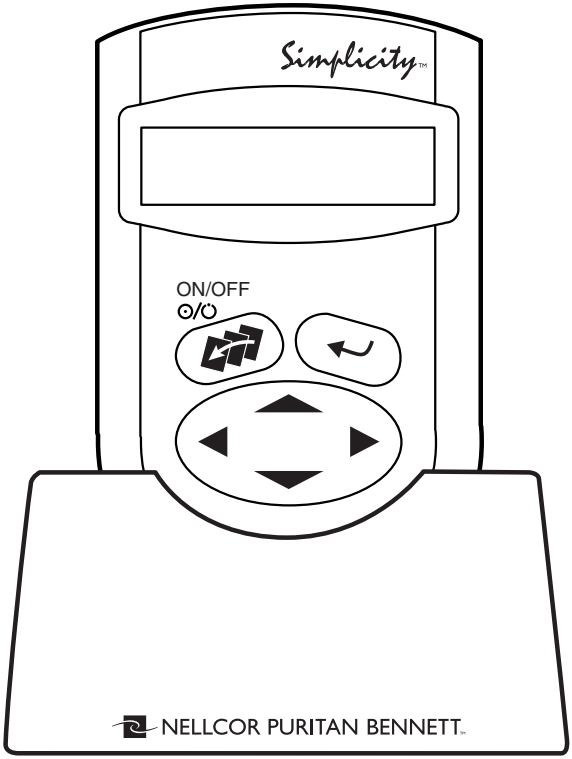
Simplicity™

NPB-500 Spirometry System
User's Manual



MALLINCKRODT

English

P-063124-EN Rev. B

Table of Contents

Definition of Statements and Symbols

Statements in this manual preceded by the following words are of special significance.

WARNING

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

CAUTION:

Means there is a possibility of damage to the instrument or other property.

NOTE: Indicates points of particular interest or emphasis that make for more efficient and convenient operation of the equipment.

CAUTION:

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

SYMBOL	DEFINITION
⊙/Ⓘ	ON is represented by the circle with the dot in the center. OFF is the circle with the dot on the edge. To turn the unit on press and hold the Options key. If the instrument is already on it can be turned off by pressing and holding the Options key.
◀ ▶	When the Right or Left arrow is displayed, these keys can be used to move the cursor. Pressing the Right arrow key causes the cursor to move right, and the Left arrow moves it to the left. After the cursor has been moved to the desired location on the screen, the Up or Down arrow can be used to change the value of the character above the cursor. If the cursor is moved all the way to the far right of the screen, the next available screen is displayed. When the cursor is moved to the far left of the screen, the previous screen is displayed. Right and left arrows can also be displayed when viewing the results of a test or session. These arrows indicate that more data is available, and can be viewed by pressing the appropriate arrow key

SYMBOL	DEFINITION
	When the Up or Down arrow is displayed, one of two things can happen. Pressing the Up or Down arrow key either displays a new option or changes the value of the character highlighted by the cursor.
	Options Key changes the display to the options menu. The Options key is also used to turn the NPB-500 ON and OFF. Pressing the Options key will also abort a test or zeroing procedure.
	Enter Key is used to move to the next display or to initiate the option highlighted by the cursor. Depending on the display being viewed this key could be disabled. When this symbol is shown on the screen, pressing the Enter key will activate the option that is displayed.
	If battery power becomes low, the low battery icon will be displayed on the spirometer.
	The dotted arrow across the bottom of the screen is an indication of the patient's exhaled volume produced during a test. The longer the arrow, the larger the volume. This is used as an incentive along with the incentive tone.
	This symbol represents the I/O communications port.
	This symbol represents the printer port.
	See instructions for use.
	The flow sensor is designed for single patient use.
	The arrows indicate the direction of air flow through the flow sensor during exhalation.

SYMBOL	DEFINITION
	The flow sensor is made of plastic that can be recycled. Number 6 represents polymers of styrene.
CE 0050	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. It therefore bears the CE marking as shown.
	Type BF Applied Part
SN	G-XXXXYYYYYY X=Year of Manufacture

WARNING

Explosion hazard, do not use the NPB-500 spirometer in the presence of flammable anesthetics.

Intended Use

The Simplicity NPB-500 spirometry system consists of a portable spirometer (NPB-500) and an optional spirometer base (NPB-510) for interfacing to parallel printers and computer (PC com) ports. The NPB-500 uses the Puritan Bennett FSII single patient use flow sensor. Basic spirometry testing consisting of FVC tests is performed by the NPB-500 spirometer. The system is intended for use with adult and paediatric patients in hospital and physician office environments.

NPB-500 Spirometry System

Figure 1 is an illustration of the parts of the NPB-500 spirometry system. Items 4 and 5 are optional. If any required parts are missing, please contact Mallinckrodt.

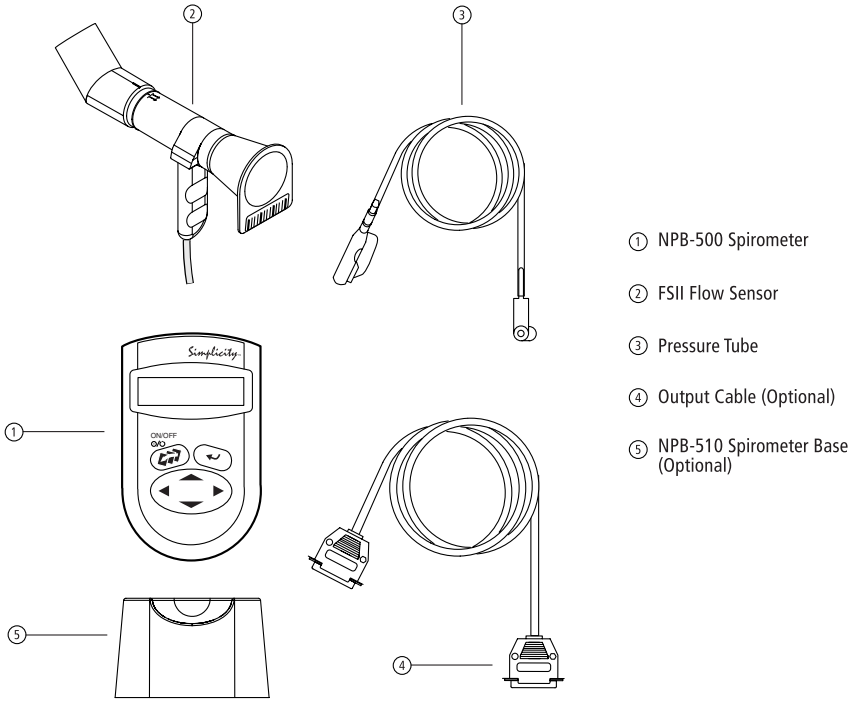


Figure 1: NPB-500 Spirometry System Components

Preparation for Use

To prepare the spirometer for use it will be necessary to install the batteries and connect the pressure tube.

Battery Installation

The NPB-500 spirometer requires two AA alkaline batteries. To install the batteries, remove the battery door as shown in Figure 2. Labeling inside the battery compartment shows how to properly install the batteries. After the batteries have been installed, close the battery door.

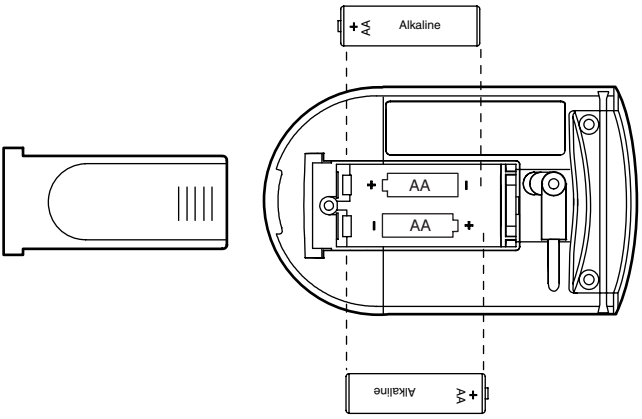


Figure 2: Battery Installation

Connecting the Pressure Tube

The pressure tube should be connected as shown in Figure 3. The spirometer is shipped with the pressure tube connected to the pressure port on the back of the instrument. The other end of the pressure tube should be connected to the flow sensor. The pressure tube does not need to be disconnected from the spirometer between patients.

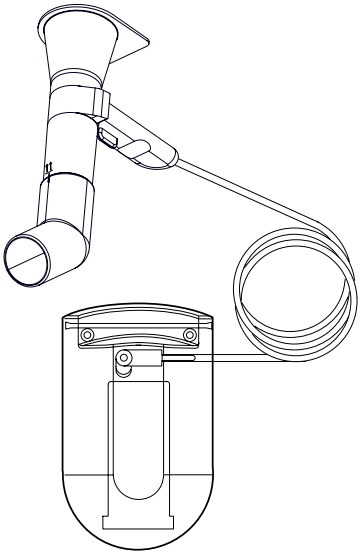


Figure 3: Pressure Tube

After the batteries have been installed and the tube is connected, the spirometer is ready for use.

User Interface and Controls

Figure 4 shows the controls that are used to access the functions of the NPB-500. Other key components needed to properly use the spirometer are also shown. The use of each part is described in the text that follows.

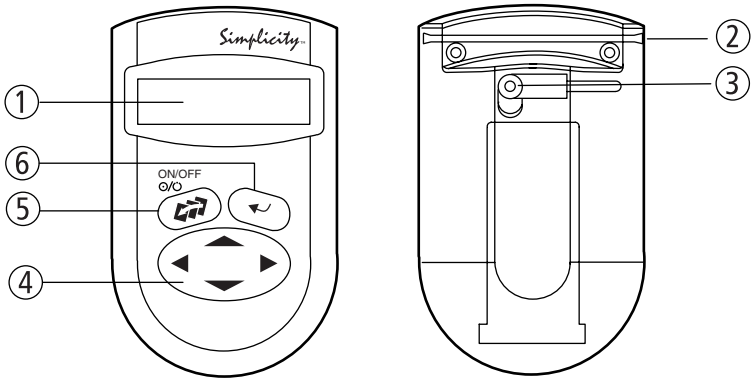


Figure 4: NPB-500 Spirometer User Interface

1	Data Display	4	Arrow Key
2	Sensor Reader	5	Options Key
3	Pressure Port	6	Enter Key

Power On/Off

Turn on the spirometer by pressing and holding the Options key for at least 2 seconds. When the spirometer has been turned on, it performs a Power On Self Test (POST). When POST is successfully completed the spirometer emits a single beep and "NPB-500 REV X" is displayed.

To turn off the NPB-500, press and hold the Options key for at least 2 seconds. The spirometer automatically shuts off if it has not been used for 5 minutes.

Control Keys

Three control keys on the front of the spirometer are used for operator input and data retrieval. The three keys and their functions are listed below:

- Arrow Key is used to move the cursor in the Data Display to select an option or to move to the next or previous display. Depending on the display being viewed, the right and left functions or the up and down functions may be disabled.

- Enter Key is used to move to the next display or to initiate the option highlighted by the cursor. Depending on the display being viewed this key could be disabled.
- Options Key changes the display to the options menu. The Options key is also used to turn the NPB-500 on and off. Pressing the Options key will also abort a test or zeroing procedure.

Error Indications

When the spirometer is turned on, it automatically performs a POST. If POST was not successfully completed the NPB-500 will display "POWER ON SELF TESTFAILED: X" and a Post Fail tone is sounded. The X represents an error code from A to K. Refer to Ta b le 8 on page43 in the troubleshooting section of this manual for more details on the error codes. Pressing any key turns the spirometer off .

The NPB-500 spirometer checks battery status every 30 seconds. If the battery power is determined to be low, a low battery icon will be shown in the upper right hand corner of the display and a Low Battery Tone will be sounded. At this time there is enough battery power to do approximately 20 more patient tests. The battery icon will be displayed in the upper right hand corner of all options screens until the batteries are replaced.

If battery power has dropped below the point that it can reliably operate the
NPB-500, "DEAD BATTERY" will be flashed 3 times and the spirometer will turn off.

NOTE: If the spirometer will not turn on check or replace the batteries.

Sensor Reader

Before any testing can be performed, data from the sensor must be entered into the spirometer. This data can be entered numerically using the keypad or by sliding the bar coded edge of the flow sensor through the slot on the back of the spirometer.

Options

When the Options key is pressed on the front of the spirometer, options can be selected by using the Up or Down arrow key. This section describes each of the options.

Blow & Go

In the BLOW & GO mode only one acceptable test is considered. This mode is for quick testing and does not require the entry of patient data. The results displayed are the same as for the screening mode, but no predictive values are presented. The Patient ID for all Blow & Go tests is recorded as Blow & Go.

New Patient

When the New Patient option has been selected, the spirometer allows the user to enter the patient's ID, Age, Height, Gender, Smoking Preference, and Ethnic Group. Testing in the Screening or Diagnostic Mode can then be performed. Table 1 on page13 shows the patient data parameters and their limits.

Start Test

After the ID number has been entered and the Enter key has been pressed, the Start Test option is displayed. Press the Enter key at this prompt to begin the patient testing procedure.

New Sensor

"**Swipe Sensor or ⇳ to enter code**" is displayed at the beginning of the "Start Test" option or if the "New Sensor" option was selected. The New Sensor option is available after a test has been performed to allow for the replacement of a contaminated or damaged sensor.

View Patient

This option is only available if patient data has been entered. View Patient allows the user to review or edit the information that was entered in the patient data fields while in the New Patient option.

Configure

When Configure is selected, the user can configure the spirometer for use at their location. Once the choices have been entered, they will stay in memory until the user goes back into the configure option and makes changes.

Options:	*Choices:*
Language:	English, Spanish, French, German, Italian, and Dutch
Date:	Enter current date
Time:	Enter current 12H time, or Enter current 24H time
Config. Mode:	USA, Europe, or Custom
Units:	English or Metric
Paper Size:	8.5"x11" or A4
Normals:	ITS/Hsu, ECCS/Zapletal, J.Roca/Zapletal, Knudson

Interpretations:	ATS, ECCS, BTS, or None
Test Mode:	Screening or Diagnostic
Printer:	None, HP, Epson 9-pin, Epson 24-pin, Canon, IBM
Elevation:	Enter elevation in feet, or Enter elevation in Meters
Quality:	Messages, Test Variance

The NPB-500 default selection for each option is listed first. Setting Config. Mode to USA or Europe presets the NPB-500's Units, Paper Size, Normals, and Interpretations configuration settings. See Table 1 on page 13 for more information.

View Results

The View Results option is only available after a test has been completed. Selecting this mode allows the user to view the results of the test session. The right and left arrow keys can be used to view different data screens after the completion of a test session.

More Tests

After a test has been completed, this option becomes available allowing the user to perform more tests. Two acceptable tests are a complete session in the SCREENING mode and three acceptable tests complete a DIAGNOSTIC session.

Post Test

After a test has been performed on a patient, Post Test becomes an option. Post tests are usually performed after medication has been given to the patient. The spirometer compares post-test data to pretest data and displays a percentage of change between the two.

Print Results

If no printer has been selected in the configuration mode or no patient test data is present, the Print Results option is not offered. When this option has been selected, data can be sent to a printer if the spirometer is placed in the NPB-510 Spirometer Base.

Patient Recall

When Patient Recall is selected, the user can scroll through a list of patient tests and calibration checks stored in memory. Once the user recalls a stored test, they can view or print results, or perform post testing.

Cal Check

When Cal Check is selected, the user is prompted through a series of steps to complete the calibration check. When the calibration check has been completed, the screen will display CAL OK or BAD CAL along with the percentage of error (X.X%).

Spirometry Tests

New Sensor

"**Swipe Sensor or ⬍ to enter code**" is displayed at the beginning of the "Start Test" option or if the "New Sensor" option was selected. The New Sensor option is available after a test has been performed to allow for the replacement of a contaminated or damaged sensor.

When a new FSII Sensor is required for testing, the Simplicity will display:

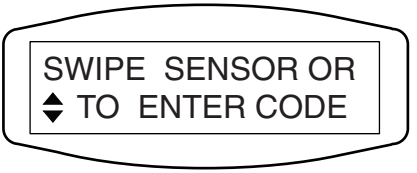


Figure 5: New Sensor

The user can enter specific data for the sensor being used by swiping the sensor's barcode. The spirometer reads the barcode on the sensor when the sensor is passed through the sensor reader on the back of the spirometer, as illustrated in Figure 10. The sensor's calibration data can also be entered numerically by pressing either the up or down arrow keys. If an arrow key is pressed the user will see:

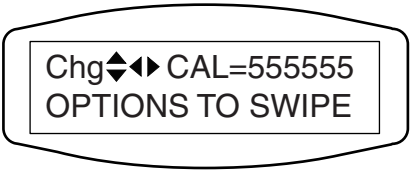


Figure 6: Calibration Data

The user should enter the 6-character CAL Code printed on the sensor.

Use the up or down arrow keys to increase or decrease the character currently selected and use the left and right arrow keys to select next character to change. Press the Enter key when the Code displayed is correct. Pressing the Options Key returns the user to the Swipe Sensor display.

Press enter to re-enter the sensor code.

If an error occurs when the sensor code is entered using the keypad the following screen is displayed:

Figure 7: Sensor Error

Press ⬍ to retype the sensor's CAL Code.

If an error occurs when the sensor is swiped the following screen is displayed:

Figure 8: Sensor Error

If three attempts to swipe the sensor (or enter the CAL Code using the keypad) have failed, Figure 9 is displayed:

Figure 9: Bad Sensor

At this point, pressing any key will return the user to the previous Options screen.

The user should re-enter the test using the Options screen and select a new sensor for testing.

Figure 10 is an illustration showing how to swipe the sensor. The spirometer reads the barcode on the sensor when the sensor is passed through the sensor reader on the back of the spirometer. The sensor can be passed through the reader from left to right or right to left as shown in the

illustration. It must be passed smoothly, and in its entirety, through the sensor reader on the back of the NPB-500.

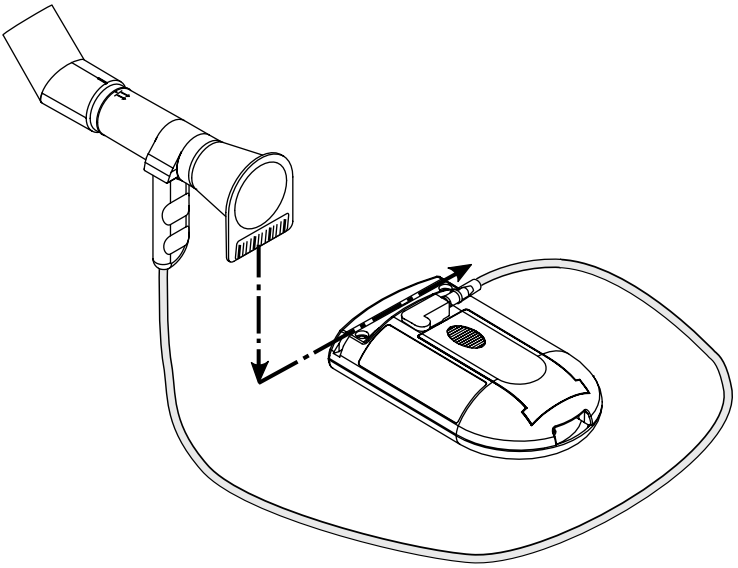


Figure 10: Swiping the Sensor

Configuration

Once a Configuration has been done, it is retained in memory. The spirometer does not have to be configured each time a test is run. To begin a configuration, press the Enter key when the Configure option is displayed. After any step during the procedure, the Options key can be pressed to exit Configuration, Save selections and go to the Options Screens.

Table 1: Options

Option	Default	Other Choices
Language	English	Spanish, French, German, Italian, Dutch
Date	Enter current date	
Time	Enter current 12 hour time	Enter current 24 hour time
Configuration Mode	USA	Europe, Custom
Units	English	Metric
Paper Size	8.5 x 11"	A4 format
Normals	ITS/ Hsu	ECCS/ Zapletal, J. Roca/Zapletal, Knudson
Interpretations	ATS	ECCS, BTS, None
Test Mode	Screening	Diagnostic
Printer	None	HP, Epson 9-pin, Epson 24-pin, Canon, IBM
Elevation	1000 ft.	0 to 9,000 ft.or 0 to 3,000 meters
Quality	Message	Test Variance

Language

The first choice in Configuration is **Language**, see Figure 11. The choices for language are: English, Spanish, French, German, Italian, and Dutch. Use the UP or Down arrow key to change the language that will be used for NPB-500 display and printout. Press the Enter key when the desired selection is displayed.

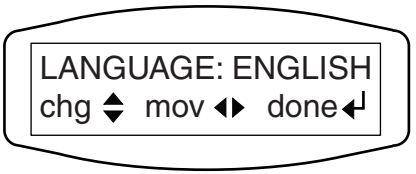


Figure 11: Language Selection

The language is saved and all subsequent NPB-500 text screens will appear in the selected language. The display advances to the next screen of the Configuration Menu.

Date

Use the Up or Down arrow key to change the value of the character above the cursor as shown in Figure 12. Press the Enter key when the desired date is displayed.

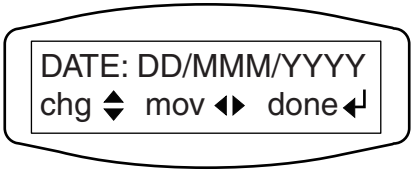


Figure 12: Date Selection

The Right and Left arrow keys are used to move the cursor to the value that needs to be changed. The format for the date display is dd/mmm/yyyy. In the display, dd and yyyy, will be replaced by characters representing the day and the year, mmm is a three letter abbreviation for the month. Press the Enter key and the screen moves to the Time adjust screen shown in Figure 13.

Time

The Right and Left arrow keys are used to move the cursor to the value that needs to be changed. Use the Up and Down arrow keys to adjust the value of the character over the cursor. The format for the **Time** display is hh:mm am. In the display, hh and mm, will be replaced by characters representing the hour and the minute. The selection of AM, PM, or 24 H time can be made by moving the cursor to this selection and pressing the Up and Down arrow keys. In the 24 hour mode, time should be entered as 0 to 24-hour: minutes. Press the Enter key and the screen moves to the configuration mode selection screen.

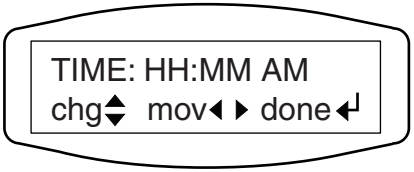


Figure 13: Time Adjust Screen

Config. Mode

The **Configuration Mode** selection allows the user to do a "Quick Start" NPB-500 configuration. If the user selects "USA" the NPB-500 will be configured with the most commonly requested configuration settings for the United States. If the user selects "EUROPE" the NPB-500 will be

configured with the most commonly requested configuration settings for Europe. If the user selects "Custom" the user will be stepped through all of the NPB-500 configurable choices. See Table 2 on page15 for the default values for U.S.A. and Europe.

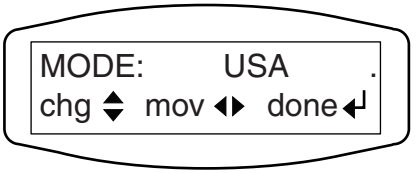


Figure 14: Configuration Mode

Table 2: Custom Configurations

	U.S.A.	EUROPE	CUSTOM
UNITS	English	Metric	User's Choice
PAPER SIZE	8.5 x 11 inches	A4 Format	User's Choice
NORMALS	ITS and HSU	ECCS and Zapletal	User's Choice
INTERPRETATION	ATS	ECCS	User's Choice

Units

If "Custom Configuration" is selected the user can use the Up or Down arrow keys to select the **Units** used for patient data entry. The choices for units are English/Imperial or Metric. When the desired choice is displayed, press the Enter key. The user's unit choice is saved. The display advances to the next screen for choosing printout paper size.

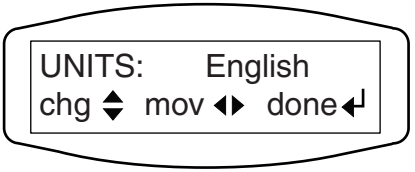


Figure 15: Units Selection

Paper Size

If "Custom Configuration" is selected the user can use the Up or Down arrow keys to select the **Paper size** used for NPB-500 printouts. The choices for paper size are 8.5 x 11" and A4. When the desired choice is displayed, press the Enter key. The user's paper size choice is saved. The display advances to the next screen for unit predictive author selection.

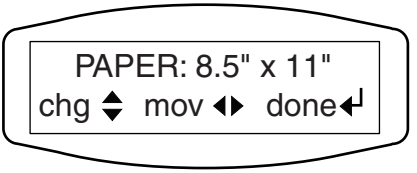


Figure 16: Paper Size Selection

Normals

If "Custom Configuration" is selected the user can use the Up or Down arrow keys to select the Normal Author used for maneuver predictive normal values. When the desired choice is displayed, press the Enter key. The user's unit choice is saved. The display advances to the next screen for choosing maneuver interpretation criteria.

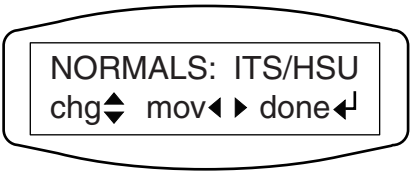


Figure 17: Normal Selection

The user can select from:

ITS / HSU

Adult Normals: Inter Mountain Thoracic Society/Crapo for ages 18 to 90 years

Paediatric Normals: HSU et al. for ages 4 to 18 years

ECCS / Zapletal

Adult Normals: European Community for Steel and Coal for ages 18 to 70 years

Paediatric Normals: Zapletal et al. for ages 6 to 18 years

J. Roca/Zapletal

Adult Normals: J. Roca, J. Sanchis, Agusti-vidal et al. for ages 20 to 70 years

Paediatric Normals: Zapletal et al. for ages 6 to 18 years

Knudson

Adult and Paediatric Normals: Knudson et al. 1983 for ages 6 and older

Note:

Knudson predictive equations will be used to produce predictive values not supported by selected normal authors. Predictive values will be extrapolated for patients with ages outside the age limits supported by the selected normal author.

Interpretation

If "Custom Configuration" is selected the user can use the Up or Down arrow keys to select the **Interpretation** standard used for maneuver analysis.

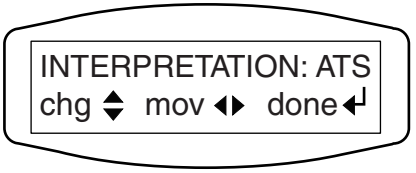


Figure 18: Interpretation Standard

The Up or Down arrow can be used to change the choice from ATS, BTS, ECCS or None. When the desired choice is displayed, press the Enter key. The display advances to the next screen for choosing test mode.

Test Mode

The NPB-500 has two test modes: SCREENING AND DIAGNOSTIC.

Table 3: Definitions

Test	Definition
FVC	Forced Vital Capacity is the total volume forcefully exhaled during a test after a maximum inhalation.
FEV1	Forced Expiratory Volume over 1 second is the volume exhaled during the first second of the test.
%FEV2	Percent Forced Expiratory Volume is the FEV1 value divided by the FVC value multiplied by 100.
PEF	Peak Expiratory Flow rate is the maximum flow rate measured during a test.
FEF25-75	Forced Expiratory Flow rate is the average flow rate measured between 25% and 75% of the FVC.

All spirometry maneuvers must be at least 6 seconds long to be acceptable. Spirometry data is collected for a maximum of 15 seconds or until the volume increase for 2 seconds is less than 0.2 liters.

Before an actual test is begun, the spirometer should be configured.

The user can choose between two test modes, either SCREENING, or DIAGNOSTIC. The mode selection screen will look like Figure 19.

The test mode cannot be changed during a test session unless new patient data is entered.

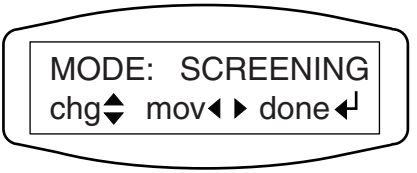


Figure 19: Choose Test Mode

The Up or Down arrow can be used to change the choice from SCREENING, to DIAGNOSTIC. When the desired choice is displayed press the Enter key. Once the choice has been selected the screen advances to the printer screen.

When the SCREENING mode is selected, two acceptable and reproducible tests are considered a complete session. After the test is completed, data for FEV1, FVC, %FEV1, and PEF is available.

If the DIAGNOSTIC mode has been selected, three acceptable and two reproducible tests are considered a session. Upon completion of a test, data for FEV1, FVC, %FEV1, PEF, and FEF 25-75 can be viewed.

The test mode cannot be changed during a test session unless new patient data is entered.

Printer

One of six choices can be selected from the Printer screen shown in Figure 20, HP, Epson 9-pin, Epson 24-pin, Canon, IBM, and None. Use the Up or Down arrow key to change the printer being displayed on the screen. Press Enter when the desired printer is being displayed. A selection of None disables the print function.

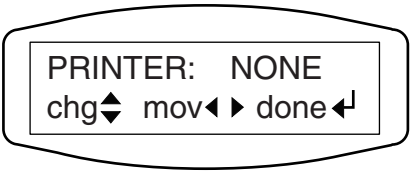


Figure 20: Select Printer Screen

Elevation

The next step in the Configuration option is to enter the **Elevation** of the location where the spirometer is to be used. The default value is 1000 feet. An elevation from 0 to 9000 feet (0 to 3000 m), in 1000 foot (300 m) increments, can be selected by pressing the Up or Down arrow key. An example of the elevation screen is shown in Figure 21. Press Enter when the desired elevation is displayed on the screen.

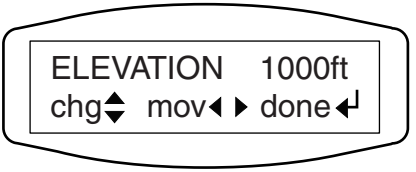


Figure 21: Elevation Selection

With no correction for elevation entered, an error of ±1.3% is introduced for every 1000 feet above sea level.

After the elevation is selected, the display moves to the quality selection screen. It is not necessary to enter the Configuration option for each patient.

Quality

The last step in the configuration process is to select quality text messages or maneuver variance data. This is done by pressing the up or down arrow keys to select "MESSAGE" or "TEST VAR".

The quality configuration option allows the user to select maneuver quality text messages or maneuver FVC and FEV1 variance, in liters, on NPB-500 printouts. Pressing enter saves the user choice and exits the configuration menu.

Calibration Check

The spirometer prompts the user through a series of steps to perform the calibration check. 1 liter and 3 liter Calibration Syringes are supported. After the calibration check has been completed, CAL OK X.X% is displayed if the error is 3% or less. If the error is greater than 3%, BAD CAL X.X% is displayed. X.X% is the percentage of error detected during the calibration.

To check the accuracy of the spirometer, pressthe Options key. Press the Up or Down arrow key until Cal Check is displayed on the screen and press the Enter key. Once the Cal Check option has been entered, prompts are displayed on the screen. These prompts are for user interaction with the spirometer.

The first prompt from the spirometer is **Swipe Sensor or ⇕ to Enter Code.** See New Sensor , on page 8 for instructions:

After the sensor is successfully read, the spirometer displays “ATTACH SENSOR TO SYRINGE”. Press any key to continue. The user is then asked to enter the temperature, see Figure 22.

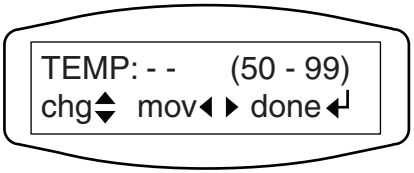


Figure 22: Temperature Screen

When prompted to enter the temperature, use the Up and Down arrows to change the value of the highlighted character. The spirometer accepts temperatures equal to 50 °F - 99°F (10 °C - 37 °C).

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

NOTE: Extreme differences between unit temperature and ambient temperature can affect the accuracy of calibration check measurements. When taking the spirometer from extreme hot or cold temperature (greater than a 3.0° F(1°C) change), allow the spirometer 30 minutes to acclimate to the room temperature before performing a cal check.

After the temperature has been entered, the pressure transducer is zeroed. During this time, a “Steady Sensor” prompt is displayed. Please hold the sensor and tubing still. After successful zeroing a single beep will be heard.

If zeroing was unsuccessful, "Error Zeroing Sensor →" is displayed and an error tone is heard. Press any key to return to the "Steady Sensor" prompt.

After successful zeroing, "WITHDRAW SYRINGE" is displayed in the window. Pull the syringe plunger out. Press any key and "PUSH SYRINGE IN" is displayed.

As the syringe is being pushed in, Figure 23 is displayed. An incentive tone is also heard and an incentive arrow is displayed on the bottom of the screen.

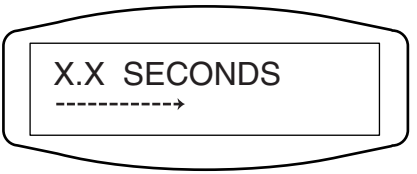


Figure 23: Test Duration

If no positive flow is sensed within 20 seconds, "Error Sensing Positive Flow→" is displayed. When no positive flow is sensed, the spirometer goes back to the "Steady Sensor" prompt when any key is pressed. This allows another attempt at a calibration check.

After the calibration is performed, the percentage of error is displayed. An error of 3% or less will result in "CAL OK X.X%" being displayed. If the error is more than 3% "BAD CAL X.X%" will be displayed (see Figure 24). X.X% is the percentage of error detected during the calibration.

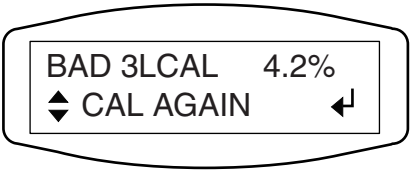


Figure 24: Calibration Volume

The Up and Down arrows allow the selection of "Cal Again", "New Sensor", or "Quit". If "New Sensor" is selected, the **Swipe Sensor or Enter Code** process will be restarted. When "Cal Again" is selected, the spirometer returns to the enter temperature screen. If "Quit" was selected, the "New Patient" options screen is displayed.

Blow & Go

In the BLOW & GO mode only one acceptable test is considered. This mode is for quick testing and does not require the entry of patient data. The results displayed are the same as for the screening mode, but no predictive values are presented. The Patient ID for all Blow & Go tests is recorded as Blow & Go. After performing a Blow & Go test the user can use "View Patient" to enter the patient's demographic information and change the test ID from Blow & Go to the patient's ID. If "View Results" is then selected predictive values will be presented. The user can perform "More Test" or "Post Tests". If "More Test" or "Post Test" is selected the test mode will be that selected during configuration, Diagnostic or Screening.

New Patient

The New Patient option should be used each time a new patient is to be tested. This allows the user to enter information that is specific to the patient that is being tested (See Table 1 on page13). Options can be reached at any time during New Patient set-up by pressing the Options key.

NOTE: If the New Patient option is selected, any previous test data will be stored in memory. "Are You Sure Yes/No" is displayed when New Patient is selected. If Yes is selected, data from previous tests is stored. In No is selected, the display returns to the Options screen.

NOTE: Test data is available in current memory for 30 minutes. Test data is stored and must be recalled if the New Patient option is selected, or if more than 30 minutes have passed since testing.

Table 4: Patient Data

Parameter	Limits
Age	4 to 99 years
Height	3' 4" up to 6' 11" (102 cm. to 210 cm.)
Gender	Male, Female
Smoker	Yes, No
Ethnic Group	White, African, Asian, Hispanic, Other
ID	13 alphanumeric characters

The patient's age, Figure 25, is the value to be entered in the New Patient option. The Right and Left arrow keys are used to move the cursor to the character to be changed. Use the Up and Down arrow key to change the value of the highlighted character. Press the Enter or Right Arrow key when the desired age is shown on the screen.

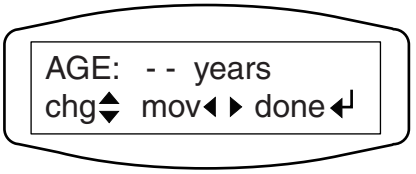


Figure 25: Age Entry Screen

The spirometer will accept ages from 4 to 99 years.

Height is the next value to be entered. Figure 26 is the height entry screen. Use the Right and Left arrow keys to move the cursor to the value that needs to be changed. The Up and Down arrow keys are used to change the value of the character above the cursor.

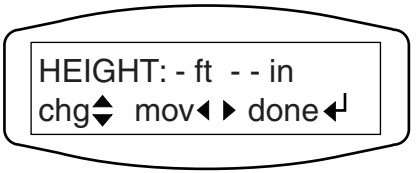


Figure 26: Height Entry Screen

Press the Enter key when the desired height is shown on the screen. Heights from 3' 4" to 6' 11" or 102 cm. to 210 cm. are accepted by the spirometer.

Figure 27 is displayed next, to select the patient's gender. Use the Up or Down arrow key to toggle between Male and Female. Press the Enter key when the patient's gender is displayed.

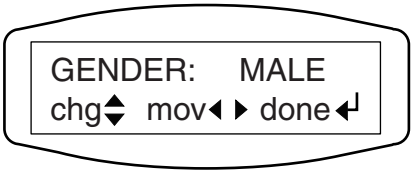


Figure 27: Gender Entry Screen

Smoker is the next item to be entered. Figure 28 is the Smoker screen. Use the Up or Down arrow key to toggle between Yes and No. If the Enter key is pressed when Yes is selected, the spirometer will make a Lung Age calculation after the patient test has been completed. Lung age is not calculated if No is selected.

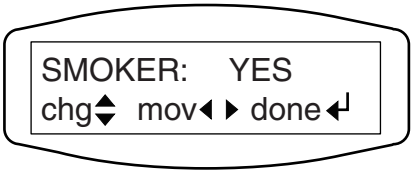


Figure 28: Smoker Screen

The spirometer also makes adjustments to the predicted values for ethnic group. Figure 29 is the screen displayed when the patient's ethnic group can be entered. The user can choose between African, White, Asian, Hispanic, and Other. White is the default value. Use the Up or Down arrow key to change the ethnic group being viewed on the screen. Press Enter when the patient's ethnic group is displayed. The predicted values for African adults are adjusted to 88%.

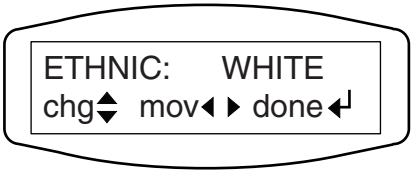


Figure 29: Ethnic Entry Screen

Figure 30 is the ID entry screen. This is the last step of the New Patient option. An ID up to 13 alphanumeric characters can be entered. Move the cursor, with the Right or Left arrow key, under the character to be changed. The character can be changed by pressing the Up or Down arrow key. Pressing the Up arrow will display numbers from 0 to 9. Pressing the Down arrow will display letters from A through Z and several special characters. Press the Enter key when the ID number has been completed.

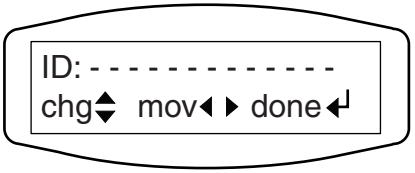


Figure 30: ID Entry Screen

Coaching the Patient

At this point, " Start Test" is displayed as an option. Before continuing, you should coach the patient on how to perform the test. Actually demonstrating the test using your own sensor is strongly recommended for patients who have not done this before.

Unlike many other diagnostic measurements such as blood pressure or cholesterol, spirometry is a test that requires active patient participation to ensure reliable results. You play an important role in this process by coaching the patient how to perform the test. This is not difficult, but it does require practice and familiarity with the spirometer.

There are 4 things your patient needs to do to ensure a good test result.

1. Hold sensor with the arrows on top. Relax. At the end of a normal breath, PLACE SENSOR INSIDE MOUTH, on top of the tongue, so that airflow is not blocked. Don't breathe while doing this. Seal teeth and lips around the sensor to avoid leakage.
2. DEEP BREATH IN. Take as deep a breath in as possible. Breathe in smoothly, without hesitation. Try to fill the lungs completely.
3. BLAST OUT. When the lungs are completely filled, BLAST OUT. Don't just blow out, BLAST OUT. Try to get as much air out as possible during the first second of the test. Maintain an upright position during the test.
4. KEEP GOING. Try to empty the lungs completely. Keep the air flowing for at least 6 seconds.

Achieving Quality Results

There could be several reasons why quality results on the first try are not achieved. The three major faults are: 1) not taking a maximal inhalation at the beginning, 2) slow starts (not blasting out quickly), and 3) not blowing out completely. Observe the patient while he/she is performing the test. Some patients may not form a good seal around the sensor with their lips. With practice you will be able to recognize these faults and coach the patient on how to avoid them.

At the end of each effort, the spirometer will provide feedback on how the session is going and suggestions for improvement.

Table 5: Coaching Messages

Coaching Message	What It Means
GOOD EFFORT DO NEXT EFFORT	The effort met all QC requirements. Another effort is required to assess reproducibility.
BLAST OUT HARDER TRY AGAIN	The patient did not blast out hard enough at the start of the test. Instruct patient to concentrate on the initial blast out portion of the test.
BLOW OUT LONGER TRY AGAIN	The patient ended the test abruptly and did not completely empty his/her lungs. Instruct the patient to squeeze every last bit of air out.
NOT REPEATABLE DEEPER BREATH IN or DO NEXT EFFORT	If the current test values are lower than previous efforts by more than 200 ml, instruct the patient to take a deeper breath. If the current test values are higher than previous efforts by more than 200 ml, instruct the patient to do next effort.
AVOID COUGHING TRY AGAIN	The patient coughed during the first second of the effort. Instruct the patient to concentrate on not coughing.
SESSION COMPLETE ANY KEY TO VIEW	At least two tests have been done that meet all the quality checks. The session is complete. Good job!
POOR TEST QUALITY QUIT TESTING	You were not able to meet the QC requirements after at least 6 tries. You have the option to quit testing or to do more tests to try and improve the quality of the test session. To view the test results and reasons for the POOR TEST QUALITY, select the QUIT TESTING option.

Start Test

When the Start Test option is selected **"Swipe Sensor or ⇕ Enter Code"** is displayed. Press any key to continue the procedure. If the sensor code is read successfully by swiping the sensor or numerically entering the sensor code, Figure 31 is displayed.

NOTE: Use only Puritan Bennett FSII flow sensors with the NPB-500 spirometer.

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.

If the patient is 50 pounds overweight or is less than 12 years of age they should stand. If the patient is standing during the test it is recommended that a chair be placed nearby where the patient can 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 repeat tests can be performed in the same position.

CAUTION:

Follow instruction for use and cautions supplied with the FSII Sensor.

NOTE: Inspect the sensor before use to verify that there is no foreign material on the sensor membrane.

NOTE: FSII flow sensors are single patient use.

Press any key to begin zeroing the transducer. The spirometer displays "STEADY SENSOR WAIT....". It is important that the sensor and pressure tube are held steady. When zeroing is complete, a beep tone is heard.

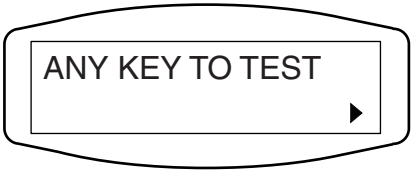


Figure 31: Any Key to Test

An error tone will sound and Figure 32 will be displayed if there was an error during the zeroing process. Press the Options key to stop the zeroing process and return to the Options screen. Press any other key to repeat the zeroing process. If this step has been repeated unsuccessfully three times the Options screen will be displayed.

Figure 32: Zeroing Error

When the spirometer displays "START TEST", instruct the patient to place the sensor in their mouth, take a deep breath in and blast out as hard and fast as possible. See Coaching the Patient, on page 25. A positive flow must be detected within 20 seconds. When the positive flow is detected, an incentive tone is sounded and the prompts cycle between the screens shown in Figure33 and Figure 34.

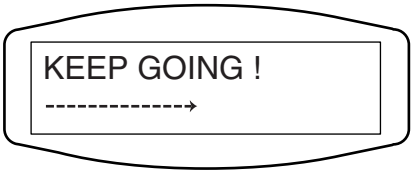


Figure 33: Keep Going Incentive Screen

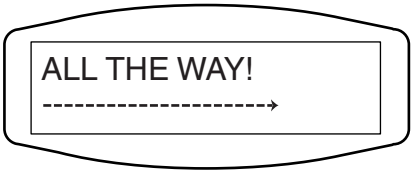


Figure 34: All The Way Incentive Screen

A failure to detect positive flow results in Figure 35 being displayed. Press the Options key to stop the test and return to the Options screen. Press any other key to go back to the "START TEST" prompt. The third time a breath sensing error has occurred, the Options menu is displayed after any key has been pressed.

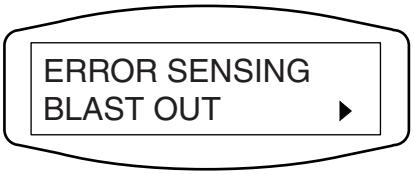


Figure 35: Blast Out Sensing Error

After the first successful test, Figure 36 is displayed on the screen. Pressing any key steps back to the "Steady Sensor...Wait" prompt and the procedure can be repeated.

Figure 36: Good Effort

A poor quality test results in a "Try Again" screen. This screen contains additional instructions like, "Blast Out Harder", "Blow Out Longer", or "Avoid Coughing". Press any key to "Try Again". The "Steady Sensor" prompt is displayed and the test can be repeated. To view the results of a test session before it is completed, press the OPTIONS key.

When more than one test has been done the spirometer compares them to each other. If the tests were acceptable (no poor test quality messages), but the current effort (FVC, or FEV1) is more than 200 ml lower than previous efforts Figure 37 will be displayed. Press any key to try again. If the current effort is more than 200 ml higher than previous efforts, the message will be "Not Repeatable Do Next Effort".

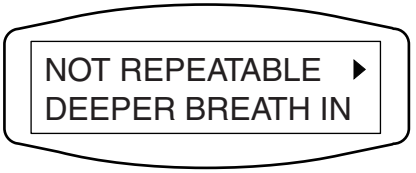


Figure 37: Test Not Repeatable

After six unacceptable, or non repeatable tests in the Screening mode, or eight in the Diagnostic mode, a poor test quality screen is displayed, (see Figure 38). Two options are offered: "Test Again" or "Quit Testing". Use the Up or Down arrow key to toggle between the two choices.When Quit is selected, the test session results can be viewed. Test Again goes back to the "Steady Sensor Wait" screen.

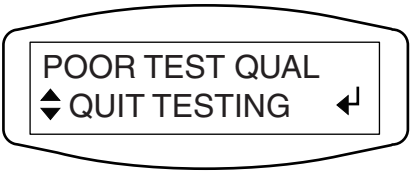


Figure 38: Poor Test Options

Two acceptable and repeatable tests in the Screening mode, or three acceptable and two repeatable tests in the Diagnostic mode, results in Figure 39 being displayed on the screen. Press any key to view the results of the session. Viewing the results is discussed in the next section.

Figure 39: Session Complete

View Results

When Figure 39 is displayed, press any key to view the test results. Right and left arrows may be displayed in the lower right corner of thedisplay. These arrows indicate that more data is available on the previous, or next screen. For more information on moving around between screens see Definition of Statements and Symbols , on page 1. The first screen to be displayed is
Figure 40.

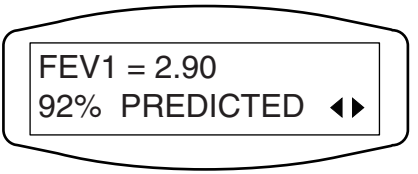


Figure 40: FEV1

The top number is the volume of air exhaled in the first second of the test. The second number in the display is actual FEV1 expressed as a percentage of the predicted FEV1.

To view the FVC, press the Right arrow key and Figure 41 is displayed. The first number represents the total volume of air exhaled during the test. The second number in these figures is the actual exhaled volume expressed as a percentage of the predicted exhaled volume.

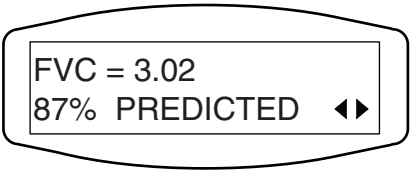


Figure 41: FVC

When the Right arrow key is pressed, the screen proceeds to the next display as shown in Figure 42.

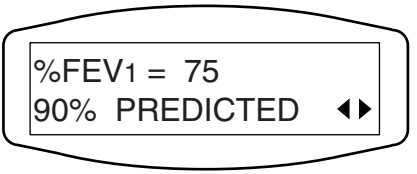


Figure 42: % FEV1

The first value in Figure 42 is FEV1 is expressed as a percentage of the total exhaled volume. The second value shown on the screen is the actual % FEV1 compared to predicted value, expressed as a percentage.

Press the Right arrow key to view the next screen. Peak expiratory flow is expressed in liters per minute in the first line of the display, see Figure 43. The actual PEF is compared to the predicted PEF, and expressed as a percentage in the second line of the display.

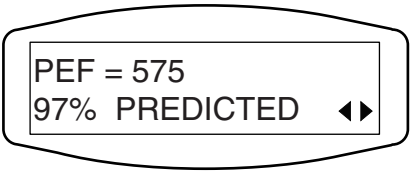


Figure 43: PEF

Press the Right arrow key to view the next screen. At this point the Quality screens are displayed if SCREENING was chosen during configuration. Figure 44 is only displayed if DIAGNOSTIC was selected.

The first line of the display is the measured FEF 25-75. This is the average flow rate in liters per second measured from 25% to 75% of the total exhaled volume. The second line is a comparison between the actual FEF 25-75 and the predicted FEF 25-75 expressed as a percentage. Pressing the Right arrow key advances to the Quality screens.

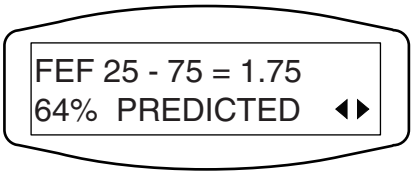


Figure 44: FEF 25-75

Quality Screens

"**Good Session**" is only displayed after two acceptable and repeatable tests in the SCREENING mode. "**Good Session Meets ATS**" is only displayed after three acceptable and two repeatable tests when DIAGNOSTIC is selected in configuration. In either case, this message means that no quality errors were detected and the results were repeatable.

The remaining possible screen displays all describe a problem that occurred during the test. One, or any combination of the screens, could be displayed depending on how the test was run. If post tests are done, these same Quality screens may be displayed.

When "**Poor FEV1 Qual Slow Start**" is displayed, it means more than 100 ml or 5% of the total exhaled volume was detected before the peak flow occurred.

If "**Poor FEV1 Qual Coughing**" is displayed, rapid fluctuations in flow were detected during the test. This occurs if a flow rate decrease occurs two times before the peak flow is achieved, or a flow rate increase occurs two times after the peak flow has been reached.

"**Poor FVC Qual Abrupt End**" being displayed indicates that the flow being measured stopped suddenly. If the maneuver time is less than 6 seconds or flow abrubtly ends, the Abrupt End screen is displayed.

Any of the Poor Test Qual screens described above may also result in a display of "**Poor Test Qual No FEV1 Match**" or "**Poor Test Qual No FVC Match**". These screens are displayed if there is more than 200 ml difference between the two largest measurement of FEV1 and FVC.

When patient data is being entered, the user is offered the choice of Yes or No for smoker. If Yes is selected, Figure 45 is displayed when all of the quality screens have been viewed and the Right arrow key is pressed.

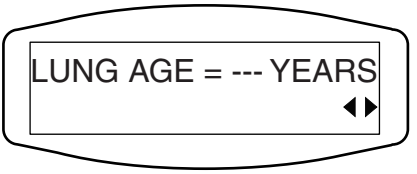


Figure 45: Lung Age

The value displayed is a calculation of the patient's lung age. Lung age is calculated by substituting the predicted value of FEV1 with the patient's actual FEV1. The FEV1 equation is solved for age. Lung age will not be calculated if the patient age is less than 18 or if the session had poor FEV1 test quality.

Pressing the Right arrow key from the lung age display results in one of three options. If the spirometer is configured for Interpretations, see below. If it is not configured for interpretations but there are Post tests to view, see Viewing Post Tests, on page 34. When there are no Post tests and the spirometer is not configured for interpretations, the Options screen will be displayed. Use the Up or Down arrow key and press Enter when the desired option is displayed. Quality messages on printouts will depend on Configuration Quality Selection, Text Messages or FVC and FEV1 Variance data.

Interpretations

The following screens are a subset of the View Patient screens. They are available in the DIAGNOSTIC and SCREENING modes. These screens are displayed if Interpretations was selected during configuration. For more about moving between screens see Definition of Statements and Symbols, on page 1.

The patient's test results can be viewed from the interpretation screens by pressing the Left arrow key. When the Right arrow key is pressed Post tests can be viewed if they are available. If there are no Post tests, press the Options key to exit.

"**Normal Spirometry**" is displayed if the % FEV1 is above the LLN (lower limit of normal) and if the FVC is more than 80%of the predicted value. If Post tests are available for viewing, they can be reached by pressing the Right arrow key (see Viewing Post Tests on page 34). When there are no Post tests available, press the Options key to return to the Options screen. Pressing the Left arrow key allows the user to review the tests that were done before the Post tests.

If an obstruction interpretation is displayed or FVC is less than 80% of the predicted value, "**Low Vital Capacity**" will be displayed.

Restriction screens are displayed if FVC is less than 80% of the predicted value. Three levels of restriction are possible: Mild, Moderate, or Severe. The following criteria are used to determine the level to display:

"**Mild Restriction**" is displayed if FVC is between 60% and 80% of the predicted value.

"**Moderate Restriction**" is displayed when FVC is between 50% and 60% of the predicted value.

"**Severe Restriction**" is displayed if the FVC is less than 50% of the predicted value.

Obstruction screens will be displayed if the %FEV1 is below LLN. Four levels of obstruction are possible: Borderline, Mild, Moderate, or Severe. The following criteria are used to determine the level to display:

See Table 6 on page34 for interpretation level thresholds for ATS, ECCS, and BTS.

"**Borderline Obstruction**" is displayed when the FEV1 is greater than *Level 1* of the predicted value.

A "**Mild Obstruction**" screen is displayed if the FEV1 is between *Level 2* and *Level 1* of the predicted value.

"**Moderate Obstruction**" is displayed if the FEV1 is *Level 3* to *Level 2* of the predicted value.

"**Severe Obstruction**" is displayed if the FEV1 is less than *Level 3* of the predicted value.

Table 6: Interpretation Levels

Standard	Level 1	Level 2	Level 3
ATS	80%	60%	40%
ECCS	80%	70%	50%
BTS	80%	60%	40%

Viewing Post Tests

Post tests are usually conducted after medication has been given. Many of the screens viewed in Post Tests are similar to those viewed during View Patient. The difference is that the Post Test values are compared to the tests done before medication was given, and a percent change is displayed.

See Definition of Statements and Symbols , on page 1 for instructions on moving between screens. Press any key to view and Figure 46 will be displayed.

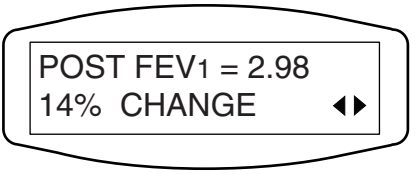


Figure 46: Post FEV1

FEV1 for the Post test is displayed in the first line. The second line compares the Post FEV1 to the FEV1 done prior to receiving medication. The value displayed is the percentage change of the FEV1 from the Post test as compared to the FEV1 from the best pretest.

When the Right arrow key is pressed, the next screen displayed will be the same as shown in Figure 47

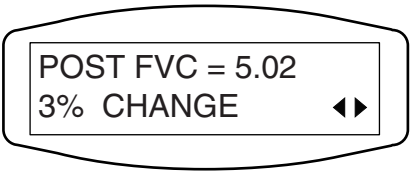


Figure 47: Post FVC (Diagnostic mode)

FVC for the post test is displayed in the first line of Figure 47. The percentage of change between the pretest and post test values is displayed in the second line.

In Figure 48, the Post %FEV1 value is displayed in the first line.

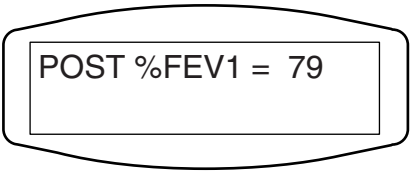


Figure 48: Post % FEV1

Press the Right arrow key and Figure 49 is displayed.

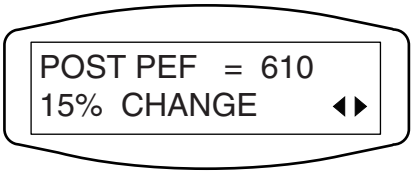


Figure 49: Post PEF

This screen displays the PEF values for the current Post test. The percentage of change between the pretest and post test values is displayed in the second line. Pressing the right arrow key advances to Quality screens if the SCREENING mode is selected. If the DIAGNOSTIC mode was selected Figure 50 is displayed.

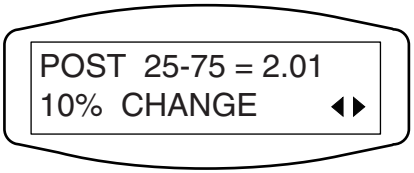


Figure 50: Post FEF 25-75

The Post FEF 25-75 is displayed in the first line of data. The second line is a comparison of the Post FEF 25-75 to the Pre FEF 25-75 expressed as a percentage. Exiting this screen by pressing the Right arrow key advances to the Quality screens. Quality Screens on page32 defines the quality screens and their meanings.

If Interpretations was selected and the test showed the patient to be obstructed on the Pre test, one of two screens will be displayed. If the Post test shows a change of more than 12% Figure 51 is displayed. If the Post test change is less than 12% Figure 51 is displayed. If the pre-session and/or post session has unacceptable results (coughing, slow start, or abrupt end), no interpretation will be given. “PoorQuality, No Interpretation” will be displayed.

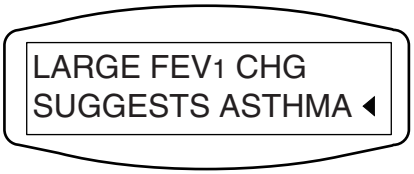


Figure 51: Large FEV1 Change

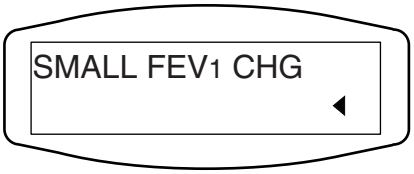


Figure 52: Small FEV1 Change

From either of these screens press the Options key to return to the Options screen. From the Options screen the Up or Down arrow key can be used to select other options. When the desired option is displayed press the Enter key.

Patient Recall

Using the Patient Recall option, a calibration check or patient can be recalled from the spirometer's memory. When Patient Recall is selected, the unit will prompt with "Are You Sure? Yes/No". If Yes is selected, any previous data will be stored in memory, and the screen in Figure53 will be displayed.

Patient test information can be recalled by searching for the patient's ID, by pressing the Right arrow key, or by reviewing a list of all patients tested, by pressing the UP or Down keys, starting with the most recent test completed. If search by ID is selected, Figure 54 will be displayed.

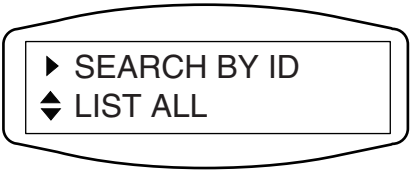


Figure 53: Patient Recall Screen

When searching by ID the first ID located which exactly matches the search ID will be returned. If no exact match is found then the first occurance of the best match is returned. Cal Check and Blow & Go IDs are not returned in this mode. If patient data review by list is selected Figure 55 is displayed.

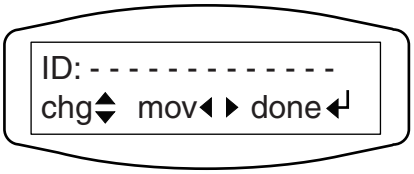


Figure 54: Search by ID

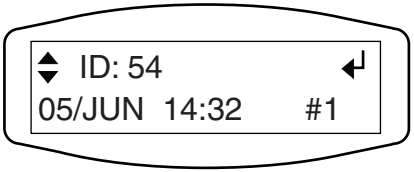


Figure 55: Review Patient List

The ID number of the patient is displayed on the top line. If a calibration check is the most recent entry, Cal Check will be displayed. The second line displays the date and time stamp (24 hour clock) for the recalled test. The lower right corner displays the sequence number of the test (i.e. the most recent data will have a sequence number of 1 and be displayed as #1).

To scroll back through the list of stored data press the Up arrow key. Press Enter when the desired test number is displayed. The spirometer will display the option VIEW RESULTS. Other options available include: PRINT RESULTS, NEW PATIENT, VIEW PATIENT, CONFIGURE, CAL CHECK, NEW SENSOR, and PATIENT RECALL.

Other options are available that are dependent upon the time stamp of the patient test that was recalled. MORE TESTS is available for up to one hour after the time stamp of the recalled patient test. POST TEST is available for up to 6 hours from the patient recalled time stamp. Once a post test is performed, the user has one hour to complete post testing.

The spirometer is capable of storing up to 999 tests. A test is defined as: pre/post sessions with curves or a calibration check. When the memory is full, the oldest test session will be deleted.

Printing Results

The NPB-510 spirometer base and output cable are needed to obtain printouts from the spirometer. Connect the cable to the output port of the NPB-510 as shown in Figure 54. Connect the other end of the cable to the printer. Printers that can be used include: Epson 9- or 24- pin printers, HP, Canon, or IBM . If no printer type is selected, the Print Results option will not be available. See Figure 20 on page 19 for more details in selecting the type of printer.

Select the Print Results option on the NPB-500 spirometer. The spirometer displays "PLACE UNIT IN BASE TO PRINT". Place the spirometer in the NPB-510 spirometer base, then turn the printer on.

NOTE: Power OFF the spirometer if it is to remain in the NPB-510 after a printout. This will help prolong the spirometer's battery life.

NOTE: To recall a patient test or a calibration check for a printout, see Patient Recall, on page 37.

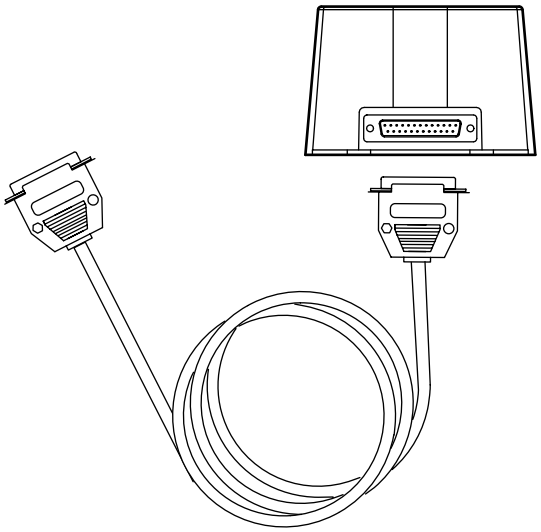


Figure 56: Spirometer Base Connection

The pin locations for the connector in the base unit are shown in Figure 55. The function of the pins is described in Table 7 on page40. Pins 13, 16, and 18 are used for RS-232 communications of test/configuration data and for remote control of the spirometer. Contact Mallinckrodt Technical Support for the interface protocol specifications. All other pins are used for printer interfacing via standard IEEE 1284 printer cable.

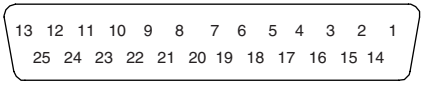


Figure 57: NPB-510 Pin Locations

Table 7: Base Connector Pin Outs

Pin #	Direction	Description
1	To Printer	Data Strobe
2	To Printer	Printer Data Bit 0
3	To Printer	Printer Data Bit 1
4	To Printer	Printer Data Bit 2
5	To Printer	Printer Data Bit 3
6	To Printer	Printer Data Bit 4
7	To Printer	Printer Data Bit 5
8	To Printer	Printer Data Bit 6
9	To Printer	Printer Data Bit 7
10	To Base	Print ACK
11	To Base	Printer Busy
12		N/A
13	To Base	RS-232 Receive Data
14		N/A
15	To Base	Printer Error
16	To PC	RS-232 Transmit Data
17		N/A
18, 19		Ground
20		N/A
21		Ground
22		N/A
23, 24, 25		Ground

Maintenance

Cleaning

Because the NPB-500 spirometry system uses disposable, single-patient-use flow sensors, there is no need to clean or sterilize any part of the spirometer or pressure tube. You may, however, wish to remove dust or fingerprints from the exterior by wiping with a damp cloth.

If a need for a more thorough cleaning arises, the spirometer and base can be wiped down with a solution of 70% isopropyl alcohol or 10% bleach. Use the established procedures of your facility for the use of these agents.

A POST error code of E, F or K may indicate that the sensor reader is dirty. The sensor reader may be cleaned by sliding an alcohol wipe through the slot. A low flow gas source can also be used to remove any dust or debris from the sensor reader.

CAUTION:

Do not immerse the NPB-500 spirometer or base in liquid or clean with caustic or abrasive cleaners. Do not spray or pour any liquid on the spirometer or base.

Pressure Tube

The tube should be replaced at least once every two years or if it becomes discolored or cracked. To remove the tube grasp the tube near the back of the spirometer and pull until it is disconnected.

The exterior of the tube can be cleaned by wiping with a damp cloth. If a need for more thorough cleaning arises, the pressure tube can wiped down with a solution of 70% isopropyl alcohol, or 10% bleach. The pressure tube can also be soaked in a disinfecting solution, following the manufacturer's recommendations. Use the procedures established by your facility for the use of these agents.

When replacing the pressure tube hold it near the end and firmly press it onto the pressure port on the back of the spirometer (see Figure 3 on page 5).

Batteries

Battery life for the two AA alkaline batteries is 6 months under normal use. Normal use is defined as 10 patient sessions per week, each session consisting of 4 maneuvers and one printed report.

CAUTION:

- **Check batteries at least once per month for corrosion.**
- **If the spirometer is going to be stored for more than one month remove the batteries.**
- **Dispose of batteries properly. Do not incinerate. Mallinckrodt recommends that customers or technical services personnel follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.**

Obtaining Technical Assistance

For technical information and assistance, or to order parts, contact Mallinckrodt's Technical Services Department at 1-800255-6774 (Option #1) or your local Mallinckrodt representative.

When calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative, you may be asked to tell the representative the software version of your NPB-500.

The software version appears on the monitor display after the power-on self-test. Write the software version down and have it available whenever requesting technical assistance.

Returning the NPB-500

Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative for shipping instructions including a Returned Goods Authorization (RGA) number. It is not necessary to return the sensor. Pack the NPB-500 in its original shipping carton. If the original shipping carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the NPB-500 by any shipping method that provides proof of delivery.

Service

WARNING

The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

The NPB-500 requires no routine service or calibration other than replacing the batteries at least every 6 months.

If service is necessary, contact qualified service personnel or Mallinckrodt's Technical Services Department.

Table 8: Troubleshooting Guide

Condition	Recommended Solution
NPB-500 will not turn on.	1. Verify that the batteries are oriented as shown in the battery housing. 2. Replace the batteries 3. Return to NPB for service.
NPB-500 will turn on, but will not perform tests.	1. If the spirometer failed POST, record the error code and refer to Table 9 on page 44. Cycle power and try again. 2. Return to NPB for service.
NPB-500 beeps every 30 seconds and a low battery icon is displayed.	Batteries are low, replace the batteries.
"Error Reading Sensor" is displayed in the message window.	1. Sensor swiped incorrectly (see New Sensor, on page 8). 2. Swipe the sensor again. 3. Enter Sensor code numerically. 4. Try a new sensor. 5. Clean sensor reader (See page 38)
Calibration error is more than ± 3%.	1. Verify that 3 liters is being used for the calibration volume. 2. Check temperature and altitude values used during calibration. 3. Replace the sensor. 4. Check for leaks in tubing. 5. Return to NPB for service.

"Error Zeroing Sensor" is displayed in the message window.	1. Movement sensed during zeroing, repeat the procedure. 2. Return to NPB for service.
"Error Sensing Blast Out" is displayed in the message window.	No exhalation was sensed within 20 seconds, repeat the test.
Patient test values being displayed on the NPB-500 do not meet values expected by the physician.	1. Verify that the sensor is not contaminated with sputum or secretions. 2. Check to see if the proper altitude has been entered. 3. Verify that the patient data (height and age) being used for the test is accurate for the patient. 4. Check for leaks in the pressure tubing. 5. Check for damage to the sensor. 6. Perform a calibration check of the NPB-500 to verify its accuracy. 7. Replace the sensor.
Unable to print test results	1. Verify that the proper printer has been selected in the spirometer's configuration. 2. Verify that the printer is turned on and is on line. 3. Check the cable connections. 4. Turn off the printer and remove the spirometer from the base. Turn on the spirometer and place it in the base. Turn the printer on.

Table 9: POST Error Codes

Code	Recommended Solution
A through D	Contact NPB Technical Support.
E, F and K	Clean the Sensor Reader. (See page 38)
G and H	Make sure that the spirometer, pressure tube, and sensor are steady during POST. Turn the unit off and back on.
I and J	Contact NPB Technical Support

For technical support call: 1-800-255-6774 (Option #1).

Electro-Magnetic Interference

CAUTION:

This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN60601-1-2:1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health-care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The NPB-500 is designed for use in environments in which the reading can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic reading, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity OFF and ON to isolate the offending equipment.
- Reorient or relocate the offending device.
- Increase the separation between the interfering equipment and this equipment.

The NPB-500 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devicesin the vicinity.

If assistance is required, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

Product Specifications

NPB-500-Spirometer

- **Dimensions**: 4.9" X 3.0" X 1.1" (12.5 cm. X 7.5 cm. X 2.5 cm.)
- **Weight**: 6.2 oz. (175 grams)
- **Accuracy**: + 3% of reading or 50 ml whichever is greater for all tests except, FEF 25-75 (+ 5% of reading or 0.20 L whichever is greater), and PEF (+ 10% of reading or 0.40 L/s whichever is greater)
- **Volume Range**: up to and including 8 L BTPS
- **Flow Range**: up to and including 16 L/s

- **Resistance**: less than 1.5 cm. H2O/L/s over flow range
- **Test Time**: Acceptable maneuvers must be at least6 seconds long. Test data is recorded for up to 15 seconds from valid start of test.
- **Display**: 2 rows, 16-alpha numeric characters per row, LCD display
- **Parameters Measured**: (FEV1, %FEV1, PEF in Screening mode)- (FEV1, FVC, %FEV1, PEF, FEF 25-75 in Diagnostic mode)
- **Test Quality Criteria**: ATS Standardization of Spirometry, 1994 update
- **Battery**: 2 AA batteries, expected life 6 months during normal use
- **Operating Temperature**: 50° F to 104° F (10° C to 40° C)
- **Operating Humidity**: 15% to 95% relative humidity
- **Operating Altitude**: 0 ft to 9,000 ft (0 m - 2743 m)
- **Storage Temperature**: -4°F to 140°F (-20° C to 60° C)
- **Storage Humidity**: 15% to 95% relative humidity
- **Storage Pressure**: 500 kPa to 1060 kPa

NPB-510 Spirometer Base

- **Dimensions**: 4.24" X 2.74" X 2.83" (10.75 cm. X 7.0 cm. X 7.1 cm.)
- **Weight**: 4.3 oz. (120 grams)
- **Function**: Provides docking for the spirometer and interfaces with most parallel printers to produce an 8.5" X 11" report. (A4)
- **Interface**: The NPB-510 provides an RS232C compatible serial interface.
- **Power Source**: Supplied by the NPB-500 Spirometer

Normal Predicted Values

- **Adult**: Crapo/ITS, ECCS, Roca et al
- **Paediatric**: HSU et Al; Zapletal et al
- **Interpretation Criteria**:
  ATS, ECCS, BTS
- **Memory Capability**: Stores up to 999 tests. A test is one pre/post session with curves or a calibration check.

NPB-500 Equipment Classification

- Complies with IEC 601-1 with amendments 1 & 2, C22.2 No. 601.1-M90 and UL Std No. 2601-1.
- Type BF Applied Parts
- **Internally Powered**: 2 AA Alkaline Batteries
- **Mode of operation**: Short time operation
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- **Enclosure Degree of Protection from liquid ingress**: IPX0

- **Graph Size**:

	Flow-Volume	
	Scale	Range
Vertical Axis (Flow)	0.25cm/1 L/S	0.0 to 14.0 L/S
Horizontal Axis (Volume)	0.50cm/ 1 L	0.0 to 8.0 L
	Volume Time	
	Scale	Range
Vertical Axis (Volume)	0.5cm/1 L	0.0 to 8.0 L
Horizontal Axis (Time)	1cm/Second	0.0 to 15.0 Seconds

- **Interface**: The NPB-510 provides an RS232C compatible serial interface.
- **Power Source**: Supplied by the NPB-500 Spirometer
- **Operating Temperature**: 50° F to 104° F (10° C to 40° C)
- **Operating Humidity**: 15% to 95% non-condensing
- **Operating Altitude**: 1031 kPa to 709 kPa
- **Storage Temperature**: -4° F to 140° F (-20° C to 60° C)
- **Storage Humidity**: 15% to 95% non-condensing
- **Storage Pressure**: 500 kPa to 1060 kPa

NPB-510 Equipment Classification

- Complies with IEC 601-1 with amendments 1 & 2, C22.2 No. 601.1-M90 and UL Std. No. 2601-1.
- Type BF applied parts
- Externally powered by 5V DC located in the NPB-500
- **Mode of operation**: Short-time operation
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- **Enclosure Degree of Protection from liquid ingress: IPX0**

To Contact Mallinckrodt's representative: In the United States, call 1-800-255-6774 or 636-498-3479; outside the United States, call your local Mallinckrodt representative. In Europe contact Mallinckrodt Europe BV, see address and phone numbers below.

To obtain information about warranty, if any, for this product, contact Mallinckrodt Technical Services Department, or your local Mallinckrodt representative.

Purchase of this instrument confers no express or implied license under any Mallinckrodt patent to use the instrument with any sensor that is not manufactured or licensed by Mallinckrodt.

CE
0050

This device complies with the requirements of Directive 93/42/EEC concerning medical devices. It therefore bears the CE marking as shown.

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P-063124-EN Rev. B