American Thoracic Society

MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

STANDARDIZATION OF SPIROMETRY—1987 UPDATE

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS APPROVED BY THE ATS BOARD OF DIRECTORS, MARCH 1987.

Contents

I. INTRODUCTION

The American Thoracic Society (ATS) statement on the Standardization of Spirometry was published 8 years ago and was based on the Snowbird Workshop held in 1977 (1). Since that time, we have had years of practical experience with these recommendations, which have been widely endorsed (2–5). In addition, the "state of the art" of spirometry has advanced as a result of scientific studies that have provided additional data relating to performance of spirometry. Simultaneously, the use of computers for spirometry measurement has become commonplace. As a consequence, the American Thoracic Society's Board of Directors asked that the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories review and update the initial statement.

The ATS statement on standardization of spirometry has had a far-reaching effect on manufacturers and users of spirometers. In some cases, manufacturers have used the document as a "minimum" performance requirements document. We are concerned with this approach and encourage manufacturers to continue to seek excellence in design so that the "state of the art" for spirometers will exceed the ATS recommendations. Some research protocols will necessitate even more stringent requirements than stated here.

We frequently hear the appeal that an inexpensive and, although not explicitly stated, "less accurate" spirometer is all that is needed in clinical practice. We feel this premise is flawed since treatment decisions need to be based on the best data available, whether data arises from a hospital-based diagnostic laboratory *or* a physician's office. During recent testing of commercially available spirometers, devices were found that had FVC errors as large as 1.5 L, a 25% error (6). If a bronchodilator treatment is made based on spirometric data, subsequent spirometric measurements are often made to determine if the treatment was effective. If an inaccurate spirometer is used, especially a spirometer with poor repeatability, the improvement or degradation measured may be entirely spirometer-related and have nothing to do with the subject's response to treatment.

Spirometry is used to affect decisions about individual patients such as: Does this subject have enough evidence of impaired lung function to preclude working at a specific job? Should steroid treatment be continued? Does this person qualify for full disability compensation on the basis of impaired lung function? Should the subject's insurance status be changed? Answers to each of these questions based on spirometric maneuvers can have a dramatic effect on a person's lifestyle, standard of living, and future treatment (5).

Similarly, accurate spirometers are required for epidemiologic studies. Rates of improvement or deterioration of pulmonary function measured in relation to environmental exposures and/or personal characteristics may be erroneous if inaccurate spirometers are used or less sensitive if imprecise spirometers are used (7).

Reprints may be requested from your state or local lung associations.

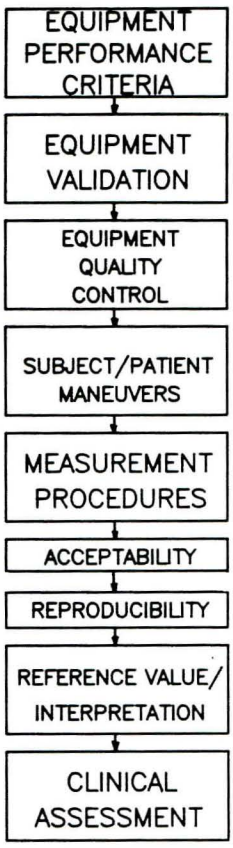

Fig. 1. Spirometry standardization steps.

Testing of commercially available spirometers, with a computer-driven mechanical syringe, has recently been completed. It was found that already 27 of 53 (51%) spirometers met the new and rigorous ATS recommendations outlined in this article. With the aid of microcomputers, several flowmeter type spirometers now meet the ATS requirements (6). Not surprisingly, computer software was one of the major reasons for device failure.

Maximizing the clinical usefulness of spirometry depends upon a number of factors, ranging from equipment selection to interpretation, and ultimately involves clinical assessment. Figure 1 is a flow diagram of these steps. The first step is choosing the equipment. The Snowbird Workshop (1) and now this update give recommendations for equipment used for spirometry. Spirometer users should carefully select equipment that meets the ATS recommendations to assure that spirometry testing can be done accurately. The second step in the process involves validating that the spirometer design and that a production device meet the recommendations. Detailed methods for performing the validation testing are outlined later in this article. Because almost no physicians and few clinical pulmonary function laboratories have the capability to exhaustively test and validate spirometers, an independent testing laboratory has been set up at LDS Hospital in Salt Lake City, Utah. Other independent laboratories are encouraged to enter the spirometer validation field.

The ATS promulgates standards but does not act as a certifying agency to verify compliance with these standards. Before a user purchases a spirometer, he or she would be wise to (*1*) ask the manufacturer to provide summary data that demonstrates that the device being considered meets the ATS recommendations, and (*2*) review results of spirometry testing from independent testing laboratories.

Even after the equipment has been found to meet ATS recommendations and has been validated, spirometers (like other pieces of mechanical, electrical, or computer equipment) must be routinely checked for performance quality. Recommendations for spirometer quality control have been developed by the ATS and are summarized in this article.

Spirometry is an effort-dependent maneuver that requires careful patient/subject instruction, understanding, coordination, and cooperation. Thus, performance recommendations are important components of testing. Part of the recommendation is to obtain a sufficient number of maneuvers that are of adequate quality and then determine if these acceptable maneuvers are reproducible. Once spirometry maneuvers have been performed, they need to be either measured by hand or by use of computer techniques. Measurement procedures are included in this article to help assure that uniform methods are used and that comparable results are obtained. These recommendations include considerations such as using "back extrapolation" for determining the "start of test" time zero point for determination of measures such as FEV_1.

Interaction between technician and patient or subject is crucial to performing adequate spirometry since it is such an effort-dependent maneuver. Technicians must be selected and trained and maintain a high level of proficiency to assure optimal results.

The effort-dependent spirogram must be carefully scrutinized for quality. Recommendations about quality, acceptability, and reproducibility of test result are presented. After adequate results are obtained, they are usually compared with reference values to make an assessment (interpretation) of the results. Future ATS efforts should be directed at investigating and providing guidelines for selecting reference values and interpretive methods. This article provides only background materials for these future developments.

Clinical assessment is a crucial part of the patient/subject-physician/investigator interaction and should be an integral part of the entire process. Results obtained from spirometry are only one part of the much more complex patient care relationship of research data analysis.

Definitions

Standard definitions are important to assure that everyone understands each test and its performance methodology. All terms and abbreviations used here are based on a report of the American College of Chest Physicians (ACCP)-ATS Joint Committee on Pulmonary Nomenclature (8).

II. EQUIPMENT RECOMMENDATIONS

Equipment selection is pivotal to acquiring accurate test results. Spirometer equipment recommendations apply to all diagnostic spirometers whether used for clinical, diagnostic, or epidemiologic purposes. Instrumentation recommendations should be followed to provide accurate spirometric data and information that is comparable from laboratory to laboratory and from one time period to another (1). The accuracy of a spirometer system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system—from volume or flow transducer to recorder, display, or processor. Errors at any step in the process affect the accuracy of the results obtained (see Appendix A). For example, if a sample point is not available at exactly 1.0 s after the back extrapolated "time zero," then linear interpolation of the volume curve should be used to find FEV_1.

The equipment recommendations for spirometry are summarized in table 1.

Recommendation—Vital Capacity (VC)

VC = The maximal volume of air exhaled from the point of maximal inhalation. This is also considered the "slow" vital capacity. Expressed in liters (BTPS). BTPS = Body conditions: normal body temperature (37° C), ambient pressure, saturated with water vapor.

Recommendation—VC Equipment

If a spirometer purports to measure VC, it should continue to accumulate volume for *AT LEAST* 30 s. Spirometers should be capable of measuring volumes of *AT LEAST* 7 L (BTPS) with flows between zero and 12 L/s. Accuracy required is *AT LEAST* ± 3% of reading or ± 0.050 L, whichever is greater.

Rationale. Based on Hankinson and Petersen's data on 9,347 working coal miners, the range for volume and flow were established (1, 9). Of these miners, 99.25% had a forced vital capacity of less than 7.25 L (1). If the spirometer is used for both inspiration and expiration, a volume capacity of greater than 7 L may be necessary. The volume requirement of 7 L also applies to children (1, 3, 10, 11). Older men and women have volumes similar to those of adolescents (10–12). A 7-L spirometer will not measure the person with "super" lungs, but it will cover the majority of the population. Accuracy of ± 3% of reading or ± 0.050 L, whichever is greater, is based on the data of Hankinson and Petersen (1, 9). Their data showed coefficient of variation on the same subject on different days of 3% or less (1). These data have been substantiated (13–15). A spirometer must be capable of measuring flows in the range of zero to 12 L/s. The 12 L/s maximal flow rate selection was determined from Hankinson and Petersen's data (1, 9) that showed that less than

TABLE 1

MINIMAL RECOMMENDATIONS FOR SPIROMETRY SYSTEMS

Test	Range/Accuracy BTPS (*L*)	Flow Range (*L/s*)	Time (*s*)	Resistance and Back Pressure	Test Signal
VC	7 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 12	30		3-L Cal Syringe
FVC	7 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 12	15		24 standard waveforms
FEV_t	7 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 12	t	Less than 1.5 cm H_2O/L/s, from zero to 12 L/s	24 standard waveforms
Time Zero	The time point from which all FEV_t measurements are taken.			Determined by back extrapolation.	
$FEF_{25-75\%}$	7.0 L ± 5% of reading or ± 0.200 L/s, whichever is greater	zero to 12	15	Same as FEV_t	24 standard waveforms
$\dot{V}$	± 12 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater	zero to 12	15	Same as FEV_t	Manufacturer proof
MVV	Sine wave 250 L/min at TV of 2 L within ± 5% of reading	zero to 12 ± 5%	12 to 15 ± 3%	Pressure less than ± 10 cm H_2O at 2-L TV at 2.0 Hz	Sine wave pump zero to 4 Hz ± 10% at ± 12 L/s

about 7% of the miners had flow rates greater than 12 L/s.

Recommendation—Forced Vital Capacity (FVC)

FVC = Maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration. Vital capacity performed with a maximally forced expiratory effort. Expressed in liters (BTPS).

Recommendation—FVC Equipment

The spirometer should be capable of measuring volumes up to *AT LEAST* 7 L (BTPS) with an accuracy of *AT LEAST* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 12 L/s. The spirometer should be capable of accumulating volume for *AT LEAST* 15 s, although longer times are recommended.

Rationale. Subjects and patients can exhale for longer than 15 s, so instruments should be capable of measuring their true FVC. For the FVC maneuver, the volume requirements are the same as for the VC (1, 9–13). The spirometer must be capable of measuring flows in the range of zero to 12 L/s. The 12 L/s maximal flow rate selection was based on the Hankinson and Petersen data that showed that fewer than 7% of their coal miners had peak flows greater than 12 L/s (1, 9).

Recommendation—Timed Forced Expiratory Volume (FEV_t)

FEV_t = The volume of air exhaled in the specified time during the performance of the FVC, e.g., FEV_1 for the volume of air exhaled during the first seconds of FVC. Expressed in liters (BTPS).

Recommendation—FEV_t Equipment

Measuring the FEV_t requires a spirometer having a volume of *AT LEAST* 7 L. The spirometer should measure the FEV_1 within an accuracy of *AT LEAST* ± 3% of reading or ± 0.050 L, whichever is greater with flows between zero and 12 L/s. The "start of test" for purposes of timing WILL BE determined by the back extrapolation method (1, 16, 17) or a method shown to be equivalent (see figure 2). For hand measurements, the back extrapolation method traces back from the steepest slope on the volume-time curve (see figure 2) (17, 18). For purposes of computer methods of back extrapolation, we recommend using the largest average slope over a 70-ms period (19) (see Appendix A). The resistance to airflow from zero to 12.0 L/s should be less than 1.5 cm H_2O per L/s.

Rationale. FEV_t measurement is influenced by the point selected as the start of the maneuver. A uniform method of selecting the point is required to maintain consistency. The back extrapolation (1, 16, 17) method is the most consistent and accepted method (see Section VI for measurement procedures) and should be used until other methods are demonstrated to give equivalent results. One attempt to demonstrate equivalency of volume or flow threshold methods for detection of start of test by back extrapolation was unsuccessful (20). Resistance to flow affects the FEV_1 and other timed expirations (21–26).

Recommendation—$FEF_{25-75\%}$

$FEF_{25-75\%}$ = Mean forced expiratory flow during the middle half of the FVC. Formerly called the maximal midexpiratory flow rate (MMEF). Expressed in liters/sec (BTPS).

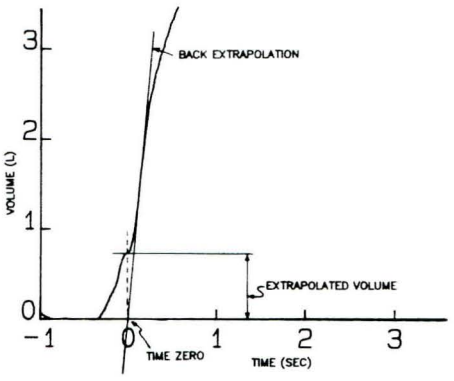

Fig. 2. Typical subject waveform of a volume-time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = V_{ext}.

Recommendation—$FEF_{25-75\%}$ Equipment

The $FEF_{25-75\%}$ should be measured with an accuracy of *AT LEAST* ± 5% of reading or ± 0.200 L/s, whichever is greater. The $FEF_{25-75\%}$ should be measured on a system that meets the FVC recommendations.

Rationale. The $FEF_{25-75\%}$ maneuver has a much larger intrasubject variability than FVC or FEV_1 (27). Additionally, 2 measurements of both volume and time are required; therefore, the relaxed accuracy requirement is justified. Manufacturers and software developers should be aware that a major error in $FEF_{25-75\%}$ can occur when slow sampling rate analog to digital converters are used. With these systems, it may be necessary to "interpolate" between sample points to get the exact 25% and 75% of FVC points.

Recommendation—Flow ($\dot{V}$)

$\dot{V}$ = Instantaneous forced expiratory flow. Expressed in liters/sec (BTPS).

Recommendation—Flow Measurement

Flow may be measured electronically or manually. Where flow-volume loops or other uses of flow are made, with flow in the range of −12 to 12 L/s, the flow should be within ± 5% of reading or ± 0.200 L/s, whichever is greater.

Rationale. Flow-measuring devices such as pneumotachometers are increasingly being used to measure spirometric parameters (6). With flow devices, volume is determined by integration of flow. Flow calibration methods with sufficient accuracy have not yet been developed. Volume spirometers differentiate volume signals to determine flow. With the "noise," phase shift, and associated problems, flows accurate to within ± 5% are thought to be adequate. Whenever a flow signal is integrated to measure volume, the volume accuracy requirements are ± 3% of reading or ± 0.050 L, whichever is greater (1). Instantaneous flow parameters such as $FEF_{75\%}$, FEF_{max}, and Peak Expiratory Flow Rate (PEFR) are very device-dependent, and as a

consequence their measurements are quite variable (6).

Recommendation—Forced Expiratory Time (FET)

FET = Time from the back extrapolated "time zero" until the first *in*spiratory effort following FVC, or the end of expiratory effort.

Rationale. The FET helps show that the duration of FVC effort was acceptable, an especially useful measure when using flow/volume loops.

Recommendation—Maximal Voluntary Ventilation (MVV)

MVV = The volume of air exhaled in a specified period during repetitive maximal respiratory effort. Expressed in liters/min (BTPS).

Recommendation—MVV Equipment

When a spirometer is used for measuring MVV, it should have an amplitude-frequency response that is flat within ± 10% from zero (DC) to 4 Hz at flow rates of up to 12 L/s over the volume range. The time for exhaled volume integration or recording should be no less than 12 or more than 15 s (21). The indicated time should be accurate to within ± 3%.

Rationale. For the MVV maneuver, the frequency content of the volume-time signal is high (28, 29). Results are dependent on the patient effort as well as the frequency response characteristics of the spirometer (21, 30–32).

General Background—Spirometry Recorders/Displays

Paper records or graphic displays of spirometry signals are **REQUIRED** and are used for 3 primary purposes:

(*1*) *DIAGNOSTIC* function—when waveforms are to be used for quality control or review of the forced expiratory maneuver to determine if the maneuver was performed properly, so that unacceptable maneuvers can be eliminated.

(*2*) *VALIDATION* function—when waveforms are to be used to validate the spirometer system hardware and software for accuracy and reliability through the use of hand measurements (for example, measurement of FEV_1 using back extrapolation by comparing computer- and hand-determined FEV_1).

(*3*) *HAND MEASUREMENT* function—when waveforms are to be hand measured for spirometric parameters (FVC, FEV_1, etc.) in the absence or failure of a computer.

With recent advances in computer technology, there are many different ways to display and record spirometric waveforms. The Committee has chosen to broaden the initial scope of the spirometry standardization article to further encourage use of computer technology.

A less stringent paper recorder requirement will suffice for *DIAGNOSTIC* purposes compared to *VALIDATION* and *HAND MEASUREMENT* needs. If no paper recorder or printer is available or if the paper recorder does not meet the requirements for *VALIDATION* and *HAND MEASUREMENT* applications, then proof of validation of the accuracy and stability of the spirometer by an independent laboratory *MUST* be provided by the manufacturer. For these computer methods, any new software releases *MUST* also be validated. *Users and manufacturers* should realize that for certain applications (for example, for disability determination and legal cases), diagnostic size displays are NOT adequate (21). For example, with the Cotton Dust standard ". . . tracings must be stored and available for recall and must be of sufficient size that hand measurements may be made. . ." (33). Also users will customarily not be able to verify accuracy and stability of spirometers by themselves in the absence of an adequate paper recording.

TABLE 2

MINIMUM REQUIRED SCALE FACTORS FOR TIME, VOLUME, AND FLOW GRAPHICS

	Diagnostic		Validation and Measurement	
	Resolution Required	Scale Factor	Resolution Required	Scale Factor
Volume (L)	0.050		0.025	
(mm/L)		5		10
Flow (L/s)	0.20		0.10	
(mm/L/s)		2.5		5
Time (msec)	20		20	
(cm/s)		1		2

Recommendation—FVC Volume-Time Curves

When a volume-time curve is plotted or displayed, the volume scale for each of the following conditions should be *AT LEAST*:

(*1*) *DIAGNOSTIC* function: 5 mm/L (BTPS) for volume so the graphs will be large enough to allow recognition of unacceptable maneuvers and disease patterns.

(*2*) *VALIDATION* and *HAND MEASUREMENT* functions: 10 mm/L (BTPS) for volume for validation and measurement functions. See section below for time scale of volume-time plots.

Recommendation—FVC Maneuver Time Scale

(*1*) *DIAGNOSTIC* function: time scale, *AT LEAST* 1 cm/s.

(*2*) *VALIDATION* and *HAND MEASUREMENT* functions: time scale, *AT LEAST* 2 cm/s; larger time scales are preferred (at least 3 cm/s) when hand measurements are made, but are not required (1, 34, 35).

Rationale. A recent study (35) evaluating the effects of time scale (paper speed) on spirometry accuracy has recommended a time scale of at least 3 cm/s if spirograms are to be accurately measured by hand. The adoption of this more stringent criterion was considered, but not adopted as a minimum recommendation. The new study further supports the current 2 cm/s requirement as a minimum recommendation (35). Because so many spirometers now make use of computers, time resolution and sampling rate become important design issues. The tutorial in Appendix A and table 2 give further specification details.

Recommendation—Flow-Volume Curves

When a flow-volume curve is plotted or displayed, exhaled flow should be plotted upwards, and exhaled volume towards the right. A 2:1 ratio should be maintained between the flow and volume scales, e.g., 2 L/s of flow and 1 L of exhaled volume should be the same distance on their respective axes. The minimum flow and volume scales should be *AT LEAST* as shown in table 2.

Rationale. Currently, flow-volume curves are displayed with a variety of orientations and aspect ratios, hindering the usefulness of visual pattern recognition. Also, some current digitally generated curves do not have sufficient flow or volume resolution. Manufacturers and users should be aware of these limitations.

III. EQUIPMENT VALIDATION

Recommendation—FVC Validation of Test Equipment

The diversity of FVC maneuvers encountered in clinical practice are currently best simulated by the use of the 24 standard waveforms developed by Hankinson and Gardner (19, 36). These waveforms can be used to drive a computer-controlled mechanical syringe for testing actual hardware and software, (6, 37) or they can be put into a system in digital form to evaluate ONLY the software. Appendix C shows a volume-time and a flow-volume plot of each of the 24 standard waveforms and includes table 4, which gives the measured values. The American Thoracic Society also provides these waveforms on floppy disks for an IBM PC. Appropriate corrections for using gas at ambient temperature, ambient humidity instead of BTPS may need to be made for some mechanical syringe-spirometer combinations.

The validation limits for volume are: Volume (FVC, FEV_1) ± 3.5% of reading or ± 0.070 L, whichever is greater; and Flow ($FEF_{25-75\%}$) ± 5.5% of reading or ± 0.250 L/s, whichever is greater. The error range was expanded from the ATS spirometry recom-

mendation stated earlier to allow for errors associated with mechanical syringes (6). Mechanical syringes used for validation must be accurate within ± 0.025 L for FVC and FEV_1 and ± 0.100 L/s for $FEF_{25-75\%}$.

Rationale. Since the publication of the ATS spirometry statement, additional efforts by the Association for the Advancement of Medical Instrumentation (AAMI) (36) have resulted in the development of 24 standard waveforms for spirometer evaluation (19). Because these waveforms were obtained from recordings of actual subject waveforms and have been accepted by AAMI, and because better standard signals are not available, the ATS recommends their use as a test signal for FVC for evaluation of software or entire spirometry systems. When evaluating spirometers in which the 24 standard waveform sets are injected from a computer-controlled mechanical syringe (6, 37), the spirometer will qualify as meeting ATS requirements if fewer than 1 in every 20 measured values is outside the limits, provided the failure does not represent an inherent design defect.

Flows cannot be easily generated without noise; therefore, the frequency of the noise should be stated. In addition, a step function signal should be generated with the mechanical syringe, and the resulting signal should be sampled at a frequency of at least 1,000 Hz to determine the dynamic characteristics of the driving syringe. Typically, these systems have second-order oscillatory characteristics. By using the step function signal, the natural frequency and damping coefficients can be determined. Some spirometer manufacturers have appropriately purchased a computer-based syringe system for dynamic testing of each of their own spirometers (MH Custom Design and Manufacturing, 70 Fern Drive, Midvale, UT 84047); however, spirometry system designs and a production model must be validated by an independent testing laboratory.

Recommendation—MVV Validation Equipment

When tested with a pump producing a sinusoidal waveform, the indicated response of the spirometer in incrementally increased flows up to 250 L/min signal, produced with stroke volumes up to 2 L, should be accurate within ± 5% of reading. During the testing, the pressure at the mouthpiece should not exceed ± 10 cm H_2O. For volume spirometers, these requirements apply throughout their volume range.

IV. EQUIPMENT QUALITY CONTROL

Routine equipment preventive maintenance, cleaning, calibration checks, verification, and quality control are important to assure accurate spirometry results (38). A spirometry procedure manual is an important base for a quality assurance program. The manual should contain a quality control plan, guidelines for ordering spirometry, guidelines for performing spirometry, and guidelines for reporting spirometry results. See the document "ATS Quality Assurance for Pulmonary Laboratories" for more details (38).

The role of spirometric equipment in the transmission of infections has not been established (39). However, general suggestions based on a reasonable theoretical rationale or data from other sources are appropriate. A recent publication by the Centers for Disease Control outlines 9 recommendations: (*1*) handwashing indications, (*2*) handwashing technique, (*3*) handwashing products, (*4*) handwashing facilities, (*5*) fluids and medications, (*6*) handling blood specimens, (*7*) maintenance of equipment, (*8*) protection of patients from other infected/colonized patients or staff, and (*9*) microbiologic monitoring (39).

Recommendation—Equipment Quality Control

The spirometer's ability to accurately measure volume should be checked *AT LEAST* daily with a calibrated syringe with a volume of at least 3 L. During industrial surveys or other field studies in which a large number of subject maneuvers are done, the equipment should be calibrated prior to testing daily if in regular use and then every 4 h during use (38). Although there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be determined within 1 day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. For survey testing in which a large number of maneuvers are done, the 4-h period of calibration checking is recommended to prevent invalidation of data from a large number of maneuvers. Spirometer systems should be evaluated for leaks on a daily basis (17, 40). The Intermountain Thoracic Society Manual suggests that leaks can be detected by applying a constant positive pressure of 3 cm H_2O or more with the volume spirometer outlet occluded. Any observed volume change after 1 min is indicative of a leak (17). *AT LEAST* quarterly, volume spirometers should have their calibration checked over their entire volume range (in 1-L increments) using a calibrated 3-L syringe (6). Two emptying times for the 3-L syringe are indicated: 0.5 to 1 s (flow in the range of 3 to 6 L/s) and at least 6 s (flows less than 0.5 L/s). Assessing the recorder time scale accuracy with a stopwatch should be performed *AT LEAST* quarterly. An accuracy of within 1% should be achieved. If equipment is changed or relocated (e.g., industrial surveys), calibration checking and quality control procedures should be repeated prior to initiating further testing.

V. MANEUVER PERFORMANCE RECOMMENDATIONS

Personnel Qualifications

The ATS has made recommendations for laboratory personnel performing a variety of pulmonary function testing tasks (41). In addition to recommending at least a high school training background, strong mathematical training was encouraged. Also 1 or more years of college or equivalent training are preferred for technicians performing spirometry. For pulmonary function laboratories, 6 months of supervised training time is recommended for performing spirometry. If troubleshooting is to be a part of the laboratory technician's responsibility, a training period of 1 year is recommended. The ATS has taken a strong position that the Medical Directors must have appropriate training and be responsible for all pulmonary function testing (42). Training for doing epidemiologic spirometric testing may be more intensive than that of a technician for a general pulmonary laboratory testing and may thus be accomplished more quickly. For industrial/occupational testing there are training requirements mandated by the National Institute for Occupational Safety and Health (NIOSH) and industry and the ACCP (18, 33, 43).

Several excellent training manuals have been prepared for performance of spirometry (17, 18, 33, 44), and NIOSH approves training courses (18).

Rationale. The testing of equipment and wide-scale proficiency testing of pulmonary function equipment is not currently feasible. However, using laboratory personnel "known subjects" and performing intra-laboratory and inter-laboratory testing can be helpful (38). In addition, the ATS has recently published guidelines for "Quality Assurance in Pulmonary Function Laboratories," (38) which are recommended.

With the decrease in size and cost of microprocessors and the increase in their speed and reliability, most spirometer systems will contain some type of digital computer. Indeed, in a recent test of 53 commercially available spirometers, only 3 did not contain a computer (6). New quality assurance problems will occur as pulmonary function laboratories become more reliant on digital computers and associated automation (45, 46).

The use of computers to perform spirometry has accelerated in the past 5 years and this trend may be advantageous to obtain accurate spirometry (5, 35). The recent testing of commercially available spirometers showed that a major source of errors was in computer software (6). Because of the increased use of computers in pulmonary laboratories and the problems associated with them (6, 45), the ATS has published "Computer Guidelines for Pulmonary Laboratories" (46), which should be followed.

Recommendation—FVC Subject Instruction and Maneuver

Subjects will be instructed in the FVC maneuver, and the appropriate technique will be *demonstrated*. A *MINIMUM* of 3 acceptable FVC maneuvers will be performed. If a subject has large variability between expiratory maneuvers, reproducibility criteria may require that up to 8 acceptable maneuvers be

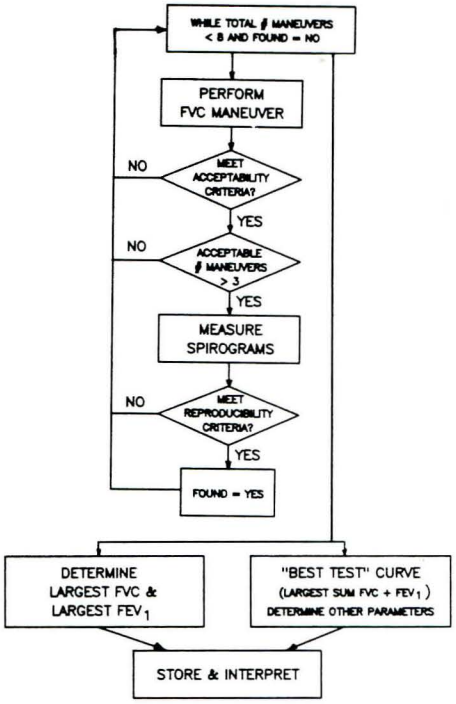

Fig. 3. Flow-chart diagram of FVC spirometry testing.

performed. See figure 3 and Section VII for further clarification.

Recommendation—FVC End of Test Criteria

Subjects should be verbally exhorted to continue to squeeze out the air at the end of the maneuver. "End of Test" will occur when there is:

(*1*) an obvious plateau in the volume-time curve resulting in no change in volume for *AT LEAST* 2 s (a volume decrease is, for the purposes of end of test selection, equivalent to no change in volume) with an exhalation time of *AT LEAST* 6 s (longer times are frequently needed for subjects with airway obstruction). For the purposes of this criterion, no change in volume is the minimal detectable volume of the spirometer. Minimum detectable volume MUST BE AT LEAST 0.040 L; OR

(*2*) a forced exhalation of reasonable duration. (For example, exhalation times of greater than 15 s in subjects with severe airway obstruction will rarely change clinical decisions and longer exhalations are seldom justified; manufacturers should note, however, that several of the 24 test waveforms have durations longer than 20 s); OR

(*3*) when, for legitimate clinical reasons, the subject cannot or should not continue further exhalation.

Although the end of test criteria defined above are reasonable and will perform adequately in most situations, spirometers should not prevent the continued accumulation of volume after the end of test criteria are met. We encourage spirometer designs that allow technicians to encourage subjects to breathe out for as long as they can or until there is an inspiration.

Rationale. A recent study (19) using standard waveforms has shown that application of the earlier ATS-recommended "end of test" criteria (1) prematurely terminates the FVC maneuver, resulting in as much as a 9% reduction in the measured FVC. Because the original recommendation was not based on data from subjects that covered the full spectrum of the population, the "end of test" criteria are now being updated.

Requiring that there be no change in volume for at least 2 s is probably similar to long-standing manual methods. We were reluctant to use the minimum volume accuracy of 0.050 L for the minimum detectable volume because most spirometers can resolve volume less than 0.050 L. Manual spirometers with a strip chart recorder can typically resolve 0.025 L, and a spirometer with a digital shaft encoder can typically resolve a 0.010-L volume (47). The second "end of test" criterion (*reasonable duration of 15 s*) is necessary to avoid prolonged expirations in subjects with severe airway obstruction in which more prolonged expiratory efforts will not change the clinical decision.

Recommendation—Minimum FVC Exhalation Time

A minimum exhalation time of 6 s, unless there is an obvious plateau, is required to obtain maximal FVC results. Longer times are often required to achieve "end of test," particularly in obstructed individuals.

Recommendation—FVC Satisfactory Start of Test Criteria

To achieve accurate "time zero" and ensure that the FEV_1 comes from a maximal effort curve, the extrapolated volume should be less than 5% of the FVC or 0.100 L, whichever is greater. See figure 2 for example of back extrapolation.

Rationale. The allowable extrapolated volume of the current ATS recommendations was 10% of the FVC or 0.100 L, whichever was greater, which can result in very slow starts with low peak flows being acceptable (1, 48–50). In addition, FEV_1 from submaximal efforts can be larger than those obtained when a maximal effort is performed, both due to a volume of air being exhaled without being timed (the extrapolated volume) and to less dynamic compression of airways in some subjects with submaximal efforts. Because the largest FEV_1 is reported, a falsely elevated FEV_1 may be used in the final report. The lower allowable extrapolated volume should reduce the effect of submaximal effect on the reported FEV_1.

Recommendation—FVC: Maximum Number of Maneuvers

Although there may be some circumstances in which more than 8 consecutive FVC maneuvers are needed, 8 maneuvers is considered a practical upper limit for most subjects.

Rationale. After several forced expiratory maneuvers, fatigue begins to take its toll on subjects and, thus, on their spirometric parameters. In addition, some subjects may exhibit spirometry-induced bronchospasm, and additional maneuvers would be of little added value. Therefore, an upper limit of the number of maneuvers is warranted. Ferris and associates (51) and Kanner and colleagues (15) have reported that for adults and children, 8 maneuvers is a practical upper limit.

Recommendation—FVC Environmental Conditions

Spirometric testing with ambient temperatures less than 17° C or more than 40° C is not recommended. Ambient temperature should ALWAYS be recorded and reported to an accuracy of ± 1° C. Spirometer users should be aware of the problems with testing done at lower temperatures. Ranges of barometric pressures that are acceptable for the spirometer should be published by the manufacturer.

Rationale. There is evidence that some subjects may develop airflow limitation with the inhalation of very cold air. Therefore, spirometry should not be conducted when the ambient temperature is cold enough to induce airflow limitation.

Recent studies also point out the problem of finite cooling times of gases in volume type spirometers and their associated tubing (52–54). In one of these studies, it was found that a + 7.7 to 14% error of FEV_1 results if the volume type spirometer is at an ambient temperature of 3° C, even with the BTPS correction. This error is less if the spirometer is warmer (nearer body temperature) (52). As a result, 17° C was judged to be an acceptable and reasonable lower limit.

Complexities related to temperature are also encountered with flow-measuring devices (54–57). Air exhaled from the mouth is estimated to be at 33° C (55, 56). If any connecting tubing is used between the mouthpiece and the flow sensor, the exhaled gas will experience a variable amount of cooling if the room temperature is not at 33° C. Details of the cooling pattern for flow spirometers have not been studied, but they may result in errors similar to those for volume devices (54–58).

Because not all spirometers are used at sea level (BP = 760 mm Hg), the range of barometric pressures allowed by the spirometer and its associated computational equipment should be specified.

Recommendation—FVC Use of Nose Clips

Use of nose clips is encouraged.

Rationale. Although the use of nose clips does not appreciably influence the FVC performed using the open circuit technique, some subjects breathe through the nose during the maneuver when a closed circuit technique is used.

Recommendation—FVC Sitting Versus Standing

Subjects may be studied in the sitting or standing position. Indication of position is necessary.

Rationale. Recent studies by Townsend show that for adults there are significantly larger forced expiratory volumes in the standing position than in the sitting position (59). The earlier ATS recommendation indicates that in children, VC is greater in the standing than in the sitting position (1).

VI. MEASUREMENT PROCEDURES

Measurement

Spirometric variables should be measured from a series of *AT LEAST* 3 acceptable forced expiratory curves.

Rationale. Best efforts cannot always be determined by simple inspection of a spirogram. Measurements and calculation are required to determine the largest values.

Recommendation—Test Result Selection/Reporting of Results

The largest FVC and the largest FEV_1 (BTPS) should be recorded, after examining the data from all of the acceptable curves, *even if the 2 values do not come from the same curve.* Other measures such as the $FEF_{25-75\%}$ and/or the instantaneous expiratory flows ($\dot{V}$) should be obtained from the single "best test" curve (1, 17). The "best test" curve is defined as the test that meets the acceptability criteria and gives the largest sum of FVC plus FEV_1.

Rationale. Two competing methods for selection of FVC and FEV_1 values have been used: (*1*) using the largest FVC and the largest FEV_1 independent of which acceptable curve they came from, or (*2*) using the FVC and FEV_1 from the single "best test" curve with the largest sum of FVC plus FEV_1.

As a result of the original recommendations made by the ATS Snowbird Workshop, several investigators have evaluated the use of the "best test" method (60–62). The University of Arizona group used the single "best test" to reevaluate their data and found that construction of "composite" maximal expiratory flow-volume (MEFV) curves gave results that were systematically higher than taking data from a "best test" waveform (60, 61). Sorensen and associates demonstrated that differences between maximal and "best test" FVC and FEV_1 were small. The mean difference between the 2-test result selection methods was only 5.8 ml for FVC and 8.4 ml for FEV_1. In 98.4% of the FVC comparisons and 95.7% of the FEV_1 comparisons, the differences were within the minimal spirometer accuracy recommendations (± 0.050 L or ± 3% of reading) (62).

The Committee decided to continue with the original Snowbird recommendation of taking the largest FVC and the largest FEV_1 independent of which curve they came from for the following reasons: (*1*) A large base of data, especially from epidemiologic studies, has been collected with the current recommended methods, and because the differences between "largest" and "best test" were small, no change in the recommendation was justified. (*2*) The FVC and FEV_1 are independent and therefore may be selected from different curves. (*3*) The largest values represent a subject's highest potential values and therefore should be used for legal/regulatory purposes. In fact, these regulations are already in place and will not likely change.

Because the average differences between the 2 methods are so small (< 10 ml), any reference value studies (63) or epidemiologic studies previously done with the "best test" method are still valid.

VII. ACCEPTABILITY AND REPRODUCIBILITY

Recommendation—FVC Maneuver Acceptability

Acceptability will be determined by ascertaining that the recommendations outlined above in the section on performing the FVC test are met. In review, these are: (*1*) end of test criteria, (*2*) minimum FVC exhalation time of 6 seconds, and (*3*) satisfactory start of test. In addition, the technician should observe that the subject understood the instructions and performed the maneuver with a maximum inspiration, with a good start, with a smooth continuous exhalation, with maximal effort, and without:

(*1*) An unsatisfactory start of expiration, characterized by excessive hesitation or false start or extrapolated volume of greater than 5% of FVC or 0.100 L, whichever is greater.

(*2*) Coughing during the first second of the maneuver, thereby affecting the measured FEV_1 value, or any other cough that, in the technician's judgment, interferes with measurement of accurate results.

(*3*) Valsalva maneuver (glottis closure).

(*4*) Early termination of expiration. (In a NORMAL subject this would be before completion of the breath—*USUALLY less than a 6-s maneuver.* In an obstructed subject, a longer time is required ([64, 65]).

(*5*) A leak.

(*6*) An obstructed mouthpiece, e.g., obstruction due to the tongue being placed in front of the mouthpiece, false teeth falling in front of the mouthpiece, etc.

Figure 3 is a flow chart outlining how acceptability and reproducibility criteria are to be applied.

Rationale. Many patients cough and sputter toward the end of their FVC maneuver, but this does not affect the important initial spirometry parameters. To eliminate these FVC maneuvers from clinical evaluation would be a waste of useful information. *AT LEAST* 3 acceptable maneuvers are required to ensure that maximal effort and cooperation are obtained and that the resulting data provide an accurate reflection of the subject's pulmonary function (1). This conclusion was achieved after reviewing the data of Knudson and associates (66) and others (17, 67).

Recent studies (48–50) have shown that the elimination of subjects for failure to meet the ATS reproducibility criteria may result in elimination of data from subjects who have abnormal lung function, resulting in a population bias. Pennock and colleagues (68) have reported that subjects with obstruction have greater coefficients of variation than do normal subjects. Therefore, these subjects are more likely to be unable to meet the ATS minimum reproducibility criteria. The reproducibility criteria have been clarified to eliminate confusion. If acceptability criteria are not applied before the reproducibility criteria, then a passive exhalation maneuver will often be labeled as the "best" maneuver because it may give the largest sum of FVC plus FEV_1.

Recommendation—FVC Test Result Reproducibility

As a goal during test result performance, the largest FVC and second largest FVC from acceptable curves should not vary by more than 5% of reading (expressed as a percentage of the largest observed FVC regardless of the curve on which it occurred) or 0.100 L, whichever is greater. In addition to the FVC criteria, the largest FEV_1 and the second largest FEV_1 (expressed as a percentage of the largest observed FEV_1 regardless of the curve on which it occurred) should not vary by more than 5% of reading or 0.100 L, whichever is greater.

The reproducibility criteria are used as a guide to whether more than 3 FVC maneuvers are needed; these criteria are *NOT* to be used for excluding results from reports or for excluding subjects from a study. Labeling results as being derived from data that do not conform to the reproducibility criteria stated above is encouraged (especially when the data suggests that bronchospasm was triggered by the FVC maneuver). The acceptability criteria should be applied before the reproducibility criteria (see figure 3). Unacceptable maneuvers should be discarded before applying the reproducibility criteria.

The only criterion for unacceptable subject performance, requiring elimination from further consideration, is less than 2 acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility, provided 3 acceptable maneuvers were obtained. Reproducibility of results should be considered at the time of interpretation. Use of data from maneuvers with poor reproducibility is left to the discretion of the interpreter.

Rationale. It was not clear from the earlier ATS statement on standardization of spirometry, whether the 5% referred to FVC, FEV_1, or both FVC and FEV_1. Recent studies (48–50) have shown that the elimination of subjects for poor reproducibility may inappropriately eliminate subjects, resulting in a population bias. Pennock and associates have reported that subjects with airway obstruction have greater coefficients of variation than do normal subjects (68). Therefore, these subjects are more likely to be unable to meet the initial ATS minimum reproducibility criteria. In addition, the reproducibility should be changed to eliminate any confusion concerning which values are used and when the reproducibility criteria are applied. If acceptability criteria are not applied before the reproducibility criteria, then a passive exha-

lation maneuver may be labeled as the "best" maneuver if it gives the largest sum of FVC plus FEV_1.

The calculation of the FVC and FEV_1 reproducibility presents no problem for a computer; however, the need for rapid determination of FEV_1 during the testing session presents a recognized logistics problem if results are hand-measured and calculated.

VIII. REFERENCE VALUES AND INTERPRETATION STANDARDIZATION

This area of spirometry standardization is at an early stage in its development. The Intermountain Thoracic Society has recently published its Manual of Uniform Laboratory Procedures (17). The California Thoracic Society has published a similar book that emphasizes the controversy associated with selecting reference values and interpretation methodology (69).

Reference value determination is clearly an area of spirometry that must be further investigated and standardized. There are well over 20 reference value equations for spirometry in common use. Few data are available for several race and age groups. Although it is too early to standardize reference values, the committee recommends that, as a minimum, reference values for FVC and FEV_1 come from the same study so that they are internally consistent.

The standardization of interpretive procedures is also in need of further investigation (70). The present situation allows enough interpretive variability to cause identical data from a patient to be interpreted differently in different laboratories (71).

IX. CLINICAL ASSESSMENT

Clinical/Epidemiologic Considerations

Whether the spirogram results are to be used for clinical or epidemiologic purposes, the above recommendations apply.

Classification

The classification of spirometry into normal and abnormal groupings and into disease categories such as mild, moderate, and severe airway obstruction is simple, and is easily performed by a computer once criteria have been established. The meaning of such classifications requires clinical information. For example, the meaning of an FVC measurement that is just below the lower limit of normal is different in a young, healthy, nonsmoking individual than it is in a person who presents for evaluation of dyspnea or who has an abnormal chest radiograph. In the first case, the probability of a false positive test is large because the prior probability of disease is very low. In the second case, the probability of a true positive test is high because the symptoms and/or the abnormal radiograph increase the prior probability of disease. One area that causes considerable controversy is the combined obstruction and restriction classification. This classification is commonly made when airway obstruction is present; the problem is the FVC is reduced out of proportion to what was expected from the degree of obstruction. This problem may be more easily resolved when absolute lung volumes are available and approached in the context of the patient's clinical problems, and other clinical information such as a chest radiograph is available.

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. Members of the Committee were:

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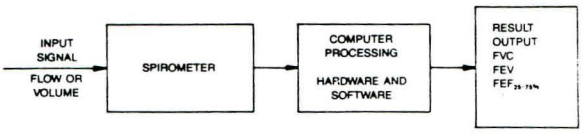


Fig. 4. Block diagram of spirometer data acquisition.

APPENDIX A – Signal Processing Tutorial

Since computers have come into such common use in spirometry and since fundamental errors have been detected in recently tested commercially available hardware and software (6), a short tutorial on signal processing is presented (figure 4).

For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (47). Flow devices of the Fleisch pneumotachometer variety also have electrical voltage outputs. For the volume spirometer with a potentiometer, and the flow device with a flow transducer, the signal is sampled by a computer's analog to digital (A to D) converter. The ability of these systems to accurately measure the spirogram depends on the volume or flow transducer's linearity, the accuracy and linearity of the electrical transducer (potentiometer), and the resolution of the A to D converter. A resolution of 12 bits (1 part in 4,096 – raw resolution of from 0.002 to 0.004 L) for the A to D is recommended, although 10 bits (1 part in 1,024 – raw resolution of from 0.008 to 0.016 L) may be adequate. The sampling rate of the spirometer volume or flow is very important. Lemen and associates (72) have shown that for both infants and adults, 95% of the signal energy in the flow-time of spirograms is within a bandwidth of zero to 12 Hz. For the volume-time curve, 95% of the signal energy is contained from zero to 6 Hz. Digital sampling theory requires that samples be taken at least twice the rate of the highest frequency contained in the signal (73). Thus for volume-time spirograms, a 12-Hz sampling rate should be adequate. However, most volume-time spirograms are sampled at a 100 Hz or greater rate to make measurements easier and more accurate. Figure 5 is a graphical illustration of time sampling of a volume-time spirogram. Computer system developers should be aware that even with 100-Hz sampling, it may be necessary to linearly interpolate between sampling points to determine accurate FEV_1, $FEF_{25-75\%}$, and other similar spirometric measures.

Volume sampling techniques with optical

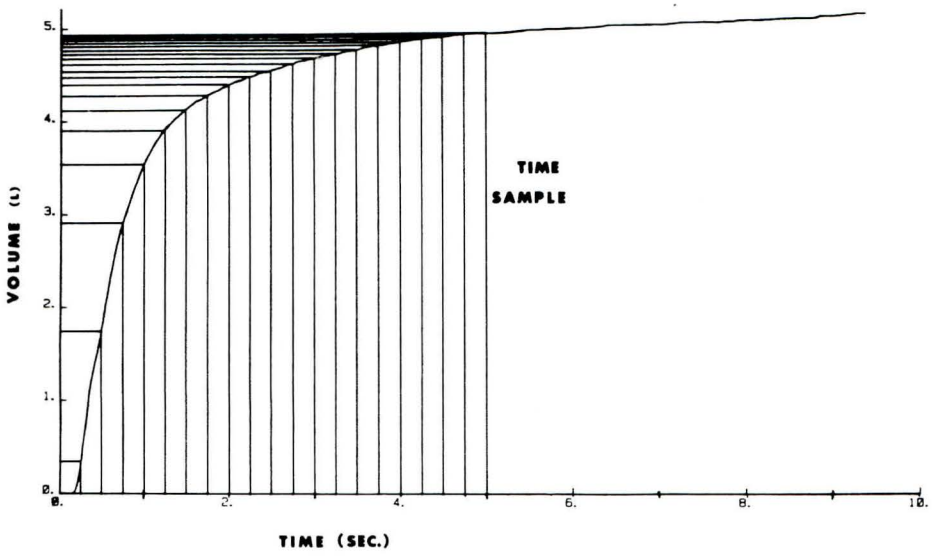


Fig. 5. Time-sampled spirogram.

and shaft or position encoders of the volume-time signal have been used (47). This approach measures the time interval between uniform volume intervals (for example, 0.010 L) as shown in figure 6. In this case, the resolution of time interval between measurements during rapid flow becomes a limiting factor. Ostler and associates have recently addressed these issues (47). For example, if a resolution of flow to within ± 5% of reading at 12 L/s for a system with 0.010-L resolution is required, then a clock resolution of at least 40 microsec is needed (47).

APPENDIX B—Standard Waveforms for Spirometer Validation

A recent study using the standard spirometry waveforms (6) described several ambiguities (areas for potential misinterpretation) in the values reported in terms of the revised ATS recommendations. The waveforms were initially obtained using an Ohio 840 spirometer (19). They were recorded on tape, then digitized with a 12-bit analog to digital (A to D) converter. The published results were then reported to the nearest 10 ml or 10 ml/s.

For clinical purposes, reporting of volumes to the nearest 10 ml is sufficient. At the time of the initial publication, it was felt that 10 ml accuracy of the standard waveform values would be sufficient for any use. Many spirometers at that time used only 10-bit A to D converters, providing a volume resolution of 6 ml for a 6-L spirometer. Because of the current availability of spirometers with 12-bit A to D converters and, consequently, better resolution, it became prudent to report all spirometry parameters to the nearest ml, decreasing the small errors that may occur because of rounding. Therefore, the original waveforms were reconverted from A to D units to volumes in ml and flows in ml/sec. In addition, all of the waveforms were extended to include no change in volume for 2.10 s following the last volume change (except 3, 4, and 17, which already stopped at 20.5 s). This satisfies the new spirometry end-of-test criteria for an "obvious plateau." The revised values for FVC and the other parameters are shown in table 4.

The changes from the published values for forced vital capacity (FVC) were primarily due to differences caused by round-off. However, several of the original waveform data files started with non-zero volume offset. The small offsets were a result of patients changing the amount of air in the spirometer by moving the patient hose before their expiration actually began. To avoid any ambiguities, these waveforms (Nos. 6, 7, 8, 11, 12, 15, 17, 21, 23) were modified by subtracting the small offset volume from all subsequent values in the data file. The largest difference was noted on Waveform 17, resulting in a decrease of 17 ml in the FVC. The other waveforms had offsets of either 1.5 or 3 ml.

The values for the FEV_1 were updated using interpolation between data points. The previous method found the zero time by back extrapolating from the highest flow, then counting 100 samples (1 s). Differences resulted because the back extrapolated time zero did not usually fall exactly at one of the sample times. The revised parameters calculated the exact time zero intercept on the time axis by linear interpolation, then calculated the FEV_1 by interpolating between points. The back extrapolated volume was also modified slightly because of the interpolation scheme used.

The FEF_{max} was unchanged since it was calculated as before, using a parabolic curve fitting routine to smooth the flow data. The parabolic curve fitting algorithm smoothed the data using a least squares parabolic fit to 80 millisec of the volume time curve. The formula used for the smoothing (74) was:

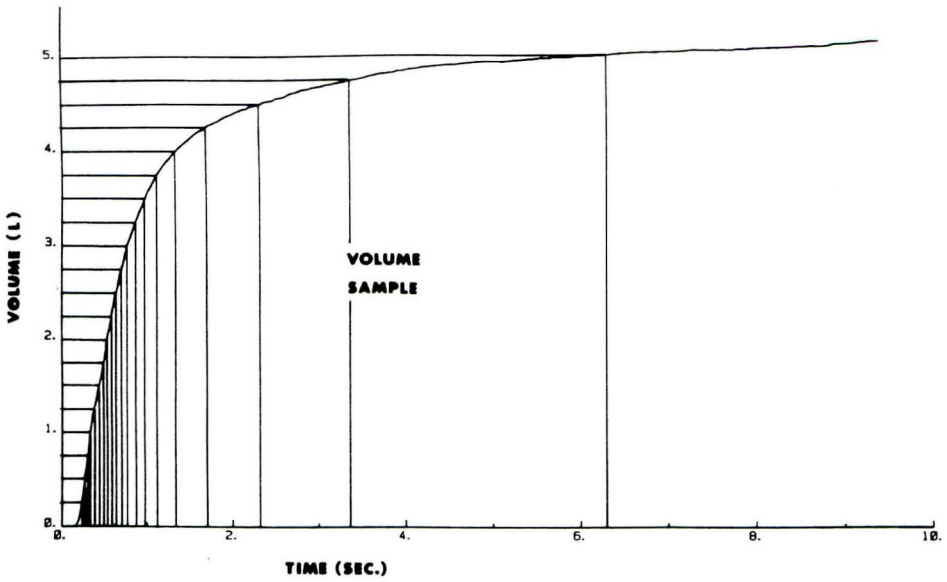


Fig. 6. Volume-sampled spirogram.

TABLE 3

SAMPLE POINTS VERSUS INTERPOLATED VALUES FOR 25% FVC AND 75% FVC

Point	Time (s)	Volume (L)	% FVC
A	0.28	1.442	24.3
	0.2839*	1.4843	25.0
B	0.29	1.549	26.1
C	0.77	4.449	74.9
	0.7711*	4.4528	75.0
D	0.78	4.479	75.4

$FEF_{25-75\%}$ USING CALCULATED VERSUS INTERPOLATED POINTS

Data Used	Calculated Flow
A–C	6.137
A–D	6.073
B–C	6.042
B–D	5.979
Interpolated	6.093

* Interpolated value.

TABLE 4

VALUES FOR STANDARD WAVEFORMS

Curve	FVC (*L*)	FEV_1 (*L*)	%FVC	V_{ext} (*L*)	%FVC	FEF_{max} (*L/s*)	$FEF_{25-75\%}$ (*L/s*)
1	6.000	4.262	71.0	0.052	0.9	6.497	3.410
2	4.999	4.574	91.5	0.068	1.4	9.873	5.683
3	3.498	1.188	32.0	0.014	0.4	1.380	0.644
4	1.498	1.371	91.5	0.019	1.3	2.952	1.704
5	5.132	3.868	75.4	0.087	1.7	7.535	3.209
6	4.011	3.027	75.5	0.317	7.9	5.063	2.572
7	3.169	2.519	79.5	0.354	11.2	4.750	2.368
8	1.993	1.615	81.0	0.151	7.6	3.450	1.857
9	4.854	3.772	77.7	0.203	4.2	7.778	3.365
10	3.843	3.031	78.9	0.244	6.3	4.650	2.899
11	2.735	1.811	66.2	0.022	0.8	3.708	1.272
12	2.002	1.621	81.0	0.094	4.7	3.807	1.780
13	4.896	3.834	78.3	0.460	9.4	5.207	3.677
14	3.786	3.053	80.6	0.338	10.2	4.368	3.122
15	5.937	5.304	89.3	0.080	1.3	12.132	6.092
16	5.458	3.896	71.4	0.215	3.9	7.395	2.892
17	5.833	2.597	44.5	0.035	0.6	5.257	1.153
18	4.343	3.155	72.6	0.042	1.0	7.523	2.335
19	3.935	2.512	63.8	0.044	1.1	5.408	1.137
20	2.881	2.563	89.0	0.041	1.4	5.822	2.695
21	4.477	3.549	79.3	0.102	2.3	9.398	3.368
22	3.857	2.813	72.9	0.036	0.9	5.055	2.204
23	3.419	1.360	39.8	0.013	0.4	2.868	0.531
24	1.237	0.922	74.5	0.037	3.0	2.095	0.709

V_{ext} = Extrapolated volume (*see* figure 2 for description).

$$y'(n) = \frac{\sum_{j=-4}^{4} j*y(n+jh)}{2*\sum_{j=1}^{4} j*j*h}$$

where h = the time between samples.

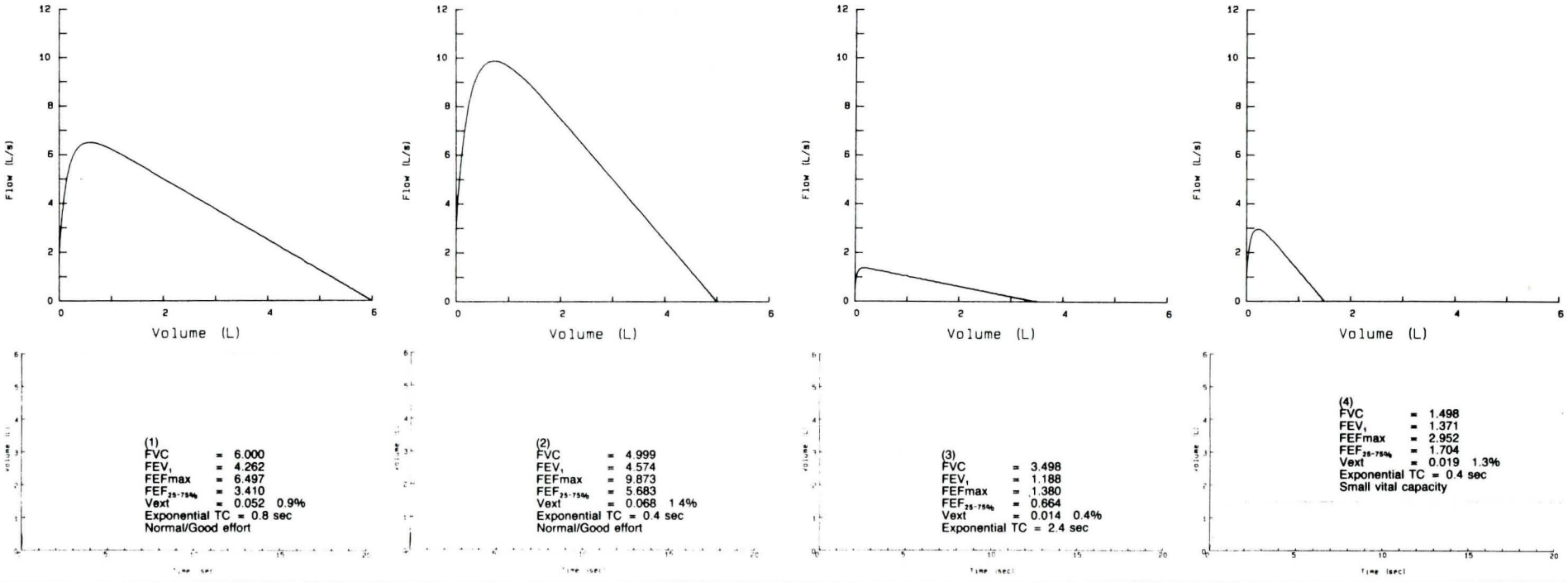
Calculating the $FEF_{25-75\%}$ from the digitized waveform data revealed a problem similar to that described for the FEV_1. When data points for 25% of the FVC and 75% of the FVC were not included in the file, these points had to be interpolated from the data points available. Errors as large as 5% were introduced into the calculation of $FEF_{25-75\%}$ when interpolation was not used (6). Table 3 illustrates the effect on Waveform 15.

The forced expiratory time (FET) was defined as the time from time zero until the time of the last change in volume.

APPENDIX C—Standard Waveforms

Values for the standard waveforms are included as table 4. Plots of the volume-time and flow-volume curves for the 24 standard waveforms are also included.

(*See following pages*)

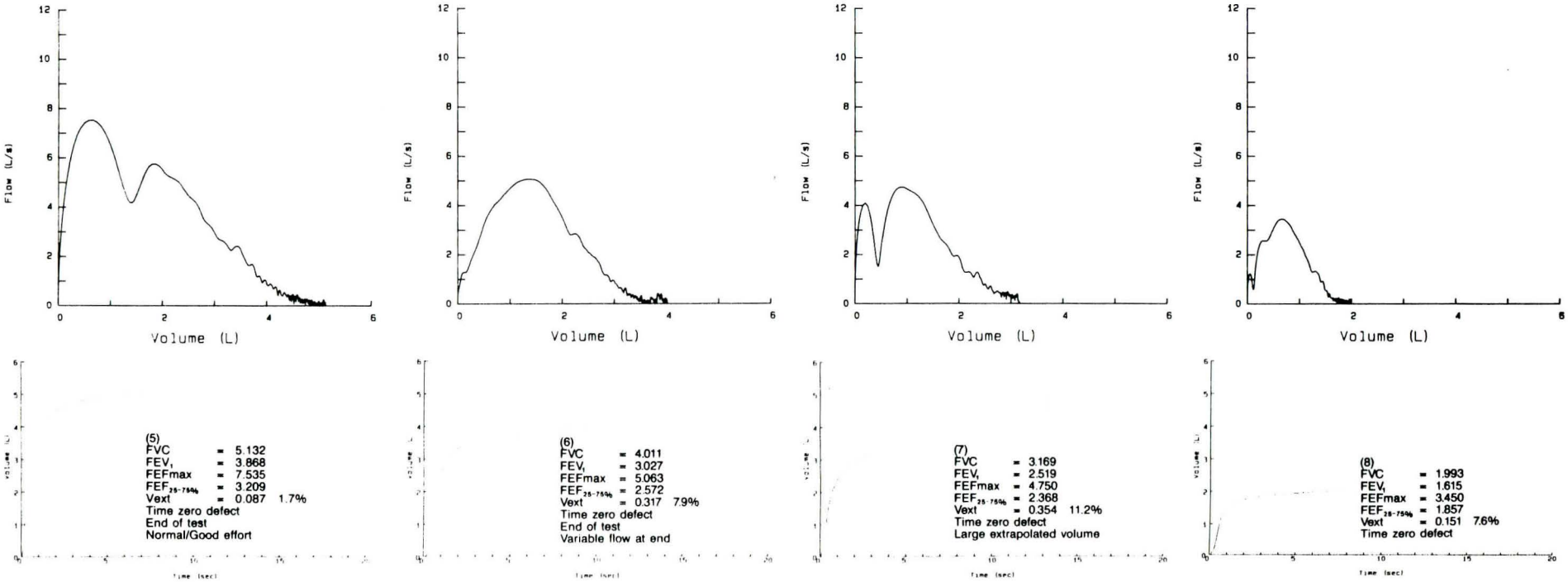


(1)
FVC = 6.000
FEV_1 = 4.262
FEFmax = 6.497
$FEF_{25-75\%}$ = 3.410
Vext = 0.052 0.9%
Exponential TC = 0.8 sec
Normal/Good effort

(2)
FVC = 4.999
FEV_1 = 4.574
FEFmax = 9.873
$FEF_{25-75\%}$ = 5.683
Vext = 0.068 1.4%
Exponential TC = 0.4 sec
Normal/Good effort

(3)
FVC = 3.498
FEV_1 = 1.188
FEFmax = 1.380
$FEF_{25-75\%}$ = 0.664
Vext = 0.014 0.4%
Exponential TC = 2.4 sec

(4)
FVC = 1.498
FEV_1 = 1.371
FEFmax = 2.952
$FEF_{25-75\%}$ = 1.704
Vext = 0.019 1.3%
Exponential TC = 0.4 sec
Small vital capacity

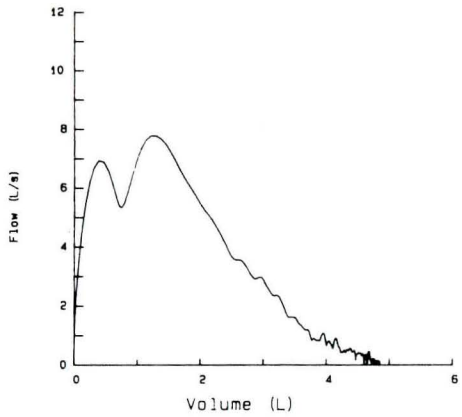


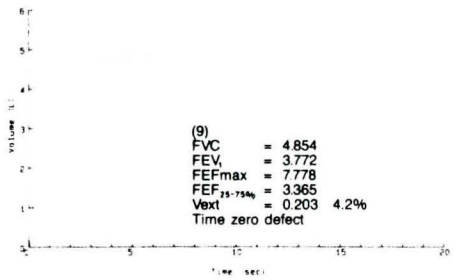
(5)
FVC = 5.132
FEV_1 = 3.868
FEFmax = 7.535
$FEF_{25-75\%}$ = 3.209
Vext = 0.087 1.7%
Time zero defect
End of test
Normal/Good effort

(6)
FVC = 4.011
FEV_1 = 3.027
FEFmax = 5.063
$FEF_{25-75\%}$ = 2.572
Vext = 0.317 7.9%
Time zero defect
End of test
Variable flow at end

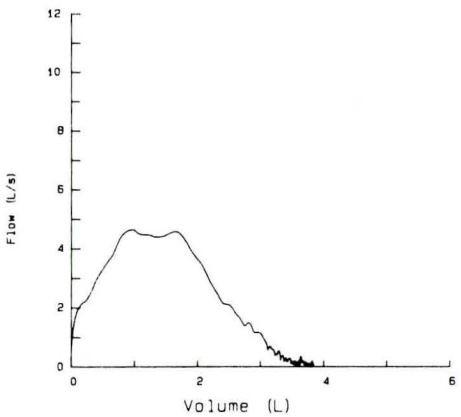
(7)
FVC = 3.169
FEV_1 = 2.519
FEFmax = 4.750
$FEF_{25-75\%}$ = 2.368
Vext = 0.354 11.2%
Time zero defect
Large extrapolated volume

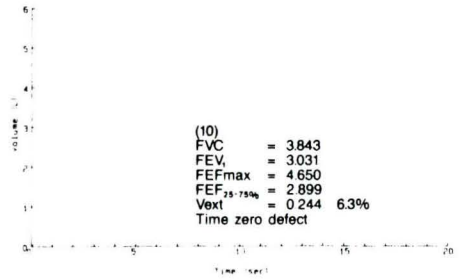
(8)
FVC = 1.993
FEV_1 = 1.615
FEFmax = 3.450
$FEF_{25-75\%}$ = 1.857
Vext = 0.151 7.6%
Time zero defect



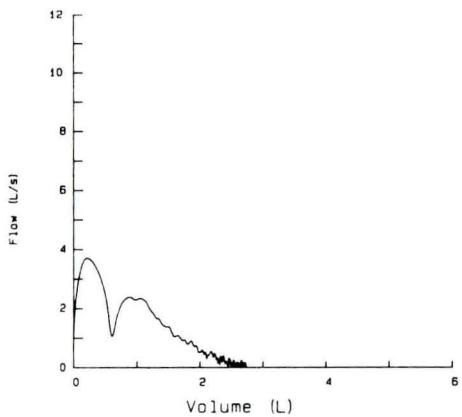


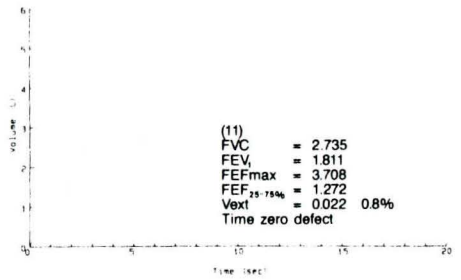
(9)
FVC = 4.854
FEV_1 = 3.772
FEFmax = 7.778
$FEF_{25-75\%}$ = 3.365
Vext = 0.203 4.2%
Time zero defect



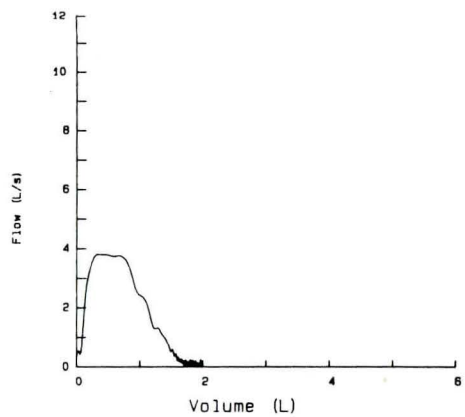


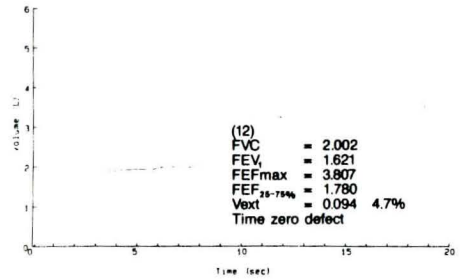
(10)
FVC = 3.843
FEV_1 = 3.031
FEFmax = 4.650
$FEF_{25-75\%}$ = 2.899
Vext = 0.244 6.3%
Time zero defect



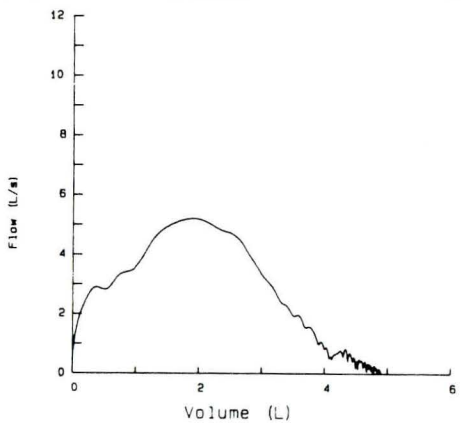


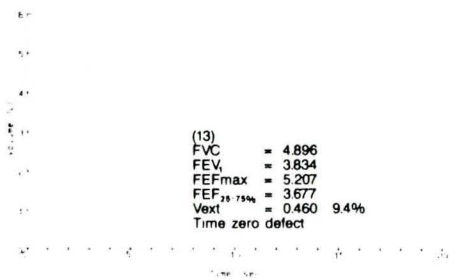
(11)
FVC = 2.735
FEV_1 = 1.811
FEFmax = 3.708
$FEF_{25-75\%}$ = 1.272
Vext = 0.022 0.8%
Time zero defect



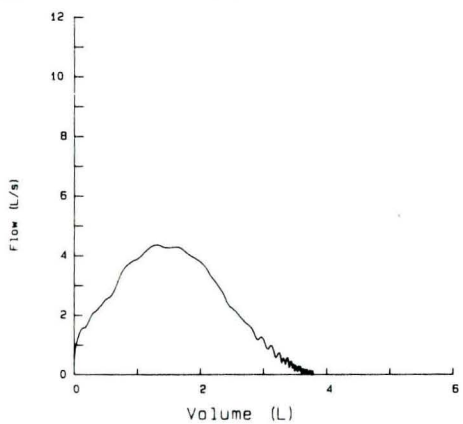


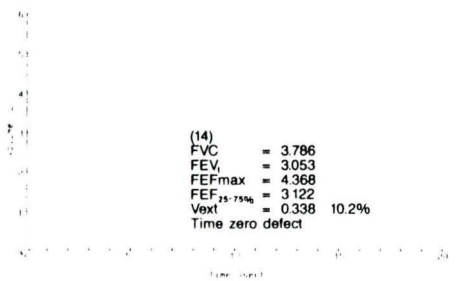
(12)
FVC = 2.002
FEV_1 = 1.621
FEFmax = 3.807
$FEF_{25-75\%}$ = 1.780
Vext = 0.094 4.7%
Time zero defect



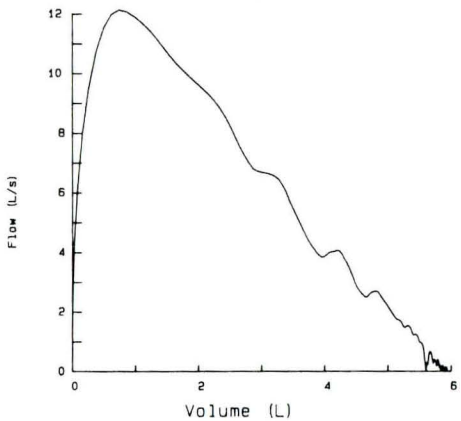


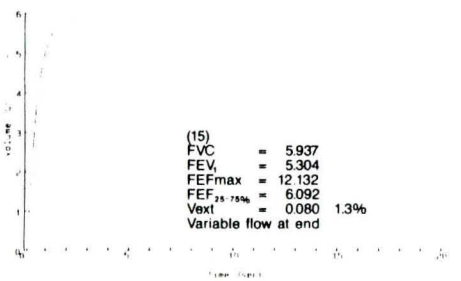
(13)
FVC = 4.896
FEV_1 = 3.834
FEFmax = 5.207
$FEF_{25-75\%}$ = 3.677
Vext = 0.460 9.4%
Time zero defect



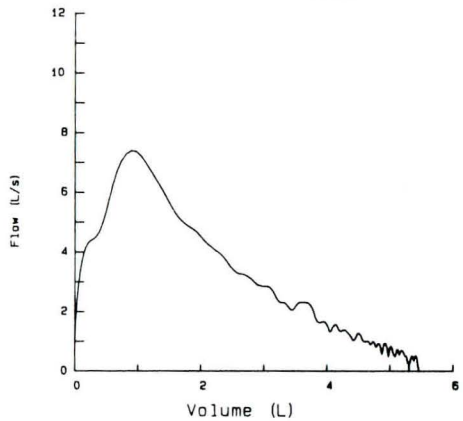


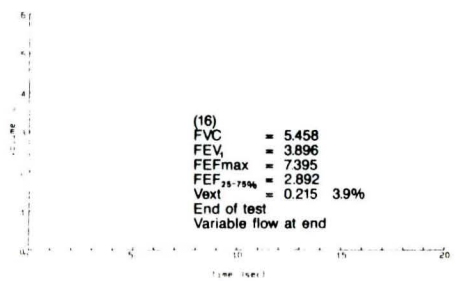
(14)
FVC = 3.786
FEV_1 = 3.053
FEFmax = 4.368
$FEF_{25-75\%}$ = 3.122
Vext = 0.338 10.2%
Time zero defect



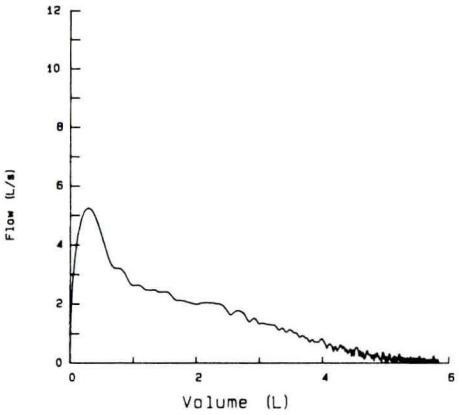


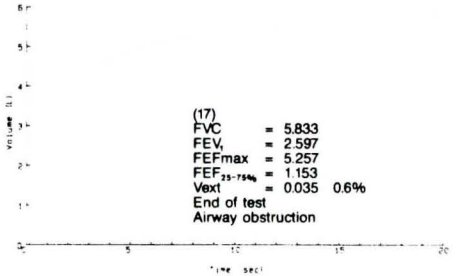
(15)
FVC = 5.937
FEV_1 = 5.304
FEFmax = 12.132
$FEF_{25-75\%}$ = 6.092
Vext = 0.080 1.3%
Variable flow at end



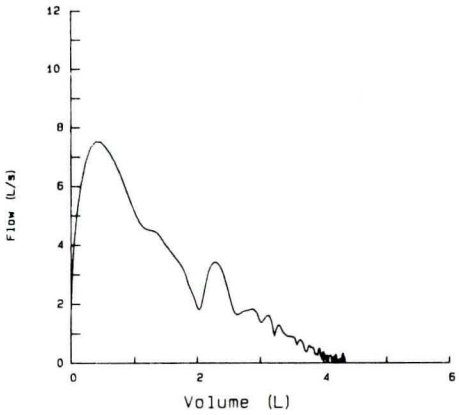


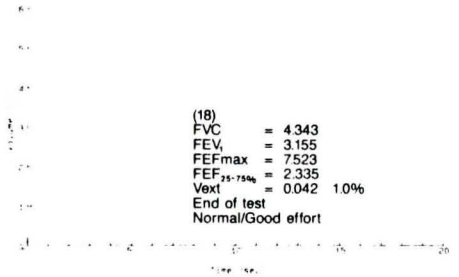
(16)
FVC = 5.458
FEV_1 = 3.896
FEFmax = 7.395
$FEF_{25-75\%}$ = 2.892
Vext = 0.215 3.9%
End of test
Variable flow at end



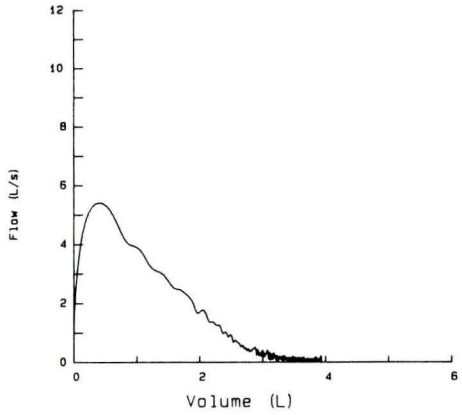


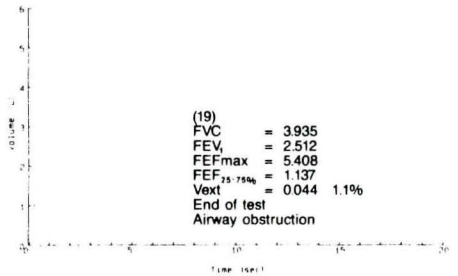
(17)
FVC = 5.833
FEV_1 = 2.597
FEFmax = 5.257
$FEF_{25-75\%}$ = 1.153
Vext = 0.035 0.6%
End of test
Airway obstruction



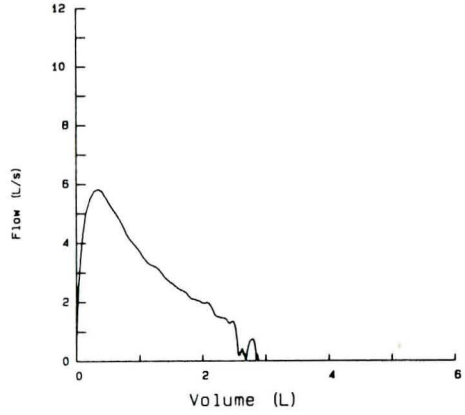


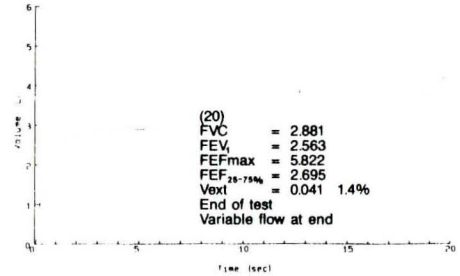
(18)
FVC = 4.343
FEV_1 = 3.155
FEFmax = 7.523
$FEF_{25-75\%}$ = 2.335
Vext = 0.042 1.0%
End of test
Normal/Good effort



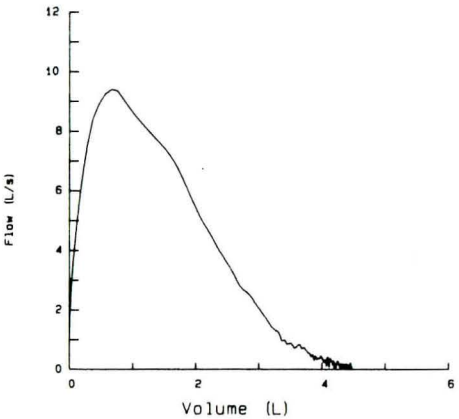


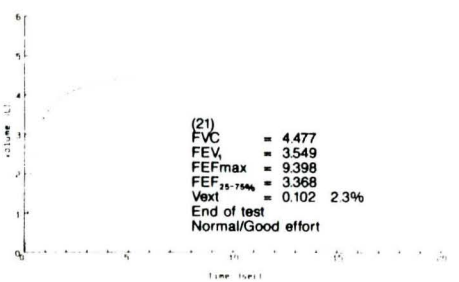
(19)
FVC = 3.935
FEV_1 = 2.512
FEFmax = 5.408
$FEF_{25-75\%}$ = 1.137
Vext = 0.044 1.1%
End of test
Airway obstruction



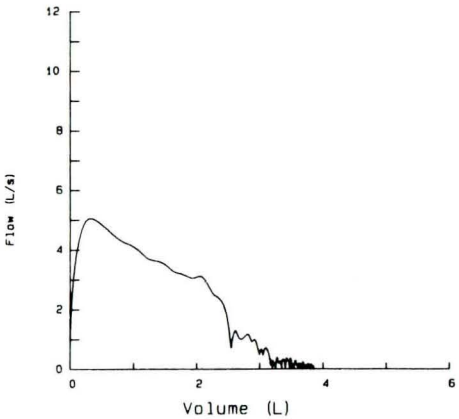


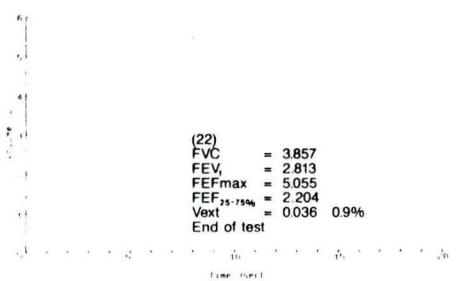
(20)
FVC = 2.881
FEV_1 = 2.563
FEFmax = 5.822
$FEF_{25-75\%}$ = 2.695
Vext = 0.041 1.4%
End of test
Variable flow at end



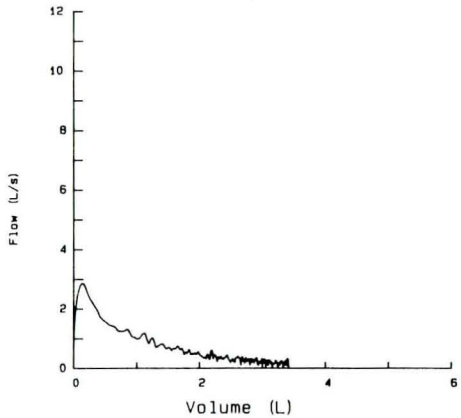


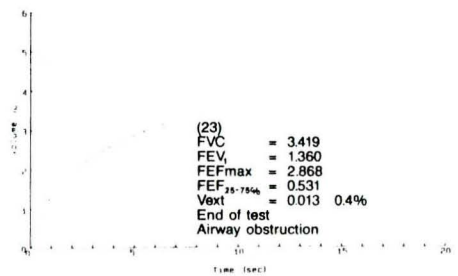
(21)
FVC = 4.477
FEV_1 = 3.549
FEFmax = 9.398
$FEF_{25-75\%}$ = 3.368
Vext = 0.102 2.3%
End of test
Normal/Good effort



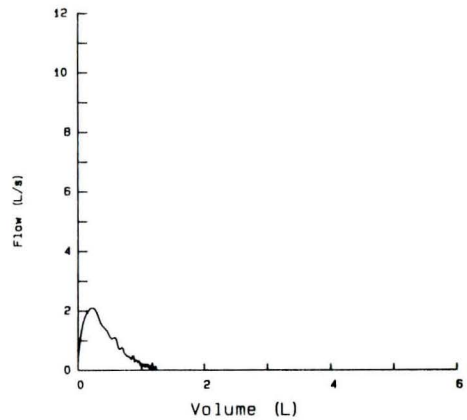


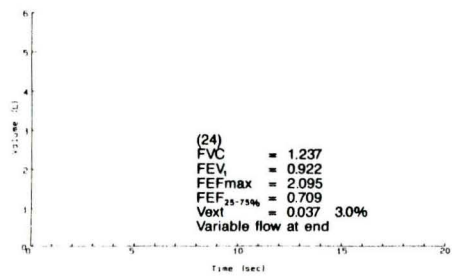
(22)
FVC = 3.857
FEV_1 = 2.813
FEFmax = 5.055
$FEF_{25-75\%}$ = 2.204
Vext = 0.036 0.9%
End of test





(23)
FVC = 3.419
FEV_1 = 1.360
FEFmax = 2.868
$FEF_{25-75\%}$ = 0.531
Vext = 0.013 0.4%
End of test
Airway obstruction





(24)
FVC = 1.237
FEV_1 = 0.922
FEFmax = 2.095
$FEF_{25-75\%}$ = 0.709
Vext = 0.037 3.0%
Variable flow at end