minute.



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Other definitions

- P.I.F. – Peak Inspiratory Flow
  is the maximum inspiratory flow achieved from a maximum forced inspiration, starting without hesitation from the point of maximal lung deflation, expressed in $L*s^{-1}$.

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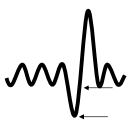
Other definitions

- ERV - Expiratory reserve volume
  volume change recorded at the mouth when taking a slow full expiration with no hesitation, from a position of passive end-tidal expiration, i.e. FRC, to a position of maximum expiration, expressed in litres at BTPS.



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Other definitions

IC – Inspiratory Capacity
volume change recorded at the mouth when taking a slow full inspiration with no hesitation, from a position of passive end-tidal expiration, i.e. FRC, to a position of maximum inspiration, expressed in litres at BTPS.

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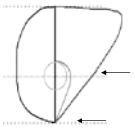
Other definitions

- F.E.F. 25-75% - Forced Expiratory Flow 25–75%.
  The mean forced expiratory flow between 25% and 75% of the FVC. Expressed in litres at BTPS.

  This index is taken from the blow with the largest sum of FEV_1 and FVC.

  It should be noted that it is highly dependent on the validity of the FVC measurement and the level of expiratory effort.



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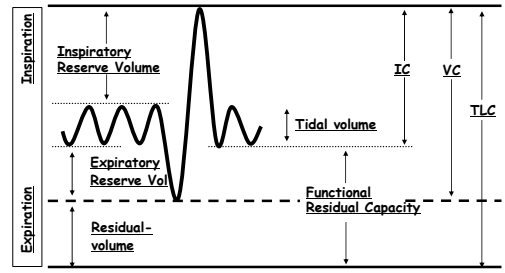
Spirogram



TLC=	Total Lung Capacity	(6 liter)
FRC=	Functional Residual Capacity	(3 liter)
RV=	Residual Volume	(1.8 liter)
TV=	Tidal Volume	(0.5 liter)
IC=	Inspiratory Capacity	(3 liter)
IRV=	Inspiratory Residual Volume	(2.5 liter)
ERV=	Expiratory Reserve Volume	(1.2 liter)
VC=	Vital Capacity	(4.2 liter)

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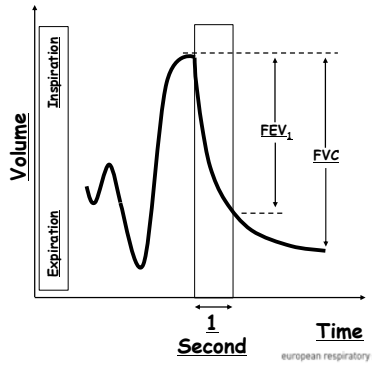
Spirogram:



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Back extrapolation

- If a patient is slow to start the expiratory manoeuvre, the measure can be corrected by back extrapolation. Time zero can be assessed by visual analysis, and should be reported.
- Most computerised spirometers correct automatically.
- If machine does not have printout, it can be difficult to assess quality of manoeuvre.

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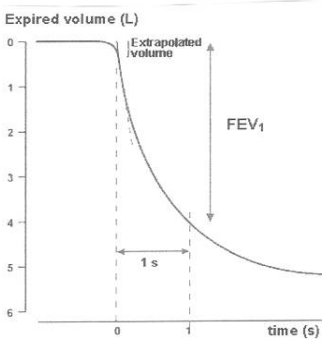
Back extrapolation



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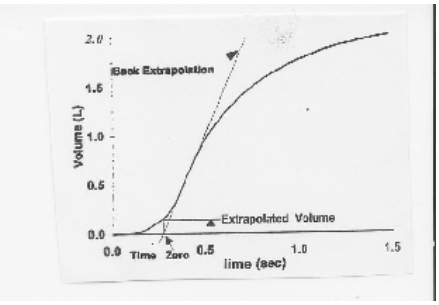
Back extrapolation



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Environmental conditions

- Environmental conditions have a significant effect on measuring lung volumes
- E.g. 5 liter in a spirometer (room air of 22 ° C) = 5.46 liter in a lung (body temp of 37 ° C)

$$\frac{P_{BTPS}V_{BTPS}}{T_{BTPS}} = \frac{P_{ATPS}V_{ATPS}}{T_{ATPS}}$$

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Ambient temperature

- All measures of gas volumes should be reported at B.T.P.S. (measuring temperature and barometric pressure).
- Results should not relate to conditions in the measuring equipment (ATPS).
- Ambient temperature must be recorded with an accuracy of $\pm$ 1ºC.
- 17ºC is the lower limit for ambient temperature unless manufacturer states otherwise.

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Ambient temperature

- Changes in spirometer temperature can be a source of variability.
- The method used to calculate or estimate the BTPS factor can potentially introduce significant errors.
- Temperature should be measured and not assumed to be constant even over the course of one testing session.

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References

1. Standardisation of Spirometry. M.R. Miller et al. E.R.J. 2005; 26:319-338. 'ATS/ERS Task Force: Standardisation of Lung Function Testing'.
2. Lung Volumes and forced ventilatory flows. Official statement of ERS. E.R.J. 1993;6. Suppl.16, 5-40.

Spirometry equipment

Mrs. Julie K. Lloyd
118 Upper Way
Upper Longdon
Rugely
WS15 1QD Staffordshire
United Kingdom
julie.lloyd@heartofengland.nhs.uk

ESDL PART 1

MODULE 3

SPIROMETRY EQUIPMENT

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Spirometry equipment

- Spirometers
  - Computer and software
  - Mouthpiece, Tubings, nose clips and bacterial filters
- Spirometer calibration syringes (3 litre)
- Thermometer, hygrometer and barometer
- Stadiometer and balance
- Reference values
- Standards & instructions for spirometry

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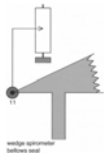
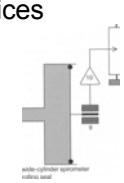
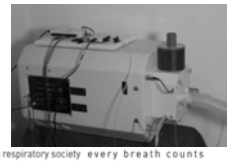
Spirometry measurement principles
Volume measuring devices



As the subject exhales the bellows expands, the chart moves and the stylus records

As the subject in- and exhales the piston moves and the movement is recorded electro-nicaly





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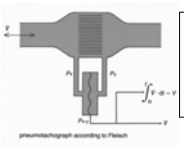
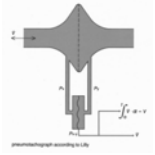
Spirometry measurement principles
Flow measuring devices



As the subject in- and exhales a pressure fall (Px-Py) is generated across the screen. The pressure fall is proportional to flow which can be integrated to a volume (V)



Other measurement principles:
Ultrasound flow sensor
Pitot tube
Hot wire anemometer

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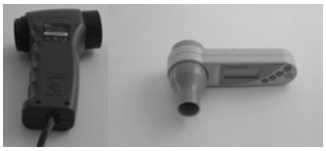
Spirometers

Opening membrane pneumotach



Fleisch pneumotach

Rotating vane

Lilly pneumotach

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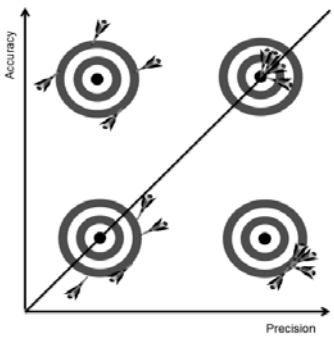
Metrology: Measurement terminology



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ATS/ERS specifications for spirometers 2005

TABLE 6 Range and accuracy recommendations specified for forced expiratory manoeuvres

Test	Range/accuracy (BTPS)	Flow range $L \cdot s^{-1}$	Time s	Resistance and back pressure	Test signal
VC	0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater	0–14	30		3-L Calibration syringe
FVC	0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater	0–14	15	<1.5 $cm H_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	24 ATS waveforms, 3-L Cal Syringe
FEV_1	0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater	0–14	1	<1.5 $cm H_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	24 ATS waveforms
Time zero	The time point from which all FEV_1 measurements are taken			Back extrapolation	
PEF	Accuracy: ±10% of reading or ±0.20 $L \cdot s^{-1}$ (20 $L \cdot min^{-1}$), whichever is greater; repeatability: ±5% of reading or ±0.15 $L \cdot s^{-1}$ (10 $L \cdot min^{-1}$), whichever is greater	0–14		Mean resistance at 200, 400, 600 $L \cdot min^{-1}$ (3.3, 6.7, 10 $L \cdot s^{-1}$) must be <2.5 $cm H_2O \cdot L^{-1} \cdot s^{-1}$ (0.25 $kPa \cdot L^{-1} \cdot s^{-1}$)	26 ATS flow waveforms
Instantaneous flows (except PEF)	Accuracy: ±5% of reading or ±0.200 $L \cdot s^{-1}$, whichever is greater	0–14		<1.5 $cm H_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	Data from manufacturers
$FEF_{25-75\%}$	7.0 $L \cdot s^{-1}$, ±5% of reading or ±0.200 $L \cdot s^{-1}$, whichever is greater	±14	15	Same as FEV_1	24 ATS waveforms
MVV	250 $L \cdot min^{-1}$ at V_T of 2 L within ±10% of reading or ±15 $L \cdot min^{-1}$, whichever is greater	±14 (±3%)	12–15	<1.5 $cm H_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	Sine wave pump

BTPS: body temperature and ambient pressure saturated with water vapour; VC: vital capacity; FVC: forced vital capacity; ATS: American Thoracic Society; FEV_1: forced expiratory volume in one second; FEV_t: forced expiratory volume in t seconds; PEF: peak expiratory flow; $FEF_{25-75\%}$: mean forced expiratory flow between 25% and 75% of FVC; MVV: maximum voluntary ventilation; V_T: tidal volume.

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Spirometer requirements - summary

Spirometers must be able to accumulate volume ≥ 15 s

Measuring volume ≥ 8 liter (BTPS)

Accuracy of reading at least 3% (or ± 0.05 liter) with flows from 0 – 14 liter/s

Total resistance of airflow at 14 l/sec should be less than 1.5 cm $H_2O\ L^{-1}\ s^{-1}$ (= 0.15 kPa $L^{-1}\ s^{-1}$)

With all filters / tubing etc in place (filters may change in resistivity due to moisture)

Up to 8 FVC measurements in 10 min (with above criteria)

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ATS/ERS Specifications for scale factors 2005

TABLE 2 Recommended minimum scale factors for time, volume and flow on graphical output

Parameter	Instrument display		Hardcopy graphical output	
	Resolution required	Scale factor	Resolution required	Scale factor
Volume#	0.050 L	5 $mm \cdot L^{-1}$	0.025 L	10 $mm \cdot L^{-1}$
Flow#	0.200 $L \cdot s^{-1}$	2.5 $mm \cdot L^{-1} \cdot s^{-1}$	0.100 $L \cdot s^{-1}$	5 $mm \cdot L^{-1} \cdot s^{-1}$
Time	0.2 s	10 $mm \cdot s^{-1}$	0.2 s	20 $mm \cdot s^{-1}$

#: the correct aspect ratio for a flow *versus* volume display is two units of flow per one unit of volume.

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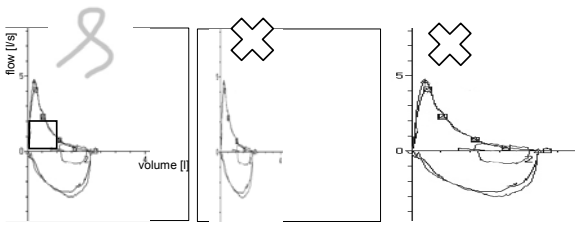
Use fixed 2:1 scale



2 : 1 1 : 1 1 : 2

Correct ratio flow:volume
= 2 units of flow versus 1 unit of volume

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ATS/ERS Specifications for quality control 2005

TABLE 3 Summary of equipment quality control

Test	Minimum interval	Action
Volume	Daily	Calibration check with a 3-L syringe
Leak	Daily	3 cmH_2O (0.3 kPa) constant pressure for 1 min
Volume linearity	Quarterly	1-L increments with a calibrating syringe measured over entire volume range
Flow linearity	Weekly	Test at least three different flow ranges
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using "known" subject

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Spirometers summary

Type	Advantages	Disadvantages
Rolling seal[1]	Accurate and precise, reliable Not affected by gas composition	Size, price, cleaning
Wedge bellows[2]	Accurate and precise, reliable Not affected by gas composition	Size, cleaning, BTPS conversion of volumes is problematic. Inspiratory tests are impractical
Pneumotachograph	Accurate and precise, reliable, portable,	Only linear over defined range Affected by gas composition Calibrated with gas at ATPD[3] and measures expiration at BTPS and inspiration at ATPD
Rotating vane	Accurate and precise, reliable Not affected by gas composition	
Ultrasound	Accurate and precise, reliable Not affected by gas composition	Needs to be zero flow

[1]Internal thermometer needed to calculate gas volume at BTPS
[2]Older models may not comply with the ATS/ERS standard due to back-pressure above specifications.
[3] ATPD is a modification since gas (room air) is partly saturated with water vapour

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Spirometers: What to look for!

Specifications	
ATS/ERS specifications	An absolute must. Look for maximum volume, back-pressure and software performance.
Software	Automatic check of "start" and "end of test" criteria and selection of best FEV_1 and FVC Storing of all quality control data Linearization of Pneumotachograph signal ATPS / BTPS conversion Can the accuracy and precision of time calculation be controlled? (a general problem)
Calibration	Practicality
Practicality	Is the system easy to operate? How many data entries has to be performed before you can measure? Infection control – cost of consumables
Robustness	Spirometer lifetime and costs

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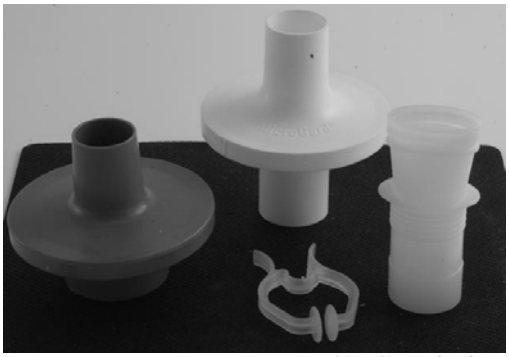
Mouthpiece, tubing's, nose clips and bacterial filters



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Spirometer calibration syringes (3

The ATS/ERS standard: A 3 litre syringe with an accuracy of ≤ 15 mL or 0.5% of the full scale. Calibration annually

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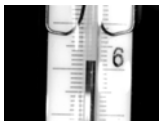
Thermometer, hygrometer and barometer

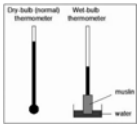
°C



P_B hPa

http://www.dmi.dk/dmi/index/danmark/vejr/observationer/vejrobservationer-land.htm

rH %



The reference is:
A certified thermometer
A certified barometer (available at the web from the local Meteorological org)
A certified wet bulb thermometer

In routine use of the electronic model and calibrate it against reference instruments

You can use an electronic device measuring, temperature, relative humidity and barometric pressure – but then you have to calibrate it against a measurement traceable to a international standard

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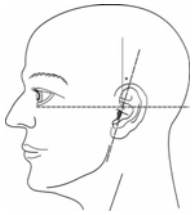
Stadiometer

- Measurement of stature: Do it correct- why not?

Harpenden

Hightronic



The subject is instructed to relax the shoulders and the subject's head is placed in the Frankfurt plane, which is the position where the line passing through the inferior margin of the left orbit and the upper margin of the left external auditory meatus is horizontal

Use stadiometers with digital counters – rapid and accurate.

Position measurands head in Frankfurt plane (not Frankfort plane)

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Reference values

- When we cannot compare a pulmonary function test with previous results we have to compare the results to a reference to estimate whether its normal or abnormal?
- We are in a process where we are moving from the use of percent of predicted towards the use of standardized residuals (or T-scores) when evaluating a lung function test
- Choose the best reference material, which is not easy and use standardized residuals to decide whether a test is normal or not.

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Metrology: A note on calibration terminology

- Although it seems practical to use a descriptive terminology adapted to suit pulmonary function testing it is instead advised to adapt the terminology agreed upon by ISO The International Organisation of Standardization in the International vocabulary of basic and general terms in metrology.
- Calibration is defined as: Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring system, or values represented by a material or a reference material, and the corresponding values realized by standards.
  - Calibration is therefore not restricted to procedures where adjustments (mechanical or electronic) are performed.
- Verification and validation is not defined by ISO, and is therefore not used.
- Verification: Also called calibration check is often used to describe a measurement where no adjustments are performed.
- Validation: Is the same as verification

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References

- ATS ERS Standard on spirometry[1] and General considerations [2]
- World Meteorological Organisation [3]
- International vocabulary of metrology [4]

- 1. Miller, M. R., J. Hankinson, V. Brusasco, F. Burgos, R. Casaburi, A. Coates, R. Crapo, P. Enright, C. P. van der Grinten, P. Gustafsson, et al. 2005. Standardisation of spirometry. *Eur Respir J* 26:319-338.
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- 3. World Meteorological Organisation. 1983. Measurement of atmospheric pressure.,5 ed. WMO, Geneva. 3.1-3.26.
- 4. ISO/IEC Guide 99:2007. International vocabulary of metrology -- Basic and general concepts and associated terms (VIM). 2007. Geneva, International Organization for Standardization.

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Factors that influence reference values

ESDL module 3, 4

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Reference equations are used for comparison of individual subjects with a healthy non-smoking population, measured under ideal conditions, and according to standards agreed upon by the scientific communities.

Reference equations are usually linear expressions of the form

$$y = a*\text{Height (m)} + b*\text{Age(years)} + c$$

There are separate equations for men and women. These equations can only be used in adult subjects and are not valid for the growth period, because they will overestimate their values. Therefore special equations must be used in children.

As lung function depends on other factors than gender, height and age, there will be a scatter around the line described by the equation.

This scatter defines the residual standard deviation (RSD) which is a statistical term so that y- RSD*1.64 will include only 5% of subjects with normal lung function.

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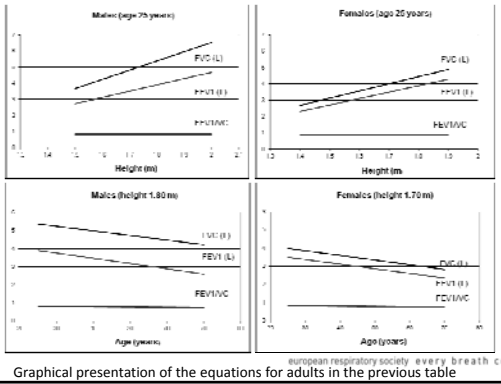
Table 4.2 ECSC Reference equations ERJ 1993; 6:Suppl. 16, 5-40

Index	Regression equation	RSD	Unit
Men			
FEV_1	4.30H - 0.029A - 2.49	0.51	L
FVC	5.76H - 0.026A -4.34	0.61	L
FEV/VC	-0.18A + 87.21	7.17	%
PEF	6.14H - 0.043A + 0.15	1.21	L/s
Women			
FEV_1	3.95H - 0.025A -2.60	0.38	L
FVC	4.43H - 0.026A - 2.89	0.43	L
FEV/VC	-0.19A + 89.10	6.51	%
PEF	5.5H - 0.030A - 1.11	0.90	L/s
Boys			
FEV_1	4.40H + 0.045A - 4.81	0.52	L
FVC	5.00H + 0.078A - 5.51	0.54	L
FEV/VC	-8.7H - 0.14A + 103.6	6.72	%
PEF	7.8H + 0.166A - 8.06	1.65	L/s
Girls			
FEV_1	2.70H + 0.085A -2.70	0.42	L
FVC	3.30H + 0.092A - 3.47	0.50	L
FEV/VC	-11.1H - 0.11A + 107.4	7.66	%
PEF	4.90H + 0.157A -3.92	1.34	L/s
	H = height in metres		**A = age in years**

From ARTP Handbook in Spirometry, 2nd edition Association for Respiratory Technology and Physiology

ERS The variability of normal lung volumes (age, height, gender)



Graphical presentation of the equations for adults in the previous table

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The variability of normal lung volumes Factors accouting for RSD

Body weight: Obesity may decrease FRC and TLC.

Posture: FRC decreases in the supine position. This is enhanced in anaesthesia.

Physical exercise: some evidence that FRC, VC and TLC increase in children receiving intense swimming training.

Genetic factors: Twin studies indicate smaller intra-pair variation in lung volumes of identical twins than of non-identical twins. Ethnic differences.

Environment: Natives of high altitude reportedly have more alveoli and larger lung volumes than lowlanders. Air pollution and maternal smoking influence lung growth

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Comments:

The figures clearly show that for a given age, FVC and FEV1 increase with height, but the ratio between them is unchanged. This only reflects that large people have larger spirometric values than small people.

For a given height, however, both FVC and FEV1 decrease with age, and FVC decreases slightly more than FEV1. This causes the ratio between them to decrease. The most likely cause is the decrease in number of elastic fibres in the lung with ageing.

The ECCS equations are known to give lower predictions than many other prediction equations and will therefore detect fewer abnormal lung functions. In the US different prediction equations are used (Hankinson's equations , AJRCCM1999,159:179-187).

An initiative is presently taken to collect multi-ethnic reference values for the 3-95 year age range. These are based on non-linear analysis that dininishes the RSD, and will be better for prediction of lung function abnormality.

Indications and contraindications of spirometry testing

Prof. Dr. Jorg Daniel Leuppi
Department of Internal Medicine
University Hospital Basel
Petersgraben 4
4031Basel
Switzerland
jleuppi@uhbs.ch

Summary
As for any clinical test, spirometry has specific reasons why it may be necessary. These indications are many and form the basis of this teaching module. Spirometry is generally well tolerated, though it has few contraindications, mainly pertaining to intercurrent illness. An important respiratory condition where spirometry is contraindicated is pneumothorax, as the maneuver could worsen this acutely. Spirometry can provide useful diagnostic and screening information but has some limitations, particularly its insensitivity to detect early stage restrictive disease.

ESDL PART 1

MODULE 4

INDICATIONS AND CONTRAINDICATIONS OF SPIROMETRY

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General considerations

- As any clinical test, spirometry has specific reasons why it may be necessary. These are called indications.
- Spirometry is generally well tolerated, though it has few contraindications.
- Spirometry can provide useful diagnostic and screening information but has some limitations.

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Indications

A. To confirm or disprove lung disease suggested by symptoms, signs or other abnormal laboratory findings

1. Symptoms
   a. Dyspnea, wheezing
   b. Cough, phlegm production
   c. Chest discomfort, orthopnea
2. Signs
   a. Abnormal breath sounds
   b. Decreased breath sounds
   c. Chest wall abnormalities
   d. Cyanosis, finger clubbing
3. Abnormal laboratory findings
   a. Chest x- ray, CT scan
   b. Arterial blood gases, pulse oximetry

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Indications

B. To quantify the impact of known disease on lung function
1. Pulmonary diseases
   a. Chronic obstructive pulmonary disease
   b. Asthma
   c. Cystic fibrosis
   d. Interstitial diseases
2. Cardiac diseases
   a. Congestive heart failure
   b. Congenital heart disease
   c. Pulmonary hypertension
3. Neuromuscular diseases
   a. Guillain-Barrè syndrome
   b. Amyotrophic lateral sclerosis
   c. Multiple sclerosis
   d. Mystenia

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Indications

C. To measure the effects of noxious exposures
1. Smoking
2. Environmental pollutants
3. Occupational agents

D. To determine changes in lung function over time or following treatments
1. Decline of lung function in disease
2. Effects of respiratory drugs
3. Effects of cardiac drugs
4. Lung resection or transplant
5. Respiratory rehabilitation

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Indications

E. To assess the risk for surgical procedures known to affect lung function
1. Lung resection
2. Thoracotomy
3. Cardiac surgery
4. Upper abdominal surgery

F. To evaluate disability or impairment
1. Social Security or other compensation programs
2. Legal, insurance or military evaluations
3. Cardiopulmonary rehabilitation assessment

G. Epidemiological or clinical research on lung health or disease

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General considerations

- Performing lung function tests can be physically demanding for a minority of patients.
- The requesting physician should be made aware that some circumstances could affect the reliability of spirometry measurements.
- Forced expiratory maneuvers may aggravate some medical conditions (contraindications), therefore it might be advisable to delay lung function testing until they resolve

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Contraindications

A. Absolute
- Myocardial infarction within the previous month

B. Relative
- Hemoptysis of unknown origin
- Pneumothorax
- Unstable cardiovascular status, recent myocardial infarction, or pulmonary embolus
- Thoracic, abdominal, or cerebral aneurysms
- Recent eye surgery
- Presence of any acute disease process that might interfere with test performance
- Recent thoracic or abdominal surgery
- dementia or confusional state

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Limitations

- Test results can show abnormalities of lung function, but these are not disease-specific.
- A reduction of vital capacity is regarded as a sign of respiratory disease, but it cannot allow differentiation between restriction and obstruction.
- Spirometry can detect obstructive abnormalities at relatively early stages, but it may not be sensitive to restrictive abnormalities before extensive damage has occurred.

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References

- 1) T.J. BARREIRO, I. PERILLO An Approach to Interpreting Spirometry *Am Fam Physician.* 2004; 69(5): 1107-1115. (http://www.aafp.org/afp/2004/0301/p1107.html)
- 2) AARC clinical practice guideline (http://www.rcjournal.com/cpgs/spirupdatecpg.html)
- 3) Gregg L. Ruppel. Manual of Pulmonary Function Testing, 9th Edition 2009
- 4) General considerations for lung function testing. ERS/ATS Task Force Report on Standardisation of Lung Function Testing *Eur Respir J 2005; 26: 153–161*
- 5) Standardisation of spirometry. ERS/ATS Task Force Report on Standardisation of Lung Function Testing *Eur Respir J 2005; 26: 319–338*
- 6) NIOSH SPIROMETRY TRAINING GUIDE http://www.cdc.gov/niosh/docs/2004-154c/pdfs/2004-154c-ch2.pdf

Quality Assurance Theory

Felip Burgos
Servicio de Pneumologia
Hospital Clinic
Villarroel 170
8036 Barcelona
Spain
fburgos@ub.edu

Summary

Definitions

Calibration
Set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Quality control (QC)
Is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer. Is part of quality management focused on fulfilling quality requirements.

Quality management
Coordinated management activities to direct and control an.

Repeatability
Closeness of the agreement between the results of successive measurements of the same item carried out under the same conditions of measurement; **NOTE 1:** Same conditions imply same method, same observer, same, instrument, same location, same condition of use, and repeated over a short space of time.

Reproducibility
Closeness of the agreement between the results of measurements of the same item carried out under changed conditions of measurement; NOTE: Changed conditions imply changes in the method of measurement, observer, instrument, location, conditions of use, and time; Example: If a technician tests a subject several times this is looking at the repeatability of the test. If the subject is then given a bronchodilator drug and tested again after 30 minutes one needs to know the reproducibility of the test in order to make a decision on this comparison.

Verification
Confirmation through the provision of objective evidence that specified requirements have been fulfilled. NOTE: Example: verification of commercial information systems, instruments, and methods; and calibration verification of results obtained on automated equipment.

Equipment Preparation

Preparation of pulmonary function equipment prior to test performance is essential to obtain reliable data. The following areas should be addressed:

- calibration and gathering equipment and supplies
- selection of reference values

- complete required equipment checks as appropriate

Proper equipment preparation is essential to obtain accurate and reliable test results. Manufacturers' instructions for use and ATS/ERS statements need to be followed. Reference values should be validated for the specific population.

Calibration vs. Quality Control

- ✓ Calibration adjusts the output of an instrument (spirometer) to match a known input
- ✓ Quality control tests an instrument to verify that the output is accurate and/or precise

What Quality Control Is

Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer. QC is similar to, but not identical with, quality assurance (QA)."

Calibration of Spirometers

- ✓ Enter ambient temperature, pressure and humidity for BTPS-Correction* if this isn´t already done automatically by the spirometer.
- ✓ The calibration pump should have a volume 3 liters (bigger is better).
- ✓ Volume 3to5 complete strokes (in and out) of a calibration pump
- ✓ If the volume of the pump is measured after the calibration, the result should lie between 97% and 103% of the declared volume. This applies only, if the BTPS-correction is switched of.

* All volumes are measured in liter (BTPS). That means the real volume inside the lung counts. BTPS stands for Body **T**emperature, ambient **P**ressure, **S**aturated with water vapor.

ERS 3 Liter syringe

The ATS/ERS standard:
• A 3 litre syringe with an accuracy of ≤ 15 mL or 0.5% of the full scale.
• Syringes must be calibrated annually !

The syringe should be stored in the same room where calibration is performed and should not be exposed to sources of heat or cold

You should check with a certified 3-L syringe, the accuracy cold measuring volume is kept within the recommended range (± 3%).

Calibration syringes should be accurate to ± 15 ml or ± 0.5% of full scale, and need checked periodically for leaks and check its stability

Perform Calibration or Calibration Check:

1. Set spirometer to "Calibration" mode or "Calibration Check" mode.
2. If filters designed specifically for spirometry testing are used, calibration or calibration checks should be done through the filter.
3. Perform a calibration or calibration check using the validated 3-L calibration syringe according to the 2005 ATS/ERS statement "Standardization of spirometry" (see

references). Pull the syringe handle out completely and push the 3 liter volume into the spirometer at the correct flow.

4. Repeat the calibration or calibration check at least three separate times at three different flow rates, as per manufacturer instructions.
5. Ensure the calibration results are within the required limits ± 3.5% (or 2.895 liters to 3.105 liters).
6. Maintain a copy of the calibration or calibration check in the log book.

ERS

Calibration with 3 Liters Syringe

✓ Objective:
Establishing a correspondence between standard measures (syringe) and measurement

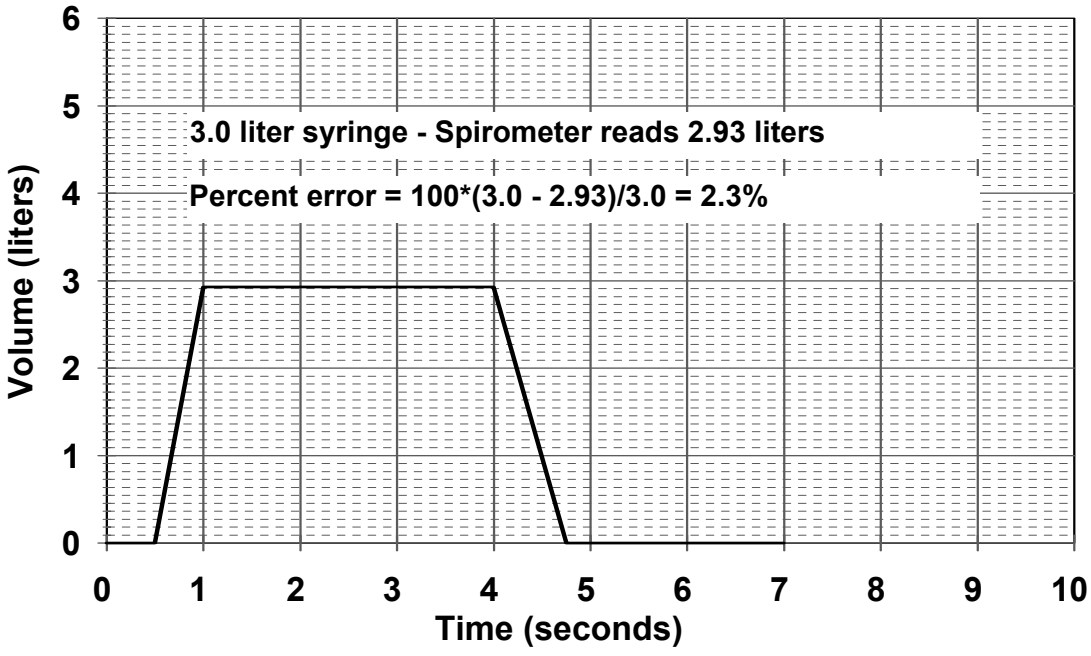
✓ Material:
3-liter syringe standardized
If not available 3L syringe, better use syringe 2L than 1L

✓ For flow measuring devices the calibration volume must be injected at different rates (between 2 and12 L/s)

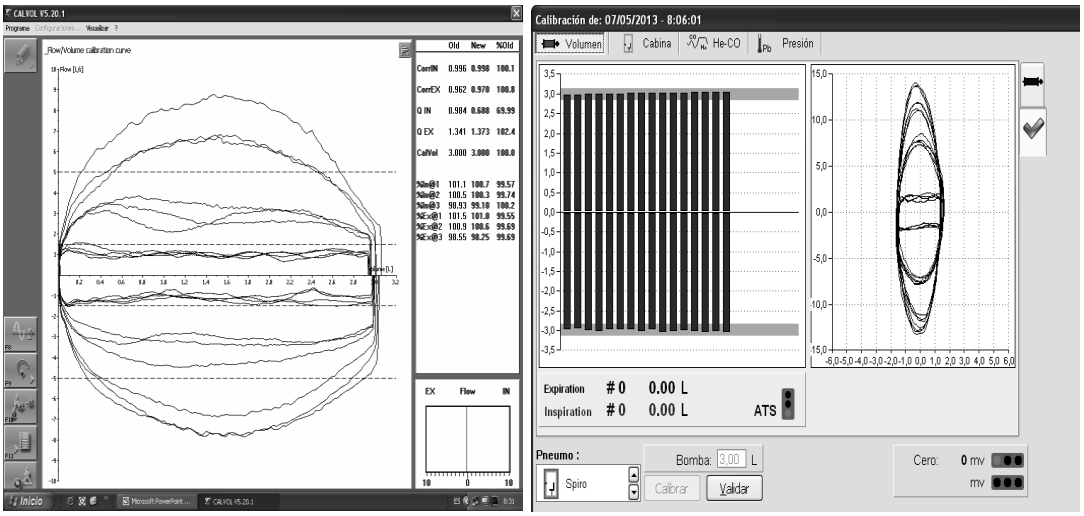
✓ Volume accuracy should be within 3.5 % at all flows

✓ Calibration syringes must be kept at the same temperature and humidity as the spirometer.

Example: Air from a 3 liter syringe was injected into the spirometer (volume/time curve), producing the tracing below. To meet the criterion of ±3% of 3 liters, a volume must fall between 2.91 - 3.09L. The volume reads 2.93 liters so it is within the acceptable range. If the baseline does not start at zero remember to adjust accordingly)



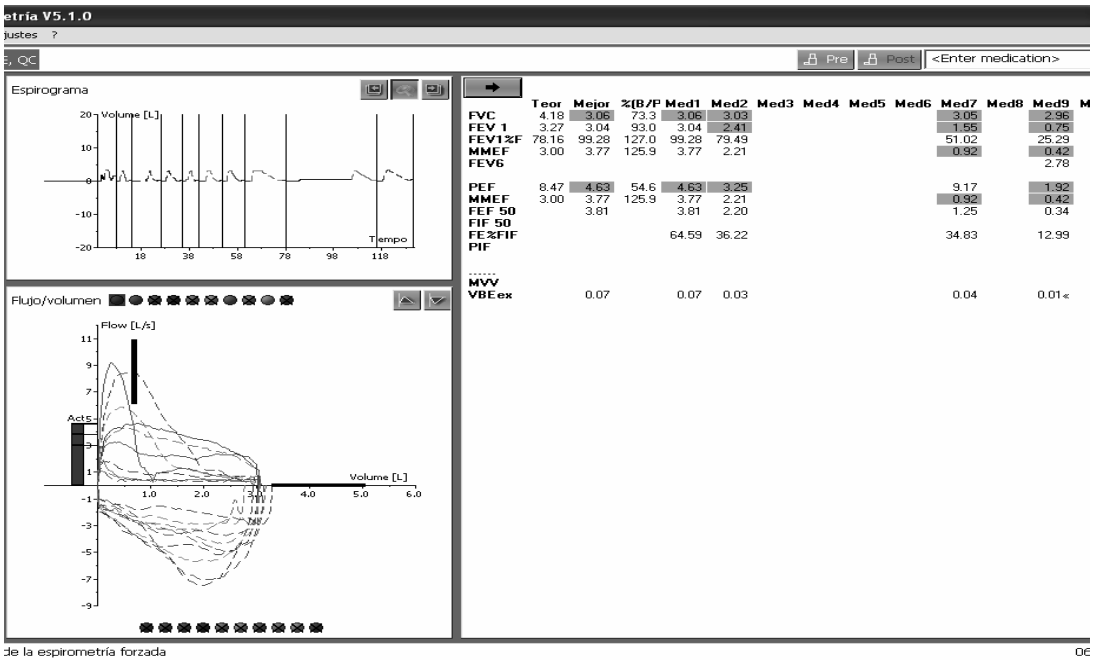
Flow check at least three different flows range



How to check the accuracy of a flow spirometer

Check the volume accuracy using a 3.00 liter calibration syringe every day before using the spirometer. Select calibration check from the menu of the spirometer (so that the software does not apply a BTPS correction factor to the results). If the flow sensor is permanent and heated (as in some older models), check the manual to see if the heater should be turned off for at least 30 minutes before calibration checks. If an unheated permanent flow sensor is used and it was recently cleaned, be sure that it is completely dry and at room temperature before the calibration check. If the spirometer uses disposable flow sensors, use a new flow sensor from each box of flow sensors for the calibration checks. For calibration checks, some flow spirometers require a special adaptor that fits between the syringe and the flow sensor.

First fill the syringe with air completely, then attach it firmly to the flow sensor, and empty it smoothly and completely. End the maneuver carefully to ensure that a soft click is heard, meaning that the syringe was emptied completely. Do not bang the syringe while emptying it, to avoid damage. Disconnect, refill with air, and then empty the syringe three times, each time at a different speed: First, empty it in less than one second (fast); next in 2 or 3 seconds (medium), and the third time take about six seconds (slow). Count one-one-thousand, two-one-thousand@ etc, while emptying the syringe, to gauge the speed of emptying. The resulting FVC for all 3 of these maneuvers should be between 2.91 and 3.09 liters. Record all three results on the daily worksheet or quality log.



Biological Control (B_{IO}QC) Testing

A biological normal quality control (BioQC) refers to a healthy non-smoking individual with normal and stable lung function, who is tested on a regular basis as a 'control'. Frequently office and staff personnel are asked to perform this function.

The facility should identify two BioQC subjects. It is recommended that al least two healthy non-smoking individuals should be identified to perform spirometry testing to assess the overall operational status of the spirometry system. Results are monitored to assess changes in equipment performance that may be undetected in routine calibration.

Establishing the BioQC Normal Range:

1. Perform 10 replicates on each BioQC subject over a period of several days. Ideally this should entail a single test performed each day; however a maximum of 2 tests spread out within any single day (e.g. morning and afternoon) may be used.
2. Use the Normal Range Calculator to determine the acceptable ranges for each person. This worksheet takes the average of the replicates and calculates two standard deviations (SD) which constitutes the normal range for this subject.
   - Fill in the values generated by the BioQC subjects. The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
   - There should be a maximum of 10% between the highest and lowest FVC and FEV1 values
   - The calculated coefficient of variation (CV) should be 3% or less.
3. Subsequent spirometry testing on each BioQC subject should fall within the ± 2 ranges for that subject. The facility should perform troubleshooting if BioQC values fall outside of their acceptable ranges.

Weekly BioQC Testing:

1. The BioQC subjects should perform spirometry procedures in the same way as a patient.
2. For consistency, BioQC subjects should ideally be tested:
   a. On the same spirometer
   b. At the same day of month
   c. At the same time of day

3. An adequate test requires a minimum of three acceptable FVC maneuvers and adherence to repeatability criteria.
    - Repeatability is achieved when the difference between the largest and the next largest acceptable FVC and FEV1, is less than or equal to 150 mL. The results for FVC and FEV1 do not need to come from the same maneuver.
    - The best trial is chosen based on the largest sum of FVC plus FEV1 from acceptable maneuvers.
4. It is recommend that the BioQC subjects be tested weekly and should be recorded on the Spirometry Quality Control Program worksheets.
    - Fill in the values generated by the BioQC subjects. The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
    - The CVs for FVC and FEV1 should be less than or equal to 3%.
    - Confirm that the results fall within the acceptable ranges for this BioQC subject.

Determining the normal range for a biological control.

- The person used as a biological control must be healthy and free of known respiratory disease
- Record your own spirometry every day (or that of a colleague if you have a respiratory condition) at the same time of day, on the same spirometer for 14 days. You will need a minimum of 10 recordings.
- Calculate the mean (average) for each spirometry parameter: i.e. add up all the readings for that parameter and divide by the number of recordings (e.g. mean 3.60 L).
- Now calculate 2.5% of the mean (i.e. 3.6 x 0.025 = 0.09 L)
- Finally, obtain the normal range for repeated measurements by adding and subtracting this 2.5% value to the mean value (i.e. 3.6-0.09 = 3.51 L; and 3.6 + 0.09 =3.69 L so the acceptable range for the person tested would be 3.51 L to 3.69 L)
- You can now use this person to check that the spirometer readings fall within this range to verify the accuracy of your spirometer on a weekly basis.

SUMMARY: Components of the spirometry QA program

- ✓ Well-chosen, enthusiastic technologists
- ✓ Trained and certified technologists
- ✓ Happy technologists
- ✓ Excellent spirometer used by everyone
- ✓ Test session quality checks and messages
- ✓ Daily 3.00 liter calibration checks
- ✓ Central review and reporting of tech quality

SUMMARY Quality control programme

Manual of procedures (Logbook):

- ✓ Calibration and check data
- ✓ Cleaning procedures
- ✓ Test-performance procedures
- ✓ Calculations
- ✓ Criteria of acceptability and repeatability
- ✓ Reference values source
- ✓ Action to be taken in case of "panic" values
- ✓ Hardware and software upgrades (version and data of change)
- ✓ Preventive maintenance service
- ✓ Records of continuing education
- ✓ Internal audit

References

1. Application of a Quality Management System Model for respiratory services; approved guideline – 2nd edition clinical and laboratory standards Institute (NCCLS). HS4-A2 Vol 26; No 15-Vol 2, No23
2. Jack Wanger. Pulmonary Function Testing: A practical aaproach (Third Edition). Jones & Bartlett Learning 2012
3. M.R Miller, J. Hankinson, V.Brusasco, F. Burgos, R. Casaburi, A. Coates, R.Crapo, P. Enright, C.P.M. van der Grinten, P.Gustafsson, R.Jensen, D.C. Johnson, N.Macintyre, R.MacKay, D.Navajas, O.F. Pedersen, R. Pellegrino, G. Viegi and J.Wanger. Standardisation of spirometry. Eur Respir J 2005; 26:319-338

Evaluation

1. Calibration is

- **a.** After introducing environmental conditions, then calibrating the spirometer with a 3 L syringe, the device corrects the deviation automatically
- **b.** Checking if temperature and pressure are measured
- **c.** Check if the spirometer is linear in all flows
- **d.** Verify if barometer is in a clean room

2. Validation /Checking is

a. Verify spirometer linearity deviation and correcting the errors manually
b. Recommended to do in all spirometer
c. Checking the humidity of spirometer
d. b and c

3. Some devices cannot be calibrated

a. Just once a week
b. False, all devices need to be calibrated
c. True, some devices are calibrated and don't need it
d. Some devices only need to be calibrated once a year

4. Quality control is

- **a.** Calibrating with a 3L syringe at all flows in the spirometer
- **b.** Review spirometer
- **c.** Assess spirometer, verify all flows, and periodically perform biological controls
- **d.** Perform biological controls

Please find all answers at the back of your handout materials

ESDL PART 1

MODULE 6

QUALITY ASSURANCE

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Definition

Quality Assurance:

- The planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled

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CALIBRATION AND VERIFICATION

ERS

Spriometer calibration

- Why do we do it?
- Calibration versus verification.
- How do we do it?

ERS

Why

- To ensure accuracy of equipment.
- To ensure good quality measurement over time.
- To check for equipment error/failure.

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Calibration V. Verification

- **Calibration:**
  - equipment is internally adjusted to read volume absolutely correctly each day/session.
- **Verification:**
  - equipment is checked to see whether it reads a calibration signal within acceptable limits.

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Calibration

- For flow measuring devices the calibration volume must be injected at different rates (between 2 and12 L/s).
- Volume accuracy should be within 3% at all flows.
- Calibration syringes must be kept at the same temperature and humidity as the spirometer.
- Syringes must be calibrated annually!

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Verification

- Some devices cannot be calibrated.
- Measured value must be within 3% of syringe volume.
  - + 90ml for a 3L syringe.
- Systems with software generated correction factors should be within range 0.97–1.03 (3%).

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Biological control

- Subject must be healthy, free of respiratory disease and have a stable lung function
- Record spirometry at the same time of the day for at least 10 days
- Calculate the mean for FVC and FEV1
- Calculate 2,5% of the mean
- Normal range = + and – 2,5% of the mean
  You can now use this person to check that the spirometer readings fall within this range.

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Prevention of infection transmission

- Wash hands prior to testing

Depending on spirometer:

- Use disposable bacterial/viral filter
- Or use disposable flow transducer
- Or disinfect flow head between patients
- Wipe down the outside of the spirometer between patients
- Using filters does not eliminate the need for cleaning and decontaminating equipment

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Rationale for regular cleaning

- Level of infection risk is low

However:

- Potential for transmission of upper respiratory diseases, TB, viral infections by direct or indirect contact
- Most likely surfaces for transmission are mouthpieces and proximal valves and tubing
- Increased awareness of hospital infection-control issues

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Quality control programme

Manual of procedures:

- Calibration and cleaning procedures
- Test-performance procedures
- Calculations
- Criteria
- Reference values source
- Action to be taken in case of “panic” values
- Hardware and software upgrades
- Preventive maintenance service
- Records of continuing education

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Patient errors

Sub maximal effort - usually due to:

- Poor understanding.
- Lack of motivation.
- Lack of co-ordination.
- Incomplete inspiration.
- Inadequate rest between attempts.

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Patient errors

Leaks - usually due to:

- 'Puffing' cheeks out.
- Lips not tightly round the mouthpiece.
- Loose fitting dentures.
- Teeth not over the mouthpiece.
- Tongue obstructing the mouthpiece.
- Facial palsy.

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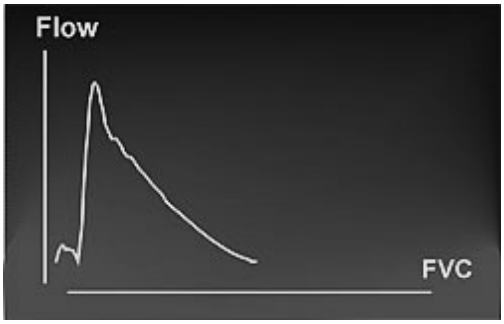
Technical errors

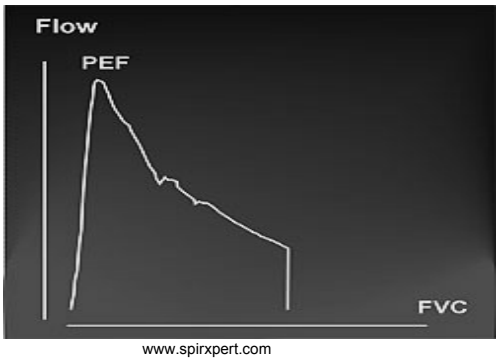
- Poor start
- Early termination
- Cough (easy to detect; just need to listen ..)
- Sub-maximal effort
- Unable to obtain 3 technically acceptable efforts

Poor start



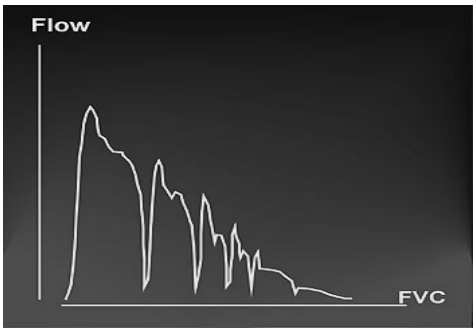
www.spirxpert.com

Early termination



www.spirxpert.com

Cough



www.spirxpert.com

Sub-maximal effort

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Over reading

- Quality of spirometry increases with expert over-reading and constructive feedback
- Independent quality review
- Useful in primary and secondary care

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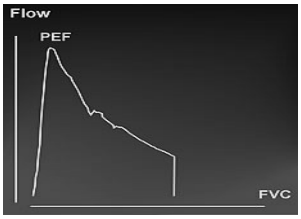
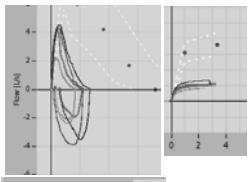
Example of feedback



- Exhalation too short
- Underestimation of FVC
- Overestimation of FEV1/FVC

Example of feedback



	Pred	LLN	Pre Best				
Trial Rank			KK				
Time							
FVC [L]	3.60	2.89	1.08	0.84	0.81	1.33	1.10
FEV1 [L]	3.09	2.47	0.89	0.71	0.69	1.16	0.99
FEV1/FVC	0.792	0.684	0.829	0.840	0.850	0.872	0.903
FEF25-75% [L/s]	3.36	1.97	0.89	0.75	0.76	1.55	1.49
PEF [L/s]	7.06	5.58	4.25	2.26	2.34	4.55	4.32
FET [s]	--	--	3.3	2.5	2.3	2.7	1.9

- Probably no maximal inspiration
- FVC's differ > 0.15L
- FEV1's differ > 0.15 L
- More manoeuvres needed with proper coaching
- No interpretation possible

Evaluation of spirometric results

Waldemar Tomalak
Institute for TBC & Lung Diseases,
Rabka Branch
Poland
wtomalak@igrabka.edu.pl

Aims

The presentation presents information contained in module 7 of ESDL Part I. Based on the spirometric standard published jointly by ERS and ATS (1-3), this presentation includes information on evaluating spirometric results during the measurements of forced manoeuver:

- acceptability and repeatability criteria
- reversibility criteria for bronchodilator test
- information on reference values and comparing the results with normal values
- normal, obstructive and restrictive patterns of spirometry
- changes of spirometric indices over time

Summary

Spirometric results evaluation may be considered as a two-step process. The first part is concentrated on the analysis of performance and evaluating with respect to quality criteria defined by the standard (1, 2). A good trial has to fulfil start of test criteria (SOT) and end of test criteria (EOT). Start of test criteria include fast rise of the flow to reach the value of peak expiratory flow fast with short time (tPEF) and the value of back extrapolated value being within defined limits (less than 150 ml or 5% FVC). End of test criteria include reaching the plateau on volume-time curve (defined as the change of volume in the last second of expiration < 25 ml) and forced expiratory time greater than 6 seconds.

Those quality criteria are illustrated by examples showing bad performance. Good spirometry implies that at least three acceptable manoeuvers should be recorded, and reproducibility criteria should be met; which are defined as the difference between the best and the second best value of FEV1 and FVC less than 150 ml. Only technically acceptable spirometries can be interpreted.

When doing a bronchodilator test, one should be aware that both spirometries (pre- and post-) should be technically acceptable and the bronchodilating agent should be properly delivered. Then, pre and

post values of FEV1 and FVC are analysed. A positive response is achieved when the increase in postbronchodilator values is greater than 200 ml and 12% of prebronchodilator value.

Recorded best values are compared with reference values, that are created using results obtained from the examination of a healthy subpopulation and have the form of equations relating respective parameters to sex, age, height and ethnic origin. Application of reference values equation for a given patient yield to a predicted value, the value expressed as % predicted and also allows to calculate limits i.e. upper and lower limits of normal.

A recommended way of interpreting the results is to compare the measured value with the lower limit of normal (LLN) – which is set at the level of 5^{th} percentile and corresponds to a value of z – score of -1.64. Using of a fixed percentile value (80% or 70%) may lead to erroneous results because LLN changes with age. Thus – in older people overestimation of obstructive ventilator defect is observed.

The interpretation of spirometric results should answer the question whether there is a ventilator defect, and if so, what is the degree of the disturbance.

With spirometry obstructive defect can be stated when the FEV1/ (F)VC factor is below the lower limit of normal. The severity of obstruction is quantified using the value of FEV1 expressed as a percentage of predicted. When FEV1/ (F)VC remains within normal limits and FVC is below LLN a restrictive ventilator defect may be suspected, but confirmation of this requires the measurement of total lung capacity (TLC) done either by plethysmography or gas dilution method (3).

References

1. MR Miller, R Crapo, J Hankinson et al. General considerations for lung function testing. Eur Respir J 2005; 26: 153-161.
2. MR Miller, J Hankinson, V Brusasco et al. Standardisation of spirometry. Eur Respir J 2005; 26: 319-338.
3. R Pellegrino, G Viegi, V Brusasco et al. Interpretative strategies for lung function tests. Eur Respir J 2005; 26: 948-968.

Evaluation

MCQs for the presentation:

1. Properly performed spirometry should include:
   a) At least one acceptable manoeuver
   b) At least three acceptable manoeuvers
   c) At least five acceptable manoeuvers
   d) At least eight acceptable manoeuvers

2. The criterion for FEV1 and/or FVC for positive bronchodilator response is:
    a) Increase >200 ml
    b) Increase >12% from baseline
    c) Increase > 200 ml or > 12% from baseline
    d) Increase . 200 ml and >12% from baseline
3. Obstruction in spirometric evaluation occurs when:
    a) FEV1 < 80% pred
    b) FEV1/FVC < 0.7
    c) FEV1/FVC < lower limit of normal
    d) Both FEV1 and FEV1/FVC < lower limit of normal

Please find all answers at the back of your handout materials

ESDL PART 1

MODULE 7

EVALUATION OF SPIROMETRY

W. TOMALAK, ESDL TEAM MEMBER
RABKA, POLAND

ERS

PRESENTATION PLAN

- Acceptability and repeatabiltiy criteria
- Reversibility criteria
- Test result selection. Best curve
- Reference values
- Advantages of LLN over % predicted
- Normal pattern
- Obstructive pattern
- Restrictive pattern

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LITERATURE

1. **MR Miller et al. General consideration for lung function testing. ERJ 2005; 26: 153-161**
2. **MR Miller et al. Standardisation of spirometry. ERJ 2005; 26: 319-338**
3. **R Pellegrino et al. Interpretative strategies for lung function tests. ERJ 2005; 26: 948-968.**

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BEFORE MEASUREMENT

- **Check spirometer (calibration, ambient conditions)**
- **Prepare the subject:**
  - ask for important information (smoking, diseases, medication used.. etc)
  - get patient's data (including sex, height, age, ethnicity)
  - describe the procedure in details, if necessary – demonstrate it to the patient
  - inform the patient on commands delivered during manoeuver

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MEASUREMENTS OF THE FLOW-VOLUME CURVE

„there are three distinct phases of FVC manoeuvre, as follows:
1) maximal inspiration
2) a „blast" of exhalation
3) continued complete exhalation to the end of test (EOT)"*

*** ERJ 2005; 26, p.323**

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MEASUREMENTS OF THE FLOW-VOLUME CURVE

A good test is free of artefacts such as:
- Cough during the first second of exhalation
- Glottis closure that influences the measurement
- early termination or cut-off
- effort that is not maximal throughout
- leak
- obstructed mouthpiece

A good (acceptable) test meets the start of test criteria (SOT) and end of test criteria (EOT)

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START OF TEST CRITERIA

- **A start of the manouver is determined by back extrapolation method. Thus, back-extrapolated volume (EV, BEV) should be less than 150 ml or 5% FVC whichever is greater**
- **PEF should be achieved with sharp rise and occur close to the point of maximal inflation i.e the start of exhalation**

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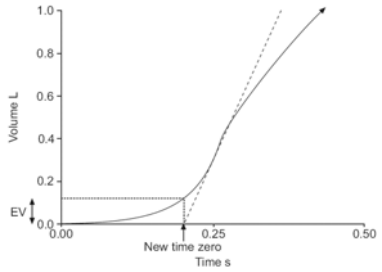
BACKEXTRAPOLATION



BEV values are usually calculated by spirometer's software

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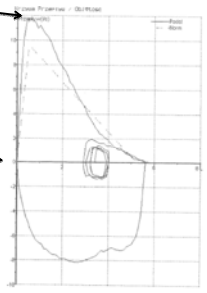
FAST RISE OF PEF

PEF

Start of exhalation



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START OF TEST

If the start of test is not maximal from the beginning of exhalation

•BEV increases;

•PEF is shifted to the right (on flow-volume trace)

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END OF TEST CRITERIA

- **The subject cannot or should not continue further exhalation**
- **The volume time curve shows no change in volume (<0.025 l) for > 1s, and the subject has tried to exhale for > 3s in children aged <10 years and for > 6 s in subjects aged >10 years.**

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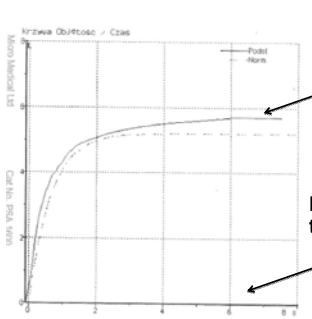
END OF TEST CRITERIA



No change in volume for >1s

Exhalation time > 6s

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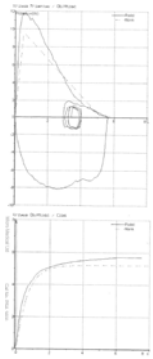
ACCEPTABLE MANOEUVER



The patient cooperates well

A steep rise of the first part of the FVC-curve

A pointed peak (the PEF) in the first part of expiration

A “smooth” Flow-Volume curve

Expiration lasts for at least 6s and exhibits a plateau

Inspiration and expiration give the same VC

ERS

FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER

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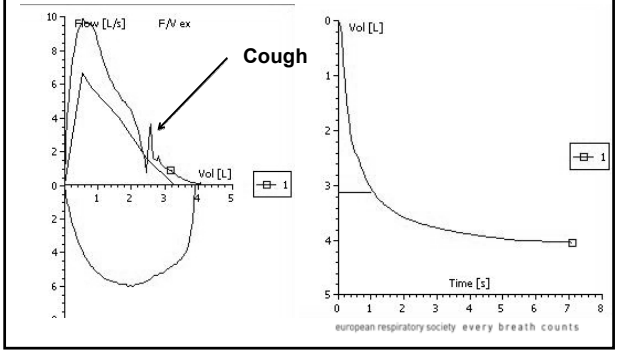
FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER



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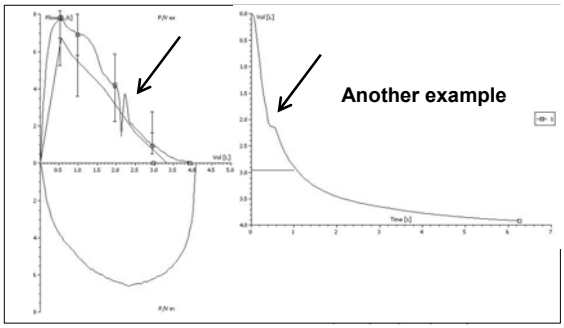
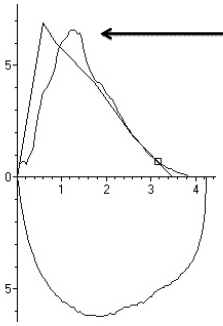
FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER



Another example

ERS

FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER



Submaximal effort; note position of PEF

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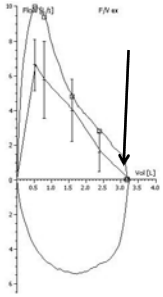
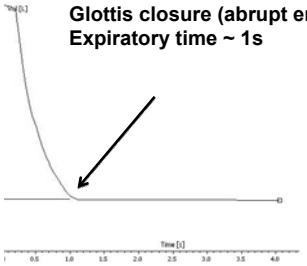
FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER



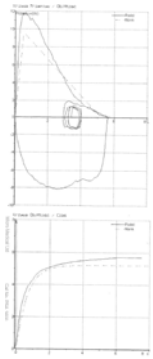
Glottis closure (abrupt end)
Expiratory time ~ 1s



h counts

ERS

ACCEPTABLE MANOEUVER



The patient cooperates well

A steep rise of the first part of the FVC-curve

A pointed peak (the PEF) in the first part of expiration

A "smooth" Flow-Volume curve

Expiration lasts for at least 6s and exhibits a plateau

Inspiration and expiration give the same VC

ERS

REPEATABILITY

- **Repeatability is the closeness of agreement between the results of successive measurements of the same item carried out, subject to all of the following conditions: same method, same observer, same instrument, same location, same condition of use, and repeated over a short space of time. In previous documents, the term reproducibility was used in this context, and this represents a change towards bringing this document in line with the ISO.**

ERJ 2005; 26:154.

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REPEATABILITY CRITERIA

- **The difference between best and the second best value of FEV1<150 ml**

and

- **The difference between best and the second best value of FVC<150 ml**

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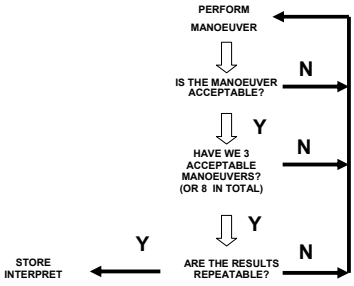
MEASUREMENT OF FLOW-VOLUME CURVE PROCEDURE



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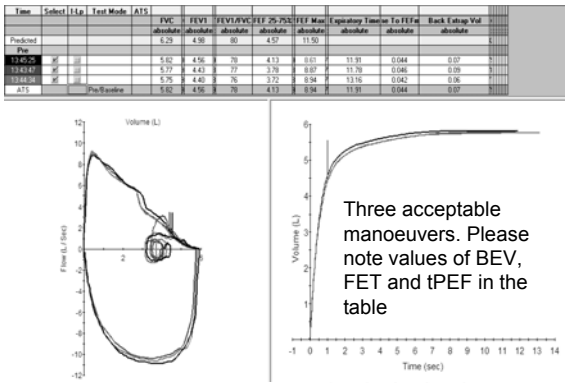

Three acceptable manoeuvers. Please note values of BEV, FET and tPEF in the table

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SELECTION OF THE BEST CURVE

After having three acceptable manouevers:

- **Check repeatability for FVC and FEV1**
- **Calculate FEV1/FVC from the highest values obtained**
- **Select the manoeuver with the highest sum of FEV1 and FVC (all other indices i.e. flows are taken from that manouever)**
- **Print result**

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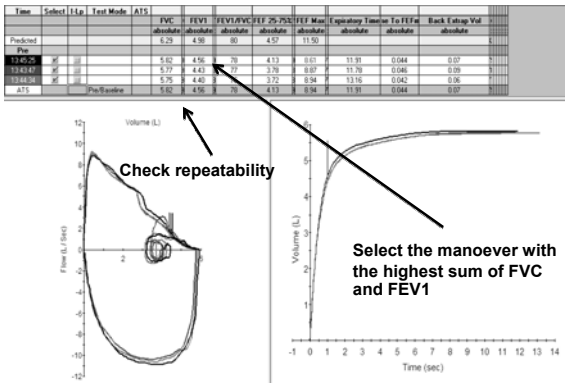

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REVERSIBILITY TESTING (BRONCHODILATOR TEST)

The response of the airways to administration of bronchodilating agent can be assessed in two ways:

-**After a single dose of brinchodilator**
-**After clinical trial lasting 2-8 weeks**

Next slides describe the test with a single dose of bronchodilator

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PERFORMING BRONCHODILATOR TEST

- **Baseline spirometry (before – the drugs affecting lung function have to be withdrawed with proper timing)**
- **Administration of standard dose of LABA**
- **Postbronchodilator spirometry (at least 15 minutes after delivering bronchodilator)**
- **Assessment of the results**

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IMPORTANT

- **Both spirometries have to be properly performed (acceptability and repatabilty criteria should be met)**
- **The drug should be properly delivered (knowledge of inhalation therapy needed)**

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ASSESSMENT OF BRONCHODILATOR TEST

- **Bronchodilator response is assessed as an absolute change of FEV1 and FVC from the baseline post – pre in ml and as a percent change in relation to prebronchodilator value: expressed in % predicted:**

  (post – pre)/pre

- **increase of >12% of FEV1 or FVC in comparison to baseline and change >200 ml is considered significant.**
- **Note: there exist also a criterion relating the change expressed in % predicted; in that case an increase >12% of predicted and a change >200 ml is considered as significant response**

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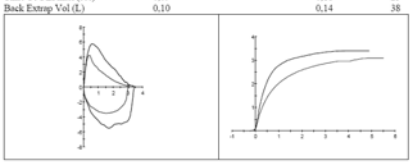
AN EXAMPLE

	Bez leku					Po leku		
	Actual	Pred	Pred	LLN	#SD	Actual	%Pred	%Chng
FEV1/FVC (%)	65,46	84,35	78	70,43	-2,90	81,63	97	25
FEV1/SVC (%)		87,2		72,8				
FVC (L)	3,09	3,59	86	3,00	-1,15	3,41	95	10
FIVC (L)	3,08	3,57	86	2,98		3,42	96	11
FEV1 (L)	2,03	3,13	65	2,61	-2,91	2,78	89	37
FEF Max (L/sec)	4,49	7,00	64	5,85	-2,79	6,18	88	38
FEF 25-75% (L/sec)	1,27	4,08	31	3,41	-3,31	3,23	79	155
Expirtory Time (sec)	5,5					4,9		-11
Time To PEFmax (sec)	0,09					0,11		23
Back Extrap Vol (L)	0,10					0,14		38



ΔFEV1 = 750 ml and 37% from the baseline (24% pred)

ΔFVC = 320 ml and 10% from the baseline (11% pred)

Significant response

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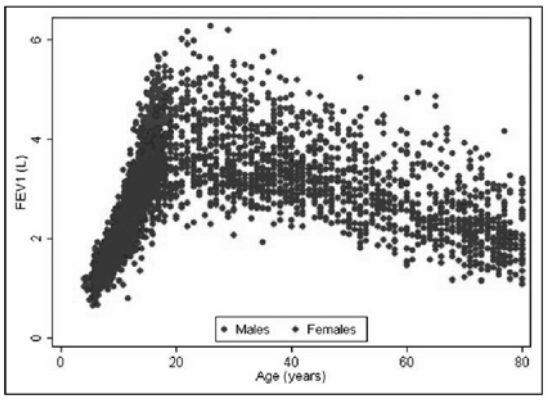
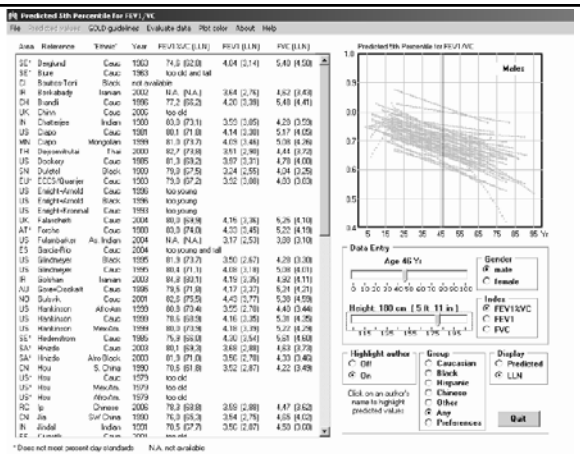
REFERENCE VALUES

Spirometric data of a patient/subject are evaluated by comparison with reference (predicted) values based on healthy subjects

- **Firstly: to check whether there is disturbance**
- **Secondly: what is the degree of disturbance**





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REFERENCE VALUES

„In Europe, the combined reference equations published in the 1993 ERS Statement are often used for people aged 18-70 yrs, with height range of 155 – 195 cm in males and 145 – 180 cm in females, and those from Quanjer et al. (ERJ 1989, Supl 4) in pediatric ages."

ERJ 2005; 26: 950.

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REFERENCE VALUES

- **The equations give expected values of spirometric indices in a healthy individual of the same sex, age, height and ethnic origin as tested patient.**
- **Spirometric reference data follow normal gaussian distribution; thus half of the healthy population is expected to have higher and half is expected to have lower values.**
- **The lower limit of normal is set at 5th percentile; which corresponds to a value of -1.645 SD (standard deviation)**
- **If the distribution is skewed; the lower limit should be estimated with nonparametric technique***

***ERJ 2005; 26:949**

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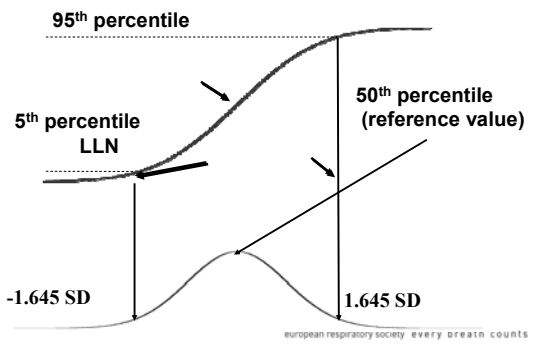

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REFERENCE VALUES

So, using reference values one can calculate the predicted value and the value of lower limit of normal (LLN)

- **„Assumption that a decrease in major spirometric parameters, such as FEV1, VC, FEV1/VC and TLC, below their relevant 5th percentiles is consistent with pulmonary defect is a useful simple approach in clinical practice"**

- **„In contrast with a fixed value of 0.7 (for FEV1/FVC), the use of 5th percentile does not lead to overestimation of the ventilatory defect in older people."**

ERJ 2005; 26: 955

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ECCS REFERENCE VALUES

Variable	Unit	Regression equation	RSD	1.64RSD
		Men		
IVC	*l*	6.10H - 0.028A - 4.65	0.56	0.92
FVC	*l*	5.76H - 0.026A -4.34	0.61	1.00
TLC	*l*	7.99H - 7.08	0.70	1.15
RV	*l*	1.31H + 0.022A - 1.23	0.41	0.67
FRC	*l*	2.34H + 0.009A - 1.09	0.6	0.99
RV/TLC	%	0.39A + 13.96	5.46	9.0
FRC/TLC	%	0.21A + 43.8	6.74	11.1
FEV_1	$l \cdot s^{-1}$	4.30H - 0.029A - 2.49	0.51	0.84
FEV_1/VC	%	-0.18A + 87.21	7.17	11.8
$FEF_{25-75\%}$	$l \cdot s^{-1}$	1.94H - 0.043A + 2.70	1.04	1.71
PEF_1	$l \cdot s^{-1}$	6.14H - 0.043A + 0.15	1.21	1.99
MEF_{75}	$l \cdot s^{-1}$	5.46H - 0.029A - 0.47	1.71	2.81
MEF_{50}	$l \cdot s^{-1}$	3.79H - 0.031A - 0.35	1.32	2.17
MEF_{25}	$l \cdot s^{-1}$	2.61H - 0.026A - 1.34	0.78	1.28
		Women		
IVC	*l*	4.66H - 0.026A - 3.28	0.42	0.69
FVC	*l*	4.43H - 0.026A -2.89	0.43	0.71
TLC	*l*	6.60H - 5.79	0.60	0.99
RV	*l*	1.81H + 0.016A - 2.00	0.35	0.58
FRC	*l*	2.24H + 0.001A - 1.00	0.50	0.82
RV/TLC	%	0.34A + 18.96	5.83	9.6
FRC/TLC	%	0.16A + 45.1	5.93	9.8
FEV_1	*l*	3.95H - 0.025A - 2.60	0.38	0.62
FEV_1/FVC	%	-0.19A + 89.10	6.51	10.7
$FEF_{25-75\%}$	$l \cdot s^{-1}$	1.25H - 0.034A + 2.92	0.85	1.40
PEF_1	$l \cdot s^{-1}$	5.50H - 0.030A - 1.11	0.90	1.48
MEF_{75}	$l \cdot s^{-1}$	3.22H - 0.025A + 1.60	1.35	2.22
MEF_{50}	$l \cdot s^{-1}$	2.45H - 0.025A + 1.16	1.10	1.81
MEF_{25}	$l \cdot s^{-1}$	1.05H - 0.025A + 1.11	0.69	1.13

Ph. Quanjer et al.

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REFERENCE VALUES: EXAMPLE OF CALCULATION

- **Caucasian males:**

	30 yrs; 180 cm	**70 yrs 180 cm**
FEV1 (LLN)	**4,38 (3,54; 80,8%)**	**3,22 (2,38; 73,9%)**
FVC (LLN)	**5,25 (4,25; 80,9%)**	**4,21 (3,21; 76,2%)**
FEV1/FVC (LLN)	**81.8 (70.0)**	**74,6 (62,8)**

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LIMITATIONS

- **Reference equations are valid for a given age and height range**
- **Lower limits of normal for spirometric indices decrease with age, so using a fixed % value may lead to errors**

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GLI2012

- **Recently, a report from the ERS Task Force (Global Lung Initiative) has been published, presenting new multi-ethnic reference values for the age range 3-95 years.**
- **The equations for caucasians are calculated using >57 000 spirometries gathered from healthy long-life non smoking people.**

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Eur Respir J 2012; 40: 1324–1343
DOI: 10.1183/09031936.00080312

ERS TASK FORCE

Multi-ethnic reference values for spirometry for the 3–95-yr age range: the global lung function 2012 equations

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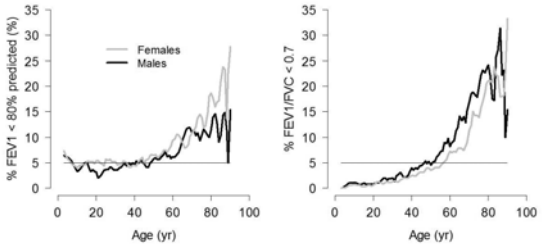
FIXED VALUES VS LLN



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INTERPRETATION
VENTILATORY DISORDERS

- **An obstructive ventilatory defect is a disproportionate reduction of maximal airflow from the lun in relation to the maximal volume (…) It implies airway narrowing during exhalation and is defined by reduced FEV/VC ratio below 5th percentile of a predicted value.**
- **A restrictive ventilatory defect is characterised by a reduction in TLC below the 5th percentile of a predicted value, and a normal FEV1/VC**
- **A mixed ventilatory defect is characterised by the coexistence of obstruction and restriction.**

ERJ 2005; 26: 955

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INTERPRETATION

TABLE 5 Types of ventilatory defects and their diagnoses

Abnormality	Diagnosis
Obstruction	FEV$_1$/VC <5th percentile of predicted
	A decrease in flow at low lung volume is not specific for small airway disease in individual patients
	A concomitant decrease in FEV$_1$ and VC is most commonly caused by poor effort, but may rarely reflect airflow obstruction. Confirmation of airway obstruction requires measurement of lung volumes
	Measurement of absolute lung volumes may assist in the diagnosis of emphysema, bronchial asthma and chronic bronchitis. It may also be useful in assessing lung hyperinflation
	Measurements of airflow resistance may be helpful in patients who are unable to perform spirometric manoeuvres
Restriction	TLC <5th percentile of predicted
	A reduced VC does not prove a restrictive pulmonary defect. It may be suggestive of lung restriction when FEV$_1$/VC is normal or increased
	A low TLC from a single-breath test should not be seen as evidence of restriction
Mixed defect	FEV$_1$/VC and TLC <5th percentile of predicted

FEV$_1$: forced expiratory volume in one second; VC: vital capacity; TLC: total lung capacity.

ERJ 2005; 26:956

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INTERPRETATION

- **OBSTRUCTION is determined by spirometry when**

  FEV1/(F)VC is below 5th percentile

- **RESTRICTION cannot be determined by spirometry as it requires that**

  TLC is below 5th percentile

  however it is very likely when FEV1/(F)VC is normal or elevated and (F)VC is decreased.

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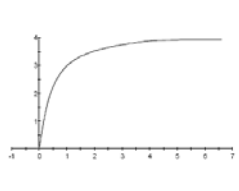
NORMAL SPIROMETRY



Bez leku	Actual	Pred	Pred	LLN	±SD
FEV1/FVC (%)	76,28	82,26	93	71,52	-0,92
FEV1/SVC (%)		86,9			
FVC (L)	3,93	3,66	107	2,95	0,63
FIVC (L)	3,98	3,66	109		
FEV1 (L)	3,00	3,18	94	2,55	-0,48

Expiratory Time (sec)	6,6
Time To FEFmax (sec)	0,07
Back Extrap Vol (L)	0,08

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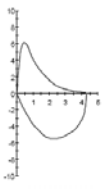
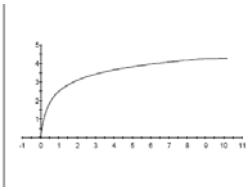
OBSTRUCTIVE PATTERN





Bez leku	Actual	Pred	Pred	LLN	±SD
FEV1/FVC (%)	58,33	83,02	70	69,32	-3,79
FEV1/SVC (%)		86,9		72,6	
FVC (L)	4,25	3,59	119	3,00	1,55
FIVC (L)	4,31	3,58	120	2,99	
FEV1 (L)	2,48	3,12	80	2,61	-1,68

Expiratory Time (sec)	10,2
Time To FEFmax (sec)	0,07
Back Extrap Vol (L)	0,09

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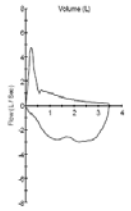
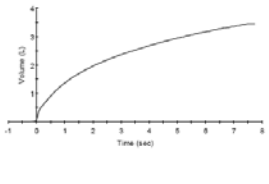
OBSTRUCTIVE PATTERN (2)





Bez leku

	Actual	Pred*%Pred	LLN	zSD
FEV1/FVC (%)	39,56	74,61	53	62,30 -4,89
FEV1/SVC (%)		76,9		64,2
FEV1 (L)	1,36	2,57	53	2,15 -2,36
FVC (L)	3,45	3,34	103	2,79 0,18

Expiratory Time (sec)	7,7
Time To FEFmax (sec)	0,05
Back Extrap Vol (L)	0,08

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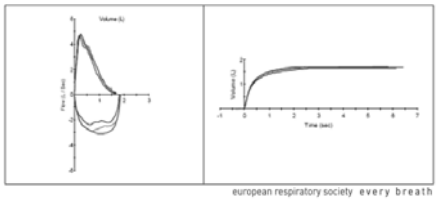
RESTRICTIVE PATTERN

	Actual	Pred*%Pred	LLN	zSD
FEV1/FVC (%)	89,26	79,00	113	65,97 1,58
FEV1/SVC (%)		84,9		70,9
FEV1 (L)	1,51	2,42	62	2,02 -2,40
FVC (L)	1,69	2,85	59	2,38 -2,70
FIVC (L)	1,86	2,82	66	2,35
FEF Max (L/sec)	4,73	6,13	77	5,12 -1,55
FEF 25-75% (L/sec)	1,87	3,15	59	2,63 -1,51
Expiratory Time (sec)	5,8			
Time To FEFmax (sec)	0,05			
Back Extrap Vol (L)	0,06			



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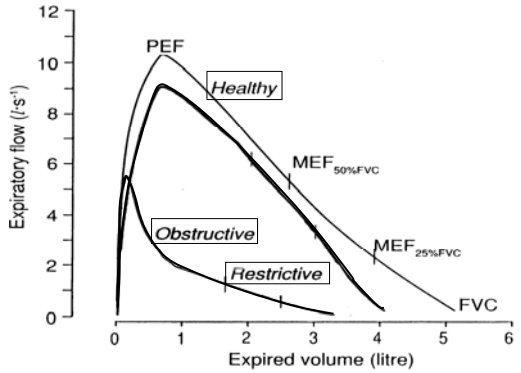

Quanjer Ph et al. ERJ 1993

ERS

Causes of **obstructive lung disorders**

Chronic or reversible airway obstruction
Examples:
- chronic (obstructive) bronchitis
- emphysema
- bronchial asthma

Causes of **restrictive lung disorders**
Intrapulmonary disorders:
Examples:
- lung fibrosis
- pneumectomy / lobectomy
- atelectasis

Extrapulmonary disorders :
Examples:
- (cooperation failure)
- diaphragm paralysis
- kyphoscoliosis

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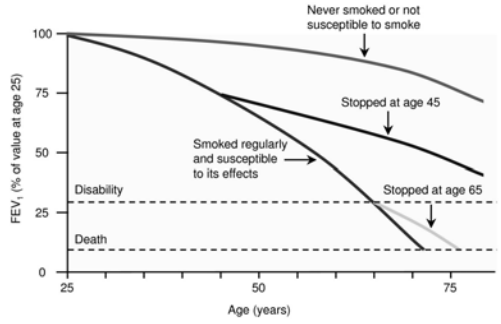
CHANGES IN LUNG FUNCTION OVER TIME – THE FLETCHER DIAGRAM



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CHANGES IN LUNG FUNCTION OVER TIME

TABLE 12 Reported significant changes in forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), mid-expiratory flow ($MEF_{25-75\%}$) and carbon monoxide diffusing capacity ($D_{L,CO}$) over time

	FVC	FEV_1	$MEF_{25-75\%}$	$D_{L,CO}$
Within a day				
Normal subjects	⩾5	⩾5	⩾13	>7%
COPD patients	⩾11	⩾13	⩾23	
Week to week				
Normal subjects	⩾11	⩾12	⩾21	>6 units
COPD patients	⩾20	⩾20	⩾30	>4 units
Year to year	⩾15	⩾15		>10%

ERJ 2005; 26:961

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CONSIDERATIONS FOR INTERPRETATION

TABLE 13 Summary of the considerations for the interpretation of change in lung function

Be aware of possible significant changes in lung function parameters over time (table 12)
Multiple measurements over time are more likely to signal a real change in lung function than two measurements
When too many indices of lung function are tracked simultaneously, the risk of false-positive indications of change increases
Clinical interpretation of serial tests should not be based solely on the coefficient of repeatability, but also on the clinical findings

ERJ 2005; 26:962

ERS

ACKNOWLEDGMENTS

- **J. Leuppi – ESDL TEAM MEMBER – for sharing examples used in this presentation.**

Overview of part II, completion and submission of the ERS spirometry workbook

Felip Burgos
Servicio de Pneumologia
Hospital Clinic
Villarroel 170
8036 Barcelona
Spain
fburgos@ub.edu

ERS Spirometry Training Programme
Information Handbook

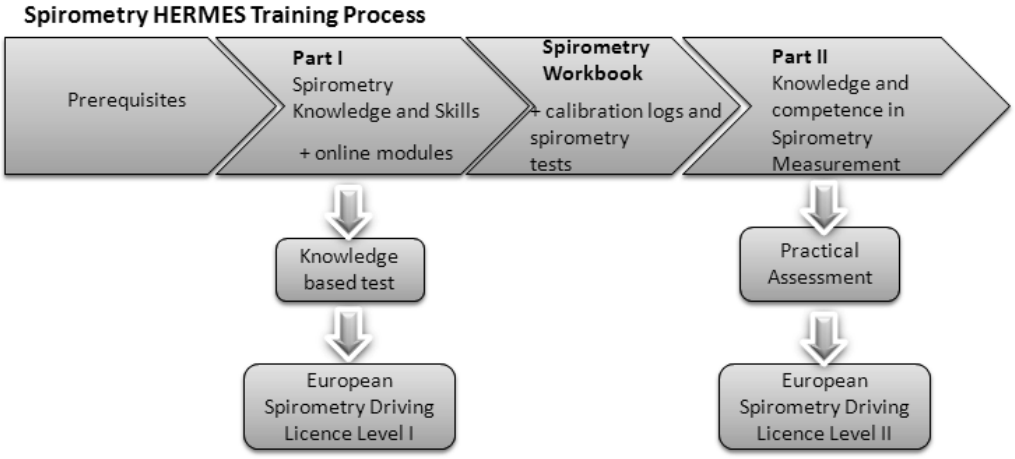
BACKGROUND INFORMATION

This document provides a step-by-step guide for those who wish to fully complete the European Spirometry training programme Part 1 and Part 2.

Training is divided into two parts and all participants must complete and be assessed on;
Part 1 – Knowledge assessment of modules 1 – 8 of the training programme via an online knowledge test

Workbook – Assignments and portfolio of spirometry tests to assess participants understanding and application of spirometry in practice – assess Module 8

Part 2 – Practical assessment to assess competence in spirometry measurement including modules 1 – 8 of the training programme



PART 1 and the ONLINE KNOWLEDGE TEST

Step 1: Access to the ERS spirometry website
Each participant will be provided with an individual access code for 12 months to the ERS spirometry website. Participants must have access to this website at least 1 month before they attend Part 1 of the training programme. On this website, participants will have access to module content for each of the 8 modules, as well as access to an online knowledge test in English. These codes provide individual access for each participant.
All questions on access codes can be directed to hermes@ersnet.org

Step 2: Online test
Participants will be expected to complete an online MCQ test within 4 weeks of attending the course and will have a total of 3 attempts to complete the test.
Each participant will receive a link to this online knowledge test after completion of Part 1 of the European Spirometry training programme.

Step 3: Awarded ERS certificate: Part 1 of the ERS spirometry driving licence
On successful completion of the test, participants can generate an online certificate to prove that they have passed the knowledge test and have been awarded Part 1 (theory only) certificate of the ERS spirometry driving licence. Part 1 certifies that participants have the knowledge and understanding of spirometry in practice, however are not yet considered competent to perform spirometry measurement. Participants must be awarded their certificate before they can register for Part 2 of the training programme.

ERS SPIROMETRY WORKBOOK

Step 1: When to complete the workbook
All participants must fully complete the ERS spirometry workbook before their attendance on Part 2 of the European Spirometry training programme.

Step 2: Preparing participants on how to complete the workbook
Participants will learn about the ERS spirometry workbook during the Part 1 training day. Each participant will receive the template of the workbook and guidelines to complete the workbook. Participants may also find support on how to complete this workbook on the ERS HERMES website under 'Activities' **W** hermes.ersnet.org

Step 3: Mentoring participants
Participants who attend the Part 1 who would like to complete the ERS Spirometry workbook as well as Part 2 will be assigned a mentor who may assist them with this task. ERS trainers will act as mentors to participants throughout the interim period between Part 1 and Part 2 training days. All workbooks should be forwarded to assigned trainers (ideally electronically) at least 1 month before Part 2 training day.

Step 4: Marking/Grading the ERS spirometry workbook
If participants have failed the workbook, they may be allowed to attend Part 2 and have the opportunity to take part in the practical assessment. All participants' workbooks must be submitted and graded within 6 weeks after Part 2. Participants will fail to receive their Part 2 certificate if they have not successfully completed the workbook.

Step 5: ERS support
ERS will provide support to participants with this process and all questions may be directed to hermes@ersnet.org

PART 2 PRACTICAL TRAINING AND ASSESSMENT

Step 1: Attending the Part 2 training day
Participants will be required to attend Part 2 of the training programme which will cover modules in knowledge and competence in spirometry measurement.

Step 2: Preparing for the practical assessment
The practical assessment will be organised during Part 2 of the spirometry training day. The ERS workbook is intended to assist participants to prepare for the practical assessment.
This process will take no more than 30 minutes and participants will receive immediate feedback from their examiner. Participants are assessed on the practical procedure of spirometry as well as communication, and professionalism. All performance criteria are listed on the marking sheet which is available on the ERS HERMES website **W** hermes.ersnet.org
Participants will be fully informed on what to expect during the practical assessment and will receive all necessary information on the test process and the modules and content that may be assessed during the practical test prior to the exam.

Step 3: During the assessment
Participants will be assigned an examination time of 30 minutes during the Part 2 training day. During the assessment, examiners will use the completed ERS spriometry workbook as a reference, as well as conducting a practical on spirometry technique. Participants should be familiar with all of the modules covered in Part 2 of the European Spirometry training programme, as all elements may be included within the practical assessment.

Participants will have the possibility to resit the examination onsite with a different examiner if they fail on their first attempt.

Step 4: Providing feedback
Following the practical exam, all participants will receive the *ERS spirometry practical_examination and feedback form.* This document will be shared with the participant no longer than 1 month following the practical assessment.

Step 5: Awarding of the European Spirometry Driving Licence Part 2
Those who successfully pass the practical assessment and ERS workbook will be awarded Part 2 of the ERS Spirometry Driving Licence, knowledge and competence in spirometry measurement.

All certificates will be sent from the ERS headquarters in Lausanne, Switzerland. A register of successful participants will be available on the ERS HERMES website W hermes.ersnet.org

ESDL
Posgraduate Course: PG 16

Overview of Part II, completion and submission of the ERS **spirometry workbook**

ERS

Disclosure

Felip Burgos :

• Stocks of Linkcare® Health Solutions SL

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European Spirometry Training Programme
Part II – Knowledge and Competence in Spirometry Measurement

Part II of the training is a 7 - 10 hours training course which will focus on competency - based training and will require participants to complete exercises and submit portfolios of spirometry tests. Examination and the award of the ***European Spirometry Driving Licence*** **Part II** will be dependent on a competency assessment.

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Aims:

Aim of Part II Training

The aim of Part II of the training programme is to ensure that participants have acquired the skills and competencies to perform high quality spirometry tests. The training programme will help participants complete a Spirometry workbook, discussing common errors and how to problem solve issues relating to spirometry testing. Part II of the training programme will assist participants with the final preparations to carry out the practical assessment to be awarded the ***Level II - European Spirometry Driving Licence***.

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Participant Goals:

Participants will gain the specific knowledge, skills and competencies required to perform high quality spirometry tests and cover the key areas of Spirometry practice.

Part II Knowledge and Competence in Spirometry Measurement will ensure participants practice spirometry according to current international standards. Following the course participants will;

a. understand the importance of best practice in spirometry service management
b. correctly perform high quality spirometry and reversibility testing, and fully competent to practice spirometric tests

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Part II – Spirometry Competency Based Training and Assessment

Module 3	**Spirometry Equipment** *Review of workbook assignments, (small group hands-on learning)*	1 hour

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SPIROMETRY WORKBOOK

Your workbook must consist of the following sections:

SECTION A

1. The contents page

2. Your Curriculum Vitae

3. Your Spirometry Training Course attendance certificate and/or accreditation of prior learning

4. Background information about your work environment, which should include:

- **a. Local arrangements for spirometry testing**
- **b. Method of referral e.g. GP, nurse led clinics etc.**
- **c. Number of tests performed (weekly/monthly etc) and the type of patients you are testing, e.g. screening for occupational health, asthma, COPD etc**
- **d. Where the tests are performed and the staff performing the tests, e.g. doctor, nurse, clinical physiologist or other.**

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SECTION A

2. CURRICULUM VITAE

Felip Burgos is a respiratory scientist in the Diagnostic Respiratory Center (Lung Function Laboratory) of Respiratory Department in Hospital Clinic, University of Barcelona, Spain. During the last 35 years, he has been involved in Lung Function Laboratory in several topics, specially related to reference values and standardization of lung function methodology. He is co-organizer of an annual Spanish Postgraduate Course (Pulmonary Function Testing) sponsored by the Department of Medicine, University of Barcelona, also supported with by the European School of Respiratory Medicine of the European Respiratory Society. He was a Research Fellow at Harbor-UCLA in Torrance. He has been involved in the Spanish Project for Standardization of Lung Function Tests. He is also a regular

3. Your Spirometry Training Course

- *International Meeting on Clinical Advances in Pulmonary Gas Exchange. Barcelona.* *(1987)*
- *II Jornadas de Pruebas de esfuerzo y función cardiorespiratoria. Barcelona.* *(1988)*
- *Jornada científica sobre la fisiologia aplicada a l'esport. Esplugas de Llobregat.* *(1988)*
- *Curs d'introducció als mètodes de Recerca Biomèdica. Fundació Privada Clínic per la Recerca Biomèdica. Maig-Juny* *(1993)*
- *International Meeting on "Oxygen transport in Health and disease". Barcelona* *(1993)*
- *Curso de Postgrado "Practical aspects of body pletismography " Stockholm September 7* *(1996)*
- *Curso de Postgrado " Practical Pulmonary Function Testing" New Orleans USA 10 Mayo* *(1996)*
- *Curso de Postgrado " Interpretation of clinical exercise testing for the clinician" New Orleans USA 10 de Mayo*
- *Curso de Postgrado " Practicum Exercise Testing " Harbor - University of California Los Angeles* *(1996)*
- *Curso de Training " Exercise Testing training" Sensor Medics, Yorba Linda, CA USA* *(1996)*
- *Master in Respiratory Medicine MSc (120 ECTS) Universidad de Barcelona - Universidad Pompeu Fabra* *(2008-2011)*

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4. Background information about your work environment

The lab is located in a separate building within the institute. It performs spirometric exams for the clinics of the institute and for outpatient department.

Patients for lung function are referred by physicians working in different clinics of the institute, other hospitals and primary care centers.

The Respiratory Diagnostic Center (CDR) is performing spirometry, lung volumes by pletimography and also He dilution, DLCO, compliance, trans-diaphragmatic pressures, P0., FOT, RINT, Methacholine, Manitol, cardio-pulmonary exercise test (CEPT), 6 MWD, multiple inert gas exchange technique (MIGET) and arterial blood gases. Our Respiratory Diagnostic Center is performing 2800

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SPIROMETRY WORKBOOK

SECTION A

5. A copy of your local protocol for performing spirometry including the guidelines that you use. ***This should be a document that you or your team use and not a photocopy of guidelines.***

6. An overview of the patient issues around spirometry. This should include the following:

a. A brief discussion of the contraindications to performing spirometry. This should state the absolute contraindications e.g. current chest infection and the relative contraindications.

b. A brief description of the instructions that the patient should receive PRIOR to having spirometry performed e.g. withholding bronchodilators, smoking etc.

7. With the aid of a diagram, describe the way in which your spirometer measures spirometry values. You should state the measurement principle of your device (e.g. is it flow measuring or volume measuring device?).

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5. A copy of your local protocol for performing spirometry including the guidelines that you use.

Normativa SEPAR

Espirometría

Francisco García-Río[a,*,1], Myriam Calle[b,1], Felip Burgos[c], Pere Casan[d], Félix del Campo[e], Juan B. Galdiz[f], Jordi Giner[g], Nicolás González-Mangado[h], Francisco Ortega[i] y Luis Puente Maestu[j]

6. An overview of the patient issues around spirometry.

As the patients are referred to the lab by doctors, they use contraindications listed in the standard. Prior to the testing the patients are instructed according to the protocol used in the lab. This includes the demonstration of spirometric manoeuvers.

Indications and contraindications:

6. INDICACIONES, CONTRAINDICACIONES Y COMPLICACIONES

6.1. Indicaciones

- Evaluar la capacidad respiratoria ante la presencia de síntomas relacionados con la respiración (tos, expectoración, disnea, sibilancias, etc.) o signos de enfermedad (malformaciones torácicas, radiografía de tórax alterada, etc.).

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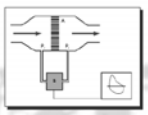
7. With the aid of a diagram, describe the way in which your spirometer measures spirometry values.

For measurement we use a spirometer being a part of Medisoft (Belgium). The spirometer in use in our lab is a flow measuring device using pneumotachographs. The volumes are obtained by integration of flow.

Pneumotacòmetre Fleisch/Lily

- Resistència coneguda
- Mesura de diferències de pressió
- Flux directament proporcional

Segons resistència, diversos tipus de pneumotacògraf



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SPIROMETRY WORKBOOK

SECTION B

The following sections should contain evidence gathered by you during your working practice. It must consist of traces, witness accounts and logs of verification and cleaning.

8. Calibration or verification of your spirometer.
9. Quality assurance of your spirometry service.
10. Cleaning of your spirometer.
11. Patient tests.
12. Problems encountered during testing.

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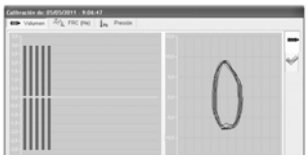
SECTION B.

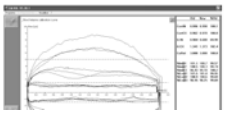
8. Calibration or verification of your spirometer.

The spirometer is calibrated on a daily basis using a 3 liter calibration syringe.



9. Quality assurance of your spirometry service.

This includes linearity control of the measuring head mode with the use of a 3 liter syringe at different flows. An example is shown in a hardcopy.



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10. Cleaning.

This section consists of TWO parts.

a. **Provide a cleaning procedure for the spirometer in your care. You must include your references for this and a copy of the work schedule to show that cleaning has been completed regularly.**

a. **Describe what contingency plans you have in place for dealing with potentially infectious patients**
e.g. suspected TB, influenza etc.

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10 Cleaning.

The lab is using disposable, individual filters protecting from eventual hazards. We regularly (in a weekly base) change and clean all the pneumotachograph, tubes and parts of the spirometry. We follow the Spanish and Catalan recommendation (see below)

Rentat de mans:

1. Abans de realitzar una espirometria.
2. Després de manipular material.
3. Espirometria en traqueostomitzats.
4. Entre exploracions de diferents pacients.
5. En totes les actuacions de teràpia respiratòria.

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SPIROMETRY WORKBOOK

SECTION B

The following sections should contain evidence gathered by you during your working practice. It must consist of traces, witness accounts and logs of verification and cleaning.

8. Calibration or verification of your spirometer.
9. Quality assurance of your spirometry service.
10. Cleaning of your spirometer.
11. Patient tests.
12. Problems encountered during testing.

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Calibration or Verification.

- **This section consists of TWO parts:**

a. A short piece of written work must be submitted explaining why your spirometer must be calibrated or verified regularly and a description of how you would do this.

b. Produce a calibration/verification record for your spirometer.

i. **If your spirometer produces a hard copy, provide evidence of at least 20 calibrations or verifications performed by you. These should be performed over a minimum of a one month period.**

ii. **If your spirometer does not produce a hard copy, design a system for recording your calibrations or verifications and record at least 20 results. These should be performed over a minimum of a one month period.**

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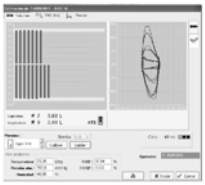

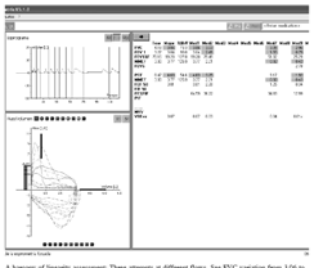

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Calibration or Verification.

- **This section consists of TWO parts:**

a. Briefly explain the purpose of Quality Control in the context of a Spirometry service.

b. Create a Quality Control record using either yourself or a member of your team. The person used for your QC record should have normal lung function.

i. **Perform Spirometry daily, on the same person, over a period of at least two weeks (at least 10 results of each in total should be collected).**

ii. **Record the values in a table.**

iii. **Calculate the mean value for the following values that you have recorded in your Quality**

Control record:

- **a. The FEV_1**
- **b. The FVC**
- **c. The PEF.**
- **iv. Calculate an acceptable range by using ±5% of the mean value of the measurements obtained.**

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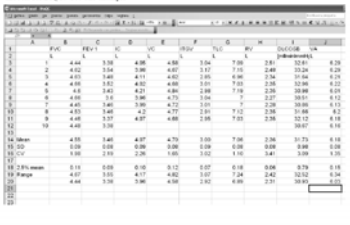
The second issue is a biological quality control. We have tested 3 members of the lab staff to choose models for BiQC. See one exemple



Audit of the Quality Spirometry in our CKD (High quality A+B: 83 %) Sample n 30 (February 2012). We are making this kind of AUDIT in a systematic and data unknown

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	A	24	80,0	80,0	80,0
	B	1	3,3	3,3	83,3
	C	2	6,7	6,7	90,0
	D	3	10,0	10,0	100,0
	Total	30	100,0	100,0	

Hardcopy of BiQC is presented for WT. Note that the measured values for FVC and FEV_1 have a Coefficient of variation (CV) of 1.98 and 2.19 respectively

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11. Patient Tests

You must produce 10 technically acceptable spirometry traces for FEV1, FVC, FEV1/FVC%, PEF

- **You must include the height, age, diagnosis, current drug therapy, smoking history and date of test for each patient included in this section.**
- **You must highlight which test results you would select for each patient from those performed.**
- **Please ensure all patient data included in your portfolio is anonymised. Failure to do so will constitute a breach of patient confidentiality and will result in an automatic fail being awarded.**
- **You must include a signed witness statement from a senior member of staff at the place where you are employed indication that all of the traces included have been performed by you**

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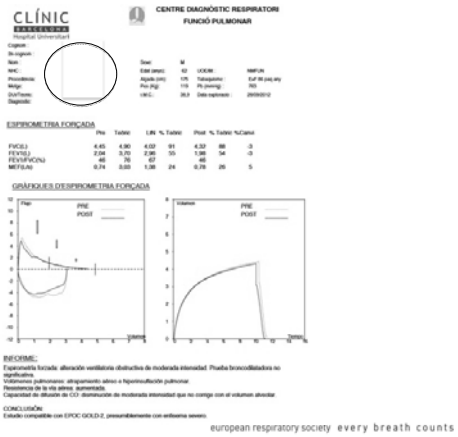
CLÍNIC BARCELONA

CENTRE DIAGNÒSTIC RESPIRATORI
FUNCIÓ PULMONAR

ESPIROMETRIA FORÇADA

GRÀFIQUES D'ESPIROMETRIA FORÇADA

INFORME:

CONCLUSIÓN:

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12. Problems Encountered During Testing.

•You must provide 5 technically unacceptable spirometry traces FEV1, FVC, FEV1/FVC%, PEF that you have recorded.

•You should describe the problem that you encountered and explain what you did/would do to overcome

•the problems. The problems may include patient, technical or equipment issues

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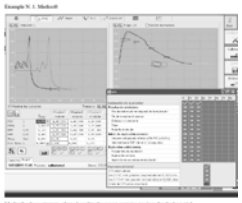
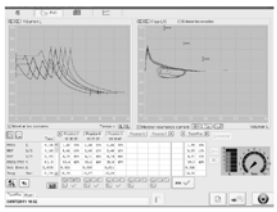


Example N. 1. Medisoft

Medisoft : three attempts of good quality the report contains tracings for the best trial.

Interpretation: Normal spirometry



Example N. 2. Medisoft

Medisoft: five attempts of good quality the report contains tracings for the best trial. (see Pmaßn 3-4-5)

Interpretation: OBSTRUCTION

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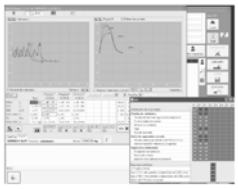
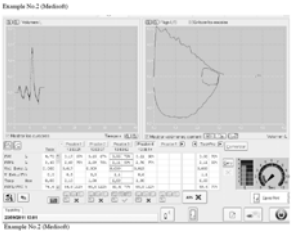


EXPLANATION: Expiratory peak flow is variable between maneuvers



Example No.2 (Medisoft)

Example No.2 (Medisoft)

EXPLANATION: Expiratory time too short (less than 6s).

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ESDL Workstation 1- Spirometers – demonstration of how different types of spirometers work and how they are cleaned and maintained.

Three types of Spirometers:

1 Rotating vane.

2 Pneumotachograph.

3 Ultrasonic.

1 Rotating vane or turbine (actually a rotating vane which spins because of the air flow generated by the subject. The revolutions of the vane are counted as they break a light beam):(eg. Carefusion/Micromedical, Cosmed, Mir.)

We discern models with disposable vanes (MIR), and models with non-disposable vanes which ideally should be used with a bacteria-filter, or should be desinfected after each patient. (Cosmed, Carefusion etc.

Strengths: Stable and accurate.

Weaknesses:Difficulty in detecting low flows, difficult to clean (except the disposable), most models can't measure inspiration.

2 Pneumotachograph.(Flow (V') is derived from the pressure difference over a small, fixed resistance, offered by a fine metal mesh.) We discern fixed devices (eg. Vitalograph) which have to be used with a bacteriafilter, and disposable devices (USB type)(eg. Welch Allyn).

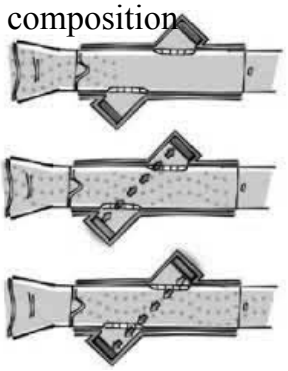
Strengths: Measures inspiration as well; very cheap and hygienic are the models with disposable flow transducers.

Weaknesses: Often problems reaching a plateau/drift. Not very stable, too much shaking of the system will change the outcomes.

3 Ultrasonic. (Transducers located on either side of the spirette® cavity emit and receive sound in alternating directions. When gas flow is present in the tube, a pulse that travels against the flow (traveling upstream) is slowed down and takes a longer time to reach the opposite transducer. Conversely, a pulse traveling with the slow (traveling downstream) is sped up and takes a shorter time to reach the opposite transducer.) (eg NDD Easy One)

Strengths: Very stable, In addition, the ultrasonic flow measurement is inherently independent of temperature, humidity, pressure, and gas composition.

Weaknesses:



When buying a spirometer: make sure that the manufacturer or dealer guarantees that the equipment meets the specifications issued by the ATS (American Thoracic Society) and/or the ECCS and ERS (European Respiratory Society).

There also exist other types of spirometers eg hot wire anemometer and water seal spirometer, these systems will not be discussed in this workshop as they're not often used outside the hospital laboratory.

Literature:

http://www.spirxpert.com/technical3.htm

http://www.ersbuyersguide.org/respiratory-actors/distributors-index/pulmonary-function/category/spirometry/

Quanjer PhH, Tammeling GJ, Cotes JE, Pedersen OF, Peslin R, Yernault JC. Lung volumes and forced ventilatory flows. Official Statement of the European Respiratory Society. Eur Respir J 1993; 6 suppl. 16: 5-40. Erratum Eur Respir J 1995; 8: 1629.

American Thoracic Society. Standardization of spirometry: 1994 update. Am J Respir Crit Care Med 1995; 152: 1107-1136.

Miller MR et al. Standardisation of spirometry. ATS/ERS task force: standardisation of lung function testing. Eur Respir J 2005; 26: 319-338.

Multiple-choice questions

1- What is the most important advantage of disposable consumables in spirometers?:
   a- Accuracy
   b- Price
   c- Infection prevention
2- When there is no 3L calibration syringe available, what is another way to control the quality of your spirometer?:
   a- biological controls.
   b- checking the repeatability of the patients tests.
   c- Auto-zeroing before each test.
3- What are the most important features for your choice of spirometer?
   a- Stability, hygiene and software version.
   b- Accuracy, hygiene and stability.
   c- Price, display and portability.

Equipment name:	
How many/which parts do you have to assemble? - - - -	Are they disposable? yes/no yes/no yes/no yes/no

Try to identify this spirometer, it is measuring by:

0 Rotating vane

0 Ultrasound

0 Pneumotachography

0 Other, please specify : ……..

Strengths and weaknesses of this specific spirometer	
Strengths: - - -	Weaknesses: - - -

What are the possibilities of printing for this instrument?.....

What are the possibilities of downloading results by mail/link?.....

Start the instrument and study the program, what do you see?

-Display:…….

-Calibration procedure/ambient conditions:……..

-Selected reference values:…….

-Selected graphs:…….

-Scale:……..

-Auto-zeroing/starting the test:……

Disassemble the instruments, how would you clean the different parts?

-

-

-

-

What do you expect to be the price of this instrument? Approximately ……euro.

What are the possibilities of downloading results by mail/link?.....

Start the instrument and study the program, what do you see?

-
Display:……
…….

-Calibration procedure/ambient conditions:……
……..

-Selected reference values:……
…….

-Selected graphs:……
…….

-
Scale:……
……..

-Auto-zeroing/starting the test:……
……

Disassemble the instruments, how would you clean the different parts?

-

-

-

-

What do you expect to be the price of this instrument? Approximately ……euro.

Infection and control

Waldemar TOMALAK
Institute for TBC & Lung Diseases, Rabka Branch, Polands
wtomalak@igrabka.edu.pl

Mrs. Julie K. Lloyd
118 Upper Way
Upper Longdon
Rugely
WS15 1QD Staffordshire
United Kingdom
julie.lloyd@heartofengland.nhs.uk

Aims

Aim of the presentation on Workstation 2 is to present information on possible hazards related to infection control procedures including:

- General information on the risks
- Some information on how to perform and document cleaning and disinfection
- Demonstration of disassemble spirometer parts to cleaning and disinfection.

Summary

The goal of infection control is to prevent the transmission of infection to patients/subjects and staff during pulmonary function testing (1). Although there are not too many documented cases of infection transmission, the risk is quite real.

There exist possibility of transmission of upper respiratory diseases, enteric infections and blood borne infections through direct contact. The most likely surfaces for contact are mouthpieces and the immediate proximal parts of valves or tubing. There is also a possibility of transmission by indirect contact through aerosol droplets.

The hospital/laboratory should define its own procedures on preventing and minimalizing the risks related to eventual transmission of infection.

Prevention of infection transmission to technicians (1) exposed to contaminated spirometer surfaces can be accomplished through proper hand washing and use of barrier devices, such as disposable gloves. To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves or interior spirometer surfaces. To avoid cross-contamination, reusable mouthpieces, breathing tubes should be disinfected or sterilised regularly. What concerns different types of spirometers, manufacturers define the list of disinfecting agents to be used for disinfection. Usually this is described in user's manual.

Another way to minimize risks is to use disposable mouthpieces (as in case of NDD EasyOne spirometer) or anti-bacterial filters (as in case of MicroLab spirometers). For detailed information see user's manual of the spirometer. When using in-line filters one should remember that the spirometer should be calibrated with the filter; as their resistance changes measured spirometric values (see module 5 presentation).

The disinfection should be documented using a spirometer cleaning log. An example of such a log is shown below.

Spirometer Cleaning Log

The spirometer must be disassembled and cleaned as per the cleaning protocol. By signing this log, you are indicating that you have undertaken this in accordance with the protocol.

Date	Name	Signed

Also other measures for safety can be undertaken – this is usually defined at the level of hospital/laboratory), for example control bacterial swabs can be taken from spirometer/equipment parts that are exposed to contact and/or possible contamination.

As the workstation is to be equipped with two types of spirometers: NDD and Micromedical MicroLab the presentation will include the use of disposable mouthpieces for NDD spirometer and also disassembling the turbine measuring head for cleaning.

References

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5. Aust N Z J Med. 1999 Feb; 29(1):3-4. Infection control in the respiratory laboratory: risk, costs, expediency. Pierce RJ.
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7. J Hosp Infect. 1993 Mar; 23(3):245-6. Use of filters for the control of cross-infection during pulmonary function testing. Leeming JP, Kendrick AH, Pryce-Roberts D, Smith D, Smith EC.

Relevant Standards for Breathing System Filters (BSF) for Anaesthetic and Respiratory Use

ISO 23328-1:200

Applicable to BSF used with a clinical breathing system. It is not applicable to other types of filter, e.g. those designed to protect vacuum sources or gas sample lines, to filter compressed gases, or to protect test equipment for physiological respiratory measurements.

Recommended reading:

1. ESDL Module 5 presentation
2. Spirometry workbook example prepared for ESDL
3. User manual for NDD EasyOne spirometer
4. User manual for Micromedical spirometer

The use of placebo inhaler devices, peak flow meters and inspiratory flow meters in clinical practice

Practical Recommendations

Each trust and health care organisation in primary and secondary care must assess the *potential* risk of infection if placebo and spacer devices, peak flow and inspiratory flow meters are used for multiple patients. Infection risks may differ between primary and secondary care. There needs to be a considered balance of the implications of the potential risks and the requirements of clinical practice, with ownership of the risks accepted by the healthcare organisations. The risks must be re-assessed at appropriate intervals.

1. The consequences of *not* teaching or checking inhaler technique or using a peak flow meter must be considered in light of national clinical guideline recommendations.
2. Patients should be reminded to bring all their inhaler devices with them to each review appointment. Handing a reminder slip to patients each time may be helpful.
3. Standard principles of infection control should be applied. This includes hand hygiene *between* patients.
4. Placebo devices, spacer devices, peak flow meters or inspiratory flow meters should never be used for different patients if there is a known infection risk.
5. As far as *reasonably practicable*, all devices should be 'single patient use'.
6. If **placebo devices** are used for more than one patient, they must be decontaminated each time they are used.
    - Inhaler canisters and other devices that can be washed must be:
        - o Disassembled where possible
        - o Washed thoroughly, ideally in an ultrasound bath* or according to guidelines (NICE 2003)
        - o Soaked for I hour in hypochlorite solution, 1000 parts per million (if there is potential for, but no visible blood the strength should be 10,000 parts per million) and
        - o Dried thoroughly prior to further use.
    - Dry powder devices and device parts that cannot be washed should be decontaminated by thoroughly wiping with an appropriate alcohol wipe.

7. Spacer devices should be single patient use whenever practicably possible. If multiple patient use is unavoidable they must be decontaminated each time they are used as in section 7.
8. If the **same peak flow meter** is used for **different patients**;
    - A peak flow meter should be purchased that can be used 'between' patients**
    - Disposable mouthpieces with one way expiratory valves should always be used and an appropriate financial budget allocated for this purpose
    - These peak flow meters should be washed and dried according to the manufacturer's instructions.

9. Inspiratory flow meters should be used and cleaned according to manufacturers recommendations. Disposable mouthpieces with one way inspiratory valves should always be used and an appropriate financial budget allocated for this purpose.

References

National Institute for Clinical Excellence (NICE) (2003). Infection Control. Prevention of healthcare-associated infection in primary and community care. Clinical Guideline 2. NICE, London

*If an ultrasound bath is not available, manual washing procedures should be adhered to (NICE 2003).
** Peak flow meters can be obtained from NHS Logistics. These are not labelled for single patient use.

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WORKSHOP STATION 3
Spirometry – performing the test, safety measures, selecting the best values, simulating errors

Dr. Jana Kivastik
University of Tartu
Department of Physiology
Ravila 19
50411 Tartu
ESTONIA
jana.kivastik@ut.ee

Prof. Dr. Jorg Daniel Leuppi
Department of Internal Medicine
University Hospital Basel
Petersgraben 4
4031 Basel
SWITZERLAND
jleuppi@uhbs.ch

Aims
This workstation is planned to give the participants the possibility to perform spirometric tests, to learn how to select the best values from those measurements and also discuss and simulate errors that can occur during the testing. Small group hands-on learning in this workshop is tightly connected with theoretical parts of ESDL Part I, all modules covered can be found in the description of the training programme [1]. We will deal mostly with module 5 (spirometry technique), but also with parts of modules 2 (definitions of spirometric values) and 7 (evaluation of spirometric results).

Summary
Spirometry is recommended for the diagnosis and management of asthma and chronic obstructive pulmonary disease. However, for results of the spirometric measurement to be valid the test must be performed in a standardized manner. The American Thoracic Society (ATS) and the European Respiratory Society (ERS) have published guidelines to assist those performing spirometry tests [2-4]. For those working in primary care settings, there is also a more recent paper with the proposed standards for diagnostic spirometry in primary care [5].
Those recommendations include detailed descriptions of equipment performance, validation and quality control, subject performance and measurement procedure. Only a short summary is presented below. In addition, you can watch online the official ERS video about conducting the spirometry [6].

Before the measurement starts:
Preparation of pulmonary function equipment prior to test performance is essential to obtain reliable data. Different types of spirometers and their quality and infection control will be discussed in other workstations. In addition to preparing the equipment, there are also several aspects in preparing the subject: for calculating the reference values there is a need to record patient's age and measure the height and weight, and also record the type, dosage and time of relevant medication. The subject must loosen any element being able to block his/her breathing, like a collar or a belt. The test can be carried out in a sitting or standing position and the position should be recorded on the report.
Spirometry depends upon the effort and cooperation of the subject performing the test. The person administrating the test should explain the goal of the test and also demonstrate the manoeuvres, and later, during the actual measurement should stimulate the patient with the voice and gestures to obtain the best possible values.

Actual measurement:
There are three important steps (FFF) the subject has to follow in spirometry:

a) Full inspiration, b) Forceful expiration, c) Full expiration.

Quality control of spirometry includes the assessment of acceptability (within-manoeuvre evaluation) and repeatability (between-manoeuvre evaluation) of the tests.

Recommended **acceptability criteria** on performing the test of forced expiration are the following:
1) There is a good start of the test,

2) Spirogram is free from artefacts: continuous blow as fast and as hard as possible, without cough, variable effort, and early termination, etc.
3) There is a satisfactory exhalation.

The rapid start is defined as a back extrapolated volume of <5% of the FVC or less than 0.15 l, whichever is greater. Most devices offer a rapid computerised feedback to the technician if the start criteria are not met. Inspection of the flow-volume curve may be added to that, PEF should be achieved with a sharp rise and occur close to the start of exhalation.
The end of test criteria are:
-The subject cannot or should not continue further exhalation or
-The volume-time curve shows an obvious plateau (no change in volume: 0.025 l for >1 second) or
-The subject has tried to exhale for at least 6 seconds (for at least 3 seconds in children < 10 yrs)

The acceptability criteria must be applied before the reproducibility criteria. Unacceptable manoeuvres should be discarded before applying the reproducibility criteria. However, failure to meet acceptability criteria does not mean that the manoeuvre is useless. In these cases, just reporting values of FVC and FEV1 that the subject achieved could also be useful information.

The **repeatability criteria** are used as a guide to whether more than three acceptable FVC manoeuvres are needed. The following reproducibility criteria are applied after three acceptable spirograms have been obtained:
1) The two largest values of FVC must be within 0.150 l of each other,
2) The two largest values of FEV1 must be within 0.150 l of each other,
3) If criteria 1 and 2 are not met, testing should be continued.

Eight manoeuvres are considered a practical upper limit for most subjects. No spirogram should be rejected only because of its poor reproducibility, provided three acceptable manoeuvres are obtained. In these cases, reproducibility of the test should be considered at the time of interpretation (e.g. the FVC manoeuvre triggered a bronchospasm that prevented reproducibility).

Selecting the best values

The largest FVC and the largest FEV1 should be recorded after examining the data from all the usable curves, even if they do not come from the same curve. FEF25-75 is taken from the blow with the largest sum of FEV1 and FVC.

Errors

There are a number of problems you are likely to encounter when conducting spirometry. Problems in performance of the test can be subject-related, for example (graphs to illustrate those examples are presented in the ppt-file):
-Effort that is not maximal throughout,
-Leaks,
-Hesitation at the start of expiration,
-Cough, particularly during the first second of exhalation,
-Glottis closure or tongue in mouthpiece, etc.

For optimal quality control, both flow-volume and volume-time displays are useful and operators should visually inspect the performance of each manoeuvre for quality assurance.
In particular, for the assessment of acceptability the **volume-time curve** allows to 1) evaluate any delay in the start of forced expiration and the amount of extrapolated volume, 2) the fulfilment of end-of-test criteria (plateau in change of volume, expiratory time) and 3) abrupt termination of expiration (glottis closure, mouthpiece obstruction).
The **flow-volume graph** allows estimating 1) the magnitude of effort, 2) the variability in effort and 3) the effect of coughing bouts during manoeuvre.

Reversibility testing

In some patients who may have airflow obstruction at baseline, spirometry can be used to measure the response before and at various time intervals after the administration of inhaled bronchodilators either when given as a single dose or following a given trial period. There is no general consensus about the drug, exact dose, or mode of administering a bronchodilator, but suggestions can be found in Miller et al [3]. In summary, there is a need to perform an adequate baseline spirometry (as explained above), then administer the drug using the method and dose agreed in your lung function lab, and finally, after a specific time interval record the post bronchodilator spirometry.

The first step in interpreting any bronchodilator test is to determine if any change greater than random variation has occurred. There is no clear consensus about what constitutes reversibility in subjects with airflow obstruction. In part, this is because there is no consensus on how a bronchodilator response should be expressed: the three most common methods of expressing bronchodilator response are per cent of the initial spirometric value, per cent of the predicted value, and absolute change.

Interpretation of bronchodilator test results is discussed more in ESDL Module 7 (evaluation of spirometric results), but the members of the ATS/ERS taskforce recommend using the per cent change from baseline and absolute changes in FEV1 and/or FVC in an individual subject to identify a positive bronchodilator response. An increase in FEV1 (and/or FVC) for more than 12% of the baseline value and more than 200 ml is considered a significant bronchodilator response [4]. However, expressing the change as a percentage of the baseline FEV1 exaggerates the response in those with the poorest FEV1, therefore, some authors suggest to use a percentage of the predicted value instead as this adjusts for differences in lung size [5].

References

1. Steenbruggen I, et al. Spirometry HERMES: A European training programme and qualification in spirometry practice. *Breathe* 2011:7; 259-275.
2. Miller MR, et al. General considerations for lung function testing. *Eur Respir J* 2005; 26:153–61. *Indications and contraindications for spirometry; equipment, personnel and subject preparation are discussed in this paper.*
3. Miller MR, et al. Standardisation of spirometry. *Eur Respir J* 2005; 26:319–38.
4. *This paper summarizes all the aspects of spirometric measurements.*
5. Pellegrino R, et al. Interpretative strategies for lung function tests. *Eur Respir J* 2005; 26:948-68.
6. Levy ML, et al. Diagnostic spirometry in primary care: Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations. *Prim Care Respir J* 2009; 18:130-47.
7. ERS spirometry video: http://www.ers-education.org/e-learning/procedure-videos.aspx

Evaluation

1. Which of the statements about the repeatability criteria and selecting the best values is CORRECT?
    a. Repeatability criteria are applied after four acceptable spirograms have been obtained.
    b. The two largest values of FVC and FEV1 must be within 0.15 L of each other
    c. The largest FVC and the largest FEV1 from the same curve should be recorded after examining the data from all the suitable curves.
    d. Eleven manoeuvres are considered a practical upper limit for most subjects.

2. The flow-volume graph allows assessment of all of the following EXCEPT:
    a. The variability in effort
    b. The magnitude of effort
    c. The effect of coughing bouts during manoeuvre
    d. Mouthpiece leaks

3. Which of the statements about preparation of subject is INCORRECT?
    a. It is preferable to avoid smoking within at least one hour of testing
    b. It is preferable to avoid performing vigorous exercise within 4 hours of testing

c. It is preferable to avoid wearing clothing that substantially restricts full chest and abdominal expansion
d. The decision to avoid bronchodilators depends on the reasons why the spirometry was ordered.

4. Which of the statements about the correct position to perform spirometry is INCORRECT?
    a. Testing should be done in the standing position.
    b. Correct posture is with chin slightly elevated and neck extended
    c. Mouth should be put firmly around the mouthpiece, the tongue should be out of the mouthpiece
    d. Dentures should be left in place if they are not loose
    e. A nose clip should be used or the subject can pinch his/her nostrils with fingers.

5. Which of the statements about height and weight measurement is INCORRECT?
    a. Height and weight are recorded with a patient wearing indoor clothes and being without shoes.
    b. There is no need to measure height of an adult patient if it was measured within 3 years
    c. For patients with a deformity of the thoracic cage the arm span can be used as an estimate of height.
    d. Height and/or weight are used in the calculation of reference values.

6. Which of the statements about documenting relevant events that occurred during the spirometric assessment is INCORRECT?
    a. It should be documented if the patient seemed not to properly understand the instructions given to him/her.
    b. It should be documented if the patient got so tired of testing that he/she could not proceed with forced spirometry
    c. It should be clearly stated how long were the intervals between acceptable tests
    d. It should be stated in which position (standing or sitting) testing was undertaken.

7. Which of the statements about the choice of bronchodilator is INCORRECT?
    a. The choice of bronchodilator is a clinical decision depending on what the clinician wishes to learn from the test
    b. Reversibility testing can only be done using the bronchodilator which has not been used by that patient within 24 hours
    c. A lower dose of bronchodilator can be used if there is concern about any effect on the patient's heart rate or tremor.
    d. You have to wait longer for the post-bronchodilator spirometry when using the short-acting anticholinergic agents than when using the short-acting beta-2-agonists

Please find all answers at the back of your handout materials

WORKSTATION 4. Calibration and quality control - how to calibrate different devices and perform biological control procedures

Definitions

Calibration – set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

Quality control – part of quality management focused on fulfilling quality requirements (example: ISO 9000).

Quality management – coordinated management activities to direct and control an

Repeatability – closeness of the agreement between the results of successive measurements of the same item carried out under the same conditions of measurement; **NOTE 1:** Same conditions imply same method, same observer, same, instrument, same location, same condition of use, and repeated over a short space of time

Reproducibility – closeness of the agreement between the results of measurements of the same item carried out under changed conditions of measurement; **NOTE:** Changed conditions imply changes in the method of measurement, observer, instrument, location, conditions of use, and time; Example: If a technician tests a subject several times this is looking at the repeatability of the test. If the subject is then given a bronchodilator drug and tested again after 30 minutes one needs to know the reproducibility of the test in order to make a decision on this comparison.

Verification – confirmation through the provision of objective evidence that specified requirements have been fulfilled. **NOTE:** Example: verification of commercial information systems, instruments, and methods; and calibration verification of results obtained on automated equipment.

Equipment Preparation

Preparation of pulmonary function equipment prior to test performance is essential to obtain reliable data. The following areas should be addressed:

- calibration and gathering equipment and supplies
- selection of reference values
- complete required equipment checks as appropriate

Proper equipment preparation is essential to obtain accurate and reliable test results. Manufacturers' instructions for use and ATS/ERS statements need to be followed. Reference values should be validated for the specific population.

Reference

Application of a Quality Management System Model for Respiratory Services; Approved Guideline—Second Edition Clinical and Laboratory Standards Institute (NCCLS). HS4-A2 Vol 26;No 15-Vol 2, No23

Calibration vs. Quality Control

- ✓ Calibration adjusts the output of an instrument (spirometer) to match a known input
- ✓ Quality control tests an instrument to verify that the output is accurate and/or precise

What Quality Control Is

Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the

requirements of the client or customer. QC is similar to, but not identical with, quality assurance (QA).”

Calibration of Spirometers

- ✓ Enter ambient temperature, pressure and humidity for BTPS-Correction* if this isn´t already done automatically by the spirometer.
- ✓ The calibration pump should have a volume 3 liters (bigger is better).
- ✓ Volume calibration: 3 to 5 complete strokes (in and out) of a calibration pump
- ✓ If the volume of the pump is measured after the calibration, the result should lie between 97% and 103% of the declared volume. This applies only, if the BTPS-correction is switched of.

* all volumes are measured in liter (BTPS). That means the real volume inside the lung counts. BTPS stands for **B**ody **T**emperature, ambient **P**ressure, **S**aturated with water vapor.

ERS 3 Liter syringe

The ATS/ERS standard:
• A 3 litre syringe with an accuracy of ≤ 15 mL or 0.5% of the full scale.
• Syringes must be calibrated annually !

The syringe should be stored in the same room where calibration is performed and should not be exposed to sources of heat or cold

You should check with a certified 3-L syringe, the accuracy cold measuring volume is kept within the recommended range (± 3%).

Calibration syringes should be accurate to ± 15 ml or ± 0.5% of full scale, and need checked periodically for leaks and check its stability

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Perform Calibration or Calibration Check:

1. Set spirometer to "Calibration" mode or "Calibration Check" mode.
2. If filters designed specifically for spirometry testing are used, calibration or calibration checks should be done through the filter.
3. Perform a calibration or calibration check using the validated 3-L calibration syringe according to the 2005 ATS/ERS statement "Standardization of spirometry" (see references). Pull the syringe handle out completely and push the 3 liter volume into the spirometer at the correct flow.
4. Repeat the calibration or calibration check at least three separate times at three different flow rates, as per manufacturer instructions.
5. Ensure the calibration results are within the required limits ± 3.5% (or 2.895 liters to 3.105 liters).
6. Maintain a copy of the calibration or calibration check in the log book.

ERS

Calibration with 3 Liters Syringe

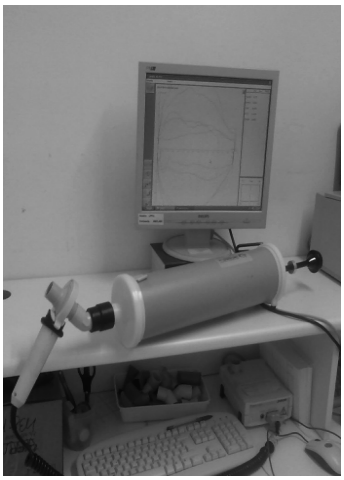
✓ Objective:
Establishing a correspondence between standard measures (syringe) and measurement

✓ Material:
3-liter syringe standardized
If not available 3L syringe, better use syringe 2L than 1L

✓ For flow measuring devices the calibration volume must be injected at different rates (between 2 and12 L/s)

✓ Volume accuracy should be within 3.5 % at all flows

✓ Calibration syringes must be kept at the same temperature and humidity as the spirometer.



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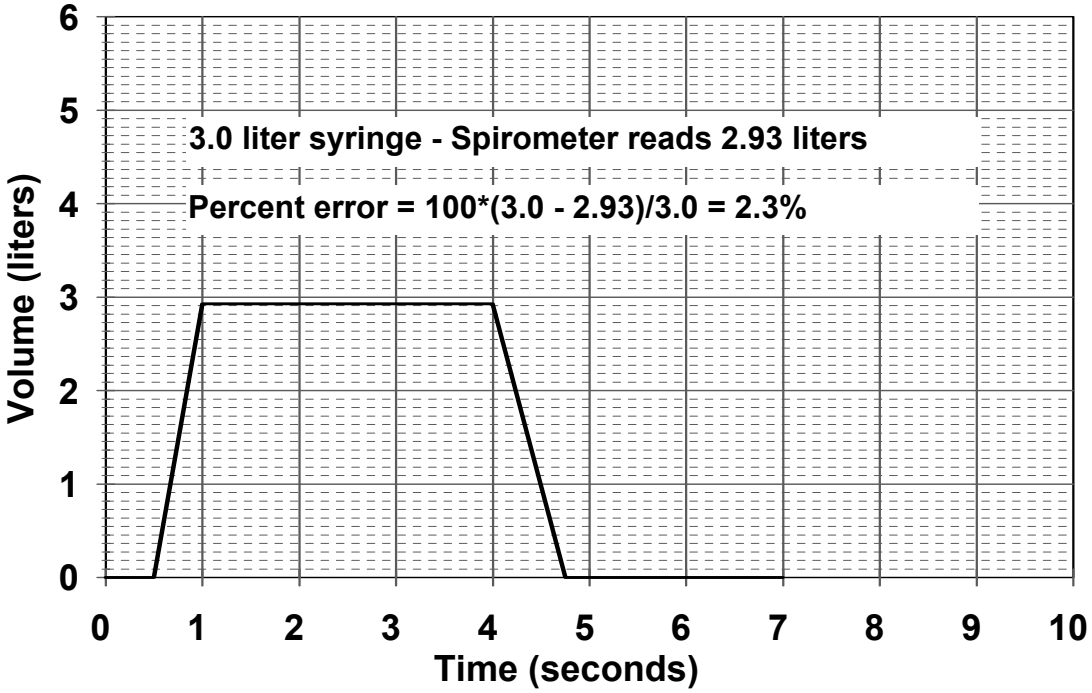
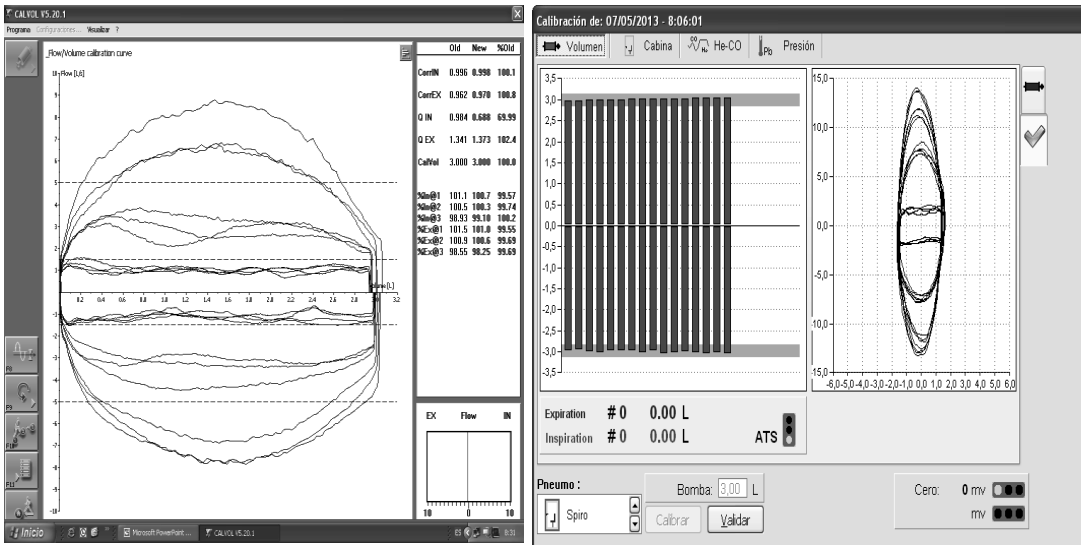
EXAMPLE: Air from a 3 liter syringe was injected into the spirometer (volume/time curve), producing the tracing below. To meet the criterion of ±3% of 3 liters, a volume must fall

between 2.91 - 3.09L. The volume reads 2.93 liters so it is within the acceptable range. (If the baseline does not start at zero, remember to adjust accordingly.)



ERS

Flow check at least three different flows range



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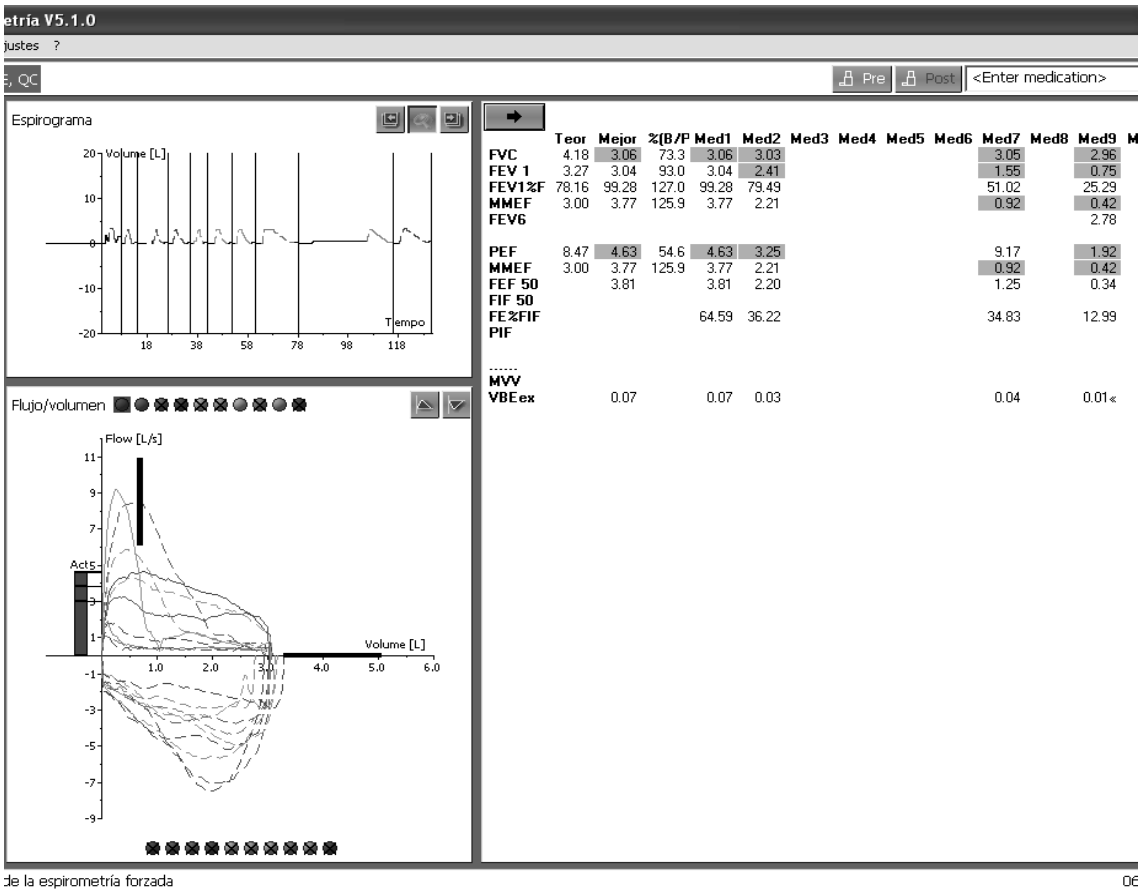
How to check the accuracy of a flow spirometer.

Check the volume accuracy using a 3.00 liter calibration syringe every day before using the spirometer. Select calibration check from the menu of the spirometer (so that the software does not apply a BTPS correction factor to the results). If the flow sensor is permanent and heated (as in some older models), check the manual to see if the heater should be turned off for at least 30 minutes before calibration checks. If an unheated permanent flow sensor is used and it was recently cleaned, be sure that it is completely dry and at room temperature before the calibration check. If the spirometer uses disposable flow sensors, use a new flow sensor from each box of flow sensors for the calibration checks. For calibration checks, some flow spirometers require a special adaptor that fits between the syringe and the flow sensor.

First fill the syringe with air completely, then attach it firmly to the flow sensor, and empty it smoothly and completely. End the maneuver carefully to ensure that a soft click is heard, meaning that the syringe was emptied completely. Do not bang the syringe while emptying it, to avoid damage. Disconnect, refill with air, and then empty the syringe three times, each time at a different speed: First, empty it in less than one second (fast); next in 2 or 3 seconds (medium), and the third time take about six seconds (slow). Count one-one-thousand, two-one-thousand@ etc, while emptying the syringe, to gauge the speed of emptying. The resulting FVC for all 3 of these maneuvers should be between 2.91 and 3.09 liters. Record all three results on the daily worksheet or quality log



Biological Control ($B_{IO}QC$) Testing

A biological normal quality control (BioQC) refers to a healthy non-smoking individual with normal and stable lung function, who is tested on a regular basis as a 'control'. Frequently office and staff personnel are asked to perform this function.

The facility should identify two BioQC subjects. It is recommended that al least two healthy non-smoking individuals should be identified to perform spirometry testing to assess the overall operational status of the spirometry system. Results are monitored to assess changes in equipment performance that may be undetected in routine calibration.

Establishing the BioQC Normal Range:

1. Perform 10 replicates on each BioQC subject over a period of several days. Ideally this should entail a single test performed each day; however a maximum of 2 tests spread out within any single day (e.g. morning and afternoon) may be used.
2. Use the Normal Range Calculator to determine the acceptable ranges for each person. This worksheet takes the average of the replicates and calculates two standard deviations (SD) which constitutes the normal range for this subject.
    - Fill in the values generated by the BioQC subjects. The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
    - There should be a maximum of 10% between the highest and lowest FVC and FEV1 values
    - The calculated coefficient of variation (CV) should be 3% or less.
3. Subsequent spirometry testing on each BioQC subject should fall within the ± 2 ranges for that subject. The facility should perform troubleshooting if BioQC values fall outside of their acceptable ranges.

Weekly BioQC Testing:

1. The BioQC subjects should perform spirometry procedures in the same way as a patient.
2. For consistency, BioQC subjects should ideally be tested:
    a. on the same spirometer
    b. at the same day of month
    c. at the same time of day
3. An adequate test requires a minimum of three acceptable FVC maneuvers and adherence to repeatability criteria.
    - Repeatability is achieved when the difference between the largest and the next largest acceptable FVC and FEV1, is less than or equal to 150 mL. The results for FVC and FEV1 do not need to come from the same maneuver.
    - The best trial is chosen based on the largest sum of FVC plus FEV1 from acceptable maneuvers.
4. It is recommend that the BioQC subjects be tested weekly and should be recorded on the Spirometry Quality Control Program worksheets.
    - Fill in the values generated by the BioQC subjects. The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
    - The CVs for FVC and FEV1 should be less than or equal to 3%.
    - Confirm that the results fall within the acceptable ranges for this BioQC subject.

ERS

Determining the normal range for a biological control.

- The person used as a biological control must be healthy and free of known respiratory disease
- Record your own spirometry every day (or that of a colleague if you have a respiratory condition) at the same time of day, on the same spirometer for 14 days. You will need a minimum of 10 recordings.
- Calculate the mean (average) for each spirometry parameter: i.e. add up all the readings for that parameter and divide by the number of recordings (e.g. mean 3.60 L).
- Now calculate 2.5% of the mean (i.e. 3.6 x 0.025 = 0.09 L)
- Finally, obtain the normal range for repeated measurements by adding and subtracting this 2.5% value to the mean value (i.e. 3.6-0.09 = 3.51 L; and 3.6 + 0.09 =3.69 L so the acceptable range for the person tested would be 3.51 L to 3.69 L)
- You can now use this person to check that the spirometer readings fall within this range to verify the accuracy of your spirometer on a weekly basis.

ERS

SUMMARY: Components of the spirometry QA program

- ✓ Well-chosen, enthusiastic technologists
- ✓ Trained and certified technologists
- ✓ Happy technologists
- ✓ Excellent spirometer used by everyone
- ✓ Test session quality checks and messages
- ✓ Daily 3.00 liter calibration checks
- ✓ Central review and reporting of tech quality

ERS

SUMMARY Quality control programme

Logbook:

- ✓ Calibration and check data
- ✓ Cleaning procedures
- ✓ Test-performance procedures
- ✓ Calculations
- ✓ Criteria of acceptability and repeatability
- ✓ Reference values source
- ✓ Action to be taken in case of “panic” values
- ✓ Hardware and software upgrades (version and data of change)
- ✓ Preventive maintenance service
- ✓ Internal audit

european respiratory society every breath counts

1 References

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DOI: 10.1183/09031936.05.00034805

SERIES “ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING”
Edited by V. Brusasco, R. Crapo and G. Viegi
Number 2 in this Series

Standardisation of spirometry

M.R. Miller, J. Hankinson, V. Brusasco, F. Burgos, R. Casaburi, A. Coates, R. Crapo, P. Enright, C.P.M. van der Grinten, P. Gustafsson, R. Jensen, D.C. Johnson, N. MacIntyre, R. McKay, D. Navajas, O.F. Pedersen, R. Pellegrino, G. Viegi and J. Wanger

Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume and the actual flow or volume.

A calibration check is different from calibration and is the procedure used to validate that the device is within calibration limits, *e.g.* ±3% of true. If a device fails its calibration check, then a new calibration procedure or equipment maintenance is required. Calibration checks must be undertaken daily, or more frequently, if specified by the manufacturer.

The syringe used to check the volume calibration of spirometers must have an accuracy of ±15 mL or ±0.5% of the full scale (15 mL for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate intervals between syringe calibration checks. Users should be aware that a syringe with an adjustable or variable stop may be out of calibration if the stop is reset or accidentally moved. Calibration syringes should be periodically (*e.g.* monthly) leak tested at more than one volume up to their maximum; this can be done by attempting to empty them with the outlet corked. A dropped or damaged syringe should be considered out of calibration until it is checked.

Quality control for volume-measuring devices

The volume accuracy of the spirometer must be checked at least daily, with a single discharge of a 3-L calibrated syringe. Daily calibration checking is highly recommended so that the onset of a problem can be determined within 1 day, and also to help define day-to-day laboratory variability. More frequent checks may be required in special circumstances, such as: 1) during industrial surveys or other studies in which a large number of subject manoeuvres are carried out, the equipment's calibration should be checked more frequently than daily [8]; and 2) when the ambient temperature is changing (*e.g.* field studies), volume accuracy must be checked more frequently than daily and the BTPS correction factor appropriately updated.

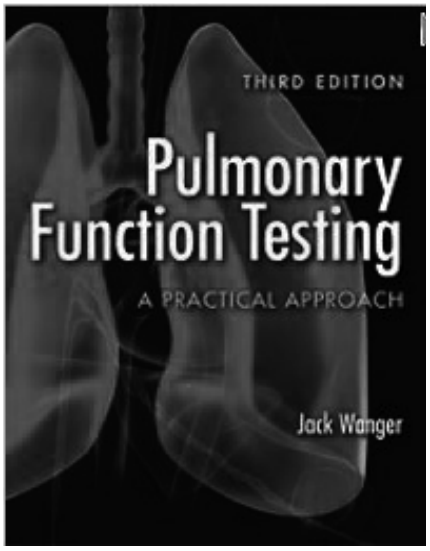
The accuracy of the syringe volume must be considered in determining whether the measured volume is within acceptable limits. For example, if the syringe has an accuracy of 0.5%, a reading of ±3.5% is appropriate.

The calibration syringe should be stored and used in such a way as to maintain the same temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer, but out of direct sunlight and away from heat sources.

Quality control for flow-measuring devices

With regards to volume accuracy, calibration checks must be undertaken at least daily, using a 3-L syringe discharged at least three times to give a range of flows varying between 0.5 and 12 $L \cdot s^{-1}$ (with 3-L injection times of ~6 s and <0.5 s). The volume at each flow should meet the accuracy requirement of ±3.5%. For devices using disposable flow sensors, a new sensor from the supply used for patient tests should be tested each day.

For linearity, a volume calibration check should be performed weekly with a 3-L syringe to deliver three relatively constant flows at a low flow, then three at a mid-range flow and finally three at a high flow. The volumes achieved at each of these flows should each meet the accuracy requirement of ±3.5%.



Jack Wanger. Pulmonary Function Testing*: A Practical Approach (Third Edition)*. *Jones & Bartlett Learning 2012*

CHAPTER 1

Forced Spirometry and Related Tests

Introduction

Forced spirometry, often referred to as *spirometry*, is an essential component in the medical evaluation of patients complaining of shortness of breath. It is also widely used to evaluate the beneficial effects and adverse reactions of therapeutic interventions and to monitor the effects of environmental and occupational exposures. In addition, forced spirometry is used in disability/impairment evaluations, in preoperative assessments, and to monitor lung function over time.

Spirometry has shown considerable growth in the past 30 years, for several reasons: (*a*) published standards and testing guidelines,[1-6] (*b*) improved spirometers and software, (*c*) evidence that both patients and physicians have inaccurate perceptions of the severity of airflow obstruction,[7-11] (*d*) evidence that history taking and physical examination by themselves are not

Faculty Disclosures

Mr. Felip Burgos owns stocks of Linkcare® Health Solutions SL.

Faculty

POSTGRADUATE COURSE

Dr. Brendan G. Cooper
Lung Function & Sleep
Queen Elizabeth Hospital Birmingham
Mindelsohn Way, Edgbaston
B15 2WB
Birmingham
UNITED KINGDOM
brendan.cooper@uhb.nhs.uk

Mr. Felip Burgos
Servicio de Pneumologia
Hospital Clinic
Villarroel 170
8036
Barcelona
SPAIN
fburgos@ub.edu

Mrs. Julie K. Lloyd
118 Upper Way
Upper Longdon
Rugely
WS15 1QD
Staffordshire
UNITED KINGDOM
julie.lloyd@heartofengland.nhs.uk

Mrs Jellien Makonga-Braaksma
Ekris 16A
3931 PW
Woudenberg
NETHERLANDS
J.Makonga@meandermc.nl

Ms. Concepción Gistau
Hospital Clinic. CDR
Villarroel 170
8036
Barcelona
SPAIN
cgistau@clinic.ub.es

Dr. Irene Steenbruggen
Pulmonary Laboratory
Isala klinieken loc Wl C2
PO box 10500
8000 GM
Zwolle
NETHERLANDS
i.steenbruggen@isala.nl

Prof. Dr. Jorg Daniel Leuppi
Department of Internal Medicine
University Hospital Basel
Petersgraben 4
34-700
Basel
SWITZERLAND
jleuppi@uhbs.ch

Prof. Waldemar Tomalak
Institute for TBC and Lung Dis.
Dept. Physiopathology of Respiratory
J Rudnik Str 3
4031
Rabka
POLAND
wtomalak@zpigichp.edu.pl

Dr. Jana Kivastik
University of Tartu
Department of Physiology
Ravila 19
50411
Tartu
ESTONIA
jana.kivastik@ut.ee

EDUCATIONAL WORKSHOP

Dr. Brendan G. Cooper
Lung Function & Sleep
Queen Elizabeth Hospital Birmingham
Mindelsohn Way, Edgbaston
B15 2WB Birmingham
UNITED KINGDOM
brendan.cooper@uhb.nhs.uk

Dr. Irene Steenbruggen
Pulmonary Laboratory
Isala klinieken loc Wl C2
PO box 10500
8000 GM Zwolle
NETHERLANDS
i.steenbruggen@isala.nl

Mrs. Jellien Makonga-Braaksma
Ekris 16A
3931 PW Woudenberg
NETHERLANDS
J.Makonga@meandermc.nl

Mrs. Julie K. Lloyd
118 Upper Way
Upper Longdon
Rugely
WS15 1QD Staffordshire
UNITED KINGDOM
julie.lloyd@heartofengland.nhs.uk

Dr. Jana Kivastik
University of Tartu
Department of Physiology
Ravila 19
50411 Tartu
ESTONIA
jana.kivastik@ut.ee

Mr. Felip Burgos
Servicio de Pneumologia
Hospital Clinic
Villarroel 170
08036 BARCELONA
SPAIN
fburgos@ub.edu

Prof. Waldemar Tomolak
Institute for TBC and Lung Dis.
Dept. Physiopathology of Respiratory System
J Rudnik Str 3
34-700 RABKA
POLAND
wtomalak@zpigichp.edu.pl

Prof. Dr. Jorg Daniel Leuppi
Department of Internal Medicine
University Hospital Basel
Petersgraben 4
4031 Basel
SWITZERLAND
jleuppi@uhbs.ch

Ms. Concepción Gistau
Hospital Clinic. CDR
Villarroel 170
08036 Barcelona
SPAIN
cgistau@clinic.ub.es

Answers to submitted MCQs

*Please find all correct answers in **bold** below*

POSTGRADUATE COURSE

Quality assurance theory – Dr. Felip Burgos

1. Calibration is
   a. **After introducing environmental conditions, then calibrating the spirometer with a 3 L syringe, the device corrects the deviation automatically**
   b. **Checking if temperature and pressure are measured**
   c. **Check if the spirometer is linear in all flows**
   d. Verify if barometer is in a clean room

2. Validation /Checking is:
   a. Verify spirometer linearity deviation and correcting the errors manually
   b. **Recommended to do in all spirometer**
   c. Checking the humidity of spirometer
   d. b and c

3. Some devices cannot be calibrated:
   a. Just once a week
   b. False, all devices need to be calibrated
   c. **True, some devices are calibrated and don't need it**
   d. Some devices only need to be calibrated once a year

4. Quality control is:
   a. Calibrating with a 3L syringe at all flows in the spirometer
   b. Review spirometer
   c. **Assess spirometer, verify all flows, and periodically perform biological controls**
   d. Perform biological controls

Evaluation of spirometric results – Prof. Waldemar Tomalak

1. Properly performed spirometry should include:
   a. At least one acceptable manoeuver
   b. **At least three acceptable manoeuvers**
   c. At least five acceptable manoeuvers
   d. At least eight acceptable manoeuvers

2. The criterion for FEV1 and/or FVC for positive bronchodilator response is:
   a. Increase >200 ml
   b. Increase >12% from baseline
   c. Increase > 200 ml or > 12% from baseline
   d. **Increase . 200 ml and >12% from baseline**

3. Obstruction in spirometric evaluation occurs when:
   a. FEV1 < 80% pred
   b. FEV1/FVC < 0.7
   c. **FEV1/FVC < lower limit of normal**
   d. Both FEV1 and FEV1/FVC < lower limit of normal

EDUCATIONAL SKILLS WORKSHOP

<u>Workstation 1:</u> Spirometers – demonstration of how different types of spirometers work and how they are cleaned and maintained – Mrs Jillian Makonga-Braaksma & Dr Brendan Cooper

1. What is the most important advantage of disposable consumables in spirometers?:
   a. Accuracy
   b. Price
   c. **Infection prevention**

2. When there is no 3L calibration syringe available, what is another way to control the quality of your spirometer?
   a. **biological controls**
   b. checking the repeatability of the patients tests
   c. Auto-zeroing before each test

3. What are the most important features for your choice of spirometer?
   a. Stability, hygiene and software version
   b. **Accuracy, hygiene and stability**
   c. Price, display and portability

<u>Workstation 3:</u> Spirometry – performing the test, safety measures, selecting the best values, simulating errors - Dr Jana Kivastik & Prof. Dr Jorg Daniel Leuppi

1. Which of the statements about the repeatability criteria and selecting the best values is CORRECT?
   a. Repeatability criteria are applied after four acceptable spirograms have been obtained.
   b. **The two largest values of FVC and FEV1 must be within 0.15 L of each other**
   c. The largest FVC and the largest FEV1 from the same curve should be recorded after examining the data from all the suitable curves.
   d. Eleven manoeuvres are considered a practical upper limit for most subjects.

2. The flow-volume graph allows assessment of all of the following EXCEPT:
   a. The variability in effort
   b. The magnitude of effort
   c. The effect of coughing bouts during manoeuvre
   d. **Mouthpiece leaks**

3. Which of the statements about preparation of subject is INCORRECT?
   a. It is preferable to avoid smoking within at least one hour of testing
   b. **It is preferable to avoid performing vigorous exercise within 4 hours of testing**
   c. It is preferable to avoid wearing clothing that substantially restricts full chest and abdominal expansion
   d. The decision to avoid bronchodilators depends on the reasons why the spirometry was ordered.

4. Which of the statements about the correct position to perform spirometry is INCORRECT?
   a. **Testing should be done in the standing position**.
   b. Correct posture is with chin slightly elevated and neck extended
   c. Mouth should be put firmly around the mouthpiece, the tongue should be out of the mouthpiece
   d. Dentures should be left in place if they are not loose

e. A nose clip should be used or the subject can pinch his/her nostrils with fingers.

5. Which of the statements about height and weight measurement is INCORRECT?
   a. Height and weight are recorded with a patient wearing indoor clothes and being without shoes.
   b. **There is no need to measure height of an adult patient if it was measured within 3 years**
   c. For patients with a deformity of the thoracic cage the arm span can be used as an estimate of height.
   d. Height and/or weight are used in the calculation of reference values.

6. Which of the statements about documenting relevant events that occurred during the spirometric assessment is INCORRECT?
   a. It should be documented if the patient seemed not to properly understand the instructions given to him/her.
   b. It should be documented if the patient got so tired of testing that he/she could not proceed with forced spirometry
   c. **It should be clearly stated how long were the intervals between acceptable tests**
   d. It should be stated in which position (standing or sitting) testing was undertaken.

7. Which of the statements about the choice of bronchodilator is INCORRECT?
   a. The choice of bronchodilator is a clinical decision depending on what the clinician wishes to learn from the test
   b. **Reversibility testing can only be done using the bronchodilator which has not been used by that patient within 24 hours**
   c. A lower dose of bronchodilator can be used if there is concern about any effect on the patient's heart rate or tremor.
   d. You have to wait longer for the post-bronchodilator spirometry when using the short-acting anticholinergic agents than when using the short-acting beta-2-agonists

Workstation 4: Calibration and quality control - how to calibrate different devices and perform biological control procedures – Mr Felip Burgos & Ms Concepcion Gistau

1. Calibration is:
   a. **After introducing environmental conditions, then calibrating the spirometer with a 3 L syringe, the device corrects the deviation automatically**
   b. **Checking if temperature and pressure are measured**
   c. **Check if the spirometer is linear in all flows**
   d. Verify if barometer is in a clean room

2. Validation /Checking is:
   a. Checking the humidity of spirometer
   b. **Recommended to do in all spirometer**
   c. Verify spirometer linearity deviation and correcting the errors manually
   d. a and b

3. Some devices cannot be calibrated:
   a. **True, some devices are calibrated and don't need it**
   b. False, all devices need to be calibrated
   c. Just once a week
   d. Some devices only need to be calibrated once a year

4. Actions to be taken in case of non-credible results
   a. First call the company
   b. Change temperature and pressure

c. **Review and calibrate/verify pneumotach**
d. b and c

5. Quality control is:
a. - Calibrating with a 3L syringe at all flows in the spirometer
b. - Review spirometer
c. - Perform biological controls
d. **- Assess spirometer, verify all flows, and periodically perform biological controls**