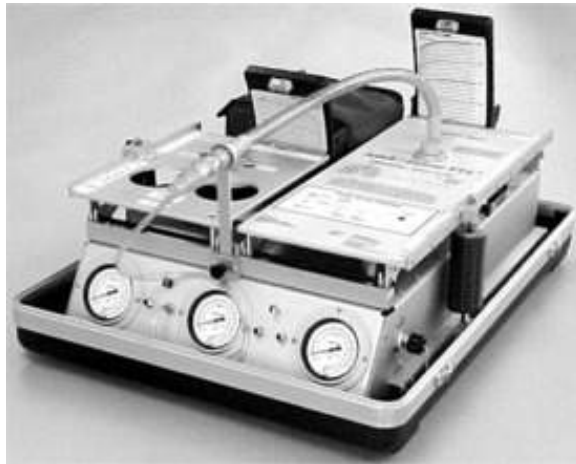
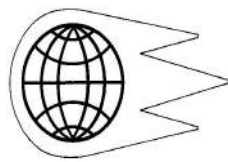


MODEL 5601i

ADULT/INFANT PNEUVIEW[®] SYSTEM OPERATION MANUAL



Manufactured By:



**Michigan
Instruments**
INC.

4717 Talon Court SE
Grand Rapids, MI 49512
Tel: (800) 530-9939 or (616) 554-9696
FAX: (616) 554-3067

Email: mii@michiganinstruments.com Website: www.michiganinstruments.com

Table of Contents

INTRODUCTION	i
1. Description	1
General Information about the TTL	1
TTL—As compared to typical patients	2
The TTL as Related to Ventilator Testing Standards	2
Specifications	3
Features and Components	3
2. Setup and Operation	6
5601i Computer Interface Setup	6
Lung Setup	6
Measuring Oxygen Concentration in the lung	8
Care of 5601i after Ventilation with Humidified Gases	8
3. Software Operation	9
Limitation of Liability	9
General Information	10
Software Installation	10
Welcome to PneuView®!	11
New Project	12
Display Windows	13
A. Measured Parameters	13
B. Notes	15
C. Graph	15
Test Lung Settings	17
Changing the Test Lung Settings	18
Saving Files	19
Save Project Command	20
Save Data Buffer	20
Begin Save/End Save	20
Trend Testing	21
Setup (From Trend Menu)	21
Begin (From Trend Menu)	22
End (From Trend Menu)	22
Tabulated Data	23
Measure	25
Pressure/Volume and Flow/Volume Loops	26
Reviewing Files	27
Reviewing a Project File	28
Changing the Graph Window	29
Reviewing Trend Test Files	31

Reviewing Data Tables	33
Printing Files	33
Creating and Saving Templates	34
Other Features of PneuView®	36
4. Applications	37
Ventilator Testing	37
Classroom Instruction/Demonstration	39
5. Maintenance and Service	41
Calibration Check	41
Model 5601i Leak Test	43
Warranty Agreement	43
Factory Service Policy	44
Requesting Factory Service for Your Model 5601i	44
6. Warnings and Cautions	46
7. Storage and Shipping	47

INTRODUCTION

The Model 5601i Adult/Infant PneuView System (Part Number 14920) combines the unique features of the TTL Training/Test Lung with the data acquisition and processing capabilities of a personal computer. This system was developed to allow the comprehensive evaluation and demonstration of ventilation devices and principles.

PneuView is a Windows® based software program that serves as the link between the TTL and computer. The interactive environment of multiple, overlapping windows, the combination of pull-down and pop-up menus, provides a user friendly system that will instill confidence and provide a useful lung simulation/data acquisition system.

PneuView has many potential applications including:

- Ventilator Testing
- Product Demonstration
- Classroom Instruction
- Pulmonary Research
- Product Evaluation
- Design Engineering
- Quality Control

ORGANIZATION OF THIS MANUAL

This manual has been designed for use as a reference manual. The beginning sections deal with general descriptions and information about the system. Subsequent sections address more specific operations and functions within the PneuView software. Please refer to the Table of Contents for quick and easy reference to the various sections included in this manual.

If you have any questions or need technical support, call Michigan Instruments at **1-800-530-9939**.

1. Description

General Information about the TTL

The Model 5601i, Adult/Infant TTL provides a gross simulation of the structures and mechanics of human ventilation. Lungs are simulated using elastomer bellows, with one adult "lung" and one infant "lung" incorporated into the 5601i.

The adult lung holds a residual capacity typical of an adult human lung. The infant lung's residual capacity is typical of a 6 to 12 month patient. Gas is inserted into the infant or adult lung through a simulated airway. This insertion causes the vertical expansion of the lung, and a corresponding rise of the top plate. Volume scales behind the top plates and pressure gauges on the front of the TTL can be used to visually see the measurements of tidal volume (in mL, airway pressure (in cmH₂O), and lung pressure (in cmH₂O).

Lung compliance is accurately set and adjusted for each lung using a steel alloy spring, which is stretched during inflation of the lung. Airway resistance is simulated by using a fixed-orifice flow resistor. These features of adjustable compliance and resistance allow the TTL to realistically simulate a wide variety of healthy and diseased pulmonary conditions.

Several special features add to the versatility of the TTL. Oxygen sensor ports in the top of each lung compartment and auxiliary pressure ports adjacent to each pressure gauge provide sites for the tie-in of related monitoring equipment.

The 5601i houses an *Electronic Interface Module*, which facilitates the transfer of information from the TTL to a personal computer. The module converts pressure signals from the lung and airway of the TTL into digital data. The data is then processed by an appropriate personal computer using our customized *PneuView* Software. The *PneuView* program is specifically designed to acquire, interpret, and display data from the TTL. Single breath information to long term trends can be dynamically displayed in real-time, and/or saved for future use. Printed reports of all displayed information may also be easily generated. The *PneuView* Software portion of this users guide provides complete installation and operating instructions.

The TTL—As Compared to Typical Patients

The Model 5601i is designed to realistically simulate the mechanics of the adult and infant ventilatory system from upper airway to the lungs. It is NOT a detailed model of actual human anatomy. However, the TTL offers simulation capabilities and versatility not seen in other devices and is useful for a wide variety of applications. The variable lung compliance and airway resistance allows for simulation of both healthy and diseased pulmonary conditions. *Table 1* offers some typical values for healthy adults and infants. However, most ventilated patients do not possess these “normal” characteristics.

	ADULT	INFANT	
Compliance	.05 to .15	.003 to .005	L/cmH ₂ O
Resistance	0.5 to 5.0	30 to 60	cmH ₂ O/L/sec
Respiratory Rate	10 to 20	30 to 50	Breaths per Minute
Tidal Volume	3 to 5	6 to 8	mL/kg body weight
I:E Ratio	1:2	1:2	

Table 1

Pulmonary disease is often associated with a change in lung compliance and/or airway resistance. *Table 2* shows some of the changes that are typically seen in restrictive and obstructive lung disease.

	Obstructive Disease	Restrictive Disease
Examples	Asthma Emphysema Bronchitis COPD Airway Neoplasms	Pneumonia Pulmonary Fibrosis Kyphoscoliosis Severe Obesity Lung Neoplasms
Changes	Increased Airway Resistance Increased Total Lung Volumes Decreased Expiratory Flowrates	Decreased Lung Compliance Decreased Lung Volumes Increased Respiratory Rate

Table 2

The TTL as Related to Ventilator Testing Standards

To evaluate the performance of any mechanical ventilating device, a quantitative test lung which dynamically simulates human physiology should be utilized. Testing should take place on every ventilator before it is used in the clinical setting, and periodic testing is needed to ensure that the unit is performing in accordance with established standards and the manufacturer’s specifications. Standards published by the American National Standards Institute (ANSI), the International Organization of Standardization (ISO), and the American Society

for Testing and Materials (ASTM) outline minimum performance standards for mechanical ventilators. These are the standards most frequently used by ventilator manufacturers. The 5601i meets or exceeds the requirements set for testing in these standards.

Reference: Standard ANSI Z79.7
 Standard ISO 5469:1987
 Standard ASTM F 1100-90

Specifications

	Adult Lung	Infant Lung
Tidal Volume Capacity:	2.0 Liters	200 mL
Residual Lung Volume:	1.022 Liters	70 mL
Lung Compliance:	.01 to .15	.001 to .015 L/cmH20
	Accuracy: $\pm 3\%$ (at calibration volumes)	
Airway Resistance:	Rp 5, 20, or 50	50, 200, 500 cmH20/L/sec
	Accuracy: $\pm 5\%$ (at calibration flows)	
Size:	20"x25.5"x8.5"	
Weight:	33 Pounds (in case)	
Power Requirements:	12 VDC 500 mA (110 or 220 VAC adaptor supplied)	
Data Link:	DB9f, PC serial cable	

Features and Components

Frame

The 5601i is built around an aluminum frame which provides stability for the components of the lung.

The Lung (Bellows)

The adult and infant lungs are simulated using elastomer bellows, constrained by aluminum rings to ensure that filling of the "lung" results in a vertical rise of the top plate. The bellows, at rest, retains a gas volume typical of an adult's or infant's functional residual capacity for a single lung. The bellows, secured to the top plate and frame of the 5601i, are designed to withstand normal environmental conditions and inflation to at least 150 mmHg pressure.

Compliance Setting

The lung compliance is simulated using a precision steel alloy spring stretched between the top plate of the lung and the track on the side of the TTL frame. Lung compliance is adjusted by positioning the spring at calibrated points

along the top plate. The greater the distance the spring is positioned from the hinge point of the top plate, the less compliant, or “stiffer” the lung.

The Airway

The adult or infant airway is constructed by using a hose assembly; various connectors and one of the PneuFlo® Airway Resistors included in your accessory kit. Tapered fittings on all of these accessories prevent gas leaks during use.

The airway resistance exhibits parabolic characteristics, in regards to pressure change as a function of flow. This nonlinear, parabolic characteristic is similar to that seen in standard endotracheal tubes.

Scales

Compliance Scale. The compliance scale is used to set a particular compliance value for the lung. This is done by positioning the compliance pointer of the compliance spring directly over one of the calibrated markings on the scale.

Volume Scale. The volume scale may be used to measure the volume within each lung. While this scale is calibrated for various lung compliances, the resolution can make data acquisition difficult. The volume scale is a useful indicator when not using the PneuView software. To correctly read the volume scale, the volume pointer must be positioned to correspond with the actual compliance setting for the lung being used.

Oxygen Analyzer Port

Oxygen concentration can be monitored in each lung through the oxygen analyzer ports located on the top plate of each lung. The 15 mm fitting is designed to accept most common oxygen analyzers. When not in use, the oxygen port is covered and sealed with the port cover.

Pressure Gauges

Three pressure gauges are found on the front of the 5601i. The right and left gauges are internally plumbed to the infant and adult lungs. The center or proximal pressure gauge is externally plumbed to the proximal airway via a pressure pickoff adaptor and the pressure input port adjacent to the gauge. These gauges are most useful when not acquiring data through PneuView, but may be used to confirm PneuView’s pressure measurements.

Auxiliary Pressure Ports

Adjacent to each pressure gauge is an auxiliary pressure port, which is internally plumbed to the corresponding gauge. These ports allow other pressure sensing or measuring equipment to be tied into the system. These ports are equipped with a check valve and remain closed until the port is mated with a miniature quick connector. These connectors are included in the accessory kit.

2. Setup and Operation

To Start:

1. Set the 5601i on a level surface.
2. Remove the top cover of the carrying case (if included with your unit) by unlatching the four clasps on each side.
3. Raise the volume plate scale by grasping the volume scale latch knobs on the bottom of the scale and pull them towards each other (see arrows on volume plate). Lift to upright position and release knobs.
4. Open the TTL accessory case. All parts needed to construct the airway are located in this box.

5601i Computer Interface Setup

1. Connect one end of the DB9F serial cable (supplied with unit) into the personal computer. Connect the other end into the serial port located on the back of the 5601i.
2. Attach the power jack into the 5601i (located to the left of the serial port connection) and plug the transformer into an appropriate AC power source.
3. Turn the power switch (located on the front of the unit) to the “on” position.
4. The PneuView Software program must be installed and operational on your personal computer. See PneuView Software setup for complete instructions on software installation and operation.

Lung Setup (Adult or Infant)

1. Loosen the rest knob (1) on the front of the TTL and insert the rest assembly (2) into the holder. Lock it in place by tightening the knob.
2. Select a PneuFlo® resistor (3) to simulate airway resistance and connect it to the proximal (outward-facing) opening on the rest assembly.
3. Connect one end of the hose assembly (4) onto the rest assembly and the other end into the lung inlet port in the top plate of the appropriate lung.
4. Attach a single-outlet pressure pickoff adaptor (5) to the proximal end of the resistor.
5. Use the 1/8” hose (6) to connect the pressure pickoff adaptor to the proximal pressure input port (7) located to the left of the center gauge.

Please see Figure 1 on page 7 for display of Lung Setup.

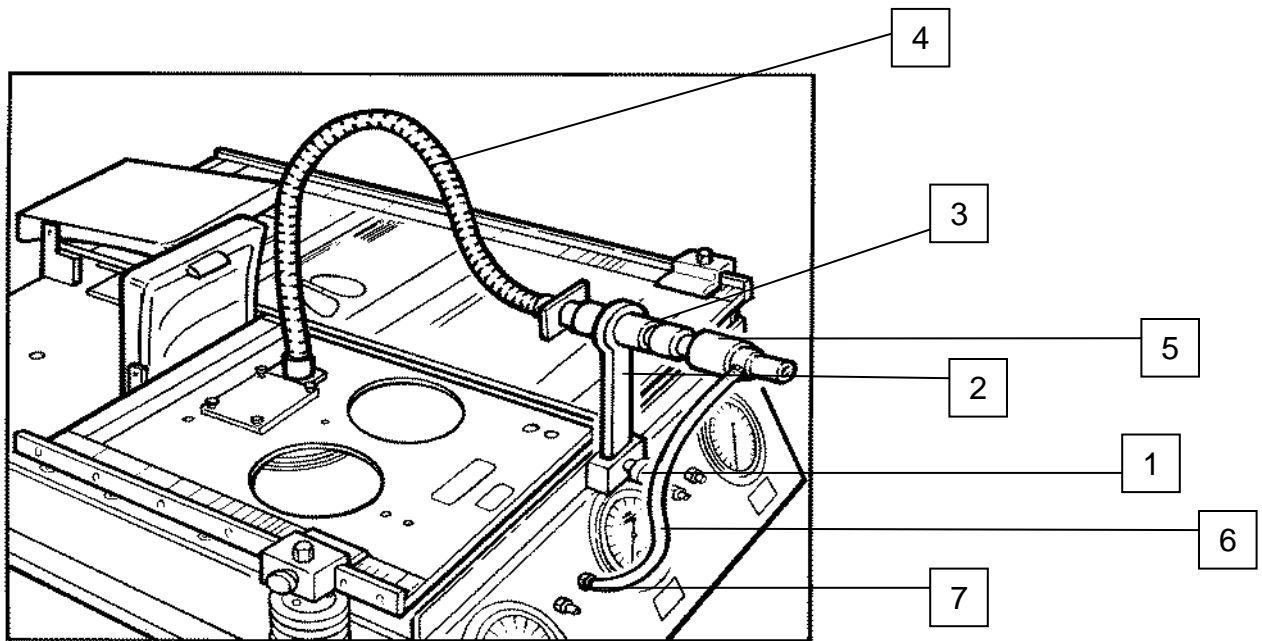


Figure 1—Lung Setup

To Set Lung Compliance

1. Loosen the knob on the compliance spring.
2. Grasp the compliance spring and slide the entire mechanism until the pointer is positioned on the desired setting. Lock in place by tightening the knob.

Please see Figure 2 for compliance spring setting.

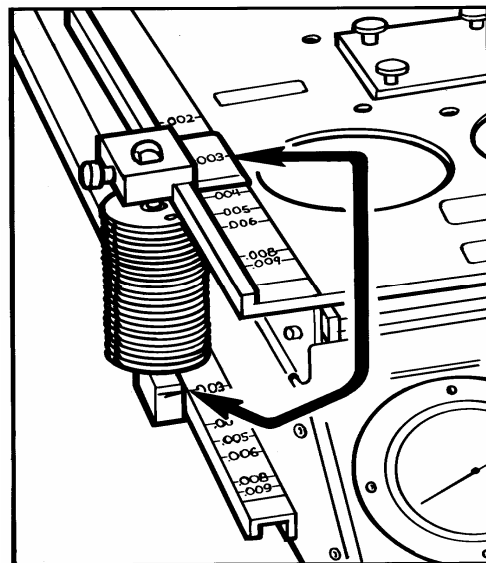


Figure 2—Compliance Spring Setting

NOTE: For accuracy and consistency, the compliance spring must be perpendicular to the top plate during use.

CAUTION: Changing the compliance setting while ventilating the lung may cause damage to the unit.

The TTL may now be ventilated by attaching an appropriate connector from a ventilation device to the airway assembly of the 5601i.

Measuring Oxygen Concentration in the Lung

1. Unscrew the oxygen port cover on the top plate of the unit.
2. Place an appropriate oxygen sensor (15 mm fitting) into the adaptor.
3. Replace the cover when finished.

Care of the 5601i after Ventilation with Humidified Gases

The airway and lungs of the 5601i are constructed of noncorrosive materials. Typical humidification agents such as sterile water or normal saline will not damage the instrument. Any accumulated fluid can be drained out through the drain ports located on the back of the unit. After any fluids are drained from the unit, the 5601i should then be ventilated with dry gas for several minutes. For more information on the use of the TTL with specific chemical agents and medications, contact Michigan Instruments, Inc.

3. Software Operation

Addendum

PneuView[®] Software Upgrade

Version 1.06

Michigan Instruments continues to add to the capabilities of the PneuView System. In response to requests from current and potential PneuView customers, our newest upgrade allows for the export of PneuView files for import of data into various software applications. This feature is described below.

Export Report Text File

This function will allow the user to generate a formatted text file containing the PneuView *Notes, Tabulated Data and Trend Test Results*. The text file is formatted to be both presentable as a readable document and easily assimilated into other databases such as Microsoft applications and other dedicated equipment management database systems.

To export this data, go to *File* on the menu bar, then select *Export Report Text File*. The *Export Test Report to Text File* dialog box appears. Select the PneuView file to be exported and where the file should be exported to in the *Save In* box. Click *Save*. An information box will appear stating: *The report text file: (destination directory and file name will be listed) has been saved*. The file will be saved with a .txt extension.

Export Real Time Data

This function allows for the translation of PneuView data files into delimited ASCII text files that should be readable by any text editor, spreadsheet program, or data analysis application.

To export this data, go to *File* on the menu bar, then select *Export Real Time Data*. The *Save Real-Time Data in ASCII Format to...* dialog box appears. Select the PneuView file to be exported and where the file should be exported to in the *Save In* box. Click *Save*. An information box will appear stating: *The text data file (destination directory and file name will be listed) has been saved*. The file will be saved with a .txt extension.

The application that the PneuView file is being translated for should have the capability to import the delimited format of the PneuView file. All data is translated into rows and columns.

3. Software Operation

Limitation of Liability

Michigan Instruments, Inc. warrants that the PneuView® software will conform to the published specifications and documentation, provided that it is used on a computer system for which it is designed. Michigan Instruments also warrants that the supplied distribution disks and documentation are free from defects in materials and workmanship for 90 days after delivery. Michigan Instruments will replace defective disks or documentation at no charge, provided you return the item to Michigan Instruments within 90 days of delivery.

Except as provided above, Michigan Instruments makes no warranty or representation, either implied or expressed, with respect to this program or documentation, including their quality, performance, merchantability, or fitness for a particular purpose.

Because computer programs are inherently complex and may not be completely free of errors, you are advised to verify your work. In no event will Michigan Instruments be liable for direct, indirect, special, incidental, or consequential damages arising out of the possibility of such damages. In particular, Michigan Instruments is not responsible for any costs including, but not limited to those incurred as a result of lost profits or revenues, loss of use of the PneuView® program or computer hardware, loss of data, claims by third parties or for other similar costs. In no case, shall Michigan Instruments' liability exceed the amount of the purchase price.

Copyright

Under the copyright laws, neither the documentation nor the software may be copied, photocopied, reproduced, translated, or reduced to any electronic medium or machine-readable form, in part or in whole, without the prior written consent of Michigan Instruments, Inc.

Copyright© 1999-2000 Michigan Instruments, Inc.
4717 Talon Ct. S.E.
Grand Rapids, MI 49512 USA

Toll Free: 800-530-9939 TEL: 616-554-9696 FAX: 616-554-3067
email: mii@michiganinstruments.com web site: www.michiganinstruments.com

Acrobat® Reader Copyright© 1987-1996 Adobe Systems Incorporated. All rights reserved.
Adobe and Acrobat are trademarks of Adobe Systems Incorporated which may be registered in certain jurisdictions.

General Information

Program Requirements

Your computer system must possess the following specifications to guarantee proper operation of PneuView®:

Minimum Requirements

- 166 MHZ Processor
- 32 MB RAM
- 10 MB Hard Disk Space Available
- 1 Free Serial Port
- 640 x 480 16 Color Display
- Windows95®, Windows98®, or WindowsNT® Operating System

Recommended Requirements

- 200 MHZ Processor
- 64 MB RAM
- 10 MB Hard Disk Space Available
- 1 Free Serial Port
- 640 x 480 16 Color Display

CAUTION: Certain screen saver programs, power management, and/or system management utilities may interfere with the continuous acquisition of data through serial ports. Therefore, it is important that such programs and utilities be disabled when running the PneuView system, particularly during trend testing.

Technical Support

To help ensure maximum performance and productivity from your equipment, PneuView comes with Michigan Instruments' commitment to total customer satisfaction. If you have a question, please call us at (616) 554-9696, or 1-800-530-9939, or e-mail us at mii@michiganinstruments.com. Our mailing address:

Technical Support – PneuView
Michigan Instruments, Inc.
4717 Talon Ct. SE
Grand Rapids, MI 49512
USA

Please include the following information when you contact Michigan Instruments:

- Product name, serial number, and Software Version number of the product.
- Computer brand, model, and type of system used with the PneuView Software.

Software Installation

The enclosed disk provides all of the program files needed to operate PneuView as it interacts with the TTL.

Installation instructions are provided at the beginning of this manual. If you have any questions about installation, please call Michigan Instruments, Inc.

Welcome to PneuView!

To begin the program, click on the PneuView icon on the Windows desktop. The "Welcome to PneuView!" title screen will appear. The following buttons can be selected to operate the system:

New Project: Begins a new project and records data from the test lung in real-time.

Select Template: Selects an existing template of specific reference conditions, notes, and display options.

Open Project: Opens an existing project of saved files.

Working Directory: Allows the user to open existing directories or create new ones. This conforms to Windows file handling structure.

Under Select Template, there is a check box titled *Connect to Test Lung at Start up*. This box should be checked for proper communications with the test lung at start up. However, if the user would want to open existing projects, or create new templates without being connected to the test lung, this box should not be checked.

At the bottom of the title screen are three more selections called *Communications*, *Test Lung*, and *Exit*. *Communications* sets the correct serial communications port for data coming in the computer. *Test Lung* allows the user to change the lung serial number if using a different TTL. *Exit* will close the PneuView program. See Figure 1 for PneuView Title Screen display.

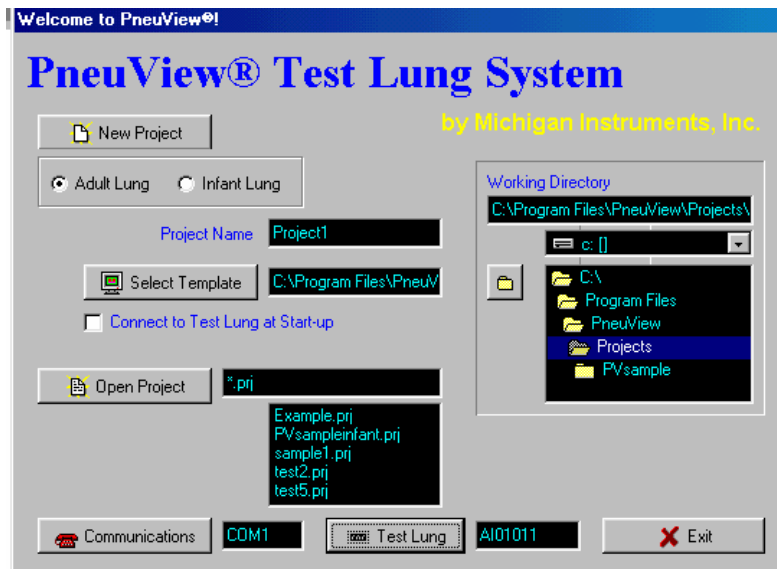


Figure 1 – PneuView Title Screen

New Project

Select New Project from the PneuView Title Screen to begin acquiring data from the test lung. The *Calibration - Zero Transducers* dialog box appears.

This box allows the user to calibrate the transducers before acquiring data. See *Figure 2 for the Calibration - Zero Transducers* dialog box.

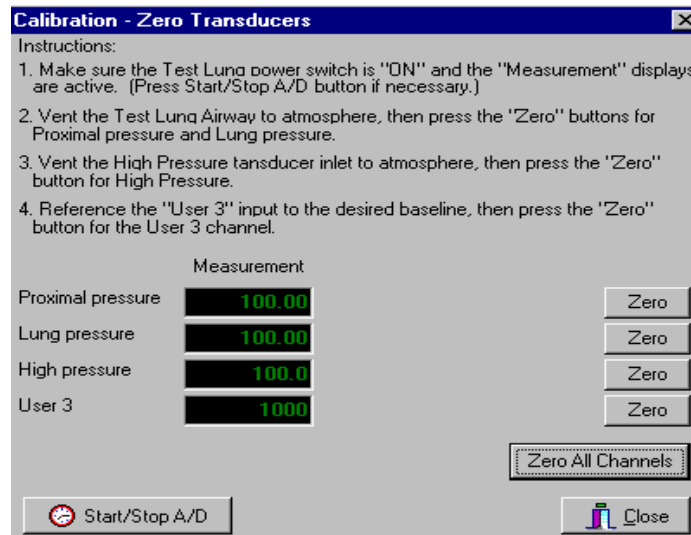


Figure 2 – Calibration - Zero Transducers Dialog Box

To ensure the greatest possible accuracy's with this program, simply press the *Zero All Channels* button. (See instructions in the dialog box.)

Once the transducers are set at zero, press the close button. The New Project Screen will appear containing three windows: *Measured Parameters*, *Graph*, and *Notes*. Data will appear in the Measured Parameters window and waveforms will appear in the Graph window. Text can be typed into the Notes window. Each window can be sized as desired; enlarged to full screen or minimized. From the New Project window, other features can be accessed such as long term trend testing and tabulated data. All information can be saved by using the standard Windows Save commands found in the File menu. (See Pages 19-20 for instructions on saving files.) *Please see Figure 3 on page 13 for display of New Project screen.*

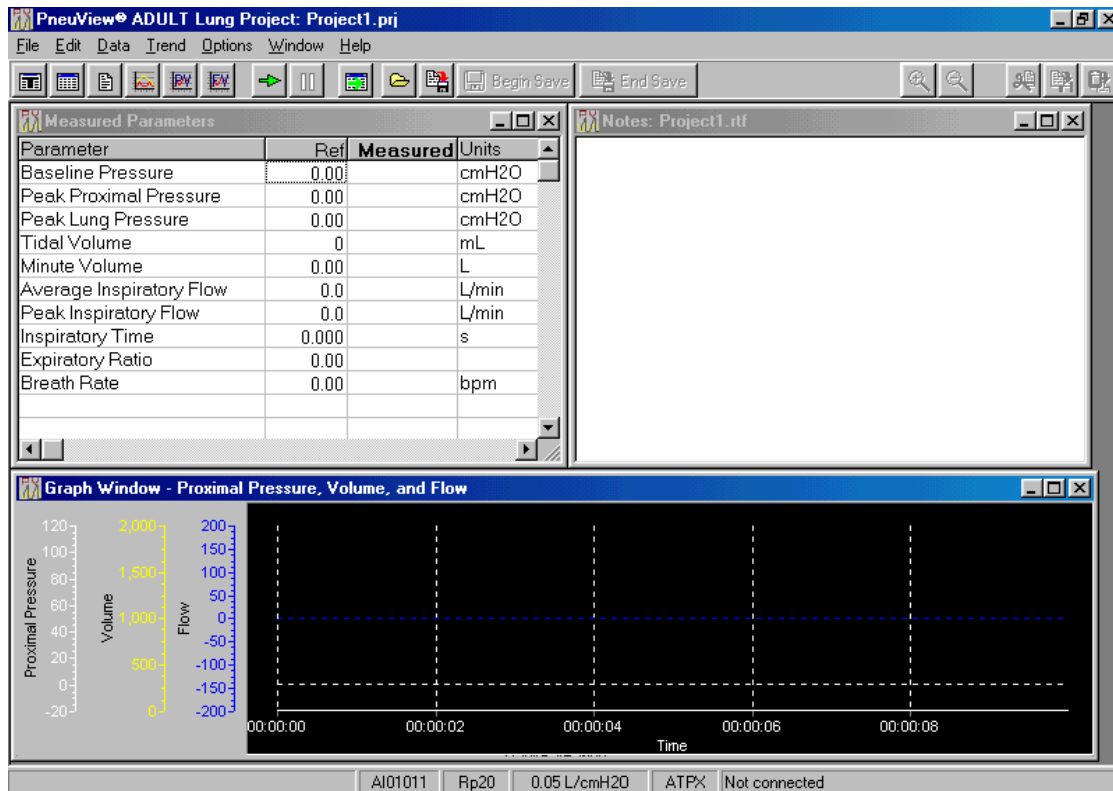


Figure 3 – New Project Screen

The *Acquire* button (the green arrow on the tool bar) is used to start acquiring data. To the right of the *Acquire* button is the *Pause* button. When *New Project* is selected from the PneuView Title Screen, the *Acquire* button will default to the “on” position and begin acquiring data. To pause the display, press the *Pause* button. To resume the display, press the *Pause* button again. See Figure 4 for a display of the *Acquire* button and *Pause* button.



Figure 4 – Acquire button and Pause button

NOTE: When *Acquire* is stopped, (button out) data is no longer being acquired. When restarted, the display begins where it was stopped. When in *Pause*, data continues to be acquired. When restarted, the data display resumes as if it was never stopped.

Display Windows

A. *Measured Parameters.* This window is a display of respiratory parameters as calculated by PneuView. The user has a choice of 24 different parameters

that can be selected from a pop-up menu. To access the pop-up menu, move the cursor into the Measured Parameter window and right click the mouse. Choose *Set Up* from the menu in the dialog box. This will open the *Select Parameters* Window, allowing the user to check the desired parameters. See *Figure 5* for the *Select Parameters* window.

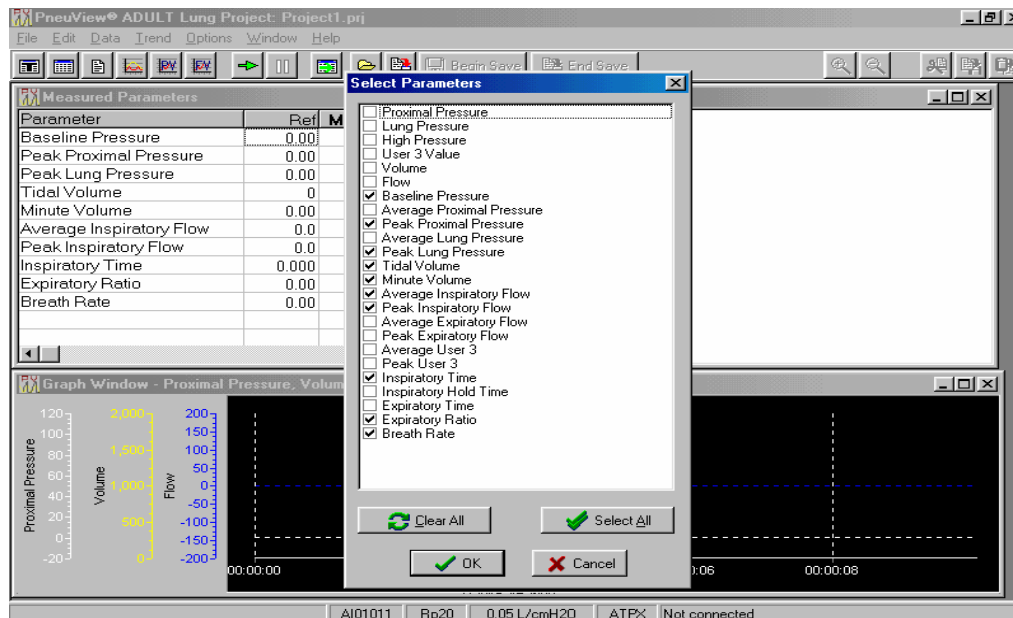


Figure 5 – Select Parameters Window

Ref is a reference value entered by the user. This is used to compare a value with an actual measured value. The reference value is not necessary for any PneuView calculations and has been provided only for references purposes.

Other commands on the menu are *Print Preview* and *Print*. (See page 33 for instructions on printing files).

On the tool bar is a *Parameter Window* button. This button will access the *Measured Parameters* if that window was closed or minimized. See *Figure 6* for a display of the *Parameter Window* button.



Figure 6 – Parameter Window Button

NOTE: The *Select Parameters* window can also be accessed by selecting the *Parameter Window* button, then going to *Window* on the Menu bar, and selecting *Set Up*.

B. *Notes*. The Notes window is a text editor and provides capabilities for entering, editing, and saving text. Right clicking the mouse in the notes window can access a menu. The menu commands are File, Edit, Justification, Font, Word Wrap, and Print Notes. Standard sub-menus appear when selecting these commands. See Figure 7 for Notes Window and Menu.

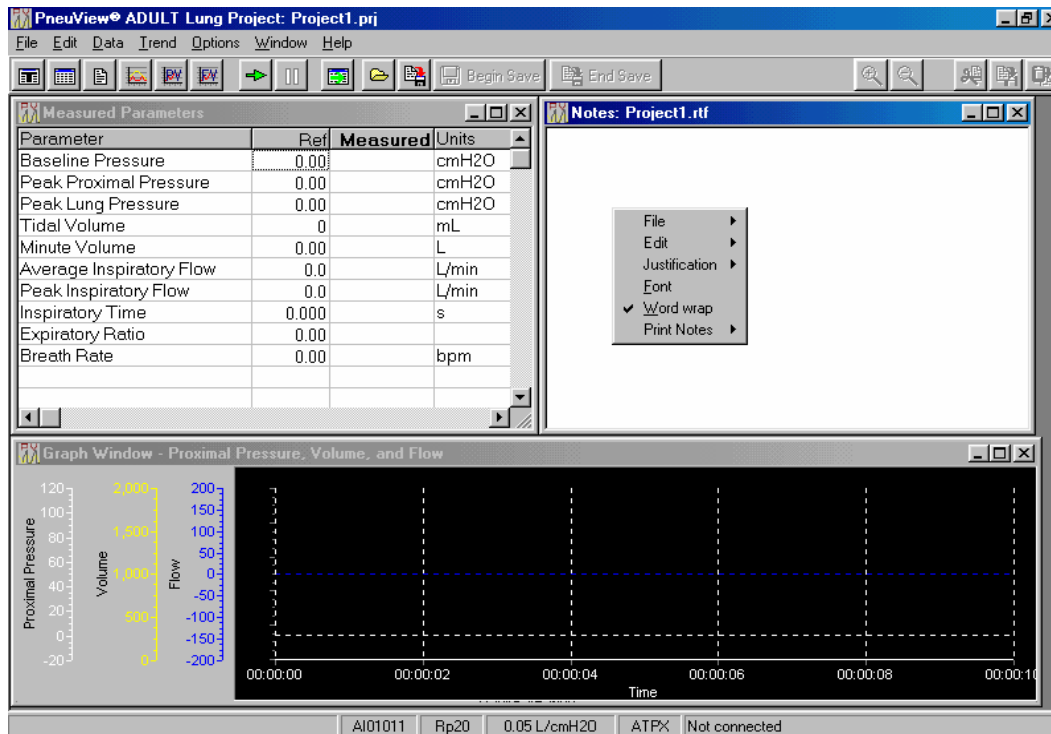


Figure 7 – Notes Window Menu

The tool bar contains a Notes button. This button is used to access the Notes if that window was closed or minimized. See Figure 8 for a display of the Notes button.



Figure 8 – Notes Button

NOTE: The Notes Window can also be accessed by selecting the Notes button, then going to *Window* on the Menu bar and selecting *Set Up*.

C. *Graph*. The Graph window is capable of displaying real time graphs

(waveforms) of up to three calculated parameters simultaneously. These waveforms are displayed in easy to distinguish colors. The color of a particular waveform will match the color of its corresponding Y-axis at the left of the plot window. The zero axis for each waveform within the plot window will also be indicated by a color coordinated dotted line matching the color of the corresponding waveform.

Right clicking the mouse in the graph area will display a menu with the commands *Set Up* and *Print*. Choose *Print* to access the real-time graph and printing options. Choose *Set Up* to access the *Graph Set Up Dialog* window. This window allows the user to set up graphs for display along with a time scale and choice of color of the waveform. See *Figure 9* for a display of the *Graph Set Up Dialog* window.

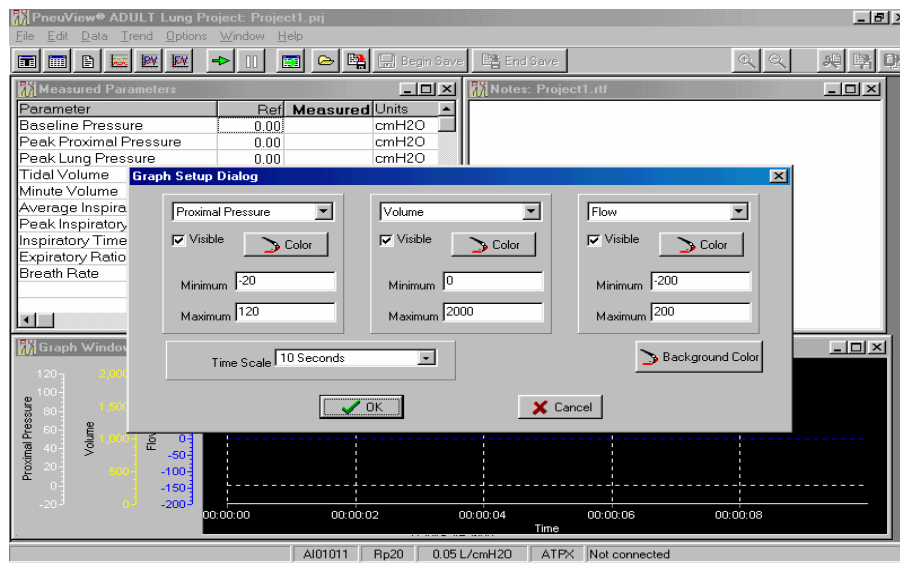


Figure 9 – Graph Set Up Dialog window

The *Graph* button on the tool bar is used to access the graphs if that window was closed or minimized. See *Figure 10* for a display of the *Graph* button.

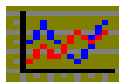


Figure 10 – Graph Button

NOTE: The *Graph Set Up Dialog* window can also be accessed by selecting the *Graph* button, then going to *Window* on the Menu bar and selecting *Set Up*.

Test Lung Settings

The Test Lung settings are displayed on the status bar at the bottom of the New Project screen. To access these settings, double click on the status bar. These settings (which can be adjusted by the user using a pull-down menu) include Lung Compliance, Airway Resistance, Gas Temperature, Barometric Pressure, Gas Reference Conditions, and Communications Port. The Serial Number of the Test Lung is also displayed here. Verify that the serial number of the test lung and the software are the same.

Choosing Options – Preferences on the menu bar can also access the Test Lung Settings.

NOTE: In order for PneuView to maintain accuracy, it is extremely important that the settings on the test lung (compliance and resistance) match the settings in the PneuView Program. The Gas Reference conditions, Barometric Pressure, and Gas Temperature should also be set as accurately as possible.

See Figure 11 for a display of the Test Lung Settings window.

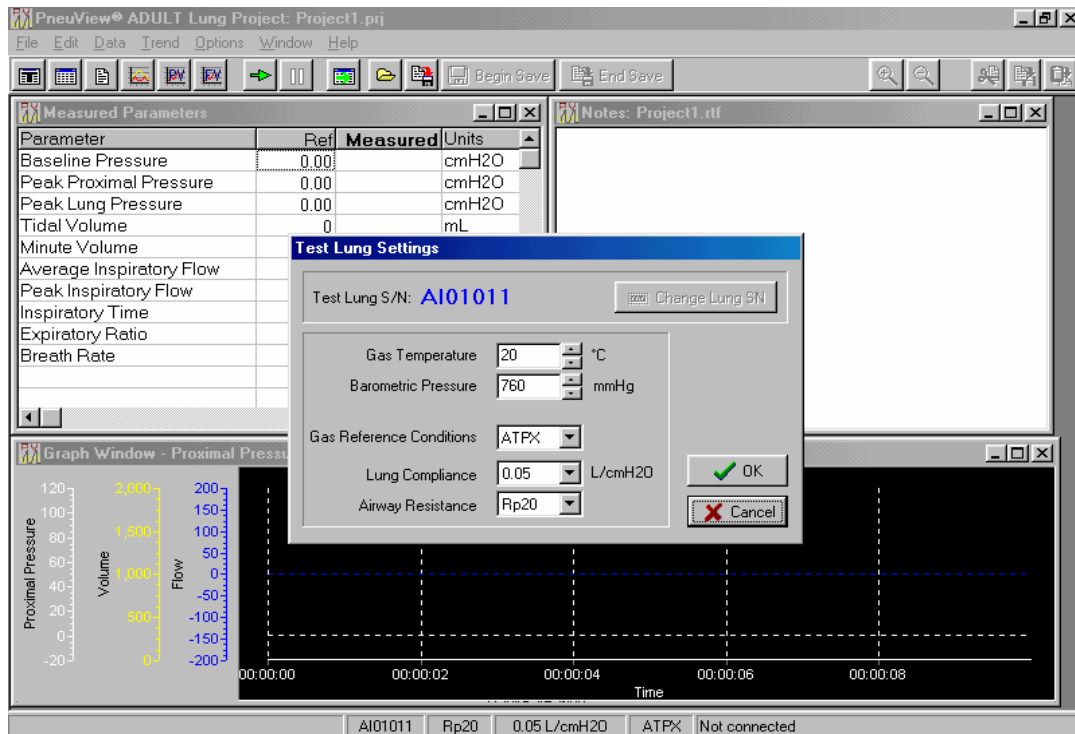


Figure 11 – Test Lung Settings window

Changing the Test Lung Settings

Test Lung S/N -- This should match the serial number on the PneuView software disk. If the serial numbers do not match, check both the test lung and software disk serial numbers. Call Michigan Instruments if you need a new disk(s).

Airway Resistance – This is adjusted by the pull-down menu to the right of the Rp value. The choice of Rp5, Rp20, Rp50, Rp200, and Rp500 is selected by the user.

NOTE: The airway resistance on the test lung must match the resistance value in the Test Lung Settings window.

Lung Compliance -- This is adjusted by the pull-down menu to the right of the Compliance number. The range is adjustable from .01 to .10 L/cmH20 for the adult lung and .001 to .010 L/cmH20 for the infant lung.

Note: The Lung compliance on the test lung must match the compliance setting in the Test Lung Settings window.

Gas Reference Conditions – Again, this is adjusted by the pull-down menu. The following choices are available:

ATPX – **A**mbient **T**emperature (current gas temperature), barometric **P**ressure (current barometric pressure) and (**X**) relative humidity. Data collected from the TTL is collected at ambient (ATPX) conditions. When ATPX is selected as the reference unit, the volumes and flowrates calculated and displayed will represent those that occurred at the TTL under the current ambient conditions. This is the default setting of the PneuView software.

ATPD – **A**mbient **T**emperature (current gas temperature), barometric **P**ressure (current barometric pressure) under **D**ry conditions (0% humidity).

ATPS – **A**mbient **T**emperature (current gas temperature) and barometric **P**ressure (current barometric pressure) under **S**aturated conditions (100% humidity).

Since relative humidity has virtually no effect on the calculations within the operating range of the TTL, selection of ATPS will produce the same results as selection of ATPX.

BTPS – **B**ody **T**emperature (98.6°F, 37°C) and Barometric **P**ressure (760 mmHg, 101.3 kPa) under **S**aturated conditions (100% Humidity).

Selection of BTPS will cause PneuView to display volume and flowrate information after it has been converted to body conditions (98.6°F, 760 mmHg)

The information supplied by PneuView will represent that which would have occurred had the gas temperature and barometric pressure been at body conditions.

NTPD – Normal Temperature (68°F, 20°C) and barometric Pressure (760 mmHg, 101.3 kPa) under Dry conditions (0% humidity).

When NTPD is selected, the calculated and displayed volumes and flowrates will be converted to normal conditions. This requires that the Gas Temperature and Barometric Pressure reference values be entered as accurately as possible for the conversion calculations to be made correctly. The volumes and flowrates displayed will be those that would have occurred had the gas temperature been at normal conditions (68°F, 760 mmHg).

STPD – Standard Temperature (32°F, 0°C) and barometric Pressure (760 mmHg, 101.3 kPa) under Dry conditions. (0% humidity).

When STPD is selected, the volumes and flowrates calculated and displayed will be those that would have occurred had the gas temperature and barometric pressure been at standard conditions (32°F, 760 mmHg). This requires that the values entered as the Gas Temperature and Barometric Pressure must be entered to represent the ambient conditions as accurately as possible. This will ensure proper calculations and conversions for the displayed volume and flowrate information.

The Importance of Test Conditions

The test conditions **MUST** be entered and adjusted before acquiring and saving data. These conditions not only serve as a reference when reviewing data, but are necessary for the proper calculation of volume and flow parameters. When data is saved, the test conditions are saved as a permanent part of the file.

Retrieving a template will not change the test conditions, as the original conditions are necessary to generate accurate calculations and waveforms.

Saving Files

The principle function of the New Project screen is collecting and saving data from the TTL. Digital pressure signals are taken from the TTL every 10 milliseconds. This raw pressure data is analyzed to determine fundamental information such as the beginning and end of breaths, and peak and baseline pressure points. Saving the data allows the user to review and reproduce the displayed breath parameters and graphs as it was originally acquired.

PneuView provides three methods of saving up to 30 minutes of this raw pressure data: The *Save Project* commands in the File menu and toolbar, the *Save Data Buffer* under the Data menu, and the *Begin Save and End Save* buttons on the toolbar provide methods of saving the raw pressure data.

Save Project Command

Files can be saved by selecting the *Save Project* icon on the toolbar of the New Project Screen, or selecting *Save Project* or *Save Project as* from the Menu. *Save Project* can save all files that are currently running within PneuView, including the Notes files, Tabulated data and the Data file. When *Save Project* is selected, the *Save all Current Project Files* dialog box will open and prompt the user for a file name. Once the file is named and saved, a *Confirm* dialog box appears with *The Data Buffer has New Data. Save New Data?* Select *Yes* to save the data file. The *Save Data File* dialog appears next asking the user to name the file. The same file name will appear as was used in the *Save all Current Project Files* dialog. The same file name can be used or renamed and saved. The *Save Notes File* dialog will appear next, followed by the *Save Data Table and Notes* dialog. Files are saved with a **.prj** extension. See *Figure 12 for Save Project Button*.

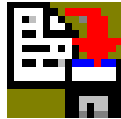


Figure 12 – Save Project Button

Save Data Buffer

The Data Buffer is a memory buffer, established by PneuView containing the last 30 minutes of data collected from the TTL. Pressure data is collected every 10 milliseconds and 30 minutes worth of the most recent digital pressure data is retained in the buffer.

The Data Buffer is initialized every time a New Project is selected, a reference condition has been changed, or after data has been saved.

To save data from the data buffer, select *Data* from the menu, and press *Save Data Buffer*. A dialog will appear prompting the user to name the file. The files will be saved with a **.dat** extension.

Begin Save/End Save

The *Begin Save* and *End Save* buttons are located at the top of the New Project screen. When the *Begin Save* button is selected, PneuView begins and continues saving incoming data until the *End Save* button is selected. When the *End Save* button is selected, the user is given the opportunity to save the data

segment under a default name or user entered name. If End Save is selected after more than 30 minutes of data has been acquired, only the last 30 minutes will be saved to a file. This is also a data file, and will be saved with a **.dat** extension.

Trend Testing

Trend Testing is valuable in analyzing and documenting the performance characteristics of mechanical ventilation and related equipment over a long period of time. With PneuView, trending is available for up to 72 hours.

To access the trending environment in PneuView, select the *Trend* option from the menu bar. A menu appears with *Setup*, *Begin*, and *End*.

Setup (From Trend Menu)

This initiates the trend test dialog, allowing the user to select conditions and parameters for a trend test. A dialog box called Set up Trend Test appears. The user will set up the Test Name, Test Length, Sample Interval (in minutes), and +/- Tolerance (in percent). Pull down menus allow the user to choose the graphed parameters.

The user has a choice of up to four different graphs under *Initially Graphed Parameters*. These can be changed with pull down menus. Also in the set up is a list of measured parameters. The parameters are listed along with the Measured value and Target value. PneuView generates the measured value; the user enters the Target value. After all of the values are selected, choose the OK button at the bottom of the Set up screen. See Figure 13 for display of the Set up Trend Test Dialog Box.

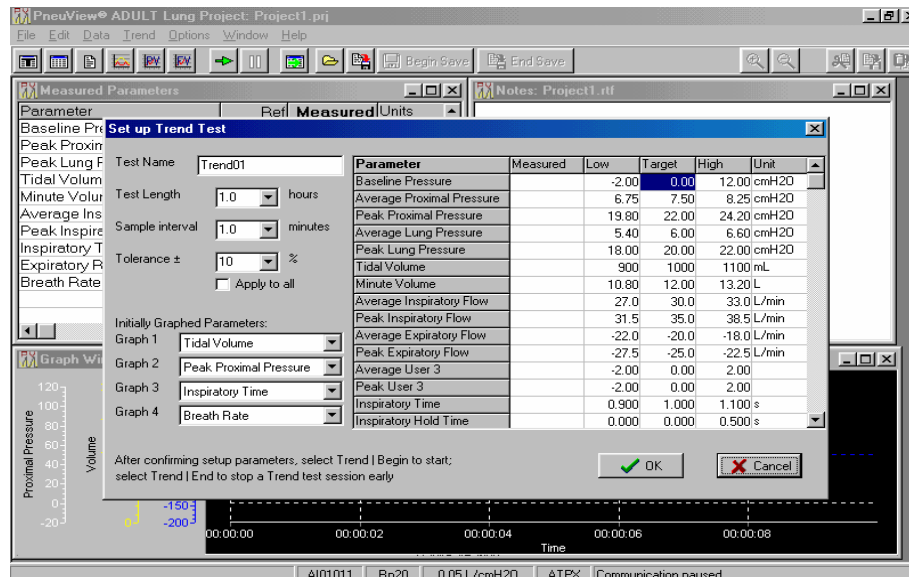


Figure 13 – Set up Trend Test Dialog Box.

Begin (From Trend Menu)

After the set up is completed, The Trend Graph screen is displayed. The user is now ready to begin trending. Choose the Trend command from the menu bar. The commands *Set up*, *Begin*, and *End* appear. Choose *Begin* to start trending. See *Figure 14* for display of the Trend Graph Screen.

NOTE: The test lung settings should be entered and adjusted before acquiring and saving data in the Trend mode.

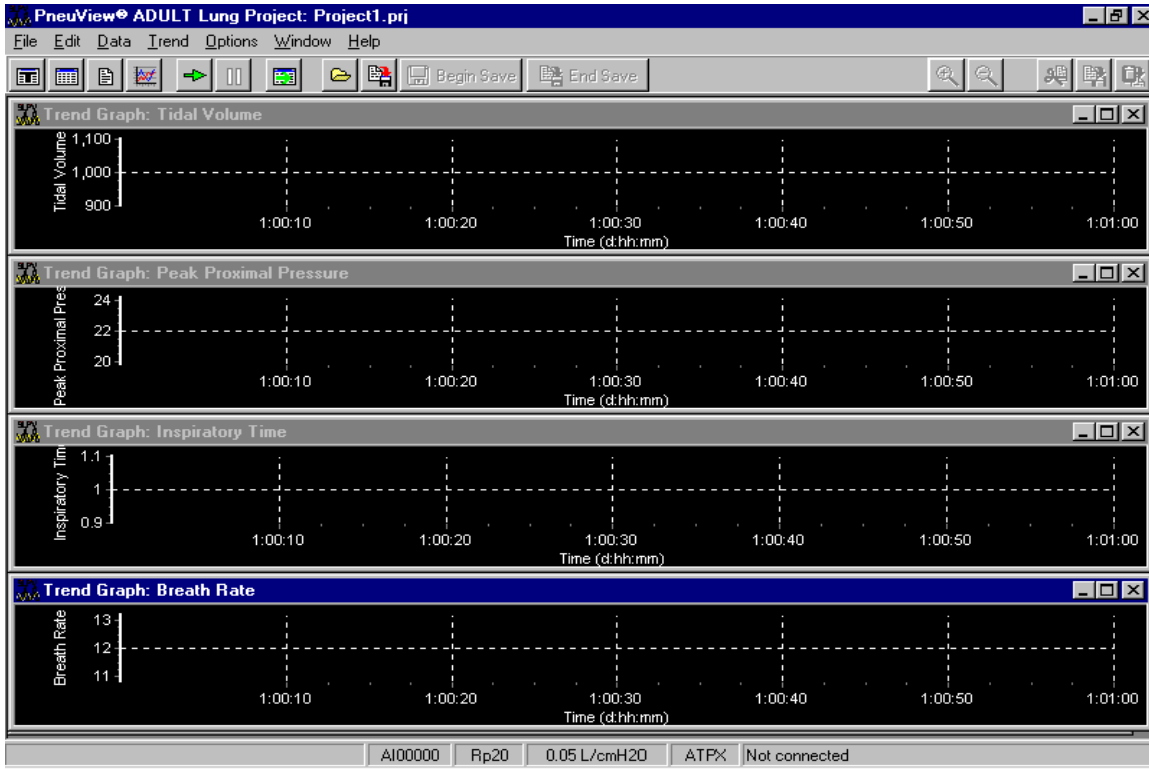


Figure 14 -- Trend Graph Screen.

End (From Trend Menu)

To end the trend, choose the Trend command from the menu bar and click *End*. This causes a trend test in progress to be terminated before its set duration is complete. The user is prompted to save or abort the test. *End* is disabled if a trend test is not in progress.

Once the test is completed, a dialog box prompts the user to save the data (as default or user selected file name.) Name the project, choose *Save*, and the file will be saved with a **.trd** extension. This file can be printed, or reviewed later.

Tabulated Data

There is a provision to save individual sets of calculated measured parameters as raw data. In PneuView, saving data in this manner is called “Tabulating.”

Choose the Tabulate function to take a “snap shot” of the current respiratory parameter values in the Measured Parameters display window. Each time the Tabulate key is pressed, another snap shot is taken and appended to the last snap shot creating a table of respiratory parameters in memory.

NOTE: Once the table is saved, no more tabulations can be added to that file.

To Tabulate Data:

1. Click on the “T” located on the tool bar. This will open the *Data Table* window. See *Figure 15* for display of the Tabulate button and *Figure 16* for display of the Data Table window.



Figure 15 – Tabulate Button

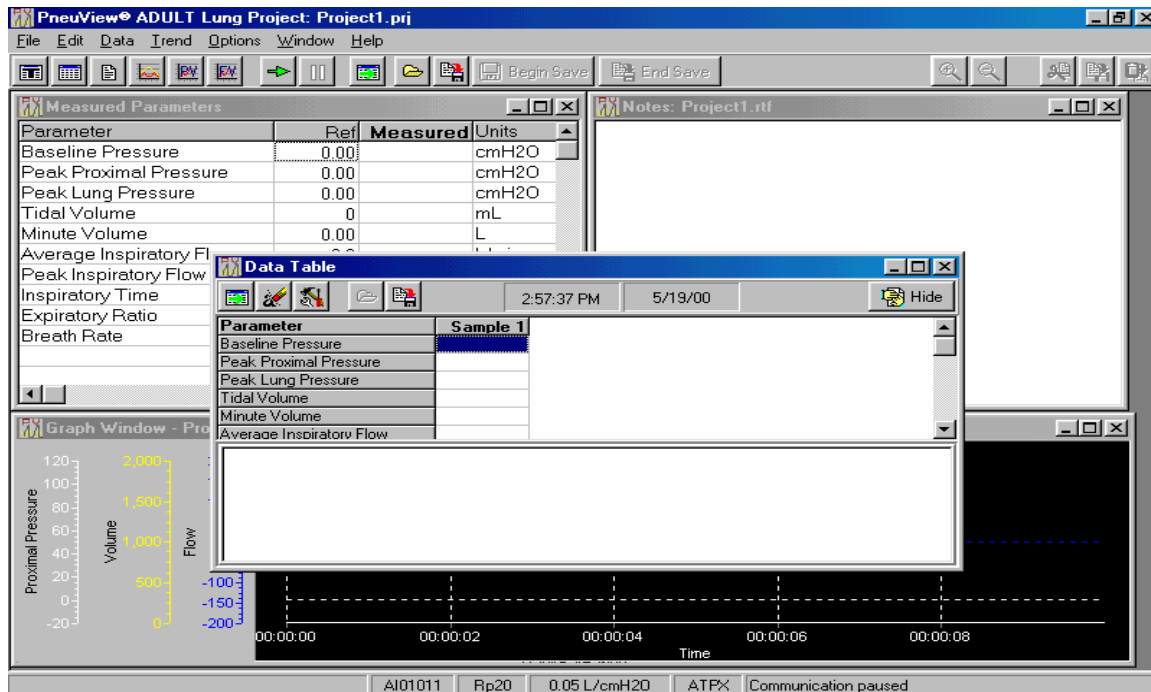


Figure 16 – Data Table Window

2. Data can now be Tabulated, or additional Measured Parameters can be selected with the *Setup* icon on the data table tool bar. The *Select Parameters* dialog box will appear and allow the user to select additional parameters. See *Figure 17 for the Setup Icon*.



Figure 17 – Setup Button

Right clicking the mouse in the top portion of the data table window and selecting Setup can also access the Select Parameters dialog box.

3. There are three ways to collect tabulated samples:
- A. Click the *Add Sample* button on the Data Table tool bar with the mouse. This button is also located on the main tool bar at the top of the screen. See *Figure 18 for a display of the Add Sample button*.



Figure 18 – Add Sample Button

- B. Press F5 on the keyboard, or
- C. Right-click the mouse button in the top portion of the Data Table dialog box and select *Tabulate*. Other functions by the right click include *Open*, *Save As*, *Clear*, *Set up*, *Preview*, and *Print*.

There are three other buttons on the tool bar with specific functions. The *Clear Table* button will clear the data table to allow the user to collect new data. See *Figure 19 for the Clear Table button*.



Figure 19 – Clear Table Button

The *Hide* button puts the data table in the background so the user can easily see the graph table. Pressing the Add Sample button or pressing F5 can still collect samples. See *Figure 20* for a display of the *Hide* button.



Figure 20 – Hide Button

The last button on the tool bar is the *Save button*. This will save all tabulated files. See *figure 12* on page 20 for the *Save button*.

By right clicking the mouse in the data table notes window, a menu appears with the commands *Insert, Edit, Justification, Font, and Word Wrap*. This allows the user to add notes after each sample, such as a date/time stamp.

NOTE: Test lung settings should be entered and adjusted before acquiring and saving tabulated data.

When a sample is collected, the values will be listed as *Sample 1*. For each sample collected thereafter, the data will be listed as *Sample 2, Sample 3, etc.*

NOTE: No more than 20 samples can be collected in a single table.

Selecting the *Save* button on the Data Table Tool Bar or selecting *Save Project* or *Save Project As* from the File menu can save these files.

These files are saved with a **.tab** extension.

Measure

Choose the *Measure* function to display continuous flow and high pressure measurement values from the ventilation device. This command is located under the *Data* menu on the *New Project* screen. The following measurements can be acquired:

Proximal Pressure (cmH₂O)

Lung Pressure (cmH₂O)

External Pressure (psig)

Flow Rate (L/min)

CAUTION: The lung hose MUST be disconnected at the proximal airway to prevent overinflation of the lung bellows while measuring continuous flow.

Resistance is also selected. Choose **Rp 5**, **Rp 20**, **Rp 50**, **Rp 200**, or **Rp 500** for the appropriate flow rate, listed as follows:

Rp 5	140-240	L/min	Rp 200	6-14	L/min
Rp 20	60-139	L/min	Rp 500	0.5-5	L/min
Rp 50	14-59	L/min			

See Figure 21 for Direct Measurement window.

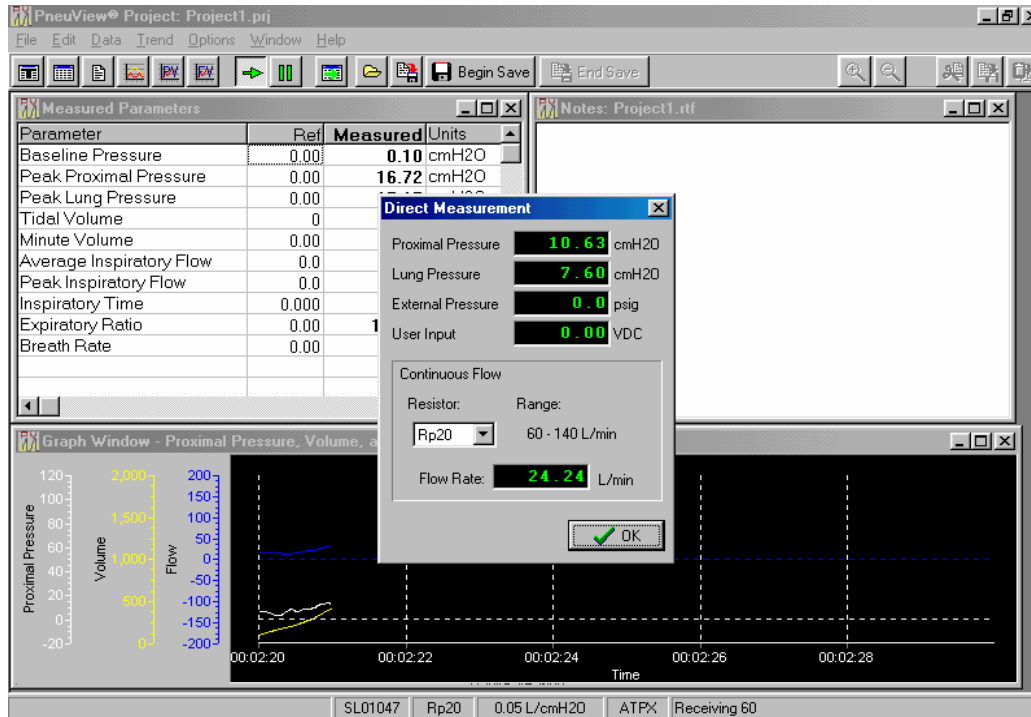


Figure 21 – Direct Measurement Window

Pressure/Volume and Flow/Volume Loops

Another feature of the PneuView software is the acquisition of Pressure/Volume and Flow/Volume loops. This allows the user to critically examine various modes of ventilation through the TTL. In the PneuView program, loops are referred to *PV Graphs* (Pressure/Volume graphs) and *FV Graphs* (Flow/Volume Graphs).

To access the *PV* and *FV* graphs, select the appropriate icons on the toolbar. See Figure 22 for a display of the *PV* and *FV* icons, and Figure 23 for a display of a *PV* Graph.

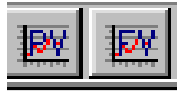


Figure 22 – Pressure/Volume and Flow/Volume Icons

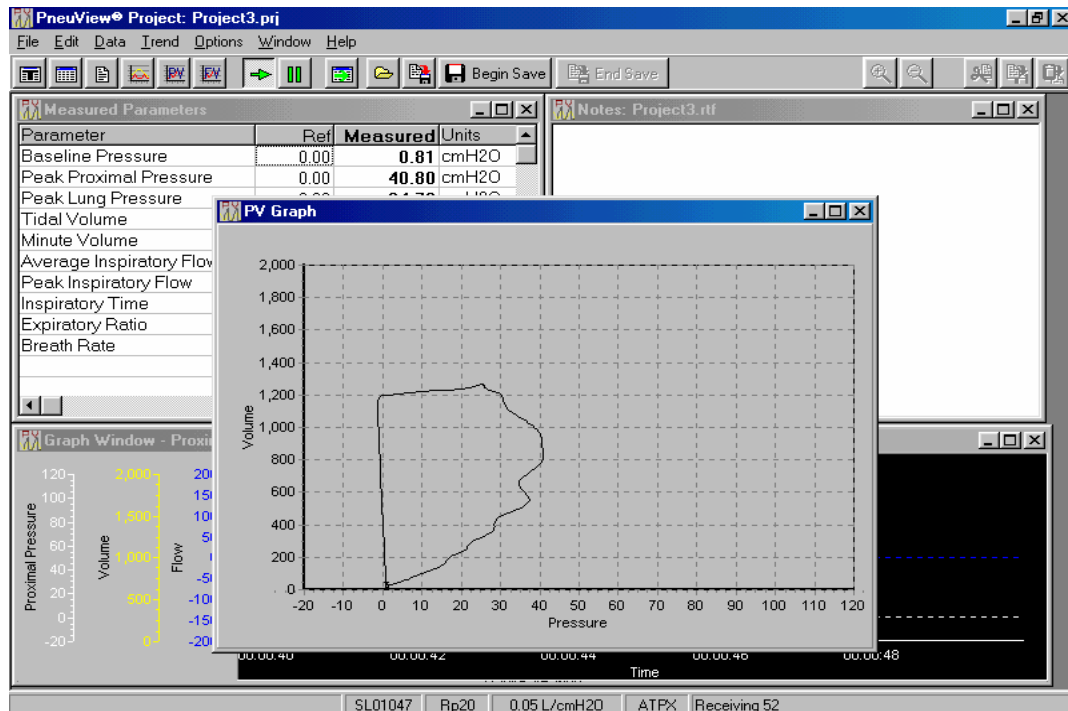


Figure 23 — Pressure/Volume Graph.

By right clicking the mouse inside the graph window, a menu will appear with the commands *Setup* and *Print*. *Setup* allows the user to scale the graph for different volumes, flows, and pressures. Also, the user can change the line color or background color of the graph.

The *Print* command gives the user the option of previewing the graph or printing the graph directly from the menu.

Reviewing Files

Reviewing files allows for the critical examination of saved data files. When data is selected for review, a static display of the entire data set is displayed in the graph window. Special features in this mode allow the user to select specific segments of the data set for closer analysis.

Files can be opened from the *Open Project* area in the PneuView Title Screen or from *Open Project...* in the file menu in the *New Project* screen. Once this command is selected, the *Open PneuView file(s)* window is opened. These files can be opened to review data files, trend data, and tabulated data. See *Figure 23* for a display of *Open PneuView file(s)* window.

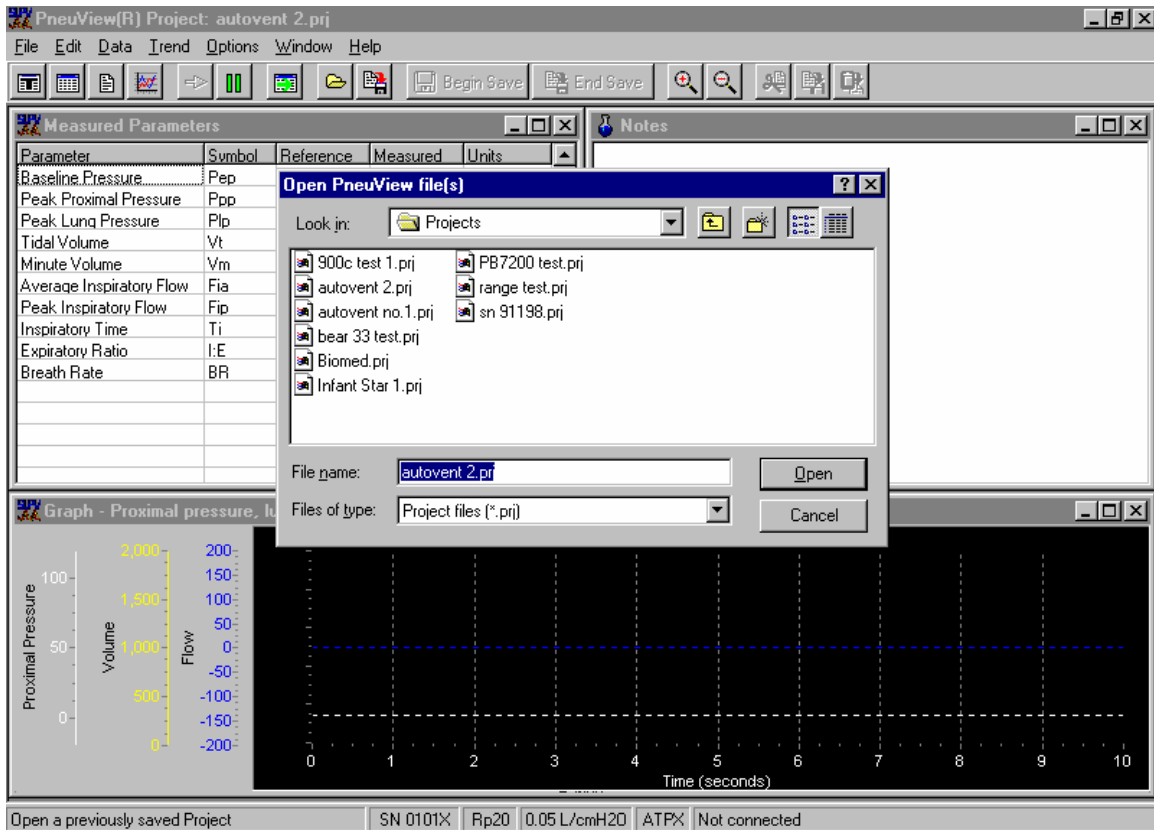


Figure 24 – Open PneuView file(s) window

This window presents a file list and the drive and directory where these files are located. All the files within the named directory are displayed alphanumeric-ically.

Reviewing a Project File

When a project file is opened for review, the file name is located at the top left of the screen. A graph will be displayed along with a scroll bar at the bottom of the screen. Any text that was entered at the time of the test will appear in the Notes window. If any tabulated data was taken, the Data Table will appear. See *Figure 25* on page 29 for a display of a reviewed file.

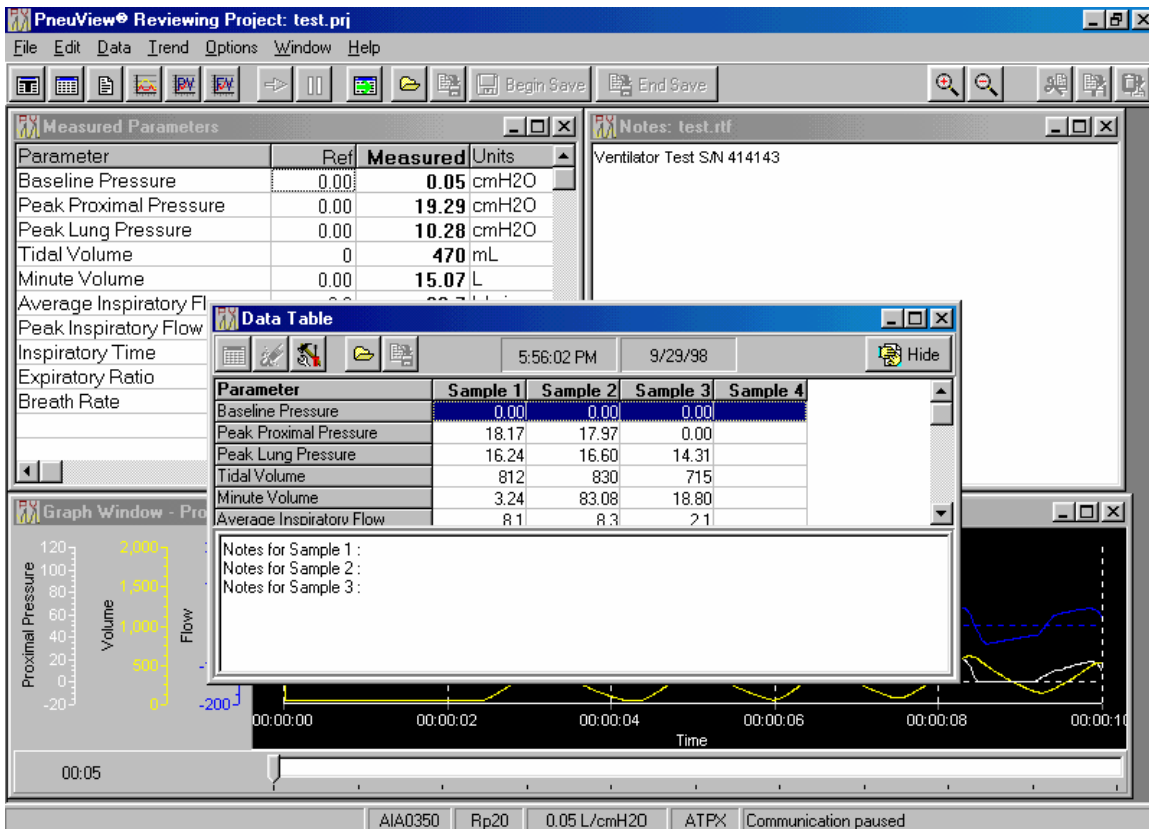


Figure 25 – Review File Display

The horizontal scroll bar at the bottom of the screen controls the time scale of the data recorded. By holding down the left mouse button with the cursor on the scroll bar, the user can drag the arrow to a specific time of that test. The waveform updates with the time scale. The arrows on the keyboard may also be used to adjust the time scale.

The measured parameters can be updated by moving the cursor into the graph display and left click the mouse at various times of the test.

Changing the Graph Window

The graph window can be changed to display other waveforms such as baseline pressure or lung pressure. To change the Graph window, move the cursor into the graph and right click the mouse. This will open a window with the commands *Zoom in*, *Zoom out*, *Set up*, and *Print*. Choose *Set up* to open the Graph Setup dialog box. See Figure 26 on page 30 for the Graph Set up dialog box.

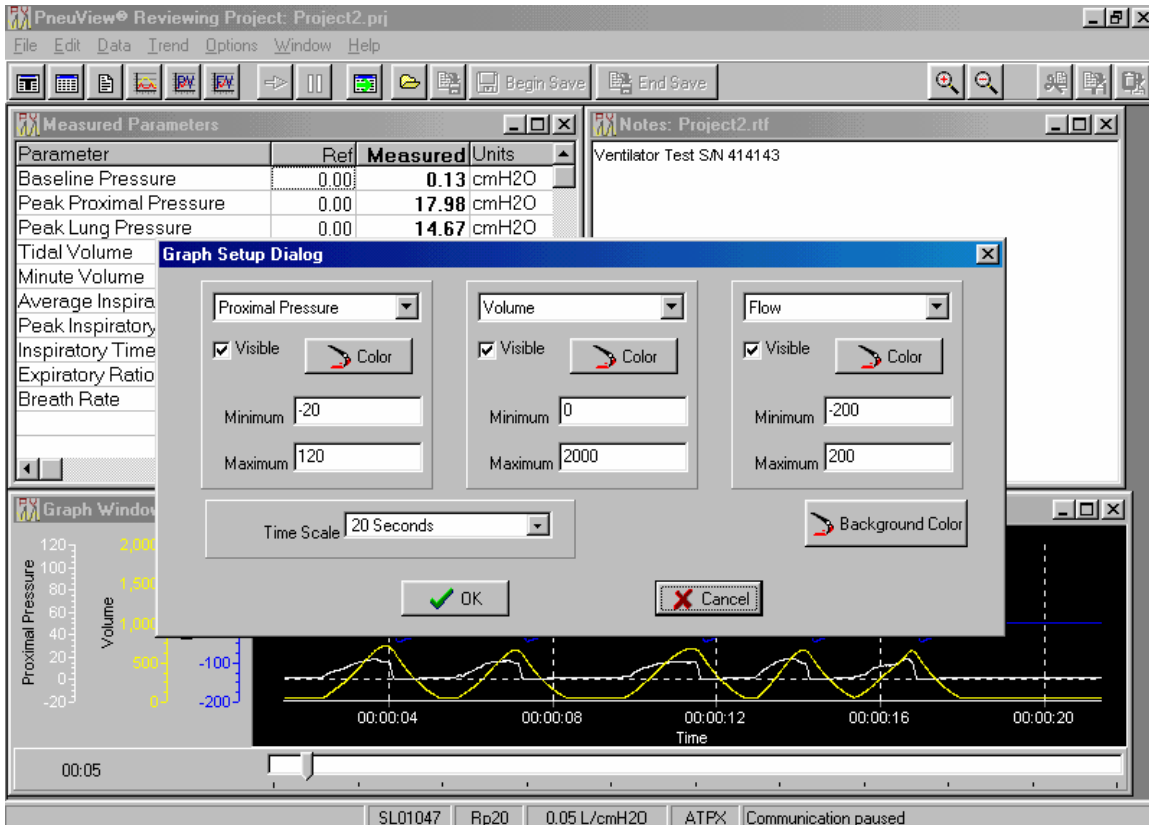


Figure 26 – Graph Setup Dialog Box

Up to three graphs can be displayed in this program. In *Figure 26*, Proximal Pressure, Volume, and Flow are the chosen graphs. To change the graph, click the down arrow to display the choice of graphs. When a different graph is chosen, click OK and the graph window will automatically change.

Multitudes of colors are available for the user to choose by accessing the *Color* button. If only one or two graphs are necessary to view, uncheck the *Visible* box. The *Minimum* and *Maximum* scale are adjusted to correspond to the measurement being displayed. The *Time Scale* will adjust the graph display from 10 seconds up to 30 minutes.

When all of the changes are complete in the Graph Setup Dialog box, choose OK to return to the review file display.

Zoom in and Zoom Out controls are accessed by choosing the buttons at the top of the screen. See figure 27 for a display of the Zoom buttons.



Figure 27 – Zoom In/Zoom Out Buttons

Zoom in will give the user a closer look of the data in a graph window. Zoom out will change the graph to allow more data to appear in the window.

NOTE: The Zoom controls can also be accessed by moving the cursor into the graph window, right clicking the mouse, and choosing either Zoom in or Zoom out.

Reviewing Trend Test Files

To review a trend file, go to the Trend command on the menu bar and select Review. A window will open displaying all of the trend files. Choose the file that is to be reviewed. The Trend Test Results window will open and display the results of the test.

See Figure 28 for display of the Trend Test Results window.

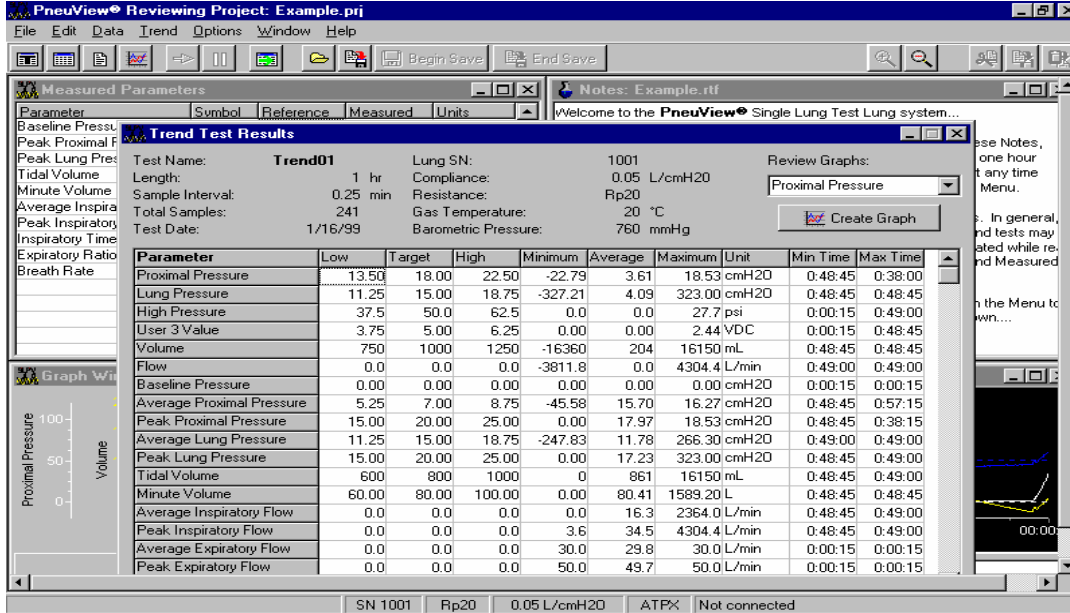


Figure 28 – Trend Test Results Window

The Trend Test Results window lists the test name, test length, sample interval, total samples, and test date along with the reference conditions.

The *Low*, *Target*, and *High* values correspond to the values that were entered in the Trend Set up. The *Minimum*, *Average*, and *Maximum* are the actual values of the parameters recorded during the test. The *Minimum time* is the time of the minimum value, and the *Maximum time* is the time of the maximum value.

Review Graphs allow the user to view the entire graph (or graphs) of the trend test. Choose the graph(s) from the pull-down menu and select *Create Graph*. The graph will appear on top of the Test Results. A horizontal scroll bar at the top left of the graph allows the user to view the entire test. This is accessed by left clicking the mouse on the scale, and sliding the arrow in either direction. A time scale is located at the bottom of the graph that will correspond with the scroll bar. There is also a pull-down time scale menu located to the right of the scroll bar. This will change the time scale on the graph without using the scroll bar. Also, the user can adjust the color of the graphs and background by using the *Avg. Color*, *Back Color*, *Min Color*, and *Max Color*. See figure 29 for a display of the Trend Graph.

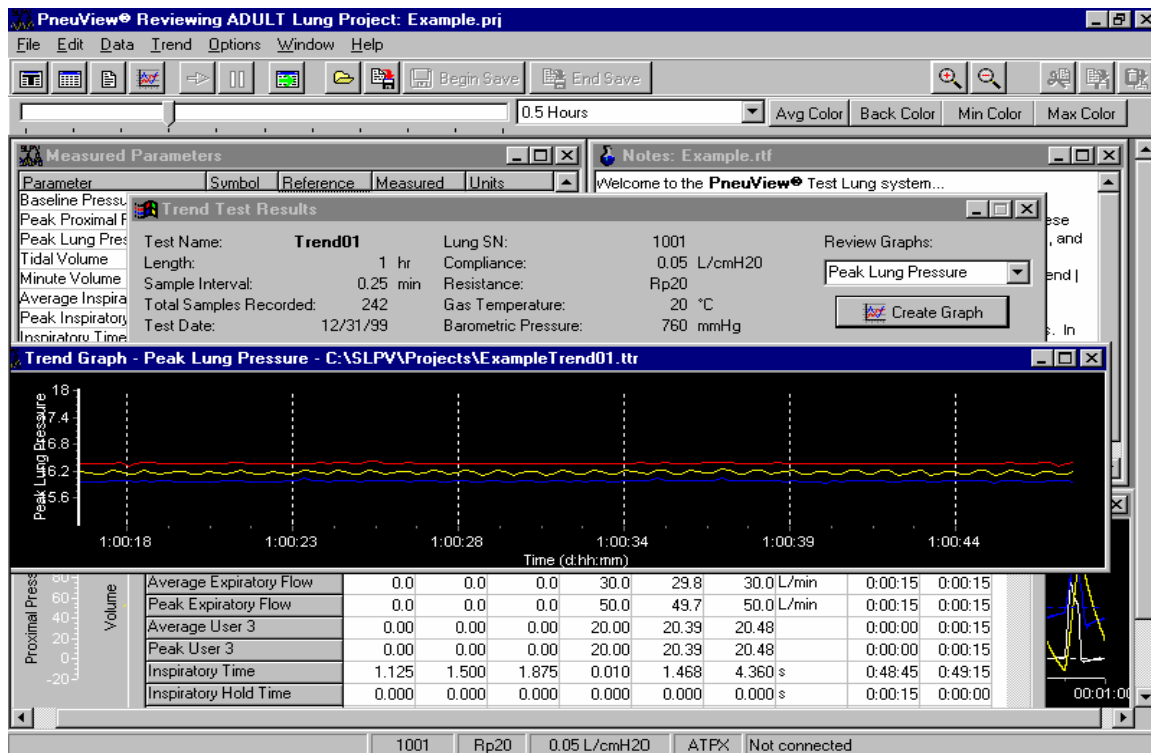


Figure 29 – Trend Graph Display

On trend graphs, there will be three lines displayed: the maximum value, the average value, and the low value. The default maximum color is red, the default average color is yellow, and the default low color is blue. The user has the option of changing these colors.

Reviewing Data Tables

To review data tables, choose *Review Data Table* under the *Data* command on the menu bar. The *Open Data Table* window will open and display the saved tabulated data files. After selecting the file for review, the *Data Table* window appears with the actual tabulated data.

See *Figure 30* for a display of the *Data Table*.

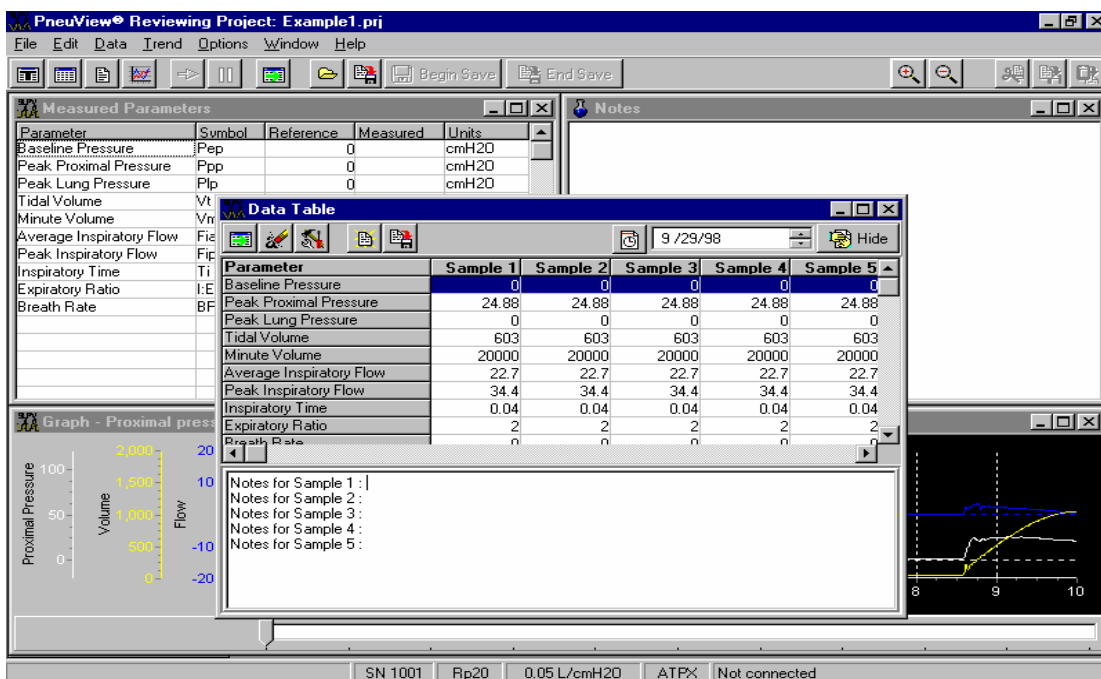


Figure 30 – Data Table Display

This table displays all of the respiratory parameters along with the reference conditions. In the right hand corner of the table is a *Hide* button. This will move the display into the background so the user can view other functions of the programs. To recall the table, select the *Tabulate* button on the tool bar.

Printing Files

To print, choose *Print* from the file menu. This will allow the user to print a number of reports listed below. Also, the *preview* command allows the user to view the report before printing.

Basic Report – This will print the Measured Parameters, Notes, Graphs, and Reference Conditions from the New Project Screen.

Trend Report – This will print the results of a trend test including the graphs, measured parameters, and reference conditions.

Data Table Report – This will print the tabulated data, notes, and reference conditions from a data table.

Notes – Notes are saved with a New Project or a Trend Test and can be printed separately from these files.

See Figure 31 for a display of the print commands.

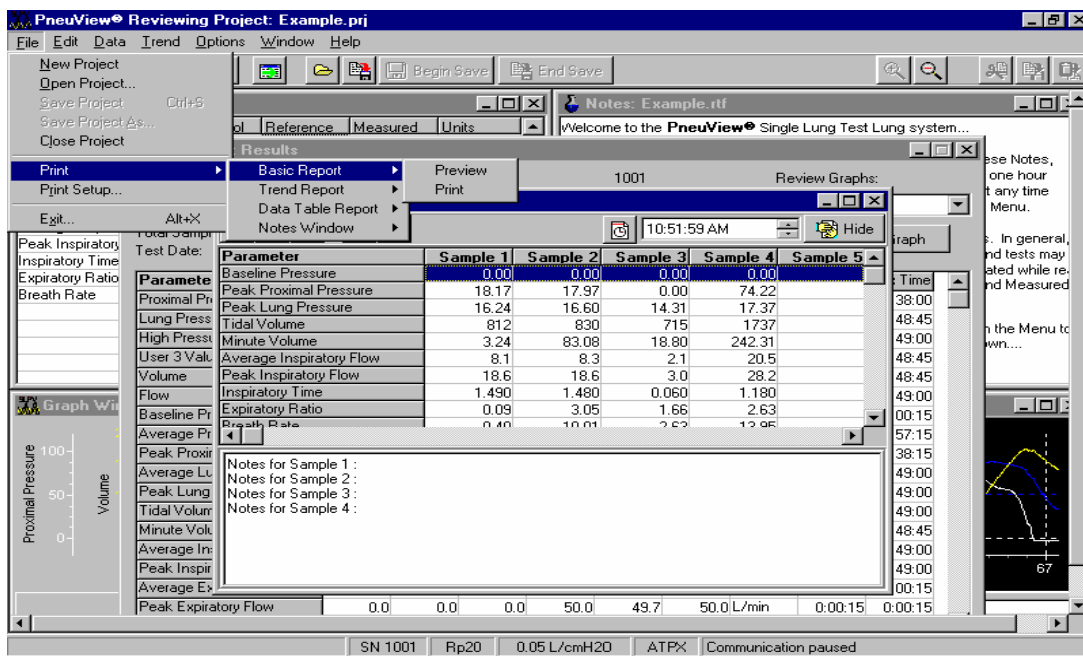


Figure 31 – Print Commands From File Menu.

Creating and Saving Templates

A template is a set of specific Measured Parameters, Graphs, Reference Conditions, and Notes inputted by the user to create a test for a specific ventilator or other application.

To create a Template, go to New Project from the PneuView Title Screen. Select the desired measured parameters, graphs, and reference conditions. Type in any notes in the *Notes* window.

After all the changes have been made, go to the *Options* command on the menu bar and select *Save Template*. The *Save Template File* dialog box will appear prompting the user to name the template file. Type in the file name, and select the *Save* button. Templates are saved with a **.pvt** extension. See *Figure 32* for the *Save Template File Dialog Box*.

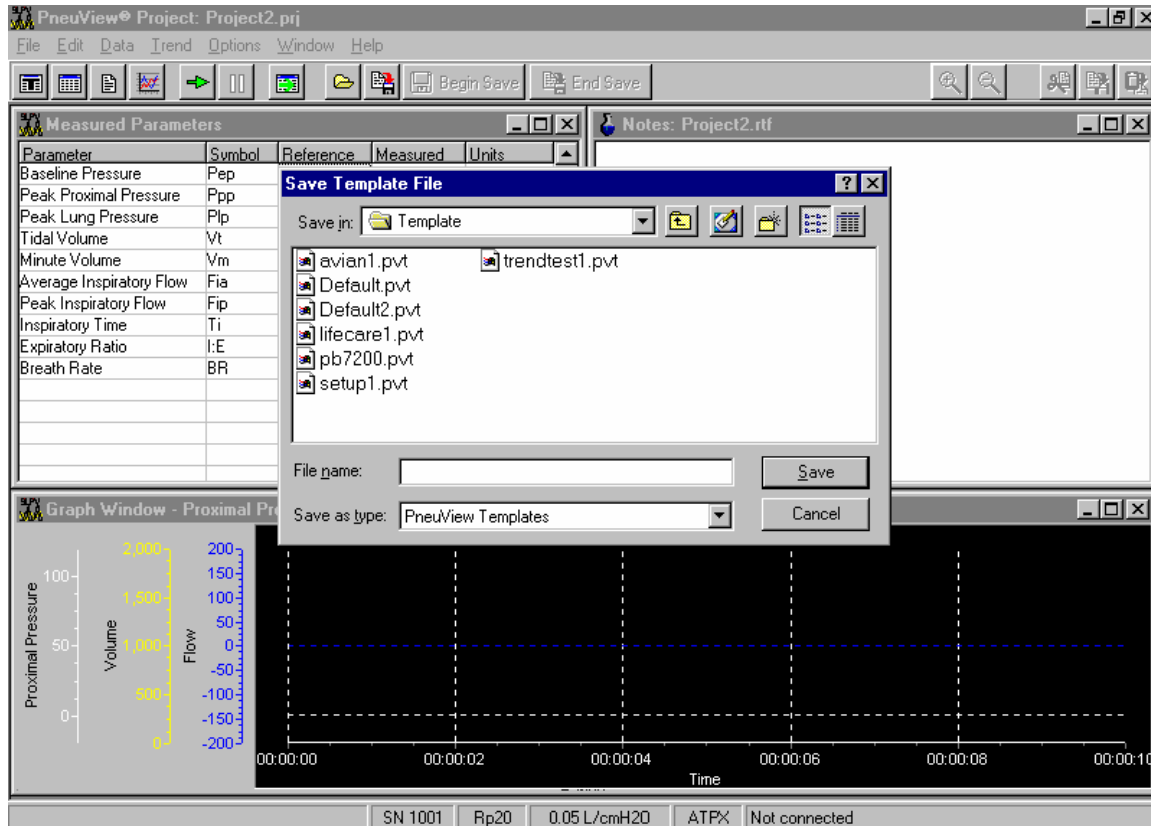


Figure 32 – Save Template File Dialog Box

To retrieve a saved template, go to *File* on the menu bar and select *New Project*. A dialog box appears asking the user to enter a name for a new project or to select a template. By pressing *Select*, a list of saved templates will appear. See *Figure 33* on page 36 for the *Select Template dialog box*.

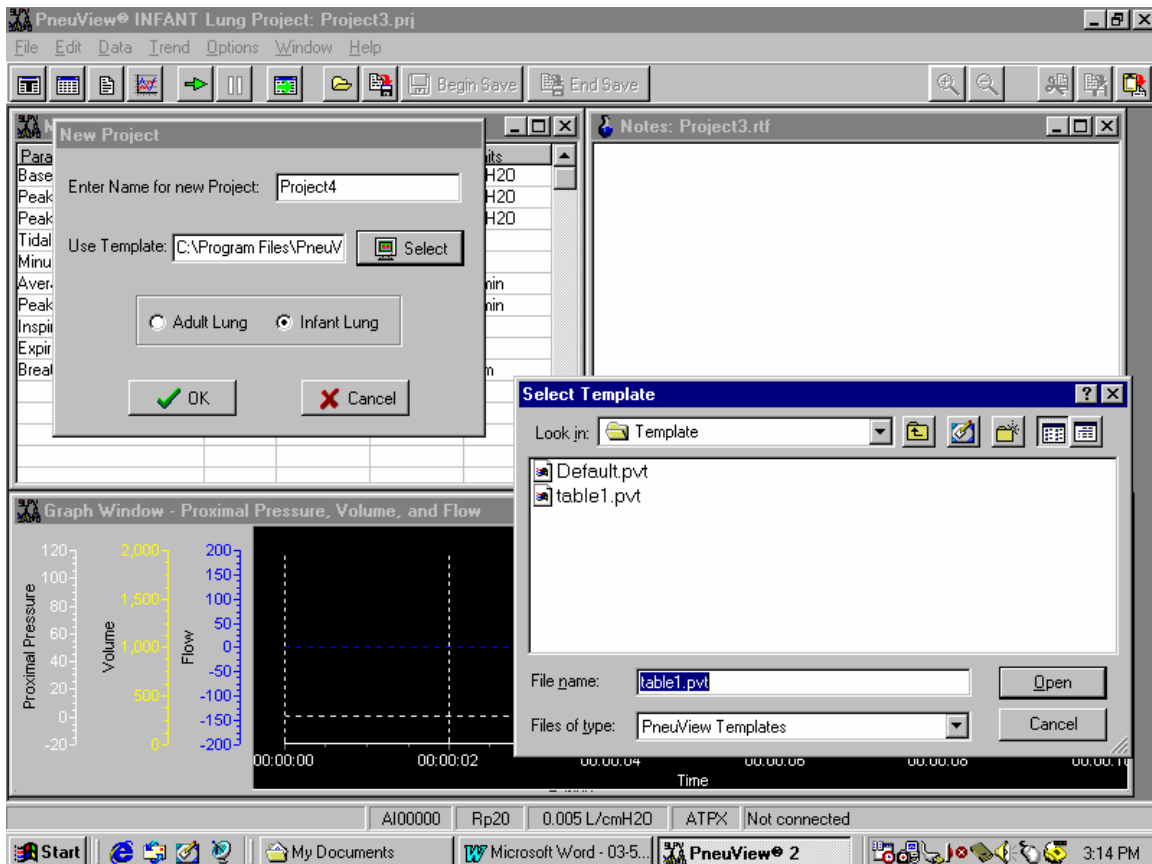


Figure 33 – Select Template Dialog Box

Other Features of PneuView

High Pressure Port

This feature is used to measure pressure from 0-100 psi. The port is located on the right hand side of the unit. The connector is a DISS oxygen connector.

The data can only be accessed in PneuView in the measured parameters window, trend tests, and data tables.

User Input

This feature is designed to allow the user to observe auxiliary inputs from other test equipment such as oxygen sensors, humidity sensors, nitrous oxide sensors, etc.

This connection is located on the front of the TTL to the right of the proximal airway gauge. This is a standard BNC connector. The data can be accessed in PneuView in the Measured Parameters window, trend tests, and data tables under *User 3 Value*, *Average User 3*, and *Peak User 3*.

4. Applications

The 5601i offers a unique combination of versatile lung simulation and comprehensive information gathering and display, including a multitude of respiratory parameters and waveforms. This makes the 5601i the perfect tool for an endless number of applications including:

- Performance testing of ventilators and related equipment.
- Classroom instruction on mechanical ventilation equipment, techniques, and phenomena.
- Product demonstration and evaluations.
- Product development and quality control.
- Pulmonary research.

To offer examples of all the applications for this system would be impossible, as new ones are continually being discovered or developed by users of the system. The following are examples of some of the common applications for which the Model 5601i PneuView System can be applied.

Ventilator Testing

The *Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) states, "All equipment shall be calibrated and operated according to the manufacturer's specifications, and shall be periodically inspected and maintained according to an established schedule as part of the hospital's preventive maintenance program."

The 5601i is designed to allow performance testing of mechanical ventilators within their range of typical use. Protocols for testing may be stored in PneuView software, allowing routine testing to be performed quickly and consistently.

Adult Ventilator Testing Application

Example A. The following is a routine test protocol to create a table for documentation of test results.

Test Protocol:

	Test 1	Test 2	Test 3	Test 4	Test 5
Rate (bpm)	10	20	20	20	30
Vt (mL)	1000	800	750	500	500
Flow (Lpm)	80	60	60	60	40
PEEP (cmH₂O)	0	60	60	60	40
Compliance (L/cmH₂O)	.05	.05	.02	.02	.01
Resistance (cmH₂O/L/sec)	5	20	20	20	50

Procedure:

1. Adjust the compliance and resistance on the 5601i as called for in Test 1 of the above protocol.
2. Attach the patient connection of the ventilator's breathing circuit to the airway of the 5601i.
3. Set the ventilator as described in Test 1 of the above protocol.
4. With the PneuView software running on your computer, enter the above protocol in the *Notes* window.
5. Select the respiratory parameters from the *Parameters* window in PneuView to be displayed and recorded in the table.
6. Select any waveforms to be displayed while testing.
7. Verify that the *compliance* and *resistance* values entered in the *Reference Conditions* window correspond with the 5601i setting.
8. When respiratory values appear on the screen, save them with the *Tabulate* function. (This will be Test 1.)
9. Run Tests 2 through 5 of the protocol, adjusting the 5601i, ventilator, and reference conditions between each test. Use the *Tabulate* function for each set of parameter values.
10. Save this format as a template for future testing.
11. Save the tabulated file and print a report of the table and notes comparing the ventilator settings to the measured values.

Example B. 24 hour trend test to evaluate an unexplained change in tidal volume after two hours of ventilator use. **NOTE:** A trend test can be set up to run for up to 72 hours.

Procedure:

1. Adjust the *compliance* and *resistance* on the 5601i to roughly simulate the patient on which the ventilator had been operating.
2. Attach the breathing circuit of the ventilator in question to the airway of the 5601i, and set the ventilator to operate as it was on the patient.
3. With PneuView running, enter the *Ventilator Performance Trending* mode.
4. Enter the correct reference conditions in the PneuView software.
5. Select the *Parameter Data Trends* (including tidal volume) to be displayed.
6. In the *Notes* window, enter a description of the problem you are assessing.
7. Enter the test setup: *Length of Test—24 hours; Interval Time—15 minutes.*
8. Enter *Begin Test* and let the ventilator run 24 hours, without interruption.
9. View the trended data, add notes, save the results, or print a report.

Pediatric/Infant Testing Application

Example C: The following is a routine test protocol to create a table for documentation of test results of an Infant Critical Care Ventilator:

Test Protocol:

	Test 1	Test 2	Test 3	Test 4	Test 5
Rate (bpm)	20	40	60	80	100
Vt (mL)	40	30	25	20	15
Flow (Lpm)	25	20	25	15	15
PEEP (cmH ₂ O)	10	5	0	5	0
Compliance (L/cmH ₂ O)	.005	.003	.003	.001	.001
Resistance (cmH ₂ O/L/sec)	50	50	200	200	200

Procedure:

1. Set the TTL for ventilation of the infant lung. Adjust the compliance and resistance as called for in Test 1 in the above protocol.
2. Attach the patient connection of the ventilator's breathing circuit to the proximal airway of the TTL.
3. Set the ventilator as described in Test 1 of the protocol.
4. With the PneuView software running in the Infant mode, enter the above protocol in the notes window.
5. Select the measured parameters from parameters window in PneuView to be displayed and recorded in the table.
6. Select any waveforms to be displayed while testing.
7. Verify that the compliance and resistance values entered in the *Reference Conditions* window corresponds with the 5601i setting.
8. Open a *Data Table* from the menu bar by using the "T" button.
9. When measured parameter functions appear on the screen, save them with the tabulate function. (This will be sample 1.)
10. Run tests 2 through 5 of the protocol, adjusting the TTL, ventilator, and reference conditions between each test. Use the tabulate function for each set of parameter values.
11. Save this format as a template for future testing.
12. Save the tabulated file and print a report of the table and notes comparing the ventilator settings to the measured values.

Classroom Instruction/Demonstration

The 5601i Adult/Infant PneuView System is a dynamic lung model, which can be of great assistance in the classroom. The adjustable lung compliance and resistance allows the instructor or student to demonstrate or investigate a wide variety of ventilation phenomena. The relationships between pressure, volume, and flow are more easily understood when dynamically displayed with the TTL,

and the *PneuView* software provides yet another mechanism to demonstrate and evaluate the patient (TTL).

Example D. The distribution of delivered tidal volume with worsening unilateral lung disease (e.g. pneumonia).

Procedure:

1. Set the lung compliance of the TTL to .05 L/cmH₂O.
2. Select an Rp5 resistor.
3. With the *PneuView* running, enter the correct compliance and resistance values in the *Reference Conditions Window*.
4. Display *Tidal Volume* in the Respiratory Parameters window and Waveform Display window.
5. Enter a description of the demonstration in the *Notes* window.
6. Using a ventilator or resuscitation bag, ventilate the TTL at a rate of 12 breaths per minute and tidal volume of approximately .800 liters.
7. Note the tidal volume measured.
8. Change the compliance of the lung to .03, then .02, and finally .01, and note the lung volumes with each change.
9. Save this demonstration as a template for future demonstrations.

Example D. AutoPEEP caused by increased upper airway resistance (e.g. use of small endotracheal tube).

Procedure:

1. Select an Rp20 resistor.
2. Set the lung compliance at .08 L/cmH₂O.
3. With *PneuView* running, enter the correct conditions in the *Reference Conditions* window.
4. Display proximal airway pressure and lung pressure in the *Waveform Display* window.
5. Enter a description of the demonstration in the *Notes* window.
6. Ventilate the TTL at a rate of 26 BPM and a tidal volume of 1.0 Liters, with a baseline (PEEP) of zero.
7. Note the inadvertent PEEP in both proximal airway and lung pressures caused by the increased airway resistance. Also, note the difference in the baseline pressure of the proximal airway and lung.
8. Save this as a template for future demonstrations.

5. Maintenance and Service

The 5601i Adult/Infant PneuView System is designed to provide years of trouble-free service. Every unit is calibrated and thoroughly checked before leaving the factory. All parts and accessories of the unit are designed for consistent, repeatable, long-term performance.

Other than replacement of accessories, the 5601i is **NOT** intended to be serviced by the customer. If problems develop which cannot be easily corrected by using this manual, please contact Michigan Instruments' Service Department at **1-800-530-9939**. Michigan Instruments also recommends that the unit be returned to the factory every 2 years for complete recalibration and any necessary repairs.

Calibration Check

The accuracy of all measurements and calculations made by PneuView is dependent upon the proper mechanical and electrical calibration of the system. This calibration can be checked using the following equipment and procedures:

Equipment Needed:

- PneuView 5601i Software (Test Lung operating with PneuView Software)
- Calibrated 1-liter syringe (or other calibrated volume injector)
- Independent, reliable pressure gauge or manometer (+/- 1% or .1 cmH₂O)

The following procedure can be used to quickly check the calibration of your 5601i system. It is not a calibration procedure and does not guarantee the accuracy of the system, but it will indicate if a more thorough recalibration is necessary.

Procedure—Adult Lung

1. Enter the *Calibration* mode of PneuView. Displayed pressures for the airway and lung should read zero (0.0).
2. Set the adult lung compliance at .10 L/cmH₂O.
3. Draw 1.0 liter of air into the insertion syringe, then connect it to the airway of the test lung.
4. Insert the 1.0 liter of air into the adult test lung using a smooth steady motion.

NOTE: It is very important that the syringe is empty after injecting air into the test lung. If the syringe is not completely emptied, the remaining air in the syringe will affect the volume and pressure readings in the lung.

5. Wait 2 seconds after the insertion to allow pressure to stabilize in the system, then record the pressure generated in the lung. Verify that it falls within the acceptable tolerance as shown in *Table 1*, below.

- Repeat these insertions into the lung using the compliance settings shown in *Table 1* and verify the pressure generated in the lung falls within acceptable limits.

<u>Compliance Setting</u>	<u>Pressure Limits</u>
.10	9.7 to 10.3
.01	97.0 to 103.0

Table 1—Adult Lung Calibration Values

If the displayed pressures do not fall within the acceptable range for either of the given compliance settings, repeat the insertion to verify that there has been no error in the technique. If the values are still not within the specified ranges, a mechanical adjustment and recalibration of the test lung may be required. Contact Michigan Instruments for details.

Procedure—Infant Lung

- Enter the *Calibration* mode of PneuView. Displayed pressures for the airway and lung should read 0.0.
- Set the infant lung compliance at .001 L/cmH₂O.
- Draw 0.1 liters (100 mL) into the insertion syringe, then connect it to the airway of the test lung.
- Insert the 0.1 liters of air into the infant test lung using a smooth steady motion.

NOTE: It is very important that the syringe is empty after injecting air into the test lung. If the syringe is not completely emptied, the remaining air in the syringe will affect the volume and pressure readings in the lung.

- Wait 2 seconds after the insertion to allow pressure to stabilize in the system, then record the pressure generated in the lung. Verify that it falls within the acceptable tolerance as shown in *Table 2*, below.
- Make 0.1 liter insertions into the infant lung using the compliance settings in *Table 2* and verify that the pressure generated in the lung fall within the acceptable limits.

<u>Compliance Setting</u>	<u>Pressure Limits</u>
.001	97.0 to 103.0
.010	9.7 to 10.3

Table 2—Infant Lung Calibration Values

If the displayed pressures do not fall within the acceptable limits for any given compliance setting, repeat the insertion to verify that there has been no error in the technique. If values are still not within the specified range, a mechanical adjustment and recalibration of the test lung may be required. Contact Michigan Instruments for details.

Model 5601i Leak Test

If you suspect an air leak in the test lung, use the following procedure to locate the source of the leak.

1. Set the compliance spring on the adult lung at .02.
2. Enter the *Calibration* mode of the *PneuView* program.
3. Inject 1.0 liter of air into the lung through the airway and read the lung pressure.
4. Hold the volume in the lung for 30 seconds, and again read the lung pressure. The pressure should not drop more than 1.0 cmH₂O in 30 seconds.
5. Repeat the test using the infant lung with a compliance of .002 and an injected volume of .100 liter.

If an unacceptable leak exists in your system, and you are unable to locate the source, please contact Michigan Instruments' Service Department.

Warranty Agreement

Your Model 5601i Adult/Infant *PneuView* System is warranted by Michigan Instruments, Inc. Grand Rapids, Michigan, to be free of defects in material and workmanship for a period of **two (2) years** from the date of its receipt by the end purchaser, excluding the diaphragm gauge contained therein.

All repairs necessitated by malfunction of this equipment during the warranty period, when in normal use in accordance with instructions provided, will be accomplished at the Michigan Instruments, Inc. factory, without charge other than the cost of transportation to the factory. Michigan Instruments, Inc. undertakes **NO LIABILITY HEREUNDER FOR SPECIAL OR CONSEQUENTIAL**

DAMAGES, or any other expense or liability beyond the furnishing of materials and labor for the repairs covered hereby. The warranty does not cover marks and blemishes, scratches or denting which may result from normal use of this equipment, or malfunctions due to mishandling or damaging accidents.

This warranty is VOID unless the equipment to be repaired is returned in the original protective factory carton. If unavailable, the protective carton may be obtained from Michigan Instruments, Inc.

If the attached warranty registration card is not returned, the warranty period will begin the date the instrument was shipped from the factory.

This warranty is in lieu of all other warranties express or implied, and shall be void as to any products which have been repaired or altered by others, or have been subject to misuse or abuse. The buyer agrees that this written warranty constitutes the entire agreement as to warranties between the parties. Any prior or contemporaneous oral statements which have not been written into this agreement are not binding and this contract shall not be rescinded or modified except by a signed agreement.

Factory Service Policy

The Model 5601i Adult/Infant PneuView® System is covered by a limited, two year warranty. Return the postage paid registration card promptly to ensure proper registration of your unit and help expedite repairs if they should ever be necessary.

The Model 5601i is manufactured to very demanding quality standards. It is designed to provide years of trouble free service if proper care is taken in its operation. This instrument should be used and maintained as outlined in this user's manual. To maintain peak performance, factory service and recalibration is recommended every two years.

Requesting Factory Service for Your Model 5601i

If you feel that factory service may be required, call the Michigan Instruments' Service Department at 800-530-9939 Monday through Friday between the hours of 9:00 a.m. and 5:00 p.m. EST. Please have available the model number, serial number, and a description of the problem. Requests for repair parts or any service related questions should also be directed to the Service Department.

If your Model 5601i must be returned to Michigan Instruments, please observe the following procedures:

- A. Use the original carton and packing material. It will provide maximum protection during shipping. If you do not have the original shipping carton, they may be purchased from Michigan Instruments.

NOTE: DO NOT USE THE 5601i CASE AS A SHIPPING CONTAINER. It is not designed to withstand the rigorous handling that may occur during shipping.

- B. Include with the unit:
 1. A description of the problem(s).
 2. The name and phone number of a contact person.
 3. A packing slip listing all of the components being returned.

4. Ship via United Parcel Service prepaid and insured.

Ship to: **Michigan Instruments, Inc.**
4717 Talon Ct. S.E.
Grand Rapids, MI 49512
ATTN: Service Department

- C. Upon receipt, the unit will be evaluated and a repair estimate prepared for approval. Michigan Instruments will contact you with the estimate and wait for approval and purchase order before repairs are started. Repairs will be completed within two weeks from the date of approval.
- D. All units returned to Michigan Instruments must be evaluated and require a \$50.00 evaluation fee plus shipping charges. This fee will be charged if repairs are not authorized and the unit is returned unrepaired.
- E. All repairs, parts, and labor are warranted for 90 days. New parts have a one year warranty. These warranties are subject to the limitations and conditions of the original warranty, and apply only to those components actually repaired, rebuilt, or replaced.
- F. A limited number of loaner units are available. Ask for details.
- G. Terms for repair service:
 1. All repairs not covered by warranty are FOB Michigan Instruments, Grand Rapids, MI. Warranty repairs are shipped to the customer at no charge.
 2. Payment is net 30 days.
 3. Open accounts are subject to credit approval.

6. Warnings and Cautions

Warning: *Explosion Hazard:* If this equipment is used to measure flammable anesthetics or other gases, provide adequate ventilation and ensure that no leaks are present in the system that would permit the accumulation of such gases in the electronics enclosure.

Warning: *Electrical Shock Hazard:* When plugged in, 12 V is present within the enclosure of the 5601i. Attachment, removal, and servicing of the Electronic Interface Module should be performed only by Michigan Instruments, Inc.

Caution: Operate the 5601i within its specified limits. Over-inflation of the bellows or excessive pressure within the system may cause damage to the bellows, gauges, or transducers.

Caution: To prevent damage during shipping and handling, set and lock the adult compliance spring at the .01 setting and the infant compliance spring at the .002 setting.

Caution: Do not sterilize the 5601i. The internal components are not compatible with sterilization techniques.

Caution: The 5601i should be turned off and unplugged while moving the unit and between uses.

7. Storage and Shipping

The Model 5601i Adult/Infant PneuView® System is shipped to the customer in a specially designed shipping carton. This carton is used to protect the 5601i when not in use, and should be used to transport the unit. If the unit needs to be shipped via United Parcel Service or other carrier, the unit **MUST** be placed in this carton. (See *Factory Service Policy* (Page 44) for servicing instructions.)

PLEASE SAVE THE SHIPPING CARTON FOR FUTURE USE!

Replacement cartons are available for purchase from Michigan Instruments.

If a carrying case was purchased with this unit, it is not necessary to remove the 5601i from the case for shipping. However, the carrying case is not meant to be used as a shipping container. If the 5601i is shipped in the case, the carton containing the foam inserts should be used.