The New 2023 ERS/ATS Lung Volume Technical Standard

What do we need to do differently?

Carl D. Mottram RRT RPFT FAARC

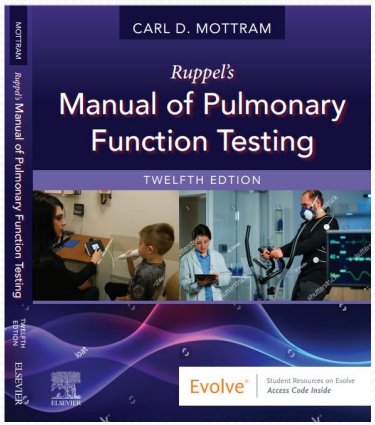
Associate Professor of Medicine

President – PFWConsulting LLC

Past President – Clinical and Laboratory Standards Institute

Disclosures

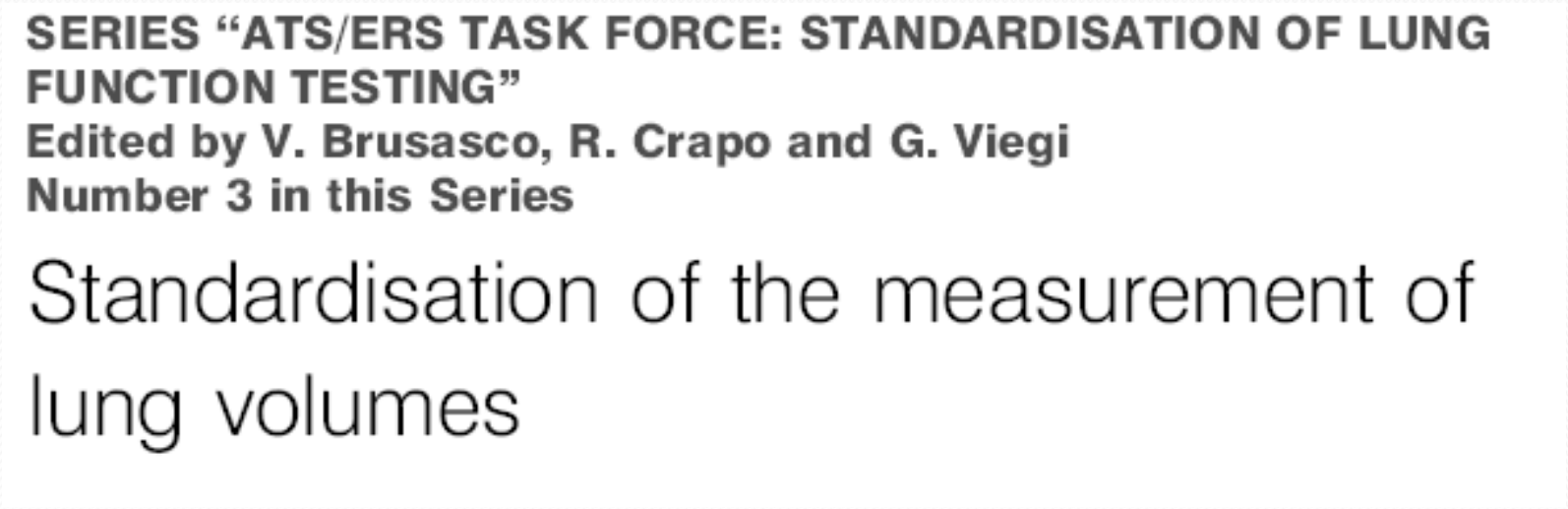
- Author of Ruppel's Manual of Pulmonary Function Testing 12th Edition 2022 Elsevier



- Member ATS-ERS Lung Volume Task Force
- Board Member – NBRC and Past-Chair of PFT Examination Committee
- Board Member and Immediate Past President - CLSI
- Consultant to the College of Physicians and Surgeons of British Columbia Diagnostic Accreditation Program

Statements, Guidelines and Standards

- 2005 ATS-ERS Statement



Statements, Guidelines and Standards

EUROPEAN RESPIRATORY *journal*

FLAGSHIP SCIENTIFIC JOURNAL OF ERS

Early View

Task force report

European Respiratory Society/American Thoracic Society Technical Standard on Standardisation of the Measurement of Lung Volumes - 2023 Update

July 27, 2023

Nirav R. Bhakta, Aisling McGowan, Kathryn A. Ramsey, Brigitte Borg, Jana Kivastik, Shandra Lee Knight, Karl Sylvester, Felip Burgos, Erik R. Swenson, Kevin McCarthy, Brendan G. Cooper, Francisco García-Río, Gwen Skloot, Meredith McCormack, Carl Mottram, Charles G. Irvin, Irene Steenbruggen, Allan L. Coates, David A. Kaminsky

Statements, Guidelines, and Standards

- Recommendations/Statements/Guidelines:
  - “a general rule, principle, or piece of advice”
  - Suggested “best practice”
- Standard:
  - something considered by an authority as an approved model
  - “Shall” versus “Should”
  - ATS and ERS now publishes “standards” to reduce variability.

Definition of Calibration vs Quality Control

Calibration

Using a standard to calibrate an instrument.

Quality Control

a system for ***verifying*** and maintaining a desired level of quality in an instrument.

Key Updates

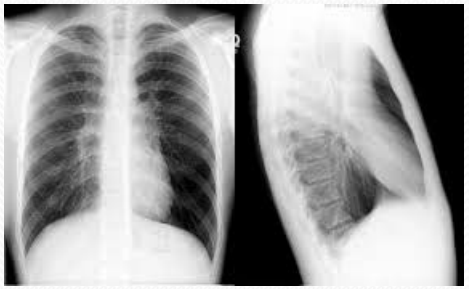
- Emphasis on importance of linked manoeuvres for determining lung volumes after measurement of functional residual capacity (FRC)
- For standardisation of linked spirometry, the method that is expected to be achievable by most patients is recommended.
- Emphasis on importance and limitations of biological controls for quality assurance assessment
- New equipment quality control and validation recommendations, including a requirement for isothermal lung mechanical models for calibration and verification of body plethysmographs
- Emphasis on pant frequency and recommendations on measuring airway resistance using body plethysmography. Comment on panting vs tidal breathing.
- Generalised concept of multiple breath washout (MBW) beyond nitrogen
- Updates on MBW technique based on recently published technical standards
- Differentiation between inert-gas dilution equipment that use volume-based vs flow-based spirometers
- A new acceptability and grading system for assessment of the quality of lung volume measurements. Examples of tracings distinguishing manoeuvres of different grades.
- Recommendation for using Global Lung Initiative lung volume reference values
- Updates on measurement of lung volumes by imaging and other new techniques
- Data file requirements, standardised operator comments, and sequence of lung function measurements

Techniques to Measure Lung Volumes

- Body plethysmography
- Dilutional gas techniques
  - Helium dilution (closed circuit)
  - Nitrogen washout (open circuit)
  - DLCO? (single breath)
- Imaging (x-ray e.g. planimetry) and CT
- MiniBox (Magic!!)
  - In the supplement

Clinical Utility of Lung Volume Measurements

- Identification of restrictive patterns is based on TLC
- Diagnostic implications of hyperinflation
  - asthma = reversible hyperinflation
  - emphysema = irreversible hyperinflation



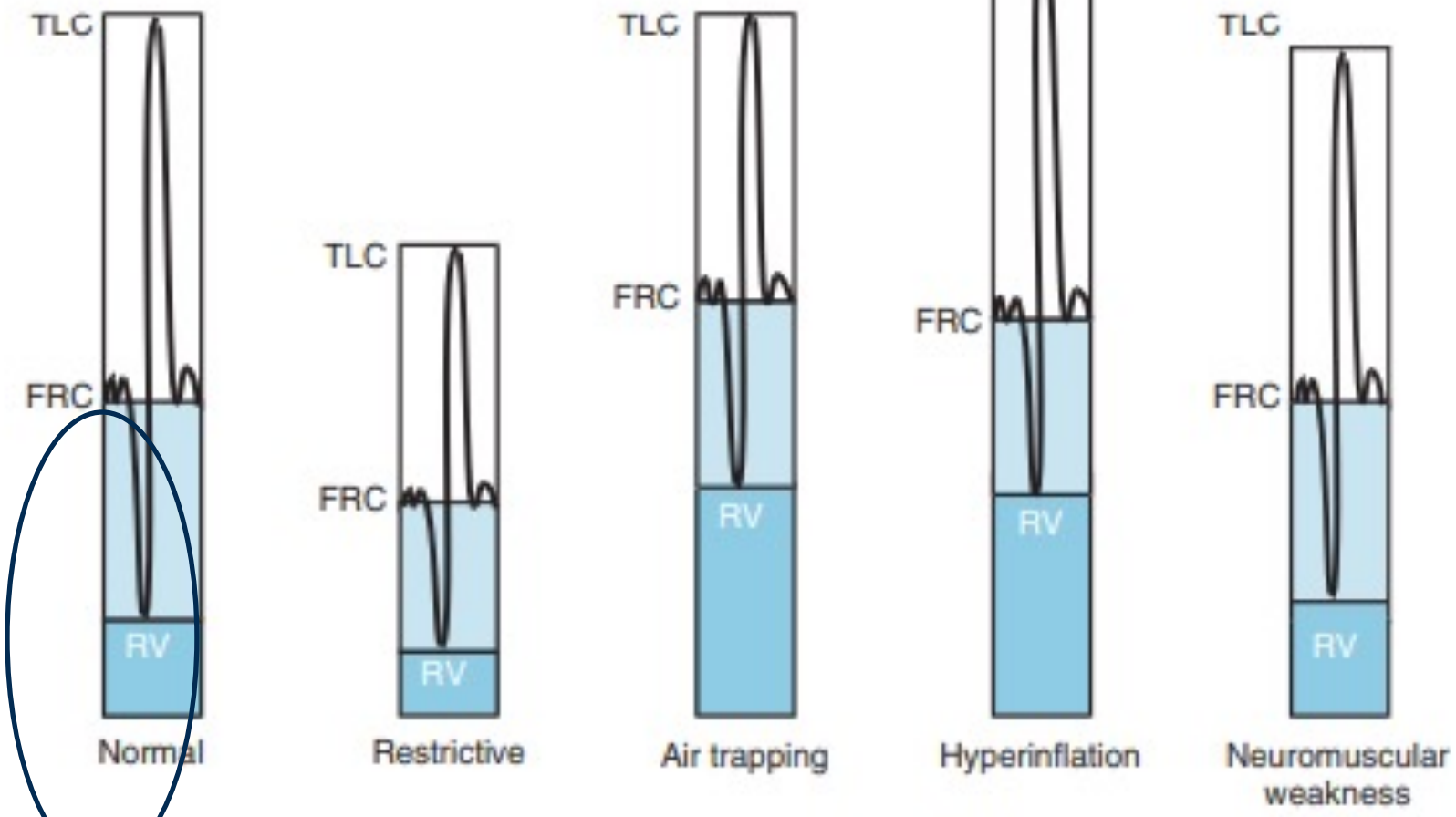
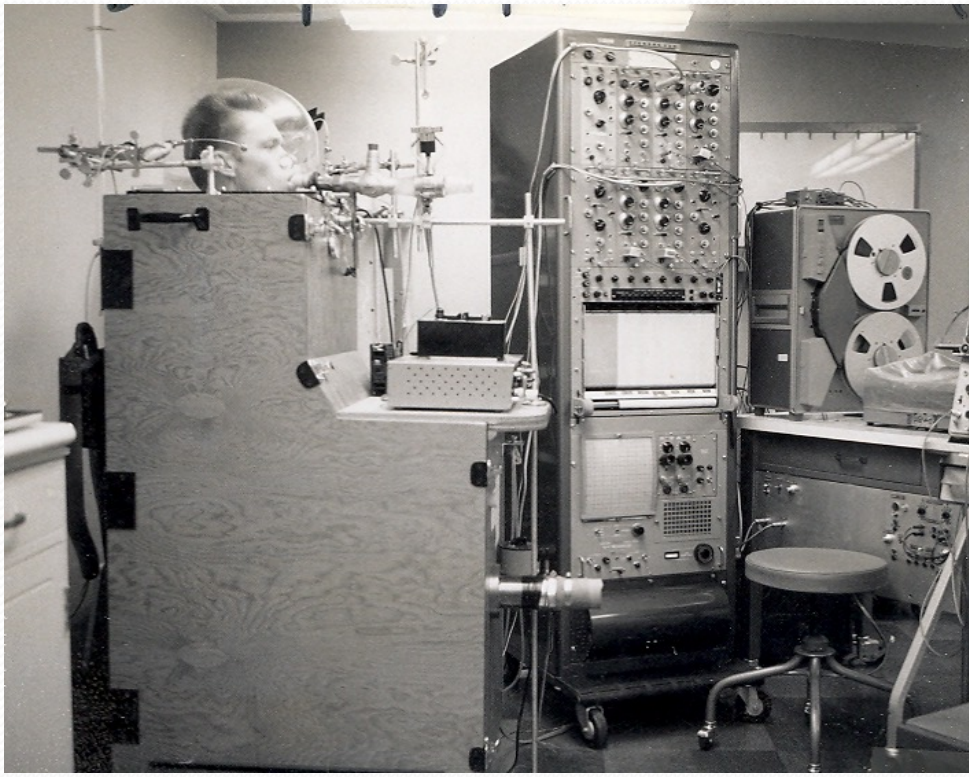


FIG. 4.8 Lung volumes in normal, restrictive, obstructive, and

Mottram 12th Ed Manual of PFTs

Plethysmographs



Mayo Clinic PF Lab 1970's

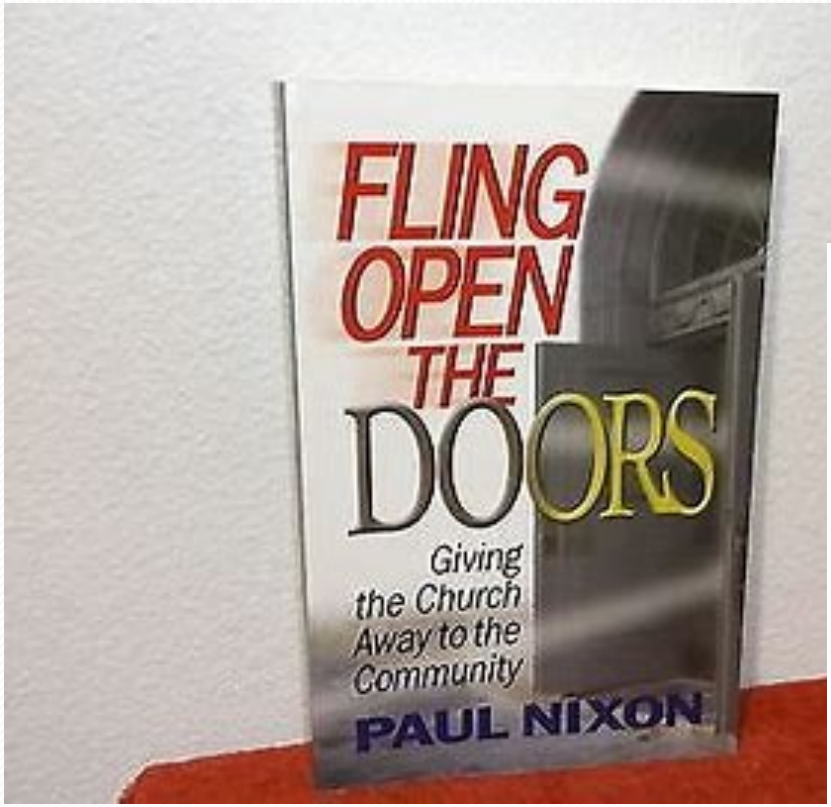
2023 ERS-ATS Standards

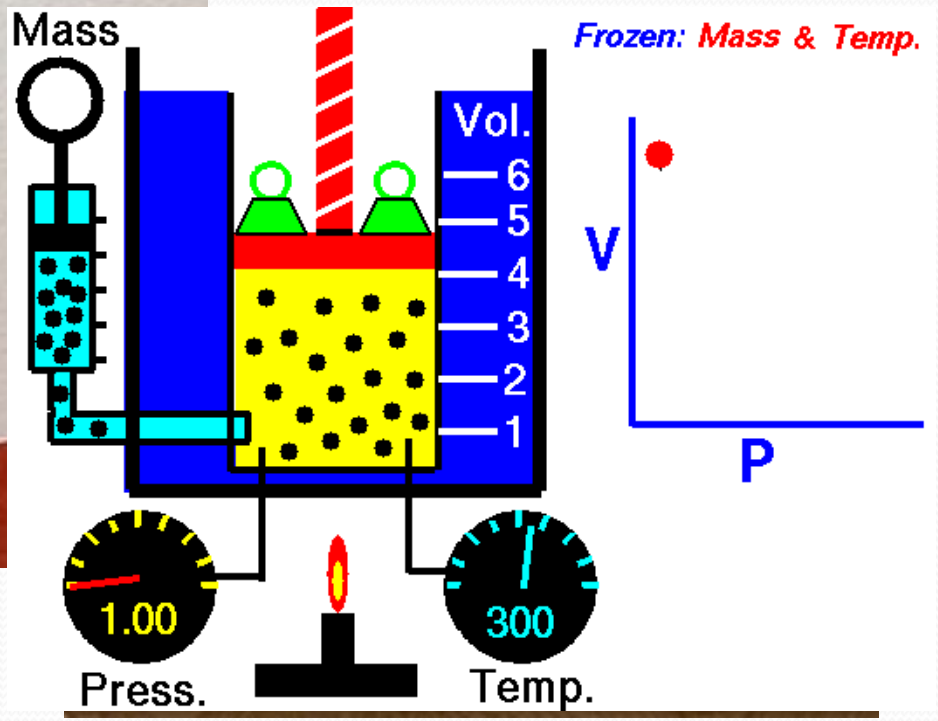
Standardization of Lung Volumes

Measurement technique – Plethysmography TGV

- Close door and wait 30 secs -2 minutes for thermo-equilibration
- Quiet breathing until a stable end-expiratory level is achieved (cheeks supported)
- Close shutter at or near FRC
  - Approx 2-3 seconds
  - Gentle pants $\pm$ 10 cmH2O
  - 0.5 to 1 Hz (30-60 breaths per minute)
    - > 1.5 Hz may lead to errors
    - < 0.5 Hz may cause problems with the controlled leak

2023 ERS-ATS LV TS Thermo-equilibration





2023 ERS-ATS Standards

Standardization of Lung Volumes

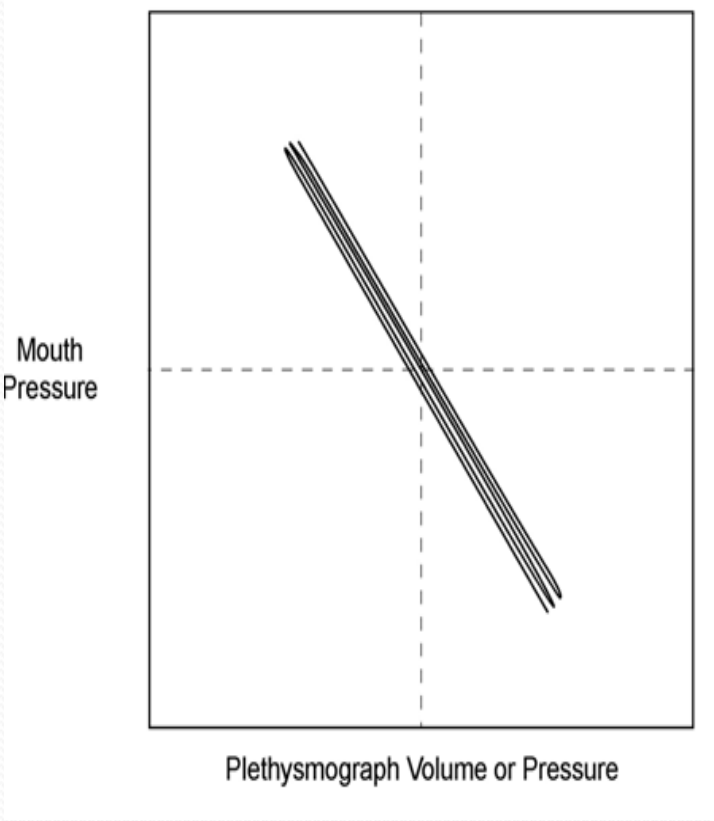
- Measurement technique – Cheek holding

2023 ERS-ATS Standards

Standardization of Lung Volumes

Measurement technique – Plethysmography (cont)

- 3-5 technically satisfactory panting maneuvers
- Patient then performs an IC followed by a linked SVC



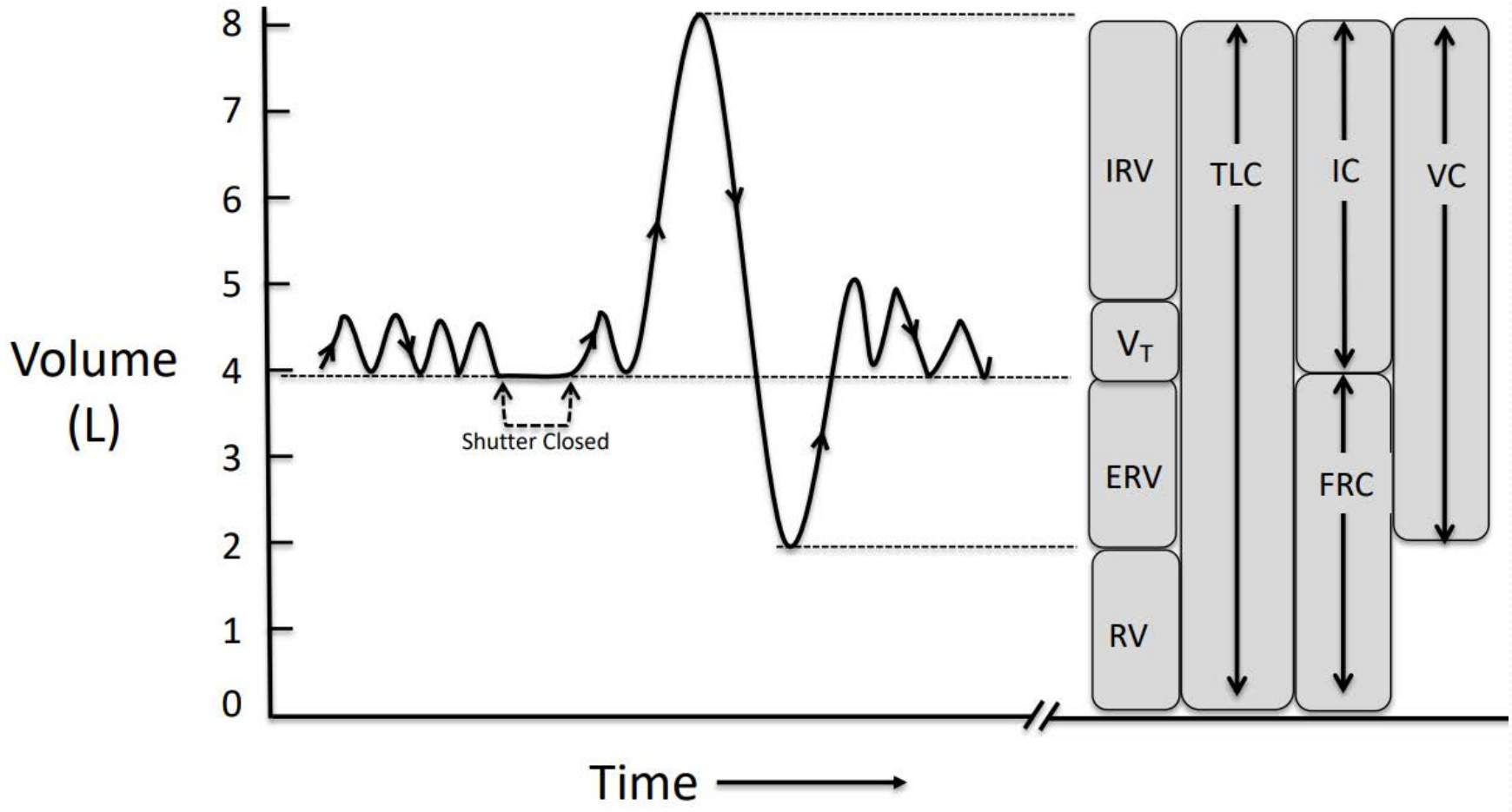


Figure 2: Volume–time display showing the sequence of quiet breathing and, after stable end-

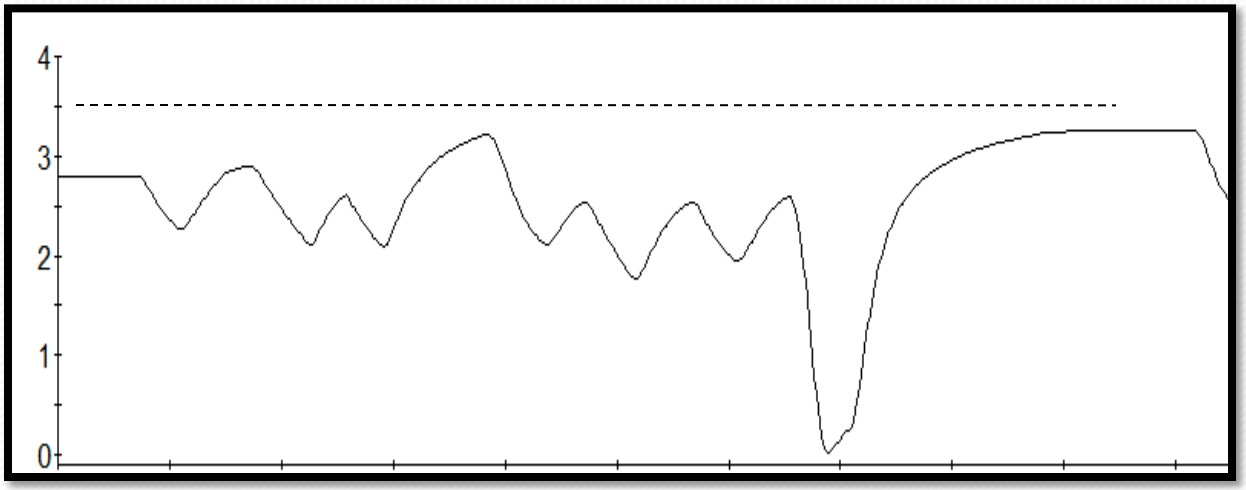
Unlike 2005 there is no preferred or alternative methods, rather only one method!

2023 ERS-ATS LV TS:
Pleth Acceptable and Usable

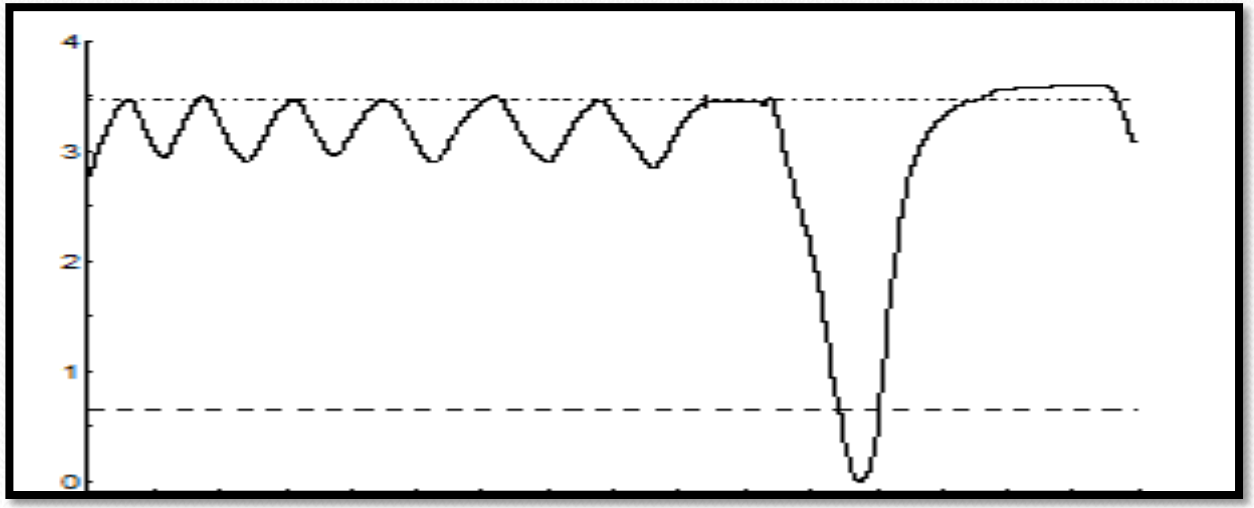
	Table 2: Acceptability Criteria for TGV (FRC) Measurement by Body Plethysmography
Classification	*Tidal breathing prior to shutter closure and pants/small breaths during shutter closure*
Acceptable	Pre-shutter closure: • Stable end-tidal lung volume* During shutter closure: • Closed pants • Overlapping straight lines with no thermal drift • Straight lines with minimal thermal drift • Pant frequency 0.5-1 Hz OR Pant freq > 1.0-1.5 Hz with no or minimal obstruction on spirometry
Useable	**Any of:** Pre-shutter closure: • Unstable end-tidal lung volume* without significant shift in either direction During shutter closure: • Portions of closed pants • Portions of overlapping straight lines • Parallel straight lines (thermal drift) • Pant frequency > 1.5-2.0 Hz with no or minimal obstruction on spirometry
Not acceptable or useable (reject)	**Any of:** Pre-shutter closure: • Unstable end tidal lung volume* with significant shift in either direction (e.g., increase in end expiratory lung volume with each breath) During shutter closure: • Open pants • No straight lines • Excessive thermal drift • Pants are clipped (mouth pressure transducer range exceeded) • Pant frequency < 0.5 Hz, > 2.0 Hz, or > 1.5 Hz and evidence of significant obstruction on spirometry

Useable – interpret with caution.

Plethysmography Technique: Evaluating Tidal Breathing

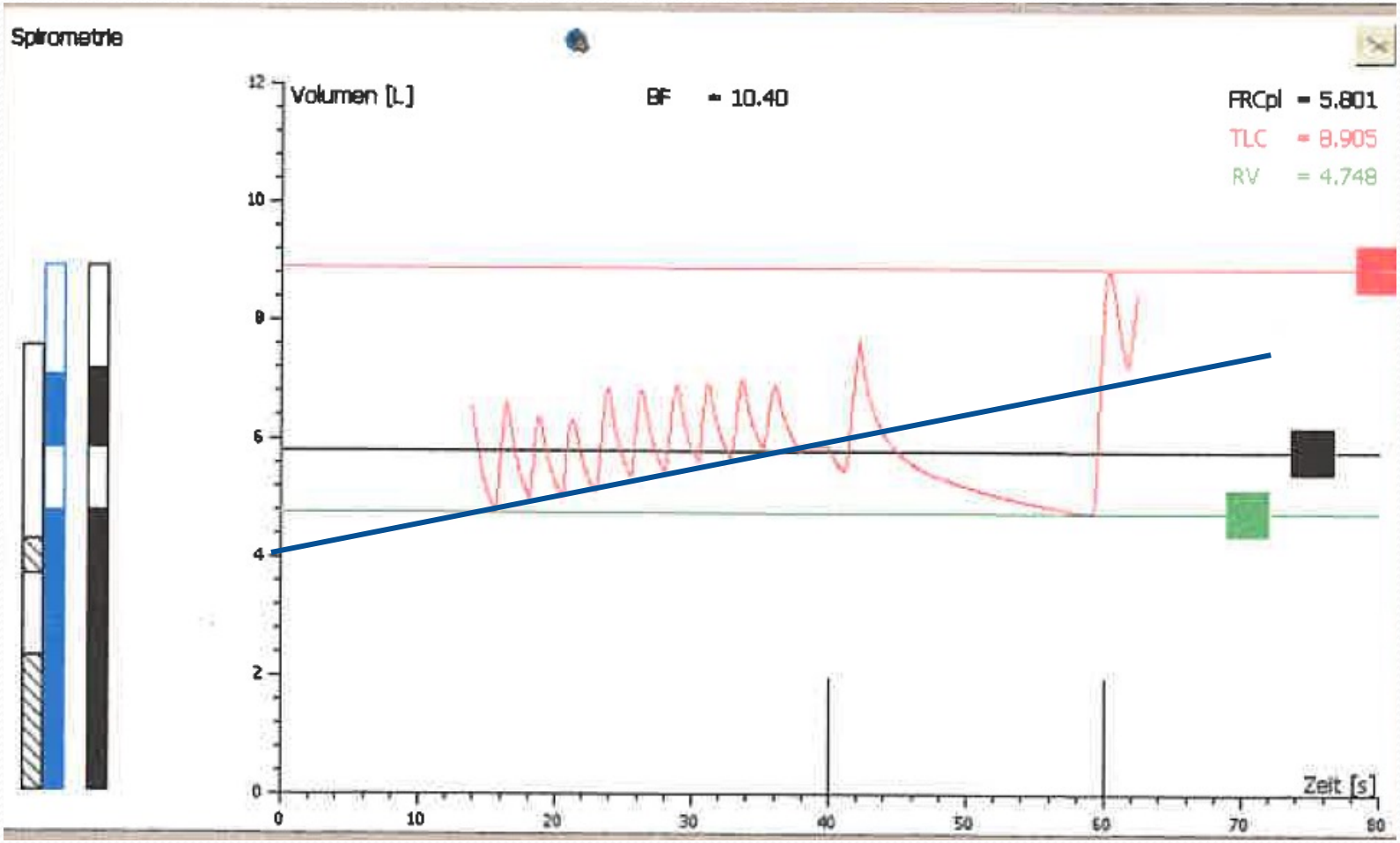


Unstable Tidal Breathing with variable FRC (usable)



Stable Tidal Breathing with consistent FRC (acceptable)

Plethysmography Technique:
Evaluating Tidal Breathing

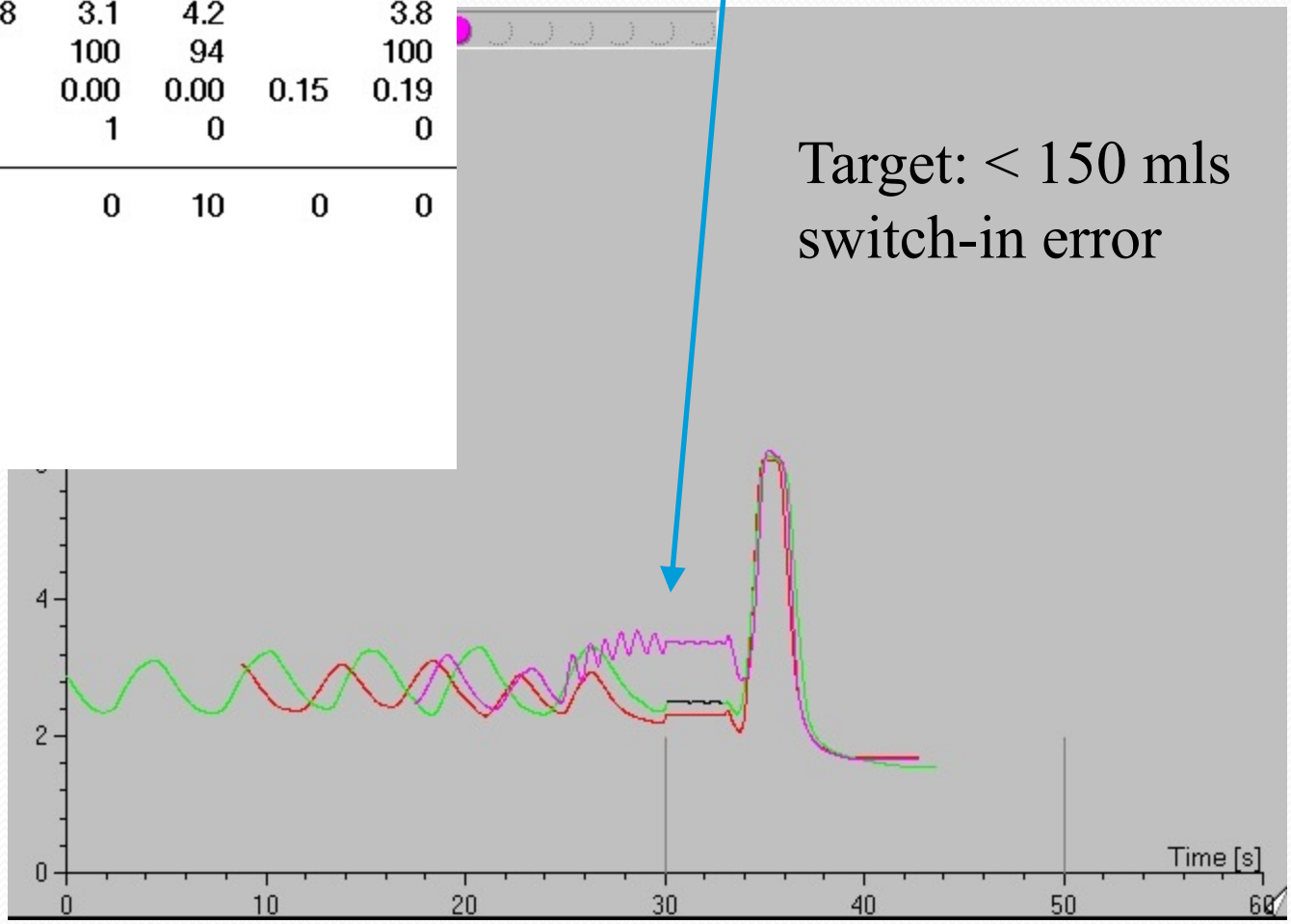


"Unusable"

	Pred	Best	%Pred	Act1	Act2	Act3	Act4
TLC	6.24	6.11	97.9		6.05	6.09	6.19
VC	4.34	4.52	104.2		4.37	4.52	4.52
VCref		4.52					
IC		3.49			3.73	3.73	3.01
RV	1.90	1.59	83.5		1.68	1.57	1.67
TGV		2.62			2.32	2.35	3.19
ETmayo				0	0	0	0
TGV'		3.84		3.84			
sR mid	4.7	3.9	84.8	3.1	4.2		3.8
BF res		96		100	94		100
dVol				0.00	0.00	0.15	0.19
ERmayo				1	0		0
mSlope		0		0	10	0	0
mBest		0					

Pant prior to shutter closure

Target: < 150 mls switch-in error



2023 ERS-ATS Standards

Standardization of Lung Volumes

Lung volume reporting

Repeatability: Obtain ≥ 3 FRC_{pleth} values that agree within 5%

- $\frac{\text{Largest FRC – smallest FRC}}{\text{mean FRC}}$

- Reported TLC is the reported value for RV plus the largest of the technically acceptable IVC's

- Results with repeatability exceeding 5% may still be of use.

2023 ERS-ATS LV TS:

Pleth Grading scheme

Table 6: Grading System for a Lung Volume Test Performed by Body Plethysmography

Grade	Number of FRC† measurements	Number of SVC measurements	Repeatability* of FRC
A	≥ 3 acceptable	≥ 3 acceptable	Within 5%
B	≥ 2 acceptable	≥ 2 acceptable	Within 5%
C	≥ 2 acceptable	≥ 2 acceptable	Within 10%
D	≥ 1 acceptable AND ≥ 1 useable	≥ 1 acceptable AND ≥ 1 useable	Within 10%
E	1 acceptable AND 0 useable	1 acceptable AND 0 useable	N/A
U	0 acceptable AND ≥ 1 useable	0 acceptable AND ≥ 1 useable	Within 10%
F	0 acceptable or useable		

Reference Values

- GLI Reference set
  - 7100, ages 5-80

Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry

Graham L. Hall[1,2], Nicole Filipow[3], Gregg Ruppel[4], Tolu Okitika[1], Bruce Thompson[5], Jane Kirkby[6], Irene Steenbruggen[7], Brendan G. Cooper[8], Sanja Stanojevic[3], on behalf of the contributing GLI Network members[9]

"Some battles you win and others you end up compromising"

"ended up" in the technical supplement

2023 ERS-ATS LV TS
Airway resistance

- Raw may be sensitive to small and rapid changes,
- can play a part in recognition of response to a bronchodilator,
- as well as contribute to the diagnosis and differentiation of obstructive airways diseases.

- Characterize the non-specific pattern
  - Reduced FVC and FEV1 with a normal TLC

Conditions Associated With an Abnormal Nonspecific Pattern of Pulmonary Function Tests

CHEST 2009; 135:419–424

- Reduction in FVC, FEV1
- Normal ratio
- Normal TLC

Table 3—*Summary of Patient Diagnosis

Diagnostic Categories	Men (n = 62)	Women (n = 38)	Combined (n = 100)
1. AHR without obesity	11 (18)	10 (26)	21 (21)
2. AHR with obesity	16 (26)	15 (40)	31 (31)
3. Chronic lung disease	13 (21)	3 (8)	16 (16)
4. Obesity	7 (11)	0 (0)	7 (7)
5. Other	15 (24)	10 (26)	25 (25)

- Characterize using sRaw or sGaw

male 60 Years Wt: 94.8 kg BMI: 29 Ht: 181.9 cm Arm Span: Test

Medical Research Council (mMRC): 1

	PREDICTED	CONTROL	POST-DILATOR
Substance			Albuterol
Dose			2 Puff
Patient Position		Sitting	Sitting

LUNG VOLUMES (PLETH)

	NORMAL	LLN	FOUND	%PRED.	FOUND	%PRED
TLC	7.45	6.30	6.44	86 %		
VC	4.89	3.72	4.13	84 %		
FRCpleth	3.71	2.72	4.05	109 %		

	NORMAL	ULN	FOUND	%PRED.	FOUND	%PRED
RV	2.47	3.15	2.32	94 %		
RV % TLC	37	46	36	96 %		

AIRWAY RESISTANCE

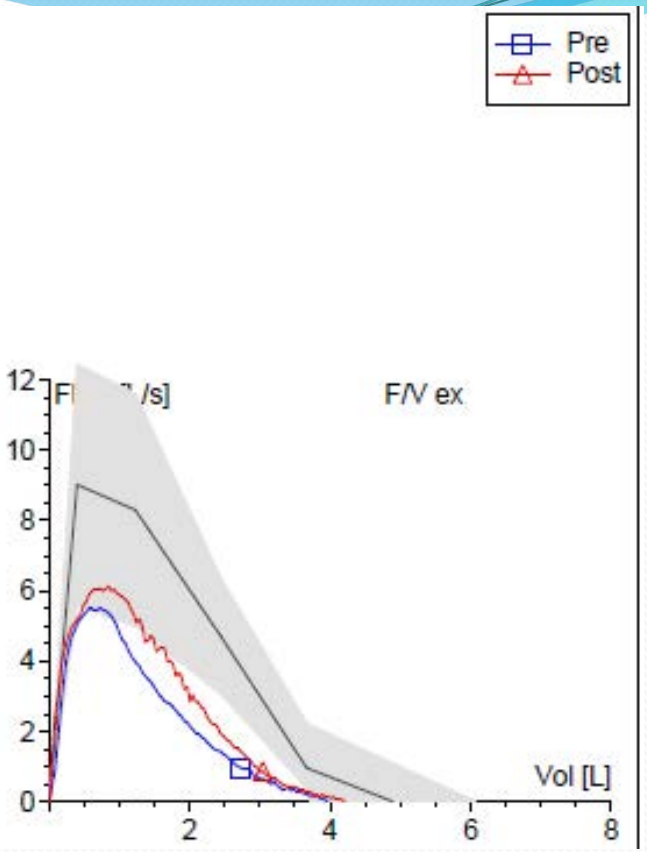
	NORMAL	ULN	FOUND	%PRED.	FOUND	%PRED
sR mid	4.65	7.87	9.63	207 %		

SPIROMETRY

	NORMAL	LLN	FOUND	%PRED.	FOUND	%CHNG	%PRED.
VC MAX	4.89	3.72	4.06	83 %	4.20	3 %	86 %
FVC	4.89	3.72	3.95	81 %	4.20	6 %	86 %
FEV 1	3.76	2.83	2.71	72 %	3.00	11 %	80 %
FEV1/FVC	77.1	65.1	68.7	89 %	71.6	4 %	93 %
FEF25-75%	3.08	1.51	1.78	58 %	2.07	16 %	67 %
PEF	9.0	5.6	5.5	61 %	6.2	11 %	68 %
FET			6.40		7.00	9 %	
MVV	147	114	100	68 %			

DIFFUSION CAPACITY

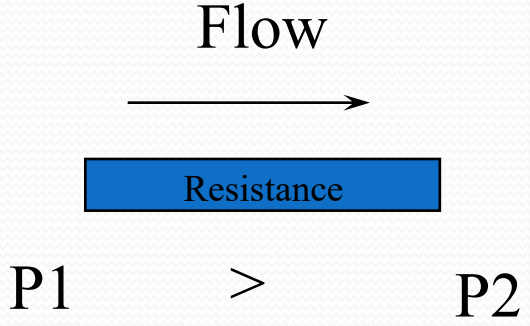
	NORMAL	LLN	FOUND	%PRED.	FOUND	%PRED
DLCO_SB	29.1	21.1			14.1	49 %
DLCOcSB	29.1	21.1			16.0	55 %
Hb					11.10	
VA_SB	6.93	5.76			6.20	90 %



2021 Interp. TS: *"Addition of BDR or SVC to characterize the abnormality"*

Add sRAW or sGaw

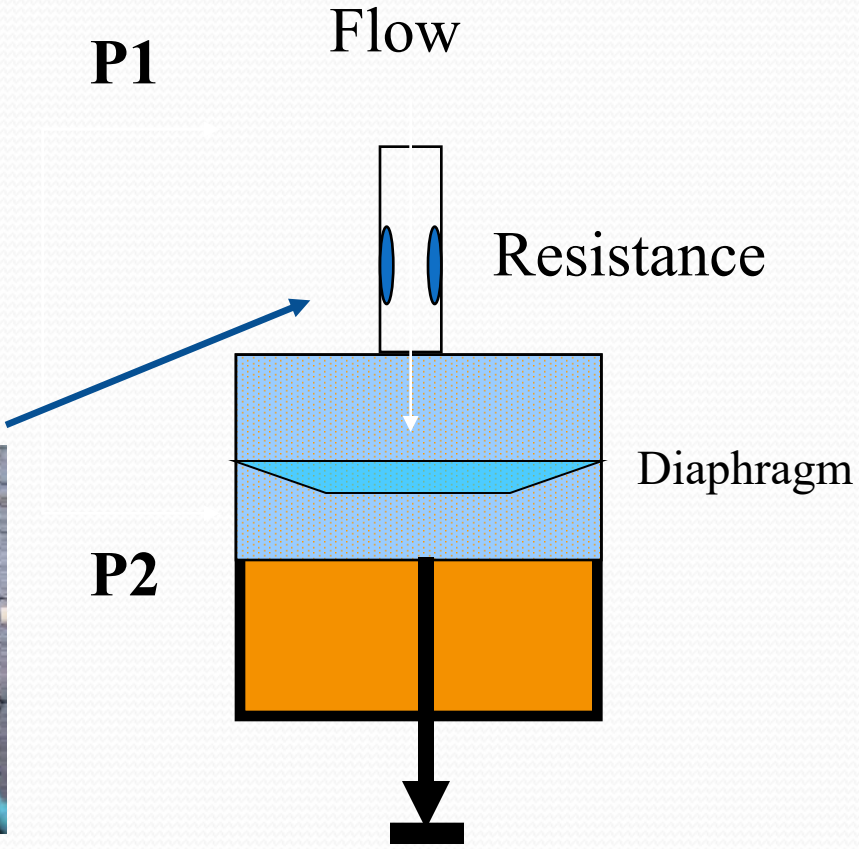
Ohm's Law



- Airway Resistance is related to airflow as illustrated by Ohm's Law
  - R = P/F where R is resistance, P is driving pressure and F is airflow.

Ohm's Law: *Flow between two points is directly proportional to the potential difference (i.e. pressure change P_1-P_2) across the two points, and inversely proportional to the resistance*

Flow occurs when Pressure differential ($P_1 > P_2$) can overcome Resistance



Inspiratory Muscles contract Diaphragm contracts pulling downward

2023 ERS-ATS measurement technique – Airway resistance

- Open-shutter panting maneuver shows a relatively closed loop, particularly in the range of +0.5 to -0.5 L/s
- Pant rate of 1.5-2 per second (60-120) with a VT of 50 to 150 mL.
- TGV after open panting for sRaw and sGaw
- The median value of up to five technically acceptable loops should be taken. The aim should be to report the mean of the results from at least three acceptable manoeuvres.

TGV and Raw together

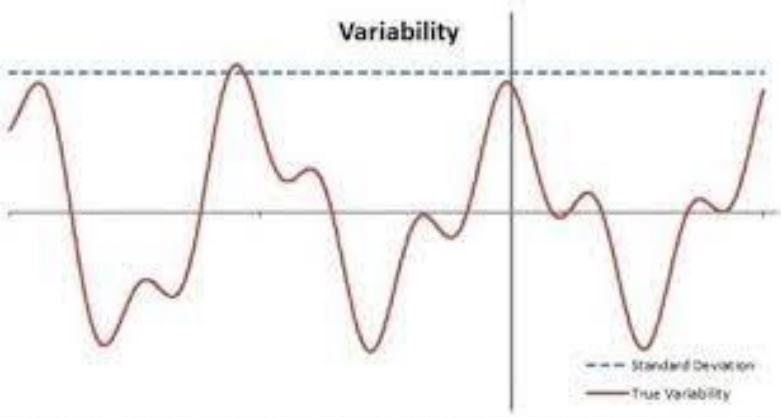
- 2023 LV TS “with emphasis on the need to separate measurement of airway resistance from lung volumes”
- The panting frequency for the parameters are different
  - TGV = 0.5-1 Hz (30-60)
  - Raw = 1.5-2.0 Hz (90-120)
  - Separate TGV with Raw to calculate sGaw and sRaw

2021 ERS Abstract

Pulmonary airway resistance variability in normal biologic quality control subjects among pulmonary function testing systems across British Columbia.

Mottram CD, McCaskill T, Road J., Rakhra N.
College of Physicians and Surgeons of British Columbia Diagnostic Accreditation Program. BC, Canada

	Panting Technique, 18 systems		Tidal Breathing Technique (TB), 10 systems	
	Raw	sGaw	Raw	sGaw
Mean CV	**7.62**	**8.52**	**10.25**	**13.74**
Min CV	**2.99**	**5.34**	**4.74**	**5.74**
Max CV	**13.1**	**12.75**	**39.6**	**40.8**



Raw/Gaw Normal values

- Reference values for airway resistance from body plethysmography. " The availability of reference values for airway resistance parameters was limited to relatively small sample sizes" 2023 ERS-ATS TS

- Resistance normal values:
  - 2.5 ± 0.6 cm H_2O/L/s for men and 3.0 + 0.6 cm H_2O/L/s for women.
  - sRaw - < 7H_2O/L/sec

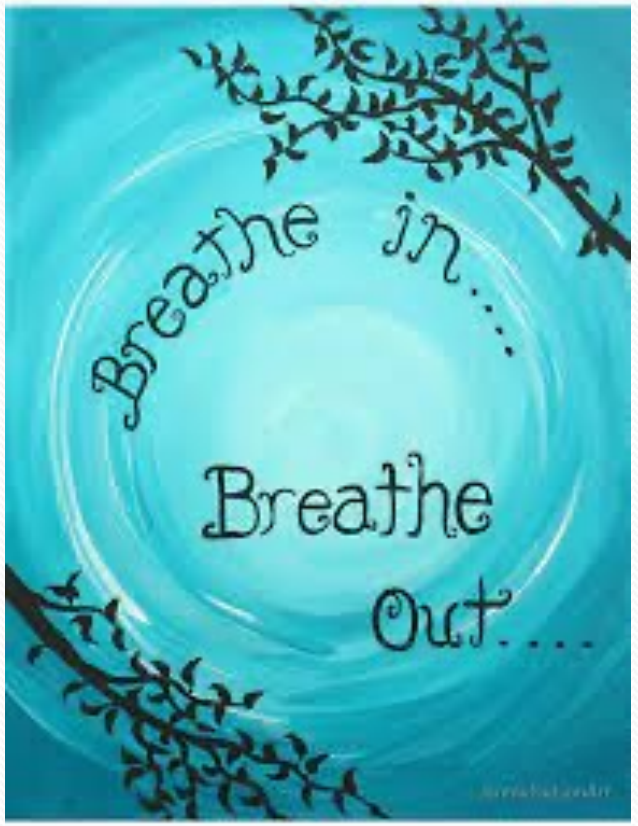
- Conductance normal values:
  - 0.42 – 1.67/L/sec/cm
  - sGaw – >0.15L/sec/cm

2023 ERS-ATS LV TS:

Multiple Breath Washout (MBW)

"Nitrogen Washout"

- 100% oxygen to washout the nitrogen of the lung.
  - "Open circuit technique"
  - or an exogenous gas (e.g., sulfur hexafluoride) washed out using room air

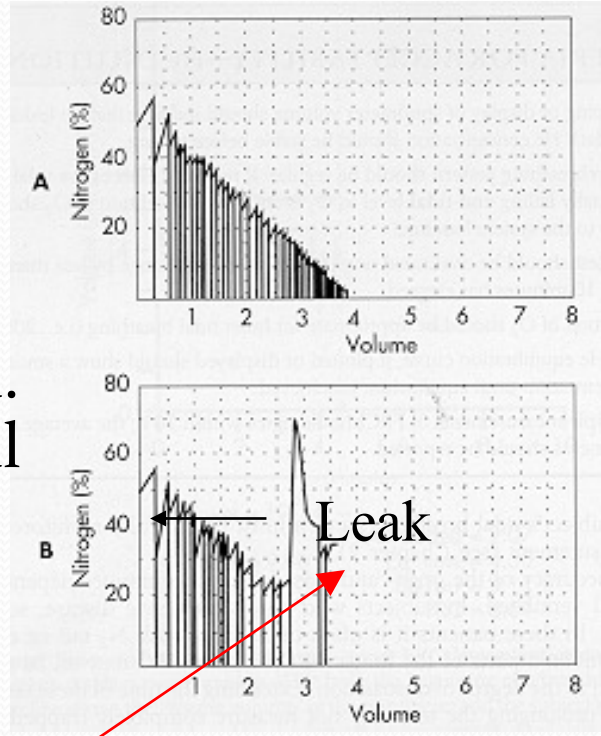


2023 ERS-ATS Standards

Standardization of Lung Volumes

Measurement technique – N_2

- Use earplugs for perforated eardrum
- Quiet breathing for 30-60s to establish a baseline FRC
- Switch patient into 100% O_2
- The patient is instructed to breathe regular tidal breaths without sighs, cough, or apnea.
- The washout is complete when the end-tidal tracer gas concentration is below 1/40th of the starting concentration for at least three consecutive tidal breaths.
- Once measurement of FRC is complete, the patient is instructed to perform a linked manoeuvre.
- N_2 rise > 1% or sudden larger increase indicate leak



2023 ERS-ATS LV TS

Standardization of Lung Volumes

Measurement technique – N_2 Washout

- Optimally measure at least 2 technically satisfactory measurement
- A waiting period of at least twice the washout time is recommended between manoeuvres. Longer waiting periods may be required in patients with severe obstructive or bullous disease
- If more than 1 trial is performed the FRC_{MBW} should be the mean of technically acceptable results that agree within 10%

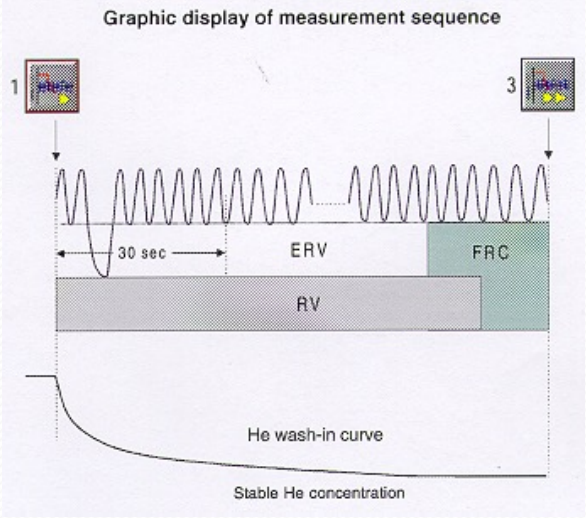
2023 ERS-ATS LV TS

Helium Dilution

- Closed-circuit technique
  - Helium gas 10% mixture
  - CO_2 and H2O absorber
  - Oxygen source

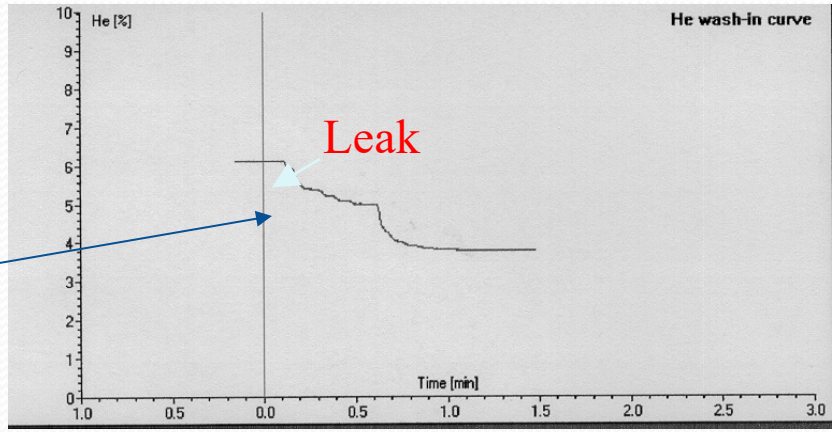
2023 ERS-ATS Standards

Standardization of Lung Volumes



He dilution

- Use earplugs for perforated eardrum
- Quiet breathing for 30-60s to establish a baseline FRC
- Turn in patient at the end of normal TV (FRC)
- The patient is instructed to breathe regular tidal breaths.
- He equilibration complete when change is < 0.02% for 30 sec.
- A sudden drop in helium indicates a system leak and will result in an overestimation of FRC.
- A waiting period of at least twice the dilution time is recommended between manoeuvres.



2023 ERS-ATS LV TS
Standardization of Lung Volumes

Measurement technique

- Optimally measure at least 2 technically satisfactory measurements
- A waiting period of at least twice the washout time is recommended between manoeuvres. Longer waiting periods may be required in patients with severe obstructive or bullous disease
- If more than 1 trial is performed the FRC_{He} should be the mean of technically acceptable results that agree within 10%

- Grading scheme for both MBW and He dilution

2023 ERS-ATS LV TS:

MBW Acceptable and Usable

	Table 3: Acceptability and Grading Criteria for FRC Measurement by Multiple Breath Washout
Classification	*Tidal breathing prior to washout and washout phase characteristics*
Acceptable	Pre-switch-in: • Relaxed tidal breathing with stable end-tidal lung volume* During washout: • Relaxed tidal breathing without sigh, cough, or breath-hold • Flow is stable with no forced breathing or signs of hyperventilation (CO_2 within 4-6% range if available) • No evidence of leak • End of test criteria met (three consecutive tidal breaths under target concentration) When performed: • Adequate wait time between MBW manoeuvres (≥ twice the washout time; longer with obstructive lung disease)
Useable	**As for acceptable except any of:** Pre-switch-in: • Unstable end-tidal lung volume* without significant shift in either direction • Irregular tidal breaths (swallow, small breath) in pre-phase During washout: • Irregular first breath of washout (swallow, small breath) • Sigh, cough, or breath-hold in rest of washout but no increase in end-tidal tracer gas concentration • End-tidal lung volume is unstable during washout but no increase in end-tidal tracer gas concentration
Not acceptable or useable (reject)	**Any of:** Pre-switch-in: • Unstable end tidal lung volume* with significant shift in either direction (e.g., increase in end expiratory lung volume with each breath) • Flow is highly erratic with or without forced breathing or hyperventilation (CO_2 outside 4-6% range if available) • Sigh, cough, or breath-hold During washout: • Sigh, cough, or breath-hold in first breath of washout • Sigh, cough, or breath-hold in rest of washout resulting in increase in end-tidal tracer gas concentration† • Significant shifts in end-tidal lung volume during washout resulting in increase in end-tidal tracer gas concentration† • Flow is highly erratic with or without forced breathing or hyperventilation (CO_2 outside 4-6% range if available) • Evidence of leak • End of test criteria not met: manoeuvre does not have three consecutive tidal

2023 ERS-ATS LV TS:

He Dilution Acceptable and Usable

	Table 4: Acceptability and Grading Criteria for FRC Measurement by Helium Dilution
Classification	*Tidal breathing prior to dilution phase and dilution phase characteristics*
Acceptable	Pre-switch-in: • Stable end-tidal lung volume* During dilution: • Relaxed tidal breathing without sigh, cough, or breath-hold • Stable end-tidal lung volume • No leak • End of test criteria met: (Δ[He]< 0.02% x 30 sec.) When performed: • Adequate wait time between manoeuvres (≥ twice the dilution time; longer with obstructive lung disease)
Useable	**As for acceptable except any of:** Pre-switch-in: • Unstable end-tidal lung volume* without significant shift in either direction During dilution: • Non-uniform dilution curve • Minimally unstable end-tidal lung volume • Sigh, cough, or breath-hold with no leak
Not acceptable or useable (reject)	**Any of:** Pre-switch-in: • Unstable end tidal lung volume* with significant shift in either direction (e.g., increase in end expiratory lung volume with each breath) During dilution: • Unacceptable breathing pattern • Evidence of leak • Failed end of test When performed: • Inadequate wait time between manoeuvres

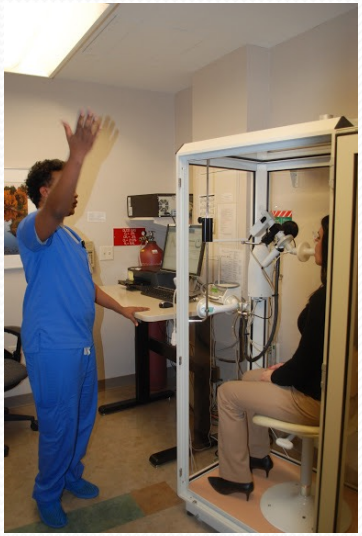
2023 ERS-ATS LV TS: MBW, He Dilution Grading scheme

Table 7: Grading System for a Lung Volume Test Performed by MBW or Helium Dilution

Grade	Number of FRC† measurements	Number of SVC measurements	Repeatability* of FRC
A	≥ 2 acceptable	≥ 2 acceptable	Within 10%
B	1 acceptable AND ≥ 1 useable	1 acceptable AND ≥ 1 useable	Within 10%
C	≥ 2 useable	≥ 2 useable	Within 10%
D	≥ 2 acceptable OR useable	≥ 2 useable	Within 25%
E	1 acceptable AND 0 useable	1 acceptable AND 0 useable	N/A
U	0 acceptable AND 1 useable	0 acceptable AND 1 useable	N/A
F	0 acceptable or useable		

Quality Control
Sources of Error

- Equipment
- Testing personnel
- Subject



Equipment - Plethysmograph

Environmental Effects

Room temperature

Ventilation

Door opening

2023 ERS-ATS Standards

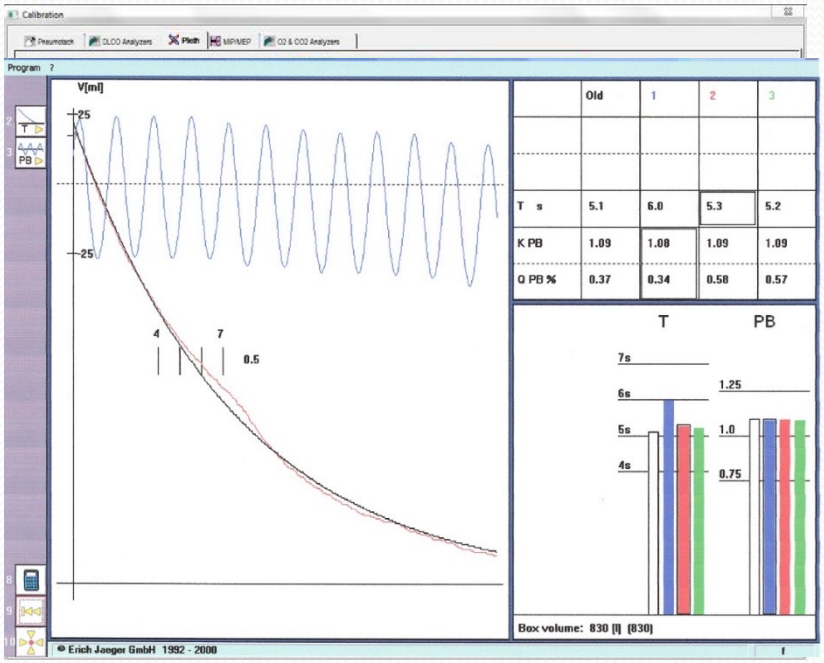
Standardization of Lung Volumes

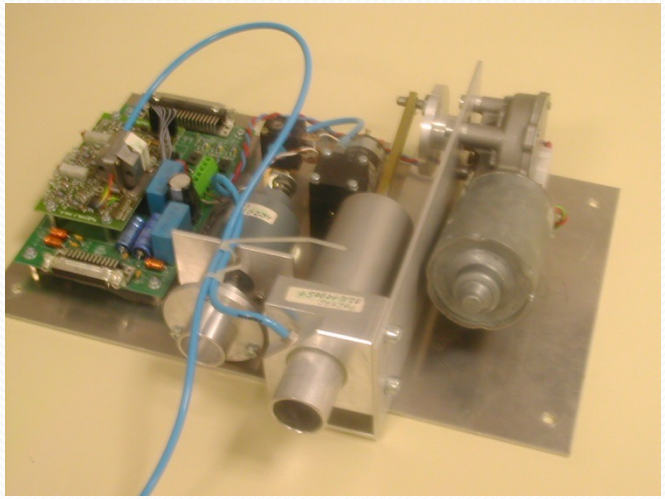
Quality Control - Plethysmography

- Flow and volume meet criteria set in the spirometry standards
- Mouth pressure transducer is calibrated daily
- Plethysmograph signal should also be calibrated daily using a volume signal of similar magnitude and frequency used during testing

Plethysmography

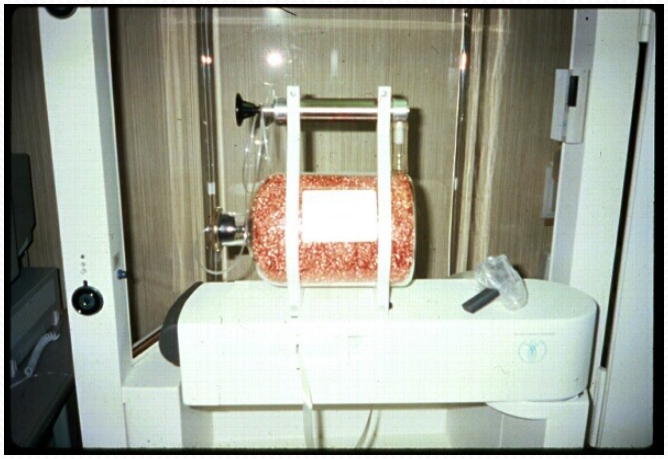
- 50 ml pump calibrates delta pressure/volume
- Frequency response
- Leak check





ATS/ERS Standards

Standardization of Lung Volumes



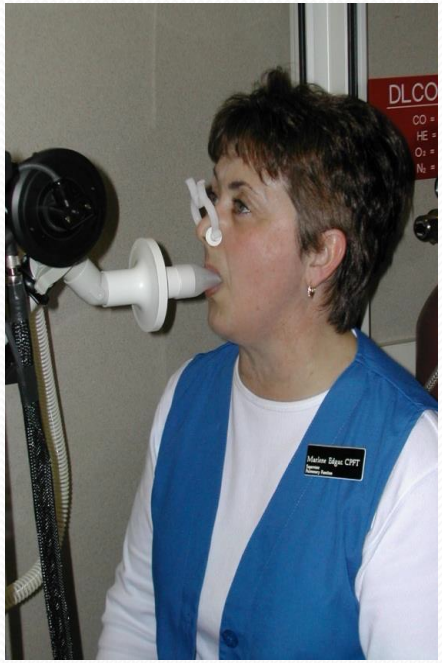
Quality Control - Plethysmography

- A validation of accuracy using a known volume *must* be performed monthly, when new software uploaded, or a problem is suspected.
- This can be carried out using a "model" lung or container of known volume, ideally of two different sizes
- Accuracy 50 ml or 3%

2023 ERS_ATS TS

"BIOLOGICAL CONTROL SUBJECTS"

- At least monthly, or whenever errors are suspected, two healthy non-smoking reference subjects (biological controls) should undergo body plethysmography.
- Two individuals minimum to avoid noncompliance during absences.
- Establish mean, SD and CV
  - 10 samples (5-6 minimum)
    - TLC and FRC CVs ≤5%
    - ERV and AR CVs ≤10% (suggested)

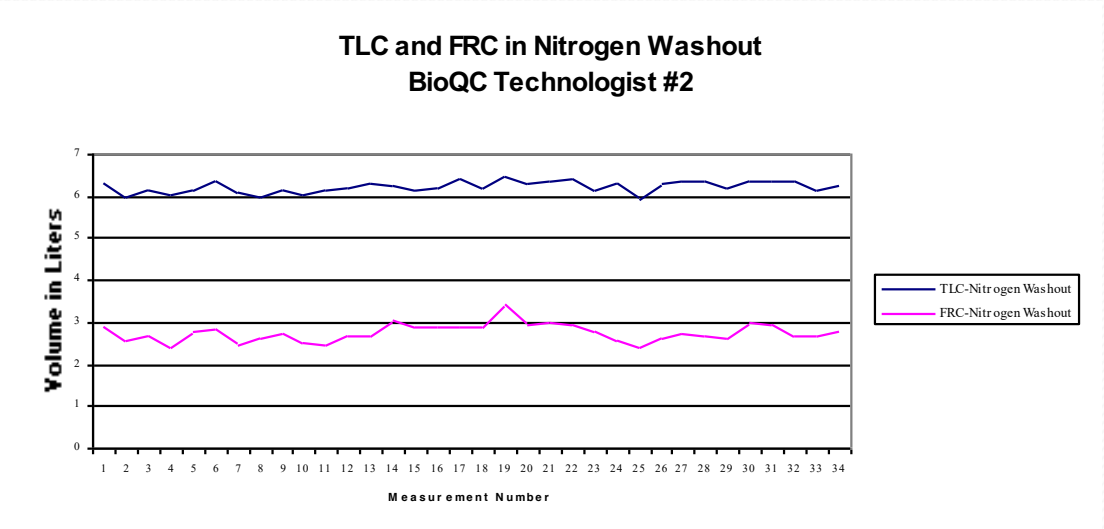


2023 ERS-ATS Standards

Standardization of Lung Volumes

Quality Control – N_2 washout

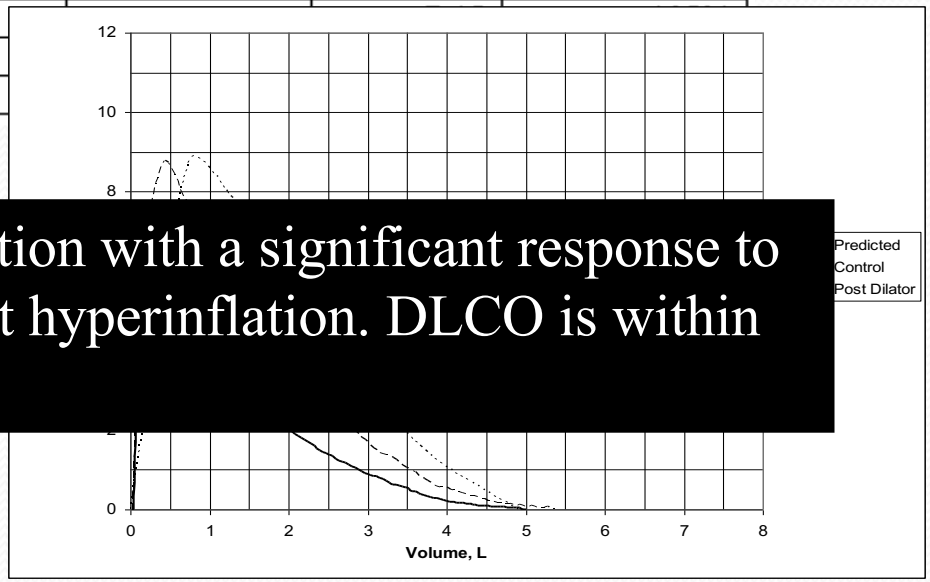
- N_2 analyzer should be zeroed prior to each test
- Initially and every 6 months confirm analyzer linearity
- At least monthly or whenever errors are suspect 2 reference subjects (biologic controls) should be tested



68 y.o Male	Wt: 89.0 kg	BMI: 26.9	Ht: 182.0 cm			
	Predicted		Control		Post-Dilator**	
	Normal	Range	Found	%Predicted	Found	%Change
Lung Volumes						
TLC (He)	7.14	>5.77	10.77	151%		
VC	4.90	>4.06	4.62	95%		
RV	2.25	<2.92	6.14	273%		
RV/TLC	31.5	<41.2	56.9	181%		
FRC			7.6			
Spirometry						
FVC	4.90	>4.06	4.93	101%	5.29	+7%
FEV1	3.73	>3.05	2.62	70%	3.30	+26%
FEV1/FVC	76.2	>67.0	53.2		62.3	
FEFmax	8.7	>5.3	6.7	76%	8.8	
Diffusing Capacity					**Found**	**%Predicted**
DLCO (SB)	23.3	>16.8			27.4	100%
VA	5.22	>4.13				

*Outside normal range.

**Bronchodilator was Albuterol.



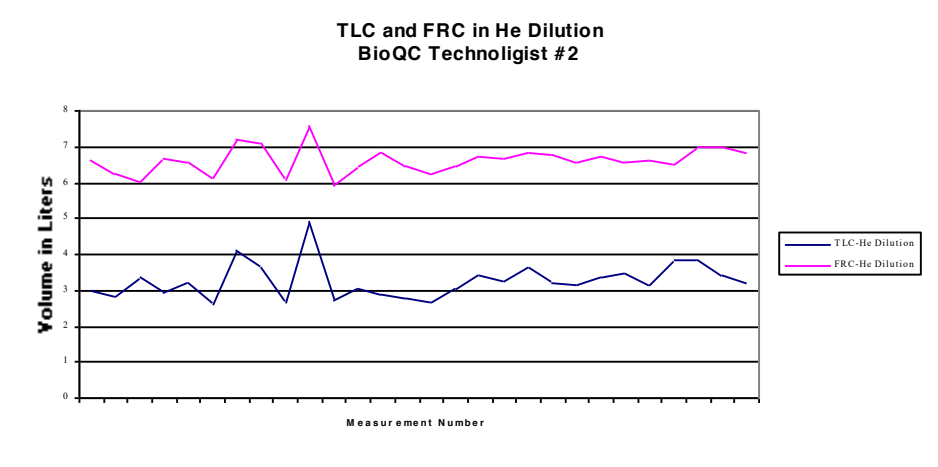
Abnormal Study: Mild airway obstruction with a significant response to bronchodilator. Lung volumes suggest hyperinflation. DLCO is within normal limits.

2023 ERS-ATS Standards

Standardization of Lung Volumes

Quality Control – He dilution

- Systems that can have gas filling volume checks should be checked for leaks at least once per month and after tubing or canister changes.
- The stability of the helium analyzer should be confirmed weekly (it should not drift > 0.02% in 10 min)
- At least monthly or whenever errors are suspect 2 reference subjects (biologic controls) should be tested



New Instrument Validation-Verification On-boarding Process

Pulmonary Function - New Equipment Acceptance Testing

Facility Name: Hospital 15 - new equipment

Do not enter data in these cells. They fill in automatically.

Current Equipment														
Equipment Purchase Date		2012												
Equipment Name		Jaeger												
Equipment Make		Jaeger Body Box												
Equipment Model		Masterscreen												
Software Version		5.71.0												
Parameter	Target CV%	1	2	3	4	5	6	7	8	9	10	Average	Standard Deviation	Coefficient of Variation
Biological QC/Gender		F	F	F	F	F	F	F	f	F	F			
Testing Therapist		lf	LF	LF	LF	LF	LF	LF	LF	LF	LF			
Date		11.08.20	29.09.20	28.10.20	19/11/20	16.12.21	12.01.21	10.02.21	08.03.21	13/04/21	08.05.21			
Time		10:00	10:00	10:00	10:00	10:00	10:00	10:00	10:00	10:00	10:00			
BODY PLETHYSMOGRAPHY														
FRC Pleth	<5	3.49	3.57	3.55	3.45	3.58	3.60	3.48	3.55	3.56	3.6	3.54	0.05	1.47
TLC(Box)	<5	4.95	4.94	5.02	4.86	4.97	5.09	5.06	4.93	5.08	5.07	5.00	0.08	1.58
[1]Pant Frequency	30-90	30											0	0
[2]Switch-in Volume	<200ml	110.00	60.0										8.99	32.66
TLC(Box)-VA	*<500ml*	*1210*	*135*											
SVCmax (Box)	<3	2.37	2.3										0.10	4.08
SVC-FVC		*0.00*	*-0.0*											
ERV(Box)	<10	0.91	1.0										0.12	12.40
IC(Box)	<10	1.46	1.3										0.08	5.13
RAW eff	<10	1.66	2.1										0.28	16.85

New Equipment															
Equipment Purchase Date		May-21													
Equipment Name		Vyntus Body Box													
Equipment Make		Vyaire													
Equipment Model		Body box													
Software Version		SP.3.20.1													
Parameter	Target CV%	1	2	3	4	5	6	7	8	9	10	Average	Standard Deviation	Coefficient of Variation	
Biological QC/Gender		F	F	F	F	F	F	F	F	F	F				
Testing Therapist		LF	LF	LF	LF	LF	LF	LF	LF	LF	LF				
Date		19/05/21	19/05/21	20/05/21	20/05/21	01.06.21	02.06.21	02.06.21	03.06.21	03.06.21	03.06.21				
Time		10:00	14:00	10:00	14:00	10:00	10:00	14:00	10:00	12:00	14:00				
BODY PLETHYSMOGRAPHY															
FRC Pleth	<5	2.68	2.58	2.48	2.71	2.57	2.58	2.92	2.35	2.47	2.87	2.62	0.18	6.79	-26%
TLC(Box)	<5	4.22	4.17	3.98	4.18	4.06	4.05	4.15	3.77	3.82	4.25	4.07	0.16	4.05	-19%
[1]Pant Frequency	30-90	30	30	30	30	30	30	30	30	30	30	30	0	0	0%
[2]Switch-in Volume	<200ml	50.00	110.00	120.00	150.00	140.00	80.00	70	130	120	170	114.00	37.48	32.87	-24%
TLC(Box)-VA															
SVCmax (Box)												2.61	0.03	1.31	8%
SVC-FVC															
ERV(Box)												1.17	0.08	6.94	21%
IC(Box)												1.44	0.10	7.17	-2%
RAW eff												1.65	0.30	18.16	0%

Average	Standard Deviation	Coefficient of Variation
3.54	0.05	1.47
5.00	0.08	1.58
30	0	0

Average	Standard Deviation	Coefficient of Variation	% difference
2.62	0.18	6.79	-26%
4.07	0.16	4.05	-19%
30	0	0	0%

A Verification-Acceptability Process for Onboarding New PFT Systems in a Canadian Provincial Accreditation Program

Mottram CD, Ervin F, Rakhra N, McCaskill T. College of Physicians and Surgeons of British Columbia Diagnostic Accreditation Program, Canada

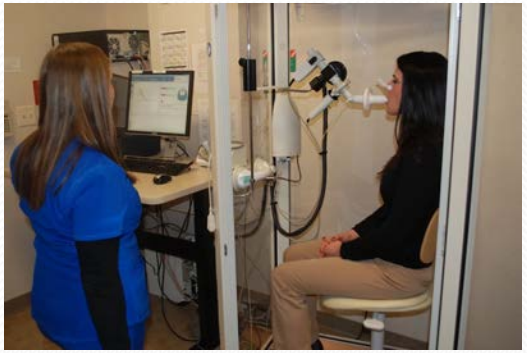
Introduction

The College of Physicians and Surgeons of British Columbia's Diagnostic Accreditation Program (DAP) is responsible for accrediting pulmonary function (PF) laboratories across the province. DAP has defined an onboarding process for new or repaired equipment and significant software upgrades that includes both mechanical and biological model testing. The mechanical model testing includes syringe linearity and DLCO testing along with isothermal lung volume measurement. We want to share the components of this program (figure 1) and the BioQC comparison results to date.

Figure 1

PES2.1		**Acceptance testing is performed after purchase and prior to clinical use of equipment.**
PES2.1.1	M	New, replaced, or relocated equipment has acceptance testing performed prior to clinical use.
PES2.1.2	M	The tester is independent of the manufacturer.[1]
PES2.1.3		Results from the acceptance testing are used to establish baseline values of operational performance.
PES2.1.4	M	Acceptance testing records are available for review.
		Acceptance testing of diagnostic equipment includes:
PES2.1.5	M	• an initial inspection of the system and any ancillary equipment
PES2.1.6	M	• an inspection of documentation
PES2.1.7	M	• biological controls have 10 tests performed to ensure accuracy and repeatability
PES2.1.8		• data analysis to identify a shift or bias from the previous or other testing equipment to the new equipment
PES2.1.9	M	• a defined procedure to notify interpreting staff if a systematic bias has been identified
PES2.1.10	M	• a review of the test data by the medical leader prior to clinical use

Results



BioQC	FVC	FEV_1	TLC	FRC	DLCO
New vs old target difference	<5%	<5%	<10%	<10%	<10%
Number	10	10	8	8	8
Maximum difference (%)	8	-7	-19	-26	12
Action required	3	1	1	2	2

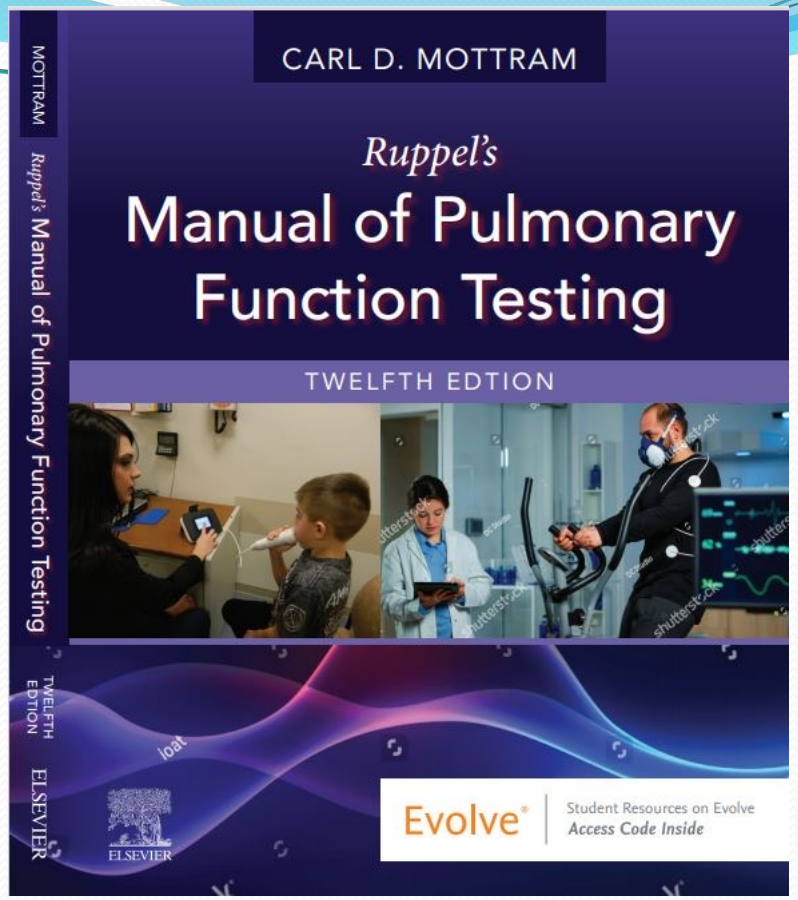
Discussion

An equipment onboarding process is well defined in Laboratory Medicine (LM) community, but not in PF labs. DAP's model is consistent with LM models, which assist a laboratory in identifying bias or clinically significant differences between testing systems. The largest difference we encountered in this limited data set was an FRC difference (-26%, 0.920L). In total there were 9 results that were above the target and required an action by the PF laboratory management team.

We wanted to share DAP's model and initial results to encourage other PF labs to adopt this method of verification for PF testing systems

Summary

- Requires linked-SVC maneuvers
- Separation of lung volumes from airway resistance
  - Panting vs TV for Raw
- Requires mechanical and biological QC testing
  - Onboarding verification process
- New acceptability and usability criteria with a grading scheme
- GLI reference



PFWConsulting@gmail.com

507-261-4525