NIOSH SPIROMETRY TRAINING GUIDE

NIOSH SPIROMETRY
TRAINING GUIDE

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Prepared by

UNIVERSITIES OCCUPATIONAL SAFETY AND HEALTH
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CONTINUING EDUCATION AND OUTREACH PROGRAM

Division of Consumer Health Education
Department of Environmental and Community Medicine
Robert Wood Johnson Medical School
University of Medicine and Dentistry of New Jersey

and

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The Universities Occupational Safety and Health Educational Resource Center (UOSHERC) is one of sixteen Educational Resource Centers (ERCs) - now called Education Research Centers - located at universities throughout the United States. The ERCs, which were first established in 1977 in response to the OSHAct, receive sponsorship from the National Institute for Occupational Safety and Health (NIOSH) to provide undergraduate, graduate, and continuing education for occupational safety and health professionals. Educational programs are primarily designed to meet the needs of occupational health physicians, occupational health nurses, industrial hygienists, safety professionals, and those professionals in related disciplines.

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DISCLAIMER

The opinions, findings and conclusions expressed herein are not necessarily those of the National Institute for Occupational Safety and Health (NIOSH), the University of Medicine and Dentistry of New Jersey (UMDNJ) or the Universities Occupational Safety and Health Educational Resource Center (UOSHERC), nor does mention of company names or products constitute endorsement by NIOSH, UMDNJ or UOSHERC.

NOTE: Due to printing constraints of the **NIOSH SPIROMETRY TRAINING GUIDE**, the distance representing one second may vary from one spirogram to another. Measure at the top of the spirogram to determine the distance for one second for each example and exercise.

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Many other individuals have contributed to the final form of this curriculum, especially Deborah K. Shields, MPH, CHES, who served as the curriculum specialist/editor for the manuscript; Lee Laustsen, BA, who chaired the Spirometry Curriculum Committee; Michael Gochfeld, MD, PhD, who wrote sections of Units One and Two and Appendices B and C and who served as contributing editor; Paul Enright MD, who wrote Unit Three, and Mitchel Rosen MS, who prepared the layout of the Data Summary Form.

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NOTICE TO ALL COURSE ATTENDEES:

Section (h) (1) (iii) of the Cotton Dust Standard (29 CFR 1910.43) promulgated by OSHA in 1978 and amended December 13, 1985 states: "Persons other than licensed physicians, who administer the pulmonary function testing required by this section shall have completed a NIOSH-approved training course in spirometry."

Within NIOSH, the responsibility of approving courses had been delegated to the Division of Training and Manpower Development but currently resides in the Division of Respiratory Disease Studies. Minimum requirements for approval of a course are contained in Appendix D. of the Standard and include criteria for apparatus, technique, interpretation, course content and hours of instruction. In addition, NIOSH has established criteria for staff qualifications and course format.

When NIOSH approves a course, it is attesting to the fact that the course meets the minimum OSHA/NIOSH criteria for teaching individuals to perform spirometry in the Cotton Dust Industry. This does not mean that the individual taking the course is certified as a pulmonary function technician by NIOSH. Students have merely completed a NIOSH-approved course. The Standard does not require the completion of a second/update course nor is there a requirement that an update course must be taken to complete the first course approved by NIOSH.

INTRODUCTION

BACKGROUND: The **NIOSH Spirometry Training Guide** is based on two earlier publications, the **NIOSH Spirometry Workbook** and the **NIOSH Manual of Spirometry in Occupational Medicine**. In the new curriculum, the material covered in the **NIOSH Manual of Spirometry in Occupational Medicine** has been simplified and incorporated into the content of the **NIOSH Spirometry Workbook**. New material has also been added, including a comparison of volume and flow spirometers and volume/time and flow/volume tracings, quality assurance procedures, occupational lung diseases and hazards, and information from the **American Thoracic Society Standardization of Spirometry--1994 Update (1).**

The American Thoracic Society is the medical section of the American Lung Association. It has provided a leading thrust in the standardization and upgrading of spirometric instruments and practices. Its first set of standards, **ATS Statement--Snowbird Workshop on Standardization of Spirometry** was essentially incorporated by OSHA in the Cotton Dust Standard, which was promulgated on June 23, 1978. The Snowbird Workshop standards were revised in 1987 (2), and again in 1994, and released as the **ATS Standardization of Spirometry--1994 Update (1)**.

PURPOSE: The **NIOSH Spirometry Training Guide** was prepared for use as an **adjunct** or **supplement** to a NIOSH approved course on spirometry. It is not intended to serve as a self-instructional package. Learning spirometry requires observation, demonstration, and hands-on practice.

INTENDED AUDIENCE: This **Guide** is intended for individuals who are responsible for conducting spirometry in the workplace. It will be of special interest to occupational health physicians, nurses, and other health professionals.

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COURSE GOAL AND OBJECTIVES

Goal: The goal of this course is to increase the number of spirometry technicians who:

1. Use standardized methods to obtain acceptable and reproducible spirograms.

2. Correctly perform calculations for basic spirometric parameters.

3. Implement appropriate quality assurance procedures for spirometric equipment.

4. Recognize the applications, strengths, and limitations of spirometry in the occupational health setting.

Objectives: At the end of this course, students will be able to do the following:

Unit One: Overview of Pulmonary Anatomy and Physiology

Briefly describe:

a. The function of the respiratory system and the mechanics of respiration.
b. Mechanisms within the respiratory system to protect the lungs from airborne hazards.
c. Obstructive and restrictive lung diseases.

Unit Two: Overview of Spirometry

Briefly describe:

a. Common spirometric terms.
b. Volume and flow spirometers.
c. Volume/time and flow/volume tracings.
d. Forced Expiratory Maneuver, Forced Vital Capacity (FVC), and Forced Expiratory Volume at One Second (FEV_1).
e. The role of spirometry in evaluating pulmonary function and detecting occupational lung diseases.
f. The limitations of spirometry as a screening tool.
g. The importance of accuracy and precision in spirometry.

Unit Three: Quality Assurance Procedures

Perform spirometric equipment quality assurance procedures:

a. Calibrate volume for volume and flow spirometers.
b. Check that the mechanical recorder is working properly.
c. Verify the accuracy of the ambient temperature reading.
d. Inspect that the start of the test begins at the right time and at the right place on the graph paper.

e. Check that the electronically-derived FEV_1 is calculated using the back extrapolation method.
f. Verify that the electronically-derived predicted normal values are calculated correctly.
g. Maintain spirometer records and calibration and maintenance logs.
h. Perform infection control procedures appropriate for the type of spirometer used.

Unit Four: Spirometric Technique

a. Properly prepare equipment prior to testing.
b. Identify suitable subjects and criteria for postponing the test.
c. Prepare subjects to perform the test.
d. Perform the test correctly.
e. Determine the acceptability of spirograms obtained.
f. Determine the reason(s) why the subject is having difficulty in completing a satisfactory test and make appropriate coaching changes as needed for retesting.
g. Obtain at least two spirograms that are reproducible from at least three that are acceptable.
h. Maintain subject records that include date/time, age, height, sex, race, testing position used, ambient air temperature, barometric pressure, spirometer used, tests performed, test results, predicted normal values used, and comment on subject cooperation and effort.

Unit Five: Basic Spirometric Calculations

Correctly calculate the basic measures used for interpreting test results:

a. Forced Vital Capacity (FVC) and variability between the two largest FVCs.
b. Forced Expiratory Volume in One Second (FEV_1) and variability between the two largest FEV_1s.
c. Back extrapolation and extrapolated volume.
d. FEV_1/FVC%.
e. Forced Mid-Expiratory Flow Rate ($FEF_{25-75\%}$) (optional measurement).
f. Conversion to BTPS.

Unit Six: Comparing Observed to Predicted Normal Values

a. Select predicted normal value tables that are appropriate for the subjects and the employment setting.
b. Use the same set of predicted values for all spirometric calculations and for future comparisons.
c. Determine subjects' predicted normal values and calculate the subjects' percentage of the predicted values.
d. List factors that affect normal predicted values (e.g., age, sex, height, race).
e. Calculate the race correction factor for appropriate ethnic categories and occupational settings.

Unit Seven: Comparing Changes in Follow-Up Spirograms

a. Determine subjects' absolute change and percent change in follow-up spirograms.
b. Identify common non-pathological factors that potentially affect changes in follow-up spirograms (e.g., age, height, season, time of day, etc.).

Unit Eight: Overview of Standards for Spirometric Equipment

a. List instrument specification for spirometers and calibration equipment from the Cotton Dust Standard and American Thoracic Society recommendations.

Unit Nine: Additional Exercises

a. Successfully complete the exercises.

UNIT ONE: OVERVIEW OF PULMONARY ANATOMY AND PHYSIOLOGY

A. The Respiratory System

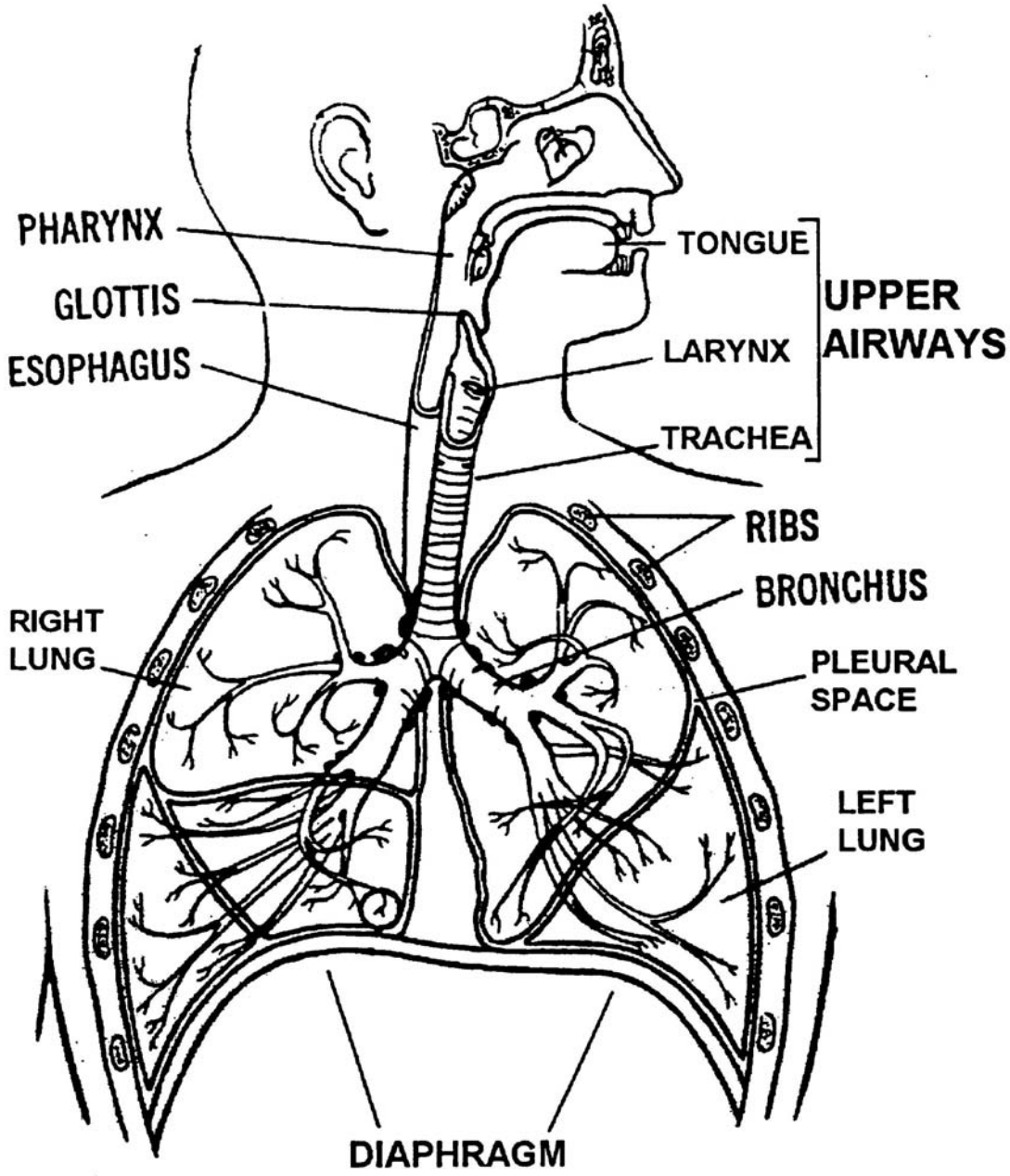
A person can live for weeks without food and a few days without water but only a few minutes without oxygen. Every cell in the body needs a constant supply of oxygen to produce energy to grow, repair or replace itself, and maintain vital functions. The oxygen must be provided to the cells in a way that they can use. It must be brought into the body as air that is cleaned, cooled or heated, humidified, and delivered in the right amounts.

The respiratory system is the body's link to this supply of life-giving oxygen. It includes the diaphragm and chest muscles, the nose and mouth, the pharynx and trachea, the bronchial tree, and the lungs, each of which is discussed below. (See **Figure 1-1. The Respiratory System**.) The bloodstream, the heart, and the brain are also involved. The bloodstream takes oxygen from the lungs to the rest of the body and returns carbon dioxide to them to be removed. The heart creates the force to move the blood at the right speed and pressure throughout the body. The smooth functioning of the entire system is directed by the brain and the autonomic nervous system.

A person at rest breathes about 6 liters of air a minute. Heavy exercise can increase the amount to over 75 liters per minute (3). During an 8-hour work day of moderate activity, the amount of air breathed may be as much as 8.5 m^3 (300 cubic feet). The skin, with its surface area of approximately 1.9m^2 (20 sq. ft.) is commonly thought to have the greatest exposure to air of any body part. However, in reality the lungs have the greatest exposure, with a surface area exposed to air of 28 m^2 (300 sq. ft.) at rest and up to 93 m^2 (1,000 sq. ft.) during a deep breath (4).

The respiratory system is susceptible to damage caused by inhaled toxic materials and irritants because the surface area of the lungs exposed to air is so large and the body's need for oxygen so great. The ability of the respiratory system to function properly has a great impact on the body. Disease in any one of its parts can lead to disease or damage to other vital organs. For example, occupational lung disease can also cause heart disease.

FIGURE 1-1. THE RESPIRATORY SYSTEM



From American Lung Association: Occupational Lung Diseases: An Introduction. New York, NY. Macmillan. 1979: pp 10. (5).

B. Mechanics of Respiration

Air containing oxygen enters the body through the nose and mouth. From there it passes through the pharynx or throat on its way to the trachea (windpipe). The trachea divides into two main airways called bronchi upon reaching the lungs; one bronchus serves the right lung and the other the left. The bronchi subdivide several times into smaller bronchi, which then divide into smaller and smaller branches called bronchioles. These bronchi and bronchioles are called the bronchial tree because the subdividing that occurs is similar to the branching of an inverted tree. After a total of about 23 divisions, the bronchioles end at alveolar ducts. At the end of each alveolar duct, are clusters of alveoli (air sacs). The oxygen transported through the respiratory system is finally transferred to the bloodstream at the alveoli. (See **Figure 1-2. Schematic Diagram of the Airway**.)

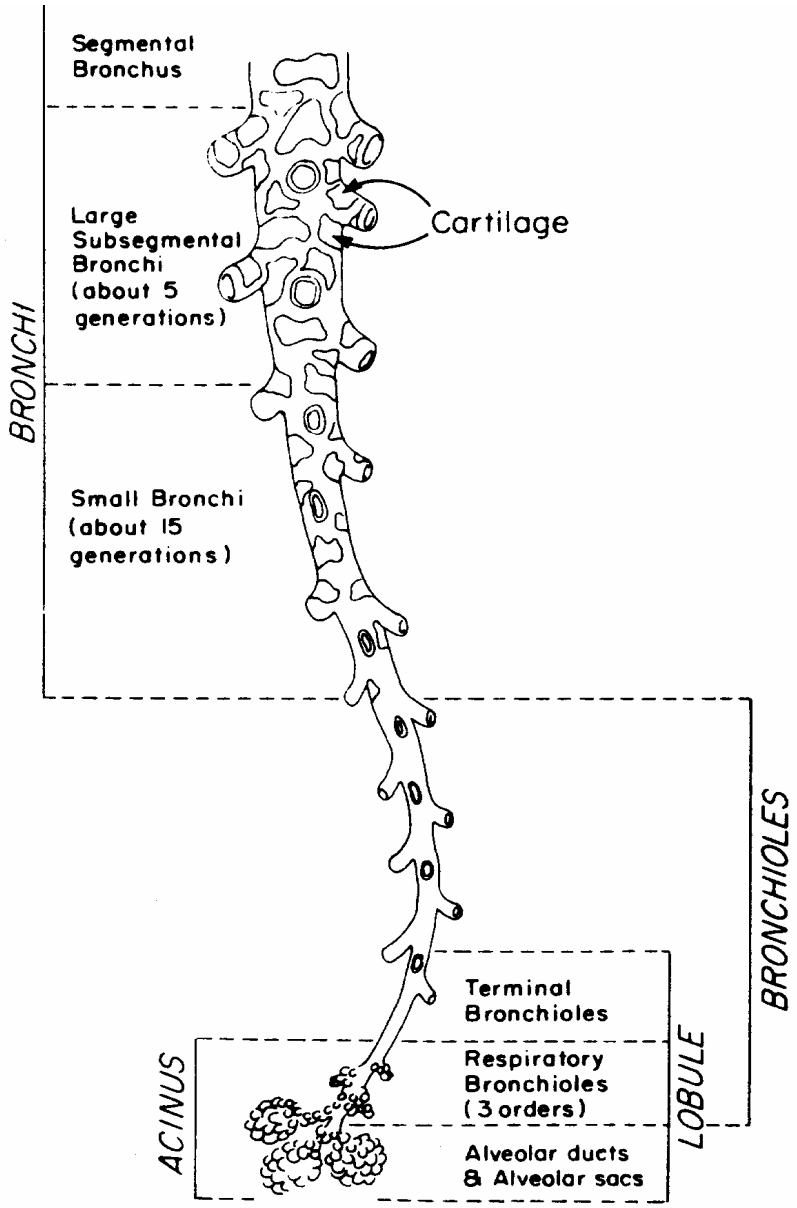
The trachea, main bronchi, and approximately the first dozen divisions of smaller bronchi have either rings or patches of cartilage in their walls that keeps them from collapsing or blocking the flow of air. The remaining bronchioles and the alveoli do not have cartilage and are very elastic. This allows them to respond to pressure changes as the lungs expand and contract.

Blood vessels from the pulmonary arterial system accompany the bronchi and bronchioles. These blood vessels also branch into smaller and smaller units ending with capillaries, which are in direct contact with each alveolus. Gas exchange occurs through this alveolar-capillary membrane as oxygen moves into and carbon dioxide moves out of the bloodstream. (See **Figure 1-3. A Close-Up View of Alveoli and Capillaries**.) Although the 300 million alveoli found in the lungs are microscopic, they have a total surface area equivalent to the size of a tennis court (6).

Diffusing capacity measures the ease with which gas exchange takes place between the alveoli and capillaries. Certain lung diseases affecting the alveoli and capillary walls can interfere with diffusion and reduce the amount of oxygen reaching the bloodstream. Spirometry does not measure diffusing capacity, but it can be measured in a pulmonary function laboratory using an instrument which cost $20,000 to $40,000.

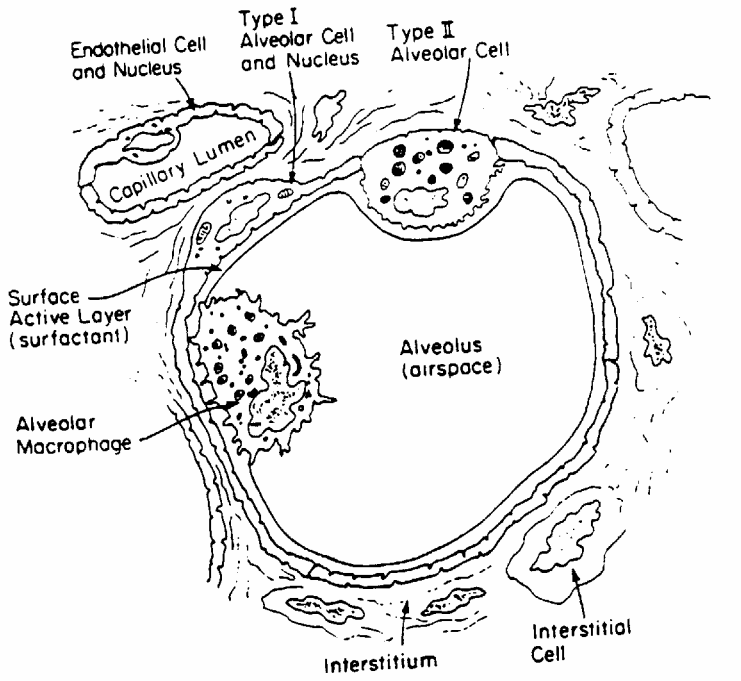
The movement of air into and out of the lungs is called ventilation. The contraction of the inspiratory muscles (principal inspiratory muscle is the **diaphragm**) causes the chest cavity to expand, creating a negative pressure. The resulting flow of air into the lungs is called <u>inspiration</u>. During a maximal inspiration, the diaphragm contracts forcing the abdominal contents downwards and outwards (See Figure 1-1). The external intercostal muscles, found between the ribs, are also involved. These muscles contract and raise the ribs during inspiration, thus increasing the diameter of the chest cavity. In addition to these muscles, the scalene muscle and the sternomastoid muscle in the neck may be employed during extreme ventilation or in conditions of respiratory distress.

FIGURE 1-2. SCHEMATIC DIAGRAM OF THE AIRWAY



Schematic diagram of the airway. Progressive subdivision of the tracheo-bronchial tree illustrating both conducting airways and respiratory unit. From E.P. Horvath Jr., S.M. Brooks, and J.L. Hankinson [1981]. Manual of Spirometry in Occupational Medicine, U.S. Department of Health and Human Services, p. 5. (6).

FIGURE 1-3. A CLOSE-UP VIEW OF ALVEOLI AND CAPILLARIES



From E.P. Horvath Jr., S.M. Brooks, and J.L. Hankinson [1981]. Manual of Spirometry in Occupational Medicine, U.S. Department of Health and Human Services, p. 9. (6)

Normal expiration is a passive process resulting from the natural recoil or elasticity of the expanded lung and chest wall. (However, when breathing is rapid, the internal intercostal muscles and the abdominal muscles contract to help force air out of the lungs more fully and quickly.) A lung can be viewed as the opposite of a sponge. When a sponge is squeezed and released, its elasticity causes it to rebound to its larger initial size. At the end of an inspiration, the elasticity of the lung causes it to return to its smaller inter-breath size. The ability of the lung to do this is called **elastic recoil**.

The degree of stiffness or **compliance** of the lung tissue affects the amount of pressure needed to increase or decrease the volume of the lung. Lung compliance can affect elastic recoil. With increasing stiffness, the lung becomes less able to return to its normal size during expiration. Lung diseases are discussed later in this unit.

The amount of airflow **resistance** can also affect lung volumes. Resistance is the degree of ease in which air can pass through the airways. It is determined by the number, length, and diameter of the airways. An individual with a high degree of resistance may not be able to exhale fully, thus some air becomes trapped in the lungs.

The total capacity of the lungs is sometimes useful for understanding pulmonary pathology. A reasonable estimate of total lung capacity can be obtained by combining several volume parameters. (See **Figure 1-4. Lung Volumes**.) The most common parameters are:

1. **Tidal Volume** (TV): during quiet, relaxed breathing, the volume of air that is inhaled or exhaled with each breath.

2. **Expiratory Reserve Volume** (ERV): the maximal amount of air forcefully exhaled after a normal inspiration and expiration. The amount of exhaled air will be more than was just inhaled.

3. **Inspiratory Reserve Volume** (IRV): the maximal amount of air forcefully inhaled after a normal inhalation.

4. **Residual Volume** (RV): the amount of air remaining in the lungs after the deepest exhalation possible.

5. **Vital Capacity** (VC): The maximum amount of air that can be exhaled after the fullest inhalation possible. Vital capacity is the sum of the tidal volume, the inspiratory reserve volume, and the expiratory reserve volume. (The amount of air that can be exhaled with a maximal effort after a maximal inhalation is called the **Forced Vital Capacity** (FVC). The FVC is the volume that is measured in spirometry and will be discussed in more detail in subsequent units.)

6. **Total Lung Capacity** (TLC): the sum of the vital capacity and the residual volume.

(The reader may find it helpful to refer to **Appendix A. Glossary of Terms Commonly Used in Spirometry** when reading this and subsequent units.)

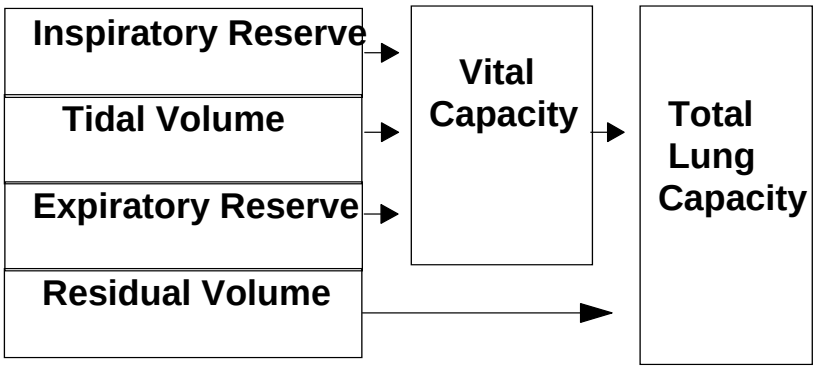


FIGURE 1-4. LUNG VOLUMES

C. Mechanisms for Protecting the Lungs against Airborne Hazards

Airborne contaminants can be in the form of gases (vapors), liquids (mists), or solids (smokes and dusts). (See **Appendix B. An Overview of Occupational Lung Hazards** for a discussion of common types of lung hazards seen in the occupational setting.) Toxic chemicals or irritating materials that are inhaled can damage the tracheo-bronchial tree or the lungs. These substances can cause harm in other parts of the body as well because the lungs provide an important route of exposure.

In order for a hazardous substance to affect the lungs, it must first pass through the bronchial tree and reach the alveoli. The body's defensive mechanisms prevent all but the smallest respirable particles from reaching the alveoli. The average person can see with the naked eye particles as small as 50 microns in diameter. (The symbol "μm" is the abbreviation for micron.) To put this in perspective, there are 25,400 microns in an inch or 10,000 microns in a centimeter. Smaller particles can sometimes be seen if a strong light is reflected from them (such as specks that can be seen in the air when sunlight streams through a window). Particles of respirable size are less than 10 microns and cannot be detected without a microscope.

The size, shape, and mass of particles affect where they are deposited in the respiratory system. Particles bigger than 5 microns usually do not remain airborne long enough to be inhaled or they are trapped by the nose. Heavier particles also settle out quickly and are easily removed if they are inhaled. Particles of intermediate size (1-5 microns) are more likely to deposit in the trachea and bronchi. Small particles (0.01-1 micron) are more likely to reach the bronchioles, alveolar ducts, and alveoli. Fibrous or irregularly shaped particles tend to become caught at bronchiole branching points. However, some fibers and small particles travel readily to the alveoli because of their aerodynamic properties.

The lungs have several mechanisms to protect themselves from contamination by particles and infectious agents. The fine hairs in the nose provide the front-line barrier by filtering out large dust particles and other materials. However, when individuals exercise or work hard, they need to breathe through their mouths to get enough air, and the nasal filtering system is bypassed.

The cough reflex clears foreign material from the trachea and main bronchi. Whenever irritating materials touch the walls of these airways, the chest and lungs quickly contract. As a result, air is rapidly forced out of the lungs, which usually expels the irritant.

The trachea, bronchi, and larger bronchioles are lined with fine, hair-like ciliary cells. These are covered with a thin layer of mucous that catches foreign material. The cilia rhythmically beat and move the mucous-trapped material up to the throat where it can be swallowed or spit out, and thus eliminated from the body. This process is called the mucociliary escalator (see **Figure 1-5. Mucociliary Escalator**).

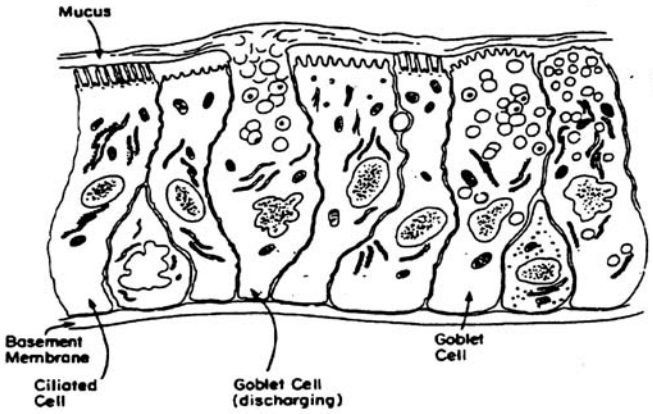


FIGURE 1-5. MUCOCILIARY ESCALATOR

The tracheal lining showing ciliated and goblet cells and the mucous layer. This is called the "mucociliary escalator."

From E.P. Horvath Jr., S.M. Brooks, and J.L. Hankinson [1981]. Manual of Spirometry in Occupational Medicine, U.S. Department of Health and Human Services, Cincinnati, p. 9. (6)

Alveolar macrophages are specialized cells that mobilize to destroy bacteria and viruses. In healthy lungs, the production of macrophages and mucous increase as needed to remove foreign matter and then return to normal levels.

Coughing usually removes irritating particles instantly and the mucociliary escalator may take only a few hours to expel foreign materials. However, the innermost areas of the lungs can take considerably longer to clear out foreign matter (7). Lungs that receive prolonged or repeated exposure to air contaminants eventually cannot keep up with the rate of deposition and/or the constant irritation. As a result, the contaminants accumulate, contributing to the development of occupational lung diseases.

D. Smoking and Occupational Lung Disease

Smoking contributes to lung disease in several ways. It impairs the lungs' natural defense mechanisms by irritating the airways and inhibiting the work of macrophages and the mucociliary escalator. In itself, it is a leading cause of serious lung and heart disease and certain types of cancer. It also has a synergistic effect with other pulmonary carcinogens, such as asbestos, chromium and uranium compounds, and arsenic. Synergistic means that the combined effect of two or more substances is greater than the effects of each added together. Smoking increases the risk of lung cancer by 15%, chronic asbestos exposure by 4%, but together they produce a 60% increase in risk, not a 19% increase (8). As a result, smokers who receive prolonged occupational exposures to other airborne contaminants develop heart and lung disease and cancer more readily than do nonsmokers with comparable exposures, and these diseases progress more rapidly because of the extra burden on the lungs created by smoking.

E. Occupational Lung Diseases

Spirometry is used to detect lung abnormalities that show obstructive or restrictive patterns, or a combination of the two. (See **Appendix C. Overview of Occupational Lung Disease** for descriptions of some of the better known occupational lung diseases. Also see **Appendix D. Respiratory Surveillance Programs** for information on the role of spirometry in the medical surveillance of occupational lung disease.) Obstructive diseases or abnormalities interfere with the flow of air into and out of the lungs. The underlying disease process frequently alters the diameter or integrity of the airways, causing increased airflow resistance from bronchospasm, mucosal edema, and increased production of secretions. Emphysema is one form of obstructive disease. When individuals with emphysema exhale (especially if they exhale forcefully) the airways narrow further or collapse. Asthma and chronic bronchitis are other common obstructive diseases. Restrictive diseases, such as asbestosis and silicosis, are caused by fibrotic tissue changes that reduce the ability of the lungs to expand (i.e., they have low compliance) but do not necessarily affect air flow. Disorders that affect the neuromuscular functioning of the chest wall may also produce a restrictive pattern. Other lung diseases, such as pneumonia, may show both obstructive and restrictive patterns.

UNIT TWO: OVERVIEW OF SPIROMETRY

A. Definition of Spirometry

Spirometry is a medical screening test that measures various aspects of breathing and lung function. It is performed by using a **spirometer**, a special device that registers the amount of air a subject inhales or exhales and the rate at which the air is moved into or out of the lungs. **Spirograms** are tracings or recordings of the information obtained from the test. The most common spirometric tests require that the subject exhale as forcefully as possible after taking in a full, deep breath. The subject's effort is called the **forced expiratory maneuver**.

B. Types of Spirometers

There are two types of spirometers: 1) those that record the amount of air exhaled or inhaled within a certain time (volume) and 2) those that measure how fast the air flows in or out as the volume of air inhaled or exhaled increases (flow). Both are used in screening for lung disease. (Standards for spirometric equipment are discussed in **Unit Eight: Overview of Standards for Spirometric Equipment**.)

1. Volume Spirometers

Volume spirometers record the forced expiratory maneuver as it is produced. When the subject breathes into a mouthpiece, the air moves a cylinder, a plastic bell, or a rubber or plastic diaphragm, which in turn moves a pen that traces a curve on a moving paper graph. The water seal, dry rolling seal, and bellows spirometers are the three most widely used types of volume spirometers (6, 9).

Key Features

1. Tracings record volume in relation to time. The "y" (vertical) axis plots volume in liters and the "x" (horizontal) axis plots time in seconds. (See **Figure 2- 1. Normal Volume Time Curve**.)

FIGURE 2- 1. NORMAL VOLUME TIME CURVE

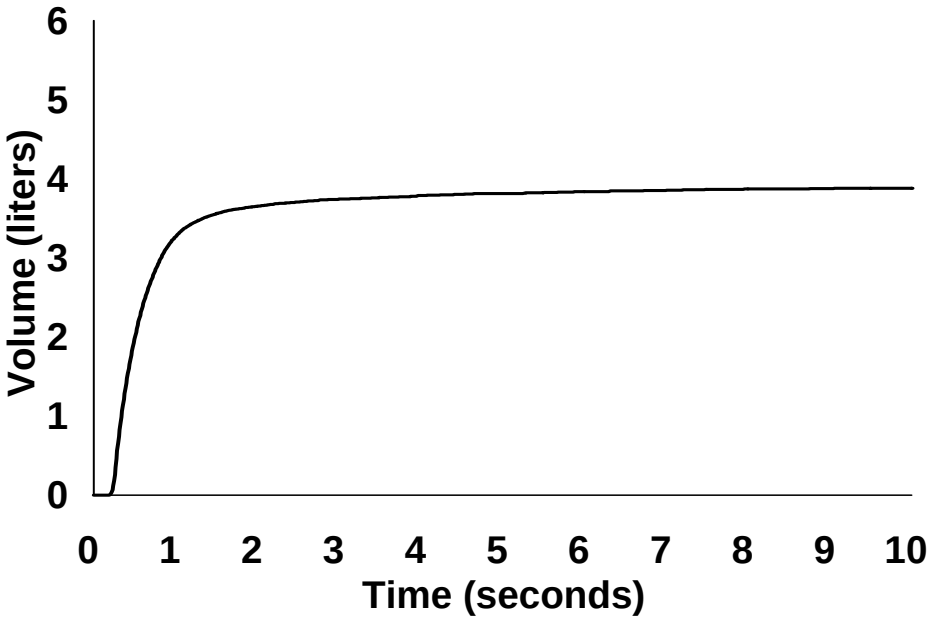
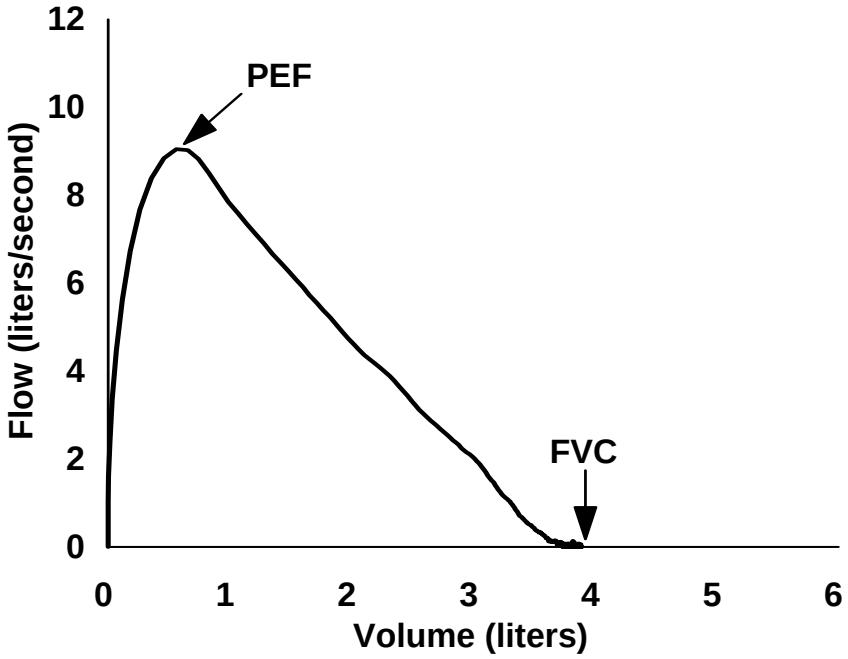


FIGURE 2- 2. NORMAL FLOW VOLUME CURVE



2. On most volume devices, the tracing is mechanically produced during the subject's expiratory maneuver. This type of spirogram is sometimes called a "real time" tracing. "Real time" tracings are useful for the following reasons:

   a. The technician can easily determine when to end the test by watching the subject's effort being recorded as it happens. However, some volume devices do not produce a real time tracing. Instead, the tracing is printed after the forced expiratory maneuver has ended and the computer has completed its calculations. If the volume/time tracing is electronically produced, the technician should watch a digitized version of the tracing on a computer screen.

   b. Mechanically produced tracings permit hand calculations of spirometric values (see **Unit Five: Basic Spirometric Calculations**). Even if the computer system fails, the data from the tracings can still be analyzed.

   c. Computers or microprocessors are not needed for basic operations.

3. Some volume spirometers are easily portable and operable under a variety of environmental conditions.

4. A leak test and a three liter syringe calibration check are easy to perform (see **Unit Three: The Quality Assurance Program**).

5. Many volume spirometers can produce flow/volume curves and loops, with the addition of special electronic or digital circuitry.

Other Considerations

1. Volume spirometers hold their calibration months to years better than flow spirometers.

2. When using volume/time tracings, it is not practical to determine by hand the peak expiratory flow (PEF - the point of maximal air flow during the forced expiratory maneuver) or instantaneous flows at a given volume. However, it is possible to add special equipment that will allow this information to be obtained. Flow-volume displays can also be derived from many volume spirometers that are equipped with a potentiometer or digital encoder connected to a PC.

3. Coughs and submaximal efforts are not as obvious as they are on flow/volume tracings. The significance of coughs during a forced expiratory maneuver is discussed in **Unit Four: Spirometric Technique**.

4. Some volume spirometers are heavy, cumbersome to move, and may be prone to fostering mold or bacterial growth if not cleaned properly.

2. Flow Spirometers

Flow spirometers measure how quickly air flows past a detector and then derive the volume by electronic means. They record the flow rate at very brief intervals, such as 30-300 times a second, and use the data obtained to reconstruct the flow rate at each point in time and volume. This process is called digitization. The most common types of flow spirometers are the pneumotachographs, hot wire anemometers, and rotating vanes (6, 7).

Key Features

1. Tracings measure flow in relation to volume. The "y" (vertical) axis plots the rate of air flow in liters per second and the "x" (horizontal) axis plots volume in liters. (See **Figure 2- 2. Normal Flow Volume Curve**.)

2. Flow/volume tracings are useful for several reasons, including:

    a. The peak expiratory flow (PEF) and instantaneous flow at any given volume can be easily determined and the patterns of slow or hesitant starts are easier to recognize.

    b. It is very easy to detect a cough because the flow drops to zero with no air flow when the glottis closes.

    c. It is easy to detect a possible artifact, such as occlusion from the subject's tongue or dentures, because the peak flow will be variable or reduced.

    d. Many flow spirometers can also print flow/volume loops. These give information about inspiration as well as exhalation.

3. The computer can produce a volume-time tracing from the digitized flow rate data. However, the tracings are not mechanically produced.

4. Flow spirometers are usually lighter and more portable than volume spirometers.

5. Disposable, single-use flow sensors, available on some flow spirometers eliminate the (extremely low) risk of cross-contamination.

Other Considerations

1. The tracings are not produced during the actual maneuver but instead are reconstructed afterwards from the computerized information that has been recorded. There is no "real time" or “hard-copy” tracing that is recorded independently of the electronic system. This can be a problem for the following reasons:

a. The equipment must include a computer, microprocessor, or other electronic circuitry; so if the electronic system fails completely, there is no tracing on which to calculate spirometric values by hand.

b. On some systems, the technician has to rely on the computer to decide when to end the test.

c. Since the tracing is reconstructed, it will usually correspond to the printout. Therefore hand calculations may not provide a reliable way to check that the system is working properly.

d. The Cotton Dust Standard and other federal regulations require tracings. According to the Cotton Dust Standard, "the tracing must be stored and available for recall and must be of sufficient size that hand measurements may be made (10)." (See **Appendix E. OSHA Cotton Dust Standard, Appendix D**.)

2. The Forced Expiratory Volume in One Second (FEV_1) cannot be calculated by hand unless the time is indicated in seconds on a flow-volume tracing. The FEV_1 is one of the basic spirometric calculations used in medical surveillance. It is discussed in more detail later in this unit and in **Unit Four: Spirometric Technique** and **Unit Five: Basic Spirometric Calculations**.

3. Some flow spirometers are harder to calibrate than volume spirometers and may lose their calibration over time if not well maintained. Flow spirometers may also be less accurate in determining volumes since volume must be derived from the flow signal.

C. Important Measures of Ventilatory Performance

Certain diseases or conditions affect the rate at which air can move through the lungs (obstructive diseases) or the ability of the lungs to expand (restrictive diseases). (See **Unit One: Overview of Pulmonary Anatomy and Physiology** and **Appendix C. Overview of Occupational Lung Disease** for more information). Since spirograms reveal both the rate of air flow and the volume of air moved, they identify individuals who have these diseases or conditions.

Three measurements obtained through spirometry are particularly useful: **forced vital capacity (FVC)**, **forced expiratory volume at one second (FEV_1)**, and the **ratio of the FEV_1 to the FVC**. Computerized spirometers frequently print out six or more measures of flow or volume. However, for most purposes, the FVC and FEV_1 suffice. The FVC is the total volume of air exhaled after a **Forced Expiratory Maneuver** (the act of exhaling as hard and fast as possible after maximal inspiration). FVC should not be confused with **vital capacity**, which is defined as the maximum amount of air that the subject can breathe out after the deepest inspiration, whether or not the air was exhaled forcefully. In subjects without airways obstruction, the FVC is usually equal to the VC. The FEV_1 is the amount of air that a person breathes out during the first second of a forced expiratory maneuver. (See **Figure 2- 3. FVC and FEV_1 on a Normal Volume Time Curve** and **Figure 2- 4. FVC and FEV_1 on a Normal Flow Volume Curve.**)

The ratio of the FEV_1 to the FVC is obtained by dividing the FEV_1 by the FVC. (See **Unit Five: Basic Spirometric Calculations** for instructions on computing these measurements.)

A person with a low FVC may have a restrictive disease while a low FEV_1/FVC ratio may indicate an obstructive disease. (See **Figure 2- 5. Normal and Restrictive Pattern Volume Time Curves**, **Figure 2- 6. Flow Volume Curves**, **Figure 2- 7. Normal and Obstructive Pattern Volume Time Curves**, and **Figure 2- 8. Flow Volume Curves**.) For example, on the average, 70-80% of the FVC is exhaled in the first second from a person who is healthy, while a person with airways obstruction may only be able to exhale 60% or less of the FVC in the first second, even though the FVC may be normal. A person with a low FVC typically will also have a low FEV_1, indicating a possible restrictive pattern. Some individuals may also show evidence of a combination of both airways obstruction and a low FVC. (See **Figure 2- 9. Normal and Mixed Pattern Volume Time Curves** and **Figure 2- 10. Flow Volume Curves**.) It should be noted that some clinicians may consider these curves to show an obstructive pattern instead of a mixed pattern. In many cases, the low FVC of a mixed impairment pattern is secondary to the air-trapping and incomplete expiration of moderate or severe airways obstruction. **Table 1. Lung Diseases and Spirometry Results** shows the possible relationships between spirometry results and lung disease.

FIGURE 2-3. FVC AND FEV_1 ON A NORMAL VOLUME TIME CURVE

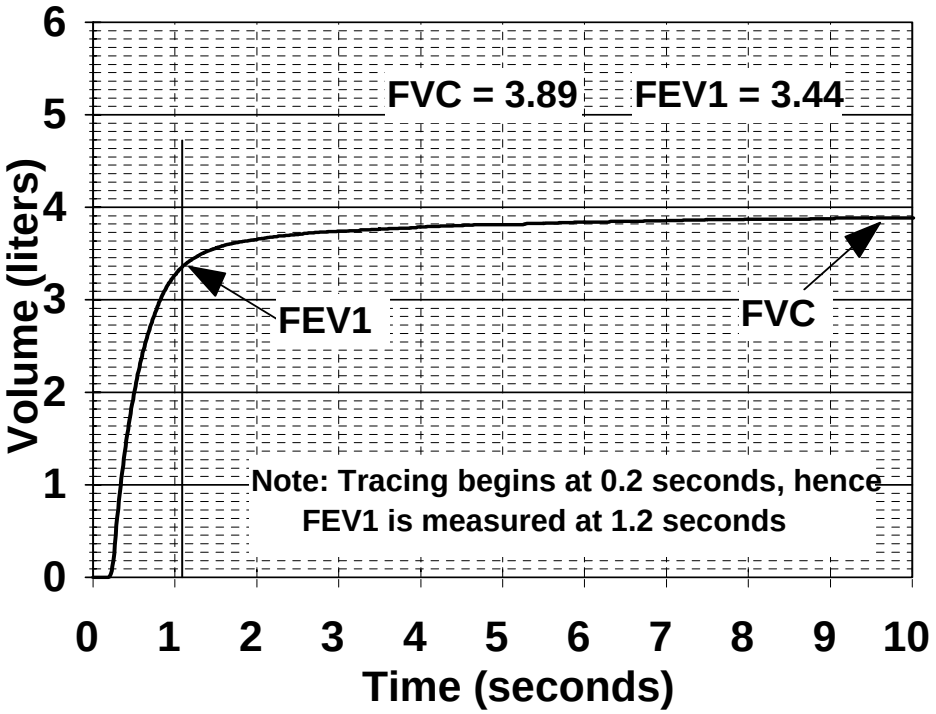


FIGURE 2-4. FVC AND FEV_1 ON A NORMAL FLOW VOLUME CURVE

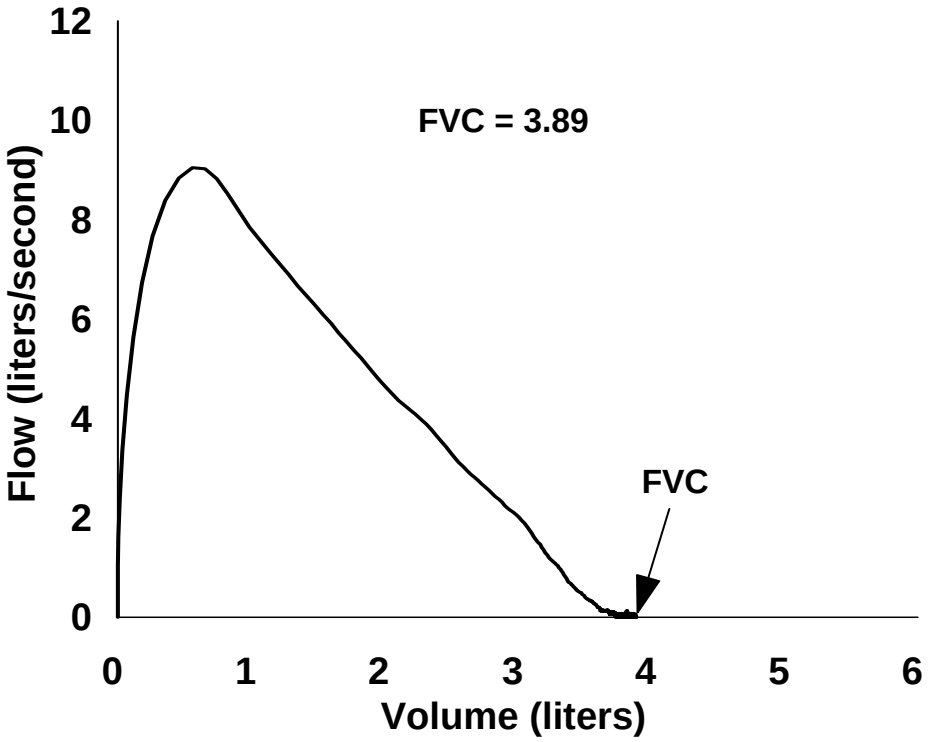


FIGURE 2-5. NORMAL AND RESTRICTIVE PATTERNS VOLUME TIME CURVES

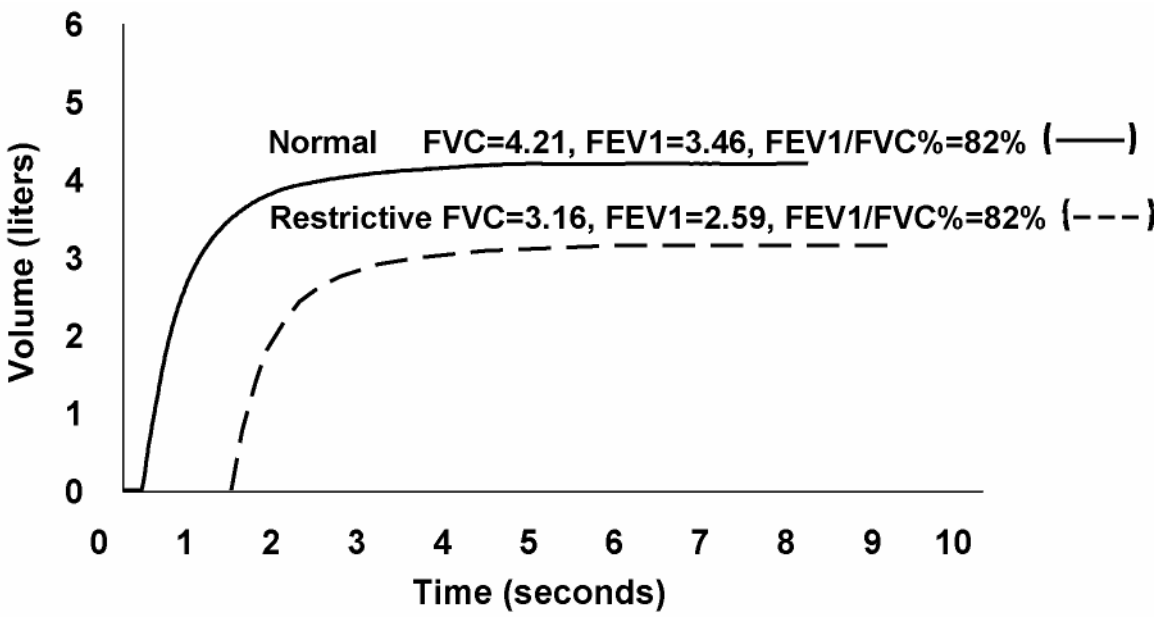


FIGURE 2-6. FLOW VOLUME CURVES

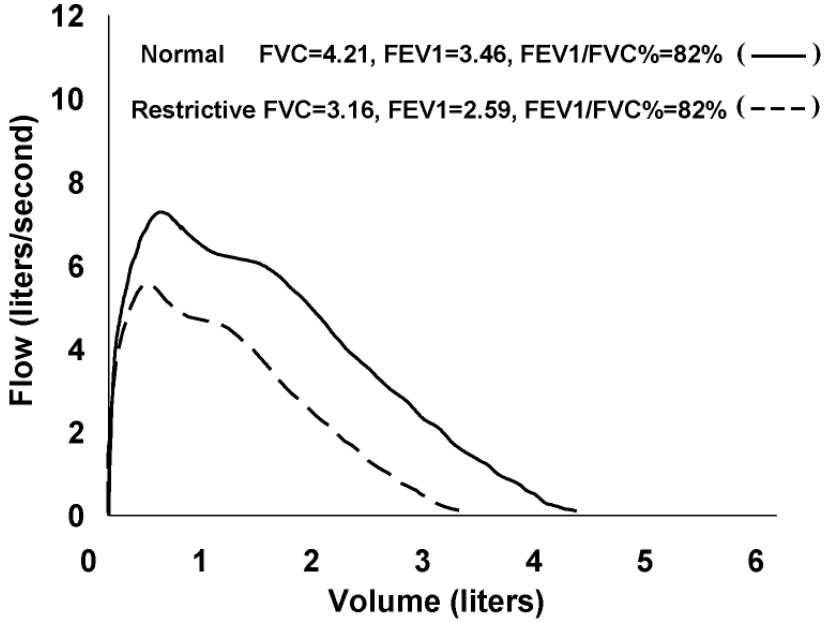


FIGURE 2-7. NORMAL AND OBSTRUCTIVE PATTERNS VOLUME TIME CURVES

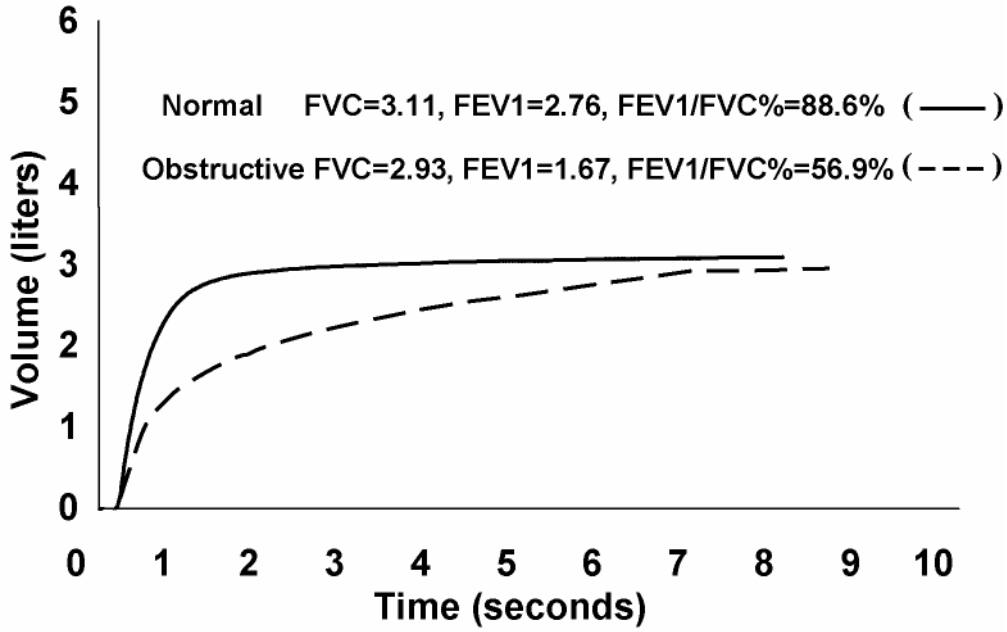


FIGURE 2-8. FLOW VOLUME CURVES

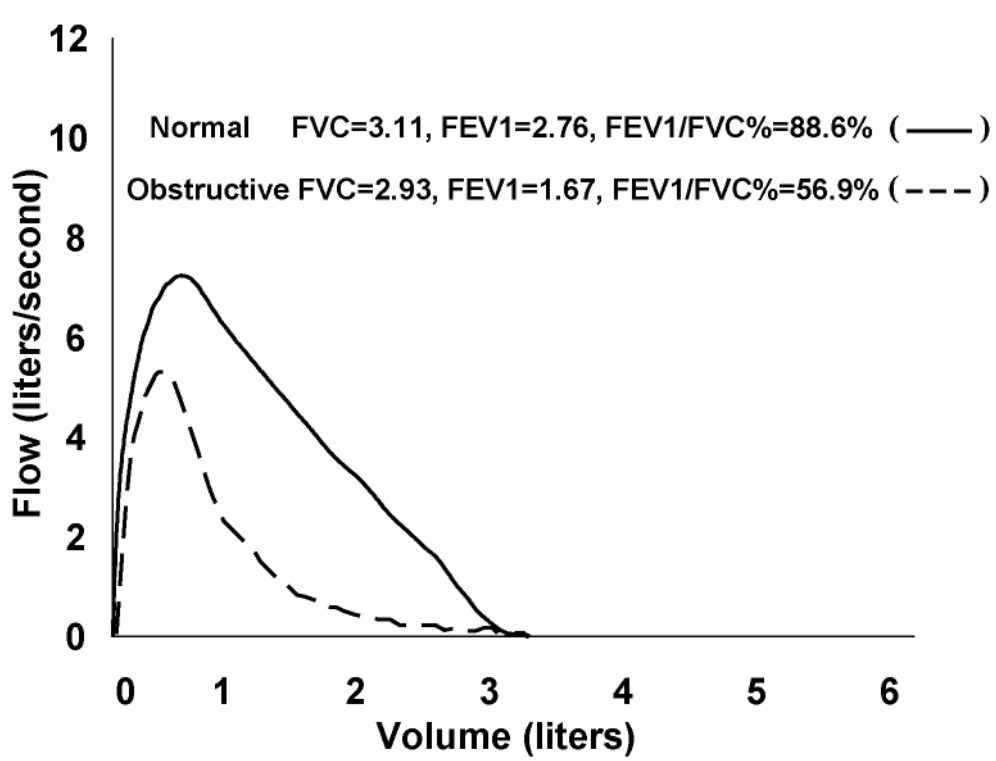


FIGURE 2-9. NORMAL AND MIXED PATTERNS VOLUME TIME CURVES

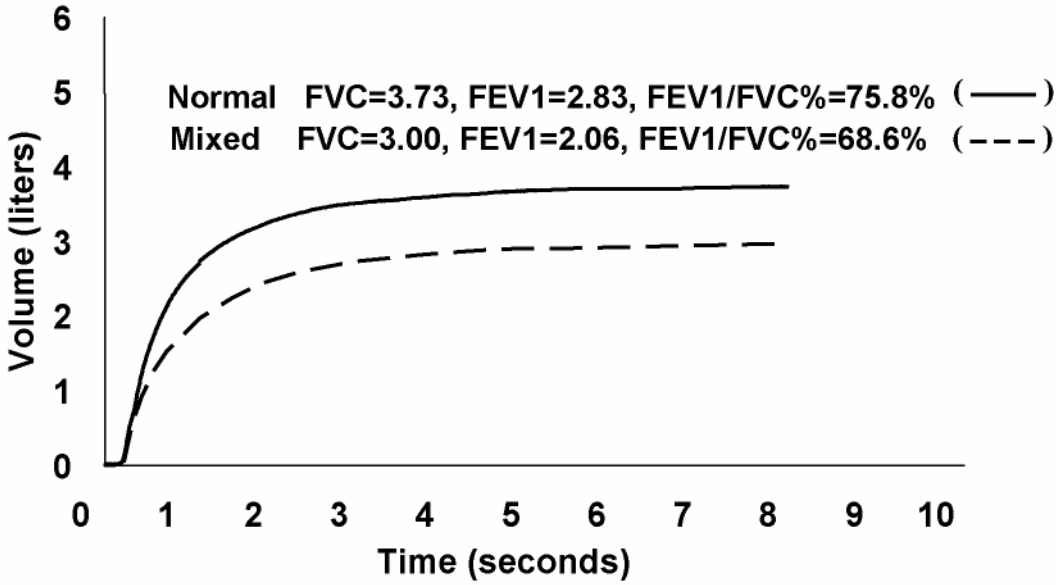


FIGURE 2-10. FLOW VOLUME CURVES

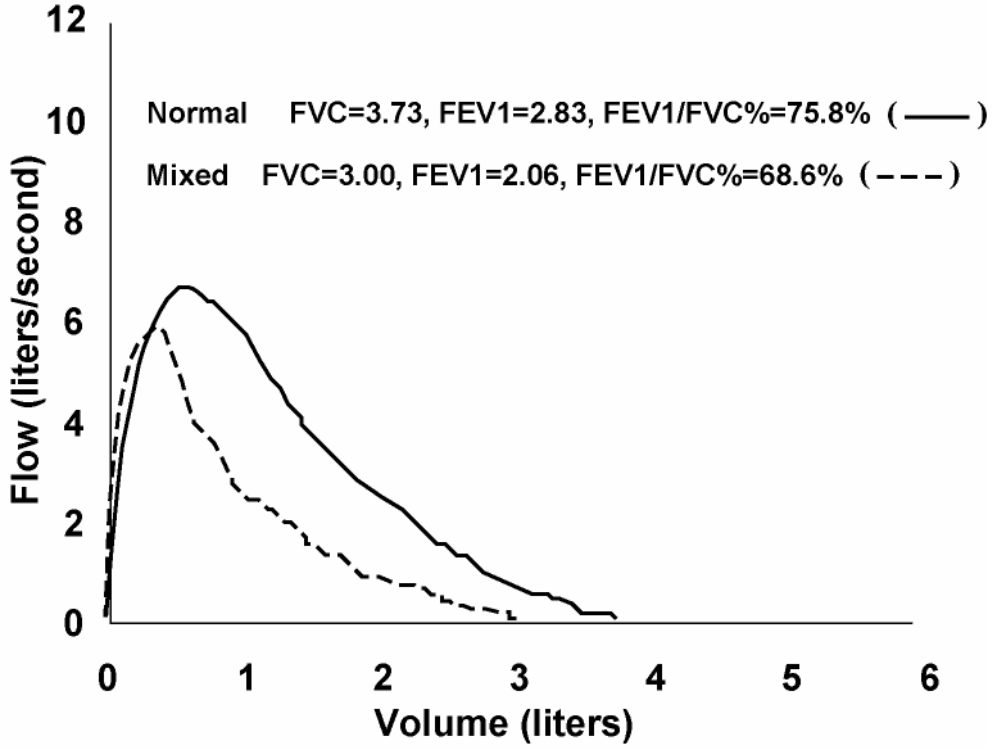


TABLE 1

LUNG DISEASES AND SPIROMETRY RESULTS

Interpretation	FVC	FEV1	FEV1/FVC%
Normal Spirometry	normal	normal	normal
Airway Obstruction	low or normal	low	low
Lung Restriction	low	low	normal
Combination of Obstruction & Restriction	low	low	low

Spirometric testing is utilized both for screening and an aid to diagnosis. As a screening tool, spirometry is performed periodically on workers at risk for occupational lung disease due to exposure to specific respiratory hazards. As a diagnostic tool, it is used when a patient has a specific medical complaint or finding, such as shortness of breath, wheezing, etc. It can also measure the effects of treatment regimens, such as use of bronchodilators or steroids.

D. Limitations of Spirometry

Although spirometry can provide useful diagnostic and screening information, it has a few limitations. Test results can show restrictive or obstructive disease patterns, but they are not disease-specific. For example, a person's spirogram may show a low FEV_1, but a physician may not be able to determine whether the cause is from asthma, emphysema, or some other obstructive disease. Additional information, such as a physical examination, chest x-rays, and health and occupational histories, are needed to make a diagnosis.

Spirometry often can detect obstructive diseases in their early stages, but for some of the restrictive diseases, it may not be sensitive enough to show abnormalities before extensive, and in some cases, irreversible damage has been done. For example, signs of silicosis and coal worker's pneumoconiosis may be found on chest x-rays while spirometry results are still normal. Thus spirometry should not be the sole screening tool of a respiratory surveillance program. Aspects of the ideal surveillance program are described in **Appendix D. Respiratory Surveillance Programs**.

E. Accuracy and Precision

Spirometric results must be **accurate**, or free from errors, to be useful. For example, three liters of air injected into a spirometer should be recorded as three liters on the tracing. The results must also be **precise**, or repeatable. For example, a spirometer must be capable of consistently recording three liters when that amount is injected into it several times. Thus the information obtained must be comparable between different settings and from one time to another.

The American Thoracic Society (ATS) has played a major role in the standardization and upgrading of spirometric instruments and practices. The ATS document, Standardization of Spirometry--1994 Update (1), points out the serious ramifications that can result if accuracy and precision are not maintained.

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

During recent testing of commercially available spirometers, devices were found that had FVC errors as large as 1.5 L, a 25% error (11). If an inaccurate spirometer is used, especially a spirometer with poor repeatability, the improvement or degradation measured may be entirely spirometer-related and have nothing to do with the subject.

Similarly, accurate spirometers are required for epidemiologic studies. Rates of improvement or deterioration of pulmonary function measured in relation to environmental exposures and/or personal characteristics may be erroneous if inaccurate, or imprecise spirometers are used (2). What can be done to assure the most accurate and precise spirometric results? Summarized below are the "Spirometry Standardization Steps" recommended by ATS in the 1994 Update (1). Each topic is covered in more detail in other units of this guide. Where appropriate, each unit refers to both the Cotton Dust Standard and ATS Standards. (See **Appendix F. American Thoracic Society Standards** for a complete copy of Standardization of Spirometry--1994 Update.)

Equipment

1. Performance. Choose equipment that meets or exceeds the Cotton Dust and ATS Standards and has been properly validated (e.g., can demonstrate that the standards have been met). Check with the manufacturer for verification and contact independent testing laboratories for information on their spirometer validation studies. (See **Unit Eight: Overview of Standards for Spirometric Equipment**.)

2. Equipment Quality Control. Check that the equipment is functioning properly by checking the calibration, checking other equipment parameters and performing maintenance procedures at regular intervals. (See **Unit Three: The Quality Assurance Program**.)

Spirometric Results

1. Performance. Obtain the best possible results from subjects through appropriate subject preparation and coaching. (See **Unit Four: Spirometric Technique**.)

2. Calculations. Use calculation methods standardized by ATS for determining test results. (See **Unit Five: Basic Spirometric Calculations**.)

3. Acceptability. Use only results from maneuvers that are free from errors. (See **Unit Four: Spirometric Technique**.)

4. Reproducibility. Use results with minimal variability whenever possible. (See **Unit Five: Basic Spirometric Calculations**.)

Interpretation of Results

1. Reference values. Select reference values appropriate to the setting and ensure that the same values are used consistently. (See **Unit Six: Comparing Observed to Predicted Normal Values** and **Unit Seven: Comparing Changes in Follow-Up Spirograms**.)

Spirometry technicians play a critical role in obtaining accurate and precise results. They frequently have primary responsibility for seeing that quality assurance measures are carried out; selecting, preparing, and coaching subjects; and determining whether results are acceptable and reproducible. Therefore it is essential that these individuals receive comprehensive training in these areas. Although the Cotton Dust Standard does not require recertification, recent studies (12, 13) have suggested that some type of quality control program that evaluates technician skills on an ongoing basis can have a dramatic effect on improving the quality of spirometry testing.

UNIT THREE: THE QUALITY ASSURANCE PROGRAM

Why worry about it? Spirometry is among the most useful and accurate measures of lung health. However, when not performed correctly, the values obtained can be misleading, and result in misclassification of the worker's health status (14,15). Some workers may be told they have normal lung function when they actually have airway obstruction (a falsely negative report), and other workers may be told that they have a disease when their lungs are actually normal (a falsely positive report). Physicians who are asked to follow-up workers who have had inaccurate tests may conclude the spirometry results cannot be trusted, and the entire worker monitoring program may be placed in jeopardy. Thus, a good quality assurance (QA) program is essential to assure that spirometry results are beneficial in monitoring the health of workers (16,17).

A. Components of a good spirometry QA program:

- Management support and sufficient resources
- Knowledgeable QA program director
- Procedure manual
- Accurate spirometry equipment
- Daily spirometer checks
- Monthly spirometry quality reports
- Equipment maintenance records
- Technician training and review
- Maneuver quality checks

Management support. Spirometry testing requires time, space, and administrative support. Technicians need proper training, equipment, supplies, and a realistic testing schedule, as well as a quiet and private testing area. Management support is essential to assure resources are sufficient for a reliable program.

QA program director. The QA program director assumes direct responsibility for the entire quality assurance program. The director ensures that technicians are trained properly and maintain their levels of competency, resources are available to technicians to do their job properly, all methods used follow sound scientific evidence, and that all technicians follow guidelines established in the quality assurance program (18). The program director should have enough confidence in the QA process that he or she can personally verify that all test results reported from that laboratory are valid and accurate. The program director should participate in continuing education to maintain proficiency in current techniques, protocols, and equipment.

Procedure manual. Each monitoring program should develop and use a spirometry procedure manual. An operator's manual from the spirometer manufacturer is not enough. The procedure manual assures that spirometry testing procedures and equipment calibration information are available for quick reference. It helps the program to maintain consistency by ensuring that the same standardized procedures are available to all staff and substitute staff, and should be used to help train new staff. A spirometry procedures manual titled "Pulmonary Function Laboratory Management and Procedures Manual" may be obtained from the American Thoracic Society (ATS). To order the Pulmonary Function Laboratory Management and Procedure Manual, go to

the ATS web site (http://www.thoracic.org/statements/) and follow the instructions located under the "Pulmonary Function and Exercise Testing" section. The program director can modify the manual to reflect the program's choice of equipment and procedures. The program's manual should be updated as needed, and copies made available to staff members.

The following topics should be included in the spirometry procedure manual:

- Spirometry standards or regulations pertaining to your industry
- A description of employees eligible and a testing schedule
- Equipment calibration and leak test procedures, and how often they are performed
- A specific description of the spirometry testing procedures
- A copy of the article from which the reference values are derived
- A sample of the pretest questionnaire and examples of reports
- Spirometer operator's manual and contact information for manufacturer and local distributor
- A list of the necessary supplies
- Instructions for infection control procedures, including cleaning or sterilizing the spirometer
- The date and filename for the current version of the procedure manual

Accurate spirometry equipment. Some electronic flow-sensing spirometer models manufactured before 1995 were not accurate. Almost all newer models are accurate when they leave the factory, but some are more likely than others to lose accuracy over months to years of use. The American Thoracic Society has published guidelines for testing spirometer accuracy using a spirometry waveform generator (1). Before buying a spirometer, review the results of accuracy testing for that model, and ask the dealer how long the spirometer is warranted to maintain its accuracy. Purchase a rugged 3.00 liter calibration syringe to perform daily checks. Ask the dealer whether the spirometer can be configured for NHANES III reference equations, maneuver quality checks, storage of the results from the 3 best maneuvers, and printing of both flow-volume and volume-time graphs.

Daily spirometer accuracy checks. Daily checks for leaks and volume accuracy of the spirometer are needed. False positive or false negative tests can result from inaccurate spirometers. Volume-sensing mechanical spirometers are prone to leaks. A leak can cause a falsely low measurement of the vital capacity of tested workers (19). On the other hand, flow-sensing spirometers are prone to clogging, which can falsely increase the results. Some spirometers may experience other problems such as high internal temperatures causing inaccurate BTPS corrections, and chart drives slipping due to old rubber belts. It is important that laboratories keep accurate records of all equipment testing done for leak detection, calibration, and maintenance. These records will assist in identifying problems with the equipment to minimize accuracy errors. (See section on **Equipment maintenance records** below).

Monthly spirometry quality reports. A supervisor, medical director, or a knowledgeable third party should review and grade the quality of all spirometry tests (and calibration check records). Monthly or quarterly reports on test session quality (by technician) are an essential part of a spirometry QA program. At least 95% all tests should have acceptable quality (meet the criteria listed below for reproducibility and maneuver acceptability). Supervision or retraining of a technician is indicated when the overall spirometry test quality falls below a 90% success rate.

Equipment maintenance records. For each spirometer, maintain a quality log which records calibration checks, maintenance, upgrades, and repairs, including the date and time, name of the technician, procedures performed and the results, and remedial steps taken. Some computerized spirometry systems store this information in a database. Record the model, serial number, and identification number for every spirometer used. Also keep the manufacturer's manuals, warranties, etc. with the procedure manual. Manufacturers often update or revise their software. The program director will want to check these updates to review their relevance to his or her laboratory's needs.

Technician training and review. A well-trained and competent technician is the most important factor in assuring good quality spirometry results (20). Each technician should have successfully completed a 16 hour NIOSH-approved spirometry training course prior to performing spirometry tests in the occupational setting. Their certificate of completion should be framed and mounted on a wall in the spirometry testing room. Ongoing professional development and seminars for technician reviews of the latest techniques, equipment, and procedures will assure that the program keeps up-to-date.

Maneuver quality checks. Technicians must vigorously coach each subject in performing acceptable maneuvers, and recognize the various patterns of poorly performed maneuvers. A slow start (poor blast effort) can cause falsely low FEV_1 values. Failure to fully inhale before the maneuver or exhale during the test can cause falsely low FVC values. Spirometers which automatically check the acceptability of each FVC maneuver can serve to remind the technician (21).

Some automated software will review each spirometry maneuver for ATS acceptability criteria. (1) An error code may or may not be displayed on the computer screen for the technician. The presence of any error code would deem that maneuver unacceptable. Remember that the technician's goal is to obtain at least three acceptable maneuvers. A maneuver is considered acceptable if it does not contain any the following seven errors:

1) extrapolated volume ≥ 5% of FVC or 150 ml
2) presence of cough during the first sec
3) variable effort
4) glottis closure
5) exhalation time < 6 seconds
6) leaks
7) baseline error

Test sessions in which the highest minus second highest FEV_1s (or FVCs) don't match within 0.20 liters indicate poor reproducibility (repeatability or degree of match) and should be interpreted with caution. Poor reproducibility of the FEV_1 or FVC within a test session is an indication that effort was submaximal. This also reduces confidence in the interpretation of subsequently measured changes in lung function (changes across the work shift or year-to-year). The repeatability of the FEV_1 and FVC, and the quality of all test sessions should be checked either manually or by an automated spirometer.

B. Calibration checks and other equipment quality control measures

Daily accuracy checks. Daily checks for leaks and volume accuracy of the spirometer are needed. Volume spirometers should be checked for a leak every day before use, and their accuracy verified using a 3.00 liter syringe. Flow spirometers should be checked for volume accuracy at 3 different flows, every day before use. During industrial surveys or other field studies where large numbers of people are tested, calibration checks should be done at least every four hours.

When using a volume spirometer, perform the following checks every three months:

1. Check the accuracy of the chart drive
2. Check the accuracy of the internal thermometer
3. Check the calibration syringe for a leak
4. Check for accurate volume measurements across the entire volume range

How to check for a leak in a volume spirometer. Leaks are common following disassembly of volume spirometers for cleaning. A leak check should be done every day before testing subjects and before the volume calibration check. Various spirometers use gravity, a metal weight, or a spring ("negator") to return the bell to zero volume at the end of each FVC maneuver. For some spirometers, this return pressure may provide sufficient pressure (about 2 cm water) for leak checks, while for others, a weight or a large rubber band may be needed. Consult the operator's manual or the dealer's customer service to determine the recommended method to increase the pressure inside the spirometer for leak checks. Start the leak check by inserting about 3 liters of room air into the spirometer (perhaps using the calibration syringe), occlude the end of the breathing hose, and use the recommended method to provide internal pressure. Then note the starting volume, wait one minute, and note the ending volume. There should be no measurable change in the volume (less than 0.02 liters). A decrease in volume by more than 0.02 liters indicates a leak, and testing should not be done until it is corrected. Look for the usual sources of leaks (such as a crack in the breathing hose, a loose hose connection, a loose plate, a missing rubber O ring, etc). To track down the problem, try repeating the leak check without a breathing hose connected, by plugging the spirometer opening with a rubber stopper. Silicone sealant may be used to fix some leaks.

How to check the accuracy of a volume spirometer. Use an accurate 3.00 liter calibration syringe. If the calibration syringe has been dropped accidentally, or has loose components, or a leak, it should be returned to the manufacturer for repair and re-calibration. Make sure that the BTPS correction is turned off, to avoid a calculation error when calibrating a computerized spirometry system. [1] Keep the syringe near the spirometer so it is at the same temperature. The volume recorded when air is injected from the syringe into the spirometer must be within $\pm$3 % of 3.00 liters (between 2.91 and 3.09 liters). (See **Figure 3-1. Volume Time Syringe Calibration**.)

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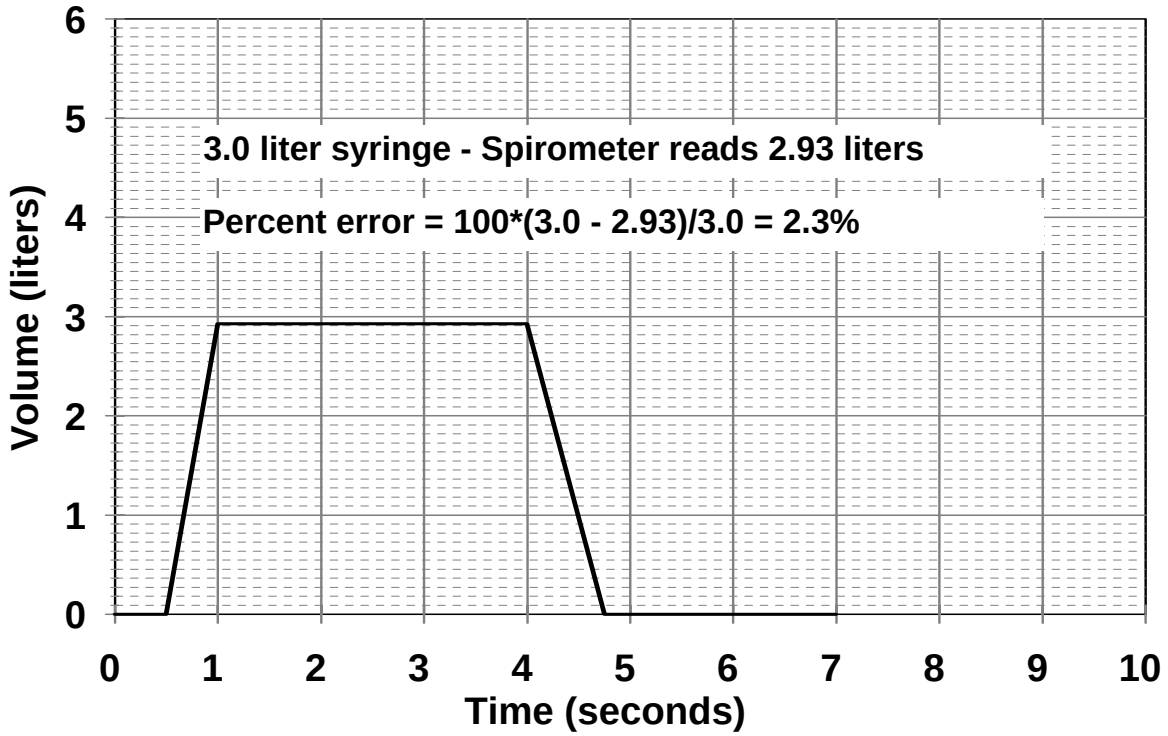
[1] This usually is done by selecting "calibration check" from the display or printout. If regular FVC testing has been inadvertently selected, and air is injected from the calibration syringe (simulating an FVC maneuver from a subject), the computer will report the FVC as if the air were exhaled at body temperature. This will falsely increase the 3.00 liter calibration result to about 3.30 liters (the BTPS correction factor).

Record the calibration and leak check results on the daily worksheet or quality log. If the volume is low (less than 2.91 liters), first repeat the leak check. If using a water-sealed spirometer, check the water level. If the volume is high (above 3.09 liters), check to see if the zero volume is correct, and ensure that the temperature of the calibration syringe is identical to the spirometer.

EXAMPLE: Air from a 3 liter syringe was injected into the spirometer, producing the tracing below (**Figure 3-1. Volume Time Syringe Calibration Check**). To meet the criterion of ±3% of 3 liters, a volume must fall between 2.91-3.09L. The volume reads 2.93 liters so it is within the acceptable range. (If the baseline does not start at zero, remember to adjust accordingly.)

FIGURE 3-1. VOLUME TIME SYRINGE CALIBRATION CHECK

It is important to understand the difference between ***calibration checks*** and re-calibration of the



spirometer. You should *check* the calibration of the spirometer every day; however, the calibration of the spirometer should not be adjusted unless repeated checks determine that it has become inaccurate, and no mechanical cause for the loss of accuracy can be determined. Review the volume-time tracing exercise (**Figure 3-2. Volume Time Syringe Calibration Check**) from a calibration check of a dry rolling seal spirometer at the end of this chapter.

How to check the accuracy of a flow spirometer. Check the volume accuracy using a 3.00 liter calibration syringe every day before using the spirometer. Select "calibration check" from the menu of the spirometer (so that the software does not apply a BTPS correction factor to the results). If the flow sensor is permanent and heated (as in some older models), check the manual to see if the heater should be turned off for at least 30 minutes before calibration checks. If an

unheated permanent flow sensor is used and it was recently cleaned, be sure that it is completely dry and at room temperature before the calibration check. If the spirometer uses disposable flow sensors, use a new flow sensor from each box of flow sensors for the calibration checks. For calibration checks, some flow spirometers require a special adaptor that fits between the syringe and the flow sensor.

First fill the syringe with air completely, then attach it firmly to the flow sensor, and empty it smoothly and completely. End the maneuver carefully until a soft click is heard, meaning that the syringe was emptied completely. Do not bang the syringe while emptying it, to avoid damage. Disconnect, refill with air, and then empty the syringe three times, each time at a different speed: First, empty it in less than one second (fast), next in 2 or 3 seconds (medium), and the third time take about six seconds (slow). Count "one-one-thousand, two-one-thousand" etc, while emptying the syringe, to gauge the speed of emptying. The resulting FVC for all 3 of these maneuvers should be between 2.91 and 3.09 liters. Record all three results on the daily worksheet or quality log.

Quarterly equipment checks for volume spirometers. To check a mechanical chart recorder, use a stopwatch to ensure that one second recorded on the tracing equals one second to within $\pm$1% (or one half of the smallest time division on the graph). Since one second is difficult to measure accurately, measure how long it takes for the pen to traverse a 10 second segment of chart paper and divide the result by ten. Observe that the chart drive is functioning smoothly, since the clutch or rubber rollers may slip (indicating the need for replacement). Record your results in the quality log.

Use a reference thermometer to check the accuracy of the thermometer used to measure the internal temperature of the spirometer. If the two temperatures do not match within one degree Centigrade, the BTPS correction factor will be inaccurate. If the volume spirometer does not measure the temperature inside the bell or volume chamber, ask the manufacturer how to install a thermometer, or ask an engineer to install one. Electronic indoor/outdoor thermometers (available for about $20) should work fine.

Check that the spirometer starts the test at the right time. Some spirometers falsely start the test if the subject shakes the mouthpiece when inhaling. This causes the FEV_1 to be artificially low (22). Some require excessive exhalation volume before the mechanical chart or pen starts moving. Calculate the FEV_1 by hand from the tracing and compare to the electronically-derived FEV_1 to ensure that the equipment is using the equivalent to the back extrapolation method to determine the start of the test. (Directions for calculating FEV_1 and back extrapolation are given in **Unit Five: Basic Spirometric Calculations.**)

C. Infection control. Although the transmission of infection through spirometry has not been documented, the theoretical risk should not be overlooked. The Centers for Disease Control and Prevention (CDC; http://www.cdc.gov) has published several guidelines for preventing cross-contamination.

Always wash your hands before and after spirometry testing.
Instruct workers to attach, remove, and discard the disposable mouthpiece for each session.

Use disposable or sterilized nose clips.
Don’t test workers who have an active respiratory infection (a cold or the flu).
When using a volume spirometer, use a clean breathing tube for each subject.
When using a volume spirometer, consider using disposable spirometry “filters.”
Don't re-use flow sensors designed for single patient use.
Follow the spirometer manufacturer's recommendations for cleaning and disinfecting.
Most hard surfaces may be disinfected by wiping with isopropyl alcohol.
Check with your state health department for state mandates on infection control in health care settings.

Figure 3-2. Volume Time Syringe Calibration Check has been included below for students to practice their calculation skills.
EXERCISE: Air from a 3 liter syringe was injected into the spirometer, producing the tracing below. Is the spirometer in need of repair?

FIGURE 3-2. VOLUME TIME SYRINGE CALIBRATION CHECK - EXERCISE

FEEDBACK: The volume from the calibration check reads 3.1 liters, which is not within the acceptable range. Check that the syringe is working properly. If it is, repair the spirometer before using.

UNIT FOUR: SPIROMETRIC TECHNIQUE

A well-trained technician is essential for achieving accurate and precise spirometric results. The consequences of not implementing quality assurance measures were discussed in units two and three. Poor subject preparation and coaching can also adversely affect results. This unit will cover the steps to be taken to help subjects produce the best tracings that they can. (See **Appendix G. Spirometry Procedure Checklist** for a summary of the material covered in this unit.)

A. Prepare the Equipment

1. Check that the **equipment has been properly cleaned** according to established policies. (See **Unit Three: The Quality Assurance Program** for infection control recommendations.)

2. Check that the **equipment is set up**:

   a. Attach breathing hose if applicable.
   b. Check paper supply.
   c. Set the paper speed.
   d. Check the position of the pens.
   e. Give the equipment a test run, preferably test yourself, since you will be familiar with your result if you have routinely performed forced expiratory maneuvers on your equipment (see **Unit Three: The Quality Assurance Program**).

3. Be sure that a **calibration check** of the equipment has been performed on the day of testing according to established policies. (See **Unit Three: The Quality Assurance Program** for more information.)

4. Check that there are **enough supplies** (mouth pieces, nose clips, denture cups, subject record forms, and any other materials used) to perform and record the tests. Note what supplies should be reordered soon.

5. Note the ambient or **room temperature** (temperature within the spirometer is preferred) and convert to centigrade if needed. (See **Unit Five: Basic Spirometric Calculations, Section I: Conversion to BTPS**, for conversion tables.) Note the barometric pressure if required.

6. Check that the **scales to measure weight and height** are working properly.

7. Set up an **area that is screened off** where subjects can loosen or remove restrictive clothing or loose dentures.

8. Have available a **chair without wheels** for subjects.

9. Make available **trash receptacles** for discarded gowns, mouthpieces, etc.

10. Follow your institution's requirements for **disposal of medical waste**.

B. Prepare the Subject

1. **Explain the purpose of the spirometry test**

   a. Introduce yourself and tell the subject that today you will be taking measurements to check on the health of his/her lungs. The word "test" often makes people nervous because they worry that they won't know the "right" answer or that they won't "pass". Try to avoid using that word when speaking to the subject to prevent him/her from developing "test" anxiety.

   b. Point to the spirometer and note that you'll be using it to record the amount of air he/she can exhale and how quickly he/she can do it. (**NOTE**: Exhaling as forcefully and quickly as possible into a spirometer is called the **Forced Expiratory Maneuver**.)

   c. Emphasize that the procedure doesn't hurt, but to get useful and valid results, he/she must breathe as hard and as fast as possible when told to do so and the procedure must be repeated a few times to obtain all of the information needed.

   d. Explain that you will tell him/her how to do the procedure and that you will also give a demonstration before he/she does it, but first you need to ask a few questions.

2. **Check whether the test should be carried out or postponed**. Certain conditions can affect test results. Follow the criteria established by your institution for postponing spirometry. If no criteria exist, the sample questions listed below can be used to guide your decision. Before using these questions, it is recommended that you review them with your organization's physician to determine if any should be deleted or others added.

   If the test is postponed, be sure to reschedule the subject before he/she leaves, and to indicate in the chart the date and the reason for the postponement.

   a. **How are you feeling today?** Find out if he/she has any acute illness that might affect his/her ability to take a deep breath or to blow out forcefully. If so, postpone spirometry at least three days.

   b. **Have you smoked any cigarettes, pipes, or cigars within the last hour?** If yes, postpone spirometry at least one hour. Smoking can have a short-term effect on the small airways.

   c. **Have you used any inhaled medications, such as an aerosolized bronchodilator within the last hour?** If yes, postpone spirometry at least one hour. These can have a short-term effect on the small airways.

   d. **What have you eaten in the last hour?** A heavy meal may have a short-term effect on the subject's ability to take the deepest breath possible. After finding out what the subject

has had to eat, decide whether or not the amount of food was sufficient to influence the results. If so, postpone spirometry at least one hour.

e. **Have you had any respiratory infections, such as flu, pneumonia, severe cold or bronchitis within the last three weeks?** If yes, consider postponing the test until at least three weeks after the symptoms have passed, or longer if there is a lingering cough. These illnesses may have a small short-term effect on the airways.

f. **Have you had any ear infections or problems in the last three weeks?** If yes, postpone the test at least three weeks. The subject may experience ear discomfort during a forceful exhalation.

g. **Have you had any recent surgeries?** If the subject has had any major surgeries, such as oral surgeries, surgeries to the trunk of the body, or eye surgery, consult with the surgeon to determine how long to postpone the test. The subject's ability to take as deep a breath as possible, or in the case of oral surgery, to obtain a tight seal, may be temporarily affected.

C. Position the Subject

1. **Sitting or Standing**: The subject may sit or stand. The standing position is preferable, particularly for obese subjects, since studies have shown that a larger FVC is obtained from standing (23). Put a chair behind subjects if they perform the test standing. They may wish to use it between tests. If subjects sit, encourage them to sit up straight. **Note in the chart the position in which the test was conducted.**

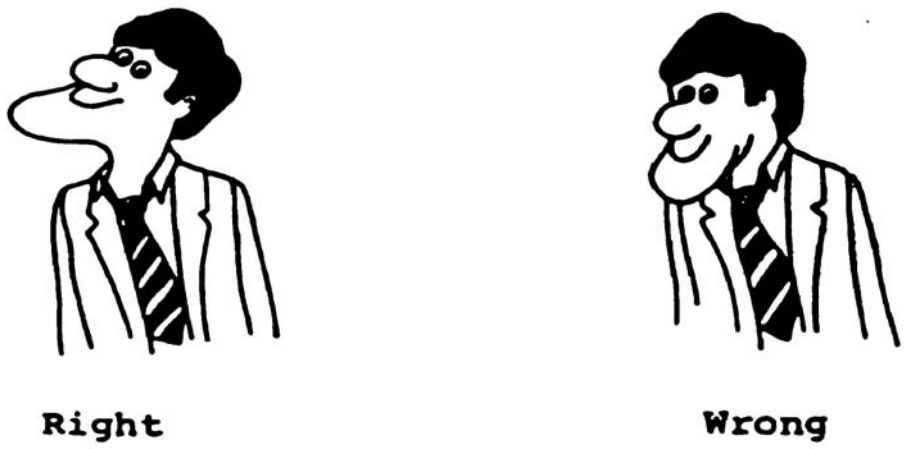
   Whenever possible, when spirometry is performed on subsequent dates, subjects should be tested in the same position as was used the first time. If a subject stands for the first testing, but sits for testing at a later date, his/her FVC may show a decrease that is the result of the position rather than lung disease. This will make interpretation of the test results difficult unless the position is noted in the chart each time. **Note: the standing position should be used for pregnant women, obese men and women, and children to obtain the best results**.

2. **Clothing**: Instruct the subject to loosen tight clothing, such as ties, belts, bras or girdles, which tend to restrict hard and fast breathing. You may want to have available disposable gowns and a screened area where the subject can loosen restrictive clothing or remove it and put on a gown if needed.

3. **Chin and Neck Position**: Instruct the subject to elevate the chin and extend the neck slightly. This position allows for the most forceful exhalation possible. (See **Figure 4-1. Chin and Neck Position**.)

4. **Nose clip**: We recommend that the subject use a nose clip. Show him/her how to use it. This clip prevents air from escaping through the nose during the test. If this is not possible, have the subject pinch his/her nostrils with fingers.

FIGURE 4-1. CHIN AND NECK POSITION.



5. **Dentures**: Ask the subject if he/she has dentures and whether they are loose. Dentures should be left in place if they are not loose, since it is often difficult to keep a tight seal around the mouthpiece without the dentures in place. Make a note in the chart if the test is to be attempted while wearing them. Watch the shape of the curves closely to determine if the dentures are obstructing the subject's airflow. Keep a supply of plastic denture cups for possible use.

D. Perform the Test

1. **Explain to the subject how the forced expiratory maneuver is performed**:

   a. Hold the spirometer tube near a shoulder so that it will be close by when needed.

   b. Take the deepest possible breath after breathing in and out normally for several seconds.

   c. Bring the spirometer tube to the mouth and place it on top of the tongue between the teeth. Put the mouth firmly around the mouthpiece, making sure not to purse the lips as if blowing a musical instrument. Instruct the subject <u>not</u> to inhale from the mouthpiece unless information on inspiration as well as expiration is to be recorded. (See **Figure 4-2. Correct Mouth Position**.)

   d. Keep the chin slightly elevated and make sure that the tongue is out of the mouthpiece.

   e. Without further hesitation, **BLAST** into the mouthpiece of the spirometer as hard, fast and completely as possible.

f. Keep blowing as long as you can or until you are told to stop.

FIGURE 4-2. CORRECT MOUTH POSITION

2. **Always demonstrate for the subject the proper technique using a mouthpiece**. Check to see if the subject has any questions.

3. **Perform last minute equipment preparations if applicable**:

   a. Place the recorder pen in the appropriate position on the chart paper.

   b. Start the paper moving at least one second before the subject blows into the mouthpiece.

4. **Coach the subject**

   a. Instruct the subject: "Whenever you are ready, take the deepest possible breath, place your mouth firmly around the mouthpiece, and without further hesitation, blow into the spirometer as hard, fast, and completely as possible." Watch the subject inhale fully, place the mouthpiece, and BLAST out the air.

   b. Actively and forcefully coach the subject as he/she performs the maneuver. **Emphasize**, "**BLAST** the air out, blow, keep blowing, keep blowing!" Studies have shown that active coaching during both inspiration and expiration help the subject to give a maximal effort.

   c. Keep coaching them to continue to exhale until the point at which the tracing becomes almost flat -- an obvious plateau in the volume-time curve. Since the end of test is hard for the technician to determine during the maneuver, tell the subject to blow as long as he/she can. After each maneuver let him/her relax for a few minutes.

<u>OSHA Cotton Dust Standard Definition of Plateau</u>: less than 25 ml volume change in 0.5 seconds (see **Appendix E. OSHA Cotton Dust Standard, Appendix D.**). This is hard to visualize and requires that the technician become familiar with this degree of change. In addition, one study has shown that strictly following the 25 ml in 0.5 seconds criterion results in premature termination of the FVC maneuver and correspondingly lower FVCs (24).

<u>ATS 1994 Definition of Plateau</u>: The American Thoracic Society defines the end of the test as: A plateau in the volume-time curve, as defined by no change in volume for at least 1 second, or a reasonable expiratory time. In a *normal* young subject, the expiration would *usually* be completed in less than 6-second. In an obstructed or older healthy subject, a longer expiratory time is required to reach a plateau. However, **multiple** prolonged exhalations are seldom justified (1). (See **Appendix F. American Thoracic Society Standards**.)

5. **Check the acceptability of each tracing before continuing the testing.** (See below)

E. Check the Acceptability and Reproducibility of the Maneuver

Rationale. Spirogram results are used to detect possible conditions that affect the subject's ability to exhale as fully and forcefully as possible. The results are compared either to the subject's previous spirogram results if they are available or to established tables of results that would be expected for a person with his/her characteristics (e.g., sex, age, height, etc.). (Comparing results will be discussed in greater detail in **Unit Six: Comparing Observed to Predicted Normal Values** and in **Unit Seven: Comparing Changes in Follow-Up Spirograms**.) If inaccurate results are obtained, the information from the comparisons will not be correct, creating the potential for not detecting serious lung diseases, or, diagnosing *disease* where none exists. Therefore, the goal of each testing session is to obtain **acceptable** maneuvers and a **reproducible** test.

1. For the purposes of spirometric testing, **acceptable** is defined as free from error. **Reproducible** is defined as being without excessive variability. Criteria for determining whether tracings are acceptable and reproducible are discussed below.

2. **Criteria for an Acceptable Spirogram**: A Forced Expiratory Maneuver which is free from the errors listed below (examples of tracings with errors are given in Section H.). Some errors can be easily seen, others require calculation.

   a. **Hesitation or false starts**, indicating that the subject did not exhale as forcefully as possible at the start of the maneuver. One check for this is the ATS criterion that the extrapolated volume be no more than 5% of the Forced Vital Capacity (FVC) or 150 ml, whichever is greater. (**See Unit Five: Basic Spirometric Calculations** for a definition of FVC and instructions for calculating extrapolated volume.) Some automated spirometers calculate and display this at the end of each maneuver. If you use an automated spirometer, verify that these calculations and extrapolated volume checks are indeed performed.

b. **Cough.**

ATS 1994: Coughing during the first second of the maneuver or at other times that might affect the results. Coughing during the first second may affect the Forced Expiratory Volume in One Second (FEV_1). However, coughing and sputtering toward the end of the maneuver does not affect spirometric calculations (1). (**See Unit Five: Basic Spirometric Calculations** for a definition and instructions for calculating FEV_1.)

c. **Variable effort**, where the subject forced out the air at an inconsistent rate.

d. **Glottis closure**. Sometimes the (epi)glottis closes involuntarily, temporarily cutting off the flow of air completely. A similar pattern will be observed if a subject stops his active pushing and keeps his mouth on the mouthpiece.

e. **Early termination**, before an obvious plateau is reached (no change for at least 1 second after an exhalation time of at least 6 seconds (10 s is optimal)). (Plateau is defined in **Section D. Perform the Test**, in this unit.)

f. **Leaks**, which are caused when the subject does not have a tight seal, or if a volume spirometer is not airtight.

g. **Baseline error**. The recording pen must start the tracing of the subject's effort at zero for the volume line and must begin moving upward when the forced expiratory maneuver begins.

3. **Criteria for Reproducible Spirograms** (after three acceptable maneuvers). The two highest values for FVC and FEV_1 taken from acceptable forced expiratory maneuvers must show minimal variability. (See **Unit Five: Basic Spirometric Calculations** for definitions and instructions for calculating for FVC, FEV_1, and excessive variability.) While it is important to calculate and determine if the test satisfies the reproducibility criteria, it is equally import to visually inspect the volume-time curves (and flow-volume curves if available) to determine if the size and shapes of the curves are reproducible (See Figures 4-20 through 4-23).

4. **Number of maneuvers to perform: Ask subjects to perform at least 3 maneuvers that are acceptable, with the highest FVCs and FEV_1s within 200 milliliters of the second highest FVC and FEV_1s** (The reproducibility criterion has changed over time: ATS - 1994 within 200 ml; ATS-1987 - within 5%; Cotton Dust - within 10%) **from acceptable maneuvers**. The ATS recommends that 8 maneuvers be the upper limit performed during any one testing session (1). However, eight maneuvers may cause too much discomfort for many individuals, particularly those with lung diseases with severe airway obstruction. If, after five attempts, the number of tracings needed to meet acceptability criteria have not been meet, check that the subject is able to proceed. Consider rescheduling another session at a later date.

After each maneuver, check to determine whether it is acceptable according to the criteria above before taking additional tests. If errors are found, discuss with the subject ways to prevent them before proceeding. (See **Section F. Retest as Needed** later in this unit for suggestions for coaching the subject.)

After three acceptable maneuvers have been obtained, check for excessive variability before proceeding (see **Unit Five: Basic Spirometric Calculations** to calculate excessive variability.)

NOTE: Individuals with normal lung functioning generally are able to perform forced expiratory maneuvers with reproducible results. However, a recent study reported that individuals of short stature may have more difficulty satisfying the reproducibility criteria (25). In addition, individuals with lung impairment, especially those with obstructive diseases, often require longer exhalation times. This can lead to more variable results and poor reproducibility (26). The ATS Standardization of Spirometry--1994 Update points out that eliminating test results not meeting reproducibility criteria can lead to bias since subjects with lung impairment may be excluded from analyses (1). The importance of this concern is illustrated in the occupational setting where group data are sometimes used to detect possible exposures to pulmonary hazards. If subjects with excessive variability are not included, the data may indicate that the workplace exposure had no adverse effect, when in fact it had. Thus, workers might continue to be subjected to hazards.

The ATS 1994 Update recommends that reproducibility be a goal to strive for during testing. It suggests that the reproducibility criteria be used as a guide to determine whether more maneuvers are needed and not to exclude subjects:

"Labeling results as being derived from data that do not conform to reproducibility criteria...The acceptability criteria must be applied before the reproducibility criteria. 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." (1)

F. Retest as Needed

1. **Coach the subject**. Review with the subject these common problems before proceeding with additional maneuvers:

    a. Quitting too soon or not completely emptying the lungs due to insufficient effort at the end of the maneuver (low FVC or no plateau).

    b. Not taking the deepest breath possible (low FVC and FEV_1).

    c. Not blowing as completely and forcefully as possible, particularly during the initial portion of the maneuver, (low peak flow, large extrapolated volume, and variable effort).

    d. Failure to maintain an airtight seal around the mouthpiece or on the nose (leaks).

    e. Pursing the lips as with a musical instrument.

    f. Obstructing the mouthpiece with the tongue or dentures. If dentures seem to be the problem, ask the subject to remove them for the remaining tests.

    g. Bending over or not extending the chin.

2. **Allow the subject to recover between maneuvers**. The subject may require several minutes before proceeding.

G. Record Keeping

Below are guidelines to consider for keeping subject records.

1. **Consistent systems**. Consistency in the record keeping system is important to ensure that all of the information needed is obtained.

2. **Data Sheets**: At a minimum, the following information should be obtained each time spirometry is performed:

    a. Test date and time.

    b. Subject's name, identification number, age, height, sex and race.

    c. Spirometer used (e.g., type, serial number, etc.).

    d. Ambient air and spirometer temperature.

    e. Sitting or standing position used.

    f. Source of reference values used (predicted normals).

g. Test results.

h. Technician's name or initials.

i. Barometric pressure. This information should be included if it is not too difficult to obtain. Barometric pressure changes are especially important when testing is conducted at different altitudes.

j. Any technician comment on subject cooperation/effort or other comments regarding the test session.

When spirometry is used for medical surveillance it is often helpful to have a data sheet that summarizes spirometric test results and comparisons in the subject's record. This provides a quick way to keep track of changes. Some spirometers are connected to a computer with a database of results which automates this process. (On the last page of this unit, the **Pulmonary Function Studies Flowsheet**, is a sample of a data sheet).

3. **Tracings**: The actual spirogram should also be incorporated into the permanent record. Federal regulations affecting spirometry require a permanent record and this ensures access to the tracing at a later date, even if computerized records are not available. Some recommend that the subject sign each tracing as it is produced. This eliminates any possibility of a mix-up, especially on mechanical tracings that don't print out the subject's name.

4. **Confidentiality**: Remember that spirometric test results and tracings are confidential, as are all medical records.

5. **Length of time to keep records**: Most federal regulations for certain workplace exposures require retention of medical records for 30 years following the date of an employee's termination. Check the requirements applicable for your company or industry.

6. **Back-up copies**: Make backup copies of all critical computerized information.

H. Sample Tracings

1. **Hesitation or false start** (this can include excessive extrapolated volume): (**Figures 4-3 and 4-4**). The volume time curves starts slowly instead of climbing sharply. The peak of the flow volume curve is displaced to the right, away from the ‘y’ or vertical axis.

FIGURE 4-3. VOLUME TIME CURVE - EXTRAPOLATED VOLUME (VEXT)

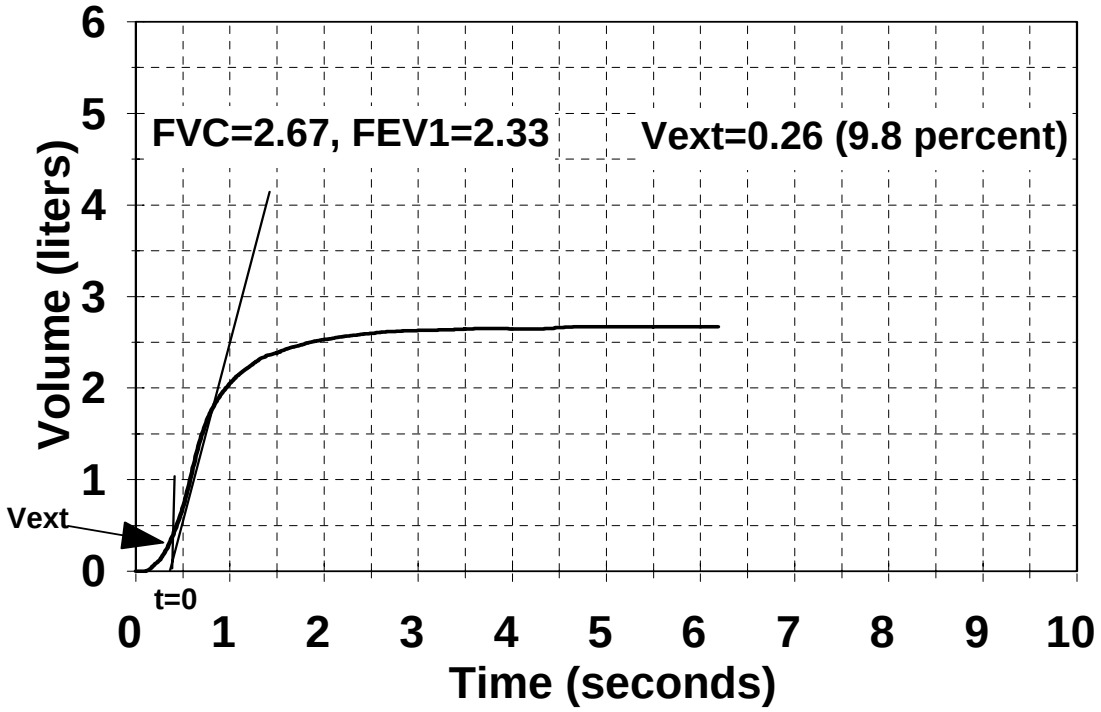
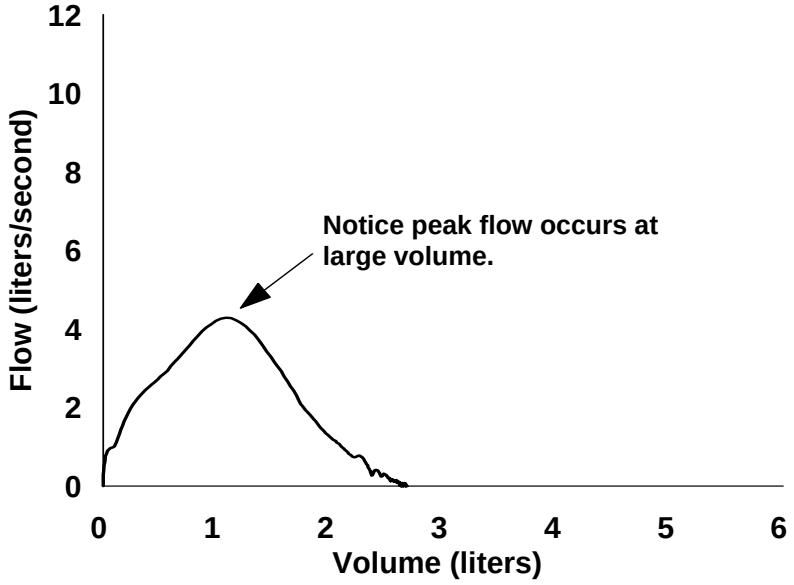


FIGURE 4-4. FLOW VOLUME CURVE - VEXT



2. **Cough:** (**Figures 4-5 and 4-6**). Both the volume time and the flow volume curves show dips instead of a smoothly-formed line.

FIGURE 4-5. VOLUME TIME CURVE - COUGH

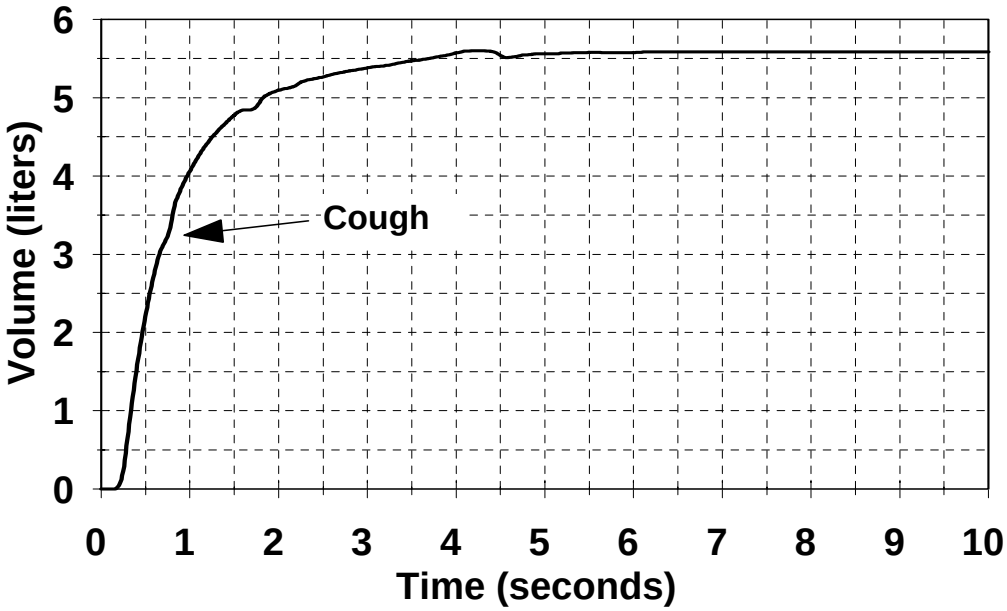
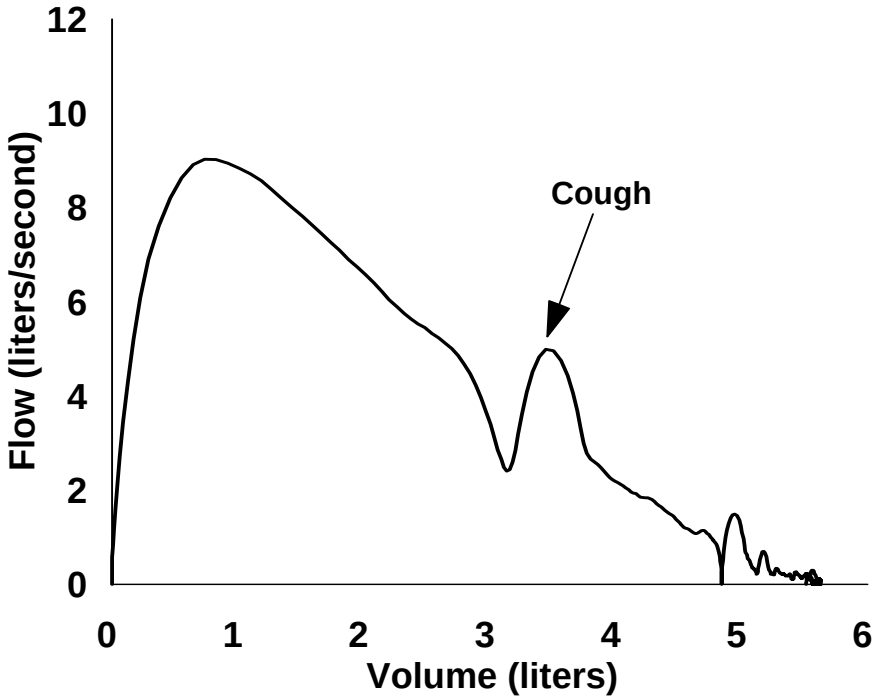


FIGURE 4-6. FLOW VOLUME CURVE - COUGH



3. **Variable effort**. (**Figures 4-7 and 4-8**). Both curves show dips in the line similar to those for a cough. It is usually difficult to distinguish between a cough and variable effort on a tracing. However, either cause during the first second will make the tracing unacceptable to use for calculations. Note that the variable effort tracings also terminate early in this sample.

FIGURE 4-7. VOLUME TIME CURVE - VARIABLE EFFORT

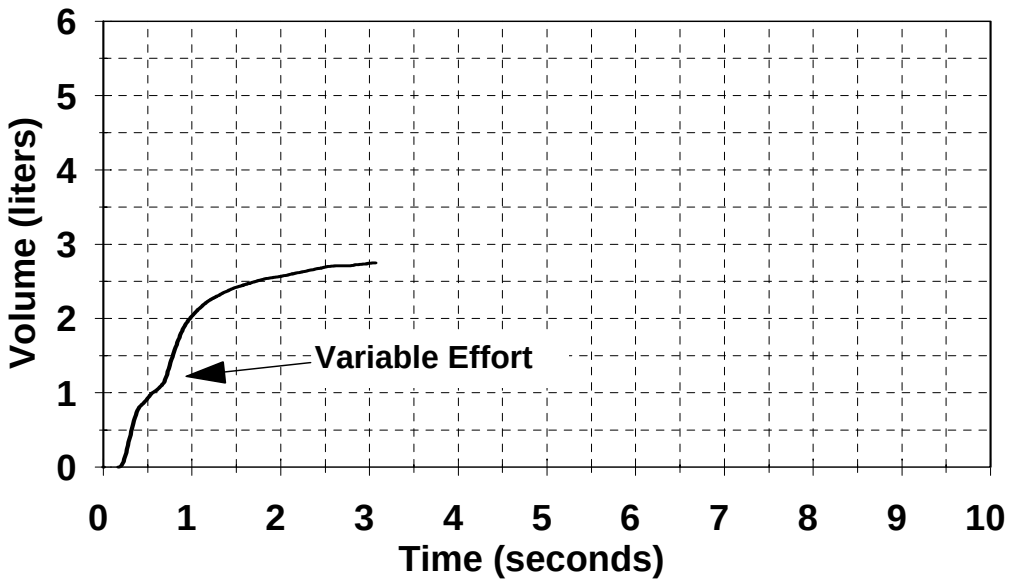
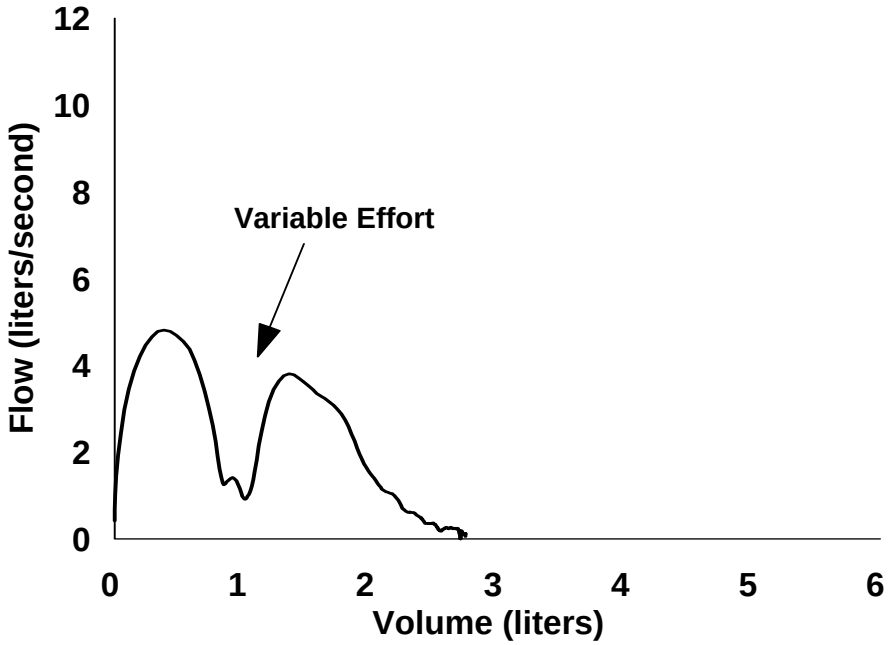


FIGURE 4-8. FLOW VOLUME CURVE



4. **Glottis closure**: (**Figures 4-9 and 4-10**). Both curves stop abruptly. On the volume time curve, an artificial plateau is reached, with a bend or knee in the curve where expiratory effort stopped. On the flow volume curve, the line drops sharply.

FIGURE 4-9. VOLUME TIME CURVE - GLOTTIS CLOSURE

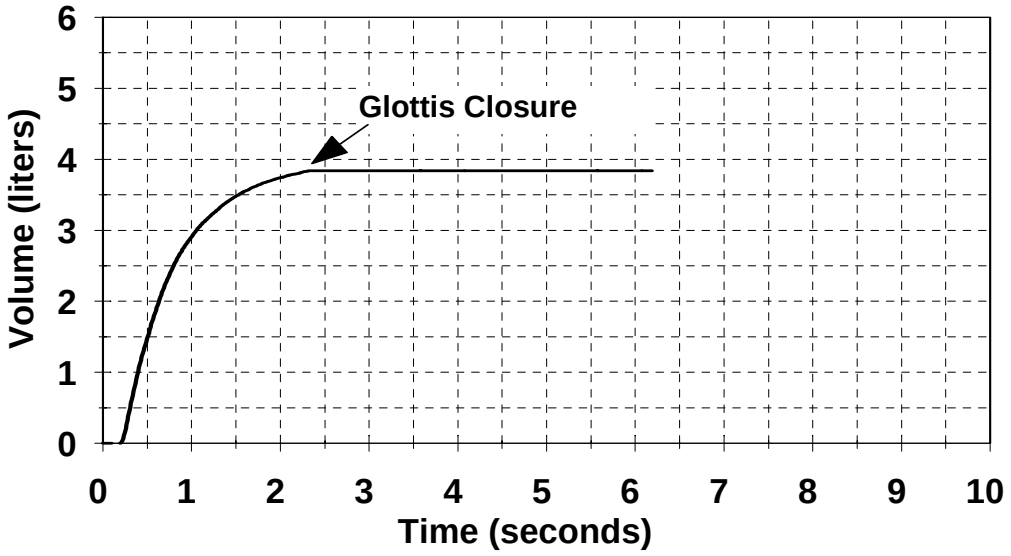
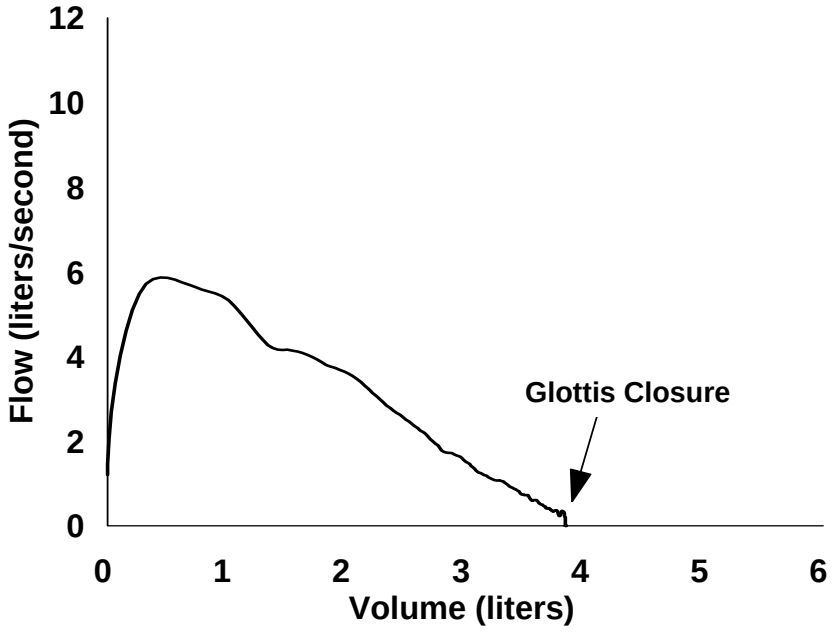


FIGURE 4-10. FLOW VOLUME CURVE



5. **Early termination**: (**Figures 4-11 and 4-12**). The volume time curve does not plateau and is less than six seconds in this example. The flow volume curve shows a low total volume and the line (flow) drops sharply at the end of expiration.

FIGURE 4-11. VOLUME TIME CURVE - EARLY TERMINATION

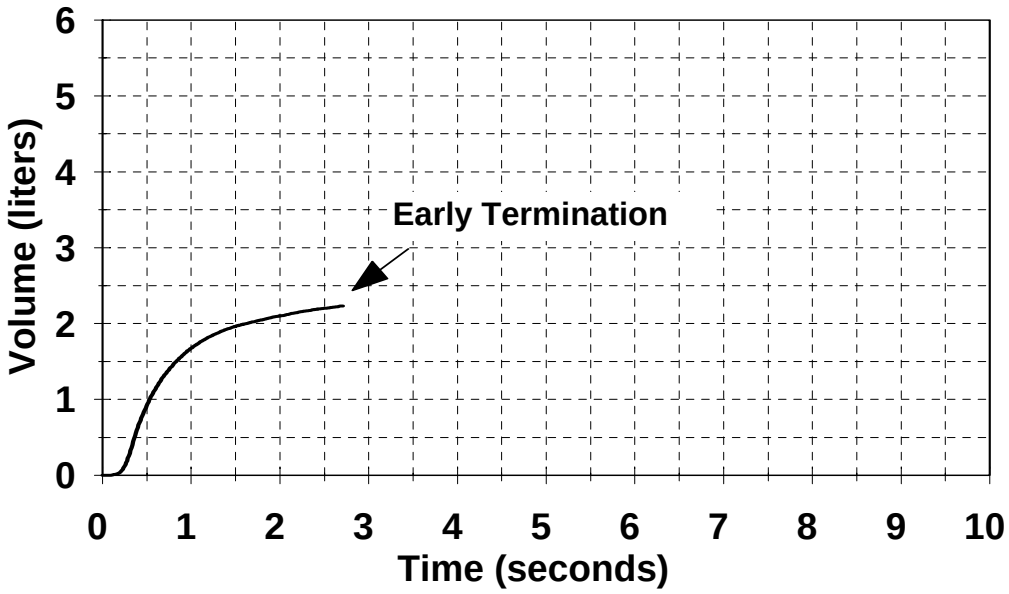
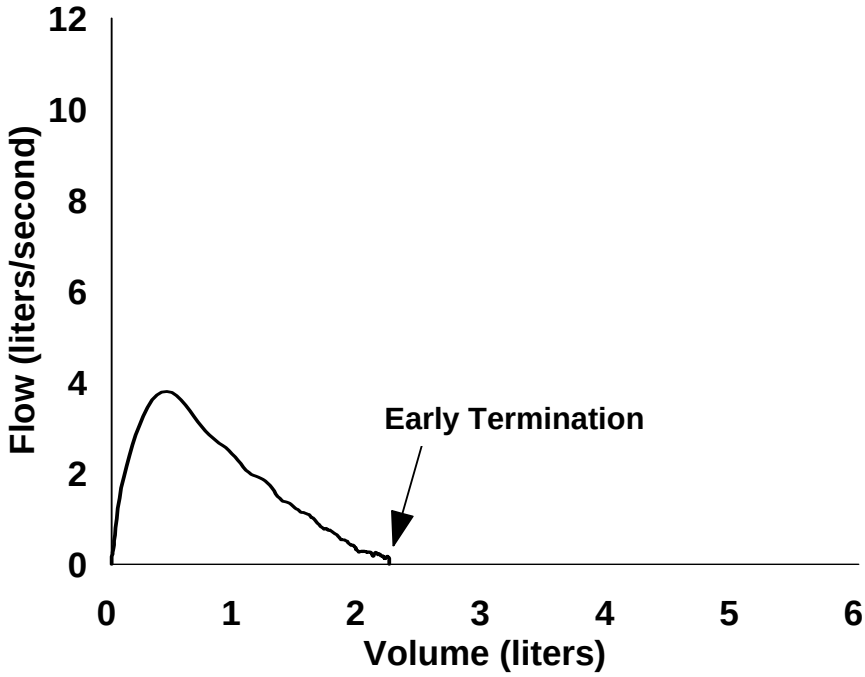


FIGURE 4-12. FLOW VOLUME CURVE



6. **Leaks**: (**Figures 4-13 and 4-14**). The volume-time curve drops instead of reaching a plateau. The flow volume curve "backtracks" at the end. This pattern can be caused by leaks in a volume spirometer or around the mouthpiece.

FIGURE 4-13. VOLUME TIME CURVE - LEAKS

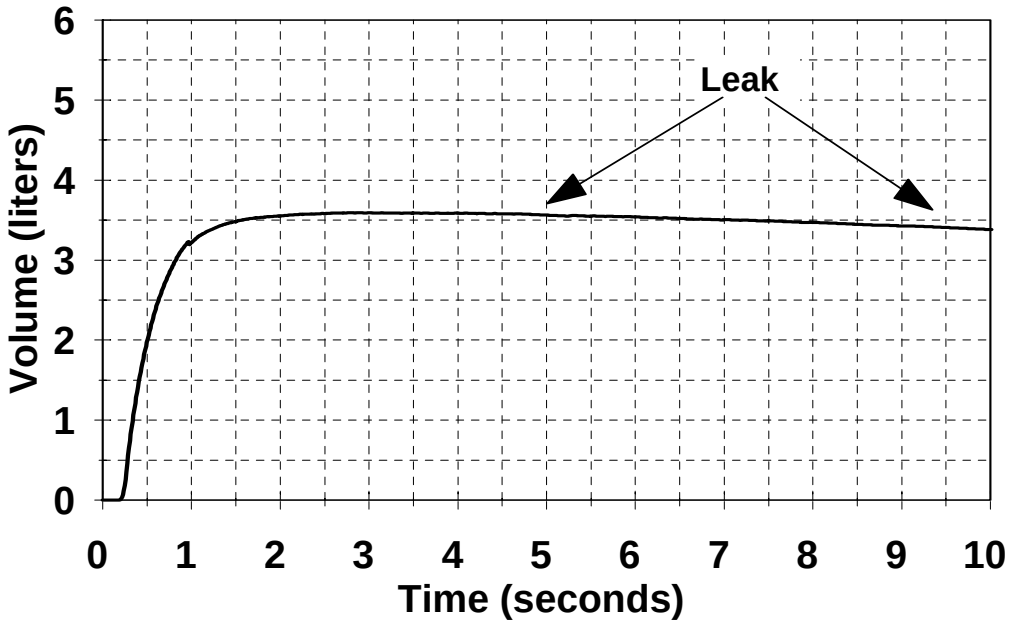
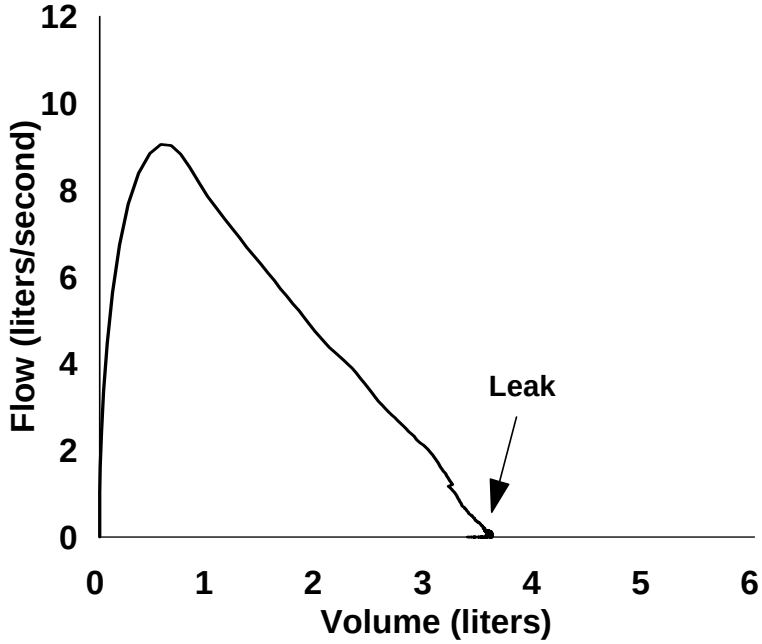


FIGURE 4-14. FLOW VOLUME CURVE



7. **Baseline error**: (**Figures 4-15 and 4-16**). Neither tracing starts at zero for volume. If other acceptability criteria are met, these tracings could be used by adjusting calculations to reflect where the baseline should have been.

FIGURE 4-15. VOLUME TIME CURVE - BASELINE ERROR

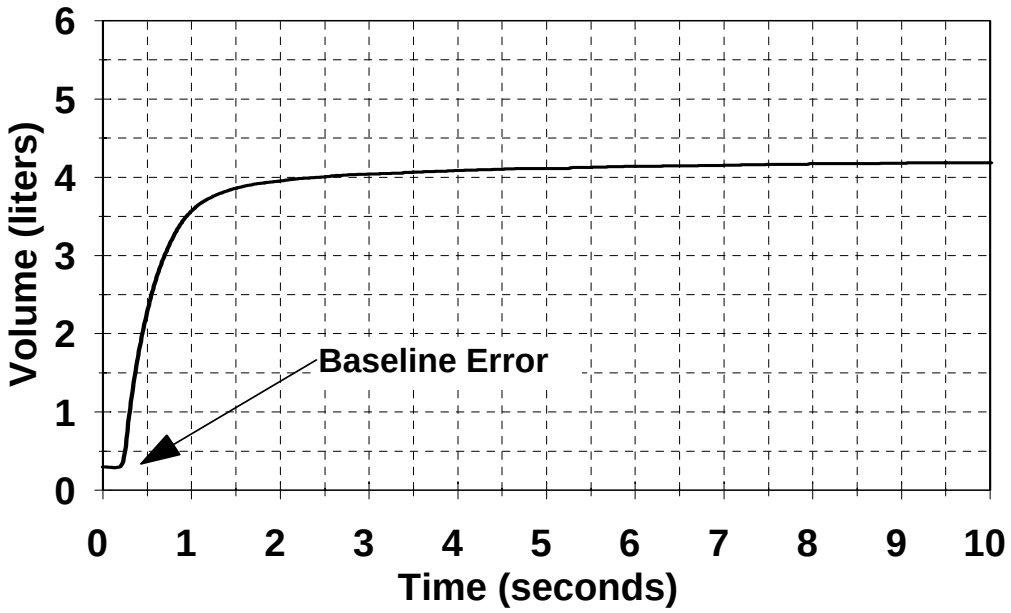
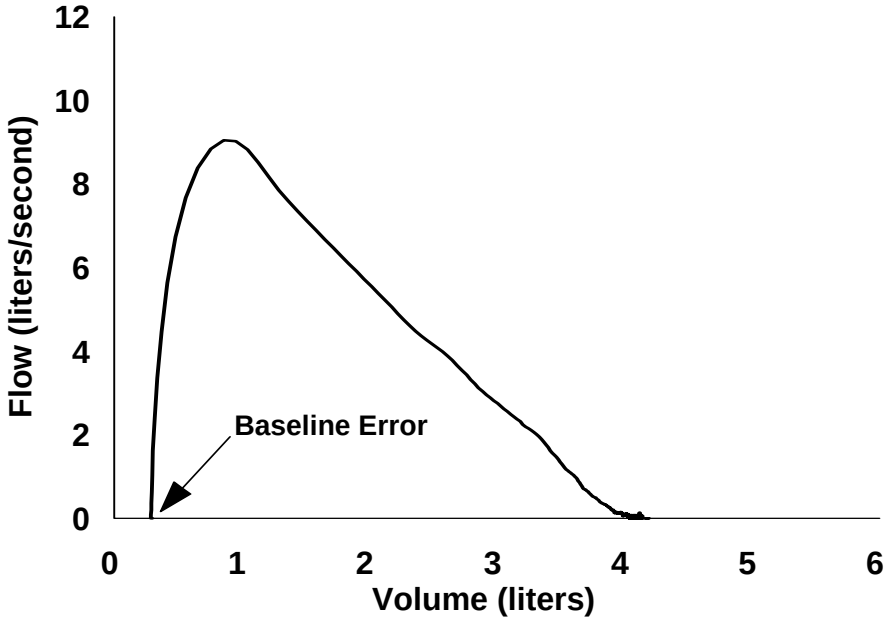


FIGURE 4-16. FLOW VOLUME CURVE



EXAMPLE: 8a. Visual inspection of curves for non-reproducible test. Figures 4-17 and 4-18 show a non-reproducible test **with** 3 acceptable curves. The actual calculation of excessive variability will be covered in Unit 5, but a visual inspection of the curves below reveal an obvious variability in the size (FVC) of the curves. Since variable volumes (FVCs) are most likely due to an incomplete inhalation, the subject should be coached to **take a deeper breath** in before performing the forced exhalation.

FIGURE 4-17. VOLUME-TIME CURVE - NON-REPRODUCIBLE TEST

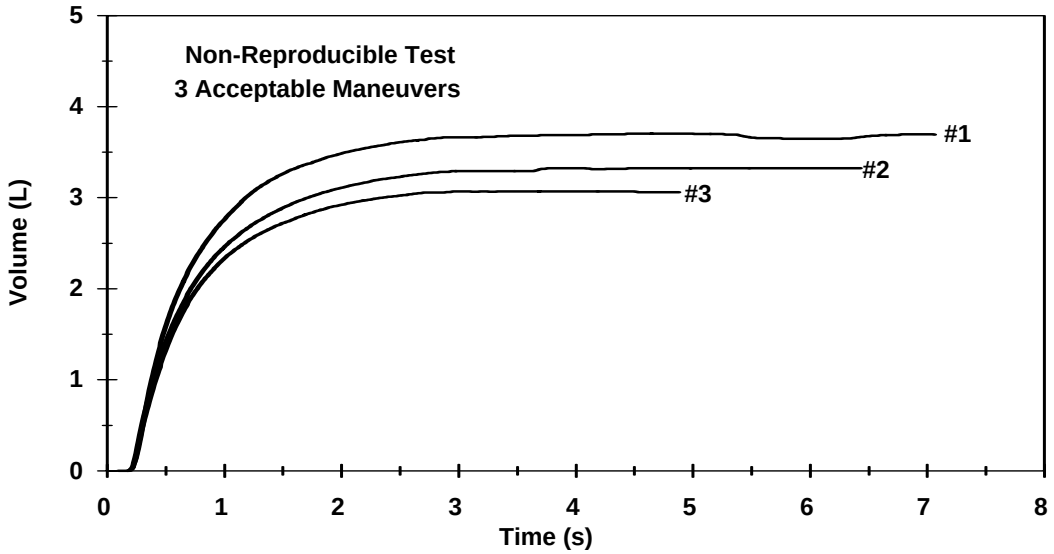
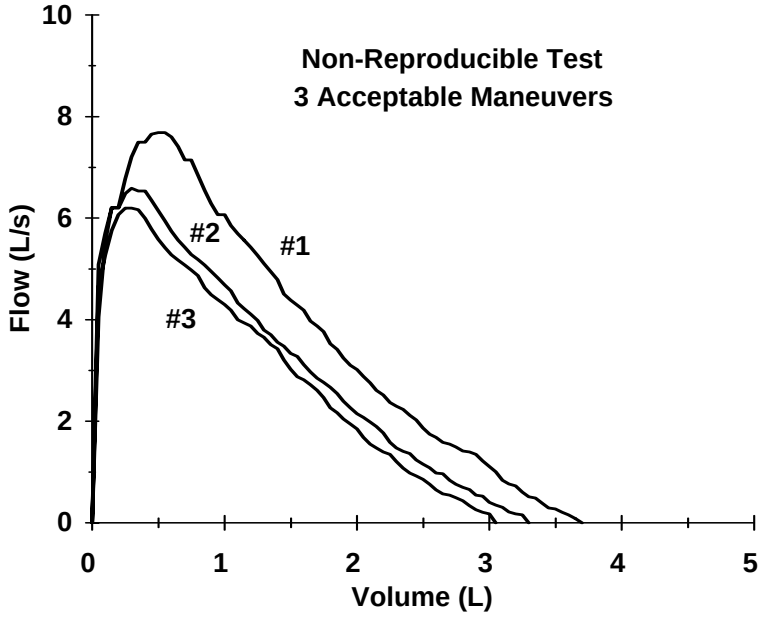


FIGURE 4-18. FLOW-VOLUME CURVE - NON-REPRODUCIBLE TEST



EXAMPLE: 8b. Visual inspection of curves for non-reproducible test. Figure 4-19 and 4-20 show a reproducible test with 3 acceptable curves. Visual inspection of the curves below reveals an obvious reproducibility in the size (FVC) of the curves. This indicates that the subject most likely completely inhaled, before performing a forced exhalation. If a flow-volume display is available, then the flows around peak flow should also be reproducible (highest flow values in Figure 4-20). If peak flows are not reproducible, then the subject should be coached to **Blast the Air Out**.

FIGURE 4-19. VOLUME-TIME CURVE - REPRODUCIBLE TEST

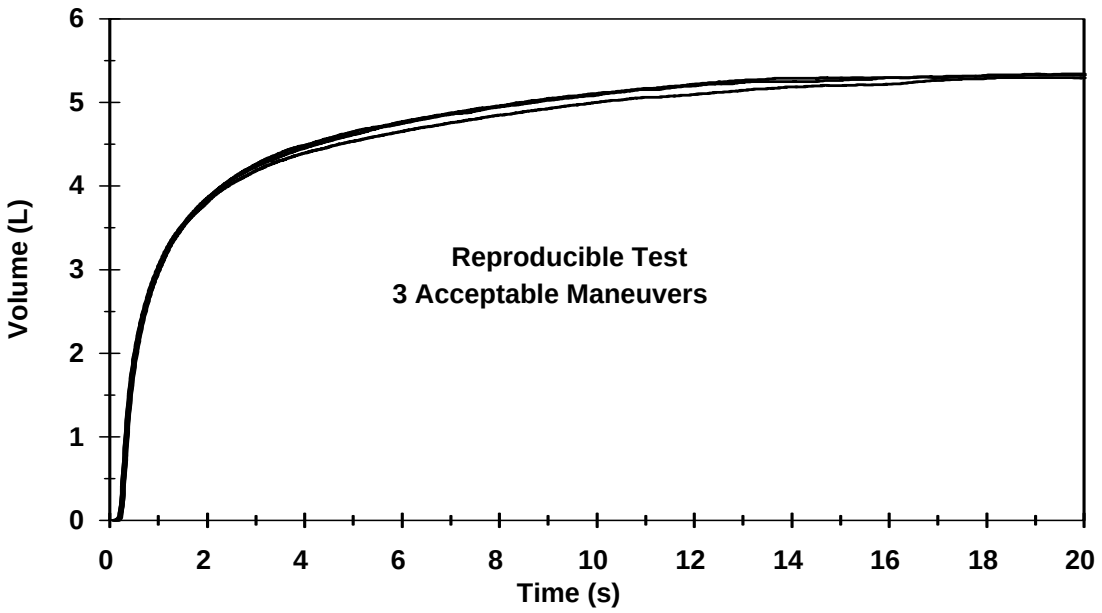
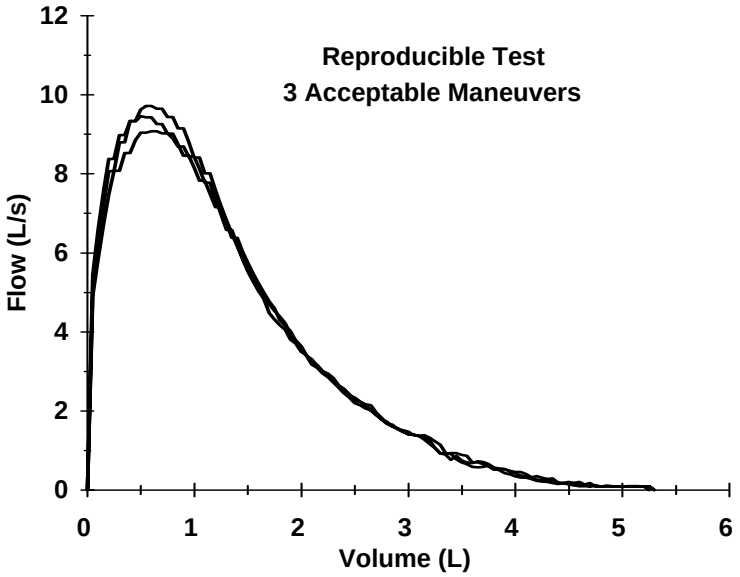


FIGURE 4-20. VOLUME-TIME CURVE - REPRODUCIBLE TEST



EXERCISES:

Exercises are given on the following pages so that students can practice selecting acceptable tracings. Determining hesitations or false starts, such as excessive extrapolated volume, will be covered in **Unit Five: Basic Spirometric Calculations**. Students can further practice acceptability skills by completing the first ten exercises in **Unit Nine:**

EXERCISE 1: (Refer to Figure 4-21.) Do the curves below meet acceptability criteria?

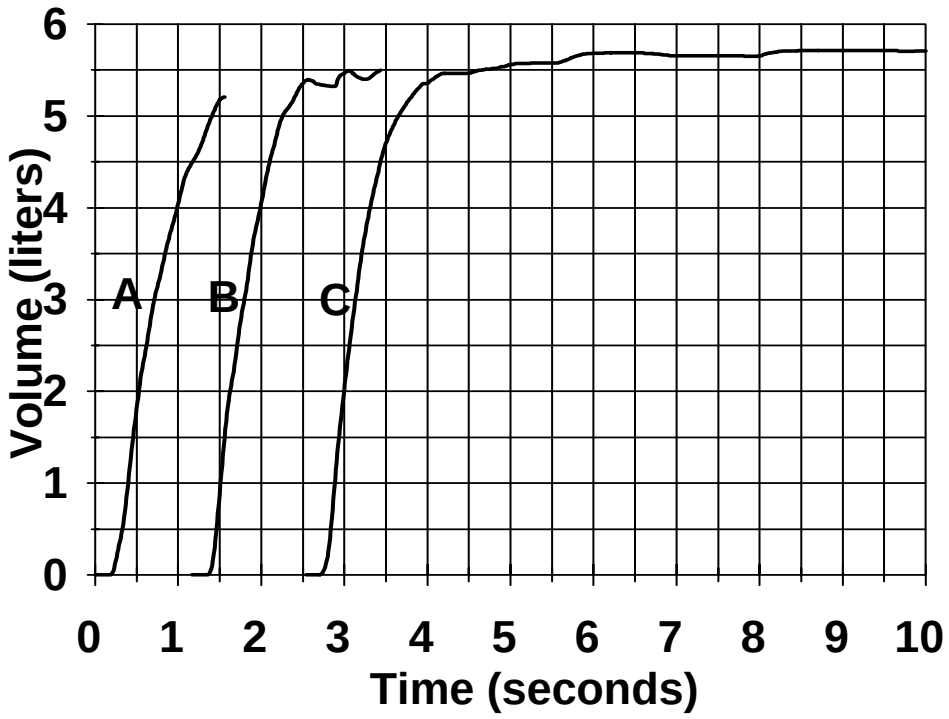


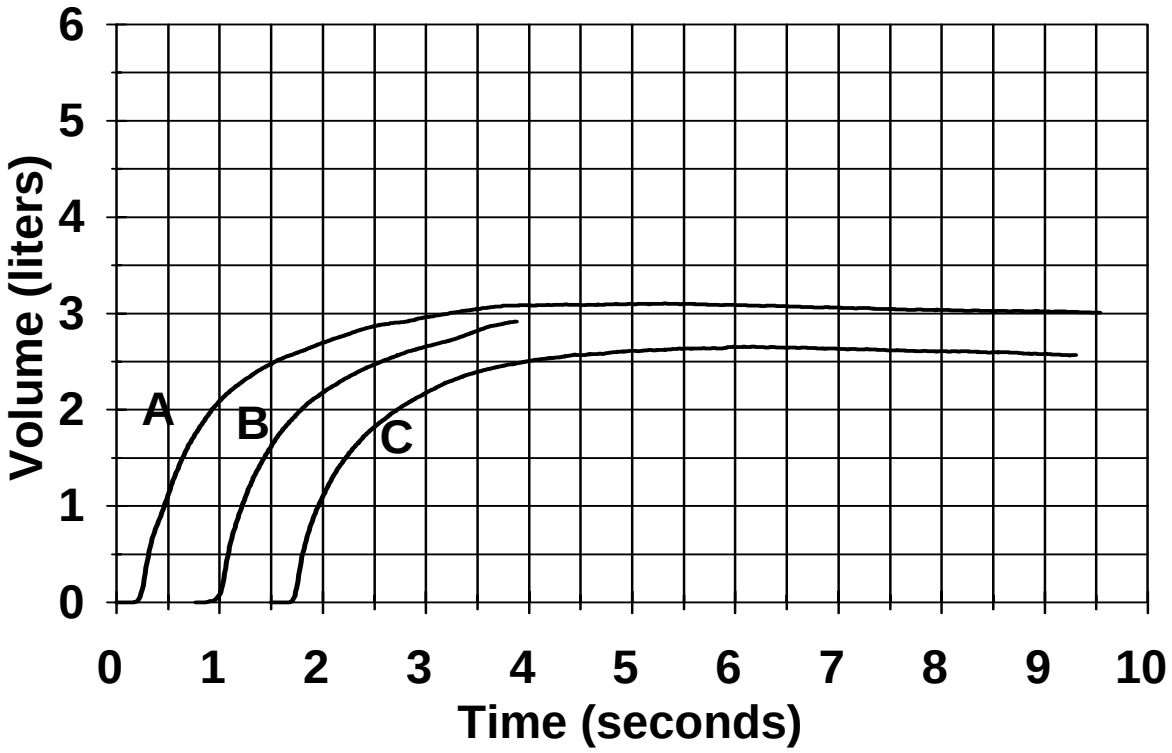
FIGURE 4-21. VOLUME TIME CURVE - EXERCISE

FEEDBACK:

No. Curves A and B show early termination. Curve B also shows a cough. Curve C shows a cough or variable effort.

EXERCISE 2:
(Refer to Figure 4-22.) Do the curves below meet acceptability criteria?

FIGURE 4-22. VOLUME TIME CURVE - EXERCISE

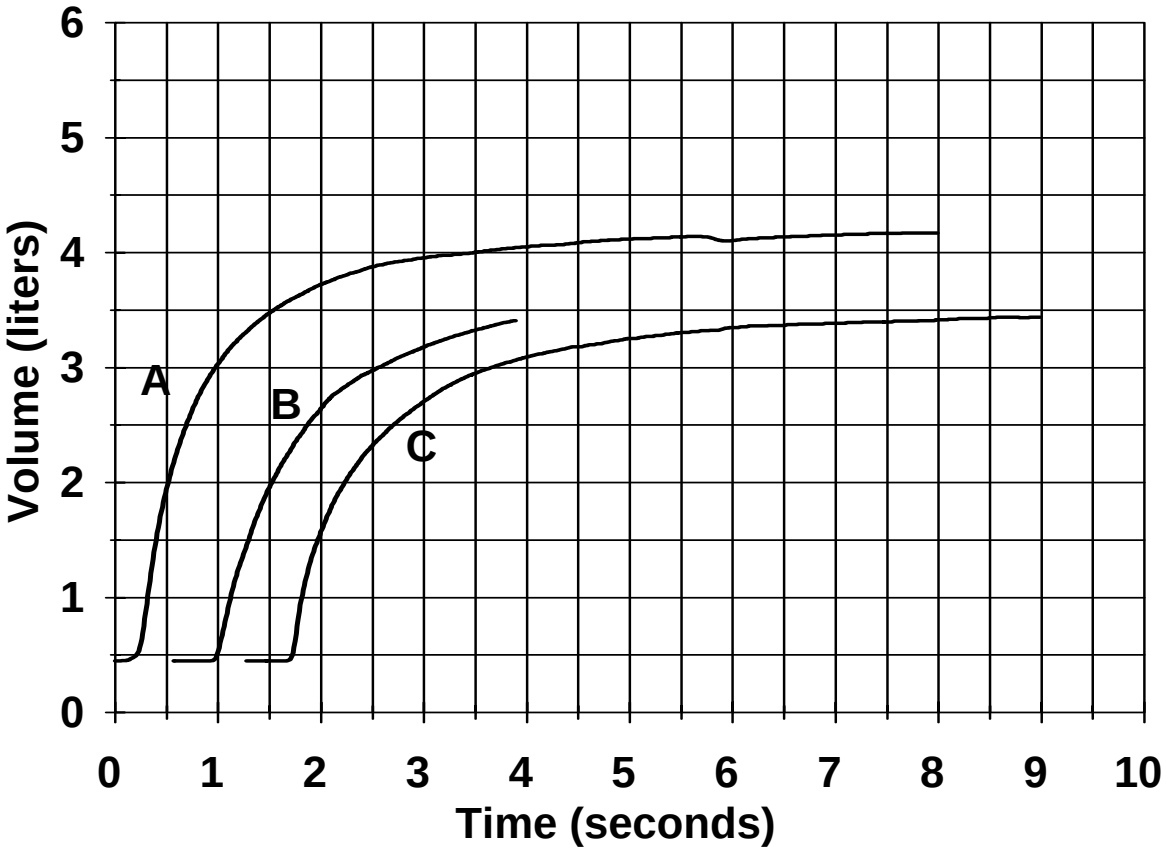


FEEDBACK:

No. Curves A and C show possible leakage. Curve B shows early termination. Check for a leak, particularly around the mouthpiece, and coach the subject to **Blow Out Longer**.

EXERCISE 3: (Refer to Figure 4-23.) Do the curves below meet acceptability criteria?

FIGURE 4-23. VOLUME TIME CURVE - EXERCISE



FEEDBACK:
No. All three tracings show a baseline error. Curve B doesn't plateau. Curve C is a judgment call on whether or not a plateau was reached.

SPIROMETRY FLOWSHEET (SAMPLE DRAFT)

Name:		SS#:
Sex:	Race[1]:	Birthdate:
Job Location:		Job Title:

Date:								
Tech. Initials:								
MD Initials:								
Spirometer type or serial #[2]								
Predicted used								
Reason for test[3]								
Temperature °C								
Position: Sit or Stand								
Age								
Height[4]								
Smokes[5] yes/no								
Job change[6] yes/no								
Subject effort (good, fair, poor)								
Observed Values (BTPS)	FVC							
	FEV_1							
	$\frac{FEV}{FVC}$ 1%							
Predicted Normal Value	FVC							
	% Pred.							
	FEV_1							
	% Pred.							
Change ± % or liters	FVC							
	FEV_1							

NOTES:
1. The predicted FEV_1 and FVC in non-Caucasians (blacks and asians) must be multiplied by 0.85.
2. Be sure serial # and other relevant information are recorded in the spirometer logbook.
3. E.g., routine, asbestos, cotton dust, etc.
4. In stocking feet.
5. If yes, record smoking history in subjects' chart.
6. Note job change information below: date, workstation, process, building, etc. Use additional paper if necessary.

a: _____ c: _____

b: _____ d: _____

UNIT FIVE: BASIC SPIROMETRIC CALCULATIONS

Several spirometric values can be calculated by hand from mechanically produced volume/time spirograms. As discussed in **Unit Two: Overview of Spirometry**, this allows the information obtained to be usable, even if the electronically produced printout malfunctions. See **Appendix H. Outline of Spirometric Calculations** for a summary of this unit. Also see **Appendix I. Basic Mathematic Calculations** and **Appendix J. Metric Conversions**.

A. Forced Vital Capacity (FVC)

DEFINITION:
The maximal amount of air that can be exhaled forcefully after a maximal inspiration or the most air a person can blow out after taking the deepest possible breath. The FVC is useful for detecting restrictive diseases, since lower than expected results may be a sign that the lungs cannot inflate as fully as normal. The FVC may also be reduced in severe obstructive diseases.

HOW TO CALCULATE:

1. After the subject has produced three acceptable tracings, calculate the total volume for each tracing (count the volume lines on the graph paper). Remember that acceptable tracings are free from error, as explained in **Unit Four: Spirometric Technique**, **Section E: Check the Acceptability and Reproducibility of the Test**.

2. Check for excessive variability between the two largest FVCs to determine if additional maneuvers are needed. (See the next section, **Calculating Excessive Variability for FVC** for instructions.) If the reproducibility criteria are not met, continue the test as needed, assuming that the subject is able to continue.

3. If the reproducibility criteria are met, use the FVC with the largest volume for future calculations unless otherwise noted.

EXAMPLE: (See Figure 5-1. Volume Time Curve - FVC Measurement): The FVC for curve A is 3.55 L.

EXERCISE: What are the FVCs for curve B and C? Which of the three curves has largest FVC?

FEEDBACK: Curve B - FVC = 3.33 L
Curve C - FVC = 3.26 L
Largest FVC - Curve A (3.55 L)

POINTS TO REMEMBER:

1. Always use the largest volume from an acceptable tracing to ensure that the maximal results are used.

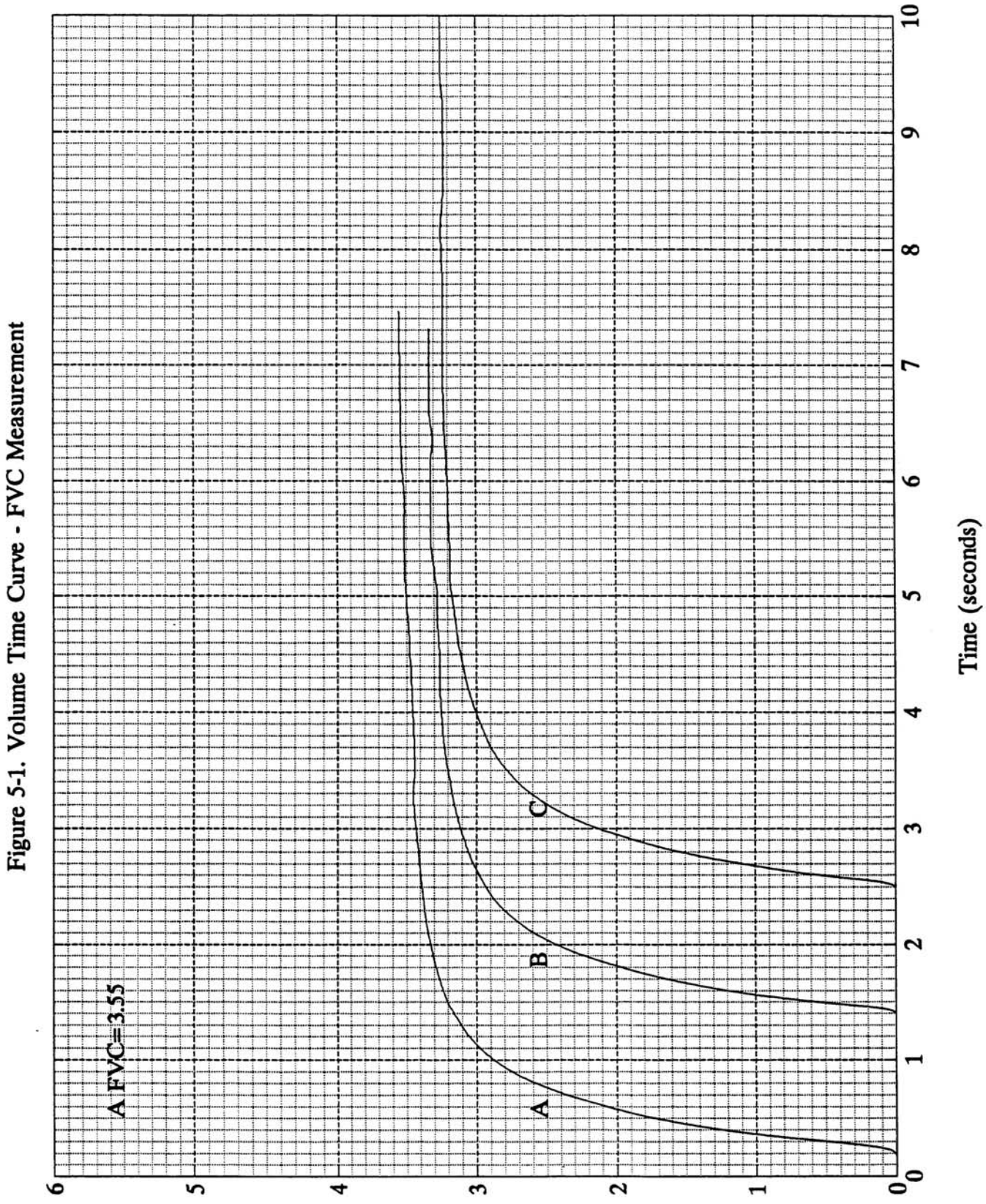
2. FVC should be given in liters rounded to 2 decimal places (e.g., 4.25 L.).

3. Remember to convert the answer to BTPS when needed. (For a definition of BTPS and calculating instructions, see **Section I.: Conversion to BTPS**, which appears later in this unit.)

B. Calculating Excessive Variability for FVC

DEFINITION:
Using three acceptable spirograms (tracings), the two with the largest FVCs are examined to determine whether there is more than a **200 milliliter** difference (0.20L) between them. [**Note (optional)**: reproducibility criteria have changed over the last 20 years: ATS-1994, 200 ml; ATS-1987 5% or 100 ml (whichever is greater); Cotton Dust-1979, 10% or 100 ml (whichever is greater). To determine "whichever is greater," if the difference is greater than 100 ml (100 ml for Cotton Dust as well), then the percentage criterion should be used. If the difference is **not** greater than 100 ml, then the percentage criterion does not need to be used as the tracings do not have excessive variability.] (See **Unit Four: Spirometric Technique**, **Section E.: Check the Acceptability and Reproducibility of the Test**, for the criteria for acceptable spirograms.)

FIGURE 5-1. VOLUME TIME CURVE - FVC MEASUREMENT



HOW TO CALCULATE:

To find if the difference is greater than 200 ml (calculate Best FVC - Second Best FVC):

1. Determine the volumes for the two acceptable tracings with the largest FVCs.

2. Subtract the volume of the second largest FVC from the volume of the largest FVC.

To find if the difference is excessive expressed in percentage (OPTIONAL):

1. Follow steps 1 and 2 above.

2. Proceed if the difference is greater than 200 ml (100 ml for Cotton Dust as well).

3. Divide the answer (the difference) by the volume of the largest FVC.

4. Multiply the answer by 100 to find the percentage of the difference, or:

$$\%\ Reproducibility = \frac{Best\ FVC - Second\ Best\ FVC}{Best\ FVC} x100$$

EXAMPLE: (See Figure 5-2. Volume Time Curve - FVC Variability).

Curve A (FVC - 3.55 L) and Curve B (FVC - 3.33 L) are the two largest curves so they are the ones to use.

3.55 - 3.33 = 0.22

Since 0.22 is greater than 200 milliliters (0.20L), there is excessive variability between curves A and B.

Since 220 ml is greater than 100 ml (ATS-1987) the 5% criterion can be appropriately applied. In addition, 220 ml is greater than 100 ml (Cotton Dust). Therefore, the percent reproducibility (optional) can appropriately be used for both the ATS-1987 and the Cotton Dust and is calculated by:

$$\%\ Reproducibility = \frac{Best\ FVC - Second\ Best\ FVC}{Best\ FVC} x100$$

0.22/3.55 = .062

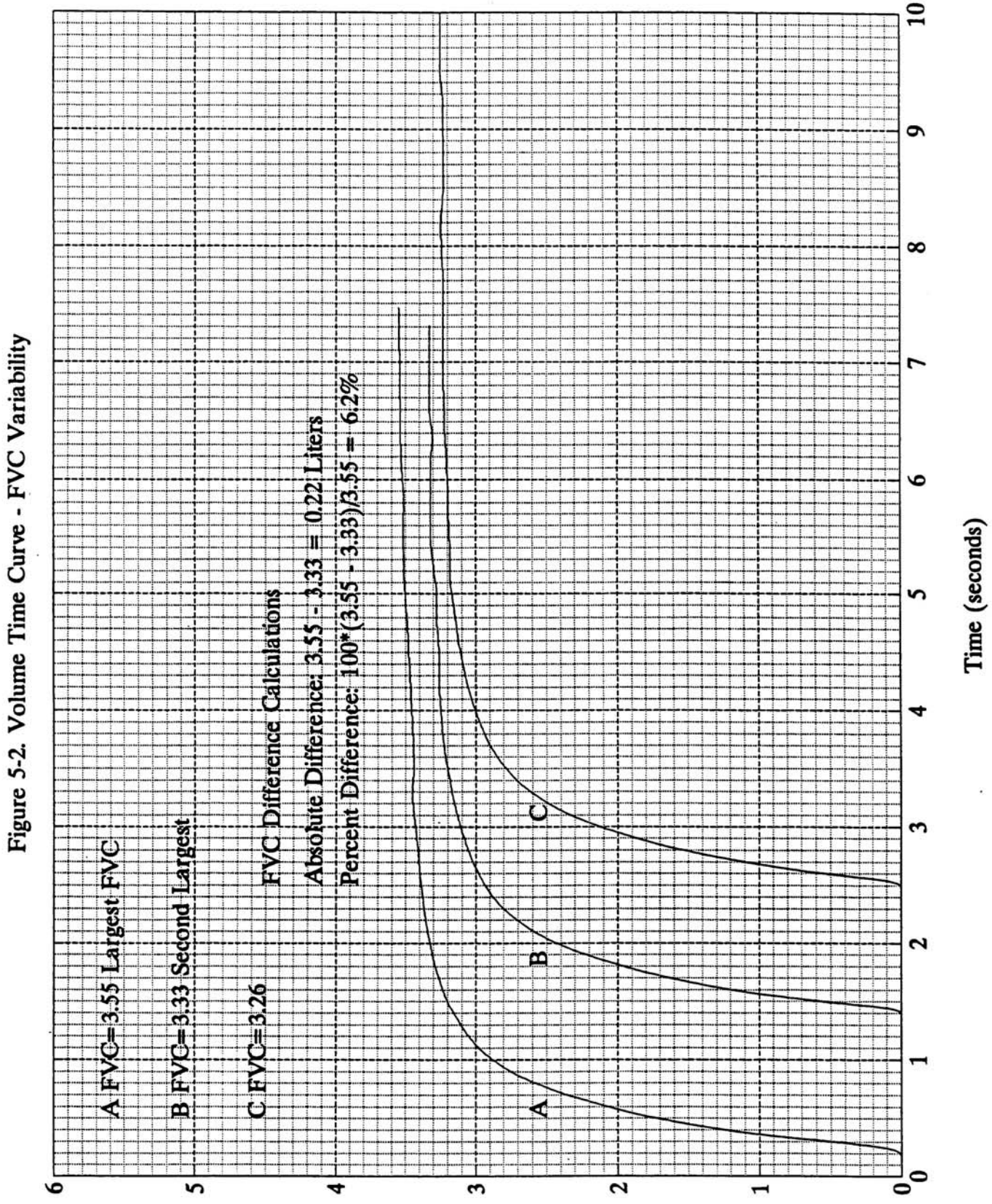
0.062 x 100 = 6.2%

Since 6.2% is greater than 5%, there is excessive variability between curves A and B using the ATS-87 (5% criterion) but not using the Cotton Dust (10% criterion).

EXERCISE: (See Figure 5-2. Volume Time Curve - FVC Variability). How much variability would there be if curves B and C had been the two largest curves?

FEEDBACK: 0.07L or [(3.33 - 3.26)/3.33] x 100 = 2.1%

FIGURE 5-2. VOLUME TIME CURVE - FVC VARIABILITY



EXERCISE: Three otherwise acceptable tracings had the following FVCs: A = 1.90 L., B = 1.19 L., C = 1.97 L. How much variability would there be between the two largest FVCs?

FEEDBACK: 70 ml. Since this is less than 200 ml (ATS-1994 criterion), there is no excessive variability. Optional: There is no excessive variability using the 100 ml ATS-1987 or Cotton Dust criteria as well.

POINTS TO REMEMBER:

1. 1 liter = 1000 milliliters (ml)

2. The ATS Standardization of Spirometry--1994 Update recommends that reproducibility be a goal to strive for in testing. It suggests that the reproducibility criteria be used as a guide to determine whether more maneuvers are needed and not to exclude subjects (1). The rationale for this is discussed in **Unit Four: Spirometric Technique, Section E. Check the Acceptability and Reproducibility of the Test**.

C. Forced Expiratory Volume in One Second (FEV_1)

DEFINITION:

The volume of air exhaled during the first second of a forced expiratory maneuver. The FEV_1 is useful for detecting obstructive diseases since a person with obstructed airways will not be able to exhale as much air in the first second as a person with normal lungs. The FEV_1 may also be low if the person has severe restrictive disease.

HOW TO CALCULATE:

1. Find the starting point of a forced expiratory maneuver along the baseline of an acceptable spirogram. A more accurate way for determining the start of the test will be described later in this unit in **Section E. Back Extrapolation**. This is the point where time (t) = zero. Note the scale on your graph paper to determine the length of one second. Measure the appropriate distance from t = 0 to t = 1 second.

2. Draw a straight line vertically up from the point on the baseline where t = 1 to where it intersects with the curve. Determine the volume on the graph paper at the point of the intersection. This is the FEV_1.

EXAMPLE: (See Figure 5-3. Volume Time Curve - FEV_1 Measurement):

For curve A, t = 0 is at 0.24 seconds, therefore t = 1 is at 1.24 seconds. A straight line drawn vertically at t = 1 intersects the curve at 3.15 liters. Therefore, the FEV_1 for curve A is 3.15 liters.

EXERCISE: Calculate the FEV_1s for curves B and C.

FEEDBACK: Curve B - FEV_1 = 2.98 L.
Curve C - FEV_1 = 2.82 L.

OPTIONAL EXERCISE: Calculate the FVC for curves A, B and C in Figure 5-3 and determine if there is excessive variability.

FEEDBACK: Curve A - FVC = 3.98 L.
Curve B - FVC = 3.86 L.
Curve C - FVC = 3.65 L.

3.98 - 3.86 = 0.12L

% Reproducibility (optional) = (0.12)/3.98) x 100 = 3.0%

The variability between curves A and B is only 120 milliliters and 3.0% so the FVCs do not have excessive variability for all the criteria. Note (optional) that 120 milliliters is greater than 100 ml; therefore, the percentage criterion is used to determine excessive variability under the Cotton Dust criteria.

POINTS TO REMEMBER:

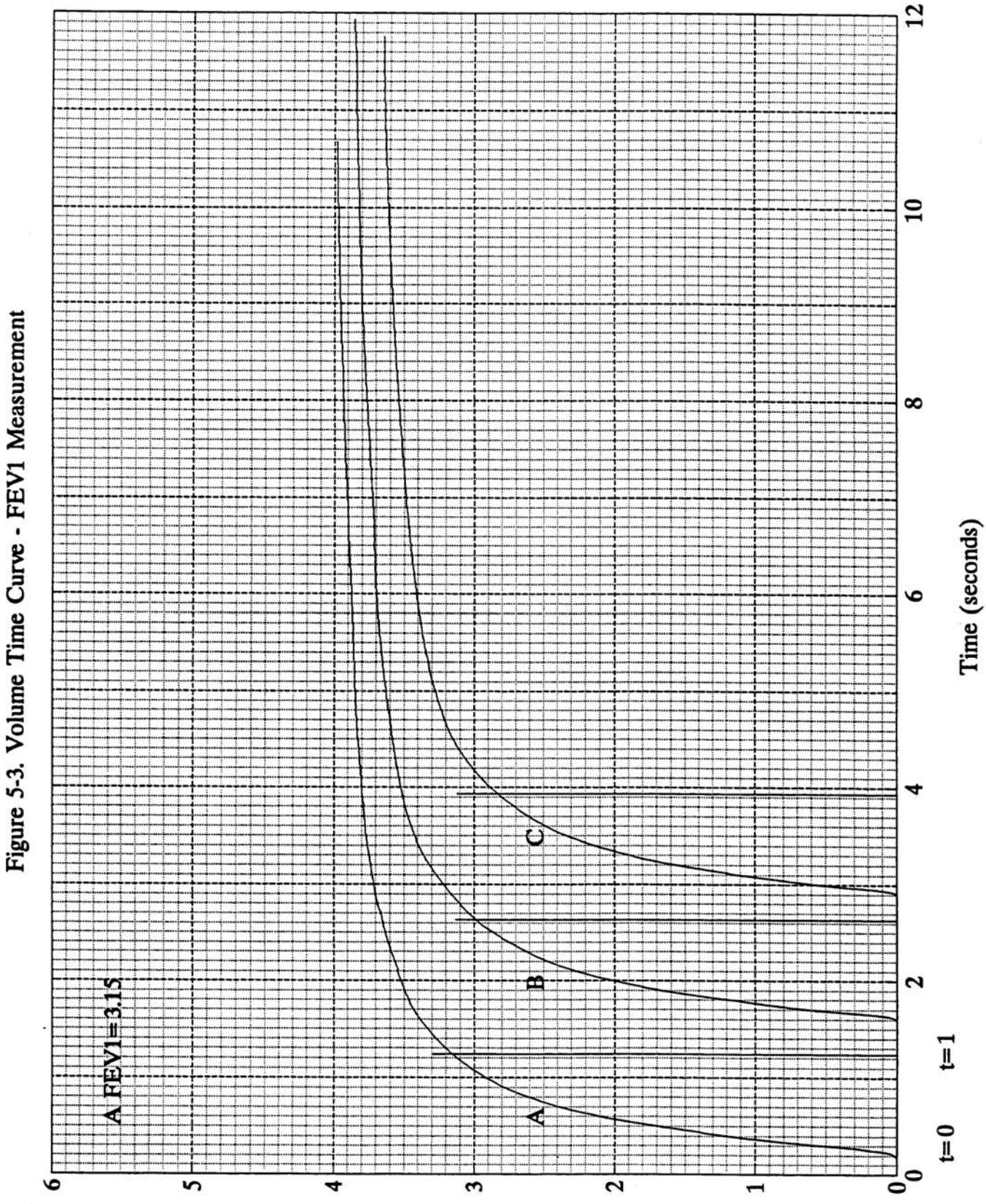
1. The FEV_1 to be used for subsequent analyses should be the largest one, regardless of the curve on which it occurs. For example, the largest FEV_1 may not be on the curve with the largest FVC.

2. The FEV_1 should be given in liters rounded to 2 decimal places (e.g., 3.15).

3. Excessive variability and extrapolated volume must be calculated to determine if additional maneuvers are needed. See the following three sections for details.

4. Remember to convert the answer to BTPS when needed. For a definition of BTPS and calculating instructions, see **Section I: Conversion to BTPS**, which appears later in this unit.

FIGURE 5-3. VOLUME TIME CURVE - FEV_1 MEASUREMENT



D. Calculating Excessive Variability for FEV_1

DEFINITION:

Using three acceptable spirograms, select the two with the largest FEV_1 and determine whether there is more than a **200 ml** difference between the two. [**Note (optional)**: reproducibility criteria have changed over the last 20 years: ATS-1994, 200 ml; ATS-1987 5% or 100 ml (whichever is greater); Cotton Dust-1979, 10% or 100 ml (whichever is greater). To determine "whichever is greater," if the difference is greater than 100 ml, then the percentage criterion should be used. If the difference is **not** greater than 100 ml, then the percentage criterion does not need to be used as the tracings do not have excessive variability.] Remember that acceptable tracings are free from error, as explained in **Unit Four: Spirometric Technique**, **Section E: Check the Acceptability and Reproducibility of the Test**.

HOW TO CALCULATE:

To find if the difference is greater than 200 ml (calculate Best FEV_1 - Second Best FEV_1):

1. Determine the FEV_1 for each of the tracings of an acceptable spirogram.

2. Subtract the second best FEV_1 from the first best FEV_1.

To find if the difference is excessive expressed in percentage (**OPTIONAL**):

1. Follow steps 1 and 2 above.

2. Proceed if the difference is greater than 200 ml (100 ml for Cotton Dust as well).

3. Divide the answer (the difference) by the volume of the largest FEV_1.

4. Multiply the answer by 100 to find the percentage of the difference, or:

$$\%\ Reproducibility = \frac{Best\ FEV_1 - Second\ Best\ FEV_1}{Best\ FEV_1} x100$$

EXAMPLE: (Figure 5-4. Volume Time Curve - FEV_1 Measurement.) Curve A (FEV_1 = 3.15 L.) and Curve B (FEV_1 = 2.92 L.) have the two largest FEV_1s.

3.15 - 2.92 = 0.23L

To express the reproducibility in a percentage (OPTIONAL):

0.23/3.15 = 0.073 and 0.073 x 100 = 7.3%

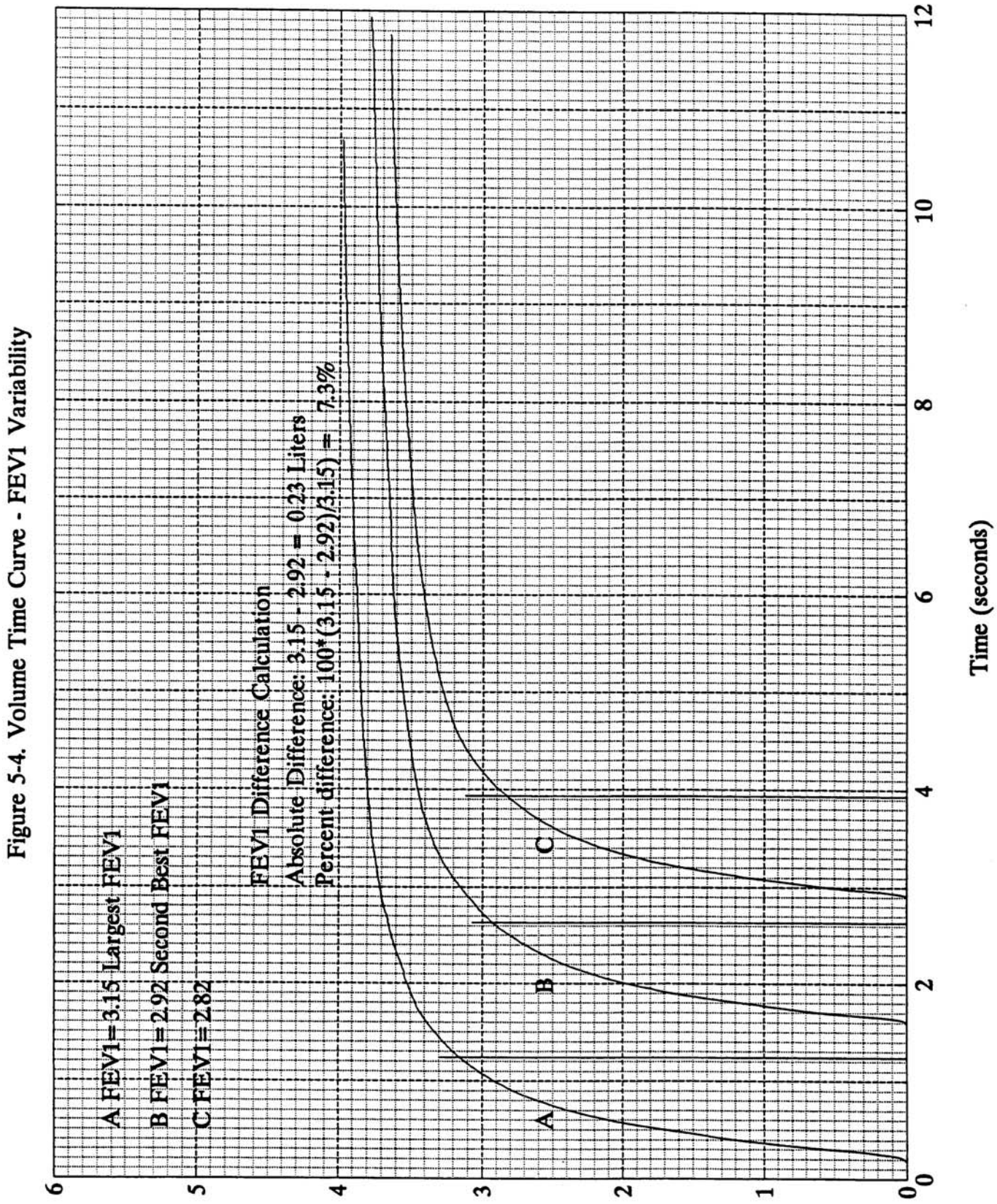
Since 230 ml is greater than 200 ml, there is excessive variability.

OPTIONAL: 7.3% is greater than 5% but less than 10%, therefore these tracings would not meet the ATS-1987 criterion but would meet the Cotton Dust criterion.

EXERCISE: Suppose that the largest FEV_1s in Figure 5-4 had come from curves B and C. Would there be excessive variability?

FEEDBACK: No, because 100 ml is less than 200 ml. **OPTIONAL**: These tracings would also meet the ATS-1987 and Cotton Dust criteria because 3.4% is less than 5%.

FIGURE 5-4. VOLUME TIME CURVE - FEV_1 VARIABILITY



EXERCISE: Three otherwise acceptable tracings had the following FEV_1s: A = 1.77 L., B = 1.71 L., C = 1.98 L. Would there be excessive variability between the two largest FEV_1s?

FEEDBACK: Yes, because 210 ml is greater than 200 ml. **OPTIONAL**: Since 210 ml is greater than 100 ml (ATS-1987 and Cotton Dust), the percentage criteria should be used. Since (0.21/1.98L = 10.6%), the FEV_1s for these tracings exhibit excessive variability using the ATS-1987 (5%) and the Cotton Dust (10%) reproducibility criteria.

POINTS TO REMEMBER:

1. 1 liter = 1000 milliliters (ml)

E. Back Extrapolation

DEFINITION:

The preferred method for determining zero time on a tracing when the exact starting point of a forced expiratory maneuver is not obvious. Since the FEV_1 is affected by the point on the graph that is selected as the start, a uniform way to determine this point must be used.

HOW TO CALCULATE AND EXAMPLE:

1. Using an otherwise acceptable tracing (see Figure 5-5), look at the FVC curve obtained and lay a straight edge along the steepest portion of the curve. (See Figure 5-6.)

2. With a sharpened pencil, draw a line along the straight edge and along the steepest portion of the curve, and extend the line to intersect the baseline. (See Figure 5-7.)

3. Where the straight line intersects the baseline is the new zero time to be used for calculating FEV_1. Mark the intersection t=0, and find the point on the baseline one second later and mark this t=1. (Note the distance for one second on your graph paper to measure t=1.) (See Figure 5-7.)

4. Proceed with the usual step for calculating FEV_1. (For the curve in Figure 5-7, the FEV_1 is 2.33 L.)

   NOTE: To see the significance of back extrapolation to the zero time point, mark the point at which the tracing actually leaves the baseline, and the point exactly one second later. As seen in Figure 5-8, the FEV_1 would have been 2.16 L. That is a sizeable difference.

FIGURE 5-5. VOLUME TIME CURVE
FEV_1 AND EXTRAPOLATED VOLUME (VEXT)

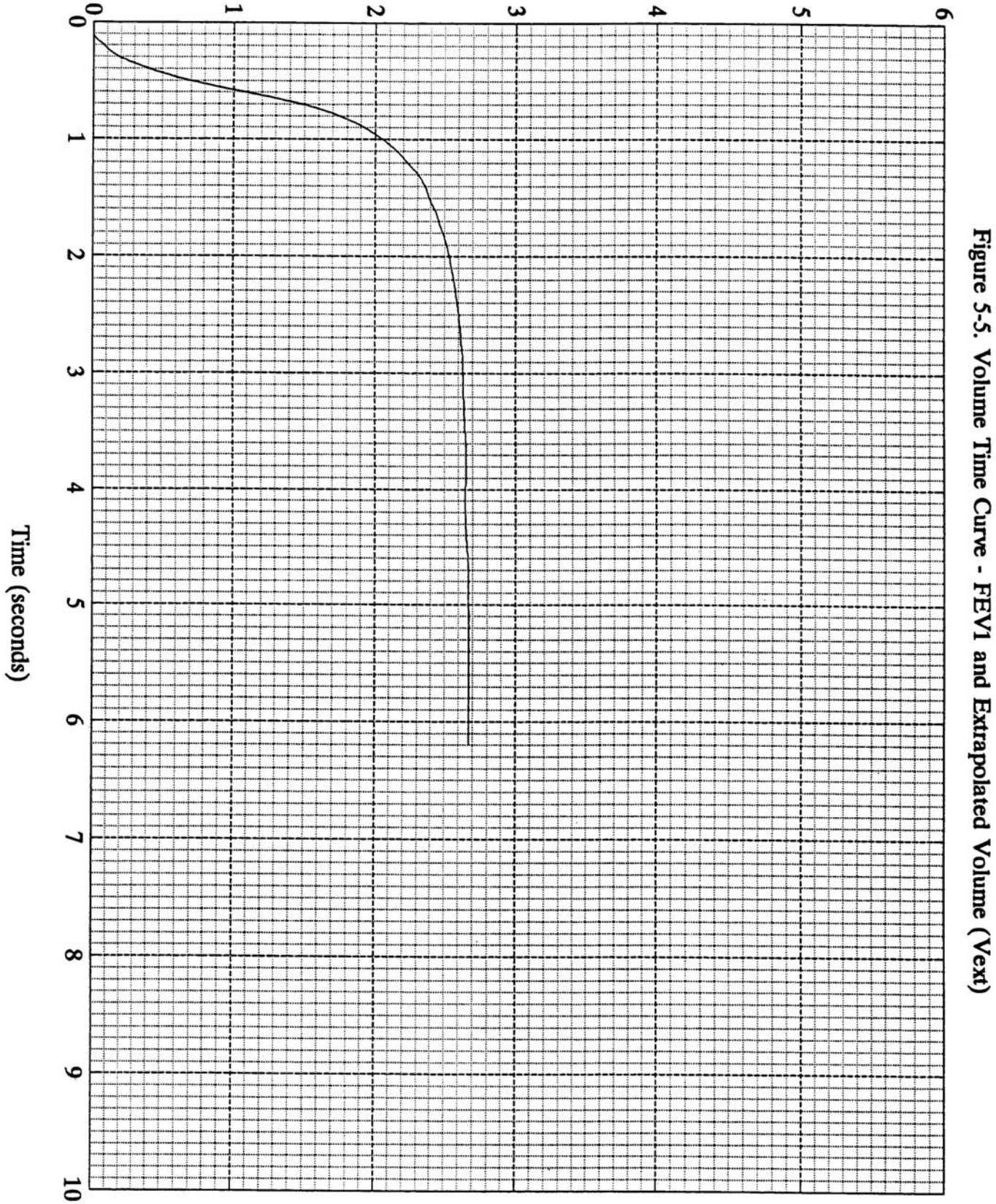


FIGURE 5-6. VOLUME TIME CURVE - DRAW LINE FOR TEXT

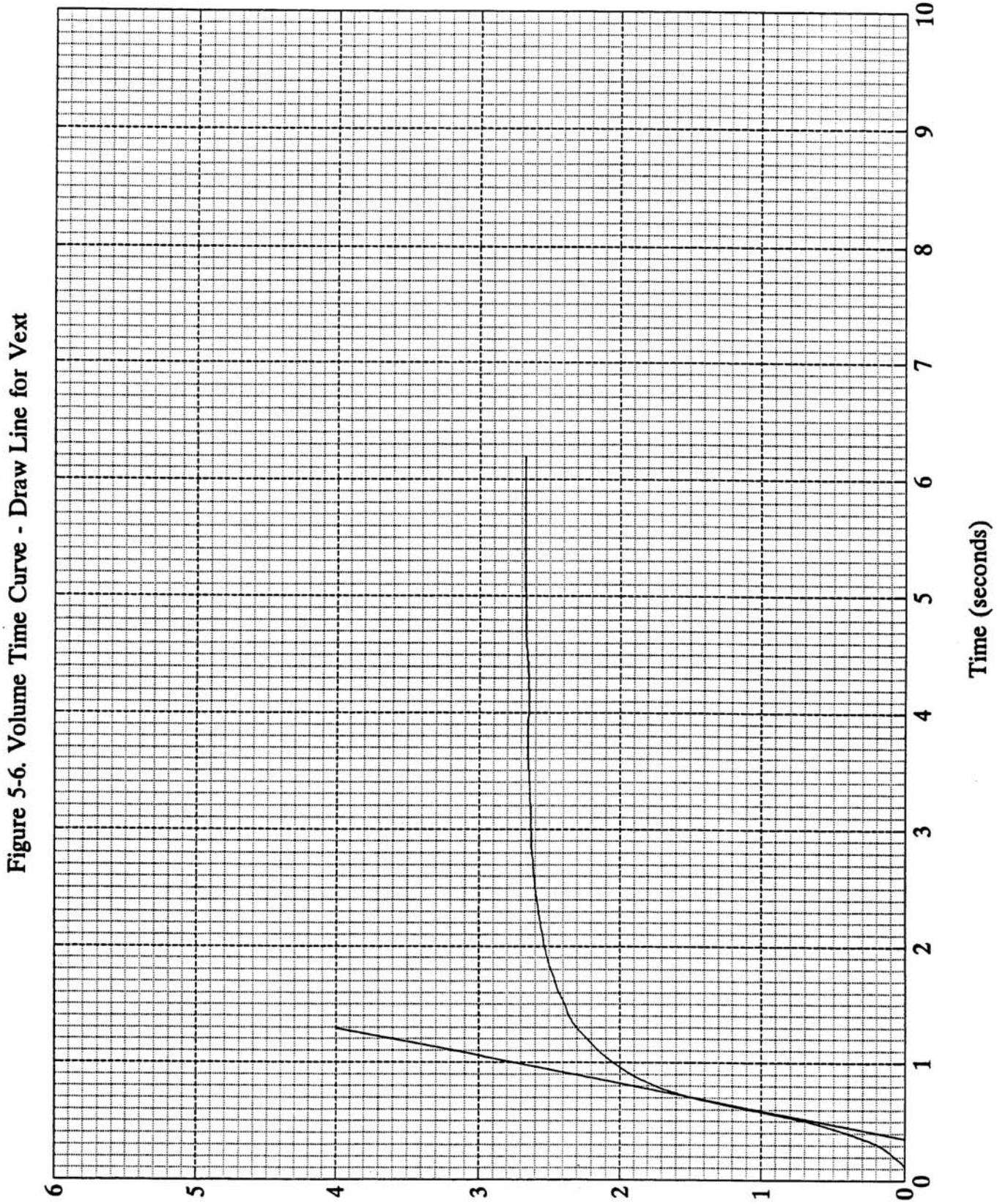


FIGURE 5-7. VOLUME TIME CURVE - MEASURE TIME ZERO AND FEV_1

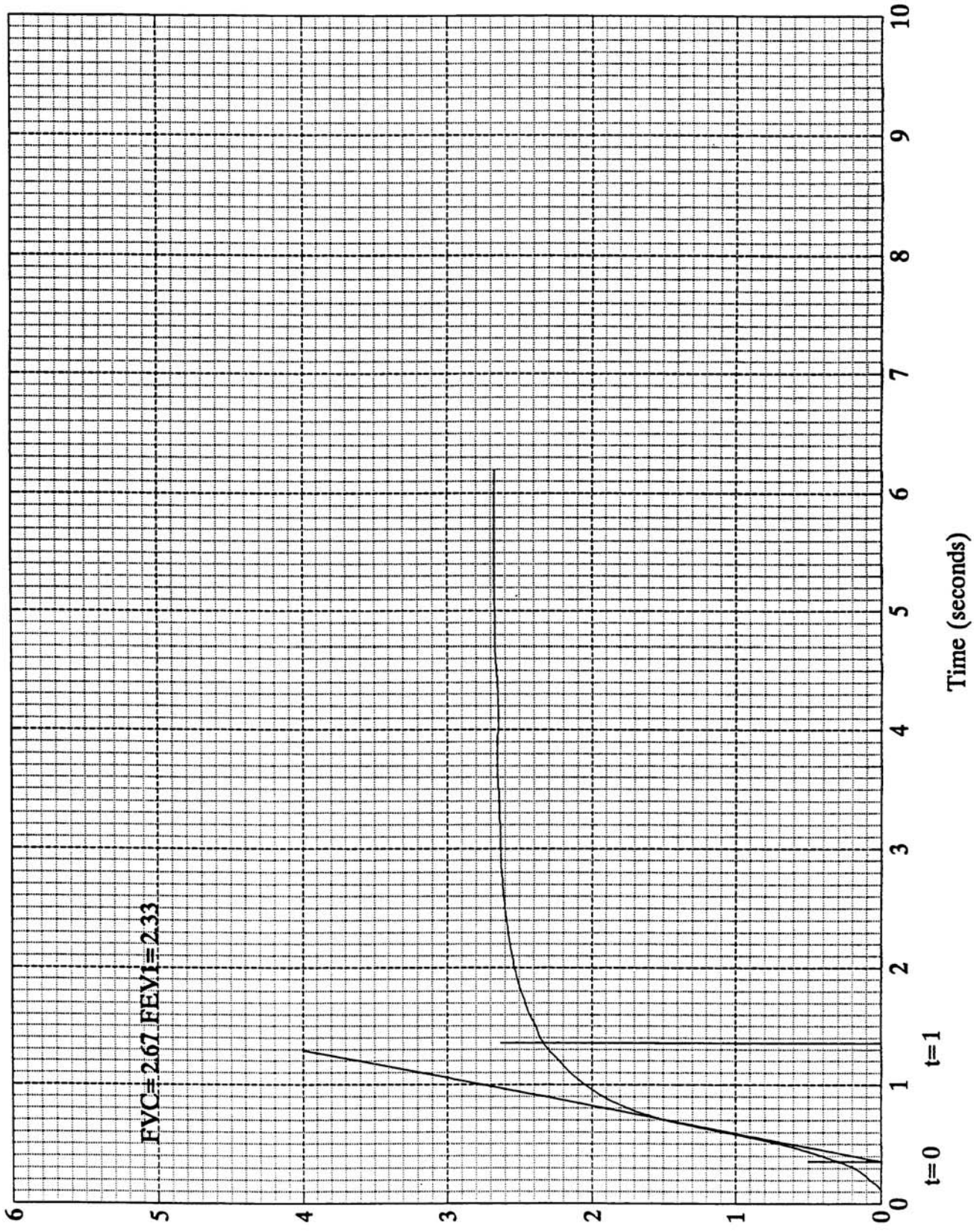
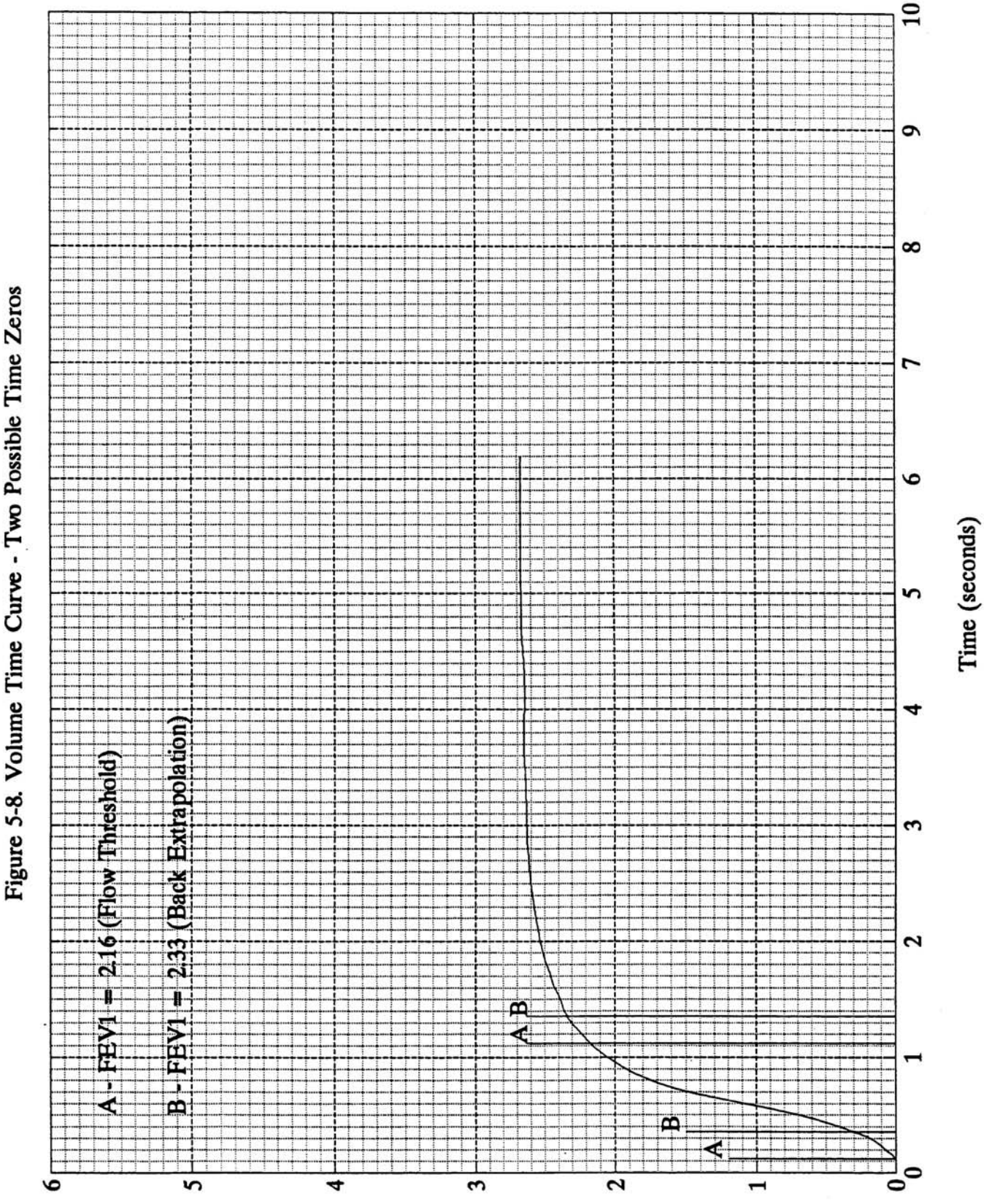


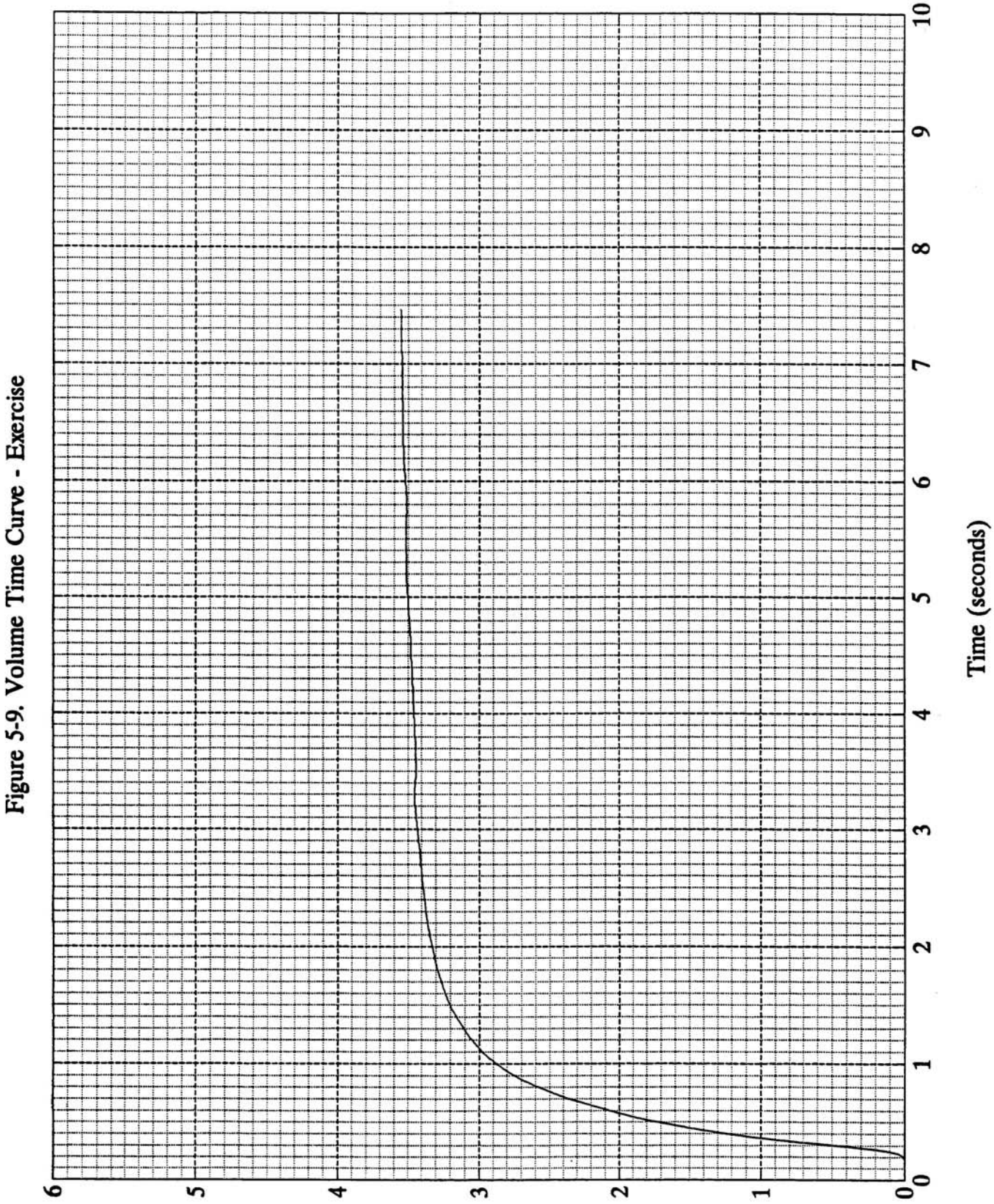
FIGURE 5-8. VOLUME TIME CURVE - TWO POSSIBLE TIME ZEROS



EXERCISE: Using the curve in Figure 5-9, calculate the FEV_1, using back extrapolation.

FEEDBACK: FEV_1 = 3.08 L.

FIGURE 5-9. VOLUME TIME CURVE – EXERCISE



EXERCISE: Using the curve in Figure 5-10, calculate the FEV_1, using back extrapolation.

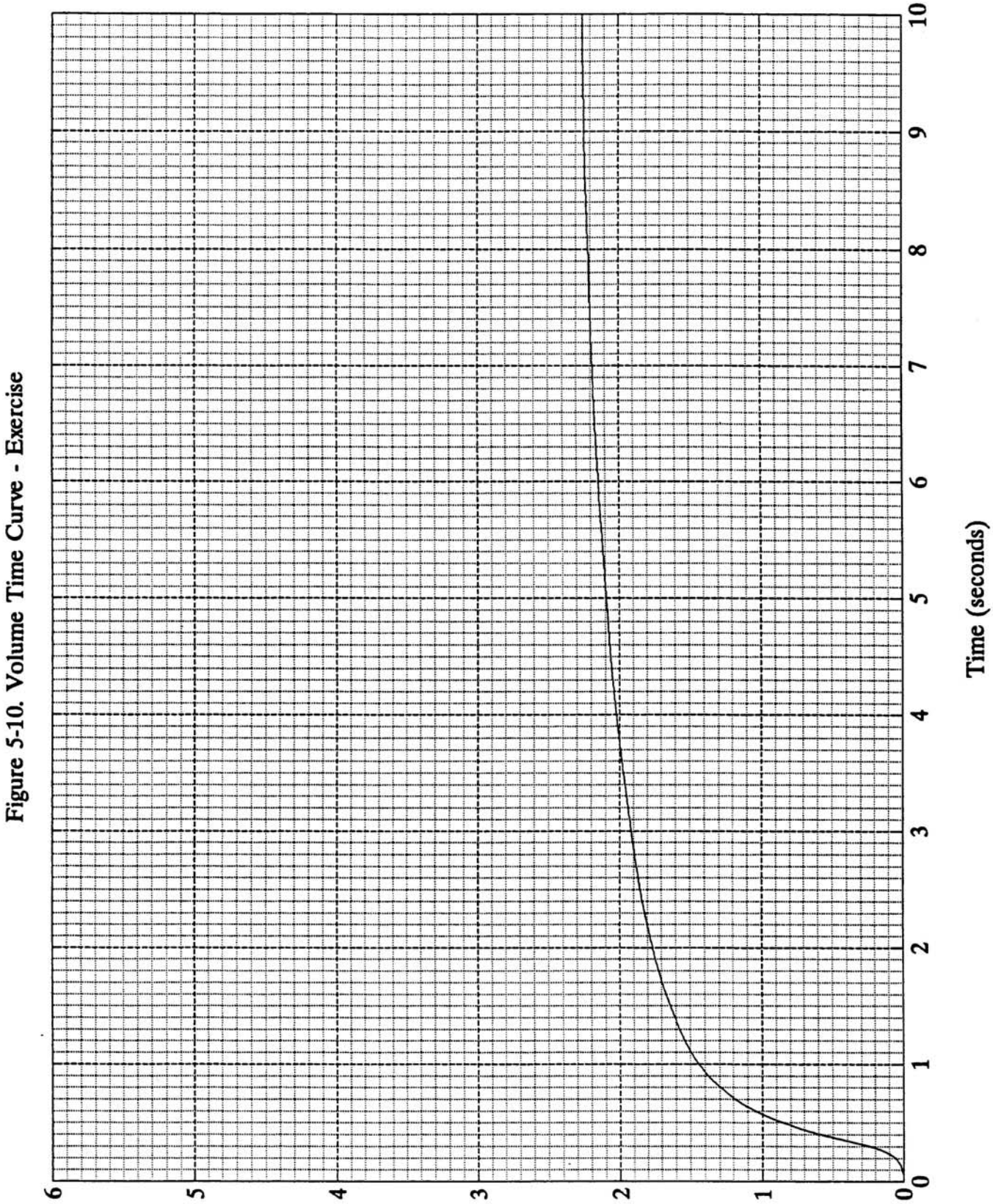
FEEDBACK: FEV_1 = 1.56 L.

POINTS TO REMEMBER:

1. The American Thoracic Society has identified the back extrapolation method as the most consistent and accepted technique for determining the zero point and has recommended its use for every calculation of the FEV_1. (1)

2. After using back extrapolation, extrapolated volume must be computed to determine the acceptability of the tracing for calculating the FEV_1. (See the next section for details.)

FIGURE 5-10. VOLUME TIME CURVE – EXERCISE



F. Calculating Excessive Extrapolated Volume

DEFINITION:

As described earlier, extrapolated volume is the volume exhaled before the timing of the maneuver has started -- "time zero". Extrapolated volume should not be greater than 5% of the FVC or 150 ml, whichever number is greater (1). Extrapolated volume is used to determine whether or not the tracing is acceptable to use for calculating FEV_1. Excessive extrapolated volume is a type of hesitation or false start and is one of the criteria for determining acceptability. Excessive hesitation can exhibit several different shapes -- two examples are given in Figures
5-11 and 5-12.

HOW TO CALCULATE AND EXAMPLE:

<u>To find if the extrapolated volume is greater than **150 ml** (use for FVCs that are 3 liters or less):</u>

1. Take the point at which t=0 was found by the back extrapolation method. (See Figure 5-13.)

2. Draw a vertical line through t=0 up to the FVC curve and read the volume at the intersection. This number is the extrapolated volume. (In Figure 5-13, the extrapolated volume is 0.175 L or 175 ml.)

3. Check to see that the extrapolated volume does not exceed 150 ml. (In Figure 5-13, the extrapolated volume of 175 ml exceeds 150 ml. Therefore this tracing would not be acceptable to use for calculating the FEV_1.)

<u>To find if the extrapolated volume is greater than 5% (use for FVCs greater than 3 liters):</u>

1. Follow steps 1 and 2 above. (In Figure 5-14, the extrapolated volume is 0.329 L. or 329 ml.)

2. Divide the extrapolated volume by the FVC. (In Figure 5-14, the FVC is 3.34 L.; .329/3.34 = .0985.)

3. Multiply the answer by 100 to find the percentage of the difference. (In Figure 5-14, 0.0985 x 100 = 9.9%. Clearly there is excessive extrapolated volume and this would not be an acceptable tracing.)

4. (Optional) Another way to determine if the extrapolated volume is greater than 5%, is to multiply the FVC by 0.05 and check that the extrapolated volume in liters does not exceed this amount. (In Figure 5-14, the FVC is 3.34 L. 0.05 x 3.34 = 0.167 liters. Since the extrapolated volume is 0.329 liters, this is not an acceptable tracing.)

FIGURE 5-11. EXAMPLE OF EXTRAPOLATED VOLUME

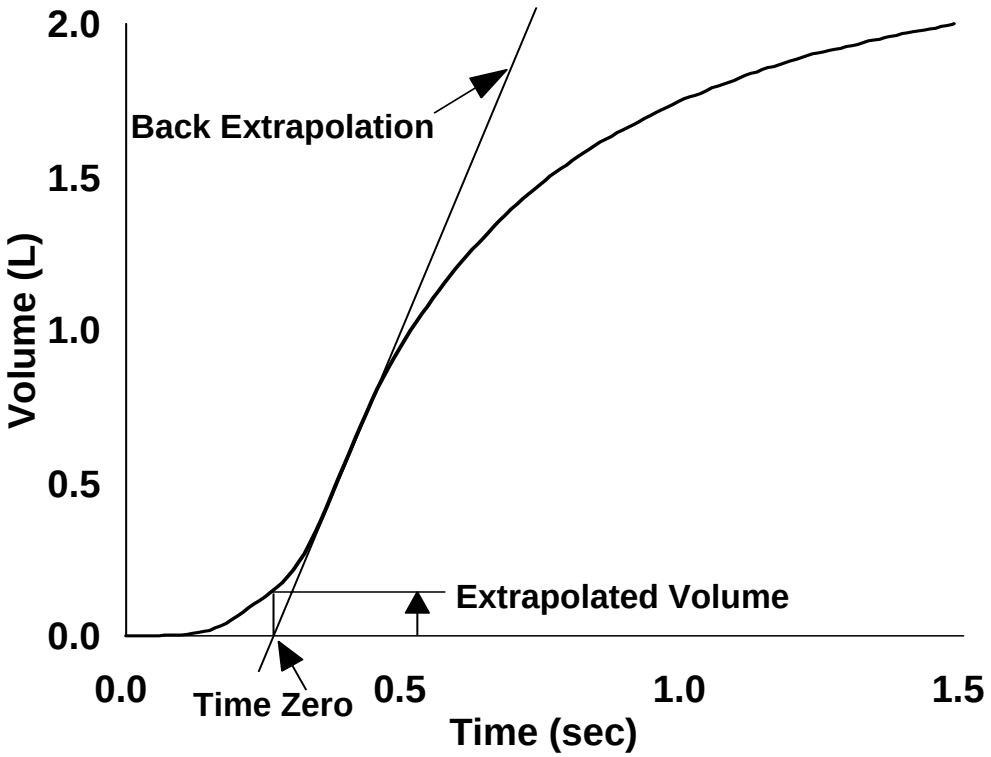


FIGURE 5-12. EXAMPLE OF EXTRAPOLATED VOLUME

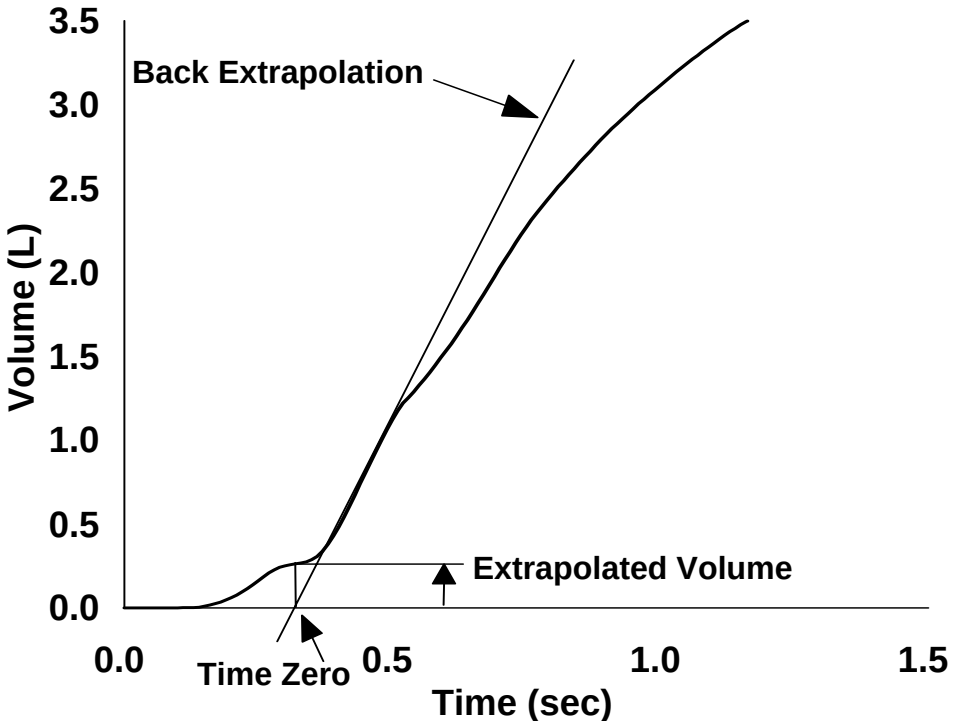


FIGURE 5-13. VOLUME TIME CURVE
MEASURE EXTRAPOLATED VOLUME (VEXT)

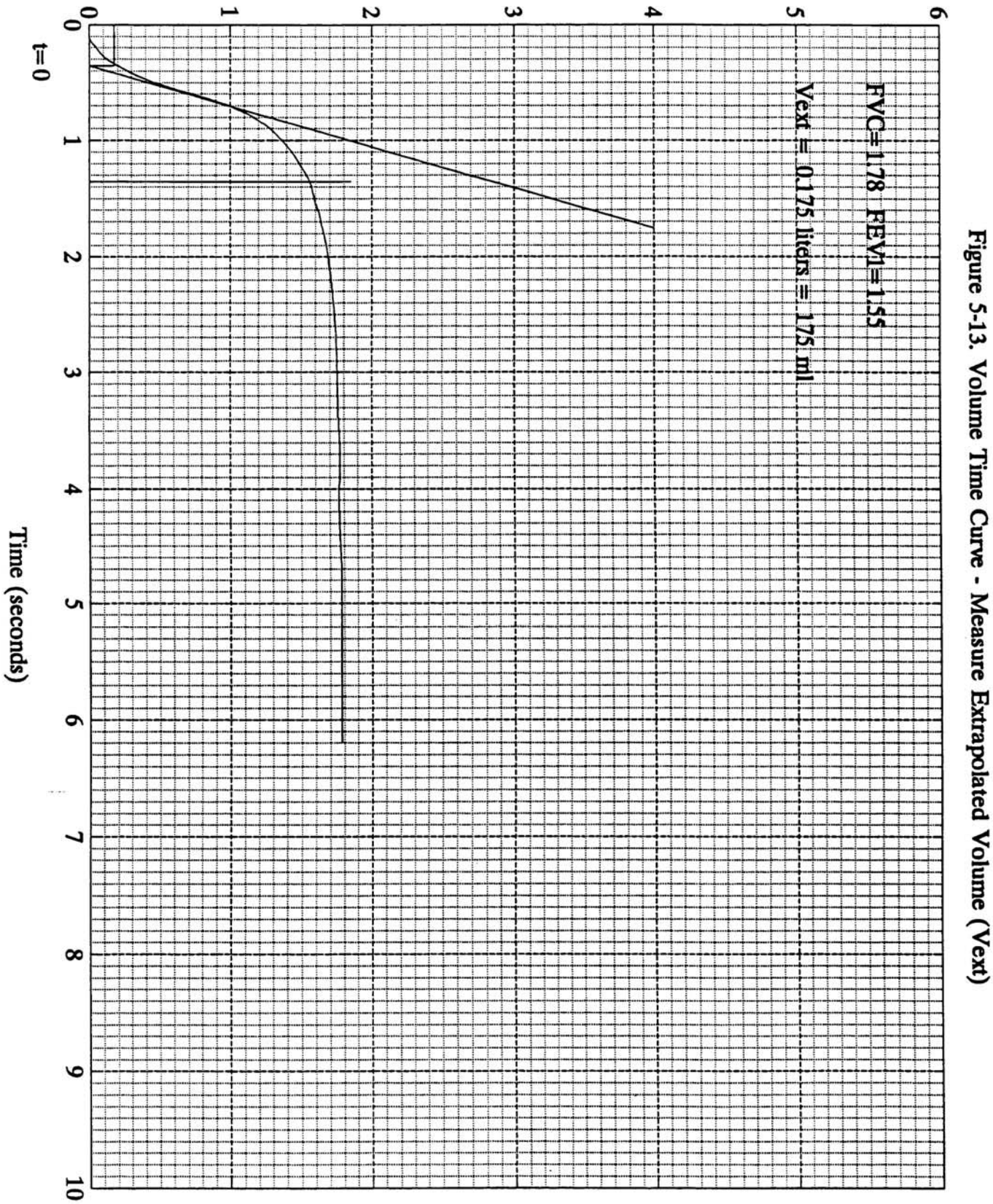
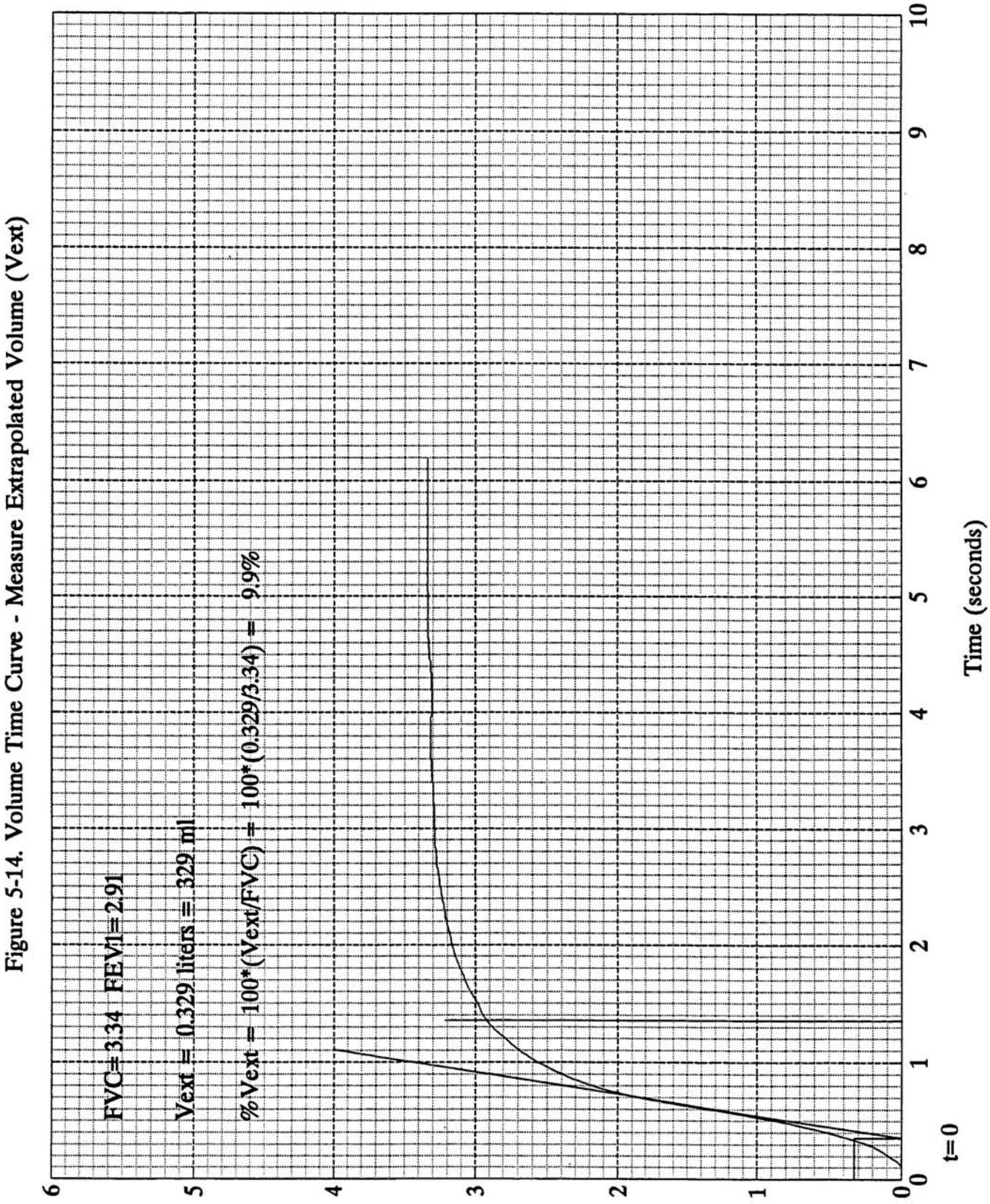


FIGURE 5-14. VOLUME TIME CURVE
MEASURE EXTRAPOLATED VOLUME (VEXT)



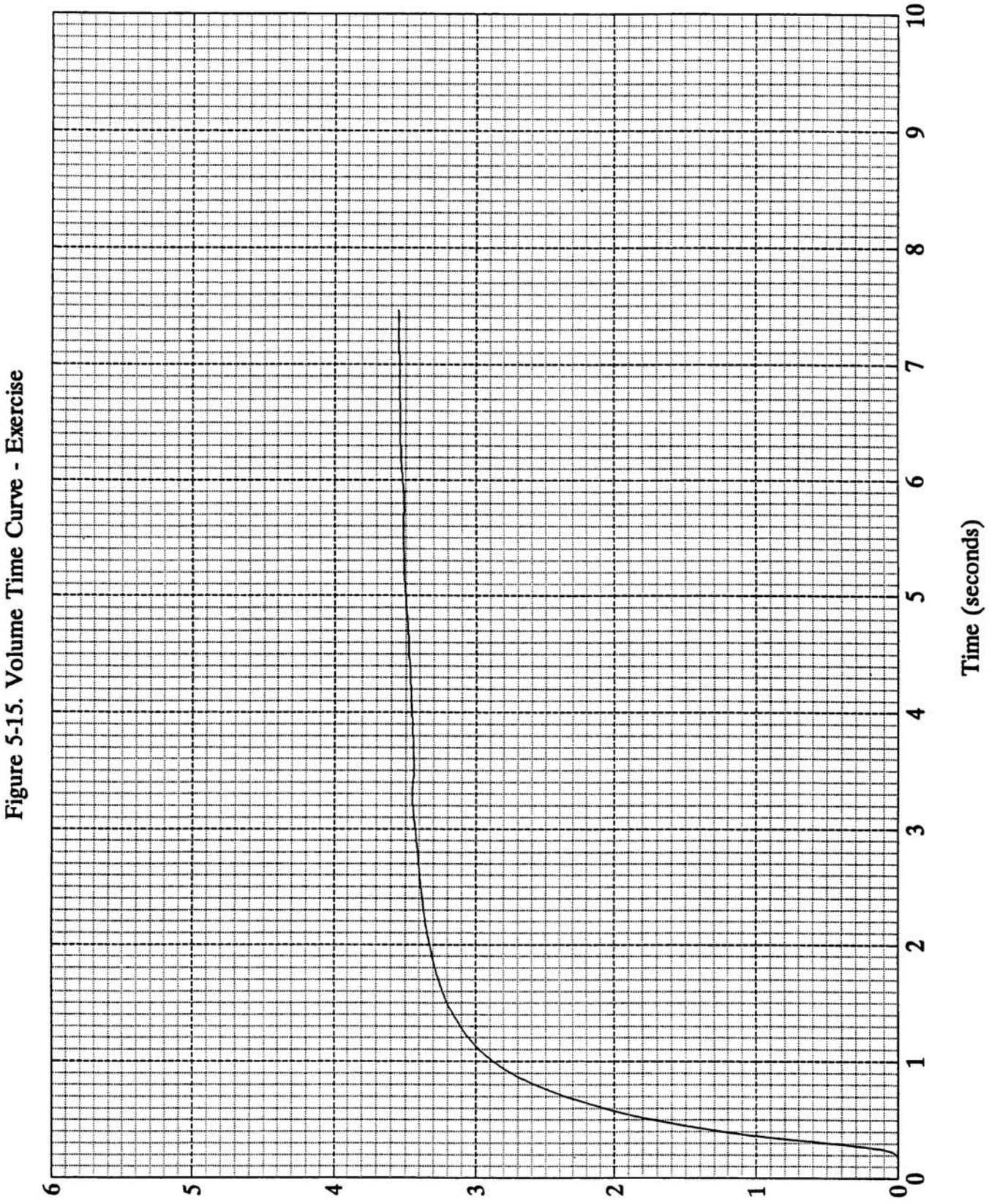
EXERCISE: Using the curve in Figure 5-15 (which is the same as Figure 5-9), determine whether there is excessive extrapolated volume.

FEEDBACK: No excessive extrapolated volume. Extrapolated volume = 0.07 L.

FVC = 3.55 L.

(0.07/3.55) 100 = 2%

FIGURE 5-15. VOLUME TIME CURVE – EXERCISE



EXERCISE: Using the curve in Figure 5-16 (which is the same as Figure 5-10), determine whether there is excessive extrapolated volume.

FEEDBACK: Excessive extrapolated volume. Extrapolated volume = 0.13 L.

FVC = 2.25 L.

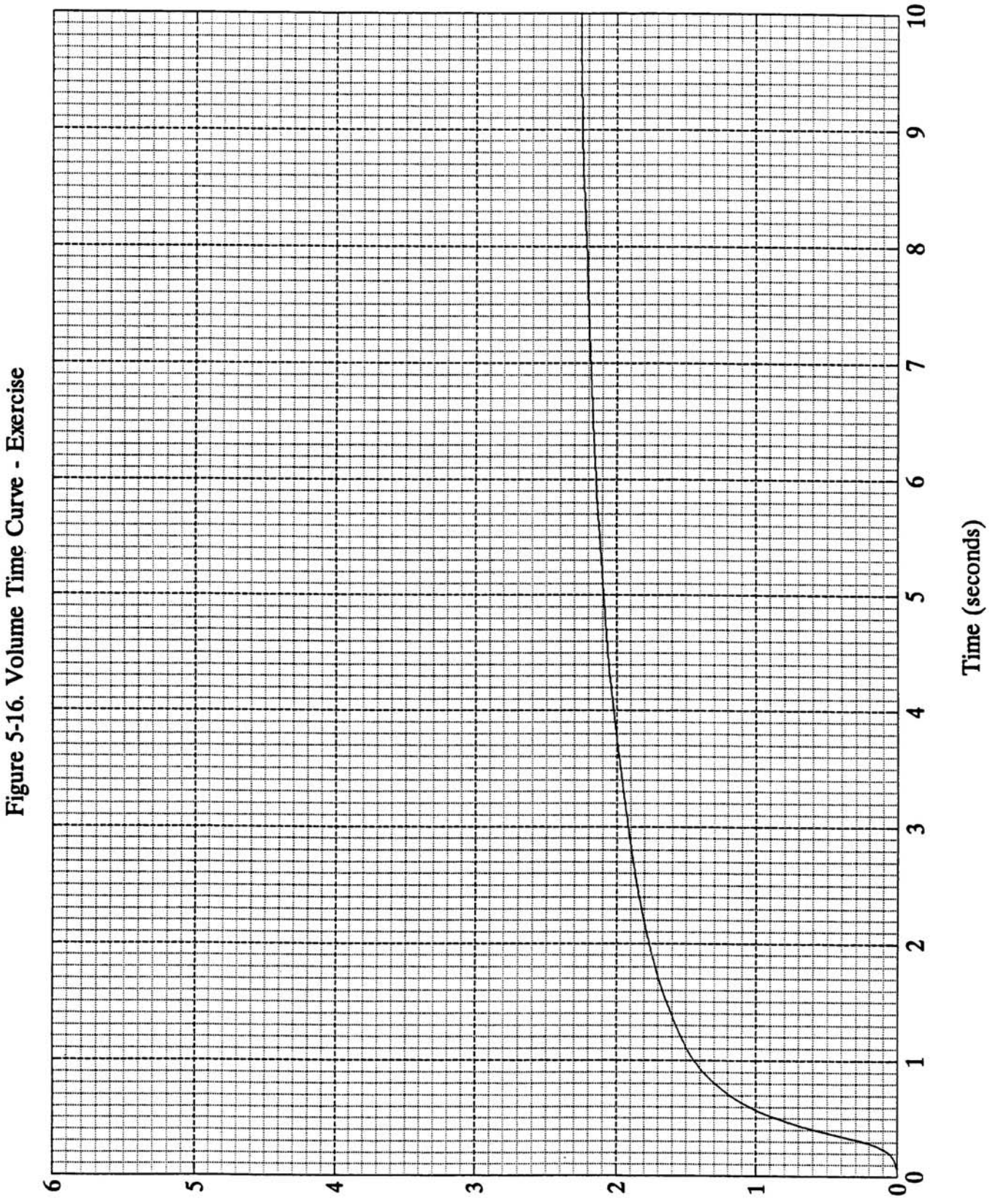
(0.13/2.25) 100 = 5.7%

POINTS TO REMEMBER:

1. 1 liter = 1000 milliliters (ml)

2. Use 150 ml for FVCs of 3 liters or less. Use 5% for FVCs greater than 3 liters.

FIGURE 5-16. VOLUME TIME CURVE – EXERCISE



G. FEV_1 as a Percentage of FVC (FEV_1/FVC)

DEFINITION:

The percent of the total observed FVC that is exhaled in the first second (FEV_1). This calculation is useful for detecting obstructive disease. A person with healthy lungs can exhale 70-80% of the FVC in the first second, while a person with airways obstruction may be able to exhale 60% or less of the FVC in the first second.

HOW TO CALCULATE:

1. Calculate the largest acceptable FVC and FEV_1, even if they are not from the same tracing.

2. Divide the FEV_1 by the FVC.

3. Multiply the answer by 100 to obtain the percentage.

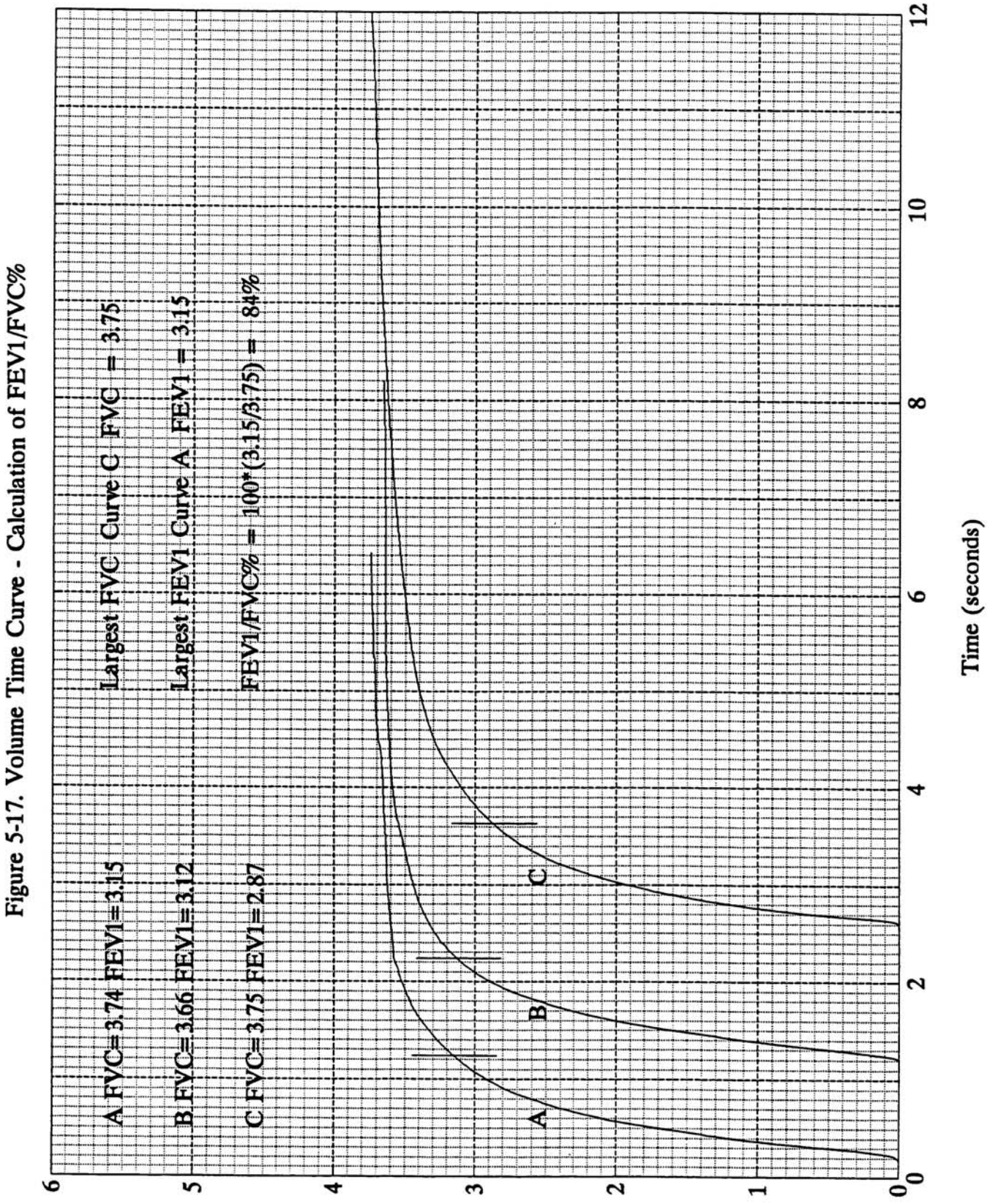
EXAMPLE: (See Figure 5-17. Volume Time Curve - Calculation of FEV_1/FVC%):

The largest acceptable FVC is 3.75 L. (from Curve C).

The largest acceptable FEV_1 is 3.15 L. (from Curve A).

(3.15/3.75) x 100 = 84%

FIGURE 5-17. VOLUME TIME CURVE - CALCULATION OF FEV_1/FVC%



EXERCISE: Using the information in Figure 5-18, calculate the FEV_1/FVC%. Before doing so, check to be sure that reproducibility criteria are met for the FVC and the FEV_1.

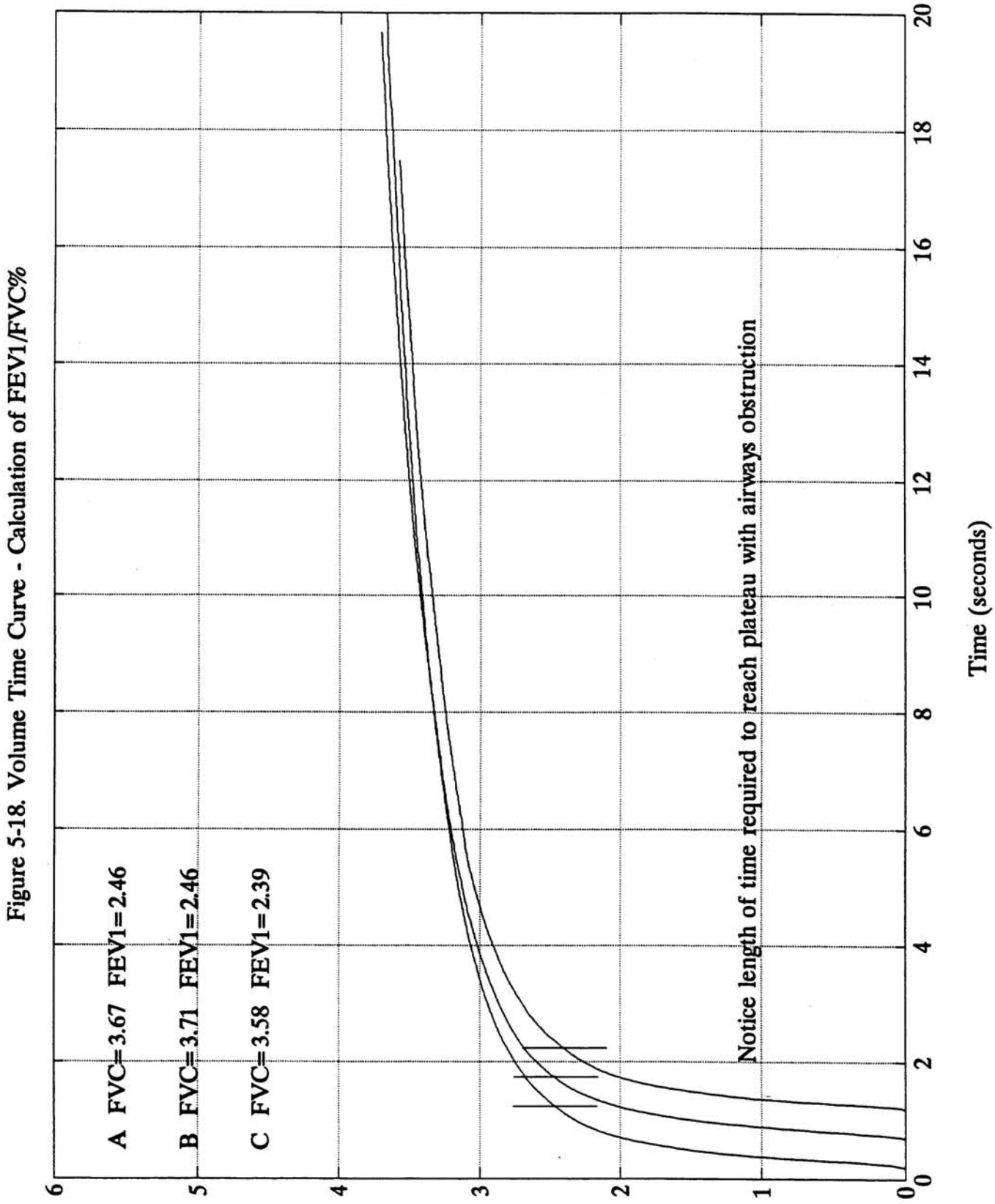
It should be noted that a larger paper size would have been needed to use a time scale meeting ATS standards. (See **Unit Eight: Overview of Standards for Spirometric Equipment.**) However, larger paper was not possible to use in this guide due to reproduction constraints. These curves were included as a reminder that many individuals, especially those with obstructive patterns, need longer than 10 seconds to complete a forced expiratory maneuver.

FEEDBACK: FVC variability = 1.1%

FEV_1 variability = 0

FEV_1/FVC% = 66.3%

FIGURE 5-18. VOLUME TIME CURVE - CALCULATION OF FEV_1/FVC%



EXERCISE: Three acceptable and reproducible curves yielded the following results:

Curve A: FVC = 3.65 L.
FEV_1 = 3.01 L.

Curve B: FVC = 3.52 L.
FEV_1 = 3.01 L.

Curve C: FVC = 3.53 L.
FEV_1 = 3.07 L.

Calculate the FEV_1/FVC%

FEEDBACK: 84.1%

Did you remember to use the largest FEV_1 and FVC, regardless of which curve?

POINTS TO REMEMBER:

1. The percentage is given rounded to one decimal place (e.g., 85.4%).

2. The FEV_1 and the FVC may come from different tracings for this calculation.

H. Forced Mid -Expiratory Flow ($FEF_{25-75\%}$) (OPTIONAL)

DEFINITION:

The mean forced expiratory flow during the middle half of the FVC (previously known as the mid-expiratory flow rate or MMEF). Although it may be more sensitive than the FEV_1, it has considerably more variability than the FVC and FEV_1. Therefore, the ATS (1) recommends that the $FEF_{25-75\%}$ only be considered after determining the presence and clinical severity of impairment and should not be used to diagnose disease in individual patients.

HOW TO CALCULATE AND EXAMPLE:

1. Using an acceptable tracing, identify the "best curve", the one with the largest sum of the FEV_1 and the FVC. In most cases, the best curve will have the largest FVC. To do this, for each curve, add together the FEV_1 and the FVC. (See Figure 5-19. In this case, the best curve is curve A.)

2. Using the best curve, calculate 25% and 75% of the FVC curve.
   25% of FVC = 0.25 x FVC
   75% of FVC = 0.75 x FVC
   Note: The FVC is given in liters, therefore the answers will also be in liters.
   (For curve A, 25% of the FVC is 0.94 L. and 75% is 2.81 L.)

3. Mark the answers on the FVC curve. (See Figure 5-20.)

4. Having found the two points which represent 25% and 75% of FVC, draw a straight line through them. (See the line drawn through these points for Figure 5-20.)

5. This line should intersect some of the time bars on the graph paper. To do the next calculation, use any two adjacent time bars that are one second apart and intersect the line that you have drawn. Read off the volumes for each of these time bars at the point where they intersect the line. (See Figure 5-20, Point A (1.70) and Point B (5.05). Other points could have been selected on the line, as long as they were 1 second apart.)

6. Find the difference between these two volumes. Subtract the volume at the 1st time bar intersection from the volume at the 2nd time bar intersection to get the difference.) (See Figure 5-20. 5.05 - 1.70 = 3.35 L.

7. Convert the answer to BTPS. For instructions, see the next section.

8. The answer is given in liters per second. This is because you have calculated a change in volume over a one second interval.

FIGURE 5-19. VOLUME TIME CURVE - $FEF_{25-75\%}$ BEST CURVE

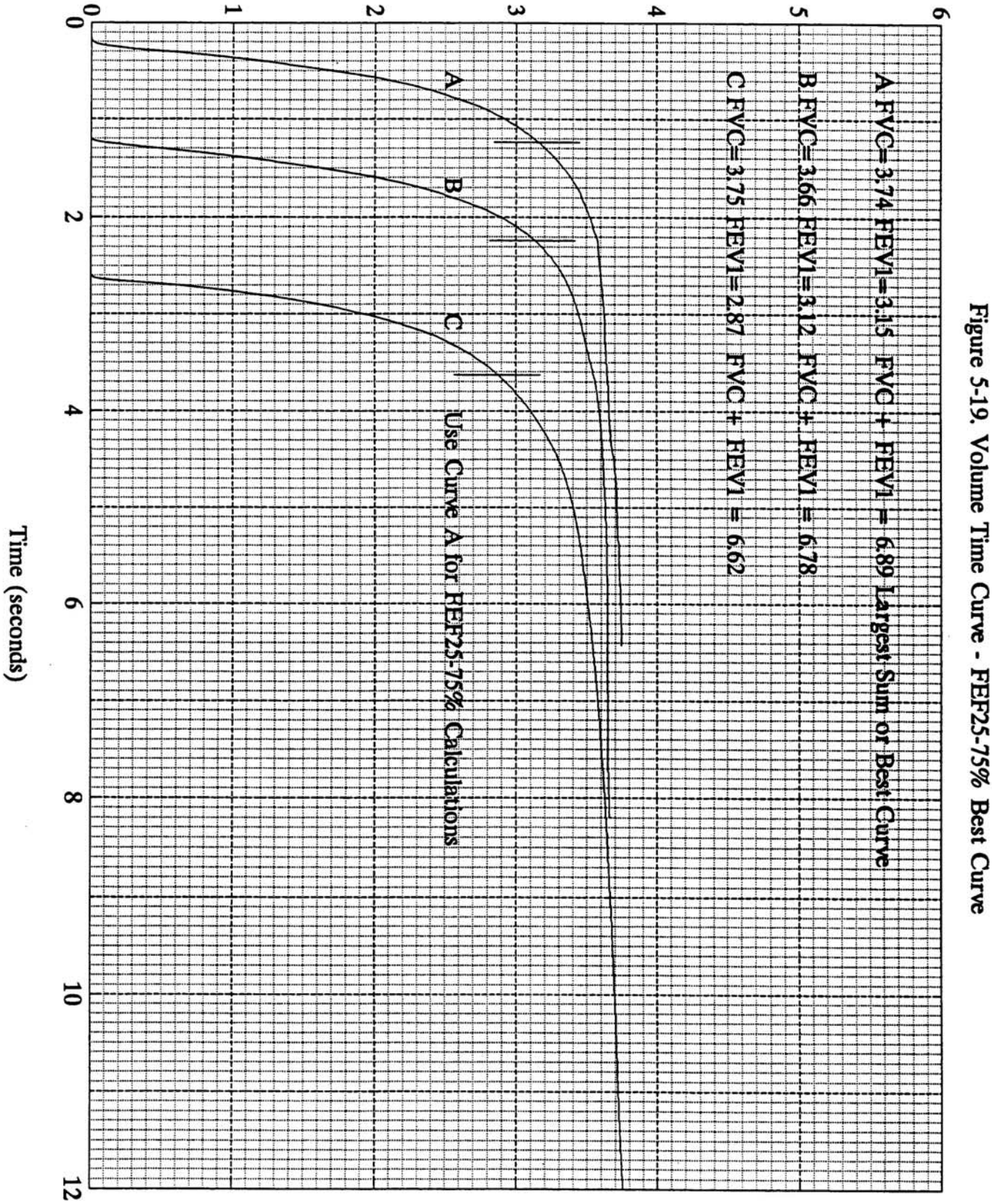
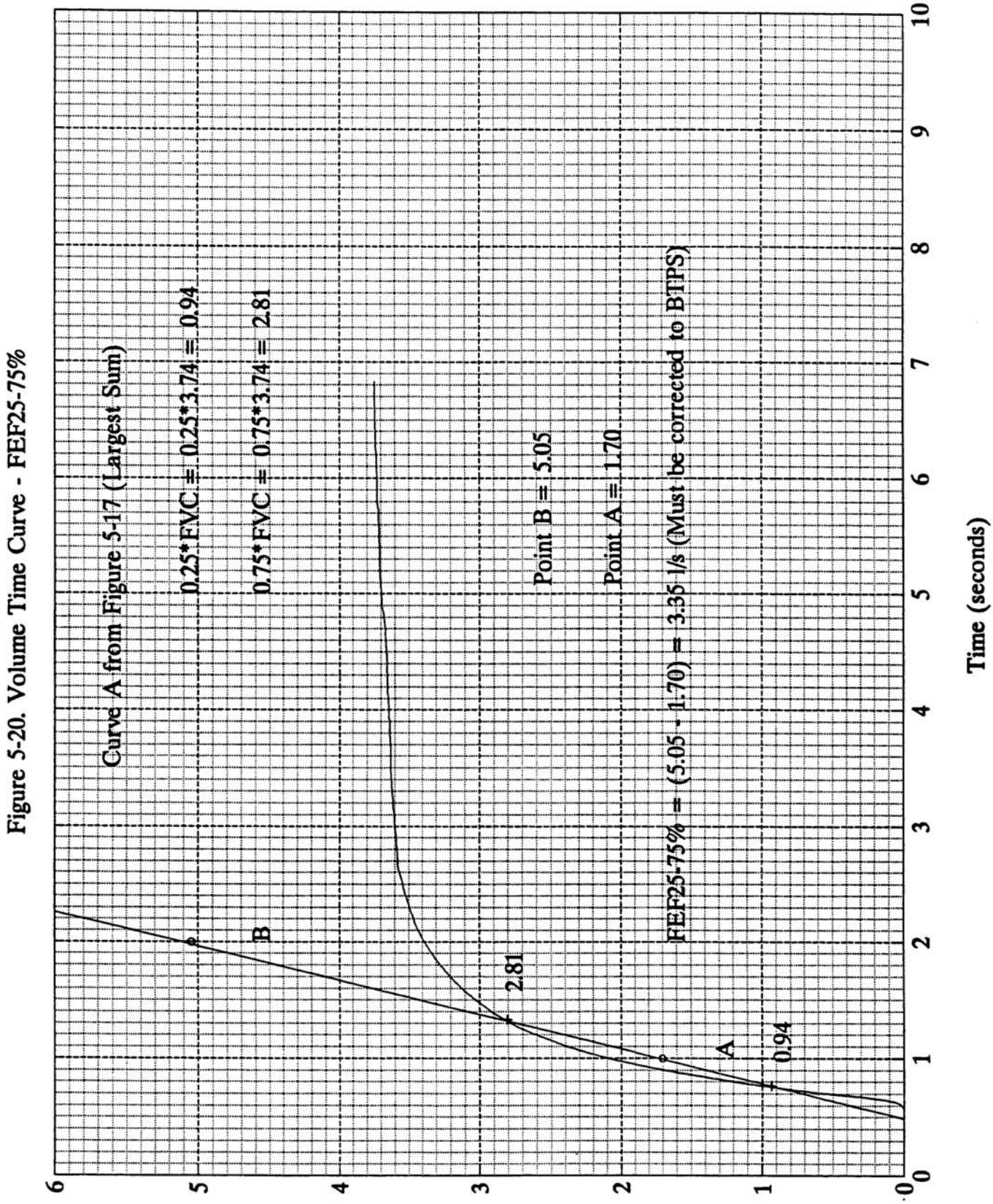


FIGURE 5-20. VOLUME TIME CURVE - $FEF_{25-75\%}$

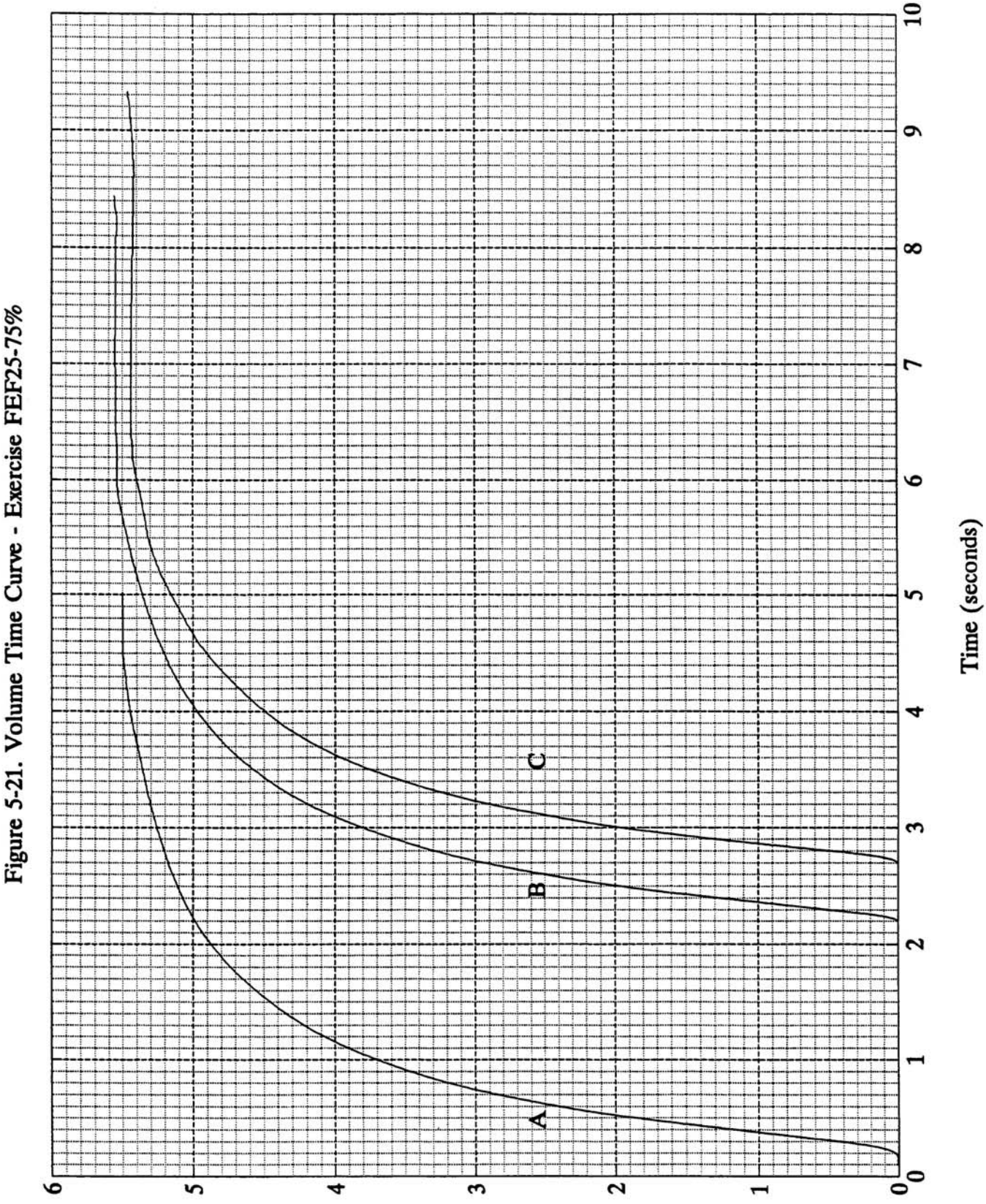


EXERCISE: Using the curves in Figure 5-21, identify the best curve (the best curve is defined as that which has the largest sum of FEV_1 and FVC).

FEEDBACK:

Curve B is the best curve.
FEV_1 = 4.22 L FVC = 5.55 L
Total of FEV_1 + FVC = 4.22 L + 5.55 L = 9.77 L

FIGURE 5-21. VOLUME TIME CURVE - $FEF_{25-75\%}$



EXERCISE: Using the curve in Figure 5-22, calculate the $FEF_{25-75\%}$.

FEEDBACK: The $FEF_{25-75\%}$ = 3.75 L/sec.

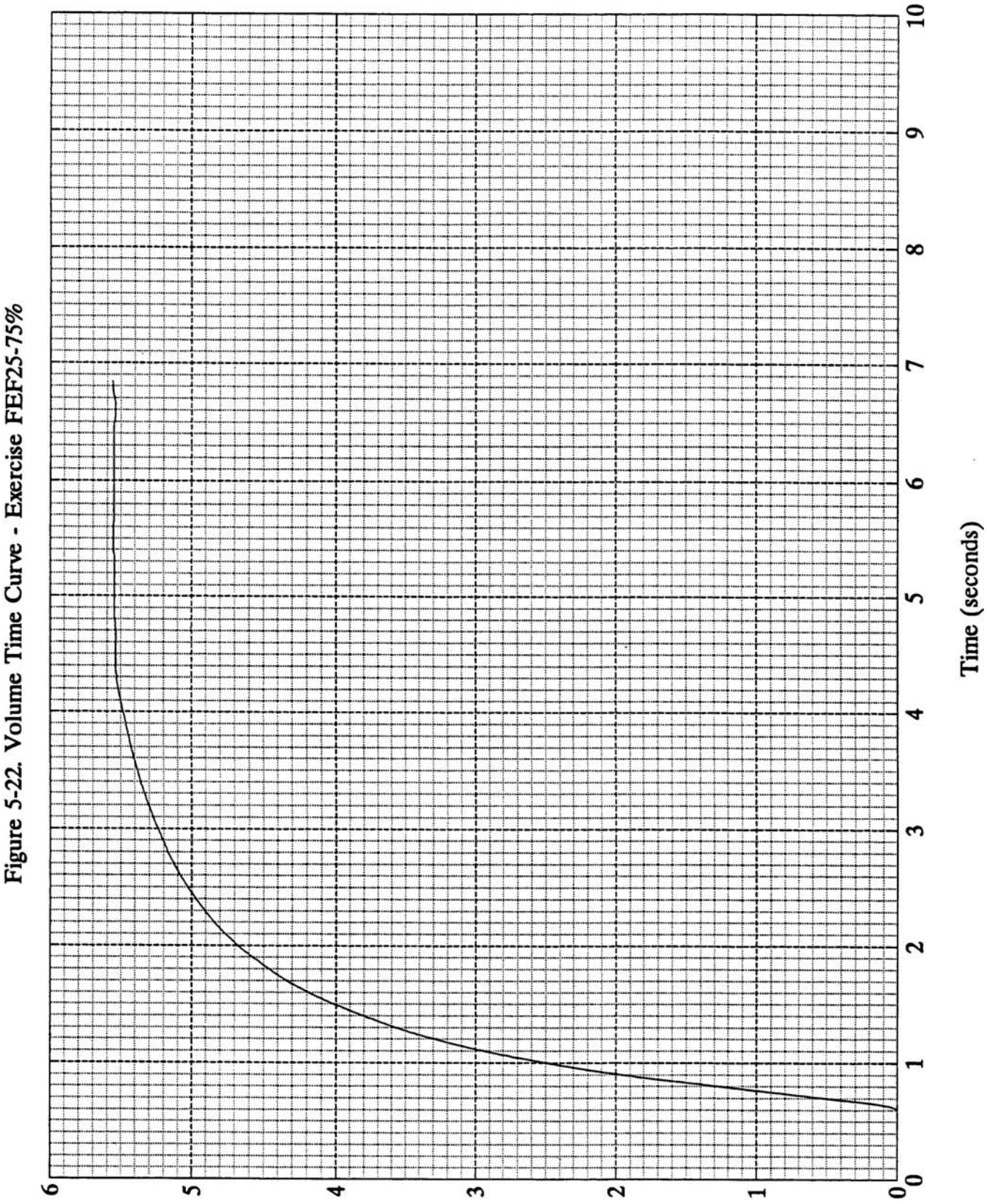
25% of the FVC (5.55 L) = 1.39 L
75% of the FVC (5.55 L) = 4.16 L

Draw a straight line at any 2 adjacent time lines and read the volumes at the intersection of the slope and 2 adjacent time lines (5.60 L and 1.85 L). Calculate the difference between these 2 numbers (5.65 L - 1.85 L = 3.75 L/sec.)

POINTS TO REMEMBER:

A number of problems have precluded widespread use of the $FEF_{25-75\%}$ in industrial screening programs. Although less dependent on voluntary effort than FEV_1, the $FEF_{25-75\%}$ is also less reproducible. The amount of variability in the same person may be as great as 20%, compared with 3% for the FEV_1. Isolated abnormalities in the $FEF_{25-75\%}$ are relatively common, particularly in asymptomatic asthmatics and young cigarette smokers. Hence, there is a danger that an abnormal $FEF_{25-75\%}$ may become reason for employment rejection or job transfer in such individuals. Although clearly not justifiable, such misapplication of screening data occurs all too frequently in the occupational setting (6). To prevent this from happening, the $FEF_{25-75\%}$ should only be interpreted by a physician experienced in its use.

FIGURE 5-22. VOLUME TIME CURVE - $FEF_{25-75\%}$



I. Conversion to BTPS

DEFINITION:

Gas (air) at:

...Body Temperature (37°C)
...Ambient Pressure (surrounding air pressure)
...Saturated with water vapor (relative humidity = 100% as is the case in the lungs).

Air is at body temperature in the lungs and is saturated with water vapor. The ambient temperature is usually much cooler and dryer, thus exhaled air contracts as it leaves the lungs and enters a spirometer. The volume of air as recorded by most spirometers is usually 6-10% less than the actual volume of air exhaled by the test subject. The BTPS correction adjusts the measured result obtained in the spirometer to what the volume originally was in the lungs. In most volume spirometers, recorded volumes that have not been converted are indicated as **ATPS** (ambient temperature and pressure saturated with water vapor).

Spirometric Tests Requiring Conversion to BTPS:

1. FVC, FEV_1, and $FEF_{25-75\%}$ all represent volumes (or volumes per unit of time). Therefore these tests must be converted to BTPS.

2. FEV_1/FVC (%) is a ratio of volumes. It does not have to be converted to BTPS since the same conversion factor would appear in both the numerator and the denominator and therefore it would cancel out.

HOW TO CALCULATE:

1. Convert the ambient, room air, or spirometer temperature to Centigrade if needed.

$$^{o}C = \frac{5\,(^{o}F - 32)}{9}$$

2. Locate the ambient, room, or spirometer temperature on the **BTPS Conversion Chart**.

3. Look across the table to find the corresponding conversion factor.

4. Multiply the volume of gas recorded by the spirometer (FVC, FEV_1, or $FEF_{25-75\%}$) by the correct conversion factor to obtain the volume at BTPS.

BTPS CONVERSION CHART

FACTORS FOR CONVERTING VOLUMES FROM AMBIENT OR SPIROMETER TEMPERATURE TO BTPS

Gas Temperature °F	°C	Conversion Factor
64	18	1.114
66	**19**	**1.111**
68	20	1.102
70	**21**	**1.096**
72	22	1.091
73	**23**	**1.085**
75	24	1.080
77	**25**	**1.075**
79	26	1.068
81	**27**	**1.063**
82	28	1.057
84	**29**	**1.051**
86	30	1.045
88	**31**	**1.039**
90	32	1.032
91	**33**	**1.026**
93	34	1.020
95	**35**	**1.014**
97	36	1.007
99	**37**	**1.000**

EXAMPLE: A subject's FVC as recorded by the spirometer reads 5 liters (volume of gas) at an ambient temperature of 21°C (ATPS).

The conversion factor that corresponds to 21°C is 1.096.

5 liters x 1.096 = 5.48 liters BTPS.

Therefore, the recorded FVC of 5 liters at 21° C (ATPS), actually represents a volume of 5.48 liters (BTPS) in the subject's lungs at body temperature.

EXERCISES: Convert the following data for several individuals from ATPS to BTPS:

FVC = 6.71 L. (ambient temperature = 75°F)

FEV_1 = 5.02 L. (ambient temperature = 26°C)

$FEF_{25\text{-}75\%}$ = 4.01 L/s (ambient temperature = 82°F)

FEEDBACK: FVC = 7.25 L. BTPS

FEV_1 = 5.36 L. BTPS

$FEF_{25\text{-}75\%}$ = 4.24 L/s BTPS

POINTS TO REMEMBER:

1. <u>Temperature:</u> ATS makes the following recommendations:

   a. Ambient temperature should be accurately recorded to within 1°C.

   b. Spirometric testing should only be done with ambient temperatures between 17°-40°C.

c. Recent studies have shown that at ambient temperatures lower than 23°C, the BTPS correction factor may cause errors in FEV_1 readings when using volume spirometers. BTPS factors are based on the assumption that the subject's exhaled breath cools immediately upon entering the spirometer. However, it has been found that expired breath takes longer than previously thought to reach equilibrium with the ambient temperature. Therefore, the BTPS correction factor falsely raises the FEV_1 and peak flow, and as the ambient temperature drops, the rate of error increases. For example, Hankinson and Viola found an error range from 7.7% at 3°C to 2.1% at 23°C for FEV_1 and 14.1% at 3°C to 4.6% at 23°C for peak flow (27). FVC readings typically are not affected because the exhaled breath usually reaches equilibrium by the time the forced expiratory maneuver is completed.

The BTPS error caused by low ambient temperature is of concern during longitudinal and pre- and post-shift studies. If testing is done at different temperatures, statistically significant changes in the FEV_1 and peak flow could be caused by ambient temperature alone.

"For example, during a recent study at a cotton-processing facility, the temperature was 10 ℃ during the pre-shift examinations. After 6 h of exposure, the spirometric examinations were repeated on the same subjects. However, the ambient temperature after the work shift was approximately 25 or 15 ℃ higher.

Upon analysis of these data, an average decrease in FEV_1 of approximately 4% over the work shift was observed. Not only was a decrease observed for the exposed workers but also for the technicians who were conducting the examinations. This decrease was thought to be explained by the increase in ambient temperature over the work shift. With low temperatures, the BTPS correction factor was falsely elevated, resulting in falsely elevated FEV_1s. After the work shift, the FEV_1s were less in error because of a higher temperature, and therefore statistically significant drops over the work shift were observed. The cotton dust standard defines a worker as a possible "reactor" if he has a 5% or greater drop in FEV_1 over the work shift" (28).

Until the BTPS correction factor is modified and new correction tables are developed, the simplest solution to this problem is to keep the ambient temperature constant with a range of no more than 3°C (23). Or keep the ambient temperature at 23°C, $\pm$ 1.5°C (28).

Since ambient temperature is difficult to control in field studies, the problem should be brought to the attention of the medical surveillance physician so that it can be considered during the interpretation of results. It is also best if the temperature sensor is located inside the spirometer and ambient (spirometer) temperature is recorded at each testing session.

2. Other Factors to Consider: Three other factors may need consideration when calculating BTPS: ambient pressure, instrument or bell factor, and the use of graph paper in BTPS units. See **Appendix K. Other Factors to Consider When Calculating BTPS** for further information.

UNIT SIX: COMPARING OBSERVED TO PREDICTED NORMAL VALUES

A. "Normal" Spirometry

Lung function increases rapidly with growth during childhood and adolescence, reaches a peak sometime between the ages of 18 and 35, and then begins to slowly decline, even in healthy persons (29). Persons who grow relatively tall also have relatively large lungs when compared to those who are shorter in stature. Women on average, have lungs that are about 20% smaller than men of the same height and age (30). For a given standing height, African-American men, on the average, have longer legs than Caucasian men, and a correspondingly shorter trunk size; and therefore slightly smaller lungs (29,31,32,33) explaining most of the differences between predicted values for Caucasian and African-American men. All of the above factors mean that to optimally interpret spirometry results (observed values), you must first know the employee's age, height, gender, and race or ethnicity.

Before performing spirometry, record on a worksheet, or enter directly into a computer, the following information about the employee (at a minimum):

1. The employee's date of birth (DOB), and their age calculated from the date of testing and their DOB. Ask the employee their age, in order to verify the calculation.

2. The employee's standing height in stocking feet should be measured using a stadiometer, and recorded in feet and inches, to the nearest half inch. Verify this height with the employee. Their height should then be converted to centimeters by multiplying their height in inches by 2.54.

3. The employee's weight (in stocking feet) should also be measured to the nearest pound, using a scale which is accurate to within one pound. The computer should convert their weight to kilograms (multiply pounds by 0.4536) and then calculate and display their body mass index (BMI) in kilograms per meter squared. A BMI greater than 30 Kg/m^2 indicates that the employee is overweight. Body weight is not used to calculate spirometry reference values, but obesity can lower the measured lung volumes, and changes in body weight can result in small changes in lung function.

4. An attempt should be made to determine and record the employee's race or ethnicity. Often this can be done with adequate accuracy merely by observation. If in doubt, ask the employee, explaining that race affects the reference values used for the test. If the employee considers the question objectionable, or if their race or ethnicity does not clearly fit the limited categories available, just record "unknown" and use Caucasian reference equations (no race correction or race-specific reference value).

B. Spirometry Reference Studies.

There have been dozens of studies published in the medical literature which have determined spirometry reference values from groups of relatively healthy persons. The OSHA Cotton Dust Standard, published in 1978 (10), mandated that spirometry reference equations, determined from healthy persons in Tucson, Arizona, and published by Knudson, et. al. in 1976 (32,33,34) be used

when performing spirometry testing to detect lung disease in employees working in the cotton textile industry. Because the Knudson-1976 study did not include African-Americans, a "race correction factor" of 0.85 times the Knudson-1976 Caucasian reference value is recommended in the Cotton Dust Standard [10]. However in 1983, Knudson et. al. (35) published revised reference equations for their 1976 published values. See Appendix E for more information about the Cotton Dust Standard. The use of the Knudson equations to determine predicted normal values was adopted during the 1980s by many other industries for spirometry testing done in the occupational setting. However, the instruments and techniques for performing spirometry have improved and the American Thoracic Society (ATS) has published updated detailed recommendations for the interpretation of spirometry in the clinical setting, most recently in 1991 (30) and 1995 (1). When spirometry is being performed to comply with current regulations, the reference equations that are specified in the regulation must be utilized, such as Knudson 1976 in the OSHA Cotton Dust Standard. When interpretation of spirometry is not specified by regulation, NIOSH recommends following the most recent update of the ATS recommendations for interpretation of spirometry and selecting reference values based on the third National Health and Nutrition Examination Survey (NHANES III), published in 1999 (29).

It may be necessary to consult with the manufacturer of some older model spirometry systems to update the software to include the NHANES III spirometry reference equations for adults. The use of older spirometry reference values when testing employees in the age range of 18-65 years of age may result in slightly lower predicted values for FEV_1 and FVC when compared to using the NHANES III equations (29).

Racial Differences in Spirometry.

The NHANES III study (29) provides a separate set of spirometry reference equations for men and women of African-American, Caucasian, and Mexican-American ethnic groups. The NHANES III study did not provide spirometry reference equations for Asian-Americans, American Indians, East Indians, or other ethnic groups. Other investigations suggest that spirometry results are not substantially different for American Indians when compared to Caucasians living in the United States (36,37); therefore, NIOSH recommends that when testing American Indian employees, the reference equations for Caucasians be used. Large studies of Asians outside of the U.S. (39, 40) suggest that Asian FEV_1 and FVC values are, on average about 15% lower than Caucasians of the same age, gender, and standing height. However, smaller studies of Asian-Americans living in the U.S. (40,41) suggest that Asian-American FEV_1 and FVC are approximately 6 to 7 % lower than Caucasians. Therefore, until separate reference equations are published and accepted for Asian-American and East Indian ethnic groups, the NHANES III reference equations for Caucasians should be used, but a correction factor of 0.94 should then be applied to the predicted values for FVC and FEV_1. Note that the **predicted values** are multiplied by the correction factor, not the observed values.

C. The Lower Limit of the Normal (LLN) Range.

The predicted value calculated from spirometry reference equations is the *average* or mean value observed from many healthy persons of the same age, gender, height, and race as the employee being tested. The predicted value is actually in the middle of a rather wide, bell-shaped

distribution (range) of normal values. For instance, some healthy persons may have FVC values as much as 20% lower than the predicted value.

The lower limit of the normal range (LLN) is the threshold below which a value is considered abnormal - usually the value is set so that 95% of a "normal" population will have values above the LLN value and correspondingly, 5% of a "normal" population will have values below the LLN. The LLN is about 80% of the predicted value for FEV_1 and for FVC, but about 90% of the predicted value for the FEV_1/FVC ratio, and about 60% of the predicted value for the FEF25-75%. However, these are only rough "rules of thumb" and the exact LLN should be determined using the reference equations. If a race correction factor is used (0.85), the same race correction factor should be applied to the LLN value.

What is Considered Abnormal?

Abnormalities detected by spirometry may show one of three patterns: obstructive, restrictive, or mixed obstructive and restrictive. Employees with obstructive lung diseases, such as emphysema or chronic asthma, often have an abnormally low FEV1/FVC and a low FEV1 (below the LLN). Employees with fibrotic lung diseases, such as asbestosis, often have an abnormally low FVC, but their FEV1/FVC will generally be above the LLN. Persons exposed to certain dusts, such as silica or coal mine dust, can develop either pattern of abnormality, or a mixed pattern with reductions of both the FEV1/FVC ratio and the FVC below the LLN.

Occasionally, spirometry results from a worker without any apparent health problems are found to be slightly below the LLN. In contrast, it is not unusual to have high FVC or high FEV1 spirometry values. In fact, when they begin working, a majority of individuals in blue collar jobs have lung function that is considerably above average, a phenomenon called the "healthy worker effect". Young adults who were competitive athletes in high school, trade school, or college (while their lungs were still growing) may have a percent predicted FVC above 120%. On the other hand, it is unusual to have a percent predicted value above 140%, so if this occurs, be sure to check that the employee's age or height was measured, recorded, transcribed, and entered correctly. If an unusually high percent predicted value cannot be explained by an error, you should check the calibration of your spirometer.

D. How to Determine Predicted Values Using Look-up Tables.

There are several methods available to calculate spirometry reference values, percent predicted values, and the LLN's for an employee: 1) using a calculator, 2) using a nomogram, 3) using "look-up" tables, 4) using a personal computer or automated spirometry system which has already been programmed with the appropriate reference equations.

There are two times when it is useful to determine spirometry predicted values without using a computer: 1) when learning about them (using this workbook); and, 2) when verifying (checking) the accuracy of the reference equations which have been programmed into a spirometry system that you are using for the first time.

Abbreviated tables based on the NHANES III reference equations are provided in Appendix L for

the purpose of completing the examples given in this workbook and for verifying the accuracy of a spirometry system for computing the predicted values. However, these small tables will not be adequate for the routine testing of employees, because the range and intervals of heights are limited. Also, there may be slight differences ($\pm$ 0.02 liters), depending on whether a reference calculator, nomogram, or table is used.

The steps for determining the predicted normal and the LLN values from the tables are:

1. Choose the appropriate table from the six tables in Appendix L, based on the employee's gender and race. Use the employee's height and age to find the predicted normal values and LLNs for the FVC, FEV_1, and FEV_1/FVC%.

2. Use a pocket calculator to determine the percentage of the predicted values as follows:
   a. Divide the observed FEV_1 and FVC by the predicted result.
   b. Multiply the answer by 100. Round to one decimal place.

An Example:

A 30 year-old woman is a firefighter in Miami. She is 4 foot 11 inches tall, 135 pounds, and states that she is a Mexican-American. To determine her spirometry predicted values, choose Table 6 from Appendix L for Mexican-American women. Then note that her height is listed as 150 cm in the first column. Find age 30 on the second vertical column and use a straight-edged ruler to underline the row of predicted values for 30 year old women of this height. Move over to the third vertical column labeled "FVC Pred" and read the value 3.21 L. This is the predicted FVC in liters (BTPS) for this employee. Also record the lower limit of the normal value for the FVC as 2.60 liters, and the other predicted and LLN values for this employee from same row.

Her FVC was measured (observed) as 2.85 liters (BTPS) and her FEV_1 was 2.28 liters. Use a pocket calculator to determine that her FEV_1/FVC was 80.0% To determine her FEV_1 percent predicted value:

$$\%\text{Pred FEV1} = 100.0 \times \frac{\text{Observed FEV1}}{\text{Predicted FEV1}}$$

Note that her FVC and FEV_1 were both above the LLNs and both above 80% of the predicted values. Her FEV_1/FVC was also above the LLN. Her results would be interpreted as normal, since all three of these values were within the normal ranges.

EXERCISES:

1. What is the predicted FVC value for a 60 year old, Caucasian male steelworker in Pittsburgh. He is 71 inches tall and weighs 220 pounds.

2. What is the predicted and LLN for FEV_1 for a 40 year old African-American man, who is a

supervisor at a petrochemical company in Alabama. He is 170 cm tall and weighs 170 pounds.

3. A 20 year old, third-generation Japanese-American man, working at an electronics plant in San Jose, has an FVC of 4.00 L. He is 5 feet 11 inches tall and weighs 135 pounds. What is his percent predicted FVC?

4. What is the predicted FEV_1 for a 40-year old African-American man, 170 cm tall, using the reference value recommended in the Cotton Dust Standard? The Knudson 1976 (Cotton Dust) FEV_1 reference value for a Caucasian subject of the same gender, age and height is 3.56 liters.

FEEDBACK:

1. His predicted FVC is 4.92 liters, based on a height of 180 cm. Note that weight is not considered when calculating spirometry reference values.

2. His predicted FEV_1 is 3.23 liters, with a lower limit of 2.47 liters.

3. Since there are no tables for Asian-Americans, use table 1 for Caucasian men who are 5 feet 11 inches (180 cm) tall. Reading from the table, the predicted FVC for a 20 year old Caucasian man of this height is 5.75 liters. Then multiply this value by the suggested Asian-American correction factor of 0.94 to estimate the predicted value for this employee as 5.41 liters. Divide his observed FVC of 4.80 liters by the predicted value of 5.41 to obtain his percent predicted FVC as 88.7%. He clearly has a normal vital capacity since his percent predicted FVC is greater than 80% and his FVC is above the LLN value of 4.51 liters (0.94 x 4.80 = 4.51).

4. The Cotton Dust standard recommends that a "correction factor" of 0.85 be multiplied times the FEV_1 reference value from the Knudson-1976 study of Caucasians. The predicted FEV_1 for a Caucasian male from Knudson-1976 is 3.56 liters. Therefore, the predicted value for this African-American worker would be 0.85 x 3.56 = 3.03 liters.

UNIT SEVEN: COMPARING CHANGES FOLLOW-UP SPIROGRAMS

A. Rationale for Comparing Changes

Medical surveillance is an important use of spirometry in occupational health. In this context, it is essential to compare an employee's present results with his or her past results. When no other data are available, comparison with predicted normal values is useful. However, predicted values are not a baseline; therefore a subject's previous test results should be used as a baseline whenever possible. (See **Unit Six: Comparing Observed to Predicted Normal Values** for information on using predicted values.) A healthy individual's performance relative to predicted values remains remarkably consistent in adulthood. For example, a person who achieves 106% of the predicted FVC in one year tends to perform between 102-110% in subsequent years, assuming that the testing is satisfactory. Repeat testing of the same subject over a period of time may be more sensitive than comparing his/her values to a set of "predicted" normals. Hankinson and Wagner (42) concluded that approximately half of a worker population may benefit from the addition of a longitudinal comparison of their spirometry results, over using only comparison with predicted normal values. They suggest a greater than 15% decrease in FEV_1 is significant. This is illustrated by the following example:

> During his first year on the job, the FVC of a healthy young worker was 110% of a predicted normal value. The following year it was 90%. If his second year FVC is compared to the value of the first year, the difference could indicate the rapid development of serious restrictive pathology. This should alert the physician to conduct additional tests to identify the problem. However, if his FVC is only compared to a predicted value, it would be considered normal. Therefore, it is likely that no follow-up action would have been taken. As a result, his health could be seriously jeopardized. Although the comparisons with the LLN are preferred, results that are at least 80% of the predicted normal value, are often considered within the normal range if no other data are available for comparison. Interpreting follow-up spirograms will be discussed in more detail later in this unit. (See **Appendix M. Tables of Obstructive/Restrictive Patterns**.)

B. Interpreting Changes in Follow-up Spirograms.

Spirometric testing is usually used in two ways for respiratory surveillance programs:

a. To compare <u>pre- and post-shift values</u> for acute changes (example: FEV_1 in cotton dust exposure).

b. To compare <u>longitudinal</u> test results (e.g., those taken over an extended period of time, such as annually) for signs of chronic disease (example: FVC in asbestos exposure).

HOW TO CALCULATE:

When comparing a current spirometric value to a previous one, the difference can be expressed in two ways:

1. As an absolute difference (+ gain, - loss) in liters or ml:
   Value at $time_1$ - Value at $time_2$ = + or - liters.

2. As a percent change from the previous value (+ gain, - loss):

$$\frac{\text{Value at time}_1 - \text{Value at time}_2}{\text{Value at time}_1} \times 100$$

   a. Calculate the absolute difference.
   b. Divide the answer by the value at $time_1$.
   c. Multiply by 100 for the percent change and indicate whether it is a gain or a loss.

3. A third method involves a least squares linear fit to the FVC and FEV_1 values as a function of time. However, this approach generally requires the use of a computer and is not described in this manual.

EXAMPLE A: In an ongoing annual surveillance of asbestos workers, a 24 year old woman is found to have an FVC of 3.59 liters. Her previous FVC was 4.17 liters. What is the absolute and percent change in her FVC from the previous value?

Absolute change: 4.17-3.59 = .58 liters
She showed a loss of .58 liters.

Percent change: ((4.17-3.59)/4.17) x 100 = 13.9%
She showed a loss of 13.9% in her FVC.

EXAMPLE B: A 23 year old cotton dust worker has a pre-shift (7AM) FEV_1 of 4.00 liters, and a post-shift (3PM) FEV_1 of 3.85 liters.

Absolute change: 4 - 3.85 = .15 liters
He showed a loss of .15 liters.

Percent change: ((4.00-3.85)/4.00) x 100 = 3.8%
He showed a loss of 3.8%.

EXERCISE: A 71-inch, 62-year-old Caucasian male maintenance worker is intermittently exposed to asbestos. In ongoing medical surveillance testing, the following results were obtained:

1989: FVC = 4.48 L. ATPS (24°C)

1990: FVC = 4.38 L. ATPS (26°C)

Calculate the absolute change in the FVC and the change as a percent.

FEEDBACK: 1989 FVC: 4.84 L. (BTPS)

1990 FVC: 4.68 L. (BTPS)

FVC absolute change: - 0.16 liters

FVC change as a %: 3.3% decline

POINTS TO REMEMBER:

1. Percent change: Percent changes in follow-up studies always refer to a percent change from a PREVIOUS value, so the PREVIOUS value always appears in the denominator. Percentages are rounded to one decimal point (e.g., 85.3%).

2. Expected decline in pulmonary function in longitudinal studies: In annual follow-up studies, the comparison of current results can be made to:
    a. The previous year's value.
    b. The previously recorded best value for each test, regardless of the year in which it occurred.

In either case, the **expected annual decline** (simply due to normal aging) in spirometry values must be taken into account. The numbers below are "averages" derived from cross-sectional studies; considerable variation may occur among individuals.

a. For males FEV_1: 30 ml/year
FVC: 25 ml/year

b. For females: FEV_1: 25 ml/year
FVC: 25 ml/year

3. Other changes: One of the purposes of respiratory surveillance programs is to detect changes in lung functioning that may be job-related. However, there may be other changes that could influence spirometric results. Some of the more common ones are given below. Be sure to note any of these changes for the physician to aid in interpretation.
   a. Height: Some individuals tend to become shorter as they age.
   b. Weight: A large weight gain or loss over the period of examination.
   c. Smoking: The FEV_1 declines more quickly from year to year in smokers than in nonsmokers.
   d. Seasonal Allergies: Someone with hayfever may not perform as well during allergy season.
   e. Medications: May influence motivation or may directly affect air flow.
   f. Illness: May reduce performance. (See **Unit Four: Spirometric Technique** for guidelines for postponing the test.)

4. Further investigation is usually recommended for follow-up results when:
   a. There is a decline in FEV_1 or FVC that is greater than 15% in longitudinal screening. However, if the period of follow-up is long (greater than 5 years), it may be necessary to adjust for the expected decline due to aging.
   B. The FVC, FEV1, or FEV_1/FVC% is less than the LLN at any time.
   c. There is a 10% or greater decline in the FEV_1 between pre- and post-shift screening, when a single exam is conducted or a 5% or greater decline (more than 150 ml for FEV_1s less than 3 liters) if a follow-up exam confirms this decline (Cotton Dust recommendation).

NOTE: The interpretation of longitudinal changes in FVC and FEV_1 are limited due to the relative considerable variability of these parameters with respect to the expected annual decline (25 to 30 ml/year). This means that either a large change must occur in a short period of time, or the length of follow-up must be longer than 5 years. In addition, a good quality control program is essential if these relatively small changes are to be detected. For this reason, the ATS has recommended that a greater than 15% year-to-year change is needed to be considered significant.

UNIT EIGHT: OVERVIEW OF STANDARDS FOR SPIROMETRIC EQUIPMENT

When purchasing spirometric equipment, check that the manufacturer's specifications meet current ATS standards. These standards are summarized below. Unless otherwise noted, the Cotton Dust Standard equipment requirements are the same. (See **Appendix E: OSHA Cotton Dust Standard, Appendix D. and Appendix F: American Thoracic Society Standards**, for copies of these standards.)

1. Volume
   The spirometer must be capable of measuring volumes of at least 8 liters (BTPS) with flows between zero and 14 L/s. It must also be able to accumulate volume for at least 15 seconds **(10 seconds for Cotton Dust Standard)**.

2. Inertia and Resistance
   There must be less than 1.5 cm H_2O/liter/second at an air flow of 12 liters/second. (Read the manufacturer's specifications to check this.)

3. Zero Time Determination.
   The spirometer must have a recording chart that is activated before the forced expiratory maneuver begins in order to calculate zero time. For computerized systems, the start of the test must be determined by back extrapolation for timing purposes. **(Cotton Dust Standard: zero time is determined by back extrapolation or an equivalent method.)**

4. Conversion to BTPS
   The instrument and/or the user must have a means for converting values to BTPS.

5. Accuracy.
   a. The equipment must be capable of being calibrated in the field.

   b. The FVC and the FEV_1 must be measured with an accuracy within $\pm$3% or $\pm$50ml, whichever is greater.

   c. The volume calibration check must show an accuracy of within $\pm$3% or $\pm$50ml, whichever is greater.

   d. If the $FEF_{25\text{-}75\%}$ is used, it must be measured with an accuracy of at least $\pm$5% or 200ml/s, whichever is greater. It should be measured on equipment that meets ATS standards for the FVC. **(Cotton Dust Standard: The $FEF_{25\text{-}75\%}$ is not required.)**

   e. Flow measurements must be accurate to within $\pm$5% or 200ml/s, whichever is greater. **(Cotton Dust Standard: No information is given.)**

6. Spirometry Recorder/Displays.
   Paper records or graphic displays are required.
   a. Recorders must have the capability of recording volume vs. time or flow vs. volume during the entire forced expiratory maneuver. **(Cotton Dust Standard: The tracing must be stored and available for recall and must be of sufficient size that hand measurements may be made.)**

   b. The paper must move at a chart speed of at least 20mm/sec.

   c. Recorders must trace flow/volume curves with exhaled flow on the vertical axis and exhaled volume on the horizontal axis, going from left to right. **(Cotton Dust Standard: It allows only tracings of the size used for validation and measurement by hand.)**

   d. The volume scale should be at least 10mm/L (BTPS), the flow scale should be 5mm **(4mm for Cotton Dust Standard)** of chart paper per liter per second of flow, and the time scale at least 2cm/s (although 3cm/s is preferred).

      (According to ATS, using tracings for doing calculations by hand allows for determining spirometric values "in the absence or failure of a computer (10)." Tracings for validation "validate the spirometer system hardware and software for accuracy and reliability through the use of hand measurements..." (10). [However, as was pointed out in **Unit Two: Overview of Spirometry**, electronically produced spirograms are reconstructed instead of mechanically produced and therefore will always correspond to the printout. As a result, hand calculations provide only a limited way to check that this type of system is working properly.])

UNIT NINE: ADDITIONAL EXERCISES

This unit contains spirograms and test results from several individuals to give you additional opportunities to practice calculation skills. Answers are given for most of the questions.

EXERCISE 1.

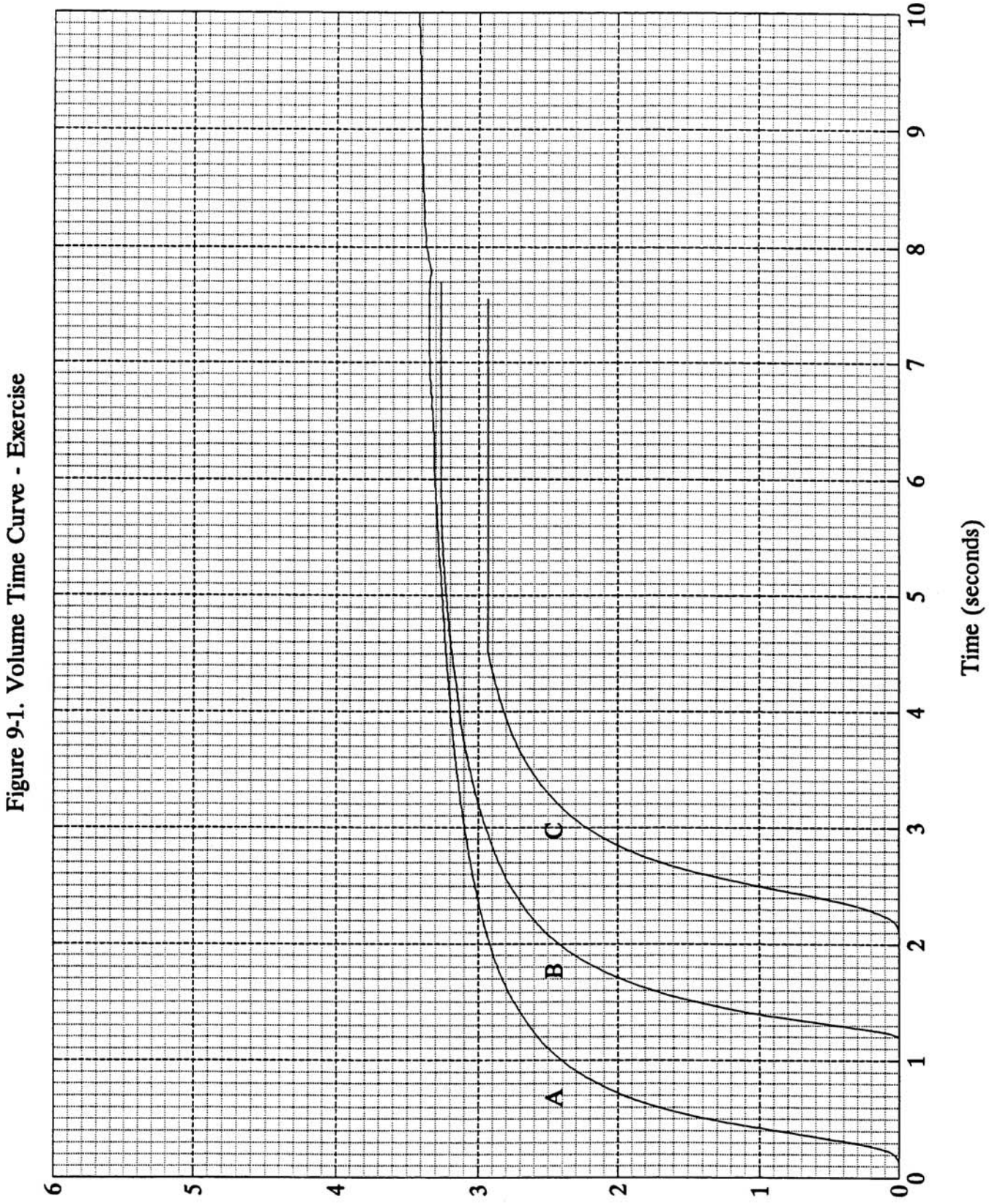
(Refer to Figure 9-1. Volume Time Curve - Exercise.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. Curve C shows a glottis closure. Curve A is a judgment call on whether or not a plateau was reached.

FIGURE 9-1. VOLUME TIME CURVE – EXERCISE



EXERCISE 2.

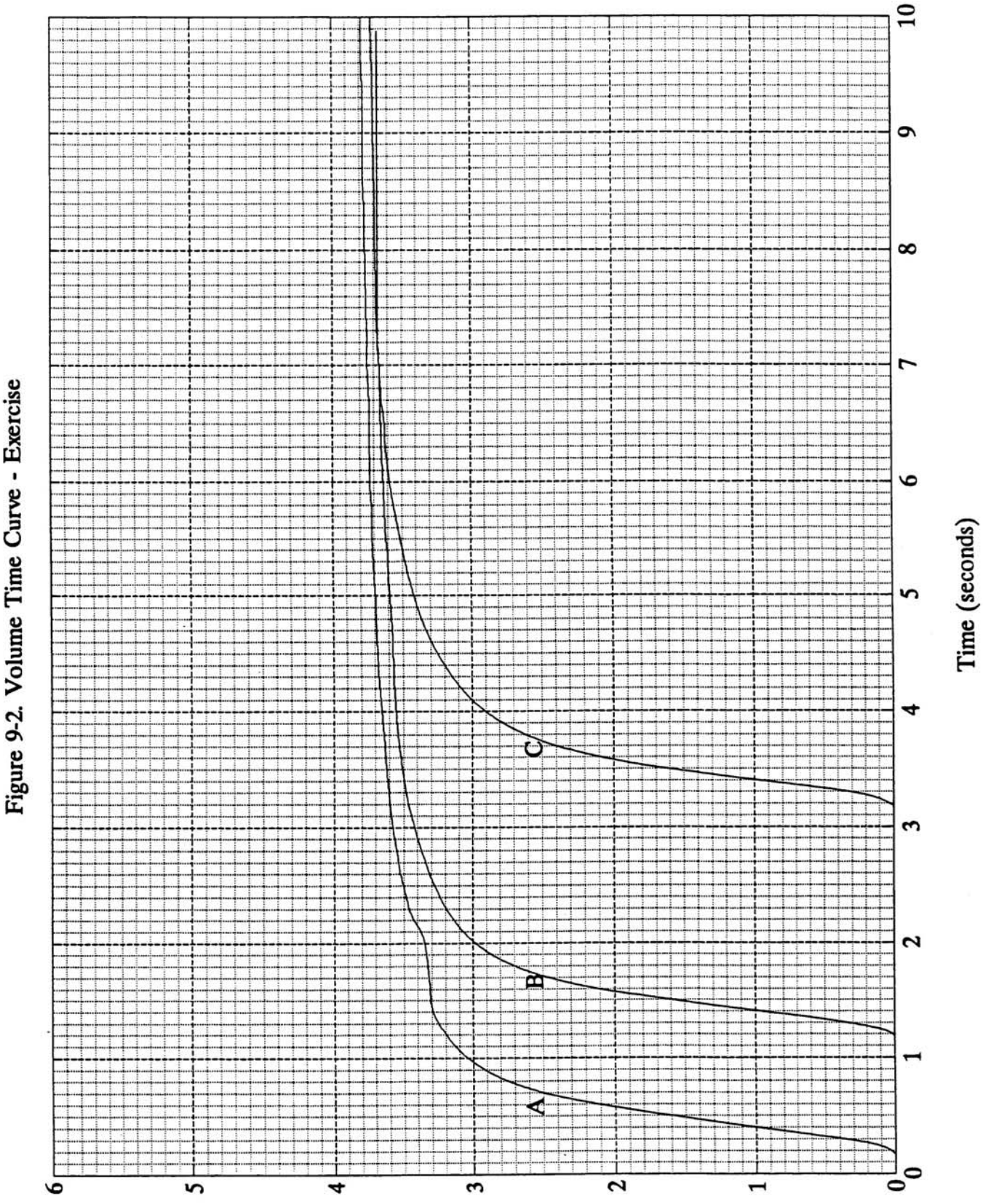
(Refer to Figure 9-2. Volume Time Curve - Exercise.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. Curve A shows a cough or variable effort early in the maneuver.

FIGURE 9-2. VOLUME TIME CURVE – EXERCISE



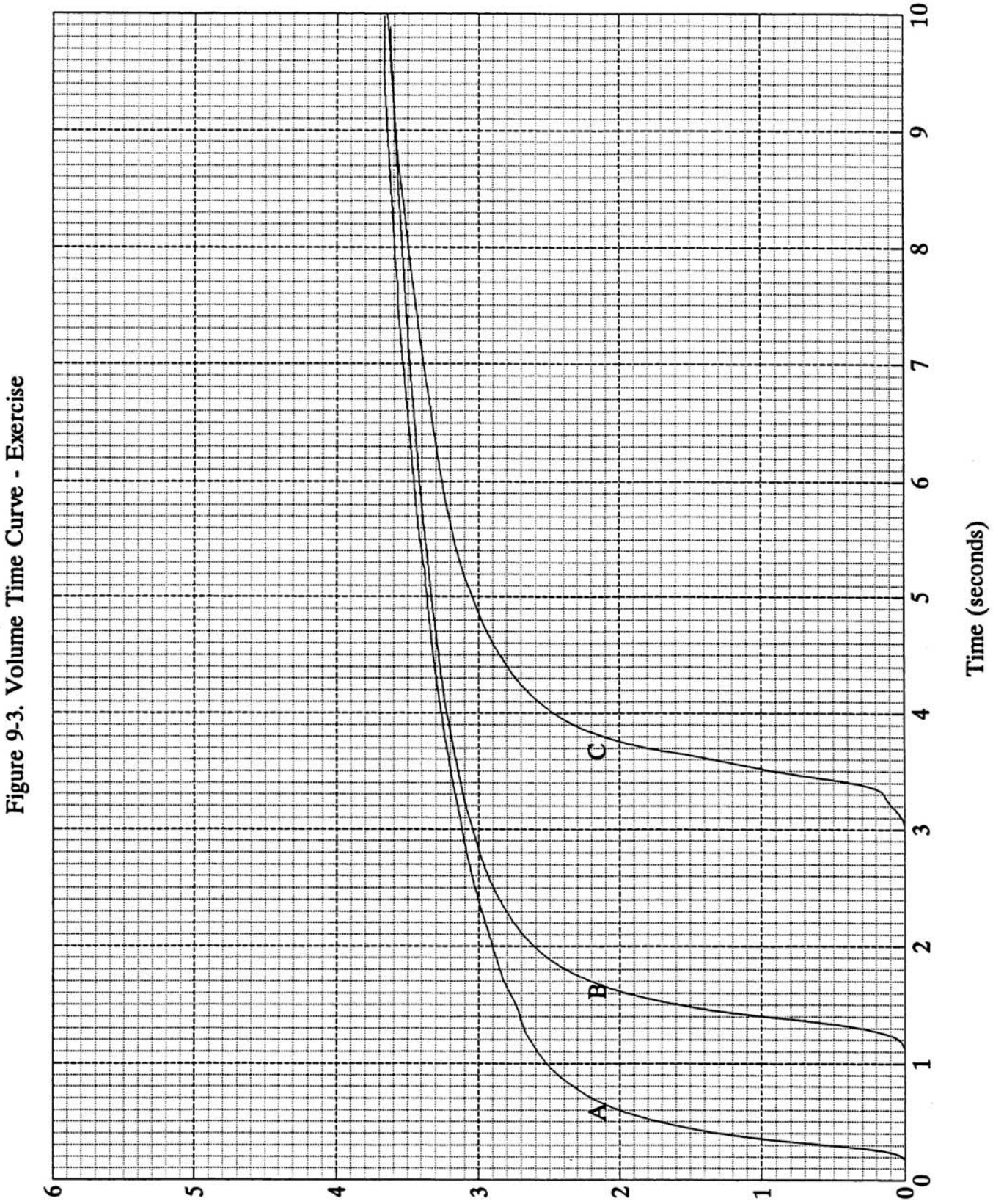
EXERCISE 3.
(Refer to Figure 9-3. Volume Time Curve Exercises.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. All curves show a failure to plateau. Curve C also had some extrapolated volume but would have been acceptable (4.4%) if a plateau had been reached.

FIGURE 9-3. VOLUME TIME CURVE – EXERCISE



EXERCISE 4.

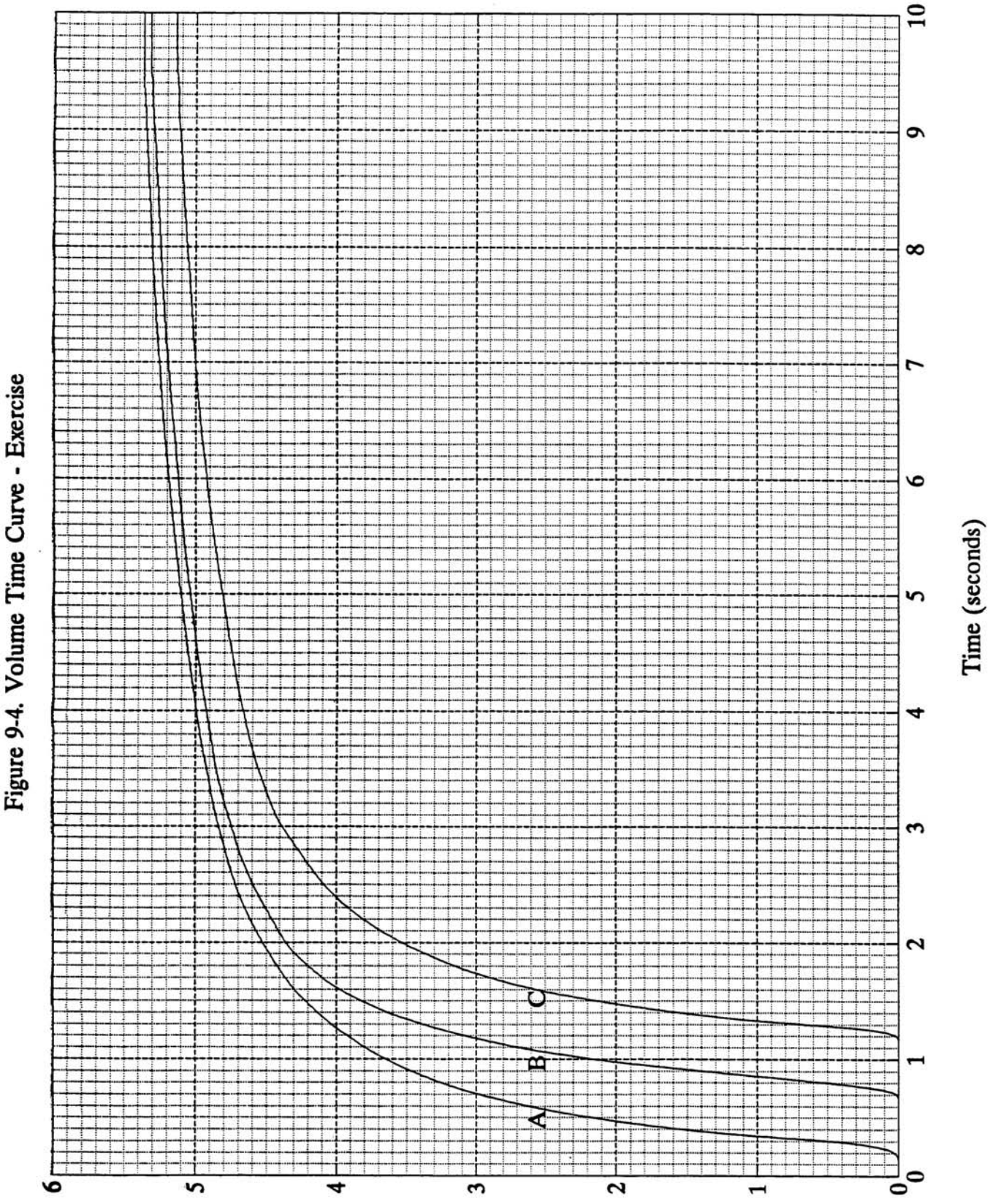
(Refer to Figure 9-4. Volume Time Curve - Exercise.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. Yes. However, the plateau is short and it would be a good idea to have the individual blow slightly longer (another half-second) to be sure a plateau has been obtained.

FIGURE 9-4. VOLUME TIME CURVE - EXERCISE.



EXERCISE 5.

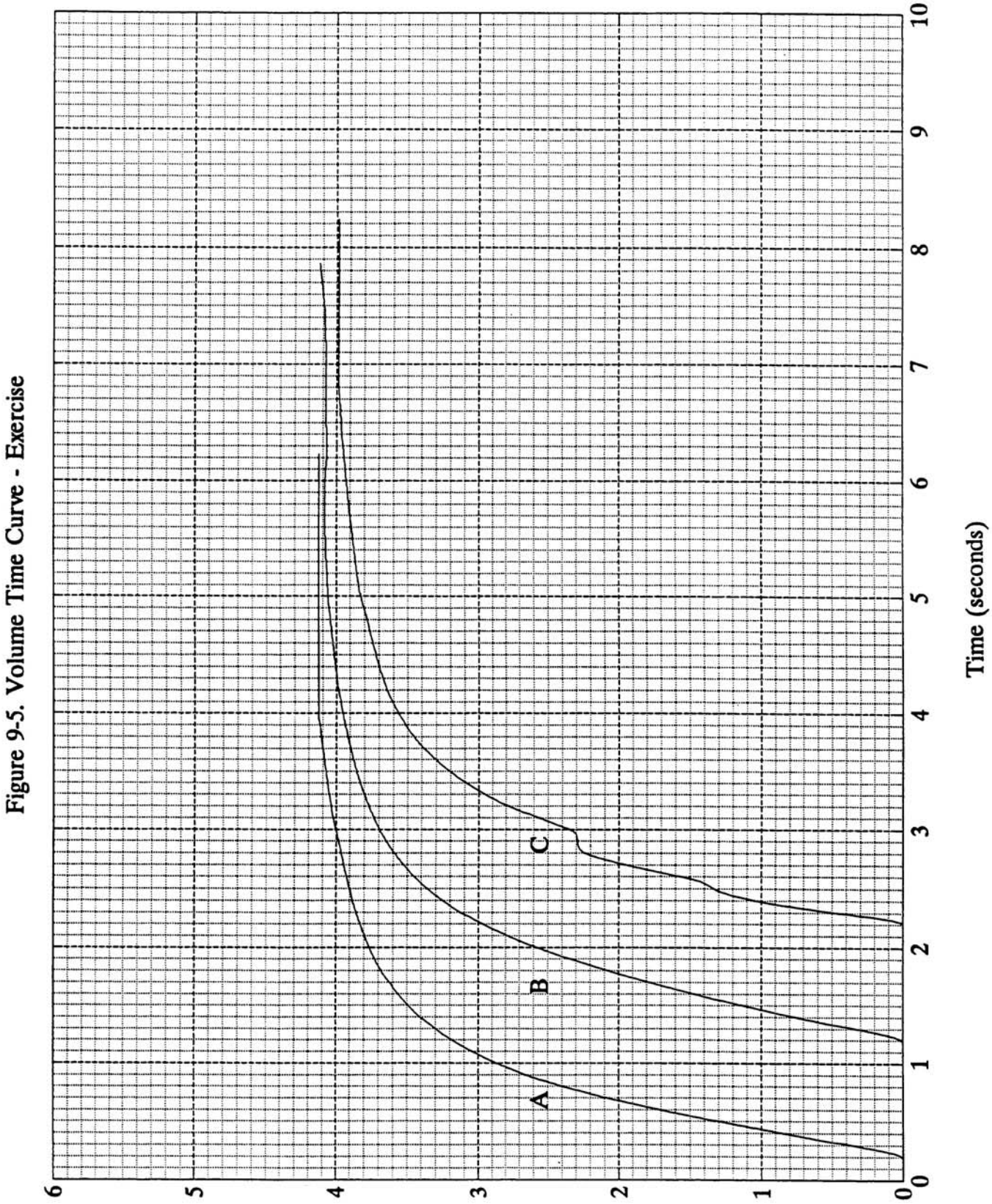
(Refer to Figure 9-5. Volume Time Curve - Exercises.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. Curve C shows a cough or variable effort early in the maneuver.

FIGURE 9-5. VOLUME TIME CURVE – EXERCISE



EXERCISE 6.

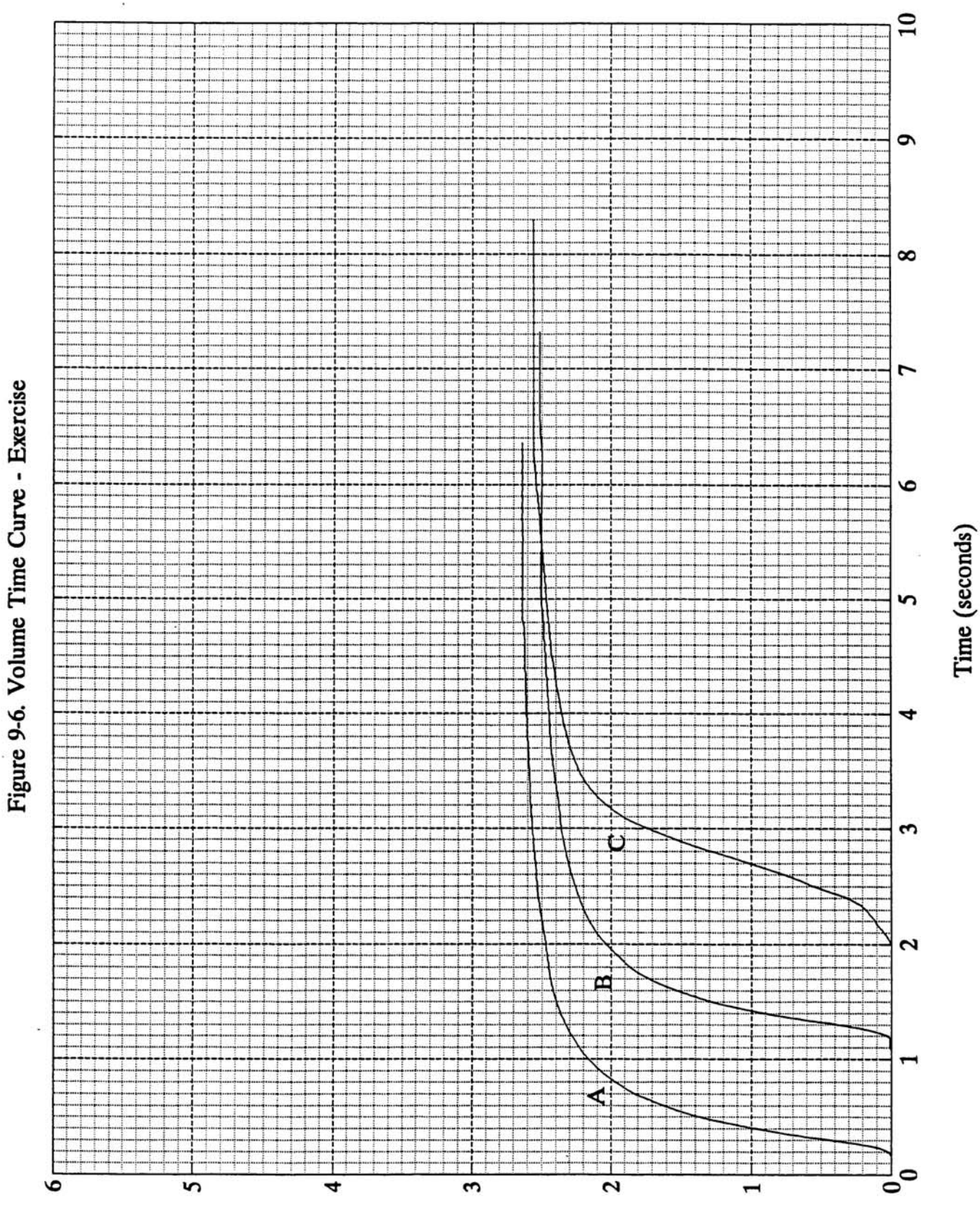
(Refer to Figure 9-6. Volume Time Curve - Exercises.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. Curve C shows excessive extrapolated volume (approximately 7.03%).

FIGURE 9-6. VOLUME TIME CURVE - EXERCISE.



EXERCISE 7.

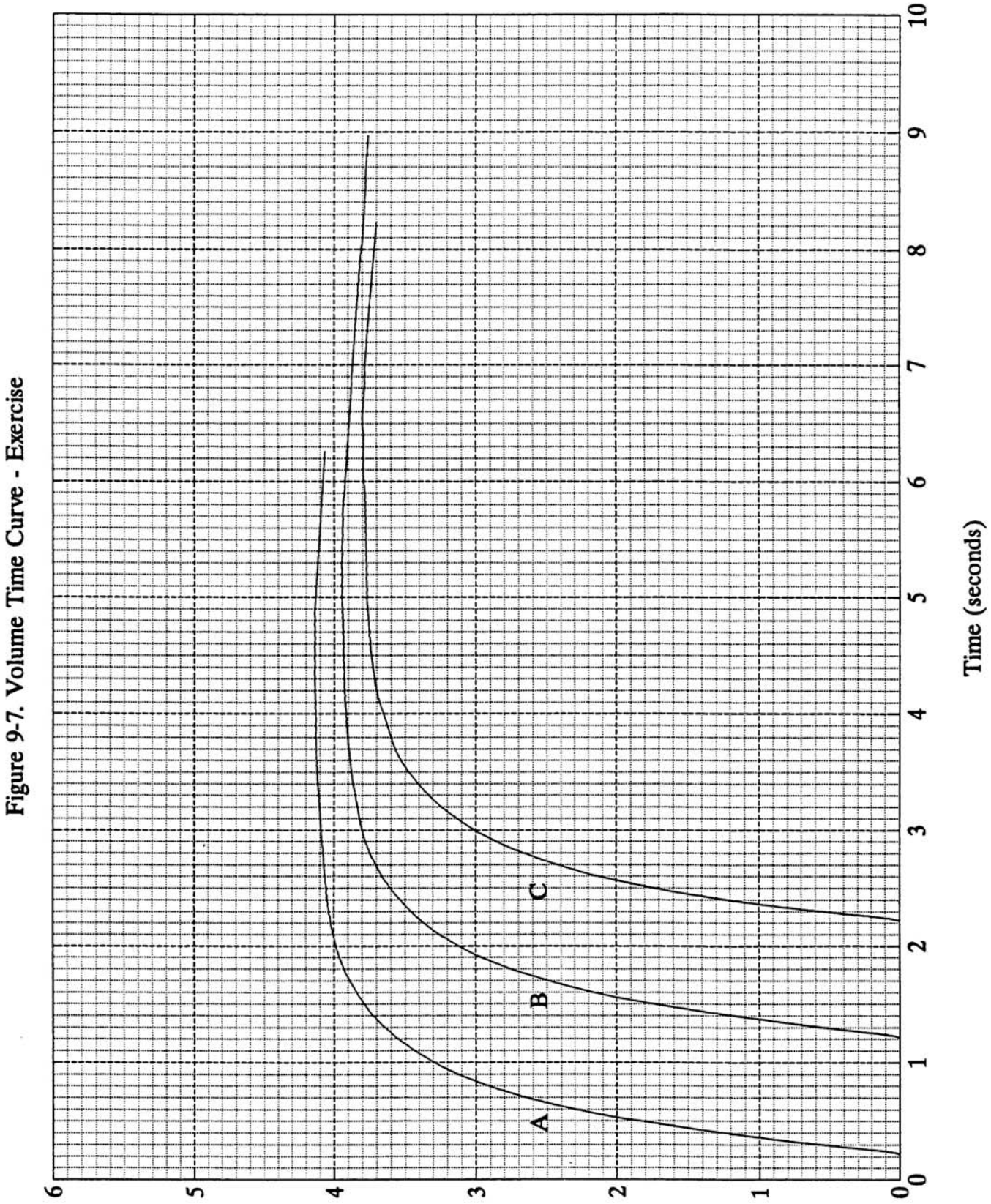
(Refer to Figure 9-7. Volume Time Curve - Exercises.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. All three indicate leakage.

FIGURE 9-7. VOLUME TIME CURVE - EXERCISE.



EXERCISE 8.

(Refer to Figure 9-8. Volume Time Curve - Exercises.)

a. Do these curves meet acceptability criteria?

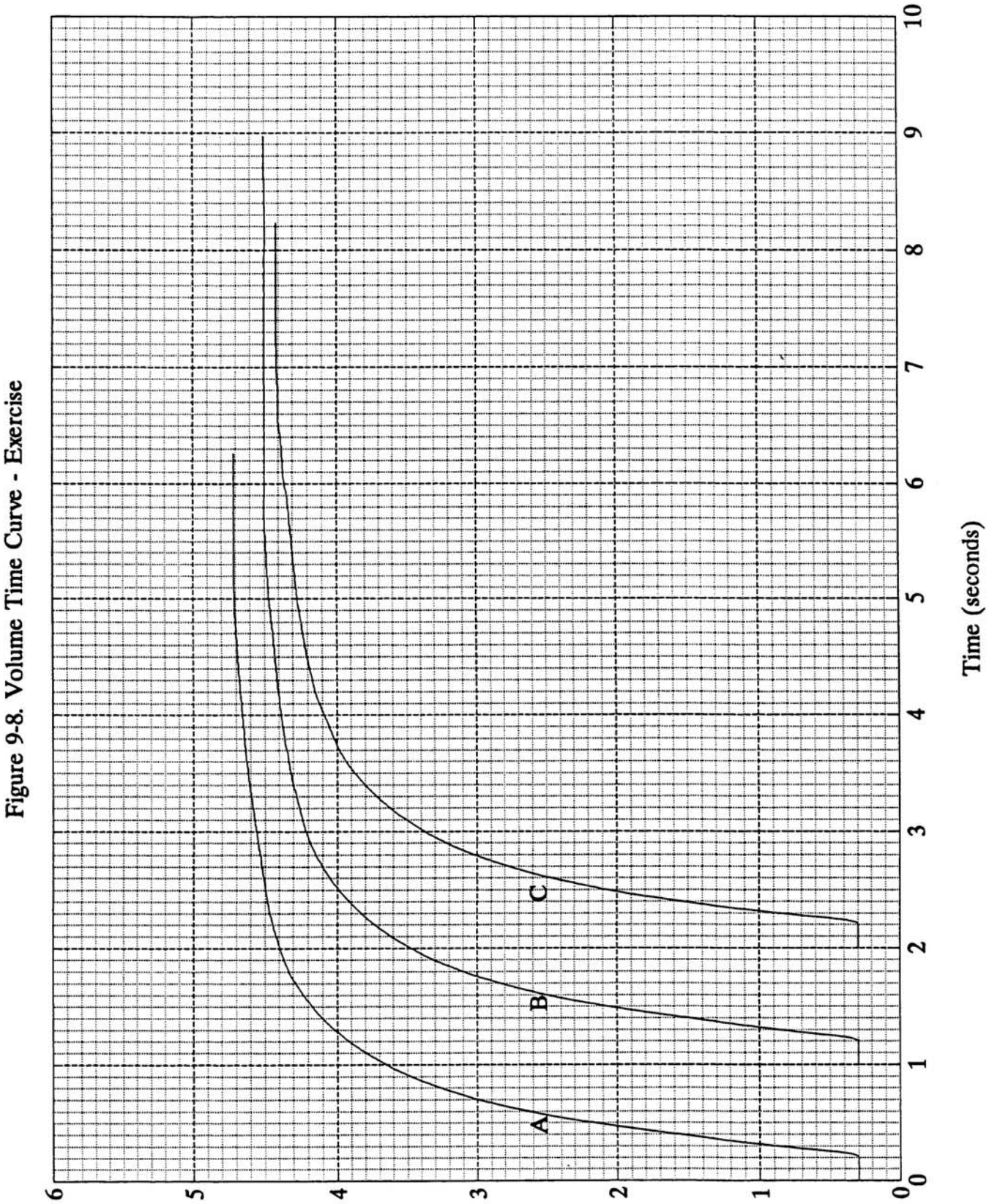
b. If not, what could be done to make them acceptable?

FEEDBACK:

a. No. All three show the same baseline error.

b. Subtract 0.3 liters from the FEV_1 and FVC results to correct for the error in this example.

FIGURE 9-8. VOLUME TIME CURVE - EXERCISE.



EXERCISE 9.

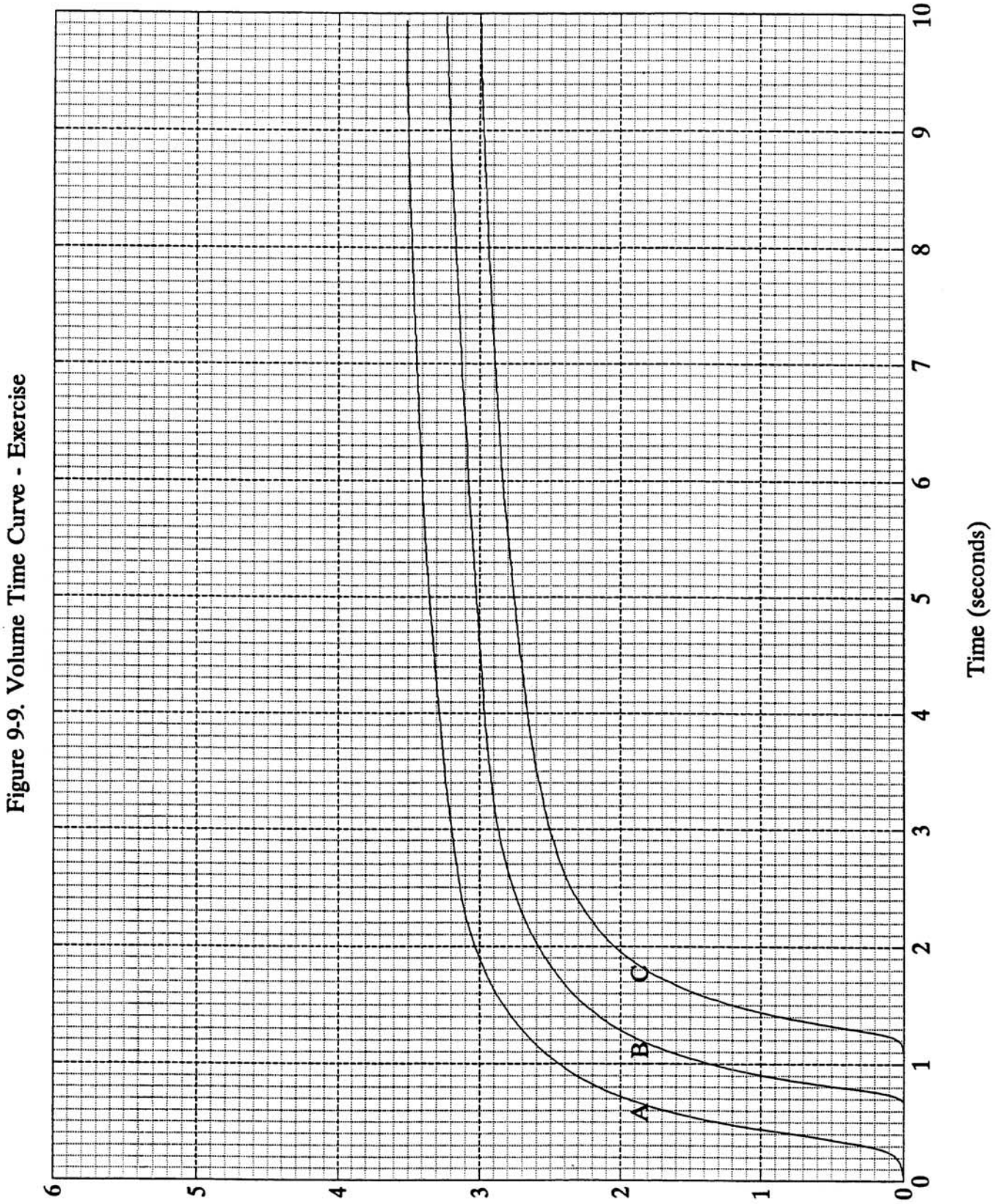
(Refer to Figure 9-9. Volume Time Curve - Exercise.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. Curves B and C did not reach a plateau. Curve A had some extrapolated volume, but would have been acceptable. (FVC A = 3.5 L, extrapolated volume = 0.15 L or 4.3% of the FVC). Coach **Blast the Air Out at first** and blow out longer.

FIGURE 9-9. VOLUME TIME CURVE - EXERCISE.



EXERCISE 10.

Refer to Figure 9-10. Volume Time Curve - Exercise.

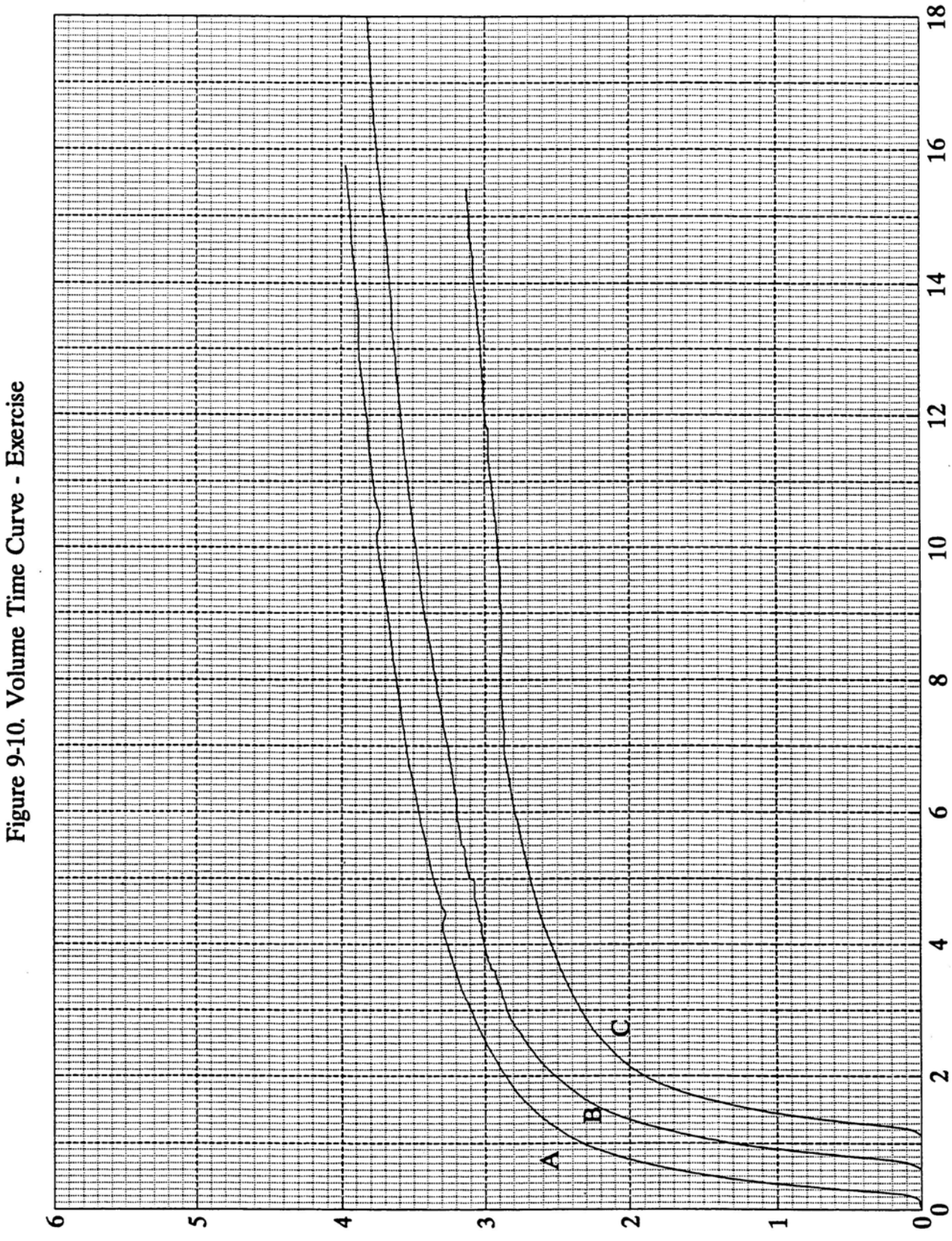
The paper size does not conform to ATS standards for hand calculations due to reproduction constraints. This exercise was included to show curves that are longer than 10 seconds in duration.

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. No. None reached a plateau. However, this individual shows an obstructive pattern and may not be able to produce reproducible tracings with plateaus. The technician may want to discuss these results with the interpreting physician before determining whether to obtain additional tracings. Although all of the curves show coughs or variable efforts, they occurred late in the maneuver and were insignificant in size.

FIGURE 9-10. VOLUME TIME CURVE - EXERCISE.



EXERCISE 11.

(Refer to Figure 9-11. Volume Time Curve - Exercises.)

a. Do these curves meet acceptability criteria?

b. Do at least two of the three curves meet FVC and FEV_1 reproducibility criteria?

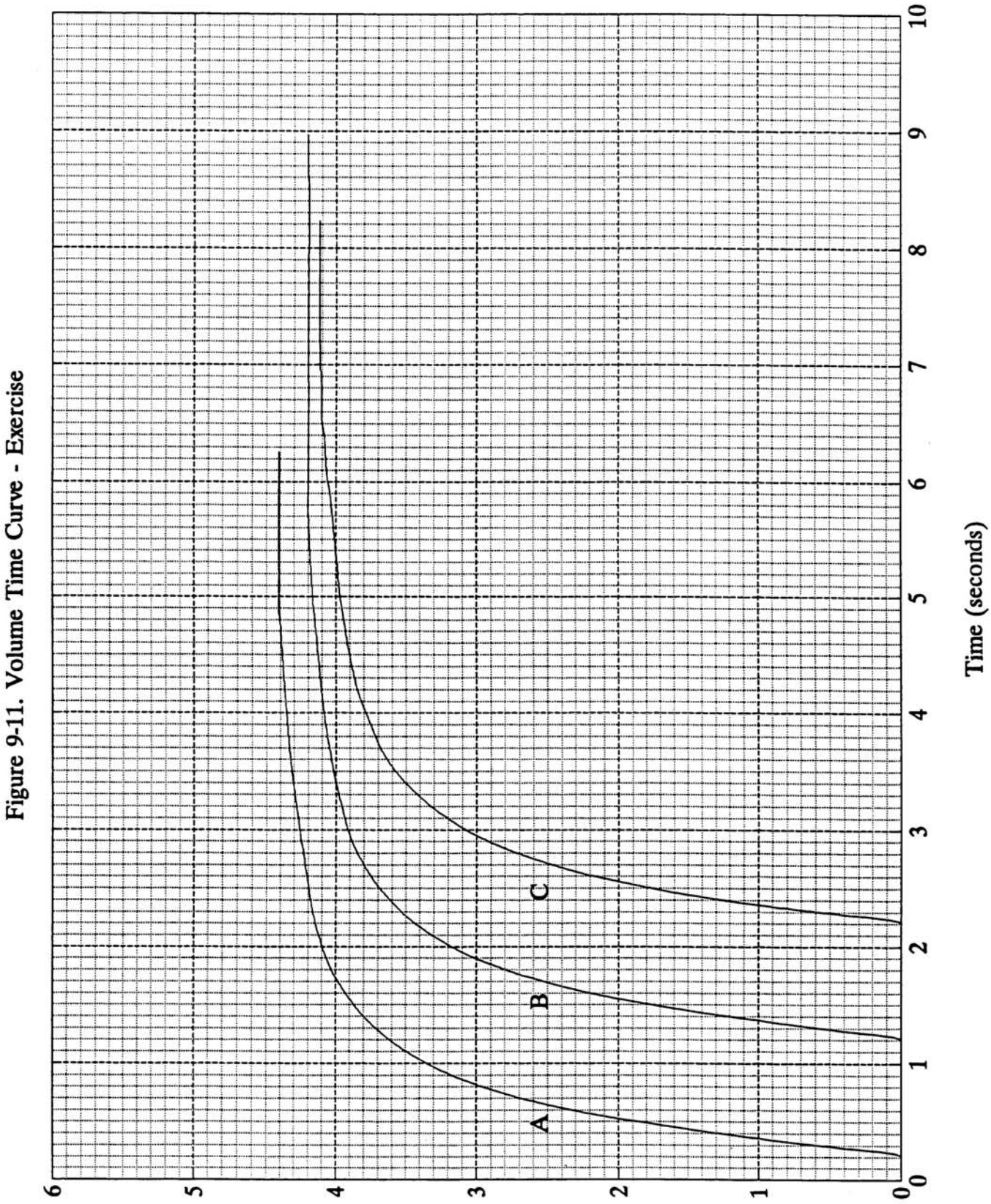
FEEDBACK:

a. Yes. Acceptability criteria are met.

b. FVC reproducibility criteria are met (190 ml difference; **optional** 4.3%).
FEV_1 reproducibility criteria are met (190 difference; **optional** 5.2% does not meet ATS-87). There are variable volumes; so, coach **Take a Deeper Breath In**.

Curve A: FVC = 4.40 L FEV_1 = 3.64 L
Curve B: FVC = 4.21 L FEV_1 = 3.45 L
Curve C: FVC = 4.12 L FEV_1 = 3.34 L

FIGURE 9-11. VOLUME TIME CURVE - EXERCISE.



EXERCISE 12.

(Refer to Figure 9-12. Volume Time Curve - Exercises.)

a. Do these curves meet acceptability criteria?

b. Do at least two of the three curves meet FVC and FEV_1 reproducibility criteria?

FEEDBACK:

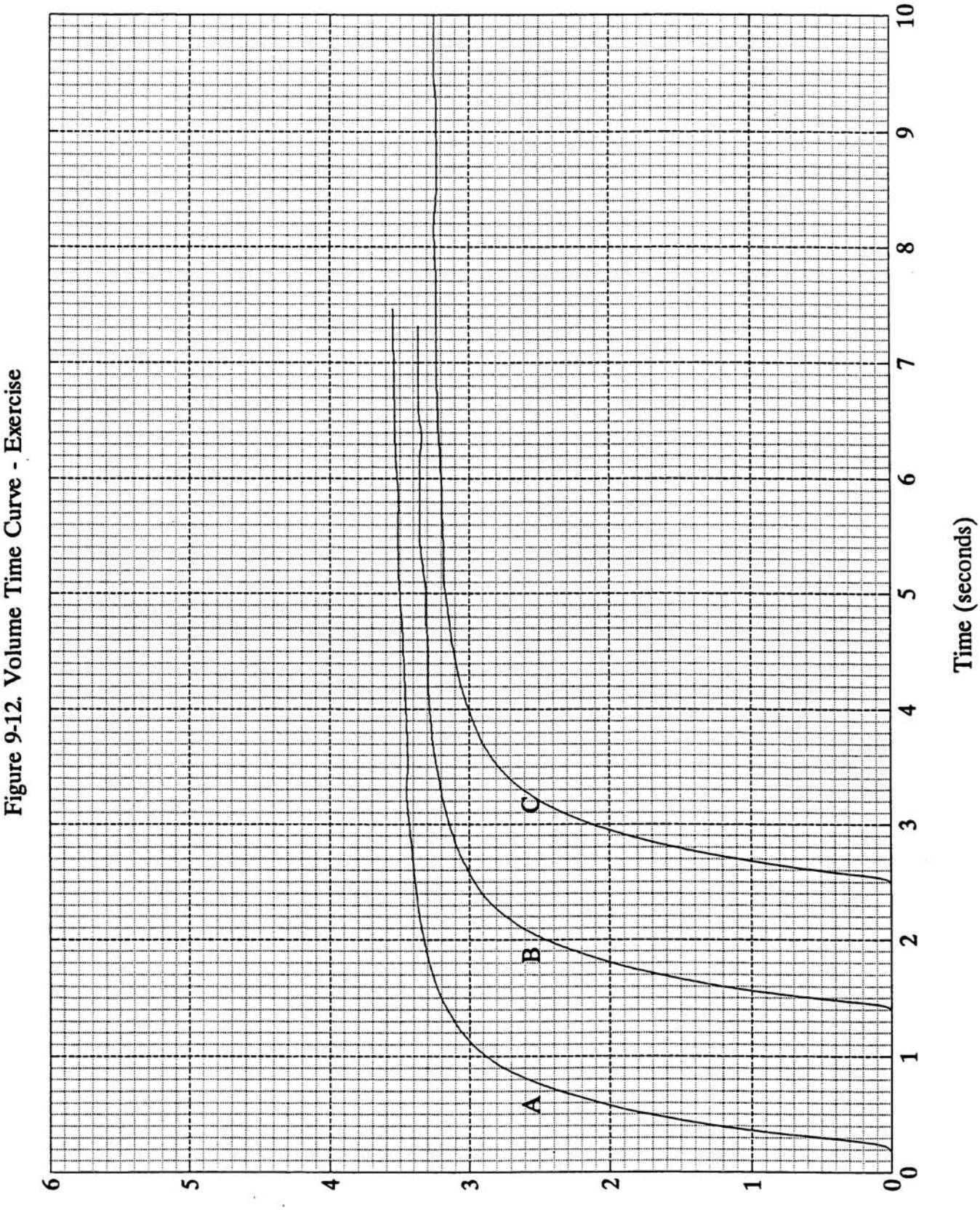
a. Yes. The curves meet acceptability criteria.

b. FVC variability = 180 ml (5.1%)
FEV_1 variability = 150 ml (4.9%)

The FVC is slightly below the ATS-1995 reproducibility criteria, and it is slightly beyond the ATS-1987 5% cut off. The technician may want to obtain further tests, depending on whether the subject feels he/she can continue. There are variable volumes, so coach **Take a Deeper Breath In**.

Curve A: FVC = 3.55 L FEV_1 = 3.07 L
Curve B: FVC = 3.37 L FEV_1 = 2.92 L
Curve C: FVC = 3.26 L FEV_1 = 2.80 L

FIGURE 9-12. VOLUME TIME CURVE - EXERCISE.



EXERCISE 13.

(Refer to Figure 9-13. Volume Time Curve - Exercise.)

Curve A is the largest of three acceptable tracings.

a. Calculate the FVC.

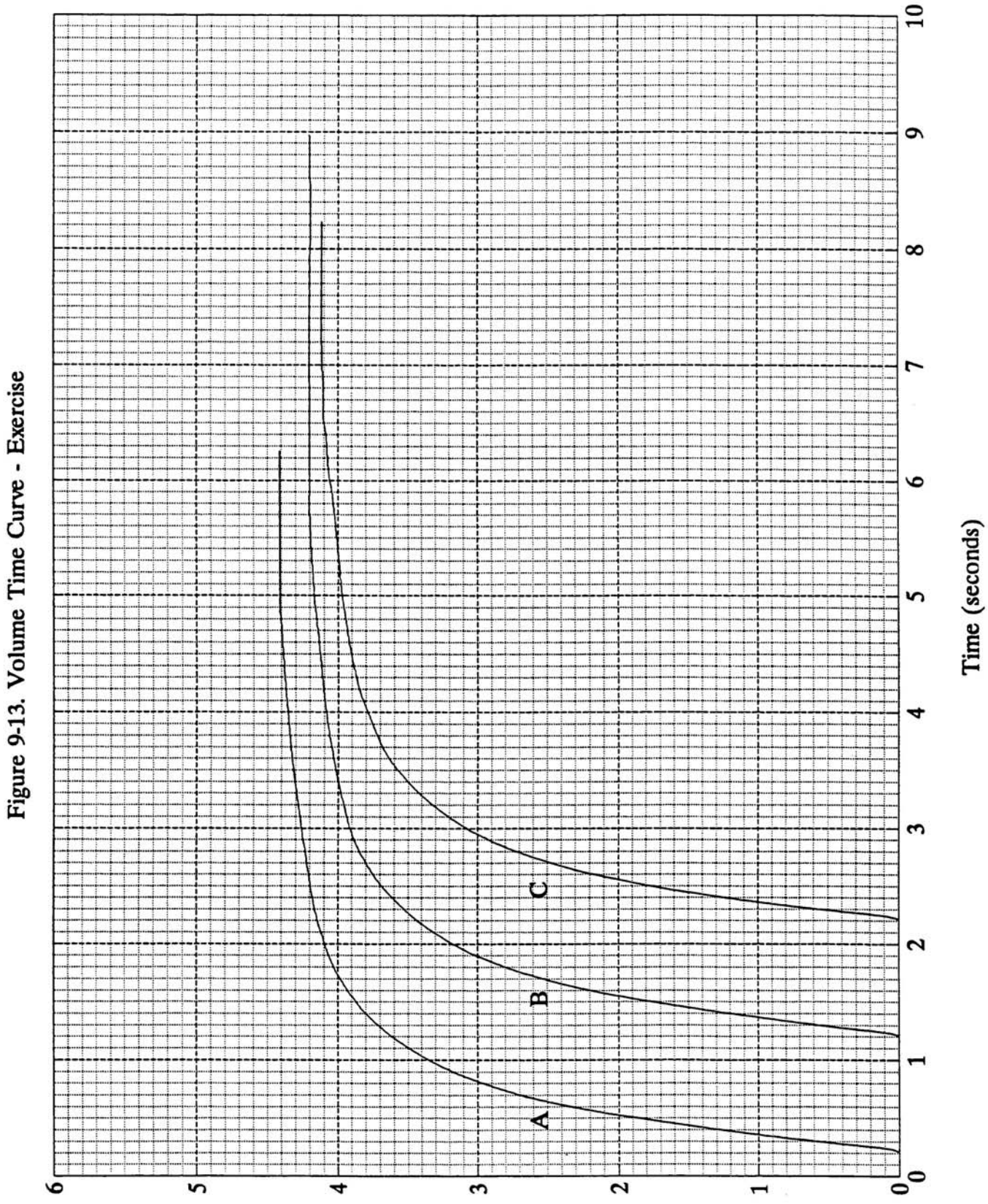
b. Calculate the FEV_1.

FEEDBACK:

a. FVC = 4.40 L.

b. FEV_1 = 3.65 L.

FIGURE 9-13. VOLUME TIME CURVE – EXERCISE.



EXERCISE 14.

(Refer to Figure 9-14, page 9-33. Volume Time Curve - Exercise.)

a. Determine the FVC for each curve:

Curve A _____

Curve B _____

Curve C _____

b. Is there excessive variability between the two largest FVCs?

c. What is the best FVC (ATPS) _____ ? What is the best FVC (BTPS) (ambient temperature = 24°C) ____ ?

FEEDBACK:

a. FVC (ATPS):

Curve A = 3.06 L.

Curve B = 2.97 L.

Curve C = 2.89 L.

b. No excessive variability, 90 ml or **optional** 2.94%.

c. Best FVC (ATPS) = 3.06 L.;
Best FVC (BTPS) = 3.30 L.

EXERCISE 14. CONTINUED:

d. Calculate the FEV_1 (ATPS) for each curve:

Curve A _____

Curve B _____

Curve C _____

e. Is there excessive variability between the two largest FEV_1s?

f. What is the best FEV_1 (ATPS)? What is the best FEV_1 (BTPS) _____ (ambient temperature = 24^oC)?

g. Do all three tracings meet acceptability criteria?

h. Do at least two of the three tracings meet reproducibility criteria?

FEEDBACK:

d. FEV_1 (ATPS): Did you remember to use back extrapolation?

Curve A = 2.71 L.

Curve B = 2.79 L.

Curve C = 2.78 L.

e. No excessive variability, 10 ml (0.36%).

f. FEV_1 (BTPS) = 3.01 L.

g. All three meet acceptability criteria.

h. The two largest FVCs and FEV_1s meet reproducibility criteria.

EXERCISE 14. CONTINUED:

i. Calculate the FEV_1/FVC% _____

j. Calculate the $FEF_{25\text{-}75\%}$ (BTPS) _____

FEEDBACK:

i. FEV_1/FVC% = 91.2% Did you remember to use the best FEV_1 and the best FVC, even if they didn't come from the same curve?

j. $FEF_{25\text{-}75\%}$ = 3.10 liters/sec (BTPS). Did you remember to convert to BTPS?

Sum of the best curve: 5.77 (Curve A)

25% of the FVC = 0.77 L.

75% of the FVC = 2.30 L.

EXERCISE 14. CONTINUED:

k. If these curves were from a 30-year-old Caucasian female, 63 inches tall, what would her predicted values be using Appendix L.?

FVC pred. _____ FEV_1 pred. _____

l. What percent of the predicted values are the following for the above individual?

% FVC pred. _____ % FEV_1 pred. _____

m. If these curves were from a 30-year-old African American female, 67 inches tall, what would her predicted values be using Appendix L?

FVC pred. _____ FEV_1 pred. _____

n. What percent of the predicted are the following for the above individual?

% FVC pred. _____ % FEV_1 pred. _____

FEEDBACK:

K FVC pred. = 3.65 L. FEV_1 pred. = 2.09 L. Note: 63 inches is about 160 cm.

l. % FVC pred. = 90.4% % FEV_1 pred = 97.4%

m. FVC pred. = 3.55 L. FEV_1 pred. = 3.01 L. Note: 67 inches is about 170 cm.
Did you remember to use the race correction?

n. % FVC pred. = 93.0% % FEV_1 pred. = 100.0%

EXERCISE 14. CONTINUED:

o. If these curves were from a 30-year-old Caucasian male, 67 inches tall, what would his predicted values be using Appendix L?

FVC pred. _____ FEV_1 pred. _____

p. What percent of the predicted values are the following for the above individual?

% FVC pred. _____ % FEV_1 pred._____

q. If these curves were from a 30-year-old African-American male, 67 inches tall, what would his predicted values be using Appendix L?

FVC pred. _____ FEV_1 pred. _____

r. What percent of the predicted values are the following for the above individual?

% FVC pred. _____ % FEV_1 pred. _____

FEEDBACK:

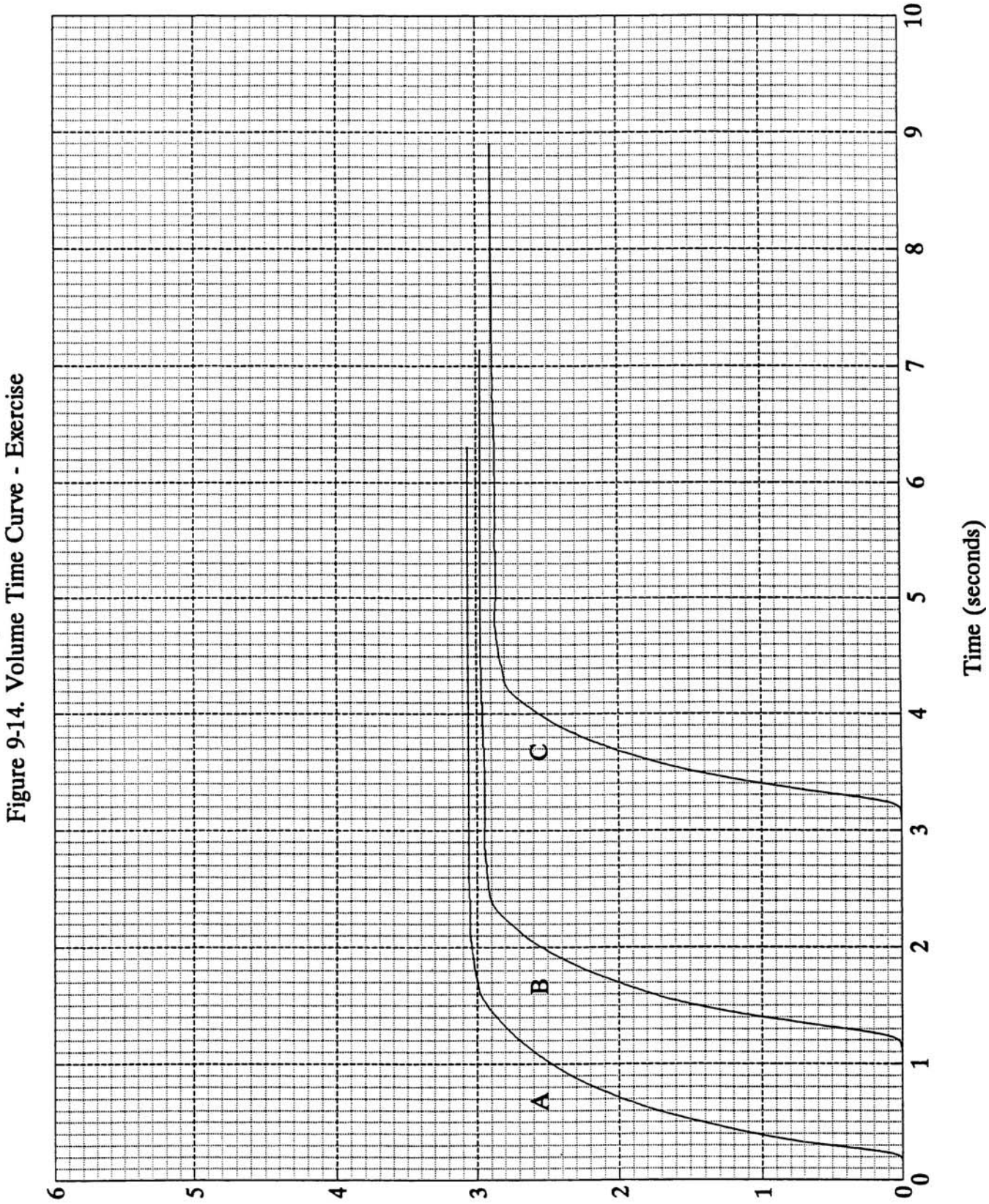
o. FVC pred. = 4.97 L. FEV_1 pred. = 4.08 L.

p. % FVC pred. = 66.4% % FEV_1 pred. = 73.8%

q. FVC pred. = 4.11 L. FEV_1 pred. = 3.46 L.

r. % FVC pred. = 80.3% % FEV_1 pred. = 87.0%

FIGURE 9-14. VOLUME TIME CURVE – EXERCISE



EXERCISE 15.

(Refer to Figure 9-15, page 9-38. Volume Time Curve - Exercise.)

a. Do these curves meet acceptability criteria?

FEEDBACK:

a. These curves meet all acceptability criteria. The cough or variable effort in curve C is late in the maneuver and is so small (less than 50 ml) that it should not affect results. Remember that the next step would be to check reproducibility criteria.

EXERCISE 15. CONTINUED:

b. Calculate the FVCs and the FEV_1 in ATPS for each curve.

Curve A: FVC _____ FEV_1 _____

Curve B: FVC _____ FEV_1 _____

Curve C: FVC _____ FEV_1 _____

c. Determine whether there is excessive variability between the two largest FVCs and the two largest FEV_1s.

FVC variability _____ FEV_1 variability _____

FEEDBACK:

b. Curve A: FVC = 3.53 L. FEV_1 = 3.09 L.

Curve B: FVC = 3.52 L. FEV_1 = 3.05 L.

Curve C: FVC = 3.35 L. FEV_1 = 2.90 L.

c. FVC variability = 10 ml (0.3%) FEV_1 variability = 40 ml (1.3%)

Curves A and B meet reproducibility criteria.

EXERCISE 15. CONTINUED:

d. Calculate the FEV_1/FVC%.

e. Calculate the $FEF_{25\text{-}75\%}$.

FEEDBACK:

d. FEV_1 /FVC% = 87.5%

e. $FEF_{25\text{-}75\%}$ = 3.5 liters/sec (ATPS)

Best curve = A

25% of FVC = 0.88 L. 75% of FVC = 2.65 L.

EXERCISE 15. CONTINUED:

f. These curves are from a 55-year-old Caucasian male welder who is 69 inches tall. The ambient temperature was 75°F. He has participated annually in his company's respiratory surveillance program. Last year his FVC was 4.34 L.(BTPS) and his FEV_1 was 3.71 L.(BTPS). What was the absolute and percent change from last year?

Absolute change FVC: _____

% of FVC change: _____

Absolute change FEV_1: _____

% of FEV_1 change: _____

FEEDBACK:

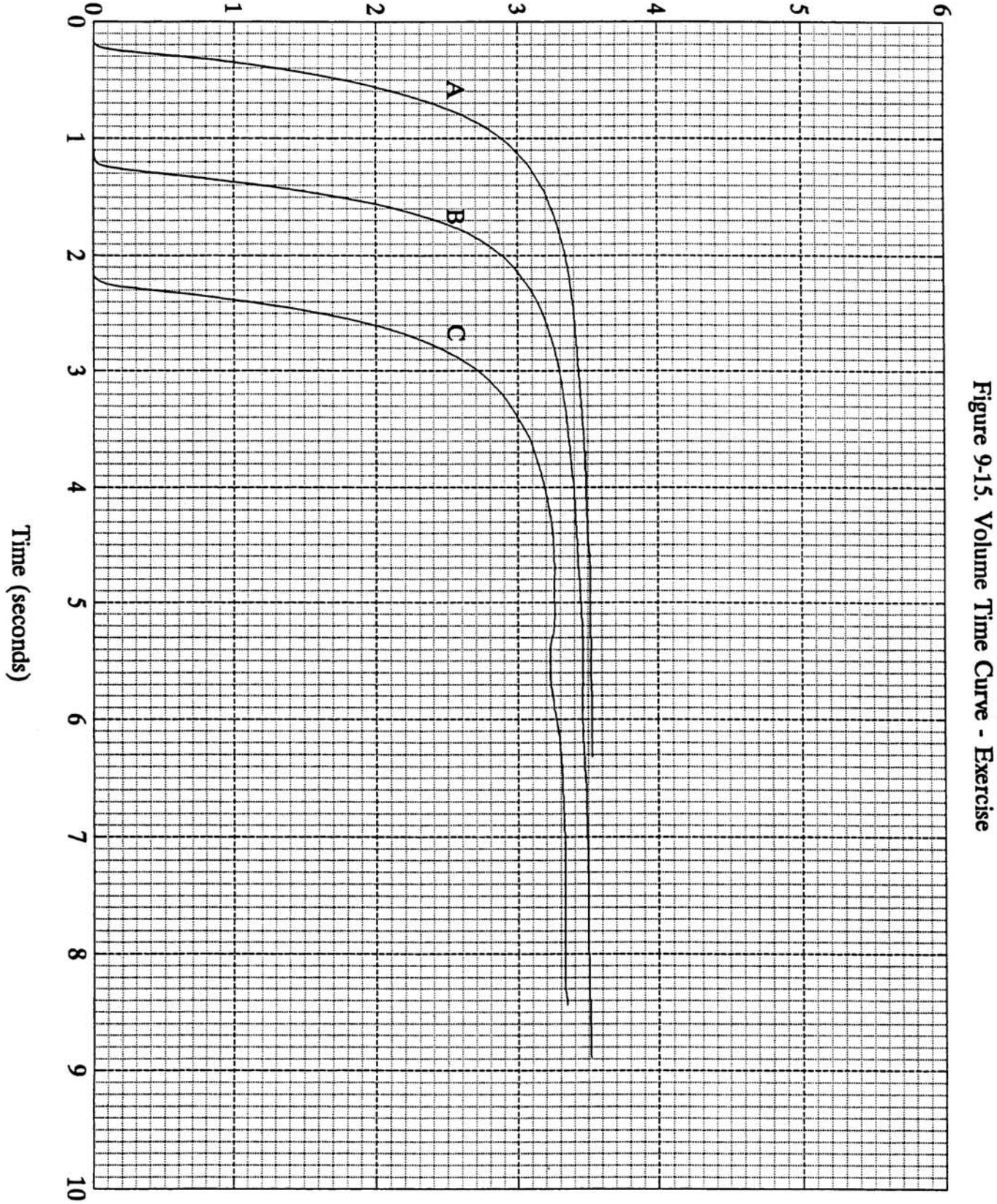
f. Absolute change FVC: -0.53 liters

% of FVC change: 12.2% decline

Absolute change FEV_1: -0.39 liters
% of FEV_1 change: 10.5% decline

Did you remember to convert the current year's test results to BTPS?

FIGURE 9-15. VOLUME TIME CURVE – EXERCISE



EXERCISE 16.

(Refer to Figure 9-16, page 9-45. Volume Time Curve - Exercise.)

a. Do at least three of these curves meet acceptability criteria?

FEEDBACK:

a. Yes. Curves A, B and C meet acceptability criteria. Curve D shows excessive extrapolated volume and early termination. To decrease the extrapolated volume, coach **Blast the Air out at first**.

EXERCISE 16. CONTINUED:

b. Calculate the FVC (ATPS) for the acceptable curves:

Curve A _____ Curve B _____ Curve C _____

c. Is there excessive variability between the two largest FVCs?

d. Calculate the FEV_1s for the acceptable curves:

Curve A _____ Curve B _____ Curve C _____

e. Is there excessive variability between the two largest FEV_1s?

FEEDBACK:

b. Curve A: FVC = 3.66 L.
Curve B: FVC = 3.60 L.
Curve C: FVC = 3.58 L.

c. No. The amount of variability is only 60 ml (1.6%) so reproducibility criteria are met.

d. Curve A: FEV_1 = 3.12 L.
Curve B: FEV_1 = 3.05 L.
Curve C: FEV_1 = 3.08 L.

e. No. The amount of variability is only 40 ml (1.3%), so reproducibility criteria are met.

EXERCISE 16. CONTINUED:

f. Convert the best FVC and FEV_1 to BTPS (the ambient temperature was 25°C).

FVC (BTPS) _____ FEV_1 (BTPS) _____

g. Calculate FEV_1/FVC%

FEV_1/FVC% _____

h. Calculate the $FEF_{25\text{-}75\%}$

$FEF_{25\text{-}75\%}$ _____

FEEDBACK:

f. FVC (BTPS) = 3.93 L. FEV_1 (BTPS) = 3.35 L.

g. FEV_1/FVC% = 85.2%

h. $FEF_{25\text{-}75\%}$ = 3.71 L/s (BTPS) Did you remember to convert BTPS?

Sum of best curve: 6.78 (Curve A)

25% of FVC = .92 L. 75% of FVC = 2.75 L.

EXERCISE 16. CONTINUED:

i. If these curves were from a 50-year-old Caucasian male, 190 cm tall, what would his predicted values be using Appendix L?

FVC pred. _____ FEV_1 pred. _____

j. What percent of the predicted are the following for the above individual?

% FVC pred. _____ % FEV_1 pred. _____

k. In the previous year's surveillance studies, his FVC was 5.01 L.(BTPS) and his FEV_1 was 4.02 L.(BTPS). Calculate the absolute and % changes for the FVC and FEV_1.

FVC absolute change _____ FVC% change _____

FEV_1 absolute change _____ FEV_1% change _____

l. Why would it be better to compare his current results to those of the previous year instead of to predicted values?

FEEDBACK:

i. FVC pred. = 5.90 L. FEV_1 pred. = 4.56 L.

j. % FVC pred. = 66.6% % FEV_1 pred. = 73.5%

k. FVC absolute change: -1.08 L.
FVC% change: 21.6% decline
FEV_1 absolute change: -0.67 L.
FEV_1% change: 16.7% decline

l. When compared to the previous year, this individual shows a greater than 15% drop in volume and FEV_1. These declines are beyond what would be expected for normal aging.

EXERCISE 16. CONTINUED:

m. If these curves were from a 50-year-old African-American male, 190 cm tall, what would his predicted values be using Appendix L?

FVC pred. _____ FEV_1 pred. _____

n. What are the percent of predicted and lower limit of normal (LLN) values for the above individual?

% FVC pred. _____ % FEV_1 pred. _____
FVC LLN _____ FEV_1 LLN _____

o. In the previous year's surveillance studies, his FVC was 4.13 L. (BTPS) and his FEV_1 was 3.60 L.(BTPS). Calculate the absolute and percent changes for the FVC and the FEV_1.

FVC absolute change _____ FVC% change _____

FEV_1 absolute change _____ FEV_1% change _____

p. What would his absolute and percentage change have been if his FVC had been 4.75 L. (BTPS) and his FEV_1 had been 3.87 L. (BTPS) in the previous year?

FVC absolute change _____ FVC% change _____

FEV_1 absolute change _____ FEV_1% change _____

q. Why would it be good to compare this individual's results to those from the previous year as well as to predicted values?

FEEDBACK:

m. FVC pred. = 4.95 L. FEV_1 pred. = 3.95 L.
Did you remember to use the race correction?

n. FVC% pred. = 79.4% FEV_1% pred. = 84.8%
FVC LLN = 3.87 L FEV_1 LLN = 3.00 L

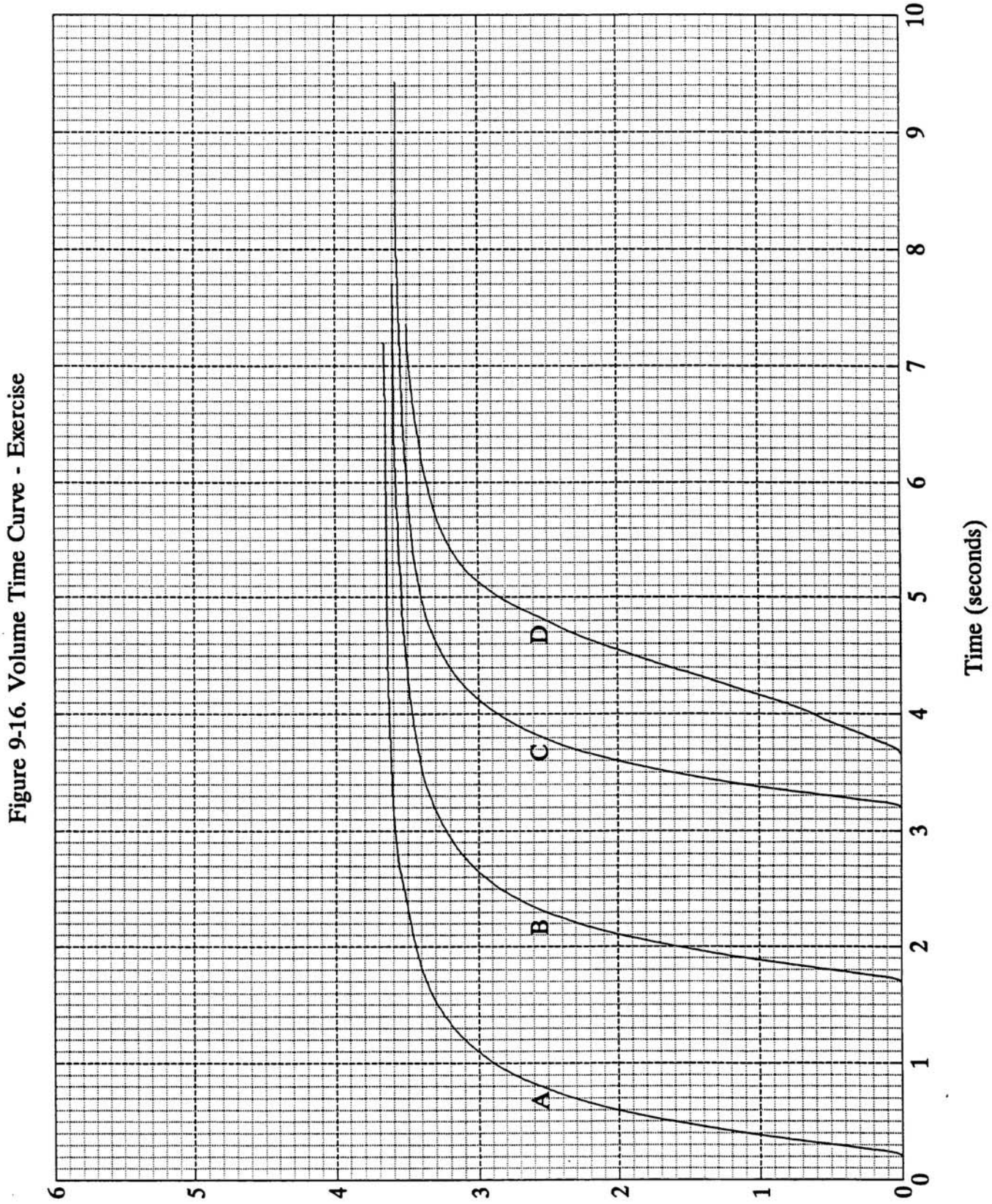
o. FVC absolute change = -0.20 L or -200 ml
FVC% change = 4.8% decline

FEV_1 absolute change = -0.25 L or -250 ml
FEV_1% change = 6.9% decline

p. FVC absolute change = -0.82 L or 820 ml
FVC% change = 17.3% decline
FEV_1 absolute change = -0.52 L or 520 ml
FEV_1% change = 13.4% decline

q. His values for the FVC and FEV_1 would be considered within the normal range because they are above the lower limit of normal (LLN). The use of the LLN is recommended by the ATS instead of percent predicted. His percent predicted FVC is 79.4% which is below 80% of predicted, but his observed FVC is 3.93 L which is above the FVC LLN of 3.87 L, so his FVC is considered normal. However, when compared to the previous year, he shows a greater than 15% drop in FVCs. This is beyond what would be expected for normal aging.

FIGURE 9-16. VOLUME TIME CURVE – EXERCISE



EXERCISE 17.

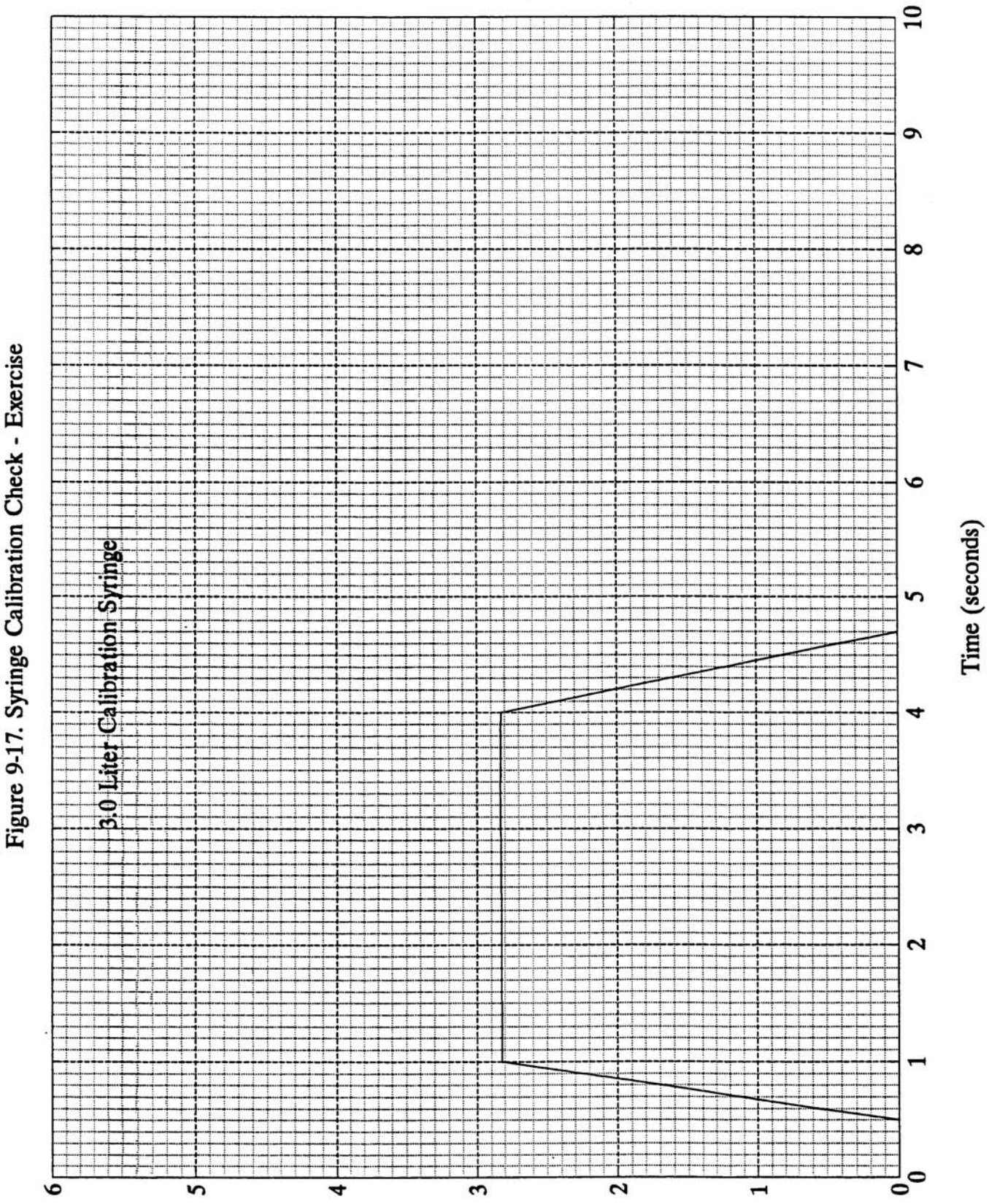
(Refer to Figure 9-17, page 9-47. Syringe Calibration Check - Exercise.)

a. The tracing in Figure 9-17 was made when you injected 3 liters of air with a calibrated syringe into your spirometer. Is your spirometer in need of repair?

FEEDBACK:

a. Yes. The tracing reads 2.83 liters, which is outside of the acceptable range (between 2.91-3.09). It is also 5.7% of 3 liters, which is outside the range of $\pm$3%.

FIGURE 9-17. SYRINGE CALIBRATION CHECK – EXERCISE



EXERCISE 18.

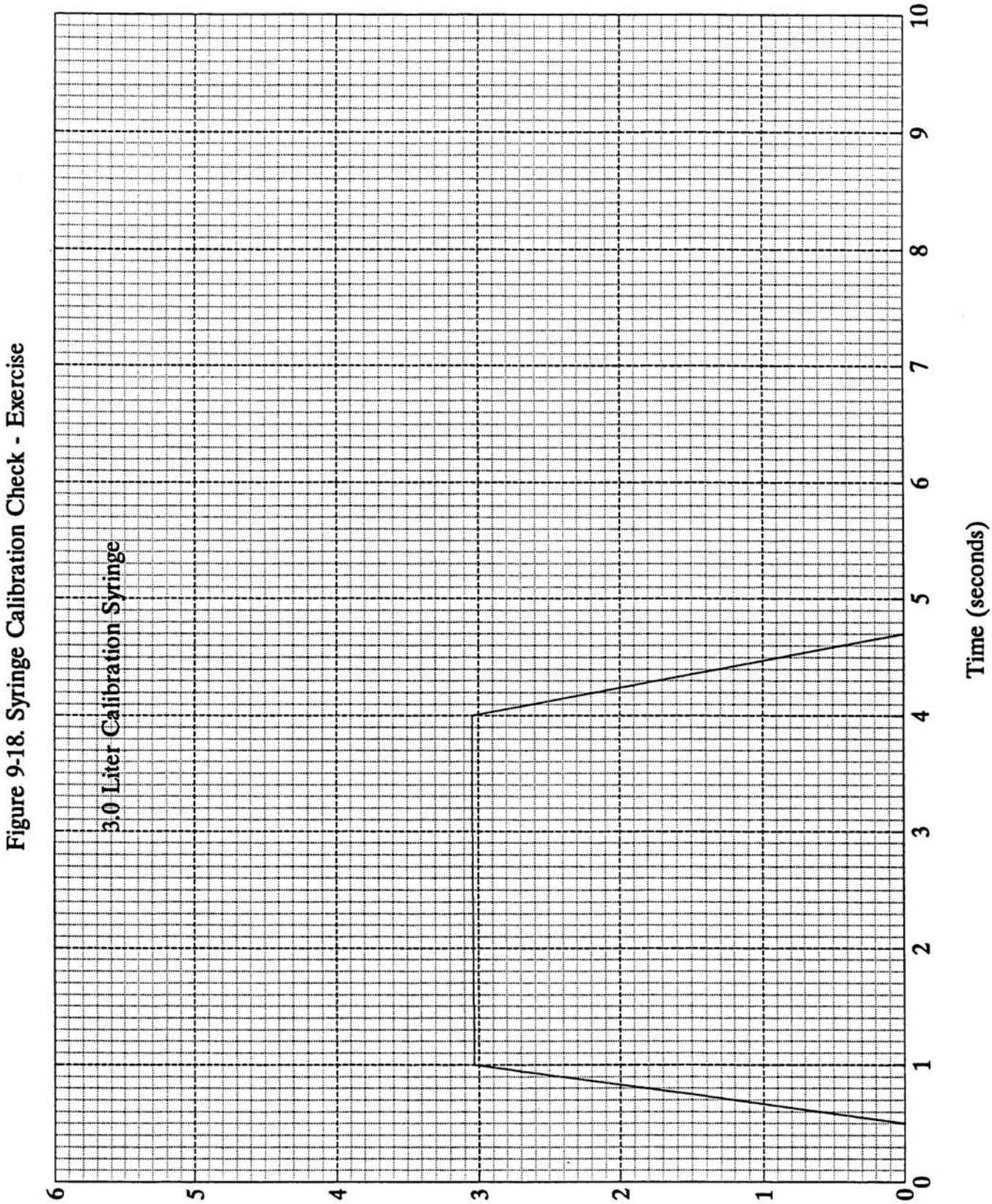
(Refer to Figure 9-18. Syringe Calibration Check - Exercise.)

a. Your spirometer has been repaired and you want to check that it is now properly recording volumes. The tracing in Figure 9-18 was made when you injected 3 liters of air with a calibrated syringe. Are the results acceptable?

FEEDBACK:

a. Yes. The tracing reads 3.04 liters, which is 1.3% more than 3 liters. This is in the acceptable range of ±3% or between 2.91-3.09 liters.

FIGURE 9-18. SYRINGE CALIBRATION CHECK – EXERCISE



EXERCISE 19.

Consider the following 10 year record of FEV_1 and FVC for a male cotton worker. All results have been corrected for BTPS.

a. How do the 1989 values for FEV_1 and FVC compare with the previous high (expressed as an absolute change)?

b. How do these changes compare with the expected decline due to aging alone?

YEAR	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
FVC	5.34	5.40	5.32	5.30	5.28	5.27	5.26	5.24	5.21	5.19
FEV_1	4.37	4.38	4.35	4.34	4.31	4.30	4.28	4.22	4.21	4.16

FEEDBACK:

a. Previous high FVC (1981) = 5.40 L.
1989 FVC = 5.19 L.
Absolute change: -0.21 L.

Previous high FEV_1 (1981) = 4.38 L.
1989 FEV_1 = 4.16 L.
Absolute change: -0.22 L.

b. Expected decline in FVC for males = 0.025 L/year on the average.
8 years x 0.025 L/year = 0.20 L loss in FVC expected over 8 years.
The observed loss of 0.21 L. is approximately what would be expected simply due to aging.

Expected decline in FEV_1 for males = 0.030 L/year on the average.
8 years x 0.03 L/year = 0.24 L. loss in FEV_1 expected over 8 years.

The observed loss of 0.22 L over 8 years is not more than would be expected simply due to aging.

EXERCISE 20:

A 20-year-old Mexican-American male, 180 cm tall, is exposed to cotton dust on his job. His company performs routine pre-and post-shift spirometry as part of its medical surveillance program. The morning ambient temperature was 24°C. The afternoon ambient temperature was 27°C.

Results from the best FVCs and FEV_1s are given below:

Pre-shift:
FVC (ATPS) = 4.42 L. FEV_1 (ATPS) = 3.87 L.

Post-shift:
FVC (ATPS) = 3.82 L. FEV_1 (ATPS) = 3.33 L.

a. Calculate the following:

Pre-shift:
FEV_1 predicted (Appendix L) _____

FEV_1 %predicted_____

FEV_1/FVC% _____

Post-shift:
FEV_1 predicted (Appendix L) _____

FEV_1 %predicted_____

FEV_1/FVC% _____

Absolute change in FEV_1 _____

% change in FEV_1 _____

b. What would you say to the company doctor?

FEEDBACK:

a. Preshift:
FVC (BTPS) = 4.77 L. FEV_1 (BTPS) = 4.18 L.

Post-shift:
FVC (BTPS) = 4.06 L. FEV_1 (BTPS) = 3.54 L.

Pre-shift:
FEV_1% predicted: 84.6%
(Appendix L predicted 4.94 L.)
FEV_1/FVC%: 87.6%

Post-shift:
FEV_1% predicted: 71.7%
FEV_1/FVC%: 87.1%
Absolute change in FEV_1: -640 ml or 0.64 liters
Percentage change in FEV_1: 15.3% decline

b. Follow your company's reporting protocols, making sure that the large FEV_1 decline is brought to the attention of the health professional in charge of the respiratory surveillance program.

EXERCISE 21:

Your department gets a new director of occupational medicine who wants to know what your spirometry quality assurance program entails. How do you respond?

FEEDBACK:

Refer to **Unit Three: The Quality Assurance Program**, **Unit Four: Spirometric Technique**, **Unit Five: Basic Spirometric Calculations** and **Unit Six: Comparing Observed to Predicted Normal Values**. You would probably want to discuss:

a. How you ensure precision and accuracy of your equipment.

b. The measures you take to obtain acceptable and reproducible spirograms.

c. The predicted values used.

EXERCISE 22:

While you were on vacation, your substitute forgot to calibrate equipment according to your company's protocols. When you return, you discover that a 3-liter syringe calibration is 10% greater than it should be. What do you tell the company physician who wants to review the test results taken in your absence? What could you do to prevent this from happening again?

FEEDBACK:

Possible responses:

a. Refer to **Unit Three: The Quality Assurance Program** to explain to the company doctor why the results can't be used.

b. Review quality assurance procedures with your substitute before taking time off and explain the consequences of not carrying out the procedures.

EXERCISE 23:

While you were at a conference, your substitute performs spirometry on several subjects in an ongoing annual surveillance program. You take a look at the results before passing them on to the physician. One subject showed a significant decline in the FVC and FEV_1 from the previous year's results. You decide to call the subject to ask a few questions since the substitute didn't indicate any problems on the chart. You find out that the subject has just returned from medical leave for abdominal surgery. What should you do?

FEEDBACK:

Possible responses:

a. Inform the company doctor of the surgery.

b. Review other test results taken by the substitute to see if other "red flags" appear since he/she may have forgotten to check on which subjects should be postponed for spirometry.

c. Review subject selection criteria with your substitute.

EXERCISE 24.

You are training a new spirometry assistant. He suggests that since the room in which you perform the test is usually around 23°C, you could use that number all of the time to calculate BTPS. How do you respond?

FEEDBACK:

A possible response might be to measure your testing room over a week's time and document the temperature fluctuations, however minor. Then you could show your assistant how even a difference of a few degrees can affect tests results.

EXERCISE 25:

The new nurse in your unit wants to try out your spirometer. After she performs three acceptable and reproducible maneuvers, the computer prints out the following best results: FVC = 3.83 L. (ATPS); FEV_1 = 2.91 (ATPS).

She is 50 years old, Caucasian and 67 inches tall. The room temperature was 75°F.

a. You decide to draw a curve for her to explain what the results mean. Draw the FVC and FEV_1 on the attached graph paper, using volume (liters) as the vertical axes and time (seconds) as the horizontal axis.

b. What would her predicted values be using Appendix L? Add the predicted curve to the curve you already drew and label accordingly.

c. Calculate her percent of predicted values for:

   % FVC pred. _____ % FEV_1 pred. _____

FEEDBACK:

b. FVC pred. = 3.91 L. FEV_1 pred. = 3.09 L. Note: 67 inches is about 170 cm. 75°F is about 24°C

c. % FVC pred. = 105.9% % FEV_1 pred. = 101.6%
   Did you remember to convert to BTPS?

   FVC (BTPS) = 4.14 L. FEV_1 (BTPS) = 3.14 L.

EXERCISE 26:

The new nurse reads in a journal that spirometry alone is not adequate for a pulmonary surveillance program and she asks you for clarification. What do you tell her?

FEEDBACK:

Refer to **Unit Two: Overview of Spirometry**.

UNIT TEN: ADDITIONAL EXERCISES MEASURING EXTRAPOLATED VOLUME

Figures 10-1 through Figure 10-9 are additional exercises to practice measuring extrapolated volumes. Determine whether there is excessive extrapolated volume.

FEEDBACK: The extrapolated volumes are:

Figure 10-1	0.160 L (10.7%) excessive
Figure 10-2	0.125 L (9.4%) less than 0.15 L so OK
Figure 10-3	0.120 L (5.8%) less than 0.15 L so OK
Figure 10-4	0.130 L (5.7%) less than 0.15 L so OK
Figure 10-5	0.270 L (5.1%) excessive
Figure 10-6	0.570 L (11%) excessive
Figure 10-7	0.370 L (11.3%) excessive
Figure 10-8	0.270 L (9.8%) excessive
Figure 10-9	0.660 L (13.0%) excessive

FIGURE 10-1. EXTRAPOLATED VOLUME EXERCISE

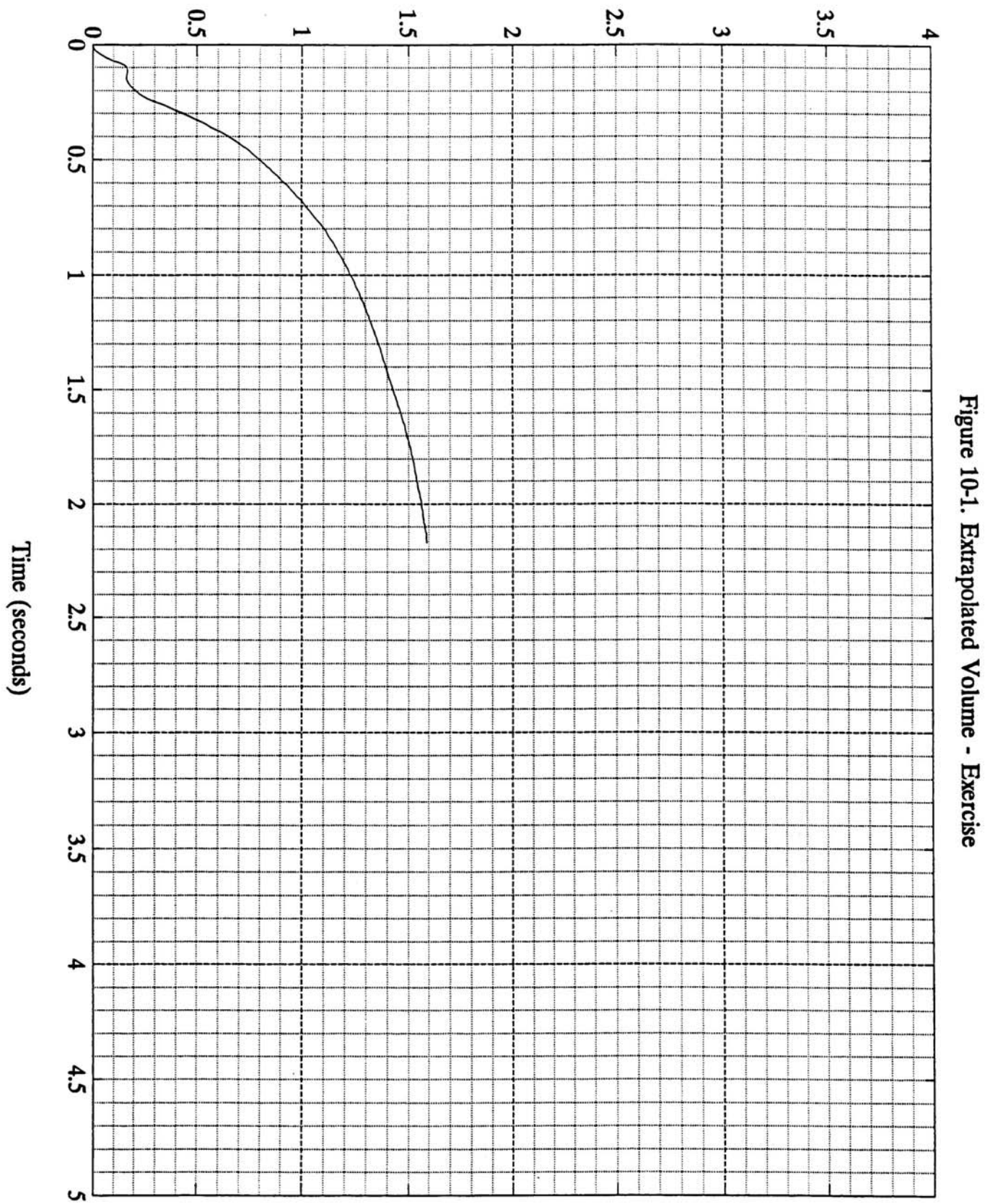


FIGURE 10-2. EXTRAPOLATED VOLUME EXERCISE

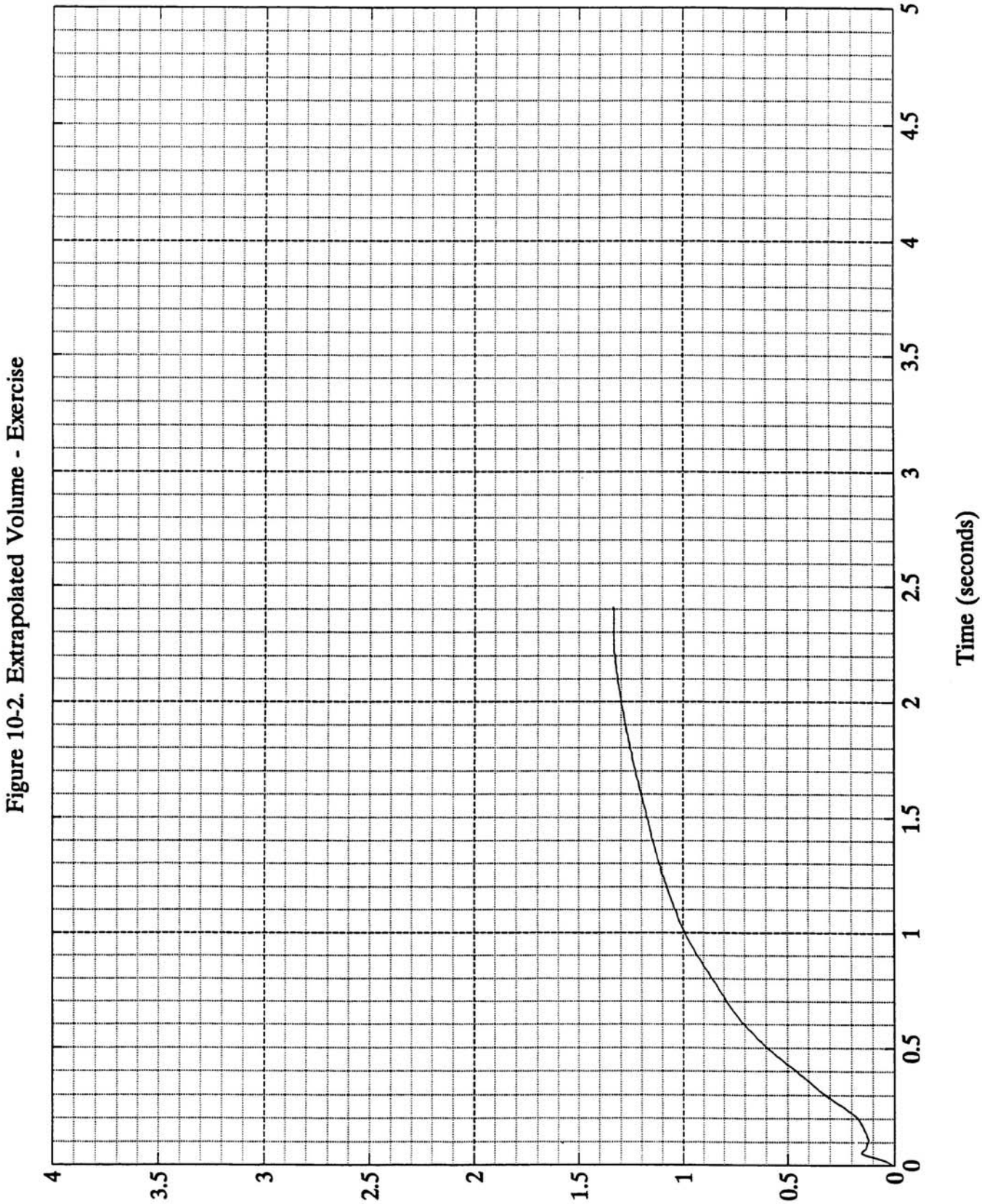


FIGURE 10-3. EXTRAPOLATED VOLUME EXERCISE

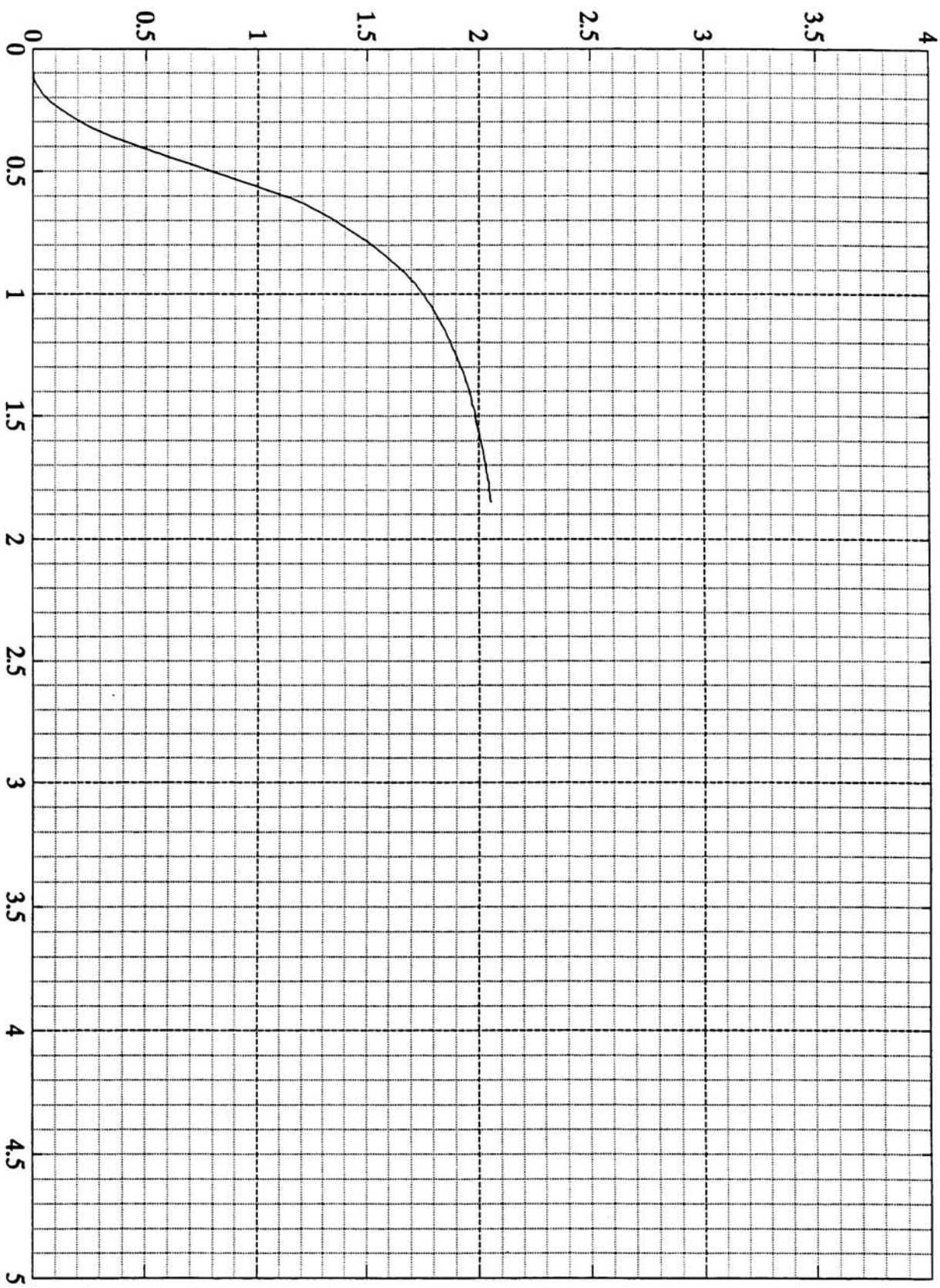


FIGURE 10-4. EXTRAPOLATED VOLUME EXERCISE

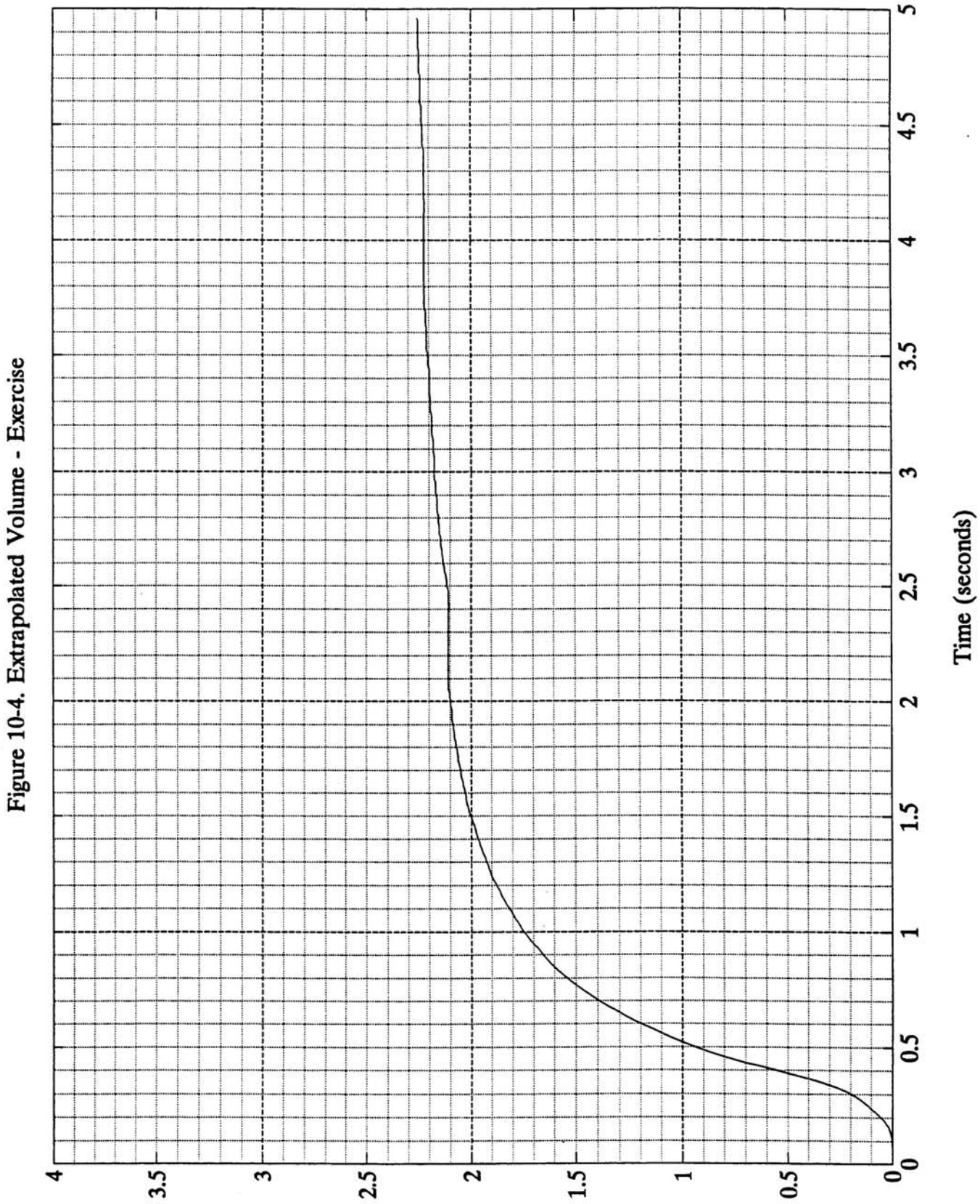


FIGURE 10-5. EXTRAPOLATED VOLUME EXERCISE

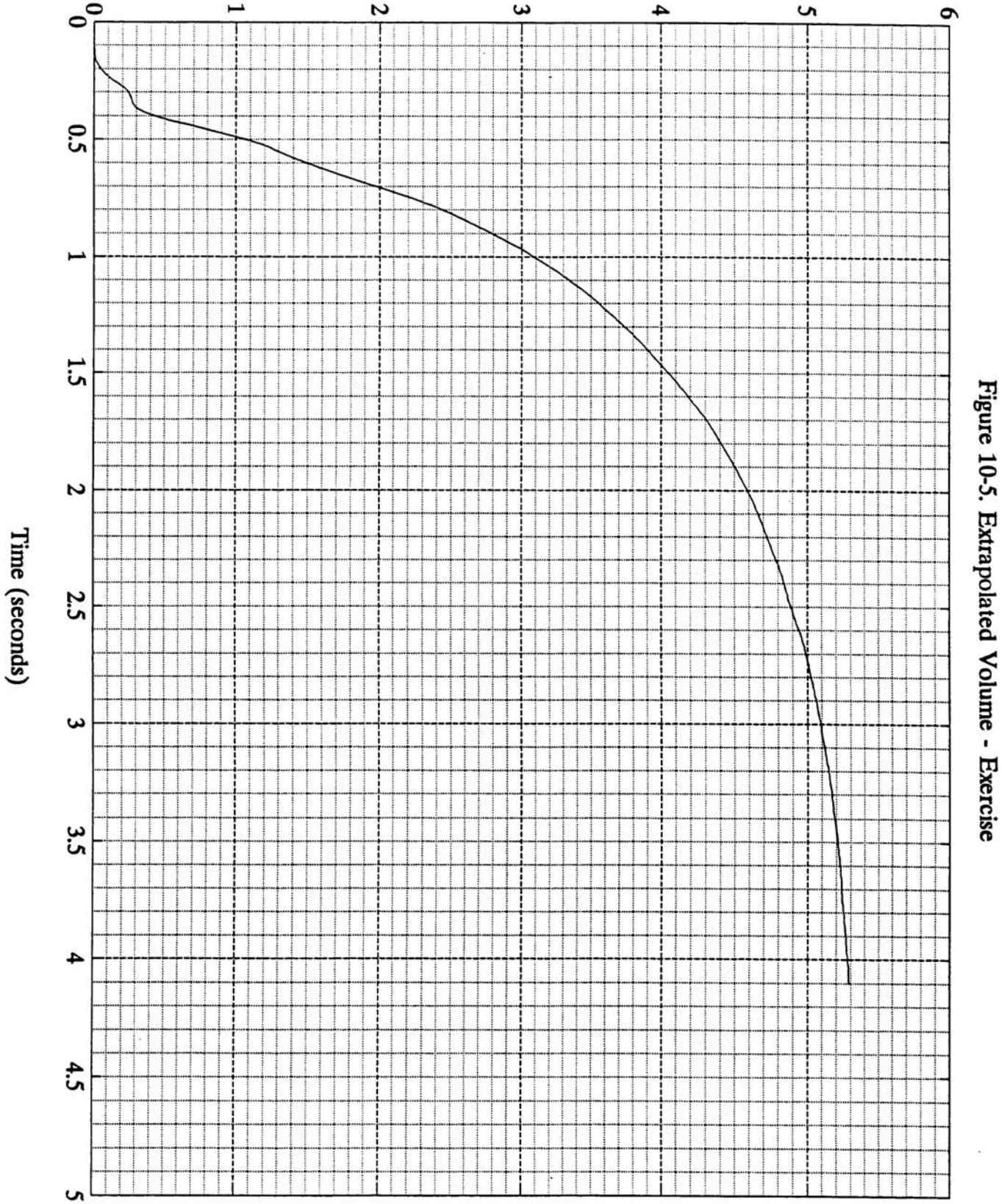


FIGURE 10-6. EXTRAPOLATED VOLUME EXERCISE

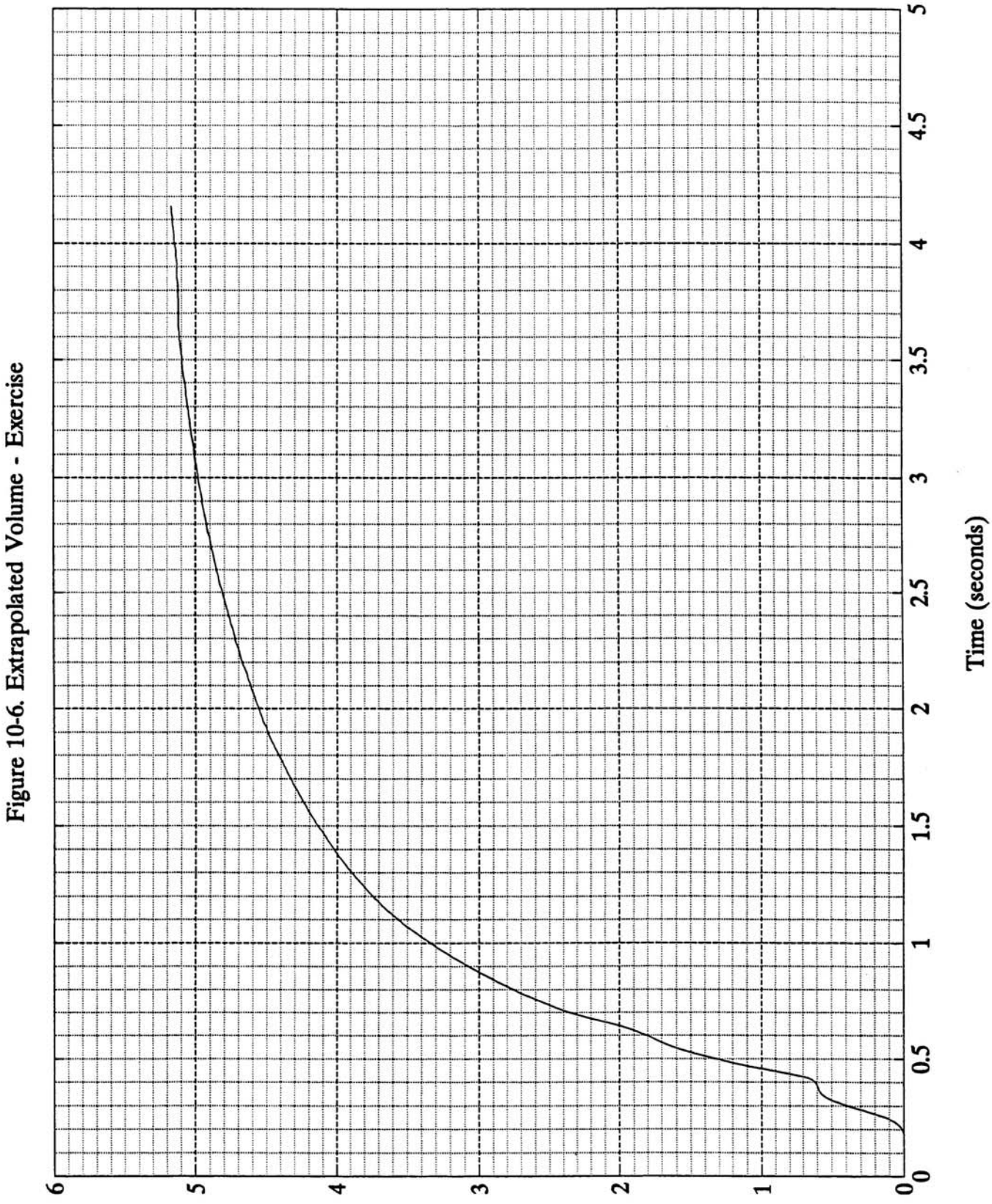


FIGURE 10-7. EXTRAPOLATED VOLUME EXERCISE

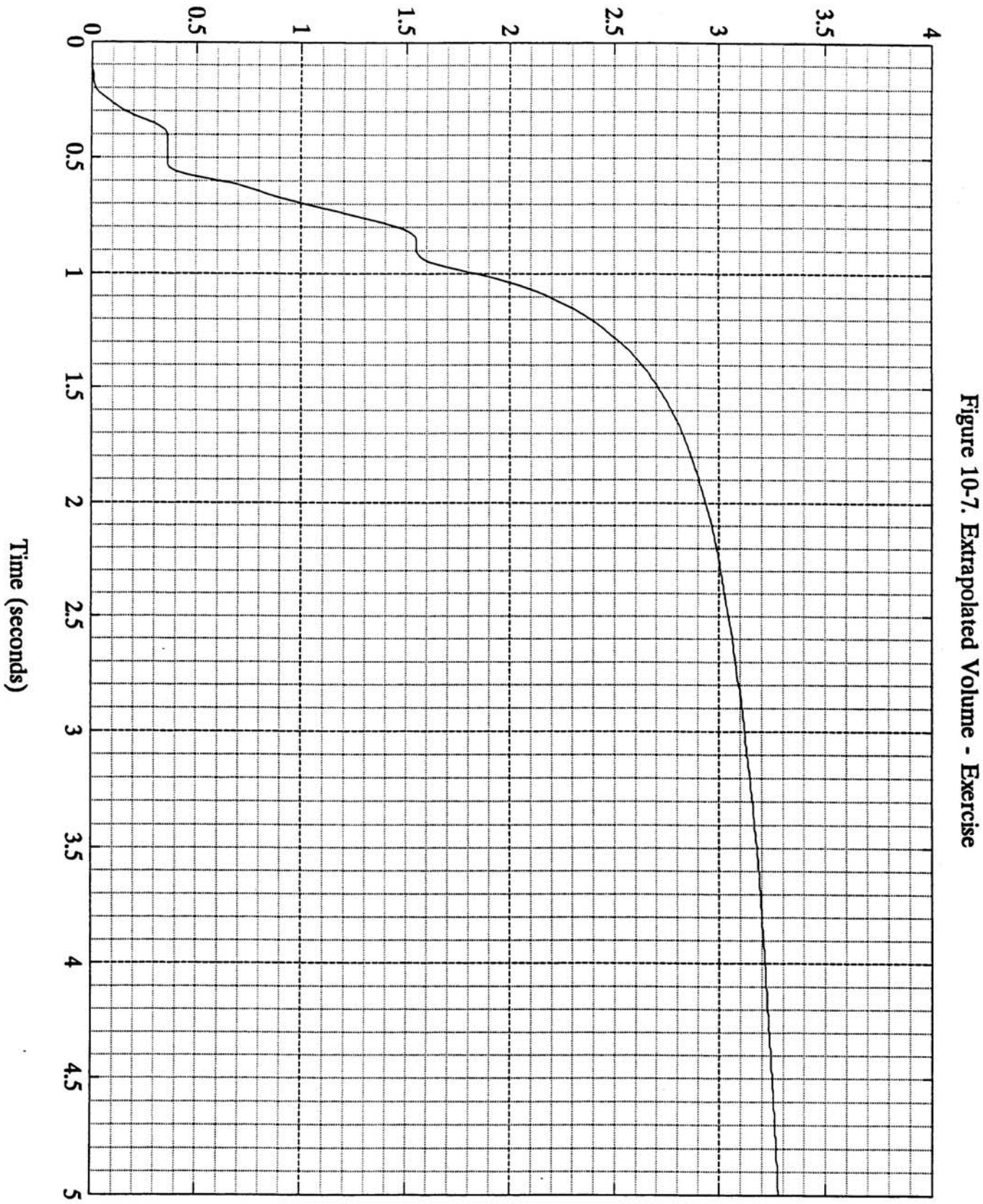


FIGURE 10-8. EXTRAPOLATED VOLUME EXERCISE

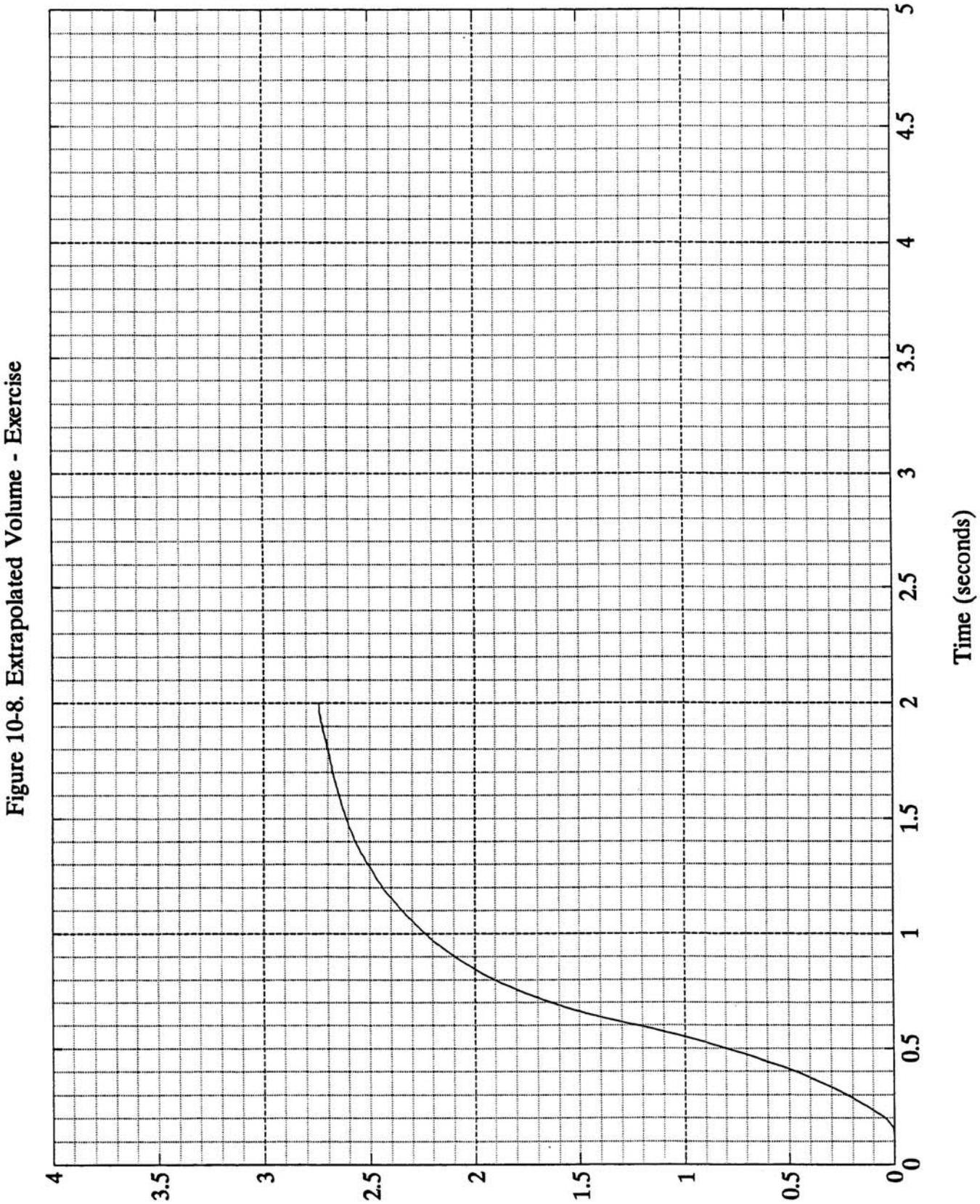
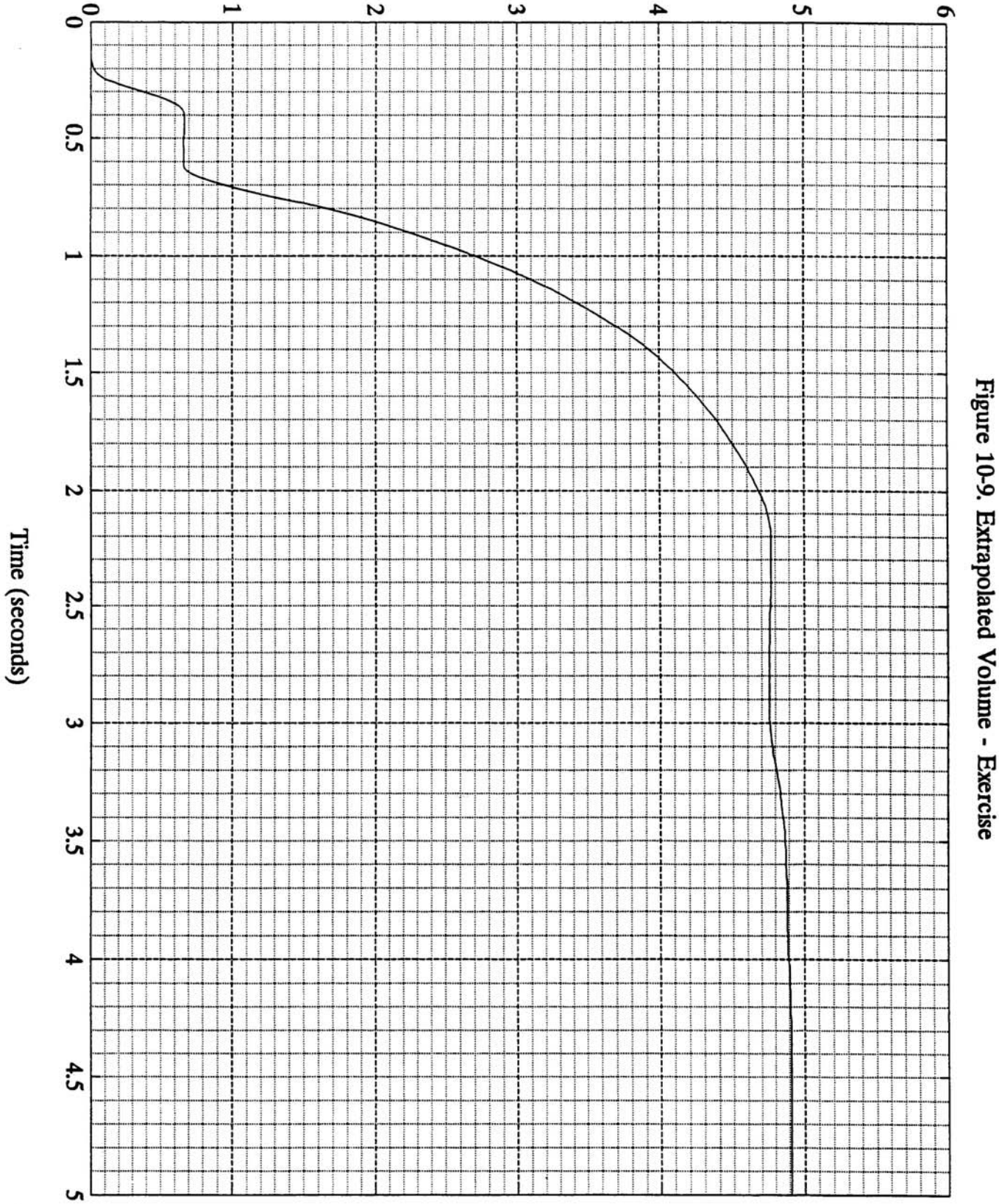


FIGURE 10-9. EXTRAPOLATED VOLUME EXERCISE



APPENDIX A: GLOSSARY OF TERMS COMMONLY USED IN SPIROMETRY

ACCEPTABLE SPIROGRAM. A forced expiratory maneuver, after a maximal inhalation, that is free from hesitation or false starts, coughs, early termination, variable effort, or baseline errors. Three acceptable maneuvers should be obtained before evaluating excessive variability.

ACCURATE. A measurement that is very close to the true value or is free of error. In practical terms, a measurement that is within a predetermined range of the true measurement value.

AIRFLOW RESISTANCE. The degree of ease in which air can pass through the airways. The number, length, and diameter of the airways determine the amount of resistance that exists.

ATS. The American Thoracic Society promotes the improvement of spirometry through the use of their recommendations.

ATPS. The letters stand for ambient temperature and pressure saturated with water vapor. Volumes measured directly from the spirogram of a volume type spirometer (not yet adjusted for BTPS) are at ATPS.

BACK EXTRAPOLATION. The method for determining zero time from a spirogram, particularly important when the exact starting point of a forced expiratory maneuver is not obvious. Since the FEV_1 is affected by the point on the graph that is selected as the start, a uniform way to determine this must be used.

BEST CURVE. An acceptable spirogram that has the largest sum of the FEV_1 and the FVC.

BTPS. The letters stand for body temperature and pressure saturated with water vapor. A volume of gas will shrink when cooled. The volume of air exhaled into a spirometer from the lungs will contract because the lungs are warmer than the spirometer. Therefore, it is necessary to adjust the recorded values with a BTPS conversion factor to determine the actual volume of air exhaled before it contracted. This corrects the volume of air saturated with water vapor to body temperature for various spirometer temperatures.

CALIBRATION CHECK. Periodic determination of a spirometer's ability to make accurate measurements of volume and time (and flow if appropriate).

COMPLIANCE. This affects the amount of pressure needed to increase or decrease the volume of the lung. Lungs with emphysema have a high compliance while lungs with interstitial lung disease have a low lung compliance.

ELASTIC RECOIL. The ability of the lung to return to its resting state. The natural recoil or elasticity of the lung during expiration.

END OF TEST. The point during the forced expiratory maneuver when a plateau is reached.

EXPIRATORY RESERVE VOLUME (ERV). The maximal amount of air forcefully exhaled after a normal inspiration and expiration.

EXPIRATORY TIME. The time required for the subject to reach his largest volume (FVC). For quality control purposes, total expiratory time is the time from the beginning of exhalation to the end of the subject's expiratory maneuver. As a rule of thumb, total expiratory time should be greater than 6-seconds.

EXTRAPOLATED VOLUME. The volume that was determined by a perpendicular line drawn from the point where time equals zero to where it intersects the FVC curve. The extrapolated volume must be less than 150 ml (for FVCs less than 3 L) or less than 5% (for FVCs greater than 3 L) for the tracing to be acceptable. A high extrapolated volume is due to a slow start or hesitation in the start of the maneuver.

$FEF_{25-75\%}$. Mid forced expiratory flow measured from the point at which 25% of the FVC is achieved to the 75% point (during the middle half of the FVC). Also called mid-expiratory flow and abbreviated MMEF, MMFR, or MMF.

FEV_1/FVC (given as % or ratio). Forced expiratory volume in one second expressed as a percent of the forced vital capacity is the fraction of the total that is exhaled in the first second. It is the index of the speed of expiratory airflow. It is calculated by using the largest FEV_1 and the largest FVC, even if they are not from the same curve. A low FEV_1/FVC% is associated with airways obstruction.

FLOW/VOLUME LOOP. A tracing of flow rate (on the "y" or vertical axis) against volume (on the "x" or horizontal axis) for a forced expiratory maneuver followed by a maximal inhalation.

FLOW SPIROMETER. A type of spirometer that measures how fast the air moves in or out of the lungs. Flow spirometers are usually smaller than volume spirometers. Examples include pneumotachograph, hot wire anemometer, and rotating vane.

FORCED EXPIRATORY MANEUVER. The basic maneuver of spirometry where the subject takes the deepest possible breath and blows into the mouthpiece as hard, fast and completely as possible. Also known as the forced vital capacity maneuver.

FORCED EXPIRATORY VOLUME IN ONE SECOND (FEV_1). The volume of air exhaled during the first second of a forced expiratory maneuver. It may also be considered the average flow during the first second of the FVC maneuver.

FORCED VITAL CAPACITY (FVC). The maximal volume of air which can be exhaled forcefully after maximal inspiration. **NOTE:** The **vital capacity** is the amount of air that can be exhaled by an individual after taking the deepest breath possible, whether or not the air is exhaled forcefully (FVC) or slowly (VC).

INSPIRATORY RESERVE VOLUME (IRV). The maximal amount of air forcefully inhaled after a normal inhalation.

INSTRUMENT FACTOR. In certain water-seal spirometers, it refers to a constant indicating the volume of displacement per millimeter of vertical movement of the bell.

LLN. The lower limit of normal is the value below which only 5% of a “normal” reference population should have observed values. The specific value of the LLN is dependent on the study population and methods used to derive the reference values. LLNs should be available from the reference value source.

LONGITUDINAL STUDIES. Data collected from the same individual or group at regular intervals over an extended period of time. The values of a current test are compared to the individual's or group's previous test results.

OBSTRUCTIVE LUNG DISEASES. Diseases that reduce flow from the lungs. These diseases include asthma, chronic bronchitis, and emphysema.

PRECISE. Capable of giving consistent, reproducible results on successive times. A spirometer that is not properly calibrated may produce precise results that are not accurate.

PREDICTED NORMAL VALUES. Expected values for various lung volumes and flow rates, derived from healthy non-smoking populations. The values are adjusted for sex, age, height, and race.

REAL TIME TRACING. A spirogram that is made as the forced expiratory maneuver is performed.

REPRODUCIBILITY. The ability of a test to obtain the same result from an individual when it is repeated several times. Reproducibility is determined by checking for excess variability between the two largest values for FVC and FEV_1 obtained from three acceptable spirograms.

RESIDUAL VOLUME (RV). The amount of air remaining in the lungs after a complete exhalation. This cannot be measured by spirometry.

RESTRICTIVE LUNG DISEASES. Diseases that reduce the ability of the lungs to expand fully but do not necessarily affect air flow. Asbestosis and silicosis, two of the most common of the occupationally caused restrictive diseases, are caused by the development of fibrotic tissue in the lungs.

SPIROGRAM. A single tracing or graphic recording of breathing maneuvers. Given as volume/time or flow/volume tracings depending on the type of spirometer used.

SPIROMETER. An instrument for measuring lung volumes and flow rates. The two primary types are volume sensing and flow sensing spirometers.

SYNERGISM. The combined effect of two or more substances is greater than the effects of each substance added together.

TIDAL VOLUME (TV). The volume of air inhaled and exhaled during quiet, normal breathing.

TOTAL LUNG CAPACITY (TLC). The sum of the vital capacity and the residual volume.

VITAL CAPACITY (VC). The maximum amount of air that can be exhaled after the fullest inhalation possible. The sum of tidal volume, expiratory reserve volume, and inspiratory reserve volume. May be measured either during inhalation or exhalation.

VOLUME SPIROMETER. A type of spirometer that records the amount of air inhaled or exhaled within a certain time. Examples include water-seal, dry rolling-seal, and bellows instruments.

ZERO TIME POINT. In the measurement of the FEV_1, the point selected as the start of the test, obtained using back extrapolation.

APPENDIX B. AN OVERVIEW OF OCCUPATIONAL LUNG HAZARDS

Types of Lung Hazards

Occupational pulmonary contaminants come in many forms. Some can be seen, smelled, or felt as irritants in the nose or throat. But others can only be detected with special equipment. Short-term exposure to many toxicants can cause immediate, acute damage. However, most contaminants take repeated or constant exposure over months or years to cause disease or permanent harm. The impact of pulmonary hazards is also influenced by air pollution in general, age, smoking history, nutritional status, and other less well understood factors such as genetics and stress.

Many work processes generate several contaminants at the same time. The health consequences of these hazards can simply be additive or, worse, they can be synergistic. Thus it is essential to know what materials and processes are used on the job to be able to evaluate, monitor, and control potential pulmonary hazards. (It is beyond the scope of this guide to cover hazard control measures. However it should be noted that most occupational exposures to airborne hazards can be greatly reduced or eliminated through engineering controls, such as improving ventilation; good work practices; and the use of personal protective equipment, such as properly selected and maintained respirators. Refer to Fundamentals of Industrial Hygiene for an overview of control measures (43).

Two approaches are commonly used to categorize occupational lung hazards. The first approach uses a medical framework to classify hazards by their impact on the respiratory tract. Thus, hazards causing similar health effects are grouped together, whether or not the hazards themselves share similar properties. In the second approach, an industrial hygiene framework is used to group hazards by their common properties and the methods by which they are generated. Both approaches are given below.

Hazards Classified by Their Impact on the Respiratory Tract

ASPHYXIANTS:	Gases that deprive the body tissues of oxygen.
Simple Asphyxiants:	Physiologically inert gases that displace oxygen in the blood and at high enough concentrations cause suffocation.
Examples:	Nitrogen, methane, argon, neon, helium.
Chemical Asphyxiants:	Gases that interfere with the body's ability to utilize oxygen (e.g., by binding to hemoglobin or preventing chemical reactions needed to utilize oxygen in the cells).
Examples:	Carbon monoxide, cyanide compounds, arsenic.
IRRITANTS:	Substances that irritate air passages leading to airway constriction. Asthmatic symptoms, difficulty breathing, pulmonary edema and infection may result.
Examples:	Chlorine, hydrogen chloride, hydrogen fluoride, ammonia, fluorine, sulfur dioxide, phosgene, oxides of nitrogen, ozone.
FIBROSIS PRODUCERS:	Substances that cause fibrotic tissues changes associated with restrictive diseases.
Examples:	Asbestos, beryllium, silica, coal dust, other inorganic and organic dusts.
ALLERGENS:	Substances that induce an allergic response characterized by bronchoconstriction. This can occur even if previous exposures produced no ill effects.
Examples:	Isocyanates, fungal spores, formaldehyde, animal dander.
CARCINOGENS:	Substances that can cause or lead to cancer.
Examples:	Asbestos, cigarette smoke, chromium, uranium, arsenic, coke oven emissions.

Hazards Classified by Their Properties

Although some contaminants may not adversely affect the lungs, the lungs provide the means through which they enter the bloodstream and harm other organs or impair the blood's oxygen-carrying capacity. These types of health effects are not detectable through spirometry. However, the hazards that cause them are included to show the range of ways in which respirable contaminants damage the body.

The information below was adapted from Occupational Lung Diseases: An Introduction (44).

DUSTS

Mineral Dusts:	Dusts and mineral fibers formed from stones, rocks, and ores. Examples include asbestos, crystalline silica, and coal dust.
Sources:	Mining, quarrying, tunneling, blasting, smelting, grinding, milling, processing, etc.
Health Effects:	Most are inert and not readily dissolved or broken down. They accumulate in the lungs after overloading lung-clearing mechanisms. Can lead to pneumoconioses, chronic bronchitis, emphysema, cardiac complications and can initiate other disease processes, such as fibrosis or cancer. They are associated with the class of fibrotic occupational lung diseases called pneumoconioses.
Organic Dusts:	Dusts formed from living materials (e.g., microorganisms, plants, and animals) and natural products such as wood and leather.
Sources:	Plant products (e.g., cotton, wood, cereal grains, spices, coffee beans, etc.): planting, harvesting, storing, transporting, processing (grinding, cutting, spinning, etc.). Animal husbandry: droppings, dander, feathers, etc.
Health Effects:	Don't usually accumulate, but dissolve or break down. Can cause hypersensitivity reactions, such as occupational asthma, byssinosis (from cotton), or hypersensitivity pneumonitis. Can lead to permanent obstructive disease or diffuse lung fibrosis. Certain wood dusts have also been associated with cancer.

Chemical Dusts:	Synthetic chemicals that come in powder form (e.g., pesticides, pharmaceuticals, dyes, bleaching agents, detergents, paints, etc.)
Sources:	While making, drying, and packaging mixtures; preparing for use, applying, drying, as a result of weathering (such as paints on exterior walls), etc.
Health Effects:	Dependent on the toxic properties of the specific chemicals. A number are irritants or allergens; others have a caustic effect and can cause chemical burns. Some are toxic to cells or tissue. Some enter the body through the lungs and cause cancer in the lungs or other parts of the body.
FUMES:	Very small solid particles formed when hot vapors (usually from metals or polymers) cool rapidly and condense. Hazardous gases may be given off at the same time. In the lungs, fumes act like a very fine mineral dust.
Sources:	High heat processes (e.g., welding, furnace work, smelting).
Health Effects:	Difficult to assess effects of individual materials since usually several hazards are present at the same time. Can lead to Metal or Polymer Fume Fever, emphysema, and lung cancer. NOTE: Smoke is not usually classified as a separate category because it is a mixture of gases and solid particles.
MISTS & SPRAYS:	Liquid droplets suspended in air or other propellant gas.
Sources:	Used widely in industry, especially for applying substances to hard-to-reach surfaces; or substances that might damage the skin if applied by hand (e.g., cleaning products, pesticides, paints, cosmetic products, rust removers, etc.) Also, as by-products from other processes, such as from cutting oils in machine shops.
Health Effects:	The finer the spray, the deeper the penetration in the lungs. Effects depend on the material being sprayed, the concentration and the temperature. Can range from chemical burns to the lungs to various forms of cancer.

GASES: Fluids that expand to fill the space that contains them. Can travel quickly from the point of origin. Many are highly flammable, explosive when mixed with air, or chemically or physiologically reactive. Some are both colorless and odorless.

Sources: Natural chemical reactions (e.g., methane from coal fields, nitrogen oxides from fermenting silage, and methane and hydrogen sulfide from sewage treatment or landfills). Manmade chemical reactions (e.g., from industrial processes, ozone from smog, and interactions between cleaning products such as ammonia and chlorine bleach). In industrial settings, gases may be emitted during their manufacture, handling, or transporting, if protective measures aren't taken. Also produced during high-heat processes (e.g., furnace work, welding, brazing, smelting, oven-drying, accidental burning of some synthetic materials).

Health Effects: Physiologically inert gases (e.g., methane and nitrogen) can cause suffocation by displacing oxygen (simple asphyxiants). Others interfere with the use of oxygen (e.g., carbon monoxide and cyanide) (physiologic asphyxiants).

Gases that are immediately irritating (e.g., ammonia, bromine, sulfur dioxide, chlorine): Sudden intense exposure to these gases can cause severe irritation that burns the lungs or closes the trachea. Low level exposures may constrict airways and aggravate existing lung disease.

Gases that are not immediately irritating (e.g., phosgene and nitrogen oxides): These gases penetrate deeply into the lungs causing pulmonary edema and other serious complications without producing upper respiratory symptoms.

Carcinogenic gases (e.g., radioactive gases, nickel carbonyl, vinyl chloride gas): Cancers from these gases typically take years to develop and the exact cause may be hard to trace. The site of the cancer may be other than the lung.

VAPORS: The technical term for the gaseous form of a liquid that always is found over that liquid. More vaporizing occurs as the liquid approaches the boiling point. Vapors affect the lungs in similar ways to gases. The main difference between vapors and gases is that vapors are always found over their parent liquids while gases aren't always associated with their liquid forms.

Sources:	Inorganic substances: Most have high boiling points and don't vaporize at room temperature. These usually are not associated with lung disease. Organic vapors: Many vaporize at room temperature. Usually used as solvents (ketones, aromatic hydrocarbons, alcohols, acetates).
Health Effects:	Many organic vapors enter the body through the lungs. Although the lungs are not harmed, extensive harm may be done to other organs. Damage to the brain and central nervous system, pulmonary edema, and tracheobronchitis (mercury and related compounds). Hypersensitivity reactions (polyvinyl chloride), cancer (benzidene and related compounds).
RADIATION:	Non-ionizing radiation includes electromagnetic waves (e.g., infrared, ultraviolet, microwave, laser, radar, radio frequency). Ionizing radiation includes alpha, beta, and gamma rays; neutron particles, and X-rays.
Sources:	Mining radioactive ores. Also used in medicine, weapons, power plants, industry (e.g., high energy electrical equipment, lasers, microwaves, and radar).
Health Effects:	Electromagnetic waves do not appear to harm the lungs unless the energy is sufficient to cause thermal burns. However, it can cause eye damage. Ionizing radiation damages human tissue and can lead to various kinds of cancer, including lung cancer.
BIOLOGICAL HAZARDS:	Bacteria, viruses, fungi, and rickettsial, chlamydial, and parasitic agents.
Sources:	Health care facilities, child care facilities, poorly maintained ventilation systems, biological research laboratories, animal care and processing facilities.
Health Effects:	Depends on the type of hazard. Can range in severity from minor allergies and respiratory infections to lethal nervous system disease and cancers. Vaccinations are available for some.

APPENDIX C. OVERVIEW OF OCCUPATIONAL LUNG DISEASE

A. Some of the Pulmonary Diseases that Show Obstructive Patterns

Occupational Asthma
Occupational asthma is caused by repeated exposure to certain airborne contaminants, which results in sensitization, leading to a chronic allergic response. On subsequent exposures, the smooth muscles of the bronchial tubes go into a spasm and some of the smaller airways close down. Excessive mucous is also produced, which further aggravates the problem by clogging small airways. Coughing, difficulty breathing, and wheezing are common symptoms. A wide variety of sensitizing agents can induce attacks. These may occur in people who are essentially normal and who become sensitized, or in individuals with a prior history of allergies or childhood asthma. (Certain agents, such as the diisocyanates, are such potent sensitizers and irritants that they cause respiratory reactions in most individuals.) Workers can sometimes relate their asthmatic symptoms to a specific exposure, or at least to a specific part of the workplace. In many cases, however, the symptoms begin after the work shift and subside by the following morning.

Reactive Airways Dysfunction Syndrome (RADS)
Reactive Airways Dysfunction Syndrome mimics asthma, but is due to an irritant rather than an allergic stimulus. Individuals with RADS will experience airflow obstruction at exposure levels much lower than would produce a response in non-affected individuals.

One special case of RADS involves a heightened response to cold air. It is known that asthmatics can have their attacks initiated by cold air. Other individuals with no known history of asthma may develop bronchoconstriction and tightness and shortness of breath when exposed to cold air, either on the job or during exercise. Removal from the exposure usually causes symptoms to subside within 1-2 hours.

Emphysema
Chronic exposure to irritant substances, most notably cigarette smoking, can cause emphysema. These exposures lead to the destruction of the elasticity of the smaller bronchi. When pressure in the chest begins to increase upon exhalation, these bronchi may collapse, trapping air inside. As a result, the air sacs remain partially expanded. Shortness of breath is a permanent problem and trying to breathe faster or more deeply only causes more air to become trapped inside. The lungs frequently become distended, causing a barrel-chested appearance. The disease is progressive and damage to the heart is a frequent side effect.

Chronic Bronchitis
Chronic bronchitis is caused by repeated infections and/or exposure to irritants such as fumes and dusts (including wood dusts and mineral fibers), oil aerosols, gases such as ozone and nitrogen dioxide, and smoke from cigarettes or exposure to fire (such as fire-fighting). Inflammation, swelling, and increased mucous production occur, fostering chronic bacterial infections in the mucous-plugged small airways. Symptoms include shortness of breath and a persistent and productive cough.

B. Some of the Pulmonary Diseases that Show Restrictive Patterns

Pneumoconioses

The three major types of pneumoconioses in the United States are asbestosis, silicosis, and coal worker's pneumoconiosis (Black Lung Disease). The pneumoconioses are some of the best-known of the occupational lung diseases, yet for a long time the courts doubted their existence and refused to consider them as compensable illnesses. Most causes of pneumoconioses are inorganic dusts or fibers, with particles less than 5 microns in size. Particles of this size are called "respirable particulates." Since these particulates are invisible, it is possible to be exposed without knowing it. However, many of the heaviest exposures were accompanied by larger particulates so that the industries were recognizably "dusty".

The pathology in the lung is fibrosis, a profusion of fibrous tissue between the alveoli which interferes with the normal expansion of the lungs. The fibrosis can take two forms: nodular and localized around the bronchi (peribronchial), (typical of silicosis), or interstitial (between the alveoli) and diffuse (typical of asbestosis). With continued exposure, the fibrosis increases, leading to shortness of breath and a persistent cough, and, in late stages, heart failure. Pneumoconioses are almost exclusively occupational diseases and therefore are compensable.

Hypersensitivity Pneumonitis

Hypersensitivity Pneumonitis is also referred to as Extrinsic Allergic Alveolitis. The disease occurs mainly in the alveoli and terminal bronchi in response to organic dusts associated with specific occupations. In some cases the offending agents are fungi, such as in Farmer's lung and Bagassosis. In other cases they are animal proteins (such as bird breeder's lung, and furrier's lung) or vegetable proteins (such as coffee worker's lung). The workers develop an acute illness with cough and shortness of breath, usually without wheezing, but often accompanied by chills and fever. The first occurrence may be mistaken for a "flu syndrome". Once workers are sensitized, they may respond to very small doses of the allergen. Fluid accumulates in the alveoli interfering with the oxygen diffusing capacity. Termination of exposure allows the acute phase to resolve over a period of 1-2 weeks. However, recurrent exposures may produce a chronic disease with interstitial fibrosis and severe shortness of breath.

Granulomatous Disease

Granulomas are inflammatory responses that occur as a reaction to infections (e.g., tuberculosis) or toxins. Large inflammatory cells move in and begin to collect around the point of exposure. Later fibrous tissue migrates in and surrounds the site, producing a globular mass that can be seen under the microscope. Berylliosis is the best known occupational example of this class of lung diseases.

Other Health Conditions

Several preexisting conditions can cause restrictive patterns. These include pregnancy, obesity, anatomical abnormalities, and thoracic or abdominal surgery. Although these conditions are not occupationally induced, they are mentioned here because their impact must be considered when reviewing spirometric results.

C. Some of the Pulmonary Diseases that Show either Obstructive or Restrictive Patterns

Pneumonias
Pneumonias may have a restrictive effect due to accumulation of fluid and inflammatory cells in the alveoli (much like alveolitis) or an obstructive effect due to accumulation of cells around the bronchi (bronchial pneumonia). Pneumonias can arise as part of a toxic process, or more commonly through infections. Occupational lung disease of infectious origin occurs primarily in health care workers, child care workers, and animal care workers. The offending agents may be fungi, bacteria, viruses, or other microorganisms. In many cases these diseases are accompanied by chills and fever.

Pneumoconioses
Although pneumoconioses are primarily restrictive diseases, in advanced cases the fibrous tissue may impinge on the bronchial tree causing obstructive symptoms as well.

Occupational Lung Cancer
Lung cancer is characterized by an enlarging mass of cells that grow uncontrollably. Smoking is the single most important cause and has a synergistic effect with some occupational carcinogens. Epidemiological studies have shown higher than normal rates of lung cancer for individuals exposed repeatedly to bis-chloromethyl ether, coal tar, pitch volatiles, mustard gas, arsenic, asbestos, radium, petroleum, chromates, and uranium. Lung cancer is especially insidious because symptoms frequently do not appear until it is too late to intervene medically. Depending on where the tumor(s) grows, in late stages it may cause obstructive or restrictive pattern

APPENDIX D. RESPIRATORY SURVEILLANCE PROGRAMS

Employment settings where workers use or are potentially exposed to pulmonary hazards should have a respiratory surveillance program. Although lung diseases are not the most common occupational diseases, they are the most significant due to their severity. The human and economic toll from occupational asthma, the pneumoconioses (asbestosis, black lung disease, silicosis, etc.), and occupational lung cancer is very large. These diseases are significant causes of morbidity, disability, early retirement, and death. Moreover, they are entirely preventable once their causes are recognized. Therefore, recognition of the hazards associated with occupational lung disease and prevention of exposure must be a high priority.

Ideally a respiratory surveillance program has four primary objectives:

1. To reduce the human suffering and economic impact of occupational disease. Prevention, early detection, and treatment are less expensive both to a company and to society than reduced productivity, worker's compensation payments, litigation, higher insurance premiums, and medical bills.

2. To detect occupational and non-occupational lung diseases in their earliest stages when reduction of exposure is likely to be most effective. For example, early detection and removal of the offending allergens reduces the chances of permanent damage for individuals with occupational asthma.

3. To identify working conditions that are hazardous so that improvements in industrial hygiene can be made. Ideally this should not be necessary. However, occupational health is not an exact science. As more is learned about the relationship between exposure and disease, it may be found that current standards are not adequate. In addition, some individuals develop occupational lung disease at exposure levels below those considered safe.

4. To establish baseline function for new employees and to identify job applicants with preexisting pulmonary damage so that they can be placed in positions that do not jeopardize their health. For example, a job that requires using a respirator may not be appropriate for someone with emphysema (45).

Spirometry plays an important role in a respiratory surveillance program. It is portable, safe for both the subject and the technician, non-invasive, inexpensive, and reproducible. With skilled and experienced staff, it is also relatively simple to perform. However, as discussed earlier, spirometric test results must be evaluated in the context of other medical information to offset its limitations. Respiratory surveillance programs should contain at least the following regularly scheduled components:

1. A detailed health history, with emphasis on smoking patterns, previous lung disease, and current respiratory symptoms.
2. A comprehensive employment history, with emphasis on potential occupational exposures to pulmonary hazards and respirator usage. Information should also be sought on potential exposures from hobbies, recreational activities, and part-time employment.

3. A thorough physical examination, with emphasis on the chest.

4. Chest radiographs (X-rays) where appropriate. It is important to consult with radiologists who have had special training in reading chest x-rays for occupational diseases, such as B-readers. These are physicians trained and certified by NIOSH to read chest x-rays for evidence of pneumoconioses.

5. Spirometry.

A respiratory surveillance program should also interface with an industrial hygiene program that identifies and controls potential pulmonary hazards and oversees employee respirator training and fit testing activities.

The frequency with which spirometry is used to monitor workers depends on the level of exposure and the severity of the potential impairment. However, as with every medical test, one must have a clear reason for performing spirometry, and guidelines for interpreting the tests and applying the results.

Medical surveillance itself must be used in conjunction with environmental monitoring and engineering controls to limit, if possible, the amount of exposure. In this context, medical surveillance is really a quality control procedure, designed to detect whether excessive exposure is occurring despite the control procedures in place.

After ruling out technical causes for low or declining pulmonary function, if abnormalities are detected or if a decline in pulmonary function compared with previous tests is detected, efforts must be made to identify the cause. If the cause is a workplace exposure, then steps must be taken to reduce the exposure and prevent further damage to the individual's lungs. It is unethical to use spirometry to detect workers with occupational pulmonary damage if no attempt is made to reduce their exposure or if the information is used as a reason for dismissal.

APPENDIX E. APPENDIX D OF THE OSHA COTTON DUST STANDARD

Appendix D of 29CFR1910.43 - Pulmonary Function Standards for Cotton Dust Standard

The spirometric measurements of pulmonary function shall conform to the following minimum standards, and these standards are not intended to preclude additional testing or alternate methods which can be determined to be superior.

I. Apparatus

a. The instrument shall be accurate to within $\pm$50 milliliters or within $\pm$3 percent of reading, whichever is greater.

b. The instrument should be capable of measuring vital capacity from 0 to 7 liters BTPS.

c. The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H_20/(liter/sec.).

d. The zero time point for the purpose of timing the FEV_1 shall be determined by extrapolating the steepest portion of the volume time curve back to the maximal inspiration volume (1, 2, 3, 4) or by an equivalent method.

e. Instruments incorporating measurements of airflow to determine volume shall conform to the same volume accuracy stated in (a) of this section when presented with flow rates from at least 0 to 12 liters per second.

f. The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.

g. The instrument used shall provide a tracing or display of either flow versus volume or volume versus time during the entire forced expiration. A tracing or display is necessary to determine whether the patient has performed the test properly. The tracing must be stored and available for recall and must be of sufficient size that hand measurements may be made within requirement of paragraph (a) of this section. If a paper record is made it must have a paper speed of at least 2 cm/sec and a volume sensitivity of at least 10.0 mm of chart per liter of volume.

h. The instrument shall be capable of accumulating volume for a minimum of 10 seconds and shall not stop accumulating volume before (1) the volume change for a 0.5 second interval is less than 25 milliliters, or (2) the flow is less than 50 milliliters per second for a 0.5 second interval.

i. The forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1) measurements shall comply with the accuracy requirements stated in paragraph (a) of this section. That is, they should be accurately measured to within $\pm$50 ml or within $\pm$3 percent of reading, whichever is greater.

j. The instrument must be capable of being calibrated in the field with respect to the FEV_1 and FVC. This calibration of the FEV_1 and FVC may be either directly or indirectly through volume and time base measurements. The volume calibration source should provide a volume displacement of at least 2 liters and should be accurate to within $\pm$30 milliliters.

II. Technique for Measurement of Forced Vital Capacity Maneuver

a. Use of a nose clip is recommended but not required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The subject may sit, but care should be taken on repeat testing that the same position be used and, if possible, the same spirometer. Particular attention shall be given to insure that the chin is slightly elevated with the neck slightly extended. The patient shall be instructed to make a full inspiration from a normal breathing pattern and then blow into the apparatus, without interruption, as hard, fast, and completely as possible. At least three forced expirations shall be carried out. During the maneuvers, the patient shall be observed for compliance with instruction. The expirations shall be checked visually for reproducibility from flow-volume or volume-time tracings or displays. The following efforts shall be judged unacceptable when the patient:

1. has not reached full inspiration preceding the forced expiration.

2. has not used maximal effort during the entire forced expiration.

3. has not continued the expiration for at least 5 seconds or until an obvious plateau in the volume time curve has occurred.

4. has coughed or closed his glottis.

5. has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.)

6. has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts), and therefore not allowing back extrapolation of time 0 (extrapolated volume on the volume time tracing must be less than 10 percent of the FVC).

7. has an excessive variability between the three acceptable curves. The variation between the two largest FVCs and FEV_1s of the three satisfactory tracings should

not exceed 10 percent or ±100 milliliters, whichever is greater.

b. Periodic and routine calibration of the instrument or method for recording FVC and FEV_1 should be performed using a syringe or other volume source of at least 2 liters.

III. Interpretation of Spirogram

a. The first step in evaluating a spirogram should be to determine whether or not the patient has performed the test properly or as described in II above. From the three satisfactory tracings, the forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1) shall be measured and recorded. The largest observed FVC and largest observed FEV_1 shall be used in the analysis regardless of the curve(s) on which they occur.

b. The following guidelines are recommended by NIOSH for the evaluation and management of workers exposed to cotton dust. It is important to note that employees who show reductions in FEV_1/FVC ratio below .75 or drops in Monday FEV_1 of 5 percent or greater on their initial screening exam, should be re-evaluated within a month of the first exam. Those who show consistent decrease in lung function, as shown of the following table, should be managed as recommended.

IV. Qualifications of Personnel Administering the Test

Technicians who perform pulmonary function testing should have the basic knowledge required to produce meaningful results. Training consisting of approximately 16 hours of formal instruction should cover the following areas. Persons who successfully complete the course will be certified by OSHA or their designee.

a. Basic physiology of the forced vital capacity maneuver and the determinants of airflow limitation with emphasis on the relation to reproducibility of results.

b. Instrumentation requirements including calibration procedures, sources of error and their correction.

c. Performance of the testing including subject coaching, recognition of improperly performed maneuvers and corrective actions.

d. Data quality with emphasis on reproducibility.

e. Actual use of the equipment under supervised conditions.

f. Measurement of tracings and calculations of results.

2. Part 1928 of Title 29 of the Code of Federal Regulations is hereby amended by adding a new paragraph (a)(5) to Section 1928.21 to read as follows:

Section 1928.21 Applicable standards in 29 CFR Part 10.
(a) * * *
(5) Exposure to cotton dust in cotton gins - Section 1910.1046.

(Secs. 6, 8, 84 Stat. 1593, 1599 (29 U.S.C. 655, 657); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR Part 1911)
[FR Doc. 78-17233 Filed 6-19-78; 11:53 am]

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

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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.

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. Members *of the committee:* Robert 0. Crapo, M.D., Chairman, John L Hankinson, Ph.D., Charles Irvin, Ph.D., Neil R. MacIntyre, M.D., Karen Z. Voter, M.D., and Robert A. Wise, M.D. *Spirometry Subcommittee:* John L Hankinson, Ph.D., Subcommittee Chairman, Charles Irvin, Ph.D., Robert A. Wise, M.D. *Invited Spirometry and DLCO Workshop participants:* Brian Graham, Ph.D., Carl O'Donnell, Sc.D., Paolo Paoletti, M.D., Josep Roca, M.D., and Giovanni Viegi, M.D. *Corresponding members:* Margaret R. Becklake, M.D., A. Sonia Buist, M.D., Gary duMoulin, Ph.D., Robert L Jensen, Ph.D., Albert Miller, M.D., and Andrea Rossi, M.D.

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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
Cuillain-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.

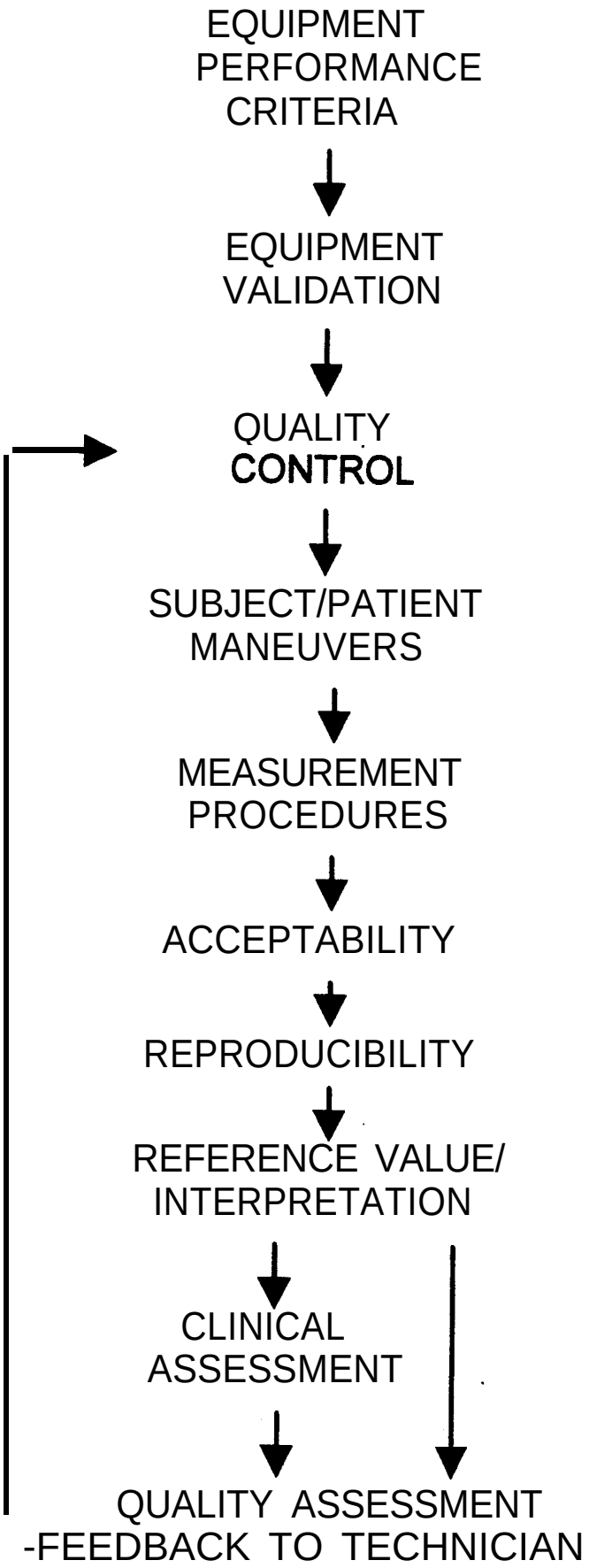


Figure 1. Spirometry standardization steps.

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: (I) 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.

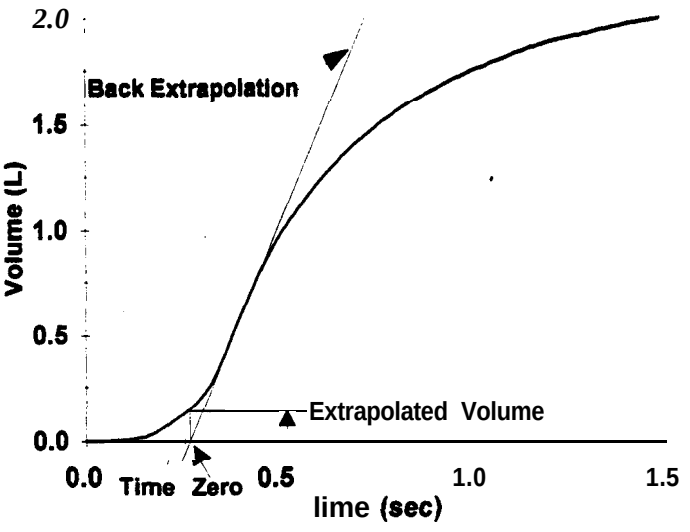


Figure 2. Typical subject waveform of a volume-time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = Vext.

For measurements of VC, the spirometer must be capable of accumulating volume for *at feast* 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 *a? feast 8* L (BTPS) with an accuracy of *a? 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, = 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 *feast* 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 IO-min period.

Monitoring. The monitoring device must be capable of measuring FEV_t up to at *feast 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. Inrerdevice 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 Dl, 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:

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

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 feast: (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 feast ± 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 re***quired*** 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_1, 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 l-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 us	5 mm/Us
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, 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, 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,) ± 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_1) 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 interdevice 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 PEE ± 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 nonreproducible 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,, 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, (47). If an in-line filter is used during spirometry, interpretation of spirometric indices other than FVC and FEV, (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. Plow 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 feast* 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 Qualify 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 Weekly (flow spirometers)	1-L increments with a calibrating syringe measured over entire volume range (flow spirometers simulate several different flow ranges)
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,.

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.

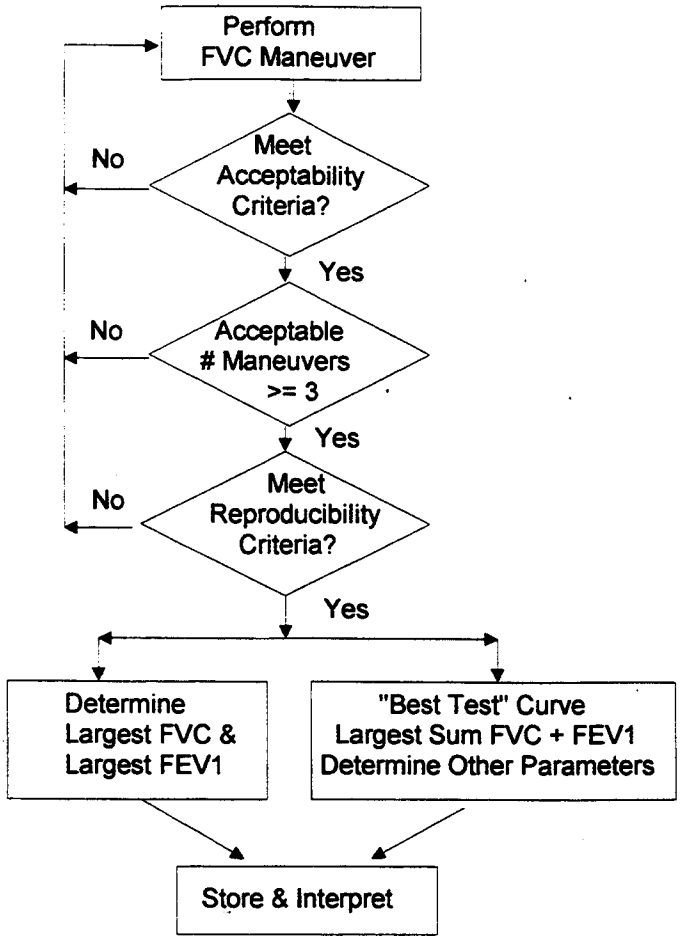


Figure 3. Flow-chart diagram of FVC spirometry testing.

Recommendation: FVC—Satisfactory Start-of-Test Criteria

To achieve accurate "time zero" and ensure that the FEV_1 comes from a maximal effort curve, the extrapolated volume 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_1 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.

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—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 of 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.

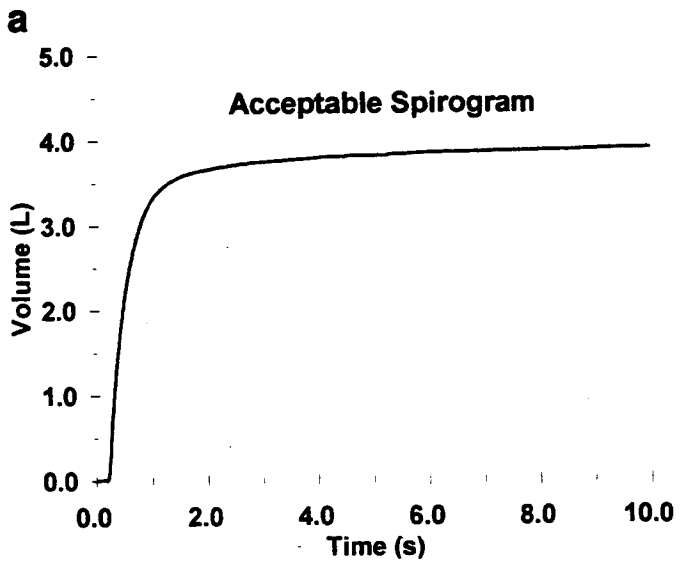


Figure A1a. Acceptable volume–time spirogram.

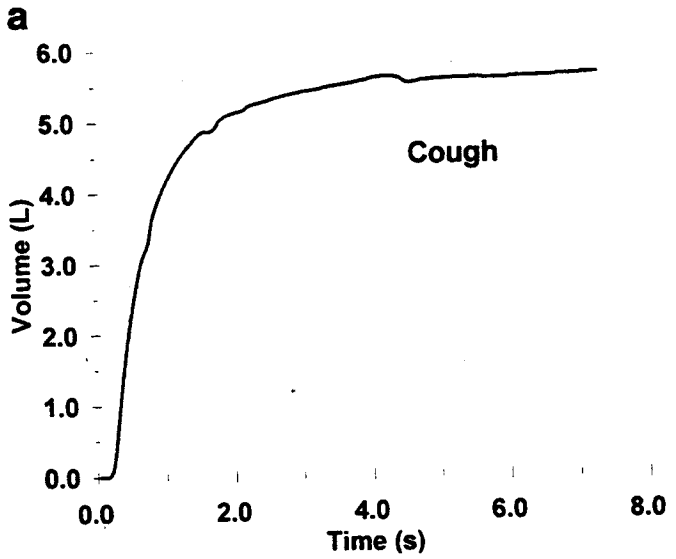


Figure A2a. Volume–time spirogram with a cough during the first second of exhalation.

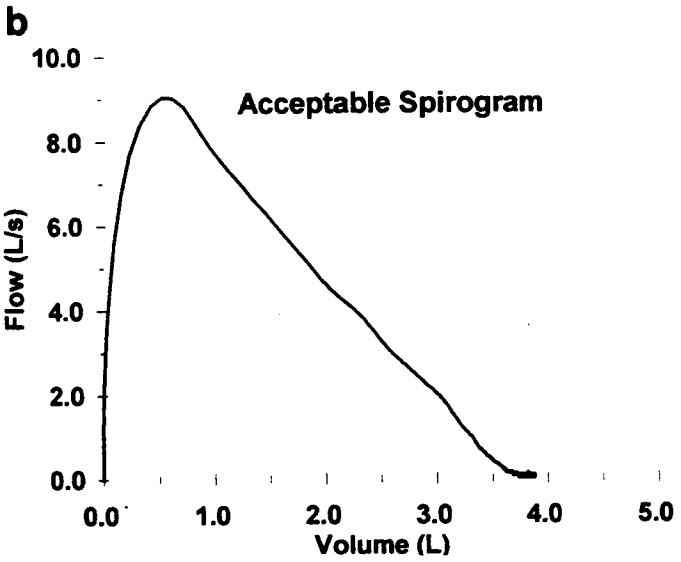


Figure A1b. Acceptable flow–volume spirogram.

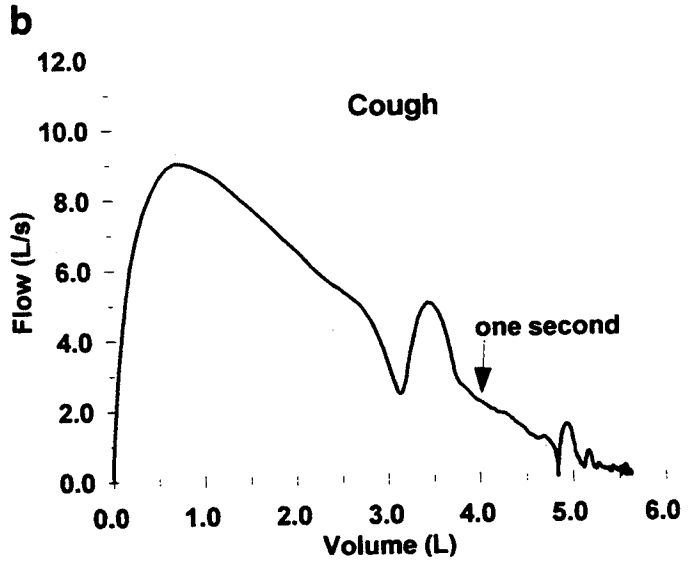


Figure A2b. Flow–volume spirogram with a cough during the first second of exhalation.

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

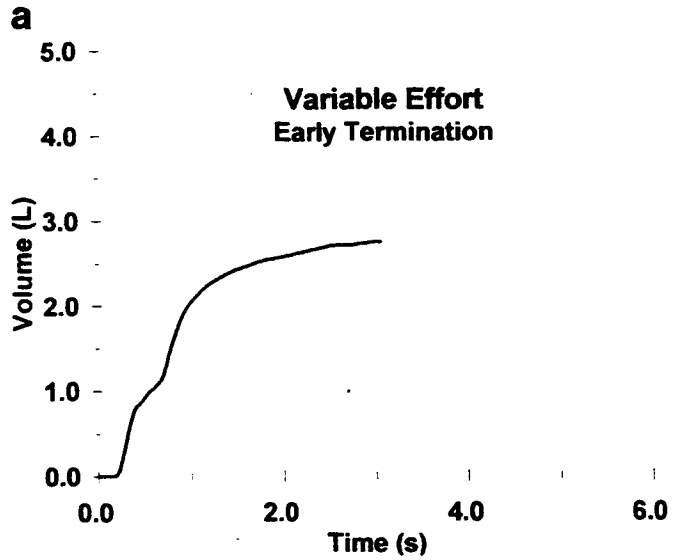


Figure A3a. Unacceptable volume–time spirogram due to variable effort and early termination.

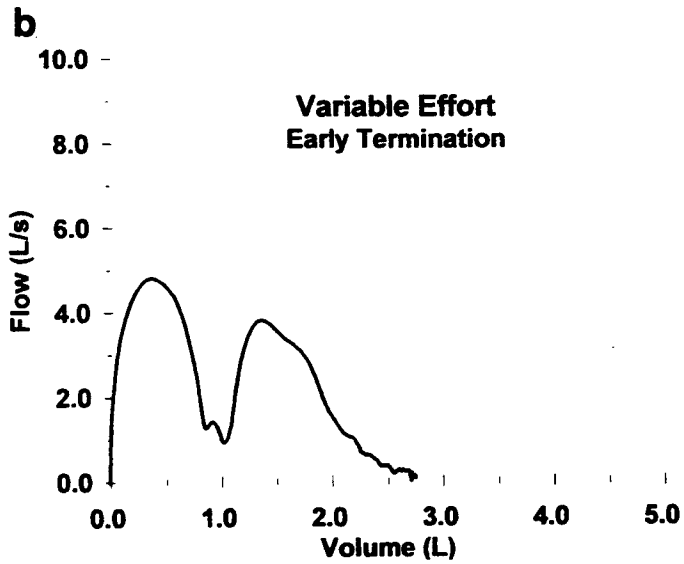


Figure A3b. Unacceptable flow–volume spirogram due to variable effort and early termination.

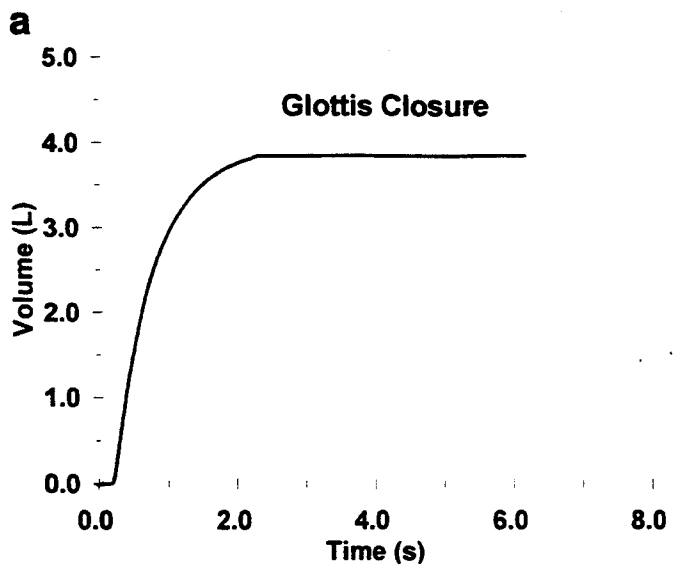


Figure A4a. Unacceptable volume–time spirogram due to possible glottis closure.

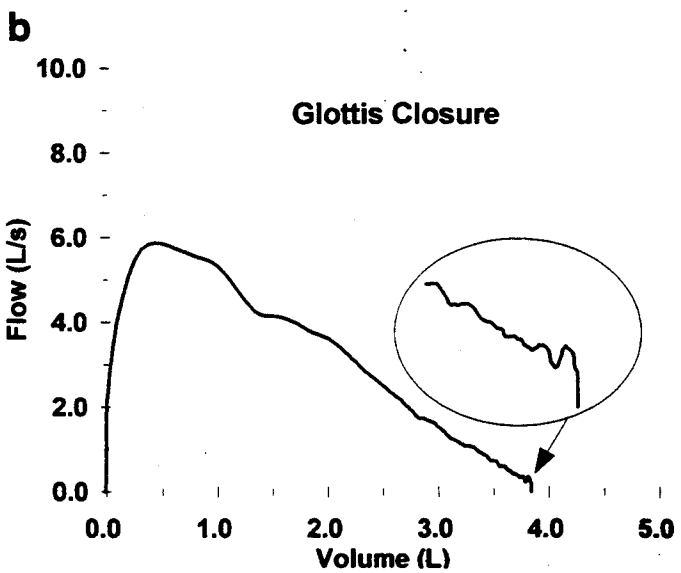


Figure A4b. Unacceptable flow–volume spirogram due to possible glottis closure.

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

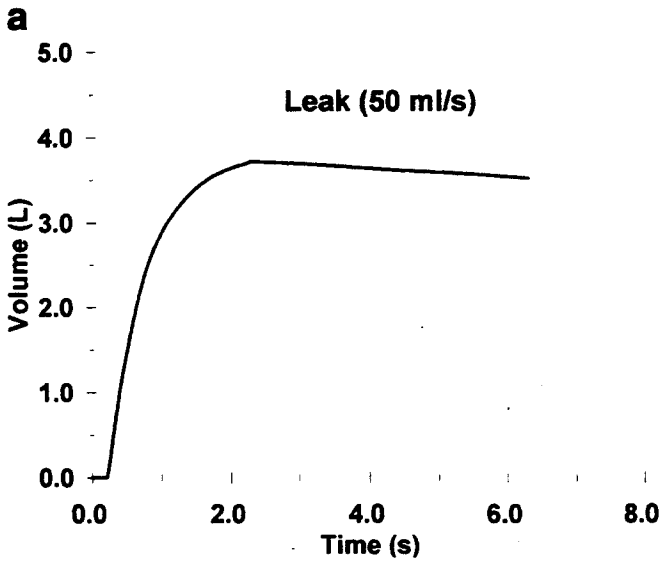


Figure A5a. Unacceptable volume–time spirogram due to a leak.

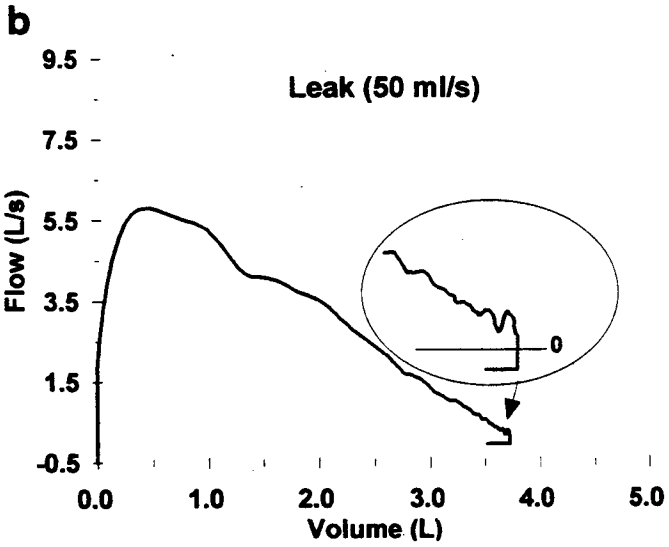


Figure A5b. Unacceptable flow–volume spirogram due to a leak.

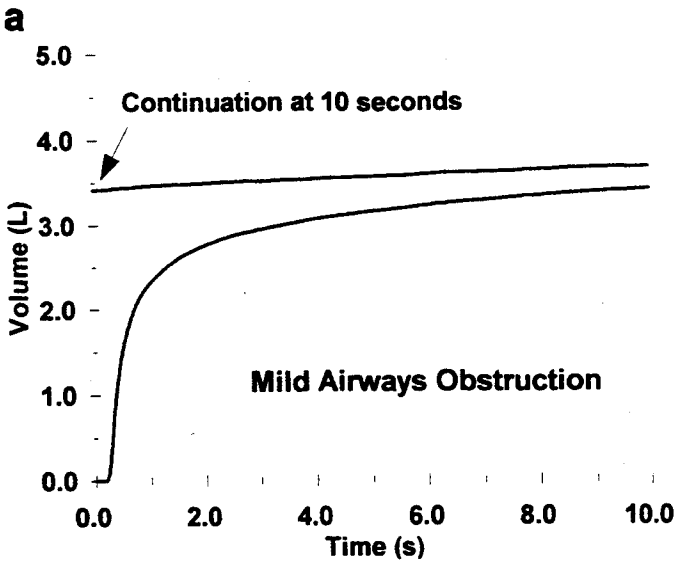


Figure A6a. Acceptable volume–time spirogram for an individual with mild airways obstruction.

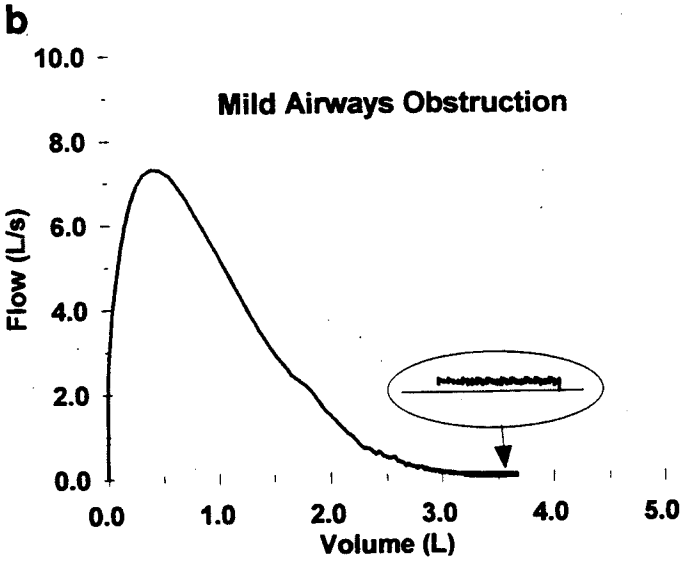


Figure A6b. Acceptable flow–volume spirogram for an individual with mild airways obstruction.

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-

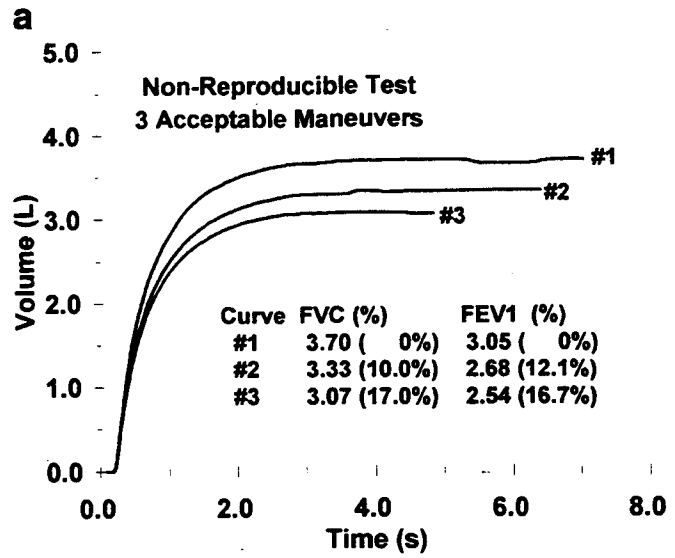


Figure A7a. Nonreproducible test with three acceptable volume–time curves. Percents are difference from largest value.

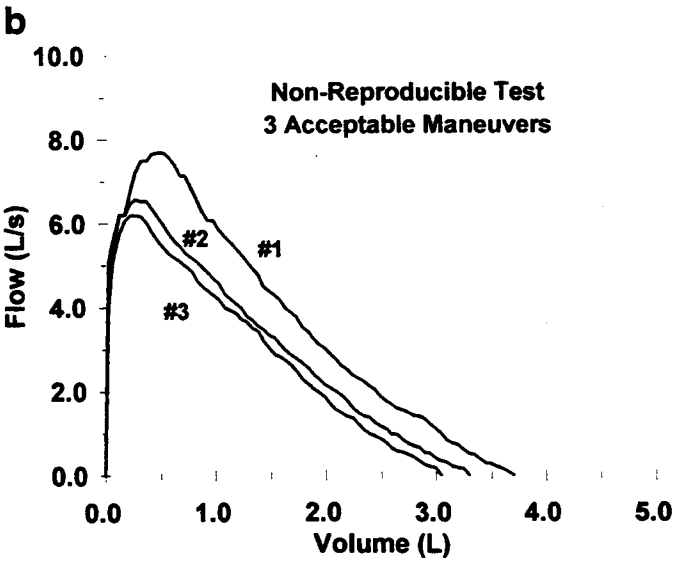


Figure A7b. Nonreproducible test with three acceptable flow–volume curves.

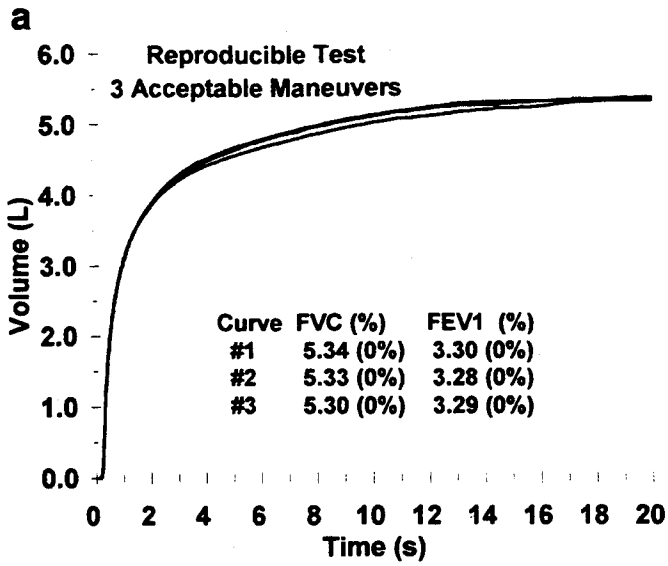


Figure A8a. Reproducible test with three acceptable volume–time curves. Percents are difference from largest value.

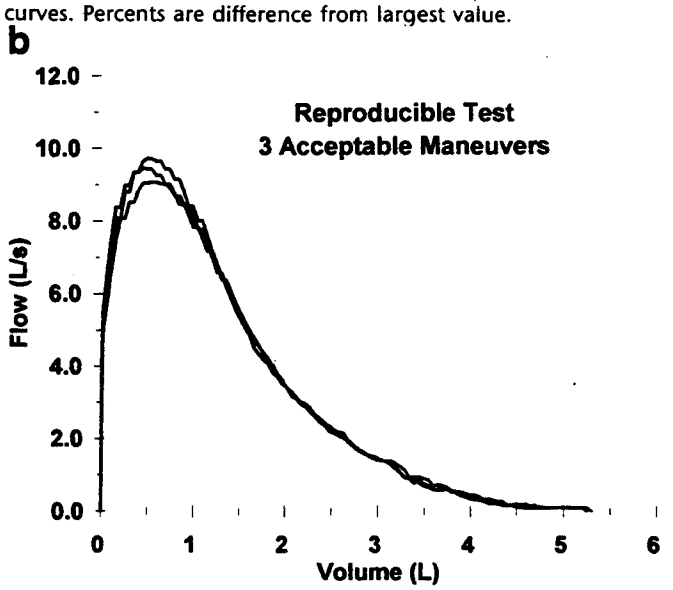


Figure A8b. Reproducible test with three acceptable flow–volume curves.

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-

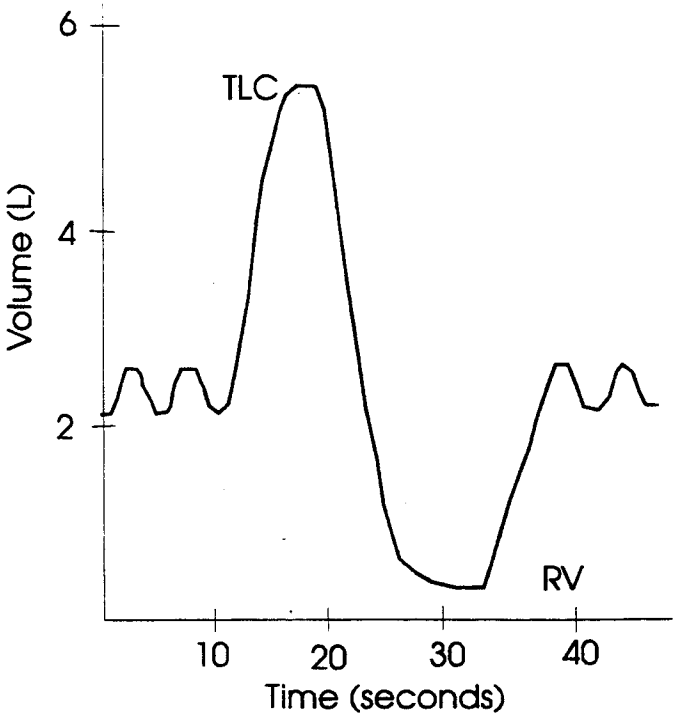


Figure A9. Sample relaxed VC maneuver in a normal subject.

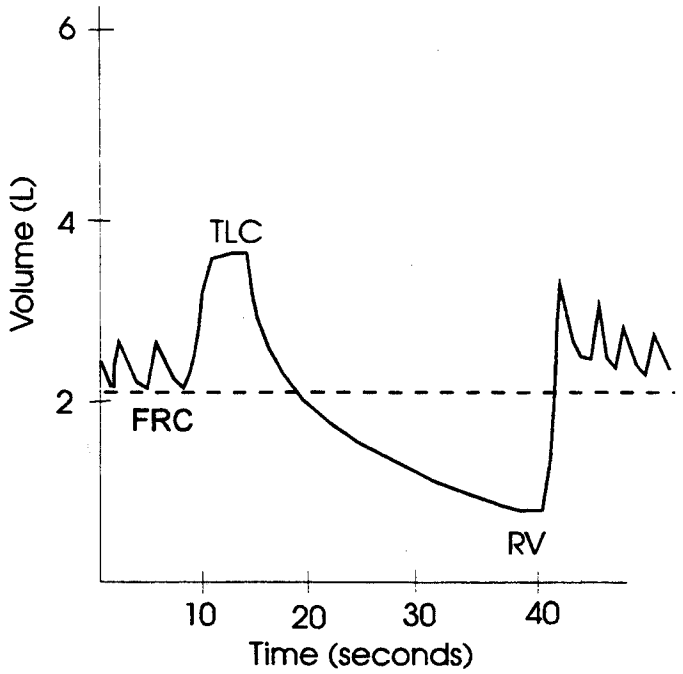


Figure A10. Sample VC maneuver from a subject with severe airways obstruction.

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_1 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_1 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).

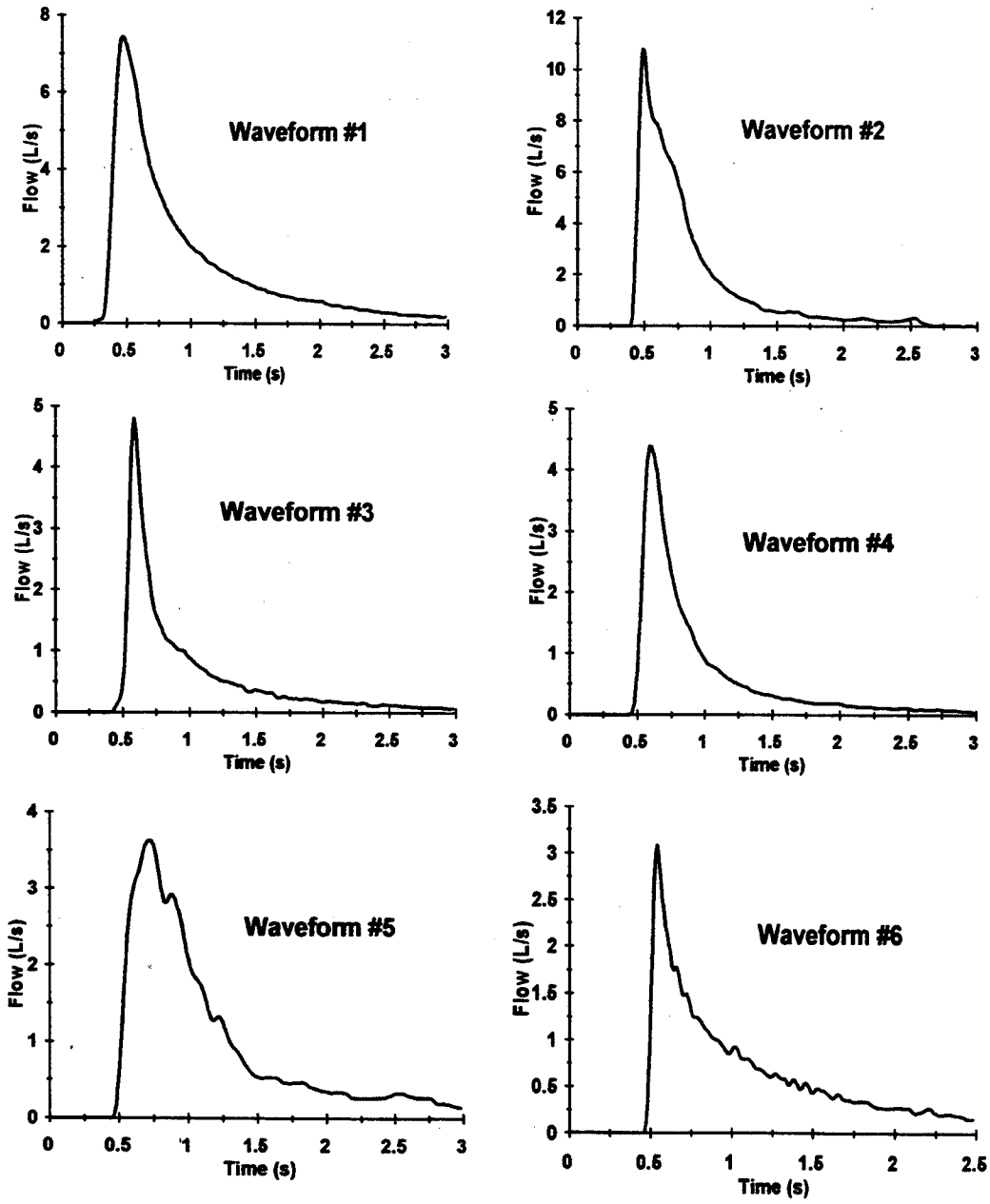
Meters tested: Ten production devices.

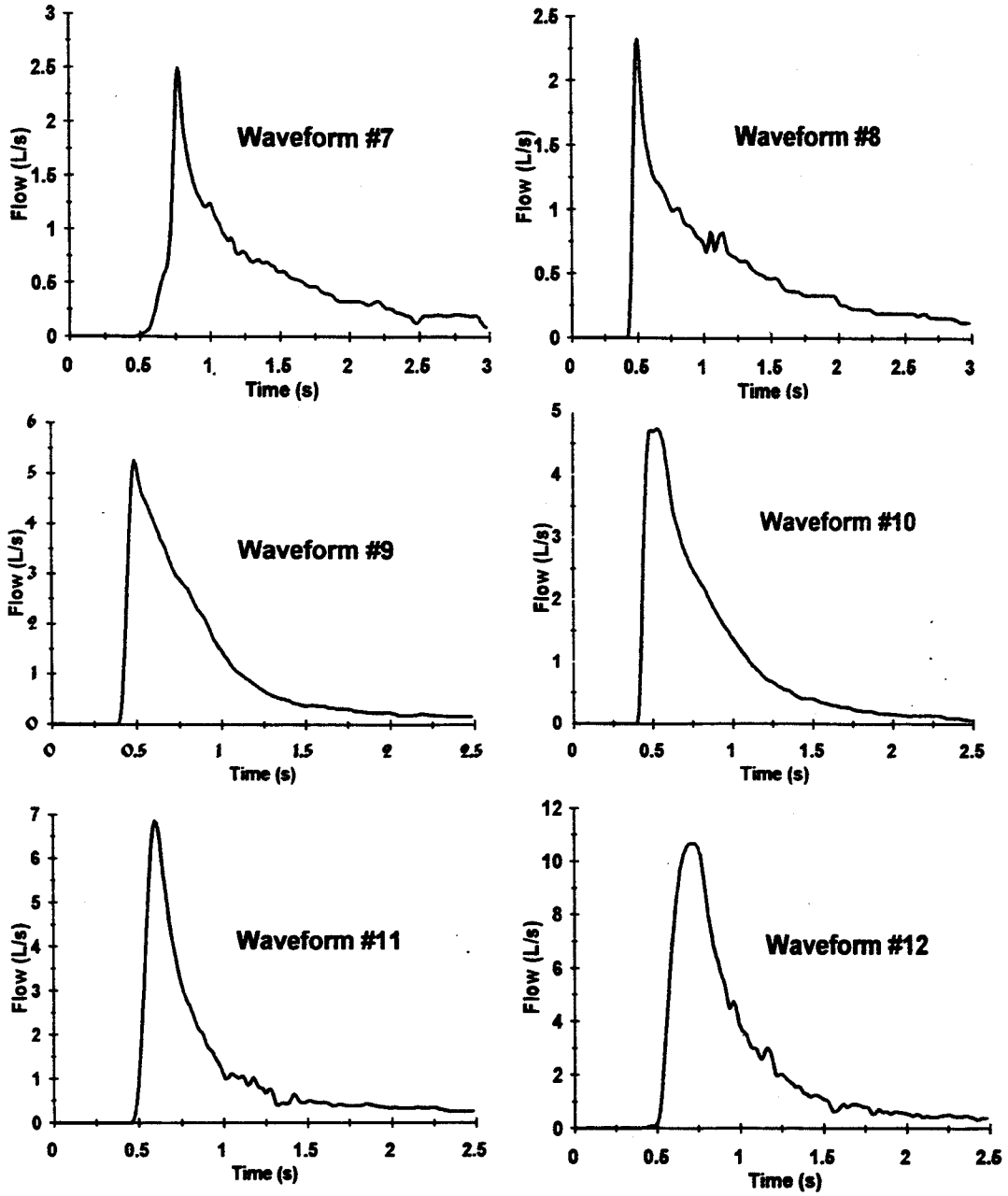
Validation: Three flows for each waveform for each device. For each waveform and for each device, calculate range (formula B1) and range (%) (formula B2) for FVC and FEV_1.

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.

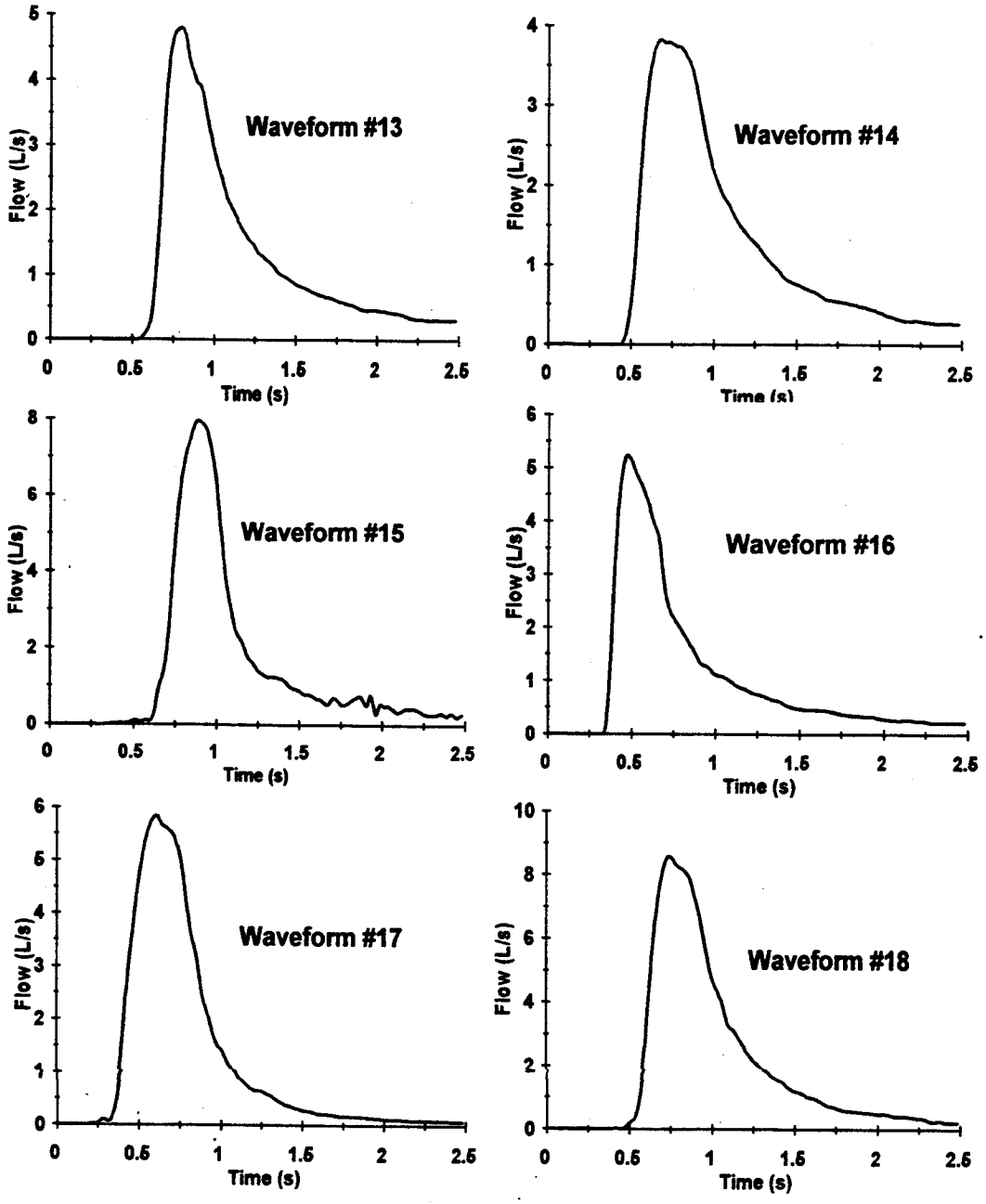
Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each device, calculate an average FVC and FEV_1 for each waveform. For each waveform and parameter, combine all data from 10 meters to calculate range (formula B1) and range (%) (formula B2) for each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



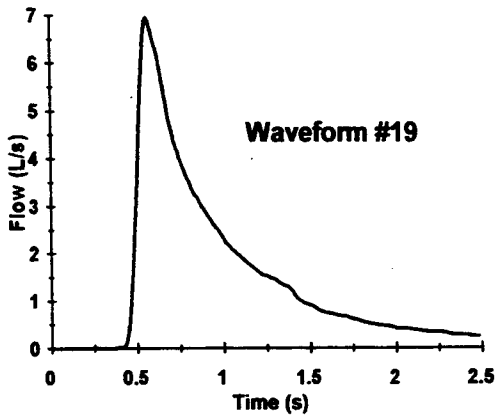
results in artificially lower time-to-PEF, as can be seen in waveform 7.

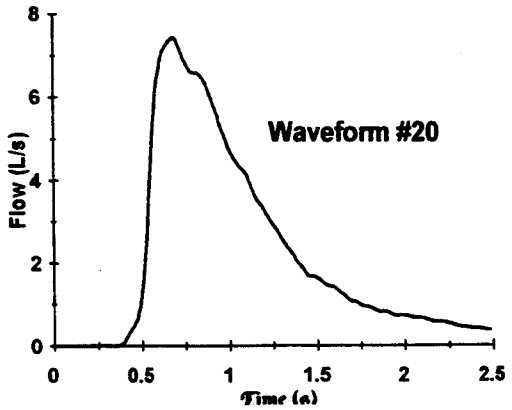
APPENDIX E

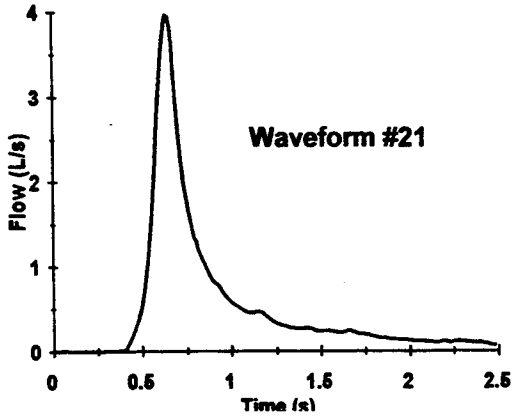
Signal-Processing Tutorial

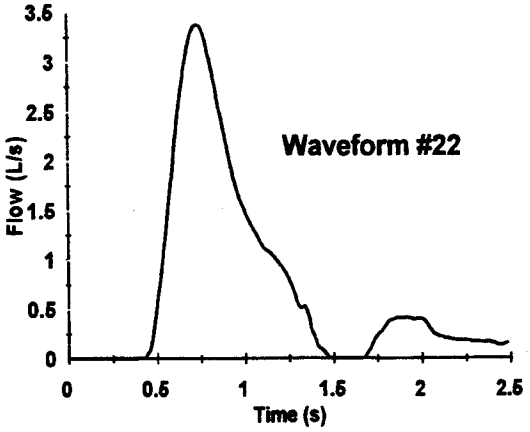
Since computers have come into such common use in spirometry and since fundamental errors have been detected in recently tested commercially available hardware and software (79), a short tutorial on signal processing is presented (Figure E1).

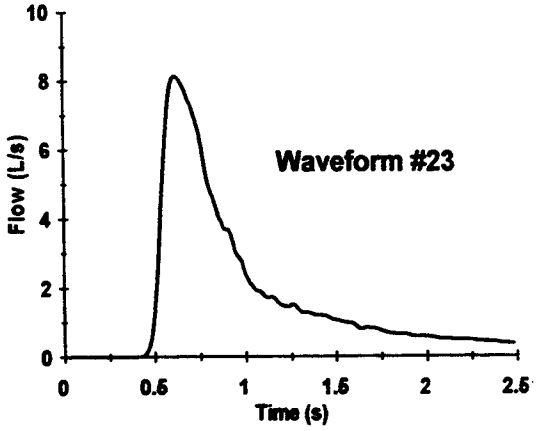
For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (80). Flow devices of the Fleisch pneumotachometer variety also have electrical voltage outputs. For the volume spirometer with a potentiometer 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

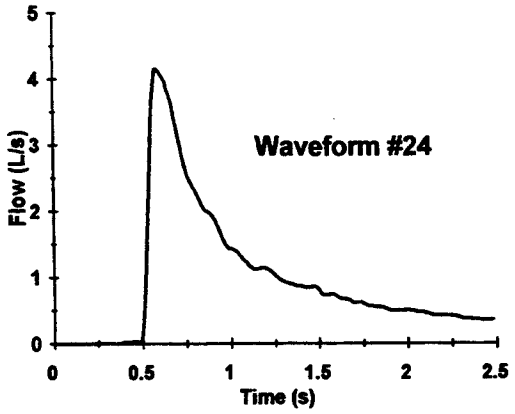

Waveform #19
Flow (L/s)
Time (s)

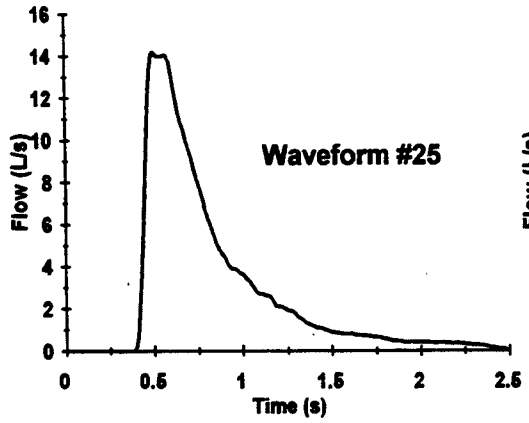

Waveform #20
Flow (L/s)
Time (s)

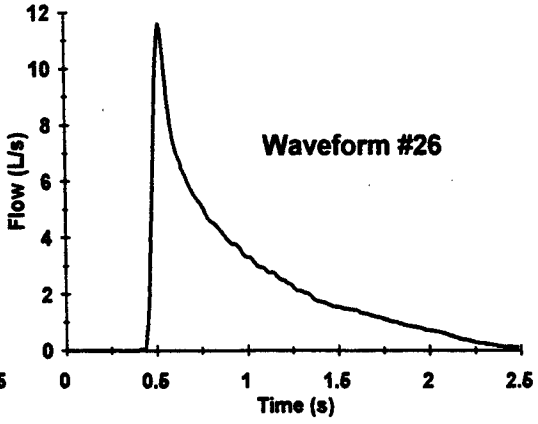

Waveform #21
Flow (L/s)
Time (s)


Waveform #22
Flow (L/s)
Time (s)


Waveform #23
Flow (L/s)
Time (s)


Waveform #24
Flow (L/s)
Time (s)


Waveform #25
Flow (L/s)
Time (s)


Waveform #26
Flow (L/s)
Time (s)

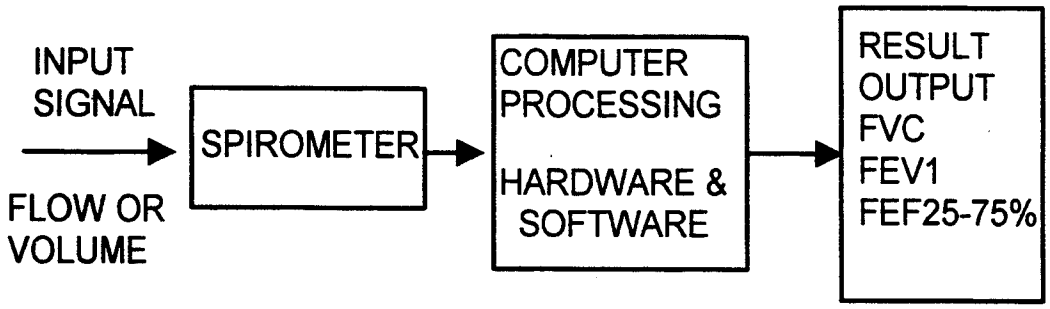


Figure E1. Block diagram of spirometer data acquisition.

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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APPENDIX G. SPIROMETRY PROCEDURE CHECKLIST

The list below is summarized from Unit Four: Spirometric Technique. Refer to that unit for further information.

1. Prepare the equipment.
   a. Set up and clean equipment.
      1. Check paper supply.
      2. Set the paper speed if applicable.
      3. Check the position of the pens.
      4. Attach the main tubing if applicable.

   b. Check to calibration of the equipment.

   c. Do a test run.

   d. Check that there are enough supplies.

   e. Note room temperature (and barometric pressure if applicable.)

   f. Check that the weight and height measuring scales are working properly.

2. **Prepare the subject.**
   a. Explain the purpose of spirometry--"I want to learn how hard and fast you can breathe."

   b. Determine if spirometry should be postponed using your institution's criteria or the sample questions below:
      1. How are you feeling today?
      2. Have you smoked any cigarettes, pipes, or cigars within the last hour?
      3. Have you used any inhaled medications, such as aerosolized bronchodilators, within the last hour?
      4. What have you eaten within the last hour?
      5. Have you had any respiratory infection, such as flu, pneumonia, severe cold, or bronchitis, within the last three weeks?
      6. Have you had any ear infections or other ear problems within the last three weeks?
      7. Have you had any recent surgeries?
      8. If you wear dentures, are they loose?

3. **Position the subject.**
   a. Note the previous position used (sitting or standing) in past spirometric tests and use the same position if possible. Record the position to be used in the chart.

   b. Instruct the subject to loosen tight clothing, elevate the chin, and extend the neck slightly.

   c. Show the subject how to apply a nose clip and check to see that it is on properly.

4. **Perform the test.**
   a. Explain how to position the mouthpiece (in mouth without obstruction from teeth or tongue, with a tight lip seal).

   b. Explain and demonstrate how to perform the forced expiratory maneuver. -- "When you are ready, take the deepest possible breath, place your mouth firmly around the mouthpiece, and without further hesitation, blow into the spirometer as hard, fast, and completely as possible, without stopping until I tell you."

5. **Perform last minute equipment preparations.**
   a. Place the recorder pen in the appropriate position on the chart paper.

   b. Start the paper moving at least one second before the subject blows into the mouthpiece.

6. **Coach the subject.**
   a. Actively and forcefully coach the subject as he/she performs the maneuver! (Blow, blow, blow!)

   b. Keep coaching until a plateau is reached -- ATS-1994. (Cotton Dust: less than 25 ml volume change in 0.5 seconds.)

7. **Check the acceptability of each tracing before continuing the testing.**
   a. Acceptable spirograms are free from:
      1. Hesitation or false starts.
      2. Cough.
      3. Variable effort.
      4. Glottis closure.
      5. Early termination, before a plateau is reached.
      6. Leaks.
      7. Baseline error.

   b. Review causes of errors with the subject if needed.

   c. Continue testing until three acceptable tracings have been obtained, allowing the subject to recover between tests, up to a maximum of eight trials.

8. **Check for excess variability of the two largest FVCs and FEV_1s.** (See **Unit Five: Basic Spirometric Calculations** and **Appendix H: Outline of Spirometric Calculations** for more information.) Have the subject perform additional forced expiratory maneuvers as needed or as is appropriate for his/her medical condition.

9. **Record information in the subject's chart.** At a minimum, note the information below in the subject's chart:
   a. Name.
   b. Age
   c. Sex.
   d. Height.
   e. Race.
   f. Position of previous testing.
   g. Previous predicted values used.
   h. Date and time of test.
   i. Ambient temperature.
   j. Barometric pressure (if possible).
   k. Test results.
   l. Technician identification

APPENDIX H. OUTLINE OF SPIROMETRIC CALCULATIONS

The list below is summarized from **Unit Five: Basic Spirometric Calculations**. Refer to that unit for further information.

1. **Use only the tracings that meet acceptability criteria** (see **Appendix G. Spirometry Procedure Checklist** and **Unit Four. Spirometric Technique** for instructions).

2. **Forced Vital Capacity (FVC)**
   a. Measure the FVC from baseline to plateau for all acceptable tracings.
   b. Determine if there is excess variability, difference between the two largest FVCs should be less than 200 ml (**Optional**: for ATS-1987, FVCs that are 2 liters or less, use 100 ml; for FVCs greater than 2 liters, use 5%; Cotton Dust - FVCs less than 1 liter use 100 ml or 10% for FVCs greater than 1 liter).
   c. Use the largest FVC obtained from all acceptable tracings.
   d. Convert to BTPS as needed (see below).

3. **Forced Expiratory Volume in One Second (FEV_1)**
   a. Measure FEV_1 on the acceptable tracings.
   b. Find t=0 and t=1 second.
   c. Do back extrapolation if t=0 is not obvious. ATS recommends to do it for all FEV_1 calculations. Draw a straight line along the steepest portion of the curve and extend the line to intersect the baseline.
   d. Calculate the volume at t=1 second.
   e. Determine if there is excessive extrapolated volume at t=0. Extrapolated volume is not acceptable if it is greater than 5% of the FVC for FVCs exceeding 3 liters -- use 150 ml for FVCs less than 3 liters.
   f. Determine if there is excess variability, difference between the two largest FEV_1s should be less than 200 ml. Optional: for ATS-1987, use 100 ml for FEV_1s that are 2 liters or less, use 5 % for those that are greater than 2 liters; Cotton Dust - for FEV_1s less than 1 liter use 100 ml or 10% for FEV_1s greater than 1 liter.
   g. Convert to BTPS as needed (see below).

4. **FEV_1 as a Percent of FVC**
   a. Use the largest acceptable FVC and FEV_1, even if not from the same tracing.
   b. $FEV_1/FVC \times 100 = FEV_1/FVC\%$
   c. Don't convert to BTPS, since the answer is a ratio.

5. **Forced Mid-Expiratory Flow Rate ($FEF_{25\text{-}75\%}$)**
   a. Use the "best curve" (acceptable tracing with the largest sum of the FVC and the FEV_1).
   b. Calculate 25% and 75% of the FVC and mark those points on the tracing.
   c. Draw a straight line through the 25% point and the 75% point.
   d. Find two adjacent time bars that are one second apart.
   e. Determine the volume at each of those two time bars.
   f. Determine the difference between those two volumes.
   g. Convert to BTPS (see below).

h. The answer is in liters per second.

6. **Conversion to BTPS**
   a. Convert the ambient temperature to Centigrade if needed.
   b. Find the ambient temperature and the corresponding conversion factor on the **BTPS Conversion Chart**.
   c. Multiply the FVC, FEV_1, and $FEF_{25-75\%}$ by the conversion factor to obtain the correct volume at BTPS.

7. **Predicted Normal Values**
   a. Be consistent in which predicted tables are used.
   b. Locate predicted values for FEV_1 and FVC, using subject's age, race, height, and sex.
   c. In some non-Caucasians, multiply the predicted values by 0.85 (the race correction factor).
   d. Calculate the percent of the predicted value:
   FVC observed/FVC predicted x 100 = FVC% of predicted normal. (Do the same for FEV_1 and $FEF_{25-75\%}$).

8. **Changes in Follow-Up Spirograms**
   a. Calculate as an absolute difference (e.g., FVC at $time_1$ - FVC at $time_2$ = + or - liters difference).
   b. Or calculate as a percent change from the previous value (e.g.,
   $$\frac{\text{FVC at time}_1 - \text{FVC at time}_2}{\text{FVC at time}_1} \times 100 = + \text{ or } - \%.$$
   c. Use the same steps for calculating percent change in FEV_1 and percent change in $FEF_{25-75\%}$.

APPENDIX I. BASIC MATHEMATIC CALCULATIONS

ADDITION: a + b = c

Example: 3 + 2 = 5

SUBTRACTION: c - b = a

Example: 5 - 2 = 3

MULTIPLICATION: a x b = d

Example: 3 x 2 = 6

DIVISION: $\frac{d}{b} = a$ or d / b = a

Example: 6 / 2 = 3

FRACTIONS: $\frac{a}{b} = \frac{\text{numerator}}{\text{denominator}}$ or a/b

Example: 3/5

DECIMALS:

1. Numbers to the left of the decimal point are whole numbers.
   Example: 3.

2. The first number to the right of the decimal point is in tenths.
   Example: .2 = 2/10

3. The second number to the right of the decimal point is in hundredths.
   Example: .05 = 5/100
   .67 = 67/100

4. The third number to the right of the decimal point is in thousandths, etc.
   Example: .009 = 9/1000
   .872 = 872/1000

CONVERTING FROM

FRACTIONS TO DECIMALS: a/b = .c

Example: 4/5 = .8

CONVERTING FROM DECIMALS TO FRACTIONS: a.bc = abc/100

Example: 3.75 = 375/100
= 3 3/4

CONVERTING DECIMALS TO PERCENT: .a = a x 100 = a %

Example: .8 = 80%
(.8 x 100 = 80%)

CONVERTING PERCENT TO DECIMALS: a% = a% ÷ 100 = .a

Example: 80% = .8
(80/100 = .8)

APPENDIX J. METRIC CONVERSIONS

The metric system follows an orderly sequence for prefixes that indicates the unit of measurement:

Prefix	Units in	Example
kilo-	thousands	1 kiloliter = 1,000 liters
hecto-	hundreds	1 hectoliter = 100 liters
deca-	tens	1 decaliter = 10 liters
no prefix	ones	
deci-	tenths	1 deciliter = 0.1 liter
centi-	hundredths	1 centiliter = 0.01 liter
milli-	thousandths	1 milliliter = .001 liter

Commonly used metric measurements and their U.S. equivalent are given below:

Metric Unit	Abbreviation	Approx. U.S. Equivalent
Distance		
kilometer	km	0.62 miles
meter	m	39.37 inches
centimeter	**cm**	**0.39 inches**
millimeter	**mm**	**0.04 inches**
Capacity (liquids)		
liter	**l**	**1.057 quarts**
Capacity (dry)		
liter	l	0.908 quarts
Weight		
kilogram	**kg**	**2.2046 pounds**
gram	g	0.035 ounces
milligram	mg	0.015 grains

	U.S. Unit	Metric Equivalent
Distance		
	1 mile	1.609 km
	1 yard	0.914 m
	1 foot	30.480 cm
	1 inch	2.540 cm
Capacity (liquid)		
	1 gallon	3.785 l
	1 quart	0.946 l
	1 pint	0.473 l
	1 fluid ounce	29.573 ml
Capacity (dry)		
	1 bushel	35.238 l
	1 quart	1.101 l
	1 pint	0.550 l
Weight (avoirdupois)		
	1 pound	.453 km
	1 ounce	28.349 g

APPENDIX K. OTHER FACTORS TO CONSIDER WHEN CALCULATING BTPS

1. Ambient Pressure: Some physicians prefer to use BTPS conversion factors that correct for ambient pressure as well as temperature. Fluctuations in ambient pressure produce changes of less than 1% in the usual spirometric tests. However at high altitudes or during research studies, the use of ambient pressure conversion factors should be considered.

   To obtain ambient pressure, use a barometer or call the weather service and use reported barometric pressure. Convert the reading from inches of mercury to millimeters if necessary (1mm = 0.04 inches).

   To take ambient pressure into account when calculating BTPS, use the following formula:

$$V_{BTPS} = V_{ATPS} \times [310 \times (PB - PH_2O)] \div [(PB - 47) \times (273 + T)]$$

PB = Barometric pressure, mm Hg.

PH_2O = Vapor pressure of water at spirometer temperature.

T = Temperature in Centigrade.

47 = Vapor pressure of water at 37°C.

310 = Absolute body temperature.

2. Instrument or Bell Factor: The Instrument or Bell Factor is occasionally mentioned in addition to BTPS. In certain water-seal spirometers, it refers to a constant indicating the volume of displacement per millimeter of vertical movement of the bell. If you use this type of spirometer, a bell factor correction is necessary. Consult the manufacturer's manual for instructions.

3. Instruments with Graph in BTPS Units: Some instruments have graph paper which assumes the spirometer is at 25°C and 760 mm of mercury (the barometric pressure at sea level). If the ambient temperature is not 25°C, data collected from this type of instrument must be corrected to the appropriate BTPS factor. Consult the manufacturer's manual for instructions.

APPENDIX L. REFERENCE VALUES TABLES FROM NHANES III (Hankinson et. al. - 1999)

Table 1. Caucasian-Males

Height	Age	FVC		FEV1		FEV1/FVC%	
		Pred	LLN	Pred	LLN	Pred	LLN
170cm	20	5.10	4.25	4.30	3.58	83.9%	74.3%
	30	4.97	4.12	4.08	3.36	81.9%	72.2%
	40	4.79	3.94	3.83	3.11	79.8%	70.1%
	50	4.55	3.70	3.55	2.83	77.7%	68.1%
	60	4.26	3.41	3.23	2.51	75.7%	66.0%
180cm	20	5.75	4.80	4.79	3.98	83.9%	74.3%
	30	5.62	4.67	4.58	3.77	81.9%	72.2%
	40	5.44	4.49	4.32	3.52	79.8%	70.1%
	50	5.21	4.25	4.04	3.23	77.7%	68.1%
	60	4.92	3.96	3.72	2.91	75.7%	66.0%
190cm	20	6.44	5.38	5.31	4.41	83.9%	74.3%
	30	6.31	5.25	5.10	4.20	81.9%	72.2%
	40	6.13	5.07	4.85	3.95	79.8%	70.1%
	50	5.90	4.83	4.56	3.66	77.7%	68.1%
	60	5.61	4.54	4.24	3.34	75.7%	66.0%

Table 2. African-American-Males

Height	Age	FVC		FEV1		FEV1/FVC%	
		Pred	LLN	Pred	LLN	Pred	LLN
170cm	20	4.29	3.43	3.69	2.93	85.6%	75.2%
	30	4.11	3.25	3.46	2.70	83.8%	73.3%
	40	3.93	3.07	3.23	2.47	81.9%	71.5%
	50	3.75	2.89	3.00	2.24	80.1%	69.7%
	60	3.57	2.71	2.77	2.01	78.3%	67.9%
180cm	20	4.88	3.91	4.15	3.30	85.6%	75.2%
	30	4.69	3.73	3.92	3.07	83.8%	73.3%
	40	4.51	3.55	3.69	2.84	81.9%	71.5%
	50	4.33	3.37	3.46	2.61	80.1%	69.7%
	60	4.15	3.18	3.23	2.38	78.3%	67.9%
190cm	20	5.49	4.42	4.64	3.69	85.6%	75.2%
	30	5.31	4.24	4.41	3.46	83.8%	73.3%
	40	5.13	4.05	4.18	3.23	81.9%	71.5%
	50	4.95	3.87	3.95	3.00	80.1%	69.7%
	60	4.76	3.69	3.72	2.77	78.3%	67.9%

Table 3. Mexican-American-Males

Height	Age	FVC		FEV1		FEV1/FVC%	
		Pred	LLN	Pred	LLN	Pred	LLN
170cm	20	5.14	4.31	4.41	3.71	85.7%	76.6%
	30	4.96	4.13	4.12	3.41	83.5%	74.4%
	40	4.74	3.91	3.82	3.12	81.3%	72.2%
	50	4.49	3.66	3.53	2.83	79.1%	70.0%
	60	4.20	3.37	3.24	2.54	76.9%	67.8%
180cm	20	5.76	4.83	4.94	4.15	85.7%	76.6%
	30	5.58	4.65	4.65	3.86	83.5%	74.4%
	40	5.36	4.43	4.35	3.56	81.3%	72.2%
	50	5.11	4.18	4.06	3.27	79.1%	70.0%
	60	4.82	3.89	3.77	2.98	76.9%	67.8%
190cm	20	6.42	5.38	5.50	4.62	85.7%	76.6%
	30	6.24	5.20	5.20	4.33	83.5%	74.4%
	40	6.02	4.99	4.91	4.03	81.3%	72.2%
	50	5.77	4.73	4.62	3.74	79.1%	70.0%
	60	5.48	4.44	4.33	3.45	76.9%	67.8%

Table 4. Caucasian-Females

Height	Age	FVC		FEV1		FEV1/FVC%	
		Pred	LLN	Pred	LLN	Pred	LLN
150cm	20	3.20	2.61	2.87	2.37	86.6%	76.8%
	30	3.19	2.61	2.74	2.24	84.4%	74.6%
	40	3.11	2.53	2.57	2.07	82.3%	72.5%
	50	2.96	2.37	2.35	1.86	80.2%	70.4%
	60	2.72	2.14	2.10	1.61	78.1%	68.3%
160cm	20	3.66	2.99	3.23	2.66	86.6%	76.8%
	30	3.65	2.98	3.09	2.53	84.4%	74.6%
	40	3.57	2.90	2.92	2.35	82.3%	72.5%
	50	3.42	2.75	2.71	2.14	80.2%	70.4%
	60	3.18	2.51	2.46	1.89	78.1%	68.3%
170cm	20	4.15	3.39	3.61	2.97	86.6%	76.8%
	30	4.14	3.39	3.47	2.83	84.4%	74.6%
	40	4.06	3.31	3.30	2.66	82.3%	72.5%
	50	3.91	3.15	3.09	2.45	80.2%	70.4%
	60	3.67	2.92	2.84	2.20	78.1%	68.3%

Table 5. African-American-Females

Height	Age	FVC		FEV1		FEV1/FVC%	
		Pred	LLN	Pred	LLN	Pred	LLN
150cm	20	2.76	2.15	2.49	1.97	87.6%	76.9%
	30	2.68	2.07	2.31	1.79	85.5%	74.9%
	40	2.55	1.94	2.12	1.60	83.5%	72.8%
	50	2.36	1.76	1.90	1.38	81.5%	70.8%
	60	2.13	1.52	1.66	1.15	79.4%	68.7%
160cm	20	3.18	2.49	2.82	2.24	87.6%	76.9%
	30	3.10	2.41	2.65	2.06	85.5%	74.9%
	40	2.97	2.28	2.45	1.86	83.5%	72.8%
	50	2.78	2.10	2.24	1.65	81.5%	70.8%
	60	2.55	1.86	2.00	1.41	79.4%	68.7%
170cm	20	3.63	2.85	3.18	2.52	87.6%	76.9%
	30	3.55	2.77	3.01	2.34	85.5%	74.9%
	40	3.42	2.64	2.81	2.14	83.5%	72.8%
	50	3.23	2.46	2.59	1.93	81.5%	70.8%
	60	3.00	2.22	2.36	1.69	79.4%	68.7%

Table 6. Mexican-American-Females

Height	Age	FVC		FEV1		FEV1/FVC%	
		Pred	LLN	Pred	LLN	Pred	LLN
150cm	20	3.29	2.69	2.91	2.40	87.9%	78.5%
	30	3.21	2.60	2.73	2.22	85.6%	76.3%
	40	3.07	2.47	2.54	2.03	83.4%	74.1%
	50	2.89	2.29	2.32	1.81	81.1%	71.8%
	60	2.66	2.06	2.07	1.56	78.9%	69.6%
160cm	20	3.73	3.05	3.28	2.70	87.9%	78.5%
	30	3.65	2.96	3.11	2.53	85.6%	76.3%
	40	3.51	2.83	2.91	2.33	83.4%	74.1%
	50	3.33	2.64	2.69	2.11	81.1%	71.8%
	60	3.10	2.41	2.45	1.87	78.9%	69.6%
170cm	20	4.20	3.43	3.68	3.03	87.9%	78.5%
	30	4.12	3.34	3.51	2.86	85.6%	76.3%
	40	3.98	3.21	3.31	2.66	83.4%	74.1%
	50	3.80	3.03	3.09	2.44	81.1%	71.8%
	60	3.57	2.80	2.85	2.20	78.9%	69.6%

APPENDIX M. TABLES OF OBSTRUCTIVE/RESTRICTIVE PATTERNS

The information below represents a method for interpretation of spirometric results. This method is not required practice and other methods exist.

LUNG DISEASES AND SPIROMETRY RESULTS

Interpretation	**FEV_1/FVC%**	**FVC**	**FEV_1**
Normal person	normal	normal	normal
Airway obstruction	low	normal or low	low
Lung Restriction	normal	low	low
Combination of Obstruction/Restriction	low	low	low

Adapted from Chronic Obstructive Pulmonary Disease, 5th Edition [1977]. American Lung Association (46).

GUIDELINES FOR ASSESSING DEGREE OF VENTILATORY IMPAIRMENT

Interpretation	**Obstructive Pattern**	**Restrictive Pattern**
Normal	FEV_1/FVC% ≥ **LLN**	FVC ≥ **LLN**
Borderline	FEV_1/FVC < LLN & FEV_1 ≥ LLN	
Mild	FEV_1 **< 100 & ≥ 70% Pred**	FVC < **LLN & ≥ 70% Pred**
Moderate	FEV_1 < **70 ≥ 50% Pred**	FVC < **70 & ≥ 50% Pred**
Severe	FEV_1 **≤ 50% Pred**	FVC≤ **50% Pred**

Adapted from American Thoracic Society: Lung function testing: Selection of reference values and interpretative strategies [1991]. American Review of Respiratory Diseases 144:1202-1218 (30).

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