Operator's Manual

774612C

SensorMedics
a subsidiary of VIASYS Healthcare

Copyright and Trademark Notices

Company Information

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Declaration of Conformity

SensorMedics
a subsidiary of VIASYS Healthcare

MANUFACTURER'S DECLARATION OF CONFORMITY
for

Product Identification:	
Products:	Vmax Spectra Series
Brand:	SensorMedics
Models:	V20, V20c, V22d, V22lv, V22, V29c, V29n, V29s, V29, V229d, V229lv, V229n, V229c, and V229
Manufacturer:	SensorMedics Corporation A subsidiary of VIASYS Healthcare 22705 Savi Ranch Parkway Yorba Linda, CA 92887
EU Representative:	QA & Technical Services Manager SensorMedics BV Rembrandtlaan 1B 3723 BG Bilthoven The Netherlands
Samples of the products have been tested by:	TUV Product Service San Diego, CA 92121 ITS-Intertek Testing Services Laguna Niguel, CA 92677 TUV Product Service GMBH
Standards used:	EN 60601-1-2; EN 55011, Class B; IEC 601-2-25; EN 60601-1/IEC 601-1; and DIN VDE 0750 T1
Test reports:	S6034-imm; S6034-em; S6033-imm; S6033-imm; S310407901; S300575201; and, 3011362
Means of Conformity:	These Class IIa products are in compliance with MDD 93/42/EEC based on test results using harmonized standards in accordance with Article 11 of the Directive.
Signature of Company Representative:	Earl W Draper 2/1/2002 Earl W. Draper Date Director, Quality Systems and Regulatory Affairs

774423-A

Precautions

- Caution: Federal law restricts this device to sale by, or on the order of, a physician.
- Caution: This device is not suitable for use in the presence of flammable anesthetics.
- Service of this device is restricted to factory-trained personnel only.

Equipment Classification

Classification of equipment described in this manual:

- Class I
- Type BF Defibrillator Proof (ECG Module)
- Type B (Vmax®, V6200, and V62J)
- Mode of Operation: Continuous

The Vmax and V6200 comply with the Medical Device Directives, MDD 93/42/EEC, and are approved to carry the CE Mark shown below.

CE
0050

The V62J complies with the Medical Device Directives, MDD 93/42/EEC, and is approved to carry the CE Mark shown below.

CE
0123

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CHAPTER 1 • INTRODUCTION

The Vmax Spectra respiratory analysis system incorporates the latest technology for performing highly accurate lung-function and metabolic analyses. Providing accuracy and stability over a wide range of uses, the Vmax Spectra makes available several significant feature enhancements, including the ability to operate on networks and enhancements to the DLCO application.

The Vmax Spectra can be used as a stand-alone system, or it can be connected to a network and linked to other Vmax systems or to mainframe computers. In conjunction with the NetLink/IS_{2000} and the NetLink/IS_{ADT} options, the Vmax Spectra system is capable of communicating with hospital information systems (HIS) and with admission, discharge, and transfer systems (ADT).

Enhancements to the DLCO application were developed in conjunction with a newly engineered, commercially available DLCO calibrator. This calibrator, developed by Hans Rudolph, is intended to be the Gold Standard Referee System to validate DLCO system performance.

The instructions provided in this manual are intended for persons responsible for performing lung-function analyses (pulmonary function and respiratory mechanics tests) and metabolic analyses (cardiopulmonary exercise tests and nutritional assessments). Read this manual thoroughly and make sure that you fully understand the procedures before using the system.

Procedures are provided in this manual for performing tests with the following instruments:

- Vmax Spectra 20 Pulmonary Spirometry Instrument
- Vmax Spectra 20c Pulmonary Spirometry Instrument
- Vmax Spectra 22 Pulmonary Function Analysis Instrument
- Vmax Spectra 22d Pulmonary Function Analysis Instrument
- Vmax Spectra 22lv Pulmonary Function Analysis Instrument
- Vmax Spectra 29 Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 29c Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 29n Nutritional Assessment Instrument
- Vmax Spectra 29s Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 229 Pulmonary Function/Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 229c Pulmonary Function/Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 229d Pulmonary Function/Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 229lv Pulmonary Function/Cardiopulmonary Exercise Testing Instrument
- Vmax Spectra 229n Pulmonary Function/Nutritional Assessment Instrument
- 2130 Series Spirometer
- Autobox Body Plethysmograph
- Autobox D_L Body Plethysmograph (with diffusion)

VMAX SPECTRA INTENDED USE

The Vmax Series has been designed and labeled as having the same indications for use as one or more of the predicate products of SensorMedics. This involves performing physician-prescribed pulmonary function and metabolic testing. More specific, intended uses are listed below.

- Differential diagnosis (Heart/Lungs)
- Disability assessment
- Rehabilitation evaluation
- Exercise prescription
- Sports medicine/research
- Energy assessment, substrate utilization
- Assessment of supplemental O2 requirement
- Evaluation of medication effects
- Pulmonary Function testing for adults and children
- Document effectiveness of broncho-dilator therapy
- Pulmonary disability evaluation
- Industrial surveillance
- Broncho-challenge testing
- Exercise induced broncho-spasm
- Pre-surgical risk evaluation
- Bedside lung function

The European version of the Vmax Spectra is also intended to be combined with a Jaeger V62J body box.

The following table identifies the chapters applicable to each instrument:

Chapter	Instrument					
	20	22	29	229	2130	Autobox
Introduction	✓	✓	✓	✓	✓	✓
Flow Volume Calibration	✓	✓	✓	✓	✓	✓
Pulmonary Function Testing	✓	✓	OP	✓	✓	✓
Plethysmography	NA	NA	NA	NA	NA	✓
Respiratory Mechanics	NA	OP	NA	OP	NA	OP
Exercise/Indirect Calorimetry Testing	NA	OP	✓	✓	NA	NA
Reports	✓	✓	✓	✓	✓	✓
File Manager	✓	✓	✓	✓	✓	✓
Maintenance and Troubleshooting	✓	✓	✓	✓	✓	✓

✓ The chapter or section applies to this instrument.

OP The chapter or section applies if the corresponding option has been added to the base instrument.

NA The chapter or section does not apply to this instrument.

CAUTION AND WARNING STATEMENTS

The caution and warning statements included in this manual alert the operator to potentially hazardous situations. “Caution” statements alert the operator to potential problems that could result from misuse of the equipment—problems such as device malfunction, device failure, and damage to the equipment or to other property. “Warning” statements, on the other hand, alert the operator to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the equipment.

General cautions and warnings that must be read and understood before operating the equipment are provided below; specific cautions and warnings that are related to particular situations are provided in the relevant sections of this manual. **Read and make sure that you understand all cautions and warnings prior to operating the equipment described in this manual and before performing the related procedure or operation.**

General Cautions

The following general cautions pertain to potential problems that could result from misuse of the equipment and that could cause device malfunction, device failure, and damage to the equipment or other property. Read and make sure that you understand these cautions before using the equipment.

- Use calibration gases that meet the specifications required by SensorMedics. If calibration gases do not meet these specifications, or they are incorrectly labeled, instrument malfunction and erroneous test results could result (refer to “Test Gases” on page 12).
- The Vmax and Autobox instruments specified in this manual have been tested and confirmed to comply with EN60601-1 (Electrical Safety) and EN60601-1-2 (EMC) and are labeled with the CE Mark to identify this compliance. These limits are designed to provide reasonable protection in a typical medical environment; however, there is no guarantee that interference will not occur in a particular installation. The instruments generate, use, and can radiate radio frequency energy and–particularly if not installed and used in accordance with the normal operating instructions–may cause interference with other devices in the vicinity. If a SensorMedics instrument causes interference to other devices (which can be determined by turning the instrument on and off), or if other devices cause interference with the SensorMedics instrument, try to correct the interference with the following measures:
    - Re-orient or relocate one or both of the devices.
    - Increase the separation between the devices.
    - Connect one of the devices to an electrical outlet on a separate circuit.

  If the above measures do not solve the problem, contact SensorMedics for technical support (refer to “Company Information” on page iii).

General Warnings

The following general warnings are to alert the operator to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the equipment. Read and make sure that you understand these cautions before using the equipment.

- The ECG Module is protected against the effects of a cardiac defibrillator discharge to ensure instrument recovery as required by test standards. If possible, remove the leads from the patient before using a cardiac defibrillator for maximum protection to the ECG Module electronics.
- Properly secure large gas cylinders. Cylinders for all the necessary gases (except oxygen) are included with the instrument. You can use larger cylinders and regulators (purchased from SensorMedics or elsewhere) if the instrument is not intended to be mobile. Large gas cylinders must be secured with cylinder safety chains or safety stands (not included).
- Keep all sources of ignition away from the equipment. The use of oxygen in testing requires that special care be taken to prevent fire. Any materials that will burn in air, and some that will not, ignite easily and burn rapidly in high concentrations of oxygen. Accordingly, keep all sources of ignition away from the equipment, such as an incubator, and preferably out of the room in which the equipment is being used. “No Smoking” signs should be prominently displayed.
- Keep oil, grease, or greasy substances away from the oxygen regulators, cylinder valves, tubing, connections, and all other oxygen equipment. A spontaneous and violent ignition could occur if oil, grease, or greasy substances are exposed to oxygen under pressure.
- On high-pressure oxygen cylinders, only use approved reducing or regulating valves marked for oxygen service. Do not use these valves for air or gases, other than oxygen, because they may be hazardous when returned to oxygen service. Such equipment must be operated strictly in accordance with the manufacturer’s directions.

  In view of the above considerations (and to avoid handling heavy cylinders in the nursery), keep high-pressure oxygen equipment outside the nursery. In any event, cylinders in use should be fixed into place to prevent them from being knocked over and should be located as far away as possible from the incubator.
- Mixtures of oxygen and flammable vapors such as alcohol, ether, ethylene, and cyclopropane could explode if ignited. Such mixtures could be ignited by electrical static spark discharges, high temperature surfaces, or all other more common sources of ignition. Only equipment designed for use in hazardous locations should be used in operating and delivery rooms. Refer to Article 517 of the ANSI/NFPA 70, National Electrical Code, for the use of flammable anesthetics.

- Only use three-prong, hospital-grade power plugs and properly grounded receptacles. In the United States and Canada, the instruments are factory-equipped with three-prong, hospital-grade power plugs. Grounding reliability and leakage current suppression can only be assured when the instruments are connected to a three-wire receptacle with the green (or yellow-green) return wire connected to earth ground. To prevent serious damage to the device and to the interconnected equipment and to prevent injuries to patients and to others associated with the device, do not use a receptacle that does not meet this specification. In addition, do not use devices to defeat the proper ground connection (such as a two-prong adapter plug).
- Any accessory equipment connected by the user to the analog/digital interfaces must be certified according to the applicable electrical safety standard. Applicable standards include UL-2601-1 for U.S. installations, IEC 950 for data processing equipment, and IEC 601-1 for medical equipment for the European Community. Furthermore, all configurations of accessory equipment with SensorMedics instruments must comply with the system standard IEC 601-1-1 (UL2601). Consult the accessory equipment documentation to verify compliance with these standards. Anyone connecting additional equipment to the signal input or signal output is configuring a medical system and is, therefore, responsible to assure that the system complies with the requirements of the applicable system standard. If you have any doubt about connecting additional equipment, contact SensorMedics for technical support (refer to “Company Information” on page iii).
- Do not attempt the insertion or maintenance of the esophageal balloon catheter unless you are thoroughly familiar with patient preparation, testing procedures, indications, and complications. Compliance testing can be considered an invasive medical procedure requiring qualified medical supervision.
- To ensure the safety of the patient, only use parts and accessories manufactured by SensorMedics Corporation. The ECG system has been tested for electrical safety using the components supplied by SensorMedics. The part numbers of these components are listed in the reference manual.

  Check every ECG electrode for wear or damage before application of the electrodes on a patient. Discard electrodes that have exposed wiring, damaged insulation, or broken components.

  The conductive parts of the electrodes and the associated connectors, including the neutral electrode, must not contact other conductive parts of the instrument, including the earth ground.

  Do not use the ECG Module the presence of cardiac pacemakers or other electrical stimulators.
- Remove the dilution mask or the canopy from the patient before troubleshooting. During dilution testing, a battery-powered alarm will sound if the on/off switch of the

pump is in the “on” position and there is a power loss to the Pneumatics Module. The dilution mask or canopy must be removed form the patient before troubleshooting.

- Stop dilution testing and remove the dilution mask or canopy from the patient before troubleshooting if any of the dilution alarm warning messages is given.
- When using specialized, indirect calorimetry-ventilator breathing circuits, closely monitor the patient and test the patient in a manner that does not increase work of breathing or introduce other additional risks.
- Follow all the cleaning procedures carefully, and thoroughly inspect the components after they are cleaned and before each patient is tested. **Cleaning residue, particulate matter, and other contaminates (including pieces of torn or broken components) in the breathing circuit create a safety risk to the patient during testing procedures. Aspiration of contaminates can be potentially life threatening**. Follow all the cleaning procedures carefully, and thoroughly inspect the components after they are cleaned and before each patient is tested.
- Certain regulatory approvals require the use of a disposable MicroGard™ filter during pulmonary function testing and the use of a sputum trap during exercise testing to achieve the required level of safety. Absence of the MicroGard™ filter or the sputum trap will degrade the safety of the equipment.

SPECIFICATIONS

Note

Features and specifications are subject to change without notice.

Flow/Volume/Gas Measurements

Flow/Volume	
Type	Mass Flow Sensor
Range	0 – 16 LPS
Resolution	0.003 LPS from 0.20 – 16 LPS
Flow accuracy	±3% of reading or 0.25 LPS, whichever is greater, across the range of 0.2 to 14 LPS
Volume accuracy	±3% of reading or 0.050 L, whichever is greater
Resistance	<1.5 cmH2O/LPS @ 12 LPS
O_2 Analyzer	
Type	Electrochemical fuel cell
Range	0 – 100%
Resolution	0.01%
Accuracy	±0.02%
CO_2 Analyzer	
Type	Non-disperse infrared, thermopile
Range	0 – 16%
Resolution	0.01%
Accuracy	±0.02% CO_2 across range of 0-10%. There is no accuracy specification above 10% CO_2.
Flash Multi-Gas[1]	
Type	Non-disperse infrared, thermopile
Range	0 – 0.33% CO
	0 – 0.33% CH_4
	0 – 0.33% C2H2
Resolution	0.0005% CO

[1] The Multi-Gas Analyzer is only included with diffusing capacity testing applications.

	0.0005% CH_4
	0.0005% C2H2
Accuracy	±0.003% CO
	±0.003% CH_4
	±0.003% C2H2

Transducers

Flow Direction (DIR) Range: ±2 cmH_2O	
Mouth Pressure (PM)	
Range	±300 cmH_2O
Accuracy	±1%
Barometric/Sample Pressure (BP)	
Range	300 – 800 mm Hg
Accuracy	±3 mm Hg
Temperature (TEMP)	
Range	0 – 40ºC
Accuracy	±1°C

Dilution Flow Blower

	0 – 80 LPM
	Manual ON/OFF switch
	Hi/Low O_2/CO_2 Flow Alarms

Environmental Requirements

Modules	Operating	
	Temperature	5 – 40ºC
	Humidity	15 – 95%, non-condensing
	Storage	
	Temperature	-20 to 50ºC
	Humidity	0 – 100%, non condensing
Autobox	Temperature	5 – 40ºC
	Humidity	15 – 95%, non-condensing
	Warm up	30 minutes

Internal Quality Assurance Gas Infusion Calibrator

VE range for constant VO_2/VCO_2 stability:	10 - >100 LPM Temporal Alignment Verification System Integrity This feature is included with the cardiopulmonary exercise testing application.

Electrical Requirements

Voltage	100 V AC to 240 V AC
Frequency	50/60 Hz
Phase	Single
Current	Console: Max. 12 A at 115 V AC
Leakage current	<100 microamperes

Computer Requirements

Processor	Intel® Pentium® III, 600 MHz. 866 MHz (PC) and 750 MHz (notebook) are recommended.
RAM	128 MB
Operating system	Microsoft® Windows® 98
HDD	6 GB or greater
All the supplied Spectra software has been validated using office-based Dell® computers. The Spectra software has not been validated with other computer brands. Using computers other than the computers used for validation can create malfunctions. For additional information about computer specifications, contact SensorMedics for technical support (refer to “Company Information” on page iii).	

Dimensions and Weights

Modules (each)	9.5 cm high x 33 cm wide x 36 cm deep
	(3.75 in x 13 in. x 14 in)
	5.79 kg avg. (13 lb)
Console	96.5 cm high x 57.2 cm wide x 78.7 cm deep (38 in x 22.5 in x 31 in) 65.25 kg (145 lb)
	(39.3 in x 23 in x 37 in)
	56.81 kg (125 lb)
Table	76 cm high x 122 cm wide x 76 cm deep
	(30 in x 48 in x 30 in)
	68.2 kg (150 lb)
V62J Cabin	185 cm high x 87 cm wide x 80 cm deep
	(72.8 in x 42 in wide x 31.5 in deep)
	119 kg (265 lb)
V62H Cabin	185 cm high x 203 cm wide x 100 cm deep
	(72.8 in x 79.9 in wide x 39.4 in deep)
	146 kg; 154 kg with ramp (325 lb; 343 lb with ramp)
V6200 Cabin	167 cm high x 132.1 cm wide x 81.3 cm deep
	(66 in x 52 in wide x 32 in deep)
	227 kg (500 lb) Approx.

Standards

Quality system registration	ISO 9001/EN 46001
FDA	510(k) market clearance
MDD 93/42/EEC	CE marked
Electrical safety	EN 60601-1
EMC	EN 60601-1-2

TEST GASES

Caution!

Use calibration gases that meet the specifications required by SensorMedics. If calibration gases do not meet these specifications, or they are incorrectly labeled, instrument malfunction and erroneous test results could result.

Warning!

Properly secure large gas cylinders. Cylinders for all the necessary gases (except oxygen) are included with the instrument. You can use larger cylinders and regulators (purchased from SensorMedics or elsewhere) if the instrument is not intended to be mobile. Large gas cylinders must be properly secured with cylinder safety chains or safety stands (not included).

Note

A high-pressure hose for using central wall oxygen is included the system.

The gas specifications for the various instrument systems are presented below. The delivery pressure for all the gases should be set at 50 to 60 PSI (345 to 414 k Pa) except as noted in Table 1.

Table 1 – Test Gas Requirements

A	**Oxygen** 99–100%
B	Diffusion Mixture
	Carbon Monoxide (CO) 0.3% (±0.006%)
	Methane (CH4) 0.3% (±0.006%)
	Oxygen (O2) 21% (±0.4%)
	Nitrogen (N2) Balance
C	**Span Gas 1**
	Oxygen (O2) 16% gravimetric analysis (±0.02% absolute)
	Carbon Dioxide (CO2) 4% gravimetric analysis (±0.02% absolute)
	Nitrogen (N2) Balance
D	**Span Gas 2**
	Oxygen (O2) 26% gravimetric analysis (±0.02% absolute)
	Nitrogen (N2) Balance

Instrument	Gases			
	A	B	C	D
2130, Vmax 20, 20c				
Vmax 22	✓	✓[1]	✓	
Vmax 22d	✓[2]	✓[1]		
Vmax 22lv	✓		✓	
Vmax 29, 29c, 29n			✓	✓
Vmax 229, 229n	✓	✓[1]	✓	✓
Vmax 229d	✓[2]	✓[1]	✓	✓
Vmax 229lv	✓		✓	✓
Autobox	✓[3]		✓[4]	

[1] 10–20 PSI (69–138 k Pa) above the oxygen delivery pressure setting

[2] Or any non-flammable gas or gas mixture

[3] Only necessary if the Autobox is used with a Vmax 20, 29, 29c, or 29n (can also be any non-flammable gas or gas mixture)

[4] Only necessary for in-cabin Gas Dilution Lung Volume or SBO2 testing

Note

To avoid calibration errors on the Vmax systems, it is important that the diffusion gas pressure always be set 10–20 PSI (69–138 k Pa) higher than the other gases (see specified pressures, above).

Note

Always set the diffusion gas pressure at 10 to 20 PSI (69 to 138 k Pa) higher than the other gases to avoid calibration errors on the Vmax systems (see the specified pressures, above).

EXPLANATION OF SYMBOLS

The symbols used on the equipment are defined in Table 2.

Table 2 – Equipment Symbols

Main Circuit Breaker On (See the following Note.)	Main Circuit Breaker Off
Local Circuit Breaker On (See the following Note.)	Local Circuit Breaker Off
Pump Switch	Sample Line Calibration Port
Attention, Consult Accompanying Documents	Alternating Current / Voltage
Direct Current / Voltage	Pulse Signal
ECG Connection	Equipment of Type B
Equipment of Type BF	Ampere
Volt	Hertz
Protective Earth Ground	Functional Earth Ground
Signal Input	Signal Output
Input/Output Interface Connector	Dangerous Voltage

CHAPTER 2 • AUTOBOX™ INSTALLATION

INSPECT FOR DAMAGE

On receipt of your instrument(s), you should immediately inspect all units and containers for shipping damage. If damage is suspected, please notify both the carrier and the SensorMedics Service Department immediately.

UNPACKING AND SETUP

A SensorMedics service representative will unpack the system and check it for proper operation and safety.

OPERATOR TRAINING

Comprehensive operator training is offered several times each year at the corporate headquarters in Yorba Linda, California, at the European headquarters in Bilthoven, The Netherlands, and at various other locations throughout the world. The Yorba Linda training seminar is three to five days in length and is accredited by the American Association of Respiratory Care.

The extensive on-line tutorial program is designed to provide comprehensive training for operators who choose not to attend the training seminars discussed above. Periodic review of the tutorial program will assure a high level of operator competence and is designed to serve as the basis for training new operators.

The SensorMedics Service Representative will provide complete instructions on using the tutorial program at the time of installation.

REQUIRED ENVIRONMENTAL AND OPERATIONAL CONDITIONS

- Temperature: 5–40°C
- Humidity: 15%–95% (non-condensing)
- Warm up time: 30 minutes

Note

The Autobox trademark describes the family of body-plethysmograph systems sold and supported by SensorMedics Corporation. When referring to a specific Autobox system, the instructions in this manual will clearly state the model number.

Note

The precision pressure transducers on the Autobox system can be affected by large, erratic changes in air pressure. The quality of the measured test data will be enhanced by operating the instrument in a location that is relatively free from pressure fluctuations. These fluctuations can be caused by excessive vibration of floors or walls; airflow from air conditioning vents; or by the opening and closing of doors.

Warning!

Do not use this equipment if it is not properly connected to earth ground. Using improperly grounded equipment could result in serious injury or death and severe damage to the equipment and interconnected equipment.

In the U.S. and Canada, the instruments are factory-equipped with three-prong, hospital-grade AC power plugs. Grounding reliability and leakage current suppression can only be assured when the power plugs are properly connected to earth-grounded receptacles.

Note

The instruments described meet the safety requirements of UL, NFPA, LACTL, CSA, TUV, BSI, and IEC-601 for leakage currents.

Note

The instruments are checked for leakage current before shipment. The SensorMedics service representative (or distributor representative outside the U.S. and Canada) will assist hospital personnel in verification if requested.

Special Environmental Considerations

Excessive amounts of dust, lint, and miscellaneous clutter in the area around the instrument could result in malfunctions created by internal tubing blockages, overheating of components, clogged ventilation ports, etc. Keep the surrounding areas clean, orderly, and well ventilated.

Electrostatic Discharge

The instruments specified in this manual are designed and tested to withstand normal amounts and occurrences of Electrostatic Discharge (ESD). Under certain circumstances, however, it is still possible for ESD to damage components of the system. ESD takes place when a person has built up enough static electricity on their body that an electric discharge occurs when they touch something conductive like metal or another person. This can damage instrument components if the “charged” individual touches something sensitive to ESD, such as the input connectors on the rear panel of the instrument. ***This destructive discharge may not cause a noticeable “shock."*** To avoid this, you should make it a habit to always touch the outer metal cabinet of the instrument before touching any other component.

Some of the conditions that tend to increase levels of ESD are extremely low humidity, carpeted floors, and walking with shoes off in stocking feet.

Electromagnetic Interference

The instruments specified in this manual are designed and tested to withstand normal amounts and occurrences of Electromagnetic Interference (EMI). EMI consists of electromagnetic waves from one electronic device interfering with the function of another electronic device. These waves can be radiated through the air or conducted through electric wires. Although unlikely, high levels of EMI could affect the function of the instrument, possibly causing noise in the measurement signals. The impact of this could range from “fuzziness” in the displayed test tracings to difficulty in calibrating the Mass Flow Sensor and analyzers. The situation would be remedied by locating and distancing the offending device. Likely causes of troublesome EMI in the hospital setting include (but are not limited to) MRI systems, lasers, diathermy equipment, cauterizers, transmitting computers, and hand-held communicators.

The instruments specified in this manual are also designed and tested to comply with the EMI emission limits for medical devices—IEC 601-1-2:1993, and EN60601-1-2:1993—and are labeled with the CE Mark to identify this compliance. These limits are designed to provide reasonable protection against harmful EMI in a typical medical environment; however, there is no guarantee that interference will not occur in a particular installation. The instruments generate, use, and can radiate radio frequency energy and—particularly if not installed and used in accordance with the normal operating instructions—may cause interference with other devices in the vicinity. If a SensorMedics instrument does cause interference to other devices (which can be determined by turning the instrument off and on), or if other devices cause interference with the SensorMedics instrument, you should try to correct the interference with the following measures:

- Re-orient or relocate one or both of the devices.
- Increase the separation between the devices.
- Connect one of the devices to an electrical outlet on a separate circuit.
- If the above measures do not solve the problem, call the SensorMedics Service Department for assistance.

FLOOR SPACE AND LOADING CAPACITY

The following diagrams show the size and weight of the instrument configurations. You will need adequate structural support to sustain the weight of the instruments plus the weight of the patient and operator. You will also need adequate floor space to assure access to the patient during testing.

You can estimate the size and weight of any instrument system from the components in the following diagrams.

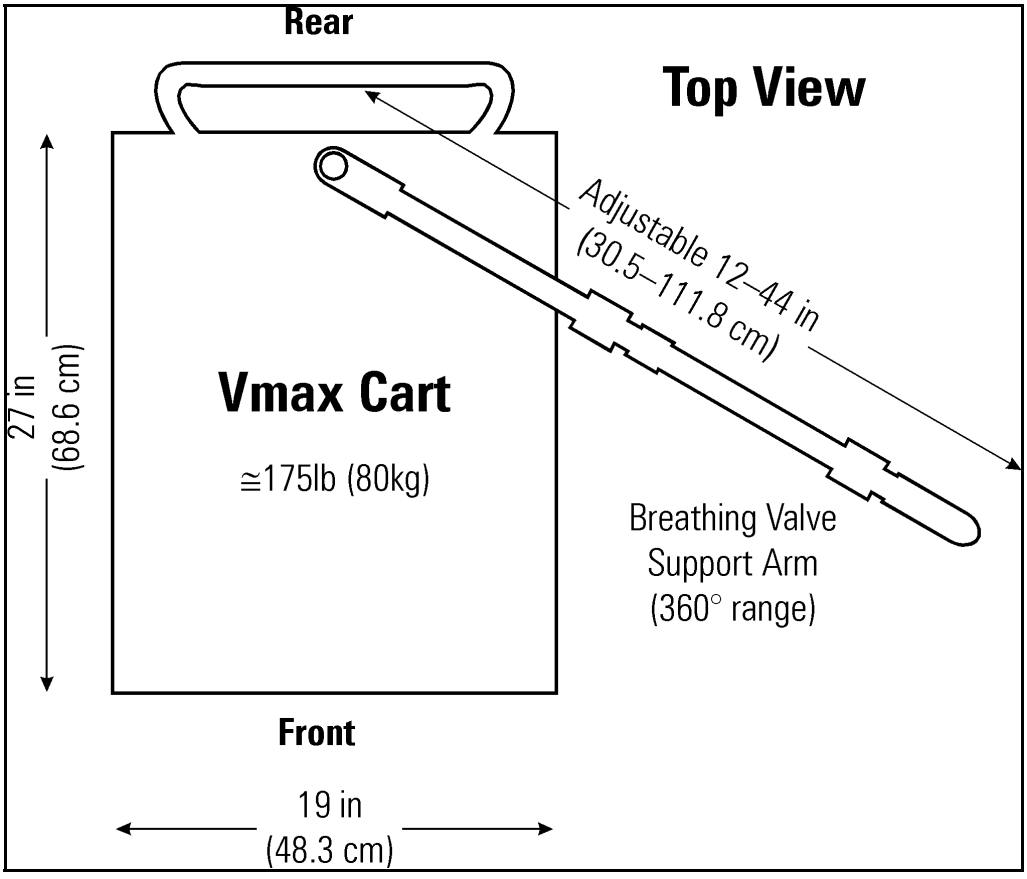

Figure 2-1 – Vmax 22 Pulmonary Function Laboratory (with Cart)

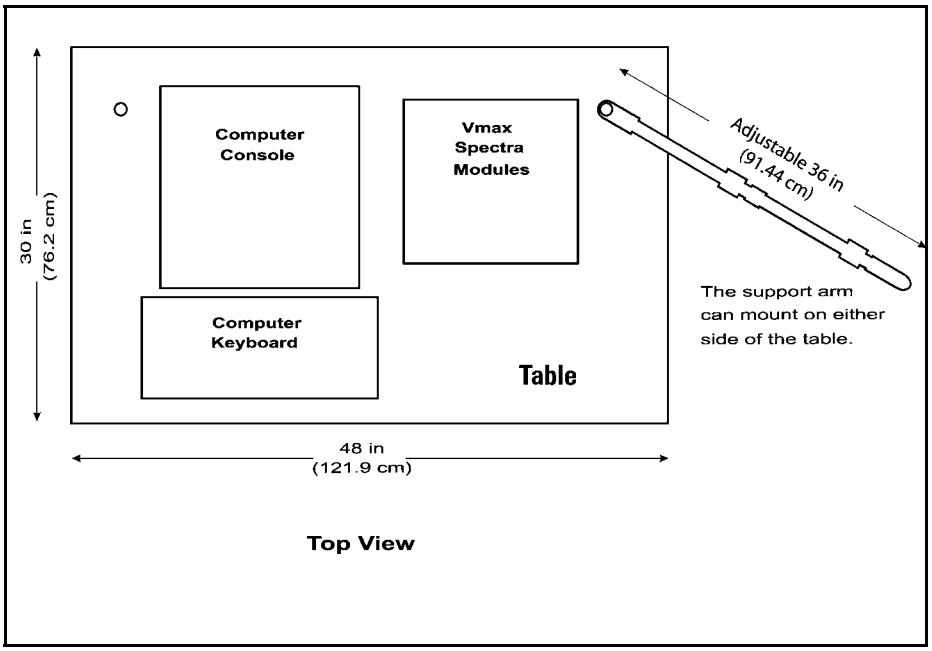

Figure 2-2 – Vmax 22 Pulmonary Function Laboratory (with System Table)

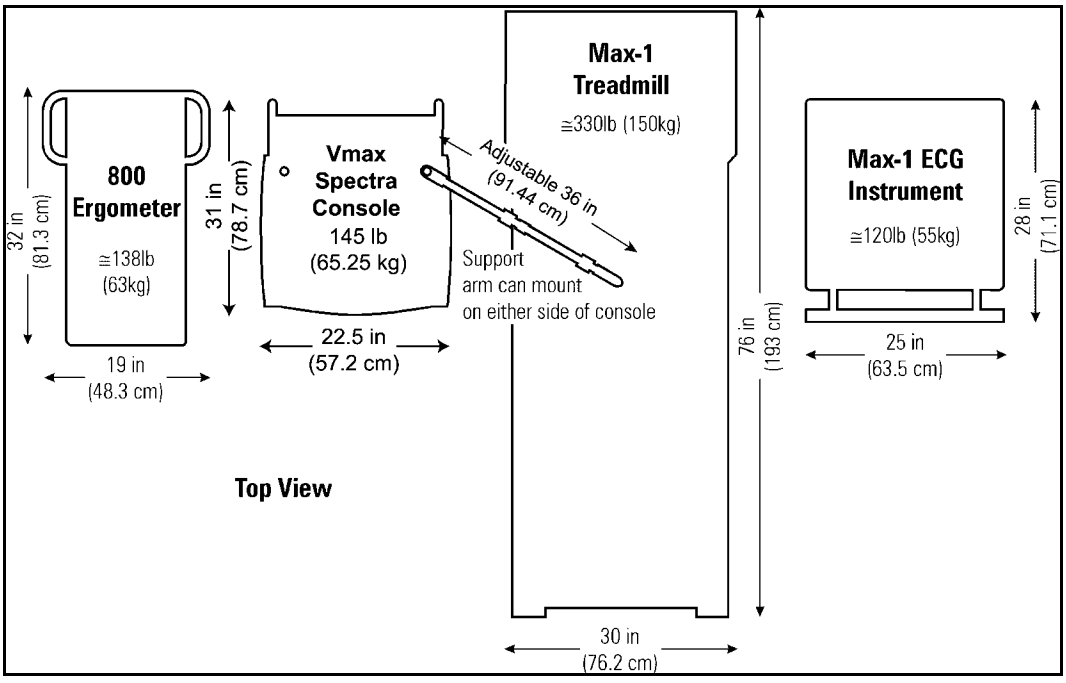

Figure 2-3 – Vmax 229 Pulmonary Function/Cardiopulmonary Exercise Testing Instrument (with Console, Treadmill, Ergometer, and ECG Instrument)

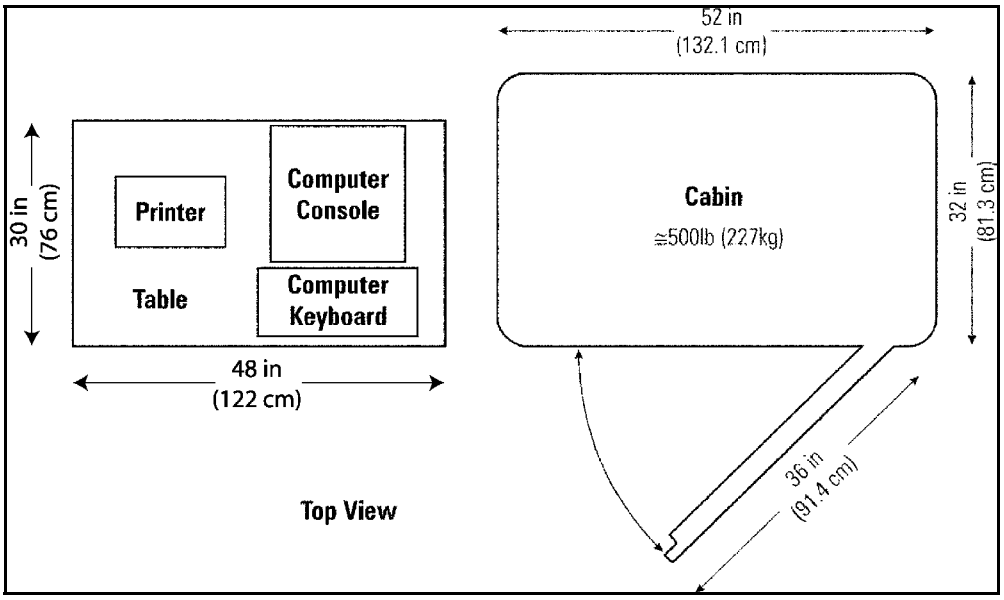

Figure 2-4 – V6200 (with Table)

The dimensions and weights of systems not shown in the previous diagrams are provided in Table 3.

Table 3 – Dimensions and Weights

V62J Cabin	185 cm high x 87 cm wide x 80 cm deep
	(72.8 in x 34.25 in x 31.5 in deep)
	119 kg (265 lb)
V62H Cabin	185 cm high x 203 cm wide x 100 cm deep
	(72.8 in x 79.9 in x 39.4 in)
	146 kg; 154 kg with ramp (325 lb; 343 lb with ramp)
Modules (each):	9.5 cm high x 33 cm wide x 36 cm deep
	(3.75 in x 13 in. x 14 in)
	5.79 kg avg. (13 lb)
Console:	100 cm high x 58.4 cm wide x 94 cm deep
	(39.3 in x 23 in x 37 in)
	56.81 kg (125 lb)
Table:	76 cm high x 122 cm wide x 76 cm deep
	(30 in x 48 in x 30 in)
	68.2 kg (150 lb)

CABLE AND TUBING CONNECTIONS

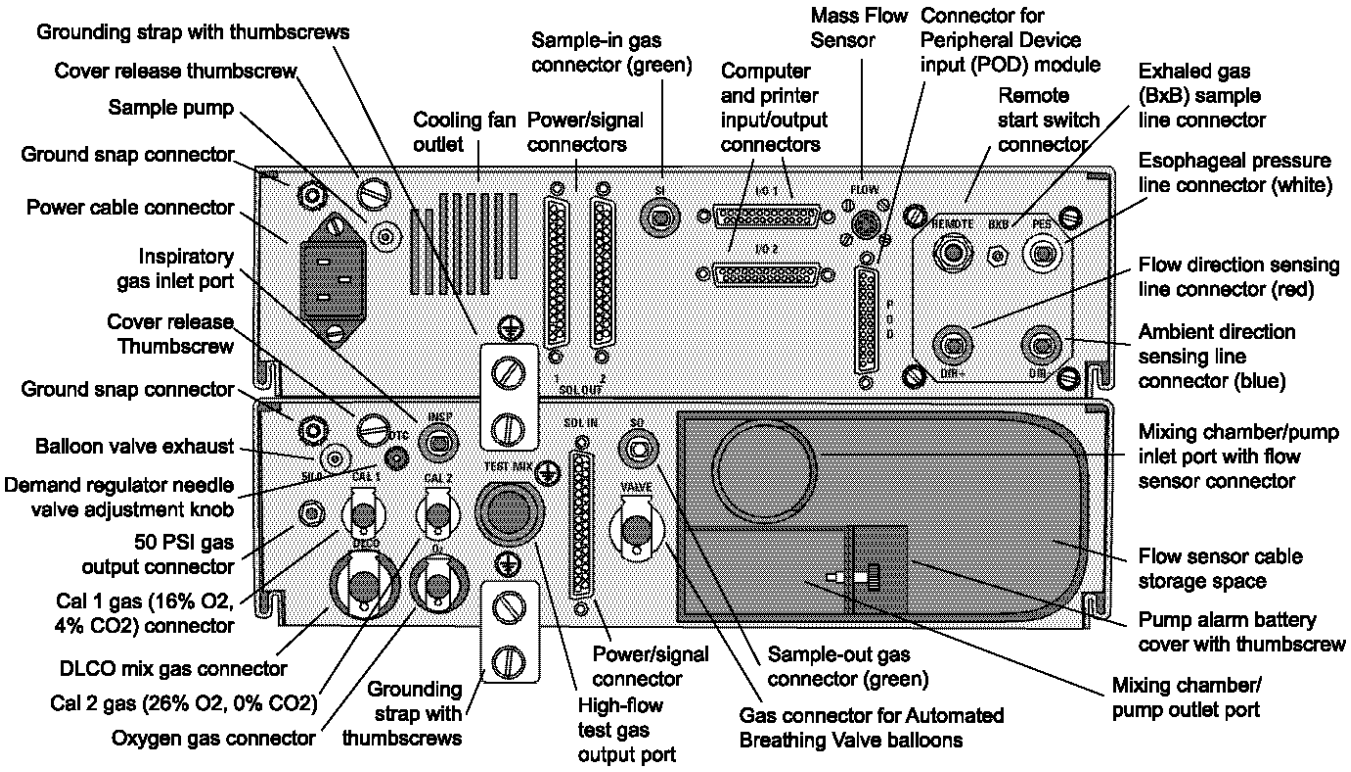

Figure 2-5 – Rear Panel Connectors—Vmax Analyzer and Pneumatics Modules

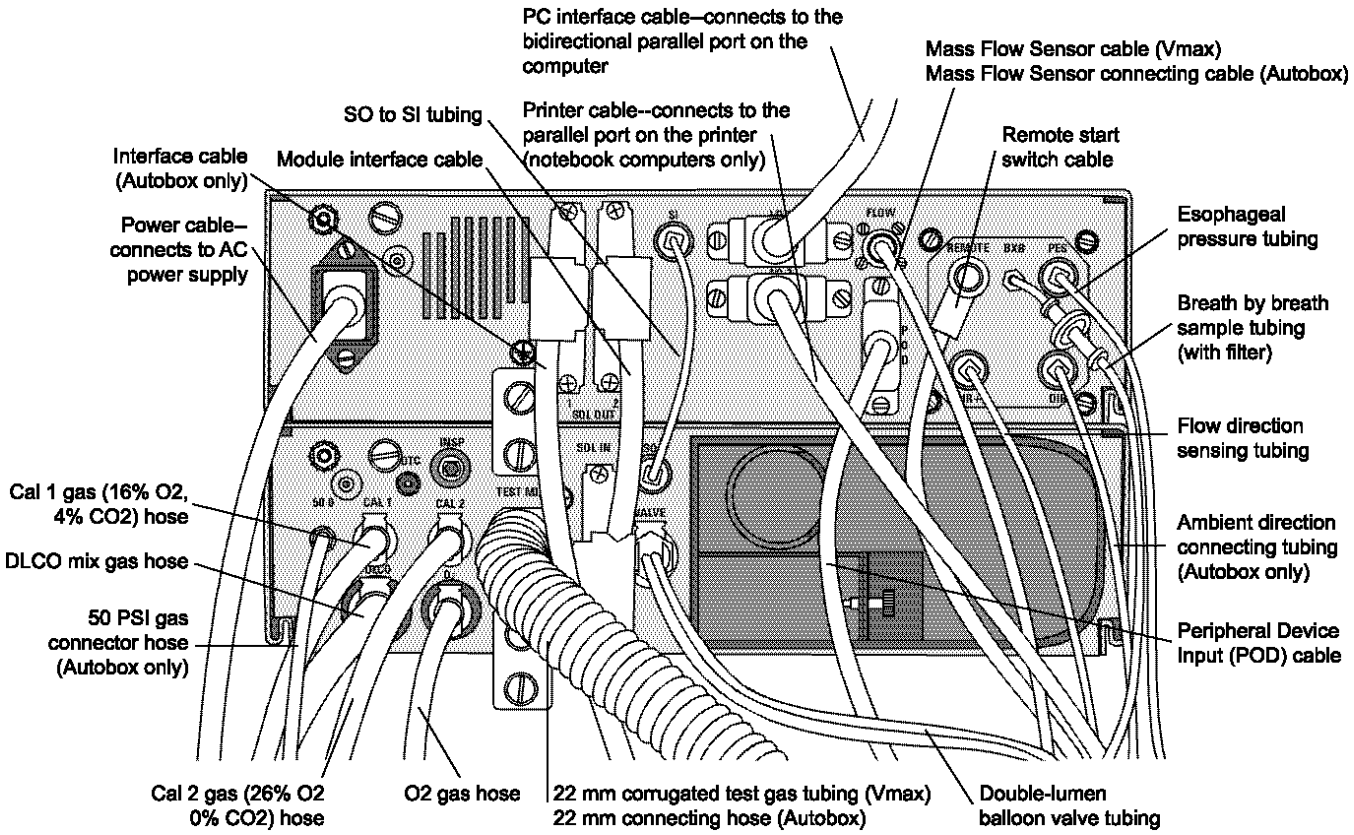

Figure 2-6 – Rear Panel Cables and Tubing—Vmax Analyzer and Pneumatics Modules

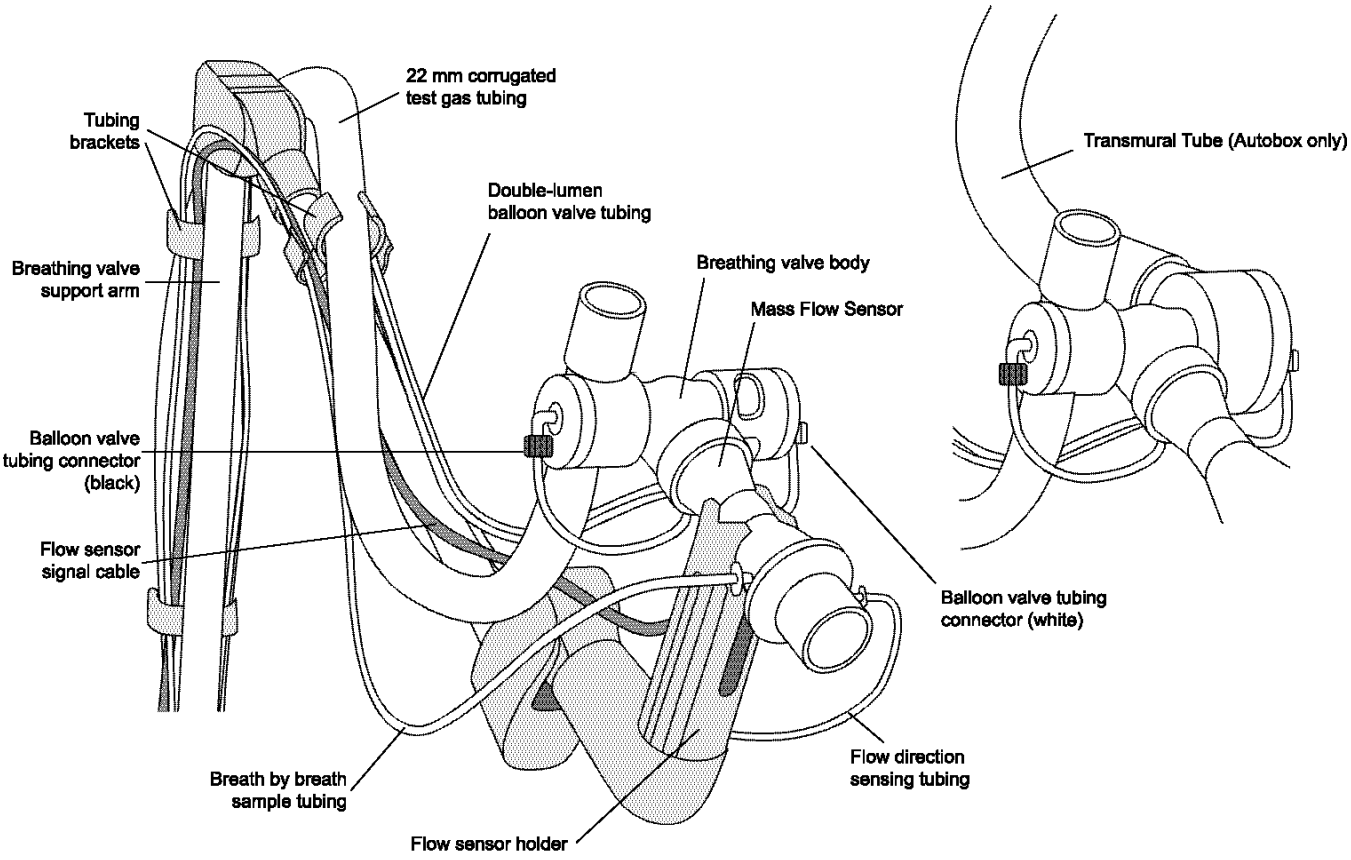

Figure 2-7 – Vmax Breathing Valve and Autobox Breathing Valve with Mass Flow Sensor Connections

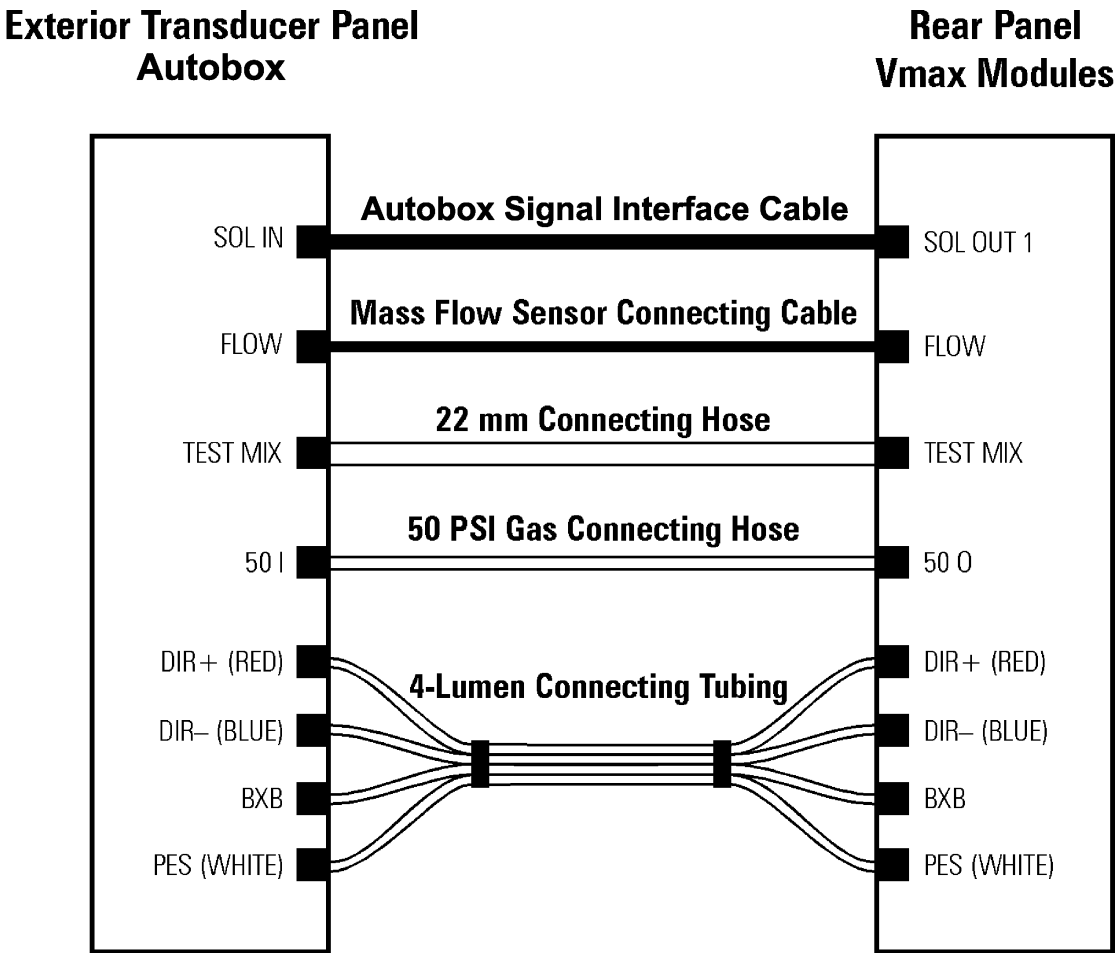

Figure 2-8 – Autobox to Vmax Connections

Table 4 – Compatible Peripheral Equipment

I/O 1 or I/O 2 Port	Computer Interface Cable
	Printer Cable (notebook computers only)
Sol Out 1 or Sol Out 2 Port	Autobox Cable
POD Port	Peripheral Device (POD) Module
Peripheral Device (POD) Module	SensorMedics 3-lead ECG Cable
	Analog ECG Cable (QRS Waveform) Marquette Max-1
	Ergometer Interface Cable (analog in: work and RPM, analog out: work) Lode Corival 400 Ergoline 800S
	Oximeter (analog in: HR and saturation) SMC SatTrak Oximeter SMC Oxyshuttle Oximeter

Note

Any accessory equipment connected by the user to the analog/digital interfaces must be certified according to the respective electrical safety standards applicable, e.g., UL-2601-1 for U.S. installations and/or IEC 950 for data processing equipment and/or IEC 601-1 for medical equipment for the European Community. Furthermore, all configurations of accessory equipment with SensorMedics instruments must comply with the system standard IEC 601-1-1 (UL2601). Consult the accessory equipment's documentation to verify compliance with the standards cited above. Anyone connecting additional equipment to the signal input or signal output is configuring a medical system, and is therefore responsible to assure that the system complies with the requirements of the applicable system standard. If there is any doubt about this, consult the SensorMedics Service Department for assistance.

PRE-USE CLEANING AND DISINFECTION

The instruments do not require cleaning before initial use. Although the rubber mouthpieces, tubing, and the patient breathing-valve are clean when they are shipped, they are not shipped sterile. These parts may, however, be disinfected by following the instructions in "Maintenance and Troubleshooting" on page 133.

CHAPTER 3 • GETTING STARTED

Before you can begin testing, you must (1) properly turn on the system and allow it to warm up, (2) select the patient file option that you want to use, and (3) enter or update the patient demographic information. This section provides the instructions for these procedures.

DAILY STARTUP

To start the system, you must (1) turn on the central-power switch, (2) turn on the computer, and (3) turn on the test gases according to this procedure.

To turn on the central power and the computer:

1. Turn on the central power switch.

   On some systems, this switch could be on an isolation transformer or on a power strip.

   All components of the system, with the exception of the computer (in most cases), will turn on simultaneously from the central power switch if the system was last shut down properly (refer to “Daily Shutdown” on page 31).

2. Turn on the computer.

   If the computer was previously shutdown properly, it will *not* turn on with the rest of the components and will have to be turned on after the central power switch.

3. If your system is *not* on a network, click **Cancel** in the **Enter Network Password** dialog box; however, if your system *is* on a network, click **OK**.

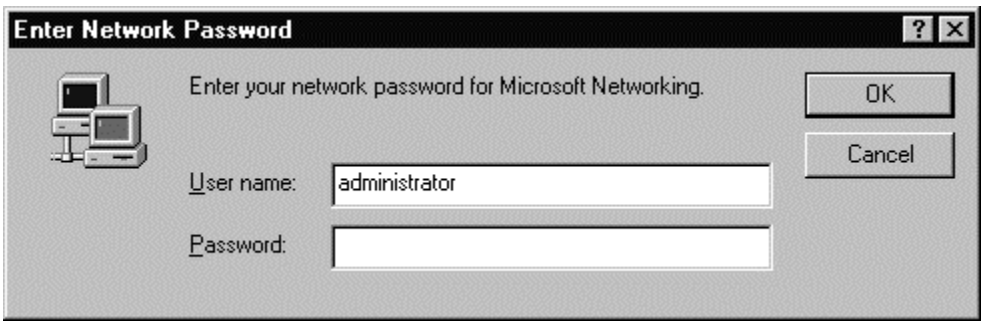

Figure 3-1 – Enter Network Password Dialog Box

To turn on the test gases:

1. Check the regulator valves and make sure that they are turned off (turned fully counter-clockwise) before opening the cylinder valves.
2. Open the cylinder valves by turning them ***fully*** counter-clockwise.
3. Adjust the regulator pressures by turning the valves clockwise to the following settings:
   - Oxygen: 50 to 60 PSI (345 to 414 k Pa)
   - Diffusion mixture, Vmax, and Vmax/6200 systems: 10 to 20 PSI (96 to 138 k Pa) *above the oxygen setting*.

Note

To avoid calibration errors on Vmax and Vmax/V6200 systems, always set the diffusion gas pressure higher than the oxygen pressure, as specified in this procedure.

Note

Allow at the instrument to warm up at least 30 minutes before you begin calibrating the system and testing the patient. Using the system before it is completely warmed up can result in erroneous test results.

The 2130 Series Spirometer does not require a warm-up period.

The Spectra Mass Flow Sensor takes 30 seconds to warm up whenever the Vmax software is started from the Windows desktop or whenever the Mass Flow Sensor is changed.

DAILY SHUTDOWN

Carefully follow the steps in this procedure to shutdown the Vmax.

> **Caution!**
> Do not turn off the computer by using the power switch on the computer. Turn off the computer by performing a proper shutdown procedure, described below.

To shut down the computer:

1. In the **Vmax Program Manager** window (Figure 3-3 on page 32), click **Exit** to return to the Windows desktop.
2. On the Windows desktop, click the **Start** button to open the **Start** menu.
3. On the **Start** menu, click **Shut Down** to open the **Shut Down Windows** dialog box.

Figure 3-2 – Shut Down Windows Dialog Box

4. In the **Shut Down Windows** dialog box, select **Shut down**, and then click **OK**.
5. Wait for the computer to turn off, and then turn off the central power switch.
6. Turn off all gas cylinders by turning the cylinder valves ***fully*** clockwise.

USING THE VMAX PROGRAM MANAGER

If the Vmax program is not running, double-click the Vmax icon on the Windows desktop, which starts the program and opens the Vmax Program Manager (Figure 3-3). You can make selections in the Vmax Program Manager window by clicking any of the function buttons, by selecting menu items, and by pressing the associated keyboard keys (identified on the function buttons).

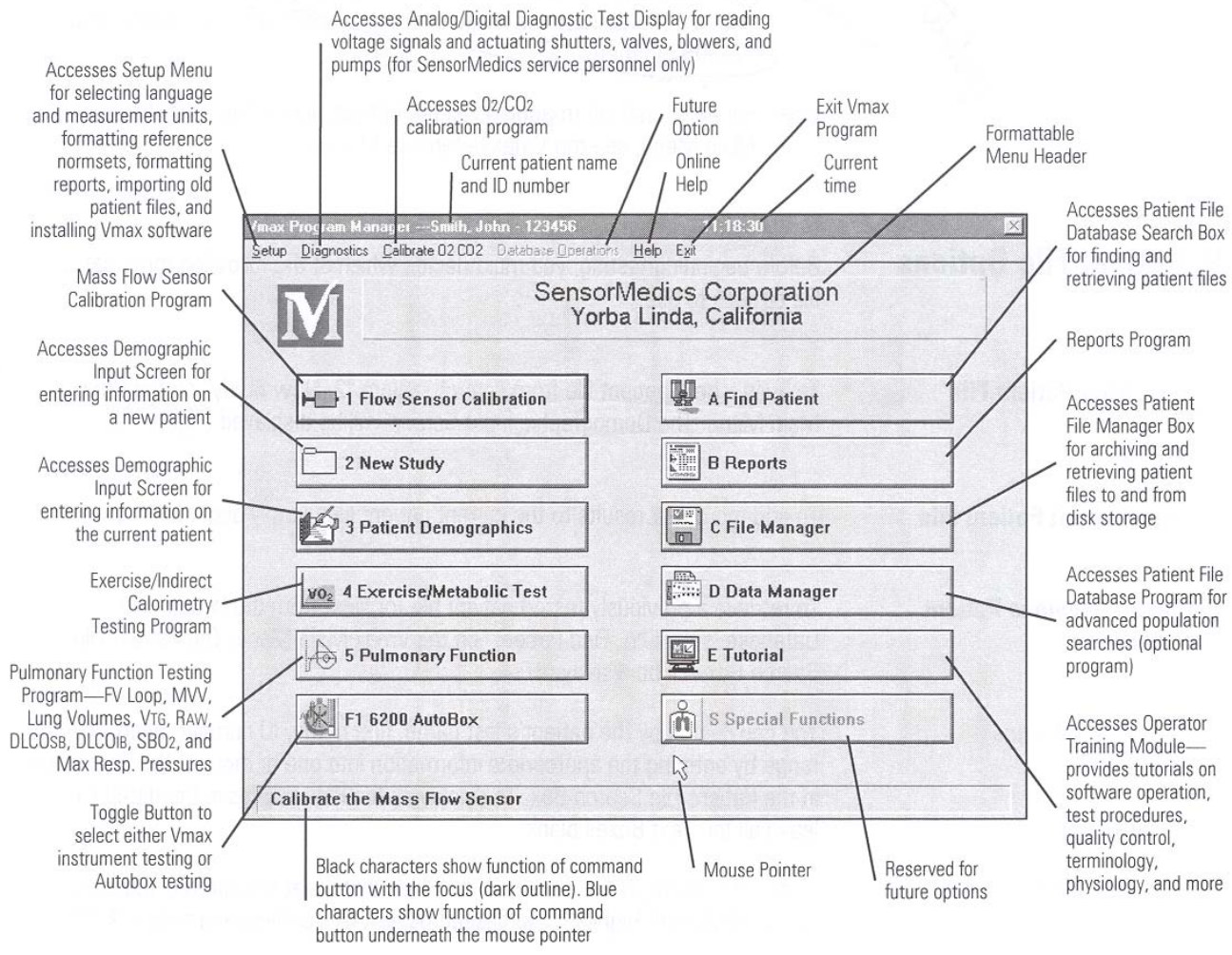

Figure 3-3 – Vmax Program Manager

Note

Make sure to select the correct system by clicking the System Selection (toggle) button (in the lower left corner of the window). The label on this button changes to indicate the selected system.

For additional information on all the options accessible from the Program Manager, refer to the reference manual.

PATIENT FILE OPTIONS

Before beginning testing, a patient file option must be selected; three patient file options are available:

- Use the current file
- Make a new file
- Retrieve an existing file

Use the Current Patient File

To add more test results to the current patient file, simply start testing. Instructions for testing begin in the chapter "Flow Volume Calibration," starting on page 39.

Make a New Patient File (New Study)

To build a new patient file for a new study, select **New Study** in the **Vmax Program Manager** window to open the **Vmax Demographic Input** dialog box (Figure 3-4). The section "Patient Demographics" on page 35 provides instructions for entering patient demographics to create a new patient file.

Retrieve a Patient's Files

You can retrieve previously established patient files by searching for files that match criteria that you provide.

To retrieve the files of a previously tested patient:

1. Select **Find Patient** in the **Vmax Program Manager** window.

   The **Patient File Search** dialog box will open where you can enter your search criteria.

2. Enter your search criteria.

   You can search the patient file database by using the patient's last name, first name, ID number, and the date range by typing this criteria into one or more of the text boxes in the **Patient File Search** dialog box.

   Note

   To display the entire database, leave all the text boxes blank.

3. Select **F1** to begin the search.

   All the files that meet the search criteria will be displayed.

4. Select the patient file (or files) that you want to retrieve and then select **F3**.

PATIENT DEMOGRAPHICS

If you select **New Study** in the **Vmax Program Manager** window to start a new patient file, or select **Patient Demographics** to edit the current patient file, the **Vmax Demographic Input** dialog box will open. This dialog box, shown in Figure 3-4, is where you enter and change patient information.

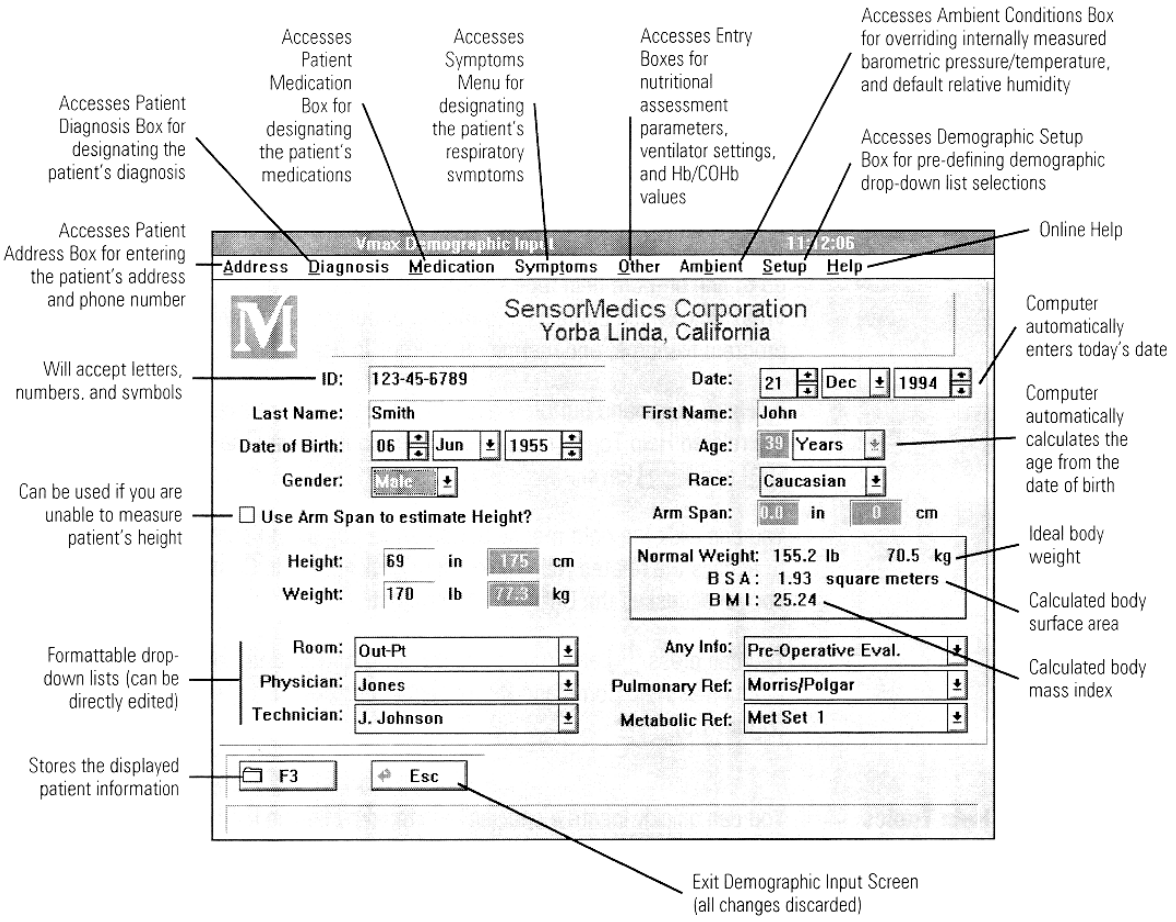

Figure 3-4 – Vmax Demographic Input Dialog Box

To enter or change patient demographics:

1. Click in each text box that you want to change, and type or select the information that you want to save for the patient. Press ENTER to move the insertion point to the next text box.

Note

You can also press TAB to move the insertion point to the next text box or press SHIFT + TAB to move the insertion point to the previous text box.

2. Select **F3** to store the new patient information and return to the **Vmax Program Manager**.

ONLINE HELP

Online help can be accessed from the Vmax testing program by using any of four different methods:

By using the **Help** menu

A menu bar with a “Help” selection is displayed at the top of most screens. You can select it by clicking **Help** or by pressing ALT + H.

Two or more further menu selections will display, giving you the opportunity to go to one or more help topics related to the test screen or to display the **About Vmax** box, which contains information about the software revision number, program filename, and memory resources in use.

By using the **Help** button:

A **Help** command button is available in most dialog boxes that will take you to the related help topic. You can select the button with the mouse or by using the TAB and ENTER keys.

By right clicking:

You can click the right mouse button while pointing to certain command buttons to access the related help topic. Right clicking a help-command button (see above) accesses the **Online Help Introduction** screen (Figure 3-5).

By pressing the F12 key:

You can press F12 anytime to access either the related help topic (same function as Help Command Button, above) or the **Online Help Introduction** screen (Figure 3-5)

To find specific help topics using the help index:

You can quickly find a specific help topic by finding its 4-digit reference number in the help index.

Let's use the topic "Extrapolated Volume" as an example:

1. Start by selecting the **More Topics** list box. Next, press the letter key for the first letter of the desired topic (e.g., press **E** for "Extrapolated Volume").
2. Press **F10** to display the index listings for all the topics beginning with the designated letter. Use the numbered tabs as necessary to locate the desired topic (e.g., you need to select tab 3 in the **E** Index to locate "Extrapolated Volume").
3. Note the desired topic's 4-digit reference number (e.g., the number for "Extrapolated Volume" is 1740). Select the **More Topics** list box again and scroll down through the reference numbers to the one you are looking for. Select (highlight) the topic. In our example, you would select "1740 Quality Assurance Guide, Spirometry."
4. Press **F10** to display the Topic. Use the numbered tabs to locate the desired page (e.g., "Extrapolated Volume" is found on pages 6, 7, and 8 of Topic 1740).

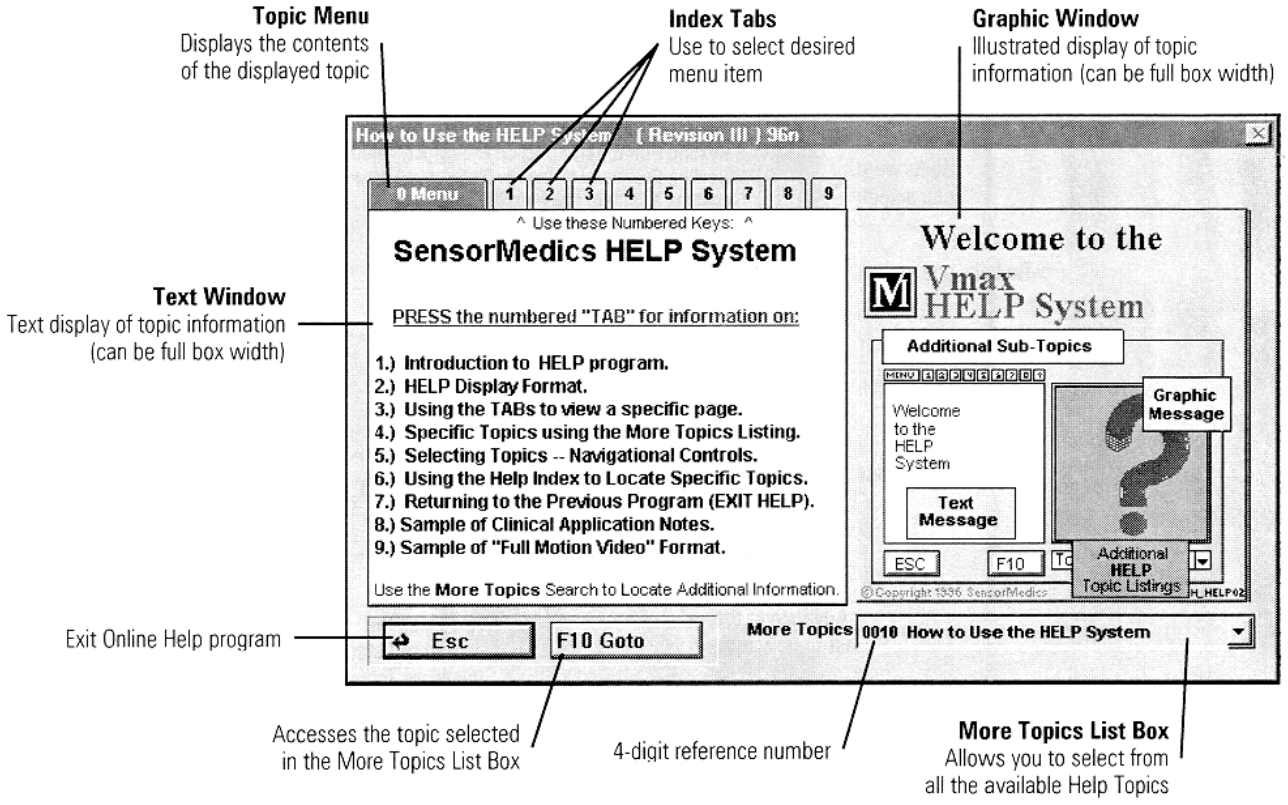

Figure 3-5 – Online Help Introduction Screen

TUTORIAL PROGRAM

Select **E Tutorial** from the **Vmax Program Manager** or **Tutorial** from the **Help** menu to access the **Vmax Training Module Menu** screen.

You can select from any of the displayed topics to display the tutorial box associated with that topic.

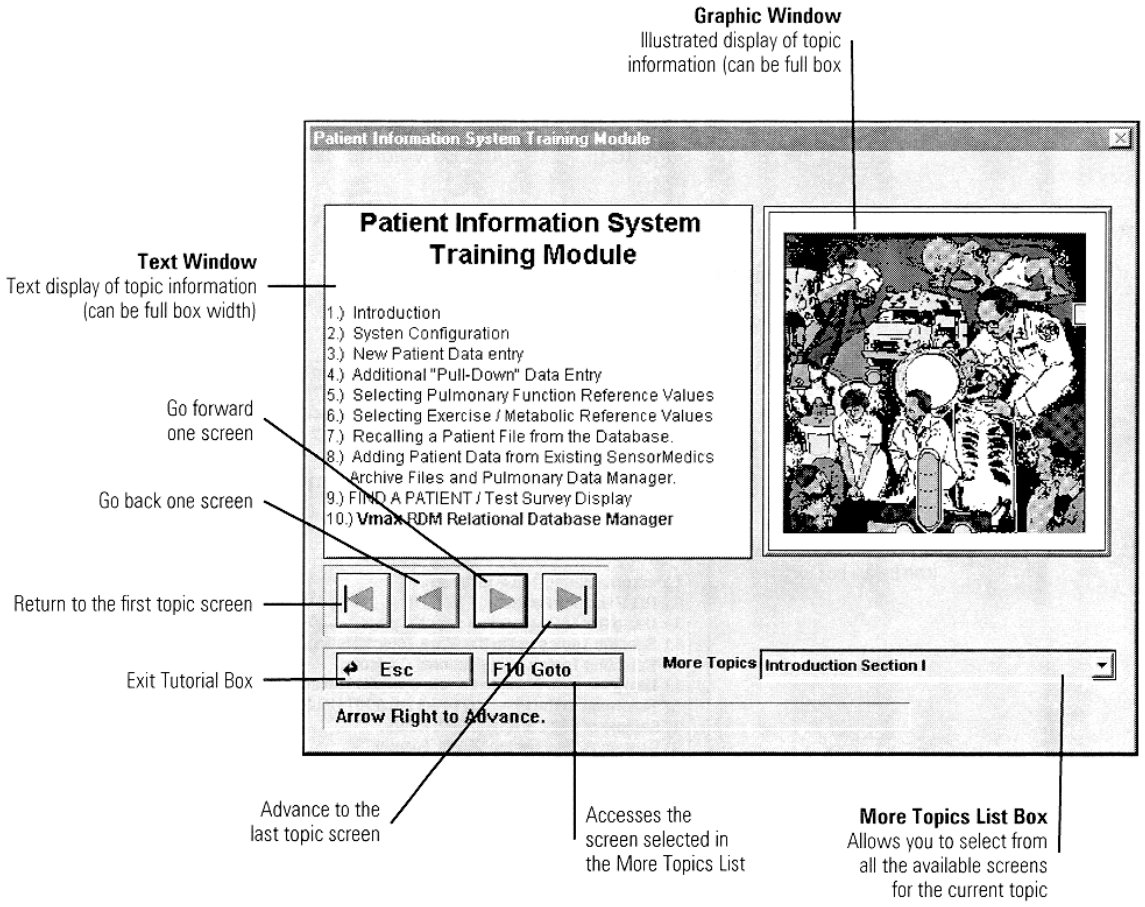

Figure 3-6 – Example Tutorial Box

CHAPTER 4 • FLOW VOLUME CALIBRATION

CALIBRATION PROCEDURE

This chapter covers the calibration and verification of flow volume and calibration of plethysmograph pressure.

Note

Calibrate the system at least once every testing day to ensure accurate test results.

Calibration Setup (Vmax and Autobox)

1. Select **1 Flow Sensor Calibration** on the **Vmax Program Manager** screen to access the **Flow Volume Calibration** screen.

Note

For information on all the options accessible from the Flow Volume Calibration screen, refer to the reference manual.

2. Select **F1** on the **Flow Volume Calibration** screen.
   The **Mass Flow Sensor Zero** dialog box will be displayed.
3. Attach the calibration syringe to the mass flow sensor using a cardboard mouthpiece and calibration hose or by using the calibration adapter. Stroke the syringe two times, and then select **Space Continue**.

Caution!

Do not use the FRC Adapter to connect the syringe for calibration; use only the calibration hose or the flexible calibration adapter. Using the FRC Adapter will reduce the accuracy of the calibration.

Do not, unnecessarily, move the mass flow sensor or the sensor cable. Excessive movement of these components can affect the accuracy and success of the calibration procedure.

A timer will count down to zero seconds before continuing to the zeroing routine.

Next, the mass flow sensor will be automatically calibrated to zero gas flow. If the instrument fails the auto-flow sensor zero calibration, the following message will be displayed:

The Mass Flow Sensor Does Not Respond. Check the Sensor Cable or Substitute Another Sensor	Refer to "Troubleshooting" on page 147 for further instructions.

When the zeroing routine is complete, the **Flow Volume Calibration** screen will be re-displayed.

Calibration Setup (2130 Series Spirometer)

1. Select **F1** on the **Flow Volume Calibration** screen.
   The **2130 Calibration Setup** dialog box will be displayed.
2. Enter the temperature and barometric pressure into the appropriate boxes.
3. Position the spirometer piston so that the volume indicator in the **Setup** box reads between 2 and 5 liters.
4. With the syringe piston at minimum volume (pushed in all the way), attach the calibration syringe to the spirometer hose reducer using the rubber coupler.
5. Select **F3**.
   The **Flow Volume Calibration** screen will be re-displayed.

Calibration Procedure (All Systems)

1. In the **Vmax Program Manager**, select **1 Flow Sensor Calibration**.
2. Select **F1** to open the **Mass Flow Sensor Zero** dialog box.
3. Connect the mass flow sensor to the syringe, and do a room-air purge by performing two complete strokes.
3. Select **Spacebar to Continue**.

   The flow sensor automatically goes through a stabilizing and zeroing process. When this process is complete, the **Calibration Bar Graph** is displayed.
4. Perform inspiratory and expiratory strokes within the following target ranges:

   0 to 0.6 LPS

   0.9 to 1.6 LPS

   2.4 to 5.5 LPS

   7.0 to 12.0 LPS

These target ranges are shown on the graph in yellow. The bar graph segments on the right turn to green when the mean flow rate of a stroke falls within the adjacent range.

If you complete 15 strokes, or the three-minute clock reaches zero, before you turn on the required number of green segments, the following message will be displayed:

Minimum Calibration Requirements have not been met.
F1 to repeat calibration.

This message will be given if:

- There are less than three green segments for the inspiratory strokes (in any combination).
- There are less than three green segments for the expiratory strokes, and the second and third segments are not green.

Select **F1** to repeat the calibration; select **Esc** to terminate the calibration and return to the **Mass Flow Sensor Calibration** screen.

If the required number of bar graph segments is turned to green before you complete the 15 strokes, or before the three-minute timer reaches zero, the **Calibration Bar Graph** screen is replaced by the **Calibration Verification** window. The following message will then be displayed:

Minimum Calibration Requirements have been met.
F1 to repeat the calibration.

Select **F1** to repeat the calibration; select **F2** to accept the calibration.

This message is displayed either automatically or manually, as designated in the **Flow Volume Setup Calibration** dialog box. Refer to the *Vmax Reference Manual* for a description of this dialog box. You can now proceed to the next step.

5. In the **Verification** window, perform five full inspiratory and full expiratory strokes. Perform these strokes at the ATS (American Thoracic Society) recommended flow rates.

   Four of the five strokes are displayed and should appear as follows:

   - One stroke (inspiratory and expiratory) should reach the lowest dotted line (0.5 LPS).

- One stroke (inspiratory and expiratory) should reach the highest dotted line (3.0 LPS).
- One stroke should be halfway between the dotted lines (1.5 LPS).
- One stroke (the fourth stroke) should represent a peak-flow rate near 12 LPS (8 LPS minimum). This stroke should be created without "banging" the piston at either end of the stroke.

VERIFICATION PROCEDURE

Caution!

Perform this procedure before testing each patient to prevent erroneous test results.

1. On the **Flow Volume Calibration** screen, select **F2**.
2. Perform five full inspiratory and full expiratory verification strokes of the syringe. Perform these strokes at the ATS (American Thoracic Society) recommended flow rates.

Note

If a warning message box is displayed, it generally indicates that you need to perform a complete calibration procedure. You cannot proceed with patient testing until the system meets the verification criteria (a warning message is ***not*** displayed).

Caution!

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

Four of the five strokes are displayed and should appear as follows:

- One stroke (inspiratory and expiratory) should reach the lowest dotted line (0.5 LPS).
- One stroke (inspiratory and expiratory) should reach the highest dotted line (3.0 LPS).
- One stroke should be halfway between the dotted lines (1.5 LPS).
- One stroke (the fourth stroke) should include a peak-flow rate near 12 LPS (8 LPS minimum). This stroke should be created without "banging" the piston at either end of the stroke.

PLETHYSMOGRAPH PRESSURE CALIBRATION PROCEDURE

Note

This procedure applies only to the Autobox.

Caution!

Calibrate the pressure at least once every testing day to prevent erroneous test results.

Note

Nobody should be inside the cabin during this procedure.

1. Select **F4** on the **Flow Volume Calibration** screen to access the **Pressure Calibration** dialog box (Figure 4-1).

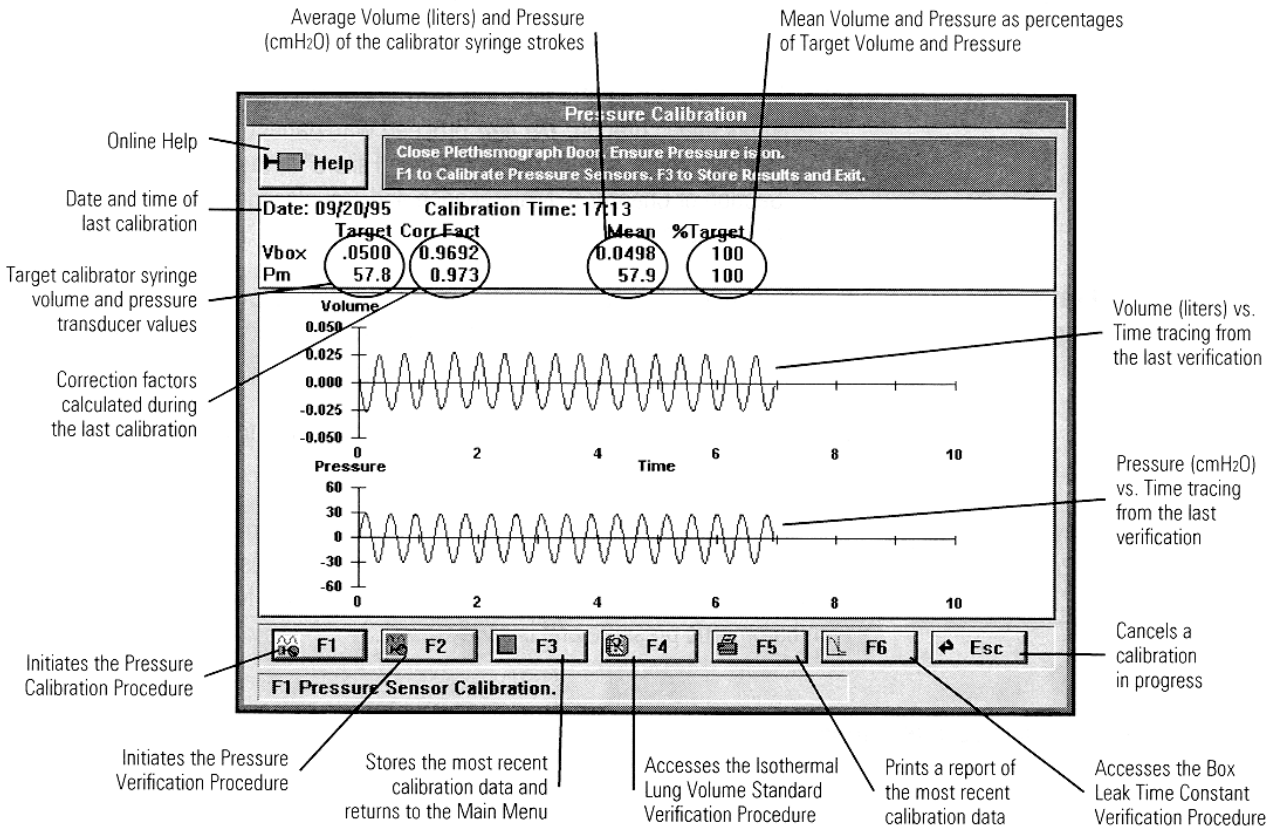

Figure 4-1 – Pressure Calibration Screen

Note

For additional information on all the options accessible from the Pressure Calibration screen, refer to the *Vmax Reference Manual*.

2. Close and latch the cabin door.
   Make sure the gas cylinder is completely turned on and the secondary pressure gauge is set between 50 and 60 PSI (345–414 k Pa).
3. Select **F1** to begin the calibration procedure.

   The internal calibrator syringe will begin pumping 50 ml of air into and out of the cabin. The screen will display sixteen calibration strokes (red) followed by sixteen verification strokes (blue). When the procedure is complete, the Vbox and Pm values will be updated.
4. Verify that the %Target values for Vbox and Pm are within the range 97 to 103. If the values are not within this range, repeat the calibration.

Caution!

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

In addition to displaying the %Target values, the computer evaluates the correction factors calculated during the calibration procedure and displays a warning message if the factors are out of range.

Caution!

Do not proceed with patient testing if the following warning message is displayed. Proceeding under this condition could cause erroneous test results.

The Calibration Factors are Out of Range. Ensure Gas Pressure is On and Door is Closed

This message means that one or both of the calculated calibration factors are out of range. The acceptable range for Vbox varies with the barometric pressure, but is approximately 0.7 to 1.3 at sea level. The acceptable range for Pm does not vary with barometric pressure and is always 0.7 to 1.3.

Selecting **F1** restarts the calibration routine. This encourages you to do another calibration after failure of the Calibration Accuracy Standards.

Selecting **Esc** allows you to ignore the warning message and displays the calibration verification results.

Caution!
Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

PLETHYSMOGRAPH PRESSURE VERIFICATION PROCEDURE

Note
This procedure applies only to the Autobox.

Note
Without performing another complete pressure calibration, you can perform a Pressure Verification Procedure to check the accuracy of the last calculated pressure-calibration factors.

Note
Nobody should be inside the cabin during this procedure.

1. Select **F4** on the **Flow Volume Calibration** screen to access the **Pressure Calibration** screen (Figure 4-1).
2. Close and latch the cabin door.
   Make sure the gas cylinder is completely turned on and contains adequate pressure.
3. Select **F2** to begin the verification procedure.
   The internal calibrator syringe will begin pumping 50 ml of air into and out of the cabin. The screen will display 16 blue verification strokes. When the calibration is complete, the Vbox and Pm values will be updated.
4. Verify that the %Target values for Vbox and Pm are within the range 97 to 103.
   If the values are not within this range, perform a complete pressure calibration.

Caution!

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

CHAPTER 5 • PULMONARY FUNCTION TESTING

PULMONARY FUNCTION MENU

Select **5 Pulmonary Function** on the **Vmax Program Manager** to enter the Pulmonary Function Program. The **Pulmonary Function** menu will be displayed (Figure 5-1).

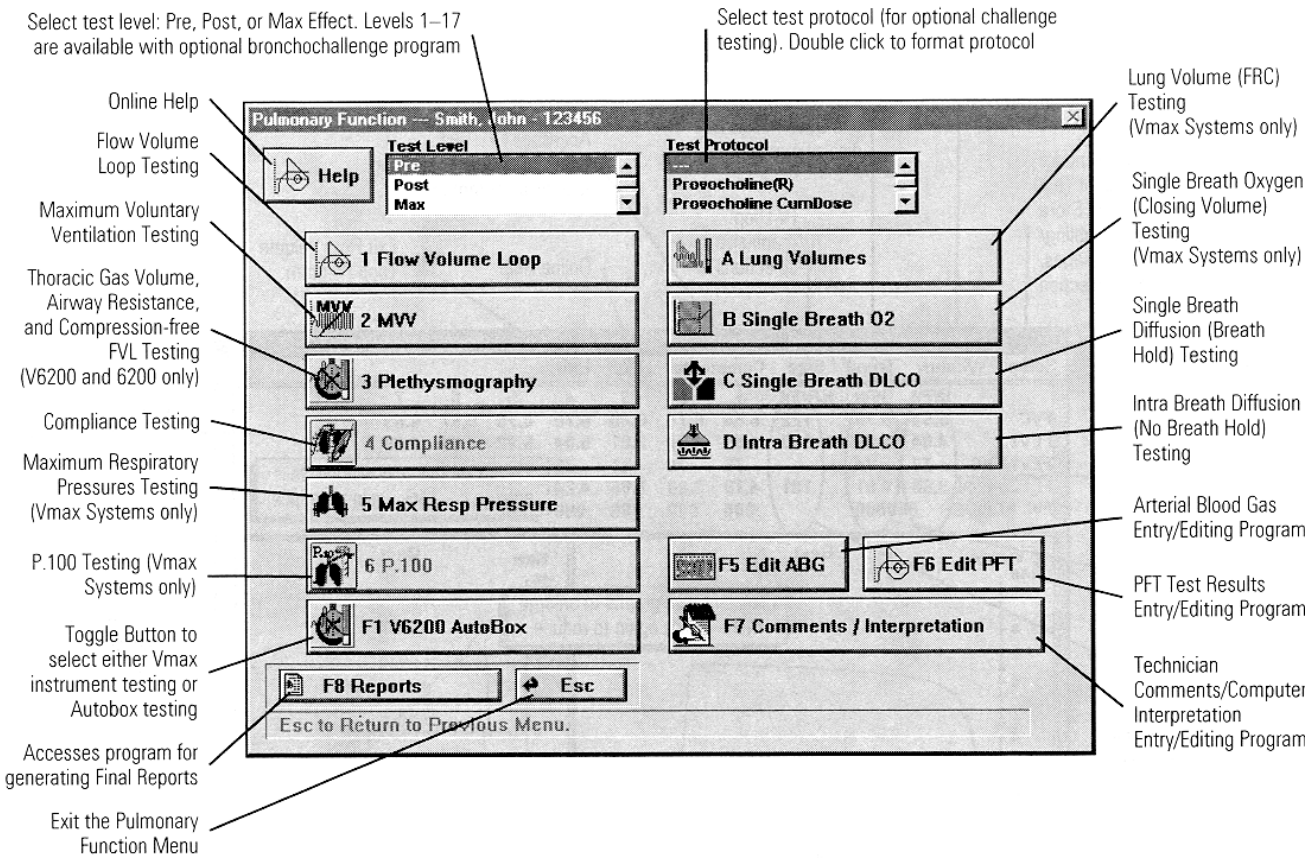

Figure 5-1 – Pulmonary Function Menu

Note

Toggle the System Selection button (lower left corner of the menu) to select the correct system: **Vmax PFT/Metabolic**, **2130 Spirometer**, or **Autobox**.

Note

For additional information on all the options accessible from this menu and from all the individual PFT Test screens, refer to the *Vmax Reference Manual*.

FLOW VOLUME LOOPS

1. From the **Pulmonary Function** screen (Figure 5-1) under **Test Level**, select **Pre**, **Post**, or **Level 1–17**.
2. Under **Test Protocol**, select a challenge protocol ("---" = no protocol).
3. Select **1 Flow Volume Loop**.

   The **Flow Volume Loop Test** screen will be displayed (Figure 5-2).

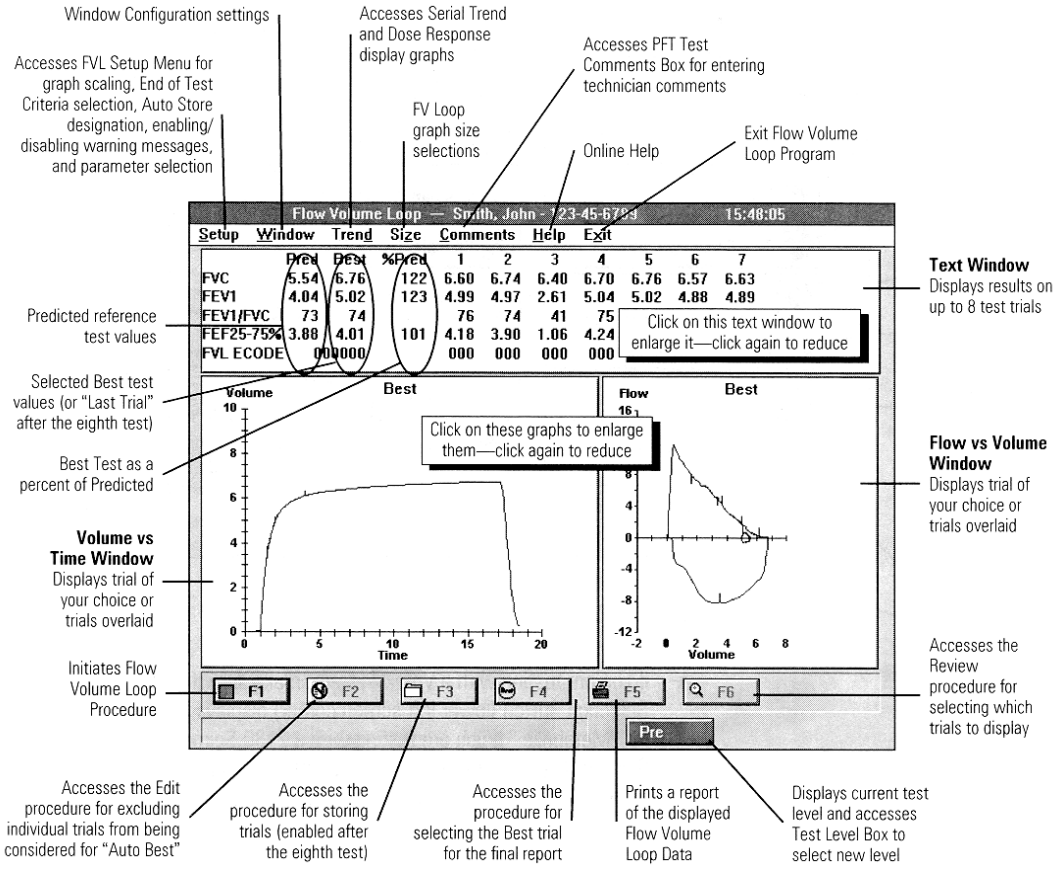

Figure 5-2 – Flow Volume Loop Test Screen

Test Procedure

Caution!

Successful flow-volume verification should be performed before testing a new patient. Not performing a successful verification could cause erroneous test results (see “Flow Volume Calibration” on page 39).

Note

Vmax and Autobox. The flow-volume loop test can be performed with or without the automated breathing valve attached to the mass flow sensor.

Autobox. If the breathing valve is attached, the test-gas tubing must be ***detached***.

The DLCO test-gas adapter must be disconnected from the breathing head assembly.

The flow volume loop procedure run from this program is always performed with the cabin door open. For instructions on performing a “closed door” (compression-free) flow volume loop procedure, see “Plethysmography” on page 85.

1 Select **F1** to begin the test procedure.

For the 2130 Series Spirometer only, flush the spirometer and then position the spirometer piston between 4 and 6 liters on the screen volume indicator. Select **F3** to continue.

2. *Tidal Breathing*. Instruct the patient to insert the mouthpiece and attach the nose clips.
Record at least three stable tidal breaths.
3. *Maximal Inspiration/Expiration.* Tell the patient to take in a deep breath and then to forcefully exhale and completely empty the lungs.
4. *Six-second Line.* Coach the patient to keep exhaling until the tracing crosses the vertical dotted six-second line.
5. *End of Test Criteria*. In addition to exhaling for at least six seconds, the patient should exhale (if possible) until the message “End of Test Criteria Met” is displayed at the bottom of the screen.

6. *Maximal Inspiration End Test*. After maximum expiration, instruct the patient to forcefully inspire until the lungs are full.
7. Select **End Test**. The patient can now remove the mouthpiece.

Flow Volume Loop Quality Assurance Messages

Note

Do not store the test if any of the following three quality assurance messages appear during a test. Repeat the test to obtain a better effort.

Exhalation Time Too Short. Minimum Exhalation Time of 6 Seconds Not Met	This message occurs when the patient's total-expiratory time was less than six seconds.
End of Test Criteria Not Met	This message occurs when the patient's expiration did not meet the end-of-test criteria.
Unsatisfactory Start of Test. Extrapolation Volume Exceeds 5% or .15 L.	The test had a back-extrapolation value greater than 5% of the FVC (or 150ml, whichever is greater).

Note

Repeat the test to obtain reproducible results if any of the following three quality assurance messages appear.

The Best Peak Flow and the Next Largest Vary by More Than 10%.	This message occurs when there are no trials within 10% of the “best” trial for peak flow.
The Best FEV_1 and the Next Largest Vary More Than .2 Liters	This message occurs when there are no trials within 0.2 liters of the “best” (largest) trial for FEV_1.
The Best FVC and the Next Largest Vary More Than .2 Liters	This message occurs when there are no trials within 0.2 liters of the “best” (largest) trial for FVC.

Flow Volume Loop Quality Assurance Message Options

F1 Start

Restarts the FVL test routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

ENHANCED SPIROMETRY

From the **Pulmonary Function** menu (Figure 5-1), select **Pre**, **Post**, or **Level 1–17** in the **Test Level** list box, select a challenge protocol (“---” = no protocol), and then select **3 Enhanced Spirometry**. The **Enhanced Spirometry Test** screen will be displayed (Figure 5-3).

Note

This test is not available for the Autobox.

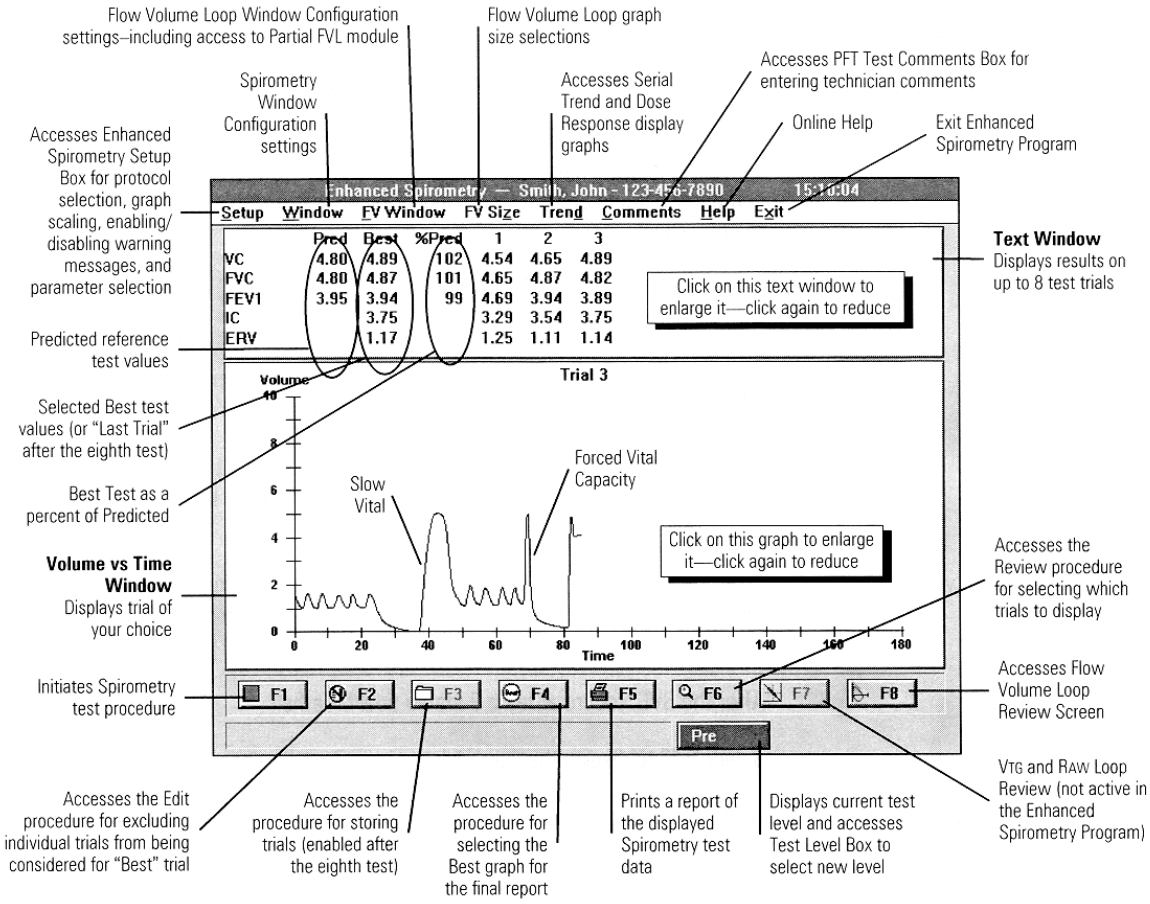

Figure 5-3 – Enhanced Spirometry Test Screen

Test Procedure

Caution!

Successful flow-volume verification should be performed before testing a new patient to prevent erroneous test results (see "Flow Volume Calibration" on page 39).

Note

Vmax and Autobox. The enhanced spirometry test can be performed with or without the automated-breathing valve attached to the mass-flow sensor.

1. Select **F1** to begin the test procedure.

   2130 Series Spirometer only:

   1. Flush the spirometer.
   2. Position the spirometer piston between 4 and 6 liters on the screen volume indicator.
   3. Select **F3** to continue.

Slow Vital Capacity

Note

If you do not want the patient to perform a SVC (Slow Vital Capacity), select F1 to override the SVC requirement. The **Flow Volume Loop Test** screen will be displayed.

2. Instruct the patient to put in the mouthpiece and attach the nose clips.
3. Instruct the patient to breathe normally with the mouthpiece.
   After the computer detects at least three tidal breaths with a stable baseline, it will display the message:

   Perform VC — F1 Start FV Loop

4. Instruct the patient to perform a complete inspiration followed by a complete expiration and then to return to resting breathing. (A complete expiration followed by a complete inspiration is also acceptable.)

Note

After the SVC, if you do not want to perform a Flow Volume Loop, select **End** to terminate the test at this point. Instruct the patient to remove the mouthpiece.

Tidal Breathing

5. After the SVC, record at least three stable tidal breaths.
6. Select **F1** to display the **Flow Volume Loop Test** screen.

Maximal Inspiration/Expiration

7. Tell the patient to take in a deep breath and then to forcefully exhale and completely empty the lungs.

Six Second Line

8. Coach the patient to keep exhaling until the tracing crosses the vertical dotted six-second line.

End of Test Criteria

9. In addition to exhaling for at least six seconds, the patient should exhale, if possible, until the message “End of Test Criteria Met” is displayed at the bottom of the screen.

Maximal Inspiration End Test

10. After maximum expiration, instruct the patient to forcefully inspire until the lungs are full.
11. Select **End Test**.
    The patient can now remove the mouthpiece.

Enhanced Spirometry Quality Assurance Messages

Slow Vital Capacity Messages

Note

Do not store the test if either of the following SVC quality-assurance messages is given. Repeat the test to obtain better results.

The Vital Capacity is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured SVC falls outside the range of 20% to 200% of predicted, making it physiologically questionable.
The IC is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured IC falls outside the range of 20% to 200% of predicted, making it physiologically questionable.

Note

Repeat the test to obtain reproducible results if either of the following quality-assurance messages appears during the test.

The Vital Capacity CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with SVC values within 10%—the Coefficient of Variation (CV)—of one another.
The IC CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with IC values within 10%—the Coefficient of Variation (CV)—of one another.

Flow Volume Loop Messages

Note

Do not store the test if any of the following three quality-assurance messages is given. Repeat the test to obtain a better effort.

Exhalation Time Too Short. Minimum Exhalation Time of 6 Seconds Not Met	This message occurs when the patient's total-expiratory time was less than six seconds.
End of Test Criteria Not Met	This message occurs when the patient's expiration did not meet the end-of-test criteria.
Unsatisfactory Start of Test. Extrapolation Volume Exceeds 5% or .15L.	This message is given when the test has a back-extrapolation value greater than 5% of the FVC (or 150 ml, whichever is greater).

Note

Repeat the test to obtain reproducible results if any of the following three quality-assurance messages is given during a test.

The Best Peak Flow and the Next Largest Vary by More Than 10%.	This message occurs when there are no trials within 10% of the “best” trial for peak flow.
The Best FEV_1 and the Next Largest Vary More Than .2 Liters	This message occurs when there are no trials within 0.2 liters of the “best” (largest) trial for FEV_1.
The Best FVC and the Next Largest Vary More Than .2 Liters	This message occurs when there are no trials within 0.2 liters of the “best” (largest) trial for FVC.

Enhanced Spirometry Quality Assurance Message Options

F1 Start

Restarts the Enhanced Spirometry Test. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

MAXIMUM VOLUNTARY VENTILATION

1. On the **Pulmonary Function Menu** screen (Figure 5-1), under **Test Level**, select **Pre**, **Post**, or **Level 1–17**.
2. Under **Test Protocol**, select a challenge protocol ("---" = no protocol).
3. Select **2 MVV**. The **Maximum Voluntary Ventilation Test** screen will be displayed (Figure 5-4).

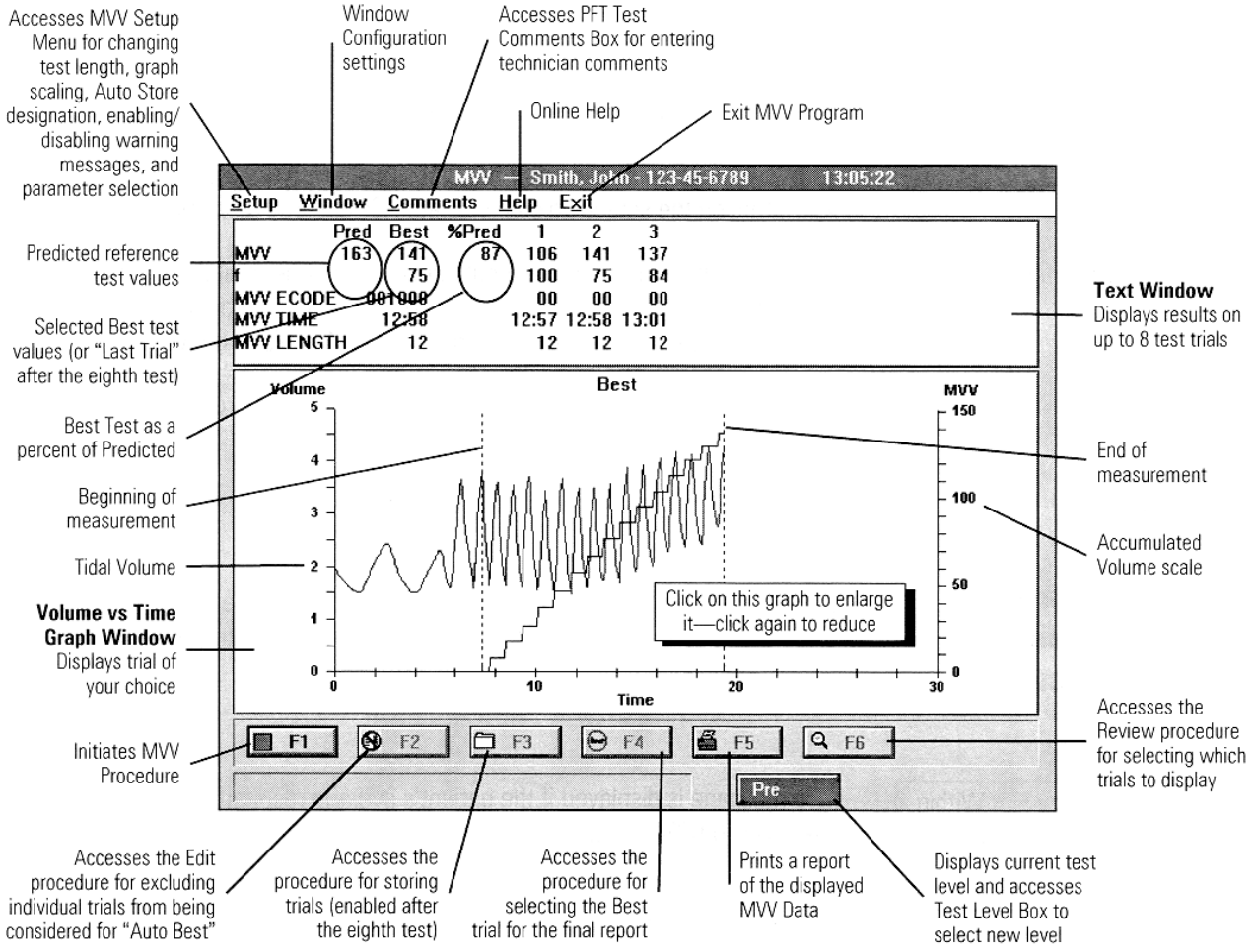

Figure 5-4 – Maximum Voluntary Ventilation Test Screen

Test Procedure

Note

Vmax and Autobox Systems. The Maximum Voluntary Ventilation test can be performed with or without the Automated-breathing valve attached to the Mass flow sensor.

Autobox. If the Breathing Valve is attached, the Test Gas Tubing must be ***detached***.

The DLCO Test Gas Adapter must be disconnected from the breathing head assembly.

The Maximum Voluntary Ventilation test is always performed with the cabin door open.

1. Select **F1** to begin the test procedure.

   2130 Series Spirometer only:

   1. Flush the spirometer.
   2. Position the spirometer piston between 4 and 6 liters on the screen volume indicator.
   3. Select **F3** to continue.

Maximum Breathing

2. Instruct the patient to put in the mouthpiece and attach the nose clips.
3. Instruct the patient to begin breathing fast and deep.

   Target rate: 70 to 150 breaths per minute

   Target depth: 1/4 to 3/4 of his or her vital capacity.
4. After the patient seems to achieve maximum breathing, select **F1** to start collecting data.

The test automatically terminates at the end of the measurement interval.

Maximum Voluntary Ventilation Quality Assurance Messages

Note

Do not store particular test if any of the following three quality-assurance messages is given. Repeat the test to obtain a better effort.

Breathing Frequency Not Within 70 to 150 Breaths Per Minute	This message is displayed if the patient's average respiratory rate was outside the 70 to 150 BPM range.
The Average Tidal Volume is not Within 25% to 75% of the Vital Capacity	This message is displayed if the patient's average breathing volume was not within the 25 to 75% range as calculated from the patient's previously measured vital capacity.
The Measured MVV is Inconsistent with the MVV Estimated from Spirometry (FEV_1 x 35 to 40)	This message is displayed if the measured MVV is less than the FEV_1 multiplied by 35 or more than the FEV_1 multiplied by 40.

Note

Repeat the test to obtain reproducible results if the following quality-assurance message is given.

The Next Best MVV is not Within 10% of the Best MVV	This message is displayed if there are no trials within 10% of the "best" trial for MVV.

Maximum Voluntary Ventilation Quality Assurance Message Options

F1 Start

Restarts the MVV test routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

GAS DILUTION LUNG VOLUMES

Note

This test is only available on the Vmax Spectra and the Autobox. It is not available on the 2130 Series Spirometer.

1. In the **Pulmonary Function** screen (Figure 5-1), under **Test Level**, select **Pre**, **Post**, or **Level 1–17**.
2. Under **Test Protocol**, select a challenge protocol ("---" = no protocol).
3. Select **A Lung Volumes**.
   The **Lung Volumes Test** screen will be displayed (Figure 5-5).

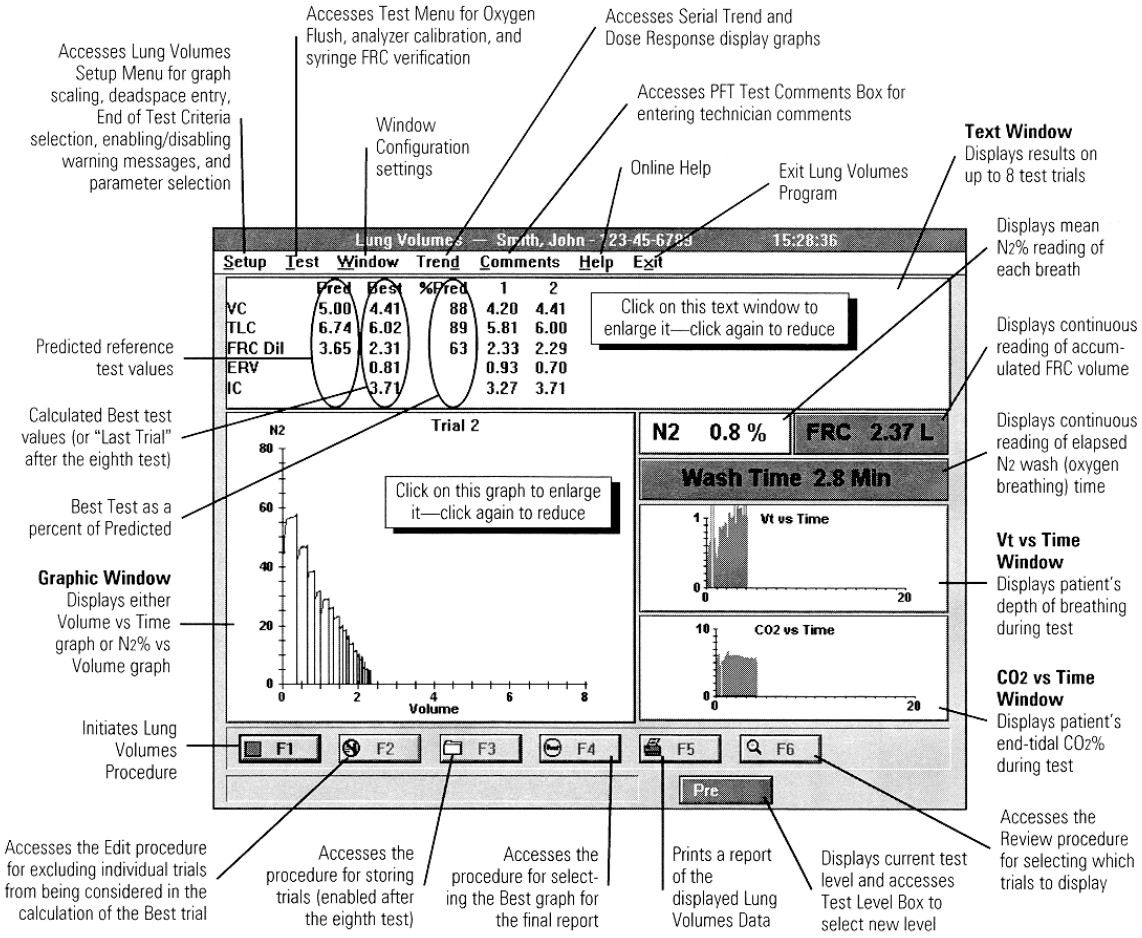

Figure 5-5 – Lung Volumes Test Screen

Note

You can skip the Analyzer Calibration section if you will not be measuring an FRC (Slow Vital Capacity measurement only).

Analyzer Calibration

Note

Although the program does not force you to perform a calibration, you should do one at least once every testing day.

You should perform a verification procedure before testing each patient (see the following section).

The 100% oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

The Span 1 calibration gas (16% O_2, 4% CO_2) must be turned on completely. If the regulator has an adjustable secondary pressure gauge, it should be set between 50 and 60 PSI (345 and 414 k Pa).

For Autobox, the Span 1 calibration gas must be connected to the Cal 1 port on the transducer panel that is on the back of the cabin.

Analyzer Calibration Screen

1. Select **Analyzer Calibration** from the **Test** menu on the **Lung Volumes Test** screen.
2. Select **Space** to flush the tubing with oxygen and display the **Analyzer Calibration** screen.

Attach the Sample Tubing

3. Connect the sample line to the calibration fitting on the front of the Pneumatics Module.

   If testing inside the Autobox cabin, connect the sample line to the calibration fitting on the interior transducer panel.

F1 Cal

4. Select **F1** to initiate the O_2 and CO_2 analyzer calibration sequence. When the calibration finishes successfully (no warning messages), a green "Calibration Complete" message will be displayed in the lower right corner of the screen.

F3 Store

5. Select **F3** to store the calibration results and return to the **Lung Volumes Test** screen.

Calibration Warning Messages

Caution!
Do not proceed with patient testing until the system meets all the analyzer verification criteria and no warning messages are displayed.

The Sensors are Responding Incorrectly to Calibration Gas. Check Calibration Gas Tank Pressures and Connections.	This message is displayed if the O_2 and CO_2 analyzers are not reading the correct O_2 and CO_2 concentrations from the Span 1 and 100% O_2 gases.
Ensure that the Sample Line is Connected to the Calibration Fitting.	This message is displayed if the correction factors for the CO_2 and O_2 concentrations are inappropriately large.
O_2 Outside Accuracy Range	This message is displayed if the difference between the expected and actual O_2 concentrations is greater than 2%.
CO_2 Outside Accuracy Range	This message is displayed if the difference between the expected and actual CO_2 concentrations is greater than 0.25%.

Transit Time Warning	This message is displayed if the gas transit time is greater than one second.
O_2 Response Time Warning	This message is displayed if the O_2 response time is greater than 0.15 second.
CO_2 Response Time Warning	This message is displayed if the CO_2 response time is greater than 0.15 sec.

Calibration Warning Message Options

You are presented with the following options when a **Calibration Warning** box is displayed.

F1 Cal

Restarts the Calibration Routine; allows you to re-attempt the calibration sequence.

Esc Cancel

Ignores the warning message and displays the calibration verification results.

Caution!

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

Verification Procedure

Note

Although the program does not force you to perform this verification procedure, this procedure should be done before testing each patient to ensure accurate test results.

Select **F2** to initiate the O_2 and CO_2 analyzer verification sequence.

One or more warning messages may be displayed. These warning messages generally indicate that you need to perform a complete calibration procedure.

Caution!

Do not proceed with patient testing until the instrument meets all the verification criteria and no warning messages are displayed. Testing when the verification criteria have not been met will cause erroneous test results.

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

Test Procedure

Note

Autobox: The Gas Dilution Lung Volumes test is always performed with the cabin door open.

The automated breathing valve must be attached to the mass flow sensor.

Autobox only: The transmural tube must be disconnected from the breathing valve.

If a calibration was performed, reconnect the sample line to the flow sensor port.

1. Select **F1** to begin the test procedure.

Oxygen Flush

2. Select **Space** to flush the breathing valve with 100% oxygen.

Slow Vital Capacity

Note

If you do not want the patient to perform a vital capacity test, select **F1** to override the SVC requirement. The SVC message will disappear.

3. Instruct the patient to put in the mouthpiece and attach the nose clips. Tell the patient to breathe normally with the mouthpiece. After the computer detects at least

three tidal breaths with a stable baseline, it will display the message “Full inspire and expire.”

4. Instruct the patient to perform a complete inspiration followed by a complete expiration and then return to resting breathing. (A complete expiration followed by a complete inspiration is also acceptable).

Note

If you do not want to measure the patient’s FRC (Slow Vital Capacity only), select **Space to End** to terminate the test at this point. Instruct the patient to remove the mouthpiece.

Oxygen Breathing

After the computer again detects at least three stable tidal breaths, it will reconfigure the breathing valves and the patient will begin breathing 100% O_2 from the demand valve.

5. Coach the patient to continue with resting breathing.

End Test

When the patient’s measured exhaled N_2% drops below the designated N_2 Stability Criteria (default = 1.5%) for three consecutive breaths, the following message will be displayed:

“N_2 Stability Criteria Met”

6. Select **Space to End** and instruct the patient to remove the mouthpiece.

Lung Volumes Quality Assurance Messages

Note

If either of the following quality-assurance messages appears, the test will automatically terminate.

End Tidal Nitrogen Out of Range. Recalibrate Analyzer and Check Breathing Circuit.	This message is displayed at the beginning of the test (before oxygen breathing) if the end-tidal N_2 concentration is outside the range of 60 to 90%.
Inspired Oxygen Not Detected. Recalibrate Analyzer, Check Sample Line, O_2 Supply, and Breathing Circuit.	This message is displayed at the beginning of the FRC measurement if the oxygen concentration of the inspired gas is less than 50%.

Note

Do not store the test if any of the following six quality-assurance messages is given. Repeat the test to obtain better results.

Leak Detected. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the N_2 concentration increases by at least 10% during the test, indicating a leak in the system.
The Final Nitrogen was not below 1.5%. Carefully evaluate the Lung Volume Parameters.	This message is displayed if the measured end-tidal N_2 concentration never falls below 1.5%. This situation indicates a strong possibility of a leak.
The IC is outside Physiologic Range. Carefully evaluate the Lung Volume Parameters.	This message is displayed if the measured IC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.

The FRC is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured FRC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.
The Vital Capacity is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured VC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.
The TLC is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured TLC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.

Note

Repeat the test to obtain reproducible results if any of the following four quality-assurance messages appear.

The IC CV is Greater than 10%. Carefully evaluate the Lung Volume Parameters.	This message is displayed if there are not at least two trials with IC values within 10%—the Coefficient of Variation (CV)—of one another.
The FRC CV is Greater than 10%. Carefully evaluate the Lung Volume Parameters.	This message is displayed if there are not at least two trials with FRC values within 10%—the Coefficient of Variation (CV)—of one another.
The Vital Capacity CV is Greater than 10%. Carefully evaluate the Lung Volume Parameters.	This message is displayed if there are not at least two trials with VC values within 10%—the Coefficient of Variation (CV)—of one another.

The TLC CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with TLC values within 10%—the Coefficient of Variation (CV)—of one another.

Lung Volumes Quality Assurance Message Options

F1 Start

Restarts the Lung Volumes Test. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

SINGLE BREATH DIFFUSING CAPACITY

From the **Pulmonary Function Menu** (Figure 5-1), under **Test Level**, select **Pre**, **Post**, or **Level 1–17**. Under **Test Protocol**, select a challenge protocol ("---" = no protocol) and then select **C Single Breath DLCO**. The Single Breath DLCO Test screen will be displayed (Figure 5-6).

Note

This test is not available on the 2130 Series Spirometer.

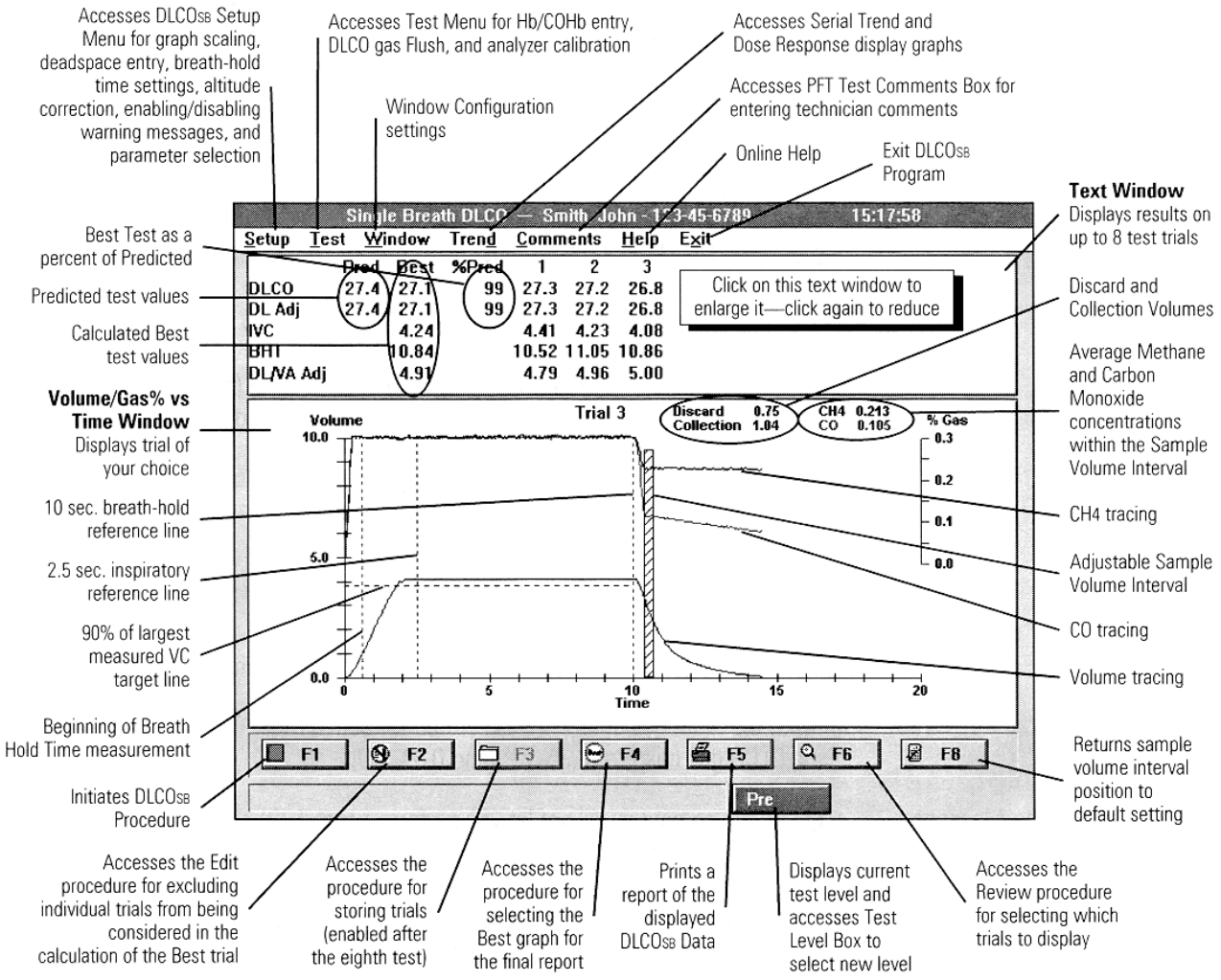

Figure 5-6 – Single Breath DLCO Test Screen

Test Procedure

Note

Autobox: The $DLCO_{SB}$ test is always performed with the cabin door open. The automated breathing valve must be attached to the Mass flow sensor.

Note

Autobox only: The Test Gas Tubing must be attached to the Breathing Valve and the Transmural Tube must be ***detached***.

Vmax systems: The 100% Oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

The DLCO Mix cylinder must be turned on completely and the secondary pressure gauge set as:

Vmax and Autobox: 10 to 20 PSI (69 to 138 k Pa) above the oxygen tank pressure.

Vmax systems: To avoid calibration errors, it is important that the diffusion gas always be set at a higher pressure than the other gases (see the specified pressures, above).

1. Select **F1** to begin the test procedure.

DLCO Gas Flush

2. Select **Space to Continue** to flush the breathing valve with 100% DLCO gas. The multi-gas analyzer is calibrated to room air (0% CH_4 and 0% CO) and to the DLCO gas mixture (0.3% CH_4 and 0.3% CO).

Note

The computer will not let you perform a test if either of the following warning messages is displayed. If, after your repeated calibration attempts, the warning messages are still being displayed, refer to “Troubleshooting” on page 147 for further instructions.

Multi-gas Sensor Zero Out of Range. Recalibrate Analyzer.	This message is displayed if the multi-gas analyzer is not reading 0% CO and 0% CH_4 while sampling room air.
Multi-gas Sensor Calibration Out of Range. Recalibrate Analyzer. Check Gas Supply Circuit.	This message is displayed if the multi-gas analyzer is not reading 0.3% CO and 0.3% CH_4 while sampling gas from the diffusion mixture tank.

Begin Tidal Breathing

3. After the calibration is complete, instruct the patient to put in the mouthpiece and attach the nose clips. Tell the patient to begin stable resting breathing.

Maximal Expiration/Maximal Inspiration

4. Instruct the patient to exhale completely; select **F1** during the maximal exhalation.
5. When “Full Inhalation Then Hold” is displayed, instruct the patient to inhale completely.

Breathe Hold

6. The exhalation valve will close at end-inspiration. Coach the patient to hold his or her breath until the exhalation valve opens.

Maximal Expiration

7. When the exhalation valve opens, coach the patient to exhale completely until the computer ends the test.

Note

If necessary, use the mouse to adjust the collection volume interval in the $DLCO_{SB}$ window to assure analysis of an alveolar gas sample (make sure the sample interval bar is completely on the alveolar plateau).

DLCOSB Quality Assurance Messages

Inspired Mixture Out of Range. Check Breathing Circuit. Check Gas Supply Circuit.	This message is displayed (and the test automatically terminates) if the CO or CH_4 concentration of the inspired gas measured during the IVC is less than 0.27%.

Note

Do not store the test if any of the following six quality-assurance messages is given. Repeat the test to obtain better results.

Inspired Vital Capacity is less than 90% of Vital Capacity. The DLCO May be Underestimated.	This message is displayed if the measured IVC is less than 90% of the previously measured “best” Vital Capacity (either SVC or FVC).
DLCO Standard Error. Inspiratory Time Exceeds 2.5 Seconds	This message is displayed if the inspiratory time exceeds 2.5 seconds, indicating the inspiration was too slow.
DLCO Standard Error for Patients with Airflow Obstruction. Inspiratory Time Exceeds 4 Seconds	This message is displayed if the inspiratory time exceeds 4 seconds, indicating the inspiration was too slow, even for patients with significant airflow obstruction ($FEV_1/FVC < 0.5$).
DLCO Standard Error. Breath Hold Time is Less Than 9 Seconds	This message is displayed if the measured Breath Hold Time is less than 9 seconds.
DLCO Standard Error. Breath Hold Time is More Than 11 Seconds	This message is displayed if the measured Breath Hold Time is more than 11 seconds.

The DLCO is Outside the Physiologic Range.	This message is displayed if the measured DLCO falls outside the range of 20 to 200% of predicted, making it physiologically questionable.

Note

Repeat the test to obtain reproducible results if the following quality-assurance message appears.

The DLCO Reproducibility Criteria Not Met. Two Tests Should be Within 10%.	This message is displayed if there are not at least two trials with DLCO values within 10% of one another.

$DLCO_{SB}$ Quality Assurance Message Options

F1 Start

Restarts the $DLCO_{SB}$ test. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

INTRABREATH DIFFUSING CAPACITY

From the **Pulmonary Function Menu** box (Figure 5-1), under **Test Level**, select **Pre**, **Post**, or **Level 1–17**. Under **Test Protocol**, select a challenge protocol ("---" = no protocol) and then select **D Intra-breath DLCO**. The Intra-breath DLCO Test screen will be displayed (Figure 5-7).

Note

This test is not available on the 2130 Series Spirometer.

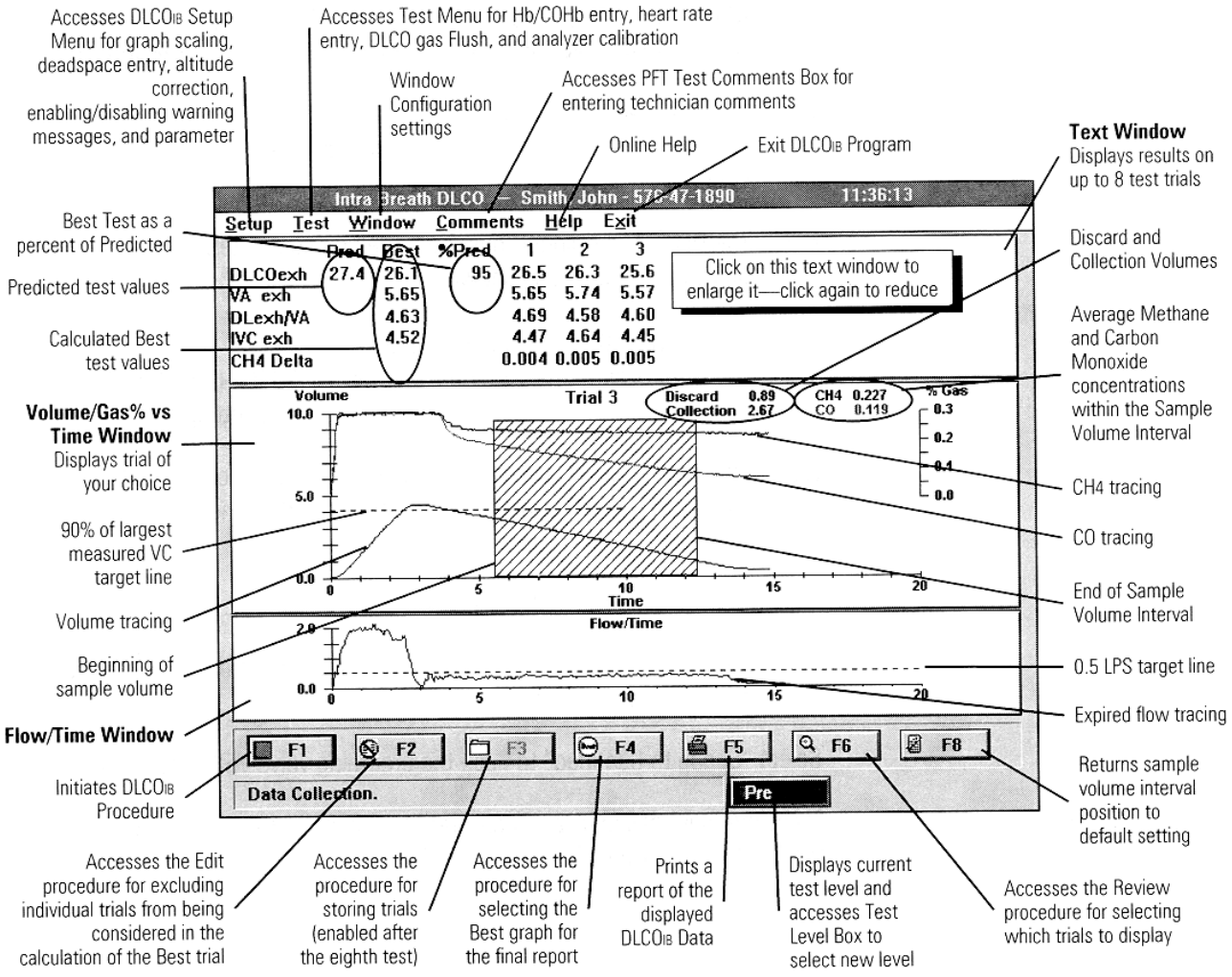

Figure 5-7 – Intra Breath DLCO Test Screen

Test Procedure

Note

Autobox: The $DLCO_{IB}$ test is always performed with the cabin door open. The automated breathing valve must be attached to the mass flow sensor.

Autobox only: The test-gas tubing must be attached to the breathing valve and the transmural tube must be ***detached***.

Vmax systems: The 100% oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

The DLCO Mix cylinder must be turned on completely and the secondary pressure gauge set to 10 to 20 PSI (69 to 138 k Pa) above the oxygen setting

Vmax systems: To avoid calibration errors, it is important that the diffusion gas always be set at a higher pressure than the other gases (see the specified pressures, above).

1. Select **F1** to begin the test procedure.

Note

If it is attached, remove the expiratory flow restrictor from the expiration port of the breathing valve.

DLCO Gas Flush

2. Select **Space to Continue** to flush the breathing valve with 100% DLCO gas.

   The multi-gas analyzer is calibrated to room air (0% CH_4 and 0% CO) and to the DLCO gas mixture (0.3% CH_4 and 0.3% CO).

Note

The computer will not let you perform a test if either of these warning messages is displayed. If, after your repeated calibration attempts, the warning messages are still being displayed, refer to “Troubleshooting” on page 147 for further instructions.

Multi-gas Sensor Zero Out of Range. Recalibrate Analyzer.	This message is displayed if the multi-gas analyzer is not reading 0% CO and 0% CH_4 while sampling room air.
Multi-gas Sensor Calibration Out of Range. Recalibrate Analyzer. Check Gas Supply Circuit.	This message is displayed if the multi-gas analyzer is not reading 0.3% CO and 0.3% CH_4 while sampling gas from the diffusion mixture tank.

Attach Flow Restrictor

3. Attach the expiratory flow restrictor to the expiration port of the breathing valve.

Begin Tidal Breathing

4. After the calibration is complete, instruct the patient to put in the mouthpiece and attach the nose clips. Tell the patient to begin stable resting breathing.

Maximal Expiration/Maximal Inspiration

5. Instruct the patient to exhale completely; select **F1** during the maximal exhalation. When “Full Inhalation Then Hold” is displayed, instruct the patient to inhale completely.

Slow Maximal Expiration

6. Coach the patient to immediately exhale slowly, smoothly, and completely until the computer ends the test.

   During the exhalation, instruct the patient to control the rate of expiration by observing the Flow/Volume window and keeping the displayed tracing close to the 0.5 LPS target line.

Note

If necessary, use the mouse to adjust the sample interval in the $DLCO_{IB}$ window to assure analysis of an alveolar gas sample (make sure the sample interval bar is completely on the alveolar CH_4 plateau).

$DLCO_{IB}$ Quality Assurance Messages

Note

Do not store the test if any of the following four quality-assurance messages appear. Repeat the test to obtain better results.

Inspired Vital Capacity is less than 90% of Vital Capacity. The DLCO May be Underestimated.	This message is displayed if the measured IVC is less than 90% of the previously measured “best” Vital Capacity (either SVC or FVC).
DLCO Standard Error. Inspiratory Time Exceeds 2.5 Seconds	This message is displayed if the inspiratory time exceeds 2.5 seconds, indicating the inspiration was too slow.
DLCO Standard Error for Patients with Airflow Obstruction. Inspiratory Time Exceeds 4 Seconds	This message is displayed if the inspiratory time exceeds 4 seconds, indicating the inspiration was too slow, even for patients with significant airflow obstruction.
The DLCO is Outside the Physiologic Range.	This message is displayed if the measured DLCO falls outside the range of 20 to 200% of predicted, making it physiologically questionable.

Note

Repeat the test to obtain reproducible results if the following quality-assurance message appears,

The DLCO Reproducibility Criteria Not Met. Two Tests Should be Within 10%.	This message is displayed if there are not at least two trials with DLCO values within 10% of one another.

$DLCO_{IB}$ Quality Assurance Message Options

F1 Start

Restarts the $DLCO_{IB}$ Test Routine. The results of the last test are rejected.

Esc Cancel

Ignores the Message and displays the test results.

SINGLE BREATH OXYGEN TEST

Note

This test is only available on the Vmax Spectra and the Autobox. It is not available on the 2130 Series Spirometer.

From the **Pulmonary Function Menu** (Figure 5-1), under **Test Level**, select **Pre**, **Post**, or **Level 1–17**. Under **Test Protocol**, select a challenge protocol ("---" = no protocol) and then select **B Single Breath O2**. The **Single Breath Oxygen Test** screen will be displayed (Figure 5-8).

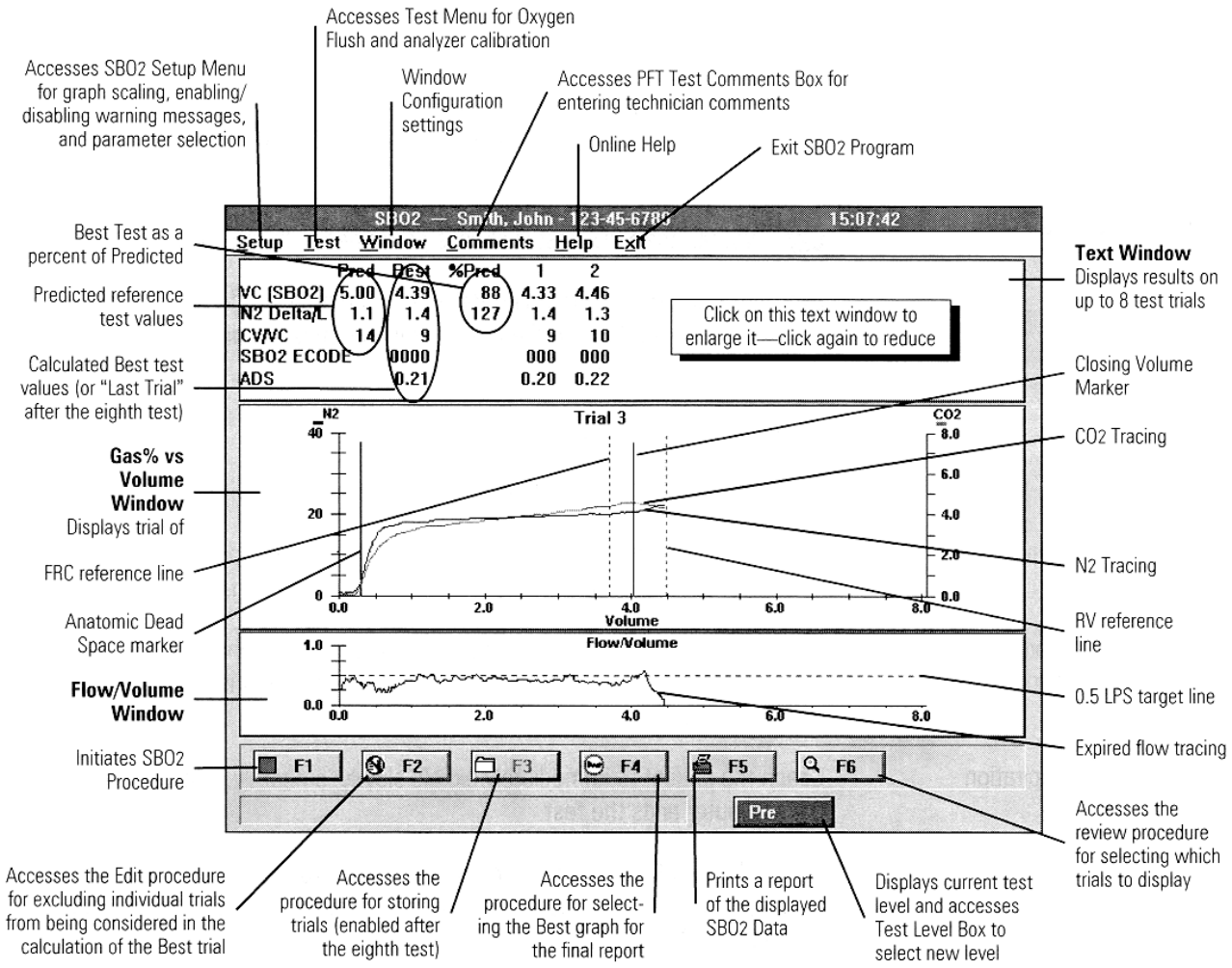

Figure 5-8 – Single Breath Oxygen Test Screen

Analyzer Calibration

For instructions on performing a pre-test analyzer calibration/verification, see “Gas Dilution Lung Volumes“ on page 62.

Note

Although the program does not force you to perform a calibration or verification, do a calibration at least once every testing day and do a verification before testing each patient.

The Span 1 calibration gas must be turned on completely. If the regulator has an adjustable secondary pressure gauge, it should be set between 50 and 60 PSI (345 and 414 k Pa).

The 100% oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

Test Procedure

Note

Autobox: The SBO_2 test is always performed with the cabin door open.

The automated breathing valve must be attached to the mass flow sensor.

Autobox only: The transmural tube must be disconnected from the breathing valve.

1. Select **F1** to begin the test procedure.

Oxygen Flush

2. Select **Space to Continue** to flush the breathing valve with 100% oxygen.

Begin Tidal Breathing

3. Instruct the patient to put in the mouthpiece and attach the nose clips. Tell the patient to begin stable resting breathing.

Maximal Expiration/Maximal Inspiration

4. Instruct the patient to exhale completely; select **F1** during the maximal exhalation. When the patient cannot exhale any further, instruct the patient to inhale completely.

Slow Maximal Expiration

5. Coach the patient to immediately exhale slowly, smoothly, and completely until the computer ends the test.

   During the exhalation, instruct the patient to control the rate of expiration by observing the Flow/Volume window to keep the displayed tracing close to the 0.5 LPS target line.

Mark ADS and CV Points

6. Use the mouse to mark the ADS and CV points to accurately reflect the Anatomic Dead Space and Closing Volume positions.

Note

The computer does not automatically detect the ADS and CV points.

SBO_2 Quality Assurance Messages

Note

Do not store the test if either of the following two quality assurance messages appears. Repeat the test to obtain better results.

Inspired Vital Capacity is less than 90% of Vital Capacity.	This message is displayed if the measured IVC is less than 90% of the previously measured best Vital Capacity (either SVC or FVC).
The CV/VC is Outside the Physiologic Range.	This message is displayed if the measured CV/VC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.

Note

Repeat the test to obtain reproducible results if the following quality-assurance message appears.

The CV/VC Reproducibility Criteria Not Met. Two Tests Should be Within 10%.	This message is displayed if there are not at least two trials with CV/VC values within 10% of one another.

SBO_2 Quality Assurance Message Options

F1 Start

Restarts the SBO_2 test routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

CHAPTER 6 • PLETHYSMOGRAPHY

PLETHYSMOGRAPHY TEST SCREEN

Note

This test module is only available on the Autobox.

1. From the **Vmax Program Manager**, select **5 Pulmonary Function** to display the **Pulmonary Function** menu (Figure 5-1).
2. From the **Pulmonary Function** menu, select **3 Plethysmography** to display the **Plethysmography Test** screen (Figure 6-1).

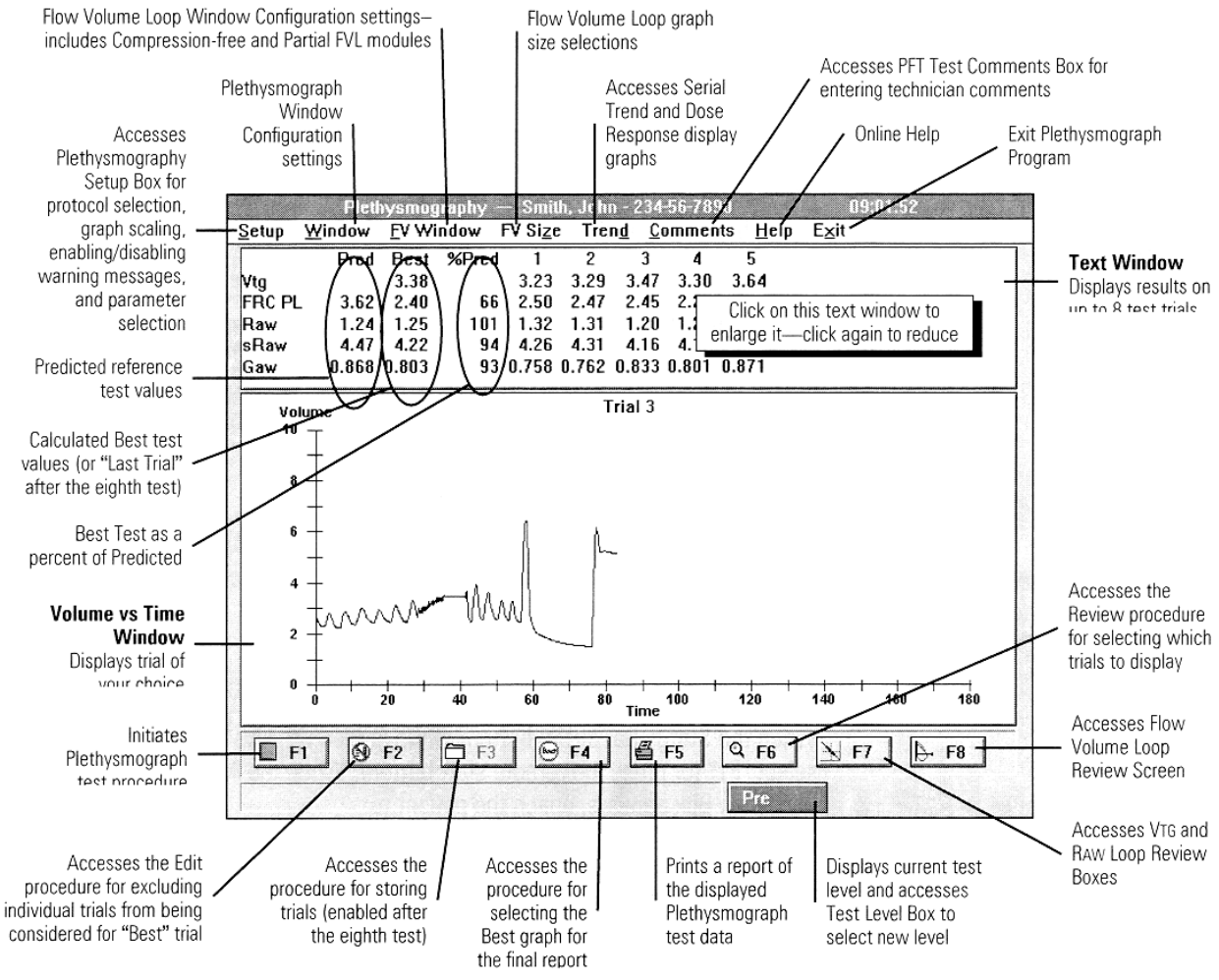

Figure 6-1 – Plethysmography Test Screen

Note

For additional information on all the options accessible from the Plethysmography Test screen, refer to the reference manual.

TEST PROCEDURE

Note

The gas cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

A successful flow volume verification should be performed before testing a new patient (see “Flow Volume Calibration“ on page 39).

Autobox: The automated breathing valve must be attached to the mass flow sensor and the test gas tubing must be ***detached***.

1. Close and latch the cabin door.
   Allow adequate time for the cabin to thermally stabilize after the door is closed before beginning the breathing maneuver. Thermal stability usually takes about 30 seconds.
2. Instruct the patient to put in the mouthpiece and attach the nose clips.
3. Select **F1** to begin the test procedure.

Tidal Breathing

4. Record at least three stable tidal breaths.

F1 Measure RAW Loops

Note

If you only want to measure VTG and not RAW, you can skip this step, but make sure you have previously selected “None” for RAW Protocol in the Plethysmography Setup Box. Refer to the reference manual for complete instructions on the Plethysmography Setup Box.

5. When the status bar at the bottom of the screen displays “RAW – F1 Start,” select **F1** (or press the remote start button).

6. When the **Airway Resistance Collection** box appears, coach the patient to:

   Panting Protocol Setup: Begin panting at 60 to 180 breaths/minute.

   Resting Protocol Setup: Slightly increase the respiratory rate to 18 to 24 breaths/minute.

   F1 to Restart Loop Collection:

   During this phase, you can select **F1** to clear the screen and restart RAW loop collection, if desired.

   Esc to Stop Loop Collection:

   You can select **Esc** to terminate RAW loop collection and continue to the next step (VTG loops). The last four RAW loops displayed will be stored.

Measure VTG Loops

After six RAW loops in succession have been collected (or you select **Esc**), the computer will wait one full second and then switch to the **VTG Collection** box.

7. Coach the patient to:

   Panting Protocol Setup: pant against the closed shutter.

   Resting Protocol Setup: take a normal breath against the closed shutter.

   F1 to Restart Loop Collection

   During this phase, you can select **F1** to clear the screen and restart VTG loop collection, if desired.

   Esc to Stop Loop Collection

   You can select **Esc** to terminate VTG loop collection, open the shutter, and continue to the next step. The last four VTG loops displayed will be stored.

   The computer will open the shutter and re-display the **Plethysmography Test** screen:

   Panting Protocol Setup: after six VTG loops in succession have been collected (or you select **Esc**).

   Resting Protocol Setup: after the computer detects a single breath attempt of at least ±5 cmH_2O (or you select **Esc**).

Slow Vital Capacity

8. After the shutter opens, coach the patient to perform a Slow Vital Capacity maneuver (either inspiratory-first or expiratory-first is acceptable). If you feel that the patient has not performed maximally during the maneuver, multiple SVC maneuvers

can be performed. The computer will choose the maneuver with the largest measured SVC.

Note

You have the option of doing the SVC before or after the VTG maneuver.

F1 Flow Volume Loop

You now have the option of coaching the patient to perform a Flow Volume Loop maneuver.

9. Select **F1** to display the **Flow Volume Loop Test** screen.
10. Instruct the patient to take in a deep breath and then to forcefully exhale and completely empty his or her lungs.
11. After maximum expiration, instruct the patient to forcefully inspire until the lungs are full.
12. Select **End Test**. The patient can now remove the mouthpiece.

Note

See “Flow Volume Loops” on page 50 for details about performing the Flow Volume Loop maneuver.

Note

It is not mandatory to perform a FVL measurement. If desired, you can skip this step and select **End**.

LOOP REVIEW BOXES

Following the test maneuver, you should review and possibly edit the measured VTG loops and RAW loops by accessing the Loop Review Boxes as described below.

VTG Loop Review Box

1. Select **F7** to access the **VTG Loop Review** box (Figure 6-2).
   The **VTG Loop Review** box allows you to inspect the last four VTG loops collected and make any adjustments or deletions to the slope lines displayed by the computer.
2. After adjusting or deleting any slope lines, select **F3** to store the changes.

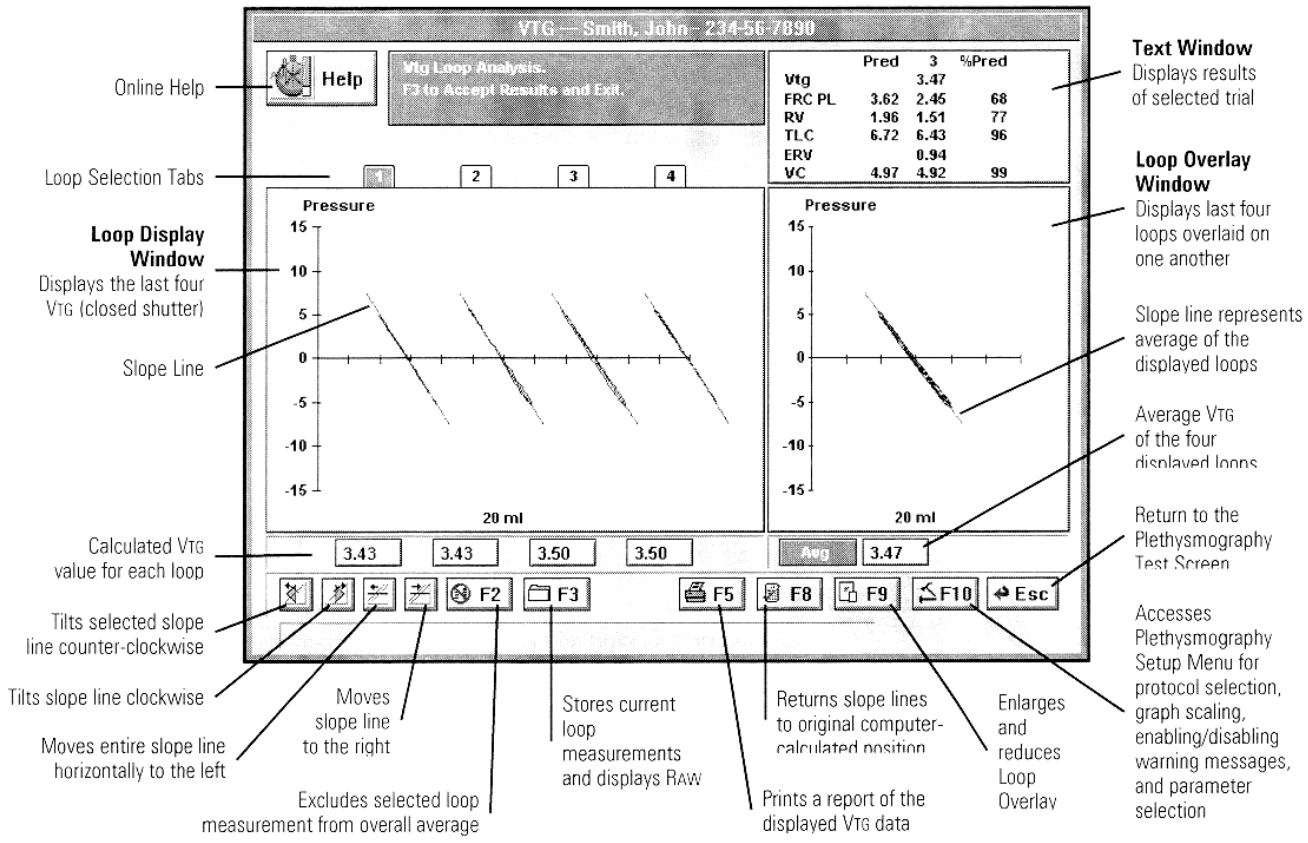

Figure 6-2 – VTG Loop Review Box

RAW Loop Review Box

After you select **F3** in the **VTG Review** box, the **RAW Loop Review** screen will be displayed (Figure 6-3). The **RAW Loop Review** screen allows you to inspect the last four RAW loops collected and make any adjustments or deletions to the slope lines displayed by the computer.

After adjusting or deleting any slope lines, select **F3** to store the changes and re-display the **Plethysmograph Test** screen.

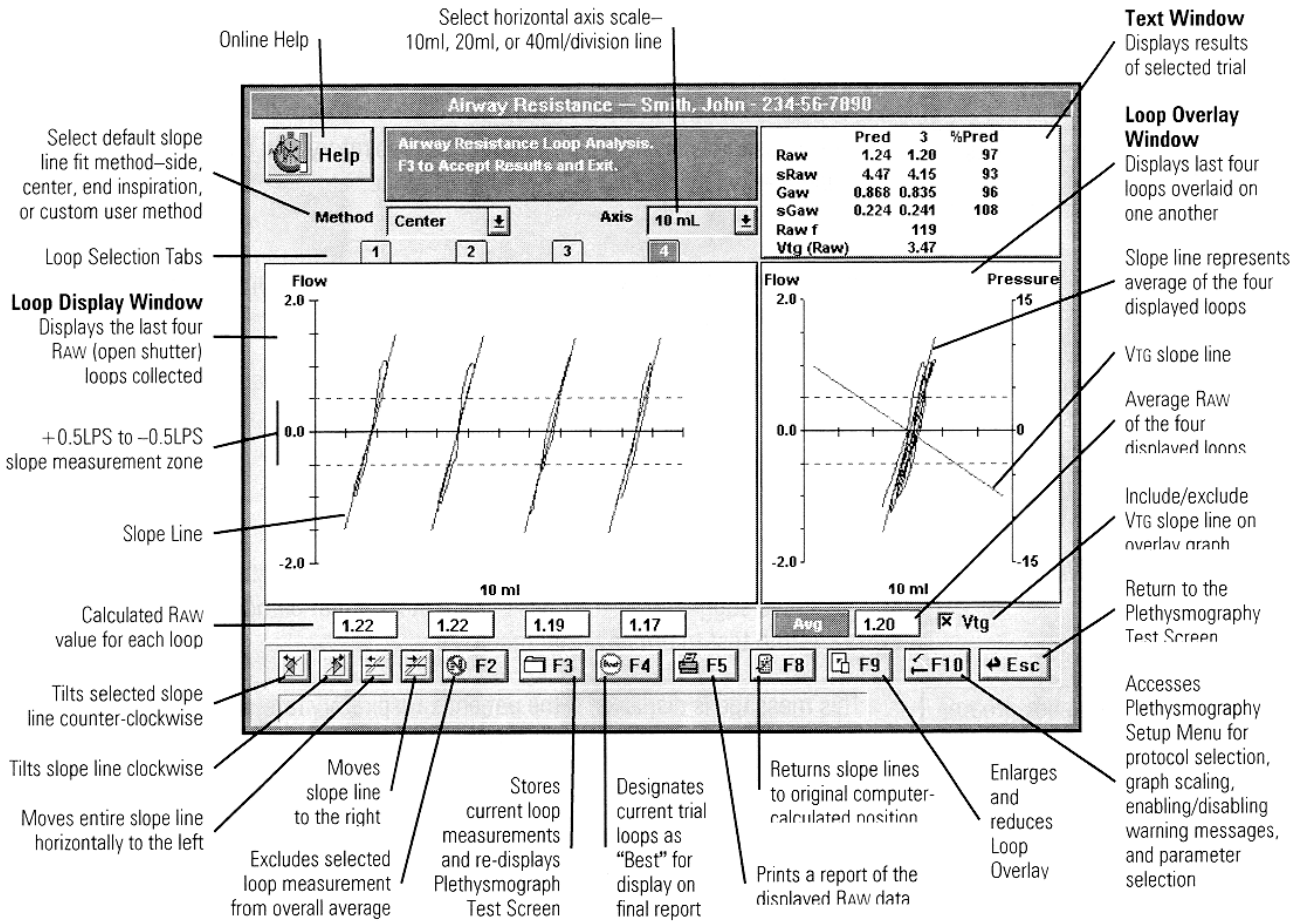

Figure 6-3 – RAW Loop Review Box

PLETHYSMOGRAPH QUALITY ASSURANCE MESSAGES

RAW Messages

Note

If the following RAW Quality Assurance Message appears, consider not storing that particular trial, and repeat the test to obtain better results.

RAW Breathing Frequency outside 18 to 180	This message is displayed if the patient's respiratory rate during the RAW maneuver was outside the 18 to 180 BPM range.

Note

If the following quality-assurance message appears, repeat the test to obtain reproducible results.

The RAW Reproducibility Criteria is Not Met. Two tests should be within 10%	This message is displayed if there are not at least two trials with RAW values within 10% of one another.

VTG/Lung Volume Messages

Note

If any of the following six VTG quality-assurance messages appear, do not store that particular test, and repeat the test to obtain better results.

VTG Breathing Frequency greater than 180	This message is displayed if the patient's respiratory rate during the VTG maneuver was faster than 180 BPM.
VTG Mouth Pressure too high (15 cmH_2O)	This message is displayed if the patient's respiratory effort during the closed-shutter VTG maneuver exceeded ±15 cmH_2O pressure.

The IC is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured IC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.
The FRC is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured FRC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.
The Vital Capacity is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured VC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.
The TLC is Outside Physiologic Range. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if the measured TLC falls outside the range of 20 to 200% of predicted, making it physiologically questionable.

Note

If any of the following five VTG quality-assurance messages appear, repeat the test to obtain reproducible results.

The VTG Reproducibility Criteria is Not Met. Two tests should be within 10%.	This message is displayed if there are not at least two trials with VTG values within 10% of one another.
The IC CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with IC values within 10%—the Coefficient of Variation (CV)—of one another.

The FRC CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with FRC values within 10%—the Coefficient of Variation (CV)—of one another.
The Vital Capacity CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with VC values within 10%—the Coefficient of Variation (CV)—of one another.
The TLC CV is Greater than 10%. Careful Evaluation of the Lung Volume Parameters is Suggested.	This message is displayed if there are not at least two trials with TLC values within 10%—the Coefficient of Variation (CV)—of one another.

Flow Volume Loop Messages

Note

If any of the following three FVL quality-assurance messages appear during a test, do not store that particular test, and repeat the test to obtain a better effort.

Exhalation Time Too Short. Minimum Exhalation Time of 6 Seconds Not Met	This message occurs when the patient's Total Expiratory Time was less than six seconds.
End of Test Criteria Not Met	This message occurs when the patient's Expiration did not meet the End of Test Criteria.
Unsatisfactory Start of Test. Extrapolation Volume Exceeds 5% or .15L.	This message occurs when the test has a back-extrapolation value greater than 5% of the FVC (or 150ml, whichever is greater).

Note

If any of the following three FVL quality-assurance messages appear, repeat the test to obtain reproducible results.

The Best Peak Flow and the Next Largest Vary by More Than 10%.	This message occurs when there are no trials within 10% of the "best" trial for Peak Flow.
The Best FEV_1 and the Next Largest Vary More Than .2 Liters	This message occurs when there are no trials within 0.2 liters of the "best" (largest) trial for FEV_1.
The Best FVC and the Next Largest Vary More Than .2 Liters	This message occurs when there are no trials within 0.2 liters of the "best" (largest) trial for FVC.

General Messages

Note

If the following quality-assurance message appears during a test, do not store that particular test, and repeat the test to obtain better results.

Too many Test Errors. Careful Evaluation of the Results is Suggested	This message is displayed if there are so many warning messages that they will not fit on the screen.

Quality Assurance Message Options

F1 Start

Restarts the Plethysmograph Test Routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

CHAPTER 7 • RESPIRATORY MECHANICS

MAXIMAL RESPIRATORY PRESSURES

Note

This test is only available on the Vmax Spectra and the Autobox. It is not available on the 2130 Series Spirometer.

1. From the Vmax Program Manager, select **5 Pulmonary Function** to display the **Pulmonary Function Menu** (Figure 5-1).
2. From the **Pulmonary Function Menu**, select **6 Max Resp. Pressure**. The **Maximal Respiratory Pressures Test** screen will be displayed (Figure 7-1).

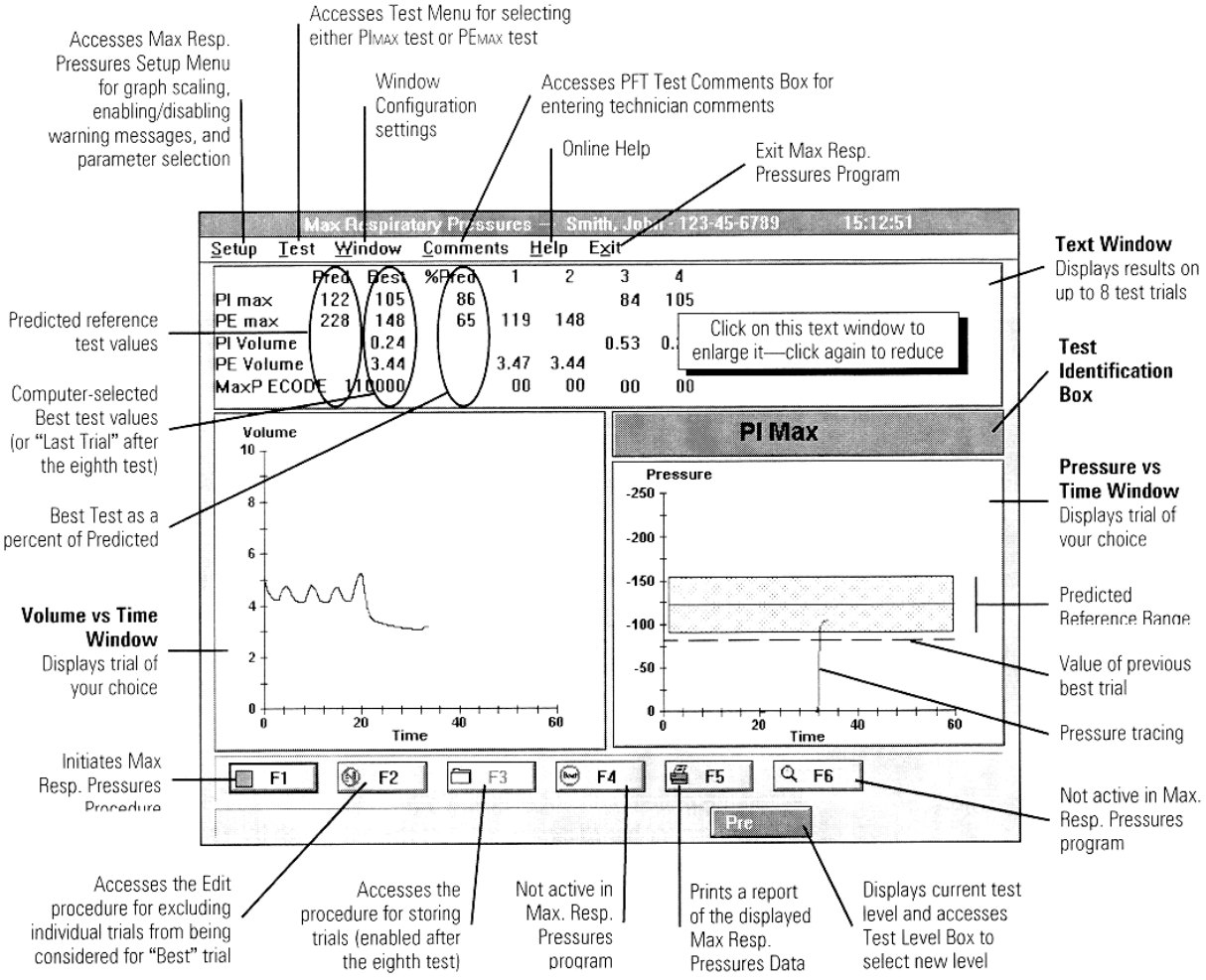

Figure 7-1 – Maximal Respiratory Pressures Test Screen

Note

For additional information on all the options accessible from the Maximal Respiratory Pressures Test screen, refer to the reference manual.

Test Procedure

Note

The maximum-pressure adapter plug should be inserted into the mass-flow sensor sample port.

Note

The automated breathing valve must be attached to the mass flow sensor.

Autobox: The test gas tubing must be ***detached*** from the breathing valve.

The 100% oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

A successful flow volume verification should be performed before testing a new patient (see “Flow Volume Calibration” on page 39).

Maximal Inspiratory Pressure

1. If **PI Max** is not displayed in the **Test Identification** box, select **PI Max** from the **Test** menu.
2. Select **F1** to begin the test procedure.

Begin Tidal Breathing

3. Instruct the patient to put in the mouthpiece, attach the nose clips, and begin stable resting breathing.

Maximal Expiration

When the computer detects three tidal breaths with a stable baseline, it will display the message:

“Start after full exhalation”

4. Instruct the patient to perform a complete expiration.

Maximal Inspiratory Effort

5. When the patient cannot exhale any further, select **F1**.
   The valve will close, not allowing the patient to inhale. Instruct the patient to try as hard as possible to inspire against the closed valve. After two seconds, the valve will open automatically and the patient can then remove the mouthpiece.

Maximal Expiratory Pressure

1. If **PE Max** is not displayed in the **Test Identification** box, select **PE Max** from the **Test** menu.
2. Select **F1** to begin the test procedure.

Begin Tidal Breathing

3. Instruct the patient to put in the mouthpiece, attach the nose clips, and begin stable resting breathing.

Maximal Inspiration

When the computer detects three tidal breaths with a stable baseline, it will display the message:

"Start after full inhalation"

4. Instruct the patient to perform a complete inspiration.

Maximal Expiratory Effort

5. When the patient cannot inhale any further, select **F1**.
   The valve will close, not allowing the patient to exhale. Instruct the patient to try as hard as possible to expire against the closed valve. After two seconds, the valve will open automatically and the patient can then remove the mouthpiece.

Maximal Respiratory Pressures Quality Assurance Messages

Note

If either of these quality-assurance messages appears, repeat the test to obtain reproducible results.

Static Lung Volume Data not Found.	This message occurs when there are no previously measured lung volumes (including FRC), so the maximal pressures cannot be referenced to specific lung volumes.
The Next Best PE Max is not within 10% of the Best PE Max.	This message occurs when there are no trials within 10% of the “best” trial for PE_{MAX}.
The Next Best PI Max is not within 10% of the Best PI Max.	This message occurs when there are no trials within 10% of the “best” trial for PI_{MAX}.

Max Resp. Pressures Quality Assurance Message Options

F1 Start

Restarts the Max Resp. Pressures Test Routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

COMPLIANCE

Note

This test is not available on the 2130 Series Spirometer.

1. From the Vmax Program Manager, select **5 Pulmonary Function** to display the **Pulmonary Function Menu** (Figure 5-1).
2. From the **Pulmonary Function Menu**, select **4 Compliance** to display the **Compliance Test** screen (Figure 7-2).

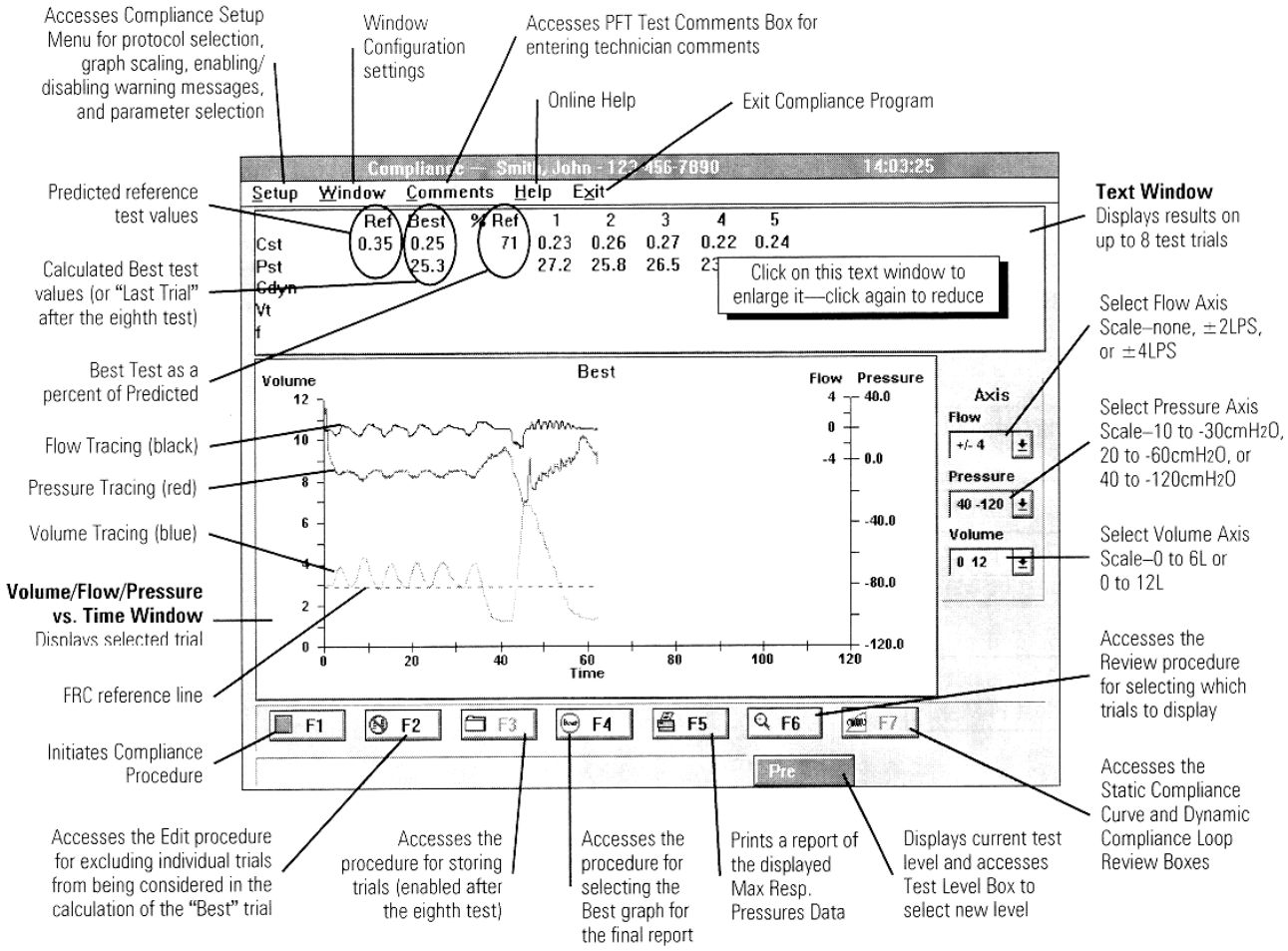

Figure 7-2 – Compliance Test Screen

Note

For additional information on all the options accessible from the Compliance Test screen, refer to the reference manual.

For complete instructions on preparing the instrument, preparing the patient, and inserting the esophageal balloon catheter, refer to the reference manual.

Compliance testing can be considered an invasive medical procedure. Insertion and maintenance of the esophageal balloon catheter should not be attempted unless you are thoroughly familiar with patient preparation, testing procedures, indications, and complications. Qualified medical supervision is also essential.

Test Procedure

Note

Vmax: The 100% Oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

Autobox: The 100% Oxygen (or alternate drive gas) cylinder must be turned on completely and the secondary pressure gauge set between 50 and 60 PSI (345 and 414 k Pa).

The automated breathing valve must be attached to the mass flow sensor.

Autobox: The test gas tubing must be ***detached*** from the breathing valve.

Autobox: The compliance test is always performed with the cabin door open.

A successful Flow Volume Verification should be performed before testing a new patient (see “Flow Volume Calibration” on page 39).

Static Compliance

Note

The Static Compliance protocol must be selected on the Compliance Test Setup screen.

Start Test

1. Instruct the patient to put in the mouthpiece, attach the nose clips, and select **F1** to begin the test procedure.

Tidal Breathing

2. Instruct the patient to breathe as comfortably and as normally as possible.

Maximal Inspiration

When the computer detects three tidal breaths with a stable baseline, it will display the message:

"Full Inhalation – F1 Start to Close Shutter"

3. Instruct the patient to perform a complete inspiration.
4. Select **F1** during the maximal inspiration.
5. At full inspiration, select **F1** again, and instruct the patient to exhale slowly.

   #### Manual Shutter Control

   If **Manual** shutter control is selected in the **Test Setup** box, press **F1** (or the remote start button) to close the shutter and coach the patient to relax against it. Release the button to open the shutter. The shutter can be closed and opened as many times as desired.

   #### Automatic Shutter Control

   If **Automatic** shutter control is selected, coach the patient to relax against the closed shutter when it automatically closes. The shutter will close at the intervals specified on the **Test Setup** box and will open after the specified duration threshold is reached.

6. When the patient finishes exhaling and begins to inhale (should be below the FRC level), select **End**. The patient can then remove the mouthpiece.

Dynamic Compliance

Note

The Dynamic Compliance protocol must be selected on the Compliance Test Setup screen.

If you perform multiple tests at different respiratory rates to measure the frequency dependence of compliance, the patient should be coached to breathe at the same V_T during each test.

Start Test

1. Instruct the patient to put in the mouthpiece, attach the nose clips, and select **F1** to begin the test procedure.

Tidal Breathing

2. Instruct the patient to begin by breathing as comfortably and normally as possible. The respiratory rate should be <16 with a normal V_T.

   When the computer detects three tidal breaths with a stable baseline, it will display the message:

   "Paced Breathing – F1 Start to Collect Loops"

3. Select **F1** to start loop data collection.
   The Dynamic Compliance Loop Collection box will be displayed.

F1 to Restart Loop Collection

You can select **F1** to clear the screen and restart loop collection, if desired. You may want to do this to erase unsatisfactory loops (too large, open, and/or fat loops).

Esc to Stop Loop Collection

4. Select **Esc** to capture and store the last compliance loop displayed, terminate loop collection, and return to the **Compliance Test** screen. The patient can then remove the mouthpiece.

   Only two command buttons will be displayed at this point:

   Select **End** to accept the test and display the results.

   Select **Esc** to reject the test.

Compliance Review Boxes

Following the Static or Dynamic Compliance maneuvers, you should review and possibly edit the measured Static Compliance curve or Dynamic Compliance Loop by accessing the **Compliance Review** box as described below.

Static Compliance Review Box

1. Select **F7** from the **Static Compliance Test** screen to access the **Static Compliance Review** screen (Figure 7-3).
   The **Static Compliance Review** screen allows you to inspect the static compliance tracing and adjust the slope line displayed by the computer. The slope of the line is determined over the interval between FRC and FRC+500 ml.
2. After adjusting the slope line, select **F3** to store the changes.

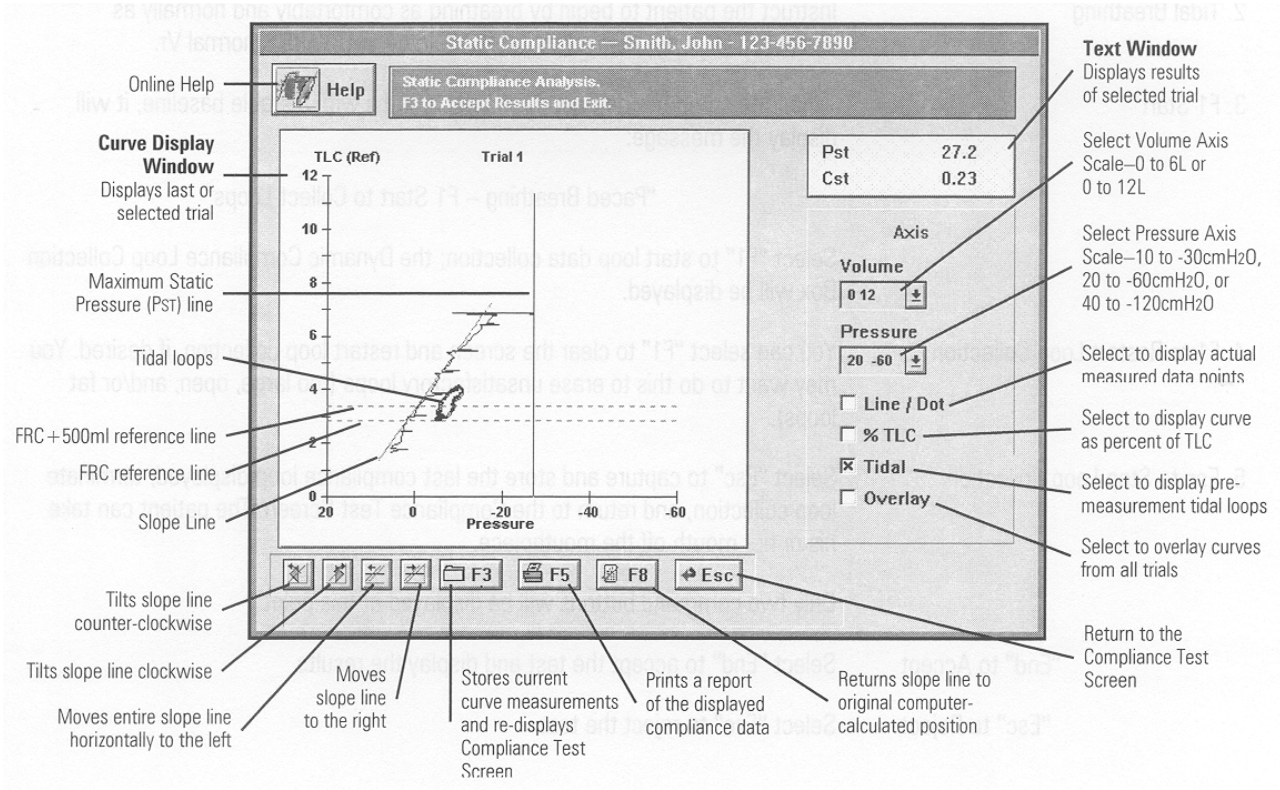

Figure 7-3 – Static Compliance Review Screen

Dynamic Compliance Review Screen

1. Select **F7** from the **Dynamic Compliance Test** screen to access the **Dynamic Compliance Review** screen (Figure 7-4).
   The **Dynamic Compliance Review** screen allows you to inspect the dynamic compliance tracing and adjust the slope line displayed by the computer. The line is drawn between the zero-flow points (minimum and maximum volume points, i.e., the FRC level and the FRC + V_T level).
2. After adjusting the slope line, select **F3** to store the changes.

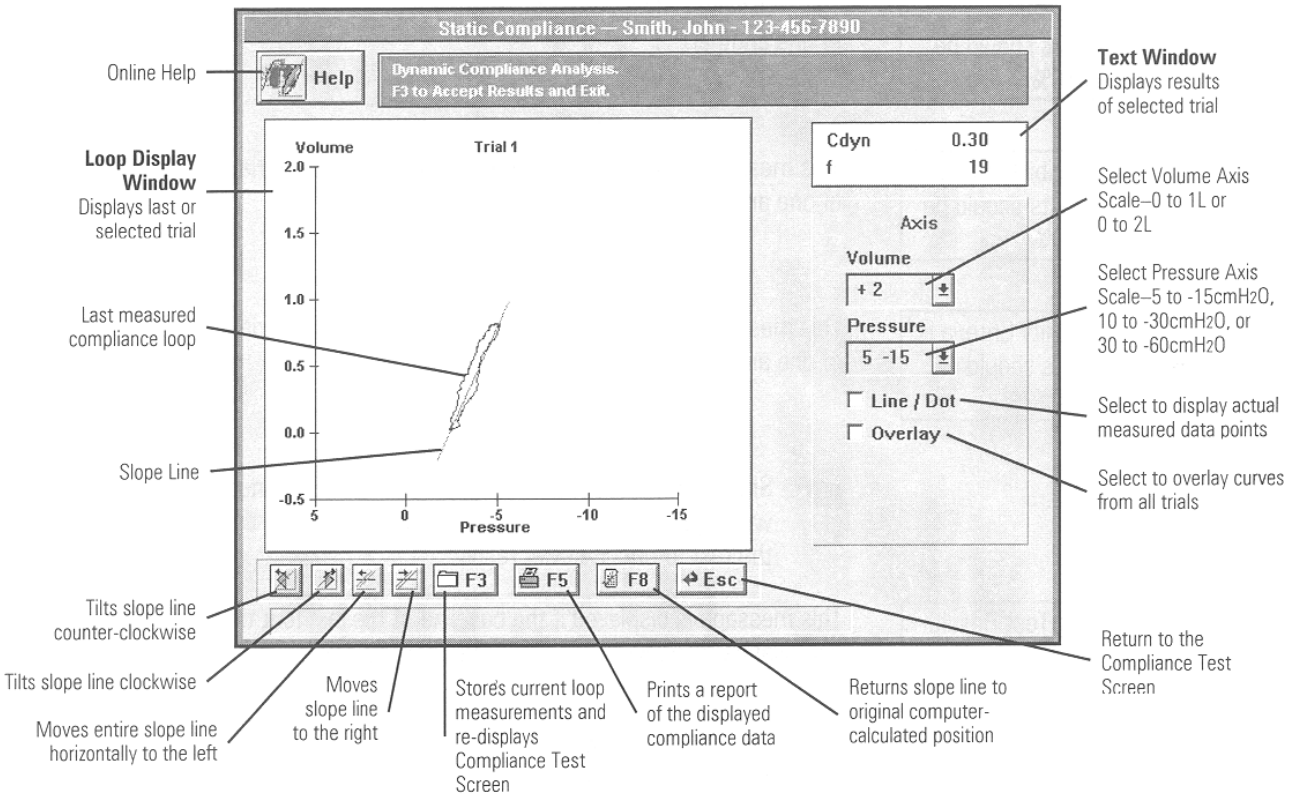

Figure 7-4 – Dynamic Compliance Review Box

Compliance Quality Assurance Messages

Note

If any of the following three quality-assurance messages appear, repeat the test to obtain reproducible results.

The Cst Reproducibility Criteria is not met. Two tests should be within 10%.	This message is displayed if there are not at least two trials with C_{ST} within 10% of one another.
The Cdyn Reproducibility Criteria is not met. Two tests should be within 10%.	This message is displayed if there are not at least two trials with C_{DYN} within 10% of one another.
The Pst Reproducibility Criteria is not met. Two tests should be within 10%.	This message is displayed if there are not at least two trials with P_{ST} within 10% of one another.

Note

If either of the following quality-assurance messages appears, do not store that particular test, and repeat the test to obtain better results.

FRC Baseline Error. Test Results Should be Carefully Examined.	This message is displayed if the baseline of the last four tidal breaths prior to the compliance maneuver varied by more than 200 ml.
The IC is less Than .5 Liters. Test Results Should be Carefully Examined.	This message is displayed if the patient's Inspiratory Capacity is less than 500ml. Since the compliance measurement is made from the FRC level to FRC+500ml, the patient's IC may not be large enough for an accurate measurement.

Compliance Warning Message Options

F1 Start

Restarts the Compliance Test Routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

P.100 AND ANALYSIS OF NATURAL BREATHING

Note

This test is only available on the Vmax Spectra and the Autobox. It is not available on the 2130 Series Spirometer.

From the Vmax Program Manager, select **5 Pulmonary Function** to display the **Pulmonary Function Menu** screen (Figure 5-1). From the **Pulmonary Function Menu** screen, select **6 P.100**. The **P.100 Test** screen will be displayed (Figure 7-5).

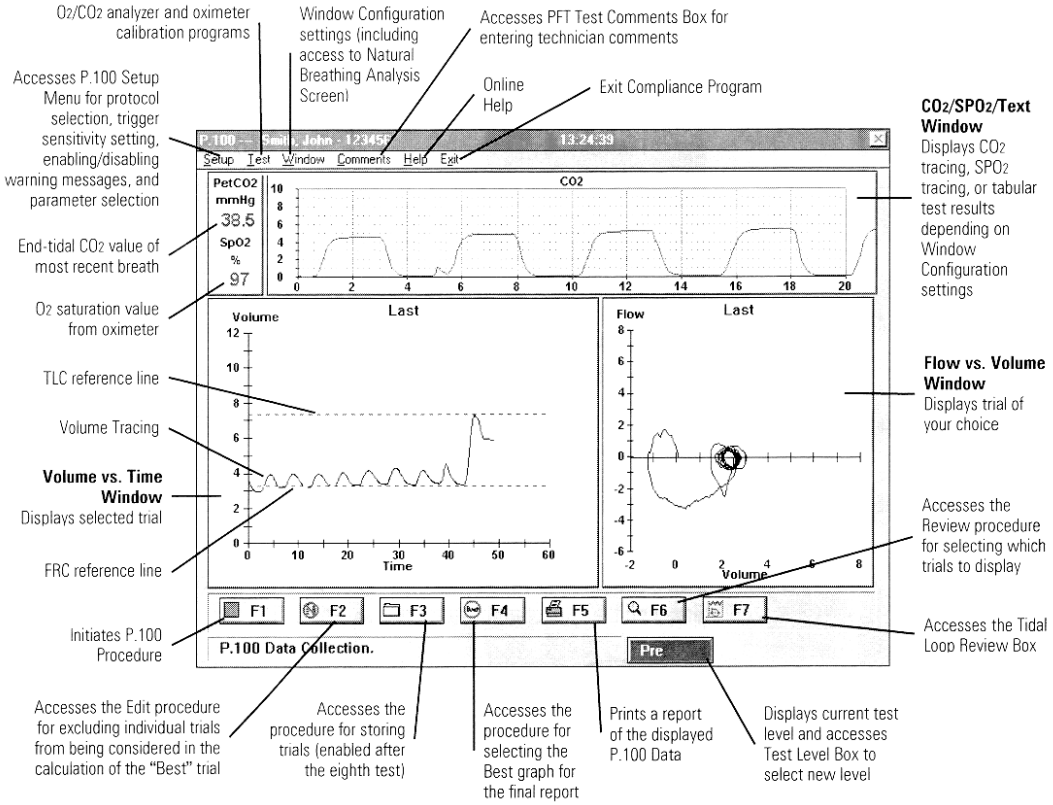

Figure 7-5 – P.100 Test Screen

Note

For additional information on all the options accessible from the P.100 Test screen (including hardware configurations and alternate inspired gas setups), see the on-line help and tutorial programs. These programs are described in “Online Help” on page 36 and “Tutorial Program” on page 38.

You can skip the Analyzer Calibration section if you will not be using the CO_2 + O_2 Drive Protocol (selected in Test Setup box).

Analyzer Calibration

Note

Although the program does not force you to perform a calibration, you should do one at least once every testing day.

You should perform a Verification Procedure (see following section) before testing each patient.

The 100% oxygen cylinder must be turned on completely and the secondary pressure gauge set between 50–60 PSI (345–414 k Pa).

The Span 1 calibration gas (16% O_2, 4% CO_2) must be turned on completely. If the regulator has an adjustable secondary pressure gauge, it should be set between 50 and 60 PSI (345 and 414 k Pa).

Autobox: The Span 1 calibration gas must be connected to the Cal 1 port on the transducer panel that is on the back of the cabin.

Analyzer Calibration Screen

1. Select **CO_2 Calibration** from the **Test** menu on the **P.100 Test** screen. The **Analyzer Calibration** screen will be displayed.

Attach Sample Tubing

2. Connect the sample line to the calibration fitting on the front of the Pneumatics Module.

Note

If testing inside the Autobox cabin, connect the sample line to the calibration fitting on the interior transducer panel.

F1 Cal

3. Select **F1** to initiate the O_2 and CO_2 analyzer calibration sequence. When the calibration finishes successfully (no warning messages), a green **Calibration Complete** message will be displayed in the lower right corner of the screen.

F3 Store

4. Select **F3** to store the calibration results and return to the **P.100 Test** screen.

Calibration Warning Messages

Note

Do not proceed with patient testing until the instrument passes all the Analyzer Verification Criteria checks and no warning messages are displayed.

The Sensors are Responding Incorrectly to Calibration Gas. Check Calibration Gas Tank Pressures and Connections.	This message is displayed if the O_2 and CO_2 analyzers are not reading the correct O_2 and CO_2 concentrations from the Span 1 and 100% O_2 gases.
Ensure that the Sample Line is Connected to the Calibration Fitting.	This message is displayed if the correction factors for the CO_2 and O_2 concentrations are inappropriately large.
O_2 Outside Accuracy Range	This message is displayed if the difference between the expected and actual O_2 concentrations is greater than 2%.

CO_2 Outside Accuracy Range	This message is displayed if the difference between the expected and actual CO_2 concentrations is greater than 0.25%.
Transit Time Warning	This message is displayed if the gas transit time is greater than 1 sec.
O_2 Response Time Warning	This message is displayed if the O_2 response time is greater than 0.15 sec.
CO_2 Response Time Warning	This message is displayed if the CO_2 response time is greater than 0.15 sec.

Calibration Warning Message Options

You are presented with the following options when a **Calibration Warning** box is displayed:

F1 Cal

Restarts the calibration routine and allows you to reattempt to pass the calibration sequence.

Esc Cancel

Ignores the warning message and displays the calibration verification results.

Caution!

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

Verification Procedure

Note

Although the program does not force you to perform a verification procedure, this procedure should be done before testing each patient to ensure accurate test results.

Select **F2** to initiate the O_2 and CO_2 analyzer verification sequence.

One or more Warning Messages may be displayed. These warning messages generally indicate that you need to perform a complete calibration procedure.

Caution!

Do not proceed with testing when the instrument does not meet all the verification criteria or when warning messages are displayed. Proceeding under such conditions could cause erroneous test results.

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

Test Procedure

Note

Autobox: The P.100 test is always performed with the cabin door open.

The automated breathing valve must be attached to the mass flow sensor.

Autobox: The transmural tube ***and*** the test gas tubing must be ***detached*** from the breathing valve.

A successful Flow Volume Verification should be performed before testing a new patient to ensure accurate test results (see “Flow Volume Calibration” on page 39).

If a calibration was performed, reconnect the sample line to the flow sensor port.

1. Select **F1** to begin the test procedure.

Begin Tidal Breathing

2. **Instruct** the patient to put in the mouthpiece, attach the nose clips, and begin stable resting breathing.

The computer will evaluate the baseline stability of the first four tidal breaths and display one the following two messages:

F1 Start. Resting Breathing Until Test Over	This indicates that the stability criteria were met (the end-expiratory points of the first four breaths were all within a 200 ml. range).
Resting Breathing Stability Criteria Not Met	This indicates that the stability criteria were ***not*** met (the end-expiratory points of the first four breaths were not all within a 200 ml. range). Although it is not mandatory, you may want to select **Esc** and restart the tidal breathing measurement to obtain breaths with a stable baseline.

F1 to Initiate Measurement Sequence

3. After **the** Tidal Stability Message is displayed, select **F1** to initiate the P.100 measurement sequence.
   The computer will then randomly select one of the next eight tidal breaths and close the mouth shutter briefly at the end of the exhalation to make the P.100 measurement.
4. Instruct the patient to continue breathing normally.

Maximal Inspiration

5. Coach **the** patient to inspire as deep as possible.
6. Select **End**.
   The patient can now remove the mouthpiece.

P.100 Quality Assurance Messages

Note

If the following quality assurance message appears, repeat the test to obtain reproducible results.

The P.100 Reproducibility Criteria is not met. Coefficient of Variation is greater than 50%.	This message is displayed if there are not at least two trials with P.100 values within 50% of one another.

Note

If any of the following four quality-assurance messages appear during a test, do not store that particular test, and repeat the test to obtain better results.

FRC Baseline Stability Criteria (.2 L) not met.	This message is displayed if the baseline of the first four tidal breaths varied by more than 200 ml.
P.100 not measured	This message is displayed if there was no P.100 detected. The breathing valve may be assembled incorrectly, the O_2 tank may be turned off, or the test was terminated prematurely.
$PetCO_2/SpO_2$ not detected	This message is displayed if the CO_2 or oximeter signals were not detected. The sample line may be disconnected or the oximeter may not be connected correctly.

Either the $PetCO_2$ exceeds 12% or the SpO_2 is less than 80%	This message is displayed if the expired CO_2 concentration measures above 12% or the oximeter reading goes below 80%. The analyzers or oximeter may not be calibrated correctly or the inspired gas mixture may be inappropriate.

Note

If the following quality-assurance message appears, perform a Lung Volume measurement to obtain better results.

TLC data not available. Reference values replace measured values	This message is displayed if there are no previously measured lung volumes (including FRC and TLC), so the P.100 cannot be referenced to specific lung volumes.

P.100 Warning Message Options

F1 Start

Restarts the P.100 test routine. The results of the last test are rejected.

Esc Cancel

Ignores the message and displays the test results.

CHAPTER 8 • EXERCISE/INDIRECT CALORIMETRY TESTING

ENTERING THE PROGRAM

Note

These tests are not available on the 2130 Series Spirometer or the Autobox.

For instructions on setting up the various hardware configurations involving the treadmill, ergometer, ECG, oximeter, mouthpiece, mask, canopy, ventilator, etc., refer to the reference manual.

1. Select **4 Exercise/Metabolic Test** on the **Vmax Program Manager** screen to enter the Exercise/Metabolic Testing Program.
   The **Exercise/Metabolic Study** screen will be displayed (Figure 8-1).

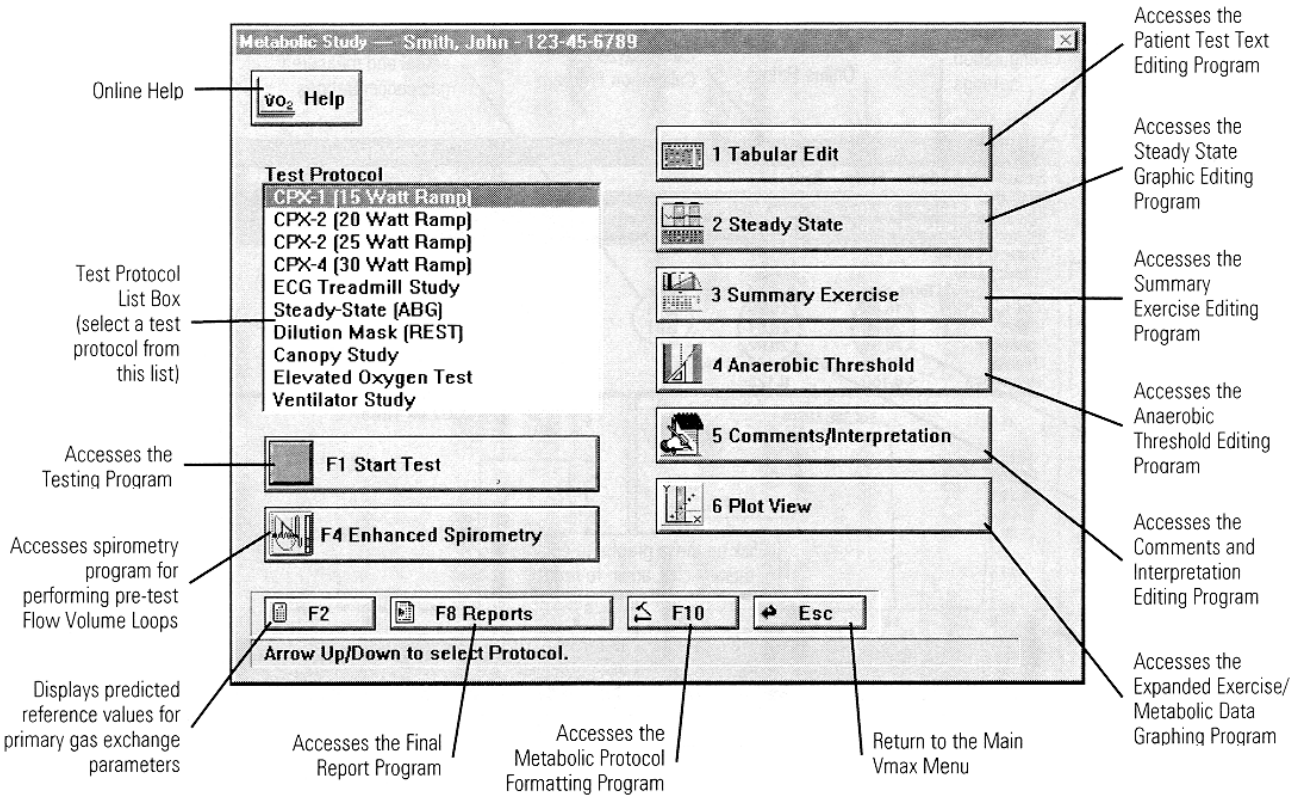

Figure 8-1 – Exercise/Metabolic Study Screen

Note

The editing and protocol formatting programs are explained in the reference manual.

Select Test Protocol

2. Select one of the displayed test protocols.

F1 Start Test

3. Select **F1** to continue.
   The **Analyzer Calibration** screen (Figure 8-2) will be displayed.

ANALYZER CALIBRATION SCREEN

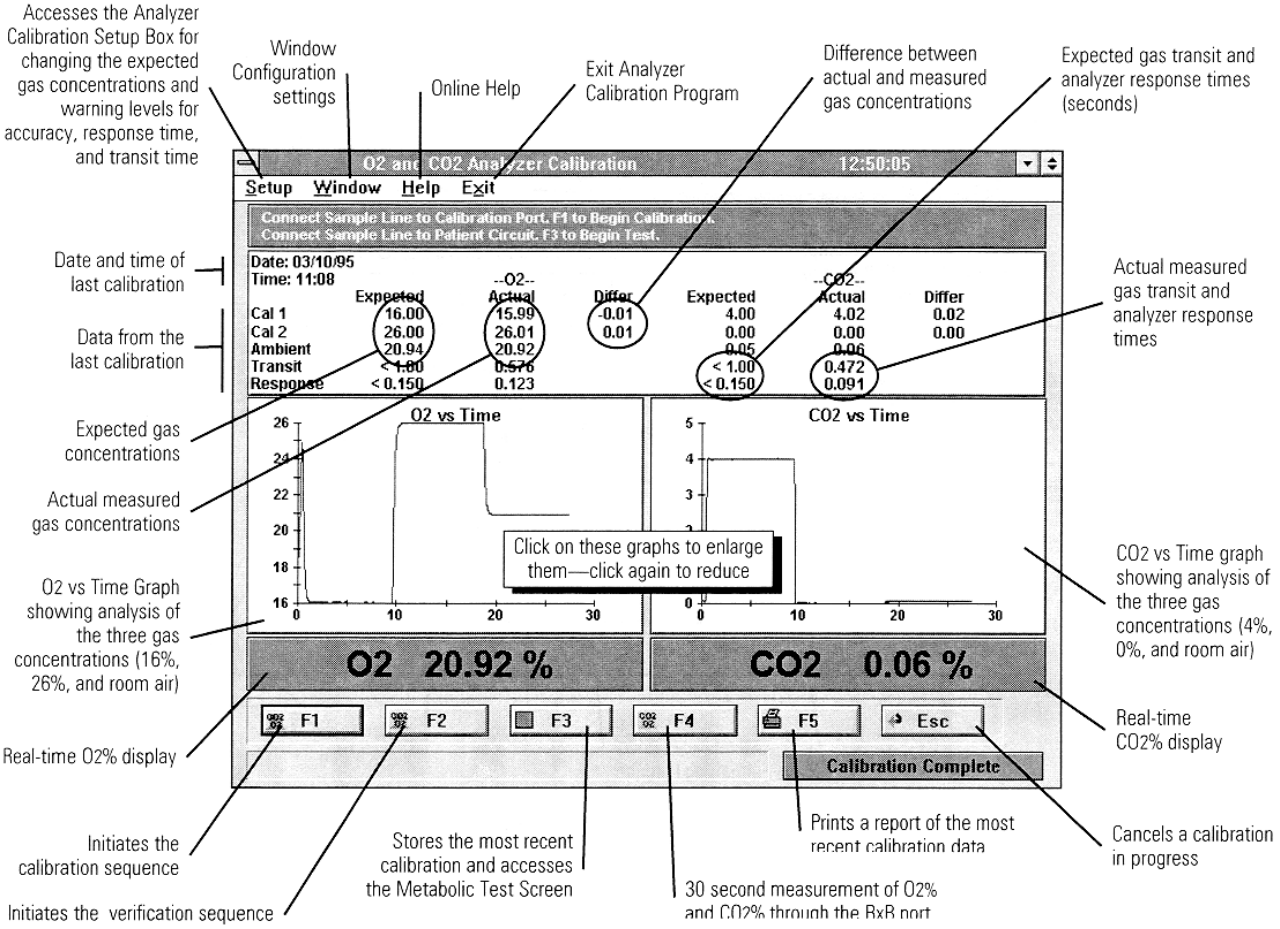

Figure 8-2 – Analyzer Calibration Screen

Note

For additional information on all the options accessible from the Analyzer Calibration screen, refer to the reference manual.

Calibration Procedure

Note

Although the program does not force you to perform a calibration, one should be done before patient testing.

The Span 1 and Span 2 calibration gases must be turned on completely. If the regulators have adjustable secondary pressure gauges, they should be set between 50 and 60 PSI (345 and 414 k Pa).

Allow at least 30 minutes warm-up time before performing a calibration or patient testing.

BxB Exercise Only: Connect the sample line to the calibration fitting on the front of the Pneumatics Module.

F1 Cal

Select **F1** to initiate the O_2 and CO_2 analyzer calibration sequence. When the calibration finishes successfully (no warning messages), a green “Calibration Complete” message will be displayed in the lower right corner of the screen.

Calibration Warning Messages

Caution!

Do not proceed with patient testing until the instrument passes all the Analyzer Verification Criteria checks and no warning messages are displayed.

The Sensors are Responding Incorrectly to Calibration Gas. Check Calibration Gas Tank Pressures and Connections.	This message is displayed if the O_2 and CO_2 analyzers are not reading the correct O_2 and CO_2 concentrations from the Span 1 and Span 2 gases.
Ensure that the Sample Line is Connected to the Calibration Fitting.	This message is displayed if the correction factors for the CO_2 and O_2 concentrations are inappropriately large (independent of the accuracy setting for the warning levels).
O_2 Outside Accuracy Range	This message is displayed if the difference between the expected and actual O_2 concentrations is greater than the value designated in the **Calibration Setup** box (see above).
CO_2 Outside Accuracy Range	This message is displayed if the difference between the expected and actual CO_2 concentrations is greater than the value designated in the **Calibration Setup** box.
Transit Time Warning	This message is displayed if the gas transit time is greater than the value designated in the **Calibration Setup** box.
O_2 Response Time Warning	This message is displayed if the O_2 response time is greater than the value designated in the **Calibration Setup** box.
CO_2 Response Time Warning	This message is displayed if the CO_2 response time is greater than the value determined in the **Calibration Setup** box.

Calibration Warning Message Options

You are presented with the following options when a **Calibration Warning** box is displayed:

F1 Cal

Restarts the calibration routine and allows you to reattempt to pass the calibration sequence.

Esc Cancel

Ignores the warning message and displays the calibration verification results.

Caution!

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

Verification Procedure

Note

This verification procedure can be done whenever you want to check the calibration without going through the entire calibration procedure.

Select **F2** to initiate the O_2 and CO_2 analyzer verification sequence.

One or more warning messages may be displayed. These messages generally indicate that you need to perform a complete calibration procedure.

Caution!

Do not proceed with patient testing until the instrument passes all the Verification Criteria checks and no warning messages are displayed.

Do not proceed with patient testing if, after your repeated attempts to calibrate the instrument, it fails to meet the verification criteria. Proceeding under this condition could cause erroneous test results. Refer to “Troubleshooting” on page 147.

EXERCISE/INDIRECT CALORIMETRY TEST SCREEN

Select **F3** from the **Analyzer Calibration** screen to display the **Exercise/Indirect Calorimetry Test** screen (Figure 8-3).

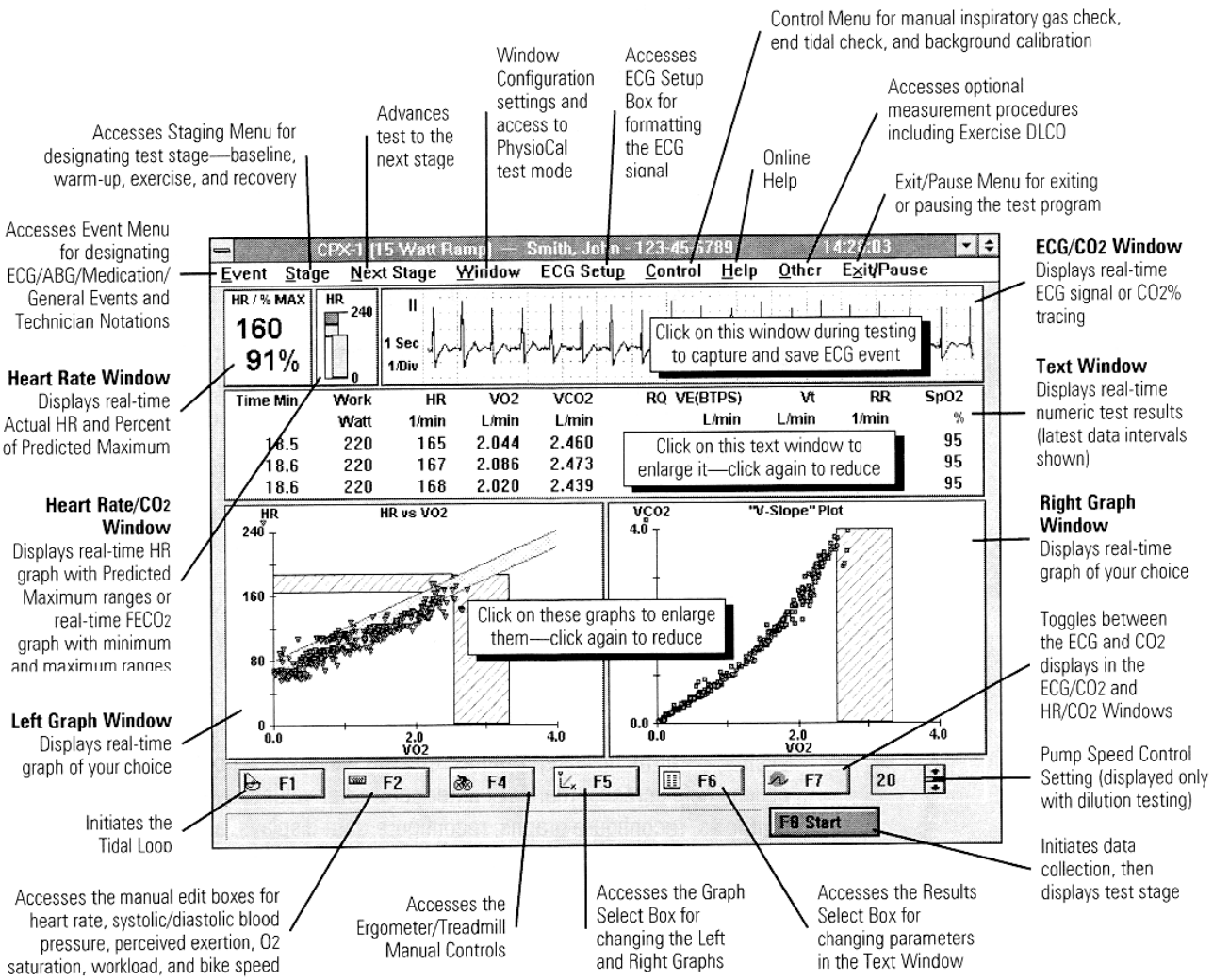

Figure 8-3 – Exercise/Indirect Calorimetry Test Screen

TEST PROCEDURE

Note

For instructions on setting up the various hardware configurations involving the treadmill, ergometer, ECG, oximeter, mouthpiece, mask, canopy, ventilator, etc., see the on-line help and tutorial programs. These programs are described in “Online Help” on page 36 and “Tutorial Program” on page 38.

Dilution Testing Only: turn on the dilution pump when the computer screen prompts you to do so. Adjust the Pump Speed Control setting during testing to keep the measured $FECO_2$ between 0.005 and 0.010. The CO_2 bar graph in the Heart Rate/CO_2 Window is helpful in monitoring the $FECO_2$ within this range. (The bar will stay green if the pump speed is correct.)

Warning!

Remove the dilution mask or the canopy from the patient before troubleshooting. During dilution testing, a battery-powered alarm will sound if the on/off switch of the pump is in the “on” position and there is a power loss to the Pneumatics Module. The dilution mask or canopy must be removed from the patient before troubleshooting.

When using specialized, indirect calorimetry-ventilator breathing circuits, closely monitor the patient and test the patient in a manner that does not increase work of breathing or introduce other additional risks.

Data Collection

F8 Start

Select **F8 Start** to begin data collection. The parameter values displayed in the Data Window will now scroll down as they are updated and stored to the patient file.

Using the Top Menu and Bottom Command Buttons during testing, you can mark events, enter technician notations, enlarge windows, reconfigure ECG settings, access help screens, manually enter parameter values, override ergometer protocols, reconfigure graphs, reconfigure data displays, and toggle between HR/ECG and CO_2 displays. You can also perform Tidal Loop and Exercise Diffusion measurements. Refer to the reference manual and to the online help and tutorial programs for complete instructions.

Staging (Exercise Only)

No Stage

When data collection first begins, the test data will be not be designated with a test stage until you initiate the staging process as explained below:

Baseline

Begin by using either the **Stage** or **Next Stage** selection on the menu bar to designate the Baseline stage of the test.

Warm-up

After sufficient Baseline data has been collected, select the **Warm-up Stage**.

Ergometer System: Instruct the patient to begin pedaling. The Vmax computer will initiate the preformatted warm-up workload.

Treadmill System: Instruct the patient to begin walking. The ECG will initiate the warm-up workload (if the ECG “Pre-test” mode is so formatted).

Exercise

After sufficient warm-up data has been collected, select the **Exercise Stage**.

Ergometer System: The Vmax computer will automatically increment or ramp the system through the preformatted exercise workload protocol.

Treadmill System: The “Exercise” workload protocol formatted in the ECG instrument will be initiated.

Recovery

When you or the patient desires to end the test, select the **Recovery Stage**.

Ergometer System: The Vmax computer will initiate the preformatted recovery workload.

Treadmill System: The “Recovery” workload protocol formatted in the ECG instrument will be initiated.

Steady State (Indirect Calorimetry Only)

When the patient reaches the formatted steady state conditions for V_E, VO_2, RQ, FIO_2, and HR, a green box will be displayed in the lower right corner of the screen labeled “Steady State.” The box will remain there until the steady state conditions are no longer being met.

Terminating the Test

After sufficient recovery data has been collected, terminate the test as follows:

1. Select the **Exit/Pause** menu.
2. Select **Y to End Test**.
   Data collection will terminate, and the **Exercise/Indirect Calorimetry End of Test Comments** box will be displayed.

The **Exercise/Indirect Calorimetry End of Test Comments** box is the first of two (indirect calorimetry) or three (exercise) data boxes displayed in succession immediately upon exiting the testing program. These boxes allow you to enter comments and verify/designate the data locations of Baseline, Anaerobic Threshold, Peak Exercise, Maximum Values (exercise), or Steady State (indirect calorimetry). If you do not want to make any entries or designations, you can select **Escape** and return to the Vmax Program Manager.

Note

If you do not access the Data Boxes at this time and verify/designate the Baseline, AT, Peak, Max, or Steady State data, the associated test values will ***not*** be printed on the final report. You will need to return to the appropriate data boxes later and make the designations so they will be printed.

The data boxes are explained in detail in the reference manual.

Quality Assurance Messages

During testing, one or more of the following quality assurance messages may be displayed on the status bar at the bottom of the screen. It is not unusual for one or more of the messages to be displayed ***occasionally***, especially during baseline quiet breathing. However, if one or more are displayed ***frequently***, the associated problem may need to be resolved before continuing with the test.

Note

If the following message is displayed, ***do not*** begin patient testing until the associated problem is resolved (usually the sample line needs to be connected to the mass flow sensor).

Check Sample Line Connection	This message is displayed if there has not been a measured VO_2 and VCO_2 above 9ml/min since the patient began breathing through the mass flow sensor (BxB testing only).
Check Cal Gas	This message is displayed if a background calibration of is out of range (cal gas 1).
Breath Reject (Time)	This message is displayed if a measured tidal volume is less than 80ms in duration (40ms if the RR>60). This can be due to such things as tubing/flow sensor movement, a leaky mask, a leaky mouthpiece, the patient swallowing, or the patient coughing.
Breath Reject (O_2)	This message is displayed if the measured VO_2 from a single breath is less than 10ml/min.
Breath Reject (CO_2)	This message is displayed if the measured VCO_2 from a single breath is less than 10ml/min.

Breath Reject (O_2/CO_2)	This message is displayed if the measured VO_2 and VCO_2 from a single breath are both less than 10ml/min.
Data Reject (RQ)	This message is displayed if a calculated RQ from a single breath or data interval is less than 0.5 or greater than 2.5.

Warning Messages

Warning!

If any of the next five messages are displayed, stop the test and remove the dilution mask or canopy from the patient before troubleshooting the problem.

Dilution Alarm Flow Lower than Set Point.	When this message is displayed, do the following: • Check the flow sensor, and all tubing, canopy, and mask components for poor connections or leaks. • Check for hose blockage.
Dilution Alarm Low CO_2	When this message is displayed, do the following: • Check all tubing, canopy, and mask components for poor connections or leaks. • Decrease pump flow. • Recalibrate analyzers.
Dilution Alarm High CO_2	When this message is displayed, do the following: • Increase pump flow. • Recalibrate analyzers.

Dilution Alarm Low O_2	When this message is displayed, do the following: • Increase pump flow. • Recalibrate analyzers.
Dilution Alarm High O_2	When this message is displayed, do the following: • Check all tubing, canopy, and mask components for poor connections or leaks. • Decrease pump flow. • Recalibrate analyzers.

CHAPTER 9 • REPORTS

PRINTING A REPORT

Use the following procedure to print a patient report.

Note

For complete instructions on generating reports, including printing batch reports and formatting/editing reports, refer to the reference manual and to the online help and tutorial programs.

1. Select **B Reports** from the **Vmax Program Manager** to display the **Reports** screen (Figure 9-1).
2. Select a report from the **Reports** list box.
3. Select **Print** on the **Reports** screen to send the chosen report to the printer.

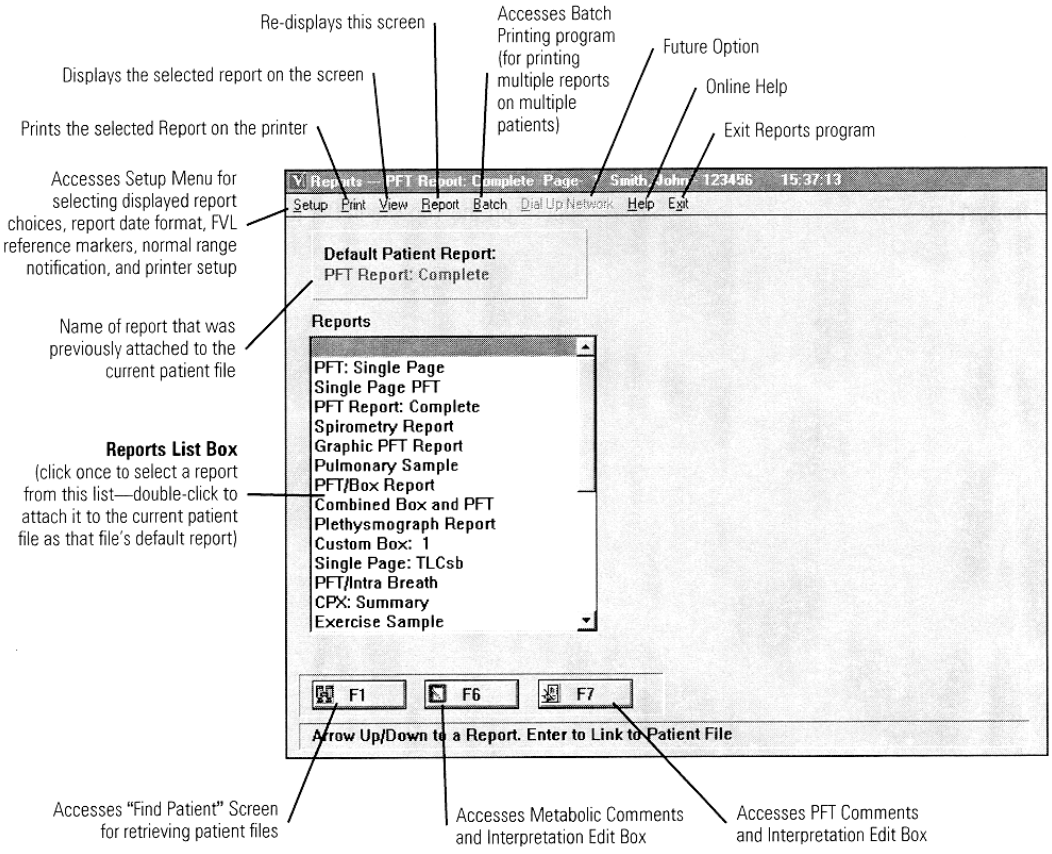

Figure 9-1 – Reports Screen

VIEWING A REPORT

Use the following procedure to preview a patient report on the computer screen.

1. Select a report from the **Reports** list box on the **Reports** screen.
2. Select **View** on the **Reports** menu screen to display the top of the chosen report's first page on the screen.

   You can use the scroll bar or the UP ARROW, DOWN ARROW, PAGE UP, PAGE DOWN, HOME, AND END keys to move up and down through the report for viewing.
3. Select **Report** on the menu bar to redisplay the **Reports** screen.

CHAPTER 10 • FILE MANAGER

FILE MANAGER SCREEN

Note

For comprehensive information on the Vmax patient file structure and organization, refer to the reference manual.

Select **C File Manager** on the Vmax Program Manager to access the **File Manager** screen (Figure 10-1).

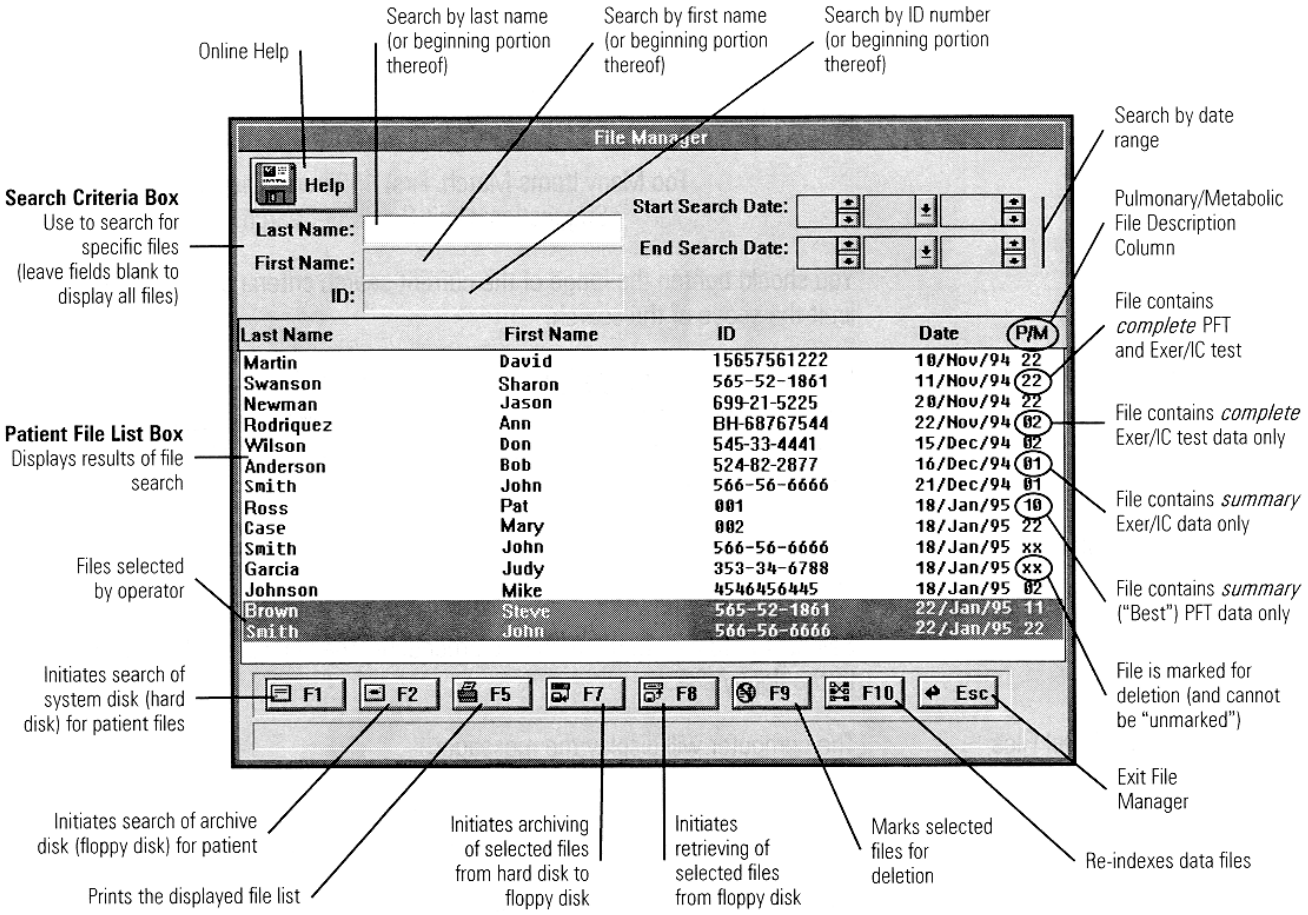

Figure 10-1 – File Manager Screen

ARCHIVING PATIENT FILES

Use the following procedure to archive patient files from the computer hard disk to a floppy disk in drive A.

1. Select **F1** to display the patient's files currently on the computer system (hard disk).

   You can enter search data into one or more of the "Last Name," "First Name," "ID," "Start Date," and "End Date" fields to narrow the scope of the listed files. To display all the system files, leave the fields blank.

   If an **F1** search results in more than 150 patient files matching the search criteria, the following message will be displayed:

Too Many Items Match. First 150 Items Displayed. Suggestion: Limit Scope of Search.

   You should reduce the range of the current search criteria or add more criteria to limit the scope of the search.

2. Select the files to archive.

   Use the mouse or the UP and DOWN ARROW keys to highlight the file(s) that you want to archive. You can select multiple adjacent files by holding down the SHIFT key while you select or by dragging the mouse pointer. You can select multiple non-adjacent files by holding down the CTRL key while you select.

3. Insert a formatted floppy disk into Drive A.
   New files can be added to a disk that already contains files from a previous archiving job.

4. Select **F7** to initiate the archiving procedure.
   The highlighted files will be copied to the floppy disk.

Delete Interval/Level Files

The computer will display the message:

F1 to Delete Interval/Level Files Esc to Keep Interval/Level Files

You have the option of retaining only the summary data (Baseline, AT, Peak, Max, Steady State values for Exercise/IC, and Best values for PFT) by deleting the interval data (Exercise/IC) and levels data (PFT).

Note

Complete files (Summary + Interval/Level) are indicated by the number “2” in the P/M column. Summary files are indicated by the number “1.” Files with no test data are indicated by the number “0.”

F1 to Delete

Select **F1** to remove the interval/level data from the patient file on the hard disk after the file is copied to the floppy disk. The summary data will be retained.

Esc to Keep

Select **Esc** to save the entire patient file on the hard disk after it is copied to the floppy disk.

RETRIEVING PATIENT FILES

Use the following procedure to retrieve patient files from a floppy disk in drive A to the computer hard disk.

1. Insert the floppy disk with the desired archived patient files into Drive A.
2. Select **F2** to display the patient’s files currently on the archive (floppy) disk.

   You can enter search data into one or more of the “Last Name,” “First Name,” “ID,” “Start Date,” and “End Date” fields to narrow the scope of the listed files. To display all the archive files, leave the fields blank.
3. Select the files to be retrieved.

   Use the mouse or the UP and DOWN ARROW keys to highlight the file(s) that you want to retrieve. You can select multiple adjacent files by holding down the SHIFT key while you select or by dragging the mouse pointer. You can select multiple non-adjacent files by holding down the CTRL key while you select.
4. Select **F8** to initiate the retrieval procedure. The highlighted files will be copied to the hard disk.

DELETING PATIENT FILES

You can delete patient files from the hard disk using the following procedure (you ***cannot*** delete files from archive disks).

Note

Only summary files can be deleted. This means you must first archive the patient file ***and delete interval/level files as part of the archive process*** before you will be able to delete the file (see "Archiving Patient Files" on page 130). Summary files are indicated by the number "1" in the P/M column.

1. In the **Patient File** list box, select the files that you want to delete by using the mouse or the UP ARROW and, DOWN ARROW keys.
2. Select **F9** to designate the files as marked for deletion.

   A confirmation box will be displayed with the message:

   F1 to Confirm Delete of Selected Record(s). Esc to Cancel.

   Select **F1** to continue. The files will be marked for deletion as referenced by the **xx** in the P/M column.

Caution!

Files marked for deletion cannot be "unmarked."

The marked files will be removed the next time the system files are listed (F1 selected).

CHAPTER 11 • MAINTENANCE AND TROUBLESHOOTING

CLEANING AND DISINFECTING

Exterior of Instrument

Aside from the components of the patient-breathing circuits described below, the instruments should not require frequent cleaning and disinfection. When surface cleaning is needed, use a weak disinfectant liquid or diluted bleach solution to wipe down the surfaces of the instruments.

Caution!

Do not use alcohol or sterilization liquids containing glutaraldehyde on the surfaces of the instruments.

Do not use abrasive powders or glass cleaners containing alcohol or ammonia on the patient canopy or on the windows of the Autobox.

Using these cleaning agents will damage the equipment.

2130 Series Spirometer

The large-bore hose and hose-reducer used with the 2130 Series Spirometer should be cleaned according to the general “Breathing Circuit” instructions below. For specific instructions on cleaning and maintenance of the spirometer hardware, see the spirometer instruction manual (included with the 2130 Series Spirometer).

Breathing Circuits

The procedures in this section explain the proper cleaning and decontamination of the patient-breathing circuit components (PFT and Exer/IC). The most appropriate cleaning interval and decontamination method should be determined by the diseases and infections control board of your hospital.

Caution!

Do not use solutions containing >2.6% glutaraldehyde. Using this type of solution can damage polycarbonate plastics.

Do not steam autoclave any Vmax, 2130 Series Spirometer, or the Autobox parts unless the item is clearly labeled “May be Steam Autoclaved.”

All the breathing circuit components described below should optimally be cleaned (soap and water) and disinfected after each patient use. For best results, use a cold liquid sterilization or disinfection solution according to the directions on the solution container. ***Soaking longer than the recommended interval can result in damage to the breathing circuit components.*** Rinse and dry the components thoroughly before use.

Low temperature (<130°F) ethylene oxide sterilization is also acceptable. Aerate thoroughly before use.

Rubber Mouthpieces, Extension Hoses, Sputum Traps, and Connectors

Rubber mouthpieces, extension hoses, sputum traps, and any rubber or plastic connectors can be cleaned and completely submerged in liquid disinfectant.

Mass Flow Sensor

This section describes three different mass flow sensors: two different types used with the Autobox and the Vmax Spectra instruments and one used with the Autobox.

The two types of mass flow sensors are described first:

- The ***Detachable Mass Flow Sensor*** is the newer style with a detachable sensor cable.
- The ***Single Assembly Mass Flow Sensor*** is the older style with the sensor cable and the sensor housing permanently attached as a single unit.

Caution!

Since you may possibly use both types of mass flow sensors, it is important to be aware of which one you are using. You can damage the single-assembly sensor by trying to detach the cable, and you can damage the detachable sensor by submerging it in liquid disinfectant without disconnecting the cable.

Do not insert anything into the mass-flow sensor housing; doing this could damage the sensing wires.

Do not use any concentration of household bleach (sodium hypochlorite) to disinfect the Vmax/V6200 mass flow sensor. Using this type of solution will severely corrode the sensing wires.

Detachable Mass Flow Sensor

With the detachable mass flow sensor, the sensor housing is designed to be disconnected from the sensor cable for cleaning.

Caution!

Do not immerse the detachable Mass Flow Sensor Cable.

The entire mass-flow sensor can be safely immersed in liquid disinfectant. The sensor cable ***cannot*** be submerged, because the connectors on each end can be damaged by liquids.

Single Assembly Mass Flow Sensor/Cable

With the single assembly mass-flow sensor/cable, the sensing wires, electronics, housing, and cable are manufactured as one assembly and cannot be separated. Attempts to separate the components of a single-assembly, mass-flow sensor will result in damage and sensor failure.

Mass Flow Sensor (Vmax and Autobox)

> **Caution!**
> Do not immerse the connector limb of the Mass flow sensor.

The mass-flow sensor must be removed from the breathing valve assembly and disconnected from its cable for cleaning and disinfection. The exposed electrical connector on the mass-flow sensor assembly should not get wet during this process. A plastic cap is provided to cover the exposed connector, but the connector limb of the sensor should still not get wet—only the airflow tube should be immersed.

Automated Breathing Valve Assembly (Vmax and Autobox)

The automated breathing valve can be completely submerged as long as the inlet ports on the balloon valves are occluded with the plugs provided. It is not necessary to remove the balloon valves from the valve assembly. The rubber spiral valve should be removed and submerged separately.

> **Caution!**
> Make sure that all parts are rinsed and dried thoroughly before they are reassembled.
>
> After cleaning the valve, inspect the valve body to see that no cleaning solution or rinsing liquid is trapped in the space between the valve body and the flow-laminating insert. **Discard the valve if moisture is detected.**

Non Re-breathing Valve

The non re-breathing valve assembly used with mixing chamber/mouthpiece testing must be disassembled for cleaning. It is particularly important to remove the rubber one-way spiral valves and submerge them separately.

Note

Make sure that the parts are rinsed and dried thoroughly before they are reassembled.

Inspection and Replacement of Components after Cleaning

All plastic and rubber components can be expected to deteriorate with age and cleaning. Although some components of the breathing circuit will last longer than other components, most of the components will eventually need to be replaced. Carefully following the above cleaning recommendations will assure the longest possible life span for all components.

Inspecting for Wear and Tear

It is important that you visually inspect all the breathing circuit components after each cleaning cycle. If you notice any cracking, tearing, tackiness, hardening, or stretching, replace the component immediately.

The rubber balloon valves and spiral valves in the automated-breathing valve assemblies and in the non re-breathing valve require particular attention during your post-cleaning inspection. These items are subjected to the most activity and stress during patient testing and are the most likely candidates for replacement.

Caution!

Parts or components that are damaged, or that cause calibration failure, cannot be reused and must be replaced.

Inspecting for Contaminates

It is also important that you visually inspect all the breathing circuit components for contaminate and particulate matter. Of particular concern is residue from cleaning or disinfecting liquids left behind from inadequate rinsing and drying. If you notice any liquid or solid residue on a component, you should repeat the entire cleaning procedure for that component.

Warning!

Follow all the cleaning procedures carefully, and thoroughly inspect the components after they are cleaned and before each patient is tested. **Cleaning residue, particulate matter, and other contaminates (including pieces of torn or broken components) in the breathing circuit create a safety risk to the patient during testing procedures. Aspiration of contaminates can be potentially life threatening.** Follow all the cleaning procedures carefully, and thoroughly inspect the components after they are cleaned and before each patient is tested.

Post-cleaning Performance Verification

Before using the clean breathing circuit for patient testing, a complete calibration procedure must be performed (refer to the chapter "Flow Volume Calibration" on page 39). If the system calibrates and meets the calibration criteria, the breathing circuit is functional and will perform accurate measurements during patient testing.

ROUTINE MAINTENANCE

The following procedures are the only routine maintenance requirements (other than the previously described cleaning procedures) that must be performed by the operator.

Note

None of the following procedures applies to the 2130 Series Spirometer.

Replacing the Permapure™ Sample Tube

Vmax only: if the Permapure™ sample tube is used for ***three breath-by-breath exercise tests within a twelve-hour period***, it should be removed from operation and allowed to dry.

The Permapure™ sample tube should be replaced every three months.

Vmax or Autobox: no matter what type of testing you are doing, if the Permapure™ sample tube shows any signs of cracking, stretching, crimping, or other damage, it should be disposed of and replaced immediately.

Pump Alarm Battery (Vmax)

Vmax models with mixing chambers contain a battery-powered pump alarm. The condition of the alarm battery is verified every time the Analyzer Module is powered on, by two or three “beeps” if the battery is still good. If the battery is beginning to fail, there will be no “beeps,” and it needs to be replaced. The replacement procedure is explained later in this chapter.

The condition of the alarm battery can also be manually verified by switching on the pump (front of the Pneumatics Module) with the Vmax system power switched off (front of Analyzer Module). If the battery is still good, the alarm will begin to beep.

Note

Even if the battery continues to test as “good,” replace it yearly with a good quality alkaline battery.

Replacing the O_2 Sensor

This procedure provides instructions for removing and replacing the O_2 sensor, which must be replaced annually.

Warning!

Turn off and unplug your system before removing the cover of the unit. Removing the cover without removing the power will expose a potential electrical-shock hazard that could result in serious injury or death.

To remove the old sensor:

1. Make sure that the power is turned off and that the power cord is disconnected.

Caution!

Take precautions to prevent damage from electrostatic discharge (ESD). Removing the cover of the Vmax module exposes static-sensitive components that could be damaged by ESD.

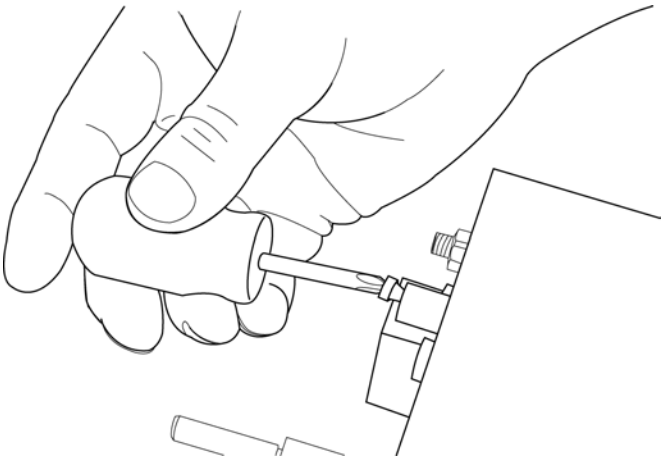

Figure 11-1 – Cover Retaining Screw

2. Loosen the cover retaining screw that is on the back of the Vmax analyzer (top) module (Figure 11-1).

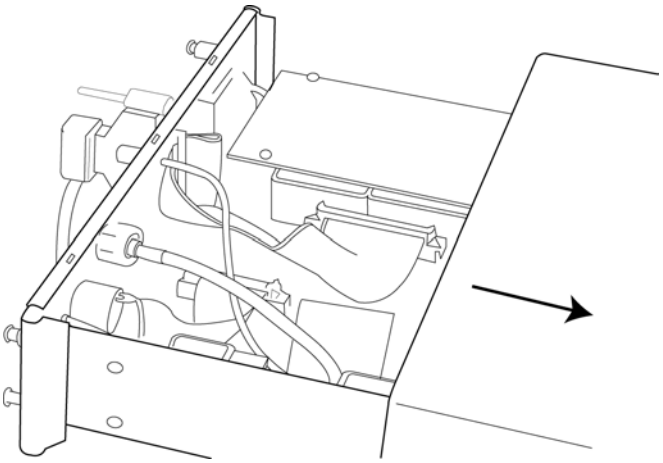

Figure 11-2 – Removing the Cover

3. Gently remove the cover by sliding it toward the front of the module (Figure 11-2).

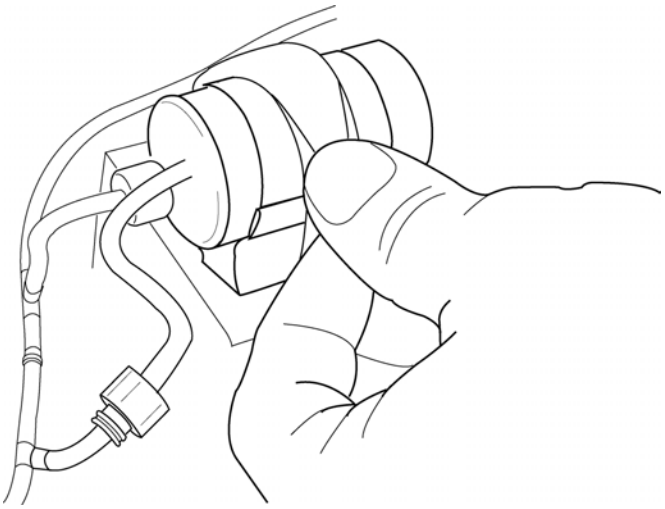

Figure 11-3 – Sensor Retaining Strap

4. Unfasten the strap that secures the O_2 sensor, which is at the front of the module (Figure 11-3).

Caution!

Do not twist or pull the ribbon cable up or down. Twisting or pulling the cable could damage the connector pins.

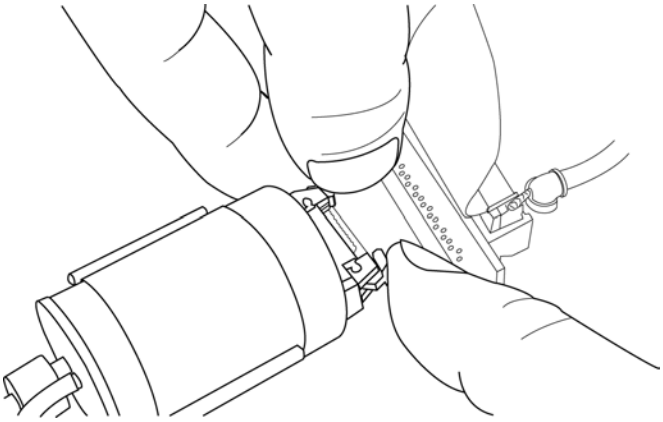

Figure 11-4 – Ribbon Cable Connection

5. Disconnect the ribbon cable by carefully pushing outward on the two locking "ears" of the connector. This connector is on the end of the O_2 sensor (Figure 11-4).

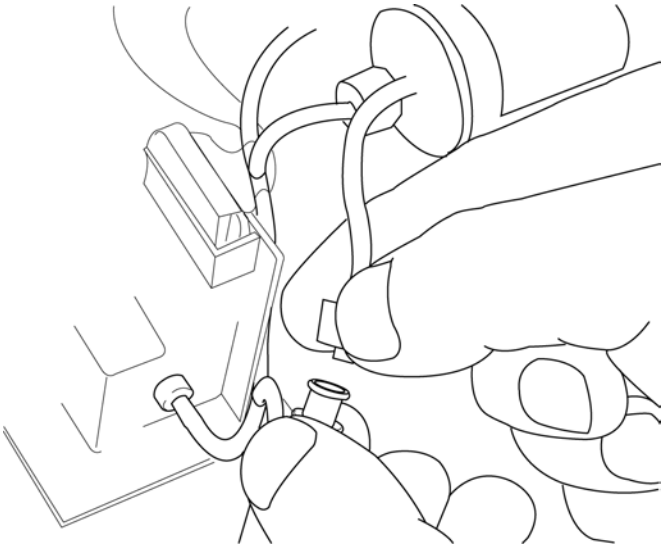

Figure 11-5 – Disconnecting the In-line Luer Fitting

6. Disconnect the in-line luer fitting (Figure 11-5).

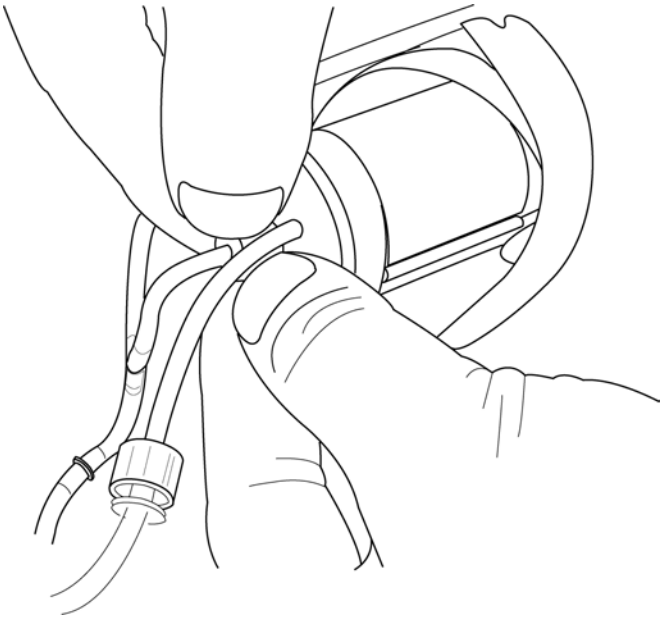

Figure 11-6 – Disconnecting the Luer Fitting

7. Disconnect the luer fitting that is attached to the top of the O_2 sensor (Figure 11-6).
8. Carefully lift the old O_2 sensor out of the cradle and set the sensor aside.
9. Remove the new O_2 sensor from the packing tube, and inspect the sensor for damage. Put the old sensor into the packing tube and replace the lid.
10. On the new sensor, twist the white luer fitting to loosen it and disconnect it from the O_2 cell port.

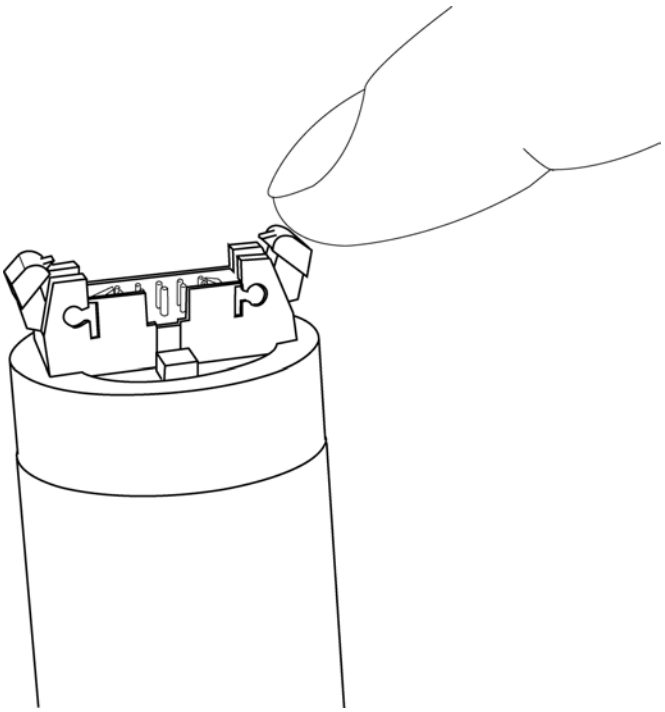

Figure 11-7 – Connector Locking Ears

Note

Notice the slot on the bottom of the sensor connector (Figure 11-7). This slot must face downward as you seat the new O_2 cell into the cradle so that the cable connector attaches correctly.

11. Carefully connect the ribbon-cable to the O_2 sensor, and close the locking ears to secure the connector.

Figure 11-8 – Reconnecting the Luer Fitting

12. Reconnect the luer fitting to the sensor (Figure 11-8).

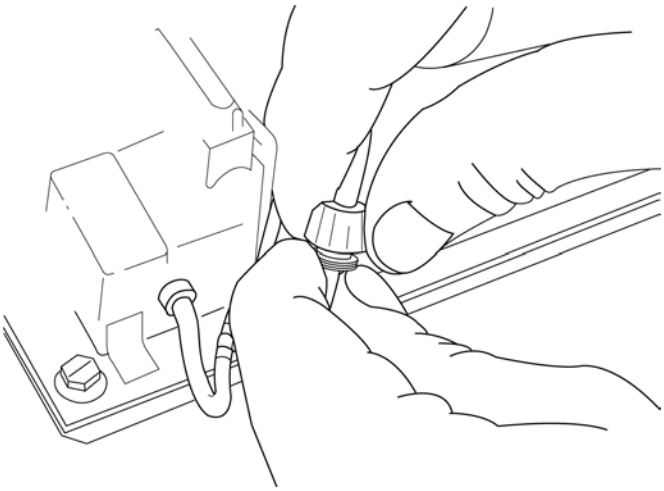

Figure 11-9 – Reconnecting the In-line Luer Fitting

13. Reconnect the in-line luer fitting (Figure 11-9).

14. Position the O_2 Sensor in the cradle, and fasten the retaining strap.

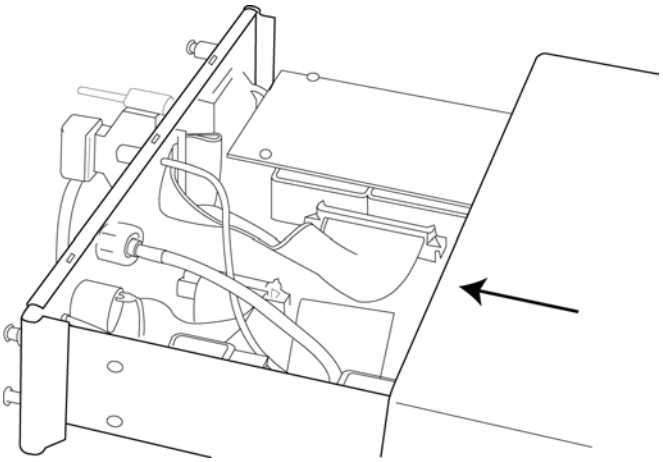

Figure 11-10 – Replacing the Cover

15. Slide the cover of the unit back into place and tighten the cover retaining screw (Figure 11-10).

16. Dispose of the old O_2 cell according to the toxic-material handling procedures of your facility.

OTHER MAINTENANCE

The following maintenance procedures only need to be performed on an “as needed” basis—generally at the direction of a SensorMedics service representative.

Mass Flow Sensor Zero Check

The mass-flow sensor zero calibration can be checked with the following procedure.

Flow Sensor Calibration

1. Select **1 Flow Sensor Calibration** on the **Vmax Program Manager** screen to access the **Flow Volume Calibration** screen.

Zero

2. Select **Zero** on the menu bar.
   The **Mass Flow Sensor Zero** box will be displayed.

Stroke Syringe

3. Attach the mass-flow sensor to the calibration syringe using the calibration adapter.
4. Stroke the syringe two times to purge the mass-flow sensor with room air.
   Select **Space Continue** when you have completed this step.

Mass Flow Sensor Zero

A ten-second timer will count down to zero seconds before continuing to the Zero Routine. The mass flow sensor will then be automatically calibrated to zero gas flow.

Note

During the Zero routine, hold the syringe still. It is also important that you do not stroke the syringe piston.

If the calibration check is successful, there will be no error messages displayed.

If the instrument fails the Auto Flow Sensor Zero Check, the following message will be displayed:

The Mass Flow Sensor does not Respond. Check the Sensor Cable or Substitute Another Sensor	If this happens, inspect the patient breathing circuit (including the entire mass-flow sensor assembly) for, incorrect connection, incorrect assembly, or damage. Replace components with obvious damage.

Note

Parts or components that are damaged or cause calibration failure cannot be reused and must be replaced.

If you are able to pass the Mass Flow Sensor Zero Check with one flow sensor and not able to pass it with another, discard the defective flow sensor.

If, after repeated attempts with different flow sensors, you are unable to pass a Mass Flow Sensor Zero Check, contact SensorMedics technical support (refer to “Company Information” on page iii).

Mass Flow Sensor Cleaning (Superheating)

The mass flow sensor cleaning procedure burns off any accumulated contaminates by superheating the sensing wires in the mass flow sensor.

1. Select **1 Flow Sensor Calibration** on the **Vmax Program Manager** screen to access the **Flow Volume Calibration** screen.
2. Select **Clean** on the menu bar on the top of the screen.
   The mass flow sensor will go through a ten second superheating phase followed by a zero calibration phase. When the procedure is finished, the **Flow Volume Calibration** screen will be redisplayed.

TROUBLESHOOTING

General Problems

The following is a list of potential problems you may eventually encounter using the Vmax, 2130 Series Spirometer, or Autobox instruments. For problems not covered by this list, or for any questions, contact technical support (refer to "Company Information" on page iii).

Condition	Possible Causes	Possible Remedies
No power to system (computer, monitor, Vmax modules, Autobox cabin)	Loose power cable	Check all power cable connections
	Defective power outlet	Try a known, good power outlet
Flow Volume Calibration Failure	Defective calibration syringe	Try an alternate calibration syringe Verify the syringe volume setting in Calibration Setup
	Defective breathing circuit	Check the breathing circuit assembly for incorrect connection, incorrect assembly, or damage.
	Balloon valve tubing connection	Switch tubing connectors
	Dirty or defective mass-flow sensor	Mass Flow Sensor Zero Check and Mass Flow Sensor Cleaning (superheating). See "Other Maintenance" on page 145 for procedures
	Leak in spirometer dry rolling seal	Replace seal
	Incorrectly assembled spirometer	Disassemble and re-assemble
Plethysmograph Pressure Calibration Failure	Cabin Leak	Ensure cabin door is securely closed
	Cabin shutter not closing	Check driving gas pressure and connections

Condition	Possible Causes	Possible Remedies
Analyzer Calibration Failure	Inadequate warm-up time before calibration	Allow 30 minute warm-up time
	Calibration tank turned off or only slightly opened	Make sure calibration gas is completely turned on
	Inadequate gas pressure in calibration tank	Make sure there is at least 200 PSI remaining in the calibration gas cylinders
	Hoses from gas tanks are switched or disconnected at the rear of the Pneumatics Module	Make sure gas hoses are attached correctly
	Erroneous gas concentrations in calibration tank	Enter correct gas concentration in calibration setup box or change to tank with known accurate concentration
Poor quality VTG and/or RAW loops	Patient leak	Ensure good seal at mouth and nose
	Breathing Assembly leak	Ensure correct assembly and tight fit of all Breathing Assembly parts
	Cabin leak	Ensure cabin door is securely closed
	Cabin shutter not closing	Check driving gas pressure and connections
	Calibrated leak too large	Recalibrate leak time constant
	Mass Flow Sensor Calibration error or Pressure Calibration error.	Recalibrate
Pump alarm sounding	Power to the Pneumatics Module has been interrupted while the pump power switch is turned on	Check all power connections
		Check communications cable between the Vmax Modules
		Turn off the pump if you are not doing a canopy test

Condition	Possible Causes	Possible Remedies
Resistance to breathing during any test	Breathing circuit defective or incorrectly assembled	Check breathing circuit for damage or incorrect assembly.
	Spirometer incorrectly assembled	Disassemble and re-assemble spirometer
	Balloon valve tubing incorrectly assembled	Switch tubing connectors
	Inadequate oxygen or diffusion mix gas pressure	Make sure gas cylinders are completely turned on, contain at least 200 PSI internal pressure, and are set to 50–60 PSI delivered pressure (10–20 PSI above oxygen pressure for Vmax diffusion mix)
ECG signal not displayed on Vmax test screen	Improper cable connections	Review cable connections in Chapter 18 and make necessary adjustments
	Improper software configuration	Review protocol configuration in Chapter 17 and make necessary adjustments
	Defective 3-lead ECG Module	Disconnect the electrodes from the ECG Module. Press and hold the cal button on the module; the cal pulse will not be displayed. Call the SensorMedics Service Department for assistance.
	Defective electrode(s)	Disconnect the electrodes from the ECG Module. Press and hold the cal button on the module; the cal pulse will be displayed. Replace with fresh electrodes.

Warning Messages

The following is a list of warning messages that may be displayed on the computer. For warning messages not covered by this list or for any questions, contact technical support (refer to “Company Information” on page iii).

Message	Possible Causes	Possible Remedies
Hardware Check Warning. Check Power, Cables.	Analyzer Module turned off	Verify that the Analyzer Module is turned on.
	Loose or disconnected interface cable between the computer and the Analyzer Module or the spirometer	Verify that the interface cable is securely attached
	Hardware lock-up	Turn the entire system off and then turn it back on
The Mass Flow Sensor does not Respond. Check the Sensor Cable or Substitute Another Sensor.	The mass-flow sensor cable is loose or disconnected from the flow signal port on the rear of the Analyzer Module.	Verify that the cable is securely attached.
	Defective mass flow sensor	Replace the entire Mass Flow Sensor Assembly
The Sensors are Responding Incorrectly to Calibration Gas. Check Calibration Gas Tank Pressures and Connections.	Calibration tank turned off or only slightly opened.	Make sure calibration gas is completely turned on.
	Inadequate gas pressure in calibration tank.	Make sure there is at least 200 PSI remaining in the calibration gas cylinders.
	Hoses from gas tanks are switched or disconnected at the rear of the instrument.	Make sure gas hoses are attached correctly.
Ensure that the Sample Line is Connected to the Calibration Fitting.	The Permapure™ sample tubing is not connected to the inlet port on the front of the Analyzer Module. (Vmax breath-by-breath calibration only.)	Connect the sample tubing to the inlet port.

Message	Possible Causes	Possible Remedies
Note If any of the next five messages are displayed, **you should stop the test and remove the patient from the dilution mask or canopy before troubleshooting**.		
Dilution Alarm Flow Lower than Set Point.	The flow sensor is reading a much lower flow than the Pump Speed Control setting on the Exercise/Indirect Calorimetry Test screen.	Check the flow sensor, and all tubing, canopy, and mask components for, incorrect connection, incorrect assembly, or leaks. Check for hose blockage.
Dilution Alarm Low CO2.	FECO2 <0.004 for one minute.	Check all tubing, canopy, and mask components for, incorrect connection, incorrect assembly, or leaks. Decrease pump flow. Recalibrate analyzers.
Dilution Alarm High CO2.	FECO2 >0.02 for one minute.	Increase pump flow. Recalibrate analyzers.
Dilution Alarm Low O2.	FIO2 – FEO2 >0.02 for one minute.	Increase pump flow. Recalibrate analyzers.
Dilution Alarm High O2.	FIO2 – FEO2 <0.004 for one minute.	Check all tubing, canopy, and mask components for, incorrect connection, incorrect assembly, or leaks. Decrease pump flow. Recalibrate analyzers.

PARTS REPLACEMENT PROCEDURES

Note

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

Refer to *Model 1022 Spirometer Operator's Manual* for procedures for replacing parts on the 2130 Series Spirometer (strip-chart paper, dry rolling seal, etc.),

Replacing the Pump Alarm Battery (Vmax)

On Vmax models with mixing chambers, an alarm will sound if the pump power switch on the front of the Vmax instrument is in the "on" position and there is a power loss to the Pneumatics Module. The alarm is powered by a 9-volt battery that will eventually need to be replaced. The condition of the battery is verified every time the Analyzer Module is powered on. Two or three alarm "beeps" will be heard if the battery is still good. If the battery is beginning to fail, there will be no "beeps," and it should be replaced with a good quality, new alkaline battery.

To replace the battery:

1. Unscrew the battery cover thumbscrew, swing the cover out, and remove it from the rear of the Pneumatics Module.
2. Slide the old battery straight back until it disconnects from the terminals, and then snap it out of the two holding clips.
3. Snap the new battery into the two holding clips, and then slide it forward until it connects into the terminals.
4. Reinstall the battery cover and screw in the thumbscrew.

Replacing the Module (Vmax)

The primary hardware components for the Vmax Instruments are housed in two compact removable units: Analyzer Module and Pneumatics Module. If your system has a hardware failure, the module with the defective component can be easily replaced.

Caution!

Do not remove either module unless instructed to do so by a SensorMedics technical support specialist, field service representative or, if you are outside the U.S. and Canada, an authorized local distributor.

Warning!

Disconnect the main Vmax power cable **from the wall outlet** before beginning this procedure.

Labels with serial numbers are affixed to the module covers. ***These covers will always remain at your facility*** and will be referred to as the "Vmax covers." Replacement modules come with covers to protect them during shipment and are referred to as the "service covers."

Removing the Module

The following procedure applies to either module:

1. Disconnect all cables, connectors, gas hoses, tubing, and ground straps from the back panel of the failed module.
2. Separate the modules (not required for Vmax 20 Pulmonary Spirometry Instrument).
3. Unscrew the cover thumbscrew located on the back panel of the module being replaced.
4. Once the thumbscrew is loose, slide the module cover forward and off.

Note

Keep the Vmax cover to install onto the replacement module.

Installing the Module

1. Remove the replacement module from its shipping container.
2. Remove the service cover from the replacement module.
3. Install the Vmax cover (from Step 4, above) onto the replacement module.
4. Install the replacement module, reconnecting all cables, connectors, gas hoses, tubing, and ground straps.
5. Install the service cover onto the failed module.

6. Place the failed module into the module-shipping container and send it back to SensorMedics according to the shipping instructions included with the replacement module.

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