

MODEL 1600

Dual Adult TTL[®]

Training/Test Lung

USER'S MANUAL

Manufactured by:



**Michigan
Instruments**
INC.

4717 Talon Court SE

Grand Rapids, MI 49512 USA

Tel: (800) 530 9939 or (616) 554 9696

Fax: (616) 554 3067

e-mail: mii@michiganinstruments.com

website: www.michiganinstruments.com

TABLE OF CONTENTS

INTRODUCTION

i

1. DESCRIPTION

1-1

General

1-1

The TTL--As Compared to Human Lungs

1-2

The TTL--As Related to Ventilator Testing Standards

1-2

Specifications

1-3

Features and Components

1-3

Standard Accessories

1-8

2. SETUP AND OPERATION

2-1

Dual-Lung Setup

2-1

Single-Lung Setup

2-2

Spontaneous Breathing Simulation

2-3

3. APPLICATIONS

3-1

Equipment Testing

3-1

Classroom Instruction

3-2

Other Common Applications

3-3

4. MAINTENANCE AND SERVICE

4-1

Calibration

4-1

TTL Leak Test

4-3

Warranty Agreement

4-3

Factory Service Policy

4-4

5. CAUTIONS AND WARNINGS

5-1

6. STORAGE AND SHIPPING

6-1

INTRODUCTION

The Model 1600 TTL® Training/Test Lung is a dynamic dual adult lung simulator commonly used to evaluate and demonstrate mechanical ventilation devices and phenomena.

This user's manual is intended to fully describe the Model 1600 TTL and provide you with the information necessary to utilize and maintain this instrument. It does not contain the documentation and directions required to fully service the unit. Please contact Michigan Instruments if service or assistance is required.

For customer service, call (800) 530-9939

This equipment is protected by the following patents:

| | |
|---------------|----------------------|
| United States | 4,430,893, RE 29,317 |
| France | 7,402,762 |
| West Germany | 2,403,616 |
| Great Britain | 1,456,099 |
| Japan | 882,209 |
| USSR | 576,583 |
| Spain | 517,371 |
| Canada | 1,196,391 |

1. DESCRIPTION

General

The Model 1600, Dual Adult TTL is a unique, versatile instrument providing gross simulation of the structures mechanics of human ventilation. The 1600 incorporates two elastomer lung compartments (bellows) with a typical adult residual capacity. Gas is inserted into the lungs through a simulated airway. This insertion causes the vertical expansion of the lungs, and a corresponding rise of the top plate. Gauges on the front of the unit provide measurement of right and left intralung pressures as well as the pressure in the airway.

Compliance is accurately and independently settable for each lung using the precision, steel alloy springs which are stretched during inflation of the lungs. Airway resistance is simulated using fixed-orifice, metal flow restrictors which are interchangeable in the simulated airway. It is these features of adjustable compliance and resistance which allow the TTL to realistically simulate a wide variety of healthy and diseased pulmonary conditions. The 1600 can even be used to simulate a spontaneous breathing patient.

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.

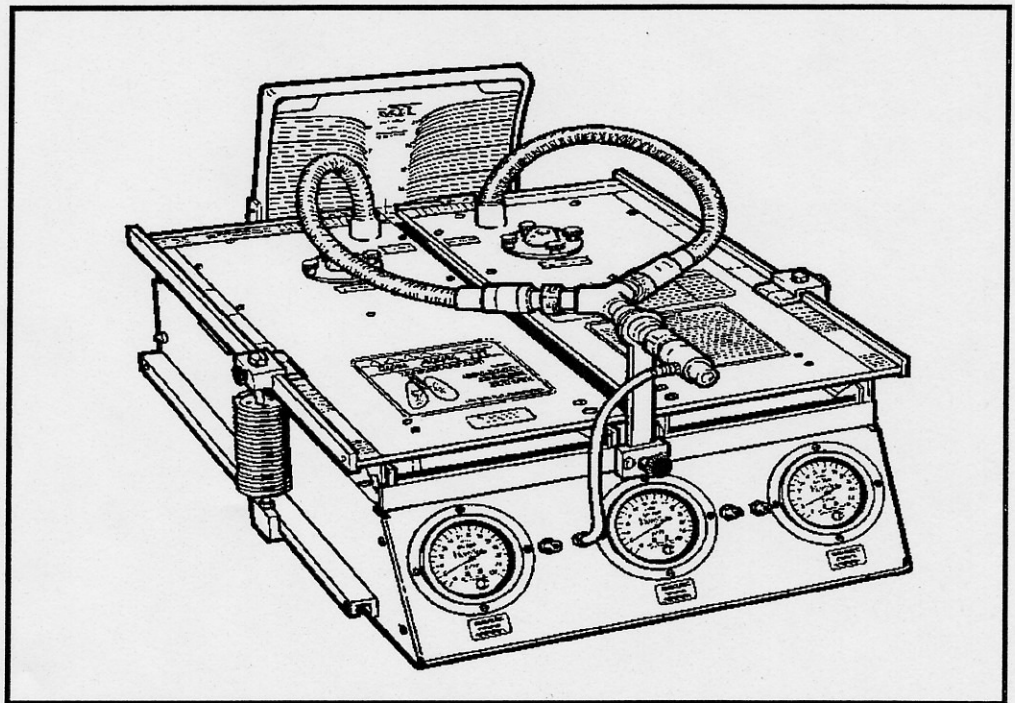


Figure 1-A
Model 1600
Dual Adult TTL

The TTL--As Compared to Human Lungs

The Model 1600 TTL is designed to realistically simulate the mechanics of the adult ventilatory system from upper airway to the lungs. Obviously, it is not a detailed model of actual human anatomy. Such a model would be extremely complex and prohibitively expensive. Still, the TTL offers simulation capabilities and versatility not seen in other devices, and is useful for a wide variety of applications. For your reference, Table 1 offers some normal values for healthy adults. It's important to remember that most ventilated patients do not possess these "normal" characteristics.

Table 1
Normal Values of
Healthy Adults

| | | |
|------------------|------------|--------------------------|
| Compliance | .05 to .15 | L/cmH ₂ O |
| Resistance | 0.5 to 5.0 | cmH ₂ O/L/sec |
| Respiratory Rate | 10 to 20 | bpm |
| Tidal Volume | 3 to 5 | mL/kg of body weight |
| I:E Ratio | 1:2 | |

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.

Table 2
Common Pulmonary
Diseases and Their Effects
on Lung Dynamics

| | 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 |

The TTL may be set up to simulate healthy lungs, obstructive lung disease, restrictive lung disease, or disorders exhibiting both obstructive and restrictive characteristics.

The TTL--As Related to Ventilator Testing Standards

To evaluate the performance of any mechanical ventilating device a quantitative test lung system 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 International Organization for Standardization (ISO), and the American Society for Testing and Materials (ASTM) outline minimum performance standards for mechanical ventilators. The TTL meets or exceeds the standards set for testing adult mechanical ventilators.

Specifications

| | |
|------------------------|--|
| Tidal Volume Capacity: | 2.0 liters-each lung 4.0 liters-total |
| Residual lung volume: | .92 liters-each lung 1.84 liters-total |
| Lung compliance: | Adjustable: .01 to .15 L/cmH ₂ O-each lung Accuracy: $\pm 3\%$ (at calibration volumes) |
| Airway resistance: | Adjustable, 5, 20, or 50 cmH ₂ O/L/sec Accuracy: $\pm 5\%$ (at calibration flows) |
| Pressure Measurements: | Airway: -10 to 120 cm H ₂ O Right Lung: -10 to 120 cm H ₂ O Left Lung: -10 to 120 cm H ₂ O Accuracy: $\pm 2\%$ |
| Size: | 20"x 25"x 8" |
| Weight: | 37 lbs. (16.8 kg) |

Features and Components

Frame (Figure 1-B)

The frame of the 1600 is the aluminum "box" around which the TTL is built. The frame is referred to in some of the following descriptions.

The Lungs (Bellows) (Figure 1-B)

Human lungs are simulated using two elastomer bellows. These bellows are constrained by aluminum rings to ensure that filling of each "lung" results in a vertical rise of the top plate. Each bellows, at rest, retains a gas volume typical of an adult's functional residual capacity for a single lung. The bellows are secured to the top plates and frame of the 1600, and designed to withstand normal environmental conditions and inflation to at least 150 mmHg pressure.

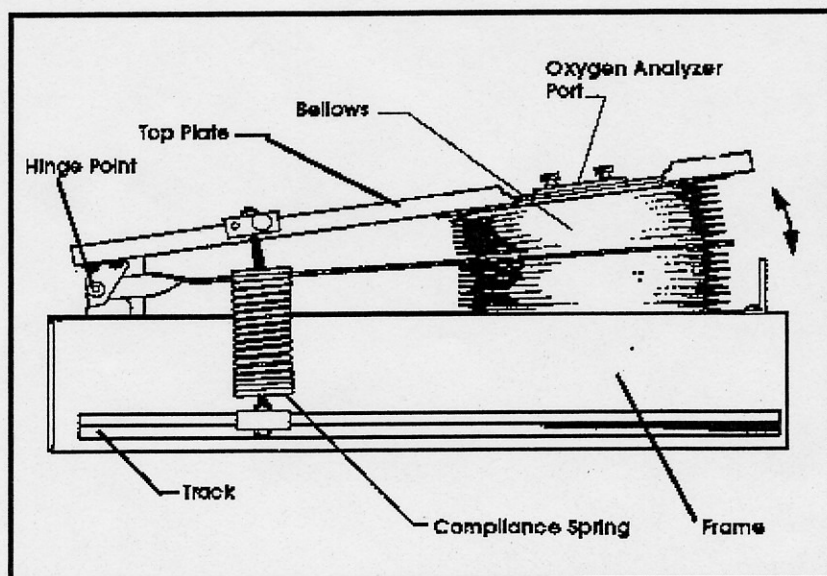


Figure 1-B
TTL Side View

Compliance Settings (Figure 1-B)

Thoracic and lung compliance are simulated through a precision steel alloy spring stretched between the top plate of each lung and the track on each side of the TTL frame. Compliance for each lung is adjusted by positioning the spring at various points along the top plate. The further the spring is positioned from the hinge point of the top plate, the less compliant, or stiffer, the lung.

The Airway (Figure 1-C)

The airway is constructed using the hose assemblies, various connectors, and PneuFlo® Airway Resistors included in your accessory kit. Tapered fittings on all of these accessories prevent gas leaks during use. The airway may be constructed for one or two-lung use. (See Section 2) The rest assembly is used to support and stabilize the airway, minimizing the effect of the weight of the airway in determining lung compliance.

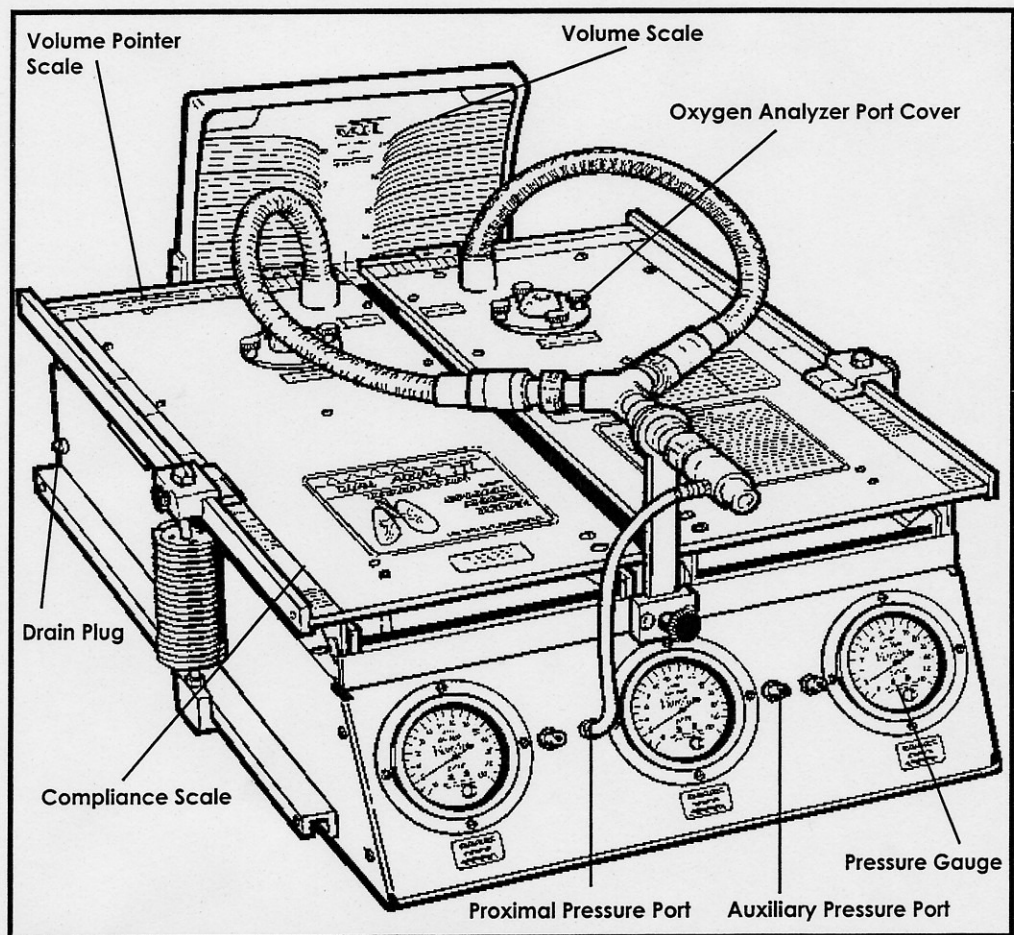


Figure 1-C
TTL Top View

PneuFlo® Airway Resistors

The resistors supplied with the TTL are used in constructing the airway to create the desired levels of airway resistance. Each resistor consists of a thin stainless steel disk held in a metal housing. An accurately machined orifice in each disk determines its resistance value. These resistors are each carefully calibrated to ensure that they perform within specified limits. Typically, one upper and two lower airway resistors are used when ventilating both lungs,

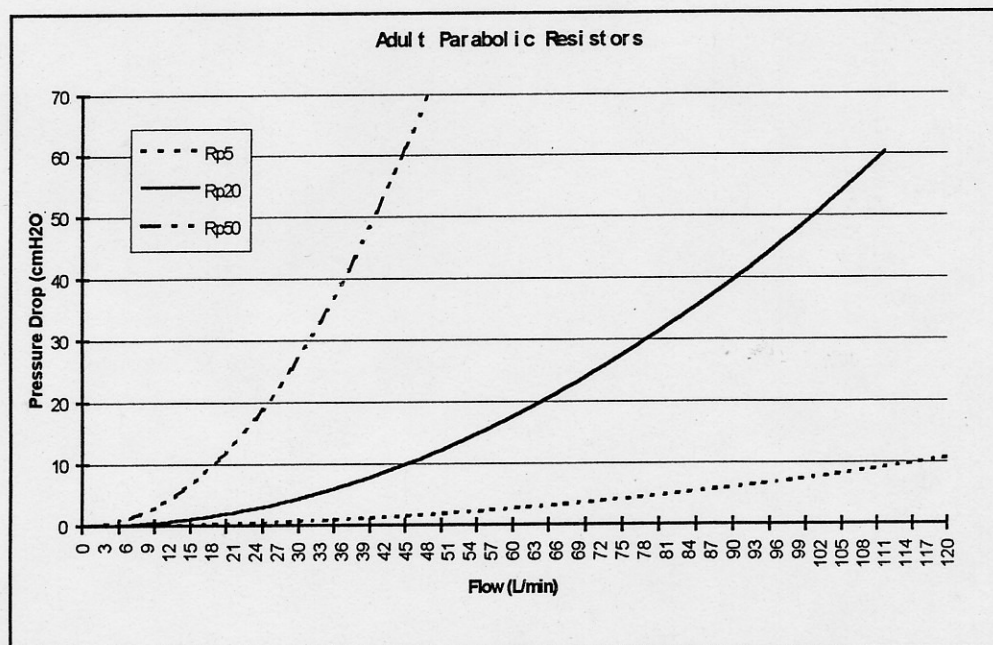
(Figure 2-A) and a single resistor is used when working with a single lung (Figure 2-B).

The Pneuflo Resistors exhibit parabolic characteristics, in regards to pressure change as a function of flow. This non-linear, parabolic characteristic is similar to that seen in standard endotracheal tubes. The specific pressure-flow relationships of the Rp5, Rp20, and Rp50 resistors are shown in Table 3 and Figure 1-D.

Table 3
Pressure Drop at
Calibration Flow Rates

| Parabolic Resistor | Pressure drop (cmH ₂ O \pm 5%) At Calibration Flow Rates | | | | | | | | Corresponding Linear Resistor |
|--------------------|--|-----|-----|------|------|------|-------|--|----------------------------------|
| Rp50 | — | — | — | 6.8 | 27.2 | — | — | | R50 |
| Rp20 | — | — | — | — | 4.4 | 17.6 | — | | R20 |
| Rp5 | — | — | — | — | — | 2.7 | 10.8 | | R5 |
| | 3.0 | 4.5 | 6.0 | 15.0 | 30.0 | 60.0 | 120.0 | | |
| | Flow Rate (L _(NTPD) /Min \pm 1%) | | | | | | | | |

Figure 1-D
Pressure Drop vs. Flow



NOTE Most experts believe that the bronchi and bronchioles exhibit pressure-flow characteristics which are nearly linear. Linear resistors are not provided with the 1600 because of their fragile nature and prohibitive manufacturing cost.

Compliance Scale (Figure 1-C)

The compliance scale may be used to set a particular compliance value for each lung. This is done by positioning the compliance pointer of the compliance spring directly over one of the calibrated markings on the scale. Each lung is individually calibrated during assembly to ensure the accuracy of this scale.

NOTE || When ventilating both lungs, the total lung compliance is equal to the sum of the individual lung compliances.

Volume Scale (Figure 1-C)

The volume scale is used to measure the volume within each lung. The scale is marked in 100 mL increments with a range of 0-2 liters in each lung. Filling of the bellows causes the top plate to rise against the volume scale.

NOTE || During positive pressure inflation, the gas within the TTL lungs is compressed and the bellows will experience a degree of radial expansion. The volume scale reflects this non-linear relationship between volume and rise of the top plate.

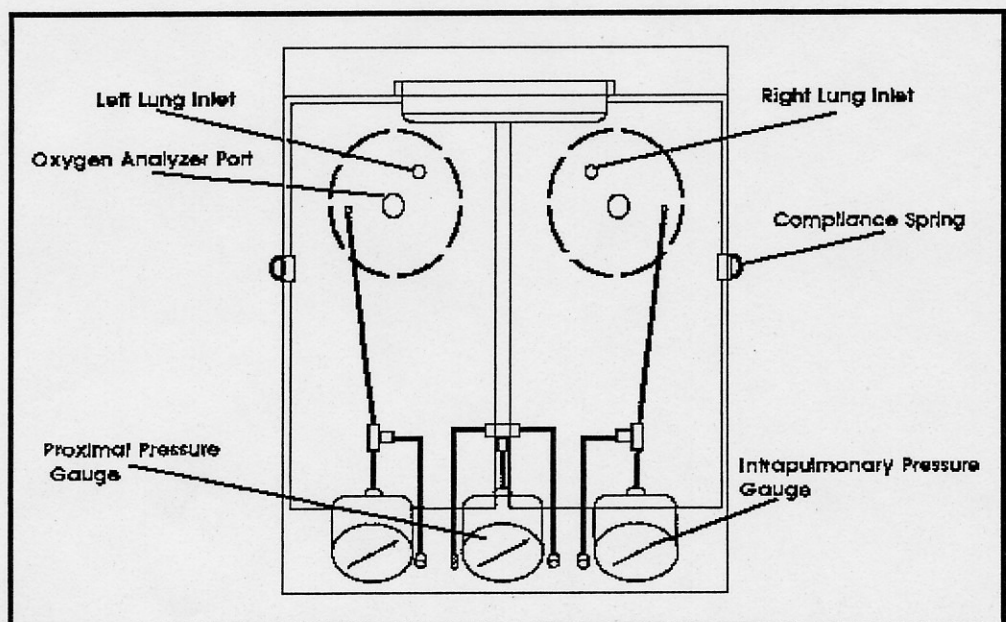
Volume Pointer Scale (Figure 1-C)

To correctly read the volume scale, the volume pointer must be positioned to correspond with the actual compliance setting for each lung. The volume pointer scale is located at the base of the volume scale.

Oxygen Analyzer Ports (Figure 1-E)

Oxygen concentration can be monitored in each lung through the oxygen analyzer ports. Special adaptors, designed to accept common oxygen sensors, are an optional accessory. When not in use, the oxygen ports are covered and sealed with the oxygen analyzer port covers.

Figure 1-E
Schematic of
Model 1600 TTL



Pressure Gauges (Figure 1-E)

Three pressure gauges are found on the front of the 1600. The right and left gauges are internally plumbed to the right and left lungs (Figure 1-E). 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.

Auxiliary Pressure Port (Figure 1-C)

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. Such connectors are included in the accessory kit.

Counterbalance Springs

Within the frame and beneath each lung is a counterbalance spring. This spring minimizes the effect of the weight of the top plate during filling and emptying of the lung. The tension on this spring is factory-set during the calibration procedure, and is not intended to be adjusted in the field.

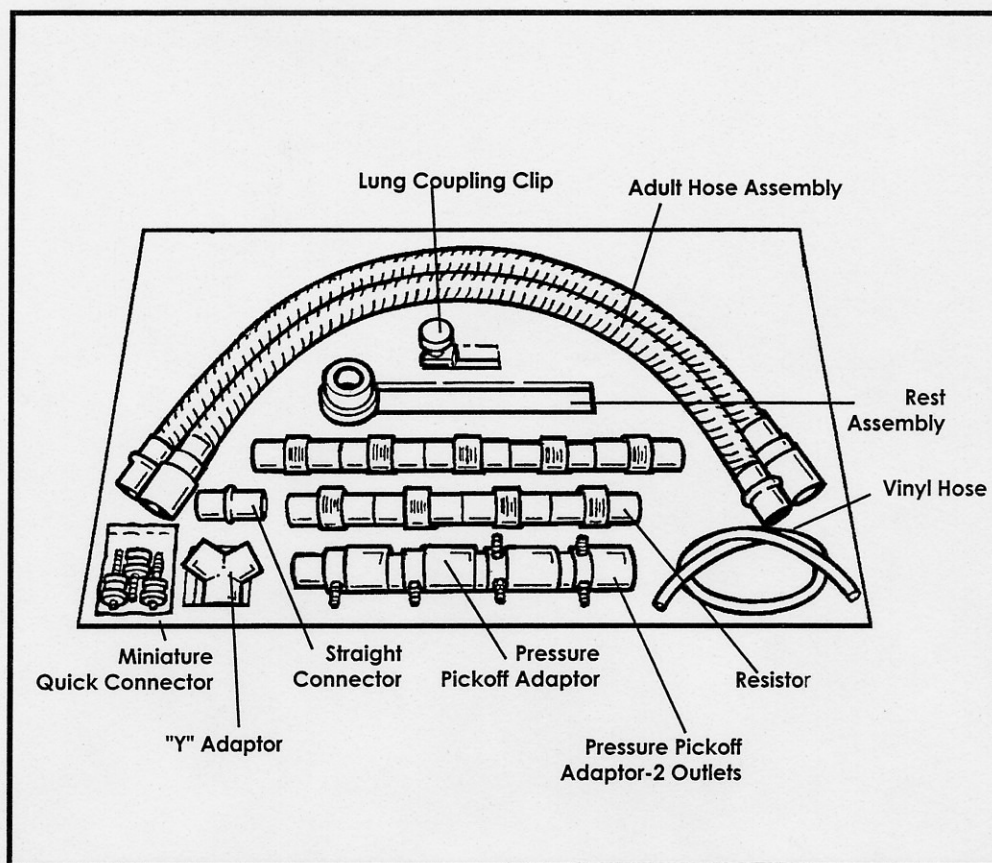
Pressure Pickoff Adaptors

Four pressure pickoff adaptors are included in your accessory kit. They may be strategically placed in the airway to monitor pressures during ventilation of the TTL. A single outlet pressure pickoff adaptor is usually used to monitor proximal airway pressure. This setup is shown in Figure 1-C, 2-A, and 2-B.

Lung Coupling Clip

This clip is utilized when one lung is being used to drive the second for spontaneous breathing simulation. The clip mounts on one lung which is used to "lift" the other lung's top plate. This set up is shown in Section 2, Figure 2-C.

Figure 1-F
Accessories



Standard Accessories

| Accessory | Quantity | Part Number |
|------------------------------------|----------|-------------|
| Rest Assembly | 1 | 12907 |
| Pneuflo® Resistor-Rp5 | 3 | 13394-05 |
| Pneuflo® Resistor-Rp20 | 3 | 13394-04 |
| Pneuflo® Resistor-Rp50 | 3 | 13394-03 |
| Adult Hose Assembly | 2 | 12904-03 |
| "Y" Adaptor | 1 | 11173 |
| Pressure Pickoff Adaptor-1 outlet | 2 | 13197-01 |
| Pressure Pickoff Adaptor-2 outlets | 2 | 13197-02 |
| Straight connector (15 mm) | 1 | 12905-02 |
| 1/8" I.D. x 22" vinyl hose | 1 | 10068-16 |
| Miniature Quick Connector | 3 | 11254-02 |
| Lung Coupling Clip | 1 | 12423 |

Optional Accessories

| Accessory | | Quantity | Part Number |
|-----------------------|-------|----------|-------------|
| Oxygen Sensor Adaptor | Small | 1 | 11808 |
| Oxygen Sensor Adaptor | Large | 1 | 11695 |

2. SETUP AND OPERATION

To Start:

1. Set the TTL on a level work surface.
2. Raise the volume scale plate to its upright and locked position.
3. Open the TTL accessory box. All parts needed to construct the airway are located in this box.

Dual-Lung Setup (Figure 2-A)

1. Loosen the rest knob on the front of the TTL and insert the rest assembly (❶) into the holder. Lock it in place by retightening the knob.
2. Select one Pneuflo resistor to simulate upper airway resistance and two resistors to simulate lower airway resistance.
3. Connect the upper airway resistor (❷) to the proximal (outward-facing) opening on the rest assembly.
4. Connect the 15mm straight connector (❸) to the distal (lung) side of the rest assembly.
5. Attach the Y-adaptor (❹) to the distal end of the straight connector.
6. Insert the lower airway resistors (❺) into the Y-adaptor.
7. Connect one end of the hose assemblies (❻) to the lower airway resistors and the other end to the lung inlet ports in the top plates.
8. Attach a single-outlet pressure pickoff adaptor (❼) to the proximal end of the upper airway resistor, and connect this adaptor to the proximal pressure input port (❽) using the 1/8" hosing (❾) included with the accessories.

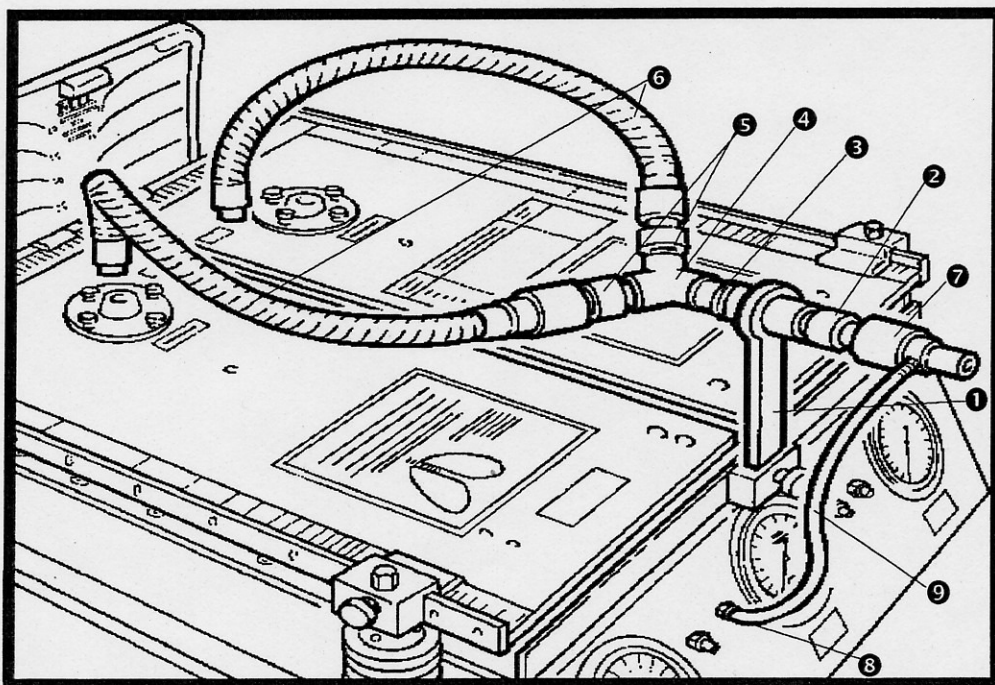


Figure 2-A
Dual Lung Setup

Single-Lung Setup (Figure 2-B)

1. Loosen the rest knob on the front of the TTL and insert the rest assembly (❶) into the holder. Lock it in place by retightening the knob.
2. Select one Pneuflo resistor (❷) to simulate total airway resistance and connect it to the proximal (outward-facing) opening on the rest assembly.
3. Connect the 15mm straight connector (❸) to the distal (lung) side of the rest assembly.
4. Connect one end of a hose assembly (❹) into the straight connector and the other end into the lung inlet port in the top plate of one lung.
5. Attach a single-outlet pressure pickoff adaptor (❺) to the proximal end of the resistor, and connect this adaptor to the proximal pressure input port (❻) using the 1/8" hosing (❼) included with the accessories.

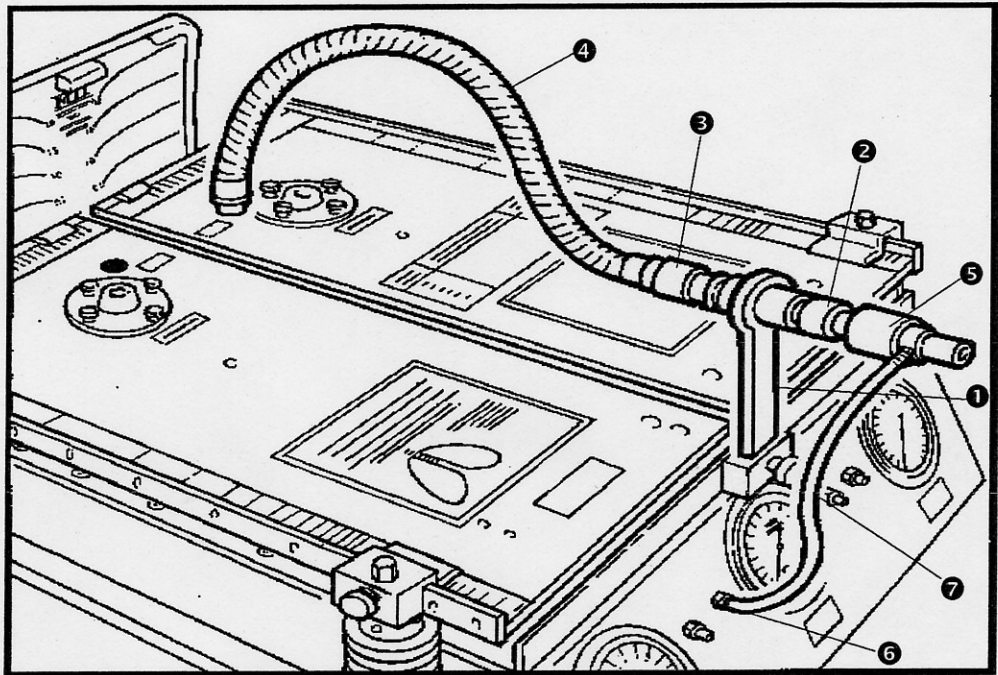


Figure 2-B
Single-Lung Setup

To Set Lung Compliance:

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

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

CAUTION || Changing the compliance setting while ventilating the lung may cause damage to the TTL.

The TTL may now be ventilated by attaching an appropriate connector from the ventilating device to the airway of the TTL.

To Measure Oxygen Concentration in Either Lung:

1. Remove the oxygen port cover by removing the four knurled thumb-screws and lifting the cover off the anchor posts.
2. Select the appropriate oxygen sensor adaptor (optional) and place it over the oxygen sensor port, onto the anchor posts.
3. Secure the adaptor by replacing the four knurled thumb screws.
4. Place an appropriate oxygen sensor into the adaptor.

Care of the TTL After Ventilation With Humidified Gases

The airways and lungs of the TTL are constructed of non-corrosive materials, and typical humidification agents (e.g. sterile water, normal saline) will not damage the instrument. A drain port is provided on the back panel of the TTL to remove any accumulation of fluid from the bellows of the TTL (Figure 1-C). After ventilating the unit with a humidified gas, this port should be opened to air, and the TTL should 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.

Spontaneous Breathing Simulation (Figure 2-C)

1. Set up the TTL for single-lung ventilation (Figure 2-B). *This lung will serve as the spontaneous breathing lung.*
2. Set an appropriate compliance and resistance for the lung conditions being simulated.
3. Attach the Lung Coupling Clip to the top plate of the other lung with the lifting extension in proper position. *This lung will be the "driving chamber" which will basically serve as the musculature for the spontaneous breathing lung.*
4. Attach a hose assembly to the driving chamber.
5. Ventilate the driving chamber with the appropriate rate, volume, waveform, etc. for spontaneous breathing.

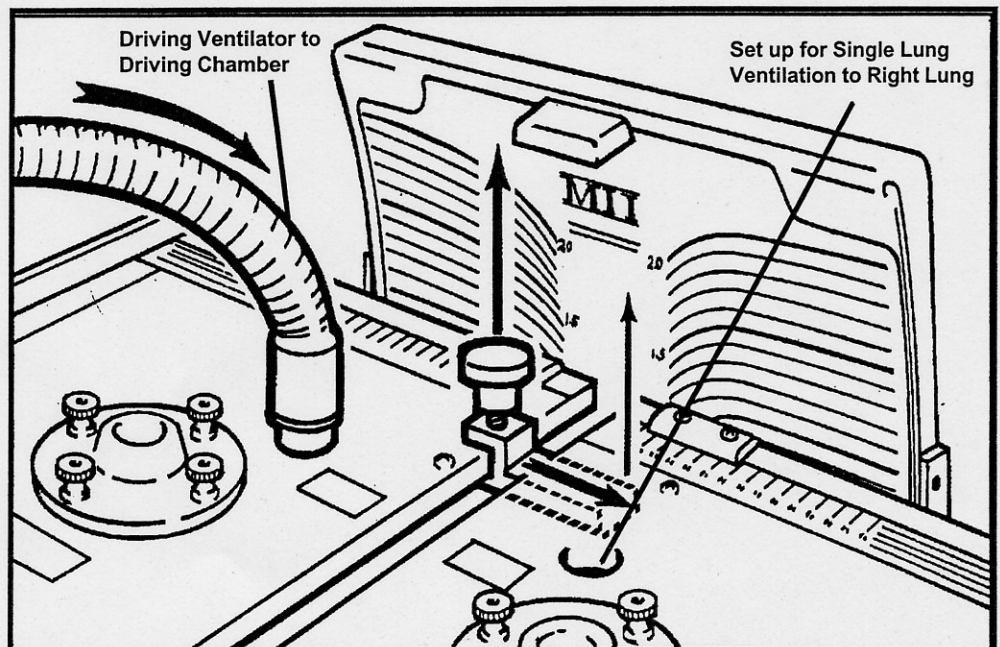


Figure 2-C
Spontaneous Breath
Simulation

NOTE || The compliance and resistance of the driving lung are typically set as to not interfere with the filling or passive exhalation of the spontaneous breathing lung.

As the driving chamber fills, the Lung Coupling Clip will lift the top plate of the spontaneous breathing lung. This will create a negative pressure in the lung during inspiration and allow passive exhalation, as seen in normal spontaneous breathing.

APPLICATIONS NOTE || The spontaneous breathing TTL setup is used in several applications including the evaluation of spontaneous breathing ventilator modes, and work of breathing studies.

3. APPLICATIONS

Thousands of users have found the TTL to be an ideal instrument for a variety of applications including:

- Performance Testing of Ventilators and Associated Instruments
- Classroom Instruction on Mechanical Ventilation Equipment, Techniques, and Phenomena
- Pulmonary Research
- Product Demonstrations and Evaluations
- Product Development and Quality Control

To offer examples of all the applications for this system would be impossible, as new ones are continually being discovered or developed by TTL users. To follow are some of the common applications for which the TTL is ideally suited.

Equipment Testing

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) states that "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 Model 1600 TTL is designed to allow performance testing of ventilators designed for use on adult human patients. For most testing, a single lung of the TTL will be sufficient to test the ventilator within its range of typical use.

Application: Routine Testing of an Adult Critical Care Ventilator

Example A. Following 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 (cmH ₂ O) | 0 | 10 | 20 | 10 | 5 |
| FIO ₂ | .21 | .40 | .60 | .80 | .100 |
| Compliance (L/cmH ₂ O) | .05 | .05 | .02 | .02 | .01 |
| Resistance (cmH ₂ O/L/sec) | 5 | 20 | 20 | 20 | 50 |

Procedure:

1. Set up the TTL for single lung ventilation. 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 above protocol.
4. Verify that the compliance and resistance values on the TTL correspond with the test protocol.
5. Record the observed pressure, volume, FIO_2 , timing and flow measurements.

NOTE || The Model 1600 TTL is not equipped for direct flow and timing measurements.

6. Run Tests 2 thru 5 of the protocol, adjusting the TTL, and ventilator.
7. Record the results of each test, comparing the ventilator settings to the measured values.

Classroom Instruction

The Model 1600 TTL can be of great assistance in the classroom. The adjustable lung compliance and airway resistance allows the instructor or student to demonstrate or investigate a wide variety of ventilation phenomena. The unique two lung design further enhances the realistic simulation provided by the unit. The relationships between pressure, volume, and flow are more easily understood when dynamically displayed with the TTL.

Application: Demonstration of Ventilation Phenomena

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

Procedure:

1. Set up the TTL for dual lung ventilation.
2. Set the compliance at .05 L/cmH₂O in both the right and left lung.
3. Assuming normal airway resistance, place Rp5 resistors in the proximal, right, and left airways..
4. Using a ventilator or resuscitation bag, ventilate the TTL at a rate of 12 bpm and tidal volume of approximately .800 liters.
5. Note the tidal volume delivered to each lung.
6. Change the compliance of the right lung to .03, then .02, and finally .01, and note the lung volumes with each change.

Application: Demonstration of Ventilation Phenomena

Example C. AutoPEEP caused by increased upper airway resistance (as seen with the use of a small endotracheal tube).

Procedure:

1. Set up the TTL for dual lung ventilation.
2. Place Rp5 resistors in the right and left lower airways, and an Rp20 resistor at the proximal airway. (Comparable to the resistance of a #6.0 endotracheal tube.)
3. Set the compliance at .04 L/cmH₂O in both the right and left lung.
4. Ventilate the TTL at a rate of 26 bpm and a tidal volume of 1.0 liters, with a baseline (PEEP) of zero.

5. Note the inadvertent PEEP in both proximal airway and right lung pressures caused by the increased airway resistance. Also note the difference in the baseline pressure of the proximal airway and right lung.

Other Common Applications

- Performing in-hospital ventilator training sessions
- Troubleshooting ventilator malfunctions
- Checking ventilator systems for leaks
- Performing routine ventilator performance testing
- Testing the fail safe features of a mechanical ventilator
- Demonstrating the changes in functional residual capacity caused by PEEP and CPAP
- Demonstrating the difference in cycling and limiting mechanisms in mechanical ventilators
- Demonstrating the difference between airway pressure and intralung pressures
- Evaluating new mechanical ventilators and ventilation monitoring equipment
- Identifying optimal ventilator settings for particular patients and conditions
- Performing work of breathing studies
- Evaluating the performance of high and low flow oxygen delivery systems
- *AND MANY MORE.*

4. MAINTENANCE, CALIBRATION, AND SERVICE

The 1600 is designed to provide years of trouble-free service. Every unit is calibrated and thoroughly checked before leaving the factory. The compliance springs operate within only a small fraction of their potential range, and exhibit no significant change in their performance characteristics after years of use. Likewise, the Pneuflo resistors and all accessories are designed for consistent, repeatable, long-term performance.

Other than calibration of the TTL, and replacement of missing parts, the unit is not intended to be serviced by the customer. If problems develop which cannot be easily corrected using this manual, please contact the Michigan Instruments' Service Department at (800) 530-9939. Michigan Instruments also recommends that the unit be returned to the factory every 3 years for complete recalibration and any necessary upgrades.

Limits of Tolerance and Accuracy

Manufacturing and cost considerations mandate the use of practical tolerances on parts and components of any product, including the TTL. Major factors affecting final accuracy are compliance spring stiffness, bellows area and stiffness, scale calibration accuracy, resistor variations in inside diameter and interior wall geometry and smoothness. In the TTL, it is believed that a practical balance has been achieved between cost and performance, and that the accuracy tolerances are quite adequate for most applications.

The repeatability of any one unit, however, is considerably better than the overall accuracy limits specified. This permits special calibration of individual units, and the development of "correction curves" for a particular unit, extending its accuracy well beyond the standard manufacturing tolerance spread. This special calibration can be accomplished by an individual user, or special factory calibration can be ordered. However, the specific differences between the individual "lungs" of the TTL may result in small but discernible "tracking" differences during dynamic motion of the lungs. This is likely to be most evident during exhalation at high compliance settings.

Calibration

The accuracy of TTL volume measurements are dependent upon the proper operation of the unit (as described in this manual) and the accuracy of the compliance settings on each lung. To check the calibration of the compliance settings, use the following equipment and procedures:

| | |
|--------------------------|--|
| Equipment Needed: | Calibrated 1-liter syringe (or other calibrated volume injector) |
| | Independent, calibrated pressure gauge |
| | Small regular screwdriver |

Calibration Check:

1. Assemble the airway for ventilation to the right lung (Section 2) using a dual outlet pressure pickoff adaptor instead of the single outlet adaptor.
2. Attach the second port of the pressure pickoff adaptor to the independent pressure gauge.
3. With the airway open to air, ensure that the right lung, airway, and pressure gauges are reading zero. If any of the gauges must be zeroed, remove the plug in the gauge crystal, and turn the adjusting screw until the needle of the gauge is set to zero (Figure 4-A).

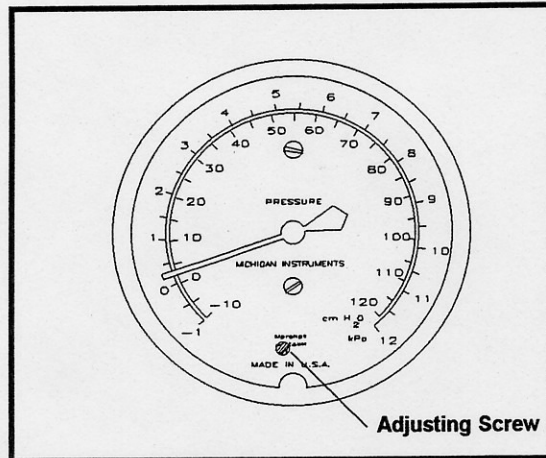


Figure 4-A
TTL Pressure Gauge

4. Using the 1-liter syringe, make injections of 1.0 liter at the compliance settings specified in Table 1 below. The intrapulmonary (intrapulmonary) and proximal pressure should be within the specified limits.

| Compliance setting | Pressure Limits |
|--------------------|-----------------|
| .15 | 6.5 to 6.9 |
| .10 | 9.7 to 10.3 |
| .05 | 19.4 to 20.6 |
| .01 | 97.0 to 103.0 |

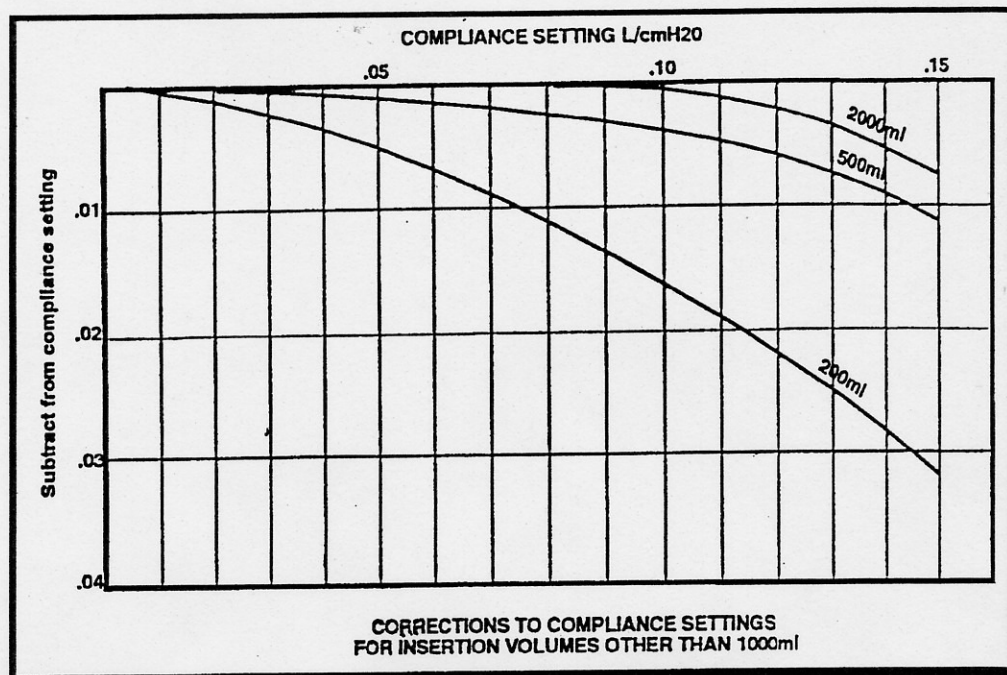
Table 1
Calibration Values

5. Repeat Step 1-4 with the airway connected to the left lung of the TTL.

If you find that your TTL is out of calibration contact Michigan Instruments for further information.

NOTE || Your TTL has been calibrated with 1.0 liter volume insertions. When using volumes other than 1.0 liters, the TTL may exhibit a compliance which differs from the set value. Corrections to the compliance setting are shown in Figure 4-B.

Figure 4-B
Corrections to
Compliance Settings



TTL Leak Test

1. Assemble the airway for ventilation of the right lung (Section 2). Make sure all connections are secure.
2. Set the compliance spring at the .02 position.
3. Inject 1.0 liter of air into the right lung through the airway and read the right lung and airway pressure.
4. Hold the volume in the lung for 30 seconds, and again, read the pressures. The pressure should not drop more than 1.0 cmH₂O in 30 seconds.
5. Repeat the test using the left lung.

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

Warranty Agreement

Your Model 1600 TTL Training/Test Lung 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 diaphragm gauges 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, or authorized service facility, without charge other than the cost of transportation to the factory or authorized service facility. 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 mars 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 factory carton and protective foam plastic form. If unavailable, the protective carton and foam plastic form may be obtained from the manufacturer.

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

Factory Service Policy

The Michigan Instruments, Inc. Model 1600 TTL, Training/Test Lung is covered by a limited two year warranty. Please refer to the warranty above for specific terms. 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 1600 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 three years.

What to do if your TTL, Training/Test Lung requires service:

- A. If you feel that factory service may be required, call Michigan Instruments' Service Department at (800) 530-9939 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.
- B. If your TTL must be returned to Michigan Instruments, please observe the following procedures: (Refer to section 6. STORAGE AND SHIPPING)
 - 1. Use the original carton and packing material. It will provide maximum protection during shipping. (Shipping cartons may be purchased from Michigan Instruments.)

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

2. Include with the unit:
 - a. A description of the problem(s).
 - b. The name and phone number of a contact person.
 - c. A packing slip listing all of the components being returned.
3. Ship via United Parcel Service, prepaid & insured to:

Michigan Instruments, Inc.
4717 Talon Court SE
Grand Rapids, MI 49512
Attn: Service Department

UPS Call tag service is available. Charges will be added to the repair invoice.

- 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 written approval and/or a 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 unrepared.
- 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.

5. CAUTIONS AND WARNINGS

- CAUTION** || Operate the Model 1600 TTL within its specified limits. Over-inflation of the bellows or excessive pressure within the system may cause damage to the bellows, or gauges.
- CAUTION** || To prevent damage during shipping and handling, set and lock the compliance springs at the .01 settings on the compliance scale.
- CAUTION** || Do not sterilize the TTL. The internal components are not compatible with sterilization techniques.

6. STORAGE AND SHIPPING

An optional Carrying/Storage Case which offers optimal protection to the 1600 TTL Training/Test Lung is available. This case may be used for storing the instrument when not in use or when transporting the instrument. The case is not intended as a shipping container. Additional protection is recommended when shipping the unit. Replacement cartons are available from Michigan Instruments.

(See Factory Service Policy for servicing instructions.)

To secure the 1600 TTL to a Carrying/Storage Case:

1. Disassemble the airway and return all accessories to the accessory box.
2. Remove the Lung Coupling Clip, if attached, and lower the volume scale.
3. Position and secure the compliance springs at the .01 compliance settings. (If shipping, wrap protective plastic around each spring.)
4. Set the TTL into the bottom portion of the case. Visually center the TTL.
5. Secure the TTL to the case using the six screws and washers provided. Place the screws/washers through the holes in the case bottom.
6. Locate alignment arrows near case latches and place case top over TTL.
7. Ensure that case top and bottom align snugly. Secure latches.

CAUTION || Damage to the TTL can occur during shipping if the unit is improperly packaged. Complete the following proper packaging procedures prior to shipping your TTL.

To ship the unit with the Carrying/Storage Case:

1. Secure the TTL in the case as described above.
2. Open original shipping container and remove top foam nest.
3. Place unit on bottom foam nest making sure it is seated and level.
4. Place top foam nest on unit ensuring insert is flush with carton top.
5. Apply packaging tape to top, bottom, and both top side seams.

To ship the unit without the Carrying/Storage Case:

1. Place TTL in a plastic bag prior to packaging.
2. Place protective plastic sheets over bottom foam insert in shipping carton.
3. Place TTL over plastic and drape additional plastic sheets over top of TTL.
4. If available, place original accessory box shipping carton behind TTL to prevent shifting, otherwise, use packaging to fill in gap behind TTL..
5. Place top foam insert on TTL ensuring insert is flush with carton top.
6. Apply packaging tape to top, bottom, and both top side seams.

NOTICE || When shipping the TTL without using the original shipping carton,

1. If shipping the TTL in its case, ensure it is secured as described above.
2. If shipping just the TTL, place it in a plastic bag prior to packaging.
3. Allow a minimum 2" clearance on all sides for packaging material.
4. Place 2" of packing in a sturdy corrugated carton (200 lb burst rated).
5. Center TTL on packing and fill in sides and top with packing material.
6. Apply packaging tape to top, bottom, and both top side seams.