SPIROMETRY
Standards, Guidelines and “Other Stuff”

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“vital capacity”
“complemental air”
“breathing air”
“reserve air”
“residual air”

Coined the term VC based on his observations that it accurately predicted the capacity to live
Spirometers

- 1800’s
- Measures volume only
Spirometers

Hand-held

Computer-Interfaced
Spirometers

Single component of a complex PFT Lab
GUIDELINES and STANDARDS
American Thoracic Society/European Respiratory Society

- 1979 ATS Snowbird Spirometry Standards
- 1987 ATS Revised Spirometry Standards
- 1991 ATS Reference Values & Interpretation
- 1994 ATS Revised Spirometry Standards
- 1999 NHANES Reference Values
- 2005 ATS/ERS Spirometry Standards
- ATS Pulmonary Function Laboratory Management and Procedure Manual
GUIDELINES and STANDARDS
National Institute of Occupational Safety & Health (NIOSH)

• 1979 Cotton Dust Standards
• 1986 Asbestos Standards
• 1996 Respirator Standards
• 2011 ACOEM: Spirometry in the Occupational Setting
Screening and Surveillance: A Guide to OSHA Standards

<table>
<thead>
<tr>
<th>Standard Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-placement exam</td>
</tr>
<tr>
<td>Periodic exam</td>
</tr>
<tr>
<td>Emergency/exposure examination and tests</td>
</tr>
<tr>
<td>Termination exam</td>
</tr>
<tr>
<td>Examination includes special emphasis on these body systems</td>
</tr>
<tr>
<td>Work and medical history</td>
</tr>
<tr>
<td>Chest x-ray</td>
</tr>
<tr>
<td>Pulmonary function test (FFT)</td>
</tr>
<tr>
<td>Other required tests</td>
</tr>
<tr>
<td>Evaluation of ability to wear a respirator</td>
</tr>
<tr>
<td>Additional tests if deemed necessary</td>
</tr>
<tr>
<td>Written medical opinion</td>
</tr>
<tr>
<td>Employee counseling re: exam results, conditions of increased risk</td>
</tr>
<tr>
<td>Medical removal plan</td>
</tr>
</tbody>
</table>
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ATS-ERS Statements

American Thoracic Society

ATS DOCUMENTS: PULMONARY FUNCTION TESTING

- Standardisation of lung function testing: the authors' replies to readers' comments
- ATS/ERS Task Force Standardisation of Lung Function Testing: General considerations for lung function testing (2005)
- ATS/ERS Task Force Standardisation of Lung Function Testing: Standardisation of the measurement of lung volumes (2005)

www.thoracic.org
ATS/ERS SPIROMETRY STANDARDS

- Accuracy
- Chart display
- Acceptability criteria
- Repeatability criteria
ATS/ERS SPIROMETRY STANDARDS

Accuracy

- **Volume**  Within 3% or 0.05L up to 8 L
- **Flow**    Within 5% or 0.20 L/sec up to 14 L/sec
ATS/ERS SPIROMETRY STANDARDS
Chart Display
(refer to examples in workbook)

Minimum Required Scale Factors

Flow  5 mm/L/sec
Volume  10 mm/L
Time  20 mm/sec
ATS/ERS SPIROMETRY STANDARDS

Acceptability

- Free from artifacts
- Have good starts
- Have a satisfactory exhalation
ATS/ERS ACCEPTABILITY

Free from artifacts

- Cough or glottic closure during the 1st sec
- Early termination or cutoff
- Variable effort
- Leak
- Obstructed mouthpiece
ATS/ERS ACCEPTABILITY
Free from artifacts

Flow/Volume
Volume/Time
Flow/Volume

Test 1
Test 2
Test 3
Test 4

Flow(l/s)
Vol(l)
Time(s)

Vol(l)
Flow(l/s)
ATS/ERS ACCEPTABILITY
Have Good Starts

- Extrapolated volume <5% of FVC, or 150 ml, whichever is greater
- Time-to-PEF < 120 ms (optional)
ATS/ERS ACCEPTABILITY
Have Good Starts
ATS/ERS ACCEPTABILITY

Have a satisfactory exhalation

- 6 sec exhalation and/or plateau
  OR
- Reasonable duration or a plateau
  OR
- If a subject could not or should not continue to exhale
ATS/ERS ACCEPTABILITY

Have a satisfactory exhalation
ATS/ERS ACCEPTABILITY

Have a satisfactory exhalation
“OLD” ATS SPIROMETRY STANDARDS
Reproducibility

- **1987** Two largest FVC’s & FEV₁’s within 5% or 100 ml, whichever is greater

- **1994** Two largest FVC’s & FEV₁’s within 200 ml
2005 ATS/ERS Standards
General Considerations

- **Repeatability:**
  Closeness of agreement between the results of successive measurements

- **Reproducibility:**
  Closeness of agreement of 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.
2005 ATS/ERS SPIROMETRY STANDARDS

Repeatability

Two largest FVC’s & the two largest FEV$_{1}$’s must both be within 150 ml

(If the FVC is 1.00 liters or less, they both need to be within 100ml)

Apply the acceptability criteria, then check repeatability
Evidence of Quality Spirometry Testing

Spirometry in Primary Care Practice*

- 30 primary care clinics
- 15 trained group / 15 usual group
- 3.4% in usual group and 13.5% in trained group met ATS acceptability and repeatability criteria
- 1,012 pt. tests, 2,928 blows (2.89)

Evidence of Quality Spirometry Testing

**Improving the Quality of Bedside Spirometry**

– Audit of testing outside the PF lab - Cleveland Clinic
– 15% - ATS acceptability/repeatability criteria
– CI Project - 63.5% acceptability/repeatability

Quality Assurance

“Systematic” approach of monitoring and evaluating quality.
CLSI’s Quality Systems

- QMS01-A4: Quality Management Systems A Model for Laboratory Services
- QMS04-A2: Quality Systems in Respiratory Care
Quality Systems in the PFL

- CLSI’s “Path of workflow” Model
Quality Assurance
Path of workflow model

Pre-Test
- Pre-test instructions
  - Medications
  - Eating
  - Exercise
  - Smoking
- Questionnaire
- Height* and weight
- Equipment quality assurance program
Quality Assurance
Path of workflow model

- **Height and Weight**
- Do not ask the height!
- Measure height and weight wearing indoor clothes without shoes
- Feet together, standing as tall as possible

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<table>
<thead>
<tr>
<th>Height Comparisons</th>
<th>PF Laboratory Height</th>
<th>HIM Height</th>
<th>Difference</th>
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</thead>
<tbody>
<tr>
<td>182.7</td>
<td>164.5</td>
<td>182.7</td>
<td>-1.8</td>
</tr>
<tr>
<td>162.2</td>
<td>165.9</td>
<td>162.2</td>
<td>-3.7</td>
</tr>
<tr>
<td>171.7</td>
<td>175.8</td>
<td>171.7</td>
<td>-4.1</td>
</tr>
<tr>
<td>183.5</td>
<td>185.8</td>
<td>183.5</td>
<td>-2.3</td>
</tr>
<tr>
<td>190.5</td>
<td>190.1</td>
<td>190.5</td>
<td>0.5</td>
</tr>
<tr>
<td>171.5</td>
<td>173.7</td>
<td>171.5</td>
<td>-2.2</td>
</tr>
<tr>
<td>164.2</td>
<td>164.7</td>
<td>164.2</td>
<td>-0.5</td>
</tr>
<tr>
<td>165</td>
<td>175</td>
<td>165</td>
<td>-6</td>
</tr>
<tr>
<td>181.2</td>
<td>183.6</td>
<td>181.2</td>
<td>-2.4</td>
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<td>159.8</td>
<td>165.1</td>
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<td>-5.3</td>
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<td>182.6</td>
<td>181.6</td>
<td>182.6</td>
<td>1</td>
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<tr>
<td>185.7</td>
<td>186</td>
<td>185.7</td>
<td>-0.3</td>
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<tr>
<td>173.2</td>
<td>173.3</td>
<td>173.2</td>
<td>-0.1</td>
</tr>
<tr>
<td>168.4</td>
<td>168.4</td>
<td>168.4</td>
<td>0</td>
</tr>
<tr>
<td>168.5</td>
<td>171.3</td>
<td>168.5</td>
<td>-2.8</td>
</tr>
</tbody>
</table>

Min (cm) -6.00
Max (cm) 1.00
Measuring Arm Span

Patients with deformities of the thoracic cage or cannot stand should have their arm span measured.

- Regression equations
- $Ht = \text{arm span}/1.06$
Quality Systems in the PFL
Pre-test

- Equipment quality assurance
  - Validation/Verification
  - Preventive maintenance
  - Documentation and records (logbooks)

- Mechanical models
- Biological models
Quality Systems in the PFL
Pre-test

- Mechanical Model
  - 3-liter syringe
  - Stored and used in such a way as to maintain the same temperature and humidity of the testing site
  - Validated based on manufacturer recommendations

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum interval</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Leak</td>
<td>Daily</td>
<td>Calibration check with a 3-L syringe 3 cmH2O (0.3 kPa) constant pressure for 1 min</td>
</tr>
<tr>
<td>Volume linearity</td>
<td>Quarterly</td>
<td>1-L increments with a calibrating syringe measured over entire volume range</td>
</tr>
<tr>
<td>Flow linearity</td>
<td>Weekly</td>
<td>Test at least three different flow ranges</td>
</tr>
<tr>
<td>Time</td>
<td>Quarterly</td>
<td>Mechanical recorder check with stopwatch</td>
</tr>
<tr>
<td>Software</td>
<td>New versions</td>
<td>Log installation date and perform test using &quot;known&quot; subject</td>
</tr>
</tbody>
</table>

2005 ATS/ERS Standards
Standardization of Spirometry
Quality Systems in the PFL
Pre-test

- Biological Model
  Normal laboratory subjects
  Two individuals (16)
  Establish mean and SD
  (minimum 20 samples)

2005 ATS/ERS Standards
General Laboratory
Quality Assurance
Path of workflow model

Testing

– Patient instructions
  Understanding, effort & cooperation
– Technologist’s performance & training
– Meeting ATS-ERS testing standards
– Equipment
– Reference equations
Quality Assurance
Path of workflow model

Post-test
– Maneuver selection
– Report review
Demographic Data
Interpretation
Post-Test Quality Assurance

- Consistent Interpretation (ATS/ERS Guideline)
- Turn-around time:
  Average TRT: <1 day (15%), 1-2 d (30%), 3-4 d (27%), 5-6 d (15%), >7 d (3%)

  ATS PFL Registry Abstract AARC 2005, OF-05-037

Mayo’s PFL: ½ day to Electronic Medical Record
Technician Training and Feedback
Improve Test Quality

Lung Health Study

- Volume grade
- Flow grade
- Quality control feedback started
- Site visits and training update

GPA

Year

1 2 3 4 5 6 7

Volume grade
Flow grade

Quality control feedback started
Site visits and training update
Evidence of Quality Spirometry Testing

Quality Control in Spirometry in the Elderly*

- 984 controls, 638 COPD pts.
- 95.8% repeatable tests in controls, 87.6% in COPD
- 4.8 ± 1.7 tests per session

* Bellia et al, AJRCCM 2000; 161:1094-1100
Evidence of Quality Spirometry Testing

Quality of Spirometry Test Performance in Children and Adolescents**

– 4,000 public school students 9-18 yrs.
– 95% of the tests met adult-based ATS standards

** Enright et al, Chest 2000; 118:665-671
Quality Systems in the PFL
Does it Work?

- Retrospective review of 18,000 consecutive pts. at Mayo Clinic
- Ninety percent of the patients were able to reproduce FEV1 within 120 ml (6.1%), FVC within 150 ml (5.3%), and PEF within 0.80 L (12%).
"That settles it, Carl! ... From now on, you're getting only decaffeinated coffee!"
Spirometer Types

- Volume
  \[ \text{volume} \div \text{time} = \text{flow} \]
- Flow
  \[ \text{flow} \times \text{time} = \text{volume} \]
Volume Spirometer

- Directly accumulates and measures the volume of expired air.
- Flow parameters are obtained by measuring the volume displaced per second.
- Larger in size
- Must hold up to 8 liters of air

Examples:  Water-seal
            Dry-rolling seal
            Bellows
Volume Spirometer: Water-seal

Stead-Wells spirometer
Volume Spirometer: Dry-rolling seal

SpiroTech
(VIASYS Healthcare)
More dry-rolling seal spirometers…

OMI (SensorMedics)

nSpire (Collins)

Morgan SpiroAir-LT
Volume Spirometer: Bellows

Vitalograph
Flow Spirometer

- Directly measures rate of air flow and calculates volume from flow
- Smaller, more portable
- Needs frequent calibration

Pneumotachographs:
- Fleisch
- Screen
- Rotating vanes
- Hot Wire
Flow Spirometer:
Brass Core “Fleisch” Pneumotachometer

Koko Trek spirometer

Koko Legend spirometer
Flow Spirometer: Screen Pneumotach
“Silverman pneumotachograph”

Jaeger spirometer
Flow Spirometer: Ultrasonic Pneumotach

ndd EasyOne spirometer

ndd Easy-on PC spirometer
Flow Spirometer: other pneumotachs

Turbine pneumotach

Vitalograph copd-6 spirometer

Hot wire pneumotach

Heated platinum wires

Energy supply to maintain platinum wires at constant temperature
Flow Spirometer: Disposable Screen

- QRS SpiroCard PC
- MidmarkIQ Spiro
Spirometry Testing in Occupational Health Programs

Best Practices for Healthcare Professionals
“Hold still, Carl! ... Don’t ... move ... an ... inch!”
Calibration

Daily calibration check is required for ALL spirometers!!!
(every 4 hours during heavy use)

- Detects leaks in a volume spirometer
- Detects clogged sensor in a flow spirometer
- Daily calibration (minimal) with a calibrated syringe with a volume of at least 3 liters (ATS/ERS)
- Check syringe for leaks and damage
- Store the syringe next to the spirometer.
ATPS $\rightarrow$ BTPS CORRECTION

- Temperature
- Barometric pressure
Spirometry Demo

Patient takes a deep breath and blows as hard as possible into tube

Clip on nose

Technician monitors and encourages patient during test

Machine records the results of the spirometry test
Flow-measuring Devices

Daily Calibration Check
• Slow 6 sec (0.5 L/sec)
• Medium 1-2 sec (1.5-3.0 L/sec)
• Fast 0.5 sec (6.0 L/sec)

Weekly Linearity Check
• 3 injections at slow speed
• 3 injections at medium speed
• 3 injections at fast speed

Maximum allowable error is 105 ml (3.5%) (ATPS reading between 2.90-3.10)
Volume-measuring Devices

Daily
- Inject 3 L syringe at a single speed
- Leak check—3 cmH\textsubscript{2}O (kPa) constant pressure for 1 min

Quarterly
- Mechanical recorder check with stopwatch (within 2% accuracy)
- Linearity check over entire volume range
Volume-measuring Device
Linearity Check

Two Methods

- Consecutive injections of 1-L volume increments while comparing observed volume with the corresponding cumulative measured volume, e.g. 0–1, 1–2, 2–3,…6–7 and 7–8 L, for an 8-L spirometer.

- Injection of a 3-L volume starting at a minimal spirometer volume, then repeating this with a 1-L increment in the start position, e.g. 0–3, 1–4, 2–5, 3–6, 4–7 and 5–8 L, for an 8-L spirometer.

  Maximum allowable error is 105 ml (3.5%) (ATPS reading between 2.90-3.10)
Checklists for Troubleshooting Equipment Calibration Check Failures (in your workbook):

Flow spirometer
1. Measured volume is below 2.90 liters
2. Measured volume is above 3.10 liters

Volume spirometer
1. Measured volume is below 2.90 liters
2. Measured volume is above 3.10 liters
3. Leak check failure (>30ml over 60 seconds)
Cockroach nightmares
Transmission to technologists (either direct or indirect)

- Proper hand washing
- Protective barrier – gloves

Cross-contamination

Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected, sterilized, or, if disposable, discarded after each use.
Tuberculosis

Proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air should be used to prevent disease transmission.
ATS/ERS Standards
Hygiene and Infection Control

- In-line filters
  Effect not well defined
  Johns DP: FEV1 44 mls, PEF -0.47 L/s\(^1\)
  Fusco L: FEV1 30 mls, FVC 50 mls\(^2\)
  Inexpensive method of preventing equipment contamination
  “Not mandated” - ATS/ERS guidelines

Effect of a Microaerosol Barrier Filter on the Measurement of Lung Function*

David P. Johns, CBIol, MIBiol; Corrie Ingram, BSc;
Helen Booth, MBBS; Trevor J. Williams, MBBS; and
E. Haydn Walters, BM, BCch, FCCP

Chest 107 (4) April 1995\(^1\)

Effects of a filter at the mouth on pulmonary function tests


Table 2. - Mean differences and limits of agreement between measurements with and without filter

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Mean differences</th>
<th>Limits of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC l</td>
<td>0.05</td>
<td>0.31</td>
</tr>
<tr>
<td>FEV1 l</td>
<td>0.03</td>
<td>0.21</td>
</tr>
<tr>
<td>FEF25-75 l/s</td>
<td>0.03</td>
<td>0.39</td>
</tr>
<tr>
<td>TLC l</td>
<td>-0.02</td>
<td>0.52</td>
</tr>
<tr>
<td>RV l</td>
<td>-0.02</td>
<td>0.44</td>
</tr>
<tr>
<td>Raw cmH2O-l/s</td>
<td>-0.18</td>
<td>0.38</td>
</tr>
<tr>
<td>sGaw s^-1cmH2O^-1</td>
<td>0.02</td>
<td>0.08</td>
</tr>
</tbody>
</table>

For abbreviations see legend to table 1.

European Resp. Journal 8(2), 1995\(^2\)
Hygiene and Infection Control

Hiebert et al

“a significant transfer of aerosolized organisms does not occur during routine pulmonary function testing as long as an interval of 5 min or more is allowed between tests.”

Am J Respir Crit Care Med 1999;159:610-612.
Hygiene and Infection Control Agents

- Sani-Cloth (disposable wipes)
- Glutaraldehyde (cold chemical)
- Ethylene oxide (gas)
- Acetic acid (vinegar)
“I lift, you grab. ... Was that concept just a little too complex, Carl?”