

SPIRO • PD 2.0



User Manual

PMD *Healthcare* 

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CHAPTER 1 Introduction

Intended Use

The Spiro PD 2.0 spirometer is intended to be used by a patient under the instruction of a physician or respiratory therapist to test lung function in a child, adolescent or adult. It is also intended to be used as a single-patient device only and can be used in the home, factory, hospital or physician's office.

The Spiro PD 2.0 spirometer is indicated for the following age groups:

- 2–12 years — Child
- 13–21 years — Adolescent
- 22 and over— Adult



CAUTION

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

Features of Your Spiro PD 2.0



Standby Button

The standby button is located on the top of your Spiro PD 2.0.

Indicator Lights

There are blue Indicator Lights that flash when an Alarm is activated, during start up or when you are performing a spirometry test.

Mouthpieces

Your Spiro PD 2.0 comes with 2 removable mouthpieces: a child mouthpiece and an adult mouthpiece. The mouthpiece directs your exhaled breath into your Spiro PD 2.0 so it can be measured. The mouthpieces are considered the applied parts.

Child
Mouthpiece



Adult
Mouthpiece



Spiro PD 2.0 Cradle

The cradle is used to hold your Spiro PD 2.0 while charging or when it is not in use.



USB Connector

A USB connector is located on the top of the Spiro PD 2.0. It is used to recharge the battery or connect Spiro PD 2.0 to your computer.



Battery

Your Spiro PD 2.0 is equipped with a rechargeable Lithium-ion battery.

It will take up to 3 hours to recharge. If battery is removed from SpiroPD 2.0 and stored, the average lifespan of the battery is 3 years.

Power Adapter

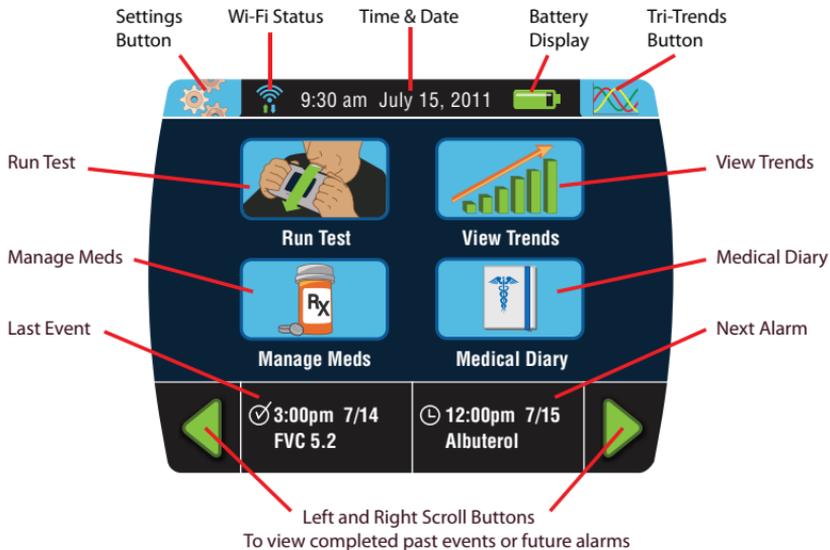
Your Spiro PD 2.0 is equipped with a power adapter which is used to charge the rechargeable Lithium-ion battery. Connect the USB connector to the Spiro PD 2.0 and the power adapter. Then plug the power adapter into an approved electrical outlet to charge the Spiro PD 2.0 battery. Only use the supply power adapter supplied with your Spiro PD.

LCD Display

The LCD display is a touch screen and is used to control your Spiro PD 2.0. Using your Spiro PD 2.0 is as easy as touching the screen!



Home Screen



Run Test

Run Test allows you to conduct your spirometry tests. You will be guided through three spirometry tests and then the results of the best of the three tests are displayed. Your Spiro PD 2.0 also prompts you with audible coaching, indicator lights, and on-screen instructions to help you achieve optimal results. All results are sent through Wi-Fi to your HIPPA compliant Wellness Management Services system (WMS), a companion web portal.

View Trends

Trend Data allows you to view and compare your spirometry and weight/BMI data over time. This can be shown in tabular or graphical format by pressing the Table or Graph button. Trend data is also available on the companion web portal.

Manage Meds

Manage Meds allows you to:

- Create, edit, or delete a medication and its schedule
- Log a medication that you've taken
- View your medication history
- Track quantity left of each medication

Medications can also be managed on the companion web portal.

Medical Diary

Medical Diary allows you to enter standard symptom assessments based on a selected chronic condition. You can then track medical symptoms or occurrences of that condition daily. Free text notes can also be entered and tracked to provide more information about your day. Medical Diary entries can also be viewed or entered on the companion web portal.

Alarms & Alerts

Alarms allow you to create reminders to take spirometry tests, do breathing exercises, make medical diary entries and/or enter your weight. You can also create an alert that will let you know if your results fall below a predetermined threshold. Use the companion web portal to take advantage of additional alert and alarm options such as email and cell phone text messaging for reminders and alerts.

Wellness Management Services

Spiro PD 2.0 synchronizes your data to a HIPPA Compliant web portal when you are connected to Wi-Fi. Spirometry data and trends are sent to the web portal for additional viewing. There are many other features available on the web portal such as medication management, medical diary entry, alarms and alerts all of which can be managed on your Spiro PD 2.0 or through the web portal.

CHAPTER 2

Safe Use of Your Spiro PD 2.0

Your Spiro PD 2.0 is designed to be an easy to use personal medical device. Please read your User Manual carefully before use to avoid any danger to you or damage to your device and accessories.



WARNING

Do NOT disassemble your Spiro PD 2.0. Contact with voltage inside the device may cause injury or may damage the device.



WARNING

Do NOT use damaged accessories. Using damaged accessories could cause damage to the Spiro PD 2.0 or the user.



WARNING

Do NOT submerge parts of your Spiro PD 2.0 in any liquid. Consult the equipment cleaning instructions in Chapter 13. Submerging the Spiro PD 2.0 in liquid could cause damage to the device or end user.



WARNING

Do NOT use accessories other than those provided with your Spiro PD 2.0. Using other cables or accessories may negatively affect the EMC performance.



WARNING

Do NOT extract data via the USB port during testing. Extracting data via the USB port during testing could result in a loss of data.

**WARNING**

No modification of this equipment is allowed. Modifying the Spiro PD 2.0 or its accessories could cause damage to the Spiro PD 2.0, the accessories or end user

**CAUTION**

Store your Spiro PD 2.0 in dry conditions and at temperature ranges between -4°F to 140°F (-20°C to 60°C) and less than 95% humidity.

**CAUTION**

Your Spiro PD 2.0 is intended as a single user personal device. It is not recommended that multiple users use your Spiro PD 2.0.

**CAUTION**

Your Spiro PD 2.0 is not intended to be used while it is plugged into the wall outlet. The power adapter is intended for charging of your Spiro PD 2.0 only.

**CAUTION**

Your Spiro PD 2.0 is intended to be used by someone 2 years of age and older. Children ages 2 – 10 require adult supervision when using their Spiro PD 2.0. Keep your Spiro PD 2.0 and its accessories away from young children.

**CAUTION**

Your Spiro PD 2.0 is not intended to be used adjacent to or stacked with other equipment.

**CAUTION**

If your Spiro PD 2.0 acts unusual or does not work correctly, move to another location to avoid potential electromagnetic or other interference from nearby devices.

Limitations of Use

An analysis of the results of spirometry tests is not enough to give an accurate diagnosis of the patient's clinical condition. The patient's records, clinical history and any tests that the healthcare provider believes necessary must also be considered. A healthcare provider must interpret all data to determine the course of treatment required.

The alarms feature of your Spiro PD 2.0 is intended to remind you to take a medication, run a spirometry test, log weight, log medical diary entry or perform a breathing exercise. You are responsible for taking your medication at the correct time, in the correct dosage, and in the correct manner as prescribed by your doctor. You are responsible for entering your alarm schedule and medication information correctly into your Spiro PD 2.0. Your Spiro PD 2.0 does not, in any way, replace your personal responsibility to take your medication correctly.

Contraindications of Use

Reference: American Academy of Family Physicians (AAFP)

Use of your Spiro PD 2.0 is not recommended if you have any of the following medical conditions:

- Acute disorders affecting test performance (e.g., vomiting, nausea, vertigo)
- Hemoptysis of unknown origin (FVC maneuver may aggravate underlying condition.)
- Pneumothorax
- Recent abdominal or thoracic surgery
- Recent eye surgery (increases in intraocular pressure during spirometry)
- Unstable cardiovascular status
- Recent myocardial infarction or unstable angina
- Thoracic aneurysms (risk of rupture because of increased thoracic pressure).

Spiro PD 2.0 Labels

The following symbols are included on the labels on your Spiro PD 2.0.

	Type BF: Protection against electrical shock (IEC 60601-1)		Manufacturer
	This product is compliant with accepted national safety standards.		Date of Manufacture
	Observe precautions for handling electrostatic sensitive devices.		Manufacturer's catalog number or part number.
	Warning Caution		Serial number.
	Consult accompanying documents		Lot code or batch code numbers.
	Caution, consult accompanying documents.		Authorized Representative in the European Community.
	Caution		Standby
	Prescription only (in USA)		Barometric Pressure Limits 85kPa to 106kPa
	Potential for electromagnetic interference		Temperature Limits -20°C to 60°C
	Class II Device		Humidity Limits 0% to 95%
	AC Power		DC Power
IP22	<p>Ingress of water or particulate matter into device</p> <p>The first digit indicates the level of protection that the enclosure provides against access to hazardous parts (e.g., electrical conductors, moving parts) and the ingress of solid foreign objects >12.5 mm diameter.</p> <p>The second digit indicates the level of protection that the enclosure provides against harmful ingress of water while tilted up to 15°.</p>		

CHAPTER 3

Setting Up Your Spiro PD 2.0

Initial Setup

When you first turn on your Spiro PD 2.0, you must go through the following screens. This information is used to calculate the % predicted values.

You can modify all of this information later by going to the appropriate screens via Device Settings or Personal Settings.

- Language
- Unit of Measure
- Name: first, middle, & last
- Date of birth
- Gender
- Height
- Weight
- Ethnicity
- Time & Date
- Privacy Policy and Terms of Use Acknowledgement

NOTE: You must complete all of the settings in order to move to the next screen. All information must be accurately completed in order for your Spiro PD 2.0 to produce accurate results.

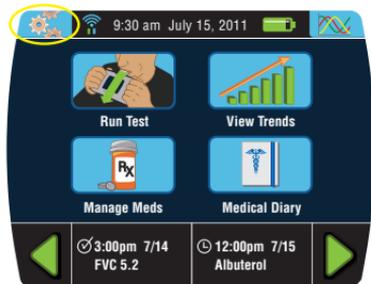
Privacy Policy

Details on the Privacy Policy and Terms of Use can be found on <https://MyPMD.com>. You must agree to these policies prior to using your Spiro PD 2.0.

Your Personal Settings

You can enter your name, date of birth, gender, height, weight, and ethnicity.

1. Press the **Settings** button on the Home screen.



2. Press **Profile** button.



There are six personal settings:

- Name: first, middle, & last
- Date of birth
- Gender
- Height
- Weight
- Ethnicity

Name

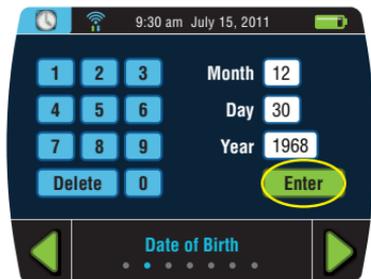
1. From the Personal Settings screen, press **Name**. A keyboard is provided to enter your full Name.
2. Key in your First Name and press **Enter**.
3. Then your Middle Name and press **Enter**.
4. Finally your Last Name and press **Enter**.



Date of Birth

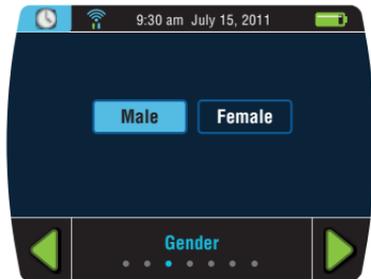
1. From the Personal Settings screen, press **Date of Birth**.
2. Enter your birth date using the numeric keypad.
3. Press **Enter** when finished.

NOTE: Use the Delete key to erase letters or numbers in the white boxes.



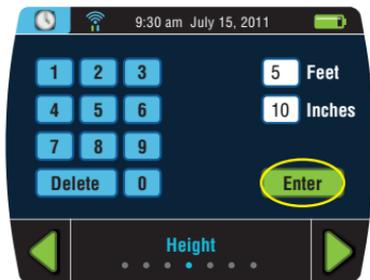
Gender

1. From the Personal Settings screen, press **Gender**.
2. Select your gender.



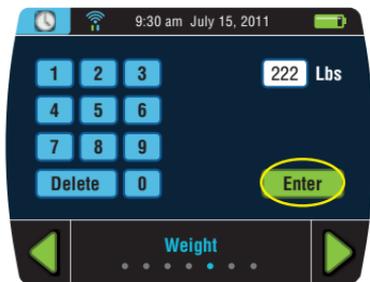
Height

1. From the Personal Settings screen, press **Height**.
2. Enter your height using the numeric keypad and press **Enter**.
Round your height to the nearest whole number. For example, if you are 5 foot 8 1/2 inches tall, enter 5 feet and 9 inches.



Weight

1. From the Personal Settings screen, press **Weight**.
2. Enter your weight using the numeric keypad and press **Enter**.
Round your weight to nearest whole number.



Ethnicity

1. From the Personal Settings screen, press **Ethnicity**.
2. Enter your ethnicity from the multiple choices.



Your Device Settings

You can set the time and date. You can also adjust your LCD brightness, set the volume control, set the date format, set the measurement units and set the language.

1. Press the **Settings** button on the Home screen.



2. Press the **Device** button.



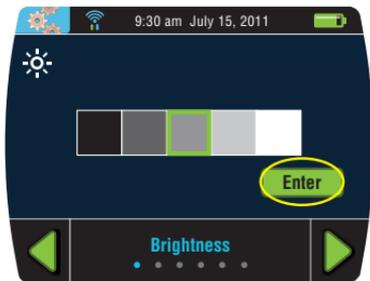
There are six device settings that can be selected:

- Brightness
- Volume
- Date/Time Format
- Time & Date
- Unit of Measure
- Language



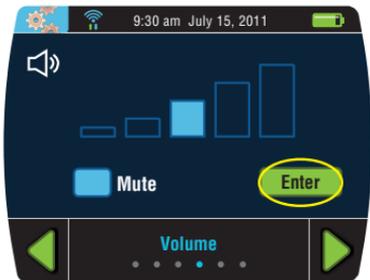
Set LCD Brightness

1. From the Device Settings screen, press **Brightness**.
2. Press the desired brightness box to adjust the LCD Brightness and press **Enter**.



Set Volume

1. From the Device Settings screen, press **Volume**.
2. Press one of the volume boxes to adjust the volume or press **Mute** to eliminate sound and press **Enter**.



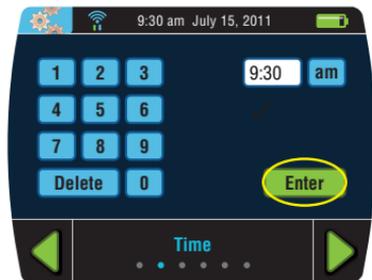
Set Date/Time Format

1. From the Device Settings screen,
2. Select Date/Time Format
3. Select one of three date formats and one time format.



Set Time & Date

1. From the Device Settings screen, press **Time & Date**.
2. Enter the time and press **Enter**.
3. You are then prompted to enter the date using the numeric keypad.
4. Enter the date and press **Enter**.



Set Unit of Measure

1. From the Device Settings screen, press **Unit of Measure**.
2. Select Imperial or Metric.



Set Language

1. From the Device Settings screen, press **Language**.
2. Select English, Español, or Français.

NOTE: Some versions of software may have some Language options disabled.



CHAPTER 4

Running a Test with Your Spiro PD 2.0

Before you perform a spirometry test it is important for you to remember that spirometry is an effort dependent test. The test results can change based on whether you are standing or sitting, so you should be consistent when you perform the test. For example, if you perform the test when you are sitting then you should perform all future tests while you are sitting. This will ensure that your spirometry test results are consistent from day to day. All spirometry results are automatically sent to the companion web portal when you are connected to Wi-Fi.

Your Spiro PD 2.0 has features to help you get the most out of your spirometry test. There are detailed instructions on the LCD screen, audible coaching, and personalized error messages to help you successfully and accurately complete the test.

There are seven Indicator Lights which light up based on the amount of air that is blown into your Spiro PD 2.0. The Indicator Lights are scaled to your personal profile. If you can light all seven Indicator Lights, you are meeting or exceeding the FVC lung capacity for a healthy individual of your age, gender, height, weight, and ethnicity.

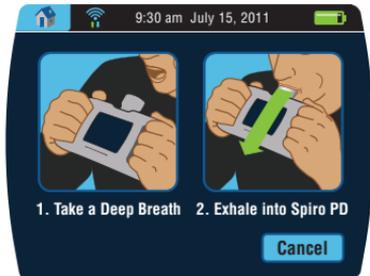
Running a Test

With your Spiro PD 2.0, you can run your test and record your results, enabling you to keep track of your lung function over time.

1. Press the **Run Test** button on your Home screen.



2. Follow the audible coaching and on-screen instructions described in detail below.



- a. Hold your Spiro PD 2.0 with the LCD screen facing away from you as shown.



- b. You may optionally place a nose clip on your nose to close off your nostrils. This helps to keep any air from leaking from your nose.



- c. Take a big deep breath away from the mouthpiece, breathing in as much as you can inhale.

Once the audible coaching tells you to exhale, move your Spiro PD 2.0 gently to your mouth. Be careful, an abrupt movement of your Spiro PD 2.0 could cause a false start reading, resulting in an error message.



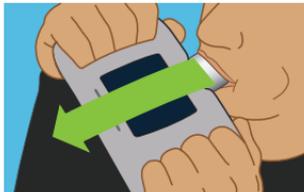
- d. Place your lips around the mouthpiece to create an airtight seal so that all of your breath is collected by your Spiro PD 2.0. Make sure your teeth and lips extend past the rim of the mouthpiece.



- e. In order to open your airway, keep your chin elevated and extend your neck slightly. Do not breathe in with your mouth on or close to the mouthpiece.



- f. When told, exhale as hard and fast as you can, emptying your lungs as forcefully and quickly as possible.



- g. During expiration, squeezing the handles can help expel the air from your lungs.



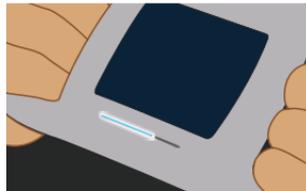
- h. As you exhale into the Spiro PD 2.0, the audible coaching feature will encourage you to exhale forcefully and completely.

Note: You do NOT have to breathe out the entire time you hear the “keep going” message.

This message is for encouragement only.



- i. The blue Indicator Lights will light in sequence as you are exhaling. The harder and longer you blow, the more lights you see. The goal is to light all of them, which means your lungs are working at their best.



When you have completed your exhale, take your mouth off the mouthpiece and turn your head to the side, keep the unit relatively still until Spiro PD 2.0 says “Good Effort”.

NOTE: Be careful, an abrupt movement of your Spiro PD 2.0 at the end of the test could cause a failed test.

3. If the test was successful, a green check mark appears. If the test was not successful, then a red semicircular arrow appears. You will be asked to repeat the test.



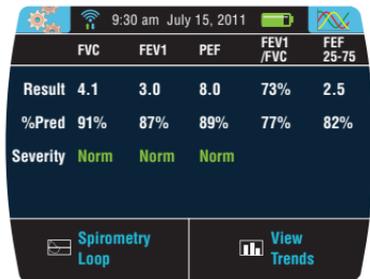
4. You will be guided through this process for three successful tests. Press the **Run Test** button when you are ready to begin the next test.

NOTE: Your Spiro PD 2.0 will allow you to rest for up to 5 minutes between tests but you should keep the screen active while resting between tests. If you are unable to complete the third test Spiro PD 2.0 will save your test results with just 2 successful tests. Select the Cancel button once you have two green checkmarks and confirm that you wish to cancel on the pop up. Your results will then be presented.



- The best results out of the three tests are then displayed and saved.
- Once completed, you can view your results on your Spiro PD 2.0 or online with your web portal account.

You can view trends of your test results and view your spirometry loop, such as your Flow-Volume loop and your Volume-Time curve.



Common Errors that May Produce Incorrect Results:

Coughing	If you cough during a test, press the Cancel button and try again
Exhaling too slowly	<ul style="list-style-type: none">• You need to exhale as hard and as fast as you can• Do not try to exhale long and steadily• Your device may say “Keep Going” after you’ve completed your exhale
Exhaling too soon	<ul style="list-style-type: none">• Do not inhale on the mouthpiece• Wait until Spiro PD 2.0 completes saying, “Exhale Now” before starting your exhale• Keep Spiro PD 2.0 relatively still during the inhalation
Not exhaling completely	You need to exhale as long as you can without coughing or gasping for air

CHAPTER 5 Viewing Your Trends

Your Spiro PD 2.0 allows you to view your past test results. This data can be shown in a tabular format or graphically by pressing the Graph button. Additional Trend views are also available on the companion web portal.

1. Press the **View Trends** button on your Home screen.



2. Your most recent test results are displayed. Press the **Up and Down arrows** to scroll through your results. You can sort your test results by touching the titles. For example, touching Data & Time sorts your test results chronologically.

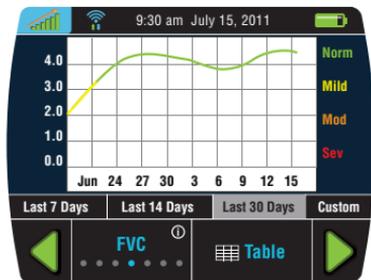


3. The right and left green arrows allow you to cycle through your test measurements:

- All Trends
- FVC
- FEV1
- FEV1/FVC ratio
- PEF
- FEF 25-75
- Weight/BMI



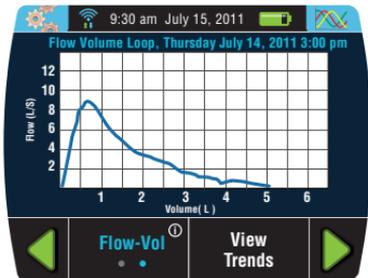
4. Press the **Graph** button to view a trending graph of data.



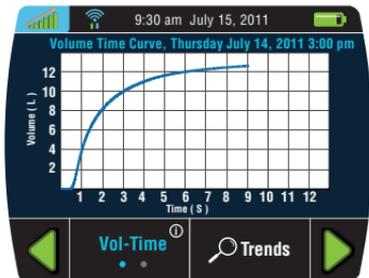
- Choose the column heading to filter the display to the last 7, 14 or 30 days of data. You can also choose a range of dates by touching the Custom button from the filter popup.



- On the All Trends screen, press the **Spirometry Loop** button to display the Flow Volume loop



- Use the Right Arrow button to display the Volume-Time curve.



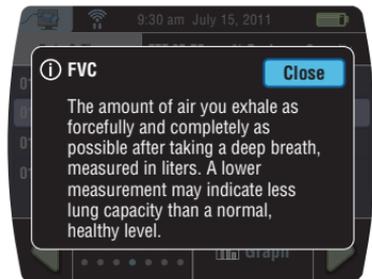
- Touching a row presents a window with the results of that test.

12:00am, December 12				
FVC	FEV1	FEV1/FVC	FEF	PEF
5.2	5.2	100%	300	400
Norm	Norm	Sev	Mild	Norm

Close

12:00am 12/12 FVC 5.2 12:00pm 12/12 2 Meds & Test

- Select the title in the lower left of a trend screen to see a detailed explanation of the measurement being displayed.



Disease Severity

Severity Levels are provided as a guideline. Follow your care plan as specified by your health care provider.

Normal	Indicates your disease is under control.
Mild	Indicates caution. Additional medication may be required. Contact your doctor.
Moderate	Indicates extra caution. Contact your doctor as soon as possible for further examination and consultation.
Severe	Indicates a medical emergency. Immediate action needs to be taken. Call your doctor, go to the emergency room, or call 911.

NOTE: To get a complete picture of your lung health, your doctor may need to analyze the results of several different lung function test measurements together.

CHAPTER 6 Tri-Trends®

Your Spiro PD 2.0 allows you to review multiple sets of trends simultaneously. Tri-Trends is a snapshot of Spirometry results, medication adherence, and medical diary entries. Tri-Trends is also available for viewing on the companion web portal.

The Tri-Trends page is easily accessible and available from most screens.



On the Tri-Trends page you will see a large graph with two lines. These show your FVC and FEV1 data over time. The color coded lines make it easy to see your overall lung functionality.

If an alert is set it will be represented by a dotted line. Alerts are optional and can be set up in Alarms & Alerts.



Tri-Trends also shows your Medical Diary history and your Medication history over the last 14 days. The legend in the upper portion of the page provides detail for each icon.

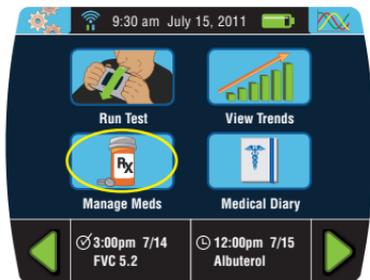
Med Diary  Entry Made  No Entry
Med History  Took Med  Missed Med  Used Rescue Inhaler

CHAPTER 7

Managing Your Medication

You can use your Spiro PD 2.0 to manage your medication. By creating a schedule for your medication your Spiro PD 2.0 will remind you when it is time to take it. You can also log when a medication is taken and view medication history. You can set a low dose point when you need to refill your medication. You can also set an alert when your medication reaches that designated Low Dose point. All medication can also be managed on the companion web portal.

1. Press the **Manage Meds** button on your Home screen.



- The Manage Meds screen shows the medication details for each of your medications. Use the green arrows to display each medication detail, dosage, and schedule.



History displays a list of the medications that you've recorded on your Spiro PD 2.0.

New Med allows you to add a new medication.

Edit Med allows you to modify the medication being displayed.

Delete Med removes the displayed medication.

Log Med records the current date and time for the medication being displayed in History and reduces the quantity left by one dose. This can be used for a medication without an alarm schedule, such as taken as needed, like an emergency inhaler.

Creating a New Medication

1. Select **New Med** from your Manage Meds screen.



2. Enter the new medication name and press **Enter**.



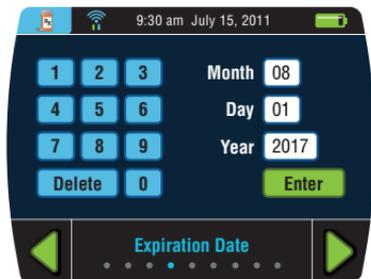
3. Select the Medication Class and press **Enter**.



4. Using the keyboard, enter the Prescription number, if applicable. The Prescription number is optional.



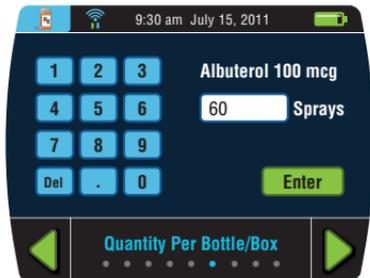
- Using the number pad, enter the expiration date and press **Enter**.



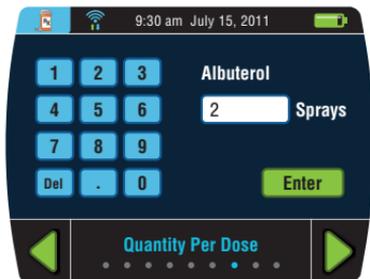
- Select the Form of Medication
Use the other button to specify your own form of medication on the provided keyboard screen.



- Using the number pad, enter the total quantity per bottle/box and press **Enter**. This is the total quantity of medication that you have on hand.



- Using the number pad, enter the quantity taken per dose and press **Enter**.



9. Select a Start Date and press **Enter**.



10. Select the frequency:

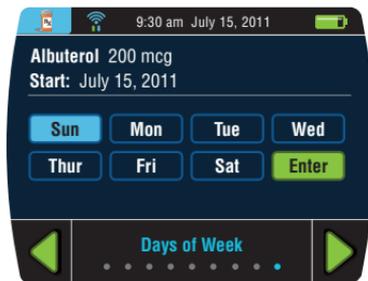
- Daily
- Weekly
- Monthly
- Yearly
- Once
- As Needed



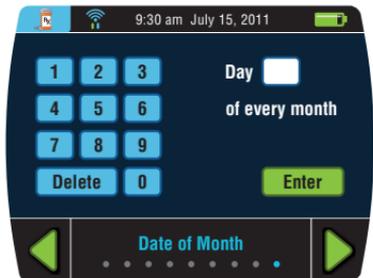
NOTE: Select 'As Needed' for a medication that does not have a set schedule. For example, an emergency inhaler is often taken on an 'as needed' basis.

You can set your medication schedule by choosing one of the recurrences and entering the required information.

- **Daily** – select a time option based on how you are taking your medication each day.
 - **Specific Times** allows you to enter up to 6 times per day that you take your medication. You will be prompted for additional times if you take your medication more than once a day.
 - **Set Every X Hours** allows you to enter how often you will take your medication throughout the day at a regular interval.
- **Weekly** - used for a medication that is taken on specific days of each week.
 - Choose the day(s) and then enter the times you will take your medication.



- **Monthly** – used for a medication that is taken on a monthly basis. You will first choose the day(s) of the month you will take your medication and then enter the times you take the medication. For example, every 1st of the month.



11. Once you've entered the medication detail, you can add an optional end date.
12. Press **Confirm** to save the medication.

Changing Your Medication

Your Spiro PD 2.0 allows you to edit any existing Medication. You can easily make changes to any value.

1. Press the **Manage Meds** button on your Home screen.
2. Press the **left or right green arrows** until the medication schedule you want to edit is displayed.

3. Select **Edit Med** from the Medication screen.

Use the green arrows at the bottom of the screen to navigate to the screen that you would like to update. Once you've made all changes, press confirm on the confirmation screen to save.

NOTE: The Quantity Per Bottle/Box screen will display your current quantity left of the medication.

Deleting a Medication

1. Press the **Manage Meds** button on your Home screen.
2. Press the **left or right green arrows** until the medication you want to delete is displayed.
3. Press the **Delete Med** button to delete the medication being displayed.

Logging Your Medication

Your Spiro PD 2.0 can record when you take your medication.

1. Press the **Manage Meds** button on your Home screen.
2. Press the **left or right green arrows** until the medication you want to log is displayed.
3. Press the **Log Med** button to indicate that you took the medication being displayed. Your Spiro PD 2.0 will record the current date & time for that medication in your medication history.

Refilling a Prescription or Changing Dosage

Your Spiro PD 2.0 records when you take your medication and calculates the quantity left of each medication. If you refill a medication you can change the total quantity left by editing the medication.

1. Press the **Manage Meds** button on your Home screen.
2. Press the **left or right green** arrows until the medication you want to change is displayed.

Refilling: To refill a medication navigate to the Quantity Per Bottle/Box screen and enter your current total quantity of the medication. You may have to add your newly received amount to the number that you currently have. For example, if you have 5 tablets left and refill that medication with a new bottle of 30 tablets, you would type in 35 as your total quantity.

Changing Dose: To change a medication dosage, navigate to the Quantity Per Dose screen and enter the new dosage.

3. Once your changes are complete, navigate to the confirmation screen and press the **Confirm** button to save your information.

Viewing Your Medication History

Your Spiro PD 2.0 allows you to view your medication history.

1. Press the **Manage Meds** button on your Home screen.
2. Press the **History** button.
3. Use the blue up and down buttons to navigate through the Medication History Log.

You can sort your medication history by touching Date & Time or Medication.

A medication alarm that was dismissed and not logged is shown in red.



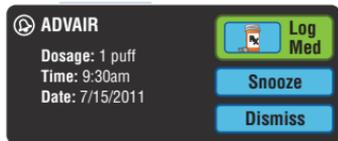
Date & Time	Medication	Dosage	Dose Left
2/9/2014 8:00am	ADVAIR	1 puff	79
2/8/2014 8:00am	ADVAIR	1 puff	79
2/7/2014 8:00am	ADVAIR	1 puff	80
2/6/2014 8:00am	ADVAIR	1 puff	81
2/5/2014 8:00am	ADVAIR	1 puff	82
2/4/2014 8:00am	ADVAIR	1 puff	82

Medication Alarm Reminder

Your Spiro PD 2.0 will remind you to take your medication based on the schedule you have entered. This can help you comply with your medication treatment regimen.

A reminder pop up window is displayed when it is time to take your medication.

1. Select the **Log Med** button to record that you took the medication. Your Spiro PD 2.0 will record the current date & time for this medication in your medication history.
2. Select the **Snooze** button to delay this reminder by another 8 minutes.
3. Select **Dismiss** if you will not be taking this medication. Your Spiro PD 2.0 will record that you did not take this medication in your medication history.



CHAPTER 8 Medical Diary

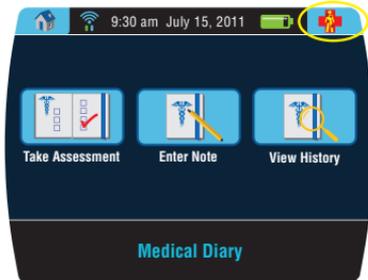
Your Spiro PD 2.0 allows you to create a diary of medical symptoms. The medical diary allows you to keep track of your daily lung function, respiratory symptoms and free text notes. Medical Diary entries can be entered and viewed on the Spiro PD 2.0 or the companion web portal.

Setting Your Chronic Conditions

1. Press the **Medical Diary** button on the home screen.

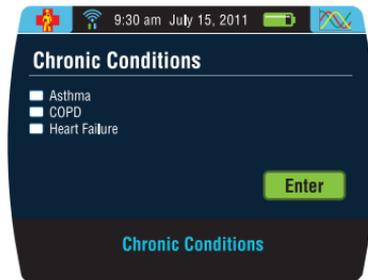


2. Press the **Chronic Conditions** button in the upper right corner.



3. Select any conditions that you would like to enter any medical diary entries about and press **Enter**.

Each option displays the corresponding questionnaire in the Medical Diary entry. If you select all conditions you will see all questionnaires displayed one after another when entering your medical diary entries.



Creating a Diary Entry

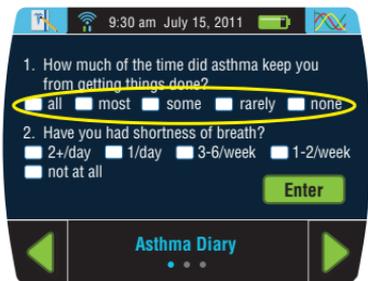
1. Press the **Medical Diary** button on the Home screen.



2. Press the **Take Assessment** button.



- The assessment test associated with the selected chronic condition is presented. Select the checkbox to select an answer to the question. All questions must be answered prior to selecting the Enter button. Proceed through each page of questions to complete the assessment test. The score shall be presented in the View History section of the Medical Diary.

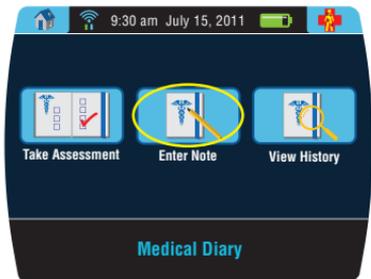


Creating a Free Text Diary Note

- Press the **Medical Diary** button on the Home screen.



2. Press the **Enter Note** button on the Medical Diary screen.



3. Enter your own notes and press the **Enter** button to complete the entry.

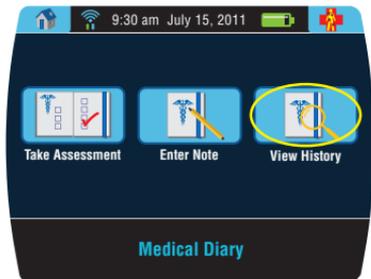


Viewing Your Diary

1. Press the **Medical Diary** button on the Home screen.



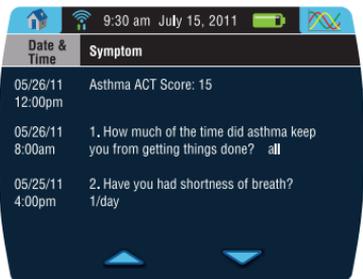
2. Press the **View Diary** button.



- Diary entries appear in chronological order with the most recent at the top.

A header row separates each condition containing the name of the condition along with any applicable scores for that questionnaire. For example, the header for Asthma also shows the ACT score.

- Press the blue up and down arrows to scroll through your entries.
- Use the Home button in the upper left hand corner to exit diary to the Home screen.



CHAPTER 9

Alarms & Alerts

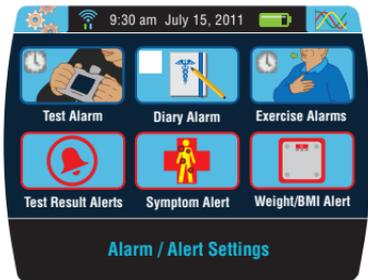
Spiro PD 2.0 can be set up to remind you to complete actions such as taking your spirometry tests, breathing exercises, or updating your medical diary. You can also set thresholds for your spirometry results or changes to your Weight/BMI and have an alert sent if you fall below that threshold. Additionally these alarms and alerts can be managed on the companion web portal and can incorporate email or text messages into the reminders or alerts.

Creating, Editing, and Deleting Alarms

1. Select the **Settings** button on your Home screen.
2. Select the **Alarm/Alert** button on the Settings screen.

There are three alarms:

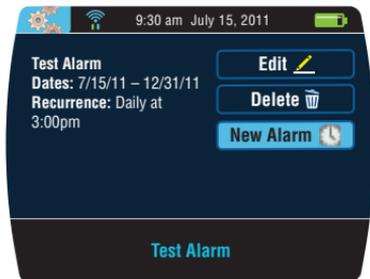
- Test Alarm
- Diary Alarm
- Exercise Alarm



Scheduling Your Test Alarm

The Test Alarm screen allows you to create a new test alarm and edit or delete an existing test alarm. This can help you evaluate your lung health by enabling you to track your progress and trends.

1. From the Alarm/Alert Settings screen, tap on the Test Alarm button
2. Select the **New Alarm** button to create a new alarm.
3. Enter the alarm details and press confirm to save.



Test Alarm Reminder

Your Spiro PD 2.0 will remind you to take your spirometry test based on the schedule you have entered.

A reminder pop up window is displayed when it is time to take your spirometry test.

1. Select the **Run Test** button to start a spirometry test.
2. Select the **Snooze** button to delay this reminder by another 8 minutes.
3. Select **Dismiss** if you will not be doing this test.

Scheduling Your Diary Alarms

Your Spiro PD 2.0 can be programmed to alarm when it is time to create a new diary entry. This can help you keep records of your daily respiratory symptoms.

Scheduling Your Breathing Exercise Alarms

Your Spiro PD 2.0 can be programmed to alarm when it is time for your breathing exercises. This can help you follow your respiratory therapy.

Breathing Exercise Alarm Reminder

Your Spiro PD 2.0 will remind you to do your breathing exercises based on the schedule you have entered.

A reminder window is displayed when it is time to do your breathing exercises.

1. Select the **Do Exercise** button and perform your breathing exercise.
2. Select the **Snooze** button to delay this reminder by another 8 minutes.

Alerts

Creating a Biometric Alert

1. Click the **Settings** button on the Home screen.
2. Click the **Alarm/Alert** button on the Settings screen.

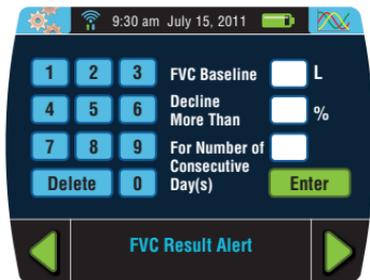
There are three Biometric Alerts:

- Test Result Alerts
- Symptom Alert
- Weight/BMI Alert



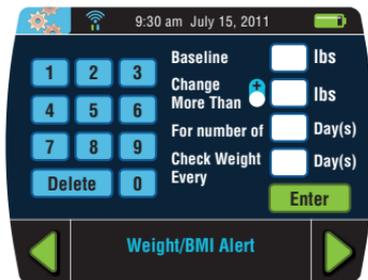
Test Result Alerts

Your Spiro PD 2.0 can be programmed to alert you when your FVC, FEV1, and/or FEV1/FVC levels go below a certain baseline. This can help you see trends and adhere to your emergency medication plan.



Weight/BMI Alerts

Your Spiro PD 2.0 can be programmed to alert you when your weight goes above or below your baseline. This function allows you to keep track of trends.



CHAPTER 10 Wi-Fi

Your Spiro PD 2.0 synchronizes your data with your online WMS Web Portal. The data is stored on your device and a secure Wi-Fi network. Spiro PD 2.0 uses a Wi-Fi signal to send and receive data from the Web Portal. This allows your Spiro PD to connect to your WMS Web Portal account and send information to the people you designate.

Connecting to Wi-Fi

1. Press the **Settings** button in the top left corner.
2. Press the **Wi-Fi** button on the Settings screen.
3. Press a **Wi-Fi network** from the Available Networks list.
4. Enter the password, if applicable, and press **Connect**.



NOTE: Spiro PD will remember the password for your network and will automatically connect when the network is available.

Wi-Fi Symbols



Wi-Fi connected



Wi-Fi disconnected

CHAPTER 11 Technical Information

Product Specifications

Interpretation based on

- ATS (American Thoracic Society)

Measurements

- Measurement Scale (BTPS)
 - Flow (l/s) 0 to 16
Flow Accuracy +/- 5% or 200ml/sec
 - Volume (l) 0 to 15
Volume Accuracy +/- 3% or 50ml

Operating temperature range: 32° F to 113° F (0° C to 45° C)

Operating relative humidity: 0 to 95% (without condensation)

Barometric pressure: 85 kPa to 106 kPa

Power supply: Rechargeable Lithium-ion battery

- Size: 7.9 x 3.8 x 1.6 inches (200 x 96 x 40mm)

Weight: 9 ounces (256 g)

Wi-Fi: Transmits and receives at a frequency and bandwidth of 8.02.11 b/g/n

ERP (Effective Radiated Power): -12.25 dBW

Battery Usage:

- Up to 13 days of standby time
- Up to 2.5 hours of continued use

Device & Accessories (excluding Battery) Lifetime: 5 years

EMC Regulations

Guidance and manufacturer's declaration— electromagnetic emissions

The Spiro PD is intended for use in the electromagnetic environment specified below. The customer or the user of the Spiro PD should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The Spiro PD is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration — electromagnetic immunity

The Spiro PD is intended for use in the electromagnetic environment specified below. The customer or the user of the Spiro PD should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T for 1 cycle <5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in UT) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T for 1 cycle <5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in UT) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment, If the user of the Spiro PD requires continued operation during power mains interruptions, it is recommended that the Spiro PD be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration — electromagnetic immunity

The Spiro PD is intended for use in the electromagnetic environment specified below. The customer or the user of the Spiro PD should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Spiro PD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d=1.17\sqrt{P}$</p> <p>$d=1.17\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d=2.33\sqrt{P}$ 80 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p>

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
- b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
- c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Spiro PD is used exceeds the applicable RF compliance level above, the Spiro PD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Spiro PD.
- d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Spiro PD

The Spiro PD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Spiro PD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Spiro PD as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2,5 GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Glossary

This glossary defines key terms used to discuss spirometry and lung health. If you have any questions, please talk with your doctor.

Spirometry

The measurement of the amount (volume) and speed (flow) of air you inhale and exhale. Using these measurements help you evaluate your lung health.

FVC

(Forced Vital Capacity): The amount of air you exhale as forcefully and completely as possible after taking a deep breath. The result is measured in liters. A lower measurement may indicate less lung capacity than a normal, healthy level.

FEV1

(Forced Expiratory Volume in 1st second) The amount of air you exhale in the first second after taking a deep breath. The result is measured in liters. A lower measurement may indicate an obstruction of your airway that keeps air from leaving your lungs.

FEV1/FVC Ratio

The ratio of FEV1 to FVC. A lower measurement may indicate an obstruction of your airway that causes you to exhale less air than normal. A higher measurement may indicate a restriction of your lungs, meaning less lung capacity than a normal, healthy level.

FEF25-75

(Forced Mid-expiratory Flow) The average speed of air flow during the middle part of your breath as you exhale. The result is measured in liters per second. A lower measurement may indicate a narrowing of your airway.

PEF

(Peak Expiratory Flow) The maximum speed of air you exhale. The result is measured in liters per second. A lower measurement may indicate a narrowing of your airway.

Flow-Volume Loop

The speed of air you exhale measured against the amount of air you exhale.

Volume-Time Curve

The amount of air you exhale measured against time.

% Pre (% Predicted)

The result of your spirometry test compared to the predicted value that matches your age, gender, height, weight, and ethnicity. This percentage is used to diagnose your lung health and is expressed in terms of severity.

Minimum System Requirements

Microsoft Windows

- Windows PC with a 1GHz Intel or AMD processor and 512MB of RAM
- Windows XP Service Pack 2 or later or Windows 10 (32-bit or 64-bit editions)
- USB 2.0
- 2MB of available disk space

Apple Macintosh

- Mac computer with an Intel, PowerPC G5 or G4 processor and 512MB of RAM
- Mac OS X version 10.5 or later
- USB 2.0
- 2MB of available disk space

CHAPTER 12 Maintenance and Troubleshooting

Cleaning and Disinfecting

Mouthpiece Cleaning Instructions

NOTE: Your Spiro PD 2.0 mouthpiece should be removed from the spirometer and cleaned immediately and thoroughly after each use.

1. Hand wash the mouthpiece using a clean bottle brush with warm water (min. 100° F.) and an antibacterial dishwashing detergent (containing L-Lactic Acid 2.00%) for at least one minute.
2. Rinse thoroughly under warm running water (min. 100° F.) for at least a minute.
3. Shake off excess water and let the mouthpiece air dry completely.

Mouthpiece Disinfecting Instructions

1. Clean as per above cleaning instructions.
2. Submerge mouthpiece in household bleach (sodium hypochlorite 5.25%) at 1:50 dilution (1 US tsp per 1 US cup of water) for 10 minutes
3. Rinse thoroughly under warm running water (min. 100° F.) for at least a minute.
4. Shake off excess water and let the mouthpiece air dry completely.

NOTE: If the mouthpiece is discolored or cannot be cleaned, replace the mouthpiece by calling 888-PMD-4YOU.

Spiro PD 2.0 Unit Cleaning Instructions

1. Wipe all surfaces clean with disinfecting wipes (containing Alkali and Dimethyl Benzol Ammonium Chloride).
2. Let surface air dry completely.

Spiro PD 2.0 Unit Disinfecting Instructions

1. Wipe all surfaces to be disinfected with disinfecting wipes (containing Alkali and Dimethyl Benzol Ammonium Chloride).
2. Use enough wipes for treated surface to remain visibly wet for 10 minutes.
3. Let surface air dry completely.

NOTE: Avoid getting moisture into the unit.



CAUTION

Avoid pets and loose hair around the Spiro PD device. Loose hair can become entangled in the Turbine Assembly of the device causing the Spiro PD to provide inaccurate results or cease functioning.



CAUTION

Do not use solvents or other similar substances, such as alcohol, for cleaning as they may cause damage.

Battery Replacement

To remove the battery, turn your Spiro PD 2.0 upside down. Press on the battery door with your thumbs and slide the battery door out towards the handle. Then flip your Spiro PD 2.0 over and the battery will drop into your hands with a mild tap.



To install the battery, place the battery into the battery compartment with the battery connections lined up. Then place the battery door into back cover, slide the battery door into place and close. The battery door must snap into place.



Troubleshooting Guide

Problem	Solution
Unsuccessful Test: Do not exhale too soon	Turbine was already in motion when Spiro PD 2.0 said 'Exhale Now' Make sure: <ul style="list-style-type: none">• there's no fast movement of the unit during inhale• a fan or breeze is not present• you're not inhaling on the mouthpiece• you didn't exhale before instructed
Unsuccessful Test: Exhale more forcefully and quickly	Make sure: <ul style="list-style-type: none">• exhale was not long and steady• exhale quickly and forcefully
Unsuccessful Test: Exhale longer	<ul style="list-style-type: none">• No exhale• Exhale shorter than 1 second Make sure: <ul style="list-style-type: none">• there is an exhale during the test• the exhale is longer than 1 second
The Redo symbol and "try again" message keep occurring during a Run Test	<ul style="list-style-type: none">• Make sure your Spiro PD 2.0 is free of debris

Problem	Solution
LCD screen is black or dim	Make sure: <ul style="list-style-type: none">• The brightness is turned up• The battery is charged• Turn your Spiro PD 2.0 off and then back on
The LCD screen is white or images appear incorrect on the LCD screen	<ul style="list-style-type: none">• Remove the battery, wait 5 seconds, and then reinstall the battery
Your Spiro PD 2.0 does not respond to touches	<ul style="list-style-type: none">• Confirm that you are touching only a single point on the LCD screen at a time• Turn your Spiro PD 2.0 off and then back on• Remove the battery and wait 5 seconds and then reinstall the battery
The Indicator Lights are not lighting up or do not go off after a spirometry test	<ul style="list-style-type: none">• Turn your Spiro PD 2.0 off and then back on• Remove the battery and wait 5 seconds and then reinstall the battery

Problem**Solution**

Your Run Test values appear normal but the severity is Severe or your values appear out of range but the severity is Normal

- Verify that your personal settings are correct

Your computer does not recognize your Spiro PD 2.0 when you plug in the USB cable

- Turn your Spiro PD 2.0 off and then back on
- Check that your computer meets the minimum system requirements
- Try another USB cable
- Try another computer

Your Spiro PD 2.0 is not reminding you with its alarms

- Check your alarm schedules are correct including the start and end dates
- Confirm the current date & time are correct

There is low or no audio during an alarm or spirometry test

- Check the volume
- Turn the mute feature off

Your Spiro PD 2.0 does not turn off or turn on

- Check that the on/off button moves in and out and is free from debris
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Problem	Solution
Your Spiro PD 2.0 is not charging	<ul style="list-style-type: none">• Try another USB cable• Connect your Spiro PD 2.0 to your computer and try to charge it from your computer• Remove the battery, check that the electrical contacts are clean, then reinstall the battery
The charge on your Spiro PD 2.0 does not last several days	<ul style="list-style-type: none">• Remove the battery, check that the electrical contacts are clean, then reinstall the battery• Replace the battery
The mouthpiece won't fit into your Spiro PD 2.0	<ul style="list-style-type: none">• Ensure that you are inserting the correct end of the mouthpiece into your Spiro PD 2.0
Wi-Fi does not connect	<ul style="list-style-type: none">• Incorrect password entered• Wrong Network selected

For assistance, if needed, in setting up, using or maintaining the Spiro PD 2.0 device or to report unexpected operation or events, please contact the Manufacture or the Manufacture's representative shown on the back of the cover of the manual.

Return Policy

Any unopened merchandise may be returned to PMD Healthcare within 15 days of the ship date. Please contact PMD Healthcare at customercare@Spiro PD.com or by calling 888-PMD-4YOU. Customer is responsible for return freight charges.

Proper Disposal of Your Spiro PD 2.0

Your Spiro PD 2.0 contains electronics that must be disposed of properly. It also has a lithium-ion battery that also must be disposed of in accordance with local environmental regulations. Consult your local recycling center on how to properly dispose of the electronics and the battery contained in your Spiro PD 2.0.

LIMITED WARRANTY CONDITIONS

PMD Healthcare warrants that Spiro PD 2.0 personal spirometer shall be free of defects in material and workmanship for a period of one year from the date of purchase for the original purchaser only. PMD Healthcare will repair or replace the defective parts or product at the discretion of PMD Healthcare. The warranty does not apply to the following cases:

- The problem was caused by improper use of the device
- The device has been altered, tampered with, abused, or repaired by personnel not authorized by PMD Healthcare
- The defect was originated by a power source or another product that the device was connected to
- The device was damaged or subjected to physical stress
- The serial number of the device is missing, altered, and/or not legible

The freight of the returned goods to and from PMD Healthcare is the customer's responsibility.



Australian Sponsor
Emergo Asia Pacific Pty Ltd.
Level 20, Tower II Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

Emergo Group
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Ph (31) 70.345.8570
Fax (31) 70.346.7299

PMD Healthcare
6620 Grant Way
Allentown, PA 18106
888-PMD-4YOU
www.mypmd.com
10000197 Rev. B