ATS/ERS 2019 Spirometry Standarc

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PFTs are weird

- No accreditation of labs
- Important decisions are based on the results yet the tes are not covered by CLIA
  - qualification, training and competency are not standardized
- Unique interaction of operator, patient and equipment

We're not going to go over everything

- IMPORTANT CHANGES
  - What is most important?
- What might not be right?

Where can I get the standards?

- The ATS/ERS 2019 Spirometry Standards:
  - https://www.thoracic.org/statements/pulmonary-function.php
  - from there you can also access the Online Supplement
    - (good stuff here)
- The Spirometry Patient Survey:
  - https://openres.ersjournals.com/content/7/1/00712-2020

2019 Standards; What's in it?

- Patient
- Equipment
- Operator
- Procedure
- Analysis
- Quality Assessment

Changes from ATS/ERS 2005 Standarc

- New list of relative contraindications
- Spirometers are now required to meet International Organization for Standardization (ISO) 26782 standards, but with a maximum permissible accuracy error of 2.5%
- Device quality assurance procedures updated
- Operator training and maintenance of competency addressed
- List of activities patients should avoi testing updated
- Focus on devices that measure both expiration and inspiration
- Maneuver acceptability and repeata criteria updated*
- Bronchodilator responsiveness vs. r
- End of forced expiration (EOFE) red

Changes from ATS/ERS 2005 Standard

- Requirements for spirometry systems to provide uniform cues an feedback to the operator added
- New withholding times for bronchodilators for responsiveness tes
- New grading system for assessment of spirometry quality develo
- Standardized operator feedback options that promote synoptic re developed
- Preliminary findings derived from an international patient survey presented

Quality Control

- Equipment Installation
- Equipment quality control
- Equipment and software updates

3 Liter Syringe Calibration

- Accuracy tolerance reduced from 3.0% to 2.5%
  - when 0.5% tolerance for syringe accuracy, total tolerance is 3.0%
- Daily calibration or verification
- Syringe must be revalidated
  - manufacturers recommendation
  - when dropped

Table of Potential Re
Calibration Failure is in t

Contraindications

- Acute MI changed from 1 month to 1 week
- Eye surgery – 1 week
- Thoracic or abdominal within 4 weeks
- Sinus or middle ear surgery within 1 week
- Hypo- or hypertension
- Significant atrial or ventricular arrhythmia
- Non-compensated heart failure
- Uncontrolled pulmonary hypertension
- Acute cor pulmonale
- More…….

All are relative contraindicatio

D/C if patient experiences pai

Performance of Spirometry

- Patient preparation
  - meds to withhold, if applicable
- Arrival in lab
  - check for contraindications
  - meds
  - age to nearest decimal
  - shoeless height in cm to nearest decimal
  - weight in kg to nearest 0.5kg
  - birth sex and ethnicity*

Operator training and attainment
maintenance of competency mu
in any spirometry testing service

Filters, nose clips – Use them!

- Saliva can cause measurement errors; filter preven
- Clean exhalate during forced exhalations protects c and patients that follow
- Use the same filter during calibration/verification

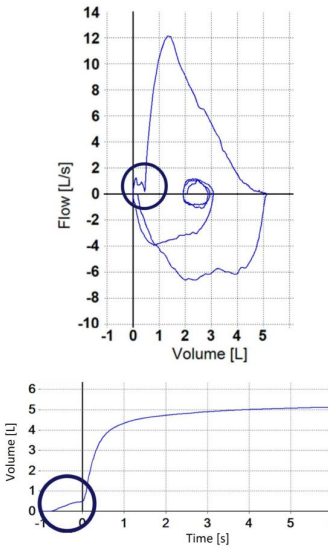
Patient Instruction

- Demonstrate the procedure
- Emphasize posture
- Tell them what to expect
- Stay on mouthpiece and inhale back to full lungs

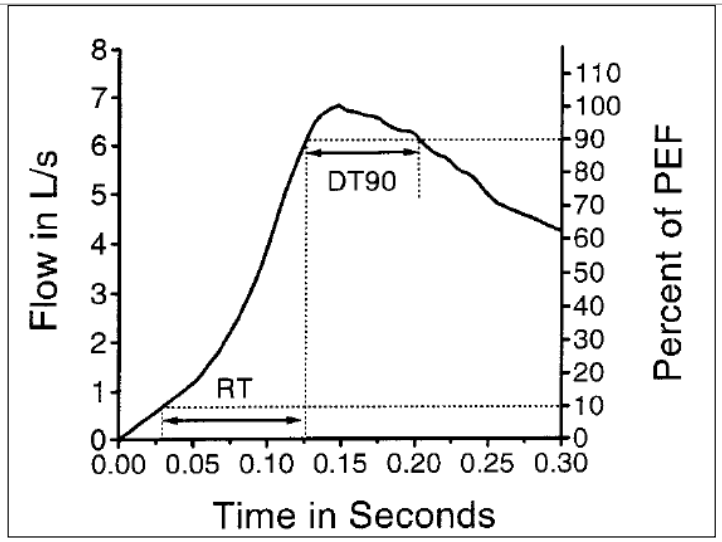
- Vigorously coach to full inflation; both before and the forced exhalation
- ‘Deepest breath, more, more, more…’

Satisfactory Start of Test

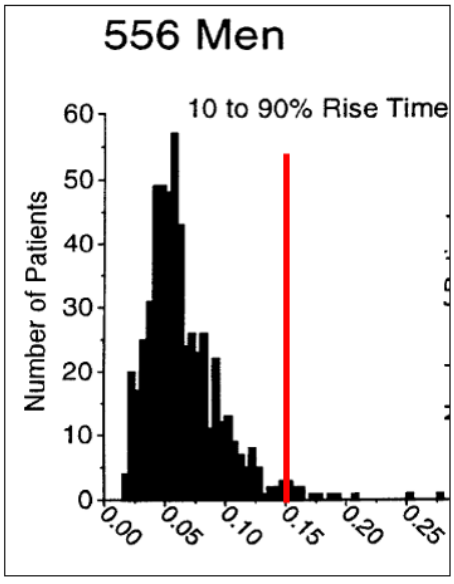
- Back extrapolated volume less than 5% is greater
- Do not pause at TLC for > 2 seconds
  - can decrease PEF and FEV1
  - so can a slow inspiration
- Rise time from 10-90% of PEF should be less than 150 msec

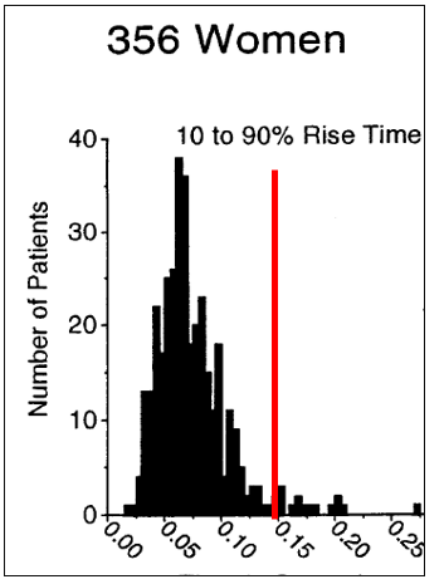


Rise Time from 10% to 90% of Peak Flow ≤ 150ms



$RT_{10\%-90\%}$ in COPD and Normals





End of Forced Expiration Criteria (EOFE)

- Obvious plateau of 1 second (no more minimum FET)
  - < 25 ml/second without glottic closure
- 15 second exhalation if no plateau
- When unable to achieve or maintain a plateau
- (e.g., children with high elastic recoil and patients with restrictive lung disease), acceptability is based on repeatability of FVC within 0.15L
- Cannot or should not continue to expire

Summary of Acceptability, Usability and Repeatability Criteria for F

Acceptability and Usability Criterion	Required for Acceptability	Required for Usability
BEV ≤ 5% of FVC or 0.100L	YES	YES
No evidence of faulty zero flow	YES	YES
No glottis closure after 1st s	YES	YES
No evidence of obstructed mouthpiece	YES	YES
No evidence of leak	YES	YES
Evidence that forced exhalation was from full inflation	YES	YES
• Plateau (≤ 0.025L in last 1s) **or**	YES	NO
• FET ≥ 15s **or**	YES	NO
• FVC within repeatability tolerance of largest FVC or is > largest prior FVC	YES	NO
Evidence that forced exhalation was from full inflation	**YES**	**YES**

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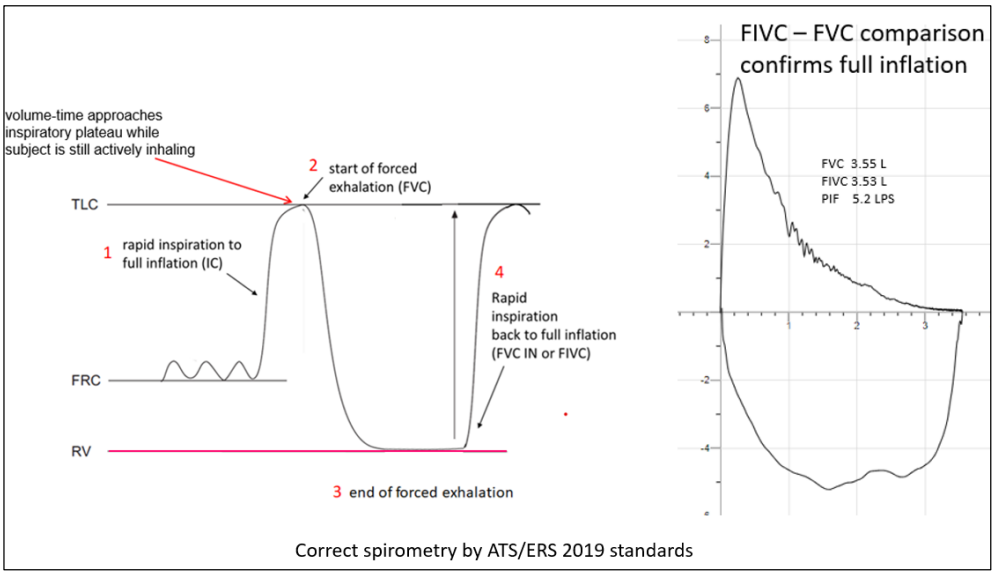
BEV as FVC acceptability criterion?

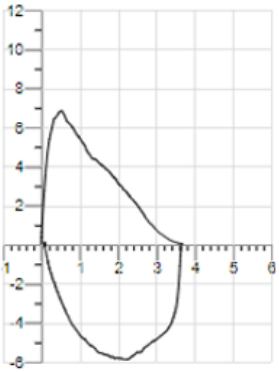
- Meant to prevent reporting SVC as FVC
- No data shows BEV protects against this
- Says operator should be able to override an unacceptable rating for FVC, if appropriate.

Proving the forced exhalation started from full inflation – Phase 4



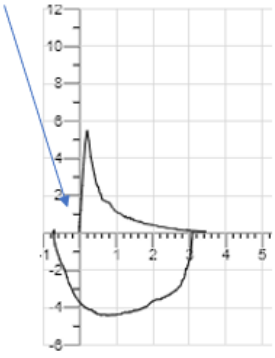
Correct spirometry by ATS/ERS 2019 standards

FIVC must be a maximal inspiratory mane



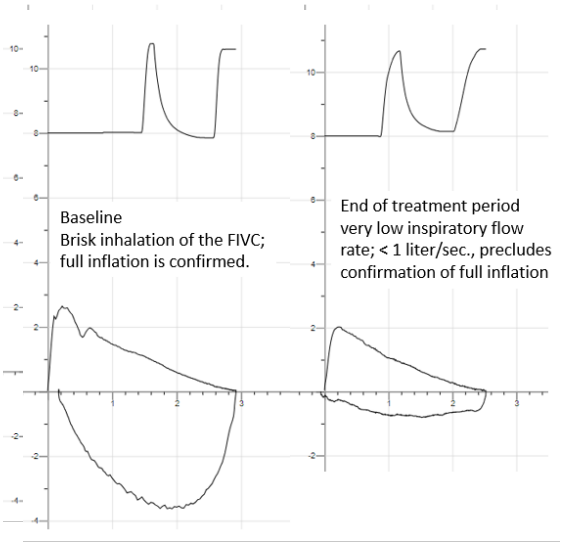
A properly performed FIVC that demonstrates the forced exhalation started from full inflation.
Note the rounded, 'upside-down haystack appearance of the inspiratory flow-volume loop.

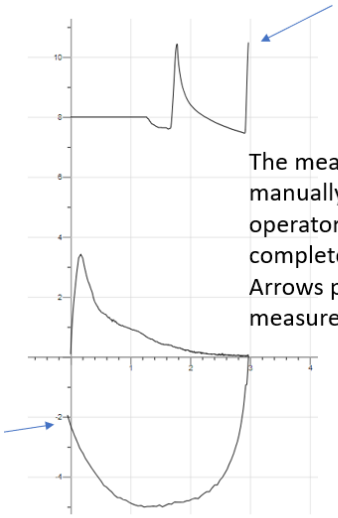
FIVC is significantly larger than the FVC



A properly performed FIVC that demonstrates the forced exhalation started before full inflation was reached.
Note the rounded, 'upside-down haystack appearance of the inspiratory flow-volume loop.

If FIVC is not maximal, might as well not c



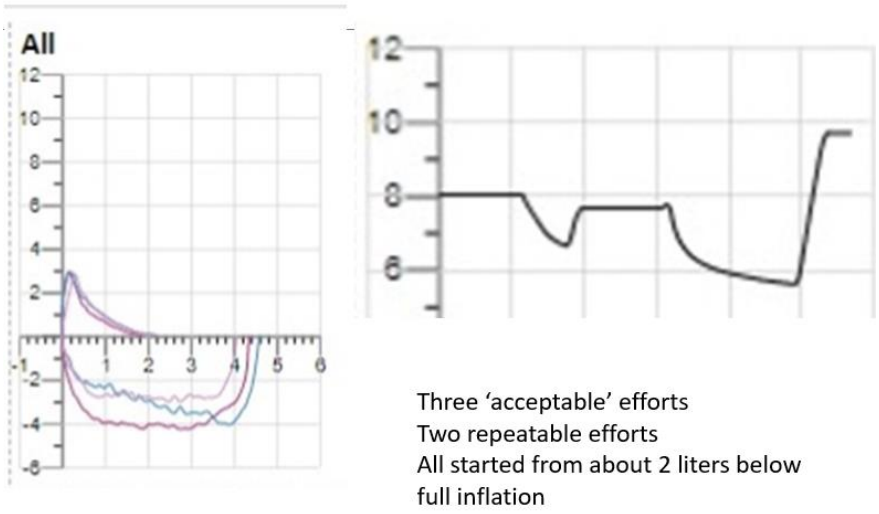


The measurement of
manually terminated
operator before the
completed the inspir
Arrows point to whe
measurement ended

Acceptable SOT and EOT
Two repeatable FEV1s and FVCs

Parameter	Best	Pred.	Pre.%	✓	✓	✓
Time				09:51	09:52	09:54
FEV1	1.297	3.847	33.7	1.140	1.297	1.284
FVC	2.194	4.810	45.6	1.862	2.194	2.144
FEV1%F	0.59	0.80	73.6	0.61	0.59	0.60
25-75	0.61	3.69	16.5	0.61	0.61	0.59
PEF	176.41			176.41	173.45	168.26
FETPEF	0.083			0.055	0.083	0.114
FET	7.21			6.56	7.21	6.94
VBEex	0.03			0.03	0.03	0.09
VBe%FV	1.48			1.86	1.48	4.19

Repeatability does not mean full inflation



Three 'acceptable' efforts
Two repeatable efforts
All started from about 2 liters below full inflation

Grading Spirometry Quality

- Grading system adapted from ATS Recommendat for a Standardized Pulmonary Function Report (2
- FVC and FEV1 are graded separately.
- Based on number of acceptable efforts (for each parameter) and repeatability of two largest effor

Grading System for FEV1 and FVC
Graded Separately

Grade	Number of measurements	Repeatability: age >6 yr	Repeatability: age ≤6 yr*
A	≥3 acceptable	within 0.150 L	within 0.100 L*
B	2 acceptable	within 0.150 L	within 0.100 L*
C	≥2 acceptable	within 0.200 L	within 0.150 L*
D	≥2 acceptable	within 0.250 L	within 0.200 L*
E	≥2 acceptable OR 1 acceptable	>0.250 L n/a	>0.200 L* n/a
U	0 acceptable AND ≥1 useable	n/a	n/a
F	0 acceptable and 0 useable	n/a	n/a

* Or 10% of the highest value; applies to age ≤ 6 yr only

Standardized Operator Comments

1. Relating to Patient condition:

- No comments
- First attempt at spirometry
- Reference values are based on ethnicity that may not be suitable for this
- Patient used bronchodilator(s) prior to test *[prompt for drugs, doses and used]*
- Patient smoked < 1 hr prior to test
- Patient had difficulty understanding directions
- Patient reported consumption of an intoxicant
- Observed symptoms e.g. cough, wheeze, dyspnea or cyanosis *[prompt for symptoms]*
- Other [prompt for description]

Other:

For part 1, **Other** should include information of any deviation from standard protocol

- patient tested standing
- ulna length or arm span used to estimate height
- patient did not use nose clip
- If birth sex and/or ethnicity data are not disclosed
  - state which default values were used for calculating predicted values
  - adapters described: face mask, tubing connectors or occlusion valves (e.g. with tracheostomy or nasal resection), a brief description of how the spiro was adapted, including the diameter of the smallest connector used to ada patient to the spirometer should be included in the notes.

Standardized Operator Comments

2. Relating to quality of each maneuver

- No comments
- Cough during the first second of expiration
- Glottis closure
- Early termination
- Hesitant start of test
- Obstructed mouthpiece or breathing tube
- Leak around mouthpiece
- Not at TLC prior to expiration
- Operator changed maneuver designation from acceptable to una *[prompt for reason]*
- Other [prompt for description]

Standardized Operator Comments

3. Relating to bronchodilator responsiveness t

- Facility bronchodilator responsiveness protocol followed type, dose and delivery method of bronchodilator and w time before post-BD testing
- Post-BD measurements obtained using other bronchodila dose(s), delivery method or wait time. *[prompt for bronchodilator(s), dose(s), delivery method and wait time*
- Other [prompt for description]

Other…

- For part 3, **Other** should include any deviation f the default bronchodilator responsiveness testir protocol used by the facility that has not otherw been entered.

Standardized Operator Comments

- **4.Relating to quality of testing session**
  - No comments
  - Acceptability and/or repeatability criteria not met despite pati best efforts
  - Spirometry-induced bronchospasm
  - Patient was too tired to continue
  - FEV1 dropped more than 20% from baseline
  - Motivation difficulties
  - Coordination difficulties
  - Other [prompt for description]

Standardized Operator Comments

- Spirometry system software should provide pop windows allowing the operator to click on the appropriate comments as follows:
  - Part 1 – when patient information is entered
  - Part 2 – at the completion of each maneuver
  - Part 3 – just prior to post-bronchodilator testing Part 4 – at completion of the testing session

Patient survey of 1,760 patients from 52 countrie

Most think spirometry is not so bad.

Though many patients gave suggestions about how spirometry testing could be improved, it is important note that 90% of patients found spirometry testing acceptable and not problematic.

Uncomfortable, but important….

While some patients found the test to be uncomfortable, they felt it was a necessary, temporary discomfort.

Don't make me feel like it's my fault we aren't c

Patients also felt that it was important that operators did not express disappointment when patients have trouble completing the test.

Don’t make me ask….

Patients would like to have water, tissues and sputum pots provided without having to ask.

They need your encouragement….

Some felt that the operato
to fulfill the role of a cheer
and that it made a differen
their results.

Please don’t yell at me…..

Though many felt encouragement or coaching is important, some patients would have preferred a gentler approach rather than shouting instructions to blow.

You matter to them….

Many patients emphasized the importance of the operator. Those who have had several tests felt that it made a real difference how friendly and encouraging the operator is.

Please be kind….

Patients also felt that operators need to “have empathy before, during and after the maneuver” and that it is important to check if the patient is ready and how they feel about performing the next maneuver.

Why didn’t anyone tell me this?

Patients felt that it is ver
important to be prepare
what is going to happen
during the test and then
coached through the pro

Questions