GOLDILOCKS AND THE THREE LUNG VOLUME MEASUREMENTS

Robert Brown, MD
Director PFT Lab, Massachusetts General Hospital, Boston, MA
Associate Professor of Medicine, Harvard Medical School

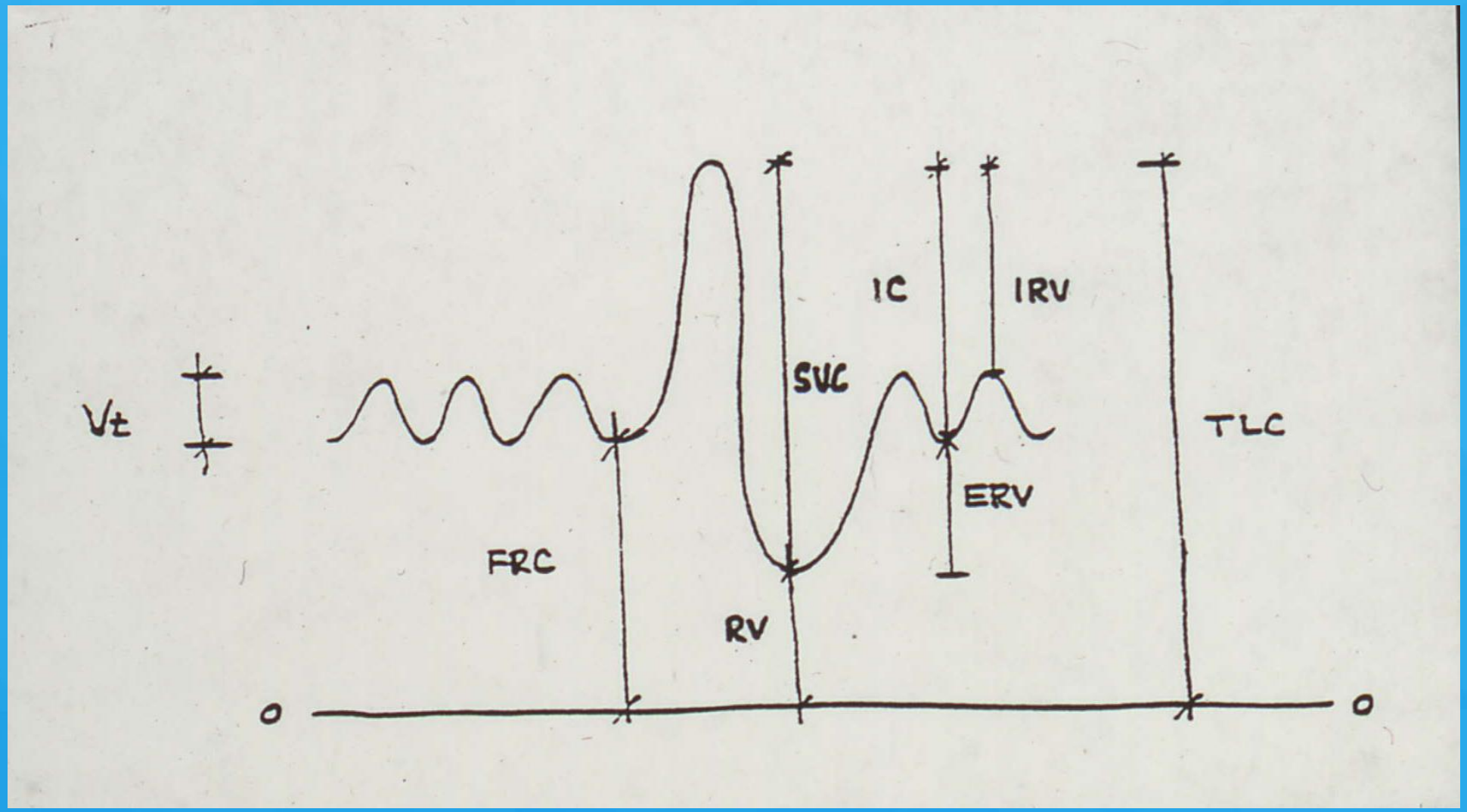
- HARD (Gas Dilution)
- HARDER (Plethysmography)
- EASIEST (MiniBox+)

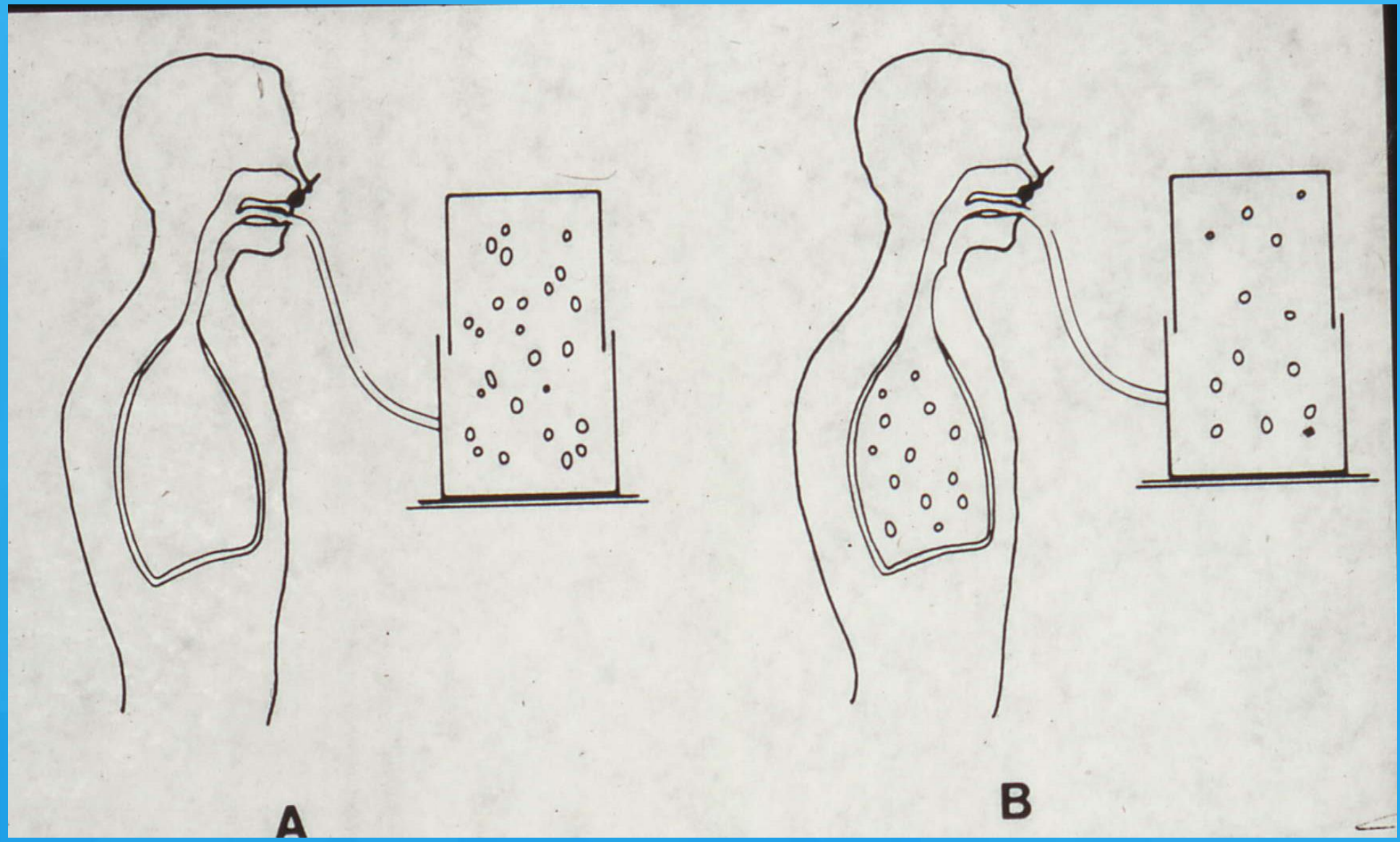
Mercy Hospital RT Conference, St. Louis, MO Oct 17, 2017

Disclosure

- NONE
- ON SAB OF PULM-ONE
- NO PAYMENT, NO EQUITY

Helium Gas Dilution


Vt
FRC
RV
SVC
IC
IRV
ERV
TLC
0
0


A
B

HELIUM DILUTION

$$(V_{gas})(C_1) = (V_{gas} + V_L)(C_2)$$

$$V_L = \frac{(V_{gas})(C_1 - C_2)}{C_2}$$

Where C_1 = helium concentration at the start of the experiment

C_2 = helium concentration when gas mixing is complete

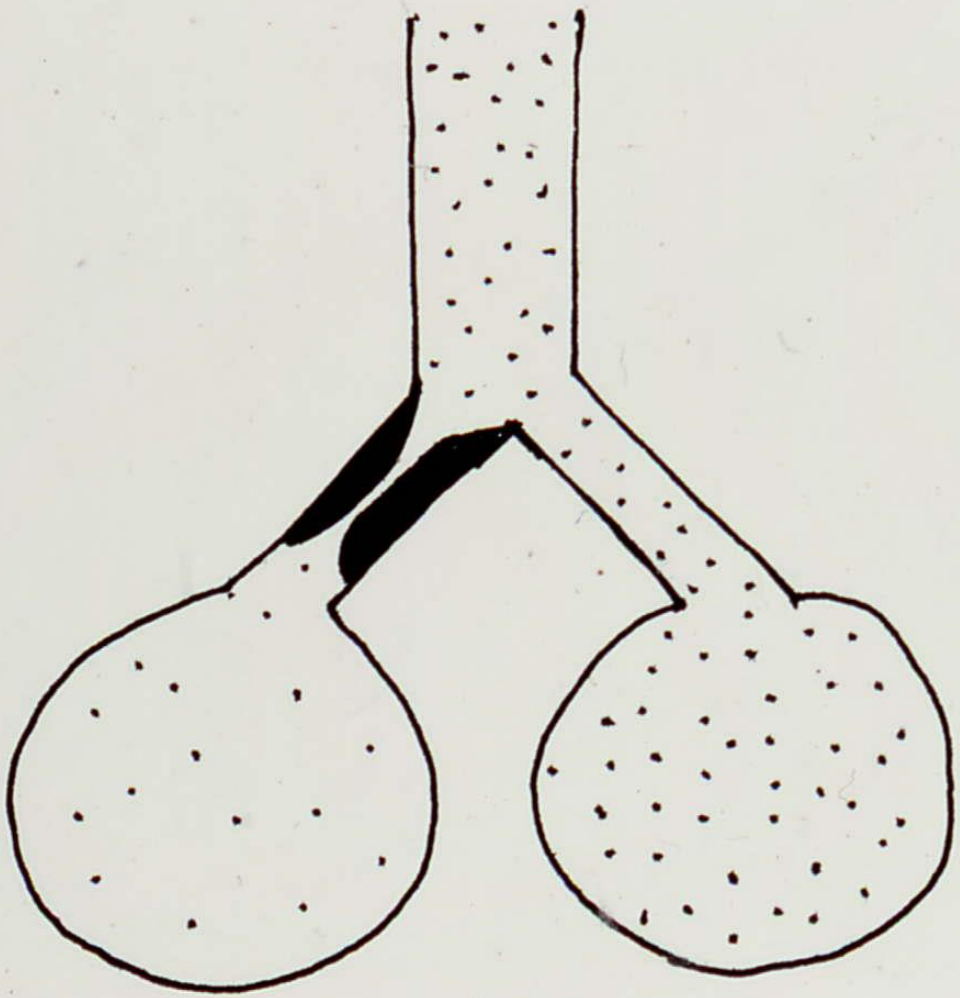
HELIUM DILUTION METHOD

- KNOWN [He] EQUILIBRATED WITH LUNG VOLUME
- ACCOUNT FOR CO_2 PRODUCTION / O_2 CONSUMPTION
- BTPS CORRECTION
- ASSUME
  - NO LEAK
  - NO HELIUM SWALLOWED
  - TURN IN AT FRC
  - He NOT ABSORBED
  - COMPLETE EQUILIBRATION
  - NITROGEN NOT EXCRETED

Paths of Helium Loss

- Solution in H2O (negligible)
- Equipment leaks (equilibration fails)
- Leaks around nose clip, mouthpiece
- Ruptured tympanic membrane
- Swallowing
- Absorption into fluids, tissues

? COMPLETE EQUILIBRATION



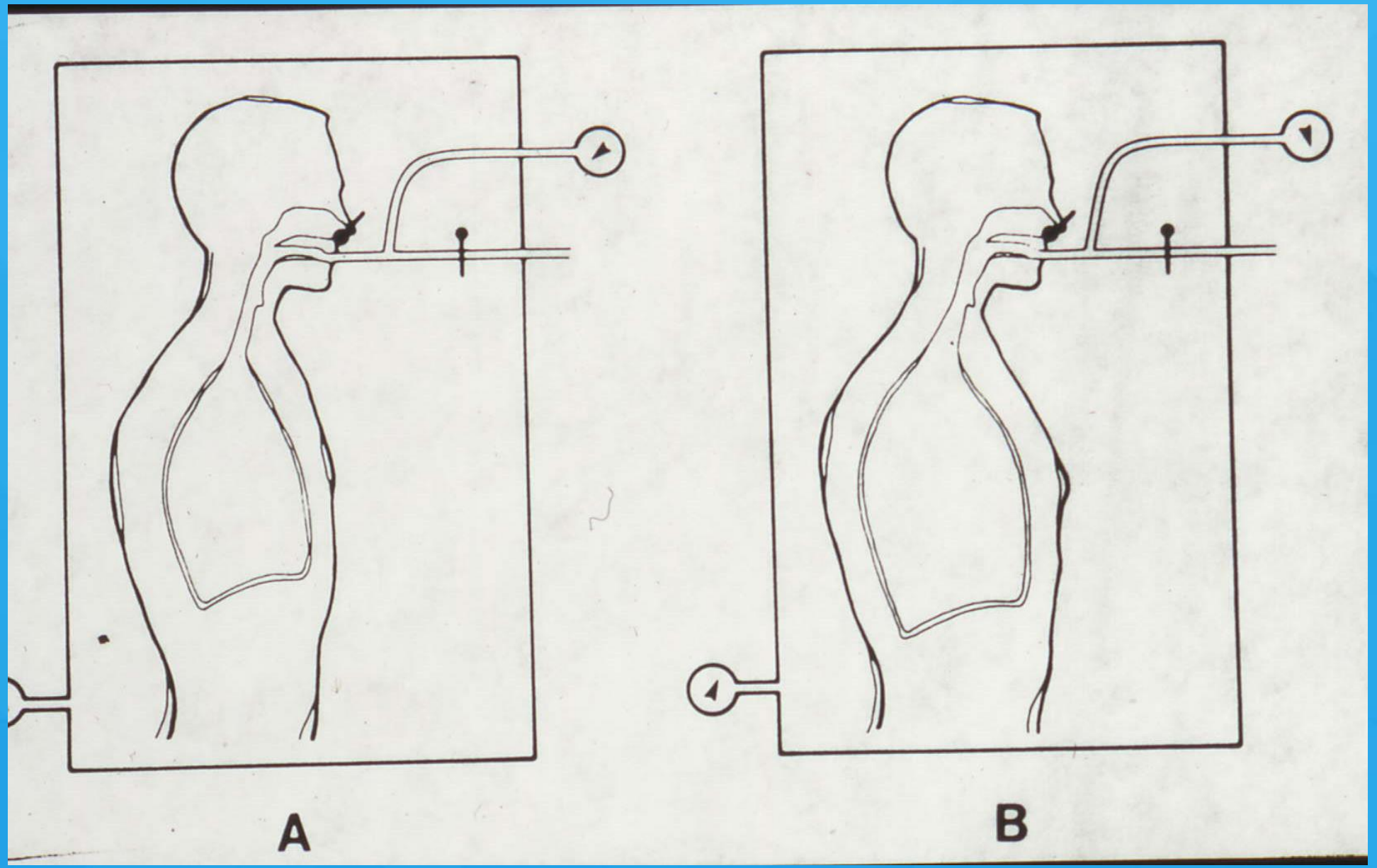
HELIUM ANALYZER

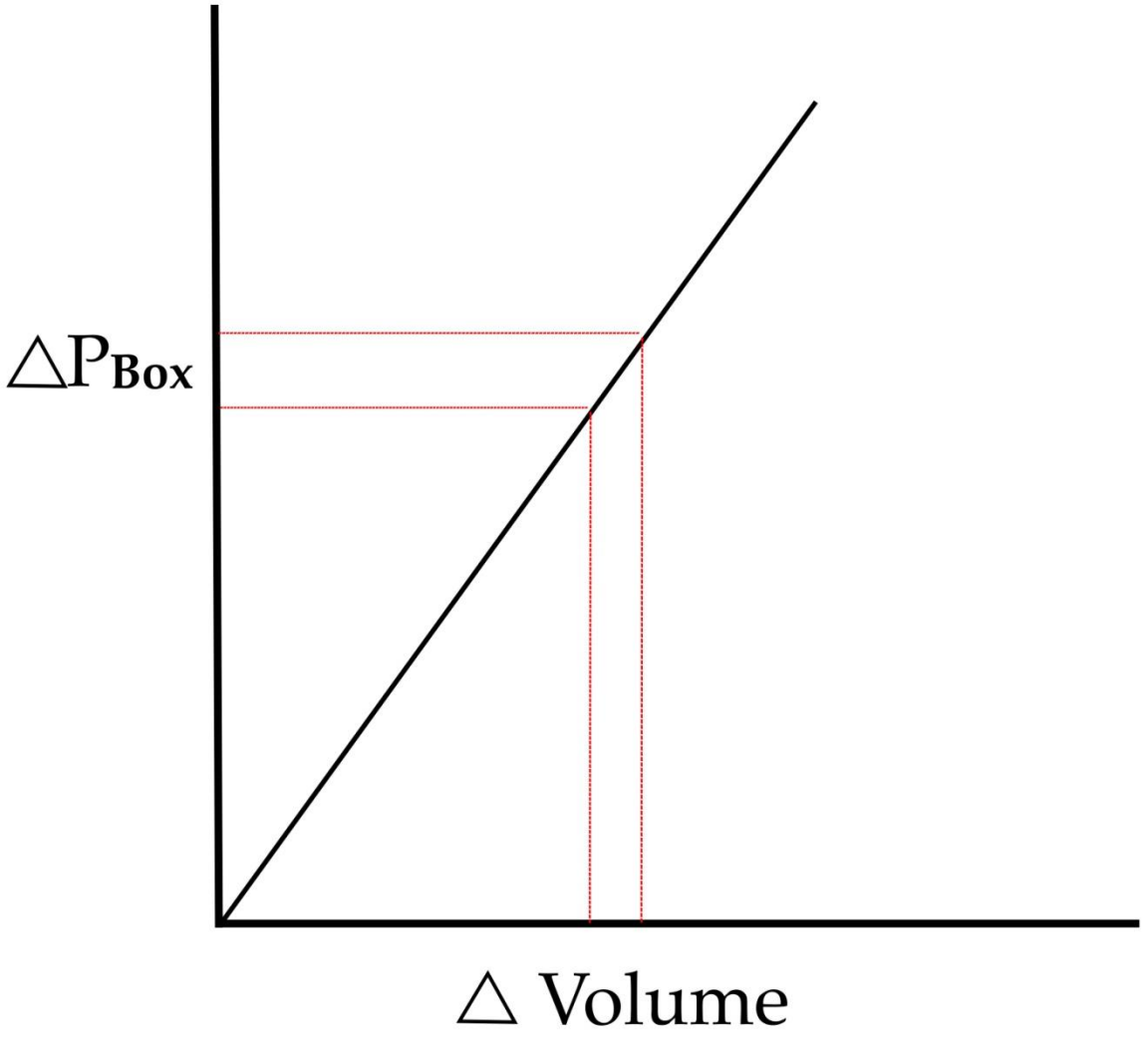
- Range 0-10%
- Resolution: 0.01%
- 95% response time of < 15 sec to 2% step change in HE concentration
- < 0.02% drift for 10 minutes

End of Test Criteria

- Δ [HE] < 0.02% in 30 secs (3x, z 15 seconds)
- Based on:
  - Limits of resolution of He meter
  - Estimate of Δ [He] of < 0.01% per minute due to He absorption and N2 excretion

Body Plethysmography


A
B


△P Box
△ Volume

PLETHYSMOGRAPHY

$$P_1V_1 = (P_1 + \Delta P)(V_1 + \Delta V)$$

$$V_{tg} = -\frac{\Delta V}{\Delta P} \cdot (P_{ALV} - 47)$$

PLETHYSMOGRAPHY ASSUMPTIONS

- ISOTHERMAL GAS COMPRESSION IN LUNG
- PROPER CALIBRATION FOR POLYTROPIC CONDITIONS IN PLETHYSMOGRAPH
- UNIFORM PRESSURE CHANGES THROUGHOUT LUNG
- ONLY THORACIC GAS IS COMPRESSED
- NO GAS FLOW

Helium vs Plethysmograph

- NORMAL: results very similar
- RESTRICTION: results very similar
- OBSTRUCTION: Pleth>helium but……CONTROVERSIAL

Helium vs Plethysmograph controversy

- **REFERENCE:**
  - **Comparison of Plethysmograph and Helium Dilution Lung Volumes: which is best in COPD? O'Donnell CR, Brown R, Loring SH et al CHEST 2010; 137: 1116-1121**

MiniBox+



MINIBOX+

LUNG VOLUME MEASUREMENT WITHOUT BODY PLETHYSMOGRAPHY OR GAS DILUTION

MiniBox+

- Measurements
  - Spirometry
    - FEV1
    - FEV6
    - FEF25-75%
  - Lung Volume Measurement
    - TLC and subdivisions
  - Diffusion
    - CO Diffusion capacity
    - Real-time analysis/rapid gas analyzer



MiniBox+

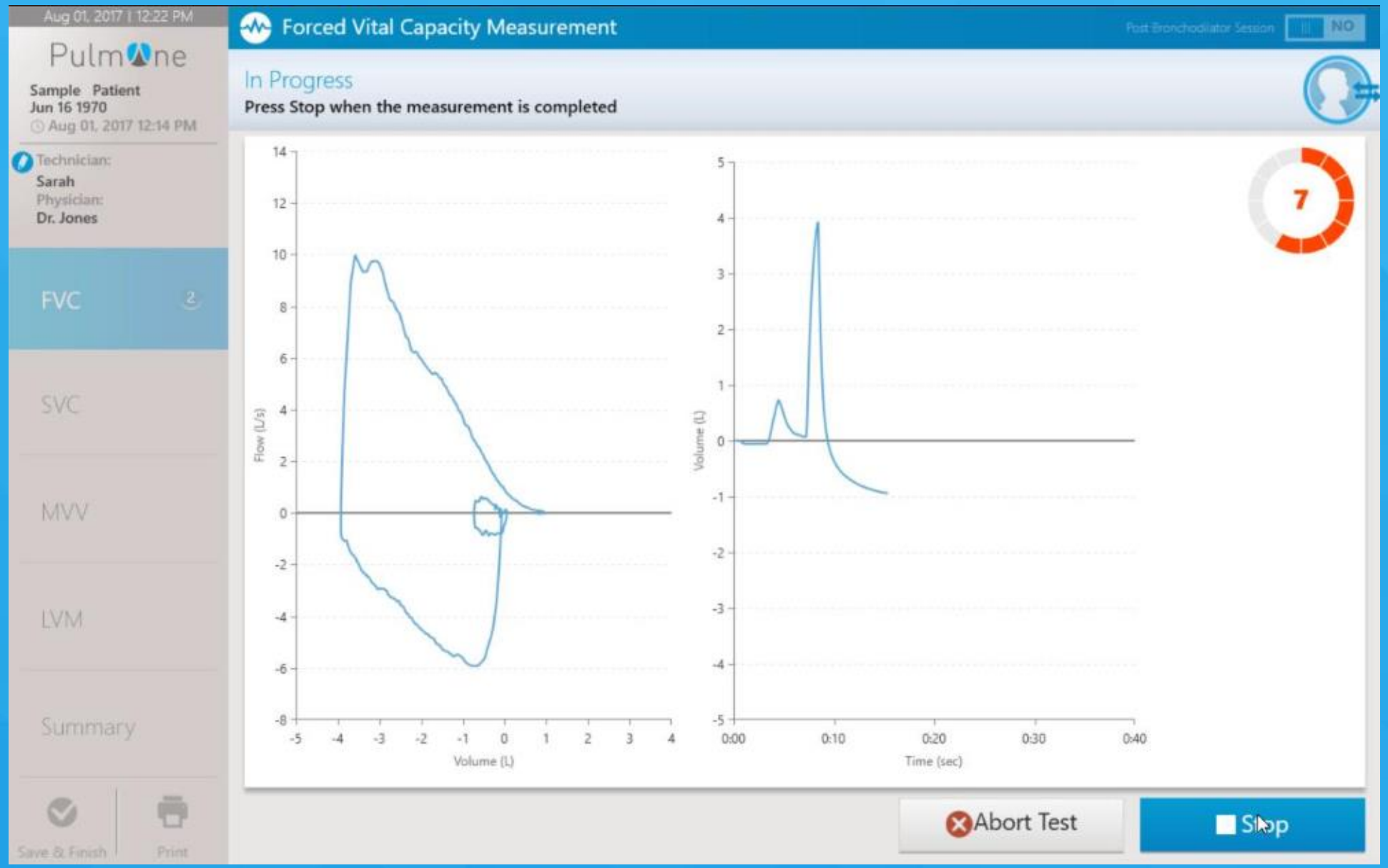
- Key Features
  - Easy to learn, easy to use touch screen tablet
  - Small footprint
  - Low maintenance
  - Low cost per test

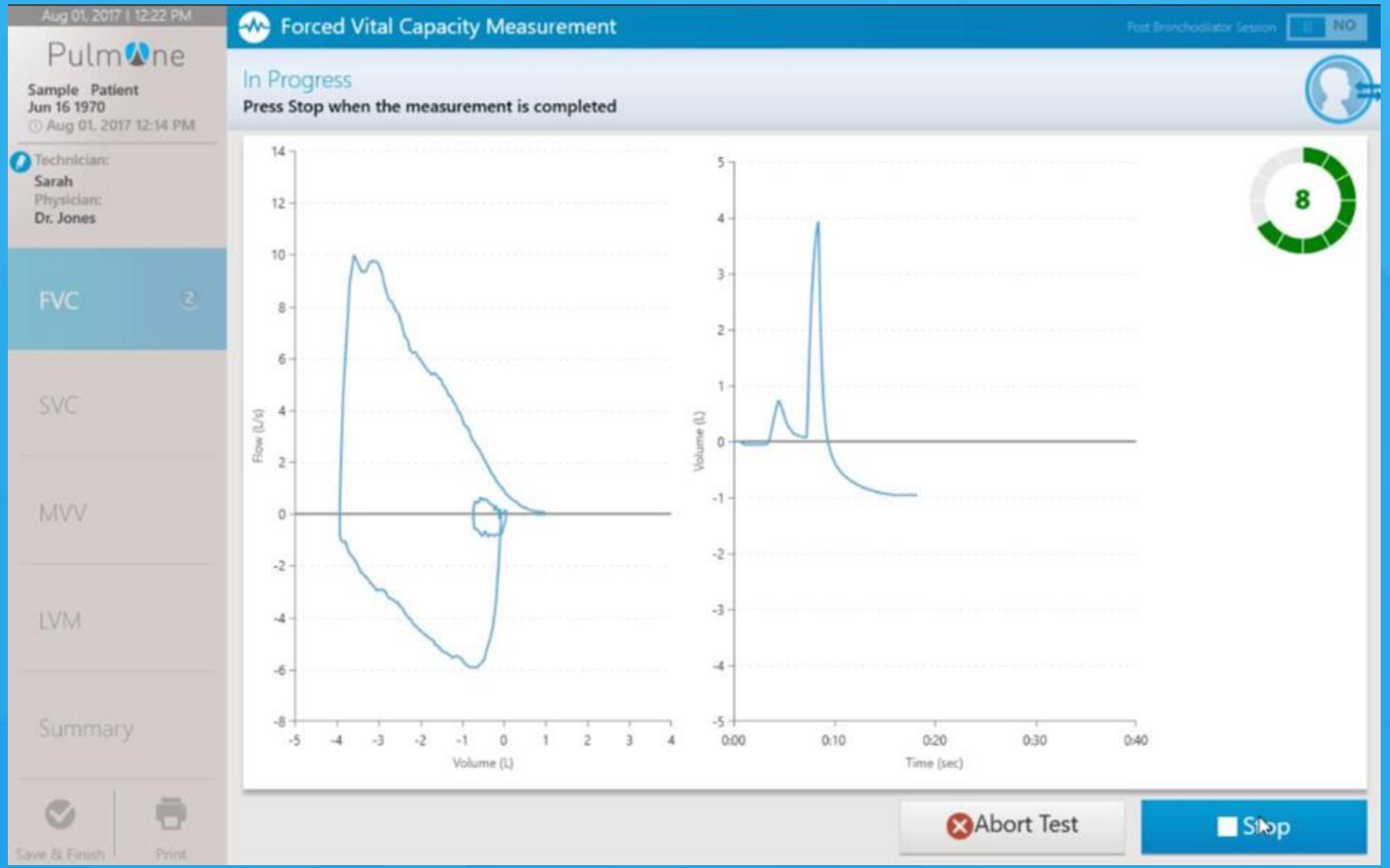


Spirometry

- Meets ATS/ERS standards
  - Heated pressure differential pneumotach
  - End of test criteria *Progress Wheel*
    - At least 6 seconds and <25 ml volume change for 1-second


Aug 01, 2017 | 12:22 PM
PulmOne
Sample Patient
Jun 16 1970
Aug 01, 2017 12:14 PM
Technician:
Sarah
Physician:
Dr. Jones
FVC
SVC
MVV
LVM
Summary
Save & Finish
Print
Forced Vital Capacity Measurement
Post Bronchodilator Session
NO
In Progress
Press Stop when the measurement is completed
4
Flow (L/s)
Volume (L)
Volume (L)
Time (sec)
Abort Test
Stop


Aug 01, 2017 | 12:22 PM
PulmOne
Sample Patient
Jun 16 1970
Aug 01, 2017 12:14 PM
Technician:
Sarah
Physician:
Dr. Jones
FVC
SVC
MVV
LVM
Summary
Save & Finish
Print
Forced Vital Capacity Measurement
Post Bronchodilator Session
NO
In Progress
Press Stop when the measurement is completed
7
Flow (L/s)
Volume (L)
Volume (L)
Time (sec)
Abort Test
Stop


Aug 01, 2017 | 12:22 PM
PulmOne
Sample Patient
Jun 16 1970
Aug 01, 2017 12:14 PM
Technician:
Sarah
Physician:
Dr. Jones
FVC
2
SVC
MVV
LVM
Summary
Save & Finish
Print
Forced Vital Capacity Measurement
Post Bronchodilator Session
NO
In Progress
Press Stop when the measurement is completed
8
Flow (L/s)
Volume (L)
Volume (L)
Time (sec)
Abort Test
Stop

Diffusion

- Meets ATS/ERS standards
  - Multi-gas analyzer for CO, CH_4
  - Single gas tank
    - 0.300% CO, 0.300% CH_4, 21% O_2, Balance N_2

05 Oct, 2016 | 15:57

PulmOne

Elinor Raz Lavie
30 Jul 1977
05 Oct, 2016 15:53

Technician:
Mike
Physician:
Aop

FVC 1

SVC

MVV

LVM

DLCO 1

Summary

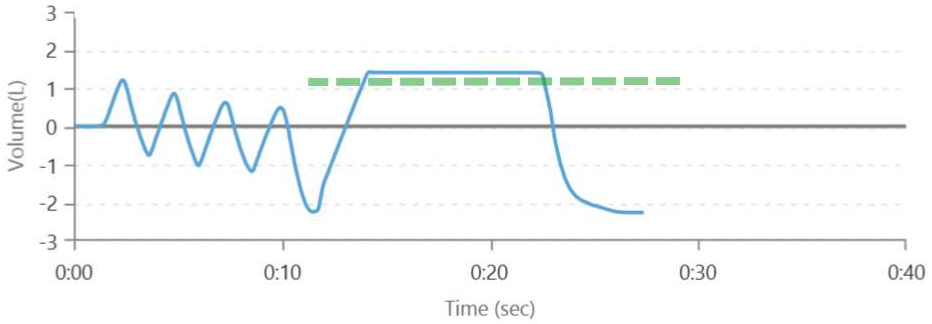
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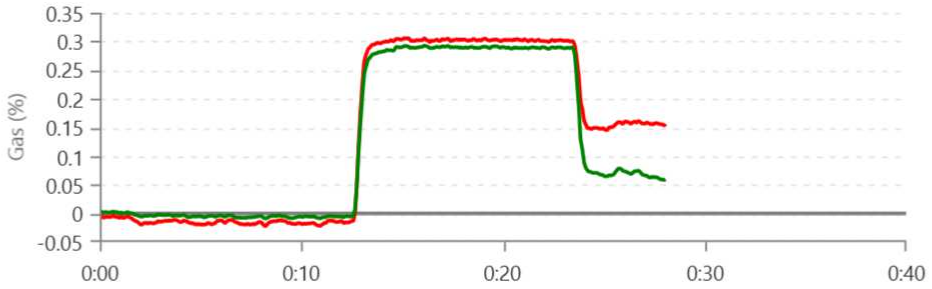
Print

Lung Diffusion Capacity Measurement

Test completed successfully

Press Save to see results



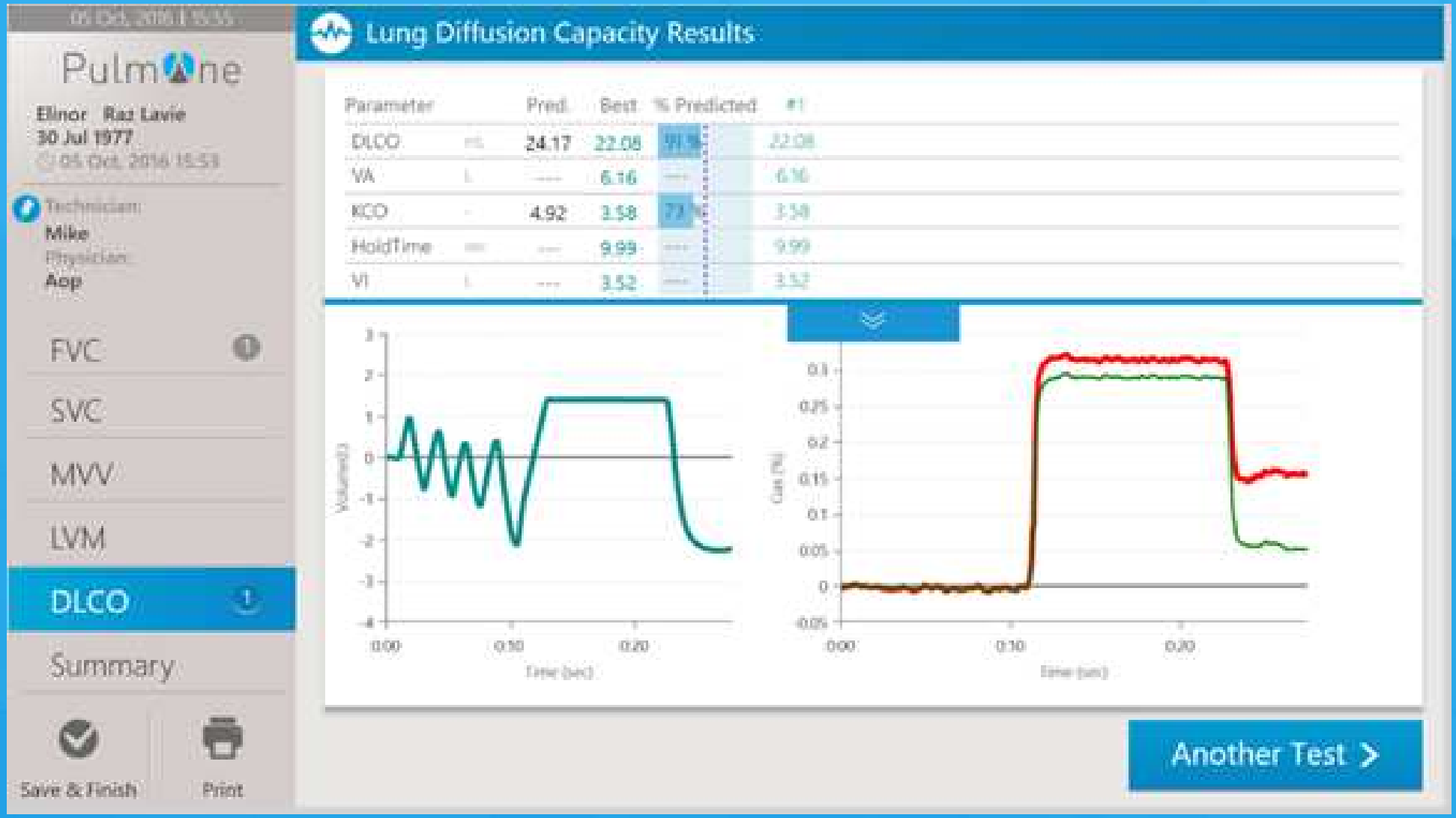




Manual Mode

Discard Test

Save


PulmOne
Elinor Raz Lavie
30 Jul 1977
Technician:
Mike
Physician:
Aop
FVC
SVC
MVV
LVM
DLCO
Summary
Save & Finish
Print
Lung Diffusion Capacity Results
Parameter
Pred.
Best
% Predicted
DLCO
24.17
22.08
VA
6.16
KCO
4.92
3.58
HoldTime
9.99
VI
3.52
Another Test

Lung Volume Measurement

- Traditional
  - Gas dilution
    - Long duration (4-7 minutes)
    - Wait time for repeatability
  - Body Plethysmography
    - Specific panting maneuver
    - No airflow for 4-7 seconds
    - Respiratory maneuver complex
    - Technologist influence

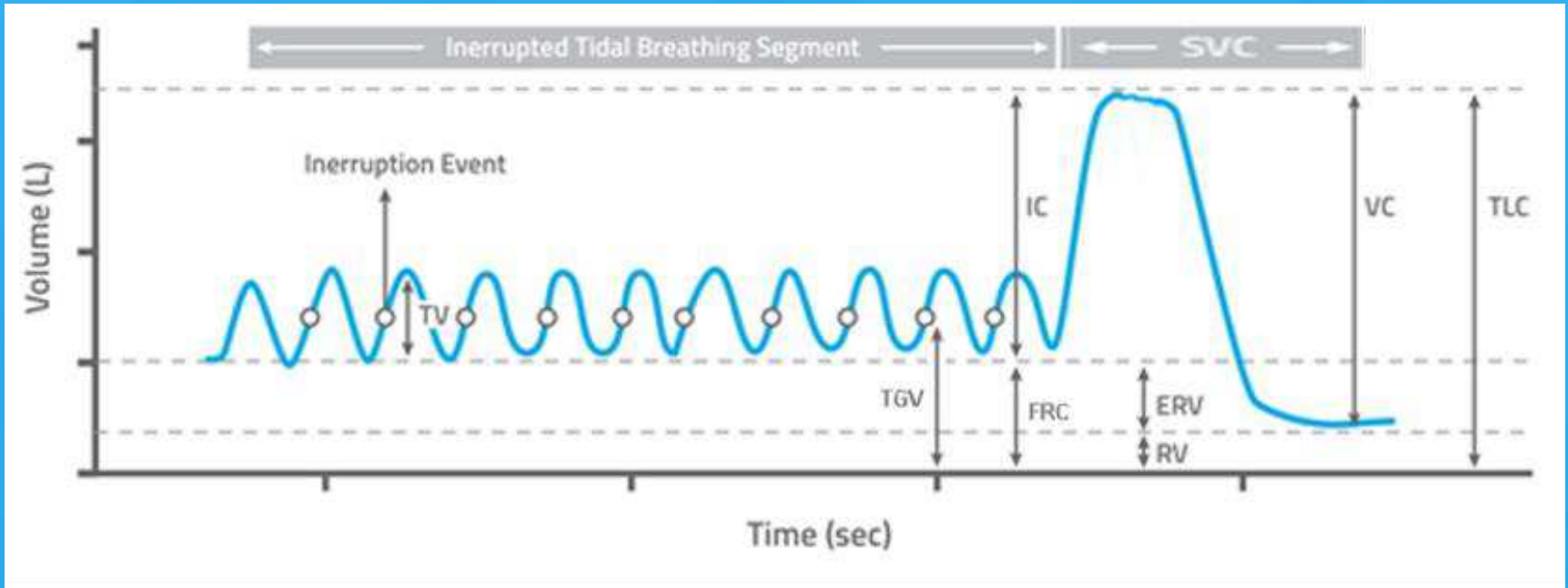
Lung Volume Measurement

- MiniBox+
  - Innovative solution
  - Tidal breathing and slow vital capacity
  - ~90 seconds to complete
  - Respiratory maneuver not complex

Lung Volume Measurement

- How it works
  - 6 interruptions during tidal breathing
    - Rapid 100 msec shutter close and open (mouth pressure)
  - Effect of interruptions on internal box
    - Pressure and flow
  - Data Model
    - Proprietary Model and Algorithm
  - Thoracic Gas Volume (TGV) is determined from which FRC is measured spirometrically as the difference between TGV and end-expiratory lung volume

Lung Volume Measurement



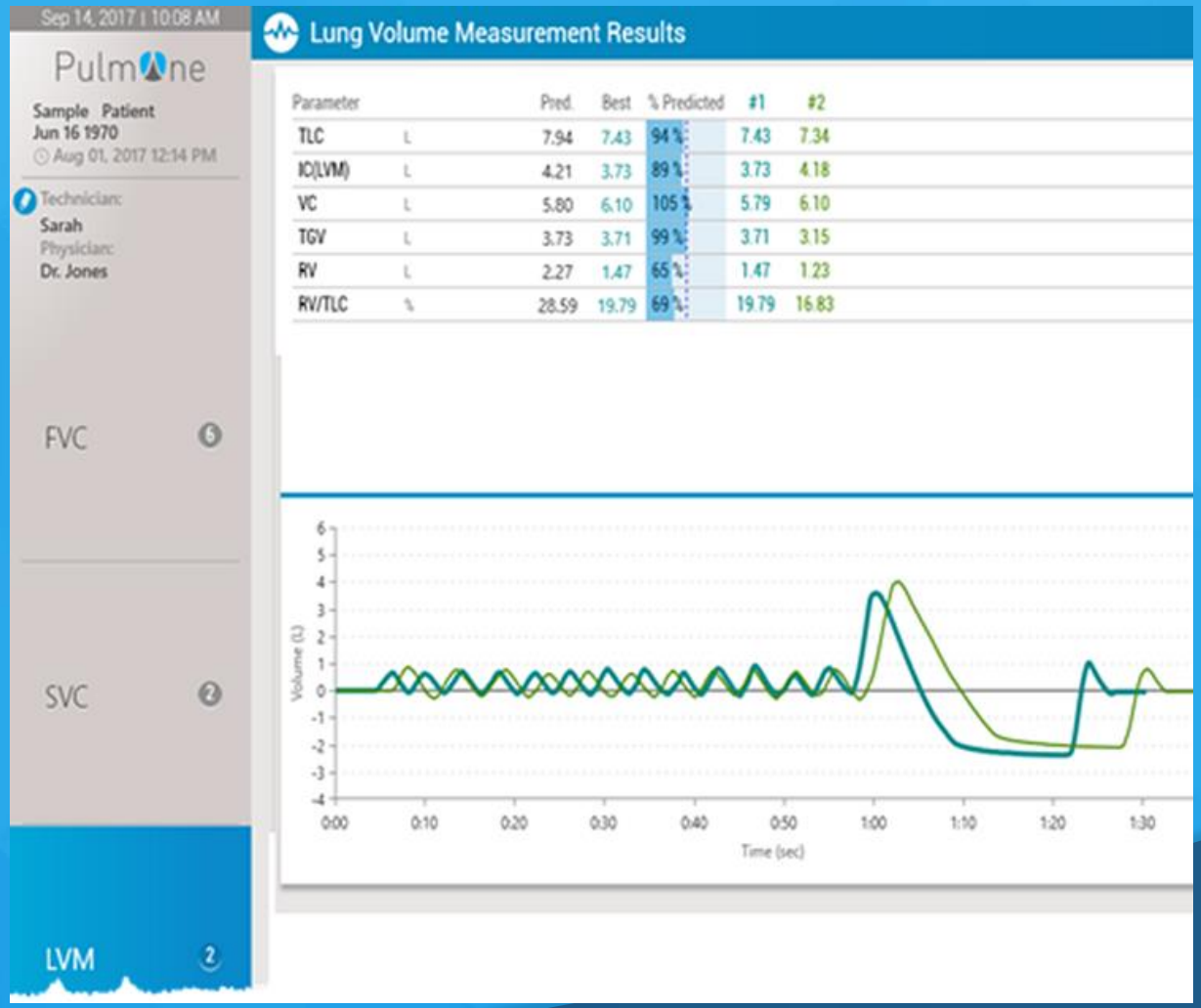
- Interruption is during inspiration (~1/3 of normal tidal)
- Interruption counter provides feedback on when interruption segment is complete
- Slow vital capacity can be performed either IC, VC or ERV, VC method

Lung Volume Measurement

No wait time requirement between efforts

No body cabin

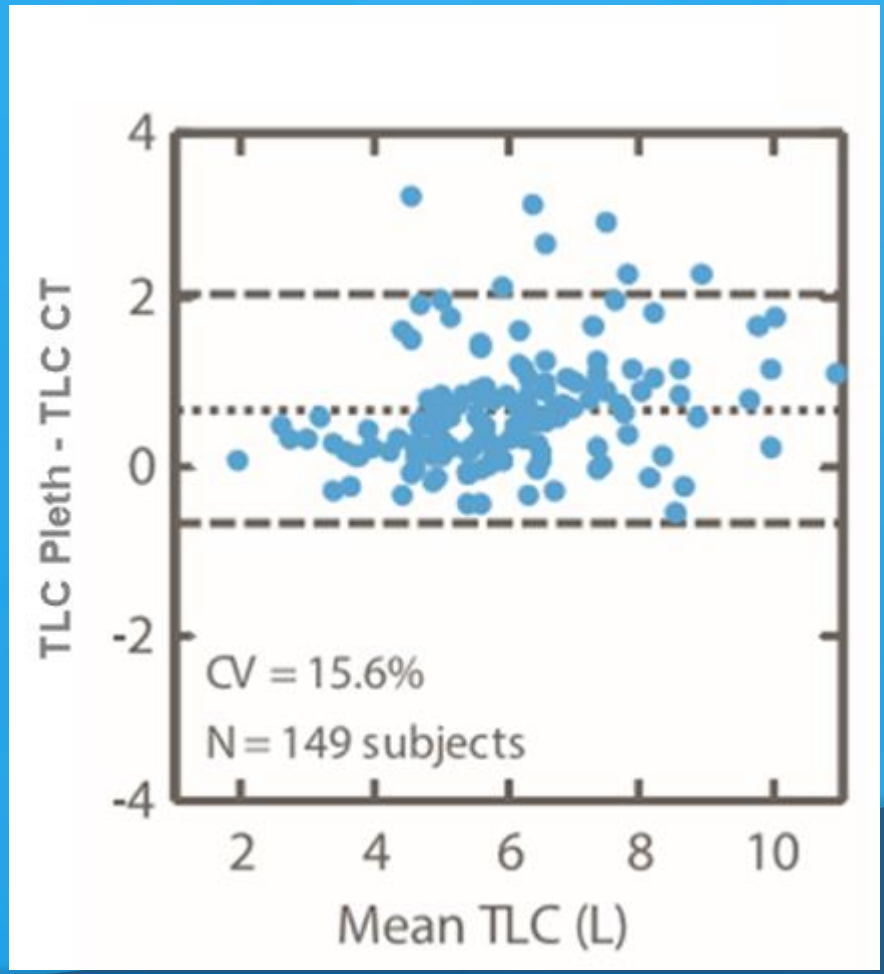
No complex panting maneuver against an occluded airway



Lung Volume Measurement

- Comparison – CT scan vs. plethysmography

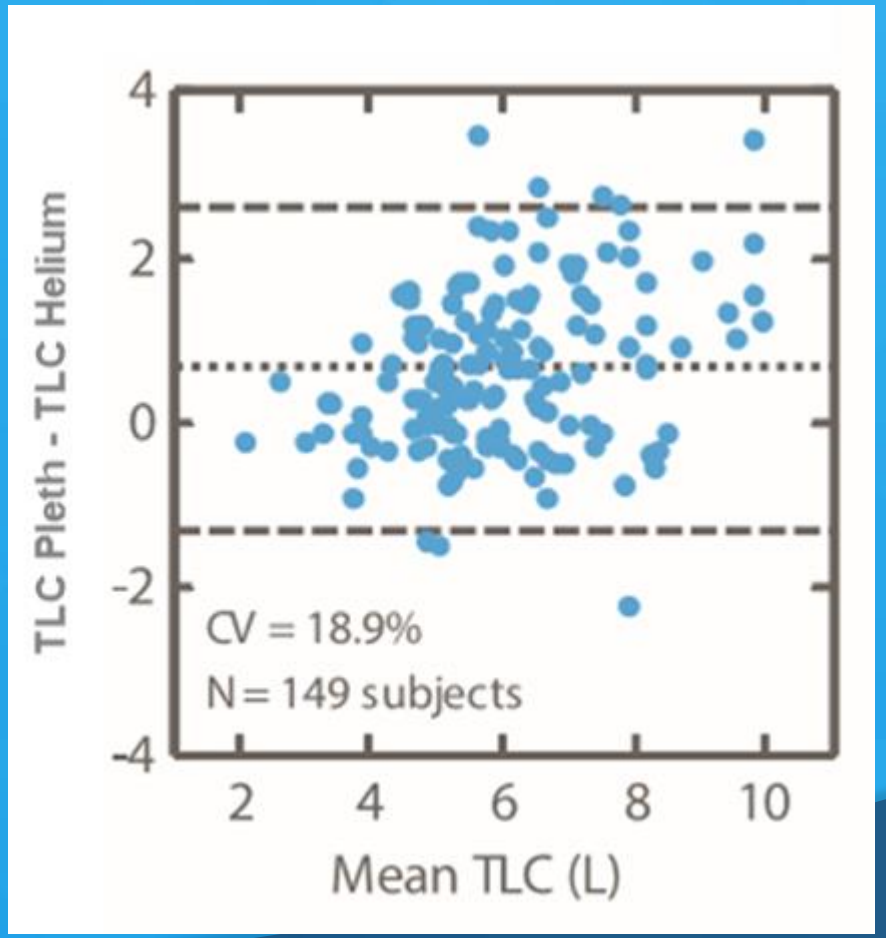
O'Donnell, Carl R. (2010). Comparison of Plethysmographic and Helium Dilution Lung Volumes. *CHEST*, 1*37*(5), 1108-1115.



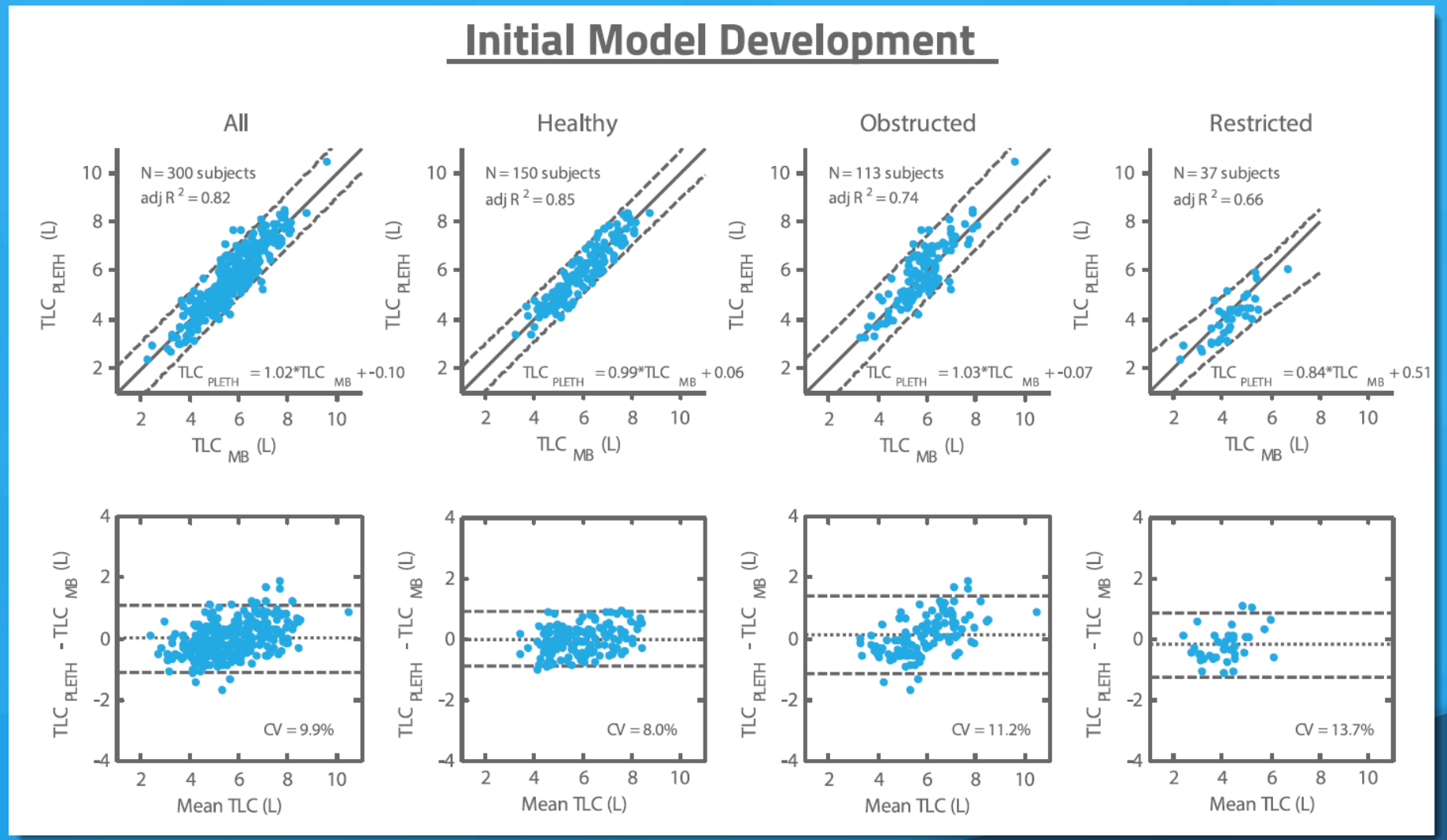
Lung Volume Measurement

- Comparison – He dil. vs. plethysmography

O'Donnell, Carl R. (2010). Comparison of Plethysmographic and Helium Dilution Lung Volumes. *CHEST*, *137*(5), 1108-1115.

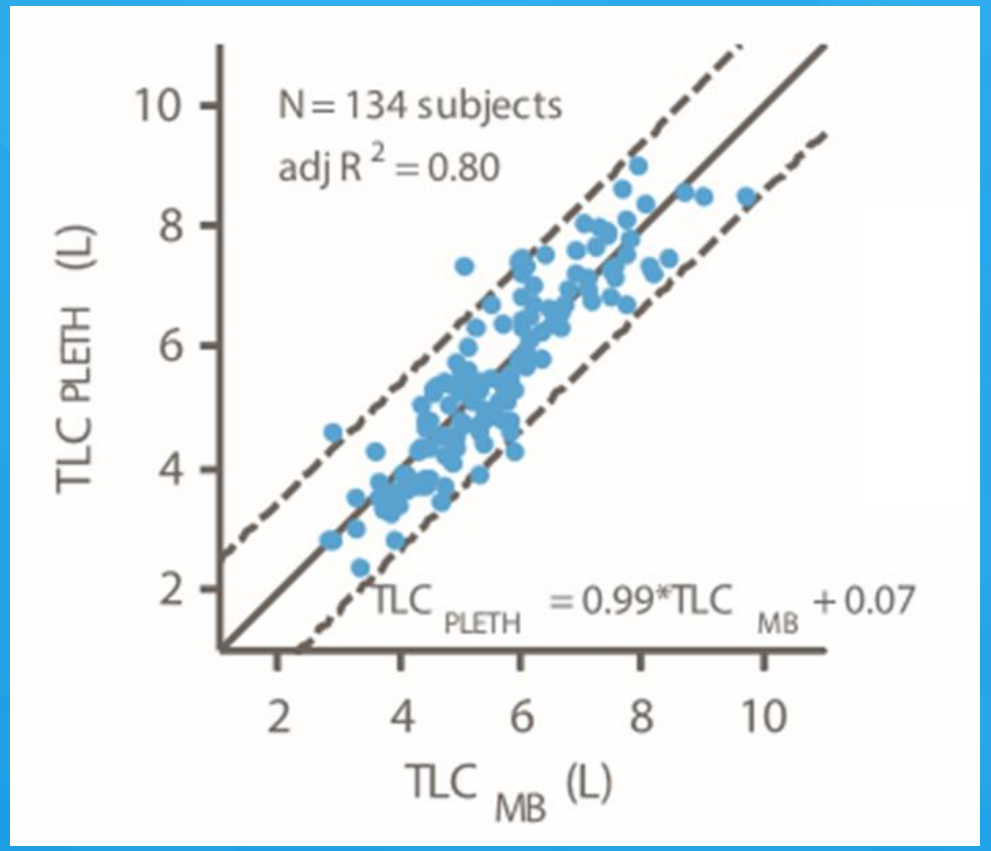


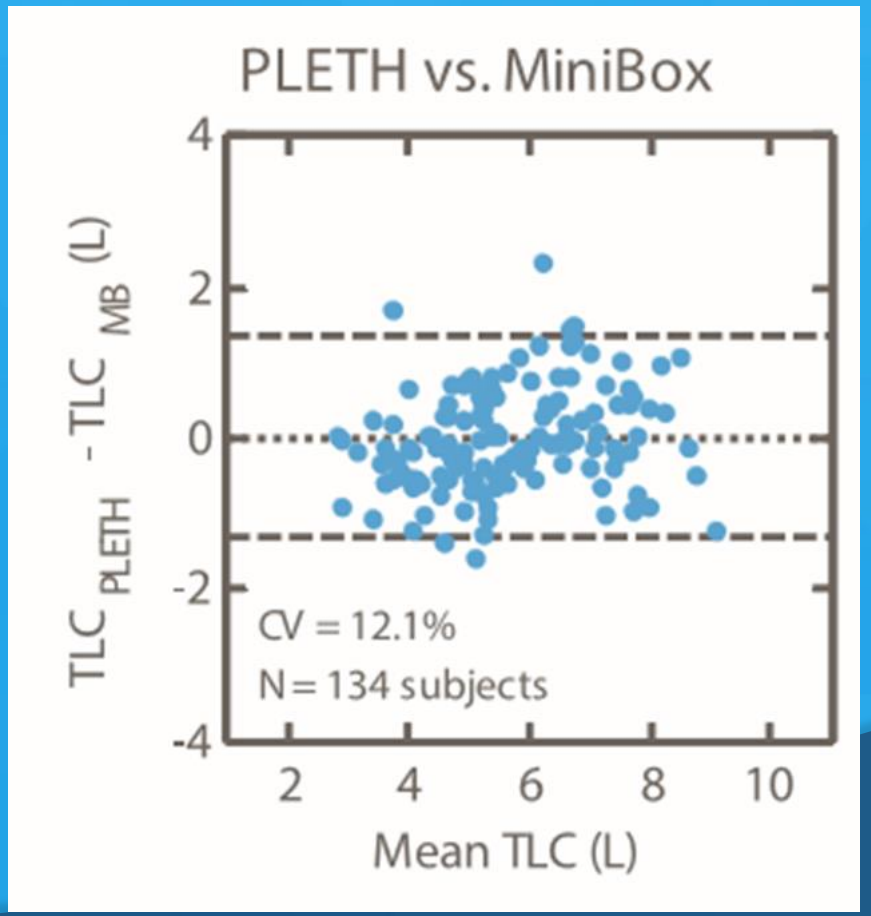
MiniBox+ Lung Volume Measurement



MiniBox+ Lung Volume Measurement

- Comparison – MiniBox+ vs. Plethysmography

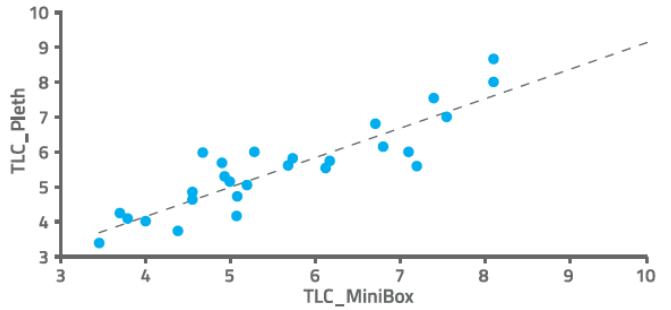


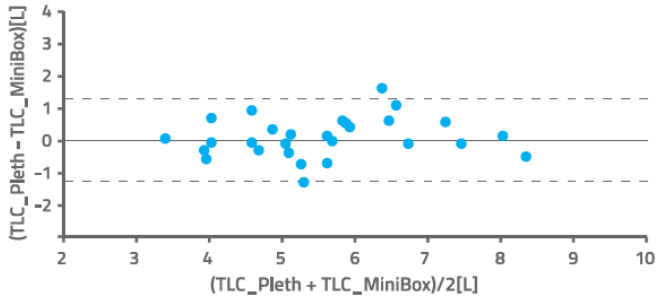


MiniBox+ Lung Volume Measurement

STUDY DATA		
Body Box device- Morgan Scientific Inc.	No. subjects	27
	Male / Female	14 / 13
	Age (years)*	67.6
	Height (cm)*	167.5
	Weight (Kg)*	78.5
	No. Healthy	12
	No. Unhealthy	15

* Mean

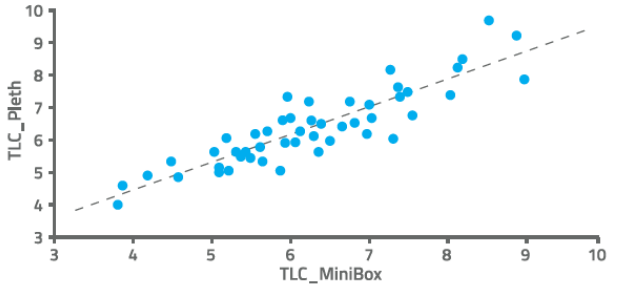


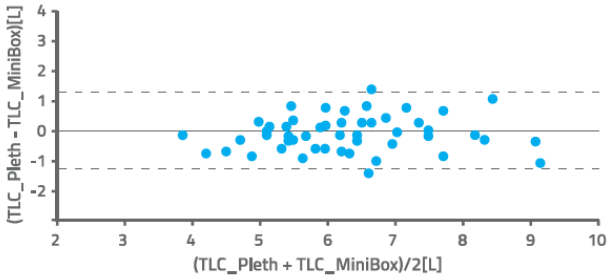


Boston Study

STUDY DATA		
Body Box device- MGC Diagnostics.	No. subjects	50
	Male / Female	28 / 22
	Age (years)*	71.1
	Height (cm)*	166.9
	Weight (Kg)*	75.4
	No. Healthy	18
	No. Unhealthy	32

* Mean





Cincinnati Study

MiniBox+ Lung Volume Measurement

COMPARATIVE STUDIES RESULTS VERSUS BODY PLETHYSMOGRAPHY

	MiniBox multi-center study, in Israel	MiniBox Boston study	MiniBox Cincinnati study
No. subjects	134	27	50
CV [%]	12.1%	10.9%	9.1%

	O'Donnel et al. (CHEST, 2010) – Helium Gas Dilution	O'Donnel et al. (CHEST, 2010) – CT (Computerized Tomography)
No. subjects	149	149
CV [%]	18.9%	15.6%

MiniBox+ Lung Volume Measurement

- Review
  - Unique and innovative technique
  - Compares well to Body Plethysmography
  - Simple respiratory maneuvers that are easy for the patient to perform
  - Very user friendly for technicians and patients

MiniBox+ Lung Volume Measurement

- Review (cont.)
  - Short test time (~90 seconds)
  - Multiple efforts without wait period
  - Small footprint
  - Notably less expensive than body plethysmography

Q&A