



Spiro✓ Lung Monitor

Operating Manual

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

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Introduction

The Micro Direct **spiro✓ Lung Monitor** was specifically designed for situations where low cost, easy to use, accurate spirometry with a report is required.

The **spiro✓ Lung Monitor** accurately measures, displays and stores the actual FEV_1 , FEV_6 , FEV_1/FEV_6 , FEF_{25-75} and the percent of Personal Best FEV_1 . The personal best FEV_1 can be set by the clinician with future patient efforts compared to their personal best. The three color action zones are preset but can be customized by the clinician.

With the Spirometry Reports Software, the results can be uploaded to a computer to generate a report that can be sent to the physician.

Package Contents

The Spiro✓ Lung Monitor is packaged with the following items:

- 1 Spiro✓ Spirometer
- 2 Plastic reusable mouthpiece
- 3 Two AAA batteries
- 4 Reports Writer CD-Rom
- 5 Model 4000 User Manual
- 6 Computer Cable

Setting Personal Best (Reference) Values

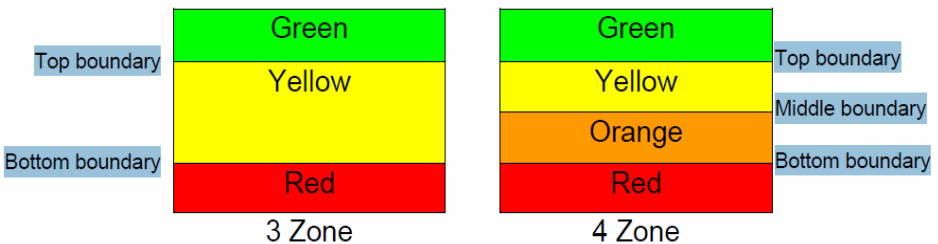
Personal Best (reference) values can be set for forced expiratory volume after 1 second (FEV1). To set the Personal Best (reference) FEV1, follow these steps:

1. Turn the device on.
2. When the device is ready for a test, (🔄) press the ▲ and ▼ buttons together for 3 seconds.
3. The reference FEV1 value is set by pressing the ▲ button and releasing when the value is reached. Press the ▼ to roll back. The values will increase/decrease in values of 0.10. If the button is kept depressed, the values will scroll faster.
4. Press ENTER to keep this reference FEV1 value. The device will return to the test screen.

Note: to de-activate zones, set the FEV1 reference value to 0.00.

Setting Management Zones

The Spiro✓ lung monitor can be set for use with 3 or 4 zone management plans. The zone percentages are factory set to 2 boundaries, 95% & 90%, i.e. 3 Zones (95-100%, 90-95%, 0-90%). For 4 zones the middle boundary is set last. The color systems for each zone type are as follows:





Setting Management Zones (3 Zones)

1. Turn the device on.
2. When the device is ready for a test (P), press the ▲ and “Enter” buttons together for approximately 10 seconds.
3. The top (Green/Yellow) boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is reached.
4. Press “Enter” to set the top (Green/Yellow) boundary value.
5. The bottom (Yellow/Red) boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is reached. Press “Enter” to set the bottom (Yellow/Red) boundary value.
6. Only 2 boundaries are required for the 3 zone system, so the next value should be selected as 0% (default). Press “Enter”. The device will return to the test screen.

Setting Management Zones (4 Zones)

1. First set the top and bottom boundaries – see above procedure (steps 1 - 6).
2. The middle (Yellow/Orange) boundary can now be set. This is done by pressing the ▲ button and releasing when the middle boundary value is reached. The values will increase/decrease in values of 1% after an initial jump to the lower boundary value. If the button is kept depressed, the values will scroll faster. This boundary value cannot be set at a value that is greater than the top boundary value or less than the bottom boundary value.
3. Press “Enter” to set the middle (Yellow/Orange) boundary value. The device will return to the test screen.

Performing the Test

1. Sit down when blowing into the device (unless the physician advises otherwise).
2. Turn the device on and insert the mouthpiece.
3. When the device is ready for a test () , breathe in as deeply as possible, hold the Spiro✓ lung monitor ready in front of the mouth.
4. Holding the breath, place the mouthpiece into the mouth, biting the mouthpiece lightly, and with the lips firmly sealed around it.
5. Blow out as HARD, as FAST and as LONG as possible (the device will stop taking readings after 6 seconds). Be careful not to block the mouthpiece with the tongue or teeth. A ‘spitting’ action will give false readings.
6. Following each blow and at the end of the test session, the FEV1 value will be displayed and below that, FEV1 % Personal Best results for that blow.
7. Pressing the ▲ button will show the FEV6 result.
8. Pressing the ▲ button again will show the FEV1/FEV6 result.
9. Pressing the ▲ button again will show the FEF25-75 result.
10. With the blow icon showing, blow again (). Usually 3 blows are required.
11. To view the best test in the session (best FEV1 and best FEV6), press the “Enter” button. This is the value that is recorded for the session in the device history.

Note: if an exclamation mark **!** appears, this means it was not a good quality blow and the subject should blow again. **!** appears when: The Vext (extrapolated volume) is > 5% or 150mL of FEV6 or a cough is detected in the 1st second

If the subject experiences dizziness or fatigue during the test session, wait until this passes before blowing again or terminate the session.

Reviewing Previous Results

The Spiro✓ lung monitor can store up to 200 test sessions. In order to view previously performed test sessions, follow these steps:

1. Turn the device on.
2. When the device is ready for a test (🌀), press the “Enter” button for approximately 3 seconds.
3. The most recent test session will now be displayed. The best FEV1 result will be displayed for approximately 3 seconds, followed by the best FEV6 result. The session number ‘1’ is also displayed, this is the latest session.
4. Earlier test sessions can also be viewed. Pressing the ▲ button once will show ‘2’ the previous test, and so on.
5. Press “Enter” button. The device will return to the test screen.

Deleting All Results History




Caution: Once the history has been deleted it cannot be recovered.

To delete the history entirely, i.e. all previously stored session results, follow these steps:

1. Turn the device on.
2. When the device is ready for a test (🌀), press the ▼ and “Enter” buttons simultaneously for approximately 10 seconds.
3. A long beep will indicate success and the device will return to the test screen.

Creating a PDF Report

The test session may be transmitted to the Reports Utility on your PC where it can be stored as a PDF file and viewed or printed. Before you can transmit you must first have the Reports Utility installed and running on your PC.

1. Connect the Spiro✓ lung monitor USB device to the PC using the USB cable supplied.
2. On the Reports Utility ensure 'Spiro✓ lung monitor' is selected as the device.
3. There are two ways to print the test results from the lung monitor;
 - a. When the device is ready for a test () press the ▲ button for 3 seconds on the device will show the Report icon () .
 - b. After completing the test session, press the ▲ or ▼ button until the print () screen is displayed. Press the "Enter" button.
4. On the Utility Reports enter the Subject Demographic details and Comments. Select 'Continue' on the Utility Reports when you are finished entering the information.
5. Select a location for the test report on your PC as requested by the Utility Reports. A PDF of the test results will appear and will also be stored to the PC.

Customer Contact Information

For all sales order processing, training and spare parts, service and technical support inquiries, please contact the following:

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