

**THIRD NATIONAL HEALTH AND NUTRITION
EXAMINATION SURVEY III**

Spirometry Procedure Manual

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August 1988

PREFACE

The technical descriptions and documentation of the NIOSH Spirometry System and examination procedures were provided by Dr. John Hankinson and Ms. Beth Knutti, R.N., from the NIOSH Appalachian Laboratory in Morgantown, West Virginia.

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1. INTRODUCTION

1.1 Description and Application of Data Collected

Pulmonary function was targeted for inclusion in the NHANES III data collection effort by the National Institute for Occupational Safety and Health (NIOSH), the Environmental Protection Agency (EPA), and the National Heart, Lung and Blood Institute (NHLBI). Information for this component will be obtained from spirometry examinations which will be performed on all examinees over the age of eight years, and data collection from interviews and physical examinations.

The procedures for spirometric assessment of pulmonary function will be based on the most current standards of the American Thoracic Society (ATS). The training, measurement and quality control protocols will closely adhere to NHLBI protocols, developed for the Atherosclerotic Research in Communities (ARIC) Project.

COPD affects nearly 20 percent of the adult U.S. population and includes such conditions as asthma, chronic bronchitis and emphysema, as well as occupationally related lung disorders. COPD is the fifth leading cause of mortality, and the mortality trends associated in the COPD are rising steadily, especially among female smokers. COPD is also the third leading contributor to excess mortality associated with cigarette smoking, after coronary heart disease and lung cancer.

Information from NHANES III pulmonary studies will be used to provide reference data for occupational exposure research, air quality studies, and specialized cardiovascular research, as well as documentation of the relationship of smoking to COPD. It will also yield data for national estimates of the distribution of pulmonary function, and prevalence of impaired function and chronic obstructive pulmonary disease (COPD) in a representative sample.

Finally, NHANES III data will allow observation of trends and changes in COPD disease and impaired pulmonary function over time.

1.2 Principles of Operation - The Respiratory System

The respiratory tract consists of the trachea, the right and left lungs, and two types of branching airways in each lung--bronchi and bronchioli. The main purpose of the respiratory tract is to conduct air between the external environment and the respiratory unit to permit exchange of oxygen and carbon dioxide.

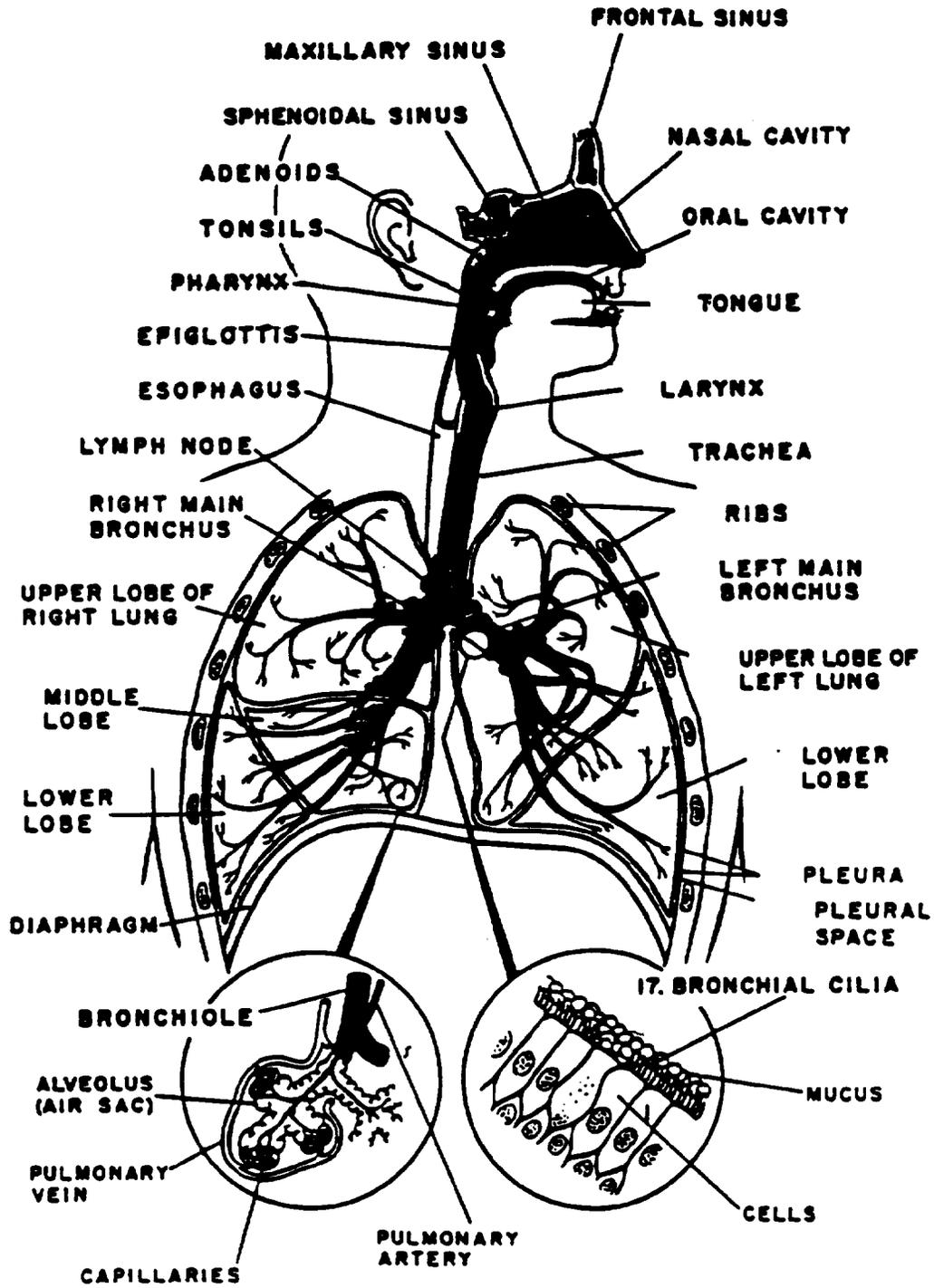
A unique organ, the lung not only provides a means for the transfer of oxygen from air into the blood and the removal of carbon dioxide, it is also capable of metabolizing and detoxifying a wide range of substances, protects against infectious agents and environmental pollution, and synthesizes certain key materials such as surfactant, which helps maintain surface tension in the lung, and prostaglandins, which are important in inflammatory reactions.

From the trachea, the airways divide progressively like branching trees in both symmetrical and asymmetrical fashion (see Exhibit 1-1). Each branch of airways away from the trachea becomes smaller, but in turn the total area of cross-sectional airways actually increases. As a result, airflow resistance decreases as air moves from the large airways to the smaller bronchioli.

This exchange occurs in the respiratory unit, consisting of bronchioli, alveolar duct, alveolar sac, and individual alveoli. The alveoli have a surface area for gas exchange that is equivalent to the size of a tennis court.

The lung is served by two blood supplies--pulmonary circulation, which involves cardiac output and oxygenation of the blood; and bronchial circulation arising from the aorta, which receives only a small amount of cardiac output with oxygenated blood. The bronchial arteries are the principle blood supply for the pulmonary tissue itself, and ultimately join the pulmonary circulation at the level of the respiratory bronchioli. The interconnection between these two circulations permits adjustment and compensations for pressure changes. For example, a rise in pressure in one system is balanced by a decrease in pressure in the other system.

Exhibit 1-1. The Respiratory System



Special cells and structures in the lining of the lung also perform protective functions in the lung. A mucous layer that rests on hair-like cilia, which move in wave-like motions towards the mouth, provides the first line of defense against inhaled particulate matter. However, these defenses may be rendered inefficient by noxious agents such as cigarette smoke and lung diseases.

1.3 Overview of Procedure - NIOSH Spirometry System

The spirometer system developed for the National Institute for Occupation Safety and Health occupational respiratory disease research is the result of a continuing evolution of spirometer systems. For the past 15 years, there have been three basic requirements of NIOSH spirometer systems: (1) the system must be as accurate as possible using available technology; (2) the system must have sufficient backup to prevent the loss of at least basic spirometric parameters; and (3) the system must be reliable for use in remote field locations where subject testing time is limited. An additional requirement is that the spirometer system must meet the NIOSH and American Thoracic Society's 1979 (ATS) minimum Spirometry Recommendations and the ATS 1987 updated recommendations.

A description of the basic design criteria for the NIOSH/DRDS spirometer system and the rationale for each of these criteria is included in Section 2.2.1.

2. EQUIPMENT

2.1 Spirometry Area in the MEC

One room in the Mobile Examination Center (MEC) is devoted to the performance of spirometry examinations. The room includes the NIOSH Spirometry System, a computerized data entry system for screening and recording examination data, and supplies needed for the component.

The arrangement of the room is designed to assure privacy for sample persons in order to encourage maximum effort and to facilitate performance of the exams. Soundproof padding is installed on the walls and vents for additional privacy.

2.2 Description of Equipment and Supplies

The spirometry system includes a customized Ohio Sensormed 827 dry rolling seal spirometer, light enough to be portable, with breathing tubes and a calibration syringe. It has a computer which analyzes the expiratory curves, calculates the key pulmonary parameters, and determines acceptability of tests. A strip chart is attached to provide hard copy records. A Codonics graphics terminal 1550 and HF4 microprocessor are used to record exam data. An Epson FX-86 can be added to the system to provide hard copies of analyzed exams.

The list of equipment and supplies is as follows:

- Ohio Sensormed 827 Spirometer, including a strip chart recorder
- Codonics Graphics Terminal 1550 and Keyboard
- HF4 Microprocessor
- Epson FX 86 Printer (optional)
- Calibration Syringe
- Spirometer Hose
- Spirotubes (mouthpieces, disposable)
- Noseclips
- Pens
- Stopwatch
- Log Sheets
- Chart Paper

Supplies continued:

Barometer
Ammonia Inhalants
Tape Measure (heights)
4 x 4 Sponges
Isopropyl Alcohol
Covered Basin
Kleenex
Stopcock Grease
Floppy Disks
3M DC1000 Mini Data Cartridge
Room Thermometer
Foam Swabs
Magnetic Tape Head Cleaner
Disk Head Cleaning Kit
Utilities Floppy

2.2.1 Features of the NIOSH Spirometry System

2.2.1.1 Accuracy

The ATS recommends that the spirometer have an accuracy for FVC and FEV1 of at least 3 percent of reading or 50 milliliters, whichever is greater. While it is desirable to use a spirometer system which exceeds the ATS accuracy requirements, an accuracy better than one percent or reading has little practical advantage - considering a within subject coefficient of variation for FVC between 2.5 to 3 percent. The dry rolling seal spirometer with an analog potentiometer has an accuracy of approximately three percent, or only slightly within the ATS accuracy requirement. To improve the spirometer accuracy, a digital shaft encoder is used to convert the volume displacement to a digital signal, replacing the analog potentiometer. To further improve the accuracy of the spirometer system, a linear model is used to estimate the volume as a function of the counts obtained from the digital shaft encoder ($Y = mx + b$). We chose to use a model with an intercept term (b) or offset volume to improve the accuracy of the spirometer, particularly at volumes greater than 0.5 liters. It is possible to force the line through zero ($y = mx$), but this model will result in an apparent non-linearity at higher volumes and corresponding degradation in accuracy. Typically, the intercept term is 50 ml with a gain or slope of 2.65 milliliters per count ($r > 0.9999$). The model is not used in the calculations of the extrapolated volume. Extrapolated volumes are usually less than 0.5 liters and using a 50 ml intercept term below 0.5 liters is inappropriate. For this reason, an

intercept term or offset volume of approximately 15 ml is used in the model for extrapolated volume calculations. Since the raw volume time curve is saved, other correction algorithms can be used "off-line."

An 11.5 Hz digital filter is used to filter the volume time signal to eliminate the high frequency noise. This filter has no effect on the volume parameters (FVC, FEV1, etc.) but does improve the accuracy of the flow parameters (Peak Flow, FEF50%, etc.). Flow parameters are calculated using the algorithm described in the ATS 1987 revised spirometer recommendations.

NIOSH test results indicate that using this technique improved the spirometer system accuracy to better than 1.5 percent of reading, well within the ATS accuracy recommendations of three percent of reading or 50 milliliters whichever is greater. In addition, testing conducted by the LDS Hospital under a NIOSH contract found:

"The HF4 system easily meets ATS specifications. In fact, we found the performance of this spirometer to be superior. Of the 53 spirometer systems recently tested by Mr. Nelson, none outperformed the NIOSH HF4 even though we applied a more stringent test protocol."

2.2.1.2 Return Spring

The spirometer system is designed to use the return spring ("negator") that is standard on most dry rolling seal spirometers. The advantages of using the return spring are: (1) the spirometer piston is returned to the zero position at the end of each maneuver, reducing the time required to test a subject; (2) any leak in the spirometer or between the subject and his/her mouthpiece is easily detected because of the obvious loss in volume as a result of the positive pressure (0.4 cm H₂O) generated by the return spring; (3) there is a clear indication when the subject comes off the mouthpiece, avoiding the slight increase in volume which can occur in some dry rolling seal spirometers when not used with a return spring (due to seal "memory"); and (4) the spirometer is always stored with minimal volume in the spirometer which eliminates the development of seal memory. The primary disadvantage of using the return spring is that a minimal pressure is necessary to cause the piston to start its displacement. However, the static pressure is small (approximately 0.4 cm H₂O - approximately the same as for a Stead-Wells Spirometer) and constant over the entire volume range of the spirometer. The maximum pressure recommended by the ATS is less than 1.5 cm H₂O.

The intercept term and the calibration factor (gain) for each spirometer is estimated through testing of each spirometer. Upon system power-up, the technician enters a code containing the spirometer's calibration factor and offset volume. This code also has provision for checking for possible errors during entry of the code. By using a manually entered code for each spirometer, the computer component can be interchanged between spirometers.

2.2.1.3 Hardcopy Backup Procedure

A manual strip chart recorder is mounted on each spirometer so the chart drive can be used concurrently or independently of the computer. The accuracy of this manual system meets the ATS requirements for manual spirometry; however, the manual reading on average reads approximately 50 milliliters lower than the actual volume. While use of this recorder for most studies may not be necessary, it can be used to provide backup data if desired or if the computer malfunctions.

2.2.1.4 Digital Data Redundancy

The volume time curve is acquired from the digital shaft encoder, for up to 20 seconds and with a sampling rate of 100 points per second. All data points for each curve are stored on digital cassette tape (provided option is selected). Calculated parameters along with a 45 point flow volume curve (approximately 2% increments of the FVC) can be stored on digital floppy and cassette tape (raw unprocessed data). The first 128 bytes of raw data will contain the calculated results. Values for all maneuvers will be stored regardless of quality, unless the expiratory effort is less than one second or less than 200 milliliters in volume. Saving all of the curves, in the order they were performed, allows use of the data for investigating spirometry induced bronchial spasms or other order effects. For most applications, only the data from the digital floppy disk will be used. Standard calculated spirometry parameters are contained on the floppy disk for each curve as well as the flow rates in approximately 2 percent increments of the FVC (FEF2% through FEF98%) The resolution of the flow volume curve on the floppy disk is sufficient for reviewing the data on each subject for quality and reproducibility. A complete list of parameters is given in Table 2-1.

If the floppy disk data are lost or destroyed or if additional parameters are to be calculated, the

digital cassette tapes, containing the raw data, can be processed on an IBM PC or similar computer. A cassette tape drive is available which can be interfaced to any digital computer through a serial RS232, 9600 baud communications port. See Tables 2-1 and 2-2 for a list of calculated parameters.

The digital cassette tape writes and verifies the data with each write operation and errors are reported to the technician as data are collected. The cassette tape has been tested for over 50 hours of continuous operation without a single error.

2.2.1.5 Calibration Techniques

All calibration checks are performed using a standard three liter calibrating syringe. Extensive dynamic calibration checks will be performed at Morgantown approximately every three months. Dynamic calibration will consist of volume ramps to check linearity, and testing using the 24 ATS standard waveforms. Calibration factors (gain and intercept coefficients) are determined and updated during the system checks performed by DRDS/Clinical Investigations Branch. These calibration values are contained in the spirometer code entered into the computer after the computer system is first turned on.

Field calibration checks should be performed before each testing session when the spirometer is dry and at ambient temperature. Using a three liter syringe, two different syringe calibration procedures are used:

1. With the spirometer at its zero position, the three liter calibrating syringe will be emptied into the spirometer. This procedure will be repeated three times, with the spirometer piston returning to the zero position after each syringe check. The spirometer should read within \pm three percent of the syringe volume. However, the spirometer chart volume will read approximately 50 milliliters lower than the syringe volume (intercept term or offset volume) of the spirometer. The computer will make the necessary corrections, but this correction will not appear on the manual chart drive volume located in the rear of the spirometer.

Table 2-1. List of Spirometric Parameters (for each curve stored on floppy and raw data tape)

Parameter	Description
ID	Subject Identification Code
FVC	Forced Vital capacity (ml)
FEV0.5	Forced expiratory volume in 0.5 second (ml)
FEV1	Forced expiratory volume in 1.0 seconds (ml)
FEV3	Forced expiratory volume in 3.0 seconds (ml)
FEV6	Forced expiratory volume in 6.0 (ml)
Pkflow	Peak expiratory flow (ml/s)
FEF25-75%	Forced expiratory flow from 25 to 75% of FVC (ml/s)
Vext	Extrapolated volume (ml)
ERR	Error codes for any errors detected during maneuver and calculations
NV	Time at which end of test occurred
ETIM	Expiratory time (centiseconds)
SCODE	Spirometer identification code (unique to each system)
SPCODE	Code to indicate type of spirometry (e.g. post-shift data)
SEX	Sex, race code for predication equations
CQ	Computer generated quality code
TQ	Technician entered quality code (entered after each maneuver)
TEM	Spirometer temperature measured by temperature probe
BP	Barometric pressure entered by technician at start of session
Age	Subject's age in years
HT	Subject's height in centimeters
TCODE	Technician identification code
SOFT	Software version code (update with each new version)
MM	Date of examination (month)
DD	Date (day)
YY	Date (year)
HH	Time of examination (hours)
MN	Time (minutes)
FV	45 point flow volume curve in approximately 2% increments of FVC (ml/s)

Note: The above values are both in the calculated results file on the floppy and on the raw data tape (first 128 bytes).

Table 2-2. List of Additional Raw Data Parameters (for each curve, raw data tape only)

Parameter	Description
OP	Options Code selected at start of session
CN	Number of curves for current ID
NA	Number of acceptable curves up to this point in testing
SCA	Average syringe calibration (3 liter count)
SPG	Spirometer gain factor (3 liter count)
SPO	Spirometer opening volume in counts
SY1	First calibration syringe volume (counts)
SY2	Second calibration syringe volume (counts)
SY3	Third calibration syringe volume (counts)
TFVC	Time or index of point at FVC or highest observed volume
FVCC	FVC in counts
SNAME	Eight character study name or identification
NAME	Subject's name
SCPV	Starting volume of pressure calibration check
SCP1	First pressure volume calibration value (counts)
SCP2	Second pressure volume calibration value (counts)
SCP3	Third pressure volume calibration value (counts)
SCPF	Final volume of pressure volume calibration (counts)
HHC	Time of last calibration (hours)
MMC	Time of last calibration (minutes)
VOL	Up to 1775 volume data points with a 10 millisecond sampling rate to 15.25 seconds, then a 20 millisecond sampling interval from 15.25 to 20.5 seconds. The first 0.25 seconds of data are taken before the subject begins exhalation. Volume data points are in counts or the number of counts over the previous 10 milliseconds level.

Note: SPG and SPO are contained in the code entered by the technician at the start of a session or power-up. The code is located on the front of each spirometer and is unique for each spirometer. The code also has an error checking capability included in the code. Thus, if an error occurs in the entering of a digit of the code, the error will be detected.

2. A "pressure" calibration check procedure will be performed in addition to (1) above. Two to three liters of air will be pulled into the spirometer by pulling on the spirometer pen shaft. Once this volume of air has been entered, a full three liter calibrating syringe will be connected to the spirometer hose. The technician will answer the computer prompt and enter and extract three liters of air three times without disconnecting the syringe. The technician will then wait for the computer to indicate that 20 seconds has elapsed (completion of lead test). The manual chart drive should displace and record three liters of volume, unlike procedure #1. No intercept coefficient is present during the "pressure" calibration check since a volume change is being measured.

2.2.1.6 Screen Display

It has been our experience that, for most experienced technicians, display of a flow volume curve is usually sufficient for obtaining high quality data. The addition of reproducibility percentages for FVC, FEV1, and Peak Flow are helpful but often are not as useful as the raw flow volume curves displayed for each subject. Expiratory time is useful because of the recent ATS requirement of an expiratory time of at least six seconds. Most of the computer generated acceptability and reproducibility codes are obvious from observing the flow volume curves superimposed on each other.

The computer terminal displays all of the flow volume curves, with the current flow volume curve being displayed as a solid line and the previous curves with dashed lines. The current flow volume curve is displayed in "real-time" as the subject is exhaling. After six seconds, the terminal portion of the flow volume curve is displayed in an expanded mode (zoom of 2:1). Enlargement of the flow volume curve indicates to the technician that six seconds has elapsed and enables the technician to observe the low flow rates typical near the end of the expiratory maneuver. In addition, the trial number, FVC, FEV1, Peak Flow, Expiratory Time, and Acceptability Quality Code are displayed on the terminal after each maneuver for use by the technician. Acceptability and reproducibility messages are displayed in a coded format for the technician to use in coaching the subject. We chose not to display a detailed sentence for each acceptability or reproducibility problem because of limited screen space. The technician should be aware of any quality problems by either inspecting the flow volume curves or reviewing the messages provided.

Acceptability detection criteria have been developed by NIOSH using a data base of approximately 2,890 spirograms from 592 subjects, some of which contain technical problems such as hesitations and coughs.

2.2.1.7 Options

Whenever the system is started, the options menu is displayed. These options include: (1) tape storage; (2) floppy disk storage; (3) entering of age, height, sex, and race information (for printing calculated results); (4) printing of calculated results; and (5) shift study.

The printer options will print the calculated results as well as predicted values and percent of predicted for each subject. The system will use an Epson or equivalent printer. The use of a printer is entirely optional.

2.2.2 Inventory of Equipment and Supplies

An inventory of all spirometry equipment and supplies is conducted at the start and end of each stand, in conjunction with the general MEC inventory. A health technician will be assigned by the MEC manager to conduct the inventory.

Inventory Forms

An inventory form, listing the supplies specific to the spirometry exam, will be generated by the computerized inventory system at Westat and sent to the MEC at the start of each stand. The form will list the quantities of each item that should be available on the MEC for spirometry, and technicians will determine the actual quantities during the inventory.

The MEC manager will collect the inventory forms and send them to Westat for processing and ordering.

Stocking Supplies

Supplies ordered by the previous team should be on-site at the MEC when the examination staff arrives at the stand. Spirometry supplies should be checked against the packing slips before being incorporated into the existing inventory. The MEC manager will assist the technicians in checking the new supplies and completing an accurate inventory.

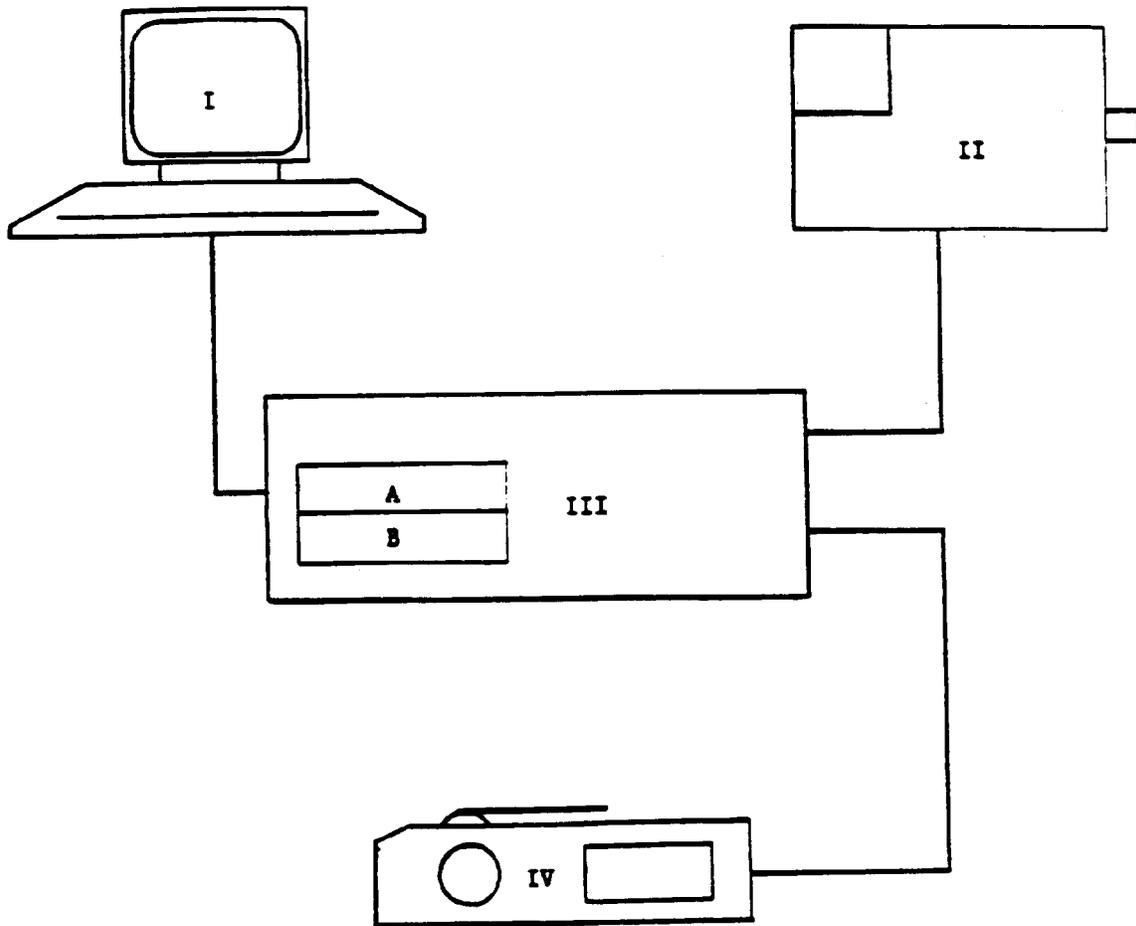
After reconciling the supplies, the new items should be added to the spirometry supplies stored in the MEC belly compartments. As items are needed, technicians, in cooperation with the MEC manager, will remove the required supplies and stock the spirometry area in the MEC.

2.3 Equipment Setup Procedures

2.3.1 Start of Stand Procedures

1. Set up equipment and connect with cables; connections are labeled. (See System Diagram, Exhibit 2-1.)
2. Connect power cords to grounded electrical receptacles.
3. Check chart paper. Load new paper if needed. Be sure the paper is allowed to flow freely; it will jam and kink if allowed to hit anything.
4. Slide the pen on the piston to the 0 liter line of the chart paper. The return spring should be left engaged.
5. Attach the spirometer hose to the spirometer, and the hose reducer to the other end of the spirometer hose.
6. Turn power to the terminal on first. Wait a few seconds.
7. Turn power to the microprocessor on and wait for logon to appear on terminal screen. Note: The equipment should be allowed ½ hour to warm up.
8. Insert floppy disk and cassette tape in microprocessor drives. Note: The tapes must have been previously bulk erased, servo written and formatted. The floppy disk must have been formatted and initialized. If the equipment is turned off and on at any time, always disengage the tape and floppy before doing so.

Exhibit 2-1. System Diagram



- I. Codonics 1550 Terminal and Keyboard
- II. Ohio 827 Spirometer
- III. HF4 Microprocessor
 - A. Cassette Drive
 - B. Floppy Disk Drive
- IV. Printer

9. Hit any key on keyboard and menu will appear:
 - 1) Spirometry; and
 - 2) System utilities
10. Hit key 1, return.
11. Time appears; if correct, return. If not correct, enter correct time, return.
12. Data appears; if correct, return. If not correct, enter correct date, return.
13. Will ask for studyname. The study name will be NHANESXXX; use the three digit location code as part of the study name and enter without spaces (e.g., NHANE996). Return.
14. Spirometer code, enter code found on the front of the spirometer and unique to this particular spirometer, return.
15. Block with options will appear:

Tape Storage
Disk Storage
Age, Height, Sex
Printer
Shift Study

Beside each option will appear either "selected" or "not selected." If you do not want to change the options selected, hit return. If you need to change, the prompt will ask for each option and you will answer accordingly. Note: The usual selections would be "tape storage" and "disk storage." If you are planning to print results, you would also need to select "age, height and sex" and "printer."
16. Wait, opening disk for data transfer.
17. Wait, retensioning tape will appear.
18. Wait, opening tape for data transfer.
19. Tape ready, return.
20. Next, syringe calibration will appear. Answer prompts as they appear.

2.3.2 Calibration Procedures

2.3.2.1 Syringe Calibration Check

Perform syringe calibration check. A spirometer calibration check and a "pressure" calibration check should be performed before each testing session when the spirometer is dry and at ambient temperature. After the calibration check, the technician should perform five maneuvers on himself. At the end of the testing sessions, a calibration check without the "pressure" calibration check will be done. This time the technician should do five blows (no less than three) on himself before the syringe check.

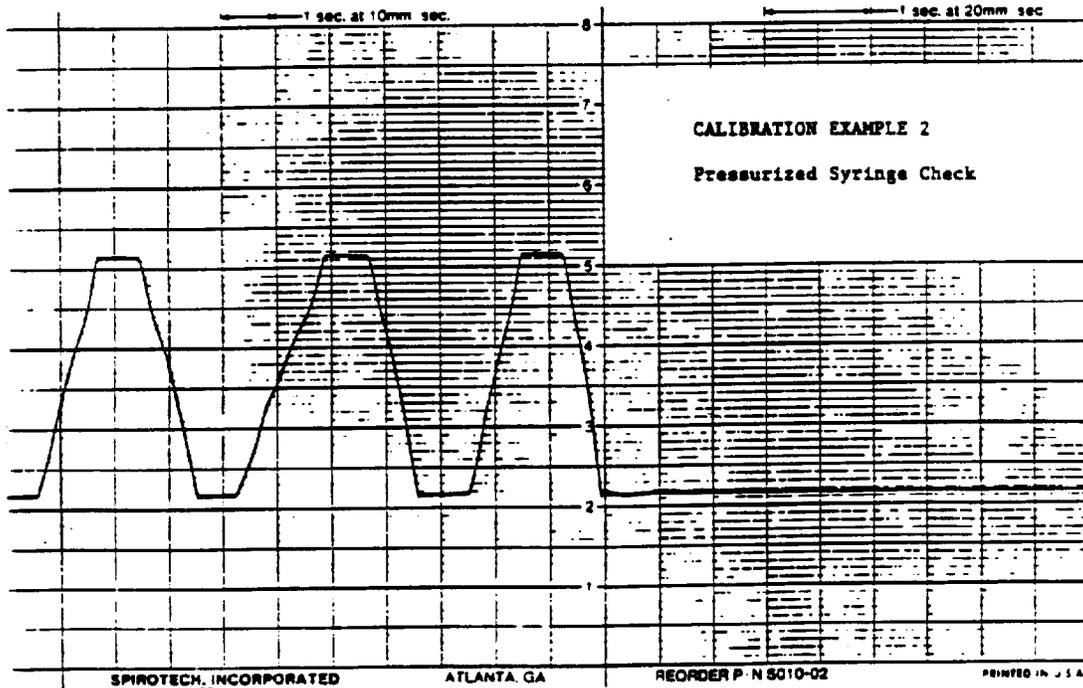
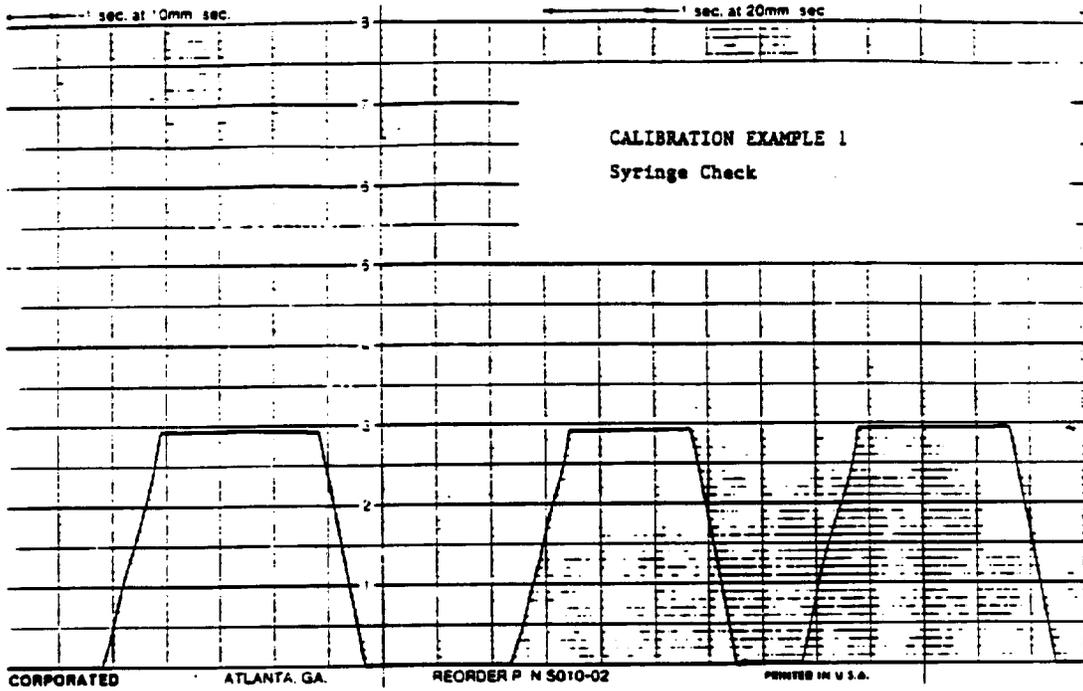
2.3.2.2 Volume Calibration Check and Leak Test

1. Make sure steps 1-20 of Beginning of Stand Procedures are completed. Follow prompts of computer.
2. Position the pen over the chart paper at the 0 liter line. Do not allow the pen to contact the chart paper at this time.
3. Enter Barometric Pressure when asked.
4. Enter actual volume written on calibration syringe.
5. Temperature will appear, answer that it is correct unless obviously wrong (much different from room temperature).
6. Pull the plunger of the calibration syringe all the way back (maximum volume position) and attach the syringe to the hose of the spirometer using an adapter if necessary.
7. Lower the pen onto the chart paper. Check to see that it is positioned at the zero line.
8. Push the plunger of the calibration syringe all the way forward (minimum volume position). Remove the syringe from the hose and repeat the procedure twice more. Proper support is essential to avoid damaging the calibration syringe. Three syringe checks must be completed. (See Exhibit 2-2 Calibration Example 1)

9. Compare the recorded volume on the chart paper with the known volume of the calibration syringe. The recorded volume should not differ from the calibration syringe volume by more than \pm three percent, contact the MEC Manager for assistance. Acceptable range: 2.91 - 3.9 liters, for a 3.00 liter syringe. The inserted air volume will also appear on the computer screen and whether or not it is within the acceptable range of the syringe volume. It should be noted that while the computer corrects for spirometer opening volume, the manual chart drive does not perform this correction. Therefore, the volume of the chart drive will appear approximately 60 milliliters lower than the syringe volume (still within the $\pm 3\%$ range). The acceptable range for the chart drive using a three liter syringe should be from 2.85 to 3.03.

10. Check that the pen returns to the original start point.

Exhibit 2-2. Calibration Examples 1 and 2



11. After the syringe check, the computer will ask if you want to do a "pressurized syringe check." If this is the beginning of the session, answer "Y" and follow prompts for the check. A "pressure" calibration check procedure will be performed in addition to the above procedure at the beginning of each session. Two to three liters of air will be pulled into the spirometer by pulling on the spirometer pen shaft. Once this volume of air has been entered, a full three liter calibrating syringe will be connected to the spirometer. The technician will answer the computer prompt and enter and extract three liters of air three times without disconnecting the syringe. The technician will then wait for the computer to indicate that 20 seconds have elapsed (completion of leak test). (See Exhibit 2-2 Calibration Example 2, and Exhibit 2-3, Calibration Examples 3, and 4).
12. After the pressure check is done, the main menu will appear:
 1. Initial setup/change
 2. Syringe calibration check
 3. Perform PFT maneuver
 4. End of session

Select:

13. Hit 3, return
14. Do blows on yourself, following the prompts on the screen.
15. You are now ready to test subjects.

CAUTION: Change the pen position as necessary for each check only after removing the calibrating syringe.

2.3.2.3 Chart Speed Check

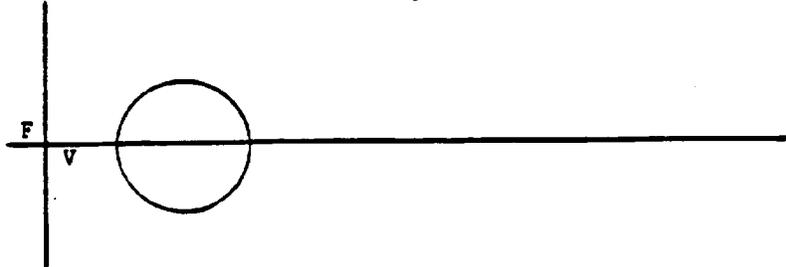
The Chart Speed Selector Switch is a three position toggle switch which selects recorded speeds of 10 mm/sec. or 20 mm/sec. The OFF position separates the two speed selections.

The Chart Drive Handswitch activates the chart drive when the Chart Speed Selector Switch is either in the 10mm/sec. or 20mm/sec. position. The handswitch will not activate the recorder if the Chart Speed Selector Switch is in the OFF position.

Exhibit 2-3. Calibration Examples 3 and 4

CALIBRATION EXAMPLE 3

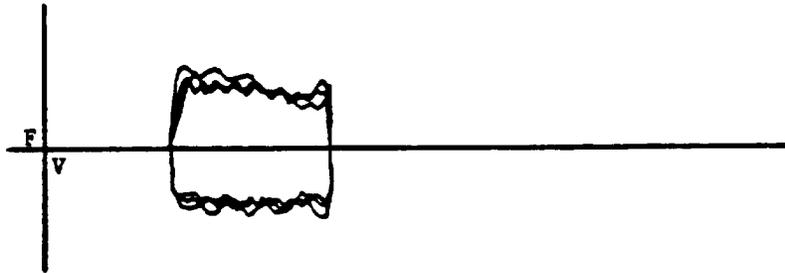
Pressurized Test - Pressurizing
The Spirometer



- Step 1. Position spirometer volume inside circle.
- Step 2. Connect full syringe to spirometer hose.
- Step 3. Spirometer is now pressurized. Any key to continue.

CALIBRATION EXAMPLE 4

Pressurized Test - Measuring Syringe Volumes



- Step 4. Force 3 complete syringe volumes into the spirometer.
- Step 5. Return syringe to the FULL position and hold until the 20 second timeout occurs. [Any key to ABORT].

A chart speed check should be performed daily to insure that the chart recorder is in good working order.

1. The chart paper should always be run at 20 mm/sec. Set toggle switch to appropriate position.
2. Every ten intervals, or every five seconds at the 20 mm/sec. speed, a heavy vertical line extends below the baseline of the chart paper. Use these lines as your checkpoints. Start the paper with the Chart Drive Handswitch and let it run a few seconds to reach full speed. Keep the button depressed and observe the paper. When the pen crosses a heavy time line, start the stopwatch. When the third time line crosses under the pen, stop your watch. It should read 10 seconds.
3. If the timing is off, a service representative should be called.

2.3.3 Daily Procedures

The daily procedures for operation and calibration of the spirometry equipment are the same as those described in Section 2.3.1, Start of Stand Procedures, and 2.3.2 Calibration Procedures.

In addition, technicians will perform cassette tape copying and backup procedures as described in Section 5.0.

2.4 Care and Maintenance of Equipment

2.4.1 Spirometer Cleaning and Lubrication

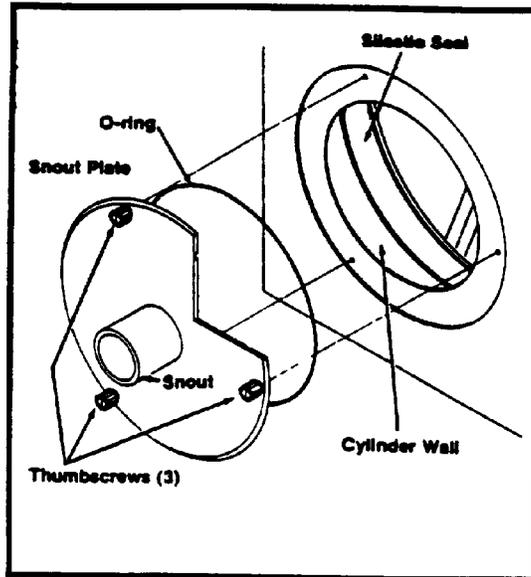
A. Spirometry Hose

1. The hose should be cleaned and disinfected daily by soaking in isopropyl alcohol, 70% for 30 minutes, then rinsed with water. The tube should be allowed to thoroughly dry before reusing.

B. Internal Spirometer (see Exhibit 2-4)

1. Clean the internal parts of the spirometer each week.

Exhibit 2-4. Spirometry Interior and O - Ring Lubrication



2. Disassemble spirometer for cleaning.
 - Unplug power cord.
 - Remove the snout plate by rotating the three thumbscrews counterclockwise until the snout plate is free.
 - Carefully reach inside cylinder and slowly push piston back to its maximum volume position.
3. Wipe the snout plate, o-ring and cylinder wall with alcohol. Dry. Do not use alcohol, acetone, other volatile agents or abrasive cleaners on the rolling seal.
4. Before reassembly, be sure the interior of the spirometer is thoroughly dry.
5. Examine the o-ring for any irregularities. If damaged, replace it. Lubricate the o-ring lightly with petroleum jelly or stopcock grease. Fit the o-ring into the groove on the back of the snout plate.
6. Position the snout plate so that the three thumbscrews are aligned with the three holes on the spirometer housing. Tighten the thumbscrews clockwise gradually, one at a time, so that the plate is evenly secured. Tighten only "finger-tight".
7. At this time you should check for leaks around the snout plate. You do this by pulling 2-3 liters of air into the spirometer, plugging the snout with a rubber plug, running the chart paper a few seconds, then letting the spirometer set a few minutes. After 4-5 minutes, run the chart a few more seconds and check to see that no drop in the volume has occurred.

C. External Spirometer

1. Clean the painted cabinet surfaces with a solution of mild detergent and warm water, rinse and wipe dry with a soft cloth.

2.4.2 Maintenance of Tape/Disk Drives

Maintenance of both the tape and disk drives consists solely of cleaning the read/write heads. On the average, this service should be performed once a month if the system is used on a daily basis. Maintenance time must be shortened when operating in a particularly smoky or dusty environment and may be extended with less frequent operation.

A. Tape Head Cleaning

Use only magnetic head cleaner and lint-free foam swabs. Do not use Q-tips as the cotton fibers may become lodged in the head grooves.

1. Apply a small amount of cleaner to a fresh swab.
2. Open the drive door and lightly rub the head a few times. Discard this swab.
3. Wait a moment and with a new swab, dry the tape head.
4. Allow the head to dry thoroughly before inserting a data tape.

B. Disk Head Cleaning

Use a head cleaning kit suitable for 5 1/4" floppy drives. The kit will contain cleaning diskettes and the necessary cleaning solution.

1. Leave system power on when cleaning the disk heads.
2. Apply a moderate amount of cleaning solution to the cleaning diskette.
3. Insert the diskette in the drive and close the latching tab. Allow the diskette to spin (clean) for 30 seconds.
4. Remove the cleaning diskette.
5. Wait a few moments for the heads to dry before inserting a data diskette.

2.4.3 Malfunctions

Other than the authorized system calibration and checks, no effort should be made to adjust or repair the 827 equipment or computer system.

The MEC manager should be notified immediately of any equipment problems. If necessary, the MEC manager will consult with the NCHS engineer for service recommendations.

All repair and adjustments will be made by staff from the NIOSH Appalachian Laboratory in Morgantown, West Virginia.

2.5 End of Stand Procedures

1. Make sure that spirometer and hose have been cleaned and disinfected.
2. Check that all floppy disks and magnetic tapes have been removed from the computer and labeled.
3. Check that all equipment power is turned off and power cords are unplugged.
4. Secure spirometer for transport.
5. Secure computer for transport.
6. Complete inventory for next stand.
7. Pack supplies for storage.
8. Pack magnetic tape and floppy disks in floppy disk mailers for transport to NIOSH. Deliver to MEC manager for shipment.

3. EXAMINATION PROTOCOL

The accuracy of the spirometry examination depends on the effort exerted by the examinee and the conscientiousness of the technician. Consequently, it is crucial that the examination protocol be observed consistently, and that the examinee be carefully prepared and "coached" for this examination. Insufficient effort on the part of the SP will cause the test results to be inadequate for analysis.

3.1 Eligibility Criteria

Examinees aged 8 and above are eligible for the spirometry exam. Examinees should be excluded from spirometric testing if any of the exclusion criteria are positive. These criteria are as follows:

- Chest or abdominal surgery within past three weeks; and
- Myocardial infarction (or "heart attack").

These criteria are included on the Spirometry Examination Form on the automated system as described in Section 3.3.4.2.

Spirometry should always be completed before the allergy test is administered. Performing the allergy test first could cause SPs to be excluded because of possible reactions to the allergens.

3.2 Pre-Examination Procedures

3.2.1 Calibration Procedures

All calibration procedures, as described in Section 2.3.2, should be completed at the start of each session before beginning SP exams.

3.2.2 Read Barometric Pressure from Barometer and Record in Daily Log If Using Hard Copy Logs

3.2.3 Adult SP Instruction and Preparation

1. Confirm that the SP has not had the allergy test.
2. Enter the SP's NGHS Number into the MEC automated system. Select spirometry exam. Enter cassettes (magnetic tape number and floppy disk number into the system. Ask the SP each screening question under "PHYSICAL CAPACITY." If SP is excluded, proceed to the exit screen and select reason SP was excluded. Do not perform spirometry exam. See Section 3.3.4 for detailed instructions for completing the examination form.
3. Explain the purpose of the examination and the need for extra effort from the SP to get maximal results. Instructions such as "I want to measure how hard and fast you can breath" are helpful and may be sufficient.
4. Explain the procedure in simple language and demonstrate a deep inspiration, proper placement of the mouthpiece, and blasting of air into tube. Blow for at least four seconds to make the demonstration as realistic as possible.
5. Ask the SP to loosen any tight clothing and remove dentures (if not secure).
6. Install a new spirotube (mouthpiece) into the spirometer hose.
7. Ask SP to stand during the examination. Be sure the bench is positioned behind the SP. If the SP cannot stand, make a notation on the log sheet if using hard copy, or in the comments portion of the automated exam form, that exam was performed with SP sitting and enter a TQ code of 100 after each blow as appropriate.
8. Have SP elevate the chin and extend neck slightly.
9. Place noseclip on nose. Clips may be removed between trials.
10. Have the SP do a trial exhalation. The following instructions may be helpful:
 - (a) "Take a great big deep breath of air as far as you can inhale." (Have the examinee inhale from room air).
 - (b) "Put the mouthpiece into your mouth and seal your lips tightly around it." (Demonstrate the right way.)
 - (c) "Blast your air into the tube as hard and fast as you can." (The exhalation should be made with the lips tight around the mouthpiece with maximal force and speed.)
 - (d) "Keep on blowing out the same breath of air, until I tell you to stop."

11. Review the procedure and correct any problems from the trial.
12. Before the subject does his blows, you will need to enter his identifying characteristics on the Spirometry System. Be sure the information is accurate and complete. For race, there are five choices. You also need to determine if the person is of Hispanic origin or not. Answer yes or no to the question.
13. Proceed with Section 3.3, Examination.

3.2.4 Child SP Instruction and Preparation

Younger children, particularly the 8 to 10 year olds, may benefit from simpler explanations and a more relaxed approach to the exam. Try to use fewer words, don't rush them, and provide a clear, realistic demonstration. Do not lecture about the purpose of the exam or the equipment but offer to answer any questions.

1. Confirm that the child has not had the allergy test.
2. Ask if the child has used a bronchodilator within the last hour. If so, postpone test one hour.
3. Loosen tight clothing.
4. Ask child to stand during the exam.
5. Place new spirotube into spirometer hose.
6. Demonstrate how to elevate chin and extend neck slightly.
7. Explain the procedure to the child and demonstrate the steps. Use the following example as a reference:

"We want to see how your lungs work. We will measure how much air you can take (demonstrate vividly and strenuously) and how much you can blow out -- as hard and fast as you can.

Proceed through each step of the procedure while demonstrating, observing, and encouraging the child to practice with you.

"Take in as much air as you possibly can. Like this." "When you're full, close your lips around the tube like this."

"Then blow out all of your air as fast and hard as you can. Keep blowing out hard until I

tell you to stop."

Allow the child one or two more practice trials in a relaxed fashion.

If still unsure of the child's understanding and ability to perform, demonstrate again (repeat the above steps), stressing anything that was not done properly. Reemphasize by exaggerated demonstration rather than words on how to do it correctly, e.g., "take as much air in as you possibly can;" "hold all your air until I tell you to blow." Accent the positive; don't say, "You did it wrong."

8. Place nose clip on nose.
9. Proceed to Section 3.3, Examination.

REMINDER: Your attitude and encouragement is more likely to evoke a good response than formal instruction.

3.3 Examination

3.3.1 Procedures

1. Follow prompts from Spirometry System to begin exam.
2. Tell SP to take a deep breath.
3. Press return key on Spirometry System to start chart drive.
4. After chart drive starts rolling, tell the SP to put the tube in their mouth and start blowing out hard and fast. (See instructions from Section 3.1.5 and 3.1.6).
5. Encourage SP to keep blowing for at least the six second minimum required by ATS. The terminal screen will expand at the six second mark as a cue, but look at the spirogram before terminating the test.
6. Tell SP to stop blowing and remove the mouth tube.
7. Continue to follow prompts from the Spirometry System for repetition of trials. Note error messages. Enter tech codes as needed to explain or comment on results.
8. End the exam for the SP when five acceptable/reproducible trials are obtained. Do not obtain more than eight trials on one SP.

3.3.2 Spirometry System Screen Text

Exhibit 3-1, 3-2, and 3-3 display samples of the text portion of the NIOSH Spirometry System screen which will be displayed after each maneuver is performed. In addition, all flow volume curves will be displayed, with the current flow volume curve being displayed as a solid line and the previous curves with dashed lines. The text will be displayed slightly to the right and above the flow volume curve(s) is unacceptable, it is not used to satisfy the three acceptable curves criteria and more trials are needed. An "*" is displayed before the trial number and the quality code after the values if a curve is unacceptable. If the current curve fails to meet any of the acceptability criteria, then a message is displayed below the values (see acceptability criteria). Any reproducibility criteria failures are also displayed as appropriate, although no "*" is displayed for failure to meet reproducibility criteria. Multiple acceptability and reproducibility messages are displayed per trial. See the attached acceptability and reproducibility criteria for details.

3.3.3 Technician Code

The following codes can be entered by the technician after each FVC maneuver; however, if the curve is acceptable, it is not necessary to enter a code. Codes with two digits (10 or greater) will cause the computer to delete the curve from the report, with one exception--a code of 100 or above will not cause deletion. The code 100 is to be entered after a blow if the SP was seated while doing the maneuver. The 100 code may also be used in combination with the other TQ codes. For example, if the SP is seated and did a submaximal effort on expiration, enter the code 103. Curves that are deleted from the screen by entering codes 10-20 will be saved on the raw data tape and are retrievable.

<u>Code</u>	<u>Explanation</u>
1 -	Did not understand test directions--language/communications problem
2 -	Early termination of expiration
3 -	Submaximal effort on expiration
4 -	False start of test (do not delete)
5 -	Leak, e.g., mouthpiece, etc.

Exhibit 3-1. Sample Screen Display

Subject: 506	Temperature 25.0				Date: 5-May-87			
Trial	FVC		FEV1		PkFlow		Time	Q
1	5.62	2.3%	4.55	0.0%	10.30	1.4%	8.5	
* 2	5.32	7.5%	4.34	4.6%	9.88	5.4%	7.6	03
3	5.75	0.0%	4.25	7.0%	10.45	0.0%	9.0	
4	5.60	2.6%	4.04	11.2%	9.77	6.5%	6.5	

ACCEPTABLE CURVE
NonRep -FEV1

Enter your quality code for last curve, or return to continue:

Note: A minimal number of spaces are used between variables to avoid any overlap between the test data and the flow volume curves. A minimum of five trials should be obtained from each SP, with at least three acceptable curves within the reproducibility criteria.

Exhibit 3-2. Acceptability Criteria

<u>Code (Octal)</u>	<u>Message/Description</u>
0	- "ACCEPTABLE CURVE" is displayed if the maneuver was acceptable.
1	- "EXTVOL" is displayed if the extrapolated volume is more than 5% (or 100 ml, whichever is greater) of the forced vital capacity (FVC).
2	- "PKFLOW" is displayed if there is a poor peak flow effort. This is defined using the flow volume curve and using the volume at which the flow value of 90% of peak flow (after peak flow) occurs. When this volume is greater than 35% of the FVC exhaled, a late peak flow is indicated. See discussion for rationale in Appendix A.
4	- "COUGH" is displayed when there is a cough within the first second of expiration. A cough is detected by calculating the first derivative of flow versus volume, from peak flow to the FVC. When this value is greater than a critical threshold, a cough is indicated. See the attached detailed description in Appendix A.
10	- "TIME" is displayed if a maneuver is terminated early or there is no plateau in the volume time curve. This occurs if the maneuver lasts less than 6 seconds, or if the curve does not satisfy the 40 ml rule. Under the 40 ml rule, end of test occurs when there is no change in volume for 2 seconds. If the 40 ml rule is not satisfied, then the end of test does not occur and early termination is indicated.

Note: Any combination of the above criteria can occur and is indicated by individual display of the above messages, all on the same line. For example if the code is 17, the following message will be displayed:

UnAcc EXTVOL-PKFLOW-COUGH-TIME

Note: Only a COUGH or EXTVOL code will cause the computer to not use a curve in further analyses (e.g., printed results of observed values with percent predicted, or computation of reproducibility criteria). PKFLOW is not an ATS requirement for an acceptable curve and TIME can usually be met by one of the other ATS end of test criteria (e.g., reasonable duration).

Exhibit 3-3. Reproducibility Criteria

<u>Code (Octal)</u>	<u>Message/Description</u>
0	- "REPRODUCIBLE TEST" or "LESS THAN 5 CURVES" is displayed if the maneuver was acceptable and, depending on the number of trials performed, reproducible.
1	- "PKFLOW" is displayed if from acceptable maneuvers the second largest observed peak flow (PkFlow) is not within 10% (or 400 ml/s, whichever is greater) of the largest observed peak flow.
2	- "FEV1" is displayed if from acceptable maneuvers the second largest FEV1 is not within 5% (or 100 ml, whichever is greater) of the largest observed FEV1.
4	- "FVC" is displayed if from acceptable maneuvers the second largest FVC is not within 5% (or 100 ml., whichever is greater) of the largest observed FVC.
10	- "LESS THAN 3 ACCEPTABLE CURVES" is displayed if there are 3 trials or more and there are not 3 acceptable curves which meet the acceptability criteria.
Note:	In accordance with the 1987 ATS Recommendations, the reproducibility criteria are applied after the acceptability criteria. However, only EXTVOL and COUGH are checked. Curves which do not meet the acceptability criteria (EXTVOL and COUGH) are not included in the above analysis. Any combination of the above codes can occur and is indicated by the display of the individual messages described above. For example, if the code is 7, the following message will be displayed:

NONREP PKFLOW-FEV1-FVC

<u>Code</u>	<u>Explanation</u>
6 -	Excessive variability of effort
7 -	Insufficient inhalation to TLC
8 -	Refused or could not perform additional tests
9 -	
100 -	SP sealed for blow

Omit curves with following codes from further processing:

10 -	Nonspecific error, omit from further processing
11 -	Extra breath at end of maneuver
12 -	Cough
13 -	Very submaximal effort on expiration (delete)
14 -	False start of test (delete)

3.3.4 Spirometry Examination Form

3.3.4.1 Hard Copy Form

The Spirometry Examination Form is used to record responses to the SP screening questions, and the outcome of the spirometry procedure. The form should be started at the beginning of each examination and completed at the conclusion of the exam. An example of the Spirometry Examination Form is shown in Exhibit 3-4.

Technicians should first place the SP barcode ID label on the upper right section of the form, and then write in their technician number, the cassette (magnetic tape) number and floppy disk number.

After the identification information is completed, the technician performing the exam should ask the SP the five screening questions on the form. If there is no reason to exclude or delay the SP, the technician should proceed to conduct the spirometry exam. Once the exam is completed, the technician should mark the appropriate box to indicate the result of the exam, and explain unsatisfactory

Exhibit 3-4. Spirometry Examination Form

SPIROMETRY AGES 8 AND OLDER			
Staff No.	Cassette No.	Disk No.	NCHS ID NO
_____	_____	_____	_____
PHYSICAL CAPACITY			
1. In the past three weeks have you had any surgery on your chest or abdomen? <input type="checkbox"/> yes <input type="checkbox"/> no			
2. Have you had a myocardial infarction (or "heart attack") within the past six weeks? <input type="checkbox"/> yes <input type="checkbox"/> no			
EXCLUDE FROM SPIROMETRY ANY PERSON WHO HAS HAD RECENT CHEST OR ABDOMINAL SURGERY OR A RECENT HEART ATTACK ("YES" IN 2 OR 3)			
3. Have you smoked a cigarette, eaten a heavy meal or used any medications to help your breathing in the past hour? <input type="checkbox"/> yes <input type="checkbox"/> no			
4. In the past few days have you had a cough, cold, or other acute illness? <input type="checkbox"/> yes <input type="checkbox"/> no			
5. In the past three weeks have you had any respiratory infections, such as flu, pneumonia, bronchitis, or a severe cold? <input type="checkbox"/> yes <input type="checkbox"/> no			
RESULTS OF EXAMINATION:			
1 <input type="checkbox"/> Satisfactory test (3 valid tests)			
2 <input type="checkbox"/> Test incomplete or Unsatisfactory			
3 <input type="checkbox"/> Test not done			
REASONS TEST INCOMPLETE, UNSATISFACTORY OR NOT DONE:			
1 <input type="checkbox"/> Equipment failure			
2 <input type="checkbox"/> Coughs detected			
3 <input type="checkbox"/> Early termination of expiration, insufficient effort			
4 <input type="checkbox"/> Acute illness (VRI, flu, pneumonia)			
5 <input type="checkbox"/> COPD (severe bronchitis, emphysema, asthma)			
6 <input type="checkbox"/> Ate heavy meal			
7 <input type="checkbox"/> Examinee unable to understand test instructions due to language barrier			
8 <input type="checkbox"/> Examinee unable to understand test instructions due to other reasons			
9 <input type="checkbox"/> Insufficient time available or room not available			
10 <input type="checkbox"/> Examinee refused or uncooperative			
11 <input type="checkbox"/> Examinee medically excluded by staff for safety			
12 <input type="checkbox"/> Comments: _____			

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or incomplete exams. Should the SP be excluded or delayed, this information should also be recorded in the boxes provided on the form.

A section is provided at the end of the form to allow technicians to record comments regarding unusual events.

All boxes should be clearly and legibly marked.

3.3.4.2 Automated Spirometry Examination Form

The automated version of the Spirometry Examination Form was designed to simulate the hard copy version described in Section 3.3.4.1. Technicians will enter their ID number, and the SP NCHS identification number on the entry screen, and select "Spirometry" to reach the Spirometry Examination Form.

After accessing the spirometry form, technicians will enter the cassette (tape) and disk numbers from the NIOSH Spirometry System. If the tape and disk numbers recorded in the system are correct, no entries need to be made; however technicians should always check to make sure the numbers on the screen match the numbers on the tape and disk before exiting the screen.

Screening Questions

The screening questions will appear individually on the spirometry program screens and should be read by the technician exactly as written on the screen. A "Yes" response to either of the first two questions will evoke a warning message that the SP should be excluded from the exam. Spirometry exams should not be performed on excluded sample persons. Following a "Yes" response the program will skip to the Results of Examination section and technicians should record that the exam was not done, and select "Medically Excluded" as the reason the examination was not performed.

If the examinee answers "No" to the initial questions, the program will proceed to the remaining screening questions. These questions are not exclusion questions; therefore a "Yes" response will not affect

the eligibility of the examinee. However, the procedure may need to be postponed if the examinee ate a large meal, smoked a cigarette or used a bronchodilator within the hour prior to the exam.

Results of Examination

After conducting the spirometry examination on the NIOSH Spirometry System, the technician will return to the Spirometry Form and record whether the result of the examination was satisfactory, complete but unsatisfactory or not done. Exhibit 3-5 shows the screen that will be displayed with the examination result choices. If the exam was complete but unsatisfactory or not done, another screen will appear so that reasons may be recorded. If the exam was satisfactory, the cursor will move to the comments section to allow notation of pertinent remarks. Enter comments carefully because it is not possible to back up and review your comment once it scrolls off the screen. Backing up the cursor will delete words.

Reasons

A screen with reasons for complete but unsatisfactory exams and exams not done will appear whenever these options are selected in the result of examination section. There is a separate screen with reasons for unsatisfactory exams and for exams not performed.

The reasons for Test Complete but Unsatisfactory are shown in Exhibit 3-6. Technicians should select the reason that best explains the unsatisfactory test results based on the following definitions:

- Equipment failure - NIOSH system malfunction but exam obtained. Includes manually performed exams.
- Coughs detected - SP coughed during trials and, though completed, trials may be unsatisfactory.
- Early termination/insufficient effort - SP unable to sustain maximum effort for test.

Exhibit 3-5. Examination Results

Name Test Sample# 9876543

Examination results

Select one

- Satisfactory test
- Test complete but unsatisfactory
- Test not done

Comments:

Char Mode: Replace Page 1

Count: *3

Exhibit 3-6. Reasons for Test Complete but Unsatisfactory

Name Test Sample# 9876543

Examination results

Select one

- Equipment failure
- Coughs detected
- Early termination of expiration, insufficient effort
- Acute illness(VRI, flu, pneumonia)
- COPD(severe bronchitis, emphysema, asthma)
- Ate heavy meal
- Did not understand test directions
- Insufficient time available
- Refused or uncooperative
- Language/communication problems

Comments:

Char Mode: Replace Page 1

Count: 10

- Acute illness - SP tests not optimal due to a reported recent illness such as a viral infection.
- COPD - SP unable to exert best effort due to a chronic pulmonary disease.
- Ate heavy meal - Test may not be best effort as SP ate a full meal within the hour prior to the exam.
- Did not understand directions - Test obtained but SP did not appear to understand the instructions for performing the test. May apply to young children or an elderly SP.
- Insufficient time - Test was abbreviated because of a shortage of time in the examination session.
- Refused or uncooperative - SP refused to perform test or to perform correctly.
- Language/communication problem - SP did not speak or understand English well, or had a communication problem such a hearing impairment.

Upon completion of this entry, the cursor will move to the Comments section. Any remarks pertinent to the test, or that may explain further the problems encountered in the exam, should be entered in this section. There is a large amount of space provided for comments, but technicians should be brief and concise in their remarks. Enter comments carefully because moving the cursor backwards will delete words, and thus comments that have scrolled off the screen cannot be reviewed.

Exhibit 3-7 displays the list of reasons that will appear when technicians select Test Not Done as a result for the examination. These reasons are defined as follows:

- Equipment Failure - Examination could not be performed (including manually) due to malfunction of equipment. A comment describing the problem should be entered in the comment section that follows this screen.
- COPD - The SP could not complete the exam because of a chronic respiratory disease.
- Language/communication problems - The exam was not completed due to a language barrier, such as inability to speak English, or a communication problem, such as a hearing impairment.
- Did not understand instruction - SP did not fully understand instructions and thus could not perform the test.
- Insufficient time - Not enough time to complete the exam during the session.

Exhibit 3-7. Reasons for Test Not Done

Name Test _____ Sample# 9876543

Examination results

Select one

- Equipment failure
- COPD(severe bronchitis, emphysema, asthma)
- Language/communication problems
- Did not understand test directions
- Insufficient time available
- Refused or uncooperative
- Medically excluded by staff for safety

Comments:

Char Mode: Replace Page 1

Count: *7

- Refused or uncooperative - SP refused to perform exam or to cooperate sufficiently enough to obtain a complete exam.
- Medically excluded - SP was excluded from test due to recent surgery or myocardial infarction, or for reasons of safety as determined by the MEC physician.

The cursor will also move to a Comments section upon completion of this screen and any pertinent comments regarding the exam should be entered as described previously.

After exiting from the Comments section, the program will return to the introductory screen and clear all data in preparation for the next SP. It is important to complete and exit the comments section and return to the introductory screen so the computer system can assign an ending time to the SP exam.

3.3.4.3 Questionnaire Specifications

Identification Information

The initial portion of the Spirometry Examination Form is composed of identification information. Enter the information into the these sections as follows:

- **Cassette number.** Enter the identification number of the tape from the NIOSH Spirometry System. Usually only one tape is needed per stand.
- **Disk number.** Enter the identification number of the floppy disk from the NIOSH Spirometry System. There will be more than one disk used in each stand, as one disk holds 300 trials.

Exclusion and Screening Questions

The first two questions on the form are asked to exclude SPs with recent chest or abdominal surgery, or myocardial infarctions. Questions 3, 4 and 5 are screening questions; a positive response does not exclude an SP from the exam. However, examinees who answer "Yes" to the screening questions may not be able to complete the exam with an optimal effort, so it is important to record the reasons that could explain why the test results may be below normal levels.

Read each question exactly as it is written. Refer to Exhibit 3-4 for the exact screening questions.

- Question 1. Question 1 is an exclusion question. If the SP answers "Yes" to chest or abdominal surgery within the past three weeks, record "Yes" and exclude the SP from the exam. Skip to the Results of Examination Section. If "No", proceed to Question 2.
- Question 2. Question 2 is an exclusion question. If the SP answers "Yes" to a myocardial infarction within the past six weeks, record "Yes" and exclude the SP from the exam. Skip to the Results of Examination section. If no, proceed to Question 3.
- Question 3. If SP answers "Yes" to having eaten a heavy meal, smoked a cigarette or used medications to assist breathing within the hour prior to the exam, record "Yes" and postpone exam until the appropriate time. If postponement is not possible, record "Yes" and continue with exam. Proceed to Question 4.
- Question 4. If SP answers "Yes" to cough, cold or other acute illness within the past few days, record "Yes". However, be sure to change spirometer hoses as described in Section 2.3.4 after completing the exam. Continue to Question 5.
- Question 5. If SP answers "Yes" to a respiratory infection within the past three weeks, record "Yes" and proceed with the exam. Follow hose cleaning procedures as outlined in Section 2.3.4 immediately after exam.

Results of Examination

If the test result was complete and satisfactory, record the appropriate response and proceed to the next SP. If the exam could not be conducted or completed (unable to obtain the required number of trials) or was unsatisfactory in some way (excessive coughing, suboptimal effort), record this result, and the reason as described in the next section.

Reasons Test Incomplete, Unsatisfactory, Not Done

After recording that the exam was not done, incomplete or unsatisfactory, the technician should indicate the primary reason for the problem exam. Do not complete this section if the examination was complete and satisfactory.

Responses 1-4 refer to equipment problems, coughs during the trials, poor or weak effort, or

acute illness. If the SP reported a chronic obstructive disease (COPD) such as emphysema or bronchitis in the screening questions, mark response number 5.

Response 6 should be used for examinees who ate a heavy meal within the hour prior to the exam. Mark this box only if the exam was not adequate. SPs who answer "Yes" but perform well should receive no notations in this section.

Responses 7 and 8 should be used to record examinees who cannot understand the instructions for participation and thus perform poorly. SPs who cannot speak English or are unable to comprehend the effort required for the test and cannot complete the exam should also be recorded in this section. Spanish translations of instructions for the examination are available.

Response 9 should be used to record exams not completed because of insufficient time remaining in the exam session.

Response 10 should be used for SPs who do not cooperate with the exam, or refuse to have the exam.

Response 11, medical exclusions, is used to record examinees excluded from the exam because of positive responses to exclusion questions, or for other medical reasons such as the SP became ill during the session.

Comments

Record any unusual occurrences or pertinent remarks in the comments section at the end of the form. Notes may be made in this section for any SP exam, regardless of the result of the exam. Information such as the SP became fatigued or did not appear to be exerting such effort, can be helpful during review of the exam.

4. DATA FORMS AND LOGS

The spirometry technician will be required to complete two forms for the spirometry exam, the Spirometry Examination Form and the Spirometry Daily Log. The Spirometry Examination Form has already been described in Section 3.3.4.

Both forms are included in the MEC automated system, but it is important that you be familiar with the hard copy versions in the event of a problem with the system. Hard copy versions of these forms will be available on the MEC if needed.

4.1 Hard Copy Forms

4.1.1 Spirometry Daily Log Sheet

A Daily Log, as shown in Exhibit 4-1 will be maintained by the technician in the spirometry exam room. The SP NCHS identification number, date of exam, duration of exam (time), technician ID number, room temperature, barometric pressure, and pertinent comments are recorded for each exam. A barcoded label with the SP identification number is placed on the log sheet with each SP entry. One log sheet provides space to record exams for one examination session.

The log is used as a hard copy backup of the computer tape information, so it is important that information entered on the log is correct. In the event of a discrepancy between the tape and the log, the log will be given priority. It is important that SPs are entered on the log in the order that they perform the pulmonary function exam. Remember also to use your own staff ID number when doing trials during calibration procedures.

A place is provided on the form to record the cassette (magnetic tape) number and floppy disk number used on the NIOSH Spirometry System during the session. The disk and tape numbers link the hard copy log record with the spirometry exams.

Exhibit 4-1. Spirometry Daily Log

National Health and Nutrition Examination Survey III
SPIROMETRY DAILY LOG SHEET

Cassette No. _____ Stand No. _____
 Disk No. _____ Location _____
 Disk Copied _____ (Y/N) _____ Date _____
 Session: AM PM EVE

SP ID #	Examiner ID #	Barom Press	Room Temp	Time In/Time Out	Age	Sex	Race	Height	Status Code	Comments
1.				____/____/____						
2.				____/____/____						
3.				____/____/____						
4.				____/____/____						
5.				____/____/____						
6.				____/____/____						
7.				____/____/____						
8.				____/____/____						
9.				____/____/____						
10.				____/____/____						

STATUS CODES: C - Complete, PC - Partially Complete (must include comments), NE - No Exam (must include comments)

Unusual occurrences or reasons for cancellations of the procedure should be recorded in the log. In particular, events that may affect the results or interpretation of the data should be noted on the form, such as faint SPs or equipment malfunctions. It is important to record this information as it happens, otherwise the exact order of events may be difficult to reconstruct at a later time.

All entries should be legible and in the proper sections.

4.2 Automated Forms

4.2.1 Spirometry Daily Log

The Spirometry Daily Log will not appear as a separate form on the MEC automated system. The date of the exam will be loaded into the system at another station. A clock in the system will keep track of examination times by logging the entry and exit of each data form. SP and technician identification numbers will be recorded on the entry screen. The cassette (tape) and disk numbers will be entered on the data form, which will also include a comments section to record unusual occurrences. It is not necessary to maintain a separate daily log when using the automated system.

4.3 Shipment of Forms and Logs

Each week, copies of the Spirometry Daily Logs for all exam sessions should be printed from the automated system (or if hard copy forms were used, xerox copies should be made) and sent to NIOSH with the quality control floppy disk as described in Section 5.2.4.2.

All hard copy versions of the Spirometry Examination Forms and the Daily Logs produced during the stand should be collected, separated by type, and shipped to NCHS at the end of the stand as outlined in Part 1, Section 2.0, Standardized Procedures. Each type of form requires a separate transmittal form which is generated from the automated system.

A copy of the complete set of Spirometry Daily Logs for the stand should also be sent to the Director of MEC Operations at Westat at the end of the stand. If daily logs were not generated by the automated system, reproductions of the hard copy versions of the logs, along with the transmittal form prepared for NCHS, should be sent to Westat.

4.3.1 Hard Copy Transmittal Forms

In the event of a problem with the computer-generated transmittal forms, the hard copy NCHS Transmittal Form will be available to prepare shipments. Forms should be recorded and reconciled as described in Part 1, Section 2.0, Standardized Procedures.

5. QUALITY CONTROL

5.1 Examination Forms

5.1.1 Hard Copy Forms

After completing the Spirometry Examination Form, health technicians should review the form for completeness, accuracy, and legibility before the SP leaves the examining room. Responses for appropriate items should be completed, exclusions and screening questions should be complete, no conflicting responses should be marked and all entries should be legible.

Forms will also be reviewed by NCHS staff for completeness and accuracy.

5.1.2 Automated Examination Forms

Automated versions of the Spirometry Examination Forms will be reviewed at NCHS by staff responsible for the spirometry component.

Feedback from reviews of the forms will be forwarded to the Director of MEC Operations at Westat.

5.2 Field Quality Control Activities

At the end of each examination session, the raw data from the tape storage device are copied to a blank floppy disk using the utility program. If fewer than ten subjects have been tested during any session, the technician may wait until ten subjects have been tested before copying the raw data. Backing up the raw data in this manner will insure that data for no more than ten subjects can be lost due to failure of the tape storage device.

When the raw data are copied to a floppy, the coping program will also select a random sample of 10 percent of the subjects for hand measurement. The technician will measure the FVC and FEV1 for these subjects. Volume time spirometry tracings for these selected subjects, the pre-session calibration tracings,

the hand calculated results, a list of the subjects on the floppy, and the floppy disk will be sent to the review center. Any corrections to the data should also be noted on the "log" sheet, if hard copy logs were used.

If the session includes testing by more than one technician, 10 percent samples for each technician will be selected. If there are fewer than 10 subjects for any technician represented on the floppy, then a minimum of one tracing per technician will be hand measured.

5.2.1 Utility Program Procedure

To copy from the tape to a disk, you will need a preprogrammed utilities disk and a clean initialized formatted disk. Each disk will hold about 180 raw data curves so you must be prepared to use several disks and you must use care to label them properly. You will need also to keep track of the sessions by number and make notations when the sessions are copied.

Start out by booting up the system the same way as you would to perform pulmonary function maneuvers. When the menu appears, you will this time select 2 (System Utilities/ Diagnostics). On the screen will appear:

```
SYSTEMS UTILITIES/DIAGNOSTICS SELECTED  
Insert Appropriate System Disk into Drive  
Ready to Proceed?
```

When this appears, insert the utilities disk into the disk drive. Then answer Y to the prompt and hit return. Then the HF4 utility menu will appear. The Menu may change from time to time as new programs are developed. You need only be concerned with the NHANES Utility

Program. Note carefully the number for "Raw Data Transfer and Random ID Selection" and enter that number to continue with the NHANES Utility Program.

Select:

You will enter the number for "NHANES Raw Data Tape-To-Disk Transfer." Then the following will appear:

Transfer/QC Utility for NHANES Study

1. Print random 10% sample of subject IDs only.
2. Print random 10% sample and all transferred curves.
3. Do not print any results.

Select line printer option:

Select 1, then you will be asked:

1. Transfer Entire Data Tape To Disk.
2. Transfer Most Recent Spirometry Sessions Only.

Select Data Transfer Option:

This is why you need to keep good records. You will not want to transfer the entire tape each time, so you must keep track of what you have copied previously so that you can continue your copying from that point. The first time you copy from a tape you will select one to transfer the entire data tape.

After you have started transferring a tape you will only need to copy the most recent sessions and then you would select two. When you select either 1 or 2, the following prompts will appear:

Perform The Following:

- Remove The Utility Disk.
- Insert The Disk On Which Raw Data Will Be Transferred.
- Insert The Spirometry Data Tape That Contains The Raw Data.

Press <RETURN> When Ready To Proceed With Transfer:

Wait ...Opening Tape...

If you selected Data Transfer Option 2, you will be told the last session on the data tape and then you must enter the number of the session that you want to start copying.

Last Session On Data Tape:
Enter Starting Session Number:

WAIT ...Opening Tape...

Transfer in Progress
Data Transfer Completed
Computing Random ID Samples for Hand Calculations
STOP

The printer will print a list of random samples. These are the patient numbers that you should do hand calculations on.

Next you will be prompted to "Remove Data Disk" then "Insert Utilities Disk". After you do this the HF4 Utility Menu will reappear. This time select the number for "Return Disk/Tape to Data Storage Mode" and you will be returned to the standard operating procedures. Don't forget to remove the utilities disk and insert a data floppy before starting to test subjects.

5.2.2 Review Center Quality Control Activities

A comparison of hand measured results with the computer determined results will be made from the 10 percent random sample submitted by the technicians. Differences will be traced to determine the source of the difference and appropriate corrective action will be taken as necessary.

A sample of calibration tracings and all calibration results will be reviewed to insure that the spirometer does not need calibration and does not have a leak. The review center will calibrate the spirometer at least every three months, unless results from the reviews indicate that more frequent calibration is needed.

The review center will review the flow volume curves for all subjects and the review center technician will identify or confirm the field technician's identification of unacceptable curves.

This is accomplished by simultaneous review of the technician entered quality codes and flow volume curves for each subject. Other corrections noted on the log sheets will also be made at the review center so that corrected raw and calculated data files can be created and maintained by the review center.

Table 5-1 shows the routine steps and programs used to process incoming field spirometry data.

5.2.3 Quality Control Reports and Feedback to Field Technicians

Upon completion of review of each batch of incoming data, technicians will be notified immediately of any serious errors with calibration and/or procedures. With the completion of a study site or more than 100 subjects, statistics will be compiled for each technician summarizing the following:

- Distribution of number of curves per subject.
- Distribution of number of acceptable curves per subject.
- Number of subjects with non-reproducible peak flows.
- Number of subjects with non-reproducible FEV1's.
- Number of subjects with non-reproducible FVC's.
- Number of curves with unacceptable extrapolated volumes.
- Number of curves with unacceptable peak flows (late peak flows).
- Number of curves with coughs.
- Number of curves with unacceptable expiratory times or end of test.
- Number of curves with expiratory times less than six seconds.
- Number of curves with end of test plateaus lasting less than 0.5 seconds.
- Number of curves with end of test plateaus lasting between 0.5 and 1.5 seconds.
- Number of curves with end of test plateaus lasting more than 1.5 seconds.

Table 5-1. Steps in Processing Field Spirometry Data

No.	Step	Program Used
1	Log Incoming Data	DBASE III
2	Copy Data from Floppies	SPCOPY
3	Print List of Subjects	SPIDPRNT
4	Print Summary Values for Each Subject	SPPRINT
5	Display and Select Curves for Deletion	SPFV
6	Create Corrections File	SPEDIT
7	Create Corrected Raw and Calculated Data Files	SPCORR
8	Merge Individual Data Files	SPMERGE
9	Print Calibration Check Results	SPCCHK
10	Perform Quality Control Checks	SPQUAL
11	Create Summary Spirometry Files	SPSUMM
12	Print Participant Letters	SPPRED

Table 5-2 shows the results of the Program SPQUAL for the study NHANES996 for all technicians and Table 5-3 shows the results just for technician 5. The overall values are also shown on individual technician reports as a vertical line. For example, in Table 5-3 technician 5 has more subjects with greater than five curves than was observed overall for the study. Table 5-4 lists the seven different possible error codes.

In addition to the quality control summary report, a calibration summary report is also generated for each study. The program SPCCHK provides a listing of all syringe calibration and pressure calibration check results. If necessary, the program SPCDSP can display the pressure calibration curves as needed. Table 5-5 shows the results for study NHANE996. The two occurrences of leak errors and non-linearity errors resulted from the technicians entering the syringe volume before the computer was ready to accept the volume. The revised version of the software does not allow the technician to make this error without overriding with an error detected warning.

The quality control reports will be furnished to each technician through the Director of MEC Operation for his review. Depending on the results, the technicians will receive additional training as necessary.

It should be noted that NHANE996 was the first field use of the spirometry system software as well as the first study conducted by the technicians. Several improvements in the software, in particular error warnings with override requirements, have been made to the original versions of the spirometry system software. Therefore, fewer errors should be observed in future studies due to software improvements and increased technician experience.

5.2.4 Shipping Data Items

5.2.4.1 Preparation of Floppy Disk and Tapes

After the calibration and utility programs are run at the end of the last exam session of the stand, the magnetic tape and floppy disk should be removed from the system. Both items should be labeled clearly; and prepared for mailing by NIOSH.

Table 5-2. Quality Control Summary Report (Program SPQUAL) for Study NHANE 996.Z00, All Technicians

Quality control summary report (Program SPQUAL) for study NHANE996.Z00, all technicians.

FILE:NHANE996.Z00 SOFTWARE: 2 SPIROMETER: 2 DATE: 10/ 6/87 THROUGH: 12/ 9/87 1445 CURVES 280 SUBJECTS
 REPORT FOR ALL 6 TECHNICIANS 1445 TOTAL CURVES 280 TOTAL SUBJECTS

Category	TOTAL	N	PERCENT	SUM
=====				
<= 4 CURVES	280	23	8.2%	8.2%
=====				
5 CURVES	280	199	71.1%	79.3%
=====				
>= 6 CURVES	280	58	20.7%	100.0%
=====				
<= 2 ACCEPT	280	15	5.4%	100.0%
=====				
3 ACCEPTABLE	280	22	7.9%	7.9%
=====				
4 ACCEPTABLE	280	41	14.6%	22.5%
=====				
>= 5 ACCEPT	280	202	72.1%	94.6%
=====				
NONREP PKFLOW	280	14	5.0%	
=====				
NONREP FEV1	280	5	1.8%	
=====				
NONREP FVC	280	6	2.1%	
=====				
LUA EXTVOL	1445	97	6.7%	
=====				
LUA PEAK FLOW	1445	73	5.1%	
=====				
LUA COUGH	1445	56	3.9%	
=====				
LUA EXP TIME	1445	340	23.5%	
=====				
< 6 SECONDS	1445	149	10.3%	10.3%
=====				
EDT < 0.5SEC	1445	81	5.6%	5.6%
=====				
EDT 0.5-1.5S	1445	212	14.7%	20.3%
=====				
EDT >= 1.5 S	1445	1152	79.7%	100.0%

0 20% 40% 60% 80% 100%

Table 5-3. Quality Control Summary Report (Program SPQUAL) for Study NHANE 996.Z00, Technician 5

Quality control summary report (Program SPQUAL) for study NHANE996.Z00, technician 5.

FILE:NHANE996.Z00 REPORT FOR TECHNICIAN: 5 445 CURVES 84 SUBJECTS

Category	TOTAL	N	PERCENT	SUM
===== < 4 CURVES =====	TOTAL	84	4.8%	4.3%
===== 5 CURVES =====	TOTAL	84	79.8%	84.5%
===== >= 6 CURVES =====	TOTAL	84	15.3%	100.0%
===== < 2 ACCEPT =====	TOTAL	84	2.4%	100.0%
===== 3 ACCEPTABLE =====	TOTAL	84	11.9%	11.7%
===== 4 ACCEPTABLE =====	TOTAL	84	16.7%	28.6%
===== >= 5 ACCEPT =====	TOTAL	84	69.0%	97.6%
===== NHREP PEFLOW =====	TOTAL	84	7.1%	
===== NHREP FEV1 =====	TOTAL	84	1.2%	
===== NHREP PVC =====	TOTAL	84	3.6%	
===== UA EXTVOL =====	TOTAL	445	8.1%	
===== UA PEAK FLOW =====	TOTAL	445	6.3%	
===== UA COUGH =====	TOTAL	445	4.0%	
===== UA EXP TIME =====	TOTAL	445	109	24.5%
===== < 6 SECONDS =====	TOTAL	445	10.1%	10.1%
===== EOT < 0.5SEC =====	TOTAL	445	6.3%	6.3%
===== EOT 0.5-1.5S =====	TOTAL	445	16.9%	23.1%
===== EOT >= 1.5 S =====	TOTAL	445	342	76.9%

0 20% 40% 60% 80% 100%

Table 5-4. Error Codes

Bit	Code	Explanation
0	12	Temperature sensor malfunction, user entered temperatures
1	2	Syringe calibration check error > 1.5 percent
2	4	Lead > 20 ml detected during pressure calibration check over 20 second period
3	8	3 liter syringe not used during calibration
4	16	Non-linearity detected during pressure calibration check
5	32	For future use
6	64	Raw data not saved on cassette tape

Note: A combination of errors can occur and is indicated by simply a sum of the codes for the errors which did occur.

Table 5-5. Calibration Check Summary Report (Program SPCCHK) for Study File NHANE 996.X01

FILE:NHANE996.X01 STUDY: NHANES 3 7 CALIBRATION CHECKS
 177 CURVES MASSTORE VERSION: 122 SOFTWARE VERSION: 2
 FROM: 10/ 6/87 8:32 TO: 10/ 8/87 21:09

SESSION NUMBER	NUMBER	SUBJECTS	DATE	TIME	SPR	TECH	SYRINGE ERRORS (ML)			PRESSURE CAL ERRORS (ML)			LEAK (ML)	CAL VOL
	1	0	10/ 6/87	8:32	2	8	-30	-3	7	76	7	15	79	1765
	1	12	10/ 6/87	17:14	2	3	42	42	42	21	15	13	42	1792
	2	12	10/ 7/87	8:18	2	5	-30	-3	-14	-16	10	0	5	1951
*	2	7	10/ 7/87	17:54	2	5	21	31	47	-577	23	23	-560	1983
*	2	13	10/ 7/87	21:22	2	3	29	37	39	-579	18	13	-525	1930
	3	13	10/ 8/87	9:35	2	5	-6	13	26	5	-11	18	2	2015
	3	3	10/ 8/87	17:47	2	5	23	61	47	5	15	7	34	2017

MEAN (STD) SYRINGE: 20.048 (27.484) PRESSURE CAL: -42.810 (188.451)
 LEAK VOLUME (ML):-131.857 (281.872)

- * N= 112 MANUAL TEMPERATURE (BIT 0) ERRORS DETECTED *
- * N= 35 LEAK DETECTED > 10ML (BIT 2) ERRORS DETECTED *
- * N= 99 NON LINEARITY > 1.5% (BIT 4) ERRORS DETECTED *

Note: The pressure cal errors of -577 and -579 and the leak values of -560 and -525 resulted from the technicians entering the syringe volume before the computer was ready to accept the volume. The revised version of the software does not allow the technician to make this error without overriding with an error-detected warning. Also note that the "CAL VOL" is the volume in the spirometer when the pressure calibration is performed.

Place all floppy disks in a disk mailer envelope, and be sure to include all disks that may have spirometry exams copied to them.

Place the magnetic tape in a separate floppy disk mailer.

Close both envelopes and place inside a Federal Express envelope. Complete the shipping label, using the NIOSH address, and slide into plastic sleeve on outside of envelope.

A Transmittal Form, either the automated version or a hard copy form should be completed for each separate item (tape or disk), shipped, and a copy of the form placed in the Federal Express Envelope. In addition, a copy of the same Transmittal Form or a duplicate hard copy backup form should be sent under separate cover to NCHS.

5.2.4.2 Daily Logs

Copies of the Daily Logs pertinent to the Spirometry exams recorded on the floppy disks should be enclosed whenever disks are sent to NIOSH for review. No Transmittal Form is required for the log.

At the end of the stand, a complete set of hard copy logs, either those produced on the automated or hard copy forms used for backup, should be sent to the Director of MEC Operations at Westat.

If the hard copy backup logs were used during the stand at any time, they should be collected, and sent to NCHS at the end of the stand with a Transmittal Form. This shipment could be reproduced, along with a copy of the Transmittal Form, and sent to Westat to fulfill the requirement described previously.

5.2.4.3 Spirograms

All hard copy spiograms should be collected at the end of the stand and sent to NCHS with a Transmittal Form. Each spiogram should have on it a barcode label with NCHS SP identification number, the examiner ID number, and the date of exam.

The Transmittal Form should be produced by the automated system, but hard copy backup forms should be used if automated versions are not available.

The spiograms, with the copy of the Transmittal Form, should be placed in box and sent to NCHS at the end of the stand. A few spiograms will have been removed earlier and sent to NIOSH as part of the hand calculated quality control sample. These spiograms should be noted as missing from the shipment on the Transmittal Form.

5.3 Review, Observation and Replication

5.3.1 Review

As described in Section 5.2, floppy disks containing records of the spirometry exams will be sent to consultant reviewers at NIOSH on a weekly basis, with copies of the Spirometry Daily Log. The disks will be reviewed, and recommendations transmitted to MEC technicians through the Director of MEC Operations as soon as possible after the review to insure continued accurate performance of exams and collection of data.

5.3.2 Observations and Replication

On a quarterly basis, spirometry consultants will be responsible for observing a sample of spirometry exams performed by MEC technicians. The consultant will observe whether appropriate procedures and techniques are followed and deviations from standard procedures will be noted.

Variations in procedures and problems will be reviewed with the technician at the end of the day. If problems or other issues are considered serious by NCHS or the consultant, the Director of MEC Operations will be contacted and retraining issues discussed.

One other measure, replication of some exams by the consultant, may be instituted. Replicate exams, if determined to be feasible, will be conducted by the dry run at the beginning of a stand.

5.4 Refresher Sessions

Several times each year, refresher sessions will be scheduled for all spirometry technicians to provide an opportunity for review of procedures, for questions to be answered, as well as to confirm the consistency of procedures performed in the field.

6. SAFETY PROCEDURES

6.1 Equipment Precautions

The major equipment precautions for the spirometry exam are prevention of electrical shock during the procedure, and prevention of transmission of infection to other SPs or staff.

6.1.1 Electrical Shock

Prevention of electrical shock for SPs and staff will be managed in two major ways:

- Use of the Ohio Sensormed 829, a widely used instrument approved by the Underwriter's Laboratory; and
- Electrical isolation of the SP from the instrument by a plastic hose and a disposable mouthpiece.

6.1.2 Transmission of Infection

Transmission of infections between examinees in spirometry or from examinees to staff is a remote possibility. No cases of infections transmitted through spirometry exams have ever been reported. However, several steps have been taken to minimize even a slight possibility of infection among SPs or staff.

Precautions to prevent transmission of infections include:

- Examinees will be screened for recent upper respiratory infections, pneumonia or other illnesses. If the response to the screening question is positive for recent infections, the technicians will remove the spirohose immediately after the SP exam and soak it in alcohol at least one hour. A new hose will be attached for the next SP exam so the flow of exams can continue without delay.
- Disposable mouthpieces are used and discarded by the SP after each examination.
- The SP's mouth will always be higher than the orifice of the equipment.

- SPs will be instructed to remove their mouth from the equipment when inhaling to avoid inhalation of a potentially infectious agent.
- The spirometer and accessories will be cleaned and disinfected at regular intervals:
 1. Tubing will be cleaned and disinfected daily.
 2. Instrument will be cleaned at least once every week.
 3. Seal will be inspected and cleaned once each week.

6.2 SP Movement and Positioning

6.2.1 Standing and Sitting Exams

Examinees should stand for the spirometry examinations. A sturdy bench seat has been built into the corner of the spirometry room, and SPs should always be positioned to stand in front of the bench during the procedure. However, occasionally examinees become faint as a result of the exertion during the exam. Ammonia inhalants are kept in the spirometry room to be available if an SP should faint.

Examinees in wheelchairs should perform the procedure sitting in their wheelchairs. SPs should not be removed from wheelchairs for this exam. The code for sitting exams should be used to record that the exam was conducted with the SP sitting down.

The sitting code may also be used for an examinee who becomes faint or tired and must sit for the remainder of the procedure.

6.2.2 Comprehension of Instructions

Caution should be exerted when attempting to examine SPs who are unable to comprehend the instructions for the spirometry procedure. Failure to follow the correct procedures regarding positioning and use of the mouthpiece may present some risk to examinees.

If the examinees do not understand English, a Spanish version of the exam instructions is available on the MEC. If the examinee speaks a language other than Spanish, technicians will attempt to locate a relative or friend in the MEC who could translate for the SP. If no translator can be found, and

if the instructions cannot be communicated by the SP successfully by demonstration, the SP should be excluded from the exam.

Examinees who appear confused and disoriented should attempt the exam, but if it is clear to the technician that the individual is unable to understand and adequately perform the test, the examinee should be excluded from the procedure.

6.3 Emergency Procedures

The spirometry examination should pose no risk of medical emergency to SPs. In rare cases, an SP may hyperventilate and feel dizzy during the examination, and as mentioned previously, ammonia capsules will be available in the event an SP becomes faint.

Examinees who feel faint should be guided onto the bench seat and encouraged to breathe slowly and deeply until recovered. The MEC physician should be summoned whenever an examinee fails to recover normal breathing, faints or reports feeling ill.

As discussed in Part 1, Emergency Procedures, the MEC emergency procedures should be followed in the event of a medical emergency. The physician should be notified immediately, and will assume command of the emergency response.

The physician should always be consulted if there is any question regarding an examinee's status during the exam.

Appendix A

Discussion of Acceptability Criteria

PKFLOW

When a subject does not perform a forced exhalation with sufficient effort during the initial portion of his/her FVC maneuver, then a reduced peak flow will be observed. In addition, the lack of a sufficient effort may result in slightly larger flow rates at middle lung volumes and a higher FEV₁. The higher flow rates observed with slightly reduced efforts is usually caused by reduced gas compression and a lack of sensitivity to lung volume changes when flow is measured at the mouth.¹ While there may not be agreement on whether such curves should be used (Cotes² even recommends that such variable efforts be obtained), it is clear that attempts should be made to obtain curves with a better effort. This usually is achieved by having the subject try harder to "blast the air out at first." The computer must detect these curves so the technician can so inform the subject.

Several techniques have been proposed such as comparing peak flow with the FEV 50% or observing the flow volume angle at peak flow. We chose to use a simple technique based on the observation of Mead, et al.³ Mead concluded that the "effort-independent range of maximum flow extends to at least 70 percent of VC, or over most of the declining phase of flow." When subjects perform the FVC maneuver with sufficient effort and within the effort-independent range of the flow volume curve, maximum flow expiratory flow is limited by: (a) the static recoil of the lung; and, (b) the flow-resistance of the airways upstream from the equal pressure point. Since "a" and "b" are relatively fixed for a given lung volume, the flow volume curves are very reproducible over the effort independent range of maximum flow. With sufficient effort, peak flow occurs at a volume higher than the effort independent portion of the flow volume curve. Therefore from Mead's observations, with sufficient effort peak flow should occur within the first 30 percent of the FVC exhaled.

¹Ingram, R.H., Schilder, D.P.: Effect of gas compression on pulmonary pressure flow and volume relationship; J. Appl. Physio., 21:1821:2826, 1966.

²Cotes, J.E.: Lung Function - Assessment and application in medicine, pg. 108, 1975.

³Mead, J., Turner, J.M., Macklem, P.T., Little, J.B.: Significance of the relationship between lung recoil and maximum expiratory flow. J. Appl. Physio, 22:95-108, 1967.

In our analysis of 2,890 curves from 592 subjects, we observed that peak flow occurred at a mean volume of 16.3 percent of FVC and the point 10 percent down from peak flow (PF10) occurred at a mean volume of 25.5 percent of FVC. In addition, for 94 percent of the curves, peak flow occurred at a volume less than 30 percent of FVC and the PF10 occurred at a volume of less than 35 percent of FVC for 73 percent of the curves. Slightly better results were obtained with only the best curve (FVC+FEV1) for each subject was used. The volume (in %FVC exhaled) 10 percent down from peak flow (PF10) was used, rather than volume at peak flow, to reduce the algorithms susceptibility to noise in the flow volume curve. At higher lung volumes, the flow volume curve sometimes has double peaks - one only slightly smaller than the other. Using PF10 reduces this problem and provides better confidence that flow limitation due to sufficient effort has been achieved.

COUGH

Detection of a cough is based on observations from the flow volume curve. After peak flow has occurred, flow limitation should occur and the flow rates should be decreasing with increasing volume exhaled. Therefore, the first derivative of flow versus volume should be negative from volume at peak flow to the FVC or over the effort independent portion of the flow volume curve.

The COUGH detection algorithm calculates the sum of all **positive** first derivative values from the volume at peak flow to FVC. Specifically, from the flow volume curve the differences in adjacent flow rates at approximately two percent increments of FVC are computed from peak flow to FVC. Since the first derivative of flow as a function of volume should always be negative over this volume segment, any positive values are due to either noise or an anomaly. The most common cause for positive derivatives is a cough. We use a threshold of positive derivatives of 20 percent of peak flow. The algorithm was checked using a subset of 2,890 curves with coughs.

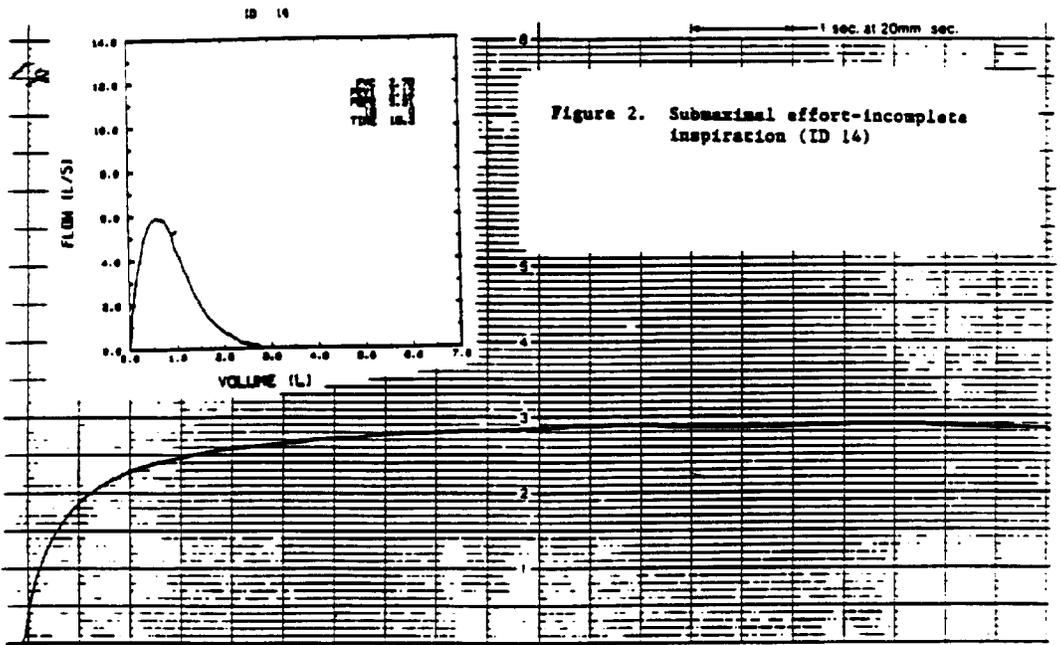
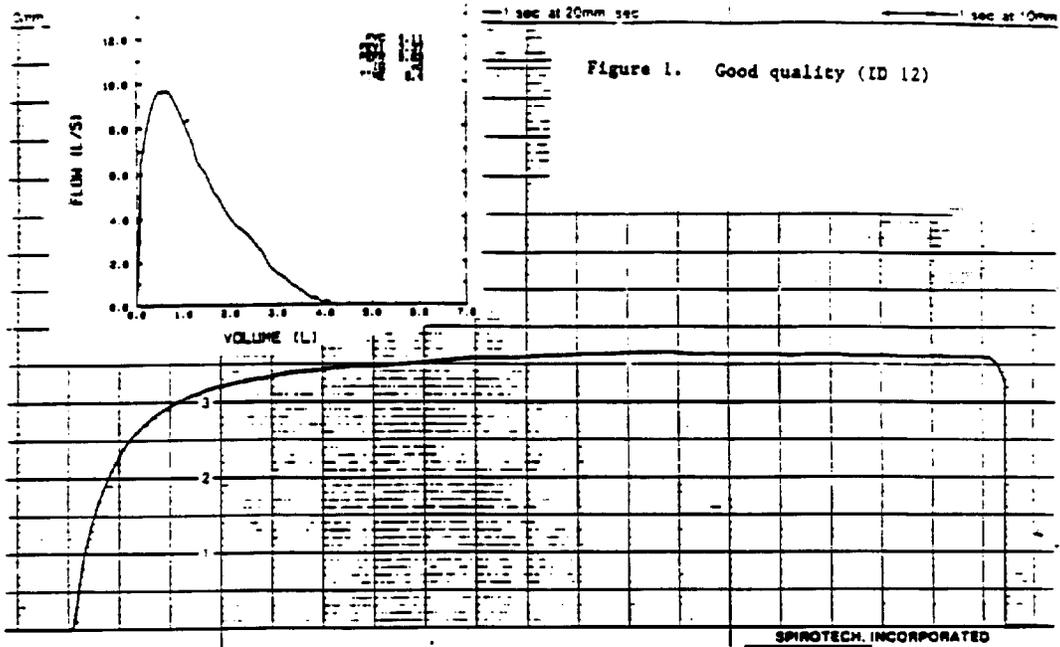
In addition to checking for a cough, extending the COUGH detection algorithm beyond the FEV1 allows for checking of the terminal portion of the flow volume curve for anomalies. In particular, subjects can take in extra air near the end of their maneuver and then exhale this air. The resultant larger FVC is obviously in error which should be identified. The COUGH detector will identify such occurrences for further consideration. Recall that curves with a COUGH are not used in other calculations or reproducibility checks.

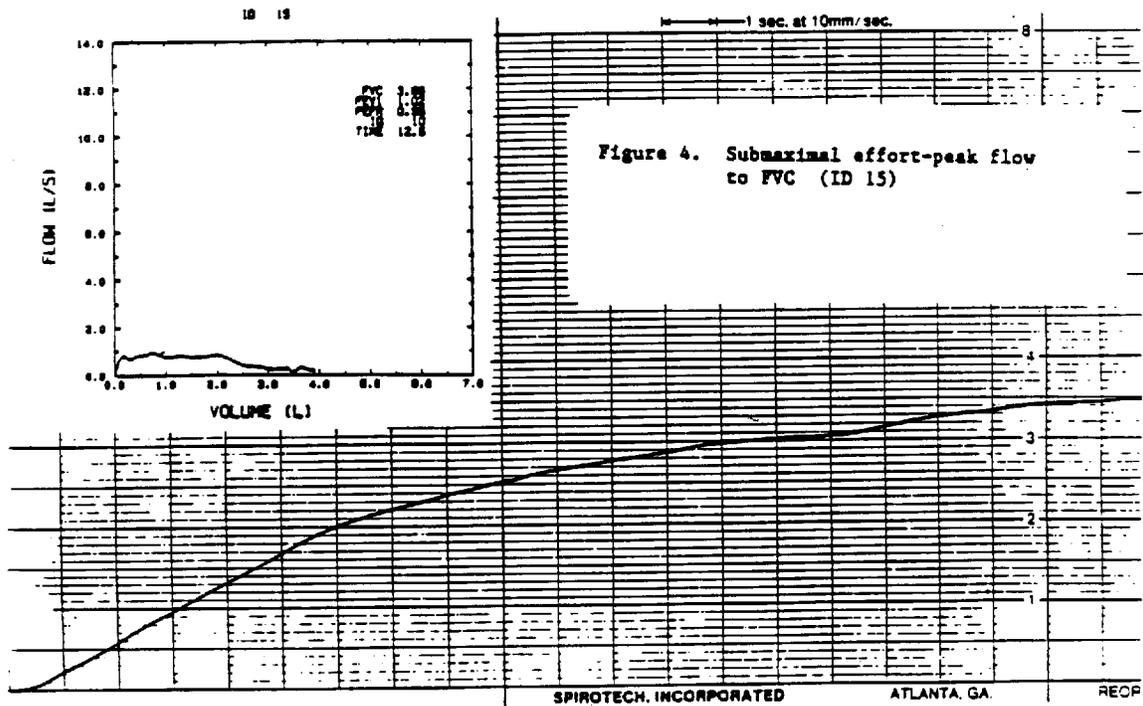
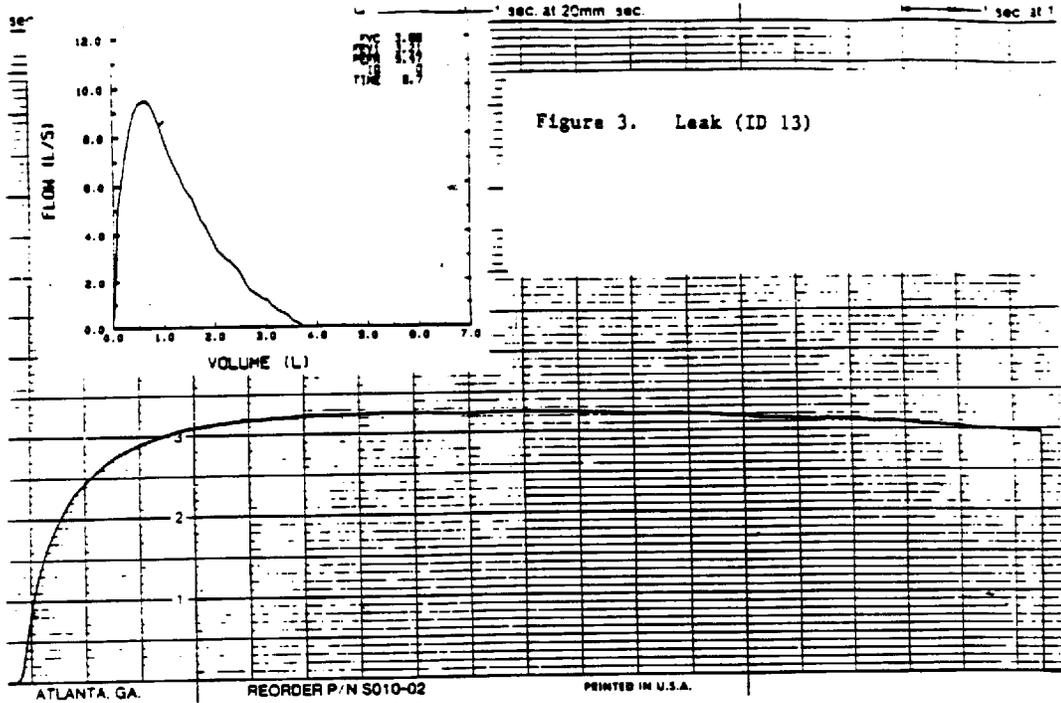
Appendix B

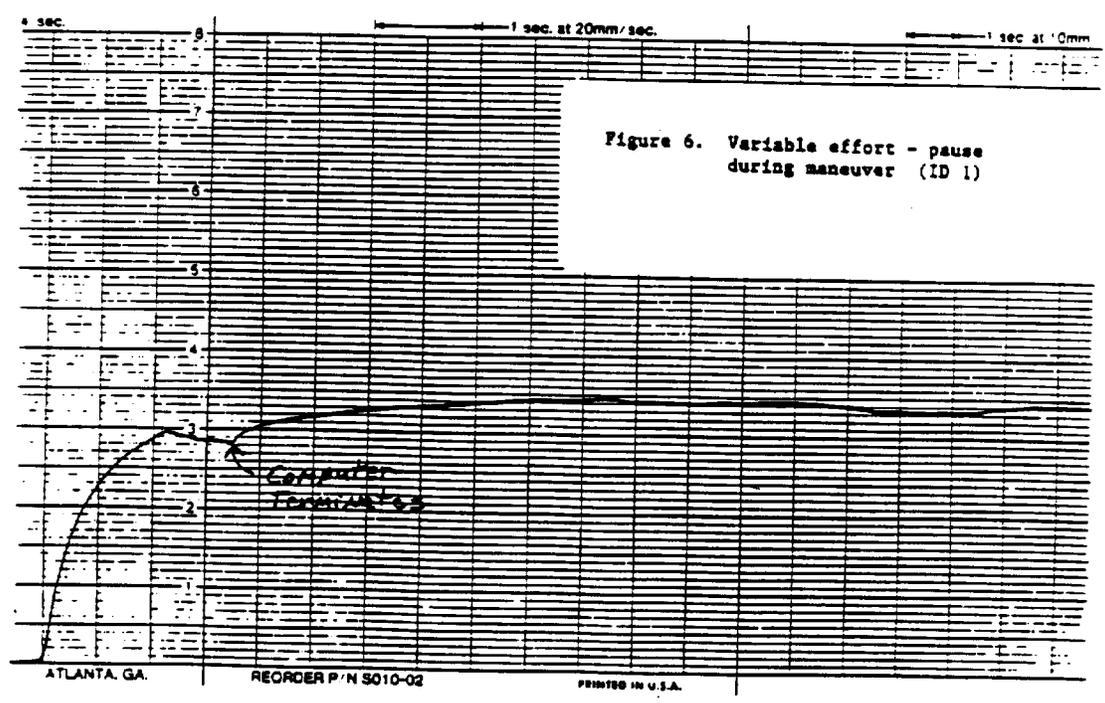
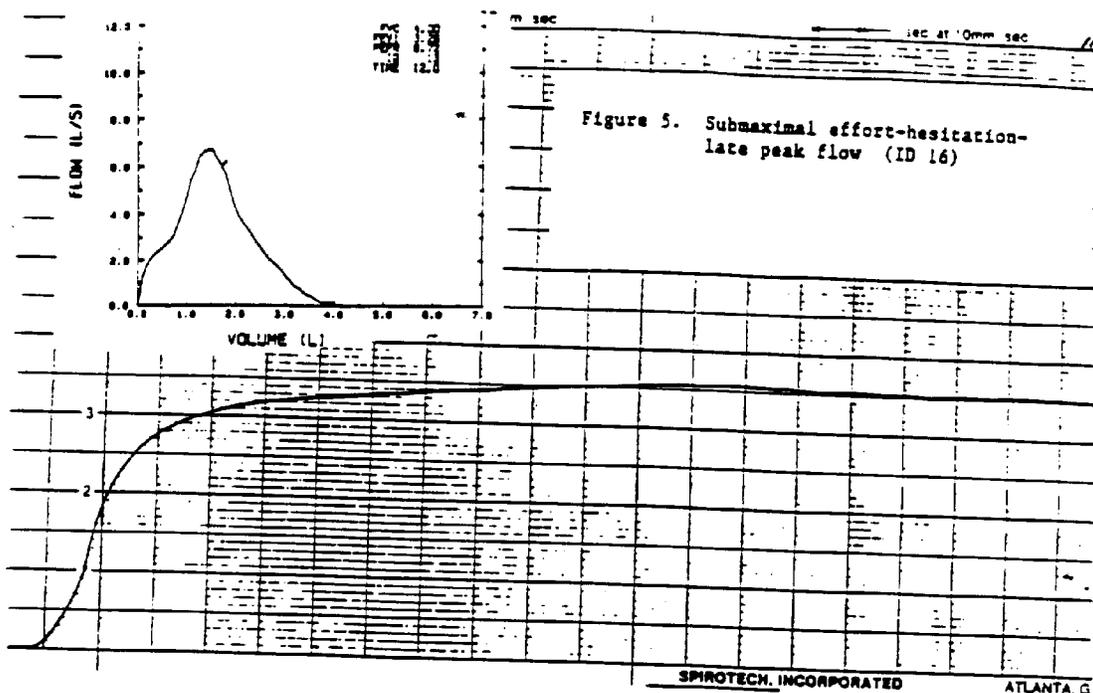
Sample Curves

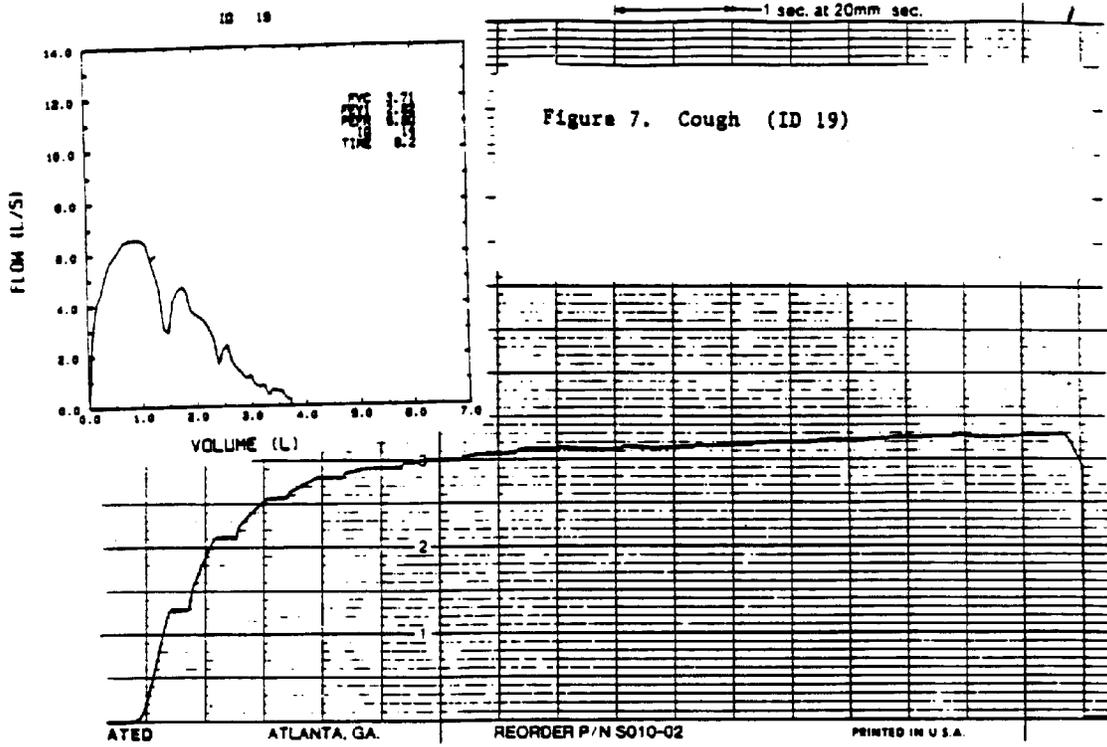
The attached curves are sample curves which you may encounter during the testing of subjects. The volume time curves are shown with the corresponding flow volume curve. Both of these are displayed so that you can compare the two methods of inspecting a subject's effort. A brief description of each curve follows:

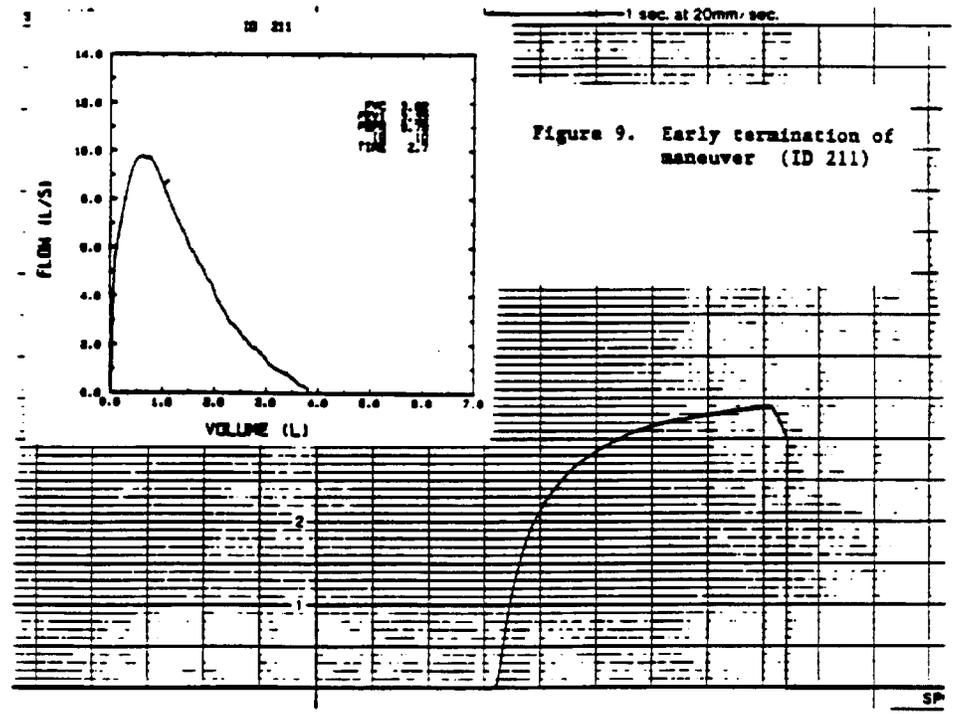
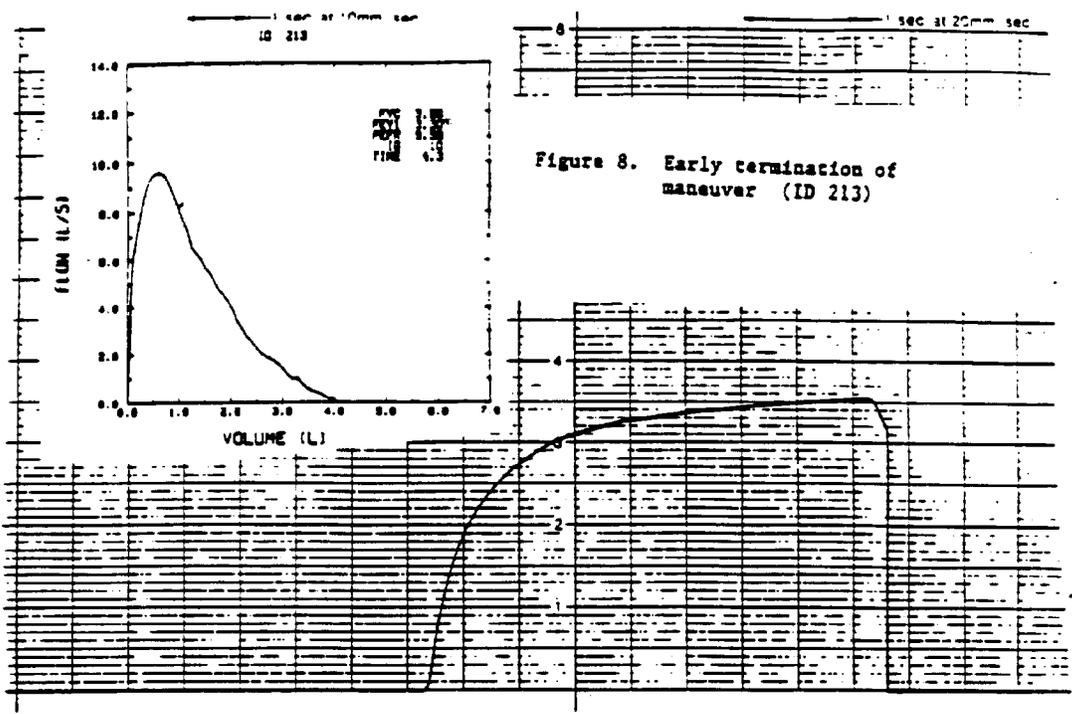
- Figure 1. Shows a good effort. The curve has a good initial start and continues until an obvious plateau in the volume time curve occurs.
- Figure 2. This curve is from the same subject. Obviously the volume is much less than the previous curve. Therefore, the subject probably had an incomplete inspiration before he placed his mouth on the mouthpiece. You should have the subject take a deeper breath performing his FVC maneuver.
- Figure 3. The subject has a good effort but the volume is dropping at the end of the maneuver. Since the volume is decreasing at a relatively constant rate, you would suspect a leak. On the flow volume curve, the flow rate would be slightly negative with a slightly negative with a slight decrease in volume.
- Figure 4. This curve is an obvious submaximal effort, particularly during the initial portion of the curve.
- Figure 5. With this curve, the subject has excessive hesitation at the beginning of the maneuver. The peak flow occurs late and the extrapolated volume is too large. You should have him "blast" the air out at first.
- Figure 6. In this curve, the subject begins to inhale shortly after starting the exhalation. The computer will terminate the maneuver if he inhales more than 200 ml.
- Figure 7. The subject has several abrupt stops in this volume time curve, simulating a cough. Repeat the test.
- Figure 8 & 9. In both of these curves, the subjects terminate the maneuver early. There is no plateau in the volume time curve and the expiratory times are small. Have the subject exhale longer.
- Figure 10. This subject inhales and the computer terminates the maneuver.
- Figure 11. In this example, the technician did not start the chart drive before the subject begins his exhalation.

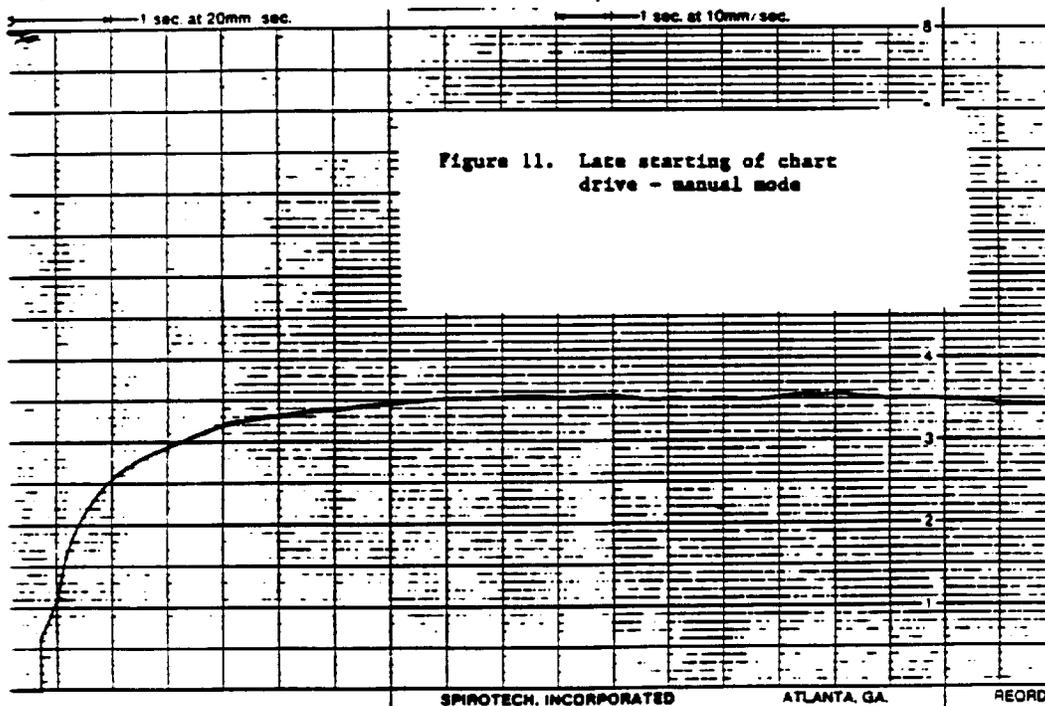
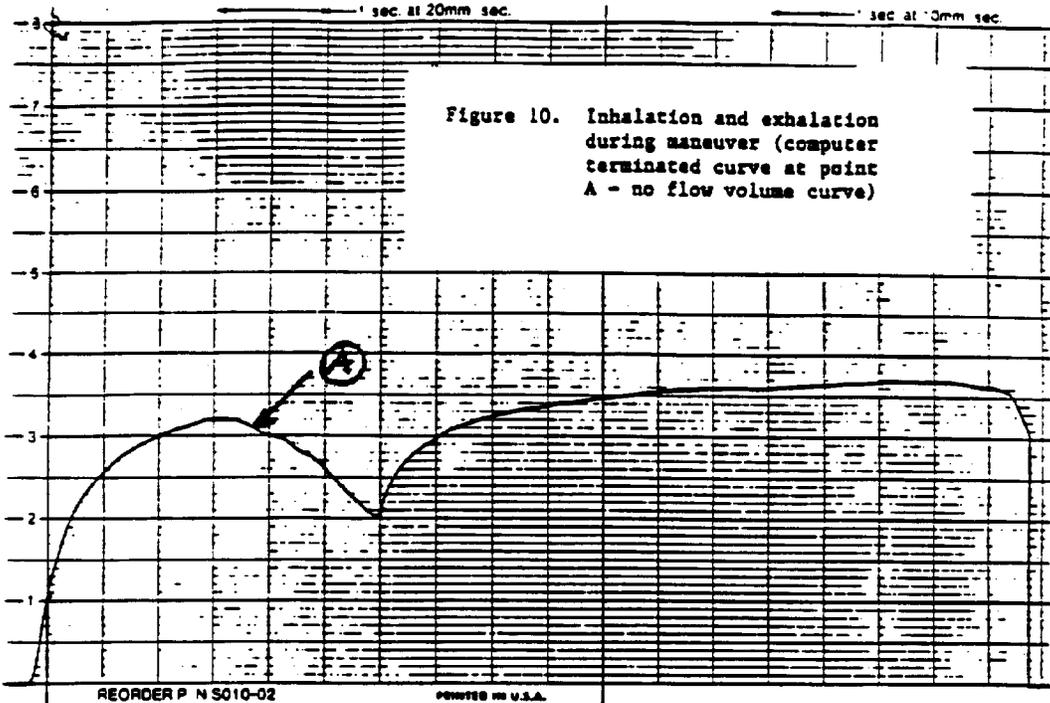












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3. Mead J, Turner JM, Macklem PT, Little JB: Significance of the relationship between lung recoil and maximum expiratory flow; J Appl Physio, 22:95-108, 1967.