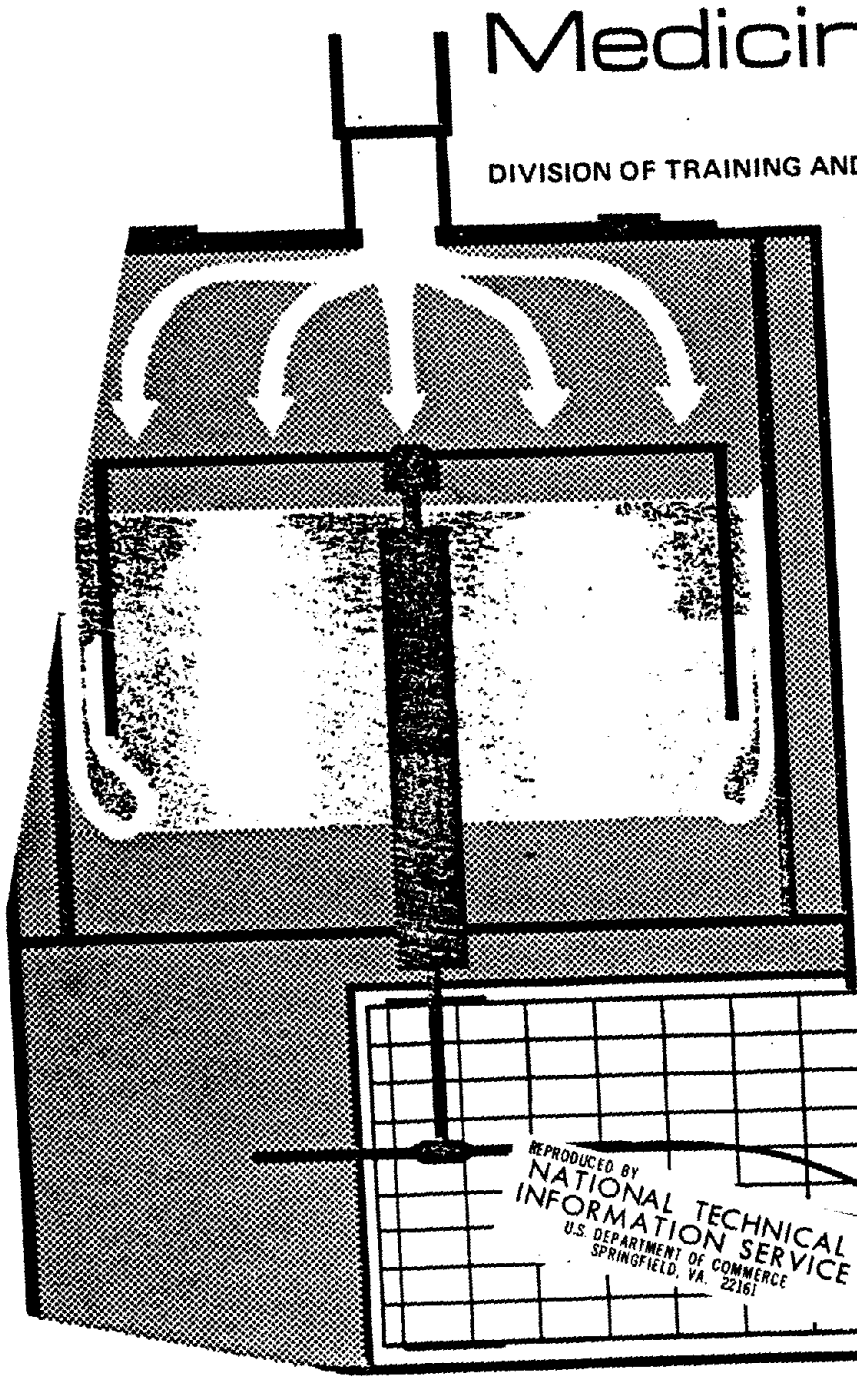
NIOSH

Manual of Spirometry in Occupational Medicine

DIVISION OF TRAINING AND MANPOWER DEVELOPMENT



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The routine assessment of ventilatory function with a simple spirometer is becoming an increasingly common practice in occupational medicine. Spirometry is now properly regarded as an essential component in any respiratory medical surveillance program for pre-employment evaluation and periodic monitoring. Combined with medical history, physical examination, and chest roentgenogram, spirometry can identify the job applicant with pre-existing pulmonary disease, thereby facilitating his proper placement in industry. Routine follow-up studies in workers exposed to hazardous airborne substances can detect respiratory impairment in it's earliest stages when corrective measures are more likely to be beneficial.

The utility of screening spirometry has been recognized by federal regulatory agencies. The Occupational Safety and Health Administration (OSHA) presently requires spirometry for employee exposure to asbestos, coke oven emissions and cotton dust. In addition, the National Institute for Occupational Safety and Health (NIOSH) recommends spirometry for several dozen other airborne substances including beryllium, cadmium, chlorine, formaldehyde, nitrogen dioxide, silica, sulfur dioxide, toluene diisocyanate (TDI) and wood dust.

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MANUAL OF SPIROMETRY IN OCCUPATIONAL MEDICINE

Division of Training and Manpower Development

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The opinions and conclusions expressed herein are not necessarily those of the National Institute for Occupational Safety and Health. Mention of trade names or commercial products does not constitute endorsement or recommendation by NIOSH. The spirometers pictured in Chapter 6 were selected by the editor as representative examples of instruments meeting American Thoracic Society specifications.

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Credit is also due the Intersociety Ad Hoc Committee to Study Pulmonary Function Testing and Training Procedures in Industry. Organized by the American Occupational Medical Association and chaired by David P. Discher, M.D., this committee was the stimulus for revision and expansion of the original Navy Manual.

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Chapter One

INTRODUCTION

Edward P. Horvath, Jr., M.D., M.P.H.

The routine assessment of ventilatory function with a simple spirometer is becoming an increasingly common practice in occupational medicine. Spirometry is now properly regarded as an essential component in any respiratory medical surveillance program for pre-employment evaluation and periodic monitoring. Combined with the medical history, physical examination, and chest roentgenogram, spirometry can identify the job applicant with pre-existing pulmonary disease, thereby facilitating his proper placement in industry. Routine follow-up studies in workers exposed to hazardous airborne substances can detect respiratory impairment in it's earliest stages when corrective measures are more likely to be beneficial.

The utility of screening spirometry has been recognized by federal regulatory agencies. The Occupational Safety and Health Administration (OSHA) presently requires spirometry for employee exposure to asbestos, coke oven emissions and cotton dust. In addition, the National Institute for Occupational Safety and Health (NIOSH) recommends spirometry for several dozen other airborne substances including beryllium, cadmium, chlorine, formaldehyde, nitrogen dioxide, silica, sulfur dioxide, toluene diisocyanate (TDI) and wood dust.

However, serious obstacles have hindered the widespread utilization of spirometry in the industrial setting. Many technicians, nurses, and physicians have been inadequately trained and perform or calculate tests incorrectly. Certain spirometers have been demonstrated to be technically unsatisfactory. Test methodology and procedure have lacked standardization, rendering difficult the comparison of results obtained at different facilities. Surprisingly, not a small number of physicians have lacked the necessary knowledge to properly interpret test results. Diagnostic information obtained under these circumstances can be worse than no information at all.

Recognizing that these serious deficiencies noticeably impeded the medical surveillance for occupational respiratory diseases, professional attention was focused on the three essential components of proper spirometry: standardized methodology for performance and calculation of tests, technician competence, and minimum instrument performance standards.

In January, 1977, the American Thoracic Society (ATS) published the results of it's Snowbird Workshop on the standardization of spirometry. Methodologic principles and instrument specifications were approved by concensus and recommended for "both clinical laboratories and epidemiologic studies." While objections have been raised that certain provisions are too stringent for "office spirometry," most occupational health professionals have recognized the ATS standards as "State of the Art" recommendations applicable to the industrial setting.

Concurrent with the formulation of these technical standards, a national intersociety ad hoc committee addressed the issue of technician training. Comprised of representatives from five health professional groups,[1] this committee reviewed current spirometry practice in industry. It also attempted to learn of any available spirometry training for industrial health personnel and the existence of any

validated examination techniques to assess the efficacy of such training. The committee concluded that many spirometry technicians, particularly those in out-patient settings, had received no formal training and their competence was therefore in question. Few spirometry training courses existed outside of the associate degree programs in cardio-pulmonary technology offered by some universities. Finally, no validated examination procedure to assess technician skill and knowledge could be identified.

To remedy this situation, the committee collaborated with two educational institutions, the U.S. Navy Environmental Health Center and the University of Cincinnati, who conducted experimental courses in November, 1977 and January, 1978. The subsequent evaluation of these two courses guided the committee's curriculum design recommendations and ultimately, the formulation of national standards for technician training and competence.

The sum total of the aforementioned standards for technician training and competence, test methodology and instrument specifications were adopted by OSHA in June, 1978, as part of it's requirements for medical monitoring for cotton dust exposure. Currently NIOSH[2] approves courses for spirometry technicians from the cotton industry as well as other occupational settings. The Council on Occupational Respiratory Diseases (CORD),[3] a separate organization incorporated from the professional membership of the original ad hoc committee, also certifies spirometry training programs.

Although OSHA spirometry standards are presently mandatory only for cotton dust exposure, other industries are achieving voluntary compliance. By so doing, they recognize not only the scientific validity of these recommendations, but also the likely future extension of these requirements to their companies either by regulatory action or by their widespread adoption as the accepted "standard of practice."

1. American Occupational Medicine Association, American Academy of Occupational Medicine, American Thoracic Society, American Association of Occupational Health Nurses and the American College of Chest Physicians.

2. Director, Division of Training and Manpower Development, National Institute for Occupational Safety and Health, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

3. David P. Discher, M.D., CORD President, Palo Alto Medical Clinic, 300 Homer Ave., Palo Alto, California 94301.

Chapter Two

PULMONARY ANATOMY AND PHYSIOLOGY

Stuart M. Brooks, M.D.

Although sometimes regarded as little more than a modified bellows system for moving air, the lung is in fact a complex organ involved in a number of indispensable physiologic processes. While it is true that its major function is to provide a means for transfer of oxygen from the atmosphere into the blood and for elimination of carbon dioxide, this is not its only task. It is capable of metabolizing and detoxifying a host of endogenous and exogenous substances, the latter including both drugs and toxic compounds. The lung is an important defense organ, protecting against infectious agents and environmental pollutants. In this role it is assisted by the ciliated bronchial lining epithelium, phagocytic cells and lymphatic network. Important immunologic processes can occur locally in the lung independent of other parts of the body. Finally, the lung is active in the synthesis of certain important body constituents such as pulmonary surfactant which lines the surface of the respiratory units. This material reduces surface tension and allows the lungs to remain expanded even at low lung volumes. Prostaglandins which are important in inflammatory reactions, are also synthesized by pulmonary tissue.

It is clear that some familiarity with the basic features of pulmonary anatomy and physiology is helpful in understanding the rationale behind spirometry as well as the pathogenesis of certain occupational lung disorders.

ANATOMY—THE CONDUCTING AIRWAYS AND RESPIRATORY UNIT

The tracheo-bronchial system contains two types of airways: The bronchi which consist of cartilage and the bronchioles which are non-cartilaginous or membranous airways. The primary function of the airways is to serve as a conductor of air between the external environment and the terminal respiratory unit.

From the trachea downward, the airways divide progressively, analogous to the branching of a tree (Figure 2-1). This branching may be symmetrical, where two daughter branches are of uniform diameter, or it may be asymmetrical. Regardless, the average internal diameter of each new generation of airways becomes progressively smaller as one proceeds from the trachea out to the smallest bronchi. However, over the complete number of some 23 generations, the total cross-sectional area of airway lumens surprisingly increases. The significance of this total increase in cross-sectional area is that resistance to air flow actually decreases as one moves down from the larger airways to the bronchioles.

The smaller bronchi and bronchioles less than 2 mm. in diameter are often referred to as the "small airways." It is in this portion of the tracheobronchial tree that airborne substances are thought to exert their initial deleterious effects. Yet because these small airways contribute only 15% to total airway resistance, considerable disease must be present in them before usual spirometric tests become abnormal.

The bronchioles, or non-cartilaginous airways, continue to subdivide in a distinctive fashion

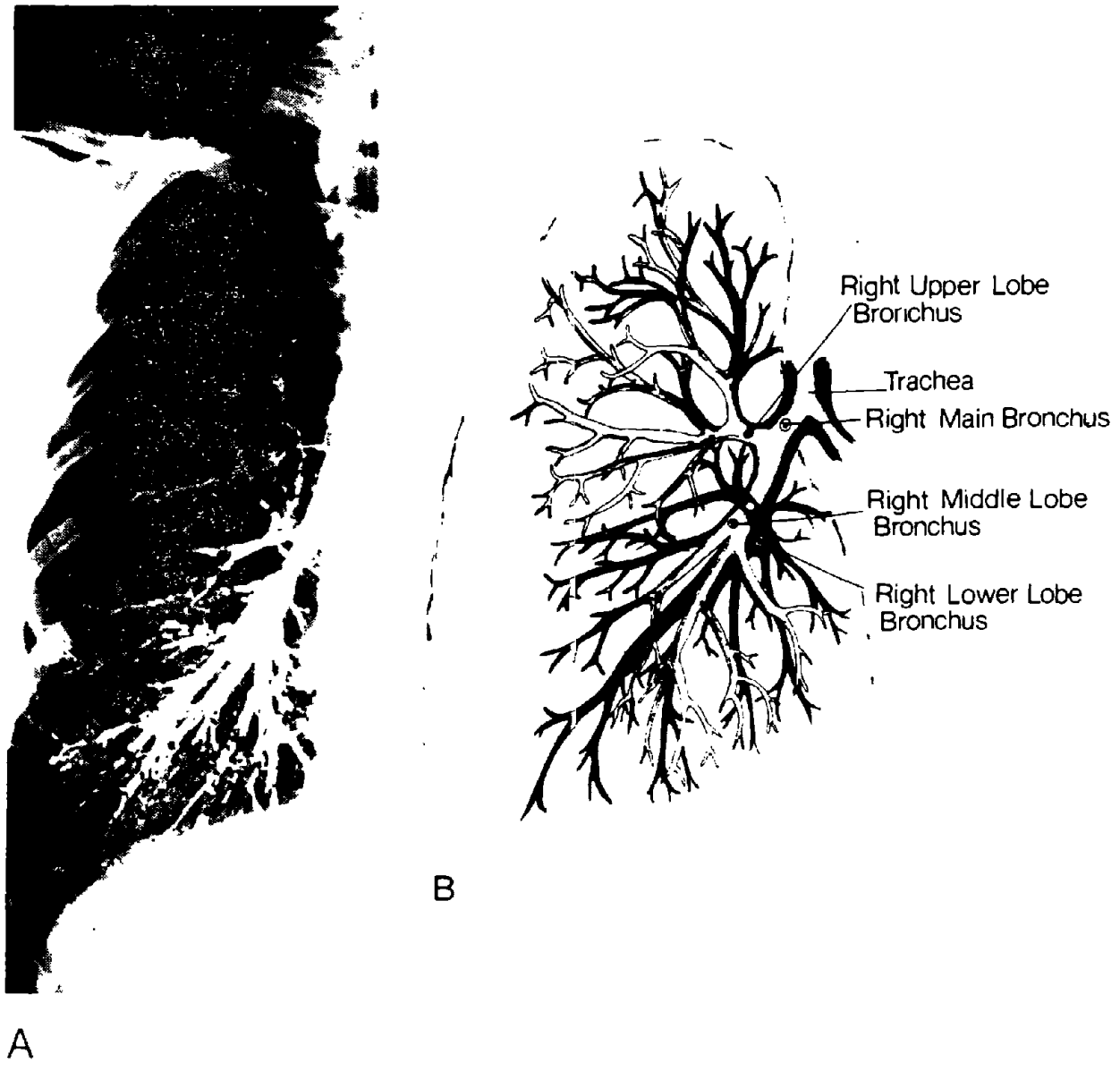


Figure 2-1. A. Normal bronchogram of the right bronchial tree.
B. Semidiagrammatic illustration.

and serve mainly as conductors of air. Once the level of the respiratory bronchioles is reached, gas exchange can occur since there is respiratory tissue in their walls. The conducting airways, therefore, refer only to the trachea, bronchi, and non-respiratory bronchioles.

Gas exchange of oxygen and carbon dioxide takes place in the respiratory unit consisting of the respiratory bronchiole, alveolar duct, alveolar sac and individual alveoli (Figure 2-2, 2-3).

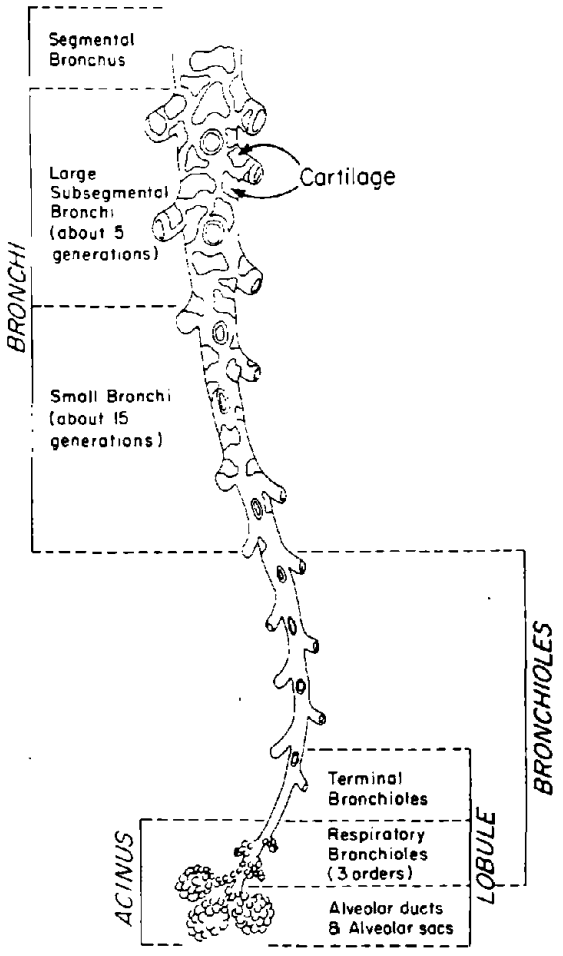


Figure 2-2. Progressive subdivision of the tracheobronchial tree illustrating both conducting airways and respiratory unit.

Deoxygenated blood reaches the alveoli via the pulmonary arterial system which accompanies the branching bronchi and bronchioles. These arterials become a rich capillary network at the level of the respiratory bronchiole, (Figure 2-4). This capillary plexus is in intimate proximity to the alveolar epithelium so that red blood cells are separated from the inhaled air only by the thickness of the alveolar-capillary membranes (Figure 2-5). The alveoli have a surface area of about 70 square meters providing a contact area for gas exchange equivalent to the size of a tennis court. Having been oxygenated in the alveolar capillaries, the blood then is carried back to the left atrium via the pulmonary veins.

The lung is unique in that it has two separate blood supplies. The pulmonary circulation handles virtually the entire cardiac output, its major function being to oxygenate the blood. In contrast, the bronchial circulation arising from the aorta, receives only a small portion of cardiac output and contains only oxygenated blood. These bronchial arteries are the principal source of nutrient blood to the pulmonary tissue itself including the tracheobronchial tree, pulmonary nerves, lumph tissue and the visceral pleura. The bronchiolar arteries from this system join the pulmonary circulation at the level of the respiratory bronchioles. This interconnection between the two circulations allows for a protective mechanism when, if the perfusion pressure in one system decreases, it is counterbalanced by an increase in perfusion pressure in the other.

The lining of the airways as far as the terminal bronchiole consists of two basic cell types: ciliated columnar epithelial cells and goblet cells. Goblet cells create a mucous layer which rests on top of the cilia and is swept mouthward by coordinated movement of the cilia. This "mucous blanket" or "ciliary escalator" is an important defense mechanism for removal of inhaled particulate matter, (Figure 2-6). Unfortunately, its efficiency may be impaired or destroyed by noxious agents such as cigarette smoke. Furthermore, excessive mucous secretion which occurs in chronic bronchitis, may impose an undue burden on cilia and contribute to plugging and narrowing of airways.

The alveolar-capillary area is populated by a number of cells including Type I and Type II pneumocytes, alveolar macrophages, capillary endothelial cells, connective tissue cells, leukocytes and lymphocytes (Figure 2-7). These cells are variously responsible for gas exchange, disposal of inhaled foreign material,

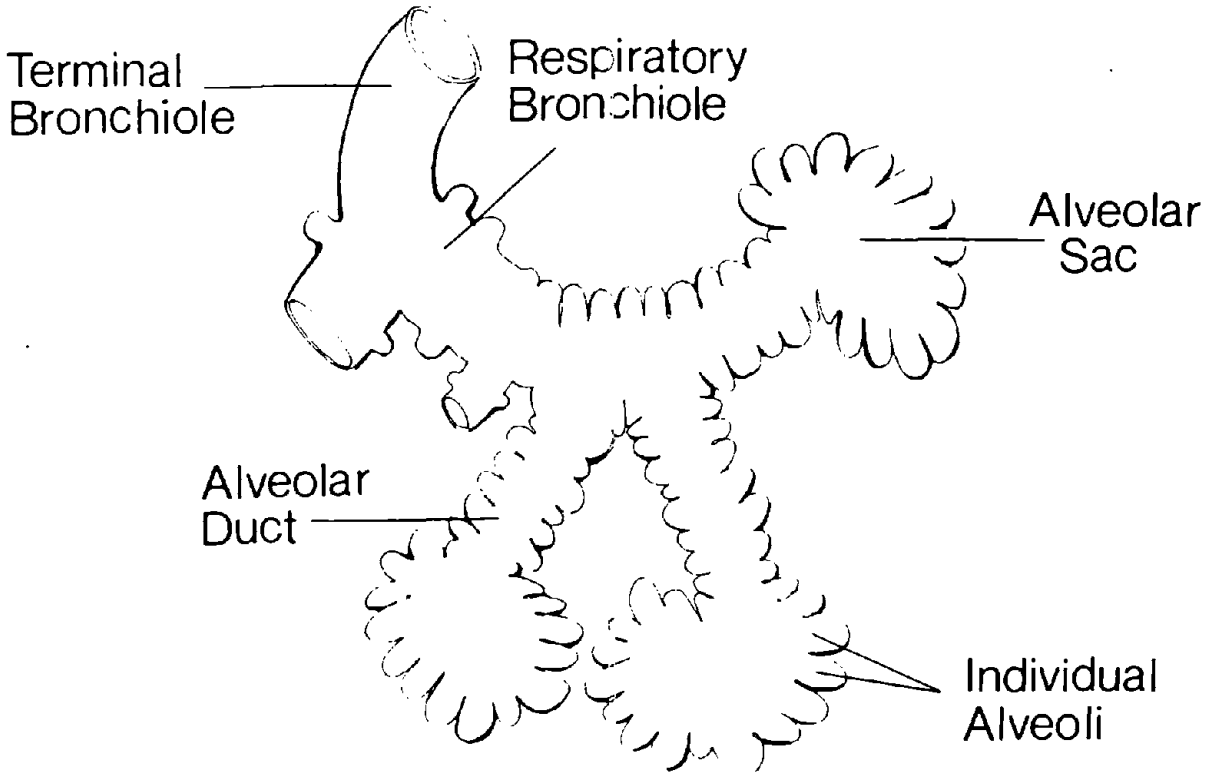


Figure 2-3. Respiratory unit.

synthesis of surfactant, and immunologic activity. A detailed discussion of their precise physiologic roles is beyond the scope of this chapter.

The cellular elements of the lung are supported mainly by a frame work consisting of reticulin, elastin and collagen fibers. The presence of these fibers helps determine the compliance (stiffness) and the elastic recoil properties of the lung.

PHYSIOLOGY

The maneuver where one takes a maximal inspiration and then rapidly and forcefully exhales this air is known as the forced vital capacity maneuver. A number of physiologic principles determine the shape of the forced expiratory curve and can be arbitrarily divided into mechanical properties of the lungs and airflow resistance. When one speaks of mechanical properties of the lung, the terms compliance and elastic recoil are often mentioned. Compliance generally describes stiffness or distensibility of the lung. It represents the relationship between the change in volume of air within the lung and the accompanying pressure change needed to cause that volume change, i.e., volume change/pressure change ratio. When the pressure needed to change the volume is great, the lung is stiff and compliance will be low. This is a situation found in various forms of pulmonary fibrosis such as asbestosis. In emphysema, on the other hand, the volume change occurs with less exerted pressure and compliance is increased, i.e., the lung is less stiff. Compliance can be measured either during tidal breathing (dynamic compliance) or at different lung volumes (static compliance). (Figure 2-8).

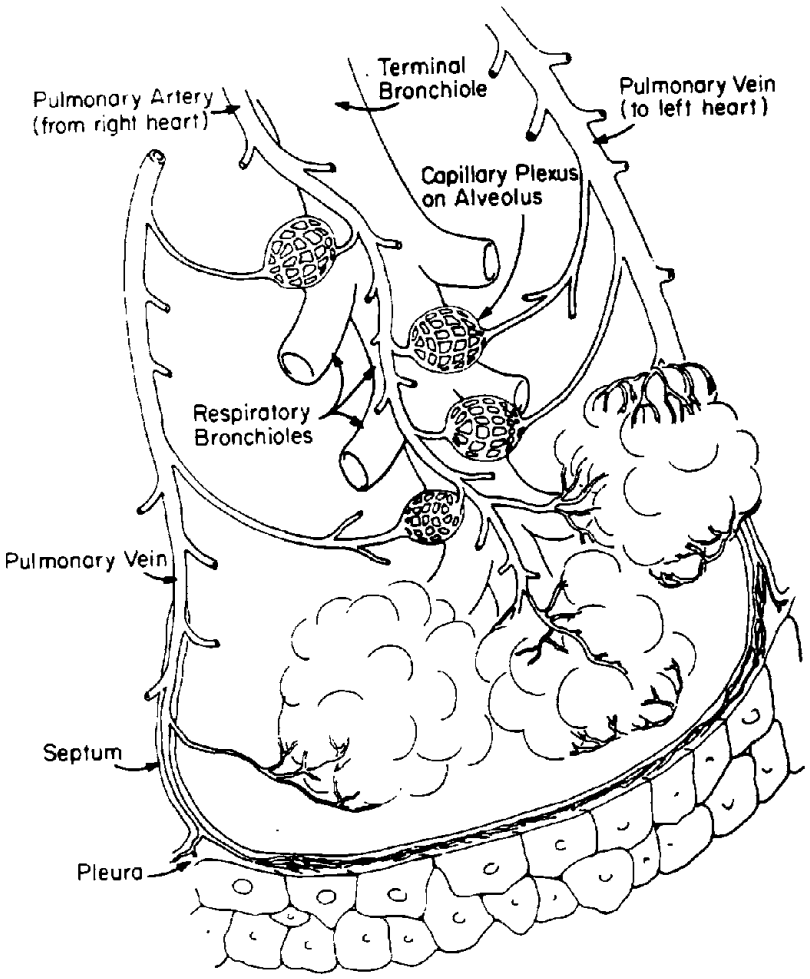
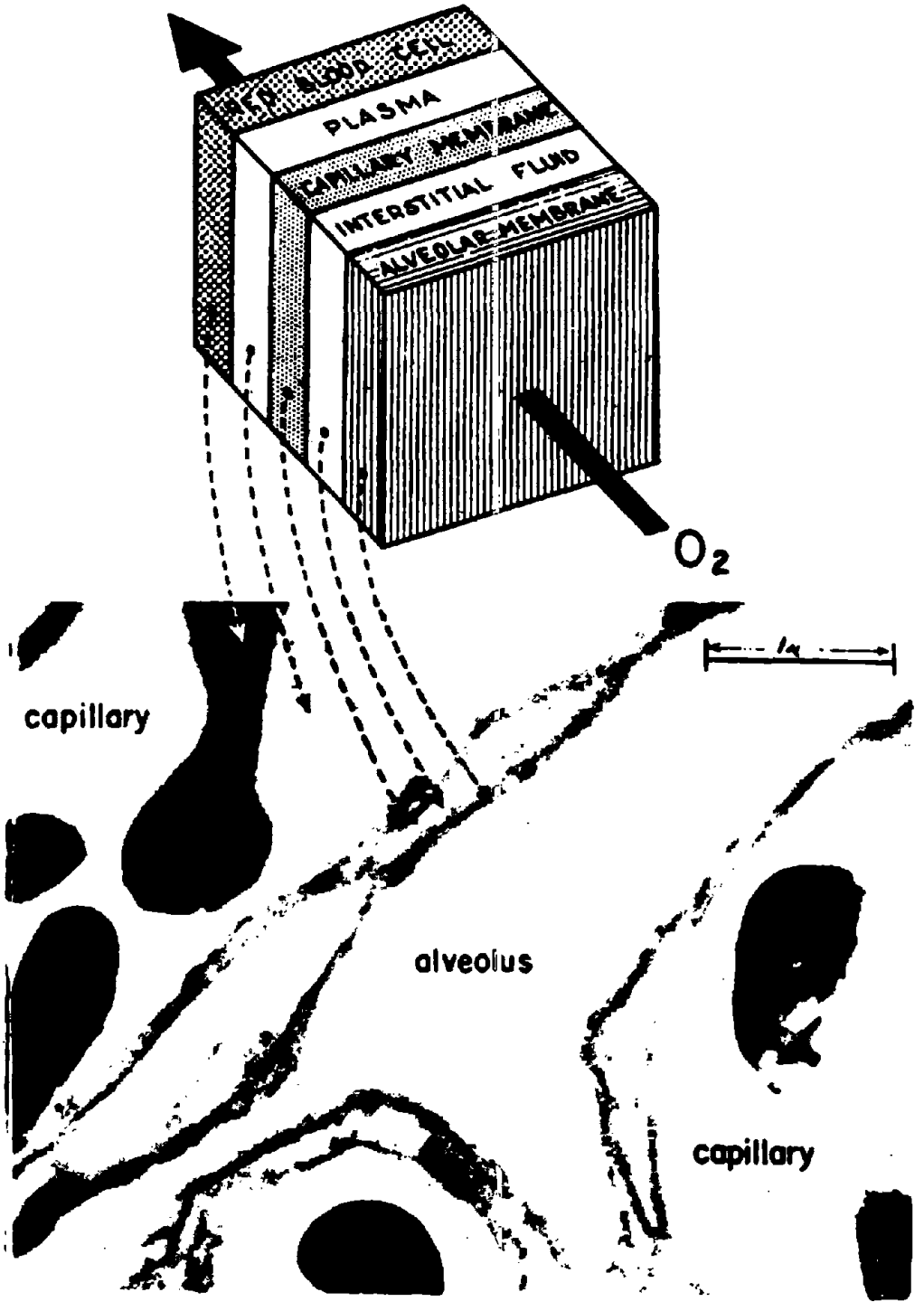


Figure 2-4. Pulmonary vascular system.

Because compliance measures the distensibility of the respiratory system, it in fact reflects the elasticity of the lungs or, more specifically, the elastic recoil properties of the lung and chest wall. Elastic recoil refers to the tendency of the lungs to return to the relaxed state at functional residual capacity. This elastic property is due to the intrinsic qualities of the lung tissue itself as well as a film of surfaceactive material that lines the terminal respiratory units (surfactant). Like a balloon, the elastic recoil pressure is greatest when there is maximum inflation and least when the lungs are relatively deflated. Elastic recoil pressure varies with disease states. The stiff lungs characteristic of pulmonary fibrosis demonstrate increased elastic recoil pressure On the other hand, emphysematous lungs are more distensible due to loss of supporting parenchymal tissue and, therefore, have less elastic recoil.

Another factor affecting performance of spirometry is airflow resistance, which is determined by the numbers, length and cross-sectional area of the conducting airways. Cross-sectional area of the airways is the most important determinant because resistance in



Reprinted with permission from Low, F. N., ANAT Record, 17:241, 1953.

Figure 2-5. Alveolar-capillary interface.

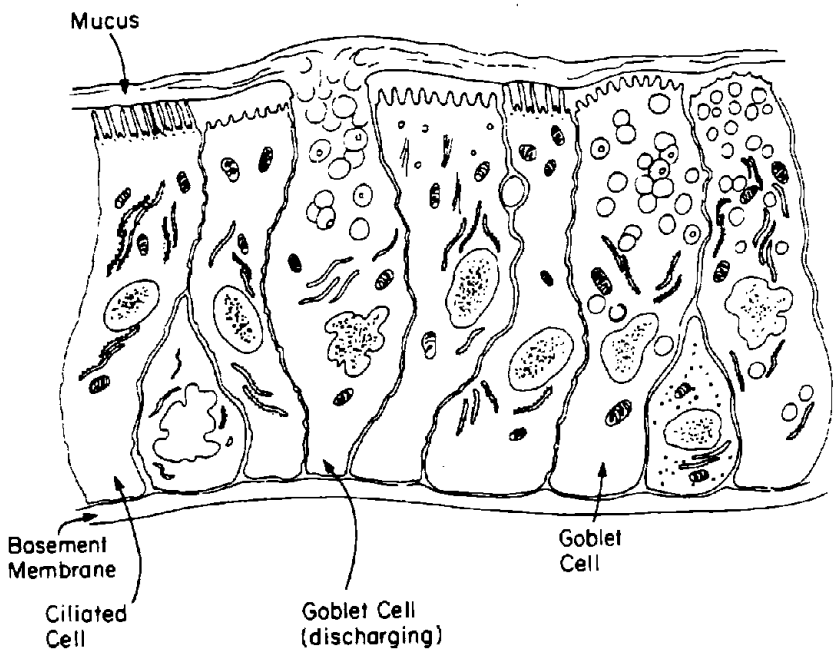


Figure 2-6. Mucociliary escalator.

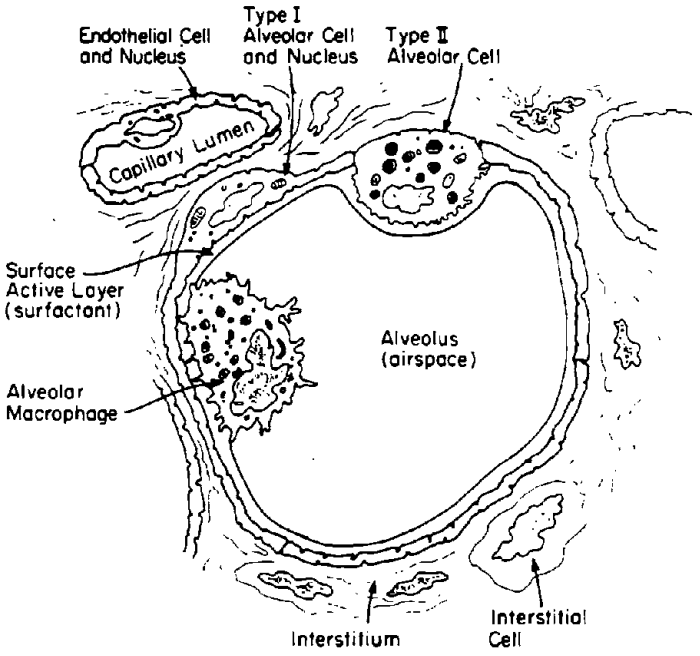
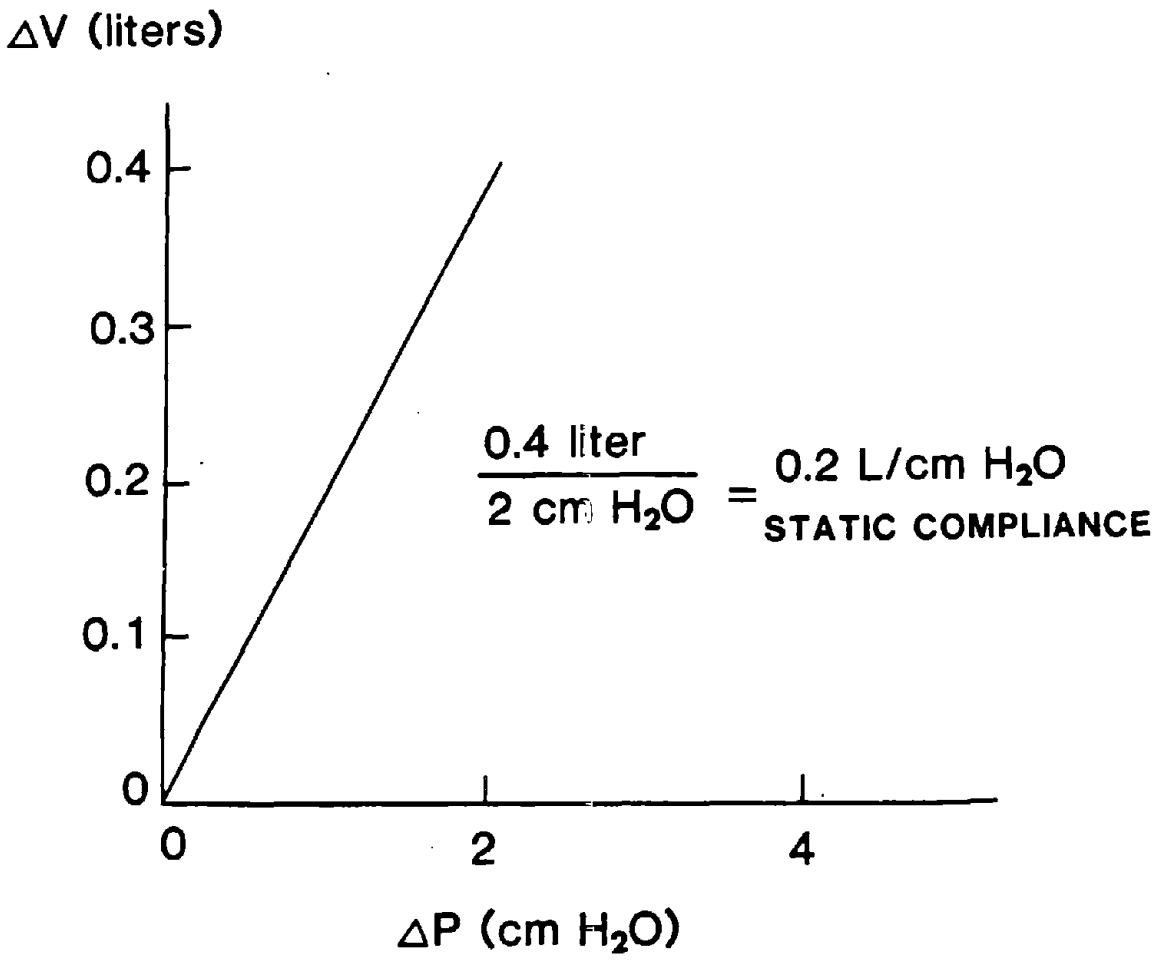


Figure 2-7. Cells of the alveoli.



Adapted and reprinted from Fraser, R. G. and Paré, J. A., *Diagnosis of Diseases of the Chest*, W. R. Saunders, Philadelphia, 1970.

Figure 2-8. Pressure-volume relationship. A change of 2 cm. H_2O in pressure (Δ P) results in a volume change (Δ V) of 0.4 liters in this hypothetical example. The static compliance in this instance is 0.2 L/cm H_2O.

any given airway increases exponentially as its diameter decreases. Dynamic compression narrows the airways during the performance of the forced expiratory maneuver due to increase in intrathoracic pressure.

Elastic recoil and airway resistance tend to exert their maximal effects at different stages during the forced expiratory maneuver. In normal adults, elastic recoil is maximal at high lung volumes at the end of inspiration. On the other hand, airway resistance predominates as airways narrow with diminishing lung volume during expiration. The net decrease of airflow which occurs toward the end of the forced expiratory maneuver, therefore, reflects both an increased airway resistance *and* a decreased elastic recoil pressure.

It should be obvious at this point that the proper performance of spirometry is dependent on patient cooperation and effort. The subject must expend maximal effort to overcome elastic recoil during inspiration. Similarly, maximal effort is also required to overcome airway resistance during the latter portion of forced expiration.

PATTERNS OF DISORDERED LUNG FUNCTION

Chronic obstructive pulmonary disease, which includes asthma, chronic bronchitis, and emphysema, is characterized by airway obstruction and reduced airflow. This obstruction in airflow is greatest during expiration and is generally due to decreased elastic recoil and/or increased airway resistance. Increased airway resistance results from narrowing of the smaller bronchi. In chronic bronchitis this is secondary to mucosal edema and hypersecretion of mucous; in asthma, a component of bronchial spasm is also present. In the emphysematous lung, loss of alveolar surface area and surrounding supportive pulmonary tissue results in exaggerated bronchiolar collapse during forced expiration. During performance of spirometry, the degree of airway obstruction is measured by the forced expiratory volume in one second (FEV_1). The FEV_1 may be expressed as a percentage of the forced vital capacity, $FEV_1/FVC\%$. In obstructive airway disease this proportion is reduced.

In restrictive disorders such as pulmonary fibrosis, the lungs are stiff because of the presence of fibrotic tissue. The elastic recoil pressure is greater than normal, and its reciprocal, compliance, is reduced. This increase in elastic recoil and diminished compliance prevent the lungs from expanding as fully as they should and result in a reduced forced vital capacity (FVC). Classically in a pure restrictive disorder, there is no airways obstruction and $FEV_1/FVC\%$ remains normal.

A mixed pattern of obstructive and restrictive spirometric patterns can be present in any given patient with more than one disease process, e.g., asbestosis and asthma. However, in the presence of severe airway obstruction, one cannot make the diagnosis of restrictive disease solely on the basis of a decreased total forced vital capacity. In such individuals, the forced vital capacity may be substantially smaller than the untimed vital capacity because of air trapping and hyperinflation. In the presence of severe airway obstruction, it is recommended the vital capacity be performed without forced effort and additional parameters, such as total lung capacity, be obtained.

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Chapter Three

TECHNIQUE

Edward P. Horvath, Jr., M.D., M.P.H.

There are three essential prerequisites for valid spirometry: Standardized methodology for performance and calculation of tests, technician competence and minimum instrument performance standards. Of these, the training and skill of the individual performing spirometry will often make the difference between a successful and unsuccessful program of pulmonary function testing. For this reason, the spirometry technician must devote meticulous effort to subject preparation, testing technique; and assessment of the spirogram for validity.

Subject preparation consists of explaining the purpose of the test, knowing when to postpone spirometry and properly positioning the subject for the forced expiratory effort. The procedure should be explained to the patient in simple terms. The brief statement "I want to test how hard and fast you can breathe" may not be physiologically precise, but is usually the only explanation necessary.

Because the proper performance of spirometry is an effort dependent phenomenon, it is prudent to postpone testing if the individual is acutely ill from any cause. This is particularly true in respiratory infections, such as influenza, pneumonia and bronchitis where actual involvement of the airways or pulmonary parenchyma may further lower spirometric results. A three week recovery period is recommended in such circumstances before testing is undertaken. The author has personally documented improvements in the forced vital capacity up to one liter which have occurred in individuals three weeks after recovering from an episode of nonspecific bronchitis. Postponing spirometry is usually not necessary in uncomplicated upper respiratory tract infections (colds) unaccompanied by profound systemic complaints. Cigarettes or aerosolized bronchodilators may transiently alter airway resistance, particularly in the smaller bronchi or bronchioles. It may be advisable to postpone spirometry if the patient used either of these in the past hour. Although unusual in the industrial setting, a recent heavy meal is also regarded as reason to postpone spirometry for approximately one hour.

The subject should then be instructed to loosen tight clothing and to remove any dentures. He may sit or stand, whichever is more comfortable or convenient. Most test subjects are comfortable sitting and under normal circumstances there is little difference in pulmonary function values obtained in either position. The sole exception is in the case of a grossly obese individual where seated test results may be lower. The chin should be elevated and the neck slightly extended. While the use of a noseclip is not explicitly required, it is highly recommended, particularly when the closed circuit technique is used (see next page).

The subject should then be instructed to take the deepest possible inspiration from a normal breathing pattern, close his mouth firmly around the mouthpiece and without further hesitation blow into the apparatus as hard, fast and completely as possible. This particular method of eliciting the forced expiratory maneuver is often referred to as the open circuit technique and is the most common way of performing spirometry in the screening setting. Almost all subjects master this tech-

nique with minimal explanation and practice, consistently performing reproducible forced expiratory efforts. An occasional individual may have difficulties such as failure to maintain an airtight seal around the mouthpiece, pursing of the lips as with a musical instrument or obstruction of the mouthpiece with the tongue. Some technicians avoid these problems by routinely demonstrating proper mouthpiece positioning to each subject. Spirometry procedure utilizing the open circuit technique is outlined in Appendix A.

Some pulmonary physicians prefer the closed circuit technique. This is where the subject establishes a constant tidal breathing pattern after insertion of the mouthpiece. The patient is then instructed to slowly exhale. When expiration is maximal, the subject then breathes in as deeply as possible. When full inspiration is reached, the patient initiates the forced expiratory maneuver. Some physicians feel this technique avoids loss of inspired air which theoretically may occur during positioning of the mouthpiece in the open circuit method. Because some subjects may breathe through the nose during testing with the closed circuit technique, use of a noseclip is strongly recommended. Regardless of which technique is used, vigorous coaching is necessary throughout the entire forced expiratory effort.

A valid spirogram must consist of three "acceptable" forced expiratory maneuvers. These three tracings must be free from cough, early termination of expiration, inconsistent effort or excessive variability. Tracings marred by cough or inconsistent effort are readily apparent as are illustrated in Figures 3-1 and 3-2, respectively. Early termination of expiration occurs when the tracing fails to become horizontal or to plateau as depicted in Figure 3-3. Mathematically, the plateau or end-of-test is reached when there is less than 25 ml. volume change over 0.5 seconds. To avoid excessive variability, the two largest forced vital capacities

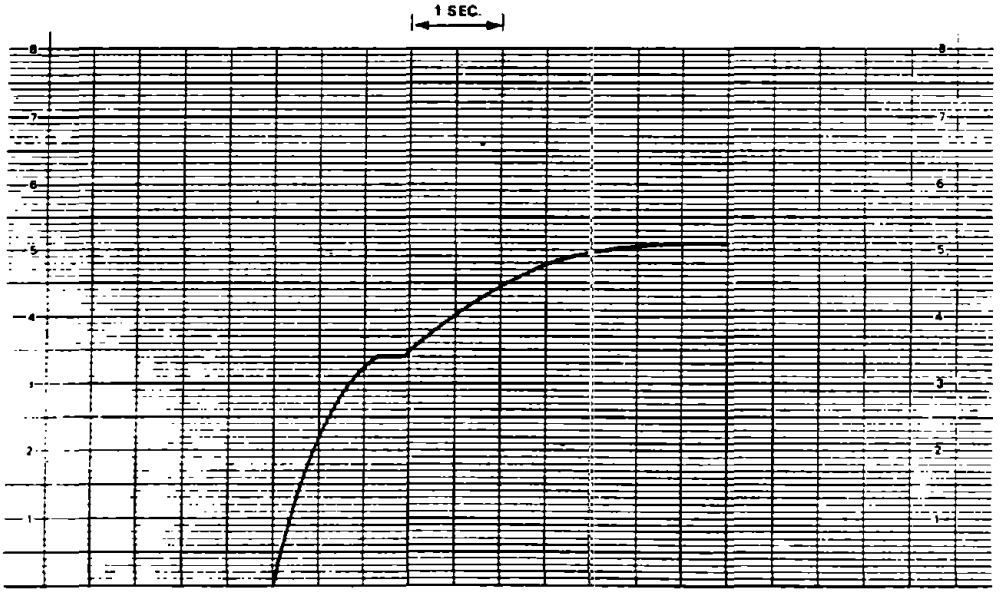

Figure 3-1. Unacceptable tracing – cough.

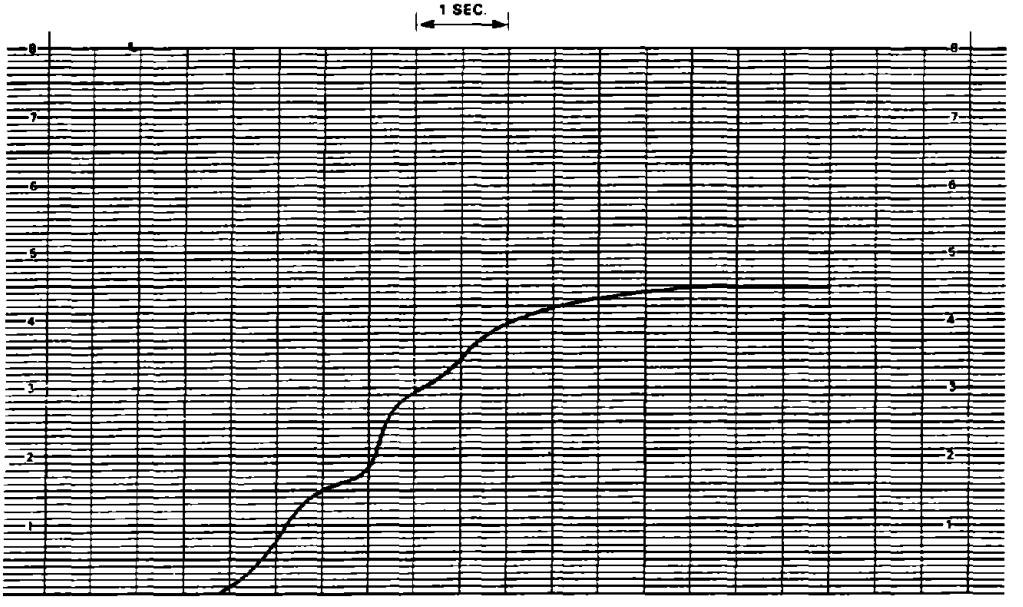

Figure 3-2. Unacceptable tracing – inconsistent effort.

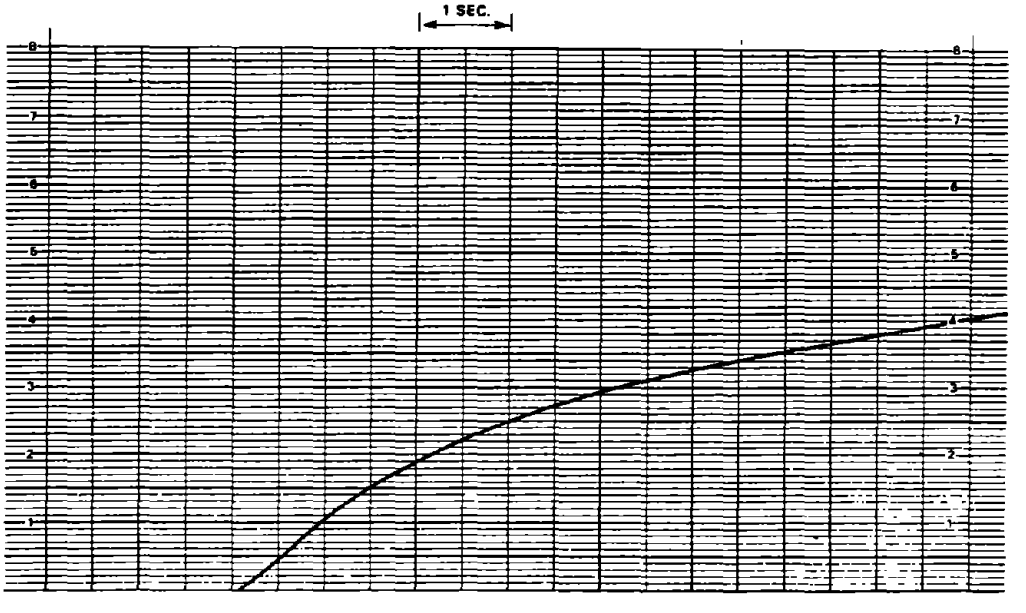

Figure 3-3. Unacceptable tracing – early termination of expiration – failure to 'plateau'.

Table 3-1

CRITERIA FOR A VALID SPIROGRAM

Three "Acceptable" Forced Expiratory Maneuvers Free From:
1. Cough
2. Early termination of expiration—"end-of-test" occurs when "plateau" is noted in tracing or mathematical definition—less than 25 ml volume change in 0.5 seconds.
3. Inconsistent effort—active coaching a "must" throughout the entire effort
4. Excessive variability – two best FVC's should not vary by more than 5% or 100 ml whichever is greater

of the three acceptable tracings should not vary by more than 5% or 100 ml., whichever is greater (Figure 3-4). In this example, and most other spirograms, 5% of the largest FVC is the criterion used because it is greater than 100 ml. Almost all subjects when properly instructed and actively coached, can produce a valid spirogram with three to five forced expiratory efforts. The criteria for a valid spirogram are summarized in Table 3-1.

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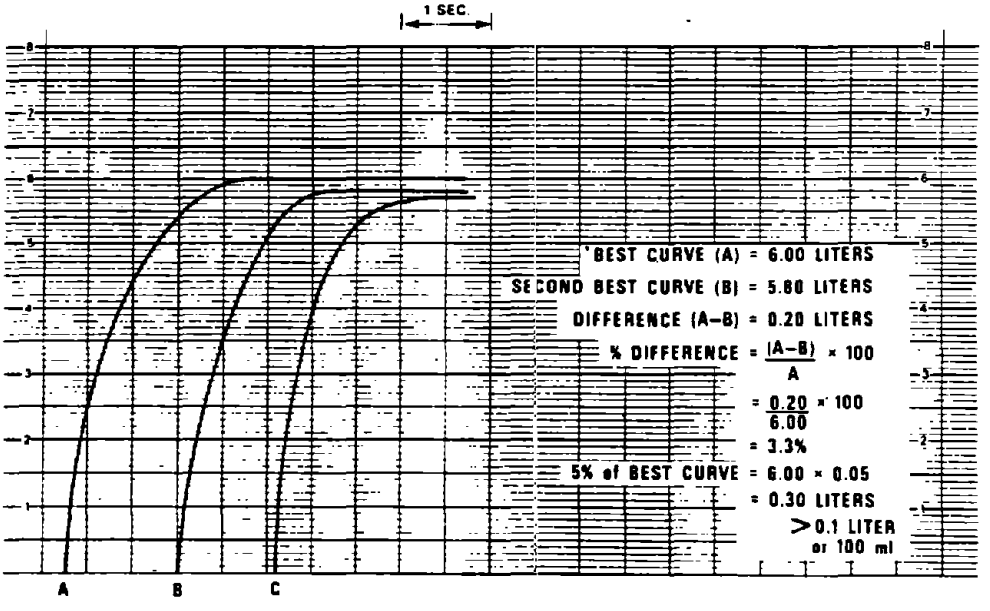


Figure 3-4. Valid spirogram – two best curves within 5%.

Chapter Four

CALCULATIONS

Edward P. Horvath, Jr., M.D., M.P.H.

Several spirometric indices can be calculated from the time-volume tracing. These include the forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), forced expiratory volume in one second as a percent of the total forced vital capacity ($FEV_1/FVC\%$), and the mean forced expiratory flow during the middle half of the FVC, ($FEF_{25-75\%}$).

FORCED VITAL CAPACITY (FVC)

The vital capacity (VC) is defined as the maximal volume of air exhaled from the point of maximal inspiration. The forced vital capacity (FVC) is the volume of air which can be exhaled *forcefully* after full inspiration. The determination of the FVC is illustrated in Figure 4-1.

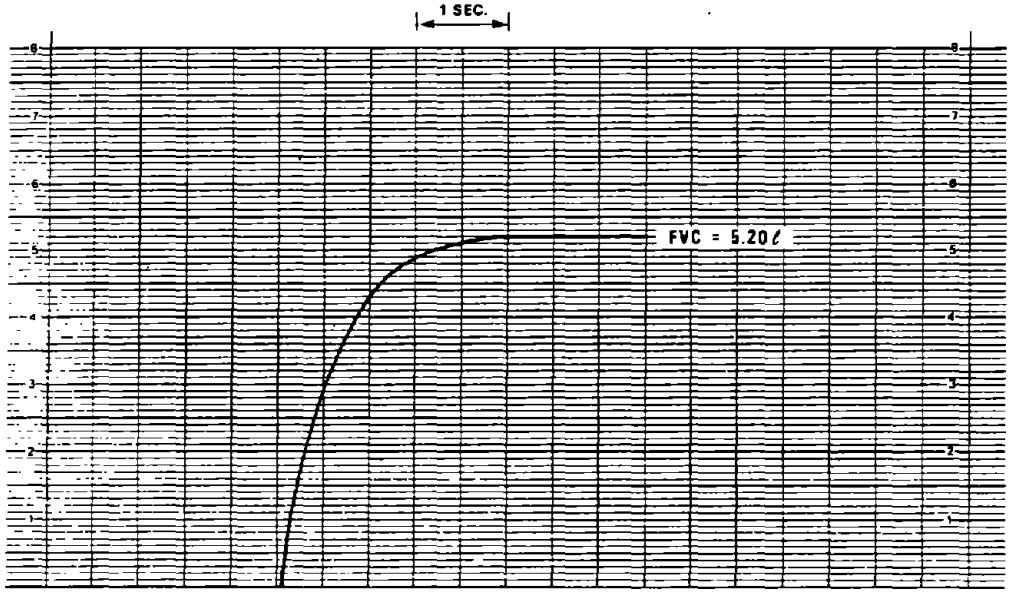


Figure 4-1. Forced vital capacity (FVC).

In most individuals, the values obtained for the VC and FVC are nearly identical. In patients with severe obstructive pulmonary disease, however, the FVC is often smaller than the VC because of expiratory slowing, air trapping and hyperinflation. In the absence of airway obstruction, reduction of the FVC is usually described as a restrictive ventilatory defect. This term encompasses conditions in which there is an actual reduction in the volume of air which can be inspired. Extra-pulmonary factors such as neuromuscular disorders (Guillain-Barré) or chest wall abnormalities (kyphoscoliosis) can interfere with full expansion of the chest. Replacement or removal of functional lung tissue by tumor, fluid, or surgery directly diminishes lung volume. Interstitial fibrosis stiffens the lungs, lowering pulmonary compliance. This interferes with the ability to achieve full inspiration and thereby decreases the FVC.

FORCED EXPIRATORY VOLUME IN ONE SECOND (FEV_1)

The forced expiratory volume in one second (FEV_1) is the volume of air exhaled during the first second of the forced expiratory effort. Determination of FEV_1 is influenced by the point selected as the start of the test, the zero time point. A uniform method of selecting this point is required to maintain consistency of results. In a published statement on the standardization of spirometry, the American Thoracic Society identified the back extrapolation method as the most consistent and accepted technique for determining the zero time point and recommended its use "until other methods are demonstrated to give equivalent results." The determination of the zero time point and FEV_1 by the back extrapolation method are illustrated in Figure 4-2. Exceptionally hesitant expiratory starts may prevent accurate back extrapolation and determination of the zero time point. Any tracing with an extrapolated volume in excess of 10 percent of the total FVC or 100 ml., whichever is greater, should be repeated. In actual practice, such tracings are a rare occurrence. The determination of extrapolated volume is illustrated in Figure 4-3.

FORCED EXPIRATORY VOLUME IN ONE SECOND AS A PERCENT OF THE FVC ($FEV_1/FVC\%$)

The subject's FEV_1 can be expressed as a percent of the predicted normal value:

$$\frac{\text{Observed } FEV_1}{\text{Predicted } FEV_1} \times 100 = \%\text{ of predicted } FEV_1$$

or; as a percent of the total observed FVC:

$$\frac{\text{Observed } FEV_1}{\text{Observed FVC}} \times 100 = FEV_1/FVC\%$$

Calculation of $FEV_1/FVC\%$ is particularly useful in severe restrictive pulmonary disease where a reduction in the FEV_1 may falsely suggest airway obstruction. A normal individual should be able to expire 70 to 80 percent of the FVC in one second, depending upon age and sex. A patient with pulmonary fibrosis may have a significantly reduced FVC of only 2 liters, but in the absence of airway obstruction, he should be able to expire 80% of this forced vital capacity in one second. However, this FEV_1 of 1.6 liters would be only 50% of his predicted normal FEV_1 of 3.2 liters. Therefore, one could erroneously assume he has obstructive disease when in fact only a restrictive ventilatory impairment is present. The calculated $FEV_1/FVC\%$ (1.6/2.0 x 100) in this case is a normal 80%.

In determination of FEV_1, FVC, and $FEV_1/FVC\%$, the largest FEV_1 and FVC should be used, regardless of the curve(s) on which they occur. For example, in the calculation of the $FEV_1/FVC\%$, the FEV_1 and FVC need not come from the same curve. This admittedly arbitrary decision has been adopted by the American Thoracic Society as the recommended uniform methodology.

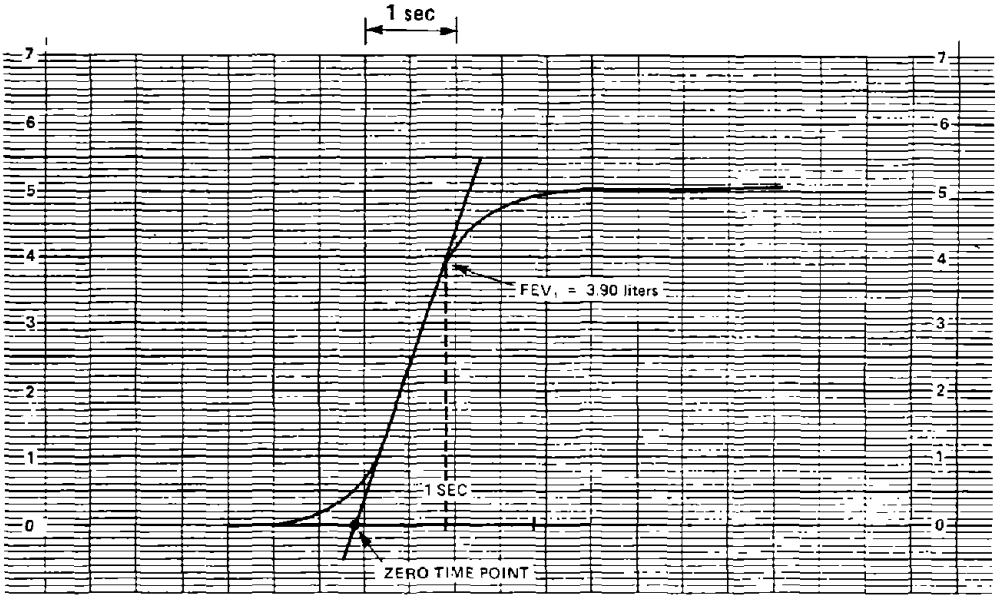


Figure 4-2. Determination of zero time point and FEV_1 by the back extrapolation method. Draw a line along the steepest portion of the volume curve to intersect the baseline. This intersection is the zero time point for purpose of timing the FEV_1.

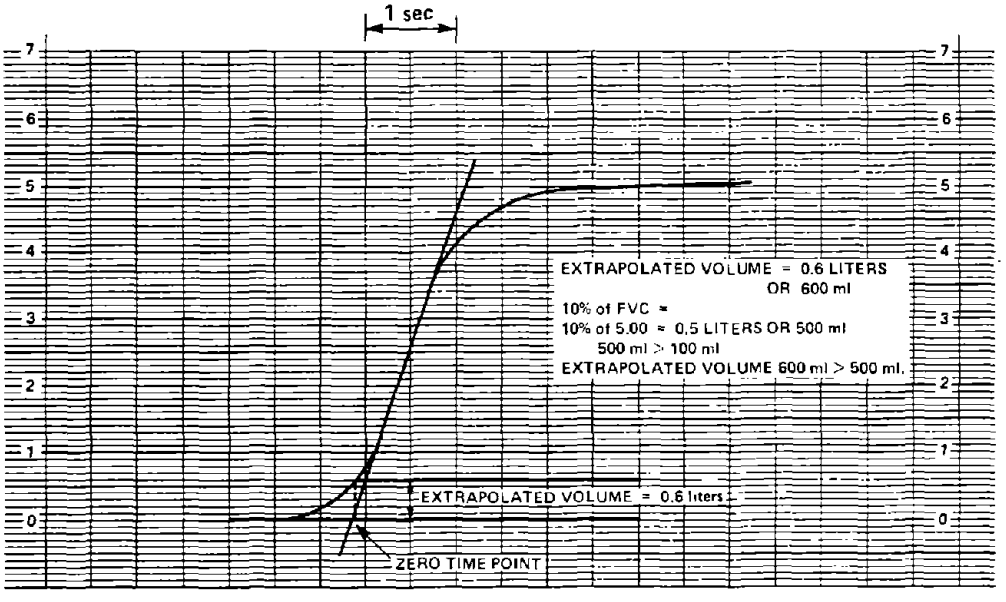


Figure 4-3. Determination of the extrapolated volume. Draw a perpendicular line from the zero time point up to the curve and read the volume at the intersection. In this example, the extrapolated volume at 600 ml is greater than 10% of the FVC (500 ml) making it an unacceptable tracing. 10% of the FVC is the criterion used here because it is greater than 100 ml.

If a reduced FEV_1 indicates airway obstruction, an assessment of reversibility may be desirable. The patient is asked to inhale a nebulized bronchodilator such as isoproterenol. After five minutes, the FEV_1 is repeated. An increase of 15% or more from the baseline value indicates an element of reversibility. Such information can have both diagnostic and therapeutic implications. Reversibility, particularly if it is complete or nearly so, is usually seen with asthma rather than chronic bronchitis or emphysema. Reversibility is also predictive of probable improvement with oral bronchodilators.

Conversely an individual with asthma may have normal pulmonary function studies on a given day. Inhalation of the cholinergic drug methacholine can induce mild bronchospasm in asymptomatic asthmatics, allowing the correct diagnosis to be made. A decrease of 20% or more in the FEV_1 as compared to the baseline is regarded as a positive test. Methacholine inhalation is unnecessary and potentially hazardous if airway obstruction is clearly present on the initial spirogram.

Although neither isoproterenol nor methacholine inhalation are regarded as routine screening procedures, they can provide further useful information with little additional risk. Under no circumstances should either be performed without the supervision of an experienced physician.

MEAN FORCED EXPIRATORY FLOW DURING THE MIDDLE HALF OF THE FVC ($FEF_{25-75\%}$)

The $FEF_{25-75\%}$ is defined as the average rate of flow during the middle two quarters of the forced expiratory effort, i.e., from 25% to 75% of the vital capacity. It was previously known as the maximal mid-expiratory flow rate (MMEF). Compared to the FEV_1, it is more sensitive in detecting early airway obstruction and tends to reflect changes in airways less than 2 mm. in diameter. It is in these smaller bronchi and bronchioles that airborne substances are thought to exert their initial deleterious effects; yet because they contribute only 15% of the total airway resistance, considerable disease may be present in them without being reflected in the FEV_1. Furthermore, some physicians prefer the $FEF_{25-75\%}$ because it is regarded as less dependent on voluntary effort than the FEV_1.

A number of problems have precluded widespread use of the $FEF_{25-75\%}$ in industrial screening programs. Although less dependent on voluntary effort than the FEV_1, the $FEF_{25-75\%}$ is also less reproducible. Its coefficient of variation (variability in the same individual) may be as great as 20% compared to 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. As with all spirometric tests, interpretation of $FEF_{25-75\%}$ should be undertaken only by a physician qualified to evaluate chest disease. Finally, calculation of $FEF_{25-75\%}$ is relatively complicated when compared to other spirometric indices (Figure 4-4). If determination of the $FEF_{25-75\%}$ is to be done, it should be calculated only from the best curve, the one which gives the largest sum of the FEV_1 and FVC.

Several additional tests should be mentioned if only to discourage their routine use. The $FEF_{200-1200}$ is the flow between 200 and 1200 cc's of the forced vital capacity. Formerly known as the maximal expiratory flow rate (MEFR), it reflects changes in the large airways but adds little to information already available from the FEV_1 and FVC. The maximum voluntary ventilation (MVV) is unpleasant, exhausting and very effort dependent. In addition, it may be difficult to perform adequately

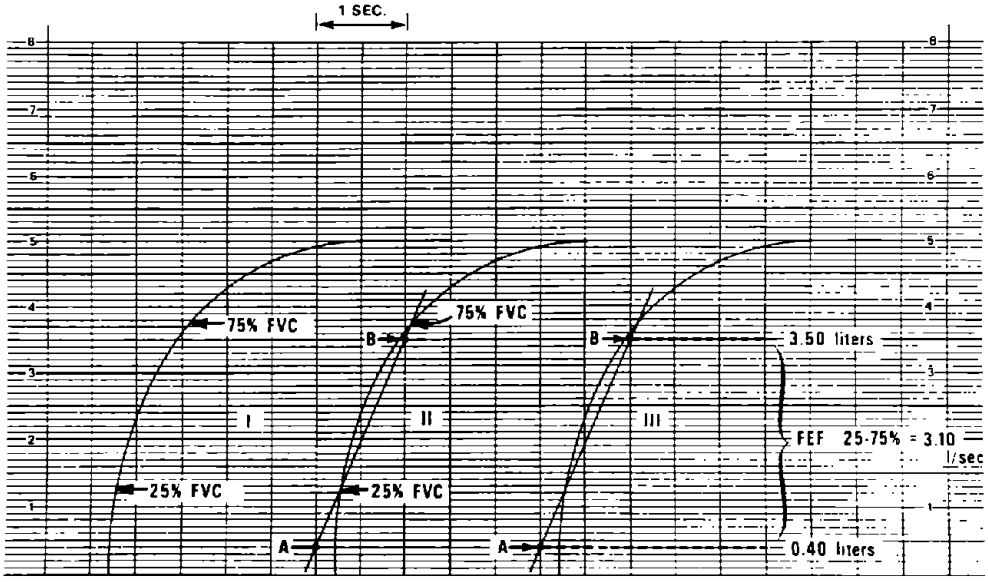


Figure 4-4. Determination of $FEF_{25-75\%}$. I. Locate points on the curve representing 25% and 75% of the FVC. II. Draw a straight line connecting these points and extend it to intersect adjacent time lines one second apart, points "A" and "B". III. The $FEF_{25-75\%}$ in the liters/second is the vertical distance between these two points; in this case 3.10 liters/second.

on some types of spirometers. Although sometimes required by law in the evaluation of pulmonary disability (Social Security and Black Lung), it is generally not a useful screening test in the occupational setting.

CONVERSION TO BTPS

Before the results of spirometric tests can be incorporated in the patient's permanent record, they must be corrected to BTPS (body temperature, ambient pressure, saturated with water vapor). This is necessary because the patient exhales a volume of gas at body temperature (37°C). This volume, when collected in the spirometer, rapidly cools to approach the lower ambient temperature (ATPS) and contracts. This reduced volume as recorded by the spirometer must then be multiplied by the appropriate BTPS conversion factor (Table 4-1) to correct it to what it should be at normal body temperature. This

Table 4-1

FACTORS FOR CONVERTING GAS VOLUMES FROM AMBIENT TEMPERATURE TO BTPS

Temperature °C	Conversion Factor
18	1.114
19	1.111
20	1.102
21	1.096
22	1.091
23	1.085
24	1.080
25	1.075
26	1.068
27	1.063
28	1.057
29	1.051
30	1.045
31	1.039
32	1.032
33	1.026
34	1.020
35	1.014
36	1.007
37	1.000

$$°C = \frac{5(°F - 32)}{9}$$

usually increases the volume recorded by the spirometer by approximately 8%, although it may vary from 5—10% depending upon ambient temperature. This correction is particularly important in field studies where ambient temperature may vary considerably.

The calculation sequence for BTPS conversion is summarized in Appendix B along with other calculation procedures. Although the temperature of exhaled gas collected by the spirometer is actually slightly higher than ambient temperature, it is simply more feasible to use room temperature in selecting the proper conversion factor. For a more detailed discussion of this issue see Chapter Six.

Some spirometer manufacturers incorporate an automatic correction factor, either into the apparatus itself or on the recording paper. The flow-measuring instruments (electronic spirometers) automatically convert to BTPS. The graph paper from some spirometers may record results corrected to a pre-determined ambient temperature such as 20°C. This latter approach is less desirable than a calculated BTPS conversion, particularly in industrial medical units where ambient temperatures may occasionally vary from 18 to 30°C.

Some physicians prefer to use BTPS conversion factors which correct for ambient pressure as well as temperature. While fluctuations in ambient pressure usually produce changes of less than 1% in test results, consideration may be given to using such conversion factors in geographic areas varying considerably from sea level pressure (mountains) and during research studies.

In addition to BTPS, another "factor" is occasionally mentioned, the so-called "instrument or bell factor." In certain water-seal spirometers, it refers to a constant indicating the volume of displacement per millimeter of vertical movement of the bell. For example, in the 13.5 liter Collins instrument, the spirometer bell is calibrated so that each millimeter of excursion corresponds to a volume displacement of 41.27 cubic centimeters (cc). The kymograph paper is graduated so each horizontal line equals 50 cc. The user has the option of determining volume either directly off the paper in cc's or by measuring millimeters of chart displacement and multiplying by the bell factor.

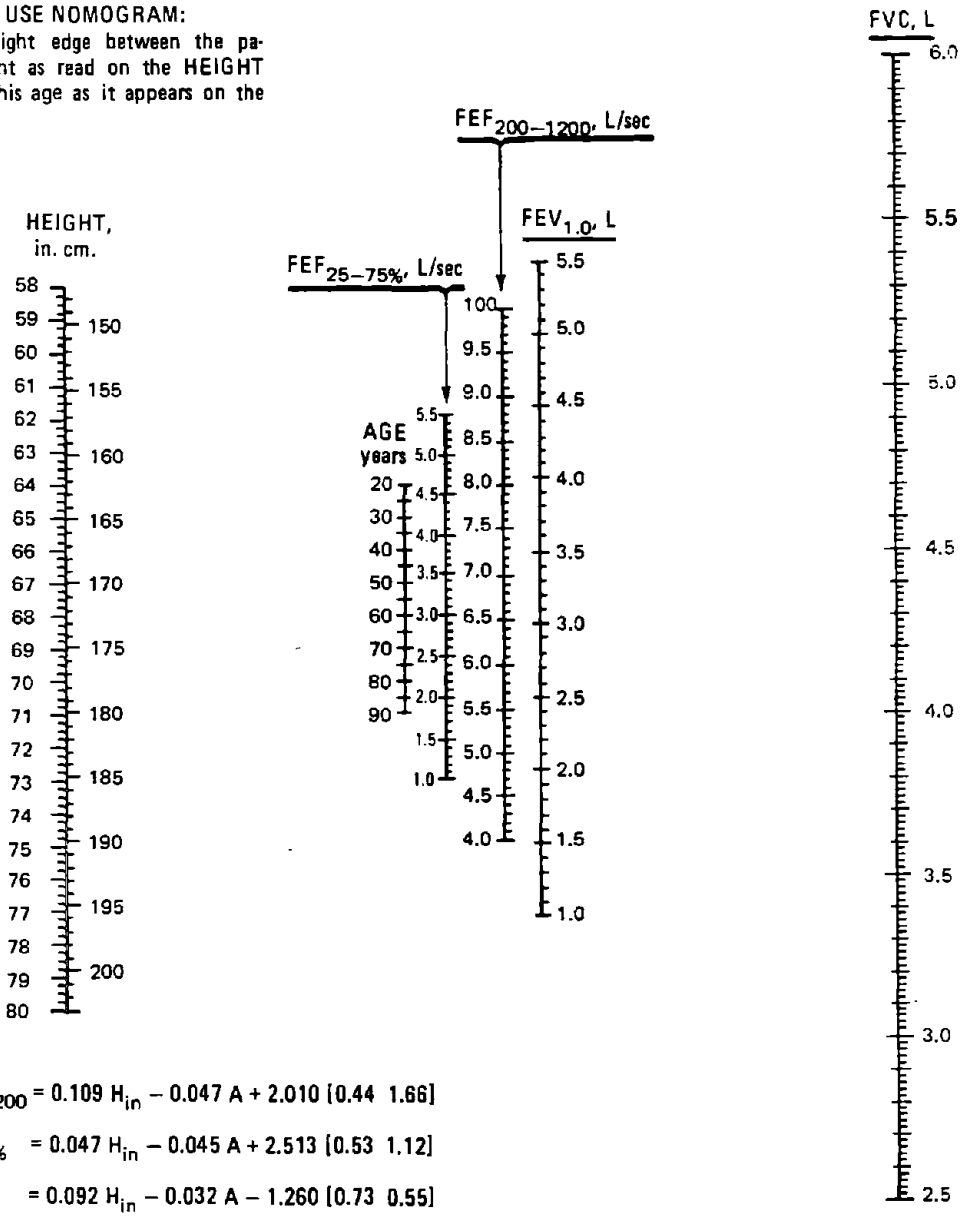
DETERMINATION OF PERCENT OF PREDICTED NORMAL VALUES

The decision as to whether spirometric tests are "normal" is usually made by comparing them with a set of published predicted normal values. Many physicians still use data derived by Kory and his associates from the 1960 VA-Army Cooperative Study of Pulmonary Function. This group contained a large proportion of smokers and its values generally run lower than those of Morris and his coworkers published in 1971 by the *American Review of Respiratory Disease* (Figures 4-5, 4-6). These were derived from a population of healthy, non-smoking men and women with relatively little exposure to air pollution. A third set of predicted normals has been submitted by Knudson (Figures 4-7 to 4-10). In part because Knudson's testing and analysis procedures most closely matched the recent ATS recommendations, his predicted normals were adopted by OSHA in its cotton dust standard. The only potential problem with the Knudson method was their use of the average of the best two of five values; whereas, the ATS standard recommended the use of the largest value. Knudson subsequently performed a comparison of both methods and found no difference in the mean FEV_1 and FVC.

In all studies of predicted normal values, it was found several factors affect lung capacity and flow rates including: age, height, sex and race. Even in the absence of a superimposed disease process, pulmonary function declines rather predictably with advancing age. Taller individuals tend to have larger lung volumes. In the measurement of height, it is important to have the subject in stocking feet to preclude the influence of variably-sized heels. Men generally have larger lung volumes than women of the same age and height.

Finally, it is now well known that the FEV_1 and FVC of non-Caucasions is approximately

TO USE NOMOGRAM:
Lay a straight edge between the patient's height as read on the HEIGHT scale, and his age as it appears on the AGE scale.



$FEF_{200-1200} = 0.109\ H_{in} - 0.047\ A + 2.010$ [0.44 1.66]

$FEF_{25-75\%} = 0.047\ H_{in} - 0.045\ A + 2.513$ [0.53 1.12]

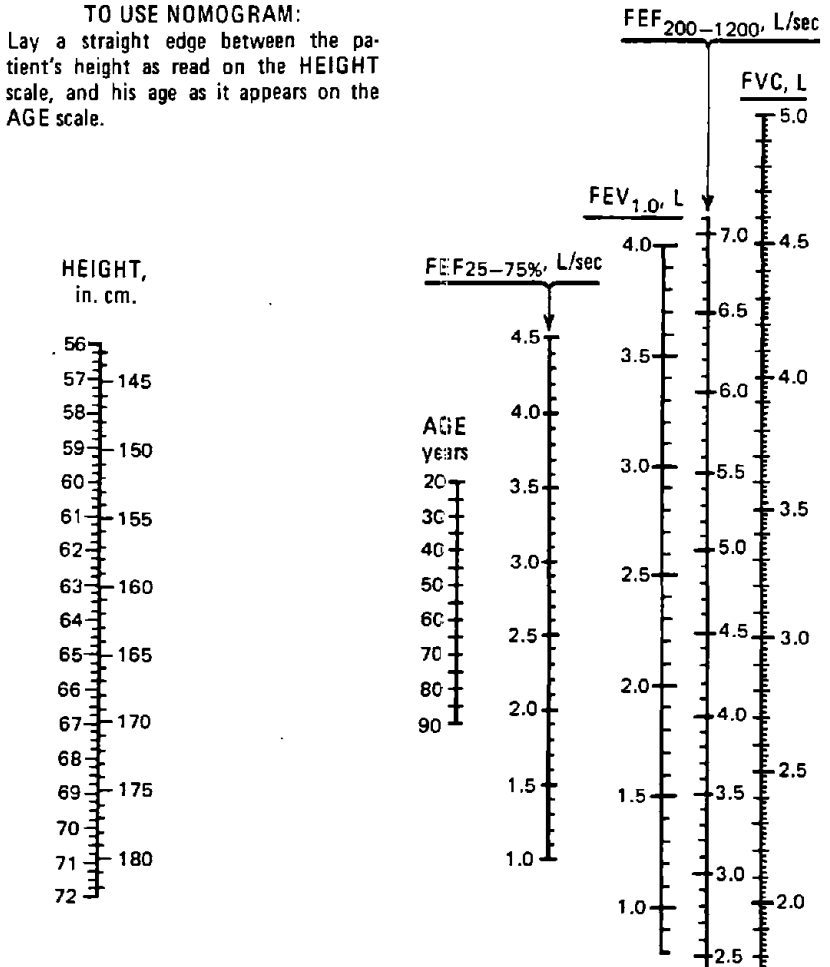
$FEV_{1.0\ sec} = 0.092\ H_{in} - 0.032\ A - 1.260$ [0.73 0.55]

$FVC = 0.148\ H_{in} - 0.025\ A - 4.241$ [0.65 0.74]

Morris, J. F., et al.: Am. Rev. Respir. Dis., 103:57–67, 1971

Note: The predicted FEV_1 and FVC in non-Caucasians must be multiplied by 0.85.

Figure 4-5. Spirometric standards for normal males (BTPS).



$FEF_{200-1200} = 0.145\ H_{in} - 0.036\ A - 2.532$ [0.53 1.19]

$FEF_{25-75\%} = 0.060\ H_{in} - 0.030\ A + 0.551$ [0.56 0.80]

$FEV_{1.0\ sec} = 0.089\ H_{in} - 0.025\ A - 1.932$ [0.73 0.47]

$FVC = 0.115\ H_{in} - 0.024\ A - 2.852$ [0.71 0.52]

Morris, J.F., et al.: Am. Rev. Respir. Dis., 103:57–67, 1971

Note: The predicted FEV_1 and FVC in non-Caucasians must be multiplied by 0.85.

Figure 4-6. Spirometric standards for normal females (BTPS).

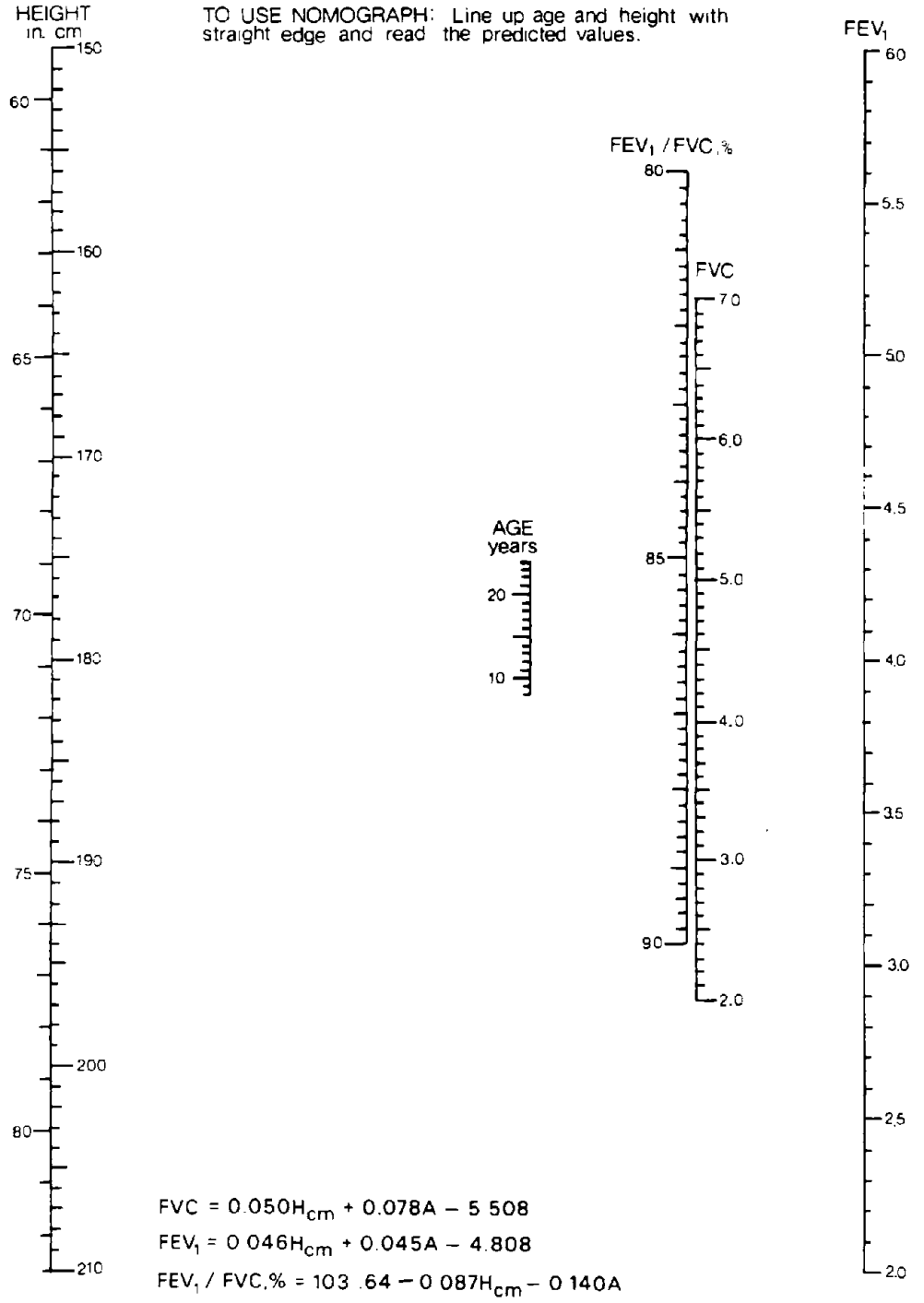


Figure 4-7. Spirometric standards for normal males under 25 years of age.

Prepared by NIOSH, derived from Knudson, R. J. American Review of Respiratory Disease. Vol. 113, 1976.

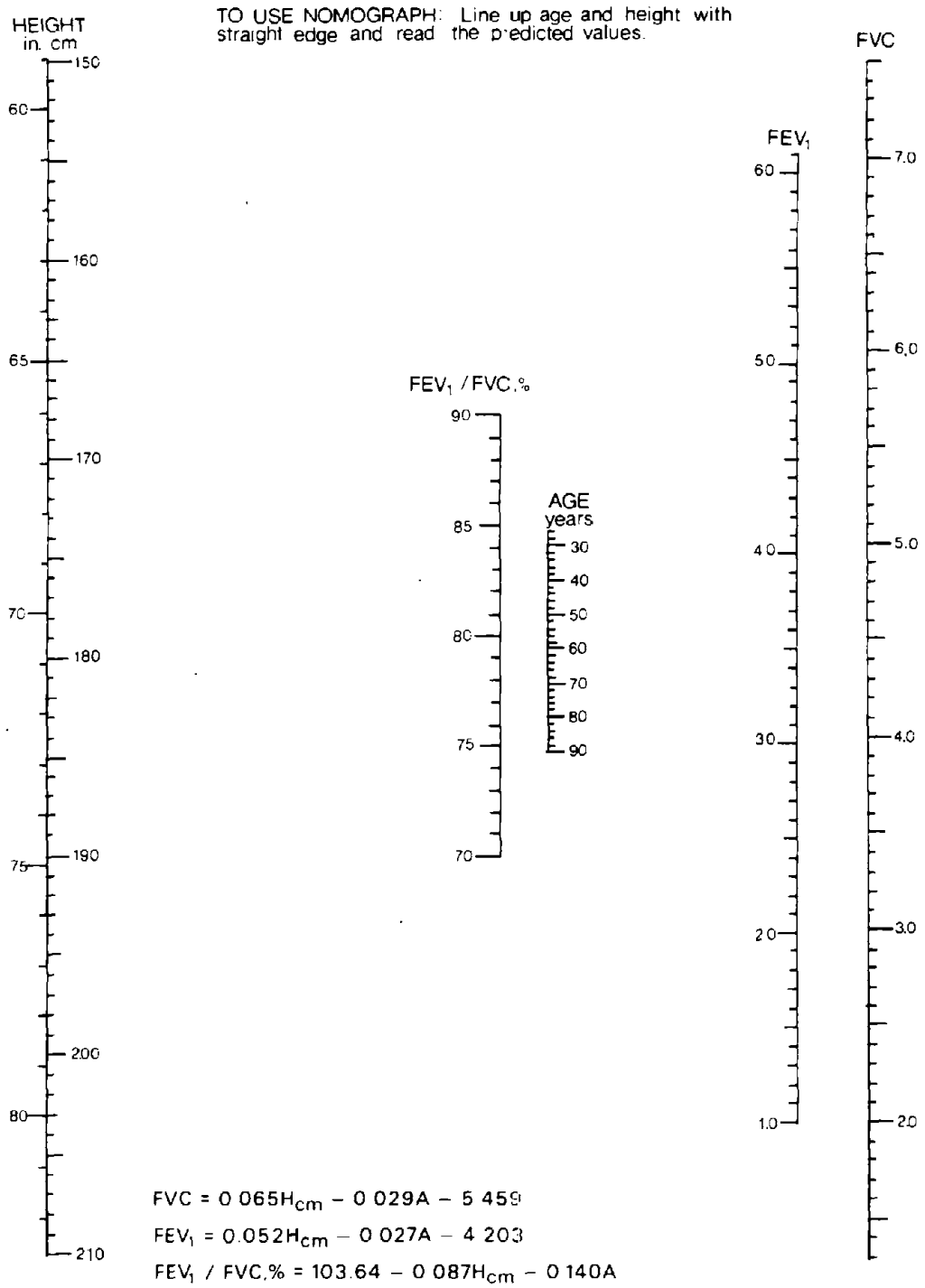


Figure 4-8. Spirometric standards for normal males 25 years of age and over.

Prepared by NIOSH, derived from Knudson, R. J. American Review of Respiratory Disease. Vol. 113, 1976.

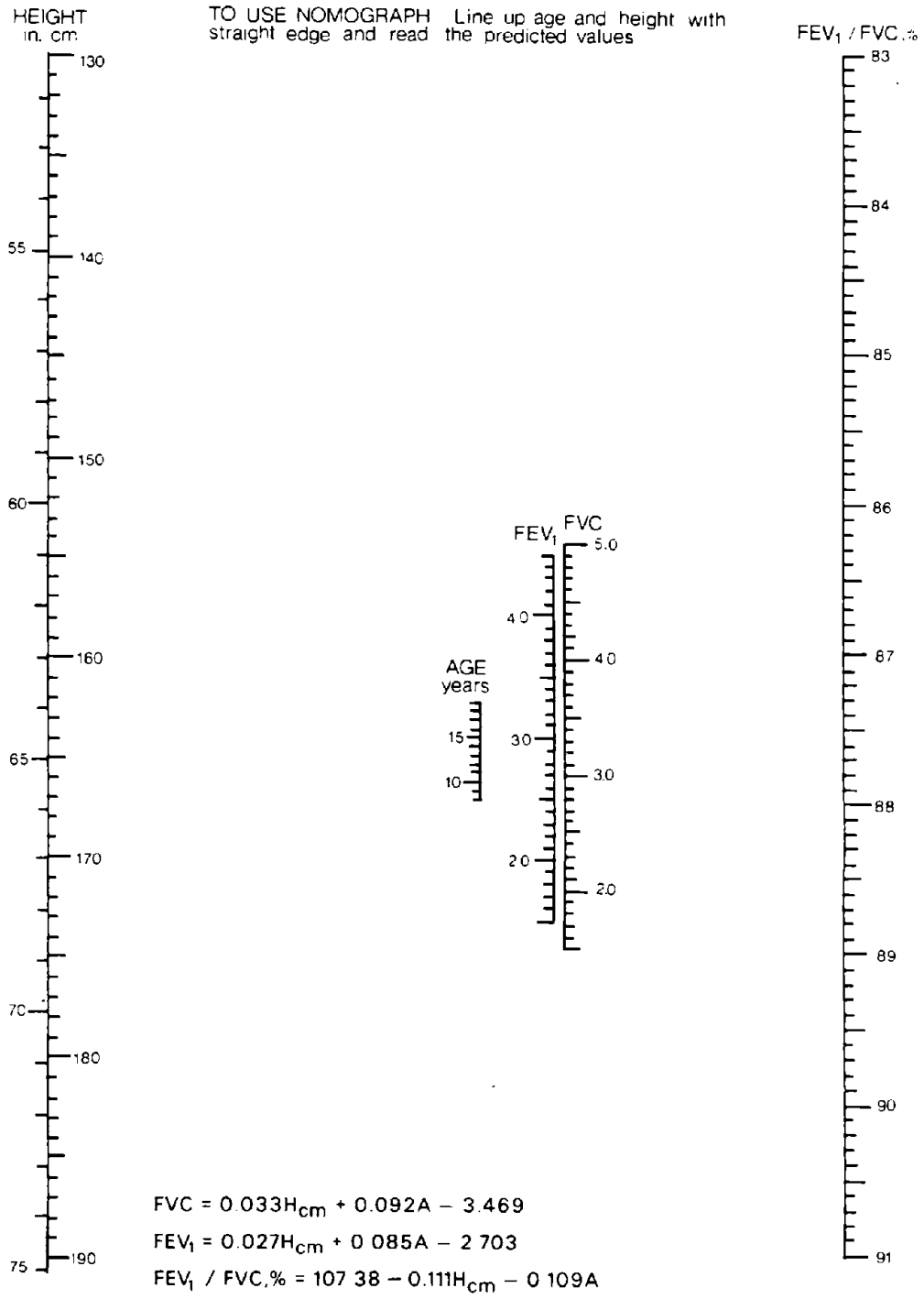


Figure 4-9. Spirometric standards for normal females under 20 years of age.

Prepared by NIOSH, derived from Knudson, R. J. American Review of Respiratory Disease. Vol. 113, 1976.

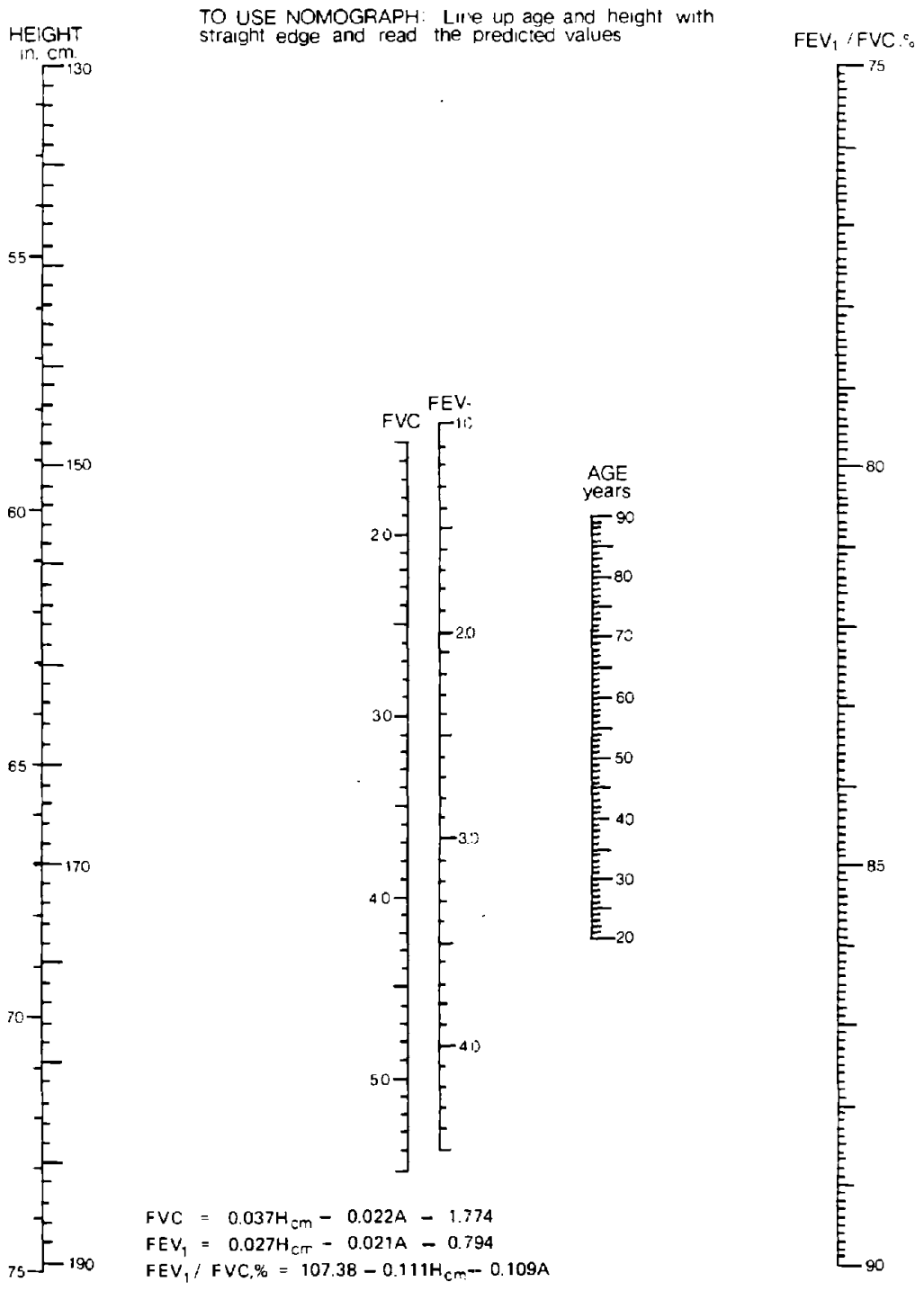


Figure 4-10. Spirometric standards for normal females 20 years of age and over.

Prepared by NIOSH, derived from Knudson, R. J. American Review of Respiratory Disease. Vol. 113, 1976.

15% lower than in whites of the same age, height and sex. This difference has been noted both in blacks and those of Asian background. The explanation for this phenomenon is not clear although speculation has centered around differences in thoracic configuration and diaphragmatic position. Allowance for this ethnic factor must be made to avoid serious errors in interpretation. OSHA's cotton dust standard requires the predicted FEV_1 and FVC for blacks be multiplied by 0.85 to adjust for this difference. This procedure will facilitate proper interpretation of spirometry without inadvertently fostering discrimination in employment practices. It should be used until race-specific tables and nomograms become accepted. No such ethnic correction factor is necessary for the $FEV_1/FVC\%$ which is relatively less effected by race.

Regardless of race, the actual calculation of percent of predicted normal is relatively simple. The observed lung volume or flow rate converted to BTPS is divided by the predicted value and multiplied by 100 to obtain the percentage (Appendix B). In the absence of airway obstruction, a restrictive ventilatory impairment is present when the FVC is less than 80% of predicted. An obstructive ventilatory impairment is defined as an FEV_1 of less than 80% of predicted or an $FEV_1/FVC\%$ less than 70%. However, it should be underscored that these figures do not discriminate between health and disease with complete certainty. An occasional individual may be slightly below the normal value (e.g., 78% of predicted) and not have a respiratory disorder. Conversely a patient may exhibit radiographic manifestations of disease and still have spirometric values technically within the "normal" range. In such instances, more sophisticated tests (e.g., diffusion capacity, exercise studies) may be necessary to characterize the nature and degree of pulmonary impairment.

The relationship of lung volumes to the type of ventilatory impairment is summarized in Table 4-2. Spirometric guidelines for the assessment of the degree of ventilatory impairment are provided in Table 4-3.

CALCULATION OF CHANGES IN FOLLOW-UP SPIROGRAMS

When no previous spirograms are available, comparing an individual's test results to a set of predicted normals is the usual interpretative method. However, an even more desirable approach is the longitudinal or repeat testing of the same worker over a period of time as occurs in medical surveillance programs. Here he serves as his own control and follow-up values can be compared to changes in pulmonary function which might normally be expected with aging. In males, a 30 ml. annual decline in FEV_1 and 25 ml. in FVC can be attributed to normal aging. In females it is 25 ml. for both the FEV_1 and FVC. However, it must be pointed out that these are group averages and considerable variation may occur among individuals.

When comparing a current spirometric value to a previous one, the difference can be expressed either as an absolute change in liters or as a percent change. For example, in an annual surveillance program for asbestos workers, a 24 year old woman is found to have a FVC of 3.59 liters. Her previous year's FVC was 4.17 liters.

Absolute changes
= Previous FVC - Current FVC
= 4.17 - 3.59
= 0.58 liters or a loss of 0.58 liters

Percent change

$$= \frac{\text{Previous FVC} - \text{Current FVC}}{\text{Previous FVC}} \times 100$$

$$= \frac{4.17 - 3.59}{4.17} \times 100$$

= 13.9% or a decline of 13.9% in FVC

Comparison of current results can be made to last year's value or to the previously recorded best value for each test regardless of when it occurred. In any event, the expected normal decline in pulmonary function over that period of time must be considered in the final interpretation.

Table 4-2

RELATIONSHIP OF LUNG VOLUMES TO TYPE OF VENTILATORY IMPAIRMENT

Interpretation	FVC	FEV_1	$FEV_1/FVC\%$
Normal	Normal	Normal	Normal
Airway obstruction	Normal or low	Low	Low
Lung restriction	Low	Normal	Normal
Both obstruction and restriction	Low	Low	Low

Adapted and reprinted from *Chronic Obstructive Pulmonary Disease*, 5th Edition, American Lung Association, 1977.

Table 4-3

SPIROMETRIC GUIDELINES FOR ASSESSING DEGREE OF VENTILATORY IMPAIRMENT

	Obstructive Disease		Restrictive Disease
	$FEV_1/FVC\%$	$\frac{FEV_1\ Obs.}{FEV_1\ Pred.}\ \%$	$\frac{FVC\ Obs.}{FVC\ Pred.}\ \%$
Normal	≥ 0.70	≥ 0.80	≥ 0.80
Mild	0.61 – 0.69	0.66 – 0.79	0.66 – 0.79
Moderate	0.45 – 0.60	0.51 – 0.65	0.51 – 0.65
Severe	< 0.45	≤ 0.50	≤ 0.50

Adapted from Kanner, R. E. and Morris, A. H., (editors), *Clinical Pulmonary Function Testing*, Intermountain Thoracic Society, Salt Lake City, Utah, 1975.

In any respiratory surveillance program, the responsible physician must be aware of other variables besides the effects of age and disease. Cigarette smoking may transiently alter certain pulmonary function tests, particularly the forced expiratory flow rates. Recent use of aerosolized bronchodilators can produce misleading results. Instrument-dependent factors also introduce variability. Some spirometers inherently give inconsistent results, while any instrument may lose proper calibration during repeated use or when subjected to trauma. Comparing follow-up values obtained on different instruments can be an additional source of error. However, inconsistent spirometric technique, including fluctuating patient effort, remains the single most important source of variability. Widespread adoption of the minimum instrument specification standards and methodologic principles recommended by the American Thoracic Society will significantly ameliorate such problems.

All the aforementioned variables aside, what criteria should be used to decide if a given change is due to disease? The cotton dust standard considers a decrement in the FEV_1 of 5% or 200 ml. over the course of a working day to be potentially significant. Individuals exhibiting such declines must be monitored on a more frequent basis. Apart from this situation, little specific guidance is available from either the medical literature or government regulation. Additional experience in respiratory medical surveillance will be necessary before certain changes in spirometric tests can be regarded as clinically significant. In the interim, individual physicians will need to exercise considerable judgement in assessing year-to-year changes in pulmonary function tests. When not specifically superceded by existing regulation or policy, the author suggests the following guidelines as potentially useful in the assessment of changes in annual spirometry: a decline in the FEV_1 or FVC greater than 10%, or a decrease in the FEV_1/FVC% greater than 5%. If these changes are not clearly attributable to non-disease related variables, they should be regarded as potentially abnormal. It is further suggested that any abnormal results in either baseline or follow-up spirometry be verified by repeat testing.

It should be re-emphasized that pulmonary function tests are nonspecific; one can seldom make a diagnosis based on spirometric findings alone. The total clinical presentation must be considered including the medical history, physical examination, chest x-ray and appropriate ancillary laboratory studies. Similarly, medical management in the occupational setting must be tempered by clinical judgment. It is seldom justifiable to deny an individual employment or transfer him to another job solely on the basis of minimally abnormal spirometry. Experience has shown that most abnormalities on screening spirometry are not due to work-related disorders. Smoking, non-occupational pulmonary disease and other variables noted above are more common causes of alterations in pulmonary function. Finally, decisions regarding hiring or job transfer are ofttimes complicated by non-medical issues such as socio-economic considerations, legal constraints, and labor-management relationships. These factors, combined with the lack of clear-cut medical guidelines, require the physician to maintain a degree of flexibility in individual circumstances.

The necessity of maintaining complete and permanent medical records must also be underscored. Spirometric results should be inscribed on an appropriate flow sheet in the patient's record (Figure 4-11). The FEV_1 and FVC should be expressed in liters rounded to two decimal places; e.g., 5.61 liters. The $FEF_{25-75\%}$ is also rounded to two decimal places and expressed in liters/second; e.g., 2.94 liters/second. The FEV_1/FVC% and all percent predicted normals are rounded to one decimal place; e.g., 85.4%. Changes in spirometric values over time can be expressed in liters/milliliters or as a percent change. A (+) prefix arbitrarily indicates an increase while a (-) refers to a decline in pulmonary function. The technician should always record an assessment of subject cooperation.

PULMONARY FUNCTION STUDIES RECORD

Name	Location	Job Name/Description	Sex ☐ Male ☐ Female	Race*	Social Security No.

Test Date	Spirometer Type	Ambient Temp °C	Age	Height‡	OBSERVED VALUES (BTPS)			PREDICTED NORMALS*				CHANGE (±% or liters)			Subject Cooperation (Good, Fair, Poor)
					FEV_1	FVC	FEV_1/ FVC%	FEV_1	% Pred.	FVC	% Pred.	FEV_1	FVC	FEV_1/ FVC%	

*The predicted FEV_1 and FVC in non-Caucasians must be multiplied by 0.85.
‡In stocking feet.

Figure 4-11

The spirogram itself should be retained either in a separate folder or in the medical record. Government regulation may require retention of medical records for 20 yrs. or more, depending on the specific chemical exposures involved.

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Chapter Five

SPIROMETRY AND RESPIRATORY MEDICAL SURVEILLANCE

Edward P. Horvath, Jr., M.D., M.P.H.

Medical surveillance, the periodic health evaluation of workers engaged in potentially hazardous occupations, has achieved widespread acceptance in occupational medicine in recent years. Along with the respiratory and occupational history, physical examination of the lungs and chest roentgenogram, spirometry has been recognized as a necessary component of any comprehensive respiratory surveillance program (Table 5-1).

Before the role of spirometry in such programs can be properly assessed, some consideration must be given to methodologic principles. Medical surveillance is accomplished by screening examinations. It must be appreciated that a screening examination is not necessarily equivalent to a diagnostic one (Table 5-2). The key distinction is that a diagnostic test is performed on a patient *because of a specific medical complaint or finding* while a screening test is conducted on a worker because he is *at risk from a specific occupational exposure.*

Table 5-1

RESPIRATORY SURVEILLANCE PROGRAM

1. A medical history with emphasis on the presence of respiratory symptoms and smoking.
2. A comprehensive occupational history detailing prior exposure to potentially harmful chemical or physical agents. Any adverse effects related to these exposures must be recorded.
3. A physical examination with special emphasis on the chest.
4. A 14" by 17" posterior-anterior chest roentgenogram. For pneumoconioses, films should be interpreted by qualified radiologists in accordance with the ILO-U/C International Classification of Radiographs of Pneumoconiosis.
5. Pulmonary function tests including forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC). Such tests should be performed, calculated, and interpreted in accordance with American Thoracic Society Standards.
6. Other tests — for example, sputum cytology for workers exposed to pulmonary carcinogens.

Table 5-2

SCREENING VS. DIAGNOSTIC EXAMINATION

Screening Examination – Performed periodically on a worker who is judged to be at risk from an occupational exposure.

Example – Spirometry in an Asbestos Worker

Diagnostic Examination – Performed on a patient because of a specific medical complaint or finding.

Example – Sputum Culture in a Patient with Pneumonia

To better assess the utility of a given medical test or procedure in the screening setting, Weiss has described the characteristics of a useful screen (Table 5-3). Spirometry exhibits most, if not all, of these desirable characteristics. It can be performed by a properly-trained nurse or technician, thereby sparing physician time. Spirometers are generally compact instruments and can be easily maintained even in the typically small industrial medical unit. The convenience in having testing capability at the plant site greatly minimizes lost production time resulting from travel to nearby medical facilities. Serious complications from screening spirometry are extremely rare.

Spirometers satisfying all ATS minimum instrument specifications can be purchased for approximately $1,200. With the cost of clinical spirometry running anywhere from $10 to $25 per subject, it is readily apparent that such an instrument would quickly pay for itself in any sizable surveillance program. Calculation of results by attached digital computer has greatly reduced the time and cost per test. With proper attention to testing procedure and instrument factors, spirometry can achieve a high degree of reproducibility.

Validity is a measure of how closely results correspond to the actual state of affairs and requires that a test be both sensitive and specific. Sensitivity is defined as the proportion of truly abnormal individuals designated as abnormal by the screening test. Specificity is the proportion of truly normal individuals correctly designated as such by the screen. Ideally, tests should achieve 100% sensitivity and specificity, but in reality this is rarely attainable.

Depending on the given disease, spirometry exhibits variable degrees of sensitivity and specificity. It is relatively insensitive in some

Table 5-3

CHARACTERISTICS OF A GOOD SCREENING TEST

SIMPLE

CONVENIENT

SAFE

INEXPENSIVE

REPRODUCIBLE

SENSITIVE

SPECIFIC

of the pneumoconioses, such as uncomplicated silicosis and simple coal-workers pneumoconiosis, where radiographic changes are frequently present without abnormal spirometry. It is somewhat more sensitive in detecting early asbestosis although not usually before some parenchymal change is evident on x-ray. However, in chronic berylliosis, a declining forced vital capacity may antedate roentgenographic abnormalities. Spirometry is of greatest utility in those occupational lung diseases such as byssinosis and asthma, which primarily affect the airways. Here specificity becomes a problem though, since it is extremely difficult, if not impossible, to distinguish fixed airway obstruction occurring in the chronic byssinotic or asthmatic from the same type of ventilatory abnormality produced by cigarette smoking.

Despite the recognized problems with spirometry and other components of the respiratory surveillance program, this type of screening remains a potentially useful tool in the prevention of occupational pulmonary disease. The objectives of medical surveillance are outlined in Table 5-4 and are further explained below.

The identification of pre-existing functional impairment on the preplacement evaluation is an important first step in any on-going surveillance effort. It is not the intent of the occupational physician to medically reject an applicant, rather to provide the employer with sufficient information to assure proper placement of the individual in industry. To this end, the physician assesses whether the worker is capable of performing a particular job without substantial risk of imminent danger to self or others.

The second objective of medical surveillance is to identify disease in its earliest stages, thereby enhancing the likelihood of successful therapeutic intervention. Treatment of chronic beryllium disease with corticosteroids is one such example. Unfortunately, this is usually not the case for most occupational pulmonary conditions where effective therapy is unavailable and early detection and removal from exposure are of questionable value. This is particularly true of the pneumoconioses which generally tend to progress regardless of further dust exposure.

Table 5-4

OBJECTIVES OF MEDICAL SURVEILLANCE

1. To identify the job applicant with pre-existing functional impairment and facilitate his proper placement.
2. To detect both occupational and non-occupational disease in an early stage when corrective measures are most likely to beneficial.
3. To identify hazardous working conditions and underscore the need for improvements in industrial hygiene.
4. To reduce the human and economic toll of occupational disease.

This raises one of the most serious problems facing the occupational physician—whether to allow the patient to continue work in the same occupation which resulted in development of his pulmonary disease. Serious gaps in medical knowledge and possible legal ramifications cloud this issue and lead to wide differences of opinion. In addition to these concerns, the physician must also consider the age of the employee and number of work years remaining, the total duration of previous exposure, present environmental conditions, the availability of alternate employment and management/union policy regarding job transfer. The unknown and perhaps minimal medical benefits of removal from further exposure must be balanced against the known and potentially damaging economic consequences of forced early retirement or involuntary job transfer. In the author's opinion, many physicians tend to recommend job transfer almost reflexly without sufficient thought being given to the complexities involved. This is sometimes done on the basis of a single laboratory abnormality of uncertain significance, e.g., an FVC of 78% of predicted in a worker with no other screening abnormalities. Such action is generally unwarranted and probably reflects insecurity stemming from both the lack of knowledge about the natural history of certain occupational pulmonary diseases and medical liability/worker's compensation concerns. In the absence of medically-validated guidelines in this area, decisions regarding job transfers will continue to require an extraordinary exercise of clinical and sociological judgment with due consideration for individual circumstances.

The third objective of medical surveillance is to identify work conditions requiring improvements in industrial hygiene or other control techniques. Although this admittedly retrospective approach is less than ideal and may be interpreted by some as tantamount to human experimentation, it is precisely the means by which most occupational diseases have been identified in the past. Furthermore, even firm adherence to threshold limit values (TLV's) may not protect everyone. Because of variations in individual suspectibility, a small percentage of workers may experience discomfort or disease at concentrations well below the TLV. For example, individuals who have become sensitized to toluene diisocyanate (TDI) may develop symptoms to exposures of 0.001 ppm, well below the present TLV of 0.02 ppm.

While cost/benefit analysis of respiratory medical surveillance is beyond the scope of this manual, the economic consequences of past neglect of occupational lung disorders are becoming increasingly apparent. Direct expenses, including medical bills, worker's compensation insurance premiums and payments for disability, have all increased dramatically. Indirect expenses, such as clerical and administrative costs and product liability claims, may exceed direct expenses in some instances. Properly managed medical surveillance programs can play an important role in bringing such costs under control.

Finally, to be maximally effective, a medical surveillance program must be fully coordinated with existing modes of medical care delivery in the community. This requires scrupulous attention to notification of the employee and the employee's family physician of test results, referral to the appropriate medical consultants when indicated and the maintenance of complete and confidential medical records.

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Chapter Six

INSTRUMENT SPECIFICATIONS

John L. Hankinson, Ph.D.

HISTORICAL BACKGROUND AND DEVELOPMENT

The most recent, comprehensive attempt at standardization of spirometric equipment was by the American Thoracic Society (ATS). Earlier equipment standards or specifications, such as those developed by the American College of Chest Physicians, were directed towards instruments used in epidemiologic studies and were not generally applicable to spirometers for clinical or screening programs.

The American Thoracic Society's efforts in this regard began in June of 1976 with the development of a rough draft of proposed standards by its Medical Devices Committee. In January 1977, the ATS sponsored a workshop on standardization of spirometry at Snowbird, Utah. The workshop's 22 participants comprised a broad representation from both clinical and epidemiologic disciplines. At the two-day workshop the draft of the Medical Devices Committee was revised, and the workshop's recommendations were later published in the ATS News (Summer, 1977). After comments were received, a final ATS statement on Standardization of Spirometry was approved by the ATS Council in May, 1978. This report has since been published in the American Review of Respiratory Diseases. A review of these instrumentation standards and specifications is presented below.

REVIEW OF THE ATS RECOMMENDATIONS

It should be emphasized that the following instrument specifications are minimum recommendations. For the sake of brevity, the review presented here is limited to the parameters most often used in screening or surveillance programs (FVC, FEV_1, and $FEF_{25-75\%}$). The basic provisions of the ATS statement are outlined in Appendix C. For a more complete review the reader is encouraged to read the complete ATS statement.

FORCED VITAL CAPACITY (FVC)

STANDARD

The instrument should be capable of measuring volumes up to at least 7 liters (BTPS) independent of flow rate for flows between 0 to 12 liters per second. The instrument should be capable of accumulating volume for at least 10 seconds. For all types of spirometers, the volume accuracy is the primary determinant of flow accuracy, and the volume should be accurate within ± 3 percent of reading or ± 50 milliliters, whichever is greater. The instrument should provide some means of correcting volumes to BTPS under conditions of varying ambient temperature and pressure.

RATIONALE

The range for flow and volume were based on data from Hankinson and Petersen. In a survey of 9,347 working coal miners, 97 percent of the miners had a forced vital capacity of less than 7.25 liters and a peak flow of less than 13.25 liters per second. Accuracy requirements were derived from Hankinson and Petersen, Glindmeyer, and Cochran, et al. These data

showed a coefficient of variation on the same subject on different days of approximately 3 percent. The need to record the FVC maneuver for at least 10 seconds is based on the work of Hankinson and Petersen who showed that FVC maneuvers must be recorded for at least 10 seconds if 94 percent of a population of 205 subjects with obstructive lung disease were to be correctly classified. Obstructive lung disease was defined for the purpose of their study as an $FEV_1/FVC\%$ of less than 70 percent. Most of the subjects in the obstructed group had mild or moderate obstructive lung disease.

TIMED FORCED EXPIRATORY VOLUME (FEV_1)

STANDARD

The instrument should be capable of measuring volumes up to at least 7 liters (BTPS) with an FEV_1 accuracy of at least ± 3 percent of reading or ± 50 milliliters, whichever is greater, over a flow range of 0 to 12 liters per second. The "start of test" for purposes of timing the FEV_1 should be determined by back extrapolation or an equivalent method. The resistance to airflow at 12 liters per second should be less than 1.5 cm H_2O per liter per second.

RATIONALE

To obtain consistent results a uniform method of determining the start of test is required. Smith and Gaensler have shown that different FEV_1 values are obtained when different criteria for "start of test" are used on the same curve. The participants at the Snowbird Conference felt that the back extrapolation method was the most consistent and accepted method and should be used until other methods are demonstrated to give equivalent results.

MEAN FORCED EXPIRATORY FLOW DURING THE MIDDLE HALF OF THE FVC ($FEF_{25-75\%}$)

STANDARD

The instrument used to measure the $FEF_{25-75\%}$ should meet the same requirements necessary for measurement of the FVC. The instrument should measure the $FEF_{25-75\%}$ with an accuracy of at least ± 5 percent of reading or ± 100 milliliters per second, whichever is greater.

RATIONALE

A less stringent accuracy is required for the $FEF_{25-75\%}$ because it has been shown to have a much higher within subject coefficient of variation than the FVC and FEV_1.

RECORDER REQUIREMENTS

STANDARD

The device used to record the FVC and FEV_1 should provide a tracing of volume-time or flow-volume for the entire forced expiration. For the volume-time tracing, the recorder must be capable of displaying the entire FVC maneuver at a constant speed from maximum inspiration for at least 10 seconds after the start of the maneuver. The recorder should have a paper speed of at least 20 millimeters per second (higher speeds are preferred). Volume sensitivity of the recorder should be at least 10 millimeters per liter of volume and flow sensitivity of at least 4 millimeters per liter per second of flow. In order to reliably determine the start of the FVC test by back extrapolation, the recorder should be up to speed before forced expiration is begun.

RATIONALE

A tracing is the best method of ensuring that the test was properly performed. The chart speed and volume sensitivity requirements are needed to have an adequate visual resolution on the record to allow accurate measurement of the FVC, FEV_1, and $FEF_{25-75\%}$.

CALIBRATION

The simplest and most accurate method of calibrating a spirometer is with a large calibrating syringe. Each instrument manufacturer should provide a method of calibration using a syringe of at least 3 liters. A calibrating syringe can also be used to determine whether a spirometer meets the minimum ATS recommended requirements. The syringe can be emptied into the spirometer at various flow rates and the corresponding volumes compared to the syringe volume. For spirometers which measure volume directly, care should be taken to ensure that the air inside the syringe is at the same temperature and relative humidity as the air inside the spirometer.

TYPES OF SPIROMETERS

There are two general types of spirometers, those devices which measure volume directly and those devices which measure flow and derive volume by some method such as integration of the flow signal. If the primary measurements of interest are the FVC and FEV_1, which are volume measures, then any instrument which measures volume directly will in general be superior to any instrument which measures flow and derives volume. The main advantage of flow measuring devices is their smaller size and portability. However, flow devices are usually less accurate and more difficult to calibrate and maintain.

VOLUME SPIROMETERS

The three most common types of direct volume measuring spirometers are the water seal, the dry rolling seal, and the bellows type. The water seal spirometer is simple to operate, accurate and requires little maintenance other than checking occasionally for leaks. The Stead-Wells water seal spirometer, which consists of a lightweight plastic bell with a pen mounted on the bell, was originally proposed as the standard instrument against which other spirometers would be compared (Figure 6-1). While the Stead-Wells spirometer is somewhat bulky, a smaller more portable "survey" water seal spirometer is available (Figure 6-2).

The bellows type of spirometer is also simple to operate and is perhaps one of the most popular types of screening instruments. Some bellows spirometers are quite accurate and meet or exceed all of the ATS recommended requirements (Figure 6-3).

However, a few bellows spirometers have difficulty in meeting the minimum requirements for several specifications. First, the mechanical linkages on some bellows spirometers are too bulky and introduce an excessive amount of inertia. In some instances, this excessive inertia results in a falsely low FEV_1.

Second, the chart or recorder must record volume from the beginning of exhalation for at least 10 seconds. Some bellows spirometers do not record the FVC maneuver for a full 10 seconds and therefore may underestimate the FVC for patients with obstructive lung disease. Other bellows spirometers do not start their chart recorder until the exhalation has begun. Use of such spirometers is not recommended because an accurate record of the start of the FVC test is needed to achieve a reliable result by back extrapolation and to determine the quality of the start of the FVC test.

The rolling seal spirometer consists of a cylinder and piston which are sealed by a rolling plastic seal. The rolling seal offers very little friction, and most rolling seal spirometers meet or exceed the minimum ATS requirements (Figures 6-4, 6-5, and 6-6). Most rolling seal spirometers provide electrical output signals, and therefore a separate recording device must be used. However, at least one manufacturer provides a direct recording rolling seal spirometer.

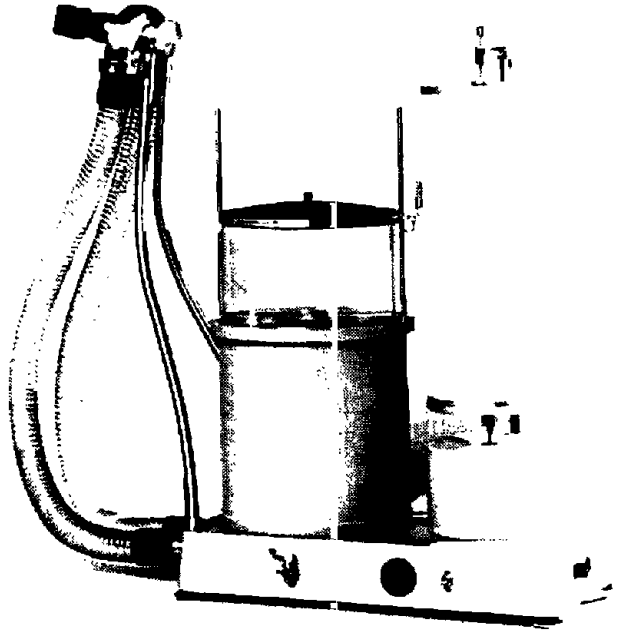

Figure 6-1. Stead-Wells water seal spirometer with lightweight, noncounterweighted bell. (Courtesy of Warren E. Collins, Inc., Braintree, Massachusetts).

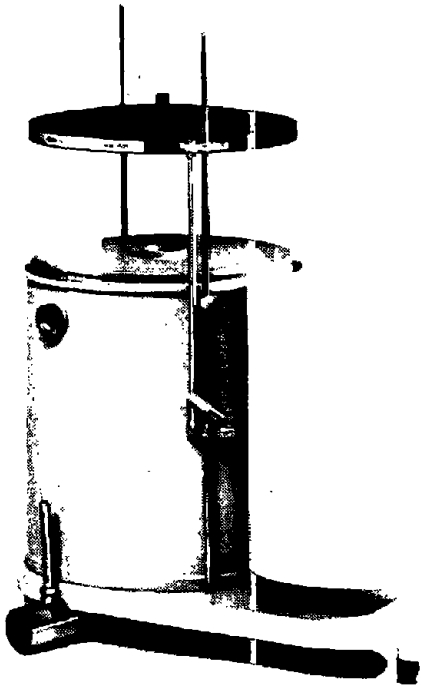

Figure 6-2. Collins Survey Spirometer. (Courtesy of Warren E. Collins, Inc., Braintree, Massachusetts).

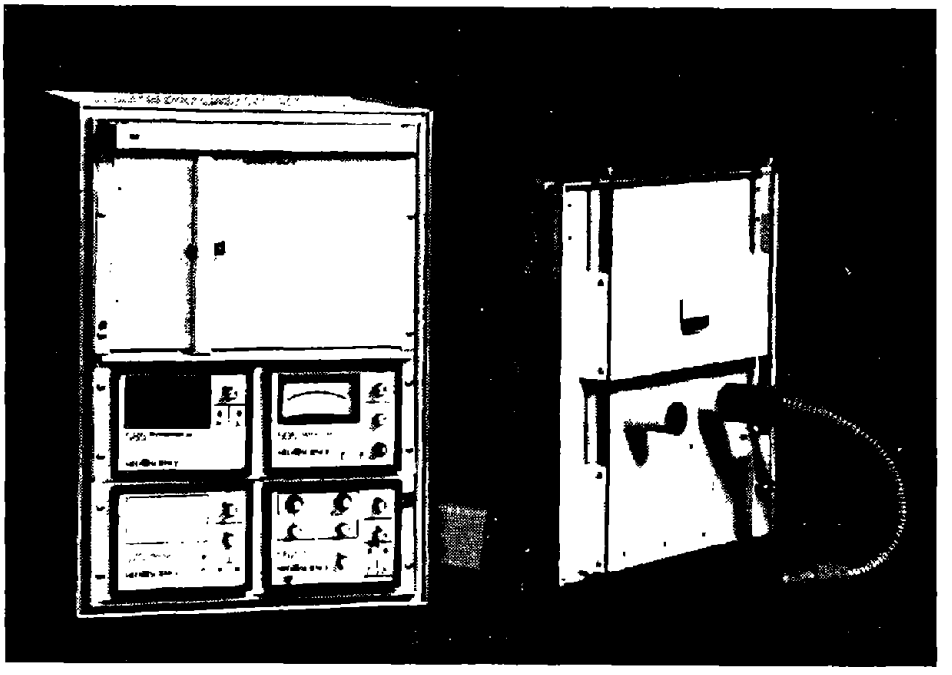

Figure 6-3. Med-Science 570, a bellows device. (Courtesy of Med-Science Electronics, Inc., Burlington, Massachusetts).

Figure 6-4. Ohio Medical Model 822 dry rolling seal spirometer. (Courtesy of Ohio Medical Products, Division of Airco, Inc., Madison, Wisconsin).

FLOW TYPE SPIROMETERS

The three most common types of flow spirometers are pneumotachographs, hot wire anemometers, and rotating vanes. In general, devices which measure flow and derive volume are more difficult to calibrate and maintain, and are less accurate in determining volumes. Since flow is usually integrated to obtain volume, a small flow error or a small flow

offset can become significant when integrated over 5 to 10 seconds. For this reason, some flow measuring devices terminate the measurement of volume prematurely in order to reduce the time over which small errors in flow are integrated. Premature termination of the FVC maneuver, especially in patients with obstructive lung disease, often results in a falsely low FVC and a more normal $FEV_1/FVC\%$.

Another potential problem with flow measuring devices is that volume accuracy may be dependent on the flow profile presented to the sensor. A flow spirometer may give very accurate volumes with moderate flow rates and yet underestimate volumes with high flow rates or overestimate volumes with low flow rates. This means that some flow spirometers may give accurate volumes for normal subjects and incorrect volumes for subjects with reduced ventilatory capacities. However, several well-engineered flow type spirometers do meet the ATS minimum requirements and are acceptable if they are checked on a regular basis (Figure 6-7).

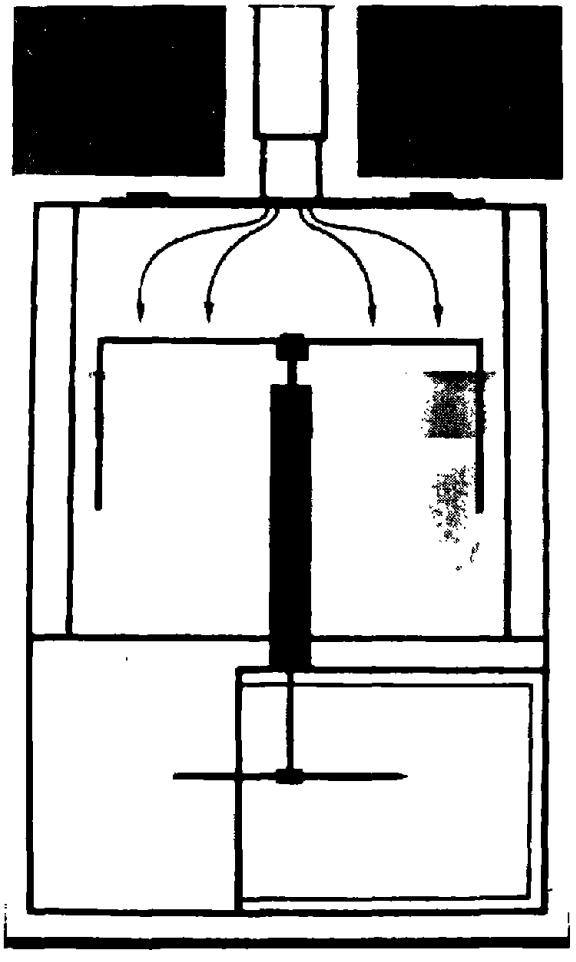

Figure 6-5. Dry rolling seal spirometer. Cutaway view demonstrating the U-Shaped silastic seal between the piston and the cylinder. (From advertising brochure for Model 822, Ohio Medical Products, Division of Airco, Inc., Madison, Wisconsin).

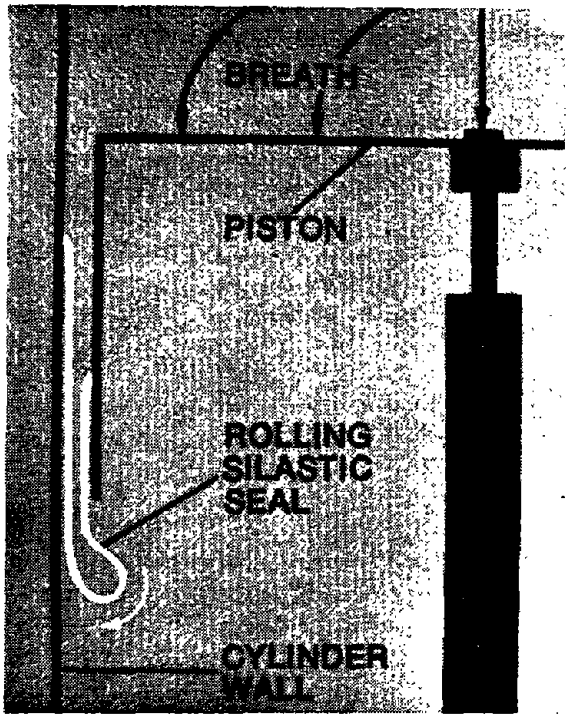

Figure 6-6. Dry rolling seal spirometer. Plastic seal rolling freely upon itself during performance of the test. (From advertising brochure for Model 822, Ohio Medical Products, Division of Airco, Inc., Madison, Wisconsin).

Figure 6-7. Hewlett-Packard 47804A, a flow measuring spirometer. (Courtesy of Hewlett-Packard, Andover, Massachusetts).

AUTOMATED SPIROMETRY SYSTEMS

The advent of more automated spirometry systems, while reducing the necessity for time-consuming hand measurements and calculations, has created some special problems. Due to the complexity of computer software, it is often difficult for the user to determine exactly how the automated system determines the start of test and other parameters. Any evaluation or testing of a spirometry system should include an evaluation or testing of the software or algorithms used to determine the various parameters. The simplest method to perform this evaluation is to compare computed values with those measured by hand for several patients. The manufacturer should also provide a routine method for ensuring that the automated system is functioning properly within ATS specifications.

ENVIRONMENTAL CONSIDERATIONS

All volumes and flows should be corrected to body temperature (37°C) ambient pressure

saturated with water vapor (BTPS). This correction of observed volumes to BTPS assumes the patient's exhaled air is immediately cooled to room (ambient) temperature. Unfortunately, for most volume spirometers, this assumption is not completely correct. (Some flow instruments avoid this problem by measuring flow at BTPS). At a room temperature of approximately 25°C, the error in the FEV_1 for a typical volume spirometer is usually less than 2 percent. However, if the room temperature is approximately 15°C, the FEV_1 error (false increase) can be as high as approximately 5 percent, and the error is even greater at lower room temperatures. The reason for the greater FEV_1 error at lower room temperatures is that the patient's exhaled air (37°C) requires a much longer time to reach a lower ambient temperature. The resulting error can be estimated from the difference between ambient temperature and the temperature of the gas inside the spirometer at the instant a measure is obtained.

Suppose a patient performs an FVC maneuver into a spirometer, and the gas in the spirometer has cooled to only 28°C in one second and not to the ambient temperature of 15°C. The BTPS Factor for 15°C is 1.13; however, the correct BTPS for the temperature of the gas inside the spirometer at one second (28°C) is 1.06. Therefore, by assuming the gas inside the spirometer is at 15°C instead of its actual temperature of 28°C, we introduce an error of approximately 6 percent:

$$\frac{1.13 - 1.06}{1.13} \times 100 = 6.2\%$$

It is impossible to consistently correct for this error because the rate of cooling is dependent on the type of spirometer, the patient's flow rates and volumes, and the ambient temperature. The simplest solution to the problem is to conduct all pulmonary function tests at a room temperature of approximately 25°C.

SPIROMETER TESTING

The ATS recommended specifications include spirometer testing procedures to determine if a spirometer meets the ATS requirements. To verify compliance with FVC and FEV_1 accuracy requirements, the ATS recommended test signals consist of two FVC maneuvers simulated by exponential volume time curves. The first simulated exhalation should have an FVC of 5 liters and a time constant of 0.4 seconds (giving a peak flow of 12.5 liters per second). The second simulated FVC maneuver should have an FVC of 3.5 liters and a time constant of 2.4 seconds (peak flow of 1.46 liters per second). These two maneuvers are intended to simulate a normal subject and one with obstructive lung disease, respectively.

Gardner, et al. described a set of 16 different waveforms which were used to test 19 different spirometers. These waveforms simulated a range of subjects with FVC's from 1.5 to 6 liters and varying degrees of obstructive lung disease. The set of 16 waveforms also included 4 FVC maneuvers or waveforms from actual patients. Gardner and associates then used these waveforms to derive a mechanical pump which forced these volume time curves into the spirometer being tested. They concluded that simulated FVC maneuvers are a practical method of testing spirometer systems. As discussed earlier, the entire spirometer system should be evaluated, including its software. A simulated FVC maneuver is the most practical method of testing not only the spirometer but also the software and algorithms used to determine parameters such as the FVC, FEV_1, and $FEF_{25-75\%}$.

FUTURE OF STANDARDIZATION

The ATS recommendations have served as a major impetus for spirometry standardization. The Association for the Advancement of Medical Instrumentation (AAMI) has initiated the development of its own standards in this

area. The AAMI considers the ATS recommendations as primarily "user's" guidelines and hopes to formulate a "manufacturer's" standard with more emphasis on engineering and technical considerations. It is likely a more detailed testing procedure will also be included. After this work has been completed and approved by the AAMI, it will be sent to the American National Standards Institute (ANSI) for final public review and approval.

The Federal Government has also mandated instrument standards for use in the medical surveillance of cotton workers and in the disability evaluation of coal miners. This trend is likely to continue with specific spirometry requirements being extended to include other medical surveillance and disability determination programs. Finally, the Food and Drug Administration (FDA) may adopt any new consensus standards in accordance with recent medical devices legislation. This will probably consist of minimum requirements which all spirometers must meet. Most of the responsibility for spirometry testing and labeling would probably remain with the manufacturer.

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APPENDIX A

SPIROMETRY PROCEDURE CHECKLIST

1. Briefly explain purpose of spirometry — "I want to test how hard, how fast and how long you can breathe."

2. Ask appropriate questions to determine if spirometry should be postponed:

   a. "How are you feeling today?"

   b. "Have you smoked a cigarette, used an aerosolized bronchodilator, or had a heavy meal in the past hour?"

   c. "Have you had pneumonia, bronchitis, influenza or a severe cold in the past three weeks?"

3. Position the subject comfortably, requesting that he either stand or sit.

4. Instruct him to loosen tight clothing, remove dentures and extend his chin slightly.

5. Apply noseclips securely.

6. Instruct the subject in proper performance of the forced expiratory maneuver— "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."

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

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

9. Coach actively throughout the entire forced expiratory effort until a plateau occurs in the tracing.

10. Examine the tracing and re-instruct if necessary.

11. Continue testing until three acceptable tracings have been obtained. The two largest forced vital capacities (FVC's) should not vary by more than 5% or 100 ml., whichever is greater.

APPENDIX B

SPIROMETRY CALCULATION OUTLINE

1. Measure FVC in each tracing from baseline to plateau.

2. Select largest FVC from the three acceptable tracings.

3. Measure FEV_1 in each curve. Use back extrapolation if necessary to determine zero time point.

4. Select largest FEV_1 from the three tracings. (Usually found on the same curve as the largest FVC).

5. Determine BTPS conversion factor from table using ambient temperature.

6. Multiply:

   $FEV_{1\ (ATPS)} \times$ BTPS conversion factor $= FEV_{1\ OBS\ (BTPS)}$

   $FVC_{(ATPS)} \times$ BTPS conversion factor $= FVC_{OBS\ (BTPS)}$

7. Determine FEV_1 predicted and FVC predicted from nomogram using sex, height and age. In non-Caucasians, FEV_1 predicted and FVC predicted must be multiplied by 0.85 ethnic correction factor.

8. Divide:

   $FEV_{1\ OBS} \div FEV_{1\ PRED} = FEV_1\%$ predicted normal

   $FVC_{OBS} \div FVC_{PRED} = FVC\%$ predicted normal

9. For $FEV_1/FVC\%$, divide:

   $FEV_{1\ OBS} \div FVC_{OBS} = FEV_1/FVC\%$

   Note: Use the largest FEV_1 and FVC in this calculation, even if they do not come from the same curve.

10. Summary:

    $FEV_{1\ (ATPS)} \times$ BTPS conversion factor $= FEV_{1\ OBS\ (BTPS)}$

    $FVC_{(ATPS)} \times$ BTPS conversion factor $= FVC_{OBS\ (BTPS)}$

    $FEV_{1\ OBS} \div FVC_{OBS} = FEV_1/FVC\%$

    $FEV_{1\ OBS} \div FEV_{1\ PRED} = FEV_1\%$ predicted

    $FVC_{OBS} \div FVC_{PRED} = FVC\%$ predicted

APPENDIX C

ATS MINIMAL SPIROMETRY STANDARDS — SUMMARY

1. Accuracy — ± 50 ml. or within 3% of reading, whichever is greater for:
   a. FEV_1
   b. FVC
   c. Calibration check.
2. Volume — capable of measuring volume from 0 to 7 liters (BTPS)
3. Inertia and resistance — less than 1.5 cm. H_2O/liter/second at an air flow of 12 liters/second.
4. Zero time point determination — "back extrapolation" method or equivalent; requires activation of recording chart prior to forced expiratory maneuver.
5. Conversion to BTPS — instrument or user must have a means of correcting to BTPS.
6. Provision of a written tracing; requirements include:
   a. Recording of flow versus volume or volume versus time.
   b. Paper speed of at least 20 mm./second.
   c. Volume sensitivity — at least 10 mm. of chart paper per liter of volume.
7. Calibration check — must be capable of calibration in the field.
   a. Method — 3 liter volume source (syringe)
   b. Accuracy — ± 50 ml. or 3% of reading, whichever is greater.

APPENDIX D

GLOSSARY OF TERMS AND ABBREVIATIONS

1. *Forced expiratory maneuver.* Technique during spirometry where the subject takes the deepest possible inspiration from a normal breathing pattern and blows into the mouthpiece as hard, fast and completely as possible. Also known as the forced vital capacity maneuver.

2. *Vital capacity (VC).* The maximal volume of air exhaled from the point of maximal inspiration.

3. *Forced vital capacity (FVC).* Vital capacity performed with a maximally forced expiratory effort.

4. *Forced expiratory volume in one second (FEV_1).* Volume of air exhaled during the first second of the FVC.

5. *FEV_1/FVC%.* Forced expiratory volume in one second expressed as a percentage of the forced vital capacity.

6. *Mean forced expiratory flow during the middle half of the FVC ($FEF_{25-75\%}$).* Self explanatory. Formerly called the maximal mid-expiratory flow rate (MMEF).

7. *Spirometer.* An instrument for measuring lung volumes and flow rates.

8. *Spirogram.* A graphic recording of the forced expiratory maneuvers, as either volume-time or volume-flow tracings.

9. *Valid Spirogram.* A spirogram consisting of at least three acceptable forced expiratory tracings where the two best FVC's do not vary more than ± 5% or ± 100 ml., whichever is greater.

10. *Volume-measuring spirometer.* Spirometers which directly accumulate and measure the volume of exhaled air. Examples include water-seal, dry rolling seal and bellows instruments.

11. *Flow-measuring spirometer.* Indirectly measures volume of exhaled air by measuring the rate at which air is exhaled and deriving the volume. Examples include pneumotachograph and rotating vane.

12. *Back extrapolation.* In the calculation of FEV_1, a method for determining the zero time. A straight line is drawn through the steepest portion of the volume time curve back to the baseline. Where this straight line intersects the baseline is the zero point for timing the FEV_1.

13. *Zero time point.* In the measurement of FEV_1, the point selected as the start of the test.

14. *Extrapolated volume.* That volume determined by a line drawn through the zero time point perpendicular to the baseline. The extrapolated volume is read where this perpendicular line intersects the volume curve; it should be less than 10% of the FVC or 100 ml. whichever is greater.

15. *End of test.* That point during the forced expiratory maneuver when a plateau is noted on the tracing; it is defined mathematically when the volume change in 0.5 seconds is less than 25 ml.

16. *Best curve.* That curve which gives the largest sum of FEV_1 and FVC. The best curve is used in the calculation of the $FEF_{25-75\%}$.

17. *BTPS.* Body temperature and pressure saturated with water vapor. All spirometric volumes and flows must be corrected to BTPS.

18. *ATPS.* Ambient temperature and pressure saturated with water vapor. Volumes read directly off the spirogram are at ATPS.

19. *Instrument factor.* In some instruments a constant indicating the volume of displacement per milliliter of vertical movement of the bell; also known as the "bell factor."

20. *Predicted normal values.* Expected values for various lung volumes and flow rates derived from healthy populations.

21. *Calibration check.* Periodic determination of a spirometer's ability to accurately measure volume. Calibration checks should be performed using a syringe or other known volume source of three liters. The instrument should maintain an accuracy of ± 3% of the reading.

22. *Reproducibility.* In the absence of disease-related changes, the ability of a test to obtain the same result from an individual repeatedly tested over a period of time.

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