ComPAS2 Reference Manual
Model 9100 Vitalograph Morgan PFT (VitaloROV and LAB)

ComPAS2 v2023.1.0
Document Version/Revision 1.08

Precautions

Caution: Federal law restricts this device to sale by, or on the order of a physician

Caution: Not suitable for use in the presence of flammable anesthetics

Service of this instrumentation is restricted to factory trained personnel only

ComPAS2 Manual	Written and illustrated by: Patrick Morgan with additional diagrams from Laura King	
©	Morgan Scientific, Inc.	
MD	ComPAS2 v2023.1.0	
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UDI ℞ Only	(01)00851845007187(10)2023.1.0	FDA 510(k): K213872
CE	TUV is certified to: MDSAP QS6 094965 0004 Rev. 02 ComPAS2 was created in a facility whose quality management system is certified to: * ISO 13485:2016 * MDSAP USA: 21 CFR Part 803; 21 CFR Part 806; 21 CFR Part 807; 21 CFR Part 820 Canada: Medical Device Regulations SOR/98-282, Part 1	G1 094965 0005 Rev. 00
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ComPAS2 with Model 9100 Vitalograph Morgan PFT (VitaloROV and LAB)

Table of Contents

Introduction to ComPAS2 with the Model 9100 Vitalograph Morgan PFT (VitaloROV) and (VitaloLAB)

1:0 Introduction

1.1 Model 9100 Vitalograph Morgan PFT(VitaloROV) and (VitaloLAB)

The Model 9100 Vitalograph Morgan PFT Range brings together simplicity of operation, precision measurement, outstanding reliability and great versatility.

Instruments are available with demand valve or inspiratory bag reservoir for DLCO and N2 testing.

VitaloLAB

VitaloROV

Testing capability includes:

- Static Spirometry - Slow Vital Capacity
- Dynamic Spirometry - Flow Volume Loop
- Maximum Voluntary Ventilation
- Cough Peak Flow
- Respiratory Muscle Strength (MIP & MEP)
- Sniff Nasal Inspiratory Pressure
- Bronchial Challenge (Methacholine, Exercise, Cold Air etc.)
- Fast Gas Single Breath Diffusion
- Multi-breath Nitrogen Washout with LCI
- Single-breath Nitrogen Washout
- Six Minute Walk (an additional Nonin WristOx is optional)
- Manual Entry of ABG's etc.
- HAST Testing

The instruments are suitable for subjects ranging from small children to adults with severe COPD.

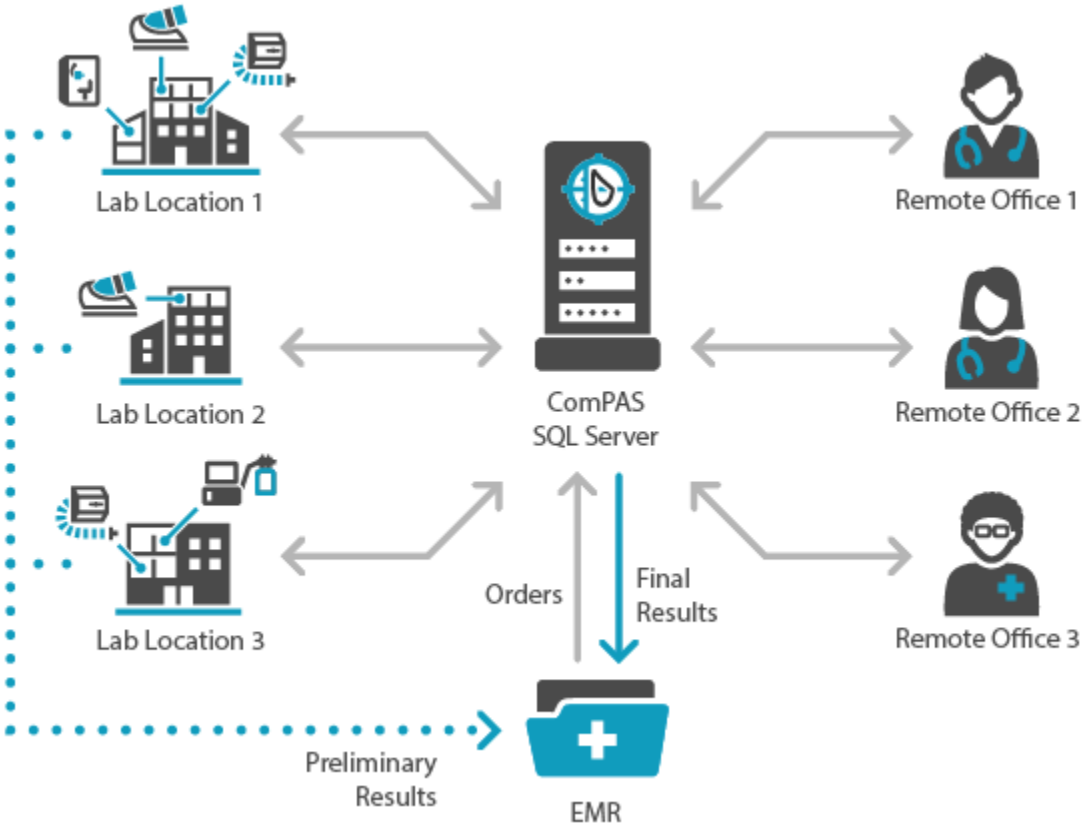
1.2 Morgan ComPAS2 Software

The ComPAS2 suite of software has evolved over years of clinical work at Morgan Scientific, Inc. It is an amalgamation of expertise in pulmonary function testing (PFT), scientific techniques of measurement and the very latest in software design. From the finest teaching hospitals to private offices, ComPAS2 offers the total PFT software solution.

Since 1985 Morgan Scientific has specialized in providing comprehensive information sharing solutions; ComPAS2 delivers a complete workflow system that combines healthcare industry standards and best clinical practices with elegant and user-friendly remote interpretation capability. Our design scales easily from private physician practices to large university teaching center models.

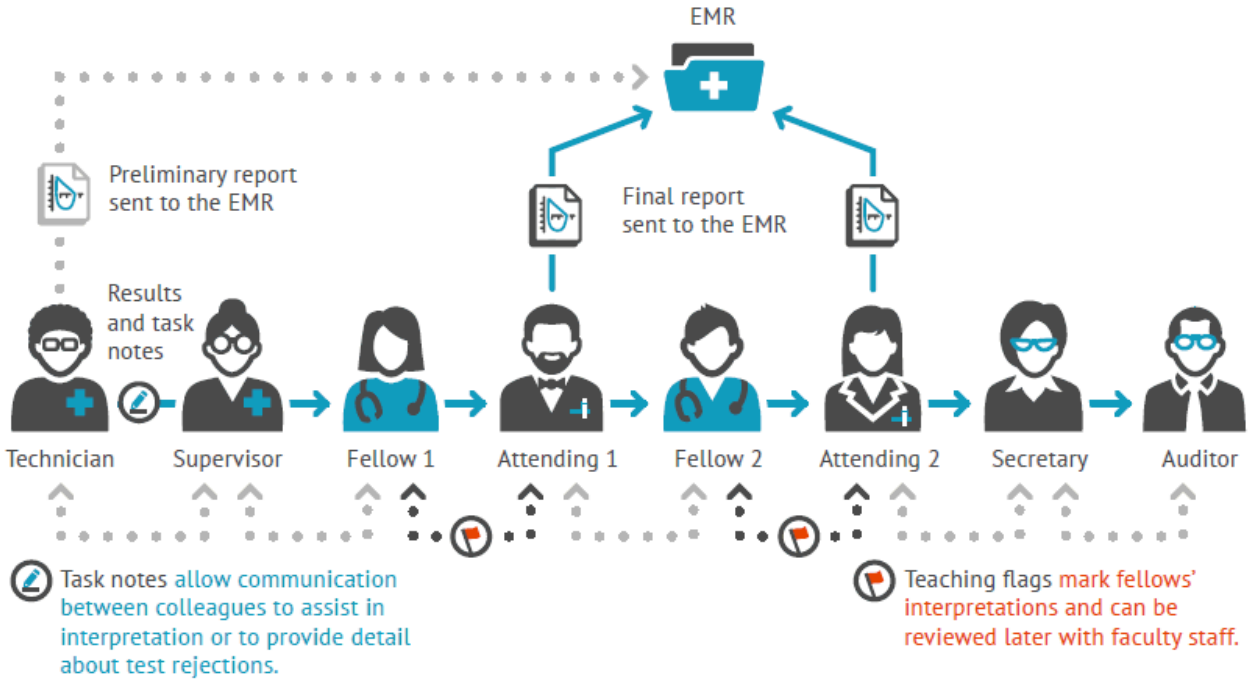
ComPAS2 software protects all Patient Health Information (PHI) data at rest and in transit using industry leading encryption to meet HIPAA compliance.

The design, implementation and support of information system solutions is provided directly by Morgan Scientific engineers.



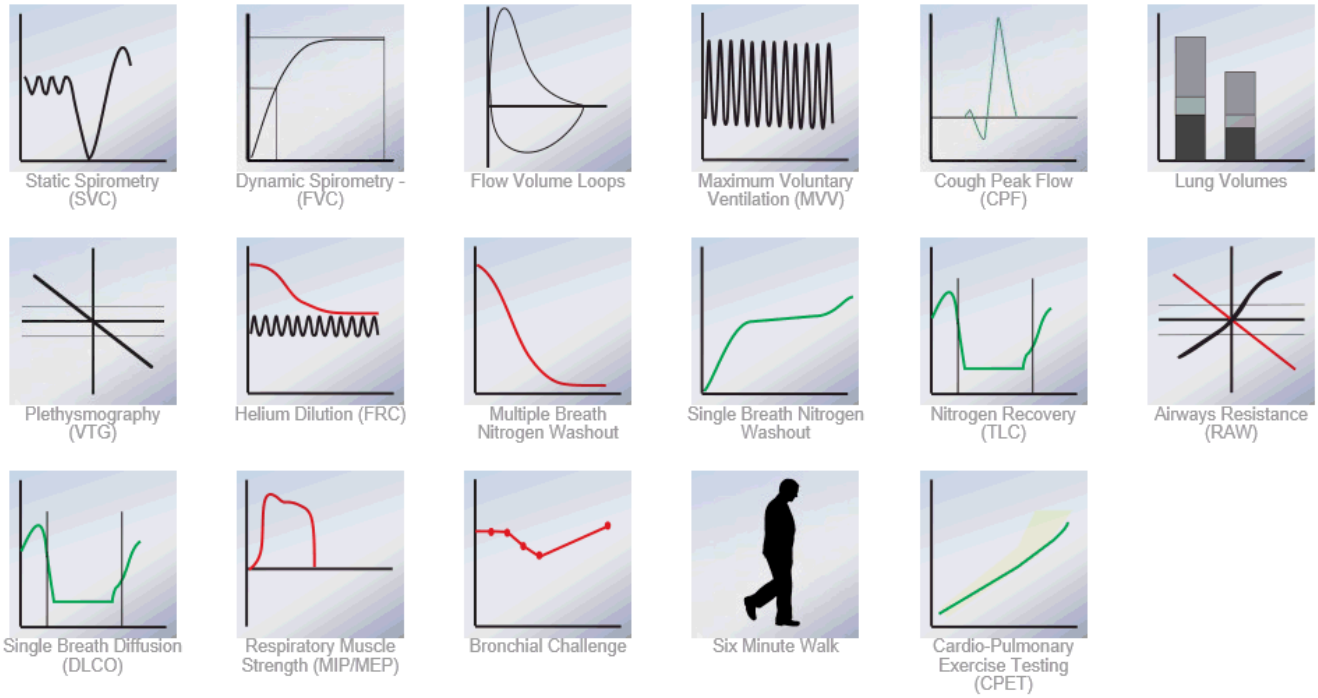
Whether operating in a small office practice or as part of a vast university teaching hospital system, ComPAS2 provides the most advanced physician-designed remote interpretation and data exchange capability.

The ComPAS2 Task Manager can be configured to suit any size of facility with a variety of 'roles' turned-on or off so that data can be exchanged between colleagues and the hospital or office information system. Remote interpretation is easy to use with a stunning array of report options, instant historical review, dictation capability and template creation for frequently used text.



ComPAS2 works with a vast array of quality instrumentation, utilizing data acquisition techniques that are proven and verifiable. Our software specialists have over 250 collective years of respiratory testing experience. Expertise that is vital when gathering data from the very sick or very young. ComPAS2 is the quintessence of data integrity. Each clinical test is first measured with great accuracy, then reviewed by the software for testing validity and data preserved in a fully encrypted database.

Test capability includes:



1-2-1 Medical Purpose

Pulmonary Function Tests (PFT's) are valuable investigations in the management of patients with suspected or previously diagnosed respiratory disease. They aid diagnosis, help monitor response to treatment and can guide decisions regarding further treatment and intervention. The interpretation of pulmonary functions tests requires knowledge of respiratory physiology.

A physician may order these tests:

- if a subject is having symptoms of lung problems as part of a routine physical
- to monitor how effective a subject's treatment is if they have a lung disease, such as asthma
- to assess how well the lungs are working before surgery

PFTs can help diagnose:

- asthma
- allergies
- chronic bronchitis
- respiratory infections
- lung fibrosis
- bronchiectasis, which is a condition in which the airways in the lungs stretch and widen
- chronic obstructive pulmonary disease (COPD)
- asbestosis, which is a condition caused by exposure to asbestos
- sarcoidosis, which is an inflammation of your lungs, liver, lymph nodes, eyes, skin, or other tissues
- scleroderma, which is a disease that affects your connective tissue
- pulmonary tumor
- lung cancer

1-2-2 Patient Population

The ComPAS2 product operates with various pieces of PFT hardware designed to work with subjects ranging in age from 4 to 99.

Within this age range, much research has been undertaken to determine what are the normal values for pulmonary function. This has made PFT's very useful since now we know that we can compare the patient's PFT results with those measured on thousands and thousands of "normal" adults. By having tables of normal values, it is then easy to compare the severity of the disease process or the rate of recovery taking place in the patient's lungs. There are a few variables such as age, gender and body size which have an impact on the lung function of one individual compared to another.

Age: As a person ages, the natural elasticity of the lungs decreases. This translates into smaller and smaller lung volumes and capacities as we age. When determining whether or not your patient has normal PFT findings, it would be important to compare the subject with the PFT results of a normal person of the same age and gender.

Birth Sex: Usually the lung volumes and capacities of males are larger than the lung volumes and capacities of females. Even when males and females are matched for height and weight, males have larger lungs than females. Because of this sex-dependent lung size difference, different normal tables must be used for males and females.

Body Height & Size: Body size has a tremendous effect on PFT values. A small man will have a smaller PFT result than a man of the same age who is much larger. Normal tables account for this variable by giving predicted PFT data for males or females of a certain age and height. Sometimes as people age they begin to increase their body mass by increasing their body fat to lean body mass ratio. If they become too obese, the abdominal mass prevents the diaphragm from descending as far as it could and the PFT results will demonstrate a smaller measured PFT outcome then expected - i.e. the observed (measured) values are actually smaller than the predicted values (predicted values from the normal tables).

Ethnicity: Ethnicity affects PFT values. African American, Northeast Asian and Southeast Asian have different PFT results compared to Caucasians. Therefore, a clinician must use a race appropriate table to compare the subject's measured pulmonary function against the results of the normal table written for that subject's racial group.

Other factors such as environmental factors and altitude may have an effect on PFT results but the degree of effect on PFT is not clearly understood at this time.

1-2-3 Standards Compliance

Safety:	ISO 14971:2019 EN ISO 13485:2016/ISO 13485:2016 21 CFR Part 801, 803 and 820 IEC 62304
Medical Instrument Directive (CE mark)	G1 094965 0005 Rev. 00
Medical Device Regulations MDSAP United States/Canada	QS60949650004 Rev 01 21 CFR Part 801, 803, 806, 807 and 820 MDR – Part 1 – SOR 98/282
FDA 510(k)	K190568

1-2-4 ComPAS2 Indications for Use

The Morgan Scientific ComPAS2 software application is intended to be used to connect to compatible Morgan Scientific or third-party devices to acquire, view, store, export, and print the device output. The product is designed for use on adults and pediatrics 3 years and older, in a variety of healthcare environments such as, but not limited to, primary care, hospitals, occupational health, and research health centers under the supervision of a healthcare provider.

1-2-5 Cyber Security Instructions for Use

1. ComPAS2 should be installed on a Windows 10 PC with the following cybersecurity controls
    a. All Windows 10 security patches are up to date
    b. Antivirus software running with up-to-date definitions
    c. Malware software detection with up-to-date definitions
    d. Windows 10 Firewall for local PC in use
    e. Unique Windows login credentials for each user

2. ComPAS2 Networked Installation – Cybersecurity Controls
    a. Network is behind a firewall that has all unused ports blocked

3. Cybersecurity Maintenance for ComPAS2
    a. Install latest ComPAS2 software major version release
    b. If available, install ComPAS2 latest security patch updates
    c. Report to Morgan Scientific any virus/malware incidents related to ComPAS2

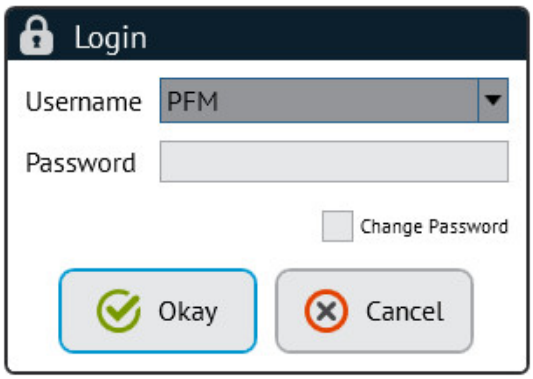
4. ComPAS2 Networking/Connection Dependencies
    a. Networked install where SQL database is hosted on a SQL server and ComPAS2 is installed on workstations pointed to the SQL database over the network.
        i. The default communication port for Microsoft SQL server is 1433, but this can be user configurable.
    b. ComPAS2.Server is a remote resource for the workstation that uses HTTPS over TCP/IP. Note this is a windows service that is hosted on the customer's internal network, such as on an application server.

5. ComPAS2 does not inherently detect cybersecurity events as it is out of scope for the software. Events like user profile lock out due to too many failed attempts is tracked in the audit trail, so Cybersecurity officers are advised to periodically view the audit trail log for such events.

2:0 ComPAS2 Login

2.1 Standard ComPAS2 Login

When ComPAS2 first launches, it will ask for a login access.



Enter **User Name** and **Password**.

All Users entered in the system can be accessed by clicking on the down-arrow.

To change the User currently logged into the system, click on the 

icon.

2.2 Using Active Directory and Single Sign-On

Please refer to Section:13 for full details of setting-up and use.

3.0 Patient Biographical

3.1 Race and Ethnicity-agnostic Approach to Reference Equations
Questioning the use of race and ethnicity in PFT interpretation has been the focus of clinicians and investigators for some time and has recently led to new recommendations to replace race and ethnicity-specific equations with race-neutral average reference equations. For full details of the statement, see the following:

Race and Ethnicity in Pulmonary Function Test Interpretation
An Official American Thoracic Society Statement

OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS APPROVED FEBRUARY 2023
THE ATS STATEMENT WAS ENDORSED BY THE EUROPEAN RESPIRATORY SOCIETY ON MARCH 1, 2023
Am J Respir Crit Care Med Vol 207, Iss 8, pp 978–995, Apr 15, 2023 www.atsjournals.org

These recommendations however, have not yet been fully accepted across all pulmonary centers and therefore ComPAS2 cannot yet be race-agnostic. In ComPAS2, ethnicity is an open editable field which can be used by choice or totally ignored and 'hidden'. In this way the application can accommodate both past and newly revised practices.

Currently, an option to use ethnic-specific equations needs to remain in ComPAS2 for specific clinical situations such as the determination of employment eligibility and research. Morgan Scientific is committed to closely following this evolution in PFT interpretation and making appropriate changes according to the evidence.

3.2 Adding a New Patient
Patient Data is divided into two entry screens; firstly, there is the initial or foundation data for any given patient that will rarely ever be changed (i.e. ID, Name, Date of Birth and Gender etc.). Secondly, there is the "Test Specific" information that can change from test date to test date (i.e. Height, Weight, Physician etc.).

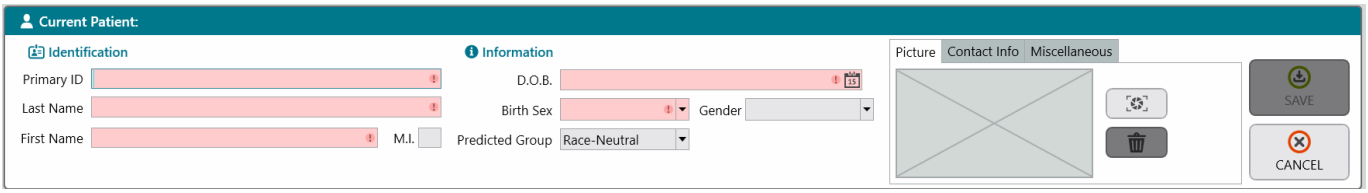
If desired, the user can enter the initial Patient Information for subjects scheduled to be tested and save them to the patient list. At the actual time of testing, the additional information can be entered needed for the calculation of predicted values.

From the ComPAS2 desktop, click on the Patients icon.

A single left-click will bring you to the Patient Entry screen.

The screen will appear blank. Clicking on 

will allow entry of new patient information.



In Configuration there is the ability to display and use "Predicted Group" and "Ethnicity" or to hide options from view.

Sites wanting to be completely race-agnostic, can remove these fields entirely.

Sites preferring to use GLI Global for spirometry and a mix of equations for other PFT parameters may want to continue selecting Predicted Group. The Configuration options are very flexible.

Upon entering the foundation entry screen, the first field "ID" is highlighted ready for keyed input. Customers with a patient demographic ADT interface can enter the patient ID number and all other fields will be automatically updated from the hospital information system.

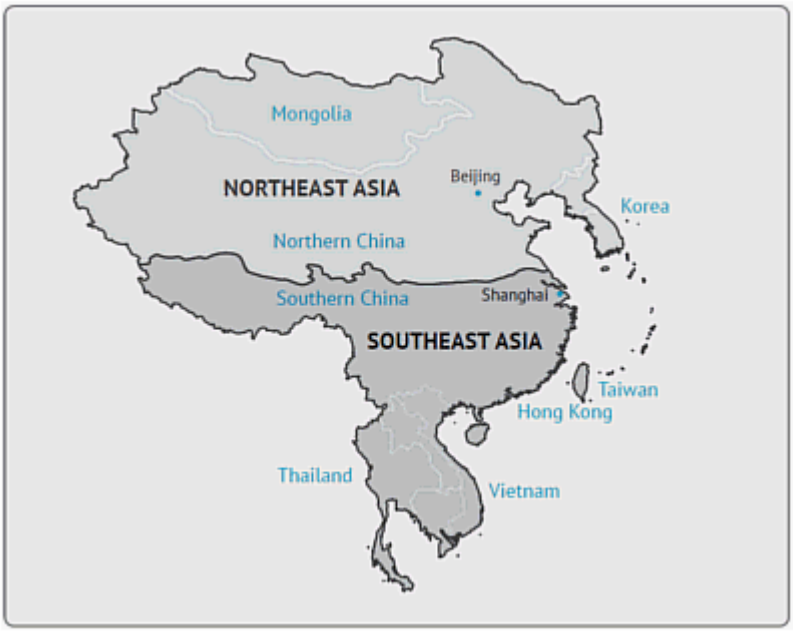
Most of the fields are self-explanatory data entry options. Those fields highlighted in red are mandatory entry fields. To move between fields, use either the [Tab] key or use the mouse.

The entry fields are as follows:

Field	Description	Action
Primary ID	**Subject's ID NUMBER - This number must be a number that is always associated with this patient. (i.e. a medical record number etc.)** **For customers linked to an information system, entering an ID can return the foundation patient information (i.e. Last Name, First Name, Middle Initial, Date of Birth and Birth Sex).**	Mandatory Field **Type ID Number. The entry can be alpha numeric.** **Type ID Number. The entry can be alpha numeric.**
Last Name	**Subject's LAST NAME**	Mandatory Field **Type Last Name**
First Name	**Subject's FIRST NAME**	Mandatory Field **Type First Name**
M.I	**Subject's MIDDLE INITIAL**	**Optional Field** **Type Initial**
D.O.B	**Subject's DATE OF BIRTH - Once entered, the patient's AGE will be calculated and displayed.**	Mandatory Field **Date format/preference is set by the Windows Regional Settings in Configuration** **For US Customers: Type the Month Day and Year**
Birth Sex	**Subject's Biological Sex [M]ale or [F]emale - this distinction identifies which will be used in predicted normal value calculations**	Mandatory Field **Type [M] or [F] or click on the down arrow.**

Gender	**Subject's personal identification of Gender (a range of identities that may not correspond to established ideas of male and female).**	Optional Field **Typing a Gender, or any portion of it will provide a pull-down list of options.** **If the gender is not on the pull-down list, use the icon to enter a new option.**
Predicted Group	**[C]Caucasian, [AA]African American, [NE]Northeast Asian, [SE]Southeast Asian, [O]Other, [MA]Mexican American and other choices.** **This distinction identifies which predicted group will be used in normal value calculations.** **Mousing over the Northeast or Southeast Asian choices will display a helpful map showing where the dividing line exists and which countries are covered by the GLI predicted normals.**	Optional Field **From the pull-down options select the predicted group.** *Predicted Group selection can be displayed or hidden in Configuration*
Ethnicity	**Subject's Ethnicity, refers to cultural factors, including nationality, regional culture, ancestry, and language.** **Many different ethnicities are covered by the GLI "Other" predicted group. Identifying a subject's actual ethnicity can be helpful if using the Research Query.**	Optional Field **Typing an ethnicity, or any portion of it will provide a pull-down list of choices.** **If the ethnicity is not on the pull-down list, use the icon to enter a new option.** *Ethnicity selection can be displayed or hidden in Configuration*

If still using Predicted Group options, mousing-over either Northeast Asian or Southeast Asian will bring a helpful map forward:

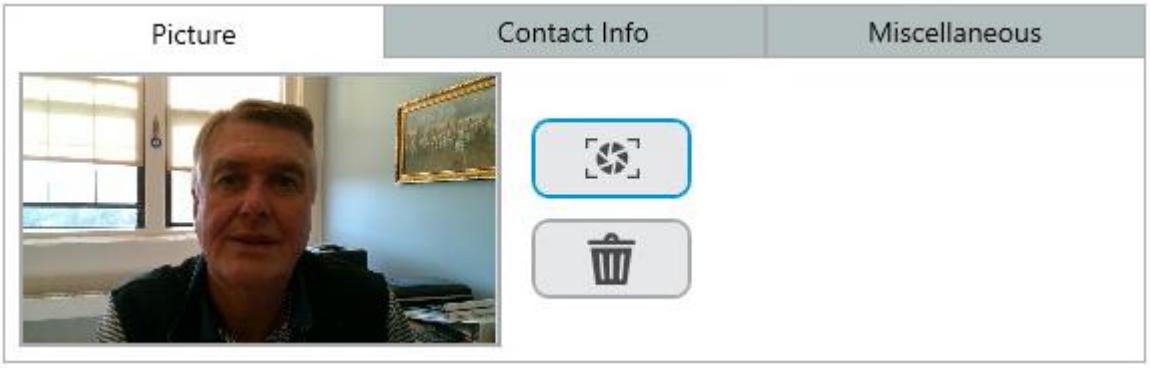


The foundation subject information section also allows for storage of a subject photo, subject contact information and miscellaneous information to track subjects with kyphosis/scoliosis and identifying lung transplant.

3.2.1 Photo Identification

A photo ID of the test subject can be taken and stored or printed with the subject biographical information.

To capture an image, click the  button.



3.2.2 Miscellaneous - Kyphosis/Scoliosis Identification

Subjects with conditions that effect standing height can present particular problems when considering normal values. The purpose of the Kyphosis/Scoliosis flag in ComPAS2 is to identify those patients who require height to be measured by arm span.

Having completed the mandatory fields and any others desired, either [Tab] through to the next section or click the

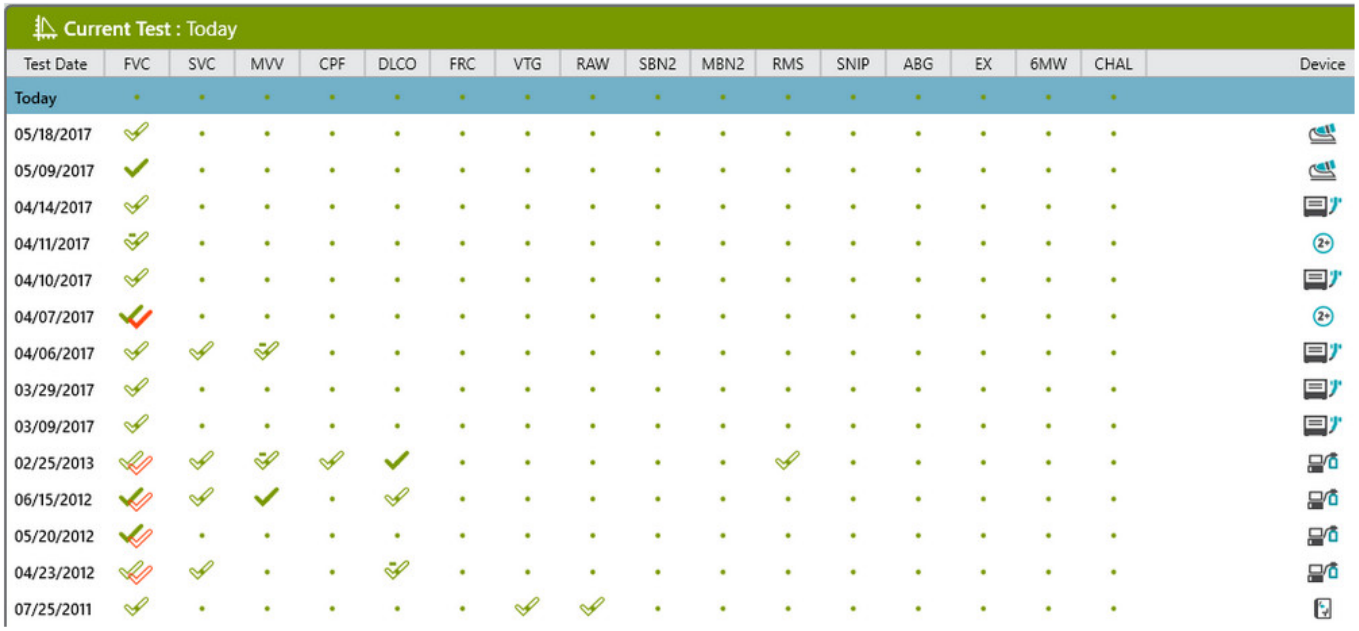
button.

3.3 Test Specific Data

Whether it is a new subject or someone returning for further testing, the "Test Specific" data entry sections deal with data that can change and are stored by test date with the pulmonary function test data.

Any of the dialogue boxes that have the  icon beside them indicate a list where information can be added. For example, if a new physician needs to be added to the list of physician names, a simple click of the  will make it possible.

For returning patients, the left-hand table displays tests that were completed on past visits.



The check marks indicate the quality of the test(s) on each date and the far column displays the device that tests were completed on. The green check marks denote completed "Pre-Bronchodilator" tests and the red check marks are "Post Bronchodilator" tests.

Mousing over the individual check marks will display the quality information of that test.

When two or more devices were used in any testing session, a 2+ icon will display; clicking on the 2+ icon will show the instruments used in testing.

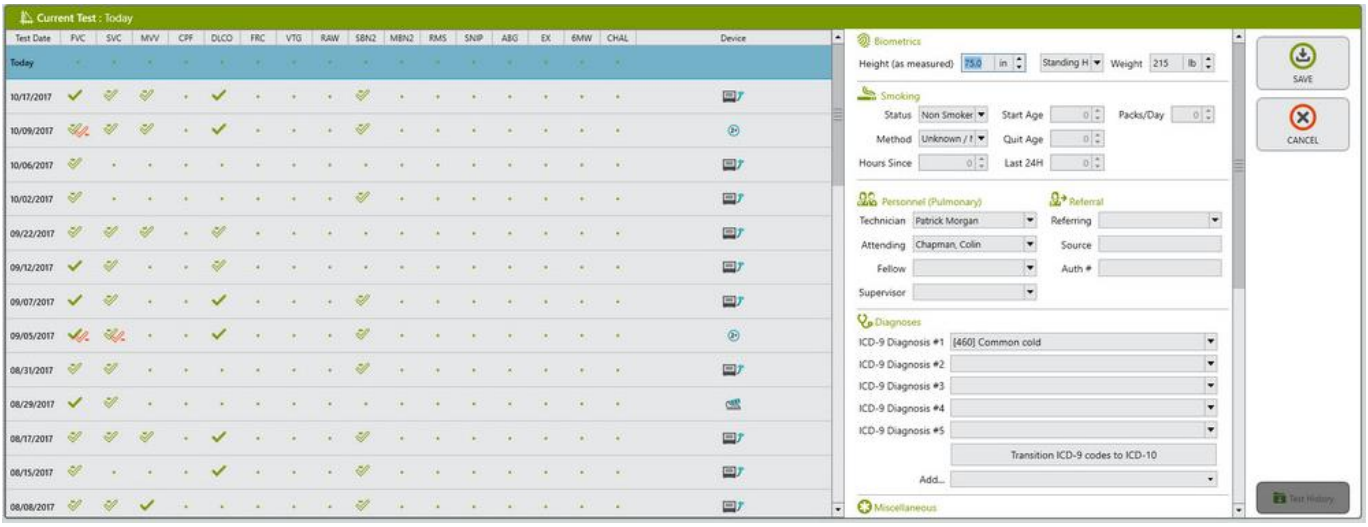
On the Test Specific entry screen, the first field "Height" is highlighted ready for keyed input.

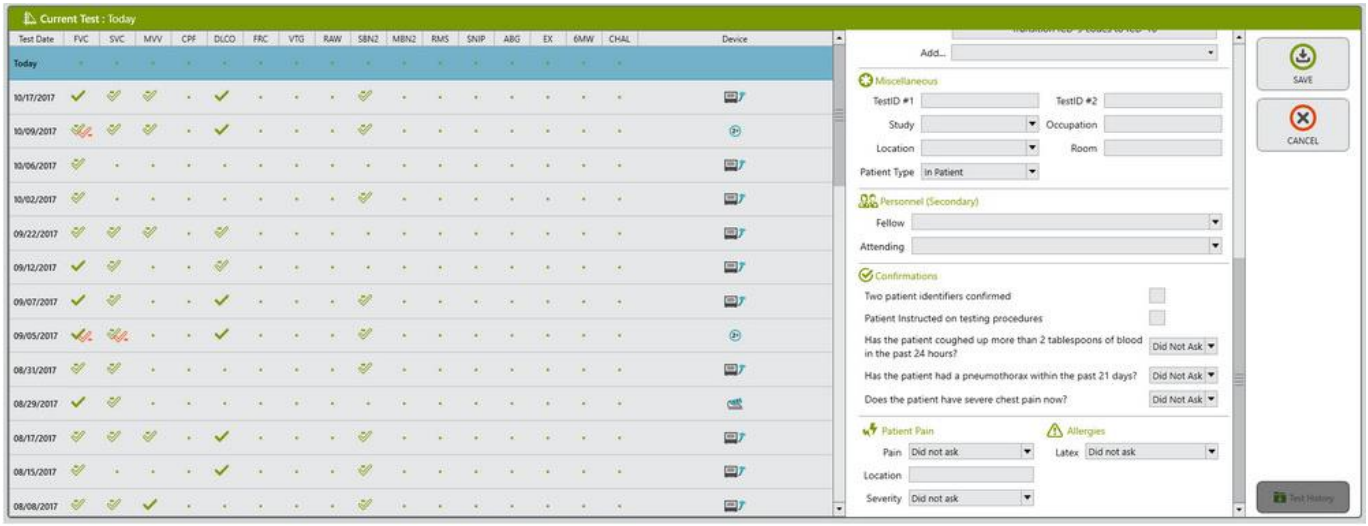
Most of the fields are self-explanatory data entry options. To move between fields, use either the [Tab] key or the mouse.

The side-bar slider can also be used to navigate down to data inputs off the screen.

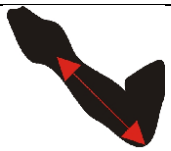
It is very important to understand that the personnel entry fields are dictated by the workflow configuration; if the selected workflow does not include an Attending2 for example, then the field will not be shown.

Slider bar moves display of fields up and down





The entry fields are as follows:

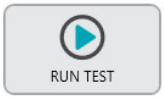
Field	Mandatory	Description	Action
Height	**Y**	**Patient's HEIGHT** **The default height setting is always "Standing Height", however for users wanting to estimate standing height by other means, a pull-down list of options is available.** **One of the height choices must be selected for calculation of predicted normal values.** ***Clicking on the units box will scroll the view through choices:(in, cm and M)*** ***Height as measured*:**  ***Setting for units comes from the "Regional" setting in Configuration.*** ***Equations used in estimating standing height from other options are contained in the "Alternative Height" script.***	**Type Height in inches, cm or M**
Height (Arm Span)	**N**	 **Patient's HEIGHT based on FULL ARM SPAN WIDTH**	**Type Height in inches or cm**
Height (Forearm	**N**	 **Patient's HEIGHT based on FOREARM LENGTH** **The calculated height based on Forearm Length is shown under the pull-down option.** **The ulna length is measured between the point of the elbow and the midpoint of the prominent bone of the wrist. The patient's height is then estimated using a standard formula.**	**Type Height in inches or cm**

Field	Mandatory	Description	Action
Height (Knee Height)	**N**	 **Patient's HEIGHT based on KNEE HEIGHT** **Knee height is correlated with stature and, until recently, was the preferred method for estimating height in bedridden patients. Knee height is measured using a sliding broad-blade caliper. The patient's height is then estimated using a standard formula.**	**Type Height in inches or cm**
Weight	**Y**	**Patient's WEIGHT** ***Clicking on the units box will toggle the view between choices:* (lbs or kg)** **Weight** 225 lb	**Type Weight in lbs or kgs**
Smoking	**N**	**Patient's SMOKING HISTORY** **The dialogue options for smoking history allow for calculation of Pack/Years based on dates of starting and ceasing smoking and entry of packs per day smoked.** **Method of smoking lets you identify the material used.** **The last two entries are optional. They relate to very recent smoking history:** **Hours Since Last Cigarette and Number of Cigarettes in the Last 24 Hours.**	**Type [N] for non-smoker** **or** **Type [X] for ex-smoker** **or** **Type [S] for smoker** **or** **Type [U] for unknown**
Workflow	**Y**	**The default or selected Workflow choice** ***The personnel entry fields in the patient entry screen are dictated by the workflow configuration. Only personnel fields configured in the selected workflow will be displayed.***	**If the default Workflow is selected, no action is required. If a different workflow is to be used, select from the pull-down options.**

Field	Mandatory	Description	Action
Pulmonary Fellow Attending 1	**N**	**The PULMONARY FELLOW and ATTENDING 1 PHYSICIANS** **The Technician field will automatically be populated with the current technician logged-into ComPAS2.** **Typing the Physician Name, or any portion of it will make the physician list active.** **If the physician you are searching for is not on the pull-down list, use the icon.**	**Select**
Pulmonary Fellow2 and Attending2	**N**	**The PULMONARY FELLOW2 and ATTENDING 2 PHYSICIANS** ***This optional entry location only gets displayed if the choice is selected in Configuration.***	**As Above**
Other personnel Attending 3 Attending 4 Reviewer etc.	**N**	**The ComPAS2 workflow designer allows for addition of further personnel if desired.** **As personnel are added to a workflow design, locations for their entry are expanded in the Patient Entry screen.**	**As Above**
Referring	**N**	**The REFERRING PHYSICIAN**	**As above**
Diagnoses	**N**	**ComPAS2 allows for entry of both ICD-9 and ICD-10 codes.** **The first location for DIAGNOSIS - both code and description.** **The codes used in ComPAS2 conform to the ICD9 and ICD10 lists and they can be amended/updated as desired.**	**The extensive list of ICD-10 codes that match any part of your description will be listed.** **Select the appropriate code and click [Confirm]** **Sometimes with ICD-10 you may need to add a second or third code to fully cover the diagnosis. As each choice is made and confirmed, the code is saved**

Field	Mandatory	Description	Action
Special Diagnoses feature for converted test data:	**N**	**This is a special feature of great use to customers who have converted legacy data from another manufacturer's database.** **Converted data rarely, if ever, contains usable diagnosis information. This utility allows labs to "back-fill" diagnosis information into past test dates.** **Whenever a diagnosis is being entered (ICD-9 or 10) ComPAS2 looks to see if past records exist for that patient and asks if the same diagnosis should be attached to each record.** **Some predicted sets are based on diagnosis (for example those sites using CF Foundation normal values), so a choice is given to re-calculate predicted data at the same time.**	
Test ID	**N**	**This is a location where a special ID (Alpha/Numeric) can be entered that is different to the patient ID.**	**Type the Test ID #1 and Test ID #2 if required.**
Occupation	**N**	**Patient's OCCUPATION**	**Type the Occupation**
Room	**N**	**Patient ROOM**	**Type the Room**
Study	**N**	**A field where a STUDY name or ID can be associated with individual patient tests.**	**Typing the Study name, or any portion of it will make the study list active.** **If the study name you are searching for is not on the pull-down list, use the [+] icon to enter new study details.**
Location	**N**	**The LOCATION field provides a pull-down list of specific hospital locations that can be selected.**	**Typing the Location, or any portion of it will make the list active.** **If the location you are searching for is not on the pull-down list, use the [+] icon to enter new location details.**

Field	Mandatory	Description	Action
Patient Type	**N**	**In Patient or Outpatient**	**Pulldown choice**
Pain	**N**	**The PAIN screen can be a mandatory field if set in configuration.**	**If pain is present, type the location and choose a severity from the pull-down list (1-10).**
Latex Allergy	**N**	**The LATEX ALLERGY screen can be a mandatory field if set in configuration.**	**Use the pull-down list to answer.**
Test Confirmations	**N**	**The CONFIRMATIONS screen can be a mandatory field if set in configuration.**	**Check the boxes to confirm that two patient identifiers have been confirmed and that the patient will be instructed on all testing procedures.**

Having completed entry of subject data, click the 

button to enter the testing screens.

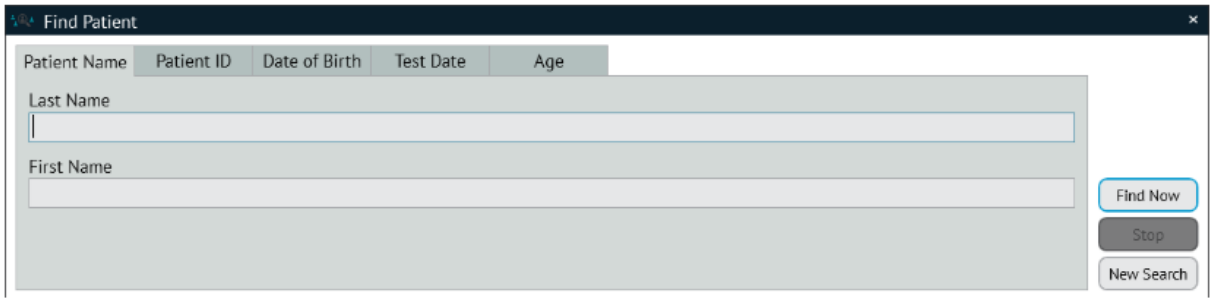
3.4 Searching for Patients

Using either of the 

buttons, test subjects can be found and retrieved from the database.

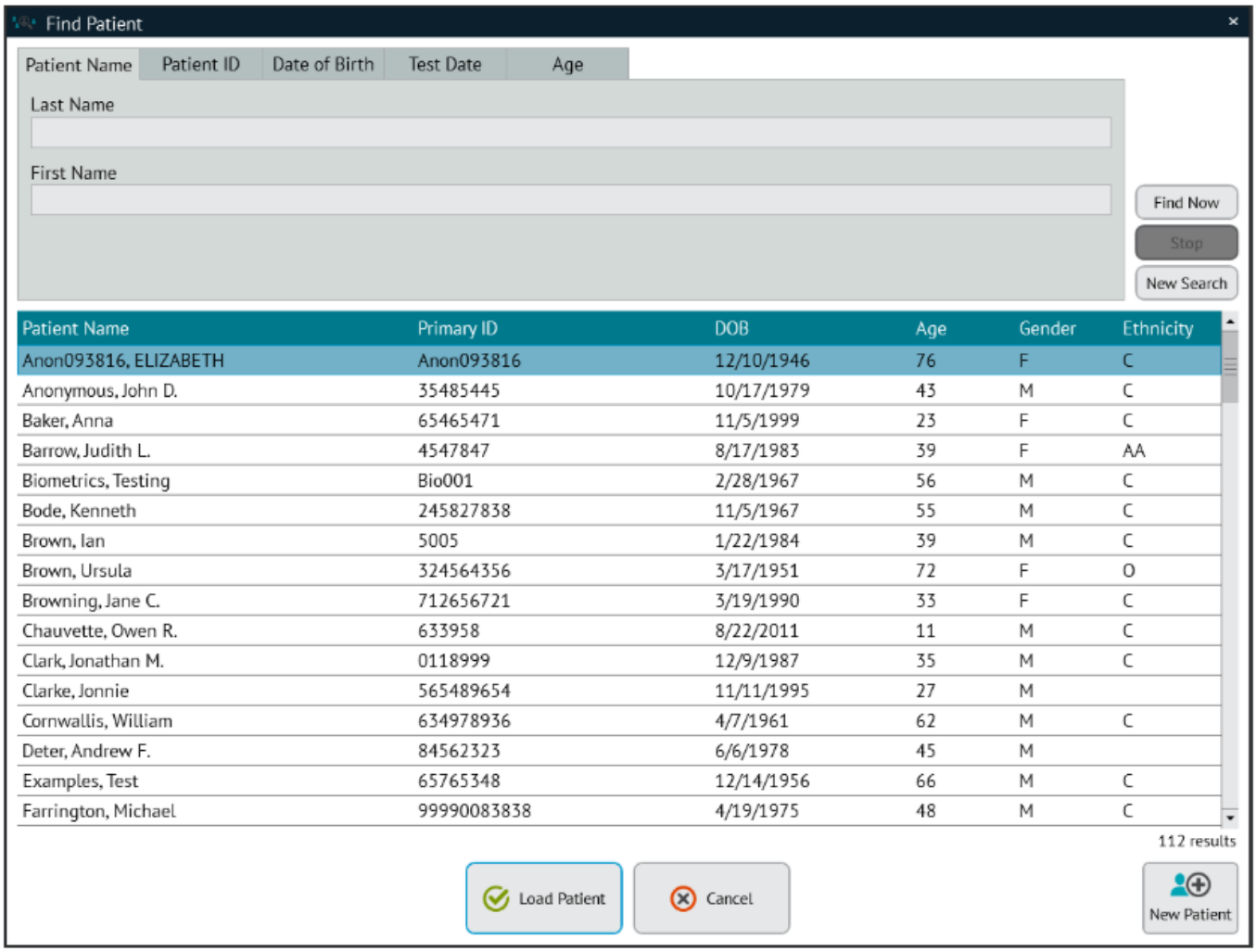
Subjects stored in ComPAS2 can be quickly found using a number of different search methods:

Last Name
First Name
Patient ID
Date of Birth
Test Date



Searching in all categories operates the same way. The more characters or numbers entered into the search field, the greater the focus of search.

Clicking Find Now with no entry will list all subjects in the database in alphabetical order.



To select the subject desired, simply highlight them on the list and click Load Patient.

If the test subject is not found, the button will direct the user to new subject input.

Searching by test date can be useful if trying to locate a test subject whose name has been forgotten.

The date can be specific, (i.e. only enter the one date to search) or it can be a date range.

When the desired date(s) have been entered in the search field, click Find Now to reveal the search results:

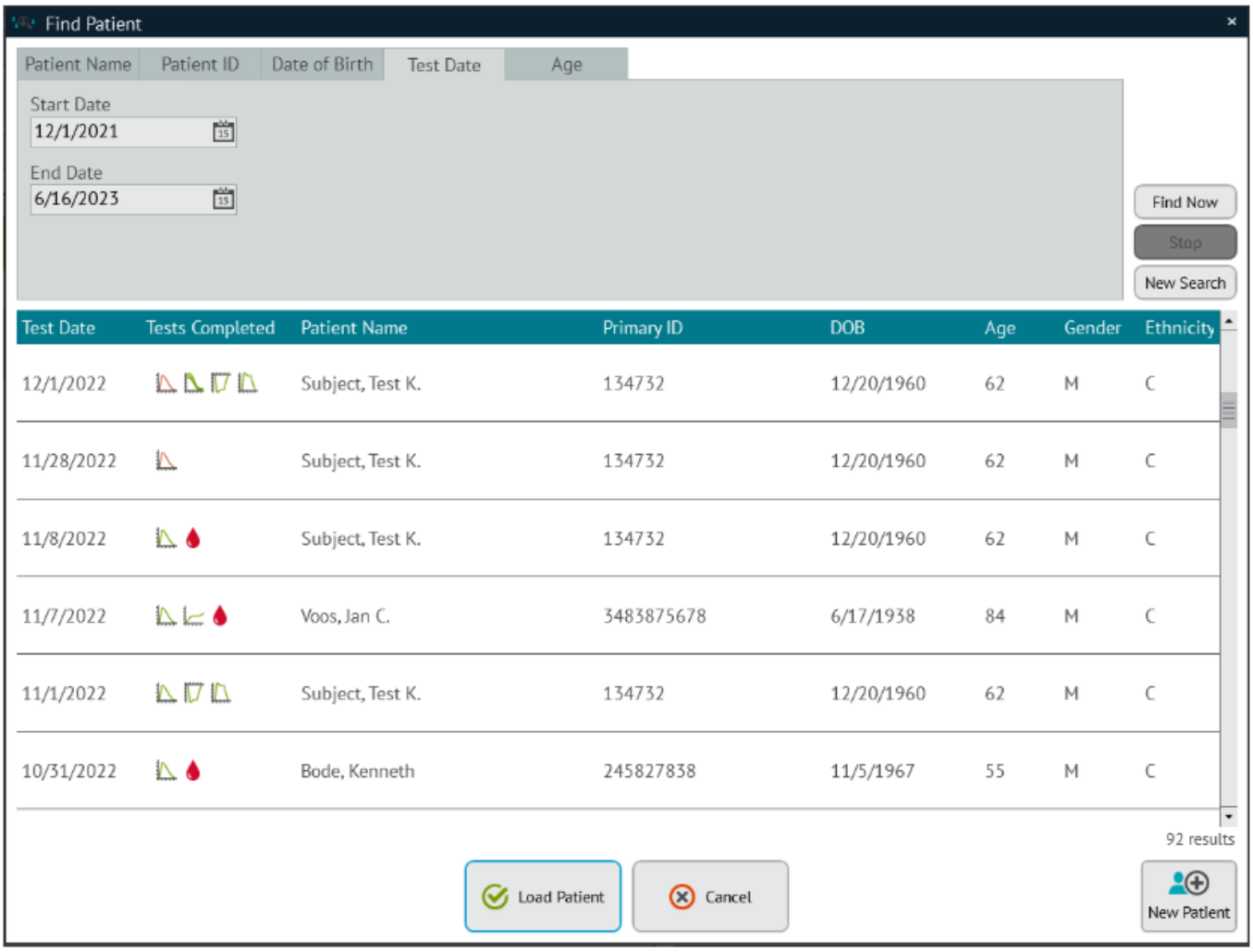
A helpful column in the date range search is "Test Completed"; symbols show which test types were completed on that day. Mousing-over the symbol will display the test type.

For the Flow Volume icon, the color immediately indicates what type of spirometry was completed on that date:


Green loop = Pre Test


Red loop = Pre & Post or just Post


Purple loop = A test protocol was run (challenge or supine etc.)



3.5 Searching for Patients Using Orders

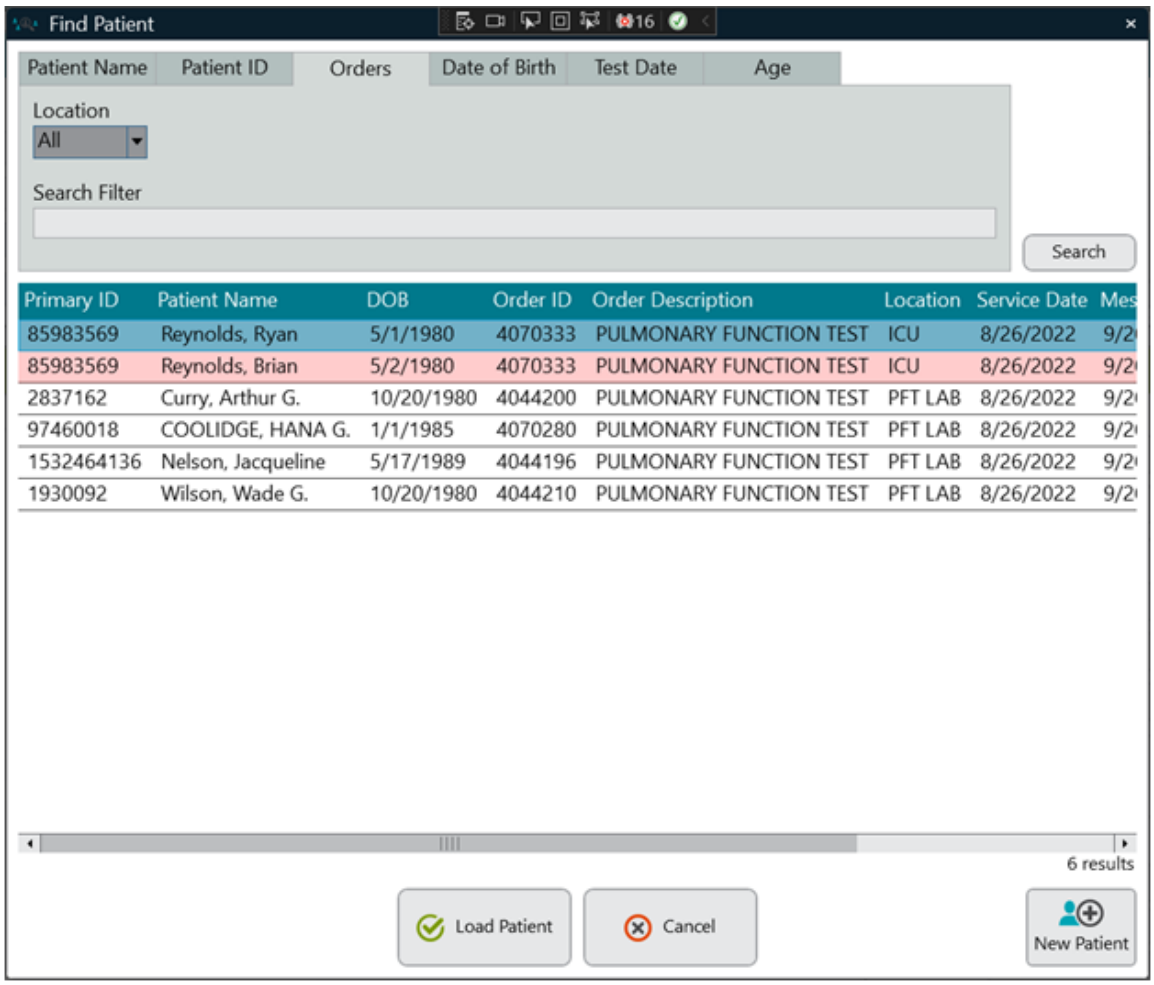
If the ComPAS2 environment has an HL7 Interface configured to receive orders from an Electronic Medical Record (EMR) system, patients should be identified by selecting the HL7 order from the Orders tab on the Patient Find screen.

To load a patient from their HL7 order, complete the following steps:

Open the Patient Find screen by clicking the 

button.

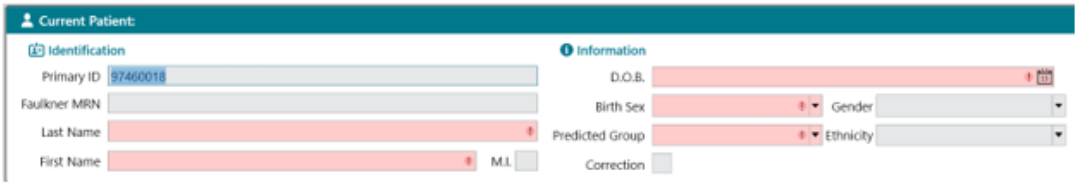
Click on the [Orders] tab. By default, the list of available HL7 orders will be shown for ALL locations. You can use the Location drop-down to filter by the locations created in Configuration. You can also use the Search Filter box to filter by Patient ID, Patient Name and Feed Name.

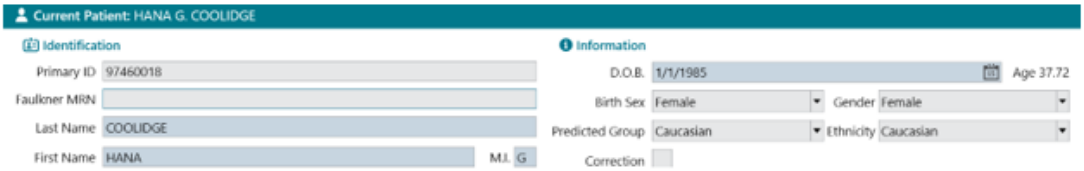


Select the patient you wish to load and either double-click on the row or highlight the row and click the 

button.

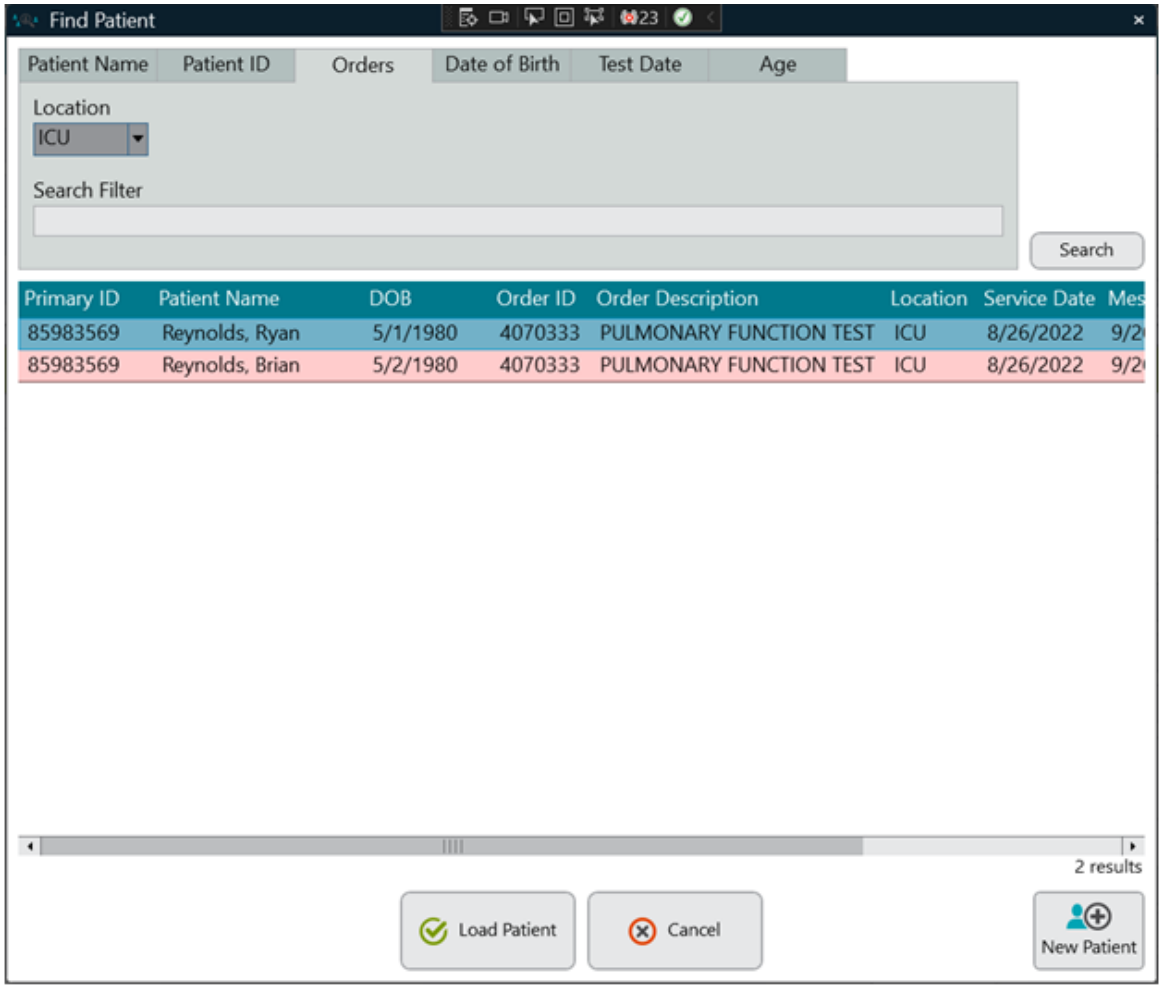
NOTE: If the selected order is a new patient, the Primary ID will be populated for you in the Patient screen. Press the TAB key or click into another field and the patient's information will be automatically loaded from the HL7 order.





3.5.1 Duplicate Patients in an Order

Two or more rows in the orders list, highlighted in red, indicates that one HL7 order contains a patient Primary ID that matches two or more patients already stored in ComPAS2. In this instance, select and load the correct patient.



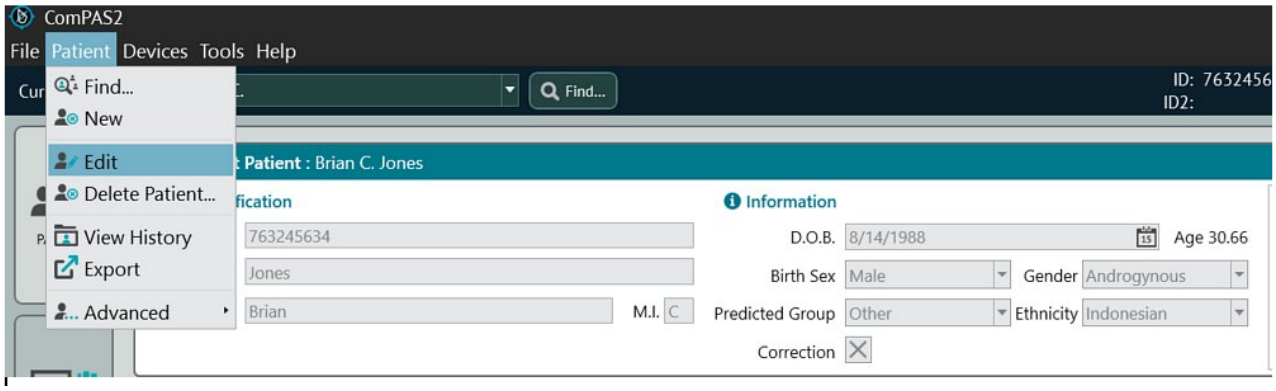
3.6 Correcting Foundation Patient Data

This option allows users to correct any errors made after a test subject has been saved.

These data include:

Primary ID
Secondary ID
Last name
First Name
DOB
Birth Sex
Gender
Predicted Group
Ethnicity

To edit any of the foundation subject information, click "**Patient**" and "**Edit**" as shown:



3.7 Correcting Patient Biographical Information Stored with Each Test Date

This help covers those situations where it is discovered that data entered prior to testing was invalid.

These data include:

Height
Weight
Physician
Diagnosis
etc.

Typically, the error is identified after completing testing and then printing a report; usually it is noticed that the predicted values were incorrect!

Making a change to any of the subject daily test information is easy, first load the test subject needing attention then click on the 

button to access all information stored for that day.

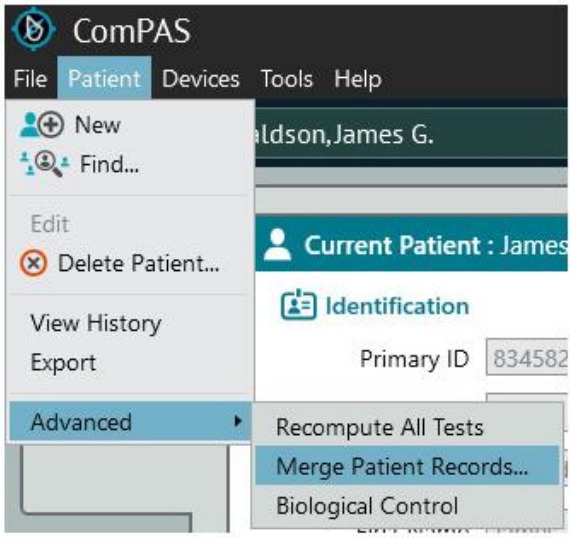
Once changes are made, click the 

button to save changes.

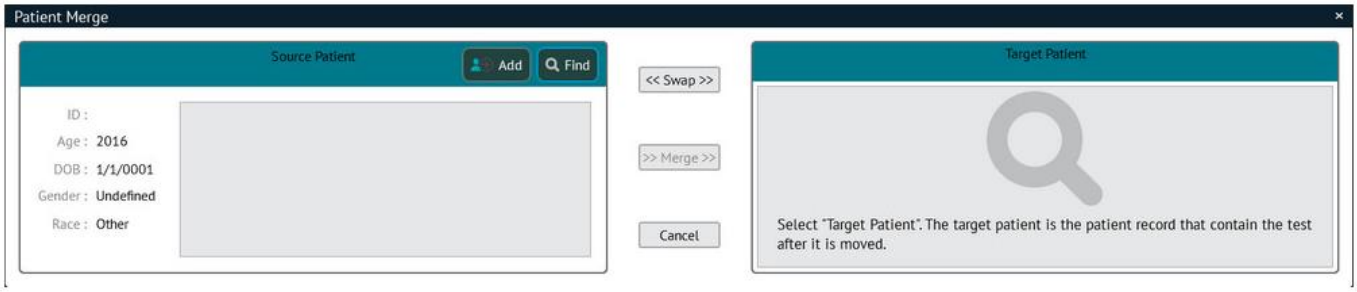
3.8 Merging Patient Data
This option allows users to combine patient data under a single name and ID. This can be particularly useful following the conversion of patient data from an older system provided by a different vendor. Often the older data sets did not enforce patient ID or prompt for duplicate entries.

If the same patient has been entered and tested under perhaps the wrong ID number, or perhaps their last name was inadvertently spelt wrong, then the MERGE utility will enable users to bring these records together. Once the records are merged, the serial test data can be displayed and viewed appropriately.

To open the merge dialogue, click on "**Patient**" then "**Advanced**" then "**Merge Patient Records**":



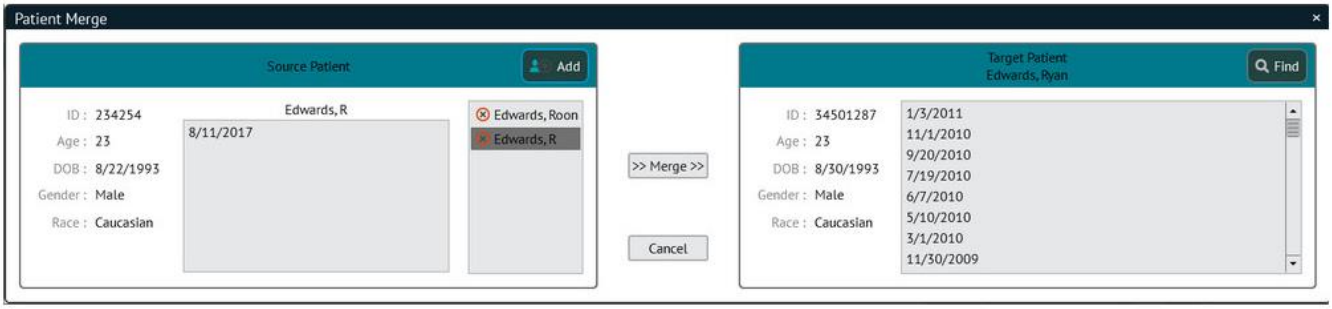
The merge utility allows for the merging of two or multiple patient records.
The opening screen will load with the patient details currently active.



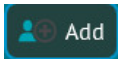
The first and most important step is to identify the "target" patient.

Click on the search icon  in the target area to find the desired patient.

If the source and target records need to be swapped, use the << Swap >> button.



If the merge only has to look after two records, click on >> Merge >> to complete the action.

If there are more additional records that need to be merged with the target patient, click on 

to include them in the source data. Multiple records can be merged in this way if required.

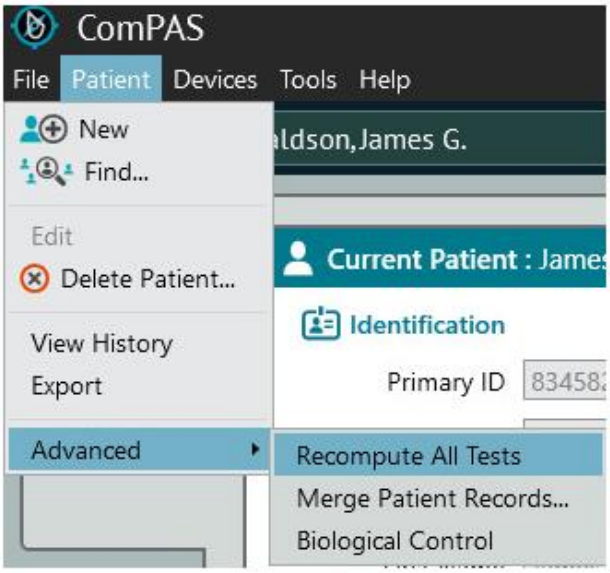
Click 

when ready to combine the records.

3.9 Recompute Past Test Results
This option allows users to correct current and past test data if an error was made in the original patient biographical information.

For example, if the subject's age, height, weight, sex or race were incorrectly entered, the predicted values calculated for the tests completed will be erroneous. Once the biographical information has been corrected, the "Recompute All Test" utility will go through all tests and test dates correcting any information needing attention.

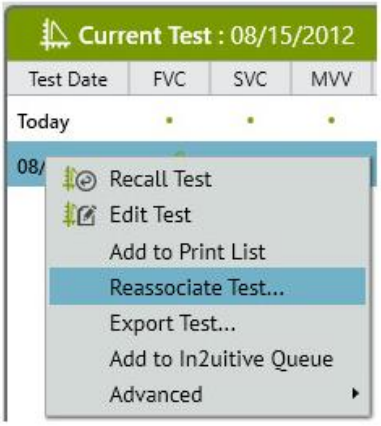
To open the recompute dialogue, click on "**Patient**" then "**Advanced**" then "**Recompute All Tests**":



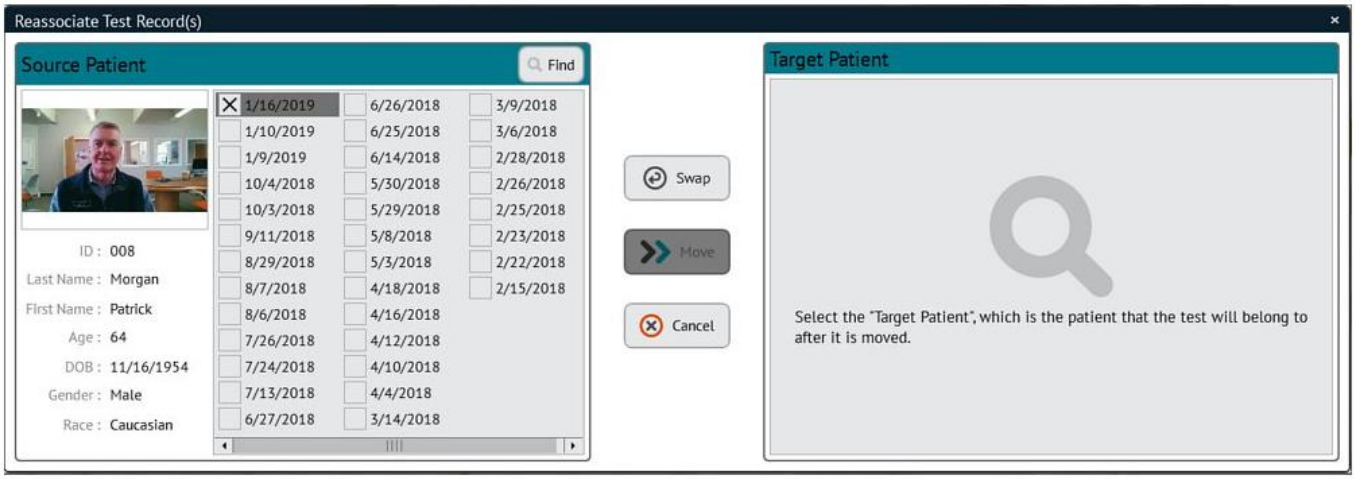
3.10 Reassociate Patient Data
This option allows you to correct the problem of having tested a subject under the wrong name and ID number.

To place all the test data under the correct subject information, right-click on the date of the patient record where the data has been stored.

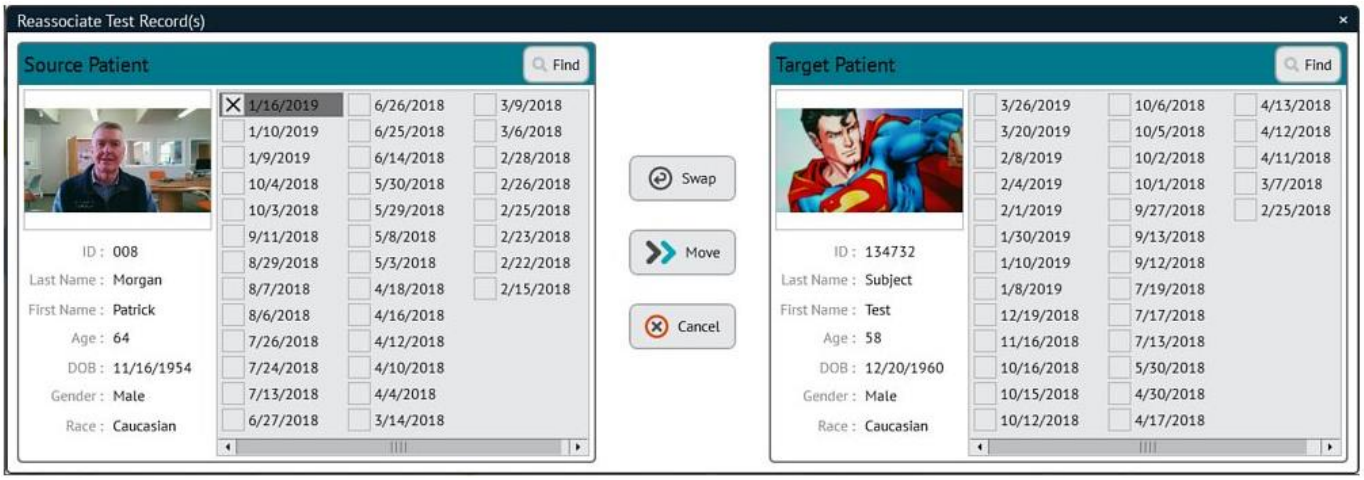
Highlight "**Reassociate Test**" and left-click.

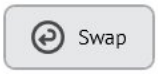


The screen will show all the test records for the current "**Source Patient**". Place a check mark in the date needing to be associated with the "**Target Patient**".



Click on the search icon  in the target area to find the desired patient.



If the source and target records need to be swapped, use the 

button.

Having identified the correct **Target Patient**, two options are available for data transfer:

1. Simply click the 

button to transfer the data between patient records. This will transfer the test date and associated data to the records for the **Target Patient**.

2. Select a particular test date in the **Target Patient** records and click the 

button. This action will to append data from the **Source Patient** into the particular date selected in the **Target Patient** records.

Whenever data is to be exchanged, a warning message is displayed to make the user double-confirm the action.

3.11 Deleting a Patient
This option allows you to permanently delete patient records from the database.

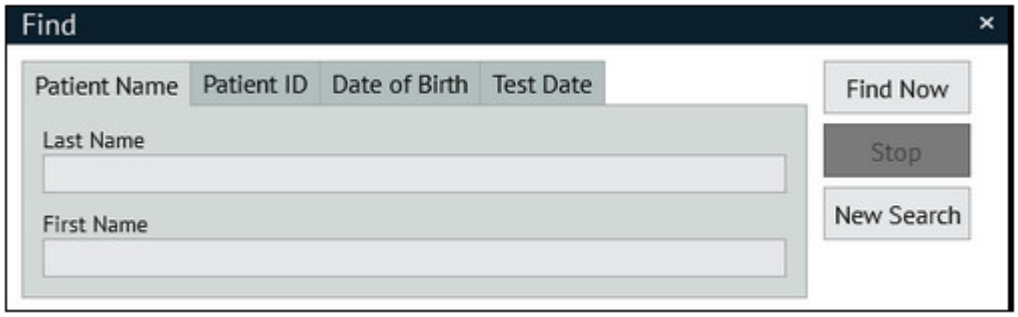
3.11.1 Locate the Patient Record to Delete

Using either of the 

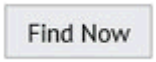
buttons, test subjects can be found and retrieved from the database.

Subjects stored in ComPAS2 can be quickly found using a number of different search methods:

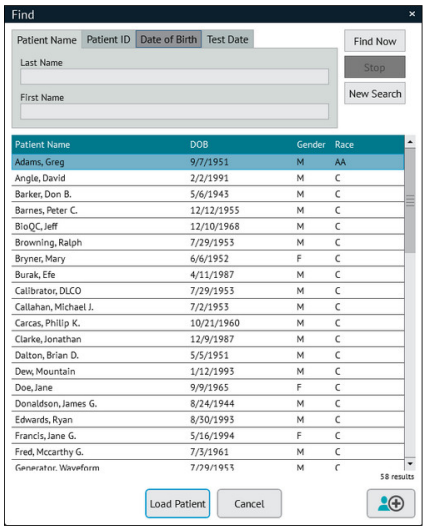
Last Name
First Name
Patient ID
Date of Birth
Test Date

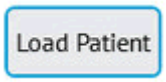


Searching in all categories operates the same way. The more characters or numbers entered into the search field, the greater the focus of search.

Clicking 

with no entry will list all subjects in the database in alphabetical order.

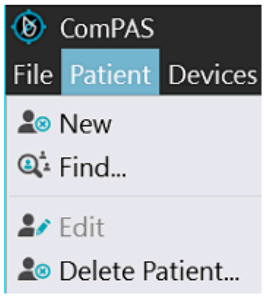


To select the subject desired, simply highlight them on the list and click 

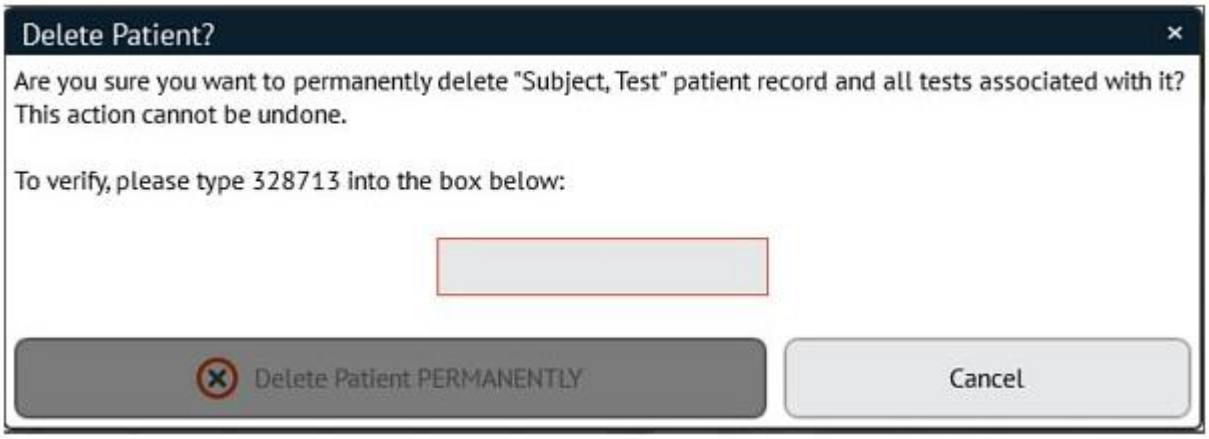
3.11 2 Deleting the Patient from the Database

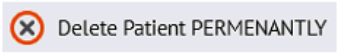
Having identified and loaded the patient for deletion, the details will be displayed in the usual patient screen.

Select "Patient" and "Delete Patient" from the top tool bar.



A double confirmation will be requested; typing the unique alpha characters displayed is required.



Click the 

button.

As a second confirmation check the program will prompt for an 

before the patient is permanently removed from the database.

4:0 General ComPAS2 Navigation

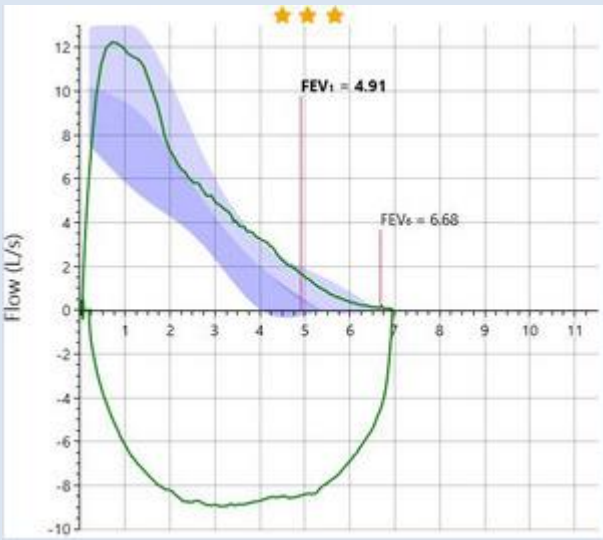
4.1 Testing Navigation
Once the "Run a Test" button has been selected, the first screen to appear will be an empty "Mini Results" set to perform Flow Volume Loop tests.

The type of test to be run is activated by clicking on any of the side tabs.

Side Tab	Test
FVC	Flow Volume Loop Testing
SVC	Slow Vital Capacity Testing
MVV	Maximum Voluntary Ventilation Testing
CPF	Cough Peak Flow Testing
MIP	Maximum Inspiratory Pressure (MIP) Testing
MEP	Maximum Expiratory Pressure (MEP) Testing
SNIP	Sniff Nasal Inspiratory Pressure Testing
FRC	Helium Dilution (FRC) Testing
DLCO	Traditional Single Breath Diffusion Testing
DLCO FG	Fast Gas Single Breath Diffusion Testing
VTG	Volume of Thoracic Gas (Plethysmography) Testing
RAW	Airways Resistance Testing
MBN2	Multi-breath Nitrogen Washout with LCI Testing
SBN2	Single-breath Nitrogen Washout Testing

The testing screen layout has icons, buttons and tabs which provide a variety of immediate display information:

Icon	Function
	The Tools Icon loads the tools associated with the test you are currently running (i.e. If you want to change the axis scale for Flow Volume).
	The Recycle Bin houses any data and graphics that have been deleted. Data can be restored at any time.
	The Notes Icon allows users to enter notes and view the computer interpretation during testing.
	The History Icon will bring up a display of past testing data for the current patient.
	The Environmental Icon displays the current conditions of testing and the resultant conversion factors being used.
	The Arterial Blood Gas Icon brings up a manual entry screen for blood gases, oximetry and MIP/MEP's. The entry screen provides spaces for resting data and 10 additional levels of entry.
	The Syringe Icon in spirometry mode allows 3-Liter calibration syringe efforts within the testing screens. When the syringe icon is selected, the BTPS conditions are set to 1.0 and spirometry tests can be simulated to validate the QC. When on the DLCO test, the syringe icon will launch the utility for quality testing that provides a choice to the user of either a 3L Syringe or the Hans Rudolph DLCO Simulator.
	The Zero Flow Icon allows the user to check the flow zero coming from the device attached.
	The Incentive Icon allows access to a menu of available spirometry and MBN2 incentive graphics/videos. Left clicking on the icon will turn-on the default incentive graphic/video. Right-clicking on the icon will provide a menu of different incentive/video selections.

Icon	Function
	The Bronchodilator Icon launches a manual entry input screen where bronchodilator information and administration details can be recorded.
 *Flashing*	The **Patient Memo Icon** provides access to a special notes area where information to assist colleagues in the testing of this test subject can be saved. If notes have been entered in this area, the icon will flash for ten seconds when entering the testing screens to draw attention to the fact that useful information is available.
	Clicking on Start Pre Effort will begin the test type selected. The Up Arrow allows the user to select a different mode of testing (Pre, Post, Upright, Supine, Hypertonic Saline or Challenge). The P key toggles quickly between Pre and Post modes.
	Clicking on Start Post Effort will begin the test type selected. The Up Arrow allows the user to select a different mode of testing (Pre, Post, Upright, Supine, Hypertonic Saline or Challenge). The P key toggles quickly between Pre and Post modes.
	The Spreadsheet button toggles to the full data spreadsheet view
	The Mini Results button toggles to the default testing mini result view
	At the top of each test graphic are "Confidence Stars". If an individual test effort is seen as flawed in any way, the confidence message screen will automatically be presented. This screen details the reasons why a test was questionable and offers possible solutions. 3 x white stars indicates that the individual test effort results are questionable 1 x gold star indicates that the individual test effort results are only fair 2 x gold stars indicates that individual test effort results are good 3 x gold stars can only be achieved if the test results for this effort are good and that repeatability has been met

	The Replay Tool at the bottom of selected graphics, allows the test to replayed as a teaching function. Clicking the "Play" icon will replay at normal speed, clicking and moving the slider icon allows manual play forwards and backwards.

4.2 Test History Graphic Display and Tools

4.2.1 Introduction

The "Historical View" is often incorporated with the report data, however, it can be immediately viewed separately in three places within ComPAS2:

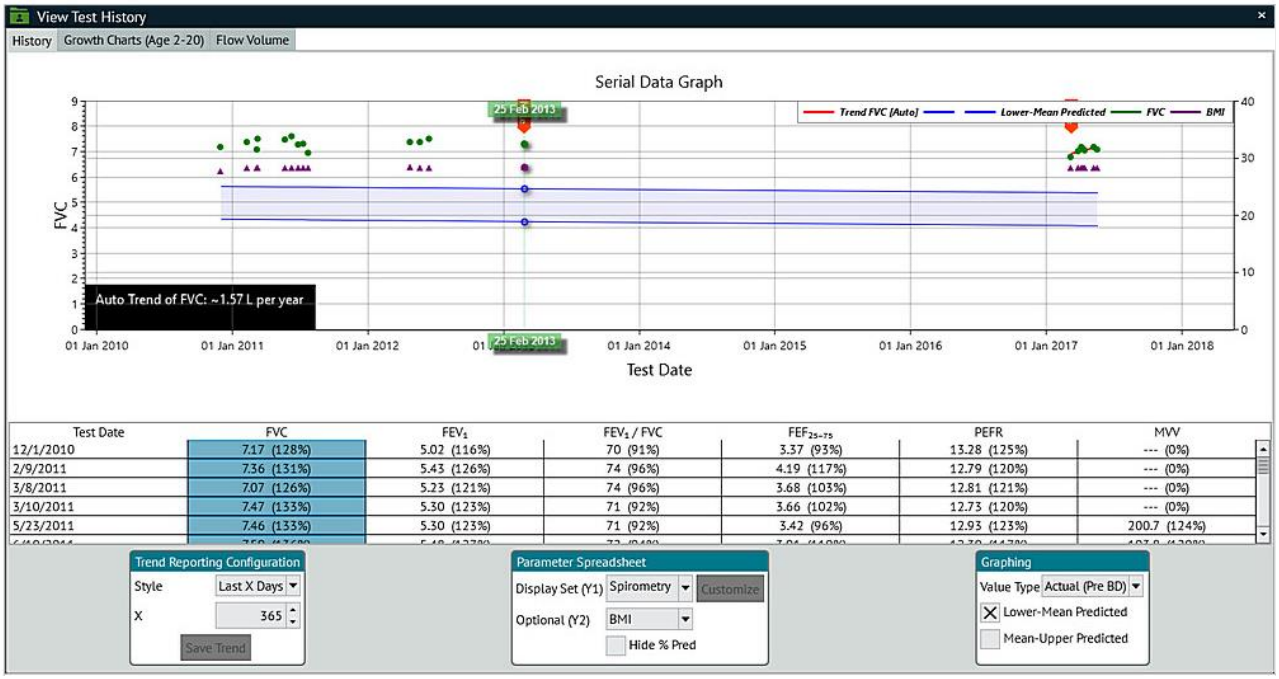
1. On the Patient Biographical screen
2. During patient testing
3. On the Task Manager screens (both on the tabular patient listing screen and while viewing the report screen)

The "History" presentation provides useful tools for scrutiny of testing trends:

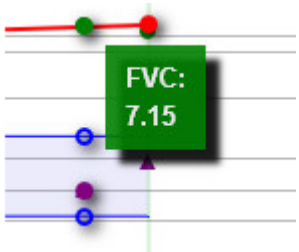
- Instant plots of actual data with options for predicted information (Mean, Lower and Upper)
- Instant plots of percent predicted data
- Ability to present a Y2 axis showing height, weight, BMI or FeNO
- Ability to zoom-in on any time period
- Ability to view the CDC growth charts for children (height, weight and BMI)
- Ability to add and edit text on the graph
- Ability to plot trends between any two points and display and save trend data
- Ability to have trending automatically calculated based on options of:
    - plotting between two user-defined dates
    - plotting from the most recent test back to a user-defined 'anchor' date
    - plotting from the most recent test back a set number of days (user selectable)

The order of data presentation and preferences for the "History" presentation are saved by each individual user so that each time the history functions are presented the user's personal choices will be used.

Any changes to display preferences the user makes using the history screen are recalled when next viewing test history.



Navigation around the history screen is very quick and simple. To view any particular data set, for example FEV1, click on the corresponding column. The graphs are drawn instantaneously using the preferences of plots chosen by the user. To see any data value on the graphic, simply mouse-over the point of interest and the value data plus date will display:



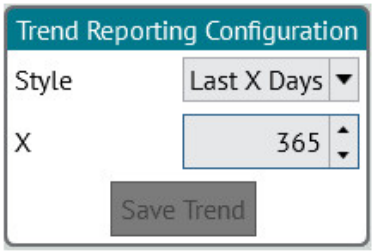
4.2.2 Setting Personal Display Preferences

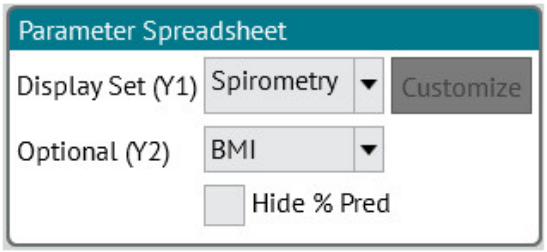
To select individual data, simply click on the column desired; the graph is instantly updated and changed.

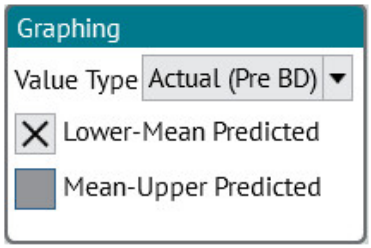
The serial data presentation can instantly show past data and trends. The presentation of what to display can be set-up by each individual user and those preferences will be used as a default graphic when looking at subsequent patients.

Data can be presented from a choice of: "Actual Pre-Bronchodilator", "Actual Post-Bronchodilator" or "Percent Predicted" by selecting from the pull-down choices.

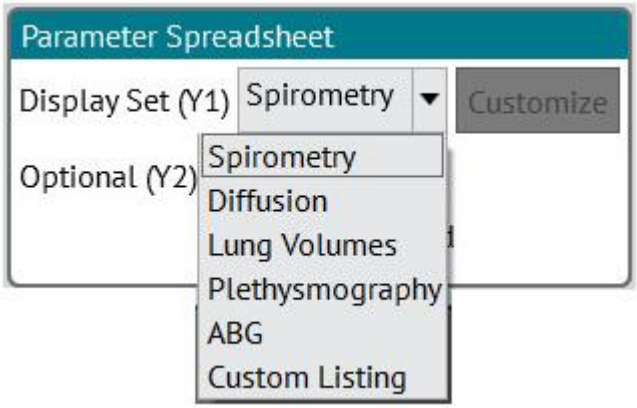
Controls are given at the bottom of the screen which allow the user to design the preferred view.



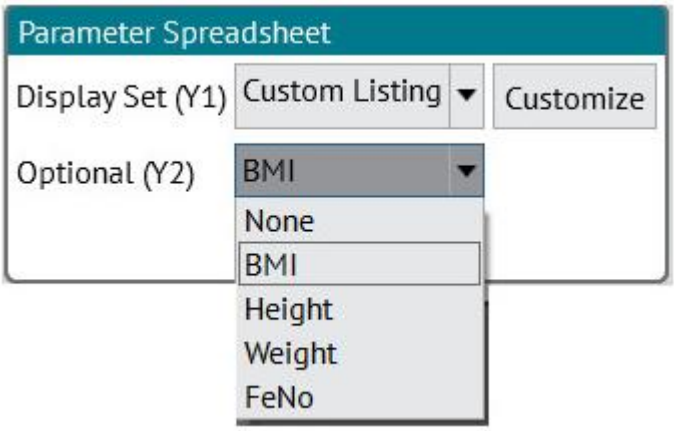




The Display Sets (Y1) control shows most common parameters from tests of Spirometry, Diffusion, Lung Volumes, Plethysmography, Blood Gases or Custom.



A Y2 axis can also be displayed offering patient's height, weight, BMI or FeNO.

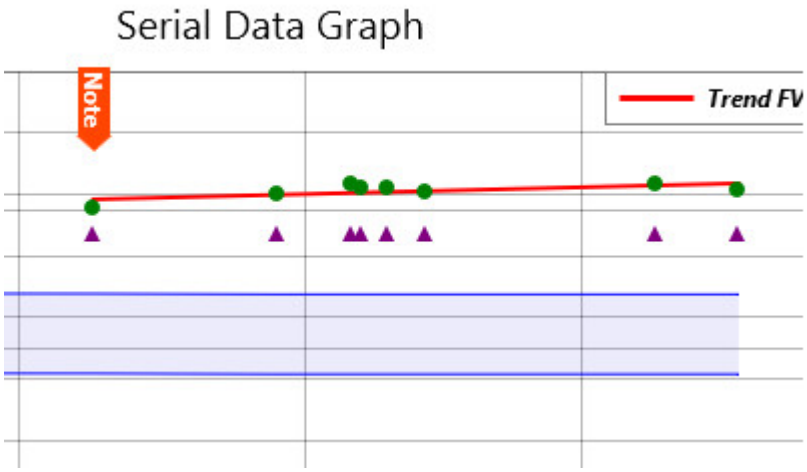


The "Custom" category allows each user to create a personalized list of parameters from any parameter stored in the database. To create a custom list, click the [Customize] button and then simply check those parameters desired.

To order the parameters from left to right on the spreadsheet, highlight the item and use the [Up] and [Down] buttons to shift their position. The top position = far left on the spreadsheet display.

4.2.3 Zooming-in on test data

To select a particular date period for display and consideration, simply left-click and drag the mouse over the desired period (a grey area box will indicate the period being selected). When the mouse is released the new date range will be displayed.



To return to the full data display, double-click anywhere on the graph.

4.2.4 Adding Notes to Test Dates/Data on the graph

To add a note corresponding to a test date on the graphic, left-click on a data point.

An "Information Box" appears to allow entry of text and to view the Physician interpretations, Technician Notes and Computer Impression. The graphic is re-drawn with a red note tag marking the text date. There is no limit to the number of notes.

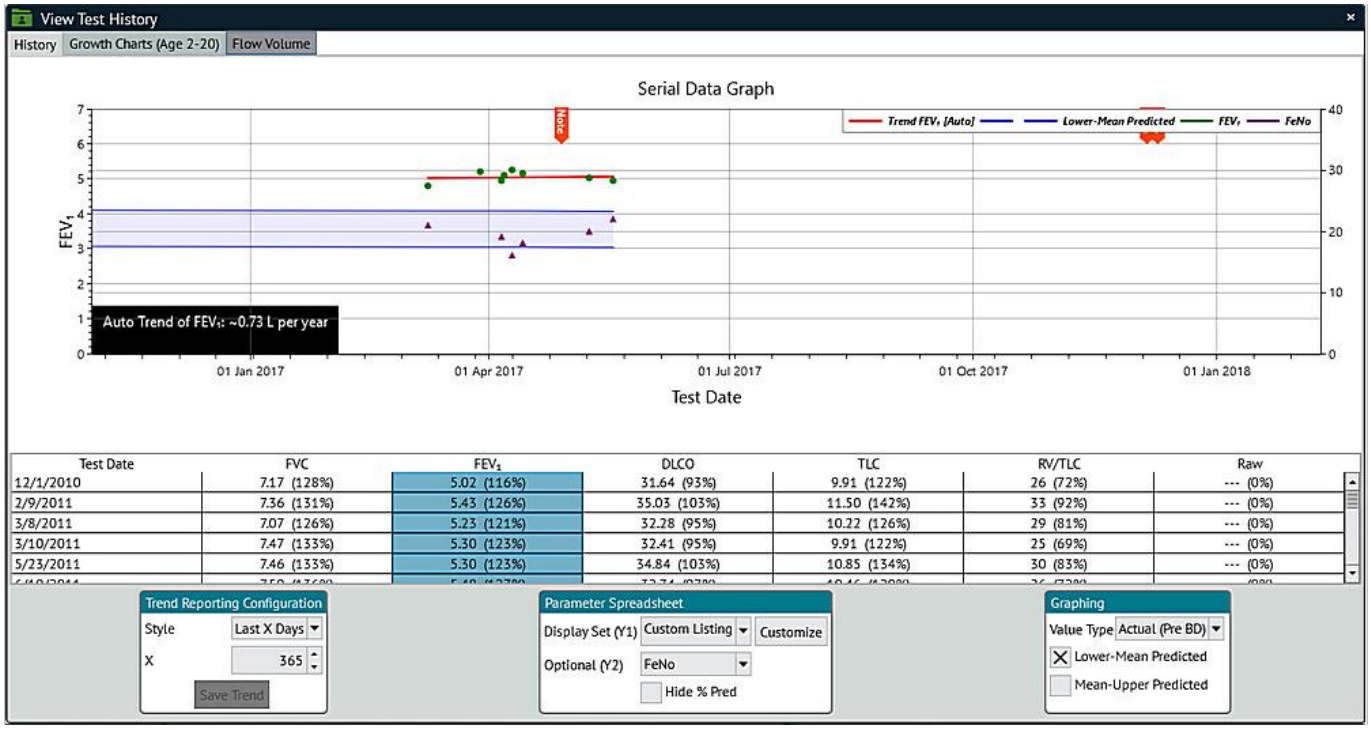
To remove a note all together, click on note and remove any text in the History Notes section.

4.2.5 Viewing Past Notes

Clicking on any test data point or red note tag will display a dialogue to view any historical notes, physician interpretations, technician notes and computer impression from that date. This function is primarily used within the ComPAS2 Task Manager and is a useful utility for physicians considering new interpretations. Any text within the viewer can be copied to the clipboard for pasting elsewhere.

4.2.6 Plotting FeNO against any spirometry value

The optional Y2 axis can toggle between Height, Weight, BMI and FeNO. This is particularly useful in assessing asthma.
The default Y2 axis can be selected from either Height, Weight or BMI.

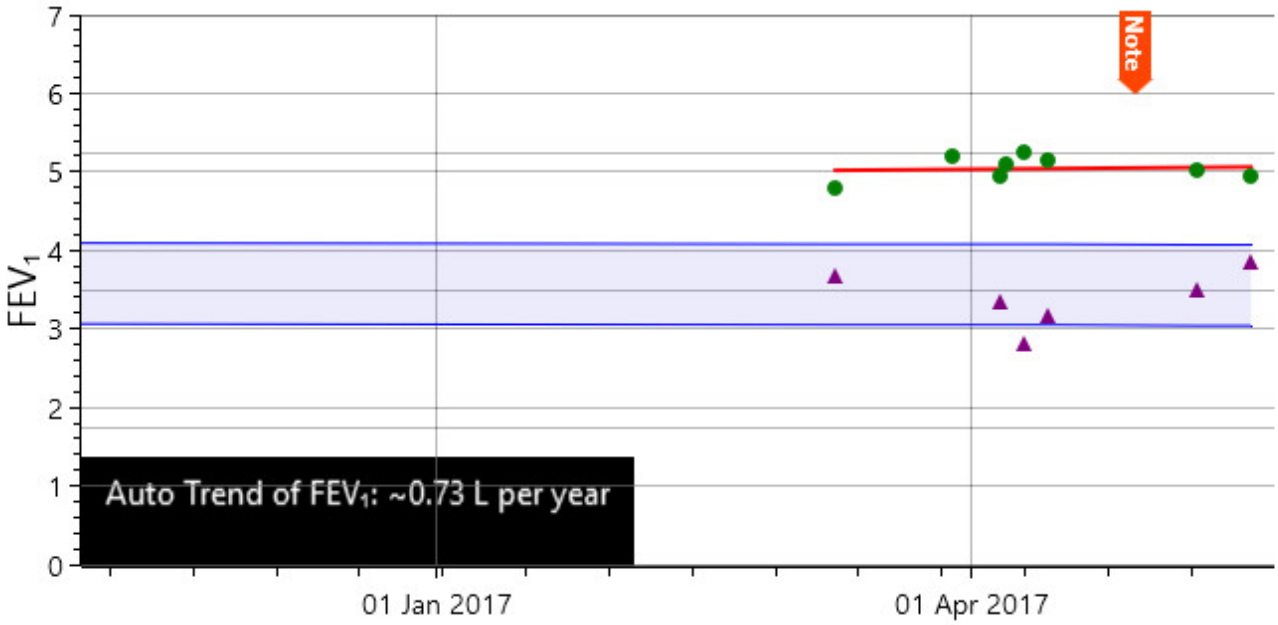


Test Date	FVC	FEV_1	DLCO	TLC	RV/TLC	Raw
12/1/2010	7.17 (128%)	5.02 (116%)	31.64 (93%)	9.91 (122%)	26 (72%)	--- (0%)
2/9/2011	7.36 (131%)	5.43 (126%)	35.03 (103%)	11.50 (142%)	33 (92%)	--- (0%)
3/8/2011	7.07 (126%)	5.23 (121%)	32.28 (95%)	10.22 (126%)	29 (81%)	--- (0%)
3/10/2011	7.47 (133%)	5.30 (123%)	32.41 (95%)	9.91 (122%)	25 (69%)	--- (0%)
5/23/2011	7.46 (133%)	5.30 (123%)	34.84 (103%)	10.85 (134%)	30 (83%)	--- (0%)

4.2.7 Plotting and saving trends

Trends can be plotted over any particular date period on the graph for any and each parameter in the database.

The trend option automatically calculates a "best fit" line through the data selected.



Trends can be plotted in several ways:

- Plotting between two user-defined dates
- Plotting from the most recent test back to a user-defined 'anchor' date
- Plotting from the most recent test back a set number of days (user selectable)

There are two types of trending available:

1. Manual trend and instant analysis which displays results that are not saved in the database
2. Automatic trending which calculates trend data based on the automatic trend settings. These data are stored in the database and are available for inclusion in reports or interpretation scripts etc.

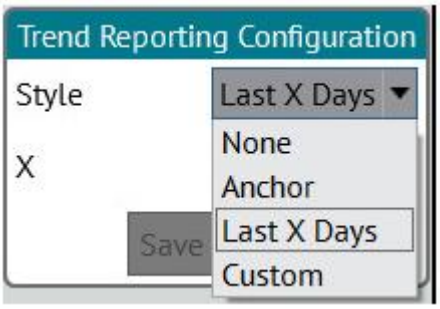
4.2.7.1 Manual Trending:

To trend across data, simply hold the [Shift] key then click on the first and second point to draw the trend line between them. The best fit line will be calculated and displayed between the selected data and a trend calculated. The trend information will indicate "upwards" or "downwards" in the units of the parameter selected.

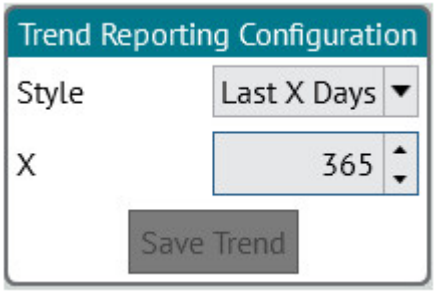
4.2.7.2 Automatic Trending:

Automatic trend settings allow the user to decide the period of time used for reporting. In each case, the time period starts from the date of the most recent test and looks back either to an "anchor" date selected by the user or a "set number of days" also selected by the user. Having chosen the desired settings, a best fit line will be calculated and displayed between the selected data and a trend calculated. When displayed on the graph or used in reports, the trend information will indicate "upwards" or "downwards" in the units of the parameter selected.

To use an "Anchor" date, select [Anchor] from the pull-down options:



To use number of days, select [Last X days] and then enter the value for X:



Remember to click 

for the settings to take effect and be available in reporting.

4.2.8 Past Flow Volume Loops

The history function also allows for the display and overlay of any or all past Pre and Post flow volume loops. For those users interested in assessment of curvilinearity, the ability to draw a straight line across any portion of the loop displayed is provided.

Use the [Flow Volume] tab at the top of the history screen to access the data.

Test Date	FVC		FEV_1		DLCO		TLC		RV/TLC		Raw		FeNo	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
2/9/2011	7.36 (131%)	---	5.43 (126%)	---	55.03 (103%)	---	11.50 (142%)	---	33 (92%)	---	---	---	---	---
3/8/2011	7.07 (126%)	---	5.23 (121%)	---	32.28 (95%)	---	10.22 (126%)	---	29 (81%)	---	---	---	---	---
3/10/2011	7.47 (133%)	---	5.30 (123%)	---	32.41 (95%)	---	9.91 (122%)	---	25 (69%)	---	---	---	---	---
5/23/2011	7.46 (133%)	7.31 (131%)	5.30 (123%)	5.19 (120%)	34.84 (103%)	---	10.85 (134%)	---	30 (83%)	---	---	---	---	---
6/10/2011	7.59 (136%)	7.66 (137%)	5.48 (127%)	5.42 (126%)	32.74 (97%)	---	10.46 (129%)	---	26 (72%)	---	---	---	---	---
6/29/2011	7.24 (129%)	7.33 (131%)	5.16 (120%)	5.30 (123%)	---	---	---	---	---	---	---	---	---	---
7/12/2011	7.28 (130%)	7.48 (134%)	5.26 (122%)	5.32 (124%)	32.33 (96%)	---	10.98 (136%)	---	31 (86%)	---	1.57 (92%)	---	---	---
7/25/2011	6.94 (124%)	---	5.25 (122%)	---	---	---	10.57 (130%)	---	34 (94%)	---	1.18 (69%)	---	---	---

The display plots the first flow volume data highlighted on the numerical table. The Pre-bronchodilator loop is displayed on the left and the corresponding Post-bronchodilator loop from the same date (if completed) is displayed on the right. The numerical table lists the parameters as selected by the user and as shown on the serial data graph screen. However, the columns now display the following information for each parameter:

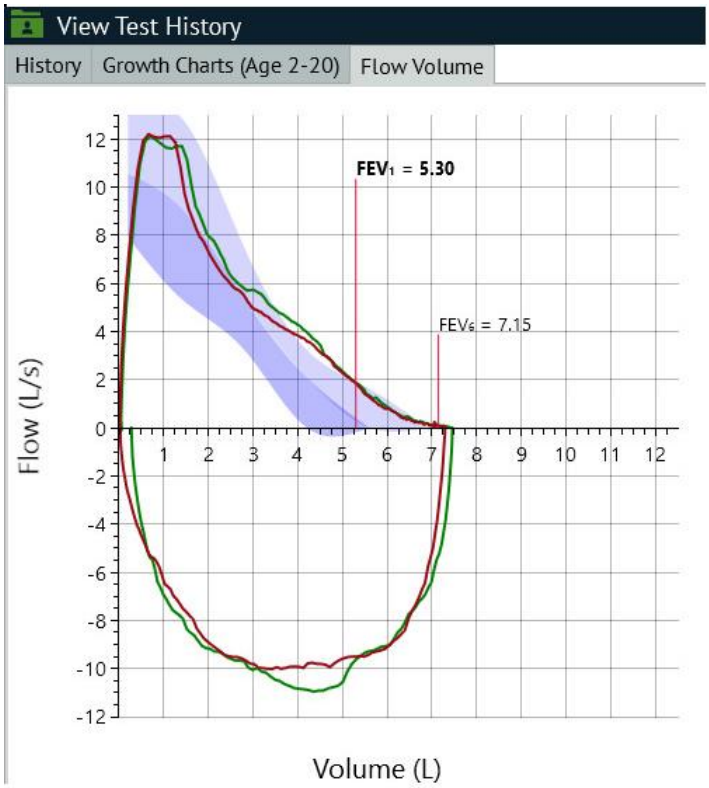
Date Tested Pre Actual Value (Pre Percent Predicted) Post Actual Value (Percent Change)

The horizontal order of parameters follows the user selection of the Display Set (Y1) in the Parameter Spreadsheet dialogue.

The test dates can be listed from most recent to past or vice versa by clicking on the arrow symbol beside "Test Date" at the top of the column.

Test Date	FVC		FEV_1		DLCO	
	Pre	Post	Pre	Post	Pre	Post
2/9/2011	7.36 (131%)	---	5.43 (126%)	---	35.03 (103%)	---
3/8/2011	7.07 (126%)	---	5.23 (121%)	---	32.28 (95%)	---
3/10/2011	7.47 (133%)	---	5.30 (123%)	---	32.41 (95%)	---
5/23/2011	7.46 (133%)	7.31 (131%)	5.30 (123%)	5.19 (120%)	34.84 (103%)	---
6/10/2011	7.59 (136%)	7.66 (137%)	5.48 (127%)	5.42 (126%)	32.74 (97%)	---
6/29/2011	7.24 (129%)	7.33 (131%)	5.16 (120%)	5.30 (123%)	---	---
7/12/2011	7.28 (130%)	7.48 (134%)	5.26 (122%)	5.32 (124%)	32.33 (96%)	---
7/25/2011	6.94 (124%)	---	5.25 (122%)	---	---	---

To overlay the Post BD data over the Pre BD data on either single or multiple selections of dates, click the  button.



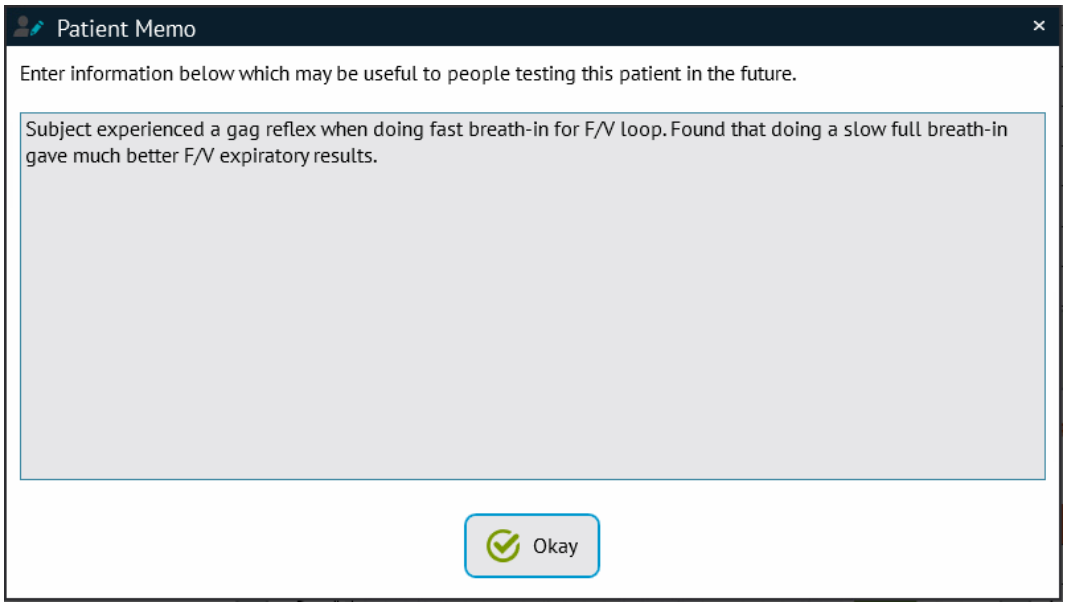
Multiple past test loops can be selected using conventional Windows mouse techniques. The user can drag and click over multiple test dates or they can use the [Ctrl] left-click on any dates in the table. When multiple dates are selected, the loops are color matched to the row color in the table.

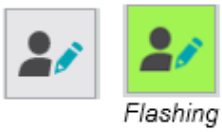
4.3 Adding Bronchodilator Administration Information

Bronchodilator information can be accessed by clicking on the  icon from any testing screen.

4.4 Adding and Accessing Patient Memo Notes

The Patient Memo Icon  provides access to a special notes area where information to assist colleagues in the testing of this test subject can be saved. If notes have been entered in this area, the icon will flash for ten seconds when entering the testing screens to draw attention to the fact that useful information is available.

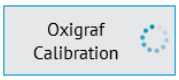


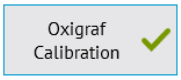


5:0 Calibration and Daily Quality Check

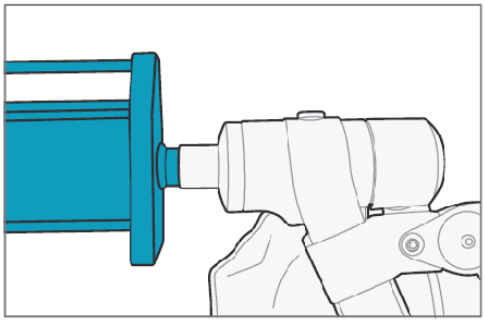
5.1 First-time Installation Set-up
This is a utility only required when the instrument is first installed.

The Oxygen laser-diode fast gas analyzer has firmware that sets the default calibration range from room air to 100% O2. A utility in ComPAS2 runs a sequence to establish the output signals that are stored in the analyzer firmware.

Go to "Diagnostics" and "Utilities" and click 

to establish the firmware gas output settings. Having completed the routine a confirmation check will be displayed: 

5.2 Flow Volume Daily Quality Check
A quality check should be completed on the device each day prior to testing.



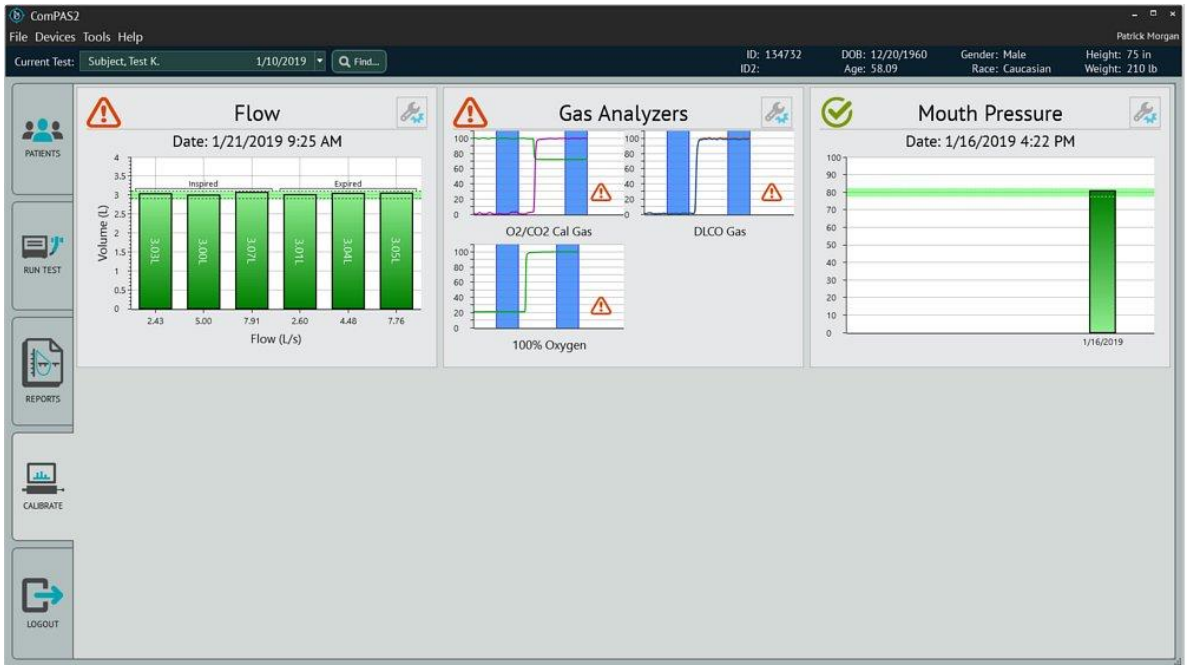
Syringes perfectly matched to the quality and durability of the Vitalograph Morgan PFT are available from Vitalograph.

The action of the syringe is engineered for smooth strokes at both low and high flows.

They also allow for direct and simple connection to the flow head.

From the ComPAS2 desktop, click on the Calibration icon.

The opening calibration screen will indicate when the last successful syringe quality check was completed. The ATS guidelines recommend that a calibration verification be carried-out.



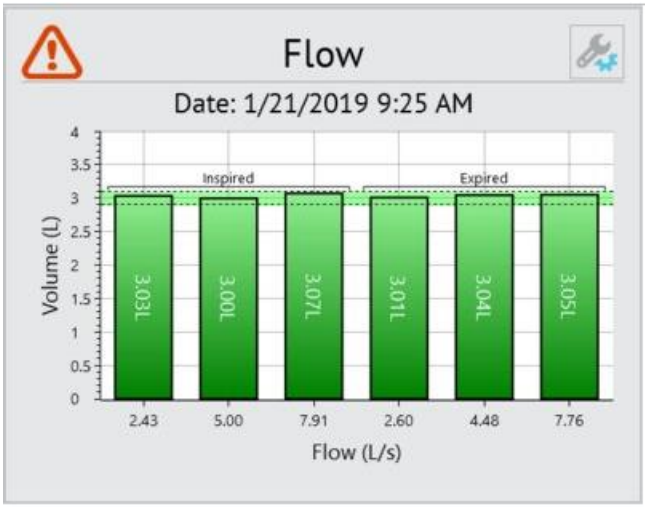
The symbols used on this screen give immediate indication of the status of each transducer.

Indicates that this section requires calibration/quality check

For Flow this indicates that this section has passed calibration/quality check within the past 24 hours

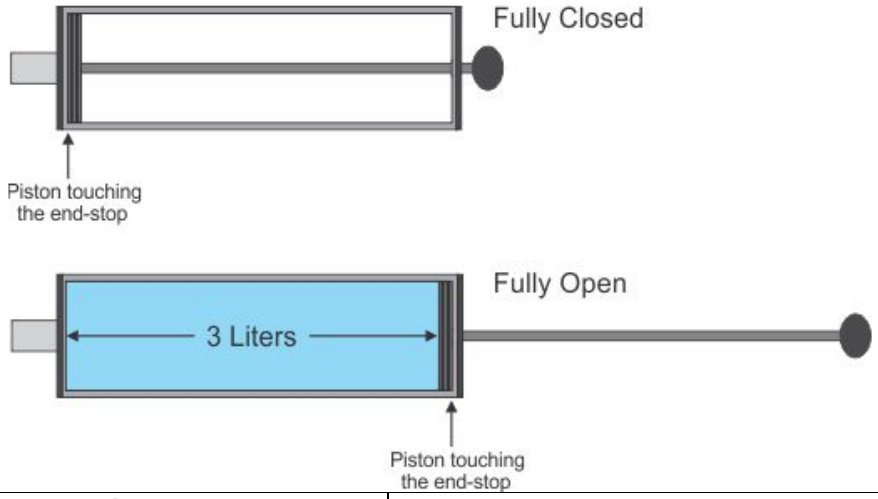
5.2.1 Performing a Flow Volume Daily Quality Check

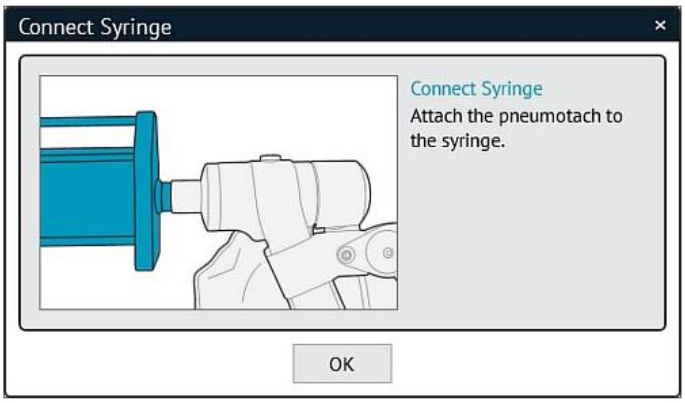
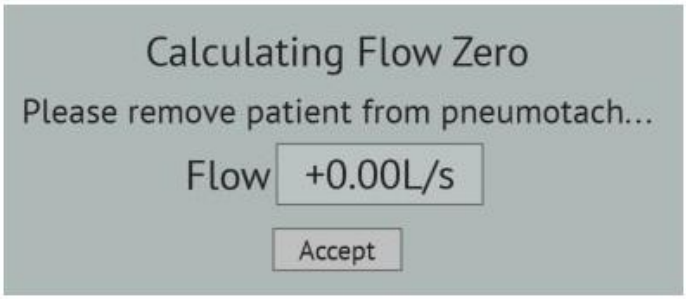
To enter flow quality check, click anywhere in the "Flow" graphic area:

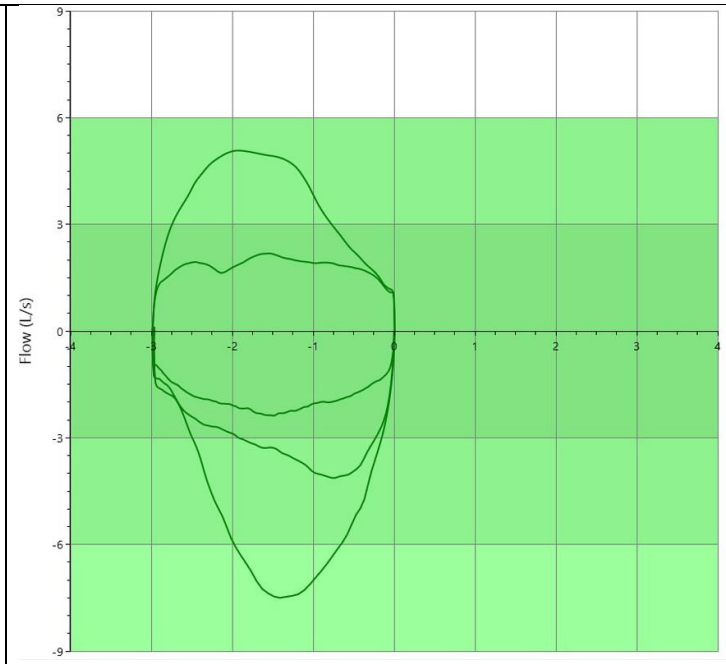


Before starting a daily quality check, it is VERY IMPORTANT to understand that each stroke of the 3L syringe must be a complete stroke

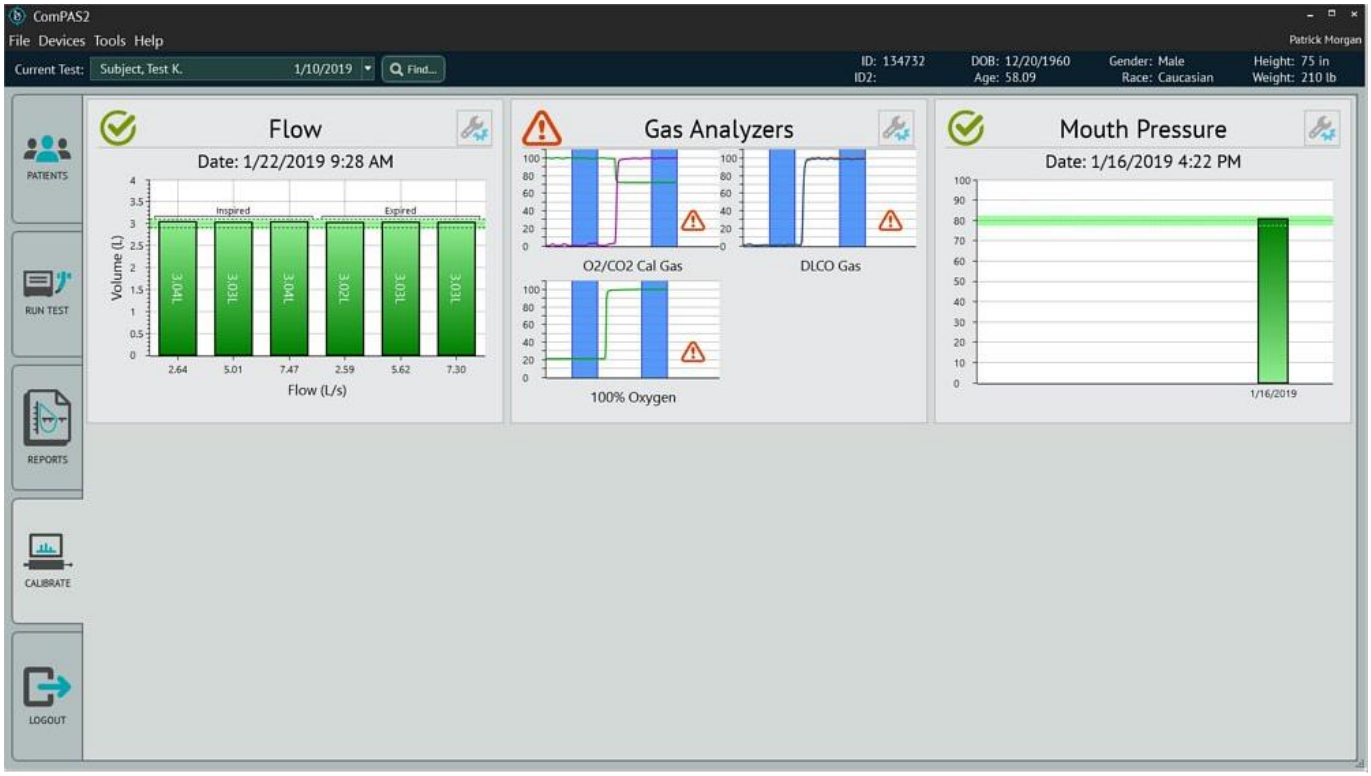
To produce 3 liters of volume with the syringe, each stroke must start and finish with a full excursion gently 'bumping' each end of the syringe.



Step 1. Connect the 3L Syringe Connect the flow head firmly to the 3L syringe.	
Step 2. Record Flow Zero Make sure the syringe is still and allow ComPAS2 to record flow zero.	
Step 3. Quality Check The display now presents a flow volume axis with inspiratory and expiratory target areas.	

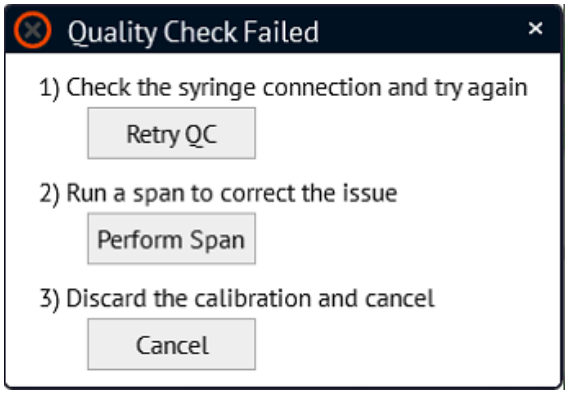
Complete a series of full 3-Liter inspiratory and expiratory syringe strokes until all flow areas have been satisfied. Each area turns green when acceptable flow rates and volumes have been achieved. There is no limit to the number of strokes performed.	

Pressing [Spacebar] will end the quality check and return the user to the main calibration screen. The results of each stroke within the designated flow areas are shown together with the date and time of the most recent QC.



5.2.2 If the Daily Quality Check Fails

If the results across any of the flow ranges are outside of +/- 2.5% the user will be prompted as follows:



User can retry the quality check, perform a new span or discard the current calibration effort.

5.3 Performing a F/V Span

5.3.1 Introduction

What is the Pneumotach span factor?

In an ideal world, having created a reliable linearity table, the results of each 3-Liter syringe stroke across physiological flow ranges would result in an exact value of 3.00 liters. However, subtle differences in each pneumotach screen may require minute mathematical correction to ensure precise accuracy.

The diagnostic utility outlined below, allows the user to perform a number of full inspiratory and expiratory strokes at varying flow rates with a 3-Liter syringe and then have ComPAS2 determine a span factor.

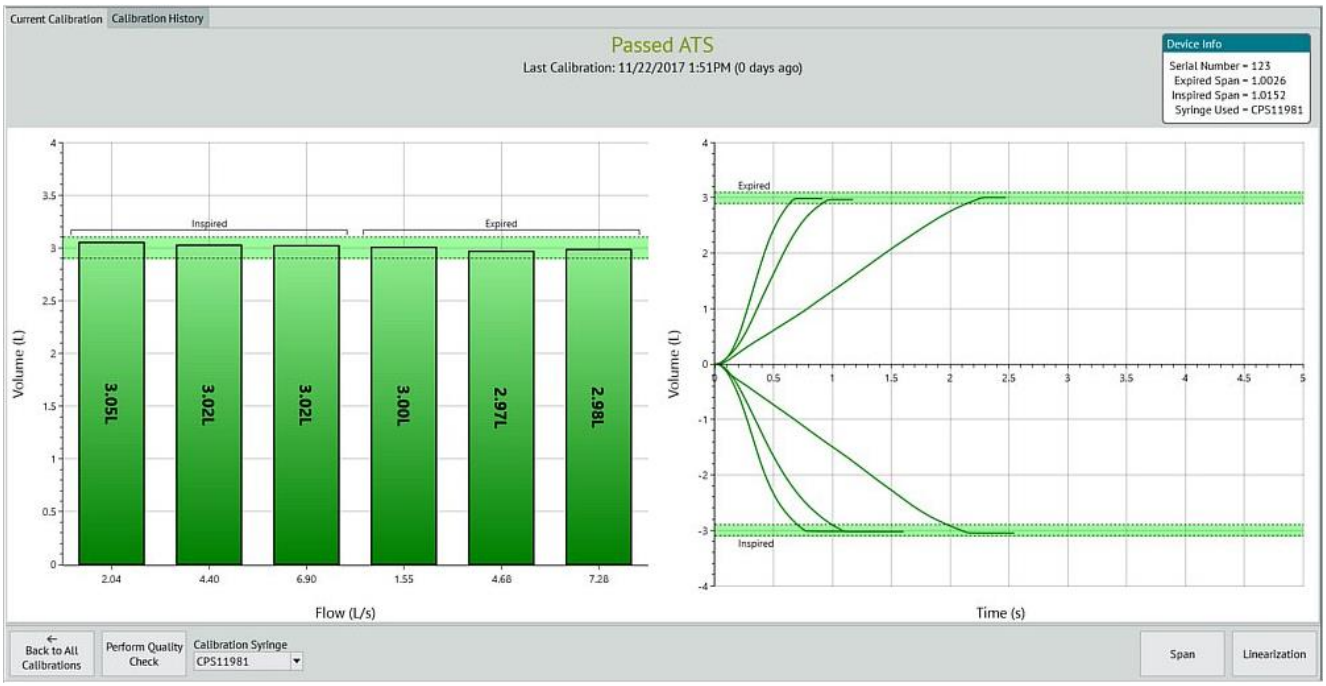
The span factor is the value derived that is required to bring the end result to exactly 3.00 liters.

For example, having performed a number of 3-Liter syringe strokes, the software may show that multiplying the flow output by 0.998 will result in a perfect 3.00 liters.

5.3.2 Performing a Span

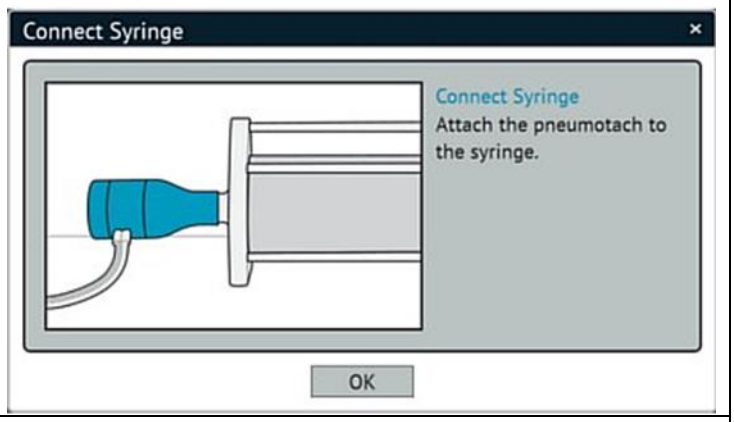
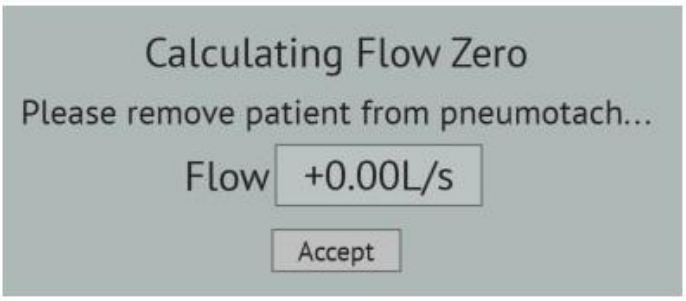
From the main calibration screen, click on the tools icon  within the Flow graphic

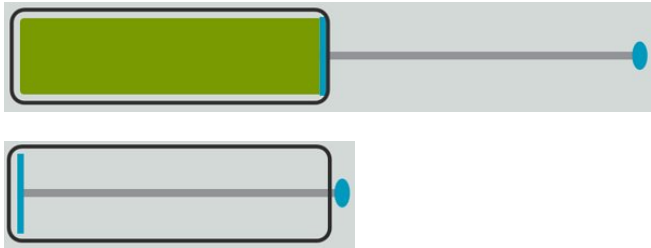
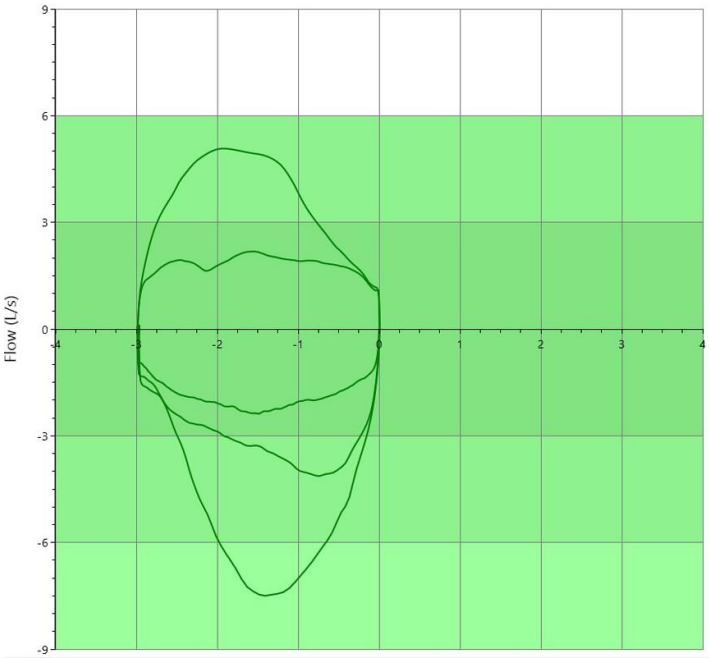
This will open the flow calibration options screen.



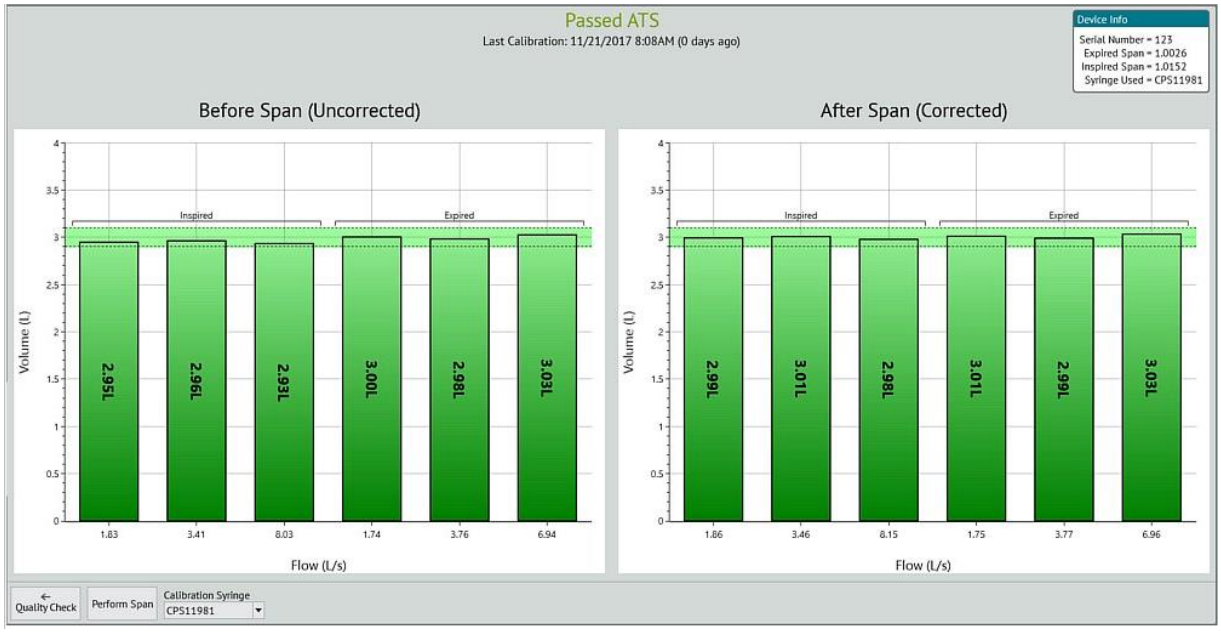
Before starting a Span, it is VERY IMPORTANT to understand that each stroke of the 3L syringe must be a complete stroke.

To produce 3 liters of volume with the syringe, each stroke must start and finish with a full excursion gently 'bumping' each end of the syringe.

Step 1. Connect the 3L Syringe Connect the flow head firmly to the 3L syringe.	
Step 2. Record Flow Zero Make sure the syringe is still and allow ComPAS2 to record flow zero.	

Step 3. Span Strokes The screen will present a simple image of the 3-liter syringe. and instruct the user to complete full strokes in and out until span is confirmed with a "Passed" message:	
Step 4. Passed Span Once the Span indicates "Passed", pressing [Spacebar] will direct the user to perform a Quality Check.	
Step 5. Quality Check Strokes The display now presents a flow volume axis with inspiratory and expiratory target areas. Complete a series of full 3-Liter inspiratory and expiratory syringe strokes until all flow areas have been satisfied. Each area turns green when acceptable flow rates and volumes have been achieved. There is no limit to the number of strokes performed.	

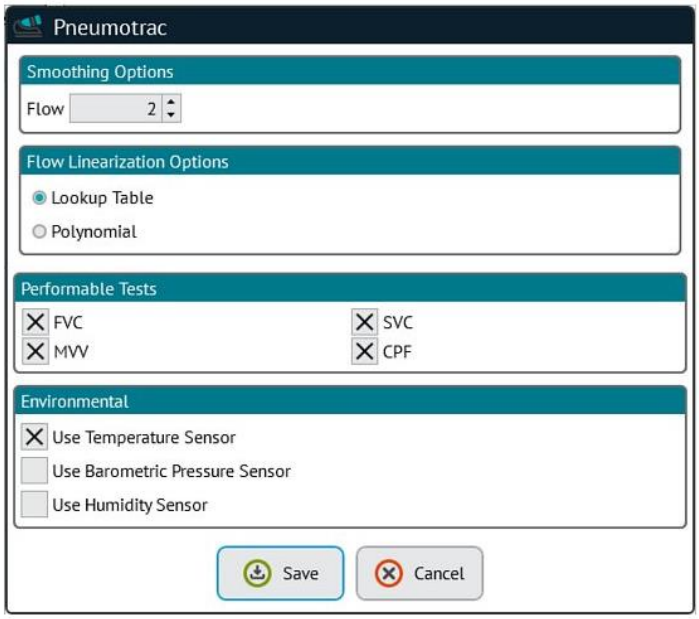
Pressing [Spacebar] will end the Span and display the results. The result of each stroke before and after the span function are shown together with the date and time.



5.4 Creating the Flow Volume Linearity Table

5.4.1 Principles used in calibrating Flow and Volume

There are two "Flow Linearization Options" available in ComPAS2 for calibration of flow devices; the choice is selected in the Pneumotrac Device Configuration:

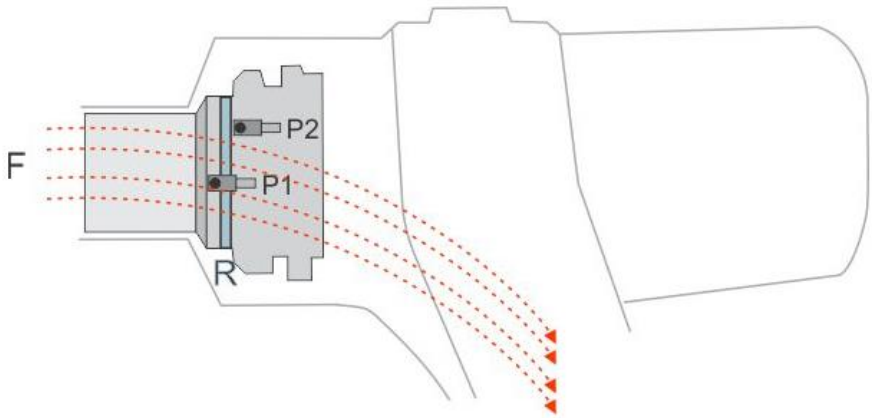


<u>Lookup Table</u>
This is a user-created linearity table based on the paper described below

<u>Polynomial</u>
This is a factory default profile that has been created and tested against verifiable standards

5.4.2 Lookup Table Principles

Flow and Volume are measured using a principal called pneumotachography. A pneumotach is a cylinder with a partial obstruction to air flow constructed across the inner diameter of the tube. It is designed to be of a very low resistance but of sufficient resistance to cause a small pressure-drop across the obstruction. When gas flows down the tube, the pressure (P2) beyond the obstruction (R) is less than that immediately before it (P1).



The principal employs the Poiseuille-Hagen equation for pressure (P) and flow (F):

$$F = \Delta P \Pi R^4 / 8hL$$

Where h is viscosity, L is length and R is radius. Everything is constant in this equation (i.e. the length and radius of the flow tube) except the pressure gradient (ΔP) and the flow (F). The pressure difference caused by the obstruction is therefore a function of the rate of gas flow.

When using a pneumotachograph, the flow rate is directly measured by the pressure drop across a differential pressure transducer. On the Vitalograph Morgan PFT product, tubes within the flow head assembly connect the pneumotach to a pressure transducer mounted inside the system base console. This pressure signal is compared differentially to atmospheric pressure and is integrated to obtain volume. Therefore, any change in flow rate will result in a change in volume.

The accuracy and operating flow range of the pneumotachograph is greatly enhanced through the use of a performance ”look-up” table based on the conductance characteristics. Conductance values of the pneumotach which correspond to all pressure values are determined by a weighted averaging technique using a precision 3-Liter syringe.

The volume measurement of any gas is also affected by the conditions under which it is measured. The condition of expiratory gas varies from the beginning of an expiration (dead space gas) to the end (alveolar gas). Among the variations are: temperature, water vapor content, gas composition, viscosity, and, in some cases, thermal conductivity. These variations are already accounted for and handled within ComPAS2.

The method of calibrating the Pneumotachograph within the Vitalograph Morgan PFT is based upon the following paper:

"Computerized Determination of Pneumotachometer Characteristics Using a Calibrated Syringe" by: Minken P.Yeh, Reed M. Gardner, Ted D. Adams, and Frank G.Yanowitz

Department of Medical Biophysics and Computing, Department of Medicine, University of Utah School of Medicine and the Fitness Institute, Latter Day Saints Hospital, Salt Lake City, Utah 84143, U.S.A.

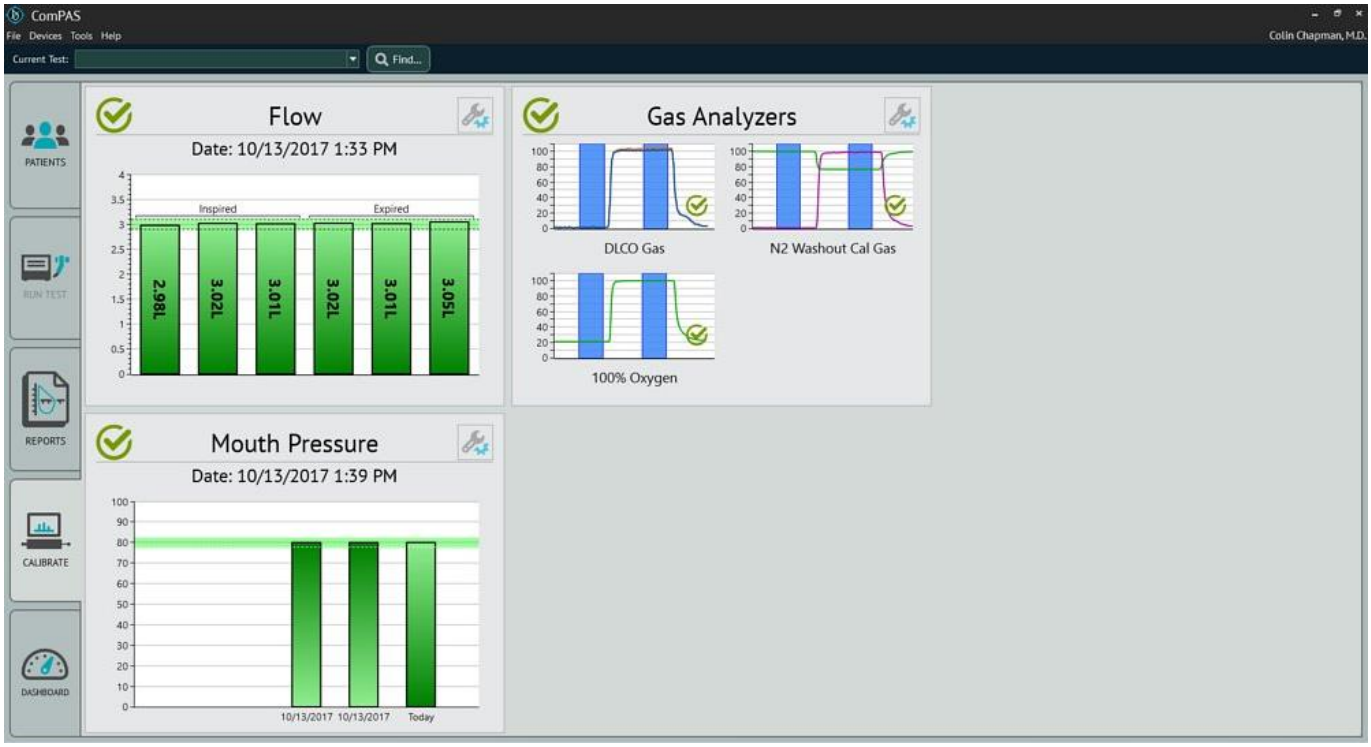
The above research resulted in a computerized method to determine the conductance characteristic of flow-based instruments. Precise 3-Liter syringe strokes are pushed in and out of the pneumotach at differing flow rates. Using a weighted average technique, the differential pressure values (conductance's) are converted point by point into flow values. A linearity table is created based on this information that is referred to during performance of all volumetric maneuvers. The technique provides accuracy within +/- 0.5%.

The Vitalograph Morgan PFT uses a combination of calibration methods based on the above work and the research of Morgan Scientific, Inc. engineers. This calibration method is designed to be accurate over all clinical flow ranges.

5.4.3 Opening the Linearity Table Functions

From the ComPAS2 desktop, click on the Calibration icon.

This will open the general calibration status screen.

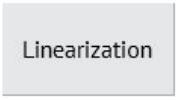


The symbols used on this screen give immediate indication of the status of each transducer.

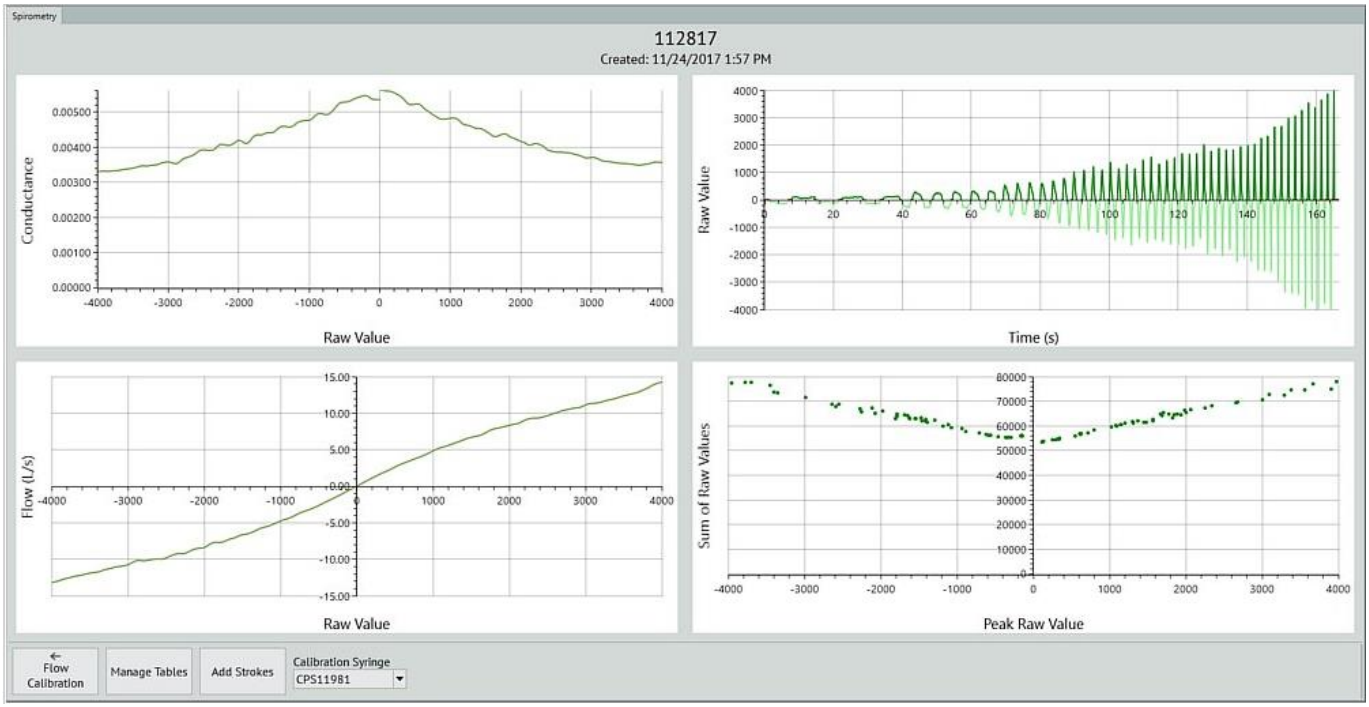
Indicates that this section requires calibration/quality check

For Flow this indicates that this section has passed calibration/quality check within the past 24 hours

To enter the creation and management of flow linearity tables, click on the tools icon  within the Flow panel. This will load the Flow calibration detail Screen.

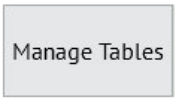
Click on the 

button to enter the full Linearization menu:

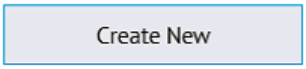


The current or "default" linearization table will load showing its properties and date of creation.

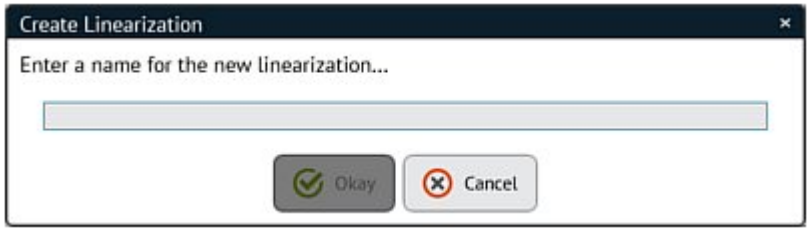
5.4.4 Creating a New Linearity Table

To create a new linearization table, first click 

to access the naming and selection of defaults.

Click 

and enter a name for the new table. This can be any alpha or numeric combination.

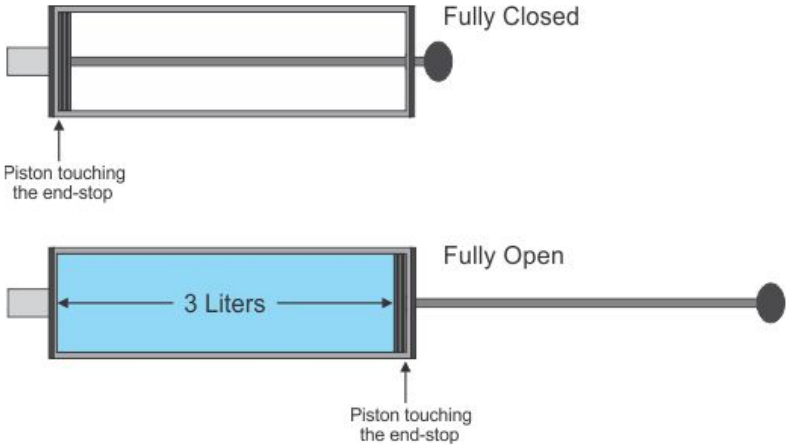


Once the 

s pressed, the linearity screen will show a blank table ready to accept new strokes:

Before starting a new linearization, it is VERY IMPORTANT to understand that each stroke of the 3L syringe must be a complete stroke.

To produce 3 liters of volume with the syringe, each stroke must start and finish with a full excursion gently 'bumping' each end of the syringe.



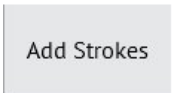
Step 1. Connect the 3L Syringe

Connect the flow head firmly to the 3L syringe.

Step 2. Record Flow Zero

Make sure the syringe is still and allow ComPAS2 to record flow zero.

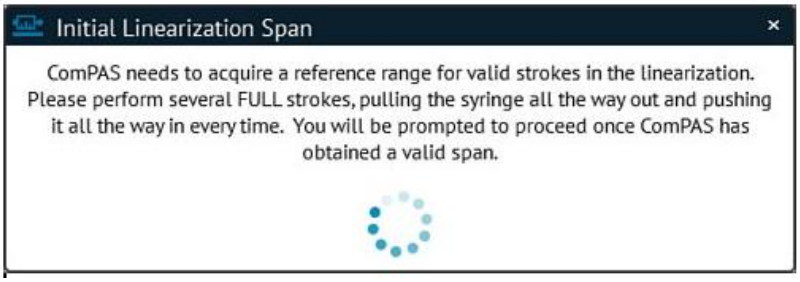
Step 3. Linearization

Click 

to begin the linearization process.

For "Advanced" Users, clicking the down-arrow will provide an option that by-passes the need to meet the set flow guide ranges. Customers familiar with previous ComPAS2 versions will likely prefer the "Expert Mode"

The first phase of linearization is the gauging of flow gain; to achieve this simply pump the 3L syringe in and out 4 times as soon as the 'spinner' is active.



Once sufficient strokes have been captured the screen will pause:

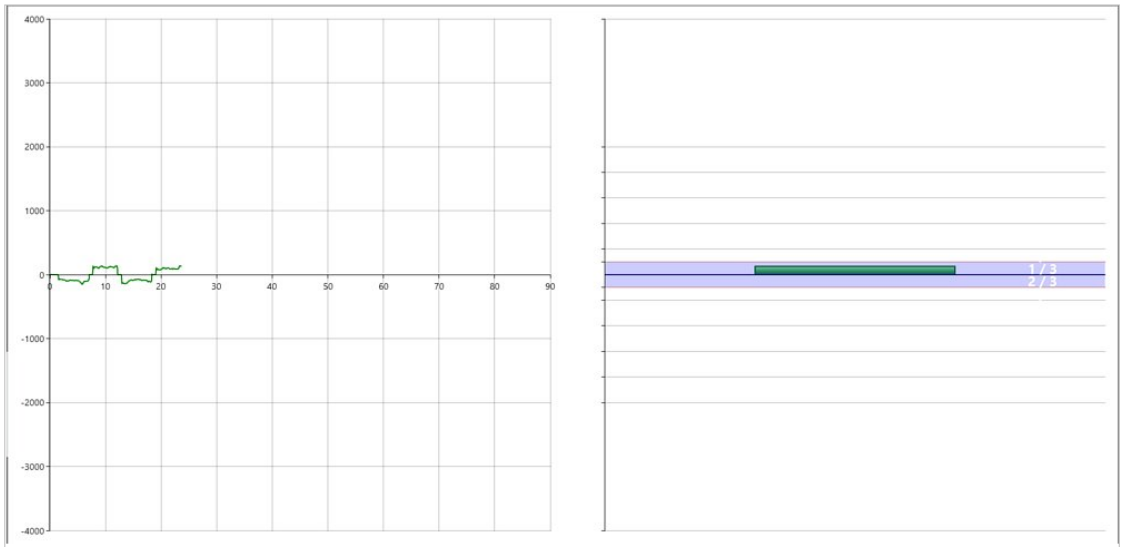
Press the [Spacebar] or click 

to continue.

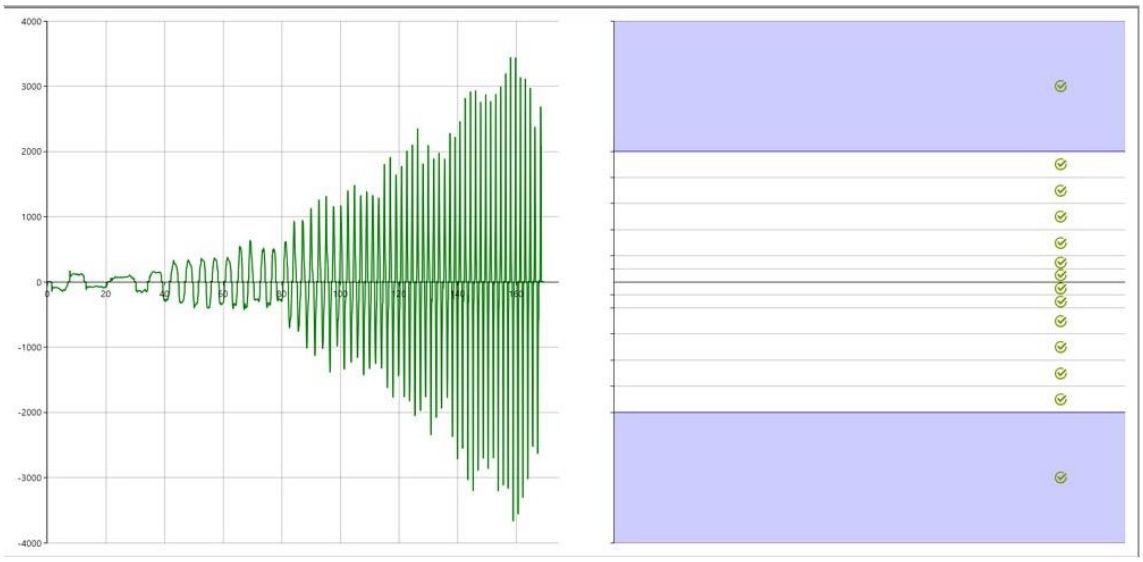
A dynamic screen is presented to guide the user through creation of the linearity table. On the right-hand side of the screen, target areas are shown representing the speed of inspiratory and expiratory syringe strokes. Simply operate the syringe so that the green bar graphs reach the ranges shown. As each range is satisfied, the target areas are shifted; a countdown of strokes that satisfy the flow range is shown. The user must simply aim to hit each target area until it is complete.

It begins with very low flow rates; each stroke must stay within the highlighted boundary shown on the right-hand side.

Please note that the very low flow region is not mandatory because some labs have difficulty with sticky syringes. We strongly recommend changing the syringe if it cannot produce smooth low flow rates!



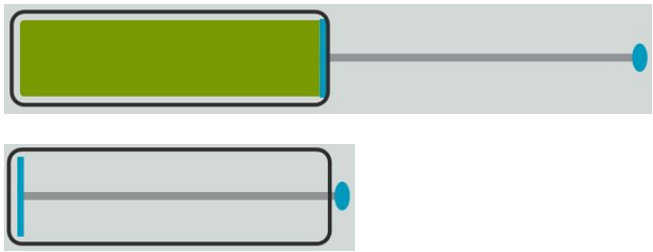
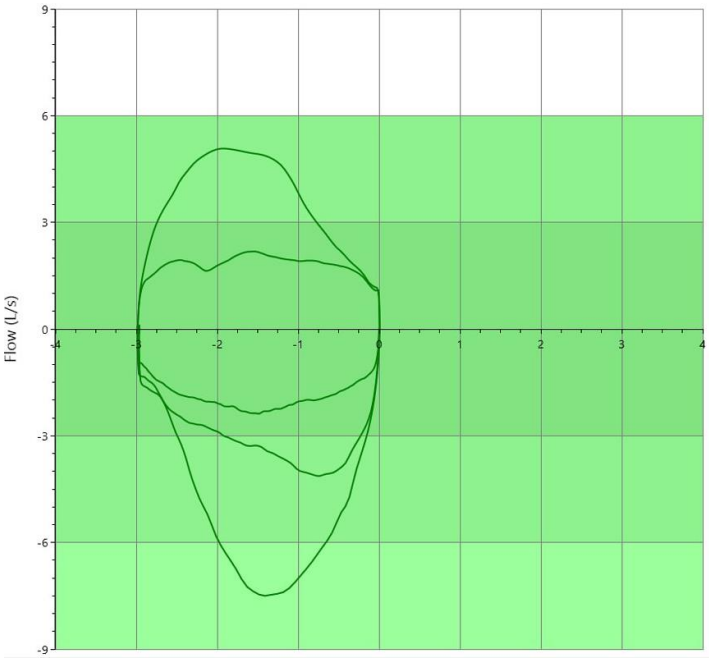
As each flow range is satisfied, a green check mark is displayed and the process continues with each advancing range requiring higher flow rates:



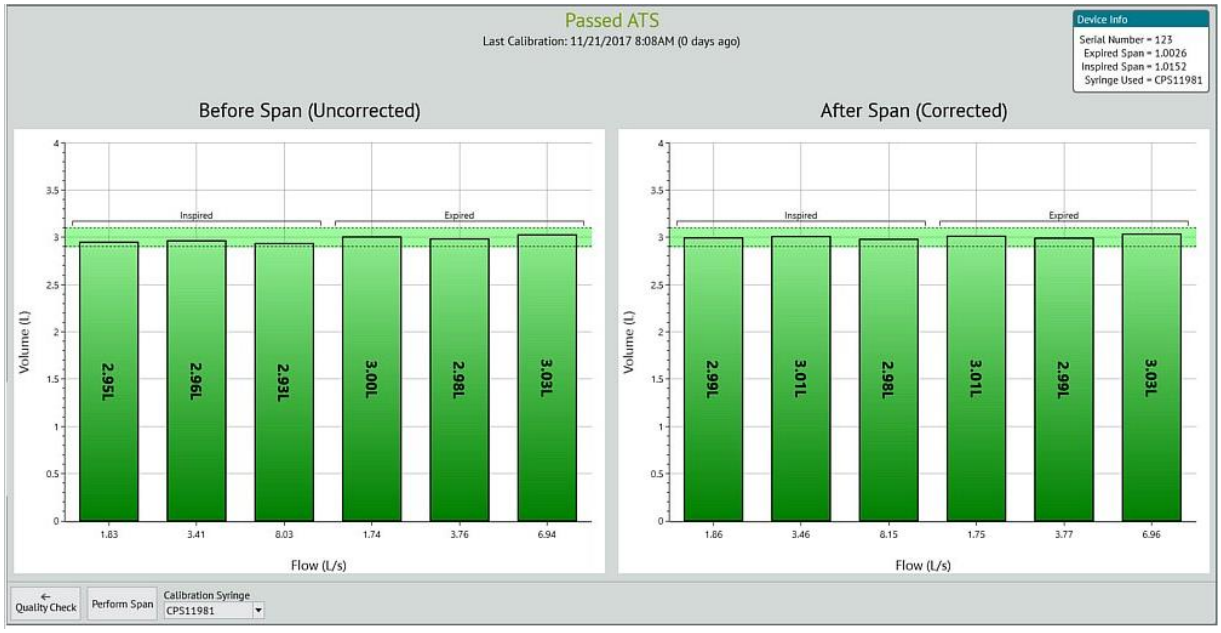
When all ranges have been satisfied, further strokes at any flow rate can added if desired. Pressing the [Spacebar] will end the table creation.

Step 4 Creating the Span

Having built a new table, the program will instruct the user to now perform a calibration or span.

Step 1. Span Strokes The screen will present a simple image of the 3-liter syringe. and instruct the user to complete full strokes in and out until span is confirmed with a "Passed" message:	
Step 2. Passed Span Once the Span indicates "Passed", pressing [Spacebar] will direct the user to perform a Quality Check.	
Step 3. Quality Check Strokes The display now presents a flow volume axis with inspiratory and expiratory target areas. Complete a series of full 3-Liter inspiratory and expiratory syringe strokes until all flow areas have been satisfied. Each area turns green when acceptable flow rates and volumes have been achieved. There is no limit to the number of strokes performed.	

Pressing [Spacebar] will end the Span and display the results. The result of each stroke before and after the span function are shown together with the date and time.



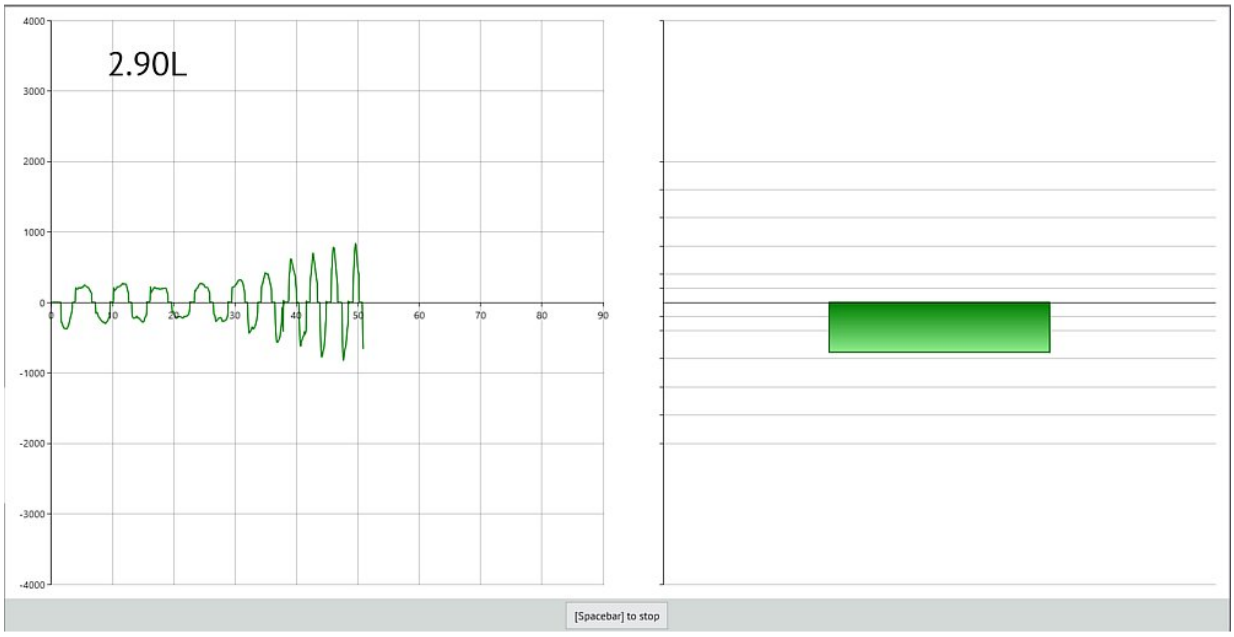
5.4.5 Adding Strokes to an Existing Linearity Table

To enter the creation and management of flow linearity tables, click on the tools icon  within the Flow panel. This will load the Flow calibration detail Screen.

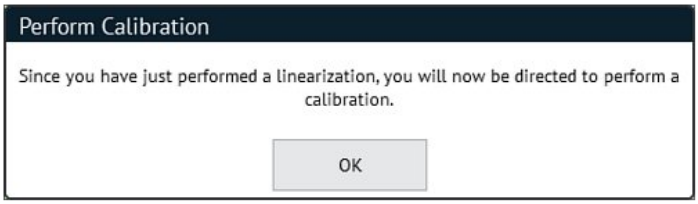
Click on Linearization and then the Add Strokes button to augment any table. When adding strokes there are no flow guides, each stroke can be at any flow rate desired. In the top left-hand side of the screen the volume of each stroke (inspired and expired) is displayed as the stroke is produced. The number will rise and hopefully reach 3.00L based upon the current linearity table.

If there is a particular area of flow that yields poor 3.00L results, produce a number of syringe strokes in that area.

Only when the new data are added to the table will the results will be improved.



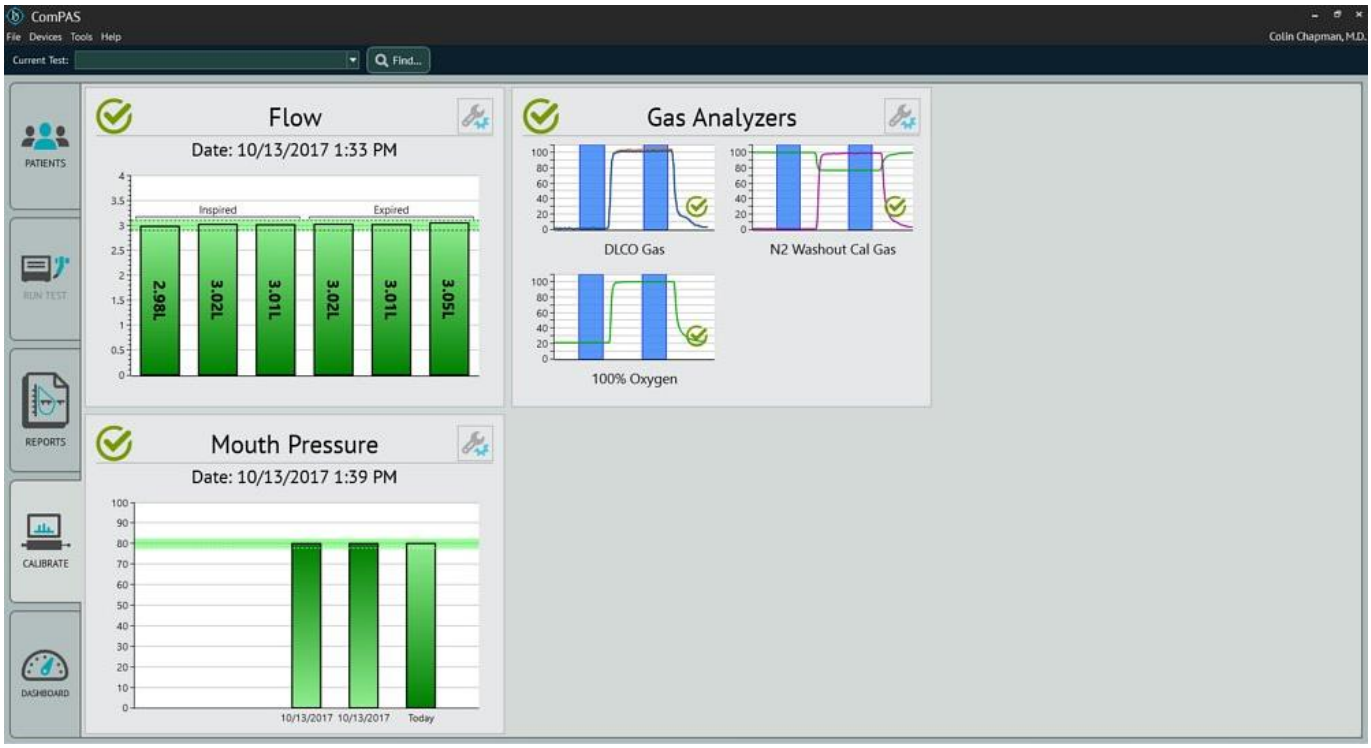
Having built a new table, the program will instruct the user to now perform a calibration or span.



5.5 Gas Analyzer Calibration

From the ComPAS2 desktop, click on the Calibration icon.

This will open the general calibration status screen.



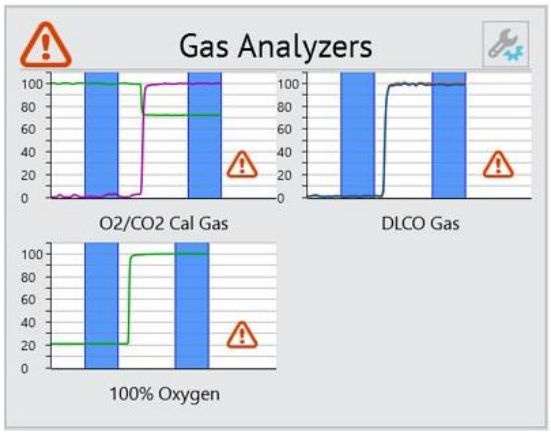
The symbols used on this screen give immediate indication of the status of each transducer.

Indicates that this section requires calibration/quality check

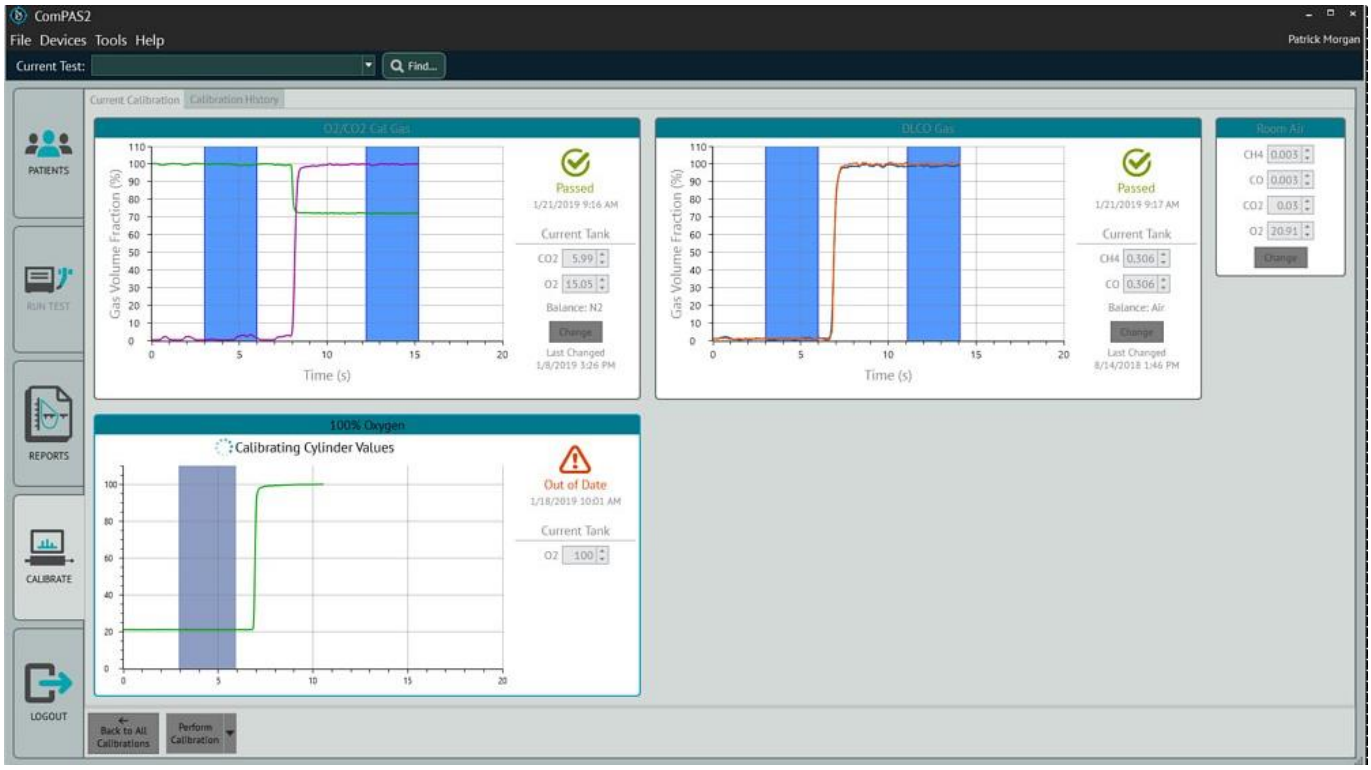
Indicates that this section has passed calibration/quality check within the past 24 hours

5.5.1 Automated Combined Gas Calibration

To run an automated sequence that steps through each gas analyzer calibration and returns to the main calibration screen, click anywhere in the "Gas Analyzer" area:



For each gas cylinder fitted to the instrument, the appropriate gas analyzers will run through a sequence that measures room air and then introduces the test gas.



The color blocks on each calibration sequence indicate the area where analyzer voltages were used to average both Room Air and Calibrated Mixture values.

Having completed the automated run of calibrations, the screen returns all the results:

5.5.2 Individual Gas Analyzer Calibration

To enter a full menu for gas calibrations, click on the tools icon  within the Gas Analyzer panel.

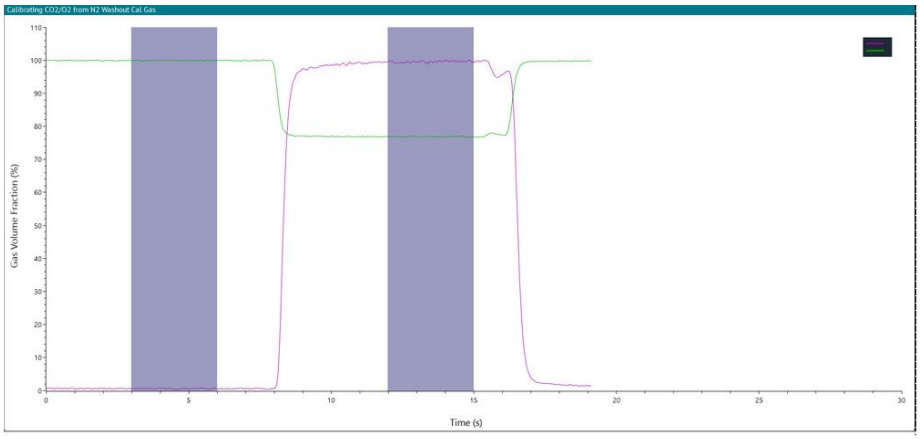
For DLCO only systems a single cylinder of gas is used and thus only the DLCO gas will be displayed on the screen. The mixture is typically:

1) 0.300% CO, 0.300% CH4, 21.0% O2 balance N2

For the Vitalograph Morgan PFT system, there are three cylinders required; the mixtures are typically:

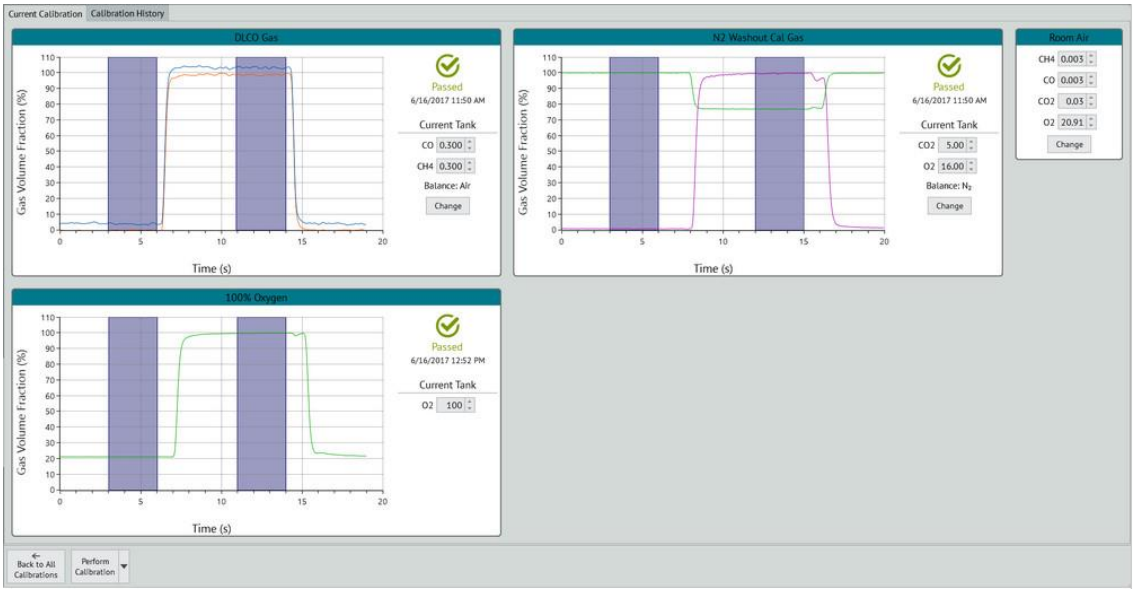
1) 0.300% CO, 0.300% CH4, 21.0% O2 balance N2
2) 6.0% CO2 and 15.0% O2 balance N2
3) 100% O2

It is very important to enter the exact cylinder values used for calibration. Enter the values under "Current Tank" in each gas block.

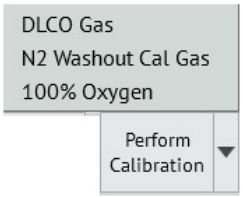


The color blocks on each calibration sequence indicate the area where analyzer voltages were used to average both Room Air and Calibrated Mixture values.

Having completed the automated run of calibrations, the screen returns all the results:

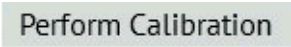


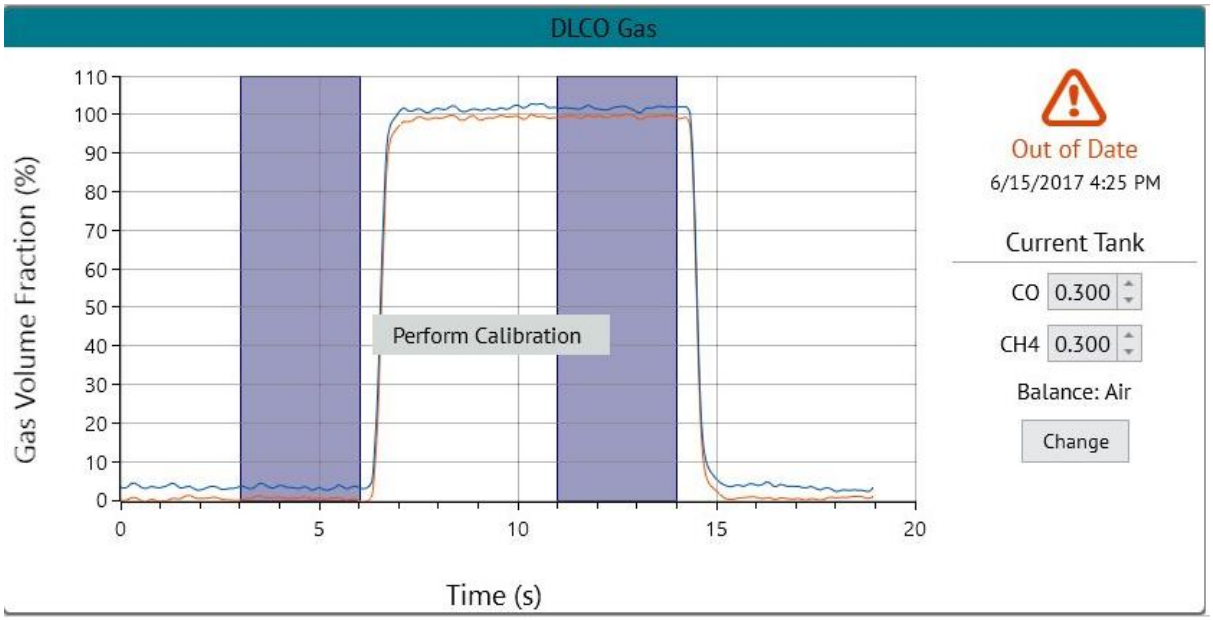
Selecting an individual gas calibration can be achieved in two ways:



1) Click on the down arrow and select the gas desired

OR

2) Right-click on any of the gas screens and select 



5.5.3 Replacing a Gas Cylinder

There are three cylinders of gas used for testing with the Vitalograph Morgan PFT instrument as follows:

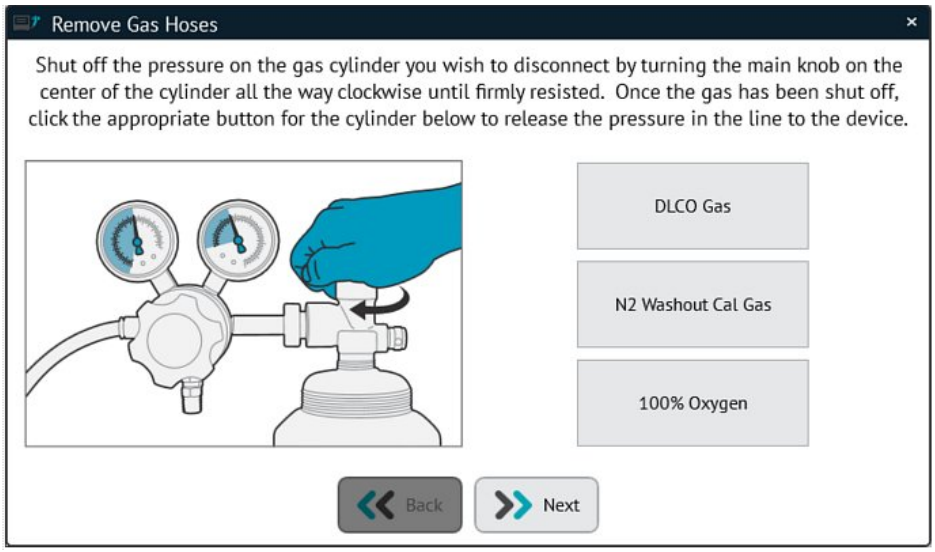
Gas Cylinder	Typical Mixture	Recommended Range	Use with the Device
Lung Diffusion Mix	0.300% CO 0.300% CH4 21.0% O2 Balance N2	0.250 - 0.350 0.250 - 0.350 18 - 22 Balance	Gas Analyzer Calibration and Single Breath Diffusion Testing
100% Oxygen	100% O2	-	Gas Analyzer Calibration and MBN2 and SBN2 Testing
CO2 and O2 Calibration Mix	6.0% CO2 15.0% O2 Balance N2	3.5 - 7.5 12.0 - 18.0 Balance	Gas Analyzer Calibration Only

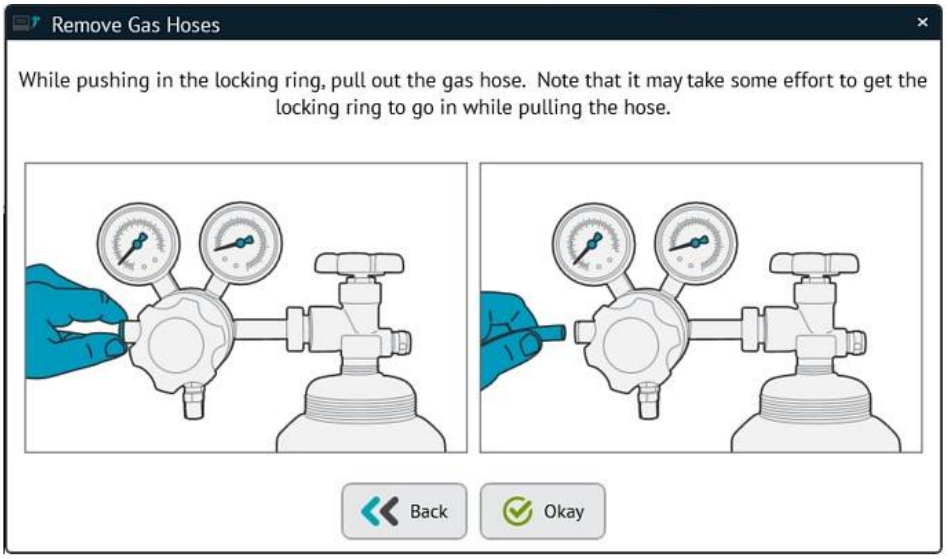
Whenever a gas cylinder is changed in the laboratory, we HIGHLY recommend that the technician carefully read the cylinder contents and confirm that they are correct. Each cylinder is supplied with a clearly marked label or certificate detailing the gas contents.

5.5.3.1 Steps to Changing the Cylinder

Before removing any of the high-pressure hoses from the gas cylinders, it is important to drain pressure from the system. The following illustrations and instructions can be run from the Diagnostics menu.

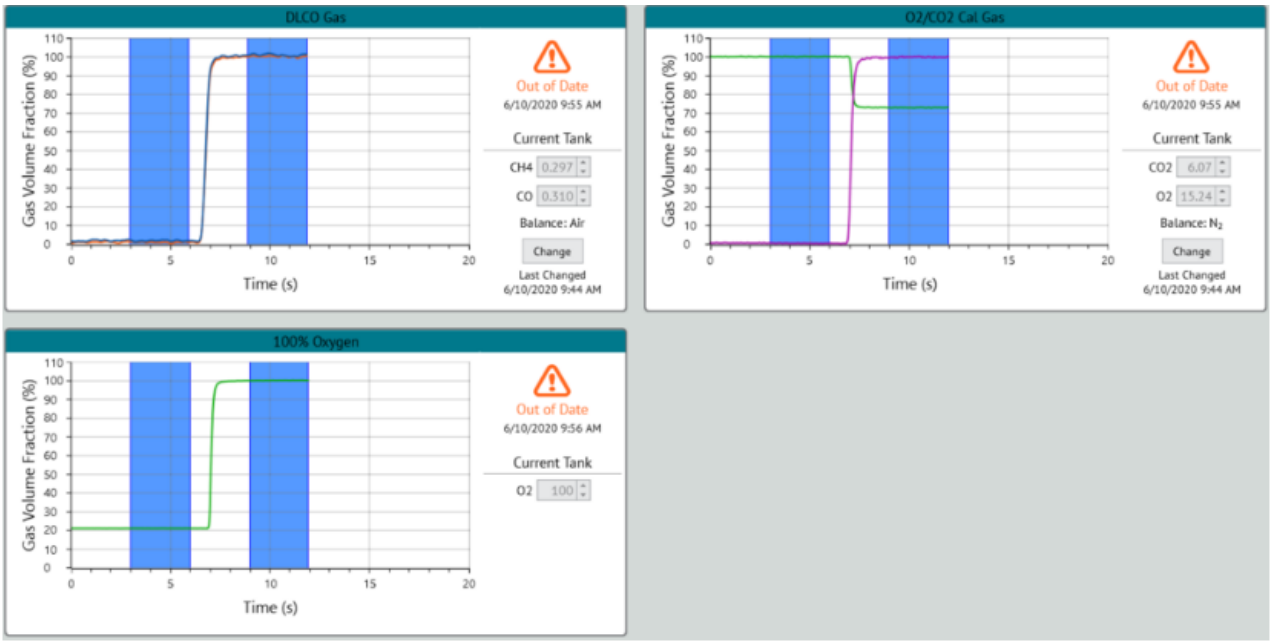
Click on Remove Gas Hoses and follow the on-screen instructions to relieve any gas pressure.





5.5.3.2 Changing the Cylinder Contents Details

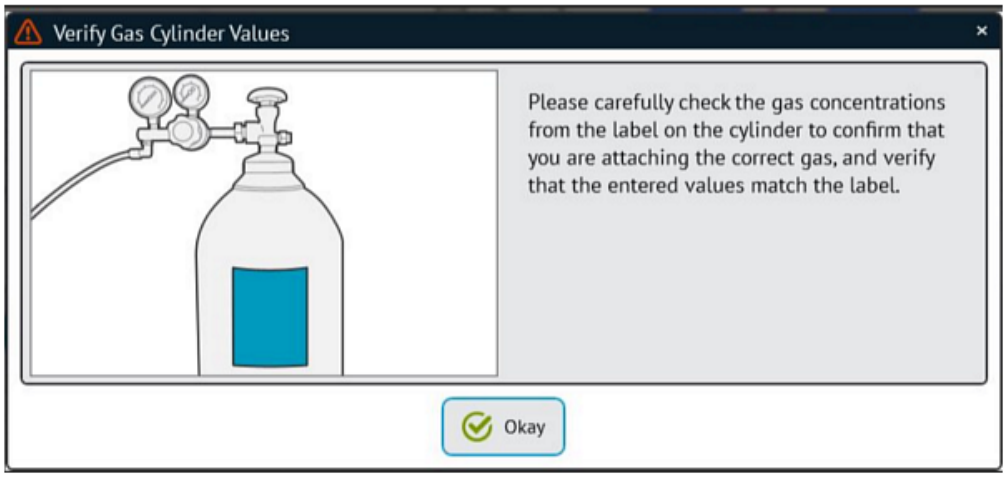
To enter revised cylinder contents, click on the tools icon  within the Gas Analyzers panel in Calibration. This will load the Gas Analyzer detail Screen.



For the appropriate gas analyzers, click on the 

button.

The technician will be prompted to confirm the contents of the cylinder.



Enter the gas concentrations marked on the cylinder label and then click on the Save button. A new gas calibration will be prompted following the change.

5.6 Mouth Pressure Calibration

5.6.1 Introduction

The respiratory muscles perform the vital function of sustaining ventilation, driving the inspiratory and expiratory breathing cycle, determining the ability to breathe. MIP and MEP measure the strength of the respiratory muscles as the patient forcibly inhales and exhales, respectively, through a closed mouthpiece attached to a pressure transducer. Using the Vitalograph Morgan PFT patient valve, the volume at which the measurement of pressure is taken is recorded by the pneumotachograph and the piston valve is used to provide occlusion. The mouth pressure measurement comes from a separate transducer linked to the pneumotach circuit.

To calibrate mouth pressure in the ranges typical for MIP and MEP measurement, an accessory digital manometer is available from Vitalograph or Morgan Scientific.

Cat No. EX31701 Digital Respiratory Muscle Force Calibrator

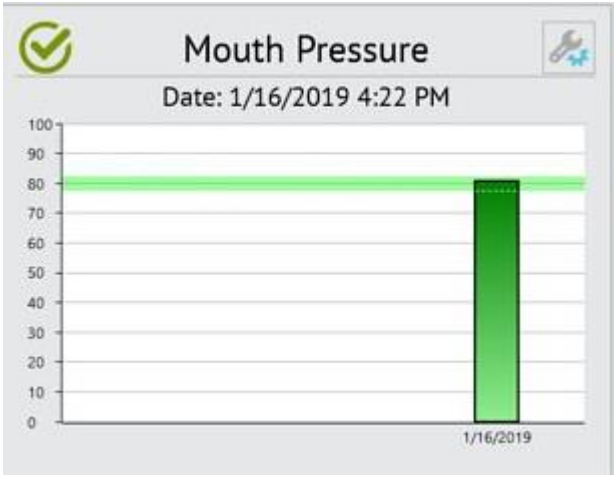
The manometer is supplied with a rubber stopper that fits into the front of the patient valve and also a hand bulb to generate the necessary pressure.

5.6.2 Configuring the Frequency of Mouth Pressure Calibration

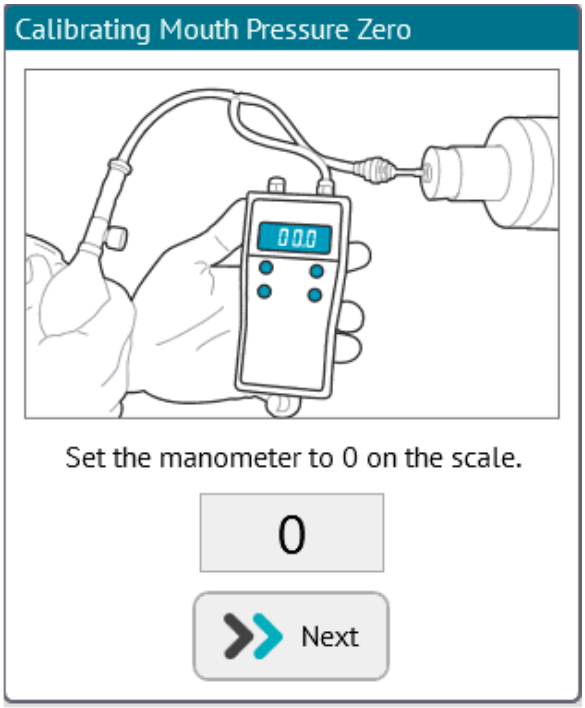
Since the Mouth Pressure transducer is so very stable, few laboratories calibrate Mouth Pressure each day. The frequency of calibration can be configured by the user by going to "Tools" then "Configuration" and "Devices". 5.5.2 Mouth Pressure Calibration

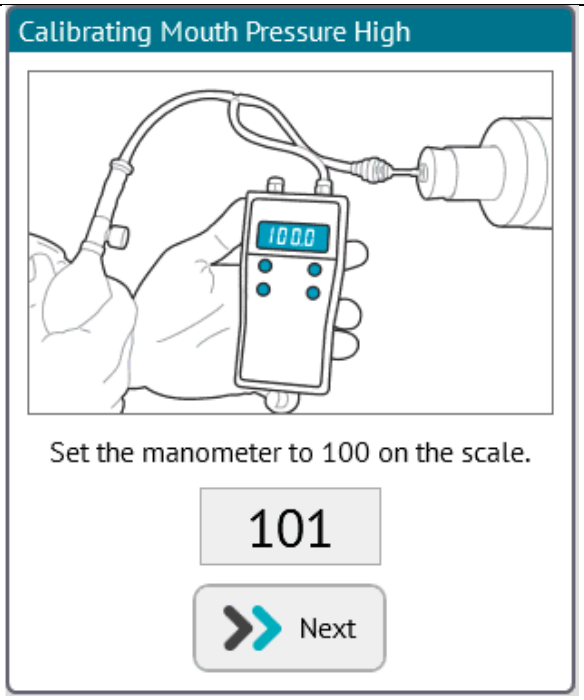
5.6.3 Performing Mouth Pressure Calibration

To enter the mouth pressure calibration section, click anywhere in the "Mouth Pressure" area:



The screen instructions will guide the user through each step:

Step 1. Set Manometer to Zero Pressure Adjust the manometer to zero on the digital display. Press [Spacebar] or click [Next] when ready.	
Step 2. Set Manometer to High Pressure Value The value used for the mouth pressure calibration point comes from the device configuration setting. In this example the setting is 100 cmH2O.	

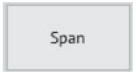
Carefully pump the manometer bulb until you obtain a reading of 100 on the digital display. Press [Spacebar] or click [Next] when complete.	

5.6.4 Mouth Pressure Span Setting

The original span setting for Mouth Pressure is usually only required when an instrument is set-up for the first time. The span teaches the software what to expect in digital response to a known pressure. For subsequent quality checks of Mouth Pressure, the master span value is used to identify any pressure readings that appear out of range, so it is important to be careful when setting the span!

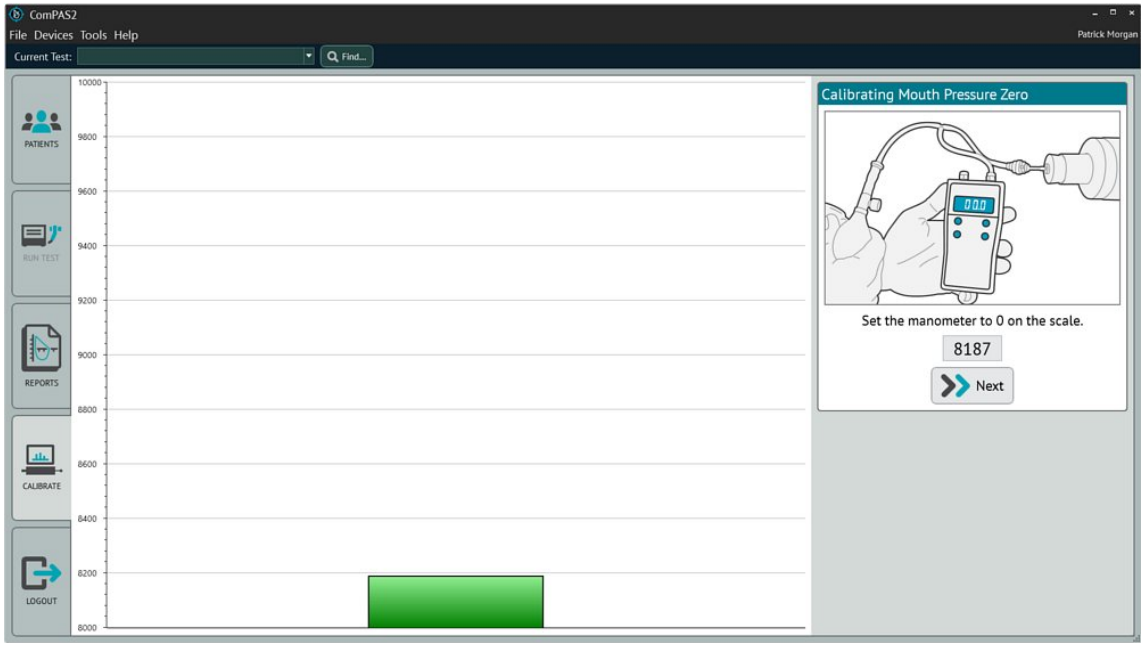
From the main calibration screen, click on the tools icon  within the Mouth Pressure graphic. This will open the Mouth Pressure calibration options screen.

5.6.5 Running a Mouth Pressure Span

Click on the  button to begin:

Step 1. Set Manometer to Zero Pressure

For span settings, attention should only be on the manometer display; at this stage the reading shown on the screen is purely a digital number.



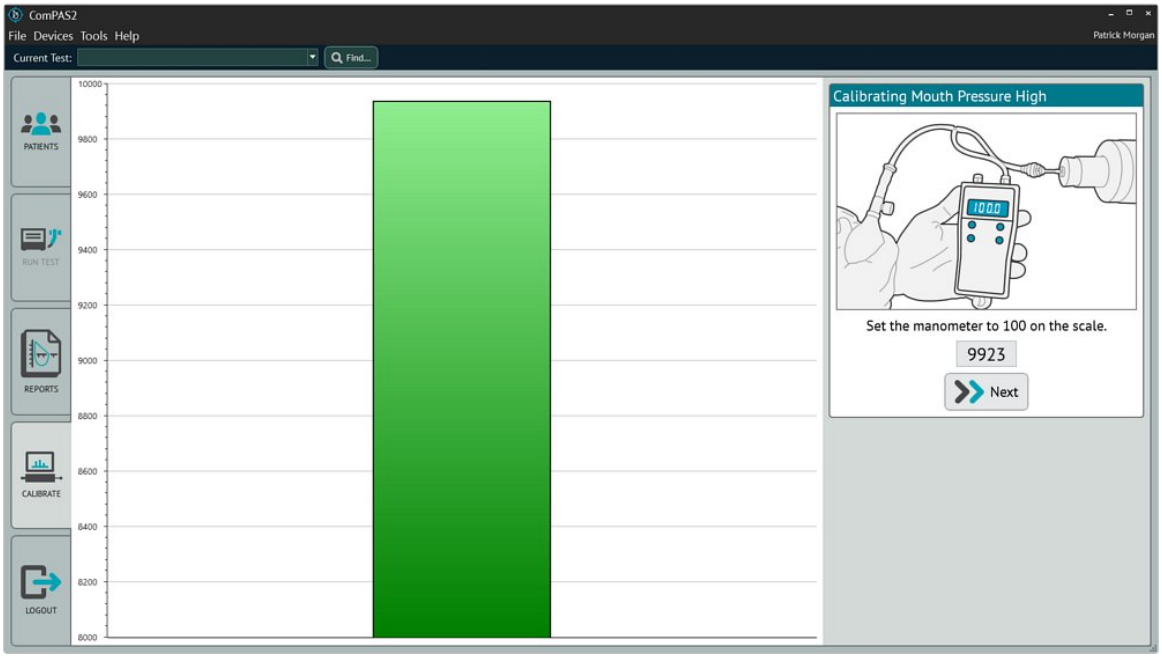
Adjust the manometer to zero on the digital display. Press [Spacebar] or click 

when ready

Step 2. Set Manometer to High Pressure Value

The value used for the mouth pressure calibration point comes from the device configuration setting. In this example the setting is 100 cmH2O.

Carefully pump the manometer bulb until you obtain a reading of 100 on the Manometer display.



Press [Spacebar] or click 

when the Manometer display reads 100.

Step 3. Performing a Mouth Pressure Quality Check

Since the master calibration span has been set, the display will indicate that the last quality check for Mouth Pressure failed:

A new Quality Check must be performed; click 

and follow the instructions. For complete details go 5.6 Mouth Pressure Calibration.

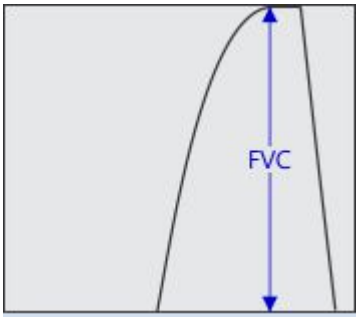
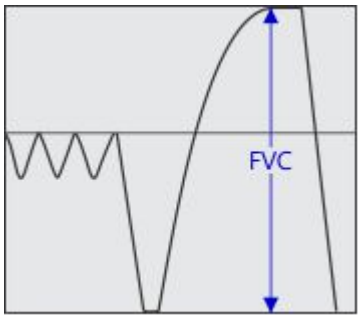
6:0 Flow Volume Loop

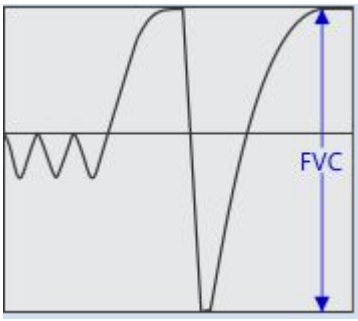
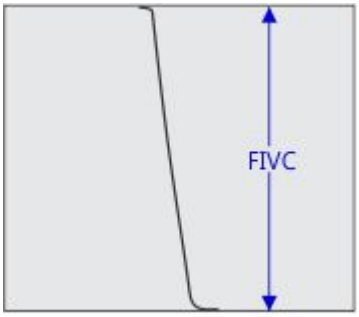
For all runtime tests within ComPAS2, there is an automatic clinical review of the patient effort and repeatability that is designed to guide the technician and help minimize the time of testing.

The testing screens present information in a direct way and are informative and simple to navigate.

6.1.1 Optional Loop Methods

The ComPAS2 software allows Flow Volume Loops or Forced Inspiratory Loops only to be completed by any method. For example:

Graphic Image	Method	Subject Instructions
	**Forced Expiration Only**	With the subject removed from the mouthpiece, ask them to: **"Take a deep breath-in as far as you can".** Make sure the subject is fully inflated to TLC, then instruct them to go onto the mouthpiece and vigorously encourage them to: **"Blast the air out as hard and as fast as you can and keep the effort going until you are completely empty".**
	**FEVC before FIVC**	Begin the test with normal breathing. Once you see a stable tidal volume, ask the subject to: **"Take a deep breath-in as far as you can".** Make sure they are fully inflated to TLC, then vigorously encourage them to: **"Blast the air out as hard and as fast as you can and keep the effort going until you are completely empty".** When the subject is completely empty, instruct them to: **"Suck the air rapidly back-in until you are full".**

Graphic Image	Method	Subject Instructions
	**FIVC before FEVC**	Begin the test with normal breathing. Once you see a stable tidal volume, ask the subject to: **"Breathe slowly all the way out until you are completely empty".** When they the subject is empty, encourage them to: **"Suck the air rapidly back-in until you are completely full".** Make sure they are fully inflated to TLC, then vigorously encourage them to: **"Blast the air out as hard and as fast as you can and keep the effort going until you are completely empty".**
	**Forced Inspiration Only**	With the subject removed from the mouthpiece, ask them to: **"Breathe out as far as possible until you are completely empty".** Make sure the subject is completely empty at RV, then instruct them to go onto the mouthpiece and vigorously: **"Suck in until you are completely full".**

6.1.2 Preparing for a Flow Volume Test

Although Flow Volume Loops are perhaps the most recognized of all pulmonary function tests, they are often measured without enough insistence on effort and repeatability. Common mistakes are not paying enough attention to patient posture when performing the maneuver, the lack of initial peak flow effort and the duration of the expiratory effort.

The ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

Preparing the Vitalograph Morgan PFT for Flow Volume Loops

1) Connect a new bacterial/viral filter; be sure to push the filter into the valve to ensure a snug fit.

2) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for Flow Volume Loops

There are two versions of the Vitalograph Morgan PFT, one using a demand valve and the other an inspiratory reservoir

1) Make sure the subject is sitting upright with both feet on the ground and is wearing a nose clip.

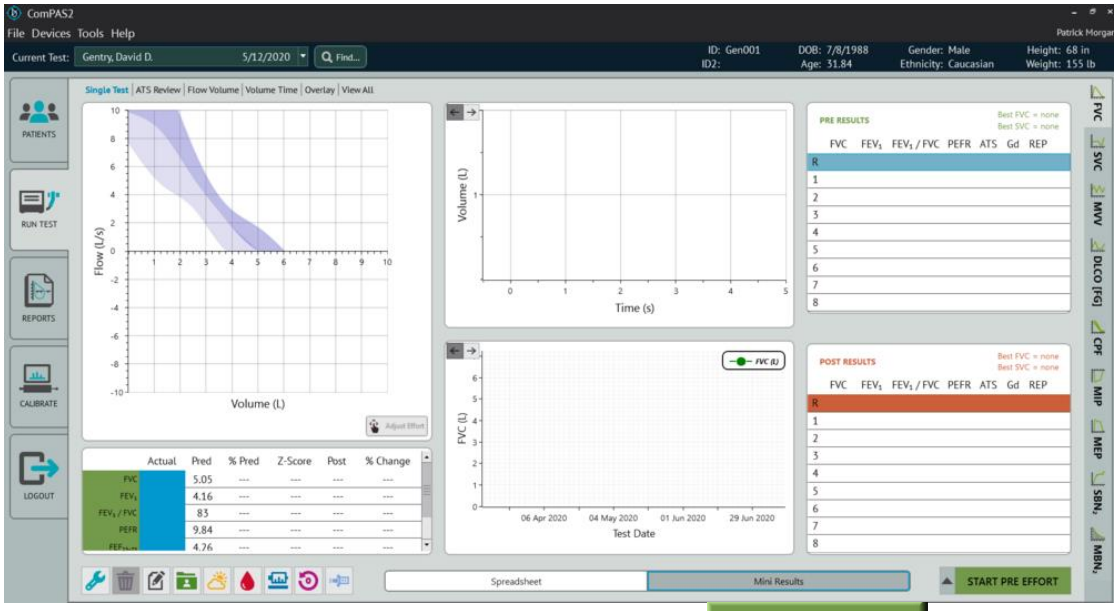
2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test; dramatically demonstrate the effort that is required!

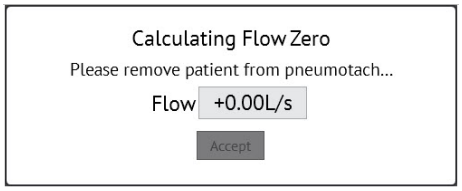
Peak Flow is so often overlooked when considering the subject's effort. The initial "blast out" must be emphasized and encouraged vigorously followed by instruction to keep breathing out until completely empty!

6.1.3 Performing Flow Volume Loops

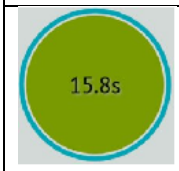
The opening screen of testing always defaults to Flow Volume in the mini results mode.



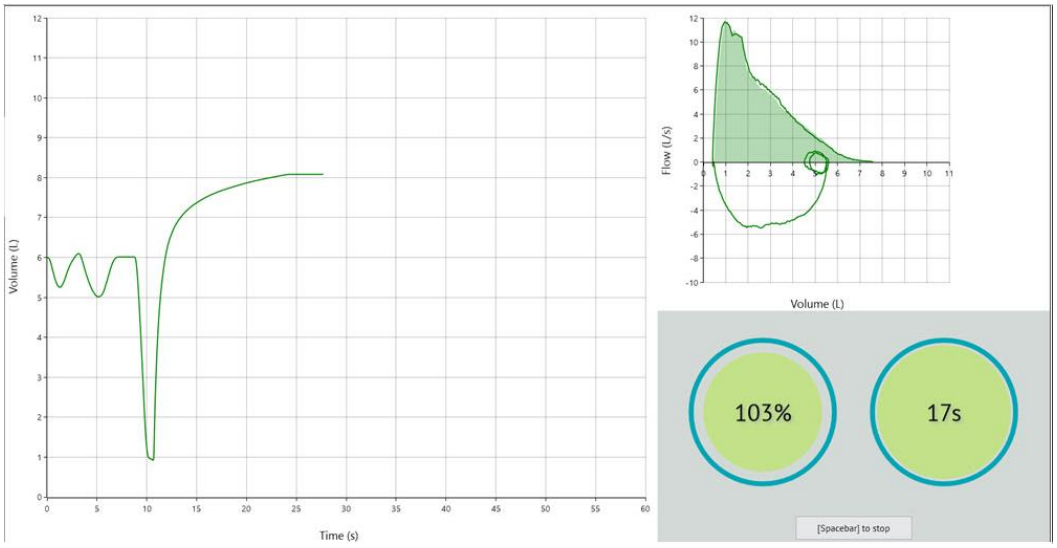
On the first test effort of a new patient, pressing [Spacebar] or clicking START PRE EFFORT will initiate a flow zero. Make sure the patient is not breathing on the flow head.



If you are interested in acquiring and storing the tidal volume with each loop, be sure to complete two or more tidal breaths before continuing the Flow Volume effort.

	During expiratory effort the left-hand %FVC Meter shows orange beyond 85% of FVC and turns green when the volume is within 150ml of best effort. If no historical data exists, on the very first FVC effort, the %FVC meter displays in real time the FVC compared to predicted value. If past test data exists, the meter will compare to the best last recorded FVC. On subsequent tests the meter will display in real-time the FVC compared to the best FVC achieved in this testing session. As FVC is improved with successive efforts, the meter target is continuously updated.
	The right-hand, End of Forced Expiration Meter is useful in seeing that the expiratory effort achieves a plateau in the volume time curve. End of Forced Expiration (EOFE) criteria is a < 0.025L volume change over 1 second duration. If desired, the EOFE criteria can be configured in the configuration by clicking on “Testing”. Further to the visual indication of a plateau, audible beeps can be configured. A single beep can be sounded when a plateau in the volume time is reached. A double beep can be sounded when 15 seconds of expiratory effort has been reached.

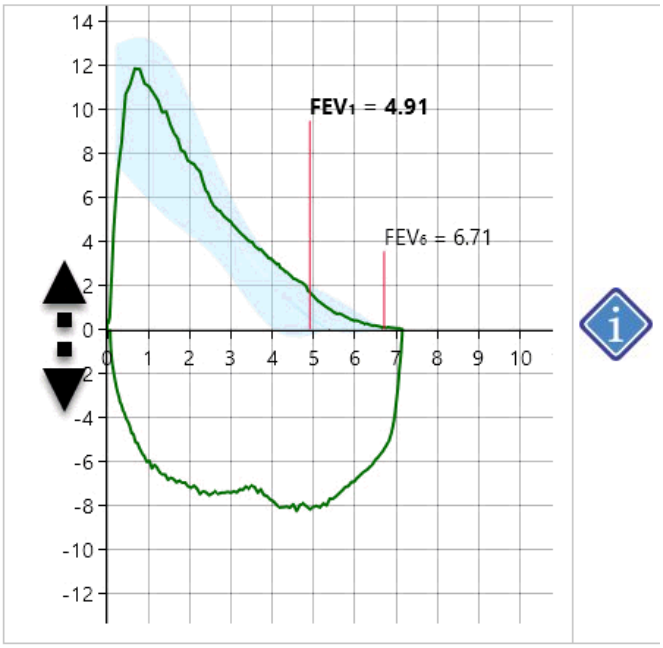
As FVC is improved with successive efforts, the meter target is continuously updated.



Once the effort is complete, click or press the [Spacebar] to end the test.

Having completed the first Flow Volume effort, on subsequent efforts a 'ghosted' image of the best flow volume loop (by ATS review) performed in the current testing session is drawn as soon as the patient fully breathes-in to TLC. The purpose of this is to terminate any sub-par efforts if the initial peak flow is inadequate.

The screen now displays the results and will determine whether or not the effort met the ATS guidelines for performing a Flow Volume Loop.



Clicking on either the F/V or V/T graphic allows re-sizing/scaling of the graphic.

Click on the left-hand axis, hold the mouse and drag up or down to change the size.

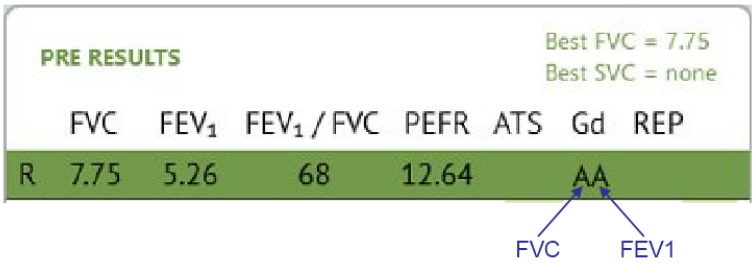
An arrow symbol appears on the graph to indicate that the user can now scale to preferred size.

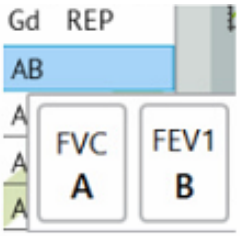
The concept behind the Mini Results Screen is to provide the technician with the key data regarding the clinical acceptability of each maneuver. As each test is evaluated, the ATS column on the right-hand side of the screen will indicate progress towards meeting the ATS testing guidelines.

6.1.4 Spirometry Grading for Flow Volume

ComPAS2 uses spirometry grading for the reported FVC and FEV1 based on the following recommendations:

Standardization of Spirometry 2019 Update - An Official American Thoracic Society and European Respiratory Society Technical Statement
Brian L. Graham, Irene Steenbruggen, Martin R. Miller, Igor Z. Barjaktarevic, Brendan G. Cooper, Graham L. Hall, Teal S. Hallstrand, David A. Kaminsky, Kevin McCarthy, Meredith C. McCormack, Cristine E. Oropez, Margaret Rosenfeld, Sanja Stanojevic, Maureen P. Swanney†, and Bruce R. Thompson; on behalf of the American Thoracic Society and the European Respiratory Society





On the mini results screen, the left-hand grade is for FVC and the right-hand grade for FEV1.

Holding the mouse over the grade and row will confirm FVC and FEV1 grades.

There are two steps in gaining a grade:

1) Individual efforts are evaluated for "Acceptability" or "Usability"

2) All efforts are then evaluated with FVC and FEV1 considered individually for "Acceptability" AND "Repeatability"

6.1.4.1 Identifying Acceptable or Usable Spirometry Efforts:

As each individual spirometry effort is concluded, it is first evaluated for "Acceptability" or "Usability". The term "Usable" defines test efforts that may be the best a test subject can manage; they do not meet the acceptability requirements but may still be clinically useful.

The quality criteria for FVC and FEV1 are the same with one exception. The definition of an acceptable effort for FEV1 does not consider anything after the first second, whereas FVC does. The adult quality criteria extend to children age 7 or greater.

The evaluations used to separate "Acceptable" and "Usable" are summarized in the table below:

Summary of Acceptability, Usability and Repeatability Criteria for FEV1 and FVC				
	Acceptability		Usability	
Acceptability and Usability Criterion:	FEV1	FVC	FEV1	FVC
Must have BEV <= 5% of FVC or 0.100 L whichever is greater	Yes	Yes	Yes	Yes
Must have no evidence of a faulty zero-flow setting	Yes	Yes	Yes	Yes
Must have no cough in the first second of expiration	Yes	No	Yes	No
Must have no glottic closure in the first second of expiration	Yes	Yes	Yes	Yes
Must have no glottic closure after 1 second of expiration	No	Yes	No	No
Must achieve one of these three EOFE indicators:	No	Yes	No	No
1. Expiratory plateau (<= 0.025 L in last 1 second of expiration)				
2. Expiratory time >= 15 seconds				
3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC				
Must have no evidence of obstructed mouthpiece or spirometer	Yes	Yes	No	No
Must have no evidence of a leak	Yes	Yes	No	No
If the maximal inspiration after EOFE is greater than FVC, then FIVC-FVC must be <= 0.100 L or 5% of FVC, whichever is greater	Yes	Yes	No	No

6.1.4.2 Final Grading of the test effort using FVC and FEV1:

For each test effort and row, FVC and FEV1 are graded separately.

The key consideration here, is that the grading combines acceptability and repeatability and must consider data across all efforts.

On the very first effort, the grade for FVC and FEV1 will always show **EE** unless the effort is so poor that it gains an **F**. This is because there is only a single effort to consider for the repeatability grade.

As each effort is evaluated and saved, the grades will change on each row reflecting the progress towards a final reported grade for FVC and FEV1 individually. Based upon the recommended table below, the grade column could show for example "**AA**" or "**BA**" and so on.

Grade	Acceptance Criteria for FVC and FEV1 Individually
A	≥ 3 acceptable tests with repeatability within 0.150 L For age 2–6, 0.100 L, or 10% of highest value, whichever is greater
B	≥ 2 acceptable tests with repeatability within 0.150 L For age 2–6, 0.100 L, or 10% of highest value, whichever is greater
C	≥ 2 acceptable tests with repeatability within 0.200 L For age 2–6, 0.150 L, or 10% of highest value, whichever is greater
D	≥ 2 acceptable tests with repeatability within 0.250 L For age 2–6, 0.200 L, or 10% of highest value, whichever is greater
E	One acceptable test
U	No acceptable tests AND ≥1 usable
F	No acceptable tests

*It should be noted that a grade of "**BB**" meets previous ATS/ERS recommendations for repeatability. As regards lower grades, the following statement is made by the ATS/ERS:*

<u>Reporting recommendations from the paper state:</u>
*"In general, tests with a grade of **A**, **B**, or **C** are usable; tests with grade **D** are suspect; tests with grade **E** might be used by the interpreter only to show values "within the normal range" or "at least as high as," without demonstrated repeatability; and tests with grade **F** should not be used."*

When ATS/ERS repeatability shows an **A** grade for both FVC and FEV1, a large solid check-mark is 'ghosted' behind all the data.

When ATS/ERS repeatability shows a **B** grade for both FVC and FEV1, a large hollow check-mark is 'ghosted' behind all the data.

<table>
<tr>
<td>

PRE RESULTS

Best FVC = 7.37
Best SVC = 7.52

	FVC	FEV_1	FEV_1 / FVC	PEFR	ATS	Gd	REP
R	7.37	5.06	69	11.95		AB	
1	7.16	4.70	66	12.26		DE	
2	7.30	5.06	69	11.95		AB	EXP
3	7.37	4.80	65	11.55		AE	INS
4	7.35	5.00	68	11.48		AB	
5							
6							
7							
8							

</td>
<td>

PRE RESULTS

Best FVC = 7.38
Best SVC = 7.52

	FVC	FEV_1	FEV_1 / FVC	PEFR	ATS	Gd	REP
R	7.38	5.06	69	11.95		AA	
1	7.16	4.70	66	12.26		DE	
2	7.38	4.98	67	11.82		AA	EXP INS
3	7.37	4.80	65	11.55		AE	
4	7.35	5.00	68	11.48		AA	
5	7.30	5.06	69	11.95		AA	
6							
7							
8							

</td>
</tr>
<tr>
<td>

Having Met **B** Grades for both FVC and FEV1
OR
Having an **A** and a **B** Grade for either FVC or FEV1

(≥ 2 acceptable tests with repeatability within 0.150 L)

</td>
<td>

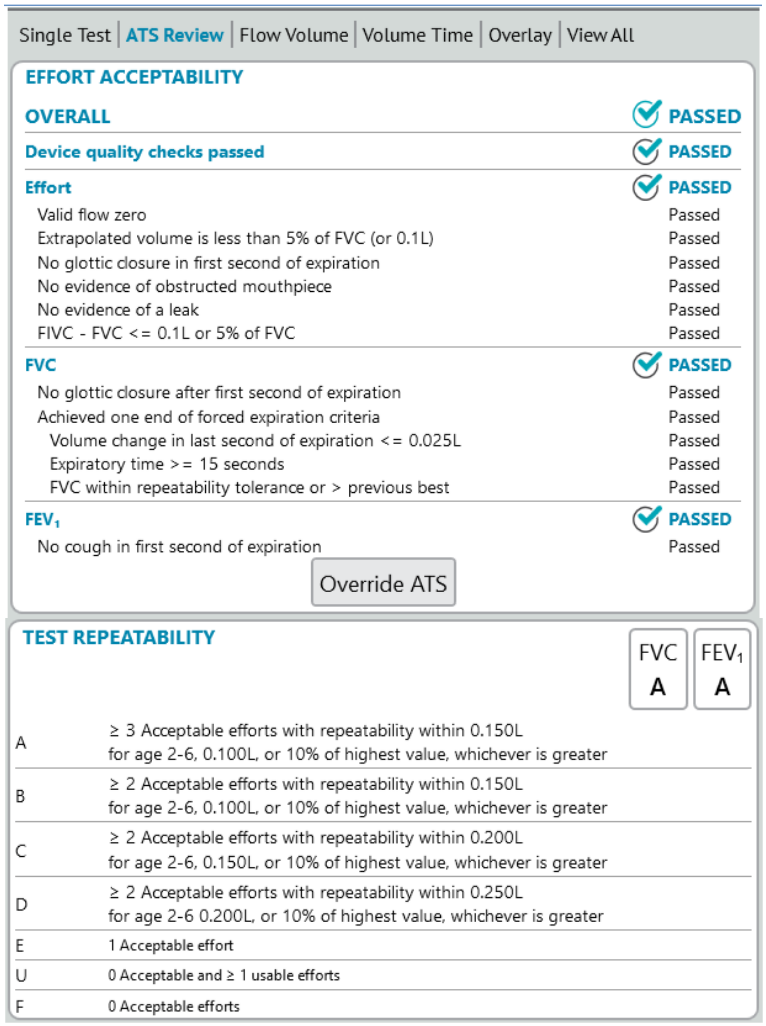
Having Met **A** Grades for both FVC and FEV1

(≥ 3 acceptable tests with repeatability within 0.150 L)

</td>
</tr>
</table>

Clicking on the [ATS Review] tab will provide a complete summary of effort acceptability and repeatability:

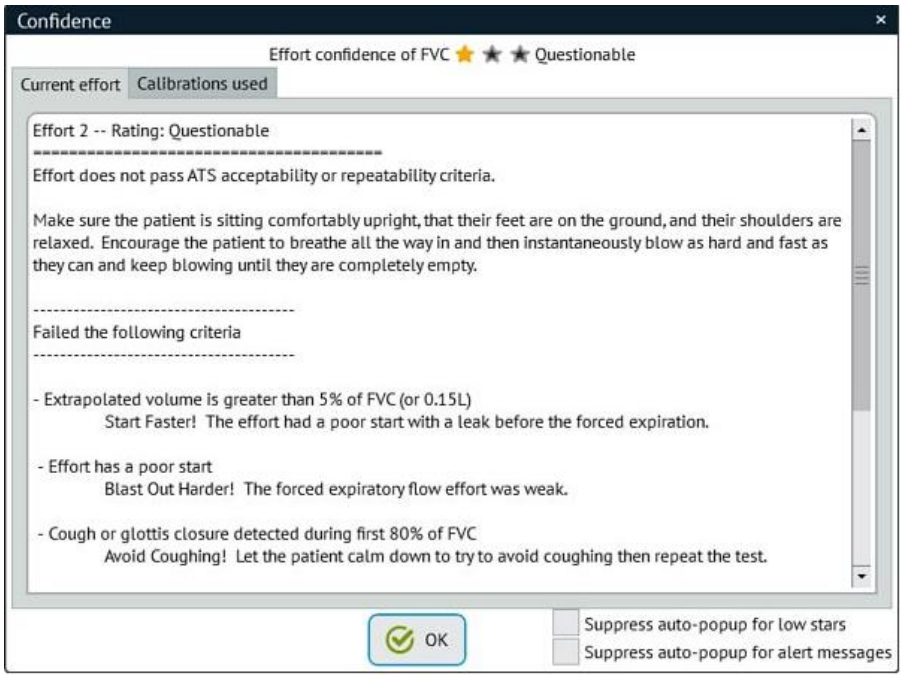
6.1.5 Spirometry Test Confidence and Common Errors



Since spirometry is such an effort dependent test, the grading system combined with ComPAS2 "Confidence" messages are provided to help ensure good quality and clinically useful data. Several errors are commonly made when recording spirometry:

#	Common Performance Errors	Result
1	Failure to start from the true total lung capacity (TLC)	The forced expiratory volume in one second (FEV1), peak expiratory flow (PEFR) and forced vital capacity (FVC) will be low.
2	A Failure to continue to the true end of expiration	FVC will be low, FEV1/FVC ratio will be falsely high.
3	A Failure to reach or achieve the best PEFR	FEV1 can be increased, FEV1/FVC ratio can be falsely low.
4	A leak at the mouthpiece	PEFR will be low and FEV1 and FVC may also be low.
5	A hesitation in blowing out before the initial blast	A large extrapolated volume can falsely elevate FEV1, though occasionally the FEV1 may be reduced.
6	A poor or weak initial blast out	Will falsely reduce PEFR, FEV1 and FEV1/FVC ratio.

If any of these errors (or others) are detected by ComPAS2, a test confidence message is presented to the user:

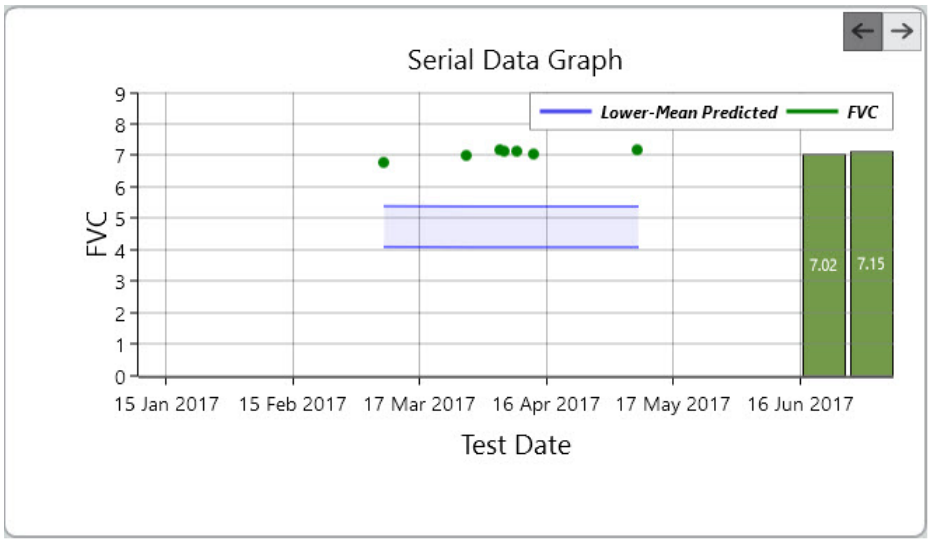


The Test Confidence goes beyond ATS/ERS acceptability criteria and utilizes years of pulmonary function testing experience and knowledge of experts in the field.

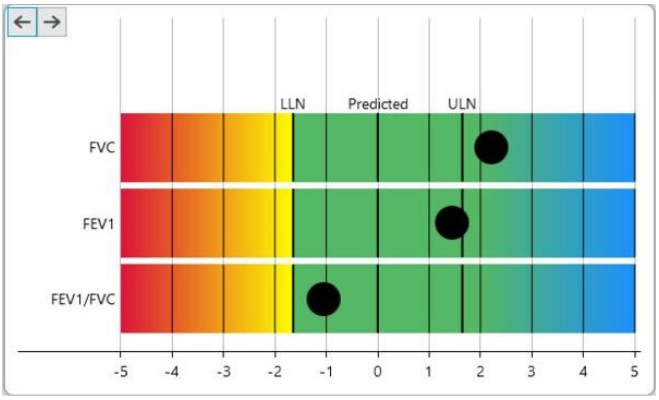
6.1.6 Spirometry History and Z-Score Display

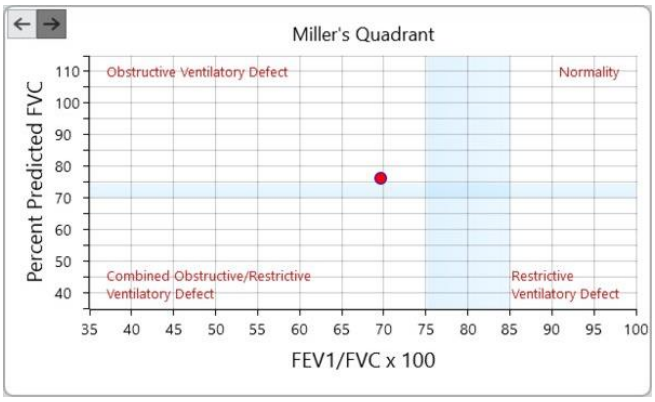
For subjects that are returning for tests, the instant view of current test results compared to previous can be a helpful training and incentive to explain effort.

Toggling between the graphic options is achieved by clicking the  arrow keys.



A helpful series of graphics are available for instant review during testing; they include serial data, Z-score profile and the Miller's Quadrant plot.



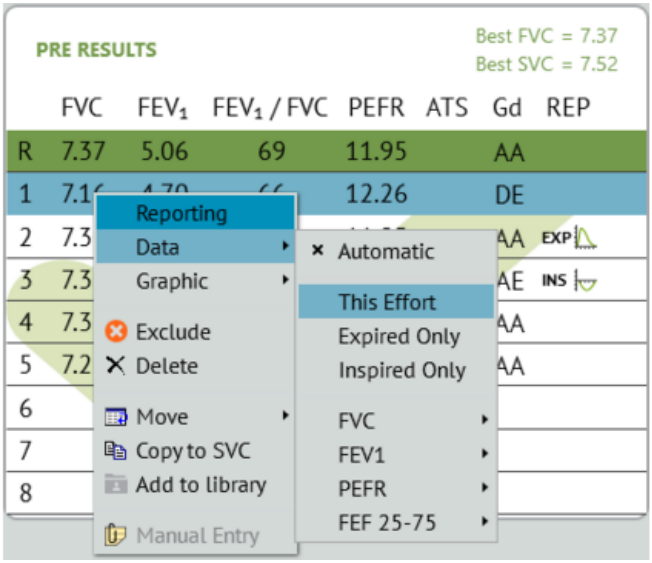


To repeat a test effort, simply click or press [Spacebar]. Once each test is concluded, it is reviewed and posted on the "Mini Results" screen. When three efforts pass the individual effort criteria then repeatability is evaluated. The hollow green check-marks become solid and a large 'ghosted' check is drawn in the results box to indicate that both individual effort and repeatability have been met.

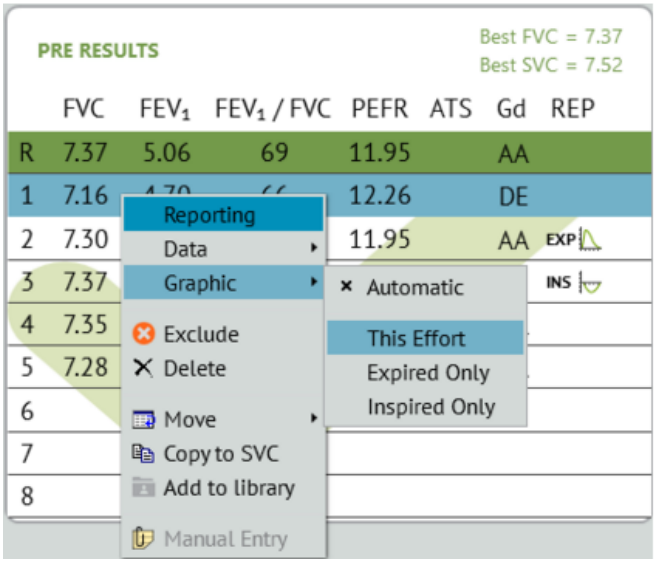
6.1.7 Manual Selection of Loop Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. Selection of data within ComPAS2 is very versatile providing both automatic selections based on ATS recommendations and also user control and selection of both data and graphical information. This is rarely required, but in difficult cases the technician may feel that the flow volume graphic coming from the test with the highest sum of FVC and FEV1 may not represent the best patient effort. In some cases, a larger FVC (or FEV1, PEFR or FEF25-75) may not come from an acceptable maneuver, but you want that individual value reported anyway.

Through use of the right-click functions, the technician can individually select the data and loop preferred for the final report.



Manual Selection of Test Data



Manual Selection of Test Graphic

For data, the user selected choices are:

User Choice	Explanation
Automatic	This will use the ATS selection automatically set by ComPAS2
This Effort	Use this to select all data for reporting
Expired Only	Use this to select the expiratory data for reporting
Inspired Only	Use this to select the inspiratory data for reporting
This FVC	Override the automatic choice and report this FVC
This FEV1	Override the automatic choice and report this FEV1
This PEFR	Override the automatic choice and report this PEFR
This FEF25-75	Override the automatic choice and report this FEF25-75

For Graphical choices, the user selections are:

User Choice	Explanation
Automatic	This will use the ATS selection automatically set by ComPAS2
This Effort	Use this to select the full graphic for reporting
Expired Only	Use this to select the expiratory graphic for reporting
Inspired Only	Use this to select the inspiratory graphic for reporting

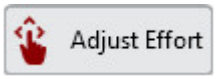
EXP INS 	Automatically selected full flow volume graphic and data	This identifies the effort where both the flow volume data and the full flow volume graphic that will be printed on the final report are coming from
	Automatically selected full flow volume graphic	This identifies the full flow volume graphic that will be printed on the final report is coming from
EXP INS	Automatically selected full flow volume data	This identifies the effort where flow volume data that will be printed on the final report are coming from
EXP 	Automatically selected expiratory flow volume graphic and data	This identifies the effort where the expiratory flow volume data and the expired flow volume graphic are coming from that will be printed on the final report

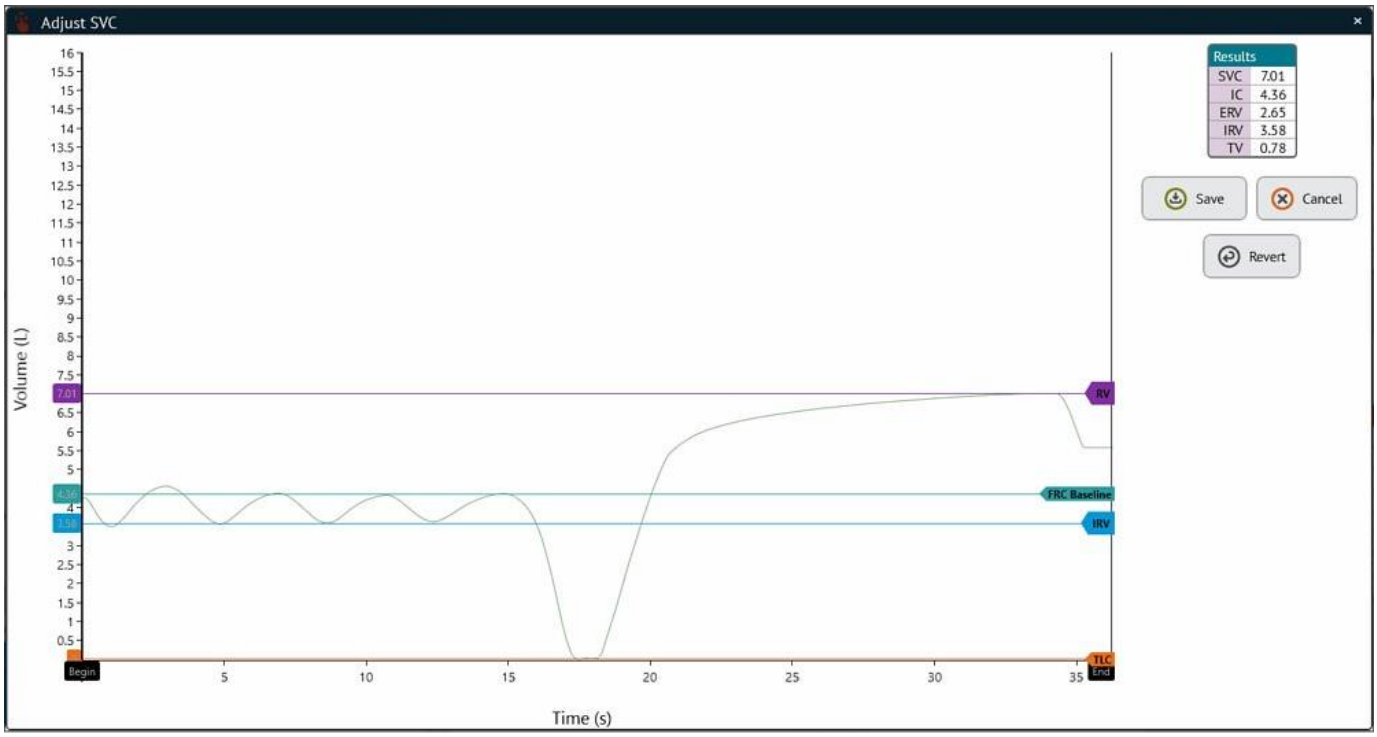
INS	Automatically selected inspiratory flow volume graphic and data	This identifies the effort where the inspiratory flow volume data and the inspiratory flow volume graphic are coming from that will be printed on the final report
	Data and graphic from a 3L syringe	This identifies the use of a 3L syringe. If the syringe icon is displayed, the data are recorded with a BTPS of 1.0

Selection icons under the REP column shown in **red** indicate technician selection of data or graphic.

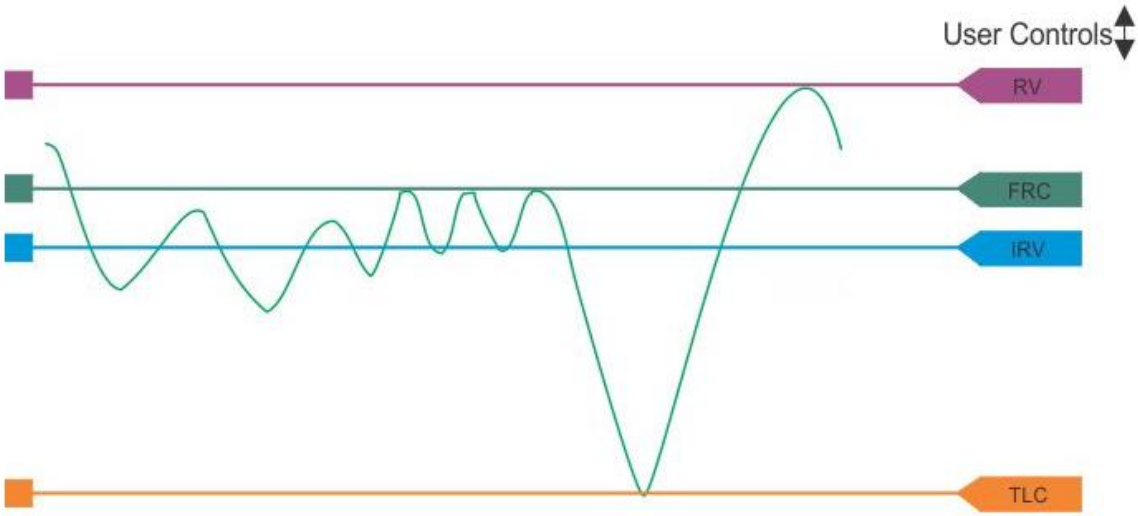
EXP INS	Technician selected full flow volume graphic and data	This identifies the technician selected effort where both the flow volume data and the full flow volume graphic that will be printed on the final report are coming from
EXP INS	Technician selected full flow volume data	This identifies the technician selected effort where flow volume data that will be printed on the final report are coming from
EXP	Technician selected expiratory flow volume data	This identifies the technician selected effort where expiratory flow volume data that will be printed on the final report are coming from
INS	Technician selected inspiratory flow volume data	This identifies the technician selected effort where inspiratory flow volume data that will be printed on the final report are coming from
	Technician selected full flow volume graphic	This identifies the technician selected full flow volume graphic that will be printed on the final report is coming from
	Technician selected expiratory flow volume graphic	This identifies the technician selected effort where the expired flow volume graphic is coming from that will be printed on the final report
	Technician selected inspiratory flow volume graphic	This identifies the technician selected effort where the inspired flow volume graphic is coming from that will be printed on the final report
PEFR	Technician selected PEFR	Individual data (either FVC, FEV1, PEFR or FEF25-75) shown in red identifies the technician selection.

6.1.8 Adjusting the FRC Baseline and Loop Cropping

Once an FVC test is completed, the computer will look at the Tidal Volume data and establish automatically where it considers the FRC Baseline to be. If you want to change the position of the baseline, click on 



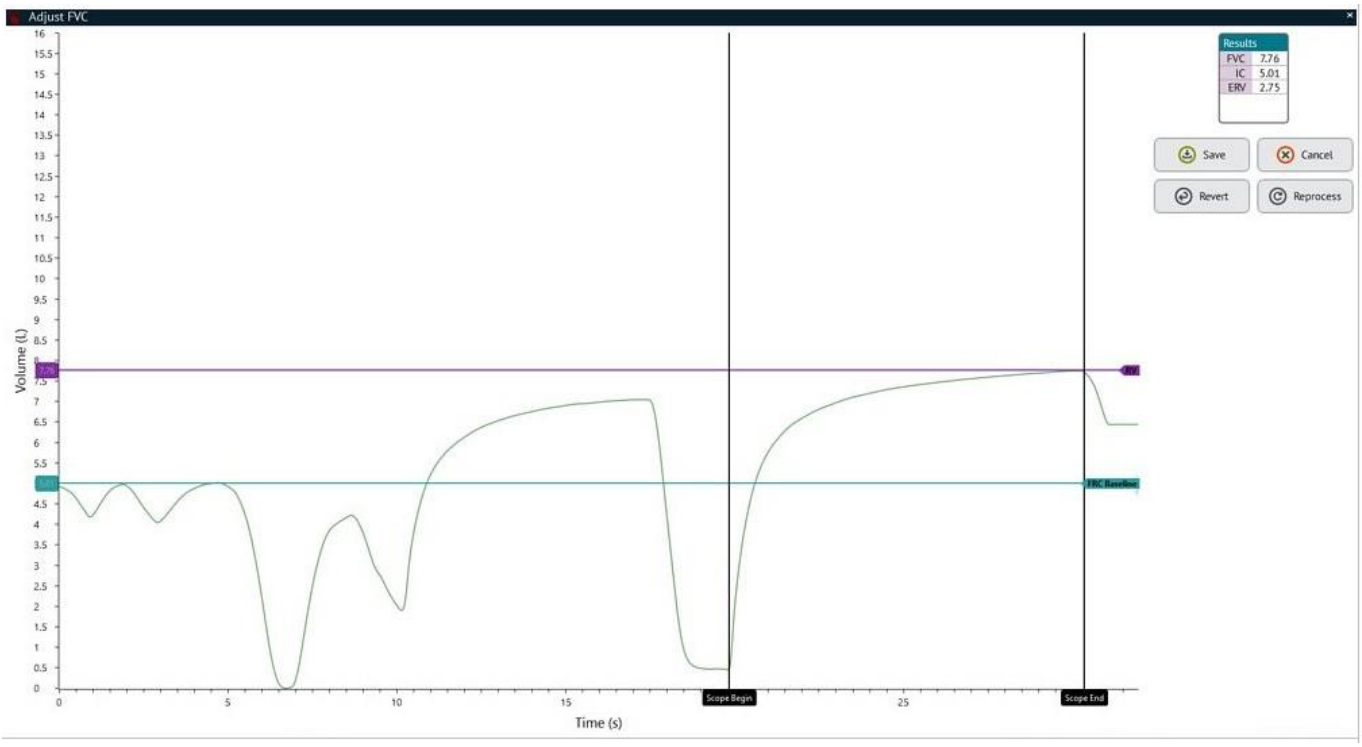
To move a computed position for FRC baseline, TLC, RV or IRV to a preferred location, simply left-click the desired pointer and drag to a new position.

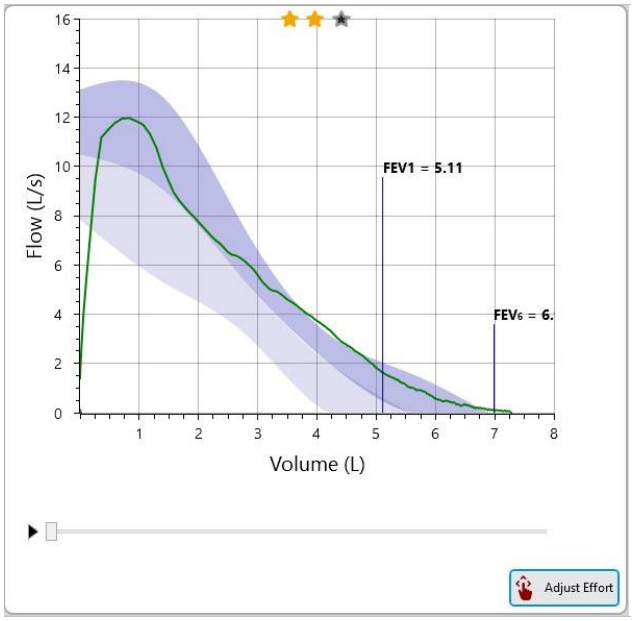


A further adjustment or edit can be made to the flow volume loop by employing the "Scope" controls.

By adjusting the vertical **[Scope Begin]** or **[Scope End]** controls, sections of the flow volume loop effort can be cropped and ignored. For example, if a test subject opens their mouth around the mouthpiece (near RV), then takes a breath in, re-seals their lips and then continues blowing out, resulting in an inaccurately high FVC.

The loop can be cropped using the **[Scope End]** control thus preserving a likely valid loop and FVC.





In rare cases, a test subject may be having extreme difficulty following instructions in the performance of a Flow Volume effort. However, out of a difficult test performance there may be useful clinical data. In the example above, adjusting the **[Scope Begin]** and **[Scope End]** controls, can capture the useful expiratory curve while ignoring all other data.

Once the new position is accepted, the lung sub-divisions will be recalculated. The user can either continue to change any position or accept the new setting. The 

button will revert all settings to the original computed positions.

If the tidal volume appears to be drifting up or down the screen rather than running parallel across the horizontal axis, it could be that either the flow zero needs adjusting or that incorrect BTPS conditions are the cause.

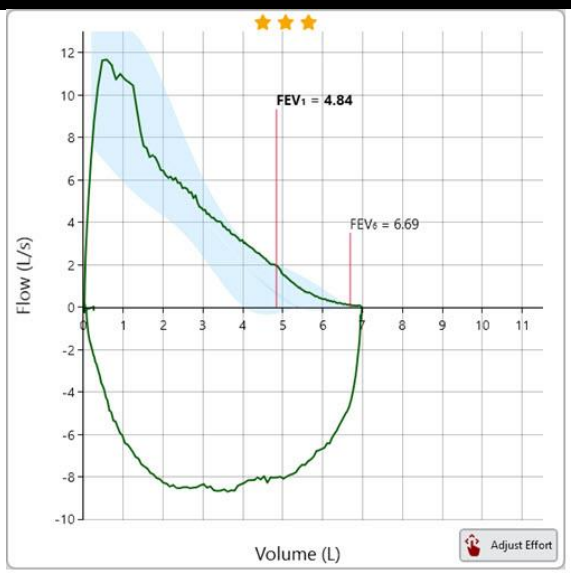
1) To check the flow zero, click on  to ensure a true flow zero has been accepted.

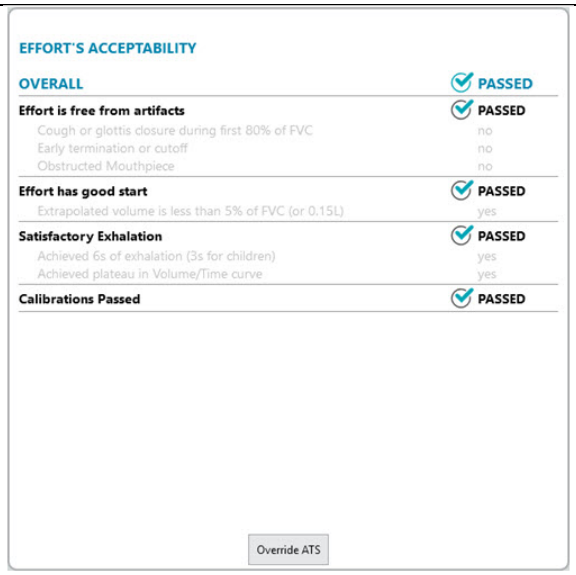
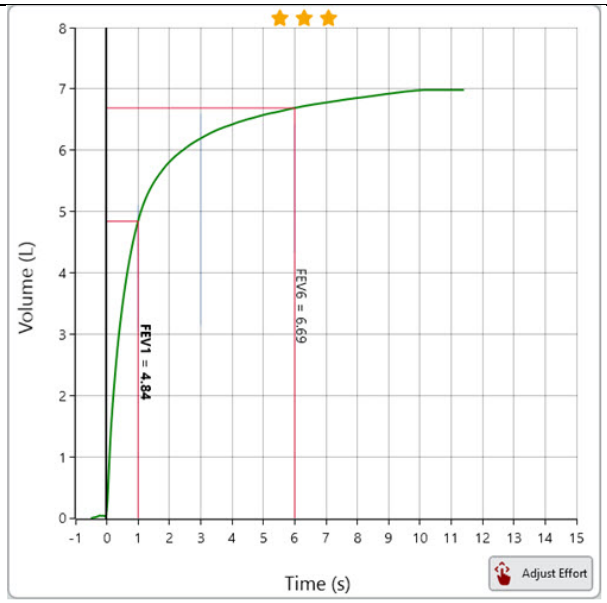
2) For BTPS errors, check that the inputs of Barometric Pressure and Temperature are correct. Click  and compare the values against an independent laboratory environmental monitor.

6.1.9 Reviewing the Flow Volume Loop Data

The "Mini Results" test screen provides key summary information on the test in progress. If you wish you see more detail of the results a variety of screens are available.

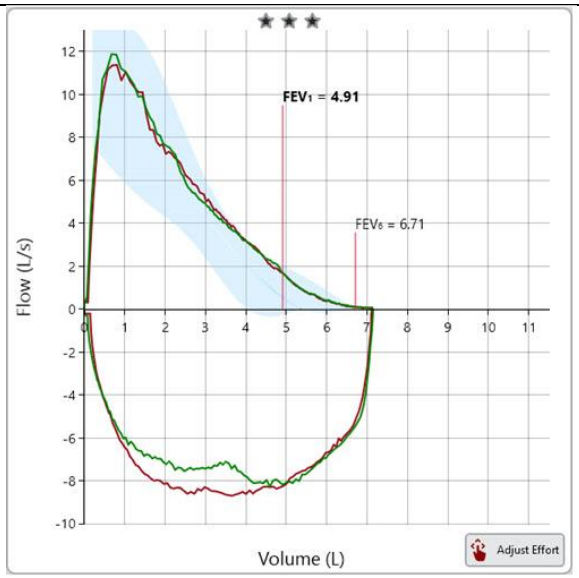
Along the top of the "Mini Results" page are a group of tabs that provide helpful review options:

[Single Test] and [Flow Volume] The default position for the tabs displays the current highlighted test effort. The Flow Volume Loop selected is drawn compared to predicted values.	
[[ATS Review] Details the clinical review of the highlighted individual test effort and also compares it against other efforts completed. There are two reviews that have are undertaken on each loop: Firstly, there is the 'Effort Acceptability" and secondly there is 'Repeatability". Effort Acceptability is how that individual effort was performed and whether an artifact was detected and if so, what was it? Repeatability compares each test against the best to ensure that three efforts fall within the accepted guidelines.	

The [Override ATS] button should only ever be used if a user wishes to negate ATS effort or repeatability consideration in reporting.	
[Volume Time] Displays a large Volume-Time graphic together with each effort overlaid. This is a very helpful display to see which efforts should be kept and which should be discarded. Sometimes the numerical data passes the recommended ATS review of effort but the Volume-Time graphic reveals a less than adequate effort. The selected effort is shown as a bolder line on the overlaid tests screen.	

[Overlay] - Example 1

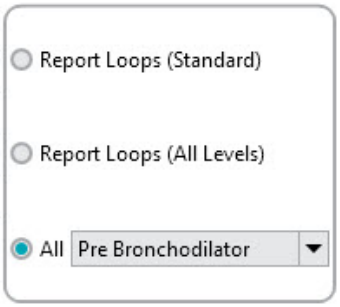
Overlays the best Pre and Post Flow Volume Loops (i.e. those currently selected to go to the final report).



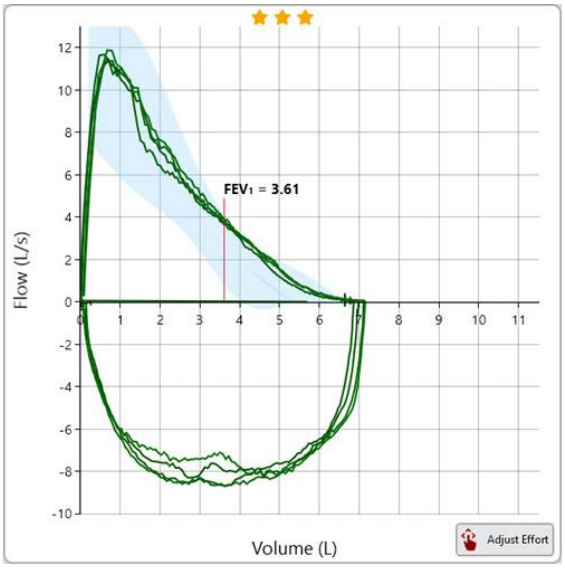
[Overlay] - Example 2

Overlaying of loop efforts can be achieved two ways:

1) By using the overlay tool.



2) By holding the [Ctrl] key and clicking on the desired efforts in the mini result table.

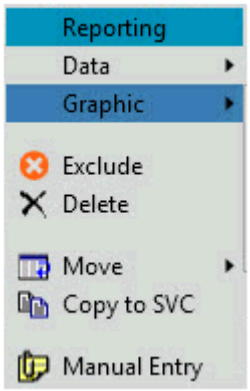


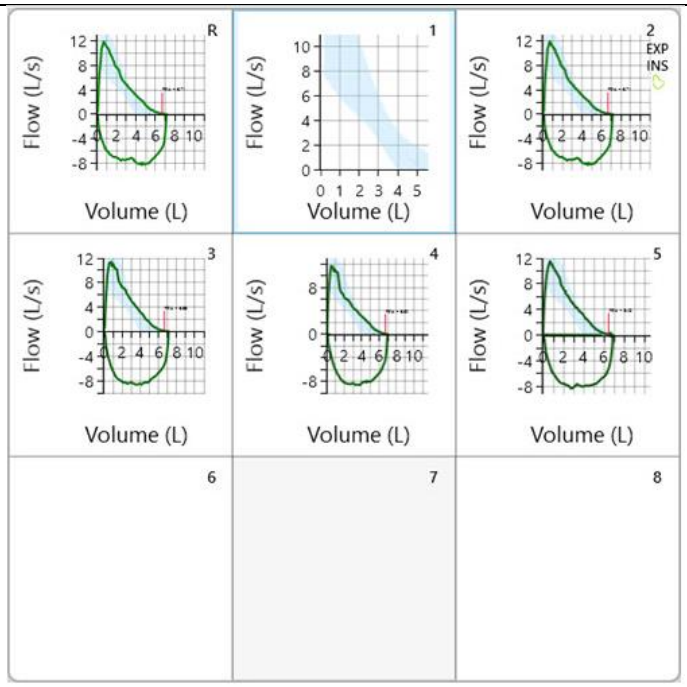
[View All]

Displays a miniature graphic of each Flow Volume Loop completed.

The currently selected effort is indicated by a green box drawn around the loop.

The same right-click functions that are available in the data view are also available here. The technician can individually select the data and loop preferred for the final report.

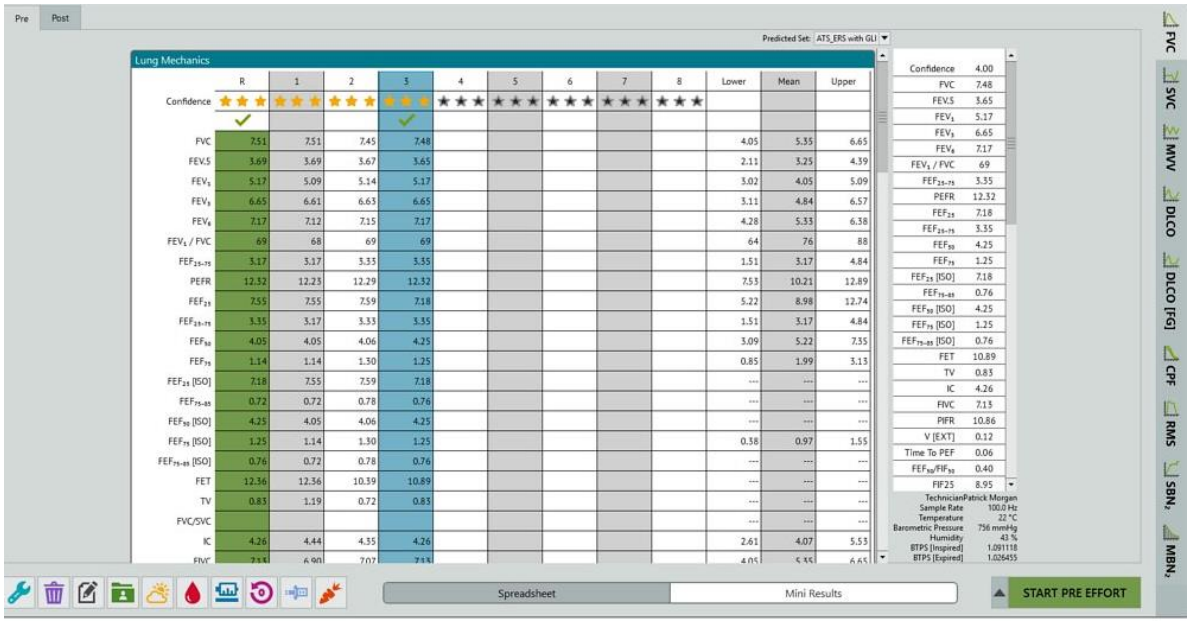




6.1.10 Reviewing the Flow Volume Spreadsheets

Although the 'Mini Results" screen can provide you with essential information when performing tests, the spreadsheet provides much greater numerical data.

Users can toggle between Spreadsheet and Mini Result views using the navigation button:



6.1.11 Incentive Spirometry Option for Children

Incentive spirometry is available within ComPAS2 to assist in the testing of children. The option must first be selected in the "Configuration" menu under Incentives.

There are a number of incentive configuration options that allow the user to set target values and graphic defaults.

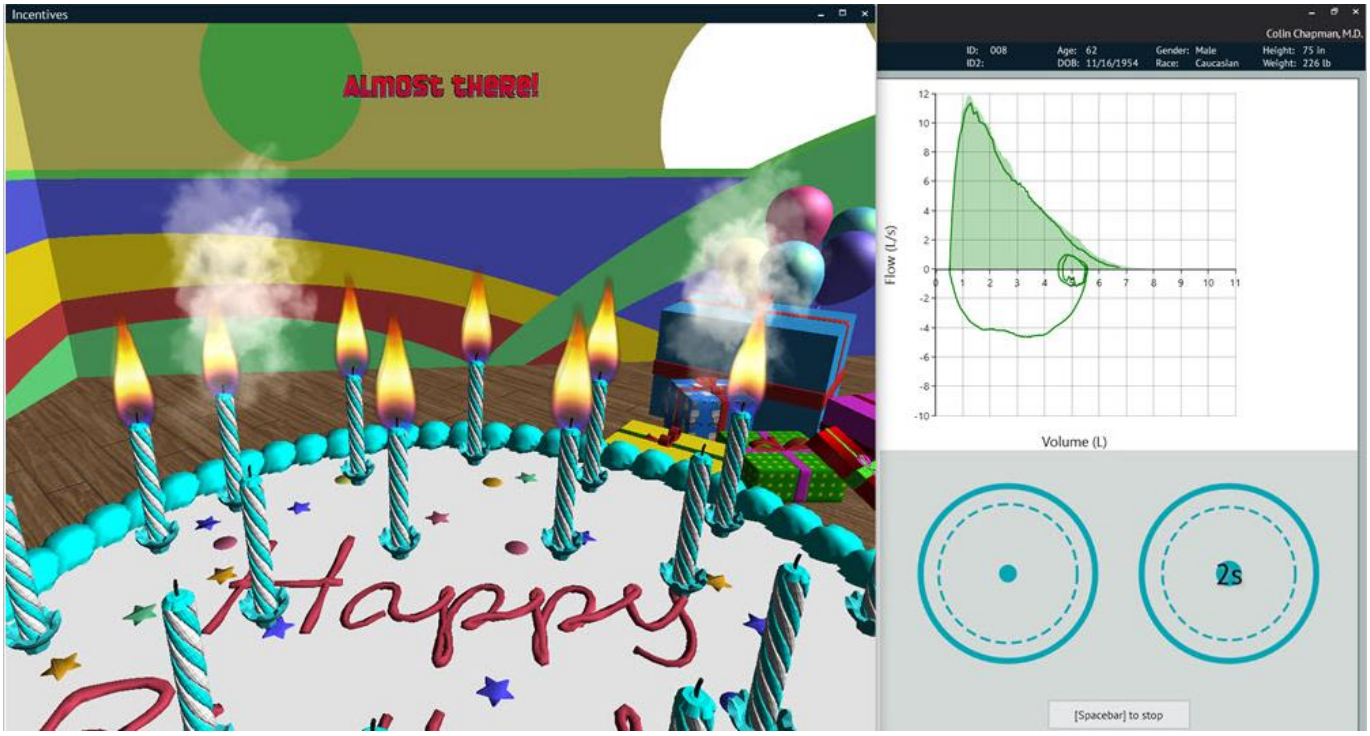
Once configured, the following icon will appear on the flow volume testing screen: 

Right- clicking on the icon will open the incentive selection. Incentive animations can be changed during testing at any time.

Typically, the settings for incentives are designed to encourage greater FVC effort from children, therefore a typical effort target is 103% of the best FVC achieved so far. In ComPAS2 the incentive screens have post-test "success" and "failure" animations which can be turned off if desired. For "success" the user can allow "end of test criteria" to be used even if the percent FVC has not been achieved.

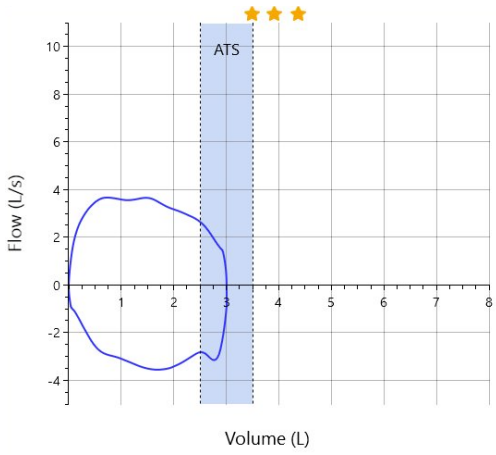
The incentive screens can 'pop forward' and be sized for optimal display.
Clicking and holding the top bar of the animation window will allow the user to move position to anywhere on the desktop. We recommend that you choose a position that allows you to see the Flow Volume effort as the animation is running.

To resize the animation window, click on any corner and drag the window to the desired size. Settings will be remembered for subsequent incentive displays.



6.1.12 Checking Accuracy of Volume During Testing with a 3L Syringe

At any time during testing, a 3L syringe can be used to verify volume accuracy. When the syringe icon  is selected, the system expects the user to be using a 3L syringe. The flow volume graphic is drawn in blue and BTPS conditions are set to 1.0. The test graphic shows the result of the syringe stroke and displays the ATS acceptability range for volume +/- 2.5% around 3L.

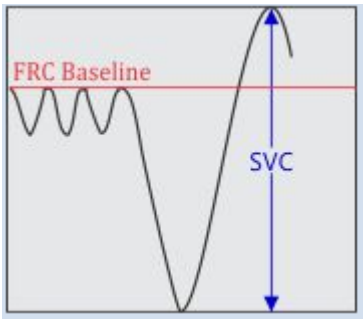
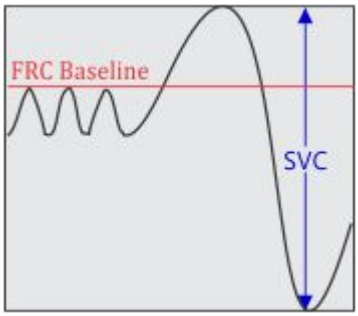


6.2 Slow Vital Capacity (SVC)

6.2.1 Optional Slow Vital Capacity Methods

The ComPAS2 software allows the Slow Vital Capacity to be completed by either method.

For example:

Graphic Image	Method	Subject Instructions
	**Tidal breathing then:** **Slow inspiration followed by slow expiration**	Begin the test with normal tidal breathing. Once three or more stable tidal breaths have been recorded, ask the subject to: **"take a steady deep breath-in as far as you can".** Make sure they are fully inflated at TLC, then encourage them to: **"blow steadily out and keep the effort going until you are completely empty".** Once the full expiration is reached the subject can relax and come off the mouthpiece
	**Tidal breathing then:** **Slow expiration followed by slow inspiration**	Begin the test with normal tidal breathing. Once three or more stable tidal breaths have been recorded, ask the subject to: **"breathe slowly all the way out until you are completely empty".** When they are empty, encourage them to: **"breathe steadily back-in until you are completely full".** Make sure they are fully inflated at TLC. Once the full inspiration is reached the subject can relax and come off the mouthpiece.

6.2.2 Preparing for a Slow Vital Capacity Test

The ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

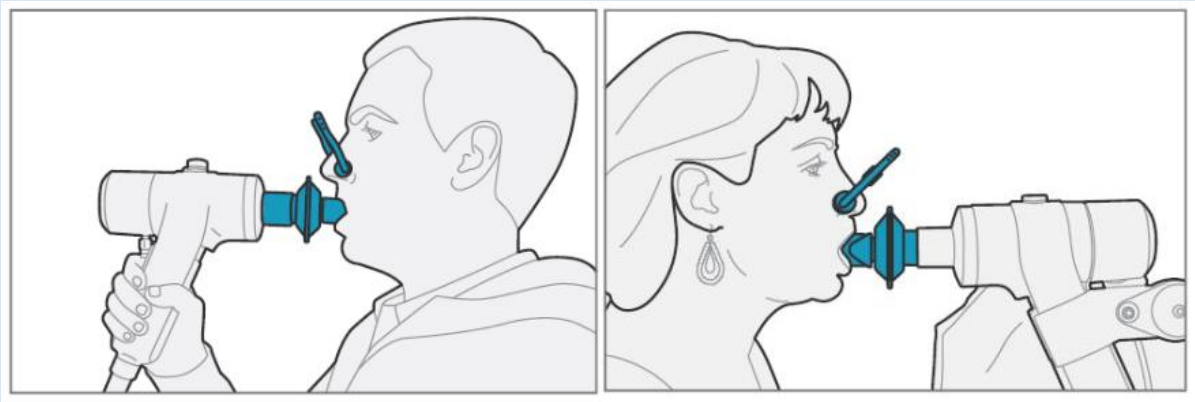
Preparing the Vitalograph Morgan PFT for Slow Vital Capacity

1) Connect a new bacterial/viral filter; be sure to push the filter into the valve to ensure a snug fit.

2) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for Slow Vital Capacity

There are two versions of the Vitalograph Morgan PFT, one using a demand valve and the other an inspiratory reservoir



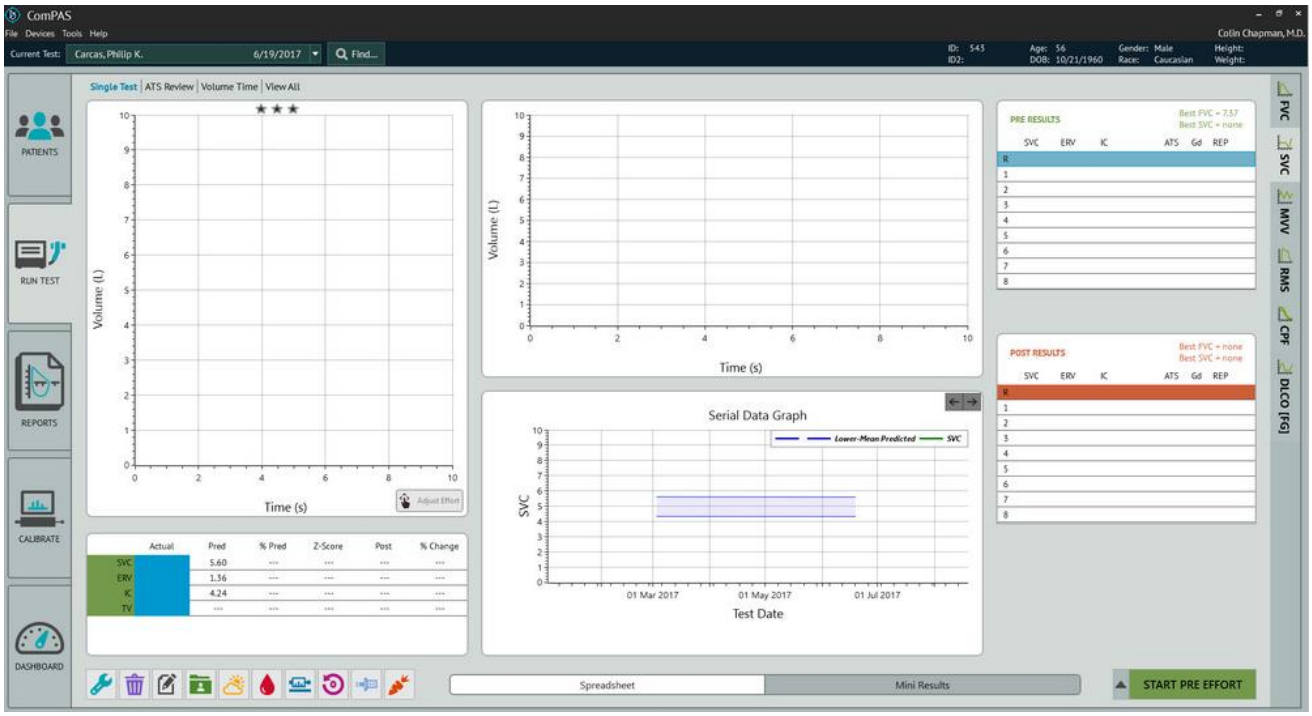
1) Make sure the subject is sitting upright with both feet on the ground and is wearing a nose clip.

2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

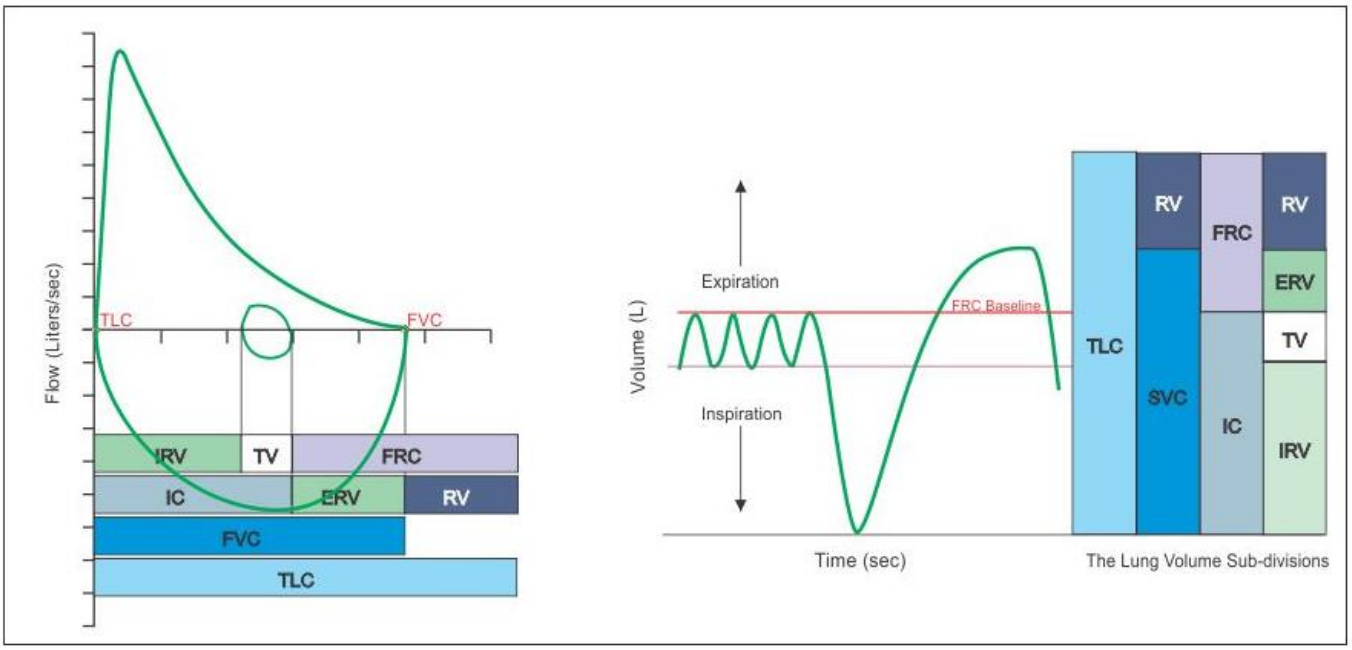
3) Instruct the subject about the performance of the test; dramatically demonstrate the effort that is required!

6.2.3 Performing Slow Vital Capacity

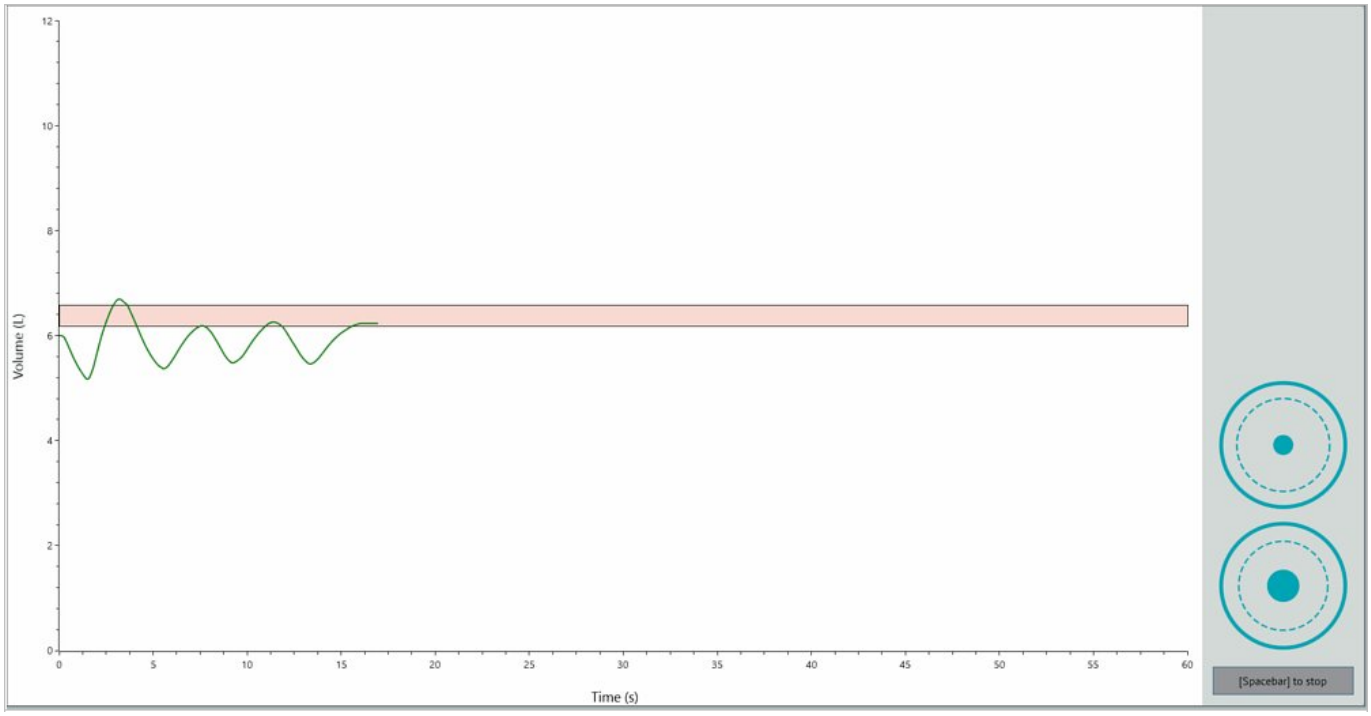
The opening screen of testing always defaults to Flow Volume in the mini results mode.



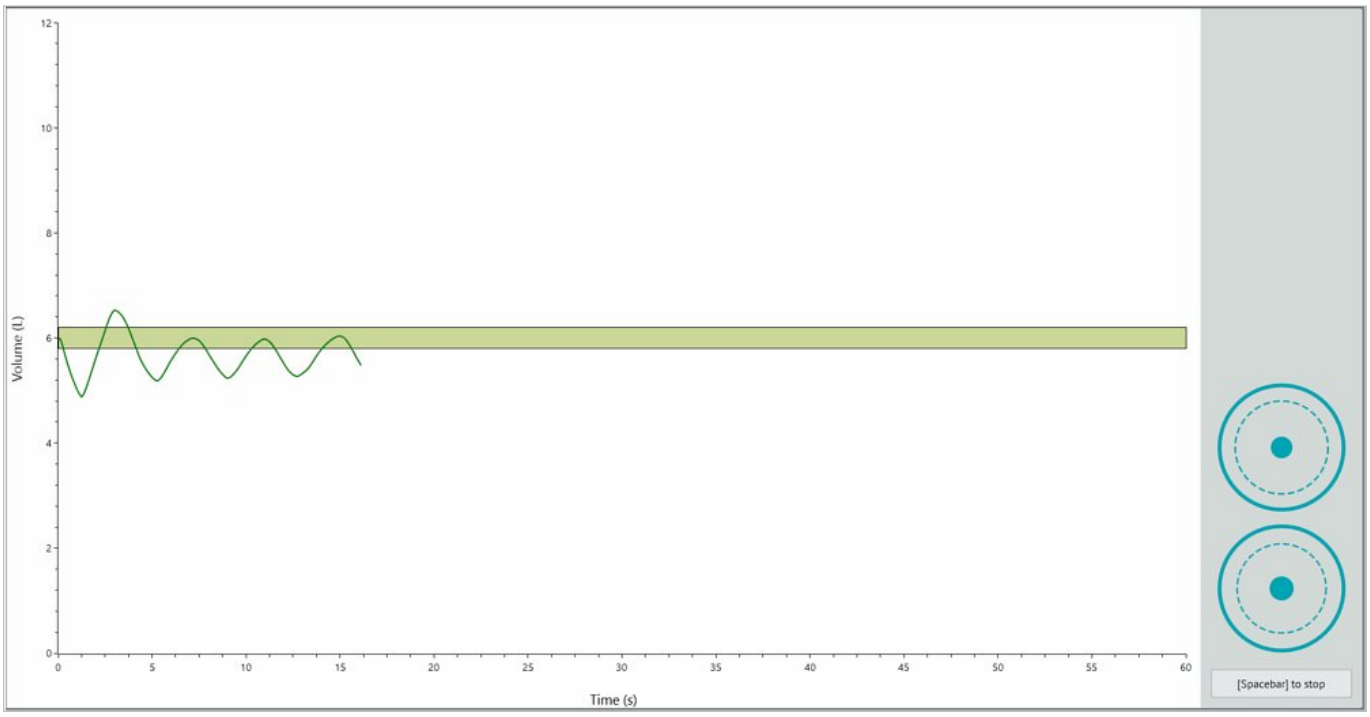
Since the lung sub-divisions of Expiratory Reserve Volume (ERV) and Inspiratory Capacity (IC) are going to be measured during this test, it is very important to first insist that the patient is sitting upright and secondly that a stable tidal volume be established before continuing.



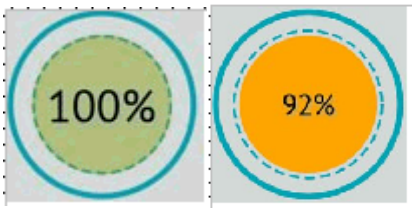
To run the test, click or press the [Spacebar] and watch for three or more steady quiet stable tidal breaths. A helpful guide moves with each tidal breath to look for repeatable end-tidal positions; when 3 or more show stability the bar turns green to indicate that the full SVC maneuver can commence.



Once FRC has been established the indicator bar turns green:

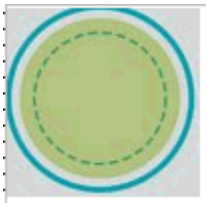


Once a full inspiration is completed, two meters guide the user to ensure quality measurement:



During expiratory effort the top %VC Meter shows orange beyond 85% of VC and turns green when the volume is within 150ml of best effort.

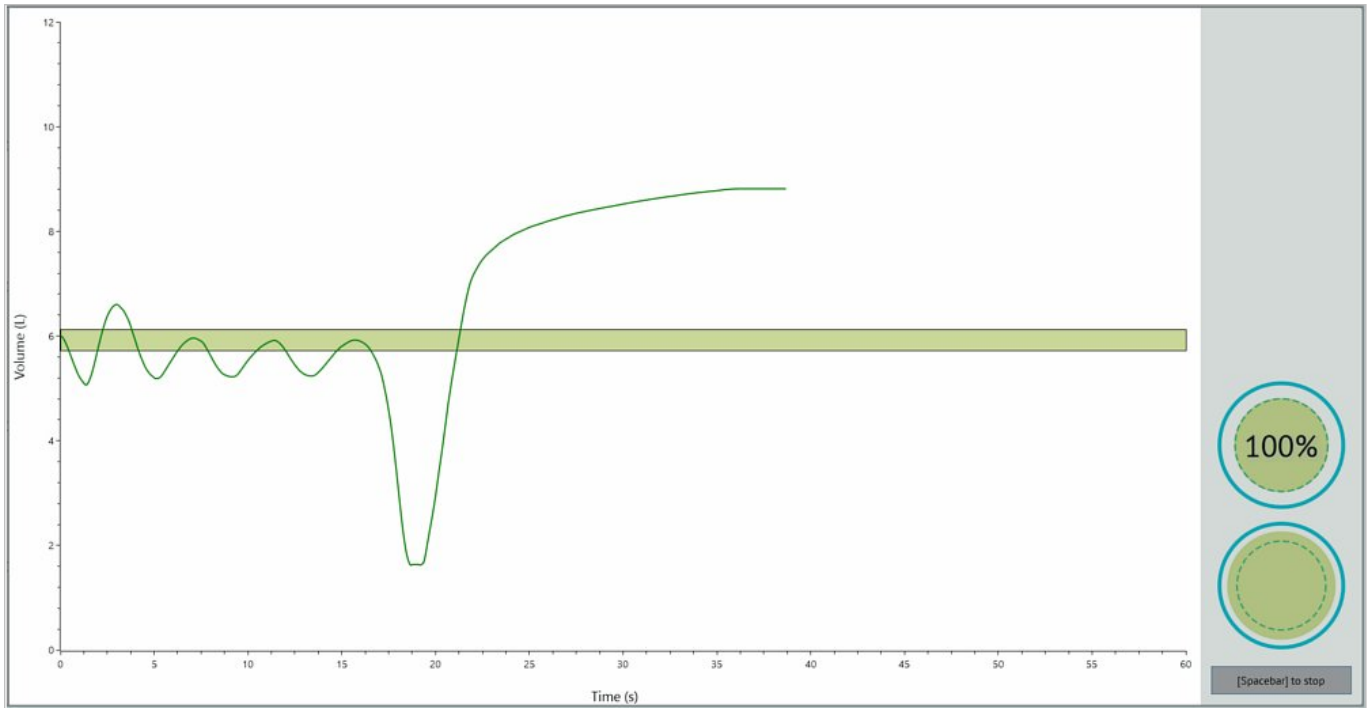
If no historical data exists, on the very first VC effort, the %VC meter displays in real time the VC compared to predicted value. If past test data exists, the meter will compare to the best last recorded VC. On subsequent tests the meter will display in real-time the VC compared to the best VC achieved in this testing session. As VC is improved with successive efforts; the meter target is continuously updated.



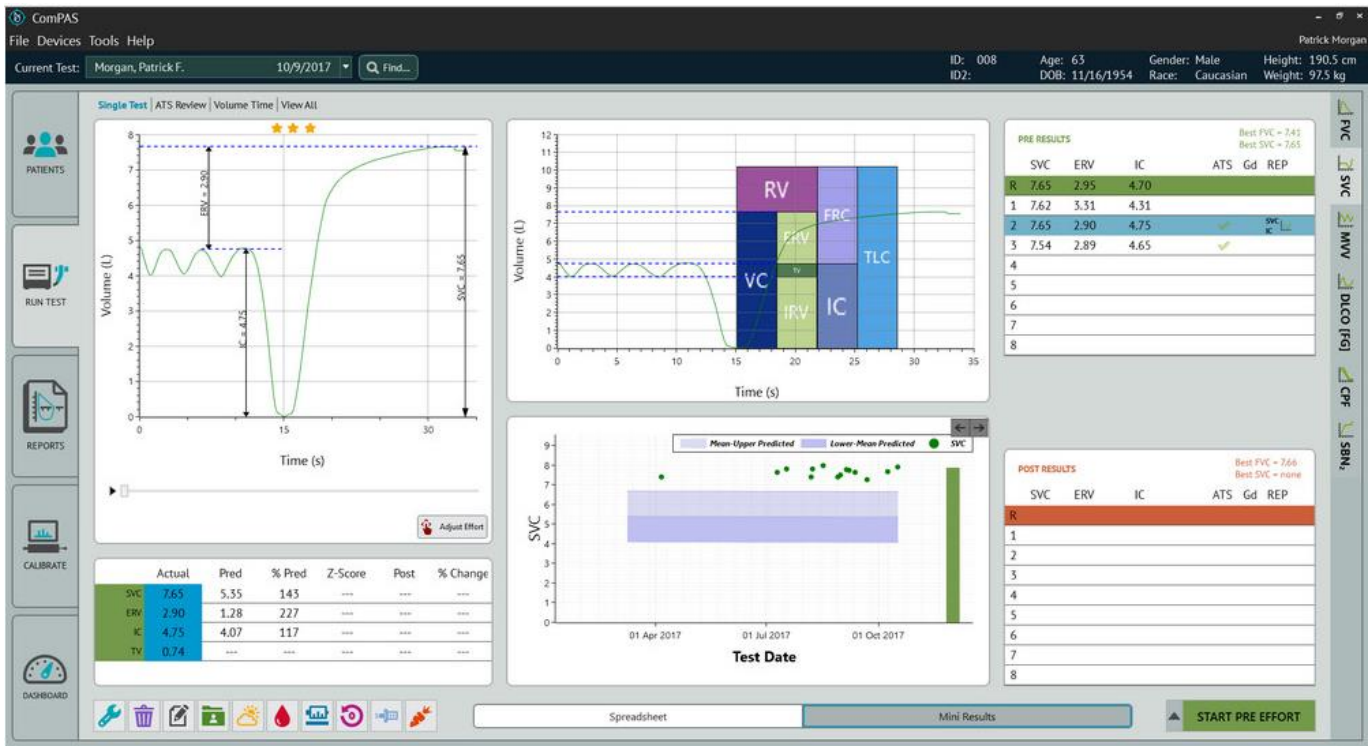
The bottom End of Expiration Meter is useful in seeing that the expiratory effort achieves a plateau in the volume time curve.

End of Expiration (EOE) criteria is a < 0.025L volume change over 1 second duration. If desired, the EOE criteria can be configured in the configuration by clicking on “Testing”.

Further to the visual indication of a plateau, an audible beep can be configured. A single beep can be sounded when a plateau in the volume time is reached.



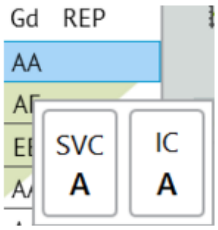
The screen now displays the results and will determine whether or not the effort met the ATS guidelines for performing a Slow Vital Capacity.



6.2.4 Spirometry Grading for Slow Vital Capacity

The concept behind the Mini Results Screen is to provide the technician with the key data regarding the clinical acceptability of each maneuver. As each test is evaluated, the ATS column on the right-hand side of the screen will indicate progress towards meeting the ATS testing guidelines:

ComPAS2 uses spirometry grading for the reported SVC and IC extrapolated from the spirometry recommendations:



On the mini results screen, the left-hand grade is for SVC and the right-hand grade for IC.

Holding the mouse over the grade and row will confirm SVC and IC grades.

For each row, SVC and IC are graded separately; the grading is for repeatability and has to consider data across all efforts. On the very first effort, the grade for SVC and IC will always show **EE** unless the effort is so poor that it gains an **F**.

This is because there is only a single effort to consider for the repeatability grade. As each effort is saved, the grades will change on each row reflecting the progress towards repeatability for SVC and IC individually.

Based upon the recommended table below, the grade column could show for example "**AA**" or "**BA**" and so on.

Grade	Acceptance Criteria for SVC and IC Individually
A	≥ 3 acceptable tests with repeatability within 0.150 L For age 2–6, 0.100 L, or 10% of highest value, whichever is greater
B	≥ 2 acceptable tests with repeatability within 0.150 L For age 2–6, 0.100 L, or 10% of highest value, whichever is greater
C	≥ 2 acceptable tests with repeatability within 0.200 L For age 2–6, 0.150 L, or 10% of highest value, whichever is greater
D	≥ 2 acceptable tests with repeatability within 0.250 L For age 2–6, 0.200 L, or 10% of highest value, whichever is greater
E	One acceptable test
F	No acceptable tests

It should be noted that a grade of "BB" meets previous ATS/ERS recommendations for repeatability and that the test efforts are still worthy of reporting!

<u>Reporting recommendations from the paper state:</u>
*"In general, tests with a grade of **A**, **B**, or **C** are usable; tests with grade **D** are suspect; tests with grade **E** might be used by the interpreter only to show values "within the normal range" or "at least as high as," without demonstrated repeatability; and tests with grade **F** should not be used."*

When ATS/ERS repeatability shows an **A** grade for both SVC and IC, a large solid check-mark is 'ghosted' behind all the data

When ATS/ERS repeatability shows a **B** grade for both SVC and IC, a large hollow check-mark is 'ghosted' behind all the data.

Remember that IC values are AVERAGED for reporting.

Through use of the right-click functions, the technician can individually select the data and graphic preferred for the final report.

PRE RESULTS

Best FVC = 7.37
Best SVC = 7.52

	SVC	ERV	IC	ATS	Gd	REP
R	7.52	2.43	5.09		AB	
1	7.38	2.84	4.54		AE	
2	7.23	2.55	4.68		EE	
3	7.46	2.37	5.09		AB	IC
4	7.52	2.56	4.96		AB	SVC
5						
6						
7						
8						

Manual Selection of Test Data

PRE RESULTS

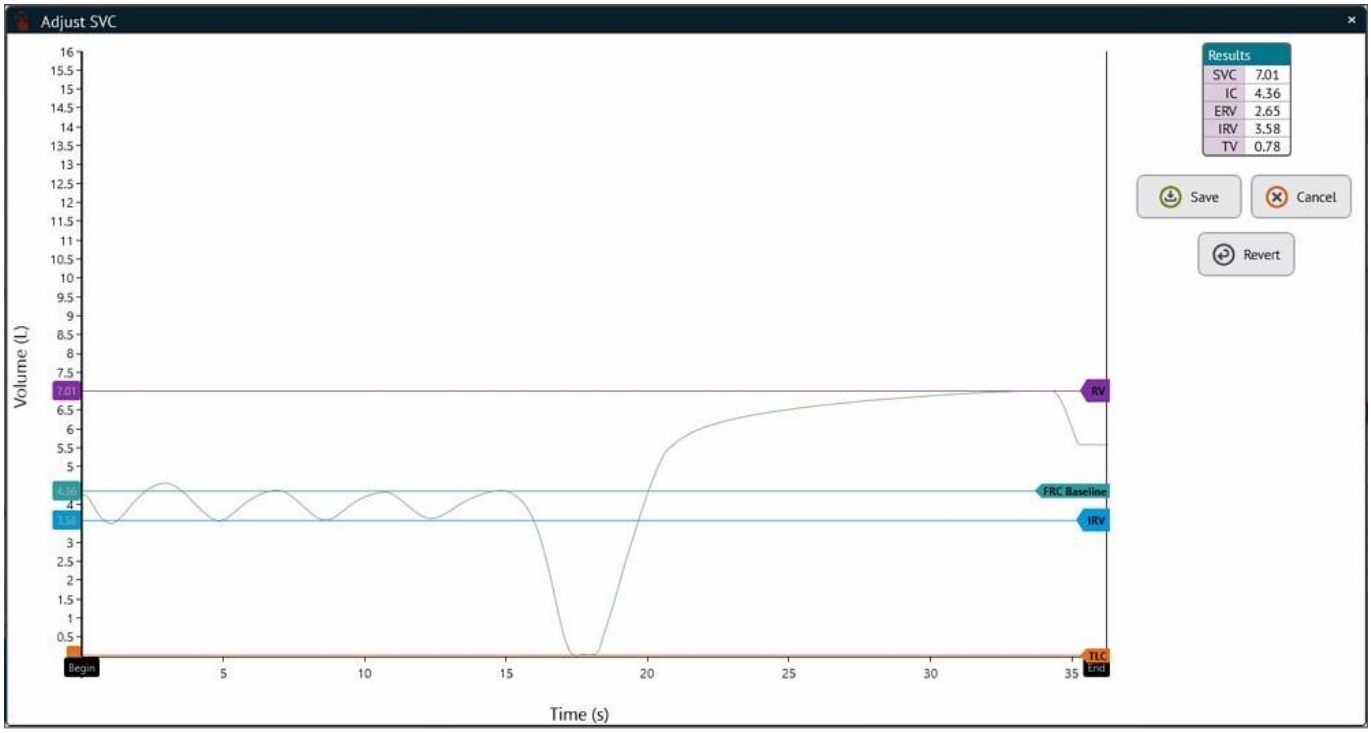
Best FVC = 7.37
Best SVC = 7.52

	SVC	ERV	IC	ATS	Gd	REP
R	7.52	2.43	5.09		AA	
1	7.38	2.84	4.54		AE	
2	7.23	2.55	4.68		EE	
3	7.46	2.37	5.09		AA	IC
4	7.52	2.56	4.96		AA	SVC
5	7.33	2.30	5.03		CA	
6						
7						
8						

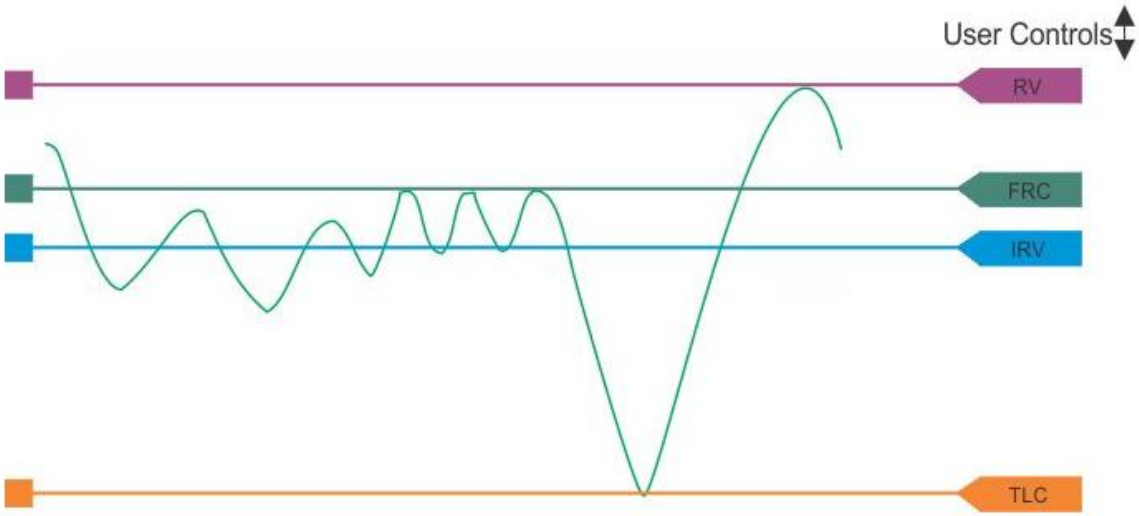
Manual Selection of Test Graphic

6.2.5 Adjusting the FRC Baseline

Once an SVC test is completed, the computer will look at the Tidal Volume data and establish automatically where it considers the FRC Baseline to be. If you want to change the position of the baseline, click on Adjust Effort



To move a computed position for FRC baseline, TLC, RV or IRV to a preferred location, simply left-click the desired pointer and drag to a new position.



Once the new position is accepted, the lung sub-divisions will be recalculated. The user can either continue to change any position or accept the new setting. The 

button will revert all settings to the original computed positions.

If the tidal volume appears to be drifting up or down the screen rather than running parallel across the horizontal axis, it could be that either the flow zero needs adjusting or that incorrect BTPS conditions are the cause.

3) To check the flow zero, click on  to ensure a true flow zero has been accepted.

4) For BTPS errors, check that the inputs of Barometric Pressure and Temperature are correct. Click  and compare the values against an independent laboratory environmental monitor.

6.2.5 Manual Selection of SVC Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. ComPAS2 allows the user to override the automatic selection of both data and graphical information.

Through use of the right-click functions, the technician can individually select the data and SVC graphic preferred for the final report.

1) It is not uncommon for the reported graphic to be slightly out of line with the reported data because the IC values are averaged. Therefore, the ERV can graphically be represented different to the data

2) When either the SVC or IC are user-selected, the ERV will be automatically recalculated in the reported column.

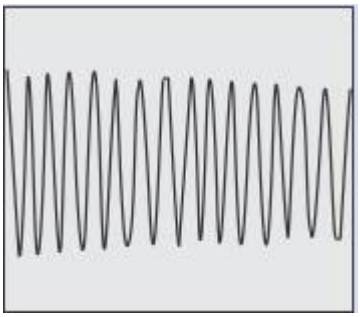
Selection icons under the REP column shown in **black** indicate automatic selection by ComPAS2.

Selection icons under the REP column shown in **red** indicate technician selection of data or graphic.

REP	Automatically selected SVC graphic and data	This identifies the effort where both the SVC graphic and data that will be printed on the final report are coming from
SVC	The user has selected the SVC	This individual SVC effort has been selected by the user and will be reported
IC	The user has selected the IC	This individual IC effort has been selected by the user and will be reported
SVC IC	The user has selected "This Effort" for the SVC data	The complete SVC data has been selected by the user and will be reported
	The user has selected "This Effort" for the SVC graphic	The SVC graphic has been selected by the user and will be reported

6.3 Maximum Voluntary Ventilation (MVV)

6.3.1 Maximum Voluntary Ventilation Method

Graphic Image	Method	Subject Instructions
	**Tidal breathing then:** **Deep and fast inhalation and exhalation for 12 seconds**	Enthusiastically encourage the patient to: **"breathe deeply and rapidly moving as much air as possible and keep the effort going for 12 seconds"** Test can be accepted between 6 and 12 seconds; data will be extrapolated.

6.3.2 Preparing for a Maximum Voluntary Ventilation Test

The ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

Preparing the Vitalograph Morgan PFT for MVV

1) Connect a new bacterial/viral filter; be sure to push the filter into the valve to ensure a snug fit.

2) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for MVV

1) Make sure the subject is sitting upright with both feet on the ground and is wearing a nose clip.

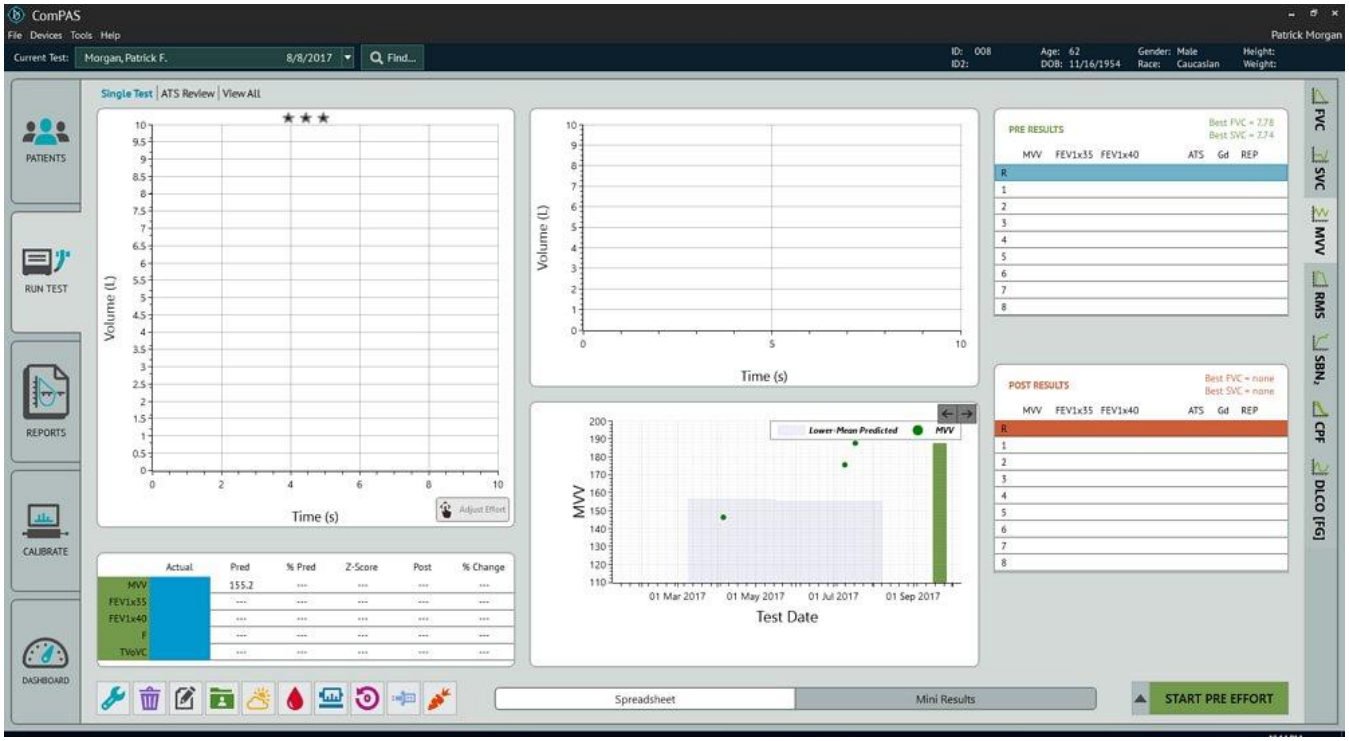
2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test; dramatically demonstrate the effort that is required!

6.3.3 Performing Maximum Voluntary Ventilation

This is the only test that requires you get the subject to start the test effort before pressing the [Spacebar].

Enthusiastically encourage the subject to "**breathe deeply and rapidly moving as much air as possible**" and then press the [Spacebar].



Have the subject start the MVV effort and then immediately press the [Spacebar] to begin the recording.

Encourage the subject to breathe deep and fast and try to reach beyond 12 seconds.

The run-time screen displays target lines at 6 and 12 seconds.

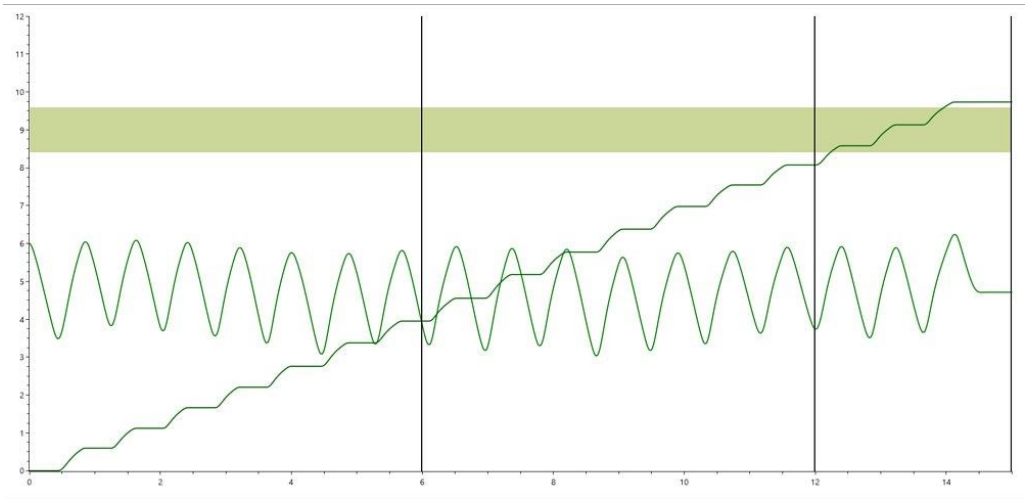
The subject MUST reach the 6-seconds, but it is preferable to encourage them to go beyond 12 seconds.

If the subject reaches 15 seconds, the test will automatically end.

As each maximal breath is taken, the cumulative volume climbs the screen. A green target area is displayed which represents the subject's actual FEV1 x 35 to FEV1 x 40. This should be used to encourage the subject to try and reach or surpass that target area.

If a test is run without first having completed an FVC, the target area is based on the predicted FEV1 x 35 and predicted FEV1 x 40

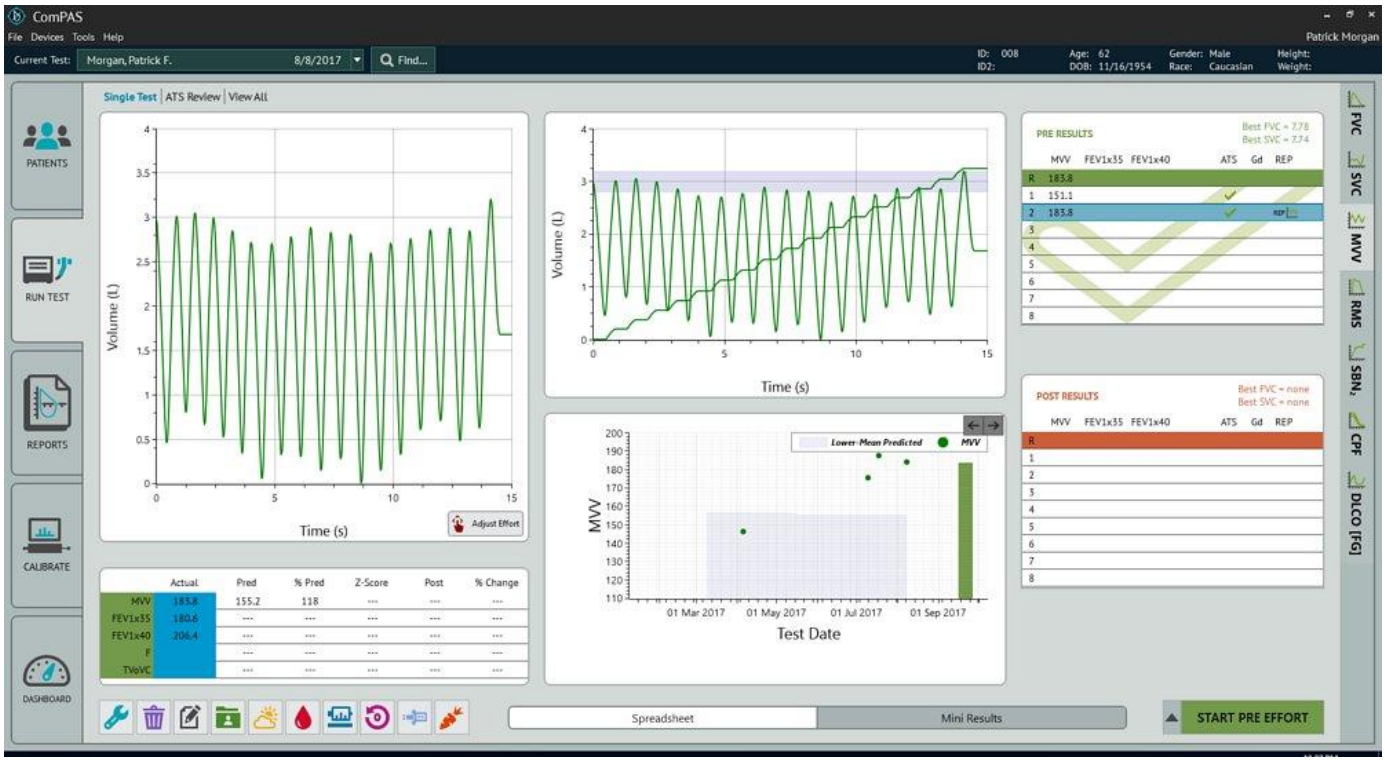
Pressing or clicking [Spacebar] any time after 6 seconds test duration, will end the test and the result will be calculated and stored but will of course not pass the ATS recommended criteria.



The values shown for FEV1 x 35 and FEV1 x 40 are helpful guides of what to expect from a good subject effort.

They will only be displayed if you have completed a flow volume loop prior to doing the MVV test.

A genuine effort should get very close to the FEV1 x 35 or exceed it.



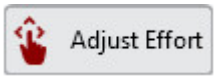
The concept behind the Mini Results Screen is to provide the technician with the key data regarding the clinical acceptability of each maneuver. As each test is evaluated, the ATS column on the right-hand side of the screen will indicate progress towards meeting the ATS testing guidelines:

Test	Acceptance Criteria
MVV	After 2 acceptable efforts have been completed, MVV's are evaluated for the following: 2 acceptable MVV efforts agree within 20%

Beside each effort in the Mini Results table, check marks indicate progress towards, or confirmation of effort repeatability.

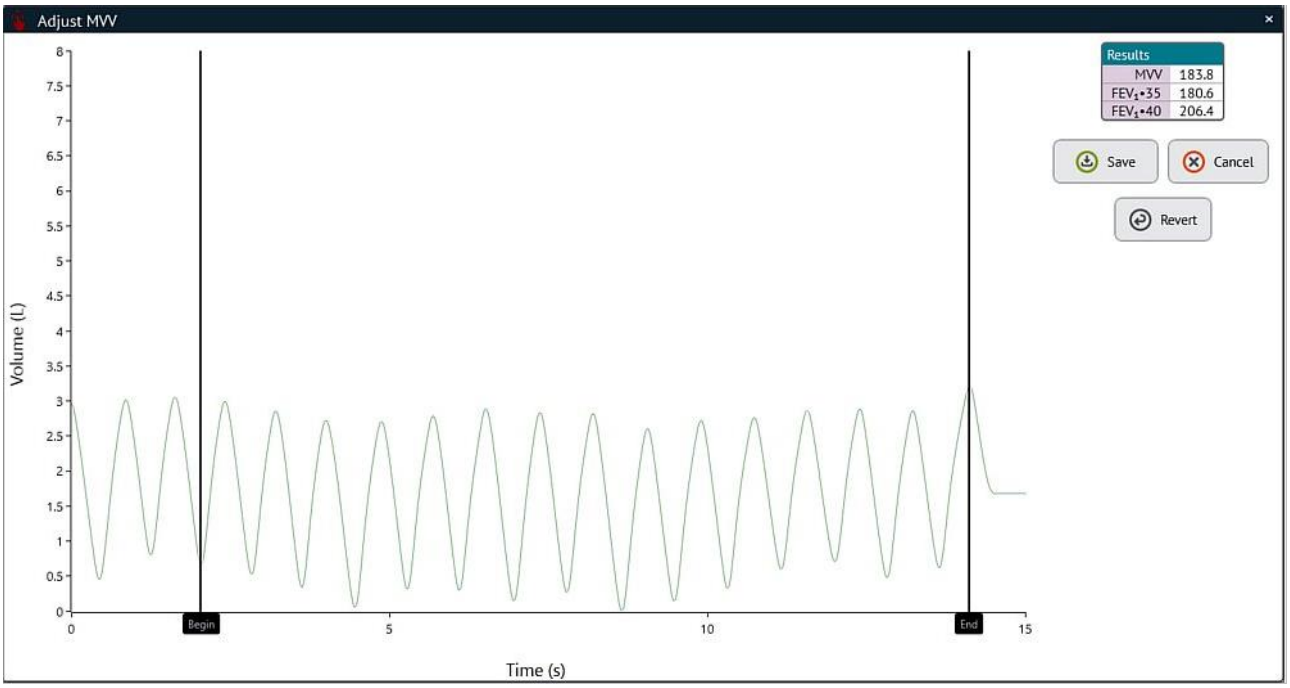
		Explanation
		An open green check mark indicates that this effort passed all the ATS criteria for the performance of an individual test. This makes it available for consideration for repeatability.
		Solid green check marks show which test efforts contain MVV repeatable data. When ATS repeatability standards have been met a large check mark is 'ghosted' behind all the data to confirm that you can now move to the next test.

6.3.4 Manual Adjustment of MVV

The MVV result is automatically processed to obtain the greatest value across the maximal effort. At the same time, each test effort is evaluated and given a "confidence" rating. By clicking 

the user can review which segment of the effort was evaluated to calculate the result and view a detailed evaluation.

By clicking on either the starting or ending markers, the user can drag them to include or exclude different segments of the test. Once released, the MVV will be recalculated.



6.3.5 Manual Selection of Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. ComPAS2 allows the user to override the automatic selection of both data and graphical information.

Through use of the right-click functions, the technician can individually select the data and MVV graphic preferred for the final report.

In cases of both the data and the graphic, the user selected choices are:

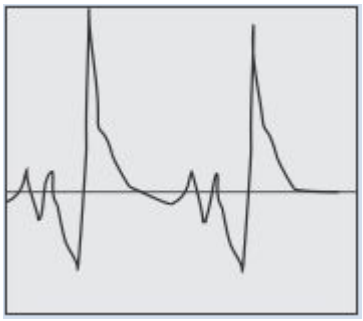
Automatic	Automatically selected MVV graphic and data
This Effort	Use this to select all data or the MVV graphic for reporting

Selection icons under the REP column shown in **black** indicate automatic selection by ComPAS2; those shown in **red** indicate technician override.

REP	Automatically selected MVV graphic and data	This identifies the effort where both the MVV graphic and data that will be printed on the final report are coming from
REP	The user has selected "This Effort" for the MVV data	This individual MVV effort has been selected by the user and will be reported
	The user has selected the "This Effort" for the MVV graphic	This individual MVV graphic has been selected by the user and will be reported

6.4 Cough Peak Flow Testing

6.4.1 Cough Peak Flow Method

Graphic Image	Method	Subject Instructions
	**Tidal breathing then:** **Full breath-in and then a cough with maximal effort** **Repeat**	After a few tidal breaths, instruct the patient to: "**breathe-in fully and then cough with maximal effort**". A number of cough efforts can be collected in each test run.

6.4.2 Preparing for a Cough Peak Flow Test

The ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

Preparing the Vitalograph Morgan PFT for Cough Peak Flow

1) Connect a new bacterial/viral filter.

2) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for Cough Peak Flow

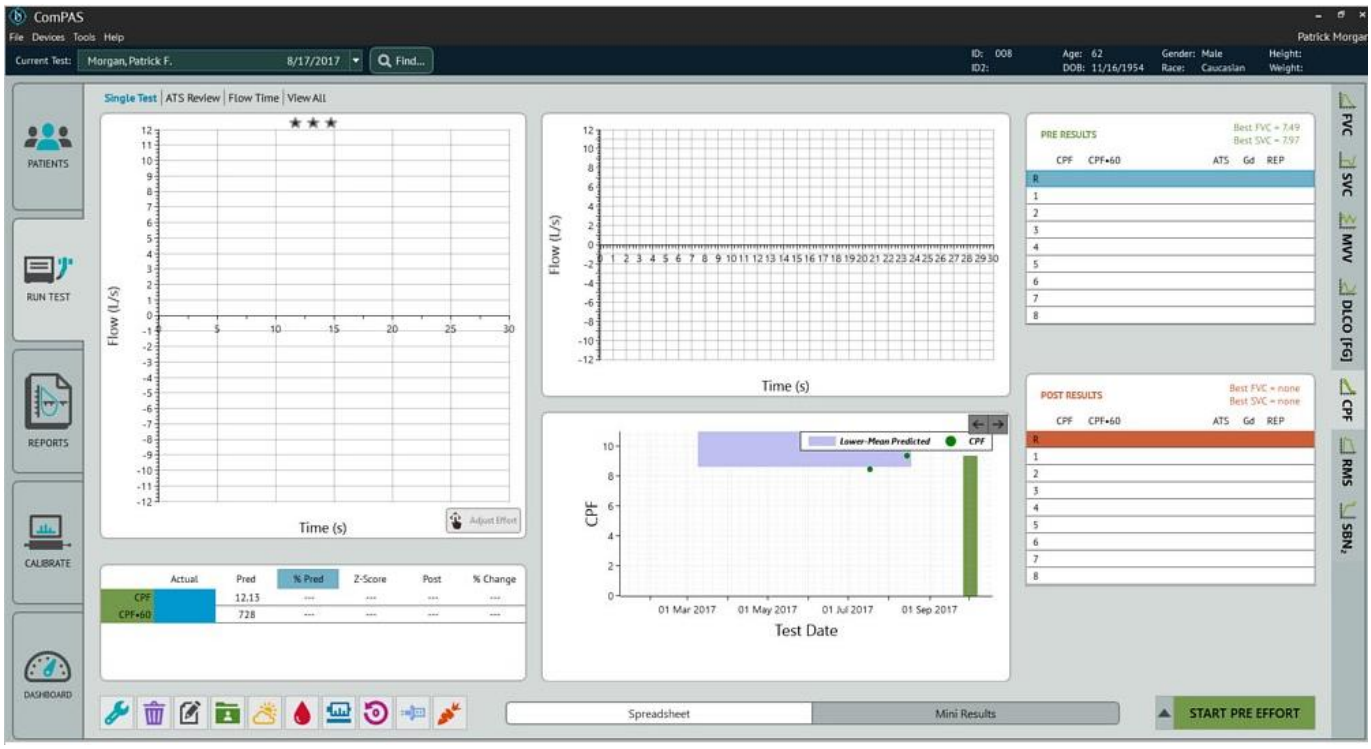
1) Make sure the subject is sitting upright with both feet on the ground and is wearing a nose clip.

2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test; dramatically demonstrate the effort that is required!

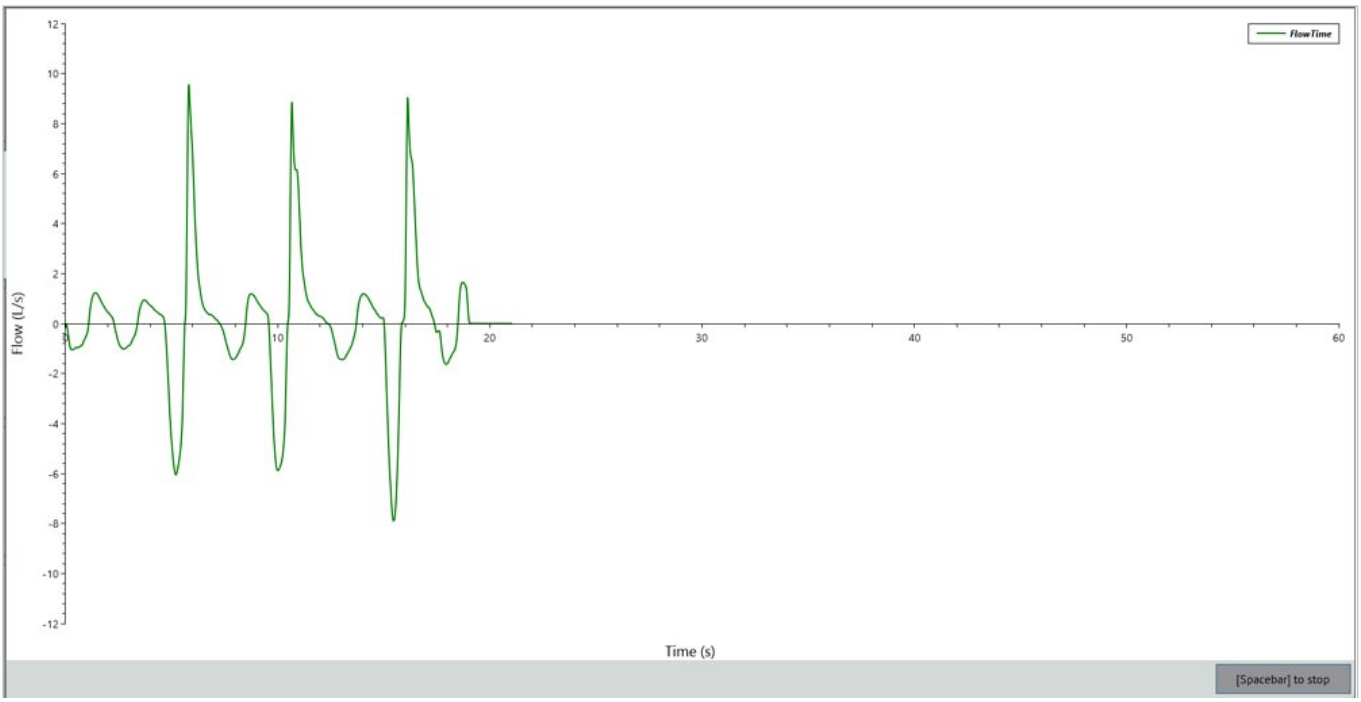
6.4.3 Performing Cough Peak Flow

Since the Cough Peak Flow test requires considerable movement in the generation of coughs, a filter with snorkel mouthpiece is strongly recommended.



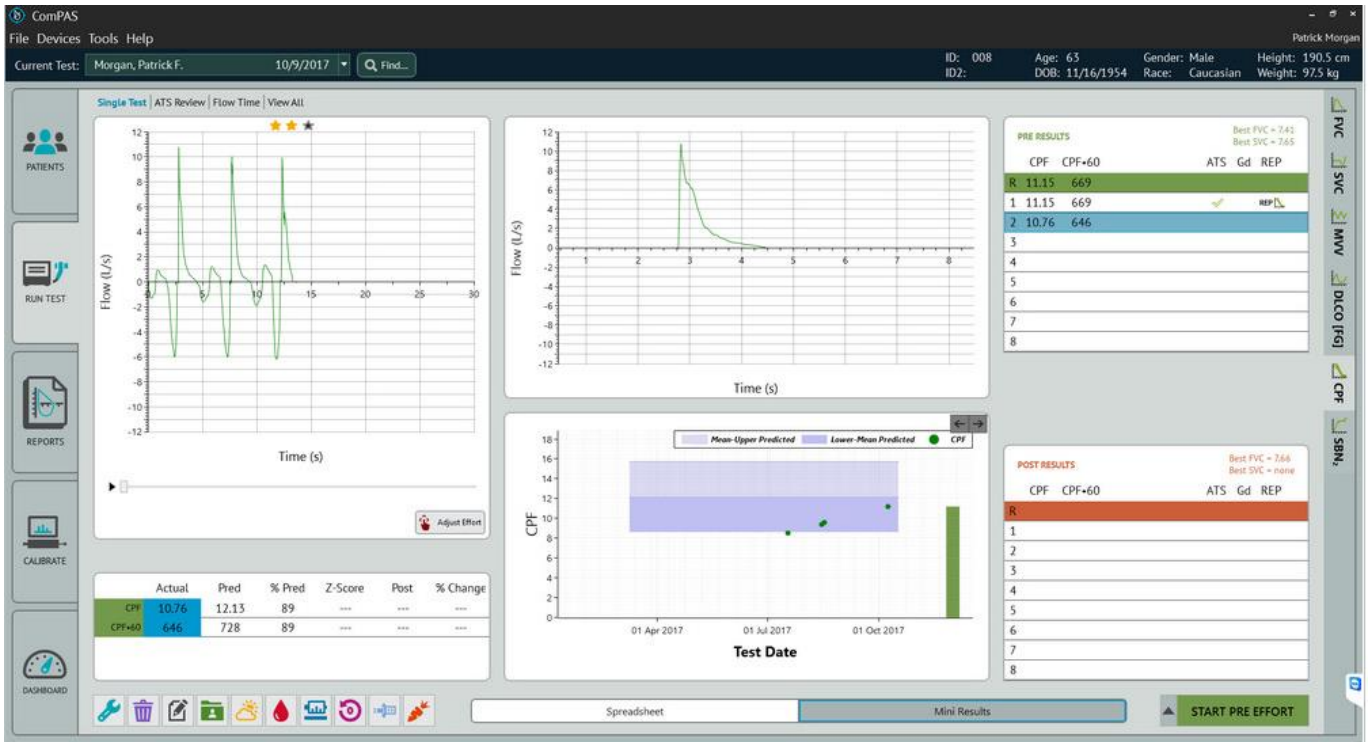
The [Spacebar] begins the test data acquisition and a screen showing Flow -v- Time is displayed. Ensure that the mouthpiece is properly sealed and encourage them to breathe normally.

Instruct the patient to "**breathe-in"** and then, "**cough with maximal effort**". Once the effort is complete, click or press the [Spacebar] to end the test.



Individual cough efforts can be stored or a sequence of coughs in any test run. The highest cough peak flow will be used in reporting.

The screen now displays the results and will determine whether or not the effort met the guidelines for performing a Cough Peak Flow. Note: There are no published ATS/ERS guidelines, so the ComPAS2 evaluation only looks for an acceptable calibration and repeatability.



6.4.4 Manual Selection of Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. ComPAS2 allows the user to override the automatic selection of both data and graphical information.

Through use of the right-click functions, the technician can individually select the data and CPF graphic preferred for the final report.

In cases of both the data and the graphic, the user selected choices are:

Automatic	Automatically selected CPF graphic and data
This Effort	Use this to select all data or the CPF graphic for reporting

Selection icons under the REP column shown in **black** indicate automatic selection by ComPAS2; those shown in **red** indicate technician override.

REP 	Automatically selected CPF graphic and data	This identifies the effort where both the CPF graphic and data that will be printed on the final report are coming from
REP	The user has selected "This Effort" for the CPF data	This individual CPF effort has been selected by the user and will be reported
	The user has selected the "This Effort" for the CPF graphic	This individual CPF graphic has been selected by the user and will be reported

6.5 Respiratory Muscle Strength (MIP and MEP) Testing

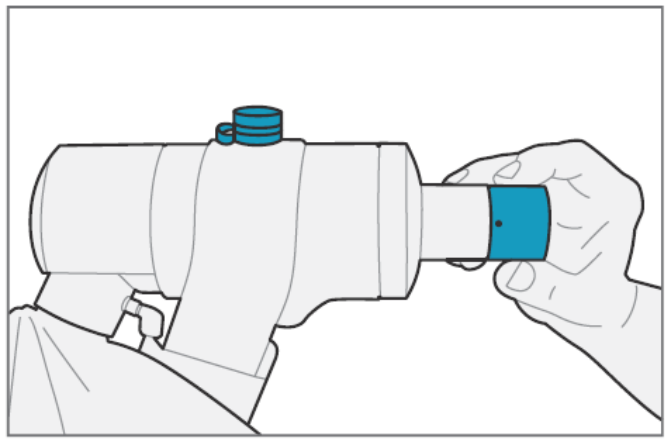
Neuromuscular disease (respiratory muscle dysfunction) is an important cause of respiratory disability. The measurement of Maximal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP) at the mouth is an accepted clinical method for evaluating the strength of the Respiratory Muscle. Like the MVV, maximal pressures are reduced in neuromuscular disorders (e.g., myasthenia gravis, muscular dystrophy, Guillain-Barre' syndrome). The measurement is also useful in monitoring those patients undergoing a program of lung rehabilitation.

MIP and MEP measure the strength of the respiratory muscles as the patient forcibly inhales and exhales, respectively, through a closed mouthpiece attached to a pressure transducer. Using the patient valve, the volume at which the measurement of pressure is taken can be recorded by the pneumotachograph and the piston valves combined are used to provide occlusion.

6.5.1 Preparing for a Respiratory Muscle Strength (MIP or MEP) Test

The ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

Preparing the Vitalograph Morgan PFT for MIP and MEP



The MIP/MEP adaptor uses a 2mm hole to prevent glottis closure during either MIP or MEP efforts.

1) Connect the MIP/MEP adaptor to the valve and ensure that the top stopper is secured.

2) Connect a new bacterial/viral filter to the MIP/MEP adaptor.

3) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for MIP and MEP

There are two versions of the Vitalograph Morgan PFT, one using a demand valve and the other an inspiratory reservoir

1) Make sure the subject is sitting upright and is wearing a nose clip.

2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test.

4) For MEP testing it is helpful to have the subject place their hands on their cheeks.

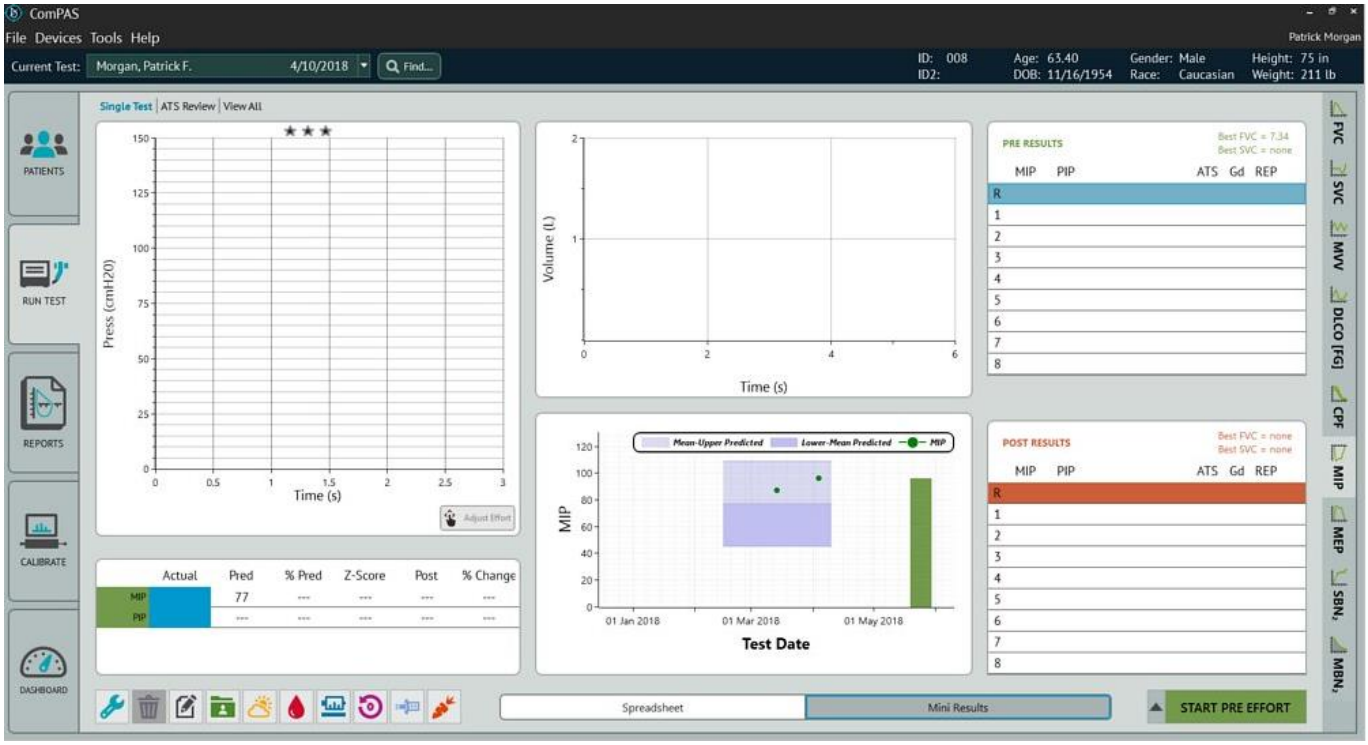
6.5.2 Performing MIP and MEP

It is important to emphasize that the respiratory muscle strength tests of MIP (Maximal Inspiratory Pressure) and MEP (Maximal Expiratory Pressure) are totally dependent on patient effort. The tests require vigorous technician encouragement to avoid falsely low results being recorded!

Traditionally, MIP is recorded from RV (fully empty) and MEP is recorded from TLC (fully inflated). However, ability to measure both values at FRC has been provided in ComPAS2. If an effort has been made at FRC, it is necessary to right-click on the mini-results column and indicate that it was an FRC maneuver. The reason a technician intervention is required for FRC measurements of MIP and MEP, is that in cases of severe disease or obesity, the subjects end expiratory level may be the same as, or very close to RV.

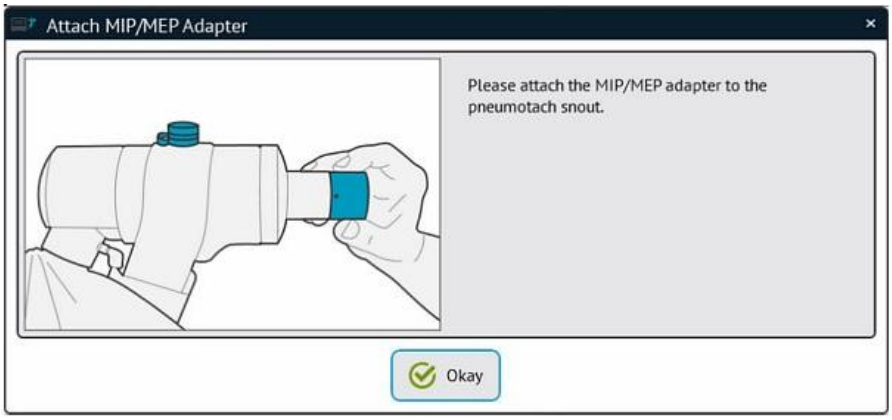
6.5.3 Running a MIP Test:

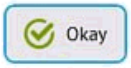
Click on the [MIP] tab to access the test:



Press 

and the screen will remind the user to fit the MIP/MEP adaptor:



Clicking 

will launch the MIP testing screen.

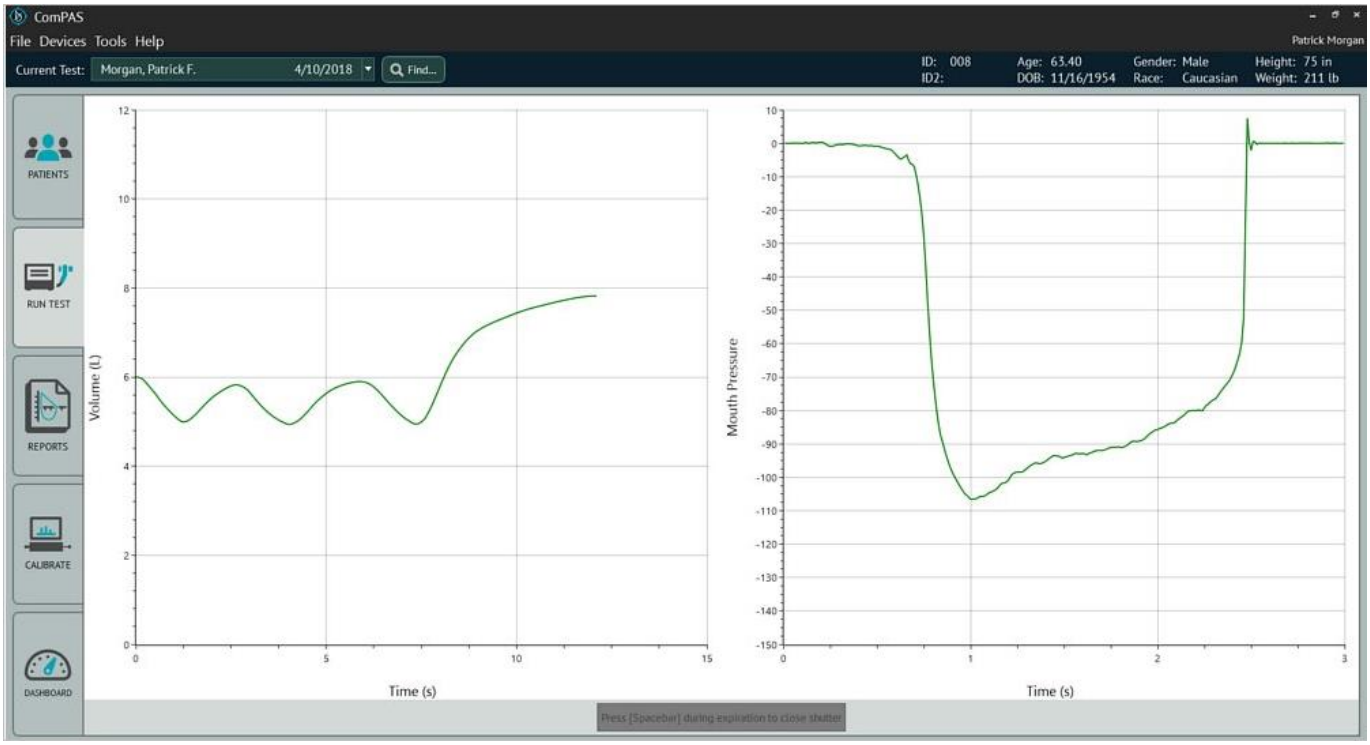
Begin with the patient sitting comfortably upright and ask them to place their hands on their cheeks. Be sure that their lips are tight around the mouthpiece and if necessary, ask them to support their lips to avoid any leaks. Since this test is rather unusual, it requires firm encouragement to obtain meaningful results!

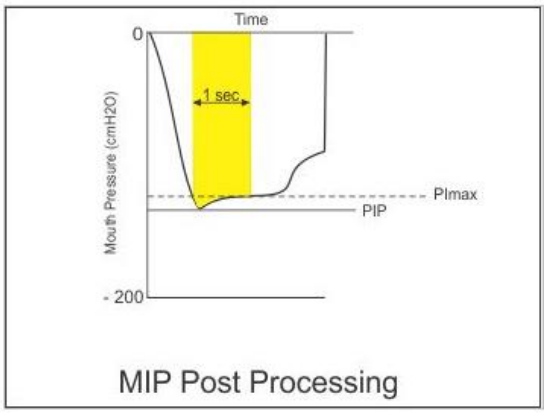
Begin the MIP effort by observing the tidal volume; instruct the patient to "**breathe right out**". During the expirate effort, press the [Spacebar]. When they reach RV, the valve will automatically close then instruct the patient to "**pull your breath in as hard as possible**". The valve will automatically open after 2 seconds (depending upon the configuration setting).

It is important to emphasize that this has to be an absolutely maximal inspiratory effort of breathing against the closure.

To ensure the most reliable values of MIP and PIP (Peak Inspiratory Pressure), three or more efforts should be completed. As a general guide, you should try and obtain values that vary by less than 20%.

The Report column will automatically select the highest value from each of the efforts.

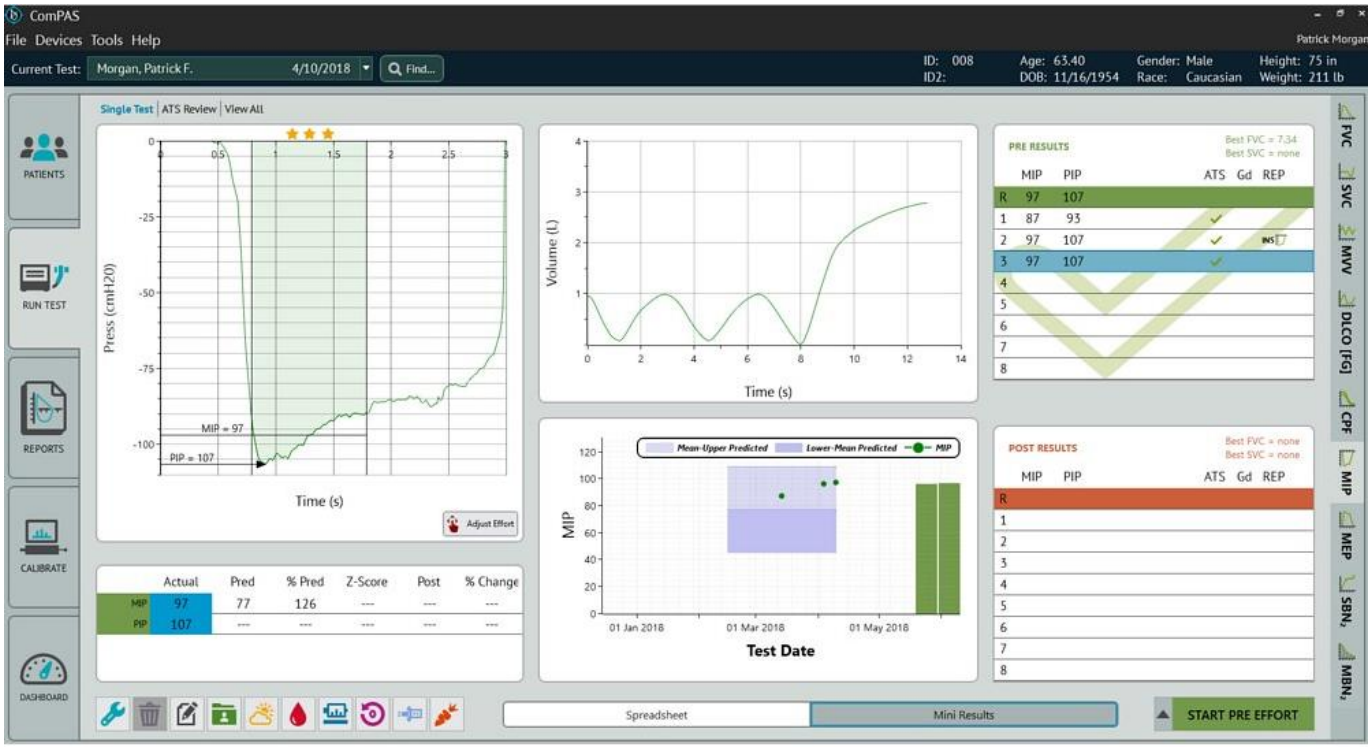


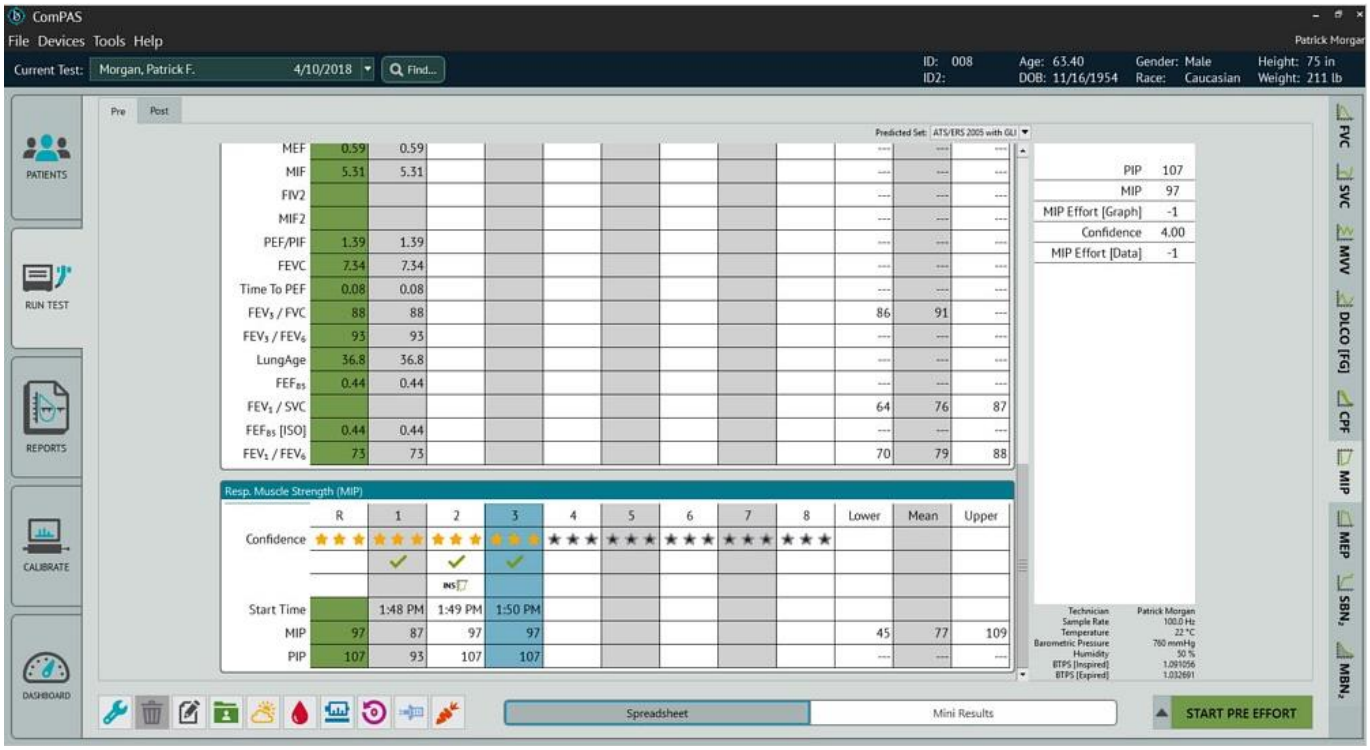


For the MIP processing, the maximal inspiratory pressure sustained over a 1 second period during the Muller maneuver at or near RV is determined. From the same graphic recording, the Peak Inspiratory Pressure (PIP) is also recorded.

*A **Muller** maneuver is making forceful effort to inhale with glottis closed.*

The Report column will automatically select the highest value from the MIP efforts.





6.5.3.1 Manual Selection of MIP Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. ComPAS2 allows the user to override the automatic selection.

Through use of the right-click functions, the technician can individually select the MIP effort preferred for the final report.

In cases of both the data and the graphic, the user selected choices are:

Automatic	Automatically selected MIP graphic and data
This Effort	Use this to select all data or the MIP graphic for reporting

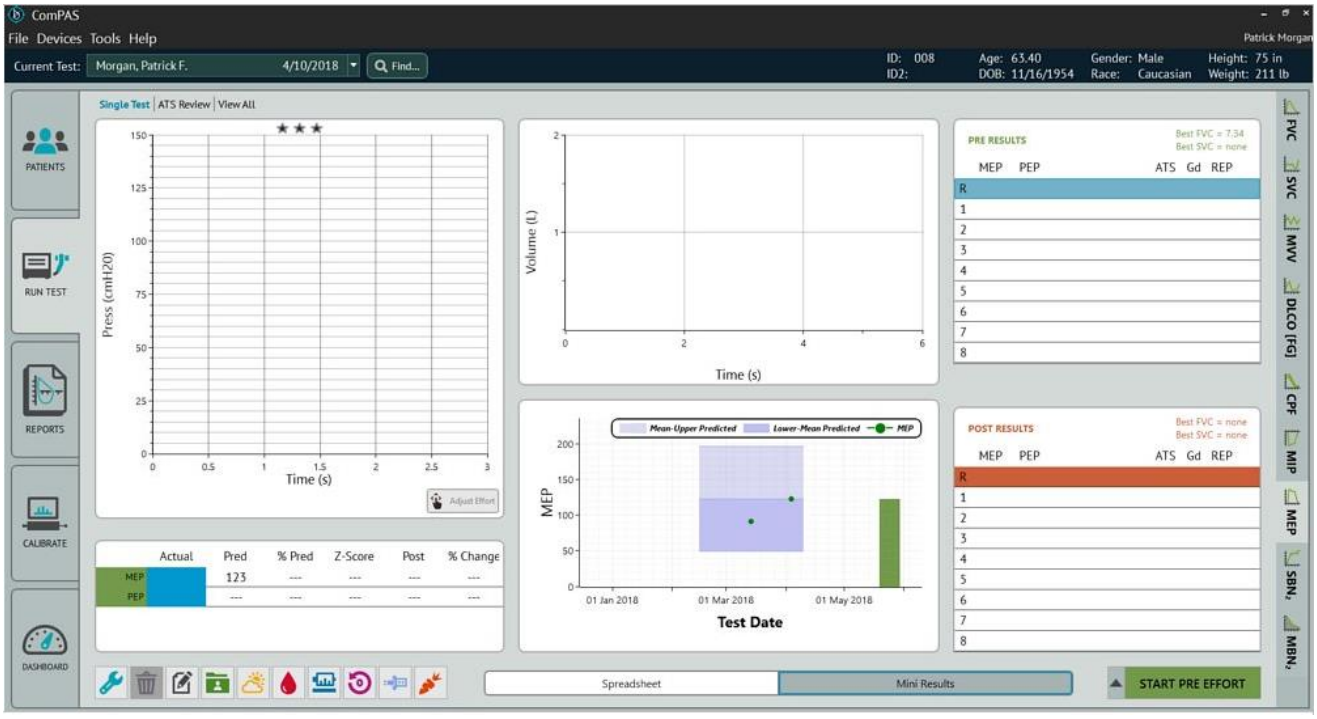
Selection icons under the REP column shown in **black** indicate automatic selection by ComPAS2; those shown in **red** indicate technician override.

REP	Automatically selected MIP graphic and data	This identifies the effort where both the MIP graphic and data that will be printed on the final report are coming from
REP	The user has selected the MIP data	This individual MIP effort has been selected by the user and will be reported
REP	The user has selected "This Effort" for MIP graphic	This individual MIP graphic has been selected by the user and will be reported

6.5.4 Running a MEP Test:

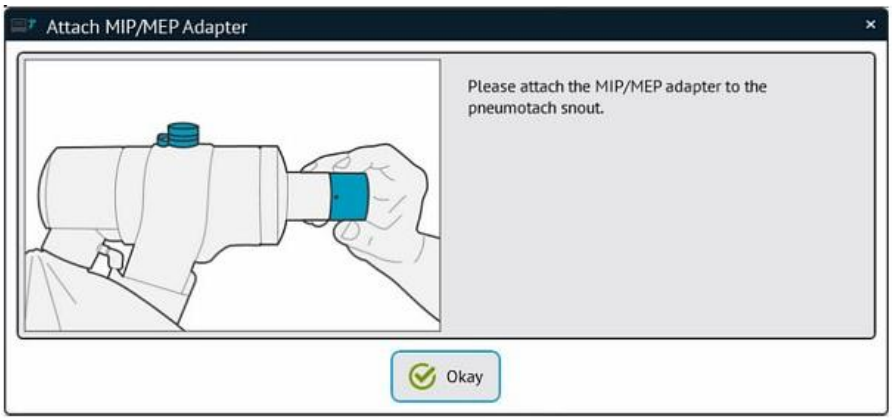
Click on the [MEP] tab to access the test:

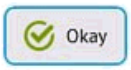
Begin with the patient sitting comfortably upright and ask them to place their hands on their cheeks. Be sure that their lips are tight around the mouthpiece and if necessary, ask them to support their lips to avoid any leaks. Since this test is rather unusual, it requires firm encouragement to obtain meaningful results!



Press 

and the screen will remind the user to fit the MIP/MEP adaptor:

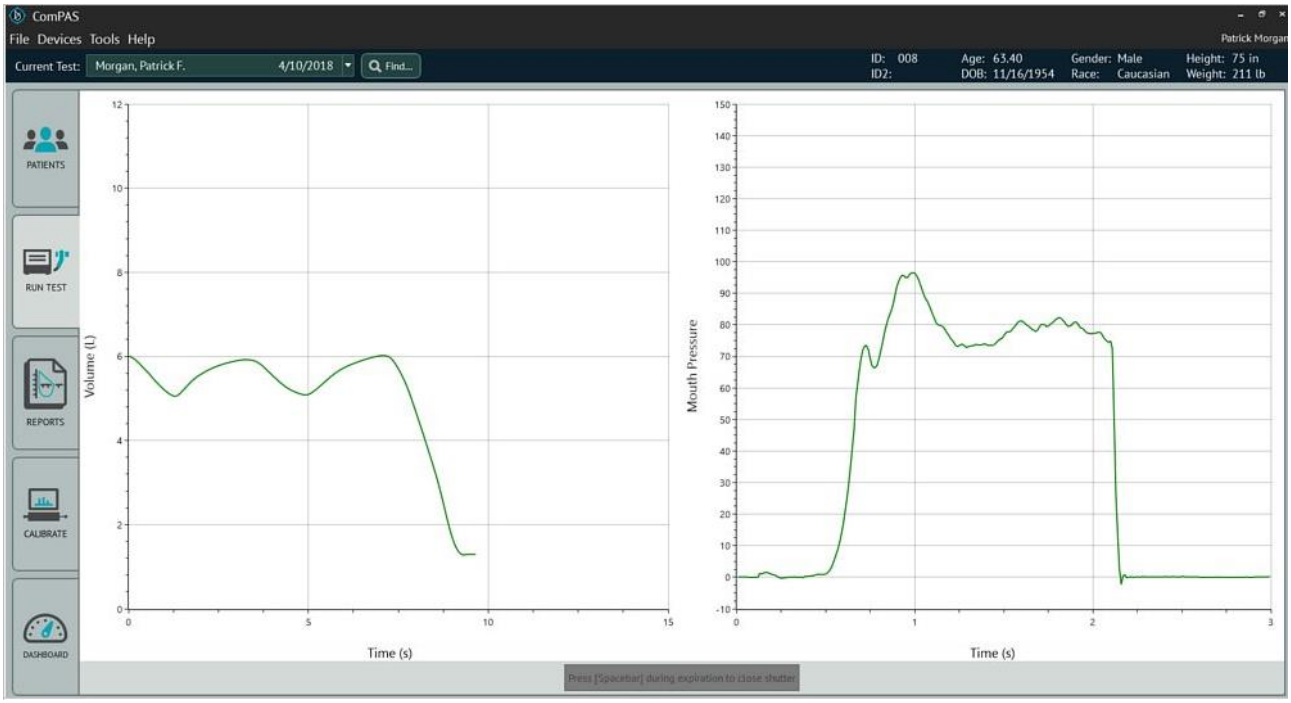


Clicking 

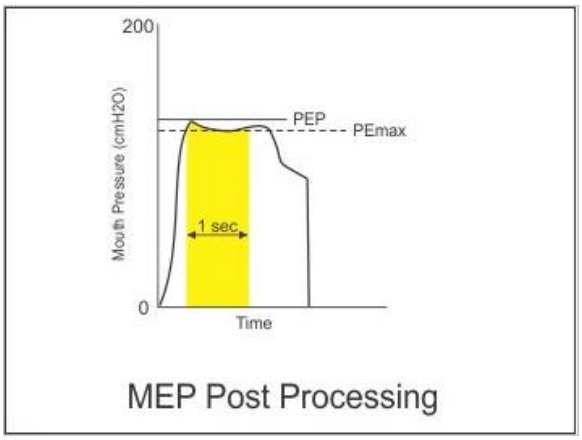
will launch the MEP testing screen.

Begin the MEP effort by observing the tidal volume; instruct the patient to "**breathe all the way in**". During the inspirate effort, press the [Spacebar]. When they reach TLC, the valve will automatically close then instruct the patient to "**push your breath out as hard as possible**". The valve will automatically open after 2 seconds (depending upon the configuration setting).

It is important to emphasize that this has to be an absolutely maximal expiratory effort of breathing against the obstruction.



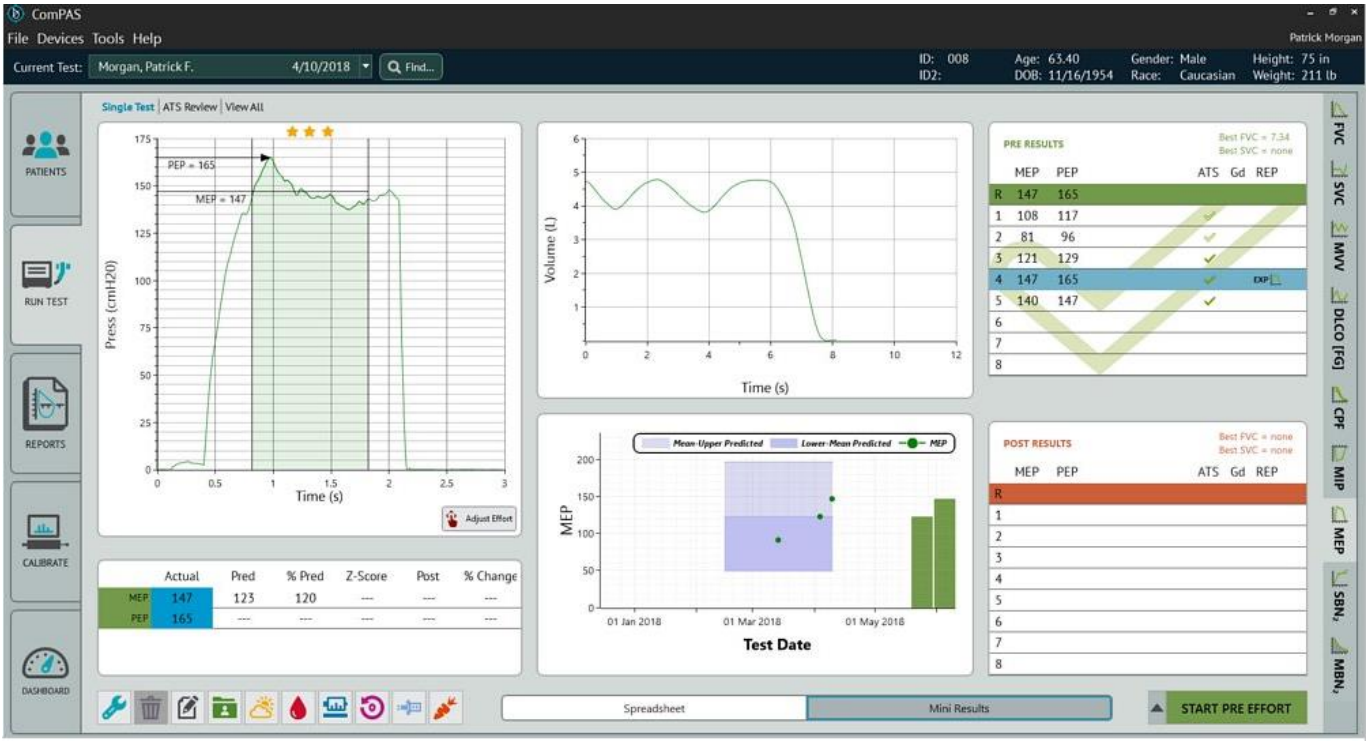
To ensure the most reliable values of MEP and PEP (Peak Expiratory Pressure), three or more efforts should be completed. As a general guide, you should try and obtain values that vary by less than 20%.

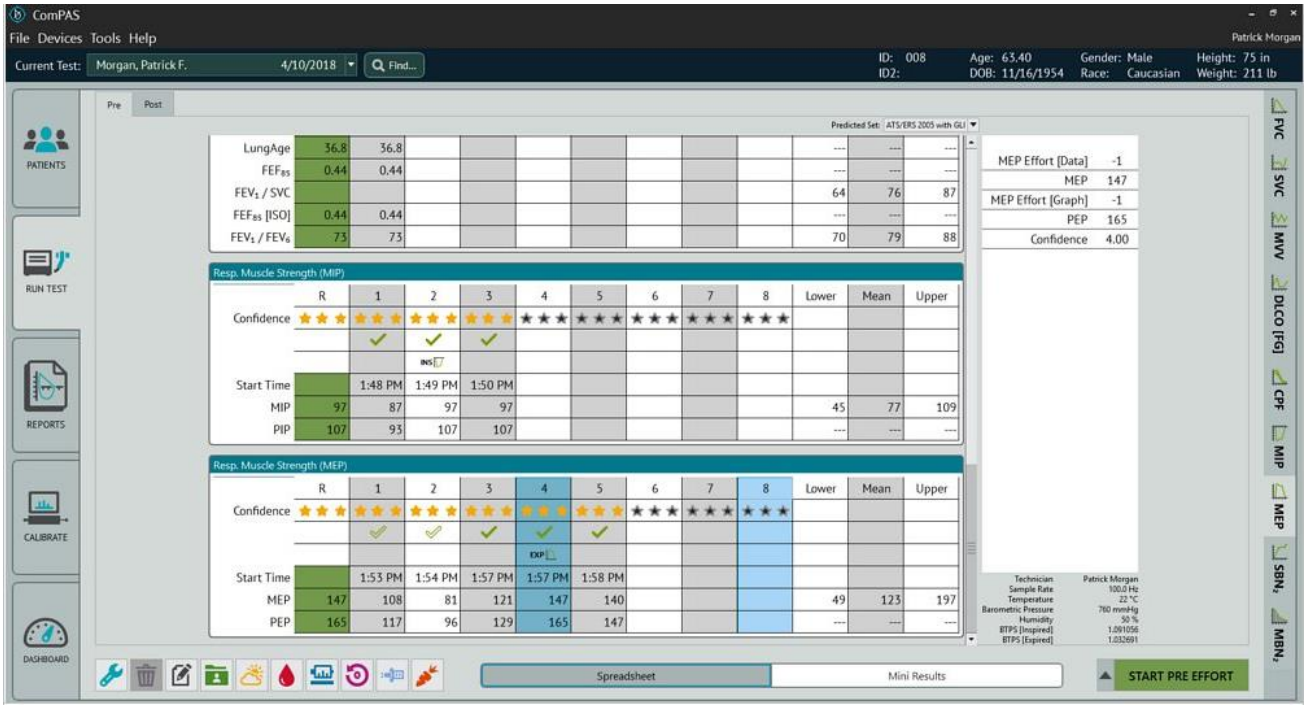


For the MEP processing, the maximal expiratory pressure sustained over a 1 second period during the Valsalva maneuver at or near TLC is determined. From the same graphic recording, the Peak Expiratory Pressure (PEP) is also recorded.

*A **Valsalva** maneuver is a strain against a closed airway combined with muscle tightening, such as happens when a person holds his or her breath and tries to move a heavy object.*

The Report column will automatically select the highest value from the MEP efforts.





6.5.4.1 Manual Selection of MEP Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. ComPAS2 allows the user to override the automatic selection.

Through use of the right-click functions, the technician can individually select the MEP effort preferred for the final report.

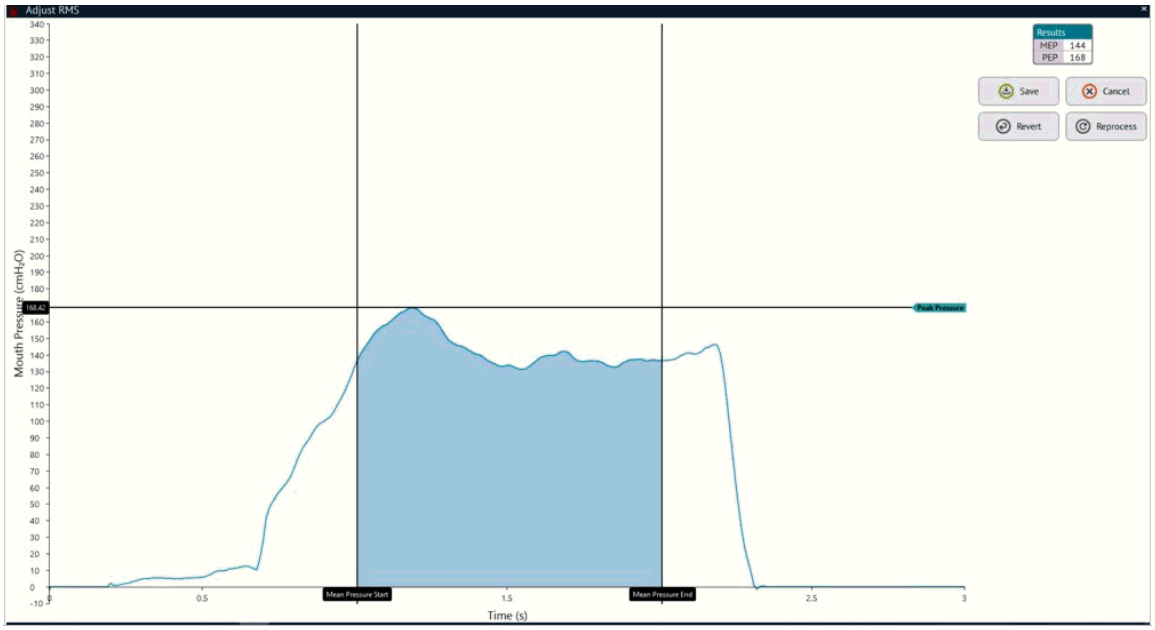
Automatic	Automatically selected MEP graphic and data
This Effort	Use this to select all data or the MEP graphic for reporting

REP	Automatically selected MEP graphic and data	This identifies the effort where both the MEP graphic and data that will be printed on the final report are coming from
REP	The user has selected the MEP data	This individual MEP effort has been selected by the user and will be reported
REP	The user has selected "This Effort" for MEP graphic	This individual MEP graphic has been selected by the user and will be reported

6.5.5 Adjusting MIP and MEP Tests

Once either a MIP or MEP test is completed, the computer will process the pressure sustained over a 1 second period and also the peak PIP or PEP produced. These values can be manually adjusted; to change any computed data, click on the 

button on the Mini Results screen.



To move a computed position for PIP or PEP to a preferred location, simply left-click the horizontal pointer and drag to a new position.

By sliding the vertical [Scope Begin] or [Scope End] controls, the area used to compute MIP or MEP can also be adjusted.

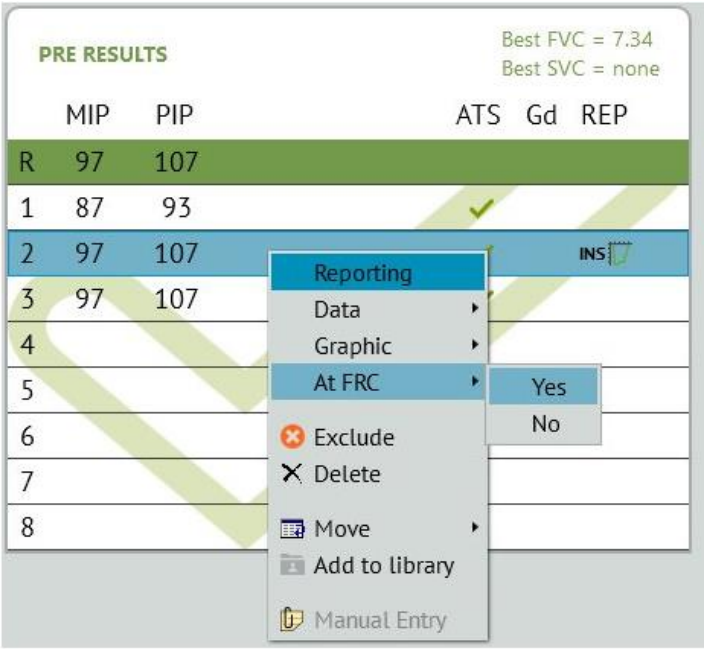
6.5.6 Indicating a test done at FRC

Some researchers are interested to make respiratory pressure measurements from FRC.

The tests are carried-out in the same way as normal MIP and MEP efforts with the exception that the [Spacebar] is depressed during tidal breathing. When zero flow is detected at end tidal expiration, the valve is occluded ready for either a MIP or a MEP effort.

Since in cases of obesity, the end tidal position can be very close to RV, it is necessary to 'mark' those efforts completed at FRC.

Simply right click on the effort and select "At FRC" and highlight "Yes".

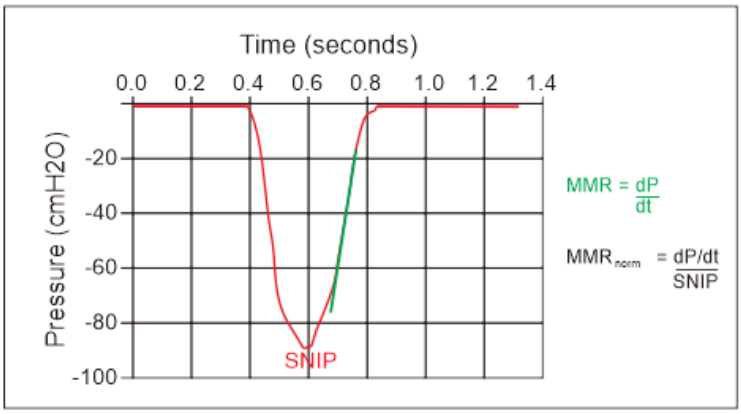


A check mark will appear in the "At FRC" column to help with reporting.

6.6 Sniff Nasal Inspiratory Pressure (SNIP)

6.6.1 Background on SNIP

Sniff Nasal Inspiratory Pressure (SNIP) is a test to assess inspiratory muscle strength. Neuromuscular diseases negatively affect both inspiratory and expiratory muscle strength; however, inspiratory pressure (unlike expiratory pressure) is predictive of hypercapnic respiratory failure. In addition, reductions in inspiratory pressure may indicate respiratory muscle dysfunction earlier than changes in vital capacity. In addition to assessing muscular strength, SNIP has been used as a predictor of respiratory muscle fatigue by analyzing the Maximum Relaxation Rate (MRR) of inspiratory muscles, calculated based on test kinetics.

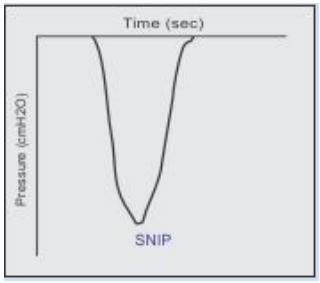


Inspiratory muscle strength has been more commonly measured via the maximum inspiratory pressure (MIP) maneuver. To measure MIP the patient must use a mouthpiece and nose clip, exhale fully to residual volume, then inhale with maximum force for 1.5 seconds. The MIP procedure may be difficult and fatiguing in patients with neuromuscular disease.

During the SNIP test, a nasal pillow attached to a pressure manometer in placed in a nostril. The patient is instructed to close their mouth then take a series of short, sharp sniffs every 30 seconds. The patient performs these sharp sniffs at the end of a normal breath (functional residual capacity), so there is no need for the patient to exhale completely. The largest of ten measurements is reported. The reported value can be reported as a percent of predicted and interpreted using the lower limit of normal.

SNIP may be preferable to MIP in some patients because it uses a more natural and less strenuous breathing maneuver.

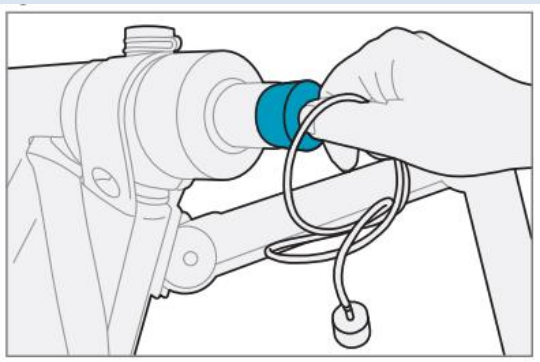
6.6.2 Sniff Nasal Inspiratory Pressure (SNIP) Method

Graphic Image	Method	Subject Instructions
	**Tidal breathing then:** **Tidal breath-out then a short maximal sniff with mouth closed** **Repeat**	Instruct subject to: **"From a normal breath out, perform a short, sharp sniff with your mouth closed".** Let the subject relax between efforts.

6.6.3 Preparing for SNIP Test

The ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

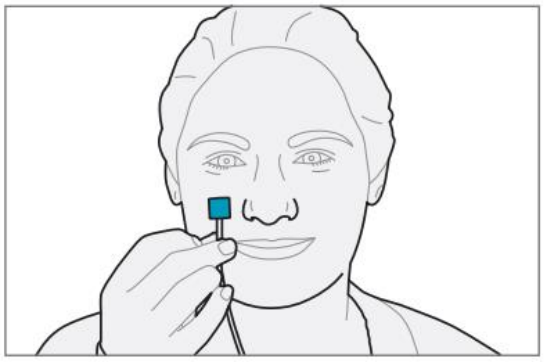
Preparing the Vitalograph Morgan PFT for SNIP

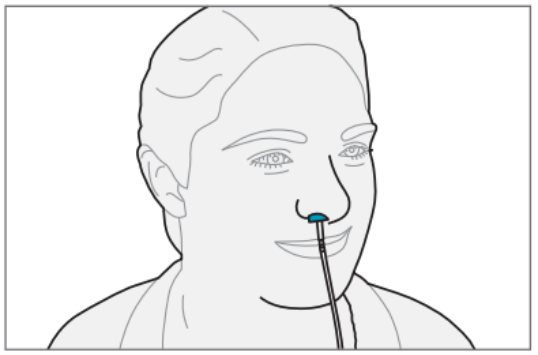


Connect the rubber stopper with Luer fitting onto the patient valve as shown.

Attach the selected nasal probe/pillow suitable for the test subject

Preparing the Subject for SNIP





1) Make sure the subject is sitting upright and place the nasal pillow securely into one nostril.

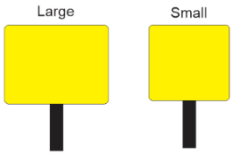
2) Instruct the patient about the performance of the test.

The opening screen of testing always defaults to Flow Volume in the mini results mode. If you want to change to SNIP, click on the side folder tab.

6.6.3.1 Nasal probes for SNIP testing

There are several nasal probe/pillow options for SNIP measurements available from different suppliers; the choice of which to use is up to the user. These come in different sizes and can be made from re-purposed equipment such as an ear tip intended for auditory evoked potentials or the nasal cushions from sleep apnea equipment.

Probe-type option



Pillow-type option

6.6.4 Performing a SNIP test

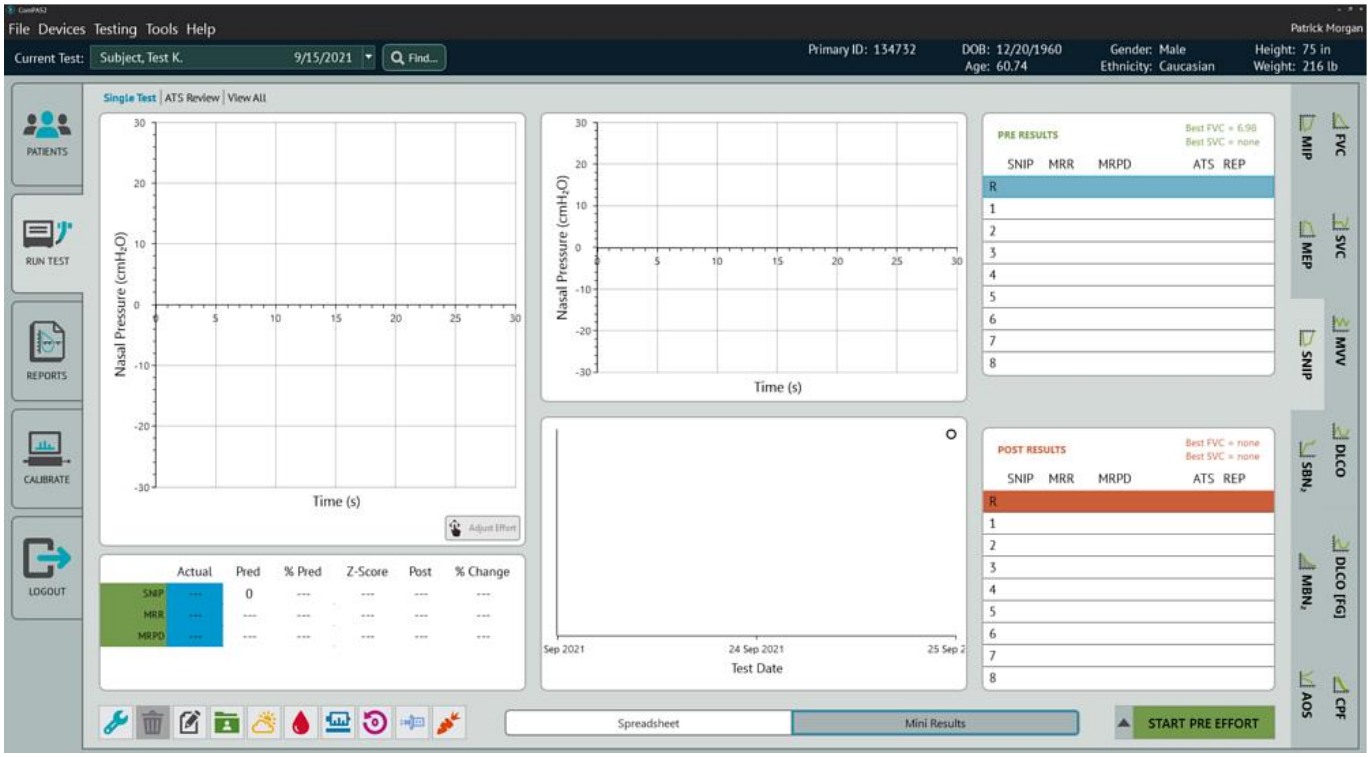
It is important to emphasize that tests of SNIP are totally dependent on patient effort. The tests require vigorous technician encouragement to avoid falsely low results being recorded!

Start with the subject in sitting position; the nasal pillow should be gently inserted into one nostril. A simple way to check for an air leak is to obstruct the other nostril during an inspiratory effort maneuver. If a leak is seen, adjust the nasal pillow or change to a different size accordingly.

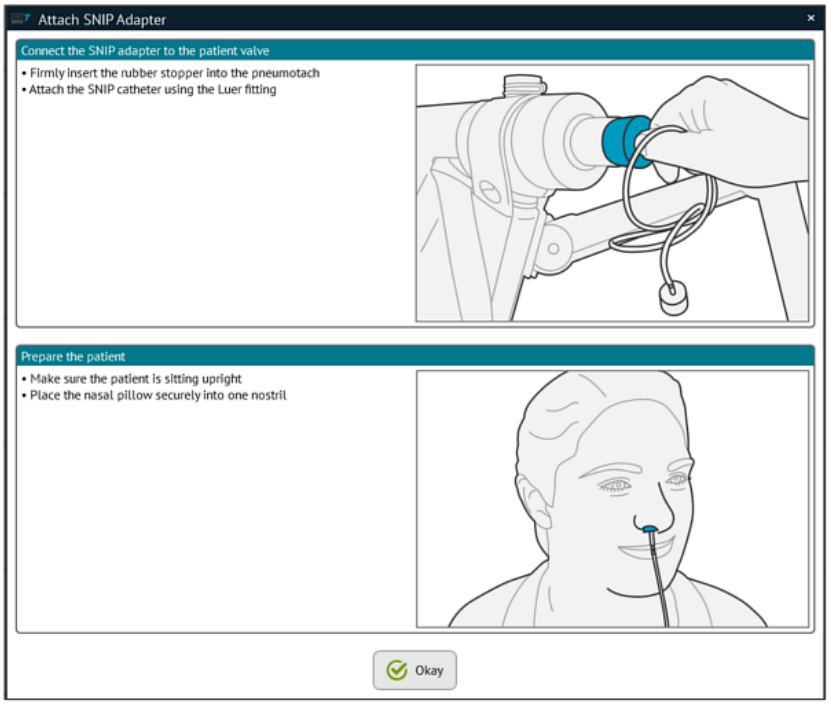
The subject is instructed to perform short, sharp sniffs with a closed mouth, starting from the end-expiratory volume after a quiet tidal breath out. Each sniff should be associated with strong verbal encouragement from the technician.

Sniffs can be repeated in any test run; the deepest sniff is automatically determined for analysis. At any time after a test run, the full sequence of sniffs can be viewed and alternative selections made if necessary.

In cases of nostril obstruction (by polyps or adenoids), the SNIP should be performed on the 2 nostrils, the highest value will be automatically selected for reporting.

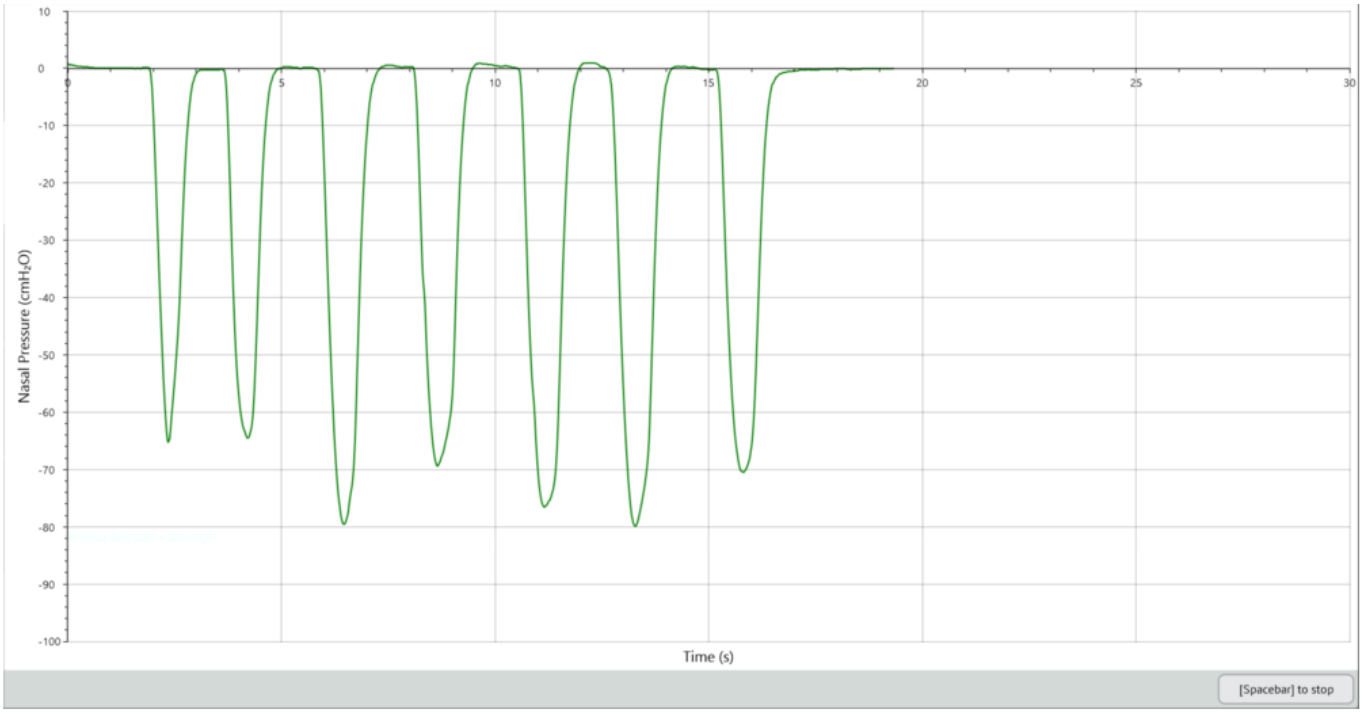


The [Spacebar] begins the test and a prompt appears to prepare for the measurement:

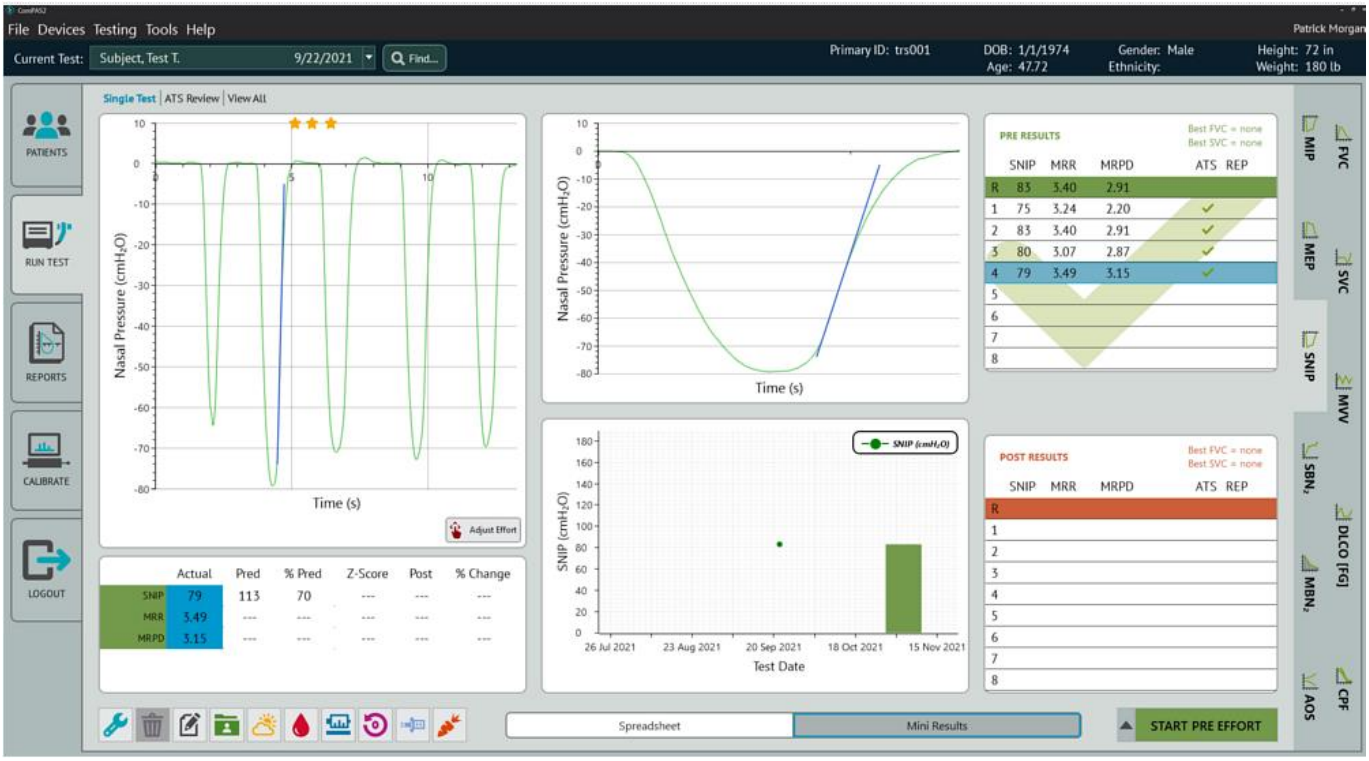


Pressing 

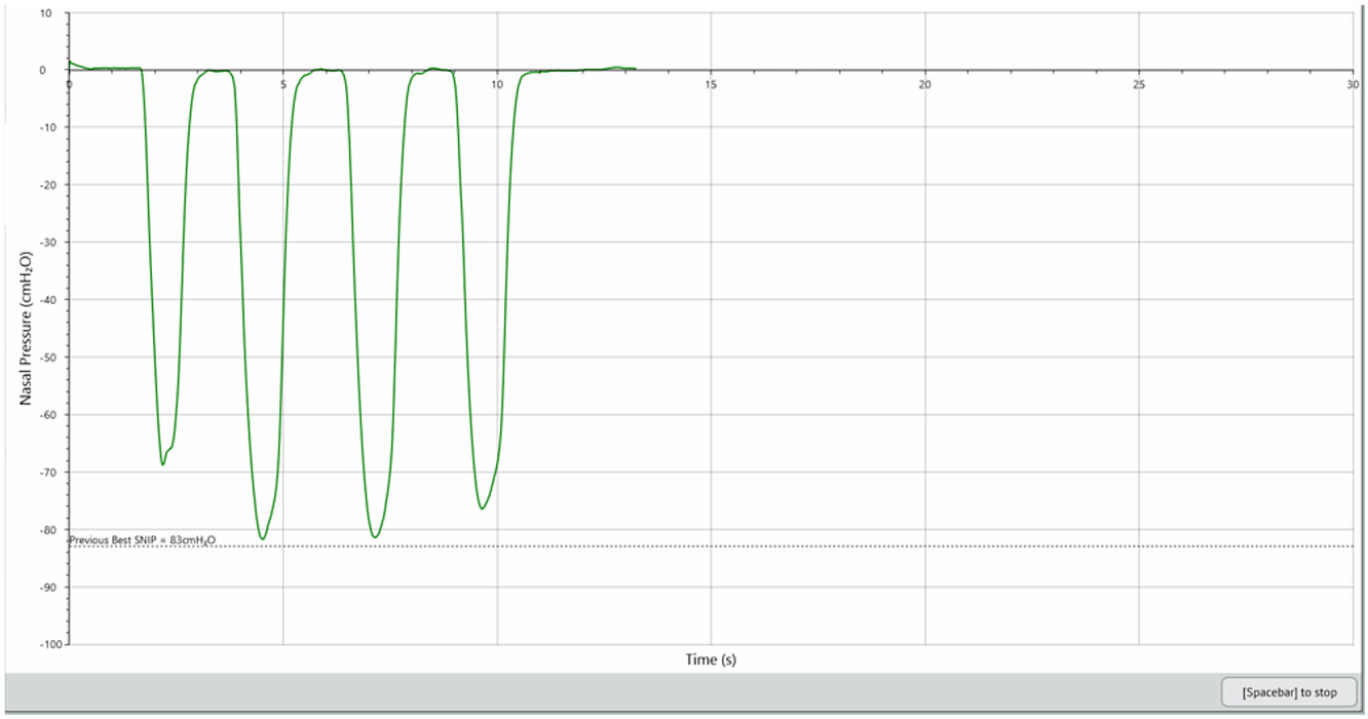
begins the test data acquisition and a screen showing Pressure -v- Time is displayed. Ensure that the nasal pillow is properly seated and encourage the subject to breathe normally. Instruct the subject to "From a normal breath out, perform a short, sharp sniff with your mouth closed". This can be repeated any number of times in one test capture. Once the effort is complete, click or press the [Spacebar] to end the test.



When the SNIP test is saved for each test run, the highest SNIP achieved is shown together with the slope of Maximum Relaxation Rate (MRR). Whenever tests of MIP have been recorded, the SNIP/MIP ratio is also shown.

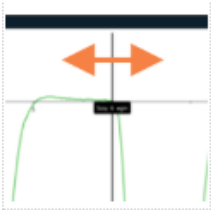


On subsequent SNIP test efforts, the best result achieved in the testing session so far is shown on the runtime screen. This gives the user the opportunity to always encourage the greatest sniff effort.



6.6.5 Adjusting SNIP Efforts

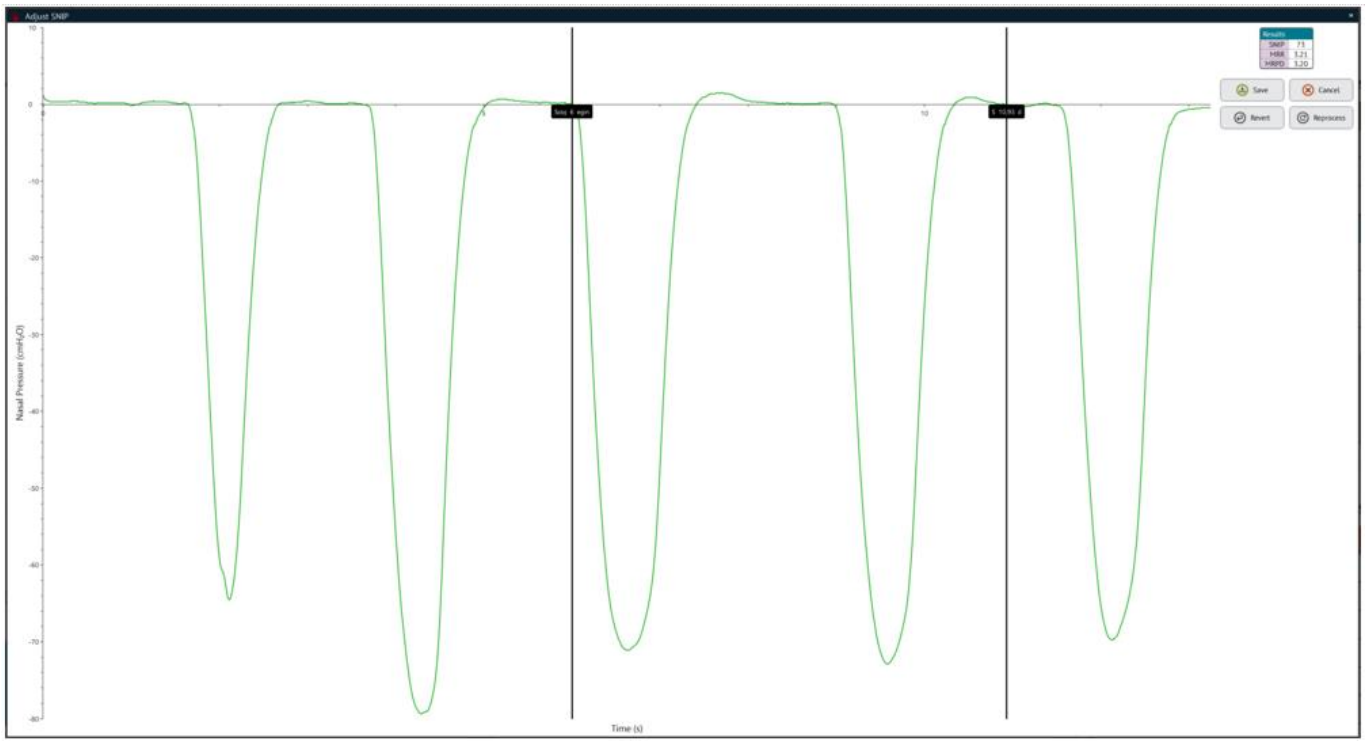
All the data from any SNIP test sequence is saved to allow for test review and re-selection if desired. The individual SNIP effort automatically selected will always be the highest value in any sequence of efforts.



To 'zoom-in' on an individual SNIP effort, use the [Scope Begin] and [Scope End] markers.

For the arrow functions to be visible, navigate the mouse above the zero scale as shown to the left.

The highest SNIP in any selected area will be used.



6.7 Single Breath Diffusion (DLCO) Testing

6.7.1 Preparing for a DLCO Test

Although diffusion is a "lung function" measurement, it is influenced by the volume of blood in the lung capillaries. Therefore, anything which affects that capillary blood volume will change the DLCO result.

The test should be carried-out when the subject is relaxed, sitting upright and preferably without having recently smoked.

Once the user presses or clicks [Spacebar], the software will guide them through the Vitalograph Morgan PFT unit preparation to ensure the instrument is ready to begin the test.

ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

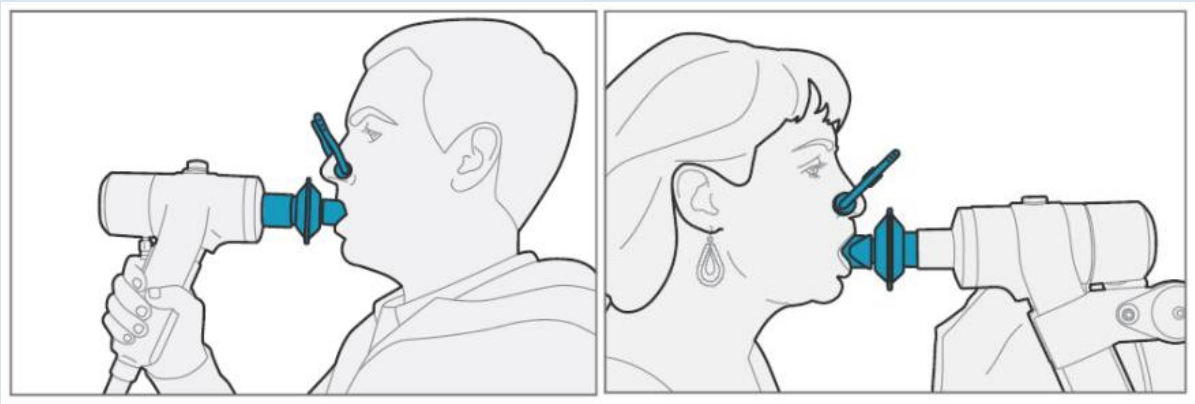
Preparing the Vitalograph Morgan PFT for DLCO

1) Connect a new bacterial/viral filter; be sure to push the filter into the valve to ensure a snug fit.

2) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for DLCO

There are two versions of the Vitalograph Morgan PFT, one using a demand valve and the other an inspiratory reservoir



1) Make sure the subject is sitting upright and is wearing a nose clip.

2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test.

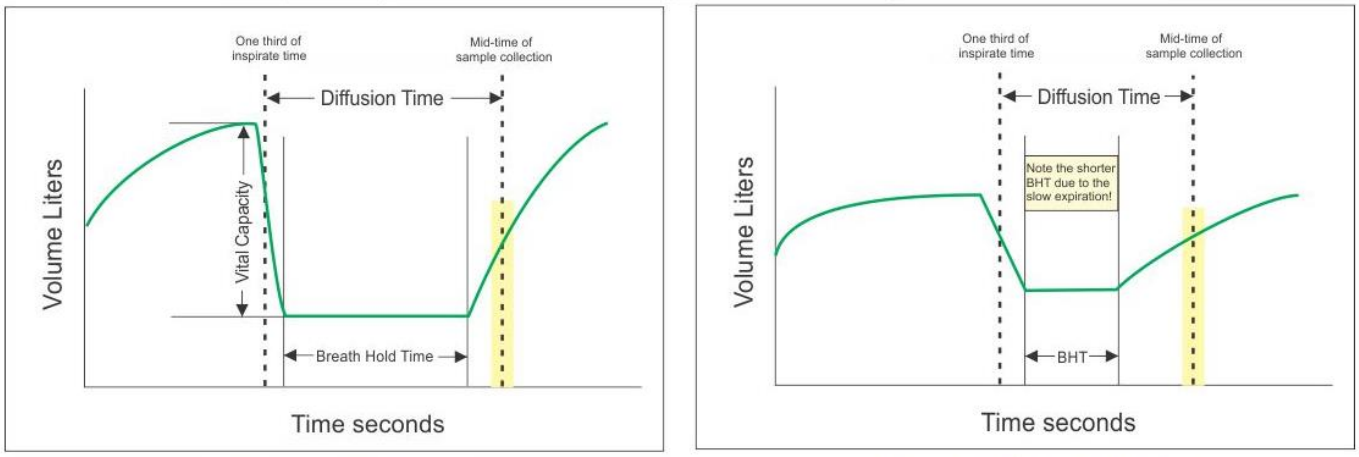
6.7.2 The Difference Between Breath Hold Time and Diffusion Time

A common misunderstanding is that "Breath Hold Time" and "Diffusion Time" are the same value. To help meet ATS guidelines, ComPAS2 uses the patient's FEF25-75 to dynamically set the time for opening the valve at the end of breath-hold. The aim is to obtain a "Diffusion Time" that falls between 8 and 12 seconds.

> **Diffusion Time** is defined as the time between "1/3 of Inspirate Time" to the "Mid-Time of Sample Collection".
>
> **Breath Hold Time** is simply the period when the valve is occluded.

For subjects with considerable obstruction, the "Breath Hold Time" may be reduced because it takes them longer to breathe out. The software always tries to meet the standard of a 9 to 11 second "Diffusion Time" goal.

Examples of Dynamic Breath-Hold Settings to Obtain an Acceptable ATS Diffusion Time



A Typical Normal Subject

A Severely Obstructed Subject

6.7.3 Understanding Washout Volume and Sample Volume

The challenge of Single Breath Diffusion testing is to obtain a representative sample of gas from an area of the lungs where diffusion is taking place. After having held their breath for 8 to 9 seconds, the first amount of gas that leaves the lips when the subject breathes out, has been resident in the physiological dead-space and must therefore, be discarded before collecting a valid gas sample.

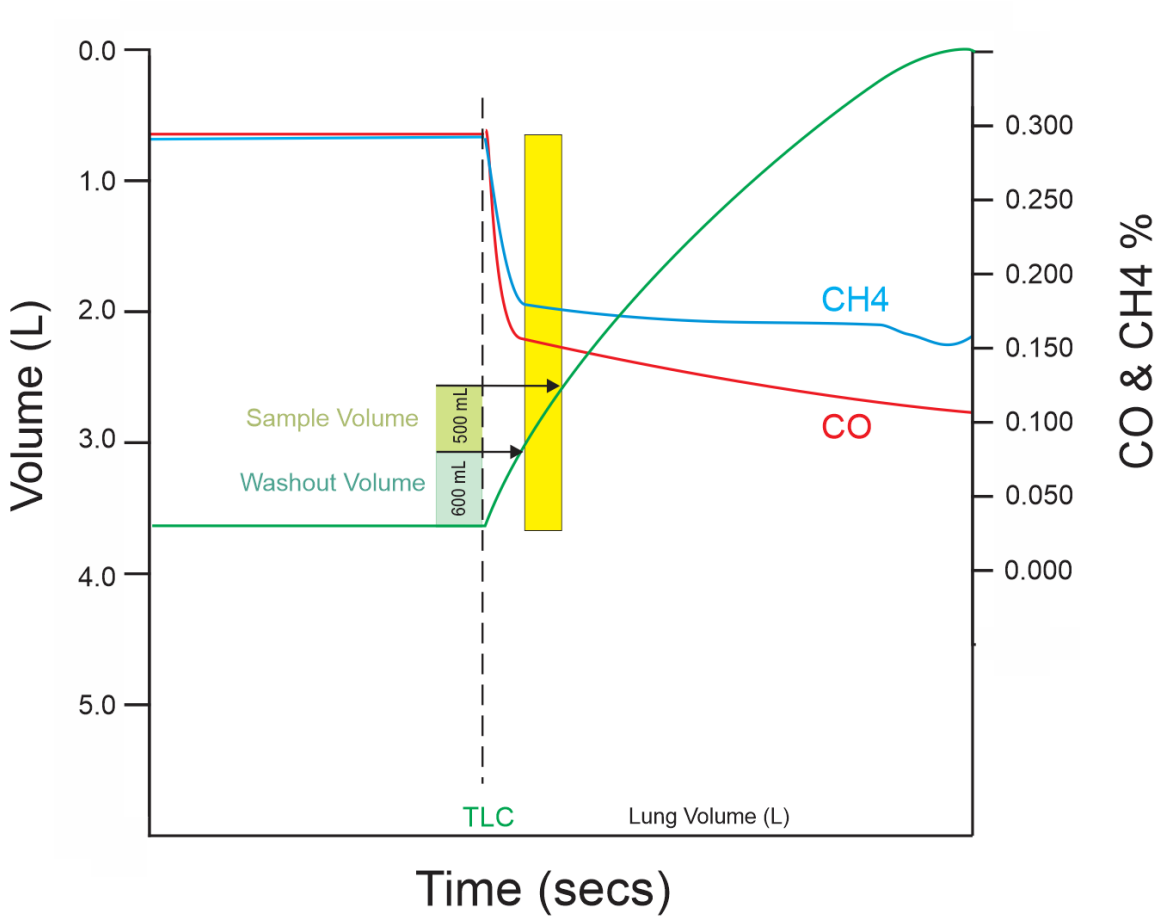
The software looks at the expiratory gas phase to automatically determine when the physiological dead space or washout volume has been cleared.

> **Washout Volume**
> Washout volume is that volume of gas thrown away before collecting a representative sample from the diffusing alveoli. Users can adjust the volume discarded following any DLCO test.
>
> **Sample Volume**
> Sample volume refers to the volume of gas sampled after the washout volume has been discarded. ComPAS2 determines the optimum sample volume based on the subject's vital capacity using the following logic:

Vital Capacity	Sample Volume
< 1.5L	100mL
< 2.0L	200mL
< 2.5L	300mL
< 3.0L	400mL
> 3.0L	500 mL

The setting for Sample Volume can be adjusted manually if desired following any DLCO test.

The Model 9100 PFT unit takes advantage of fast-responding analyzers (CO, tracer gas - Methane) with the advantage that given ideal matching of lag times and alignment of the flow to gas response, the physiological dead space can be properly determined, and alveolar gas measurement assured. At the conclusion of breath-hold, the subject breathes out and the two gases (CO and tracer gas) deflect dramatically once alveolar space is reached.



6.7.4 Understanding Hemoglobin Adjustment

Hemoglobin Adjustment (Hb)

Molecules of CO transfer across the pulmonary capillary membrane into the blood and there combine with hemoglobin. Therefore, if the Hb value is abnormal, it will in turn affect the DLCO (i.e. DLCO is reduced when

hemoglobin concentration is reduced). Anemia, COPD with emphysema, ILD, and pulmonary vascular diseases can decrease DLCO below the normal range.

When at all possible, a hemoglobin should be measured before completing DLCO tests. The Hb value is used to mathematically correct the **actual** or **predicted** diffusing capacity (depending upon configuration choice) to what it would be if the subject's hemoglobin was normal.

The corrected value being shown on reports etc. as **DLCO_Cor**.

ComPAS2 provides default Hb settings for male and female subjects.

Carboxyhemoglobin Adjustment (COHb)

If the COHb value is known, it can be entered either prior to the test.

The ComPAS2 configuration allows for adjustment of the DLCO **actua**l or the **predicted** value if either Hb or COHb are known.

Under "Runtime Options" in the "Configuration" menu, users can now select which method they prefer to adopt. If you check-off "Adjust DLCO predicteds based on actual Hb and COHb" then the predicted scripts will leave the actual DLCO value untouched and adjust the predicted value.

If left unchecked, then the DLCO Cor value shown on the spreadsheets and reports will be adjusted for Hb and or COHb.

6.7.5 Understanding the DLCO test sequence

Once the [Spacebar] has been pressed, the program will guide the user through a simple sequence of screens to prepare for testing.

Once the system detects the subject breathing, the display will show the tidal volume.

Instruct the subject to "**Breathe all the way out until you are completely empty**".

During the breath-out, press the [Spacebar]. It is very important that the subject is completely empty before starting the breath-in; the software looks for a plateau in the volume-time curve and then automatically switches the valve for inspiration.

If the subject cannot reach a plateau, a second [Spacebar] will trigger the valve to switch for inspiration. The most common reason for subjects not reaching TLC when performing a DLCO maneuver is the lack of expiratory effort at this stage.

Now instruct the subject to "**Breathe all the way in until you are completely full".**

As soon as the breath-in begins, a yellow target area appears on the screen. This area is based on the subject’s best VC (SVC or FVC whichever is the greater); the area is drawn between 90% and 110% of the best VC.

A dotted line is drawn at 85% of best VC. If a subsequent DLCO test effort has an inspiratory volume which falls between 85% and 90% of target AND the resultant Alveolar Volume is within 200ml of a test with a 90% or better inspiratory volume then it can be considered for repeatability criteria.

If the subject reaches the inspiratory target area, the valve will automatically close for breath hold once inspiratory flow has ceased.

Now instruct the subject to **"Hold your breath**".

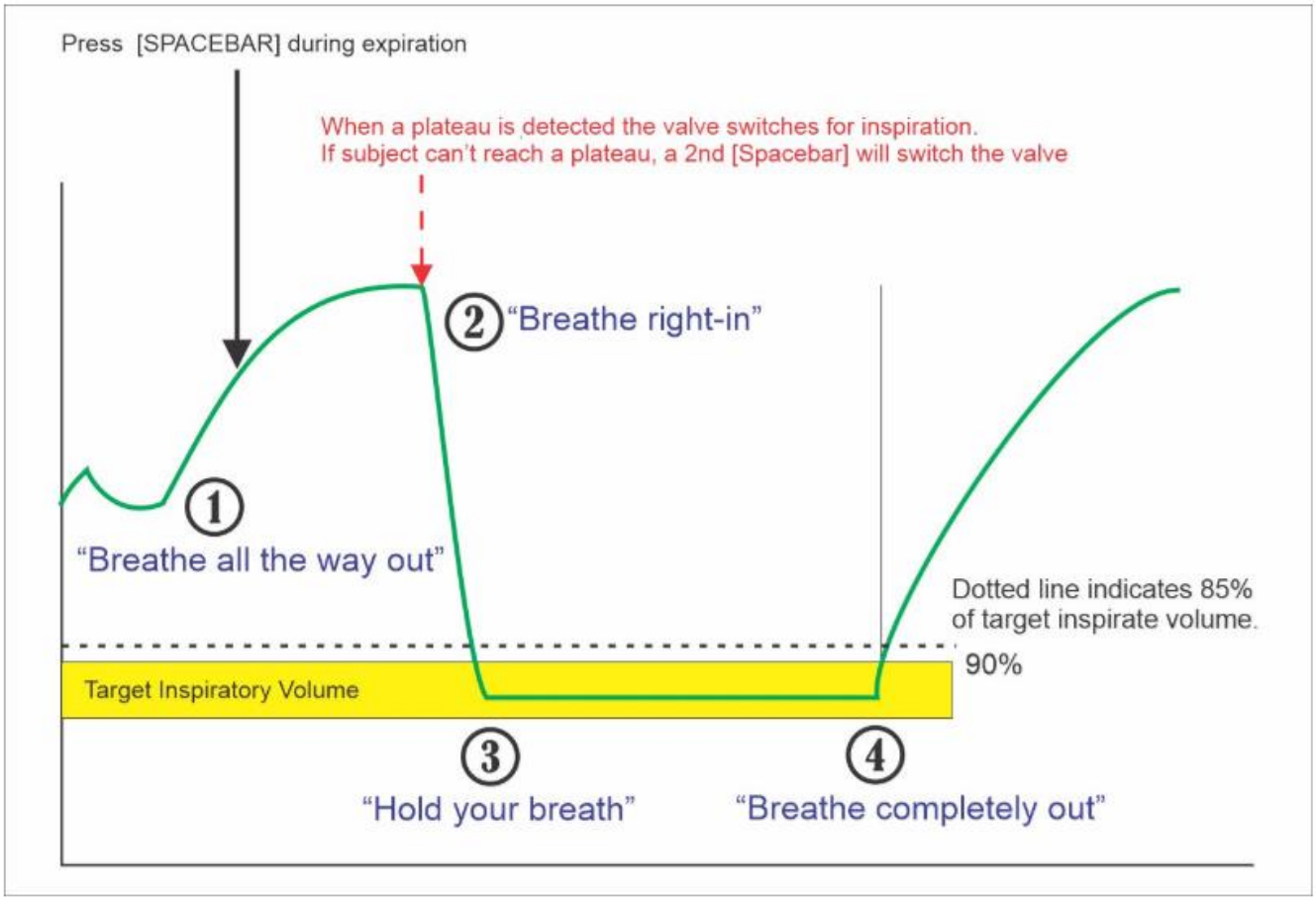
If the subject fails to reach the inspiratory target volume, breath hold can be manually triggered by pressing the [Spacebar].

A common problem for subjects trying to achieve full inspiration is muscular tension. If the subject is very tense across their shoulders, then it is impossible to fully inflate their chest. Encourage the subject to roll their shoulders prior to testing, this helps relax any muscular tension.

Two vertical lines are drawn on the screen. The right-hand line indicates when the Breath Hold Time will be complete and the subject can breathe out to collect an expired sample and end the test. The subject's breath hold can be seen as a horizontal line progressing across the screen.

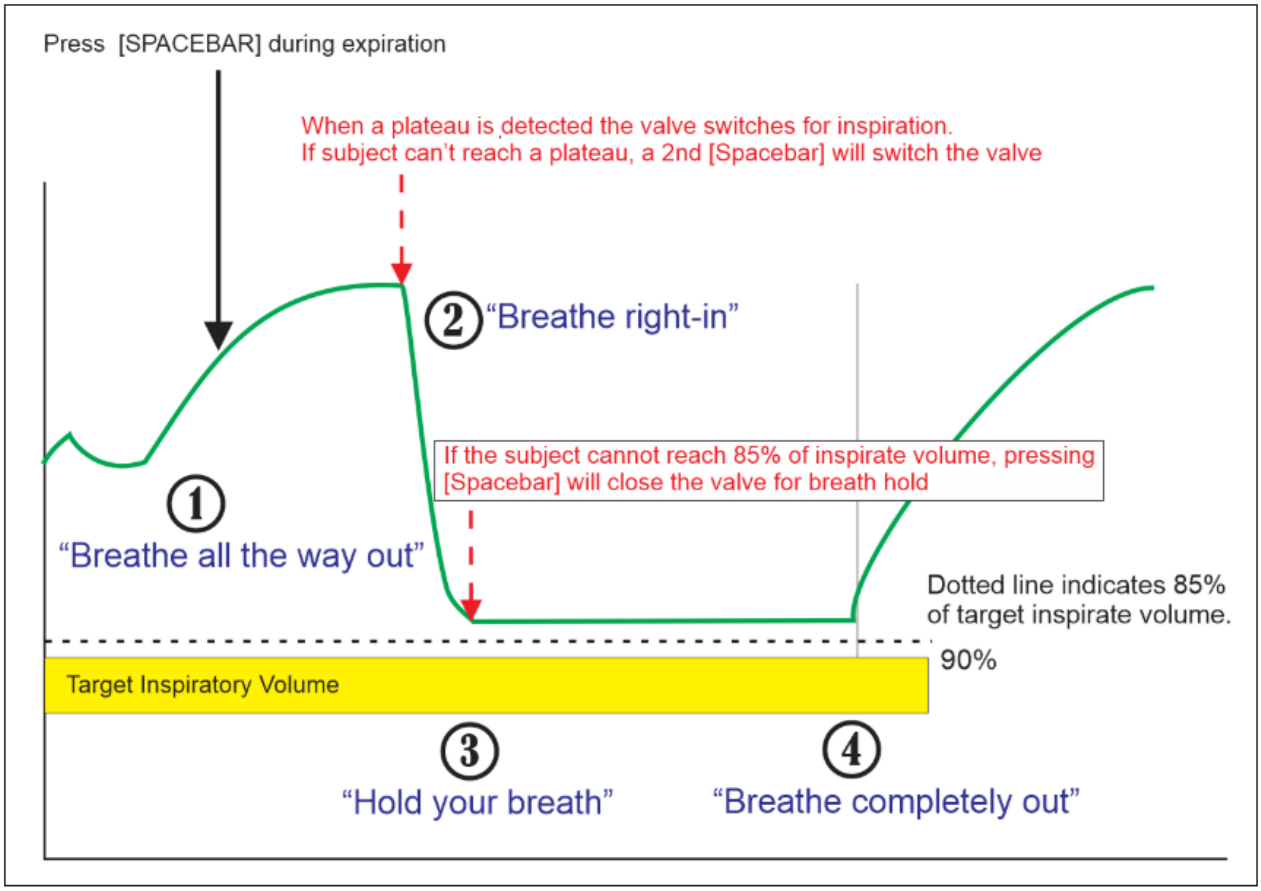
Once the line reaches the end of breath hold marker, instruct the subject to "**Breathe steadily and completely out**"

VERY IMPORTANT! *This should not be a forced breath out similar to a Flow Volume Loop effort. It should only be a steady breath out until completely empty. A visual flow meter is displayed during the expiratory effort to help subjects maintain the optimum expiratory flow rate.*



Although measuring DLCO with inadequate inspirate volume is questionable, ComPAS2 does let the technician do so in difficult cases. A great tip is to have the subject roll their shoulders before any maximum breathing tests to relax the neuromuscular frame. When test subjects fail to reach the target of inspirate volume it is always one of three causes:

1. Their shoulders are tense
2. They failed to fully empty before breathing in
3. The inspirate effort was poor and the test should be repeated



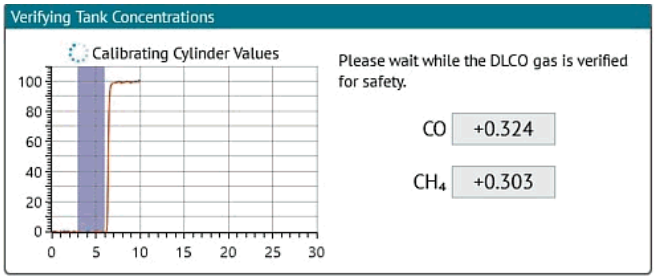
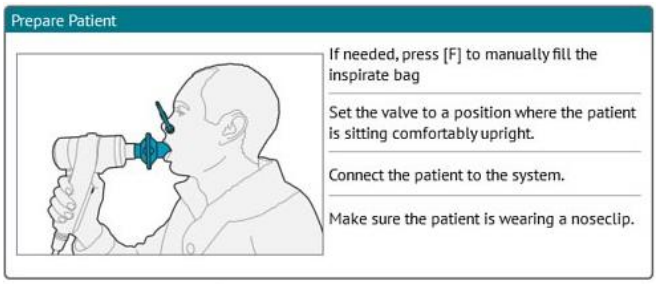
6.7.6 Performing DLCO Test

The opening screen of testing always defaults to Flow Volume in the mini results mode. Select the DLCO FG from the side folder tabs.

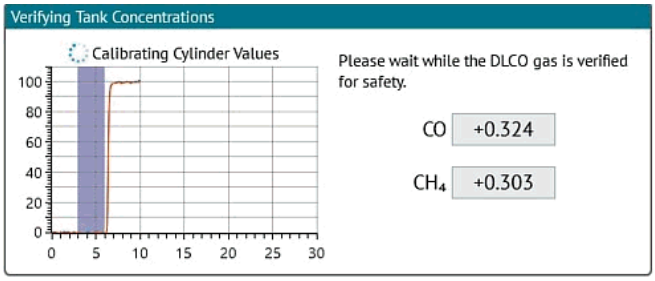
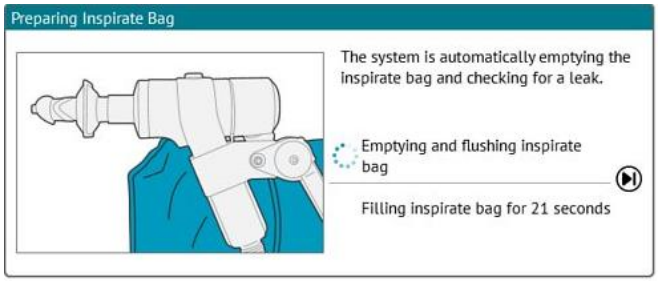
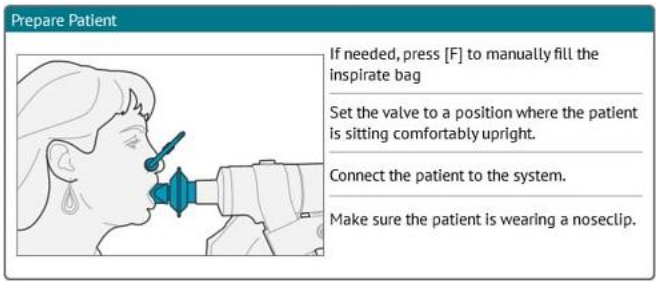
The test begins with a DLCO preparation sequence:

There are two versions of the Model 9100, one using a demand valve for gas delivery and the other an inspiratory reservoir bag.

DLCO Test Set-up with the Demand Valve

Step 1. Sampling the Gas Cylinder Prior to any DLCO test effort the inspiratory gas mixture is measured as a safety precaution.	
Step 2. (Optional) Addition of Hb and COHb At any time, the subject's Hb and or COHb can be input and used for correction in the final DLCO results. *Hb and COHb can also be entered at any time after a completed DLCO test and the results will be automatically re-calculated.*	
Step 3. Connect Subject Once the gas mixture has been confirmed, it is time to sit the subject comfortably upright and ask them to go onto the mouthpiece. Remember to ensure that the subject is wearing a nose clip! Once the "Next" button has been clicked, or the [Spacebar] pressed, the test will commence.	

DLCO Test Set-up with Inspiratory Bag

Step 1. Sampling the Gas Cylinder Prior to any DLCO test effort the inspiratory gas mixture is measured as a safety precaution.	
Step 2. Preparation of the Inspirate Bag The inspirate bag will first be completely emptied and then automatically filled with a volume appropriate to the subject's best Vital Capacity (FVC or SVC). The [F] or [F5] buttons can be used to manually add additional gas to the bag if desired. If too much gas is entering the bag, clicking the icon will halt gas flow and move to the next screen.	
Step 3. (Optional) Addition of Hb and COHb At any time, the subject's Hb and or COHb can be input and used for correction in the final DLCO results. *Hb and COHb can also be entered at any time after a completed DLCO test and the results will be automatically re-calculated.*	
Step 3. Connect Subject Once the gas mixture has been confirmed, it is time to sit the subject comfortably upright and ask them to go onto the mouthpiece. Remember to ensure that the subject is wearing a nose clip! Once the "Next" button has been clicked, or the [Spacebar] pressed, the test will commence.	

The first part of DLCO testing is important; that is, having the subject breathe all the way out until they are completely empty (at Residual Volume). Sometimes this is best achieved by asking them to breathe out from the top of a tidal inspiration rather than from TLC.

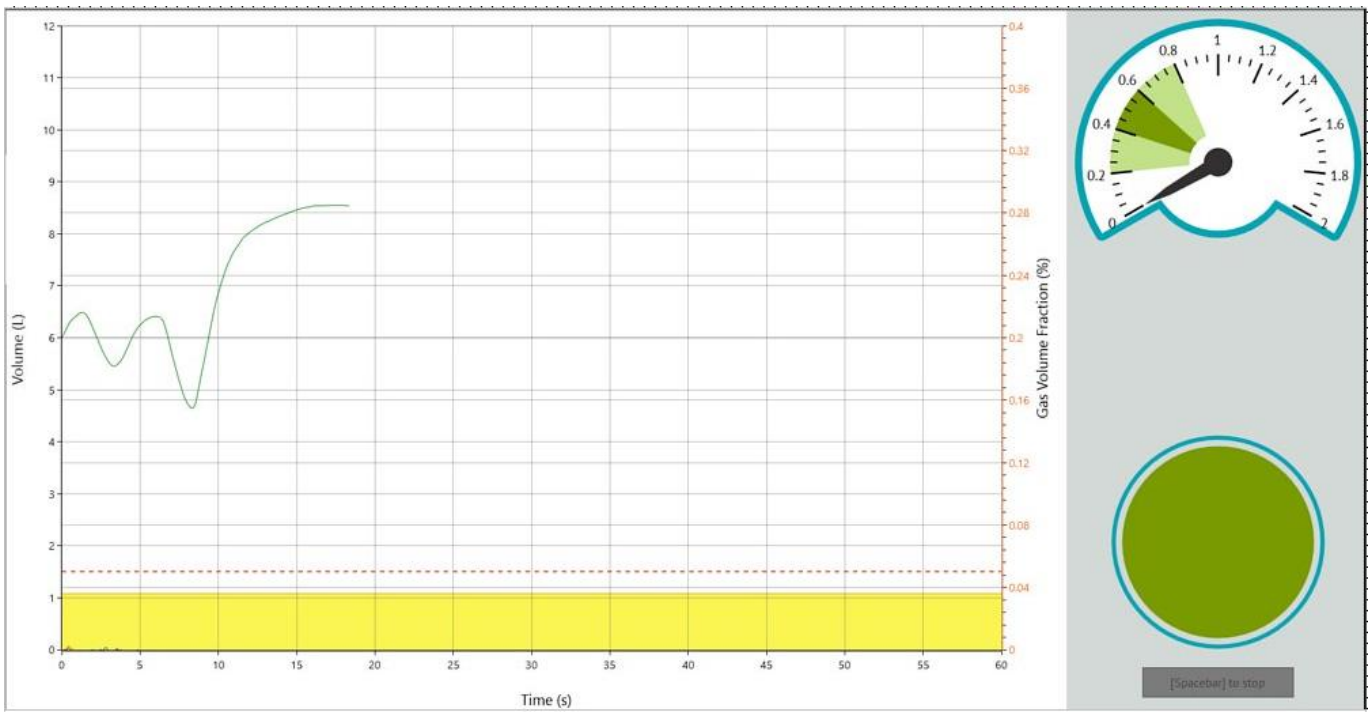
Instruct the subject to "**breathe all the way out**". During the breath out, press the [Spacebar].

It is important that the subject breathe all the way out until they are completely empty (at Residual Volume).

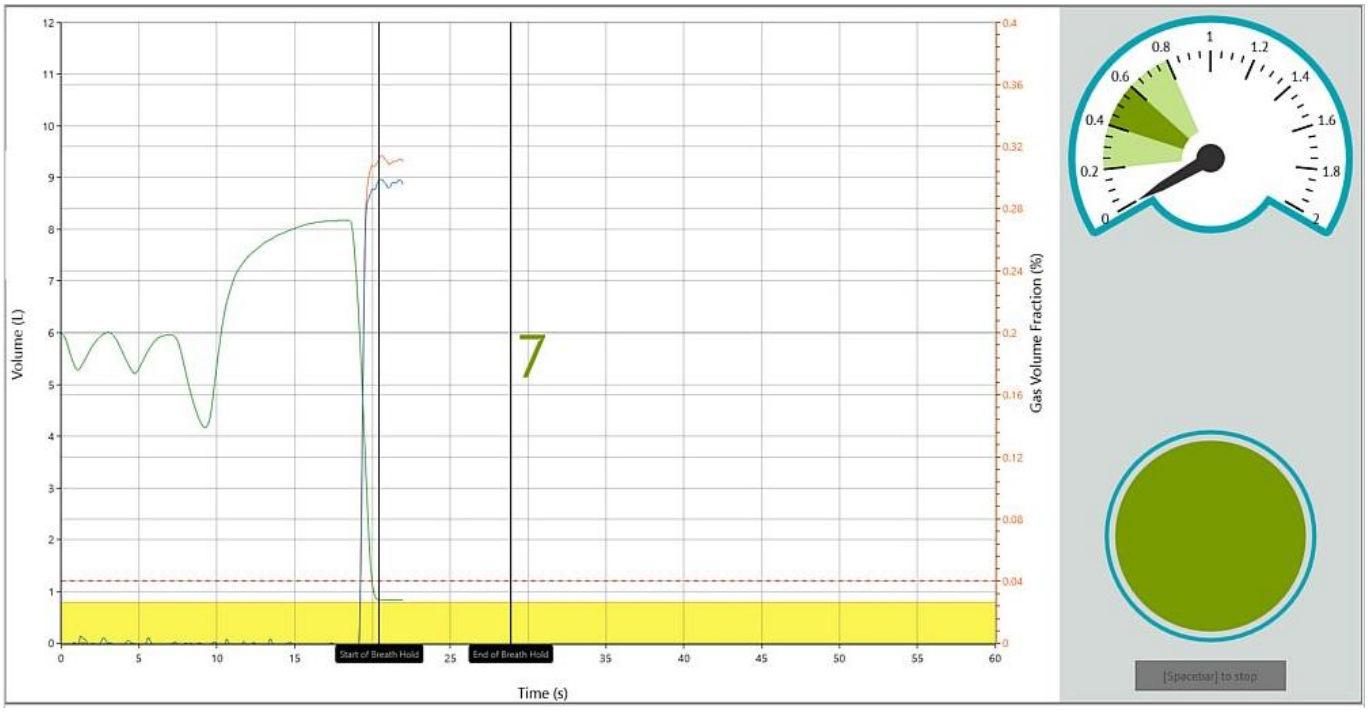
The bottom End of Expiration Meter is useful in seeing that the expiratory effort achieves a plateau in the volume time curve.

End of Expiration (EOE) criteria is a < 0.025L volume change over 1 second duration. If desired, the EOE criteria can be configured in the configuration by clicking on “Testing”.

Further to the visual indication of a plateau, an audible beep can be configured. A single beep can be sounded when a plateau in the volume time is reached.in the bottom right of the screen looks for End of Test (EOT) criteria to be met.



When the subject has fully emptied their lungs, the valve switches them to the diffusion gas, ask the subject to **"breathe all the way in**!”



A yellow target area is presented on the screen which is based on 90% to 105% of the subjects best Vital Capacity. A dotted line at 85% of best VC indicates a volume that can indicate a valid inspiratory volume only if at least one test has achieved 90% or above inspiratory volume. Always try and achieve 90% inspiratory volume to have the best likelihood of DLCO repeatability!

The routine allows the subject breathe-in beyond any target lines if they are able to. The valve will automatically trigger breath hold when flow ceases.

If the subject consistently fails to reach the required inspiratory volume it could be the result of tension in their upper body. A good technique to use prior to any pulmonary test, is to ask the subject to "roll their shoulders'. This will release tension and often improve inspiratory volume.

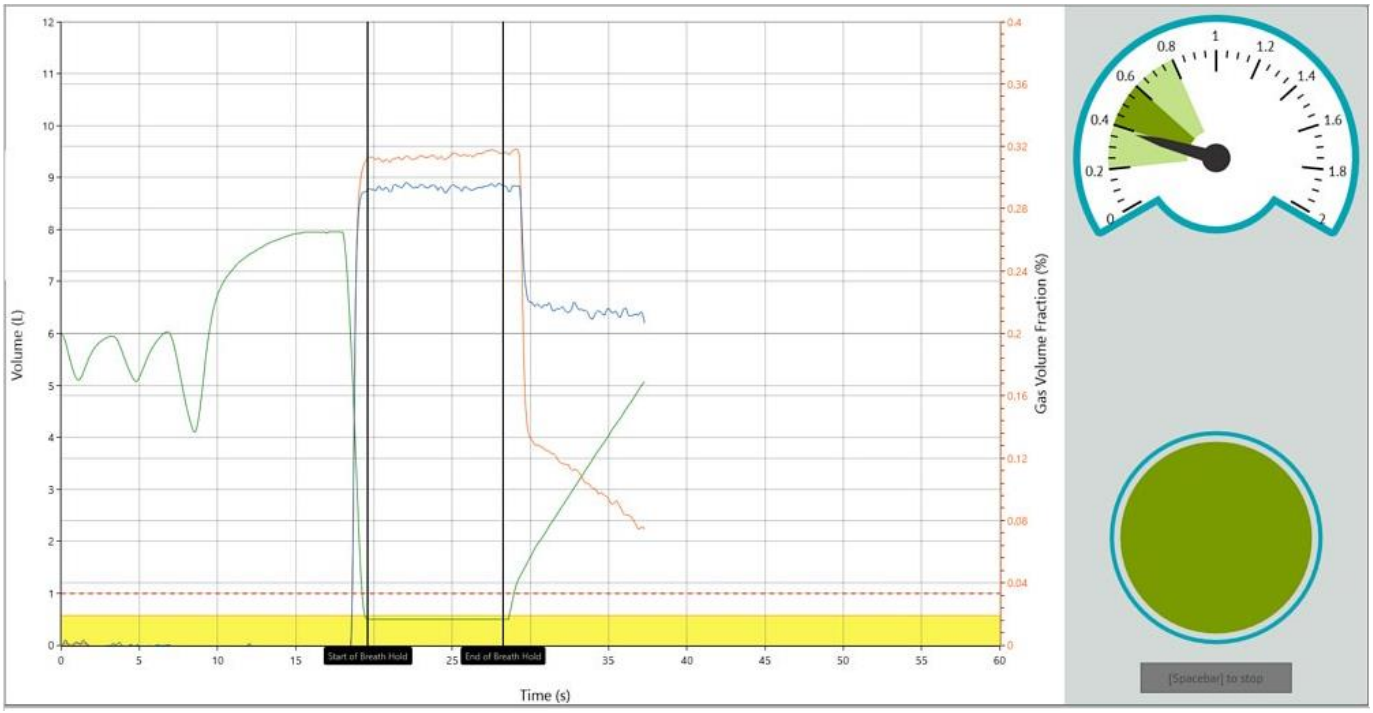
Once inspiratory flow has ceased, the valve will automatically trigger to breath-hold. If they fail to reach the 85% line, breath hold can be manually triggered by pressing the [Spacebar], however the test really should be considered inadequate.

Once the breath-hold has been reached, two vertical lines are drawn on the screen. Instruct the subject to "**hold your breath"**.

A countdown clock appears on the screen, encourage the subject to "**keep holding**".

When the countdown is complete, and the subject reaches the second vertical line, the valve switches to allow a steady breath out. Instruct the subject to "**watch the meter and breathe steadily all the way out**".

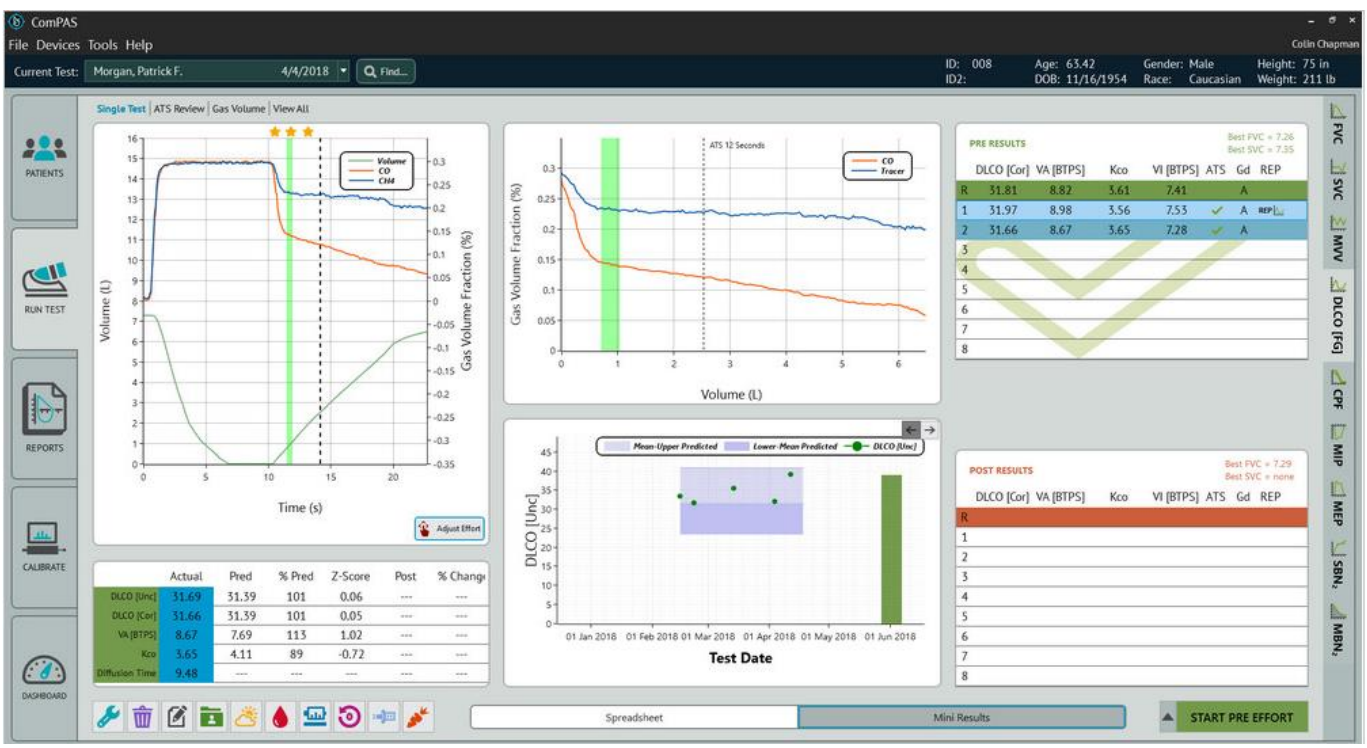
Since this breath out needs to be at a constant a flow rate, a helpful flow meter is shown on the screen to guide the subject's effort. The 'Green' area on the flow meter represents the optimal expiratory flow rate. Instruct the subject to: "**keep breathing out until completely empty**".



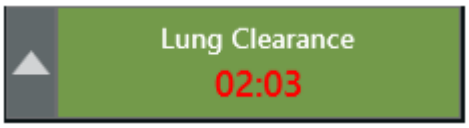
Press the [Spacebar] when the test is concluded.

During the entire test sequence, volume, time and gas analysis is displayed.

Having completed the test, all results and captured graphics are displayed for review.



Having measured the gases, the screen is returned to the mini-result display with the key test results.



To help guide the technician on the recommended time between DLCO efforts, a clock appears on the start button to countdown between test efforts.

The countdown clock will also appear if a test has been aborted. It is only a guide, so tests can continue before the countdown has elapsed if desired.

To optimize testing time, the countdown takes into consideration the time taken to set-up for the next DLCO maneuver

As each test is evaluated, the ATS column on the right-hand side of the screen will indicate progress towards meeting the ATS testing guidelines:

<table>
<tr><th>Test</th><th>December 2017 Acceptance Criteria</th></tr>
<tr><td>DLCO</td><td>

For Acceptability:

Inspiratory volume >= 90% of best VC or >= 85% if the VA is within 200ml or 5% (whichever is larger) of patient's highest acceptable VA

85% of Inspiratory volume achieved within 4 seconds

Diffusion Time between 8 and 12 seconds

End of sample taken <= 4 seconds from end of breath hold

Required interval between tests (4 minutes minimum, 10 minutes for patients with severe obstruction)

For Repeatability:

The December 2017 standards include a suggested scoring/grading system for test quality based on inspired volume, breath-holding time and sample collection time. The grading has been added to the test confidence message. See table below.

Note: When a "B" grade test meets the requirements for repeatability, it is promoted to A* so that the user can determine which tests were used in averaging on the report.

<table>
<tr><th>Score/Grade</th><th>Vi/VC</th><th>tBH</th><th>Sample Collection</th></tr>
<tr><td>A</td><td>>= 90%</td><td>8 - 12 s</td><td><= 4 s</td></tr>
<tr><td>B</td><td>>= 85%</td><td>8 - 12 s</td><td><= 4 s</td></tr>
<tr><td>C</td><td>>= 80%</td><td>8 - 12 s</td><td><= 5 s</td></tr>
<tr><td>D</td><td>>= 80%</td><td><8 or >12 s</td><td><= 5 s</td></tr>
<tr><td>F</td><td>Any test not</td><td>meeting A, B, C</td><td>or D</td></tr>
</table>

Only Grade A or A* maneuvers meet all acceptability criteria.

Average of two or more acceptable DLCO's that agree within 2 mlCO/min/mmHg

<u>New December 2017 Recommendations Now Used in Reporting:</u>

The average DLCO from two or more grade A maneuvers that are repeatable should be reported.

If two or more grade A maneuvers are not repeatable, then the average DLCO value from the acceptable maneuvers (all grade A maneuvers) is reported.

If only one grade A maneuver is obtained, then the DLCO value from that maneuver is reported.

If no acceptable Grade A maneuvers are obtained, then the average DLCO value of the maneuvers with grades B, C or D is reported.

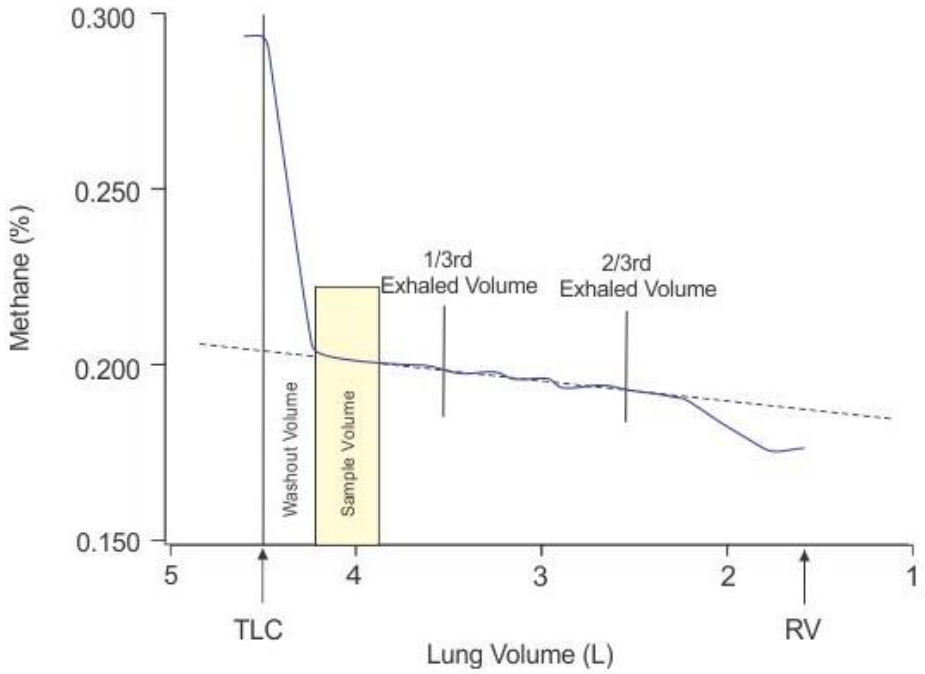
If only grade F maneuvers are obtained, then no DLCO value is reported. ComPAS2 automatically excludes grade F results.

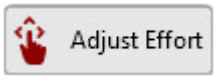
</td></tr>
</table>

6.7.7 Manual Adjustments of the alveolar gas sampling area

Automatic selection of the discard or Washout Volume is based upon a subroutine that fits a regression line to the mid third of the exhaled tracer gas concentration plotted against lung volume and the point of last departure from the line. This provides an objective method for ensuring that the virtual alveolar gas sample is collected appropriately.

The Sample Volume area over which the gas values are sampled is based upon the configuration setting.



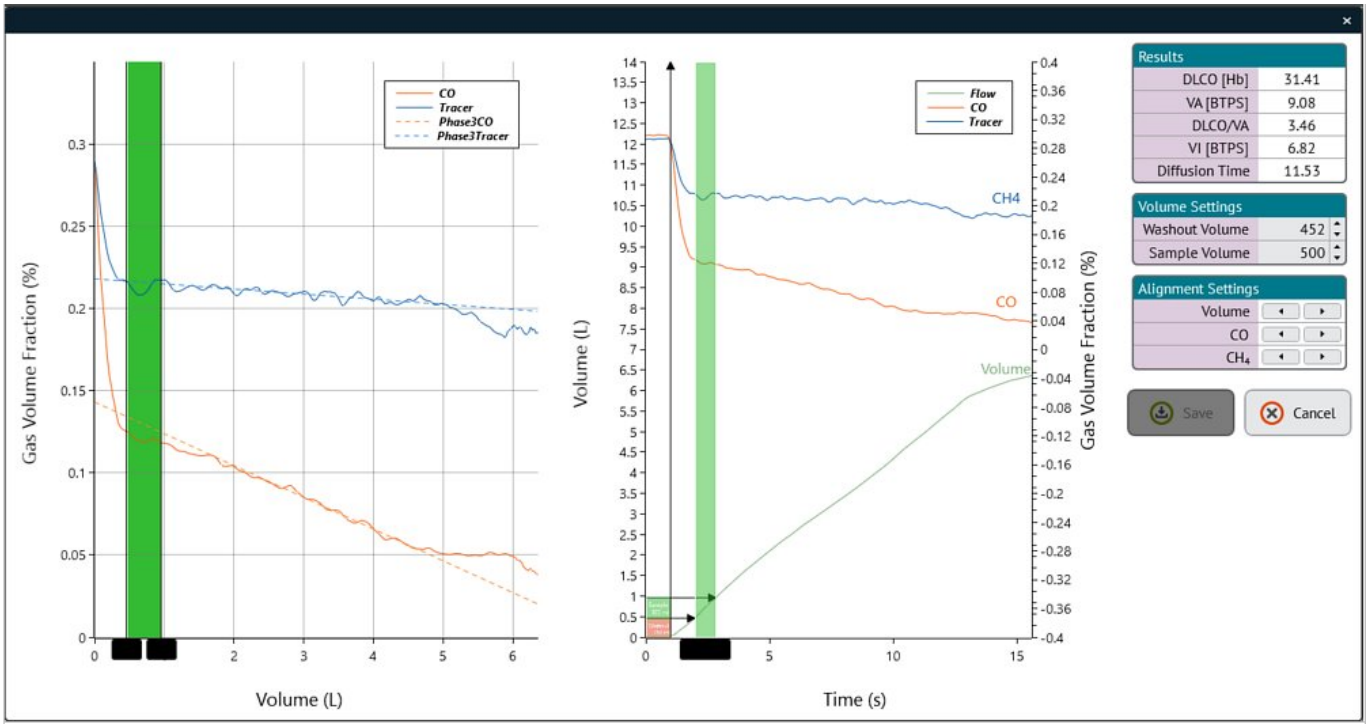
Manual override of the automatic selection is available by clicking the 

button.

The adjust screen will load with the automatic selection of the washout and sample volume. Adjustments can be made on either graph in several ways. The bottom line anchors can be moved, the entire volume 'bar' can be moved or either vertical line can be clicked and moved.

Line anchors

If, at any time, the sample volume area chosen causes the diffusion time to exceed 12 seconds, the Diffusion Time result will be highlighted in red as a user warning. If this occurs, reducing the Sample Volume can sometimes bring the Diffusion Time into valid ATS/ERS range.



6.7.8 Manual Selection of Data and Graphic

The mini-result screen indicates clearly where information going to the final report is coming from. ComPAS2 allows the user to override the automatic selection of both data and graphical information.

Through use of the right-click functions, the technician can individually select the data and DLCO graphic preferred for the final report.

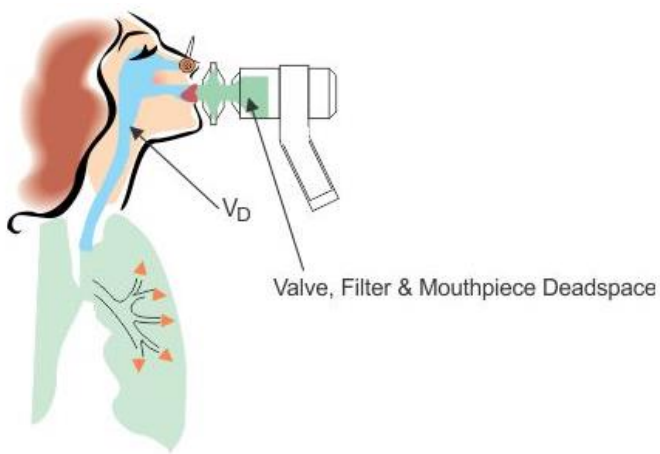
In cases of both the data and the graphic, the user selected choices are:

Automatic	Automatically selected DLCO graphic and data
This Effort	Use this to select all data or the DLCO graphic for reporting

Selection icons under the REP column shown in **black** indicate automatic selection by ComPAS2; those shown in **red** indicate technician override.

REP	Automatically selected DLCO graphic and data	This identifies the effort where both the DLCO graphic and data that will be printed on the final report are coming from
REP	The user has selected the DLCO data	This individual DLCO effort has been selected by the user and will be reported
	The user has selected "This Effort" for DLCO graphic	This individual DLCO graphic has been selected by the user and will be reported

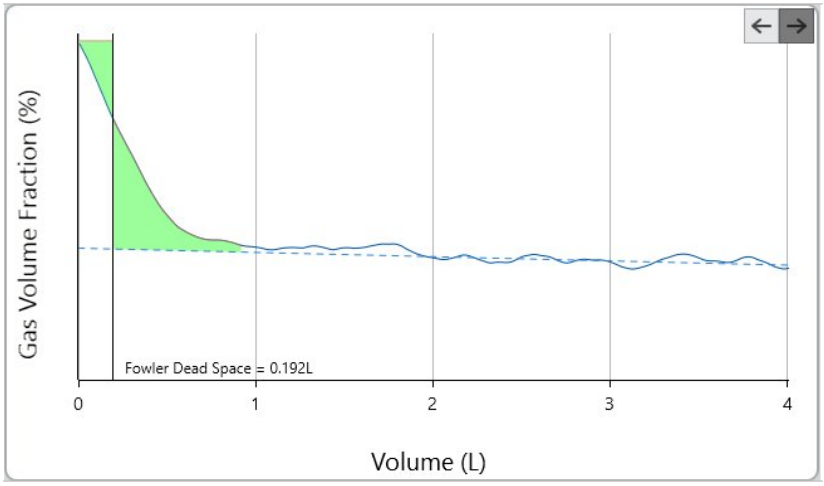
6.7.9 Display and Calculation of Fowler's Dead Space

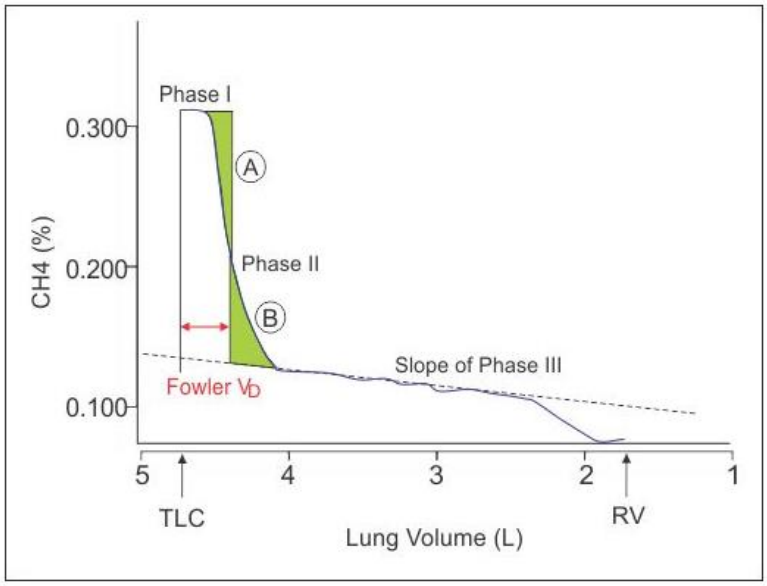


Anatomical dead space (VD) is that it is that part of the inhaled volume that remains in the airways at the end of inhalation and does not participate in gas exchange. It includes that portion of the airways (such as the mouth and trachea to the bronchioles) which conducts gas to the alveoli. No gas exchange is possible in these spaces

Total dead space has to also consider the instrument dead space which includes the valve, filter and mouthpiece.

The Fowler dead space method has the advantage of measuring both the anatomic dead space and instrument dead space between the gas sampling port and the subject. In ComPAS2 this value is stored as Total Dead Space.





The graphical solution identifies the slope of phase III along the alveolar plateau of the expired volumetric tracer gas. The downstroke of the Phase II curve is partitioned into two equal trapezoid areas (A and B).

The total dead space = the volume between the start of Phase I and the intercept of the equal trapezoids from Phase II aligned to the slope of Phase III.

6.7.10 Adjusting for Volume Lost to the Sample Pump

During each phase of the DLCO maneuver (initial expiration, inspiration, breath hold and final expiration), the sample pump is drawing volume from the mouth port; the pump sample rate is set at 600ml/min. The DLCO routine automatically adds back the volume 'lost' to the sample pump so that all volumes inspired and expired are corrected.

6.7.11 DLCO Calculations

ComPAS2 shows both an uncorrected and a corrected DLCO.

DLCO_Unc = uncorrected DLCO
DLCO_Cor = corrected DLCO

<u>6.7.11.1 Alveolar Volume Calculation (VA):</u>

VA_BTPS = (VI_BTPS - Total Dead Space) * (FITracer / FETracer)

Where:
Fractional concentrations of tracer gas (Methane) - Inspired = FITracer, Expired = FETracer
*BTPS to STPD Correction = ((Barometric Pressure mmHg - 47.1) / 760) * (273 / 310)*
*VA_STPD = VA_BTPS * BTPS to STPD*

<u>6.7.11.2 DLCO Uncorrected Calculation (DLCO_Unc):</u>

DLCO_Unc = ((VA_STPD * 1000 * 60) / ((BaroP - 47.1) * Diffusion Time)) * Log((FICO * FETracer) / (FECO * FITracer))

Where: Breath-hold time in seconds (calculated by the method of Jones and Meade)
Barometric pressure in mmHg
Fractional concentrations of carbon monoxide and tracer gas (Methane)
Inspired = FICO & FITracer
Expired = FECO & FETracer

6.7.11.3 DLCO Corrected Calculations (DLCO_Cor):

A configuration option allows for correction of either the actual DLCO or the predicted DLCO.

The DLCO_Cor is always corrected for barometric pressure/altitude; corrections for Hb and COHb require data input.

Barometric Pressure/Altitude Correction:

DLCO_Cor = DLCO_UNC * (0.505 + 0.00065 * Barometric Pressure mmHg)

HB Correction:

```
If Hb > 0 Then
   If Age < 15 Or Female
      DLCO_Cor = DLCO_Cor * (Hb + 9.38) / (1.7 * Hb)
   Else
      DLCO_Cor = DLCO_Cor * (Hb + 10.22) / (1.7 * Hb)
   End If
End If
```

COHb Correction:

```
If COHb > 0 Then
   DLCO_Cor = DLCO_Cor * (1 + COHb / 100)
End If
```

6.7.12 Adjusting DLCO and KCO for Lung Volume

ComPAS2 provides new reporting of adjustments to DLCO and KCO for lung volume. The work is fully described in the following reference:

Johnson DC, DLCO: adjust for lung volume, standardized reporting and interpretation
Eur Respir J 2017; 50: 1700940

"The equations were included in the 2005 ATS/ERS DLCO standards], and describe how to adjust DLCO and KCO for lung volume. They were developed studying normal subjects with experimental reductions in inspired volume (VI; and thus VA) and fit the model that DLCO and KCO change in a manner expected from having DLCO reduced proportionate to the surface area for gas exchange with the capillary blood component unchanged. Mathematically, they result in DLCO % predicted for lung volume equaling KCO % predicted for lung volume when using the equation: KCO(predicted) = DLCO(predicted)/VA(predicted)."

The new calculated parameters can be seen on the spreadsheet as:

Traditional Units:
DACO = DLCO
DACO Predicted Value = DLCO[predicted] x (0.58+0.42x(VAm/VAp)) ml/min/mmHg

KACO = KCO
KACO Predicted Value = KCO[predicted] x (0.42+0.58/(VAm/VAp)) ml/min/mmHg/L

SI Units:
TACO = TLCO
TACO Predicted Value = TLCO[predicted] x (0.58+0.42x(VAm/VAp)) mmol/min/kPa

KACO_SI = KCO
KACO_SI Predicted Value = KCO[predicted] x (0.42+0.58/(VAm/VAp)) mmol/min/kPa/L

where VAm/VAp = measured VA/Predicted VA

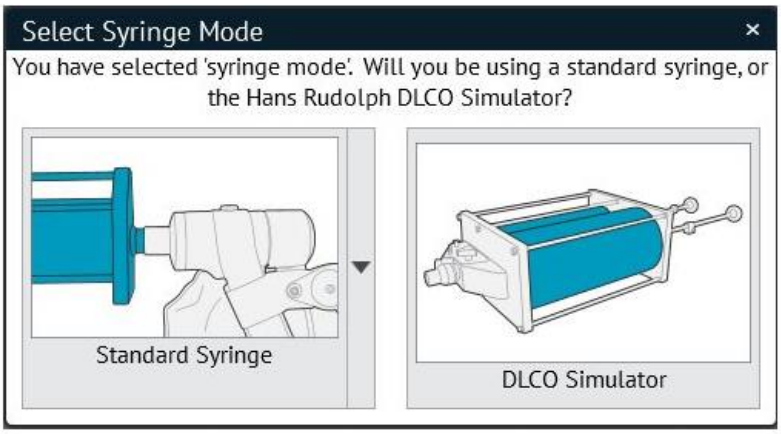
6.8 Single Breath Diffusion Quality Control

6.8.1 Introduction

Two fully integrated DLCO quality checks are available within ComPAS2:

Using a 3L Calibration Syringe
Using the Hans Rudolph Model 5560 DLCO Simulator

To access Quality Control options, first depress the syringe icon  on the testing screen.
When the user attempts to run a DLCO test, a screen prompt is showing asking which QA device is being employed.



6.8.2 Using a 3L Syringe

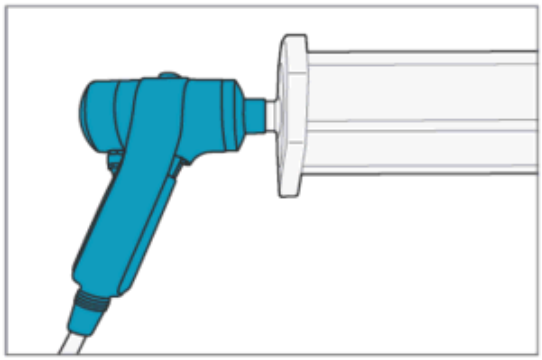
When selecting the Standard Syringe option, the pull-down arrow will allow the user to select any of the 3L syringes listed in the configuration. We strongly recommend the Vitalograph syringe because it adapts directly onto the patient valve without any additional adaptors or dead space volume.

The 2017 ERS/ATS DLCO standards recommend that two DLCO simulations be performed weekly. The recommended DLCO simulation method is performed with a 3L calibration syringe. The simulation should be performed twice, once with a full syringe of test gas and again with 1L of air mixed with 2L of test gas. Performing both simulations tests the DLCO system with two different gas mixtures.

An acceptable DLCO simulation value is < 0.5 ml/min/mmHg or <0.166 mmol·min−1·kPa−1 and an acceptable alveolar volume (VA) simulation value is 3L ± 0.3L at atmospheric, temperature and pressure (ATP).
The technique in testing is very straightforward as follows:

Connect the 3L Syringe

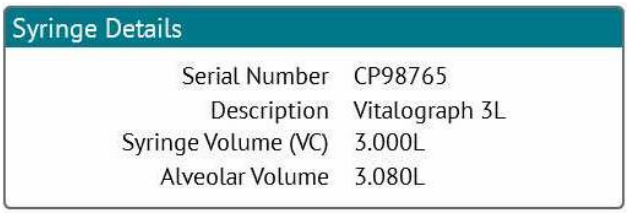
1. Connect the 3L syringe directly onto the patient valve.
2. Set the 3L syringe to 1 liter on the shaft.



VERY IMPORTANT!

It is critical to **FLUSH THE SYRINGE** with room air in between syringe QA tests.

The syringe default values for dead space volume come from the configuration section under "Calibration Syringes". Different syringes can be configured there for later use in QC testing.



Simulate a DLCO Test

1. Press the [Spacebar] to begin the DLCO sequence. First the gases will be analyzed.

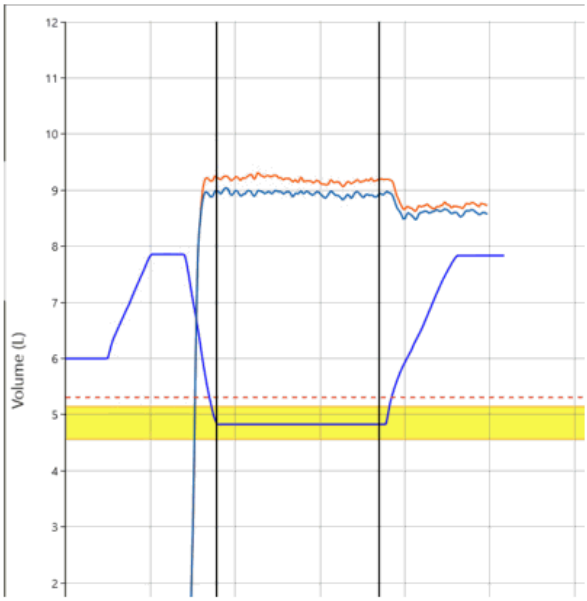
   Systems equipped with an inspiratory bag will prepare the bag and fill to 3.3L

2. When ready to test:
   Empty the syringe slowly and press the [Spacebar]

3. The valve will switch connecting the syringe to the test gas
   Pull back the syringe plunger all the way out to a full 3L

4. Wait for the breath hold period to elapse then:
   Empty the syringe while trying to keep the flow rate on the meter guide

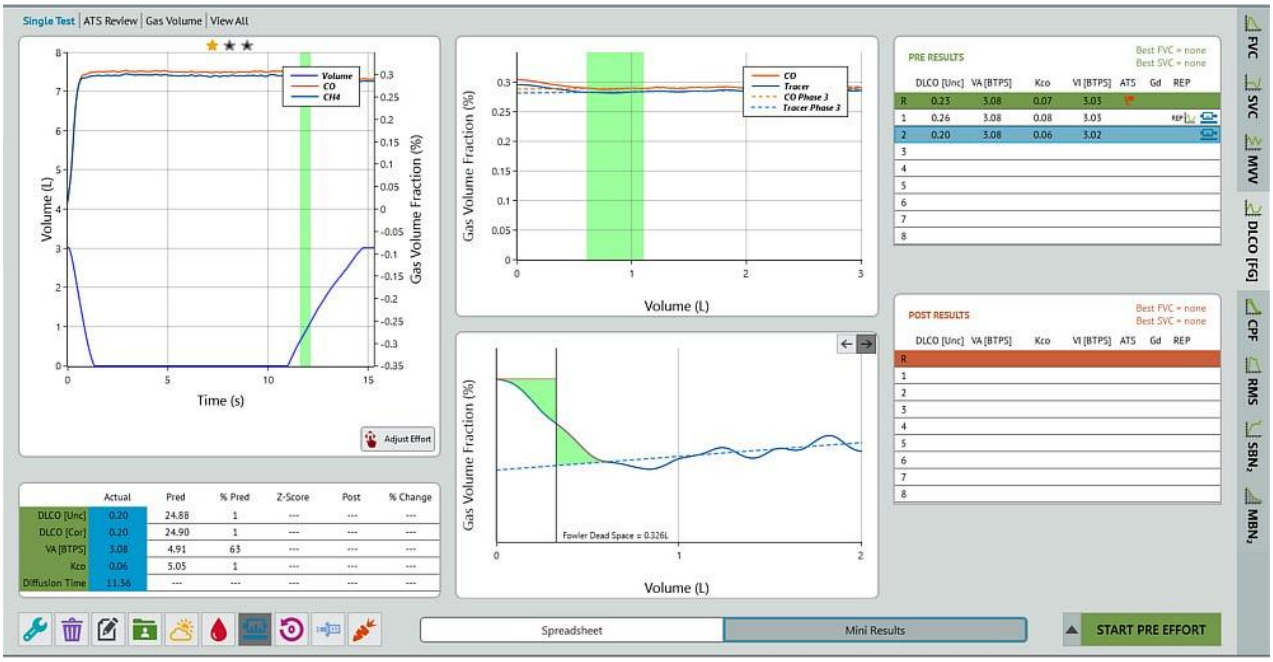
   [Spacebar] ends the test and returns to the results screen



Expected Results

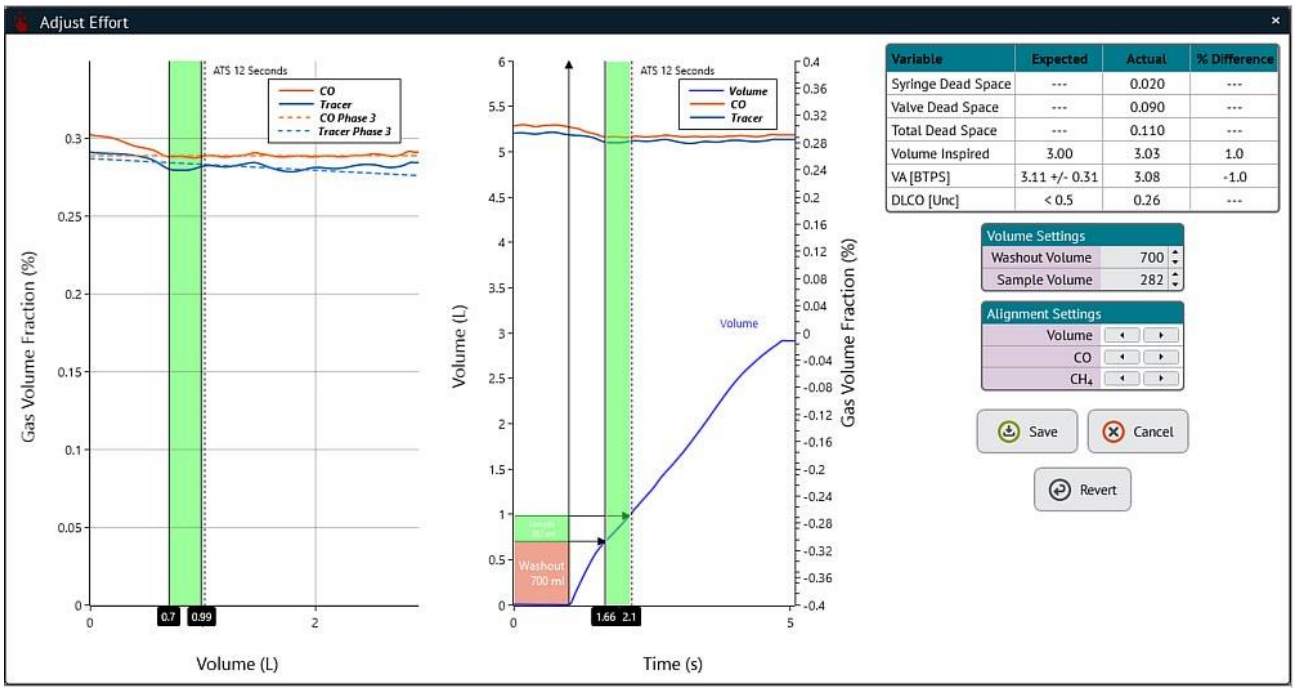
VA at STPD should be 3.00L + Total Dead Space (Syringe Dead Space + Valve Dead Space) with an acceptable range of +/- 10%

DLCO should be <0.166 mmol/min/kPa or <0.5 mL/min/mmHg



Full details of the 3L syringe test can be viewed by clicking the 

button:



6.8.2.1 Performing a Second Syringe Simulation at 2L Volume

The 2017 ERS/ATS DLCO standards recommend performing a second simulation with 1L of air mixed with 2L of test gas. Performing both simulations tests the DLCO system with two different gas mixtures.

For the second simulation, only use 2L of the 3L syringe. This can be achieved by grasping the plunger at the 2L mark.

During the DLCO maneuver pull back the syringe plunger completely, this will add 2L of test gas to the 1L of room air. At the end of the breath hold time push the syringe plunger in to the 2L mark.

An acceptable DLCO simulation value is < 0.5 ml/min/mmHg or <0.166 mmol·min−1·kPa−1 and an acceptable alveolar volume (VA) simulation value is 3L ± 0.3L at atmospheric, temperature and pressure (ATP).

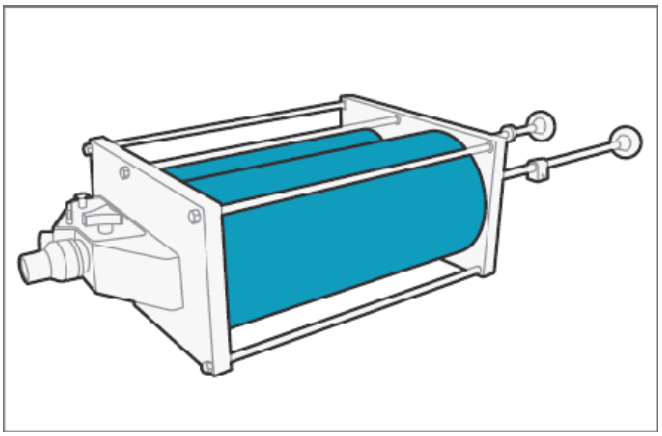
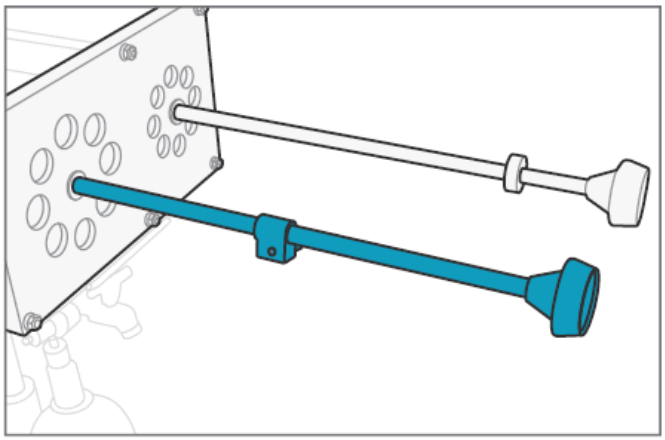
6.8.3 Introduction to the DLCO Simulator

A quality control device is available from Hans Rudolph for the verification of diffusing capacity measurement. The Model 5560 DLCO Simulator combines precision adjustable syringe volumes for assessment of Inspiratory Volume with a gas delivery mechanism that connects to gas cylinders filled with simulated expiratory alveolar gas. The gas cylinders are available from Hans Rudolph in different mixtures to simulate differing DLCO results across a wide physiological range of final results.

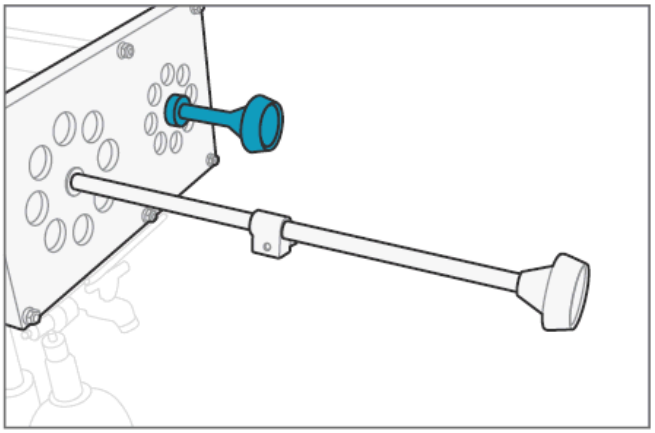
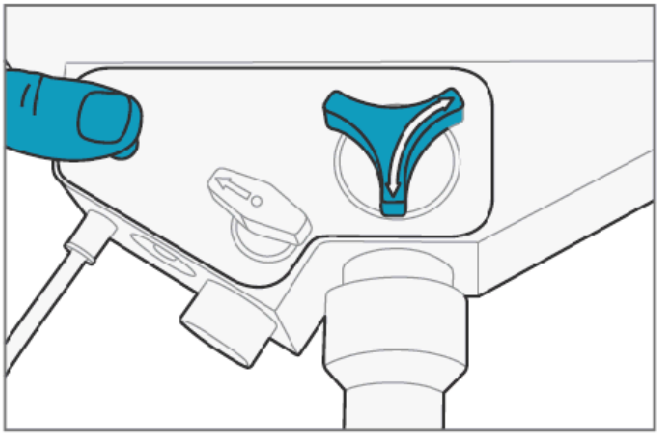
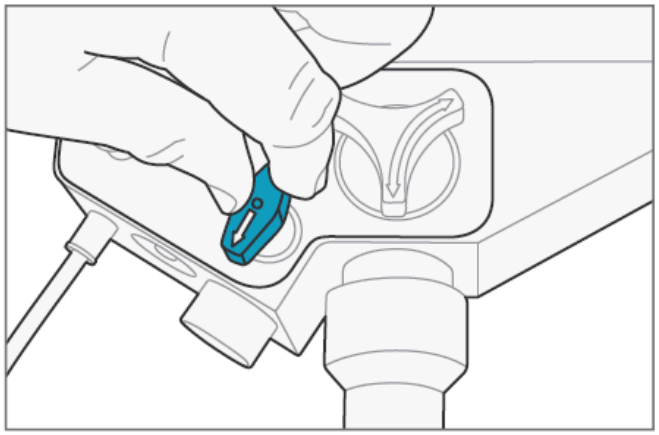
The DLCO Simulator is designed for use with any PFT system measuring DLCO. With connection to the patient valve, it simply takes the place of a patient in order that measurements can be made and compared.

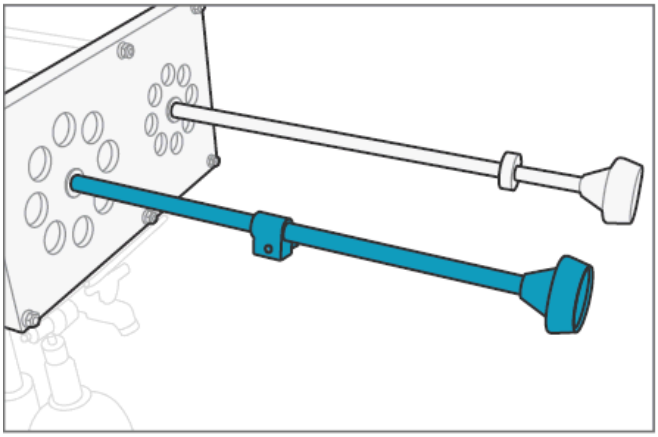
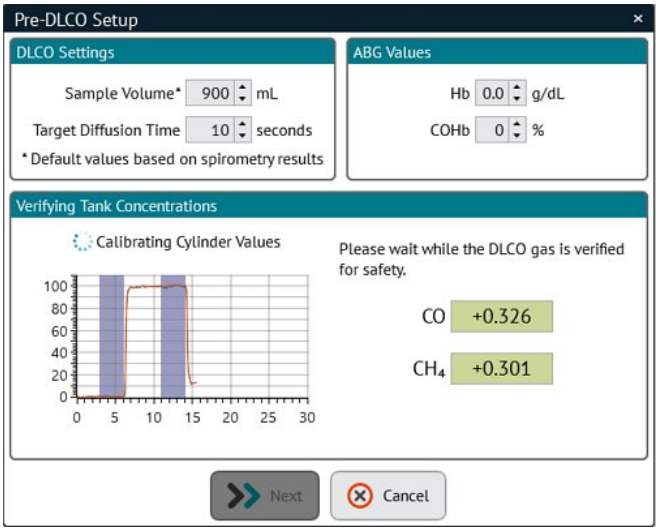
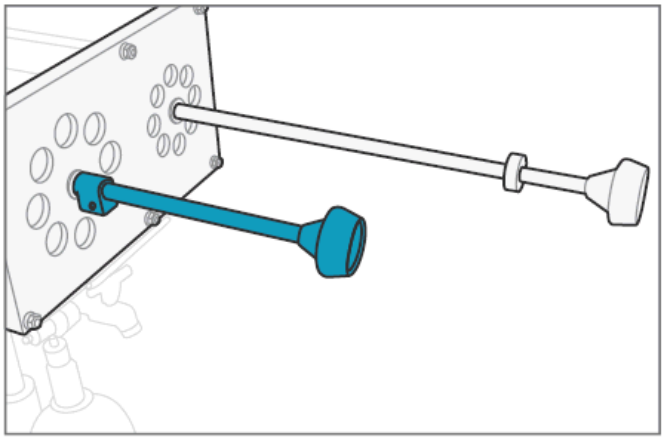
When the syringe icon is selected on the diffusion runtime screen, the test sequence steps the user through use of the DLCO Simulator:

6.8.2 Preparing to Use the DLCO Simulator

<u>Connect the 1% precision calibration gas</u> Connect gas to the PFT Device (typically 0.300% CO, 0.300% CH4, 21.0% O2 balance N2). **VERY IMPORTANT!** *This is a very important step, because most gas cylinders used in pulmonary labs are +/- 2% accuracy and if this is used for calibration when trying to compare against +/- 1% precision mixtures the discrepancy can be enough to cause errors in simulator results!* Connect a 1% precision simulated expiratory gas cylinder to the DLCO simulator.	
<u>Enter the Gas Mixture and Inspirate Volume</u> The Inspirate Volume Syringe can be set to volumes from 0.5 to 5.00L. The gas cylinder mixture can be read directly from the cylinder label, for example: **Inspirate Volume Setting: 3.00L** **FACO : 0.1001** **FA Tracer: 0.2000**	

6.8.3 Performing Tests with the DLCO Simulator

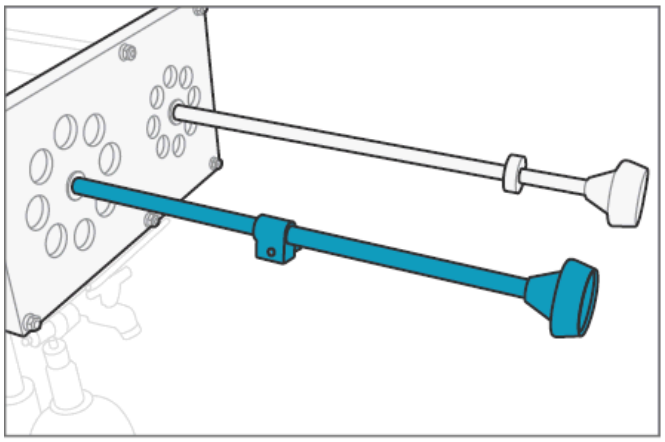
<u>Step 1. Getting DLCO Simulator Ready</u> Start with the small "Standard Gas Syringe" syringe closed.  With the selector valve in the "Standard Gas Syringe" position, push the small syringe until it is completely empty.  Return the selector valve to the "Inspirate Volume Syringe" position.	
<u>Step 2. Priming the Standard Gas Syringe</u> With the exhaust valve in the "Closed" position, push the fill button to add the calibrated gas to the small "Standard Gas Syringe" syringe.	
<u>Step 3. Relieve any Over-Pressure</u> Momentarily, turn the exhaust valve to “Open” and then return it to the “Closed” position. This will allow any over-pressure to escape.	

Step 4. Position the Large Inspirate Volume Syringe Pull the large "Inspirate Volume Syringe" to its full position.	
Step 5. Calibrate the Gas Analyzers The gas analyzers will now be calibrated using the precision calibration mixture. Instruments fitted with an inspiratory reservoir will automatically empty the bag and then fill it with a volume slightly above the best VC. The test is now ready to start. Press the [Spacebar] to begin the test sequence.	
Step 6. Empty the Large Inspirate Volume Syringe Push the large "Inspirate Volume Syringe" all the way to the stop (fully empty). When the end of test detection confirmation turns green, press the [Spacebar]	

Step 7. Fill the Large Inspirate Volume Syringe

Pull-in the large "Inspirate Volume Syringe" until it reaches the stop point (full inspirate volume).

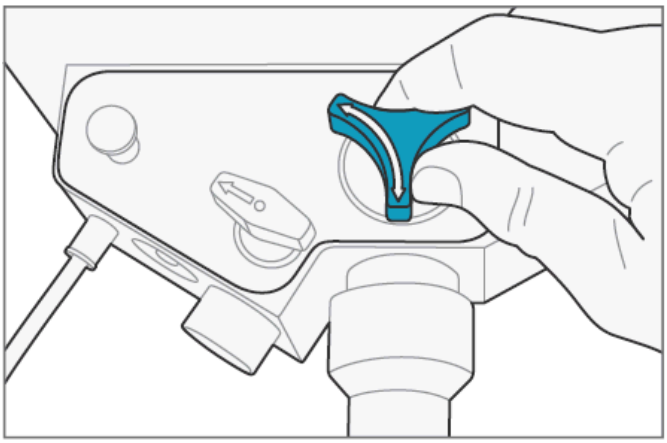
The software will go into breath hold.



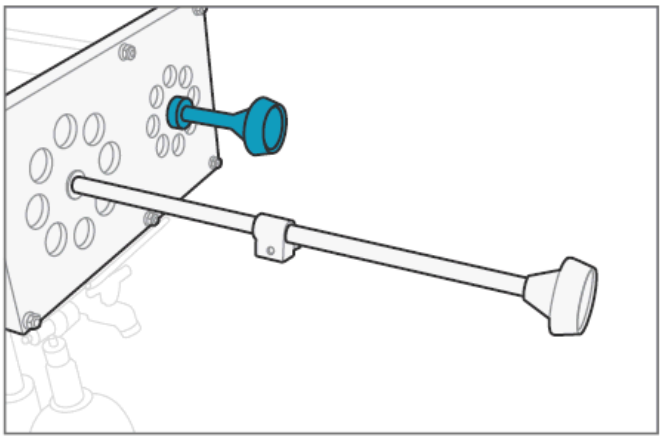
Step 8. At the Conclusion of Breath Hold

1. Turn the selector valve to the "Standard Gas Syringe" position.

By turning this valve at the conclusion of breath hold, it allows the inspiratory gas tracings to remain at the cylinder values. If it is turned too soon, the gases will fall resulting in an odd gas pattern.



2. Empty the contents of the "Standard Gas trying to keep the flow within the scale of the expired meter shown.



6.9 Single Breath Nitrogen Washout Testing

6.9.1 Preparing for an SBN2 Test

Once the user presses or clicks [Spacebar], the software will guide them through the Vitalograph Morgan PFT unit preparation to ensure the instrument is ready to begin the test.

ComPAS2 software goes a long way in identifying problematic tests, but some simple checks before starting the testing can prevent prolonged testing times.

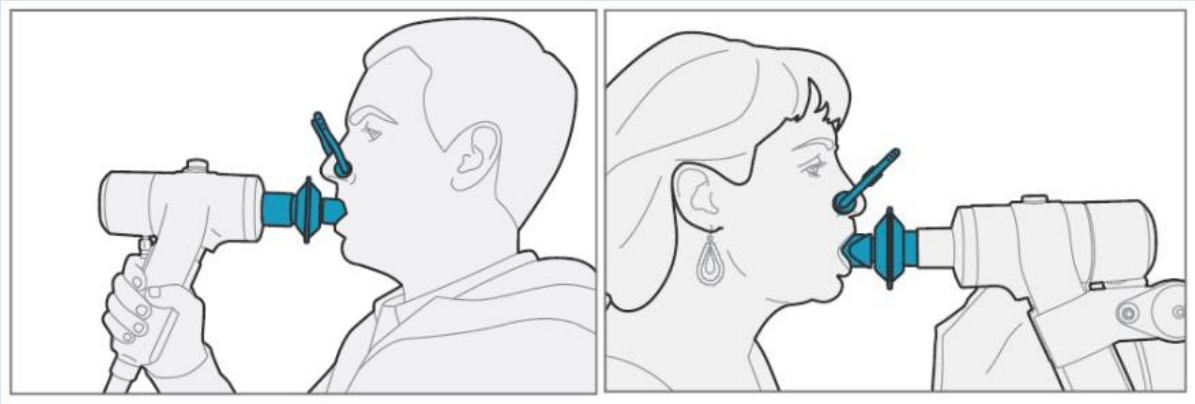
Preparing the Vitalograph Morgan PFT for SBN2

1) Connect a new bacterial/viral filter; be sure to push the filter into the valve to ensure a snug fit.

2) Have a box of tissues handy for the subject when they remove their mouth from the mouthpiece.

Preparing the Subject for SBN2

There are two versions of the Vitalograph Morgan PFT, one using a demand valve and the other an inspiratory reservoir



1) Make sure the subject is sitting upright and is wearing a nose clip.

2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test.

6.9.2 Understanding the test sequence

Once the [Spacebar] has been pressed, the program will guide the user through a simple sequence of screens to prepare for testing. The 100% O2 is sampled prior to testing to serve as a safety precaution.

Once the system detects the subject breathing, the display will show the tidal volume. Instruct subject to "**breathe normally".**

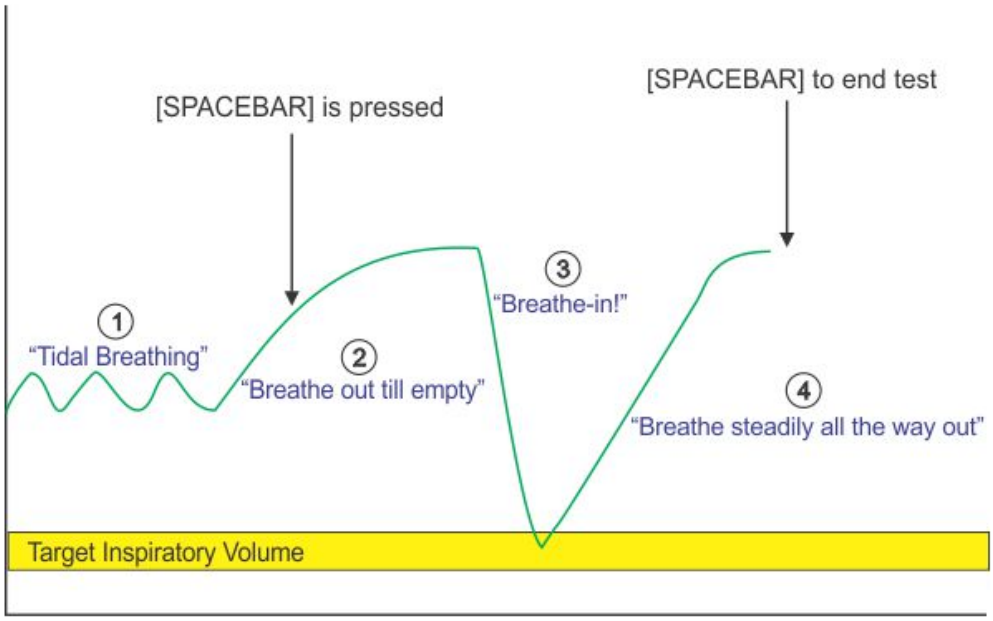
Tidal volume is evaluated for FRC stability, when the baseline indicator area turns green, instruct the subject to "**Breathe all the way out until you are completely empty**".

It is very important that the subject is completely empty before starting the breath-in. The most common reason for subjects not reaching TLC when performing an SBN2 maneuver is the lack of expiratory effort at this stage. When confident the subject is empty, press or click the [Spacebar].

Now instruct the subject to "**Breathe all the way in until you are completely full**".

As soon as the breath-in begins, a 'yellow' target area appears on the screen. This target is based on the subjects best SVC or FVC (whichever is the greatest) ± 5%.

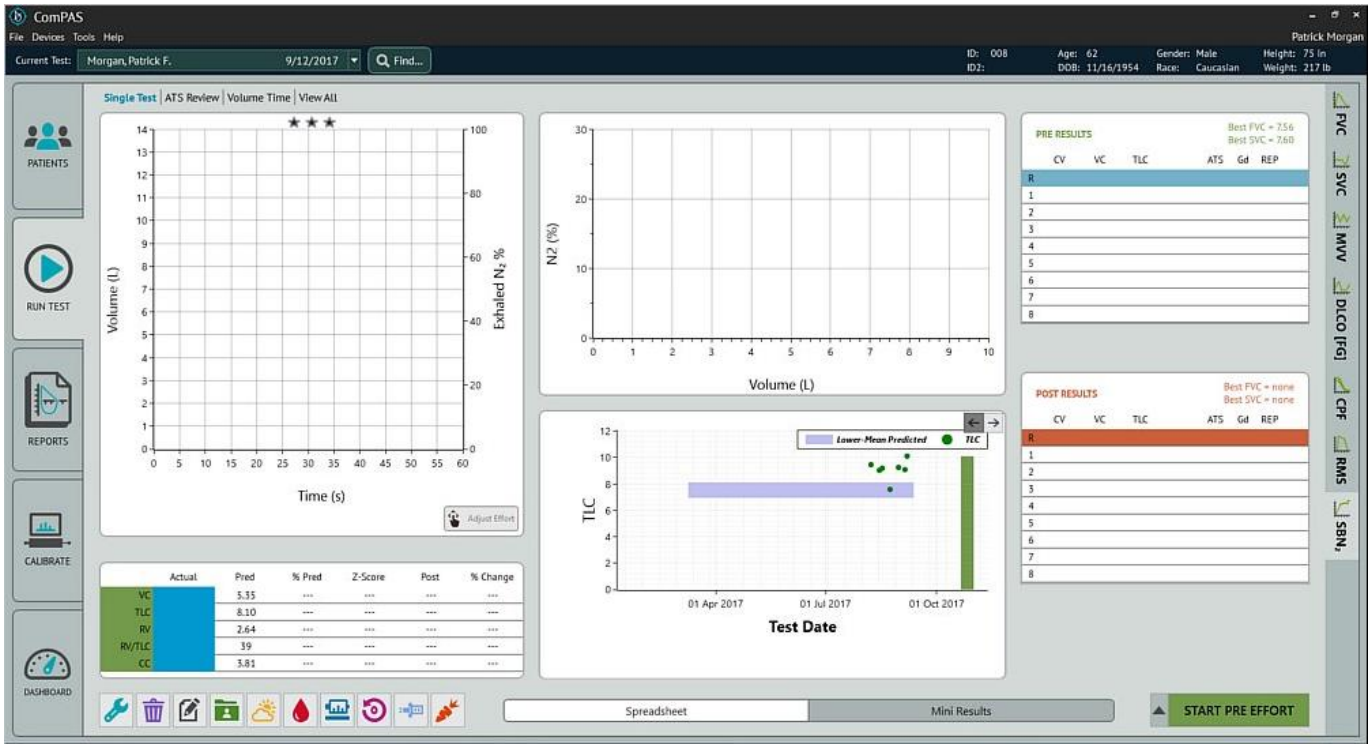
Once at TLC, instruct the subject to "**Breathe out steadily trying to keep the meter on the screen in the green range".**



A common problem for subjects trying to achieve full inspiration is muscular tension. If the subject is very tense across their shoulders, then it is impossible to fully inflate their chest. Encourage the subject to roll their shoulders prior to testing, this helps relax any muscular tension.

6.9.3 Performing the SBN2 Test

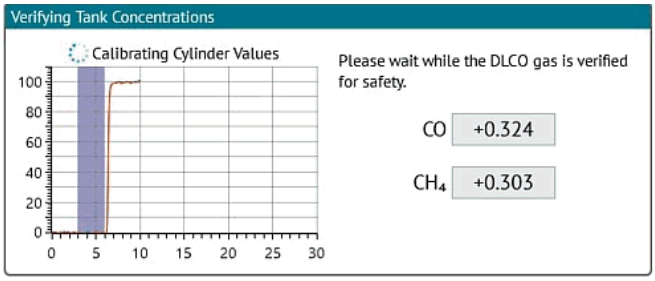
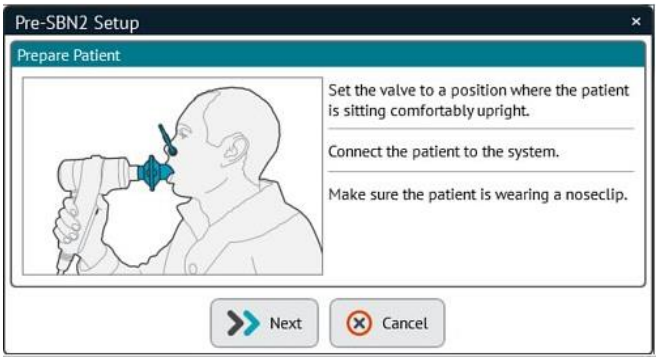
The opening screen of testing always defaults to Flow Volume in the mini results mode. Select the SBN2 from the side folder tabs.



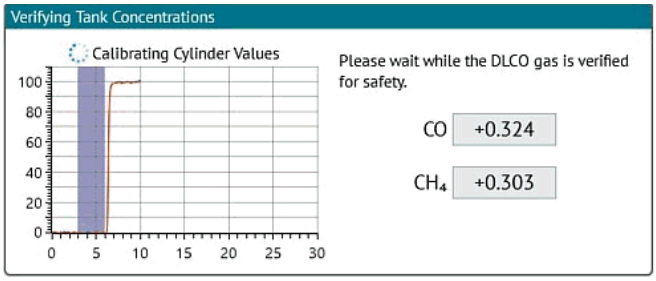
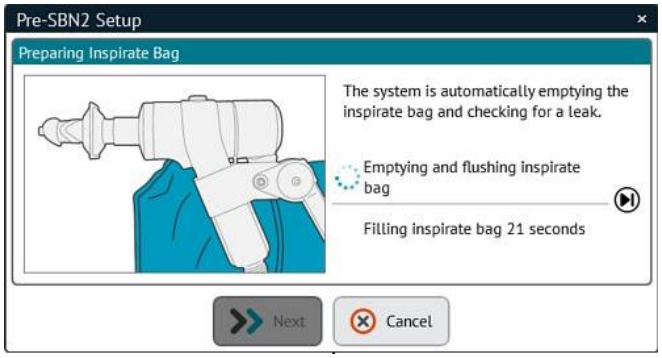
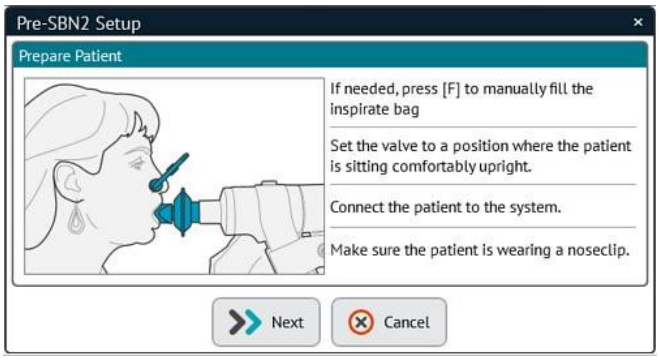
The test begins with an SBN2 preparation sequence:

There are two versions of the instrument, one using a demand valve for gas delivery and the other an inspiratory reservoir bag.

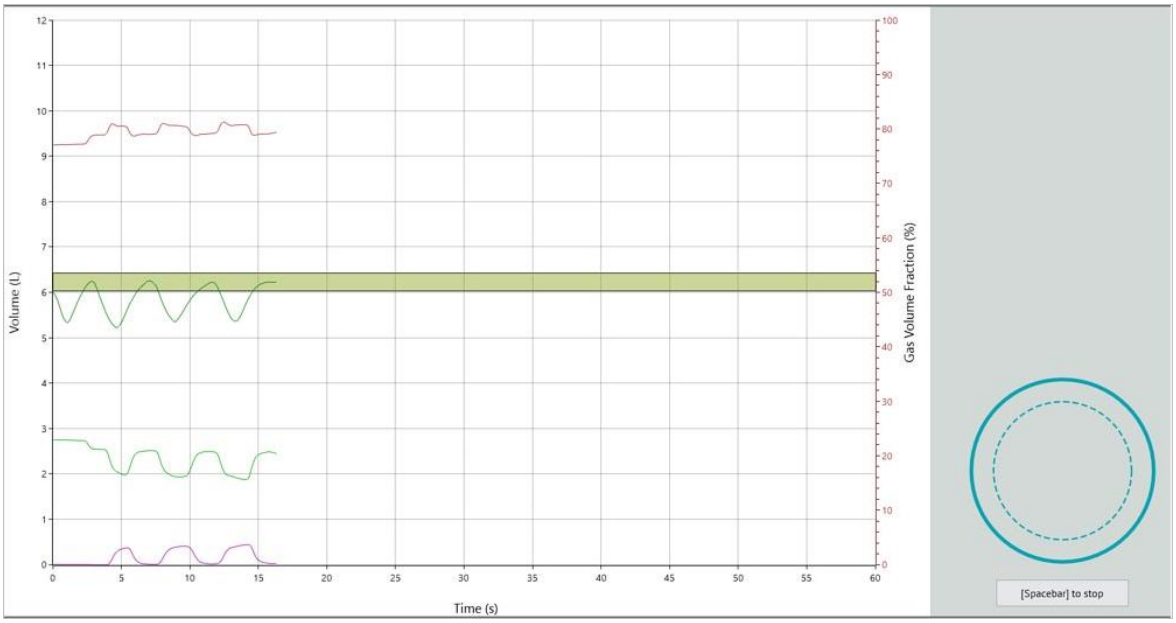
SBN2 Test Set-up with Demand Valve

Step 1. Sampling the Gas Cylinders Prior to any SBN2 test effort the gas analyzers are calibrated and the inspiratory gas mixture is measured as a safety precaution. First the O2/CO2 gas mixture is sampled followed by the 100% O2. The meters turn green when analyzer performance and gas content is confirmed.	
Step 3. Connect Subject Once the gas mixture has been confirmed, it is time to sit the subject comfortably upright and ask them to go onto the mouthpiece. Remember to ensure that the subject is wearing a nose clip! Once the "Next" button has been clicked, or the [Spacebar] pressed, the test will commence.	

SBN2 Test Set-up with Inspiratory Bag

Step 1. Sampling the Gas Cylinder Prior to any SBN2 test effort the gas analyzers are calibrated and the inspiratory gas mixture is measured as a safety precaution. First the O2/CO2 gas mixture is sampled followed by the 100% O2. The meters turn green when analyzer performance and gas content is confirmed.	
Step 2. Preparation of the Inspirate Bag The inspirate bag will first be completely emptied, flushed and then automatically filled with 100% O2 at a volume appropriate to the subject's best Vital Capacity (FVC or SVC). The [F] or [F5] buttons can be used to manually add additional oxygen to the bag if desired. If too much gas is entering the bag, clicking the icon will halt oxygen flow and move to the next screen.	
Step 3. Connect Subject Once the gas mixture has been confirmed, it is time to sit the subject comfortably upright and ask them to go onto the mouthpiece. Remember to ensure that the subject is wearing a nose clip! Once the "Next" button has been clicked, or the [Spacebar] pressed, the test will commence.	

As the test commences, a helpful guide moves with each tidal breath to look for repeatable end-tidal positions; when 3 or more show FRC stability the bar turns green to indicate that the full expiratory maneuver can commence.



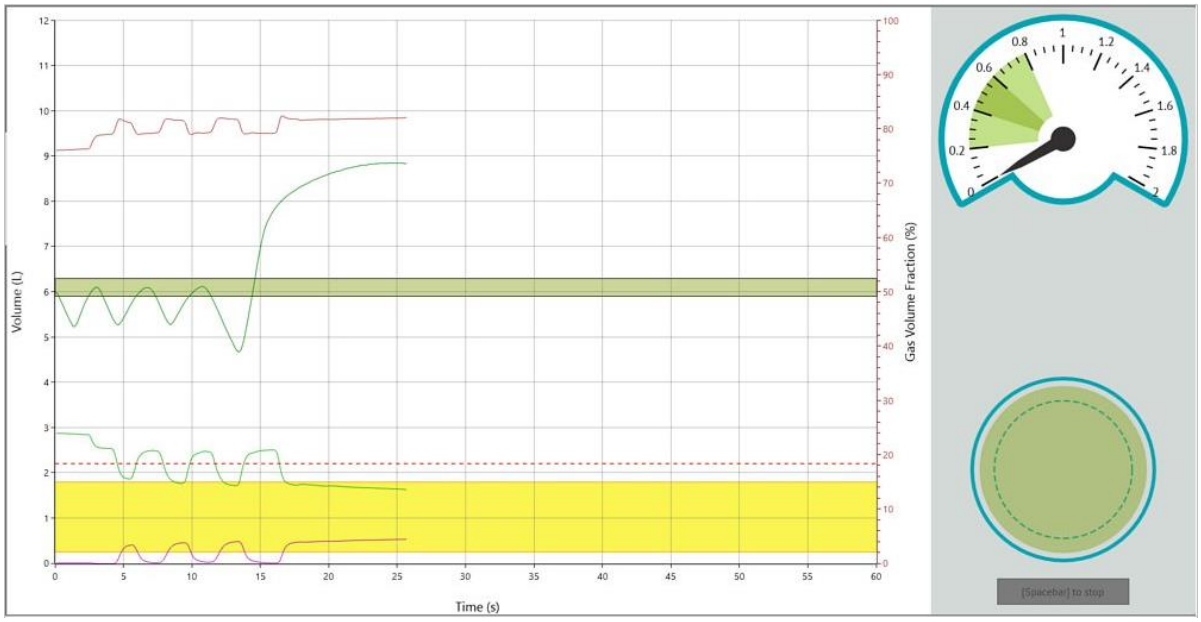
Instruct the subject to "**breathe all the way out**". During the breath out, press the [Spacebar]. It is important that the subject breathe all the way out until they are completely empty (at Residual Volume).

The meter in the bottom right of the screen looks for End of Expiration (EOE) criteria to be met.

The bottom End of Expiration Meter is useful in seeing that the expiratory effort achieves a plateau in the volume time curve.

End of Expiration (EOE) criteria is a < 0.025L volume change over 1 second duration. If desired, the EOE criteria can be configured in the configuration section under "Runtime Options" and FVC.

Further to the visual indication of a plateau, an audible beep can be configured. A single beep can be sounded when a plateau in the volume time is reached.

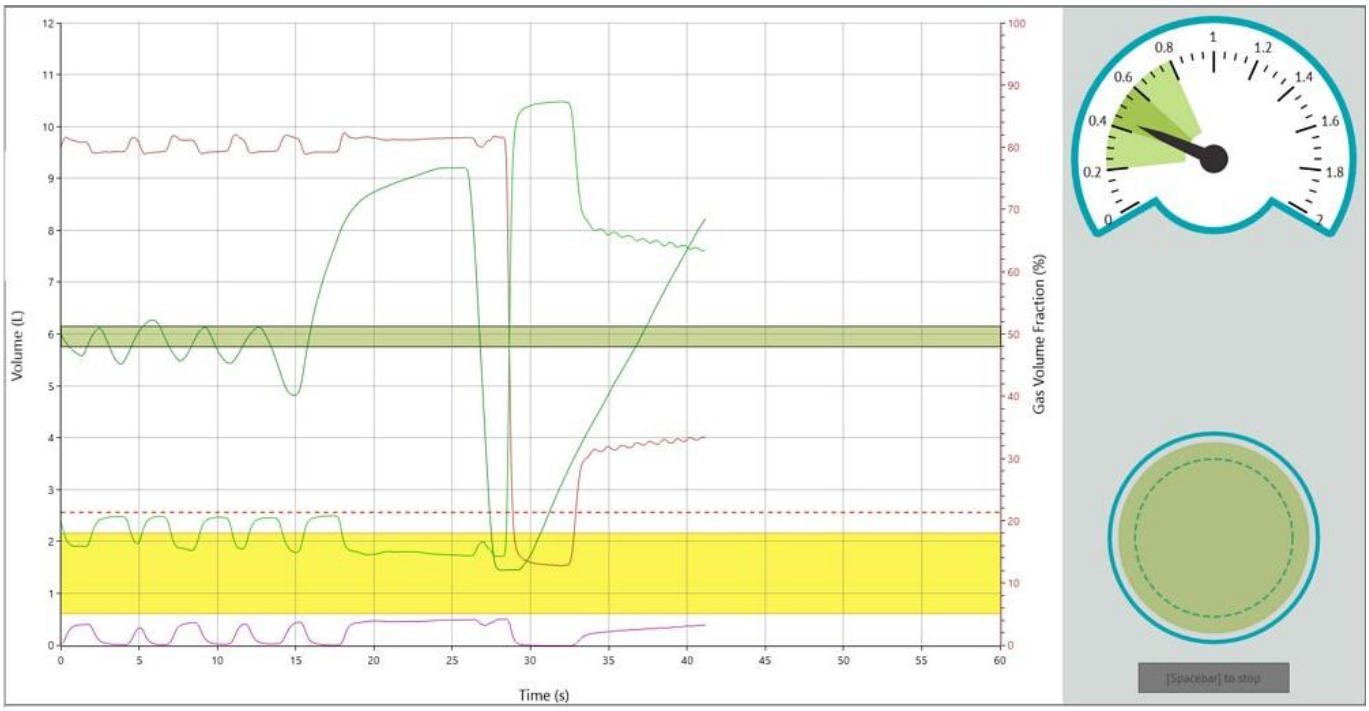


When the subject has fully emptied their lungs, the valve switches them to 100% O2, ask the subject to "**breathe all the way in**"! A yellow target area is presented on the screen which is based on 90% to 105% of the subjects best Vital Capacity.

If the subject consistently fails to reach the required inspiratory volume it could be the result of tension in their upper body. A good technique to use prior to any pulmonary test, is to ask the subject to "roll their shoulders'. This will release tension and often improve inspiratory volume.

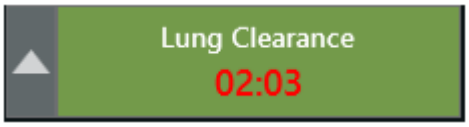
As soon as the subject reaches full inspiration the valve switches to allow a steady breath out. Instruct the subject to "**watch the meter and breathe steadily all the way out**".

Since this breath out needs to be at a constant a flow rate, a helpful flow meter is shown on the screen to guide the subject's effort. The 'Green' area on the flow meter represents the optimal expiratory flow rate. Instruct the subject to: "**keep breathing out until completely empty**".



Press the [Spacebar] when the test is concluded.

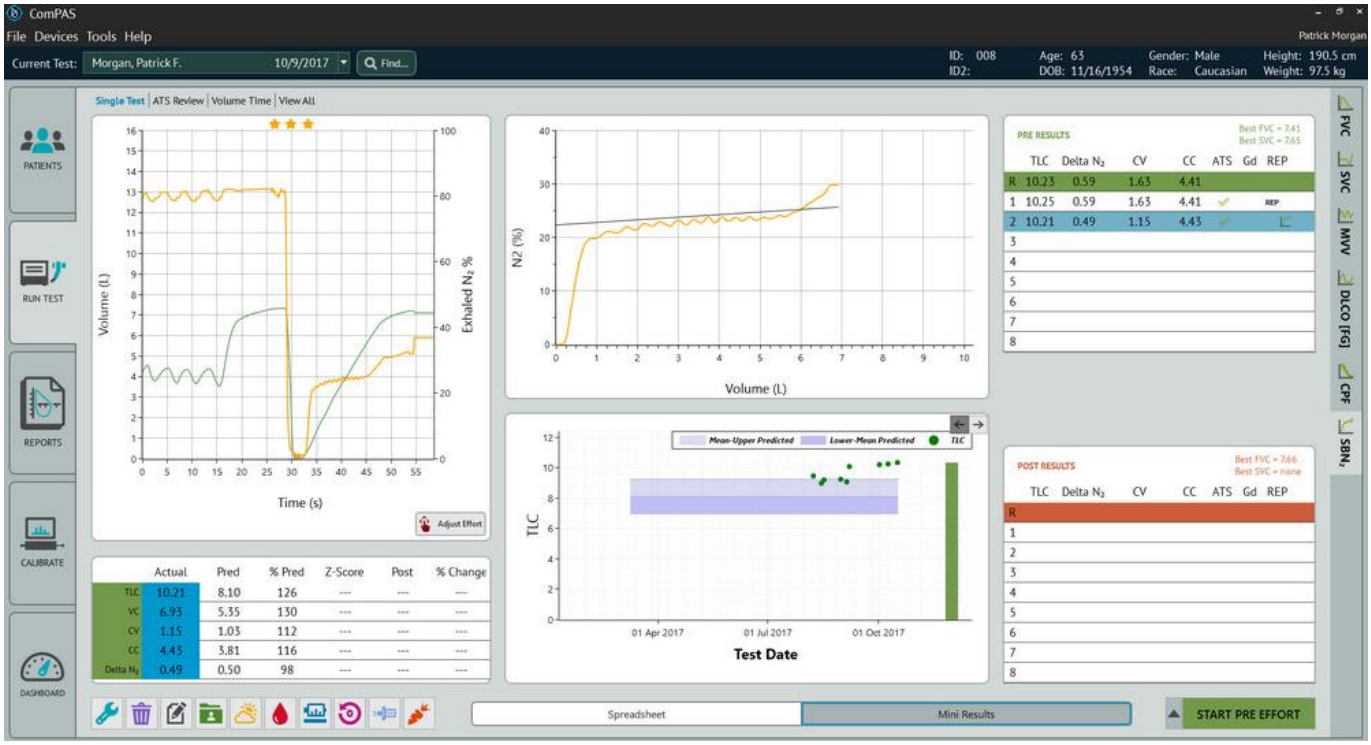
Having measured the gases, the screen is returned to the mini-result display with the key test results.



To help guide the technician on the recommended time between SBN2 efforts, a clock appears on the start button to countdown between test efforts.

The countdown clock will also appear if a test has been aborted. It is only a guide, so tests can continue before the countdown has elapsed if desired.

To optimize testing time, the countdown takes into consideration the time taken to set-up for the next SBN2 maneuver



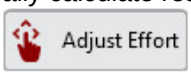
The concept behind the Mini Results Screen is to provide the technician with the key data regarding the clinical acceptability of each maneuver. As each test is evaluated, the ATS column on the right-hand side of the screen will indicate progress towards meeting the ATS testing guidelines:

Test	Acceptance Criteria
SBN2	Difference between the best VC and the SBN2 expired VC less than 15% Difference between the SBN2 inspired VC and the SBN2 expired VC less than 15% Mean expiratory flow <= 0.5 L/s Calibrations passed For repeatability: Three acceptable tests must be completed Two closest and acceptable TLC's agree within 10%

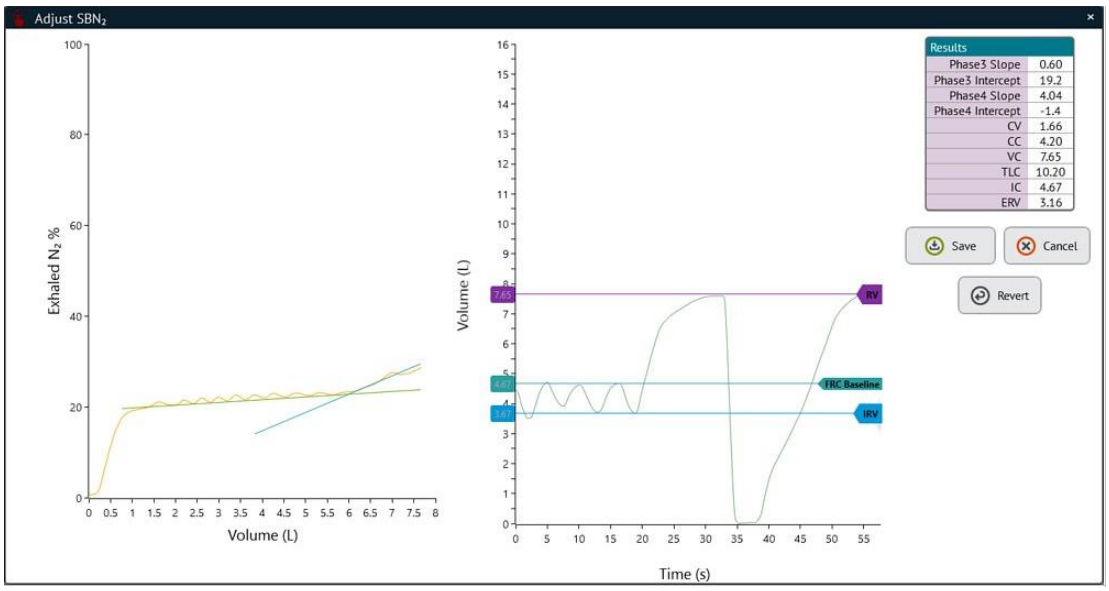
Beside each effort in the Mini Results table, check marks indicate progress towards, or confirmation of effort repeatability.

		Explanation
✓		An open green check mark indicates that this effort passed all the ATS criteria for the performance of an individual test. This makes it available for consideration for repeatability.
✓		Solid green check marks show which test efforts contain SBN2 reproducible data. When ATS repeatability standards have been met a large check mark is 'ghosted' behind all the data to confirm that you can now move to the next test.

6.9.4 Adjusting the Slope of Phase III, Phase IV or FRC Baseline

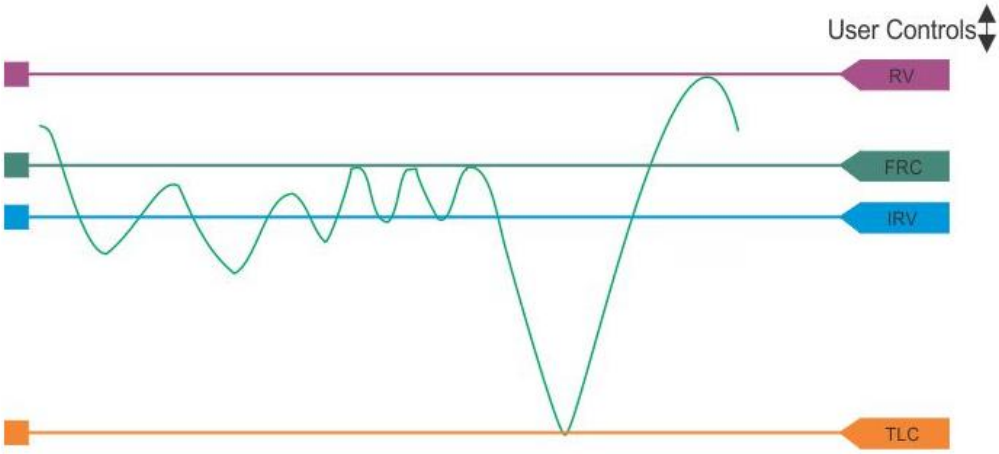
Once an SBN2 test is completed, the computer will look at the data to automatically calculate results. The user can make manual adjustments of slopes and spirometry positions by clicking on the 

button.



Adjusting the Spirometry:

To move a computed position for FRC baseline, TLC, RV or IRV to a preferred location, simply left-click the desired pointer and drag to a new position.



Adjusting Slope of Phase III or Slope of Phase IV:

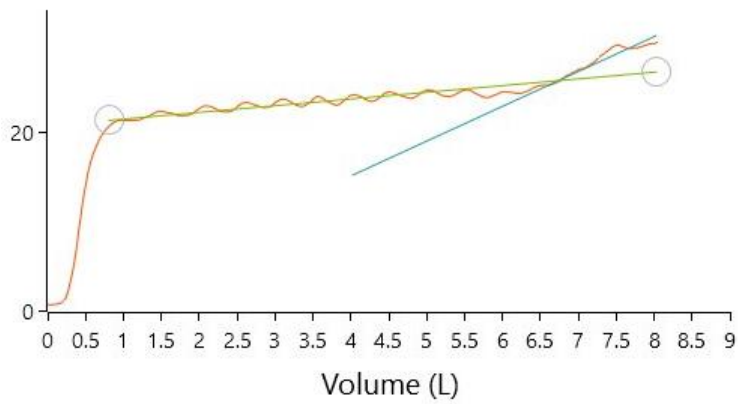
The graphic of the exhaled nitrogen curve shows four distinct phases:

Phase I: Expirate gas from anatomic dead space, which will not contain any nitrogen
Phase II: Expirate gas is a mixture of dead space and alveolar gas

Phase III: Expirate gas is mixed alveolar gas from the upper and lower regions of the lungs, also called the alveolar plateau phase
Phase IV: The expirate phase of airway closures

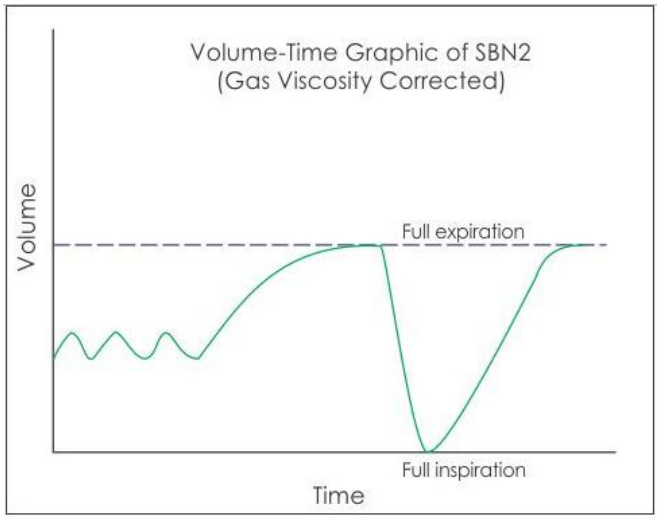
Airway closures occur in a part of the lungs where the alveoli have less elastic recoil and therefore will close first. When the inhalation of 100% oxygen begins, the part of the lungs containing dependent alveoli would be mostly closed and the nitrogen concentration low. As airway closure begins, the expired nitrogen concentration rises abruptly because more and more of the expired gas is coming from the alveoli in the upper parts of the lungs. These upper alveoli have the highest nitrogen concentration.

The sharp rise in the nitrogen curve near end exhalation is the beginning of Phase IV representing airway closure. Residual Volume is not shown on the curve because it occurs beyond the tracing.



6.9.5 Calculations and Principles Used in the SBN2 Test

During the SBN2 study, we are measuring TLC and VC; calculations are then made to obtain the balance of the lung sub-divisions as follows:

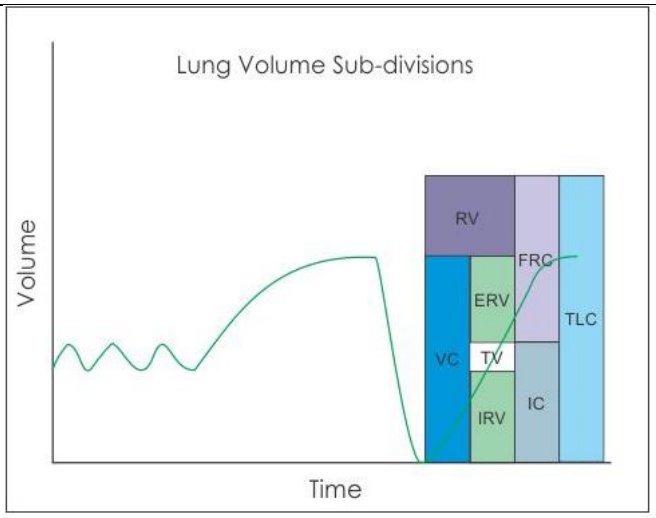
Correction of the Pneumotachograph for Gas Viscosity Since the pneumotach is calibrated with room air, the measures of flow and volume would be incorrect when breathing 100% oxygen if gas viscosity effect was not considered. The gas viscosity of oxygen is approximately 12% greater than that of room air. Correcting the inspirate volume is straightforward only having to consider inspiratory BTPS conditions and 100% oxygen viscosity. However, the expirate corrections are more complicated because the gas concentrations for oxygen, carbon dioxide, nitrogen and water vapor are always changing. ComPAS2 utilizes a dynamic viscosity correction while aligning the expiratory flow with that of the nitrogen signal.	

If the subject expiratory effort is reliable, the end expiratory volumes as recorded in the volume-time graphic of the single breath nitrogen study should be very close to the same.

Lung Volume Calculations in Single Breath N2 Tests

Measured parameters:
TLC
VC

Calculations:
TLC - VC = RV
TLC - IC = FRC
FRC - RV = ERV



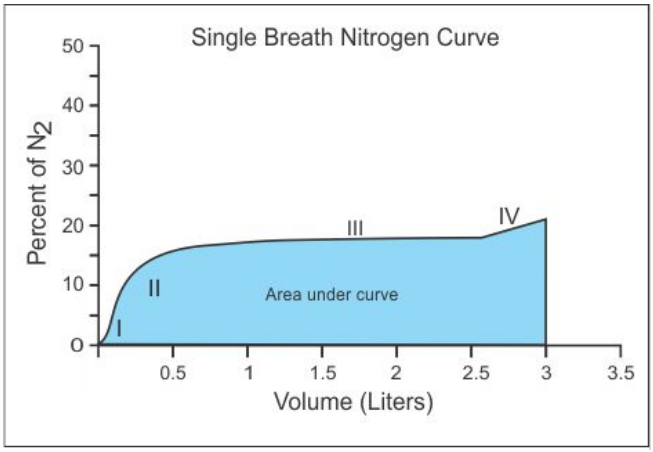
TLC Equation Used

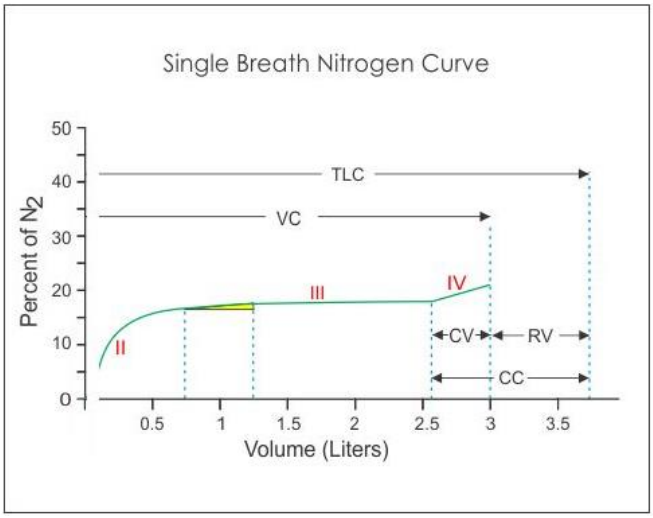
The TLC equation uses integration of the area under the single breath curve to determine the expired volume of nitrogen (VE FEN2).

$$TLC = \frac{V_I F_A N2 - V_E F_E N2 \dfrac{V_D}{V_E - V_D}}{F_A N2 - \dfrac{V_E F_E N2}{V_E - V_D}}$$

Where:

VI = volume inspired
VE = volume expired
FAN2 = initial N2 concentration
FEN2 = mean alveolar N2 concentration during expiration
VD = dead space of subject plus equipment dead space (valve & pneumotach)



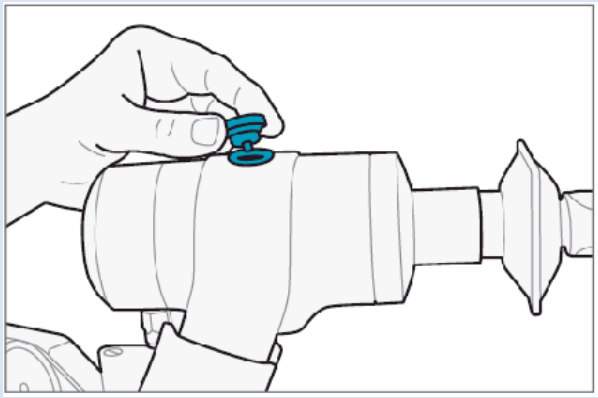
Closing Volume To determine the Closing Volume, the computer fits "best-fit" lines through the slope of Phase II and slope of Phase IV. These lines can be manually adjusted if desired. The program fits a line through the latter half of Phase III and looks for a point of departure to determine the onset of Phase IV. Sometimes this "departure" is not easily determined because a sharp rise in N2 did not occur. The Closing Volume is the volume from the onset at Phase IV to Residual Volume. CV is usually expressed as a % of the expired VC, CV/VC %	
Phase III A plateau caused by the exhalation of alveolar gas in which relative O2 and N2 concentrations change slowly and evenly.	
Phase IV Usually, a sharp rise in the concentration of N2 occurs which marks the onset of the closing volume. It is assumed that dependent airways have closed while gas continues to emerge from the nitrogen-rich upper regions.	
Closing Capacity Closing Capacity is defined as CV + RV and is usually expressed as a % of TLC, CC/TLC %.	

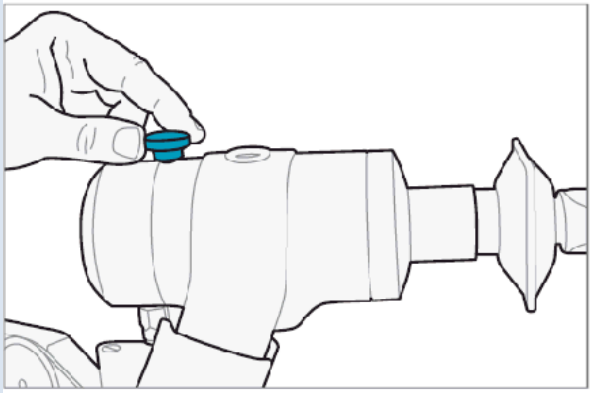
6.10 Multiple Breath Nitrogen Washout

Once the user presses or clicks [Spacebar], the software will guide them through the Vitalograph Morgan PFT unit preparation to ensure the instrument is ready to begin the test.

Preparing the Vitalograph Morgan PFT for MBN2

1) Unscrew the top exhaust stopper; there is a holding place at the rear of the valve



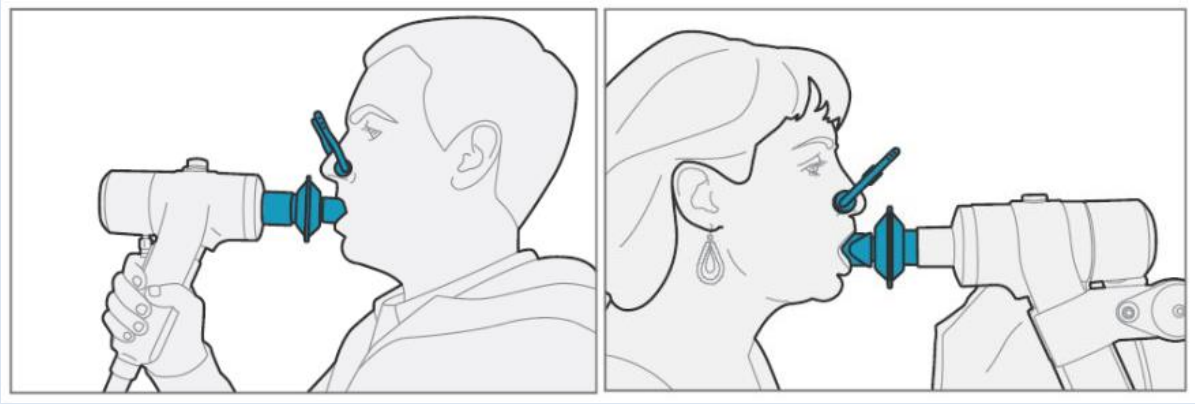


2) Connect a new bacterial/viral filter; be sure to push the filter into the valve to ensure a snug fit.

3) Have a box of tissues handy for the subject.

Preparing the Subject for MBN2

There are two versions of the Vitalograph Morgan PFT, one using a demand valve and the other an inspiratory reservoir



1) Make sure the subject is sitting upright and is wearing a nose clip.

2) Instruct the subject about how to use the mouthpiece. (For people with dentures, it is often easier to request that they be taken out)

3) Instruct the subject about the performance of the test.

6.10.1 Understanding the test sequence

Once the user has pressed or clicked the [Spacebar], the program will step through a simple sequence of screens to prepare the instrument for MBN2 testing.

The gas analyzers will be calibrated and the inspiratory source of 100% O2 confirmed. If the system is fitted with a reservoir bag, the bag will be fully emptied and then filled with 100% O2.

Having started the test running, the testing display will be showing tidal breathing from room air.

Instruct the subject to "Relax and breathe normally".

Once the subject is comfortable and has become accustomed to the mouthpiece and valve:

Instruct the subject to "Relax and continue breathing normally".

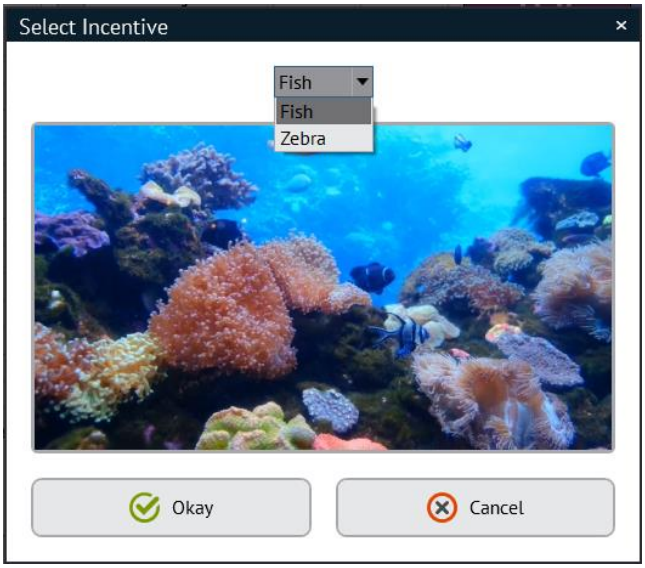
It is very important to reach a comfortable steady state to avoid minute ventilation rates that are exaggerated. The test simply continues with quiet breathing for typically 3 to 6 minutes.

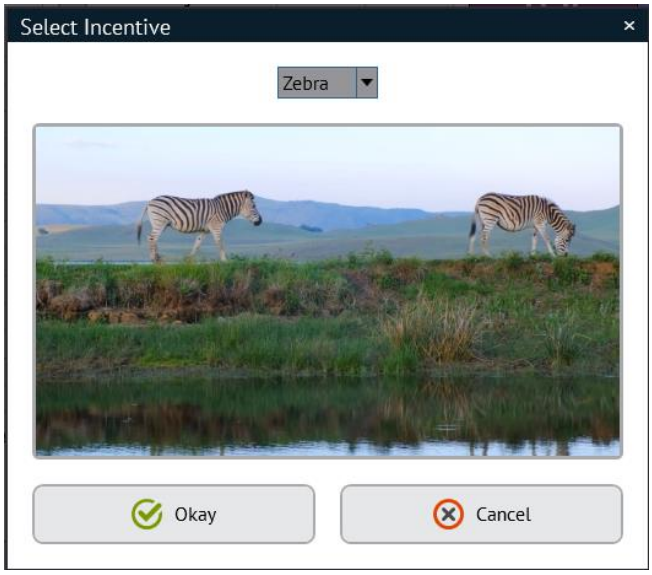
When 3 consecutive breaths have been recorded at N2 levels under 2% or 8 minutes have elapsed the test concludes.

6.10.2 Relaxing Video Incentive Option

For those instruments fitted with available second monitor, a relaxing video can be displayed during the performance of MBN2. This has proven to be very effective when testing children but is recommended as an excellent ‘distraction’ for all subjects. Watching the video can result in steady state breathing with respiratory rates and tidal volumes remaining consistent.

To engage the video during MBN2 testing click on the incentive icon  . Right-clicking on the icon will present a selection screen



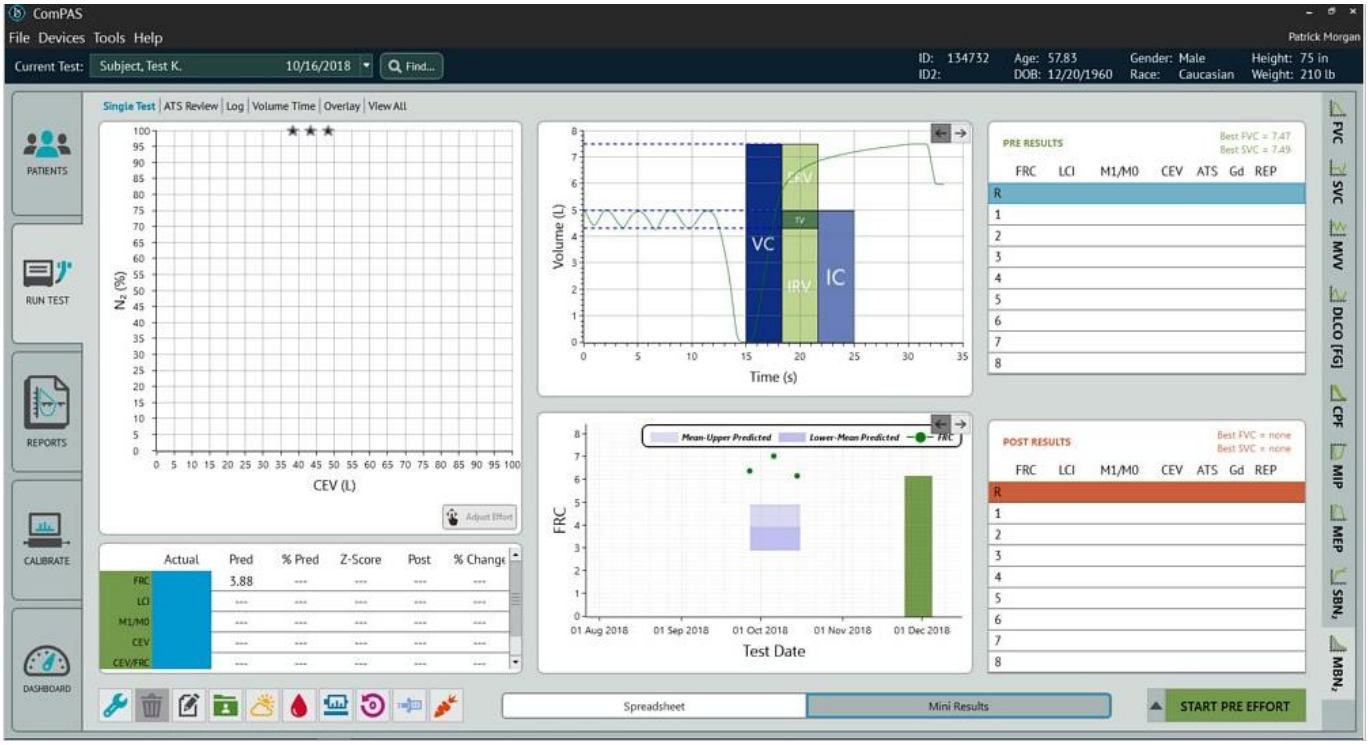


The pull-down arrow will show the choices.

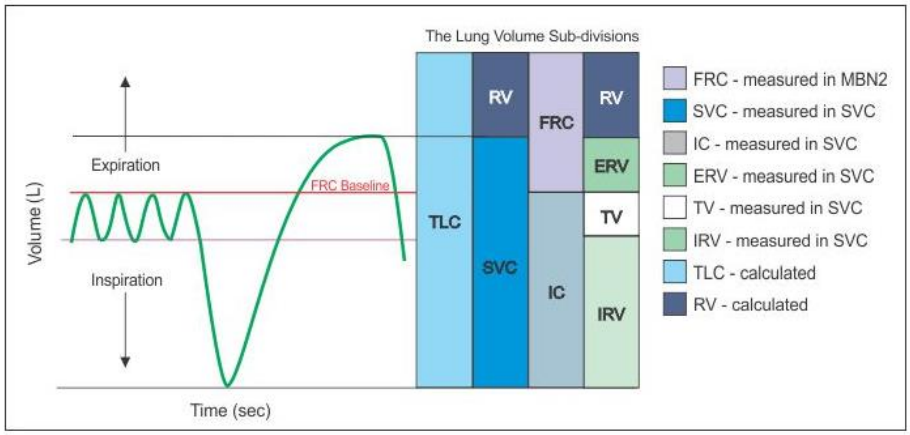
6.10.3 Performing the MBN2 Test

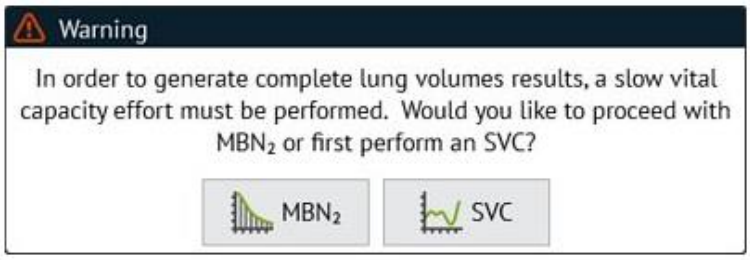
It is recommended that DLCO measurements be made before any multi-breath nitrogen washout tests as residual oxygen may result in underestimation of DLCO

The opening screen of testing always defaults to Flow Volume in the mini results mode. Select the MBN2 from the side folder tabs.



During the MBN2 test Functional Residual Capacity (FRC) is measured together with Lung Clearance Index (LCI). The full lung subdivisions will be calculated from existing Slow Vital Capacity (SVC) test data. If the MBN2 test is run without SVC data being present, a message will be displayed giving the user the option of running an SVC or going directly into MBN2.





Clicking the 

option will launch an SVC test.

To return to MBN2 will require selecting MBN2 from the test options.

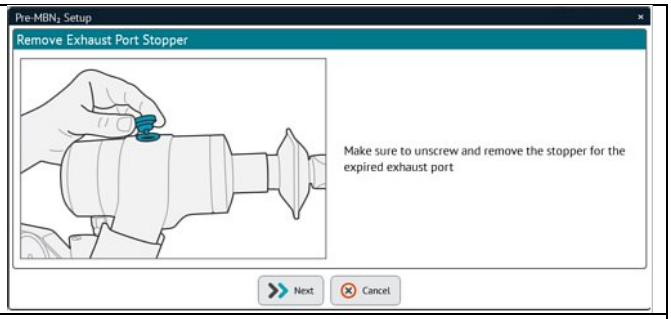
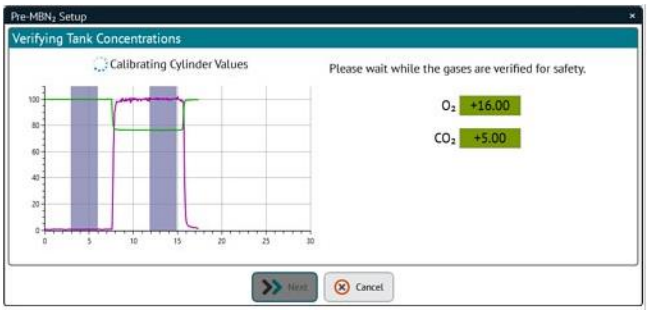
licking the 

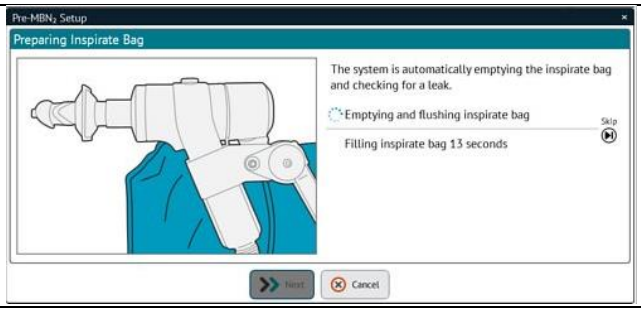
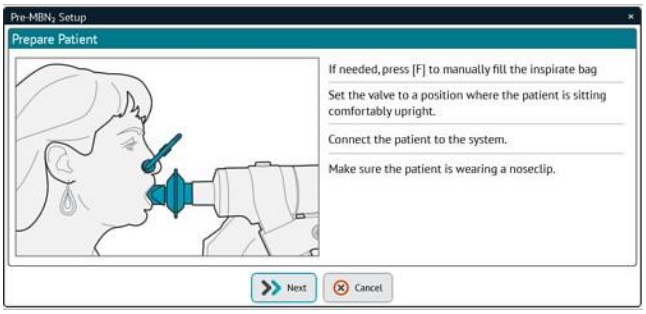
option will continue on the MBN2 test.

Once starting and MBN2 test, the routine begins with an instrument preparation sequence:

There are two versions of the instrument, one using a demand valve for gas delivery and the other an inspiratory reservoir bag.

MBN2 Test Set-up with Inspiratory Bag

Step 1. Remove and Secure the Exhaust Cover	
Step 2. Sampling the Gas Cylinders Prior to any MBN2 test effort the gas analyzers are calibrated, and the inspiratory gas mixture is measured as a safety precaution. First the O2/CO2 gas mixture is sampled followed by the 100% O2. The meters turn green when analyzer performance and gas content is confirmed.	
Step 3. Preparation of the Inspirate Bag The inspirate bag will first be completely emptied, flushed and then automatically filled with 100% O2 at a volume appropriate to the subject's best Vital Capacity (FVC or SVC). The [F] or [F5] buttons can be used to manually add additional oxygen to the bag if desired.	

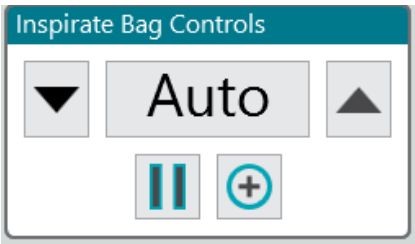
If too much gas is entering the bag, clicking the icon will halt oxygen flow and move to the next screen.	
Step 4. Connect Subject Once the gas mixture has been confirmed, it is time to sit the subject comfortably upright and ask them to go onto the mouthpiece. Remember to ensure that the subject is wearing a nose clip! Once the "Next" button has been clicked, or the [Spacebar] pressed, the test will commence.	

The first part of MBN2 testing establishes the subject on the valve and mouthpiece; the purpose is to have the subject breathing comfortably and regularly. A helpful guide moves with each tidal breath to look for repeatable end-tidal positions; when 3 or more show stability the bar turns green to indicate that end expiratory lung volume has been established and the MBN2 test can continue.

When steady state is achieved (the subject is resting comfortably and breathing in a regular pattern), press the [Spacebar].

At the next end-tidal expiration, the subject will be automatically connected to the 100% O2 source. This routine is designed to assure connection at FRC and avoid problems with switch-in errors. From this point until the end of the test, the subject will be breathing-in from a source of 100% O2 (demand valve or inspirate bag) and breathing out into room air.

Inspirate Bag Filling Control:
The inspiratory bag volume is maintained automatically, but it should be carefully observed during the test.

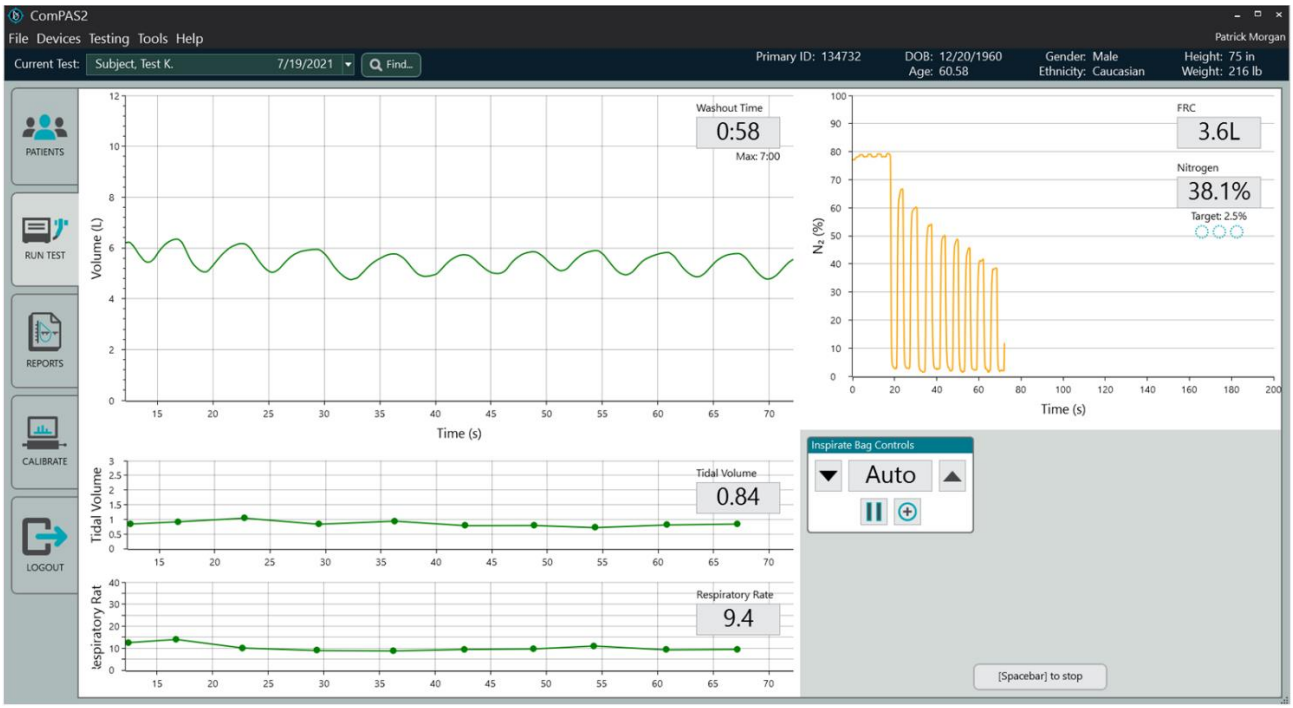


Clicking the pause button will temporarily pause O2 delivery to the bag with a 20 second countdown and then immediately resume.

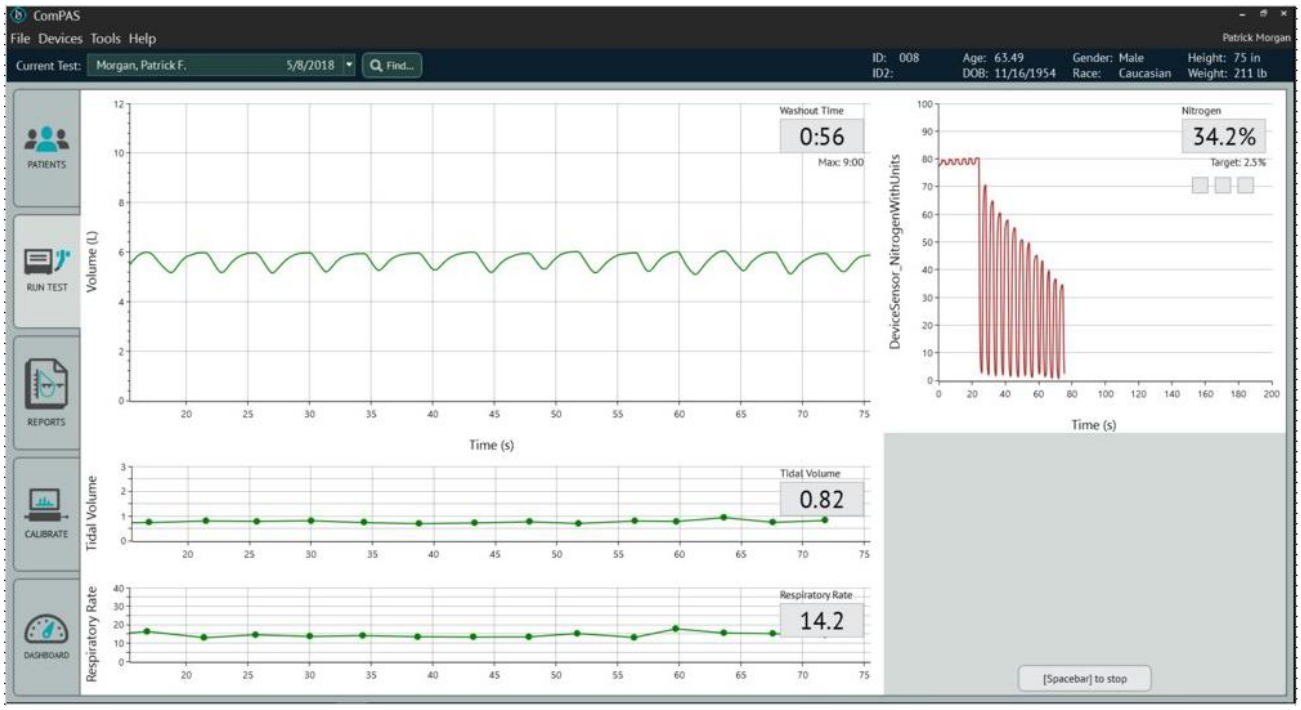
Clicking the "Up" or “Down” arrows will increase or reduce oxygen delivery to the bag per fill cycle.

Clicking the plus button will deliver oxygen manually all the while the button is depressed

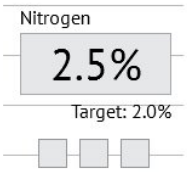
Simply watch the subject's breathing and observe the inspiratory bag using the controls to make any changes necessary. The ideal bag filling rate should always leave the bag with ample volume without being over-filled. During the entire test sequence, volume, time and gas analysis is displayed. The graphics of Tidal Volume and Respiratory Rate are shown to observe the subject's breathing pattern; when a subject is at steady state, the values should be consistent and maintained.



Runtime Screens (Inspiratory Bag above and Demand Valve below)

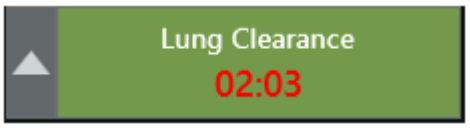


This is an open-circuit test; the subject is automatically switched to breathing 100% O2 and from this point the volume of N2 exhaled is determined. As the nitrogen is washed-out of the lung, the graph of nitrogen vs CEV (Cumulative Exhaled Volume) is plotted showing progress towards an exhaled N2 value below 2.5%.



The test continues until the end of test criteria have been met. The criteria can be configured under "Tools", "Configuration" and "MBN2". A typical end of test choice is when either 3 consecutive breaths under 2.5% N2 have been recorded or 7 minutes (whichever comes first).

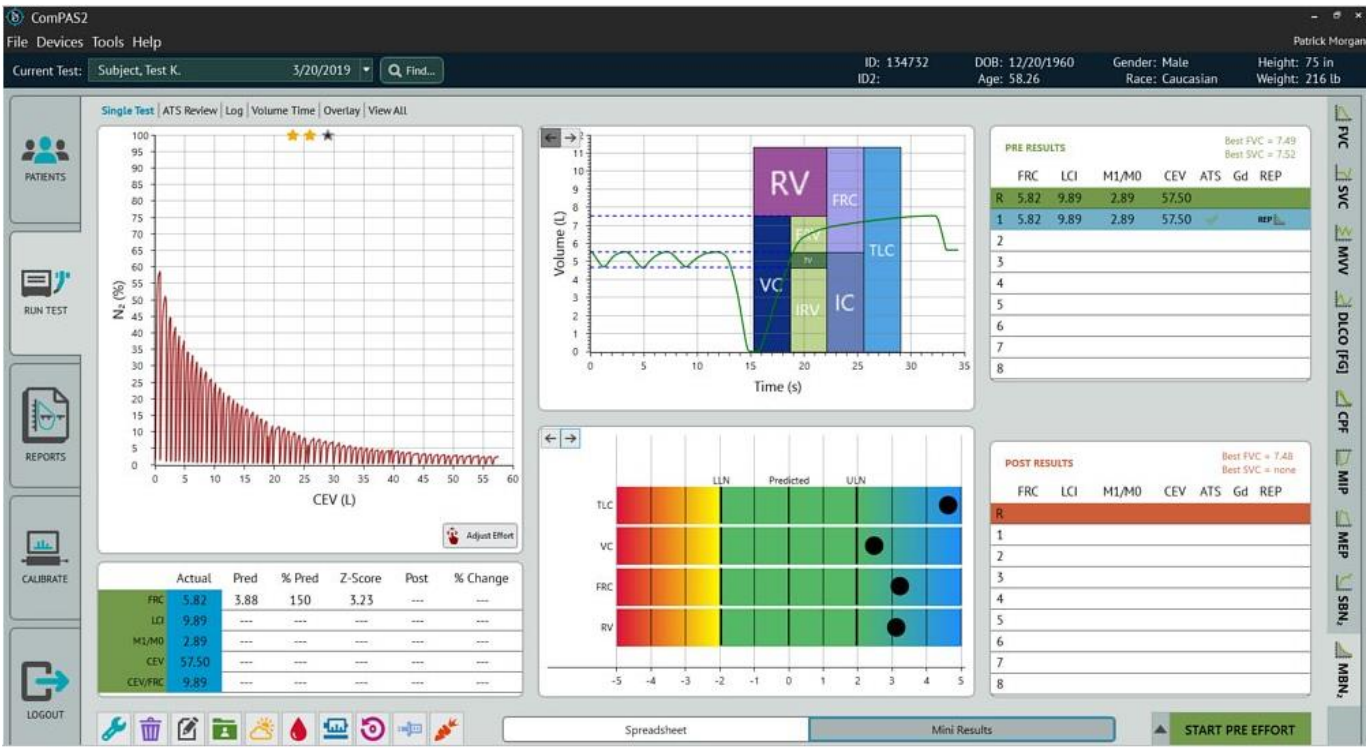
Having measured the gases, the screen is returned to the mini-result display with the key test results.



To help guide the technician on the recommended time between MBN2 efforts, a clock appears on the start button to countdown between test efforts.

The countdown clock will also appear if a test has been aborted. It is only a guide, so tests can continue before the countdown has elapsed if desired.

To optimize testing time, the countdown takes into consideration the time taken to set-up for the next MBN2 maneuver



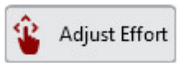
The concept behind the Mini Results Screen is to provide the technician with the key data regarding the clinical acceptability of each maneuver. As each test is evaluated, the ATS column on the right-hand side of the screen will indicate progress towards meeting the ATS testing guidelines:

Test	Acceptance Criteria
MBN2	Calibrations passed **For acceptability:** • No evidence of a sudden changes in N2 concentration during inspiration. • Three consecutive breaths where the normalized end-tidal concentration of N2 fell below 2.5%. • Sufficient interval between runs when using resident inert gases to allow inert gas concentration to return to baseline values. • Stable Tidal Volume and End Expiratory Level prior to switching in to 100% O2 • No coughing during the test. • No evidence of hyper or hypoventilation based on progression of end-tidal CO2 concentration. **For repeatability:** FRC within 10% of the mean FRC of all technically acceptable trials.

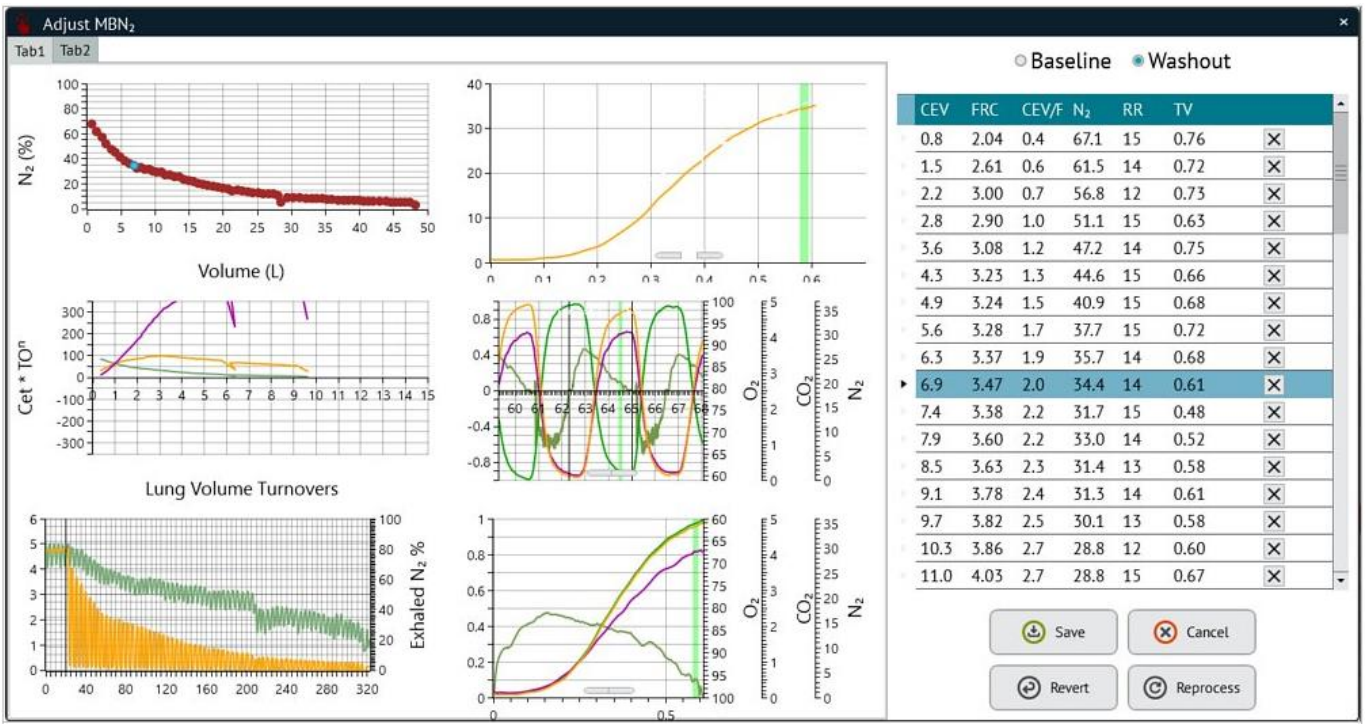
Beside each effort in the Mini Results table, check marks indicate progress towards, or confirmation of effort repeatability.

		Explanation
		An open green check mark indicates that this effort passed all the ATS criteria for the performance of an individual test. This makes it available for consideration for repeatability.
		Solid green check marks show which test efforts contain MBN2 reproducible data. When ATS repeatability standards have been met a large check mark is 'ghosted' behind all the data to confirm that you can now move to the next test.

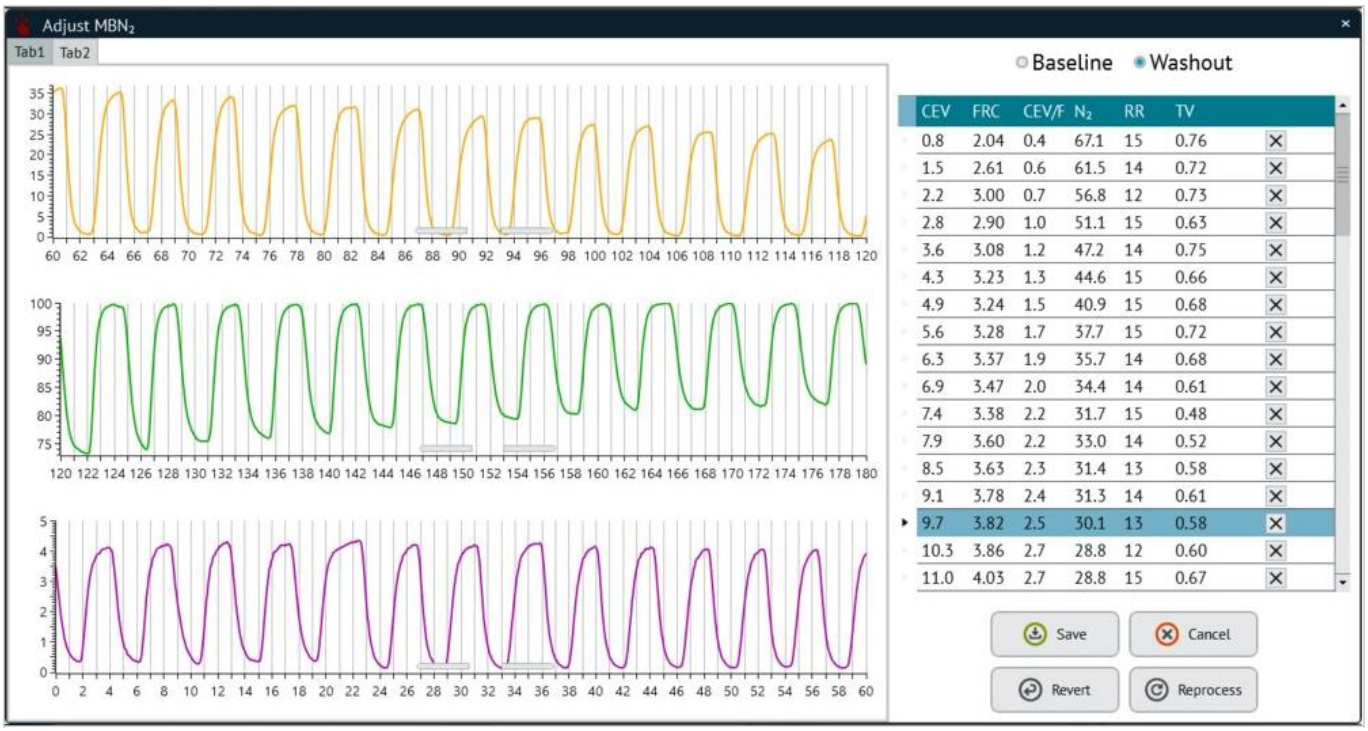
6.10.4 Making Adjustments to an MBN2 Test

To view raw test data or make any edits to spurious data events, click on the 

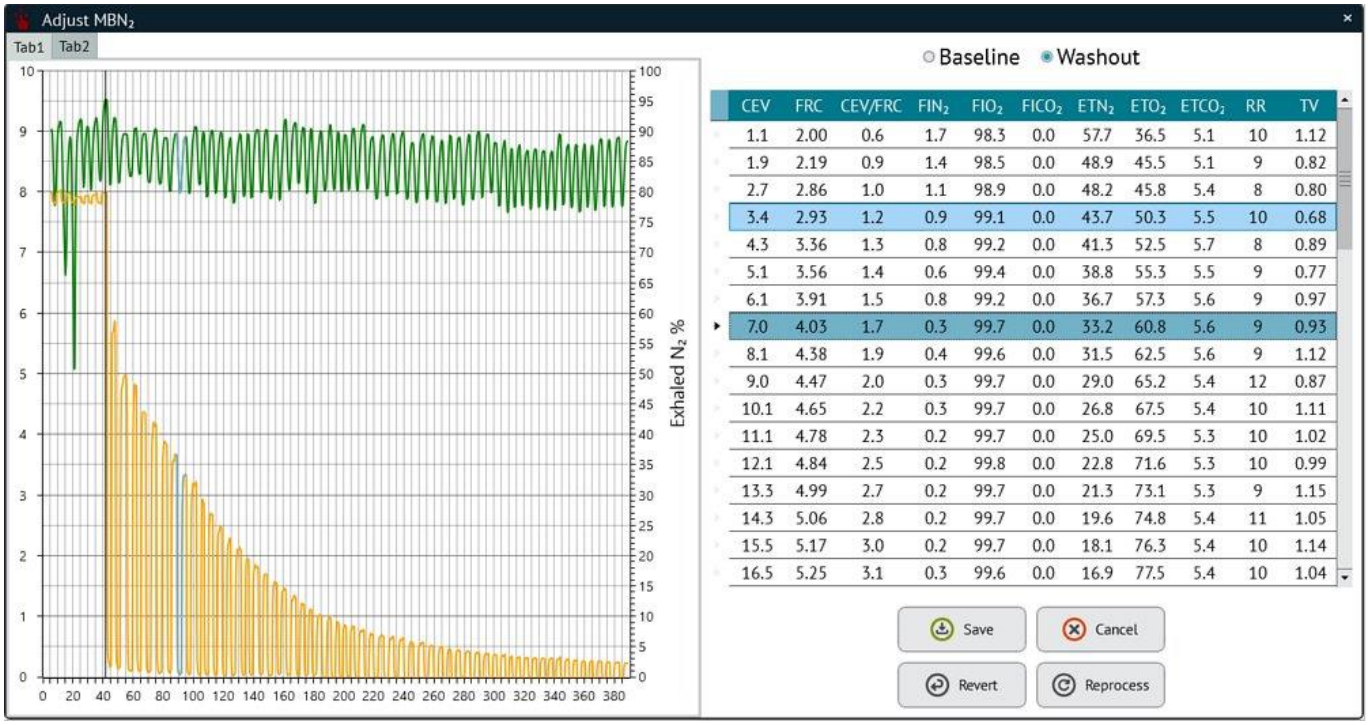
button.



Clicking on any of the graphics will allow a full screen view.



On the [Tab2] screen, adjustments can be made to the runtime data, perhaps removing any odd or spurious breaths.



As the mouse is moved down the table of breaths, each N2 waveform is highlighted.

Individual breaths can be "Disabled" or "Enabled" by right-clicking on the desired row.

CEV	FRC	CEV/FRC	FIN_2	FIO_2	$FICO_2$	ETN_2	ETO_2	$ETCO_2$	RR	TV
1.1	2.00	0.6	1.7	98.3	0.0	57.7	36.5	5.1	10	1.12
1.9	2.19	0.9	1.4	98.5	0.0	48.9	45.5	5.1	9	0.82
2.7	2.86	1.0	1.1	98.9	0.0	48.2	45.8	5.4	8	0.80
3.4	2.93	1.2	0.9	99.1	0.0	43.7	50.3	5.5	10	0.68
4.3	3.36	1.3	0.8	99.2	0.0	41.3	52.5	5.7	8	0.89
5.1	3.56	1.4	0.6	99.4	0.0	38.8	55.3	5.5	9	0.77
6.1	3.91	1.5	0.8	99.2	0.0	36.7	57.3	5.6	9	0.97
7.0	4.03	1.7	0.3	99.7	0.0	33.2	60.8	5.6	9	0.93
8.1	4.38	[illegible]	[illegible]	99.6	0.0	31.5	62.5	5.6	9	1.12
9.0	4.47	2.0	0.3	99.7	0.0	29.0	65.2	5.4	12	0.87
10.1	4.65	2.2	0.3	99.7	0.0	26.8	67.5	5.4	10	1.11
11.1	4.78	2.3	0.2	99.7	0.0	25.0	69.5	5.3	10	1.02
12.1	4.84	2.5	0.2	99.8	0.0	22.8	71.6	5.3	10	0.99
13.3	4.99	2.7	0.2	99.7	0.0	21.3	73.1	5.3	9	1.15
14.3	5.06	2.8	0.2	99.7	0.0	19.6	74.8	5.4	11	1.05
15.5	5.17	3.0	0.2	99.7	0.0	18.1	76.3	5.4	10	1.14
16.5	5.25	3.1	0.3	99.6	0.0	16.9	77.5	5.4	10	1.04

Disable Breath

7.0	4.03	1.7	0.3	99.7	0.0	33.2	60.8	5.6	9	0.93
8.1	4.38	[illegible]	[illegible]	99.6	0.0	31.5	62.5	5.6	9	1.12
7.9	3.99	2.0	0.3	99.7	0.0	29.0	65.2	5.4	12	0.87

Enable Breath

6.10.5 Comparison of MBN2 to Plethysmographic Lung Volumes

Although it is well recognized that both methods yield similar FRC values in healthy adults, there is evidence of FRC by MBN2 yielding higher values than by plethysmography in some patients.

The below paragraph's taken from the PFT Forum by permission from Richard Johnston (author of the PFT Blog which is highly recommended as a resource for wide ranging topics on pulmonary function testing).

> *As examples in a study of patients with COPD the N2 washout FRC averaged 14% higher than the plethysmographic FRC. In other studies of normal subjects, the N2 washout FRC was on average 0.20 to 0.21 L higher than plethysmographic FRC.*
>
> *So why is there such a discrepancy?*
>
> *One of the primary reasons appears to be N2 excretion from N2 body stores during the 100% O2 washout. Nitrogen excretion is complex because nitrogen comes from a variety of body stores with different time constants. Depending on the time interval during a 100% O2 washout, nitrogen will be excreted from blood first, well perfused tissue second, poorly perfused tissue third and fat last. N2 excretion has been studied several times since the 1930's and although results are in general similar, the derived formulas differ. In addition, the excretion rates of individuals have been shown to differ due to differences in body mass and in ventilation, and likely for differences in cardiac output, ventilation inhomogeneity and dead space as well.*
>
> *The extent to which the N2 washout FRC differs from plethysmographic FRC tends to increase as test time increases. This makes sense in that during longer tests individuals spend a proportionally longer time at lower alveolar N2 concentrations which enhances N2 excretion and increases the relative contribution it*

makes to exhaled N2. Interestingly, during the latter part of the washout the best ventilated parts of the lung will contain the highest concentrations of oxygen and have the highest N2 gradient. N2 excretion will therefore be highest in these parts of the lung.

6.10.6 Calculations and Principles Used in the MBN2 Test

Obtaining N2 from measurement of O2 and CO2

The Plethysmograph system uses an indirect technique to determine N2 concentration. Carbon dioxide (CO2) and Oxygen (O2) are measured using internal infra read and laser diode analyzers. N2 is then calculated by the following formula:

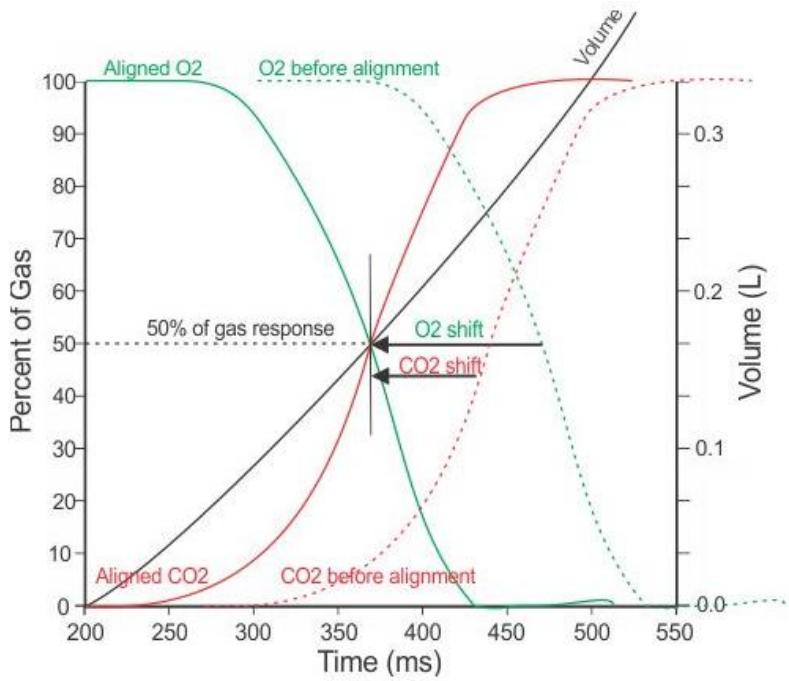
1 = FO2 + FCO2 + FN2 + FAr*

** where F is the fractional concentration of gas; FAr (Argon) is treated as a fixed proportion of FN2 during the washout (FAr = FN2 x 0.0093/0.7881)*

Synchronization of Gas and Flow Signals

Asynchrony exists between gas and respiratory flow signals that are created by transit time of gas within sampling tubing and the individual analyzer response characteristics.

Since Nitrogen is derived from measurements of oxygen and carbon dioxide, the performance characteristics of each individual gas analyzer have to be considered and aligned with flow. Transit time is the time from initial expiration or inspiration to the first response in the gas analyzers. Synchronization time shift is defined as transit time plus from initial gas response to 50% of full deflection.



With the likelihood of spurious breathing patterns and varied gas transit times during run-time measurement, meticulous synchronization of the flow and gas signals in real-time is very difficult. Hence, the software uses a very

close approximation during run-time analysis (based on a median value from testing) and then corrects and aligns all signals post-test.

Correction of the Pneumotachograph for Gas Viscosity

Since the pneumotach is calibrated with room air, the measures of flow and volume would be incorrect when breathing 100% oxygen if gas viscosity effect was not considered. The gas viscosity of oxygen is approximately 12% greater than that of room air.

Correcting the inspirate volume is quite straightforward because only inspiratory BTPS conditions with 100% oxygen viscosity has to be considered. However, the expirate corrections are more complicated because the gas concentrations for oxygen, carbon dioxide, nitrogen and water vapor are always changing.

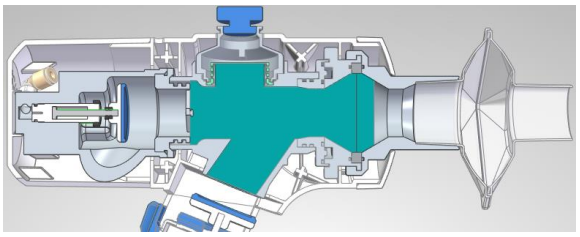
ComPAS2 utilizes a dynamic viscosity correction while aligning the expiratory flow with that of the nitrogen signal.

Vitalograph Morgan PFT System Dead Space Definitions

Valve Post-gs Dead Space Volume - Inspiratory Bag:

This includes all valve dead space between the inspiratory reservoir one-way valve and the gas sampling point.

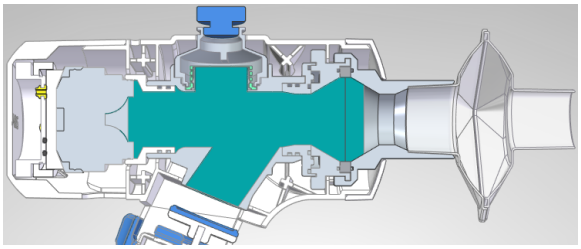
75ml



Valve Post-gs Dead Space Volume - Demand Valve:

This includes all valve dead space between the demand valve and the gas sampling point.

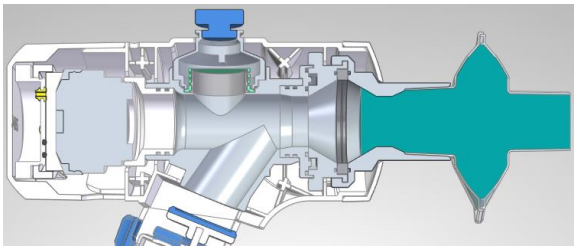
85ml



Pre-gs Dead Space Volume - Both Systems:

This includes dead space between the airway opening and the point at which the gases are sampled + Filter dead space

21 ml (common to both devices)
+
75 ml (using the Vitalograph BVF)

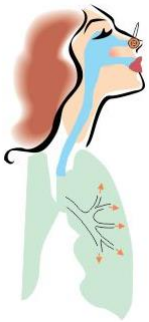


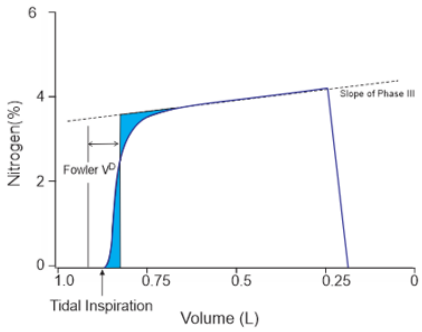
Filter dead space can be edited in configuration

Anatomic Dead Space:

Anatomic dead space is the total volume of the conducting airways from the nose or mouth down to the level of the terminal bronchioles (about 150 ml on the average)

This is measured directly using the Fowler method.





FRC Calculation

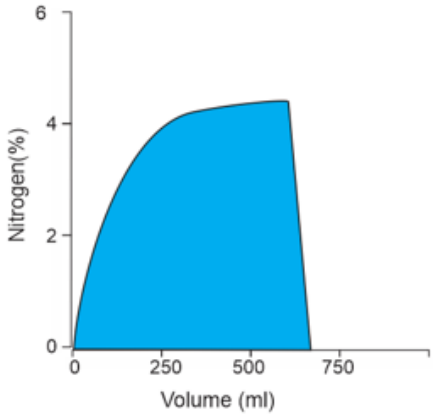
Each breath is first aligned with flow and then the area under the expired nitrogen curve integrated.

VIG is the sum of the integral products of exhaled flow and gas concentration for each washout breath corrected for re-inspired gas contained within the dead space after the post-gas sampling point (Post-gs Dead Space Volume).

VIG = ∫ V' • FN2 dt (expired breath) - ∫ V' • FN2 dt (re-inspired post-gs)

FRCgas = VIG /Cet,IG(initial-final)

Where:
VIG is net volume of inert gas expired
Cet is end tidal concentration of inert gas



Lung Volume Calculations in MBN2 Tests

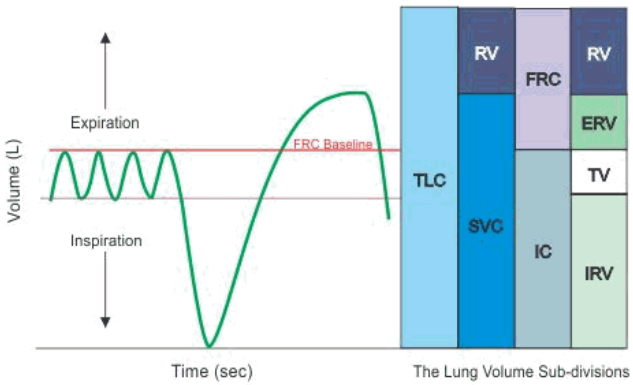
Measured parameters:

FRC

The spirometry data for SVC, ERV and IC come from a separate measure of SVC prior to the MBN2 test. It is therefore very important to make sure that the SVC is measured after first reaching a steady state FRC position!

Calculations:

FRC + IC = TLC
TLC - VC = RV



6.11 Bronchial Challenge Testing

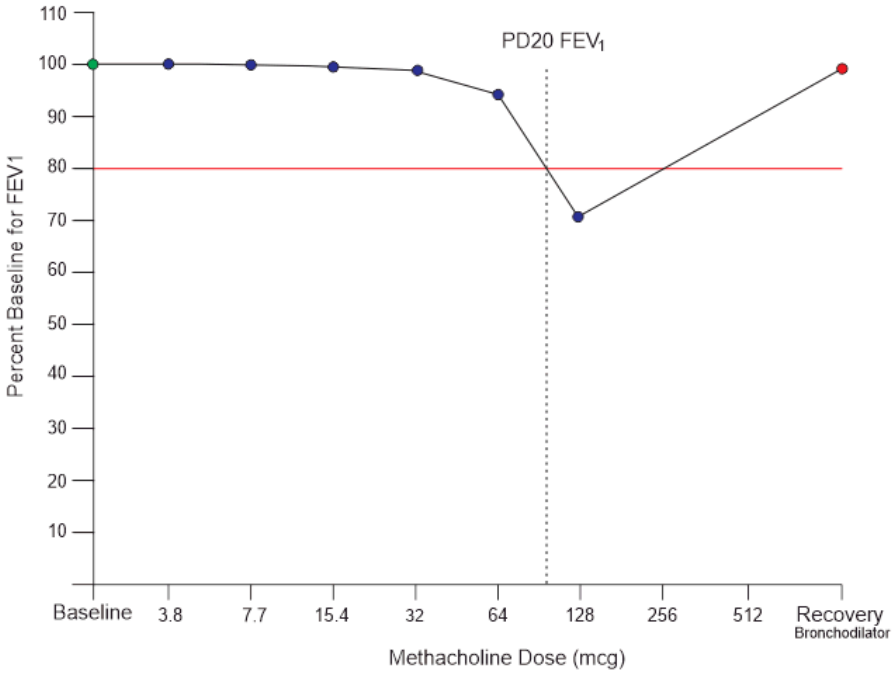
Bronchial Challenge testing is perhaps one of the highlights of ComPAS2 design. With the many years of clinical experience within Morgan Scientific, this sometimes complex and confusing test has been made easy to run and understand. Furthermore, the user is guided by helpful screen prompts and graphical presentations to ensure the highest quality of testing.

6.11.1 Background on Challenge Testing

The bronchial challenge section within ComPAS2 can be configured to accommodate various methodologies for provocation: Methacholine, Provocholine, Aridol (Mannitol inhalation powder), Exercise and Cold Air.

Bronchial challenge testing is most frequently used to assess airway responsiveness. The test requires the patient to breathe an ever-increasing concentration of a bronchoconstrictor drug (typically Methacholine and latterly Mannitol). Results of pulmonary function tests (i.e. spirometry - FEV1, Raw or sGaw) performed before and after the inhalations are used to quantitate response. Challenge testing is carried out to assess the bronchial hyper responsiveness of an individual. Testing is compared to Baseline or Diluent Level results. The Baseline or Diluent Level 'anchor' is the best value for the parameter being followed (i.e. FEV1); the best value is set to a value of 100%. Testing continues with an ever-increasing exposure to the challenge drug until a drop of 20% from Baseline has been recorded. The value obtained from the dose-response curve is called PD20 and is a measure of the inflammation of the airway walls. Some centers prefer to utilize the PC20 which is the concentration of the drug used at which the measured parameter falls at or greater than 20%; the PD20 is the dose of the drug used at which this fall occurs.

In the case of Mannitol testing, a positive response is achieved when the patient experiences a 15% reduction in FEV1 from (0mg) baseline or a 10% incremental reduction in FEV1 between consecutive doses. The test result is expressed as PD15.



The PD20 Calculation:

$$PD20 = \text{antilog}\left[\text{Log } D1 + \frac{[(\log D2 - \log D1)(20-R1)]}{(R2 - R1)} \right]$$

where:

D1 = the dose at the second to last methacholine step (i.e. step preceding the final step)

D2 = the dose at the final methacholine step (i.e. step resulting in a 20% or greater fall in FEV1)

R1 = % fall in FEV1 after D1

R2 = % fall in FEV1 after D2

How to interpret PD20 and airway hyper responsiveness:

Normal = > 400 mcg
Borderline = 100-400
Mild = 25-100
Moderate = 6-25
Severe = < 6

The bronchial challenge test can be used in many ways:

- as a diagnostic tool for asthma.
- to assess the severity of asthma (the lower the PD20 value, the more severe the asthma).
- to assess changes in treatment (a rise in PD20 values after treatment with inhaled steroids indicates that the drug is reducing inflammation, thus improving asthma control).
- in Clinical Trials (the test can be used to either assess the stability of a subject's asthma before entry into a trial or to gauge the efficacy of a drug and its effect on asthma).

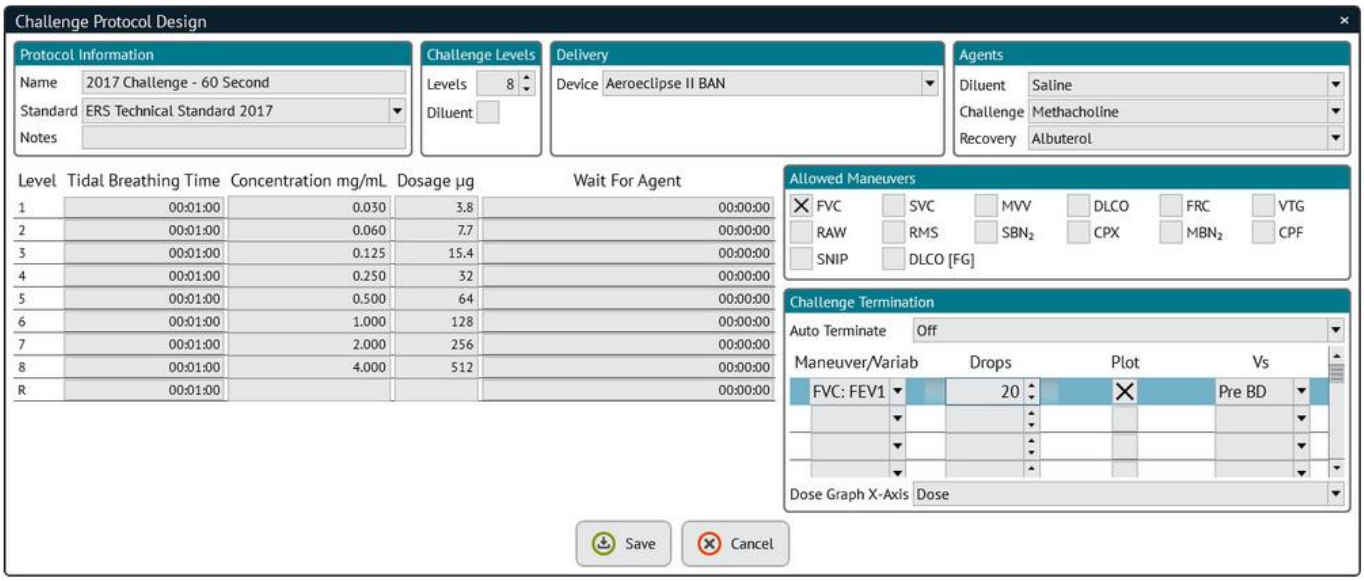
6.11.2 Exiting out of a Challenge Test if it was started inadvertently

The ComPAS2 Smart Report look to see what type of test was performed and presents the appropriate report accordingly. If the user has started a challenge test by accident and wants to remove the challenge 'flag', click on the  icon next to the Challenge Name. A message will be presented to confirm that the user wishes to exit challenge for this test subject:

If data had been collected and it is to be discarded, those data are moved to the recycle bin where they could be retrieved if necessary.

6.11.3 How a Bronchial Challenge Test is Sequenced

The design of ComPAS2 allows for a wide range of testing protocols to accommodate the differences in methods and drug levels etc. The protocol designer is elegant, versatile and easy to use. Please refer to Configuration and Bronchial Challenge Protocols for complete details.



Without a challenge protocol, the test cannot be started. The protocol forms the 'road map' for the challenge testing sequence and methodology. If more than one challenge protocol has been designed, one protocol can be designated as the "default" protocol.

Challenge testing can be started at any time by simply clicking on the up-arrow of the Pre, Post or Challenge button on the test screen.

If more than one protocol exists, the user will be prompted to select the appropriate protocol when starting a challenge test.

The sequence of challenge testing engages the "Challenge Timer". This is a combination message box, notepad, clock and instructional guide through each level of testing displayed in the central panel of the test screen.

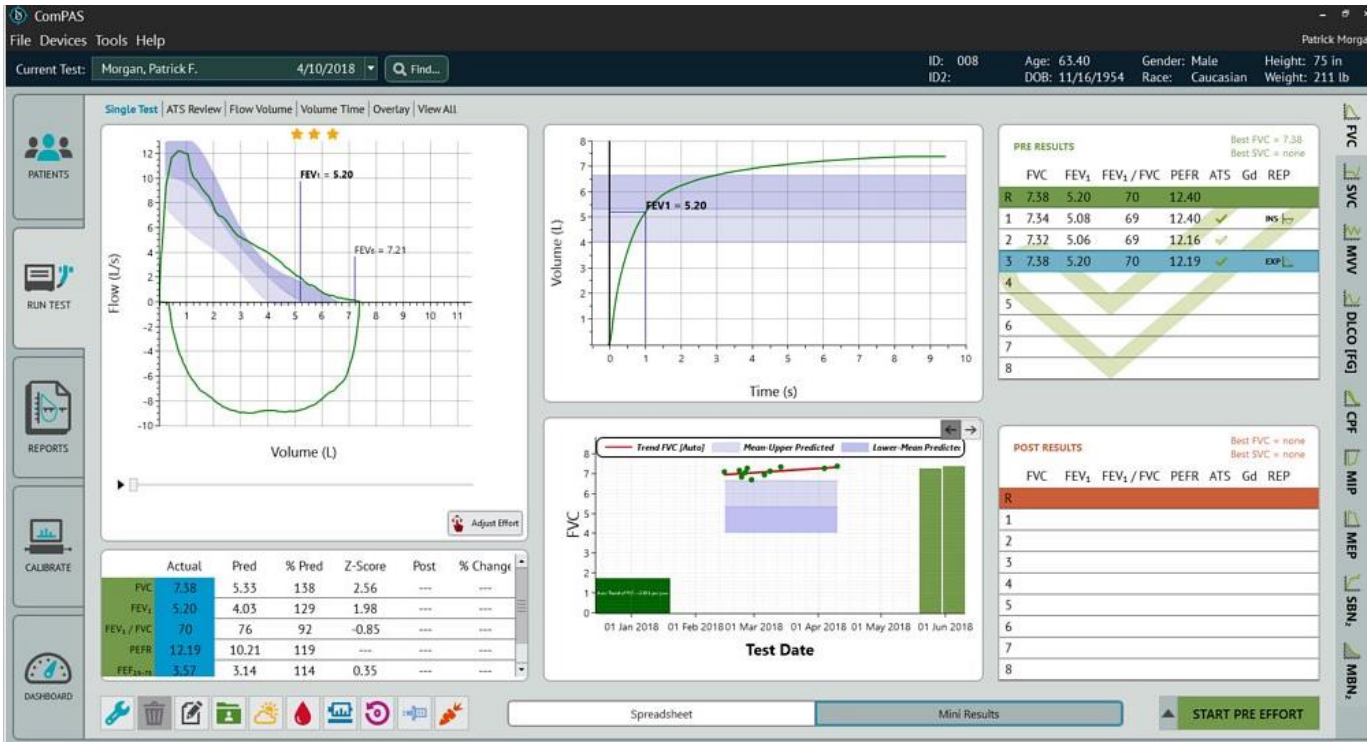
The "Challenge Timer" follows the protocol being used and has been carefully designed to give structure and quality control to provocation tests.

To identify each stage of the challenge test, the following colors are used for the graphics and the challenge timer dialogue box:

Baseline (Pre Bronchodilator)
Diluent (Saline etc.)
Challenge (Methacholine etc.)
Reversal (Post Bronchodilator - Albuterol etc.)

6.11.4 Running a Methacholine Challenge Test

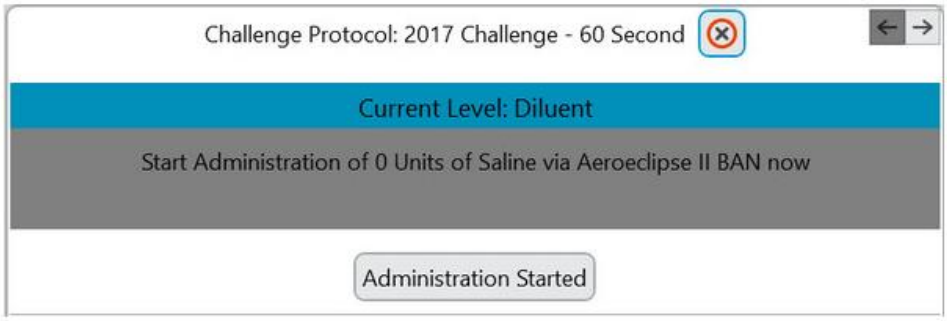
If Pre-Bronchodilator (Baseline) data already exists, then the Challenge will move automatically to the first item in the protocol. If no baseline data exists, Pre-Bronchodilator testing will be requested.



The bottom middle panel of the testing screen provides timers, user prompts and ability to add notes at each challenge level if desired.

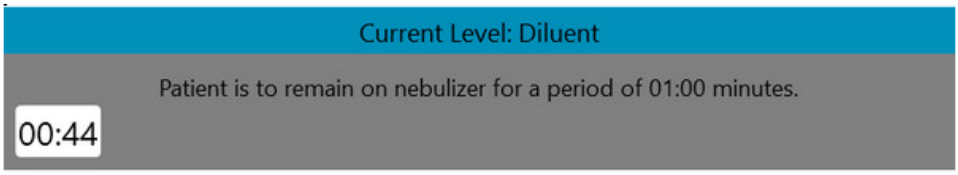
6.11.4.1 DILUENT LEVEL

If the challenge protocol calls for a Diluent Level, then that will be presented first:



Each level of challenge will be guided by the protocol design; messages and prompts will depend upon the drug delivery method. As soon as the drug delivery begins, the user must click the Administration Started button.

A countdown clock will be started and concludes with a "**bell**" chime to alert the user that a flow volume effort can be started.



As soon as the bell sounds, the Start Effort button will appear; click the button to begin testing.

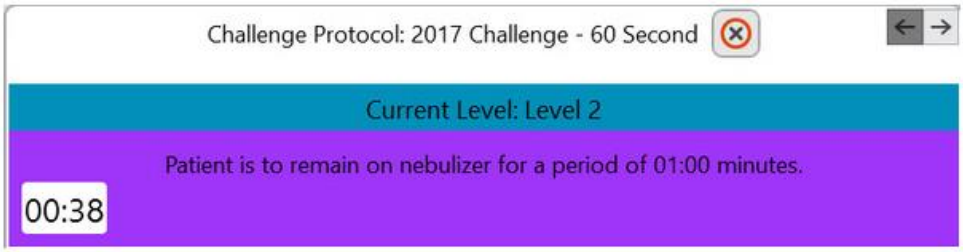
Testing can continue at any level with up to 8 efforts possible.

For repeat efforts at any level click the Another Effort button.

When ready to advance to the first Methacholine dose, click the Next Level button.

6.11.4.2 CHALLENGE LEVELS

Once the Administration Started button is pressed, the timer will activate for the first challenge dose.



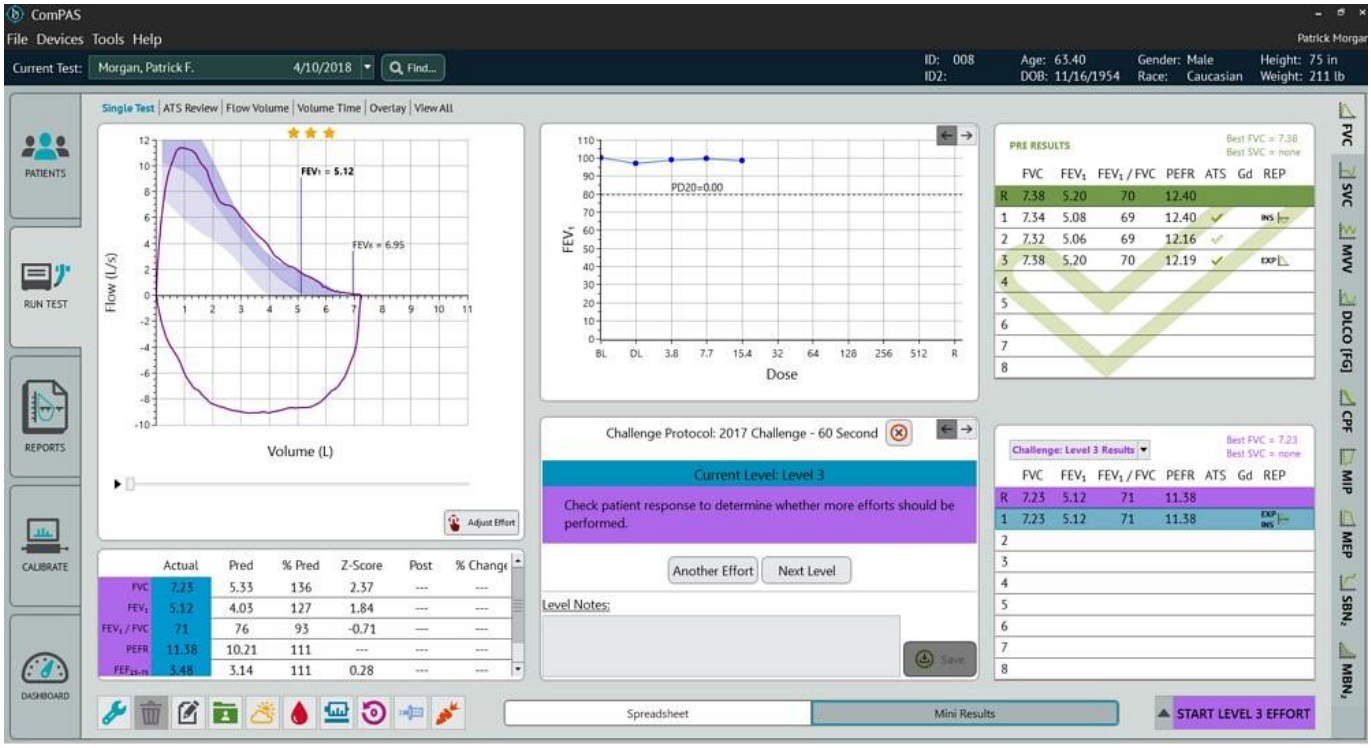
As soon as the bell sounds, the Start Effort button will appear; click the button to begin testing.

Testing can continue at any level with up to 8 efforts possible.

For repeat efforts at any level click the Another Effort button.

When ready to advance to the next Methacholine dose, click the Next Level button.

As the challenge test progresses, the dose response curve will be shown.



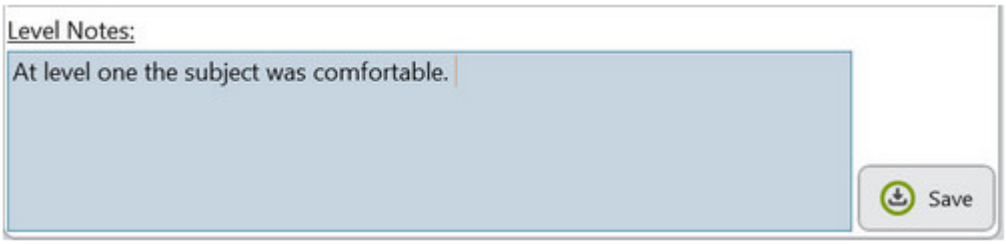
If necessary, the user can go back or jump ahead levels using the Up Arrow of the START LEVEL 2 EFFORT Start Button

Clicking the Up Arrow will show each level of the protocol and by highlighting the desired level a 'jump' can be made:

If this option is selected, the user will be asked if skipping levels was intended?

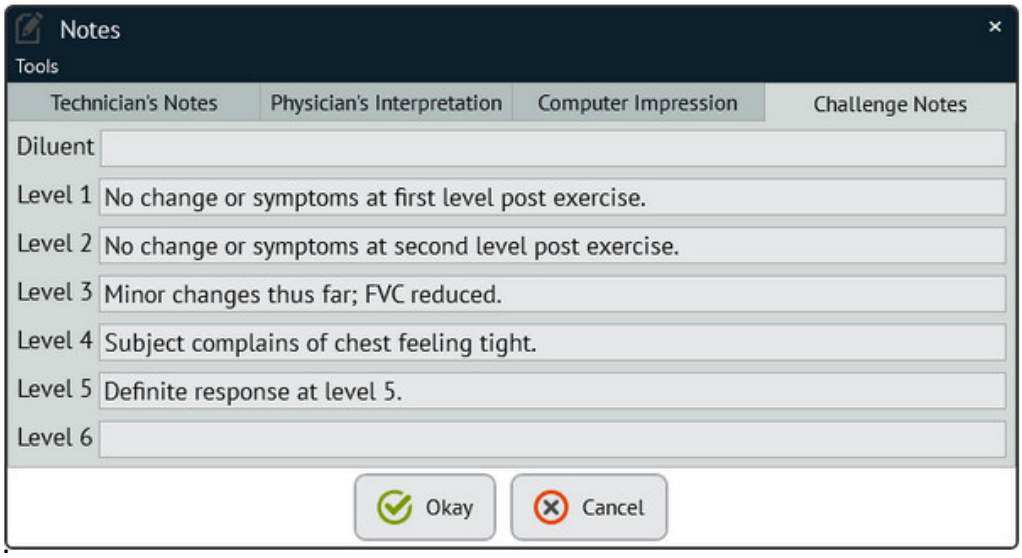
6.11.4.3 LEVEL NOTES

At each level, notes can be stored; simply type in the Notes field and click 



Notes can later be edited on the testing screen and loading the appropriate level, or by clicking on the notes icon 

Notes can extend way beyond the displayed space if more detail is required.



6.11.4.4 RECOVERY LEVEL

As each level is underway, ComPAS2 is always looking to see if the end of test conditions set-up in the protocol have been met. Most typically this is a 20% reduction from Baseline or Diluent levels (depending upon the protocol). If the 20% reduction is recorded, a user prompt immediately alerts the user.

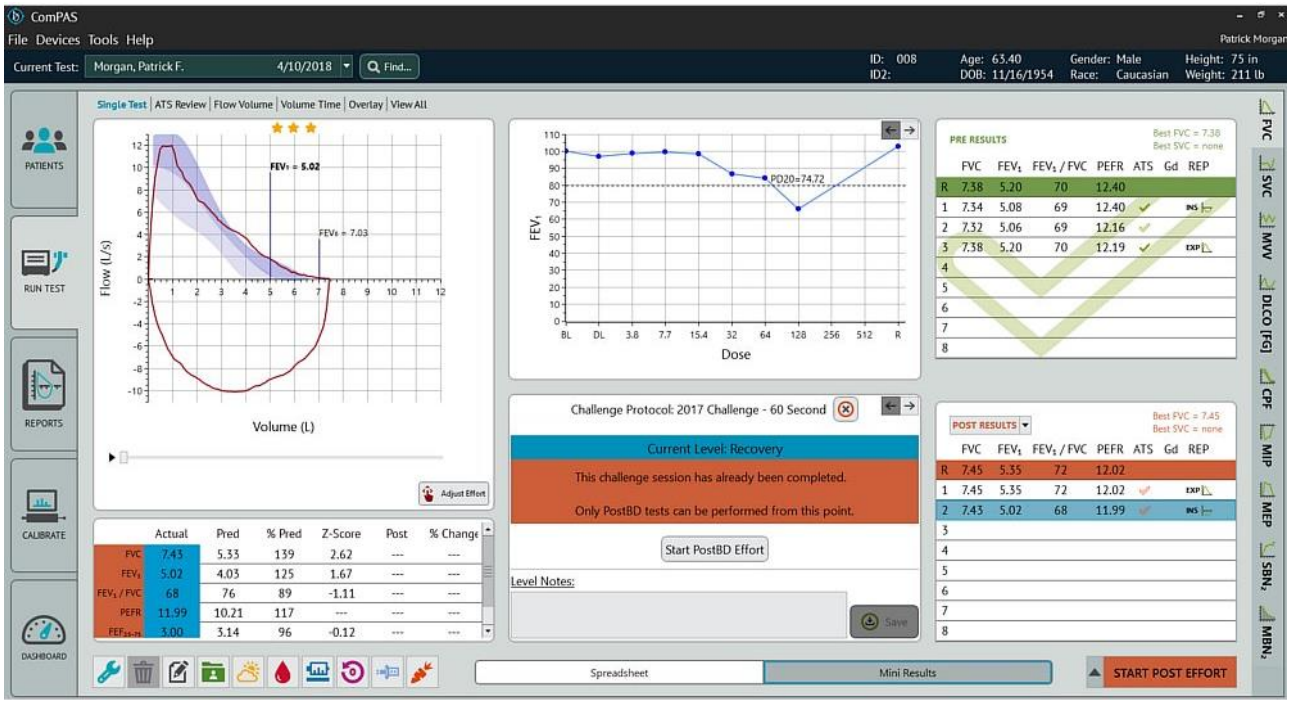
Typically, a second effort is measured to confirm the subject's response and then the user can select the 

button.

Recovery usually follows the recommendations of Albuterol or other bronchodilator administration so that the original subject lung function can be restored.

Once the recovery level data has been captured, click the 

button to conclude testing.



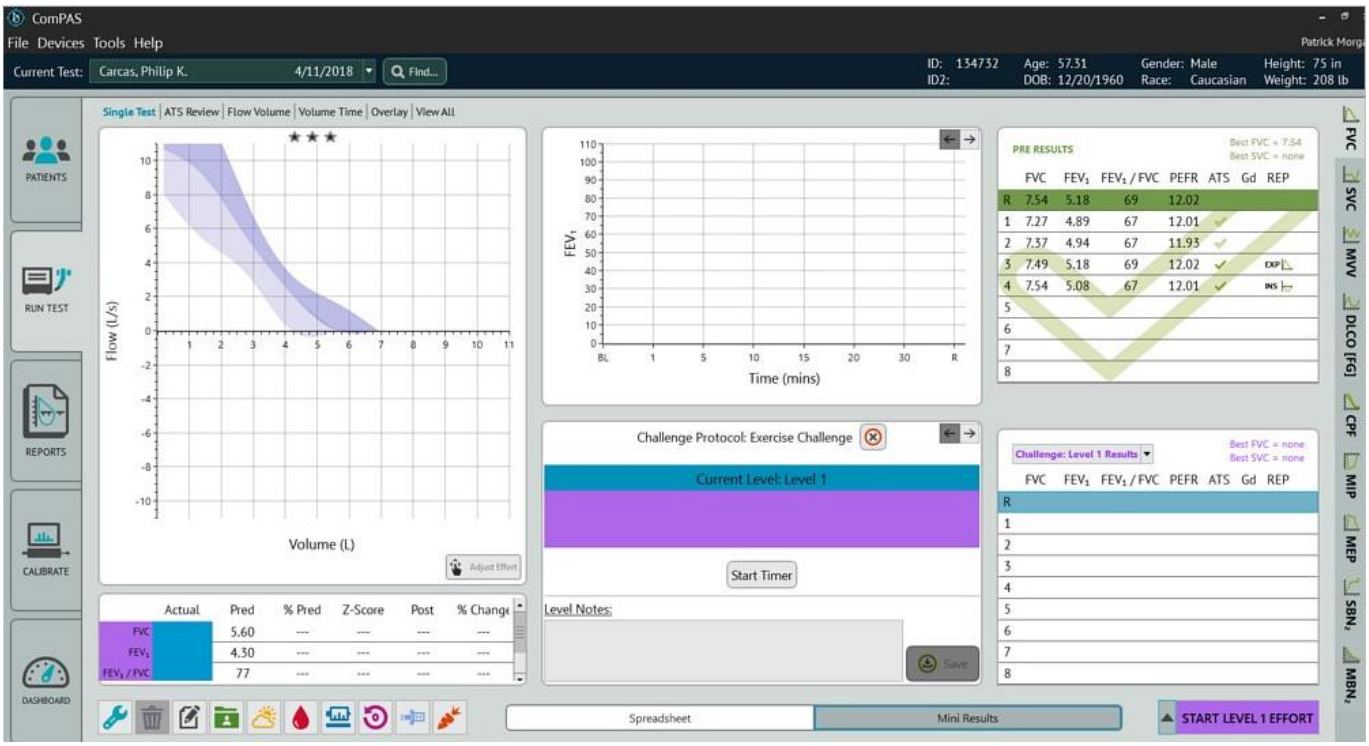
6.11.5 Running an Exercise Challenge Test

Exercise challenge testing can be started at any time by simply clicking on the up-arrow of the Pre, Post or Challenge button on the test screen.

If more than one protocol exists, the user will be prompted to select the appropriate protocol when starting a challenge test.

The sequence of exercise challenge testing engages the "Challenge Timer". This is a combination message box, note-pad, clock and instructional guide through each level of testing. The "Challenge Timer" follows the protocol being used and has been carefully designed to give structure and quality control to provocation tests.

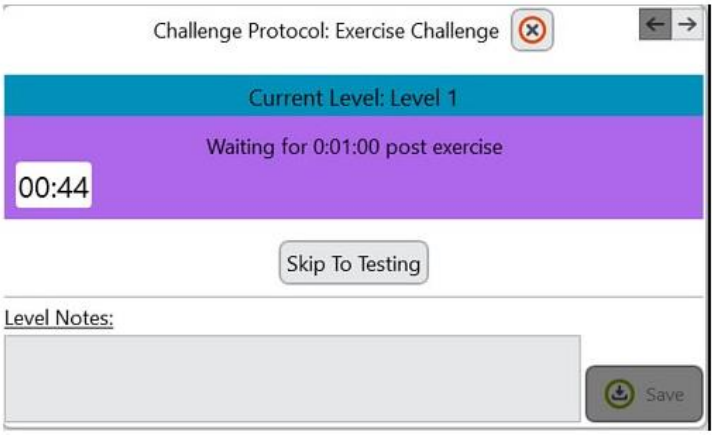
For Exercise Challenge tests, baseline Pre-Bronchodilator testing must be completed before the subject is instructed to exercise.



The bottom middle panel of the testing screen provides timers, user prompts and ability to add notes at each exercise challenge level if desired.

6.11.5.1 EXERCISE CHALLENGE LEVELS

Each level of the exercise challenge will be guided by the protocol design. As each level (time post exercise) is completed, the user must click the Start Timer button.



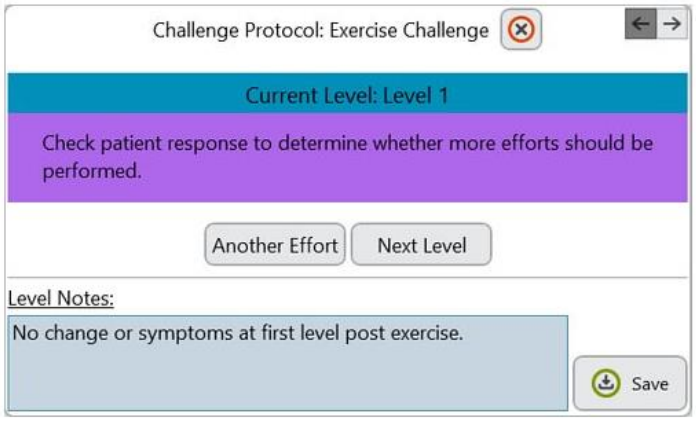
As soon as the bell sounds, the Start Effort button will appear; click the button to begin testing.

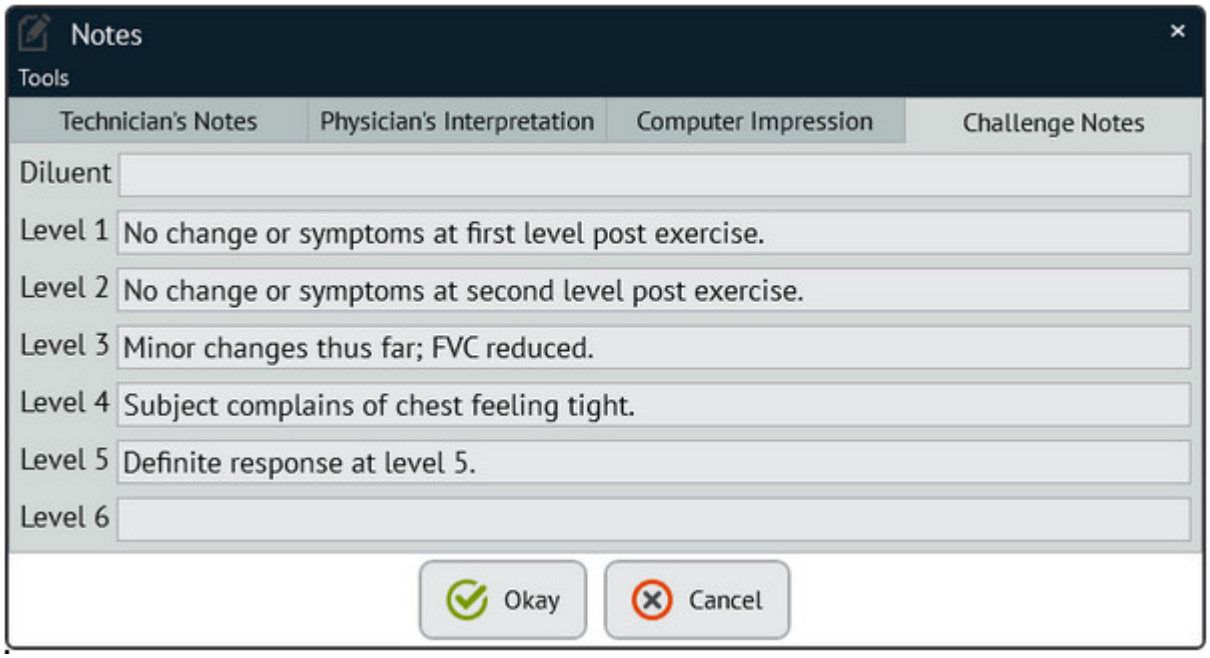
For repeat efforts at any level click the Another Effort button.

When ready to advance to the next time level, click the Next Level button.

6.11.5.2 EXERCISE CHALLENGE LEVEL NOTES

At each level, notes can be stored; simply type in the Notes field and click Save

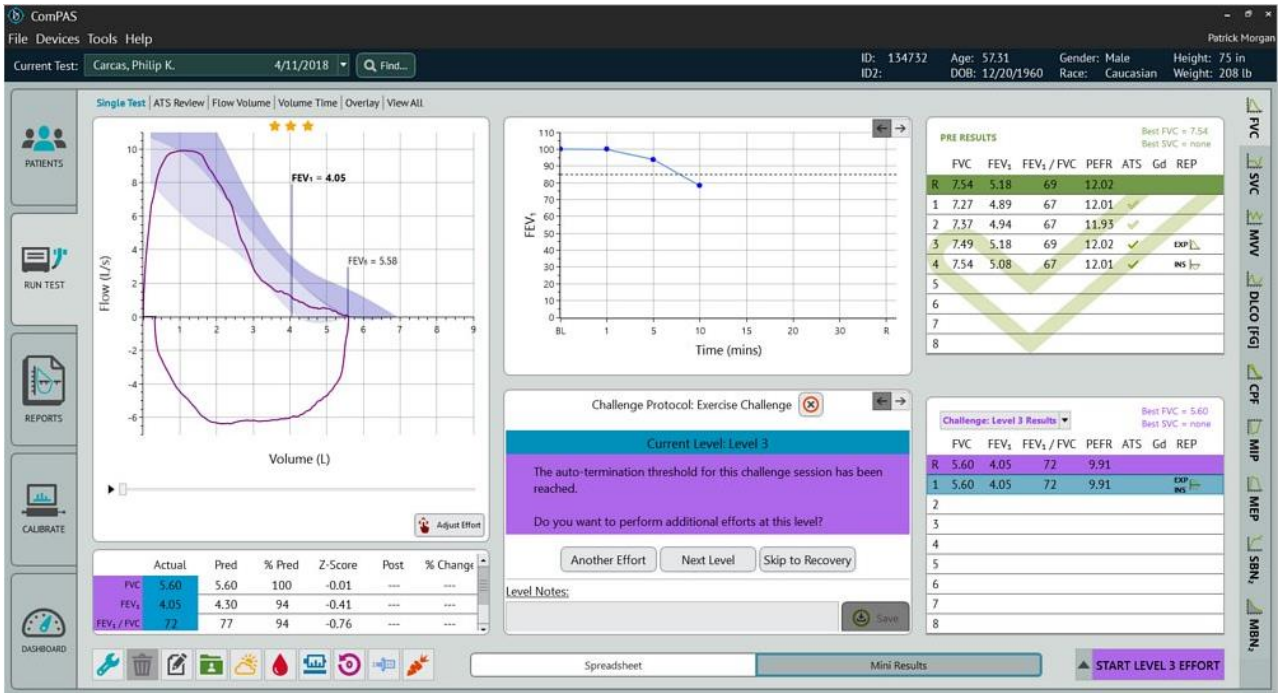




As soon as the next level loads, click the Start Timer button to countdown the next time interval.

As the exercise challenge test progresses, the post exercise response curve will be shown.

ComPAS2 is always looking to see if the end of test conditions set-up in the protocol have been met. Most typically in exercise protocols, this is a 15% reduction from Baseline. If the 15% reduction is recorded, a user prompt is immediately displayed. Another test effort can be completed to confirm the reduction in FEV1 or the test can be moved to the Recovery level.

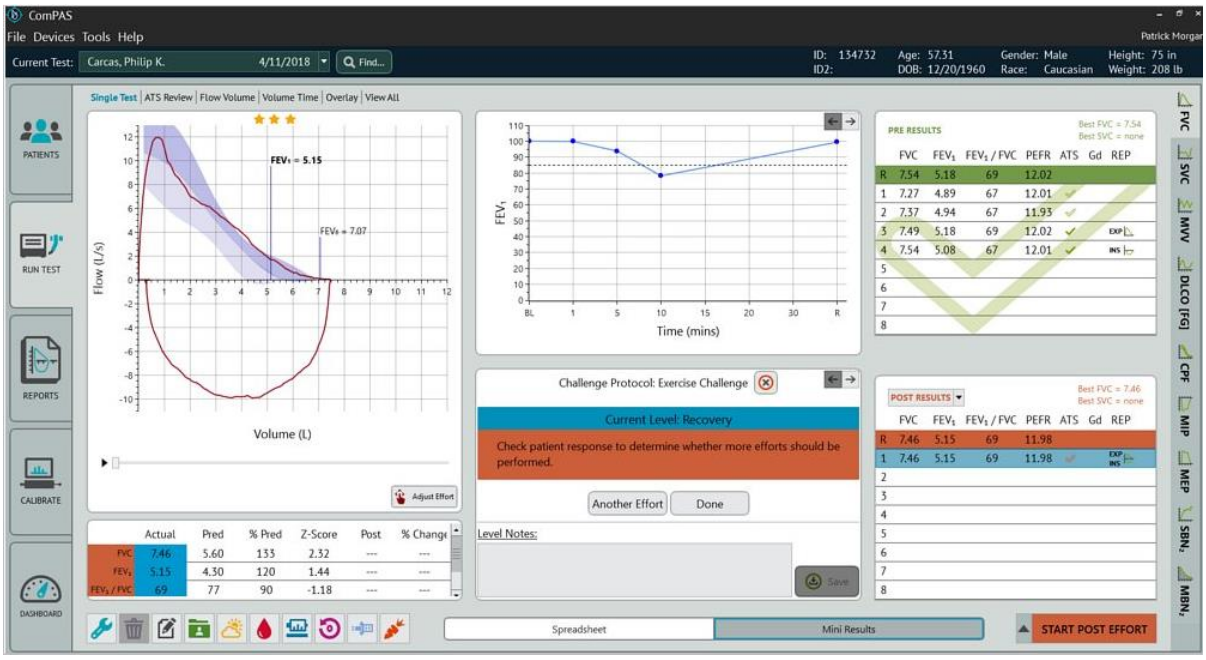


Typically, a second effort is measured to confirm the subject's response and then the user can select the Skip to Recovery button.

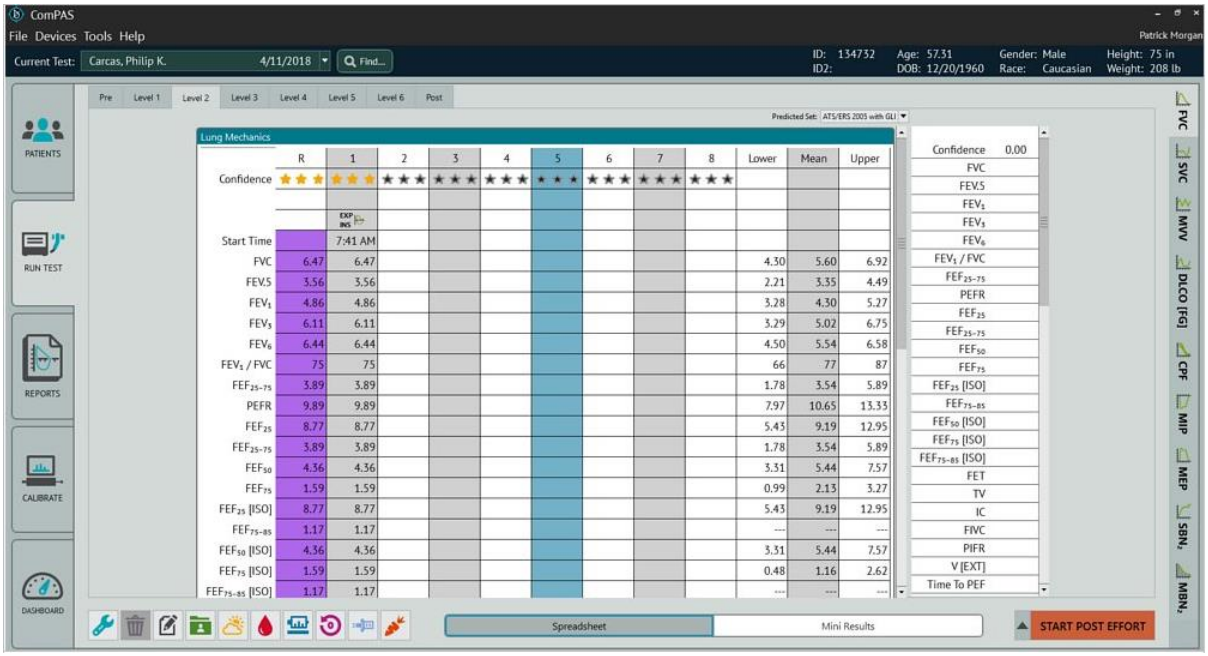
6.11.5.3 EXERCISE CHALLENGE RECOVERY LEVEL

Recovery usually follows the recommendations of Albuterol or other bronchodilator administration so that the original subject lung function can be restored.

Once the recovery level data has been captured, click the Done button to conclude testing.



The spreadsheet view will show all efforts at each level of challenge by navigating across the top tabs.



6.12 Six Minute Walk Using the Nonin WristOx

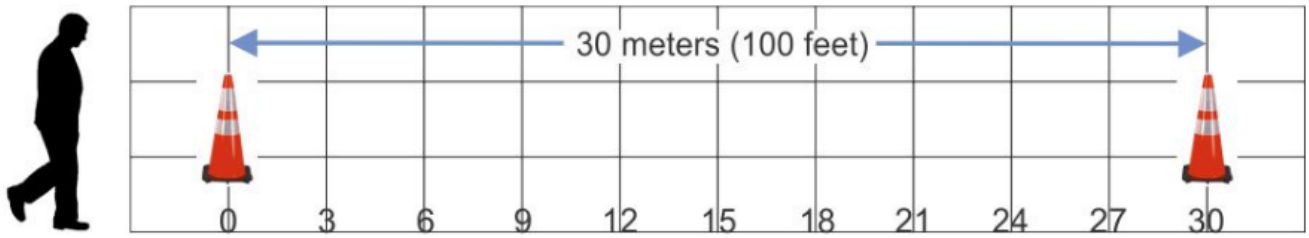
6.12.1 WristOx Connection

The WristOx is auto detected when plugged into any USB port; no special connection settings are required.

6.12.2 Introduction to Six Minute Walk (6MW)

The Six Minute Walk Test (6MWT) is simple to set-up; it requires a hallway/corridor of 100 feet (30 meters). Ideally, the length of the corridor should be marked every 3m and the turnaround points marked with a cone. When ready to begin the test, the patient should be instructed as recommended by the ATS Statement: Guidelines for the Six-Minute Walk Test. 6.15 Manual Entry of ABG and Other Data

The manual entry spreadsheets are accessed by clicking the  icon on the bottom task bar.



The technician should guide and encourage the individual throughout the six minutes and at the conclusion of the effort record the following:

- The 6MWT distance rounding to the nearest meter
- The Borg dyspnea or perceived exertion scale (1-10)
- FIO2 or Oxygen Delivery (L/min) if supplemental O2 was used
- Reasons for stopping the test if the effort concluded early

A stopwatch or timer is required to accurately record the six minutes and a counter is helpful for recording the number of laps.

Using the WristOx, the automatic data storage is achieved in two steps:

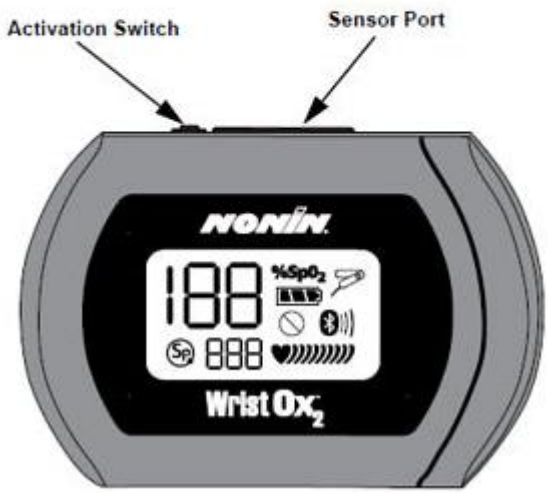
First the resting data are recorded and saved

Secondly, the six-minute walk data together with 4 minutes of recovery data are recorded and saved

The WristOx will always show two files for downloading if the correct procedure is followed.

6.12.3 Collecting and Storing RESTING Data

Follow the instructions in the Nonin manual for attaching the device.



The WristOx device will begin recording automatically as soon as reliable SpO2 data are seen. Resting data need to be collected for a minimum of three minutes; we recommend gathering at least 5 minutes of resting data.

Once the resting period has ended, remove the finger probe and let the WristOx power down. The data will be automatically saved as the first record file on the WristOx.

Note:
Resting data will be stored in the "Rest 1" column once downloaded (either Room Air or Elevated O2).

6.12.4 Collecting and Storing SIX-MINUTE WALK and RECOVERY Data

When ready to begin the test, the patient should be instructed as recommended by the ATS Statement: Guidelines for the Six-Minute Walk Test:

"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able".

"You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation."

To start the walking phase of the test, re-connect the finger probe and begin the six minutes of walking.

It is important to encourage and reassure the individual as the test progresses while at the same time keep careful record of the number of laps completed. As each minute is completed, continue to encourage the patient and count down the minutes left to complete the test. The technician should not be instructing the subject to "speed up" or in any way change what they feel is their own level of maximal walking effort. It is fine to reassure the subject if they have to rest, but they should encourage them to try and finish six minutes of walking if they can.

When the test is close to the conclusion of six minutes, instruct the individual that the "test is near the end and when I tell you to stop, please stay exactly where you are".

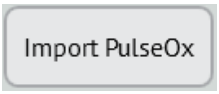
Record the distance to the nearest meter.

If collecting recovery data is part of the test protocol, be sure to leave the finger probe connected and let the patient rest.

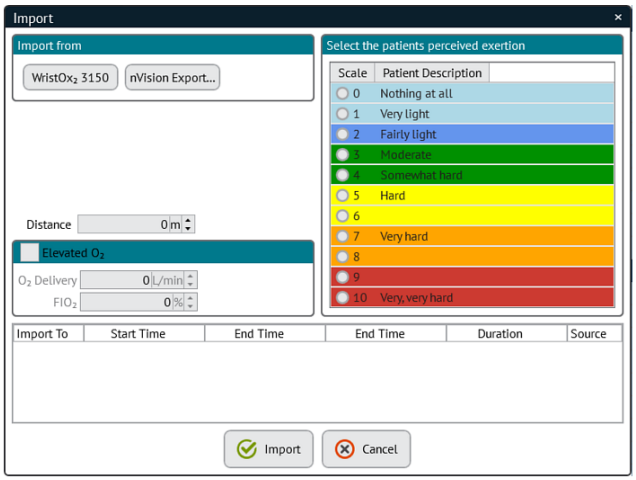
6.12.5 Downloading the 6MW Test Data

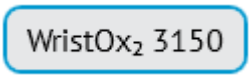
Six-Minute Walk data are stored in the versatile manual entry screens of ComPAS2. Click on the  icon to enter the spreadsheet.

Unplug the finger probe and connect the WristOx to the PC using the USB cable.

Click on the 

button to access the import dialogue:



Click on the 

to access the WristOx import.

There are five simple steps to completing the import:

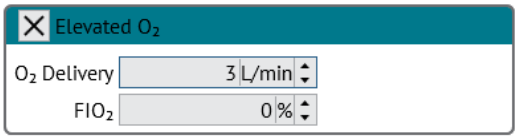
Step 1

Enter the distance walked.

Step 2a

If the test was completed without any supplemental oxygen, go to step 3.

Step 2b
If the test was completed using supplemental oxygen, first check the "Elevated O2" box and enter the O2 details.

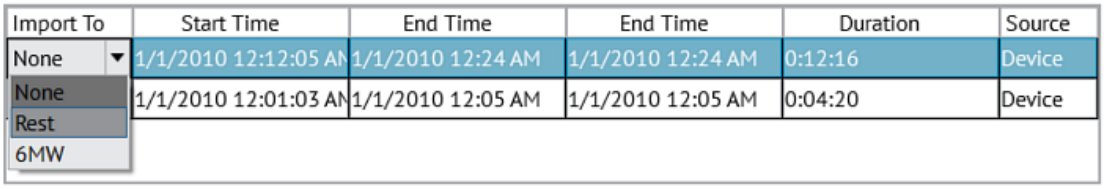


Step 3

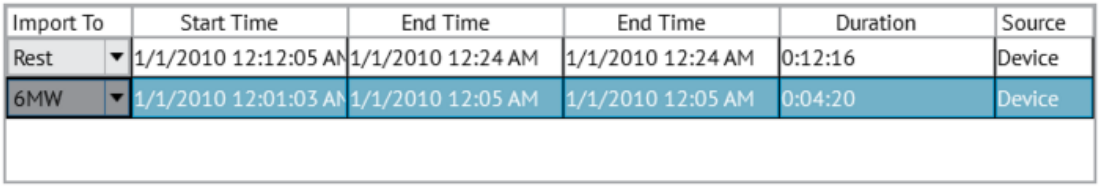
Enter the perceived exertion on the scale 1 - 10

Step 4

Confirm the two sets of data (Rest and 6MW) using the pull-down arrows:



Import To	Start Time	End Time	End Time	Duration	Source
None	1/1/2010 12:12:05 AM	1/1/2010 12:24 AM	1/1/2010 12:24 AM	0:12:16	Device
None	1/1/2010 12:01:03 AM	1/1/2010 12:05 AM	1/1/2010 12:05 AM	0:04:20	Device
Rest					
6MW					



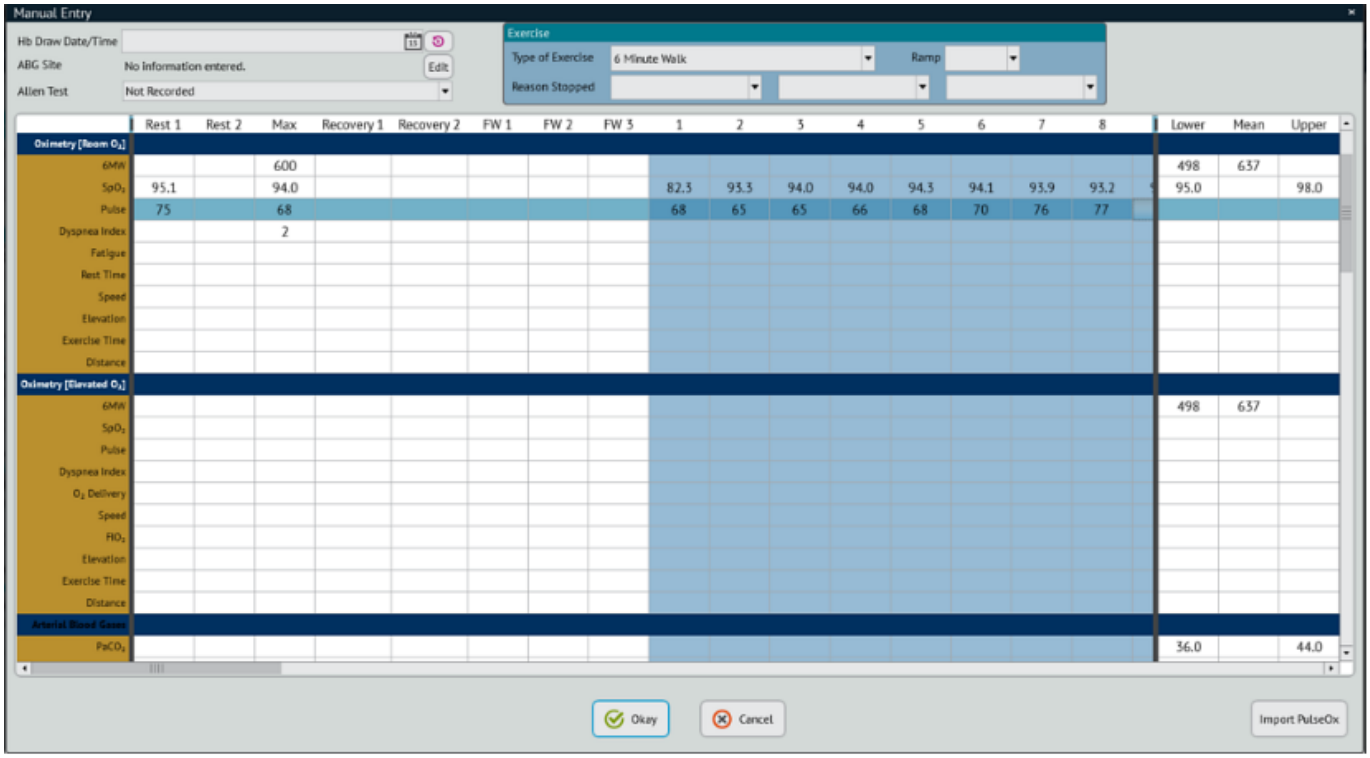
Import To	Start Time	End Time	End Time	Duration	Source
Rest	1/1/2010 12:12:05 AM	1/1/2010 12:24 AM	1/1/2010 12:24 AM	0:12:16	Device
6MW	1/1/2010 12:01:03 AM	1/1/2010 12:05 AM	1/1/2010 12:05 AM	0:04:20	Device

Step 5

When satisfied that the information is correct, click the 

button.

Before adding the data to the spreadsheet, the user is prompted about clearing data from the WristOx after import. The advantage of doing so leaves the unit cleared of data and ready for the next test.



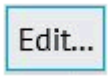
6.13 Manual Entry of ABG, Oximetry and Other Data

The manual entry spreadsheets are accessed by clicking the  icon on the bottom task bar.

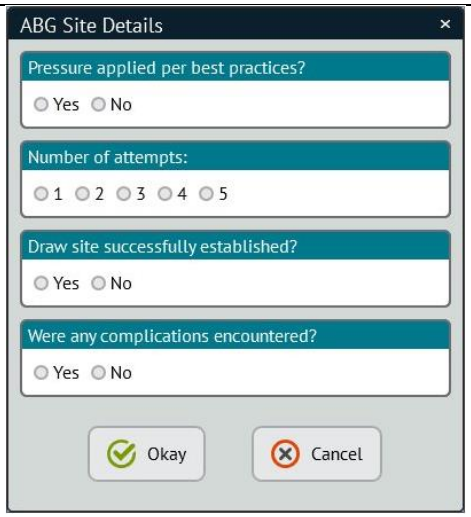
The spreadsheet provides inputs for ABG, Oximetry, iCPET and Exercise. Beyond the fixed columns of Rest, Max, Recovery and Free Wheel, there are a possible further 100 columns of input.

6.13.1 Arterial Blood Gases

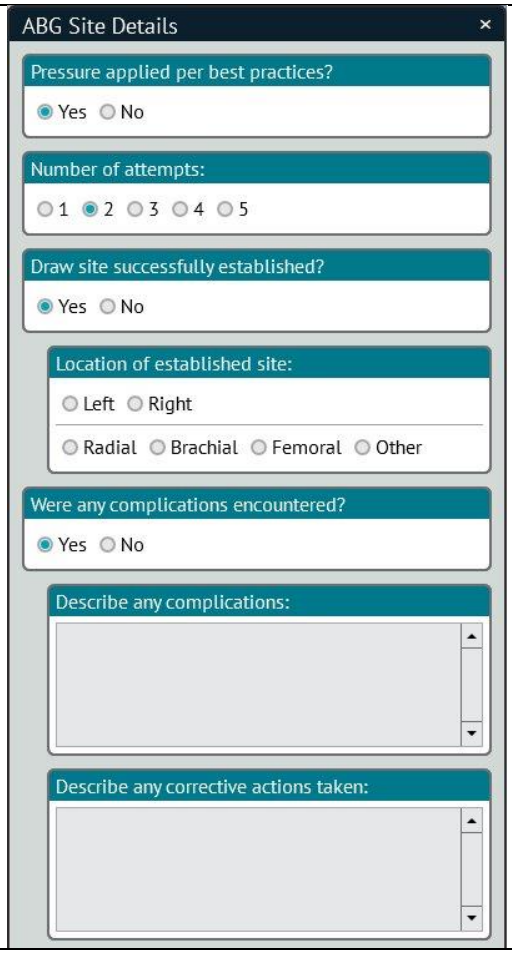
For ABG entry, the top left-hand section of the spreadsheet has dialogues for recording site information when desired.

Clicking on the 

button opens the site detail screen:



Answering “Yes” expands data options



Beyond the fixed columns of Rest, Max, Recovery and Free Wheel, there are a possible further 100 columns for recording Manual Entry fields.

There are calculations that will automatically be made if ABG inputs trigger the computation of further parameters. These calculations come from the Manual Entry script.

Hb data can be either entered prior to a single breath diffusion test or after. As soon as a Hb value is recorded, the test-recalculate will be triggered and DLCO values (actual or predicted value depending upon configuration selection) will be corrected.

Arterial Blood Gases																				
$PaCO_2$	40.0		30.0			31.0			34.0	31.0	32.0	33.0	30.0	30.0				36.0		44.0
pH	7.41		7.39			7.39												7.37		7.43
PaO_2	107.0		125.0			112.0			103.0	119.0	117.0	110.0	112.0	116.0				86.0	93.8	98.0
HCO_3-	24.0		24.1			23.9												23.0		27.0
SaO_2	97.3		97.6			97.2												95.0		98.0
Hb	14.0																	12.0	14.6	16.0
COHb																		0.5		2.5

6.13.1.1 Example ABG Report

Pulmonary Function Report

Morgan Scientific, Inc.

151 Essex Street
Haverhill, MA 01832 **Phone: (978) 521-4440**

Patient Information

Name: Test K. Subject	**ID: 134732**		**Test date/time: 9/27/2018 3:14:53 PM**
Height at test: 75 in			
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960	Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C	
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan	
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:	

Arterial Blood Gases

Parameter		Normal Values	Resting Values	Resting 2 Values	Exercise Values
pH	units	7.35 to 7.45	**7.40**	----	----
$PaCO_2$	mmHg	35 to 43	**37.0**	----	----
PaO_2	mmHg	>65	**96.0**	----	----
HCO_3-	mEq/L	18 to 26	**23.0**	----	----
B.E.	mEq/L	-3.0 to +3.0	**-2.1**	----	----
SaO_2	%	>92	**98.0**	----	----
FIO_2	%	21	----	----	----
Hb	gm %	12 to 16	**13.8**	----	----

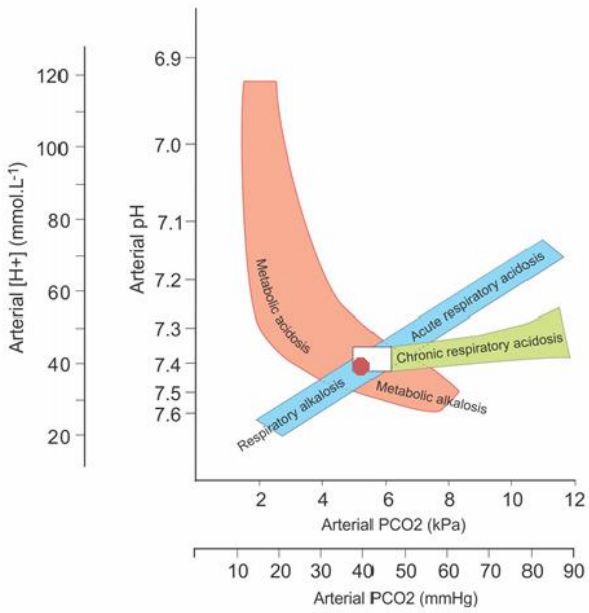
ABG Site Information:

Pressure applied per best practices: Yes
Established after following attempts: 1
Draw site successfully established: Yes (on the left side) Location:

Complications Encountered:

Corrective Actions:

6.13.1.2 Example ABG Report with Acid Base Diagram



ABG Table

Allen Test: Not Recorded

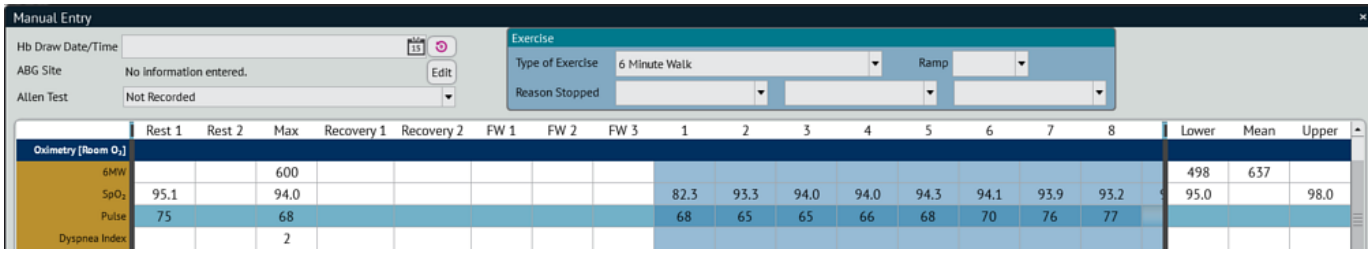
		pH 7.35 to 7.45	PaCO2 35 to 45 mmHg	PaO2 80 to 100 mmHg	HCO3- 22 to 26 mEq/L	O2 Sat 93 to 97.5 %	P(A-a)O2 5 to 15 mmHg	Hb 14 to 17.4 g/dL
Rest	(Room Air)	**7.41**	**40.0**	**107.0**	**24.0**	**97.3**	**-18**	**14.0**

6.13.2 Six Minute Walk Data

Six Minute Walk data can either be manually entered or automatically imported from a Nonin WristOx device (see 6.12).

For Six Minute Walk manual entry, there are two sections available to record the appropriate information. Tests can be recorded when done on Room Air or Elevated Oxygen.

For reports, the key value is the 6MW result posted into the Max column.



	Rest 1	Rest 2	Max	Recovery 1	Recovery 2	FW 1	FW 2	FW 3	1	2	3	4	5	6	7	8	Lower	Mean	Upper
Oximetry [Room O_2]																			
6MW			600														498	637	
SpO_2	95.1		94.0						82.3	93.3	94.0	94.0	94.3	94.1	93.9	93.2	95.0		98.0
Pulse	75		68						68	65	65	66	68	70	76	77			
Dyspnea Index			2																

Six Minute Walk Data can vary depending upon the departments protocol, additional fields that are often added include:

Dyspnea Index
BP [Systolic]
BP [Diastolic]
RR (Respiratory Rate)

These variables can be found further down on the spreadsheet.

Variable order in the spreadsheet can be changed in configuration

6.13.2.1 Example Six Minute Walk Report:

There are several standard six-minute walk reports in ComPAS2, this is one example:

Pulmonary Function Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	**ID: 134732**	**Test date/time: 9/27/2018 3:14:53 PM**	
Height at test: 75 in			
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960	Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C	
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan	
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:	

Six Minute Walk Study

		Resting	1 min	2 min	3 min	4 min	5 min	6 min	Max	Recovery Min 1	Recovery Min 2	Recovery Min 3
SpO2	(%)	98.2	97.8	97.0	96.9	96.6	96.5	96.5		97.0	98.1	98.1
HR	(bpm)	60	65	69	78	79	89	91		96	81	72
BP	(mmHg)	120 / 79							122 / 82			
Dyspnea	(1 - 10)	----	----	----	----	----	----	----	3			
Fatigue	(1 - 10)	----							----			

Actual 6MW distance:	778	meters
Predicted distance:	669	meters
Percent of predicted:	116	%

6.13.3 Hypoxia Altitude Simulation Test (HAST) Tests

HAST testing is undertaken to determine how much additional oxygen, if any, a patient may need when flying or traveling to high altitudes.

Typically, the equipment used is as follows:

> *Rolling pole with two tank carriers, E size compressed Oxygen tank, E size compressed gas HAST tank with 85% Nitrogen and 15% Oxygen, oximeter, nasal cannula, non-rebreather mask, and a stopwatch.*

HAST data is entered through the manual entry spreadsheets accessed by clicking the  icon on the bottom task bar.

6.13.3.1 A Typical HAST Testing Procedure:

1) Measure oximetry at rest with FiO2 of 21% (room air at sea level) for three minutes and document oxygen saturation and heart rate with the patient in the sitting position.

> If oxygen saturation drops below 89% add supplemental oxygen (L/min) to maintain > 89% via a nasal cannula connected to an oxygen tank. Document oxygen saturation, heart rate, and oxygen liter flow if applicable. If supplemental oxygen is not needed proceed as below.

2) Once oxygen saturation is maintained >89% place patient on a non-rebreather connected to a tank containing 85% Nitrogen and 15% oxygen (HAST gas). Turn the flow meter to 10 liters/minute or enough flow to keep the bag on the mask inflated without over distending. Monitor in the sitting position for five minutes.

Document oxygen saturation, oxygen liter flow if applicable, and heart rate.

> If oxygen saturation remains > 89% begin ambulatory oximetry. Ambulate for approximately 200 feet on a flat surface or as tolerated by the patient with the HAST gas.
>
> If oxygen saturation drops below 89% during ambulation increase the oxygen via the nasal cannula to maintain saturation >89%. Document oxygen saturation, heart rate and oxygen liter flow if applicable.

3) Patient is returned to a seated position for a recovery period of one minute. Oxygen saturation, heart rate, and oxygen liter flow if applicable is documented.

The non-rebreather mask is removed, and testing is completed.

6.13.3.2 Manual Input of HAST data in ComPAS2:

In the HAST section of the spreadsheet, data should be entered into columns 1 – 6 as shown below:

	Rest 1	Rest 2	Max	Recovery 1	Recovery 2	FW 1	FW 2	FW 3	1	2	3	4	5	6
HAST														
SpO_2									94.0	85.0	93.0	85.0	91.0	98.0
Pulse									64	64	65	87	71	65
O_2 Delivery											1.0	1.0	3.0	
FIO_2									0.21	0.15	0.15	0.15	0.15	0.15

6.13.3.3 Example HAST Report:

The standard HAST report in ComPAS2 provides the following output:

Pulmonary Function
151 Essex Street
Haverhill, MA 01832
Phone: (978) 521-4440

Date: 10/1/2018

Name: Test K. Subject
Birth Date: 12/20/1960 Age: 57 BMI: 26.4
MR #: 134732 AC #:
Race: C
Smoker: N Pack yrs: N/A
Diagnosis:
Gender: M
Attending Physician: Colin Chapman, M.D.
Height: 190.5 cm 75 in
Referring Physician:
Weight: 95.4 Kg 210.32 lb
Therapist: Patrick Morgan

Hypoxia Altitude Simulation Test (HAST)

Patient was referred for a Hypoxia Altitude Simulation Test.
After measuring Oximetry at rest with FiO2 of 21% (room air at sea level), we proceed the simulation with FiO2 15% (equivalent to 8,000 feet above sea level or cabin pressure in comercial flight). The test was performed with the patient at rest and during ambulation.

Activity	HR (b/min)	SpO2 %	FiO2	Supplemental O2 (L/min)
Resting Oximetry, Minute 3	64	94.0	0.21	
Resting Oximetry, Minute 5	64	85.0	0.15	
Resting Oximetry, O2 titration	65	93.0	0.15	1.0
Ambulatory Oximetry	87	85.0	0.15	1.0
Ambulatory Oximetry, O2 titration	71	91.0	0.15	3.0
Recovery, Minute 1	65	98.0	0.15	

6.13.4 Shunt Fraction

The material below describing shunt fraction is presented by permission from Richard Johnston, author of the PFT Blog which is highly recommended as a resource for wide ranging topics on pulmonary function testing.

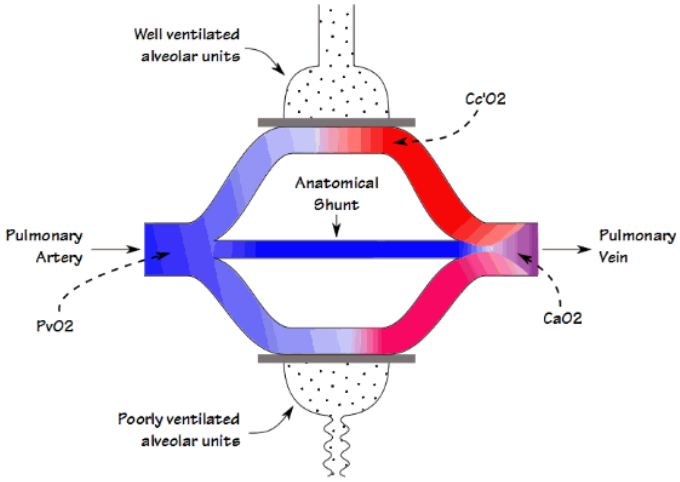
PFT BLOG

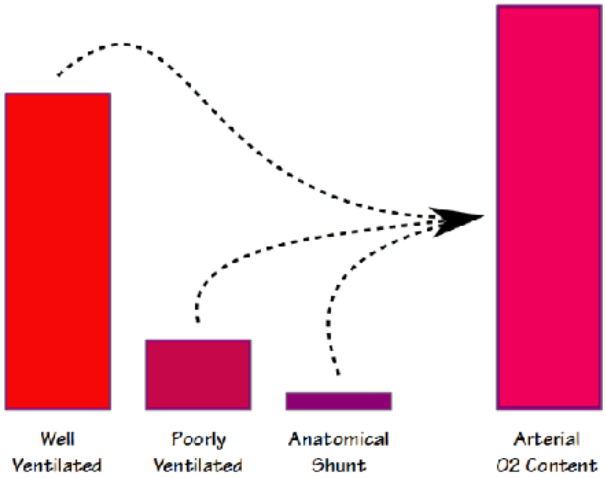
OBSERVATIONS, OPINIONS AND IDEAS ABOUT PULMONARY FUNCTION TESTING

To reach the PFT Blog, go to:

www.pfttforum.com/blog/

6.13.4.1 What is a Shunt Fraction Test?





When blood flows through the lung some blood passes through well ventilated alveoli and becomes fully saturated; some blood passes through poorly ventilated alveoli and is only partially saturated; and some bypasses the alveoli entirely. The resulting arterial oxygen content is the summed average of all of these compartments.

There are two different ways that shunt fraction can be measured and calculated; physiological and anatomical. The physiological shunt equation used in ComPAS2 is performed with an FiO2 at room air and then again using 100% O2. It requires that arterial blood samples be taken and then analyzed for pH, PaCO2, PaO2, HCO3-, SaO2 and Hb. The Barometric Pressure is also required to complete calculations.

6.13.4.2 Performing a Shunt Fraction test

Firstly, an arterial blood gas measurement is taken from the radial artery of the subject seated in a comfortable chair while breathing room. The subject is then asked to continue breathing normally for approximately 20 minutes while connected to a 100% oxygen source (using either a face mask or mouthpiece and nose clip).

A further arterial blood gas is then taken and analyzed; the results are recorded for entry into ComPAS2.

6.13.4.3 Entering Shunt Fraction Data

Measurements of shunt fraction are often taken in both "upright" and 'supine" positions. Upright data are entered in the **FW1** column and Supine data are entered in the **FW2** column.

Arterial Blood Gases						
pH				7.43	7.43	
$PaCO_2$				34.9	36.7	
PaO_2				559.3	500.0	
HCO_3-				23.4	24.6	
SaO_2				100.0	100.0	
Hb				14.0	14.0	
COHb						
MetHb						
O_2Hb						
Base Excess						
Barometric Pressure				760	760	
CaO_2				20.44	20.26	
CvO_2				15.94	15.76	
PAO_2				678.1	676.3	
CcO2				20.79	20.79	
Qs				0.36	0.53	
Qt				4.86	5.03	
Qs/Qt				0.07	0.11	

6.13.4.4 Example Shunt Fraction Report

Upright Measured Values on 100% O2

pH	7.35 to 7.45		**7.43**
PaCO2	35 to 45	mmHg	**34.9**
PaO2	80 to 100	mmHg	**559.3**
HCO3-	22 to 26	mEq/L	**23.4**
SaO2	90 to 100	%	**100.0**
Baro P		mmHg	**760**
Hgb		mmHg	**14.0**

O2 Content Calculations:

			Formula:
Arterial O2 Content:	CaO2	**20.44**	1.34 * Hgb * (SaO2/100) + 0.003 * PaO2
Venous O2 Content:	CvO2	**15.94**	CaO2 - 4-5
Alveolar PaO2	PAO2	**678.1**	(Baro P - 47) - PaCO2
Alveolar Capillary O2 Content:	CcO2	**20.79**	1.34 * Hgb * 1 + 0.003 * PAO2

Shunt Calculations:

Capillary O2 Decrement Due to Shunt:	Qs	**0.36**	CcO2 - CaO2
Total Capillary O2 Decrement:	Qt	**4.86**	CcO2 - CvO2
Shunt Fraction in Upright Position:	Qs/Qt	**0.07**	

Supine Measured Values on 100% O2

pH	7.35 to 7.45		**7.43**
PaCO2	35 to 45	mmHg	**36.7**
PaO2	80 to 100	mmHg	**500.0**
HCO3-	22 to 26	mEq/L	**24.6**
SaO2	90 to 100	%	**100.0**
Baro P		mmHg	**760**
Hgb		mmHg	**14.0**

O2 Content Calculations:

			Formula:
Arterial O2 Content:	CaO2	**20.26**	1.34 * Hgb * (SaO2/100) + 0.003 * PaO2
Venous O2 Content:	CvO2	**15.76**	CaO2 - 4-5
Alveolar PaO2	PAO2	**676.3**	(Baro P - 47) - PaCO2
Alveolar Capillary O2 Content:	CcO2	**20.79**	1.34 * Hgb * 1 + 0.003 * PAO2

Shunt Calculations:

Capillary O2 Decrement Due to Shunt:	Qs	**0.53**	CcO2 - CaO2
Total Capillary O2 Decrement:	Qt	**5.03**	CcO2 - CvO2
Shunt Fraction in Supine Position:	Qs/Qt	**0.11**	

6.13.5 Oxygen Titration

For subjects with COPD, long term oxygen therapy can be provided to maintain an SpO2 of > 90% during rest, sleep and exertion. For these subjects, an oxygen titration test is used to determine supplemental oxygen requirements using a pulse oximeter with readings taken at rest and during exercise.

6.13.5.1 Entering O2 Titration Data

Manual entry spreadsheets are accessed by clicking the  icon on the bottom task bar.

The below example shows just three levels of titration on oxygen; however, the table can automatically expand to show further columns of input if populated.

Oximetry [Room O_2]									
6MW									
SpO_2	98.0		85.0						
Pulse	60		90						
Dyspnea Index									
Fatigue									
Rest Time									
Speed									
Elevation									
Exercise Time			180.00						
Distance			100						
Oximetry [Elevated O_2]									
6MW									
SpO_2							88.0	89.0	95.0
Pulse							88	86	84
Dyspnea Index									
O_2 Delivery							2.0	4.0	6.0
Speed									
Elevation									
Exercise Time							220.00	240.00	360.00
Distance							150	200	300

6.13.5.2 Example O2 Titration Report

Supplemental Oxygen Titration

Oxygen Delivery	Resting		Walking				
	SpO2 (%)	*HR (bpm)*	*SpO2 (%)*	*HR (bpm)*	*Distance (m)*	*Time (m:ss)*	*BP*
Room Air	98	60	85	90	100	3:00	--/--
2.0	88	88	88	88	150	3:40	--/--
4.0	89	86	89	86	200	4:00	--/--
6.0	95	84	95	84	300	6:00	--/--

6.13.6 BODE Index

6.13.6.1 Entering BODE Index Data

Introduction:
The BODE index, for **B**ody-mass index, airflow **O**bstruction, **D**yspnea, and **E**xercise, is a multidimensional scoring system and capacity index used to test patients who have been diagnosed with chronic obstructive pulmonary disease (COPD) and to predict long-term outcomes for them.

Calculating BODE uses the sum of the following components:

FEV1 % Predicted	>= 65%	0
	>= 50%	1
	>= 36%	2
	<= 35%	3
Six Minute Walk Distance	>= 350m (1,148 feet)	0
	>= 250m (820 feet)	1
	>= 150m (492 feet)	2
	<= 149m (491 feet)	3
MMRC Dyspnea Scale	<= 1	0
	= 2	1
	= 3	2
	= 4	3
BMI	> 21	0
	<= 21	1

A BODE score of 0 to 2 points is associated with 80% survival; A score of 3 to 4 points - 67% survival; A score of 5 to 6 points - 57% survival; and. A score of 7 to 10 points - 18% survival.

The BODE index is a variable saved in the manual entry screen and available for reporting.

Entering BODE Information into ComPAS2:

The FEV1 % Predicted information is saved once spirometry testing is complete, all other information must be entered into the Manual Entry spreadsheet.

The BMI value is calculated from the subject's biographical information.

The data for both Six Minute Walk Distance (6MW) and MMRC Dyspnea Scale, the Manual Entry screen is used.

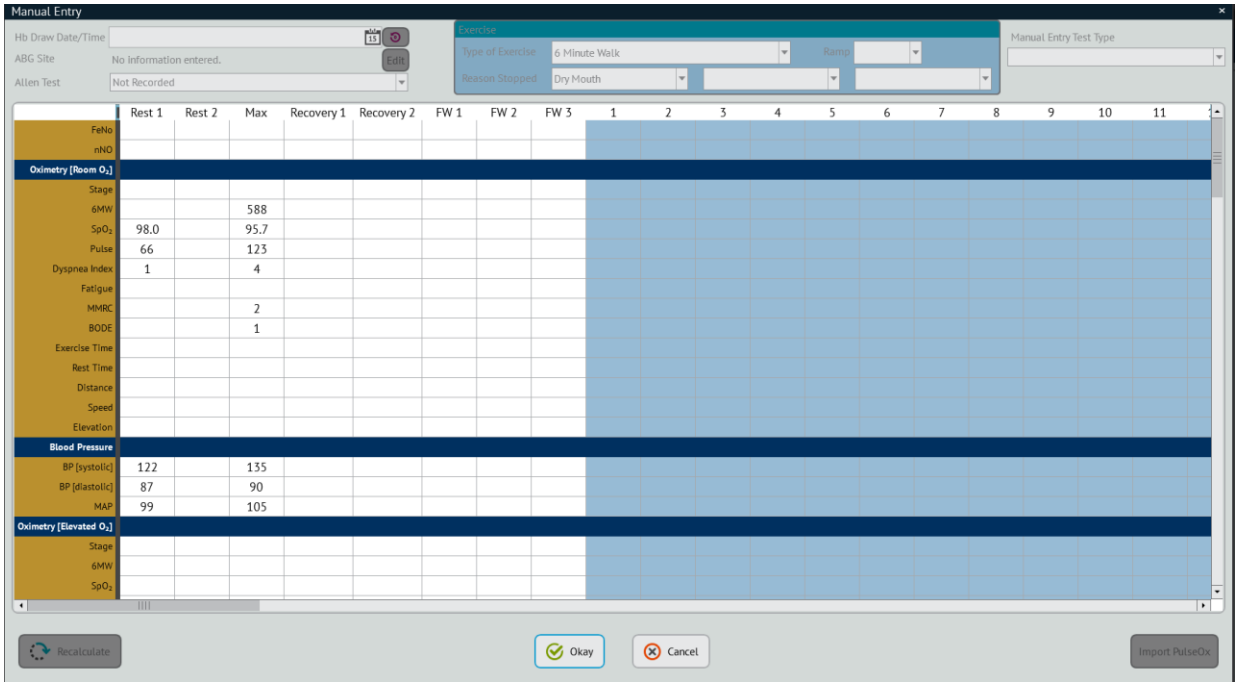
The Manual Entry spreadsheet is accessed by clicking the  icon on the bottom task bar.

Both sets of data should be posted into the **Max** column.

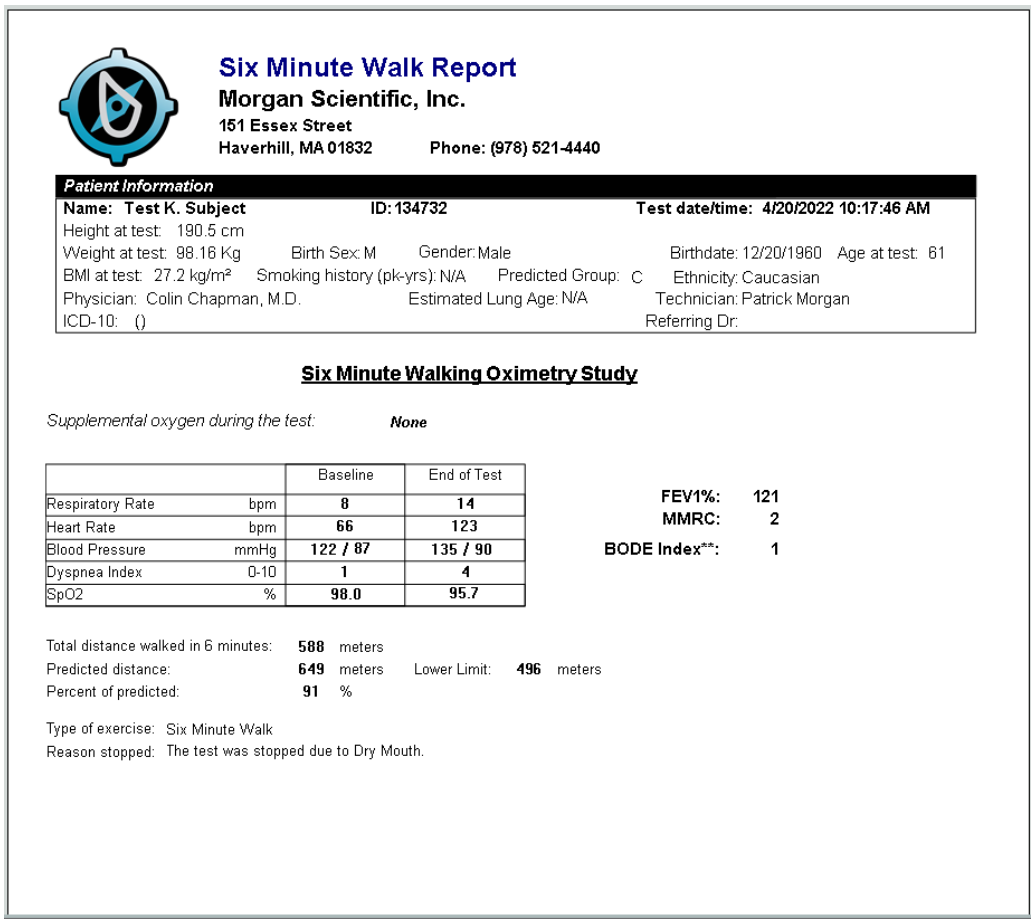
Note: 6MW data can be recorded when done on Room Air or Elevated Oxygen.

The BODE calculation will be made automatically or can be forced using the using the 

button.



6.13.6.2 Example Report using BODE Index



Six Minute Walk Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 **Phone: (978) 521-4440**

Patient Information

Name: Test K. Subject **ID: 134732** **Test date/time: 4/20/2022 10:17:46 AM**
Height at test: 190.5 cm
Weight at test: 98.16 Kg Birth Sex: M Gender: Male Birthdate: 12/20/1960 Age at test: 61
BMI at test: 27.2 kg/m² Smoking history (pk-yrs): N/A Predicted Group: C Ethnicity: Caucasian
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: () Referring Dr:

Six Minute Walking Oximetry Study

Supplemental oxygen during the test: ***None***

		Baseline	End of Test
Respiratory Rate	bpm	**8**	**14**
Heart Rate	bpm	**66**	**123**
Blood Pressure	mmHg	**122 / 87**	**135 / 90**
Dyspnea Index	0-10	**1**	**4**
SpO2	%	**98.0**	**95.7**

FEV1%: 121
MMRC: 2
BODE Index: 1**

Total distance walked in 6 minutes: **588** meters
Predicted distance: **649** meters Lower Limit: **496** meters
Percent of predicted: **91** %

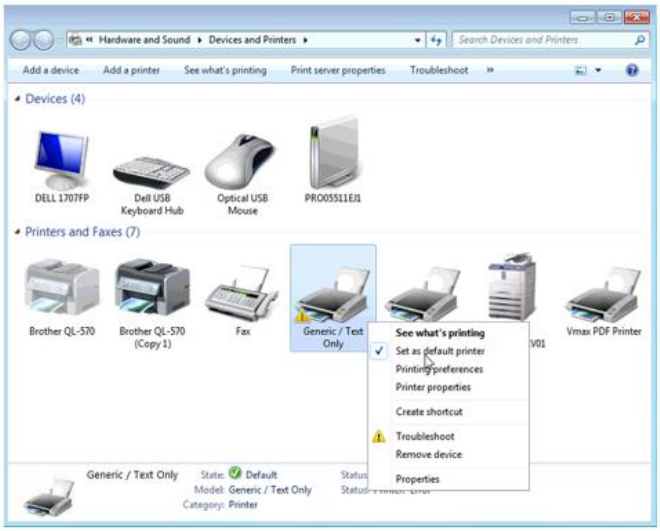
Type of exercise: Six Minute Walk
Reason stopped: The test was stopped due to Dry Mouth.

6.14 CPET DATA

Third-party CPET breath by breath data can be imported into ComPAS2 and combined with all other tests for comprehensive cardio-pulmonary reporting. ComPAS2 supports extensive CPET reporting capability in both graphical and tabular data formats.

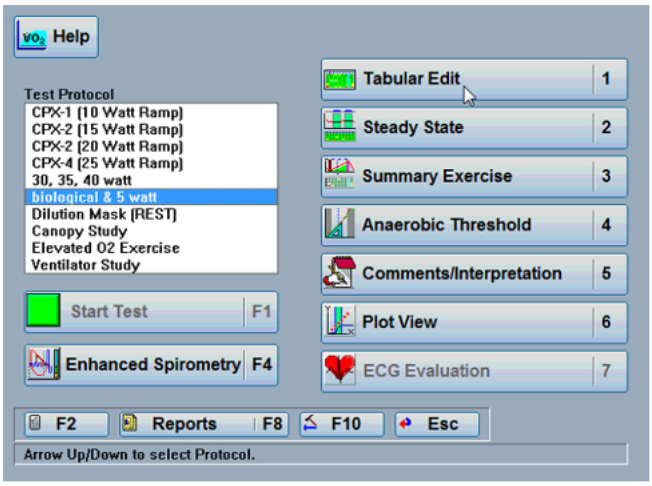
6.14.1 Instructions for collecting Vyaire/Care Fusion CPET Data

These instructions will create the two export files that ComPAS2 will merge and import into the patient record. Set the Generic Printer as the default Windows printer.

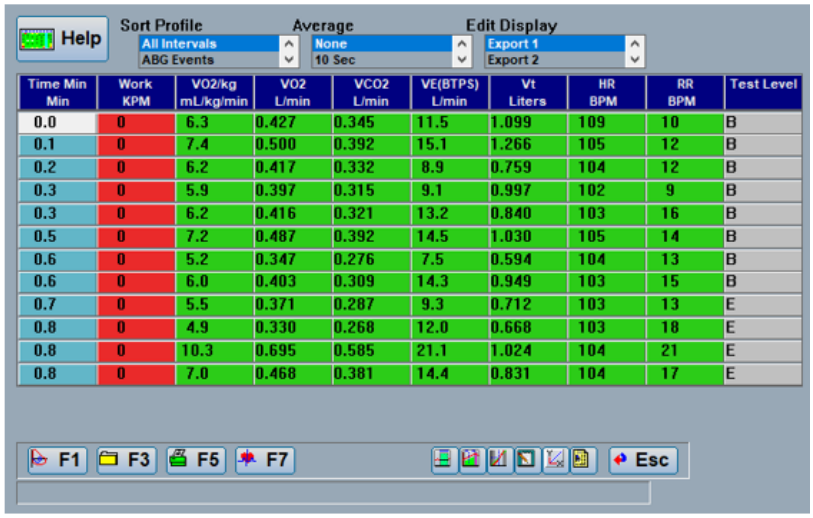


1) Open the Vmax program, select a Patient file and then select Exercise/Metabolic test from the main menu.

2) Select Tabular Edit:

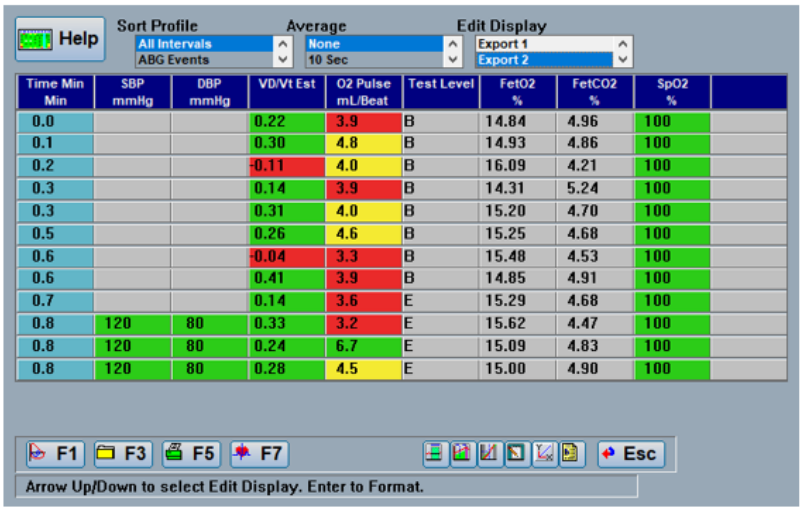


3) Choose “Export 1” in Edit Display selection. Press [CRTL] + F5 to print these results to a file. Watch for the mouse to quickly change to an hourglass to show the file has been created (there is no other feedback given to indicate success).



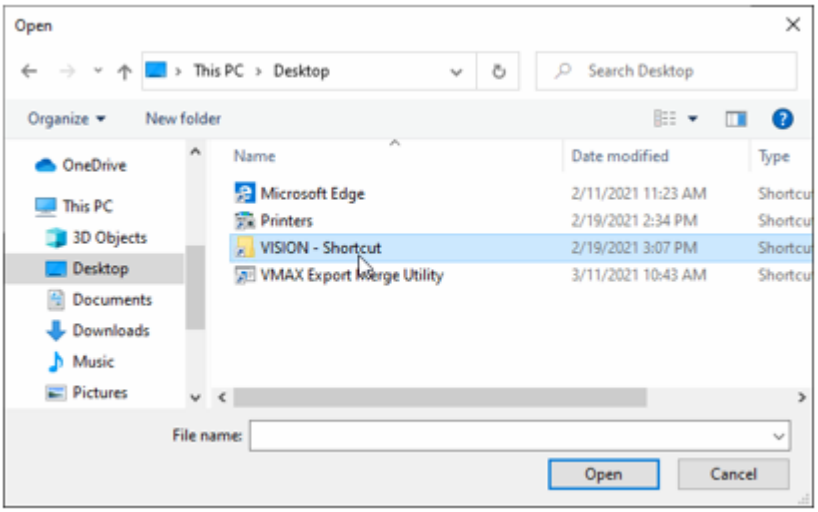
Time Min Min	Work KPM	VO2/kg mL/kg/min	VO2 L/min	VCO2 L/min	VE(BTPS) L/min	Vt Liters	HR BPM	RR BPM	Test Level
0.0	0	6.3	0.427	0.345	11.5	1.099	109	10	B
0.1	0	7.4	0.500	0.392	15.1	1.266	105	12	B
0.2	0	6.2	0.417	0.332	8.9	0.759	104	12	B
0.3	0	5.9	0.397	0.315	9.1	0.997	102	9	B
0.3	0	6.2	0.416	0.321	13.2	0.840	103	16	B
0.5	0	7.2	0.487	0.392	14.5	1.030	105	14	B
0.6	0	5.2	0.347	0.276	7.5	0.594	104	13	B
0.6	0	6.0	0.403	0.309	14.3	0.949	103	15	B
0.7	0	5.5	0.371	0.287	9.3	0.712	103	13	E
0.8	0	4.9	0.330	0.268	12.0	0.668	103	18	E
0.8	0	10.3	0.695	0.585	21.1	1.024	104	21	E
0.8	0	7.0	0.468	0.381	14.4	0.831	104	17	E

4) Next repeat the steps starting at the Tabular Edit screen for “Export 2” in the Edit Display section. Press [CRTL] + F5 and watch for the hourglass to confirm the file has been created.



Time Min Min	SBP mmHg	DBP mmHg	VD/Vt Est	O2 Pulse mL/Beat	Test Level	FetO2 %	FetCO2 %	SpO2 %
0.0			0.22	3.9	B	14.84	4.96	100
0.1			0.30	4.8	B	14.93	4.86	100
0.2			-0.11	4.0	B	16.09	4.21	100
0.3			0.14	3.9	B	14.31	5.24	100
0.3			0.31	4.0	B	15.20	4.70	100
0.5			0.26	4.6	B	15.25	4.68	100
0.6			-0.04	3.3	B	15.48	4.53	100
0.6			0.41	3.9	B	14.85	4.91	100
0.7			0.14	3.6	E	15.29	4.68	100
0.8	120	80	0.33	3.2	E	15.62	4.47	100
0.8	120	80	0.24	6.7	E	15.09	4.83	100
0.8	120	80	0.28	4.5	E	15.00	4.90	100

5) The files will be generated and placed in the C:\VISION folder by default. A shortcut on your computer’s desktop will take you there for easy access during the next step.



6.14.2 Instructions for collecting MGC CPET Data

These instructions will create the two export files that ComPAS2 will merge and import into the patient record.

1) At the conclusion of the CPET test in Breeze click on the [GX] tab

2) Click on the “Time” field, hold the mouse and drag to the bottom right-hand corner until all test data are highlighted. Release the mouse and press [Ctrl] [C]. Note: You can also right-click the mouse and select “Copy”. This will “Copy” the CPET data into the Windows clipboard.

The configuration of the Excel columns is within Breeze and not something Morgan Scientific controls. The following column format is what ComPAS2 expects:

Time	Work	VO2	VO2	VCO2	RER	RR	Vt BTPS	VE BTPS	METS	HeartRate	HRR	VE/VO2	VE/VCO2	SpO2	Vd/Vt - est	VO2/HR	PETO2	PETCO2
(min)	(Watts)	(mL/kg/min)	(mL/min)	(mL/min)		(br/min)	(mL)	(L/min)		(BPM)	(%)			(%)		(mL/beat)	(mmHg)	(mmHg)
16:35	0	8.6	796	1069	1.34	29	1249	36.3	2.4	60	63.0	46	34	98	0.23	13	122	35
16:37	0	8.4	778	1054	1.36	27	1287	35.4	2.4	60	63.0	45	34	98	0.22	13	122	35
16:39	0	7.7	720	1008	1.40	32	1127	36.0	2.2	62	62.2	50	36	98	0.25	12	124	33
16:42	0	7.1	661	926	1.40	27	1150	31.5	2.0	64	60.2	48	34	98	0.24	10	123	35
16:44	0	6.5	604	833	1.38	24	1141	27.8	1.9	64	60.2	46	33	98	0.23	9	123	35
16:46	0	7.1	660	925	1.40	27	1150	31.5	2.0	72	55.4	48	34	98	0.24	9	123	35

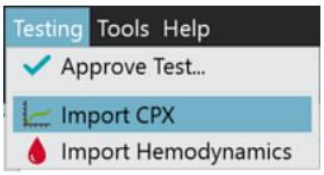
3) Open a blank data sheet in Excel, click on the top left-hand filed and type [Ctrl] [V]. Note: You can also right-click the mouse and select “paste”. This will “paste” the CPET data into Excel. Click “File” and “Save As”. Select a destination folder and use the subject’s name.

6.14.3 Importing CPET Data

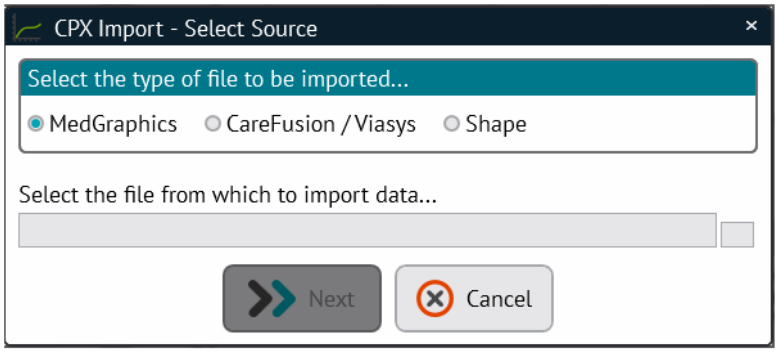
To import breath by breath data into ComPAS2, the files need to be in Excel format with a .xlsx extension. Most manufacturers allow export of their data and the choice of file format can be made when saving those data.

The first step to any import is to first identify the test subject in ComPAS2. Either create a new patient or recall the patient if they already exist in the ComPAS2 database.

The "Import CPX" option is under Testing on the top menu:

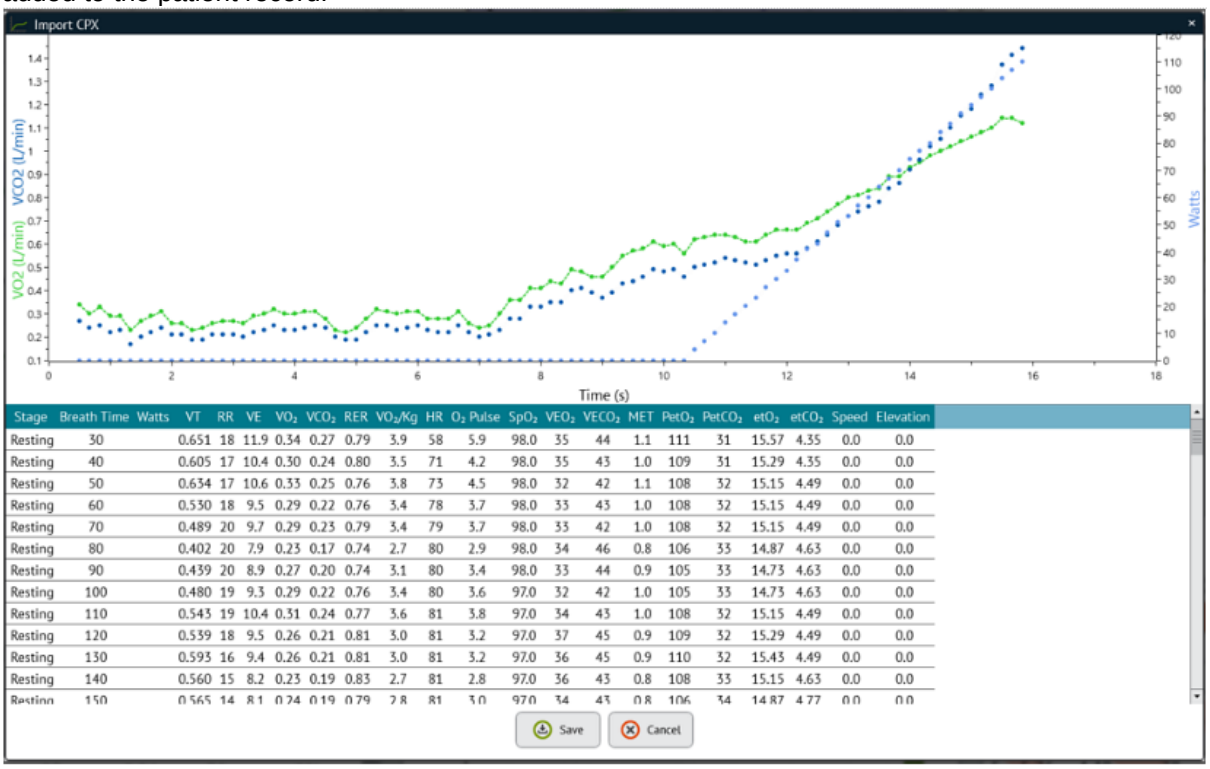


The import dialogue will appear:



Once the file has been selected and 

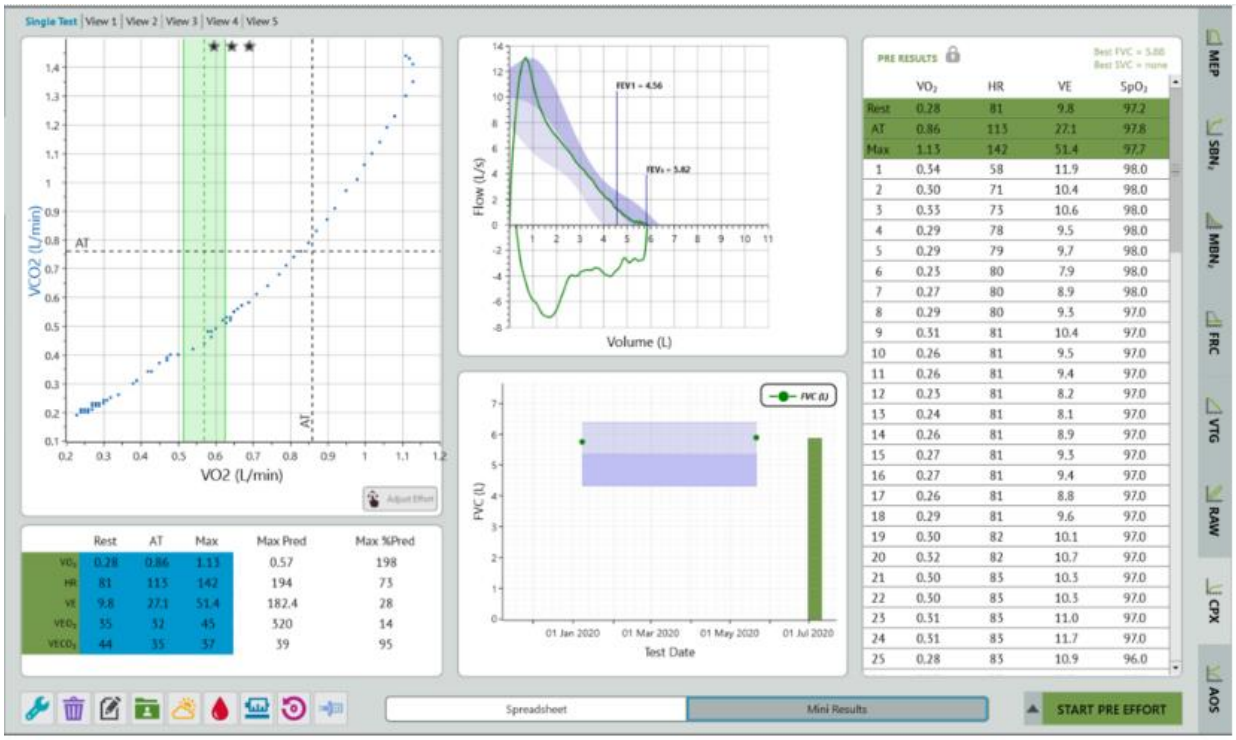
is selected, the data will be displayed for confirmation before being added to the patient record:



Stage	Breath Time	Watts	VT	RR	VE	VO_2	VCO_2	RER	VO_2/Kg	HR	O_2 Pulse	SpO_2	VEO_2	$VECO_2$	MET	$PetO_2$	$PetCO_2$	etO_2	$etCO_2$	Speed	Elevation
Resting	30		0.651	18	11.9	0.34	0.27	0.79	3.9	58	5.9	98.0	35	44	1.1	111	31	15.57	4.35	0.0	0.0
Resting	40		0.605	17	10.4	0.30	0.24	0.80	3.5	71	4.2	98.0	35	43	1.0	109	31	15.29	4.35	0.0	0.0
Resting	50		0.634	17	10.6	0.33	0.25	0.76	3.8	73	4.5	98.0	32	42	1.1	108	32	15.15	4.49	0.0	0.0
Resting	60		0.530	18	9.5	0.29	0.22	0.76	3.4	78	3.7	98.0	33	43	1.0	108	32	15.15	4.49	0.0	0.0
Resting	70		0.489	20	9.7	0.29	0.23	0.79	3.4	79	3.7	98.0	33	42	1.0	108	32	15.15	4.49	0.0	0.0
Resting	80		0.402	20	7.9	0.23	0.17	0.74	2.7	80	2.9	98.0	34	46	0.8	106	33	14.87	4.63	0.0	0.0
Resting	90		0.439	20	8.9	0.27	0.20	0.74	3.1	80	3.4	98.0	33	44	0.9	105	33	14.73	4.63	0.0	0.0
Resting	100		0.480	19	9.3	0.29	0.22	0.76	3.4	80	3.6	97.0	32	42	1.0	105	33	14.73	4.63	0.0	0.0
Resting	110		0.543	19	10.4	0.31	0.24	0.77	3.6	81	3.8	97.0	34	43	1.0	108	32	15.15	4.49	0.0	0.0
Resting	120		0.539	18	9.5	0.26	0.21	0.81	3.0	81	3.2	97.0	37	45	0.9	109	32	15.29	4.49	0.0	0.0
Resting	130		0.593	16	9.4	0.26	0.21	0.81	3.0	81	3.2	97.0	36	45	0.9	110	32	15.43	4.49	0.0	0.0
Resting	140		0.560	15	8.2	0.23	0.19	0.83	2.7	81	2.8	97.0	36	43	0.8	108	33	15.15	4.63	0.0	0.0
Resting	150		0.565	14	8.1	0.24	0.19	0.79	2.8	81	3.0	97.0	34	43	0.8	106	34	14.87	4.77	0.0	0.0

To confirm and attach these data to the patient record, press 

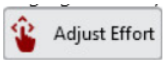
The screen will load to Mini Results and a new [CPX] tab will appear:



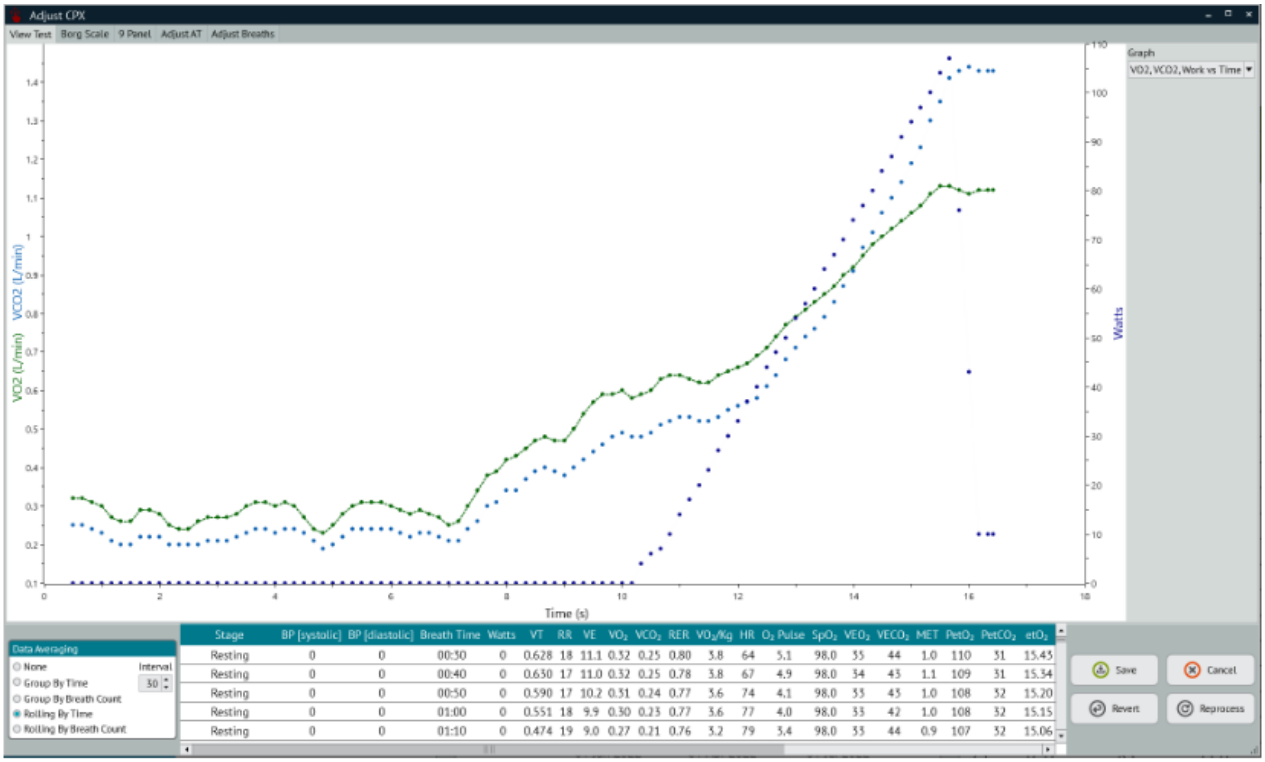
6.14.3.1 Editing Imported Breath by Breath CPET Data

Once CPET data has been imported, it can be edited prior to reporting. Edit capability includes:

- Selecting data averaging choices
- Setting/Editing the various stages of exercise (Resting, Free Wheel and Recovery)
- Including/excluding spurious data
- Entering Borg Scale exertion

To make changes to the CPET data, click on the 

button on the Mini Results screen.



Stage	BP [systolic]	BP [diastolic]	Breath Time	Watts	VT	RR	VE	VO_2	VCO_2	RER	VO_2/Kg	HR	O_2 Pulse	SpO_2	VEO_2	$VECO_2$	MET	$PetO_2$	$PetCO_2$	etO_2
Resting	0	0	00:30	0	0.628	18	11.1	0.32	0.25	0.80	3.8	64	5.1	98.0	35	44	1.0	110	31	15.45
Resting	0	0	00:40	0	0.630	17	11.0	0.32	0.25	0.78	3.8	67	4.9	98.0	34	43	1.1	109	31	15.34
Resting	0	0	00:50	0	0.590	17	10.2	0.31	0.24	0.77	3.6	74	4.1	98.0	33	43	1.0	108	32	15.20
Resting	0	0	01:00	0	0.551	18	9.9	0.30	0.23	0.77	3.6	77	4.0	98.0	33	42	1.0	108	32	15.15
Resting	0	0	01:10	0	0.474	19	9.0	0.27	0.21	0.76	3.2	79	3.4	98.0	33	44	0.9	107	32	15.06

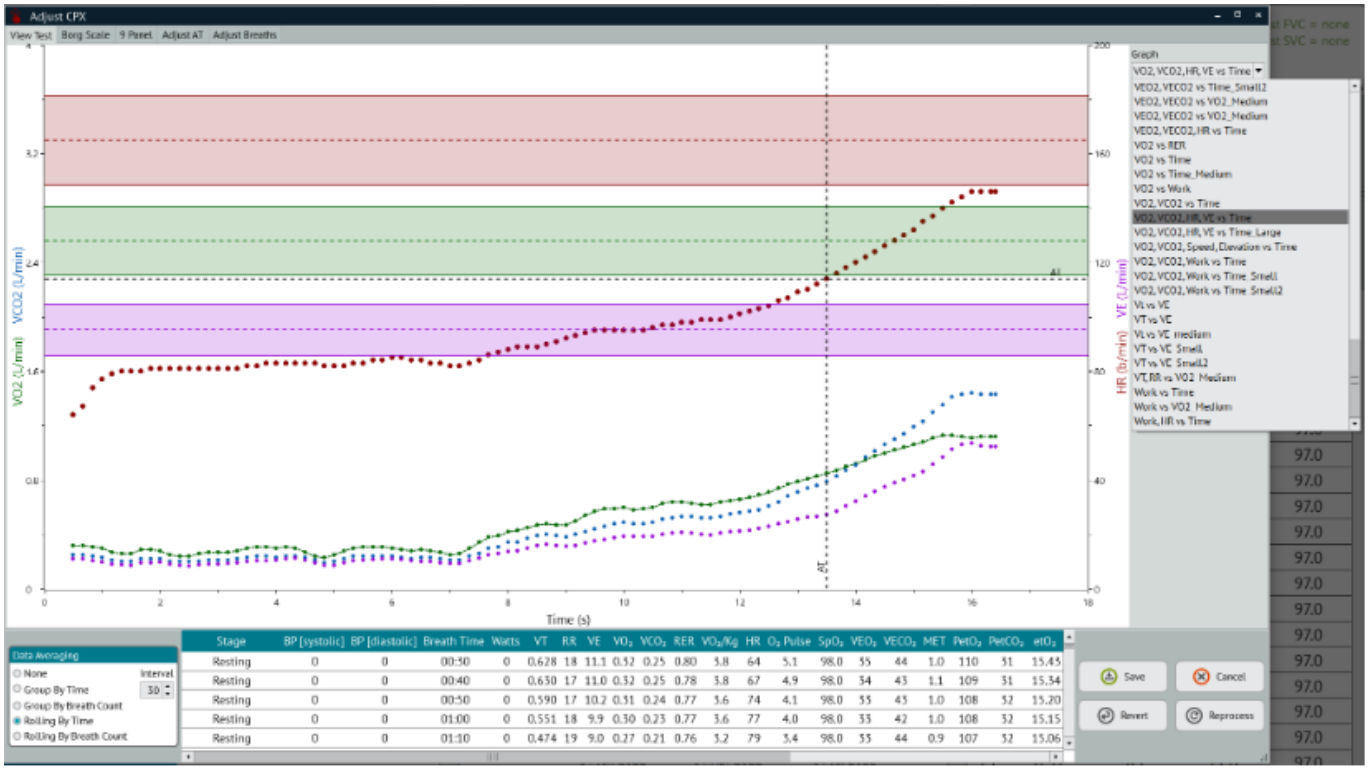
6.14.3.2 Adjusting Data Averaging

The "Data Averaging" dialogue allows smoothing of breath by breath data with the graph displaying selections made in real time.

There are options for two averaging filters:

Group Average	The group average selection measures the arithmetic mean and is calculated by adding a group of numbers and then dividing by the count of those numbers. For example, the average of 2, 3, 3, 5, 7, and 10 is 30 divided by 6, resulting in 5. The user can select the number of breaths or the time interval to average.
Rolling Average	The rolling average is obtained by first taking the average of either a certain number of breaths or certain number of seconds (each can be selected by the user). This creates a subset of data. The fixed subset size is then shifted forward, creating a new subset of numbers, which is averaged. This process is repeated over the entire data series. The rolling average is then a set of numbers, each of which is the average of the corresponding subset of a larger set of data points.

A pull-down of all available graphs can change the selected view.



6.14.3.3 Adjusting the Report Level Data

The [Adjust Breaths] tab provides ability to select periods from the imported data and mark them for the correct stage of exercise. Furthermore, it also allows the user to select either individual rows of data for the reported summary of each stage or average a group of rows to be the reported summary information for each stage.

6.14.3.3.1 Setting the Stage of Exercise:

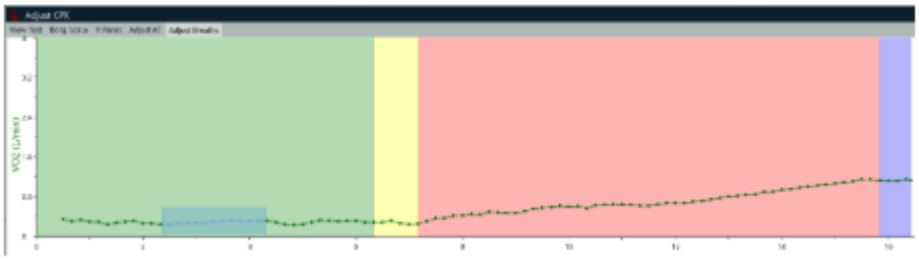
Some of the third-party CPET systems have no way to mark or adjust the stages of exercise:

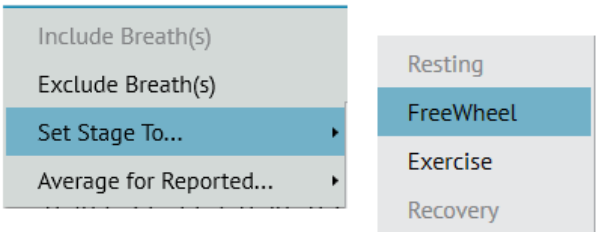
- Resting
- Free Wheel
- Exercise
- Recovery

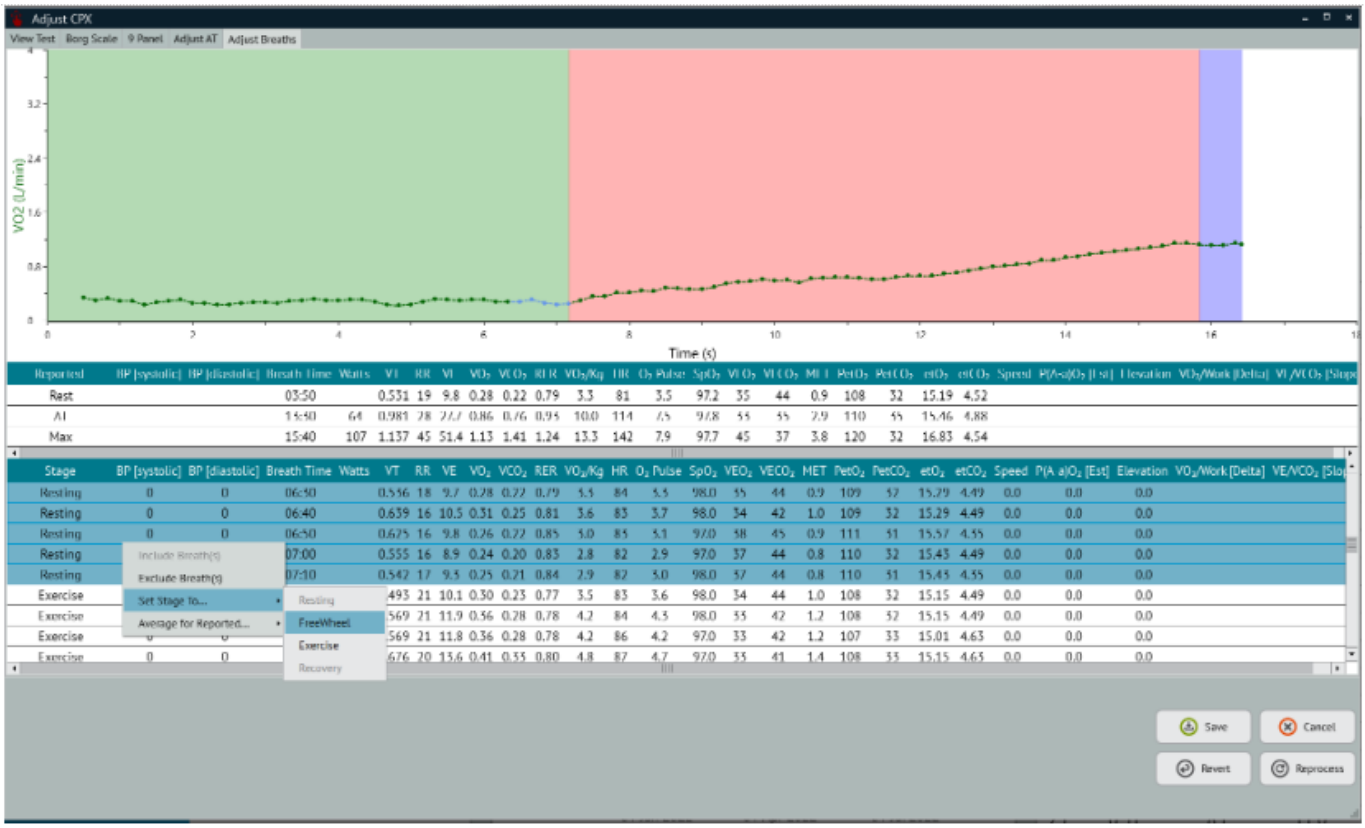
To select or change the Stage of exercise:

Using keyboard: click on the starting time for a stage and hold the [Shift] key then click on the ending time of the stage then right-click and "Average for Reported:" and select the desired label.

Using mouse: click drag and highlight data points on the graphic then right-click and "Average for Reported:" and select the desired label.







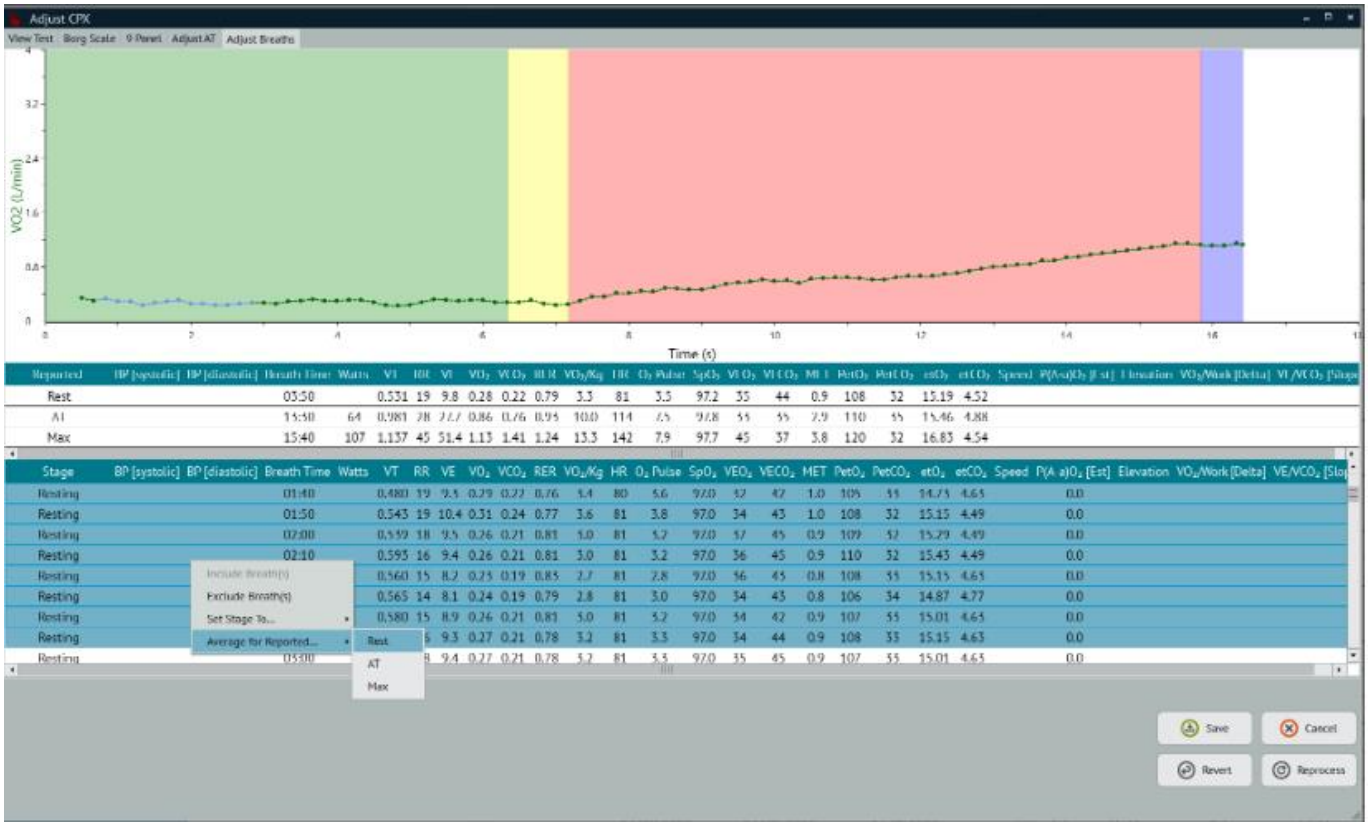
6.14.3.3.2 Setting the Average for Reported:

For summary data of Resting, AT (Anerobic Threshold) and Max, the user can select individual or average of data if they want to override the computed values.

To select or change the reported summary value:

Using keyboard: click on the starting time desired and hold the [Shift] key then click on the ending time then right-click and "Average for Reported:" and select the desired label.

Using mouse: click drag and highlight data points on the graphic then right-click on the highlighted data segment and "Average for Reported:" and select the desired label.



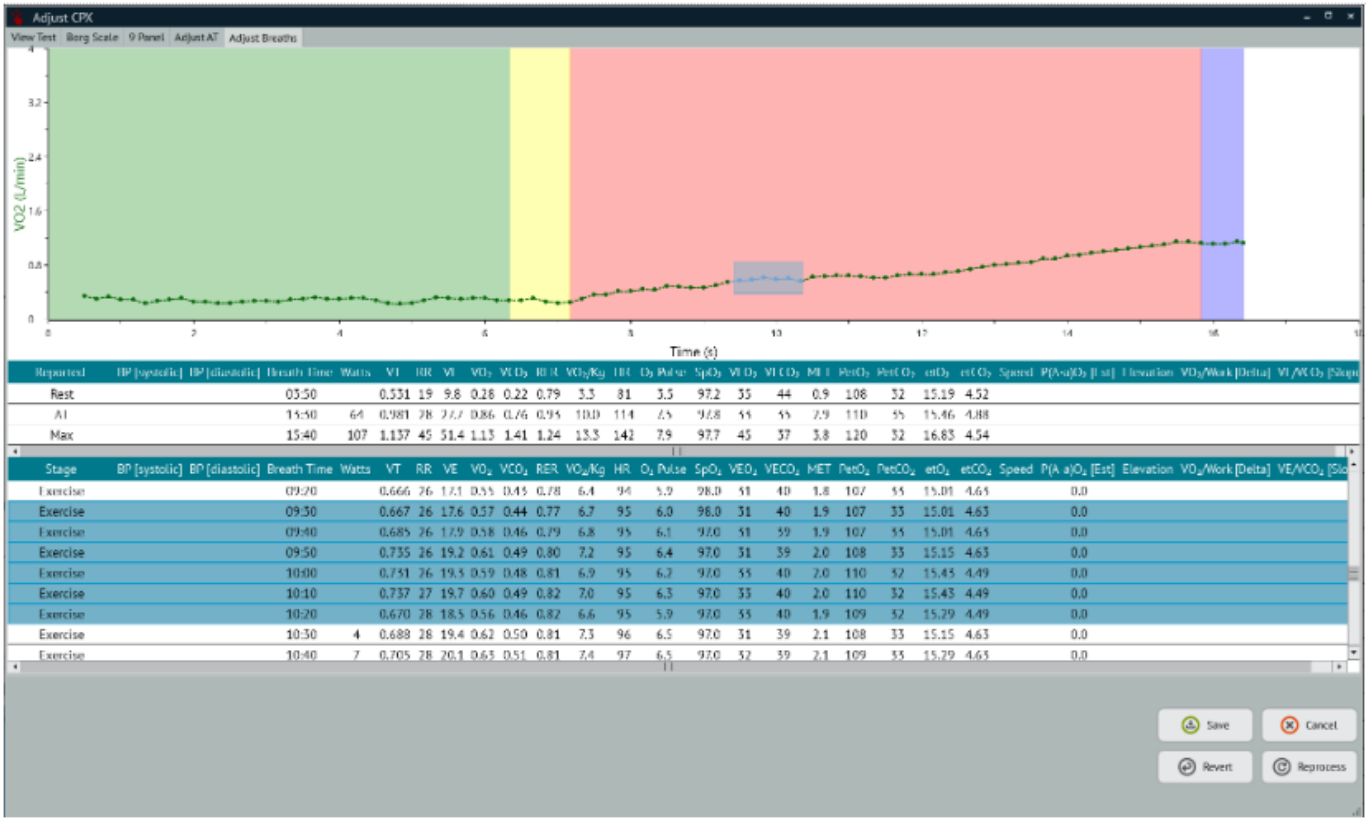
6.14.3.3.3 Excluding/Including Data:

Sometimes during a CPET study some spurious data can be collected; for example, an electrode could fall off causing wild heart rate values or the subject could lose the mouthpiece for a brief time.

To exclude or included previously excluded data:

Using keyboard: click on the starting time and hold the [Shift] key then click on the ending time then right-click and "Exclude" or "Include".

Using mouse: click drag and highlight data points on the graphic then right-click on the highlighted data segment and "Exclude" or "Include".



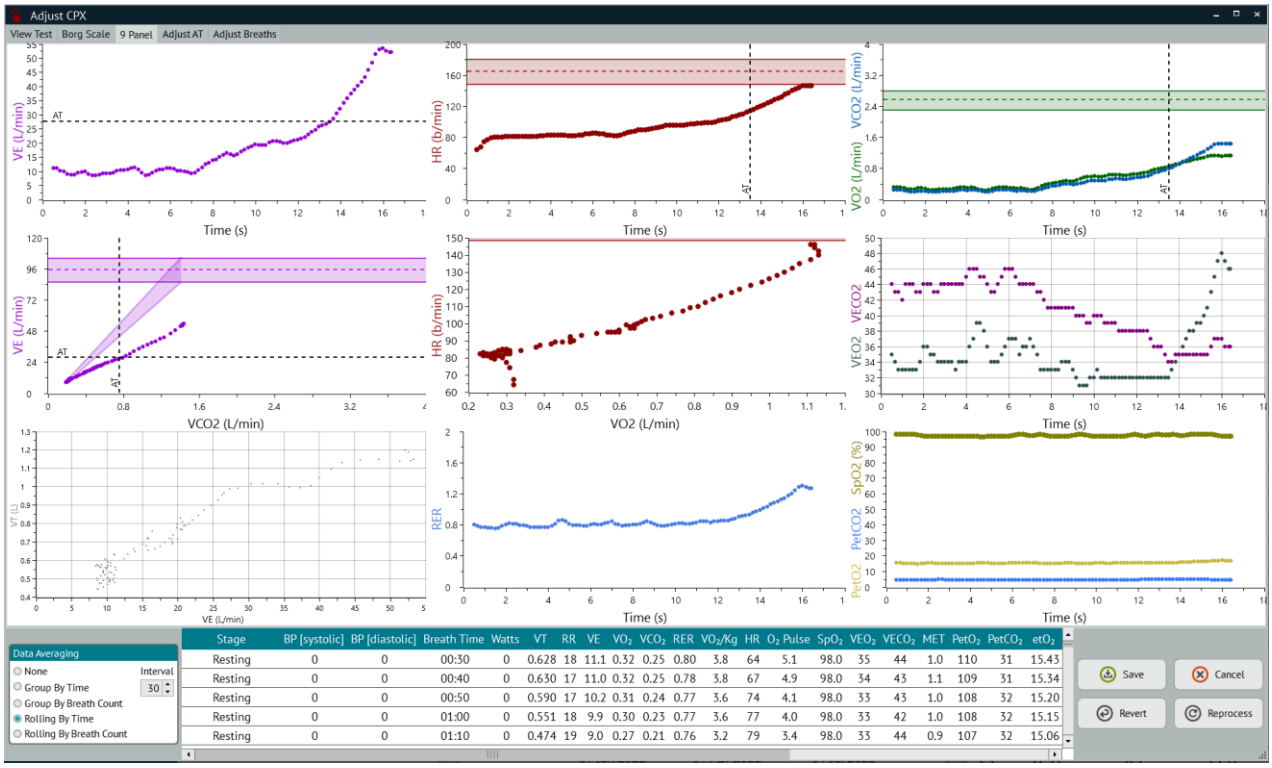
6.14.3.4 Adding a Borg Scale Value

Select the [Borg Scale] tab and enter the value:

Scale	Patient Description
0	Nothing at all
1	Very light
2	Fairly light
3	Moderate
4	Somewhat hard
5	Hard
6	
7	Very hard
8	
9	
10	Very, very hard

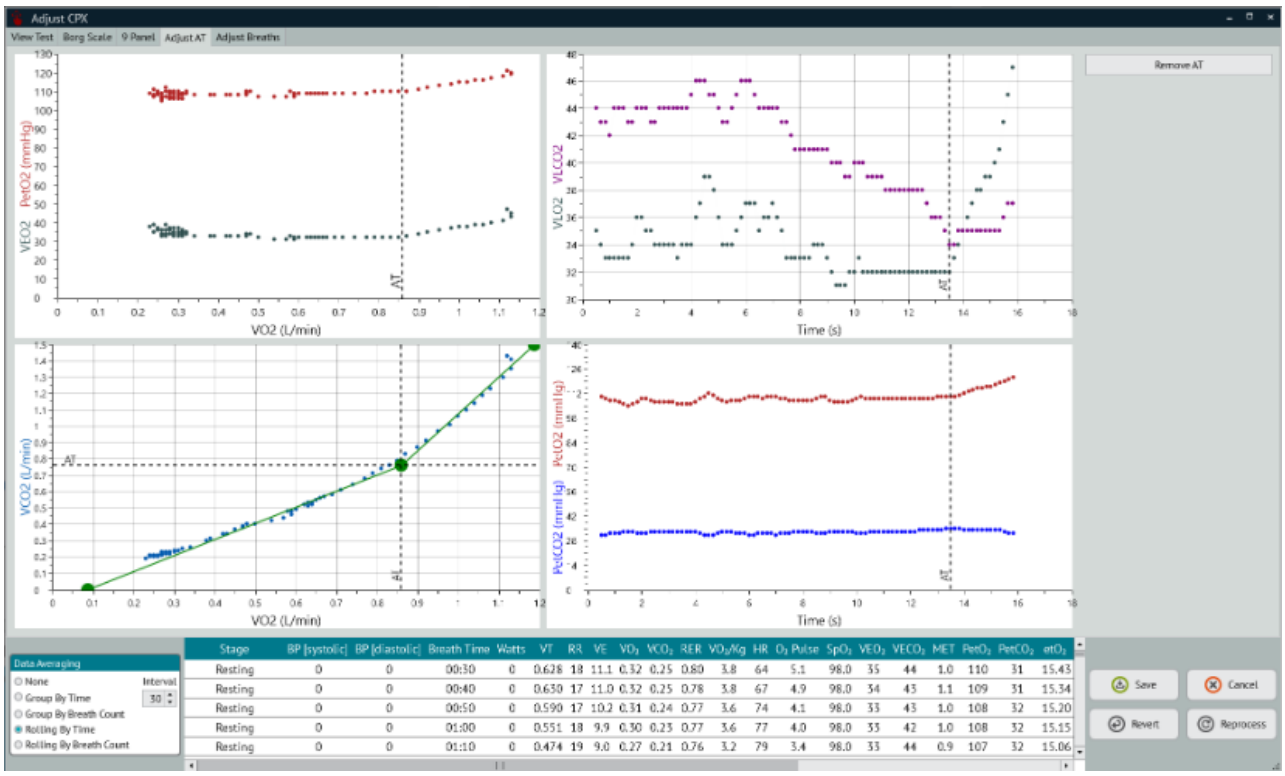
6.14.3.5 Quick 9 Panel View

Select the [9 Panel] tab to view graphs. Note that this view will change if the data averaging selection is adjusted.



6.14.3.6 Adjusting AT

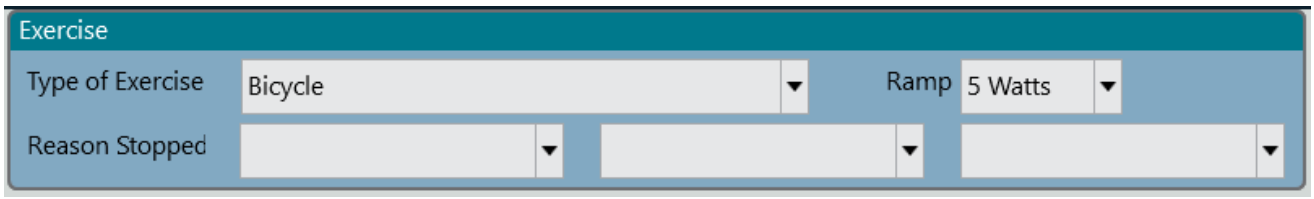
Select the [Adjust AT] tab to make any changes.



Changes can be made by simply clicking-on any vertical AT line and moving the line to the preferred location. Alternatively, on the VCO2 v VO2 graph, clicking on any of the fulcrum points will move the position and slope.

6.14.3.7. Recording Type of Exercise and Ramp

On the Manual Entry screen is provision to record the type of exercise together with the ramp used and reasons exercise may have stopped.



6.15 iCPET DATA

6.15.1 Importing Hemodynamics Data

The following key hemodynamic data are retrieved from the Philips Xper system:

RV systolic
RV diastolic
CVP a-wave
CVP v-wave
CVP mean (RAP)
RA a-wave
RA v-wave
RA mean
PW a-wave
PW v-wave
PW mean
AO systolic
AO diastolic
AO mean
PA systolic
PA diastolic
PA mean

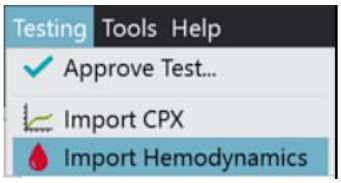
These data are put through the Manual Entry script in ComPAS2 to calculate the following:

Fick CO
SV
CI
SVI
PAC
TPG
mPA
PVR Wood Units
ES
EA

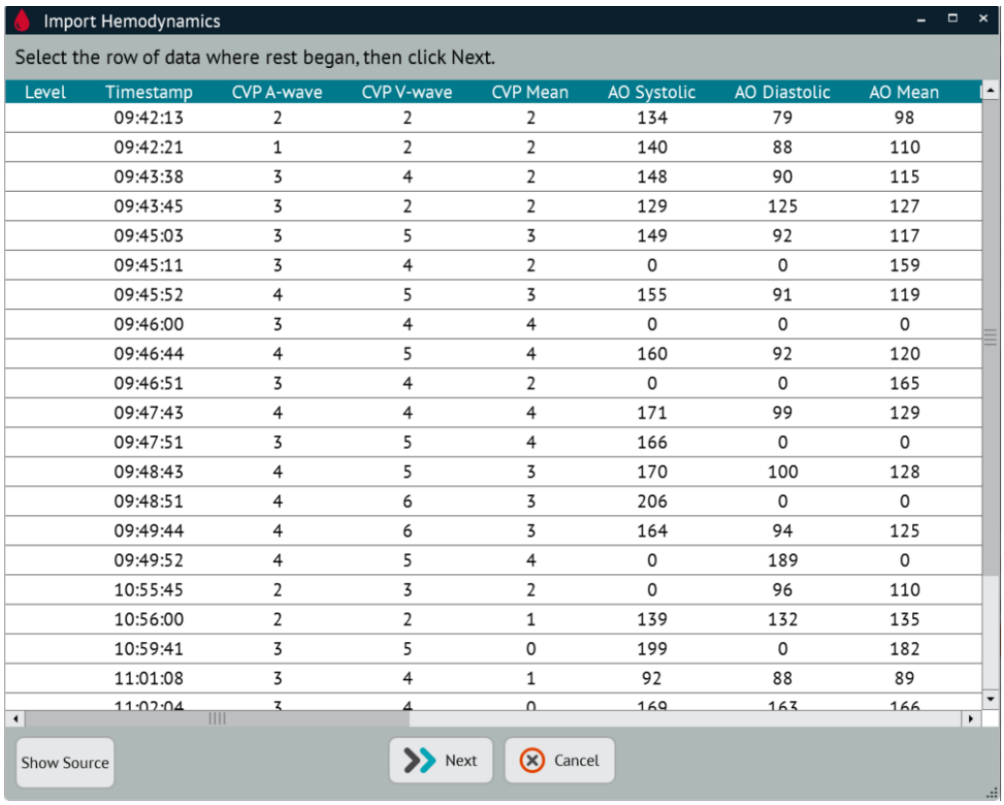
EA/ES
PVα
SYSα

The first step to any import is to first identify the test subject in ComPAS2. Either create a new patient or recall the patient if they already exist in the ComPAS2 database.

The "Import Hemodynamics" option is under Testing on the top menu:



The import dialogue will appear:



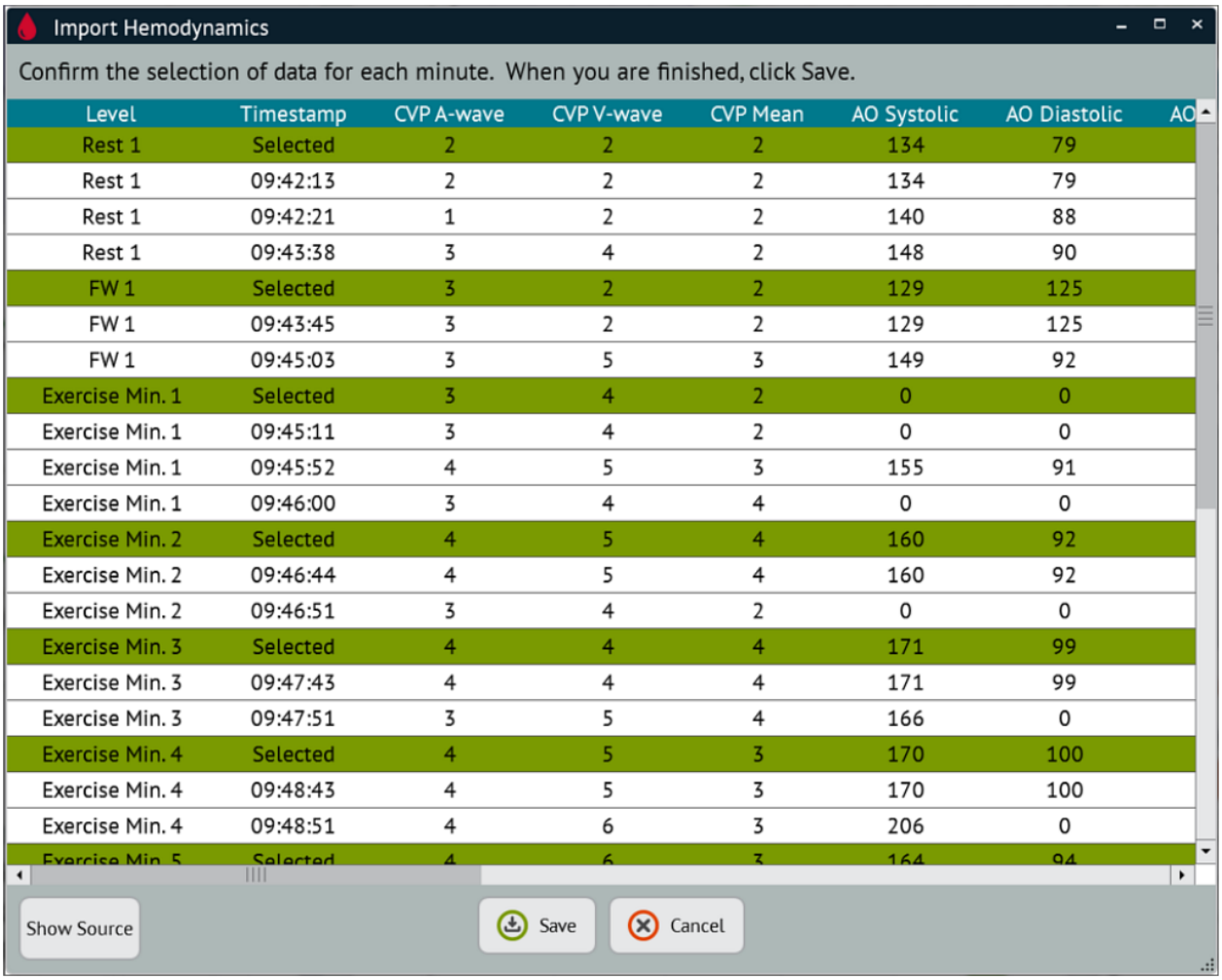
Level	Timestamp	CVP A-wave	CVP V-wave	CVP Mean	AO Systolic	AO Diastolic	AO Mean
	09:42:13	2	2	2	134	79	98
	09:42:21	1	2	2	140	88	110
	09:43:38	3	4	2	148	90	115
	09:43:45	3	2	2	129	125	127
	09:45:03	3	5	3	149	92	117
	09:45:11	3	4	2	0	0	159
	09:45:52	4	5	3	155	91	119
	09:46:00	3	4	4	0	0	0
	09:46:44	4	5	4	160	92	120
	09:46:51	3	4	2	0	0	165
	09:47:43	4	4	4	171	99	129
	09:47:51	3	5	4	166	0	0
	09:48:43	4	5	3	170	100	128
	09:48:51	4	6	3	206	0	0
	09:49:44	4	6	3	164	94	125
	09:49:52	4	5	4	0	189	0
	10:55:45	2	3	2	0	96	110
	10:56:00	2	2	1	139	132	135
	10:59:41	3	5	0	199	0	182
	11:01:08	3	4	1	92	88	89
	11:02:04	3	4	0	169	163	166

There are no stage identifiers in the Philips data, so the technician is guided to mark the periods of:

Rest
Free Wheel
Exercise
Recovery

To identify a row as the beginning of any stage, simply click on the appropriate row and then click 

This is best achieved by looking at the Time Stamp. For each stage of the procedure, there may well be several 'snapshots' of hemodynamic data; all data are available for later selection or editing. In the example below, it can be seen that there were 3 snapshots at 'Exercise Minute 1" yet only 2 at "Exercise Minute 2".



Level	Timestamp	CVP A-wave	CVP V-wave	CVP Mean	AO Systolic	AO Diastolic	AO
Rest 1	Selected	2	2	2	134	79	
Rest 1	09:42:13	2	2	2	134	79	
Rest 1	09:42:21	1	2	2	140	88	
Rest 1	09:43:38	3	4	2	148	90	
FW 1	Selected	3	2	2	129	125	
FW 1	09:43:45	3	2	2	129	125	
FW 1	09:45:03	3	5	3	149	92	
Exercise Min. 1	Selected	3	4	2	0	0	
Exercise Min. 1	09:45:11	3	4	2	0	0	
Exercise Min. 1	09:45:52	4	5	3	155	91	
Exercise Min. 1	09:46:00	3	4	4	0	0	
Exercise Min. 2	Selected	4	5	4	160	92	
Exercise Min. 2	09:46:44	4	5	4	160	92	
Exercise Min. 2	09:46:51	3	4	2	0	0	
Exercise Min. 3	Selected	4	4	4	171	99	
Exercise Min. 3	09:47:43	4	4	4	171	99	
Exercise Min. 3	09:47:51	3	5	4	166	0	
Exercise Min. 4	Selected	4	5	3	170	100	
Exercise Min. 4	09:48:43	4	5	3	170	100	
Exercise Min. 4	09:48:51	4	6	3	206	0	
Exercise Min. 5	Selected	4	6	3	164	94	

Once the stages of exercise have been identified, the "Selected" data for that stage are highlighted in green.

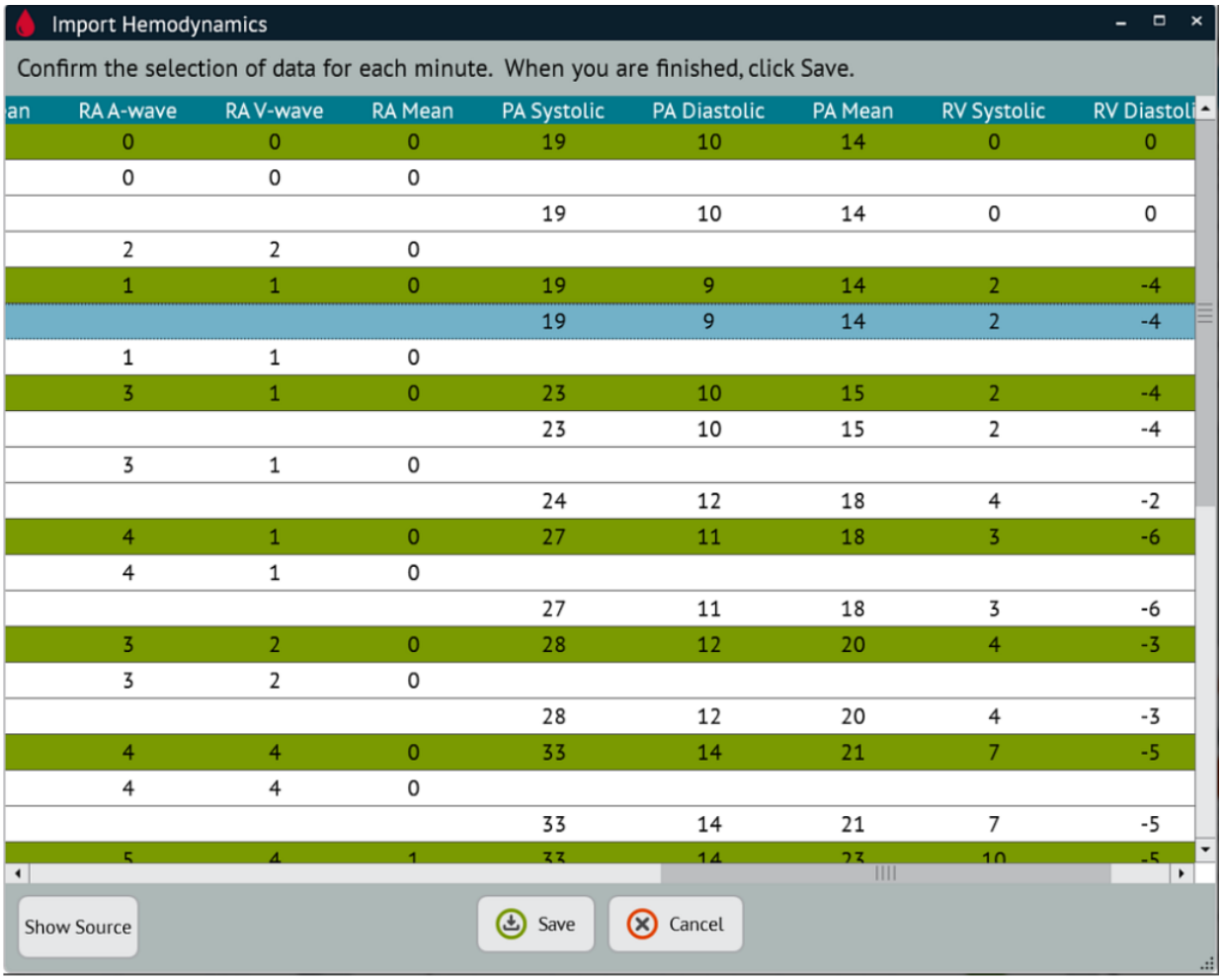
6.15.2 Editing Imported Hemodynamics Data

The user has full control over the selection of data from any snapshot; to change individual choices, simply go to the desired parameter column and click on an alternative in the white rows beneath the stage to be edited.

CVP Mean
2
2
2
2
2
2
3

In the example on the left, clicking on "3" will move that to the selected data row.

The bottom 'slider' control allows navigation across the spreadsheet of hemodynamic data.



an	RA A-wave	RA V-wave	RA Mean	PA Systolic	PA Diastolic	PA Mean	RV Systolic	RV Diastoli
	0	0	0	19	10	14	0	0
	0	0	0					
				19	10	14	0	0
	2	2	0					
	1	1	0	19	9	14	2	-4
				19	9	14	2	-4
	1	1	0					
	3	1	0	23	10	15	2	-4
				23	10	15	2	-4
	3	1	0					
				24	12	18	4	-2
	4	1	0	27	11	18	3	-6
	4	1	0					
				27	11	18	3	-6
	3	2	0	28	12	20	4	-3
	3	2	0					
				28	12	20	4	-3
	4	4	0	33	14	21	7	-5
	4	4	0					
				33	14	21	7	-5
	5	4	1	33	14	23	10	-5

Having made any changes to snapshot selections, click 

to bring the data into the ComPAS2 Manual Entry Spreadsheet.

The Manual Entry spreadsheet in ComPAS2 is accessed by clicking the  icon on the bottom task bar.

Manual Entry

Hb Draw Date/Time

ABG Site: No information entered. Edit

Allen Test: Not Recorded

Exercise

Type of Exercise | Ramp

Reason Stopped

	Rest 1	Rest 2	Max	Recovery 1	Recovery 2	FW 1	FW 2	FW 3	1	2	3	4	5	6	7	8
BP [systolic]	124		174	127		131			127	136	138	148	159	158		
BP [diastolic]	72		88	79		74			66	72	73	82	84	83		
MAP	89		117	95		93			86	93	95	104	109	108		
PCW/RAP			1.00			1.00			0.50	1.00	2.00	2.00	2.00			
PAP/PCW			6.50			2.00			3.00	1.00	3.00	3.50	3.50			
iCPET																
RV Systolic	0		10			2			2	3	4	7	10			
RV Diastolic	0		-6			-4			-4	-6	-3	-5	-5			
RV EDP	-1		-4			-2			0	-4	-1	-3	-1			
PW A-wave	4		8	9		5			8	6	7	7	8			
PW V-wave	4		8	10		7			7	7	7	8	8			
PW Mean	4		6	7		5			6	5	6	6	6			
CVP A-wave	2		4	4		3			3	4	4	4	4			
CVP V-wave	2		6	4		2			4	5	4	5	6			
CVP Mean	2		4	1		2			2	4	4	3	3			
RA A-wave	0		5	3		1			3	4	3	4	5			
RA V-wave	0		4	3		1			1	1	2	4	4			
RA Mean	0		1	0		0			0	0	0	0	1			
PA Systolic	19		33	29		19			23	27	28	33	33			
PA Diastolic	10		14	6		9			10	11	12	14	14			
PA Mean	14		23	16		14			15	18	20	21	23			
AO Systolic	134		199	177		129			0	160	171	170	164			
AO Diastolic	79		165	168		125			0	92	99	100	94			
AO Mean	98		182	172		127			159	120	129	128	125			

Data are automatically placed into the appropriate columns of Rest1, FW1, Minutes of Exercise (1-100) and peak data are placed into Max.

Data can be edited if desired. The spreadsheet is directly linked to the Manual Entry script in ComPAS2; the spreadsheet will automatically recalculate any parameters affected by a user edit.

Manual Entry

Hb Draw Date/Time

ABG Site: No information entered. Edit

Allen Test: Not Recorded

Exercise

Type of Exercise | Ramp

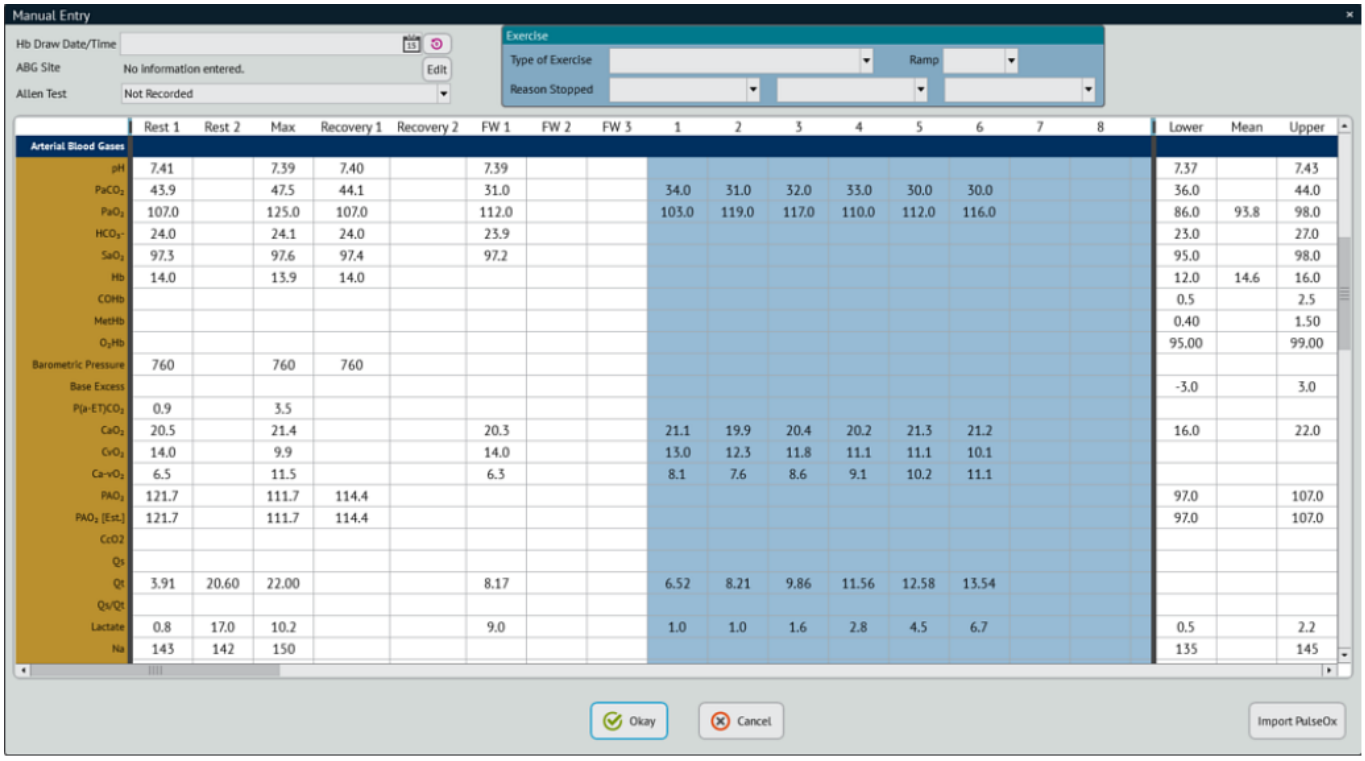
Reason Stopped

	Rest 1	Rest 2	Max	Recovery 1	Recovery 2	FW 1	FW 2	FW 3	1	2	3	4	5	6	7	8
DPG	68		82	72		69			60	67	67	76	78			
TPG	7	9	16	8		4			9	9	12	14	14	15		
CO	3.90	8.98	14.57	4.10		8.17			6.52	8.21	9.86	11.56	12.58	13.54		
Fick CO	0.04		0.10			0.07			0.05	0.07	0.07	0.07	0.07	0.08		
CI	2.2	5.0	8.2	2.3		4.6			3.7	4.6	5.5	6.5	7.1	7.6		
SV	48.1	81.6	102.6	28.5		100.9			74.9	89.2	103.8	116.8	119.8	116.7		
SVI	27.2	45.5	57.7	16.0		56.8			42.5	50.0	57.9	65.7	67.6	65.5		
SVR	88		117	95		93			86	93	95	104	109			
PVR	2		1	2		1			1	1	1	1	1			
TPR	18		6	19		9			11	9	8	7	7	6		
PAC	5		5	1		10			6	6	6	6	6			
Ea			0.17			0.04			0.05	0.06	0.07	0.11	0.15			
Es			4			2			2	4	4	3	3			
Ea/Es			4			2			2	2	2	4	5			
α																
Exercise																
Exercise Time			5.0	6.0		2.0			8.0	9.0	10.0					
Exercise Ramp																
HR	81	110	142	144		81			87	92	95	99	105	116	130	
Watts																
VT	0.531		1.137	1.205					0.607	0.699	0.707	0.792	0.848	0.993	1.059	
RR	19		45	42					21	23	27	26	27	29	38	
VE	9.8		51.4	51.1					12.8	16.4	19.2	20.4	23.1	29.3	40.3	
VO_2	0.28		1.13	1.12		0.44			0.39	0.50	0.60	0.63	0.72	0.88	1.04	

6.15.3 Entering Arterial and Mixed Venous Blood Gas Data

The Manual Entry spreadsheet in ComPAS2 is accessed by clicking the  icon on the bottom task bar.

There are two sections within the Manual Entry spreadsheet to enter blood gas information: Arterial and Mixed Venous.



	Rest 1	Rest 2	Max	Recovery 1	Recovery 2	FW 1	FW 2	FW 3	1	2	3	4	5	6	7	8	Lower	Mean	Upper
Arterial Blood Gases																			
pH	7.41		7.39	7.40		7.39											7.37		7.43
$PaCO_2$	43.9		47.5	44.1		31.0			34.0	31.0	32.0	33.0	30.0	30.0			36.0		44.0
PaO_2	107.0		125.0	107.0		112.0			103.0	119.0	117.0	110.0	112.0	116.0			86.0	93.8	98.0
HCO_3-	24.0		24.1	24.0		23.9											23.0		27.0
SaO_2	97.3		97.6	97.4		97.2											95.0		98.0
Hb	14.0		13.9	14.0													12.0	14.6	16.0
COHb																	0.5		2.5
MetHb																	0.40		1.50
O_2Hb																	95.00		99.00
Barometric Pressure	760		760	760															
Base Excess																	-3.0		3.0
$P(a-ET)CO_2$	0.9		3.5																
CaO_2	20.5		21.4			20.3			21.1	19.9	20.4	20.2	21.3	21.2			16.0		22.0
CvO_2	14.0		9.9			14.0			13.0	12.3	11.8	11.1	11.1	10.1					
$Ca-vO_2$	6.5		11.5			6.3			8.1	7.6	8.6	9.1	10.2	11.1					
PAO_2	121.7		111.7	114.4													97.0		107.0
PAO_2 [Est.]	121.7		111.7	114.4													97.0		107.0
CcO2																			
Qs																			
Qt	3.91	20.60	22.00			8.17			6.52	8.21	9.86	11.56	12.58	13.54					
Qs/Qt																			
Lactate	0.8	17.0	10.2			9.0			1.0	1.0	1.6	2.8	4.5	6.7			0.5		2.2
Na	143	142	150														135		145

The spreadsheet is directly linked to the Manual Entry script in ComPAS2; as foundation data are entered each column is recalculated to populate resultant parameters.

To ensure blood gas data are properly associated with the CPET and Hemodynamic data, care must be taken to enter values in the appropriate columns:

Rest1
Max
Recovery1
FW1
Columns 1 - 100 - minutes of exercise data

6.15.4 Calculations used in iCPET

References used: http://www.scymed.com/en/smnxph/smnxph.htm

Variable	Description	Calculation	Units
CaO2	Arterial oxygen content	(1.36 * Hb) * (SaO2 / 100) + (0.0031 * PO2_arterial) Note: *In cases where no PO2_arterial data are available we substitute SaO2:* (1.36 * Hb) * (SaO2 / 100) + (0.0031 * SaO2)	mL/dL
CvO2	Mixed venous oxygen content	(1.36 * Hb) * (ScvO2 / 100) + (0.0031 * PmvCO2)	mL/dL
CO	Cardiac Output	(VO2 * 1000)/(CavO2 * 10) *Note1: VO2 is multiplied by 1000 to adjust mL* *Note2: Ca-v02 is multiplied by 10 to adjust mL/dL to bmL/L*	L/min
Fick CO	Fick Cardiac Output	(VO2 * 1000)/(CavO2 * 10)	L/min
SV	Stroke Volume	CO / HR	mL/min
CI	Cardiac Index	CO / BSA	L/min/m2
SVI	Stroke Volume Index	CI / HR * 1000	mL/m2
SVR	Systemic Vascular Resistance	(MAP - RA_MEAN) / CO	Wood Units
PAC	Pulmonary Artery Compliance	SV / (PA_SYSTOLIC - PA_DIASTOLIC)	mL/mmHg
MAP	Mean Arterial Pressure	(BP_SYSTOLIC + (2 * BP_DIASTOLIC)) / 3	mmHg
mPAP	Mean Pulmonary Artery Pressure	(PA_SYSTOLIC + (2 * PA_DIASTOLIC)) /3	mmHg
TPR	Total Peripheral Resistance	mPAP / CO	Wood Units
TPG	Transpulmonary Pressure Gradient	mPAP - PW_MEAN	Wood Units
DPG	Diastolic Pulmonary Gradient	PA_DIASTOLIC - PW_MEAN	mmHg
PVR	Pulmonary Vascular Resistance	(mPAP - PW_MEAN) * 79.92 / CO *Note1: 79.92 is a conversion term to equalize units.*	dyn*s/cm5
ES	End-Systolic Elastance	RA_MEAN - (RV_SYSTOLIC / SVI)	mmHg/mL
EA	Pulmonary Arterial Elastance	RV_SYSTOLIC / SVI	mmHg/mL
EA/ES	Right Ventricular-Pulmonary Artery Coupling	EA/ES	
PCW/RAP	Pulmonary Capillary Wedge Pressure/Right Atrial Pressure	(PW_MEAN - Resting PW_MEAN").value) / (RA_MEAN - Resting RA_MEAN)	mmHg
PAP/PCW	Pulmonary Artery Pressure /Pulmonary Capillary Wedge Pressure	(PAP -Resting PAP) / (PW_MEAN - Resting PW_MEAN)	mmHg
PVα	Pulmonary Vascular Distensibility	See below	%/mmHg
Sysα	Systemic Distensibility	See below	%/mmHg

Distensibility Equations:

PVα:

$$\mathrm{mPAP} = \frac{\left[(1+\alpha \mathrm{PAWP})^5 + 5\alpha \mathrm{R_0 CO}\right]^{\frac{1}{5}} - 1}{\alpha}$$

where: PAWP = PW_Mean (mmHg)
R0 = TPR at rest (Wood Units)
CO = CO (L/min)
α = is the rate of increase of resistive vessel diameter per millimeter of mercury of transmural vascular pressure.

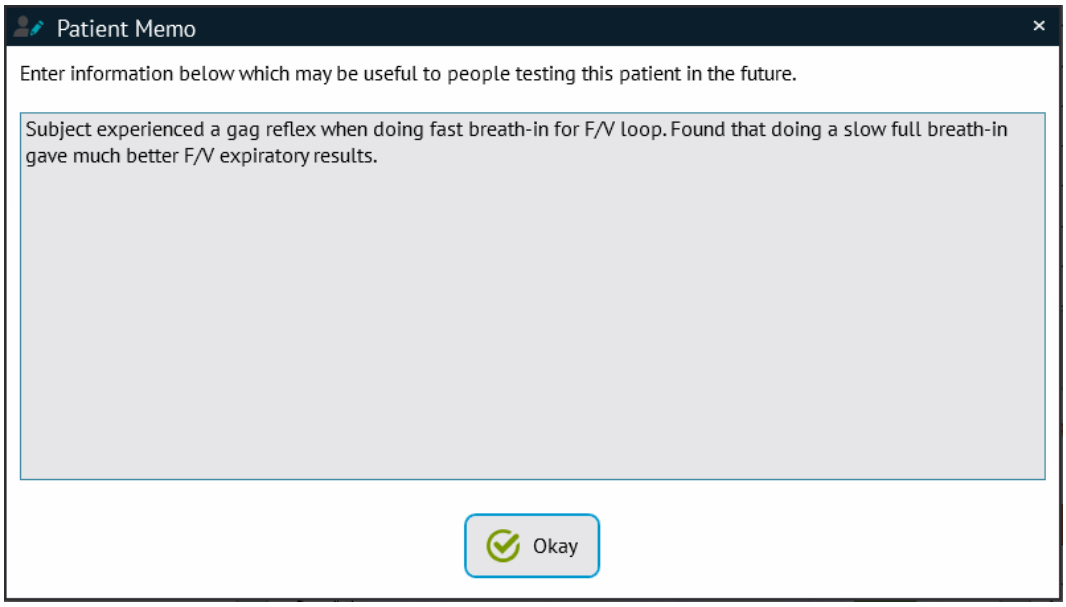
Sysα:

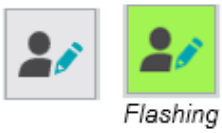
Same equation substituting: PAWP for AO_Mean
R0 for RA_Mean

7:0 Notepads

7.1 Patient Memo Notes

The Patient Memo Icon  provides access to a special notes area where information to assist colleagues in the testing of this test subject can be saved. If notes have been entered in this area, the icon will flash for ten seconds when entering the testing screens to draw attention to the fact that useful information is available.





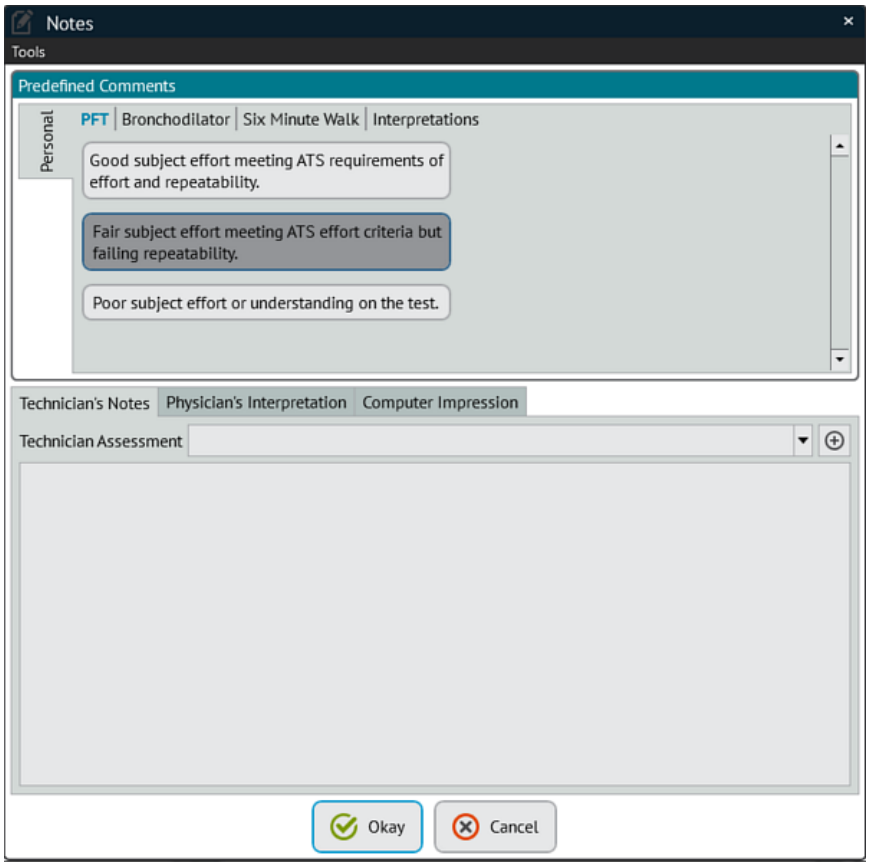
7.2 Technician Notes

ComPAS2 makes provision for frequently used comments, sentences, or paragraphs to be stored and recalled during subject testing.

Each technician can create a personal template for comments or alternatively, can be pointed to a master technician for ”Standardized Notes”.

On the testing screen, the  icon will open the notes dialogue.

The Notes screen will open showing a blank editing area. The 'white space' is a free text area where anything can be typed (or dictated if Dragon Voice is active) at any time. Predefined comments that have been created are displayed under Group Name tabs. These are comments that can be a personal set for each technician or a shared group of comments that one technician manages.

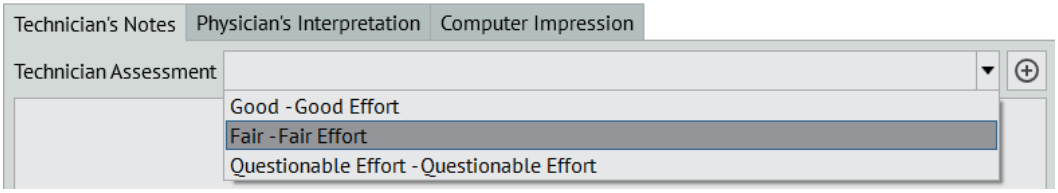


7.2.1 Technician Assessment

ComPAS2 makes provision for a technician assessment of subject effort. This is an "assessment" that can take the place of or work in parallel with ATS acceptability /repeatability. The text of technician assessment can be integrated into final reports or used within a computer impression script.

Technician assessments are created in the Configuration section. Go to Tools then Configuration and Tech Assessment.

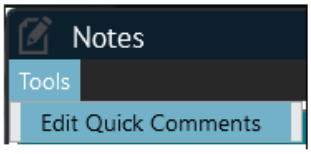
Once created, the text will be available from the pull-down menu.



7.2.2 Creating Technician Note Templates

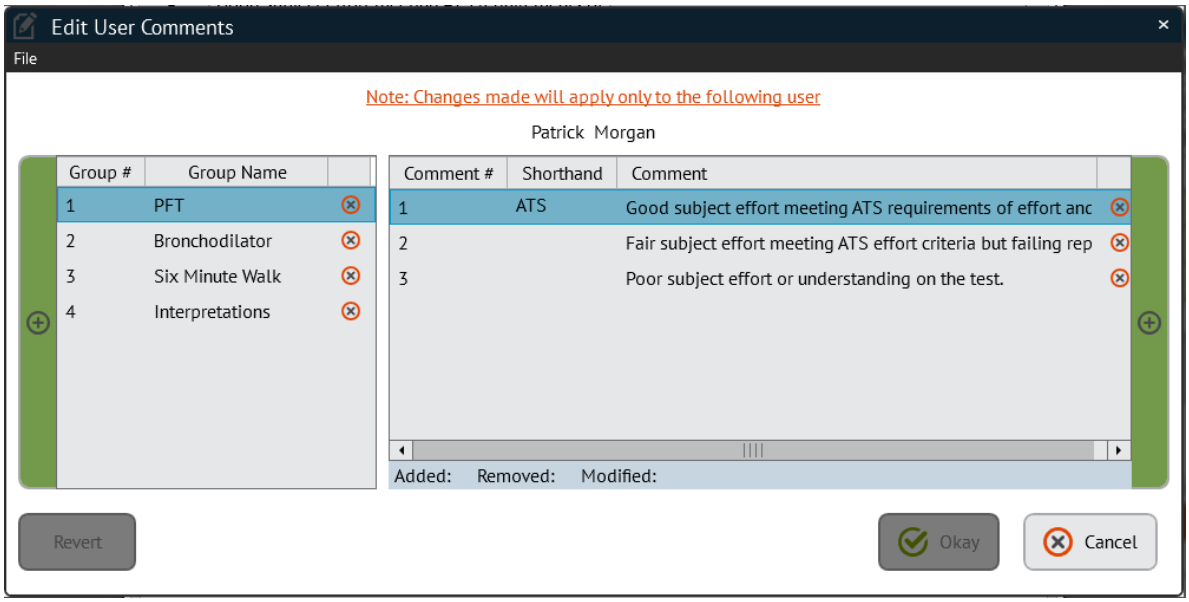
Editing or creating note templates can be accessed in two ways:

1) On the Notes screen click on **Tools** and then **Edit Quick Comments**.



2) In Configuration, select **Personnel** and then select the individual desired and navigate to the **[Task Manager]** tab. Click **Edit Comments**.

Either method of opening the note designer screen will display the following:

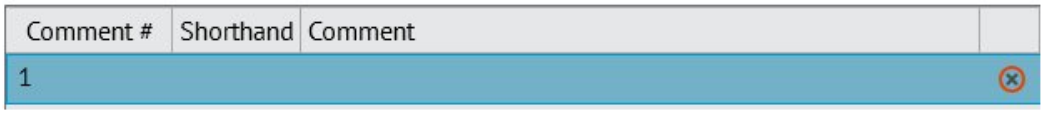


The left-hand menu allows for the creation of a **Group Name**. Each Group can contain an unlimited number of comment lines/paragraphs.

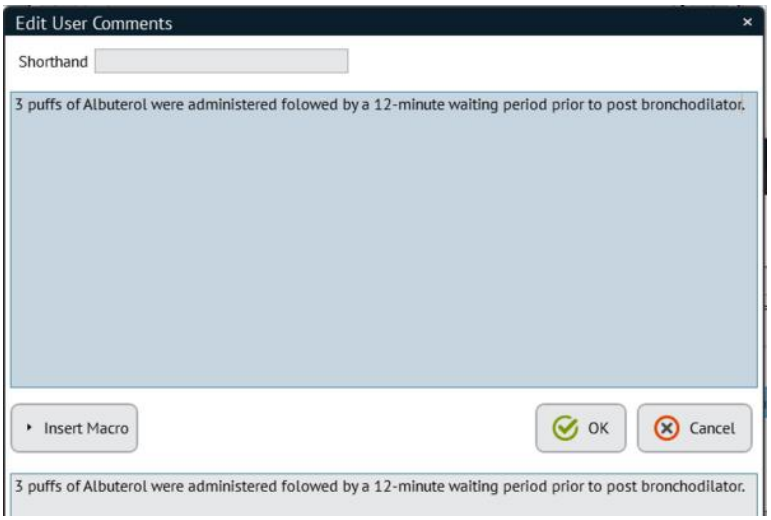
The right-hand menu allows users to add Comments to any highlighted Group.

To add either a new group name or a new comment line, click the  icon associated with each menu. To delete either a group or a comment line, click the  icon beside the associated item.

When a new comment is added, a highlighted row will appear:



Double-click on the highlighted row to launch the Edit User Comments tool.



Enter the desired text into the top half of the designer.

When completing any text, always end with a space after the final period. This will ensure that when appended to other sentences in any interpretation, the text is appropriately displayed.

The bottom window is used to display the text as it will be seen in the use anywhere that notes are displayed.

The shorthand field is optional. Each available comment block has a position to enter a shorthand code. Any alpha-numerical code placed in the shorthand position will bring the associated sentence to the notes area when used.

From the example shown, typing **ATS** followed by a [Spacebar] in the white space of the notes area will bring up the sentence:

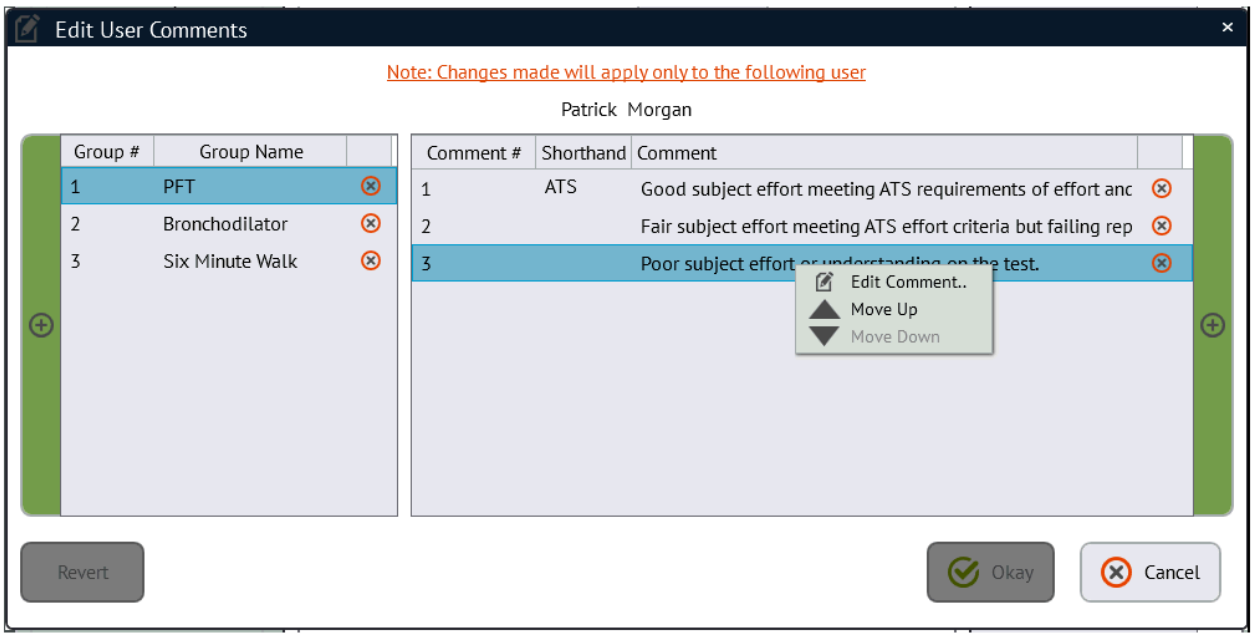
"**Good subject effort meeting ATS requirements of effort and repeatability**. "

When completing any text, always end with a space after the final period. This will ensure that when appended to other sentences in any interpretation, the text is appropriately displayed.

The bottom window is used to display the text as it will be seen in the use anywhere that notes are displayed.

7.2.3 Changing the Vertical Order of Technician Comments

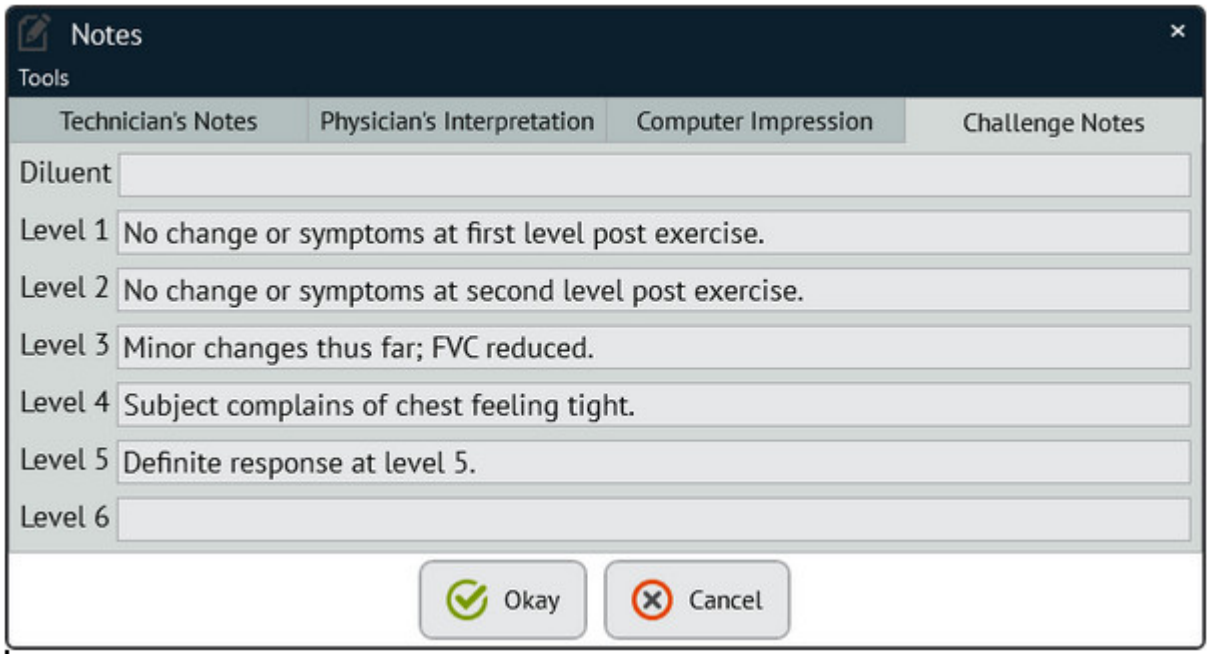
To move the order of any Comment, simply right-click and use the Up or Down Arrow.



7.2.4 Bronchial Challenge Level Notes

If the test contains bronchial challenge results and notes, the notes from any level of the challenge test can be viewed, edited and saved from the [Challenge Notes] tab.

Text can extend way beyond the row length displayed. Each row will auto-grow if further space is needed for extensive notes.



7.3 Physician Notes

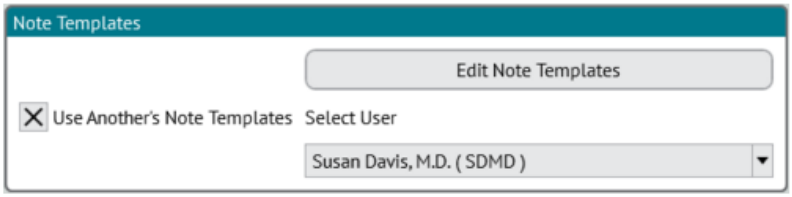
ComPAS2 makes provision for frequently used comments, sentences or paragraphs to be stored and recalled by individual physicians. The notepad allows for both personal templates for each physician and/or a departmental template that can be accessed by all users. The latter option is often employed by institutions that want a common or standardized interpretation 'language' used in reporting.

The notepad can also support Macro functions which allow each user to 'imbed' actual data within the text of any comment or interpretation line. For example, "**Mild obstruction is indicated by an FEV1 of 2.21 being 70% of predicted**". The values of 2.21 and 70% have been read using the macro capability from the database.

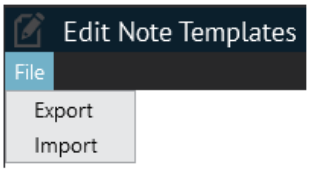
7.3.1 Creating Physician Note Templates

The notes can be accessed from **Configuration**, select **Personnel** and then select the individual desired and navigate to the **[Task Manager]** tab. Click **Edit Note Templates**.

The key notes dialogue allows a choice of using a personal set of note templates, or pointing to a common set. If "**Use Another's Notes**" is selected, a drop-down menu of Users is displayed. Typically, a key colleague is responsible for maintaining or editing the common templates.



7.3.2 Copying Templates from one Physician to Another.

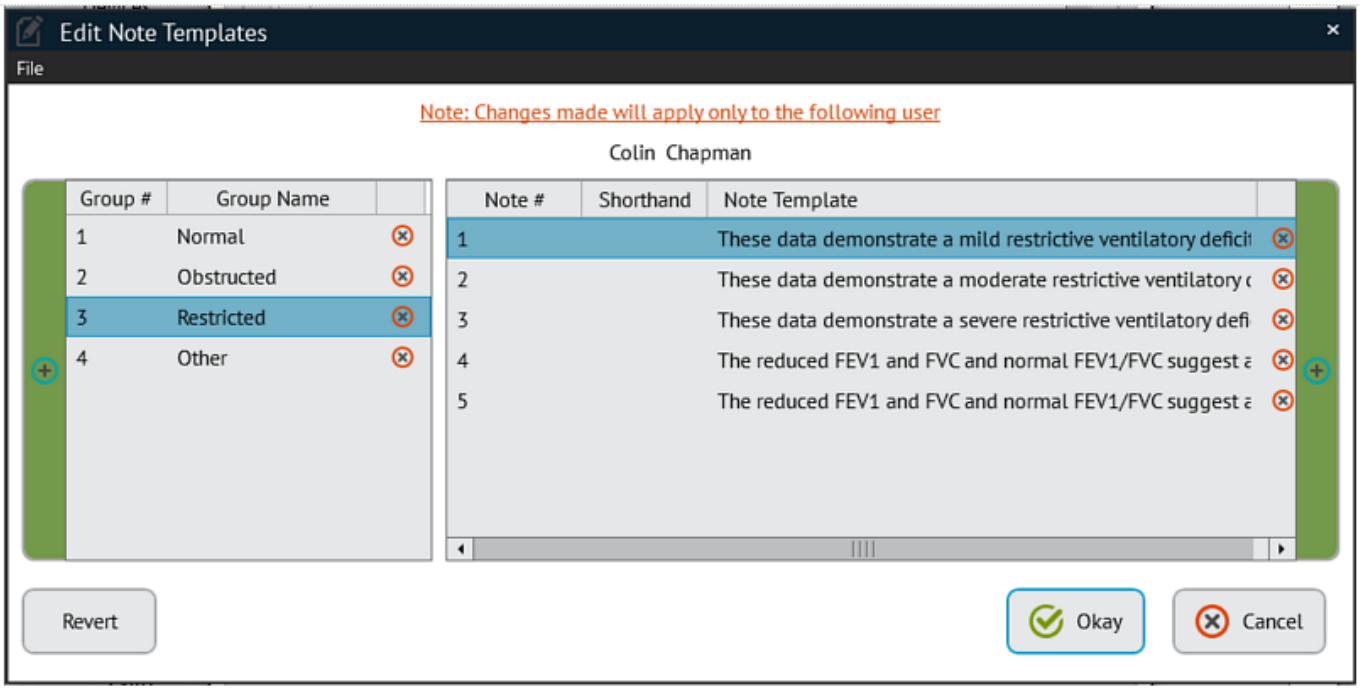


Another option under "File" allows a set of notes to be "exported" and then "imported" from one individual to another. This is a fast way to use a set of templates as a starting point from which additions, modifications or subtractions can be made.

7.3.3 Editing Note Templates

To load the personal notes menu, click the 

button:

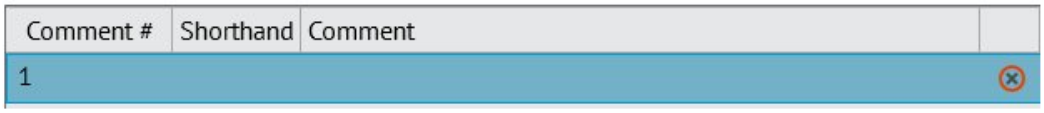


The left-hand menu allows for the creation of a Group Name. Each Group can contain an unlimited number of comment lines/paragraphs.

The right-hand menu allows users to add **Comments** to any highlighted Group.

To add either a new group name or a new comment line, click the  icon associated with each menu. To delete either a group or a comment line, click the  icon beside the associated item.

When a new comment is added, a highlighted row will appear:



Double-click on the highlighted row to launch the Edit User Comments tool.
The top edit area allows users to type (or dictate if Dragon voice is active) complete sentences or paragraphs of text.

Enter the desired text into the top half of the designer.

When completing any text, always end with a space after the final period. This will ensure that when appended to other sentences in any interpretation, the text is appropriately displayed.

The bottom window is used to display the text as it will be seen in the use anywhere that notes are displayed.

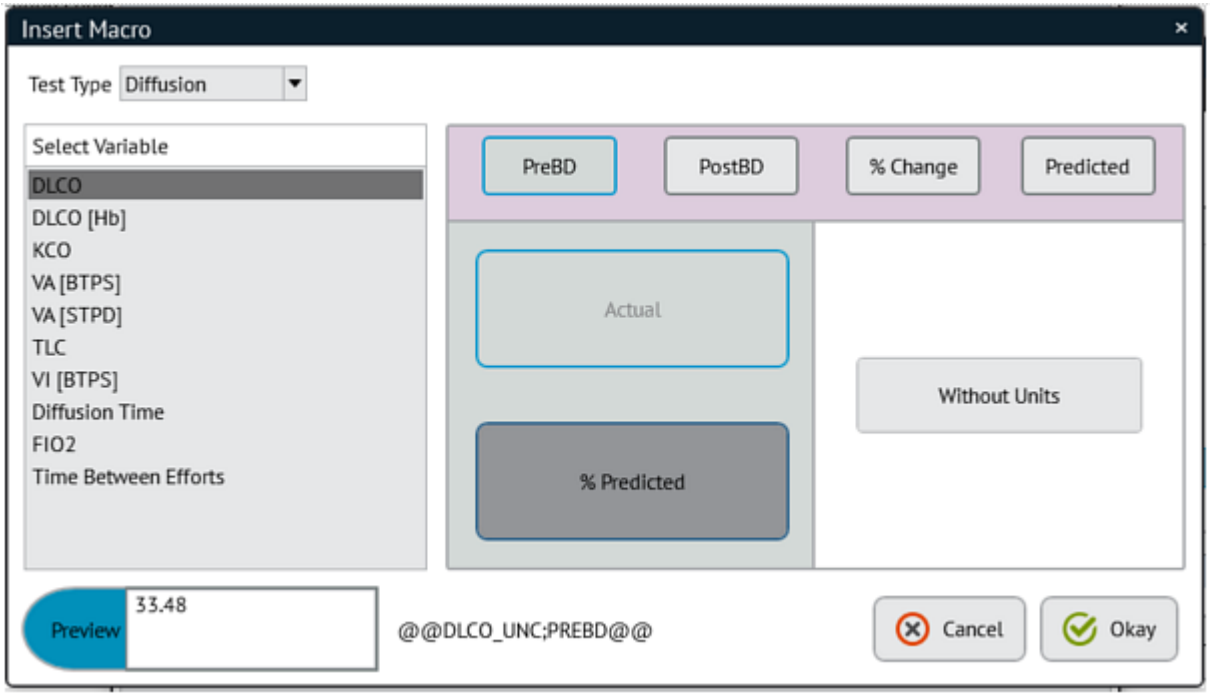
The shorthand field is optional. Each available comment block has a position to enter a shorthand code. Any alpha-numerical code placed in the shorthand position will bring the associated sentence to the notes area when used.

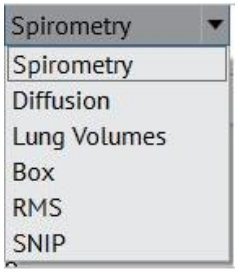
From the example shown, typing **OB3** followed by a [Spacebar] in the white space of the notes area will bring up the sentence.

7.3.4 Inserting Data (Macros) into the Text.

Click on the 

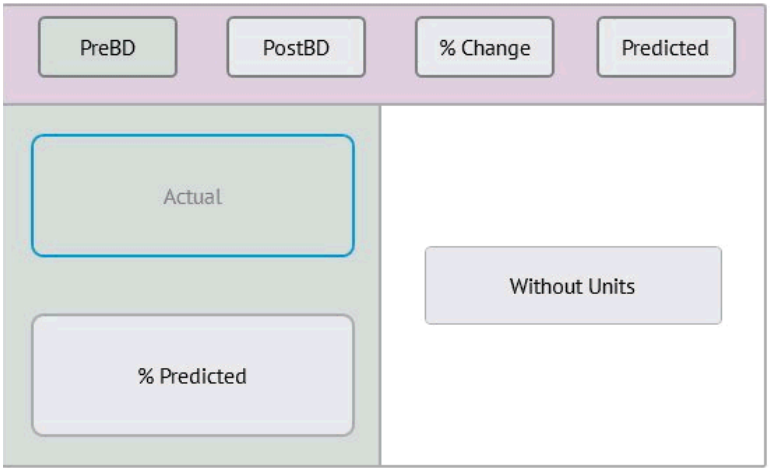
icon to display the macro menu:





Data can be selected from the category of various test types using the pull-down choices.

The full listing of available variables will be displayed beneath the test type selection.



Having identified the parameter desired, the choices of data insertion are:

Actual:

Pre Bronchodilator
Post Bronchodilator
% Change
Predicted

% Predicted:

Pre Bronchodilator
Post Bronchodilator

Each of the choices can be inserted with or without units.

When entering a macro, the top field will display the coded message, but the bottom field will show an example of how it will appear in use.

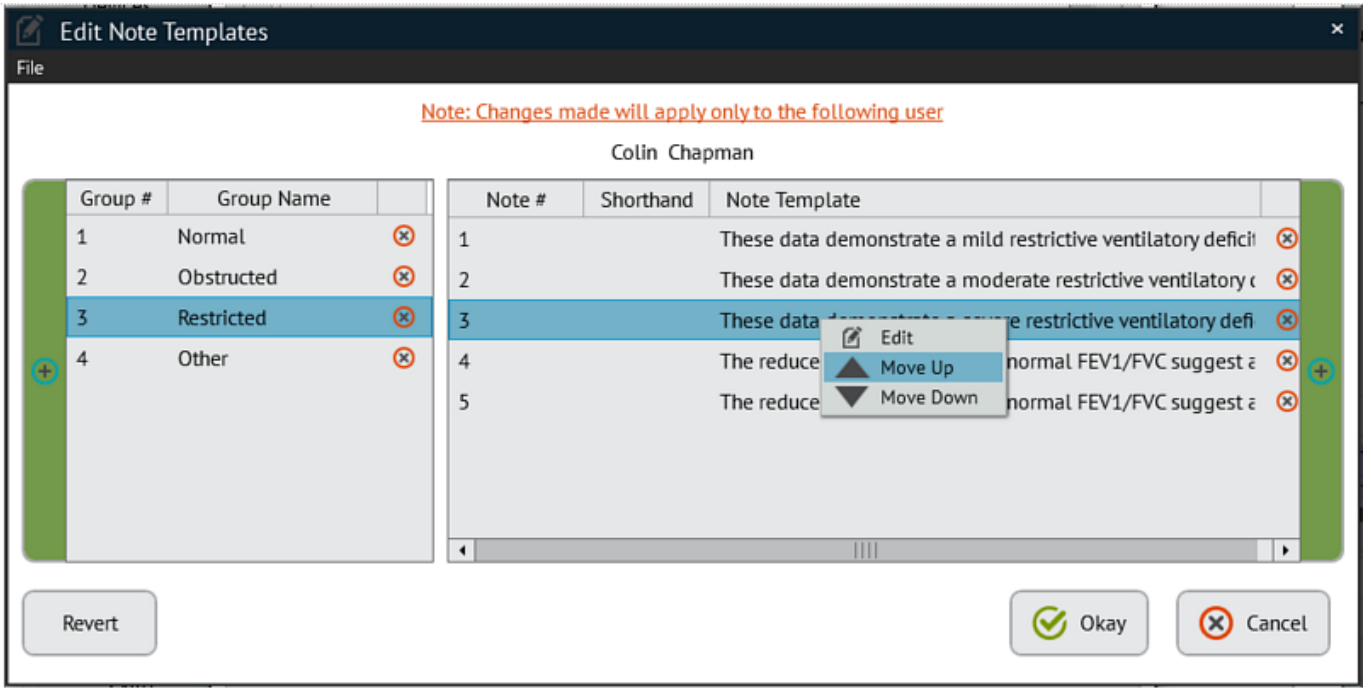
For actual data to show in the macro fields, an active patient with appropriate test data must be loaded in 'today's print list'.

For example:

> **The DLCO of @@DLCO_UNC;PREBD@@ (being @@DLCO_UNC;PP_PREBD@@ % of predicted) indicates a normal diffusing capacity**.
>
> When using the predefined comments options during interpretation of tests, the text is parsed and evaluated so the user will view the actual content with test values inserted:
>
> **The DLCO of 33.48 (being 92% of predicted) indicates a normal diffusing capacity.**

7.3.5 Changing the Vertical Order of Physician Templates

To move the order of any Comment, simply right-click and use the Up or Down Arrow.



8:0 Reports

8.1 Introduction

Reporting capability within ComPAS2 is extensive with a myriad of standard report formats to choose from. In most cases, reports will be set-up by your local product specialist to make use of the Smart Report capability.

What is "Smart Reporting"?

The Smart Report option in ComPAS2 automatically loads the appropriate information (to build the Report) when leaving testing. For example:

> If a bronchial challenge test has been completed, then the style of report will default to the chosen challenge report
>
> If a six-minute walk test has been completed, then the chosen six-minute walk report will be presented
>
> If the test contains spirometry only then the chosen screening report will be presented
>
> If the test contains spirometry, diffusion and lung volume data then the chosen full PFT report will be presented

Reports that can combine any and all test information are available including combinations of full PFT and CPET data

In simple terms, the Smart Report follows logic which can be edited in the Configuration - Smart Report Scripts section. Any database field can be used in the Smart Report logic to build and present the appropriate report style without the need for users to have to individually select a style of report.

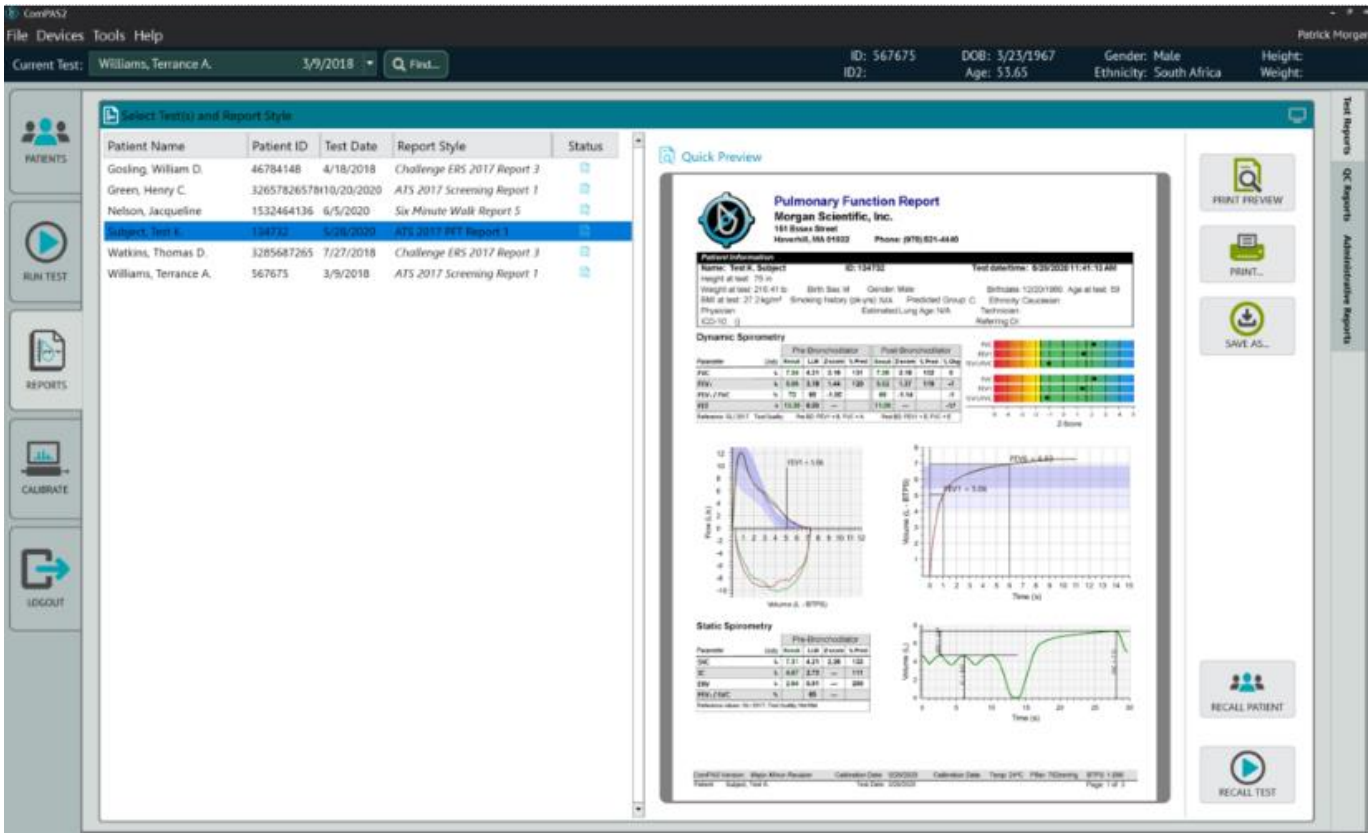
ComPAS2 employs a Report Generator Service which is a Windows Service that runs automatically in the background, allowing for pre-generation of pulmonary function testing reports. On multi-station networks, it serves to distribute the load of report generation amongst all computers that have ComPAS2 installed.

The report styles generated are based on configuration settings which use logic determined by the Smart Report Script.

8.2 Printing the Current Test

From the testing screen, clicking on the 

icon will load to the reporting menu and highlight the patient test just completed.



At any point the report can be printed by clicking the 

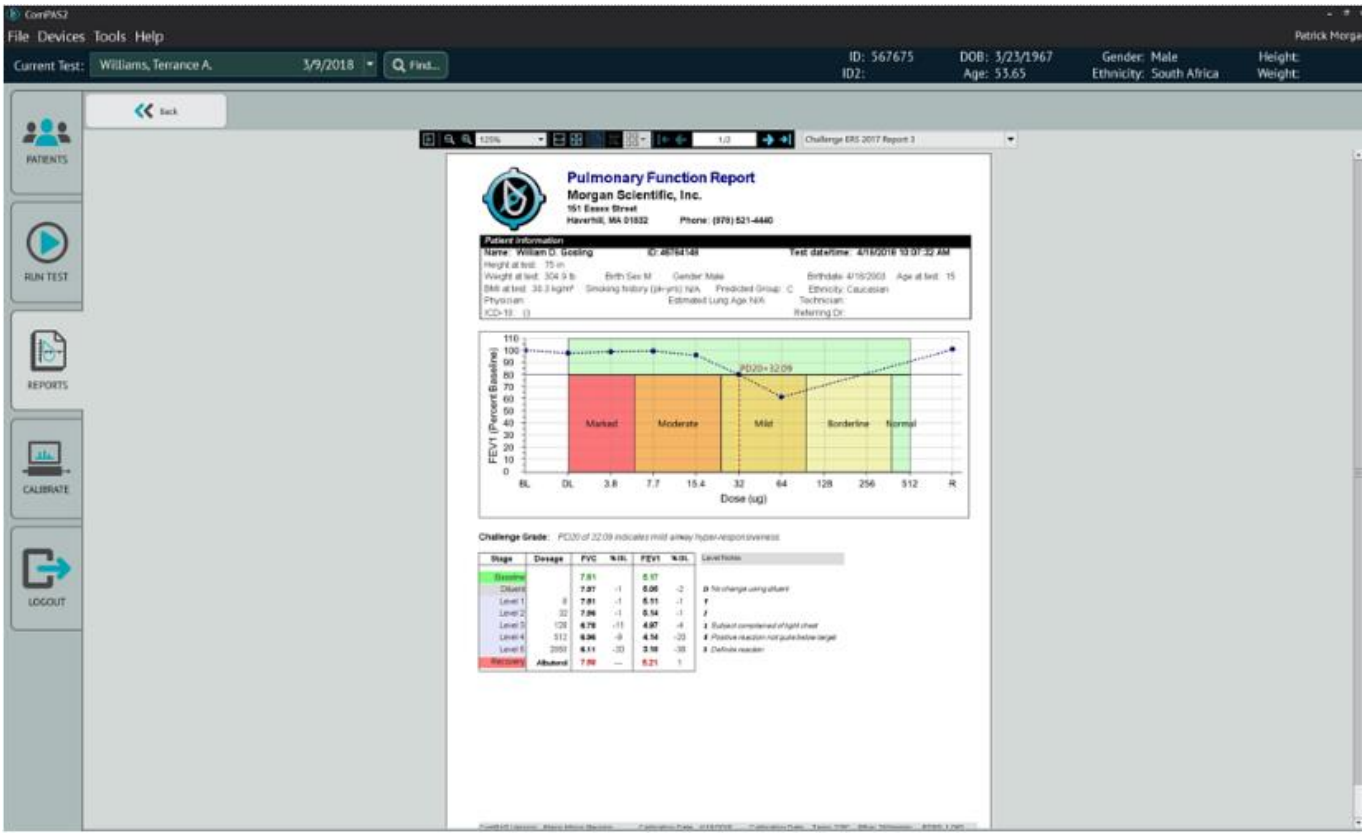
button. If preferred, the report can also be saved to a file by selecting the 

button.

8.3 Print Preview

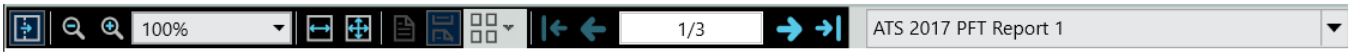
The Quick Preview image of the report is simply a quick rendition of the first page, to view the full fidelity report and additional pages, click the 

button.

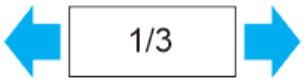


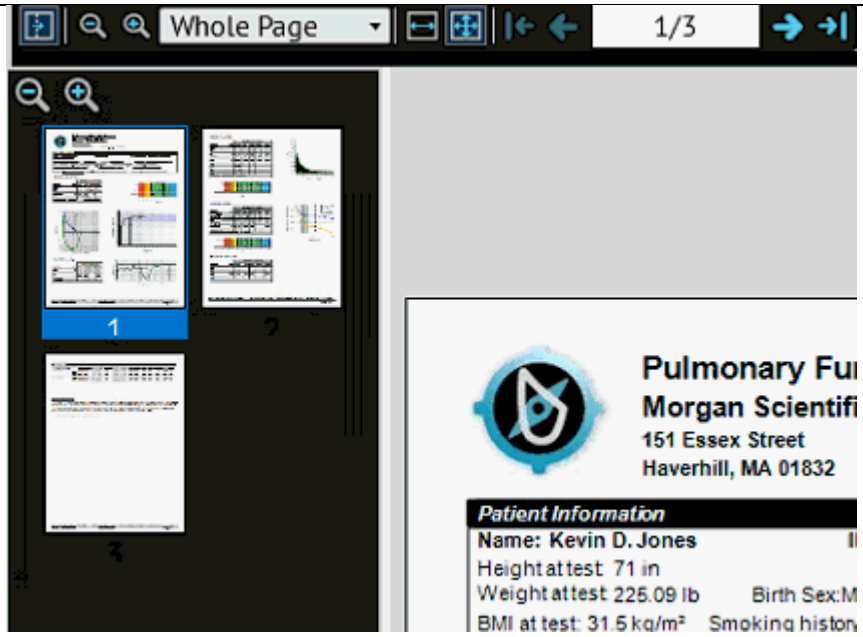
Single Page Report View

The preview provides report options and scaling that will be saved for each user's preference. Report pages can be displayed individually or in a continuous scroll mode.

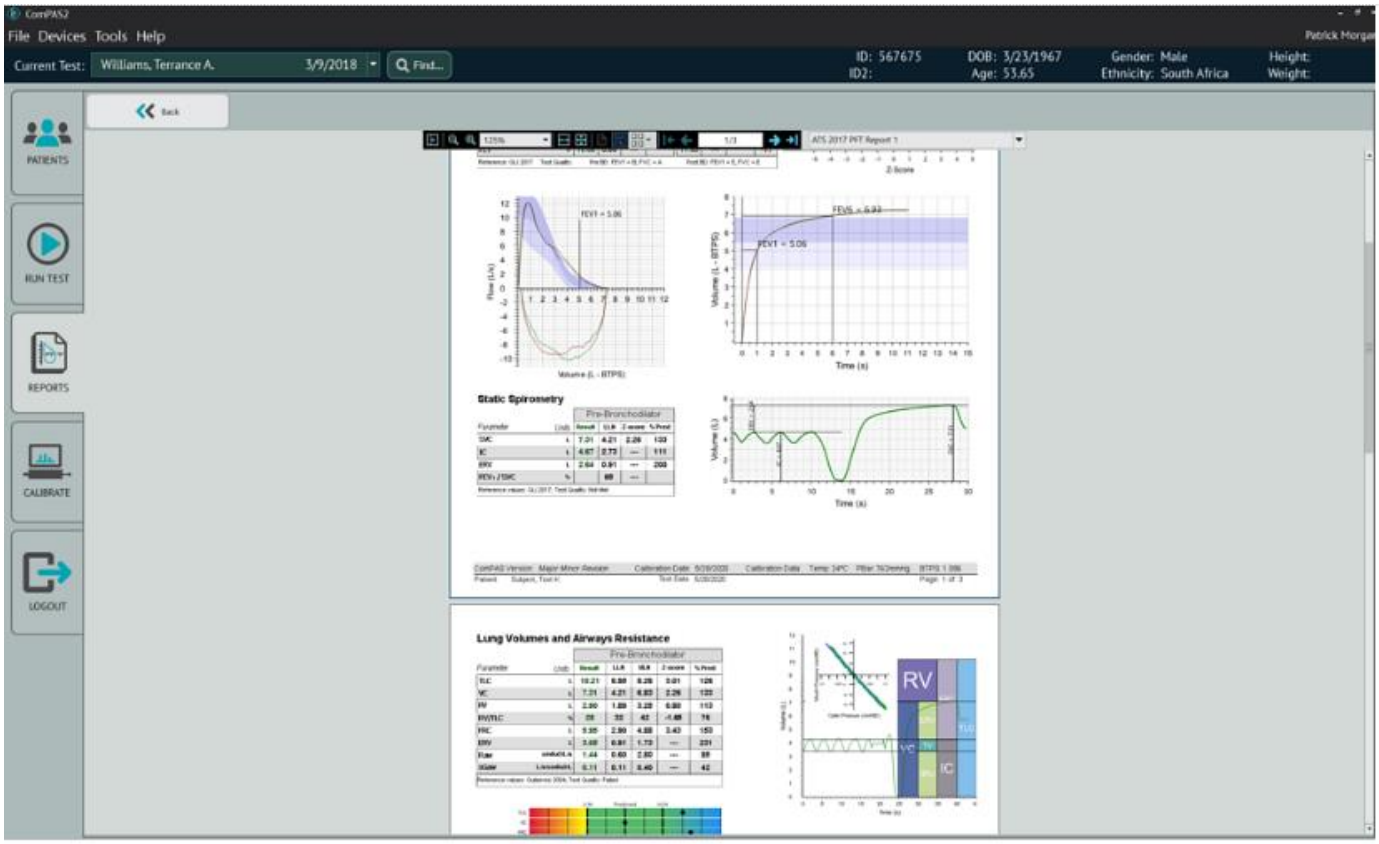


Report Navigation Tools	
<u>Selecting a Different Style of Report</u> The Smart Report script can pre-generate any number of report styles for immediate viewing. A pull-down of available choices is available above the report; selecting any option will instantly present the new format.	

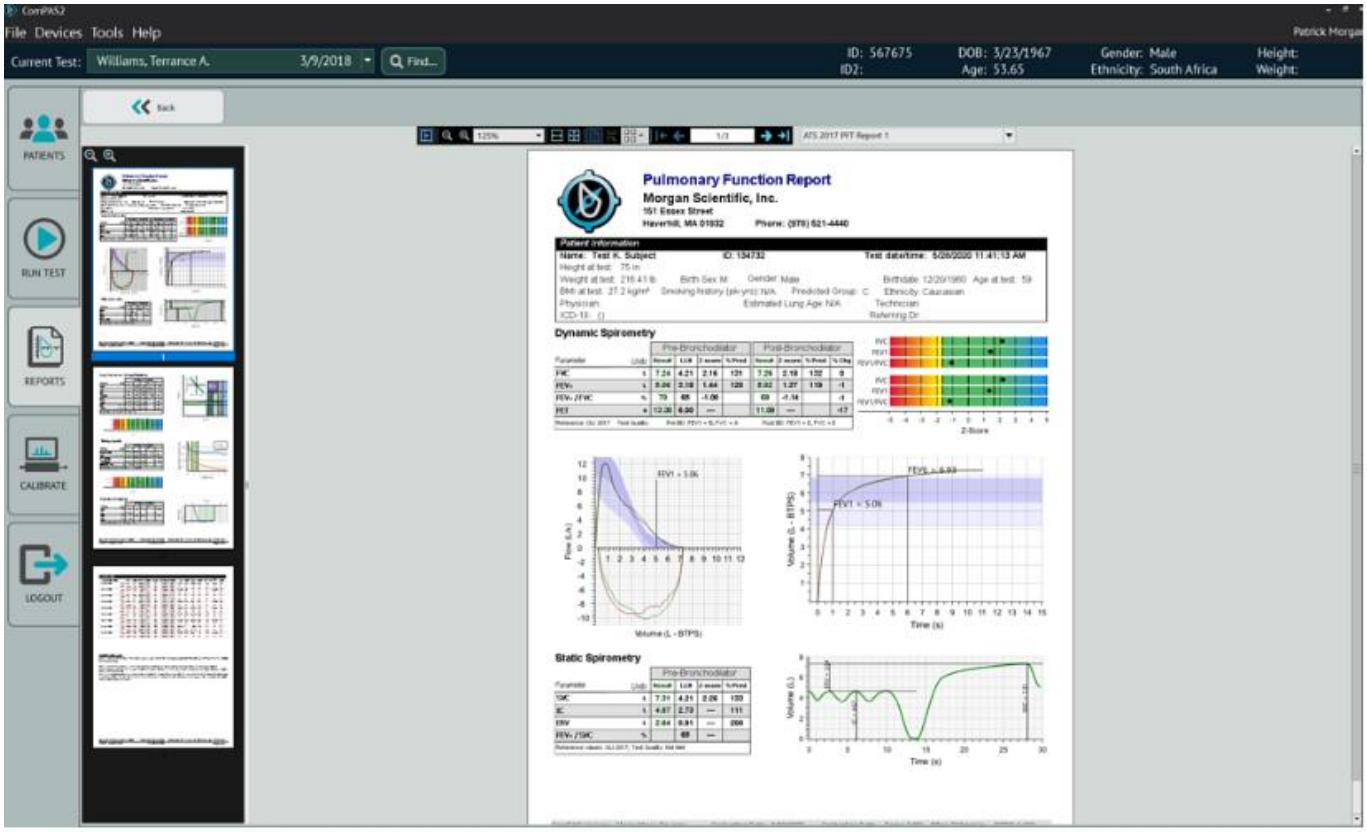
Report Navigation Tools continued	
Moving Between Pages Pages of the report can be viewed by either advancing the arrow keys (forwards or backwards) or using the **[Page Up]** and **[Page Down]** keys.	
Report Page View Clicking each of the icons shown will present a different view of the main report page:  Presents a page by page view  Provides a continuous scroll view  Presents a multi-page view	
Enlarging the Report View To zoom in or out on any report page, use either the magnifying tools or press and hold the [Ctrl] key while using the wheel on the mouse.	
Toggle Side Bar View Clicking on the icon beside the magnifying glasses will present miniatures of each page of the report.  For fast loading to any page of the report, simply click on the page desired; this can be particularly	

useful if the report has multiple pages.	

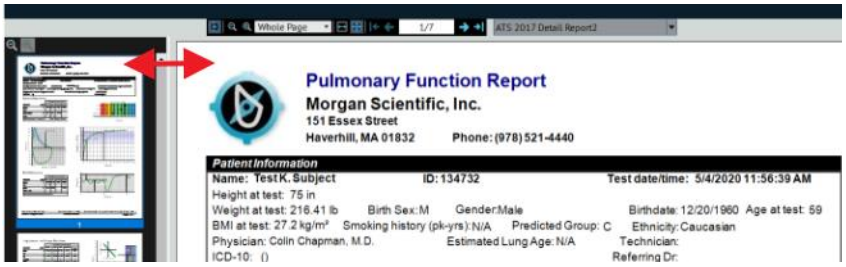
Continuous scroll view can be selected with or without the option of side bar.



Continuous Scroll View



Using the Optional Side Bar View

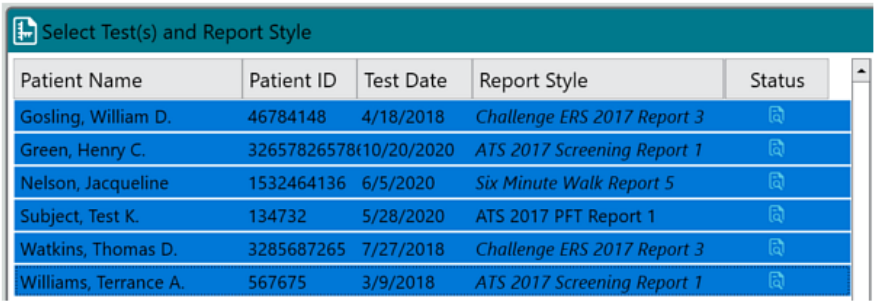


The report size can be adjusted to suit individual preferences.

Hold the mouse over the left report view line as shown and when the double arrow symbol appears, stretch the view right or left to scale to the desired size. Once scaled, the selection will be remembered until it is changed by the individual user.

8.4 Viewing Multiple Patient Reports

From the list of patients available for reporting, highlight any or all that are desired.



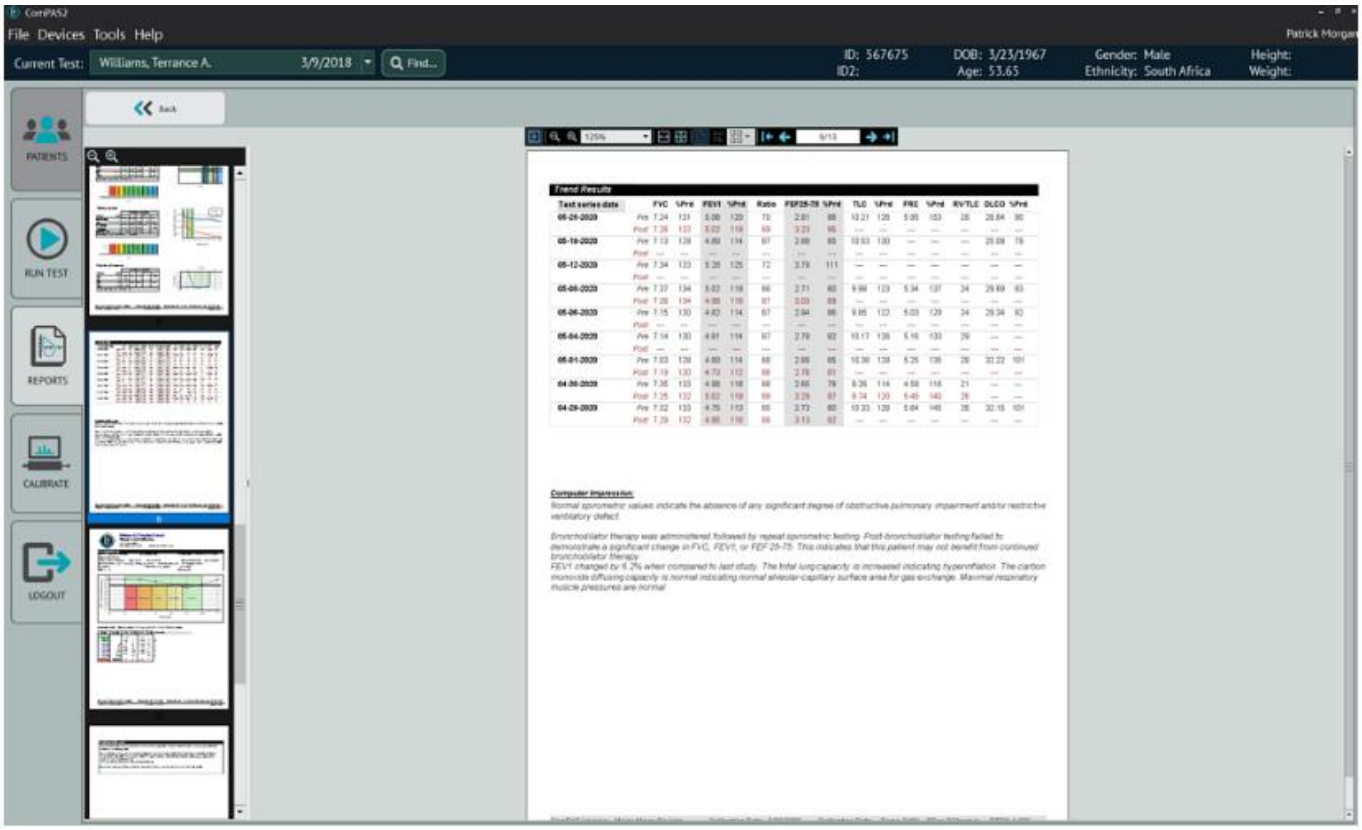
Select Test(s) and Report Style

Patient Name	Patient ID	Test Date	Report Style	Status
Gosling, William D.	46784148	4/18/2018	*Challenge ERS 2017 Report 3*	
Green, Henry C.	3265782657810/20/2020		*ATS 2017 Screening Report 1*	
Nelson, Jacqueline	1532464136	6/5/2020	*Six Minute Walk Report 5*	
Subject, Test K.	134732	5/28/2020	ATS 2017 PFT Report 1	
Watkins, Thomas D.	3285687265	7/27/2018	*Challenge ERS 2017 Report 3*	
Williams, Terrance A.	567675	3/9/2018	*ATS 2017 Screening Report 1*	

Now click the 

button.

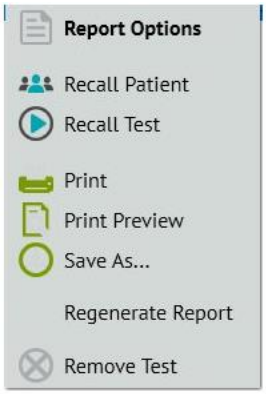
The reports will all be loaded into the side bar view showing all those selected; simply click any page for the expanded display.



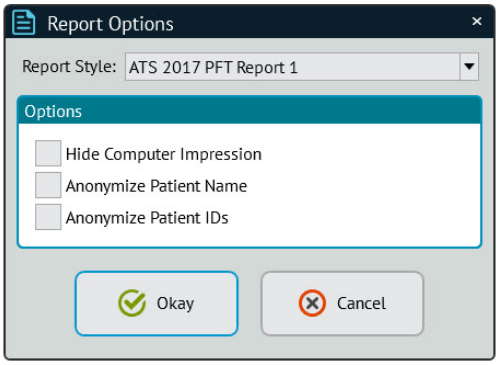
Multiple Patient Tests View

8.5 Selecting a Different Report Style

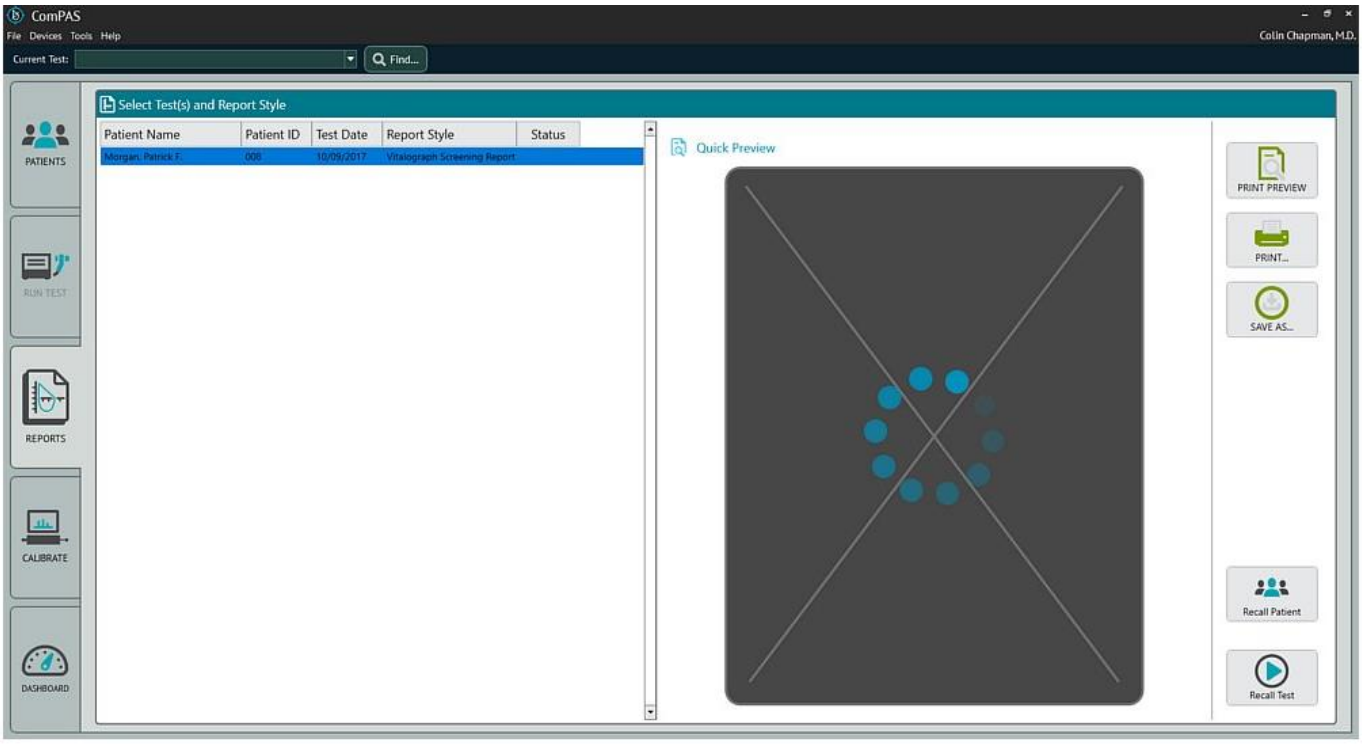
To change the style of report at any time, right-click on the patient and select "Report Options":



The styles of available reports are listed in the pull-down. This dialogue also provides ability to hide any computer impression or anonymize patient data.



When a new report style is selected, the report is then generated and displayed when complete.

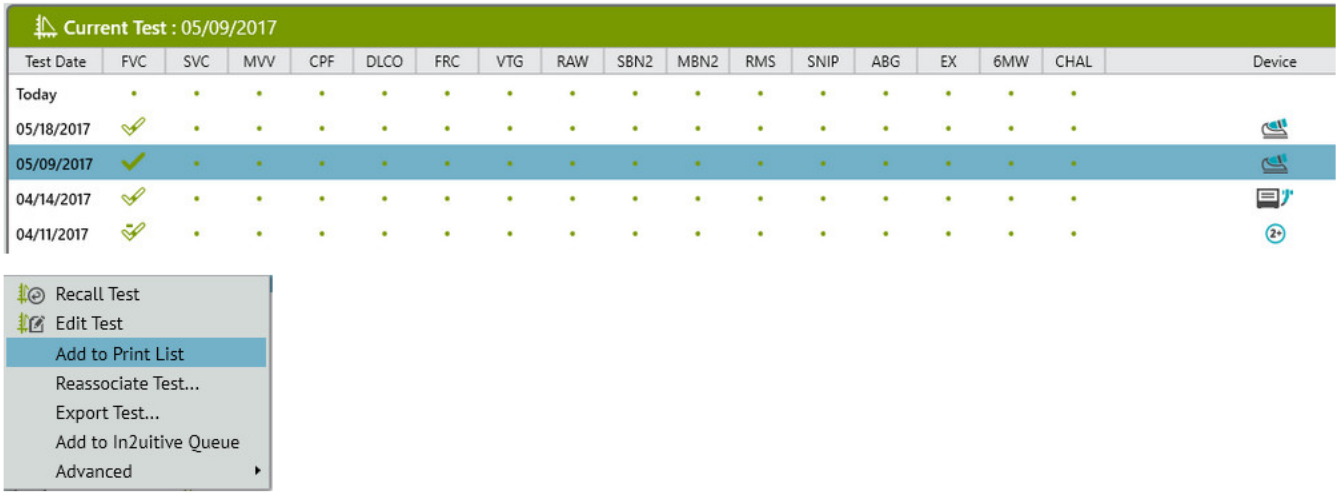


8.6 Printing Past Test Results

To print results from days other than the current testing day, first use either of the 

buttons, to locate the test subject.

Once the subject has been retrieved, right-click on the desired test date and select "**Add to Print List**":



This will place the test onto the daily list and be made available to print using the normal reporting options.

8.7 Quality Control Reports

Quality Control reports provide record of each time the instruments have been calibrated and how they performed.

From the main screen, click on the 

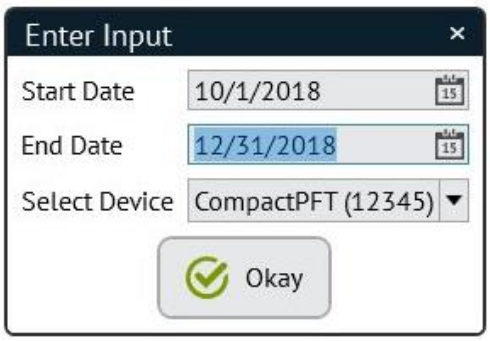
icon to load to the report screen.

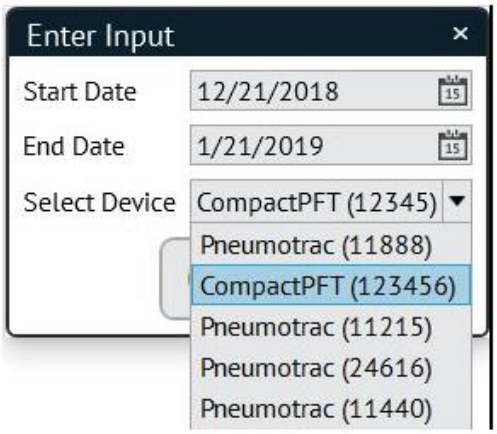
Click on the right-hand [QC] tab:

To produce a quality control report for a given date range, right-click on any of the available report styles, for example: "Spirometry QC for Date Range":

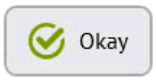
When the 

button is selected, the date range dialogue will appear:

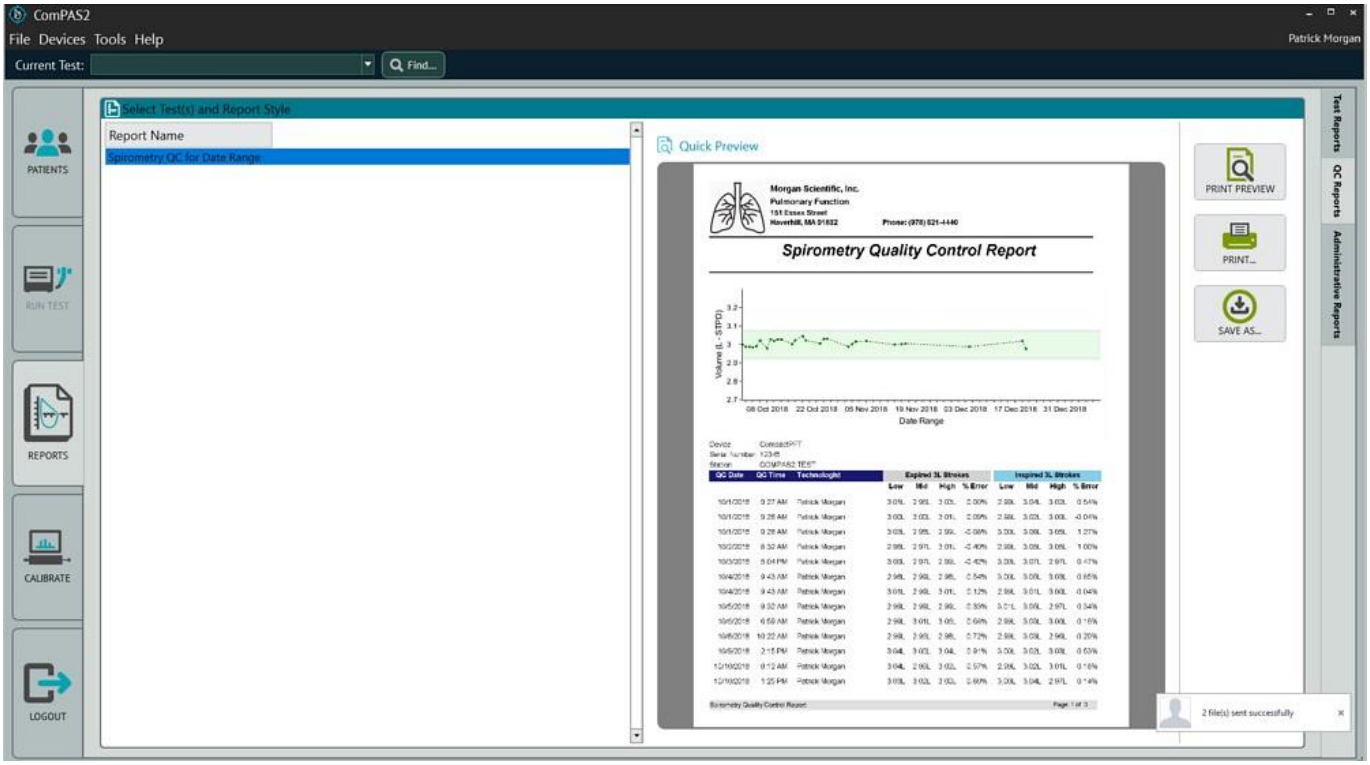




If this station is part of a network, it is possible to view and print QC data for any device on the network. Use the "Select Device" pull-down to identify a different device.

Once the date range and device have been established, pressing 

will generate the desired report.



8.8 Administrative Reports

Administrative reports provide very helpful information for the management of the pulmonary function laboratory.

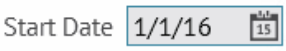
From the main screen, click on the 

icon to load to the report screen. Then click on the right-hand [Administrative Reports] tab:

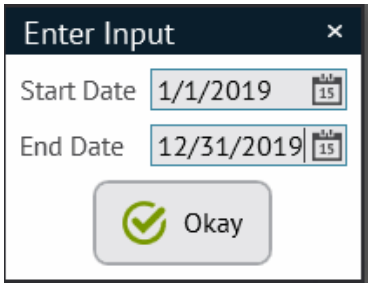
Double-clicking any of the desired report options will prompt for further input.

<u>8.8.1 Using the Date Selector</u>

Entering specific dates for review on the 'date tool' can be either manual or mouse driven.

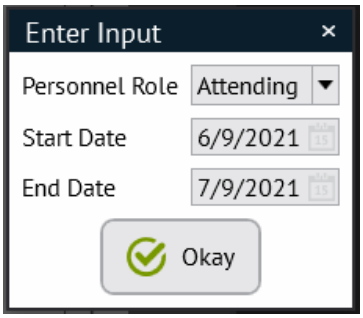
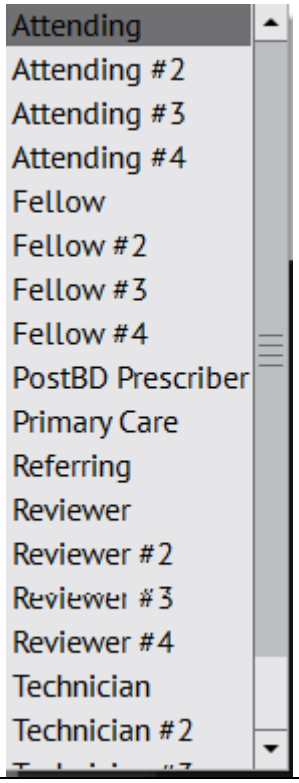
Manual: Simply type the date required into the date field and press [Enter] - 

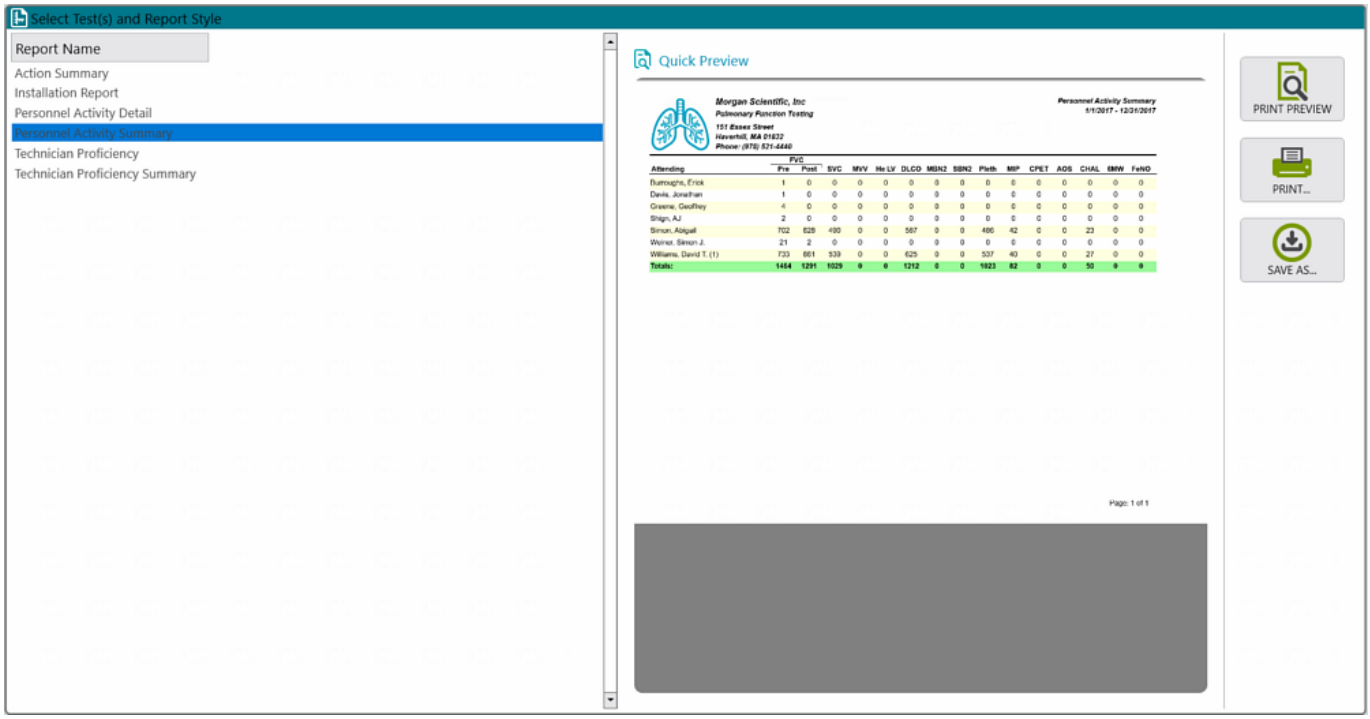
Mouse Action: Click the calendar icon and navigate to the date desired. Clicking in the year area will allow faster navigation to the desired year January 2014



8.8.2 Activity Reports

These reports are designed to show testing activity broken out by the type of tests done. Activity reports can show summary information or detail information which includes the patients seen by any role selected. These can be useful to show for example the total number and type of tests completed by personnel in the facility.

Step1 Click [Generate]	Step 2 Using the pull-down arrow, select the role and then the date range that is desired.	Step3 Role Selection:
		



8.8.3 Technician Proficiency Reports

Technician proficiency details the quality of testing in the laboratory; how many tests meet the ATS/ERS guidelines for acceptability and repeatability. Both a summary and detail listing are available.

Click [Generate] and enter the desired data range to view the report.

Tests completed using ComPAS2 use the 2019 spirometry standards. A solid check indicates tests achieving Grades A or B. The hollow check indicates tests achieving a Grade C.

Morgan Scientific, Inc
Pulmonary Function Testing
151 Essex Street
Haverhill, MA 01832
Phone: (978) 521-4440

Technician Proficiency
1/1/2017 - 12/31/2017

	FVC Pre			FVC Post			SVC			MVV			FRC			DLCO			RAW		
Technician	✓	✓	⊗	✓	✓	⊗	✓	✓	⊗	✓	✓	⊗	✓	✓	⊗	✓	✓	⊗	✓	✓	⊗
Williams, David T. (1)	1	0	2	2	0	0	2	0	1	0	0	0	0	0	0	1	0	2	0	0	0
Simon, Abigail	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0
Gagne, Julie	636	0	152	602	0	99	337	0	223	0	0	0	0	0	0	567	0	72	0	0	0
Leung, Kaling	416	0	20	388	0	7	219	0	81	0	0	0	0	0	0	343	4	6	0	0	0
Desk, Front	0	0	1	1	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Poulter, Lisa	183	0	23	179	0	11	132	0	31	0	0	0	0	0	0	131	1	1	0	0	0
,	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1

8.8.4 Action Reports

Action Summary is designed for customers using the Task Manager. It can show all approval activity and detail the number of days tests have been waiting for approval.

Click [Generate] and using the pull-down arrow, select the role and then the date range that is desired.

8.9 Examples of Report Styles

A brilliant library of report presentations come standard with ComPAS2, but each users 'dream' layout is both welcomed and easily accommodated.

Test Reports - presentations of test data really have no limit. These can include any combination of the best pre and post results with preference of numerical column order and any of the following:

- Showing selected PRE and POST test results
- Arranging the order of parameters vertically
- Arranging the numerical data format in any configuration horizontally
- Wide ranging header designs
    - Subject photo included in the header
    - Incorporating the custom hospital logo in the header
- Including calibration data with test data
- Showing past test results either vertically or horizontally
- Display of trend data graphics
- Wide variety of test graphics options
    - Numerous Flow Volume Graphics
    - Numerous Volume-Time Graphics
    - Z-Score Plots
    - Miller’s Quadrant Graph
    - Lung volume bar Graphs
    - Comprehensive array of Test Graphics (DLCO, SBN2, MBN2, MIP/MEP, CPF etc.)
- Showing test variable data (i.e. Gas analysis etc. from DLCO)
- Computer impression
- Technician and Physician notes
- Displaying the captured Physician Signature
- Overlays of all test efforts
- Wide array of Challenge Reports (Methacholine, Aridol, Exercise, Cold Air)
- Combining CPET graphics and data with full PFT results

A full complement of report examples is available in PDF form.

Some examples of the myriad report options follow:

8.9.1 Screening Report Example

ATS 2017 Screening Report	

Pulmonary Function Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

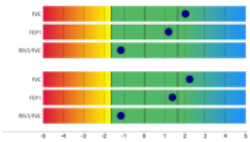
Patient Information

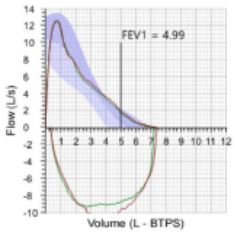
Name: Test K. Subject ID: 134732 Test date/time: 9/27/2018 3:14:53 PM
Height at test: 75 in
Weight at test: 211.53 lb Sex: M Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6 Smoking history (pk-yrs): N/A Ethnic group: C
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated Referring Physician:

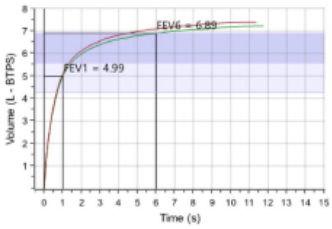
Dynamic Spirometry

Parameter	Units	Pre-Bronchodilator Result	LLN	Z-score	% Pred	Post-Bronchodilator Result	Z-score	% Pred	% Chg
FVC	L	7.21	4.28	2.03	129	7.38	2.24	132	2
FEV_1	L	4.99	3.25	1.20	117	5.10	1.39	119	2
FEV_1 / FVC	%	69	65	-1.16	90	69	-1.16	90	0
FET	s	11.77	8.00	—		11.37	—		-3

Reference values: GLI 2017; Test Quality: Effort Met



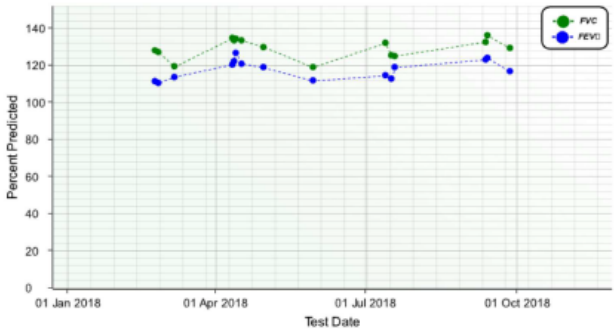




Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Interpretation:

ComPAS Version: v2018.1.0 (Build 0) Calibration Date: 9/27/2018 Calibration Data: Temp: 27ºC PBar: 757mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 1 of 2



Trend Results

Test series date		FVC	%Prd	FEV1	%Prd	Ratio	FEF25-75	%Prd	TLC	%Prd	FRC	%Prd	RV/TLC	DLCO	%Prd
9/27/2018	Pre	7.21	129	4.99	117	69	3.21	91	11.50	142	6.35	164	35	33.15	102
	Post	7.38	132	5.10	119	69	3.30	94	—	—	—	—	—	—	—
9/13/2018	Pre	7.61	136	5.31	124	70	3.45	98	—	—	—	—	—	—	—
	Post	7.49	134	5.29	124	71	3.54	101	—	—	—	—	—	—	—
9/12/2018	Pre	7.42	133	5.27	123	72	3.40	97	—	—	—	—	—	0.41	1
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—
7/18/2018	Pre	6.99	125	5.10	119	73	3.77	107	—	—	—	—	—	—	—
	Post	7.06	126	5.13	120	73	3.71	105	—	—	—	—	—	—	—
7/17/2018	Pre	7.00	125	4.84	113	69	3.00	85	—	—	—	—	—	—	—
	Post	7.00	125	5.00	117	71	3.46	98	—	—	—	—	—	—	—
7/13/2018	Pre	7.38	132	4.91	114	67	2.80	80	—	—	—	—	—	—	—
	Post	7.26	130	5.02	117	69	3.15	89	—	—	—	—	—	—	—
5/30/2018	Pre	6.66	119	4.79	112	72	3.40	96	—	—	—	—	—	—	—
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4/30/2018	Pre	7.28	130	5.11	119	70	3.41	96	—	—	—	—	—	—	—
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4/17/2018	Pre	7.47	133	5.20	121	70	3.41	96	—	—	—	—	—	—	—
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—

ComPAS Version: v2018.1.0 (Build 0) Calibration Date: 9/27/2018 Calibration Data: Temp: 27ºC PBar: 757mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 2 of 2

8.9.2 Full PFT Report Example 1

Full PFT Report_1

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject ID: 134732 Test date/time: 9/27/2018 3:14:53 PM
Height at test: 75 in
Weight at test: 211.53 lb Sex: M Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6 Smoking history (pk-yrs): N/A Ethnic group: C
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated Referring Physician:

Spirometry

Parameter	Units		Pred	LLN	Pre	% Pred	Z-score	Post	% Pred	Z-score	% Chg
FVC		L	5.58	4.28	7.21	129	2.03	7.38	132	2.24	2
FEV_1		L	4.28	3.25	4.99	117	1.20	5.10	119	1.39	2
FEV_1 / FVC		%	77	65	69	90	-1.16	69	90	-1.16	0
FEF_{25-75} [SO]		L/s	3.51	1.76	3.21	91	---	3.52	100	---	10
PEFR		L/s	10.48	7.84	12.48	119	---	12.65	121	---	1
FET		s		6.00	11.77		---	11.37		---	-3
MVV		L/min	160.1	103.3	180.0	112	---			---	

Multi Breath N2

Parameter	Units		Pred	LLN	Pre	% Pred	Z-score
TLC		L	8.10	6.95	11.50	142	4.86
VC		L	5.58	4.28	7.43	133	2.33
RV		L	2.54	1.86	4.07	160	3.73
RV/TLC		%	37	32	35	95	-0.37
FRC		L	3.88	2.89	6.35	164	4.12
ERV		L	1.34	0.93	2.28	170	---
LCI							---

Diffusing Capacity

Parameter	Units		Pred	LLN	Pre	% Pred	Z-score
DLCO [Unc]		mL/min/mmHg	32.53	24.50	33.15	102	0.12
DLCO [Cor]		mL/min/mmHg	33.34	24.50	33.15	99	0.12
Kco		mL/min/mmHg/L	4.22	3.21	3.68	87	-0.86
VA [BTPS]		L	7.76	6.26	9.02	116	1.30
VI [BTPS]		L	5.58	4.28	6.97	125	---
Diffusion Time		s			9.73		---

Muscle Force

Parameter	Units	Pred	LLN	Pre	% Pred	Z-score
MIP	cmH_2O	83	51	49	59	---
MEP	cmH_2O	128	54			---

PF Reference: Spirometry (3-5): Eigerv/Bieler, (6-7), GLI & Knudson (8-95); Lung Volumes: Quanjer; DLCO: GLI
Calibration Date: 9/27/2018 Calibration Data: Temp: 27°C PBar: 757mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 1 of 5

Trend Results

Test series date		FVC	%Prd	FEV_1	%Prd	Ratio	FEF_{25-75}	%Prd	TLC	%Prd	FRC	%Prd	RV/TLC	DLCO	%Prd
9/27/2018	Pre	7.21	129	4.99	117	69	3.21	91	11.50	142	6.35	164	35	33.15	102
	Post	7.38	132	5.10	119	69	3.30	94	—	—	—	—	—	—	—
9/13/2018	Pre	7.61	136	5.31	124	70	3.45	98	—	—	—	—	—	—	—
	Post	7.49	134	5.29	124	71	3.54	101	—	—	—	—	—	—	—
9/12/2018	Pre	7.42	133	5.27	123	72	3.40	97	—	—	—	—	—	0.41	1
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—
7/19/2018	Pre	6.99	125	5.10	119	73	3.77	107	—	—	—	—	—	—	—
	Post	7.06	126	5.13	120	73	3.71	105	—	—	—	—	—	—	—
7/17/2018	Pre	7.00	125	4.84	113	69	3.00	85	—	—	—	—	—	—	—
	Post	7.00	125	5.00	117	71	3.46	98	—	—	—	—	—	—	—
7/13/2018	Pre	7.38	132	4.91	114	67	2.80	80	—	—	—	—	—	—	—
	Post	7.26	130	5.02	117	69	3.15	89	—	—	—	—	—	—	—
6/30/2018	Pre	6.66	119	4.79	112	72	3.40	96	—	—	—	—	—	—	—
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4/30/2018	Pre	7.28	130	5.11	119	70	3.41	96	—	—	—	—	—	—	—
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4/17/2018	Pre	7.47	133	5.20	121	70	3.41	96	—	—	—	—	—	—	—
	Post	—	—	—	—	—	—	—	—	—	—	—	—	—	—

Six Minute Walk Study

		Resting	1 min	2 min	3 min	4 min	5 min	6 min	Max	Recovery Min 1	Min 2	Min 3
SpO2	(%)	98.2	97.8	97.0	96.9	96.6	96.5	96.5		97.0	98.1	98.1
HR	(bpm)	60	65	69	78	79	89	91		96	81	72
BP	(mmHg)	/							/			
Dyspnea	(1 - 10)	---	---	---	---	---	---	---	3			
Fatigue	(1 - 10)	---							---			

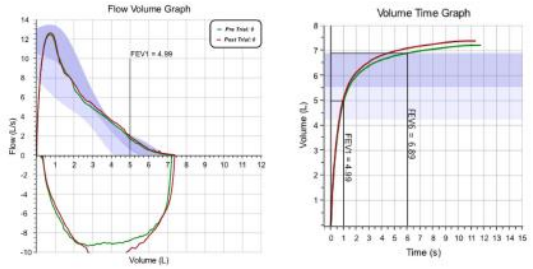
Actual 6MW distance: 778 meters
Predicted distance: 669 meters
Percent of predicted: 116 %

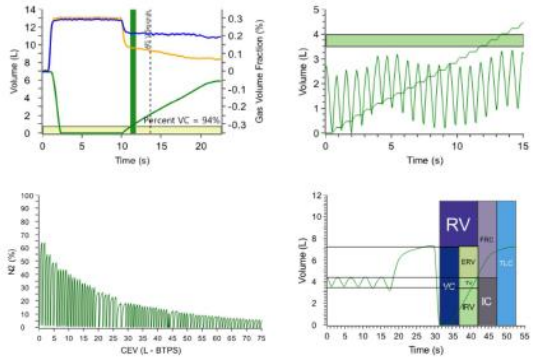
ABG Table

Allen Test: Left Hand - Negative

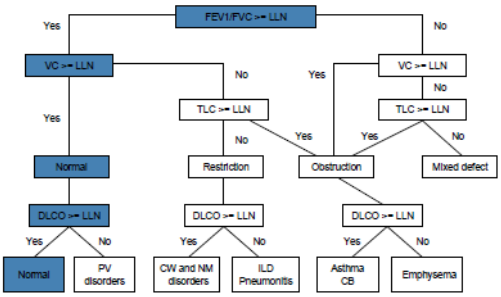
		O2 Liter Flow	Respiratory Rate b/min	pH 7.35 to 7.45	PaCO2 35 to 45 mmHg	PaO2 80 to 100 mmHg	HCO3- 22 to 26 mEq/L	O2 Sat 93 to 97.5 %	AaDO2 5 to 15 mmHg
Rest	(Room Air)	None		7.40	37.0	96.0	23.0	98.0	6.8

PF Reference: Spirometry (3-5): Eigerv/Bieler, (6-7), GLI & Knudson (8-95); Lung Volumes: Quanjer; DLCO: GLI
Calibration Date: 9/27/2018 Calibration Data: Temp: 27°C PBar: 757mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 2 of 5





PF Reference: Spirometry (3-5): Eigerv/Bieler, (6-7), GLI & Knudson (8-95); Lung Volumes: Quanjer; DLCO: GLI
Calibration Date: 9/27/2018 Calibration Data: Temp: 27°C PBar: 757mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 3 of 5



Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Interpretation:

PF Reference: Spirometry (3-5): Eigerv/Bieler, (6-7), GLI & Knudson (8-95); Lung Volumes: Quanjer; DLCO: GLI
Calibration Date: 9/27/2018 Calibration Data: Temp: 27°C PBar: 757mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 5 of 5

8.9.3 ATS 2017 PFT Report 1

ATS PFT Report

Pulmonary Function Report
Morgan Scientific, Inc
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

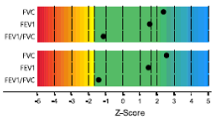
Patient Information

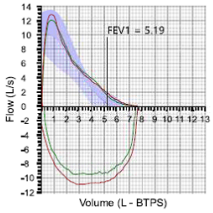
Name: Test K. Subject ID: 134732 Test date/time: 10/16/2018 12:17:17 PM
Height at test: 75 in
Weight at test: 210.32 lb Sex: M Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.4 Smoking history (pk-yrs): N/A Ethnic group: C
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated Referring Physician:

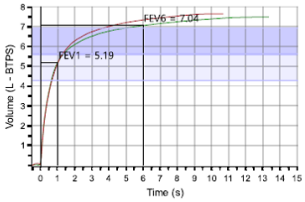
Dynamic Spirometry

Parameter	Units	Pre-Bronchodilator Result	LLN	Z-score	% Pred	Post-Bronchodilator Result	Z-score	% Pred	% Chg
FVC	L	7.47	4.28	2.36	134	7.63	2.55	137	2
FEV_1	L	5.19	3.25	1.55	121	5.15	1.48	120	-1
FEV_1 / FVC	%	69	65	-1.16	90	67	-1.43	87	-3
FET	s	13.37	6.00	---		10.71	---		-20

Reference values: GLI 2017; Test Quality: Effort Met



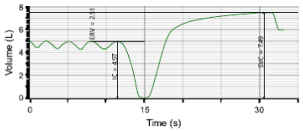




Static Spirometry

Parameter	Units	Pre-Bronchodilator Result	LLN	Z-score	% Pred
SVC	L	7.49	4.28	2.39	134
IC	L	4.97	2.78	---	117
ERV	L	2.51	0.93	---	187
FEV1o5VC			65	---	

Reference values: GLI 2017; Test Quality: Effort Met

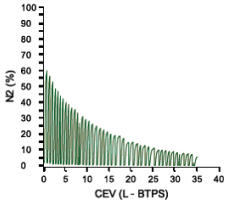


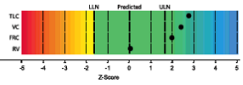
ComPAS Version: v2018.1.0 (Build 0) Calibration Date: 10/16/2018 Calibration Data: Temp: 23ºC PBar: 768mmHg BTPS: 1.084
Patient: Subject, Test K. Test Date: 10/16/2018 Page: 1 of 3

Multiple Breath N2

Parameter	Units	Pre-Bronchodilator Result	LLN	ULN	Z-score	% Pred
TLC	L	10.04	6.95	9.26	2.77	124
VC	L	7.47	4.28	6.90	2.38	134
RV	L	2.57	1.86	3.21	0.08	101
RV/TLC	%	26	31	42	-2.02	70
FRC	L	5.07	2.89	4.87	1.98	131
ERV	L	2.50	0.93	1.75	---	187
LCI		6.92			---	
M0		1.27			---	
M1		3.35			---	

Reference values: Gutierrez 2004; Test Quality: Acceptability Met

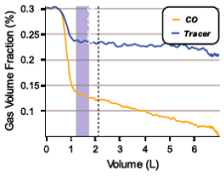


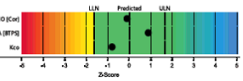


Diffusing Capacity

Parameter	Units	Pre-Bronchodilator Result	LLN	ULN	Z-score	% Pred
DLCO [Unc]	mL/min/mmHg	31.92	24.49	41.98	-0.11	98
DLCO [Cor]	mL/min/mmHg	31.92	24.49	41.98	-0.11	95
Kco	mL/min/mmHg/L	3.71	3.21	5.32	-0.80	88
VA [BTPS]	L	8.59	6.26	9.36	0.87	111
V1 [BTPS]	L	7.75	4.28	6.90	---	139
Diffusion Time	s	10.91			---	

Reference values: GLI 2017; Test Quality: A PB: 768mmHg

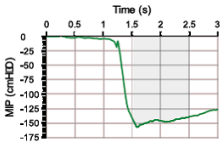




Respiratory Pressures

Parameter	Units	Pre-Bronchodilator Result	LLN	ULN	Z-score	% Pred
MIP	cmH-O	147	51	115	---	177
PIP	cmH-O	157			---	
MEP	cmH-O		54	202	---	
PEP	cmH-O				---	

Reference values: Wilson 1984; Test Quality: Acceptability Met



ComPAS Version: v2018.1.0 (Build 0) Calibration Date: 10/16/2018 Calibration Data: Temp: 23ºC PBar: 768mmHg BTPS: 1.084
Patient: Subject, Test K. Test Date: 10/16/2018 Page: 2 of 3

Trend Results

Test series date		FVC	%Prd	FEV1	%Prd	Ratio	FEF25-75	%Prd	TLC	%Prd	FRC	%Prd	RV/TLC	DLCO	%Prd
10/16/2018	Pre	7.47	134	5.19	121	69	3.18	91	10.04	124	5.07	131	26	31.92	98
	Post	7.63	137	5.15	120	67	3.18	91	---	---	---	---	---	---	---
10/15/2018	Pre	7.43	133	5.20	121	70	3.32	95	9.49	117	5.56	143	21	37.82	116
	Post	7.48	134	5.06	118	68	3.07	88	---	---	---	---	---	---	---
10/12/2018	Pre	7.30	131	5.15	120	71	3.43	98	---	---	---	---	---	---	---
	Post	7.14	128	5.13	120	72	3.58	102	---	---	---	---	---	---	---
10/6/2018	Pre	7.28	130	4.92	115	68	2.91	83	10.75	133	5.46	141	30	---	---
	Post	---	---	---	---	---	---	---	---	---	---	---	---	---	---
10/5/2018	Pre	7.34	132	5.20	121	71	3.54	101	---	---	---	---	---	---	---
	Post	7.36	132	5.11	119	69	3.24	92	---	---	---	---	---	---	---
10/2/2018	Pre	7.34	132	5.10	119	71	3.08	88	---	---	---	---	---	---	---
	Post	7.29	131	5.09	119	70	3.33	95	---	---	---	---	---	---	---
10/1/2018	Pre	6.29	113	4.68	109	74	3.70	105	---	---	---	---	---	---	---
	Post	---	---	---	---	---	---	---	---	---	---	---	---	---	---
9/27/2018	Pre	7.21	129	4.99	117	69	3.21	91	10.76	133	5.61	145	31	33.14	102
	Post	7.38	132	5.10	119	69	3.30	94	---	---	---	---	---	---	---
9/13/2018	Pre	7.61	136	5.31	124	70	3.45	98	---	---	---	---	---	---	---
	Post	7.49	134	5.29	124	71	3.54	101	---	---	---	---	---	---	---

Technologist Comments:
Test of the Full PFT Report 8

Computer Impression:

Normal spirometric values indicate the absence of any significant degree of obstructive pulmonary impairment and/or restrictive ventilatory defect.

Bronchodilator therapy was administered followed by repeat spirometric testing. Post-bronchodilator testing failed to demonstrate a significant change in FVC, FEV1, or FEF 25-75. This indicates that this patient may not benefit from continued bronchodilator therapy.
The total lung capacity is increased indicating hyperinflation. The carbon monoxide diffusing capacity is normal indicating normal alveolar-capillary surface area for gas exchange. The arterial PCO2 is normal. Acid-base status is normal.

The MVV is consistent with the level of FEV1.

ComPAS Version: v2018.1.0 (Build 0) Calibration Date: 10/16/2018 Calibration Data: Temp: 23ºC PBar: 768mmHg BTPS: 1.084
Patient: Subject, Test K. Test Date: 10/16/2018 Page: 3 of 3

8.9.4 Full PFT Report 11

Full PFT Report 11

Pulmonary Function Report
Morgan Scientific Inc
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Name: Test K. Subject **ID:** 134732 **Test date/time:** 4/29/2020 8:26:11 AM

Reference Value Inputs
Birth Sex: **M** Birthdate: **12/20/1960**
Gender: **Male** Age at test: **59**
Ref Group: **C** Height at test: **75 in**
Ethnicity: **Caucasian** Weight at test: **216.4 lb**

Smoking Considerations:
Smoking history (pk-yrs): **N/A**
Estimated Lung Age: **N/A**
BMI at test: **27.2 kg/m²**

Diagnoses: **ICD-10:**
1:
2:
3:

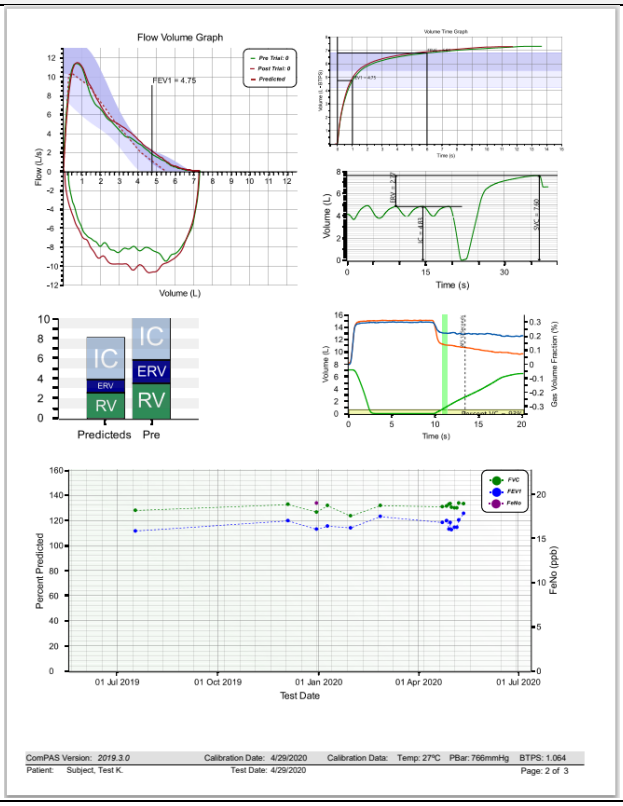
Clinical Personnel:
Attending Physician:
Referring Physician:
Technologist:

Spirometry at BTPS		Pre	Pred	LLN	% Pred.	Z-Score	Post	Pred.	% Chg.	Z-Score
FEV_1	L	4.75	3.18		113		4.95	118	4	
FVC	L	7.32	4.21		133		7.29	132	0	
FEV_1 / FVC	%	65	65				68		5	
FEF_{25-75}	L/s	2.73	1.68		80		3.13	92	15	
FEF_{25}	L/s	6.79	5.26		75		7.47	83	10	
FEF_{50}	L/s	3.45	3.15		65		4.01	76	16	
FEF_{75}	L/s	1.06	0.90		52		1.13	55	7	
PEFR	L/s	11.40	7.74		110		11.51	111	1	
FEF_{50}/FIF_{50}		43.73					38.63		-12	

Lung Volumes		Pre	Pred	LLN	% Pred.	Z-Score
TLC	L	10.33	6.95		128	
FRC	L	5.64	2.90		145	
ERV	L	2.29	0.92		172	
RV	L	3.54	1.88		138	
RV/TLC	%	34	32		92	
VC	L	6.79	4.21		123	

Diffusing Capacity		Pre	Pred	LLN	% Pred.	Z-Score
DLCO [Unc]	mL/min/mmHg	32.15	24.19		100	
Kco	mL/min/mmHg/L	3.67	3.17		88	
VA [BTPS]	L	8.90	6.24		115	
VI [BTPS]	L	7.06	4.21		128	
Diffusion Time	s	9.95				

ComPAS Version: *2019.3.0* Calibration Date: 4/29/2020 Calibration Data: Temp: 27ºC PBar: 766mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 4/29/2020 Page: 1 of 3



Parameter	Units	Today's Test 4/29/2020	% Ref	Previous Test Results - Most Recent to Past 4/27/2020	% Ref	4/23/2020	% Ref	2/26/2020	% Ref	1/30/2020	% Ref
FVC	L	7.32	(133)	7.22	(131)	7.21	(131)	7.27	(132)	6.81	(123)
FEV_1	L	4.75	(113)	5.03	(119)	4.98	(118)	5.19	(123)	4.81	(114)
TLC	L	10.33	(128)	---	---	9.64	(119)	9.24	(114)	10.91	(135)
DLCO [Unc]	mL/min/mmHg	32.15	(100)	---	---	31.95	(99)	28.37	(88)	---	---

Technologist Comments:
Not Implemented

Interpretation:
Not Implemented

ComPAS Version: *2019.3.0* Calibration Date: 4/29/2020 Calibration Data: Temp: 27ºC PBar: 766mmHg BTPS: 1.064
Patient: Subject, Test K. Test Date: 4/29/2020 Page: 3 of 3

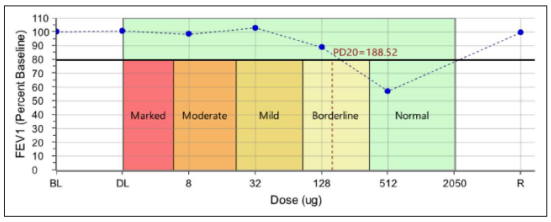
8.9.5 Bronchial Challenge Report Example

Challenge ERS 2017 Report3

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	ID: 134732	Test date/time: 9/13/2018 1:40:18 PM
Height at test: 75 in		
Weight at test: 207.9 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.1	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:



Challenge Grade: *PD20 of 188.52 indicates borderline airway hyper-responsiveness*

Stage	Dosage	FVC	% BL	FEV1	% BL	Level Notes
Baseline		7.61		5.31		
Diluent		7.43	-2	5.35	1	0
Level 1	8	7.36	-3	5.22	-2	1 *No reaction at this level*
Level 2	32	7.30	-4	5.47	3	2
Level 3	128	6.71	-12	4.72	-11	3
Level 4	512	4.76	-37	3.03	-43	4
Level 5	2050	---	---	---	---	5
Recovery	Albuterol	7.49	-2	5.29	---	

ComPAS Version: *v2018.1.0 (Build 0)* Calibration Date: 9/13/2018 Calibration Data: Temp: 21ºC PBar: 758mmHg BTPS: 1.094
Patient: Subject, Test K. Test Date: 9/13/2018 Page: 1 of 2

Technologist Comments:
Example of technician notes for the challenge report.

Preliminary Impression:
An FEV1/FVC Ratio of 91% predicted is normal. Spirometry is within normal limits. Exhaled volume within normal limits. Lung Volume study not done. Diffusion study not done. After Bronchodilator, values either decreased or are essentially unchanged. (Note: A lack of response to Bronchodilators does not preclude their use).

ComPAS Version: *v2018.1.0 (Build 0)* Calibration Date: 9/13/2018 Calibration Data: Temp: 21ºC PBar: 758mmHg BTPS: 1.094
Patient: Subject, Test K. Test Date: 9/13/2018 Page: 2 of 2

8.9.6 Mannitol Challenge Report Example

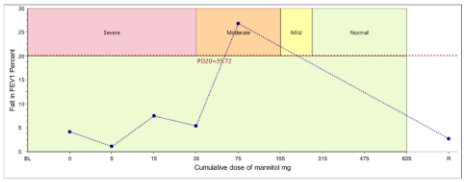
Mannitol Challenge Report 1

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	ID: 134732	Test date/time: 5/17/2021 9:27:38 AM
Height at test: 75 in		
Weight at test: 216.41 lb	Birth Sex: M Gender: Male	Birthdate: 12/20/1960 Age at test: 60
BMI at test: 27.2 kg/m²	Smoking history (pk-yrs): N/A Predicted Group: C	Ethnicity: Caucasian
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: ()		Referring Dr:

Mannitol Challenge Test



Challenge Grade: *PD15 of 35.72 indicates moderate airway hyper-responsiveness.*

Mannitol Challenge: Baseline Compares each level to Baseline

Dose	0 mg/ml	5 mg/ml	10 mg/ml	20 mg/ml	40 mg/ml	80 mg/ml	160 mg/ml	160 mg/ml	160 mg/ml		
Cumulative	0 mg/ml	5 mg/ml	15 mg/ml	35 mg/ml	75 mg/ml	155 mg/ml	315 mg/ml	475 mg/ml	635 mg/ml		Recovery
Parameter	Pre	%BL	1	%BL	2	%BL	3	%BL	4	%BL	5	%BL	6	%BL	7	%BL	8	%BL	Post	%BL
FVC	6.98		6.74	100	6.45	96	6.55	97	6.55	97	6.25	93	----	----	----	----	----	----	6.97	100
FEV_1	4.85		4.65	100	4.80	103	4.49	97	4.59	99	3.55	76	----	----	----	----	----	----	4.72	97
FEV_1 / FVC	69		69	100	74	107	69	100	70	101	57	83	----	----	----	----	----	----	68	99
FEF_{25-75}	2.91		2.89	100	3.73	129	2.81	97	3.19	110	1.71	59	----	----	----	----	----	----	2.81	97

Mannitol Challenge: Previous Level Compares each level to previous level *Recovery*

Parameter	Pre	%Ch	1	%Ch	2	%Ch	3	%Ch	4	%Ch	5	%Ch	6	%Ch	7	%Ch	8	%Ch	Post	%BL
FEV_1	4.85		4.65	96	4.80	103	4.49	94	4.59	102	3.55	77	----	----	----	----	----	----		

ComPAS Version: *2021.1.0* Calibration Date: 5/17/2021 Calibration Data: Temp: 25ºC PBar: 760mmHg BTPS: 1.077
Patient: Subject, Test K. Test Date: 5/17/2021 Page: 1 of 2

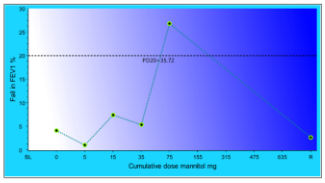
Mannitol Challenge Report 2

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	ID: 134732	Test date/time: 5/17/2021 9:27:38 AM
Height at test: 75 in		
Weight at test: 216.41 lb	Birth Sex: M Gender: Male	Birthdate: 12/20/1960 Age at test: 60
BMI at test: 27.2 kg/m²	Smoking history (pk-yrs): N/A Predicted Group: C	Ethnicity: Caucasian
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: ()		Referring Dr:

Mannitol Challenge Test



Challenge Grade: *PD15 of 35.72 indicates moderate airway hyper-responsiveness.*

Mannitol Challenge: Baseline Compares each level to Baseline

Dose	0 mg/ml	5 mg/ml	10 mg/ml	20 mg/ml	40 mg/ml	80 mg/ml	160 mg/ml	160 mg/ml	160 mg/ml		
Cumulative	0 mg/ml	5 mg/ml	15 mg/ml	35 mg/ml	75 mg/ml	155 mg/ml	315 mg/ml	475 mg/ml	635 mg/ml		Recovery
Parameter	1	%BL	2	%BL	3	%BL	4	%BL	5	%BL	6	%BL	7	%BL	8	%BL	9	%BL	Post	%BL
FVC	6.74	100	6.45	96	6.55	97	6.55	97	6.25	93	----	----	----	----	----	----	----	----	6.97	100
FEV_1	4.65	100	4.80	103	4.49	97	4.59	99	3.55	76	----	----	----	----	----	----	----	----	4.72	97
FEV_1 / FVC	69	100	74	107	69	100	70	101	57	83	----	----	----	----	----	----	----	----	68	99
FEF_{25-75}	2.89	100	3.73	129	2.81	97	3.19	110	1.71	59	----	----	----	----	----	----	----	----	2.81	97

Mannitol Challenge: Previous Level Compares each level to previous level *Recovery*

Parameter	1	%Ch	2	%Ch	3	%Ch	4	%Ch	5	%Ch	6	%Ch	7	%Ch	8	%Ch	9	%Ch	Post	%BL
FEV_1	4.65	96	4.80	103	4.49	94	4.59	102	3.55	77	----	----	----	----	----	----	----	----	4.72	97

ComPAS Version: *2019.3.0* Calibration Date: 5/17/2021 Calibration Data: Temp: 26ºC PBar: 760mmHg BTPS: 1.077
Patient: Subject, Test K. Test Date: 5/17/2021 Page: 1 of 2

8.9.7 Exercise Challenge Report Example

Exercise Challenge Report

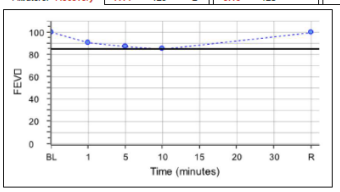
Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

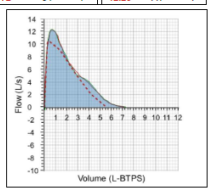
Patient Information

Name: Test K. Subject	ID: 134732	Test date/time: 10/12/2018 1:43:46 PM
Height at test: 75 in		
Weight at test: 210.32 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.4	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:

Exercise Induced Asthma Challenge Test

Time	Stage	Pred = 5.58 FVC	% Pred	% Chg	Pred = 4.28 FEV1	% Pred	% Chg	Pred = 77 FEV1/FVC	% Pred	% Chg	Pred = 10.48 PEFR	% Pred	% Chg
	Baseline	7.30	131	---	5.15	120	---	71	92	---	12.34	118	---
1.00 min	Stage 1	6.53	117	-11	4.67	109	-9	72	94	1	12.20	116	-1
5:00 min	Stage 2	6.43	115	-12	4.49	105	-13	70	91	-1	11.55	110	-6
10:00 min	Stage 3	5.49	98	-25	4.37	102	-15	80	104	13	10.52	100	-15
15:00 min	Stage 4	---	---	---	---	---	---	---	---	---	---	---	---
20:00 min	Stage 5	---	---	---	---	---	---	---	---	---	---	---	---
30:00 min	Stage 6	---	---	---	---	---	---	---	---	---	---	---	---
Albuterol	Recovery	7.14	128	-2	5.13	120	---	72	94	1	12.25	117	-1



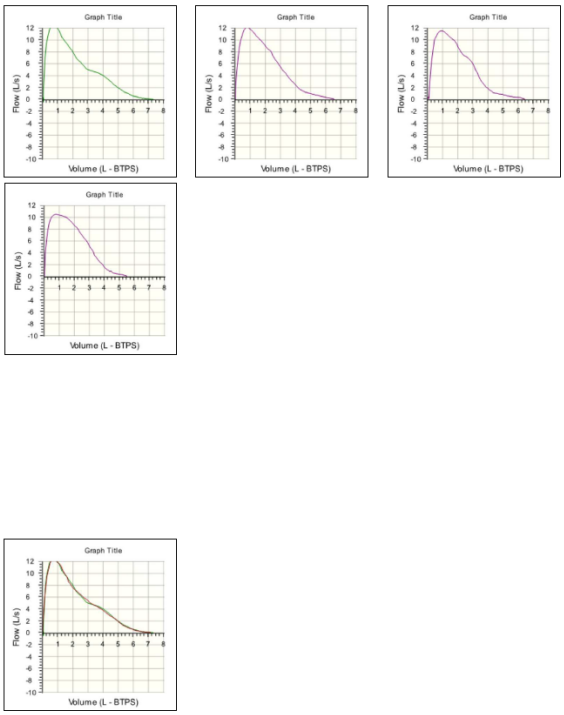


Technologist Comments:
Example EIA test.

Preliminary Impression:
An FEV1/FVC Ratio of 92% predicted is normal. Spirometry is within normal limits. Exhaled volume within normal limits. Lung Volume study not done. Diffusion study not done. After Bronchodilator, values either decreased or are essentially unchanged. (Note: A lack of response to Bronchodilators does not preclude their use).

ComPAS Version: *v2018.1.0 (Build 0)* Calibration Date: 10/12/2018 Calibration Data: Temp: 24ºC PBar: 759mmHg BTPS: 1.081
Patient: Subject, Test K. Test Date: 10/12/2018 Page: 1 of 2

Per-Stage Flow vs. Volume



ComPAS Version: *v2018.1.0 (Build 0)* Calibration Date: 10/12/2018 Calibration Data: Temp: 24ºC PBar: 759mmHg BTPS: 1.081
Patient: Subject, Test K. Test Date: 10/12/2018 Page: 2 of 2

8.9.8 ABG and HAST Report Examples

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	ID: 134732	Test date/time: 9/27/2018 3:14:53 PM
Height at test: 75 in		
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:

Arterial Blood Gases

Parameter		Normal Values	Resting Values	Resting 2 Values	Exercise Values
pH	units	7.35 to 7.45	7.40	---	---
$PaCO_2$	mmHg	35 to 43	37.0	---	---
PaO_2	mmHg	>65	96.0	---	---
HCO_3^-	mEq/L	18 to 26	23.0	---	---
B.E.	mEq/L	-3.0 to +3.0	-2.1	---	---
SaO_2	%	>92	98.0	---	---
FIO_2	%	21	---	---	---
Hb	gm %	12 to 16	13.8	---	---

ABG Site Information:

Pressure applied per best practices: Yes
Established after following attempts: 1
Draw site successfully established: Yes (on the left side) Location:

Complications Encountered:

Corrective Actions:

Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Pulmonary Function
151 Essex Street
Haverhill, MA 01832
Phone: (978) 521-4440

Date: 10/8/2018

Name: Test K. Subject	Birth Date: 12/20/1960	Age: 57 BMI: 26.4
MR #: 134732 AC #:	Race: C	Smoker: N Pack yrs: N/A
Diagnosis:	Gender: M	
Attending Physician: Colin Chapman, M.D.	Height: 190.5 cm	75 in
Referring Physician:	Weight: 95.4 Kg	210.32 lb
Therapist: Patrick Morgan		

Hypoxia Altitude Simulation Test (HAST)

Patient was referred for a Hypoxia Altitude Simulation Test.
After measuring Oximetry at rest with FiO2 of 21% (room air at sea level), we proceed the simulation with FiO2 15% (equivalent to 8,000 feet above sea level or cabin pressure in comercial flight). The test was performed with the patient at rest and during ambulation.

Activity	HR (b/min)	SpO2 %	FiO2	Supplemental O2 (L/min)
Resting Oximetry, Minute 3	64	94.0	0.21	
Resting Oximetry, Minute 5	64	85.0	0.15	
Resting Oximetry, O2 titration	65	93.0	0.15	1.0
Ambulatory Oximetry	87	85.0	0.15	1.0
Ambulatory Oximetry, O2 titration	71	91.0	0.15	3.0
Recovery, Minute 1	65	98.0	0.15	

Technologist Comments:
HAST test

8.9.9 Cystic Fibrosis Screening Report with FEV1 Alert Example

ATS 2017 CF Screening Report

Pulmonary Function Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

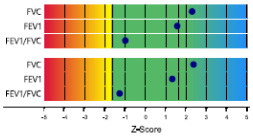
Name: Test K. Subject	ID: 134732	Test date/time: 10/15/2018 10:15:50 AM
Height at test: 75 in		
Weight at test: 210.32 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.4	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Matt Barnes
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:

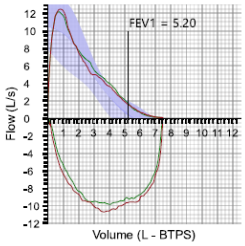
Spirometry

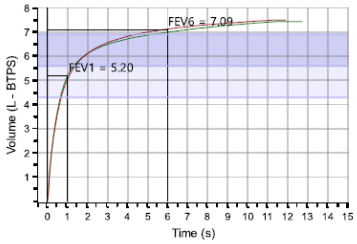
Δ in FEV1 Percent Predicted
FEV1 decreased ≥10% of baseline
FEV1 decreased 5-9% of baseline
FEV1 is at baseline

Parameter	Units	Pre-Bronchodilator Result	LLN	Z-score	% Pred	Post-Bronchodilator Result	Z-score	% Pred	% Chg
FVC	L	7.43	4.28	2.30	133	7.48	2.37	134	1
FEV_1	L	5.20	3.25	1.56	121	5.06	1.33	118	-3
FEV_1 / FVC	%	70	65	-1.03	91	68	-1.30	88	-3
FET	s	12.75	6.00	---		11.92	---		-7

Reference values: GLI 2017; Test Quality: Repeatability Met



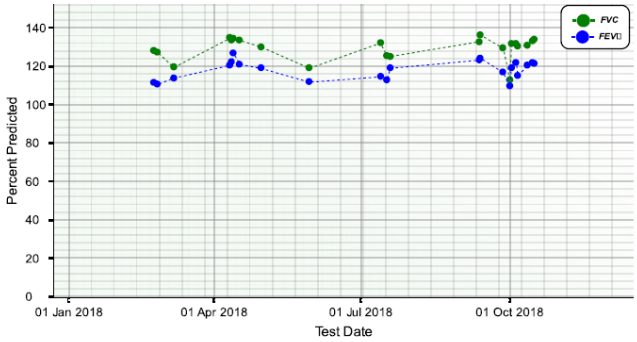




Technologist Comments:
Good effort.

Preliminary Impression:
An FEV1/FVC Ratio of 91% predicted is normal. Spirometry is within normal limits. Lung volumes are within normal limits. Diffusion study not done. After Bronchodilator, values either decreased or are essentially unchanged. (Note: A lack of response to Bronchodilators does not preclude their use).

ComPAS Version: *v2018.1.0 (Build 0)* Calibration Date: 10/15/2018 Calibration Data: Temp: 17ºC PBar: 760mmHg BTPS: 1.118
Patient: Subject, Test K. Test Date: 10/15/2018 Page: 1 of 2



Trend Results

Test series date		FVC	%Prd	FEV1	%Prd	Ratio	FEF25-75	%Prd	TLC	%Prd	FRC	%Prd	RV/TLC	DLCO	%Prd
10/15/2018	*Pre*	7.43	133	5.20	121	70	3.32	95	10.08	124	6.15	159	26	37.94	117
	Post	7.48	134	5.06	118	68	3.07	88	---	---	---	---	---	---	---
10/12/2018	*Pre*	7.30	131	5.15	120	71	3.43	98	---	---	---	---	---	---	---
	Post	7.14	128	5.13	120	72	3.58	102	---	---	---	---	---	---	---
10/6/2018	*Pre*	7.28	130	4.92	115	68	2.91	83	12.31	152	7.02	181	39	---	---
	Post	---	---	---	---	---	---	---	---	---	---	---	---	---	---
10/5/2018	*Pre*	7.34	132	5.20	121	71	3.54	101	---	---	---	---	---	---	---
	Post	7.36	132	5.11	119	69	3.24	92	---	---	---	---	---	---	---
10/2/2018	*Pre*	7.34	132	5.10	119	71	3.08	88	---	---	---	---	---	---	---
	Post	7.29	131	5.09	119	70	3.33	95	---	---	---	---	---	---	---
10/1/2018	*Pre*	6.29	113	4.68	109	74	3.70	105	---	---	---	---	---	---	---
	Post	---	---	---	---	---	---	---	---	---	---	---	---	---	---
9/27/2018	*Pre*	7.21	129	4.99	117	69	3.21	91	11.50	142	6.35	164	35	33.14	102
	Post	7.38	132	5.10	119	69	3.30	94	---	---	---	---	---	---	---
9/13/2018	*Pre*	7.61	136	5.31	124	70	3.45	98	---	---	---	---	---	---	---
	Post	7.49	134	5.29	124	71	3.54	101	---	---	---	---	---	---	---
9/12/2018	*Pre*	7.42	133	5.27	123	72	3.40	97	---	---	---	---	---	0.41	1
	Post	---	---	---	---	---	---	---	---	---	---	---	---	---	---

ComPAS Version: *v2018.1.0 (Build 0)* Calibration Date: 10/15/2018 Calibration Data: Temp: 17ºC PBar: 760mmHg BTPS: 1.118
Patient: Subject, Test K. Test Date: 10/15/2018 Page: 2 of 2

8.9.10 Spirometry Study Report Example

Study Summary Report 2

Pulmonary Function Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

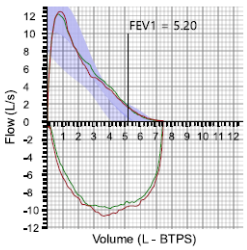
Patient

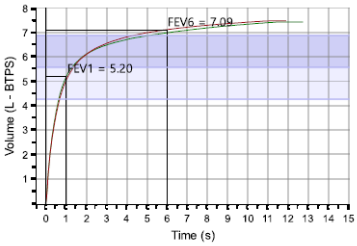
Patient ID: Test K. Subject Site Number: Test date/time: 10/15/2018 10:15:50 AM
Height at test: 75 in Gender: M
Weight at test: 210.32 lb Age at test: 57 Birthdate: 12/20/1960 Technician: Matt Barnes
Race: Caucasian Predicted set: ATS/ERS 2005 with GLI

Technician Notes:

Good effort.

Results					BD Administration Time:			
Result		Pred	Pre	% Prd	Post	% Prd	%Chg	Abs Chg
StartTime								
FVC	L	5.58	7.43	133	7.48	134	1	51 mL
FEV_1	L	4.28	5.20	121	5.06	118	-3	-136 mL
FEV_1 / FVC	%	77	70	91	68	88	-3	
FET	s		12.75		11.92		-7	
EV	L		0.13		0.11		-15	-16 mL

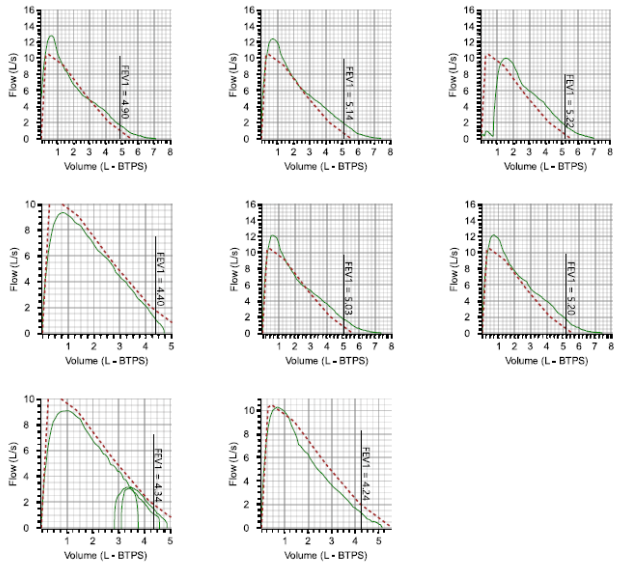




Calibration Data: Mean Volume (L) *Date and Time of cal*
Patient: Subject, Test K. Test Date: 10/15/2018 Page: 1 of 3

Summary of all Pre Efforts																			
Ordered by ATS (Best sum):		Pred	Best	%	2nd	%	3rd	%	4th	%	5th	%	6th	%	7th	%	8th	%
FVC	L	5.58	7.40	133	7.43	133	7.35	132	6.99	125	7.19	129	5.14	92	4.87	87	4.72	85
FEV1	L	4.28	5.14	120	5.20	121	5.03	118	5.22	122	4.90	114	4.24	99	4.34	101	4.40	103
FEV1/FVC	%	77	69	90	70	91	68	88	75	97	68	88	82	106	89	116	93	121
FEF25-75	L/s	3.50	3.38	97	3.32	95	3.13	89	4.16	119	2.98	85	4.10	117	1.62	46	5.54	158
PEFR	L/s	10.48	12.39	118	12.19	116	12.13	116	10.00	95	12.81	122	10.30	98	9.07	87	9.35	89
FET	s	----	11.03	----	12.75	----	12.94	----	5.83	----	13.82	----	2.92	----	3.70	----	1.58	----
Start of Test			Y		Y		Y		N		Y		Y		Y		Y	
End of Test			Y		Y		Y		Y		Y		Y		Y		Y	
Cough Free			Y		Y		Y		N		Y		Y		N		Y	
FET > 6 seconds			Y		Y		Y		N		Y		N		N		N	

Best Three Meets ATS Effort Meets ATS Repeatability



Calibration Data: Mean Volume (L) *Date and Time of cal*
Patient: Subject, Test K. Test Date: 10/15/2018 Page: 2 of 3

8.9.11 Six Minute Walk Report Examples

Six Minute Walk Report

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	**ID: 134732**	**Test date/time: 9/27/2018 3:14:53 PM**
Height at test: 75 in		
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:

Six-Minute Walk Test

		Baseline	End of Test	O2 (L/min)	
SBP	(mmHg)	120	122	Distance (feet)	778
DBP	(mmHg)	79	82	Last Test Date:	9/27/2018
HR	(bpm)	60		Last Test Distance:	
O2 Sat	(%)	98.2			
Dyspnea Index (Borg Scale):		----	3		

Reason stopped: None Specified

Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Six Minute Walk Report1

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	**ID: 134732**	**Test date/time: 9/27/2018 3:14:53 PM**
Height at test: 75 in		
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:

Six Minute Walk Study

		Resting	1 min	2 min	3 min	4 min	5 min	6 min	Max	Recovery Min 1	Recovery Min 2	Recovery Min 3
SpO2	(%)	98.2	97.8	97.0	96.9	96.6	96.5	96.5		97.0	98.1	98.1
HR	(bpm)	60	65	69	78	79	89	91		96	81	72
BP	(mmHg)	120 / 79							122 / 82			
Dyspnea	(1 - 10)	----	----	----	----	----	----	----	3			
Fatigue	(1 - 10)	----							----			

Actual 6MW distance:	778	meters
Predicted distance:	669	meters
Percent of predicted:	116	%

Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Interpretation:

Six Minute Walk Report3

Morgan Scientific, Inc.
Pulmonary Function
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Name: Test K. Subject	**ID: 134732**	**Test date/time: 9/27/2018 3:14:53 PM**
Height at test: 75 in Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
Diagnosis:		Referring Physician:

Six Minute Walk Study

		Resting	1 min	2 min	3 min	4 min	5 min	6 min	Recovery Min 1	Recovery Min 2	Recovery Min 3
SpO2	(%)	98.2	97.8	97.0	96.9	96.6	96.5	96.5	97.0	98.1	98.1
HR	(bpm)	60	65	69	78	79	89	91	96	81	72
BP	(mmHg	120 / 79						122 / 82			
Dyspnea	(1 - 10)							3			

Total distance walked in 6 minutes:	778	meters	*Supplemental oxygen during the test:*	***O2 Label Units***
Predicted distance:	669	meters	*Previous Test:*	
Percent of predicted:	116	%	Last Test Date: 9/27/2018	Last Test Distance:

Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Interpretation:

Six Minute Walk Report4

Pulmonary Function Report
Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	**ID: 134732**	**Test date/time: 9/27/2018 3:14:53 PM**
Height at test: 75 in		
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:

Six Minute Walk Test

Feet	Meters	Predicted	% Predicted	Average Speed
778	237	669	116	---- (MPH)

Parameter		Baseline	End of Walk	1 Min Post	At Recovery
Heart Rate	(BPM)	60		65	
SpO2	(%)	98.2		97.8	
Borg Dyspnea	(0 - 10)	----	3		
Borg Fatigue	(0 - 10)	----	----		
Blood Pressure	(mmHg)	120 / 79	122 / 82	/	/
Times	(H:min)	----	----	----	----

Resting period during the test: ---- (Secs)

Six Minute Walk Statement: This study shows a moderate degree of functional impairment

Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Interpretation:

8.9.12 CPET Report Examples

ComPAS2 provides ability to import breath by breath data from third-party CPET systems. Once those data are in ComPAS2 extraordinary report capability is available.

CPET graphs can be designed and presented with numerous options and there are extensive choices of tabular data designs.

For more advanced centers, there are also options for iCPET reporting including data and graphics for hemodynamics.

Here are just a couple of examples:

CPET Wasserman Report

CPET Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 **Phone: (978) 521-4440**

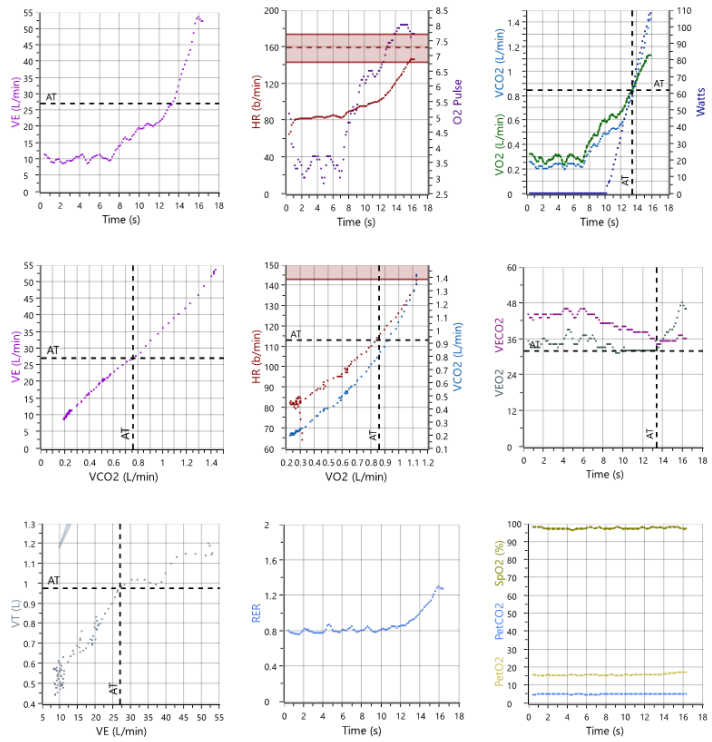
Patient Information

Name: Test K. Subject **ID: 134732** **Test date/time: 6/28/2021 4:06:15 PM**
Height at test: 75 in
Weight at test: 216.41 lb Birth Sex: M Gender: Male Birthdate: 12/20/1960 Age at test: 60
BMI at test: 27.2 kg/m² Smoking history (pk-yrs): N/A Predicted Group: C Ethnicity: Caucasian
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: () Referring Dr:

Exercise Duration: 8.67 Min **Perceived Exertion (Borg): B** - Borg

		Rest	AT	VO2 Max	Pred	AT/VO2 Max (%)	VO2 Max/Pred (%)
Time	(min)	3:50	13:25	15:30			
WORK							
Work	(watts)		62	107	237	58	
VENTILATION							
Vt BTPS	(L)	0.531	0.976	1.137	3.008	86	38
RR	(Br/min)	19	28	45		62	---
VE BTPS	(L/min)	9.8	27.1	51.4	110.0	53	47
BR	(%)	----	----	----		---	---
VD/VT (Est)		53	44	43		---	---
SpO2	(%)	97.2	97.8	97.7		100	---
O2 CONSUMPTION							
VO2	(ml/kg/min	2.9	8.6	11.5	27.7	75	42
VO2	(L/min)	0.28	0.86	1.13	2.72	76	42
VCO2	(L/min)	0.22	0.76	1.41	3.29	54	43
RER		0.79	0.93	1.24		75	102
METS		0.8	2.5	3.3	7.9	76	42
CARDIAC							
HR	(bpm)	81	113	142	159	80	89
VO2/HR	(mL/beat)	3.5	7.5	7.9	17.1	95	46
V/Q							
VE/VO2		35	32	45	40	71	113
VE/VCO2		44	35	37	----	95	112
PETO2	(mmHg)	108	110	120			
PETCO2	(mmHg)	32	35	32			
sysBP	(mmHg)	----	----	----			
diaBP	(mmHg)	----	----	----			

ComPAS Version: *2019.3.0* Calibration Date: 4/30/2021 Calibration Data: Temp: 23°C PBar: 760mmHg BTPS: 1.086
Patient: Subject, Test K. Test Date: 4/30/2021 Page: 1 of 4



ComPAS Version: *2019.3.0* Calibration Date: 4/30/2021 Calibration Data: Temp: 23°C PBar: 760mmHg BTPS: 1.086
Patient: Subject, Test K. Test Date: 4/30/2021 Page: 2 of 4

CPET Report 5

CPET Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

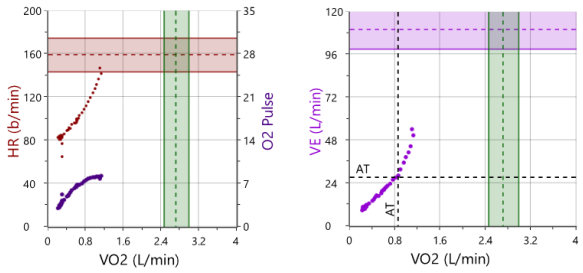
Name: Test K. Subject **ID: 134732** **Test date/time: 6/28/2021 4:06:15 PM**
Height at test: 75 in
Weight at test: 216.41 lb Birth Sex: M Gender: Male Birthdate: 12/20/1960 Age at test: 60
BMI at test: 27.2 kg/m² Smoking history (pk-yrs): N/A Predicted Group: C Ethnicity: Caucasian
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: 0 Referring Dr:

Measurement (peak)	Predicted	Measured	% Predicted
VO2 (l/min) IBW	4.08		
VO2 (l/min) ABW	2.72	**1.12**	42
HR (bpm)	159	**140**	89
Breathing Reserve (%)	20-40	**71**	
VE Max (l/min) BTPS	110.0	**48.5**	47

Spirometry	Predicted	Measured	% Predicted
FVC Liters	5.47	**7.20**	132
FEV1 Liters	4.17	**4.80**	115
MVV L/min	168		

Resting Data HR (bpm): **81** SpO2: **97.2** SPB (mmHg): **120** DPB (mmHg): **78**
Max Data HR (bpm): **140** SpO2: **97.0** SPB (mmHg): **135** DPB (mmHg): **87**

Predicted VO2 based on Actual Body Weight



ComPAS Version: 2019.3.0 Calibration Date: 4/30/2021 Calibration Data: Temp: 23°C PBar: 760mmHg BTPS: 1.086
Patient: Subject, Test K. Test Date: 4/30/2021 Page: 1 of 5

Measurement (peak)	Predicted	Measured	% Predicted
VO2 (l/min) IBW	4.08		
VO2 (l/min) ABW	2.72	**1.12**	42
HR (bpm)	159	**140**	89
Breathing Reserve (%)	20-40	**71**	
VE Max (l/min) BTPS	110.0	**48.5**	47

Spirometry	Predicted	Measured	% Predicted
FVC Liters	5.47	**7.20**	132
FEV1 Liters	4.17	**4.80**	115
MVV L/min	168		

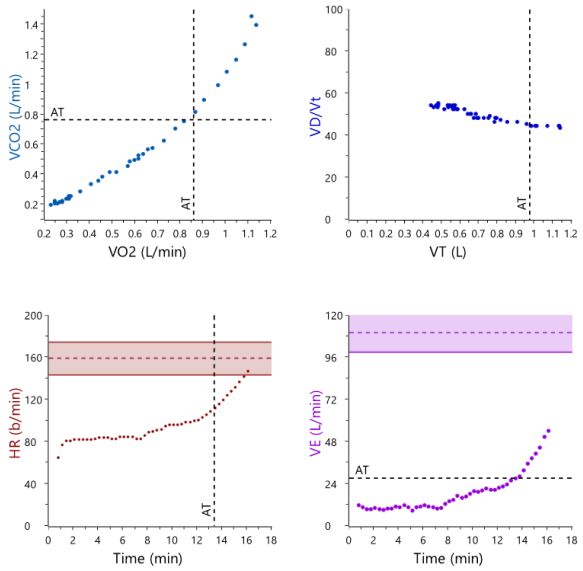
Arterial Blood Gases

	pH	PaCO2 mmHg	PaO2 mmHg	SaO2 %	BE	P(A-a)O2 mmHg	Hb gm/dL	HbCO %	HbO2 %	FIO2 %
Rest	**7.40**	**37.0**	**93.0**	**98.0**	**1.1**	**-16.6**	**14.8**	**0.5**	**98**	**0.21**
Exercise	**7.42**	**41.0**	**89.0**	**94.0**	**1.2**	**-18.4**	**14.8**	**0.6**	**95**	**0.21**

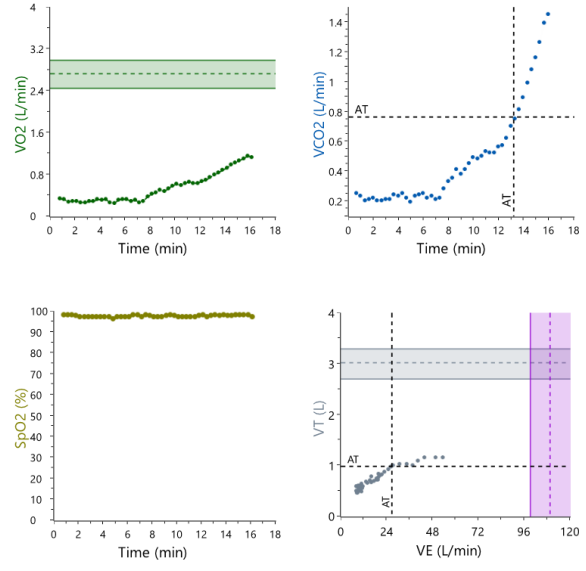
Exercise Minute Data

Time m:sec	HR BPM	O2 Pulse mL/beat	VO2 L/min	VO2/kg mL/kg/min	VCO2 L/min	RQ	VE (BTPS) L/min	Vt Liters	RR BPM
1:10	70	4.6	0.31	3.2	0.25	0.78	10.6	0.605	18
2:20	80	3.4	0.27	2.8	0.21	0.77	9.3	0.498	19
3:30	81	3.2	0.26	2.6	0.20	0.79	8.9	0.527	17
4:40	83	3.7	0.30	3.1	0.24	0.79	10.7	0.515	21
5:50	83	3.3	0.27	2.8	0.22	0.81	9.6	0.535	18
7:00	84	3.4	0.29	3.0	0.23	0.81	10.5	0.532	20
8:10	85	3.9	0.33	3.4	0.27	0.80	11.3	0.579	20
9:20	90	5.1	0.47	4.8	0.38	0.82	15.5	0.692	22
10:30	95	6.1	0.58	5.9	0.46	0.80	18.5	0.699	26
11:40	98	6.4	0.63	6.4	0.52	0.83	20.2	0.768	26
12:50	102	6.7	0.68	6.9	0.58	0.85	21.8	0.810	27
14:00	112	7.4	0.83	8.5	0.77	0.92	27.0	0.961	28
15:10	126	7.9	1.00	10.2	1.05	1.06	37.2	1.024	36
16:20	142	7.9	1.11	11.3	1.37	1.23	49.8	1.145	44

ComPAS Version: 2019.3.0 Calibration Date: 4/30/2021 Calibration Data: Temp: 23°C PBar: 760mmHg BTPS: 1.086
Patient: Subject, Test K. Test Date: 4/30/2021 Page: 2 of 5



ComPAS Version: 2019.3.0 Calibration Date: 4/30/2021 Calibration Data: Temp: 23°C PBar: 760mmHg BTPS: 1.086
Patient: Subject, Test K. Test Date: 4/30/2021 Page: 3 of 5



ComPAS Version: 2019.3.0 Calibration Date: 4/30/2021 Calibration Data: Temp: 23°C PBar: 760mmHg BTPS: 1.086
Patient: Subject, Test K. Test Date: 4/30/2021 Page: 4 of 5

8.9.13 Oxygen Titration Reports

Oxygen Titration Report	Oxygen Titration Report2

Pulmonary Function Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject **ID: 134732** **Test date/time: 6/16/2020**
Height at test: 75 in
Weight at test: 216.41 lb Birth Sex: M Gender: Male Birthdate: 12/20/1960 Age at test: 59
BMI at test: 27.2 kg/m² Smoking history (pk-yrs): N/A Predicted Group: C Ethnicity: Caucasian
Physician: Estimated Lung Age: N/A Technician:
ICD-10: () Referring Dr:

Supplemental Oxygen Titration

Oxygen Delivery	Resting		Walking				
	SpO2 (%)	*HR (bpm)*	*SpO2 (%)*	*HR (bpm)*	*Distance (m)*	*Time (m:ss)*	*BP*
Room Air	98	60	85	90	100	3:00	--/--
2.0	88	88	88	88	100	3:40	--/--
3.0	89	86	89	86	150	4:00	--/--
4.0	92	84	92	84	200	4:40	--/--
5.0	94	85	94	85	250	5:20	--/--
6.0	96	85	96	85	300	6:00	--/--

Technologist Comments:
Not Implemented

Interpretation:
Not Implemented

O2 Titration Report
Patient: Subject, Test K. Test Date: 6/16/2020 Page: 1 of1

Six Minute Walk with O2 Titration Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject **ID: 134732** **Test date/time: 5/8/2020 10:23:14 AM**
Height at test: 75 in
Weight at test: 216.41 lb Birth Sex: M Gender: Male Birthdate: 12/20/1960 Age at test: 59
BMI at test: 27.2 kg/m² Smoking history (pk-yrs): N/A Predicted Group: C Ethnicity: Caucasian
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: () Referring Dr:

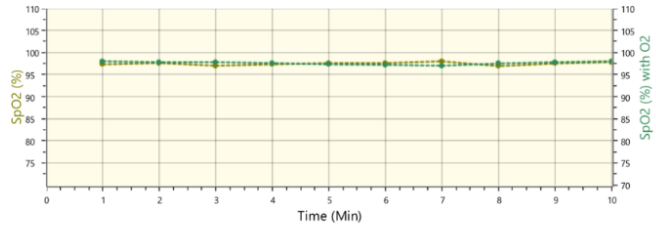
Oxygen Titration Study

Room Air	Resting	1 min	2 min	3 min	4 min	5 min	6 min	Max	Recovery Min 1	Recovery Min 2	Recovery Min 3
SpO2 (%)	97.2	97.3	97.6	97.0	97.3	97.6	97.6	97.7	98.0	96.9	97.5
HR (bpm)	60	64	70	79	88	99	102	110	110	85	76
Dyspnea (1 - 10)	0	----	----	----	----	----	----	5			
Fatigue (1 - 10)	0							5			
BP (mmHg)	120 / 80							125 / 83			

Actual 6MW distance: (Room Air) **750** meters
Predicted distance: LLN: **505** **658** meters
Percent of predicted: **114** %

Supplemental Oxygen	Resting	1 min	2 min	3 min	4 min	5 min	6 min	Max	Recovery Min 1	Recovery Min 2	Recovery Min 3
SpO2 (%)	98.0	98.0	97.8	97.8	97.6	97.3	97.2	97.0	97.0	97.5	97.8
HR (bpm)	62	64	70	77	86	97	102	109	109	100	88
O2 Delivery (L/min)	----	----	----	----	----	----	----		----	----	----
Dyspnea (1 - 10)	0	----	----	----	----	----	----	2			
Fatigue (1 - 10)	0							3			

Actual 6MW distance: (With O2) **780** meters
Predicted distance: LLN: **505** **658** meters
Percent of predicted: **119** %



Six Minute Walk With O2 Titration
Patient: Subject, Test K. Test Date: 5/8/2020 Page: 1 of 2

8.9.14 Dual Post Bronchodilator Report

Dual Post Bronchodilator Report	

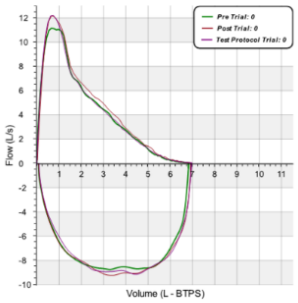
Dual Post BD Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 **Phone: (978) 521-4440**

Patient Information

Name: Test K. Subject **ID: 134732** **Test date/time: 8/16/2021 12:35:08 PM**
Height at test: 75 in
Weight at test: 216.41 lb Birth Sex: M Gender: Male Birthdate: 12/20/1960 Age at test: 60
BMI at test: 27.2 kg/m² Smoking history (pk-yrs): N/A Predicted Group: C Ethnicity: Caucasian
Physician: Colin Chapman, M.D. Estimated Lung Age: N/A Technician: Patrick Morgan
ICD-10: () Referring Dr:

Parameter	Units		FVC B FEV1 D Pre BD	Pred	LLN	Z-score	% Pred	FVC E FEV1 E Post BD1	% Pred	% Chg	FVC E FEV1 E Post BD2	% Pred	% Chg
FVC		L	6.84	5.45	4.15	1.74	126	6.95	128	2	6.97	128	2
FEV_1		L	4.64	4.15	3.13	0.82	112	4.79	115	3	4.62	111	0
PEFR		L/s	11.16	10.29	7.65		108	12.17	118	9	12.22	119	9
FEF_{25-75}		L/s	2.88	3.32	1.61	-0.37	87	3.06	92	6	2.67	80	-7



Preliminary Impression:

Normal spirometric values indicate the absence of any significant degree of obstructive pulmonary impairment and/or restrictive ventilatory defect.

Bronchodilator therapy was administered followed by repeat spirometric testing. Post-bronchodilator testing failed to demonstrate a significant change in FVC, FEV1, or FEF 25-75. This indicates that this patient may not benefit from continued bronchodilator therapy.

ComPAS Version: *2021.1.0* Calibration Date: 8/16/2021 Calibration Data: Temp: 26°C PBar: 760mmHg BTPS: 1.067
Patient: Subject, Test K. Test Date: 8/16/2021 Page: 1 of 1

8.9.15 Lung Transplant Report

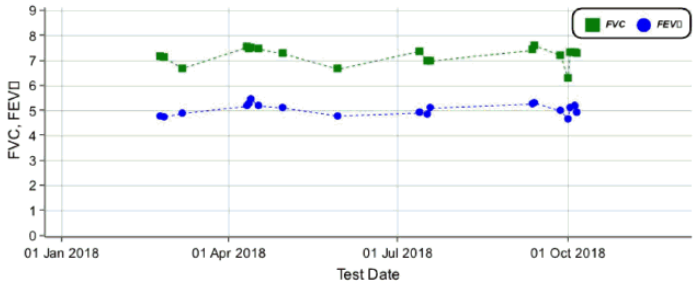
Lung Transplant Report

Pulmonary Function Report

Morgan Scientific, Inc.
151 Essex Street
Haverhill, MA 01832 Phone: (978) 521-4440

Patient Information

Name: Test K. Subject	**ID: 134732**	**Test date/time: 9/27/2018 3:14:53 PM**
Height at test: 75 in		
Weight at test: 211.53 lb	Sex: M	Birthdate: 12/20/1960 Age at test: 57
BMI at test: 26.6	Smoking history (pk-yrs): N/A	Ethnic group: C
Physician: Colin Chapman, M.D.	Estimated Lung Age: N/A	Technician: Patrick Morgan
ICD-10: (J45.30) Mild persistent asthma, uncomplicated		Referring Physician:



Technologist Comments:
Good subject effort meeting ATS requirements of effort and repeatability. 3 puffs of Albuterol given with 12-minute activation prior to Post testing.

Interpretation:

PF Reference: Spirometry (3-5): Eigen/Bieler, (6-7), GLI & Knudson (8-95); Lung Volumes: Quanjer; DLCO: GLI
Calibration Date: 9/27/2018 Calibration Data: Temp: 21ºC PBar: 758mmHg BTPS: 1.094
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 1 of 2

Serial Spirometry Test Data

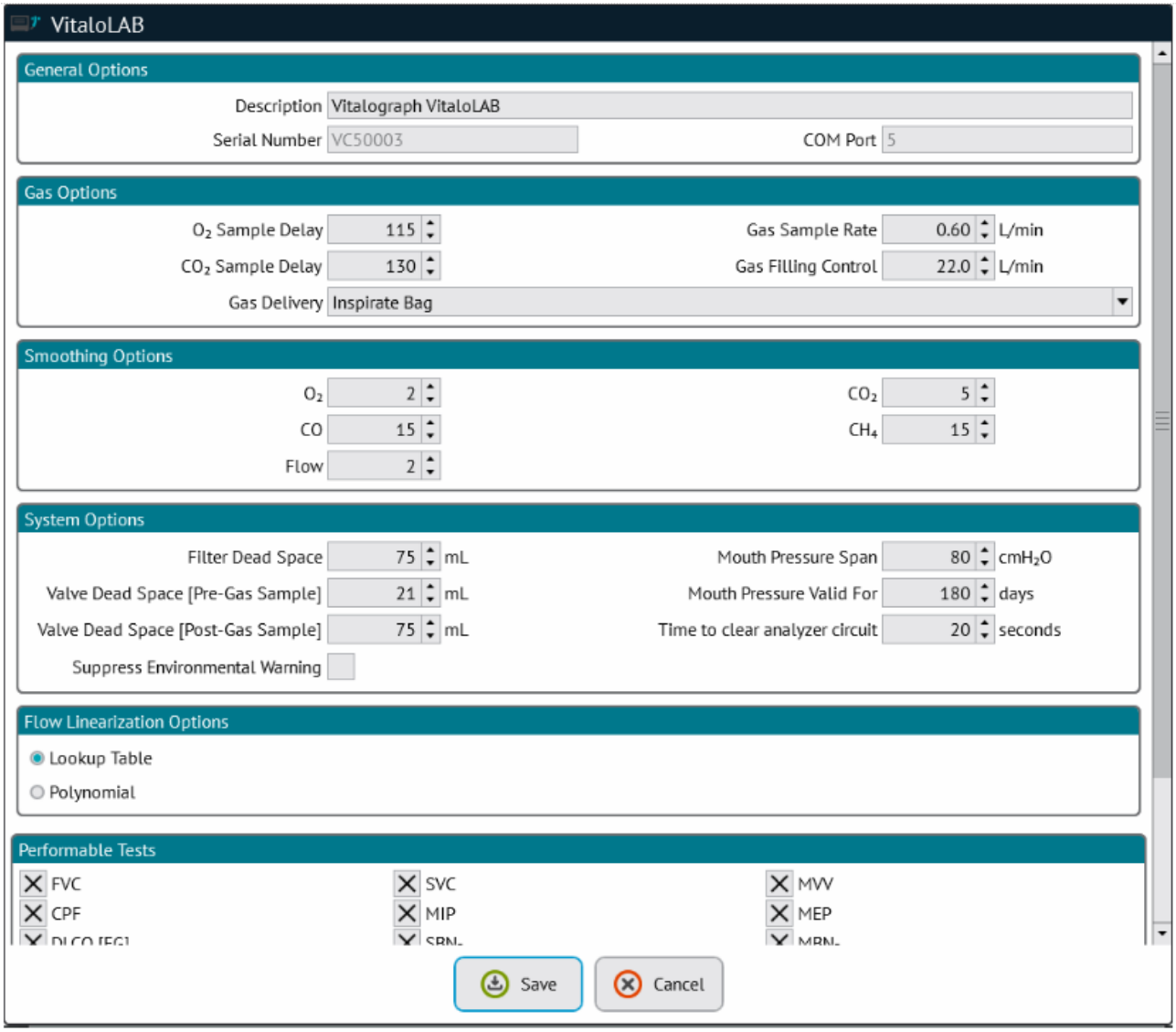
Lung Transplant Date: 3/18/2018
%Change calculated from date(s) with the two best FEV1 separated by three weeks following lung transplant

Test Dates	FEV_1 L	FEV_1 % Chg	FVC L	FVC % Chg	FEF25-75 L/sec	FEF25-75 % Chg	BOS Stage
9/27/2018	4.99	----	7.21	----	3.21	----	
9/13/2018	5.31	6	7.61	6	3.45	7	0p
9/12/2018	5.27	6	7.42	3	3.40	6	0p
7/19/2018	5.10	2	6.99	-3	3.77	17	0p
7/17/2018	4.84	-3	7.00	-3	3.00	-7	0p
7/13/2018	4.91	-2	7.38	2	2.80	-13	0p
5/30/2018	4.79	-4	6.66	-8	3.40	6	0p
4/30/2018	5.11	2	7.28	1	3.41	6	0p
4/17/2018	5.20	4	7.47	4	3.41	6	0p
4/13/2018	5.45	9	7.53	4	3.86	20	0p
4/12/2018	5.26	5	7.46	3	3.60	12	0p
4/11/2018	5.18	4	7.54	5	3.13	-2	0p
3/7/2018	4.89	-2	6.69	-7	3.58	12	0p
2/25/2018	4.75	-5	7.14	-1	2.62	-18	0p
2/23/2018	4.78	-4	7.18	<1	2.73	-15	0p

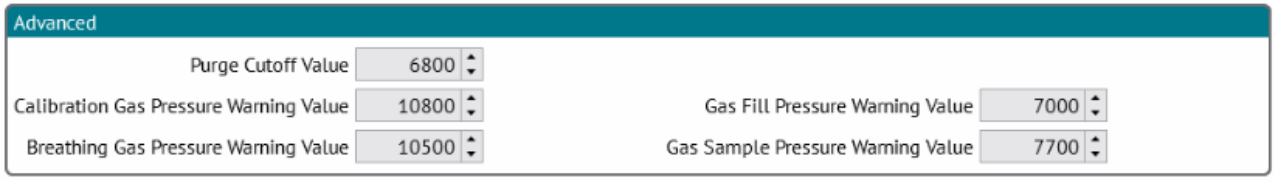
PF Reference: Spirometry (3-5): Eigen/Bieler, (6-7), GLI & Knudson (8-95); Lung Volumes: Quanjer; DLCO: GLI
Calibration Date: 9/27/2018 Calibration Data: Temp: 21ºC PBar: 758mmHg BTPS: 1.094
Patient: Subject, Test K. Test Date: 9/27/2018 Page: 2 of 2

9:0 Model 9100 Vitalograph Morgan PFT Device Diagnostics

9.1 VitaloROV and VitaloLAB Device Configuration
Device configuration is accessed from the "Station Configuration" category. It is here that settings for each individual instrument can be chosen.



Advanced features for device warning messages are available. Type [Ctrl], [Alt], [Shift] and [P]:

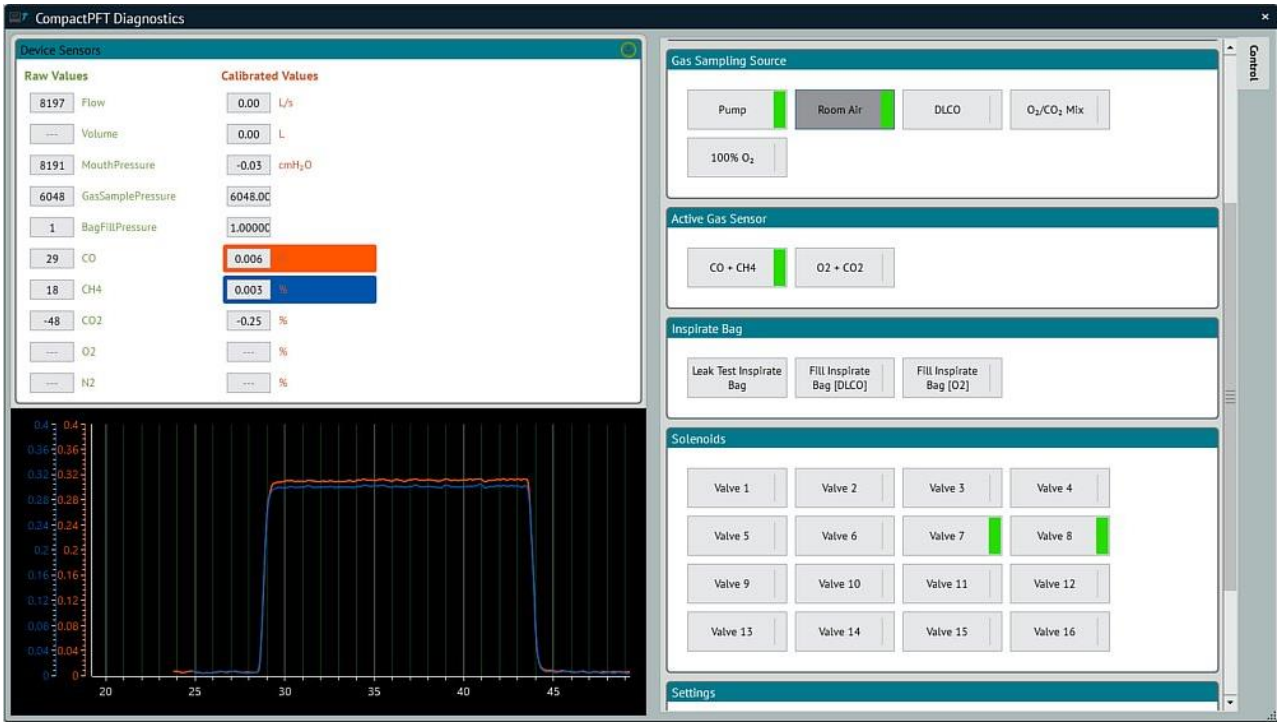


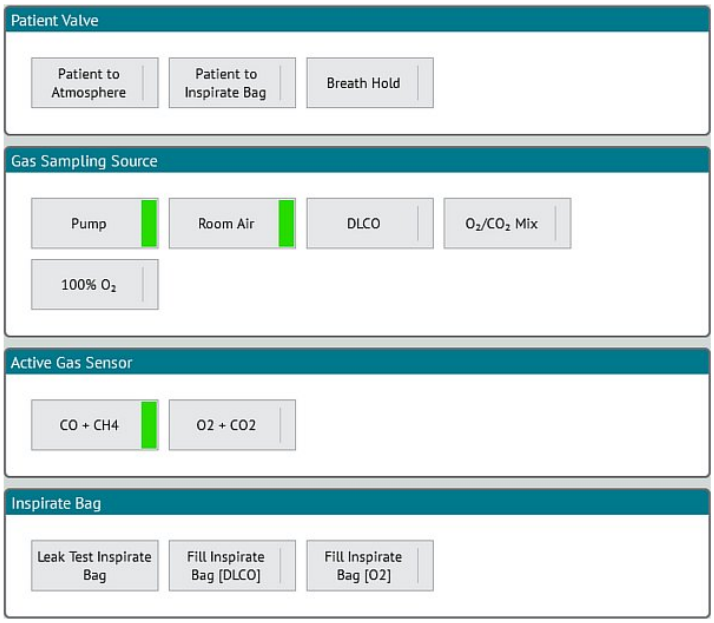
Configuration Item	Input	Default	Detail
General Options:			
Name	Type	VitaloLAB	Name of the device
Serial Number	Type	xxxxxxx	7-digit Serial number of the device – Auto Detected
Communications	Selection	COM1	The COM Port being used by the device
Gas Options:			
O2 Sample Delay	xxx	100	O2 Gas Analyzer Sample Delay
CO2 Sample Delay	xxx	100	CO2 Gas Analyzer Sample Delay
Override Auto-Detection	x	x	Turns ON/OFF auto-determination of sample alignment
Gas Delivery	Selection	Device dependent	Demand Valve or Inspiratory Bag
Gas Sample Rate	Selection	0.30 L/min	Pump speed during testing
Gas Fill Rate	Selection	24 L/min	Bag filling speed
Smoothing Options:			
O2	xxx	2	O2 Gas Analyzer Signal Smoothing
CO2	xxx	5	CO2 Gas Analyzer Signal Smoothing
CO	xxx	15	CO Gas Analyzer Signal Smoothing
CH4	xxx	15	CH4 Gas Analyzer Signal Smoothing
Flow	xxx	0	Flow Signal Smoothing
System Options:			
Filter Dead Space	xx	65ml	The dead space of the bacterial/viral filter being used
Valve Dead Space Pre	xx	75ml	The dead space of the patient valve – Pre Gas Sampling
Valve Dead Space Post	xx	21ml	The dead space of the patient valve – Post Gas Sampling
Flow Filter	x	0	Flow sampling filter to smooth F/V loops
Mouth Pressure Span	100	100cmH2O	The setting in cmH2O used when calibrating the span of mouth pressure
Mouth Pressure Valid For:	xxx	180 days	Days between calibration of Mouth Pressure
Time to Clear Analyzer Circuit:	xxx	12 secs	Time to allow room air to purge and clear the gas circuit before analyzing gases
Advanced:			
Purge Cutoff Value	Selection	6800	Digital setting for vacuum detection
Calibration Gas Pressure Warning	xxxxx	10800	Warning trigger for over-pressure in the manifold going to the gas analyzers
Breathing Gas Pressure Warning	xxxxx	10500	Warning trigger for over-pressure in the manifold going to the inspirate bag or demand valve
Gas Fill Pressure Warning Value	xxxxx	7000	Value that triggers a warning for over-pressure in the inspirate bag
Gas Sample Pressure Warning Value	xxxxx	7700	Value that triggers a warning for over-pressure in the manifold
Flow Linearization Options			
Lookup Table		No	Using a user-created linearization table
Polynomial		Yes	Using a factory-default polynomial equation
Environmental			
Use Temperature Sensor	Check box	Yes	Turns ON/OFF the on-board temperature sensor reading
Use BP Sensor	Check box	Yes	Turns ON/OFF the on-board barometric pressure sensor reading
Use Humidity Sensor	Check box	Yes	Turns ON/OFF the on-board humidity sensor reading

9.2 Model 9100 Vitalograph Morgan PFT Device Instrument Diagnostics

The diagnostics screen will show all the voltages coming from the instrument electronics. At the same time, it will allow the service or biomedical engineer to test the digital control functions of the instrument.

To access diagnostics, go to "**Tools**" and then click on the "**Diagnostics**" option.





Each of the digital functions can be controlled using the buttons.

A green acknowledge indicator shows which buttons are active at any given time.

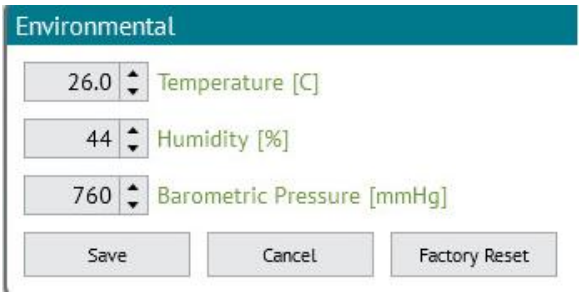
Only two gases can be analyzed at any one time.

CO + CH4

O2 + CO2

9.2.1 Changing the Environmental Settings

To change the environmental settings or perhaps align them with a third-party monitor, use the up and down arrows to alter any value.



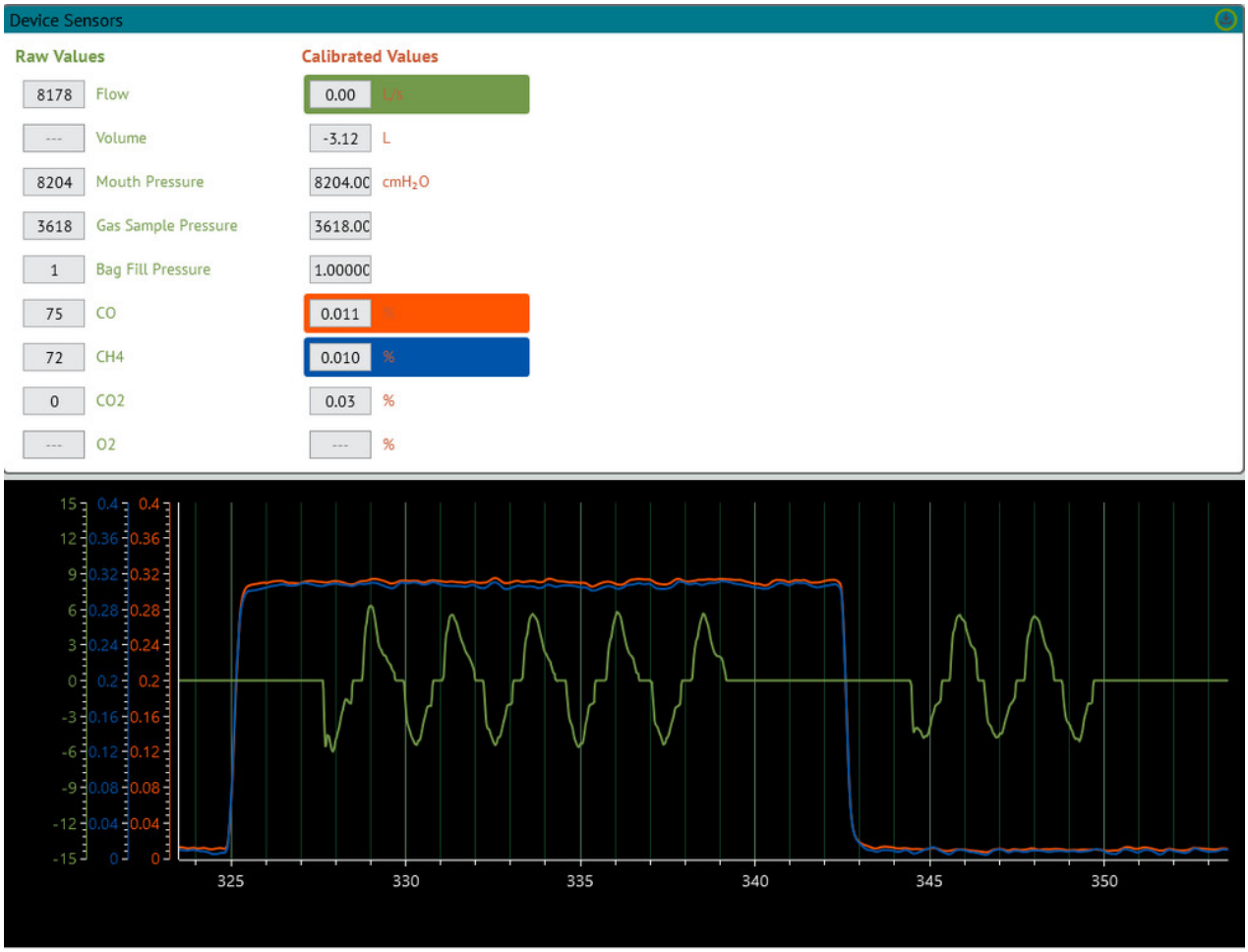
Change made will be stored and used as corrections to the factory setting.

9.2.2 Oscilloscope Function

The oscilloscope is a useful tool to display either raw signals or calibrated voltages. Clicking on any signal in the desired column will display that value on the scope. The colors correspond to the signal(s) being displayed.

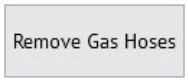
The oscilloscope can be dragged and stretched to any size vertically on the screen. When first launched, all diagnostic channels are displayed making the oscilloscope rather small; stretching the window vertically makes the scope far more useful.

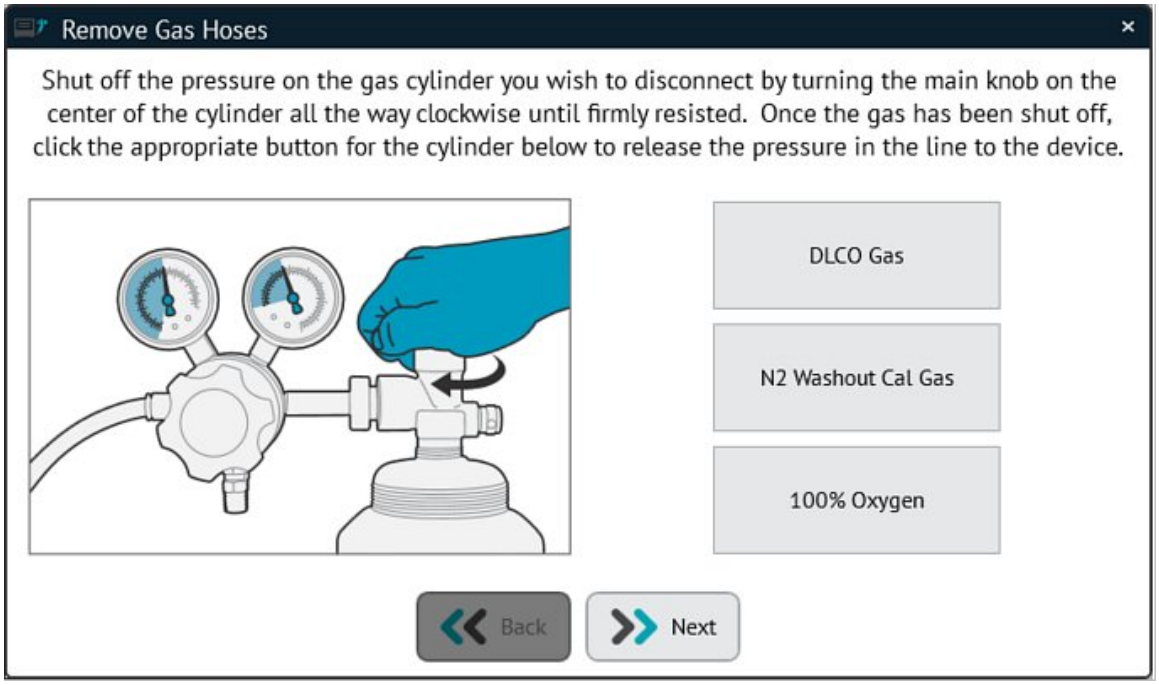
Clicking and dragging on the left-hand side of the oscilloscope scale provides control over the scale display.

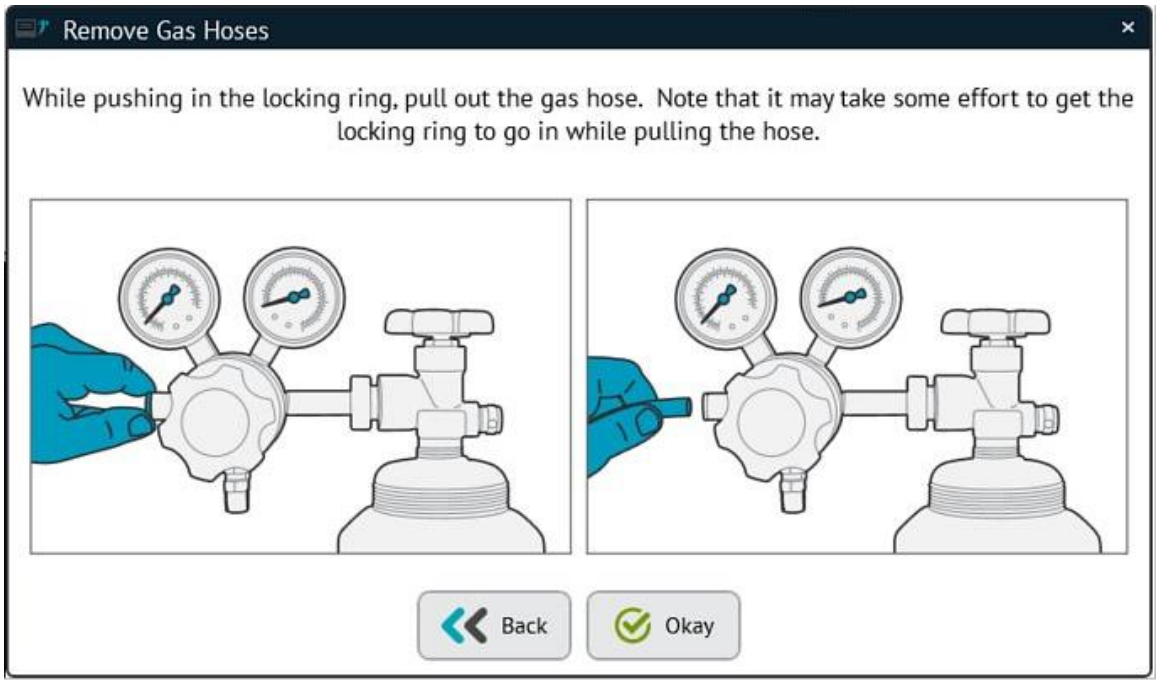


9.2.3 Service Function

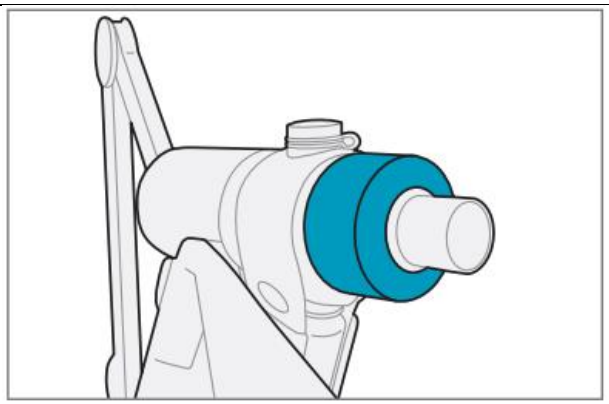
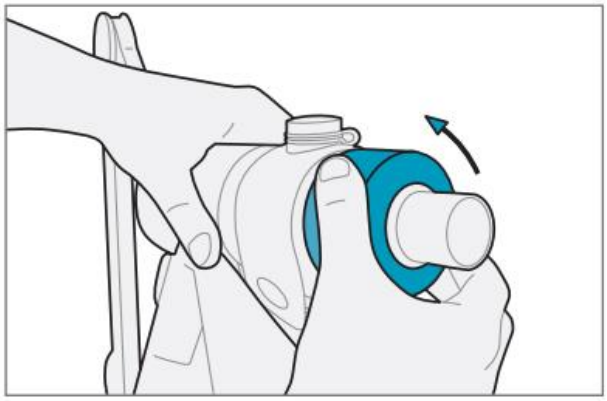
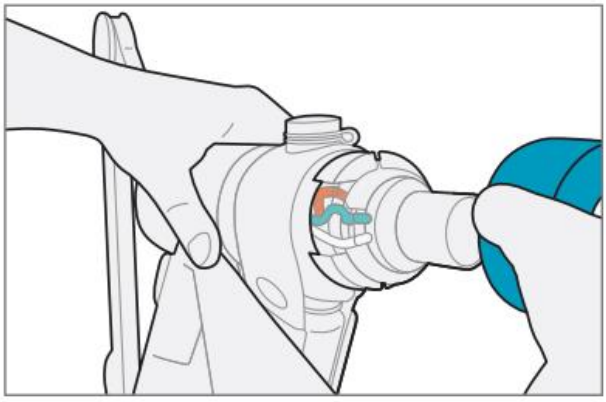
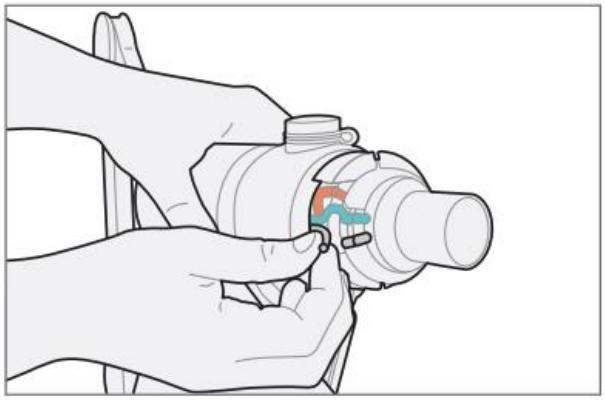
Before removing any of the high-pressure hoses from the gas cylinders, it is important to drain pressure from the system. The following illustrations and instructions can be run from the Diagnostics menu.

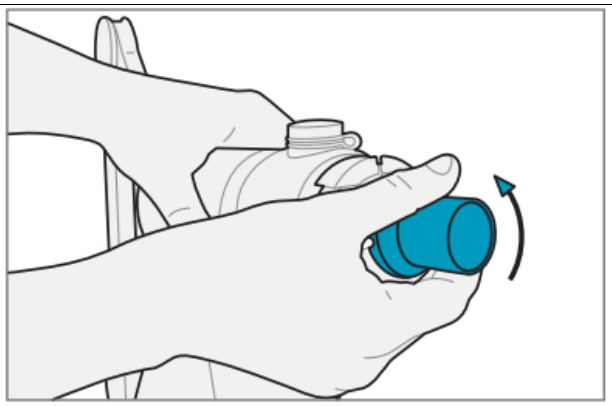
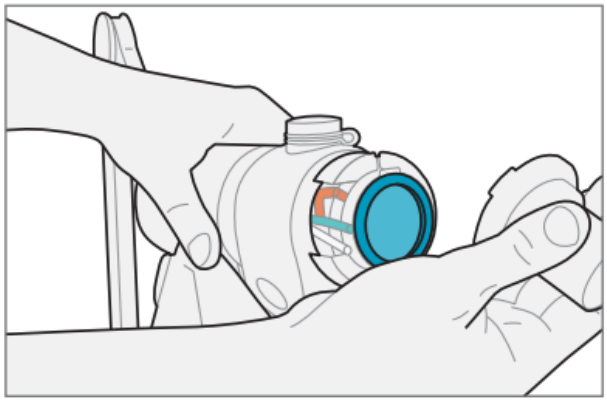
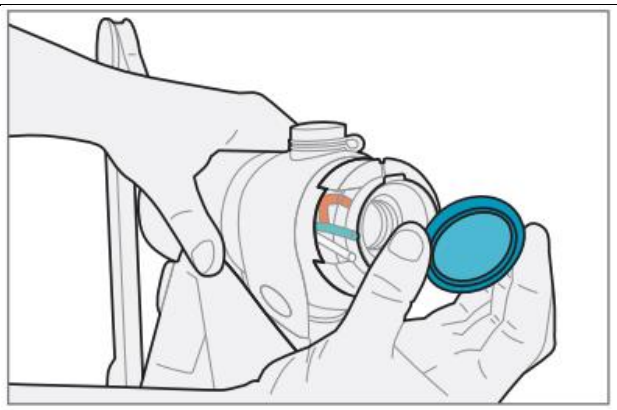
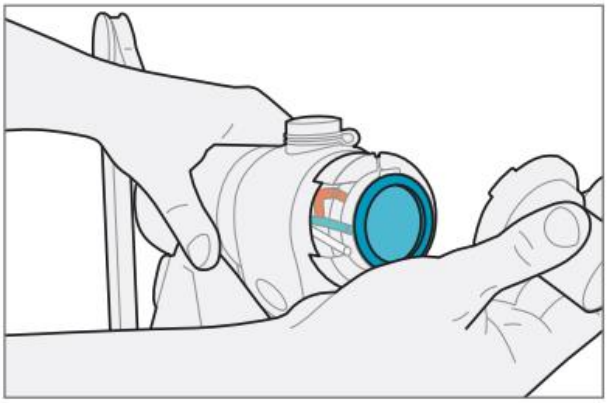
Click on 

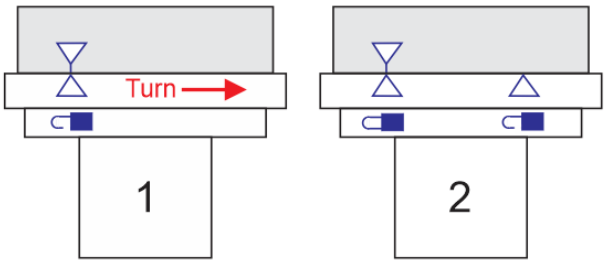
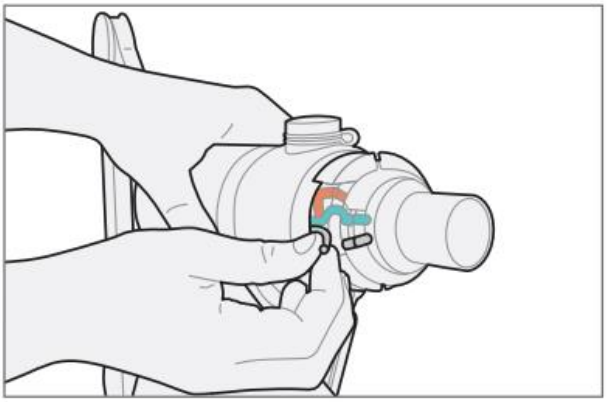
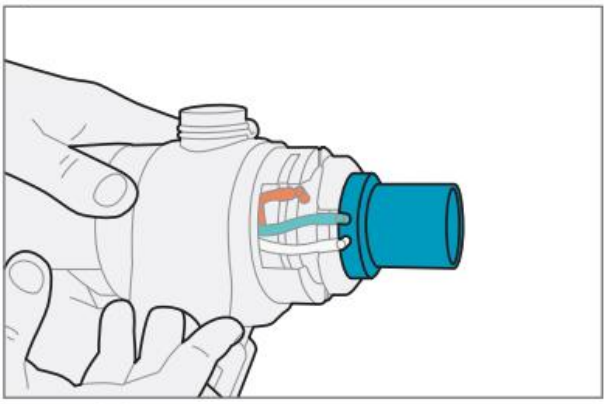
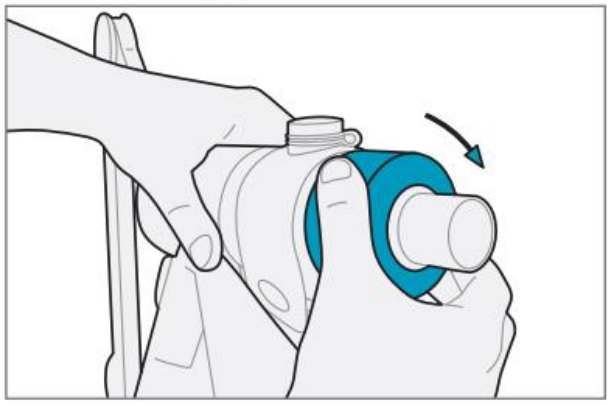




9.2.4 Changing the Lilly Pneumotachograph Screen in the Patient Valve

The following steps describe the replacement of the Lilly pneumotachograph screen as used in the following models:	
Step1 Rotate the aluminum cover in an anti-clockwise direction and remove the cover.	 
Step 2 Carefully remove the white, green and red tubes.	

Step 3: Rotate the Lilly housing in an anti-clockwise direction and lift away.	 
Step4 Remove the Lilly screen and replace it with a clean spare screen.	
Step 5a Replace the Lilly housing and lock in place using a clockwise rotation.	

Step 5b To assist in replacement, align the open padlock symbol with the arrow on the housing and rotate clockwise until it is in the locked position.	
Step 6 Replace the tubing, pushing each one firmly into place.	 
Final Step Replace the aluminum cover in a clockwise direction locking it into place.	

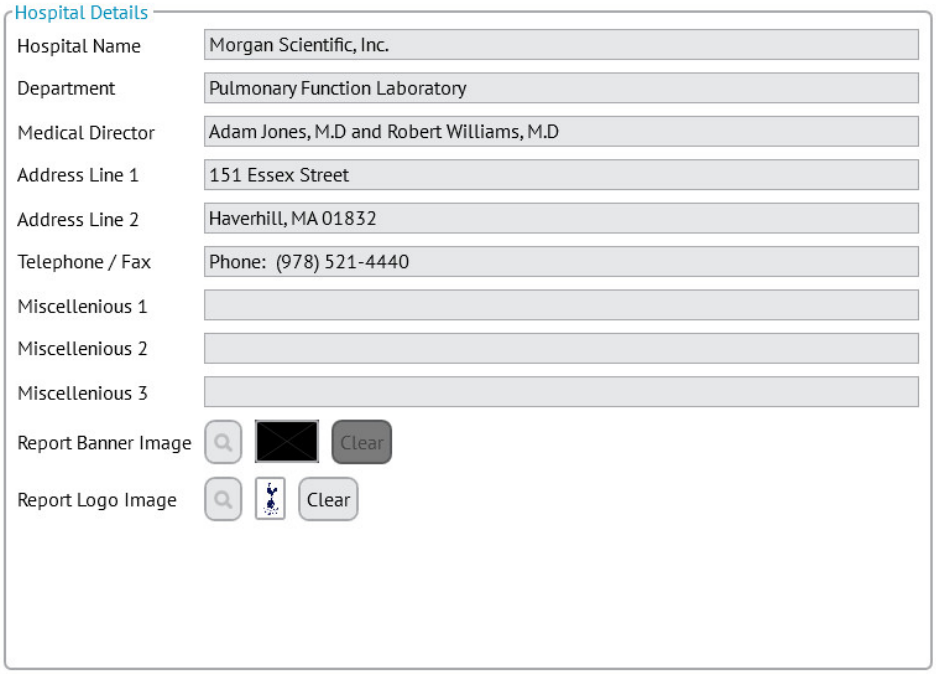
10:0 ComPAS2 Configuration

10.1 Introduction
ComPAS2 software can be configured to suit individual customer requirements. The Configuration menu is accessed from the top menu bar by clicking on **"Tools".**

Once Configuration has been chosen, the various "Categories" are displayed. To open an individual category, click the **[+]** sign to access the contents.

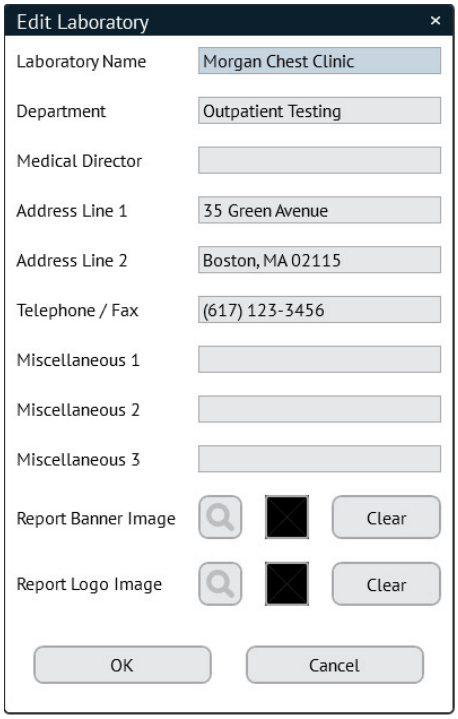
10.2 Configuration of Clinic Information
This is the configuration section for the main hospital or location address including the possibility of multiple locations linked to the same database.

For the main location information, use the "Hospital Details" fields to enter address, phone number and logo etc.



For subsidiary locations use the 

button in the "Laboratories" fields to enter address, phone number and logo etc.

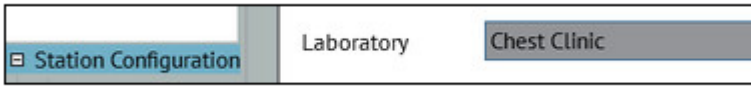


Very Important!

When laboratories are added, they must be linked to the Station ID in the database. In this way, the reports will be able to identify where tests were completed and use the appropriate laboratory information.

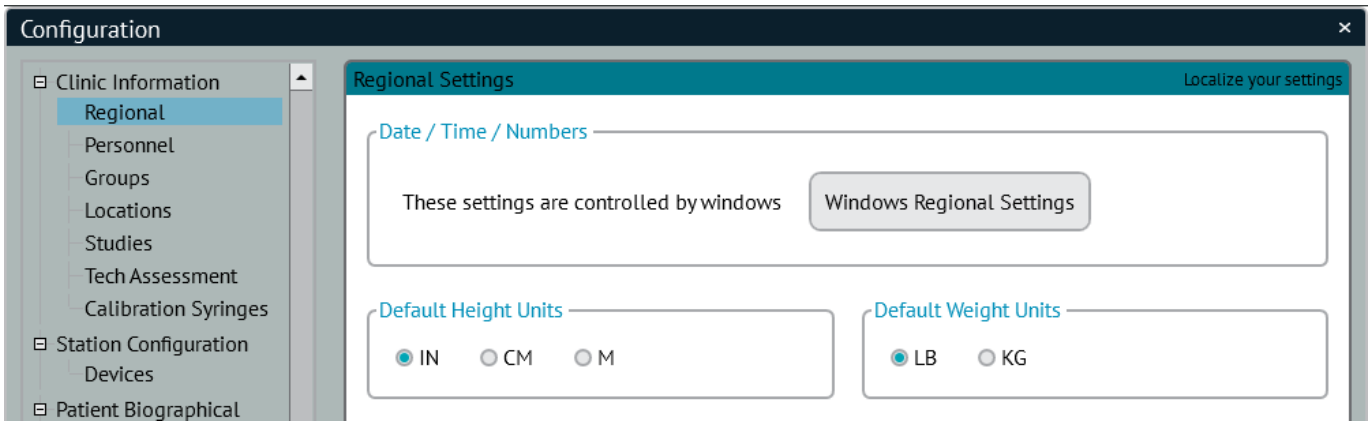
This can only be completed when using the PC at the laboratory location.

In Configuration, go to "Station Configuration" and beside "Laboratory" use the down arrow to locate the correct laboratory.



10.2.1 Configuration of Regional Settings

The regional settings allow users to configure settings for Date and Time and defaults for traditional or metric units for height and weight. It also allows users to change the field labeling for postal code and state.



<u>10.2.1.1 Test Units – Setting Traditional or SI</u>

This setting is for the calculation and display of DLCO

Traditional :
DLCO = mL/min/mmHg
KCO = mL/min/mmHg/L
Hb = gm%

Scientific International:
DLCO = mmol/min/kPa
KCO = mmol/min/kPa/L
Hb = mmol/L

Values in SI units can be multiplied by 2.987 to obtain values in traditional units.

10.2.1.2 Touch Screen

The Touch screen setting optimizes ComPAS2 screens for tablets.

10.2.2 Introduction to Personnel and Groups within ComPAS2

ComPAS2 utilizes a true Role Provider system as designed in Windows or ASP.Net security. This design is to allow Active Directory support. Active Directory is a Microsoft technology used to manage computers and other devices on a network. As a network grows, Active Directory provides a way to organize a large number of users into logical groups and subgroups, while providing access control at each level

There are 3 active parts of the ComPAS2 design: Personnel, Groups and Access Rights (or Roles).

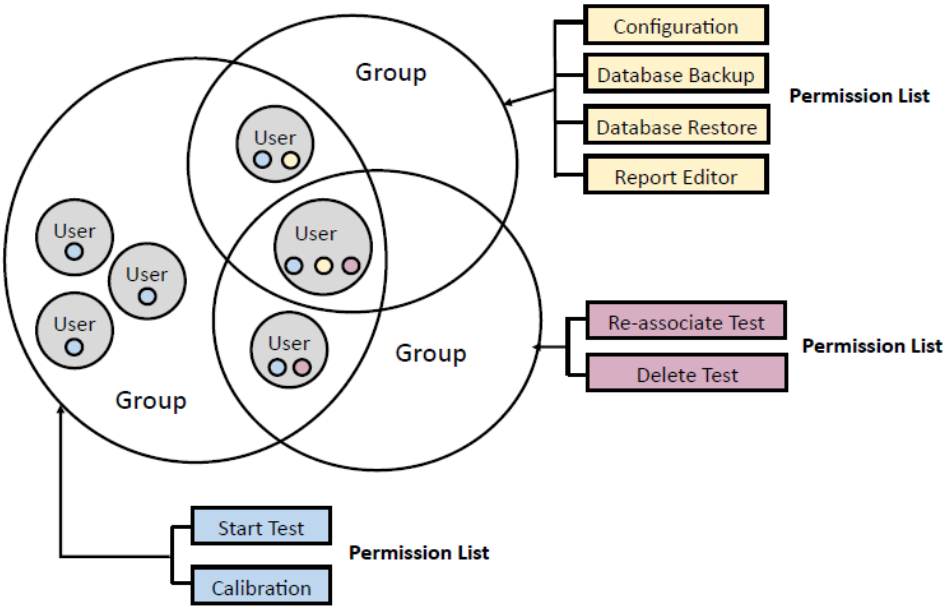
Personnel:
Personnel represents all Users in the system. Individual Users can have any number of access rights assigned to them directly or through the Groups configuration screen.

Groups:
A Group is container for holding one or more users, to which access rights can be applied. Once access rights have been applied to a Group, all users who are members of that group will inherit those access rights. From an administrative perspective, this is easy to implement and maintain; access rights only have to be granted once
on the group. If a user is no longer valid, removing them from the group will remove their access.

Access Rights (Role):
An Access Right or Role is a security concept applied to a specific function within ComPAS2. For example, being able to open the configuration menu is tied to one access right. If a user, or group to which the user is a member, has the configuration access right, then that user can see the associated menu options. ComPAS2 has a list of access rights that are applied throughout the system.

Access rights are cumulative. A given User has the sum of access rights from their individual user assignments as well as any access rights assigned to the Groups of which they are a member.

The diagram below illustrates how Users can be part of a single or multiple Groups. With each Group participation come the permissions or access rights associated with that Group.



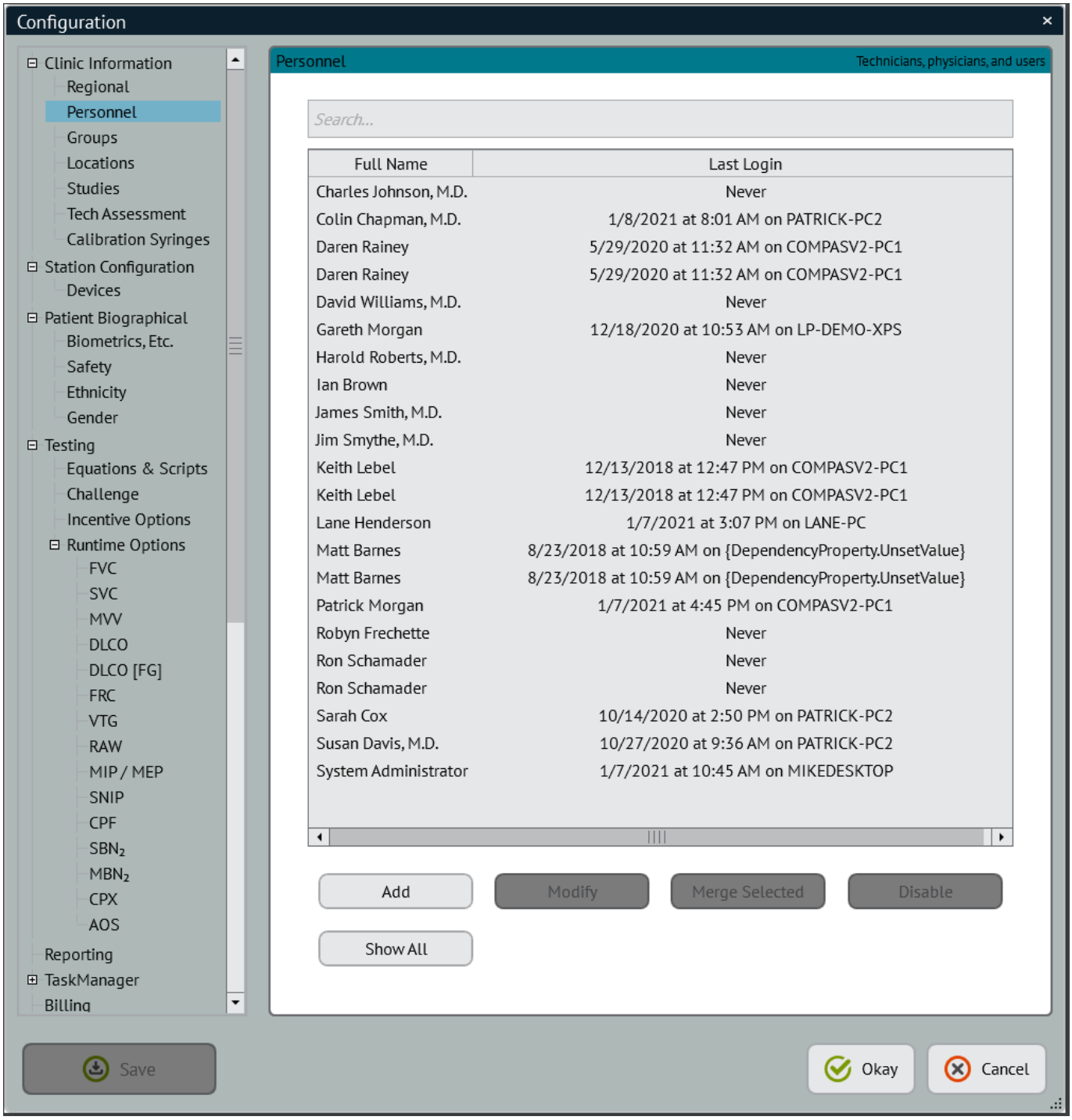
10.2.3 Adding and Editing PERSONNEL Information

To gain access to Configuration, individuals must first be added within Personnel.

At large institutions the personnel list can become very large, so a "search" option is provided at the top of the listing.

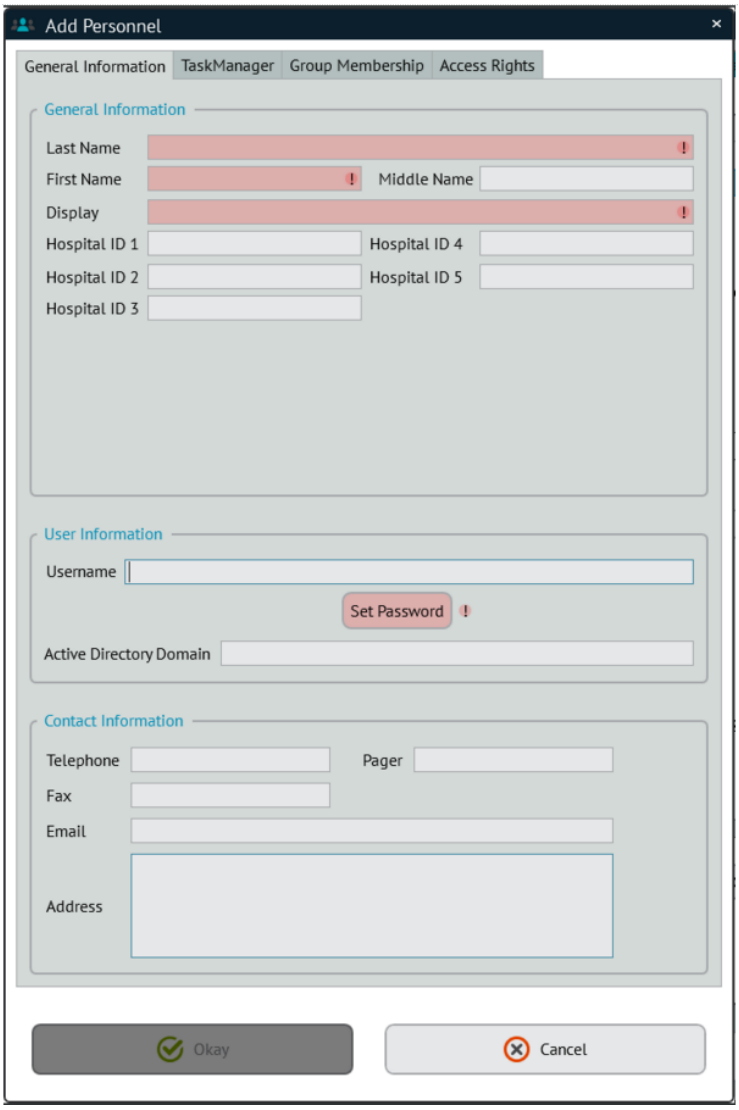
For simplicity of operation, adding any Personnel should be done in two steps:

1) Add the new individual
2) Assign the individual to a Group (See 10.2.4)

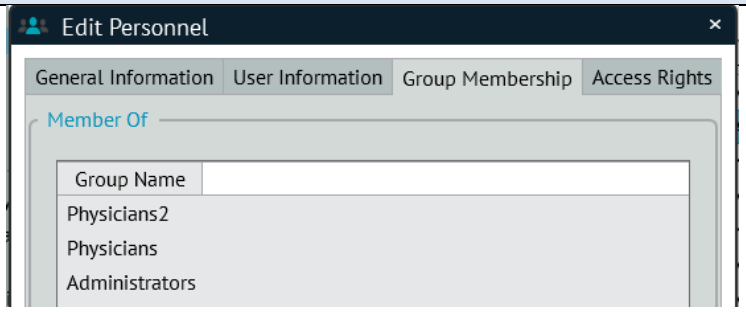


To enter new individuals, click the 

button. The Personnel listing includes all individuals linked to any record in ComPAS2: that includes technicians, administrators, and physicians.

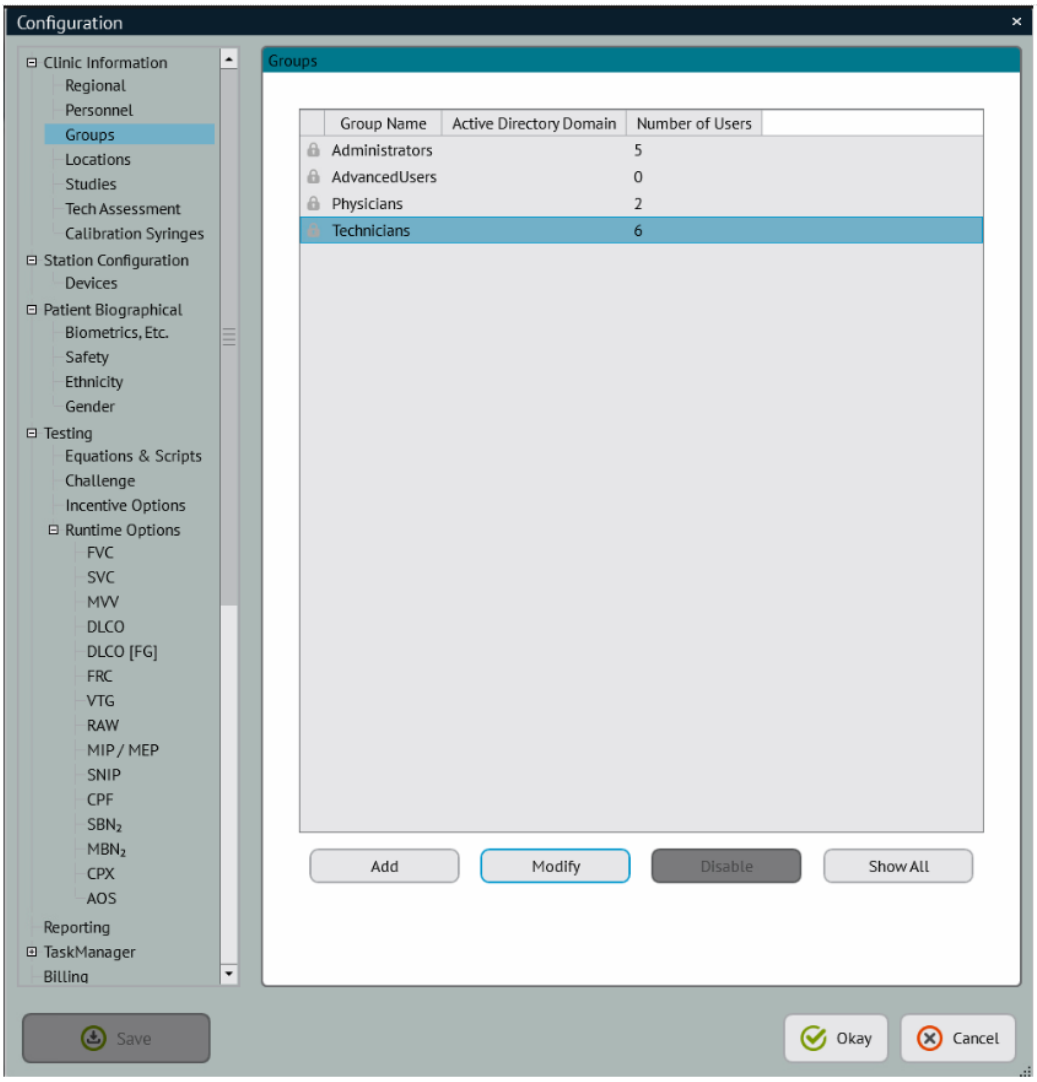


General Information:	
Last Name	Individual's Last Name
First Name	Individual's First Name
Middle Name	Individual's Middle Name
Display	How the individual's name and credentials will be displayed on reports. If a Display Name is entered, it will take priority over Active Directory Display Names.
Username	The Username is the string of characters used to identify users in ComPAS2
Password	The password is the string of characters used for user authentication to prove identity and gain access to ComPAS2
Active Directory Domain	Microsoft Active Directory Domain to which the individual is a member
Contact Information	Self-explanatory
Task Manager	
Roles	The role or roles of the individual
Notes	

	[Edit Notes] accesses the dialogue for creation of frequently used notes or interpretation statements. Notes can be individual templates or pointed to a common set of departmental notes to provide a uniform language of notes or interpretations in the department. For individual notes click "**Use Customized Notes**" To point to a common set of notes click "**Use Another's Notes**". In this case, one key individual in the laboratory should be designated to edit and control the templates. Full details on the creation and editing of technician of physician notes can be found in Section 6: Notepads.
Signature	 The signature field operates with digital signature pads to capture an image of the user signature.
Group Membership	
	 This determines which group or groups the current user is assigned to.See Groups 10.2.4 for further information.
Access Rights	
	This will display the access rights assigned to the current user record. Users rights can either automatically 'inherit' the rights of their Group membership or be applied individually. To see more information on group rights see 10.2.4.2 Assigning Rights to Groups. Individual rights can be assigned by clicking on "Personnel", highlighting an individual, or multiple individuals, and clicking the  button.

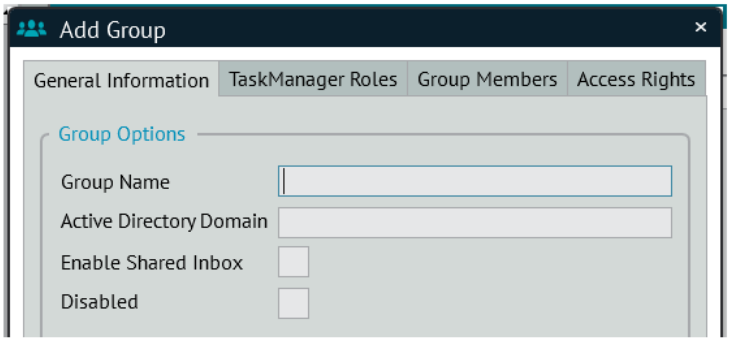
10.2.4 Editing GROUP Information

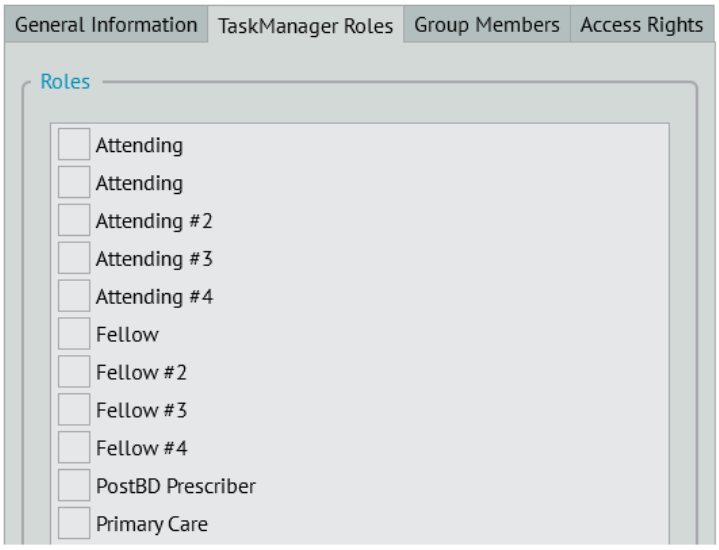
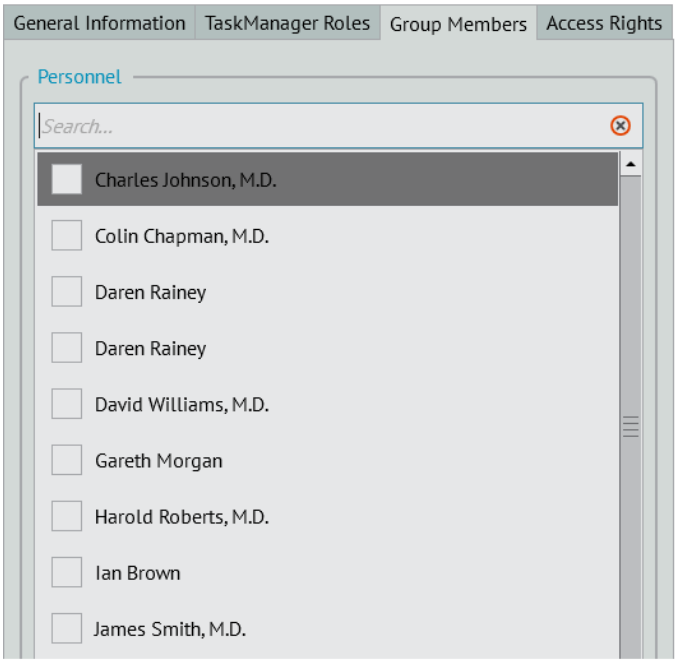
This is where any members of the Personnel listing can be added to single or multiple group participation.

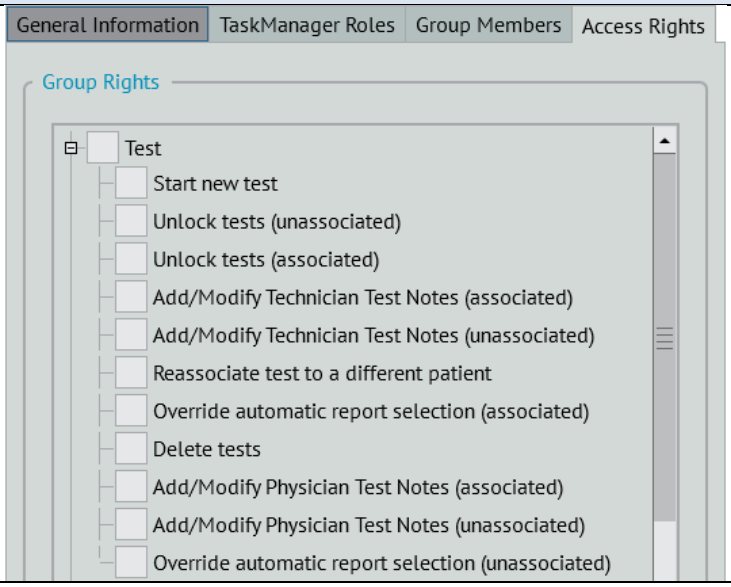


10.2.4.1 Adding or Modifying a Group

Click on the Add or Modify button depending upon the desired action.



General Information:	
Group Name	Add a new Group Name
Active Directory Domain	Microsoft Active Directory Domain to which a given group is a member
Enable Shared Inbox	This flags a group to have a “Group” inbox in the Task Manager folder list. When a user opens Task Manager, they will see all groups to which they belong as long as those groups have that flag checked.
Disabled	Disables a group from being considered for security access purposes. If a given user tries to perform an action within ComPAS2 and their only access rights granted are through a disabled group, they should not be able to perform that action.
Task Manager Roles	
Check-off any that apply	
Group Members	
Check-off any individuals to be members of the group:	

Access Rights	
Check-off the access rights for the group:	

10.2.5 Locations

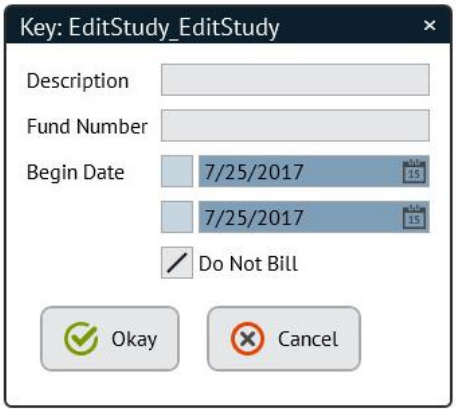
Locations can be added to the database and used in reporting.

To enter a new location, click the [Add] button.

Code	Used for locations using a code or room number, enter the details here.
Description	The location name i.e. "PFT Lab".

10.2.6 Studies

Studies can be created in the database with a defined time period. These can be particularly helpful to customers wishing to make use of the Research Query in ComPAS2. As patients are entered they can be linked to a study and later easily identified for research statistics and study.



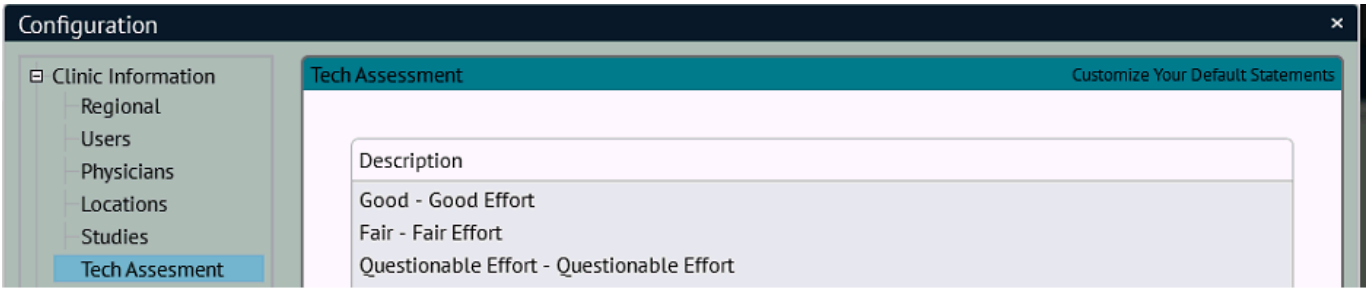
To show a study in the biographical screen, the description is necessary, but all other fields are optional.

The Do Not Bill check is used for sites that have a billing interface and do not want a particular study to be billed.

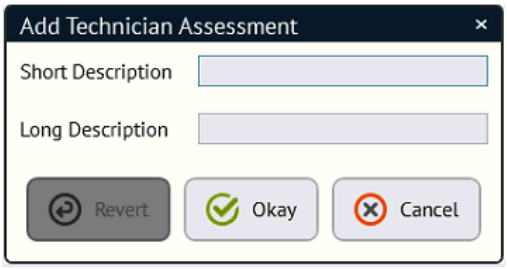
10.2.7 Technician Assessment

Quick-key technician assessments can be created and entered in the Notes section of the test screen.

These are individual customized ratings that can be used in reporting or computer impression scripts.



Simply use the Add button to create new settings.



Short and long description fields are available.

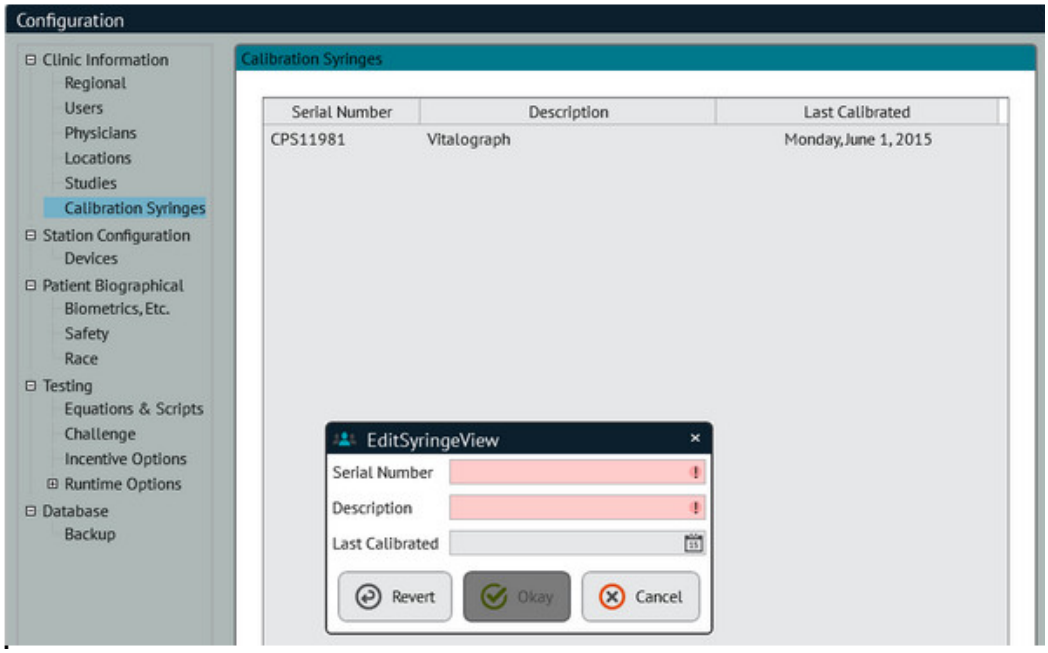
Existing assessments can be modified using the Modify button. or they can be deleted using Delete

10.2.8 Calibration Syringes

Information on the 3L syringes used for calibration in the facility can be saved and recorded with daily QC.

Simply add the Serial Number, Description and Date Last Calibrated.

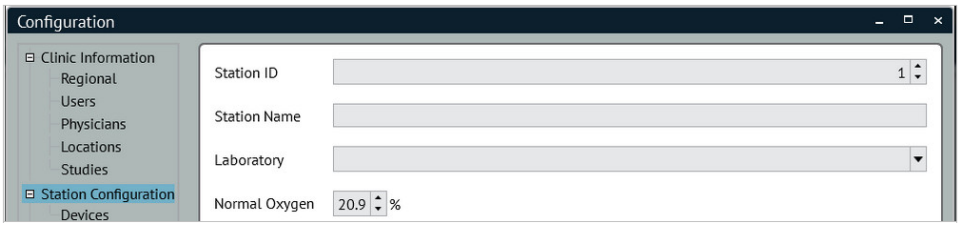
Each syringe added will be available from the pull-down shown in Flow Calibration.



10.3 Station Configuration

10.3.1 Station Information

Key identifying information for each station on the PFT network.

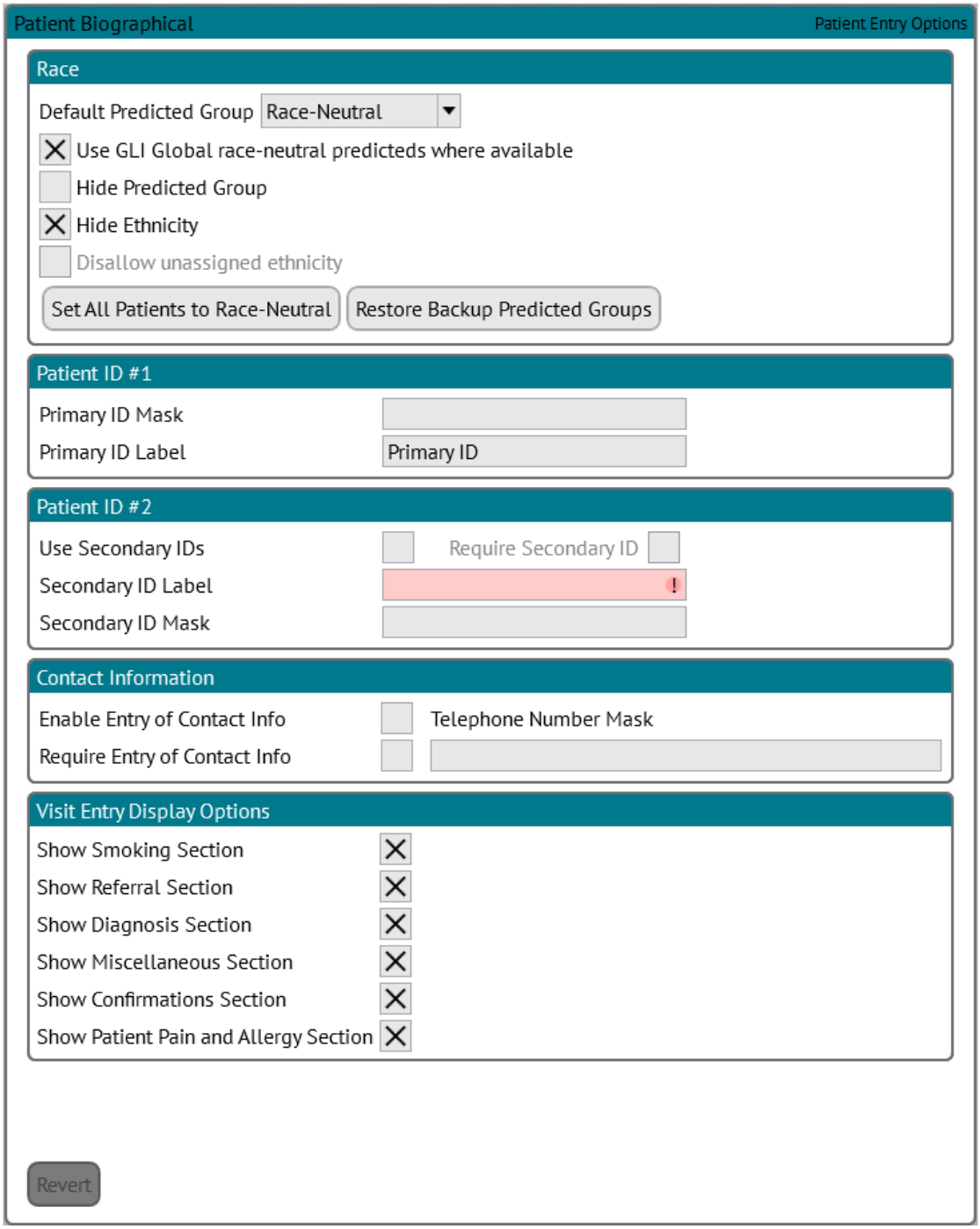


Station ID	An ID number that is automatically set by the ComPAS2 installer
Station Name	An optional field to name each station
Laboratory	When laboratories are added, they must be linked to the Station ID in the database. In this way, the reports will be able to identify where tests were completed and use the appropriate laboratory information. This can only be completed when using the PC at the laboratory location.
Normal Oxygen	A setting that establishes the room air oxygen level used in all calibrations

10.3.2 Devices

See 9.1 for information on setting the Vitalograph Morgan PFT device configuration

10.4 Patient Biographical Settings



Settings used in the Patient Biographical entry screen.

Name Format	The preference for listing patients in ComPAS2
Race	**Default Predicted Group -** A setting to set a default predicted group, choices are: Race-Neutral Other

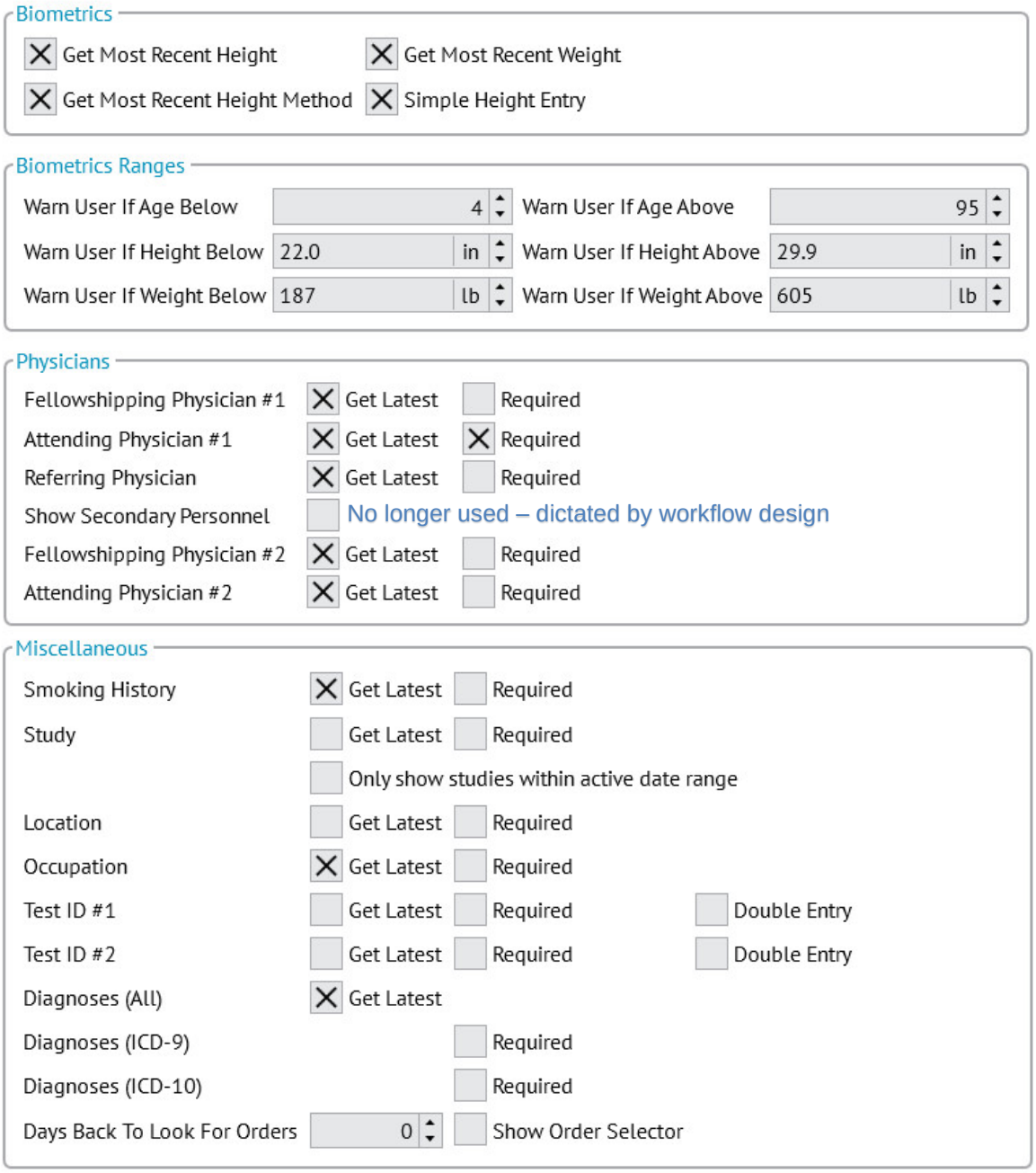
	Caucasian African American Mexican American Northeast Asian Southeast Asian With the recent release of GLI Global reference equations it is possible to default all testing to "Race-Neutral" or use a mix of predicted equations. **Use GLI race-neutral predicteds where available -** This option is to satisfy labs where a mix of GLI Global (race-neutral) and other reference equations are used. **Hide Predicted Group -** Those sites that want to employ race-neutral equations ONLY, the UI for Predicted Group can be hidden from view. **Hide Ethnicity -** Those sites that prefer to hide the UI for Ethnicity from view. **Disallow unassigned ethnicity -** This setting allows the forcing of an ethnicity if the field is being used **Set All Patients to Race-Neutral -** Use this option to set all patients in the database to race-neutral. **Restore Backup Predicted Groups -** Having set all past patient biographical information to race-neutral, this option provides a 'restore' in the event predicted group information wants to be used for research purposes.
Patient ID #1	**Patient ID Mask** - This can set format and number of characters used in the Primary ID field **Enforce ID Length** - Select when wanting to enforce the length
Patient ID #2	**Use Secondary IDs** - Select to use a secondary ID in the identification section **Secondary ID Prompt** - Type-in the label desired when entering a secondary ID **Secondary ID Mask** - This can set format and number of characters used in the Secondary ID field **Enforce ID Length** - Select when wanting to enforce the length
Contact Information	**Enable Entry of Contact Info** - Select to show Contact Information on the entry screen **Require Entry of Contact Info** - Select if wanting to enforce entry of contact Information **Telephone Number Mask** - For example: (xxx) xxx-xxxx
Visit Entry Display Options	Simply check-off those areas of biographical input that are required. This will configure the patient biographical entry screen as desired.

10.4.1 Biometrics Configuration

The features in the Biometrics section are self-explanatory. Here users can set up the ranges of 'warning messages' and checking for erroneous data input on height, weight and age.

For users wishing to "**Require**" or force entry of information on the biographical screen, the options are provided.

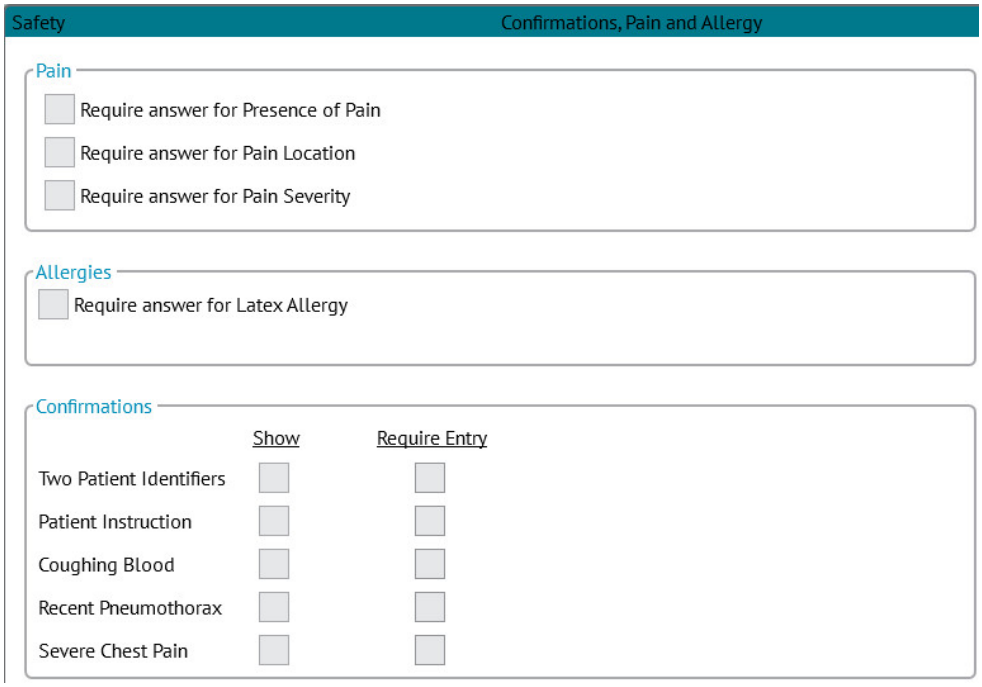
Using the "**Get Most Recent**" box will recall whatever information was stored with the subject record on their previous visit.



10.4.2 Safety Configuration

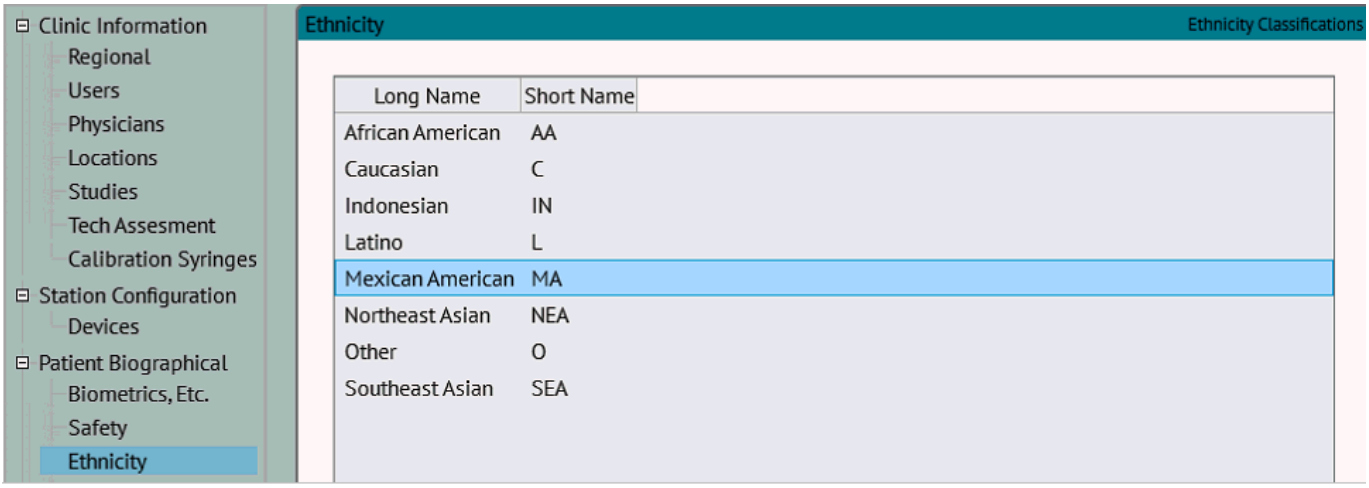
These are optional configuration settings to be used in patient biographical entry.

Each of the questions can be made mandatory if desired.

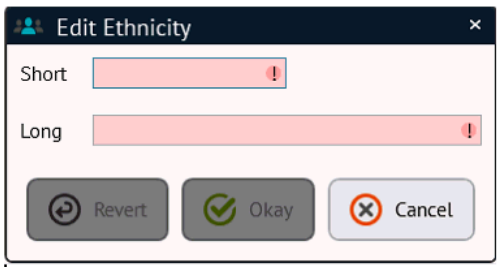


10.4.3 Ethnicity

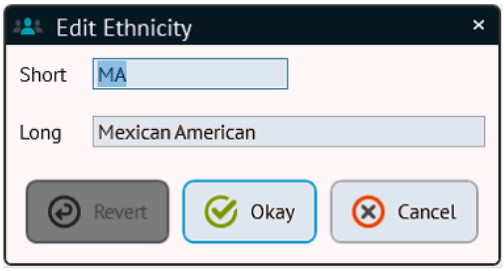
Ethnicity is an open editable field in ComPAS2; additions can be made to the pull-down list of choices at the time of patient entry or here in Configuration.



To add a new ethnicity, click [Add



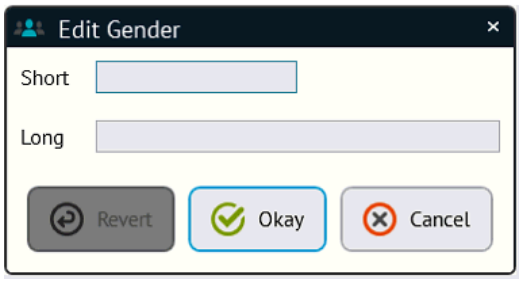
To edit a misspelling or change any entry, click Modify



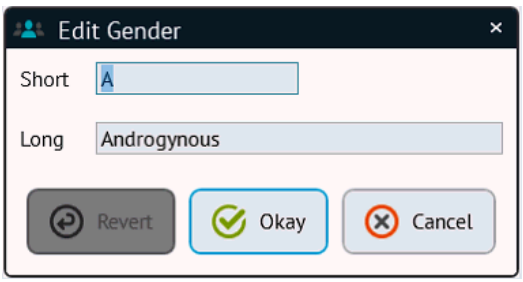
10.4.4 Gender

Gender is an open editable field in ComPAS2; additions can be made to the pull-down list of choices at the time of patient entry or here in Configuration.

To add a new gender, click [Add



To edit a misspelling or change any entry, click Modify

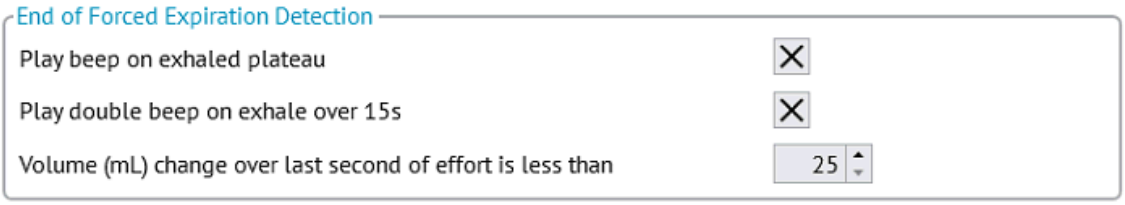


10.5 Testing Settings
Settings used in the testing screens.

10.5.1 End of Forced Expiration Settings

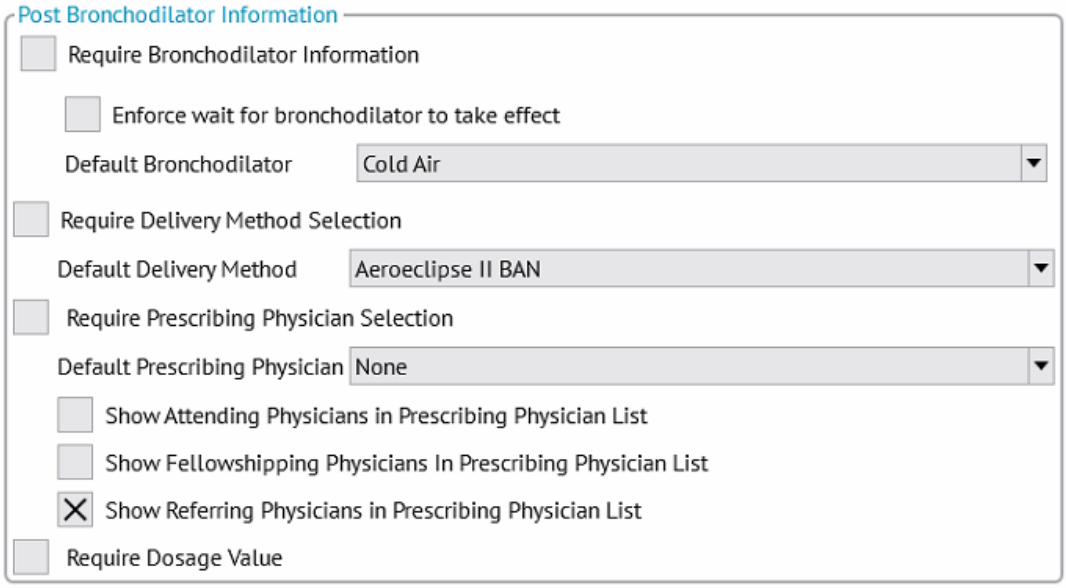
These settings for both sound and plateau detection apply to all tests where a plateau in end expiration are desired.

The visual meters for end expiration are set in each test type under "Runtime Options".



10.5.2 Post Bronchodilator Settings

These defaults allow the user to configure the options used in the runtime testing when the Post Bronchodilator icon is engaged: 



Require Bronchodilator Information	Turning this on will always insist on Bronchodilator information
Enforce wait for bronchodilator to take effect	Setting this will utilize the "Onset Time"
Default Bronchodilator	A pull-down list of drugs to select from
Require Delivery Method Selection	Turning this on will insist on the delivery method being selected
Default Delivery Method	A pull down of delivery methods to be able to select a default
Require Prescribing Physician Selection	Turning this on will insist on a physician being identified
Default Prescribing Physician	A pull-down of physicians available to select one as the default
Show Attending Physicians in Prescribing List	Will add all available Attending Physicians as possible choices

Show Fellowshipping Physicians in Prescribing List	Will add all available Fellowshipping Physicians as possible choices
Show Referring Physicians in Prescribing List	Will add all available Referring Physicians as possible choices
Require Dosage Value	Turning this on will insist on a dosage value

10.5.3 Drugs

This configuration allows the user to add, modify or disable any drug name used within ComPAS2.

10.5.4 Drug Delivery Devices

This configuration option is used to add, modify or disable any drug delivery device used within ComPAS2.

10.5.5 Equations & Scripts

ComPAS2 utilizes a powerful script 'engine' that provides a very versatile and 'open' architecture for all equations used in the program. It is through the "Equations and Scripts" section that predicted sets can be selected or edited.

Access to this very sensitive section of ComPAS2 is only available to users with the highest level of "User Rights".

Each equation set maintains the original script in a default file in case of accidental corruption.
Do not check the "Debug Mode" unless asked to do so by a Morgan Scientific support engineer. This is used to track down script errors when editing or developing new algorithms.

To change to a different predicted set, simply click on "Predicteds" and "Modify". From the pull-down selector, highlight the desired predicted set.

Editing equations or predicteds should only be done by a knowledgeable user or under guidance from a Morgan Scientific support engineer.

10.5.6 Test Protocols

A "Test Protocol" allows configuration of additional "levels" of testing. Typical pulmonary function tests consider just two levels of testing:

Pre-Bronchodilator
Post-Bronchodilator

In bronchial challenge testing there can be any number of additional levels of testing depending upon the protocol design, but typically these could be:

Typical Challenge protocol:

Baseline Level (Pre Bronchodilator)
Diluent Level (Saline)
Level 1 of challenge (0.625 mg/ml)
Level 2 of challenge (0.250 mg/ml)
Level 3 of challenge (1.000 mg/ml)
Level 4 of challenge (4.000 mg/ml)
Level 5 of challenge (16.000 mg/ml)
Recovery Level (Post Bronchodilator)

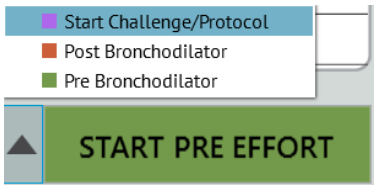
Beyond challenge testing, there are other testing protocols that can be configured, for example:

Dual Post Bronchodilator:
Pre-Bronchodilator
Post-Bronchodilator
Post2 for a second bronchodilator drug

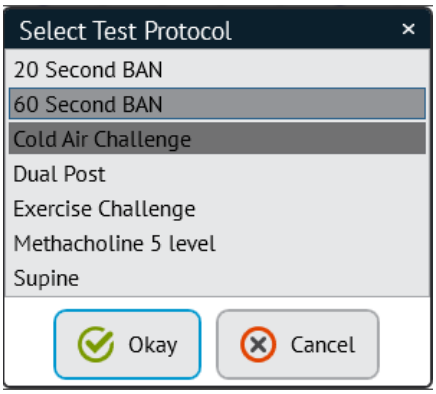
Hypertonic Saline:
Pre-Bronchodilator
Hypertonic Saline
Post-Bronchodilator

Upright Supine Testing:
Pre-Bronchodilator
Upright Position
Supine Position
Post-Bronchodilator

Any testing protocols that have been designed and saved in configuration are accessed in the runtime screen by selecting "**Start Challenge/Protocol**":



Once this option is selected, a menu of active protocol choices will be shown for selection:



The Test protocol designer can be configured to suit individual customer requirements.

10.5.6.1 Creating a Test Protocol:

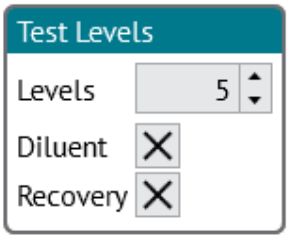
10.5.6.1.1 Bronchial Challenge:

For bronchial challenge testing, the protocol designer accommodates a wide variety of bronchial challenge testing techniques including: Challenge testing using an inhaler or nebulizer, cold air challenge or post-exercise challenge.

Challenge testing is usually carried-out in a timed-sequence of drug delivery followed by actual test efforts. The Protocol Designer allows users to set-up the exact sequence of testing following the particular method of challenge desired. It is very straightforward to use and extremely versatile!

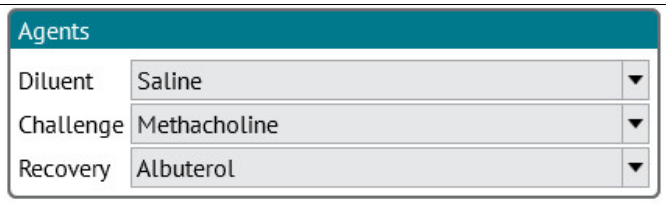
Creating or modifying a challenge protocol requires the following information to be entered:

1. Protocol Information **Name:**	

The name of the protocol is the identifier which will appear on both the configuration and testing screens. ComPAS2 has no limit for the number of protocols that can be saved. The name is also used to identify the type of test for reporting purposes. **Standard:** There are options that are used to identify the type of challenge testing: Legacy ERS Technical Standard 2017 Exercise Cold Air Aspirin	
2. Test Levels The number of test levels refers to the number of different drug solutions or time intervals not including a "diluent" or "Recovery" level. In other words, it is the number of challenge agent levels or time steps in the protocol. Some protocols call for a test to include a "Diluent" level. If this is required, check the diluent box. For challenge tests there should always be a "Recovery" level; check this option for the post bronchodilator step used to complete a test.	
3. Challenge Delivery For delivery, select the delivery method from the pull-down options. New delivery methods can be added if required. Delivery of challenge can include: Time Inhaler Nebulizer This choice governs the column choices and timing choices in the designer table.	
4. Agents This block requires information about the agents being used for "diluent", "challenge"	

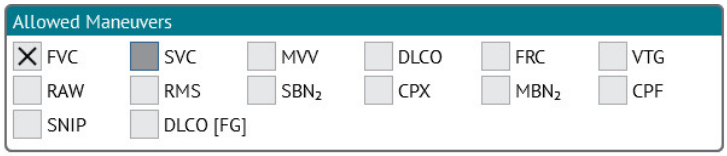
and "recovery". There is a pull-down list associated with each level.

If the drug or material desired is not displayed, simply click the "+" symbol to enter a new agent name.



5. Allowed Maneuvers

ComPAS2 will allow a challenge study to be carried-out in any test if desired. These check-boxes determine the test types where challenge can be activated.



6. Challenge Termination

In this section users can set up which parameters to follow for the dose response and also, under which conditions the test should be concluded.

The "Auto Terminate" sets conditions for signaling the technician that the maneuver can move on to "recovery" (administering the bronchodilator). This 'termination' can follow a single parameter (i.e. FEV1) or multiple parameters.

The "Maneuver Variable" column provides a pull-down list of all the available variables to follow (FEV1, FVC, Raw etc.).

The "Drops" column allows the setting of percentage drop (from baseline, diluent or previous level). This setting will trigger an alert to the technician during the runtime test. The alert will ask if a further effort is required to confirm the drop or whether the test should now move to the reversal stage.

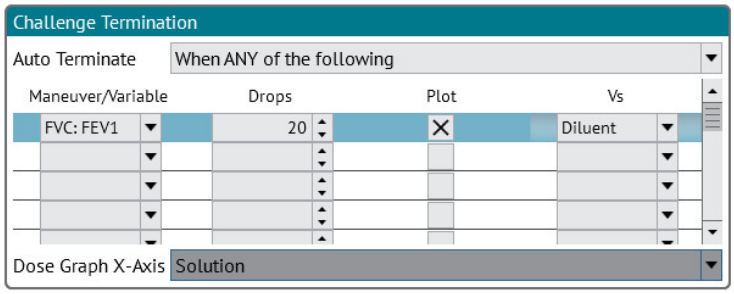
The "Plot" box turns-on the runtime dose response graphic.

Tracking the percentage drop/response in any protocol can be selected in the "Vs" column from three choices:

Drop from Diluent
Drop from Baseline
Drop from Previous Level

The "Dose Graph X-Axis" choice determines the graphing options from:

Concentration



Dose Cumulative Dose	

10.5.7 Examples of Challenge Protocols

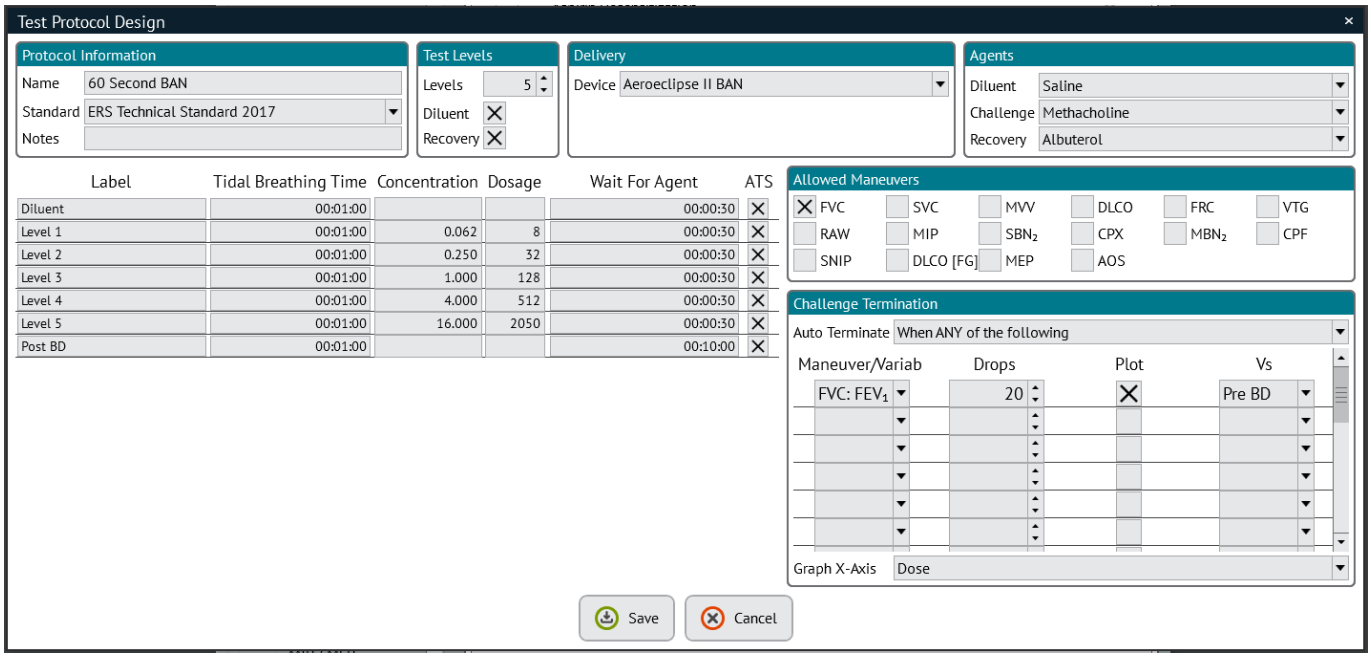
10.5.7.1 ATS Check Column in protocols

When building a test protocol, a column labelled “ATS” is provided to determine if spirometry grading should be applied, displayed, and saved for each level. Some protocols only demand one or two efforts at any given level rendering the grading perhaps unnecessary. This is a user choice.

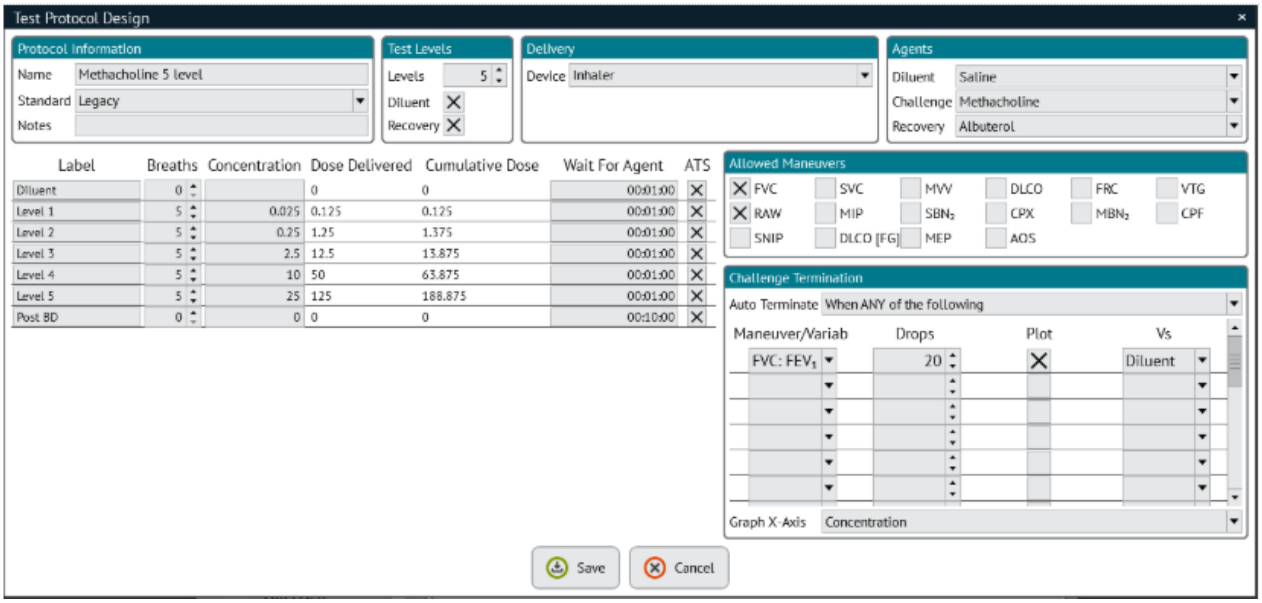
10.5.7.2 Methacholine Challenge

Bronchoprovocation testing using a bronchoconstrictor agent like Methacholine is used to evaluate reactivity of the lungs. The degree and type of reactivity (cough, chest discomfort or shortness of breath) help differentiate or confirm the presence of Asthma. The procedure requires the test subject to inhale different doses of Methacholine, a drug that can cause narrowing of the airways. The dose levels steadily increase if no reaction is present. Repeated flow volume loops are performed at each drug level to assess the FEV1 and compare it against either the baseline (normal room air) or sometimes against the diluent used to titrate the Methacholine (usually saline). Delivery of the Methacholine or provocation agent is typically by either by nebulizer or inhaler. As the test proceeds the FEV1 is monitored, and the user alerted if and when a reduction of 20% is identified. The test is concluded with the subject being given a bronchodilator to confirm that their breathing condition has been returned to pre-drug interference.

The "ATS" column can be activated or not; checking the option will engage the spirometry grading.



Example using a Nebulizer



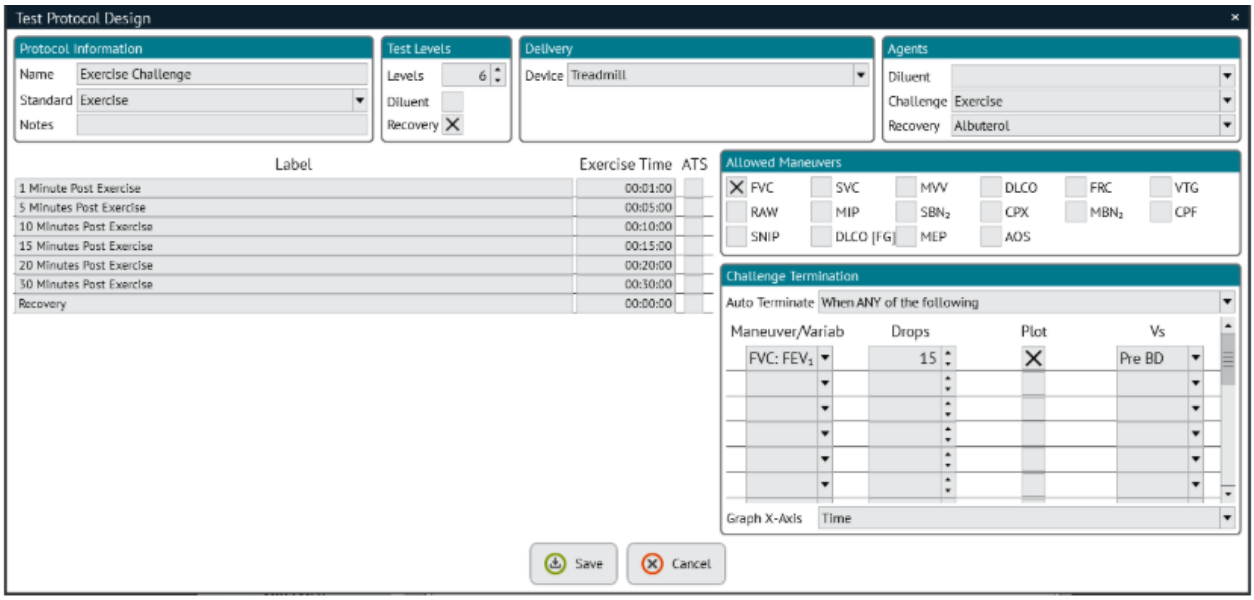
Example using a Breath Activated Inhaler

10.5.7.3 Exercise Challenge

Exercise is perhaps the most common trigger for subjects with asthma and hence testing to simulate exercise induced asthma (EIA) or exercise induced bronchoconstriction (EIB).

Protocols vary for exercise challenge, but typically subjects are asked to refrain from using their breathing medications and avoid any vigorous exercise for up to four hours before the study. When using a treadmill to simulate exercise, most protocols attempt to reach the subjects target heart rate within 4 minutes while wearing a nose clip to force mouth breathing.

Having challenged the subject with exercise, a common protocol is to measure FEV1 in time intervals as shown with a 15% reduction regarded as significant.



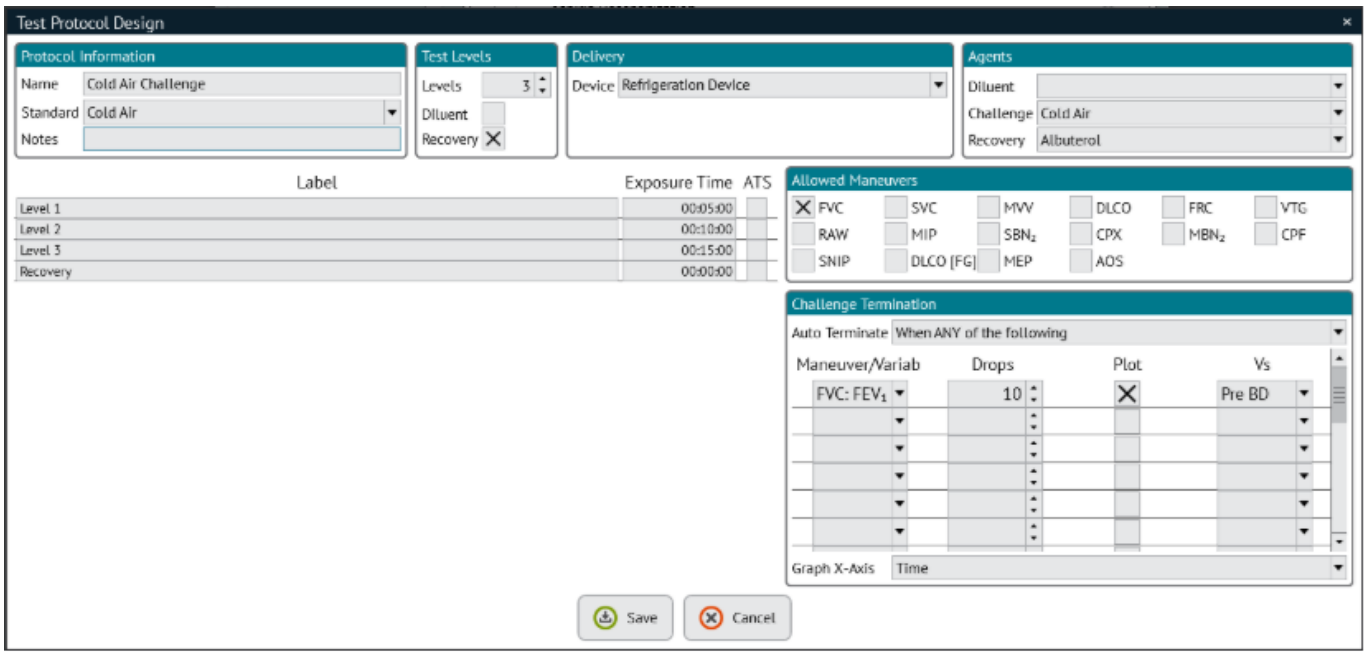
10.5.7.4 Cold Air Challenge

A Cold Air Challenge test consists of having a subject hyperventilate while breathing air that has been cooled to a temperature of between -10°C and -20°C. It is usually performed using a mixture of 5% CO2, 21% O2, 74% N2 to prevent dizziness from hypocapnia.

Most cold air challenge tests are performed with a single level of refrigerated air and with a minute ventilation target that ranges from 15 to 30 times the FEV1 or 40% to 80% of measured MVV. The period of hyperventilation is usually 3 to 4 minutes.

Having challenged the subject with cold air, a common protocol is to measure FEV1 in 5-minute intervals as shown with a 10% reduction regarded as significant.

The "ATS" column can be activated or not; checking the option will engage the spirometry grading.



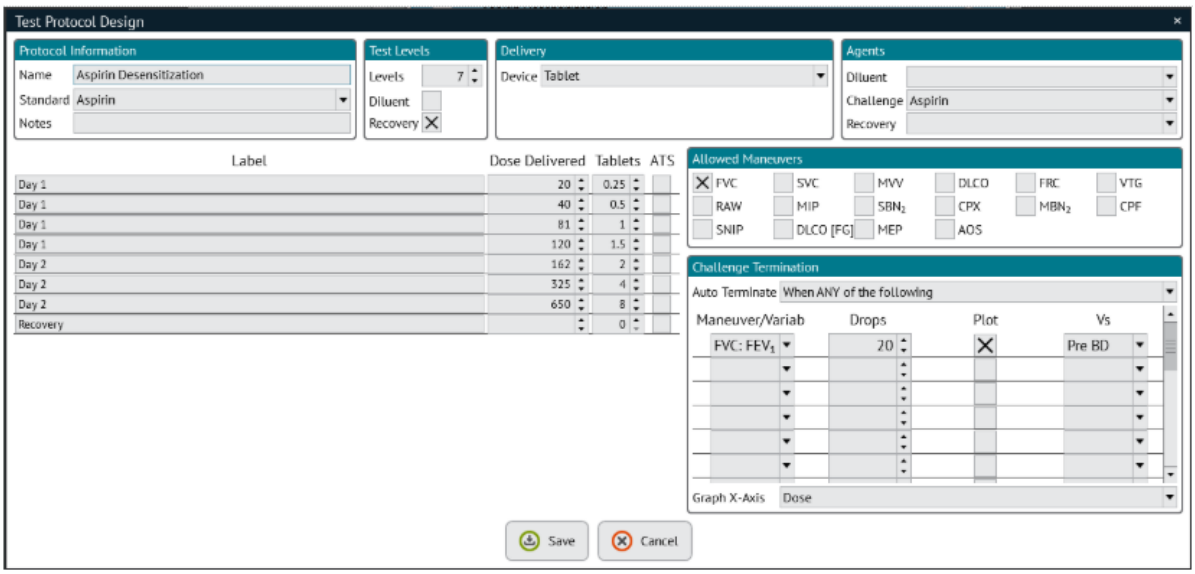
10.5.7.5 Aspirin Desensitization Challenge

Aspirin is an inhibitor that prevents platelet aggregation and is a common treatment for patients with coronary artery disease. However, hypersensitivity or intolerance may restrict its use in some patients. An Aspirin desensitization study is often considered in patients who require long-term therapy for cardiovascular indications.

The typical aspirin study spans two days but to report the data in ComPAS2 the test record **must continue** from Day1. In simple terms this means that the test from the previous day is recalled and the protocol continued until completion of the study.

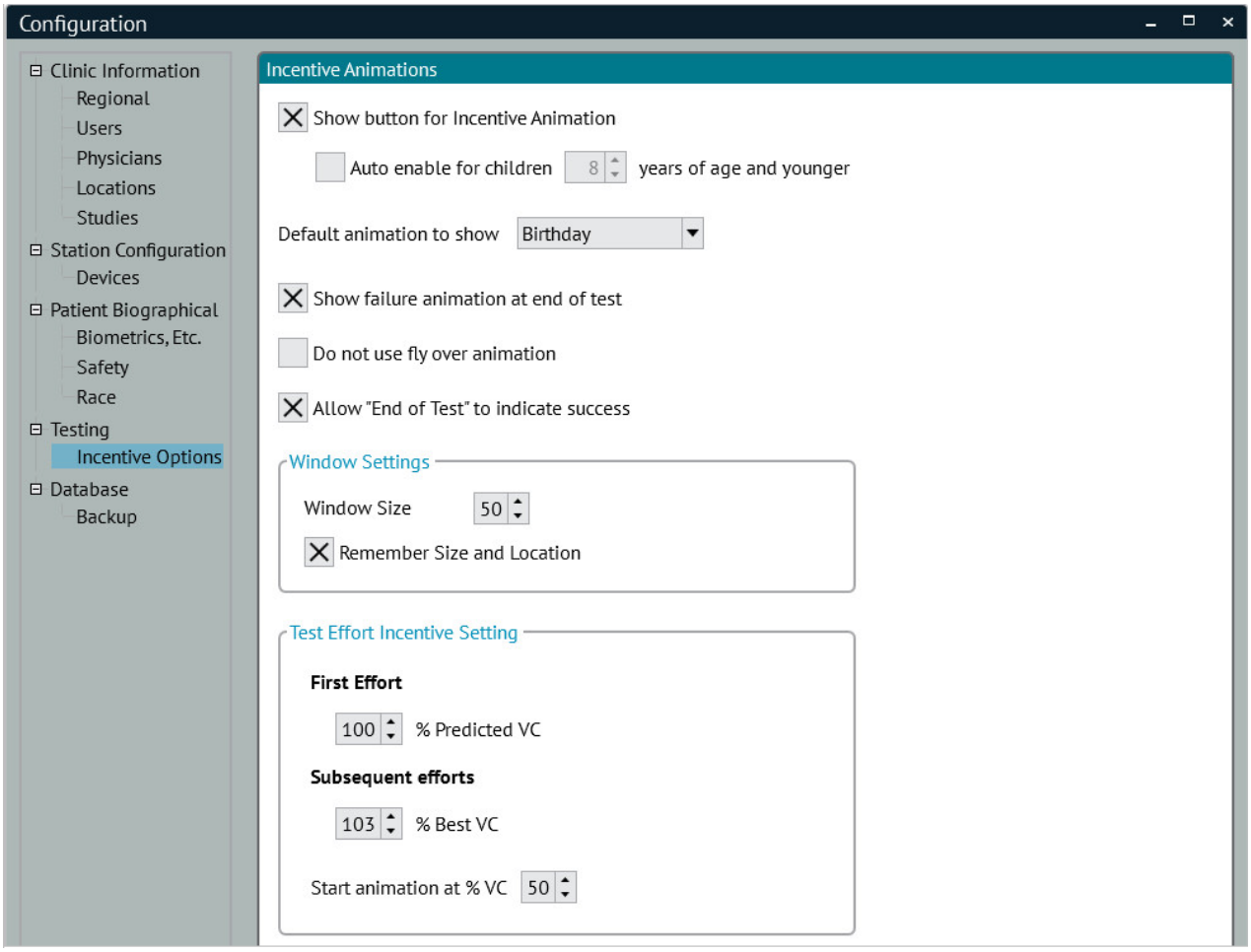
To accommodate this requirement, the protocol designer allows labelling of the "Day" so that it can be shown as the aspirin study advances.

The "ATS" column can be activated or not; checking the option will engage the spirometry grading.



10.5.8 Spirometry Incentives

These are optional configuration settings to be used when using spirometry incentives.

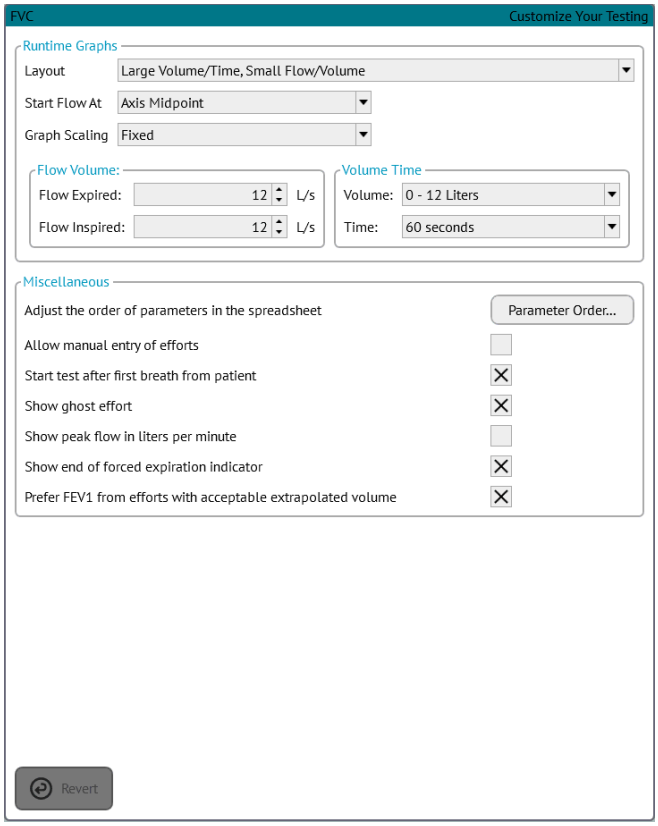


Incentive animation to show:	This is the default animation graphic. Choices include: • Birthday Cake • Fire Breathing Dragon • Rocket Ship • Dandelion
Show failure animation at end of test	If the subject fails to reach the measures of a successful test: • End of test detection achieved • Percent Best VC target achieved An animation of failure together with sound is generated.
Do not use fly over animation	Some animations use a moving camera view as the test effort is running. This can be turned-off if desired.
Allow "End of Test" to indicate success	This option accepts "end of test detection" as a successful effort even if the subject fails to reach the % FVC target volume.
Window Size	This setting sizes the pop-up window for the incentive graphic
Remember size and location	With this setting checked, the size and location of the pop-up window will be remembered on subsequent efforts
First Effort	***First Effort Incentive Setting*** This allows the user to set an incentive target based on a percentage increase from the predicted value. A setting of 5 will mean that the incentive target is 105% of predicted value.
Subsequent Efforts	***Subsequent Effort Incentive Setting*** This allows the user to set an incentive target based on a percentage increase from the best FVC value. A setting of 5 will mean that the incentive target is 105% of best FVC achieved so far.

10.5.9 Runtime Options

10.5.9.1 FVC Runtime Options

These are optional configuration settings to be used in FVC testing.

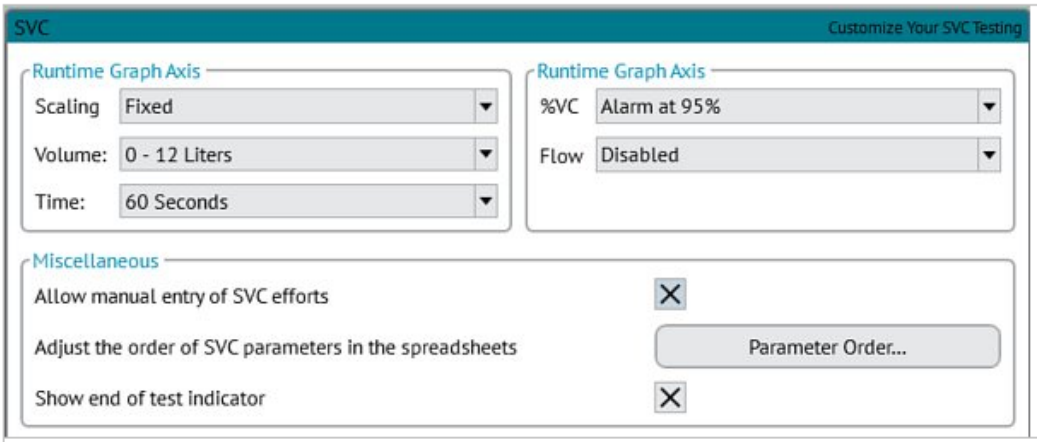


Optional settings include:

Runtime Graphs:	**Layout:** Choice of graphics display in runtime with preferences for Large Volume-Time or Large Flow Volume **Start Flow at:** Typically, all tests start the graphic at the axis midpoint, but starting at zero can be selected **Graph Scaling:** Fixed scaling will use the scale settings shown below. Dynamic will auto-scale to the Predicted PEFR or actual PEFR (whichever is the greatest) always maintaining a 2:1 relationship to volume
Miscellaneous:	**Adjust the order of FVC parameters in the spreadsheets:** Ability to order parameters in all data tables used in ComPAS2 **Allow Manual Entry:** Turn ON/OFF the ability to enter third-party data into the Mini-Results or Large Spreadsheet screens **Start test after first breath from patient:** Start the test running when a breath is detected from the subject **Show ghost effort:** Turn ON/OFF the ghosted Flow Volume loop of the best effort so far during each Flow Volume test **Show peak flow in liters per minute:** This setting will change the PEFR to show Liters/min **Show end of forced expiration indicator:** This setting should always be used. It is the graphic and audible sound (if turned-on) for achieving a plateau at the conclusion of forced expiration. **Prefer FEV1 from efforts with acceptable extrapolated volume:** When considering the reported FEV1 on all F/V efforts, even those with poor test grades, only efforts that pass the back extrapolated volume will be evaluated.

10.5.9.2 SVC Runtime Options

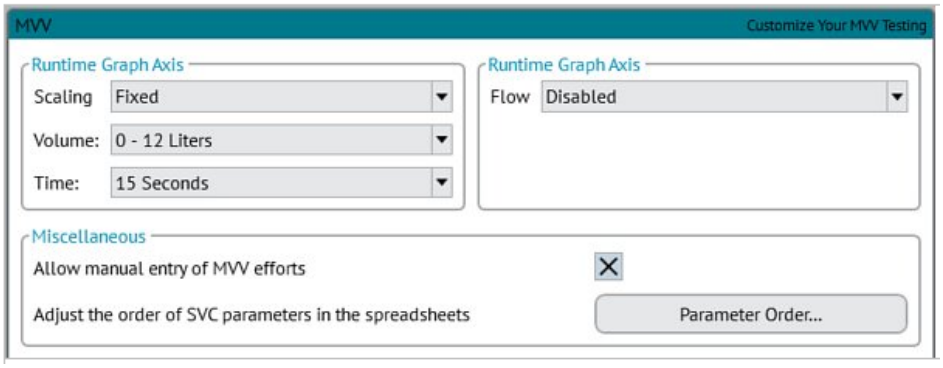
These are optional configuration settings to be used in SVC testing.



Miscellaneous:	**Allow Manual Entry:** Turn ON/OFF the ability to enter third-party data into the Mini-Results or Large Spreadsheet screens **Adjust the order of SVC parameters in the spreadsheets:** Ability to order parameters in all data tables used in ComPAS2 **Show end of test indicator:** Turn ON/OFF the end of test meter during testing

10.5.9.3 MVV Runtime Options

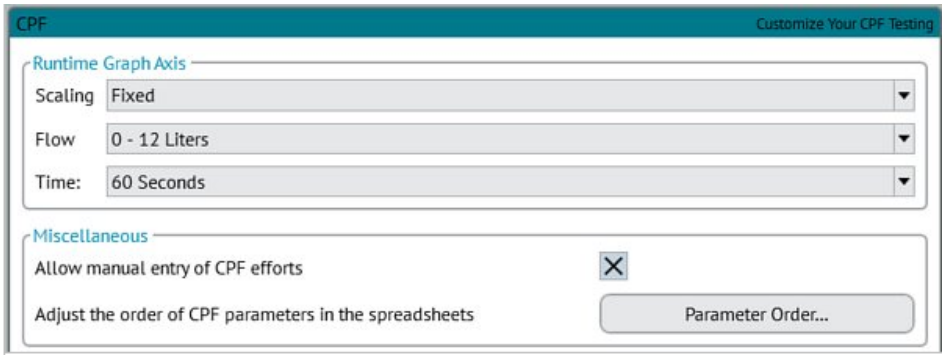
These are optional configuration settings to be used in MVV testing.



Scaling:	**Fixed scaling**: will use the scale settings shown below. **Dynamic:** not used in MVV
	Allow Manual Entry: Turn ON/OFF the ability to enter third-party data into the Mini-Results or Large Spreadsheet screens **Adjust the order of MVV parameters in the spreadsheets:** Ability to order parameters in all data tables used in ComPAS2

10.5.9.4 CPF Runtime Options

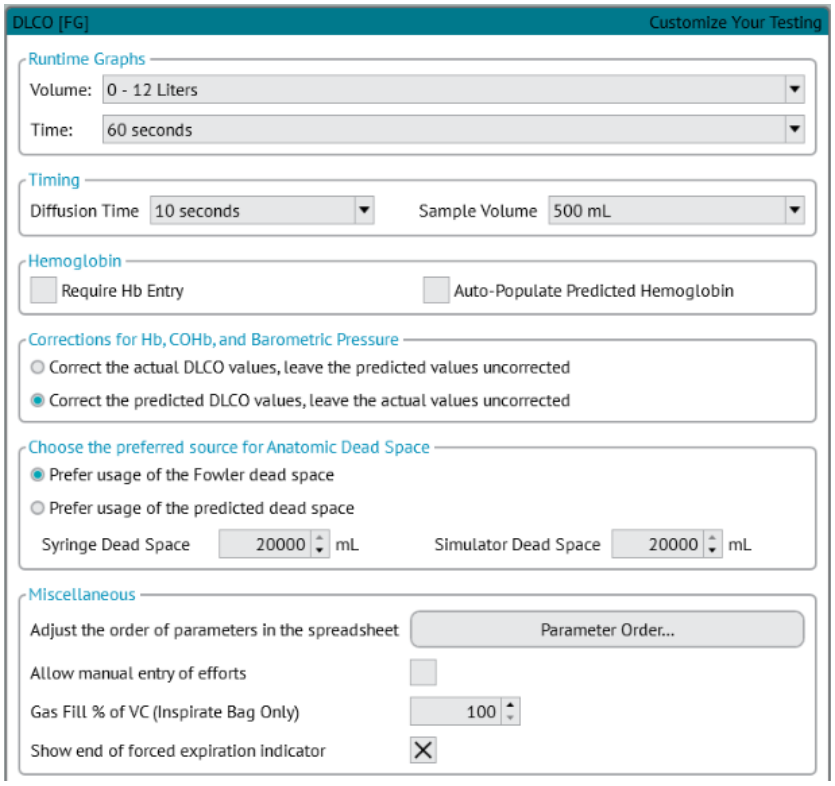
These are optional configuration settings to be used in CPF testing.



Scaling:	**Fixed scaling**: will use the scale settings shown below
	Allow Manual Entry: Turn ON/OFF the ability to enter third-party data into the Mini-Results or Large Spreadsheet screens **Adjust the order of CPF parameters in the spreadsheets:** Ability to order parameters in all data tables used in ComPAS2

10.5.9.5 FG DLCO Runtime Options

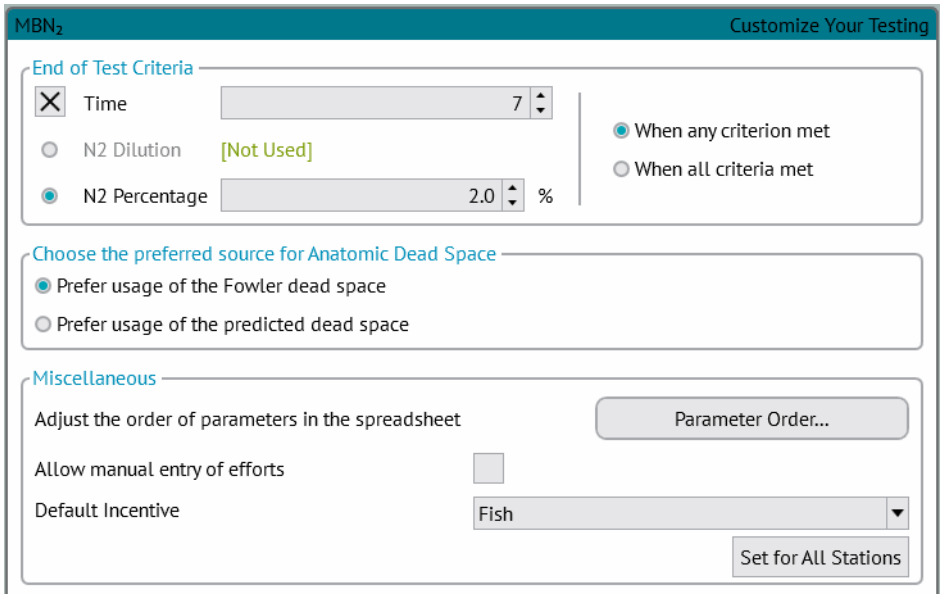
These are optional configuration settings to be used in FG DLCO testing.



Scaling:	**Fixed scaling**: will use the scale settings shown below.
Timing:	**Diffusion Time:** The target for Diffusion Time. Reducing or increasing this value will change the estimated breath hold time during the DLCO test. **Sample Volume:** The volume over which the fast gas expirate sample is averaged.
Hb Entry:	**Require Hb Entry:** Selecting this option will force the entry of Hb before any DLCO effort. **Auto-Populate Predicted Hb:** If no actual Hb is entered for a subject, gender-based default values coming from the predicted script can be used if this option is selected.
Corrections for Hb, COHb, MetHb and PB	Since the consensus on how to handle Hb corrections for DLCO reporting is divided, two options are provided in ComPAS2: 1) Correct the actual DLCO values 2) Correct the predicted DLCO values
Preferred Source for Anatomic Dead Space:	1) Use the automated Fowler Dead Space measurement 2) Use the predicted anatomic Dead Space value *Note: Total Dead Space includes the setting for Anatomic Dead Space + Valve Dead Space + Filter Dead Space (the latter two values are configured in the Device Configuration)*
Miscellaneous:	**Adjust Order of DLCO Parameters in the spreadsheets:** See Adjusting Order of Parameters **Allow manual entry of DLCO efforts:** Turning this option ON adds the right-click menu item for manual entry of DLCO values

10.5.9.6 MBN2 Runtime Options

These are optional configuration settings to be used in MBN2 testing.



For instruments fitted with a second monitor, video incentives are available when running MBN2, the default can be selected here.

Note: When using the second monitor, select "Extend these displays" from the "Display Settings" in Windows.

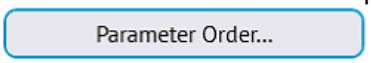
10.5.9.7 Adjusting Order of Parameters

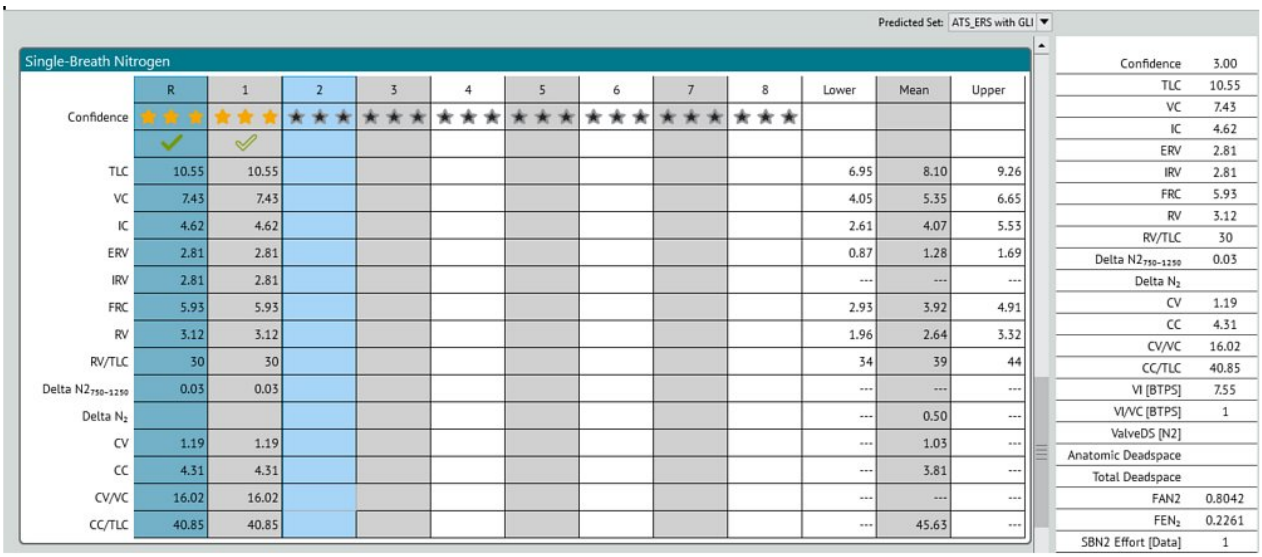
The ability to change the order of parameters in each of the ComPAS2 tables is common to every test type.

On each test type Runtime Options screens, there is a button to allow custom configuration of parameter order:

Adjusting the Main Spreadsheet Variable Order:

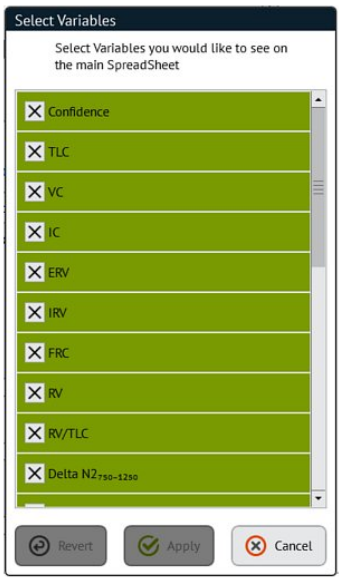
There are two sections of the spreadsheet, the left-hand spreadsheet view and the right-hand variable





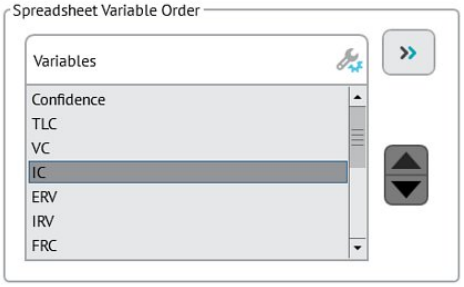
	R	1	2	3	4	5	6	7	8	Lower	Mean	Upper
Confidence	★★★	★★★	★★★	★★★	★★★	★★★	★★★	★★★	★★★			
TLC	10.55	10.55								6.95	8.10	9.26
VC	7.43	7.43								4.05	5.35	6.65
IC	4.62	4.62								2.61	4.07	5.53
ERV	2.81	2.81								0.87	1.28	1.69
IRV	2.81	2.81								---	---	---
FRC	5.93	5.93								2.93	3.92	4.91
RV	3.12	3.12								1.96	2.64	3.32
RV/TLC	30	30								34	39	44
Delta $N2_{750-1250}$	0.03	0.03								---	---	---
Delta N_2										---	0.50	---
CV	1.19	1.19								---	1.03	---
CC	4.31	4.31								---	3.81	---
CV/VC	16.02	16.02								---	---	---
CC/TLC	40.85	40.85								---	45.63	---

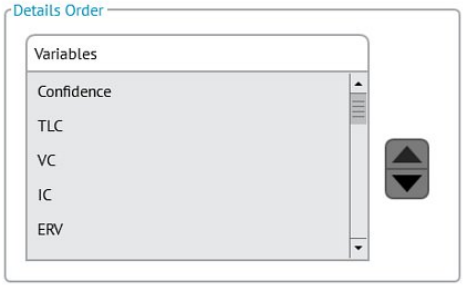
Confidence	3.00
TLC	10.55
VC	7.43
IC	4.62
ERV	2.81
IRV	2.81
FRC	5.93
RV	3.12
RV/TLC	30
Delta $N2_{750-1250}$	0.03
Delta N_2	
CV	1.19
CC	4.31
CV/VC	16.02
CC/TLC	40.85
VI [BTPS]	7.55
VI/VC [BTPS]	1
ValveDS [N2]	
Anatomic Deadspace	
Total Deadspace	
FAN2	0.8042
FEN_2	0.2261
SBN2 Effort [Data]	1

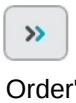


On the Spreadsheet Variable Order screen is a tool icon  that allows users to select the parameters available to order.

Selecting or de-selecting variables here will either make them available for listing or not.



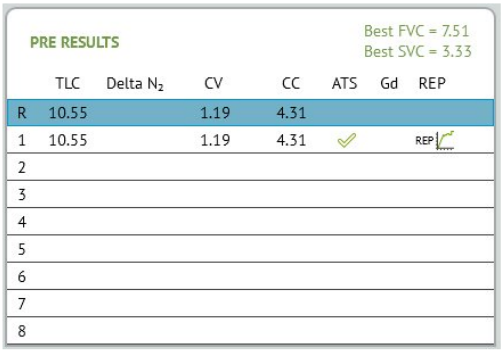


Since the order of main parameters between the "Spreadsheet Variable Order" table and the "Details Order" is often the same, a move button  allows users to replicate the same order between tables. The "Details Order" has further variables that can be ordered beyond those shown on the left. These typically include variables that make up the calculation of final results.

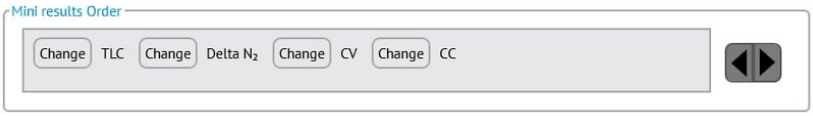
To move variables up and down in either table, simply highlight the variable desired and use the  arrows.

Adjusting the Mini Results Data Order:

For each test type the Mini Results allows display of 4 key parameters.

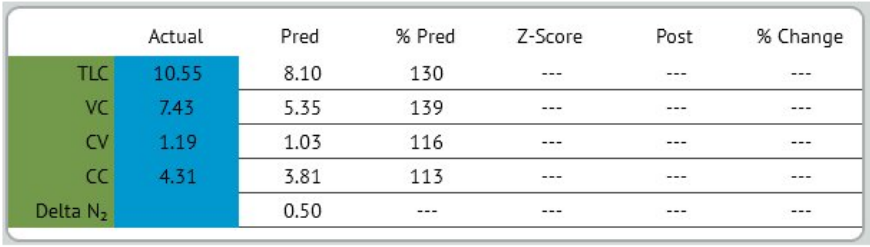


To select which parameters and a preferred left to right order click [Change] and select the variable desired.



Adjusting the Predicted Results Data Order:

For each test type the Predicted display section on Mini Results allows display of 5 key parameters.



	Actual	Pred	% Pred	Z-Score	Post	% Change
TLC	10.55	8.10	130	---	---	---
VC	7.43	5.35	139	---	---	---
CV	1.19	1.03	116	---	---	---
CC	4.31	3.81	113	---	---	---
Delta N_2		0.50	---	---	---	---

To select which parameters and a preferred top to bottom order click [Change] and select the variable desired.

10.6 Reporting

The reports configuration determines which of the numerous report styles are viewable for the user. Reports marked with an "X" will be available from the pulldown of choices in the reports section.

The 

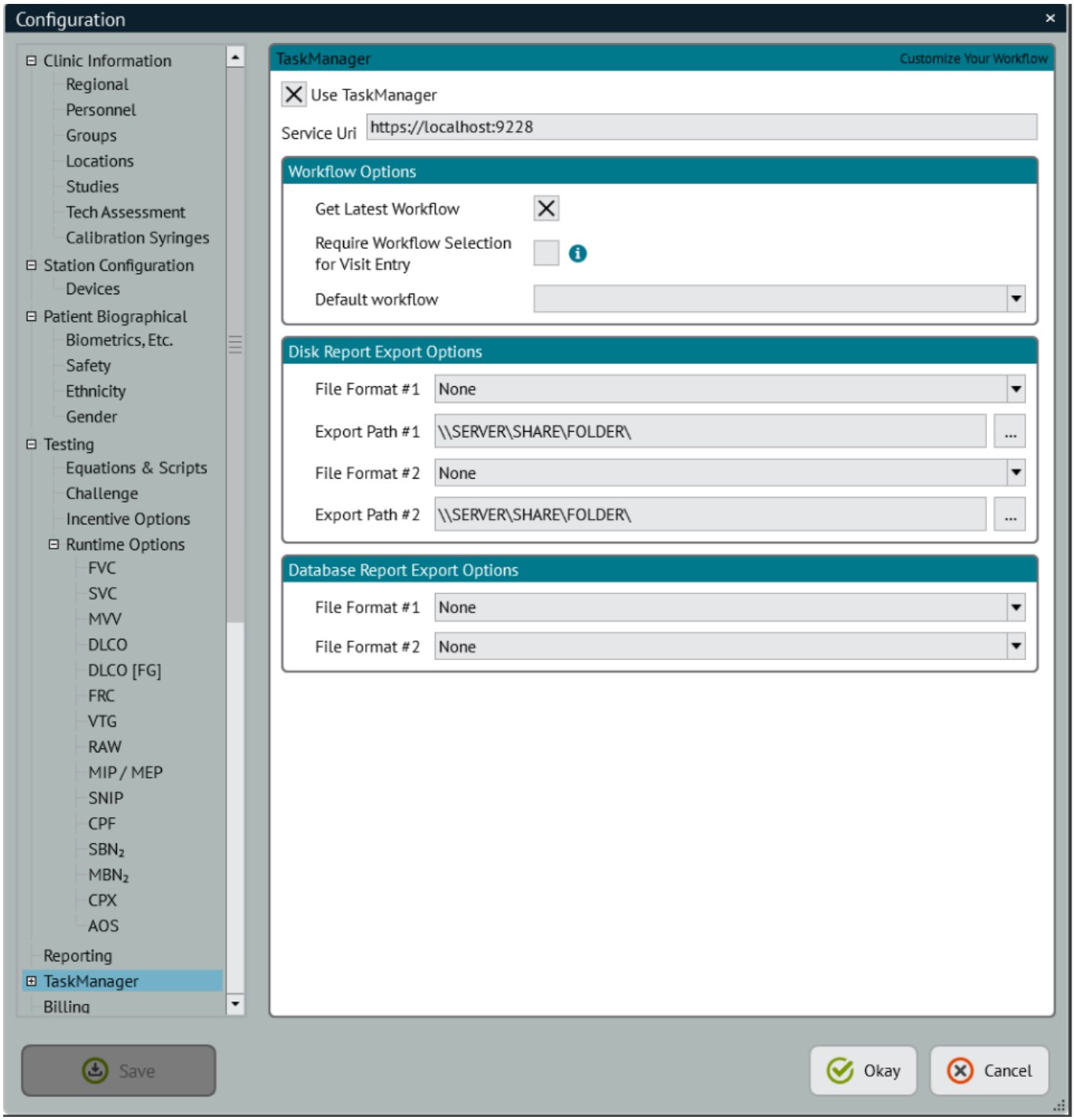
button allows users to select a report style as a default presentation.

10.7 Task Manager

10.7.1 Task Manager Configuration

Settings for Task Manager within ComPAS2

Set "Use Task Manager" to turn-on all the features of Task Manager.

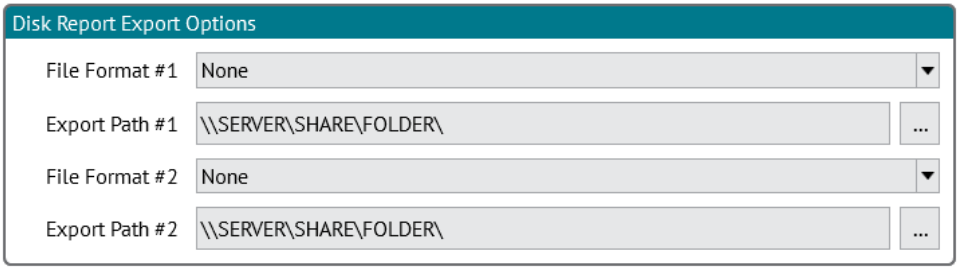


10.7.2 Workflow

Require Workflow Selection - Setting this option will force the technician to select a workflow when entering patient testing.

Default Workflow - Sets the default workflow to be used.

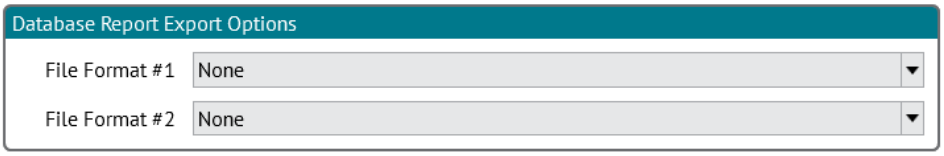
10.7.3 Disk Report Export Options



These are settings that allow the automatic export of reports in various formats to file share locations.

File Format #1 - Options of all file formats supported in ComPAS2 (PDF, TIFF, RDF, XML, TXT & DOC)
Export Path #1 - Sets the export file share location that File Format #1 will be sent to
File Format #2 - Options of all file formats supported in ComPAS2 (PDF, TIFF, RDF, XML, TXT & DOC)
Export Path #2 - Sets the export file share location that File Format #2 will be sent to

10.7.4 Database Report Export Options



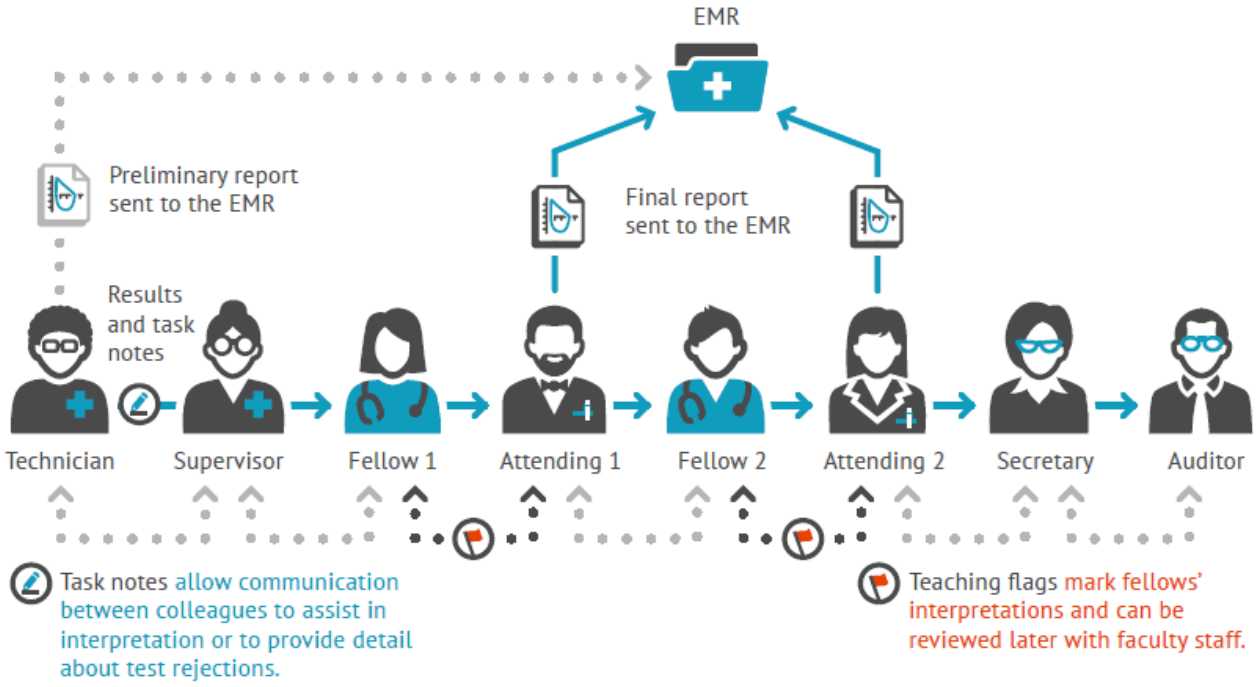
When exporting a report to the database, to be sent to an EMR, it specifies the file type (PDF, TIFF, etc.). Many locations cannot accept a PDF and require a TIFF. Some locations may need ComPAS2 to generate both – one being sent to the EMR in one format and another being sent to an archival system in a different format.

File Format #1 - Options of all file formats supported in ComPAS2 (PDF, TIFF, RDF, XML, TXT & DOC)
File Format #2 - Options of all file formats supported in ComPAS2 (PDF, TIFF, RDF, XML, TXT & DOC)

10.7.5 Workflows Configuration in Task Manager

The workflow configuration of Task Manager allows for incredible flexibility to suit all situations.

A workflow is a repeatable pattern of activity or stops as test data is moved from one colleague to another within the organization. It can be thought of as a line of colleagues down a corridor with a patient file being handed from one to the other. The workflow configuration not only sets up the number of colleagues or stops in that line, it can set actions taken at any given stop in the activity.



Once set-up the Workflow establishes the columns displayed in the Administrative View of Task Manager and dictates which fields of personnel are displayed in patient entry.

10.7.5.1 Workflow Synchronization with the Patient Entry Screen

The fields of personnel available in the patient entry screen are dictated by the design and workflow selected. For example:

Standard Workflow

Technician
Attending Physician1
Referring Physician

Other examples of workflow could expand the locations for personnel as follows:

Teaching Workflow

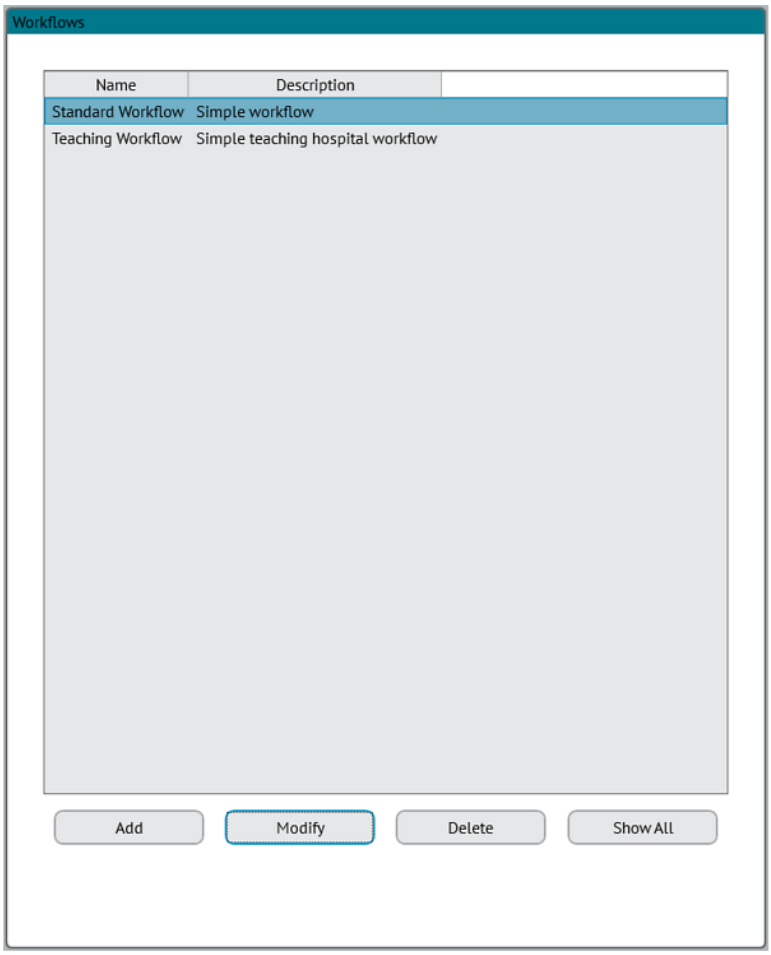
Technician
Pulmonary Fellow1
Attending Physician1
Referring Physician

Advanced Workflow (if configured this way)

Technician
Pulmonary Fellow1
Attending Physician1
Pulmonary Fellow2
Attending Physician2
Referring Physician

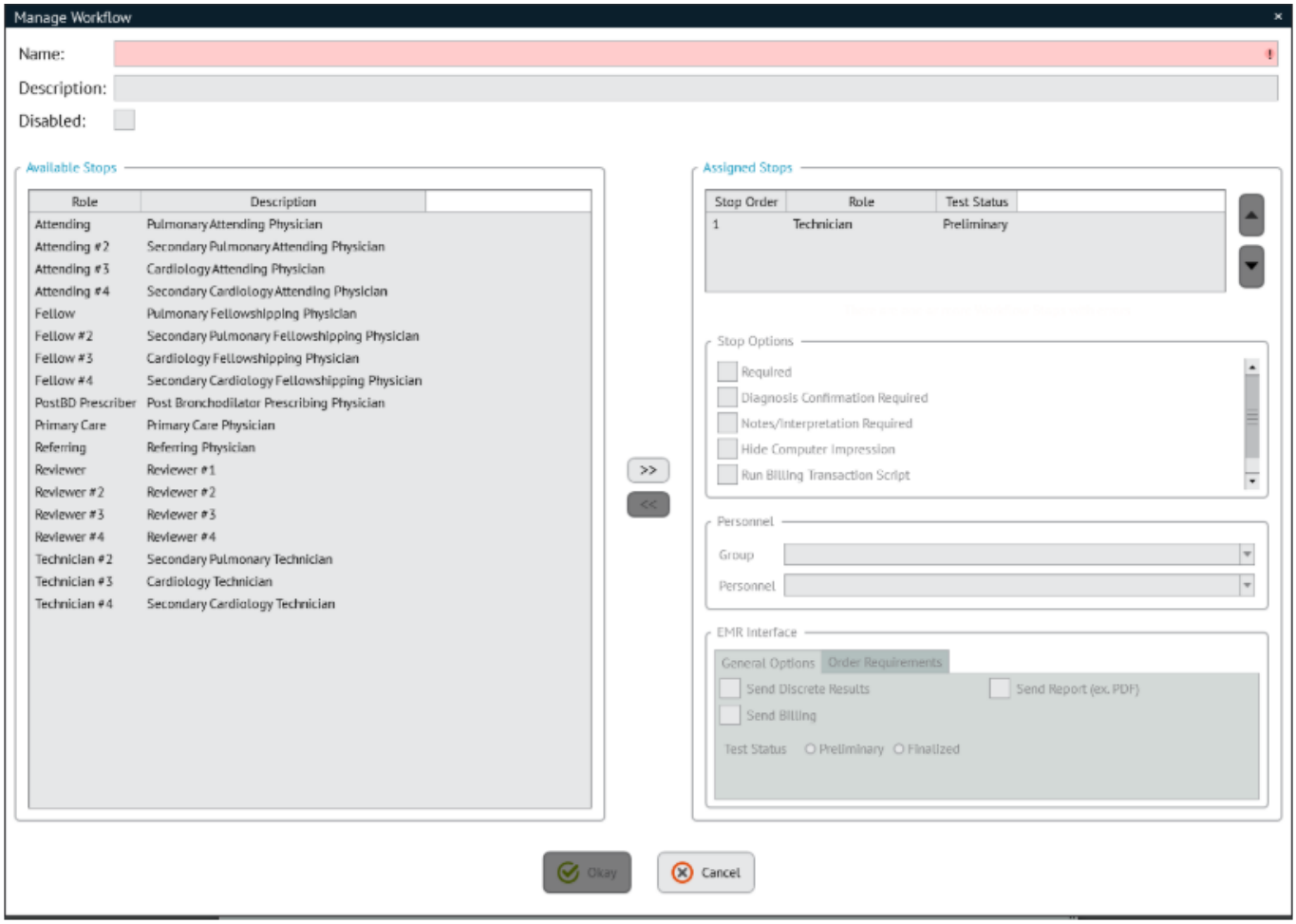
10.7.5.2 Creating a New Workflow

From ComPAS2 configuration, click on Task Manager and Workflows



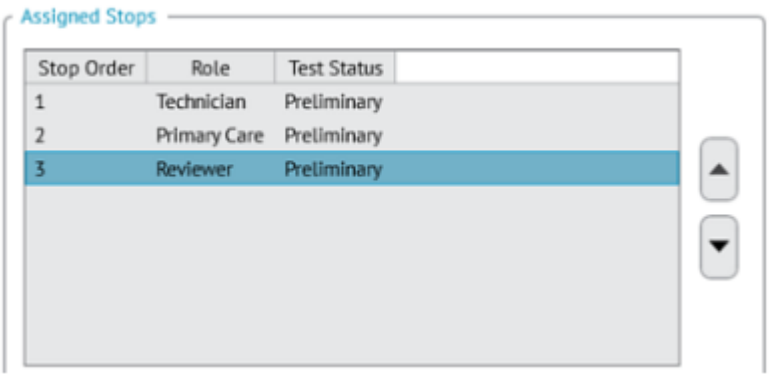
Click 

to create a new workflow.

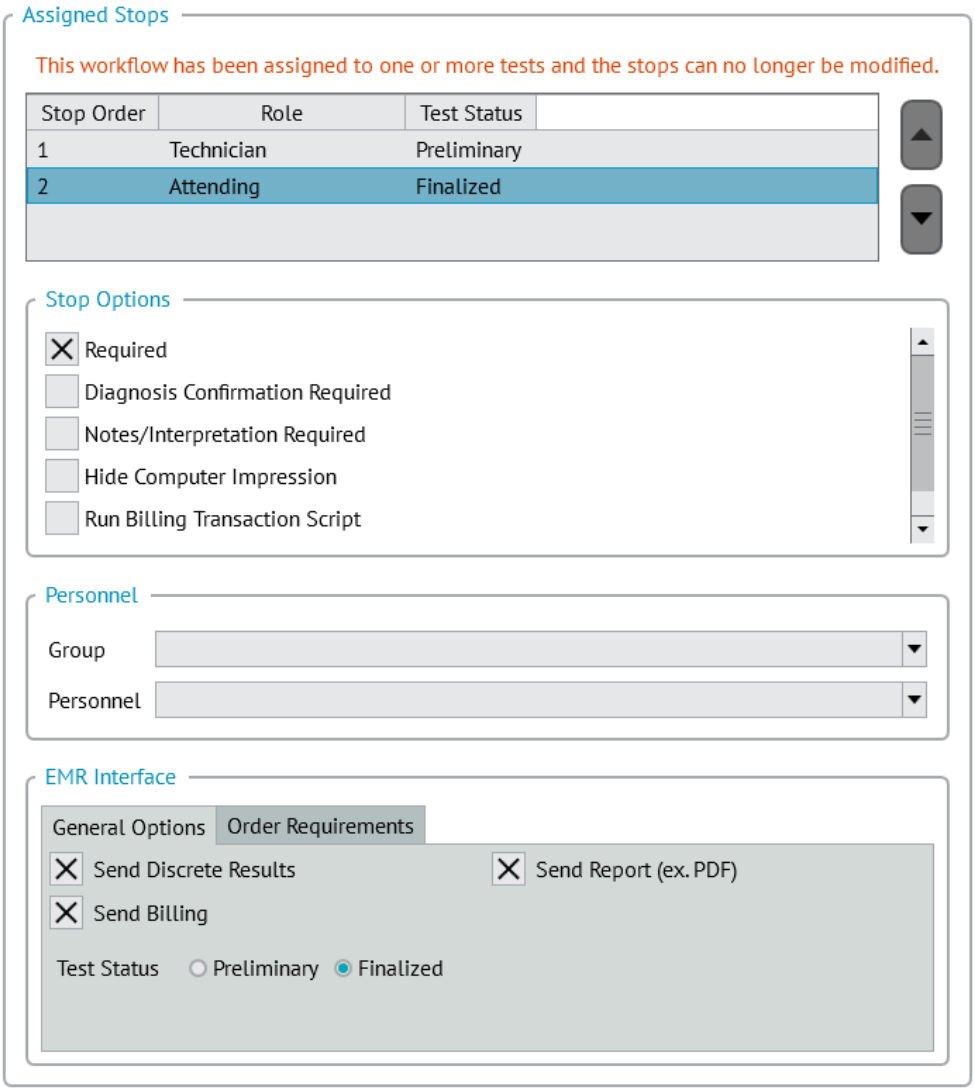


The first entry is to give the workflow its own unique name.

Creating the workflow is an easy case of moving the appropriate "Available Stops" into the "Assigned Stops" area. Simply highlight the stop required and click >> . If a stop has been mistakenly moved into the assigned area, it can be moved back by highlighting and clicking << .

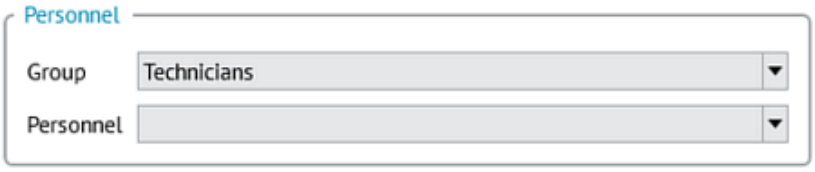


The order of stops can be adjusted using the Up and Down arrows.

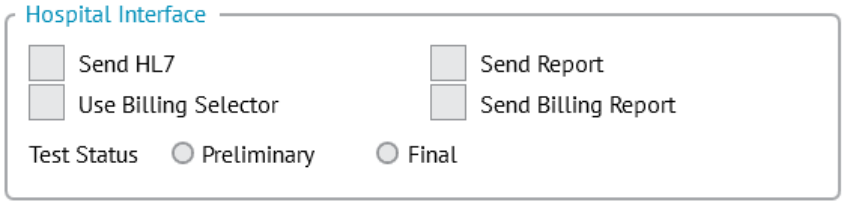


Each stop along the workflow can have assigned properties or actions. These include:

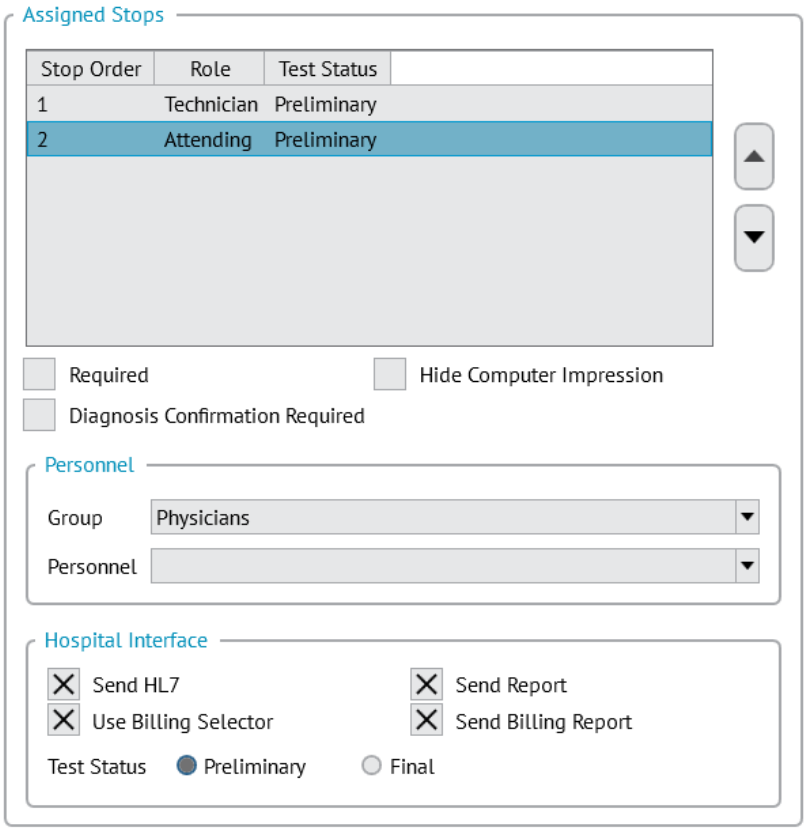
Option	Explanation
Required	Making any stop a "required" stop in workflow
Hide Computer Impression	This will hide the computer impression at any stage in workflow. Often the computer impression is hidden from Pulmonary Fellows.
Notes/Interpretation Required	This will prevent a test being approved without either notes or an interpretation being completed depending upon the workflow stop
Diagnosis Confirmation Required	This demands that an ICD-10 diagnosis be confirmed before moving to the next stop



The "Personnel" section is used to determine which groups or individuals can be included in any stop. Only one or the other choice can be made.



The "Hospital Interface" section is used to decide what is sent to the electronic medical record at any stop and whether the test status is preliminary or final. It also provides options send a billing at any stop.



For each stop in the new workflow, the actions can be selected. Highlight the stop to make configuration choices.

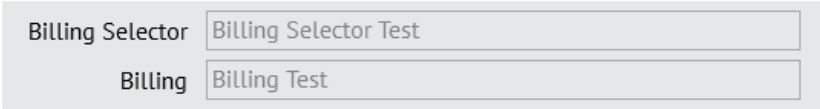
The [Order Requirements] tab can set required fields that must contain information before approval is accepted.

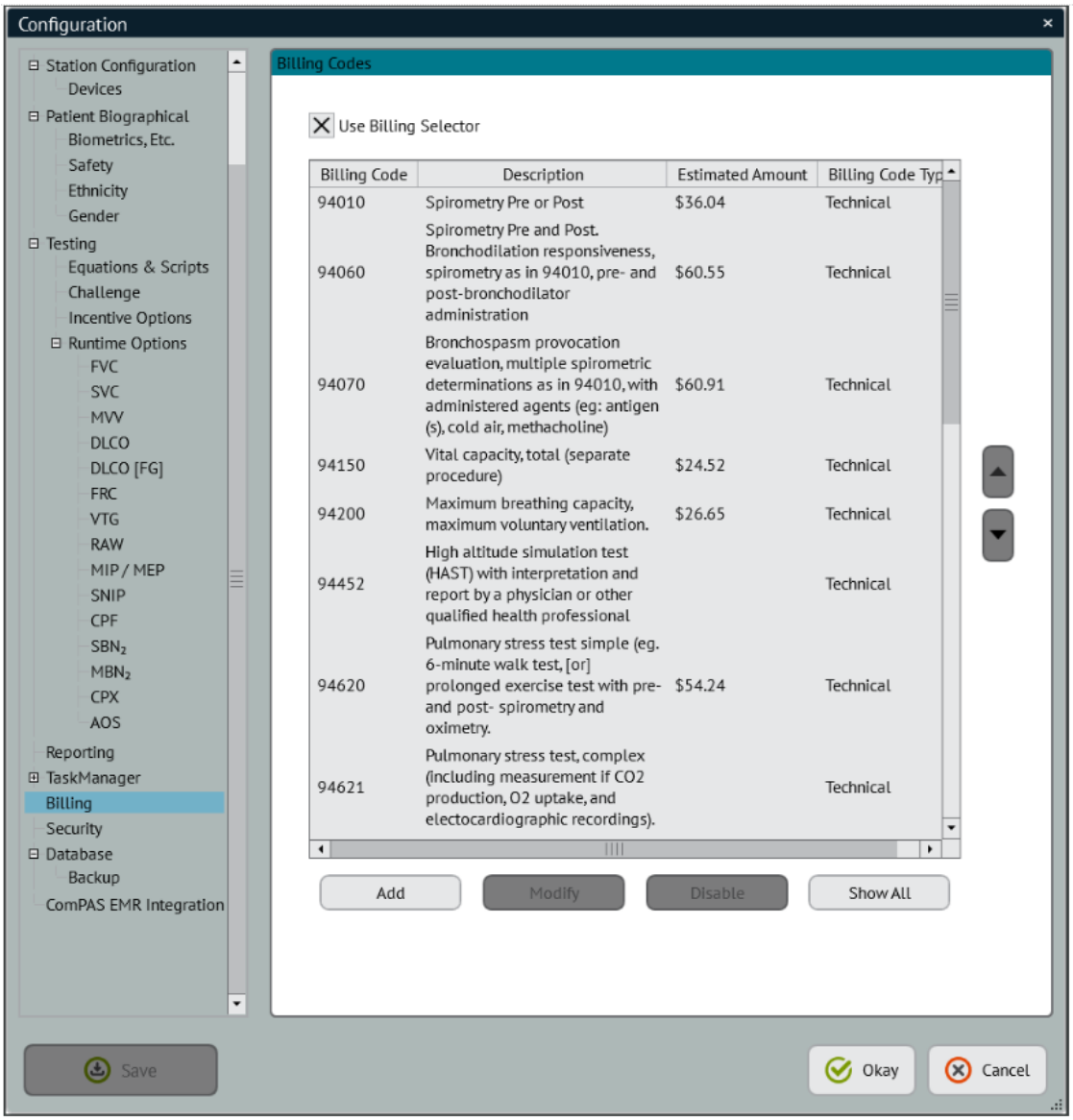
The label field is used within the macro of error messages to the end-user to identify any problem.

10.8 Billing

Settings for billing within ComPAS2.

Note: For the billing options to operate, the necessary scripts should be selected in the "Equations and Scripts" section:

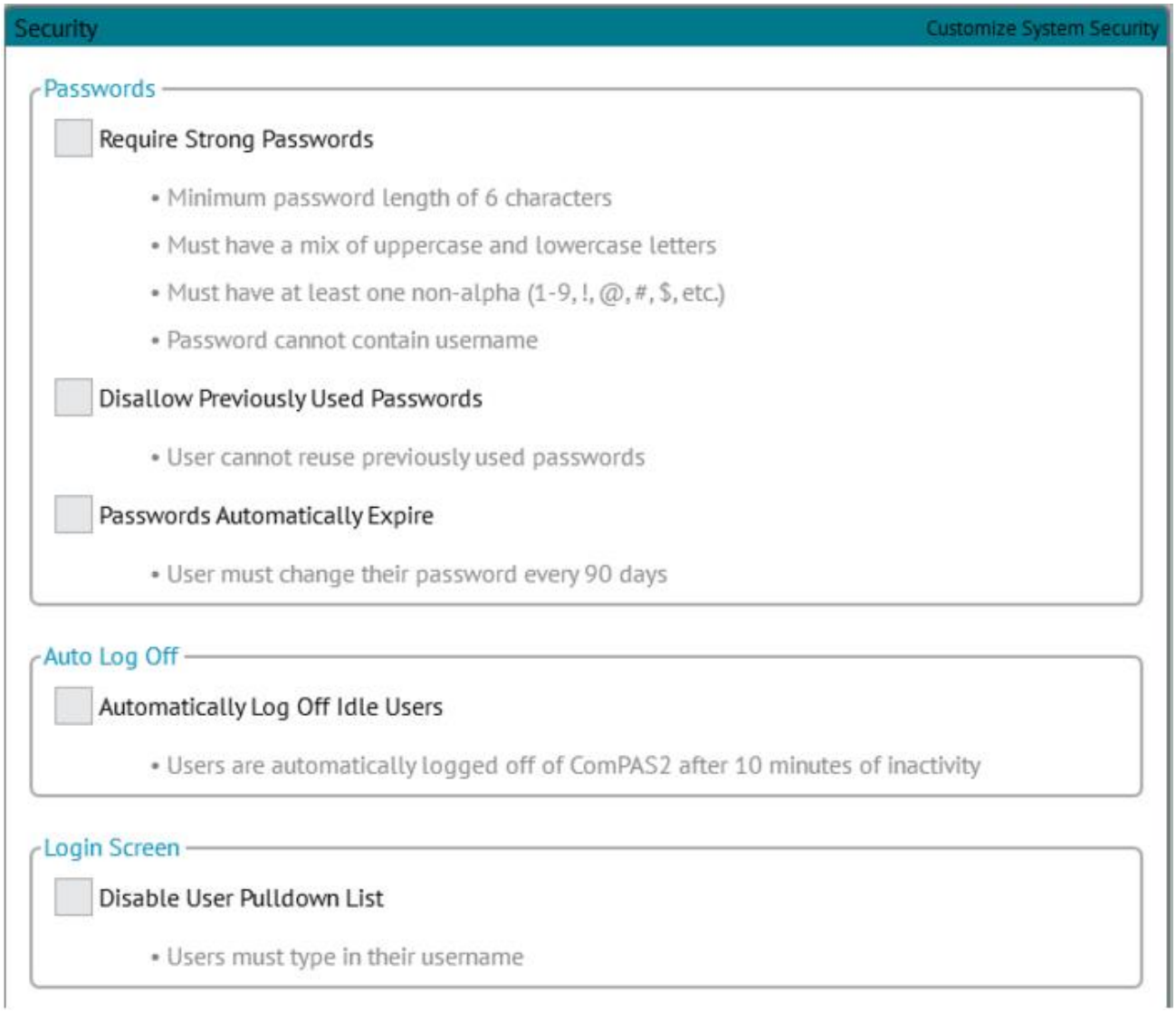




The billing configuration is pre-populated with common CPT codes for pulmonary function tests. Further codes can be added as desired. The "Estimated Amount" shown for reimbursement is very much an average amount, these values should be edited to reflect local figures if reports of financial activity are of interest.

10.9 Security

Settings for security and logins around ComPAS2.

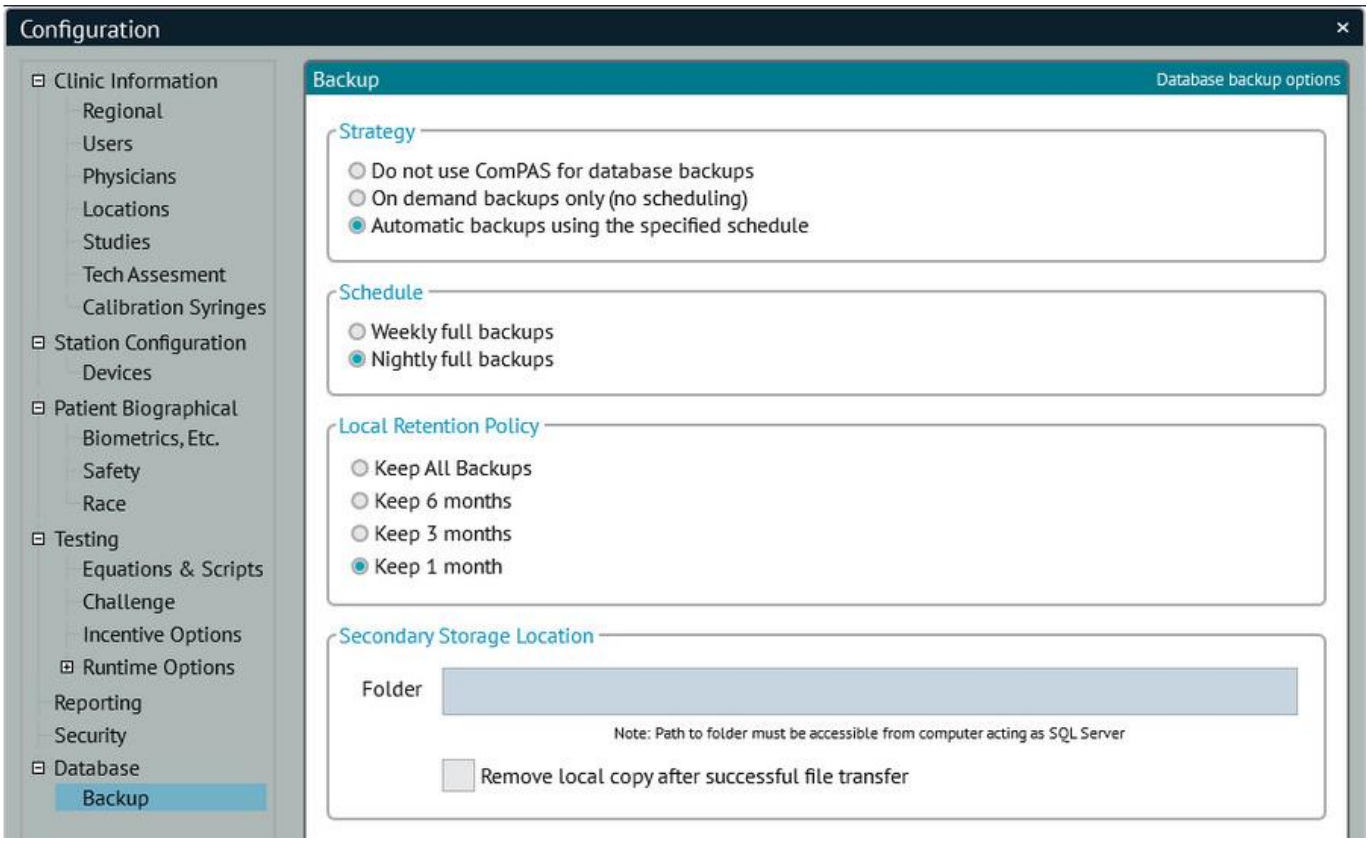


11:0 ComPAS2 Database Utilities

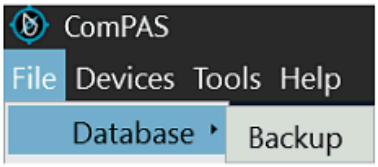
11.1 Backing-up the SQL Database
Although computers are more reliable than ever today, hard disks can fail; it is paramount that data are preserved or backed-up to prevent loss of historical records!

ComPAS2 comes with a built-in backup utility which can be set-up to run automatically storing files both locally (on the PC) and to an independent connected storage device or LAN.

The back-up scheduler can be configured in Configuration.



Having the automatic back-up provides excellent security for data, but at any time a back-up can be generated manually. Go to "File", "Database" and "Backup":



Once selected the backup will commence:

By default, the local edition of the backup is stored in the following directory:

C:\ProgramData\Morgan Scientific\ComPAS2\Backup

The storage location can be changed in configuration if desired.

The data are stored and encrypted into a Zip file (Database Name Year Month Day) with a name similar to:

ComPAS2 2018-05-09 15-58-04.zip

Automatic backups are set to run at midnight and can be identified with the following time stamp:

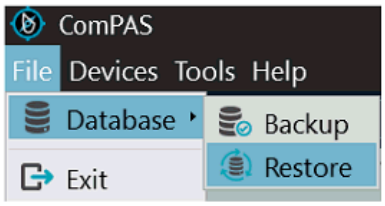
ComPAS2 2018-07-12 00-00-00.zip

11.2 Restoring the SQL Database

When working with a stand-alone ComPAS2 installation it is very important to understand that any backup files that have been moved to storage away from the computer **MUST BE** copied into the following location before they can be restored:

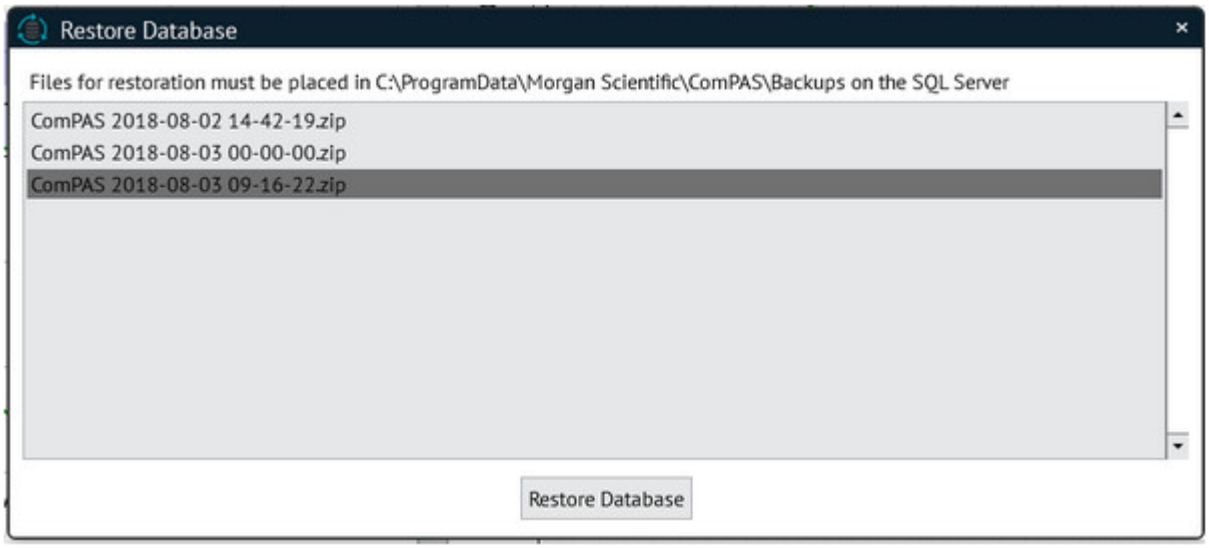
C:\ProgramData\Morgan Scientific\ComPAS2\Backup

To restore data, go to "File" then "Database" and "Restore":

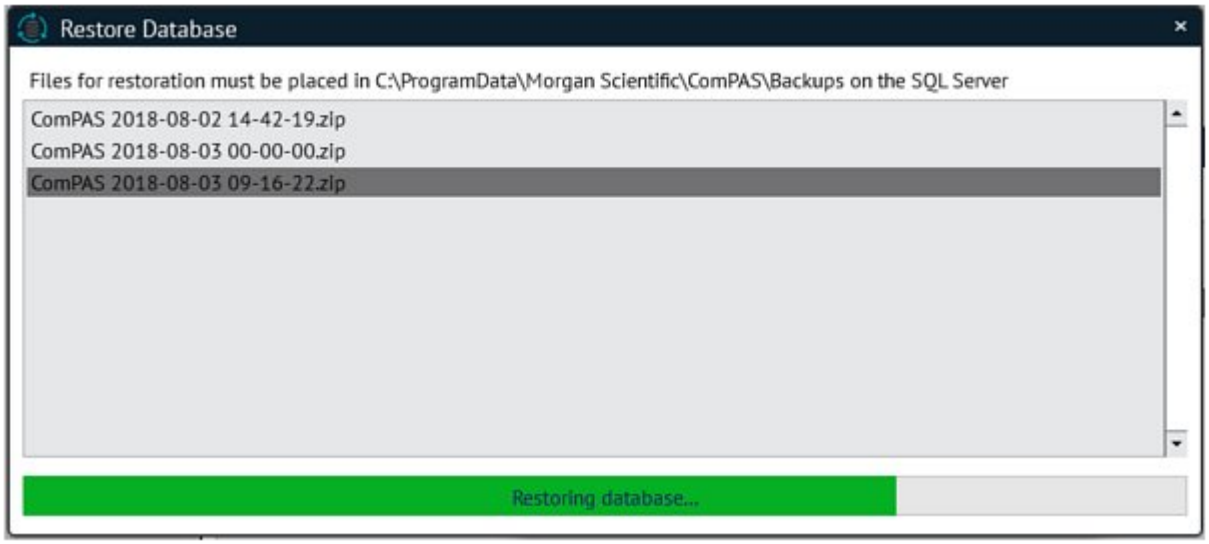


The restore function will look in the **C:\ProgramData\Morgan Scientific\ComPAS2\Backup** directory and list all backups by date and time that exist.

Those files with a time stamp of "00-00-00" are backups that were set to be automatically saved at midnight.



Highlight the backup file desired and click 



The restore will run and at the conclusion ComPAS2 will be closed.

11.3 Data Export

The purpose of the test data Export and Import is to provide a means of moving data from locations/computers not attached to the main database. In circumstances for example where tests are done at a screening clinic with a laptop that the user wants stored in the main laboratory or network database. There are a couple of key points to understand:

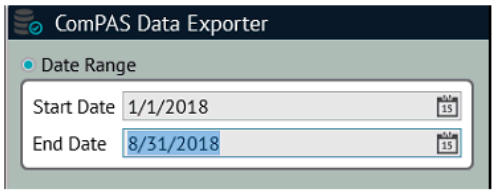
1. The data are encrypted to meet HIPAA regulations.
2. Data can ONLY be transported if the versions of ComPAS2 are the same on the data export and import PC's. If in doubt, check the "Build Number" under Help and "About ComPAS2" from the top menu bar.

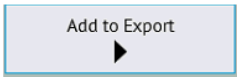
Exporting and Importing are available under "File" from the main ComPAS2 menu:

Data Export can be done by selecting a date range or by finding specific patients.

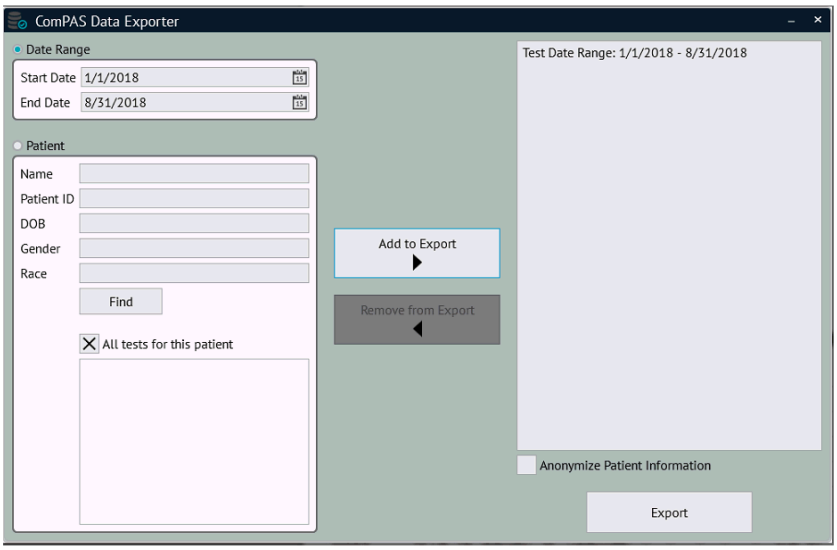
11.3.1 Exporting by Date Range

Simply use the dialogue box to select a starting and ending date.

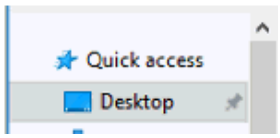


Click 

and the range will be added to the right-hand folder.



Click Export to begin the file transfer. Select the location where the export should be saved.

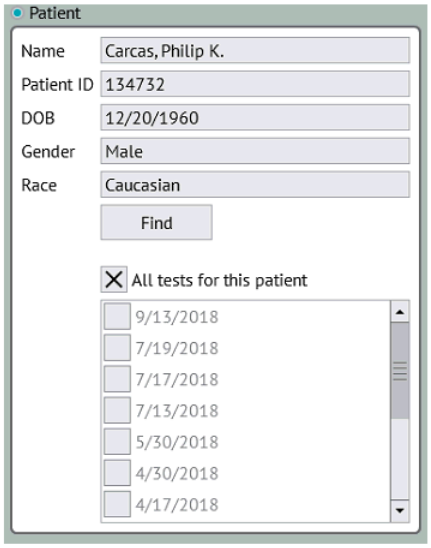


The Export file will be created.

11.3.2 Exporting Individual Subjects/Patients

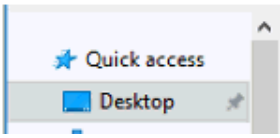
Select the "patient" radial button and then use the imply use the Find button to locate the patient in the database.

All tests for an individual patient will be the default selection. If only select dates are desired, un-check the "All tests for this patient" option and then indicate the dates required.



Click Add to Export and the range will be added to the right-hand folder.

Click Export to begin the file transfer. Select the location where the export should be saved.



The Export file will be created.

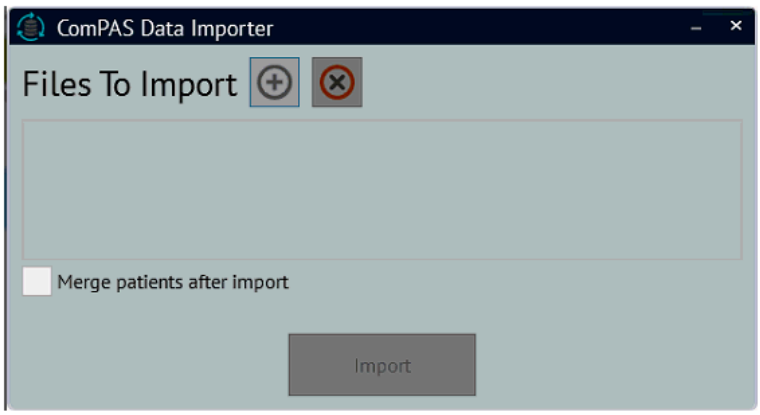
11.4 Data Import

Exporting and Importing are available under "File" from the main ComPAS2 menu:

11.4.1 Selecting the Source and Importing Data

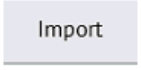
Data Import simply reads any exported data set and merges those data with the host database.

Having selected Import, a dialogue will appear requesting the location of the exported file.



Click on the  icon to navigate to the data export file.

We recommend that the "merge" option always be selected. This will automatically merge subject data and dates with information already resident on the target database.

Click 

when ready to proceed.

12:0 ComPAS2 with the Micro Spirometer

12.1 Introduction

The Vitalograph micro™ is a high-quality spirometer from the leading provider of spirometry devices to general healthcare and occupational health markets. Through connection to ComPAS2, all data and graphics can be imported and routed through the ComPAS2 Task Manager and EMR interfaces.

The Micro features the same high-performance measuring technology used across the Vitalograph range. The precise and durable measurement technology is extremely accurate and stable over time, assured through its simple calibration check routines as recommended by international spirometry guidelines (ARTP, ATS/ERS, etc.) and good practice.

The micro is the ideal choice for bedside testing or where fast accurate spirometry is required away from the pulmonary function laboratory.

Standard testing capability includes:

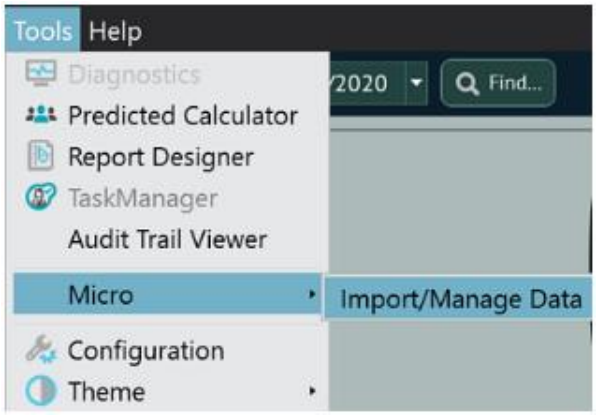
Static Spirometry - Slow Vital Capacity
Dynamic Spirometry - Flow Volume Loop
Maximum Voluntary Ventilation

The instruments are suitable for subjects ranging from small children to adults with severe COPD.

12.1 Downloading Data from the Micro Spirometer

Communication with the Vitalograph Micro™ is via USB; once connected, ComPAS2 will recognize the device automatically. Connect the Micro to any USB port.

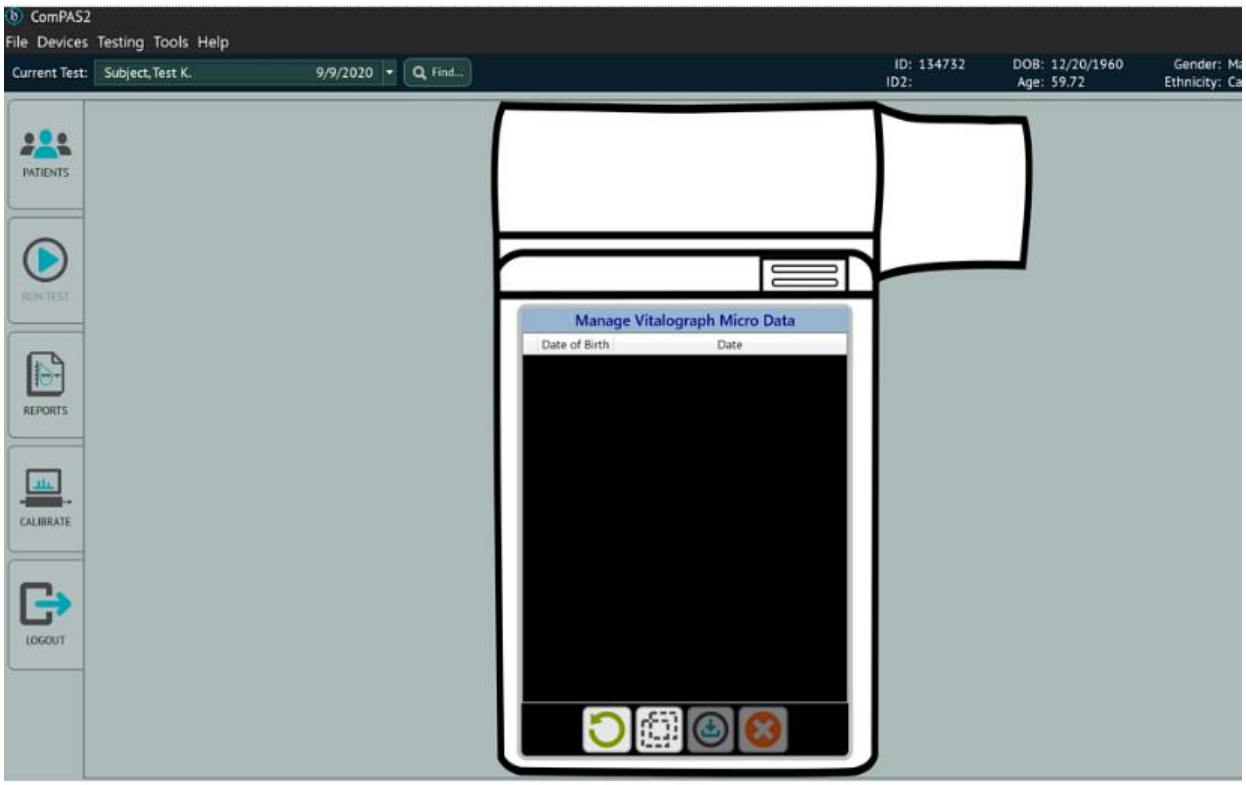
12.1.1 Managing Micro Data



Data sets are identified in the Micro by "Date of Birth" and "Date"; to import flow volume loop data into ComPAS2, go to "Tools" and open the Micro "Import/Manage Data" option:

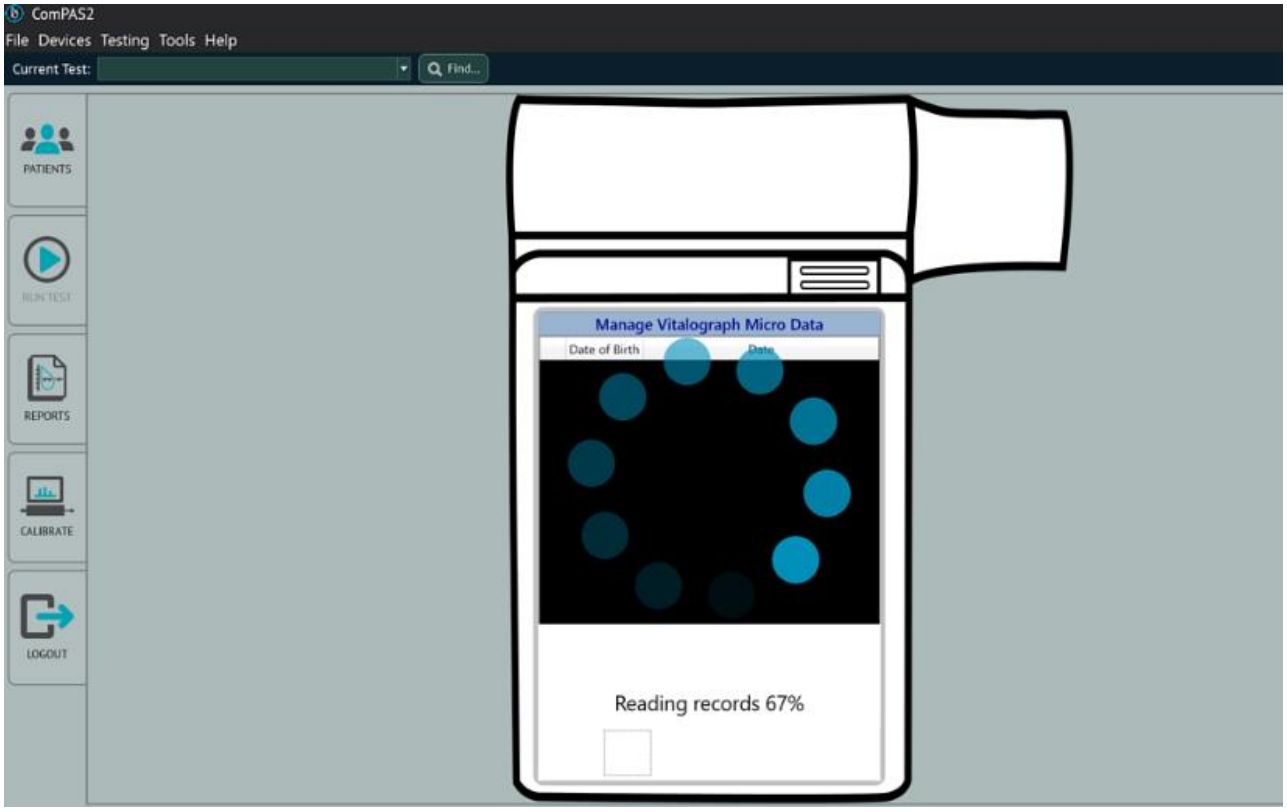
There are four operational buttons on the Manage Micro Data screen:

Refresh Display List	Select All	Import Selected Records	Delete Selected Records
			



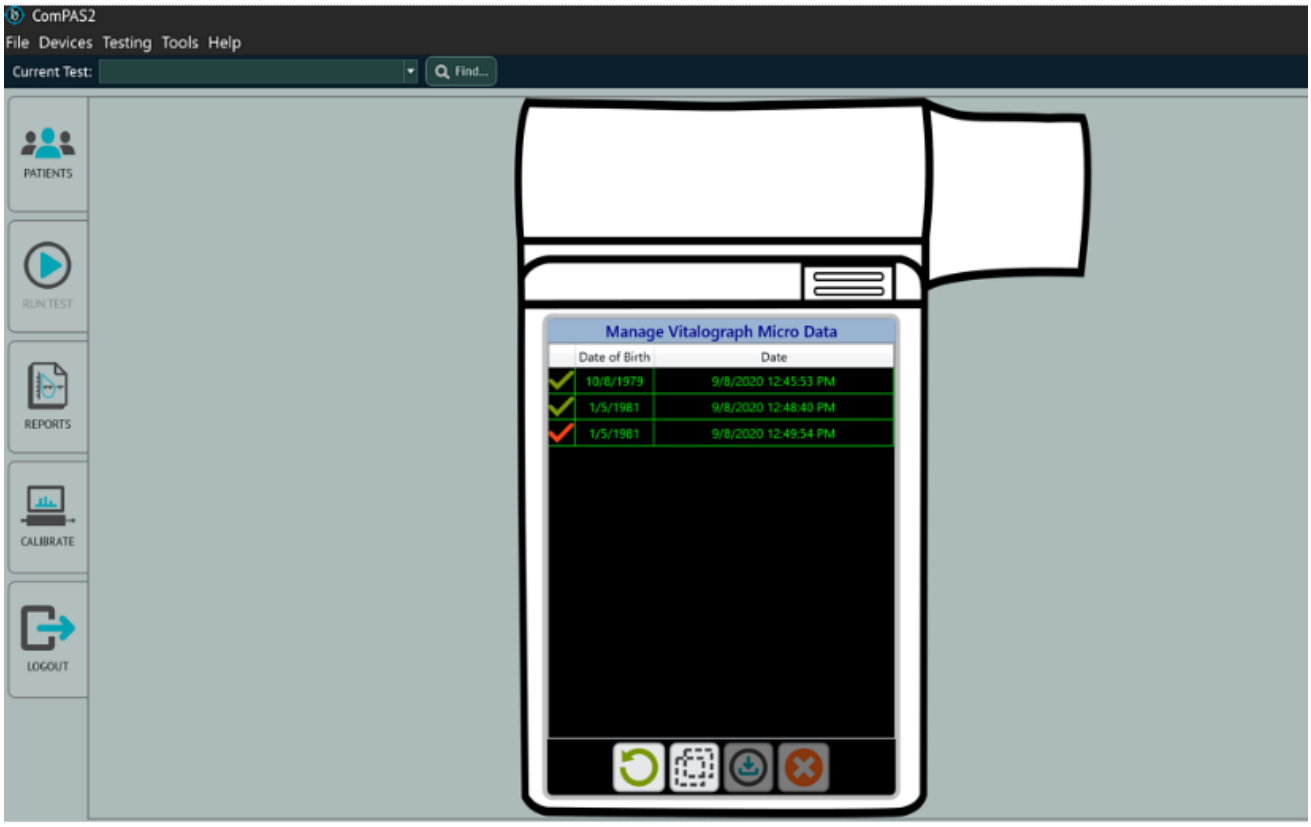
12.1.2 Retrieving Data from the Micro

Click  to open and display the stored data sets on the Micro. Depending upon the number of tests stored this can take 30 seconds or more.



12.1.3 Associating Data from the Micro with Patient Records in ComPAS2

Once data have been read from the Micro, the list of tests will be shown on the display:



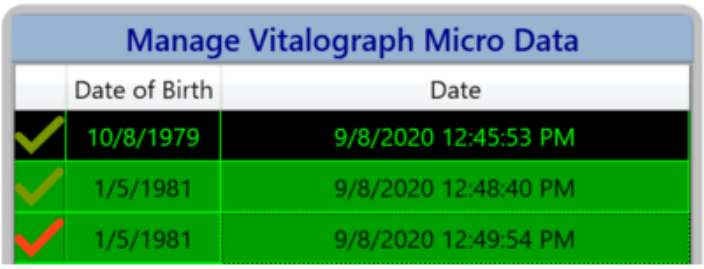
There are a couple of options for associating Micro data and loops with patient records in ComPAS2:

12.1.3.1 Individual Effort Selection

Using the mouse, the user can click on the appropriate rows to highlight those data to be imported. Note: Pre and Post data sets will have the same Date of Birth, with Pre and Post identified by a green and red check mark.

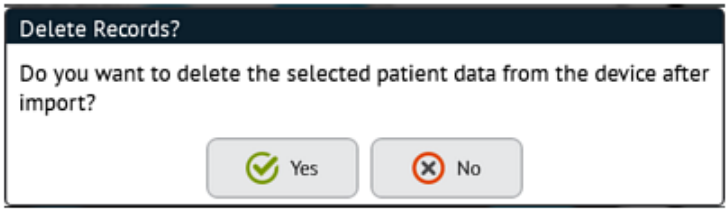
To highlight multiple rows, hold the [Ctrl] key while clicking on the rows desired.

In the example below, the two records for the test subject with a date of birth of 1/5/1981 have been highlighted.



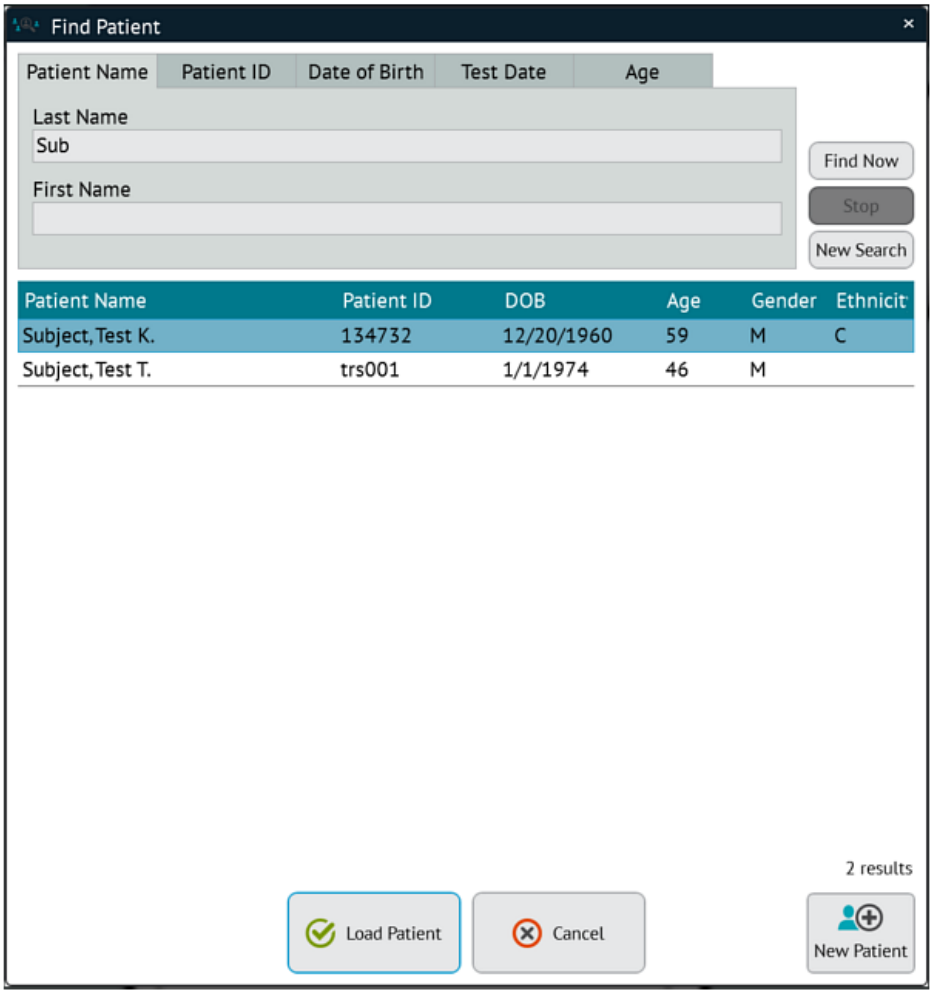
Click  to start the association with a test subject in ComPAS2.

A prompt will ask if data should be deleted from the Micro after import into ComPAS2:



At this point a patient record can either be created using the 

button or records that exist in ComPAS2 can be found and confirmed.



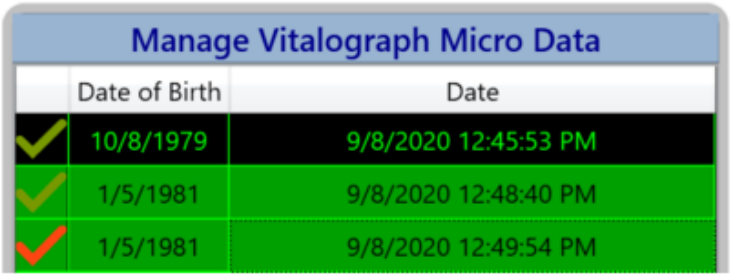
Having selected or entered the appropriate test subject record and clicked 

, the data will be imported to the test record.

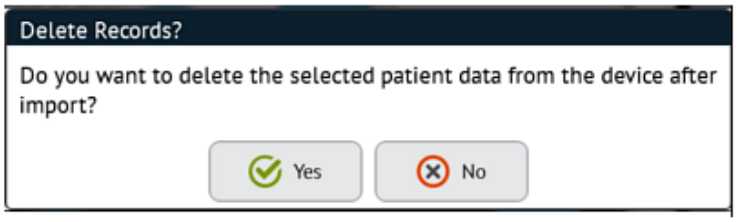
The test can immediately be printed by going to [Reports]; to view the imported loops and data select the test subject from the daily list and select [Run a Test].

12.1.3.2 Multiple Effort Selection

Click  to employ the "Select All" function. This will highlight all records stored on the Micro.

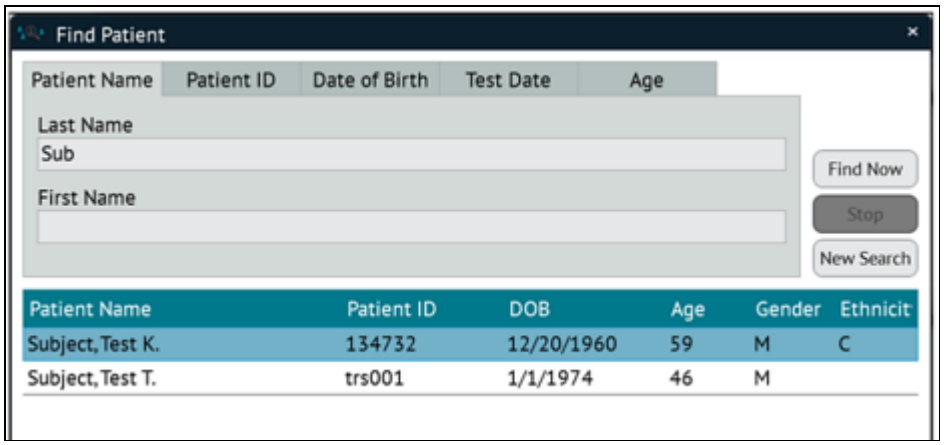


A prompt will ask if data should be deleted from the Micro after import into ComPAS2:



At this point a patient record can either be created using the 

button or records that exist in ComPAS2 can be found and confirmed.



Having selected or entered the appropriate test subject record and clicked 

, the data will be imported to the test record.

The test can immediately be printed by going to [Reports]; to view the imported loops and data select the test subject from the daily list and select [Run a Test].

13:0 Using Active Directory and Single Sign-On

13.1 Introduction

Active Directory is used by organizations of all sizes to help manage permissions and control access to critical network resources. Active Directory is a directory service that runs on Microsoft Windows Server. The main function of Active Directory is to enable administrators to manage permissions and control access to network resources. In Active Directory, data is stored as objects, which include users, groups, applications, and devices, and these objects are categorized according to their name and attributes.

Active Directory Domain Services are a core component of Active Directory and provide the primary mechanism for authenticating users and determining which network resources they can access. They also provide additional features such as Single Sign-On, security certificates and access rights management. The domain server authenticates and authorizes all users and computers in a Windows domain type network, assigning and enforcing security policies for all computers.

Utilizing Active Directory support within ComPAS2 consists of four steps:

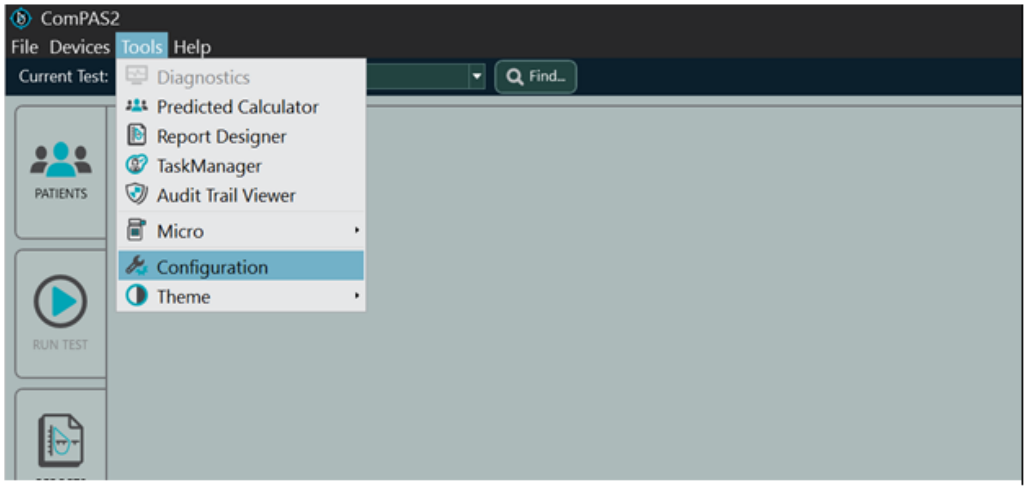
1. Import Active Directory Groups and Users
2. Require ComPAS2 to use Active Directory Authentication
3. Enable Single Sign-On (Optional)
4. Allow workstations to use Single Sign-On (Optional)

13.2 Importing Active Directory Groups and Users

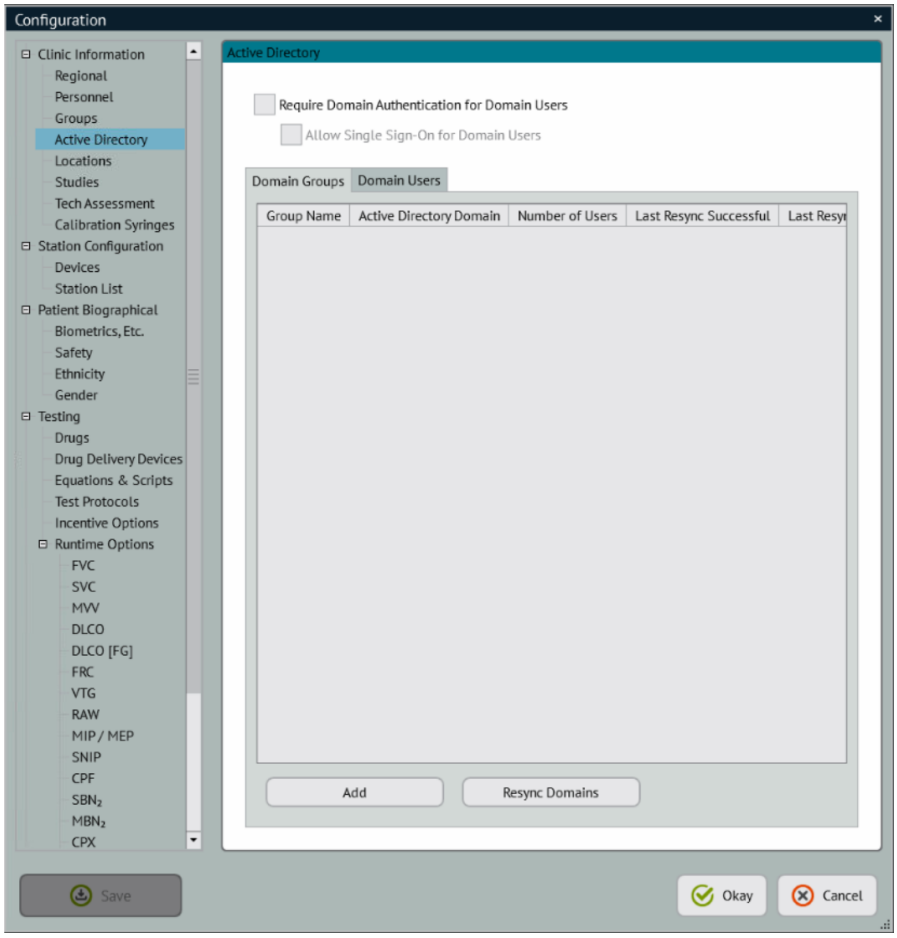
To import Active Directory Groups and Users you will need to install ComPAS2 on a PC that has been joined to an Active Directory Domain. We highly recommend getting your IT department to create one or more Active Directory groups and add all users that need access to ComPAS2 to those groups. This will make synchronization between ComPAS2 and Active Directory much easier by just adding or removing users from the group within Active Directory.

13.2.1 Steps to Import Groups from Active Directory

1. Open ComPAS2 and login with an account that has access to Configuration. Click on the "Tools" menu option and then "Configuration".

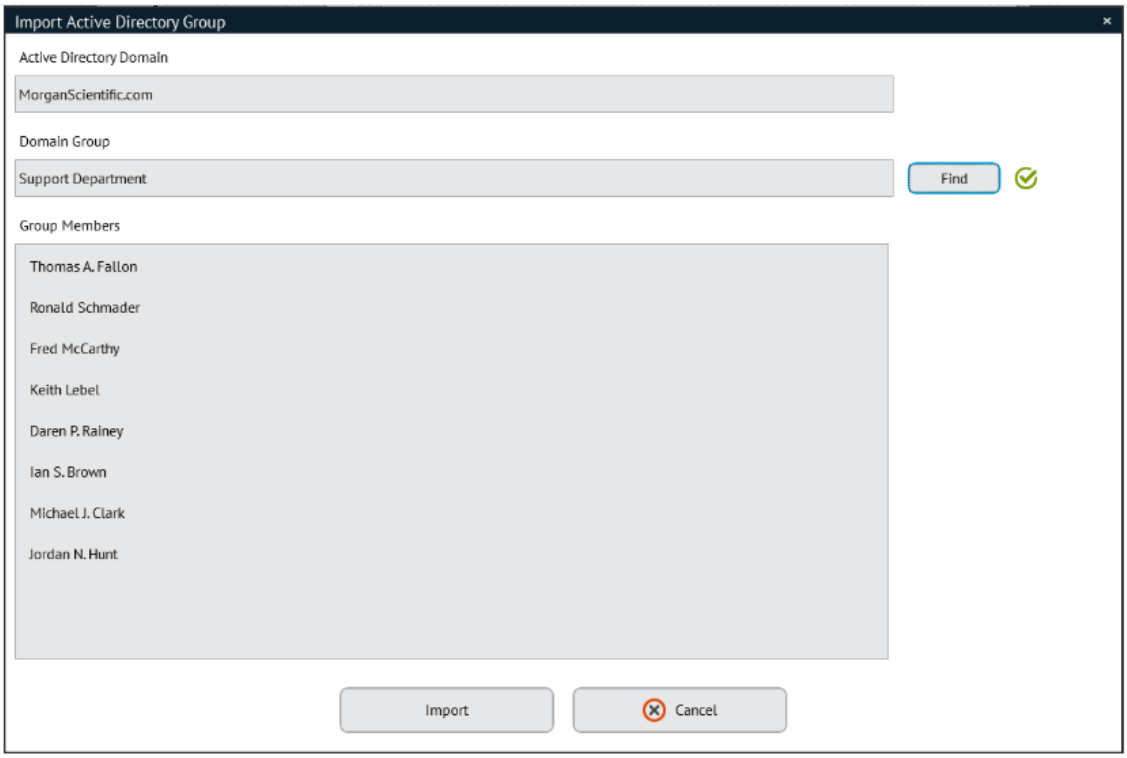


2. Inside the Configuration screen, select Active Directory under the Clinic Information section.



3. Make sure the Domain Groups tab is selected and click the 

button.



a. Fill out the Active Directory Domain.

Note: If you do not know your domain name, you can get it from your IT administrator.

b. Fill out the name of the Domain Group you want to import. You can get the name of the group to import from your IT administrator as well.

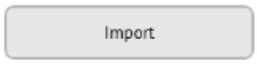
c. Click the Find button. If the domain and group name are valid, a green check mark will indicate they were found successfully, and a list of the users will appear in the Group Members box.

Note: If you already have local users created in ComPAS2 and their First and Last names or their username match what is in Active Directory, those users will be automatically mapped for you. If there is no match between Active Directory user and ComPAS2 user, the drop-down list will be set to “New User”.

d. If you have a ComPAS2 user that should have matched an Active Directory user, you can select them from the drop-down list. Otherwise leave the selected option as New User and a new ComPAS2 user will be created using the information from Active Directory.

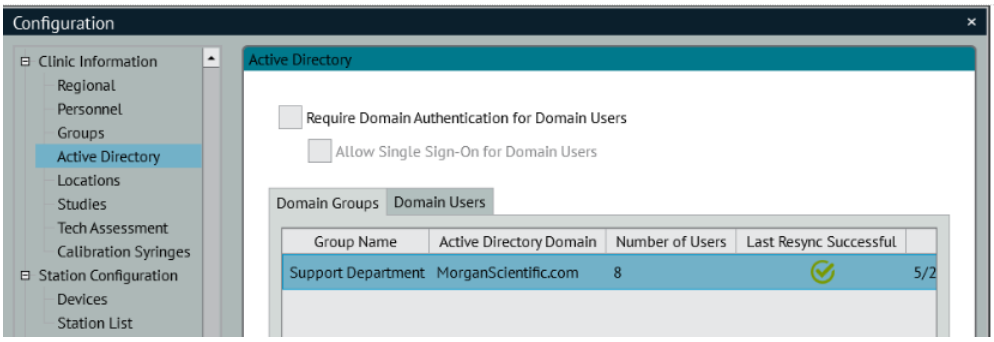
Note: You also have the option to select Ignore User from the drop-down. This will ignore the user when importing and they will not have a ComPAS2 user created for them. We highly recommend removing ignored users from the Active Directory group and they will continue to appear in the import list every time a re-sync is done.

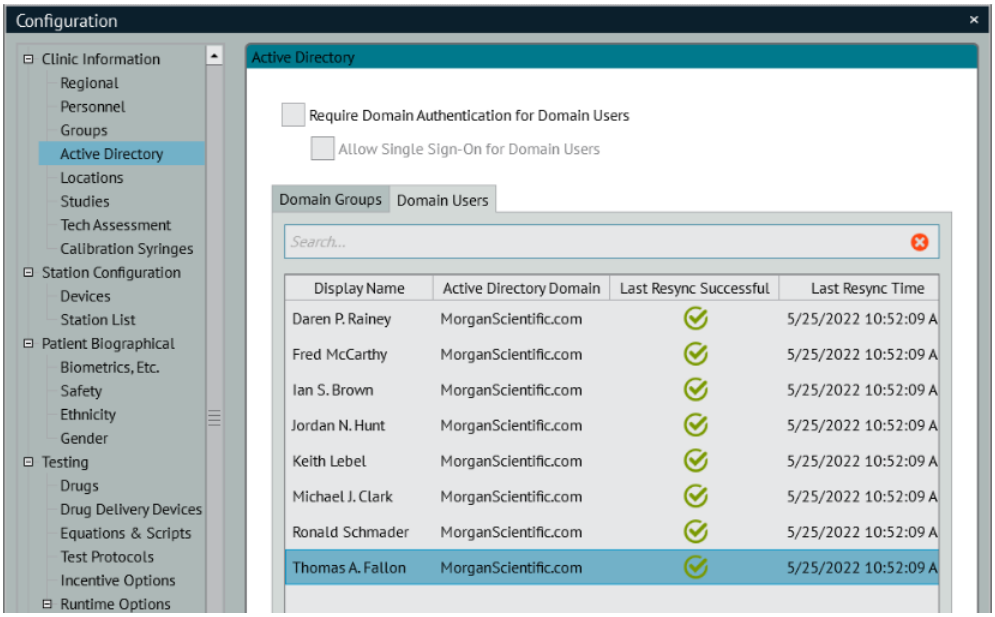
e. Once all users have been mapped correctly, click the 

button to import them into ComPAS2. For all mapped users, this process will update the existing ComPAS2 user with the proper Active Directory domain information instead of creating a new user. All tests and historical operations associated with that user will remain intact. After clicking the 

button, you should see a confirmation dialog confirming the successful import of the Active Directory users. If not, please contact support for assistance.

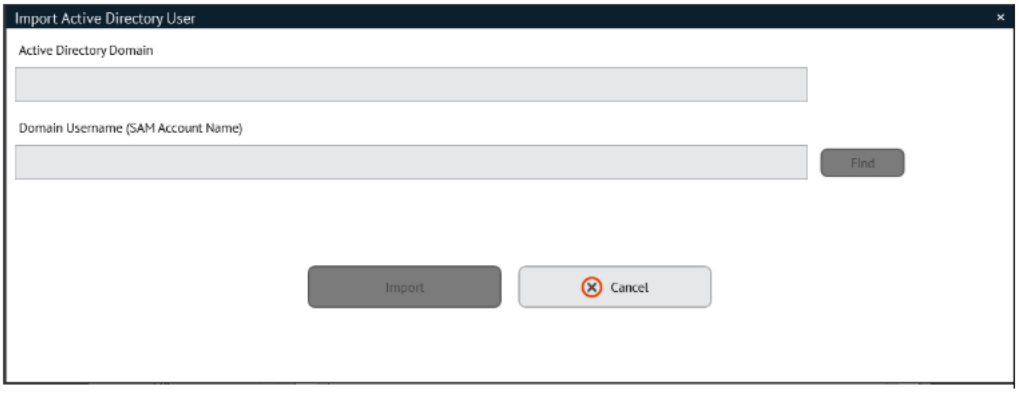
f. Upon clearing the confirmation dialog, the Import Active Directory Group window will clear except for the Active Directory Domain name to allow you to import another group if desired. If you are finished, click the Cancel button to close the import window.





g. While not encouraged, you can also import individual users from Active Directory into ComPAS2. The process is similar except instead of entering the group name, you will enter the Active Directory Username for the user to import.

In the Active Directory window, select the [Domain Users] tab and then click the Add button.



h. Fill out the Active Directory Domain and Domain Username and click the Find button. If successfully found, the user and their mapped ComPAS2 equivalent (or New User) will be displayed. Click the Import button to import the user.

i. Once all groups and users have been imported you can then configure ComPAS2 to require Active Directory authentication for logins.

13.3 Require ComPAS2 to use Active Directory Authentication

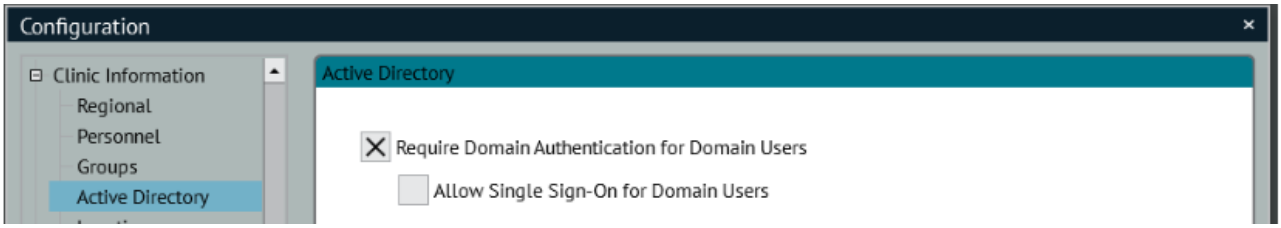
For users imported from Active Directory to login and access the system, ComPAS2 must be configured to Require Domain Authentication for Domain Users. Once configured and a user tries to login to the system, ComPAS2 will take the entered password and contact the user's Active Directory Domain (configured during import) to authenticate that password and make sure it's correct. Once the user is properly authenticated via the Active Directory Domain, they are allowed into the system.

Note: Once a local user has been converted to an Active Directory user, they will not be able to login with their ComPAS2 password (unless it was the same as their Domain password). If the user's Domain password expires or the account is locked out within the Domain, the user will be unable to log into ComPAS2 until they have changed their password or have their account unlocked by an IT administrator.

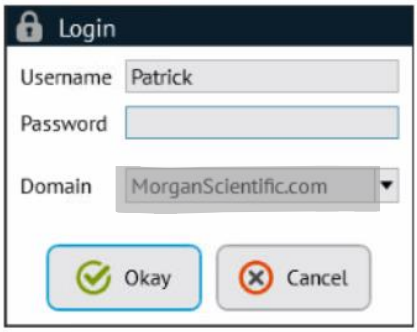
13.3.1 Steps to Configure Active Directory Domain Authentication:

1. Open the Active Directory screen within Tools->Configuration.

2. Select the Require Domain Authentication for Domain Users checkbox at the top of the screen and click the [Okay] or [Save] button.



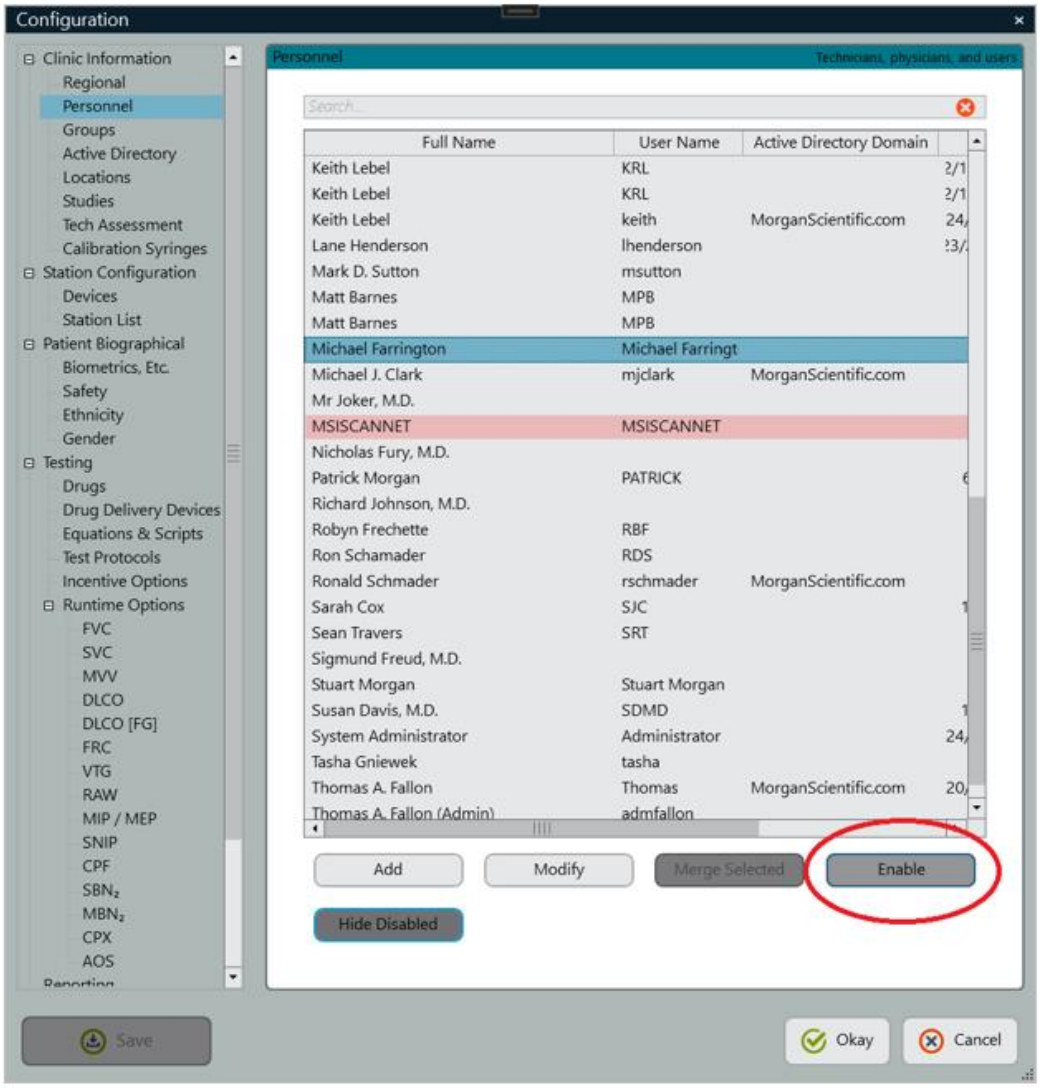
3. Now when a user logs into ComPAS2, a new Domain drop-down will appear in the Login prompt. If you have more than one Active Directory Domain, all domains configured for imported users will be listed in the drop-down.

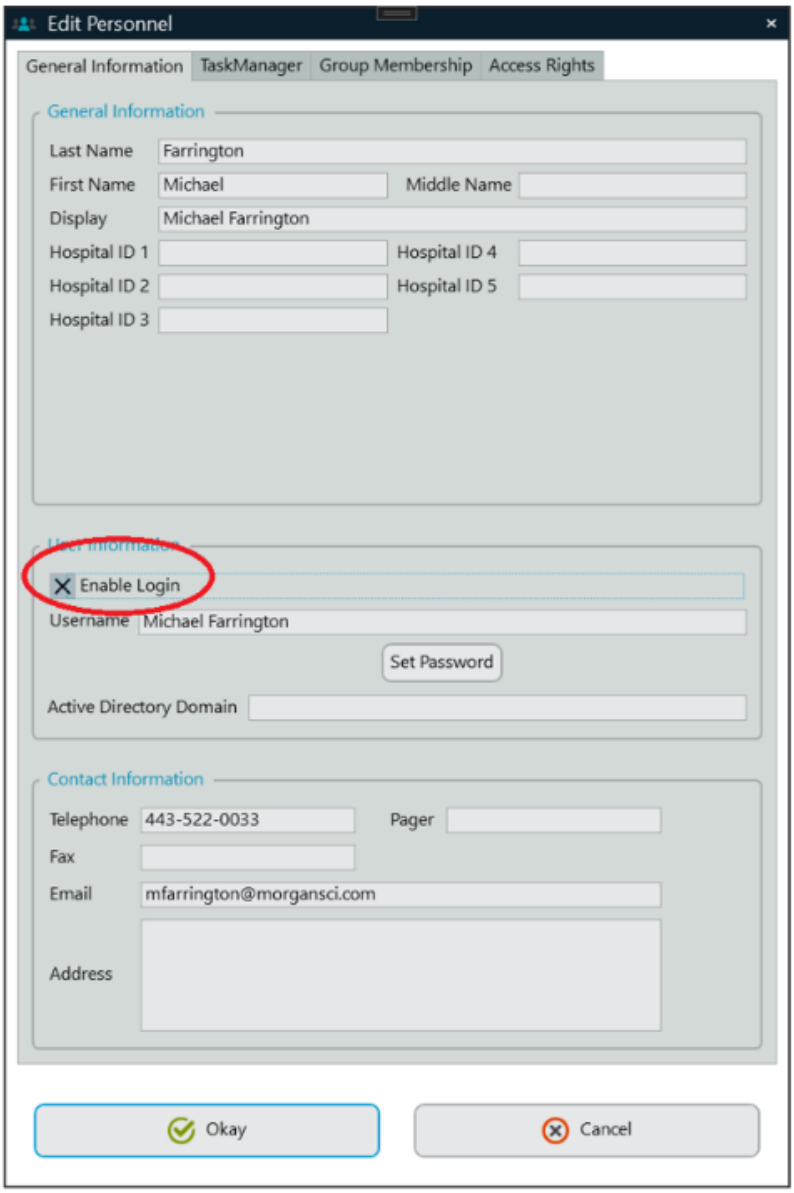


13.4 Turning Off Require ComPAS2 to use Active Directory Authentication

If it becomes necessary to turn off the requirement for Active Directory Domain authentication, you will be prompted with a dialog box stating that performing this operation will convert all imported Active Directory users into local users. Any Active Directory users imported as New users will need their passwords updated before they can login.

Note: If after turning off Domain Authentication and converting the imported users to local ComPAS2 users you want to use Domain Authentication again, you will need to remove all imported groups and import them again. Removing an imported group will disable all users in that group as well as disabling their logins. For users to be properly mapped again, you will need to **Enable** the user in the **Personnel** section of **Configuration** and then enable their login as shown below:





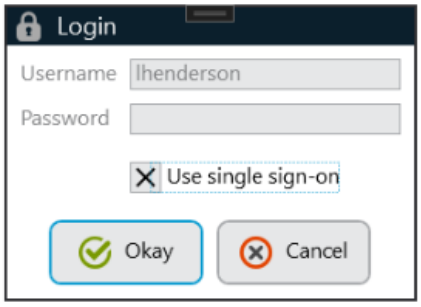
13.5 Enable Single Sign-On (Optional)

After configuring ComPAS2 to require domain authentication, you will have the option to turn on Single Sign-On.

Single Sign-On bypasses the authentication process and logs in the current Windows user. To turn on Single Sign-On, go to the Active Directory section of Tools->Configuration and select the Allow Single Sign-On for Domain Users option and click either the [Okay] or [Save] button.

Note: The allow single sign-on option will not be enabled unless Require Domain Authentication for Domain Users has been turned on.

Once single sign-on has been turned on, the user will now have an option to enable single sign-on when they log into ComPAS2 if the workstation has been configured to allow it.



When Use single sign-on is selected, the Domain list will disappear, and the Username field will be auto-populated with the currently logged in Windows user.

13.5.1 Single Sign-On Explained

Allowing Single Sign-On in ComPAS2 is trusting the Windows operating system to handle authenticating the user and then making sure that user has been configured within the system. This process can be summarized by the following steps:

1. A user attempts to login to a ComPAS2 workstation that has been configured to allow single sign-on and selects the single sign-on option.
2. ComPAS2 checks the Windows operating system and gets the information for the user currently logged in and authenticated with the domain.
3. ComPAS2 then checks to make sure that user has been imported into the system by matching their domain username (or SAM Account Name) and domain name to a user configured in the system database.
4. If ComPAS2 finds a match, the user can log into the system.
5. If ComPAS2 does not find a match, the user will be notified their Username and Password do not match and they will be brought back to the login prompt.
6. The user can then uncheck the single sign-on option and manually enter a valid domain username and password combination or they will be unable to log into the system.

13.5.2 Allow workstations to use Single Sign-On (Optional)

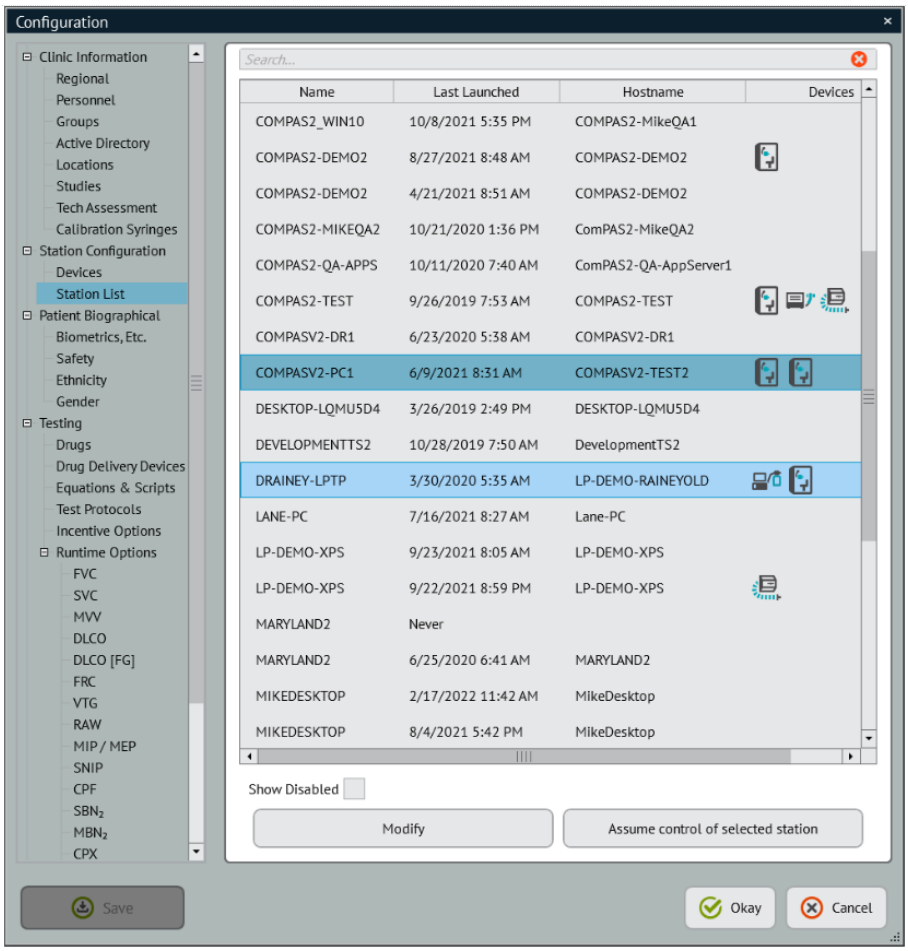
For a user to use single sign-on, their workstation must allow it. Note: all workstations do NOT allow single sign-on by default. The option to allow single sign-on must be enabled for each workstation that needs to allow it.

SPECIAL NOTE: We do NOT recommend configuring “shared” workstations to allow single sign-on. This would potentially have multiple users of the system “sharing” the same Windows user account to gain access to ComPAS2. This would negate all traceability for individual users and render audit information difficult to differentiate users on the shared workstation.

To configure a workstation to allow single sign-on:

1. Go to the Station List section of Tools->Configuration.

2. Find the workstation where you want to enable single sign-on double-click the entry or select it and click the [Modify] button.



3. Select the Allow Single Sign-On option and click the Okay button.

Now when a user tries to log into the workstation they will have the option to enable single sign-on.