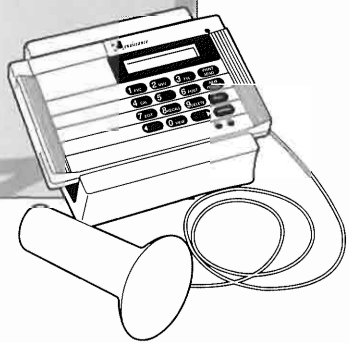
Operator's Guide

Renaissance®
Spirometry System



NELLCOR PURITAN BENNETT™

Table of Contents

Symbols

The following symbols appear on the *Renaissance* Spirometry System.

Consult Documentation before using equipment.

Direct current (DC)

Polarity

Warnings, Cautions, and Notes

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance.

WARNING: Means there is a possibility of injury or death to yourself or others.

CAUTION: Means there is the possibility of damage to the unit or other property.

NOTE: Indicates points of particular interest for more efficient and convenient operation.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

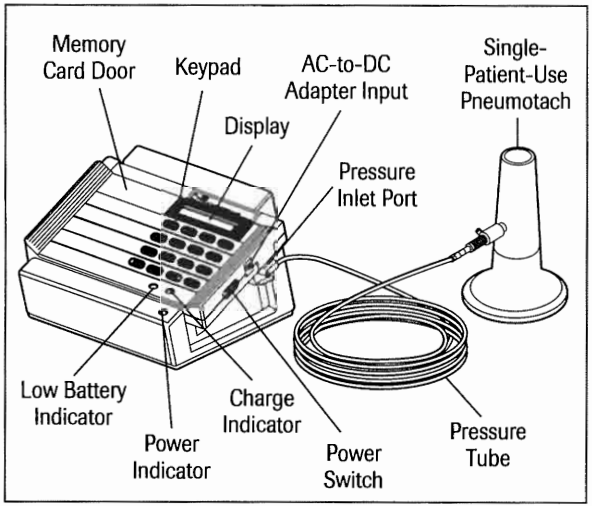
Introduction to the Renaissance Spirometry System

Features

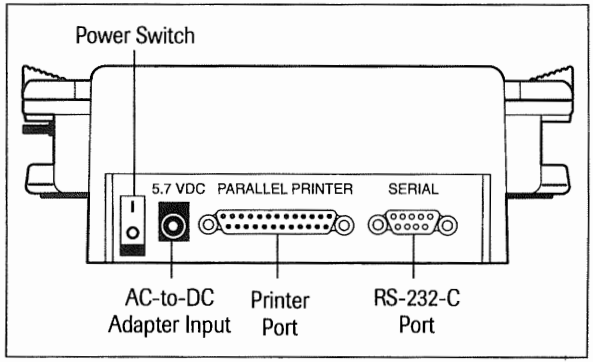
- Hand-held, battery-powered portability
- Disposable, single-patient-use pneumotachs
- Audio and visual incentive
- Built-in quality assurance of test results
- Optional patient data memory card
- 8½" x 11" printed reports on external printer

Front Panel Indicator Lights

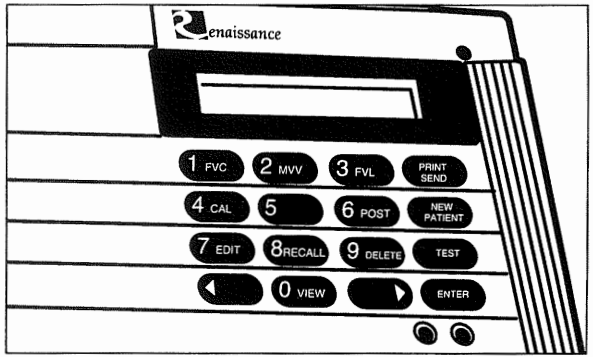
LOW BAT	Low battery indicator: indicates that battery power is running out; unit has five minutes or less of power left.
CHG	Charge indicator: indicates unit is charging.
POWER	Indicates that the base power switch is turned on and the unit is receiving power.



PB100 Spirometer with PB110 Base Station



PB110 Base Station (Rear View)



PB100 Spirometer Keypad

Keypad Functions

FVC (1)	Initiates the Forced Vital Capacity test.
MVV (2)	Initiates the Maximal Voluntary Ventilation test.
FVL (3)	Initiates the Flow Volume Loop test.
CAL (4)	Initiates the calibration check routine, performed using a calibration syringe (usually 3 liters).
POST (6)	Used to indicate a post-medication test (FVC, MVV, or FVL) that allows a pre/post comparison of results.
EDIT (7)	Allows you to review or change the patient data (ID, age, height, sex, etc.).
RECALL (8)	Allows you to recall test information that is saved on the optional patient data memory card.
DELETE (9)	Serves three functions. It allows you to delete the last effort, allows you to delete a saved patient record, and allows you to delete a patient session.
VIEW (0)	Allows you to view last test or best test summary information for the current patient.
◀ ▶	The left and right arrow keys are used to make corrections while entering data and to scroll through test data and patient records.
PRINT/SEND	Sends data to the base station for printing or for communication with a computer.
NEW PATIENT	Allows the entry of new patient data.
TEST	Switches the spirometer into the test mode, which allows you to select FVC, MVV, FVL, or CAL.
ENTER	Used throughout operation to allow you to make selections and enter data.

List of Accessories

Order Number	Description
P-000100-00	PB100 portable spirometer
P-000110-00	PB110 base station
P-000130-00	PB130 patient data memory card
P-000190-00	*Renaissance* DB software
P-000150-00	Canon bubblejet printer
P-000200-00	FS200 disposable pneumotachs (box of 50)
P-000201-00	FS200 disposable pneumotachs (box of 250)
P-000250-00	BD250 bidirectional pneumotachs (box of 25)
P-000251-00	BD250 bidirectional pneumotachs (box of 100)
P-063214-00	*Renaissance* video–Spirometry by Design
P-000170-00	Spirometer and base soft case
P-000300-00	3-liter calibration syringe
P-062522-00	Spirometer rechargeable battery pack
P-062528-00	Battery for memory card
P-010602-00	Pressure tube
P-062521-00	Spirometer AC-to-DC adapter
P-062523-00	Printer cable
P-000157-00	Canon printer ink cartridge (BJ200 series)
P-000152-00	Canon printer ink cartridge (BJ10 series)
P-010582-00	Spirometer memory card door
P-010581-00	Spirometer battery compartment door
P-001001-06	Spirometer operator's guide with technical reference

For the name of your Nellcor Puritan Bennett distributor call:

U.S. 1-800-255-6774 (Option 1)
Canada 1-800-263-7530
Quebec 1-800-363-7898
Mexico 1-510-463-4000

Installation and Configuration

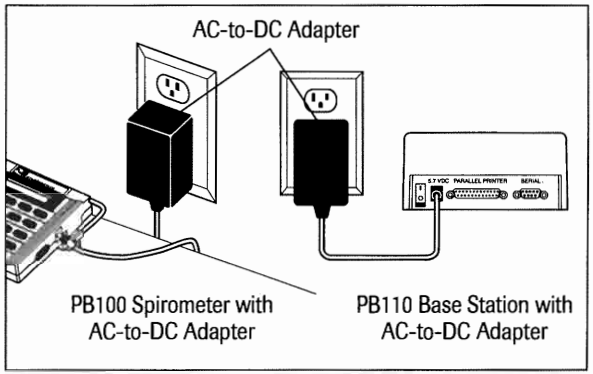
This section gives information on the rechargeable battery pack, the printer connection, and how to set the configuration of the spirometer to meet your specific needs.

Battery Information

The PB100 Spirometer is shipped with an internal nickel-cadmium rechargeable battery pack which must be charged for at least eight hours before portable operation. The AC-to-DC adapter (P/N 062521-00) can be connected directly to the PB100's power input. If you are using a PB110 base station, the spirometer should be docked into the base with the AC-to-DC adapter connected to the base station's power input.

The green charging LED indicator will light to indicate that the AC-to-DC adapter is properly connected. To assure that your spirometer is always ready for portable use, we recommend that the system remain charging when not in use. The yellow low battery indicator lights when the battery is low and needs recharging. If the battery is low, the spirometer can be used when powered by the AC-to-DC adapter.

The PB100 spirometer can perform approximately 100 spirometry tests following eight hours of battery charge. To ensure long-term, trouble-free operation, replace the battery pack after one year.



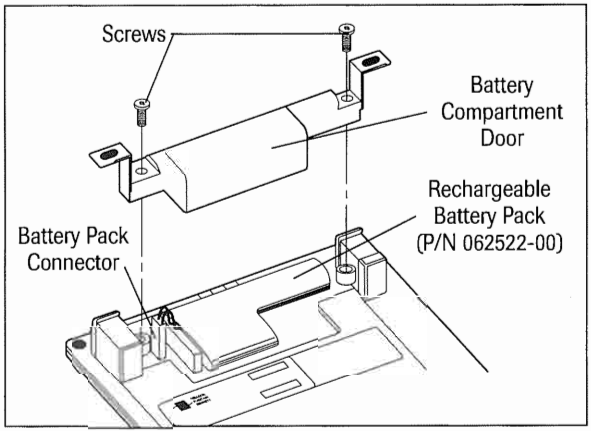
WARNING:
Use ONLY the *Renaissance* AC-to-DC adapter (P/N 062521-00) to charge the PB100 spirometer.

Battery Replacement

While changing the battery, the AC-to-DC adapter should be connected to the spirometer and the power switch turned off. This allows the unit to retain its configuration while the battery is disconnected. To change the battery pack, remove the two screws on the battery compartment door on the bottom of the spirometer. Disconnect the old battery pack by pressing the locking tab on the connector. Insert the new battery pack and reinstall the door. If you are using a base station, you can now remove the AC-to-DC adapter from the spirometer, connect it to the base, and dock the spirometer into the base for charging. It may be necessary for the new battery pack to be charged for several hours before the spirometer can be used without the AC-to-DC adapter.

WARNINGS:

- Use ONLY the *Renaissance* battery pack (P/N 062522-00) to charge the PB100 battery.
- Do not incinerate or mutilate the used battery pack as it may burst or release toxic materials.
- Do not short circuit the battery pack as it may cause burns.



PB100 Spirometer (Bottom View)

Printer Installation

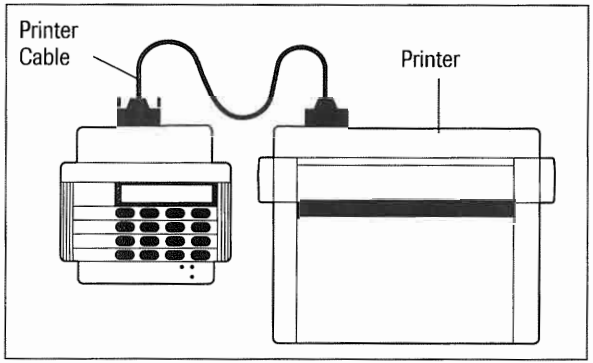
Printing test reports from your PB100 spirometer requires that you have the spirometer docked into the PB110 base station and that a compatible printer is connected to the parallel port of the base station. The *Renaissance* spirometry system operates with a variety of printers that use Epson, IBM, Canon, or Hewlett-Packard (HP) compatibility standards. You may need to change the spirometer's configuration to match the printer you are using. Refer to the following page or to the System Configuration section for spirometer configuration information.

Refer to the owner's manual for information on specific printer compatibility and operation.

WARNING:
Use only with equipment that complies with UL standards for information technology and business equipment.

Configuration

Your new PB100 spirometer is factory set with the standard configuration. You should, however, go through the configuration routine to customize operation and to set the correct date and time. The accompanying table shows the standard and optional settings for each function.



PB100 Spirometer and PB110 Base Station with Printer

To begin the configuration, press TEST and then press the forward arrow key (▶). Current configuration and options are displayed for each function. To retain the current configuration, press ENTER. To change the configuration press the number of the desired option and then press ENTER. For more information about each option, see the System Configuration section.

Function	Standard Configuration	Options
1. Technician Code	No	Yes
2. Units	English	Metric
3. Interpretation	Yes	No
4. Date Format	American	European
5. Time Format	12 Hour	24 Hour
6. Adult Normals	Knudson 1983	Morris, Crapo, Knudson1976
7. Pediatric Normals	Polgar	Hsu
8. PEF Units	L/Sec	L/Min
9. Report Format	Clinical	Industrial Short
10. Summary Values	Best Sum	Best Value, Enright
11. Graph Format	Both	Flow-Vol, Vol-Time
12. Graph Size	Diagnostic	Validation
13. Scale Graph	No	Yes
14. Number of Curves	Three	One, Two
15. Overlay Curves	Yes	No
16. Predicted Points	Yes	No
17. Printer Type	Epson	IBM, Canon, HP
18. Grid	Yes	No
19. Lung Age	Yes	No
20. Cal. Syringe Vol.	3 L	1-8 L
21. Quality Grades	No	Yes
22. Inspiratory Incentive	No	Yes, Man Start
23. Audio Incentive	Yes	No

Function		Standard Configuration	Options
24.	Race Adjustment	85%	50%-99%
25.	All Data	No	Yes
26.	All Curves	No	Yes
27.	Barometric Pressure	760 mmHg	435-800 mmHg
28.	Custom Header	No	Yes

Once configured, the settings will be retained in memory even after the unit is turned off. Consider circling the options you chose for future reference.

NOTE:
It is important to enter the average barometric pressure based on the elevation of your location. Otherwise, there will be an error in the inspired volume (FIVC) of approximately -1.3% for every 1000 feet you are above sea level. Refer to the System Configuration section of this guide for more information.

Calibration

There are two calibration types: calibration check and disability calibration. To perform a calibration check see the section below. To perform a disability calibration refer to the Disability Calibration section.

Calibration Check

To perform a calibration check you need a calibration syringe, a room thermometer, and an FS200 or BD250 single-patient-use pneumotach. Connect the pneumotach to the pressure tube and to the calibration syringe.

Press TEST.
Press CAL (4).

Select CHECK (1).
Press ENTER.

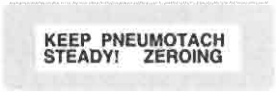
Enter the room temperature.
Press ENTER.

NOTE:
An incorrect room temperature setting will affect the accuracy of the inspiratory and calibration check parameters by approximately 0.15% for each degree Fahrenheit above or below the actual temperature.

Select pneumotach type.
Press **ENTER**.

If BD250 is selected, type the inspiratory code from the label on the BD250 pneumotach.
Press **ENTER**.

Keep syringe and pneumotach steady until the STEADY message disappears.

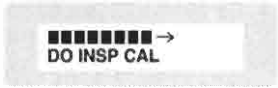


Adjust syringe to calibration volume (usually 3.0 liters).

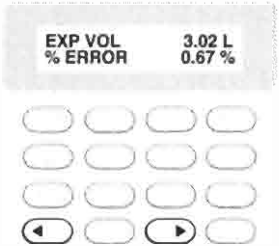
Press any key.

Push syringe plunger in evenly and completely.

If using a BD250, wait until DO INSP CAL appears. Then pull syringe plunger out evenly and completely.

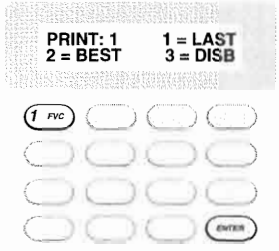


The expiratory check results are displayed. Press an arrow key to view the inspiratory cal check results.



Now press **CAL** to do another cal check, or press **PRINT** to print a record of the cal check results.

From the print menu, press LAST (1) to print cal check results.
Press **ENTER**.



If a calibration check or disability calibration has been performed within the last two weeks, the most recent cal date will be printed on the report.

The date of the last calibration check or disability calibration is displayed as part of the spirometer's turn-on message. To assure testing accuracy, the volume error should be 3% or less. If the error is more than 3%, check the following and repeat the calibration check.

1. Did you use a new pneumotach?
2. Was the syringe adjusted to the correct volume?
3. Does the syringe leak?
4. Was the pneumotach properly connected?
5. Is the syringe accurate?

If you cannot achieve acceptable calibration check results, call Nellcor Puritan Bennett technical support for help:

U.S.	1-800-255-6774 (Option 1)
Canada	1-800-263-7530
Quebec	1-800-363-7898
Mexico	1-510-463-4000

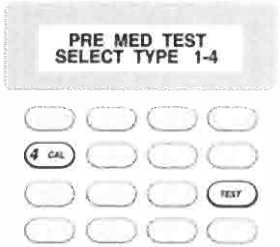
Disability Calibration

Disability testing requires that calibration be done at three flow rates: 3L/S, 1L/S, and 0.5 L/S (1, 3, and 6 seconds). It is also required that the calibration error at these flow rates be within ±1%.

To perform a disability calibration, you need a calibration syringe and an FS200 single-patient-use pneumotach. Connect the pneumotach to the pressure tube and insert the pneumotach into the syringe.

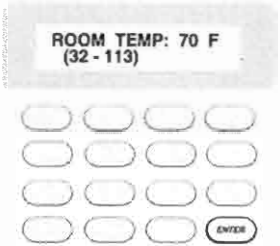
Enter a patient ID and all patient data before performing the disability calibration and subsequent tests. The pneumotach that is used for the disability cal check *must* be used for the disability testing.

Press TEST.
Press CAL (4).



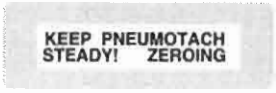
Select DISB (2) and press ENTER.

Enter the room temperature and press ENTER.



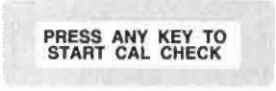
NOTE:
An incorrect room temperature setting will affect the accuracy of the inspiratory and calibration check parameters by approximately 0.15% for each degree Fahrenheit above or below the actual temperature.

Keep syringe and pneumotach steady until the STEADY message disappears.

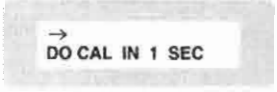


Withdraw syringe completely.

Press any key.

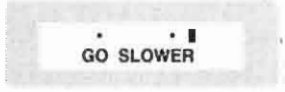


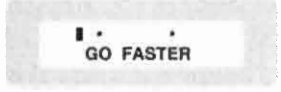
Push syringe plunger in evenly and completely over one second when prompted.



The flow rate is displayed on the screen as a black square. While pushing the syringe plunger, keep the black square in the target area defined by the two asterisks. Time (in seconds) is displayed in the lower right hand corner.

Messages, which suggest a modification to your technique will be displayed if the black square goes outside the target area.



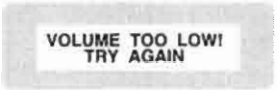


If the cal is not successful, one of the following four error messages will be displayed. Perform the cal again using the displayed suggestion.

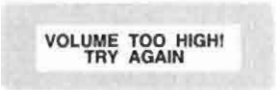
If the syringe was pushed too fast...

If the syringe was pushed too slow...

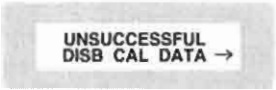
If the volume was too low...



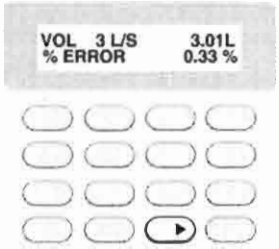
If the volume was too high...



If you continue to get error messages (after up to six tries), an unsuccessful cal message will be displayed.

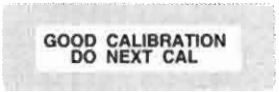


Press the right arrow key to observe the data. Look at the % error.



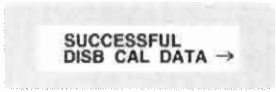
If the % error is less than ±1%, the rate at which the syringe was pushed needs to be improved. If the % error is greater than ±1%, repeat the cal with a new pneumotach.

Upon successful completion of a one-second calibration a message is displayed...

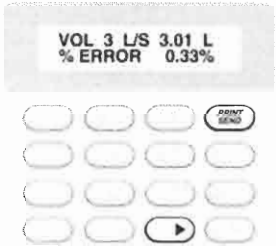


Press any key to go on to the three-second calibration. The spirometer will guide you through each step. When you have successfully completed the three-second calibration, the spirometer will prompt you to do the next cal. Repeat the same steps for the six-second calibration.

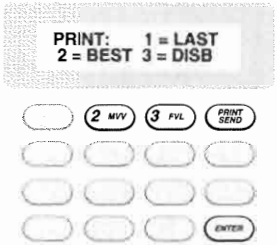
After successful completion at one, three, and six seconds, the calibration is finished.



Press the right arrow key to scroll through the data. Test flow rate, measured expiratory volume in liters, and % error are displayed.



To print a record of the disability calibration, press **PRINT/SEND**. Select BEST (2) or DISB (3) and press **ENTER**.



If you are experiencing problems obtaining a successful disability calibration, check the following:

1. Did you use a new pneumotach?
2. Was the syringe adjusted to the correct volume?
3. Was the syringe on a firm, flat surface?
4. Was the pneumotach properly connected?
5. Are you able to push the syringe in evenly and completely in the designated time (one, three, and six seconds)?

If you cannot achieve acceptable disability calibration results, call Nellcor Puritan Bennett technical support for help:

U.S.	1-800-255-6774 (Option 1)
Canada	1-800-263-7530
Quebec	1-800-363-7898
Mexico	1-510-463-4000

Patient Preparation

Explain...

...the purpose of the test to the patient. A spirometer is used to assess lung function: how quickly you can blow out air and how much air is in your lungs. If the test is performed properly, the results can show the presence or absence of asthma, emphysema, or pneumonia.

Instruct...

...the patient to:

- Loosen tight clothing, such as neckties or tight collars.
- Remove dentures.
- Elevate chin and extend the neck slightly.
- Use a nose clip if available.

WARNING:
There is a possibility that the patient could faint and be injured while performing the spirometry test.

To minimize the risk of injury, the patient should sit during the test unless he or she is obese (more than 50 pounds overweight) or less than 12 years of age. If this is the case, the patient should stand.

If the patient stands for the test, it is recommended that a chair be placed nearby where he/she could be guided if fainting occurs. The immediate area should be clear of sharp or dangerous objects that could cause injury in the event of a fall.

The test position should be noted so that on repeat testing the patient can be tested in the same position.

Demonstrate...

...the maneuver yourself:

- Place teeth and lips around the pneumotach.
- Do not block the opening with the tongue.
- Take the deepest breath possible.
- Then, blow as hard, as fast, and as completely as possible, squeezing all the air out.
- Pull back to perform another deep inspiration.

Coach...

...the patient firmly and enthusiastically, for example:

"Take a big, deep breath in, all the way. Now BLAST out, keep going, blow all the way out. Keep going. Now deep breath in, deep, deep. Good job!"

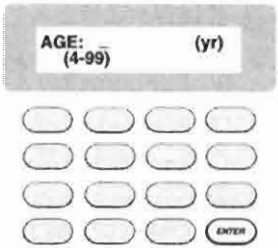
Entering Patient Data

Press NEW PATIENT. If no memory card is installed, the first screen will ask if you want to delete last patient information. You must delete any previous information before testing a new patient. Selecting NO allows you to continue testing the last patient. Select YES (1) to delete last patient and to enter new patient and press ENTER.

If you make a mistake while entering data, use the arrow and number keys to edit the screen. To review or change the data once the entry routine is complete, press EDIT (7). The entry routine will begin again, showing the data that was entered.

Type the patient ID number and press ENTER.

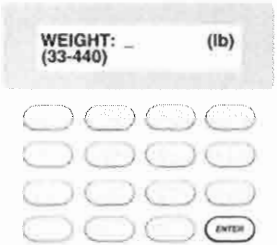
Type the patient's age and press ENTER.



Type the patient's height and press ENTER.

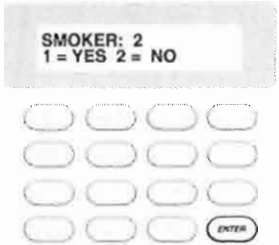
Select the patient's sex and press ENTER.

Type the patient's weight and press ENTER.

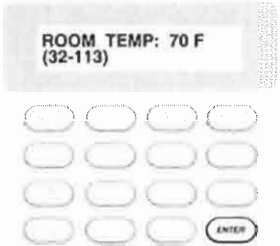


Select YES (1) to correct predicted values for race. Select NO (2) for no correction and press ENTER.

If the lung age function is enabled, select YES (1) for smoker or NO (2) for nonsmoker and press ENTER.



Enter the room temperature and press ENTER.



NOTE:
An incorrect room temperature setting will affect the accuracy of the inspiratory and calibration check parameters by approximately 0.15% for each degree Fahrenheit above or below the actual temperature.

Editing Patient Data

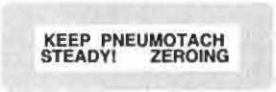
Press **EDIT** (7) to review or change the patient data. The entry routine will begin again showing the data that was entered. Use the arrow and number keys to edit the data. Press **ENTER** when the data is correct.

FVC Testing

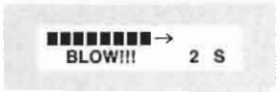
NOTE:
The following procedure assumes that the Inspiratory Incentive Configuration option is set to NO. IF this option is set to YES or MANUAL START, refer to the System Configuration section.

FVC testing begins after patient data is entered or after you press TEST. Press the FVC (1) key.

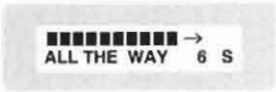
Hold the pneumotach steady in your hand until this message disappears:



When the word BLOW is displayed, instruct the patient to take a deep breath until lungs are completely full. Then instruct patient to put pneumotach in mouth and then blast out, hard and fast.



The screen and audio incentive will continue to encourage the patient until the unit senses no more air flow. The effort time is also displayed.



Continue encouraging and coaching the patient until this message is displayed.

After a second or two, the screen displays a test quality message, the test number, and the test quality grades (if enabled). After each effort you can use the arrow keys to scroll through the numeric results of the last test.

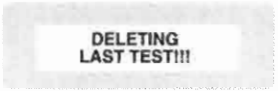
Press the FVC (1) key to perform another test. Repeat the above steps until you obtain three good tests.

NOTE:
If the test quality grades are enabled or the last test is flawed to the point of preventing you from getting satisfactory quality grades for the current patient, the unit will beep and the screen will give you an opportunity to immediately delete the last effort.

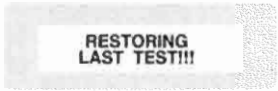
Deleting/Restoring Test Results

You may want to delete the results of a single test because of erroneous results or poor effort. To delete the last test, press the DELETE (9) key. Select LAST (1) and press ENTER.

This screen confirms the deletion of the last test.



To restore the deleted test press the DELETE key again. Select LAST (1) and press ENTER.

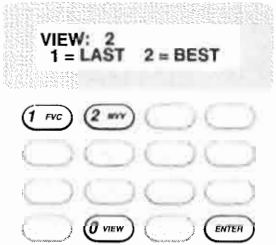


The **DELETE** key is also used to erase information from a PB130 Patient Data Memory Card. Refer to the Memory Card section for information on deleting data from a memory card.

Viewing Test Results

The **VIEW (0)** key allows you to display the results of the last test or the best test summary.

Press the **VIEW (0)** key. Select LAST (1) or BEST (2) and press **ENTER**.



Selecting LAST (1) allows you to use the arrow keys to scroll through the numeric results of the last effort. Selecting BEST (2) allows you to use the arrow keys to scroll through the numeric results of the best test summary.

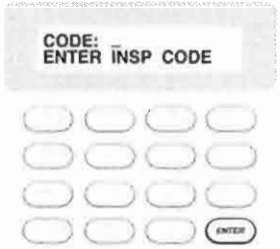
FV Loop Testing

NOTE:
The following procedure assumes that the Inspiratory Incentive Configuration option is set to NO. If this option is set to YES or MANUAL START, refer to the System Configuration section.

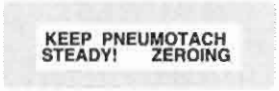
In order to detect upper airway obstruction, FV Loop testing adds a forced inspiratory maneuver after the expiratory (FVC) maneuver. The FV Loop test requires a BD250 pneumotach.

Press **TEST** to begin the FV Loop test.
Press the **FVL (3)** key.

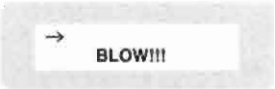
Type the inspiratory code from the label on the BD250 pneumotach and press **ENTER**.



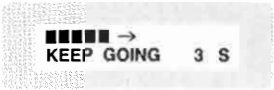
Hold the pneumotach steady in your hand until this message disappears.

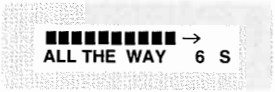


When the word BLOW is displayed, instruct the patient to take a deep breath until lungs are completely full. Then instruct patient to put pneumotach in mouth and blast out, hard and fast.

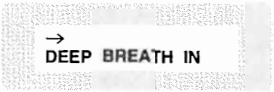


The screen and audio incentive will continue to encourage the patient until the unit senses no more air flow. The effort time is also displayed.



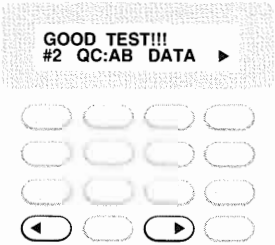


Instruct patient to inhale as quickly as possible when this message is displayed.



Continue encouraging the patient until this message is displayed.

After a second or two, the screen displays a test quality message, the test number, and the test quality grades (if enabled). After each effort you can use the arrow keys to scroll through the numeric results of the last test.



Press the FVL (3) key to perform another test. Repeat the above steps until you obtain three good tests.

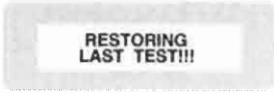
NOTE:
If the test quality grades are enabled or the last maneuver is flawed to the point of preventing you from getting satisfactory quality grades for the current patient, the unit will beep and the screen will give you an opportunity to immediately delete the last effort.

Deleting/Restoring Test Results

You may want to delete the results of a single test because of erroneous results or poor effort. To delete the last test, press the **DELETE** (**9**) key. Select LAST (1) and press **ENTER**.

The display confirms the deletion of the last test.

To restore the deleted test, press the **DELETE** (**9**) key again. Select LAST (1) and press **ENTER**.



The **DELETE** (**9**) key is also used to erase information from a PB130 patient data memory card. Refer to the Memory Card section for information on deleting data from a memory card.

Viewing Test Results

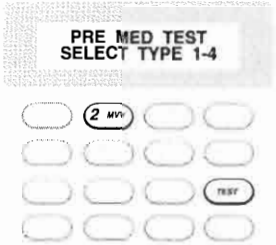
The **VIEW** (**0**) key allows you to display the results of the last test or the best test summary.

Press the **VIEW** (**0**) key. Select LAST (1) or BEST (2) and press **ENTER**.

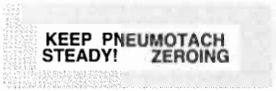
Selecting LAST (1) allows you to use the arrow keys to scroll through the numeric results of the last effort. Selecting BEST (2) allows you to use the arrow keys to scroll through the numeric results of the best test summary.

MVV Testing

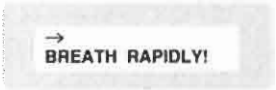
MVV testing begins after entering patient data or after pressing TEST. Press MVV (2).



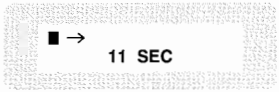
Hold pneumotach steady in your hand until this message disappears.



Instruct patient to take a deep breath. When this message appears on the screen, instruct the patient to put pneumotach in mouth and begin the MVV maneuver, breathing in and out quickly, the same as during strenuous exercise.

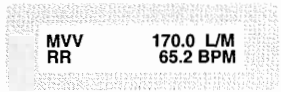


The screen and audio incentive will continue to encourage the patient for twelve seconds.



Continue encouraging and coaching the patient until this message is displayed (twelve seconds).

After one or two seconds, the screen displays the MVV test result and the respiratory rate.



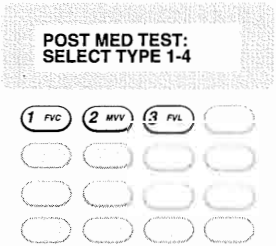
Post-Medication Testing

After completing all of the pre-medication (baseline) testing and administering the medication (usually an inhaled bronchodilator), the post-medication testing begins.

If you are performing post-medication testing on a patient whose pre-medication results are stored only on the memory card and not in the current patient memory of the spirometer, you must first recall the pre-medication results from the memory card. This is done by pressing **TEST** and **RECALL** (**8**). This situation typically occurs when you have either turned the spirometer off or pressed **NEW PATIENT** after performing the pre-medication testing. Refer to the Memory Card section for more information on recalling data from the memory card.

Press the **POST** (**6**) key. Confirm your choice by selecting YES (1) and press **ENTER**.

Select the desired test.



FVC, FV Loop, and MVV testing can now be performed using the same procedures as pre-medication testing. The pre- and post-medication results will be compared on the best test summary report.

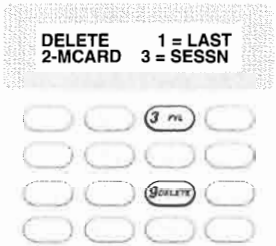
You are not able to select post-medication tests unless pre-medication tests have been done.

If, after post-medication testing, you choose to use the VIEW (**0**) mode to see the results of the best test summary, you will then choose to see either the pre-med or the post-med summary. If you choose post-med, the post-med summary values are displayed along with the percent change from pre-med.

Deleting a Session

You can delete and redo a current test session. This is useful if you suspect erroneous test results or if you want to perform and print multiple POST test sessions. A pre-med session cannot be deleted after post-med testing has been selected.

Press the **DELETE** (**9**) key. Select SESSN (3).



The spirometer will display the option to delete the current session. Select YES (1) and press **ENTER**.

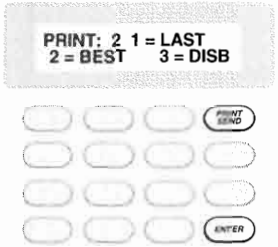
The spirometer will confirm that the session has been deleted.

Printing Results

Dock the spirometer onto the base station with the printer connected to the parallel port of the base station. The *Renaissance* spirometry system operates with a variety of parallel printers that are Epson 9-pin, IBM 9-pin, Canon Bubblejet, or HP Laserjet compatible. You may need to change the spirometer's configuration to match the printer you are using. Refer to the Installation and Configuration section or to the System Configuration section for configuration information.

Be sure that the base station is turned on and that the printer is connected, turned on, and on-line.

Press **PRINT/SEND**.
Select the desired report format: for Last Test, LAST (1); for Best Test Summary, BEST (2); or for Disability, DISB (3).
Press **ENTER**.



The report is sent to the printer.

The elements of the report are determined by the spirometer's current configuration (see the Installation and Configuration section). Once the SENDING DATA message disappears, the spirometer is ready for use. You do not have to wait until the report is printed.

NOTE:
If a PB130 patient data memory card is installed when you press **PRINT**, you will have the option to print the current patient information or information from the memory card. See the Memory Card section for more information on printing from a memory card.

Test Quality Messages

Two important aspects of quality testing are patient effort and technician coaching. After each effort the PB100 spirometer will display a test quality message that will help both you and the patient achieve accurate results. Listed here are the messages that can appear and what they mean. See the Quality Message and Grading Criteria section for more information.

START FASTER	Extrapolated volume is greater than 5% of FVC and greater than 100 ml. Patient must not hesitate or leak out air before the blast out.
BLAST OUT HARDER	The time from beginning of test to peak flow is greater than 90 msec. Patient must BLAST out the air more quickly at the beginning of the test.
AVOID COUGHING	Substantial drop and recovery in flow within the first second. Ask the patient to clear their throat and offer a drink of water.
BLOW OUT LONGER	Exhalation time is too short. Coach the patient to blow out longer.
ABRUPT ENDING	The patient quit before lungs were completely empty. Coach the patient to keep blowing as long as possible.
FEV1 VARIABLE	There is a difference of at least 5% and 100 ml between the two best FEV1 values. Try again.
FVC VARIABLE	There is a difference of at least 5% and 200 ml between the two best FVC values. Try again.
PEF VARIABLE	There is a difference of at least 10% and 1 l/s between the two best PEF values. Try again.
GOOD TEST!!!	No problems detected.

FVC and FEV1 Grades

If enabled, the best test summary report includes two test grades: an FVC grade and an FEV1 grade, from A to F. The FVC grade is an index of the degree of confidence that should be placed in the reported FVC. The FEV1 grade indicates the reliability of the reported FEV1. These grades are generated using criteria similar to that of the test quality messages. These test grades are useful in improving the overall coaching abilities of test technicians. See the Quality Message and Grading Criteria section for more information.

Memory Card

The PB100 spirometer includes a PB130 patient data memory card interface. By adding the optional memory card you can store patient tests for future printing or processing. The number of patients that can be stored on the memory card is affected by the following factors:

- **Type of test performed**
  For example, storing an FV Loop test requires more memory than storing an FVC test. Even more memory is used if you add an MVV test or perform post-medication testing.
- **Number of curves saved** (as selected in the spirometer's configuration) Storing three curves requires more memory than storing one or two curves.
- **Memory fragmentation**
  Memory fragmentation is avoided by periodically deleting all stored data using the DELETE ALL function described later in this chapter.

Depending upon these factors, the maximum number of patients that can be stored on one memory card is typically 100, and the minimum is approximately 12. For example, when performing pre-medication FVC testing and storing three curves with no memory fragmentation, you can store approximately 70 patients on one memory card.

CAUTION:
Do not remove or install the memory card while the spirometer is turned on.

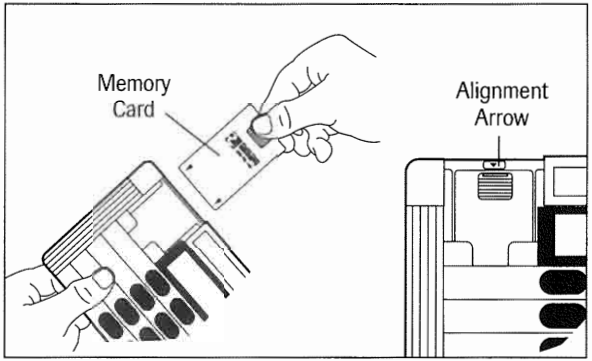
Installing the Memory Card

Make certain that the spirometer is turned off. Remove the memory card door. Slide the memory card into the slot, making sure that the card is properly oriented as shown. Gently push until the memory card settles into place. The card is fully installed when the top of the card is aligned with the arrow on the inside of the compartment. Replace the door.

Saving Patient Reports

The key to successfully saving patient reports on the memory card is typing in a unique patient ID number for each patient tested. Once the memory card is installed and a patient ID number is typed in, patient reports will automatically be saved. The information that is saved is the same as a best test summary report, the contents of which are determined by the spirometer's current configuration (see the Installation and Configuration section).

NOTE:
There is a write-protect switch located on the memory card. The spirometer cannot communicate with the memory card when this switch is on (see page 44).



PB100 Spirometer with PB130 Patient Data Memory Card

Printing Saved Patient Reports

To print patient reports that are saved on a memory card, you may:

1. Print all saved reports through the spirometer.
2. Print a selected report through the spirometer.
3. Print all saved reports through the PB110 base station.

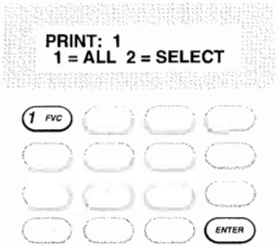
1. Printing all saved reports through the spirometer

Dock the spirometer in the base station. Turn on the base station and ensure that the printer is connected and ready to print.

Press **PRINT**.
Select BEST (2) and press **ENTER**.

Select MCARD (1) and press **ENTER**.

Select ALL (1) to print all saved reports and press **ENTER**.



When printing is complete, select YES (1) to erase all reports from memory card or select NO (2) to leave the memory card unchanged and press **ENTER**.

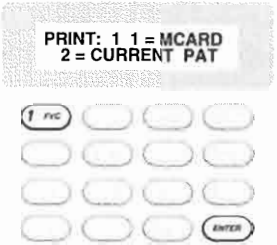
NOTE:
For efficient management of memory, we recommend that patient reports be erased from the memory card after they are printed.

2. Printing a selected report through the spirometer

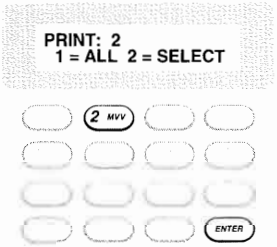
Dock the spirometer into the base station. Turn the base station on and ensure that the printer is connected and on-line.

Press PRINT.
Select BEST (2) and press ENTER.

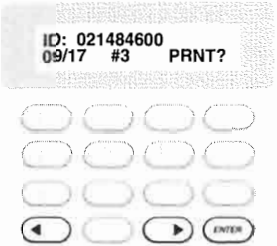
Select MCARD (1) to select memory card and press ENTER.



Select SELECT (2) to select a patient and press ENTER.



Use the arrow keys to scroll through the patient ID numbers until you find the desired patient.
Press ENTER.



After the report is printed, select YES (1) to erase report or select NO (2) to leave memory card unchanged and press ENTER.

If, after printing the selected report, you would like to edit the patient data, select NO (2) to leave memory card unchanged. Then press **EDIT** (7). You can then cycle through the patient data screens and edit the data as necessary.

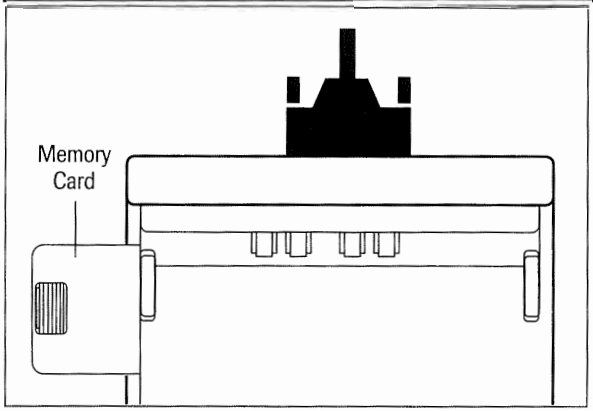
3. Printing all saved reports through the base station

All of the saved reports on the memory card can be printed in a batch directly from the PB110 base station without using the spirometer. To print from the base station, perform the following steps:

- Remove the spirometer from the base station and make sure printer is connected, turned on, and on-line.
- Turn off the power switch at the rear of the base station.
- Insert the memory card into the slot located on the left side of the base station. Gently push until the memory card settles into place. The card will only insert about one-third of the way.
- Turn on the power switch at the rear of the base station. All saved reports will now print.
- When printing is complete, turn off the power switch at the rear of the base station.
- Remove the memory card.

CAUTION:
Do not remove or install the memory card while the base is turned on.

NOTE:
Once a saved report has been printed through the base station, it cannot be reprinted through the base station. However, previously printed reports can be reprinted using the spirometer.



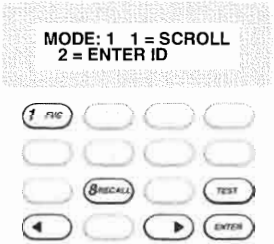
PB110 Base Station with Memory Card

Recalling Saved Patient Reports

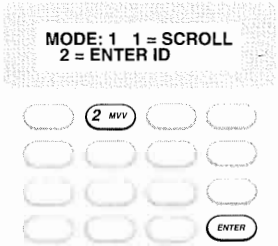
Patient reports that are saved on the memory card can be recalled into main memory for viewing, printing, editing, or adding post-medication tests. Once the data has been recalled, it is then considered current patient data.

Press TEST.
Press RECALL (8).

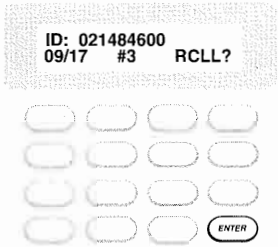
Select SCROLL (1), press ENTER and use the arrow keys to cycle through all of the patient ID numbers on the memory card to select a report.



Or, select ENTER ID (2), press ENTER and enter the patient ID number of the desired report.



Once the desired patient ID number is displayed, press ENTER.



The selected patient data is now restored and becomes the current patient. You can view, print, edit, or begin post-medication testing.

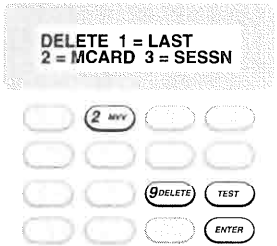
Deleting Saved Patient Reports

Patient reports that are saved on the memory card can be deleted as a group or one at a time.

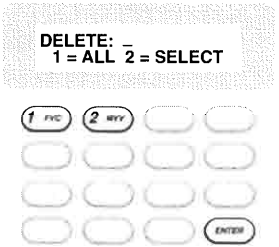
CAUTION:
Do not remove or install the memory card while the spirometer is turned on.

Press TEST.
Press DELETE (9).

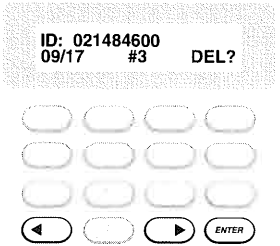
Select MCARD (2) to delete reports from the memory card and press ENTER.



Select ALL (1) to delete all reports from the memory card. Or, select SELECT (2) to select an individual patient and press ENTER.



If you chose to select a patient, use the arrow keys to scroll through the patient ID numbers until you find the desired patient. Then press ENTER.



Use the arrow keys again to find the next patient for deletion. Or press another function key to exit delete mode.

Memory Card Battery

The memory card is powered by a 3-volt, CR2016-type battery when not installed in the spirometer or when the spirometer is turned off. We recommend that the battery be replaced after one year when you replace the spirometer's battery pack. Be sure you have printed the reports that are saved on the card before changing the battery, because the data may be lost when you remove the battery.

To replace the battery:

- Turn the spirometer off and remove the memory card.
- Use your thumbnail to remove the battery holder from the top left side of the card.
- Install a new 3-volt, CR2016-type battery into the holder, making sure that the side marked "+" is facing up.
- Reinsert the battery holder into the memory card.

Write-Protect Switch

Your new PB130 Memory Card is sent to you with the write-protect switch turned off. For normal spirometer/memory card operation, the write-protect switch should remain turned off (as shown).

PB130 Memory Card

Special Messages and Troubleshooting

Special Messages

The PB100 spirometer can display several special messages to help guide you through operation. These messages and their indications are listed below.

Message	Indication
NO INFORMATION TO DELETE	No last test data found when attempting to delete last test.
NO INFORMATION TO DISPLAY	No test data found when attempting to display last or best test results.
NO PATIENTS ON MEMORY CARD	No patient data found when attempting to delete data from memory card.
PATIENT ID NOT ON MEMORY CARD	No matching patient ID found when attempting to recall data from memory card.
MEMORY CARD FULL!!!!	No more space on memory card. Delete old data or use another memory card.
NO PRE MED TESTING DONE!!	Post-med testing cannot be done unless pre-med testing has been done first.
UNABLE TO ZERO SENSOR	Hold disposable pneumotach still during ZEROING message.
KEEP PNEUMOTACH STEADY! ZEROING	Hold disposable pneumotach still while this message is displayed.
MCARD WRITE PROTECTED	Unable to communicate with memory card. See page 44 to turn off write-protect switch.

UNABLE TO READ MCARD... PRESS ANY KEY TO INITIALIZE MCARD	Spirometer cannot communicate with the memory card. Pressing any key will attempt to initialize (format) the card. Any data already stored will be erased. If re-initializing does not work, try changing the memory card battery (see page 44). If the spirometer still cannot read the memory card, call for service.
UNABLE TO SEND DATA	Spirometer is not communicating with base station when it attempts to print or send data. Check power to base station and make sure spirometer is securely docked into base station. Check that printer is on, ready to print, and that the printer cable is secure. Clean the four contacts on the spirometer and base station with alcohol.

For the name of your Nellcor Puritan Bennett distributor call:

U.S.	1-800-255-6774 (Option 1)
Canada	1-800-263-7530
Quebec	1-800-363-7898
Mexico	1-510-463-4000

Troubleshooting

Listed below are other potential problems and solutions.

Problem	**Solution**
Yellow low battery LED on	Battery needs recharging or replacing. See the Installation and Configuration section.
Green charging LED not on	Connect AC-to-DC adapter to spirometer, or dock spirometer firmly into base and connect AC-to-DC adapter to base.
Will not print properly	Check cabling between base station and printer. Printer must be turned on and ready to print. Spirometer must be properly configured for printer. See the Installation and Configuration, or System Configuration sections.
No response to patient test	Pressure tube must be connected to spirometer. Check for kinks, leaks, or damage to pressure tube.

For the name of your Nellcor Puritan Bennett distributor call:

U.S.	1-800-255-6774 (Option 1)
Canada	1-800-263-7530
Quebec	1-800-363-7898
Mexico	1-510-463-4000

Introduction to Spirometry

What is Spirometry?

Spirometry is derived from the Greek SPIRO (to breathe) and METER (to measure). The purpose of spirometry is to assess the subject's lung condition. The simplest test to evaluate lung condition (and the one you will be performing most with subjects) is the Forced Vital Capacity (FVC) test. This test requires the subject to take a deep breath and then to exhale as rapidly and completely as possible. Remember that this is an effort-dependent test, so obtaining the subject's full cooperation is essential.

The FVC test results indicate:

1. How fast air was exhaled (flow rate).
2. How much air was exhaled (volume).

Depending on those results, the doctor will be able to determine whether a subject's PULMONARY FUNCTION has a:

A. Normal Pattern
B. Obstructive Pattern
C. Restrictive Pattern
D. Combined Restrictive/Obstructive Pattern

Lung disease can be classified into two general categories: obstructive and restrictive.

1. Obstructive diseases are characterized by an increased resistance to air flow. This resistance makes it more difficult for a subject to move air out of his lungs rapidly. An obstructive pattern is, therefore, characterized by a reduction in the volume that can be exhaled in the first second of the test (FEV1) and by a low FEV1/FVC ratio.
   The three most common obstructive diseases are asthma, chronic bronchitis, and emphysema. Asthma reversibly constricts the bronchial tubes. It can usually be controlled by drug therapy. Bronchitis also constricts the bronchial tubes but may not respond to drug therapy. Emphysema is slow, irreversible destruction of the alveoli, leading to collapsible airways.
2. Restrictive disorders impair the movement of the lung and are characterized by a reduction in the total volume of air that can be exhaled (FVC). The FEV1/FVC ratio remains normal or increases. Restrictive diseases can be caused by gross obesity, lung fibrosis, neuromuscular disease, or paralysis.

Spirometry Indications

The main use of spirometry tests is the early detection of pulmonary disease. In general, spirometry is used to:

1. Help in the clinical diagnosis and management of subjects with pulmonary disorders.
2. Establish the presence of unsuspected small airway disease.
3. Confirm the presence of suspected disease.
4. Indicate the type (restrictive disease, obstructive disease, combined disease) and degree of disability (slight, moderate, severe).
5. Decide what can be done, for example, (a) refer the patient to a hospital or pulmonary specialist, (b) determine the type of additional testing which needs to be done to confirm diagnosis, or (c) determine appropriate drug therapy.
6. Indicate a degree of improvement that can be expected from therapeutic programs, such as bronchodilators or steroids.
7. Provide a better understanding of pulmonary physiology in healthy men and women of all ages (mass screening, annual physicals, exams).
8. Help encourage smokers to stop smoking.

When to do Pulmonary Screening

Unlike the electrocardiograph, which shows only established damage, the spirometer, when used to perform a series of tests over a period of time, can show trends in a patient's pulmonary condition. "Assessment of pulmonary condition by simple spirometry would, if used routinely, permit early identification of abnormalities associated with many respiratory diseases. These tests would also provide a valuable tool for determining progress in patients undergoing therapy. The tests are simple and reliable enough for use by practicing physicians and should be part of all initial and periodic examinations of patients. They are especially important for persons exposed to high levels of community air pollution or dusts in the working environment."

Testing is particularly recommended for the following types of subjects:

1. Patients with known or suspected pulmonary disease.
2. Patients over forty years of age.
3. Smokers.
4. Patients using or requiring bronchodilators, to establish a baseline for and to monitor the effects of medication.
5. Those exposed to air pollutants in the workplace.
6. Patients with a history of respiratory disorders, (for example, asthma, pneumonia, "influenza"), even though symptoms are not present at the time.
7. Subjects who complain of chronic cough, sputum, shortness of breath.
8. Pre-operative patients, for the assessment of the risk of respiratory insufficiency and/or the effects of anesthesia.
9. Patients with severe pulmonary disease, to document disability.

Definition of Terms

- **FVL:** A Flow Volume Loop is an FVC maneuver that is immediately followed by a maximal inspiration.
- **FVC (Forced Vital Capacity) measured in liters:** The maximum volume of air exhaled as rapidly, forcefully, and completely as possible from the point of maximal inhalation.
- **FEV.5 (Forced Expiratory Volume) measured in one-half second (liters):** The volume of air exhaled in the first half-second of an FVC maneuver.
- **FEV1 (Forced Expiratory Volume) measured in one-second (liters):** The volume of air exhaled in the first second of an FVC maneuver.
- **FEV3 (Forced Expiratory Volume) measured in three seconds (liters):** The volume of air exhaled in the first three seconds of an FVC maneuver.
- **%FEV1:** The ratio of FEV1 to FVC, expressed as a percentage. Also called FEV1/FVC%.
- **FEF 25-75 (Forced Expiratory Flow) measured in liters/sec:** The MEAN flow rate between 25% and 75% of the Forced Vital Capacity.
- **PEF (Peak Expiratory Flow Rate) measured in liters/sec or liters/min**
- **Flow-Volume Curve:** A graphic printout of an FVC/FVL maneuver plotting flow vs. volume.
- **Volume-Time Curve:** A graphic printout of an FVC maneuver, or the expiratory portion of an FVL maneuver, plotting volume vs. time.

- **MVV (Maximal Voluntary Ventilation) measured in liters/min:** The volume of air expired during twelve seconds of breathing in and out rapidly and deeply, extrapolated to one minute.
- **FIVC (Forced Inspiratory Vital Capacity) measured in liters:** The maximum volume of air inspired with maximum effort after maximal exhalation.
- **PIF (Peak Inspiratory Flow Rate) measured in liters/sec**
- **Extrapolated Volume:** The amount of air exhaled relatively slowly before the peak expiratory flow is achieved. If this volume is more than 5% of the FVC, the maneuver started too slowly.
- **ATPS:** Ambient temperature, pressure, saturated with water vapor.
- **BTPS:** Body temperature (37°C), ambient pressure, saturated with water vapor.
- **ATPS to BTPS Conversion Factor:** Factor used to convert flow and volume data from values measured at ambient temperature (ATPS) to body temperature (BTPS).
- **FEF50/FIF50:** Ratio of forced expiratory flow at 50% of FVC to forced inspiratory flow at 50% of FIVC.
- **FET (Forced Expiratory Time) measured in seconds:** Test time at which highest volume was achieved during an FVC maneuver.
- **RR (Respiratory Rate or BPM):** The frequency of breaths during an MVV maneuver.

Product Specifications

PB100 Spirometer

- **Dimensions:** 4.5" H x 7.25" W x 1.75" D (11.4 cm H x 18.4 cm W x 4.5 cm D)
- **Weight:** 15 oz (425 g)
- **Accuracy:** Validated to comply with American Thoracic Society Standards for Spirometry (1987 update).
  Volume: ±3% of reading or ±50 ml, whichever is greater. FEV1 measured by back extrapolation method.
  Flow: ±5% of reading or ±200 ml/sec, whichever is greater.
  MVV: ±5% of reading.
- **Volume Range:** 0-12 liters BTPS
- **Flow Range:** -16 to + 16 l/sec
- **Resistance:** Less than 1.5 $cmH_2O/l/sec$ from 0-12 l/sec
- **Test Time:** FVC/FVL - 30 seconds; MVV - 12 seconds
- **Display:** Supertwist LCD
- **Parameters Measured:** FVC, FEV1, %FEV1, FEV 3, FEF25-75%, PEF, FET, FIVC, PIF, FEF50%/FIF50%, MVV
- **Test Quality Criteria:** Enright PL, Johnson LR, Connett JE, Voelker HT, Buist AS, "Spirometry in the Lung Health Study: Methods and Quality Control," *American Review of Respiratory Disease*, June 1991
- **Battery:** 3.6 V rechargeable NiCad battery pack, P/N 062522-00
- **Power Source:** 5.7 VDC, 500 mA AC adapter/charger, 105-130 VAC, 60 Hz, 8.0 W, UL & CSA approved, P/N 062521-00
- **Operating Temperature:** 36° to 113°F (2° to 45°C)*
- **Operating Humidity:** 15% to 95% at 110°F (40°C)
- **Operating Altitude:** Up to 15,000 feet, 580 hPA to 1067 hPA
- **Storage Temperature:** -40° to 158°F (-40° to 70°C)
- **Storage Humidity:** 10% to 100%, including condensation
- **Storage Pressure:** 500 hPA to 1060 hPA

***NOTE:**
Extreme differences between unit temperature and ambient temperature can affect the accuracy of the inspiratory and calibration check measurements. When taking the spirometer from extreme hot or cold temperatures (greater than a 30°F change), allow the spirometer to acclimate for 30 minutes at room temperature before performing a flow-volume loop or a calibration check.

PB110 Base Station

- **Dimensions:** 6.0" H x 5.5" W x 3.0" D (7.6 cm H x 14.0 cm W x 15.2 cm D)
- **Weight:** 1 lb, 3 oz (539 g)
- **Function:** Provides docking for the PB100 spirometer to charge the NiCad battery pack, interfaces with most external IBM, Epson, Canon, or HP compatible printers to produce a data and graphic report, and provides RS-232-C port for computer interface.
- **Printout Size:** 8½" x 11"
- **Predicted Normal Values:**
  Adult: Morris et al, 1971; Knudson, 1983, 1976; Crapo (ITS THORACIC), 1981
  Pediatric: Polgar, Hsu
- **Interpretation Criteria:** Enright PL, Hyatt RE; *Office Spirometry:* A Practical Guide to the Selection and Use of Spirometers, Lea & Febiger, 1987
- **Interface:** Centronics-compatible parallel port for printer, RS-232-C-compatible serial port for computer interface
- **Power Source:** Uses AC-to-DC adapter supplied with PB100 spirometer
- **Operating Temperature:** 36° to 113°F, 2° to 45°C*
- **Operating Humidity:** 15% to 95% at 40°C
- **Operating Pressure:** Up to 4,572 meters, 580 hPA to 1067 hPA
- **Storage Temperature:** -40° to 158°F (-40° to 70°C)
- **Storage Humidity:** 10% to 100%, including condensation
- **Storage Pressure:** 500 hPA to 1060 hPA

PB130 Patient Data Memory Card

- **Dimensions:** 3.37" L x 1.12" W (8.6 cm L x 5.4 cm W)
- **Function:** Stores patient test information for future printing; interfaces with the PB100 spirometer or the PB110 base station.
- **Storage:** 32 Kbyte
- **Battery:** 3-volt Lithium (CR2016 or equivalent)

Graphic Specifications

- **Diagnostic Size:**

Flow-Volume	flow:	1 l/s = 0.25 cm	-14 to 14 l/s
Graph	volume:	1 liter = 0.50 cm	max. 10 liters
Volume-Time	volume:	1 liter = 0.5 cm	max. 10 liters
Graph	time:	1 second = 1.0 cm	max. 15 seconds

- **Validation Size:**

Flow-Volume	flow:	1 l/s = 0.5 cm	-14 to 14 l/s
Graph	volume:	1 liter = 1.0 cm	max. 10 liters
Volume-Time	volume:	1 liter = 1 cm	max. 10 liters
Graph	time:	1 second = 2.0 cm	max. 16 seconds

The Single-Patient-Use Pneumotach

The *Renaissance* spirometry system uses Nellcor Puritan Bennett's unique, individually calibrated, disposable pneumotachs: the FS200 and the BD250. These single-patient use pneumotachs eliminate the need to clean or sterilize any part of the spirometry system. The disposability also minimizes the effects of contamination on calibration, resulting in a spirometry system that requires infrequent calibration.

The FS200 disposable pneumotach is used for expiratory testing only (FVC, MVV). It is packaged in a clear bag.

The BD250 disposable pneumotach can be used for all testing, including the flow-volume loop test. The BD250 is packaged in a blue bag and has an identifying label that contains an inspiratory code that is unique to each pneumotach. This code is entered into the spirometer each time you begin a flow-volume loop test session, or when you are using a BD250 during a calibration check. The inspiratory code contains information about the inspiratory linearity characteristics of the pneumotach. The spirometer needs this information to deliver accurate inspiratory measurements.

Your supply of pneumotachs should be stored in a cool location. Each pneumotach should remain sealed in its plastic bag until ready to use. Inspect the resistive element of each pneumotach before use. Do not use the pneumotach if the element shows any visible sign of damage.

System Configuration

The *Renaissance* spirometry system offers a wide range of configuration options that allow you to customize printed reports and operations. The PB100 is set at the factory for the standard configuration. These settings can be easily changed. This section describes each configuration option.

To begin the configuration routine, press TEST, then press the forward arrow key. The current configuration and options are displayed. To retain the current configuration, press **ENTER** for each function. To change the configuration, press the number of the desired option and then press **ENTER**. The next configuration is now displayed. To return to the previous configuration, press the reverse arrow key while the cursor is in the first digit position.

1. Technician Code

Technician code is a report option that allows you to identify the spirometry technician on the printed report. The standard configuration is NO. When you choose yes, the next screen allows you to enter up to ten digits. This code will be retained in memory and will be printed on all subsequent reports. You will have to re-enter the configuration routine should you want to change or eliminate the code.

2. Units

The unit options are metric and English. The standard configuration is ENGLISH. When English is selected, the patient's height is entered and reported in inches (in), the patient's weight is entered and reported in pounds (lbs), and the ambient temperature is entered and reported in degrees Fahrenheit (F). When metric is selected, the height is entered and reported in centimeters (cm), the weight is entered and reported in kilograms (kg), and the temperature is entered and reported in degrees centigrade (C).

3. Interpretation

The interpretation option determines whether the best test summary reports will include an interpretation. The standard configuration is YES. If yes is selected, the interpretation appears near the bottom of the summary reports. There is a separate interpretation generated for pre- and post-medication tests. For information on the specific criteria for the interpretation, refer to the Clinical Interpretation Criteria section.

4. Date Format

This setting determines how dates are reported. The date format options are European and American. AMERICAN is the standard configuration. The American format is mm dd yy. The current date is entered after choosing the time format, which is the next configuration. The European format is dd mm yy.

5. Time Format

This setting determines how the time is entered and reported. The time format options are twelve-hour clock (am/pm) or twenty-four-hour clock. TWELVE-HOUR clock is the standard configuration. This format is hhmm, where the highest hour that can be entered is 12 and the highest minute that can be entered is 59. After the twelve-hour clock time is entered the next screen allows you to enter AM or PM. The twenty-four-hour format is hhmm, where the highest hour that can be entered is 23 and the highest minute that can be entered is 59. After the time is entered the next screen allows you to enter the current date, according to the date format previously set.

NOTE:

There are three times that can print on the spirometry report. They all appear in the upper right-hand corner of the report. One is the time of day when new patient data is entered (ID, age, sex, height, etc.). The second time is the time that the first pre-medication FVC/FVL test is performed. The third time is printed only if post-medication testing is performed, and is the time that the first post-medication FVC/FVL test is performed.

6. Adult Normals

This configuration determines which set of equations will be used to generate the predicted values for patients 18 to 99 years of age. These predicted values appear on the printed reports and are used to derive the percent of predicted and the interpretation. The options are Morris, Knudson 1976, Knudson 1983, or Crapo. The standard configuration is KNUDSON 1983. The option chosen will appear in the upper-right corner of each printed report. For the specific equations and references see the Predicted Normal Equations and References section.

7. Pediatric Normals

This configuration determines which set of equations will be used to generate the predicted values for patients 4 to 17 years of age. These predicted values appear on the printed reports and are used to derive the percent of predicted and the interpretation. The options are Hsu and Polgar. The standard configuration is POLGAR. The option chosen will appear in the upper-right corner of each printed report. For the specific equations and references see the Predicted Normal Equations and References section.

8. PEF Units

This configuration determines which units will be used when measuring peak expiratory flow. The options are liters/second and liters/minute. The standard configuration is LITERS/SECOND.

9. Report Format

This setting determines the number of FVC test parameters that will appear on the printed report. The options are clinical and industrial short. The chosen format is printed on each report. The standard configuration is CLINICAL. The test parameters for each setting are as follows:

Clinical	Industrial Short
FVC	FVC
FEV1	FEV1
%FEV1	%FEV1
FEF25%-75%	
PEF	
FEV3	
FET	

10. Summary Values

This setting determines how the values of best test summary are chosen. The three options are: best value, best sum, and Enright. BEST SUM is the standard configuration. The definition of each option is as follows:

best value	The best test summary will include the best values of FVC and FEV1. The remainder of the values will be taken from the test with the highest sum of the FVC and the FEV1.
best sum	The best test summary will use the values of the single test with the highest sum of the FVC and the FEV1.
Enright	The best test summary will use the values of the single test with the highest sum of the FVC, the FEV1, and one-half the PEF.

NOTE:
The best value method is recommended by the American Thoracic Society and mandated by NIOSH/OSHA standards and should be used for all industrial and disability testing.

11. Graph Format

The graph format setting allows you to choose which graphs will appear on the printed reports. The options are flow-volume, volume-time, and both. The standard configuration is BOTH.

12. Graph Size

The graph size setting allows you to choose the size of graphs that appear on the printed report. The options are diagnostic size and validation size.

DIAGNOSTIC is the standard configuration and will usually allow the entire report to be printed on a single page, unless an MVV test is performed. Validation-size graphs are larger in scale and are designed to allow hand validation of test values. Due to its large size, a printed report with validation-size graphs may require more than one page. Scaling information is printed with all graphs. For graphic specifications, see the Product Specifications section.

13. Graph Scale

This setting determines whether to scale the graph size up during printing based on the size of the FVC/FVL curves stored or whether to leave the graph size fixed. The standard configuration is NO. When set to yes, the graphs will be scaled automatically to 1-times, 2-times, 4-times, or 8-times the normal size.

14. Number of Curves

This setting allows you to choose how many test curves will be included on a pre-medication best test summary printout. The options are one, two, or three. The standard configuration is THREE curves. This selection affects both the flow-volume and volume-time graphs. For each graph type, all curves will appear on the same grid. This setting will not, however, affect a pre-/post-medication summary, where only the best pre- and the best post-medication curves will be printed.

NOTE:
With the configuration set for three curves, the PB130 patient data memory card will store approximately 70 pre-med patient tests. If you only need to see the best curve, setting this configuration to ONE will allow you to store more patient tests on the memory card.

15. Overlay Curves

This setting allows you to choose how curves will be positioned on the grid. If you choose yes to overlay, all of the curves will be superimposed on one another and will begin at the zero point of the grid. If you choose no, all of the curves will be offset from one another. The flow-volume curves will be offset by one liter and the volume-time curves will be offset by one second. Overlay (YES) is the standard configuration. Your selection will affect diagnostic size and validation size graphs. Pre-/post-medication comparison graphs, however, will always be overlaid.

16. Predicted Points

This setting determines if predicted value points will appear on the printed graphs. The standard configuration is YES. The position of these points is determined by the predicted values for each patient. The intent of these points is to produce a graphic reference of the patient's predicted values. The points appear on the grid as small blocks. If you choose yes to this option, the following predicted points are plotted on each graph:

Flow-Volume Graph	Volume-Time Graph
PEF	FEV.5
FEF50%	FEV1
FEF75%	FEV3
FVC	FVC

17. Printer Type

The *Renaissance* spirometry system operates with variety of parallel printers that use the Epson 9-pin, IBM 9-pin, Canon Bubblejet, or HP Laserjet compatibility standards. This configuration allows you to set the spirometer's software to best match the printer that you want to use. The four options are Epson compatible, IBM, Canon, and HP. The standard configuration is EPSON.

The PB110 base station is designed to operate with as many brands of printer as possible. If you have a printer that you would like to use, but are not sure whether it will work, we suggest that you try it. The method of testing is as follows:

- Connect the printer to the base station, using the cable provided.
- Ensure that the printer is turned on, is on-line, and has paper loaded, and that the base station is turned on.
- Perform a test on the spirometer and try printing a report.
- If it does not print, or if the printout looks wrong, enter the configuration routine and change the printer setting. Try reprinting the report.
- Try all four of the configurations. You may also refer to the printer's owner's manual for other printer configuration options.

18. Grid

This setting determines whether there will be grid lines on the printed graphs. The grid lines may make it easier to read test values from the curves. However, the addition of these lines will increase the time it takes to print a report. The standard configuration is YES. If yes is chosen, grid lines will appear on all graphs.

19. Lung Age

Lung age is a smoking cessation tool available on the printed report as part of the interpretation. YES is the standard configuration. When lung age is enabled, the patient data routine will ask if the patient is a smoker. The lung age value is calculated by substituting the predicted value of FEV1 with the smoker's actual FEV1. Then the FEV1 predicted equation is solved for age. The reported lung age value will never be less than the patient's actual age. It should be emphasized that the lung age parameter is intended to be used solely as a smoking cessation tool and not as a diagnostic measurement. Refer to the Clinical Interpretation Criteria section for more information on lung age.

20. Calibration Syringe Volume

This configuration sets the value that the system will use during the calibration check routine described in the Calibration Check section of this guide. This number should equal the exact volume (in liters) of the calibration syringe that you will be using. The spirometer will compare this volume to the volume that is measured during calibration check. This allows the results of the calibration check to be expressed in terms of percent difference. The standard configuration is THREE LITERS. You can enter any value from one to eight liters.

21. Quality Grades

This setting determines whether the best test summary will include the test quality grades. There are two grades, an FVC grade and an FEV1 grade, that are useful in judging the reliability of a particular report and for evaluating and improving the coaching abilities of test technicians. The test grades are A, B, C, D, and F. The standard configuration is NO. For the specific grading criteria, refer to the Quality Message and Grading Criteria section.

22. Inspiratory Incentive

This option determines how the test is to begin. The choices are yes, no and man start. The standard configuration is NO.

If no is selected, the patient should be instructed to take a deep breath before putting the sensor in his/her mouth. The first blow into the sensor will be the maximal exhalation.

If yes is selected, the patient should be instructed to put the sensor in his/her mouth prior to taking the first deep breath. The unit will provide an inspiratory incentive to help coach the patient to achieve a maximal inhalation.

If man start is selected, the unit will wait for the technician to press a key before displaying the BLOW message and starting the test. This mode is useful for patients who experience difficulty with coordination. When the unit displays PRESS ANY KEY TO START TEST do the following:

1. Have the patient place the sensor in his or her mouth and breathe normally for a few seconds.
2. Have the patient take a maximal inhalation and hold his or her breath.
3. Press any key. When the screen displays BLOW, coach the patient as you normally would for an FVC test.

NOTE:
If man start is selected, do not allow the patient to start the FVC maneuver before the BLOW message appears. The spirometer will not begin measuring until the BLOW message appears.

23. Audio Incentive

This setting allows you to turn on or off the audio incentive that is heard during the patient's effort. The audio incentive feature can help the patient and technician achieve better test results. The standard configuration is YES.

24. Race Adjustment

This configuration determines how much the predicted values will be reduced when the race adjust feature of the patient data entry routine is set to YES. The range of adjustment is 50% to 99%. The standard configuration is 85% and is the generally accepted adjustment for black patients.

25. All Data

This setting determines which tabular test data will be printed on the best test summary report. When set to yes, the best test summary will include a listing of data for each of the three best pre-medication efforts and each of the three best post-medication efforts. The best values, as determined by the Summary Values configuration (page 59), will be labeled with an asterisk. The standard configuration is NO. This setting has a lower priority than the Number of Curves configuration (page 60). Therefore, if you want data for all three efforts, the Number of Curves configuration must be set to three.

26. All Curves

This setting determines how many curves will be printed on a best test summary report that includes post-medication testing. When set to yes, the pre/post summary will include the three best pre-medication curves on one graph and the three best post-medication curves on another graph. When set to no, only the best pre-medication and the best post-medication curves are printed, and they are on the same graph. The standard configuration is NO. This setting has a lower priority than the Number of Curves configuration (page 60). Therefore, if you want all three post-medication curves printed, the Number of Curves configuration must be set to three.

27. Barometric Pressure

The barometric pressure value is used to convert the volume from ATPS to BTPS and to correct the inspiratory code for elevation. The PB100 is set at the factory for a mean sea level barometric pressure of 760 mmHg. If you are not at sea level, you must change this setting to reflect the actual barometric pressure for the elevation at which the instrument is used. This may be done as follows:

1. Determine the actual elevation at the test site (within 200 feet is sufficient). One way to do this is to contact the airport nearest you.
2. In the table, Barometric Pressure Values (page 65), find the elevation that is closest to your actual elevation. Note the corresponding barometric pressure and input this value into your PB100.

NOTE:
It is important to enter the average barometric pressure based on the elevation of your location, otherwise there will be an error in the inspired volume of approximately 1.3% for every 1000 feet you are above sea level. Daily variations in barometric pressure at the test site will cause small variations in the inspiratory measurements. However, the accuracy of your PB100 will remain within specified guidelines.

Barometric Pressure Values

Elevation (feet)	Pressure (mmHg)	Elevation (feet)	Pressure (mmHg)	Elevation (feet)	Pressure (mmHg)
-1000	790	4400	647	9600	531
-800	784	4600	642	9800	527
-600	778	4800	637	10000	523
-400	772	5000	632	10200	519
-200	766	5200	628	10400	515
0	760	5400	623	10600	511
200	754	5600	618	10800	507
400	749	5800	613	11000	503
600	743	6000	609	11200	499
800	738	6200	604	11400	495
1000	733	6400	600	11600	491
1200	727	6600	595	11800	487
1400	722	6800	591	12000	483
1600	717	7000	586	12200	479
1800	711	7200	582	12400	475
2000	706	7400	577	12600	471
2200	701	7600	573	12800	467
2400	696	7800	568	13000	463
2600	691	8000	564	13200	459
2800	686	8200	560	13400	455
3000	681	8400	556	13600	452
3200	676	8600	551	13800	449
3400	671	8800	547	14000	446
3600	666	9000	543	14200	443
4000	656	9200	539	14400	440
4200	651	9400	535	14600	437
				14800	435

NOTE:
If, as an alternative, you choose to obtain and enter barometric pressure directly, make certain that it is not corrected to sea level, which is what the weather service normally reports.

28. Custom Header

This configuration allows you to generate a custom header on each page of the printed report. The custom header will appear centered at the top of each page. The header can consist of up to two lines, and each line can have up to 34 characters. The characters available are shown below.

0 1 2 3 4 5 6 7 8 9 : ;
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
a b c d e f g h i j k l m n o p q r s t u v w x y z , - . /

Once you have entered the custom header configuration mode, the following keys function as described below:

◀ ▶	moves the cursor left and right
8,0	moves the cursor up and down
7,9	changes the character
4	changes the case of the character
6	creates a blank space
ENTER	enters the entire header

To generate a custom header, perform the following steps:

1. From the CUST HEADER screen of the configuration mode, select YES. Press ENTER.
2. The cursor will flash in the first position of the first line. Use the arrow keys to move the cursor to where you want the first character to appear.
3. Use the 7 and 9 keys to scroll through the characters until the character that you want appears. Use the arrow key to move to the next position. Repeat this step until the first line of your header is complete.
4. Use the 0 key to move the cursor to the second line. Use the arrow keys to move the cursor to where you want the first character to appear. Repeat the process in step three until the second line of your header is complete.
5. When you are satisfied that your header is as you want it, press ENTER.
6. If you want to change your header, repeat the above steps.

Predicated Normal Equations and References

Hi = Height in inches • Hc = Height in centimeters • A = Age in years

Predicted Equations		Reference
	Morris MALE	
	Limits age (18-90) height (58-80)	
FVC	-4.241 - 0.025A + 0.148Hi	(Morris, et. al.,1971)
FEV1	-1.260 - 0.032A + 0.092Hi	(Morris, et. al.,1971)
%FEV1	107.12 - 0.2422A - 0.3118Hi	(Morris, et. al.,1975)
FEV3	FVC * .95	(Morris, et. al.,1971)
FEF25-75	2.513 - 0.045A + 0.047Hi	(Morris, et. al.,1971)
FIVC	-4.241 - 0.025A + 0.148Hi	(Morris, et. al.,1971)
MVV	-37.9489 - 0.8162A + 3.0291Hi	(Cherniak, et. al., 1972)
	Age <25	
PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et. al.,1976)
FEV.5	-3.054 + 0.043A + 0.030Hc	(Knudson, et. al.,1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et. al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et. al.,1983)
	Age ≥ 25	
PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et. al.,1976)
FEV.5	-2.746 - 0.017A + 0.037Hc	(Knudson, et. al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et. al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et. al.,1983)
	Morris FEMALE	
	Limits age (18-90) height (56-72)	
FVC	-2.852 - 0.024A + 0.115Hi	(Morris, et. al.,1971)
FEV1	-1.932 - 0.025A + 0.089Hi	(Morris, et. al.,1971)
%FEV1	88.70 - 0.1815A - 0.0679Hi	(Morris, et. al.,1975)
FEV3	FVC * .95	(Morris, et. al.,1971)
FEF25-75	0.551 - 0.030A + 0.060Hi	(Morris, et. al.,1971)
FIVC	-2.852 - 0.024A + 0.115Hi	(Morris, et. al.,1971)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al., 1972)
	Age <20	
PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et. al.,1976)
FEV.5	-1.738 + 0.061A + 0.019Hc	(Knudson, et. al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et. al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc -0.0075 * A^2	(Knudson, et. al.,1983)
	Age ≥ 20 and <70	
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al.,1976)
FEV.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et. al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et. al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et. al.,1983)
	Age ≥ 70	
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al.,1976)
FEV.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et. al.,1976)
FEF50	6.2402 - 0.0755A + 0.0118Hc	(Knudson, et. al.,1983)
FEF75	1.8894 - 0.0172A	(Knudson, et. al.,1983)
	Knudson 1983 MALE	
	Limits age (18-85) height (58-80)	
	Age <25	
FVC	-6.8865 + 0.0739A + 0.0590Hc	(Knudson, et. al.,1983)
FEV1	-6.1181 + 0.0636A + 0.0519Hc	(Knudson, et. al.,1983)
FEV3	-5.531 + 0.066A + 0.052Hc	(Knudson, et. al.,1976)
%FEV1	92.8965 - 1.4612FVC	(Knudson, et. al.,1983)
FEF25-75	-6.1990 + 0.0749A + 0.0539Hc	(Knudson, et. al.,1976)
PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et. al.,1976)
FIVC	-6.8865 + 0.0739A + 0.0590Hc	(Knudson, et. al.,1983)
FEV.5	-3.054 + 0.043A + 0.030Hc	(Knudson, et. al.,1976)

FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et. al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et. al.,1983)
MVV	-37.9489 - 0.8162A + 3.0291Hi	(Cherniak, et. al.,1972)
	Age ≥ 25	
FVC	-8.7818 - 0.0298A + 0.0844Hc	(Knudson, et. al.,1983)
FEV1	-6.5147 - 0.0292A + 0.0665Hc	(Knudson, et. al.,1983)
FEV3	-5.245 - 0.031A + 0.063Hc	(Knudson, et. al.,1976)
%FEV1	96.3074 - 0.1677A - 1.4232FVC	(Knudson, et. al.,1983)
FEF25-75	-4.5175 - 0.0363A + 0.0579Hc	(Knudson, et. al.,1983)
PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et. al.,1976)
FIVC	-8.7818 - 0.0298A + 0.0844Hc	(Knudson, et. al.,1983)
FEV.5	-2.746 - 0.017A + 0.037Hc	(Knudson, et. al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et. al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et. al.,1983)
MVV	-37.9489 - 0.8162A + 3.0291Hi	(Cherniak, et. al.,1972)
	Knudson 1983 FEMALE **Limits age (18-88) height (56-72)**	
	Age <20	
FVC	-4.4470 + 0.0699A + 0.0416Hc	(Knudson, et. al.,1983)
FEV1	-3.7622 + 0.0694A + 0.0351Hc	(Knudson, et. al.,1983)
FEV3	-3.417 + 0.086A + 0.033Hc	(Knudson, et. al.,1976)
%FEV1	91.9381 + 1.5226A - 7.7593FVC	(Knudson, et. al.,1983)
FEF25-75	-2.8007 + 0.1275A + 0.0279Hc	(Knudson, et. al.,1983)
PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et. al.,1976)
FIVC	-4.4470 + 0.0699A + 0.0416Hc	(Knudson, et. al.,1983)
FEV.5	-1.738 + 0.061A + 0.019Hc	(Knudson, et. al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et. al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc - 0.0075 * A^2	(Knudson, et. al.,1983)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al.,1972)
	Age ≥ 20 and <70	
FVC	-3.1947 - 0.0169A + 0.0444Hc	(Knudson, et. al.,1983)
FEV1	-1.8210 - 0.0190A + 0.0332Hc	(Knudson, et. al.,1983)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et. al.,1976)
%FEV1	113.694 - 0.2904A - 5.4024FVC	(Knudson, et. al.,1983)
FEF25-75	-0.4057 - 0.0309A + 0.0300Hc	(Knudson, et. al.,1983)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al.,1976)
FIVC	-3.1947 - 0.0169A + 0.0444Hc	(Knudson, et. al.,1983)
FEV.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et. al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et. al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et. al.,1983)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al.,1972)
	Age ≥ 70	
FVC	-0.1889 - 0.0296A + 0.0313Hc	(Knudson, et. al.,1983)
FEV1	2.6539 - 0.0397A + 0.0143Hc	(Knudson, et. al.,1983)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et. al.,1976)
%FEV1	113.694 - 0.2904A - 5.4024FVC	(Knudson, et. al.,1983)
FEF25-75	6.3706 - 0.0615A	(Knudson, et. al.,1983)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al.,1976)
FIVC	-0.1889 - 0.0296A + 0.0313Hc	(Knudson, et. al.,1983)
FEV.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et. al.,1976)
FEF50	6.2402 - 0.0755A + 0.0118Hc	(Knudson, et. al.,1983)
FEF75	1.8894 - 0.0172A	(Knudson, et. al.,1983)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al.,1972)
	Knudson 1976 MALE **Limits age (18-85) height (58-80)**	
	Age <25	
FVC	-5.508 + 0.078A + 0.050Hc	(Knudson, et. al., 1976)
FEV1	-4.808 + 0.045A + 0.046Hc	(Knudson, et. al., 1976)
FEV3	-5.531 + 0.066A + 0.052Hc	(Knudson, et. al., 1976)
%FEV1	103.64 - 0.140A - 0.087Hc	(Knudson, et. al., 1976)
FEF25-75	-5.334 + 0.059Hc	(Knudson, et. al., 1976)
PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et. al., 1976)

FIVC	-5.508 + 0.078A + 0.050Hc	(Knudson, et. al., 1976)
FEV.5	-3.054 + 0.043A + 0.030Hc	(Knudson, et. al., 1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et. al., 1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et. al., 1983)
MVV	-37.9489 - 0.8162A + 3.0291Hi	(Cherniak, et. al., 1972)
	Age ≥ 25	
FVC	-5.459 - 0.029A + 0.065Hc	(Knudson, et. al., 1976)
FEV1	-4.203 - 0.027A + 0.052Hc	(Knudson, et. al., 1976)
FEV3	-5.245 - 0.031A + 0.063Hc	(Knudson, et. al., 1976)
%FEV1	103.64 - 0.140A - 0.087Hc	(Knudson, et. al., 1976)
FEF25-75	-1.864 - 0.031A + 0.045Hc	(Knudson, et. al., 1976)
PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et. al., 1976)
FIVC	-5.459 - 0.029A + 0.065Hc	(Knudson, et. al., 1976)
FEV.5	-2.746 - 0.017A + 0.037Hc	(Knudson, et. al., 1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et. al., 1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et. al., 1983)
MVV	-37.9489 - 0.8162A + 3.0291Hi	(Cherniak, et. al., 1972)
	Knudson 1976 FEMALE **Limits age** (18-88) **height** (56-72)	
	Age < 20	
FVC	-3.469 + 0.092A + 0.033Hc	(Knudson, et. al., 1976)
FEV1	-2.703 + 0.085A + 0.027Hc	(Knudson, et. al., 1976)
FEV3	-3.417 + 0.086A + 0.033Hc	(Knudson, et. al., 1976)
%FEV1	107.38 - 0.109A - 0.111Hc	(Knudson, et. al., 1976)
FEF25-75	-1.893 + 0.121A + 0.025Hc	(Knudson, et. al., 1976)
PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et. al., 1976)
FIVC	-3.469 + 0.092A + 0.033Hc	(Knudson, et. al., 1976)
FEV.5	-1.738 + 0.061A + 0.019Hc	(Knudson, et. al., 1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et. al., 1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc $-0.0075 * A^2$	(Knudson, et. al., 1983)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al., 1972)
	Age ≥ 20 and < 70	
FVC	-1.774 - 0.022A + 0.037Hc	(Knudson, et. al., 1976)
FEV1	-0.794 - 0.021A + 0.027Hc	(Knudson, et. al., 1976)
FEV3	-1.633 - 0.023A + 0.035Hc	(Knudson, et. al., 1976)
%FEV1	107.38 - 0.109A - 0.111Hc	(Knudson, et. al., 1976)
FEF25-75	1.171 - 0.024A + 0.021Hc	(Knudson, et. al., 1976)
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al., 1976)
FIVC	-1.774 - 0.022A + 0.037Hc	(Knudson, et. al., 1976)
FEV.5	-0.406 - 0.014A + 0.019Hc	(Knudson, et. al., 1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et. al., 1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et. al., 1983)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al., 1972)
	Age ≥ 70	
FEF50	6.2402 - 0.0755A + 0.0118Hc	(Knudson, et. al., 1983)
FEF75	1.8894 - 0.0172A	(Knudson, et. al., 1983)
	Crapo MALE **Limits age** (18-89) **height** (155-195)	
FVC	-4.650 - 0.0214A + 0.0600Hc	(Crapo, et. al.,1981)
FEV1	-2.190 - 0.0244A + 0.0414Hc	(Crapo, et. al.,1981)
FEV3	-3.512 - 0.0271A + 0.0535Hc	(Crapo, et. al.,1981)
FEF25-75	2.133 - 0.0380A + 0.0204Hc	(Crapo, et. al.,1981)
%FEV1	110.49 - 0.1520A - 0.1300Hc	(Crapo, et. al.,1981)
FEV.5	-1.914 - 0.0152A + 0.0327Hc	(Crapo, et. al.,1981)
FIVC	-4.650 - 0.0214A + 0.0600Hc	(Crapo, et. al.,1981)
MVV	-37.9489 - 0.8162A + 3.0291Hi	(Cherniak, et. al.,1972)
	Age < 25	
PEF	-8.060 + 0.166A + 0.078Hc	(Knudson, et. al.,1976)
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et. al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et. al.,1983)

	Age ≥ 25	
PEF	-5.993 - 0.035A + 0.094Hc	(Knudson, et. al.,1976)
FEF50	-5.5409 - 0.0366A + 0.0684Hc	(Knudson, et. al.,1983)
FEF75	-2.4827 - 0.0230A + 0.0310Hc	(Knudson, et. al.,1983)
	Crapo FEMALE	
	Limits age (18-89) height (145-180)	
FVC	-3.590 - 0.0216A + 0.0491Hc	(Crapo, et. al.,1981)
FEV1	-1.578 - 0.0255A + 0.0342Hc	(Crapo, et. al.,1981)
FEV3	-2.745 - 0.0257A + 0.0442Hc	(Crapo, et. al.,1981)
FEF25-75	2.683 - 0.0460A + 0.0154Hc	(Crapo, et. al.,1981)
%FEV1	126.58 - 0.2520A - 0.2020Hc	(Crapo, et. al.,1981)
FEV.5	-0.809 - 0.0185A + 0.0238Hc	(Crapo, et. al.,1981)
FIVC	-3.590 - 0.0216A + 0.0491Hc	(Crapo, et. al.,1981)
MVV	-4.8696 - 0.685A + 2.1384Hi	(Cherniak, et. al.,1972)
	Age < 20	
PEF	-3.916 + 0.157A + 0.049Hc	(Knudson, et. al.,1976)
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et. al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc - 0.0075 * A^2	(Knudson, et. al.,1983)
	Age ≥ 20 and < 70	
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al.,1976)
FEF50	-0.4371 - 0.0240A + 0.0321Hc	(Knudson, et. al.,1983)
FEF75	-0.1822 - 0.0254A + 0.0174Hc	(Knudson, et. al.,1983)
	Age ≥ 70	
PEF	-0.735 - 0.025A + 0.049Hc	(Knudson, et. al.,1976)
FEF50	6.2402 - 0.0755A + 0.0118Hc	(Knudson, et. al.,1983)
FEF75	1.8894 - 0.0172A	(Knudson, et. al.,1983)

	Hsu MALE	
	Limits age (7-17) height (111-190)	
FVC	$3.58 * 10^{-7} * Hc^{3.18}$	(Hsu, et. al.,1979)
FEV1	$7.74 * 10^{-7} * Hc^{3.00}$	(Hsu, et. al.,1979)
FEF2575	$1.33 * 10^{-5} * Hc^{2.46}$	(Hsu, et. al.,1979)
PEF	$5.58 * 10^{-6} * Hc^{2.79}$	(Hsu, et. al.,1979)
%FEV1	(PRED FEV1/PRED FVC) 100	(Hsu, et. al.,1979)
FIVC	$3.58 * 10^{-7} * Hc^{3.18}$	(Hsu, et. al.,1979)
FEV.5	.7778 * FEV1	(Hsu, et. al.,1979)
FEV3	.98 * FVC	(Hsu, et. al.,1979)
MVV	-99.507 +1.267Hc	(Polgar, et. al.,1971)
	Age < 12	
FEF50	-2.5454 + 0.0378Hc	(Knudson, et. al.,1983)
FEF75	-1.0149 + 0.0171Hc	(Knudson, et. al.,1983)
	Age ≥ 12	
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et. al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et. al.,1983)
	Hsu FEMALE	
	Limits age (7-17) height (111-180)	
FVC	$2.57 * 10^{-6} * Hc^{2.78}$	(Hsu, et. al.,1979)
FEV1	$3.79 * 10^{-6} * Hc^{2.68}$	(Hsu, et. al.,1979)
FEF2575	$6.32 * 10^{-5} * Hc^{2.16}$	(Hsu, et. al.,1979)
PEF	$4.30 * 10^{-5} * Hc^{2.37}$	(Hsu, et. al.,1979)
%FEV1	(PRED FEV1/PRED FVC) 100	(Hsu, et. al.,1979)
FIVC	$2.57 * 10^{-6} * Hc^{2.78}$	(Hsu, et. al.,1979)
FEV.5	.7778 * FEV1	(Hsu, et. al.,1979)
FEV3	.98 * FVC	(Hsu, et. al.,1979)
MVV	-99.507 +1.267Hc	(Polgar, et. al.,1971)

	Age <11	
FEF50	0.7362 + 0.1846A	(Knudson, et. al.,1983)
FEF75	-0.1657 + 0.0109Hc	(Knudson, et. al.,1983)
	Age ≥ 11	
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et. al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc - 0.0075 * A^2	(Knudson, et. al.,1983)
	Polgar MALE	
	Limits age (4-17) height (43-67)	
FVC	4.4 * 10^{-6} * $Hc^{2.67}$	(Polgar, et. al.,1971)
FEV1	2.1 * 10^{-6} * $Hc^{2.80}$	(Polgar, et. al.,1971)
FEF2575	-3.4616 + 0.0437 * Hc	(Polgar, et. al.,1971)
PEF	-7.0929 + .08738 * Hc	(Polgar, et. al.,1971)
%FEV1	47.73 * Hc^{-13}	(Polgar, et. al.,1971)
FIVC	4.4 * 10^{-6} * $Hc^{2.67}$	(Polgar, et. al.,1971)
FEV.5	.7778 * FEV1	(Polgar, et. al.,1971)
FEV3	.98 * FVC	(Polgar, et. al.,1971)
MVV	-99.507 +1.267Hc	(Polgar, et. al.,1971)
	Age <12	
FEF50	-2.5454 + 0.0378Hc	(Knudson, et. al.,1983)
FEF75	-1.0149 + 0.0171Hc	(Knudson, et. al.,1983)
	Age ≥ 12	
FEF50	-6.3851 + 0.1150A + 0.0543Hc	(Knudson, et. al.,1983)
FEF75	-4.2421 - 0.0057A + 0.0397Hc	(Knudson, et. al.,1983)

	Polgar FEMALE	
	Limits age (4-17) height (43-67)	
FVC	3.3 * 10^{-6} * $Hc^{2.72}$	(Polgar, et. al.,1971)
FEV1	2.1 * 10^{-6} * $Hc^{2.80}$	(Polgar, et. al.,1971)
FEF2575	-3.4616 + 0.0437 * Hc	(Polgar, et. al.,1971)
PEF	-7.0929 + .08738 * Hc	(Polgar, et. al.,1971)
%FEV1	63.63 * Hc^{-08}	(Polgar, et. al.,1971)
FIVC	3.3 * 10^{-6} * $Hc^{2.72}$	(Polgar, et. al.,1971)
FEV.5	.7778 * FEV	(Polgar, et. al.,1971)
FEV3	.98 * FVC	(Polgar, et. al.,1971)
MVV	-99.507 +1.267Hc	(Polgar, et. al.,1971)
	Age <11	
FEF50	0.7362 + 0.1846A	(Knudson, et. al.,1983)
FEF75	-0.1657 + 0.0109Hc	(Knudson, et. al.,1983)
	Age ≥ 11	
FEF50	-2.3040 + 0.1111A + 0.0288Hc	(Knudson, et. al.,1983)
FEF75	-4.4009 + 0.2923A + 0.0243Hc - 0.0075 * A^2	(Knudson, et. al.,1983)

Predicted Normal Limits

The spirometer allows you to enter an age from 4 to 99 and a height from 40 to 84 inches (100 to 210 cm). These limits may go beyond the age and height limits of the normal equations. If you enter an age or height that is outside the specified limits of an equation, the following message is printed with the interpretation:

"Predicted values for this age or height are not well established."

References:

Cherniak, R.M., and Raber M.B., "Normal Standards for Ventilatory Function using an Automated Wedge Spirometer," *American Review of Respiratory Disease*, Volume 106, 1972, p 38-46.

Crapo, Robert O., Gardner Reed M., Morris Alan H, "Reference Spirometric Values Using Techniques and Equipment that Meets ATS Recommendations," *American Review of Respiratory Disease*, Volume 123, 1981, p. 659-674.

Hsu KHK, Bartholomew PH, Thompson V, Hseih GSJ, "Ventilatory Functions of Normal Children and Young Adults - Mexican-American, White, Black. I. Spirometry," *J Pediatr* 1979; 95:14-23.

Knudson, Ronald J, Michael Lebowitz, Holberg Catherine J., Benjamin Burrows, "Changes in the Normal Maximal Expiratory Flow-Volume Curve with Aging," *American Review of Respiratory Disease*, Volume 127, 1983, p. 725-734.

Knudson, Ronald J., Ronald Slatin, Michael Lebowitz, Benjamin Burrows, "The Maximal Expiratory Flow-Volume Curve," *American Review of Respiratory Disease*, Volume 113, 1976, p. 587-600.

Morris, James F., Koski, Arthur, Breese, John, "Normal Values and Evaluation of Forced Expiratory Flow," *American Review of Respiratory Disease*, Volume 111, 1975, p. 755-761.

Morris, James F., Koski, Arthur, Lavon Johnson, "Spirometric Standards for Healthy Non-Smoking Adults," *American Review of Respiratory Disease*, Volume 10-3, 1971, p. 57-67.

Polgar, P.,V. Promadhat, *Pulmonary Testing in Children*, W.B. Saunders, Philadelphia, 1971, p. 100-153.

Clinical Interpretation Criteria

Clinical Interpretation

The interpretations are produced by the PB110 base station. The computer-suggested interpretation is an option which may be turned off using the configuration routine. Caution must be used during interpretation when maneuver quality grades are low (D or F), because the results may be falsely positive.

If the %FEV1 is below the lower limit of the normal range (90% of predicted), the patient is identified as having airway obstruction. The degree of obstruction is then determined by the cutoffs suggested. The interpretation criteria are those suggested by the 1986 pulmonary impairment/disability committee of the American Thoracic Society. If the FVC is also reduced in a patient with moderate to severe obstruction, a superimposed restrictive process cannot be ruled out, but the low vital capacity is usually due to hyperinflation and air trapping, secondary to the obstruction.

When the FVC is reduced below 80% of predicted and the %FEV1 is normal or high, the patient may have restriction of lung volumes, again graded by the 1986 ATS suggestions. A mild reduction in the FVC occurs in 5% of healthy persons and may also be due to obesity or poor effort.

IF %FEV1 <90% of predicted

AND...	INTERPRETATION
FEV1 ≥ 80% of predicted	Borderline obstruction
FEV1 ≥ 60% and <80% of predicted	Mild obstruction
FEV1 ≥ 40% and <60% of predicted	Moderate obstruction
FEV1 <40% of predicted	Severe obstruction
AND ALSO	**INTERPRETATION**
FVC <80% of predicted	Plus low vital capacity possibly from a concomitant restrictive defect

IF %FEV1 >90% of predicted

AND...	INTERPRETATION
FVC ≥ 80% of predicted	Normal spirometry
FVC ≥ 60% and <80% of predicted	Mild restriction
FVC ≥ 50% and <60% of predicted	Moderate restriction
FVC <50% of predicted	Severe restriction

Lung Age Interpretation

The lung age interpretation is printed only under the following conditions:

Condition A	interpretation configuration is enabled	and lung age is enabled	and the patient is a smoker	and adult normals are Knudson and the patient is male and age 25 or older
Condition B				and adult normals are Knudson and the patient is female, age 20 or older
Condition C				and adult normals are Morris or Crapo and the patient age is 18 or older

The equations for lung age are derived from the predicted equation for FEV1. The lung age is calculated by substituting the measured FEV1 for the predicted FEV1 and then solving the equation for age. The lung age value will never be less than the patient's age.

Reference:

Enright, PL, Hyatt RE, *Office Spirometry. A Practical Guide to the Selection and Use of Spirometers.* Philadelphia, Lea and Febiger, 1987.

Morris, JF and Temple, W., "Spirometric 'Lung Age' Estimation for Motivating Smoking Cessation," *Preventative Medicine*, Volume 14, 1985, p. 655-662.

Quality Message and Grading Criteria

Introduction

Unlike many other medical tests in which the patient is passive, spirometry requires active cooperation and strenuous effort by the patient. The ability of technicians to elicit this effort varies widely but can be improved with experience and feedback.

The FVC maneuver quality messages and the FVC and FEV1 grading system used by the *Renaissance* spirometry system are the same as those proven to improve test quality by the NIH-sponsored, ten-center Lung Health Study (*Am Rev Respir Dis* 1991; 143:1215-1223).

The quality grades optionally printed on the report after the FVC and FEV1 are an indication of the reliability of each of these measurements. Physicians may use them to judge their degree of confidence in the results. The grades are also an index of the short-term reproducibility of the FVC and FEV1 for that patient.

For instance, if a patient with asthma returns for a follow-up visit after being started on therapy with inhaled bronchodilators and corticosteroids with an FEV1 increase of .2L, and both of the FEV1 grades at baseline and at today's visit are "A"s, the physician is more likely to consider the change to be significant than if one of them had a "D" grade.

You cannot expect to obtain an "A" grade for both FVC and FEV1 from all patients. The very best pulmonary function technician could not even get "D" grades from some patients. However, a high grade is a goal which should be pursued for up to 8 FVC maneuvers. You may expect better grades from patients with airway obstruction after they have inhaled a bronchodilator.

The FVC and FEV1 grades can be viewed with respect to the American Thoracic Society's test quality recommendations in the following manner:

A: exceeds ATS test quality recommendations
B: meets ATS test quality recommendations
C: slightly below test quality recommendations
D: substantially below test quality recommendations

Do not become frustrated if a quality message reappears after every maneuver from a patient despite your enthusiastic coaching and apparent maximal effort by the patient. Each criterion was set so that about 5% of patients, even when coached vigorously, did not meet the criterion.

Use these messages as guidelines, not as concrete rules. The computer is "wrong" at least five percent of the time. The technicians of the Lung Health Study considered the computer to be a "mediocre technician, looking over their shoulders," giving advice which was usually helpful and often unnecessary because the problem was obvious by watching the patient's performance, and sometimes to be ignored.

Quality Messages

A quality message appears on the display after each FVC/FVL effort. Listed below are all nine messages and what they mean. Note that the first five are acceptability messages, based on the general quality of the maneuver. The next three are reproducibility messages, based on how the values of the test compare to the previous best test. The messages are listed in order of priority. If more than one message is applicable, only the highest one on the list will be displayed.

Message	Definition
START FASTER	Extrapolated volume is greater than 5% of FVC and greater than 100 ml. Coach the patient to not hesitate or leak out air before the blast out.
BLAST OUT HARDER	The time from beginning of test to peak flow is greater than 90 msec. Coach the patient to BLAST out the air more quickly at the beginning of the test.
AVOID COUGHING	Greater than a 50% drop and recovery in flow in the first second. Ask the patient to clear their throat and offer him/her a drink of water.
BLOW OUT LONGER	Exhalation time is too short. If age is <18, FET is <2 seconds. If age is >=18 and <=25, FET is <3 seconds. If age is >25, FET is <5 seconds. Coach the patient to blow out longer.
ABRUPT ENDING	A greater than 0.2 l/s flow was detected within 0.1 second before peak volume. Coach the patient to keep blowing as long as possible.
FEV1 VARIABLE	There is a difference of at least 5% and 100 ml between the two best FEV1 values. Try again.
FVC VARIABLE	There is a difference of at least 5% and 200 ml between the two best FVC values. Try again.

PEF VARIABLE	There is a difference of at least 10% and 1 l/s between the two best PEF values. Try again.
GOOD TEST!!!	No problems detected.

Quality Grades

When the quality grade configuration is enabled, the grades are displayed after each effort and printed on each best test summary report. The grades represent the quality of the entire test session (best FVC and FEV1). Each grade is defined below.

FVC Grade	Definition
A	Not BLOW OUT LONGER, not ABRUPT ENDING, and FVC variability less than 3%
B	Not BLOW OUT LONGER, not ABRUPT ENDING, and FVC variability is less than 5%
C	Not BLOW OUT LONGER, not ABRUPT ENDING, FVC variability is less than 8%, and 3 accepted FVC tests
D	Not ABRUPT ENDING
F	All other cases

FEV1 Grade	Definition
A	Not START FASTER, not BLAST OUT HARDER, not AVOID COUGHING, FEV1 variability less than 3%, and PEF variability less than 7%
B	Not START FASTER, not BLAST OUT HARDER, not AVOID COUGHING, and FEV1 variability less than 5%
C	Not START FASTER, not BLAST OUT HARDER, not AVOID COUGHING, FEV1 variability is less than 8%, and 3 accepted FVC tests
D	Not START FASTER and not BLAST OUT HARDER
F	All other cases

Reference:

Enright, PL, Johnson LR, Connett JE, Voelker HT, Buist AS, "Spirometry in the Lung Health Study: Methods and Quality Control," *American Review of Respiratory Disease*, June 1991.

RS-232-C Interface Specifications

The *Renaissance* spirometry system supports asynchronous communications to a computer system with an RS-232-C serial port.

Data can be transmitted from the hand-held unit when it is docked in the base unit. Whenever the printer is off-line, powered off, or not connected to the printer port on the base, data transmitted from the hand-held unit is routed through the serial port on the base.

The **PRINT/SEND** key is used to initiate transmission of the LAST or BEST test results, including curve data. A last test transmission will contain configuration data, patient data, and the last test data. A best test transmission will contain configuration data, patient data, calibration check data, and pre-medication and post-medication test data.

The serial port on the base unit has a standard 9-pin IBM PC-AT-style connector and supports the following RS-232C signals:

Pin	Description
1	not connected
2	RXD (receive data)
3	TXD (transmit data)
4	DTR (pulled to +12V through 1.2K)
5	GND
6	not connected
7	RTS (pulled to +12V through 1.2K)
8	not connected
9	not connected

The communication parameters are fixed at 8 data bits, 1 stop bit, and no parity. The baud rate is adjustable from 205 to 52,083.3, by the equation BAUD = 52083.3/ACK where ACK = 1 to 254.

In order for the computer system to communicate successfully with the *Renaissance* spirometry system, an application program must first be written on the computer system. This program must do more than act as a "terminal," because the *Renaissance* system requires responses from the computer system (i.e. setting up the proper baud rate, returning a checksum). For a complete technical specification, contact a Technical Service Representative at 1-800-255-6774 (Option 1).

Cleaning

Because the *Renaissance* spirometry system uses disposable, single-patient-use pneumotachs, there is no need to clean or sterilize any part of the spirometer or the pressure tube. You may, however, wish to remove dust or fingerprints from the exterior by wiping with a damp cloth.

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