ERS EUROPEAN RESPIRATORY SOCIETY
every breath counts

ERS Annual Congress Munich
6–10 September 2014

Postgraduate Course 9
Educational Skills Workshop 7–9

Spirometry knowledge and basic skills (Part I of the European spirometry training programme)

Saturday, 6 September 2014
09:30–13:00

Room 3 (ICM)

Tuesday, 9 September 2014
ESW7 08:00–10:20
ESW8 10:40–13:00
ESW9 14:30–16:50

Room B11

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ERS Spirometry Training Programme

The following lines provide 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 will receive a 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. The next Part 2 course will be a joint course between the ERS and the German Respiratory Society. It will take place on the 13-14 March 2015 in Freiburg, Germany. This course will cover modules in knowledge and competence in spirometry measurement. Participants will be able to register shortly after completion of the Part 1 training.

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.

You can access an electronic copy of these educational materials here:

www.ers-education.org/2014pg9

To access the educational materials on your tablet or smartphone please find below a list of apps to access, annotate, store and share pdf documents.

iPhone / iPad

Adobe Reader - FREE
With the Adobe Reader app you can highlight, strikethrough, underline, draw (freehand), comment (sticky notes) and add text to pdf documents using the typewriter tool. It can also be used to fill out forms and electronically sign documents.
http://bit.ly/1sTSxn3

UPAD Lite - FREE
UPAD Lite is an advanced note-taking application with annotation features. You can handwrite notes, highlight text, add sticky notes and reference images and export any type of document as a PDF or PNG file by email or to cloud services.
http://bit.ly/1mQ1j0K

Noteability - $4.99
Noteability uses CloudServices to import and automatically backup your PDF files and allows you to annotate and organise them (incl. special features such as adding a video file). On iPad, you can bookmark pages of a note, filter a PDF by annotated pages, or search your note for a keyword.
http://bit.ly/TCrNad

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Adobe Reader - FREE
The Android version of Adobe Reader lets you view, annotate, comment, fill out, electronically sign and share documents. It has all of the same features as the iOS app like freehand drawing, highlighting, underlining, etc.
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With the ez PDF reader you can add text in text boxes and sticky notes; highlight, underline, or strikethrough texts or add freehand drawings. Add memo & append images, change colour / thickness, resize and move them around as you like.
http://bit.ly/1kdxZfT

Postgraduate Course 9 & Educational Skills Workshop 7-9
Spirometry knowledge and basic skills
(Part I of the European Spirometry Training Programme)

AIMS: *The aim of Part I Spirometry Knowledge and Basic 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 spirometic 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.*

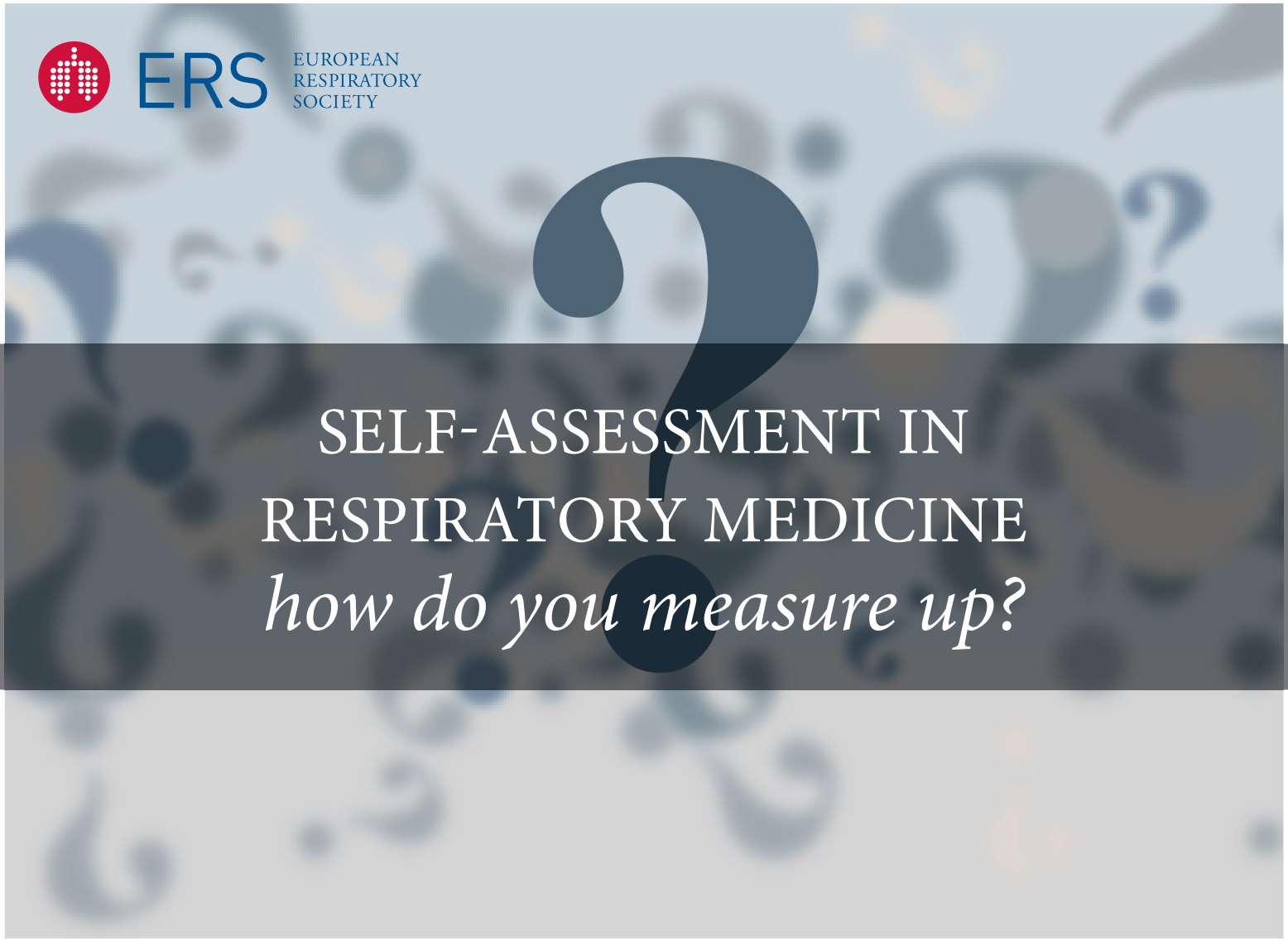
HERMES LINKS ADULT: *D.1 Pulmonary function testing.*

TARGET AUDIENCE: *Respiratory therapists, respiratory physicians, general practitioners, nurses, trainees, and medical assistants.*

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

COURSE PROGRAMME **PAGE**

WORKSHOP PROGRAMME **PAGE**



Self-Assessment in Respiratory Medicine
Edited by Konrad E. Bloch with Paolo Palange and Anita K. Simonds
ISBN 978-1-84984-029-3

Self-Assessment in Respiratory Medicine is an invaluable tool for any practitioner of adult respiratory medicine. The 111 multiple-choice questions cover the full breadth of the specialty, using clinical vignettes that test not only readers' knowledge but their ability to apply it in daily practice. The questions were compiled and tested by the HERMES Examination Committee, making the book the perfect revision aid for candidates for the European Diploma, as well as any specialists in respiratory medicine and other fields who wish to improve their understanding.

COMING SOON Self-Assessment in Respiratory Medicine iOS app

ERSBOOKSHOP.COM

european respiratory society every breath counts

Introduction

Prof. Dr Med. Heinrich Matthys
Medical Director Emeritus
University Hospital of Freiburg
Hochrüttestrasse 17
79117 Freiburg
Germany
hmatthys@t-online.de

AIMS

- To know the history and definition of the most applied spirometric measurements.
- To know the classification of spirometrically defined ventilatory defects and the most important measurements to do so.
- To know sensitivity and specifity of the most important spirometric measurements.
- To name the prognostic power of some spirometric measurements in patients with pulmonary and cardiovascular diseases.

SUMMARY

The term spirometry is used for the measurements of lung volumes and flows at the mouth during various breathing manoeuvers. The measured volumes and flows are standardised under BTPS (Body, Temperature, Pressure and 100% water Saturated)-conditions and expressed in SI-units (Litre, Seconds). Menzies (1790) measured lung volumes with a body plethysmograph and Davy (1799) "residual" volumes with a hydrogen dilution method. With John Hutchinson´s invention of the spirometer in 1846 the measurements of vital capacity (VC) became one of the first objective tools in medicine to assess patients and normal subjects with different activities e.g.workers, sportsmen and gentlemen (1). More than 100 years later the forced expiratory volume (FEV1) at 1 second was introduced by Tiffeneau into clinical medicine. This allowed to recognise patients with obstructive and restrictive ventilatory defects. FEV1 and VC became objective easy measurements of the variations of bronchial obstruction including provocation tests and long term follow ups of patients with pulmonary and extrapulmonary impairments of breathing.

Modern registration and documentation (pneumotachographs and computers) allow an immediate quality control of the measured data, a better interpretation of the measured breathing manoeuvers using not only the volume time curves but also the corresponding flow volume curves. To improve the diagnostic value of spirometry with corresponding flow volume curves the breathing manoeuvers are best performed in a whole body plethysmograph (2). This allows the recording of the simultaneously occuring absolute lung volume (TLC, FRC, RV) and airway resistance changes during quiet breathing at rest, as well as output measurements of the respiratory pump (Po,1, PImax and PEmax), if needed.

REFERENCES

1. Petty TL. John Hutchinsons mysterious machine revisited. Chest 2002; 121: 219-223.
2. Matthys H. Historische Entwicklung der klinischen Ganzkörperplethysmographie. Atemw.-Lungenkrankh. 2005;31(4):204-211.

EVALUATION

1. Which spirometric measurement was historically first defined?
- **a.** PEF
- **b.** FEV1
- **c.** VC
- **d.** IC
- **e.** MMEF

2. Which spirometric manoeuvres are suitable to assess static and dynamic overinflation?
- **a.** PEF
- **b.** FEV1
- **c.** VC
- **d.** IC
- **e.** MVV

3. When do you measure FIV1?
- **a.** To assess expiratory obstruction or inspiratory muscle force.
- **b.** To measure inspiratory muscle force or upper airway obstruction.
- **c.** To classify restrictive ventilatory defects due to lung fibrosis.

Please find all answers at the back of your handout materials

PG 9 SPIROMETRY: 6 SEPTEMBER, 2014, INTRODUCTION: 09:30 – 09:40

Prof. Dr. med. Heinrich Matthys

Medical Director emeritus

University Hospital Freiburg

Hochrüttestrasse 17

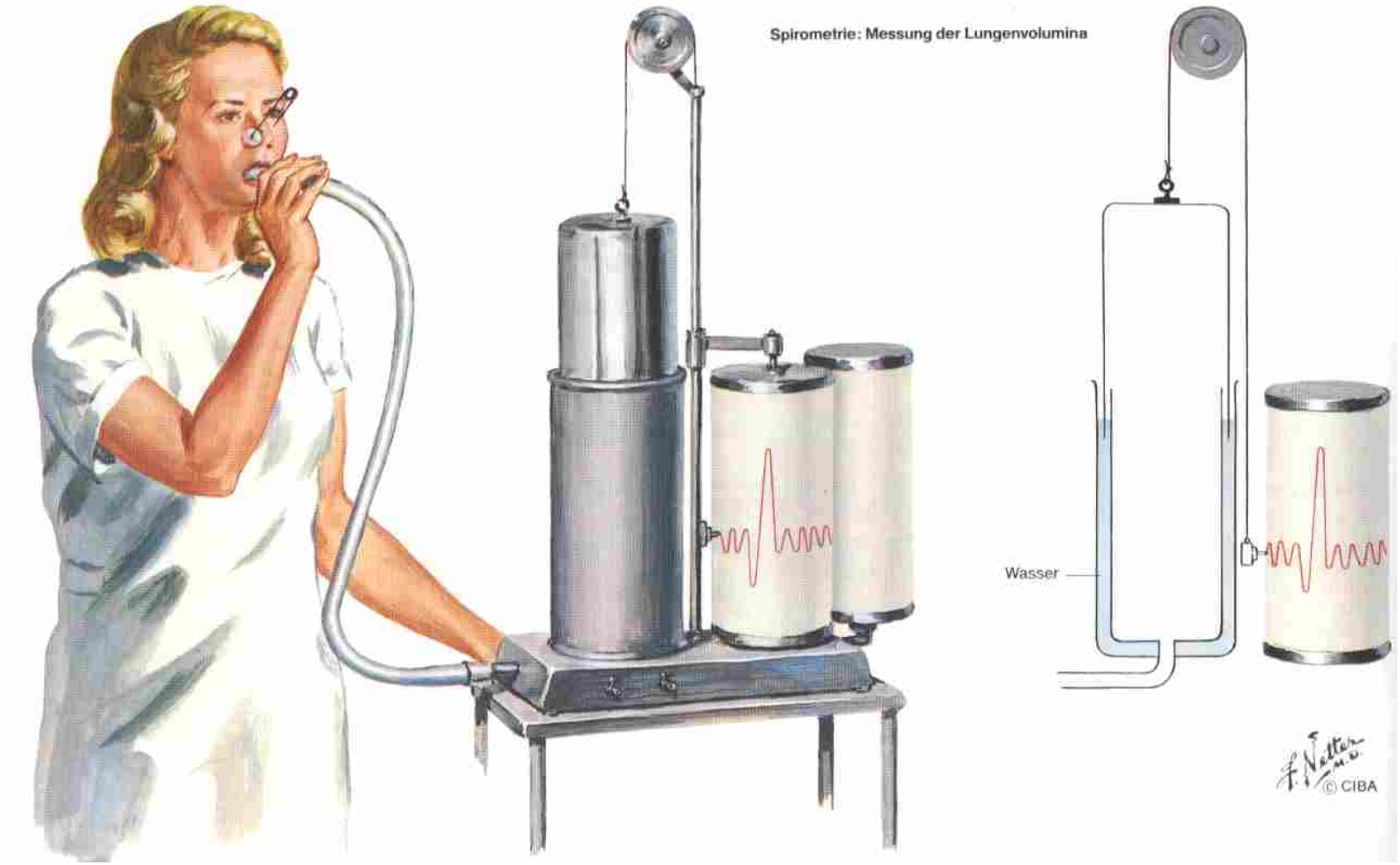
D-79117 Freiburg, Germany

E-mail: hmatthys@t-online.de

Introduction

- **Aim 1: To know the history and definition of the most applied spirometric measurements**
- **Aim 2: To know the classification of spirometrically defined ventilatory defects and the most important measurements to do so**
- **Aim 3: To know sensitivity and specifity of the most important spirometric measurements**
- **Aim 4:To name the prognostic power of some spirometric measurements in patients with pulmonary and cardiovascular diseases**

HISTORY OF SPIROMETRY



HISTORY OF SPIROMETRY

- **Vital Capacity = VC (Hutchinson 1846)**
- **measured during complete slow or forced inspiratory and expiratory manoeuvres**
- **Maximal Voluntary Ventilation = MVV (Hermannsen 1933)**
- **Peak Expiratory Flow = PEF (Hadorn 1942)**
- **Forced Expiratory Volume at 1 sec = FEV1 (Tiffeneau 1947)**

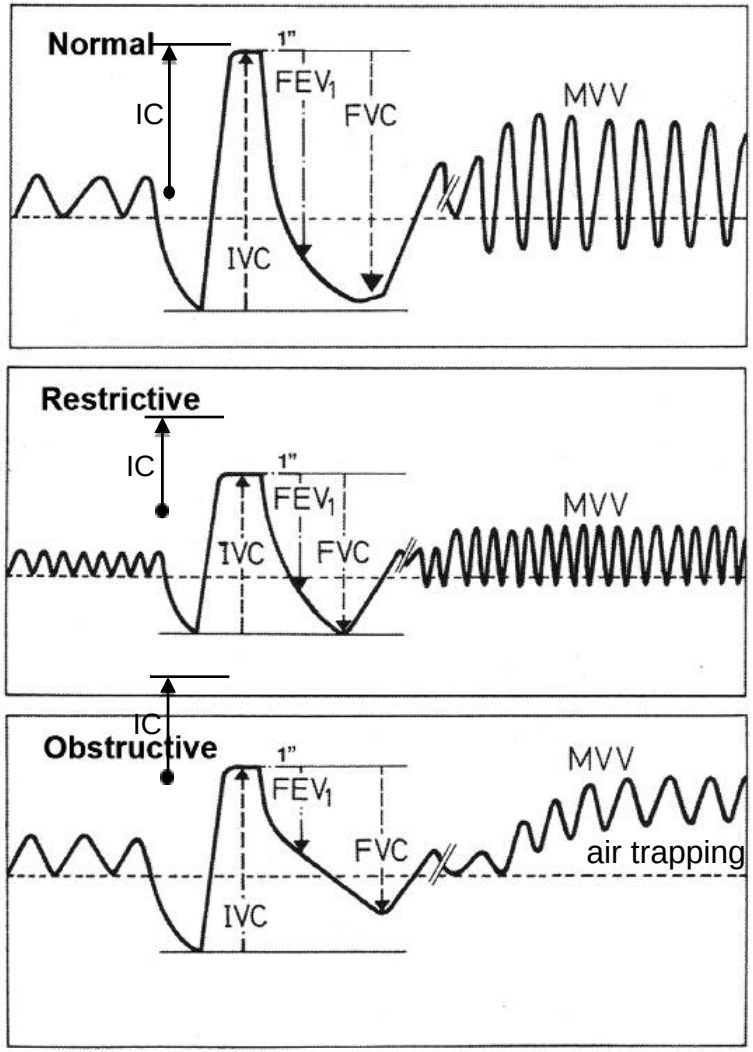
- **FEV1 and VC registrations together with the corresponding flow-volume curve allow a better interpretation of obstructive and restrictive ventilatory defects (FEV1/VC = Tiffeneau Index)**
- **The measurement of IC gives some information on hyperinflation**

JOHN HUTCHINSON´S LEGACY 1846

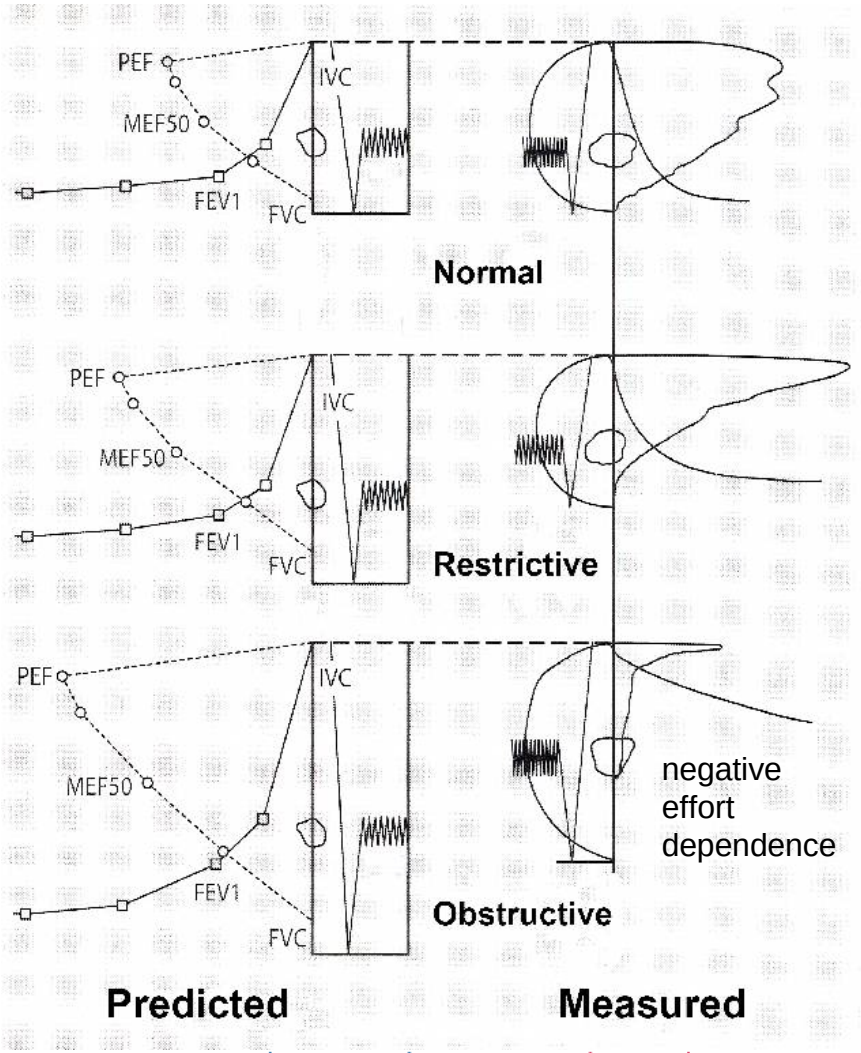
- **The volume between maximal in- and expiration measured with the spirometer is a powerful indicator of longevity called vital capacity, (measured in dead bodies IC!)**
- **He found reduced values and early deaths, in patients with Tb, heart failure and in coal miners**
- **As a consultant of the insurance industry he was convinced that vital capacity should be measured in persons applying for life insurance (nomen est omen)**
- **VC = f (height, age, weight and sex) in „normal“ subjects**

SPIROMETRIC CLASSIFICATION OF VENTILATORY DEFECTS

VOLUME – TIME CURVES



FLOW – VOLUME CURVES

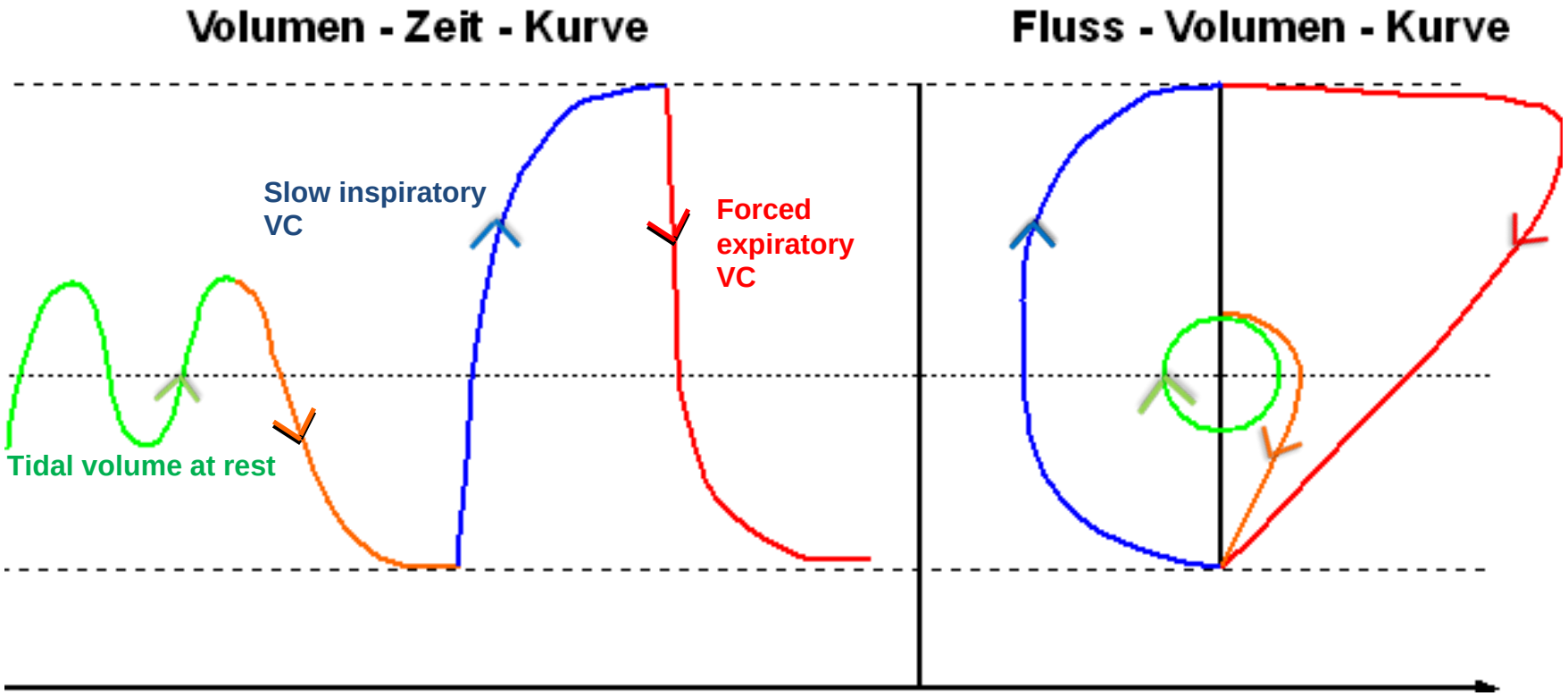


Unité de doctrine

- **The optimal spirometry measurement is similar to that needed for:**
- **The CO-single breath transfer factor manœuvre**
- **The inhalation manœuvres necessary for standardised aerosol deposition to assess bronchodilation or provocation tests**
- **Most radioactive gas and particle studies**

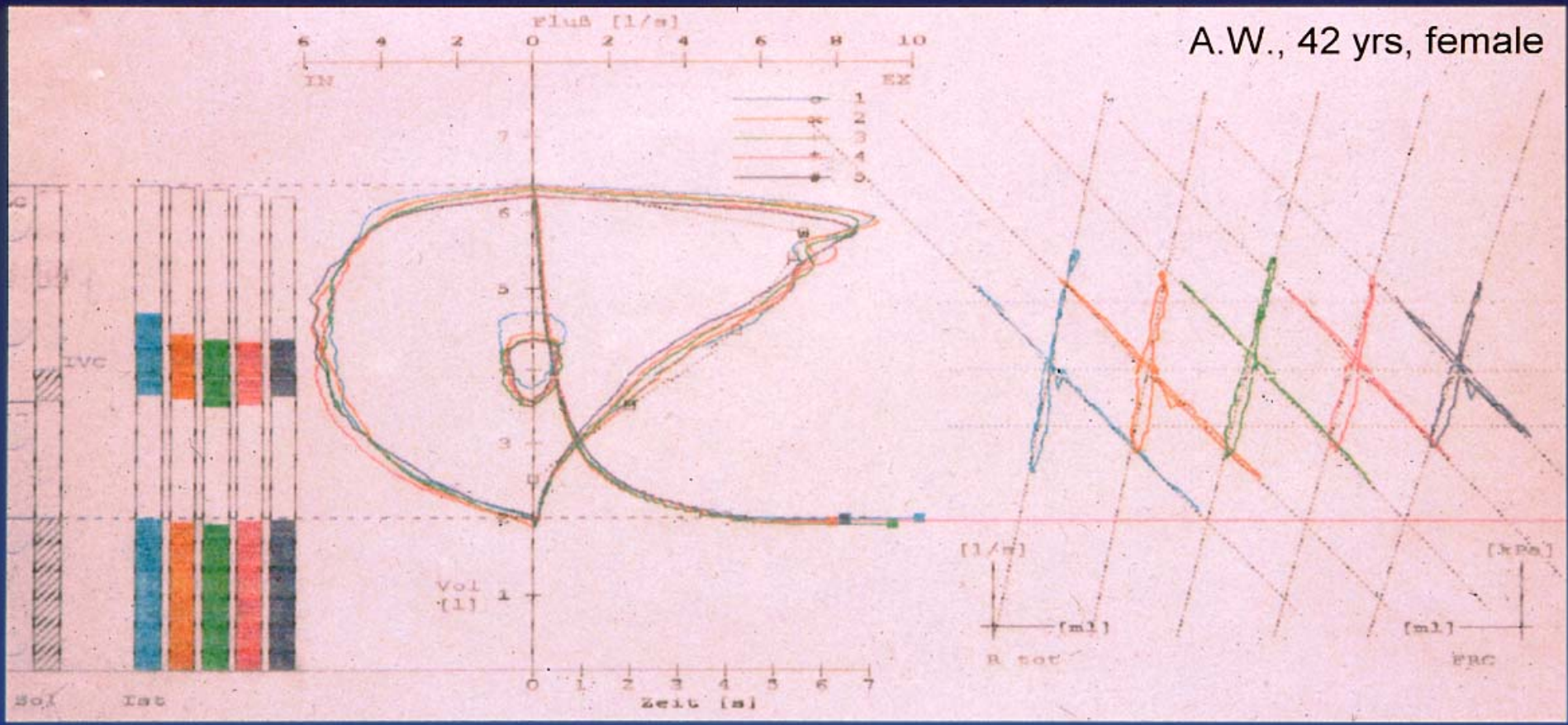
- **For all of these measurements the patient is asked to perform after a complete expiration a slow inspiratory vital capacity manoeuvre followed after a certain breath hold by a more or less complete forced expiration. To teach the patients different breathing manœuvres is time consuming!**

PERFORMANCE OF SPIROMETRY: MEASUREMENT OF VOLUMES AND CORRESPONDING FLOWS OF AIR (AT THE MOUTH) BREATHED IN AND OUT

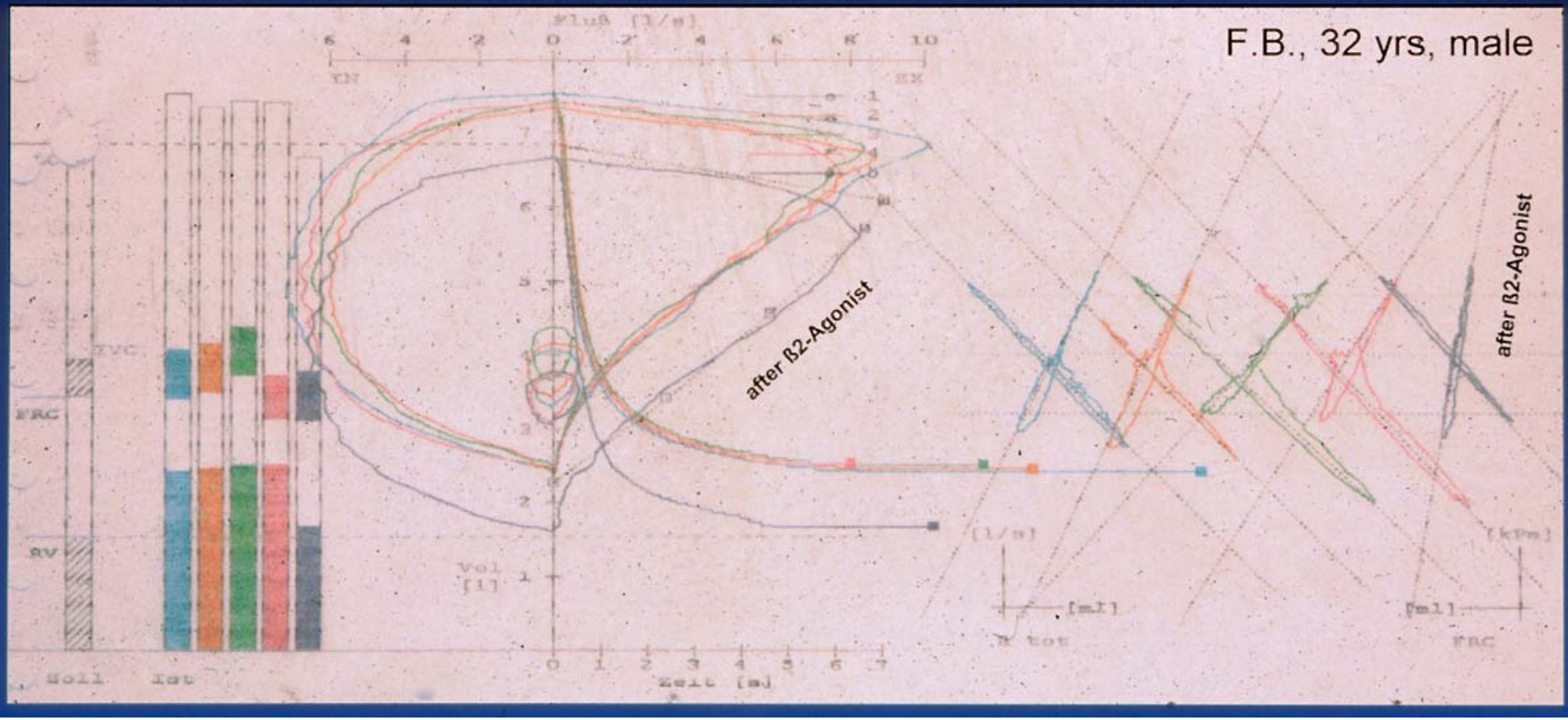


Volume - Time with corresponding Flow - Volume curve

Carbachol provocation without airway reaction



Carbachol provocation with predominantly central bronchial reaction



CLINICALLY USED INFORMATIONS FROM THE VOLUME - TIME CURVES

- **Slow inspiratory vital capacity (IVC)**
- **Forced expiratory (FVC), inspiratory (FIVC) vital capacity, generally IVC > FVC suggests air trapping**
- **Forced expiratory (FEV1), inspiratory (FIV1) volume at 1 sec (FIV1 to diagnose reduced muscle force or inspiratory obstruction)**

  MMEF (maximal midexpiratory flow, effort independant?)
- **Maximal voluntary ventilation (MVV = MBC)**
- **Tiffeneau Index: FEV1 / VCmax, (FIV1 / VCmax), generally VCmax = IVC > FVC. Normal (70-75%), obstructive < 70%, restrictive > 75% (VCmax reduced) ventilatory defect**

CLINICALLY USED INFORMATIONS FROM THE FLOW - VOLUME CURVES

- **Peak expiratory (inspiratory) flow (PEF, PIF) cooperation!**
- **Maximal expiratory flow at 25% FVC = MEF 75%**
- **Maximal flow at 50% FVC (FIVC) = MEF 50%**
- **Maximal flow at 75% FVC = MEF 25%**
- **Inspiratory and/or expiratory constant flow patterns suggest relevant central or upper airway obstruction**
- **Concave and convex flow-volume curves give information about the dynamic recoil forces of the respiratory system**
- **Higher flows during tidal breathing compared to forced expiration demonstrate effort dependant flow limitation**

OBSTRUCTIVE VENTILATORY DEFECTS ASSESSED WITH VOLUME-TIME (I) PLUS FLOW-VOLUME (II) PLUS STATIC LUNG VOLUMES AND AIRWAY RESISTANCE (III): ALL DATA MEASURED THE PATIENT SITTING IN THE BODY-BOX

Measured Data	Sensitivity (%)	Specificity (%)
I. FEV_1+ IVC + FEV_1 / IVC	81	65
II. I + PEF + MEF 75, 50, 25 %	87	86
III. II + FRC + RV + TLC + R_{aw}	90	96

H. Matthys, Pneumologie, Springer 1988

Sensitivity and specificity of body-box data increases with an increasing number of different measurements

2. SPIROMETRY AS A PROGNOSTIC FACTOR

- Classification of Severity, Mortality and Monitoring of exacerbation of patients with Asthma, COPD or CF: FEV1/VC%, FEV1% pred or PEF, personal best or baseline or variability in % www:ginaasthma.com www:goldcopd.com
- Outcome of lung resection surgery: The national emphysema treatment trial. Chest 1999;116:1750-1761
- Monitoring of interstitial and other parenchymal lung diseases including pulmonary sarcoidosis: Plastiras et al. Scleroderma lung: inital forced vital capacity as predictor of pulmonary function decline. Arthritis Rheum 2006;55:598-602
- Exercise tolerance: IC for static and dynamic hyperinflation, short and longtime reversibility. Yan S et al. Reliability for estimating end-expiratory lung volume during exercise in patients with COPD Am J Respir Crit Care Med 1997;156:55-59

1. SPIROMETRY AS A PROGNOSTIC FACTOR

-Friedmann CD et al 1976: Lung function and risk of myocardial infarction and sudden cardiac death.
New Engl J Med 294:1071-1075

-Framingham Studie 1980: Powerful indicator of premature pulmonary and cardiac death in man>30years

-Marcus EB et al 1982 Pulmonary function as a predictor of coronary artery disease. Am J Epidemiol 129:97-104

-Skillrud DM et al 1987: Higher risk of lung cancer in COPD a prospective matched controlled study.
Ann Intern Med 105; 503-527

Conclusion

- **Spirometry measured at the mouth allows to define retrictive and obstructive ventilatory defects in patients with various pulmonary and extrapulmonary diseases which interfere with the respiratory system**

- **The most important single measurements are the FEV1 and VC preferably determined during a slow inspiration followed by a forced expiration**

- **The volume time curves during various breathing manœuvres can be interpreated better, if the registration of the corresponding flow-volume curves are availabel**

- **The main disadvantage of simple spirometry is the absence of an absolute volume scale, which needs a body box**

Multiple choice questions

- **Which spirometric measurement was historically first defined?**
- **PEF, FEV1, VC, IC, MMEF**

- **Which spirometric manoeuvres are suitable to assess static and dynamic overinflation?**
- **PEF, FEV1, VC, IC, MVV**

- **When do you measure FIV1?**
- **To asses expiratory obstruction, to measure inspiratory muscle force or upper airway obstruction, to classify restrictive ventilatory defects due to lung fibrosis**

Anatomy, physiology and pathophysiology knowledge required for spirometry: short summary

Prof. Dr Jörg Daniel Leuppi
Professor of Internal Medicine
University of Basel
Head of Internal Medicine
Cantonal Hospital Baselland
Rheinstr. 26
4410 Liestal
Switzerland
Joerg.leuppi@ksbl.ch

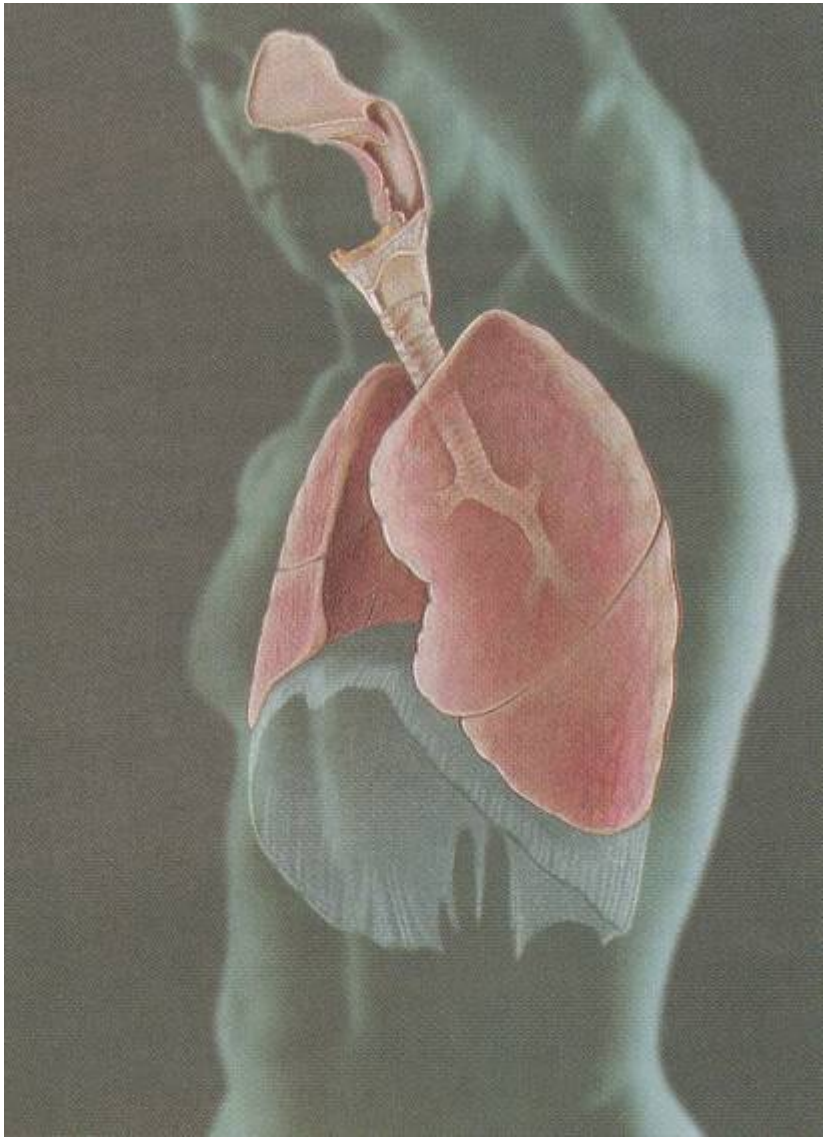
SUMMARY

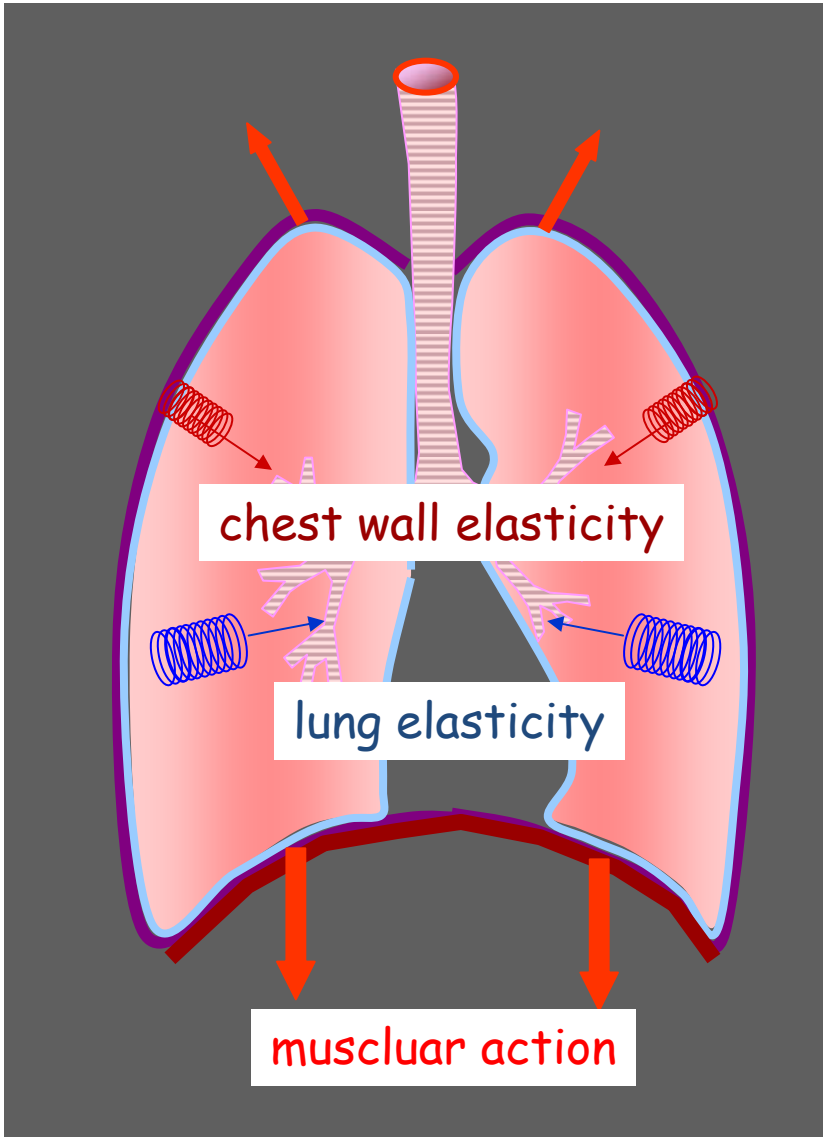
This module addresses the mechanics of tidal and maximal forced breathing, the limits of deep in and expiration, the different types of airway obstruction and the structure of airways and lung parenchyma. Spirographic examples will be used to introduce the differences between obstructive lung diseases (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).

Aims

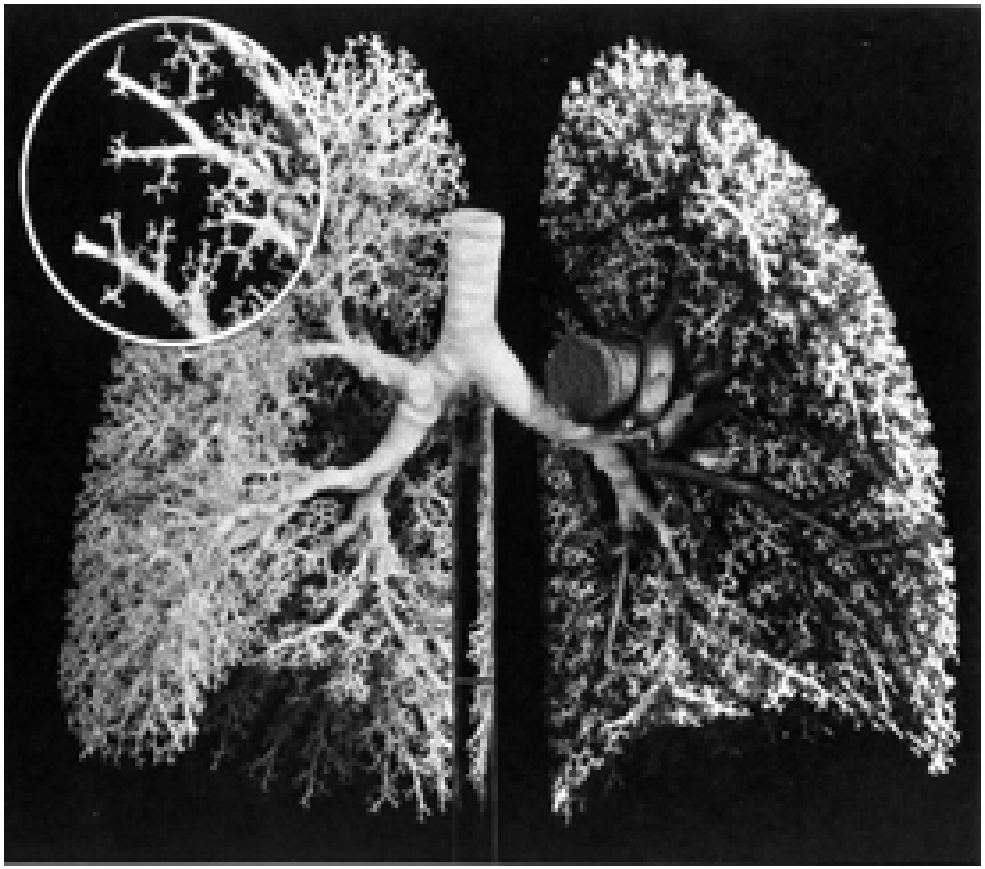
- mechanics of tidal and maximal forced breathing
- limits of deep in- and expiration
- several types of airway obstruction
- structure of airways and lung parenchyma

Lungs and chest case

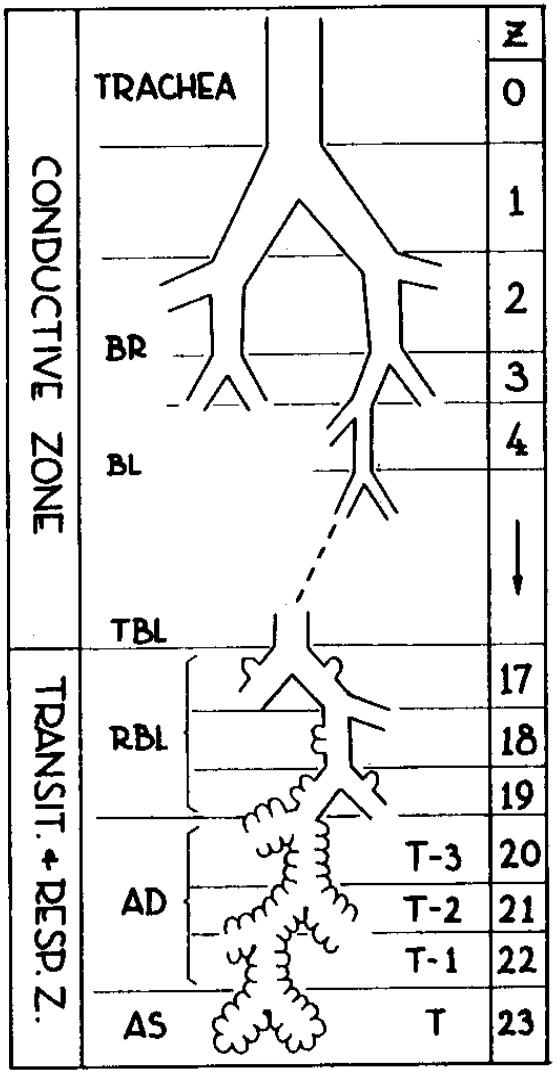




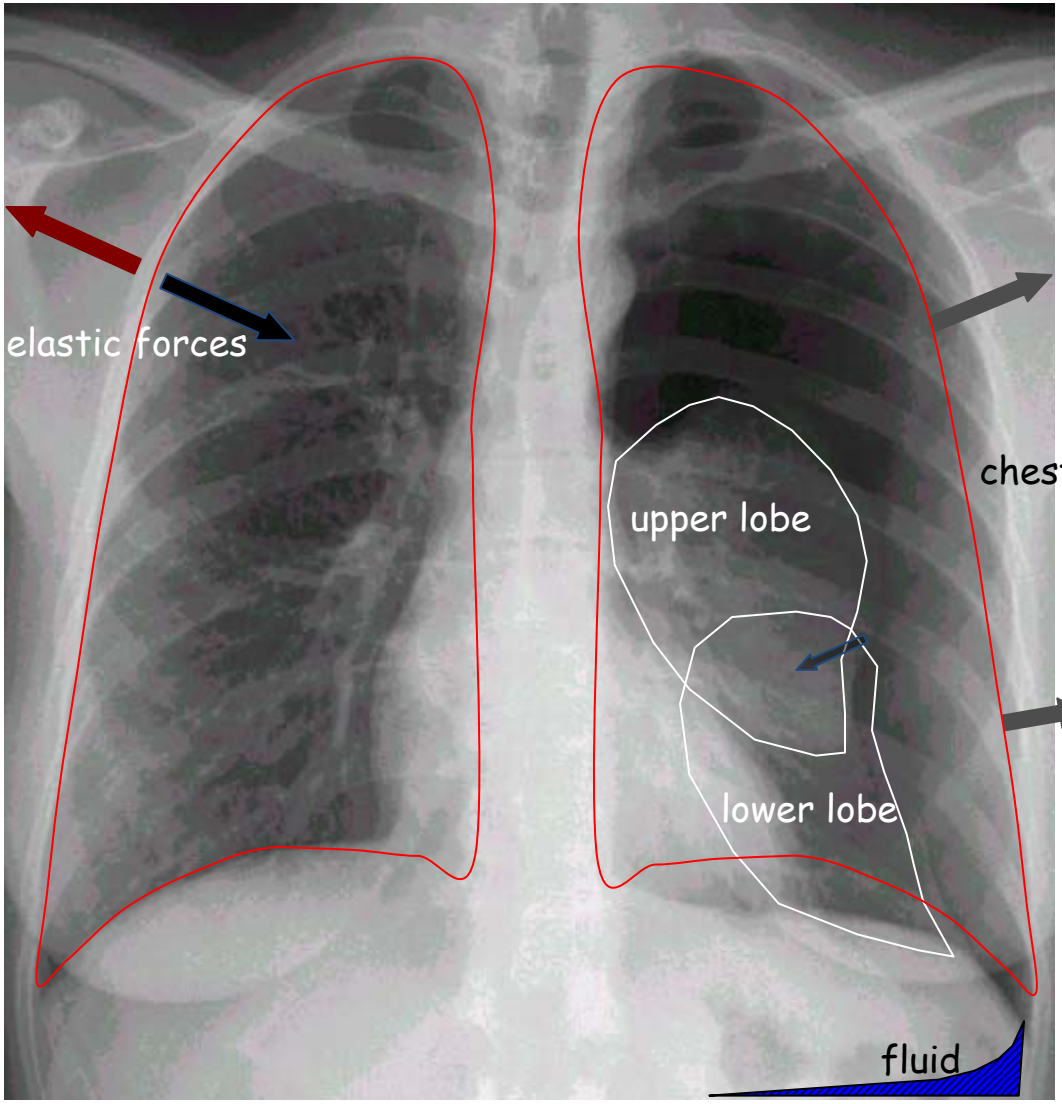
Lungs



Weibel 1984



Collapse of the left lung



chest wall is springing aside

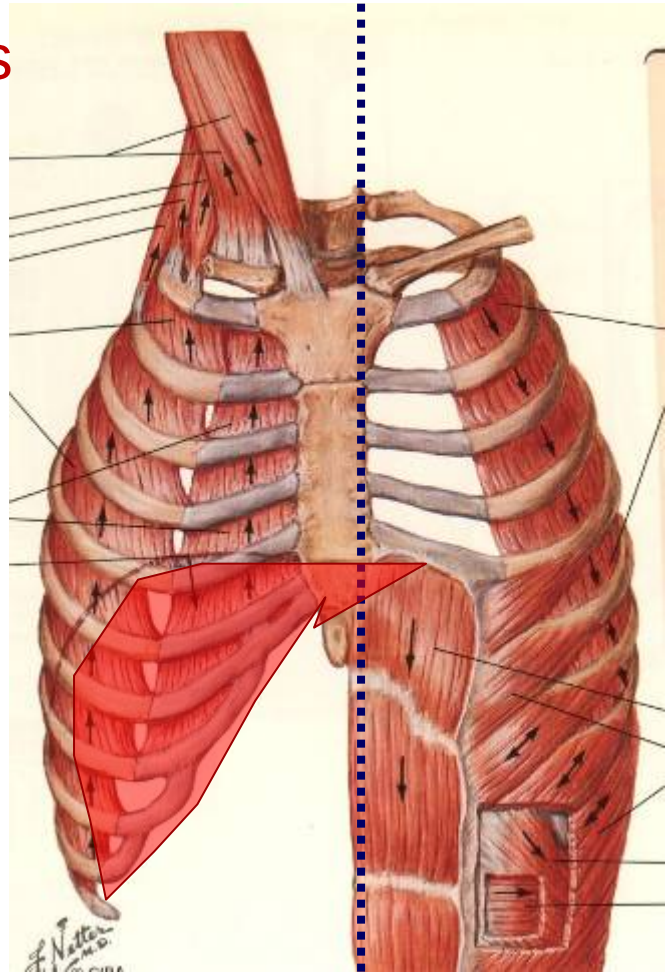
Muscles of respiration

inspiratory muscles

neck musculature

external intercostal

diaphragm

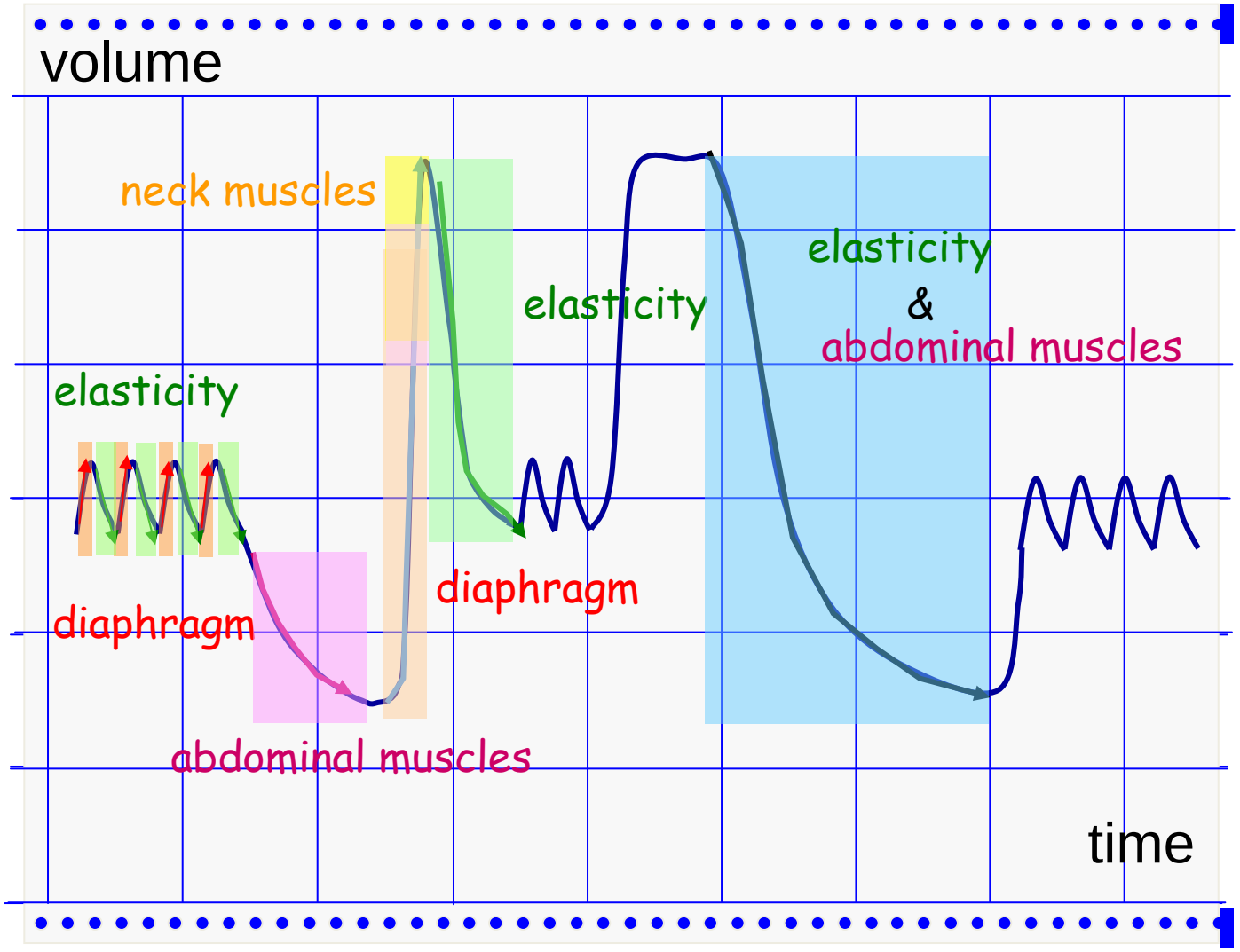


expiratory muscles

internal intercostal

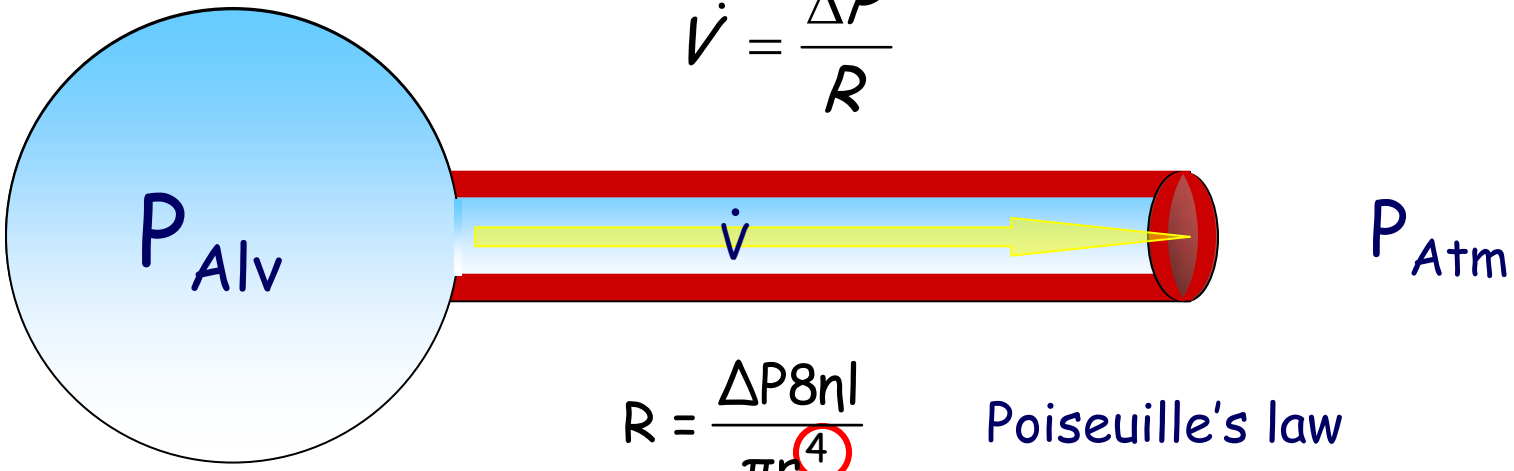
abdominal musculature

Mechanics during spirometry



Airflow

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



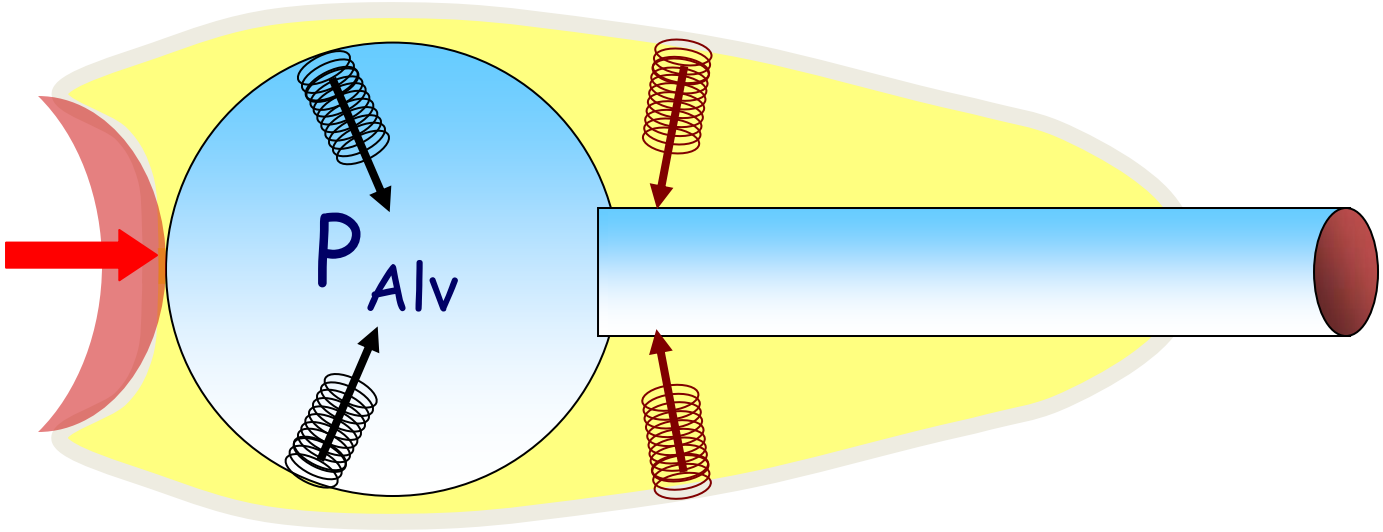
$$R = \frac{\Delta P 8 \eta l}{\pi r^4}$$

Poiseuille's law

airflow is dependent on:

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

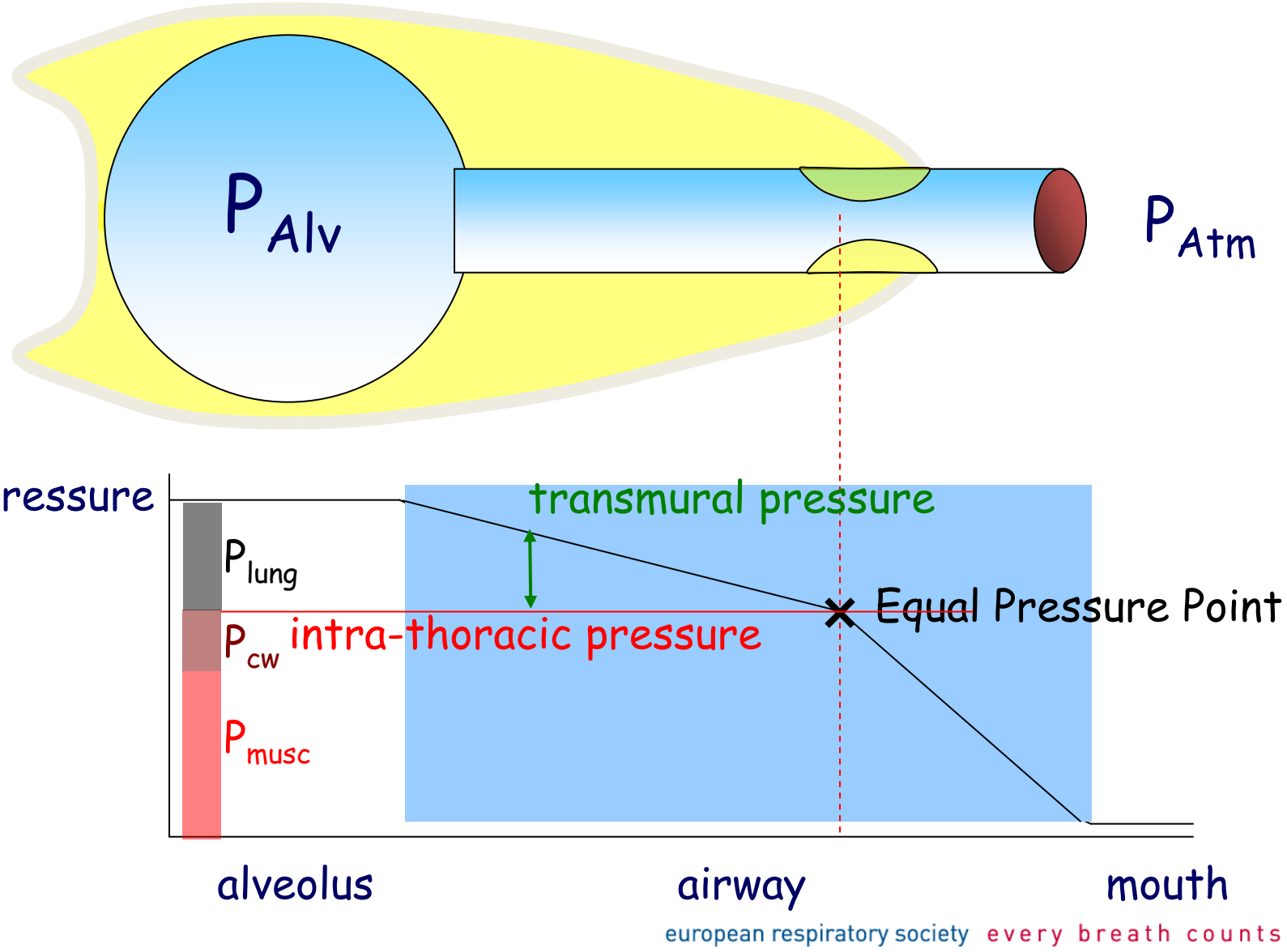
Alveolar and intrathoracic pressure



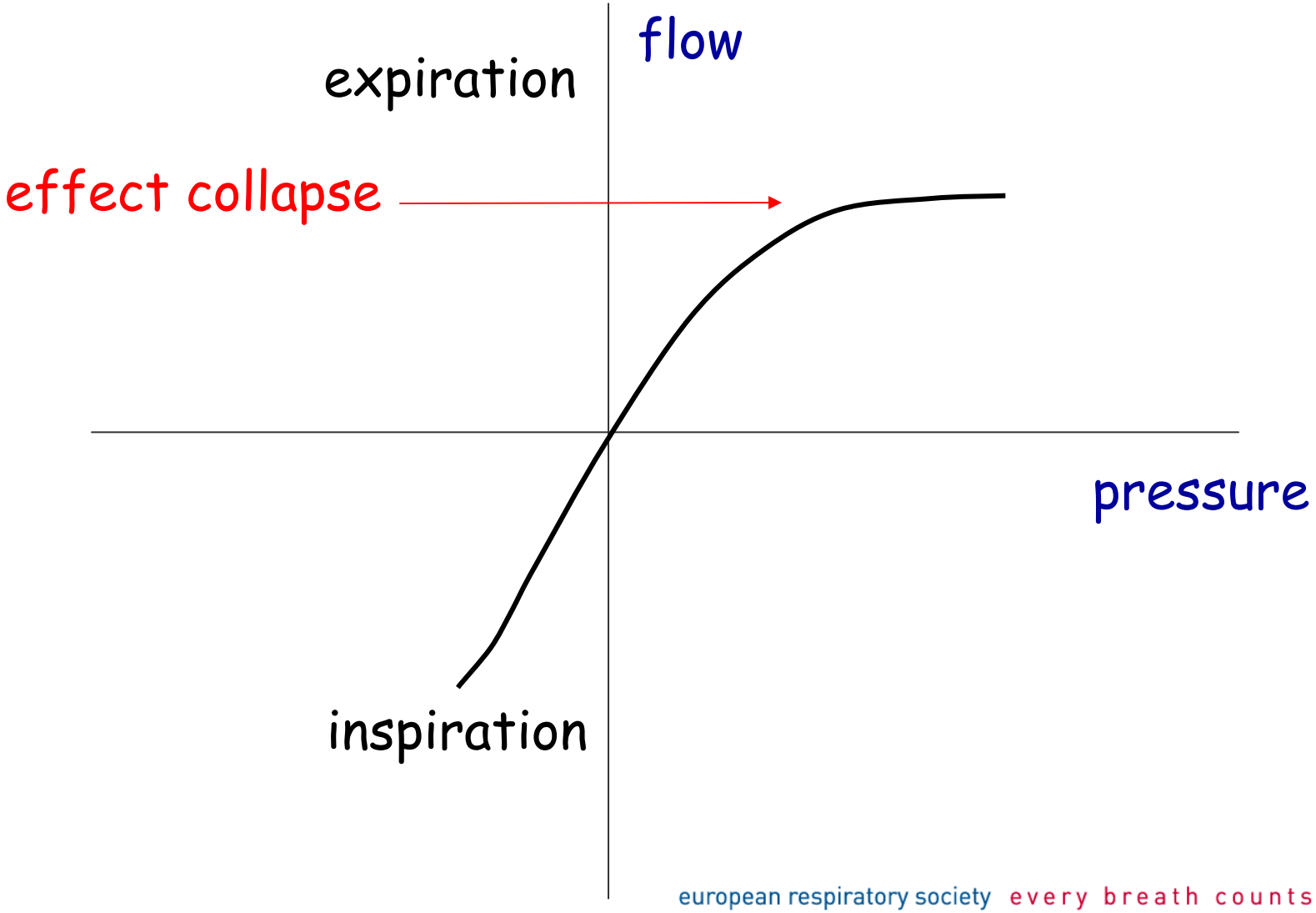
$$P_{alv} = P_{cw} + P_{musc} + P_{lung}$$

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

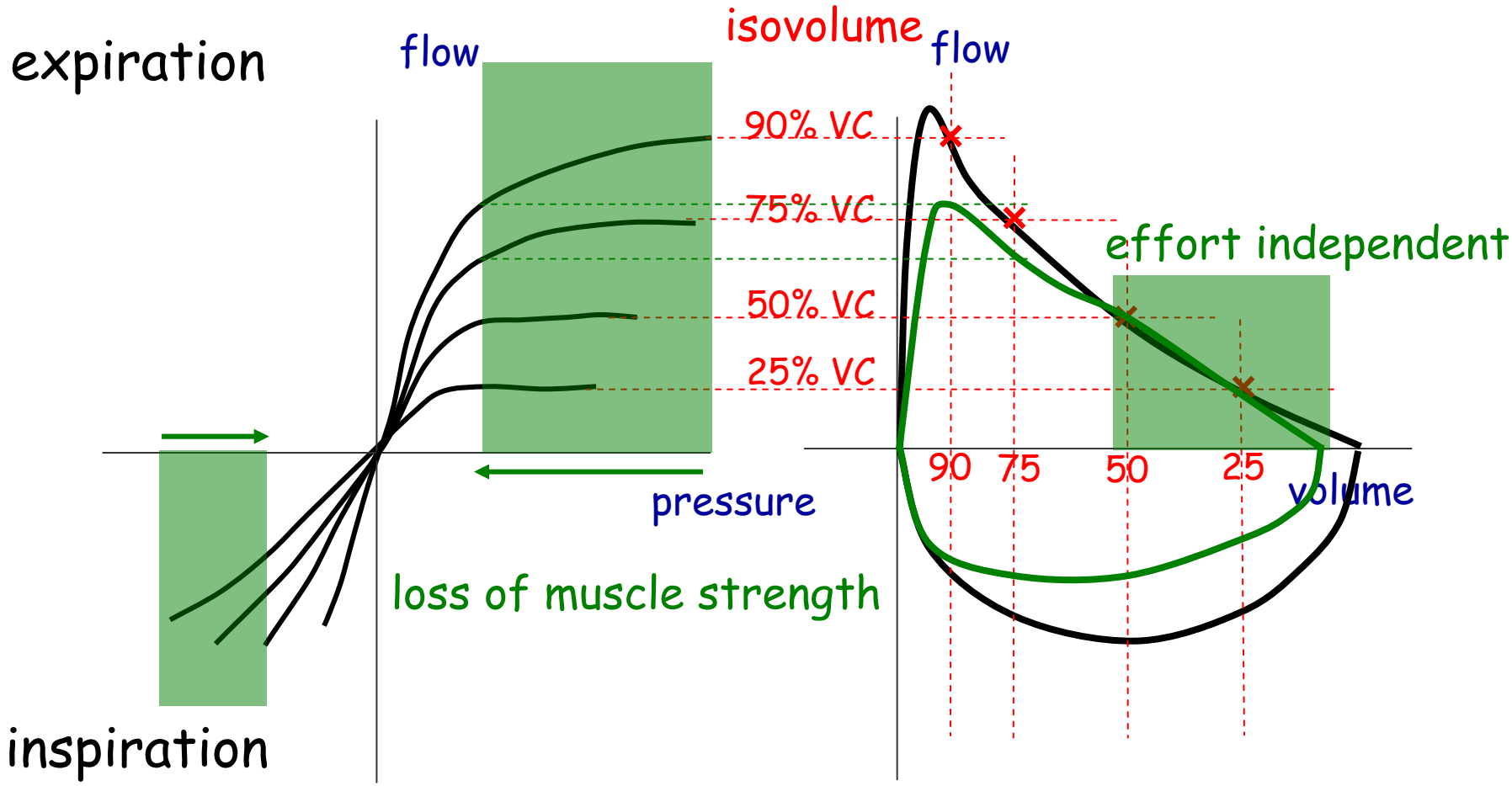
Expiratory airway collapse



ISO volume flow-pressure (50% VC)



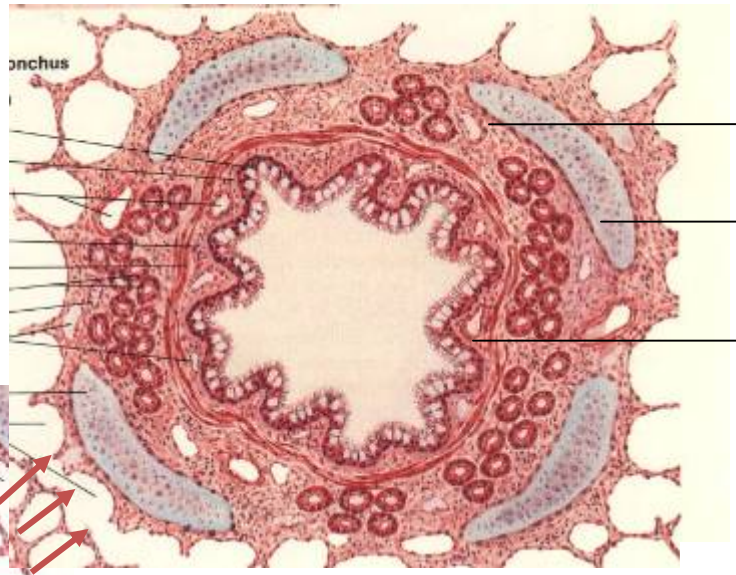
Reconstruction F -V curve



flow-pressure curve

flow-volume curve

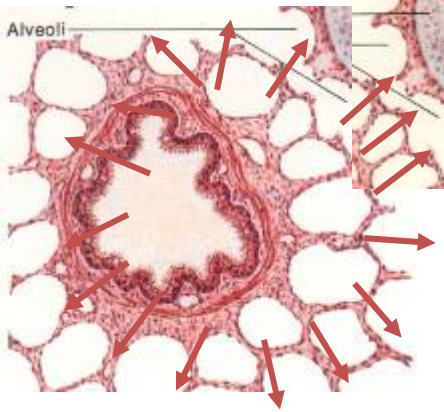
Airways and lung parenchyma



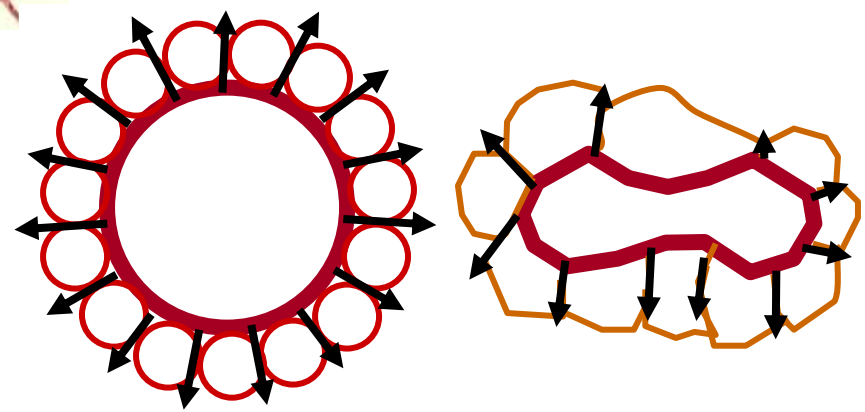
connective tissue

cartilage

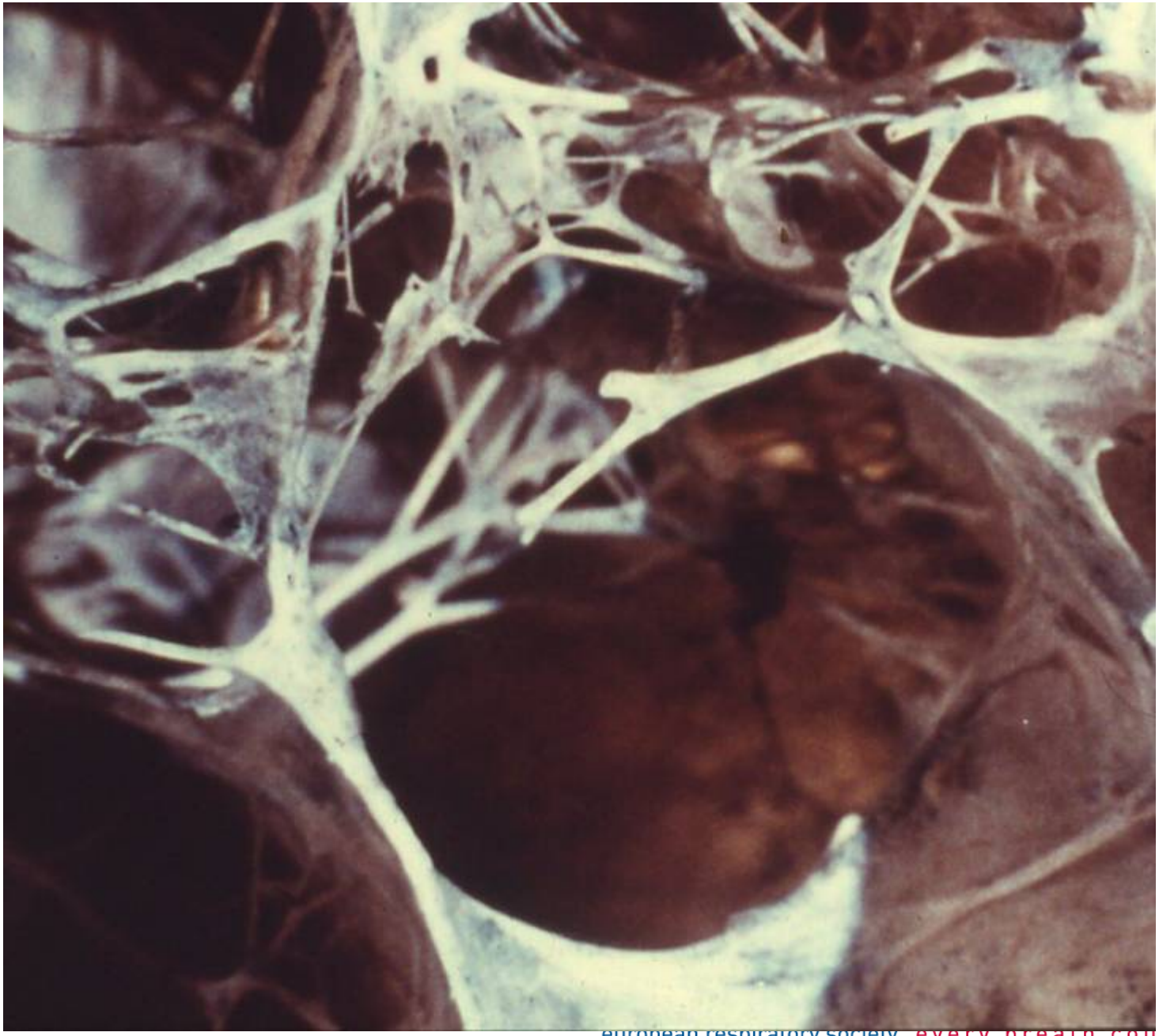
smooth muscle



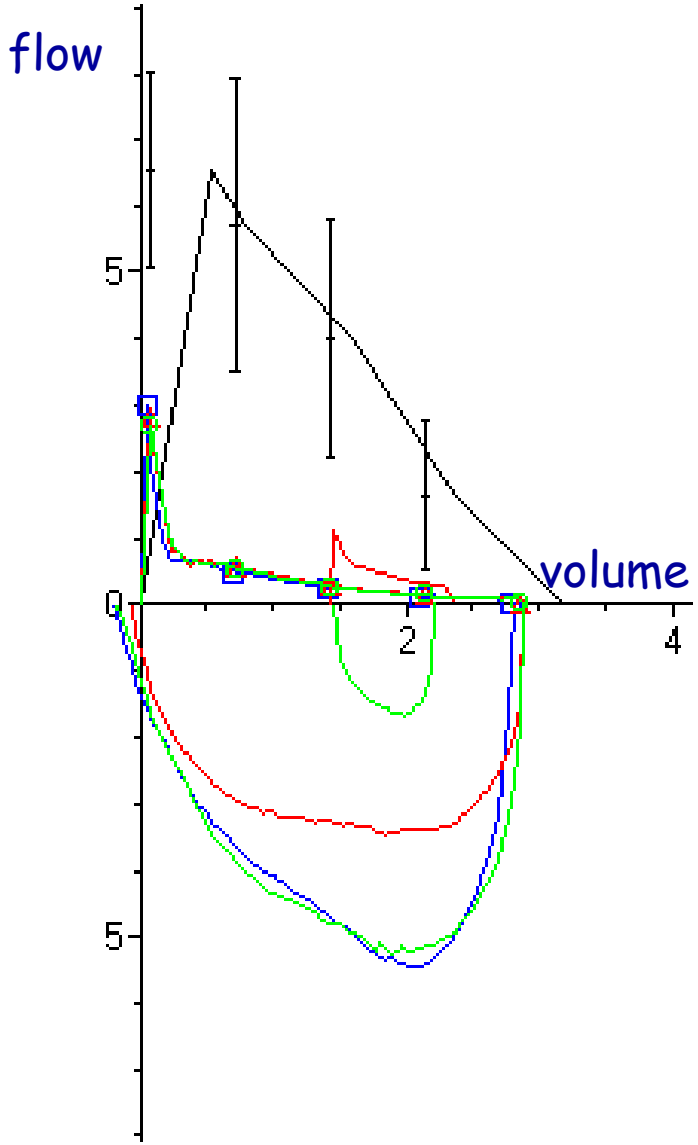
alveolar walls



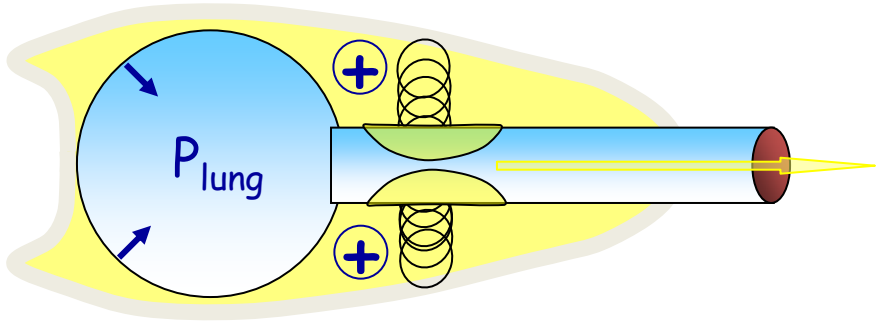
loss alveolar septa

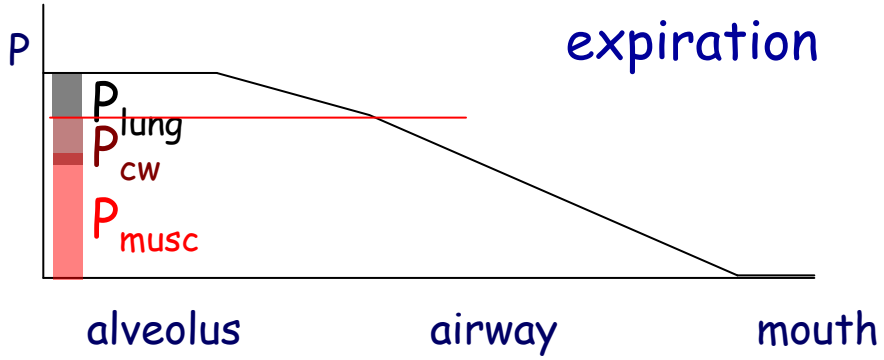


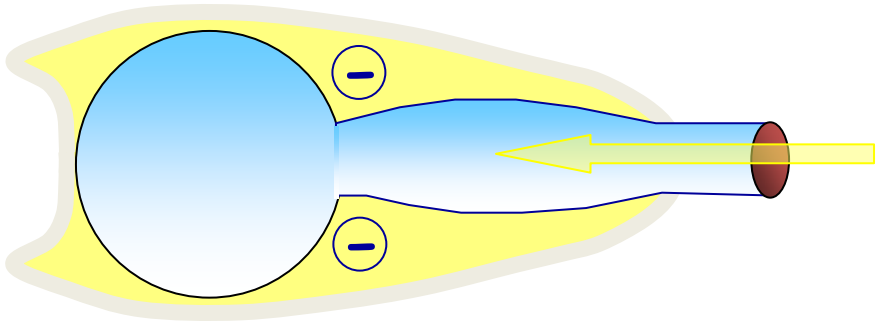
Airway mechanics in lung emphysema



F-V curve in lung emphysema

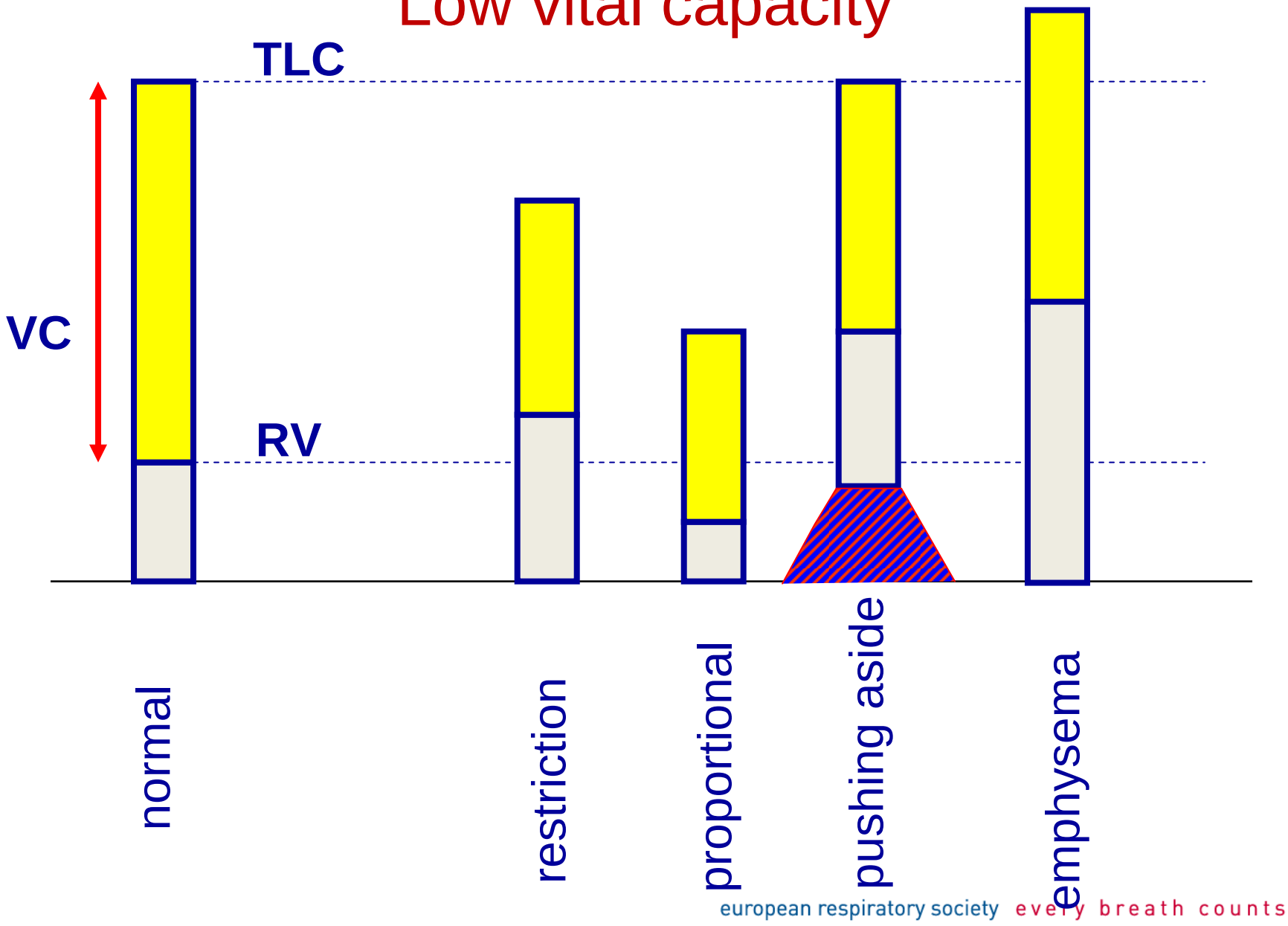




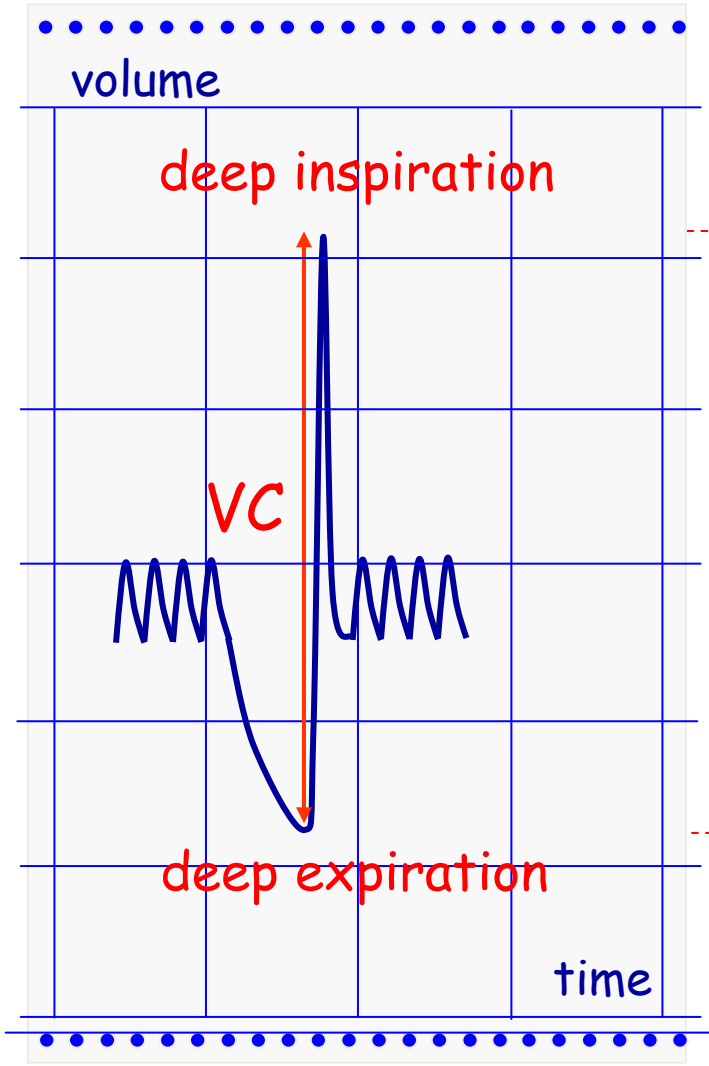


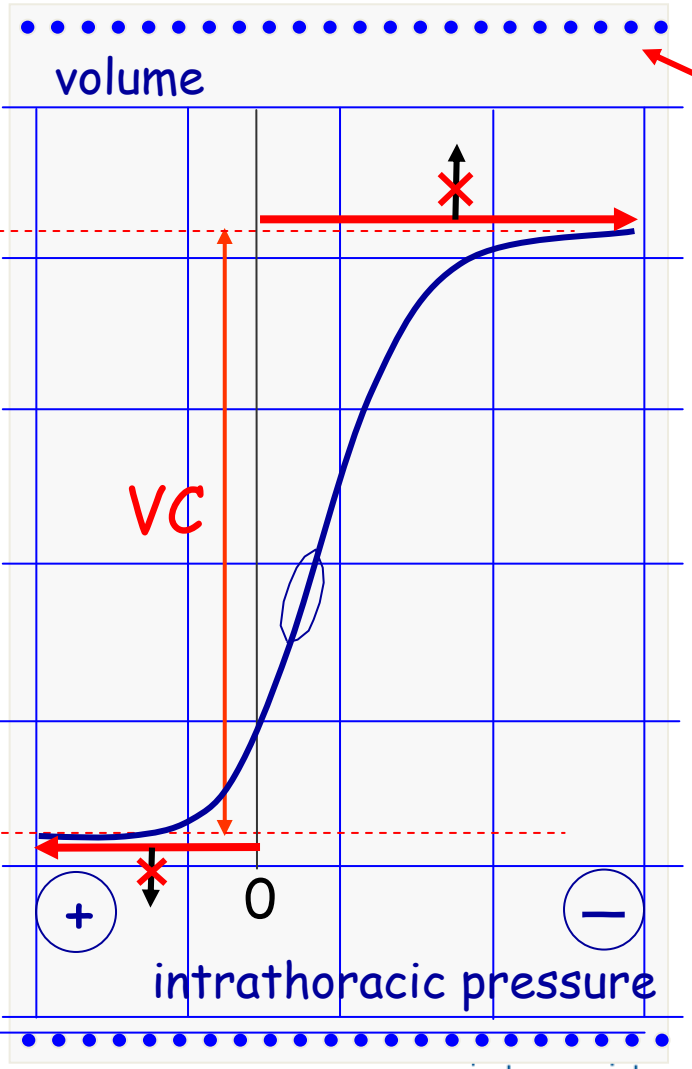
inspiration

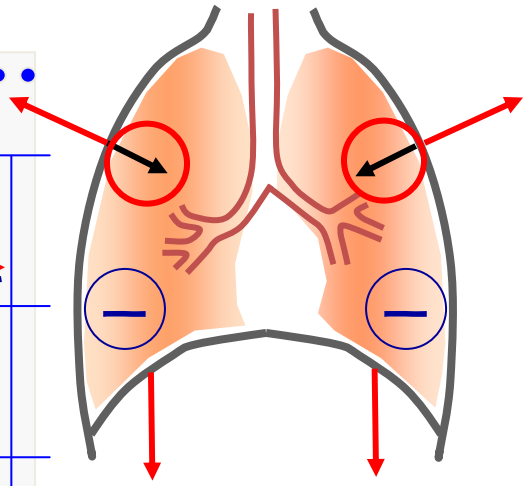
Low vital capacity

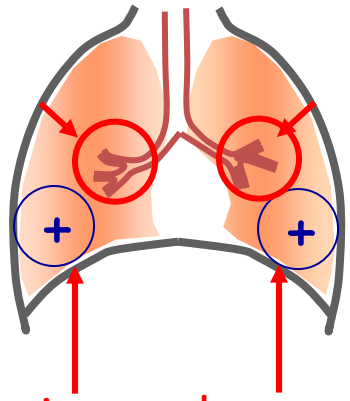


Limits of the vital capacity









Respiratory pathology

Main categories of obstructive disease:

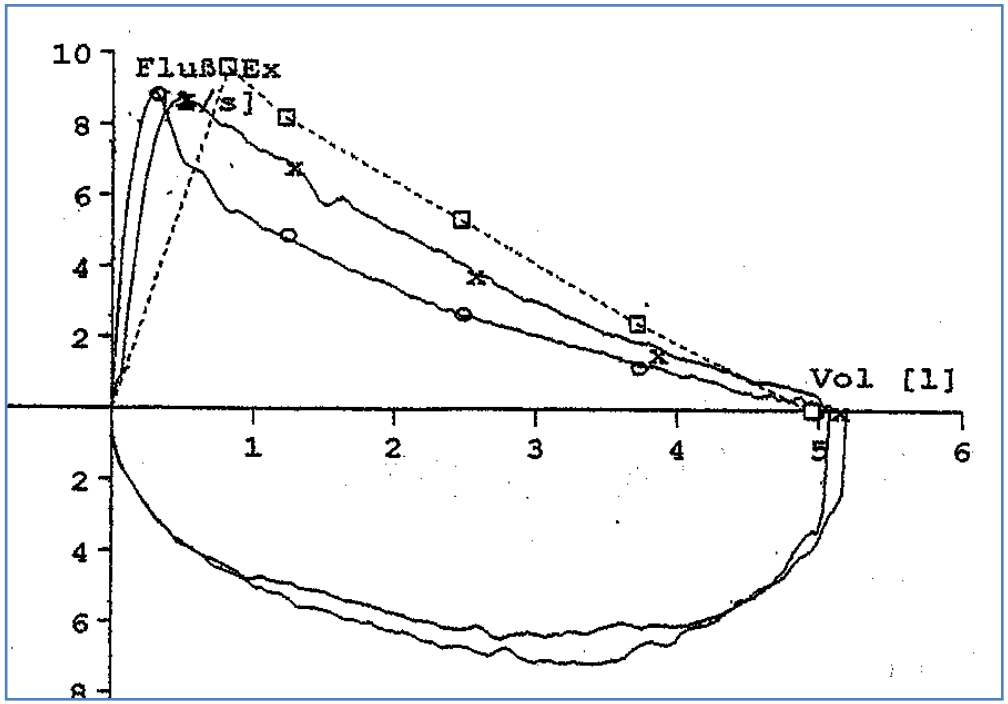
- Asthma
- COPD
  - Chronic bronchitis
  - Emphysema

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

Asthma



	Pre	**Post**
FEV_1	3.62 l/sec. (87%)	4.09 l/sec. (98%)
FVC	4.97 l (100%)	5.16 l (104%)
FEV_1/FVC	0.69	0.78

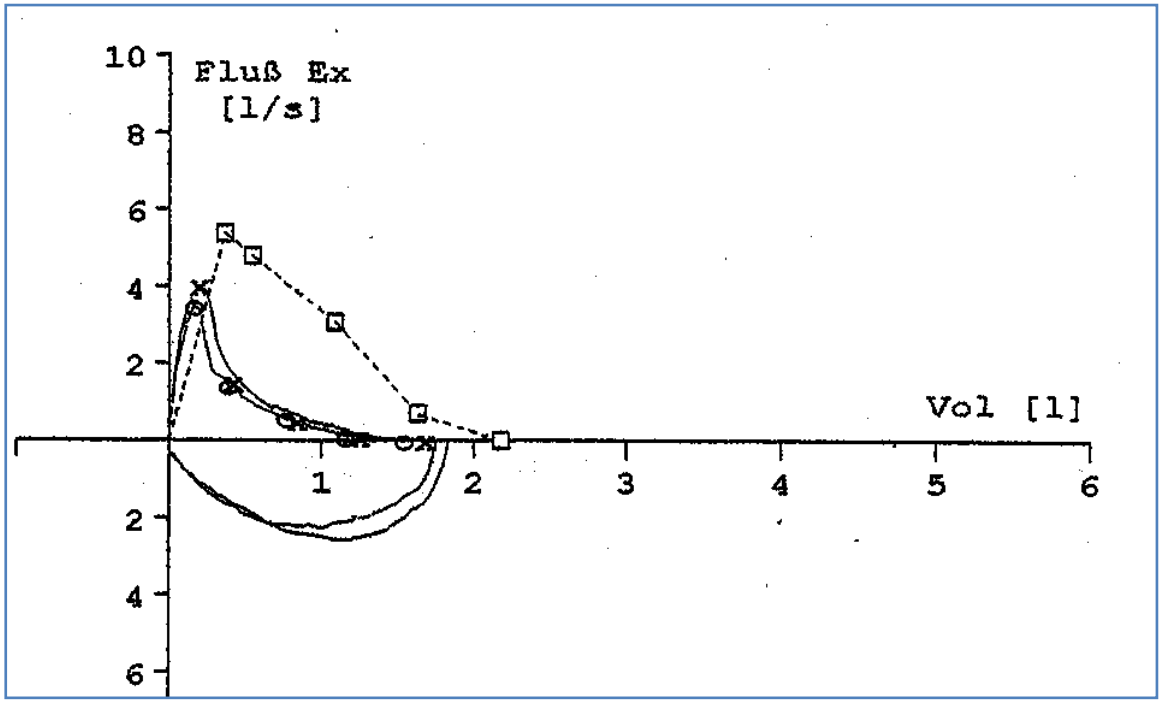
COPD

- 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

COPD



	Vor	**Nach**
FEV_1	1.05 l/sec. (59%)	1.10 l/sec. (62%)
FVC	1.55 l (71%)	1.69 l (77%)
FEV_1/FVC	0.58	0.58

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

Restriction

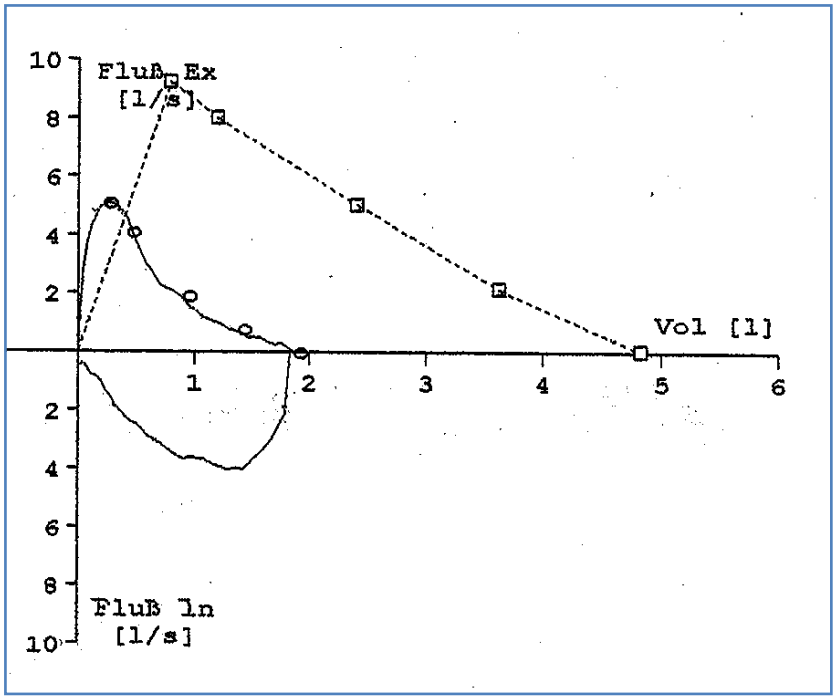
- Maximum achievable lung volume has diminished. This implies a reduction in TLC

  Due to e.g.:

  - surgical removal of part of the lung
  - lung fibrosis

- Normal FEV1/(F)VC ratio

Restriction



FEV_1	1.70 l/sec. (40%)
FVC	1.94 l (43%)
FEV_1/FVC	0.87

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

Definitions of spirometric values: a short summary

Prof. Dr Jörg Daniel Leuppi
Professor of Internal Medicine
University of Basel
Head of Internal Medicine
Cantonal Hospital Baselland
Rheinstr. 26
4410 Liestal
Switzerland
Joerg.leuppi@ksbl.ch

SUMMARY

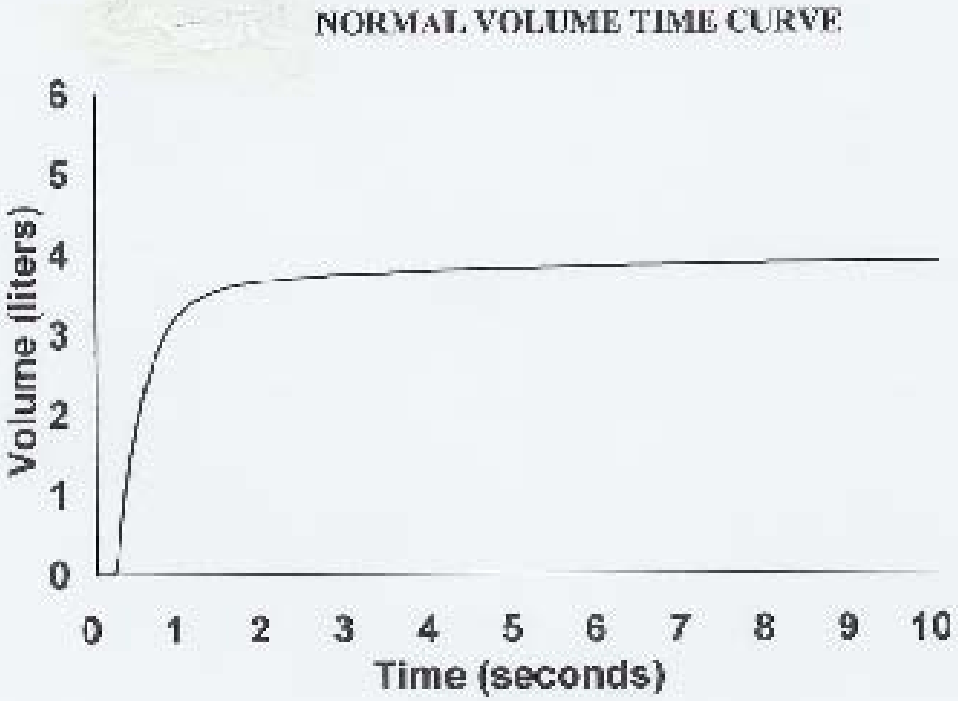
This module examines the definitions and calculations of spirometric indices. Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The primary signal measured in spirometry may be volume or flow. The test effort can be presented as 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.

Background

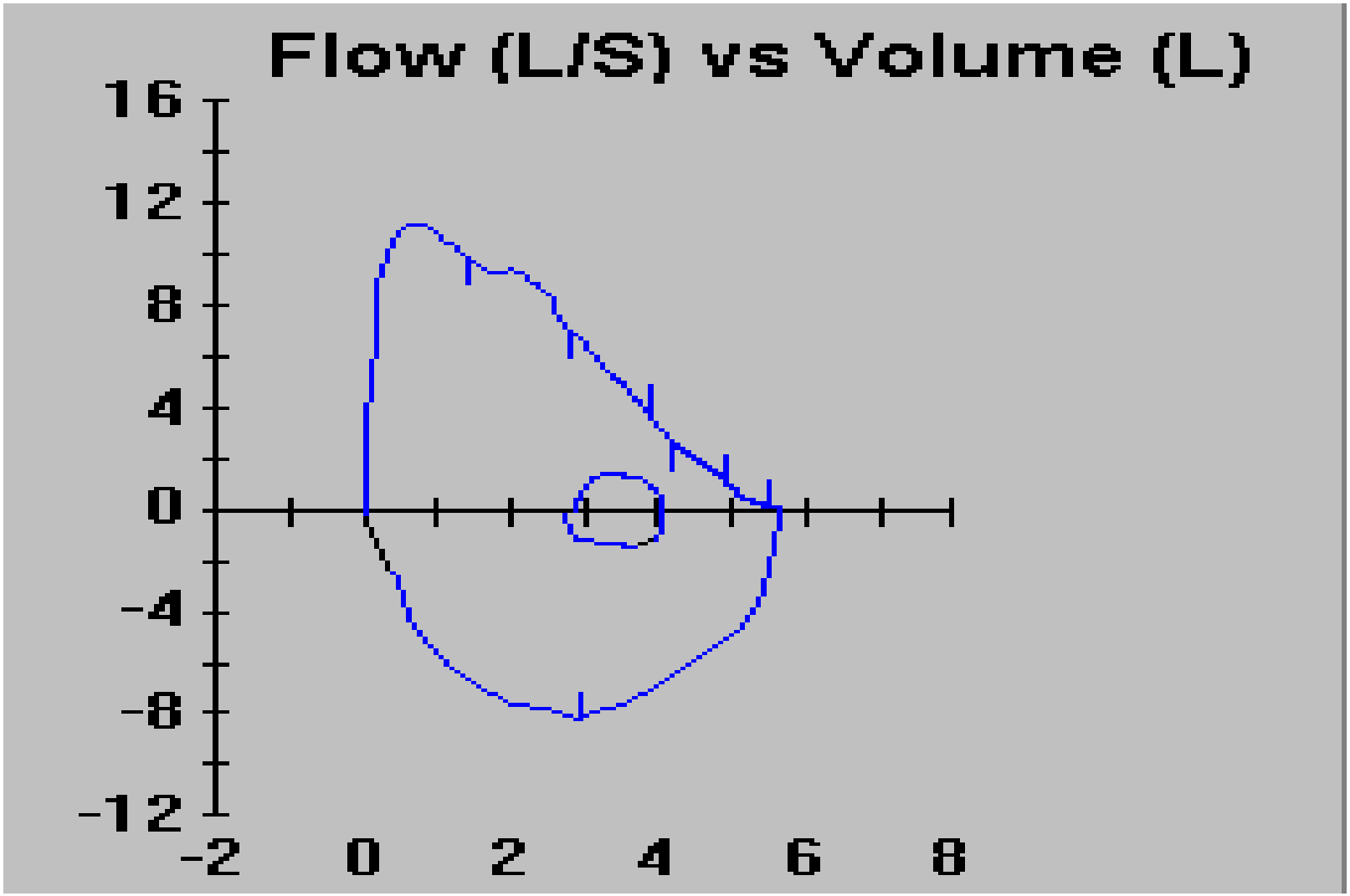
- Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The primary signal measured in spirometry may be volume or flow.

- The test effort can be presented as a ‘FLOW-VOLUME LOOP’ or as a ‘VOLUME-TIME CURVE’.

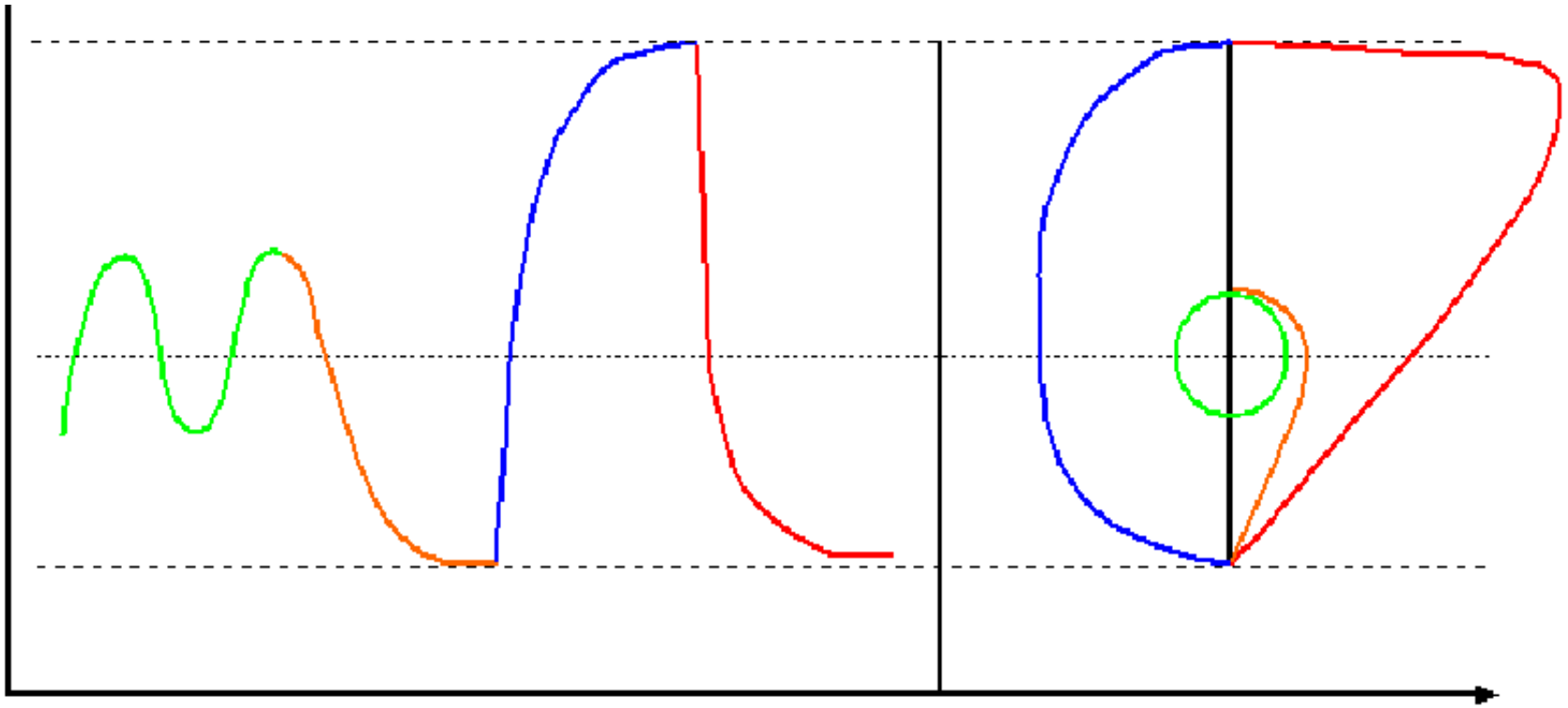
Volume time curve



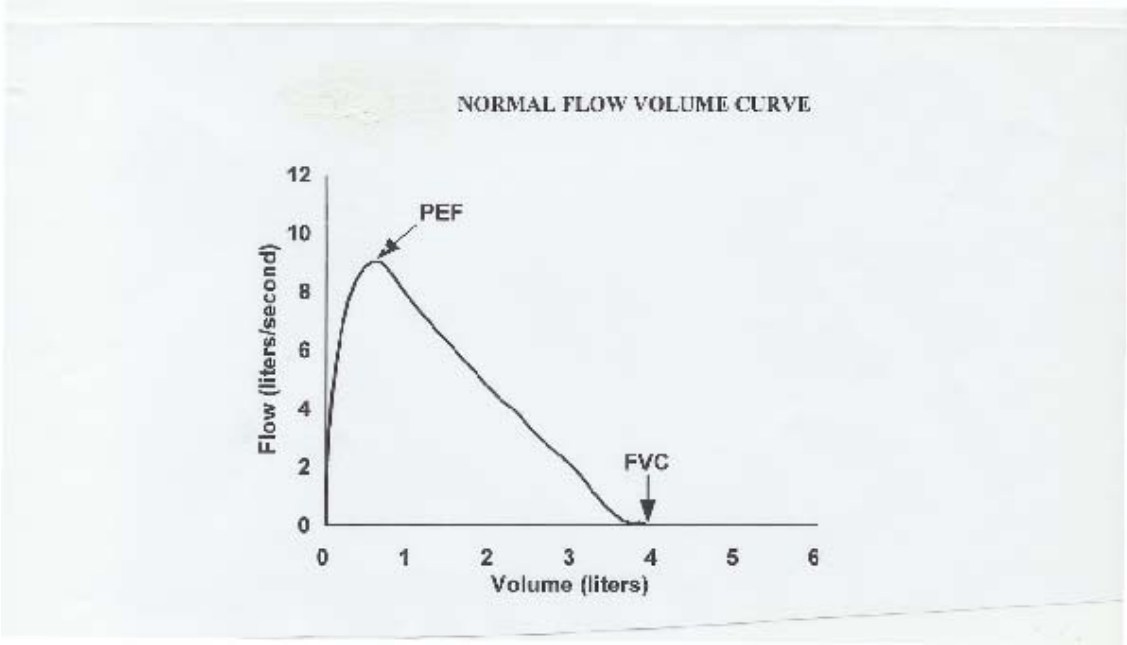
Flow volume loop



Volume – Time – Curve
Flow – Volume – Curve



Expiratory limb of flow volume curve



The main definitions

- VC – Vital Capacity –

  the maximal volume of air exhaled steadily from full inspiration to maximal expiration (not time dependent).

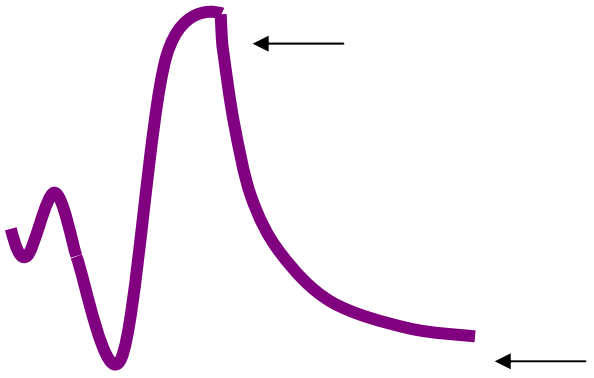
  The air in the lung between residual volume and total lung capacity.

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

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).

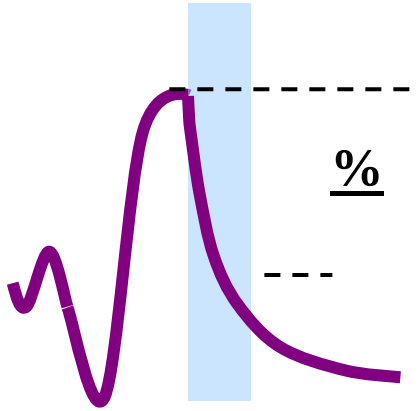
A slow or unforced VC or inspiratory vital capacity (IVC) manoeuvre may provide a larger and more appropriate denominator for calculation of the $FEV_1/VC\%$.



The main definitions

- <u>FEV1 – FORCED EXPIRATORY VOLUME IN ONE SECOND</u>

  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).



The main definitions

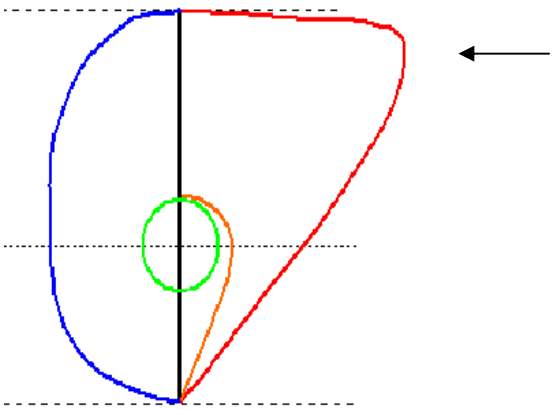
- FEV1/FVC

  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.

The main definitions

- <u>P.E.F. – Peak Expiratory Flow</u>

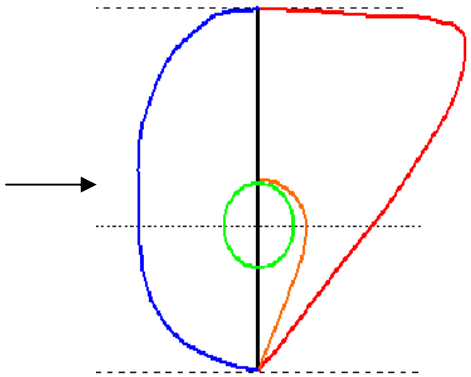
  the highest flow achieved from a maximum forced expiratory manoeuvre started without hesitation from a position of maximal inspiration. Can be expressed in litres per second, or litres per minute.



Other definitions

- <u>P.I.F. – Peak Inspiratory Flow</u>

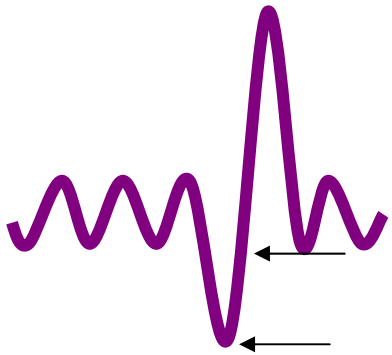
  is the maximum inspiratory flow achieved from a maximum forced inspiration, starting without hesitation from the point of maximal lung deflation, expressed in $L*s^{-1}$.



Other definitions

- ERV - Expiratory reserve volume

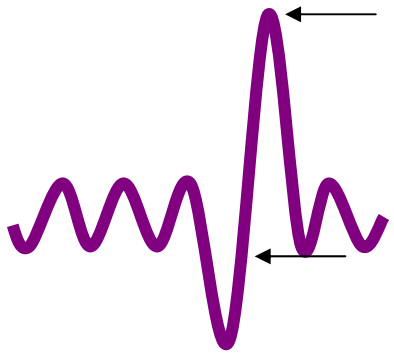
  volume change recorded at the mouth when taking a slow full expiration with no hesitation, from a position of passive end-tidal expiration, i.e. FRC, to a position of maximum expiration, expressed in litres at BTPS.



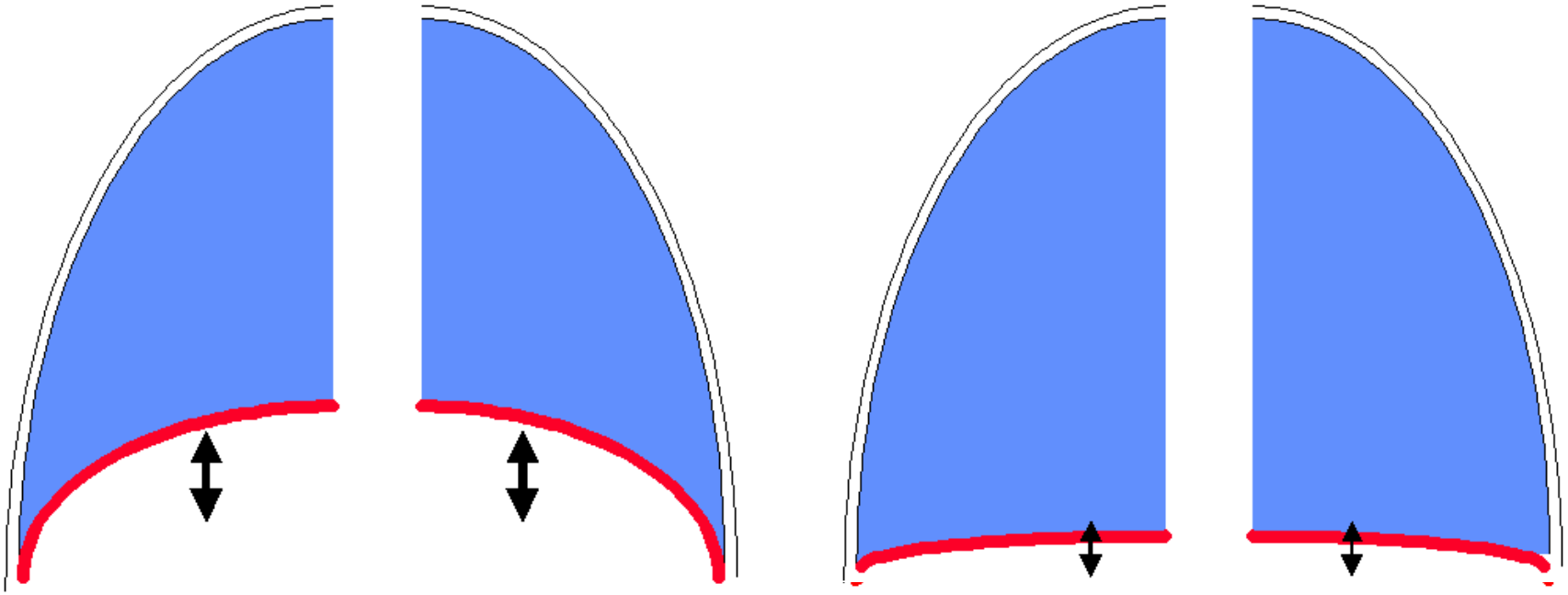
Other definitions

IC – Inspiratory Capacity

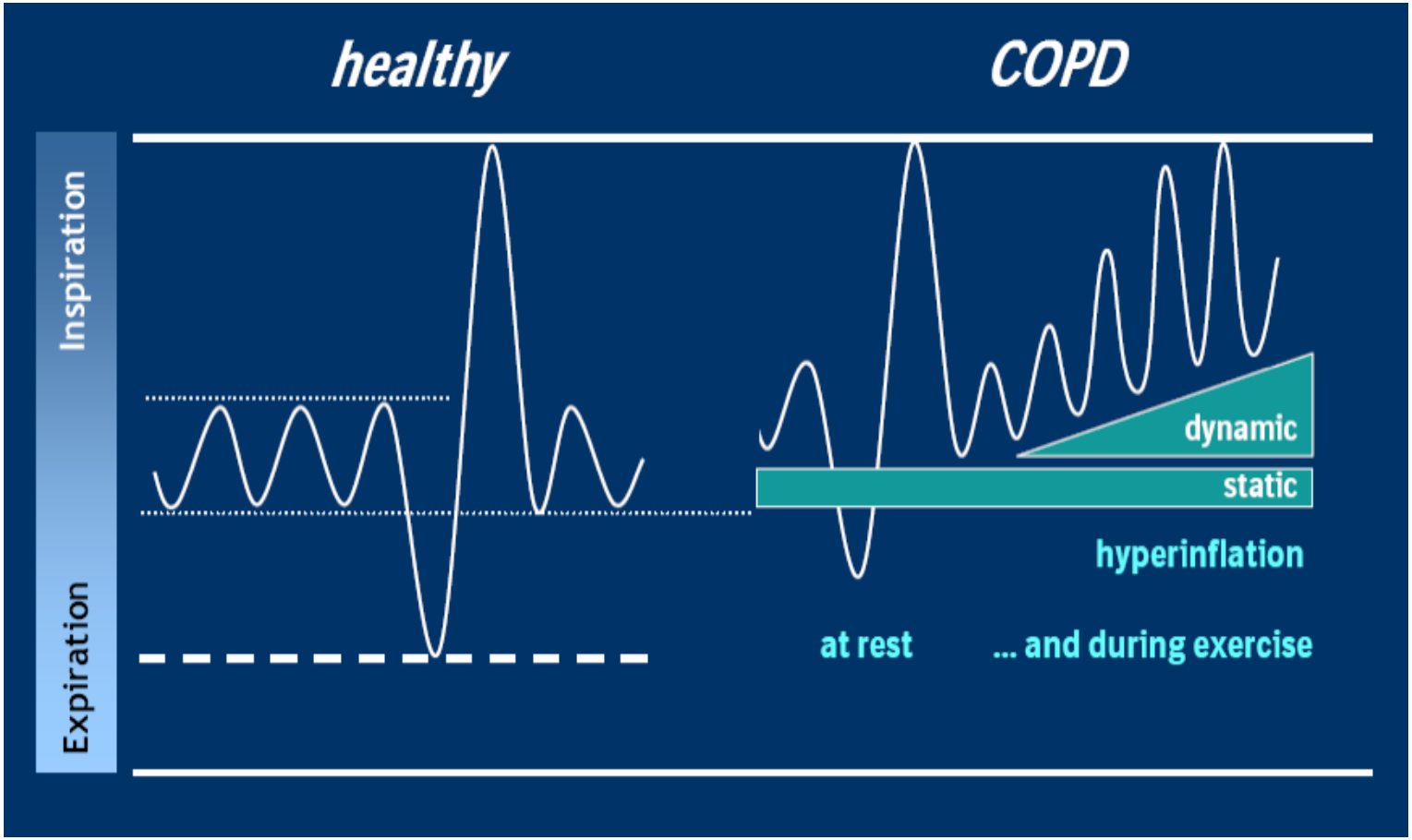
volume change recorded at the mouth when taking a slow full inspiration with no hesitation, from a position of passive end-tidal expiration, i.e. FRC, to a position of maximum inspiration, expressed in litres at BTPS.



PATHOPHYSIOLOGY



Dynamic hyperinflation – reduction of inspiratory capacity



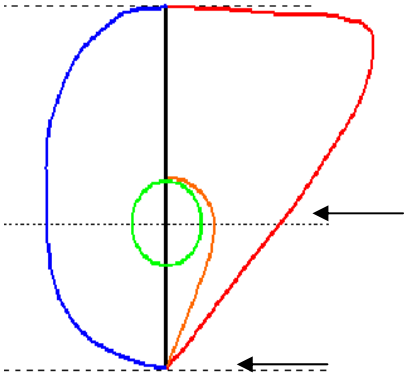
Other definitions

- F.E.F. 25-75% - Forced Expiratory Flow 25–75%.

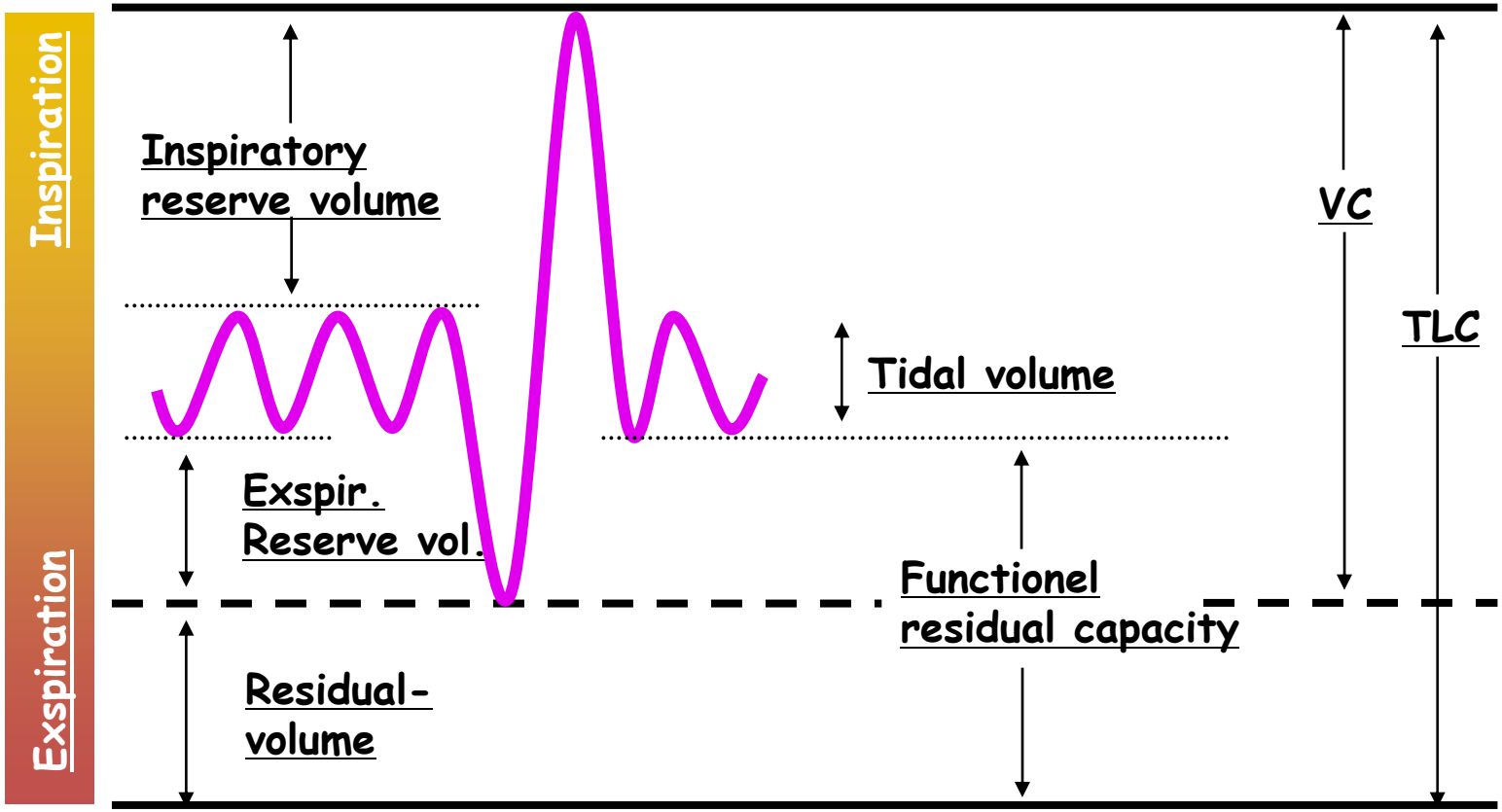
  The mean forced expiratory flow between 25% and 75% of the FVC. Expressed in litres at BTPS.

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

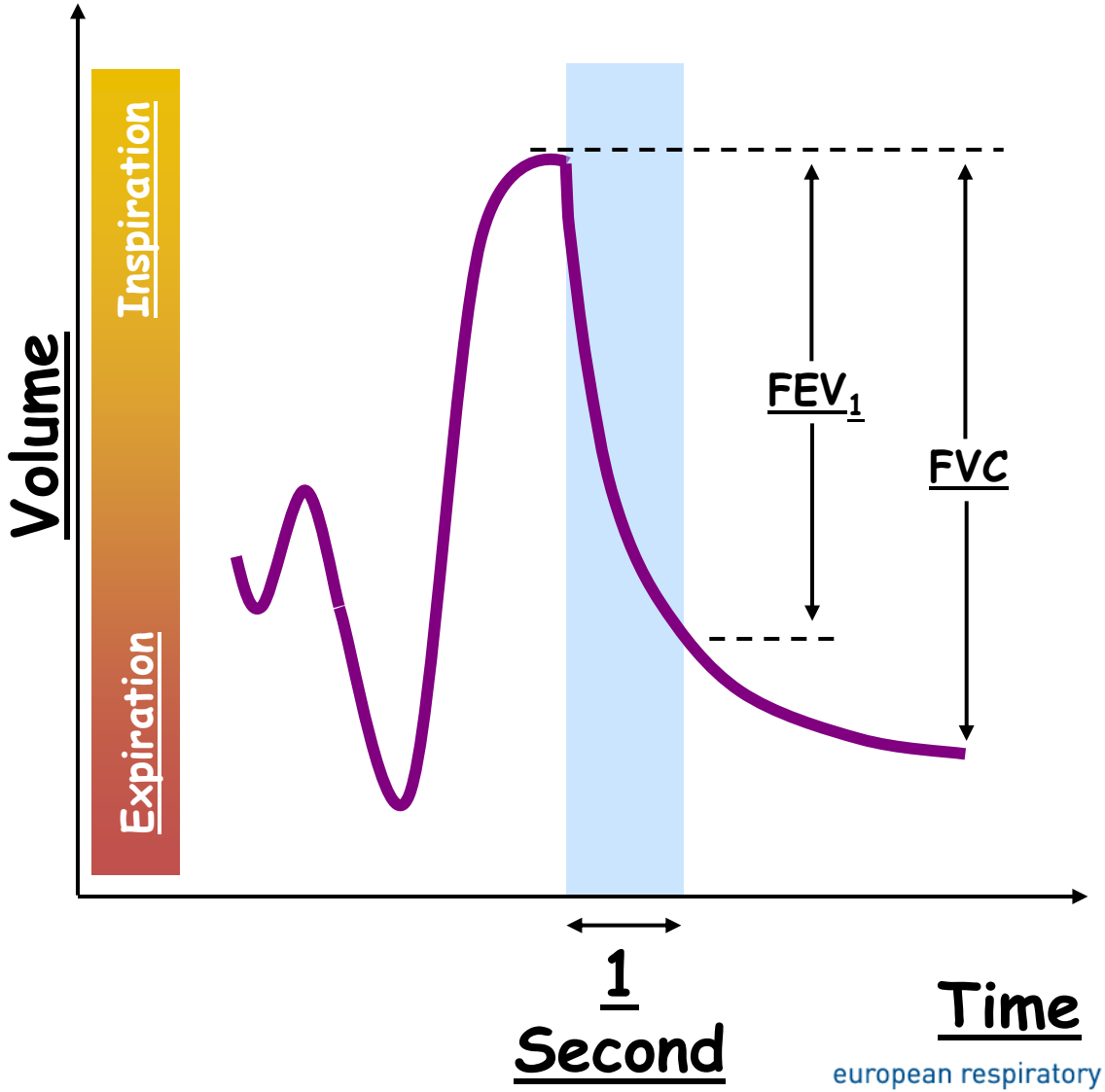
  It should be noted that it is highly dependent on the validity of the FVC measurement and the level of expiratory effort.



LUNG VOLUMES



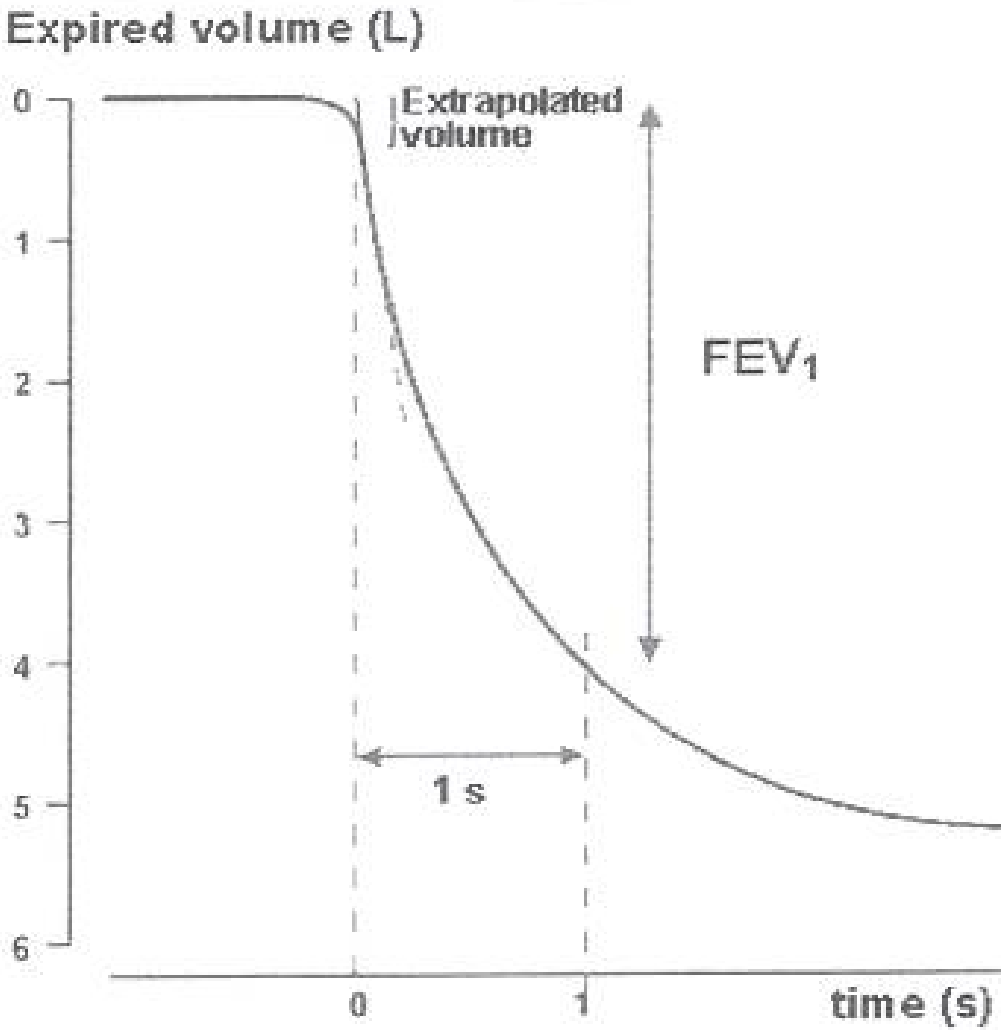
Spirogram:



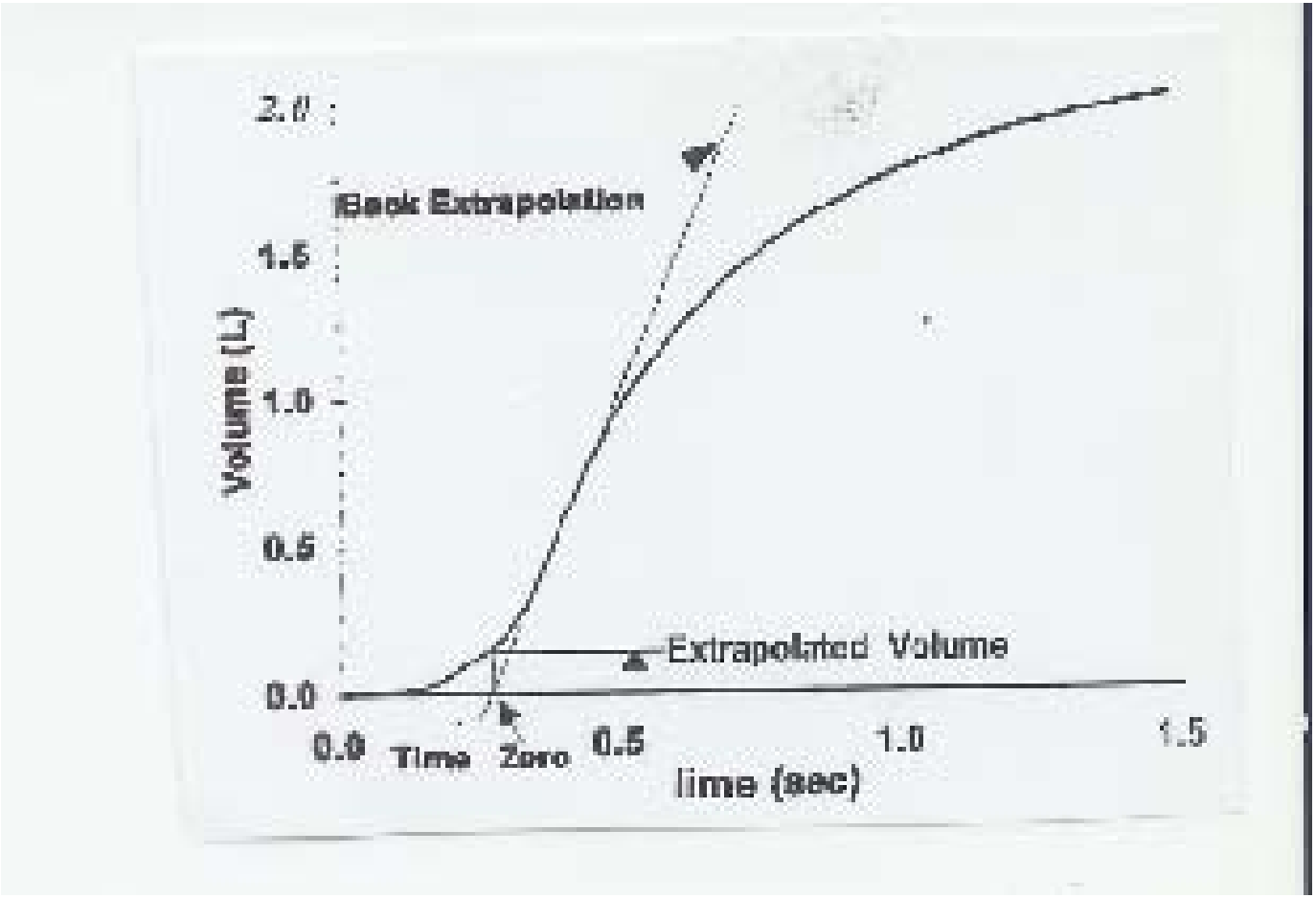
Back extrapolation

- 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.

Back extrapolation



Back extrapolation



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)

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

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 $\pm$ 1^{o}C.
- 17^{o}C is the lower limit for ambient temperature unless manufacturer states otherwise.

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.

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.

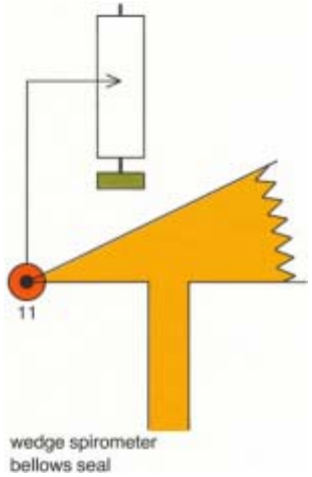
Spirometry equipment

Ms Julie K. Lloyd
Respiratory & Sleep Investigation Department
Area A, Treatment Centre
Good Hope Hospital
Rectory Road
Sutton Coldfield B75 7RR
United Kingdom
julie.lloyd@heartofengland.nhs.uk

Spirometry equipment

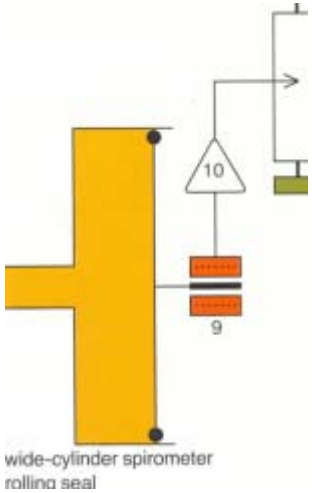
- Spirometers
  - Computer and software
  - Mouthpiece, Tubings, nose clips and bacterial filters
- Spirometer calibration syringes (3 litre)
- Thermometer, hygrometer and barometer
- Stadiometer and balance
- Reference values
- Standards & instructions for spirometry

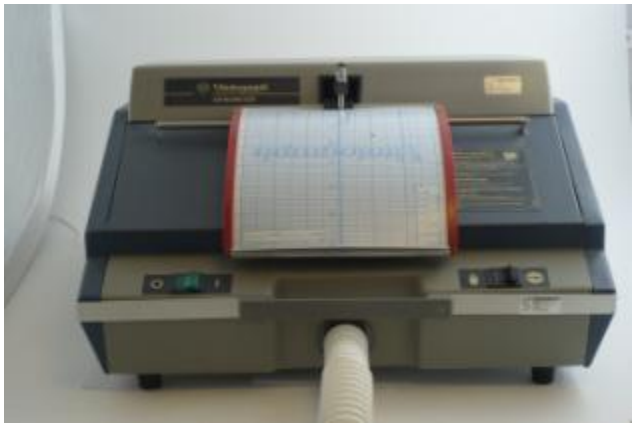
Spirometry measurement principles
Volume measuring devices



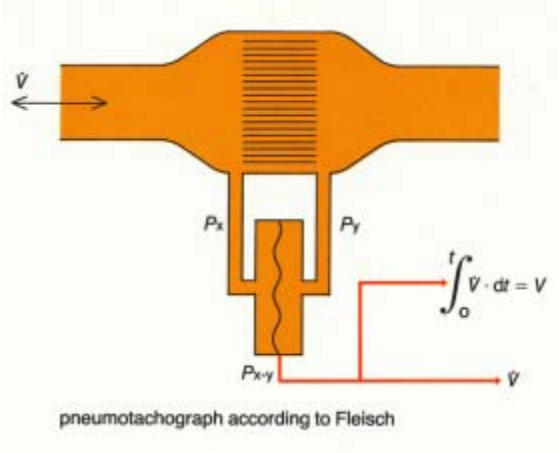
As the subject exhales the bellows expands, the chart moves and the stylus records

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



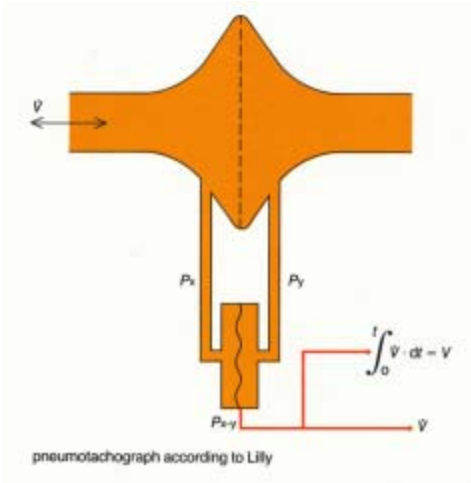


Spirometry measurement principles
Flow measuring devices



pneumotachograph according to Fleisch

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)



pneumotachograph according to Lilly

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

Spirometers

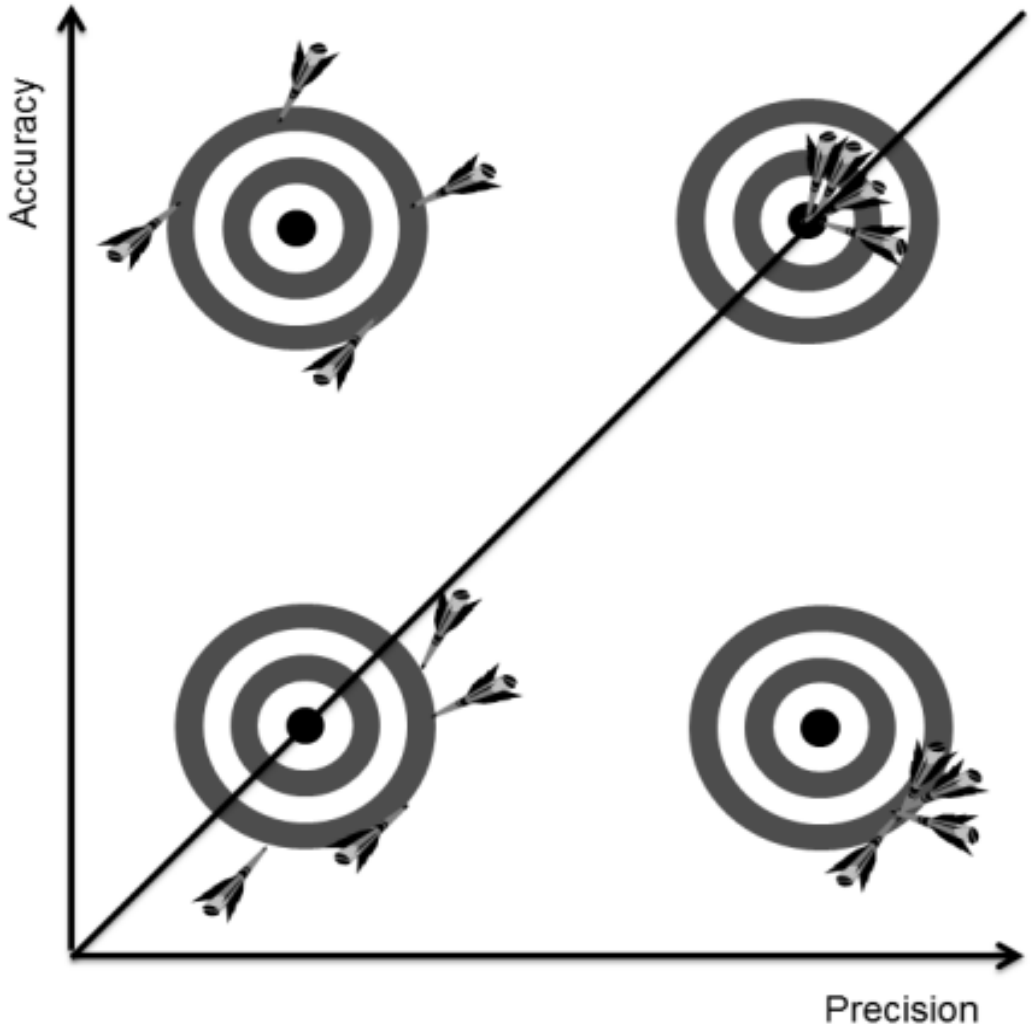
Opening membrane pneumotach

Fleisch pneumotach

Rotating vane

Lilly pneumotach

Metrology: Measurement terminology



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 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (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 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	24 ATS waveforms
Time zero	The time point from which all FEV_t measurements are taken			Back extrapolation	
PEF	Accuracy: ±10% of reading or ±0.30 $L \cdot s^{-1}$ (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 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (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 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (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 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (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.

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)

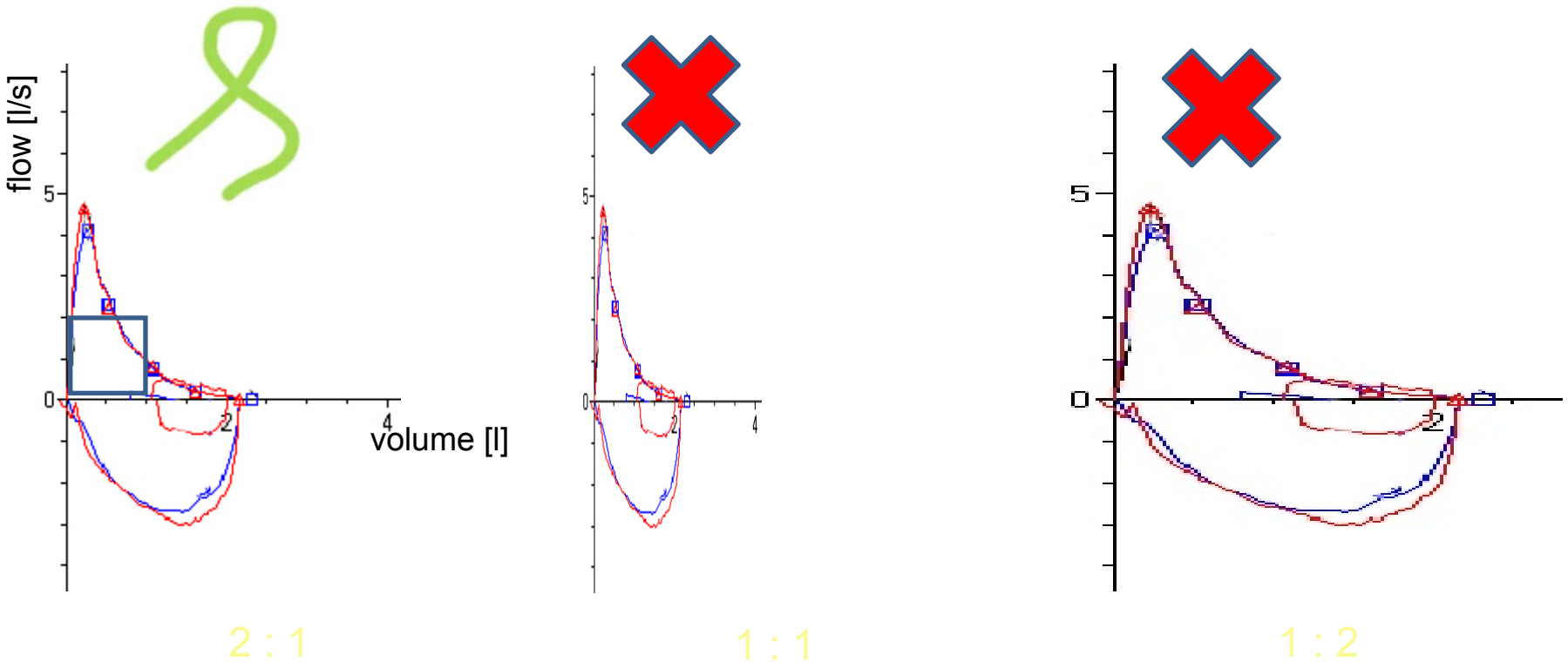
ATS/ERS Specifications for scale factors 2005

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·L^{-1}	0.025 L	10 mm·L^{-1}
Flow#	0.200 L·s^{-1}	2.5 mm·L^{-1}·s^{-1}	0.100 L·s^{-1}	5 mm·L^{-1}·s^{-1}
Time	0.2 s	10 mm·s^{-1}	0.2 s	20 mm·s^{-1}

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

Use fixed 2:1 scale



2 : 1 1 : 1 1 : 2

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

ERS

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

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

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

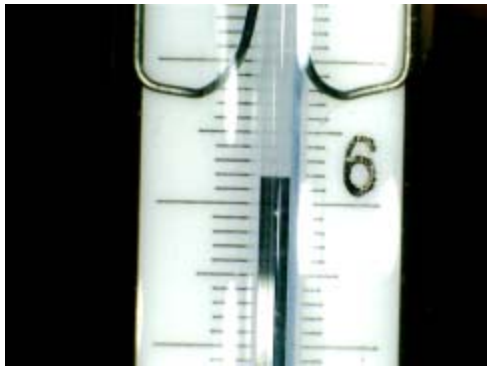
Mouthpiece, tubing's, nose clips and bacterial filters

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

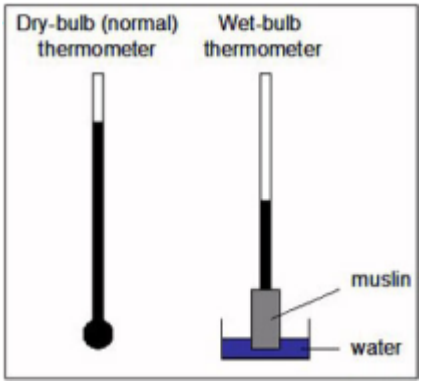
Thermometer, hygrometer and barometer

°C



P_B hPa

rH %



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

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

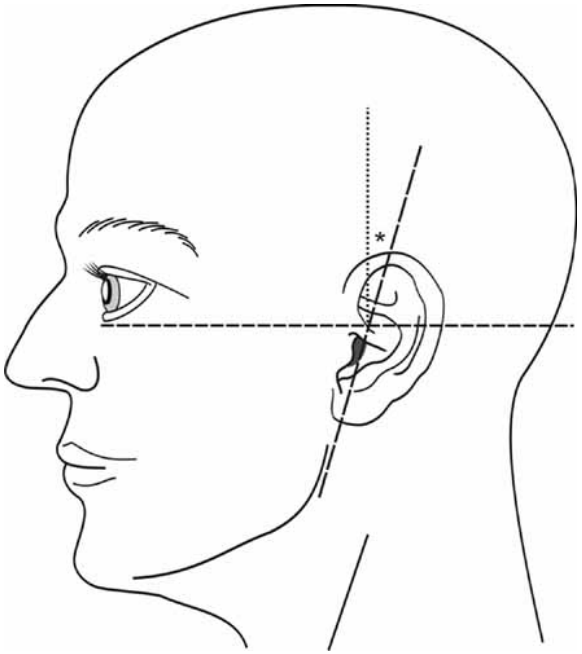
You can use an electronic device measuring, temperature, relative humidity and barometric pressure – but then you have to calibrate it against a measurement traceable to a international standard

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)

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.

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

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.

- 2. Miller, M. R., R. Crapo, J. Hankinson, V. Brusasco, F. Burgos, R. Casaburi, A. Coates, P. Enright, C. P. M. Grinten, P. Gustafsson, et al. 2005. General considerations for lung function testing. *Eur Resp J* 26:153-161.

- 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.

Factors that influence reference values

ESDL module 3, 4

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.

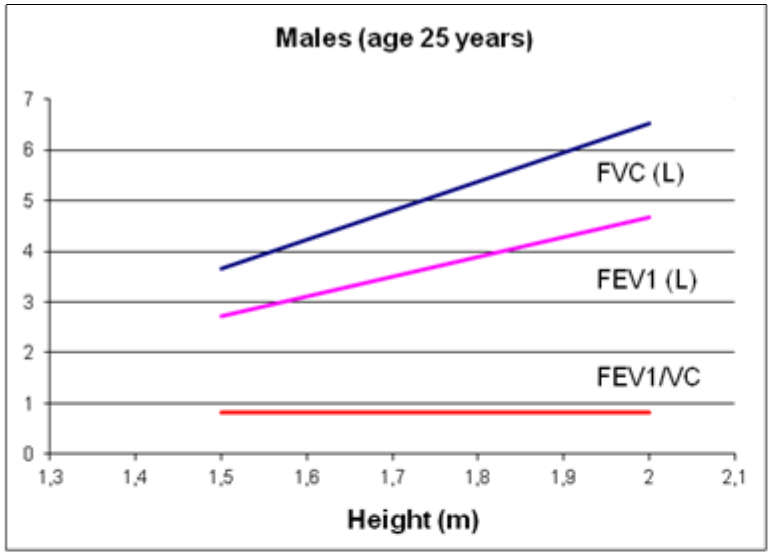
Table 4.2 ECSC Reference equations **ERJ 1993; 6:Suppl. 16, 5-40**

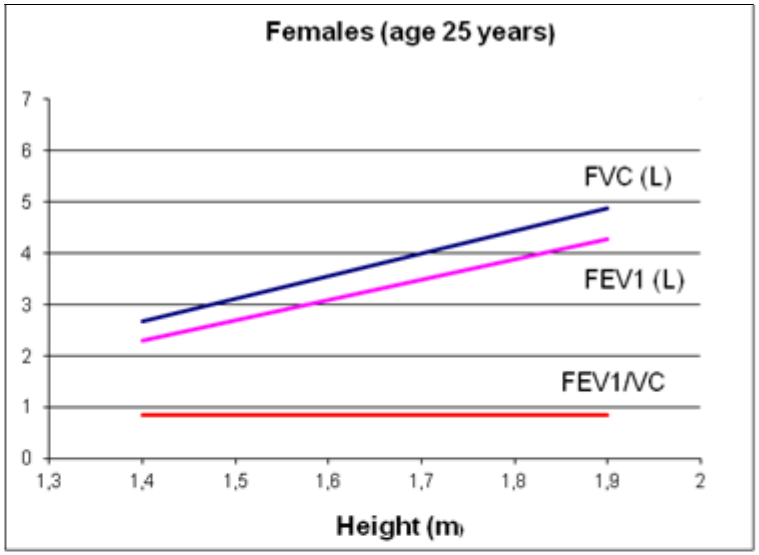
Index	Regression equation	RSD	Unit
Men			
FEV_1	4.30H - 0.029A - 2.49	0.51	L
FVC	5.76H - 0.026A -4.34	0.61	L
FEV/VC	-0.18A + 87.21	7.17	%
PEF	6.14H - 0.043A + 0.15	1.21	L/s
Women			
FEV_1	3.95H - 0.025A -2.60	0.38	L
FVC	4.43H - 0.026A - 2.89	0.43	L
FEV/VC	-0.19A + 89.10	6.51	%
PEF	5.5H - 0.030A - 1.11	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

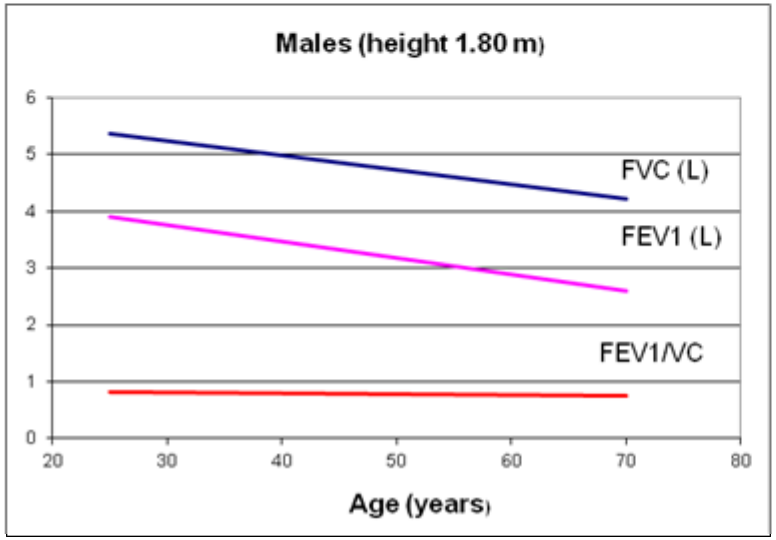
H = height in metres **A = age in years**

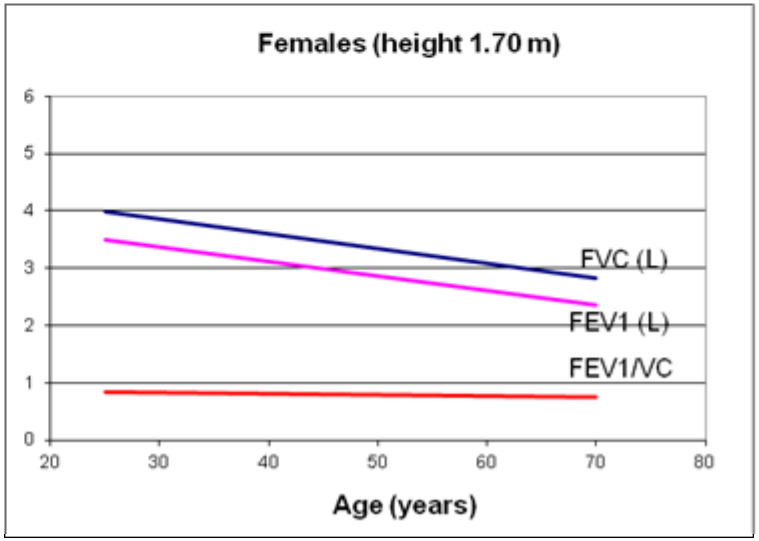
From ARTP Handbook in Spirometry, 2nd edition Association for Respiratory Technology and Physiology

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









Graphical presentation of the equations for adults in the previous table

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

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 Jörg Daniel Leuppi
Professor of Internal Medicine
University of Basel
Head of Internal Medicine
Cantonal Hospital Baselland
Rheinstr. 26
4410 Liestal
Switzerland
Joerg.leuppi@ksbl.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.

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.

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

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-Barrė syndrome
   b. Amyotrophic lateral sclerosis
   c. Multiple sclerosis
   d. Mystenia

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

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

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

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

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.

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

Dr Felip Burgos
Department of Pneumology
Hospital Clínic
Villarroel, 170
08036 Barcelona
Spain
fburgos@ub.edu

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

Disclosure

Felip Burgos :

- Socks of Linkcare® Health Solutions SL

Definitions

Quality Assurance:

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

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.

Calibration versus 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.

Steps to calibration & check

- ✓ Introduce environmental conditions if the computer doesn't have meteorological station
- ✓ Difference between calibration & check
- ✓ 3 liter calibrated syringe
- ✓ Calibration
- ✓ Verification or check
- ✓ Quality Control
- ✓ Out of range (action to be taken)
- ✓ Biological control (BioQC)

Why

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

Calibration with **3 Liters** Syringe

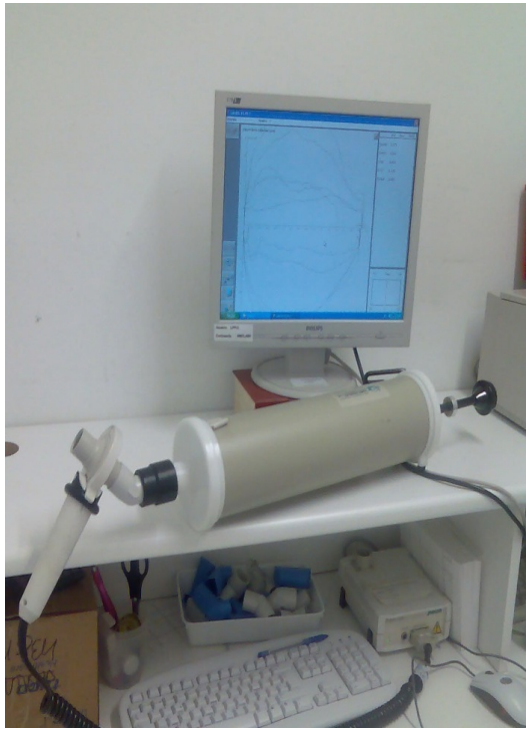
✓ Objective:
Establishing a correspondence between standard measures (syringe) and measurement

✓ 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 % at all flows

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



SYRINGE CALIBRATION

CALIBRATING THE CALIBRATOR

Annual calibration of syringe recommended

3 Liter syringe

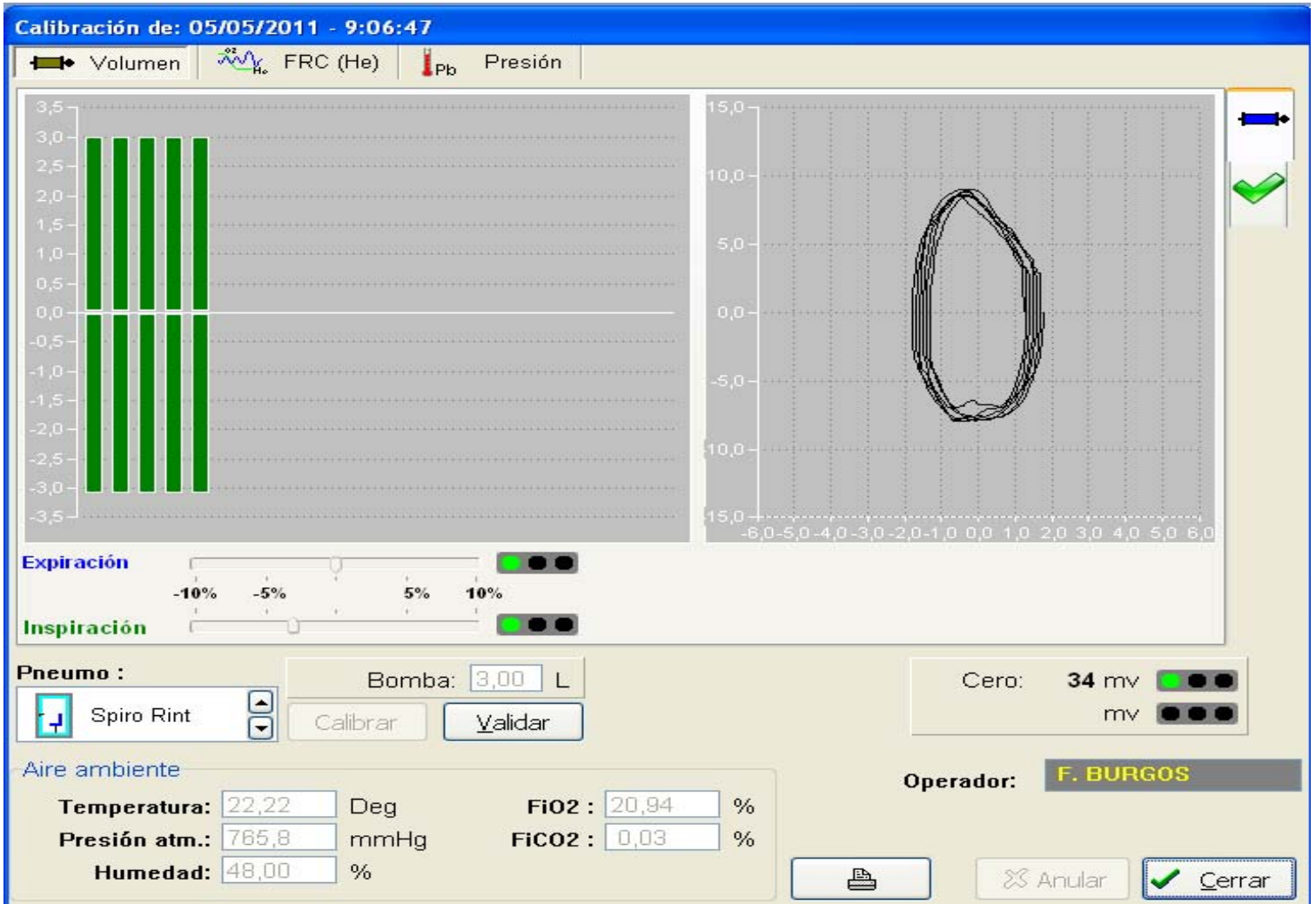
The calibration syringe should be stored and used in such a way as to maintain the same temperature and humidity of the testing site. This is best accomplished by keeping the syringe include proximity to the spirometer, but out of direct sunlight and away from heat sources.

Keep the syringe in close proximity to the spirometer, but out of direct sunlight and away from heat and cold sources.

CALIBRATION

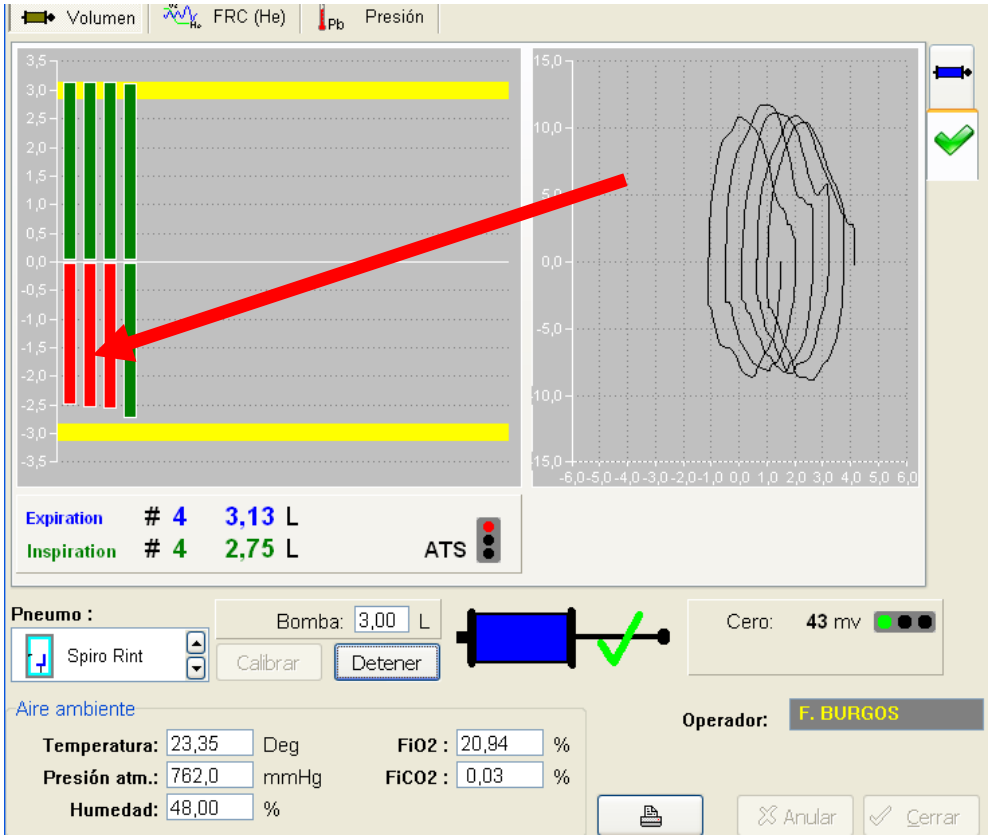
We have to calibrate equipment with a 3-liter pump syringe

3 Liter syringe (limit ± 3%)



Out of range check or calibration
What to do?

- ✓ Change pneumotachograph
- ✓ Dry the pressure tubes
- ✓ Pressure tube in upright position to
- ✓ Maintenance
  The maintenance will be carried out according to the instructions provided by the manufacturer.

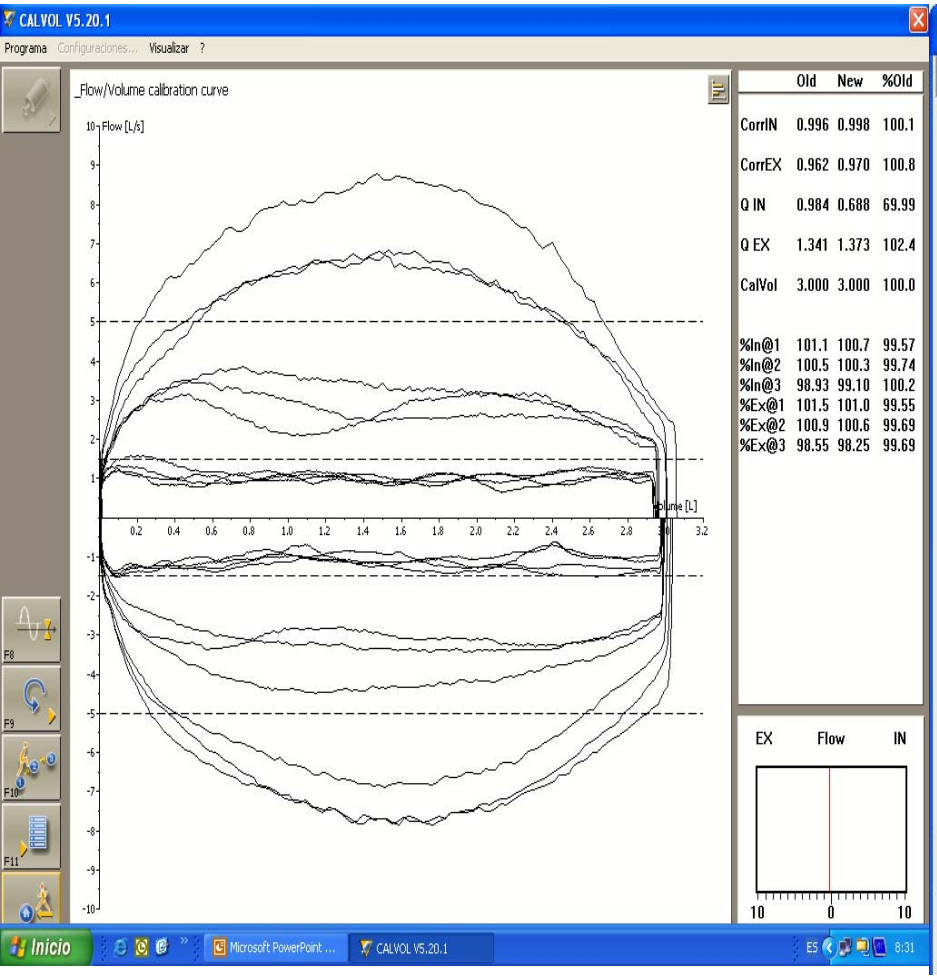


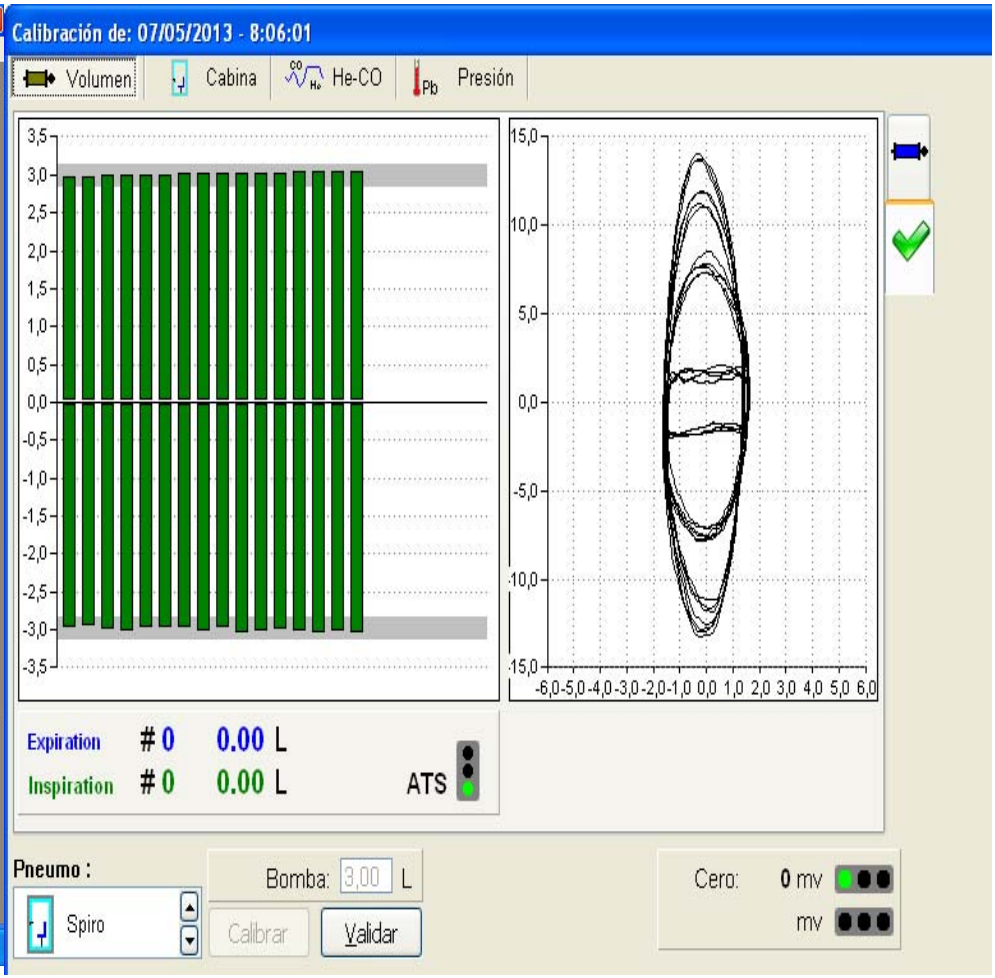
Verification

- Some devices cannot be calibrated.
- Measured value must be within 3% of syringe volume.
  - + 90ml for a 3 L syringe.

- Systems with software generated correction factors should be within range 0.97–1.03 (3%).

Flow check at least three different flows range





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.

Determining the normal range for a biological control.

J21

	A	B	C	
1		FVC	FEV 1	IC
2		L	L	L
3	1	4.44	3.38	
4	2	4.62	3.54	
5	3	4.63	3.48	
6	4	4.66	3.52	
7	5	4.6	3.43	
8	6	4.66	3.6	
9	7	4.45	3.46	
10	8	4.53	3.46	
11	9	4.46	3.37	
12	10	4.48	3.38	
13				
14	Mean	4.55	3.46	
15	SD	0.09	0.08	
16	CV	1.98	2.19	
17				
18	2.5% mean	0.11	0.09	
19	Range	4.67	3.55	
20		4.44	3.38	
21				

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**

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 (be careful with vapour of water)**
- **Increased awareness of hospital infection-control issues**

Patient errors

Sub maximal effort - usually due to:

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

Patient errors

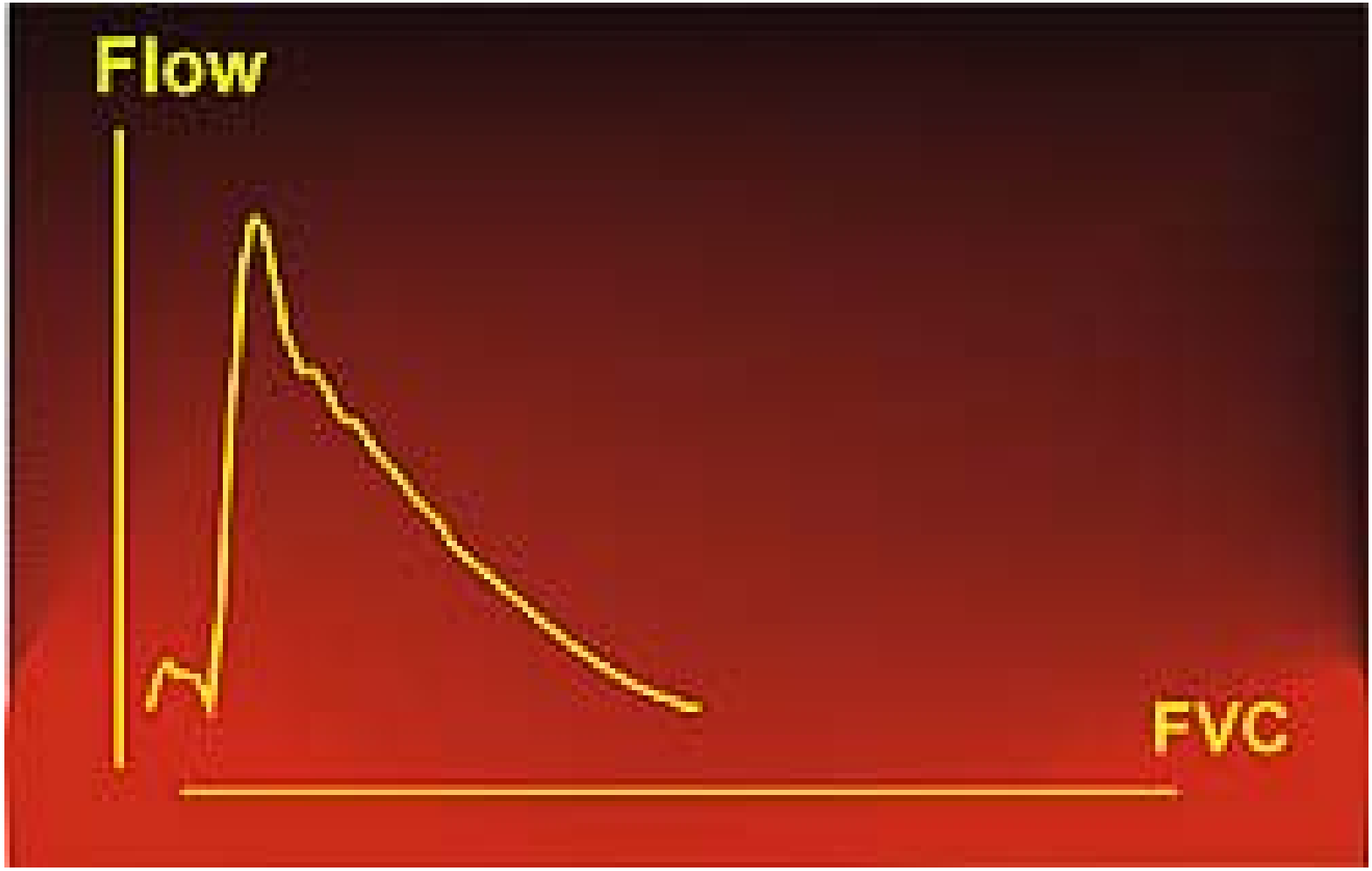
Leaks - usually due to:

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

Technical errors

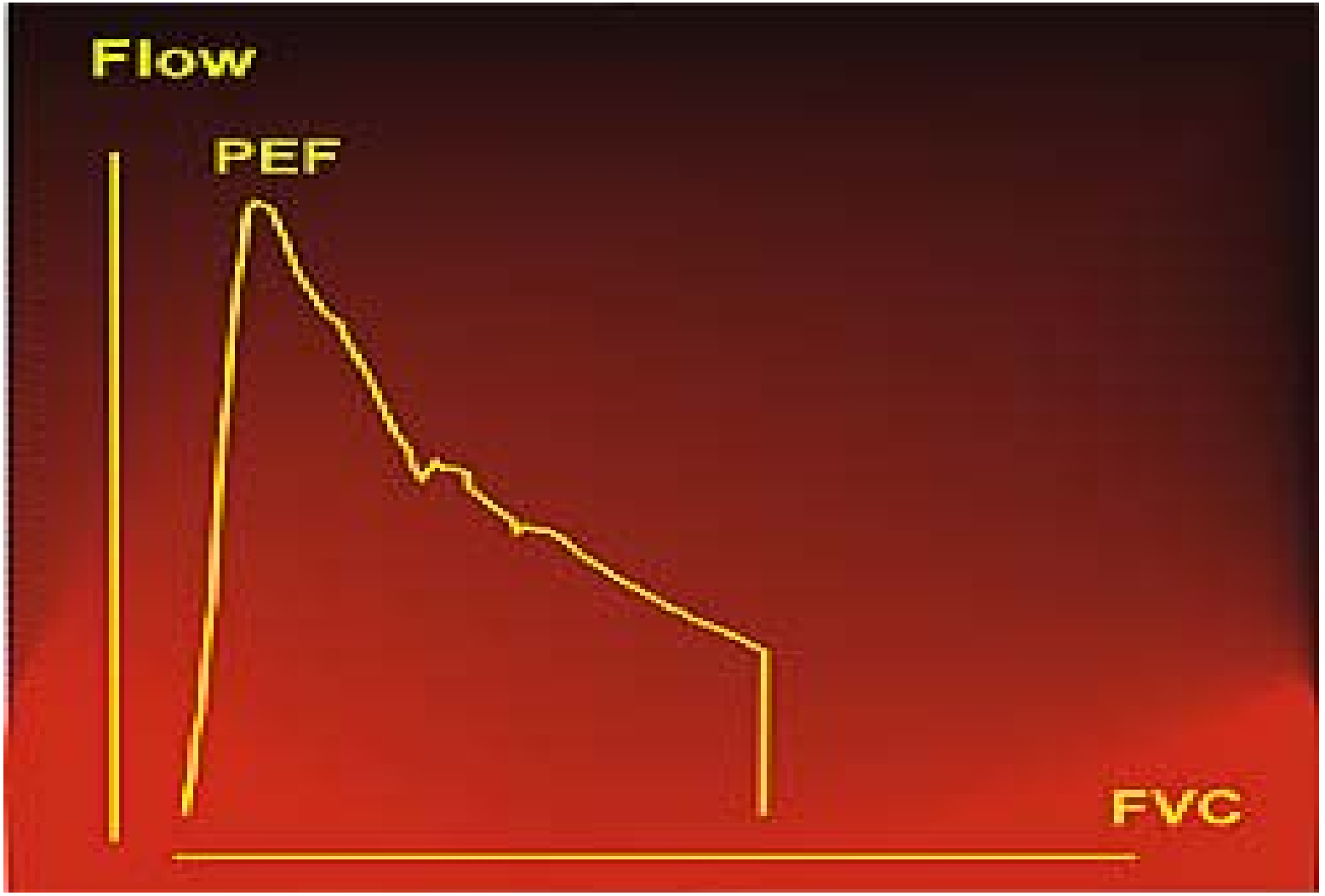
- Poor start
- Early termination
- Cough (easy to detect; just need to listen ..)
- Sub-maximal effort
- Unable to obtain 3 technically acceptable efforts

Poor start



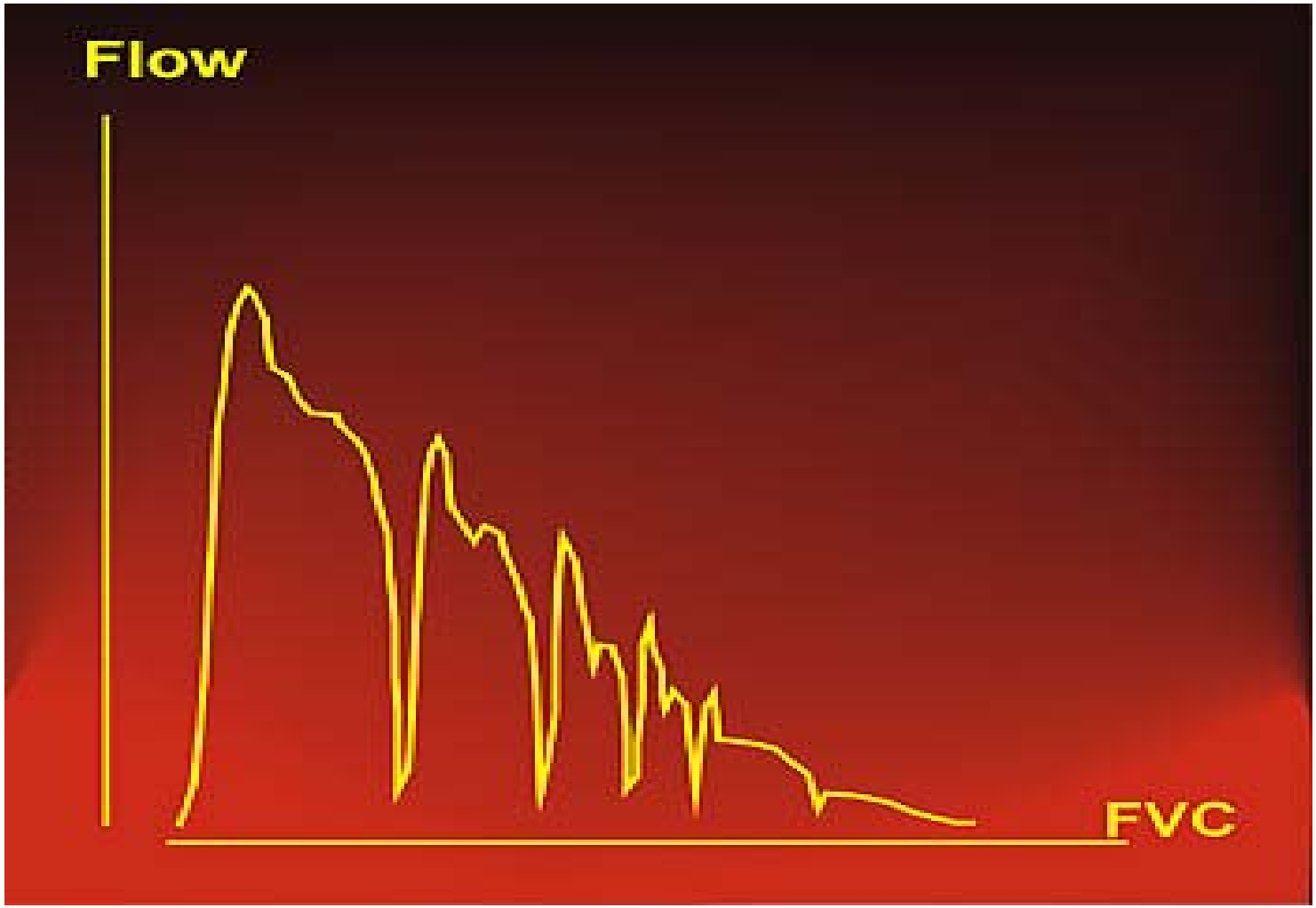
www.spirxpert.com

Early termination



www.spirxpert.com

Cough



www.spirxpert.com

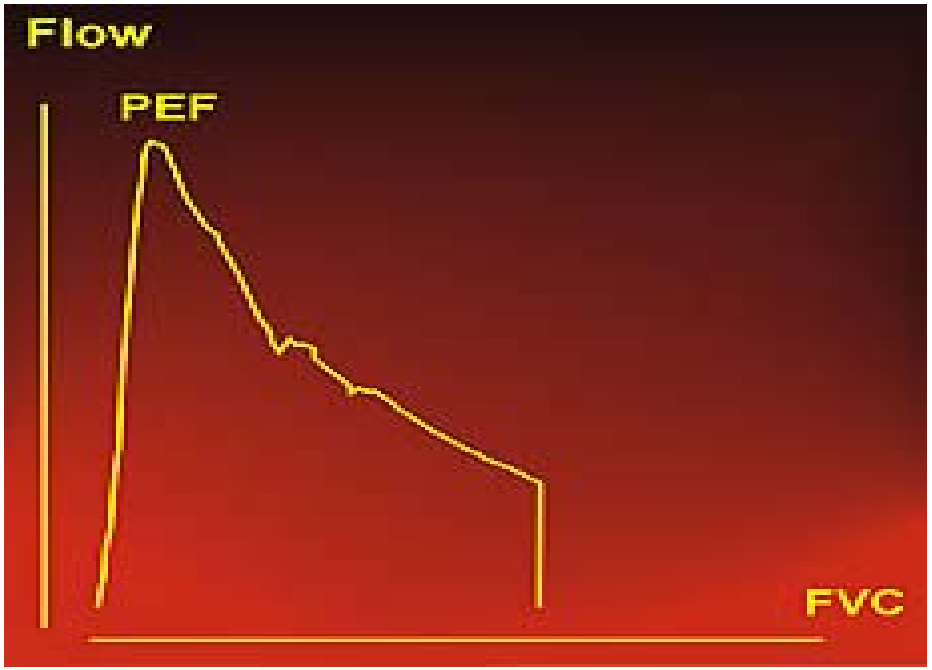
Sub-maximal effort

www.spirxpert.com

Over reading

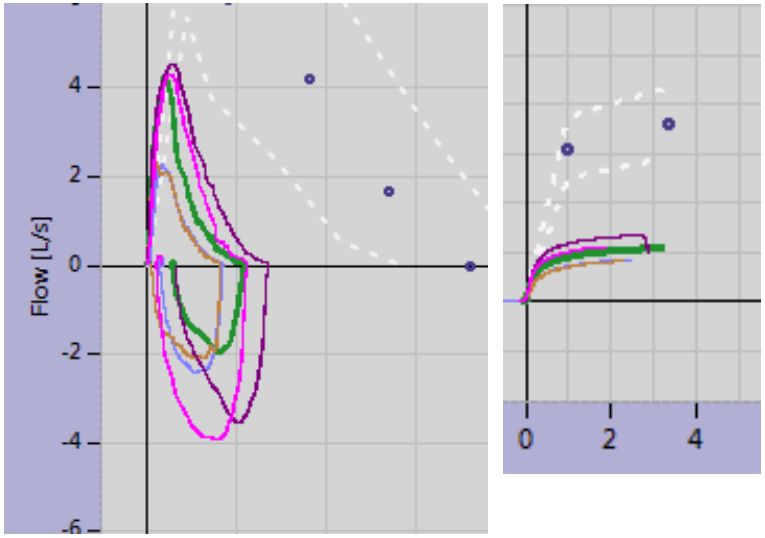
- Quality of spirometry increases with expert over-reading and constructive feedback
- Independent quality review
- Useful in primary and secondary care

Example of feedback



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

Example of feedback



	Pred	LLN	Pre Best				
Trial Rank							
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

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

Evaluation of spirometric results

Dr Emelie Ekkernkamp
Department of Pneumology
St. Josefs Hospital Freiburg
Sautierstr.1
79104 Freiburg
Germany
emelie.ekkernkamp@rkk-klinikum.de

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
• intra- and extrathoracic central and upper airway obstruction

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 fulfill 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 150ml 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 < 25ml) 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 150ml. Only technically acceptable spirometries can be interpreted.

When doing a bronchodilator test, one should be aware that both spirometries (pre- and post-) are 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 200ml 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. The global lung function 2012 equations were published 2012. This multi-ethnic reference values for spirometry for the 3-95 years age range are the first global data from 74.187 healthy non-smokers (57.1% females) using modern statistical methods, including development of age dependent lower limits of normal (4).

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 5th 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 FEV_1/(F)VC factor is below the lower limit of normal. The severity of obstruction is quantified using the value of FEV_1 expressed as a percentage of predicted. When FEV_1/(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). Examples of intra- and extrathoracic cantral and upper airway obstruction are shown.

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.
4. Quanjer PH, Stanojevic S, Cole TJ et al. Multi-ethnic reference values for spirometry for the 3-95-yr age range: the global lung function 2012 equations. Eur Respir J 2012; 40: 1324-1343.

EVALUATION

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

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.** FEV_1 < 80% pred.
   - **b.** FEV_1/FVC < 0.7
   - **c.** FEV_1/FVC < lower limit of normal.
   - **d.** Both FEV_1 and FEV_1/FVC < lower limit of normal.

Please find all answers at the back of your handout materials

ESDL PART 1

MODULE 7

EVALUATION OF SPIROMETRY

EMELIE EKKERNKAMP
FREIBURG, GERMANY

Conflict of interest disclosure

No conflicts of interest.

What have we learnt today?

- What do we measure?
- How do we prepare the equipment?
- How do we prepare the patient?
- How do we measure?
- When should and when shouldn't we measure?
- …

What will you hopefully learn in the next 40 minutes?

- *Which measurements can I use for interpretation?*

- How do I interpret a measurement?
  - What is a normal lung function?
    - Reference values: %pred vs. LLN/Z-Score
  - What is an obstructive pattern?
    - Reversibility testing
  - What is a restrictive pattern?
  - How do I recognize an upper or central airway obstruction?

LITERATURE

Eur Respir J 2005; 26: 948–968
DOI: 10.1183/09031936.05.00035205

SERIES "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING"
Edited by V. Brusasco, R. Crapo and G. Viegi
Number 5 in this Series

Interpretative strategies for lung function tests

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

LITERATURE

Eur Respir J 2005; 26: 153–161
DOI: 10.1183/09031936.05.00034505

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General considerations for lung function testing

M.R. Miller, R. Crapo, J. Hankinson, V. Brusasco, F. Burgos, R. Casaburi, A. Coates, 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

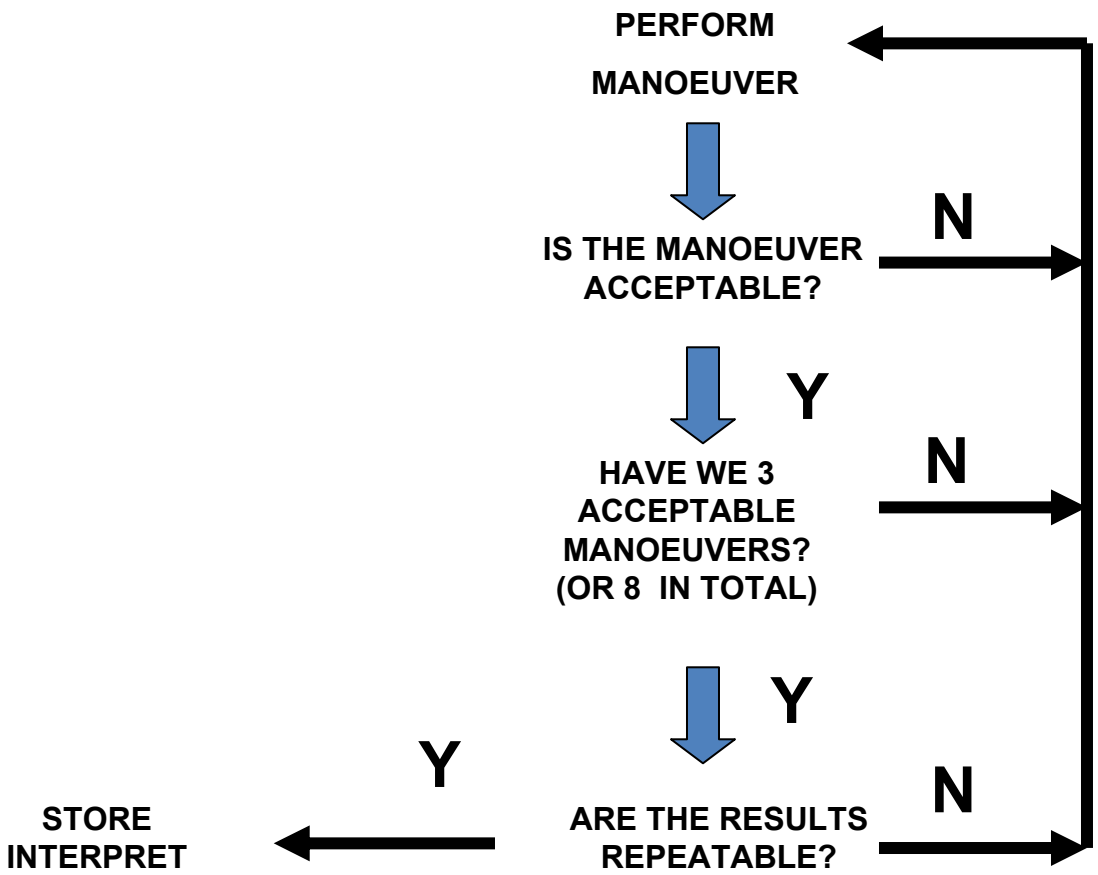
Eur Respir J 2005; 26: 319–338
DOI: 10.1183/09031936.05.00034805

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

WHEN CAN WE INTEPRETE SPIROMETRY DATA?



INTEPRETATION OF SPIROMETRY DATA?

„An interpretation begins with a review and comment on test quality.“

„The next steps involve a series of comparisons.“

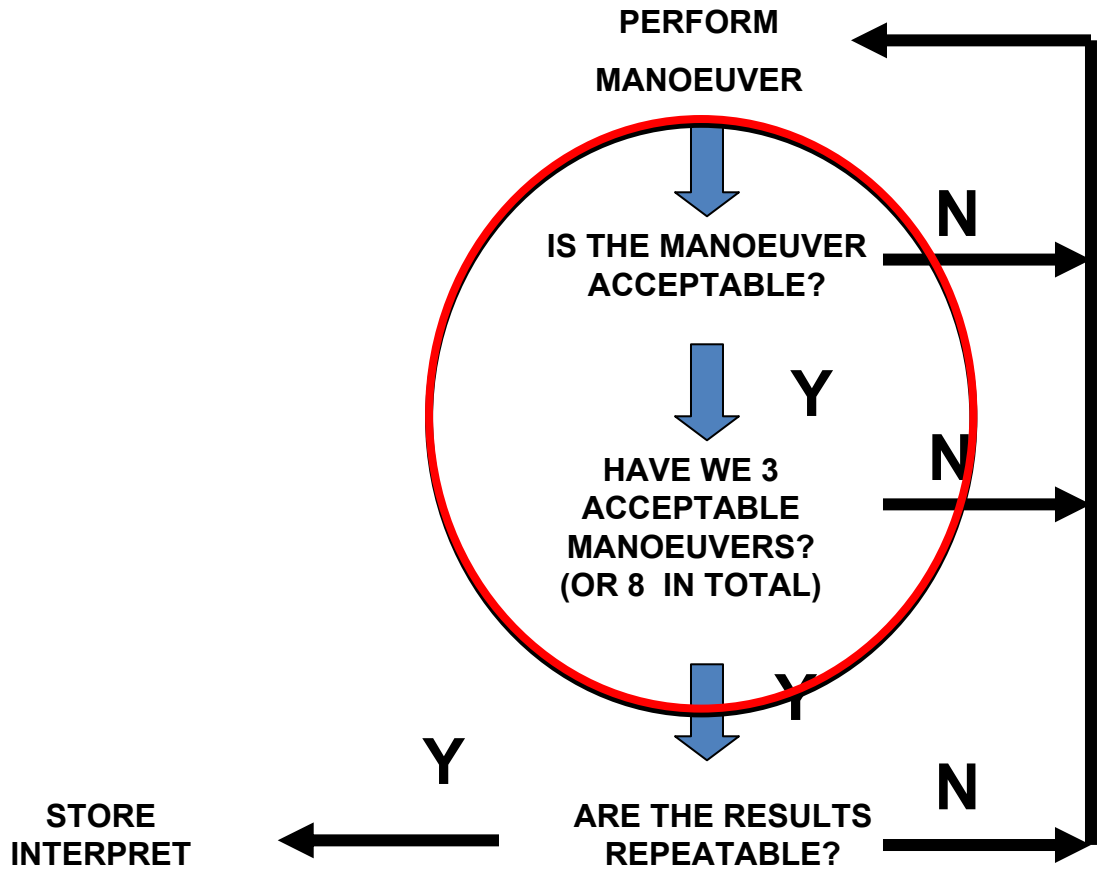
- with reference values
- with known disease or abnormal physiological patterns
- comparisons with self

„The final step in the lung function report is to answer the clinical question.“

WHAT INFORMATION DO YOU NEED TO INTERPRETE SPIROMETRY DATA?

- **Patient's data**
  - **height:** It is recommended that height is measured at each visit to one decimal point using a accurate and regularly calibrated stadiometer.
  - **age:** It is recommended that age be calculated accurately in years to one decimal point using the patient's date of birth and the date of test.
  - **gender**
  - **ethnicity/race:** PFT reports should display a patient's ethnic group, as well as the ethnic group of the reference population
- **Information about patient**
  - smoking history
  - underlying diseases
  - medication (p.i./p.o./i.v.)

WHEN CAN WE INTEPRETE SPIROMETRY DATA?

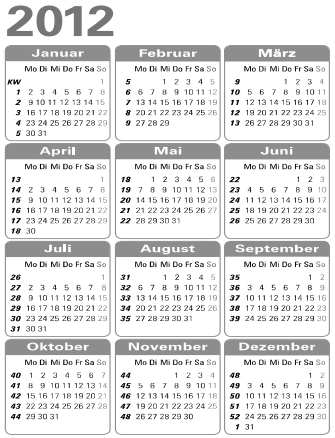


HOW CAN I REMEMBER ALL THE NUMBERS?

150 ml

200 ml

5 %



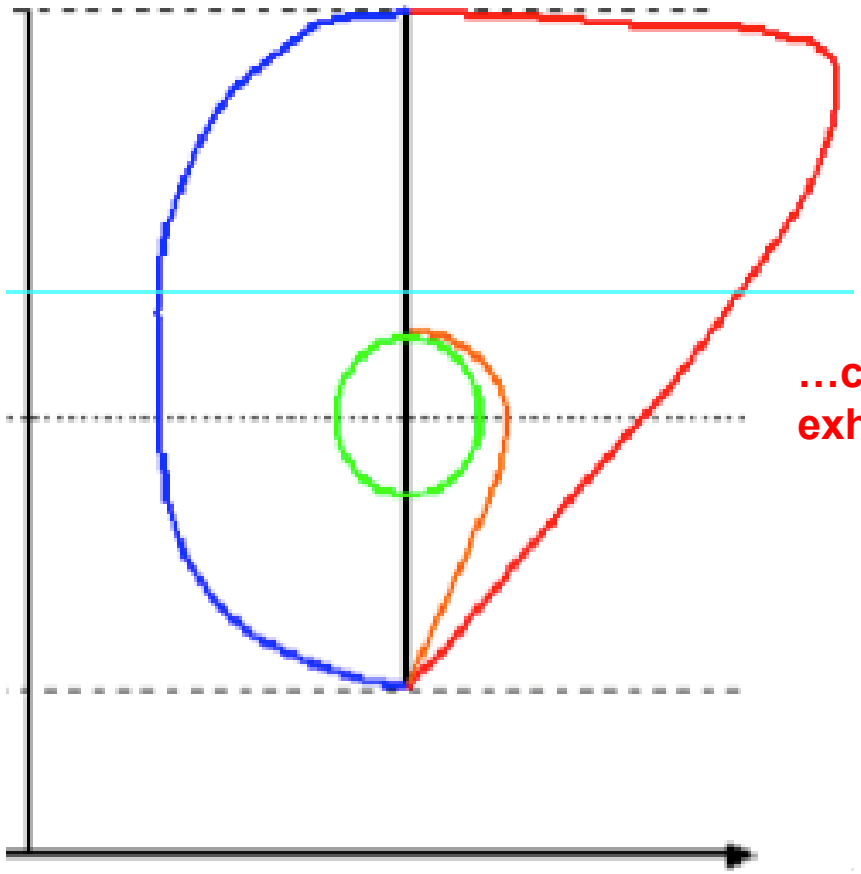
12 %

6 sec

THE „PERFECT" FLOW-VOLUME CURVE

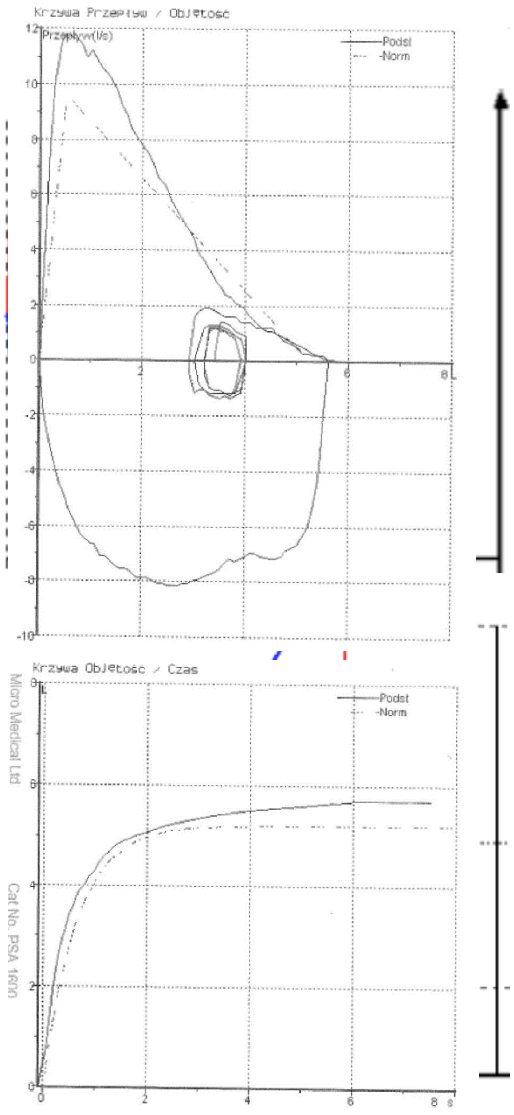
Maximal inspiration

A „blast" of exhalation



…continued complete exhalation to the end of test

A MANOEUVER IS ACCEPTABLE, IF...



1. The patient cooperates well

2. A steep rise of the first part of the FVC-curve *(start of test criteria)*
   - *Backextrapolated volume >150 ml / 5%*

3. A pointed peak (PEF) in the first part of expiration *(start of test criteria)*

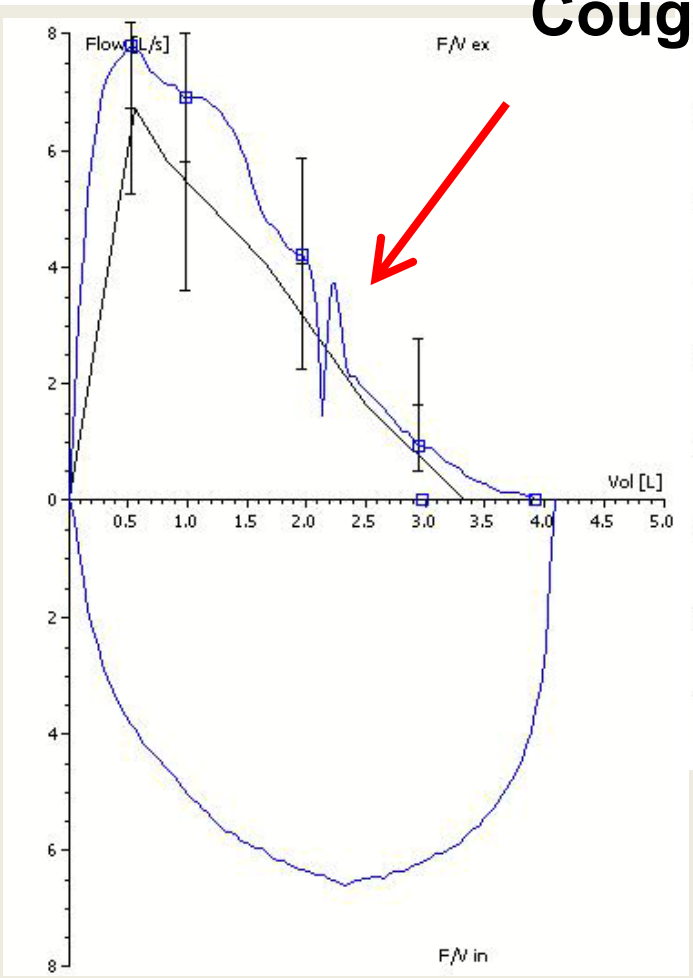
4. A "smooth" Flow-Volume curve free of artefacts

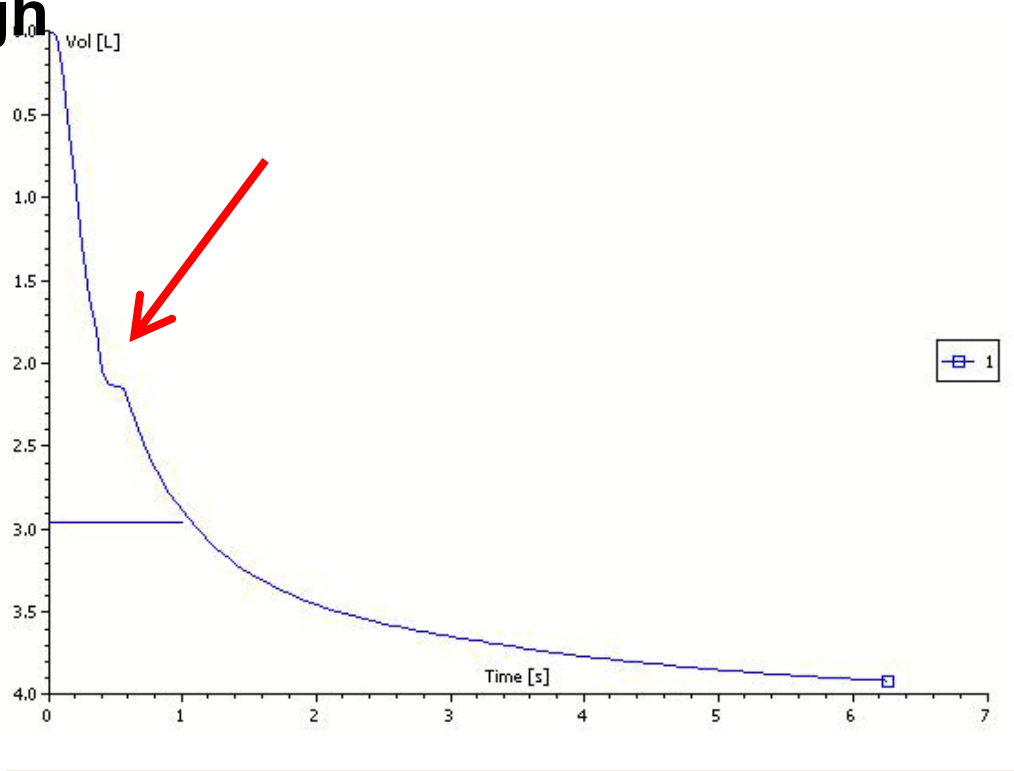
5. Expiration lasts for at least 6s and exhibits a plateau *(end of test criteria)*

1. Inspiration and expiration give the same VC

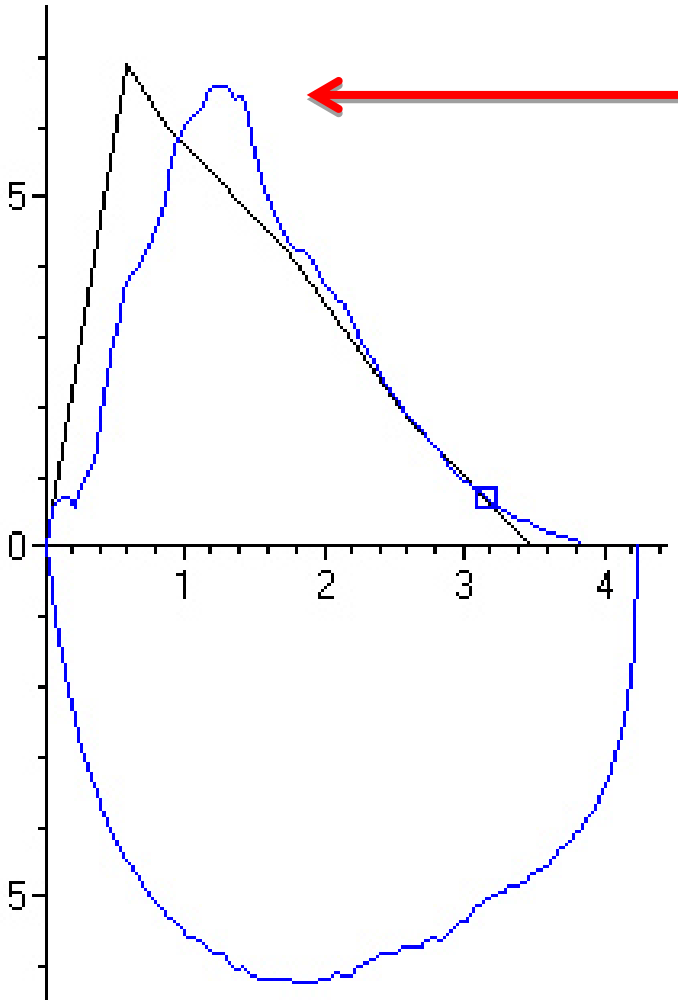
FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER

Cough



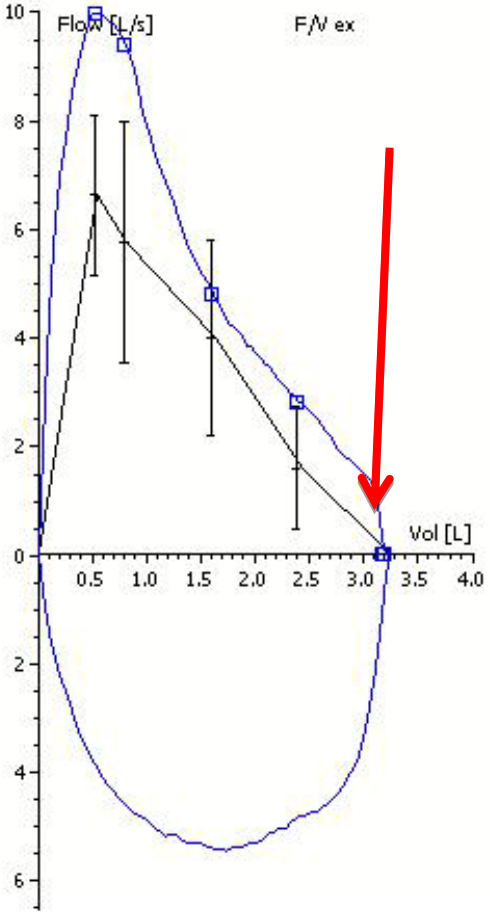


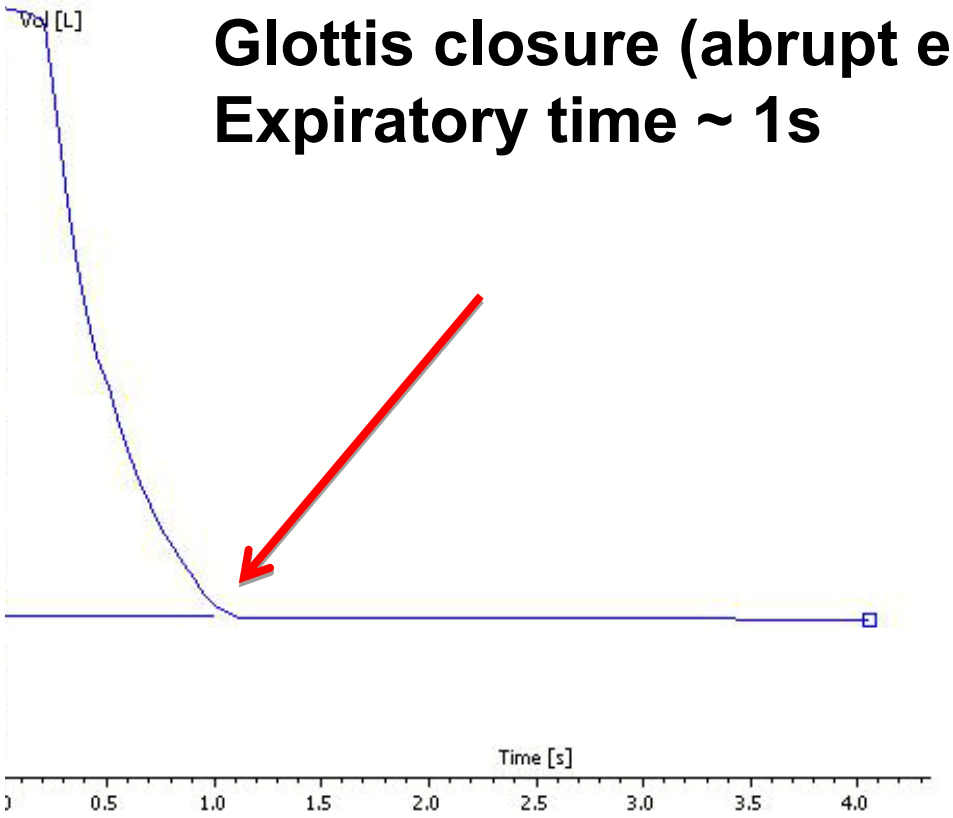
FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER



Submaximal effort
Note position of PEF!

FREQUENT PROBLEMS DURING PERFORMING FVC MANOEUVER

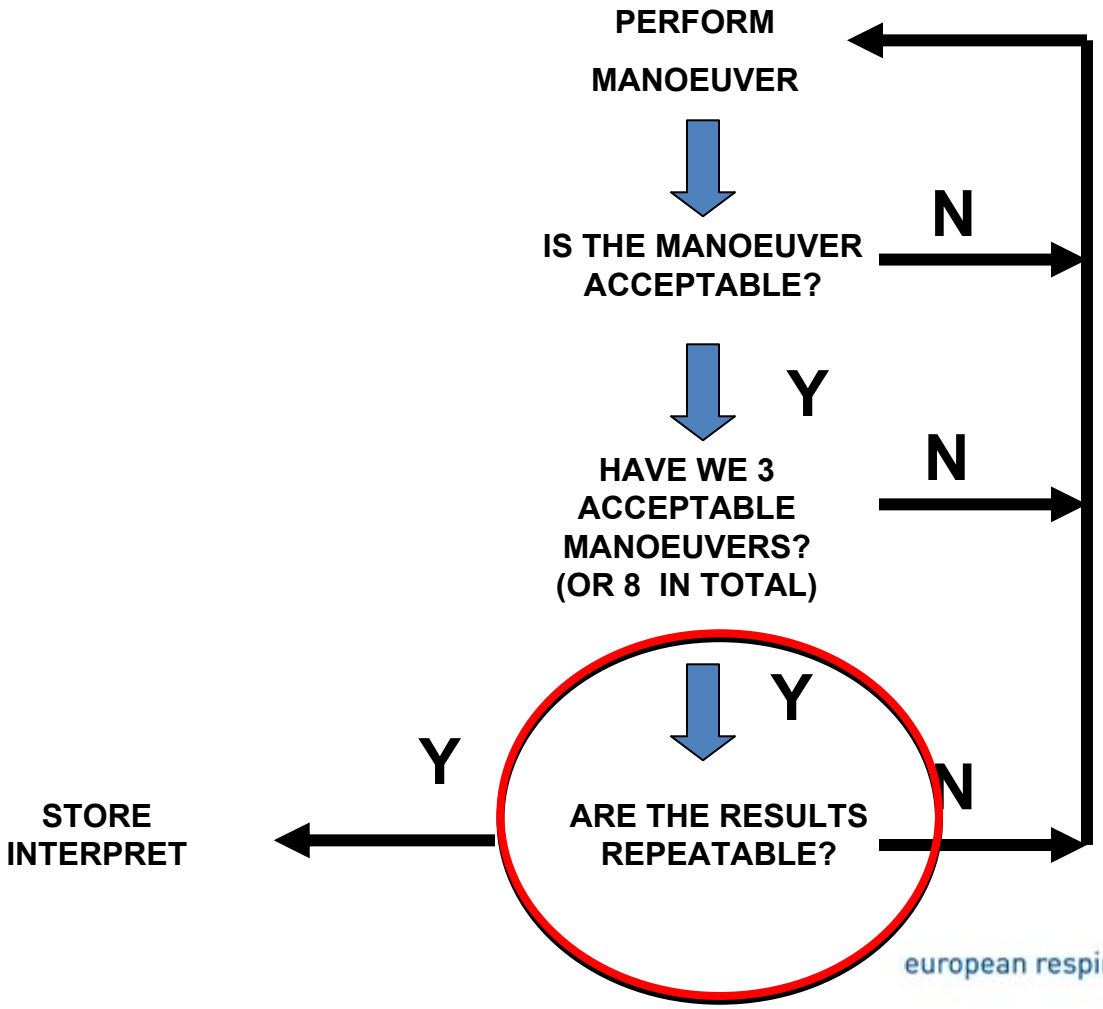




Glottis closure (abrupt end)
Expiratory time ~ 1s

h counts

WHEN CAN WE INTEPRETE SPIROMETRY DATA?



REPEATABILITY CRITERIA

The difference between best and the second best value of FEV_1 <150 ml

AND

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

SELECTION OF THE BEST CURVE

After having three acceptable manouevers:

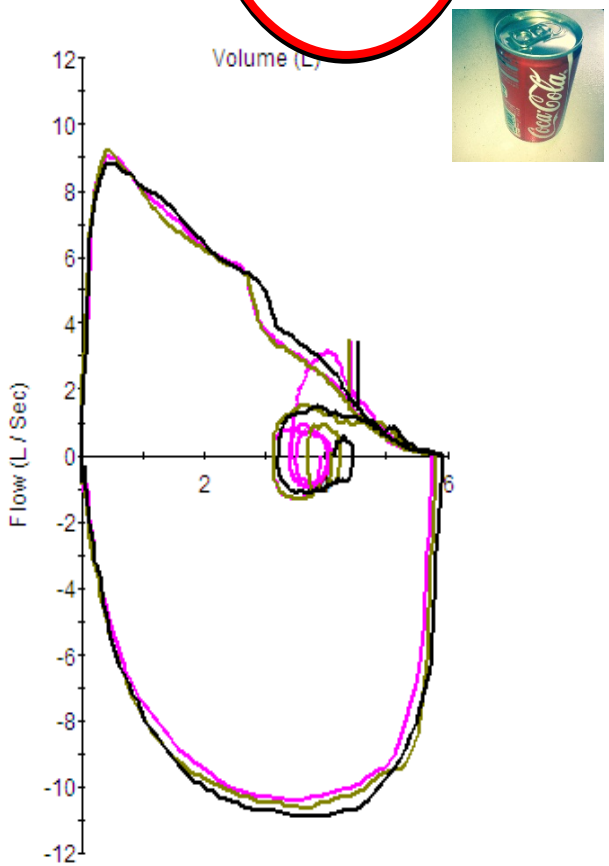
-Check repeatability for FVC and FEV_1

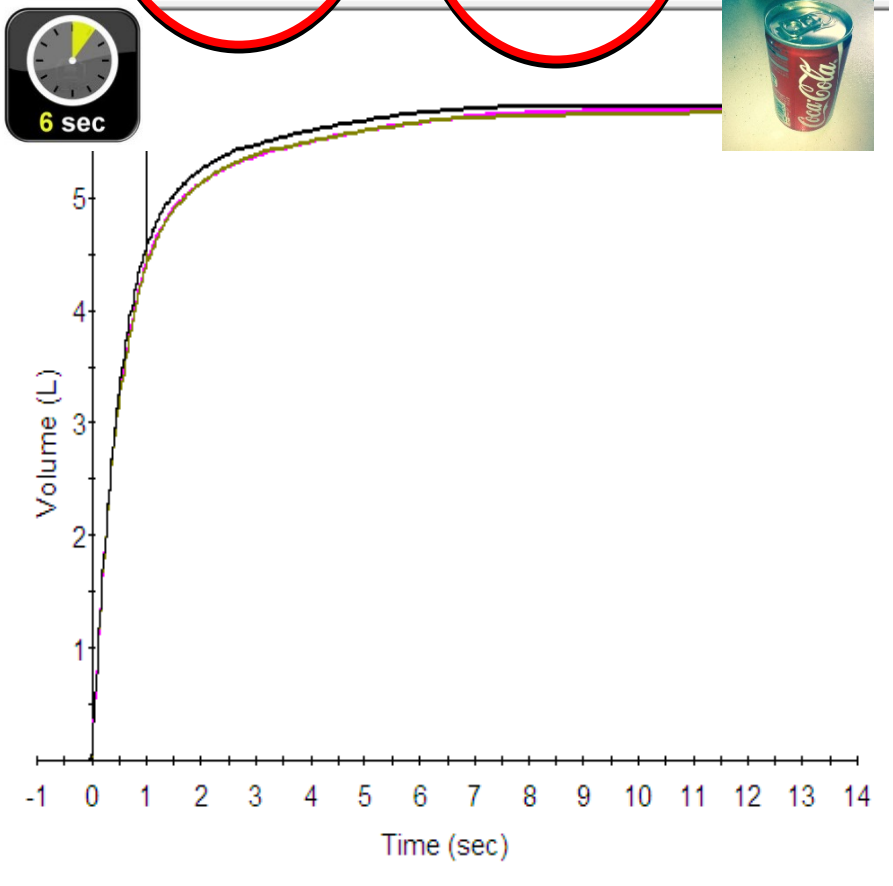
-Calculate FEV_1/FVC from the highest values obtained

-Select the manoeuver with the highest sum of FEV_1 and FVC (all other indices i.e. flows are taken from that manouever)

EXAMPLE

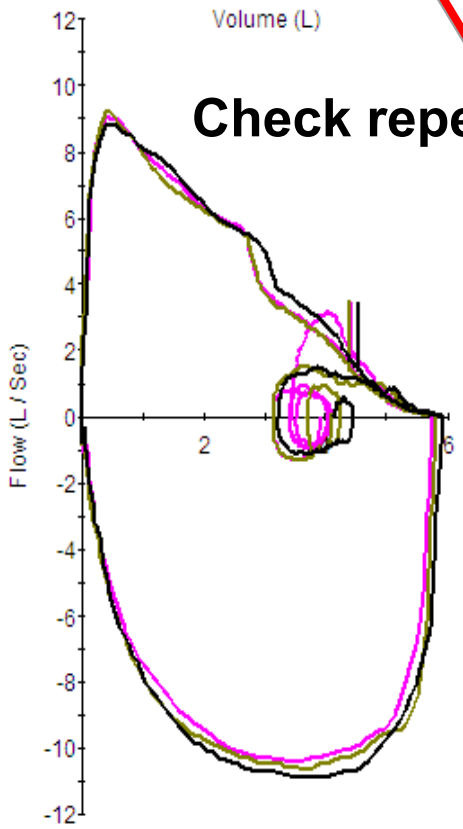
Time	Select	I-Lp	Test Mode	ATS	FVC absolute	FEV1 absolute	FEV1/FVC absolute	FEF 25-75% absolute	FEF Max absolute	Expiratory Time absolute	To FEFm absolute	Back Extrap Vol absolute
Predicted					6.29	4.98	80	4.57	11.5			
Pre												
13:45:25	☑	☐			5.82	4.56	78	4.13	8.8	11.91	0.044	0.07
13:43:47	☑	☐			5.77	4.43	77	3.78	8.8	11.78	0.046	0.09
13:44:34	☑	☐			5.75	4.40	76	3.72	8.94	13.16	0.042	0.06
ATS			Pre/Baseline		5.82	4.56	78	4.13	8.94	11.91	0.044	0.07



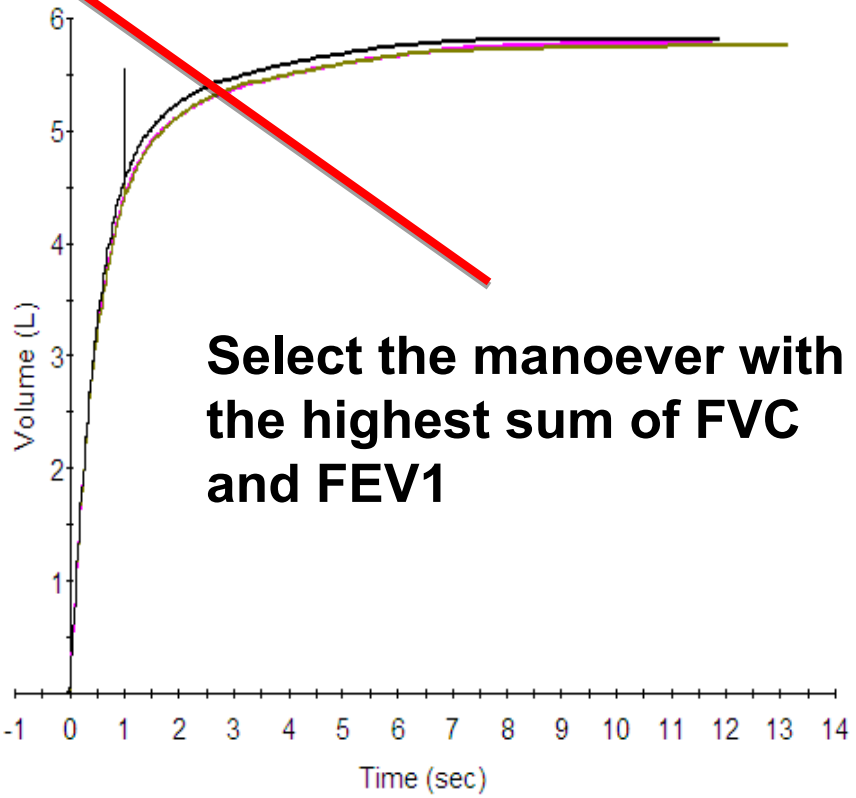


EXAMPLE

Time	Select	I-Lp	Test Mode	ATS	FVC	FEV1	FEV1/FVC	FEF 25-75%	FEF Max	Expiratory Time	ne To FEFm	Back Extrap Vol
					absolute	absolute	absolute	absolute	absolute	absolute	absolute	absolute
Predicted					6.29	4.98	80	4.57	11.50			
Pre												
13:45:25	☑	☐			5.82	4.56	[illegible]	4.13	8.61	11.91	0.044	0.07
13:43:47	☑	☐			5.77	4.43	77	3.78	8.87	11.78	0.046	0.09
13:44:34	☑	☐			5.75	4.40	76	3.72	8.94	13.16	0.042	0.06
ATS			Pre/Baseline		5.82	4.56	78	[illegible]	8.94	11.91	0.044	0.07



Check repeatability



Select the manoever with the highest sum of FVC and FEV1

REFERENCE VALUES

- Spirometric data of a patient/subject are evaluated by comparison with reference (predicted) values based on healthy subjects.
- „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."
- Currently, this committe does not recommend any specific set of equations for use in Europe, but suggests the need for a new Europe-wide study to derive updated reference equations for lung function.

ERS

BUT SINCE 2012…

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

Eur Respir J 2012

IF YOU ARE TOTALLY CONFUSED NOW…

Sanja Stanojevic[1], Philip Quanjer[2], Martin R. Miller[3], Janet Stocks[4]

[1]Division of Respiratory Medicine, Hospital for Sick Children, Toronto, Canada
[2]Department of Pulmonary Diseases and Department of Paediatrics, Erasmus Medical Centre, Erasmus University, Rotterdam, The Netherlands
[3]Institute of Occupational and Environmental Medicine, University of Birmingham, Birmingham
[4]Portex Respiratory Unit, Institute of Child Health, University College London, London, United Kingdom

Sanja Stanojevic: Respiratory Medicine, Hospital for Sick Children, Toronto, Canada

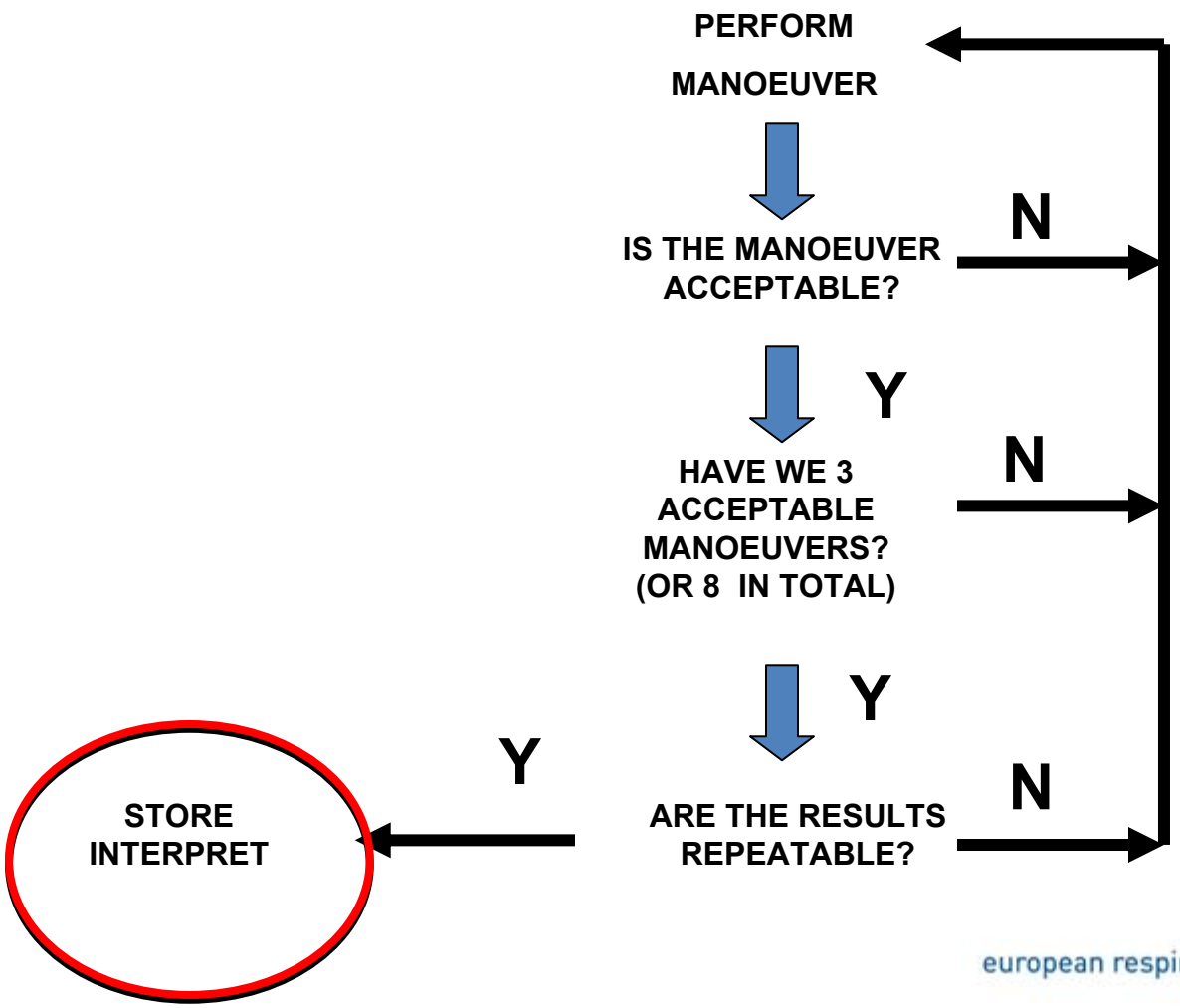
Sanja.stanojevic@sickkids.ca

The Global Lung Function Initiative: dispelling some myths of lung function test interpretation

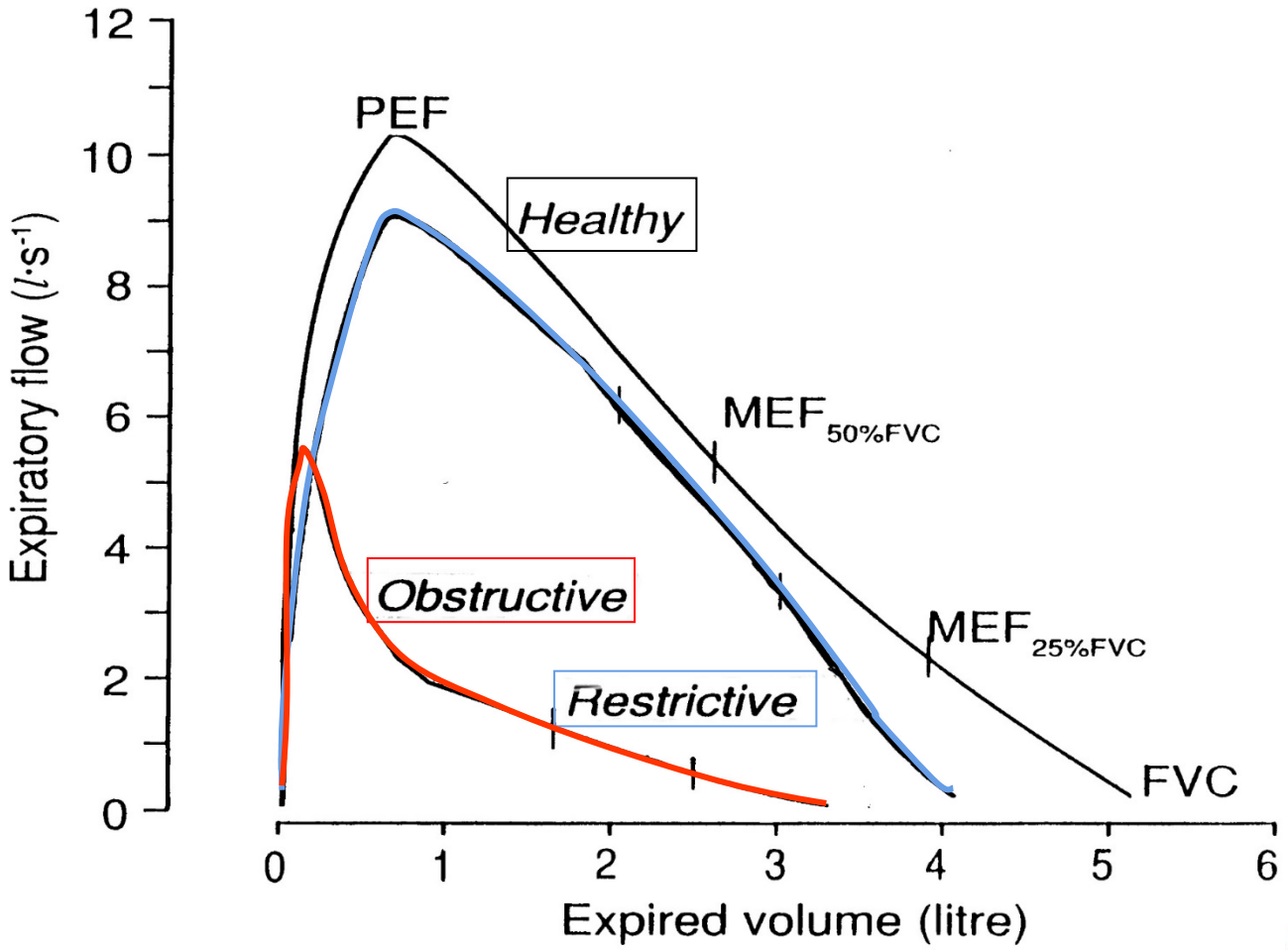
Breathe 2013

european respiratory society every breath counts

WHEN CAN WE INTEPRETE SPIROMETRY DATA?

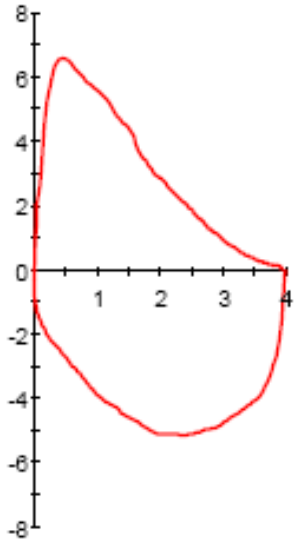


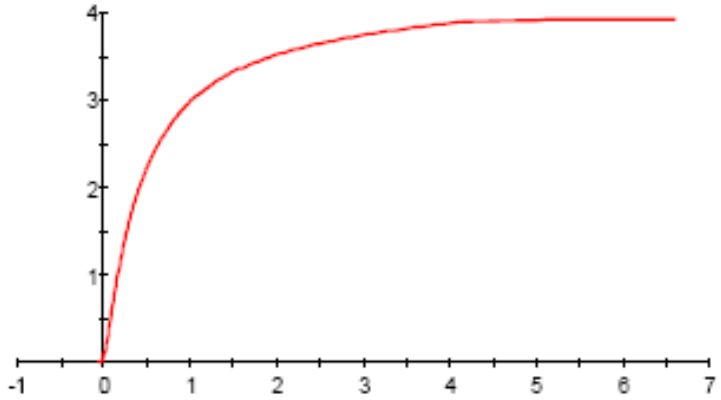
TYPES OF VENTILATORY DEFECTS



Quanjer Ph et al. ERJ 1993

NORMAL SPIROMETRY





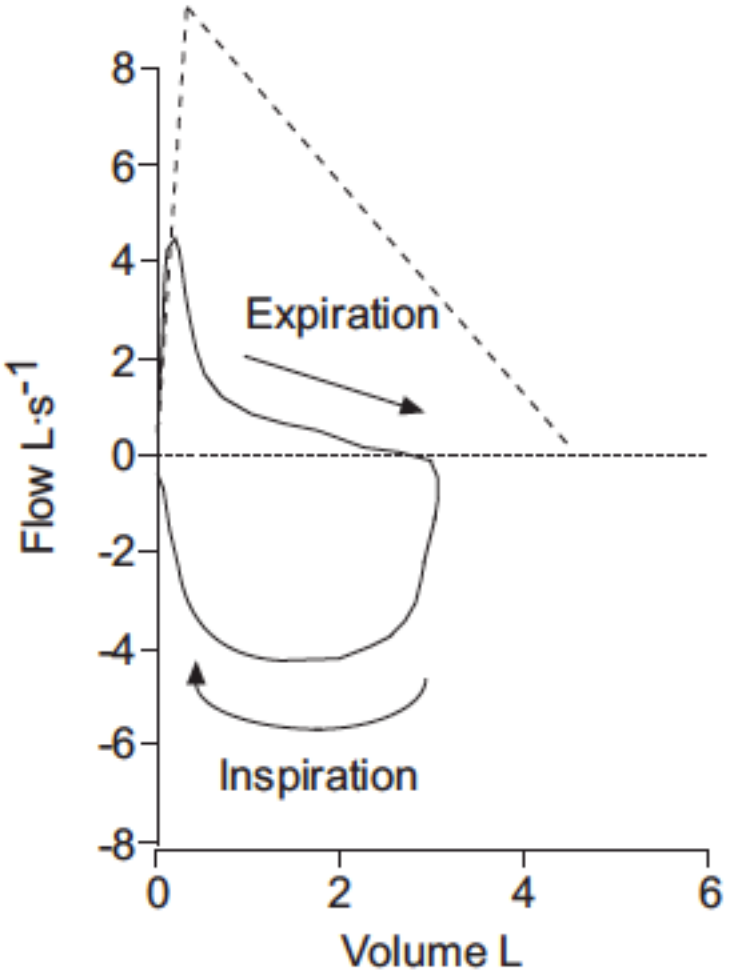
Bez leku

	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

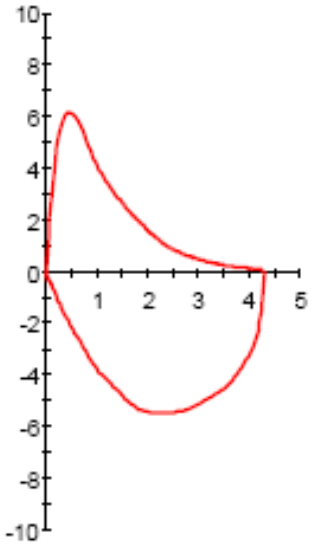
Expiratory Time (sec)	6,6
Time To FEFmax (sec)	0,07
Back Extrap Vol (L)	0,08

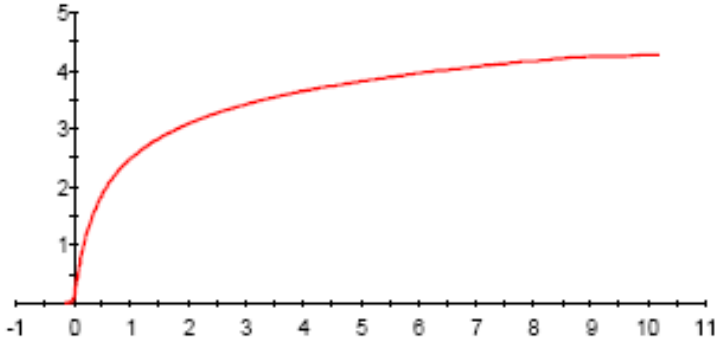
OBSTRUCTIVE ABNORMALITIES

- An obstructive ventilatory defect is a disproportionate reduction of maximal airflow from the lung in relation to the maximal volume.
- It implies airway narrowing during exhalation.
- It is defined by reduced FEV_1/VC ratio below 5th percentile of a predicted value.
- concave shape on the flow–volume curve



OBSTRUCTIVE ABNORMALITIES



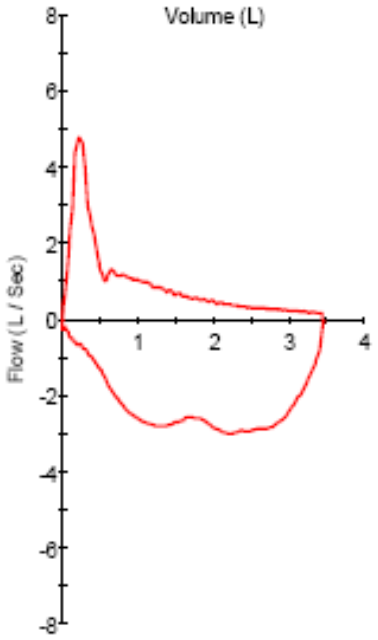


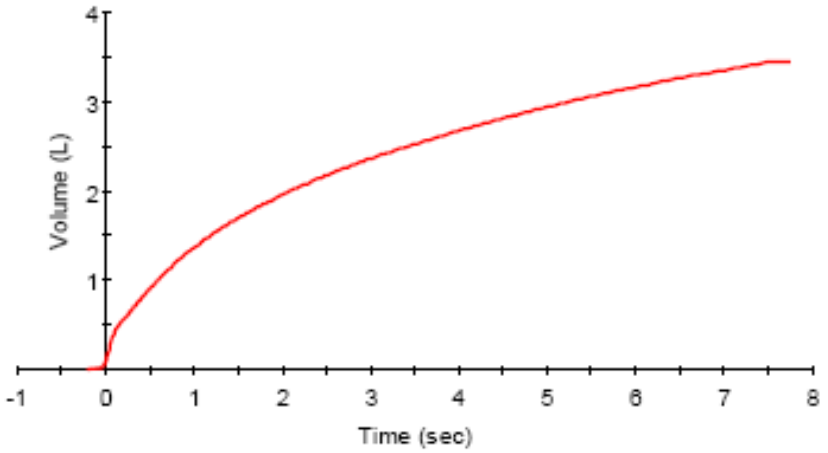
Bez leku

	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

OBSTRUCTIVE ABNORMALITIES





Bez leku

	Actual	Pred	%Pred	LLN	#SD
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

REVERSIBILITY TESTING

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

-After a single dose of bronchodilator

-After clinical trial lasting 2-8 weeks

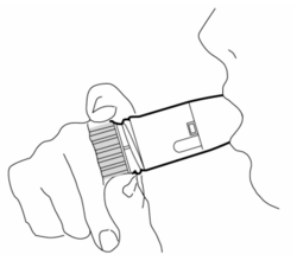
There is no consensus about the drug, dose or mode of administering a bronchodilator in the laboratory.

PERFORMING BRONCHODILATOR TEST

- Baseline spirometry
- Administration of standard dose of SABA
- Postbronchodilator spirometry
  - at least 15 minutes after delivering bronchodilator

IMPORTANT:

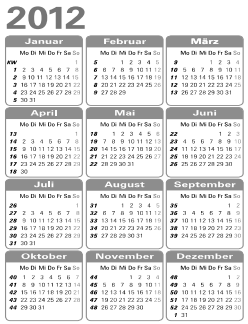
- Both spirometries have to be properly performed
- The drug should be properly delivered



ASSESSMENT OF BRONCHODILATOR TEST

Significant response (FEV1 or FVC in comparison to baseline)

- Increase of >12%

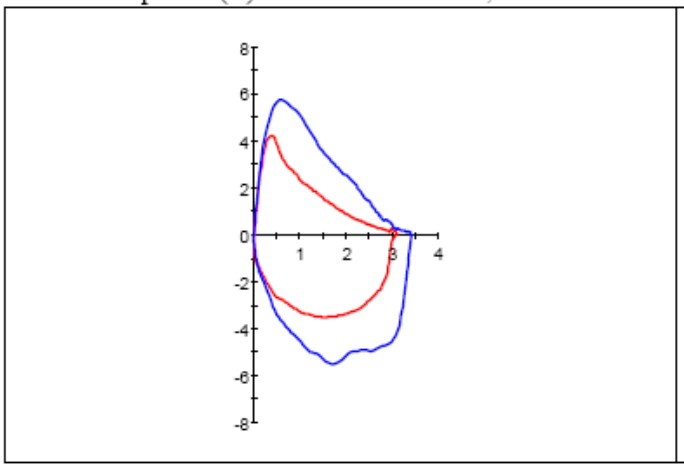


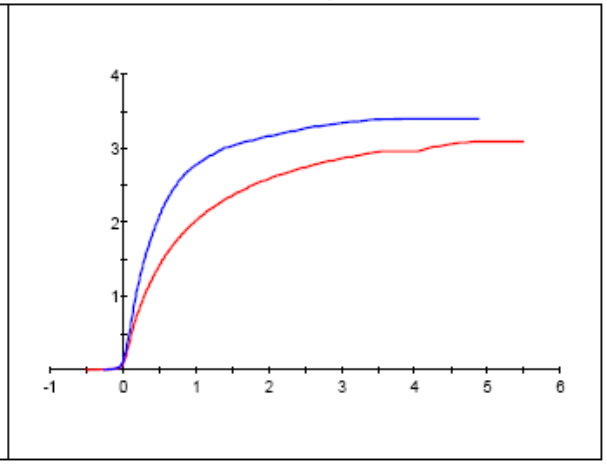
AND

- change >200 ml

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
Expiratory Time (sec)	5,5					4,9		-11
Time To FEFmax (sec)	0,09					0,11		23
Back Extrap Vol (L)	0,10					0,14		38





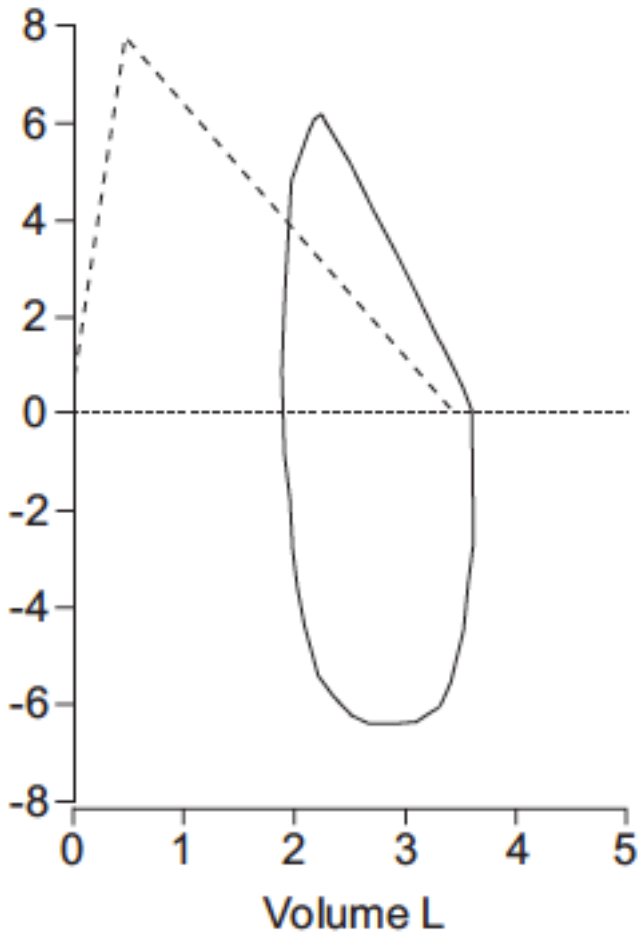
ΔFEV1 = 750 ml and 37% from the baseline (24% pred)

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

Significant response

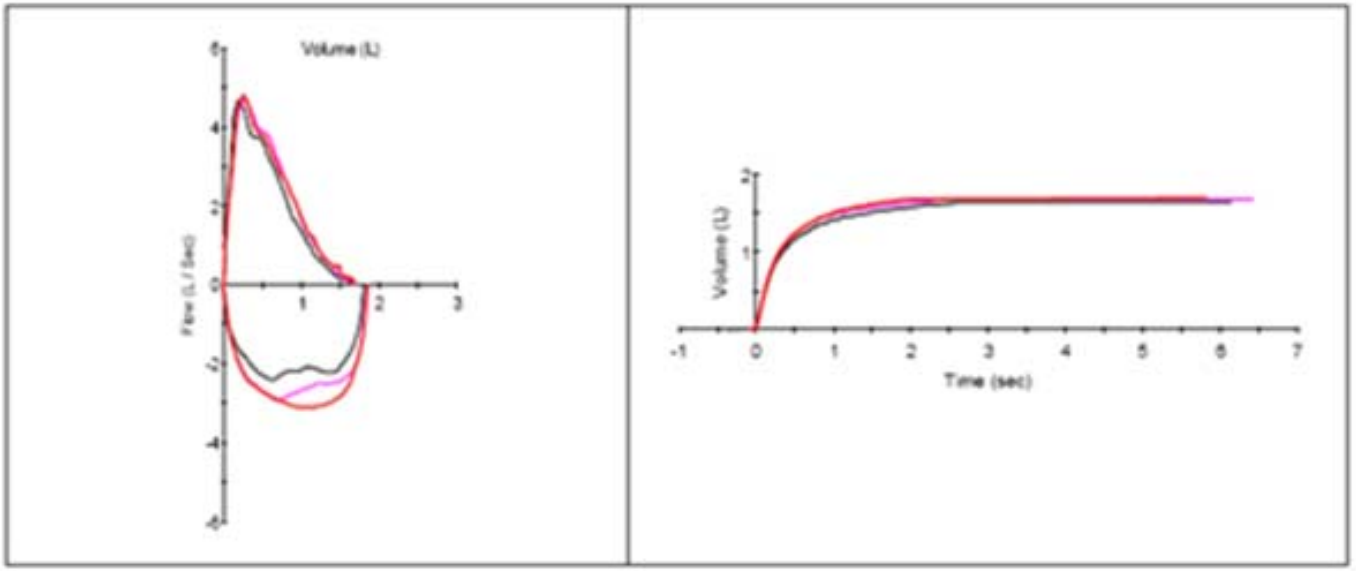
OBSTRUCTIVE ABNORMALITIES

- Cannot be determined by spirometry
  - A restrictive ventilatory defect is characterised by a *reduction in TLC below the 5th percentile of a predicted value* and a normal FEV1/VC
- The presence of a restrictive ventilatory defect may be suspected when VC is reduced, the FEV1/VC is increased (85–90%)



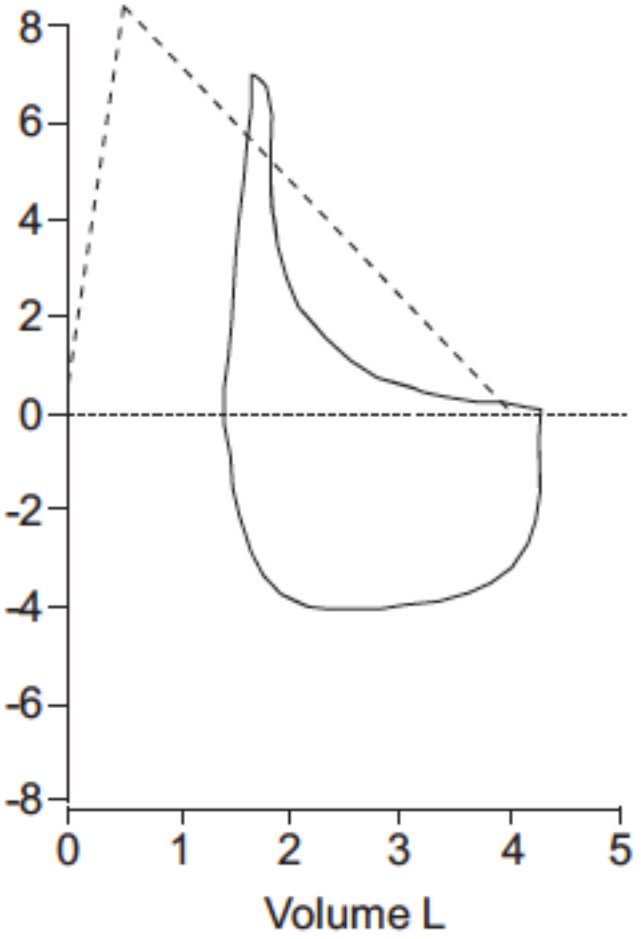
RESTRICTIVE PATTERN

	Actual	Pred	%Pred	LLN	#SD
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				



MIXED ABNORMALITIES

- A mixed ventilatory defect is characterised by the coexistence of obstruction and restriction.
- Since VC may be equally reduced in both obstruction and restriction, the presence of a restrictive component in an obstructed patient cannot be inferred from simple measurements of FEV1 and VC.



CAUSES OF LUNG DISORDERS

Chronic or reversible airway obstruction

Examples:
- chronic (obstructive) bronchitis
- emphysema
- bronchial asthma

Restrictive lung disorders

Intrapulmonary disorders:

Examples:
- lung fibrosis
- pneumectomy / lobectomy
- atelectasis

Extrapulmonary disorders :

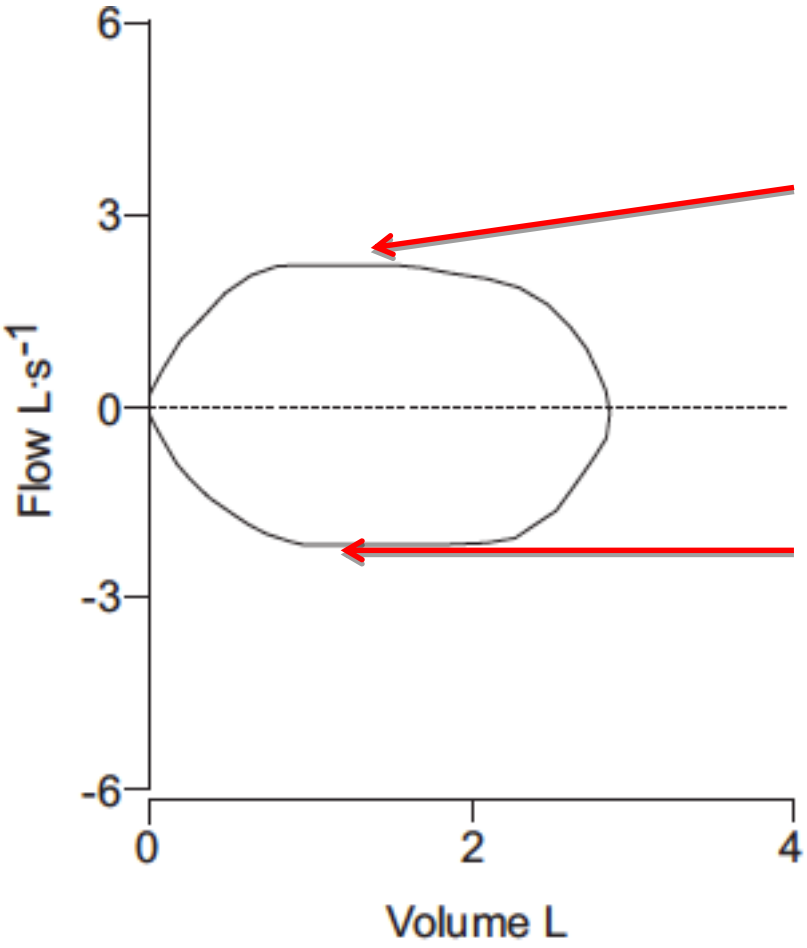
Examples:
- (cooperation failure)
- diaphragm paralysis
- kyphoscoliosis

CENTRAL AND UPPER AIRWAY OBSTRUCTION

- Central airway obstruction and upper airway obstrucion may occur in the extrathoracic (pharynx, larynx, and extrathoracic portion of the trachea) and intrathoracic airways
- Maximum expiratory flow at high lung volume (especially peak flow) is generally decreased in both intrathoracic and extrathoracic lesions

CENTRAL AND UPPER AIRWAY OBSTRUCTION

Fixed airway obstruction

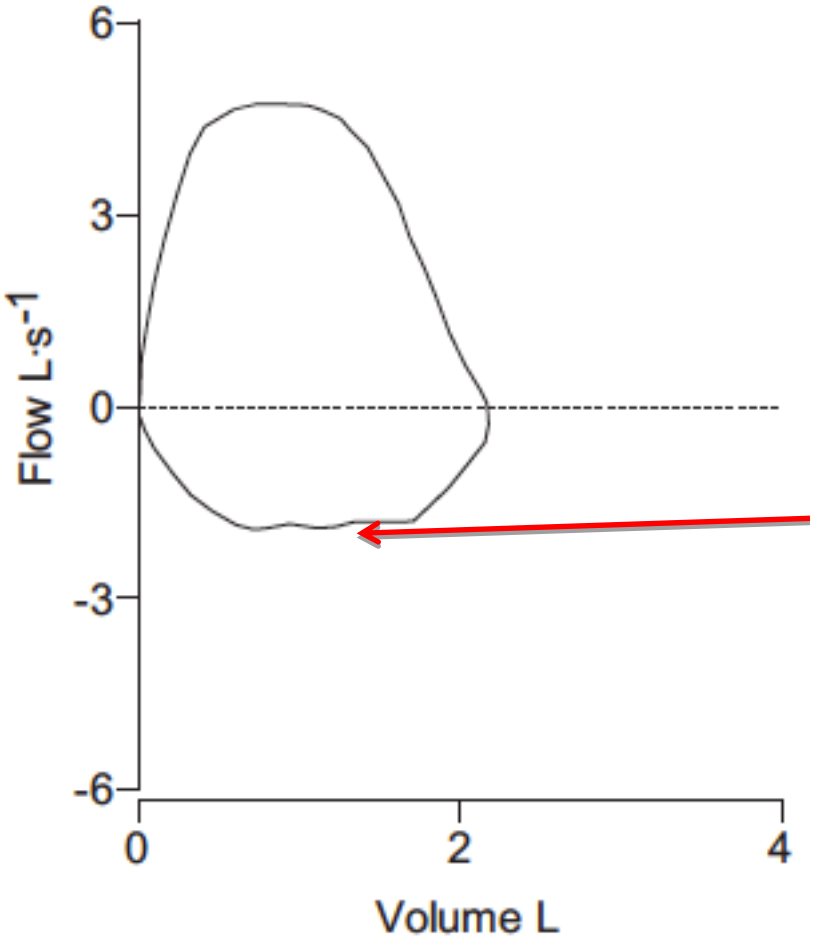


repeatable plateau of forced expiratory flow

repeatable plateau of forced inspiratory flow

CENTRAL AND UPPER AIRWAY OBSTRUCTION

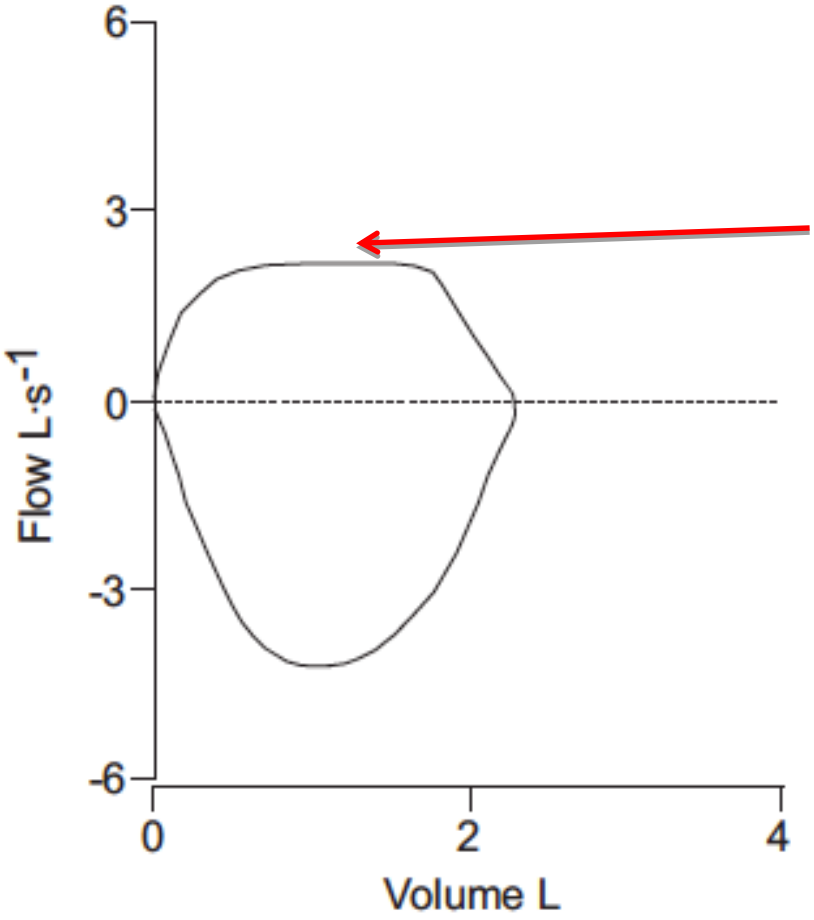
Variable extrathoracic airway obstruction



repeatable plateau of
forced inspiratory flow

CENTRAL AND UPPER AIRWAY OBSTRUCTION

Variable intrathoracic airway obstruction



repeatable plateau of forced expiratory flow

SEVERITY CLASSIFICATION

- FEV_1 % pred is generally used to grade severity in patients with obstructive, restrictive and mixed pulmonary defects *(NOT upper airway obstruction!)*
- The FEV_1/VC ratio should not be used to determine the severity of an obstructive disorder, until new research data are available.

Degree of severity	FEV1 % pred
Mild	>70
Moderate	60–69
Moderately severe	50–59
Severe	35–49
Very severe	<35

SUMMARY

Spirometric results evaluation may be considered as a two-step process.

1. Analysis of performance and evaluating with respect to quality criteria defined by the standard.
2. Interpretation of spirometric results to distinguish types of ventilator defects
   - A recommended way of interpreting the results is to compare the measured values with lower limit of normal
   - There are obstructive, restrictive and mixed patterns of spirometry

ACKNOWLEDGMENTS

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

Overview of Part II including the completion and submission of the ERS spirometry workbook

Dr Felip Burgos
Department of Pneumology
Hospital Clínic
Villarroel, 170
08036 Barcelona
Spain
fburgos@ub.edu

ERS EUROPEAN RESPIRATORY SOCIETY

every breath counts

Posgraduate Course: PG 9

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

Disclosure

Felip Burgos :

- Socks of Linkcare® Health Solutions SL

ERS

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***.

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

Part II – Spirometry Competency Based Training and Assessment

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

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 Clínic, 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)*

ounts

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?).

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.).

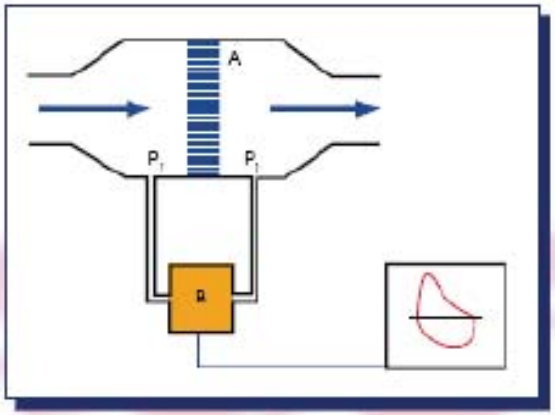
7. With the aid of a diagram, describe the way in which your spirometer measures spirometry values.

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



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.

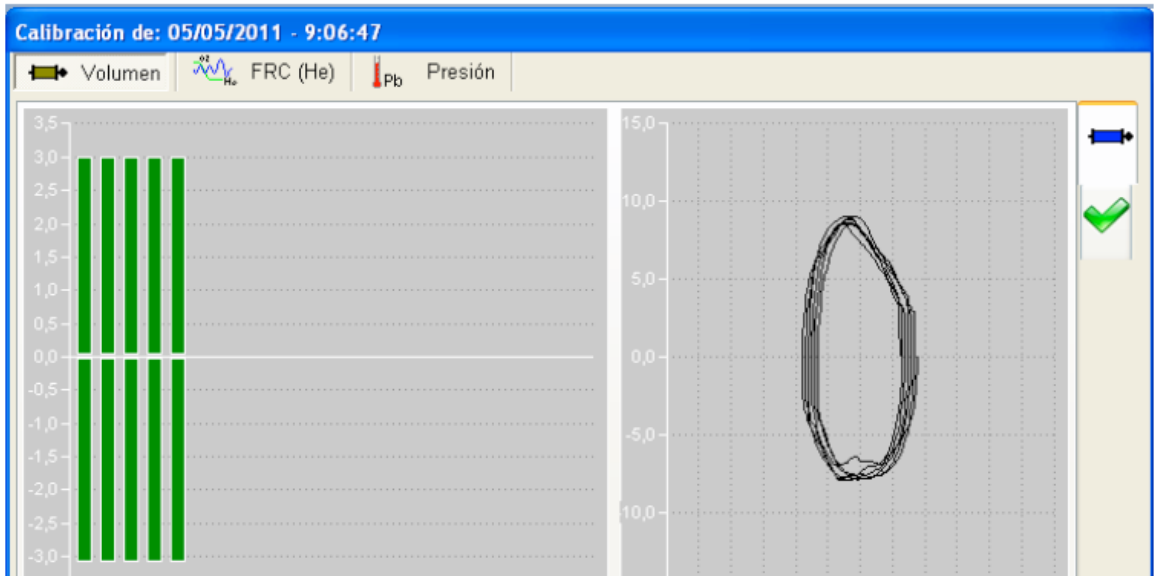
11. Patient tests.

12. Problems encountered during testing.

SECTION B.

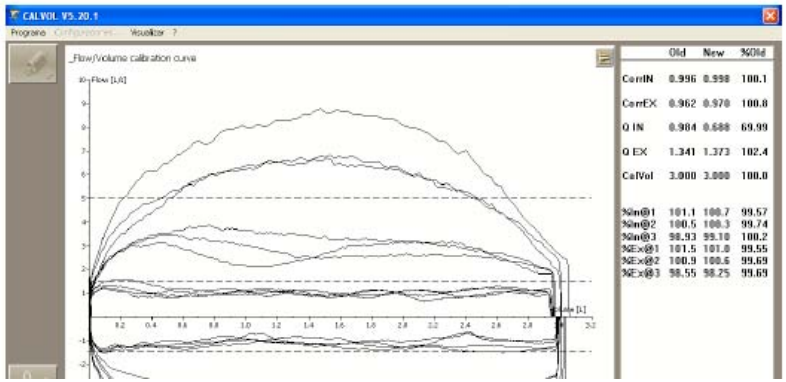
8. Calibration or verification of your spirometer.

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 made with the use of a 3 liter syringe at different flows. An example is shown in a hardcopy.



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.

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)

The use of in-line filters does not eliminate the need for regular cleaning and decontamination of spirometric equipment

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.

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.

Calibration or Verification.

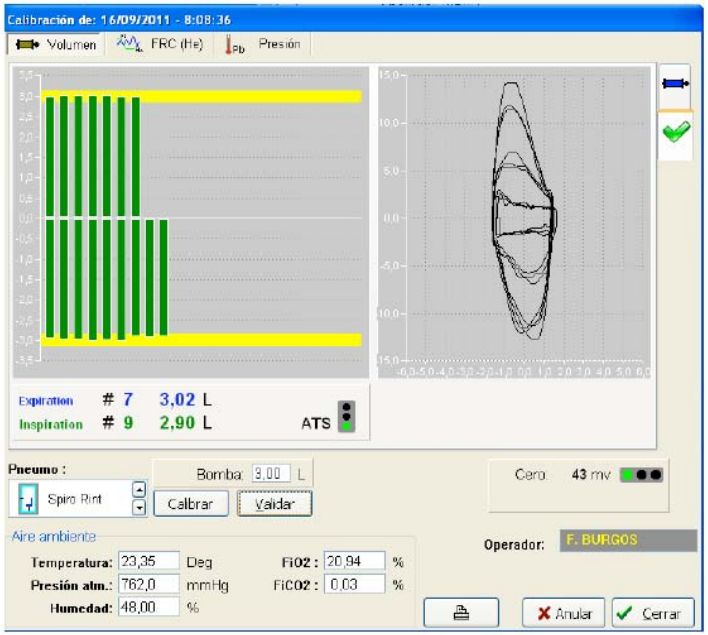
- **This section consists of TWO parts:**

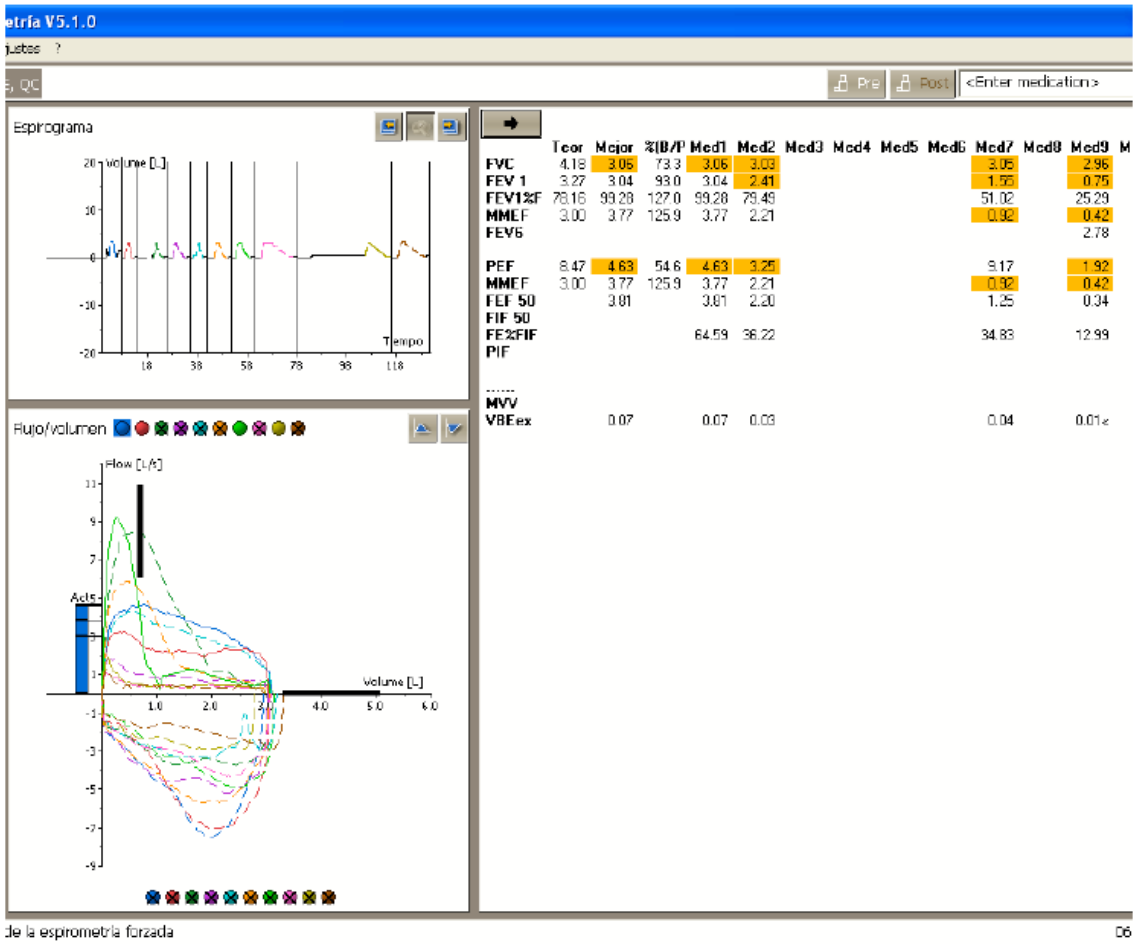
a. **A short piece of written work must be submitted explaining why your spirometer must be calibrated or verified regularly and a description of how you would do this.**

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.**





A hardcopy of linearity assessment: Three attempts at different flows. See FVC variation from 3.06 to

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.**

QUALITY CONTROL

Used a team member

Portfolio of Dr A P Foden

Date	VC	FVC	FEV1
18/20/2013	4.28	4.78	3.43
20/12/2013	3.91	4.33	3.33
23/12/2013	4.02	4.15	3.22
03/01/2014	4.11	4.22	3.11
06/01/2014	4.37	4.49	3.14
10/12/2014	4.08	4.17	3.19
12/01/2014	4.07	4.12	3.15
23/01/2014	4.23	4.31	3.22
24/01/2014	4.18	4.29	3.32
25/01/2014	4.09	4.13	3.37
Totals	41.34	42.99	32.48
Mean	4.13	4.30	3.25
SD	0.13	0.19	0.10
2SD	0.26	0.38	0.20
Range ±2SD			
from:	3.87	3.92	3.05
to:	4.39	4.68	3.45

Audit of the Quality Spiromety in our CRD (High quality A+B 83 %) **Sample = 30 (February 2012)** We are making this kind of AUDIT in a systematic and date 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	

11. Patient Tests

You must produce 10 technically acceptable spirometry traces for FEV_1, FVC, FEV_1/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**

Institution:Bishop Auckland General Hospital
Department:Cardio Pulmonary Department

Printed: 06/02/2014 10:25

Vitalograph

Pulmonary Function Report

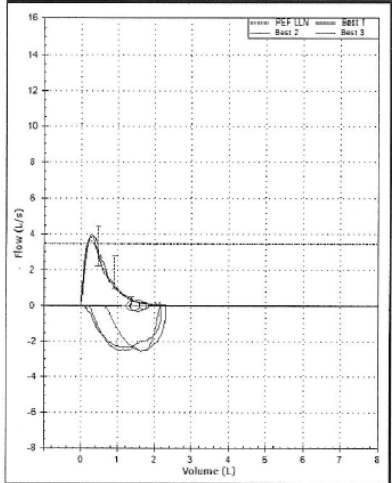
Subject Information

Last Name:	[redacted]	ID:	2009288_115146232	Alternate ID:	B320117
First Name:		Date of Birth:	29/12/1921	Age:	92
Middle Name:		Height:	160 cm	Gender:	Female
Population:	European	Weight:		BMI:	

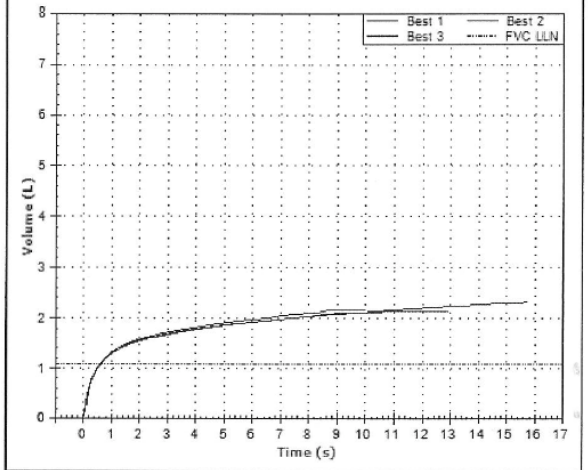
Test Session Information

Test Date:	06/02/2014 10:19	Device:	Pneumotrac	Serial Number:	06172
No. of Tests:	3	Accuracy Chk:	06/02/2014 08:46	User:	foden
Pred. Values:	ERS '93/Polgar	Pred. Factor:	100%	Posture:	Sitting
Values at BTPS					

Flow/Volume Graph



Volume/Time Graph



Results

Parameter	ATS/ERS Best	Pred	% Pred.	Best 1(Test 3)	Best 2(Test 2)	Best 3(Test 1)
				10:23:40	10:21:33	10:19:52
VC (L)	**2.33**	**1.78**	**131**	2.33	2.33	2.33
FVC (L)	**2.32**	**1.81**	**128**	2.32	2.18	2.14
FEV1 (L)	**1.32**	**1.42**	**93**	1.30	1.32	1.28
FEV1 Ratio	**0.57***	**0.72**	**79**	0.56*	0.57*	0.55*
PEF (L/Min)	**241**	**296**	**81**	236	241	220
FEF25-75 (L/s)	**0.36***	**1.79**	**20**	0.36*	0.51	0.47
FEF50 (L/s)	**0.60***	**2.78**	**22**	0.60*	0.77*	0.73*

*Below lower limit of normality (LLN)

Session Quality and Repeatability Information

Session Grade	FVC Rep:	FEV1 Rep:	Slow Start of test	End of test criteria not achieved	Cough detected in 1st second
A	0.14 L	0.02 L	0 blow(s)	0 blow(s)	0 blow(s)

Computer Suggested Interpretation

Moderate airways obstruction.

ATS

Comments: Expiratory curves meet ATS criteria. Only 2 inspiratory curves are reproducible. They also fall short of the beginning of the expiratory curve, a problem often due to doing the Expiratory blow before the Inspiratory inhalation (the opposite to which I was trained)

Interpretation: FEV1/FVC ratio and FEF25-75 fall below the LLN so compatible with mild obstruction, not moderate as suggested by the machine interpretation algorithm.

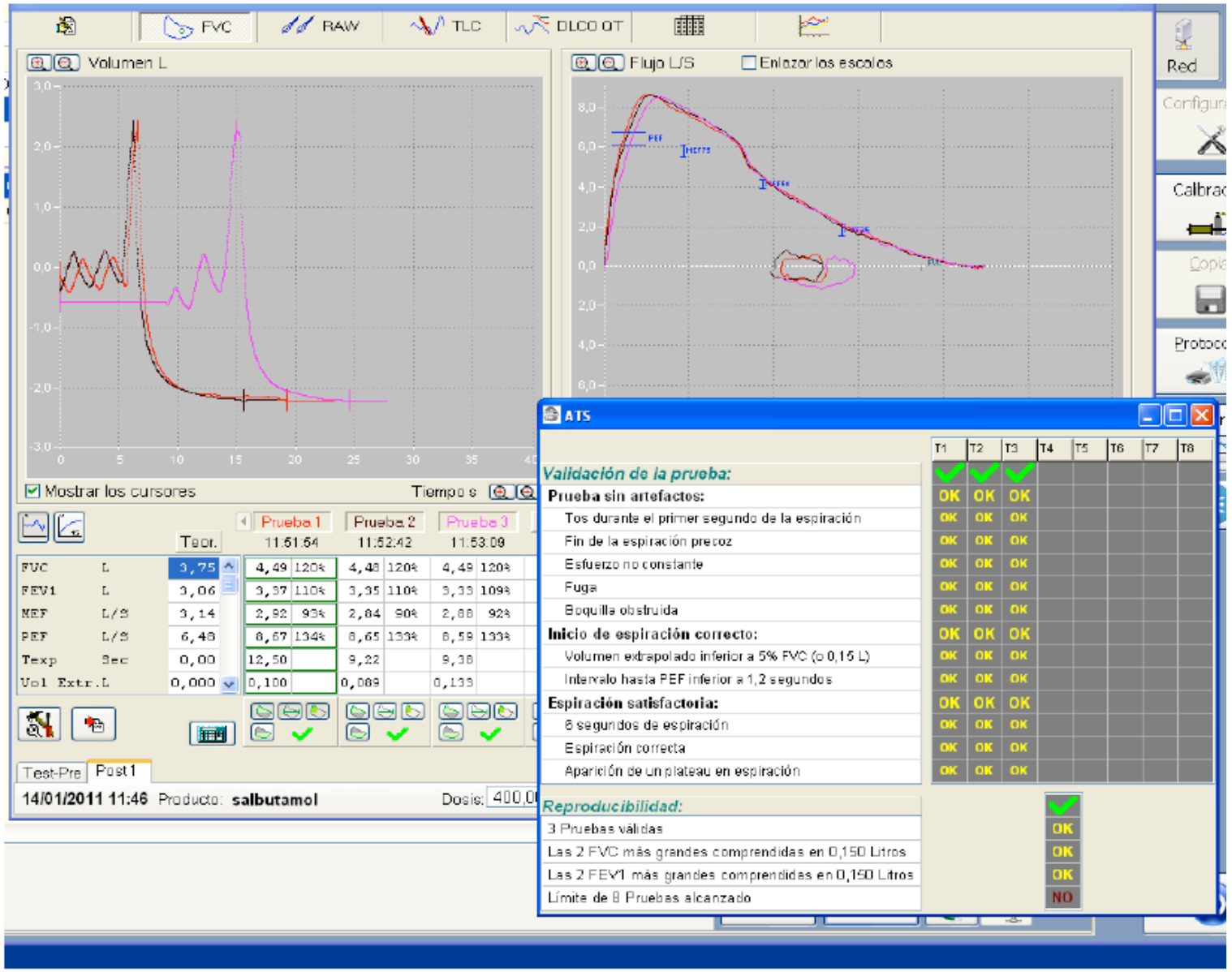
12. Problems Encountered During Testing.

- 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

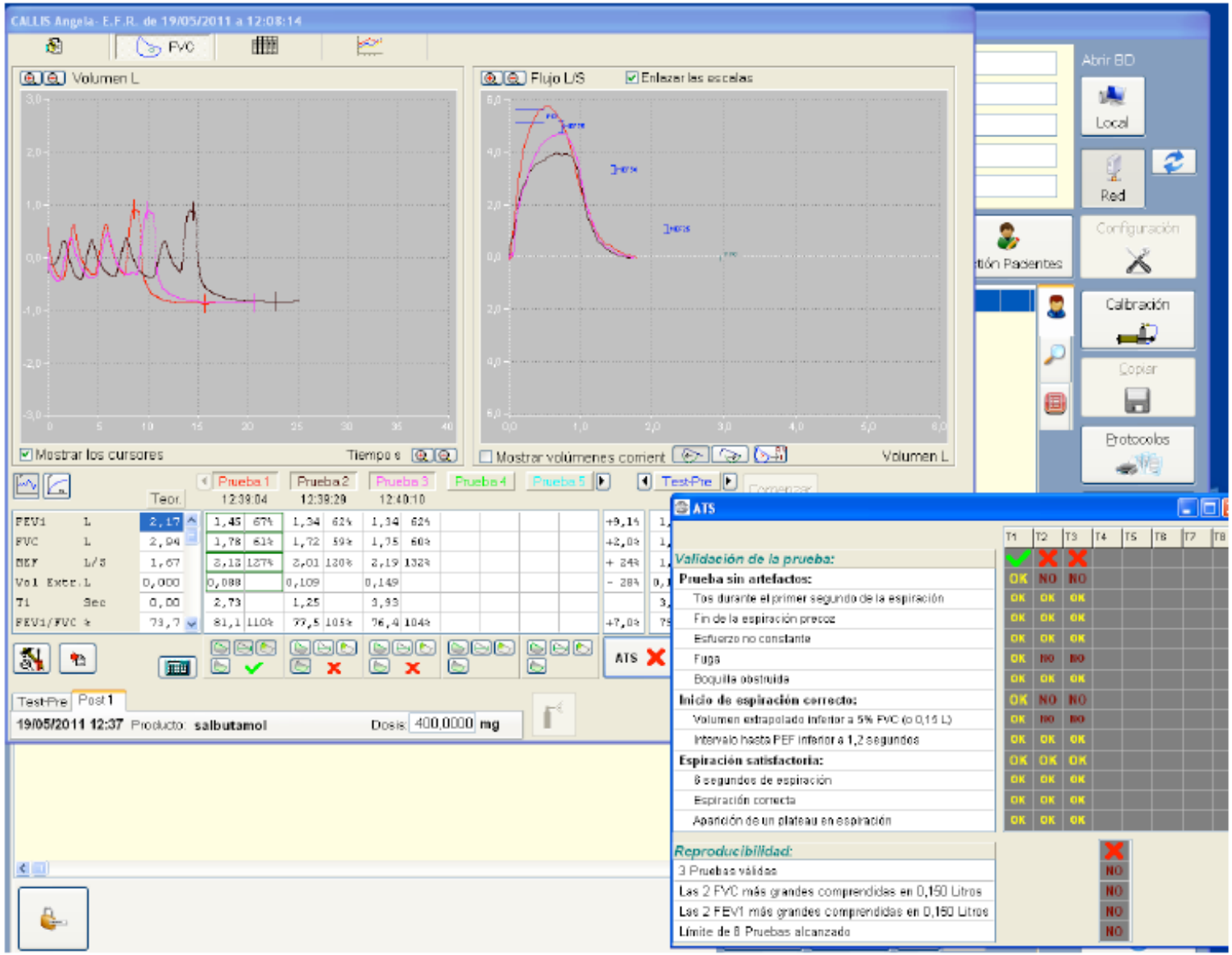
- the problems. The problems may include patient, technical or equipment issues

Example N. 1. Medisoft



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

Interpretation: Normal spirometry



EXPLANATION: Expiratory peak flow is variable between maneuvers

Equipment and infection control: demonstration of how different types of spirometers work and how they are cleaned and maintained

Ms Jellien Makonga-Braaksma
Pulmonary Function Department
Meander Medisch Centrum
Maatweg 3
3813 TZ Amersfoort
Netherlands
j.makonga@meandermc.nl

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

SUMMARY

Types of spirometers

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.

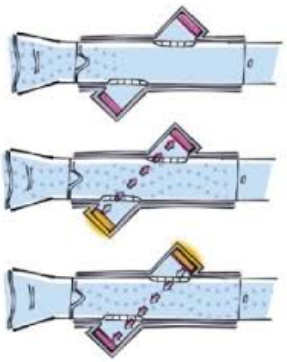
We discern fixed devices (eg. Vitalograph) which have to be used with a bacteriafilter, and disposable devices (USB type) (eg. Welch Allyn).

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: High cost of sensor.

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.

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INSTRUCTION SHEET

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.

Spirometry: performing the test, safety measures, selecting the best values and simulating errors

Ms Julie K. Lloyd
Respiratory & Sleep Investigation
Area A, Treatment Centre
Good Hope Hospital
Rectory Road
Sutton Coldfield B75 7RR
United Kingdom
julie.lloyd@heartofengland.nhs.uk

Prof. Waldemar Tomalak
Physiopathology of Respiratory System
Institute for TBC and Lung Diseases
Profesora Rudnika 3
34-700 Rabka-Zdrój
Poland
wtomalak@igrabka.edu.pl

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CHECKLIST

Before starting measurements

Spirometer

	Ensure that the spirometer is calibrated or verified using a 3 litre syringe.
	Measure and record the ambient conditions.
	Use appropriate infection control measures (wash hands, use hand gel or use gloves).

Patient

	Accurately measure the patient's height.
	Check the personal data including sex, age and ethnic origin. Obtain any other information required by your local protocol or spirometer software.
	Review the patients smoking history.
	Review any contraindication that may make the test impossible or very difficult.
	Check that the patients has adhered to any pre-test requirements (Avoiding large meal, taking inhalers, smoking etc).
	Explain carefully how to perform the test, pay special attention to the language you use. *Patients may not understand clearly very specific technical language (that is used for example in definitions)*
	Ensure that the patient is in safe position, and he is sitting properly, feet placed firmly on the floor with the head straight
	Ensure that the mouthpiece is in the correct position. Sealed tightly with the lips, and that there is no leak.

Measurement

	1. Perform the measurement
	2. During the manoeuvre encourage the patient to make a maximal effort and continue prolonged expiration
	3. Check acceptability of the manoeuvre
	4. Repeat steps 1-3 as long as you have 3 acceptable manoeuvres
	5. Check values for repeatability
	6. Choose the best manoeuvre

Calibration and quality control

Dr Felip Burgos
Department of Pneumology
Hospital Clínic
Villarroel, 170
08036 Barcelona
Spain
fburgos@ub.edu

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

AIMS

This review together with a lecture during the Postgraduate Course and a special workstation during the Educational Skills Workshop is planned to give the participants the theoretical background about quality assurance in the lung function laboratory and the possibility to perform calibration checks on different devices and to better understand biological control procedures.

Topics covered here belong mostly to Module 6 (quality assurance and infection control), but these are also important when dealing with Module 3 (spirometry equipment) and Module 5 (spirometry technique), all three of ESDL Part I, and also when preparing your workbook for ESDL Part II. Infection control and recognising abnormal traces due to technical or patient errors can also be considered as part of the quality assurance, but will be dealt with in other chapters of ESDL materials.

SUMMARY

Attention to spirometry equipment quality control and calibration is an important part of good laboratory practice. The American Thoracic Society (ATS) and the European Respiratory Society (ERS) have published guidelines for lung function testing, explanation of terms used in quality assurance and also summary of technician's role in quality control can be found from the general paper [1], more detailed description of calibration and calibration check of spirometers is given in the paper about spirometry [2]. There are also more recent papers based on ERS/ATS standards, e.g. with the proposed standards for diagnostic spirometry in primary care [3] or national quality control guidelines [4]. In addition, you can find several videos illustrating the calibration of different spirometers [5], but for your particular type of the spirometer the calibration and/or calibration check of the equipment must be performed in accordance with the equipment manual.

Definitions of some terms used in quality assurance

The metrology definitions agreed by the International Standards Organization (ISO) are recommended, some important terms with definitions are given below [1, 6-8]:

Quality management – coordinated management activities to direct and control an organization with regard to quality (example: ISO 9000). Quality control (QC) – part of quality management focused on fulfilling quality requirements. 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). The term QC can also be defined as the process of monitoring the precision and accuracy of a test procedure. The term QA not only encompasses QC but includes many other activities such as: maintaining and calibrating equipment, training personnel and continued competency assessment, reporting results, and record keeping [7]. QA is also checking that each set of tests performed adheres to international standards [8].

Accuracy is the closeness of agreement between the result of a measurement and the conventional true value. The precision of a measurement system, related to repeatability and reproducibility, is the degree to which repeated measurements show the same results. There is a nice online video explaining the difference between accuracy and precision [9].

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.

Reproducibility is the closeness of agreement between the results of successive measurements of the same item where the individual measurements are carried out with changed conditions, such as: method of measurement, observer, instrument, location, conditions of use, and time. Thus, 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 min, one needs to know the reproducibility of the test in order to make a decision on this comparison.

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

Calibration check (or verification) is different from calibration and is the procedure used to validate that the device is within calibration limits. If a device fails its calibration check, then a new calibration procedure or equipment maintenance is required.

Key aspects of equipment quality control are summarised in the table below [2]:

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

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. Standards suggest to use a 3-L syringe, if this is not available better use a syringe with a volume of 2-L than 1-L. 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.

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. Syringes must be calibrated annually.

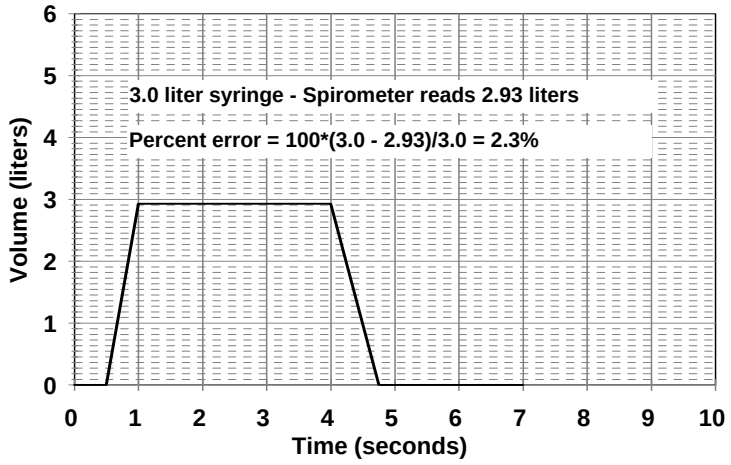
With regard to time, assessing mechanical recorder time scale accuracy with a stopwatch must be performed at least quarterly. An accuracy of within 2% must be achieved.

Quality control for volume-measuring devices

The volume accuracy of the spirometer should be within ±3% and must be checked at least daily, with a single discharge of a 3-L calibrated syringe. 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.

Volume-type spirometer systems must be evaluated for leaks every day. Leaks can be detected by applying a constant positive pressure of ≥3.0 cmH_2O (0.3 kPa) with the spirometer outlet occluded (preferably at or including the mouthpiece). Any observed volume loss >30 mL after 1 min indicates a leak and needs to be corrected. More about the quality control for volume-measuring devices can be found from [2].

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 2.91-3.09 L. 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.



Quality control for flow-measuring devices

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.

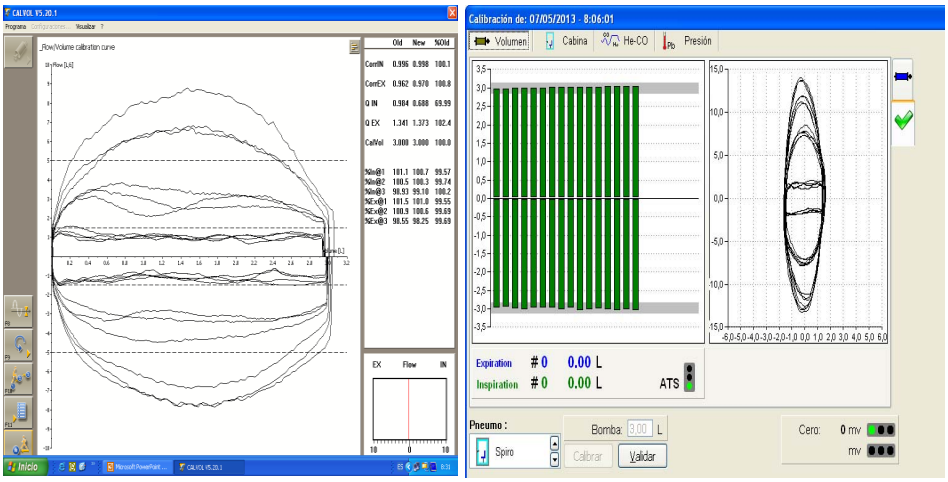
First fill the syringe with air completely, then attach it firmly to the flow sensor, and empty it smoothly and completely. End the maneuver carefully to ensure that a soft click is heard, meaning that the syringe was emptied completely. Do not bang the syringe while emptying it, to avoid damage. Disconnect, refill with air, and then empty the syringe three times, each time at a different speed to give a range of flows varying between 0.5 and 12 $L \cdot s^{-1}$: 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

For flow 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%.

EXAMPLES of calibration results can be found below:

ERS

Flow check at least three different flows range



european respiratory society every breath counts

The manufacturers and distributors of many spirometers advertise that their spirometers remain accurate over prolonged periods, so calibration is not necessary. Unlike other types of sensors used in spirometers, the ultrasonic sensor has no moving parts, therefore accuracy is not dependent on mechanical function, nor is it dependent on measurement of pressure or displacement volume [10]. The longest period reported is probably from a study where an ultrasonic spirometer retained inspiratory and expiratory volume accuracy of better than 3% for at least 4 years [11]. Despite that, when the spirometry results will be compared for detecting changes from one visit to another, the authors still recommend that the accuracy of the spirometer is verified every day.

Biological Control 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 members of staff are asked to perform this function. The facility should identify at least two BioQC subjects 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.

General rules for BioQC:

1) The BioQC subjects should perform spirometry procedures in the same way as a patient.

2) For consistency, BioQC subjects should ideally be tested:
    - on the same spirometer, at the same day of month, at the same time of day.

3) An adequate test requires a minimum of three acceptable FVC maneuvers and adherence to ERS/ATS repeatability criteria.

Establishing the BioQC normal range [4]:

1) Perform a minimum of 10 recordings 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.

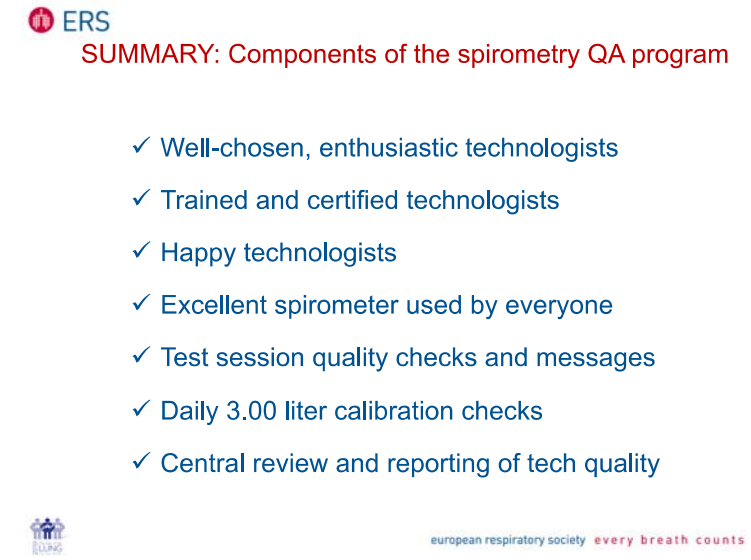
    - Use the Normal Range Calculator or make an Excel file to determine the acceptable ranges for each person. Find the average of the replicates, calculate standard deviation (SD) and coefficient of variation (CV).

    - There should be a maximum of 10% between the highest and lowest FVC and FEV_1 values.

    - The calculated coefficient of variation (CV) should be 3% or less.

2) You can now use this BioQC person to check that the spirometer readings fall within the range of ± 2 SD for that subject to verify the accuracy of your spirometer on a weekly basis. If BioQC values fall outside of their acceptable ranges the facility should perform remedial action. This might include recalibration, validation, further stripping and cleaning, or change of flow head.

Quality assurance (QA) in lung function laboratory can be summarized as following:



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EVALUATION

Multiple choice questions

1. Calibration is:
- **a.** After introducing environmental conditions and calibrating the spirometer with a 3 L syringe, the device corrects the deviation automatically.
- **b.** Checking if temperature and barometric pressure are measured.
- **c.** Taking bacterial swabs from spirometers.
- **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.
- **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.** Some devices only need to be calibrated once a week.
- **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.** Perform biological controls.
- **d.** Assess spirometer, verify all flows and periodically perform biological controls.

5. Which of the statements about the calibration syringe is INCORRECT?
- **a.** The syringe must have an accuracy of ±15 mL or ±0.5% of the full scale.
- **b.** The syringe should be stored in an unheated room to maintain the lowest possible temperature inside the syringe.
- **c.** The syringe should be periodically leak tested by trying to empty them with the outlet corked.
- **d.** A dropped or damaged syringe should be considered out of calibration until it is checked.

6. Which of the statements about biological control (BC) testing is INCORRECT?
- **a.** A healthy non-smoking person with stable lung function is tested on a regular basis as a "control".
- **b.** There should be at least five BC subjects for every spirometer used in a lab.
- **c.** The personal normal range for lung function indices is calculated as mean±2 SD from a minimum of 10 spirometric measurements from each BC subject.
- **d.** The BC subjects should perform spirometry procedures in the same way as the patients.

Please find all answers at the back of your handout materials

Definitions

Can you define some specific terms used in quality control of the spirometry? Please connect with lines the terms in the left column and the appropriate explanation from the right column:

a) ACCURACY	This is the closeness of agreement between the result of a measurement and the conventional true value.
b) PRECISION	This is the degree to which repeated measurements show the same results.
c) CALIBRATION	This is the procedure for establishing the relationship between sensor-determined values of flow or volume and the actual flow or volume.
d) CALIBRATION CHECK	This is the procedure used to validate that the device is within calibration limits. This is the checking of a volume with a calibration syringe (as a standard) without adjustment of the spirometer to the exact value of this standard. This is the checking of a volume with a calibration syringe (as a standard) and the adjustment of the spirometer to the exact value of this standard.
e) REPEATABILITY	This is the closeness of agreement between the results of successive measurements of the same item where the individual measurements are carried out with changed conditions and repeated after 30 min.
f) REPRODUCIBILITY	This is the closeness of agreement between the results of successive measurements where the individual measurements are carried out with similar conditions and repeated over a short space of time.

Hands-on activities

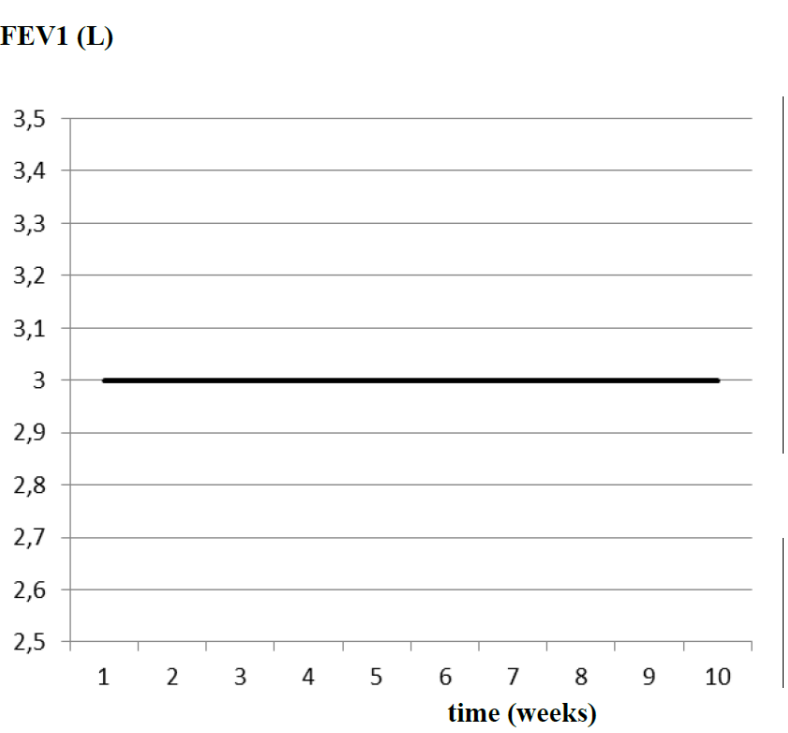
Calibration/calibration check of spirometers provided for this workstation

Biological control testing

Two lung function technicians have made 10 spirometric measurements during 2 weeks. FEV1 results (in litres) from Jim and Tim are shown in the table below. Mean value, standard deviation (SD) and coefficient of variation (CV) for both sets of results are also given. Please answer the questions at the bottom of the page!

	JIM	TIM
M	3,01	3,01
T	3,00	3,01
W	3,10	3,11
T	3,05	3,06
F	2,95	2,71
M	3,01	3,01
T	2,90	2,91
W	2,91	2,91
T	3,01	3,01
F	3,01	3,21

Mean	3,00	3,00
SD	0,06	0,13
CV (%)	2,03	4,46



1) Would you choose Jim or Tim to be your future subject for conducting biological control?

2) Which parameter helped you to choose a better subject? What is the suggested value for this parameter?

3) For your weekly measurements using your biological control subject you have to calculate the normal range for his FEV1. How can you find this range? Please add two dotted lines to the graph to show the normal range for FEV1.

Evaluation of spirometric results: review spirometry results through case studies

Dr Emelie Ekkernkamp
Department of Pneumology
St. Josefs Hospital Freiburg
Sautierstr.1
79104 Freiburg
Germany
emelie.ekkernkamp@rkk-klinikum.de

Prof. Dr Jörg Daniel Leuppi
Professor of Internal Medicine
University of Basel
Head of Internal Medicine
Cantonal Hospital Baselland
Rheinstr. 26
4410 Liestal
Switzerland
Joerg.leuppi@ksbl.ch

AIMS

This workstation is planned to give the participants the possibility to improve their knowledge of evaluation of spirometric results. In this workshop spirometry results will be reviewed through case studies. 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 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 the official ERS video about conducting the spirometry online [6].

Before the measurement starts

Preparation of pulmonary function equipment prior to test performance is essential to obtain reliable data. 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 tight clothing or any other elements which can block or restrict his/her breathing, such as 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.

The different types of spirometers and their quality and infection control will be discussed in other workstations.

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, for example, cough, variable effort, and early termination.
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

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 estimation of 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 further in ESDL Module 7 (evaluation of spirometric results).Briefly, the members of the ATS/ERS taskforce recommend using the percent 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) of 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 using a percentage of the predicted value instead as this adjusts for differences in lung size [5].

Interpretation of ventilatory disorders

An obstructive ventilatory defect is a disproportionate 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 FEV/VC ratio below the 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.

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.
   This paper summarizes all the aspects of spirometric measurements.
4. Pellegrino R, et al. Interpretative strategies for lung function tests. *Eur Respir J* 2005; 26:948-68.
5. 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.
6. 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 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 the intervals between acceptable tests were
   - **d.** It should be stated in which position (standing or sitting) testing was undertaken.

4. 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 find out 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

Additional course resources

Readings and guidelines

1. ML Levy, PH Quanjer, R Booker, BG Cooper, S Holmes, I R Small. Diagnostic Spirometry in Primary Care Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations. *Primary Care Respiratory Journal* [2009]; 18(3): 130-147.
2. B G Cooper. Review: An Update on contraindications for lung function testing. *Thorax* [2011] 6:714-723.
3. Miller MR, Hankinson J, Brusasco V et al. Series 'ATS/ERS Task Force': standardisation of spirometry. *Eur Respir J* 2005; **26**: 319-338.
4. Burgos F, Torres A. Iez J et al. Bacterial colonization as a potential source of nosocomial respiratory infections in two types of spirometer. *Eur Respir J* 1996; **9**(12): 2612-7.
5. Miller MR, Crapo R, Hankinson J et al. Series 'ATS/ERS Task Force': general considerations for lung function testing. *Eur Respir J* 2005; **26**: 153-61.

E-learning resources

1. ERS video on Spirometry: http://www.ers-education.org/Media/Media.aspx?idMedia=142739
2. Go to ERS e-learning resources and search 'spirometry' for high quality multi-media material. http://www.ers-education.org/search/quick-search.aspx

Faculty disclosures

Dr Felip Burgos has been involved with Socks of Linkcare® Health Solutions SL.

Faculty contact information

Dr Felip Burgos
Department of Pneumology
Hospital Clínic
Villarroel, 170
08036 Barcelona
SPAIN
fburgos@ub.edu

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

Dr Emelie Ekkernkamp
Department of Pneumology
St. Josefs Hospital Freiburg
Sautierstr.1
79104 Freiburg
GERMANY
emelie.ekkernkamp@rkk-klinikum.de

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

Prof. Dr Jörg Daniel Leuppi
Professor of Internal Medicine
University of Basel
Head of Internal Medicine
Cantonal Hospital Baselland
Rheinstr. 26
4410 Liestal
SWITZERLAND
Joerg.leuppi@ksbl.ch

Ms Julie K. Lloyd
Respiratory & Sleep Investigation Department
Area A, Treatment Centre
Good Hope Hospital
Rectory Road
Sutton Coldfield B75 7RR
UNITED KINGDOM
julie.lloyd@heartofengland.nhs.uk

Ms Jellien Makonga-Braaksma
Pulmonary Function Department
Meander Medisch Centrum
Maatweg 3
3813 TZ Amersfoort
NETHERLANDS
j.makonga@meandermc.nl

Prof. Dr Med. Heinrich Matthys
Medical Director Emeritus
University Hospital of Freiburg
Hochrüttestrasse 17
79117 Freiburg
GERMANY
hmatthys@t-online.de

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

Prof. Waldemar Tomalak
Physiopathology of Respiratory System Dept.
Institute for TBC and Lung Diseases
Profesora Rudnika 3
34-700 Rabka-Zdrój
POLAND
wtomalak@igrabka.edu.pl

Answers to evaluation questions

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

Introduction – Prof. Dr Med. Heinrich Matthys

1. Which spirometric measurement was historically first defined?
   a. PEF
   b. FEV1
   c. **VC**
   d. IC
   e. MMEF

2. Which spirometric manoeuvres are suitable to assess static and dynamic overinflation?
   a. PEF
   b. FEV1
   c. VC
   d. **IC**
   e. **MVV**

   If measured before, during or immediately after exercise.

3. When do you measure FIV1?
   a. **To assess expiratory obstruction or inspiratory muscle force.**
   b. To measure inspiratory muscle force or upper airway obstruction.
   c. To classify restrictive ventilatory defects due to lung fibrosis.

Evaluation of spirometric results – Dr Emelie Ekkernkamp

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

2. The criterion for FEV_1 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. FEV_1 < 80% pred.
   b. $FEV_1/FVC < 0.7$
   c. **FEV_1/FVC < lower limit of normal.**
   d. Both FEV_1 and FEV_1/FVC < lower limit of normal.

Calibration and quality control – Dr Felip Burgos & Dr Jana Kivastik

1. Calibration is:
   a. **After introducing environmental conditions and calibrating the spirometer with a 3 L syringe, the device corrects the deviation automatically.**
   b. Checking if temperature and barometric pressure are measured.
   c. Taking bacterial swabs from spirometers.

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.
   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. Some devices only need to be calibrated once a week.
   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. Perform biological controls.
   d. **Assess spirometer, verify all flows and periodically perform biological controls.**

5. Which of the statements about the calibration syringe is INCORRECT?
   a. The syringe must have an accuracy of ±15 mL or ±0.5% of the full scale.
   b. **The syringe should be stored in an unheated room to maintain the lowest possible temperature inside the syringe.**
   c. The syringe should be periodically leak tested by trying to empty them with the outlet corked.
   d. A dropped or damaged syringe should be considered out of calibration until it is checked.

6. Which of the statements about biological control (BC) testing is INCORRECT?
   a. A healthy non-smoking person with stable lung function is tested on a regular basis as a "control".
   b. **There should be at least five BC subjects for every spirometer used in a lab.**
   c. The personal normal range for lung function indices is calculated as mean±2 SD from a minimum of 10 spirometric measurements from each BC subject.
   d. The BC subjects should perform spirometry procedures in the same way as the patients.

Evaluation of spirometric results: review spirometry results through case studies – E. Ekkernkamp & J. D. Leuppi

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