T1·01

VENTILATOR TESTERS
Models VT-1B & VT-2

OPERATOR'S MANUAL

BIO-TEK
INSTRUMENTS, INC.

BIO-TEK® INSTRUMENTS, INC.

MODELS VT-1B & VT-2 VENTILATOR TESTERS

OPERATOR'S MANUAL

MANUAL PART NUMBER 8801015

REVISION A

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DOCUMENT REVISION RECORD

Revision, date, and section			Changes
A	3/4/1996	Table 2.3-1	Power Input: Changed "100/115/230 VAC" to "100/115/230/240 VAC."
			Deleted Power Output.
		Table 2.3-2	Changed timing measurement accuracy specification from "± .01%" to "± 2.5% ± 1 LSD."
			Added Note: "Infant respiration rates are dependen on pressure, volume and flow settings."
		Section 2.5	Item 1, Printer, second sentence: Changed to read "The printer rests on the top of the tester's electronic unit."
			Revised Figure 2.5-1.
		Section 2.5-1	Deleted second paragraph.
		Section 2.5-3	Revised Figures 2.5.2-1 and 2.5.3-1.
		Section 2.6	Table 2.6-1: Replaced references to "Seiko DPU printer" with "Citizen IDP 3110 printer."
		Section 3.1	Item 7: Revised printer operating instructions.
		Section 3.3	Item 24.c., first sentence: Changed "about 20 seconds" to "less than 20 seconds"; changed "standard Seiko DPU-40 printer" to "Citizen printer."
			Deleted second sentence.
		Section 4.1	Deleted second paragraph.
		Section 5	Table 5-1, PRINTER: Replaced second and th paragraphs with "Check to see if the printer is plugged into the correct line power."

Note: Above changes were made to Part Number 8801000 and released on Part Number 8801015.

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INTRODUCTION

The Bio-Tek Models VT-1B and VT-2 Ventilator Testers are stand-alone devices that simulate normal as well as pathological patient load conditions and provide test results not previously available. They are designed to compensate for barometric pressure, temperature, relative humidity, compressibility of gases under dynamic breathing conditions, partial pressures of different gas mixtures, different lung impedances of airway resistance and compliance, as well as gas reference units (ATPD, ATPX, BTPS, NTPD, & STPD). These devices address several hospital issues per JCAHO requirements such as efficient use of personnel, time and money; and safe, proper, effective, and cost efficient use of instruments for patient treatment in hospitals. They provide the hospital with documented test results, which are useful for preventive maintenance, service, equipment verification, or litigation.

1 UNPACKING AND INSPECTION

1.1 Unpacking and Inspection

To prevent damage to the ventilator tester, always unpack it in the following manner:

1. Lay the carrying case on a vibration-free work surface with the Bio-Tek name plate face-up and the handle pointed toward you.
2. Open the snap locks of the carrying case and remove the top.
3. Use both hands to lift the instrument out of the carrying case bottom.
4. If you do not anticipate repacking the unit within a short time, store the carrying case top and bottom in the shipping box.
5. Inspect the Model VT-1B or VT-2 lung, electronics unit, and accessories for physical damage and/or missing items. To report damage and receive further instructions, call the Bio-Tek Customer Service at 1-800-451-5172 or Service Department at: 1-800-24-BIOTK.
6. To report missing items, call Bio-Tek Instruments and ask for Customer Service, Biomedical Department.

2 MODELS VT-1B & VT-2 DESCRIPTION

Bio-Tek manufactures and sells the Model VT-1B Adult Ventilator Tester and the Model VT-2 Adult/Infant Ventilator Tester. The latter model differs physically from the Model VT-1B by having an infant lung assembly with 2 infant lung compliances. Other than that, the two units are identical in design and operation. The Model VT-1B and VT-2 differ from the Bio-Tek's previous models because they incorporate the following additional features:

1. Enhanced Pressure Accuracy,
2. Trend Test,
3. External Flow,
4. External Pressure,
5. Auto-Zero,
6. Computer Control provided by a bi-directional RS232, and
7. Carrying Case with wheels.

2.1 Summary of Features and Potential Users

1. The Models VT-1B and VT-2 ventilators are cost-effective, portable and simple to operate.
2. The user interface is a keyboard of pressure-sensitive pads; the user initiates tests and enters data by responding to prompts on an LCD display.
3. Fourteen parameters can be measured in automated test modes; the user can compensate for differences between reference unit conditions (ATPD, ATPS, ATPX, BTPS, NTPD, STPD) and actual test conditions by preprogramming the unit.
4. The display allows the user to observe volume, flow, and pressure waveforms as well as data in tabular form.
5. Volume, flow, and pressure waveforms may also be recorded on a chart recorder via the tester's analog output jacks.
6. A printer is provided for hard copy of test results and other data.
7. A bi-directional RS232 interface provides computer control for data collection and specialized performance analyses.

The following list highlights the features of the Models VT-1B and VT-2 testers:

* Dedicated adult and infant ventilator tester
* Provides 28 measurements through 13 test modes
* Test results in 2-to-4 breath cycles
* Corrects for atmospheric and gas conditions
* Choice of 6 reference units for volumes & flows
* Volume, flow, 2 pressure waveform displays
* Volume, flow, airway pressure analog outputs
* Status/quick test to check ventilator controls
* Full Test/Auto-Repeat for 15 measurements
* General flow and pressure measurements
* Printer port with printer, RS232 computer control
* Complies with ANSI, ISO, ASTM standards
* Trending of Tidal Volume
* Tests with lung impedance
* Tests with any gas mixture
* Leak & compliance tests
* Microprocessor based
* 6-line LCD graphic display
* Menu driven and user friendly
* Self test/diagnostic software
* Easy calibration check
* Auto-zero for transducer drift
* Upgradeable design
* Carrying case with wheels.

The Bio-Tek ventilator testers can be used by the following organizations and agencies:

1. Federal regulatory agencies
2. Organizations for evaluation of medical devices
3. Respiratory therapists and pulmonary physiologists
4. Hospital biomedical and clinical engineers and technicians
5. Equipment manufacturers, sales and marketing, inspection and calibration, quality control, production and design, service departments
6. Colleges and professional schools
7. Training organizations
8. Preventive maintenance and service organizations
9. Ventilator dealers and manufacturers' representatives.

2.2 Applications

Ventilators are used as life-support devices; therefore, it is important that their performance be clinically acceptable, without potential risks to the patients. Laboratory studies indicate that new generation of ventilators perform substantially better than the older models; however, until the Bio-Tek Ventilator Testers were available, there was no convenient method to evaluate ventilator performance according to clinical criteria.

The Models VT-1B and VT-2 ventilator testers are dedicated to test the performance of: neonatal, pediatric, adult critical care, home care, anesthesia, and transport ventilators. Additional applications are listed as the following items 1 through 19.

1. bacteria filters
2. breathing circuit valves
3. calibration syringes
4. compressors
5. CPAP/PEEP devices
6. demand valves
7. flow meters
8. flow regulators
9. IPPB machines
10. patient breathing circuits
11. pressure gauges/meters
12. pressure regulators
13. pressure relief valves
14. pulmonary function test equipment
15. resuscitators
16. respirometers
17. spirometers
18. ventilators
19. wall air/gas outlets

These testers are also capable of providing valuable information not previously available about a ventilator's performance, as well as the effects of artificial ventilation on patients, for example:

1. The tester can help diagnose ventilator failure at the patient's bedside.
2. The tester could be used by ventilator manufacturers and physicians to ensure proper operation during long-term treatment of patients by simulating actual patient conditions.
3. The ventilator tester could be used in conjunction with a ventilator synchronometer to investigate incidents of pneumothorax, hemodynamic instability and other respiratory syndromes during infant ventilation.
4. The device could be used in the development of ventilators, and to determine their appropriate applications on patients.
5. Studies can be conducted and realistic results obtained to determine perfusion and mass transfer in lungs, proper therapy during intensive care, percentage of oxygen delivered and carbon-dioxide concentration in lungs, respiratory mechanics and lung impedance, work of breathing and efficacy of exercise testing, and remote ventilator alarm/surveillance systems.
6. The device could be integrated with a patient-management system to determine appropriate treatment.

2.3 Model VT-1B or VT-2 Specifications

Table 2.3-1 gives the general specifications of the Model VT-1B and VT-2 Ventilator Testers. Table 2.3-2 provides information on the various Test and Monitor Modes, Measurements, and Performance Specifications for the 2 models.

The following list highlights the features of the Models VT-1B and VT-2 testers:

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* Corrects for atmospheric and gas conditions
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* Volume, flow, airway pressure analog outputs
* Status/quick test to check ventilator controls
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5. Equipment manufacturers, sales and marketing, inspection and calibration, quality control, production and design, service departments
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Table 2.3-1. Models VT-IB and VT-2 Specifications

Analog Outputs	Volume	1 Volt = 1 liter (Adult only)
	Flow	1 Volt = 50 LPM (Adult only)
	Airway Pressure	1 Volt = 20 cmH_2O (Adult & Infant)

Compliances (C) (L/cmH_2O) (per ANSI)

ADULT (VT-IB/VT-2)	INFANT (VT-2)
.05 (C50)	.003 (C3)
.02 (C20)	.001 (Cl)
.01 (C10)	

NOTE: Infant compliances are within ANSI specifications from sea level to 885 feet (or 717 to 777 mmHg). Although readings and accuracies are not affected above this altitude in the two models, customers may obtain higher altitude infant lungs per ANSI specification from Bio-Tek.

Awy Resistor (R_p) ($cmH_2O/L/min$) (per ANSI)

ADULT (VT-IB/VT-2)	INFANT (VT-2)
50	500
20	200
5	

NOTE: All resistors are parabolic types.

Set-Up Choices	Time:	12-hour format, AM or PM
	Date:	Entry in Month/Day/Year format
	Equipment ID:	Up to 16 numeral digits
	Atmospheric Pres.:	600 to 800 mmHg
	Relative Humidity:	0 to 100%
	Room/Gas Temp.:	15 to 50°C
	Pressure Units:	cmH_2O or psi for External High Pressure; (cmH_2O, mmHg, or kPa for others.)
	Reference Units:	ATPX, ATPD, ATPS, BTPS, STPD, or NTPD, for all volume and flow measurements.

Auto-Zero

Every time a TEST or MONITOR key is selected and/or every 10 minutes if still in any one mode, for airway and lung pressure transducers. Manual ZERO for external pressure.

Audible Over-Pressure Alarm

Over 125 cmH_2O in Infant or Adult lungs.

Table 2.3-1. Models VT-lB and VT-2 Specifications (Continued)

Computer Control	Via IBM PC-compatible, 25-pin, D-type male-to-female RS232 port. 2400 Baud Rate; 8 Data bits; I Stop bit, 0 Parity; 1 Receiving port and 1 Transmitting Port, XON/XOFF protocol. Refer to Section 3.4 for set-up requirements. (Cable for RS232 port, Bio-Tek Part #75004.)
Printer Interface	Standard parallel Centronics output.
Power Input	100/115/230/240 VAC switch selectable, 50/60 Hz, 60 Volt-Amperes.
Warm-Up Time	15 minutes after power on, from room temperature (25°C).
Operating Temperature	15° to 50°C
Dimensions	**VT-2**: 62.2 cm x 50.8 cm x 30 cm (24.5" x 20" x 12") **VT-lB**: 62.2 cm x 50.8 cm x 21.6 cm (24.5" x 20" x 8.5")
Weight	**VT-2**: 20.5 kg (45 lb) **VT-lB**: 12.3 kg (27 lb)

NOTE: The analog waveform outputs are **not** compensated for temperature, humidity, and atmospheric pressure; therefore, they do not provide quantitative data sufficient to support detailed measurements and calculations made through the use of an oscilloscope or high-speed chart recorder.

Table 2.3-2. Test and Monitor Modes, Measurements, and Performance Specifications

MEASUREMENTS	TEST MODES						MONITOR MODES						RANGE/UNITS	ACCURACY	RESOLN (DISPLAY)
							WAVEFORMS								
	STATUS	FULL/AUTO	TREND	ASSIST	LEAK	COMPLIANCE	VOLUME	LUNG PRES.	AWY. PRES.	FLOW	EXT. FLOW	EXT. PRES.			
TIME															
I:E RATIO	●	●	●										1:99 & 99:1	± 2.5% ± 1 LSD	0.1
INSP. TIME		●	●										0 TO 60 SECS	↓	↓
EXP. TIME		●	●										0 TO 60 SECS	↓	↓
INSP. HOLD		●	●										0 TO 15 SECS	↓	↓
EXP. HOLD		●	●										0 TO 99 SECS	↓	↓
CYCLE TIME		●	●										0 TO 120 SECS	↓	↓
RESPIRATION RATE	●	●	●										0 TO 75 BPM	↓	↓
PRESSURE															
PEAK/MAX AWY PRES		●	●						●				-15 TO 125 cmH_2O	±1%f.s. ±LSD	0.1
MIN AWY PRES, EEP		●	●	●					●				↓	↓	↓
MEAN AWY PRESSURE		●	●										↓	↓	↓
INSTANT AWY PRES				●					●			●	↓	↓	↓
PEAK/MAX LUNG PRES		●	●			●		●					↓	±2%f.s. ±LSD	↓
MIN LUNG PRESSURE						●		●					↓	↓	↓
INSTANT LUNG PRES					●			●					↓	↓	↓
ASSIST PRES				●									↓	↓	↓
EXTERNAL HIGH PRES												●	0 TO 75 psi(cmH_2O)	↓	↓
COMPLIANCE						●							0 TO 250 ml/cmH_2O	± 2% RDG	↓
VOLUME															
ADULT TIDAL VOLUME	●	●	●				●						0.05 TO 2.2 LITERS	±3% RDG ± 4LSD	0.001
INFANT TIDAL VOL	●	●	●				●						0.005 TO 0.3 LITERS	±4% RDG ± 4LSD	0.001
% TV VARIATION			●										3 TO 99% OF TV	TV ACCURACY	1
INSTANTANEOUS VOL							●						TV RANGE	↓	0.001
BASELINE, PEEP VOL							●						TV RANGE	↓	0.001
MINUTE VOLUME	●	●	●										0 TO 199 LITERS	↓	0.01
FLOW															
INSP FLOW		●	●							●			0 TO 250 LPM	TV ACCURACY	1
EXP FLOW		●	●							●			↓	↓	↓
INSTANT FLOW										●			↓	↓	↓
LEAK RATE					●								↓	↓	0.1
EXT GAS FLOW	(AIR, O_2, N_2O, CO, & CO_2)										●		10 TO 75 LPM AIR NTPD	±5% RDG ± 4LSD	1

DEFAULT: C=.05 L/cmH_2O: ATM PR=760 mmHg: Rh=50%: TEMP= 25°C: MV:BTPS: TV & FLOW:ATPX: PRES:cmH_2O
(MANAS KANUNGO)

Note: Infant respiration rates are dependent on pressure, volume and flow settings.

2.4 Model VT-1B Adult Lung and Model VT-2 Adult/Infant Lungs

The Models VT-1B and VT-2 have built-in adult lung models to test adult ventilators under physiologic load conditions; the Model VT-2 also has built-in infant lungs to test infant ventilators. These lungs closely approximate the physiological characteristics of human adult and pediatric lungs. Refer to Section A.3: Theory of Operation, for an explanation of how a ventilator interfaces with Bio-Tek's ventilator testers.

2.4.1 Adult Lung: Location and Description of Components

Figure 2.4.1-1 shows the profile of the Models VT-1B and VT-2 adult lung. The individual components identified on the figure are described as follows:

1. <u>2.2 Liter Bellows</u>: The Bio-Tek Adult Lung model consists of a 2.2 liter bellows as the *lung*, with a residual volume (RV) of 1.8 liters.

   The lung is simulated by an elastomer bellows, constrained to limit expansion except in a longitudinal direction. This longitudinal expansion is further constrained to be arcuate in shape, causing a hinged top plate to raise (rotate) during filling of the lung.

   Thoracic and lung stiffness (or, inversely, compliance) is simulated by a precision alloy steel spring which is stretched by rise of the lung top plate. Compliance adjustment is achieved by the positioning of the spring relative to the hinge point of the top plate, and actual compliance, in liters per centimeter of water (L/cmH_2O) pressure, can be set by positioning the spring against a calibrated scale. The adult lung **compliance settings** of 0.01, 0.02 and 0.05 L/cmH_2O are detented to aid in set-up ease and repeatability for standard (ANSI and ASTM) testing.

   Actual plate rotation about its hinge axis is used to measure tidal volume for the bellows (lung) through an angular displacement transducer (ADT). Identified as the **position encoder** in the figure, the ADT (with mechanical amplification) outputs a transistor-transistor logic-compatible signal that changes state once for every ~0.003 L change in lung volume. Because the trapped gas in each bellows will always be under a pressure greater than one atmosphere, the actual contained volume in most instances will be less than if the gas were at one atmosphere pressure. The amount of such compression is predictable given the pressure within the bellows and the compliance setting. Also, under pressure, the bellows will expand some radially, increasing its average area, thereby reducing plate rise. The volume readout is in terms of changes in actual internal geometric or incompressible lung volume, and such effects as radial bellows expansion are included.

   The bellows, at rest, retains a gas volume typical of the average corresponding adult RV for 2 lungs.

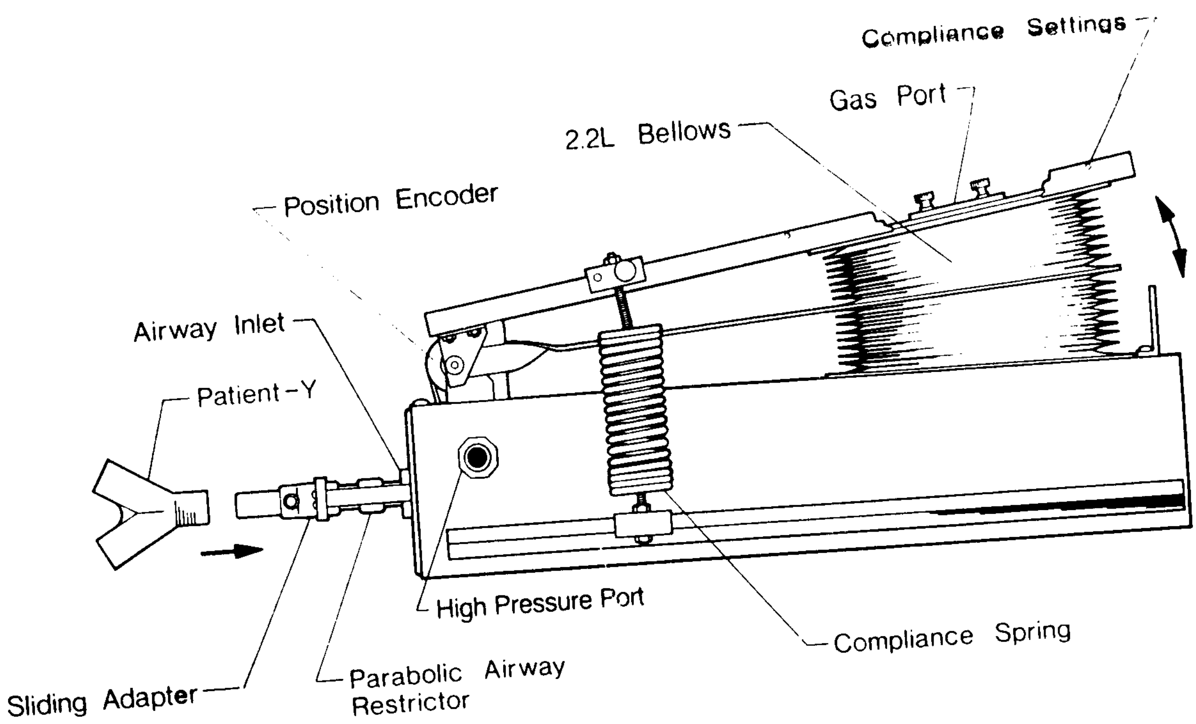


Figure 2.4.1-1. Ventilator Tester Adult Lung (Profile)

Intrapulmonary pressure (from within the lung) is measured through a 1/8" polyurethane hose connected to a pressure port from within the bellows. The cradle assembly includes a side tap-off for the measurement of oro-pharynegeal or upper-airway pressure on the inlet side of the simulated airway.

Lifting of the top plate will produce a subambient differential pressure within the lung and airway. The procedure is used to trigger a ventilator ON when in the patient assist mode, with the amount of subambient cycling pressure measured through the appropriate pressure port.

2. __Gas Port__: Near the back of the top plate of the adult lung is a gas port that allows attachment of sensors for measuring gas concentration. This opening into the lung is provided for installation of any of several types of gas concentration measuring sensors. The removable gas port through the lung plate over the bellow thus enables measurements of various gas concentrations delivered to the lung or performance of respiratory perfusion and metabolic studies.

3. __Compliance Settings__: Compliance is simulated by a vertically mounted spring between a fixed horizontal metal bar at the bottom and the movable lung plate. The **compliance spring** is moved along the right side of the adult lung to rest at one of 3 notched **compliance settings** along the top plate, in accordance with proposed ASTM standards. The adult lung **compliance settings** of 0.01, 0.02 and 0.05 L/cmH_2O are detented to aid in set-up ease and repeatability for standard (ANSI and ASTM) testing.

4. **Compliance Spring**: Thoracic and lung stiffness (compliance) is simulated by a precision alloy steel spring which is stretched by rise of the lung top plate. Compliance adjustment is achieved by the positioning of the spring relative to the hinge point of the top plate. By moving the compliance spring either towards or away from the bellows, one is able to simulate a high or a low compliance of the lung.

5. **High Pressure Port**: The external high pressure port on the right side of the adult lung assembly is connected directly to a pressure transducer to measure pressures of sources outside the lung/ventilator system.

6. **Parabolic Airway Restrictor**: Air or gas from a ventilator's **patient-Y** is input to the **bellows** through interchangeable **parabolic airway restrictors** mounted on a **sliding airway inlet adapter**.

   The airway is simulated by 1 of a set of 5 plug-in calibrated parabolic restrictors (resistors) to be inserted between 2 female 15 mm ports in a cradle assembly located on the front plate of the test lung. These restrictors have been calibrated in the laboratory to be within prescribed limits of resistance at 2 defined flow rates, as shown in the Table 2.4.1-1.

7. **Airway Inlet/Sliding Adapter**: The **patient-Y** is at the end of the tubing coming from the ventilator. It is attached to the lung by pushing it onto the **sliding adapter**. A **parabolic airway restrictor** (resistor) is inserted in the **airway inlet** and the adapter is pushed into the adult/infant lung assemblies.

8. **Patient-Y**: The **patient-Y** is at the end of the tubing coming from the ventilator. It is attached to the lung by pushing it onto the **sliding adapter**. A **parabolic airway restrictor** (resistor) is inserted in the **airway inlet**, and the adapter is pushed in.

9. **Position Encoder**: A metal plate attached to the top of the bellow at one end and hinged at the other provides an arcuate motion directly related to the volume of air or gas injected to the lung. An Angular Displacement Transducer (ADT) mounted at the hinged part of the lung plate provides 'raw signals' proportional to the amount of air or any gas mixture injected into the lung; this ADT is called the **position encoder**.

Table 2.4.1-1. Parabolic Restrictors Calibrated to Defined Flow Rates

Parabolic Restrictor [Linear Equivalent][1]	Flow Rates (liters/minute)						
	3.0	4.5	6.0	15.0	30.0	60.0	120.0
INFANT							
R_{p500}	26.7	50.2	---	---	---	---	---
R_{p200}	6.1	---	24.4	---	---	---	---
ADULT							
R_{p50}	---	---	---	6.8	27.2	---	---
R_{p20}	---	---	---	---	4.4	17.6	---
R_{p5}	---	---	---	---	---	2.7	10.8

[1] These parabolic restrictors have been designed specifically to produce flow characteristics to match the R_{p500}, R_{p200}, R_{p50}, R_{p20} and R_{p5} linear resistors specified by ASTM F1100-90. The flow characteristics are defined in the characteristic equation:

Pressure drop = K (Flow)2 cmH_2O

where K is defined (+/- 5%) empirically for each restrictor as follows:

R_{p500} = 8925 cmH_2O/L2/sec2*

R_{p200} = 2440

R_{p50} = 108.7

R_{p20} = 17.61

R_{p5} = 2.700

* R_{p500} orifice diameter is too small relative to the plate thickness for the square law to apply; constant for 4.5 liters/minute data point is 8925 instead of 10661.

The **position encoder** translates angular displacement of the bellows into an uncompensated measurement of the gas in the lung from which volume is calculated.

11. Short-Form Instructions Overlay: On the top plate of the lung is an overlay that provides a handy summary of instructions for setting up user-programmable parameters and for performing ventilator tests (refer to Section 3: Installation and Operation). This overlay is reproduced as Figure 2.4.1-2.

2.4.2 Infant Lung: Location and Description of Components

By mounting the infant lung assembly on the same base plate as the adult lung, and mounting the electronics assembly over the infant lung, the overall size of the Bio-Tek ventilator testers can be packaged in the same carrying case.

Figure 2.4.2-1 is a cut-away view of the infant lung showing the 2 internal canisters that are used to obtain the 2 compliances required to simulate infant (0.003 L/cm H_2O) and neonatal (0.001 L/cmH_2O) lungs. Note that the portion of the tester that houses the keypad and display must be removed to expose the infant lung compartment and this portion is not shown in the figure. These fixed lungs are designed to confirm with ANSI and ASTM standards.

Figure 2.4.2-2 shows the switch settings that enable the user to choose between the adult and infant lung and between the 2 compliance settings available on the infant lung.

1. ADULT/INFANT Toggle Switch: The toggle switch position determines whether the adult lung pressure transducer or the infant lung pressure transducer is used for measurement.

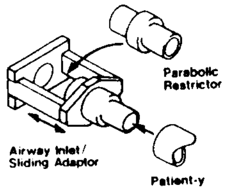
2. ADULT/INFANT Lung Select Lever: This lever is used in conjunction with the toggle switch to ensure that the desired lung is chosen in the Model VT-2 and that air from the ventilator is directed to it.

3. Infant Compliance Selector Lever: When the infant lung is selected the compliance of the lung must also be selected. The user can choose between 0.003 and 0.001. These compliance values are determined by the size of the canisters as shown in Figure 2.4.2-1.

VENTILATOR TESTER

INSTRUMENT SET-UP

1 Connect power cord
2 Switch on instrument
3 If printer is needed connect adaptor and printer cable
4 Connect 25-pin D type male connector to RS232 port if computer is desired
5 Step through set-up procedure using keypad and displayed instructions
6 Position compliance spring/lever on lung models
7 Insert parabolic restrictor in airway inlet
8 Connect patient-y to sliding adaptor



OPERATION	ACTION
CHANGE SET-UP PARAMETERS	Press (ESCAPE), then (CHANGE SET-UP), (PROMPT) until selection appears. Make change and then (ESCAPE).
COMPLIANCE SELECTION	Press (ESCAPE), then (CHANGE SET-UP), then (PROMPT) until compliance selection appears. Make selection. Press (ESCAPE), then position compliance spring (Adult) or lever (Infant) Position LUNG SELECT lever and ADULT/INFANT toggle switch in front of keypad.
PERFORM A TEST	Press (ESCAPE), then press desired TEST MODE key. Follow instructions on display.
MONITOR A WAVEFORM	Press (ESCAPE), then press desired WAVEFORM key for graphic display. Re-press WAVEFORM key for real-time, max, min values of waveform. Re-press key to return to graphics.
EXTERNAL PRESSURE	Press (ESCAPE), then (ZERO), then press (EXT PRES); connect pressure source to port on right side of Adult lung model.
EXTERNAL FLOW	Press (ESCAPE), then (EXT FLOW) Insert R20 restrictor into Sliding Adaptor; leave it disconnected from Airway Inlet.
PRINT OUT DATA	Press (PRINT).
ASSISTANCE	Call 1-800-451-5172.

REFERENCE UNITS

	TEMP	PRESS	REL HUM
ATPD	Ambient	Ambient	0%
ATPS	↓	↓	100%
ATPX	↓	↓	Ambient
BTPS	37°C(body)	↓	100%
NTPD	20°C	760mmHg	0%
STPD	0°C	↓	↓

WARNING

BEFORE TRANSPORTING UNIT, TIGHTLY SCREW DOWN COMPLIANCE SPRING AT 01 L/cm H_2O

Figure 2.4.1-2. Adult Lung Top Plate Overlay with Short-Form Instructions

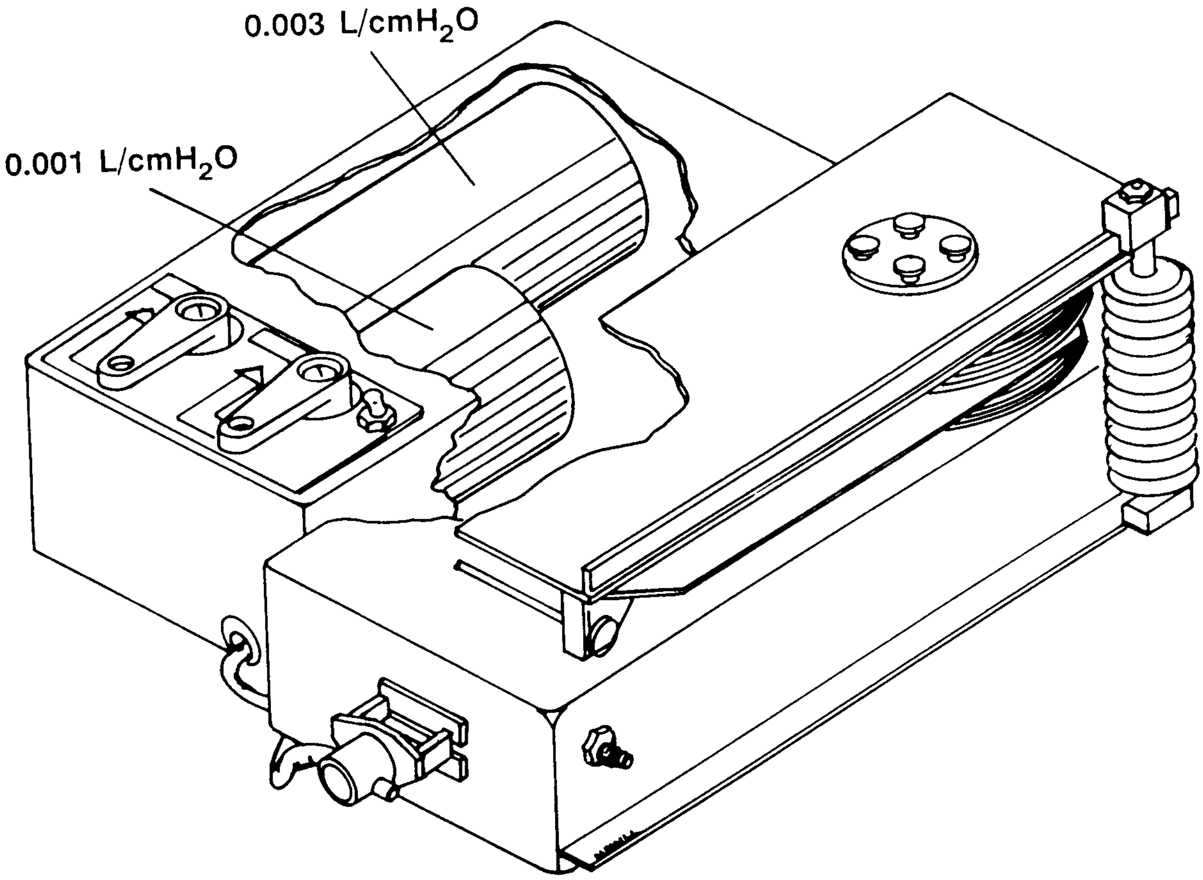


Figure 2.4.2-1. Infant Lung Fixed Compliance Models (Cut-Away View)

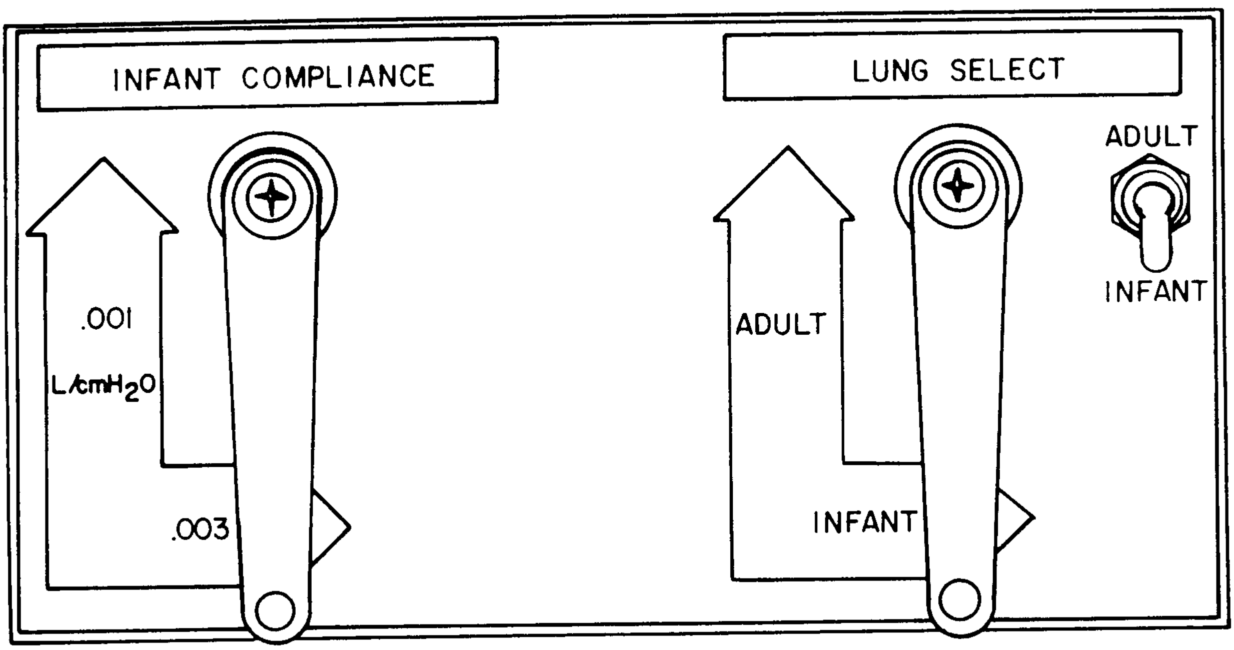


Figure 2.4.2-2. Switch and Lever Settings for Adult/Infant Lung

2.5 Model VT-1B or VT-2 Electronics Unit

Figure 2.5-1 shows an isometric view of the Model VT-I B or VT-2. This view is included to orient the user to the physical location of the components described in the preceding 2 sections and identify additional components of the ventilator tester not described in these sections.

1. **Printer**: The Models VT-IB and VT-2 are equipped with a Citizen IDP 3110 printer to provide a hard copy of the test results. The printer rests on the top of the tester's electronic unit.

2. **Over-Pressure Alarm Speaker**: The speaker for the over-pressure alarm is located on the left-hand side panel of the ventilator tester. The alarm will emit an audible tone when pressures exceed 125 cmH_2O inside the adult or infant lungs.

3. **Analog Outputs**: Refer to Section 2.5.3 for a complete description of the components located on the side panels.

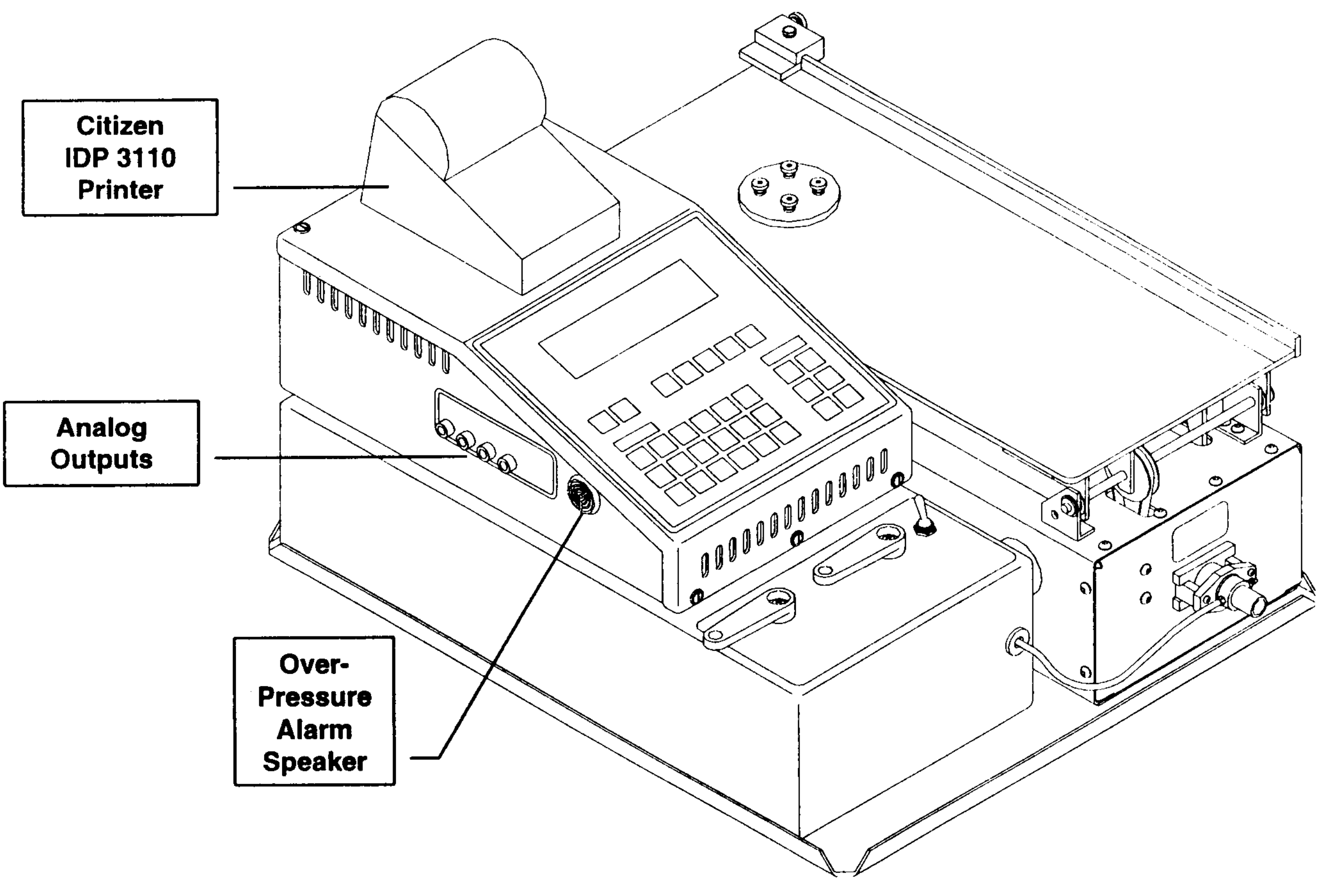


Figure 2.5-1. Isometric View of the Model VT-1B or VT-2 Ventilator Tester

2.5.1 Ventilator Tester Front Panel

The front panel consists of a liquid crystal display (LCD) and data input pads as shown in Figure 2.5.1-1. The LCD display gives instructions and displays data during set-up and testing. The pads stretching across the front display panel just below the display are pressed to exit from tests (ESCAPE), to zero the transducer before testing external pressure (ZERO), to enter user-programmable parameters (CHANGE SET-UP, OPTION, PROMPT AHEAD), and to print data (PRINT). The pads in the block headed TEST MODE are pressed to initiate automated tests. The numeric data entry block is at lower center. The pads in the block head WAVEFORM are pressed to access the waveform (EXT PRES), and to monitor the external flow (EXT FLOW). The use of all pads is describe monitors (VOLUME, LUNG PRES, AIRWAY PRES, AIR FLOW), to access the high pressure monitor d in the following section and within the context of ventilator testing in Section 3: Installation and Operation.

Space is provided for entering other information such as all ventilator settings used for a test and other information that could not be entered.

2.5.1.1 Definitions of Keys

TOP ROW KEYS

1. **ESCAPE**: Enables the user to exit from tests.

2. **ZERO**: Enables the user to zero the transducer when using the high pressure external port.

3. **CHANGE SET-UP**: Enables the user to change the parameters previously set or to change the default values.

4. **OPTION**: During parameter set-up, enables the user to select various options displayed on the LCD.

5. **PROMPT AHEAD**: Enables the user to advance during parameter set-up and displayed test results.

6. **PROMPT BACK**: Enables the user to prompt back during parameter set-up and displayed test results.

7. **PRINT**: Enables the user to transmit data and print data.

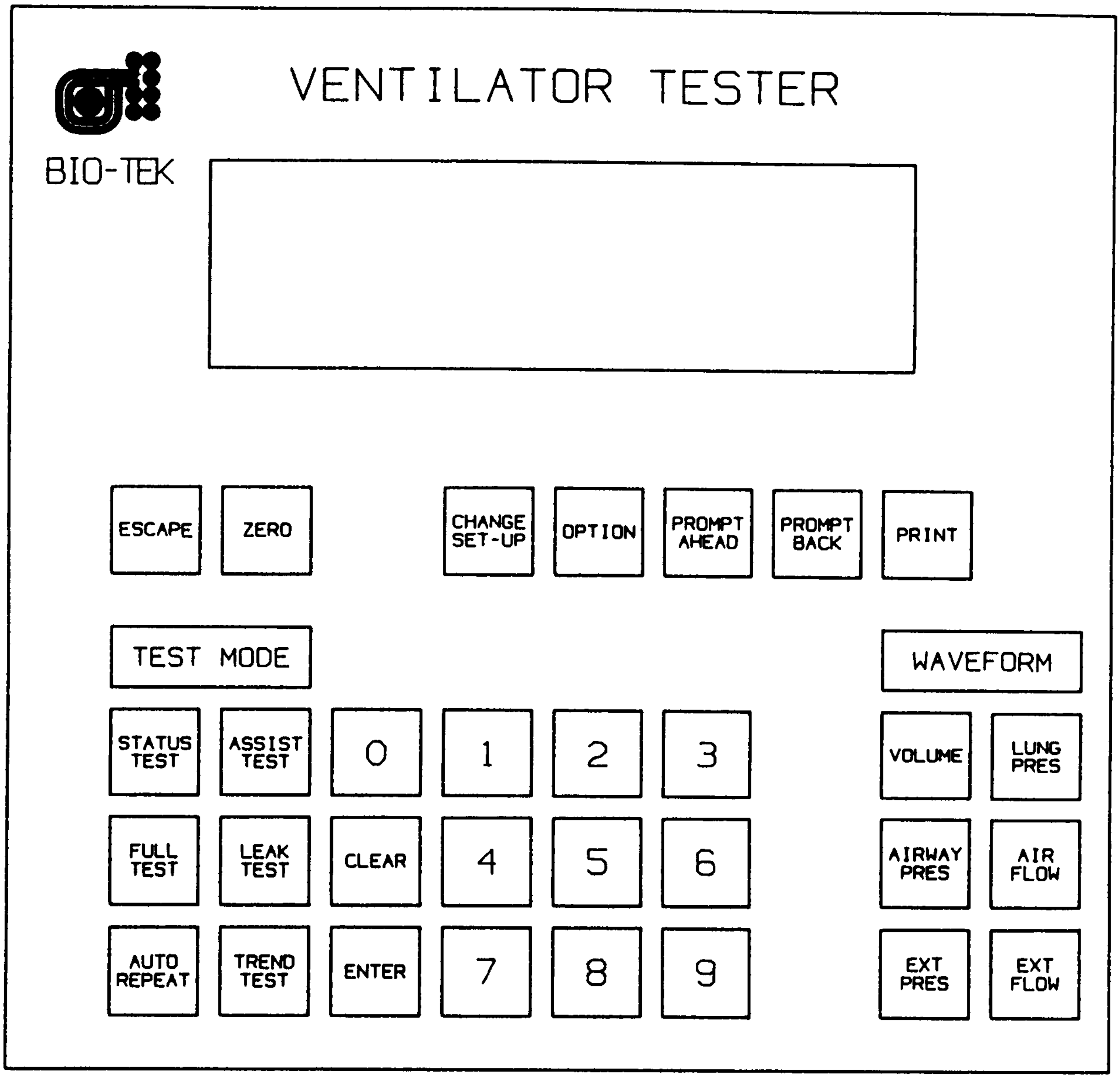


Figure 2.5.1-1. Ventilator Tester Keypad

TEST MODE KEYS

1. STATUS TEST: The unit provides the means of obtaining and displaying some key and commonly required information such as Tidal Volume (TV), Minute Volume (MV), Breath Rate, and Inspiratory Flow Rate. These readings are updated continuously for every breath so that the user can adjust ventilator controls to determine optimum settings and performance and can use this feature to calibrate the ventilator.

2. FULL TEST: By using a single key operation, the user can obtain all readings pertaining to the characteristics of the delivered breaths in addition to the ones in STATUS TEST.

3. AUTO-REPEAT: Because of the unavailability of the percentage variation feature for other parameters and a need to continuously monitor ventilator performance over several hours or days for repeatability/endurance tests or to troubleshoot intermittent problems, the tester carries out the FULL TEST at user preprogrammed intervals of from 5 to 120 minutes.

4. ASSIST TEST: The tester tests the Sensitivity Control and Assisted or Assist-Control modes of ventilators where a breathing effort simulated by the lung would trigger a breath cycle from the ventilator. The tester displays the Assist Pressure, positive or negative End Expiratory Pressure, and Minimum Airway Pressure.

5. LEAK TEST: Measures the leak rate of the Model VT-1B and VT-2 adult lung and the Model VT-2 infant lung. Measures the leak rate of external patient tubing (use the adult lung only for this type of LEAK TEST).

6. TREND TEST: Even with the AUTO-REPEAT feature, there may be instances where an intermittent fault in ventilator performance may occur in between the user programmed time intervals. The tester therefore has a feature to monitor Tidal Volume. Based on a user programmed percentage of Tidal Volume Variation with respect to the first reading as the reference, the tester prints out the Full Test values for a faulty breath.

WAVEFORM KEYS

1. VOLUME: On selecting any one of these keys, the corresponding waveform is displayed and continuously updated every other breath. By pressing the same key a second time, Instantaneous, Maximum, and Minimum Numeric values of the selected parameter are displayed.

2. AIRWAY PRES: Description the same as for VOLUME, preceding.

3. EXT PRES: General purpose pressure measurements can be made in this mode, from 0-75 psi or equivalent in cmH_2O.

4. LUNG PRES: Description the same as for VOLUME, preceding.

5. AIR FLOW: Description the same as for VOLUME, preceding.

6. EXT FLOW: General purpose flow measurements can be made in this mode, from 10-75 lpm.

NUMERIC KEYS

1. 0, 1,...9: These keys can be used to enter preferred values during the set-up mode.

2. CLEAR: This key clears wrong entries made during the set-up mode.

3. ENTER: This key enters the numeric values selected during set-up, and advances to the next step.

2.5.2 Ventilator Tester Rear Panel

1. Fuses: The fuses are located in the upper lefthand corner (see Figure 2.5.2-1). (Refer to Section 2.6: Accessories, for fuse part numbers.)

2. Power Input Jack: The power input jack that is installed, the fuse size, and the line voltage (on the line voltage select dial) should be selected to correspond to common usage in the user's locale.

3. RS232 Serial Port: The RS232 serial port on the rear panel is a 25-pin female connector. This is a bi-directional RS232 to enable computer control of the ventilator tester. (Refer to Section 3.4 for installation procedures.)

4. Printer Port: This is a 36-pin parallel Centronics connector. (Note the **mode select switch** located at this port.)

5. ON/OFF Switch: The main power is toggled ON and OFF by the switch on the rear panel.

2.5.3 Ventilator Tester Side Panels

The components on the right side panel of the Model VT-1B or VT-2 (when the viewer faces the display and front panel keypad) have been described in Section 2.4.1: Adult Lung.

1. Analog Outputs: On the left side panel of the Model VT-1B or VT-2 electronics unit are the analog outputs for connection to a chart recorder, arranged and labeled as shown in Figure 2.5.3-1.

2. Over-Pressure Alarm Speaker: The speaker on the left side panel emits an audible alarm in case of lung over-pressurization (greater than 125 cmH_2O). The speaker is shown in Figure 2.5-1.

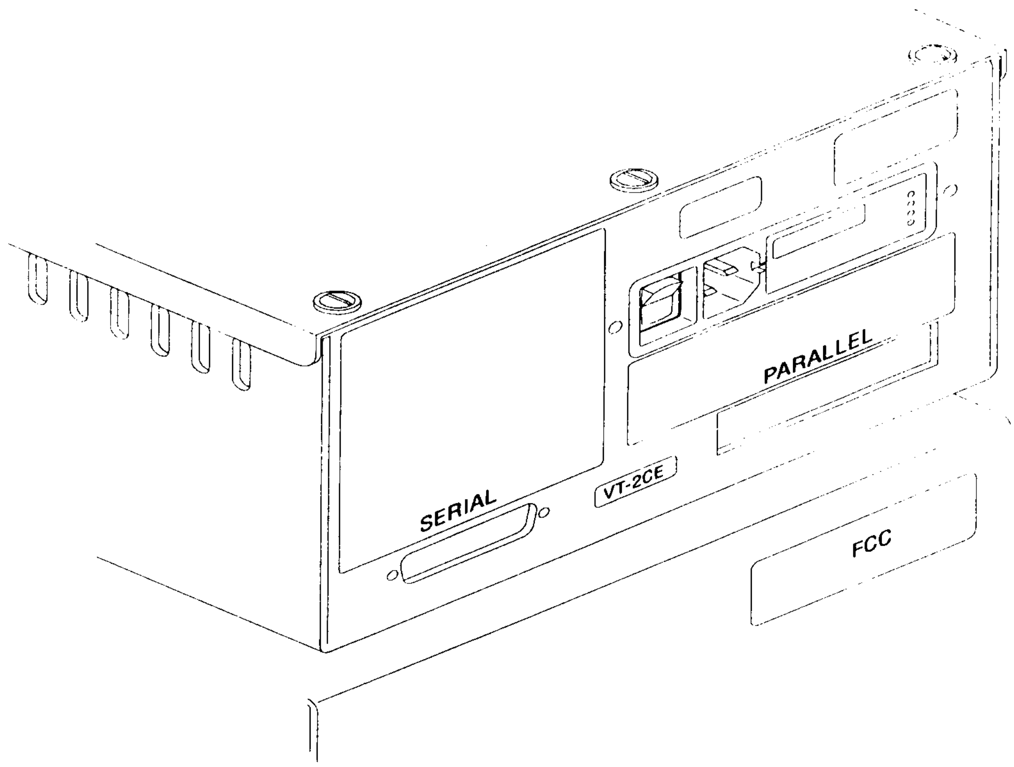


Figure 2.5.2-1. Model VT-1B or VT-2 Rear Panel

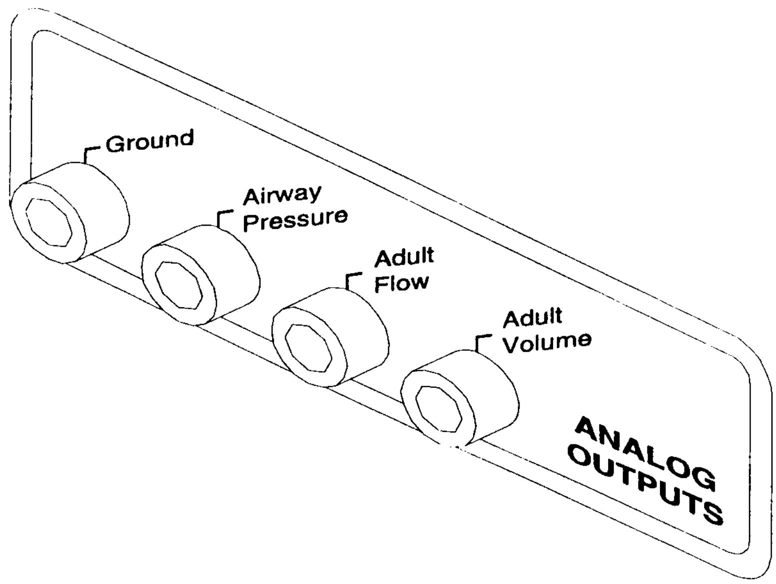


Figure 2.5.3-1. Model VT-1B or VT-2 Analog Outputs

2.6 Accessories

Accessories for the Model VT-1B or VT-2 (with the exception of this manual) are included in an accessories pouch that accompanies the unit. The accessories and their Bio-Tek part numbers to be used for ordering are listed in Table 2.6-1.

2.7 Optional Accessories

Optional accessories (not provided with the unit unless requested by the user) are listed in Table 2.7-1.

Table 2.6-1. Models VT-IB and VT-2 Accessories

Bio-Tek Part Number	Quantity Supplied	Description
6770042	1	Accessories box
91068	1	Shipping box
8802025	1	Carrying case
75004	0	IBM male-female serial interface cable
—		**Printer Subsystem:**
97128	1	Citizen IDP 3110 printer, with instruction manual and power supply
97129	1	Printer paper roll for Citizen
8810114	1	Centronics printer cable (parallel, male-male)
—		**Parabolic Airway Restrictors:**
48129	1	R_{p5}
48130	1	R_{p20}
48131	1	R_{p50}
48163	1	R_{p200} (for VT-2)
48323	1	R_{p500} (for VT-2)
—		**Power Cord (one of the following):**
75010		European ("Schuko" and French)
75011		U.S.
75012		United Kingdom
75013		Australian
—		**Fuses (one each of the following types):**
48023	1	.75A 3AG Slo-Blo (100 and 125 VAC usage)
46028	1	.375A 3AG Slo-Blo (230 VAC usage)
8810131	1	On/off valve (for patient tubing)
49342	1	Adapter, rubber hose
8801000	1	Operator's Manual

Table 2.7-1. Models VT-1B and VT-2 Optional Accessories

Bio-Tek Part Number	Description
--	Port Adapters:
48133	Hudson O_2 port adapter
48134	Ohio O_2 port adapter

INFANT LUNG OPTIONS TO MEET ANSI COMPLIANCE FOR HIGH ALTITUDES:

The Model VT-2 normally supplied has infant lungs that meet ANSI specifications for compliance between 717 and 777 mmHg only. Actual readings obtained by the Model VT-2, however, meet our published specifications. The following models (B through H) can be purchased on a made-to-order basis if infant lungs that comply with ANSI specifications at other altitudes are needed.

VT-2 Model	Atmospheric Pressure Range
VT-2 (Standard)	717 -- 777 mmHg
VT-2B	699 -- 757 mmHg
VT-2C	681 -- 738 mmHg
VT-2D	664 -- 719 mmHg
VT-2E	646 -- 700 mmHg
VT-2F	628 -- 680 mmHg
VT-2G	611 -- 661 mmHg
VT-2H	593 -- 642 mmHg

3 INSTALLATION AND OPERATION

Before installing and operating the Model VT-1B or VT-2 Ventilator Tester, the user should observe the following:

1. Ensure that the tester is inspected as described in Section 1.

2. Ensure that all safety precautions are followed (refer to Section 4.1).

3. Remember that the analog waveform outputs are **not** compensated for temperature, humidity, and atmospheric pressure; therefore, they do not provide quantitative data sufficient to support detailed measurements made through the use of an oscilloscope or high-speed chart recorder.

4. Remember that when the user presses any keypad on the ventilator tester front panel, an audible tone is produced. If the Model VT-1B or VT-2 accepts the user's input, a high beep is sounded. If the instrument does not accept the input (because an inappropriate key is pressed or because the data the user wishes to enter is out of the acceptable range of values), a low beep is sounded. Absence of any audible tone signifies that the Model VT-1B or VT-2 has not detected any input.

3.1 Preparation for Use

Follow the procedure below to prepare the instrument for use. (Refer to the rear panel overlay on the Model VT-1B or VT-2 electronics unit as described in Section 2.5.2.)

1. Remove the power cord from the accessories bag.

2. Using a coin or screw driver, select the proper line voltage at the back of the Model VT-1B or VT-2 electronic unit.

3. Connect the power cord from the power input jack at the back of the Model VT-1B or VT-2 electronics unit to the wall outlet.

4. Flip the ON/OFF switch at the back of the ventilator tester electronics unit to ON. The display should show a copyright message for a fraction of a second, then the display should show:

```
SET-UP      Time:  12:00 AM
___________________________________

Use numeric keys to enter value.
Use PROMPT key to advance.
```

If it does not, the unit may be malfunctioning. Call 1-800-451-5172 for help.

5. Make sure the 4 screws on the round plate sealing the gas port on the top of the adult lung plate are tightly screwed on.

6. Make sure the transparent tubing attached to the sliding airway adapter on the front of the adult lung is not loose.

7. If you will be using the printer:

   1) Plug the printer power supply into the wall outlet.

   2) Connect the printer cable to the printer port on the **back** of the electronics unit and to the back of the printer.

      NOTE: The connector will engage in only one orientation.

   3) Turn the printer ON and push PAPER FEED. If the printer does not work properly, check the connections made above. If the printer still does not work properly, refer to the printer's operator's manual.

      NOTE: Ensure that the printer is on-line.

8. If desired, attach a chart recorder to the analog output jacks on the left side of the electronic unit. The overlay on the unit near the jacks shows where to make the connections.

9. Record (or approximate) the atmospheric pressure of the environment. Record the temperature of the gas to be used. If you will be using **room air,** record the relative humidity of the air.

3.2 Operating Precautions

The Models VT-IB and VT-2 incorporate sensitive mechanical, pneumatic, electronic, and microprocessor-based technologies. Observe the following precautions to ensure proper and safe operation:

1. Select a vibration-free surface on which to place the Model VT-IB or VT-2 tester.

2. Avoid operating the tester in an area with high electromagnetic interference.

3. Do not test a ventilator while a heated humidifier is connected to it. This will cause incorrect readings and condensation problems within the Model VT-1B or VT-2 lungs.

3.3 Set-Up of User-Programmable Parameters

Before testing the ventilator, the user must define the following parameters, which will be used by the tester to make calculations and to display data:

1. Date and time
2. Compliance setting
3. Ventilator ID
4. Atmospheric pressure
5. Relative humidity of the ventilator source gas
6. Temperature of the ventilator source gas
7. Reference units (ATPD, ATPS, ATPX, STPD, BTPS, NTPD)
8. Units in which pressure values are to be displayed (cmH_2O or mmHg).

The parameters are entered by pressing the light grey numeric keypads on the Model VT-1B or VT-2 unit front panel in response to prompts on the Model VT-1B or VT-2 display. Once the user is familiar with the procedure, the complete sequence of steps should take less than one minute.

NOTE: At any time during the SET-UP procedure, the user can press the PROMPT BACK key to go to a previous page.

Follow the sequence of steps below to set up the user-programmable parameters. The state of the Model VT-1B or VT-2 display is shown before each step.

1. Make sure you have completed the procedures defined in Sections 3.1 through 3.3. If you are entering this set-up sequence directly after preparing the unit for use (Section 3.3), the following display should appear:

```
SET-UP    Time: 12:00 AM
________________________

Use numeric key to enter value.
Use PROMPT key to advance.
```

a. If you want to enter this set-up sequence to change a parameter after interacting with the unit, press ESCAPE. The display should show:

SELECT TEST

b. Press CHANGE SET-UP. The time displayed will be the time entered in the last set-up procedure.

2. Press ENTER to enter the time in a 12-hour format (i.e., 0:00 to 12:59). For example: 0:xx will be read as 12:xx. If an invalid time was entered , press CLEAR to re-enter the correct time.

EXAMPLE: Time is 2:06 PM. Enter 206.

SET-UP Time: 02:06 AM
Use numeric key to enter value. Use PROMPT key to advance.

The display should show:

SET-UP Time: 12:00 AM
Invalid time was entered.

3. If applicable, change "AM" TO "PM" by pressing OPTION. (To return to AM, press OPTION again).

EXAMPLE: PM is desired. Press OPTION.

SET-UP Time: 02:06 PM

NOTE: Once set, the internal clock will keep running until the time is changed by the user or until the unit is switched off.

4. Press PROMPT AHEAD or ENTER to enter the date.

SET-UP Date: MM/DD/YY
Use numeric keys to enter value. Use Prompt to advance.

5. Enter 6-digit date in the form [Month/Day/Year]. Month number must be from 01 to 12. Date number must be within maximum number of days for month entered. Any 2-digit year is acceptable. If you make a mistake, press CLEAR and re-enter; the display will show:

SET-UP Date: MM/DD/YY
Invalid date was entered.

Press CLEAR and enter correct date.

EXAMPLE: Date is September 24, 1985. Enter 092485.

SET-UP Date: 09/24/85

6. Press PROMPT AHEAD or ENTER. The display should show:

SET-UP Compliance:	*.05
Units in L/cmH_2O	.02
	.01
	.003
	.001
Use OPTION key to change setting. Use PROMPT key to advance.	

7. Move asterisk next to desired compliance value by pressing OPTION as required. If the asterisk is already next to the desired value, go to the next step.

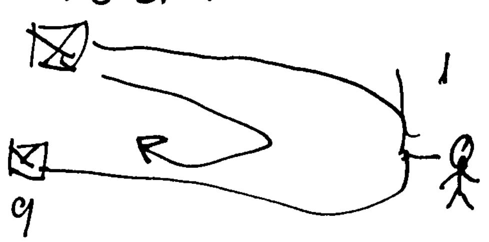
NOTE: The .003 and .001 compliance values are for the infant lung application of the Model VT-2 *only*. If you have a Model VT-IB Adult Ventilator Tester and you select the .003 or .001 settings, these test readings will not be displayed.

By selecting appropriate compliance and resistor values, the user can simulate a spectrum of lung conditions such as those shown in Table 3.3-1.

Table 3.3-1. Simulated Patient Conditions

Condition	Compliance (C)	Airway Resistor (R_r)
Adult/Pediatric		
Normal	0.05	20
Pneumothorax	0.02 or 0.01	20
Asthma or Bronchitis	0.05	50
COPD (Chronic Obstructive Pulmonary Disease)	0.02	50
Collapsed Lung	0.01	20
Emphysema	0.01	50
Normal Pediatric	0.01	20
Infant		
Newborn (2.8 kg, 6 Ib)	0.003	50
Post-operative	0.003 or 0.001	50
Hyalin Disease	0.001	200
Intubated	0.003	200 or 500
Premature (1.35 — 2 kg, 3 — 4.5 Ib)	0.003	50
Premature Extreme	0.001	200

10 LPm



EXAMPLE: Compliance desired is 0.02 L/cmH_2O. Press OPTION once.

SET-UP Compliance:	.05
Units in L/cmH_2O	*.02
	.01
	.003
	.001

8. **Ensure that the adult or infant lung compliance setting matches the compliance you selected in Step 7, preceding.**

   a. Adult: Ensure that the ADULT/INFANT toggle switch and the ADULT/INFANT lung selector (located under the VT-2 electronics box, see Figure 2.4.2-2) are in the ADULT positions.

      1. Move the compliance spring on the right side of the adult lung to the matching compliance by positioning the spring pointer to the appropriate compliance position on the top of the adult lung.

      2. Move the spring by unscrewing the black knob on the righthand side of the spring; unscrew the knob counterclockwise (towards yourself) one quarter of a full turn.

      3. Hold the top and bottom portions of the spring assembly (note that the spring is in a vertical position); use both hands. Then move the assembly until the spring pointer is over the appropriate compliance position and the top assembly clicks into a notch.

      4. Tighten the black knob; ensure that the spring remains in the vertical position as you do this.

      NOTE: Under NO conditions should you unscrew or tighten any of the other screws or mechanical parts even if the spring appears loose, too tight, or has extra space below its lower guide rail. The spring has been set with precision at the factory to attain correct lung compliances. Unless the spring was damaged or bent in transit or the unit has been dropped, the lung should remain calibrated for several years.

      If you suspect that your volume, flow, and pressure readings are inaccurate, first refer to Section 5: Troubleshooting, to try to locate the problem. If this is not successful, call the Bio-Tek Service Department Hotline at: 1-800-24-BIOTK or Customer Service at: 1-800-451-5172 to determine whether your adult lung requires recalibration.

b. **Infant:** The following steps apply to the Model VT-2 only.

1. Switch the ADULT/INFANT toggle switch and the ADULT/INFANT lung selector lever under the electronic box to the infant positions.

2. Switch the ADULT/INFANT airway lever to INFANT.

3. Switch the INFANT COMPLIANCE lever (located in front of and underneath the electronic box) to the compliance you selected in SET-UP.

9. Press PROMPT AHEAD or ENTER; the display should show:

SET-UP Vent. ID:
Use numeric key to enter value. Use PROMPT key to advance.

10. Enter ID number (up to 16 digits) of ventilator to be tested. If you make a mistake, press CLEAR and re-enter.

EXAMPLE: Ventilator ID is #1256. Enter 1256.

SET-UP Vent. ID: 1256

11. Press PROMPT AHEAD or ENTER.

SET-UP Atmos. Pressure: 760 mmHg
Use numeric keys to enter value. Use PROMPT key to advance.

12. Enter atmospheric pressure of test environment in mmHg. If you make a mistake, press CLEAR and re-enter. If the atmospheric pressure is the value already shown on the display, go to the following Step 13.

NOTE: It is very **important** to enter the correct atmospheric pressure when using the infant lung section of the Model VT-2. The Model VT-2 infant lung compliances meet ANSI standards up to 777 mmHg and will not affect displayed readings even if the infant lungs themselves may not meet ANSI specifications at other atmospheric conditions. Call Bio-Tek if your infant lungs need to meet ANSI standards beyond these limits.

EXAMPLE: Atmospheric pressure is 720 mmHg. Enter 720; the display will show:

> SET-UP Atmos. Pressure: 720 mmHg
>
> ---
>
> Use numeric keys to enter values.
> Use PROMPT key to advance.

NOTE: If you enter outside of the valid range (600 to 800) the display will show:

> SET-UP Atmos. Pressure:
>
> ---
>
> Value entered was invalid.

If you wish you can use the default value of 760 mmHg for atmospheric pressure.

13. Press PROMPT AHEAD or ENTER; the display will show the prompt for relative humidity:

> SET-UP R.H.: 50%
>
> ---
>
> Use numeric keys to enter value.
> Use PROMPT key to advance.

NOTE: The range for relative humidity is 0 to 100% and the default value is 50%, as shown in the preceding display.

a. If you enter a number exceeding this range, the display will show:

> SET-UP R.H.:
>
> ---
>
> Value entered was invalid.

b. Enter a valid number and press ENTER.

14. Enter relative humidity of the ventilator source gas (from 0 to 100). Enter 0 if you are using a wall outlet or tank(s) as the gas source(s). If you make a mistake, press CLEAR and re-enter. If the relative humidity is the default value (50%) already shown on the display, go to the following Step 15.

    CAUTION: Do not use a heated humidifier at any time.

    EXAMPLE: Room air is to be used as the ventilator gas source, and its relative humidity is 75%. Enter 75.

> SET-UP R.H.: 75%

15. Press PROMPT AHEAD or ENTER.

> SET-UP Gas Temp: 25 deg C
>
> ---
>
> Use numeric keys to enter value.
> Use PROMPT key to advance.

16. Enter the temperature (in degrees centigrade) of the ventilator source gas. Only the values 15° to 50° will be accepted. If you make a mistake, press CLEAR and re-enter. If the gas temperature is the default value (25° already shown on the display), go to the next step.

    EXAMPLE: Gas temperature is 30° centigrade. Enter 30.

> SET-UP Gas Temp: 30 deg C

17. Press PROMPT AHEAD or ENTER.

```
SET-UP Ref. Units:   ATPD   STPD
Minute Vol. Only     ATPS   *BTPS
                     ATPX   NTPD
___________________________________

Use OPTION key to change setting.
Use PROMPT key to advance.
```

NOTE: When comparing Model VT-1B or VT-2 volume and flow readings to a ventilator's settings, it is important to select the same reference units as the ventilator. The ventilator manufacturer should be able to provide you with this information; if not, call Bio-Tek's Biomedical Product Manager.

18. Move asterisk next to desired reference units (defined in the following example) for Minute Volume by pressing OPTION as required. If the asterisk is already next to the units desired or if the default setting (BTPS) is acceptable, go to the next step. Refer to Table 3.3-2 for definitions of the reference units.

EXAMPLE: If ATPD reference units are desired, press the OPTION key twice to move the asterisk next to ATPD.

```
SET-UP Ref. Units:   *ATPD  STPD
Minute Vol. Only     ATPS   BTPS
                     ATPX   NTPD
```

19. Press PROMPT AHEAD or ENTER.

```
SET-UP Ref. Units:   ATPD    STPD
Other Vol & Flows    ATPS    BTPS
                     *ATPX   NTPD
___________________________________

Use OPTION key to change setting.
Use PROMPT key to advance.
```

Table 3.3-2. Reference Units Defined

Reference Unit	Temperature	Pressure	Relative Humidity
ATPD	Ambient	Ambient	0% (Dry)
ATPS	Ambient	Ambient	100% (Saturated)
ATPX	Ambient	Ambient	Ambient
BTPS	37^{o} C (body)	Ambient	100% (Saturated)
NTPD	20^{o} C	760 mmHg	0% (Dry)
STPD	0^{o} C	760 mmHg	0% (Dry)

ATPD => Ambient temperature and pressure, dry air
ATPS => Ambient temperature and pressure, saturated air
ATPX => Ambient temperature and pressure, existing humidity

BTPS => Body temperature, ambient pressure, saturated air
NTPD => Normal temperature and pressure, dry air
STPD => Standard temperature and pressure, dry air

20. Move asterisk next to desired reference units for other volume and flow readings (e.g., Tidal Volume, Baseline Volume, Inspiration and Expiration Flow) by pressing OPTION as required. If the asterisk is already next to the units desired or if the default (ATPX) is acceptable, proceed to the next step.

    NOTE: When comparing Model VT-1B or VT-2 volume and flow readings to a ventilator's settings, it is important to select the same reference units as the ventilator. The ventilator manufacturer should be able to provide you with this information; if not, call Bio-Tek's Biomedical Product Manager.

    EXAMPLE: NTPD reference units are desired. Press OPTION 3 times until the asterisk moves next to NTPD.

```
SET-UP Ref. Units:   ATPD   STPD
Other Vol & Flows    ATPS   BTPS
                     ATPX   *NTPD
```

21. Press PROMPT AHEAD or ENTER.

```
SET-UP Pres. Units:  mmHg
                     *cmH2O
                     kPa
_______________________________

Use OPTION key to change setting.
Use PROMPT key to advance.
```

22. Move asterisk next to the units desired for all measured pressure readings **except High External Pressure** by pressing OPTION as required. If the asterisk is already next to the units desired or if the default (cmH_2O) is acceptable, proceed to the next step.

EXAMPLE: It is desired to have all pressure readings displayed in mmHg. Press OPTION key twice.

```
SET-UP Pres. Units:  mmHg
                     *cmH2O
                     kPa
```

23. Press PROMPT AHEAD or ENTER.

```
Print Set-Up?  *yes
               no
_______________________________

Use OPTION key to change setting.
Use PROMPT key to advance.
```

24. If you desire a printout of the set-up parameters:

    a. Make sure the printer is correctly hooked up and powered on (refer to Section 3.1).

    b. Make sure the printer contains at least 4 inches of paper.

c. Press PROMPT AHEAD. The printout will take less than 20 seconds using the Citizen printer included with the ventilator tester.

NOTE: If a computer is connected to the Model VT-1B or VT-2 and set up to accept data, the computer screen will display the same messages as the printout. (Refer to Section 3.4 for installation procedures.)

A printout of the sample set-up just completed is shown in Figure 3.3-1.

```
SET-UP                          02/06/96
Vent. ID: 132645                12:29 AM
----------------------------------------
Compliance = .05
Atmos. Pressure = 760 mmHg
R.H.  = 50 %
Gas Temperature = 25 deg C
Ref. Units (Minute Vol. Only) = BTPS
Ref. Units (Other Vol & Flows) = ATPX
Pres. Units = cmH2O
```

Figure 3.3-1. Set-Up Printout

25. If you do not desire a printout of the set-up parameters:

    a. Press OPTION to advance asterisk next to "no" on display.

    b. Press PROMPT AHEAD.

26. The display should now show the message:

Please wait until 15-minute warm-up period is complete. Time remaining: xx:xx.

The time remaining is updated every second.

NOTE: The temperature inside the electronics unit when it is fully warmed up is about 38° C. The colder the unit is when it is first turned on, the longer it will take to reach this temperature. A minimum warm-up time of 15 minutes is recommended from room temperature (25° C), unless the unit was recently switched ON and is still warm. If the unit has been stored or transported in a very cold environment, a longer warm-up is recommended.

If the unit has recently been switched off after having been on for a sufficient warm-up period, or if the user decides for some other reason that he cannot wait the full 15 minutes, it is possible to proceed directly to ventilator connection and testing (Sections 3.5 and 3.6). If the unit has not been warmed up sufficiently, however, test results may not be accurate. To bypass the warm-up period, press ESCAPE, then ZERO, and go to the next step.

At the end of the warm-up period, the display shown in the next step will appear automatically.

27. The following message should now appear:

PLEASE ZERO THE TRANSDUCERS ____________________ Vent the lung to atmosphere; then press ZERO.

Make sure the lungs are vented to atmosphere. If patient tubing is connected to the lung, disconnect it.

28. Press ZERO. The message TRANSDUCERS ZEROED should appear, followed by SELECT TEST.

29. Proceed to Section 3.5: Connecting the ventilator to the Model VT-1B or VT-2 lung. If you have already properly connected the ventilator, proceed to Section 3.6: Ventilator Tests.

Any or all of the user-programmable parameters can be changed at any time by following the sequence of steps below:

1. Press ESCAPE.

2. Press CHANGE SET-UP to enter the set-up sequence.

3. Press PROMPT AHEAD repeatedly to page through to the parameter you wish to change.

4. Make the desired change.

5. Press PROMPT AHEAD to continue through the sequence to make other changes, proceed to Step 6, below.

6. Press ESCAPE to exit from the sequence entirely.

3.4 Setting Up the Models VT-1B and VT-2 for Computer Control Applications

The Model VT-1B Adult Ventilator Tester and the Model VT-2 Adult/Infant Ventilator Tester have computer control capability (provided by the bi-directional RS232). After switching the testers ON, either the tester front panel keys or specified keys on a computer can be used to control or access information from the tester during: SET-UP, TEST, and MONITOR modes. All readings appearing on the tester display also appear automatically on the computer screen so that it is not necessary to press the PRINT function key. The waveforms displayed on the Models VT-1B and VT-2, however, cannot be displayed on the computer screen.

Table 3.4-1 gives pertinent information about the ventilator tester computer control feature as well as the data communication protocol required. Table 3.4-2 identifies the computer keyboard input commands and the waveform monitor modes.

You are now ready to set up the ventilator test parameters. If this is the first time you have used a Bio-Tek Ventilator Tester, please read Section 2: Models VT-1B and VT-2 Description, to learn the location and function of all of the components. If you are ready to begin operating the unit, proceed to Section 3.5.

Table 3.4-1. Data Communication Protocol and Computer Control Requirements

DATA COMMUNICATION PROTOCOL

Baud Rate	=	2400	**Parity**	=	0
Receiving Port	=	1	**Data Bits**	=	8
Transmitting Port	=	1	**Stop Bits**	=	1

COMPUTER CONTROL REQUIREMENTS

RS232 Port: IBM PC compatible, 25-pin D-type female connector.
Cable: RS232 25-pin D-type male-female (Bio-Tek part #75004)
Program: Use any Asynchronous/Serial Communications program (e.g., MESSAGE, Q-MODEM, CROSSTALK)

Table 3.4-2. Computer Keyboard Input Commands and Waveform Monitor Modes

COMPUTER KEYBOARD INPUT COMMANDS

Keyboard	VT-1B/VT-2	Keyboard	VT-1B/VT-2
	TOP LINE		NUMERICAL SECTION (Light Grey Area)
Q	ESCAPE	I	CLEAR
Z	ZERO	E	ENTER
K	CHANGE SET-UP	0	NUMBER 0
R	OPTION	1	NUMBER 1
T	PROMPT FORWARD	2	NUMBER 2
B	PROMPT BACK	3	NUMBER 3
P	PRINT	4	NUMBER 4
		5	NUMBER 5
	TEST MODES	6	NUMBER 6
		7	NUMBER 7
S	STATUS TEST	8	NUMBER 8
F	FULL TEST	9	NUMBER 9
N	AUTO REPEAT		
A	ASSIST TEST		
C	LEAK/COMP TEST		
M	TREND TEST		

WAVEFORM MONITOR MODES

V	VOLUME	J	AIR FLOW
L	LUNG PRESSURE	H	EXT. PRESSURE
G	AIRWAY PRESSURE	O	EXT. FLOW

3.5 Connecting the Ventilator to the Model VT-IB or VT-2 Lung

NOTE: The Model VT-IB or VT-2 cannot test high frequency (>75 BPM) ventilators or Jet ventilators; however, the testers will display readings, although their accuracies cannot be guaranteed.

Follow the sequence of steps below to connect the ventilator to be tested to the Model VT-IB or VT-2 lung <u>before turning on the ventilator:</u>

1. Connect the patient tubing circuit to the ventilator as required.
2. Remove the breathing mask from the patient-Y of the patient tubing circuit.
3. **IT IS RECOMMENDED TO ATTACH A STANDARD BACTERIA FILTER TO THE PA TIENT- Y TO AVOID CROSS-CONTAMINATION BETWEEN VENTILATORS.**
4. If you will be following a ventilator manufacturer's test protocol that does not call for any airway restrictor to be used with a lung model, select a connector piece having a 15mm outer diameter at both ends and a length comparable to that of the parabolic airway restrictors.
5. If you are not following such a protocol, select one of the parabolic airway restrictors (R_{p500}, R_{p200} ,R_{p50}, R_{p20}, and R_{p5}) from the accessories box. The restrictor values are given in cmH_2O/liter/ minute. Refer to Table 3.3-1 for simulated patient conditions. Parabolic restrictor pressure drops are provided in Section 2, Table 2.4.1-1.
6. Refer to the Figure 3.5-1 for an illustration of the restrictor and patient-y connection. Refer to this illustration to perform the following Steps 7 through 10.
7. Pull out the sliding adapter on the front of the Model VT-IB or VT-2 adult lung as far as it will go. It should pull out far enough to allow the parabolic airway restrictor or 15 mm connector to fit into the airway inlet.
8. Insert either end of the parabolic airway restrictor or 15 mm connector into the airway inlet.
9. Push in the sliding adapter until the resistor's center is flush inside of the adult lung front inlet (i.e., so that it is snugly connected to the parabolic airway restrictor or 15 mm connector).
10. Connect the patient-y to the sliding adapter.
11. Select the desired settings on the ventilator and switch it on. <u>DO NOT SWITCH ON THE VENTI LATOR HUMIDIFIER.</u>
12. Proceed to Section 3.6 to test the ventilator.

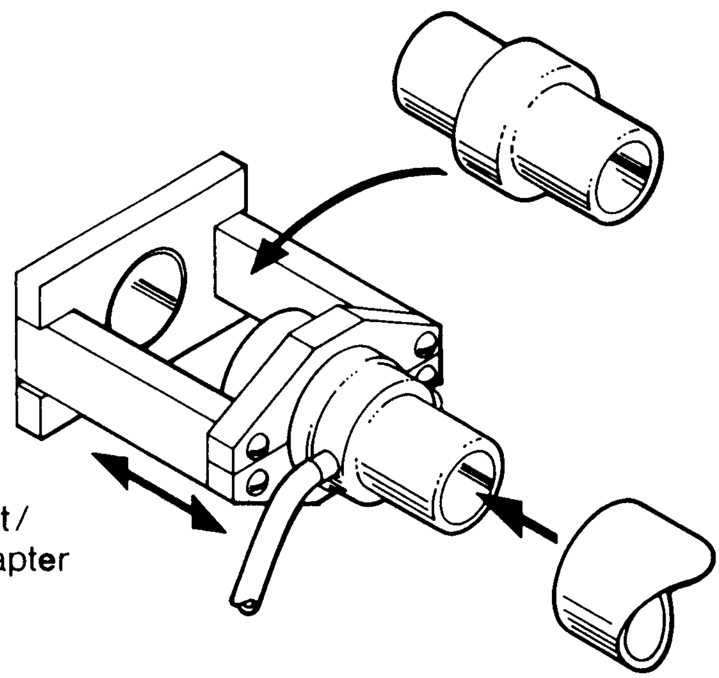


Figure 3.5-1. Restrictor and Patient-Y Connection

3.6 Ventilator Tests

This section describes the various test and monitor modes and available for the Models VT-1B and VT-2:

3.6.1 Status test
3.6.2 Full test
3.6.3 Auto-repeat full test
3.6.4 Trend test
3.6.5 Assist test
3.6.6 Leak and compliance tests

- 3.6.6.1 Model VT-1B or VT-2 lung leak test
- 3.6.6.2 Patient tubing leak test
- 3.6.6.3 Patient tubing compliance test
- 3.6.6.4 Ventilator + patient tubing compliance test

3.6.7 Waveform monitor tests

- 3.6.7.1 Volume waveform monitor
- 3.6.7.2 Airway pressure waveform monitor
- 3.6.7.3 Lung pressure waveform monitor
- 3.6.7.4 Air flow waveform monitor

3.6.8 External tests

- 3.6.8.1 External pressure test
- 3.6.8.2 External flow test

NOTE: The tests described in Sections 3.6.1 through 3.6.6 are performed by pressing the test mode keypads on the left side of the Model VT-1B or VT-2 front panel (STATUS TEST, ASSIST TEST, FULL TEST, LEAK TEST, AUTO REPEAT, TREND TEST). The tests described in Sections 3.6.7 and 3.6.8 are performed by pressing the waveform pads on the right side of the Model VT-1B or VT-2 front panel (VOLUME, LUNG PRES, AIRWAY PRES, AIR FLOW, EXT PRES, EXT FLOW).

After 3 synchronizing breaths, the Model VT-1B or VT-2 should produce an audible tone at the start of the inspiratory phase of each breath detected in all test modes except the leak and compliance tests. <u>If the tone occurs at some other point in the breath cycle, the Model VT-1B or VT-2 is not triggering properly and readings may be erroneous</u>. Should this occur:

1. Press ESCAPE.
2. Press ZERO. The following message should appear:

PLEASE ZERO THE TRANSDUCERS ——————————— Vent the lung to atmosphere; then press ZERO.

3. Unhook the patient-Y from the sliding adapter on the Model VT-1B or VT-2 lung.
4. Wait until the lung plate comes to rest.

5. Press ZERO. The message TRANSDUCERS ZEROED should appear, followed by SELECT TEST.

6. Reconnect the patient-Y.

7. Press the desired test pad to resume testing.

8. If the unit still appears not to be triggering properly and the unit has been warmed up for the minimum recommended 15 minutes, call: 1-800-451-5172 (Customer Service) or 1-800-24-BIOTK (Service Hotline) for help.

It may be convenient to begin testing by adjusting the Model VT-1B or VT-2 and the ventilator under test to simulate *normal* breathing in a *normal* patient. Appropriate values are given in Table 3.6-1. Parameters that can be measured for each of the available modes are shown in the Table 2.3-1 in the Specifications Section.

Table 3.6-1. Settings for Simulated *Normal* Breathing in a *Normal* Patient

	ADULT	INFANT	PEDIATRIC
Model VT-1B or VT-2			
Compliance (L/cmH_2O)	0.05	0.003	0.01
Resistance (R_p)	20	50	20
Ventilator			
Tidal volume	800 mL	50 mL	250 mL
Rate	10 BPM	30 BPM	20 BPM
I:E	1:1.5	1:2.33	1:2

The following items should be remembered when beginning the testing of a ventilator with the Model VT-1B or VT-2:

1. You may get erroneous readings if the PEEP setting on a ventilator is changed *after* selecting any test or if any control on the ventilator is changed *after* selecting a test other than STATUS TEST on the Model VT-1B or VT-2.

2. A ventilator may take some time before delivering the output specified on its control settings. It is recommended to wait 5-to-10 breaths before connecting the ventilator output to the Model VT-1B or VT-2 Ventilator Tester.

3. Unless default values are changed during set-up, minute volume is given in BTPS; other volume and flow readings are given in NTPD.

4. There is continuous analog output (uncompensated) of volume, airway pressure, and flow waveforms for Adult settings; on-line display of waveform and tabular readings during monitor modes. There is only continuous analog output (uncompensated) for airway pressure for the Infant settings.

All volumes displayed in the automated test modes (Sections 3.6.1 through 3.6.6) are exhaled volumes. Waveform monitors (Section 3.6.7) display inhaled volumes.

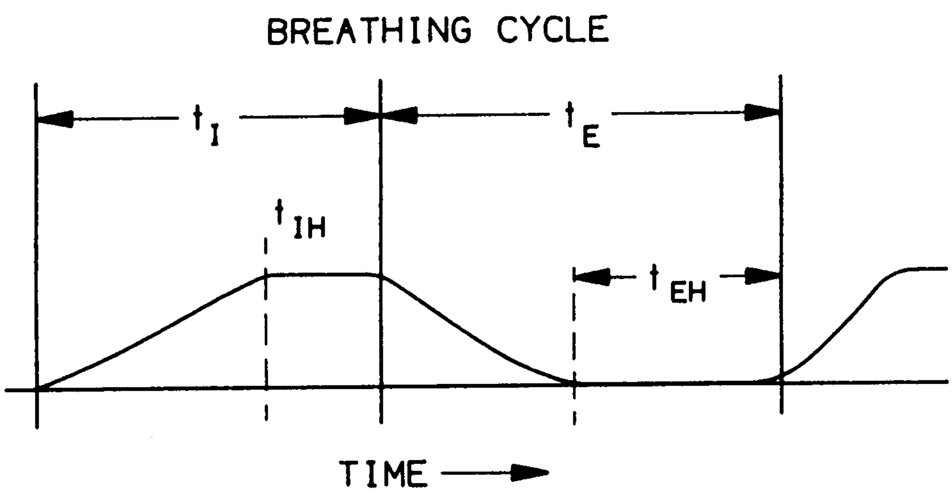


Figure 3.6-1. Breath Cycle Diagram

3.6.1 Status Test

The status test measures 4 key parameters of the ventilator:

1. Breath rate (in BPM)
2. Tidal volume (in the reference units selected)
3. Minute volume (in the reference units selected)
4. Inspiratory/expiratory (I:E) ratio.

Both volumes measured are exhaled volumes.

The status test can be used as a reference in setting the ventilator controls before performing more extensive tests (such as OVP's) or before connecting the ventilator to a patient.

To perform a status test:

1. Make sure you have completed the procedures defined in Sections 3.3 and 3.4.
2. Press ESCAPE if SELECT TEST is not displayed.
3. Press STATUS TEST. The following message should appear:

STATUS TEST ____________________ Please wait while two breaths are sampled.

This message will remain on the display during 2 complete breath cycles while the Model VT-1B or VT-2 determines the sampling rate and collects raw data. At the start of the third breath cycle, the following data should be displayed:

```
STATUS TEST
________________________________________

Breath Rate     =  aa.a BPM
Tidal Volume    =  b.bbb L [reference units]
Minute Volume   =  cc.cc L [reference units]
I:E Ratio       =  d: d.d  [or d.d: d)
```

where:

aa.a = breath rate, in breaths per minute

b.bbb = tidal volume, in reference units for "other volume and flow" measurements selected by user in latest set-up

cc.cc = minute volume, in reference units for minute volume selected by user in latest set-up

d: d.d = inspiratory/expiratory ratio

or

d.d: d = expiratory/inspiratory ratio.

The display will be updated at the start of the inspiratory phase of each subsequent breath.

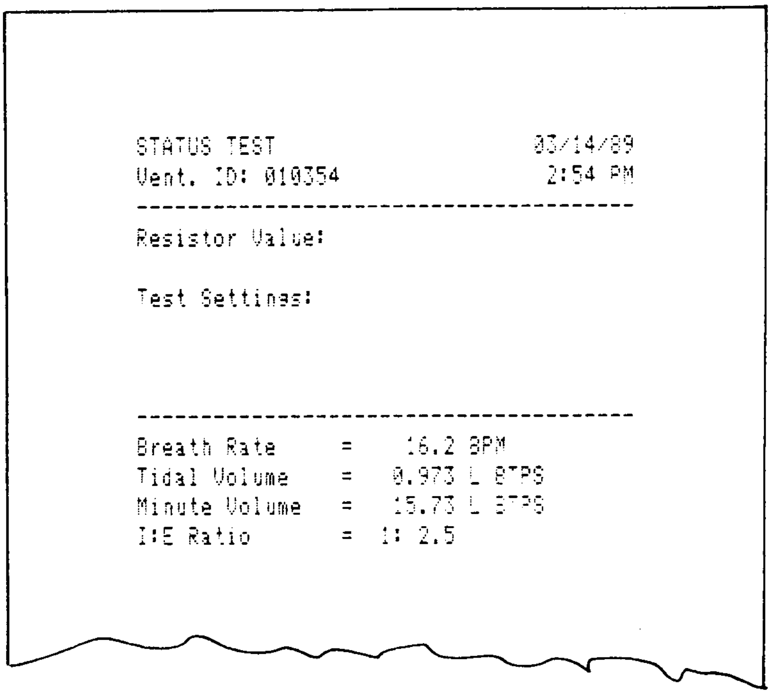
Do not change the positive end expiratory pressure setting on the ventilator after pressing STATUS TEST.

NOTE: To test at different PEEP levels, press ESCAPE, change ventilator settings, wait until ventilator has delivered a few breaths, and then press STATUS.

4. Press PRINT at any time, if desired. The data printed will be the data appearing on the display at the time PRINT is pressed. This may be repeated as often as desired.

NOTE: If a computer is connected, the same message will appear on the computer screen.

A sample status test printout is shown Figure 3.6.1-1.



```
STATUS TEST                          03/14/89
Vent. ID: 010354                      2:54 PM
---------------------------------------------
Resistor Value:

Test Settings:



---------------------------------------------
Breath Rate     =    16.2 BPM
Tidal Volume    =   0.973 L BTPS
Minute Volume   =   15.73 L BTPS
I:E Ratio       =  1: 2.5
```

Figure 3.6.1-1. Status Test Printout

Manually record the parabolic resistor value and ventilator settings in the spaces provided for that purpose on the printout.

5. Press ESCAPE at any time to exit from the status test.

   NOTE: This test can also be used to measure SIGH Volumes: If the manual sigh control on the ventilator is pressed, the tidal volume reading on the VT-1B/VT-2 will correspond to the sigh volume.

3.6.2 Full Test

The full test provides the user with detailed information on the performance of the ventilator for a given set of ventilator control settings. By performing a series of full tests and varying the ventilator settings from test to test, the user can obtain data to analyze ventilator performance throughout a spectrum of clinical patient conditions.

For each full test the following ventilator parameters are calculated and displayed:

1. Breath rate
2. Inspiratory/expiratory (I:E) ratio
3. Inspiration time
4. Inspiration hold time
5. Expiration time
6. Expiration hold time
7. Cycle time
8. Tidal volume (exhaled)*
9. Minute volume (exhaled)*
10. Peak airway pressure+
11. Peak lung pressure+
12. End expiration pressure+
13. Mean pressure/cycle +
14. Inspiratory flow rate*
15. Expiratory flow rate*

---

* in reference units selected

\+ in pressure units selected, positive or negative values

To perform a full test:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a status test (Section 3.6.1) is also recommended.
2. Press ESCAPE if SELECT TEST is not displayed.
3. Attach the ventilator to be tested to the Model VT-1B or VT-2 Airway Inlet/Sliding Adapter.

4. Turn the ventilator on.

5. Press FULL TEST. The following message should appear:

> FULL TEST
>
> ---
>
> Please wait. Data will be
> displayed after 4 breaths.

This message will remain on the display while the Model VT-1B or VT-2 performs the following:

a. The Model VT-1B or VT-2 uses the first 2 complete breath cycles to determine the sampling rate and collect the raw data.

b. The Model VT-1B or VT-2 then calculates all readings during the 2 subsequent breaths.

Values measured or calculated for the parameters given above are then output in stages of 4 displays. The first display "page" shows the first 4 parameters. The user may then step through the subsequent display "pages" by pressing PROMPT AHEAD.

Do not change any ventilator setting after pressing FULL TEST, until the readings are displayed.

6. The readings are not updated as they are in the status test. To obtain new data:

a. Reset the ventilator controls as desired.

b. Return to Step 2, preceding.

7. Press PRINT if desired while viewing any of the displays.

NOTE: Data will be automatically output via the RS232 port if a computer is used.

A sample full-test printout is shown in Figure 3.6.2-1.

```
FULL TEST                               03/14/89
Vent. ID: 010354                         2:55 PM
--------------------------------------------------
Resistor Value:

Test Settings:


--------------------------------------------------
Compliance = .05
Atmos. Pressure = 760 mmHg
R.H.  = 50 %
Gas Temperature = 25 deg C
--------------------------------------------------
Breath Rate      =    16.0 BPM
I:E Ratio        =  1: 2.6
Tidal Volume     =   0.977 L BTPS
Minute Volume    =   15.67 L BTPS
Insp. Time       =     1.0 Seconds
Insp. Hold       =     0.0 Seconds
Expir. Time      =     2.7 Seconds
Expir. Hold      =     0.0 Seconds
Cycle Time       =     3.7 Seconds
Peak Airway Pr. =    35.2 cmH2O
Peak Lung Pr.    =    20.0 cmH2O
End Expir. Pr.   =     0.2 cmH2O
Mean Airway Pr. =     7.9 cmH2O
Insp. Flow       =      56 LPM BTPS
Exp. Flow        =      22 LPM BTPS
```

Figure 3.6.2-1. Full Test Printout

Manually record the parabolic resistor value and ventilator settings in the spaces provided for that purpose on the printout.

8. Press ESCAPE at any time to exit from the full test.

3.6.3 Auto Repeat

The full test auto-repeat mode is used when it is desired to have a full test repeated automatically at specific time intervals. It is useful for monitoring drift of ventilator performance during burn-in, endurance testing, and for investigating intermittent ventilator problems.

To begin a full test in the auto-repeat mode:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a status test (Section 3.6.1) is also recommended.

2. Press ESCAPE if SELECT TEST is not displayed.

3. Press AUTO REPEAT. The following message should appear:

AUTO REPEAT
Enter interval in minutes:

4. Use the numeric pads to enter the interval desired for full test, in minutes (5 to 120). If you make a mistake, press CLEAR and re-enter.

5. Press ENTER. The Model VT-1B or VT-2 will then operate in full test mode (see Section 3.6.2), automatically performing a full test, printing out the test results, and outputting data via the RS232 port each time the interval elapses.

6. Press ESCAPE at any time to exit from this mode.

7. Manually record the parabolic resistor value and ventilator settings in the space provided for that purpose on the printout.

3.6.4 Trend Test

NOTE: This test can be used to test sighs.

The TREND TEST is used to monitor any Tidal Volume variation above or below a prescribed limit. It is useful for monitoring performance based on delivered volume and for obtaining data *only* when such a variation occurs.

To begin a TREND TEST:

1. Make sure you have completed the procedures defined in Sections 3.4 through 3.6.

2. Select desired ventilator settings; connect patient tubing to VT-airway inlet; and operate ventilator until its output stabilizes (determine by using status test).

3. Press ESCAPE.

4. Press TREND TEST. The following message will appear on the display:

```
TREND TEST
Enter T.V. % Variation:
________________________

Use numeric keys to enter value.
Use PROMPT key to advance.
```

5. Use the appropriate numeric keys to enter the desired % Tidal Volume variation (from 3 to 100%). Press CLEAR to re-enter the value if you made a mistake and entered an invalid value.

6. Press ENTER. The tester will operate in the TREND mode and use the first 2 breaths to sample, process, display, and print the reference readings (as in the FULL TEST). The unit then monitors each breath and prints out the % Tidal Volume variation value and FULL TEST readings if a breath is equal to or greater than the desired Tidal Volume variation.

7. Press PRINT if desired. The data printed will be the data appearing on the display at the time PRINT is pressed. Data will be automatically output via the RS232 port if a computer is attached.

8. Press ESCAPE to exit from the TREND mode.

9. Manually record the resistor values and ventilator settings in the spaces provided on the printout (see Figure 3.6.4-1).

```
TREND TEST                                03/14/89
Vent. ID: 010354                           2:58 PM
--------------------------------------------------
Resistor Value:

Test Settings:


--------------------------------------------------
Compliance = .05
Atmos. Pressure = 760 mmHg
R.H.  = 50 %
Gas Temperature = 25 deg C
--------------------------------------------------
Volume Variation =      0 %
Breath Rate      =   15.9 BPM
I:E Ratio        =   1: 1.0
Tidal Volume     =   0.970 L BTPS
Minute Volume    =   15.43 L BTPS
Insp. Time       =     1.9 Seconds
Insp. Hold       =     0.0 Seconds
Expir. Time      =     1.9 Seconds
Expir. Hold      =     0.1 Seconds
Cycle Time       =     3.8 Seconds
Peak Airway Pr.  =    35.5 cmH2O
Peak Lung Pr.    =    20.0 cmH2O
End Expir. Pr.   =     0.2 cmH2O
Insp. Flow       =      31 LPM BTPS
Exp. Flow        =      33 LPM BTPS
```

Figure 3.6.4-1. Trend Test Printout

3.6.5 Assist Test

The assist test is used to determine the sensitivity of the ventilator in patient assist mode and to calibrate the full range of assist pressures under which the ventilator can operate. See Figure 3.6.5-1 for a diagram of the difference between a *normal* breath and an assisted breath.

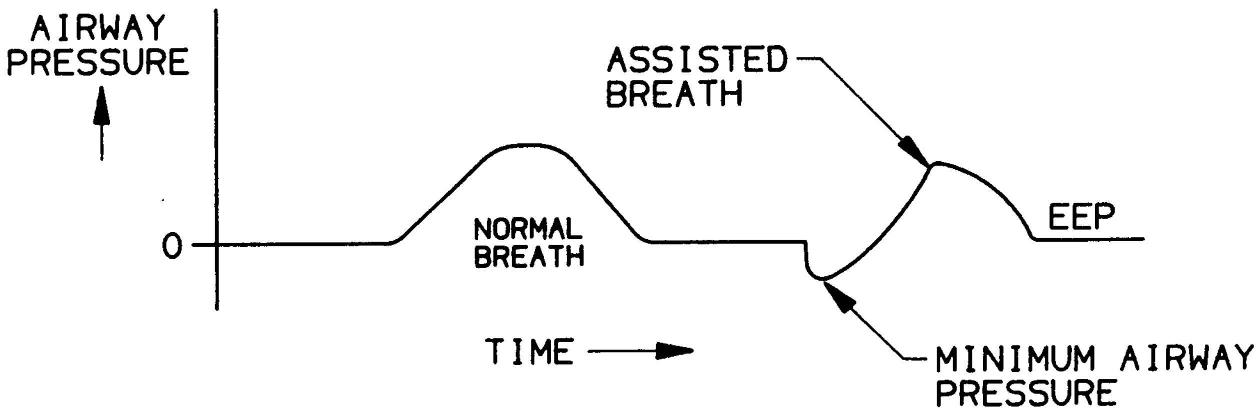


Figure 3.6.5-1. Normal versus Assisted Breaths

3.6.5.1 Assist Test with Adult Lung

To perform an assist test:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a status test (Section 3.6.1) is also recommended.

2. Adjust the ventilator controls so that an effort (negative pressure) at the lung during the expiration hold period of the ventilator's breath cycle will trigger the ventilator.

   NOTE: Use the Synchronized Intermittent Mandatory Ventilation (SIMV) mode or Intermittent Demand Ventilation (IDV) mode if the ventilator provides it.

   You will need to test the control setting by applying upward force at the back of the Model VT-1B or VT-2 lung plate and observing if the ventilator triggers as desired. Set a low breath rate to allow the distinction to be made between a triggered assist breath and a mandatory breath (see Figure 3.6.5-1).

You may wish to attach an external, motor-driven cam system, or pneumatic actuator to the top plate to carry out a more repeatable performance study, such as to determine the work of breathing.

3. Press ESCAPE if SELECT TEST is not displayed.

4. Press ASSIST TEST. The following display should appear:

```
ASSIST TEST
________________________
Please wait while two
breaths are sampled.
```

5. Allow 2 breaths to be generated. Then gently lift the back of the lung top plate during the expiratory hold period in a smooth, steady pull to create negative pressure. The absolute value of the negative pressure generated must be less than 15 cmH_20 to avoid error. Repeat several times using different forces to approximate the minimum patient effort required to trigger the ventilator.

The Model VT-1B or VT-2 will monitor airway pressure during the inspiration and expiration hold phases of each breath cycle and will calculate and display the following:

```
ASSIST TEST
________________________________
End Expir. Pr.  =  xxx.x [cmH2O or mmHg]
Min. Airway Pr. =  yyy.y [cmH2O or mmHg]
Assist Pressure =  zzz.z [cmH2O or mmHg]
```

where:

xxx.x = end expiratory pressure (EEP)
yyy.y = minimum airway pressure (APmin)
zzz.z = assist pressure (EEP - APmin)

All pressures are displayed in the pressure units selected by the user in the latest set-up. These values are updated at the end of each breath cycle.

6. Press PRINT at any time if desired. The data printed will be the data appearing on the display at the time PRINT is pressed. Pressing PRINT will automatically output this data via the RS232 port.

   A sample assist test printout is shown Figure 3.6.5.1-1.

   Manually record the parabolic resistor value and ventilator settings in the spaces provided for that purpose on the printout.

7. Press ESCAPE at any time to exit from the assist test.

```
ASSIST TEST                         03/14/89
Vent. ID: 010354                     2:57 PM
--------------------------------------------
Resistor Value:

Test Settings:



--------------------------------------------
End Expir. Pr.  =      0.4 cmH20
Min. Airway Pr. =     -5.8 cmH20
Assist Pressure =      5.5 cmH20
```

Figure 3.6.5.1-1. Assist Test Printout

3.6.6 Leak and Compliance Tests

The leak and compliance tests can be used to determine:

1. The leak rate of the Model VT-1B and VT-2 adult lung and the Model VT-2 infant lung;
2. The leak rate of the external patient tubing circuit;
3. The compliance of the external patient tubing circuit;
4. The compliance of all attached tubing, including tubing inside the ventilator (if the ventilator design allows).

Each of these tests is described in a separate subsection:

3.6.6.1 Lung leak test
3.6.6.2 Patient tubing leak test
3.6.6.3 Patient tubing compliance test
3.6.6.4 Ventilator + patient tubing compliance test.

To perform any leak or compliance test, the user will be prompted in the display sequence to perform a leak test first, then a compliance test. This does not prevent the user from omitting one or the other test. (Refer to the following procedures.)

3.6.6.1 Lung Leak Test

To measure the leak rate of the Model VT-1B and VT-2 adult lung and Model VT-2 infant lung:

1. Make sure you have completed the procedures in Sections 3.4 through 3.6.
2. If you have not yet performed the set-up procedure (Section 3.3), do so now using a compliance value of 0.01 L/cmH_2O for the adult lung or 0.003 L/cmH_2O for the infant lung. If you have previously completed the set-up procedure but entered a compliance value other than 0.01 L/cmH_2O (adult) or 0.003 L/cmH_2O (infant):

   a. Press ESCAPE if SELECT TEST is not displayed.

   b. Press CHANGE SET-UP.

   c. Press PROMPT AHEAD until the compliance setting display appears.

   d. Press OPTION until the asterisk comes to rest next to 0.01 L/cmH_2O (adult) or 0.003 L/cmH_2O (infant).

e. Press ESCAPE.

3. Set the compliances.

   a. Set the ADULT/INFANT toggle switch to the desired position.

   b. Move the ADULT/INFANT selector lever to the desired position.

   c. Ensure that the compliance spring on the right side of the adult lung is positioned at 0.01 L/cmH_2O for the adult lung or that the compliance lever for the infant lung is positioned at 0.003 L/cmH_2O.

4. Replace the parabolic airway restrictor on the Model VT-1B or VT-2 adult lung with the R_{p5} (if it is not already in place) by pulling out the Model VT-1B or VT-2 lung sliding adapter and inserting either end of the restrictor into the airway inlet. Then push in the sliding adapter so that it is snugly connected to the restrictor.

5. Set the ventilator's respiration mode to manual.

6. Press ESCAPE if SELECT TEST is not displayed.

7. Press LEAK TEST. The following display should appear:

> LEAK/COMPLIANCE TEST
>
> ---
>
> To perform a leak test, inject some air into the lung and seal equipment to be tested.
> Press ENTER when ready.

8. Attach the ON/OFF valve to the airway inlet/sliding adapter.

9. Open the ON/OFF valve.

10. Connect the patient tubing from the ventilator to the ON/OFF valve.

11. Generate a single inspiration from the ventilator to partially fill the Model VT-1B or VT-2 lung. The inspiration should be sufficient to raise the adult lung plate about 2 inches at the back or approximately 200 mL for the infant lung.

12. Close the ON/OFF valve to trap the air in the lung.

13. Press ENTER to begin the test. The following display should appear:

```
LEAK/COMPLIANCE TEST
____________________

      Testing
```

During the next 10 to 15 seconds, the Model VT-1B or VT-2 will calculate the leak rate by taking 10 volume readings at one-second intervals. The average volume change for 5-second intervals is measured and the following data should then be displayed:

```
Leak Rate    =  0.0 LPM
Lung Pres.   =  yy.y [cmH2O or mmHg]
_______________________________________

To perform compliance test, use valve
to seal inflated lung.
      Press ENTER when ready.
```

where:

xx.x = leak rate of Model VT-1B or VT-2 lung, in LPM
yy.y = lung pressure (lung interior) at which leak rate was determined, in pressure units selected.

14. Press PRINT to record this leak rate. If you wish to determine the leak rate of the patient tubing circuit in subsequent testing, you will need to subtract the above leak rate value from the leak rate of the entire system.

The data printed will be the data appearing on the display at the time PRINT is pressed. Data will be automatically output via the RS232 port if a computer is attached.

A sample leak test printout is shown in Figure 3.6.6.1-1.

Manually record the parabolic resistor value and ventilator settings in the spaces provided for that purpose on the printout.

```
LEAK/COMPLIANCE TEST            03/14/89
Vent. ID: 010354                 3:04 PM
----------------------------------------
Resistor Value:

Test Settings:


----------------------------------------
Leak Rate      =   0.1 LPM
Lung Pres.     =  14.4 cmH20




                                 3:05 PM
----------------------------------------
Resistor Value:

Test Settings:


----------------------------------------
Leak Rate      =   0.0 LPM
Lung Pres.     =  14.2 cmH20

Compliance     =   5.0 ml/cmH20
Starting Pres. =  14.1 cmH20
Final Pres.    =  12.7 cmH20
```

Figure 3.6.6.1-1. Leak Test Printout

15. If you wish to proceed directly to a compliance test:

    a. Open the ON/OFF valve.

    b. Proceed to Step 2 of Section 3.6.6.3 or 3.6.6.4.

16. Press ESCAPE at any time to exit from the leak test.

3.6.6.2 Patient Tubing Leak Test

Use the adult lung only to find the leak rate of the external patient tubing:

1-12. Follow Steps 1 through 12 of Section 3.6.6.1.

13. Disconnect the patient tubing from the ventilator.

14. Disconnect the exhalation valve on the patient tubing if it has not already been disconnected.

15. Plug all patient tubing openings.

16. Open the ON/OFF valve.

17. Press ENTER to begin the test.

    NOTE: It is recommended to perform this test at a lung pressure that may be encountered during normal ventilation.

    The following display should appear:

```
LEAK/COMPLIANCE TEST
______________________

  Testing
```

During the next 10 to 15 seconds, the Model VT-1B or VT-2 will calculate the leak rate from volume changes at specific intervals, as well as rate of pressure drop in cmH_2O/minute.

```
Leak Rate    =  x.xx LPM
Lung Pres.   =  yy.y [cmH2O, mmHg or kPa]
_________________________________________

To perform compliance test, use
valve to seal inflated lung.
   Press ENTER when ready.
```

where:

xx.x = leak rate of patient tubing + Model VT-1B or VT-2 lung, in liters per minute

yy.y = system pressure (lung interior), in pressure units selected

These values will be continually updated.

18. Press PRINT to record this leak rate. To determine the leak rate of just the patient tubing circuit, subtract the leak rate for the Model VT-1B or VT-2 adult lung (found in the test defined in Section 3.6.6.1) from the leak rate obtained here.

    The data printed will be the data appearing on the display at the time PRINT is pressed. Data will be automatically output via the RS232 port if a computer is attached.

    A sample leak test printout is shown in Figure 3.6.6.1-1.

    Manually record the parabolic resistor value and ventilator settings in the spaces provided for that purpose on the printout.

19. If you wish to proceed directly to a compliance test:

    a. Unplug the patient tubing ends.

    b. Re-attach the patient tubing to the ventilator.

    c. Proceed to Step 2 of Section 3.6.6.3 or 3.6.6.4.

20. Press ESCAPE at any time to exit from the leak test.

3.6.6.3 Patient Tubing Compliance Test

Use the adult lung only to find the compliance of the patient tubing:

1. If you are not entering this sequence immediately after performing a leak test:

    a. Follow steps 1 through 10 of Section 3.6.6.1.

    b. Press ENTER. Wait until the leak test results appear. Ignore them.

2. Generate a single inspiration from the ventilator or partially fill the Mo... VT-1B or VT-2 adult lung. The inspiration should be sufficient to raise ... lung plate about 2 inches at the back.

3. Close the ON/OFF valve to trap the air in the Model VT-1B or VT-2 adult lung.

4. Disconnect the patient tubing from the ventilator.

5. Disconnect the exhalation valve if it has not already been disconnected.

6. Seal all patient tubing openings.

7. Press ENTER. The following display should appear:

```
LEAK/COMPLIANCE TEST
______________________________

Attach equipment to be tested to
the valve and open the valve.
     Press ENTER when ready.
```

8. Open the ON/OFF valve.

9. Press ENTER. The following display should appear:

```
LEAK/COMPLIANCE TEST
______________________________________

Compliance       =  xx.x ml/cmH2O
Starting Pres.   =  yy.y [cmH2O, mmHg, or kPa]
Final Pres.      =  zz.z [cmH2O, mmHg, or kPa]
```

where:

xx.x = compliance of patient tubing, in ml/cmH_2O

yy.y = lung pressure before opening ON/OFF valve

zz.z = lung pressure after opening ON/OFF valve

NOTE: It is recommended to perform this test at a lung pressure that may be encountered during normal ventilation.

10. Press PRINT if desired. The data printed will be the data appearing on the display at the time PRINT is pressed. Data will be automatically output via the RS232 port if a computer is attached.

    A sample compliance test printout is shown in Figure 3.6.6.3-1.

11. Press ESCAPE at any time to exit from the compliance test.

```
LEAK/COMPLIANCE TEST              03/14/89
Vent. ID: 010354                   3:04 PM
------------------------------------------
Resistor Value:

Test Settings:


------------------------------------------
Leak Rate       =   0.1 LPM
Lung Pres.      =  14.4 cmH20






                                   3:05 PM
------------------------------------------
Resistor Value:

Test Settings:


------------------------------------------
Leak Rate       =   0.0 LPM
Lung Pres.      =  14.2 cmH20

Compliance      =   5.0 ml/cmH20
Starting Pres.  =  14.1 cmH20
Final Pres.     =  12.7 cmH20
```

Figure 3.6.6.3-1. Compliance Test Printout

3.6.6.4 Ventilator + Patient Tubing Compliance Test

This test can be performed only on a ventilator having a closed internal tubing circuit.

To find the compliance of the entire patient tubing circuit, including tubing inside the ventilator:

1. If you are _not_ entering this sequence immediately after performing a leak test:

    a. Follow Steps 1 through 10 of Section 3.6.6.1.

    b. Press ENTER. Wait until the leak test results appear. Ignore these readings.

2. Generate a single inspiration from the ventilator to partially fill the Model VT-1B or VT-2 adult lung. The inspiration should be sufficient to raise the lung plate about 2 inches at the back.
3. Close the ON/OFF valve to trap the air in the Model VT-1B or VT-2 adult lung.
4. Disconnect the expiration tube of the patient tubing from the ventilator end.
5. Disconnect the exhalation valve and seal the expiration tube at the ventilator end.
6. Seal all remaining patient tubing openings.
7. Press ENTER. The following display should appear:

```
LEAK/COMPLIANCE TEST
______________________________

Attach equipment to be tested to
the valve and open the valve.
     Press ENTER when ready.
```

8. Open the ON/OFF valve and press ENTER. The following display should appear:

```
LEAK/COMPLIANCE TEST

________________________________________

Compliance       = xx.x ml/cmH2O
Starting Pres.   = yy.y [cmH2O, mmHg, or kPa]
Final Pres.      = zz.z [cmH2O, mmHg, or kPa]
```

where:

xx.x = compliance of ventilator + patient tubing, in ml/cmH_2O

yy.y = lung pressure before opening ON/OFF valve in units selected

zz.z = lung pressure after opening ON/OFF valve in units selected

9. Press PRINT if desired. The data printed will be the data appearing on the display at the time PRINT is pressed. Data will be automatically output via the RS232 port if a computer is attached.

   A sample compliance test printout is shown in Figure 3.6.6.3-1.

   Manually record the parabolic resistor value and ventilator settings in the spaces provided for that purpose on the printout.

10. Press ESCAPE at any time to exit from the compliance test.

3.6.7 Waveform Monitor Tests

The Model VT-1B or VT-2 allows the user to monitor waveforms of the following parameters:

1. Volume (inhaled)
2. Airway pressure (measured at the Model VT-1B or VT-2 airway inlet)
3. Lung pressure (measured inside the Model VT-1B or VT-2 lung)
4. Air flow (from differentiating the volume readings)

Each of these waveform monitors is described in a separate subsection:

3.6.7.1 Volume waveform monitor
3.6.7.2 Airway pressure waveform monitor
3.6.7.3 Lung pressure waveform monitor
3.6.7.4 Air flow waveform monitor

1. The waveform monitors are accessed by pressing the keypads on the right side of the Model VT-1B or VT-2 front panel: VOLUME, AIRWAY PRES, LUNG PRES and AIR FLOW.

2. Corresponding graphic waveforms are displayed on the screen, when a keypad is pressed for the first time.

3. The graphic waveform displays are not in real time; they are generated from calculations made be internal software and may be up to 2 breath cycles behind.

4. There is no RS232 or printer output at any time for any of the waveforms that are displayed, although if PRINT key is pressed during this mode, the numeric equivalent values will be printed out instead of the waveform.

5. If the previously selected keypad is pressed a second time, the tester displays instantaneous, maximum, and minimum numeric values of the corresponding waveform.

   NOTE: These readings are available via the RS232 and printer ports if the PRINT key is depressed.

3.6.7.1 Volume Waveform Monitor

To monitor the volume delivered by a ventilator:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a status test (Section 3.6.1) is also recommended.

2. Set the ventilator controls as desired.

3. Press ESCAPE if SELECT TEST is not displayed.

4. Press VOLUME. The graphic display shown in Figure 3.6.7.1-1 should appear

   NOTE: The graphic display may vary slightly from the display depicted herein depending on the type of ventilator being tested.

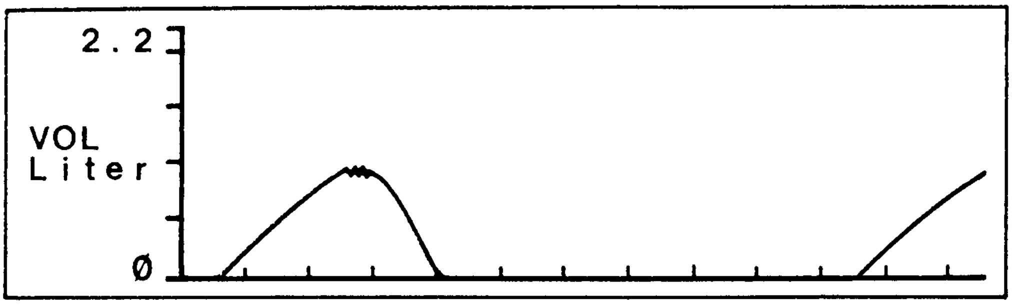


Figure 3.6.7.1-1 Volume Waveform Display

The axes will appear immediately and the waveform will be generated after 2 breaths are detected. A new waveform will be generated every second breath. The x-axis will rescale to allow at least one complete breath to appear, with each division representing 0.5 second. The vertical axis will remain fixed at a maximum 2.2 L for the adult lung and a maximum 0.2 L for the infant lung.

5. Re-press VOLUME for tabular display of real-time instantaneous volume, tidal volume, and baseline volume.

Volume	=	instantaneous volume reading
Tidal Volume	=	maximum volume measured during the test
Baseline Volume	=	volume in lung at atmospheric pressure or volume due to PEEP.

The following display should appear:

VOLUME MONITOR

Volume	=	x.xx L [reference units]
Tidal Volume	=	y.yy L [reference units]
Baseline Volume	=	z.zz L [reference units]

6. Press VOLUME again to return to the graphic display.

7. Press PRINT at any time for a printout of numeric data in tabular form. Tidal and Baseline volumes will be printed. Pressing PRINT while viewing a graph will result in a printout of numeric data corresponding to the last complete breath analyzed; graphs cannot be printed. If a computer is attached, numeric data will be automatically transferred via the RS232 port.

   A sample volume monitor printout is shown in Figure 3.6.7.1-2.

   Manually record the parabolic resistor value and ventilator settings in the space provided for that purpose on the printout.

```
VOLUME MONITOR                          03/14/89
Vent. ID: 010354                         3:00 PM
--------------------------------------------------
Resistor Value:

Test Settings:


--------------------------------------------------
Volume          =   0.022 L BTPS
Tidal Volume    =   0.983 L BTPS
Baseline Volume =   0.019 L BTPS
```

Figure 3.6.7.1-2. Volume Monitor Printout

8. Press ESCAPE at any time to exit from waveform monitoring.

   NOTE: If, without *any* input to either of the lungs, you notice a reading other than zero values on the top instantaneous line, the transducers need to be re-zeroed. Press ESCAPE, then press ZERO twice with no input to the lungs. Return to the mode you were in.

3.6.7.2 Airway Pressure Waveform Monitor

To monitor airway pressure:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a STATUS test (Section 3.6.1) is also recommended.
2. Adjust the ventilator as desired.
3. Press ESCAPE if SELECT TEST is not displayed.
4. Press AIRWAY PRES. The graphic display shown in Figure 3.6.7.2-1 should appear.

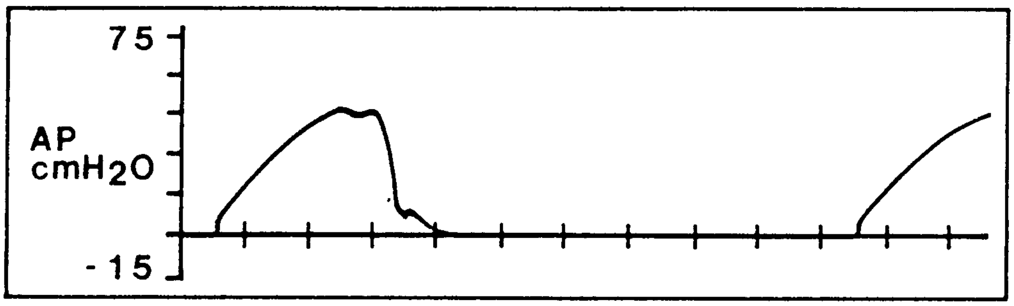


Figure 3.6.7.2-1. Airway Pressure Waveform Display

The axes will appear immediately; the waveform will be generated after 2 breaths are detected. A new waveform will be generated every second breath. The x-axis will rescale to allow at least one complete breath to appear, with each division representing 0.5 second. The vertical axis will remain fixed between -15 to 75 cmH_2O.

5. Re-press AIRWAY PRES for tabular display of real-time instantaneous lung pressure and the maximum and minimum lung pressures measured during the test. The following display should appear:

```
AP MONITOR
______________________________________
Airway Pressure      =  xx.x [pressure units]
Max Airway Pres.     =  yy.y [pressure units]
Min Airway Pres.     =  zz.z [pressure units]
```

NOTE: The minimum Airway Pressure corresponds to any PEEP in the system.

6. Press AIRWAY PRES again to return to the graphic display.

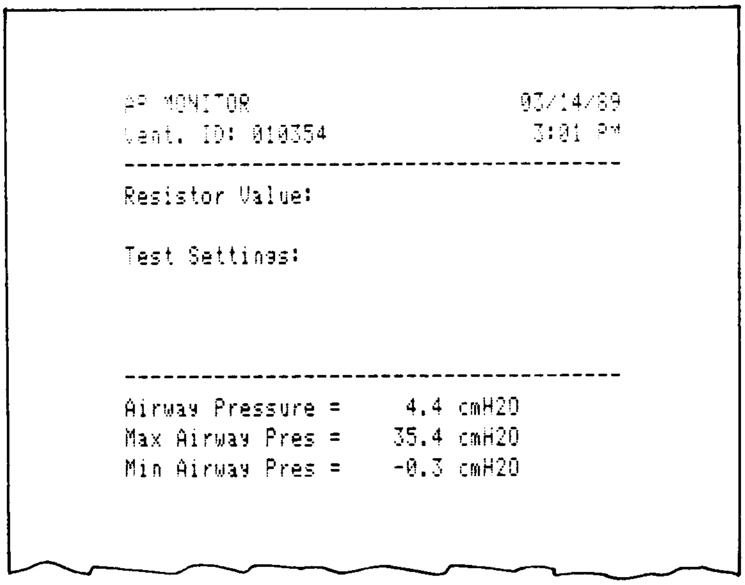
7. Press PRINT at any time for a printout of numeric data in tabular form. Maximum and minimum pressures will be printed. Pressing PRINT while viewing a graph will result in a printout of numeric data corresponding to the last complete breath analyzed; graphs cannot be printed. If a computer is attached, data will be automatically transferred via the RS232 output.

   NOTE: If, without *any* input to either of the lungs, you notice a reading other than zero values on the top instantaneous line, the transducers need to be re-zeroed. Press ESCAPE, then press ZERO twice with no input to the lungs. Return to the mode you were in.

   A sample airway pressure monitor printout is shown in Figure 3.6.7.2-2.

   Manually record the parabolic resistor value and ventilator settings in the space provided for that purpose on the printout.

8. Press ESCAPE at any time to exit from waveform monitoring.



```
AP MONITOR                           03/14/89
Vent. ID: 010354                      3:01 PM
---------------------------------------------
Resistor Value:

Test Settings:



---------------------------------------------
Airway Pressure =     4.4 cmH2O
Max Airway Pres =    35.4 cmH2O
Min Airway Pres =    -0.3 cmH2O
```

Figure 3.6.7.2-2. Airway Pressure Monitor Printout

3.6.7.3 Lung Pressure Waveform Monitor

To monitor lung pressure:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a status test (Section 3.6.1) is also recommended.
2. Adjust the ventilator as desired.
3. Press ESCAPE if SELECT TEST is not displayed.
4. Press LUNG PRES. The graphic display shown in Figure 3.6.7.3-1 should appear:

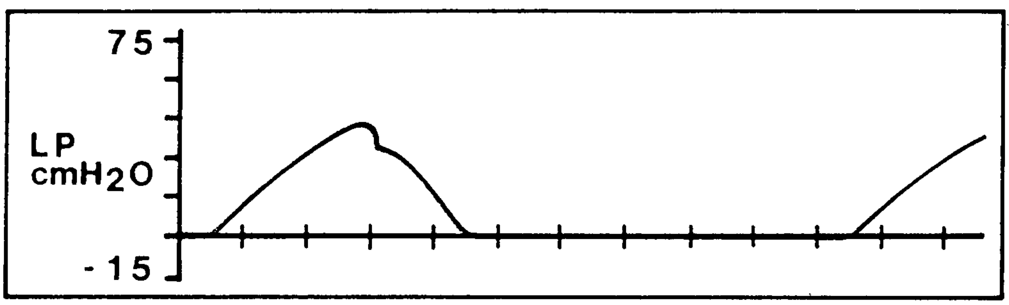


Figure 3.6.7.3-1. Lung Pressure Waveform Display

The axes will appear immediately; the waveform will be generated afte breaths are detected. A new waveform will be generated every second breath. The x-axis will rescale to allow at least one complete breath to appear with each division representing 0.5 second. The vertical axis will remain fixed between -15 to 75 cmH_2O.

5. Re-press LUNG PRES for tabular display of real-time instantaneous lung pressure and maximum and minimum lung pressures measured during the test. The following display should appear:

```
LP MONITOR
_______________________________________

Lung Pressure   =  xx.x [pressure units]
Max. Lung Pres. =  yy.y [pressure units]
Min. Lung Pres. =  xx.x [pressure units]
```

NOTE: The minimum Lung Pressure will correspond to PEEP in the system.

6. Press LUNG PRES again to return to the graphic display.

7. Press PRINT at any time for a printout of numeric data in tabular form. Maximum and minimum pressures will be printed. Pressing PRINT while viewing a graph will result in a printout of numeric data corresponding to the last complete breath analyzed; graphs cannot printed. If a computer is attached, data will be automatically transferred via the RS232 output.

A sample lung pressure monitor printout is shown in Figure 3.6.7.3-2.

```
LP MONITOR                      03/14/89
Vent. ID: 010354                 3:00 PM
----------------------------------------
Resistor Value:

Test Settings:


----------------------------------------
Lung Pressure   =    14.8 cmH2O
Max. Lung Pres. =    20.3 cmH2O
Min. Lung Pres. =    -0.3 cmH2O
```

Figure 3.6.7.3-2. Lung Pressure Monitor Printout

Manually record the parabolic resistor value and ventilator settings in the space provided for that purpose on the printout.

8. Press ESCAPE at any time to exit from waveform monitoring.

   NOTE: If, without *any* input to either of the lungs, you notice a reading other than zero values on the top instantaneous line, the transducers need to be re-zeroed. Press ESCAPE, then press ZERO twice with no input to the lungs. Return to the mode you were in.

3.6.7.4 Air Flow Waveform Monitor

To monitor the air flow to the lung:

1. Make sure you have completed the procedures defined in Sections 3.3 through 3.4. Completion of a status test (Section 3.6.1) is also recommended.

2. Adjust the ventilator as desired.

3. Press ESCAPE if SELECT TEST is not displayed.

4. Press AIR FLOW. The graphic display in Figure 3.6.7.4-1 should appear:

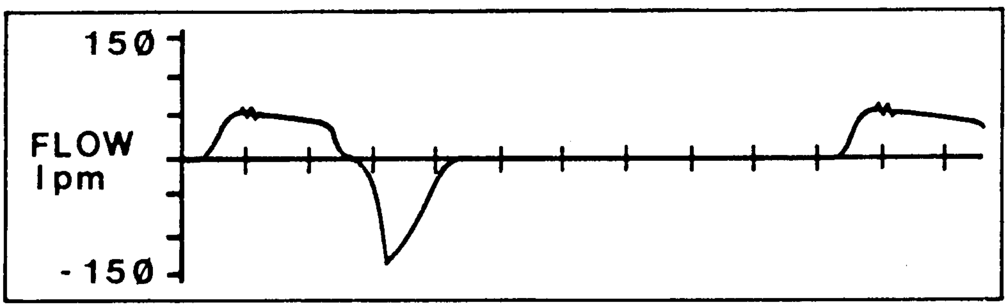


Figure 3.6.7.4-1. Air Flow Waveform Display

The axes will appear immediately; the waveform will be generated after 2 breaths are detected. A new waveform will be generated every second breath. The x-axis will rescale to allow at least one complete breath to appear, with each division representing 0.5 second. The vertical axis will remain fixed between -150 to +150 LPM for adult and between -100 to +100 LPM for infant.

5. Re-press AIR FLOW for tabular display of real-time instantaneous flow rate and maximum and minimum flow rates measured during the test.

   The following display should appear:

```
FLOW MONITOR

______________________________________

Flow Rate          = xxx LPM [reference units]
Insp. Flow Rate    = yyy LPM [reference units]
Exp. Flow Rate     = zzz LPM [reference units]
```

6. Press AIR FLOW again to return to the graphic display.

7. Press PRINT at any time for a printout of numeric data in tabular form. Pressing PRINT while viewing a graph will result in a printout of numeric data corresponding to the last complete breath analyzed; graphs cannot be printed.

   NOTE: If, without *any* input to either of the lungs, you notice a reading other than zero values on the top instantaneous line, the transducers need to be re-zeroed. Press ESCAPE, then press ZERO twice with no input to the lungs. Return to the mode you were in.

   A sample air flow monitor printout is shown in Figure 3.6.7.4-2.

```
FLOW MONITOR                          03/14/89
 Vent. ID: 010354                      3:01 PM
 ---------------------------------------
 Resistor Value:

 Test Settings:

 ---------------------------------------
 Flow Rate      =     -4 LPM BTPS
 Insp. Flow     =     56 LPM BTPS
 Exp. Flow      =     32 LPM BTPS
```

Figure 3.6.7.4-2. Air Flow Monitor Printout

Manually record the parabolic resistor value and ventilator settings in the space provided for that purpose on the printout.

8. Press ESCAPE at any time to exit from waveform monitoring.

3.6.8 External Tests

This section describes methods of measuring general external pressures and flows of gases outside the Ventilator and patient tubing loop. These features are intended to be useful in verifying performances of related devices, such as wall air/gas outlets, pressure/flow regulators, compressure output, etc.

3.6.8.1 External Pressure Test

LOW PRESSURE measurements of air up to 125 cmH_2O can be made by connecting the source pressure to the transparent tubing attached to the airway inlet/sliding adapter, and selecting the **Airway Pressure** monitor keypad. The top line reading on the tester's display will indicate instantaneous pressure. Reconnect the transparent tubing to the airway inlet/sliding adapter after completing your measurements.

HIGH PRESSURE measurements of air up to 75 psi (or equivalent in cmH_2O) can also be made with the Model VT-1B or VT-2:

1. Connect the high pressure source to the EXTERNAL PRESSURE port located on the right side of the adult lung. Use the adapter supplied if necessary.

2. Press EXT PRES monitor keypad. The display will indicate the pressure in psi as well as cmH_2O. (See Figure 3.6.8.1-1 for the printout.)

```
HIGH PRESSURE MONITOR          03/14/89
Vent. ID: 010354                3:03 PM
---------------------------------------
Pressure        =     1.4 PSI
Pressure        =     115 cmH20
```

Figure 3.6.8.1-1. External High Pressure Monitor Printout

3.6.8.2 External Flow Test

General flows of various gases can be measured by the VT-1B/2, from diff sources:

1. Pull out the sliding adapter in front of the adult lung as far as it will go.
2. Connect the R_{p20} Parabolic Airway Resistor to the sliding adapter. Do NOT push the adapter back into the lung inlet.
3. Switch on the Ventilator Tester, follow the set-up procedure, selecting cmH_2O as pressure units.
4. Press ESCAPE, then ZERO twice.
5. Remove the gas pressure port cover on top of the adult lung plate.
6. Apply a flow of gas through the resistor for at least 5 seconds (air, O_2, N_2, NO_2, CO_2, or CO).
7. Press EXT FLOW. The display will indicate flow in liters/minute for various gases. (See Figure 3.6.8.2-1 for the printout.)

EXTERNAL FLOW MONITOR 03/14/89
Vent. ID: 010354 3:02 PM

Pressure Drop	=	21.0 cmH20
Air/CO	=	58 LPM
02	=	56 LPM
N2	=	59 LPM
N20/C02	=	47 LPM

Figure 3.6.8.2-1. External Flow Monitor Printout

4 SAFETY, MAINTENANCE, STORAGE & SHIPPING

This section contains instructions for:

4.1 Electrical safety
4.2 Cleaning
4.3 Storage and shipping

4.1 Electrical Safety

The Ventilator Tester should be tested periodically with a Bio-Tek Electrical Safety Analyzer for electrical safety to meet AAMI/ISO/JCAHO requirements. Its chassis leakage should not exceed 500 microamps, and its ground wire resistance should be less than 0.5 ohms.

The Model VT-lB or VT-2 is especially free of electrical hazard during use because of its external simplicity; however, there are several shock hazards ***inside*** the ventilator tester electronics unit. The user should never open either the electronics box or the lung before consulting with Bio-Tek service personnel. If a problem arises that requires opening the electronics unit (such as debris falling into the unit through the ventilation grating), call: 1-800-451-5172 (Customer Service) or 1 -800-24-BIOTK (Service Hotline) for assistance.

4.2 Cleaning

To clean parts of the electronics unit casing and front panel:

1. **Unplug the unit.**
2. Use a mild soap on a damp (not wet) cloth for cleaning.
3. Remove soap residue with a clean, dry cloth.

4.3 Storage and Shipping

To store or ship the Model VT-1B or VT-2 unit after use:

1. Pack all accessories in the accessories pouch.
2. Set the adult lung compliance spring at the upper end of the lung's top plate (0.01 L/cmH_2O).
3. Wedge the small foam square provided with the unit between the spring and the adult lung side.
4. When replacing the top of the carrying case, make sure the 4 stand-off's on the outside are oriented as shown in Figure 4.3-1.
5. Securely fasten all clasps on the outside of the carrying case.
6. Store the Model VT-1B or VT-2 (in the original shipping box, if desired) with the top of the carrying case face up. Storage at room temperature is recommended. Most electronic components in the Model VT-1B or VT-2 have reasonably large temperature tolerances; short-term storage in colder or warmer environments should not cause component failure.
7. To ship the Model VT-1B or VT-2 :
    1. Call the Bio-Tek Service Department to obtain a Return Authorization Number. (Call: 1-800-24-BIOTK for the Service Hotline.)
    2. Put the carrying case in the original shipping box, in the original orientation (with the top of the carrying case corresponding to the top face of the box). Seal the box with reinforced tape.

Bio-Tek may not accept the Model VT-1B or VT-2 if it is shipped back in a carton other than the original shipping box. If you have lost or damaged the shipping box, please order another from Bio-Tek Instruments (Bio-Tek Part #91068).

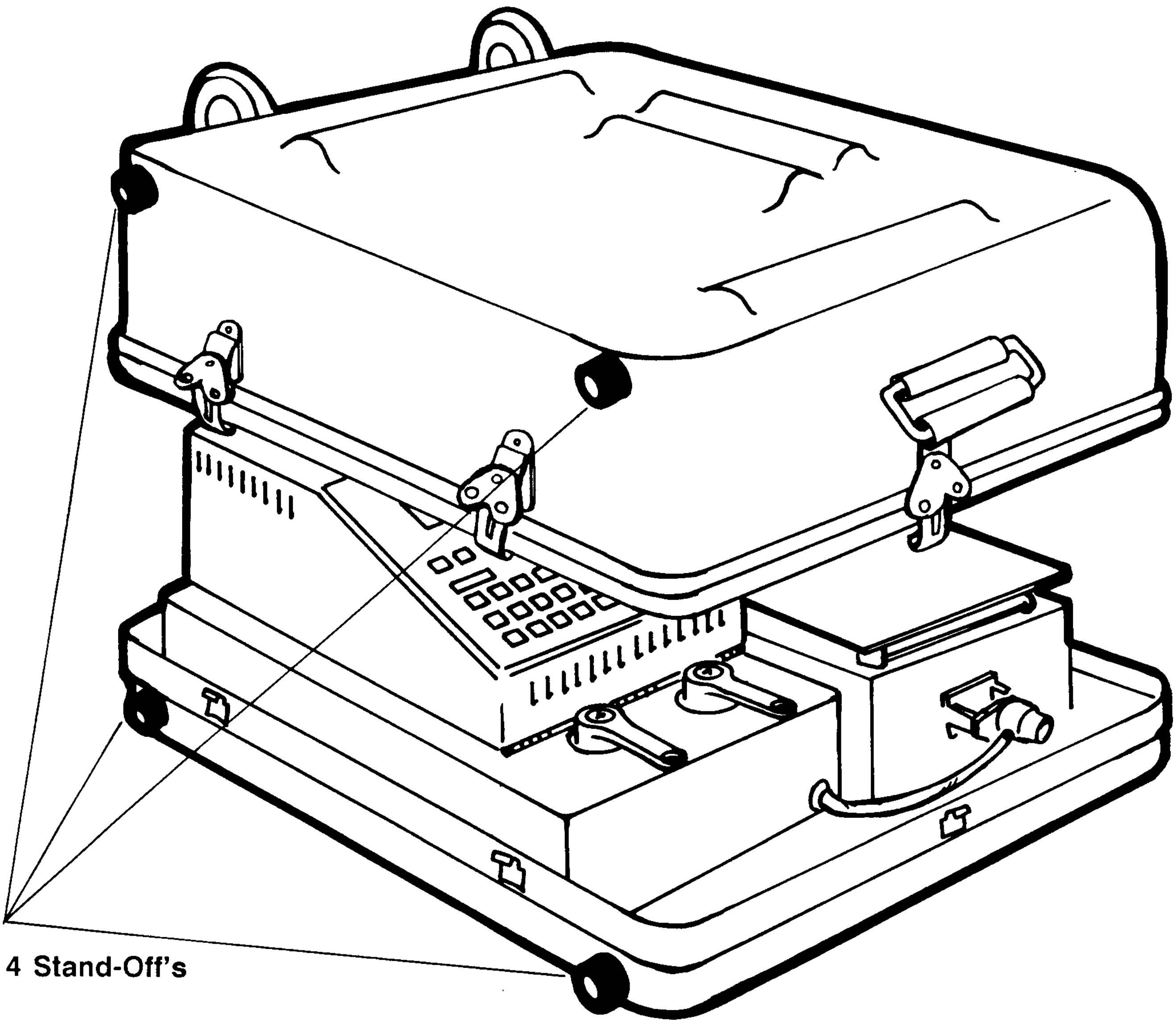


Figure 4.3-1. Repacking the Model VT-1B or VT-2 Ventilator Tester

5 TROUBLESHOOTING

Table 5-1. Troubleshooting Bio-Tek Ventilator Testers

PROBLEM	SOLUTION
DISPLAY	
No display or display ON for short time only after power ON.	Switch VT[1] power switch to OFF position.
	Ensure power is available at source, and it is not fluctuating significantly.
	Ensure power cord is properly connected at both ends.
	Ensure voltage selector switch position on back of VT is set to source voltage.
	If source voltage is higher than voltage selector switch position, check fuses.
	Switch VT power switch ON.
No readings or readings displayed after long delay.	Ensure ADULT/INFANT toggle switch and LUNG SELECT lever are in desired position corresponding to compliance selected in SET-UP and ventilator under test.
	Press ESCAPE, repeat test (other than STATUS test) *after* selecting ventilator controls and waiting for five to ten breaths for ventilator output to stabilize.
	For Status test, press ESCAPE, and select STATUS test *after* fixing the PEEP setting on the ventilator if desired and waiting for five to ten breaths for ventilator output to stabilize. During this test other ventilator controls can be changed if desired, *except* for PEEP.

1 VT refers to both Model VT-1B and Model VT-2 Ventilator Testers.

Table 5-1. Troubleshooting Bio-Tek Ventilator Testers (Continued)

PROBLEM	SOLUTION
DISPLAY (CONTINUED)	
No readings or readings displayed after long delay.	For EXT. PRES. measurements, ensure source pressure is connected to VT input. For EXT. FLOW measurements, ensure airway pressure tubing is connected to airway pressure port, proper restrictor is connected to the sliding adapter with the adapter pulled all the way towards you, and that there is constant flow from source through the restrictor for at least three seconds.
PRINTER	
Printer does not power up or operate.	Check if printer ON/OFF switch is in ON position. Check to see if the printer is plugged into the correct line power. Ensure proper printer cable is connected from printer port of VT to the printer. If a printer other than the one supplied is used, it should be Parallel Centronics. Check for paper jam in the printer. If so, follow instructions in printer manual. Ensure there is paper in the printer.

Table 5-1. Troubleshooting Bio-Tek Ventilator Testers (Continued)

THE FOLLOWING INSTRUCTIONS PERTAIN TO UNSATISFACTORY READINGS DISPLAYED BY THE VENTILATOR TESTER, AS COMPARED TO A VENTILATOR'S SETTING OR DISPLAY ONLY. IF PROBLEM PERSISTS AFTER FOLLOWING INSTRUCTIONS, FIRST CHECK APPROPRIATE VENTILATOR COMPONENTS, THEN CONTACT BIO-TEK OR ITS REPRESENTATIVE.

PROBLEM	SOLUTION
<u>UNSATISFACTORY READINGS SHOWN ON DISPLAY</u>	
Low or high I:E, inspiratory, or expiratory times.	Follow instructions for Calibration, Triggering. If problem persists, perform Full Test, subtract Exp. Hold time from Exp. Time, and manually divide this number by Insp. Time displayed to get an I:E Ratio reading. If this reading is acceptable, I:E ratio definition used by ventilator manufacturers is different than ANSI/ISO version.
High inspiratory flow or high respiration rate.	Ensure that the surface on which VT is placed and/or the patient tubings are stable and not vibrating or moved during testing. Ensure restrictor & sliding adapter are properly connected to airway inlet. Follow instructions Calibration, Triggering. If high flow reading persists, follow instructions for Calibration, Volume.
Low inspiratory flow.	Ensure proper restrictor has been used. Follow instructions for Calibration, Volume. Follow procedure for EXTERNAL FLOW measurement. If flow reading obtained is acceptable, the ventilator is not compensating for lung back pressure.

PROBLEM	SOLUTION
UNSATISFACTORY READINGS SHOWN ON DISPLAY (CONTINUED)	
Low or high volume.	Follow instructions for Calibration, Triggering. Ensure compliance selected during SET-UP corresponds to adult compliance spring or infant compliance lever positions. Ensure reference units selected in SET-UP match ventilator's reference units. Press ESCAPE, disconnect patient tubing from VT inlet, move adult compliance spring to 0.15 L/cmH_2O position if testing adult ventilator. Repeat test. If volume reading obtained is more acceptable, ventilator is not compensating for lung back pressure. If reading is unacceptable, follow instructions for Calibration, Volume.
Low or high pressure.	Follow instructions in manual to ZERO transducers. If problem persists, refer to Calibration, Triggering and Pressure Checks.
CALIBRATION AND TRANSDUCER CHECKS	
Triggering mechanism.	During any test other than Leak/Compliance, Ext. Pres., or Ext. Flow tests, observe *when* you hear a 'Beep' with respect to the phases of the breath cycle. If this beep occurs at any time other than just when the adult lung plate rises during the inspiratory phase, the transducers need to be zeroed due to temperature drift. (Continued next page.)

PROBLEM	SOLUTION
CALIBRATION AND TRANSDUCER CHECKS (CONTINUED)	
Triggering mechanism (continued).	Follow instructions to ZERO the transducers. Normally this should not be required unless the unit has recently been switched ON, or has not had sufficient warm-up time. Allow the unit to warm up for at least half an hour after reaching room temperature, before using any of its test features.
Hook-up for volume and pressure calibration checks.	Disconnect all patient tubings from ventilator to the VT. Wait until the adult lung plate is horizontal or for 3 to 4 seconds if you were in infant mode. Connect a 3-way stopcock between airway pressure tube and airway pressure port to which the tube was connected. Connect a 2-way stopcock to the lung drain tube located in the back and underneath the adult lung. Connect a calibrated digital pressure meter with ±1% reading accuracy or better and 0.01 cmH_2O display resolution to each of the 2 stopcocks. Select 'adult' positions for ADULT/INFANT toggle switch and ADULT/INFANT lung select. Press ESCAPE key, then the ZERO key twice. Offset the pressure meters to read zero. Select ATPX for 'Other volumes and flows' and 0.05 L/cmH_2O compliance in SET-UP, then press ESCAPE.

PROBLEM	SOLUTION
CALIBRATION AND TRANSDUCER CHECKS (CONTINUED)	
Hook-up for volume and pressure calibration checks (continued).	Connect a restrictor, the ON/OFF valve supplied, and a calibrated syringe of known volume (preferably over 50 ml, for full volume delivery) to the airway inlet/sliding adapter. Switch ON/OFF valve to ON position.
Volume and pressure calibration checks.	Follow instructions for Triggering, described above. Inject the known volume into the adult lung. Switch ON/OFF valve to OFF. Press Volume monitor key twice. Volume reading on VT display should match syringe volume injected, within VT specifications. If not, optical encoder (ADT) may be faulty. Contact Bio-Tek. Press Airway Pressure monitor key twice. Reading displayed by VT should match reading by pressure meter connected to airway port, within specifications. If not, the airway pressure transducer may be faulty. Contact Bio-Tek. Press Lung Pressure monitor key twice. Reading displayed by the VT should match reading on pressure meter connected to lung, within specifications. This reading should also be equal to the airway pressure reading obtained above If not, the differential pressure transducer may be faulty. Contact Bio-Tek.

6 REFERENCES

The following is a partial list of application notes, reports, and articles for further reading. Call Bio-Tek at 1-800-451-5172 and ask for the Product Manager to obtain a copy for yourself.

1. Questions and Answers About Bio-Tek's Ventilator Testers Models VT-1 and VT-2

2. QVP for Adult Ventilators

3. Competitive Analysis (Ventilator Testers)

4. Comparison Between Adult Test Lungs (Bio-Tek Part #94063)

5. Analysis of Measuring Techniques for Ventilator Testers (Bio-Tek Part #95007)

6. "Ventilator Performance Testing," Terry Torzala, Medical Electronics, June 1987.

APPENDIX A

A.1 Ventilator Testing Standards

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) Manual requires hospitals to ensure, among other guidelines, that all devices comply with applicable standards. The Respiratory Care Services section of the JCAHO Accreditation Manual requires that all equipment be calibrated and operated according to manufacturers' recommendations, United States Food and Drug Administration (FDA) mandatory or voluntary minimum performance standards, and periodically inspected and maintained according to an established schedule as part of the hospital's Preventive Maintenance (PM) program.

1. In the absence of any FDA Mandatory Standards for medical devices, the National Fire Protection Agency (NFPA) Standards, various Voluntary Minimum Performance Standards published by the American National Standards Institute (ANSI), and recommendations of relevant professional bodies become applicable. Manufacturers, hospitals, service and research organizations, therefore, use ANSI Standards as guidelines for the performance, testing, and calibration of medical devices. The ANSI Z79.7-1976 *Minimum Performance Standard for Breathing Machines* is the relevant recommended performance standard for ventilators. Countries other than the United States have similar standards issued by their governing bodies, that follow the guidelines established by the International Standards Organisation (ISO).

2. An important part of any ANSI Standard for a medical device comprises testing for safety, performance, calibration and accuracy. It requires the device to meet certain minimum performance requirements as well as the manufacturer's claims when the device is tested under normal as well as abnormal patient and operating conditions.

3. Every Critical Care and Anesthesia Ventilator should be tested under true load conditions before being used for patient care, and periodically during such use to determine that it is functioning in accordance with criteria established by various standards agencies and by the ventilator manufacturer. The VT-1B and VT-2 have been designed to allow thorough testing of most types of adult and infant ventilators conforming to testing standards defined by ANSI, ISO, and the American Society for Testing and Materials (ASTM). These standards are cited in Table A.1-1.

4. Another source for ventilator testing criteria is the Operational Verification Procedure (OVP) found in the instruction manual supplied with each ventilator. The OVP is a manufacturer-specified procedure designed to check the parameters of the ventilator on a regular basis for PM.

The FDA had asked the Standards Committee of the American Association for Respiratory Therapy (AART), now renamed as the American Association for Respiratory Care (AARC), for comments on the prevalent classification of mechanical ventilators. The committee's letter of September 9, 1983 recommended the following:

1. All ventilators should comply with ANSI Z79.7 Standards (see Table A.1-2).

2. All ventilators should be required to comply with the ANSI standard as part of FDA's approval process. By compliance it is implied that the ventilators meet performance and safety requirements, and not any unintended design restrictions that may have resulted from the language of the standard.

Table A.1-1. Ventilator Testing Standards

STANDARD	TITLE	ORGANIZATION
ANSI Z79.7-1976	*Minimum Performance Standards for Breathing Machines for Medical Use*	American National Standards Institute, 1430 Broadway, New York, NY 10018
ISO/TC 121/SC3	*Minimum Performance Standards for Breathing Machines*	International Standards Organisation, (contact ASTM below)
ASTM F29.03.01	*Proposed Draft Standard for Ventilators Intended for Use in Critical Care*	American Society for Testing of Materials, 1916 Race Street, Philadelphia, PA 19103
ASTM F29.03.02	*Proposed Draft Standard for Ventilators Intended for Use during Anesthesia*	As above.
ASTM F29.03.03	*Minimum Standards for Resuscitators*	As above.
ASTM F29.03.09	*Proposed Draft Standard for Home Care Ventilators*	As above.

Table A.1-2. ANSI Z79.7 General Requirements

PARAMETER	REQUIREMENT
<u>LUNG MODEL</u>	
Compliance	±5% of set compliance, at ATPX, from -20 to 100 cmH_2O, & 0.1 to 6.0 second Insp. Phase times. (C = ml/cmH_2O)
Resistance	±20% of set resistance, at 20° C, and dry air under ambient pressure. (R = $cmH_2o/l/s$)
<u>MEASUREMENTS</u>	
Pressure	±2.5% of reading ±2.5% of peak reading (cmH_2O)
Flow	±2.5% of reading ±2.5% of peak reading (l/min)
Volume	±2.5% of reading ±2.5% of peak reading (ml or l)
<u>VENTILATOR</u>	
Frequency	±10% of reading in Breaths per Minute (BPM)
Calibrated controls	±10% of measured reading
Other controls	±10% of measured reading
Pres. gauges' tolerance	At 0 cmH_2o, ±1.5 cmH_2O; 2.5 cmH_2O from 0 to ±10 H_2O; ±3.5 cmH_2O from 10 to 30 cmH_2O; & 5 cmH_2O over that.
Pres. relief valves	Greater of ±5 cmH_2O or ±20% of set value.
Spirometers	±10% of reading from 10° C to 37° C.

A.2 ANSI Standards for Ventilators

The ANSI Z79.7-1976 Standard for Breathing Machines is the relevant recommended performance standard for ventilators, since 1976. It provides guidelines to inspect and test various aspects of a ventilator. Table A. 1 -2 is a summary of the general requirements outlined in this standard. There are 3 performance tests required by ANSI:

Endurance Test: With I:E Ratio as close to 1:2 as possible, run a representative of the ventilator for 2000 hours, under conditions representative of each group of patients for which it is recommended. (This is a "TYPE TEST," generally for manufacturers only:)

ADULT: C = 50 ml/cm H_2O, R = 20 cm H_2O/l/s, at 20 Breaths per Minute (BPM) and 10 L Minute Volume (MV).

PEDIATRIC: C = 20 ml/cm H_2O, R = 50 cm H_2O/l/s, at 30 BPM and 4.5L MV.

NEONATAL: C = 3 ml/cm H_2O, R = 200 cm H_2O/l/s, at 40 BPM and 0.8L MV.

Waveform Performance Test: Connect the ventilator to a lung with compliance and resistance combinations appropriate to its intended use and record the ventilator settings required to obtain specified tidal volume, frequency, at I:E ratio of 1 :2. Record traces of Airway Pressure, Lung Pressure, Inspiratory Flow, and Tidal Volume (TV) waveform patterns.

ADULT: For 500 ml TV, 20 BPM, with C50/R5, C50/R20, C20/R5, C20/R20.

PEDIATRIC: For 300 ml TV, 20 BPM, with C20/R20, C20/R50, C10/R20, C10/R50; and for 50 ml TV, 30 BPM, with C3/R20, C3/R50, C3/R200.

NEONATAL: For 30 ml TV, 30 BPM, with C3/R50, C3/R200, Cl/R50, Cl/R200, Cl/R500, Cl/R1000; and for 15 ml TV, 60 BPM with Cl/R200.

NOTE: R1000 is not available commercially at the time of this manual's printing.

Volume Performance Test: With ventilator connected to appropriate lung impedance and set at specified frequencies, determine the range of tidal volumes (maximum & minimum) that it can deliver to the lung.

ADULT: With C20/R20 lung and ventilator at 10, 15, 20, and 30 BPM.

PEDIATRIC: With C10/R50 and C3/R200, at BPM = 15, 20, 30, 40.

NEONATAL: With Cl/R200 at 20, 30, 40, 60 BPM.

A.3 Lung Ventilators: Background

A lung ventilator is a mechanical *breathing* machine. It is a non-invasive device which allows a person to breathe artificially. Ventilation is a fundamental service provided by most hospitals to adults, as well as infants, during surgery or treatment of various types of lung conditions. Improvements in equipment for ventilation have been characterized by incorporating new modes of ventilation and more sophisticated patient and machine monitoring features.

Ventilators are now broadly classified as being either Adult or Infant Ventilators. Under these titles, they are further subdivided as Critical Care, Anesthesia, High Frequency, Jet, Transport, Positive Pressure Home Care, Negative Pressure Home Care, and Body or Tank types of ventilators. Furthermore, advances within the last seven years have resulted in a new generation of microprocessor-based ventilators that have the capability to capture, process, and compensate for the real-time feedback signals from patients. These more sophisticated systems also have the capability to interface with computer systems for full monitoring of vital signs and control of a patient's treatment process.

Ventilation of the lungs is an essential physiological act. During normal ventilation, as the diaphragm rises, the chest expands and air is pulled into the lungs because of the negative pressure created. The inhaled gases are warmed, filtered, and humidified by the nose and pharynx, as they are conducted to the gas exchange areas of the lungs (the alveoli). Exhalation is a passive event, which rids the body of waste carbon dioxide.

Patients who are victims of ventilatory failure may experience difficulty in the physical act of breathing because of neuromuscular diseases, restrictive or obstructive lung diseases, or difficulty with gas exchange at the alveolar level caused by a number of parenchymal diseases. Patients undergoing surgery may have to be anesthetized before and during surgery, as well as ventilated after surgery before the body recovers its normal functions. Mechanical ventilators are used in cases such as these to overcome normal ventilatory failure.

The mechanical ventilator is connected to the endotracheal tube of an intubated patient and pushes a known volume of gas or air into the patient's lungs. Since the normal upper airway is bypassed, the gas is externally warmed, filtered, nebulized, and humidified before passing through a bacteria filter into the patient's airway and lungs.

The inspired gas may also be enriched with oxygen at a level higher than that of room air and/or with anesthetic gases. Various inspiratory patterns and possibly an inspiratory pause may be introduced during this process. Expiration is usually a passive event which ventilators achieve by obstructing the expiratory limb of patient's breathing circuit. During expiration the lungs may either be allowed to return to atmospheric pressure or to a positive end expiratory pressure (PEEP). There are, therefore, basically four phases to the mechanical ventilation cycle:

1. Inspiratory Phase

2. Change from Inspiration to Expiration

3. Expiratory Phase

4. Change from Expiration to Inspiration.

A.3.1 Classification

This section describes the basic variations and corresponding terminologies used within the four ventilatory phases just mentioned. For a more complete description, the reader may refer to the ASTM F-29 *Proposed Draft Standards for Critical Care, Anesthesia, and Home Care Ventilators*, or the ANSI Z79.7 and ISO TC 121 Standards; these standards are listed in Table A.1-1.

A complete discussion of mechanical ventilation and a classification of ventilators are beyond the scope of this manual. An excellent source for this information is the American Hospital Association (AHA) Hospital Technology Series Guideline Report, Volume 3, Number 16: Adult Volume Ventilators (AHA-012823, 1984, 63 pp). This report is available from:

American Hospital Association
P.O. Box 96003
Chicago, Illinois 60693

Price: $25 (non-AHA-members); $20 (members)

A.3.1.1 Inspiratory Phase

This phase characterizes the flow pattern of the volume delivered; i.e., the rate at which gas is delivered and the mechanism that determines this pattern. There are four basic patterns (Figure A.3.1.1-1) which can be achieved by using either a flow or a pressure generator.

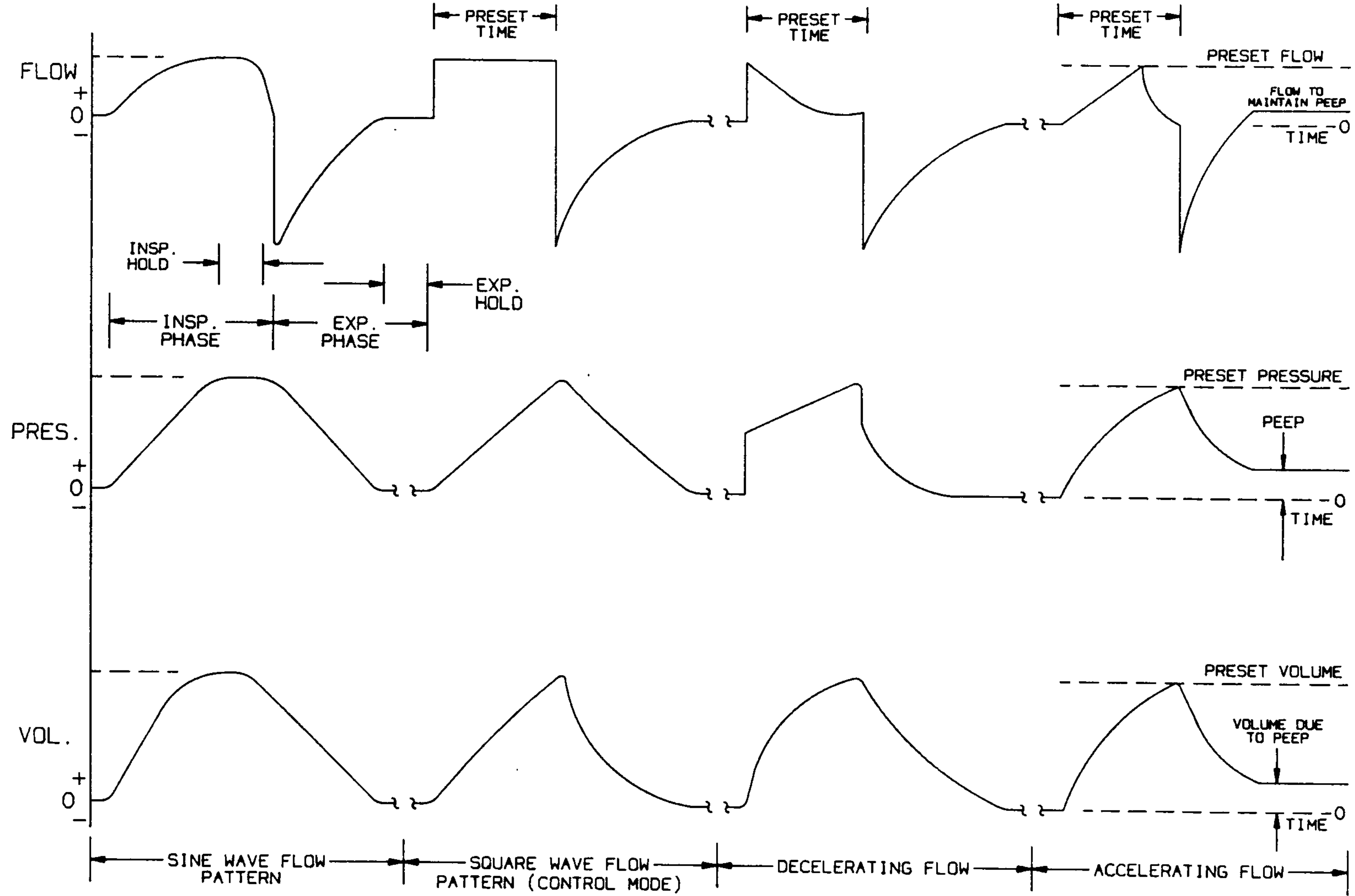


Figure A.3.1.1-1. Inspiratory to Expiratory Phases

1. **Sine Wave Flow Pattern:** Although its clinical superiority has yet to be established, the sine wave is believed to be the most physiological of breath patterns. It maintains an accelerating, then a decelerating flow of gas into the lungs. The waveform is similar in shape to that of a normal spontaneous breathing pattern, except that it is still positive pressure breathing.

2. **Square Wave Flow Pattern:** This is delivered by a mechanism that can quickly initiate and maintain flow at a constant rate for the desired inspiratory time. This output is typical of compressor bellows or pneumatic systems.

3. **Decelerating Flow Pattern:** The decelerating flow pattern is characterized by a rapid rise to peak flow, followed by a deceleration of flow. This deceleration may be in response to the resistance of the patient's pulmonary system, or may be programmed into the breath delivery system of the ventilator.

4. **Accelerating Flow Pattern:** This pattern is not widely used, but is available in the Siemens Model Servo 900C and in the Engstrom Model Erica ventilators. Its advantage is claimed to be a lower peak airway pressure and better distribution of ventilation, thereby avoiding barotrauma in patients. Its waveform is the opposite of the Decelerating Flow Pattern.

During the inspiratory phase, expiration is prevented by closing the expiration valve in the ventilator. If this valve remains closed after the completion of inspiratory flow but before expiration begins because of the ventilator's control settings, it creates an Inspiratory Hold during the Inspiratory phase. The Inspiratory Hold Period is illustrated in Figure A.3.1.1-1.

A.3.1.2 Change from Inspiration to Expiration

The cessation of inspiration and start of expiration depends on the ventilator's volume control settings. The mechanism for this change depends on whether knobs designated as VOLUME, PRESSURE, or FLOW and INSPIRATORY TIME are used on the ventilator. There are 6 common types of these mechanisms as described below and illustrated in Figure A.3.1.1-1. The term Cycled means the primary variable is controlled by monitoring the delivered flow from a ventilator. The term Limited relates to the secondary variable used to control the breath characteristic.

1. **Volume Cycled:** Inspiration ceases when the set volume has been delivered to the patient circuit within the preset airway pressure limit.

2. **Volume Limited:** Inspiration ceases when preset volume is delivered within the preset time limit.

3. **Time Cycled, Volume Limited:** Inspiration ceases when a set flow of gas is delivered for a preset time. Volume of gas delivered is dependent on flow rate.

4. Pressure Cycled: Inspiration ceases when a preset airway pressure limit is reached during gas delivery.

5. Time Cycled, Pressure Limited: Inspiration ceases when system delivers flow necessary to maintain preset airway pressure within the set time limit.

6. Time Limited, Pressure Cycled: Inspiration ceases when preset time is reached during delivery of flow necessary to maintain preset airway pressure.

A.3.1.3 Expiratory Phase

Expiration is initiated by the opening of the exhalation valve in ventilators, and occurs after the completion of the Inspiratory Phase (including the Inspiratory Hold period). It allows the patient to exhale back down to a baseline pressure of 0 cmH_2O, with a rapid loss of volume. At the end of this phase the patient reaches a baseline or resting volume known as the Functional Residual Volume (FRV). The time elapsed between the end of expiratory flow and the beginning of the next inspiratory flow is known as the Expiration Hold period. This phase, along with Inspiratory and Expiratory Hold Periods, are shown in Figure A.3.1.1-1.

In cases such as restrictive diseases, it is desirable to increase the FRV to improve gas exchange at the alveolar level. In this case, the patient is allowed to exhale passively, but instead of exhaling to zero baseline pressure, a new higher baseline pressure is continuously maintained by the ventilator. It is achieved by controlling the expiratory valve so that it closes before expiration reaches baseline pressure and by maintaining a constant flow of gas. The therapist institutes this positive end expiratory pressure (PEEP) by setting the PEEP control knob to the desired pressure level. PEEP raises the FRC level because volume in the lungs is directly related to the residual pressure after expiration. PEEP is used in various ventilation cases, and is illustrated in Figure A.3.1.1-1.

A.3.1.4 Change from Expiration to Inspiration

There are five common mechanisms for a ventilator to change from expiration to inspiration. These Modes of Ventilation are illustrated in Figure A.3.1.4-1.

1. Control Mode: This is instituted in patients who are paralyzed because of physiological reasons, who have neuromuscular diseases, or who are incapable of ventilatory effort because of anesthesia. In this mode the patient makes no effort or is not allowed to initiate a breath. The ventilator controls are set to the desired volume and rate, and breaths are delivered accordingly. For example, at settings of 500 milliliter Tidal Volume and 12 Breaths per Minute (BPM), the ventilator will provide a breath every 5 seconds and deliver 500 ml during each inspiration.

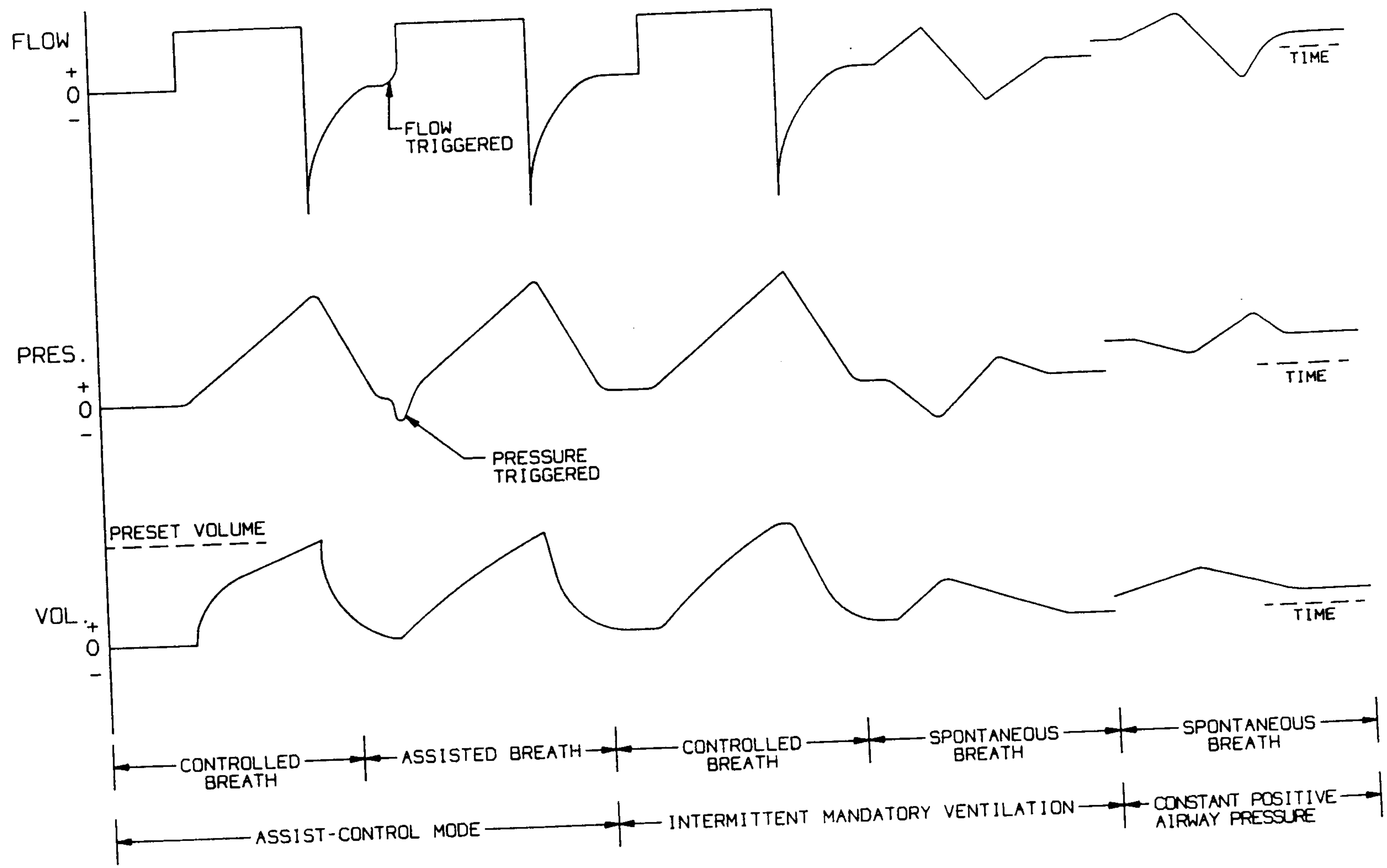


Figure A.3.1.4-1. Expiratory to Inspiratory Phases

2. Assist-Control Mode: This mechanism is based on a flow or pressure sensitive trigger level. When the patient makes an inspiratory effort, a flow- or pressure-sensitive mechanism is triggered, the inspiratory phase is initiated, and the preset volume is delivered. In addition, a back-up rate is set with a rate control so that if the patient does not initiate a breath, the preset volume is delivered. When a patient *assists* a breath, the rate timer is reset.

3. Intermittent Mandatory Ventilation (IMV): This is accomplished by maintaining a continuous flow of gas in the circuit or by using a patient-sensitive demand system to supply inspiratory gas during spontaneous breathing. The patient is allowed to breathe spontaneously at his or her desired rate and volume between mandatory breaths. This is a method used to wean ventilator-dependent patients from ventilatory support.

4. Synchronized IMV (SIMV): In this mode the breath delivery system is synchronized with the patient's spontaneous efforts, which is the only difference between this mode and IMV. It overcomes the common problem of *breath stacking* during IMV.

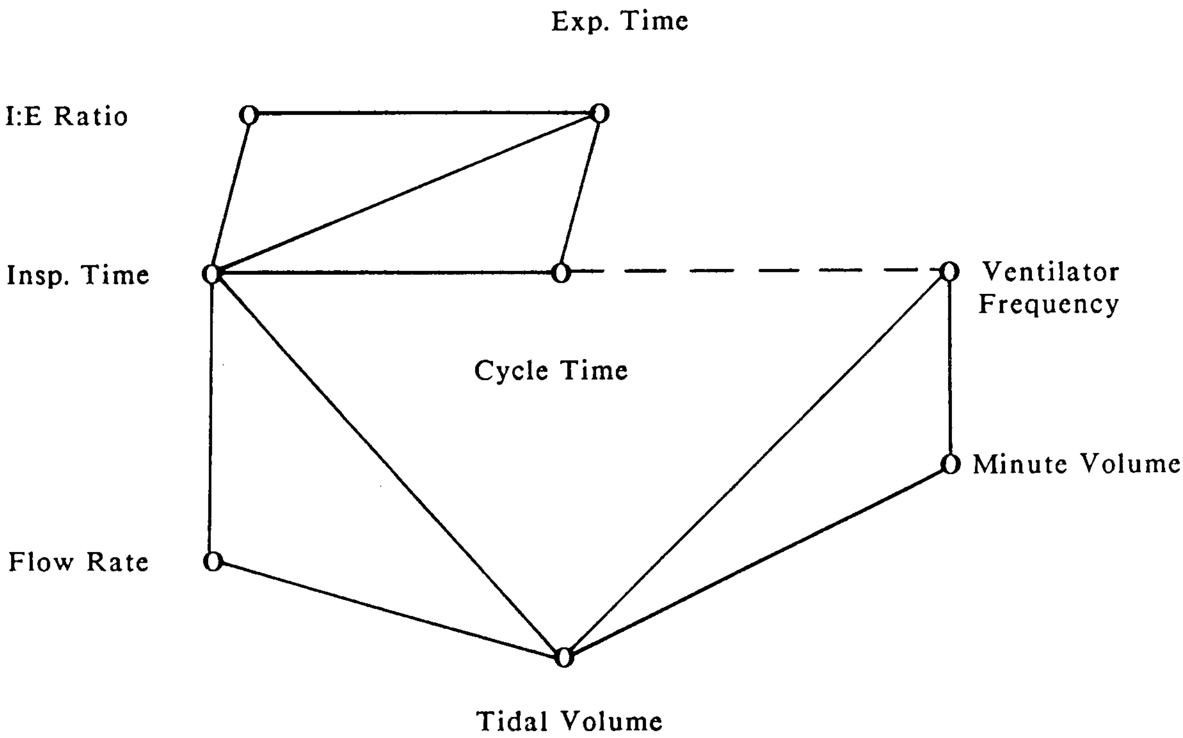
5. Continuous Positive Airway Pressure (CPAP): This mode allows the patient to breathe spontaneously at higher than ambient pressure, as with PEEP, but with little or no change in pressure about the new baseline. It is useful for patients with normal ventilation but who have significant deficiency in gas exchange.

Almost all ventilators are capable of performing the four phases of ventilation for each breath cycle : Inspiration, Change to Expiration, Expiration, and Change to Inspiration. The decision to use any combination of mode and inspiratory or expiratory patterns is dependent upon the patient's condition, the ventilator available, the physician's preference, and the skill of the respiratory therapist. It is, however, desirable to have a ventilator with the maximum flexibility since the patient's condition may change. The new generation of ventilators have additional controls, modes and features required to treat difficult patients.

A.3.2 Principles of Dynamic Ventilator Testing

In order to produce a prescribed breathing pattern, a ventilator must be set for the correct inspiratory and expiratory timing, flow rate, tidal or minute volume, and for the ventilator frequency. Not all of these controls, however, may be available in the ventilator, and not all of these parameters can be set independent of each other. Some of the basic relationships are illustrated in Figure A.3.2-1 where each triangle represents 3 interrelated variables. Table A.3.2-1 provides actual relationships between the ventilation variables in equation form.

In order to determine the performance of ventilators, the ANSI standard requires one to take measurements while the ventilator output (breathing circuit) is connected to a quantitative test lung that can simulate typical patient conditions. This method is used by almost all research workers to evaluate ventilators under various clinical situations, to ascertain better methods of ventilation and patient treatment, or to determine adverse effects of some kinds of ventilation.



(Adapted from ECRI Health Devices, August 1982, pp. 266)

Figure A.3.2-1. Primary Ventilation Variables

Table A.3.2-1. Relationships between Ventilation Variables

I:E Ratio	=	Expiration Time/Inspiration Time
Inspiration Time	=	Inspiration Flow Time + Inspiration Hold Time
Expiration Time	=	Expiration Flow Time + Expiration Hold Time
Cycle Time	=	Inspiration Time + Expiration Time
Ventilation Frequency	=	60/Cycle Time
Tidal Volume	=	Flow in liters per minute x Inspiration Time
Minute Volume	=	Tidal Volume x Ventilation Frequency
Flow	=	(Airway Pressure - Lung Pressure)/Resistance

made during measurements, by first determining the compliance of these connections within the ventilator's operating pressure, flow, and volume ranges.

These compressed volumes may be dependent on lengths, diameters and pliability of the patient's inspiratory breathing circuit as well as:

1. Other tubings in the ventilator,

2. Size of humidifiers used and amount of water in them,

3. Other reservoirs such as water traps and bellows, and

4. The peak airway pressure, and the pulmonary resistance and compliance. As much as 20% of the intended O_2 rich and CO_2 poor Tidal Volume may remain in the ventilator circuit at the end of lung inflation.

Gas is also compressed within the lungs because of their compliance thereby causing a backpressure to the ventilator's output and within the delivery system. The back pressures and gas compressions during dynamic breathing cause changes in the density of gas as well as the pressure drops across the pneumotach used to determine flow and volume readings. The pneumotach is usually calibrated by assuming its output for specific atmospheric or ambient barometric pressures and for specific gases at fixed temperature and relative humidity conditions.

Thus the pneumotach should either be recalibrated under ventilator operating conditions or under the various gas laws and thermodynamics principles used to compensate all readings for actual delivered gas temperature, viscosity, density, water vapor content, and thermal characteristics. Although mass spectrometers could easily compensate for these factors on a real-time basis, they are too expensive for practical use.

A mass of gas may exist in different volumes depending on its absolute temperature, the absolute ambient or barometric pressure, and the amount of water vapor contained in the gas. If flow and volume measurements are made with these values known, one can easily calculate the flow and volume readings at the gas reference conditions at which a ventilator is calibrated or specified, as well as at other conditions in which a respiratory therapist may be interested. Conversions from one gas reference condition to another involve complex algorithms that use Boyle's Law, Gay-Lussac's Law, Dalton's Law of partial pressures, Equation of State for Ideal Gases, water vapor pressure and humidity principles.*

Table A.3.2-3 gives an explanation of these gas reference units. Table A.3.2-4 illustrates how a fixed mass of gas occupies different volumes under different gas reference conditions with a ventilator set at 15 BPM, 500 ml Tidal Volume, and an I:E Ratio of 1:2, calibrated to BTPS conditions.

* Terry Torzala's article "Ventilator Performance Testing" in the June 1987 issue of Medical Electronics describes the application of these principles for ventilator testing.

Table A.3.2-2. Simulated Patient Conditions

CONDITION	C	Rp
<u>ADULT/PEDIATRIC</u>		
Normal	50	20
Asthma or Bronchitis	50	50
Chronic Obstructive Pulmonary Disease (COPD)	20	50
Pneumothorax	20 or 10	20
Emphysema	10	50
Collapsed Lung	10	20
Normal Pediatric	10	20
<u>INFANT</u>		
Newborn (6 lb)	3	50
Postoperative	3 or 1	50
Hyalin Disease	1	200
Intubated	3	200 or 500
Premature 3-4.5 lb	3	50
Premature Extreme	1	200

(Source: Michigan Instruments & Bio-Tek Instruments)

NOTE: Compliance = C = ml/cmH_2O

Resistance = R_p = cm H_2O/l/minute

A.4 Theory of Operation

Flow and volume readings are key ventilator performance measurements, with volume being the key data important for treatment. Oxygen in blood is dependent on the amount of fresh air injected to the lungs, therefore clinicians and respiratory therapists select a ventilator's tidal volume output based on the treatment required and the condition of the patient. The flow control on a ventilator is set to deliver the required volume within the inspiratory phase time limits.

Figure A.4-1 shows ventilator tester system configuration that enables the input to be processed to give the desired outputs.

A.4.1 Algorithms

All ventilation parameters are based on 3 groups of basic measurements: Time, Pressure, and Volume or Flow. Each of these groups involves several other measurements. Relationships between major ventilation variables have been already described in Section 1, Table A.3.2-1 and Figure A.3.2-1 (illustrating the relationships between the primary variables).

A synchronization subroutine is used during any test, to sample 'raw' data from various input signals. The sampling rate is fixed at intervals of 10 milliseconds except for external flow, leak and compliance tests, which are sampled at one second intervals. The synchronization subroutine uses raw data signals from various sources for the current breath, as well as the time information for the start of the next inspiratory phase to indicate when the current breath cycle ends.

Each phase of an event is identified by corresponding number of counts, which is the number of elapsed 10 msec intervals. Raw data are available from the ADT for volume count, the airway pressure transducer for airway pressure count, a differential pressure transducer for differential pressure count between airway and lung pressure to calculate lung pressure. An internal clock provides the reference time.

T_i = Inspiratory count

T_{ih} = Inspiratory Hold count

T_e = Expiratory count

T_{eh} = Expiratory Hold count (also the number of counts till start of next breath)

V_{ei} = End Inspiratory (Maximum) volume count, with corresponding lung pressure for conversion to reference units

V_{ee} = End Expiratory (Minimum) volume count, with corresponding lung pressure for conversion to reference units

Table A.3.2-3. Gas Reference Units

CONDITION	TEMPERATURE	PRESSURE	REL. HUMIDITY
ATPD	Ambient	Ambient	0%
ATPS	Ambient	Ambient	100%
ATPX	Ambient	Ambient	Ambient
BTPS	37°C (body)	Ambient	100%
NTPD	20°C	760 mmHg	0%
STPD	0°C	760 mmHg	0%

Given below are explanations of the acronyms used:

ATPD = Ambient Temperature & Pressure, Dry gas.
ATPS = Ambient Temperature & Pressure, Saturated gas.
ATPX = Ambient Temperature, Pressure, & Relative Humidity.
BTPS = Body Temperature & Pressure, Saturated gas.
NTPD = Normal Temperature & Pressure, Dry gas.
STPD = Standard Temperature & Pressure, Dry gas.

Table A.3.2-4. Effects of Gas Reference Units

	STPD	NTPD	ATPD	ATPX	ATPS	BTPS
TV	400	428	436	441	447	484
MV	6.06	6.49	6.77	6.68	6.77	7.33
Fi	35	38	20	39	39	43
Fe	9	10	21	10	10	11

(At 15 BPM, 1:2 I:E Ratio, 500 ml TV BTPS. Fi = Insp. Flow Rate; Fe = Exp. Flow Rate)

ap_{max} = Maximum Airway Pressure count during inspiratory phase
ap_{min} = Minimum Airway pressure count during entire cycle
ap_{ee} = Airway Pressure count at end of expiratory phase
lp_{max} = Maximum Lung Pressure count at end of inspiration
lp_{min} = Minimum Lung Pressure count during entire cycle

where:

Lung Pressure count = (Airway Pressure count) - (Differential Pressure count)

A.4.1.1 Time Readings

I:E Ratio = $(T_e - T_{eh}) / (T_i + T_{ih})$

Inspiratory Time = $(T_i + T_{ih})$ x 0.01 seconds

Inspiratory Hold = T_{ih} x 0.01 seconds

Expiratory Time = $(T_e + T_{eh})$ x 0.01 seconds

Expiratory Hold = T_{eh} x 0.01 seconds

Cycle Time = $(T_i + T_{ih} + T_e + T_{eh})$ x 0.01 seconds

Breath Rate = $\{60 / (T_i + T_{ih} + T_e + T_{eh})\}$ x 0.01 breaths/minute

A.4.1.2 Pressure Readings

Peak Airway Pres. = $(ap_{max}$ x 0.140) + 15 cmH_2O
= $(ap_{max}$ x 0.103) + 11 mmHg

Peak Lung Pres. = $(lp_{max}$ x 0.140) + 15 cmH_2O
= $(lp_{max}$ x 0.103) + 11 mmHg

End Exp. Pres. = $(ap_{ee}$ x 0.140) + 15 cmH_2O
= $(ap_{ee}$ x 0.103) + 11 mmHg

Min. Awy. Pres. = $(ap_{min}$ x 0.140) + 15 cmH_2O
= $(ap_{min}$ x 0.103) + 11 mmHg

Min. Lung Pres. = $(lp_{min}$ x 0.140) + 15 cmH_2O
= $(lp_{min}$ x 0.103) + 11 mmHg

Mean Pres./cycle = (Sum of Airway Pres. Readings)/(Total Number of Readings)

Assist Pres = (End Expiratory Pres.) - (Minimum Airway Pres.)

Instantaneous Pres. = (corresponding pressure count x 0.140) + 15 cmH_2O
(airway or lung) = (corresponding pressure count x 0.103) + 11 mmHg

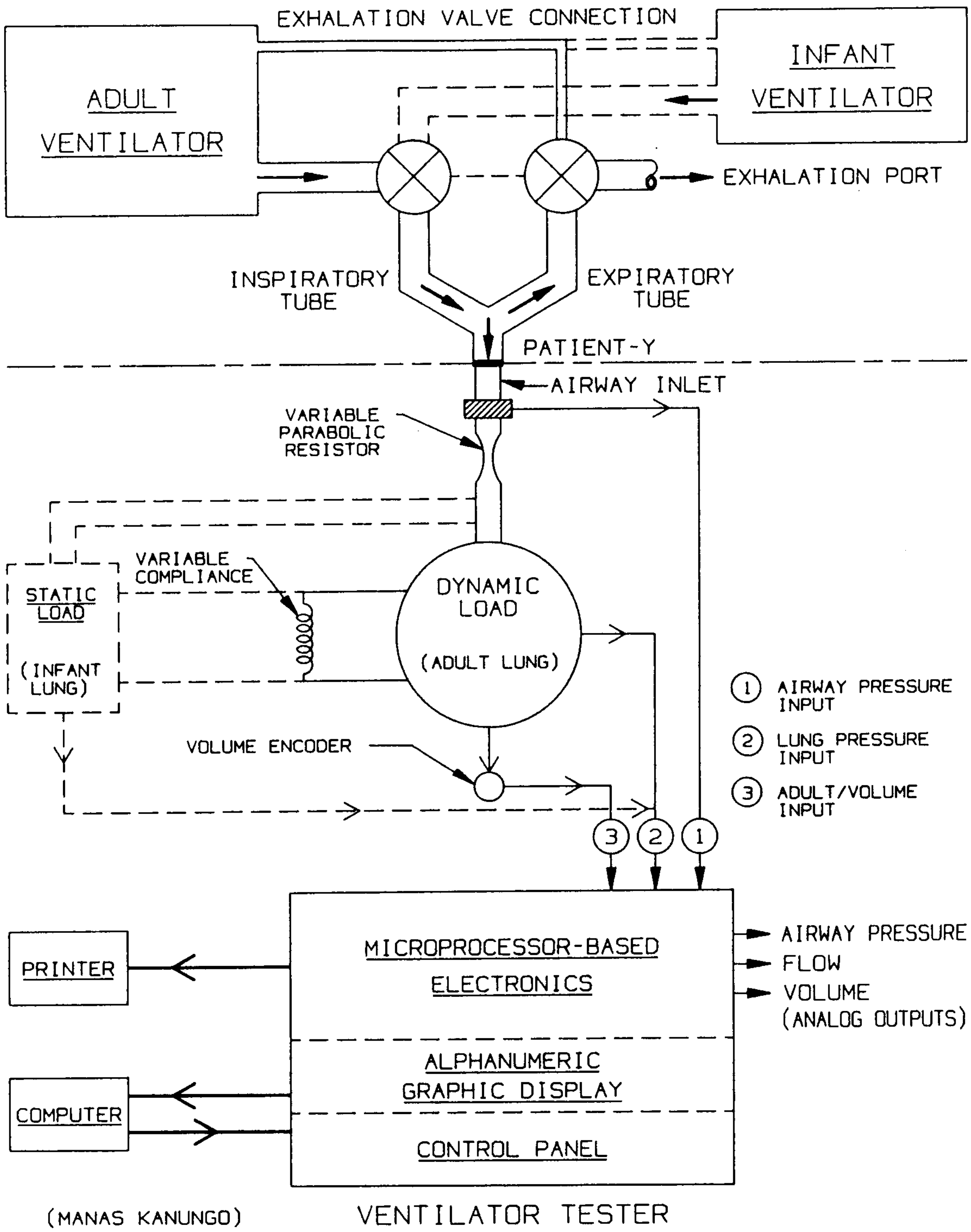


Figure A.4-1. Ventilator Tester System Configuration Block Diagram

A.4.2 Hardware and Software

See Figure A.4.2-1 for the hardware block diagram. The hardware for the Bio-Tek ventilator testers includes:

1. One 8085 microprocessor.
2. 8K RAM and 64K EPROM.
3. Three pressure transducers for airway, lung and external pressure measurements.
4. One angular displacement transducer for volume measurement.
5. One 32-key keyboard for user control and device commands.
6. One 6-line, 34 characters/line, 10 x 7 dots/character, 64 x 240 dots alphanumeric & graphic LCD for all readings, graphs, error and user prompt messages.
7. One 10-bit A/D converter to sample all pressures.
8. One 8253 Timer/Counter chip with three separate timers for serial interface,generate sample interrupts, and to provide 10 msec intervals for the real-time base.
9. One 8279 keyboard controller chip for keyboard processing.
10. One 8251 controller chip for RS232, and one Parallel Centronics printer port.
11. Three analog outputs of raw signals for adult volume, airway pressure and flow.
12. One analog output of raw signal for infant airway pressure.

The software is written in assembly language and 'C.' All sampling routines, interrupt handlers, and the basic control of the unit is written in assembly language. Numerical calculations, display and printout formatting are written in 'C.' The software is structured as an endless loop which makes calls to the different subsystems. Keyboard input and background processing subsystems are the main subsystems. (See Figure A.4.2-2 for a block diagram of the ventilator tester software.)

A.4.1.3 Volumes, Flows, Leak, and Compliance

1. Compressed Volume: Volume reading obtained is under compliance conditions.
2. Gas Densities: Volume reading represents displaced volume for any gas mixture.
3. Back Pressure: Lung pressure reading corresponds to pressure under compliance.
4. Reference Units: By proper user entries during SET-UP, and conversion factors.

Instantaneous Vol. = Volume count x K_v x K_r liters
Tidal Volume = $(V_{ei} - V_{ee})$ x K_v x K_r liters
Baseline Volume = V_{ee} x K_v x K_r liters
Minute Volume = Tidal Volume x Breath Rate

Instantaneous Flow = Instant. Vol./Time for corresponding counts in minutes LPM
Inspiratory Flow = (Tidal Vol. x 60)/(Insp. Time - Insp. Hold Time) LPM
Expiratory Flow = (Tidal Vol. x 60)/(Exp. Time - Exp. Hold Time) LPM

Leak Rate = $[(V_{ei} - V_{ee})$ x K_v x $K_r]$ / (Time between K_v & K_r in min.) LPM
Compliance = $[(V_{ei} - V_{ee})$ x K_v x $K_r]$ / Drop in Lung Pressure ml/cmH_2O

where:

K_v in liters/count is an experimentally derived constant referenced to NTPD and dependent upon the compliance setting. It is used to convert the raw volume count to a displaced volume reading in liters, as shown below, and

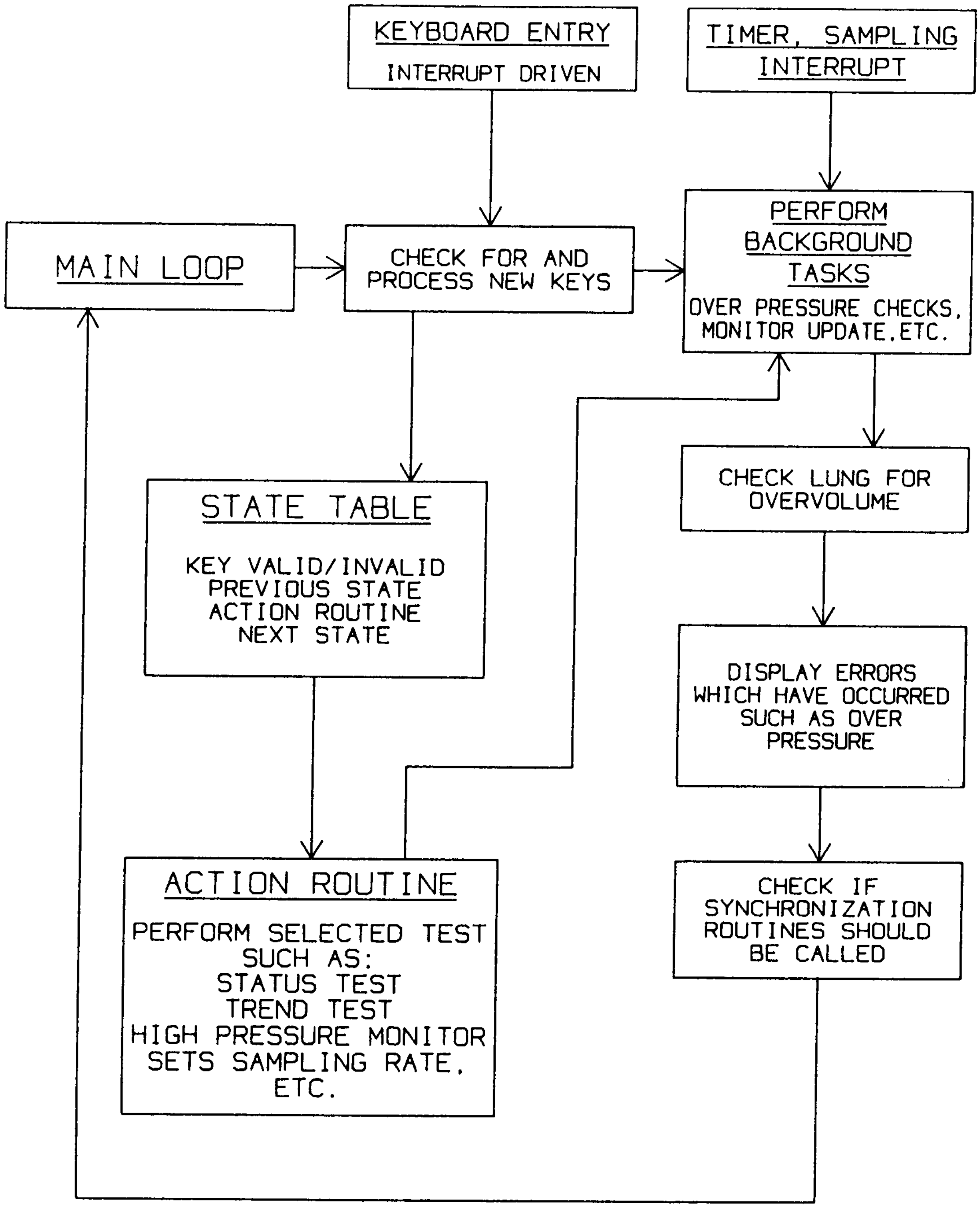
K_r is the term required to convert the displaced volume reading to an equivalent reading in different reference units. It is dependent on atmospheric pressure, temperature, relative humidity, and the reference units entered during SET-UP:

NOTES:

1. Barometric Pres. announced over the radio, by weather services, and by airports are adjusted to sea level. In order to correct this to the altitude one is in, the following equation is used:

Corrected Bar. Pres. in mmHg = (Sea Level Bar. Pres. in mmHg) x $[\{1 - (0.000006873 \text{ x Altitude in feet})\}^{5.256}]$

2. For Infant Lung the ratio of (Final Cylinder Pressure) / (Starting Cylinder Pressure) is used to calculate volumes and flows, since the ratio is directly proportional to the delivered volume.



(Bio-Tek Instruments Inc.)

Figure A.4.2-2. Ventilator Tester Software Block Diagram

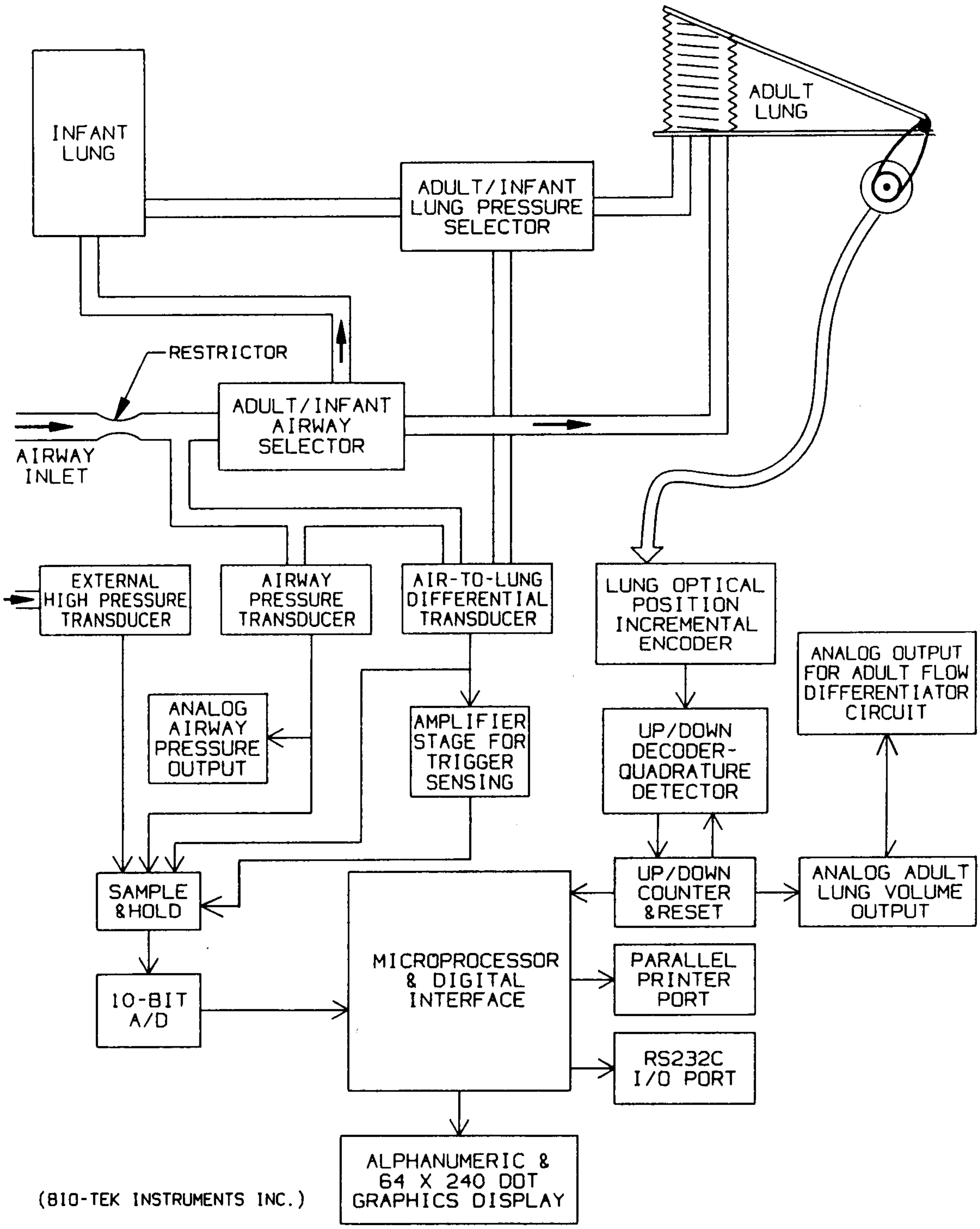


Figure A.4.2-1. Ventilator Tester Hardware Block Diagram

APPENDIX B

B.1 Airway Restrictors

The chart below contrasts the flow/pressure values of the new restrictors with those previously supplied with VT-2 and VT-1B.

The new restrict values are plotted against the previous values which are in parenthesis.

The practical impact of these changes may be relatively small, yet they are listed for your reference. The changes in restrictor construction are to satisfy ASTM F1100-90 for airway restrictions.

Parabolic Restrictors Calibrated to Defined Flow Rates

Parabolic Restrictor Linear Equivalent	Flow Rates (liters/minute) 3.0	4.5	6.0	15.0	30.0	60.0	120.0
INFANT							
R_{p500}	26.7	50.2	---	---	---	---	---
R_{p400}	(14.0)	---	(54.5)	---	---	---	---
R_{p200}	6.1(4.0)	---	24.4(20.0)	---	---	---	---
ADULT							
R_{p50}	---	---	---	6.8(6.8)	27.2(24.5)	---	---
R_{p20}	---	---	---	---	4.4(4.4)	17.6(20.8)	---
R_{p5}	---	---	---	---	---	2.7(2.7)	10.8(10.8)

These parabolic restrictors have been designed specifically to produce flow characteristics to match the Rp500, R_{p200}, R_{p50}, and R_{p5} linear restrictors specified by ASTM F1100-90. The flow characteristics are defined in the characteristic equation:

$$\text{Pressure drop} = K\,(\text{Flow})^2\ \text{cmH}_2\text{O}$$

where K is defined (+/- 5%) empirically for each restrictor as follows:

R_{p500} = 8925 $cmH_2 0/L^2/sec^2$*
R_{p200} = 2440 $cmH_2 0/L^2/sec^2$
R_{p50} = 108.7 $cmH_2 0/L^2/sec^2$
R_{p20} = 17.61 $cmH_2 0/L^2/sec^2$
R_{p5} = 2.700 $cmH_2 0/L^2/sec^2$

* R_{p500} orifice dia is too small relative to the plate thickness for the square law to apply; constant for 4.5 L/min data point is: 8925 instead of 10661.

The keyboard input subsystem is structured as a state machine. The keyboard state variable is used to indicate what processing and keyboard input has already occurred. The keyboard state variable has an entry for every valid input character in each keyboard state. When a new key is pressed, the state table is searched for the entry which corresponds to the current state and input.

The state table contains the address of a procedure to be executed and the next state to be entered. If the combination of current state and input is not found in the table, the key was not a valid entry. If the key is a valid entry, the current state is set to the value from the table and an action executed. The keyboard state variable can also be modified by the keyboard action routines or by the background processing.

The background subsystem controls the sampling and calculations for the various functions, and is controlled by a state variable. For each background state there is a procedure which is called every time the background module is entered in that state. Most of the procedures monitor the progress of the sampling to determine when calculations or display updates are required. Processes requiring significant time are divided between several states to assure that the keyboard is periodically monitored.

The ventilator tester also has 'Test' software to troubleshoot and calibrate:

1. 'Beeps' for valid and invalid key, and audible alarm for overpressurized lung.
2. CHECKSUM routines to test EPROMS, and a RAM test.
3. Datalogging for serial, parallel ports.
4. Solenoid for auto-zero feature.
5. All front-end circuits for input signals.
6. Triggering algorithm and computer control tests with simulated waveforms, from which a known output is verified.