American Thoracic Society
MEDICAL SECTION .OF THE AMERICAN LUNG ASSOCIATION

Standardization of Spirometry

1994 Update

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, NOVEMBER 11, 1994

CONTENTS

The first American Thoracic Society (ATS) Statement on the Standardization of Spirometry was published 15 yr ago and was based on the Snowbird Workshop held in 1979 (1). This initial statement was updated in March 1987 (2) after 8 yr of practical experience with the initial recommendations. The state of the art of spirometry has continued to advance as a result of scientific studies that have provided additional data relating to performance of spirometry. The use of computers for spirometry measurement has become even more commonplace. New statements by the ATS (3) and the European Respiratory Society (4) also underscore the need to update the ATS statement on spirometry. This revision of the standards for spirometry reflects the changes in clinical emphasis and in available technology since the 1987 ATS spirometry update (2) was published. The changes in clinical emphasis and equipment include:

- The strong emphasis on the use of portable peak flow meters to monitor lung function in asthmatics by the National Heart, Lung, and Blood Institute's Asthma Education Program(5), the International Asthma Management Project (6), the British Thoracic Society (7), and others.
- The corresponding development of many new model peak flow monitoring devices, some purely mechanical and some electronic
- A better understanding of the complexities of correcting spirometric values to BTPS conditions.

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- A greater appreciation of the importance of the technicians and procedures in achieving good spirometric results.
- An increased concern about the risk of transmission of infectious diseases during pulmonary function testing.

We have responded to these changes by:

- Separating the standards for laboratory or diagnostic spirometers from those of devices designed to be used primarily as monitors.
- Adding BTPS testing to the testing of spirometers.
- Adding a section on performance of slow vital capacity.
- Strengthening and updating the procedural aspects of quality control, including an appendix with sample spirograms.
- Adding a section on hygiene and infection control.

A central goal of any guideline or standardization document is to improve performance and thus decrease the variability of laboratory testing. In 1979 **(1)**, and again in 1987 **(2)**, the perception was that the major source of variability was instrumentation. More recently, instrumentation has improved to a point where other sources of variability can be identified, in particular, procedural problems. In 1991, the **ATS** Statement on Lung Function Testing: Selection of Reference Values and Interpretation Strategies (3) stated: "The largest single source of within-subject variability is improper performance of the test." More recently, **Enright** and coworkers (8) have shown a positive impact of an extensive quality control program on spirometric results. As a consequence, there is an effort in the present statement to address issues of test performance and quality control.

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

Spirometry is a medical test that measures the volume of air an individual inhales or exhales as a function of time Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health. Like the simple measurement of blood pressure, it does not suffice in certain situations where more extensive testing is warranted. Spirometric results correlate well with morbidity and life expectancy. Spirometry is used to affect decisions about individual patients, including the nature of the defect, its severity, and the response to therapy. Table 1 lists some of the potential indications for spirometry.

Results from tests based on spirometric maneuvers can have an important effect on a person's lifestyle, standard of living, and future treatment (10). Similarly, accurate and precise 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 (11).

Maximizing the clinical usefulness of spirometry depends on a number of steps, ranging from equipment selection to interpretation, and ultimately involves clinical assessment. Figure 1 is a flow diagram of these steps.

The first step is establishing equipment performance criteria. The Snowbird Workshop **(1)**, 1987 Update **(2)**, and this update give recommendations for equipment used for spirometry.

The second step in the process involves validation that the spirometer design meets the minimum recommendations through the testing of a representative device. Detailed methods for performing the validation testing are outlined later in this statement. The ATS makes equipment recommendations but does not act as a certifying agency to verify compliance with these standards. Spirometer users should carefully select equipment that meets the **ATS** recommendations to assure that spirometry testing can be done accurately. Before purchasing a spirometer, it is wise to: **(1)** ask the manufacturer to provide summary data that demonstrates that the device being considered meets or exceeds **ATS** recommendations, or (2) review results of spirometry testing from independent testing laboratories. This statement does not mandate testing by an independent laboratory. There are many calibrated computer-driven syringes available. When an independent laboratory is not used, manufacturers should make the testing protocol, the raw data, and the summary data available to potential customers for their review..

Even after spirometers have been found to meet **ATS** recommendations, they (like other mechanical, electrical, or computer equipment) must be routinely checked for performance quality.

TABLE 1

INDICATIONS FOR SPIROMETRY*

- Diagnostic
  - To evaluate symptoms, signs, or abnormal laboratory tests
    - -Symptoms: dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain
    - -Signs: diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles
    - -Abnormal laboratory tests: hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs
  - To measure the effect of disease on pulmonary function
  - To screen individuals at risk of having pulmonary diseases
    - -Smokers
    - -Individuals in occupations with exposures to injurious substances
    - -Some routine physical examinations
  - To assess preoperative risk
  - To assess prognosis (lung transplant, etc.)
  - To assess health status before enrollment in strenuous physical activity programs
- Monitoring
  - To assess therapeutic interventions
    - -Bronchodilator therapy
    - -Steroid treatment for asthma, interstitial lung disease, etc.
    - -Management of congestive heart failure
    - -Other (antibiotics in cystic fibrosis, etc.)
  - To describe the course of diseases affecting lung function
    - -Pulmonary diseases
      - Obstructive airways diseases
      - Interstitial lung diseases
    - -Cardiac diseases
      - Congestive heart failure
    - -Neuromuscular diseases
      - Guillain-Barre Syndrome
  - To monitor persons in occupations with exposure to injurious agents
  - To monitor for adverse reactions to drugs with known pulmonary toxicity
- Disability/Impairment Evaluations
  - To assess patients as part of a rehabilitation program
    - -Medical
    - -Industrial
    - -Vocational
  - To assess risks as part of an insurance evaluation
  - To assess individuals for legal reasons
    - -Social Security or other government compensation programs
    - -Personal injury lawsuits
    - -Others
- Public Health
  - Epidemiologic surveys
    - -Comparison of health status of populations living in different environments
    - -Validation of subjective complaints in occupational/environmental settings
  - Derivation of reference equations

* Adapted from reference 9.

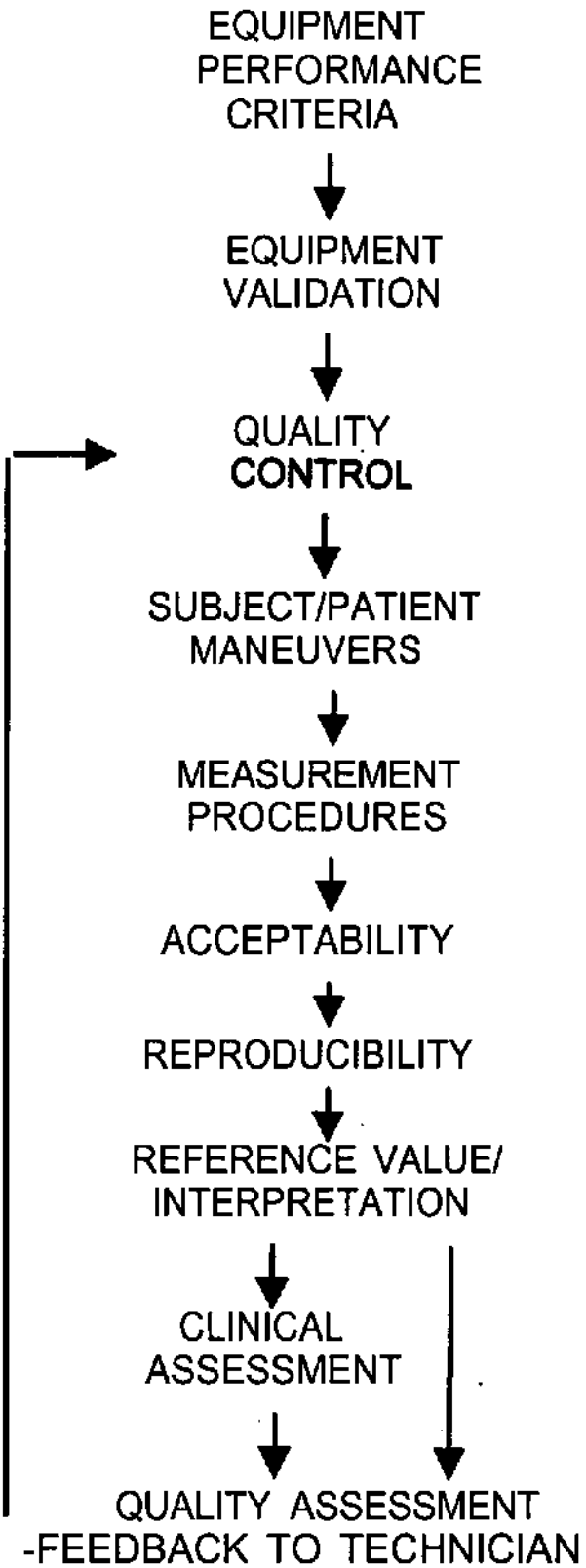


Figure 1. Spirometry standardization steps.

Recommendations for spirometer quality control have been developed by the ATS and are summarized in this statement.

Spirometry is an effort-dependent maneuver that requires understanding, coordination, and cooperation by the patient-subject, who must be carefully instructed. Thus, procedural recommendations are important components of testing. Part of the recommendation is to obtain a sufficient number of maneuvers of adequate quality and then determine if these acceptable maneuvers are reproducible, implying that maximal effort has been achieved. Once spirometry maneuvers have been performed, data are either measured by hand or computer. Measurement procedures are included in this article to help assure that uniform methods are used and comparable results are obtained. These recommendations include considerations such as using "back extrapolation" for determining the "start-of-test" time (zero point) for measures such as FEV_1 and the criteria to determine the end of the expiratory maneuver. Instruments that provide feedback to the technician in the form of checks on the adequacy of the data are clearly desirable.

The interactions between technicians and subjects are crucial to obtaining adequate spirometry, since it is such an effort-dependent maneuver. Technicians must be trained and must maintain a high level of proficiency to assure optimal results.

The spirogram tracing must be carefully scrutinized for quality. Recommendations about quality, acceptability, and reproducibility of test results are presented, as well as examples of unacceptable maneuvers (see APPENDIX A). After adequate results are obtained, they are usually compared with reference values to make an assessment (interpretation) of the results. The ATS 1991 Statement on Lung Function Testing: Selection of Reference Values and Interpretative Strategies provides guidelines for selecting reference values and interpreting the results. Clinical assessment should be an integral part of spirometry. Results obtained from spirometry are only one part of the much more complex patient-care relationship or research study analysis. It is the responsibility of the laboratory director to provide adequate quality control procedures to assure that an attempt to meet these recommendations and criteria has been made

In both the original ATS statement on spirometry and the 1987 update, a rationale was provided for each recommendation. Since many of these recommendations and their rationales have not changed since the original statements, the reader is referred to the 1987 update (2) for the rationales concerning less controversial recommendations.

DEFINITIONS

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 (12).

Accuracy and precision are important terms in equipment recommendations and warrant some definition. Accuracy error is the systematic difference between the "true" and the measured value The accuracy of a spirometer system depends on a number of factors, including linearity and frequency response of the system or processor, sensitivity to environmental conditions, calibration, and adequacy of correction factors. Its precision depends on the signal/noise ratio and on the resolution (i.e., the minimal detectable volume or flow). Precision error, usually denoted reproducibility, is the numerical difference between successive measurements (4). For example, if a volume spirometer's pen is not on zero but at 1. L, all volumes read directly from the graph would be overread by 1 L. The accuracy error would be 1 L, since the measured volume would read 3 L when the true volume is 2 L. However, the precision of the spirometer would remain unchanged, as the spirometer would consistently read 3 L each time 2 L is injected into the spirometer. For some applications, eg., peak expiratory flow (PEF) monitoring, precision is more important than accuracy.

In several sections of this document, the terms "open circuit" and "closed circuit" technique are used. The term "open circuit" spirometry refers to the method of conducting spirometry where the subject takes a full inspiration before inserting the mouthpiece to perform the test. In this approach, the subject does not inhale from the spirometer or potentially contaminated flow sensor. The term "closed circuit" spirometry refers to the method of conducting spirometry where the subject is attached to the mouthpiece before the inspiration is begun, and often several tidal breaths are obtained. In this approach, the subject does inhale from the spirometer. There are advantages and disadvantages to both of these approaches and both are recommended procedures. For example, an advantage of the closed circuit technique is that it allows measurement of expiratory reserve volume (ERV), tidal volume (TV), and inspiratory flows.

Previous recommendations (1, 2) treated all spirometers alike whether used for clinical, diagnostic, or epidemiologic purposes. However, a new class of device has been added for monitoring purposes. Monitoring devices (portable peak flow meters, etc.) have separate recommendations from diagnostic spirometers for the recorder/display requirements as well as the accuracy requirements. In addition, precision requirements have been added for monitoring devices. Recommendations concerning monitoring devices are identified in this statement by the notation, 'Monitoring." We do *not* recommend the use of monitoring devices for diagnostic purposes in the traditional diagnostic setting where one is comparing a measured value with a reference value. In this setting, monitoring instruments are likely to be inadequate because: (1) they may be less accurate than diagnostic instruments; (2) they usually cannot be calibrated or checked to assure their performance; (3) their graphical displays may be missing or inadequate to allow proper evaluation of the subject's effort and overall test quality; and (4) current PEF standards of ± 10% allow models of instruments to vary by up to 20%, adding variability to reference values derived when a monitoring instrument is used. However, monitoring instruments may be useful in diagnosing excessive variability in spirometric parameters because they tend to have excellent precision.

EQUIPMENT RECOMMENDATIONS

Accurate results require accurate equipment. Spirometer equipment recommendations apply to all diagnostic spirometers whether used for clinical or epidemiologic purposes. Instrumentation recommendations should be followed to provide accurate spirometric data and information that are comparable from laboratory to laboratory and from one time period to another (1). The accuracy of a spirometry 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 can affect the accuracy of the results. For example, if the BTPS correction factor is in error, an accurate, uncorrected FVC will be corrupted when the factor is applied.

Recommendations are first provided for diagnostic spirometers, followed by recommendations for monitoring devices under the subheading, "Monitoring." For example, the equipment recommendations for diagnostic spirometry are summarized in Table 2 and for monitoring devices in Table 3. Spirometers are not required to measure all the following parameters but must meet the recommendations for those parameters that are measured. Accuracy and precision recommendations apply over the entire volume range of the instrument.

TABLE 2

MINIMAL RECOMMENDATIONS FOR DIAGNOSTIC SPIROMETRY*

Test	Range/Accuracy (BTPS)	Flow Range (L/s)	Time (s)	Resistance and Back Pressure	Test Signal
VC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	30		3-L Cal Syringe
FVC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	15	Less than 1.5 cm H_2O/L/s	24 standard waveforms 3-L Cal Syringe
FEV_1	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	1	Less than 1.5 cm H_2O/L/s	24 standard waveforms
Time zero	The time point from which all FEV_t measurements are taken			Back extrapolation	
PEF	Accuracy: ± 10% of reading or ± 0.400 Us, whichever is greater Precision: ± 5% of reading or ± 0.200 Us, whichever is greater	zero to 14		Same as FEV_1	26 flow standard waveforms
$FEF_{25-75\%}$	7.0 L/s ± 5% of reading or ± 0.200 Us, whichever is greater	± 14	15	Same as FEV_1	24 standard waveforms
$\dot{V}$	± 14 Us ± 5% of reading or ± 0.200 Us, whichever is greater	zero to 14	15	Same as FEV_1	Proof from manufacturer
MVV	250 Umin at TV of 2 L within ± 10% of reading or ± 15 Umin, whichever is greater	± 14 ± 3%	12 to 15	Pressure less than ± 10 cm H_2O at 2-L TV at 2.0 Hz	Sine wave pump

* Unless specifically stated, precision requirements are the same as the accuracy requirements.

Recommendation: **Vital Capacity (VC)**

VC = The maximal volume of air exhaled from the point of maximal inhalation or the maximal volume of air inhaled from a point of maximal exhalation can be measured with a slow exhalation or inhalation, respectively. This was previously called the "slow" vital capacity and has been better described as the "relaxed vital capacity" (13). The VC is expressed in liters (BTPS). BTPS is body conditions: normal body temperature (37° C), ambient pressure, saturated with water vapor. When the **rebreathing** technique is used, an oxygen supply may be provided and carbon dioxide absorbed to account for oxygen consumption and the production of carbon dioxide In this case, the oxygen supply must account for the total oxygen consumed, maintaining the volume constant at functional residual capacity. If this is not done properly, an incorrect VC could be obtained. Because of this potential error, the rebreathing technique with the absorption of carbon dioxide is discouraged as a technique when only VC is to be measured.

Rationale. In some subjects, a slow or relaxed vital capacity provides a more accurate determination of the vital capacity than those obtained with a forced exhalation. Forced expiratory volumes are usually lower than those obtained with a slow exhalation in subjects with airways obstruction and in older subjects. With severe airways obstruction, VC values may be larger than FVC values by as much as 1 L.

TABLE 3

MINIMAL RECOMMENDATIONS FOR MONITORING DEVICES

Requirement	FVC & FEV_t (BTPS)	PEF (BTPS)
Range	High: 0.50 to 8 L Low: 0.5 to 6 L	High: 100 Umin to ≥ 700 Umin but ≤ 850 Umin Low: 60 Umin to ≥ 275 Umin but ≤ 400 Umin
Accuracy	± 5% of reading or ± 0.100 L, whichever is greater	± 10% of reading or ± 20 L/min, whichever is greater
Precision	± 3% of reading or ± 0.050 L, whichever is greater	Intradevice: ≤ 5% of reading or ≤ 10 Umin, whichever is greater Interdevice: ≤ 10% of reading or ≤ 20 Umin, whichever is greater
Linearity	Within 3% over range	Within 5% over range
Graduations	Constant over entire range High: 0.100 L Low: 0.050 L	Constant over entire range High: 20 Umin Low: 10 Umin
Resolution	High: 0.050 L Low: 0.025 L	High: 10 Umin Low: 5 Umin
Resistance	Less than 2.5 cm H_2O/L/s, from zero to 14 Us	Less than 2.5 cm H_2O/L/s, from zero to 14 Us
Minimal detectable volume	0.030, L	
Test Signal	24 standard volume-time, waveforms	M-standard flow-time waveforms

High = high range and low = low range devices.

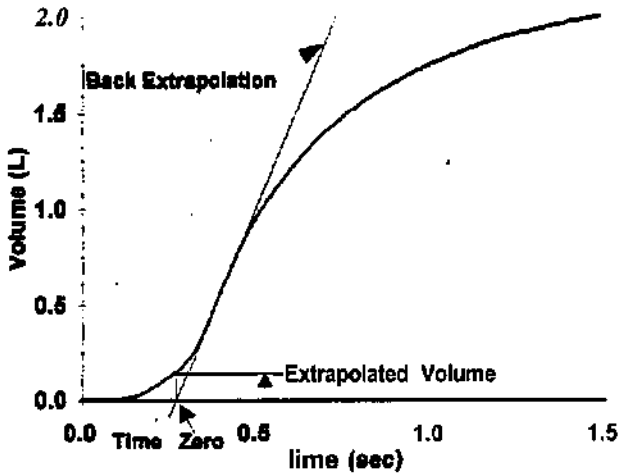


Figure 2. Typical subject waveform of a volume-time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = Vext.

For measurements of VC, the spirometer must be capable of accumulating volume for *at least* 30 s. Spirometers must be capable of measuring volumes of *at least* 8 L (BTPS) with flows between zero and 14 L/s with a volume accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater.

Recommendation: Forced Vital Capacity (WC)

FVC = Maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration, i.e., vital capacity performed with a maximally forced expiratory effort, expressed in liters (BTPS).

The diagnostic spirometer must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The 8-L range requirement applies to newly manufactured instruments; existing spirometers with a 7-L range may continue to be used. The spirometer must be capable of accumulating volume for *at least* 15 s, although longer times are recommended.

Monitoring. Monitoring devices must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. The device must be capable of accumulating volume for *at least* 15 s.

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 second of FVC, expressed in liters (BTPS).

Measuring FEV_t requires a spirometer capable of measuring volumes of at *least* 8 L. The spirometer must measure FEV_t within an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The start-of-test for purposes of timing must be determined by the back extrapolation method (1, 14, 15) or a method shown to be equivalent (Figure 2). For manual measurements, the back extrapolation method traces back from the steepest slope on the volume-time curve (Figure 2) (15, 16). For computer methods of back extrapolation, we recommend using the largest slope averaged over an 80-ms period (17). The total resistance to airflow at 14.0 L/s must be less than 1.5 cm H_2O/L/s. The total resistance must be measured including any tubing, valves, pre-filter, etc., that may be inserted between the subject and the spirometer. *Since some devices may exhibit changes in resistance due to* water vapor condensation, resistance requirements must be met under BTPS conditions when up to eight successive FVC maneuvers are performed in a 10-min period.

Monitoring. The monitoring device must be capable of measuring FEV_t up to *at least* 8 L (BTPS) with an accuracy of at least ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices for FEV_t must be at *least* ± 3% of reading or ± 0.050 L, whichever is greater. Resistance should be less than 2.5 cm H_2O/L/s and the start-of-test requirement is the same as for diagnostic spirometry.

Recommendation: PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/second (BTPS).

Measuring PEF requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 0.300 L/s, whichever is greater. Intra-instrument precision must be less than 5% of reading or 0.150 L/s, whichever is greater. Interdevice precision must be less than 10% or 0.300 L/s, whichever is greater.

The following or an equivalent method can be used in the determination of FEF, or PEF for volume-time curves. However, the method used to derive PEF may depend on the measuring instrument (18), and the final determination of compliance should be determined through testing using the standard waveforms (26 flow-time waveforms, APPENDIX D), with PEF derived from the flow-time waveform (Table D1, column 2).

Determination of PEF can be performed from the volume-time data by using a parabolic curve-fitting algorithm, which smooths the data using a least squares parabolic fit to a 40- or 80-ms segment (np = 2 or 4) of the volume-time curve, or:

$$\text{flow}(n) = \frac{\sum_{j=-np}^{np} j \cdot \text{vol}(n+j)}{2.h.\sum_{j=1}^{np} jj} \qquad \text{PEF} = \text{Max (flow)}$$

where flow = an array of flow values from start to end of test; n = index of current flow data point (n = [np + 1] to index value of end of test); vol = an array of volume values; j = an index value as indicated in the equation; h = the time between samples (0.01 s in this example); np = the number of data points (for a 40-ms segment, np = 2 and for an 80-ms segment, np = 4); and PEF is the maximum value observed in the array flow.

Rationale. Using the 26 flow-time waveforms to define PEF is a change from the ATS 1987 Update. The PEFs for the 24 standard volume-time waveforms and the FEF_{max} described in the 1987 ATS Spirometry Update used the above algorithm with an 80-ms interval. Manufacturers, through the use of mechanical simulators and the 24 standard volume-time waveforms, have been implementing this or equivalent methods through their attempts to derive PEFs similar to those defined by the 24 standard volume-time waveforms.

In addition, the National Asthma Education Program (NAEP) (5) has adopted ATS standard volume-time waveform number 24 as their standard for portable PEF meters. Hankinson and Crapo (18) have shown that reducing the time interval in the above equation from 80 to 40 ms results in as much as an 8% higher PEF for two of the 24 standard volume-time waveforms and a

5% higher PEF value for waveform number 24. Regardless of this apparent change, PEF is a flow parameter and therefore should be defined based on a flow-time waveform rather than a volume-time waveform (i.e., waveform number 24). The final determination of compliance should be determined through testing using the standard 26 flow-time waveforms (APPENDIX D) and the PEF derived from the flow-time curve (Table D1, column 2). This approach allows all of an instrument's characteristics to be considered, rather than only the PEF computational algorithm. Because PEF is more variable than FVC and FEV, and because of the confusion surrounding PEF definition, a relatively large ± 10% accuracy requirement was allowed.

Recommendation (Monitoring): PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/minute (BTPS).

Monitoring PEF also requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz and a resistance less than 2.5 cm $H_2O/L/s$ with flows up to 14 L/s. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 20 L/min, whichever is greater, with PEFs between 60 to 400 L/min for children and from 100 to 850 L/min for adults. The lower limit range of the instrument must be less than or equal to 60 L/min for children and 100 L/min for adults. The upper limit range must be greater than or equal to 275 L/min but less than 400/L min for children and greater than or equal to 700 L/min but less than 850 L/min for adults. If manual reading of the instrument is used, the reader must be able to resolve at least 5 L/min for low range (children) and 10 L/min for high range (adults) (marked PEF intervals [graduations] no greater than 10 L/min for low range and 20 L/min for high range). Intra-instrument precision must be less than or equal to 5% of reading or 10 L/min, whichever is greater. Interdevice precision must be less than 10% or 20 L/min, whichever is greater. Data on the instrument's life span and durability must be provided by the manufacturer, specified as the typical life span over which the instrument will satisfy the requirements of this section.

In addition to the above requirements, PEF measuring devices must also provide a method of reporting values at BTPS. For portable PEF meters, BTPS correction may be accomplished by limiting the environmental operational range for the instrument in terms of barometric pressure (altitude) and ambient temperature. Portable PEF meters must meet the accuracy and precision requirements above, given the range of environmental conditions encountered with typical use. A 10% accuracy requirement, higher than the 5% for other flows, is recommended to allow for potential BTPS correction complications associated with PEF measurements. Besides providing a method of correcting PEF values to BTPS, the instrument's manufacturer must also provide a correction for the effects of altitude or other environmental conditions as appropriate.

A package insert must be provided with each portable PEF meter containing *at least: (1) clear* instructions (with illustrations) for use of the instrument in simple terms that are understood by the general public; (2) instructions concerning maintenance of the instrument and methods to recognize when it is malfunctioning; and (3) appropriate actions to be taken when PEF readings change appreciably (i.e., whom to contact).

Rationale. Concerning the requirement of a flat frequency response up to 12 Hz, Lemen and coworkers (19) have shown that the mean highest frequency (HF) with significant amplitude content was 5.06 Hz in healthy individuals and 6.4 Hz in patients and smokers. They concluded that flow measuring devices should have a frequency response that is flat up to 12 Hz. Peslin and coworkers (20) found a slightly higher HF of about 10 Hz in healthy males and 7.5 Hz in female subjects. In addition, current mechanical waveform-generating equipment generally cannot accurately produce waveforms with frequency content above 12 Hz. The accuracy recommendation is less stringent for PEF than for the FVC and FEV, (10% versus 5%) because of the higher within- and between-subject variabilities associated with PEF measurements and because of testing instrument limitations. The PEF instrument precision and intra-instrument variability recommendations are lower (5%) than the accuracy and inter-instrument variability requirements (10%) because of the need for low instrument variability in the routine use of PEF meters for serial measurements. In addition, several studies have shown PEF meters to be much more precise than accurate (21-23). These recommendations are also similar to those of the NAEP (5). The range recommendations are made with the understanding that PEF measurements are often made using portable PEF meters. With these meters, reading resolution (number of graduations) must be balanced against the range of the meter (upper and lower meter limits). Therefore, different instrument ranges for children and adults are appropriate. The range recommendations for children are not intended to preclude the use of an instrument with adult ranges if the instrument meets the resolution requirements (ease of reading) for children.

An instrument's life span and durability are difficult to determine and will be specific to an instrument. However, portable peak flowmeters are often used for extended periods of time. Therefore, the instrument manufacturer must provide information on the typical life span of their instrument as well as cleaning and other maintenance instructions. The package insert requirements recommended by the NAEP (5) are similar to those recommended in this statement.

Recommendation: $FEF_{25-75\%}$

$FEF_{25-75\%}$ = Mean forced expiratory flow during the middle half of the FVC. Formerly called the maximal mid-expiratory flow (MMEF), expressed in liters/second (BTPS).

The $FEF_{25-75\%}$ must be measured with an accuracy of *at least* ± 5% of reading or ± 0.200 L/s, whichever is greater, over a range of up to 7 L/s. The $FEF_{25-75\%}$ must be measured on a system that meets diagnostic FVC recommendations.

Recommendation: Flow ($\dot{V}$)

$\dot{V}$ = Instantaneous forced expiratory flow (except for PEF), expressed in liters/second (BTPS).

Flow may be measured electronically or manually from a flow-volume display with adequate size for hand measuring. Where flow-volume loops or other uses of flow are made, with flow in the range of -14 to 14 L/s, the flow must be measurable to within ± 5% of reading or ± 0.200 L/s, whichever is greater.

Recommendation: Forced Expiratory Time (FET%)

FET% = Time from the back-extrapolated "time zero" until a specified percentage of a maneuver's FVC is exhaled, expressed in seconds. For example, FET95% would be the time required to reach 95% of a maneuver's FVC. See APPENDIX A for FET% examples. FET100% would be defined as the time required to reach the FVC or the time at which the volume was observed to be at its highest level. For maneuver quality assessment purposes, the reporting of the FET99% (24) or FET100% is encouraged but not mandated. Also, the FET25–75% (mid-expiratory time) may be a useful indicator of diminished flow when VC is decreased and may be less dependent on body or lung size than other flow parameters (25).

Recommendation: Forced Inspiratory Vital Capacity Maneuvers

These maneuvers are inspiratory vital capacity maneuvers per-

formed with maximally forced effort from a position of maximal expiration to a position of maximal inspiration. Roth volume and flow parameters are measured, which roughly correspond (except for direction) to those from the FVC maneuver. Volume measurements are expressed in liters (BTPS), flow measurements in liters/second (BTPS).

Rationale. Forced inspiratory maneuvers are useful in diagnosing and monitoring upper airway obstruction. They are usually performed either preceding or following the FVC maneuver but may be performed separately. Elderly or ill patients often have difficulty performing forced inspiratory and expiratory maneuvers as part of the same effort. Forced inspiratory maneuvers require the use of one of the closed circuit techniques.

For measurements of forced inspiratory spirometric parameters diagnostic spirometers must meet the corresponding range, accuracy, and precision recommendations specified for diagnostic spirometry systems (Table 2).

Recommendation: Maximal Voluntary Ventilation (MW)

MVV = The volume of air exhaled in a specified period during repetitive maximal respiratory efforts, expressed in liters/minute (BTPS).

When a spirometer is used for measuring MVV, it must have an amplitude-frequency response that is flat within ± 10% from zero to 4 Hz at flow rates of up to 12 L/s over the volume range. The time for exhaled volume integration or recording must be no less than 12 s nor more than 15 s (26). The indicated time must be accurate to within ± 3%. The MVV must be measured with an accuracy of ± 10% of reading or ± 15 L/min, whichever is greater.

General Background: Spirometry Recorders/Displays

Paper records or graphic displays of spirometry signals are *required* and are used for:

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 manual measurements (for example, measurement of FEV, using back extrapolation by comparing computer- and manually determined FEV,).
3. Manual measurement function-when waveforms are to be manually measured for spirometric parameters (FVC, FEV_t, etc) in the absence or failure of a computer.

With the continued advances in computer technology, there are many different ways to display and record spirometric waveforms. The committee continues to encourage use of computer technology.

Paper recorder requirements are the same regardless of the purpose, diagnostic, validation, or manual measurement. If no paper recorder or printer is available, 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.

Recommendation: Display of VC Maneuver

Either "open" or "closed" circuit technique may be used to measure the VC maneuver. Although the open circuit technique may be preferred because of hygiene concerns, this technique does not allow the monitoring (display) of the inhalation to TLC and therefore is less than optimum. Regardless of whether the open or closed circuit technique is used, a display of the entire VC maneuver must be provided. The maximal expiratory volume must be assessed to determine whether the subject has obtained a plateau in the expiratory effort. Subjects with airways obstruction usually exhibit different shaped curves at the end of their expiratory maneuver-a slope showing the nonhomogeneous emptying of lung units. Some patients with severe airways obstruction are not able to return to the level of FRC due to gas trapping (see APPENDIX A, VC maneuvers). In addition, important differences between inspiratory (IVC) and expiratory (EVC) maneuvers may be observed in patients with airways obstruction (27). For systems using a closed circuit with carbon dioxide absorption, a'volume-time display is needed to verify baseline end-expiratory level (functional residual capacity or FRC). The graph should indicate the starting volume to evaluate the correct positioning of FRC.

Recommendation: Display of NC Maneuver

Displays using flow versus volume instead of volume versus time expand the initial portions (first 1-2 s) of the forced vital capacity maneuver. Since this portion of the maneuver, particularly the peak expiratory flow, is correlated with the pleural pressure during the maneuver, the flow-volume display is useful to assess the magnitude of effort during the initial portions of the maneuver. Overlaying a series of flow-volume curves registered at apparent TLC (maximal inhalation, which may not be true TLC) is helpful in detecting a submaximal effort that may result in a large though nonreproducible FEV, as a consequence of negative effort dependence (28).

Unlike the flow-volume curve display, display of the FVC maneuver as a volume-time graph expands the terminal portions of the maneuver. Therefore, the volume-time display is useful in assessing the duration of effort and whether a plateau is achieved. Where spirometry may need to be reviewed by independent agencies, a volume-time tracing of sufficient size allows independent measurement and calculation of parameters from the FVC maneuvers. Overlaying a series of volume-time curves aligned at back-extrapolated *time zero or flow-volume curves* aligned at TLC is useful in evaluating reproducibility and submaximal efforts. For optimal quality control, both flow-volume and volume-time displays are useful and strongly encouraged. See APPENDIX A for illustrations of volume-time and flow-volume displays.

Recommendation: VC and NC Maneuver Volume and Time Scales

Volume scale: When a volume-time curve is plotted or displayed, the volume scale must be *at least:* 10 mm/L (BTPS).

Time scale: *at least* 2 cm/s; larger time scales are preferred (at least 3 cm/s) when manual measurements are to be made (1, 29, 30). When the volume-time plot is used in conjunction with a flow-volume curve (both display methods are provided for interpretations and no hand-measurements are performed), the time scale requirement is reduced to 1 cm/s from the usually required minimum of 2 cm/s. This exception is allowed because, in these circumstances, the flow-volume curve can provide the means for quality assessment during the initial portion of the FVC maneuver. The volume-time curve can be used to evaluate the terminal portion of the FVC maneuver, and the time scale is less critical. For display of the slow VC, the volume scale may also be reduced to 1 cm/L and the time scale to 0.5 cm/s.

Recommendation: Flow-Volume Curves

When a flow-volume curve is plotted or displayed, exhaled flow must be plotted upwards and exhaled volume towards the right.

TABLE 4

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

Parameter	Resolution Required	Scale Factor
Volume	0.025 L	10 mm/L
Flow	0.100 L/s	5 mm/L/s
Time	0.20 s	2 cm/s

A 2:1 ratio must be maintained between the flow and volume scales, e.g., 2 L/s of flow and 1 L of exhaled volume must be the same distance on their respective axes. The flow and volume scales must be at *least* as shown in Table 4.

Rationale. It was the committee's unanimous opinion that the previous diagnostic recorder requirements of 5 mm/L and 1 cm/s have proven inadequate for judging the quality of an expiratory effort, eg., terminal events are not detectable (APPENDIX A). For certain applications (for example, for disability determination and legal cases), diagnostic size displays are clearly not adequate (26, 30). The U.S. Cotton Dust standard requires "... tracings must be stored and available. for recall and must be of sufficient size that manual measurements may be made ..." (31). Also, users will customarily not be able to verify accuracy and stability of spirometers by themselves in the absence of an adequate paper recording.

Recommendation: Correction to BTPS

This statement recommends that diagnostic spirometric studies not be conducted with ambient temperatures less than 17° C or more than 40° C. In part, the rationale for this recommendation is based on problems with finite cooling times of gases in volume-type spirometers (32-34) and the problems of estimating BTPS correction factors for flow devices (35-37). When a subject performs an FVC maneuver, the air leaving the lungs and entering the spirometer is at approximately 33 to 35° C (38, 39) and is saturated with water vapor. Most volume-type spirometers assume instantaneous cooling of the air as it enters the spirometer. However, this is not always the case, and an error in FEV_t can occur due to the incorrect assumption of instantaneous cooling of the air. For capillary and screen pneumotachometers, the gain is dependent on gas viscosity and increases with increasing temperature. Therefore, a different correction factor is needed between patients and a calibrating syringe and between inspiratory and expiratory maneuvers. In addition, the assumption is usually made that no cooling of the air occurs as the air passes through the flow sensor. This may not be the case, particularly with unheated flow sensors (35). If the expired gas is assumed to be BTPS, an error of about 1% will result. The error will increase if the flow sensor is located further from the mouth and more cooling occurs. In addition, water condensation within or on the surface of a flow sensor may alter its calibration. Depending on environmental temperature, the BTPS correction factor may be as large as 10%. Therefore, the method used to calculate or estimate the BTPS factor can potentially introduce significant errors by the application of an erroneous BTPS correction factor.

Changes in spirometer temperature can be a source of variability; therefore, spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session. Johnson and colleagues (40) found that if ambient temperature was used in BTPS correction and applied to all maneuvers, FEV_t and FVC measurement errors of up to 6% may occur. When using volume spirometers, they recommend that the temperature of air inside the spirometer should be measured accurately during each breathing maneuver.

Recommendation (Monitoring): Correction to BTPS

For operating simplicity, monitoring devices may use one BTPS correction factor for a range of barometric pressures (altitude) and environmental temperatures. However, the use of a single BTPS correction factor or direct readings at BTPS does not eliminate the requirement to meet the accuracy specifications under BTPS conditions. Therefore, manufacturers must provide appropriate labeling concerning the environmental conditions (ambient temperature and pressure) under which their device will meet the accuracy requirements. If necessary or appropriate, the manufacturer may provide several BTPS correction factors to meet the accuracy requirements over a range of environmental conditions (altitude and temperature).

EQUIPMENT VALIDATION

Recommendation: FVC Validation

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 (17, 41). These waveforms can be used to drive a computer-controlled mechanical syringe or its equivalent for testing actual hardware and software (42, 43) or they can be put into a system in digital form to evaluate *only* the software. It is strongly recommended that spirometry systems be evaluated using a computer-driven mechanical syringe or its equivalent and that the digital forms only be used for evaluating changes in software. APPENDIX C shows the measured values for each of the 24 standard waveforms. The American Thoracic Society also provides these waveforms on floppy disks for an IBM-PC.* Appropriate corrections for using gas at ambient temperature and humidity instead of BTPS may need to be made for some mechanical syringe-spirometer combinations. In addition, precision criteria have been added, and testing of spirometry systems using heated and humidified test gas is recommended.

The accuracy validation limits (tolerance for simulator systems is included in these limits) for volume are: volume (FVC, FEV_t) ± 3.5% of reading or ± 0.070 L, whichever is greater; and average flow ($FEF_{25-75\%}$) ± 5.5% of reading or ± 0.250 L/s, whichever is greater. The error range is expanded from the earlier ATS spirometry recommendation to allow for errors associated with mechanical syringes (42). The precision validation limits are: volume (FVC and FEV_t) 3.5% (range percent) or 0.100 L, whichever is greater; and flow ($FEF_{25-75\%}$) 5.5% or 0.250 L/s, whichever is greater. Mechanical syringes used for validation must be accurate within ± 0.025 L for FVC and FEV, and ± 0.100 L/s for $FEF_{25-75\%}$.

Rationale. Testing of spirometry systems using heated and humidified test gas has been added to the validation criteria because of potential problems associated with BTPS correction (32-37). See APPENDIX B for further details.

Recommendation: PEF Validation

PEF instrument designs must be validated using a mechanically driven syringe or its equivalent, using the flow-time waveforms described in APPENDIX D. These waveforms are available on digital media from the ATS. In addition, the mechanically driven syringe must be validated (APPENDIX B) to ensure that it accurately produces these waveforms and corresponding PEFs within ± 2% of reading. The flow-time waveforms in APPENDIX D were chosen to represent a range of peak flows and flow-time signals with various times-to-PEF (time required to go from 0.200 L/s to PEF). The accuracy validation limit for PEF is ± 12% of reading or ± 25 L/min, whichever is greater.

* Available from the American Thoracic Society.

The precision (range deviation) validation limit for PEF is 6% or 15 L/min, whichever is greater.

Rationale. The NAEP (5) recommended the use of a mechanically driven syringe to test and validate the accuracy of peak flow measuring instruments and to assess intra- and inter-device precision. Their recommendations included the use of ATS waveform 24 with various multipliers to achieve different PEFs. One problem with using only waveform 24 is a lack of variability in the shape or rise-time in the waveforms used to test PEF meters. Therefore, the use of several waveforms in the testing and validation of PEF meters to provide a range of PEFs and times-to-PEF (rise-times) is recommended. The waveforms in APPENDIX D are flow-time waveforms and, therefore, the definition of peak flow obtained from these waveforms is simple to derive. In addition, a volume-time curve for use by the mechanically driven syringe can be obtained from a flow-time curve by simply summing the flow-time values (integrating the flow signal).

The accuracy of the mechanically driven syringe for PEF ± 2% of reading, was chosen based on current technical feasibility. Current technology of mechanically driven syringes is not sufficient to provide greater accuracies. This is due to the dynamic aspect of peak flow – high frequency content and PEF occurs at a point in the flow-time signal where the acceleration is changing, resulting in potential "overshoot" by a mechanical syringe. In addition, insufficient data are available concerning the accuracy of PEF meters using waveforms with higher frequency content (shorter times-to-PEF). Additional detailed information concerning spirometer testing procedures is contained in APPENDICES B, C, and D.

Recommendation: MW Validation

When tested with a pump producing a sinusoidal waveform, the accuracy validation limits of the spirometer used for MVV for flows up to 250 L/min, produced with stroke volumes up to 2 L, are ± 10.5% of reading or ± 20 L/min, whichever is greater. During the testing, the pressure at the mouthpiece must not exceed ± 10 cm H_2O. For volume spirometers, these requirements apply throughout their volume range.

QUALITY CONTROL

Routine equipment preventive maintenance – cleaning, calibration checks, verification, and quality control- is essential to assure accurate spirometry results (44). 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 (44).

Recommendation: Technician's Role in Quality Control

Quality control is important to ensure that the laboratory is consistently meeting appropriate standards. In any quality control program, an important element is a procedures manual containing: calibration procedures, test performance procedures, calculations, criteria, reference values source, and action to be taken when "panic" values are observed. A notebook should be maintained that documents daily instrument calibration as well as problems encountered with the system, corrective action required, and system hardware and software upgrades. Records of anomalous events involving either patients/subjects or the technician should be documented, with the results of subsequent evaluation and responses to the event. The technician should also maintain records of continuing education and the results of evaluation and feedback provided by the medical director. Perhaps the most important component in successful spirometry is a well-motivated, enthusiastic technician. A recent study has clearly demonstrated the importance of a quality control program with feedback to technicians in obtaining adequate spirometry results (8). A quality control program that continuously monitors technician performance is critical to the collection of high-quality spirometry data. Feedback to the technicians concerning their performance should be provided on a routine basis. This feedback should include, at a minimum:(*1*) information concerning the nature and extent of unacceptable FVC maneuvers and non-reproducible tests; (2) corrective action the technician can take to improve the quality and number of acceptable maneuvers; and (*3*) recognition for superior performance by the technician in obtaining good maneuvers from challenging patients/subjects.

Manufacturers are encouraged to include quality control aids in their software packages for spirometers. For example, a calibration logging program may be provided that stores the time and results of routine daily calibration checks. Additionally, the program could issue a warning if an acceptable daily calibration check has not been performed.

Recommendation: Hygiene and Infection Control

This section has been reviewed by the Microbiology Assembly.

The major goal of infection control is to prevent infection transmission to patients/subjects and staff during pulmonary function testing. Two major types of infection transmission are:

1. Direct contact: There is potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, this is a possibility when there are open sores on the oral mucosa, bleeding gums, or hemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.
2. Indirect contact: There is potential for transmission of tuberculosis, various viral infections, and, possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing.

Prevention:

1. Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing or use of barrier devices (latex gloves). To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if there are any open cuts or sores on technicians' hands. Hand washing should always be performed between patients. Indications and techniques for hand washing during pulmonary function testing have been reviewed by Tablan and coworkers (45).
2. To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves, and manifolds should be disinfected or sterilized regularly. Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected, sterilized, or discarded (i.e., disposable mouthpieces, nose clips, etc) after each use. The optimal frequency for disinfection or sterilization of tubing, valves, or manifolds has not been established. However, any equipment surface with visible condensation from expired air should be disinfected or sterilized before reuse Since the use of cold sterilizing agents is not without risk, laboratory staff should take care to follow all manufacturer's recommendations regarding proper handling of these products.
3. Between subjects, spirometers using the closed circuit tech-

nique should be flushed at least five times over the entire volume range to facilitate clearance of droplet nuclei. Also, the breathing tube and mouthpiece should be decontaminated between patients. When the open circuit technique is used, only that portion of the circuit through which rebreathing occurs needs to be decontaminated between patients. For example, when a pneumotachometer system is used, either inspiration from the device should be avoided or the resistive element and tubing should be decontaminated between subjects. A disposable sensor is another alternative. When an open circuit technique is used for measurement of only the forced exhalation, without inspiration from the measuring system (either volume- or flow-type spirometers), only the mouthpiece needs to be changed or decontaminated between subjects.

It should be noted that disassembling, cleaning, and/or sensor replacement requires recalibration. If patients do not inspire through the device, there is the disadvantage that test acceptability may be more difficult to assess in the absence of an inspiratory tracing. On the other hand, disassembly, cleaning, or sensor replacement has the disadvantage that recalibration is required. Alternatively, in-line filters may be effective in preventing equipment contamination (46). However, if an in-line filter is used, the measuring system should meet the minimal recommendations for range, accuracy, flow resistance, and back pressure with the filter installed. The influence of commercially available in-line filters on forced expiratory measures, such as the FVC and FEV_1, has not been well characterized.

4. In settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, should be used to prevent disease transmission.
5. Special precautions should be taken when testing patients with hemoptysis, open sores on the oral mucosa, or bleeding gums. Tubing and breathing valves should be decontaminated before reuse and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.
6. Extra precautions may be undertaken for patients with known transmissible infectious diseases. Possible precautions include: (a) Reserving equipment for the sole purpose of testing infected patients; (b) testing patients at the end of the day to allow time for spirometer disassembly and disinfection; and (c) testing patients in their own room or in rooms with adequate ventilation and easily cleaned surfaces.
7. In the absence of evidence for infection transmission during pulmonary function testing, the regular use of in-line filters is not mandated when the precautions described above are followed. However, some spirometric equipment, particularly those incorporated in multi-purpose testing systems, employ valve manifolds that are situated proximal to breathing tubes. These valving arrangements provide internal surfaces on which deposition of expired aerosol nuclei is likely. Given their complexity, they may be difficult to disassemble and disinfect between subjects. To the extent that in-line filters have been shown to remove microorganisms from the expiratory air stream and thus prevent their deposition, presumably as aerosol nuclei on spirometer surfaces (46), their use may be indicated in this setting. The economy of using in-line filters compared with tubing and valve changes depends on the PFT equipment in use. The extent to which measures such as maximum expiratory flow or other instantaneous flows are influenced by the use of in-line filters is undocumented. One study has shown that a low impedance barrier device did not have a significant impact on spirometric indices, such as the forced vital capacity and the FEV_1 (47). If an in-line filter is used during spirometry, interpretation of spirometric indices other than FVC and FEV_1 (eg., PEF) should allow for the possibility that the filter might affect spirometer performance The mechanical characteristics of the combined measuring device and filter should meet the minimal recommendations outlined in Table 2. Furthermore, if in-line filters are used, it is recommended that equipment be calibrated with the filter installed. The use of in-line filters does not eliminate the need for regular cleaning and decontamination of spirometric equipment.
8. Manufacturers of spirometric equipment are encouraged to design instrumentation that can be easily disassembled for disinfection.

Rationale. Spirometric equipment has not been directly implicated in the transmission of infections, although there is indirect evidence of infection transmission during pulmonary function testing (PFT). Organisms from the respiratory tract of test subjects can be recovered from PFT mouthpieces and from the proximal surfaces of tubing through which the subjects breathe (48, 49). There is one case report of a tuberculosis skin-test conversion after exposure to a spirometer used to test a patient with documented tuberculosis (50). Likewise, there is circumstantial evidence that contaminated PFT equipment may be implicated in the increasing prevalence of *Pseudomonas* infections among cystic fibrosis patients at one center (51). There is some evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers (52). Finally, it is well documented that community hospital water supplies can be contaminated with Mycobacteria and *Pseudomonas aeruginosa* organisms (53-55). Thus, the potential exists for both patients/subjects and health care workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing, and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients. This does not seem to pose an appreciable threat to patients/subjects with competent immune systems.

It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens. Concerns for the protection of immunocompromised hosts, along with increased public and provider awareness of hospital infection control issues over the past decade, has led many laboratory directors to use in-line filters routinely as a means of reassuring patients and laboratory personnel that adequate consideration has been given to protection. There is no direct evidence that routine spirometry testing poses an increased risk of infection to immunocompromised patients.

Recommendation: Equipment Quality Control

The recommendations that follow are primarily aimed at diagnostic devices.

Attention to good equipment quality control and calibration is an important part of good laboratory practice. Log books of calibration results must be maintained. Documentation of repairs or other alterations that return the equipment to acceptable operation need to be maintained. Dates of computer software and hardware updates or changes must also be maintained.

Volume. The spirometer's ability to accurately measure volume must be checked *at least* daily with a calibrated syringe with a volume of at least 3 L. During industrial surveys or other studies in which a large number of subject maneuvers are done, the equipment's calibration must be checked daily, before testing, and every 4 h during use (44). In circumstances where the temperature is changing (e.g., field studies), more frequent temperature corrections may be needed. 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 de-

termined within 1 day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. It is recommended that the calibration syringe be stored and used in such a way as to maintain the exact temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer. In the case of flow-type spirometers where a volume syringe is used to check the instrument, volume calibration checks using different flow rates are recommended. At least three trials where the flow rates are varied between 2 and 12 L/s must be performed (3-L injection times of approximately 1 s, 6 s, and somewhere in between 2 and 6 s).

Syringe Accuracy. The syringe used to check the volume calibration of spirometers must have an accuracy of at least 15 ml or at least 0.5% of full scale (15 ml for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate syringe calibration intervals. If the syringe has an adjustable variable stop, the syringe may be out of calibration if the stop is reset. Calibration syringes should be leak-tested periodically by trying to empty them with the outlet corked.

Leak Test. Volumetric spirometer systems must be evaluated for leaks on a daily basis **(15, 56).** The Intermountain Thoracic Society Manual **(15)** suggests that leaks can be detected by applying a constant positive pressure of 3 cm H_2O or more with the spirometer outlet occluded. Any observed volume change of greater than 10 ml after 1 min is indicative of a leak **(15)** and needs to be corrected.

Linearity. At least quarterly, volume spirometers must have their calibration checked over their entire volume range (in 1-L increments) using a calibrated syringe (42) or an equivalent volume standard. Flow spirometers must have their linearity determined *at least* weekly and given the current software capabilities, daily linearity checks are reasonable. Flow spirometer linearity can be checked by injecting the volume from a 3-L syringe with several different flows. The linearity check is considered acceptable if the spirometer meets the volume accuracy requirements for all flows and/or volumes tested.

Time. Assessing mechanical recorder time scale accuracy with a stopwatch must be performed *at least* quarterly. An accuracy of within 1% must be achieved. If equipment is changed or relocated **(e.g.,** industrial surveys), calibration checks and quality control procedures must be repeated before initiating further testing.

PEF Meters. Since it is difficult to perform a calibration check of portable peak flow monitoring meters, it is particularly important that the instructions from the manufacturer include information concerning typical instrument lifetimes and methods of recognizing when an instrument is malfunctioning.

Other Quality Assurance Procedures. In addition to calibration with physical standards, the practice of using laboratory personnel as "known subjects" and performing intralaboratory and interlaboratory testing is recommended (44). The **ATS** has published guidelines for quality assurance in pulmonary function laboratories **(44),** which can be consulted for specific details.

The use of computers to analyze spirometry has accelerated in the past 10 yr, and this trend is advantageous to obtain accurate spirometry **(10, 30).** However, testing of commercially available spirometers consistently shows that a major source of errors is in computer software (42). Because of the increased use of computers in pulmonary laboratories and the problems associated with them (42, **57),** the **ATS** has published computer guidelines for pulmonary laboratories **(58),** which should be followed. Computer software must adhere to **ATS** recommendations, especially procedural recommendations, contained in this statement. Because of the tremendous improvement in the power and speed of computers and their extensive use in hospitals and clinics, manufacturers should attempt to integrate computers into their spirometry systems. Primary data should be available, allowing independent manipulation of uncorrected values by the user. Listings or descriptions of **ATS** algorithms should be available (end of test, back-extrapolation, **etc.).** In addition, some program flexibility should be available to the user, for example, allowing user selection of appropriate reference equations, including the use of user-derived reference equations.

TABLE 5

EQUIPMENT QUALITY CONTROL SUMMARY

Test	Minimum Interval	Action
Volume	Daily	3-L syringe check
Leak	Daily	3 cm H_2O constant pressure for 1 min
Linearity	Quarterly	1-L increments with a calibrating syringe measured over entire volume range (flow spirometers simulate several different flow ranges)
	Weekly (flow spirometers)	
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using "known" subject

MANEUVER PERFORMANCE RECOMMENDATIONS

Personnel Qualifications

The **ATS** has made recommendations for laboratory personnel conducting pulmonary function tests (59). High school training was recommended. In addition, the **ATS** encouraged but did not mandate one or more years of college or equivalent training and a strong background in mathematics. For pulmonary function laboratories, 6 mo of supervised training time is recommended for conducting spirometry. If troubleshooting is to be a part of the laboratory technician's responsibility, a training period of 1 yr is recommended. The **ATS** recommends that the medical directors must have appropriate training and be responsible for all pulmonary function testing (60).

For *industrial/occupational testing,* there are *training* requirements mandated by the National Institute for Occupational Safety and Health (NIOSH), industry, and the ACCP **(16, 31, 61).** Several excellent *training* manuals have been prepared for performance of spirometry (15, 16, 31, 62, 63). NIOSH approves the content of spirometry training courses under the U.S. Cotton Dust Standard (16).

Recommendation: K-Subject Instruction and Maneuver Performance

The VC maneuver may be considered either as an inspiratory vital capacity **(IVC),** where the subject inhales completely from a position of full expiration, or as an expiratory vital capacity **(EVC),** where the subject exhales completely from a position of full inspiration. In addition, several spirometer setups are possible using either open or closed circuit techniques with or without rebreathing.

1. A closed circuit technique *without CO,* absorption **(i.e.,** using a rolling-sealed or water-sealed spirometer) may be used. Subjects may also rebreathe from the spirometer circuit. **Rebreathing** is preferable because it allows technicians to **better monitor** the entire vital capacity maneuver. In the absence of CO, absorption and the addition of supplemental oxygen, the maneuver should be brief – fewer tidal volumes before and after the VC maneuver.
2. A closed circuit technique *with CO,* absorption and the addition of supplemental oxygen may be used. This system allows

the subject to rebreathe for a longer period of time and establish a better FRC baseline. However, it requires precise replacement of oxygen to avoid shifting the baseline.
3. A modified closed circuit technique (i.e., flow-sensor-based systems where the subject can breathe in and out through the sensor without the need for CO_2 absorption) may be used.
4. An open circuit technique where the subjects may inhale completely before inserting the mouthpiece and exhaling into the spirometer may be used. This may be preferable when hygiene concerns are present.

For all systems, it is important to instruct the subject in the VC maneuver and demonstrate the appropriate technique. It is important that subjects understand they must ***completely*** fill and empty their lungs.

Standard Procedure Open Circuit Technique. The subject inhales maximally, inserts the mouthpiece just past his/her front teeth, seals his/her lips around the mouthpiece, and blows slowly and evenly until a clear plateau is seen at maximal exhalation or until end-of-test criteria (see sections on FVC and end-of-test criteria) are met. The technician must observe the subject's inhalation to ensure that it is complete and that air is not exhaled while the mouthpiece is being inserted. During the exhalation, the technician should monitor the spirometer volume-time display to ensure that a relatively constant expiratory flow and an adequate end-expiratory plateau is achieved (see APPENDIX A for examples of the VC maneuver).

Closed Circuit Techniques. The following procedure should be used when testing is conducted ***without CO,*** absorption (limited oxygen reserve available for test performance). A two-way valve may be useful, allowing the initial tidal volumes to be performed with room air before the subject is connected to the spirometer. The test is begun with quiet breathing, preferably with the subject breathing room air. No more than five tidal volumes should be recorded with the subject rebreathing from the spirometer. The subject should then perform the VC maneuver described below. When CO, absorption is not used, returning to FRC after the VC maneuver followed by three tidal volumes may be helpful but is not required.

The following procedure should be used when testing is conducted with CO, absorption and oxygen supplementation. The test is begun with quiet breathing. Several tidal volumes should be recorded (minimum of five or until a stable end-expiratory level is observed). The subject should then perform the VC maneuver described below. The end of test is reached when the subject returns to the level of FRC and performs at least three more tidal volumes.

For both procedures, the maneuver is not forced; it is performed in a relaxed manner with the subject using a mouthpiece and a nose clip. The VC maneuver is composed of the subject exhaling completely to residual volume (RV), and completely inhaling to total lung capacity (TLC), and then exhaling to residual volume again. The technician should encourage the subject to reach maximal inhaled and exhaled volumes with a relatively constant flow. Technicians should observe the subject to be certain his/her lips are sealed, that nothing obstructs the mouthpiece, that no leaks occur, and that TLC and RV are reached. The technician should check the volume display to ensure relatively linear inspiratory and expiratory volume curves and adequate maximal inspiratory and expiratory level plateaus. Oxygen should be added to the circuit to precisely counterbalance the absorption of CO_2.

For all techniques, a minimum of two acceptable VC maneuvers should be obtained, with a maximum of four attempts. The largest VC should be reported. Some investigators have reported that the VC is slightly higher than the FVC in normal subjects(64).

TABLE 6

PERFORMANCE OF FVC MANEUVER

Check spirometer calibration
Explain test
Prepare subject
Ask about smoking, recent illness, medication use, etc.
Instruct and demonstrate test to subject
Correct posture with head elevated
Inhale completely
Position mouthpiece (open circuit)
Exhale with maximal force
Perform maneuver
Have subject assume correct posture
Attach nose clip
Inhale completely; the inhalation should be rapid but not forced
Place mouthpiece in mouth and close lips around mouthpiece
Exhale maximally as soon as lips are sealed around mouthpiece*
Repeat instructions as necessary, coaching vigorously
Repeat for a minimum of three maneuvers; no more than eight are usually required
Check test reproducibility and perform more maneuvers as necessary

* D'Angelo and coworkers (65) have reported that PEF and FEV_1 for 13 normal subjects measured in a body plethysmograph are reduced (4% and 5%, respectively) when, during the inspiratory maneuver, there is a 4-6-s pause at TLC before beginning exhalation. Therefore, an excessive pause at TLC should be avoided.

Recommendation: FVC-Subject Instruction and Maneuver Performance

Instruct the subject in the FVC maneuver. The technician should demonstrate the appropriate technique (Table 6). Have the subject inhale from FRC and then, if using the open circuit method, insert the breathing tube into his/her mouth, making sure his/her lips are sealed around the mouthpiece, and begin the FVC maneuver with minimal hesitation (65). It is ***impemtive*** that the subject have a complete inhalation before beginning the forced exhalation. Prompt the subject to "blast," not just "blow," the air from their lungs, then continue to encourage him/her to fully exhale. Throughout the maneuver, enthusiastically coach the subject by word and body language. It is particularly helpful to observe the subject and the chart recorder or computer display during the test to better ensure maximal effort. Perform a ***minimum*** of three acceptable FVC maneuvers. If a subject shows large variability (FVC and/or FEV_1) between expiratory maneuvers (> 0.2 L), reproducibility criteria may require that up to but usually no more than eight maneuvers be performed. Volume-time or flow-volume curves from the best three FVC maneuvers must be retained. See Figure 3 and the section on acceptability and reproducibility for further clarification.

Recommendation (Monitoring): PEF-Subject Instruction and Test Performance

Since PEF is both effort- and volume-dependent, maximum subject cooperation is essential. Since an optimal peak flow is usually reached in about one-tenth of a second, patients must be encouraged to perform the expiratory maneuver as vigorously as possible. The subject should not cough and a prolonged exhalation is unnecessary (1 to 2 s is adequate).

When implementing unobserved self-administered PEF measurements, it is essential that:

1. The subject should be taught how to use the peak flow meter properly by someone skilled with the procedure. Trained personnel should observe the subject's performance both initially and on repeat visits.
2. The subject should be taught how and when to record PEF measurements, along with other pertinent information, such as symptoms.
3. The subject should be instructed about what action to take if PEF falls.

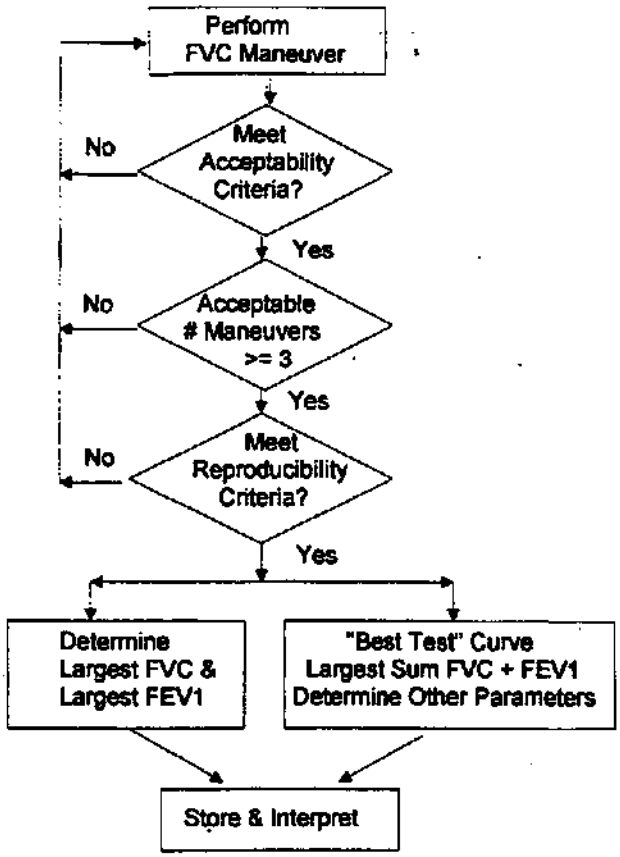


Figure 3. Flow-chart diagram of FVC spirometry testing.

TABLE 7

PERFORMANCE OF PEAK FLOW MANEUVER

Explain and demonstrate the test*
Zero the PEF monitor, if necessary
Stand up straight
Inhale completely; the inhalation should be rapid but not forced
Place PEF monitor in mouth and close lips around mouthpiece†
Exhale with maximal force‡ as soon as lips are sealed around mouthpiece§
Write down results
Repeat two more times (three total)
Record all three values

* Not necessary if at home.
† Nose clips are not necessary.
‡ Make sure subject understands to make full use of respiratory muscles, not just use the diaphragm as a "toot" or "mouth" maneuver.
§ D'Angelo and coworkers (65) have reported that PEF is reduced when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. It is not known if similar changes will be observed with portable peak flow meters.

Recommendation: FVC—Satisfactory Start-of-Test Criteria

To achieve accurate "time zero" and ensure that the FEV_t comes from a maximal effort curve, the extrapolated volume must be less than 5% of the FVC or 0.15 L, whichever is greater. See Figure 2 for an example and explanation of back extrapolation. In the example shown, the extrapolated volume is 0.16 L or 8%. In general, back-extrapolated volume should be measured on any curve with a perceptible extrapolated volume. Provisions for rapid computerized feedback to the technician when these criteria are not met are encouraged.

The committee discussed the possible use of time-to-PEF as a measure of the subject's performance early in the FVC maneuver. However, the committee felt there were insufficient data on which to base a clear recommendation, and additional research is needed. When conducting research on assessment of the subjects' correct performance of FVC maneuvers, investigators are encouraged to measure the time-to-PEF or rise-time of peak flow in addition to other quality assessment parameters. The rise-time of peak flow is defined as the time required for expiratory flow to rise from 10% to 90% of the maneuver's peak flow. Although use of other measures of acceptable efforts have been described and may be useful (8, 66), they are not recommended at this time.

Rationale. A very slow start with a low peak flow will result in a greater than allowable extrapolated volume (Figure 2) (1, 67–69). In addition, the FEV_t from a submaximal effort can be either smaller than those obtained when a maximal effort is performed because the subject fails to reach a maximal TLC, or larger due to less dynamic compression of airways in subjects where airways are relatively more collapsible. Recent experience in large epidemiologic studies (8) suggests that use of time-to-PEF and PEF reproducibility may minimize most of these problems in the majority of subjects. However, at this time, it is not recommended that maneuvers be eliminated because of a low PEF or PEF rise-time, but only because of an excessively large extrapolated volume.

Recommendation: FVC—Minimum Exhalation Time

A minimum exhalation time of 6 s (length of maximum expiratory effort), unless there is an obvious plateau in the volume–time curve display, is required to obtain maximal FVC results. There are instances (e.g., the testing of children, young adults, and some restricted patients) where shorter exhalation times are acceptable.

Recommendation: FVC—End-of-Test Criteria

To obtain an optimal effort, it is important that subjects be verbally exhorted to continue to exhale air at the end of the maneuver. End-of-test criteria are used to identify a reasonable FVC effort. Recommended end-of-test criteria are:

1. The subject cannot or should not continue further exhalation. Although subjects should be encouraged to achieve their maximal effort, they should be allowed to terminate the maneuver on their own at any time, especially if they are experiencing discomfort. The technician should also be alert to any indication the patient is experiencing discomfort and should terminate the test if a patient is becoming uncomfortable.

OR

2. The volume–time curve shows an obvious plateau. This criterion is based on no change in volume for *at least* 1 s after an exhalation time of *at least* 6 s (10 s is optimal). "No change in volume" is defined as the minimal detectable volume of the spirometer. To meet ATS criteria, the minimal detectable volume for spirometers must be 0.030 L or less.

OR

3. The forced exhalation is of reasonable duration. For patients with airways obstruction or older subjects, exhalation times longer than 6 s are frequently needed to reach a plateau. Many would not reach a plateau even with a 20-s exhalation. However, exhalation times greater than 15 s will rarely change clinical decisions. *Multiple* prolonged exhalations (longer than 6 s) are seldom justified and may cause lightheadedness, syncope, undue fatigue, and unnecessary discomfort. In such patients, a slow or unforced VC maneuver (previously described) may provide a more appropriate denominator for calculation

of the FEV_t/VC%. Manufacturers should note that several of the 24 test waveforms have durations longer than 20 s.

Achieving an end-of-test criterion is one measure of maneuver acceptability. Maneuvers that do not meet an end-of-test criterion should not be used to satisfy the requirement of three acceptable maneuvers. However, early termination is not by itself a reason to eliminate a maneuver from further consideration. Information such as FEV_1 and FEV_3 may be valid (depending on the length of exhalation) and should be reported from these early terminated maneuvers. When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g., 4 s) may be used as an approximate surrogate for FVC. In such cases, the volume label should reflect the shorter exhalation time (e.g., FEV_4 for a 4-s exhalation).

Recommendation: VC and FVC—Maximum Number of Maneuvers

Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight maneuvers is considered a practical upper limit for most subjects. After several forced expiratory maneuvers, fatigue begins to take its toll on subjects, and thus on their spirometric parameters, so additional maneuvers would be of little added value. In addition, some subjects with asthma may exhibit spirometry-induced bronchospasm. Ferris and associates (70) and Kanner and colleagues (71) have reported that for adults and children, eight maneuvers is a practical upper limit. For VC, four is considered a practical upper limit. Because of the potential for muscular fatigue and volume history effects, it is preferable that VC maneuvers be performed before FVC maneuvers.

Recommendation (Monitoring): PEF—Number of Trials

The subject must perform and record a minimum of three trials.

Recommendation: VC and FVC—Environmental Conditions

Spirometric testing with ambient temperatures less than 17° C or more than 40° C may pose problems. Ambient temperature must *always* be recorded and reported to an accuracy of ± 1° C. In situations where the ambient air temperature is changing rapidly (> 5° C in less than 30 min), continuous temperature corrections should be made. Spirometer users should be aware of the problems with testing done at lower temperatures, which in some subjects can cause airflow limitation. Due to other technical reasons, 17° C is judged to be an acceptable and reasonable lower limit (32–38, 72) for ambient temperature. Ranges of barometric pressures that are acceptable for the spirometer must 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.

Studies also point out the problem of finite cooling times of gases in volume-type spirometers and their associated tubing (32–35) when BTPS correction techniques usually assume instantaneous cooling. In one of these studies, it was found that a 7.7 to 14% error in FEV_1 results if the volume-type spirometer is at an ambient temperature of 3° C and the standard BTPS correction is used. This error is less if the spirometer is warmer (nearer body temperature) (32). 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 (34–38). Air exhaled from the mouth is estimated to be 33 to 35° C (36, 38, 39). 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 approximately 33° C. Details of the cooling pattern for many types of flow spirometers have not been studied, but they may result in errors similar to those for volume devices (34–38).

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

Recommendation: VC and FVC—Use of Nose Clips

In most people, not wearing nose clips does not appreciably influence the FVC when using the open circuit technique. However, some people breathe through the nose and the use of nose clips is encouraged, especially when performing a slow VC maneuver. Nose clips must be used if a closed circuit technique with carbon dioxide absorption is used.

Recommendation: VC and FVC—Sitting Versus Standing

Testing may be done either in the sitting or standing position. Indication of position is necessary on the report (1, 73). The standing position may not be appropriate in some circumstances, such as in hospitals where many patients may not be able to tolerate the standing position, especially when making forced maneuvers. The selection of the position for testing is, therefore, an individual one. If the standing position is used, an appropriately shaped chair should be placed behind the patient/subject so he/she can be quickly and easily eased into a sitting position if he/she becomes light-headed during the maneuver.

Rationale. Studies by Townsend show that for adults there are significantly larger FEVs in the standing position than in the sitting position (73). The earlier ATS recommendation indicates that in children, VC is greater when standing (1).

Recommendation (Monitoring): PEF—Nose Clips and Subject Position

Nose clips are not necessary when using PEF meters. Although the test can be conducted while sitting, the standing position is preferred.

Rationale. Because the PEF is dependent on a complete inhalation and an exhalation with maximal force, the standing position is preferred.

Bronchodilator Testing. Spirometry is often performed before and after inhalation of bronchodilators (or bronchoconstrictors) from a metered dose inhaler (MDI) or nebulizers. Although specific recommendations are beyond the scope of this document, it should be remembered that this is a complex procedure. Factors that can significantly affect a patient's response include: (*1*) activity, dose, and airway deposition of the medication; (*2*) recent prior medication; (*3*) timing of the postmedication maneuver; (*4*) choice and variability of the measurement used to detect a response; and (*5*) the method of calculating the magnitude of change after administering the bronchodilator.

MEASUREMENT PROCEDURES

Measurement

Spirometric variables should be measured from a series of *at least* three acceptable forced expiratory curves.

Recommendation: VC and FVC—Test Result Selection/Reporting of Results

The largest VC should be reported from all acceptable curves, including the forced maneuvers (FVC). The largest FVC and the largest FEV_1 (BTPS) should be recorded after examining the data from all of the acceptable curves, even if they do not come from the same curve. Other measures, such as the $FEF_{25-75\%}$ and the instantaneous expiratory flows, should be obtained from the single curve (1, 2, 15) that meets the acceptability criteria and gives the largest sum of FVC plus FEV_1 (best test).

Recommendation (Monitoring): PEF—Test Result/Reporting Readings

Although all readings are recorded, the highest reading at any testing session (minimum of three trials) should be used in trend analysis. All readings are recorded to allow the comparison of the trials to evaluate reproducibility and to detect possible maneuver-induced bronchospasm.

Rationale. Since the PEF is effort-dependent, the highest reading should be used. This is consistent with the current recommended selection method for FVC and FEV_1.

ACCEPTABILITY AND REPRODUCIBILITY

Recommendation: VC and FVC—Maneuver Acceptability

For FVC measurements, acceptability must be determined by ascertaining that the recommendations outlined previously in the section on performing the FVC test are met. APPENDIX A contains examples of unacceptable volume-time and corresponding flow-volume curves. In review, these acceptability criteria are: (*1*) satisfactory start-of-test; (*2*) minimum FVC exhalation time of 6 *s*; and (*3*) end-of-test criteria. 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, false start, or extrapolated volume of greater than 5% of FVC or 0.15 L, whichever is greater (*Figure 2*).
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 (APPENDIX A, Figures 2A and 2B).
3. Early termination of expiration. A plateau in the volume–time curve should be observed, as defined by no change in volume for at least 1 s or a reasonable expiratory time. In a *normal* young subject this would be before completion of the breath—*usually* less than a 6-s maneuver. In an obstructed or older healthy subject, a longer expiratory time is required to reach a plateau (2, 74, 75) (APPENDIX A, Figures 3A and 3B). However, *multiple* prolonged exhalations (longer than 6 *s*) are seldom justified.
4. Valsalva maneuver (glottis closure) or hesitation during the maneuver that causes a cessation of airflow (APPENDIX A, Figures 4A and 4B).
5. A leak (APPENDIX A, Figures 5A and 5B).
6. An obstructed mouthpiece (e.g., obstruction due to the tongue being placed in front of the mouthpiece or false teeth falling in front of the mouthpiece).

For VC measurements, all of the above requirements should be met with the exception of those related to the forced nature of the effort. In addition, plateaus in the volume–time display should be reached at both the maximal inspiratory and expiratory volumes.

Computer-based systems that provide feedback to the technician when the above conditions are not met are desirable. The reporting format should include qualifiers indicating the acceptability of each maneuver. However, it cannot be overemphasized that failure to meet these criteria does not necessarily invalidate the maneuver, since for some subjects this is their best performance. Further, such maneuvers should be retained, since these maneuvers may contain useful information.

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

Recommendation: VC and FVC—Test Result Reproducibility

As a goal during test result performance, the largest FVC (or VC) and second largest FVC (or VC) from acceptable maneuvers must not vary by more than 0.2 L. In addition for forced exhalations, the largest FEV_1 and the second largest FEV_1 must not vary by more than 0.2 L. The 0.2 L reproducibility criteria are a change from the ATS 1987 Spirometry Statement and are intended to provide an equal assessment of test reproducibility independent of lung size. However, these criteria are only goals during data collection; therefore, an immediate change in spirometry data collection software is not warranted.

The reproducibility criteria are used as a guide to whether more than three acceptable 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 suggest that bronchospasm was triggered by the FVC maneuver). In addition, the reproducibility criteria are minimum requirements and many subjects should be able to provide FVC and FEV_1 reproducibility well below 0.2 L. The acceptability criteria must be applied before the reproducibility criteria (Figure 3). Unacceptable maneuvers must be discarded before applying the reproducibility criteria.

The only criterion for unacceptable subject performance is fewer than two acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility. 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. In addition, use of data from unacceptable maneuvers due to failure to meet the end-of-test requirements is left to the discretion of the interpreter.

Rationale. Several epidemiologic studies (67–69) have shown that the elimination of data from subjects who fail to meet the ATS reproducibility criteria may result in a population bias by excluding data from subjects who have abnormal lung function. Pennock and colleagues (76) 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 simplified to eliminate confusion. If acceptability criteria are not applied before the reproducibility criteria, a passive exhalation maneuver will often be labeled as the best test maneuver because it may give the largest sum of FVC and 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. Changing to 0.2-L criterion does simplify this calculation.

Changing the reproducibility criteria to a minimum value of 0.2-L is based on evidence that within subject variability of FVC and FEV_1 is not dependent on body size. The use of a 5% or 100-ml criterion has been shown to result in more individuals of short stature being classified as nonreproducible. In contrast, a 0.2-L fixed volume criterion provides a commensurable level of difficulty for all subjects, regardless of age or height (lung volume) (77). Regardless of the reproducibility criterion for FVC or FEV_1, it should be used as a goal during data collection. Therefore, continued use of the previous criteria (5% or 0.1 L, whichever is greater) during an interim period should have little practical impact on spirometry results.

Recommendation: PEF—Maneuver Acceptability and Reproducibility

PEF values for each maneuver must be recorded in the order in which they occur. This information will be useful in detecting possible test (maneuver)-induced bronchospasms.

TABLE 8

ACCEPTABILITY AND REPRODUCIBILITY CRITERIA: SUMMARY

Acceptability criteria
- Individual spirograms are "acceptable" if:
  - They are free from artifacts (see APPENDIX A for examples)
    - Cough or glottis closure during the first second of exhalation
    - Early termination or cutoff
    - Variable effort
    - Leak
    - Obstructed mouthpiece
  - Have good starts
    - Extrapolated volume less than 5% of FVC or 0.15 L, whichever is greater; *OR*
    - Time-to-PEF of less than 120 ms (optional until further information is available)
  - Have a satisfactory exhalation
    - 6 s of exhalation and/or a plateau in the volume–time curve; *OR*
    - Reasonable duration or a plateau in the volume–time curve; *OR*
    - If the subject cannot or should not continue to exhale

Reproducibility criteria
- After three acceptable spirograms have been obtained, apply the following tests:
  - Are the two largest FVC within 0.2 L of each other?
  - Are the two largest FEV_1 within 0.2 L of each other?
- *If both of these criteria are met, the test session may be concluded.*
- If both of these criteria are not met, continue testing until:
  - Both of the criteria are met with analysis of additional acceptable spirograms; OR
  - A total of eight tests have been performed; OR
  - The patient/subject cannot or should not continue
- Save at a minimum the three best maneuvers

Rationale. Unlike the FEV_1 obtained from routine spirometry, PEF measurements are more variable, and the measurement is often conducted in patients with high variability in their PEF. Although there may be some benefit from using PEF reproducibility to improve a subject effort, no specific reproducibility criterion is recommended at this time.

REFERENCE VALUES, INTERPRETATION STANDARDIZATION, AND CLINICAL ASSESSMENT

Clinical/Epidemiologic Considerations

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

Since the last standards were issued in 1987, a detailed statement on selection of reference values and interpretation of lung function tests has been published (3). The interpretation of spirometry involves two tasks: (*1*) The classification of the derived values with respect to a reference population and assessment of the reliability of the data; and (*2*) The integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient. The first task is ordinarily the responsibility of the laboratory director or a designee and serves not only to communicate information to referring health care providers but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the medical director to develop explicit procedures for interpretation of spirometry and to select appropriate reference values. The procedures for interpretation and reference values may legitimately vary from laboratory to laboratory depending upon geographic location and the characteristics of the population being tested. In a setting where large numbers of healthy individuals are being screened for abnormality and the prevalence of disease is low, it is appropriate to set the threshold for abnormality at a higher level than in a setting where most individuals are referred because of symptoms or disease. In the latter case, where the prevalence of disease is high, an appropriate standard would be set to a more sensitive threshold for abnormality. The interpretative strategy should also take into consideration the consequences of false-positive and false-negative errors. Accordingly, no specific guidelines for interpretative procedures are recommended that would be applicable to all laboratories. More important, however, is that there be a consistent approach to the interpretation of lung function tests within a single laboratory. Therefore, referring physicians will not infer a change in the condition of the patient from a change in interpretation when it is the result of a change in the approach of the interpreting physician.

In providing the referring physician with an interpretation of spirometry results, it is also important to comment on deviations of the data from the guidelines for acceptability and reproducibility set forth herein. Although a spirometry session may not meet all of the guidelines, it may provide important clinical information and should be reported with appropriate qualification. Although some individuals display negative effort dependence, submaximal efforts usually lead to underestimation of the maximal effort values (28). Suboptimal efforts may be adequate to assist clinical decisions, where it can be judged that the recorded values underestimate true lung function.

Acknowledgment: The Committee thanks those who have provided input to this update of the Standardization of Spirometry. Special thanks go to the original participants of the Update Workshop, whose valued input was sought and used.

External reviewers: Scott T. Weiss, M.D., M.S., Gary R. Epler, M.D., and James R. Hansen, M.D.

APPENDIX A

Sample Spirograms

The sample spirograms shown in this appendix are from actual individuals and represent a few illustrations of acceptable and unacceptable maneuvers. It is imperative that the technician administering the test be capable of recognizing these anomalies and take appropriate corrective action—proper coaching. During the interpretation process, the reviewer may decide to include a maneuver that may have been considered unacceptable during test performance. As with the reproducibility criteria, some judgment must be made concerning what is an unacceptable maneuver. This decision will be based on the number of curves available, the disease pattern observed or expected for the individual, etc. However, the technician's action taken during the data collection stage of the process should almost always be to obtain additional maneuvers combined with effective coaching of the individual.

Figures A1a and A1b are volume–time and corresponding flow–volume samples that are acceptable spirograms from the draft NIOSH spirometry manual (78). In these spirograms, the individual exhibited a maximal effort for the entire maneuver, exhaling for at least 6 s with a greater than 1 s plateau in the volume–time curve. Figure A1a illustrates the relative expansion of the last portion of the FVC maneuver associated with a volume–time curve display. In contrast, Figure A1b illustrates the relative expansion of the initial portion of the FVC maneuver associated with a flow–volume curve display. Notice in the flow–volume curve (Figure A1b) it is more difficult to determine that the individual produced an acceptable plateau than in the volume–time curve display.

Figures A2a and A2b illustrate an unacceptable spirogram due to a cough during the first second of exhalation. Notice that the cough, which occurs at approximately 3.0 to 3.5 L, is very apparent in the flow–volume curve but is more difficult to detect in the volume–time curve. The anomalies seen in the volume–time curve at approximately 5.0 and 5.5 L could be slight coughs or variable effort, but occurred after the first second of exhalation.

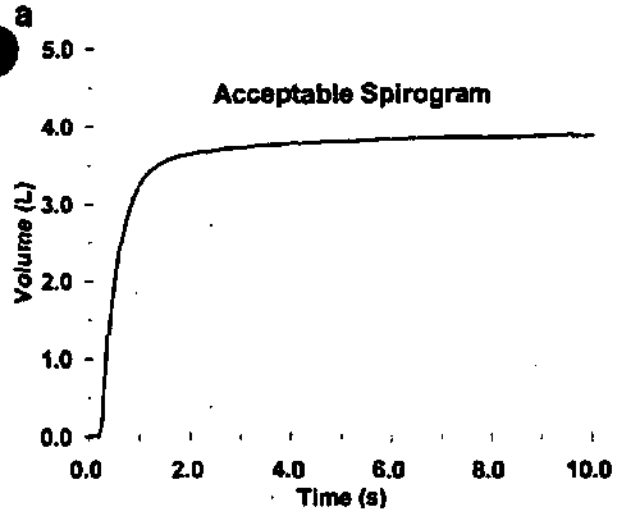


Figure A1a. Acceptable volume–time spirogram.

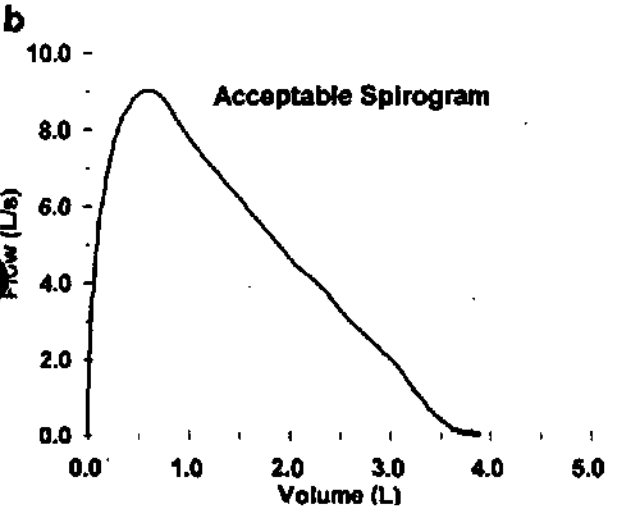


Figure A1b. Acceptable flow–volume spirogram.

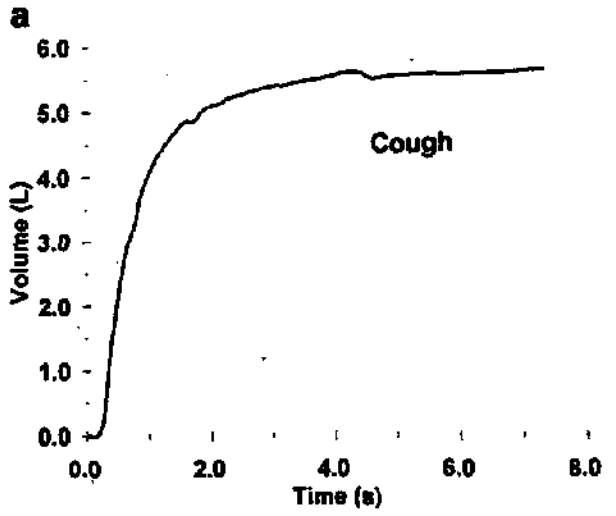


Figure A2a. Volume–time spirogram with a cough during the first second of exhalation.

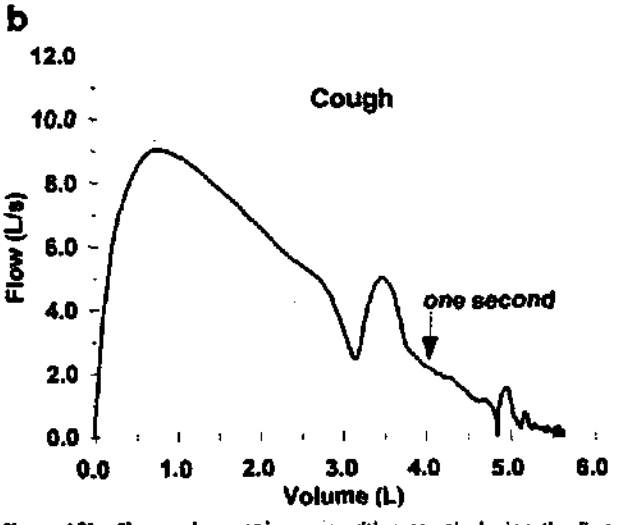


Figure A2b. Flow–volume spirogram with a cough during the first second of exhalation.

Although the fluctuations in flow observed in the flow–volume curve in Figure A2b are reasonably large, they may not result in a significantly different FEV_1. Therefore, the FEV_1 from this curve may be valid, particularly if all other curves are unacceptable. Regardless, when the technician observes the spirograms in Figures A2a and A2b, additional maneuvers should be obtained from the individual.

Figures A3a and A3b illustrate an unacceptable spirogram due to a variable effort or cough during the first second of exhalation and early termination of the maneuver. The anomaly observed at 1 L of exhalation is apparent on both the volume–time and flow–volume curves.

The duration of the anomaly and the fact that the flow immediately following the anomaly does not exceed the expected flow–volume envelope suggest that the anomaly is a variation in effort instead of a cough. The early termination is less apparent on the flow–volume curve. However, on the volume–time curve, it is apparent that the individual failed to exhale for 6 s and there is no 1-s plateau of the volume–time curve.

Figures A4a and A4b illustrate unacceptable sample spirograms due to an abrupt termination of flow at the end of the maneuver, possibly the result of the individual closing his/her glottis. Notice in Figure A4a that the volume–time curve plateau occurs abruptly at approximately 2.2 s where the volume remains constant for the remainder of the maneuver. In Figure A4b, the flow–volume curve exhibits an abrupt decrease in flow at the end of the maneuver.

Figures A5a and A5b illustrate unacceptable sample spirograms due to a leak in the volume-type spirometer or spirometer hose. This leak is approximately 50 ml/s and produces an approximate 300-ml loss in volume over the 6-s exhalation produced by this individual. Notice that the leak is very apparent on the volume–time curve and perhaps less apparent on the flow–volume curve. At the end of the maneuver when the leak is most

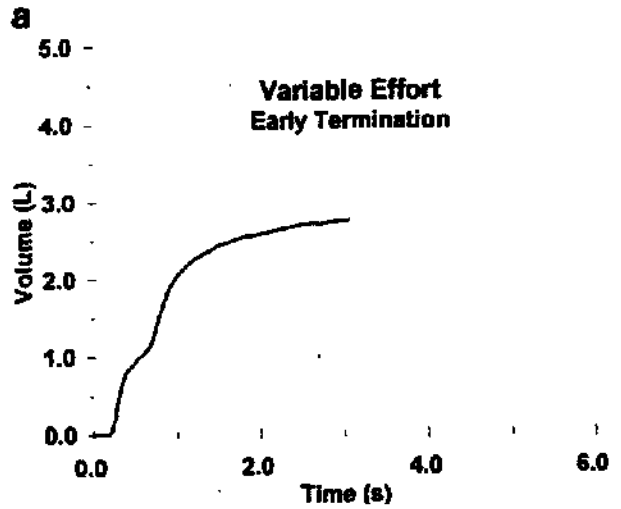


Figure A3a. Unacceptable volume–time spirogram due to variable effort and early termination.

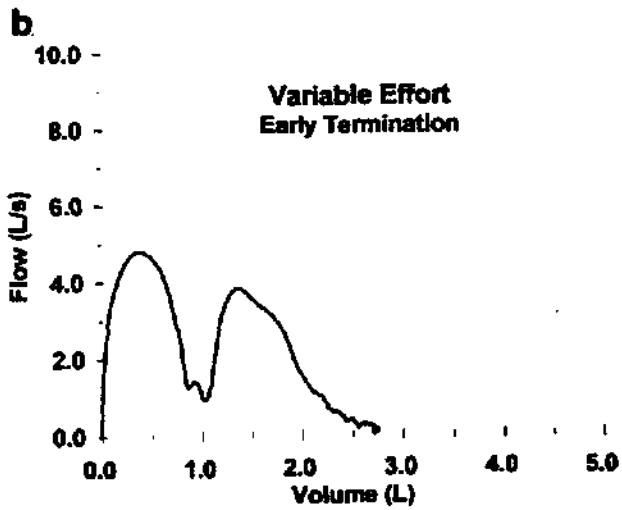


Figure A3b. Unacceptable flow–volume spirogram due to variable effort and early termination.

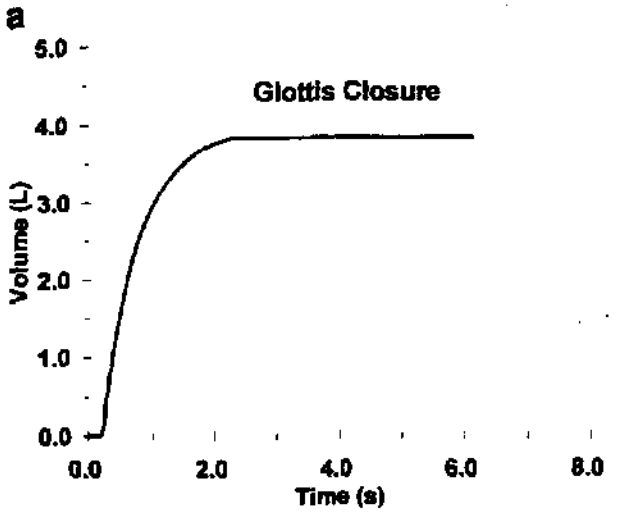


Figure A4a. Unacceptable volume–time spirogram due to possible glottis closure.

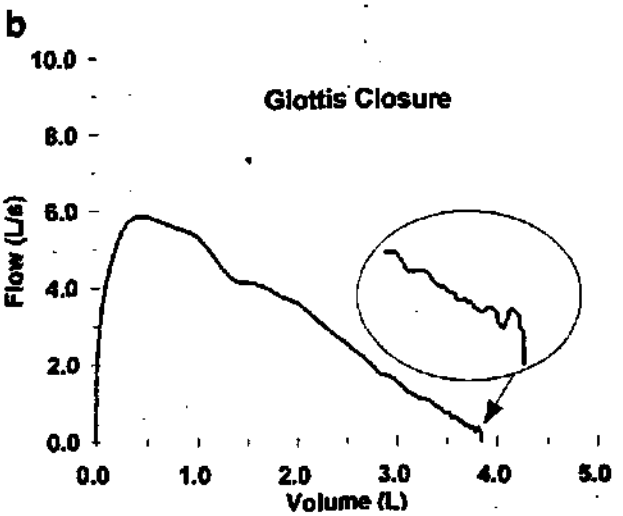


Figure A4b. Unacceptable flow–volume spirogram due to possible glottis closure.

apparent, the flow is slightly negative and volume is decreasing (*see* insert in Figure A5b, short line moving to the left below the zero flow line). If a spirometry system display does not display negative flows, then the leak would be even less apparent on the flow–volume curve.

Figures A6a and A6b illustrate acceptable sample spirograms for an individual with mild airways obstruction ($FEV_1/FVC\%$ = 67%). Notice the relatively small change in volume after 10 s of exhalation (Figure A6a) and the corresponding relative low flow (Figure A6b) at the end of the maneuver.

In addition to requiring three acceptable maneuvers, the reproducibility criteria for FVC and FEV_1 should be met as a goal during test performance. Figure A7a illustrates the volume–time curve and Figure A7b the corresponding flow–volume curve for a 22-yr-old, healthy female. In these figures, the subject did not meet the minimum reproducibility criteria for both the FVC and FEV_1 despite performing three acceptable maneuvers. The second largest FVC was 0.43 L (10%) lower than the largest, and the second largest FEV_1 was 0.37 L (12.1%) lower than the largest FEV_1. Therefore, at least one additional maneuver should be performed by this subject in an attempt to meet the FVC and FEV_1 reproducibility criteria. The most likely cause of this pattern (nonreproducible tracings but good initial effort) is a failure to achieve a maximal inhalation before performing the FVC maneuver.

Figures A8a and A8b illustrate a reproducible test with three acceptable maneuvers. Figure A8a displays the three acceptable volume–time curves, and Figure A8b displays the corresponding flow–volume curves. These maneuvers were obtained from an 80-yr-old male with an $FEV_1/FVC\%$ = 61.7%. Notice that the curves are very reproducible even though the subject required approximately 20 s to reach his final volume or FVC.

Figure A9 shows a sample VC maneuver for a normal subject. This subject starts the test with several tidal volumes through

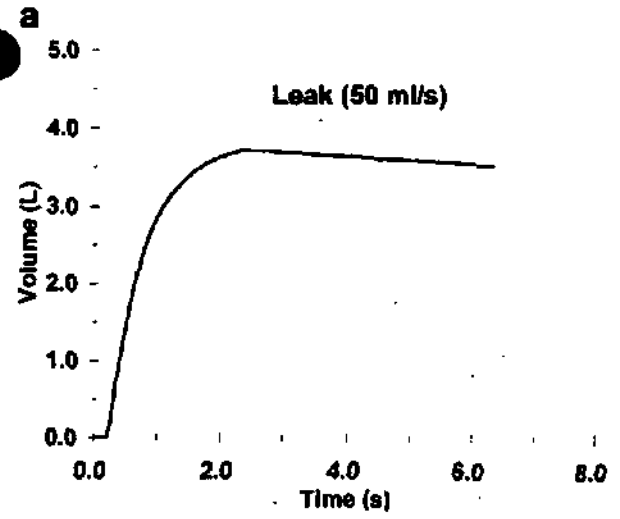


Figure A5a. Unacceptable volume–time spirogram due to a leak.

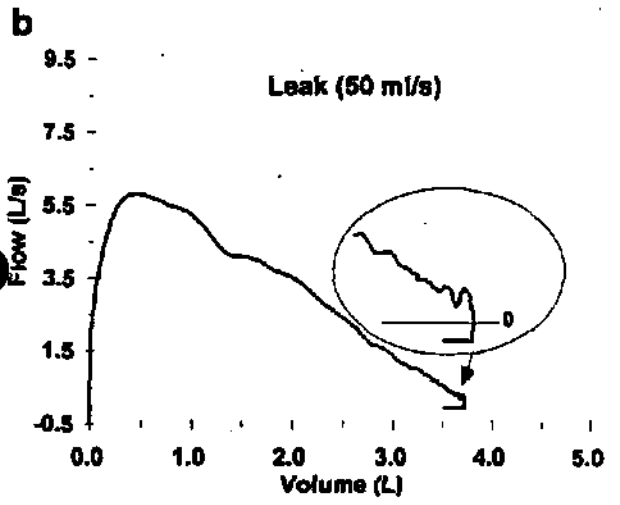


Figure A5b. Unacceptable flow–volume spirogram due to a leak.

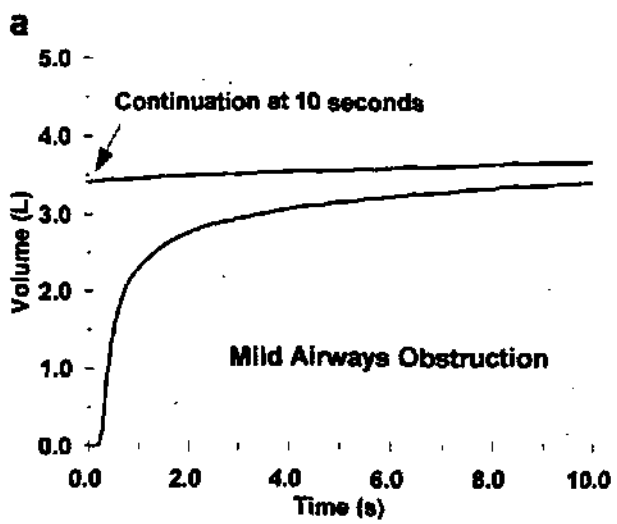


Figure A6a. Acceptable volume–time spirogram for an individual with mild airways obstruction.

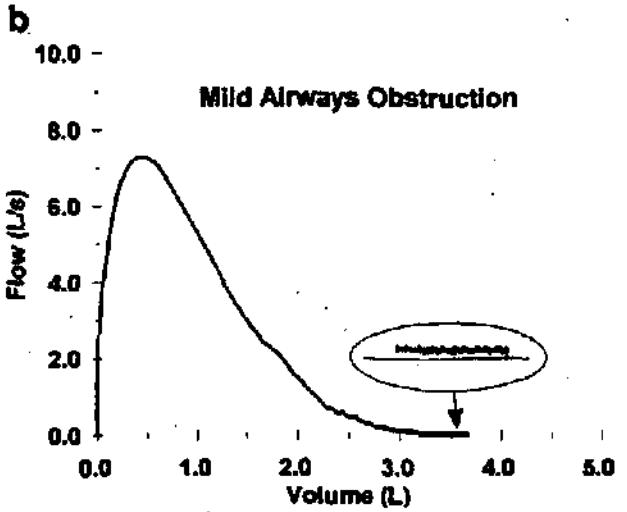


Figure A6b. Acceptable flow–volume spirogram for an individual with mild airways obstruction.

a valve opened to room air to become accustomed to breathing on the mouthpiece. The subject is then connected to the spirometer, where several additional tidal volumes are recorded. The subject then completely inhales to total lung capacity (TLC) and slowly exhales to residual volume (RV), making sure to completely inhale to TLC and exhale to RV. After reaching RV, the subject returns to FRC, where several tidal volumes are again obtained before the subject comes off the mouthpiece. Notice the plateaus at TLC and RV, indicating that the subject has completely inhaled and exhaled.

Figure A10 shows a sample VC maneuver for a subject with severe airways obstruction. The identical maneuver for the normal subject shown in Figure *A9* is repeated for this subject with severe airways obstruction. However, the tidal volumes of the subject with severe airways obstruction are much more rapid and the subject requires a longer exhalation time to reach RV, as long as 25 s. Notice that as with the normal subject, a plateau in the volume–time curve is obtained at both TLC and RV. This indicates that the subject has completely inhaled and exhaled. Also notice that the subject has some difficulty in obtaining a stable FRC after the VC maneuver, probably due to gas trapping.

APPENDIX B

Spirometer Testing Guidelines

The following testing guidelines should be used when evaluating new spirometer designs and when changes have been made to spirometer hardware or software. For production testing, the use of a smaller set of test waveforms may be appropriate. The spirometer selected for testing should be a "production" model and not one that was specifically selected because of any extraordinary calibration efforts. Once testing has begun, the device be-

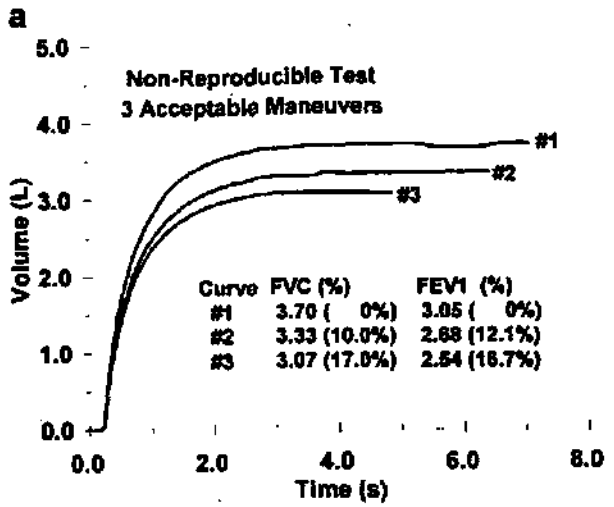


Figure A7a. Nonreproducible test with three acceptable volume–time curves. Percents are difference from largest value.

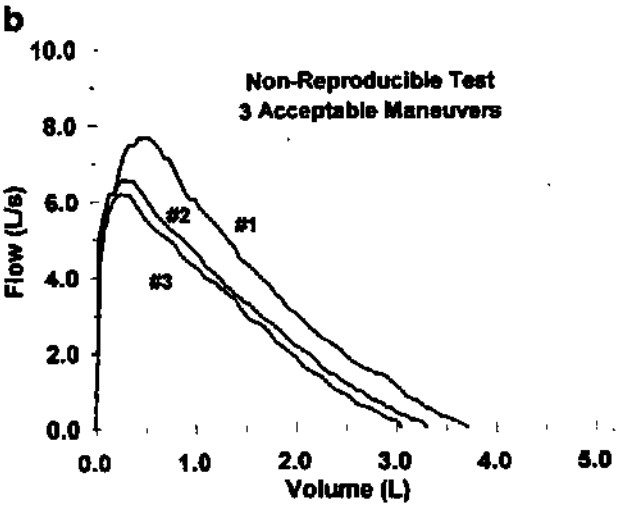


Figure A7b. Nonreproducible test with three acceptable flow–volume curves.

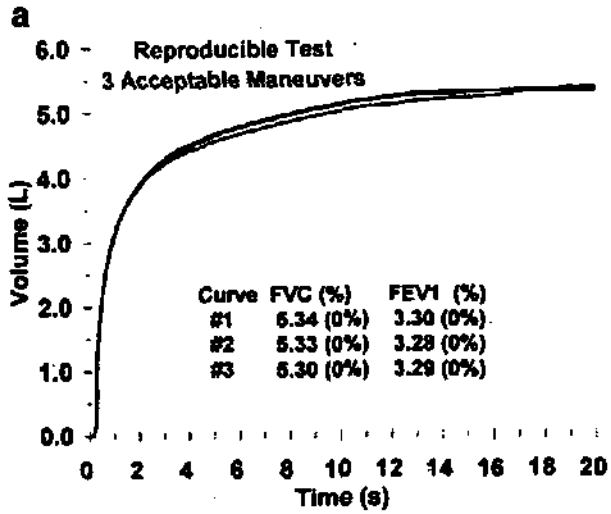


Figure A8a. Reproducible test with three acceptable volume–time curves. Percents are difference from largest value.

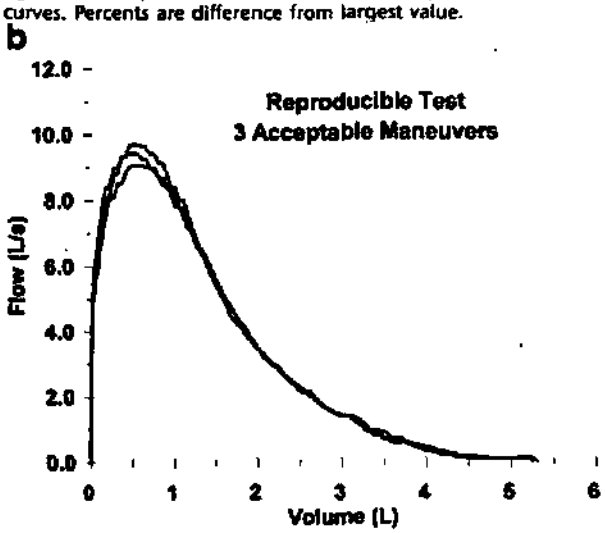


Figure A8b. Reproducible test with three acceptable flow–volume curves.

ing tested should not receive any adjustments or special calibration procedures that are not part of its routine operational procedures.

Volume parameters should be validated using the 24 volume-time standard waveforms described in APPENDIX C. For PEF and other flow parameters *not* based on a percentage of the FVC, the 26 flow–time standard waveforms should be used (APPENDIX D). The validation limits are provided for each parameter in the main sections of this statement. All tests should be conducted using the appropriate waveforms and a computer-controlled mechanical syringe or its equivalent (waveform generator). The accuracy of the waveform generator should be checked at least daily when in use, either using a spirometer for volume waveforms or a pneumotachometer for flow waveforms, or an equivalent method. The desired accuracy of the waveform generator for volume parameters is ± 0.5% (or ± 0.05 L, whichever is greater); ± 2% (or ± 5 L/min, whichever is greater) for flow parameters (e.g., PEF). In comparing results obtained from a particular spirometer, the tolerance limits of the waveform generator are to be considered by adding them to the accuracy requirement for the parameter under test, for example 0.5% (± 0.05 L) for volume parameters and 2% (± 5 L/min) for flow parameters. Therefore, the FVC accuracy requirement for comparisons with observed values would be ± 3.5% (performance accuracy requirement ± 3% plus waveform generator accuracy of ± 0.5%).

The accuracy and precision validation limits contained in this section assume a waveform generator accuracy of 0.5% for volume and 2% for flow parameters. The accuracy of available waveform generators has not been established; therefore, the desired 2% waveform generator accuracy for flow parameters may not be achieved. In this circumstance, the *actual* accuracy limit of the waveform generator should be added to the accuracy require-

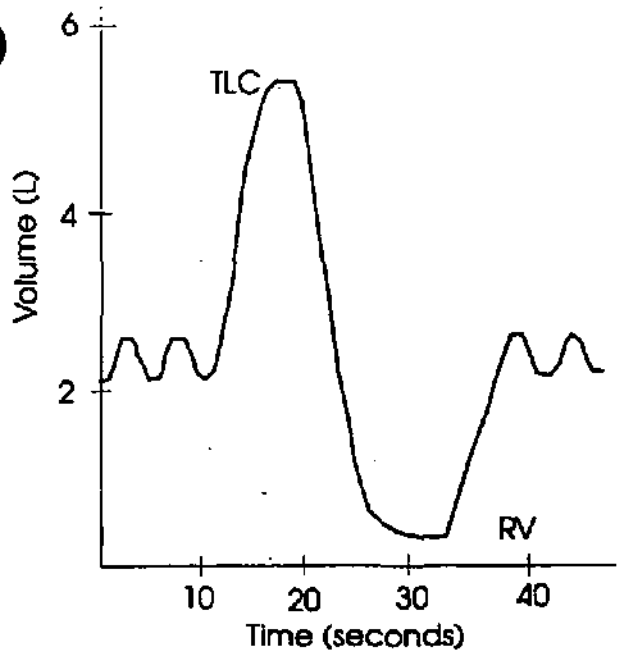


Figure A9. Sample relaxed VC maneuver in a normal subject.

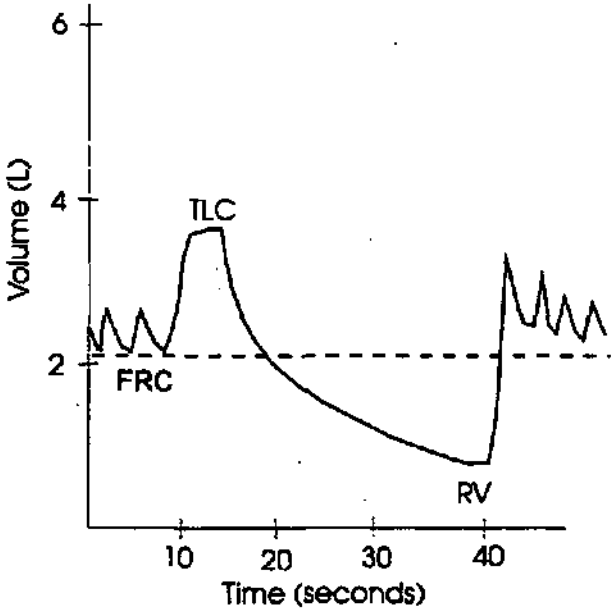


Figure A10. Sample VC maneuver from a subject with severe airways obstruction.

ment of the parameter under test. Every attempt should be made to improve the accuracy of waveform simulators, but in no case should the simulator accuracy limit be considered less than 0.5% for volume and 2% for flow parameters.

Spirometers or peak flow meters should be connected to the waveform generator in the same orientation used in the testing of subjects. Tubing or other connecting material may be used, but the volume associated with the connecting tubing should be less than 300 ml. For handheld devices, full testing should be conducted with the sensor in a horizontal position (the typical position with the patient at TLC about to initiate the maneuver). In addition, handheld devices should be tested with two waveforms (standard volume–time waveforms 1 and 6) at a typical FRC position (instrument at a 30° angle down from horizontal). These devices must meet diagnostic spirometer accuracy criteria for these two waveforms in the 30° down-angle position.

The instruments (diagnostic or monitoring devices) should be tested using the waveform generator under conditions similar to those present when testing human subjects. No special procedures should be followed in testing the instrument. Specifically, each waveform will be injected into the instrument within not less than 5 s or more than 1 min of the instrument being set to the ready condition. In measuring the resistance of the instrument, pressure should be measured in the side of the standard mouthpiece used by the instrument when constant flows are injected into the spirometer. If an in-line filter is to be used as part of routine testing of humans, a filter must be attached during spirometer validation and resistance testing.

Five repeats of each of the 24 waveforms should be injected into the test instrument using room air at ambient temperature. In those circumstances where the flow or volume sensor is changed between subjects (e.g., disposable flow sensor), a different sensor should be used for each of the repeat tests. The average of the five repeat values should be used for comparison with the standard values. The range and percent deviations of values from the five repeated tests should also be computed by:

$$\text{Range} = \text{maximum} - \text{minimum} \quad \text{(B1)}$$

$$\text{Range (\%)} = 100 * \frac{(\text{maximum} - \text{minimum})}{\text{average}} \quad \text{(B2)}$$

$$\text{Deviation} = \text{average} - \text{standard} \quad \text{(B3)}$$

$$\text{Deviation (\%)} = 100 * \frac{(\text{average} - \text{standard})}{\text{standard}} \quad \text{(B4)}$$

Averages are calculated as a simple n weighted average.

The five repeats of 24 waveforms should be considered a rigid testing sequence. The testing of a device should be completed by running all 24 waveforms with five repeated tests. If the device fails to accurately measure a value for a particular waveform, no additional repeats should be conducted for only one waveform.

Diagnostic devices should also be tested by injecting at least four waveforms using heated and humidified air (waveforms 1 through 4) to verify accuracy of volume parameters under BTPS conditions. Using volume–time waveforms 1 through 4, the average FVC and FEV, of three trials shall be compared to the standard values. The validation limits for testing under BTPS conditions are ± 4.5% or 200 ml, whichever is greater. Spirometers must meet these accuracy criteria for all four waveforms under BTPS conditions. Using 4.5% allows a 1.5% simulator error, necessary because of the added uncertainty when using heated and humidified air. The time between each of the three trials should be less than 2 min. The temperature of the air injected into the device under test should be within ± 1° C of 37° C and should be measured before the air is injected into the device. Waveform generators are being modified to allow BTPS testing. The BTPS testing requirement will be implemented when BTPS testing services are available.

In addition to testing using the waveform generator, the device should be tested using at least two healthy human subjects.

TABLE B1

STROKE VOLUME, VOLUME IN SPIROMETER AT START OF TEST (FOR VOLUME SPIROMETERS), RATE, AND CORRESPONDING MVV TARGET VALUES

Test Number	Target MVV (L/min)	Stroke Volume (L)	Rate (Strokes/min)	Starting Volume (L)
1	60	1.0	60	2.0
2	100	1.0	100	3.0
3	120	2.0	60	3.0
4	200	2.0	100	3.0

The purpose of the testing using a human subject is to verify that the instrument will function properly under conditions other than those present using a mechanical simulator. To achieve a balanced design, each subject should perform alternating maneuvers between a standard spirometer and the device being tested, performing three maneuvers on each device, for a total of six maneuvers. One subject should be randomly assigned to perform their first maneuver on the standard spirometer while the other subject's first maneuver will be performed on the device being tested, allowing the learning effect to be equally distributed across both instruments. The differences between the largest of the three trials from each device should be within ± 6% or 200 ml, whichever is greater, for FVC and FEV_1, and ± 15% or 30 L/min, whichever is greater, for PEF.

For validating MVV, a mechanical pump should be used with a sinusoidal waveform. The response of the device should be determined using incrementally increased flows up to a maximum of 250 L/min, produced with stroke volumes up to 2 L. The specific minimum patterns and for volume spirometers, the volume in the spirometer, are given in Table B1. The device should read the MVV within ± 10.5% of reading or ± 20 L/min, whichever is greater for all four test patterns specified in Table B1. In addition, the pressure measured at the mouthpiece should not exceed 10 cm H_2O during the entire MVV maneuver. No mechanical pump testing at BTPS is required for MVV.

DIAGNOSTIC DEVICES: TESTING FOR ACCURACY AND PRECISION WITH A WAVEFORM GENERATOR

Accuracy Testing

Accuracy criteria: Deviation ± 3.5% or ± 0.100 L, whichever is greater, for volume measurements; ± 5.5% or ± 0.250 L/s, whichever is greater, for $FEF_{25-75\%}$; ± 12% or ± 25 L/min (± 0.420 L/s), whichever is greater, for PEF. These criteria are increased slightly from those in Table 2 to account for the waveform generator inaccuracy. For MVV testing, deviation must be less than ± 10.5% or 20 L/min, whichever is greater.

Waveforms: Twenty-four standard volume-time waveforms (APPENDIX C) for FVC, FEV_1, and $FEF_{25-75\%}$; 26 standard flow-time waveforms (APPENDIX D) for PEF. For BTPS testing, volume-time waveforms 1 through 4 should be used with heated and humidified air as specified in this appendix. For MVV testing, sinusoidal waveforms should be used with the patterns specified in Table B1.

Spirometer tested: One production spirometer. Spirometers should not be screened or especially calibrated before testing. If an in-line filter is to be used during the testing of humans, it should be attached for this testing. When during clinical testing, if the flow or volume sensor is changed between subjects, the sensors must be changed for each of the five repeat tests described below. The spirometer may not be recalibrated after these sensor changes unless recalibration is required after each sensor change during clinical testing.

Validation: Each spirometric waveform is to be injected into the spirometer five times. MVV patterns will be injected in duplicate. Average values will be calculated for each waveform and, along with individual values, will be used to score the spirometer. See formulas B1–B4.

Acceptable performance: For FVC and FEV_1 in each of the volume-time waveforms: deviation (formula B3) must be less than 0.100 L *or* deviation (%) (formula B4) must be less than 3.5%. For $FEF_{25-75\%}$ in each of the volume-time waveforms: deviation must be less than 0.250 L/s *or* deviation (%) must be less than 5.5%. For PEF in each of the flow-time waveforms: deviation must be less than 25 L/min (0.420 L/s) or deviation (%) must be less than 12%. For BTPS testing using waveforms 1–4: deviation must be less than 0.2 L or deviation (%) must be less than 4.5%. For MVV in each of the patterns: deviation must be less than 20 L/min or deviation (%) must be less than 10.5%.

An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. For testing with ambient air, acceptable performance is present if the error rate for each individual parameter (FVC, FEV_1, $FEF_{25-75\%}$, PEF) is less than 5% (one error for each parameter when 24 or 26 waveforms are used). For MVV testing and spirometric testing with BTPS conditions, acceptable performance is present if the error rate is zero.

Precision Testing: Intradevice Testing

Precision criteria: See the acceptable performance criteria listed below.

Waveforms: Use data generated as part of accuracy testing. Acceptable performance: For FVC and FEV_1, for each of the volume-time waveforms: The range (formula B1) must be less than 0.100 L *or* range (%) (formula B2) must be less than 3.5%. For $FEF_{25-75\%}$ using each of the volume-time waveforms: The range (formula B1) must be less than 0.250 L/s or the range (%) (formula B2) must be less than 5.5%. For PEF using each of the flow-time waveforms: The range must be less than 25 L/min (0.420 L/s) or the range (%) must be less than 7%.

An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if the error rate for each individual parameter (FVC, FEV, PEF) is less than 5% (one error for each parameter if 24 or 26 waveforms are used).

MONITORING DEVICES (PEF) TESTING CRITERIA

The range and deviations from the standard PEF values should be calculated using formulas B1 through B4.

Accuracy Testing

Accuracy criterion: ± 12% or ± 25 L/min of target values, whichever is larger. The primary criterion is ± 10%; 2% is added to account for the inaccuracy of the waveform generator.

Waveforms: 26 flow-time curves (APPENDIX D).

Meters tested: Two production meters. Meters should be selected routinely from a production run and not be screened before validation testing.

Validation: Each meter will receive five maneuvers for each of the 26 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance is less than three errors out of the total 52 tests (26 waveforms, 2 meters).

Precision Testing: Intradevice Testing

Criterion: Less than 6% intradevice variability or 15 L/min, whichever is greater. The primary criterion is less than 5%. One per-

TABLE C1

VALUES FOR STANDARD WAVEFORMS

Curve	FVC (L)	FEV_1 (L)	FEV_1 (%FVC)	Vext (L)	Vext (%FVC)	FEF_{max} (L/s)	$FEV_{25-75\%}$ (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	33.9	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

Definition of abbreviations: Vext = extrapolated volume (*see* Figure 2 for description).

cent or 5 L/min is added to account for the imprecision of the waveform generator.

Waveforms: Four of the 26 standard flow–time waveforms (waveforms 1, 4, 8, and 25).

Meters tested: Ten production meters.

Validation: Three flows for each waveform for each meter. For each waveform and for each meter, calculate range (formula B1) and range (%) (formula B2) for each PEF.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is six or fewer errors (error rate ± 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 25 L/min, whichever is greater. This includes 1% or 5 L/min for the imprecision of the waveform generator.

Waveforms: Same as for intradevice testing.

Meters tested: Same as for intradevice testing.

Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each meter, calculate an average PEF for each waveform. For each waveform, combine all data from the 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

TABLE D1

CALCULATED VALUES FOR 26 STANDARD FLOW–TIME WAVEFORMS (0.002-S SAMPLING INTERVAL)*

Waveform Number	Flow PEF (L/s)	Vol-80 PEF (L/s)	Vol-40 PEF (L/s)	Rise-Time (ms)	Vext Time-to-PEF (ms)	Flow Time-to-PEF (ms)	Extr Vol (L)	%Vext (%FVC)	FEV_1 (L)
1	7.445	7.245	7.337	93.5	86.8	151.7	0.108	2.5	3.373
2	10.860	9.905	10.450	55.7	46.5	86.6	0.093	2.2	3.838
3	4.794	4.372	4.630	68.3	53.0	114.7	0.054	3.3	1.302
4	4.401	4.240	4.321	76.0	65.6	116.3	0.051	2.9	1.468
5	3.630	3.564	3.584	159.5	170.6	241.0	0.081	3.0	2.053
6	3.088	2.728	2.949	44.5	36.8	62.7	0.021	1.3	1.110
7	2.509	2.237	2.403	148.0	67.6	173.6	0.057	3.7	1.046
8	2.328	2.048	2.210	42.4	35.6	57.6	0.015	1.0	0.950
9	5.259	4.923	5.109	57.0	47.2	85.4	0.046	1.8	2.182
10	4.733	4.657	4.666	46.7	93.6	122.2	0.035	1.5	2.029
11	6.870	6.472	6.706	81.1	67.4	125.6	0.085	3.1	2.080
12	10.684	10.528	10.558	115.3	139.9	214.1	0.189	3.4	4.618
13	4.804	4.708	4.739	105.3	121.7	194.9	0.080	2.7	2.304
14	3.821	3.756	3.769	124.7	127.7	201.8	0.074	2.5	2.249
15	7.956	7.814	7.852	174.9	152.6	270.4	0.192	5.0	3.219
16	5.251	5.100	5.165	76.3	80.5	123.7	0.060	2.1	2.246
17	5.842	5.721	5.757	165.1	163.4	265.1	0.151	5.0	2.802
18	8.593	8.404	8.465	132.9	126.2	248.7	0.178	3.6	4.303
19	6.953	6.651	6.807	76.5	63.7	120.2	0.083	2.2	3.007
20	7.430	7.274	7.324	120.9	143.3	268.4	0.141	2.5	4.613
21	3.973	3.745	3.880	130.3	88.4	193.1	0.079	6.0	1.096
22	3.377	3.316	3.334	184.2	157.6	259.6	0.094	5.0	1.559
23	8.132	7.954	8.019	84.8	83.1	152.1	0.107	2.4	3.476
24	4.155	4.028	4.086	50.3	52.3	83.7	0.032	1.2	1.833
25	14.194	13.896	13.964	57.9	53.7	100.3	0.126	1.9	5.944
26	11.595	10.446	11.172	49.6	42.2	79.1	0.088	1.7	4.311

Definition of abbreviations: Flow PEF = peak flow determined by obtained highest observed flow value; Vol-80 PEF = peak flow determined from volume–time curve using an 80-ms segment; Vol-40 PEF = Peak flow determined from volume–time curve using a 40-ms segment; Rise-Time = time required for the flow to rise from 10% of PEF to 90% of PEF; Flow Time-to-PEF = time required for flow to rise from 200 ml/s to maximum flow (PEF); Vext Time-to-PEF = time required for flow to rise from Vext time zero to PEF.

* Units: flow (L/s), volumes (L), and time (milliseconds). These waveforms are available on digital media from the American Thoracic Society.

MONITORING DEVICES (FVC AND FEV_1) TESTING CRITERIA

Accuracy Testing

Criterion: Deviation ± 5.5% *or* deviation (%) ± 0.1 L, whichever is larger.

Waveforms: Twenty-four standard volume–time waveforms (APPENDIX C).

Device testing: Two production devices selected routinely from a production run and not screened before testing.

Validation: Each device will receive five maneuvers for each of the 24 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance for each individual parameter is less than three errors out of the total 48 tests (24 waveforms, 2 devices).

Precision Testing: Intradevice Testing

Criterion: Range (%) < 3.5% or range < 0.1 L, whichever is greater.

Waveforms: Four of the 24 standard volume–time waveforms (waveforms 1, 3, 6, and 11).

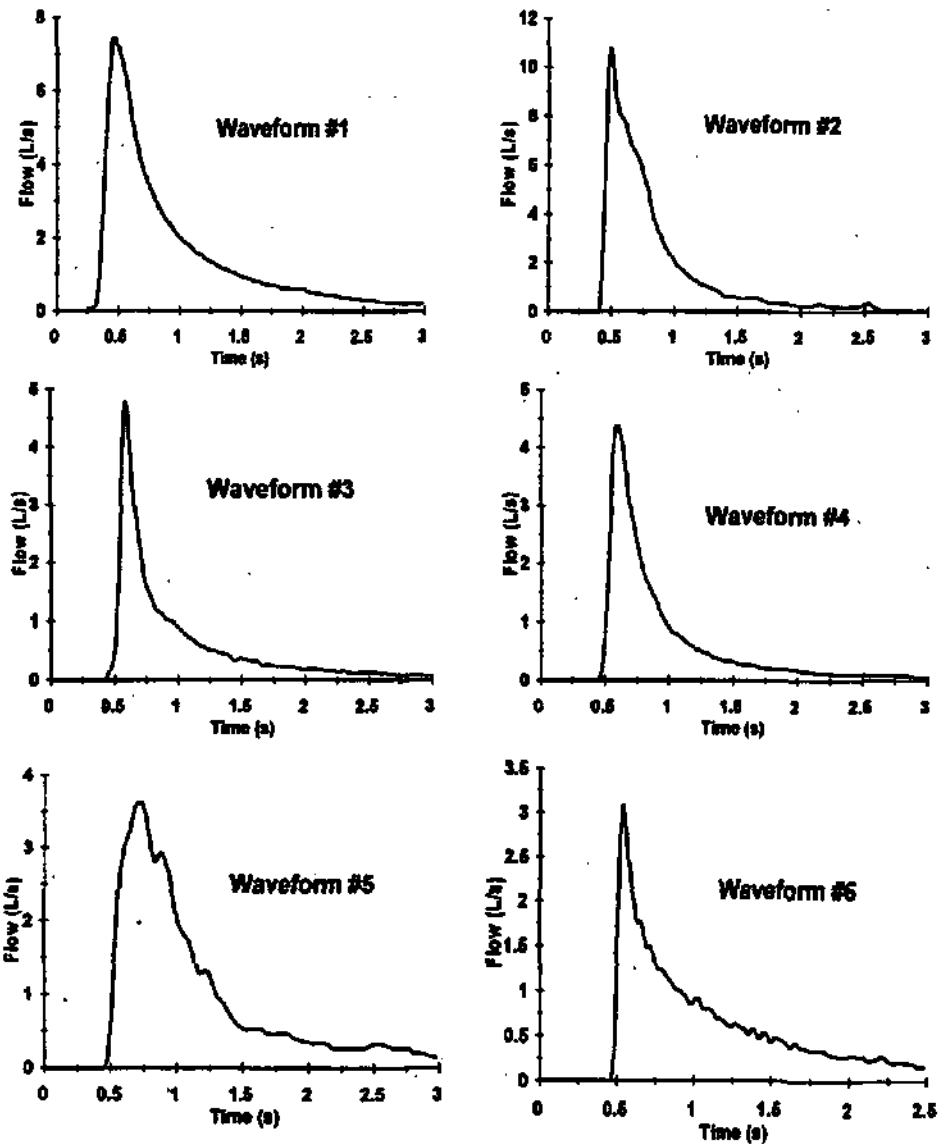
Meters tested: Ten production devices.

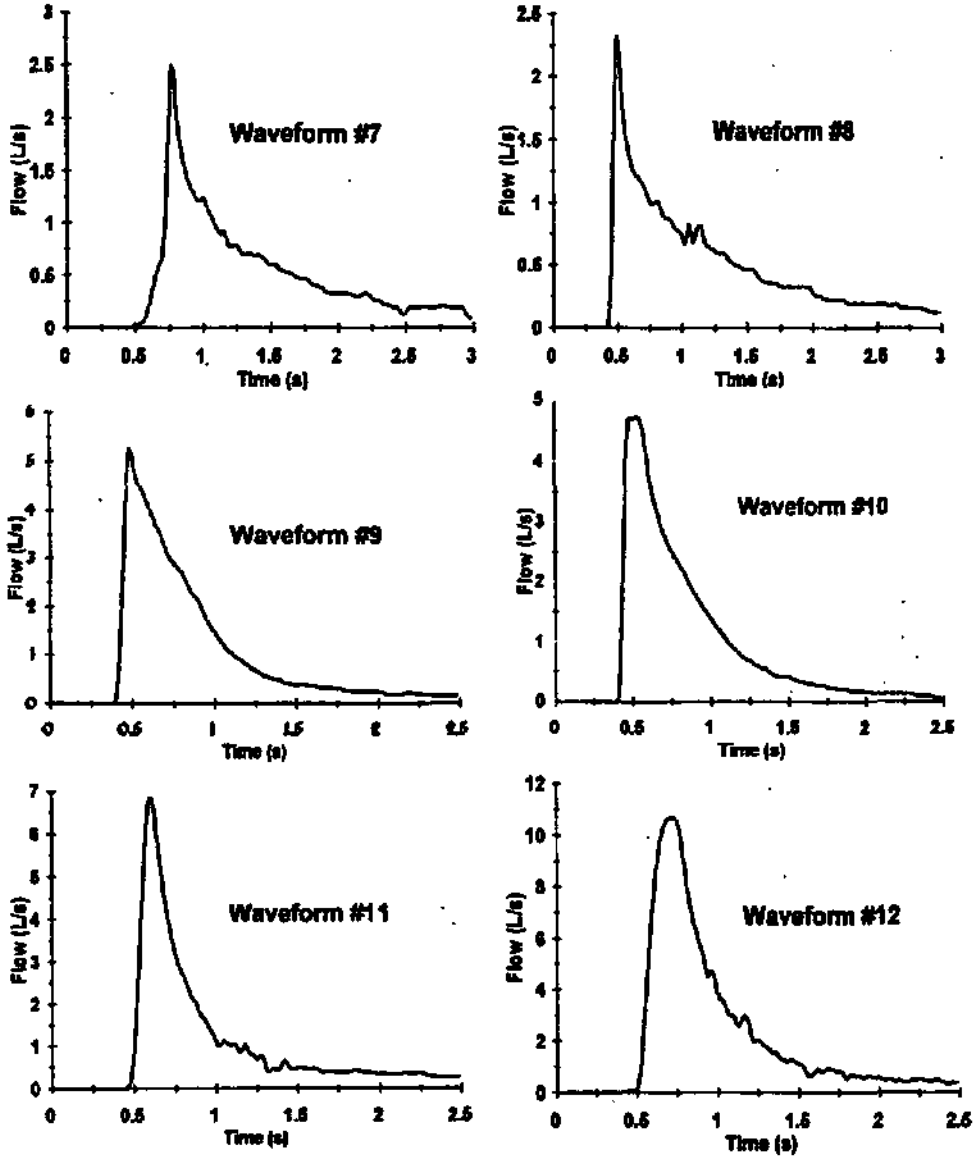
Validation: Three flows for each waveform for each device. For each waveform and for each device, calculate range (formula B1) and range (%) (formula B2) for FVC and FEV_1.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance for each individual parameter is six or fewer errors (error rate ± 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 0.2 L, whichever is greater.





Waveforms: Same as for intradevice testing.

Devices tested: Same as for intradevice testing.

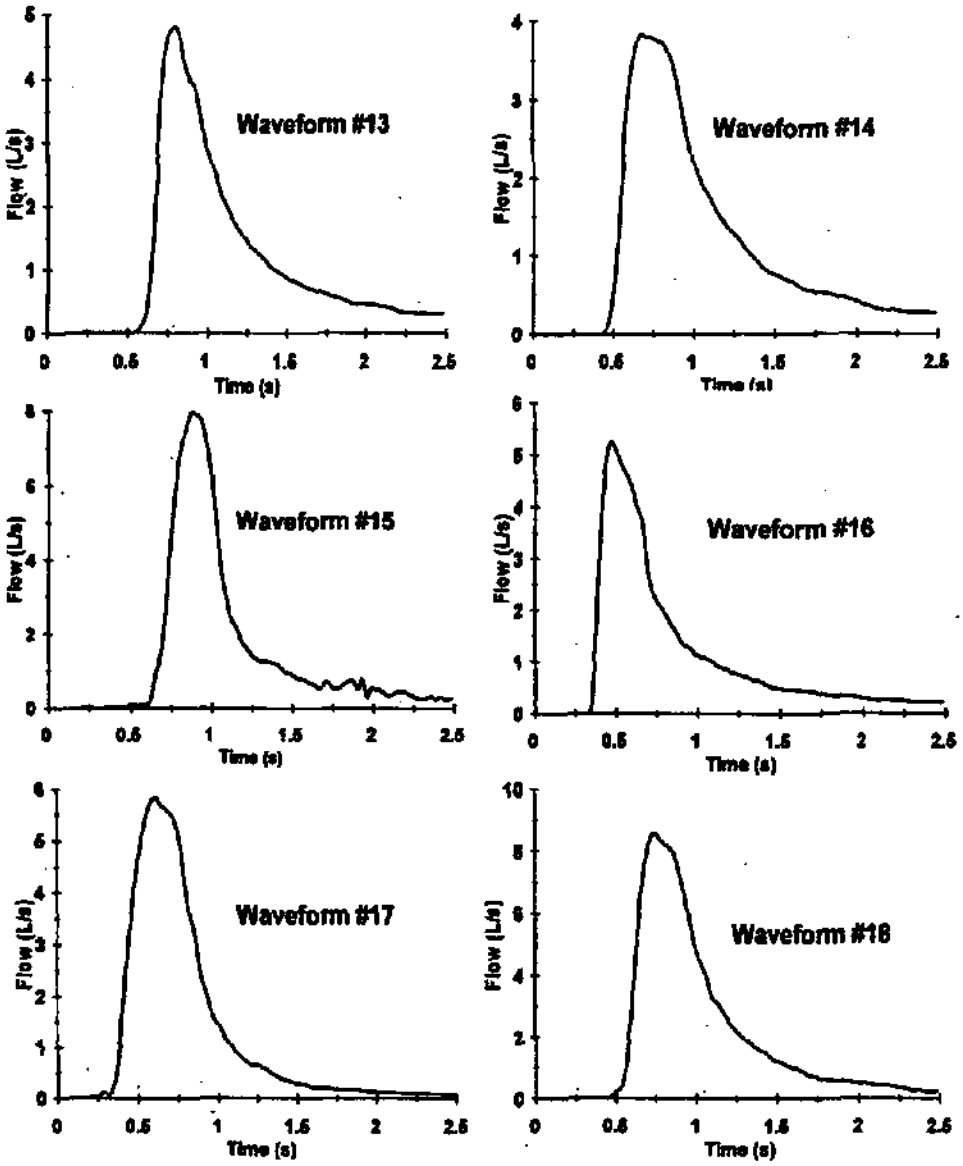
Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each device, calculate an average FVC and FEV_1 for each waveform. For each waveform and parameter, combine all data from 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

APPENDIX D

Standard Flow-Time Waveforms for Validating PEF

The following flow-time waveforms are intended primarily for testing portable PEF meters but can be used for testing other types of spirometers, especially those measuring PEF, time-to-peak flow, or rise-time. These waveforms were chosen to represent a range of PEFs and efforts (rise-times). The PEF is derived directly from the flow-time waveform–maximal observed value. To calculate the volume-determined PEF, volume is first obtained by integrating (summing) the flow values. Flow is then calculated from the volume–time waveform using the ATS 8-point smoothing function. The resulting volume PEF is usually lower than the PEF obtained from the flow–time waveform. Rise-time is defined as the time required for the flow to rise from 10% of the PEF to 90% of the PEF and is expressed in milliseconds. Other investigators have used the time-to-PEF, using the back-extrapolated technique to determine the zero time-point. Using back-extrapolation to calculate time-to-peak flow sometimes



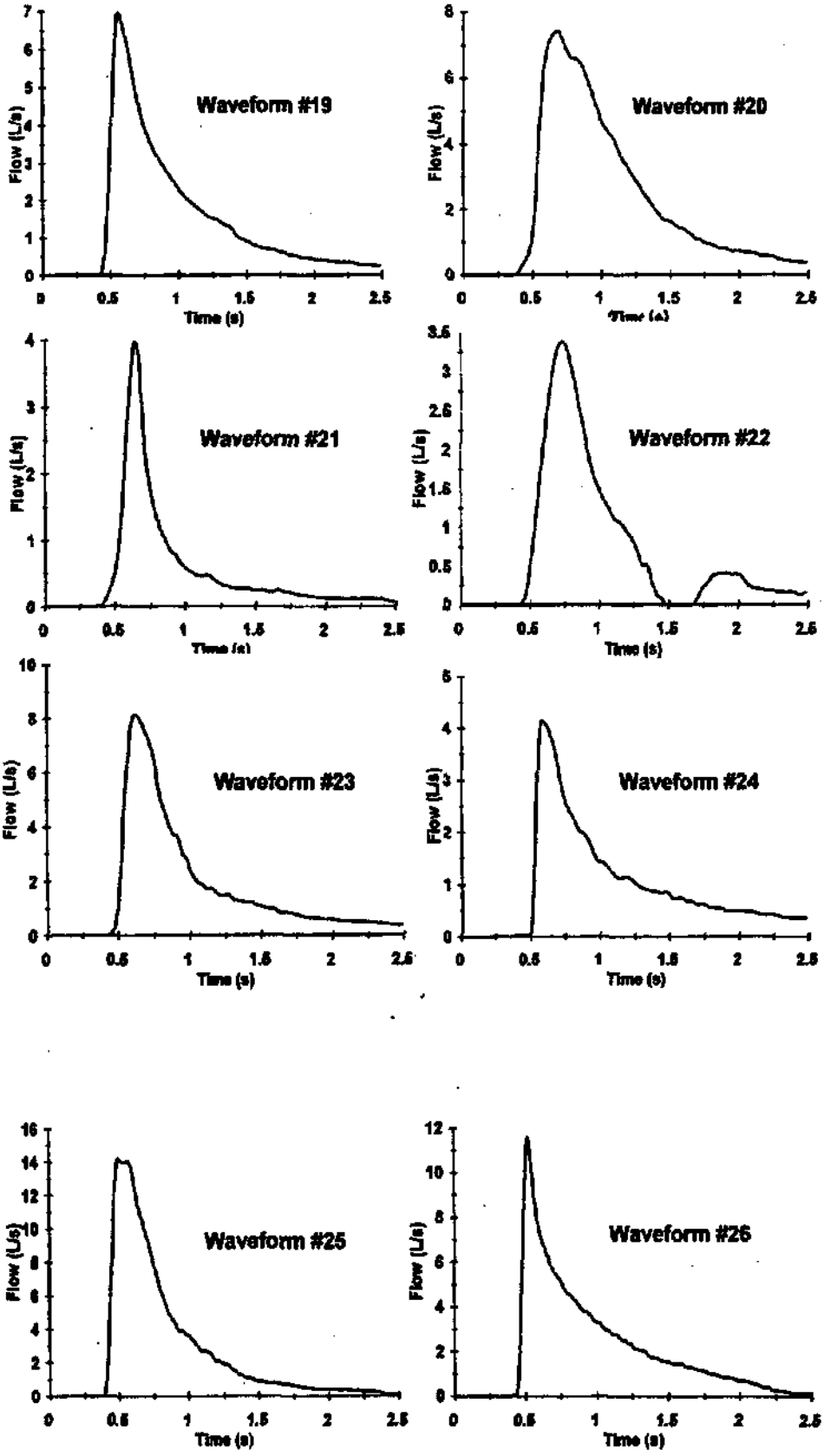
results in artificially lower time-to-PEF, as can be seen in waveform 7.

APPENDIX E

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 (79), a short tutorial on signal processing is presented (Figure E1).

For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (80). 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 from 0.003 to 0.004 L) for the A-to-D converter is recommended, although 10 bits (1 part in 1,024, raw resolution from 0.008 to 0.016 L) may be adequate for sampling volume. The sampling rate of the spirometer volume or flow is very important. Lemen and associates (19) have shown


Waveform #19
Waveform #20
Waveform #21
Waveform #22
Waveform #23
Waveform #24
Waveform #25
Waveform #26
Flow (L/s)
Time (s)

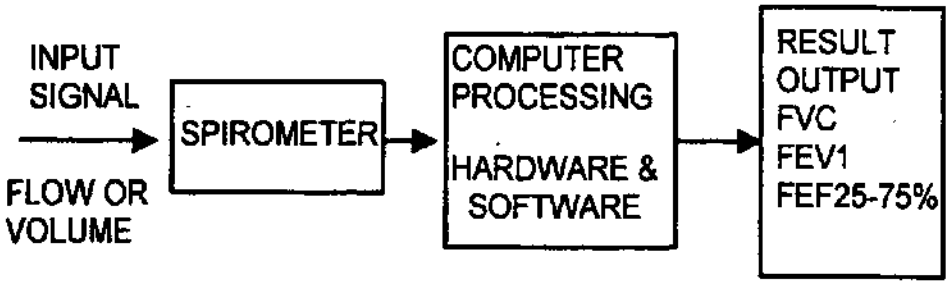


Figure E1. Block diagram of spirometer data acquisition.

that for both infants and adults, 95% of the signal energy in the flow–time spirogram 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 (81). 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. 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 and shaft or position encoders of the volume–time signal have been used (80). This approach measures the time interval between uniform volume intervals (for example, 0.010 L). In this case, the resolution of the time interval between measurements during rapid flow becomes a limiting factor. Ostler and associates have recently addressed these issues (80). 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 μs is needed (80).

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