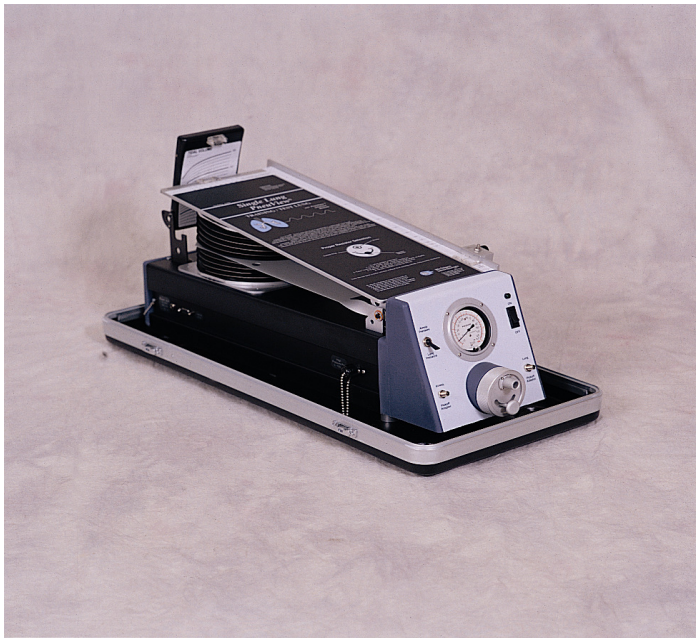
MODEL 4600
Single Lung TTL®
Training/Test Lung
Operations Manual



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INTRODUCTION

The Model 4600 TTL® Training/Test Lung is a dynamic adult lung simulator commonly used to evaluate and demonstrate mechanical ventilation devices and phenomena.

ORGANIZATION OF THIS MANUAL

This manual has been designed for use as a reference manual. It is intended to describe the setup, opertion, and application of the Model 4600 TTL. 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 4600, Single Lung TTL provides an accurate simulation of the structures and mechanics of the adult human pulmonary system. An elastomer bellows with a residual capacity typical of an adult is used to simulate the lung.

Gas is inserted into the lung through a simulated airway. This insertion causes the vertical expansion of the lung, and a corresponding rise of the top plate. A tidal volume scale behind the top plate and a pressure gauge on the front of the unit can be used to verify measurements from a ventilation device.

The lung compliance is accurately set and adjusted using a precision steel alloy spring. Airway resistance is simulated using a "turret" with adjustable settings. These features allow the TTL to realistically simulate a wide variety of healthy or diseased lung conditions.

Special features add to the versatility of the TTL. An oxygen sensor port on the back of the unit and auxiliary pressure ports adjacent to the pressure gauge provide sites for the tie-in of related monitoring equipment.

The 4600 is completely portable and is mounted in a durable ABS plastic carrying case. The top of the case is removed for use and should be replaced during transport. Rubber feet on the bottom of the case provide stability and protection for the unit during use and transport.

The TTL—As Compared to Typical Patients

The Model 4600 TTL is designed to realistically simulate the mechanics of the adult pulmonary system from the upper airway to the lung. 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 allow for simulation of both healthy and diseased pulmonary conditions. *Table 1 on Page 2* offers some typical values for healthy adults. However, most ventilated patients do not possess these "normal" characteristics.

Compliance	.05 to .15	L/cmH_2O
Resistance	0.5 to 5.0	cmH_2O/L/sec
Respiratory Rate	10 to 20	Breaths per Minute
Tidal Volume	3 to 5	mL/kg of body weight
I:E Ratio	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 4600 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

Tidal Volume Capacity:	2.0 Liters
Residual Lung Volume:	1.022 Liters
Lung Compliance:	Adjustable: .01 to .10 L/cmH_2O
	Accuracy: ±3% (at calibration volumes)
Airway Resistance:	Adjustable: 5, 20, or 50 cmH_2O/L/Sec
	Accuracy: ± 5% (at calibration flows)
Size:	25”x10”x13”
Weight:	25 Pounds (in case)

Features and Components

Frame
The 4600 is built around an aluminum frame which provides stability for the components of the lung.

The Lung (Bellows)
The lung is simulated using an 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 functional residual capacity for a single lung. The bellows, secured to the top plate and frame of the 4600, is 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 airway consists of a “turret” which houses the resistors used to create varying levels of airway resistance. To change the resistance, turn the outside ring counterclockwise. Rotate the knob at the bottom of the assembly to the desired resistance of Rp5, Rp20, and Rp50. Tighten the outside ring by turning clockwise. *Please see Figure 1 for display of the 4600 Turret Assembly.*

Figure 1 – Model 4600 Turret Assembly

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 the lung. To correctly read the volume scale, the volume pointer (located at the base of the volume scale) must be positioned to correspond with the actual compliance setting.

Oxygen Analyzer Port

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

Pressure Gauge

The pressure gauge is located on the front of the 4600. The lung pressure and proximal pressure are measured with this gauge. A toggle switch located to the left of the gauge controls which pressure is measured.

Auxiliary Pressure Ports

To the left of the gauge is an auxiliary pressure port for measuring airway pressure with other pressure sensing or measuring equipment. To the right of the gauge is an auxiliary pressure port for measuring lung pressure with other pressure sensing or measuring equipment. These ports are equipped with a check valve and remain closed until the port is mated with a miniature quick connector. These connectors are supplied with the 4600.

2. Setup and Operation

Lung setup:

1. Set the 4600 on a level surface.
2. Remove the top cover of the carrying case 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.

Single Lung Simulation

1. The desired airway resistance is selected by using the "turret" assembly on the front of the unit. Either Rp 5, Rp 20, or Rp 50 can be chosen.
   To adjust resistance:
   A. Turn outside ring on turret assembly counter-clockwise until loose.
   B. Move resistor selector to the desired resistance.
   C. Tighten outside ring by turning clockwise.
   D. Attach ventilator circuit to the airway.

2. On the right side of the unit, select the desired compliance by first loosening the knob located above the compliance spring.
3. Grasp the compliance spring and slide the entire mechanism until the pointer is positioned over the desired setting. Lock in place by tightening the knob.

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 turret assembly of the 4600.

Measuring Oxygen Concentration in the Lung

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

Care of the 4600 after Ventilation with Humidified Gases

The airway and lung of the 4600 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

oxygen sensor port. After any fluids are drained from the unit, the 4600 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. Applications

The 4600 is 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 4600 Single Lung TTL 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 4600 is designed to allow performance testing of mechanical ventilators within their range of typical use, 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 (cmH_20)	**0**	**60**	**60**	**60**	**40**
Compliance (L/cmH_20)	**.05**	**.05**	**.02**	**.02**	**.01**
Resistance (cmH_20/L/sec)	**5**	**20**	**20**	**20**	**50**

1. Adjust the compliance and resistance on the 4600 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 4600.
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 4600 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/Demonstration

The 4600 Single Lung TTL 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.

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/cmH_20.
2. Select an Rp5 resistor in the airway turret assembly.
3. Using a ventilator or resuscitation bag, ventilate the TTL at a rate of 12 breaths per minute and tidal volume of approximately .800 liters.
4. Note the tidal volume measured.
5. Change the compliance of the lung to .03, then .02, and finally .01, and note the lung volumes with each change.

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

Procedure:

1. Set the airway resistance on the turret for Rp20.
2. Set the lung compliance at .08 L/cmH_2O.

3. Ventilate the TTL at a rate of 26 BPM and a tidal volume of 1.0 Liters, with a baseline (PEEP) of zero.
4. 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.

Other Common Applications

- Performing in-hospital ventilator training sessions.
- Checking ventilator systems for leaks.
- Documentation of preventive maintenance checks of ventilators.
- Demonstrating the difference in cycling and limiting mechanisms in mechanical ventilators.
- Evaluating new mechanical ventilators and ventilation monitoring equipment.
- Identifying optimal ventilator settings for particular patients and conditions.
- Performing work of breathing studies.
- Evaluating resuscitation bag techniques of paramedics, respiratory care practitioners, and students.
- AND MANY MORE.

4. Maintenance and Service

The 4600 Single Lung TTL 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 4600 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 3 years for complete recalibration and any necessary repairs.

Calibration Check
The accuracy of TTL volume measurements are dependent upon the proper operation of the unit and the accuracy of the compliance settings on each lung. This calibration can be checked using the following equipment and procedures:

Equipment Needed:
- Calibrated 1-liter syringe (or other calibrated volume injector)
- Independent, reliable pressure gauge or manometer (+/- 1% or .1 cmH_20)
- Small regular screwdriver

The following procedure can be used to quickly check the calibration of your 4600 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
1. Set the lung compliance at .10 L/cmH_20.
2. Set the toggle switch to the left of the gauge to *Lung Pressure.*
3. With the airway open to atmosphere, ensure the pressure gauge reads zero. If the gauge needs adjustment, remove the plug in the gauge crystal, and turn the adjusting screw until the needle of the gauge reads zero.
4. Attach a miniature quick connector to the airway auxiliary pressure port.
5. Attach an independent pressure gauge to the miniature quick connector.
6. Draw 1.0 liter of air into the insertion syringe, then connect it to the airway of the test lung.
7. Insert the 1.0 liter of air into the 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.

8. 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.

Compliance Setting	**Pressure Limits**
.10	9.7 to 10.3
.05	19.4 to 20.6
.01	97.0 to 103.0

Table 1—Calibration Values

If the displayed pressures do not fall within the acceptable range for any given compliance setting, 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.

Model 4600 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 lung at .02.
2. Inject 1.0 liter of air into the lung through the airway and read the lung pressure.
3. Hold the volume in the lung for 30 seconds, and again read the lung pressure. The pressure should not drop more than 1.0 cmH_2O in 30 seconds.

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 4600 Single Lung TTL is warranted by Michigan Instruments, Inc. Grand Rapids, Michigan, to be free of defects in material and workmanship for a period of **three (3) 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 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 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 4600 Single Lung TTL is covered by a limited, three 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 4600 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.

Requesting Factory Service for Your Model 4600
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 4600 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 4600 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 and insure for $3000.00.
      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. Freight charges will be added to the invoice.
   2. Payment is net 30 days.
   3. Open accounts are subject to credit approval.

5. Warnings and Cautions

Caution: Operate the 4600 within its specified limits. Over-inflation of the bellows or excessive pressure within the system may cause damage to the bellows or gauge.

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

Caution: Do not sterilize the 4600. The internal components are not compatible with sterilization techniques.

6. Storage and Shipping

The Model 4600 Single Lung TTL is shipped to the customer in a Carrying/Storage case which is packaged in a specially designed shipping carton. The Carrying/Storage case is used to protect the 4600 when not in use, and should be used to transport the unit. However, if the unit needs to be shipped via United Parcel Service or other carrier, place the unit in the original shipping carton. Replacement cartons are available at Michigan Instruments. (See *Factory Service Policy* for servicing instructions.)