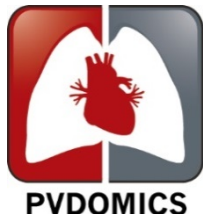


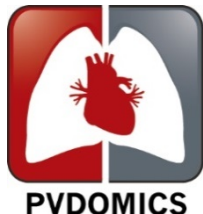
PULMONARY FUNCTION TESTING CORE



NHLBI Pulmonary Vascular Disease Phenomics Program

*Funded by the National Heart, Lung, and Blood Institute of the
National Institutes of Health with support from
the Pulmonary Hypertension Association*

Pulmonary Function and Six-minute Walk Testing



NHLBI Pulmonary Vascular Disease Phenomics Program

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Overview

- Procedures
 - Spirometry before and after bronchodilators
 - Lung volumes by plethysmography
 - DLCO
 - Six-minute walk test
- Forms
- Documentation to allow rating of test quality

QA and Data Transfer to DCC



- Evaluation of the quality of each individual efforts will be done to allow assignment of a quality score for the measurement session that reflects acceptability and repeatability of the session.
- Reports typically generated by PFT labs typically do not show individual efforts, just the 'best'
- Screen shots requirements are detailed in this presentation

PFT Requirements

- Who gets tested and when

Spirometry before and after bronchodilators

- Goal of testing sessions:
 - Pre-test questions:
 - Withhold bronchodilators for 8 hours?
 - If not – record last taken in relation to testing
 - Large meal in last 2 hours?
 - Smoking in last hour?
 - Strenuous exercise in last hour?
 - Alcohol in last 4 hours?
 - Theophylline in last 36 hours?
 - Acute respiratory illness in last 2 weeks?

Spirometry before and after bronchodilators

– Goal of spirometry session:

- Pre- and post-bronchodilator spirometry sessions consisting of at least 3 efforts that meet all ATS/ERS Acceptability and Repeatability requirements

Spirometry Acceptability

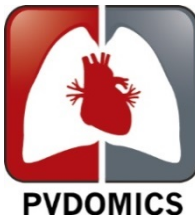
Start of test:

- » No cough in first second
- » Back-extrapolated volume less than or equal to 5% of FVC or 0.15L, whichever is greater
- » Time to peak flow less than or equal to 0.12s

End of test:

- » Forced expiratory time (FET) greater than or equal to 6s or valid expiratory plateau
- » In the absence of a plateau, FET of 15s or comment indicating why effort was terminated (for safety concerns)

Spirometry Acceptability Evaluation



- Spirometry:
 - Start of test requirements met
 - No cough in 1st second
 - Back-extrapolated volume within limits
 - Time to peak flow $\leq 0.12s$
 - End of test requirements met
 - Valid expiratory plateau demonstrated
 - No plateau: reasonable expiratory time
 - Tech comments should indicate if early termination was secondary to safety concerns
 - Required Documentation:
 - Volume-time and flow-volume curve for each effort
 - Data table showing each effort

Spirometry Repeatability

- Difference between largest and 2nd largest acceptable FVCs or FEV1s $\leq 0.15\text{L}$ unless:
 - Largest value is $\leq 1.00\text{ L}$, then the repeatability requirement changes to 0.10 L .

Spirometry QA

- Required documentation is necessary to rate the quality of the testing session(s)
- Session quality starts with rating each individual effort in the session
- Need to be able to review the acceptability of each effort in the session
- Printed reports from PFT lab sessions only show summary data – this is insufficient to rate individual efforts
- Screen shots from the testing device can provide all necessary information

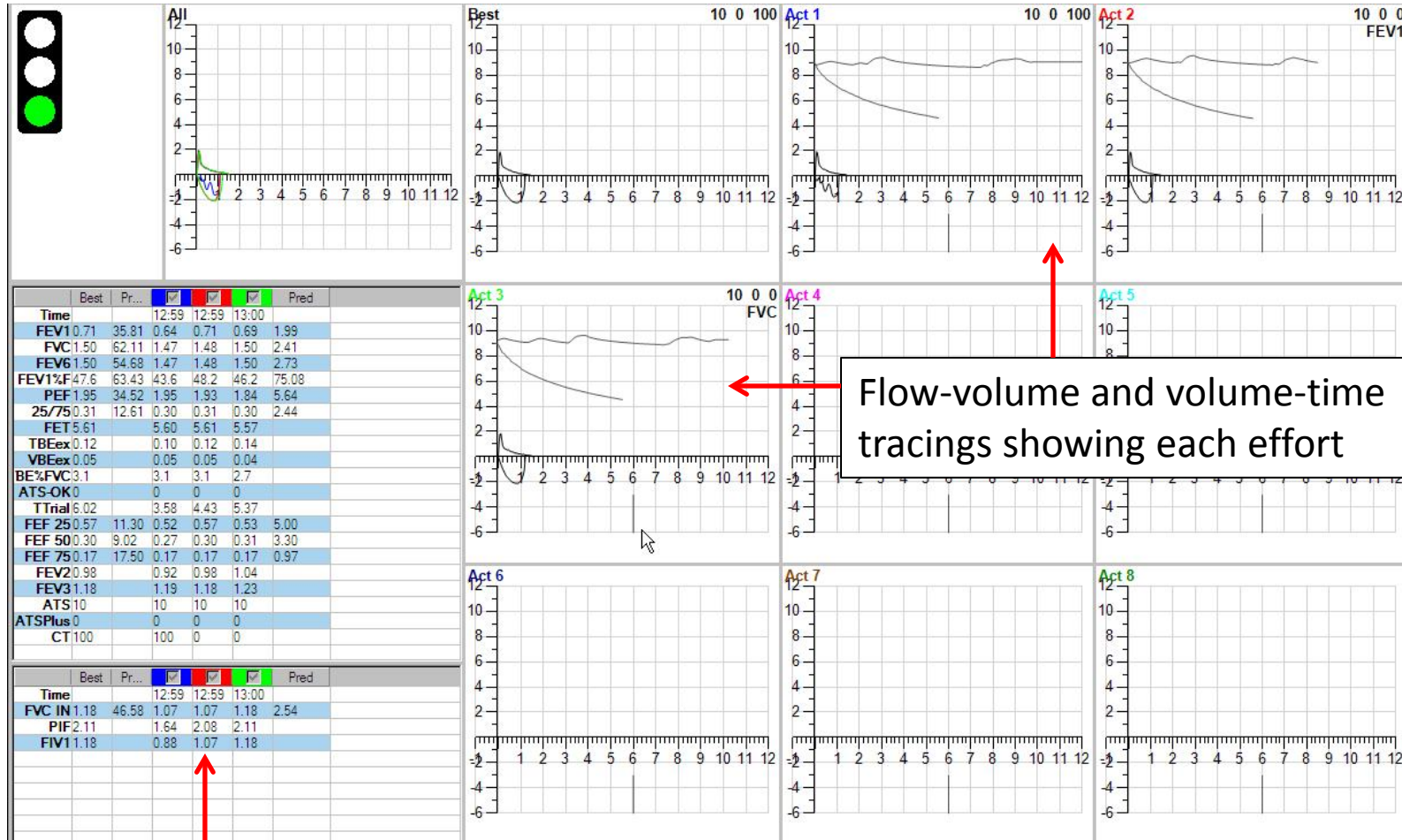
Spirometry Documentation Requirements

(both Pre- and Post-BD sessions)



- Flow-volume tracings from each effort]
 - labelled with effort numbers corresponding to data table entries
- Volume-time tracings from each effort
 - labelled with effort numbers corresponding to data table entries
- Data table showing each individual effort
 - Data table should include:
 - FVC, FEV1, FET, BEV (L), BEV (% of FVC), time to peak flow (TPEF).

Spirometry Screen Shots



Flow-volume and volume-time tracings showing each effort

Data Table showing each effort

Lung Volumes by Plethysmography

- Goal of testing session:
 - At least 3 acceptable 'linked' lung volume efforts that meet all ATS/ERS Acceptability and Repeatability requirements

Acceptability Requirements for Lung Volumes by Plethysmography



- Stable resting end-expiratory lung volume (EELV) that shows stability over at least three breaths
- Closed shutter maneuver that produces a clean artifact-free TGV loop of acceptable size that has a clearly defined slope
- Vital capacity maneuver that begins within 1-2 breaths after the shutter opens

Repeatability Requirements Lung Volume

- Difference between the largest and smallest FRCpleth should be no more than 5% of the mean FRCpleth
- Difference between the largest and 2nd largest VC from these efforts should be no more than 0.15L (no more than 0.10L if largest VC is less than 1.00L)

Lung Volume Documentation Requirements

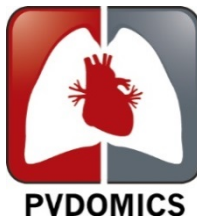
- Volume-time tracings for each lung volume effort
 - that demonstrate that all three phases of the measurement are linked,
 - labelled with effort numbers that match the data table
- TGV loops (mouth pressure vs. box pressure from the closed shutter maneuver) for each lung volume effort,
 - labelled with effort numbers that match the data table
- Data table showing the lung volume data for each effort: TGV, FRCpleth, VC, IC, ERV, RV, TLC, RV/TLC ratio

Lung Volumes by Plethysmography

- DO NOT measure airways resistance measurement in same session!
 - Workflow taught by manufacturers advise procedure that results in incorrect data
- Lung volume procedure must show evidence that on each effort the three phases are linked (patient did not come off mouthpiece)
 - Stable resting EELV
 - Acceptable TGV loop free of artifact
 - Vital capacity maneuver that begins just after (within 1-2 tidal breaths) of shutter opening

Lung Volumes by Plethysmography

Acceptability Evaluation



1. Stable resting end-expiratory lung volume demonstrated by at least 3 tidal breaths
 2. Acceptable thoracic gas volume (closed shutter maneuver) loop
 - Rate against shutter between 30 and 60/minute
 - Free of artifact without excessive thermal drift
 3. Acceptable vital capacity maneuver
- Required documentation:
 - Volume-time tracings for each effort showing all three phases linked
 - TGV loop for each effort
 - Data table showing results for each effort

[illegible]

The screenshot displays the HP 6890/5972 GC software interface. At the top, the 'Program Settings' window is open, showing the 'Data Collection' tab. A red arrow points to the 'Data Collection' tab. The main window is divided into several sections:

- Top Left:** A series of stacked plots showing detector response over time. The x-axis is labeled 'Volume (mL)' and ranges from 0 to 60. The y-axis is labeled 'Response' and ranges from 0 to 1.0.
- Top Right:** A table of peak data. The table has columns for 'Peak', 'Area', 'Height', 'Width', 'Retention Time', and 'Signal-to-Noise Ratio'. The data is as follows:

Peak	Area	Height	Width	Retention Time	Signal-to-Noise Ratio
1	1.87	3.40	3.16	1.87	1.07
2	1.82	4.33	4.33	1.82	1.07
3	1.82	2.60	3.18	1.82	1.07
4	1.81	1.81	1.36	1.81	1.07
5	1.82	0.50	0.34	1.82	1.07
6	1.82	0.05	0.07	1.82	1.07
7	1.82	0.05	0.07	1.82	1.07
8	1.82	0.05	0.07	1.82	1.07
9	1.82	0.05	0.07	1.82	1.07
10	1.82	0.05	0.07	1.82	1.07
11	1.82	0.05	0.07	1.82	1.07
12	1.82	0.05	0.07	1.82	1.07
13	1.82	0.05	0.07	1.82	1.07
14	1.82	0.05	0.07	1.82	1.07
15	1.82	0.05	0.07	1.82	1.07
16	1.82	0.05	0.07	1.82	1.07
17	1.82	0.05	0.07	1.82	1.07
18	1.82	0.05	0.07	1.82	1.07
19	1.82	0.05	0.07	1.82	1.07
20	1.82	0.05	0.07	1.82	1.07
21	1.82	0.05	0.07	1.82	1.07
22	1.82	0.05	0.07	1.82	1.07
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25	1.82	0.05	0.07	1.82	1.07
26	1.82	0.05	0.07	1.82	1.07
27	1.82	0.05	0.07	1.82	1.07
28	1.82	0.05	0.07	1.82	1.07
29	1.82	0.05	0.07	1.82	1.07
30	1.82	0.05	0.07	1.82	1.07
31	1.82	0.05	0.07	1.82	1.07
32	1.82	0.05	0.07	1.82	1.07
33	1.82	0.05	0.07	1.82	1.07
34	1.82	0.05	0.07	1.82	1.07
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37	1.82	0.05	0.07	1.82	1.07
38	1.82	0.05	0.07	1.82	1.07
39	1.82	0.05	0.07	1.82	1.07
40	1.82	0.05	0.07	1.82	1.07
41	1.82	0.05	0.07	1.82	1.07
42	1.82	0.05	0.07	1.82	1.07
43	1.82	0.05	0.07	1.82	1.07
44	1.82	0.05	0.07	1.82	1.07
45	1.82	0.05	0.07	1.82	1.07
46	1.82	0.05	0.07	1.82	1.07
47	1.82	0.05	0.07	1.82	1.07
48	1.82	0.05	0.07	1.82	1.07
49	1.82	0.05	0.07	1.82	1.07
50	1.82	0.05	0.07	1.82	1.07
51	1.82	0.05	0.07	1.82	1.07
52	1.82	0.05	0.07	1.82	1.07
53	1.82	0.05	0.07	1.82	1.07
54	1.82	0.05	0.07	1.82	1.07
55	1.82	0.05	0.07	1.82	1.07
56	1.82	0.05	0.07	1.82	1.07
57	1.82	0.05	0.07	1.82	1.07
58	1.82	0.05	0.07	1.82	1.07
59	1.82	0.05	0.07	1.82	

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DLCO

- Goal of testing session:
 - At least 2 acceptable DLCO efforts that meet all ATS/ERS Acceptability and Repeatability requirements:
 - $IVC \geq 85\%$ of largest VC (SVC from lung volumes or FVC from spirometry)
 - Breath hold time (BHT) between 8 and 12 seconds
 - Test gas inspired in less than 2s (up to 4s if lung disease severe) and sample volume exhaled within 4s
 - No evidence of Valsalva during breath hold

DLCO

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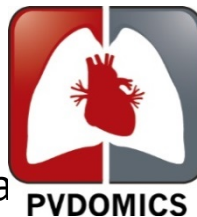
DLCO Acceptability Evaluation

- Inspired volume of test gas $\geq 85\%$ of largest VC measured on the day of the DLCO test
- Test gas inspired in less than 4 s
- Breath hold time between 8 and 12 s
- Gas analysis curve showing normal rise to equilibration (for rapid response analyzers: analysis segment past the dead space portion)
- Required documentation:
 - Volume-time tracing for each effort
 - Gas analysis curves for each effort
 - Data table showing results for each effort

DLCO Documentation Requirements

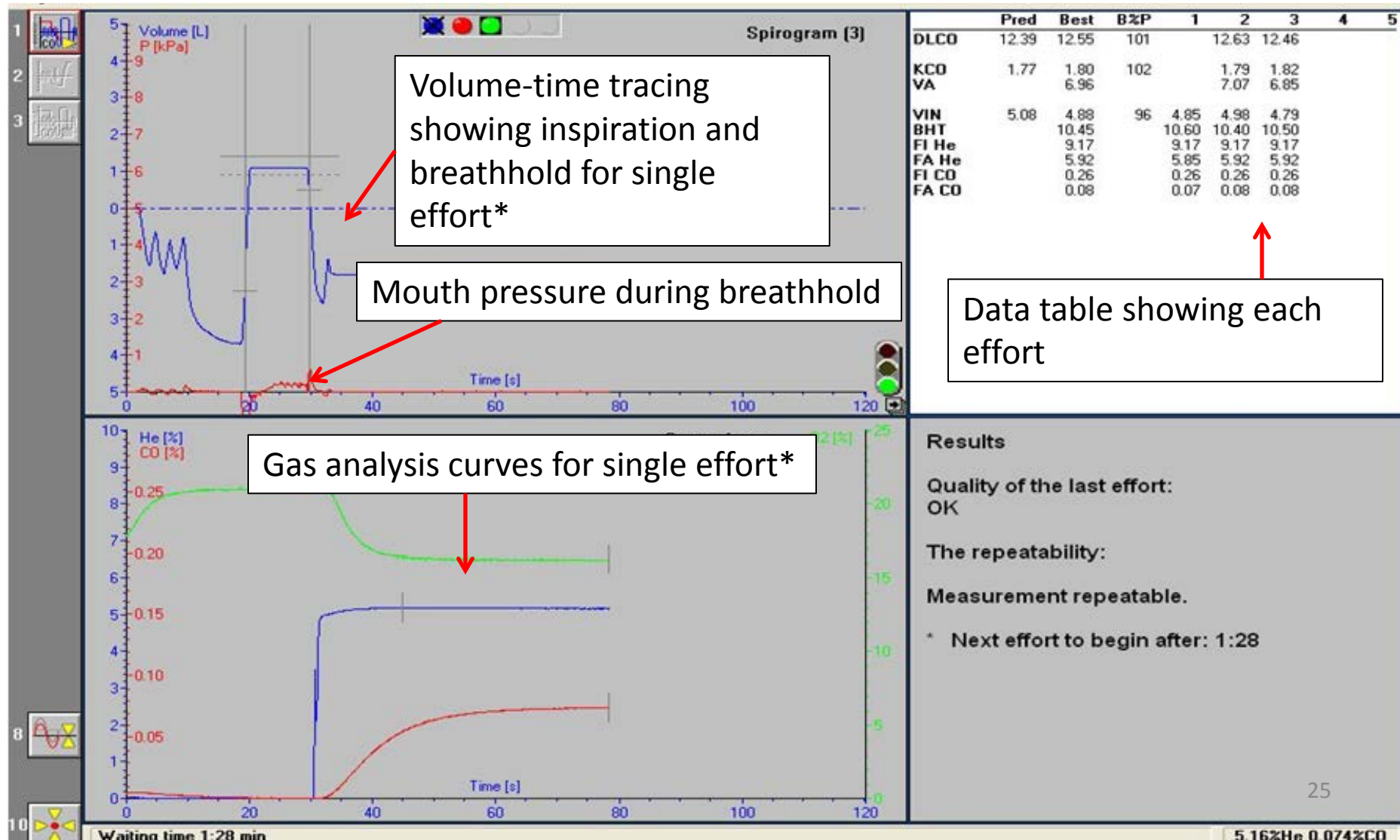
- Volume-time tracing for each effort,
 - labelled with effort numbers that match the data table
- Gas analysis curves for each effort,
 - labelled with effort numbers that match the data table
- Data table showing the DLCO data for each effort:
DLCO, DLCO/VA, VA, IVC, BHT, inspired and alveolar CO and tracer gas concentrations.

DLCO Screen Shots



*

Note: Most PFT systems will only show the gas analysis curves for one effort at a time. Separate screen shots for each effort are required



DLCO

- Patient should be off supplemental oxygen for 10 minutes before effort, if possible
 - If not possible due to patient's SpO₂, indicate how long off of oxygen in the technologist comments and on PFT Form 270
- Minimum 4 minute interval between efforts

Six-minute Walk (6MW) Test

O₂ Titration at Rest

- If Resting SpO₂ is < 92%, titrate supplemental oxygen at rest to achieve a resting SpO₂ ≥ 92%* before the 6mw test.

* If a resting SpO₂ ≥ 92% cannot be achieved, the maximum supplemental oxygen to be used for the 6mw test is 6 LPM by nasal cannula.

Six-minute Walk (6MW) Test

- Goal of testing session:
 - Administer instructions and coaching in a standardized fashion
 - Obtain 6mw distance
 - HR and SpO2 at rest and immediately at the end of the walk
 - Document supplemental oxygen used (device and flow)
 - Borg perceived exertion scores at rest and exercise (show Borg scale to patient)

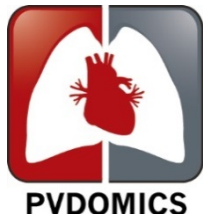
6MW

- Borg scale must be shown, not verbally described
- Standardized encouragement phrases delivered each minute in an even tone of voice
- Instructions must be read, not ad-libbed
- Patient should not be tethered to the person administering

6MW – Post-test cooldown

- Record and report the heart rate obtained @ 1 minute and 2 minutes after the patient sits down after the walk.

PFT Data Submission Requirements



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QA and Data Transfer to DCC

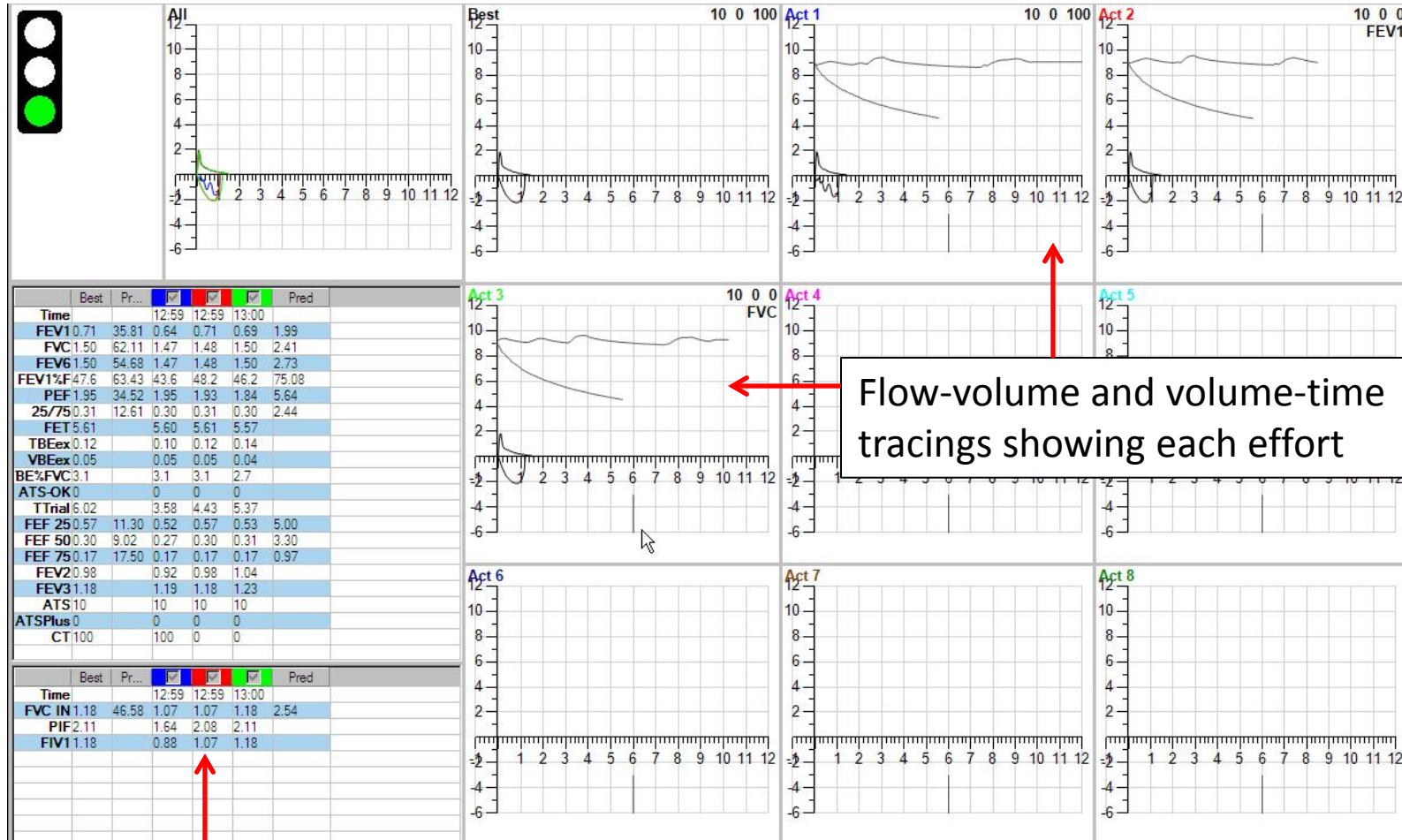


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Spirometry Acceptability Evaluation

- Spirometry:
 - Start of test requirements met
 - No cough in 1st second
 - Back-extrapolated volume within limits
 - Time to peak flow $\leq 0.12s$
 - End of test requirements met
 - Valid expiratory plateau demonstrated
 - No plateau: reasonable expiratory time
 - Tech comments should indicate if early termination was secondary to safety concerns
 - Required Documentation:
 - Volume-time and flow-volume curve for each effort
 - Data table showing each effort

Spirometry Screen Shots



Flow-volume and volume-time tracings showing each effort

Data Table showing each effort

Lung Volumes by Plethysmography

Acceptability Evaluation



1. Stable resting end-expiratory lung volume demonstrated by at least 3 tidal breaths
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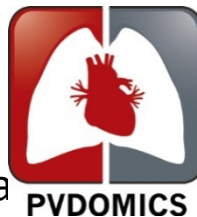
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DLCO Acceptability Evaluation

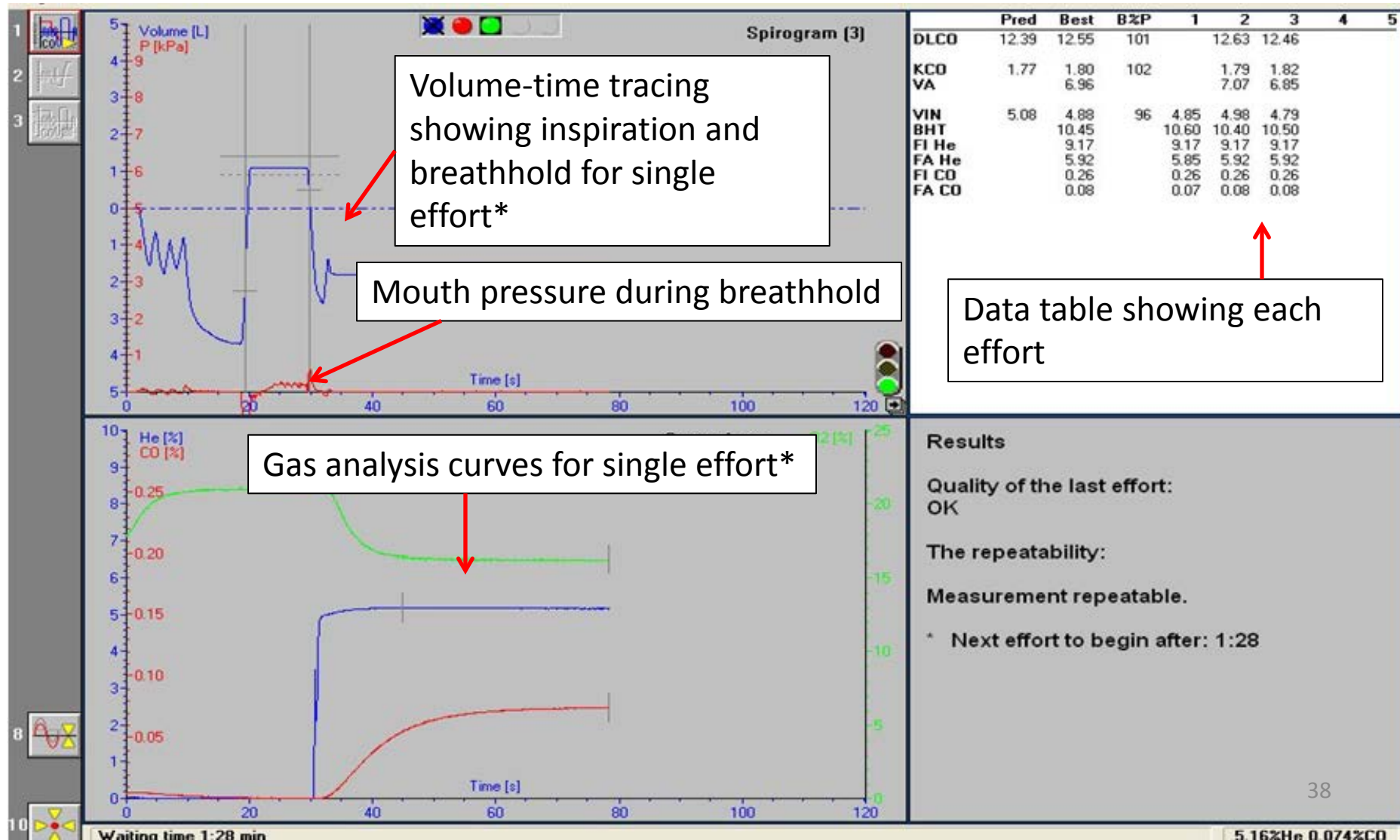
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DLCO Screen Shots



*

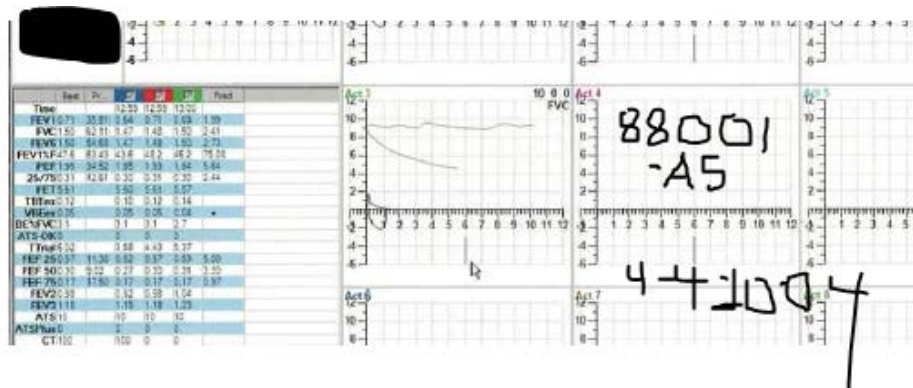
Note: Most PFT systems will only show the gas analysis curves for one effort at a time. Separate screen shots for each effort are required



Processing and Transferring

Test Documents and Tracings, *part 1*

- All documents must be de-identified prior to transferring
- Print off hard copies of requested PFT documents
- Cross through all identifying information such as name, DOB, MRN, etc.
- Write on each page, participant's 6 digit ID #, alphacode, date
- of pft tests

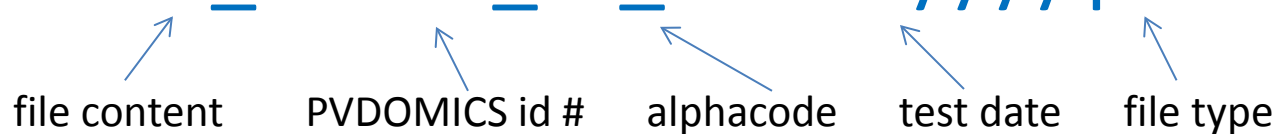


- Scan documents together in one file; save as a pdf

Processing and Transferring Test Documents and Tracings, *part 2*

- File naming convention is:

“PFT_XXXXXX_ac_mmdyyyyy.pdf”



file content PVDOMICS id # alphacode test date file type

- Log in to SSH with previously assigned account name and password
- Drag and drop file into SSH home directory for PVDOMICS on DCC server
- Document transfer date in Q100 on Forms 270 (or 271)
- DCC will move file out of home directory for processing