Quality Assurance
Mapping Your QC Program
Equipment and Test Quality

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How to Begin

- Gather resources
- Define PF scope of service
  - Procedures performed
  - Equipment
- Describe QC Needs per Equipment
- Describe test quality requirements
- Planning
  - Gap analysis

Test Method	Biologic QC	Mechanical QC	Frequency
Spirometry	monthly	Linearity check	weekly
DLCO	weekly	Syringe DLCO	weekly
DLCO		Gas analyzer linearity check (e.g. DLCO simulation or other syringe dilution method)	monthly
Plehysmography Lung Volumes	monthly	Isothermal bottle	
Airway Resistance	monthly		
Helium Dilution	monthly		
Nitrogen Washout	monthly		
Exercise with Gas Exchange	monthly		
Treadmill		Check slope and speed	monthly
Lung Clearance Index	monthly		

ATS Pulmonary Function Laboratory Management and Procedure Manual, 3rd Edition.

Procedure Name: Quality Control

Purpose and Principle:

The term "quality control" can be defined as the process of monitoring the precision and accuracy

Tests Performed

- Spirometry
- DLCO
- Lung Volumes
  - Helium dilution
  - Nitrogen washout
  - Plethysmography
- Exercise Testing

Equipment QC Needs

- List of equipment requiring QC
- QC methods for each piece of equipment
- Instructions for performance of QC
- Frequency

Equipment Quality Control

- Manufacturer's limits of acceptability
- Laboratory's limits of acceptability
- Monitoring of technologist performance
  - Equipment QC
  - Test Quality

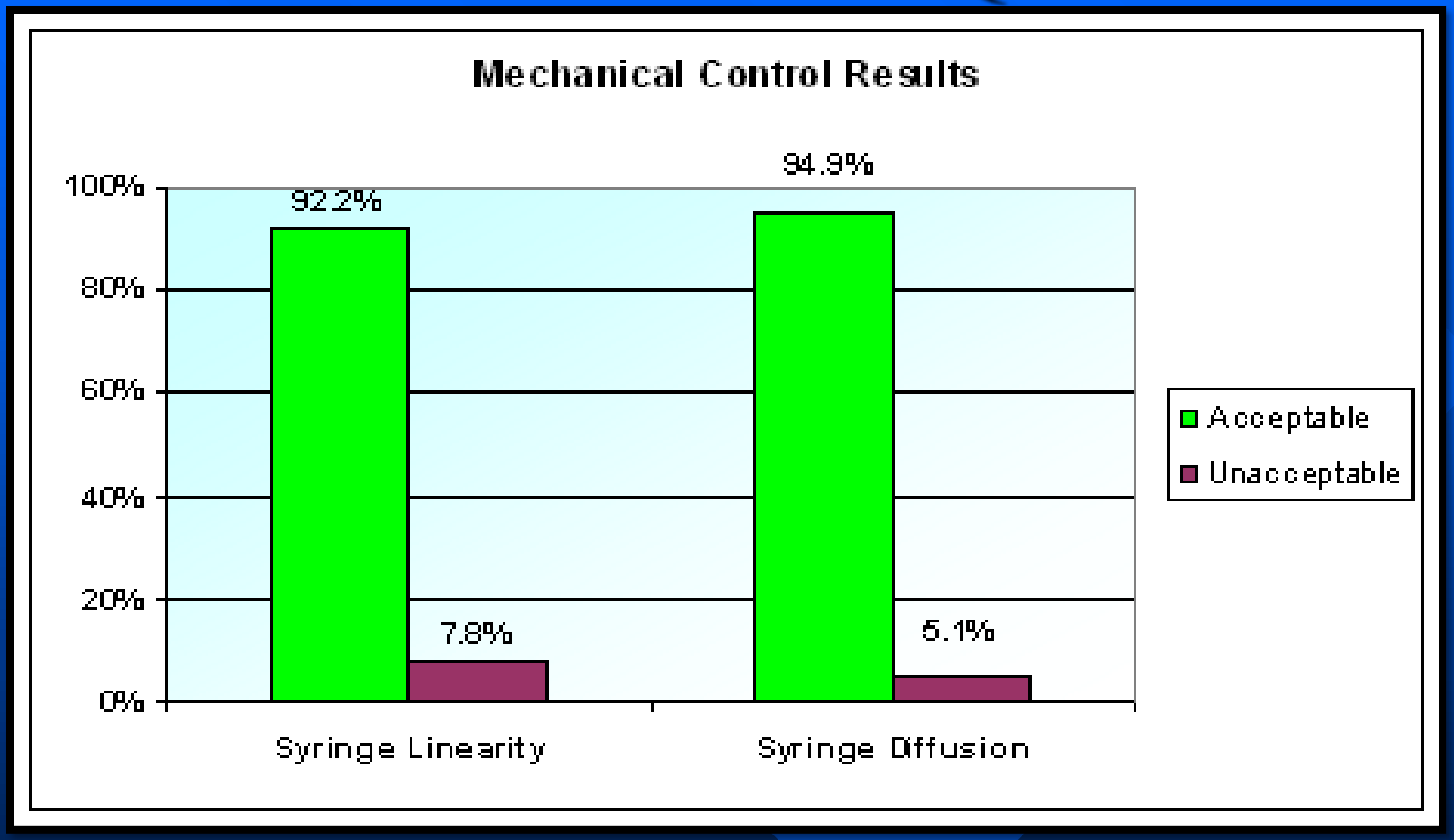
Quality Control

- Equipment Quality Control
  - Manufacturer's limits of acceptability
  - Laboratory's limits of acceptability
- Biologic Controls
- Test Method Quality Control
  - Monitoring of technologist performance
  - Feedback

Gap Analysis

Quality Control Worksheet									
Equipment Manufacturer:									
Purchase Date:									
Software Version:									
Install Records:									
Tests performed	Current QC Methods	Current Frequency	Manufacturer Limits of Acceptability	Laboratory Limits of Acceptability	QC Methods needed	Frequency	Responsible Person	Directions Available	Process for Out of Control Results
Spirometry (example)									

Mechanical QC



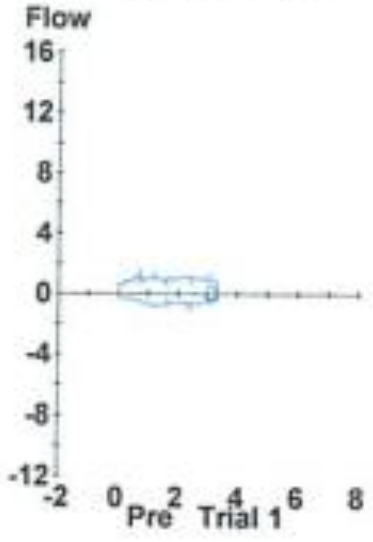
Blonshine SB, Harris R, Snow, M 2007 ERS Abstract

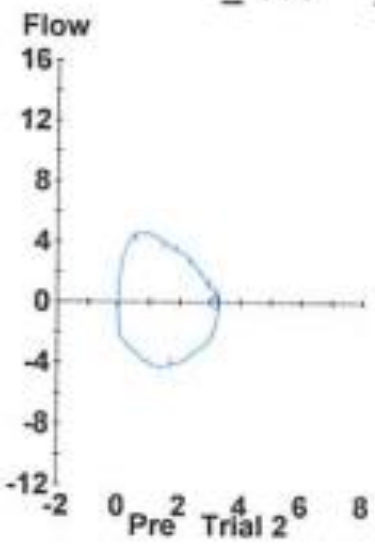
Mechanical QC

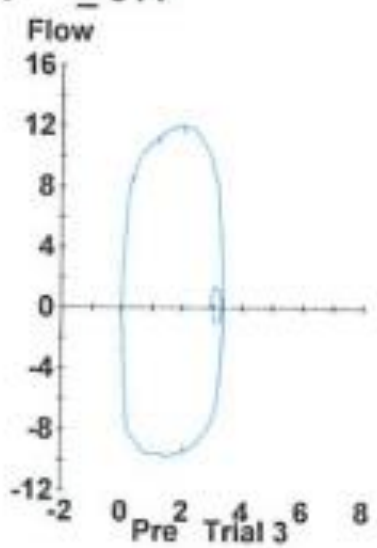
- Syringe
  - 3 Liter
  - 7 Liter
- DLCO Simulation Device
- Isothermal bottle

Syringe Loops – Linearity Check

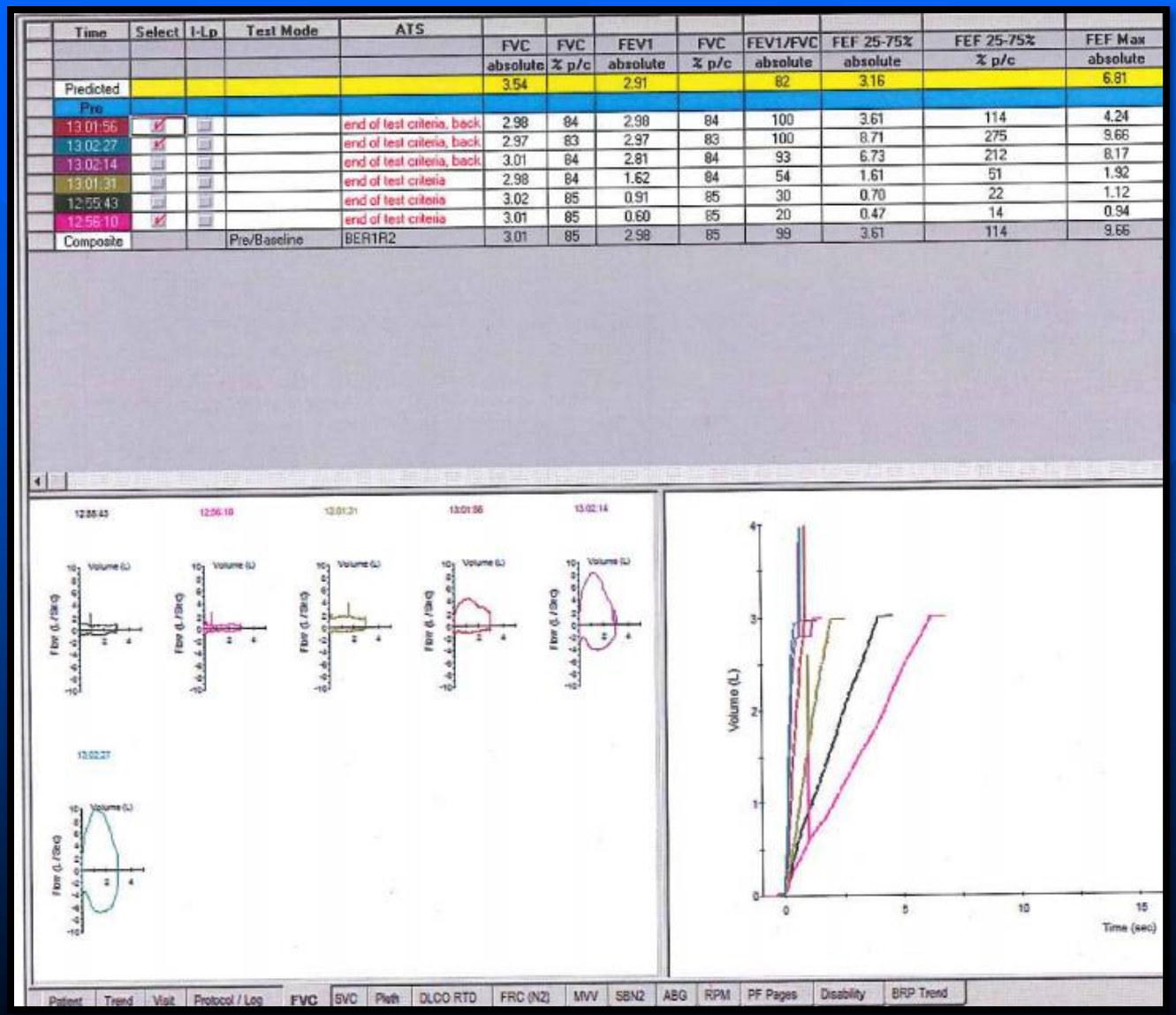
Spirometry		Pre	Best	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5
FVC	Liters		3.38	3.36	3.28	3.38		
FEV1	Liters		3.00	** 1.25	3.00			
FEV1/FVC	%			** 37	92			
PEF	L/sec		11.95	** 1.07	** 4.50	** 11.95		
FET100%	Sec			4.30	1.90	0.49		
Vol Extrap	Liters			0.34	0.06	0.12		
FVL ECode				_ 111	_ 011	_ 011		







Syringe Loops – Linearity Check



Time	Select	I-Lp	Test Mode	ATS	FVC absolute	FVC % p/c	FEV1 absolute	FVC % p/c	FEV1/FVC absolute	FEF 25-75% absolute	FEF 25-75% % p/c	FEF Max absolute
Predicted					3.54		2.91		82	3.16		6.81
Pre												
13:01:56	✓			end of test criteria, back	2.98	84	2.98	84	100	3.61	114	4.24
13:02:27	✓			end of test criteria, back	2.97	83	2.97	83	100	8.71	275	9.66
13:02:14				end of test criteria, back	3.01	84	2.81	84	93	6.73	212	8.17
13:01:31				end of test criteria	2.98	84	1.62	84	54	1.61	51	1.92
12:55:43				end of test criteria	3.02	85	0.91	85	30	0.70	22	1.12
12:56:10	✓			end of test criteria	3.01	85	0.60	85	20	0.47	14	0.94
Composite			Pre/Baseline	BER1R2	3.01	85	2.98	85	99	3.61	114	9.66

Limits of Acceptability

Linearity Check 3 liter Syringe Flow-volume Loops <.09 L variance between the highest and lowest measured FVC at 3 defined peak flows (<2L/sec, 3-7L/sec, >8L/sec) Each FVC + 3% of 3L at ATPS (2.91 – 3.09L)

How to Perform Syringe Flow-Volume Loops (linearity check - weekly)

- Set-up a **patient file** labeled “Syringe QC”. It will be used for both linearity checks and DLCO syringe checks.
- Add a new test with age, height of 163 cm and weight of 68.2 kg. The calibration syringe is used to simulate the patient.
- Confirm correct environmental parameters.
- Inject the full volume of the 3-Liter syringe into the flow sensor at various rates and record the reported volume. The peak flow rates include one injection at a rate of less than 2 liters per second, one injection at a rate of 3 to 7 liters per second, and one injection at a rate of greater than 8 liters per second. The flow-volume loops should simulate a patient test
- The maximum difference between the FVC reported volumes at each flow must be less than .09 liters to document the equipment is within control limits.
- **Check the temperature chart to ensure the FVC results are in the correct range at ATPS or BTPS. ATPS is 37 degrees and 100% humidity primarily on Jaeger systems.**
- **NOTE: The peak flow should be reviewed to verify that the trials were done in the correct flow ranges. The FVC should be reviewed to verify the reported volumes.**

DLCO Requirements

Calibration and QC Requirements

- Daily volume calibration must now be performed three time with a 3-liter syringe with using varying flow rates between 0.5 and 12.0 L/sec (injection times 0.5 – 6.0 seconds). Accuracy was not previously specified and now must be <2.5% error.
  - Disposable flow sensor from the batch used must be tested each day
  - Recheck if temperature changes 3 degrees C or relative humidity changes by more than 15%

Calibration and QC Requirements

- Calibration recheck also recommended when differences between VI and VC or VA and TLC are apparent

- Timer accuracy was specified in the 2005 standards. There are no timer specifications in the 2017 standards.

Calibration and QC Requirements

- Flow sensor zeroing prior to testing is now required.
- Gas analyzer linearity must now be checked monthly. The 2005 standards specified every three months. Manufacturers are urged to automate this process.
- A monthly calibration syringe leak test is now required.

Analyzer Linearity Check

- Serial syringe dilutions
- DLCO simulation with high precision gases
- In absence of above, manufacturer must provide test option like patient, but reported VA at ATP with 3-L syringe

Calibration and QC Requirements

- Both biological and calibration syringe QC testing are now required weekly. Previously either biological or calibration syringe QC were to be performed weekly.

Calibration and QC Requirements

- Syringe QC required measured VA to be within ± 300 ml of 3-L {STPD to BTPS conversion factor} 24% factor
  - Absolute DLCO less than 0.5 ml CO/min/mmHg (.166 SI)

- ERROR NOTED: Correction factor should be ATPD to BTPS

  "The calculation of VA must be within 300 mL of 3 L times the ATPD to BTPS (body temperature, ambient pressure, saturated with water vapour conditions) correction factor, which is 310/Tamb x PB/(PB-47), where PB is the barometric pressure in mmHg and Tamb is the ambient temperature in degrees kelvin.“
  - With 72 degrees Fahrenheit = 295.4 degrees kelvin, this would be approximately a 12% correction factor.

Calibration and QC Schedule

TABLE 2 Equipment calibration schedule

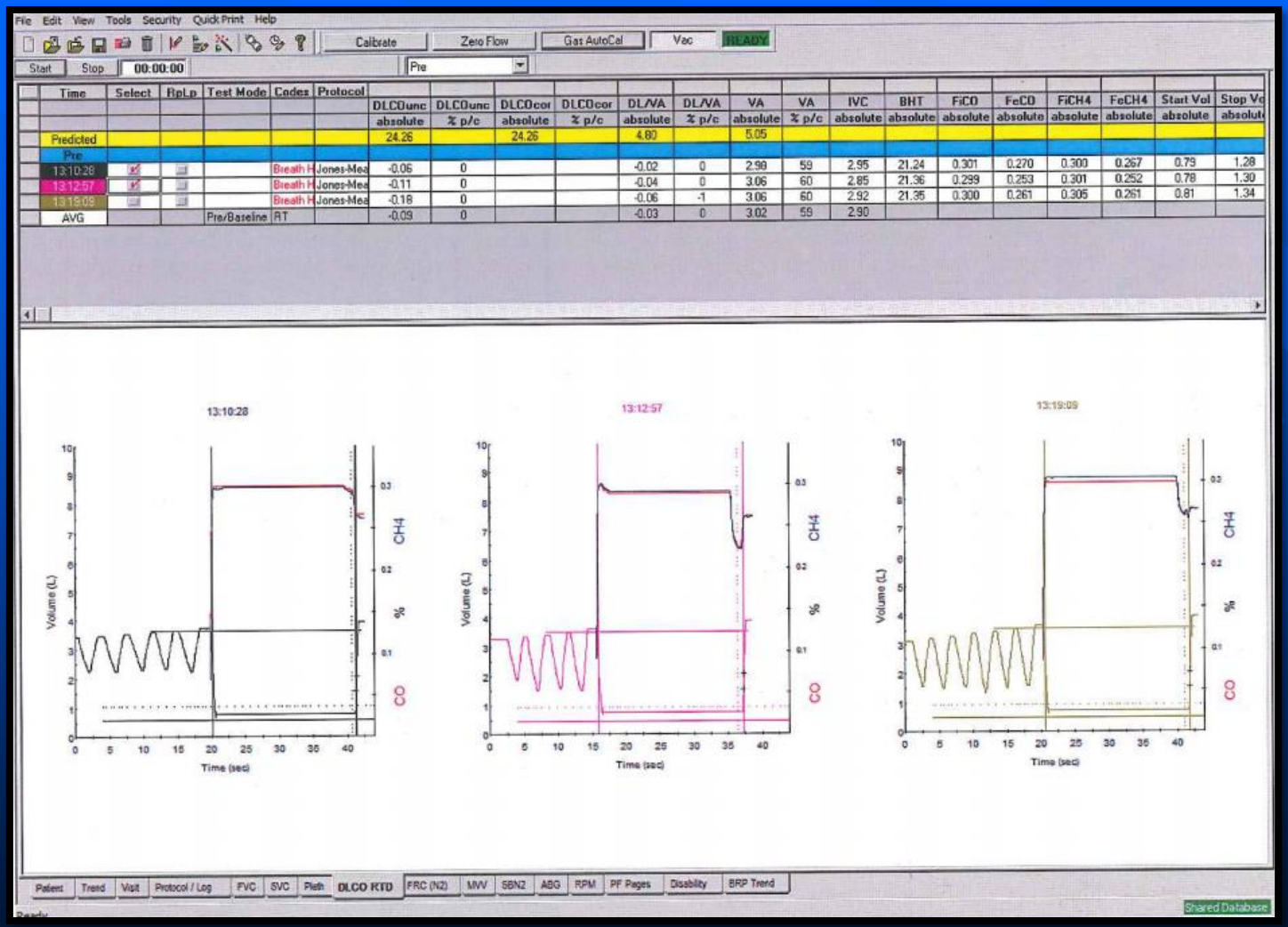
Calibration technique	Frequency
Flow analyser zeroing	Before each test
Gas analyser zeroing	Before/after each test
Volume calibration check	Daily
Biologic control	Weekly
Calibration syringe *D*LCO check	Weekly
Calibration syringe leak test	Monthly
Linearity check (calibration syringe or simulator)	Monthly

*D*LCO: diffusing capacity of the lung for carbon monoxide.

Syringe DLco

		Pre	Trial 1	Trial 2
Diffusing Capacity				
DLCO	mL/mmHg/mBest		** 0.4	** 0.4
VA	Liters		3.50	3.50
IVC	Liters	0.41	3.36	3.35
BHT	Sec	3.50	9.08	9.22
DLCO ECode		3.35	000	000
DLCO Time			09:00	09:03

Syringe DLco



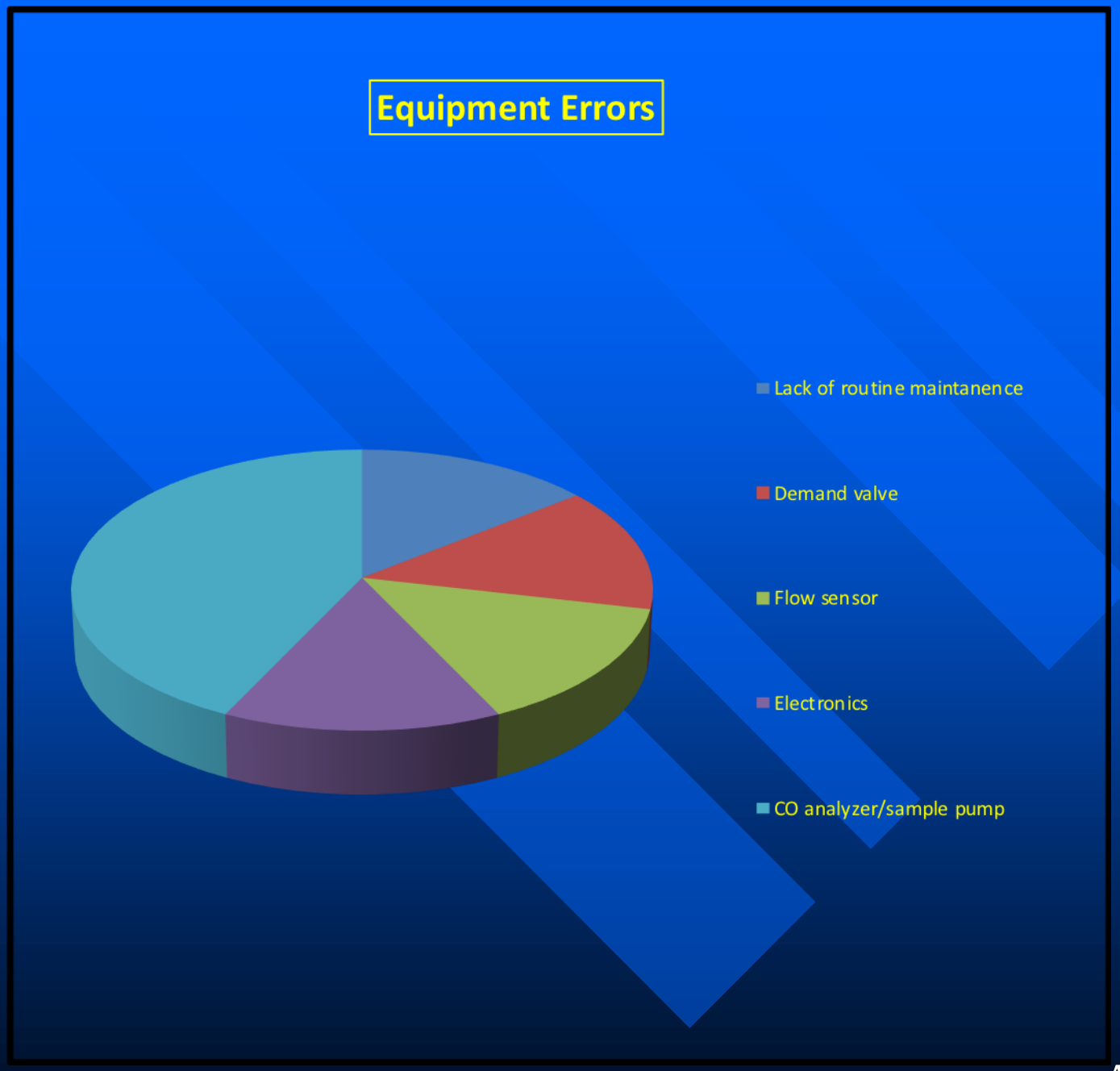
Limits of Acceptability

2 acceptable trials which meet the acceptability requirements.

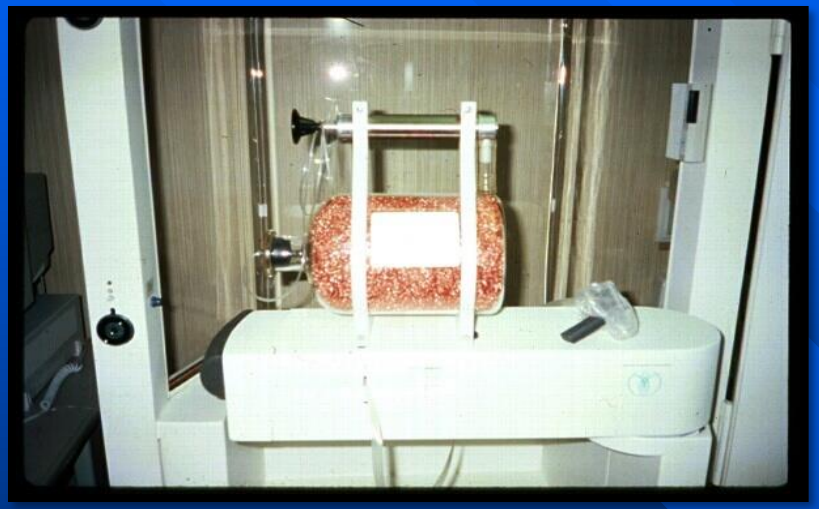
DLCO < 0.5ml CO/min/mmHg

IVC: 2.85 – 3.15L @ ATPS

VA: 2.90 – 3.36 @ ATPS


Equipment Errors
Lack of routine maintanence
Demand valve
Flow sensor
Electronics
CO analyzer/sample pump

Quality Control-Isothermal Lung Model



Biologic QC

- Biologic controls
  - Spirometry
  - Lung Volumes
  - Dlco
  - Exercise
- Mean and coefficient of variation

DLCO Bio QC Requirements

- BioQC requiring action are relaxed to a >12% change or >3 ml/min/mmHg (whichever is larger) from a simple >10% change ***
  - 2017 standards also state that a mean of 6 prior tests should be used
  - Manufacturers urged to developed automated QC
- QC and calibration records can be kept in a digital file

Biologic QC

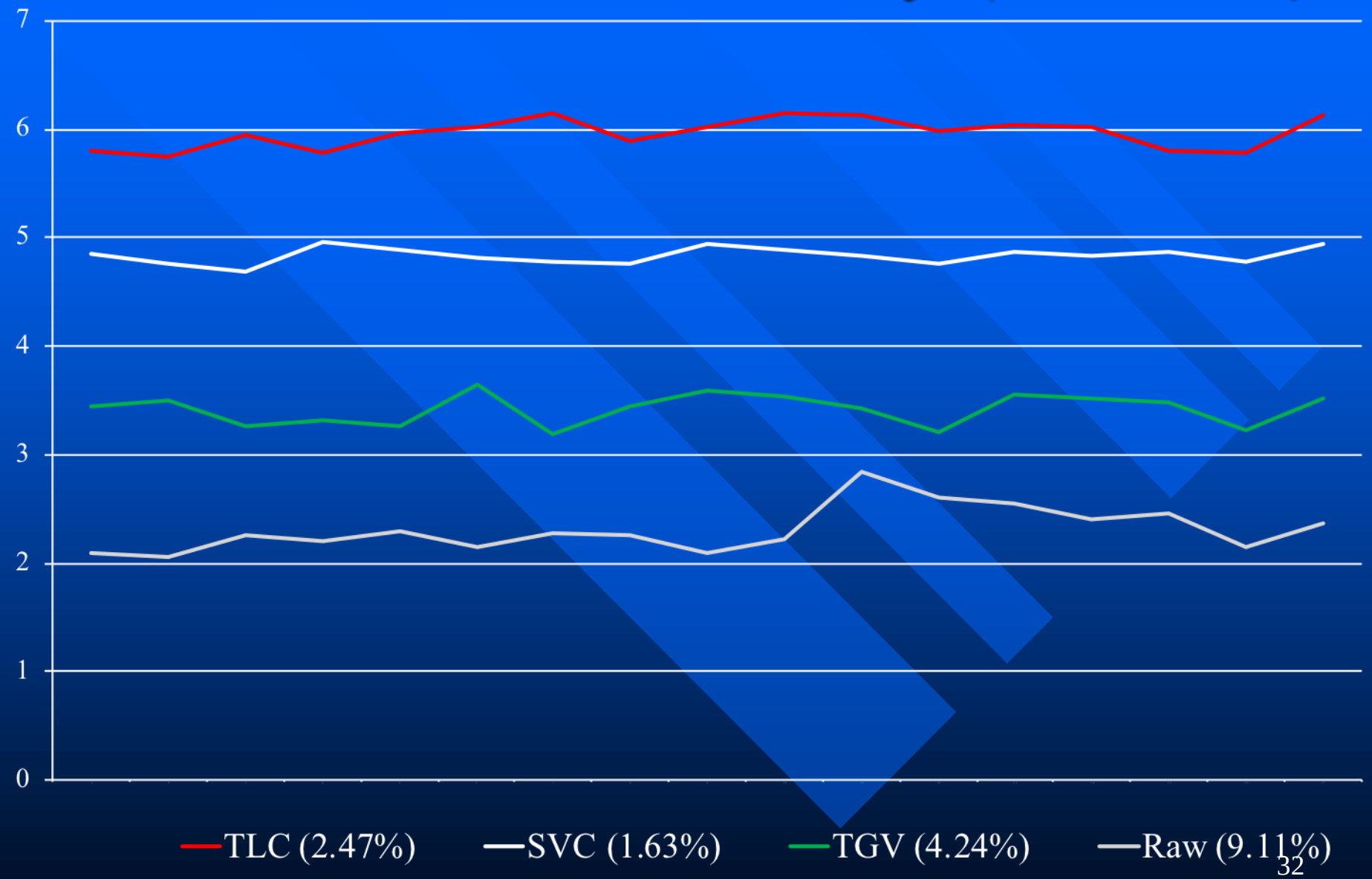
- Biologic controls DLco
- Mean and coefficient of variation

Within Visit Variation		
Within Visit	CoVar%	Acceptability%
FEV1	2.85%	96.8%
FRC	3.35%	97.6%
DLCO	3.67%	85.6%

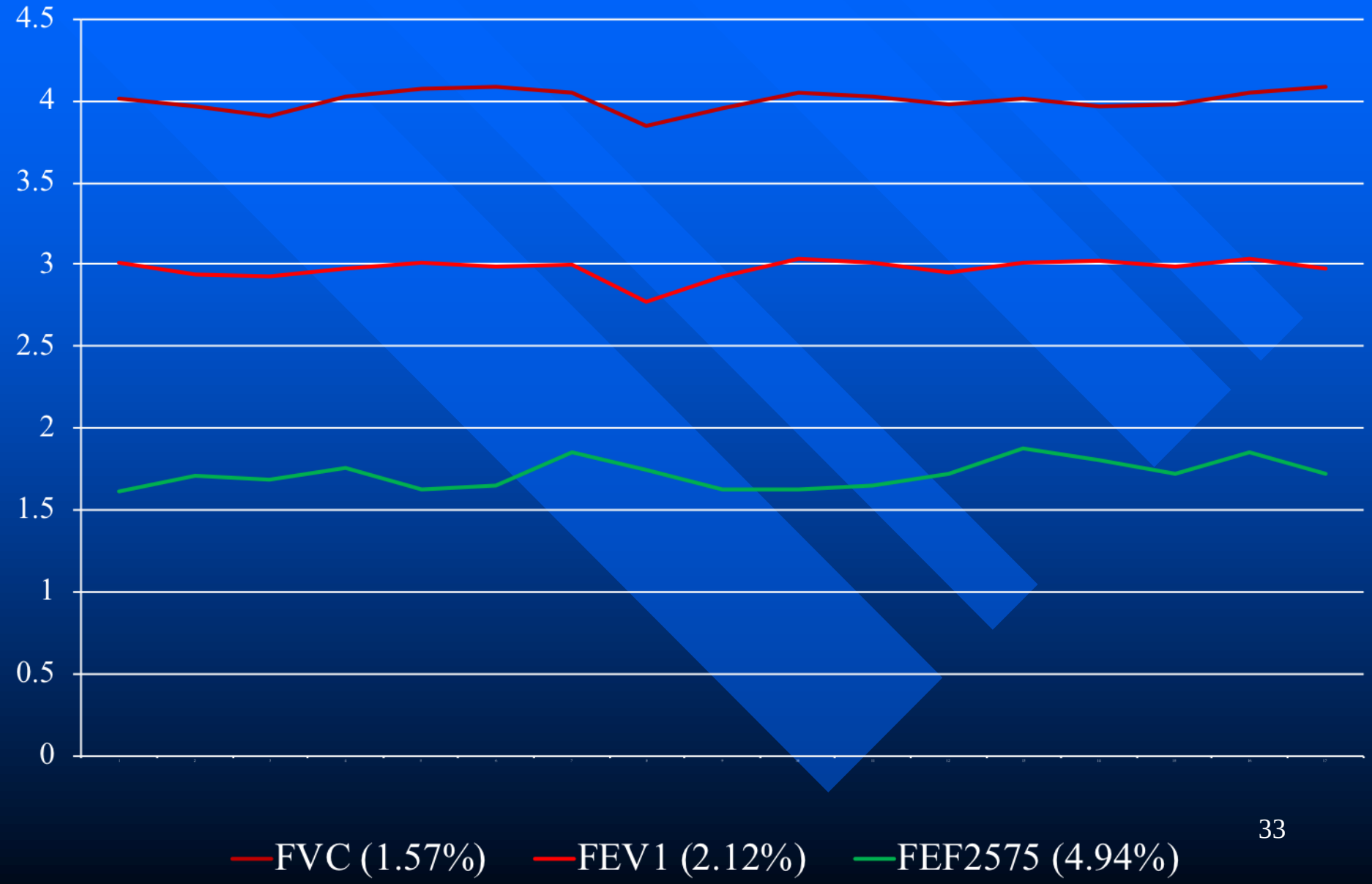
Between Visit Variation		
DLCO CoVar	FEV1 CoVar	FRC_{PL} CoVar
6.60%	3.36%	7.46%

Blonshine SB, Harris R, Snow M ERS 2007

Staff Normal Variability (Jan-Nov)



Staff Normal Variability (Jan-Nov)

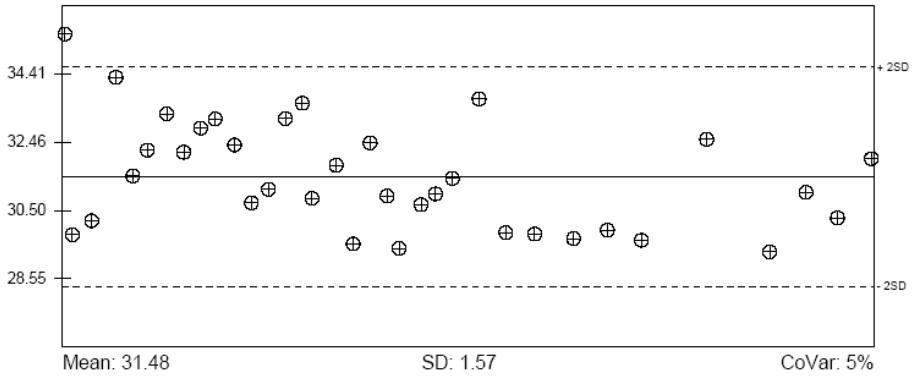


Inter-visit Repeatability in Patients

56 Patients seen weekly for 10 Weeks

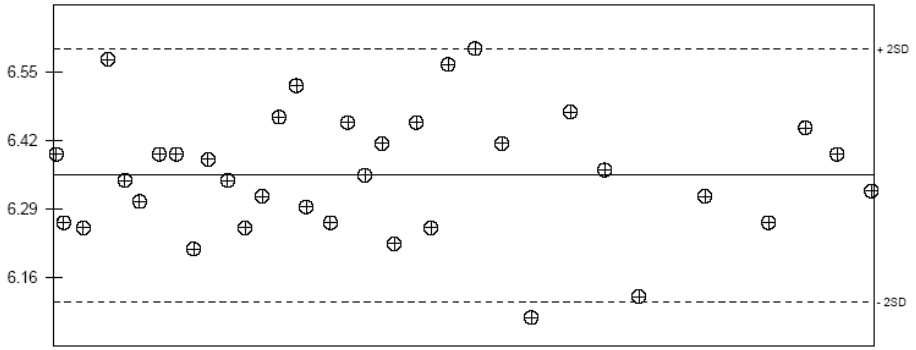
CoVar%	CPMC	Fairfax	Mean
FVC	3.1024	3.0407	3.0775
FEV1	3.2489	3.1417	3.2057
FEV1/FVC	3.0178	2.3471	2.7471
FEFmax	6.2761	8.0905	7.0082
FEF25-75%	9.1844	9.4976	9.3108
SVC	2.8004	3.9005	3.2443
TGV	7.542	8.1151	7.7733
TLC	3.3984	5.5251	4.2565
Raw	12.401	14.965	13.436
SRaw	11.305	14.584	13.436
DLCO	6.1474	6.8906	6.4473
VA	3.722	6.0199	4.6492

Pre DLCOunc (ml/min/mmHg)



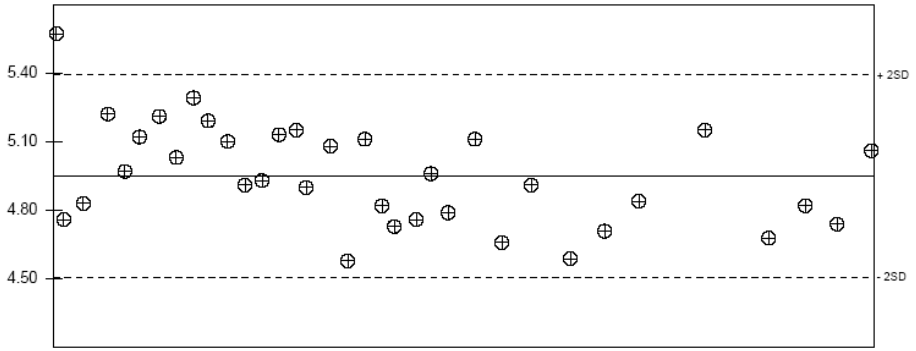
Mean: 31.48 SD: 1.57 CoVar: 5%

Pre VA (L)



Mean: 6.35 SD: 0.12 CoVar: 2%

Pre DL/VA (ml/min/mmHg/L)



Mean: 4.95 SD: 0.22 CoVar: 4%

Equipment	Patient ID	Test Date	Pre Original FEV1	Pre Original FVC	DLCO	IVC	VA	SVC
		5/29/2015 17:09	3.81	4.91	22.65	4.78	6.69	5.12
		6/15/2015 15:16	3.7	4.79	22.14	4.82	6.65	5
		6/29/2015 15:02	3.72	4.73	22.15	4.76	6.65	4.96
		7/15/2015 10:26	3.96	5.03	22.11	4.97	6.83	5.06
		2/20/2015 17:08	3.89	4.9	22.01	4.78	6.58	5.07
		1/5/2015 15:25	3.88	4.88	21.86	4.81	6.87	4.92
		8/7/2015 16:34	3.58	4.54	21	4.39	5.91	4.95
		8/13/2015 15:58	3.71	4.67	20.42	4.61	6.48	4.8
		8/11/2015 16:25	3.64	4.66	20.62	4.11	5.82	4.8
		8/18/2015 10:45	3.5	4.39	21.02	4.44	6.33	4.62
			Average					
			3.74	4.75	21.60	4.65	6.48	4.93
			Std. Deviation					
			0.145865235	0.192527054	0.763148449	0.259831142	0.360476536	0.152315462
			2 Std. Deviation					
			0.291730469	0.385054109	1.526296898	0.519662283	0.720953073	0.304630924
			Coefficient of Variation					
			3.90118306	4.053201145	3.533421841	5.591373827	5.562051172	3.089563126
			Acceptable Ranges		Based on 2 Std.			
			4.030730469	5.135054109	23.1242969	5.166662283	7.201953073	5.234630924
			3.447269531	4.364945891	20.0717031	4.127337717	5.760046927	4.625369076

Resources

- DAP Worksheets
- Manufacturer Resources
- Demonstration

Equipment QC Recordkeeping

Records Manual Table of Contents

Instructions for Manual Use

Quality Control Plan

Temperature Correction Table

Calibration Reports

Quality Control Log

Syringe Quality Control (linearity and DLCO)

Biologic Summary Reports (SD and means for each biologic standard)

Biologic QC 1 and QC 2

DLCO Simulator Documentation or DLCO linearity testing, instructions, worksheets, lo

Gas Analysis Certificates

Maintenance and Troubleshooting Log

Test Quality Review

Technologist Expectations

Test Quality Checklist

Spirometry

- ✓ Was the ATS/ERS “end of test” criteria met? (1 second plateau)
- ✓ Was the expiratory time at least 6 seconds?
- ✓ Was the back extrapolated volume less than 5% of the FVC or 150 ml, whichever is greater?
- ✓ Is exhalation smooth and continuous?
- ✓ Was the effort maximal based on the peak flow?
- ✓ Have 3 acceptable trials been completed?
- ✓ Was repeatability criteria met for FVC and FEV1 (150 ml)?

Test Quality Checklist - DLCO

- ✓ Is the BHT between 8 and 12 seconds?
- ✓ Is the IVC at least 90% of the largest VC? (See changes - 2017 standards)
  - ✓ VI of ≥85% of the patient's largest VC is acceptable if VA is within 200 ml or 5% (whichever is larger) of the patient's highest VA from acceptable DLCO maneuvers
- ✓ Is the inspiratory time less than 4 seconds?
- ✓ Are there at least 2 acceptable DLCO trials?
- ✓ Is the time between trials at least 4 minutes? (See changes - 2017 standards)
  - ✓ Wait between tests (4 minutes minimum, 10 minutes for patients with severe obstruction)
    - ✓ tracer gas concentration at end-exhalation (prior to the inhalation of the test gas mixture) should be ≤ 2% of the inspired concentration (RGA systems)
- ✓ Was repeatability criteria met?

Test Quality Checklist

Lung Volumes

- ✓ Was the EELV stable?
- ✓ Was the shutter closed at the correct level?
- ✓ Was the pant volume small (i.e. <50mL)
- ✓ Was the Pant frequency ~ 1Hz (30-60/m) for TGV
- ✓ Was the loop closed with the TGV Maneuver?
- ✓ Is there minimal hysteresis in the open shutter loop?
- ✓ Are there at least 3 acceptable trials?
- ✓ Has repeatability criteria been met?

Test Quality Checklist

Airway Resistance

- ✓ Was the Pant frequency ~1-2 Hz (90-120/m) for Raw?
- ✓ Was the loop closed with the Vpant Maneuver?
- ✓ Is there minimal hysteresis in the open shutter loop?
- ✓ Is the pant volume acceptable?
- ✓ Are there at least 3 acceptable trials?
- ✓ Has repeatability criteria been met?

Reporting Results
Grading Test Quality

Recommendations for a Standardized Pulmonary Function Report

An Official American Thoracic Society Technical Statement

Bruce H. Culver, Brian L. Graham, Allan L. Coates, Jack Wanger, Cristine E. Berry, Patricia K. Clarke, Teal S. Hallstrand, John L. Hankinson, David A. Kaminsky, Neil R. MacIntyre, Meredith C. McCormack, Margaret Rosenfeld, Sanja Stanojevic, and Daniel J. Weiner; on behalf of the ATS Committee on Proficiency Standards for Pulmonary Function Laboratories

This Official Technical Statement of the American Thoracic Society was approved October 2017

Background: The American Thoracic Society committee on Proficiency Standards for Pulmonary Function Laboratories has recognized the need for a standardized reporting format for pulmonary function tests. Although prior documents have offered guidance on the reporting of test data, there is considerable variability in how these results are presented to end users, leading to potential confusion and miscommunication.

Methods: A project task force, consisting of the committee as a whole, was approved to develop a new Technical Standard on reporting pulmonary function test results. Three working groups addressed the presentation format, the reference data supporting interpretation of results, and a system for grading quality of test efforts. Each group reviewed relevant literature and wrote drafts that were merged into the final document.

Results: This document presents a reporting format in test-specific units for spirometry, lung volumes, and diffusing capacity that can be assembled into a report appropriate for a laboratory's practice. Recommended reference sources are updated with data for spirometry and diffusing capacity published since prior documents. A grading system is presented to encourage uniformity in the important function of test quality assessment.

Conclusions: The committee believes that wide adoption of these formats and their underlying principles by equipment manufacturers and pulmonary function laboratories can improve the interpretation, communication, and understanding of test results.

Keywords: pulmonary function testing; reporting spirometry; reference equations; pulmonary function quality grading

Contents

Development and pilot evaluation of a quality grading system for paediatric spirometry

- Aims - Develop and evaluate a pediatric quality grading index for FVC and FEV1

- Methods - Criteria for a paediatric specific scale were generated by systematic literature review and content expert input (peds pulmonologists (n=6), respiratory scientist and pft technicians (n=4)). FEV1 and FVC graded separately for 89 randomly selected tests (subjects aged 5 to 17 years), independently scored by 4 technicians. Agreement was calculated using the most senior technician as the “gold standard”.

Perrem, L., Ratjen, F, Dell, S. et al. ERS Abstract 2018

Development and pilot evaluation of a quality grading system for paediatric spirometry

- Results - majority of tests met or exceeded ATS/ERS acceptability and repeatability criteria with Grade A or B for FEV1 (75%) and FVC (61%)
  - Exact agreement for FEV1 and FVC was 91% and 81%, respectively. Interrater agreement (kappa) for FEV1 and FVC was 0.8 and 0.7, respectively.
- Conclusion - pilot data evaluated for a novel quality grading system for pediatric spirometry
  - need to validate in a larger sample including longitudinal data in both health and disease.

Perrem, L., Ratjen, F, Dell, S. et al. ERS Abstract 2018

Other Requirements

- BioQC Range Update Schedule
- Instructions how to perform each QC method
- Training on QC Procedures
  - Competence Assessment
- Out of Control Process
  - Troubleshooting
- Documentation

Exercise Quality Control Components

- Technologist training/oversight
- Equipment maintenance
  - Components
  - Calibration
- Mechanical quality control
- Physiologic quality control

Any Questions?

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