Manual 4

Pulmonary Function Assessment

The National Heart, Lung, and Blood Institute
of the National Institutes of Health

ARIC PROTCOL

Manual 4

Pulmonary Function Assessment

Visit 2

Version 2.0

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FOREWORD

This manual entitled, Pulmonary Function Assessment, is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive set of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including reading centers and central laboratories, make up Manuals 4 through 11. Manual 12 on Quality Assurance and Quality Control contains a general description of the study's approach to quality assurance as well as specific protocols for each of the study procedures.

The version status of each manual is printed on the title sheet. The first edition of each manual is Version 1.0. Subsequent modifications of Version 1 (pages updated, pages added, or pages deleted) are indicated as Versions 1.1, 1.2, and so on, and are described in detail in the Revision Log located immediately after the title page. When revisions are substantial enough to require a new printing of the manual, the version number will be updated (e.g., Version 2.0) on the title page.

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1. INTRODUCTION

1.1 The Importance of Pulmonary Function Testing in ARIC

Follow-up surveys of community populations in England (1,2), Denmark (2), and the United States (3-5), have shown that impaired ventilation (spirometry) is associated with increased death rates (age-specific mortality) over periods of 4 to 15 years. Impaired pulmonary function has been found to be a risk factor for mortality even after adjustment for age, race, and smoking (6). Importantly, the mortality excess among those with impaired ventilation is due to a variety of causes (especially cardiovascular and cancer) and not to respiratory causes alone. The risk of mortality increases with the degree of spirometry impairment (7). Although the reasons for the association of impaired ventilation with cardiovascular mortality are not known, the repeatability of this association and the demonstration of a dose-response suggest that the relationship is real and important (8,9). Spirometry is the simplest, most effective, and least expensive test for assessment of pulmonary function (10). It is for these reasons that a measure of ventilation (spirometry) has been included in ARIC.

Spirometry records the relationship between time and the volume of air that can be exhaled from the lungs. The total volume of air which can be exhaled is called the forced vital capacity (FVC). A measure of how quickly that volume can be expelled is called the one-second forced expiratory volume or FEV_1. The volume expired late in the forced expiration (three and six second forced expiratory volumes, FEV_3 and FEV_6) and flow rates during the course of the expiration (peak flow and forced expiratory flows at 25%, 50% and 75% of the total volume) provide additional information about deviations from normal empyting of the lung. Most of our information regarding "normal" pulmonary function comes from cross-sectional surveys of "normal" populations. Predicted values based upon height, age, sex and race may be generated and compared with the observed values of ARIC study participants.

The Epidemiology Standardization Project (11), the Snowbird workshop on standardization of spirometry (12), and further evaluations of commercially available spirometers (13) have indicated the importance of using a volume displacement spirometer, the type of spirometer to be used by ARIC. Both the Epidemiology Standardization Project (11) and the American Thoracic Society (12) have issued statements which provide criteria for spirometry test performance and for manual measurement. However, manual measurements are tedious and prone to error (14). Also, deviations in test performance and lack of regular leak checking and calibration can result in loss of study data (15). Microprocessor computer systems are now being extensively used in spirometry to assist the pulmonary technician with quality control of test performance, measurement, analysis, and interpretation (10).

Weakness of the respiratory muscles may play a role in the association of impaired spirometry with cardiovascular mortality. Perhaps due to aging, malnutrition or neuromuscular disorders, respiratory muscle weakness leads to decreases in the Maximal Inspiratory Pressure (MIP) and FVC, and possibly to a reduced ability to withstand the stress of cardiovascular disease. Measurement of maximal respiratory pressures is a quick and easy way to determine the strength of the respiratory muscles. The diaphragm is the major muscle of inspiration. Assisted by the intercostal and scalene muscles which lift the ribs up and out, the descending diaphragm creates a negative pressure inside the chest which drives air into the lungs (inspiration).

The original techniques for measurement of maximal respiratory pressures described by Black and Hyatt (16) have been modified (17). The Maximal Inspiratory Pressure (MIP) is most easily measured at the mouth following a near-maximal expiration to low lung volume (near "residual volume"). Normal values for this test are not well established, although on average, men are expected to produce a MIP of 100 cm H_2O and women are expected to produce a MIP of 70 cm H_2O, with some decline expected with increasing age. Quality control criteria for this test have been programmed into the ARIC pulmonary function programs for Visit 2, to assist the technician in guiding the participant through the MIP maneuver. The results will be automatically incorporated into both the printed spirometry report and into the electronically stored record.

1.2 Description of the Pulmonary Function Measurement System

The pulmonary function measurements in the ARIC study are to be made on a Collins Survey II volume displacement spirometer which is connected to an IBM PC/XT computer through a 12 bit analog to digital (A-D) interface. The calibration and analytic programs of the Pulmo-Screen II system (S&M Instrument Company) have been installed on the hard disk of the IBM PC/XT computer. The computer will assist the operator in calibration, spirometric testing and analysis. An IBM Proprinter is connected to the computer for report generation.

The testing of each ARIC study participant will produce the following results:

1. A labelled spirogram (paper tracing) from the Collins spirometer.
2. A spirometry summary and interpretation (paper report) from the IBM Proprinter.
3. Hard disk (primary) storage of the three best spirograms (digitized, with calibration and identifying variables) and calculated spirometry results.
4. Floppy disk (back-up) storage of the record described in number 3.

No knowledge of programming or computers is required to operate this system. The system is driven by MENU screens from which the technician selects the desired activity.

The operator will begin a calibration check program every time the system is restarted (each morning). The calibration check program will include a test for leaks in the system, a volume calibration with a 3 liter syringe, a time calibration with a stopwatch and a linearity check. The results of the calibration checks, the date, the time and technician's code will be stored on the hard disk. Calibration of the maximal respiratory pressure (MRP) transducer will be done each week. (The calibration check program is described in detail in Chapter 6.) A log of the calibration results will also be maintained by the technician at each field center.

As the subject blows into the spirometer, the spirogram paper will display a volume-time tracing while the computer displays (real-time) flow-volume curves for operator assessment of acceptability. Simultaneously, the computer will make multiple quality measurements of each maneuver. The duration of the forced expiration will displayed on the screen. A message will be displayed when at least two out of three maneuvers are reproducible (FVC's within 5%).

During a minimum of five spirogram trials, the technician will attempt to obtain three acceptable spirograms of which the best two are reproducible within 5%. The computer will assist this determination by displaying the best three maneuvers, graphed as flow-volume curves superimposed at maximal inhalation volume (TLC). Each maneuver will be separately identified on the display. The computer will indicate which maneuver it thinks is the best one and will indicate when a sufficient number of acceptable and reproducible maneuvers have been obtained. The technician will confirm this selection by observing the volume-time spirograms produced directly by the Collins spirometer.

Following the Flow-Volume Loop (FVL) procedures for obtaining acceptable and reproducible spirometry (unchanged from Visit 1), the Visit 2 participant will be instructed in the procedures for obtaining at least three acceptable (of 2 or more seconds duration) MIP efforts the best two of which must be reproducible (within 10%). The computer will assist this determination by displaying all maneuvers, graphed as inspired pressure/ time curves. The maximum inspiratory pressure is recorded after the first second of each maneuver and is displayed, along with the percentage of the best effort.

The computer will print a summary of the subject's results from the data file at the end of each session and then store the raw data from each maneuver in the file generated for that subject on both the hard disk and a back-up floppy disk. The summary report and spirogram paper tracing are stored in the participant's file.

At the end of the week the operator will make a second copy of that week's testing by downloading the hard disk to a second (mailer) floppy disk. One floppy data (mailer) diskette will be mailed to the Pulmonary Function Reading Center every Friday and the other diskette will be archived at the field center. The computer will identify a random 10% sample of the participants tested whose spirograms will be hand measured and sent to the Pulmonary Function Reading Center.

2. PULMONARY EQUIPMENT

2.1 Description

The Collins Survey II water-seal spirometer is equipped with a device (linear motion potentiometer) which changes the mechanical motion of the spirometer bell into an electronic output. The computer interprets this electronic signal as volume. In the computer, this volume signal is processed (differentiated) with a time signal by the A/D interface to give a flow signal which is interpreted and stored.

The Collins Survey II Spirometer has been developed by and is available from the Warren E. Collins Company. The spirometer consists of two concentric metal cylinders, 22 and 24 cms in diameter respectively. Between these inner and outer cylinders is a water seal through which a bell may rise and fall. The bell consists of a thin plastic cylinder with a domed top of light gauge aluminum. A pen is attached to a plastic block projecting from the edge of the dome. Vertical rods are mounted on the outside metal cylinder to serve as guides for the bell, preventing rotation as it rises and falls. The potentiometer is mounted on one of these guide rods. The total weight of the bell is 175 grams. The bell is 23 cm in diameter and approximately 26 cm high, allowing a working volume of at least 8 liters. A large rubber tube is connected to an inlet at the bottom, allowing access of expired air to the interior of the bell. Increased pressure inside the bell causes an upward displacement. A corresponding tracing is drawn on a kymograph which rotates at a fixed speed dependent upon the 60 cycle frequency of wall current. This instrument was uniquely designed to measure breathing at great velocities and accelerations of air flow. It has been shown that at the frequency of a typical forced expiration (4 cps), the frequency response of this (Stead-Wells) type of spirometer is nearly "flat" and that breathing maneuvers of this type would be recorded with a high degree of accuracy (18).

The Maximal Respiratory Pressure (MRP) transducer is a solid-state analog device which converts positive and negative pressure differences into proportional electrical voltages. This transducer is assembled by the S&M Instrument Company with an aneroid pressure gauge which displays the measured pressures to +/- 250 cm H_2O. When connected to the modified S&M A/D interface (installed for Visit 2 in expansion slot 1 of the PC/XT), the real time pressure/time curves are displayed on the computer screen.

Supplies needed for conducting spirometry and maximal respiratory pressure include disposable mouthpieces, disposable noseclips, disposable red recording pens, calibrated chart paper, a calibrated 3-liter syringe, disposable 5-cc syringes, a Rudolph one-way valve/stopcock, connecting tubing, a thermometer, a metal leak tester (weight) and a stopwatch. Computer supplies should include very high grade double sided, double density diskettes (TDK, Brown, IBM, Verbatim or Dysan brands are recommended) and fan-fold perforated printer paper. Lists of replacement equipment, supplies and vendors are in Appendix V.

2.1.1 Hardware

1. Collins Survey II spirometer with potentiometer, 2-speed kymograph, and water drain (Collins Cat. # 006038)

2. S&M Instrument Company maximal respiratory pressure transducer with aneroid pressue guage display ($\pm$ 250 cm H_2O).

3. IBM PC/XT with a minimum of 256K of memory, a 10MB hard disk and one 360K (double sided) 5 1/4" floppy disk drive.

4. IBM Color video display monitor with color graphics adapter board (including clock/calendar).

5. IBM Proprinter, parallel printer interface card and cable.

2.1.2 A/D Pulmonary Interface and Software

1. S&M Instrument Company Pulmo-Screen II Pulmonary 12-bit, 8-channel, A/D interface (mounted in an expansion slot inside the PC/XT).

2. S&M Instrument Company Pulmonary Software

   a) Master disk and backup--installed on hard disk (drive C)
   b) Storage disk--drive A

3. INSTALLATION

Before installing the computer, read the IBM manual, Guide to Operations, Sections 1 and 2. Then proceed as outlined below.

1. Remove shipping cardboards from disk drive unit.

2. Find the four power switches and turn them off.

   a) rear right side of IBM PC/XT
   b) top knob on right of IBM color video display monitor screen
   c) front of Collins Survey II spirometer
   d) rear right side of IBM Proprinter

3. Connect keyboard cable to rear of IBM PC/XT system unit (back panel, round socket, insert plug with notch up).

4. Connect power cable 3-hole sockets into plugs on back panels of:

   a) IBM PC/XT system unit
   b) IBM video display monitor and
   c) IBM Proprinter

5. Connect data cables to rear of:

   a) IBM Proprinter (back panel, right side)
   b) Collins Survey II Spirometer

6. Connect free ends of data cables to rear of IBM PC/XT system unit in the following slots (numbered from the RIGHT side)

   a) Slot 1 - MRP Cable
   b) Slot 2 - Spirometer Cable
   c) Slot 3 - free
   d) Slot 4 - Video Monitor
   e) Slot 5 - Printer Cable

7. Connect all power lines to the grounded AC power strip or other grounded outlets. A minimum of five outlets are needed for the system if a power strip is not used.

8. Install paper in printer as directed in printer user's manual (pp. 3-13).

9. At this point all components of the system should be connected and can be turned on.

Note: The following step has been performed for you. Do not repeat unless instructed to do so.

10. To install the S&M software on the hard disk, do the following:

    a) Insert S&M disk #1 in drive A
    b) Type A:UPLOAD, press ENTER

    The screen will show names of the programs being copied from the floppy disk to the hard disk. When the UPLOAD is complete, a message about the number of files that were copied will appear on the screen.

    c) Remove disk #1 from drive A
    d) Insert S&M disk #2 in drive A
    e) Type A:UPLOAD, press ENTER
    f) Remove disk #2 from drive A
    g) Store disks #1 and #2 in a safe place
    h) Type GO, press ENTER
    i) Type INI
    j) Press [Ctrl] - [Alt] - [Del] keys simultaneously

    The screen will flash some messages very quickly before bringing up the S&M logo and the Main Pulmonary Menu screen.

4. COMPUTER SOFTWARE

4.1 General Information--Before Beginning Procedure

1. All boards should be properly installed and cables connected before turning on power to any component.

2. Familiarization with keyboard will help locate keys used often in the operation of the program.

   a) Space bar - this key is used to begin and end on-line tests as requested throughout the program.
   b) ESC - ESCAPE is used to exit from any program and to return to the MENU. The Escape key should not be used to end spirometry data collection (flow-volume loop) or to exit from the middle of a screen entry (i.e. participant information) as ESC will interrupt the program and these entries will not be stored.
   c) ENTER is used to end data entry from the keyboard. A good rule to follow is to press ENTER whenever the cursor is blinking and the information in the field is completely entered.
   d) Y/N - this option would require a Yes or No answer. The letter "Y" or "N" is all that is required.
   e) Function Keys - Function keys are located across the top of the keyboard and are labelled F1 through F12. The specific use of these keys will be described later in this manual.
   f) PrtSc - The Print Screen key will print the displayed screen to the printer.

3. To format disks for data storage, see page 51.

4.2 Pulmonary Program Menu Description

When the computer is started, the main Pulmonary menu will be displayed (See Figure 1). The programs are started by typing in the 3-letter program name or by pressing a function key. The function key for each of the programs is:

F1 - INF	F2 - FVL
F3 - MRP	F4 - DAT
F5 - CAL	F6 - ADJ
F7 - DIS	F8 - LIN
F9 - LEA	

A description of each program follows.

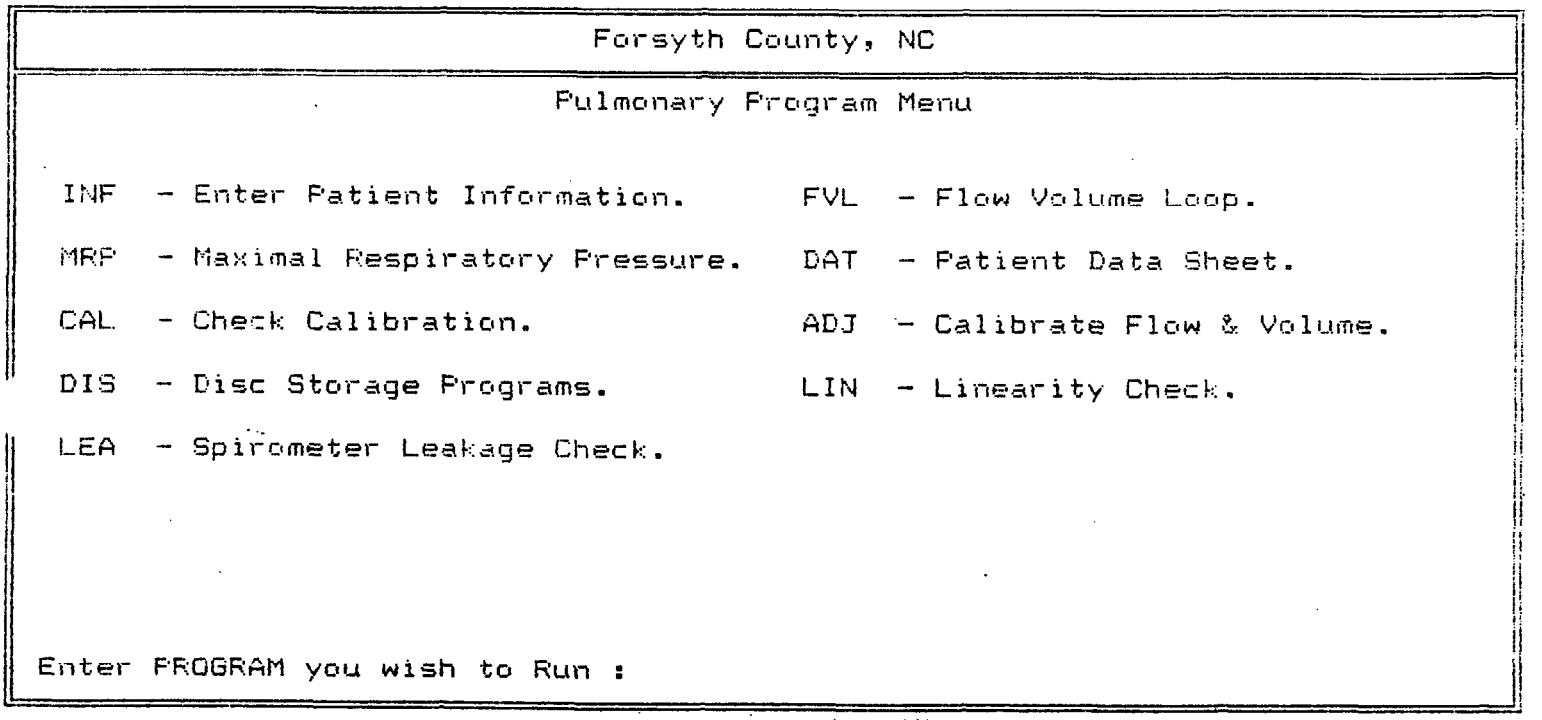


Figure 1. Pulmonary Program Menu

4.2.1 INF - Participant Information

This program is for entering participant anthropometrics which are used to calculate predicted values. For Visit 2, the INF program has been modified to record reasons for test postponement. It is essential that this program be run before performing any on-line tests on a participant.

4.2.2 FVL - Flow Volume Loop

This program runs the on-line participant spirometry testing. Flow-volume loops are displayed on the video screen in real time for quality control. (Volume-time spirograms are generated in real time on the Collins spirometer.)

4.2.3 MRP - Maximal Respiratory Pressure

This program measures the Maximal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP), although only the MIP will be tested during Visit 2. Real-time pressure/time curves are displayed on the video screen along with percent of best effort to assist quality control.

4.2.4 DAT - Participant Data Sheet

Selection of this program at the end of testing generates a summary report and interpretation from the printer and automatically stores the subject's record to both hard disk and to back-up floppy.

4.2.5 CAL - Calibration Check

This program will verify the calibration of the system and decide if an adjustment [ADJ] needs to be run.

4.2.6 ADJ - Calibration Adjustment

This program will adjust electronic volume and flow signals to the mechanical displacement from the 3-liter calibration syringe. An actual calibration factor is stored on the program disk and is updated each time ADJ is run. This program must be run each day before participant testing.

4.2.7 DIS - Disk Storage

This program will allow the operator to conduct the weekly data storage procedures, including display and printing of participant directories, and transfer of data from hard disk to floppy (mailer) disk.

4.2.8 LIN - Linearity Check

This program checks to be certain that the injection of one liter of air causes the same volume change in the spirometer, both at low and at high volumes. When operated at high volumes, this program also checks the spirometer water level. This check is made daily before participant testing. A calibrating syringe and a Rudolph 1-way valve are required.

4.2.9 LEA - Spirometer Leakage Check

This program prompts the technician through the steps necessary to find air leaks in the system. This check is made daily before participant testing. A weight is required.

5. PROTOCOL SUMMARY

Participants in the ARIC study are to perform pulmonary function tests as part of the routine cohort clinical examination. The following summary gives the operator an overview of the pulmonary testing and data management procedures. Each area will be explained in subsequent chapters.

5.1 Daily Procedures

5.1.1 Instrument Preparation and Calibration

Power-up the computer, check water level and water temperature in the spirometer, attach hose to the spirometer, check pen on the kymograph, load chart paper on the kymograph for the tracings, insert the field center archive diskette for the week in drive A: and run the calibration, leak and linearity checks before the first participant arrives for testing. On the first day of participant testing for the week (eg. Monday), run the MRP calibration after the spirometer calibration procedures. Log the results of the calibration, leak and linearity checks on the Daily Spirometer Log (see page 15) which is to be initialled by the responsible technician.

5.1.2 Participant Identification

For each participant, enter the following information into the computer:

1. ID number
2. Name
3. Age
4. Height (cm)
5. Sex
6. Ethnic group
7. Temperature

For each participant, determine if either of the following reasons exist for test postponement:

1. History of Aneurysm or BP $\geq$ 200/120
2. History of MI, other surgery in 6 weeks

If neither reason for test postponement exists, continue test, determining if either of the following is present:

1. Flu, Bronchitis, Pneumonia in 3 weeks
2. Cigarette, Pipe, Cigar in last hour

5.1.3 Participant Spirometry Testing

Perform pulmonary function tests on each participant. Prior to testing, explain the purpose of the test, position the subject, change the mouthpiece and place chart paper on the kymograph for the paper tracing.

Following the experience of Ferris et. al. (19), the ARIC protocol requires five trials for each subject.

Coach the participant through both maximal inspiration and smooth, continuous forced expiration. Place an identifying number near the kymograph tracing of each trial.

Testing will be stopped after five trials. At least two reproducible maneuvers out of three acceptable maneuvers should have been performed. Attach labels containing ID number, name and date to the tracing. Also record time, temperature and quality code on the tracing.

The technician enters an overall quality code for the acceptable tracings at the completion of testing.

5.1.4. Participant Maximal Inspiratory Pressure Testing

Perform the MIP test on each participant. Prior to testing, explain that "This test will measure the strength of your chest muscles". Seat the participant facing the computer screen, change the mouthpiece and demonstrate the MIP procedure.

Change the mouthpiece, coach the participant to blow all his/her air out (to residual volume) insert the mouthpiece and draw in air as forcefully as possible from the MIP device. Coach the participant during the inspiratory effort.

Testing can be stopped after a minimum of three trials which last at least two seconds. At two reproducible (within 10%) maneuvers should have been performed. The participant should be allowed a maximum five trials to produce the two reproducible tests.

5.1.5 Data Management

Print the pulmonary function report. At a later date, this report will be reviewed by the ARIC clinic physician, and then filed in the participant's file.

The test results are automatically saved to two files, one on the hard disk and the back-up on the archive floppy disk.

Enter ID number, name, date and time from the printed pulmonary function report onto the inventory file disk of each participant tested. This inventory file disk informs the ARIC Coordinating Center that a pulmonary function study has been performed on this participant.

At the end of the testing day, store the floppy disk, turn off the computer and detach and clean the spirometer hose.

5.2 Weekly Procedures

1. Print a listing of the contents of the hard disk and the archive floppy disk. Verify that these lists contain the same participants.

2. Copy (download) the test results for the week from the hard disk to a second (mailer) floppy disk which will be mailed to the Pulmonary Reading Center. The downloaded copy will be automatically verified and then the hard disk will be erased when this procedure is successfully completed.

Note: If more than 30 participants are tested in a week, the download should be done after the 30th participant. Failure to do this may result in data being lost when the floppy disk is full.

3. Print a listing of the contents of the mailer disk and verify that this list contains the same participants as the archive disk.

4. The computer will select the spirograms from a 10% random sample of the participants tested. The technician will measure the tracings of the three best trials. Record the FEV_1 and FVC measurements (raw and corrected to body conditions (BTPS)) on the tracing. (See Section 12.1). Make a photocopy of the tracing for the participant's file.

5. Mail the following items to the Pulmonary Reading Center on Friday for that week's testing:

   a) The mailer floppy disk.
   b) A listing of the contents of the mailer disk.
   c) The daily spirometer log for the week (a copy should be kept at the field center).
   d) The listing of the 10% random sample of the participants for the week.
   e) The actual tracings from a random 10% sample of the participants. The three best curves from these tracings must be measured.

6. Format and label two floppy disks for the next week. (The format procedure is described on page 51.) Each week two floppy disks will be used for storing pulmonary function test results. One will be stored at the field center and the other will be mailed to the Pulmonary Reading Center.

7. Empty and clean the spirometer bell. Clean the internal spirometer hose.

5.3 Manual Back-up Procedures for Recording of Raw Pulmonary Function Data

In the event that the computer or the computer programs do not function properly, pulmonary function testing will be done manually. The steps to be followed are:

1. Label the chart paper with the pulmonary function labels (containing subject ID number, name, and date).

2. Also record on the chart paper the participant's age, height, sex, ethnic group, and spirometer temperature.

3. Explain the purpose of the test and position the participant. Mount the chart paper on the spirometer drum and start the rotation of the drum at the fast speed.

4. Coach the participant through both maximal inspiration and smooth, continuous forced expiration. Place an identifying number near the tracing of each trial.

5. Examine the trials as they are performed. Testing should continue for five trials, attempting to record at least two out of three acceptable trials with FVC values that are within 5% of each other.

6. Measure the tracings of the three best trials. Record the FEV_1 and FVC measurements (raw and corrected to body conditions (BTPS))[1] on the tracing. (See Section 12.1.)

7. Add a quality code to the tracing.

8. Explain the MIP procedure, position the participant and demonstrate the test as usual. Conduct a minimum of three MIP trials (to a maximum of five trials), recording on the spirometer chart paper the greatest inspiratory pressure observed on the aneroid gauge for each trial.

9. Photocopy the tracings and mail the originals to the Pulmonary Reading Center where the curves will be digitized and added to the database. Reports of test results will be generated at the Pulmonary Reading Center and sent to the field center for review by the field center physician and for inclusion in the participant's file.

6. INSTRUMENT PREPARATION AND CALIBRATION

Each morning prior to participant testing, your spirometer system must be checked and calibrated. The LEA (Spirometer Leakage Check), LIN (Linearity Check) and ADJ (Calibration) programs will assist you. The operator must keep a log of these procedures. A 3.0 liter calibration syringe and one-way Rudolph valve/stopcock are used for the calibration and linearity checks.

6.1 Power-up the Computer

1. Each morning, enter Date/Technician Code on Daily Spirometer Log (Example on page 15).

2. Turn on the master switch on the power strip.

3. When all devices are on, the monitor should show the Pulmonary Program Menu (Figure 1), the power lights on the monitor, the printer, and the spirometer should be on, and the printer on-line light should be on.

4. Center the speed control on the Collins Spirometer.

5. Depress the white dot on the MRP on/off switch.

6.2 Water Level/Temperature

The spirometer water level should be visible through the water level gauge window.

Note: If the level is not visible, water must be added. Also, if the computer detects more than a 10% difference in linearity between the seventh and eighth liters, the operator will be prompted to add water.

Before adding water, disconnect the power cord. Raise the bell several inches and pour water from the pitcher against the side of the bell to prevent spillage. Ordinary tap water is usually quite satisfactory but, if the water in your area is "hard", distilled water is preferable.

Enter "Water Level" check on Daily Spirometer Log. Enter "*" if additional water is required.

Enter the spirometer temperature on Daily Spirometer Log.

6.3 Spirometer Hose

A dry, clean spirometer hose should be attached to the spirometer each morning. Attach the hose firmly to avoid leaks.

DAILY SPIROMETER LOG

Instructions: Complete this form every day. Keep this form in your spirometry notebook and send a good photocopy to the Pulmonary Reading Center weekly.

Daily Checks

Date/Technician Code							
Water Level/Temperature							
Pen Line (width/intensity) (Check if acceptable; star if pen replaced)							
Baseline (Check if acceptable; star if correction needed)							
Time Check (Seconds per 2 rotations) Accept 29.7 - 30.3 seconds							
Leak Check (ml drop per 2 rotations) Accept leak up to 10 cc.							
Linearity Check Accept linearity up to 0.100 Record slope: Record linearity:							
Volume Check After connecting open 3 liter syringe, Record volume From screen: From chart paper: Add 3 liters and record new volume From screen: From chart paper: Accept New Volume of 2.95 - 3.05 L. Record baseline volume From screen: From chart paper:							
Disconnect and clean hose							

Weekly Checks	Dates	
	Current	Previous
MRP Calibration Error: Positive_____ Negative_____		
Empty and clean spirometer		

Volume Number

Field Center
Archive Disk_____

Pulmonary Reading Ctr
Mailer Disk_____

Version 8 (12/89)

6.4 Pen Check

The pen line should be easily visible (not faint) and should be thin.

Note: If it is not, change the pen. Because of the variable quality of felt-tip pens, several extras should always be kept on hand. If the pens are changed fairly often, the reserve pens will remain moist and will make clear lines. The cap should always be replaced on the pen at the end of each testing day.

Enter "Pen Line" check on Daily Log Sheet. Enter "*" if pen required replacement.

6.5 Chart Paper and Baseline Checks

To load the chart paper, remove kymograph drum and carefully align the chart paper around bottom lip of drum. Remove and save adhesive backing strip. Place right edge of chart paper over the left, and smooth adhesive into place. The baseline and top (8 liter) lines should match where the ends of the chart paper overlap. Replace the kymograph drum. The pen should rest on the baseline when the spirometer is at rest.

Note: If the pen does not rest on the baseline, loosen the kymograph drum support set screw (on shaft of drum support) with an Allen wrench. Raise or lower drum support by tightening or loosening drum adjusting screw (on top of drum support) with the Allen wrench. When pen falls on baseline, retighten set screw.

Enter "Baseline" check on Daily Spirometer Log. Enter "*" if adjustment required.

6.6 Time and Leak Check

A time calibration should be done to insure that two rotations of the drum take 30 seconds ±1% (29.7-30.3 seconds).

1. Draw a vertical line on the chart paper by raising the bell up and down, drawing the line with the pen connected to the bell.

2. Type LEA (or press F9) to select the Spirometer Leakage Test. The computer will prompt:

Lift spirometer and cork, then place weight on bell - Press SPACE BAR

3. Raise the spirometer bell to approximately 4 liters and cork the mouthpiece with the #7 rubber stopper.

4. Place the weight on top of the spirometer bell to provide a constant pressure within the spirometer.

5. Press SPACE BAR. The computer will prompt (See Figure 2a):
Enter total time for leakage test (default = .5 min)

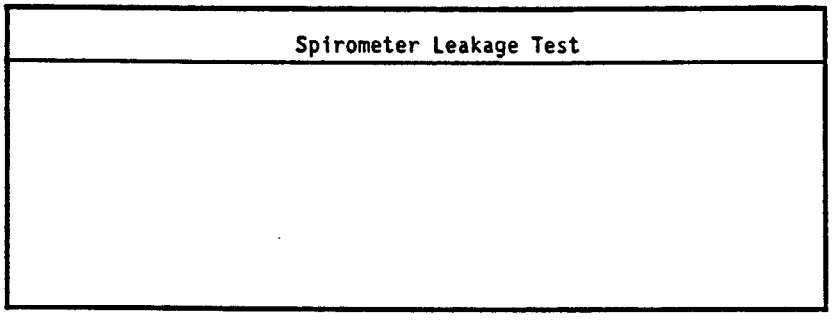


Figure 2a. Time and Leakage Check

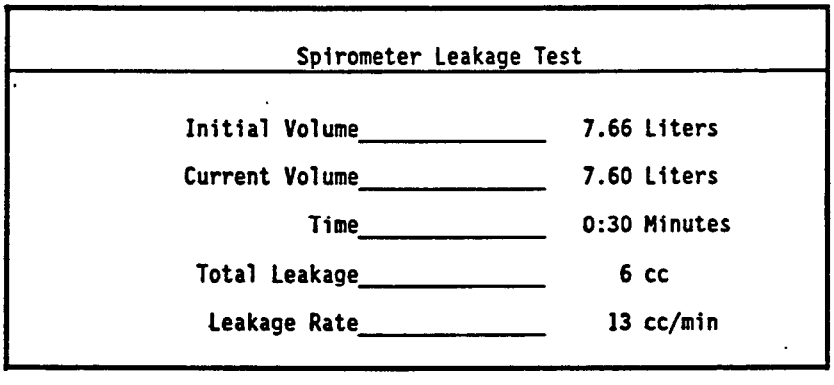


Figure 2b. End of Leakage Check

6. Start the kymograph at fast speed to record the bell position over two rotations (30 seconds).

7. Start the stopwatch when the pen crosses the vertical line.

8. Press ENTER.

9. Turn the stopwatch off as the pen crosses the line at the end of the second rotation.

10. The time for two rotations of the drum should be between 29.7 and 30.3 seconds. Enter in "Time Check", the time recorded from the stopwatch for two rotations on the Daily Spirometer Log.

11. The computer will show the display in Figure 2b.

12. If there are no leaks in the system, the kymograph tracing should remain horizontal and total leakage should be 10 cc. or less. A leak may be recognized on the kymograph tracing by the appearance of progressive thickening of the horizontal pen line (small leak) or a "barber pole" declining spiral (major leak). Enter in "Leak Check", the fall in volume (in ml.) recorded from the screen over two rotations on the Daily Spirometer Log.

Note: If time check falls outside acceptable range, check connection to power source and check that the chart paper is not slipping on the kymograph drum or that the kymograph drum is not slipping on its support. Repeat test twice. If still unacceptable, call the W.E. Collins Co. for repair. Notify the Pulmonary Function Reading Center and mark tracings that "Time axis incorrect."

Note: If any leak is detected, the operator will determine whether the leak is in the breathing tube, the internal tube or in the spirometer bell.

a) Disconnect the breathing tube from the spirometer.
b) Raise the bell halfway and insert a #7 solid stopper into the metal breathing tube connector at the front of the spirometer. Observe the reading on the kymograph drum where the recording pen touches the paper.
c) Place the weight on top of the spirometer bell; wait for five minutes (20 rotations); then observe the kymograph reading. If the reading does not go down in this period, then you know that the leak was in the breathing tube. If, however, the reading does go down, then the leak is in the internal tube or in the spirometer bell.
d) Reach underneath and inside the spirometer, and disconnect the internal tube from the topmost internal port. Raise the bell halfway and insert a #7 solid stopper into this topmost internal metal tube connector.
e) Again, place the weight on top of the spirometer bell, and run the kymograph at the fast speed. Wait for five minutes (20 rotations); then observe the kymograph reading. If the reading does not go down in this period, then you know that the leak was in the internal tube. If, however, the reading does go down, then the leak is in the spirometer bell.

f) To locate a leak in the spirometer bell, remove the bell, turn it upside down, and fill it with about an inch of water. Hold the bell upside down for a while and then roll it over onto the seam side, observing to see where water escapes.

g) When you have located the leak, you may make a temporary repair using a substance such as Pliobond, which can be purchased at most hardware stores.

h) Prepare and tie a label to the repaired bell which reads:

DATE OF REPAIR __/ __/ __
DO NOT USE BEFORE __/ __/ __

To compute the DO NOT USE BEFORE date, add two full calendar days to the DATE OF REPAIR. Remove label before putting repaired bell back into service.

i) Replace the hoses or the bell for 48 hours from the spare parts on hand to continue testing. See caution below.

j) Order new spare parts from the equipment list and use the temporarily repaired parts as spares until the new parts arrive.

Caution: Observe all manufacturer's warnings and precautions for whatever flexible plastic cement you choose to use. Make sure to let the adhesive substance dry for at least 48 hours after application, since breathing in the fumes could be harmful.

13. Press the SPACE BAR to go directly to the Linearity Check. (To return to the Pulmonary Program Menu, press ESC.)

6.7 Linearity Check

1. Having pressed the SPACE BAR after successfully completing the Time and Leak checks, the screen in Figure 3a should now appear on the display. If you are entering the Linearity Check program from the Pulmonary Program Menu, type LIN (or press F8).

2. The 3-liter calibration syringe, the Rudolph #2150 stopcock and tubing normally stored next to the spirometer will be used at this time. Flush the 3-liter syringe back and forth with room air several times, then flush the spirometer twice with room air and stop at zero volume. This ensures that the syringe and spirometer contain air at the same temperature.

3. Set the 3-liter syringe to the 1-liter position by:

   a) Opening the syringe past the 1-liter mark (Figure 4a).
   b) Using the Allen wrench to loosen the moveable (SILVER) locking collar and move it to the 1-liter mark (Figures 4b and 4c).

Note: The position of the BLACK COLLAR has been calibrated at the factory to allow the delivery of a 3-liter volume when the silver collar is locked into place against it. DO NOT ADJUST THE POSITION OF THE BLACK COLLAR.

4. Turn the arrow on the Rudolph valve counterclockwise until it stops. Attach the SHORT LENGTH OF TUBING to Rudolph VALVE PORT POINTED AT BY THE ARROW. Attach the OPPOSITE VALVE PORT to the breathing tube of the spirometer (Figure 4d).

5. Attach the 3-liter syringe to the SHORT LENGTH OF TUBING (Figure 4e).

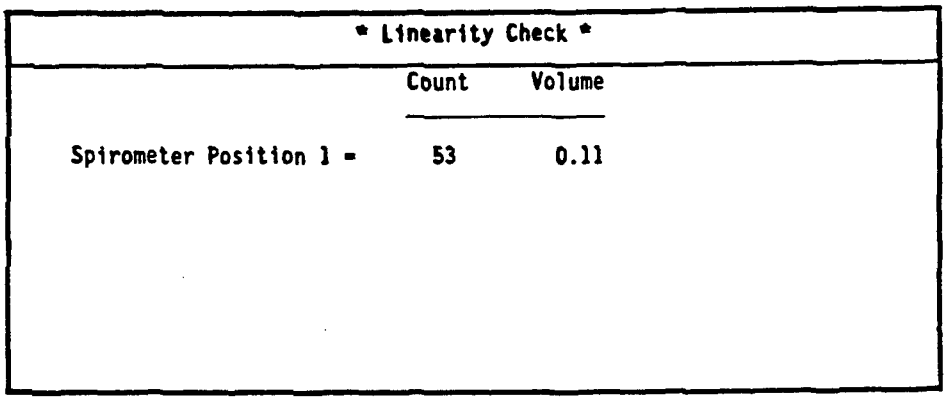


Figure 3a. Linearity Check

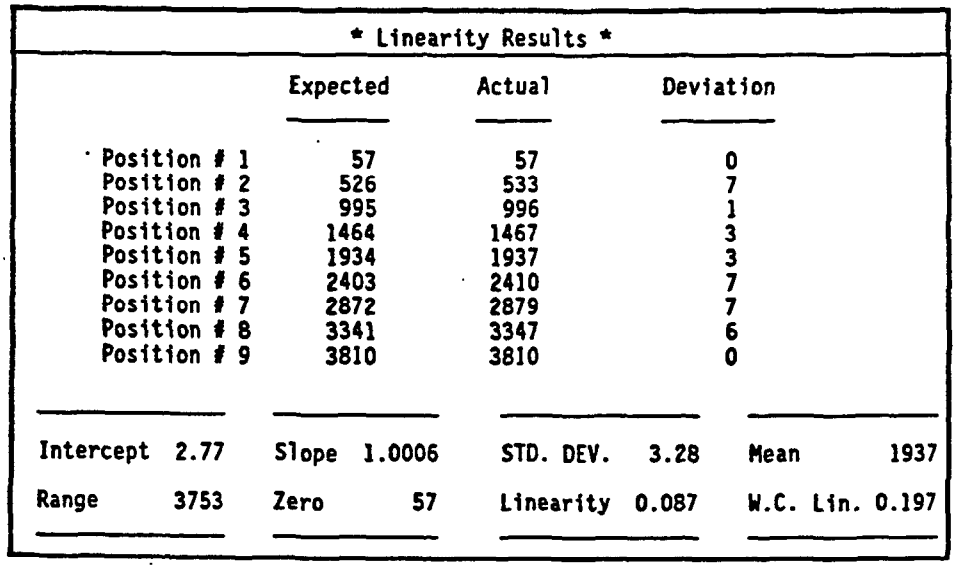


Figure 3b. Linearity Results

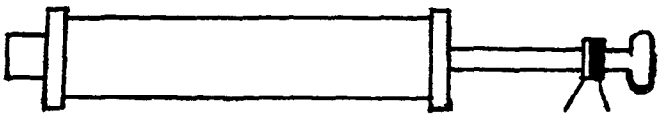


Figure 4a. Opening 3-liter syringe past the 1-liter mark.

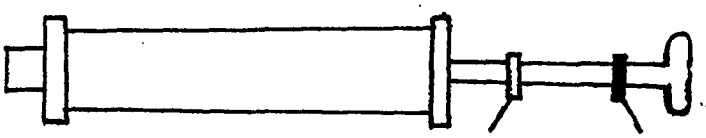


Figure 4b. Move silver collar to the 1-liter position and tighten.

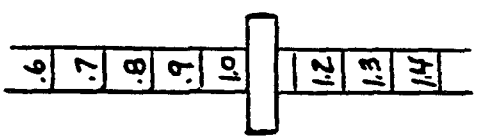


Figure 4c. Close-up of placing the collar at the 1-liter position.

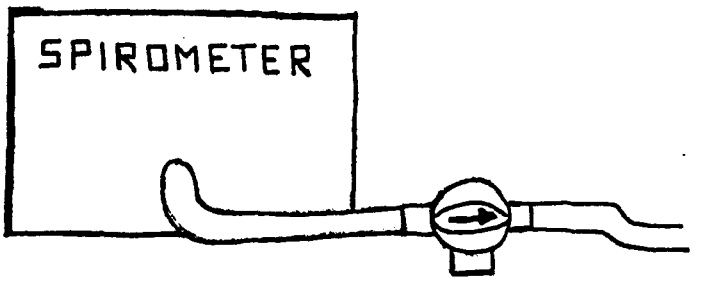


Figure 4d. Attach Rudolph valve to the short tubing and the spirometer breathing tube.

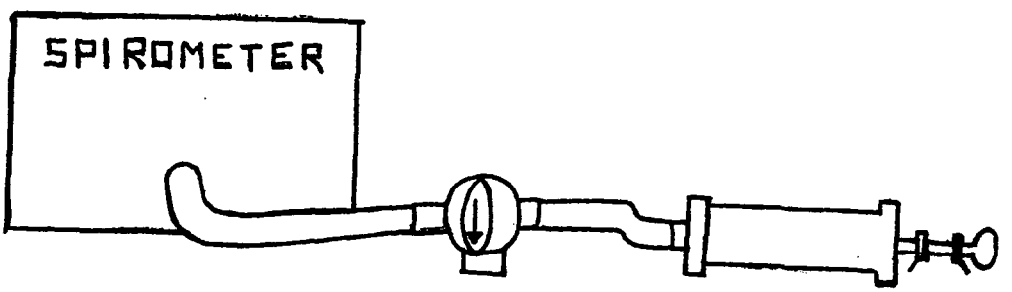


Figure 4e. Attach the 3-liter syringe to the short tubing.

6. Press SPACE BAR.

7. OPEN the Rudolph valve (turn clockwise), then OPEN the syringe fully (draw ONE LITER of air into the syringe).

8. CLOSE the valve (turn counterclockwise), then CLOSE the syringe (push this volume into the spirometer).

9. Press SPACE Bar.

10. Repeat steps 7 through 9 until eight (8) liters have been pushed into the spirometer. The screen shown in Figure 3b will appear.

Note: During steps 7 through 9, highlighted "count" and "volume" numbers are not yet entered, and indicate that the operator must press the SPACE BAR. If errors are made, pressing the minus (-) sign will return you to the previous step.

11. Enter "Slope" and "Linearity" from the screen into the "Linearity Check" of the Daily Spirometer Log.

Note: Acceptable linearity will be less than 0.100. If a linearity is greater than this, check spirometer bell or guide rods for damage. If a linearity problem persists, print a copy of the linearity screen and call the Pulmonary Function Reading Center.

12. Press SPACE BAR to go directly to the Flow and Volume Calibration Checks. (To return to the Pulmonary Program Menu, press ESC.)

6.8 Volume Calibration Check

1. Having pressed the SPACE BAR after successfully completing the Linearity check, the screen in Figure 5a should now appear on the display. If you are entering the Volume Calibration (Adjust) program from the Pulmonary Program Menu, type ADJ (or press F6) for the Flow and Volume Calibration Checks. This program will calibrate the spirometer to the 3-liter syringe and determine the calibration factor which is then stored on the program disk.

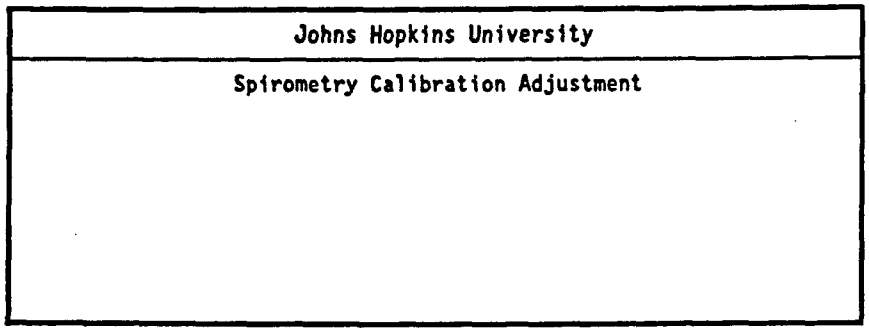
Note: ADJ must be run daily before any participants are tested, or any time the system is re-booted.

2. Return the 3-liter syringe to the 3-liter position by:

   a) Opening the syringe fully (Figure 3a).
   b) Using the Allen wrench to loosen the moveable (SILVER) locking collar and return it to the 3-liter mark (Figures 3b and 3c).

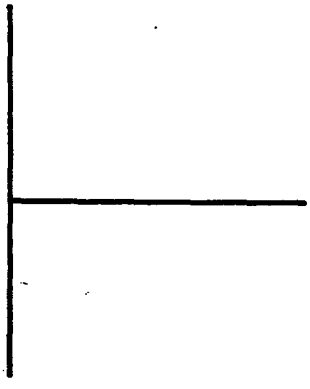
3. Lower the spirometer bell to approximately 3-liters by loosening the breathing tube at its attachment to the Rudolph valve and releasing air from the spirometer.

4. Figure 5a should be on the screen. Press SPACE BAR.



Raise bell to at least 3 liters and connect to an open 3-liter syringe.

Figure 5a. Volume Calibration Check - Screen 1



Press SPACE BAR - then pump syringe 3 times.

Figure 5b. Volume Calibration Check - Screen 2

5. Figure 5b will appear on the screen. Press SPACE BAR.

6. Pump the syringe in and out at least three (3) times. Take care not to "bang" the syringe at the end of travel to avoid flow artifact during calibration. Figure 6a will appear on screen. After completing the third cycle, press the SPACE BAR.

Note: One injection and withdrawal constitutes one cycle.

7. If the calibration was correctly done, Figure 6b will appear on the screen. Press SPACE BAR to continue.

8. Leave the syringe connected to the spirometer. The screen will show Figure 7a.

9. Advance the kymograph drum slightly by moving the SPEED control to FAST and then re-centering the SPEED control.

10. Enter the volume displayed on the screen and the volume from the kymograph chart paper in "Volume Check" of the Daily Spirometer Log.

11. Verify correct volume calibration by injecting full syringe volume. Note as to whether the volume increases by the syringe volume (i.e. 3.00 liters ±3% or 90 ml) as in Figure 7b.

Note: If the volume calibration is not acceptable, press the + [plus] key and repeat steps 6-11.

12. Advance the kymograph drum slightly by moving the SPEED control to FAST and then re-centering the SPEED control.

13. Enter the "Add 3 liters" volume displayed on the screen and the volume from the kymograph chart paper in "Volume Check" of the Daily Spirometer Log.

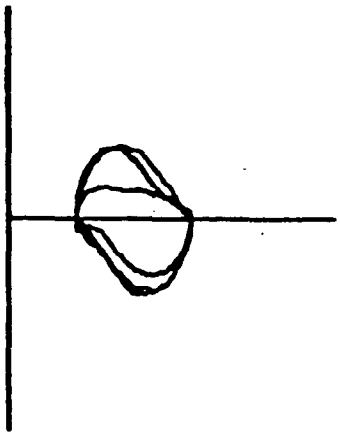
Note: The difference between the beginning volume and volume after adding 3 liters must be within 3% (2.91-3.09 liters) on <u>both</u> the screen and the chart paper. If the chart reading is off, recheck your measurements.

14. Disconnect spirometer hose from the Rudolph valve and allow the spirometer bell to fall to a resting position. Flow should read 0.00 ±50 ml/sec when spirometer is still.

15. Enter the "Baseline" volume displayed on the screen and the volume from the kymograph chart paper in "Volume Check" of the Daily Spirometer Log.

Note: Possible reasons for the volume calibration check to fail are:

a) Failure to completely fill and/or discharge the syringe into the spirometer.
b) Differences in the air temperature in the the spirometer and in the syringe. Reflush and repeat the check.
c) Air leak in the calibration syringe. Repair/replace the syringe.



Press SPACE BAR after third stroke.

Figure 6a. Volume Calibration Check - Screen 3

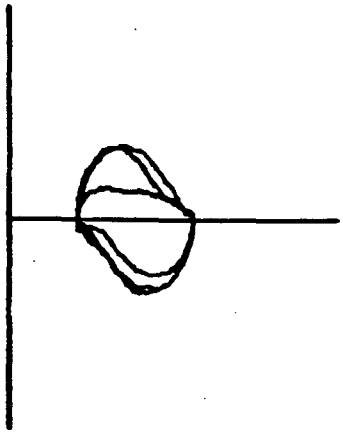


Figure 6b. Volume Calibration Check - Screen 4

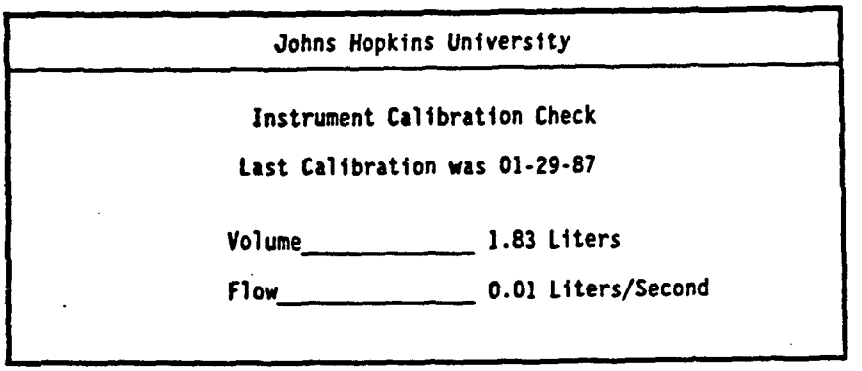


Figure 7a. Volume Calibration Check - Screen 5

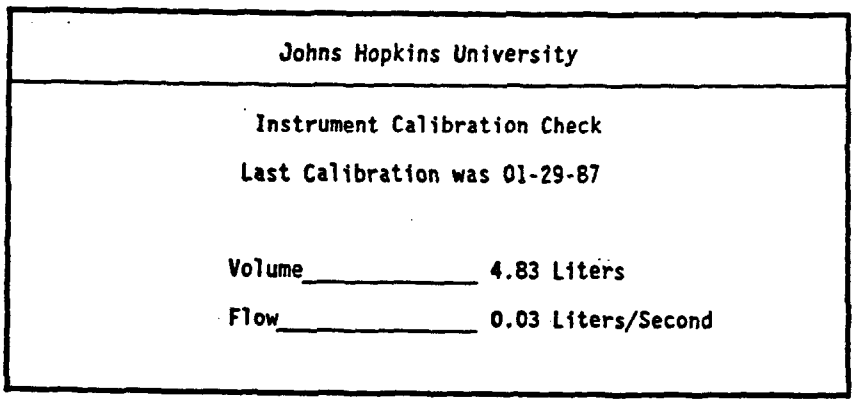


Figure 7b. Volume Calibration Check - Screen 6

Any abnormally large number (less than -20.00 liters/sec or greater than +20.00 liters/sec) may indicate a problem with the flow channel of the S&M Instrument Pulmo-Screen A/D interface. Contact the S&M Instrument Company for repair. Notify the Pulmonary Function Reading Center and mark the tracings "Flow calibration incorrect."

6.9 Maximal Respiratory Pressure Transducer Calibration Check

On the first day of participant testing for the week (eg. Monday), run the MRP calibration after the spirometer calibration procedures. Regular MRP calibration is required since the pressure transducer may drift due to changes in temperature and aging of the transducer.

1. Press F3 (Maximal Respiratory Pressure, MRP) from the Pulmonary Program Menu.

2. Press 3 (Calibrate Pressure Transducer) from the Maximal Respiratory Pressure Menu. The screen will show figure 8a.

3. Detach the MRP mouthpiece and tubing from the front of the MRP unit, replacing it with the 5 cc calibrating syringe and tubing.

4. Adjust the syringe until the aneroid pressure gauge reads "0", then press the spacebar.

5. Push in the syringe until the gauge reads 160 cm H_2O. Press the spacebar when the gauge reads <u>exactly</u> 160 cm H_2O.

6. Pull out on the syringe until the gauge reads -160 cm H_2O. When the gauge reads <u>exactly</u> -160 cm H_2O, press the spacebar.

7. The MRP calibration results screen (Calibrate Pressue Transducer, figure 8b) will demonstrate the results and the date of the <u>previously saved calibration</u> as well as the <u>new calibration results</u>.

8. Record the dates of the previous and current calibrations as well as the positive and negative errors on the Daily Spirometer Log.

The positve (MEP) and negative (MIP) pressures should both be within 5% of the previously saved results. If the new calibration results are within 5% of the previously saved results, the computer considers the system to be within calibration and the <u>previous</u> calibration values are preserved. Press the spacebar to return to the MRP menu.

If either the positive or negative MRP calibrations are out of range (>5% error), you should press "Y" (Yes) when asked whether to store the new calibration constants. You should then repeat the MRP calibration (steps 2-7 above) to confirm that the calibration remains within 5%. Press "N" if you wish to discard the new MRP calibration results for some reason.

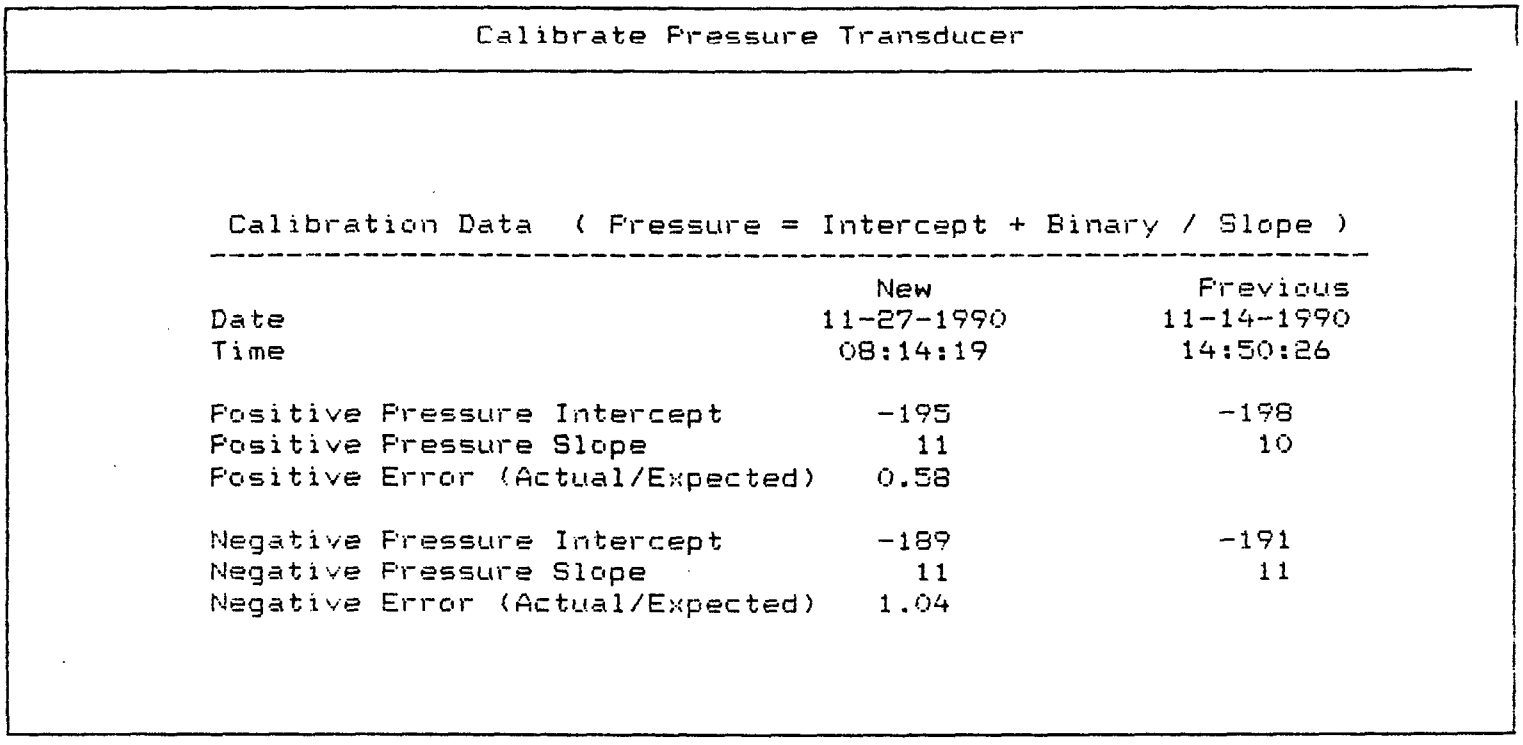


Figure 8a. Calibrate Pressure Transducer

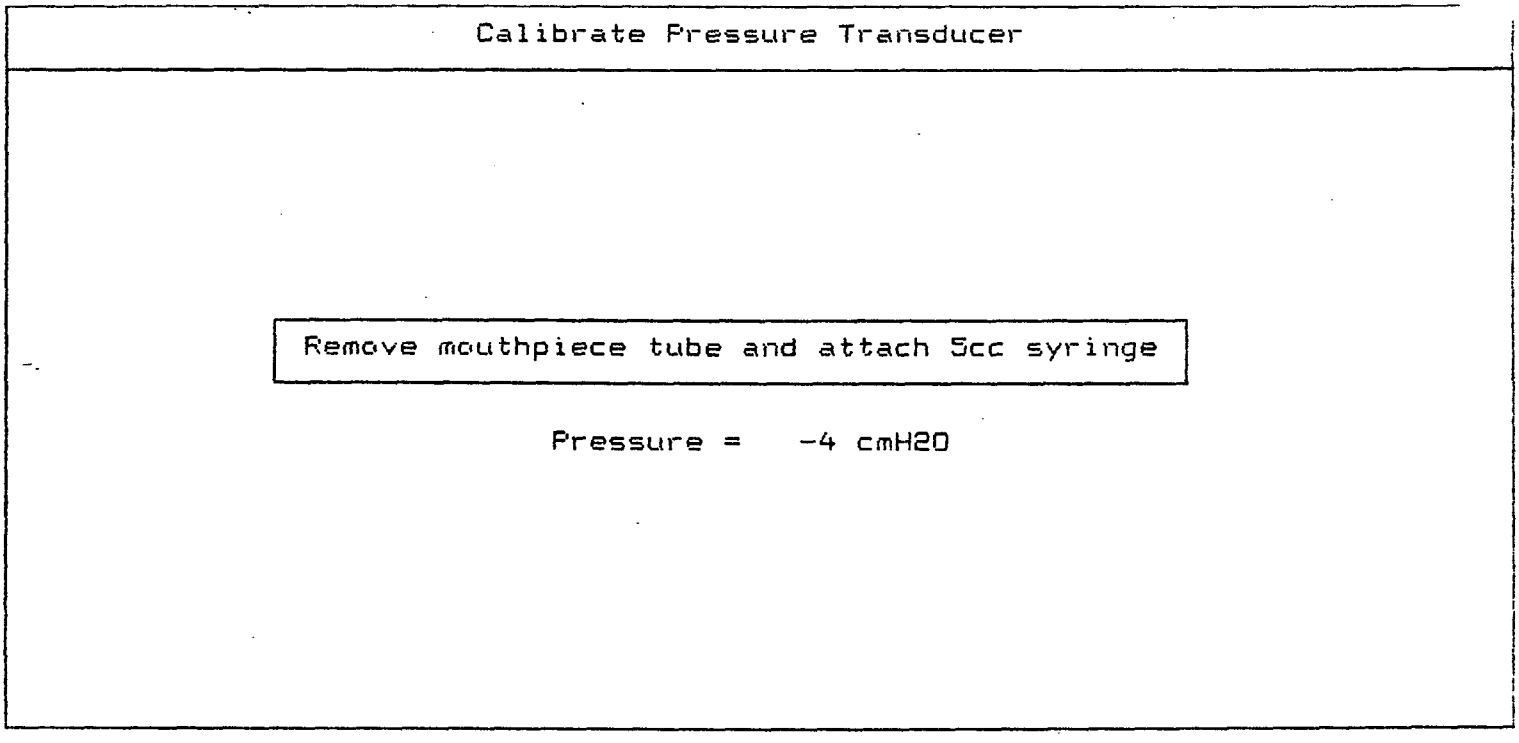


Figure 8b. Calibrate Pressure Transducer

7. PARTICIPANT INFORMATION

7.1 Entering Information on Computer

Identifying information for each ARIC subject will be entered from the computer keyboard in response to prompts from the participant information program [INF]. INF is accessed from the MENU by typing INF or pressing F1. Enter the information requested on each line, ending each entry with ENTER key. Every item MUST BE ENTERED in order to calculate predicted values accurately. (See Figure 9.)

1. DATE - will be read from the computer's internal clock.

2. TIME - will be read from the computer's internal clock.

3. NAME - a minimum of three letters must be typed in, last and then first name, with a maximum of 23 characters. USE THE SPACE BAR TO SEPARATE LAST NAME FROM FIRST NAME (Do NOT use a comma). The technician should verify with the participant that the name listed on the participant's folder is correct.

4. ID NUMBER - participant identification number. The contact year should be entered after the ID number by typing a dash then the two digit contact year number (-04, for example).

5. TECHNICIAN'S CODE - the last entered technician code will appear. The technician code consists of a unique three digit numeric code assigned to each technician at the four field centers by the Coordinating Center. To change, type in the new code. Delete an entry by pressing ENTER and typing in a new entry. DO NOT USE DELETE OR BACKSPACE KEYS TO CHANGE AN ENTRY.

6. AGE - enter age in years.

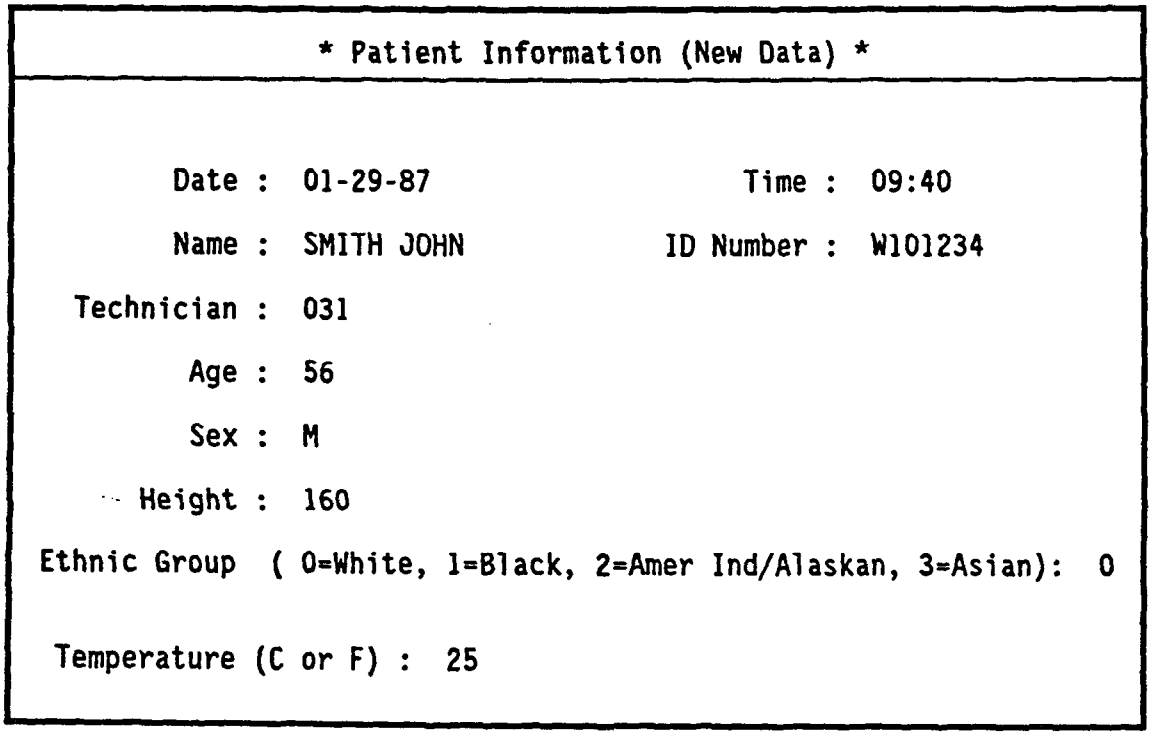
7. SEX - enter "M" for male and "F" for female.

8. HEIGHT - enter participant's measured height in centimeters.

9. ETHNIC GROUP - enter the number for the appropriate group. Non-white predicted values are reduced by 12%.

10. TEMPERATURE - 23 Centigrade or the last entered value will appear. Change by typing in the new spirometer temperature. DO NOT PRESS DELETE OR BACKSPACE.

Before leaving INF, the technician should verify that the name and the I.D. number entered match those on the participant's folder.



Enter DATA. Use up-arrow (^) to edit.

Figure 9. INF Screen

7.2 Editing Information

If a mistake was made when entering the above information, use the arrows on the right side of the keyboard (cursor pad) to move the cursor to the position which needs correcting. To correct the error, begin typing the information. The balance of the line will disappear after the first character is typed. Press ENTER to complete the typed line. Press the space bar to return to the pulmonary MENU.

To change participant information values after patient testing has been completed, send a copy of the report to the Pulmonary Function Reading Center indicating the changes that need to be made. A new report will be generated at the Pulmonary Function Reading Center and the predicted values will be changed on the computer file.

7.3 Postponement of the Test

Following the "Patient Information" Screen, the Visit 2 Pulmonary Technician will be requested to "Select Reason for Test Postponement" (figures 10a through 10d).

7.3.1 Untreated Aneurysm or Hypertension

Since spirometry is routinely conducted in the medical intensive care unit, it is unlikely that a participant, well enough to walk into the ARIC facility, will be unable to perform this test. Nevertheless, two conditions, aneurysm and poorly controlled hypertension (systolic $\geq$ 200, diastolic $\geq$ 120) make it unwise to perform spirometry. The participant's blood pressure will be found on the Itinerary sheet on the front of the chart. The presence of either of these untreated conditions is indicated by using the Arrow Keys to select

HISTORY OF ANEURYSM OR BP $\geq$ 200/120 (figure 10a).

Then PRESS ENTER.

Following selection of this alternative, the program will return to the "Pulmonary Program Menu". Type STO to store this information into the computer. No Data sheet will be printed for this participant.

7.3.2 Recent Myocardial Infarction or Chest/Abdominal/Other Surgery

Individuals who have a history of a Myocardial Infarction (MI, Heart Attack) or Surgery of the Chest or Abdomen within 6 weeks are advised to return for spirometry after 6 weeks to allow completion of the healing process. The presence of either of these conditions is indicated by using the Arrow Keys to select

HISTORY OF MI, CHEST/ABDOM SURGERY IN 6 WKS (figure 10a)

Then PRESS ENTER.

Following selection of the appropriate alternative, the program will bring up a screen asking whether the participant has had

FLU, BRONCHITIS OR PNEUMONIA IN 3 WKS (2=Y/1=N) Enter #:

Enter a 2 for an affirmative response, or a 1 for a negative response (Figure 10b). Following selection of the appropriate alternative, the program will return to the "Pulmonary Program Menu". Print a Patient Data Sheet (Enter DAT, or Press F4). If reasons for postponement exist, please terminate and reschedule the testing session. Indicate the reason for test postponement in the comments section of the Data Sheet. When retesting a participant, enter R instead of the field center letter before the ID number.

7.3.3 No Reason for Postponement, Continue Test

The absence of the conditions specified above is indicated by using the Arrow Keys to select

CONTINUE TEST

Following selection of this alternative, the program will bring up a screen asking whether the participant has had

FLU, BRONCHITIS OR PNEUMONIA IN 3 WKS (2=Y/1=N) Enter #:
CIGARETTE, PIPE, CIGAR IN LAST HR (2=Y/1=N) Enter #:

Enter a 2 for an affirmative response, or a 1 for a negative response (figure 10d). Following selection of this alternative, the program will return to the "Pulmonary Program Menu". Continue with Spirometry Testing (Enter FVL, or Press F2).

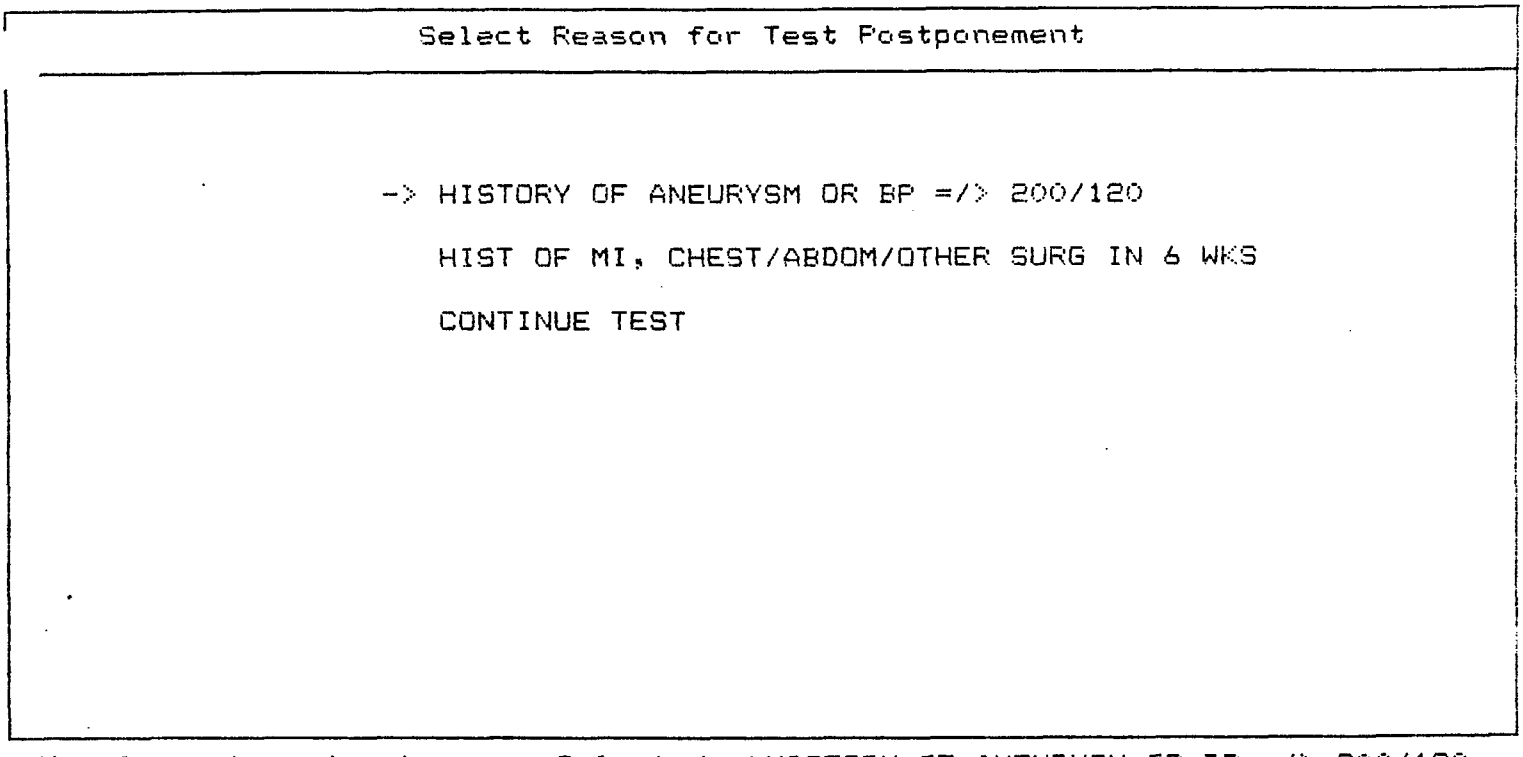


Figure 10a. Select reason for test postponement

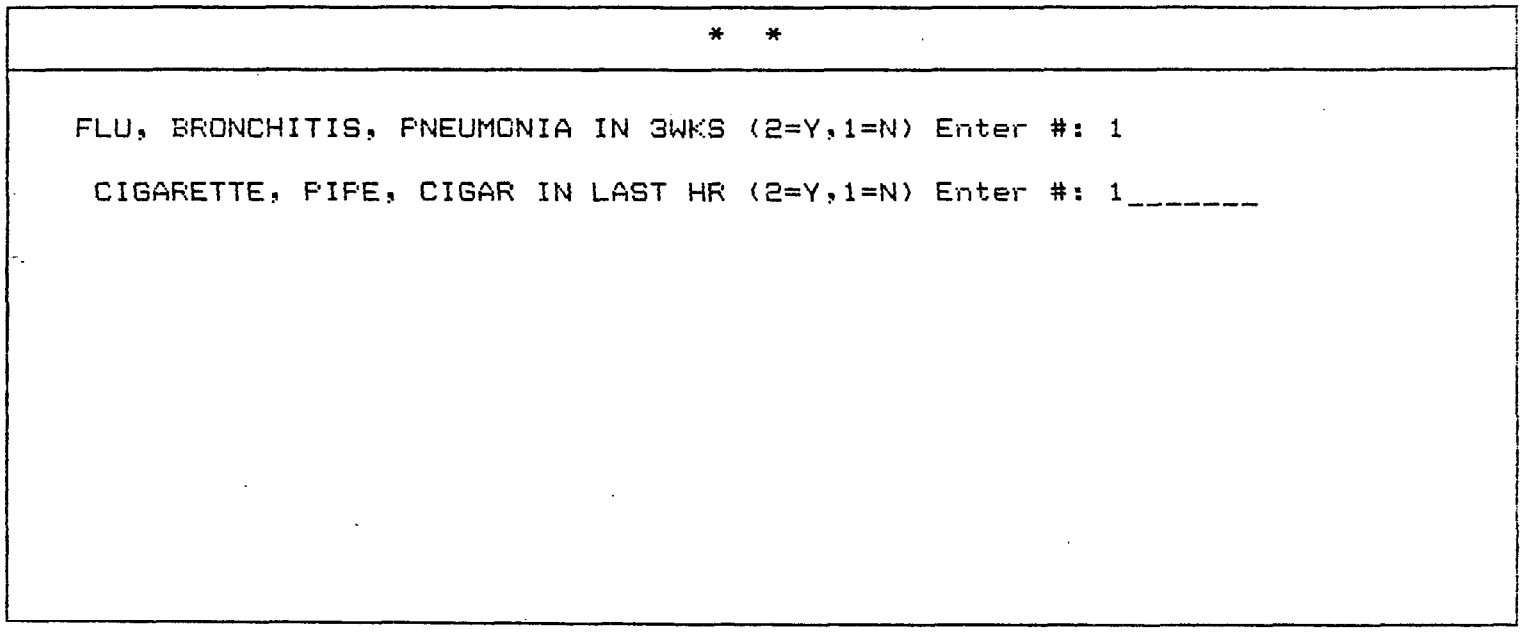


Figure 10b. Flu, bronchitis, pneumonia/smoking

8. PARTICIPANT SPIROMETRY TESTING

The technician is the critical part of the pulmonary function testing system, since he/she must guide the subject through the forced expiration, a maneuver which is highly dependent on subject effort. The technician must coach the partcipant both to maximal inspiration as well as to maximal expiration. The technician also must judge the acceptability and quality of the subject's effort. To make the spirometric testing results as accurate and consistent as possible, the testing should be done in a standardized fashion by each technician and every subject.

8.1 Explanation of the Procedure

Prior to testing, instruct the participant on proper performance of forced expiration maneuver. Explain to the participant that he is about to do a test to determine how much air he can inhale and how hard and fast he can exhale it. (Example: "Like blowing out birthday candles.")

1. Explain to the participant that he will:

   a) attach the noseclip,
   b) take in as deep a breath as possible, and when full, will
   c) place the mouthpiece between his teeth,
   d) close his lips tightly around the mouthpiece, and
   e) exhale his air through the mouthpiece into the spirometer, pushing the air out as hard, fast, smoothly, and completely as possible, until told by the technician to stop exhaling.

2. Explain to the participant that he is not to take in any additional breaths until the forced expiratory maneuver is finished.

3. Be sure to tell the subject that you (the technician) will be forcefully coaching him through the maneuver, so that he is not taken by surprise.

8.2 Positioning the Subject

1. Testing should be conducted in the standing position. A chair should be positioned behind the subject, for use between maneuvers. Smelling salts should also be kept on hand for the rare event of fainting or dizziness. Allow sufficient time between trials to avoid exhausting the participant.

2. The spirometer hose should be adjusted to the participant's height so that he/she stands erect with chin slightly elevated. Tight clothing, such as a tie or belt, which might restrict the subject's maximal

breathing efforts, should be loosened. Dentures, if they are loose, should be removed, since they will prevent a tight seal from being formed around the mouthpiece. If they are not loose, they should be left in place.

3. In order to prevent nasal leakage at full inspiration or nasal inhalation at the end of the forced expiration, a noseclip will be used during the maneuver. While wearing noseclips, the subject should avoid swallowing which blocks the ears and is very uncomfortable.

Note: Disposable noseclips have been more generally accepted by participants. However, disposable noseclips occasionally slip off certain individuals who therefore require reusable clips.

8.3 Demonstration of Procedure

1. With an extra mouthpiece, demonstrate that the teeth and lips should go around the mouthpiece. The lips should not be pursed like a trumpet player's, and the tongue should not block the mouthpiece during the expiration.

2. Demonstration by the technician of the completeness of the inspiration, and of the forcefulness, completeness, and smoothness of the expiration is required for each participant. Such a demonstration may prevent time and effort from being wasted on unacceptable forced expiratory efforts which are caused by the subject's failure to understand a verbal explanation of the procedure.

Note: A fainthearted demonstration often results in a submaximal participant performance.

3. If after an initial demonstration, the participant fails to produce an acceptable spirogram, the technician should demonstrate both the error and the correct performance.

Note: Depending upon the participant's level of understanding, a repeat demonstration may be required after each spirogram.

8.4 Operation of the Flow-Volume Loop Program

1. Change the mouthpiece.

2. Load chart paper on the kymograph for the paper tracing.

3. Type FVL or press the F2 key to load the program. The screen will display the axes seen in Figure 11.

4. Have the participant "breathe normally" through his mouth while wearing noseclips.

5. Tell participant to "Take as deep a breath in as you possibly can." Ask the participant to raise his hand when he can't take in more air. Press SPACE BAR as participant begins this inspiration. SPACE BAR MUST BE PRESSED BEFORE PARTICIPANT INHALES FULLY TO TOTAL LUNG CAPACITY (TLC), at least one second before the participant begins to expire to allow the kymograph to get up to speed. Coach the participant to "Breathe deeper...deeper...deeper."

6. Tell participant to put the mouthpiece in his mouth.

7. At TLC tell the participant to "Blow out as hard, as fast, and as long as possible, until no more air can be expired."

Note: Participant must be encouraged to blow as long as possible without re-breathing. The subject should be able to exhale for a minimum of six seconds and should continue exhaling until the the end of the test. The technician should not tell the subject to "Hold it", since this may lead to the subject's tongue being inserted in the mouthpiece or in glottis closure. Instead, the technician should urge the subject continually to "push" or "squeeze" his air out. The time of the exhalation will be displayed on the screen (Figure 11).

8. The end of the test is best seen on the spirogram. The end of the test is reached when the participant's spirogram on the Collins spirometer reaches a plateau (no volume increase) after at least six seconds. PRESS SPACE BAR AT END OF TEST. Computer displays Figure 12.

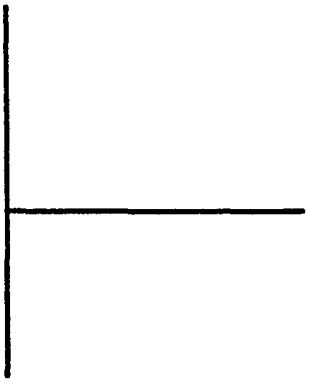
9. Have the participant perform a total of five forced expirations. To do another test on the same participant, press the SPACE BAR (e.g. Figure 12). To return to the pulmonary MENU, press the ESC key.

10. It is the technician's responsibility to determine that the two best FEV_1's and two best FVC's are reproducible (within 5%). The computer can assist this decision in the following ways:

    a) The computer screen (Figure 12) will indicate when at least two FVC's are within 5%. (The computer only looks at FVC for reproducibility. The technician must examine the two best FVC and the two best FEV_1 for reproducibility.)
    b) After the 3rd, 4th and 5th trials, F9 should be pressed to display data and graphs for evaluation.

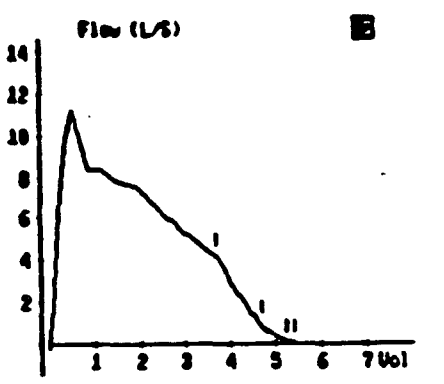
    F9 — Color graphics display - this key will overlay up to three loops in color on the screen. This is the best display for comparing reproducibility of initial (maximal) effort (Figure 13a).

    F1-F3 — F1, F2 and F3 may then be used to alternately remove and/or add selected trials. F1 presents the graphics overlay of best flow-volume loop F2 the second best and F3 the third best tests, as determined by the highest sum of FEV_1 + FVC (American Thoracic Society (ATS) criteria).



Press SPACE BAR to start FVL test

Figure 11. FVL - Screen 1



Name SMITH JOHN
Date 01-29-87 Study ARIC

Trial # 5		Actual
FVC	(l)	5.47
FEV-1	(l)	3.87
FEV-1/FVC	(%)	71
FEV-3	(l)	4.96
FEV-3/FVC	(%)	91
FEV-6	(l)	5.44
FEV-3/FEV-6	(%)	91
FEF25-75	(l/s)	4.83
PEFR	(l/s)	11.29
FEF25	(l/s)	7.92
FEF50	(l/s)	5.73
FEV75	(l/s)	2.13

2 of 5 spirograms are reproducible. Press ESC key to end.

Figure 12. FVL - Screen at end of test, indicating two IUC's are reproducible

F6 Use F6 (or V) to redraw flow-volume loop with volume-time axes and alternately use F6 (or F) to change the volume-time spirogram back to flow-volume loop display (Figure 13b).

11. WHEN PARTICIPANT TESTING IS COMPLETED, PRESS ESC. At this point, the technician is required to enter an overall quality code (Figure 13c).

8.5 Quality Assessment

Every Subject should perform five maneuvers to obtain three that are considered "acceptable" and two that are "reproducible". The criteria for acceptability and reproducibility are described below. The accuracy of spirometric measurements depends on the quality of the spirograms.

8.5.1 Acceptability

Acceptable spirograms are defined by the performance of a maximal inspiration which completely fills the lungs followed by a subsequent forceful, complete and smooth expiration, which reaches a plateau. To be "acceptable", two of the three best spirograms (highest sum of FEV_1 + FVC, see F9 above) must have none of the following errors.

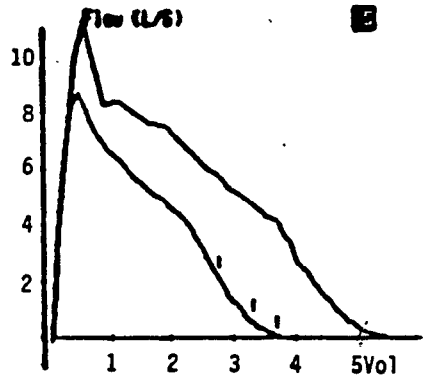
8.5.1.1 Acceptability Codes

These errors in test performance are identified and labelled with the following codes at the Pulmonary Function Reading Center from two of the three best spirograms. (These acceptability codes appear on hard-copy reports to the field centers and the Coordinating Center).

1 - Spirometer not calibrated correctly
2 - Computer started after start of expiration
3 - Breath-hold leak > 5% of FVC
4 - Submaximal effort (rounded peak on FVL loop)
5 - Cough/inhalation present
6 - No plateau (and tests not carried to 10 seconds)
7 - Low water level in spirometer
9 - Flow-volume loop not stored (either a manual entry or test started too long after space bar was pressed)

8.5.1.2 Location of Typical Errors During Forced Expiration

Each of these errors has a most common location either at the beginning, middle or end of expiration.

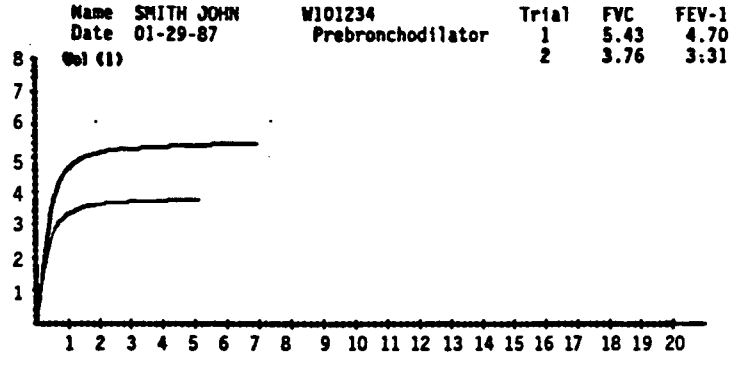


Trial # 1		Actual
FVC	(1)	5.43
FEV-1	(1)	4.70
FEF25-75	(1/S)	5.70
PEFR	(1/s)	11.15

Trial # 2		Actual
FVC	(1)	3.76
FEV-1	(1)	3.31
FEF25-75	(1/S)	4.48
PEFR	(1/s)	8.67

Press SPACE BAR for FVL or ESC for Pulmonary Menu.

Figure 13a. FVL - Screen obtained by pressing F9



Press SPACE BAR to CONTINUE.

Figure 13b. FVL - Screen obtained by pressing F6 (Volume-time curve)

Johns Hopkins University

Name SMITH JOHN
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Study ARIC

Enter Quality Code for test: 1

Figure 13c. FVL - Screen for entering quality code

Error Location	Acceptability Code
1. BEGINNING of a forced expiration (best seen on flow volume loop displayed on screen by pressing F9 after the 3rd and last trials.)	
a. Leakage over 5% of FVC (See Figures 14 and 15).	3
b. Submaximal effort (lack of steep rise to peak flow) (See Figure 16).	4
c. Obstruction of mouthpiece (Often seen as reproducible, submaximal effort with flattened top of FVL loop) (See Figure 17).	4
2. MIDDLE of a forced expiration (best seen on spirogram paper tracing)	
a. Cough or removal of mouthpiece, resulting in interruption of the smooth forced expiration (See Figure 18).	5
b. Low water level, resulting in incomplete spirometer excursion (See Figure 19).	7
3. END of a forced expiration (best seen on spirogram paper tracing)	
a. Premature termination, plateau not achieved (See Figures 20 and 21).	6

Note: We recognize that the spirograms of a participant with airway obstruction may not be able to reach a plateau due to the participant's narrowed airways and not the technician's early termination of the test. Spirograms which do not plateau should be continued for at least 10 seconds.

8.5.1.3 Error Messages Displayed by Field Center Computer

The following Error Messages identify violations of the spirogram acceptability criteria:

Error	Acceptability Code
1. "Error - Zero flow not found"	2
The technician pressed the space bar late, after the participant started to blow out. Stop the test and repeat the maneuver.	
2. "Leakage is over 5% of FVC"	3
Back extrapolation for "time zero" indicates that more than 5% of the vital capacity was expired prior to onset of forced expiratory flow. Repeat the maneuver	

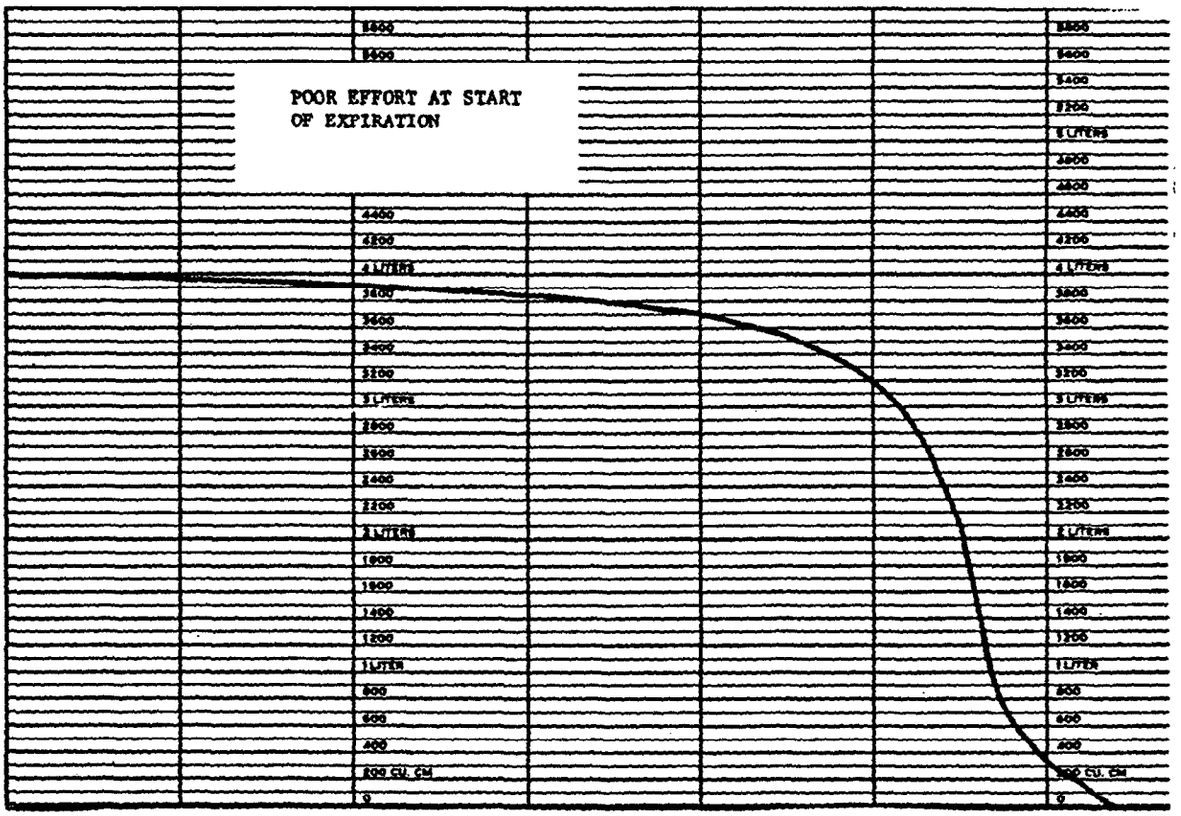


Figure 14. Leakage over 5% of FVC

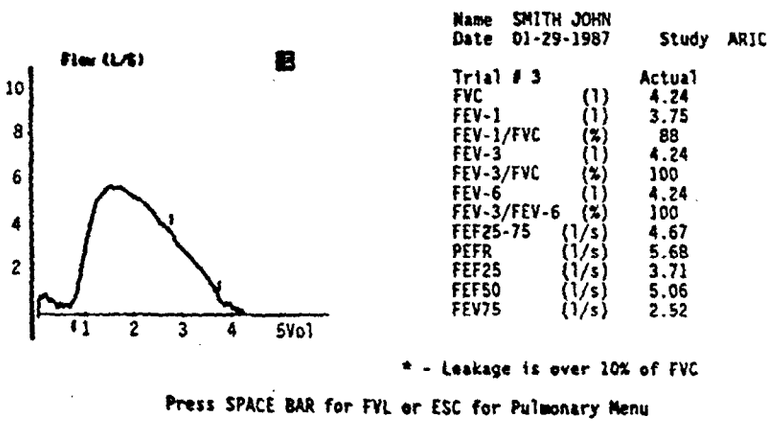


Figure 15. FVL - Screen showing leakage over 10% FVC

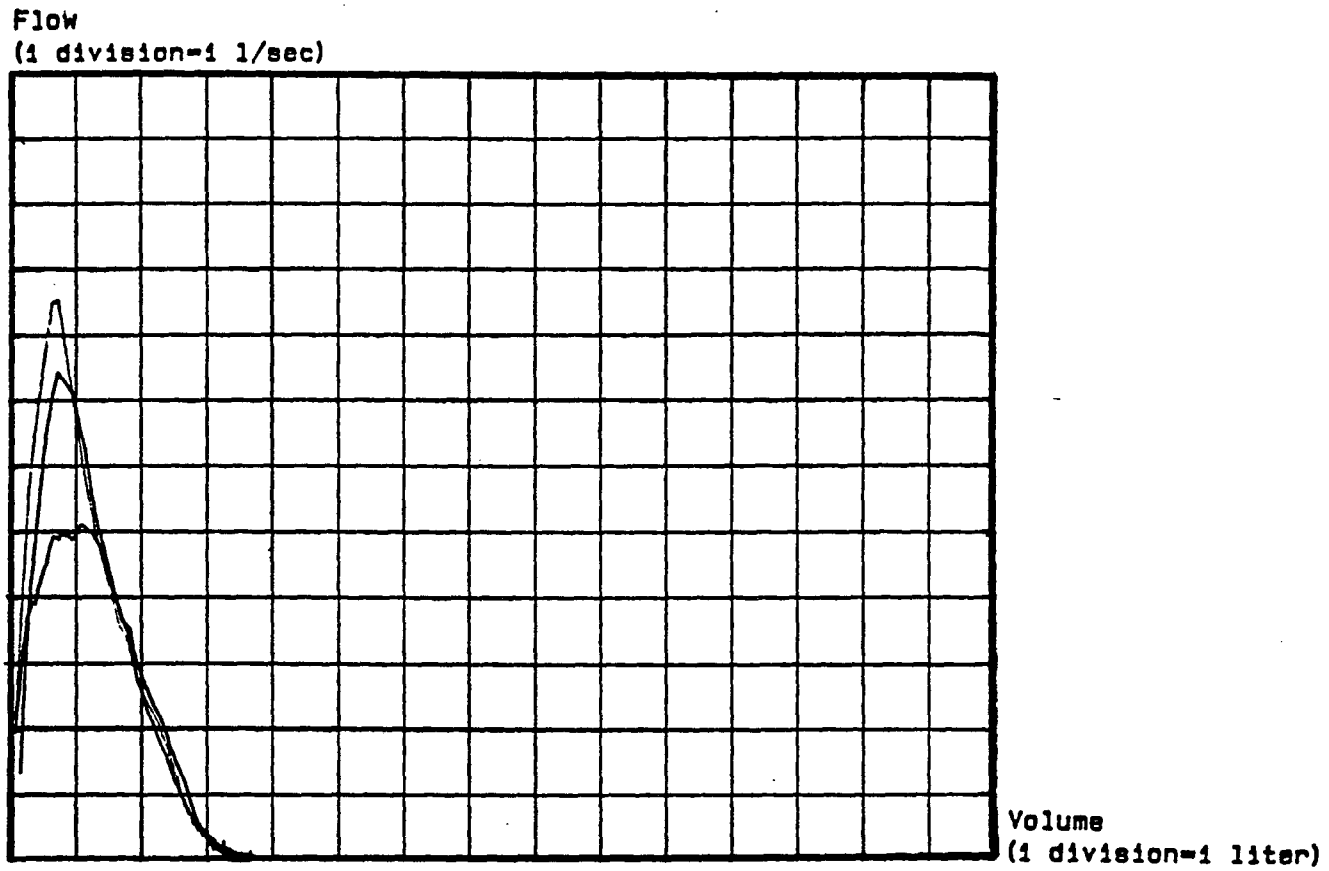


Figure 16. Submaximal Effort

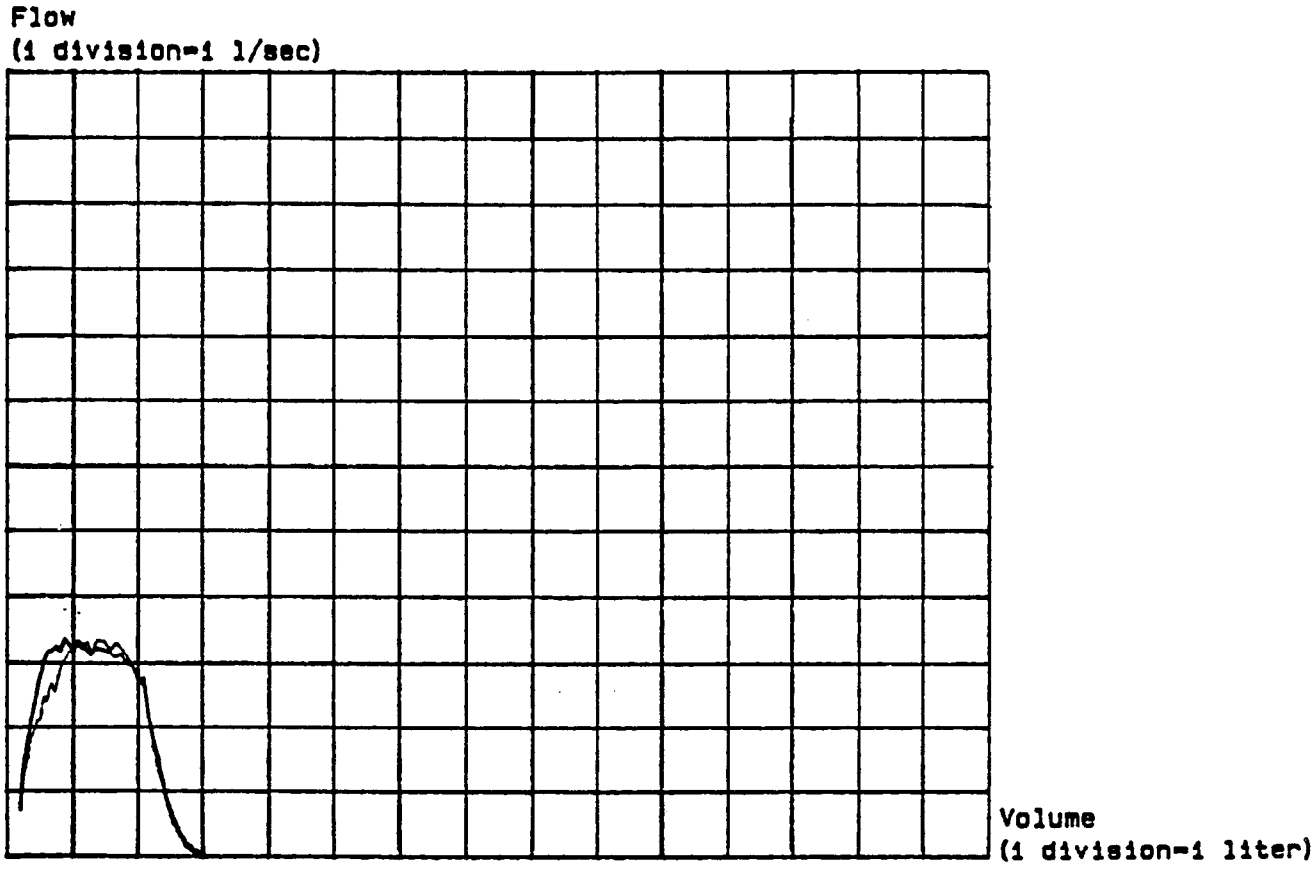


Figure 17. Obstruction of Mouthpiece

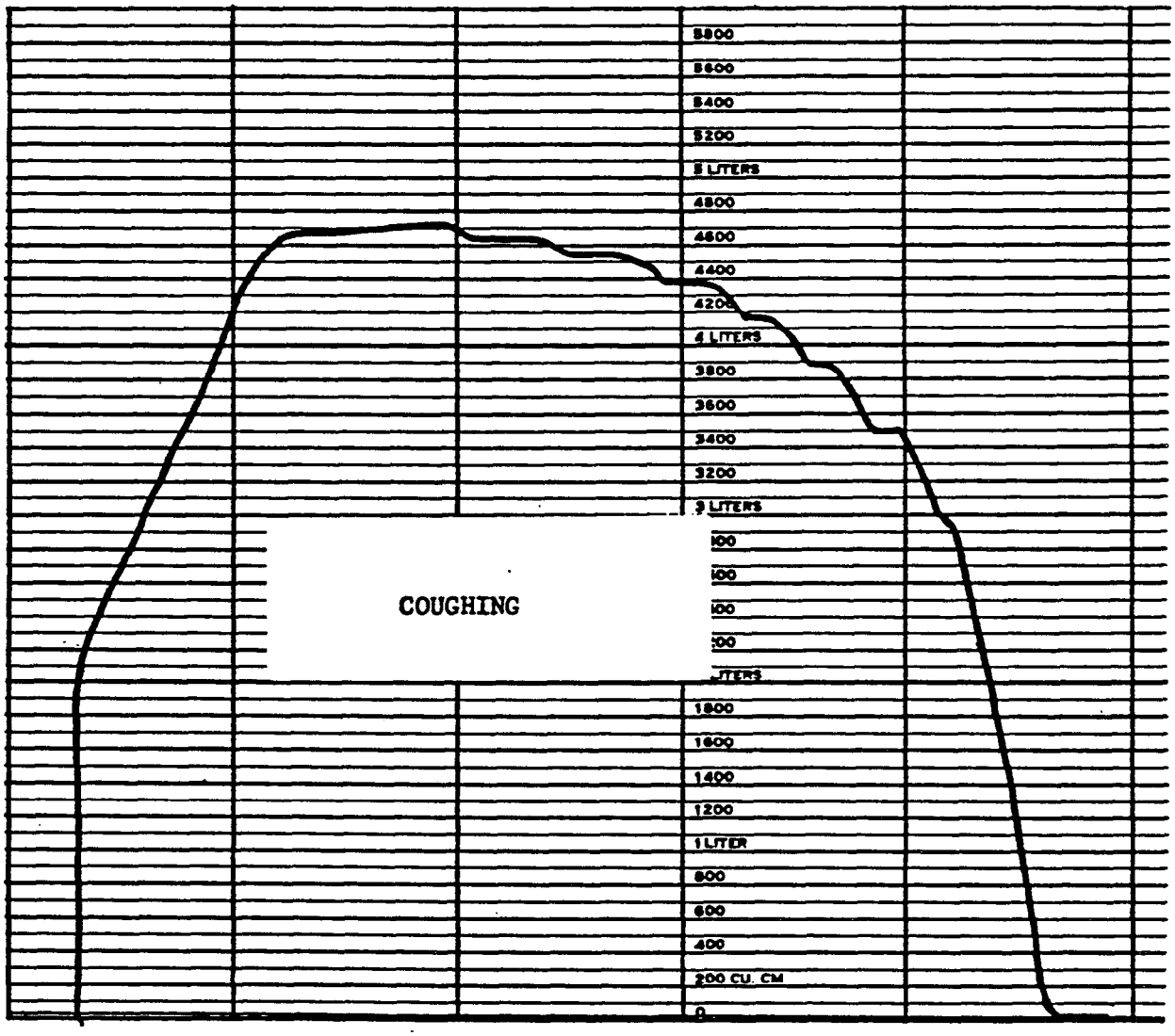


Figure 18. Cough

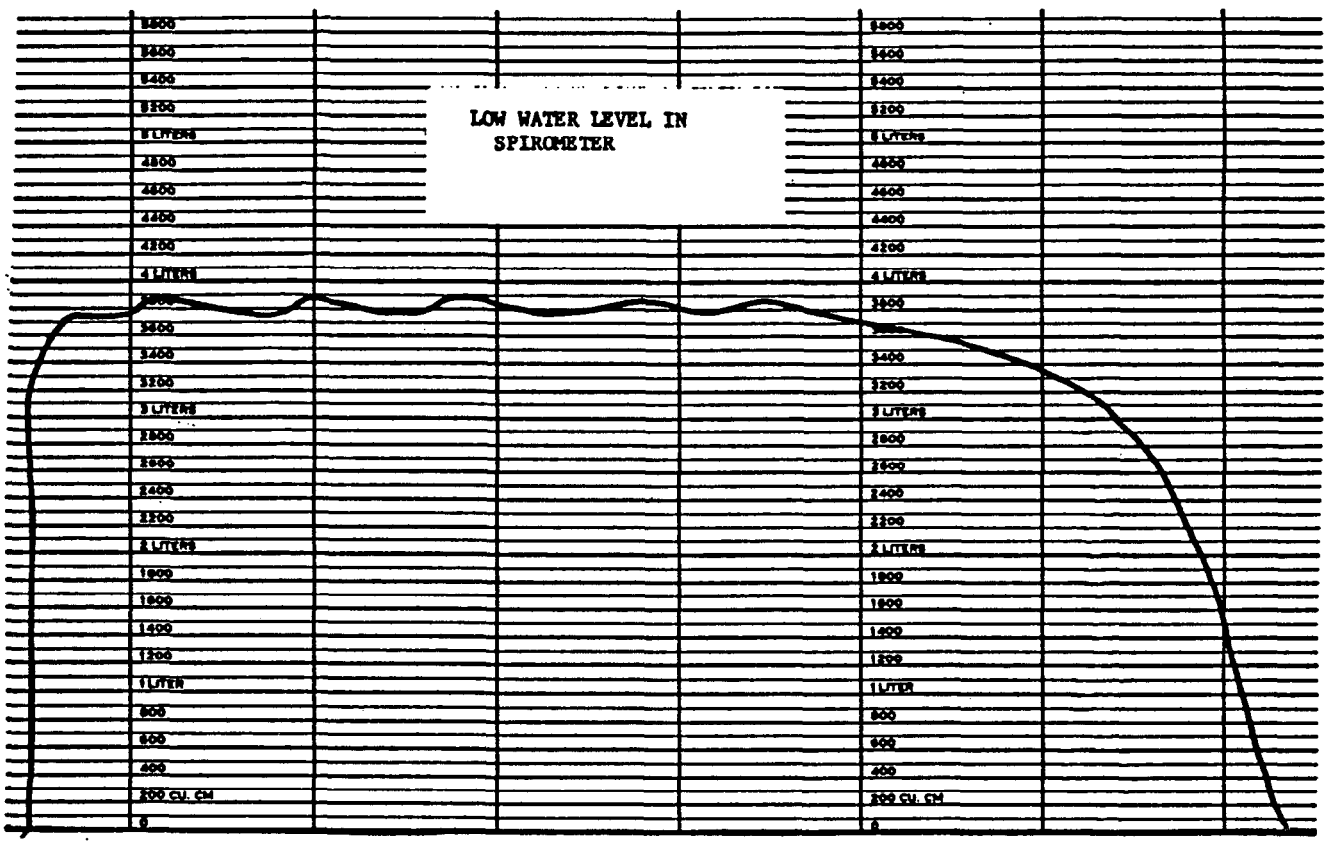


Figure 19. Low Water Level

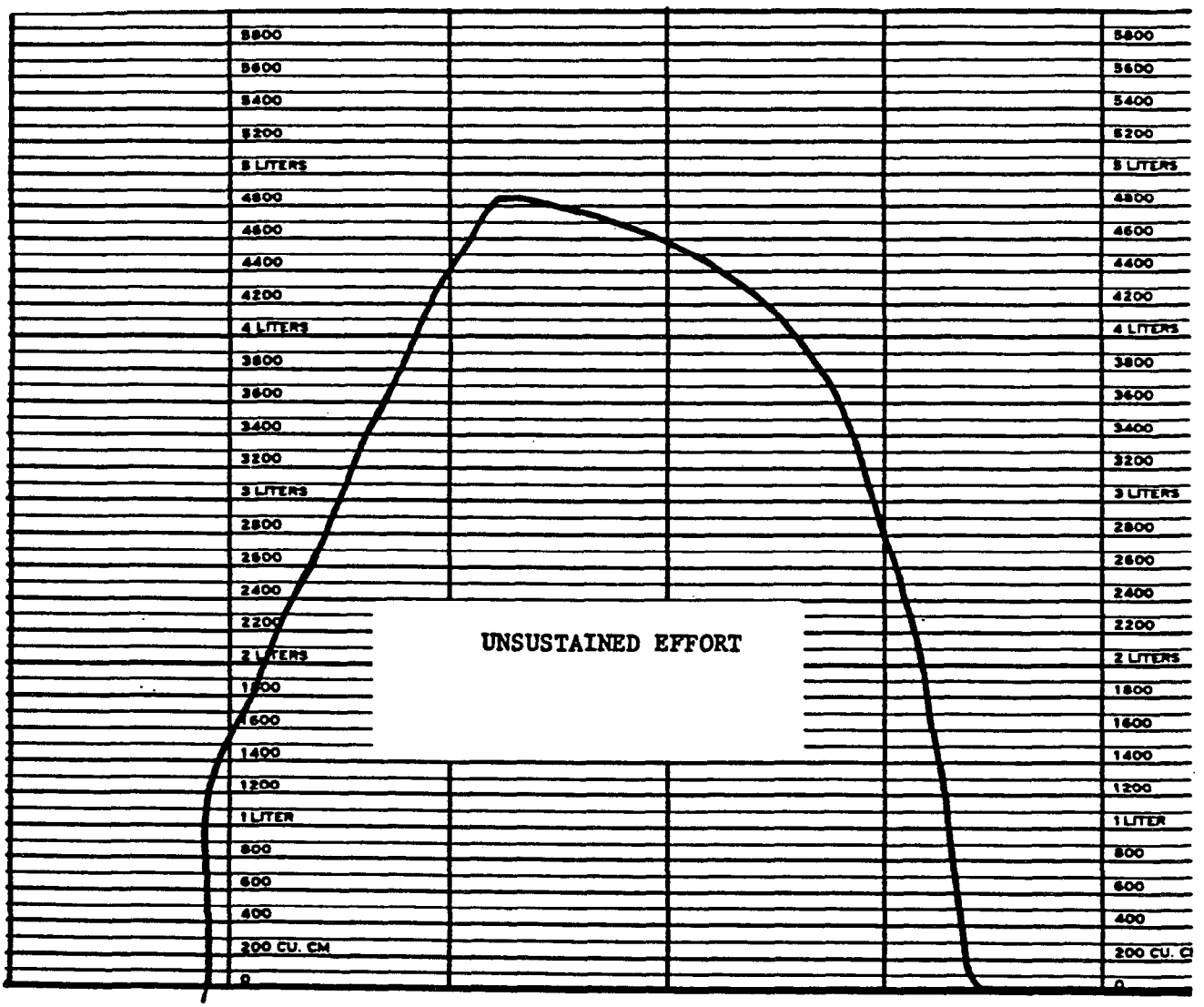
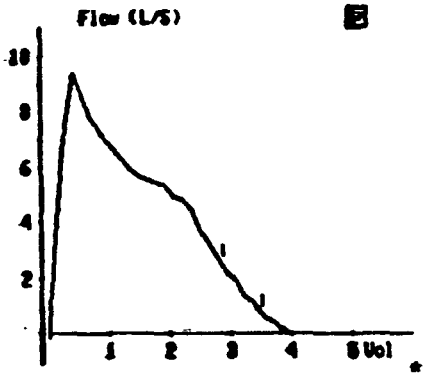


Figure 20. Premature Termination - No Plateau



Name SMITH JOHN
Date 01-29-1987 Study ARIC

Trial # 6		Actual
FVC	(l)	3.93
FEV-1	(l)	3.53
FEV-1/FVC	(%)	90
FEV-3	(l)	3.93
FEV-3/FVC	(%)	100
FEV-6	(l)	3.93
FEV-3/FEV-6	(%)	100
FEF25-75	(l/s)	4.63
PEFR	(l/s)	9.39
FEF25	(l/s)	6.94
FEF50	(l/s)	5.01
FEV75	(l/s)	2.17

* - Questionable END EXPIRATORY time.

Trial #6 not accepted. FVC+FEV1 less than best 3. Press SPACE BAR or ESC.

Figure 21. FVL - Screen for Questionable END ESPIRATORY Time.

Error	Acceptability Code
asking the participant to maximally inspire and then to immediately begin forced expiration without letting air "leak" out first (See Figure 15).	
Note: The ATS has revised this criterion to 5% and the software now checks for a 5% leak (although the screen message still shows 10%).	
3. "Error - Response Interrupted"	5
Participant failed to complete a smooth forced expiration maneuver. Repeat the study instructing the participant to continue the maneuver without removing the mouthpiece from the mouth, or without coughing.	
4. "Questionable END EXPIRATORY TIME"	6
The end of test criteria as recommended by the A.T.S. were not met. The vital capacity may be underestimated and flow rates may be overestimated and/or incorrect for that participant (See Figure 21).	

8.5.2 Reproducibility

A spirogram is considered reproducible if the second best FVC is within 5% of the best FVC and if the second best FEV_1 is within 5% of the best FEV_1.

Note: The best FEV_1 and FVC need not come from the same test and need not come from the best test (highest sum of FEV_1 + FVC).

8.5.3 End of Participant Testing

Testing will be stopped by the technician after 5 trials when two error-free, reproducible maneuvers out of three acceptable maneuvers have been performed. If, after five maneuvers, these conditions have not been met, testing should continue for up to 8 trials. If the subject refuses to continue with the required number of trials, this should be noted directly on the chart paper tracing.

8.5.4 Quality Codes

After the last trial, pressing the F9 key will identify the three best spirograms (best sum of FEV_1 and FVC). These spirograms should be given an overall quality code by the technician according to the following criteria:

Table 1. Quality Codes for Spirograms

Quality Code	Duration of of Spirogram	Reproducibile	Smooth and Continuous Transition of Slope
1	≥ 6 seconds	yes	yes
2	≥ 6 seconds	yes	no
3	< 6 seconds	yes	yes
4	< 6 seconds	yes	no
5	any duration	no	any condition

8.5.5 Labelling the Tracing

At the end of a participant test, attach labels containing ID number, name, date, time, quality code and temperature to the tracings.

The technician should verify that this information is correctly recorded on the label.

8.5.6 End of the Testing Day

At the end of the testing day, store the archive floppy disk, turn off the computer and detach and clean the spirometer hose. Enter a check in the box on the Spirometer Daily Log sheet to indicate that the hose has been cleaned.

8.5.7 Definitions of Flow-Volume Loop Parameters (all Volumes Corrected to BTPS)

The Flow-Volume Loop Parameters examined by this program include:

1. FVC: Forced Vital Capacity (expiratory) is the volume of air forcefully expired following a maximum inspiration. The accuracy of the FVC depends on whether the subject's inspiration is maximal and whether his expiration is complete.

2. FEV_1: Volume of air forcefully expired in one second from maximum inspiration. Its accuracy depends upon whether the subject expels his air as fast as he can with a maximal effort.

3. FEV_1/FVC: Ratio of volume of air forcefully expired in the first second to the total forced expiratory vital capacity (expressed as a percent).

4. FEV_3: Volume of air forcefully expired in three seconds from maximum inspiration.

5. FEV_3/FVC: Ratio of FEV_3 to FVC (expressed as a percent).

6. FEF 25-75: Mean rate of flow (expiratory) measured between 25% and 75% of the forced expiratory vital capacity.

7. PEFR: Peak expiratory flow rate (the topmost point of the flow volume loop).

8. FEF25, FEF50, FEF75: Maximum expiratory flow rate measured at a percent of the forced expiratory vital capacity (i.e. FEF25 is forced expiratory flow rate when 25% of the forced vital capacity has been expired, expressed in liters per second).

9. Predicted FEV_1 and FVC: Based on the equations developed by Crapo (20), with a 12% adjustment for Blacks and Orientals.

8.5.8 Data Defaults

All FVL data selections are based on current American Thoracic Society recommendations. The criteria are:

1.	FVC, $FEV_{0.5}$, FEV_1, FEV_3 PEFR	Highest value is selected regardless of trial in which it occurred.
2.	FEV_1/FVC FEV_3/FVC	Highest values of FEV_1, FEV_3 and FVC are selected regardless of trial
3.	FEF25-75, 75-85 FEF25, FEF50, FEF75	From curve with highest sum of FVC and FEV_1.
4.	FVL graph	Graph selected from curve with highest sum of FVC and FEV_1.

8.6 Operation of the Maximal Respiratory Pressures Program

1. Attach a new white cardboard mouthpiece to the MRP device.

2. Type MRP or Press the F3 key from the Pulmonary Program Menu. The screen will display the Maximal Respiratory Pressure menu (Figure 22).

3. Press 1 to select the Maximal Inspiratory Pressure test from the Maximal Respiratory Pressue Menu. The screen will show the MIP incentive display (Figure 23).

4. Explain that "This test will measure the strength of your chest muscles".

5. Describe the technique as "like trying to such a thick chocolate malt through a narrow straw". Instruct the participant to exhale completely, then inhale with as much force as possible.

6. Demonstrate the MIP test using a spare mouthpiece.

7. Seat the participant comfortably before the screen and attach noseclips.

8. Coach the participant to slowly expire all his/her air out until his/her lungs are empty (Residual Volume, RV). When the participant reaches RV, instruct the participant to insert the mouthpiece and PRESS THE SPACE BAR. Then coach the participant during the performance of the maximal inspiration (MIP) effort by saying "IN..IN..IN..MORE, MORE, DEEPER". During this procedure, the participant should watch the incentive display for feedback.

9. Reinstruct the participant to obtain even better results. There is a considerable learning effect, so participants need vigorous encouragement.

10. Tests lasting less than 1 second will not be saved. The MIP is measured at the highest point on the curve after the first second. Acceptable tests must last at least 2 seconds.

11. A minimum of 3 trials (with a maximum of 5 trials) should be done to get 2 reproducible curves (the second best must be within 90% or more of the best). The best trial is always listed at the top righthand side of the incentive display (Figure 24).

12. At the conclusion of testing, Press the ESC key to return to the MRP menu. Then, Press 4 (Exit to Main Pulmonary Menu).

8.6.1 Quality Criteria for the Maximal Respiratory Pressures Program

A maximal respiratory pressure is considered reproducible if the second best test is 90% or more of the first best test. An acceptable quality is assigned if the tests last at least 2 seconds.

8.7 Report Generation

8.7.1 Prepare the printer.

1. A pulmonary function report is to be printed for review by the ARIC clinic physician. The report is then filed in the participant's file along with the kymograph tracing.

2. Type the letters "DAT" or press the F4 function key to load the program. The screen will display the prompt:

   Prepare PRINTER then Press the SPACE BAR

3. Set the paper in the printer so the first printed line will be just below the perforation for the top of the page. This can be done manually or with the top of form set key on your printer (consult the User's Manual for your particular printer).

8.7.2 Comments:

After the printer is prepared for final report press ENTER (or use above options) to enter comments. The prompt will be:

Enter Comments for Line #1

Enter your comments on the keyboard - up to 80 characters (screen width) and press ENTER

A second line of comments can be entered with the prompt being:

Enter Comments for Line #2

Again you may enter up to 80 characters and then press ENTER.

If no comments are to be entered, then press ENTER only for each prompt above.

The final prompt before printing report will be:

How many copies?

Enter the number of copies of the printed report and interpretation (See Figure 25) you wish to print; then press ENTER or press the ENTER key to print the default of one (1) copy.

8.7.3 Computer Impression

The computer will compare the observed values to those predicted by the Crapo regression (20). The following are the criteria for restriction and obstruction:

1. Mild restriction: FVC% of predicted is less than 80% and greater than or equal to 66% in the presence of a normal FEV_1/FVC ratio (≥ 70%).

2. Moderate restriction: FVC% of predicted is less than 66% and greater than or equal to 51% in the presence of a normal FEV_1/FVC ratio (≥ 70%).

3. Severe restriction: FVC% of predicted is less than 51% of predicted in the presence of a normal FEV_1/FVC ratio (≥ 70%).

4. Mild obstruction: the ratio of FEV_1 to FVC is less than 70% and greater than or equal to 61%.

5. Moderate obstruction: the ratio of FEV_1 to FVC is less than 60% and greater than or equal to 45%.

6. Severe obstruction: the ratio of FEV_1 to FVC is less than 45%.

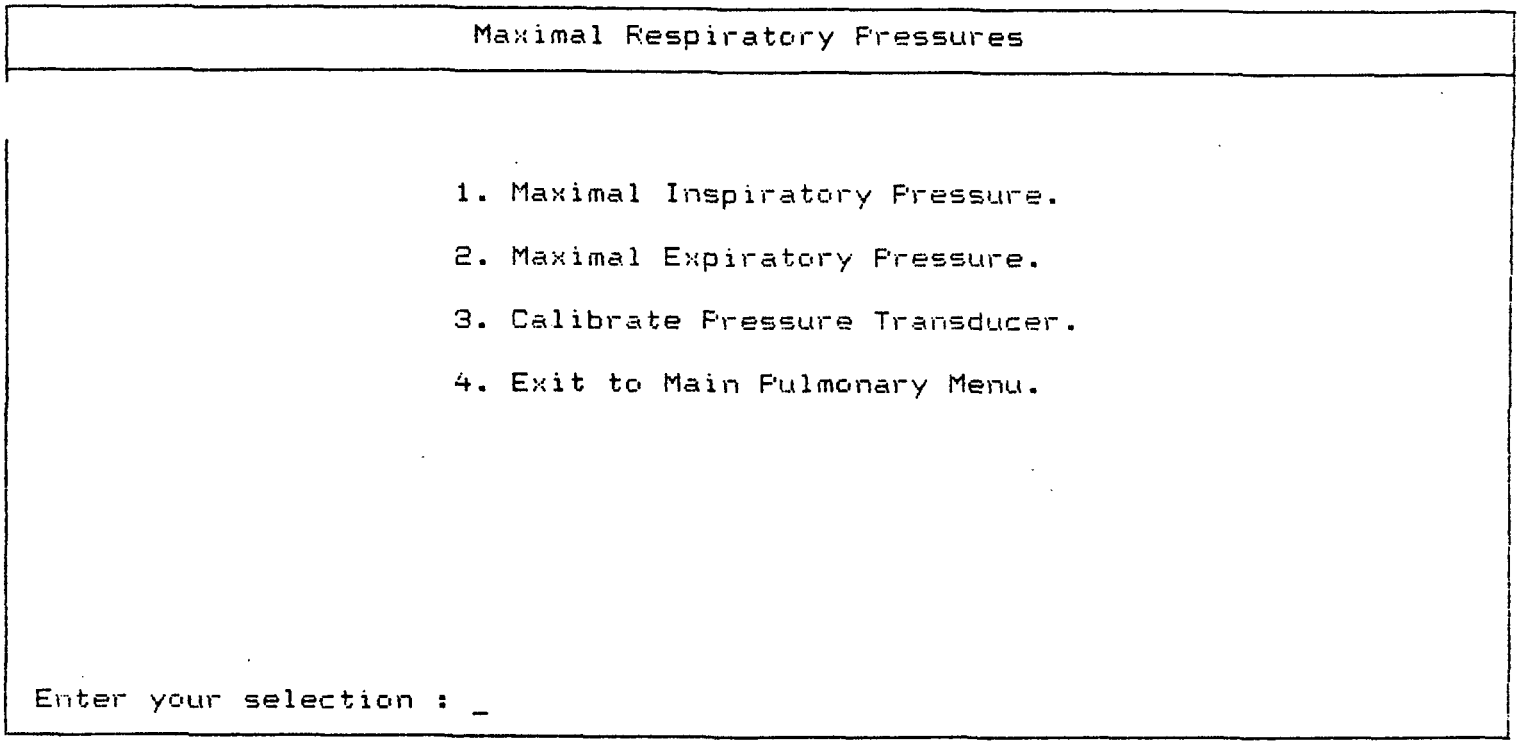


Figure 22. Maximal Respiratory Pressures

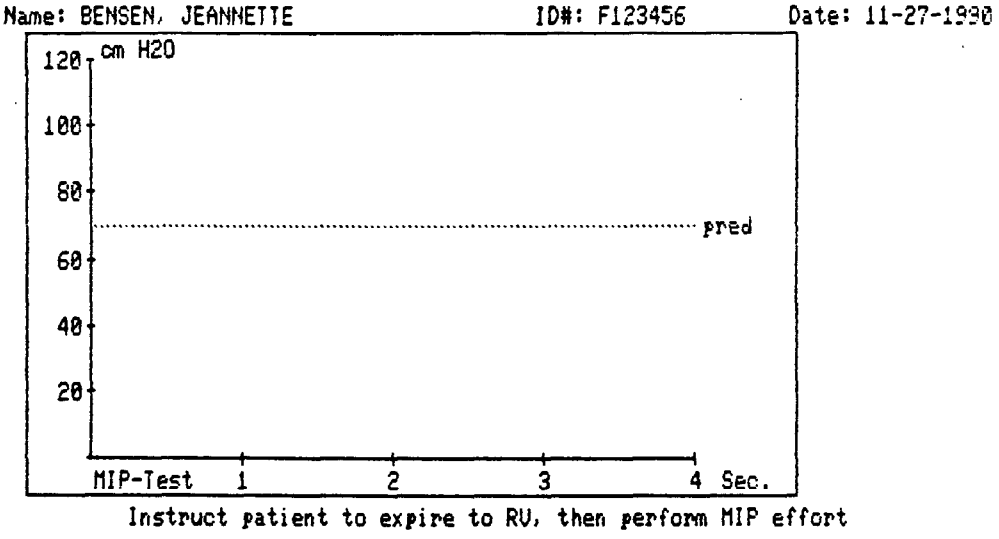


Figure 23. MRP Incentive Screen

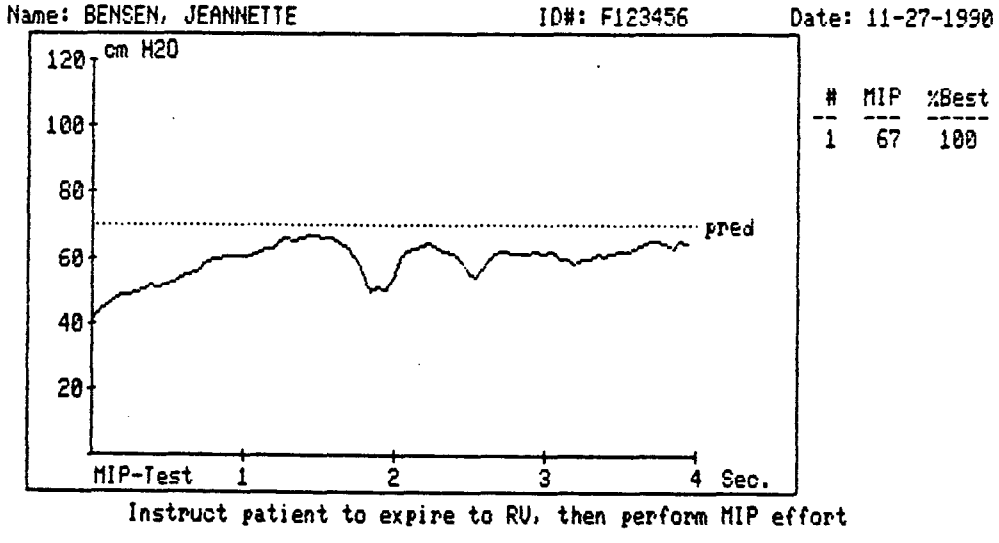


Figure 24. MRP Incentive Screen

Johns Hopkins University
ARIC Spirometry Study

Patient : SMITH JOHN
ID Number : W101234
Date : 01-29-1987 Time: 09:40
Technician : 032
Ethnic Group : White

Age : 56
Height : 63 (in) - 160 (cm)
Sex : M
Last Calibration : 01-29-87

B.P.: 760
ATPS: .931
Temp: 25
Time: 08:15

# Spirometry #	(BTPS)	Actual	%Pred	Pred
FVC	(L)	3.77	91	4.14
FEV-1	(L)	2.88	82	3.51
FEV-3	(L)	3.74	93	4.02
FEV-6	(L)	3.77	91	4.14
FEV-1/FVC	(%)	77		84
FEV3/FEV6	(%)	99		
Total Trials		5		
Quality Code		1		

Comments :

Computer Impression :

Spirometry --The Ratio FEV-1/FVC is 77%, suggesting Mild OBSTRUCTION.
Short expiratory time may hide mild Obstruction.

* Note - Computer Impression is subject to Physicians review and confirmation.

Physician

Figure 25. DAT - Spirometry Report

If the FEV_1 falls between 66% and 80% of predicted, the report will identify the type of impairment and note that the value falls into the borderline low range but will not recommend further evaluation. If the FEV_1 falls below 66% of predicted, the report will identify type of impairment (obstruction or restriction) and recommend that the participant be referred for further evaluation.

8.7.4 Data Storage

After the print function is complete, the computer will automatically store the test results to two files, one on the hard disk and the back-up on the archive disk. If an unformatted disk is inserted in drive A, the computer automatically will go to the formatting procedure. See page 51 for a description of formatting and disk labelling. After formatting, the computer will resume storing the files to the floppy disk. The screen will then return to the main Pulmonary Menu.

8.7.5 Calibration Date Check

Be certain that the date of last calibration printed on the report is correct.

9. DATA MANAGEMENT

9.1 Description

A fail-safe file management system is provided for quick and easy back-up of all data and will prevent accidental erasures. The computer will digitize and store the three best flow-volume curves and will calculate spirometry results in the file generated for each participant on both the hard disk and a back-up floppy disk as soon as the testing is completed. If errors occur or power is accidentally lost, the data will not be lost. However, before a floppy disk can be written upon, it must be formatted.

9.2 Data Disk Formatting Procedure

The storage program of the S&M Instruments Pulmo-Screen II system requires formatted floppy disks.

9.2.1 To format a disk, type the commands:

BRK (press ENTER) (Leaves Pulmonary Program)

FORMAT A:/V (press ENTER)

The screen will respond with the following:

Insert new diskette in drive A:
and strike any key when ready

9.2.2 Insert a new or blank disk in drive A and press any key

Note: Be certain that the disk in drive A is new, blank or can be overwritten. Once the format procedure has begun, the information on the disk is permanently erased.

1. The floppy disks will be labelled with the batch (volume) number ARabnnnn where:

"AR" is the two character study code for ARIC

a is a one character ARIC agency code for the sending agency.

b is a one character ARIC agency code for the receiving agency.

nnnn is a sequential batch number, counting all batches shipped from "a" to "b" since the beginning of the project.

ARIC Agency Codes

CODE	SENDING AGENCY
	Field Centers:
F	Forsyth County, NC
J	Jackson, MS
M	Minneapolis Suburbs, MN
W	Washington County, MD

CODE	RECEIVING AGENCY
P	Pulmonary Function Reading Center

2. A paper label should be attached to the floppy disk. This label should include the volume number (described above) and the date.

Note: Be certain to label disks properly so as not to erase disks that contain stored participant data.

3. When the format is complete, there will be a prompt for entering a volume number for the diskette. Enter the volume number as described above.

4. At the end of each week, two diskettes (an archive and a mailer diskette) must be formatted. Reply Y to the prompt "Format another?", insert another new disk into drive A and press {Enter} when prompted. If no more disks are to be formatted, reply N to the prompt "Format another?".

5. Enter volume number of field center (Archive) Disk and Pulmonary Reading Center (Mailer) Disk on Daily Spirometer Log. Archive disks will be given an odd number, mailer disks will receive an even number.

9.2.3 Type GO to Return to the Pulmonary Menu screen.

9.3 Data Storage Procedures (Daily)

1. Insert the properly formatted and labelled diskette for the week in drive A before running any tests.

2. At the end of each test, the current subject's tests are automatically written to a hard disk file and a backup floppy disk file.

3. At the end of a participant test, attach labels containing ID number, name, date, time, quality code and temperature to the tracings.

9.4 Data Storage Procedures (Weekly)

9.4.1 Operation of the Disk Storage Program

1. Type "DIS" or F7 from the main Pulmonary program menu to load the DISK STORAGE program.

   a) The Disk Storage (DIS) program will be run at the end of each week to record the data stored on the hard disk onto a second floppy disk for mailing to the Pulmonary Function Reading Center. The Disk Storage Program Menu will be displayed as in Figure 26.

   b) The Name, ID#, and Date of the participant currently on drive C - Pulmonary Program disk is displayed at the bottom of the Disk Storage menu.

Note: Participant data is stored both alphabetically and numerically. There is no way to differentiate between first and last names, therefore, it is advisable that when entering Name in the Participant Information program (INF), the last name be entered first. To differentiate between participants with the same name, the number and the date of the test are used.

2. Press #1 to display on the screen the directory of participants on the data storage disk.

   a) The Participant Directory can be displayed by participant name or ID# and Date. The menu shows the current order of the directory in parentheses after item number 4. To switch from one to the other and back, press the "+" key at the far right side of the keyboard or press #4.

   b) Mode selected in storage can be changed at any time by the "+" or #4 key.

   c) Select ID# mode prior to printing directory.

9.4.2 Print the Directory of the Hard Disk (Press #2)

Press #2 to print the directory of participants stored on the hard disk ranked by ID# and Date. The prompt will be:

Prepare Printer then press SPACE BAR

Prepare printer as required and press the SPACE BAR. The printer will produce the following directory:

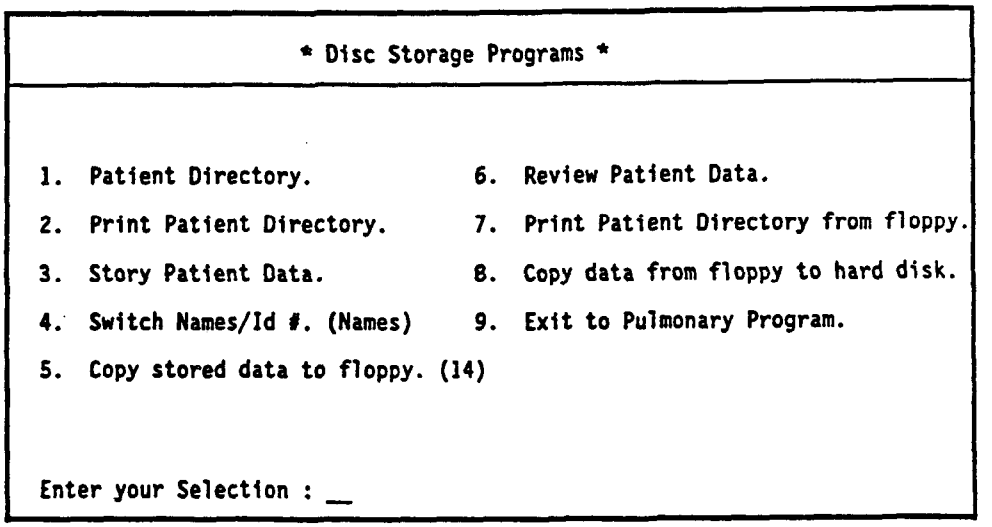


Figure 26. DIS - Disk Storage Program Menu

Participant Directory - Ordered by ID Numbers

ID Numbers	Names	Date
F121121	HEYER ROB	12/17/85
F122341	GLAZE DONNA	12/17/85
J100123	FARIS DONNA	12/18/85
J111112	ARNOLD GEORGE	12/18/85
M156575	CLOSE ANDREW	10/03/85
W162424	JORDAN DOROTHY	12/13/85
W191219	HART JOHN	12/13/85
W200001	ROSS JOHN	12/01/88

9.4.3 Print Directory of Archive Disk (Press #7)

Print a listing of the contents of the archive disk by pressing #7. Verify that the listing from the archive disk contains the same participants as the listing from the hard disk. Then remove the archive disk from drive A and store for 10 weeks.

9.4.4 Download Hard Disk to Mailer (Change disks, press #5)

Insert a new diskette (formatted with the appropriate batch code label) in drive A. The number in parentheses which appears after the procedure on the Disk Storage Program menu is the number of participant files which are on the hard disk and which will be copied to the floppy disk. Press #5 to copy data stored on the hard disk to this second (Mailer) floppy disk. After the copy is done, notice that the number in parenthesis will be zero, indicating that the files have been erased from the hard disk.

Note: A NEWLY FORMATTED DISK MUST BE AVAILABLE FOR THIS PROCEDURE. SEE SECTION 9.2.1 FOR FORMATTING DIRECTIONS. IT IS ESPECIALLY IMPORTANT TO REFORMAT DISKS WHICH ARE BEING RECYCLED AND MAY CONTAIN OLD PULMONARY FUNCTION FILES OR OTHER TYPES OF FILES.

9.4.5 Print Directory of Mailer Disk (Press #7)

Print a listing of the contents of the mailer disk by pressing #7. Verify that the listing from the mailer disk contains the same participants as the listing from the archive disk.

9.4.6 Select Random 10% Sample

Select the spirograms from a 10% sample of participants tested (this sample will include at least one tracing from each technician). To select the tracings, do the following:

a) Press #9 to return to the Main Pulmonary menu
b) With the mailer disk for the week in drive A, type: BRK
c) The computer will leave the pulmonary program. At the DOS prompt (C>) type: RANDOM

The computer will ask how many tests were NOT stored on the computer for the week. (Every participant should be eligible for selection.) If none, enter 0. The printer will print the random listing of participant names and study numbers. Obtain these tracings from the file and measure the three best curves (curves with best FEV_1's and best FVC's) on each tracing. Record the FEV_1 and FVC measurements (raw and corrected to BTPS) on the tracing. Make a photocopy of the tracing for the participant's file.

To return to the pulmonary program, type GO.

9.4.7 Prepare Mailing to the Pulmonary Reading Center

Mail the following items to the Pulmonary Reading Center on Friday for that week's testing:

1. The mailer floppy disk.
2. A listing of the contents of the mailer floppy disk.
3. A copy of the daily spirometer log for the week.
4. The listing of the 10% random sample of participants for the week.
5. A 10% sample of tracings for the week. The best three curves from each of these tracings must be measured.

9.4.8 Prepare Diskettes for Next Week's Testing

Format and label two floppy disks for the next week. (The format procedure is described on page 51.) Each week two floppy disks will be used for storing pulmonary function test results. One will be stored at the field center and the other will be mailed to the Pulmonary Function Reading Center. The disks will be stored at the field centers for ten weeks and then the oldest may be recycled. Recycled disks must be reformatted before being reused.

9.5 Additional Menu Commands

In addition to the MENU commands which are visible on the screen (INF, FVL, DIS, etc.), there are other commands which are not used as often but are nevertheless useful. These commands are invisible, however, and must be known in order to run. To load any of the programs below, simply type in the three letter code as indicated when the Main Pulmonary menu is displayed.

9.5.1 BRK - Break the Pulmonary Program

This command will interrupt the Pulmonary Program and put the operator into the IBM operating system as designated by the character C> on the screen when BRK is typed. When the character is displayed, the operator has the following options: Type GO and press ENTER to reload the spirometry software from hard disk drive C or Enter a command recognized by the IBM operating system (MS-DOS).

9.5.2 STO - Automatic Participant Data Storage

This command will automatically store the participant data from the pulmonary program disk (drive C) to the data storage disk (drive A) without running the DIS program. This will be helpful if a large number of participants are being screened in a short period of time. It is not recommended for routine use as there is no confirmation that the participant was actually stored without checking the directory in the DIS program.

9.5.3 CAL - Check Calibration

Type CAL or press the F4 function key to load the calibration check program. This program will allow the operator to verify the calibration accuracy using a 3-liter syringe.

Note: This program does not change or correct calibration. It will merely assist the operator to determine whether the ADJ program needs to be run again. The calibration should agree with syringe volume within ±3% or 90 ml, whichever is greater.

Flow should read 0.00 liter/second ±90 ml/sec.

The screen will display the following when the CAL program is loaded:

Volume	Liters
Flow	Liters/Second

The date of the last calibration adjustment [ADJ] will be displayed or if not previously adjusted the following will appear:

Last Calibration was N/A

This statement indicates that the system is not adjusted. ADJ must be run before any more participants are tested. To run ADJ directly from the CAL program, press the SHIFT and + keys.

9.5.4 Printing a Screen

Any screen with graphics or data may be printed while it is displayed by pressing the Prt Sc key. Individual data and graphics should be printed when they are displayed as not all information is transferred to the final report.

10. CLEANING AND MAINTENANCE OF THE SPIROMETER

10.1 Emptying the Spirometer

The spirometer is equipped with a petcock drain for convenience in emptying water from the spirometer body. Locate the drain at the bottom rear of the spirometer body. The top part of the drain consists of a lever which controls the valve through which the water flows. The bottom part consists of a nozzle. When this lever is at a right angle to the nozzle, the valve is closed and water will not empty from the spirometer.

10.2 Cleaning the Internal Parts

The Survey II spirometer should be cleaned weekly. You will need a small screwdriver in order to remove the spirometer bell.

1. Unplug the spirometer power cord and disconnect the cable leading from the base of the spirometer to the rear of the computer. Remove the kymograph drum by simply lifting it off of its base. Detach the breathing tube.

2. There are two vertical guide rods located on either side of the spirometer. At the top of the rod holding the linear potentiometer is a small plastic stop which prevents the spirometer bell from being raised to a position which could prove damaging to the potentiometer rod. Unscrew and remove this stop.

Note: POSITION OF THE BELL STOP
When in place, the bell stop should be located on the same side as the potentiometer. It should also be positioned so that the bell stops when the recording pen reaches the 8-liter mark on the kymograph.

3. Loosen the potentiometer clamping set screw at the side of the potentiometer clamp to allow the potentiometer rod to slide freely out of the clamp. Do not remove the rod from the body of the potentiometer.

4. At the top of the spirometer bell, across from the potentiometer clamping piece, is the recording pen holder screw. Loosen and remove this screw. At this point you should be able to raise the spirometer bell free of the guide rods.

5. Remove the spirometer bell from the rest of the apparatus, being careful not to squeeze the plastic bell.

6. Wash the inside and outside of the spirometer bell with vinegar and rinse it with water. Vinegar will remove the film that tends to build up on the bell.

7. If contamination is believed to have occurred, drain the water from the spirometer as directed at the beginning of this section. Then plug the breathing tube connector with a rubber stopper and fill the internal pipe with a dilute disinfectant solution (Cidex). (Alternatively, the internal pipe can be removed by reaching up under the spirometer and detaching the tube ends from the metal collars at the top and front of the spirometer.)

8. When you have reached the time set for disinfection to have occurred, remove the solution from the spirometer by unstopping the breathing tube connector and allowing the solution to pour out from the internal pipe. After this has been accomplished, rinse the pipe thoroughly.

9. Replace the bell by inserting it over the guides and the potentiometer slide rod in the same manner in which you removed it. Insert and retighten the pen holder screw, the plastic stop, and the potentiometer adjusting screw. Be sure to not secure the adjusting screw too tightly, as this may cause the potentiometer rod to break. Simply turn the screw until it is firmly in place; thumbnail tight is sufficient.

10. When ready to operate the spirometer again, fill it with water and attach a clean breathing tube to the breathing tube connector.

10.3 Cleaning the Breathing Tubes

Clean the breathing tubes after each day's testing. Cleaning the breathing tube involves soaking it in a disinfectant solution. After disinfecting, rinse the tube thoroughly and allow it to dry completely overnight before reusing.

11. DATA TRANSFER AND QUALITY CONTROL PROCEDURES

11.1 Pulmonary Function Data Flow Chart

A flow chart summary of data items transferred between the field centers, the Pulmonary Function Reading Center and the Data Coordinating Center may be found on page 69. Sample reports may be found in Appendix I, page A-76.

11.2 Quality Assurance Procedures at the Field Center

11.2.1 Technician Training

Each technician has completed an intensive two-day training course in spirometric testing which meets the criteria for National Institute of Occupational Safety and Health (NIOSH) certification. In addition, each ARIC pulmonary function technician has received training in the ARIC Pulmonary Function Testing Protocol, using ARIC pulmonary function calibration and test equipment, computer hardware and software.

Each ARIC pulmonary function technician has been certified in his/her abilities in:

1. Familiarity with the ARIC protocol
2. Preparation and calibration of spirometry hardware and software
3. Participant instruction
4. Spirometry testing techniques
5. Assessment of tracing acceptability and reproducibility
6. Data management and transfer procedures
7. Calculation of spirometric parameters

Only ARIC-certified technicians are to perform pulmonary function testing in this study.

To retain their certification, technicians must be responsible for one full day of testing per week or equivalent (one complete calibration plus tests on six participants). Annual recertification is to be conducted at each field center.

11.3 Information Received from the Field Centers

Each week the Pulmonary Function Reading Center will receive the following from each of the field centers:

1. One mailer diskette containing the pulmonary function data files for the previous week's testing.

2. A listing of the (mailer disk) directory for the previous week's testing.

3. A copy of the DAILY SPIROMETER LOG for the week.

4. The listing of the 10% random sample of participants for the week.

5. The actual tracings for a 10% sample of participants tested during the previous week, with the raw and BTPS corrected values (see Section 12 for BTPS correction factor) for FEV_1 and FVC of the three best spirograms.

11.4 Data Management Procedures at the Pulmonary Function Reading Center

Upon receiving the packages, the Pulmonary Function Reading Center will do the following:

1. Verify the contents of the diskettes by comparing ID's from the listing with the pulmonary function diskette files.

2. Examine the Daily Spirometer Log sheets. Compare volume number on Daily Spirometer Log with that of the mailer disk received. If a problem is apparent, a call to the field center will be made to resolve the situation.

3. Process the diskette files to check the quality of the forced expiration.

   a) The volume calibration constant recorded on the diskette will be compared with the standard calibration curve generated for each field center. A within center calibration correction is calculated and applied to the volume axis of the digitized points. Variability within 2.5% is acceptable. If more than a 2.5% deviation is recorded, the field center will be notified and the tracings for that day will be requested.

   b) The digitized flow-volume curves encoded on the field center diskettes will be independently electronically remeasured as volume-time curves and the results compared with the results recorded on the field center diskettes.

   c) The digitized volume-time curves of the three best tests are electronically evaluated for acceptability and reproducibility criteria. A reading center acceptability code and quality code will be added to each participant's record. The following criteria are used in evaluating acceptability:

      - Spirometer not calibrated correctly: if the calibration factor which is stored on each participant's computer record is not within a specified range of values, this condition is flagged. The acceptable ranges are determined from the results of the annual standardization visit.

      - Computer started after start of expirations: if the flow is greater than .10 liter/second at the beginning of a flow-volume loop, this condition is flagged.

- Breath-hold leak > 5%: if the volume at the back-extrapolated start of the test is greater than 5%, there is a leak.

- Submaximal effort: the two best tests are compared on several measures. The angle formed at the peak of the flow-volume loop, the slope of the line from the origin to peak flow and the volume at peak flow are used for determining maximal effort.

- Cough/inhalation present: if the volume drops 50cc or more from any previous volume before reaching FVC, then a cough/inhalation is detected.

- No plateau: if there is greater than 50cc change in volume in the last two seconds of the test, then no plateau has been reached. However, if the participant continues his/her exhalation for > 10 seconds, the tracing will be (borderline) acceptable even without a plateau.

d) The between-center calibration standardization factor will be applied to the reported volume values and the digitized volume-time curve. An initial between-center calibration factor was determined by transporting the Pulmonary Function Reading Center syringe to each of the four field centers in October 1986. This calibration factor will be re-established annually at the time of the recertification visit.

e) The volume-time curves are standardized to a 3-liter syringe volume common to all the field centers (repeated during the annual standardization visit) and spirometric indices will be calculated and stored.

4. A file containing the reformatted standardized pulmonary function data will be copied to a diskette with an internal and external ARIC batch number label to be sent to the Coordinating Center each week along with a listing of the disk directory.

5. The paper tracings of a 10% sampling of participants will be hand measured and the results compared with those from the field center.

6. A report of the quality control check will be sent to the field centers with a copy to the Coordinating Center. (See sample reports in Appendix I.)

A. Weekly Progress Report to the field center from the Pulmonary Function Reading Center

1) Summary page which includes:
   a. Confirmation of records and tracings received
   b. Proportion of acceptable records and tabulation of problems among the unacceptable records
   c. Proportion of agreement between field center and Pulmonary Function Reading Center quality codes
   d. Proportion of acceptable calibrations.

2) Electronic evaluation of acceptability and quality.

3) Hand measured evaluation of randomly selected spirograms. Specific corrections and recommendations are provided if the Pulmonary Function Reading Center disagrees with the hand measured results from the field center (see Appendix I).

4) Flow-volume plot of randomly selected spirograms.

B. Weekly Report to Coordinating Center from Pulmonary Function Reading Center

1) Listing of participants whose processed records were included on floppy disk.

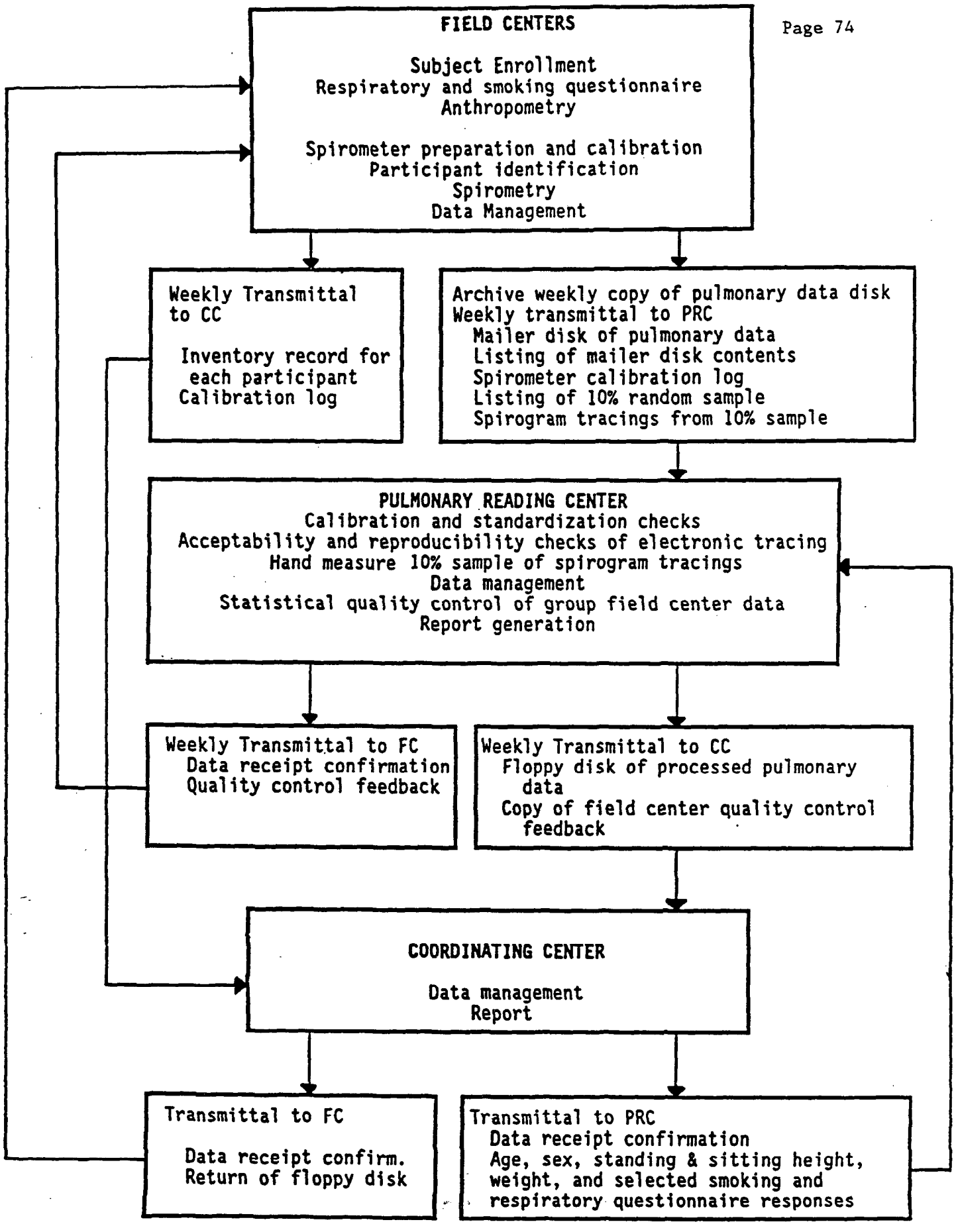
2) Copy of field center report as noted above (except #2).

7. Based upon race and sex specific regressions generated from "healthy non-smoker" pulmonary function measurements

a) Statistical quality control will be performed on the grouped data of each field center.
b) Normal pulmonary function regressions will be calculated for each field center.

11.5 The Coordinating Center will respond to the Pulmonary Function Center by doing the following:

1. Acknowledge receipt of the diskette from the Pulmonary Function Reading Center with a pre-printed postcard to which they will add a date and a count of the records received.


FIELD CENTERS
Subject Enrollment
Respiratory and smoking questionnaire
Anthropometry
Spirometer preparation and calibration
Participant identification
Spirometry
Data Management
Weekly Transmittal to CC
Inventory record for each participant
Calibration log
Archive weekly copy of pulmonary data disk
Weekly transmittal to PRC
Mailer disk of pulmonary data
Listing of mailer disk contents
Spirometer calibration log
Listing of 10% random sample
Spirogram tracings from 10% sample
PULMONARY READING CENTER
Calibration and standardization checks
Acceptability and reproducibility checks of electronic tracing
Hand measure 10% sample of spirogram tracings
Data management
Statistical quality control of group field center data
Report generation
Weekly Transmittal to FC
Data receipt confirmation
Quality control feedback
Weekly Transmittal to CC
Floppy disk of processed pulmonary data
Copy of field center quality control feedback
COORDINATING CENTER
Data management
Report
Transmittal to FC
Data receipt confirm.
Return of floppy disk
Transmittal to PRC
Data receipt confirmation
Age, sex, standing & sitting height, weight, and selected smoking and respiratory questionnaire responses

ARIC Field Center
Pulmonary Function Procedures

FIELD CENTER

Subject Enrollment
- Participant identifying data
- Generate 2 labels (for spirometry tracings)

Respiratory and smoking questionnaire

Anthropometry
- Measure standing height without shoes
- Measure sitting height
- Measure weight

Spirometer Preparation and Calibration
- Mechanical and electronic preparation of instrument
- Daily log of calibrations maintained by technicians

Participant Identification

Participant Spirometry Testing
- Participant instruction
- Attach identifying label to paper tracing
- Spirometry testing
- Real-time monitoring of quality by computer software
- Technician quality evaluation

Data Management

Raw pulmonary records are stored on hard disk and on archive floppy disk for the week

Files downloaded from hard disk to second (mailer) floppy weekly and then erased from hard disk.

Save at Field Centers:
- Participant spirometry report
- Labelled participant spirogram tracings
- Archive (back-up) floppy disks

Send to Coordinating Center:
- Respiratory inventory record

Send to Pulmonary Reading Center (every Friday)
- Mailer floppy disk files of pulmonary data
- Listing of (mailer) floppy disk directory
- Spirometer calibration log
- Listing of 10% random sample of participants
- Tracings from the random 10% sample (send original, retain copy for field center files)

ARIC Pulmonary Reading Center
Pulmonary Function Procedures

PULMONARY READING CENTER

Calibration checks
- Within center calibration reproducibility within 2.5%
- Between center calibration standardization

Acceptability and reproducibility checks of electronic tracings
- Evaluate quality and compare with technician's quality code
- Acceptability will be evaluated on the following criteria:
  a. smooth continuous exhalation
  b. apparent maximal effort
  c. and without the following discredits
     -coughing
     -early termination of expiration (forced expiration must continue for at least 6 seconds; the end of the FVC maneuver is defined by a volume change that has decreased to less than 0.025 liters over 0.5 seconds)
     -a leak
     -obstructed mouthpiece
     -unsatisfactory start
     -excessive variability between the three acceptable curves
- Hand measure paper tracings of randomly selected 10% sample

Data management
- Print record identifier and compare with transmittal forms
- Backup files received from Field Centers
- Store original and standardized curve data
- Calculate and store indices of flow and volume from individual spirogram records
- Format indices of standardized flow and volume for transmittal to Coordinating Center
- Make copies of files sent to Coordinating Center

Statistical quality control of grouped field center data
- Compare sex and race specific regressions on age and height of healthy non-smoking participants: between centers, with the same center on previous occasions and with predicted values.

Reports
- Prepare weekly report for Field Centers (see Appendix I, page 84) regarding:
  a. status of data received
     1. number of records on disk
     2. number of paper tracings received
     3. number of acceptable records and percent of total

ARIC Pulmonary Reading Center
Pulmonary Function Procedures, cont.

b. acceptability and quality
   1. number of unacceptable tracings for each acceptability criteria
   2. percent of quality code agreement
   3. identify tracings that disagree on quality code

c. sample tracings sent (see pages 86 -89)
   1. identify tracing (date, technician, participant)
   2. comments on technician's measurements and quality of test
   3. compare pulmonary reading center's measurements with field centers' measurements
   4. compare pulmonary reading center's measurements with computer's measurements

Prepare report for Coordinating Center on data being transmitted, and on status of quality codes, reproducibility and calibration for each Field Center (see page 93)

ARIC Coordinating Center
Pulmonary Function Procedures

COORDINATING CENTER

Data Management
- Add formatted files of individual spirometric flow and volume received from Pulmonary Reading Center to database
- Backup files
- Erase files from floppy disks and return to Field Centers for future data transfers

Reports
- Prepare report to Pulmonary Reading Center on files received from the Field Centers
- Prepare report to Field Centers on files received from Pulmonary Reading Center

12. TERMS AND SYMBOLS

12.1 General

1. STPD - Standard conditions: temperature at 24C, barometric pressure 760 mmHg (760 torr) and dry (0 torr water vapor).

2. BTPS - Body conditions: Body temperature (usually 37C), ambient barometric pressure and saturated with water vapor (usually 47 torr water vapor) at these conditions.

3. ATPD - Ambient temperature, pressure and dry.

4. ATPS - Ambient temperature, pressure and saturated with water vapor.

5. BP - Barometric pressure, usually in mmHg (or torr).

6. C - Degrees Centigrade.

7. F - Degrees Fahrenheit.

8. l - liters.

12.2 Equations

12.2.1 BTPS Correction Factors

Factor to Convert Vol to 37C. Sat	When Gas Temperature (Centigrade)
1.112	18
1.107	19
1.102	20
1.096	21
1.091	22
1.085	23
1.080	24
1.074	25
1.069	26
1.063	27
1.057	28
1.051	29

12.2.2 Arm Span Factors for Participants with Severe Spinal Deformities

Correction for Height.

Male - Ht. = Arm Span/1.03
Black Males - Ht. = Arm Span/1.06
Female - Ht. = Arm Span/1.01

12.2.3 Height

1. From inches to centimeters - Multiply by 2.54
2. From centimeters to inches - Divide by 2.54

12.2.4 Barometric Pressure

1. From inches of mercury to millimeters of mercury multiply by 25.4

12.2.5 Temperature

1. From Centigrade to Fahrenheit - (9/5 X C) + 32
2. From Fahrenheit to Centigrade - 5/9 X (F - 32)

12.2.6 ATPS (Ambient Temperature & Pressure Saturated with Water)

12.2.6.1 ATPS to STPD

STPD = PB - PH20/760 X 273/(273 + T)
PH20 = Water Vapor Pressure at Ambient Temperature C

12.2.6.2 ATPS to BTPS

BTPS = [(273 + 37)/(273 + T)]*[(PB - PH20)/(PB - 47)]
T = ambient temperature
PB = Atmospheric pressure mmHg
Water Vapor Pressure (see 12.3.1)

12.2.7 ATPD (Ambient Temperature & Pressure, Dry)

12.2.7.1 ATPD to STPD - PB/760 X 273/(273+T)

12.2.7.2 ATPD to BTPS - PB/PB-47 X 310/(273+T)

12.2.7.3 ATPD to ATPS - PB/PB-PH20

12.2.8 BTPS (Body Temperature and Atmospheric Pressure, Completely Saturated with Water Vapor at Body Temperature)

12.2.8.1 BTPS to STPD - PB-47/760 X 273/310

12.2.8.2 BTPS to ATPS - PB-47/PB-PH20 X 273+T/310

12.2.8.3 BTPS to ATPD - PB-47/PB X 273+T/310

12.2.9 STPD (Standard Temperature and Pressure, Dry)

12.2.9.1 STPD to BTPS - 760/PB-47 X 310/273

12.2.9.2 STPD to ATPS - 760/PB-PH20 X 273+T/273

12.2.9.3 STPD to ATPD - 760/PB X 273+T/273

Appendix I. Sample Reports

A. Weekly Report from field center to Pulmonary Function Reading Center

1. Log sheet
2. Listing of mailer disk
3. 10% sample of spirograms

B. Weekly Progess Report to the field center from the Pulmonary Function Reading Center

1. Summary page which includes:

   a) Confirmation of records and tracings received
   b) Proportion of acceptable records and tabulation of problems among the unacceptable records
   c) Proportion of agreement between field center and Pulmonary Function Reading Center quality codes
   d) Proportion of acceptable calibrations.

2. Electronic evaluation of acceptability and quality.

3. Hand measured evaluation of randomly selected spirograms.

4. Flow-volume plot of randomly selected spirograms.

C. Weekly Report to Coordinating Center from Pulmonary Function Reading Center

1. Listing of participants whose processed records were included on floppy disk.

2. Copy of field center report as noted above (except #2).
   Electronic Evaluation of Acceptability and Quality
   field center: Washington Co, MD Date: 07-17-1987

DAILY SPIROMETER LOG

Instructions: Complete this form every day. Keep this form in your spirometry notebook and send a good photocopy to the Pulmonary Reading Center weekly.

Daily Checks

Date/Technician Code							
Water Level/Temperature							
Pen Line (width/intensity) (Check if acceptable; star if pen replaced)							
Baseline (Check if acceptable; star if correction needed)							
Time Check (Seconds per 2 rotations) Accept 29.7 - 30.3 seconds							
Leak Check (ml drop per 2 rotations) Accept leak up to 10 cc.							
Linearity Check Accept linearity up to 0.100 Record slope: Record linearity:							
Volume Check After connecting open 3 liter syringe, Record volume From screen: From chart paper: Add 3 liters and record new volume From screen: From chart paper: Accept New Volume of 2.95 - 3.05 L. Record baseline volume From screen: From chart paper:							
Disconnect and clean hose							

Weekly Checks

	Dates	
	Current	Previous
MRP Calibration Error: Positive_____ Negative_____		
Empty and clean spirometer		

Volume Number

Field Center
Archive Disk_____

Pulmonary Reading Ctr
Mailer Disk_____

Version 8 (12/89)

Patient Directory - Ordered by Names in Drive C:

Names	ID Numbers	Date
Name A	W138737	07-02-87
Name B	W138005	06-29-87
Name C	W138694	07-02-87
Name D	W137923	06-29-87
Name E	W137891	06-29-87
Name F	W106364	06-29-87
Name G	W128450	07-01-87
Name H	W128559	07-01-87
Name I	W135178	07-02-87
Name J	W138071	06-30-87
Name K	W138060	06-30-87
Name L	W138106	06-30-87
Name M	W138119	06-30-87
Name N	W137996	06-29-87
Name O	W137935	06-29-87
Name P	W138480	07-01-87
Name Q	W138534	07-01-87
Name R	W138529	07-01-87
Name S	W138590	07-02-87
Name T	W138633	07-02-87
Name U	W138495	07-01-87

Tracings to be read for the week ending 02/17/88.

Please read the tracings from the 3 best tests for each of the participants who are listed below. Send the following to the Pulmonary Reading Center for the week ending 02/17/88:

1. this listing
2. the daily spirometer log
3. the mailer diskette
4. the directory of the mailer diskette
5. tracings for participants who are not on the comptuer
   Check that the tracings include ID, name, date, age, height, sex, race, technician code and temperature.
6. the measured tracings for the participants listed below

Date of Test	ID	Name	Technician
02-01-1988	M120624	PARTICIPANT NAME	001
02-03-1988	M125136	PARTICIPANT NAME	067
02-03-1988	M126785	PARTICIPANT NAME	036
02-05-1988	M131993	PARTICIPANT NAME	019

WEEKLY PROGRESS REPORT FROM THE PULMONARY FUNCTION READING CENTER
TO THE FIELD CENTER AT WASHINGTON COUNTY, MD

Date: 7/17/87

For the period 7/8/87 to 7/10/87 we have received:

9 records on 1 disk
3 paper tracings from a sample of participants

Our reading of the mailer disk has shown:
6 acceptable participant records 67%

Of the unacceptable records we found:

1 Borderline submaximal effort (FEV1's reproducible)
1 Cough/inhalation present
1 Breath-hold leak and submaximal effort

Of the acceptable tracings we agree with your assigned quality code in 6 participant records 100%

Of the acceptable tracings 6 were found to be reproducible. 100%

From 7/8/87 to 7/10/87 we have received:

3 calibrations

	# of times calibration within range	Rate
Time Check (29.7 - 30.3)	3	100%
Leak Check (10cc/30 sec)	3	100%
Linearity Check (<0.1)	3	100%
Volume Check		
Computer (2.91-3.09 L)	3	100%
Chart paper (2.91-3.09 L)	3	100%

Electronic evaluation of Acceptability & Quality

Acceptability codes:
1 = Spirometer not calibrated correctly
2 = Computer started after start of expiration
3 = Breath-hold leak > 5% of FVC
4 = Submaximal effort (rounded peak on FVL loop)
5 = Cough/inhalation present
6 = No plateau (and tests not carried to 10 sec)
7 = Low water level in spirometer
9 = Flow-volume loop not stored

*Reading center and field center quality codes disagree

Quality codes:
1 = Spirograms last at least 6 seconds, tracings reproducible, smooth with continuous transition of slope.
2 = Spirograms last at least 6 seconds, tracings reproducible but irregular.
3 = Spirograms last less than 6 seconds, tracings reproducible, smooth with continuous transition of slope.
4 = Spirograms last less than 6 seconds, tracings reproducible but irregular.
5 = Spirograms not reproducible.
9 = Flow-volume loop not stored.

Calculation of acceptability and quality codes has been done on the following:

Technician	Participant	ID	Date	Acceptable	Reading Center Quality Code	Field Center Quality Code	
031	PARTICIPANT NAME W560	W139447	07-08-1987	No	5	5	
		Acceptability code(s): 3,4					
006	PARTICIPANT NAME W561	W139766	07-08-1987	No	1	1	
		Acceptability code(s): 4 Borderline					
006	PARTICIPANT NAME W562	W139973	07-09-1987	Yes	1	1	
026	PARTICIPANT NAME W563	W140071	07-09-1987	No	5	2	*
		Acceptability code(s): 5					
031	PARTICIPANT NAME W564	W140005	07-09-1987	Yes	1	1	
031	PARTICIPANT NAME W565	W140018	07-09-1987	Yes	1	1	
006	PARTICIPANT NAME W566	W140188	07-10-1987	Yes	1	1	
031	PARTICIPANT NAME W567	W140170	07-10-1987	Yes	1	1	
031	PARTICIPANT NAME W568	W140220	07-10-1987	Yes	1	1	

ARIC Quality Control Report for Randomly Selected Spirograms in Washington County, Maryland

Date of Test 07/08/87

TECHNICIAN 026

PARTICIPANT W139540 PARTICIPANT NAME

COMMENTS

BREATH-HOLD LEAK > 5% OF FVC.
BORDERLINE SUBMAXIMAL EFFORT - SEE FVL GRAPH. THE LOOPS DO NOT RISE SHARPLY TO A PEAK, BUT THE FEV1'S ARE REPRODUCIBLE. IN YOUR COACHING & DEMONSTRATIONS BE SURE TO EMPHASIZE THE IMPORTANCE OF THAT FIRST BLAST OF AIR THE PARTICIPANT BLOWS OUT. "BLASTING" THE AIR OUT AS SOON AS SHE PUT THE MOUTHPIECE IN HER MOUTH MAY HAVE PREVENTED BOTH PROBLEMS (LEAK & SUBMAXIMAL EFFORT).

Comparison of Measured Results at Pulmonary Reading Center and Field Center

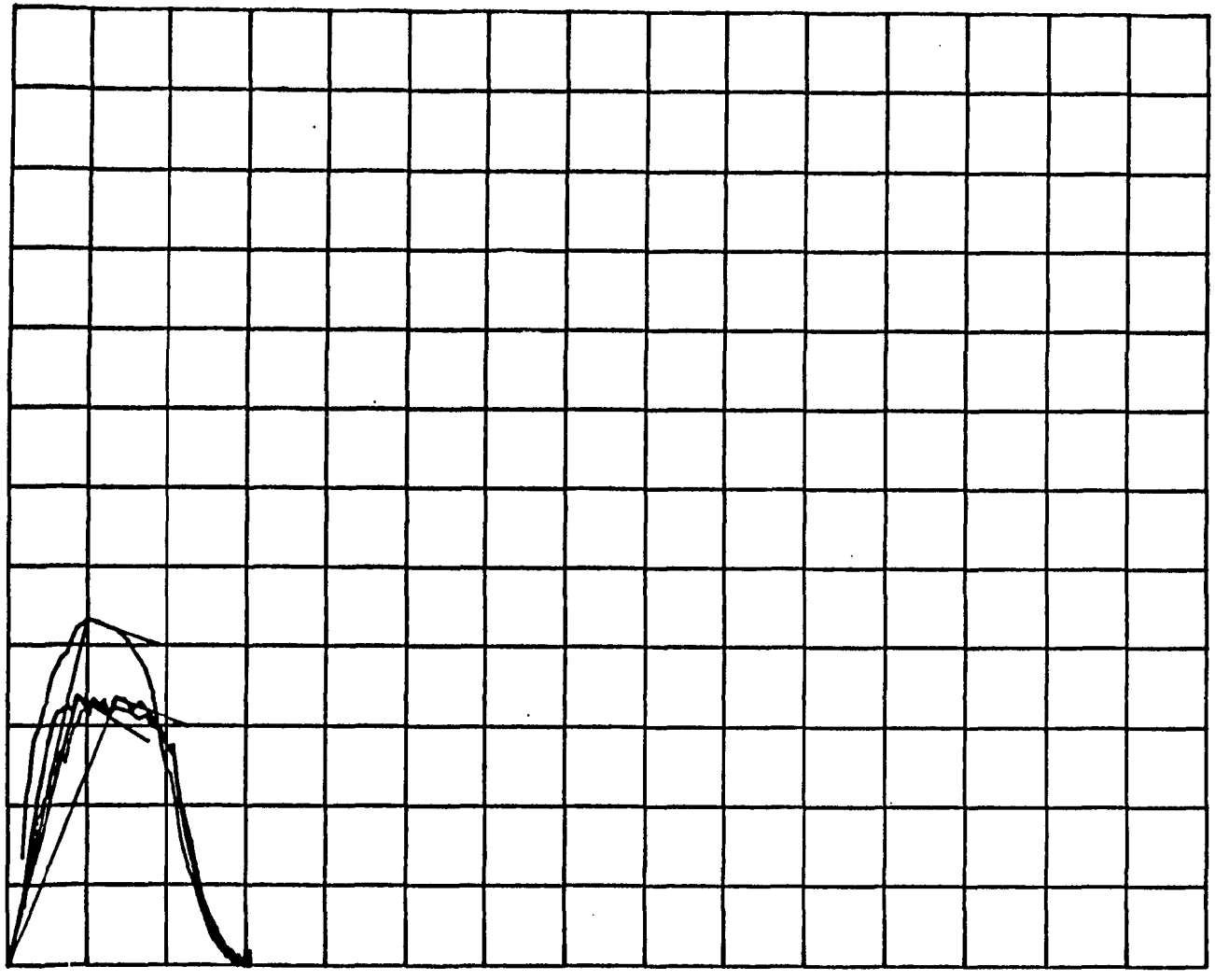
	PULMONARY CENTER	FIELD CENTER	% DIFFERENCE *
FVC	2.98	2.98	0.00
FEV1	2.51	2.51	0.00

Comparison of Measured Results to Computer Results

	MEASURED	COMPUTER	% DIFFERENCE *
FVC	2.98	3.05	-2.35
FEV1	2.51	2.52	-0.40

* Differences < 3% are acceptable

E:\WASH\W552
W139540




```
* Peak vol = 1.002.
. Angle 1  = 83.30.
Pre-slope  =  4.32.
Peak flow  =  4.33.
.      FEV1 = 2.516.
.       FVC = 3.043.

. Peak vol = 1.385.
. Angle 2  = 88.89.
Pre-slope  =  2.42.
Peak flow  =  3.35.
.      FEV1 = 2.489.
.       FVC = 3.019.

* Peak vol = 0.890.
. Angle 3  = 72.77.
Pre-slope  =  3.78.
Peak flow  =  3.36.
.      FEV1 = 2.507.
.       FVC = 3.007.


% dif pre-slopes= 12.5.
% dif peak-flows= 22.4.
```

ARIC Quality Control Report
for Randomly Selected Spirograms
in Washington County, Maryland

Date of Test 07/10/87

TECHNICIAN 031

PARTICIPANT W139088 PARTICIPANT NAME

COMMENTS

GOOD TESTS WITH MAXIMAL EFFORT.
WHEN THE BASELINE IS BELOW ZERO THE DISTANCE BELOW ZERO SHOULD BE ADDED TO YOUR MEASUREMENTS.

Comparison of Measured Results at Pulmonary Reading Center and Field Center

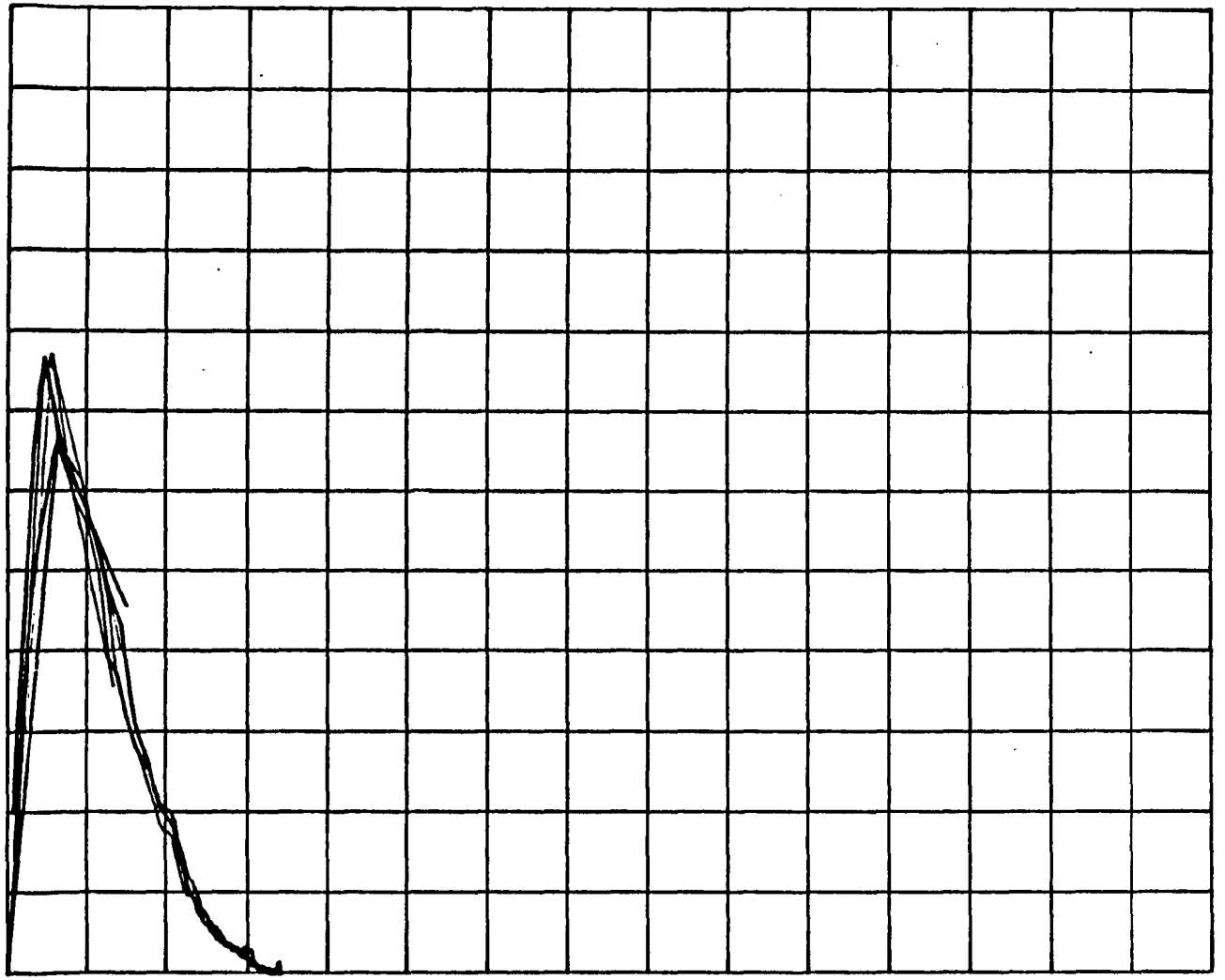
	PULMONARY CENTER	FIELD CENTER	% DIFFERENCE *
FVC	3.35	3.35	0.00
FEV1	2.55	2.52	1.18

Comparison of Measured Results to Computer Results

	MEASURED	COMPUTER	% DIFFERENCE *
FVC	3.35	3.43	-2.39
FEV1	2.55	2.57	-0.78

* Differences < 3% are acceptable

E: \WASH\W569
W139088




```
* Peak vol = 0.466.
. Angle 1  = 15.59.
Pre-slope  = 16.42.
Peak flow  =  7.66.
.      FEV1 = 2.496.
.       FVC = 3.400.

* Peak vol = 0.555.
. Angle 2  = 17.58.
Pre-slope  = 13.88.
Peak flow  =  7.70.
.      FEV1 = 2.550.
.       FVC = 3.419.

. Peak vol = 0.643.
. Angle 3  = 27.97.
Pre-slope  = 10.32.
Peak flow  =  6.64.
.      FEV1 = 2.511.
.       FVC = 3.402.


% dif pre-slopes= 15.5.
% dif peak-flows=  0.6.
```

Weekly Report to Coordinating Center from Pulmonary Reading Center

Batch number: ARPZ0015.DAT

Date: 07-14-1987

Record # in batch	File name	Participant ID	Date of test	PF Sequence number
1	E:F377.DAT	F134774	06/22/87	002221
2	E:F378.DAT	F131779	06/22/87	002222
3	E:F379.DAT	F132688	06/22/87	002223
4	E:F380.DAT	F134668	06/22/87	002224
5	E:F381.DAT	F134138	06/22/87	002225
6	E:F382.DAT	F134707	06/22/87	002226
7	E:F383.DAT	F132739	06/23/87	002227
8	E:F384.DAT	F132795	06/23/87	002228
9	E:F385.DAT	F132724	06/23/87	002229
10	E:F386.DAT	F134341	06/23/87	002230
11	E:F387.DAT	F132692	06/23/87	002231
12	E:F388.DAT	F131918	06/24/87	002232
13	E:F389.DAT	F132518	06/24/87	002233
14	E:F390.DAT	F134569	06/24/87	002234
15	E:F391.DAT	F134602	06/24/87	002235
16	E:F392.DAT	F134550	06/24/87	002236
17	E:F393.DAT	F134763	06/30/87	002237
18	E:F394.DAT	F122237	06/30/87	002238
19	E:F395.DAT	F135051	06/30/87	002239
20	E:F396.DAT	F134095	06/30/87	002240
21	E:F397.DAT	F134982	06/30/87	002241
22	E:F398.DAT	F133126	07/01/87	002242
23	E:F399.DAT	F131926	07/01/87	002243

Appendix II. Troubleshooting

Unsuccessful spirometry may be due to operator or equipment malfunction. This troubleshooting guide is to help direct the operator to where the problem may be. In any case, it is not designed to serve as a repair guide. Any problems of a serious nature should be directed to S&M Instruments or the Pulmonary Function Reading Center as soon as possible.

The first rule of troubleshooting is "There are three things to check before calling for service - CONNECTIONS, CONNECTIONS, and CONNECTIONS."

A. Troubleshooting Guide - Hardware

Problem	Cause/Solution
When computer is turned on, no display on video monitor, disk drive light off.	1. Power cable not connected to monitor and/or CPU. 2. No power to IBM. 3. No power to monitor (green light off) 4. Wall outlet power off.
When computer is turned on, no display on video monitor, disk drive light comes on.	1. Monitor not turned on, no power to monitor. 2. Video cable not properly attached to graphics board. 3. Bad graphics board or loose fit in CPU. Re-insert or repair color graphics. 4. No power to CPU unit only. 5. Check brightness control.
Keys pressed on keyboard are ignored (after program is loaded).	1. Keyboard not properly connected or in need of repair.
Printer fails to print when command is given. "Funny" characters printed instead of graphic or data display.	1. Execute printer command. 2. Check that printer is on-line. If not, re-boot with CTRL, ALT, and DEL keys after turning printer on. Must be on before turning on IBM. 3. Blown fuse on printer. 4. Cable from printer to printer card not connected. 5. Failure of internal board on printer. 6. Failure of printer card. 7. Fault light on printer on a. No paper in printer b. Printer internal failure.

B. Troubleshooting Guide - Software

Problem	Cause/Solution
Program disk does not load - Screen displays the C> character	1. System is in IBM DOS system. Type "Go", press ENTER. Use back-up disk - may be disk media failure, poor copy or electrical interference destroyed some or all of disk.
No disk will load - S&M or other source	1. Hardware failure - have IBM serviced.
Read error on video screen	1. IBM turned on with disk drive open. Close drive door and re-start the system.
No volume and/or flow when spirometry is performed.	1. Check to see if cable from PSII interface to spirometer is connected. 2. Spirometer output functional electric spirometers must be on and in operate mode. 3. A/D interface requires service.

C. Troubleshooting Guide - Calibration and Testing

Problem	Cause/Solution
Low water level	See Section 6.2
Faint pen line	See Section 6.4
Failure of pen to rest on baseline	See Section 6.5
Time check outside acceptable range	See Section 6.6
Leak	See Section 6.6
Alinearity	See Section 6.7
Volume calibration error	See Section 6.8
Error entering participant information	See Section 7.2
Unacceptable Spirometry Technique	See Sections 8.1 - 8.6
Illustrations	See pages 45 - 51
Reading Center criteria	See Section 11.4

Appendix III. Configuration (CON)--Set-up Routine

New S&M program disks should be reviewed for proper configuration. This should be done only when the system is first being set up. When the MENU is displayed, type CON to access the Configuration MENU. The following will be displayed on the screen:

SYSTEM CONFIGURED FOR:

1. Volume Output only
2. Auto - Scale FVL (On)
3. Information (Enter Race)
4. Color
5. Expired Only
6. Normal INF
8. Participant Data Storage on Drive C:
9. Printer - IBM or Oki-92(Plug'n Play)
12. Inspired to Expired Loop must be 80 %
13. No graph on Data Sheet
14. A/D Address is 640 Dec.
18. Extrapolate FEF 25-75

ENTER # TO CHANGE (ENTER TO END)

In the following, the default selections are indicated by * :

1. SPIROMETERS
   1. Med-Science (flow and volume output)
   2. Morgan with Diff
   3. Ohio with Diff (Ohio 840, 842 with Diff)
   *4. Volume Output Only (Ohio 827, Collins Survey, Stead-Wells, Jones, Breon)
   5. Jaeger (Pneumotach)
   6. Vitalograph

   ENTERED DESIRED OPTION (PRESS ENTER)
   ENTER key only will select the default [*] option.

2. AUTO-SCALE FVL (On)
   1. Auto-Scale FVL (Off)
   *2. Auto-Scale FVL (On)

   With Auto-Scale ON the flow-volume loop will be drawn with a smaller volume axis.

3. INFORMATION (Enter Race)
   1. No Race
   *2. Race

   Option #2 will ask for race in the information (INF) program (White, Black, American Indian/Alaskan Native, Asian/Pacific Islander) and will reduce predicted spirometry values by 12% for non-whites.

4. COLOR
   1. Monochrome
   *2. Color

   Option #2 requires user to have color graphics board with composite monitor for graphic displays.

   Option #2 displays graphics on a color monitor.

5. INSPIRED/EXPIRED LOOP
   1. Inspired/Expired Loop
   *2. Expired Only

   Option #2 only allows plotting of expired curve of FVL.

6. NORMAL INF

8. PARTICIPANT STORAGE ON DRIVE C
   For dual drive system, configure for storage on drive B and insert STORAGE disks in drive B.

   For XT system, configure for storage on disk C or D.

9. PRINTER
   *1. IBM or Oki-92
   2. C.ITOH B/W -black ribbon only
   3. C.ITOH Color - four color ribbon
   4. C.ITOH Color (Blue DS) - four color ribbon printing data sheet in blue only
   5. Epson (JX) B/W - black ribbon only
   6. Epson (JX) Color - four color ribbon
   7. IBM or C.ITOH-EP B/W - black ribbon only
   8. IBM or C.ITOH-EP Color - four color ribbon only
   9. IBM or C.ITOH-EP Color (Blue DS) - four color ribbon printing data sheet in blue only

12. INSPIRED to EXPIRED LOOP MUST BY 80%
   *1. Inspired to Expired Loop must be 80%
   2. Inspired to Expired Loop must be 85%
   3. Inspired to Expired Loop must be 90%
   4. Inspired to Expired Loop must be 95%

   Ratio of FIVC/FEVC must be a minimum of 80% for inspiratory flows to be calculated. Less than 80% constitutes submaximal effort.

13. FVL-VT on DATA SHEET
   *1. No graph on Data Sheet
   2. FVL (HiRes) on Data Sheet
   3. FVL (Color) on Data Sheet
   4. FVL-VT on Data Sheet
   5. VT (HiRes) on Data Sheet
   6. VT (Color) on Data Sheet
   7. VL-VT (Color) on Data Sheet

Note: Color selection will also display on color monitor if screen display only is selected. Do NOT select option #7 for Epson or C.ITOH-EP. Color graphs selection for final report will print in graphics mode on black ribbon printers.

14. A/D ADDRESS

Do not change A/D address without consulting S&M Instrument Company (pre-set to 640).

18. EXTRAPOLATE FEF 25-75

ENTERING FIELD CENTER NAME

1. The field center name which appears on the final Participant Data Sheet is entered only once during the configure [CON] program.

2. After all of the CON options are selected and entered, press ENTER. The screen will show the last entered name and will prompt for changes. Enter the name of the field center and respond "Y" when asked "OK TO SAVE DATA [Y/N]". The program then loads and displays the main MENU or INDEX.

3. Entering INI (initialize) - if the configure has been performed, it is necessary to lock-in the field center name which has just been entered. To do this, wait for the main Pulmonary Menu to display on the screen and then type INI. The screen displays the message INITIALIZING PARTICIPANT FILES followed by the MENU display again. The field center name will now appear throughout the program and on the final data sheet.

CAUTION: If initialize [INI] is run on a previously used (i.e. reconfigured disk), ALL STORED PARTICIPANT DATA AND CALIBRATION ADJUSTMENT FACTORS ARE REMOVED PERMANENTLY. It is, therefore, suggested that any INI command be followed immediately by the ADJ-CALIBRATE VOLUME and FLOW procedure to assure accurate spirometry results. After a new disk is initialized, run ADJ before beginning any participant testing.

Appendix IV. Prediction Equations

Prediction Equations: MALE - age equal to or greater than 25

Parameter	Equation	Reference
FVC	0.0600H - 0.0214A - 4.650	Crapo
FEV_1	0.0414H - 0.0244A - 2.190	Crapo
FVC	0.065H - 0.29A - 5.459	Knudson
$FEV_{0.5}$	0.037H - 0.017A - 2.746	Knudson
FEV_1	0.052H - 0.027A - 4.203	Knudson
FEV_3	0.063H - 0.031A - 5.245	Knudson
FEV_1/FVC	-0.087H - 0.14A + 103.64	Knudson
FEF200-1200	0.28H - 0.47A + 2.01	Morris
PF	0.094H - 0.035A - 5.99	Knudson
FEF25%	0.088H - 0.035A - 5.618	Knudson
FEF50%	0.069H - 0.015A - 5.4	Knudson
FEF75%	0.044H - 0.012A - 4.143	Knudson
FEF25-75	0.045H - 0.031A - 1.864	Knudson
FEF75-85	0.03H - 0.023A + 1.21	Morris

Height expressed in centimeters

Prediction Equations: FEMALE - age equal to or greater than 20

Parameter	Equation	Reference
FVC	0.0491H - 0.0216A - 3.590	Crapo
FEV_1	0.0342H - 0.0255A - 1.578	Crapo
FVC	0.37H - 0.022A - 1.774	Knudson
$FEV_{0.5}$	0.019H - 0.014A - 0.406	Knudson
FEV_1	0.027H - 0.021A - 0.794	Knudson
FEV_3	0.035H - 0.023A - 1.633	Knudson
FEV_1/FVC	-0.11H - 0.109A + 107.38	Knudson
FEF200-1200	0.37H - 0.036A - 2.532	Morris
PF	0.049H - 0.025A - 0.735	Knudson
FEF25%	0.043H - 0.025A - 0.132	Knudson
FEF50%	0.035H - 0.013A - 0.444	Knudson
FEF75%	- 0.014A + 3.042	Knudson
FEF25-75	0.021H - 0.24A + 1.171	Knudson
FEF75-85	0.06H - 0.021A + 0.321	Morris

Height expressed in centimeters

Appendix V. Equipment, Supplies and Vendors

Replacement Equipment and Supplies

The maintenance and supply kit provided with the S&M Pulmo-Screen II system includes:

1. S&M Pulmo-Screen II Instruction Manual
2. IBM PC manuals: Guide to Operations, BASIC Manual, DOS Manual and Printer Manual
3. Collins one-year warranty
4. Disposable mouthpieces
5. Disposable noseclips
6. Disposable recording pens
7. Kymograph chart paper with adhesive strip
8. Metal leak tester (weight) (Collins Cat. # 021525)
9. 3-liter calibrated syringe (Rudolph Cat. # 5528)
10. Rudolph one-way valve with Stopcock (Rudolph Cat. # 2150)

Extra spirometry supplies which should be on hand are:

1. Large disposable cardboard mouthpieces
   Dispenser of 90 mouthpieces (Collins Cat. # 22401)
2. Disposable noseclips (A-M Systems Cat. # NC-100)
3. Disposable recording pens (red) (Collins Cat. # 22411)
4. Kymograph chart paper with adhesive strip
   100 Sheets - 9" x 19-5/8" (Collins Cat. # 22037)
5. 2- participant breathing tubes 1-1/2" I.D. each consisting of:
   1- 34" plastic spiral tubing (Collins Cat. # 022263)
   2- 1-3/8" moulded tubing ends (Collins Cat. # 022254)
6. 2- internal breathing tubes 1-1/8" I.D. each consisting of:
   1- 13" plastic spiral tubing (Collins Cat. # 022261)
   2- 1-3/8" moulded tubing ends (Collins Cat. # 022253)
7. Tubing cement (Collins Cat. # 022977)
8. Metal leak tester (weight) (Collins Cat. # 021525)
9. Mercury thermometer (Collins Cat. # 22949)
10. Stead-Wells plastic spirometer bell (Collins Cat. # 700322)
11. Stopwatch
12. Pliobond glue (flexible contact cement) for repairing leaks

Other Supplies (purchase locally):

1. Cidex
2. Vinegar
3. Silicon spray lubricant
4. Rubber stoppers, size 7
5. Alcohol wipes
6. Q-tips (6 inch)
7. Smelling Salts
8. A power strip with grounded outlets, circuit breaker, pilot lights, line voltage suppressor, and master switch.
9. Allen wrench

Vendors and Technical Advice

Replacement equipment and supplies may be obtained from the companies listed below.

1. Spirometer, spirometry supplies

   Warren E. Collins, Inc.
   220 Wood Road
   Braintree, MA 02184
   Phone: 1-800-225-5158

   A-M Systems, Inc.
   917 134th Street
   Everett, WA 98204

2. 3-liter calibration syringe, metal; valves, stopcock

   Hans Rudolph, Inc.
   7200 Wyandotte
   Kansas City, MO 64114
   Phone: (816) 363-5522

The accuracy of each syringe will be verified by returning it to the manufacturer for measurement of its water displacement every year during the study or whenever any evidence of physical damage to the syringe is noticed.

3. Pulmo-Screen A/D pulmonary interface, software and spirometry supplies.

   S&M Instrument Company
   202 Airport Blvd.
   Doylestown, PA 18901
   Phone: (215) 345-9232

4. Pathophysiology, epidemiology, methods and procedures of pulmonary function measurement (Dr. Melvyn Tockman)
   ARIC Pulmonary Function Data Management (Michele Donithan)

   The ARIC Pulmonary Function Reading Center
   Johns Hopkins School of Hygiene and Public Health
   Room 7517
   615 N. Wolfe Street
   Baltimore, MD 21211
   Phone: (301) 955-4587

Appendix VI. File Format for Pulmonary Function Records

The files should be reformatted into fixed length ASCII records with the formats given below. Note that these formats may be changed at some point without this manual necessarily being revised. Please contact the Coordinating Center to verify the current layout.

Columns	Contents
1-7	Participant ID
8-12	Blanks
13-15	Form Code = PFT
16	Version = B
17	Record Type = D
18	ARIC Study Code = 3
19-21	Record type numeric code = 086
22	Record type version number = 1 (A=0, B=1, etc.)
23-24	Contact Year = 04
25-42	Blanks
43-44	Update level: A two digit numeric field which identifies which revision of the record this is. Every record begins as update level 00 when created. Each time changes are made to a record, the update level is incremented by 1.
45-52	Date of Record Creation (MM/DD/YY)
53-57	Time of Record Creation (HH:MM) 24-hour clock
58-60	Blanks
61-68	Date of previous record (MM/DD/YY). (Blank if no previous record)
69-73	Time of previous record (HH:MM). (Blank if no previous record.)
74	Transaction type A - Add a new record C - Change the record D - Delete the record
75-77	Volume ID and Workstation ID (00A)
78-83	Sequence number: A six digit numeric field, incremented each time a record is formatted for transmission to the Coordinating Center.
84-98	Blanks
99-138	Participant Name (last first initial)
139	Status Code
140	Sex (M, F)
141	Status Code

Columns	Contents
142-156	Blanks
157-161	Height (inches)
162	Status Code
163-164	Age (years)
165	Status Code
166-171	Blanks
172-176	Volume Calibration
177	Status Code
178-182	Flow Offset
183	Status Code
184-188	Flow Calibration
189	Status Code
190-196	Acceptability code detail for best test (0000000=acceptable)
190	0=spirometer calibrated 1=spirometer not calibrated correctly 9=no flow-volume loop stored for calculation of acceptability
191	0=good start 1=computer started after start of expiration 9=no flow-volume loop stored for calculation of acceptability
192	0=no breath-hold leak 1=breath-hold leak > 5% 9=no flow-volume loop stored for calculation of acceptability
193	0=maximal effort 1=submaximal effort 2=borderline maximal effort 9=no flow-volume loop stored for calculation of acceptability
194	0=no cough or inhalation 1=cough/inhalation present 9=no flow-volume loop stored for calculation of acceptability
195	0=plateau 1=no plateau 2=borderline plateau 9=no flow-volume loop stored for calculation of acceptability
196	0=water level is adequate 1=low water level in spirometer 9=no flow-volume loop stored for calculation of acceptability

Columns	Contents
197	Status Code
198-202	Blanks
203-204	Number of pulmonary function tests done
205	Status Code
206-212	Acceptability code detail for second best test (0000000=acceptable)
206	0=spirometer calibrated 1=spirometer not calibrated correctly 9=no flow-volume loop stored for calculation of acceptability
207	0=good start 1=computer started after start of expiration 9=no flow-volume loop stored for calculation of acceptability
208	0=no breath-hold leak 1=breath-hold leak > 5% 9=no flow-volume loop stored for calculation of acceptability
209	0=maximal effort 1=submaximal effort 2=borderline maximal effort 9=no flow-volume loop stored for calculation of acceptability
210	0=no cough or inhalation 1=cough/inhalation present 9=no flow-volume loop stored for calculation of acceptability
211	0=plateau 1=no plateau 2=borderline plateau 9=no flow-volume loop stored for calculation of acceptability
212	0=water level is adequate 1=low water level in spirometer 9=no flow-volume loop stored for calculation of acceptability
213	Status Code
214-216	Blanks
217-220	Spirometer Temperature (Celsius)
221	Status Code
222-227	Blanks

Columns	Contents
228-230	Race 0=white 1=black 2=American Indian/Alaskan 3=Asian/Pacific Islander
231	Status Code
232-239	FVC Predicted (liters)
240	Status Code
241-248	$FEV_{0.5}$ Predicted (liters)
249	Status Code
250-257	FEV_1 Predicted (liters)
258	Status Code
259-267	FEV_1/FVC Predicted (liters)
268	Status Code
269-276	FEV_1/FEV_6
277	Status Code
278	Blank
279-286	PEFR Predicted
287	Status Code
288-295	FEF_{25} Predicted
296	Status Code
297-304	FEF_{50} Predicted
305	Status Code
306-313	FEF_{75} Predicted
314	Status Code
315-322	FEF_{25-75} Predicted
323	Status Code
324-332	File Name of Pulmonary Function Reading Center system
333	Status Code
334-344	Blanks
345-352	FEV_3/FVC Predicted
353	Status Code
354-356	Blanks

BTPS corrected volumes:

357-364	FVC (liters)
365	Status code
366-373	$FEV_{0.5}$ (liters)
374	Status Code
375-382	FEV_1 (liters)
383	Status Code
384-391	FEV_3 (liters)
392	Status Code

Columns	Contents
393-400	FEV_6 (liters)
401	Status Code
402-409	FEV_3/FEV_6
410	Status Code
411-418	$FEV_{0.5}/FVC$
419	Status Code
420-427	FEV_1/FVC
428	Status Code
429-436	FEV_3/FVC
437	Status Code
438-445	Date of last calibration
446	Status Code
447-454	PEFR
455	Status Code
456-463	FEF_{25}
464	Status Code
465-472	FEF_{50}
473	Status Code
474-481	FEF_{75}
482	Status Code
483-490	FEF_{25-75}
491	Status Code
492-496	Time of last calibration
497	Status Code
498	Acceptability Code 0=acceptable 1=not acceptable 9=unable to assess acceptability
499	Status Code
500-504	Time to best FVC (seconds)
505	Status Code
506	Technician's Quality Code (1-5) 1=spirograms last at least 6 seconds, tracings reproducible, smooth with continuous transition of slope. 2=spirograms last at least 6 seconds, tracings reproducible, but irregular. 3=spirograms last less than 6 seconds, tracings reproducible, smooth with continuous transition of slope. 4=spirograms last less than 6 seconds, tracings reproducible, but irregular. 5=spirograms not reproducible.

Columns	Contents
507	Status Code
508	Reading Center Quality Code (computer generated) 1=spirograms last at least 6 seconds, tracings reproducible, smooth with continuous transition of slope. 2=spirograms last at least 6 seconds, tracings reproducible, but irregular. 3=spirograms last less than 6 seconds, tracings reproducible, smooth with continuous transition of slope. 4=spirograms last less than 6 seconds, tracings reproducible, but irregular. 5=spirograms not reproducible. 9=unable to assess quality
509	Status Code
510-512	Pulmonary Technician Code
513	Status Code
514-518	Reasons for Test Postponement
514	History of aneurysm or BP $\geq$ 200/120 1=yes 2=no 0=not asked
515	History of MI or chest/abdominal surgery in past 6 weeks 1=no 2=yes 0=not asked
516	Flu, bronchitis, or pneumonia within past 3 weeks
517	Status Code
518-519	Blanks
520-524	Maximal Inspiratory Pressure (CC) (MIP)
525	Status Code
526	Reproducibility Code for MIP 0=reproducible 1=not reproducible
527	Status Code
528	Acceptability Code for MIP 0=acceptable 1=not acceptable
529	Status Code

VI. References

1. Peto R, Speizer FE, Cochrane AL, Moore F, Fletcher CM, Tinker CM, Higgins ITT, Gray RG, Richards SM, Gilliland J, Norman-Smith B. The relevance in adults of air-flow obstruction, but not of mucus hypersecretion, to mortality from chronic lung disease. Am Rev Respir Dis 1983; 128:491-500.

2. Cole TJ, Gilson JC, Olsen HC. Bronchitis, smoking, and obesity in an English and Danish town: Male deaths after a 10-year follow-up. Bull Eur Physiopathol Respir 1974; 10:657-667.

3. Higgins MW, Keller JB. Predictors of mortality in the adult population of Tecumseh: Respiratory symptoms, chronic respiratory disease and ventilatory lung function. Arch Environ Health 1970; 21:418-424.

4. Ferris BG, Higgins ITT, Higgins MW, Peters JM. Chronic nonspecific respiratory disease in Berlin, New Hampshire, 1961-1967. A follow-up study. Am Rev Respir Dis 1973; 107:110-122.

5. Petty TL, Pierson OJ, Dick NP, Hudson LD, Walker SH. Follow-up evaluation of a prevalence study for chronic bronchitis and chronic airway obstruction. Am Rev Respir Dis 1976; 114:881-890.

6. Beaty TH, Cohen BH, Newill CA, Menkes HA, Diamond EL, Chen CJ. Impaired pulmonary function as a risk factor for mortality. Am J Epidemiol 1982; 116:102-113.

7. Beaty TH, Menkes HA, Cohen BH, Newill CA. Risk factors associated with longitudinal change in pulmonary function. Am Rev Respir Dis 1984; 129:660-667.

8. Tockman MS, Khoury MJ, Cohen BH. The epidemiology of COPD in Chronic Obstructive Pulmonary Disease, 2nd ed. Petty TL, Ed. Marcel Dekker, New York 1985; pp. 43-92.

9. Tockman MS, Comstock GW. Respiratory risk factors and mortality: Longitudinal studies in Washington County, Maryland. Am Rev Respir Dis 1989; 140:S56-S63.

10. Ostler DV, Gardner RM, Crapo RO. A computer system for analysis and transmission of spirometry waveforms using volume sampling. Computers Biomed Res 1984; 17:229-240.

11. Ferris BG. The Epidemiology Standardization Project. Report No. HR-53028-F, National Heart, Lung, and Blood Institute, Division of Lung Diseases. 1978.

12. Gardner RM, et al. ATS statement. Snowbird workshop on standardization of spirometry. Amer Rev Respir Dis 1979; 119:831.

13. Gardner RM, Hankinson JL, West BJ. Evaluating commercially available spirometers. Am Rev Respir Dis 1980; 121:73.

14. Gardner RM, Crapo RO, Billings JW, Shigeoka JW, Hankinson JC. Spirometry - what paper speed? Chest 1983; 84:161.

15. Tockman MS. Results of pulmonary function tests, exercise tests and blood gas analyses performed at IPPB study centers site visits, May-June 1981. Report to IPPB Advisory Board, National Heart, Lung, and Blood Institute, Division of Lung Diseases, October, 1981.

16. Black, LF, Hyatt RE. Maximal static respiratory pressures: Normal values and relationship to age and sex. Am Rev Respir Dis 1969; 99:696-702.

17. Leech, JA, Ghezzo H, Stevens D, Becklake MR. Respiratory pressures and function in young adults. Am Rev Respir Dis 1983; 128:17-23.

18. Stead WW, Wells HS, Gault NL, and Ognanovich, J. Inaccuracy of the conventional water-filled spirometer for recording rapid breathing. J Appl Physiol 14:448-450, 1959.

19. Ferris BG Jr, Speizer FE, Bishop Y, Prang G, Weener J. Spirometry for an epidemiologic study: Deriving optimum summary statistics for each subject. Bull Europ Physiopath Resp 14:146-166, 1978.

20. Crapo RO, Morris AH, Gardner RM. Reference spirometric values using techniques and equipment that meet ATS recommendations. Amer Rev Respir Dis 123:659-664, 1981.

21. Morris JF, Koski WA, Johnson LC. Spirometric standards for healthy non-smoking adults. Am Rev Resp Dis 1971; 103:57-67.

22. Bass H. The flow volume loop: normal standards and abnormalities in chronic obstructive disease. Chest 1973; 63:171-176.

23. Boren HG, Kory RC, Syner JC. The Veterans Administration-Army cooperative study of pulmonary function, II, the lung volume and its subdivisions in normal men. Am J Med 1966; 41:96-114.

24. Kory RC, Callagan R, Boren HG, Syner JC. The Veterans Administration-Army Cooperative study of pulmonary function, I, clinical spirometry in normal men. Am J Med 1961; 30:243-258.

25. Goldman HI, Becklake MR. Respiratory function tests: normal value at median altitude and predictions of normal results. Am Rev Resp Dis 1959; 76:457-467.

26. Lindall A, Medina A, Grismer TJ. A re-evaluation of normal pulmonary function measurements in adult females. Am Rev Resp Dis 1967; 95:1050-1064.

27. Bates, Macklem and Christie. Respiratory Function in Disease. WB Saunders, Philadelphia, 1971.

28. Morris JF, Koski WA, Breese JW. Normal values and evaluation of forced end expiratory flow. Am Rev Resp Dis 1975; 111:755-761.

29. Morris JF. Normal values for the ratio of one second forced expiratory volume to forced vital capacity. Am Rev Resp Dis 1973; 108:1000-1003.

30. Knudson RJ, Slatin RC, Lebowitz MD, Burrows B. The maximal expiratory flow volume curve normal standards variability and effects of age. Am Rev Resp Dis 1976; 113:587-600.

31. Cotes JE. Lung Function. 2nd Ed. FA Davis, Philadelphia, 1968, 1978.

32. Schmidt CD, Dickman ML, Gardner RM, Brough FK. Spirometric standards for healthy elderly men and women. Am Rev Resp Dis 1973; 108:933-939.

33. Gaensler EA and Wright GW. Arc Envir Hlth 1966; 12:146-189.

34. Altman PL, Dittmer DS (eds). Respiration and Circulation (Biological handbooks) Bethesda, Maryland: Fed of American Societies for Experimental Biology, 1971; 126.

35. Morris AH, Kanner RE, et al (eds). Clinical Pulmonary Function Testing. 1st and 2nd edition. Salt Lake City, Intermountain Thoracic Society, 1975.

36. Dickman ML, Schmidt CD, Gardner RM. Spirometric standards for normal children and adolescents (age 5 through 18 years). Am Rev Resp Dis 1971, 104:680-687.

37. Gaensler EA. Evaluation of respiratory impairment. Arch Envirn Hlth 1966, 12:146-189.