MedDorna Spirometry User's Manual

003-0004 Rev A

Initial Release Approvals		
Engineering	Document Control	Other
Date:	Date:	Date:

Revision History			
ECO #	Date	REV	Description

MedDorna, LLC

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Table of Contents

Table of Contents 2
Glossary of Symbols 5
General Cautions & Warnings 6
WARNINGS: 6
CAUTION: 6
ELECTRICAL SAFETY CLASSIFICATIONS: 7
CONTRAINDICATIONS: 7
Office Medic Installation 8
Installing Office Medic Software From CD-ROM: 8
Open Software 10
General Troubleshooting 10
Navigation 11
Navigating the Patient Directory 11
Office Medic Options 12
File 14
Test 19
Options 20
Tools 21
MedicSync 21
Main Database 21
Remote Database 21
Notes 22
Steps in the Configuration Process 23
Conflict Resolution 25
Scanning for Account Number Conflicts 25
Scanning Main for Missing Account Numbers 26
Scanning Remote for Missing Account Numbers 27
Scanning for Conflicts 27
Help 31
MedDorna Wireless PRN Spirometer Cautions & Warnings 32
MedDorna Wireless PRN Spirometer Introduction 34
Spirometry 34
Getting Started MedDorna Wireless PRN Spirometer 35
Installation: 35
Connect Mouthpiece 35
Performing a Spirometry Test 35
Entering Mouthpiece Number 36
Performing the Maneuver 36
Menu Buttons on the Test Results Window 40
Tabs 40
MedDorna Wireless PRN Spirometer Options 42
FVC 48
Forced Vital Capacity ⚠ (FVC) 48
Proper Procedure: 48
MVV 51
Maximum Voluntary Ventilation ⚠ (MVV) 51
SVC 53
Slow Vital Capacity (SVC) 53
MedDorna Wireless PRN Spirometer Calibration 55
Calibration Check 55

MedDorna Wireless PRN Spirometer Troubleshooting 57
MedDorna Wireless PRN Spirometer Specifications 59
MedDorna Wireless PRN Spirometer Export File Field Order 62
Predictor Equations 65
Care & Maintenance 75
Service 76
Limited Warranty 77
Glossary of Terms 78

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

⚠ Before conducting live tests on patients, read the Caution and Warnings topic that pertains not only to your particular device but the General Caution and Warnings section as well. It is also recommended that you perform some practice sessions on yourself or a colleague before performing live patient testing. Practice the procedures, setting options, setting predicted normals, and saving and deleting patients, sessions and individual maneuvers.
This manual has been divided into separate sections to better facilitate the instructional process for users who have purchased more than one PC Card device. Please read the Office Medic Software section to learn how to use and navigate through the Office Medic software. For information on the operation and the mechanics of testing patients with your Spirometer device refer to the appropriate Spirometer section.

We at MedDorna, LLC hope that this manual will be of service to you, however if you do need further assistance see Service for information on how to contact MedDorna's Technical Support department.
Important! Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Office Medic is the trademark of QRS Diagnostic, Inc.

Glossary of Symbols

	Attention: Consult Accompanying Documents
	Type B Equipment – Spirometer
	Defibrillator proof type CF Applied Part – ECG
	Federal Communication Commission
MEDICAL EQUIPMENT CLASSIFIED C UL US XXXX UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1, *(AND IEC60601-x-xx, where applicable)*	Underwriters Laboratories
	Do Not Reuse
	Class II, Electrical Equipment
BT	Bluetooth
S/N	Serial Number

General Cautions & Warnings

WARNINGS:

- Equipment is not suitable for use in presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.
- Proper supervision is necessary when using any MedDorna medical device on children or vulnerable adults.
- It is recommended that you perform some practice sessions on yourself or a colleague before doing live patient testing.
- It is recommended to frequently back-up of data to safe guard against data loss should your computer suffer a loss of power or an unrecoverable error.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION:

- The MedDorna Wireless PRN Spirometer device does not contain user serviceable components. Necessary repairs must be made at a MedDorna approved service location.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- The MedDorna Wireless PRN Spirometer device used with the Office Medic software are intended for use by a physician or by laboratory personnel under a physician's supervision. It is the physician's responsibility to assure that testing is properly administered, the test data properly evaluated and the patient referred for appropriate treatment. All numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.
- All printers used with the Office Medic software must be tested and approved per EN60601-1-1 prior to placing the system in service.
- The MedDorna Wireless PRN Spirometer device has been tested and approved per EN60601-1 and IEC60601-1. All computers used with Office Medic software must be tested and approved per EN60950. If the computer has not been tested and approved per

EN60950, the system must be tested and approved per EN60601-1-1 or IEC60601-1-1 prior to placing it into service.

- Close all other applications when installing Office Medic software.
- Battery usage is dependent upon the computer in use. Consult your computer's user manual for battery usage and recharge information.
- Low battery indication is dependent upon the computer in use. Consult your computer's user manual for battery indicators.

ELECTRICAL SAFETY CLASSIFICATIONS:

Note: These classifications apply to the MedDorna Wireless PRN Spirometer device:

- Class II Electrical Equipment
- Protection against Electrical Shock: Type B Equipment
- Protection against Harmful Ingress of Water: IPX1
- Mode of Operation: Continuous Operation

Degree of safety in the presence of flammable anesthetics mixture with with air, oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

CONTRAINDICATIONS:

- Do not operate in an explosive atmosphere.
- Do not operate in proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the MedDorna Wireless PRN Spirometer device.

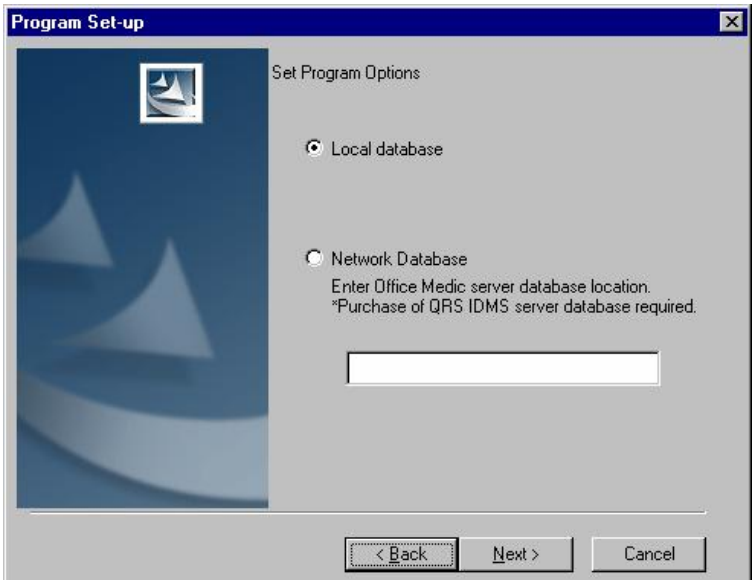
CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Office Medic Installation

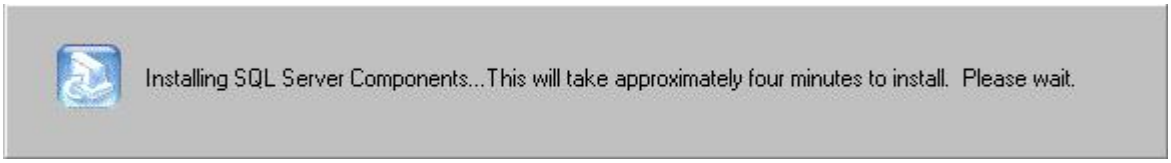
Installing Office Medic Software From CD-ROM:

1. Log out of all other programs running on your computer.
2. Insert the Office Medic CD-ROM in the CD-ROM drive of your PC
3. If the **autorun** feature on your computer is disabled go to the next instruction. If not follow the on screen prompts.
4. On the lower Windows toolbar select **Start|Run**.
5. Type in **d:\office\setup.exe** in the **Open** dialog box. **Note:** substitute the letter of your CD-ROM drive should it be different from **d:**.
6. Follow the on-screen instructions to complete the software installation.

Note that you will be given a choice of whether you wish to use a local database (one that resides only on the PC the software is being installed to) or a network database (see illustration). The network database option requires an additional software purchase.



Also during the installation the message below will be displayed. Installing these components will take about four minutes with no outward sign that anything is occurring. Please be patient.



An Office Medic shortcut icon should appear on your Windows desktop when installation is complete.

Shortcuts: Shortcut buttons are located just below the main menu. If unsure of the function, hold the mouse arrow over the button and the function's name will pull down.

Shortcuts are from left to right, **New, Open, Delete, Print, Print Preview, Refresh database, Spirometry, ECG, Oximetry Record Mode, Oximetry Spot Check Mode and Help**.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Open Software

The MedDorna Wireless PRN Spirometer device does not have any controls and is operated by the software. Its current status is indicated by two LED on top of the device as follows:

Red LED	Blue LED	Device Status
OFF	OFF	No battery or battery is fully discharged
ON	ANY	Low battery
OFF	Single blink every 10 sec	Standby mode
OFF	Dual blink every 3 sec	Device in use by the software

Make sure your device is in standby mode.

Using your mouse select the **Office Medic** icon on your computer's desktop to load the software program.

General Troubleshooting

Question: “Can I use the Office Medic software with other medical hardware?”
Answer: No. Currently the Office Medic software will work only with MedDorna Wireless PRN Spirometer.

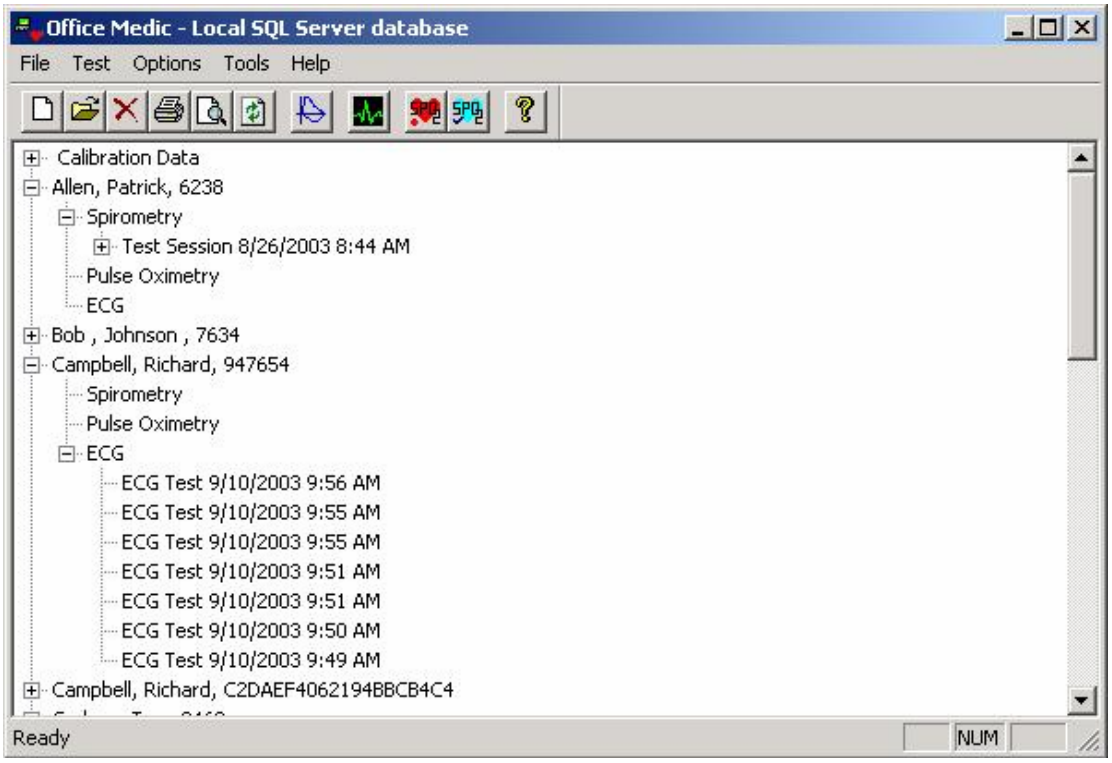
Problem: “Will not launch program”.
Solution: Make sure your spirometer device is in standby mode (see above). Check the PC's memory to assure there is enough available memory to launch the Office Medic software.

Problem: "Will not print".
Solution: Printer is not ready. Office Medic software is designed to print to the default printer you assign through Windows. In Windows go to **Start|Settings|Printers** to check that the printer you are trying to print to is on-line and selected as the default. Also try to print from a different program such as a word processor. If you cannot print from that program as well as the Office Medic program there is most likely a communication issue between the computer and the printer.

Navigation

Navigating the Patient Directory

Select the **Office Medic** icon to load the software. The initial screen (illustrated below) begins with the directory of patients, sessions and tests.



The directory is a collapsible directory of patients, sessions and tests.

To open a folder click on the "+" icon.
To close a folder click on the "-" icon.
To navigate you can use the keyboard or mouse.

The keyboard commands are:

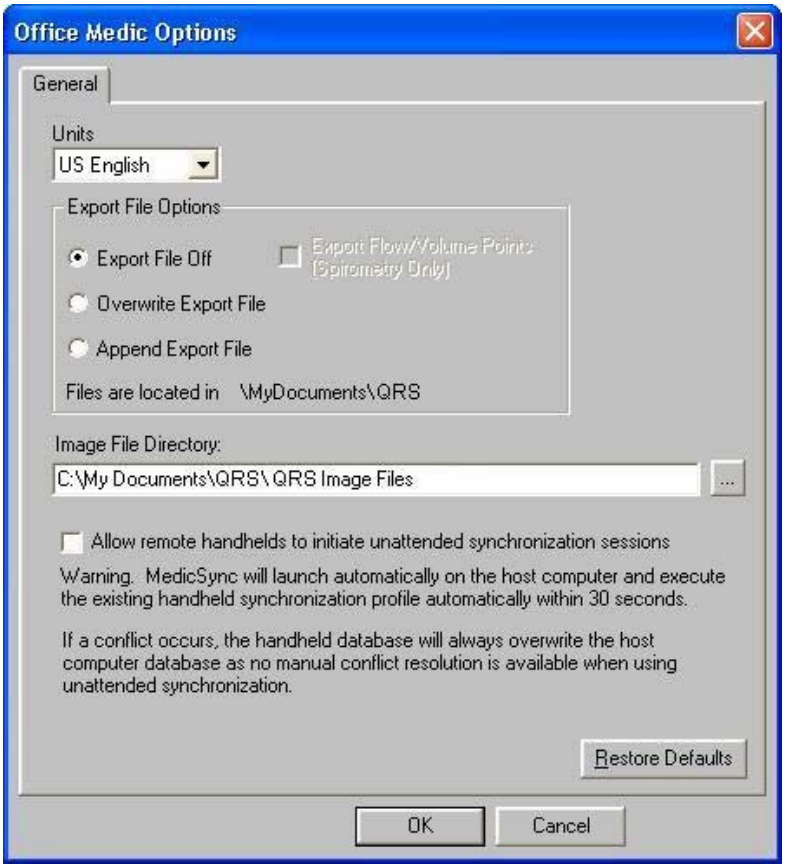
- Up/Down arrow keys move up/down the directory.
- Left arrow key closes folder.
- Right arrow key opens folder.
- The Enter key opens a test session.
- Tab key moves from field to field.

Office Medic Options

Select **Options|Office Medic** to access the Office Medic options.

Select the **General** tab to change the Measurement Units, Export options or the default path of the Image File Directory.

Units - Select **US English** or **Metric.**



Export File Options - You can create a file that will export your data into tab delimited text files. The export settings must be set prior to running a new test. The only way to export a previously saved session would be to add a new test to that session. To view the files open **"My Documents\QRS"**.

There are three options for exporting:

- **Export File Off**
- **Overwrite Export File** - after activation, this only creates a file for the last patient tested.
- **Append Export File** - this will begin creating a text file of all future patient test files from the instance this item is invoked.

Export Flow/Volume Points - this exports the graph data points for PFT reports.

Please note when exporting spirometry tests three text files are created, **Session.txt, SpTest.txt** and **SpCalibr.txt**. The Session.txt file will contain patient demographics and a list of the tests performed in that session. The SpTest.txt and SpCalibr.txt files contain test results for tests and calibrations.

Selecting the **Export Flow/Volume Points** feature creates two files called **SpGraph.txt** and **SpCalGr.txt**. The SpGraph.txt and SpCalGr.txt files contain the number of graph points and a listing of each graph point separated by a carriage return.

See the **QRS Export Field Order** topic under the Appendix section for additional export file information

Image File Directory - Select the browse button ... to change the default path where your image files will be saved.

Allow remote handhelds to initiate unattended synchronization sessions - When enabled a remote Pocket PC is able to initiate a MedicSync session. This feature allows for synchronization between PCs and Pocket PCs when the host PC is inaccessible to the user of the remote PC. Several items should be noted:

Important! If the host computer's settings were set to delete data from the remote database during a previous synchronization, data will be deleted from the remote during the current synchronization unless the host computer's settings are changed.

Once the automatic session is initiated both the PC and the Pocket PC will display messages indicating that the session has been initiated and will begin in 30 seconds.

Any conflict of Account Number or demographics will be resolved using the remote database to overwrite the host database.

A user on the host computer is able to cycle through the MedicSync screens and change the options prior to the session's beginning.

When changing options the user on the remote PC is notified that the host computer is changing the options.

During the session the remote user is kept apprised of the status by a progress bar. When the progress bar is solid (100%) the session is complete, and the remote user is notified.

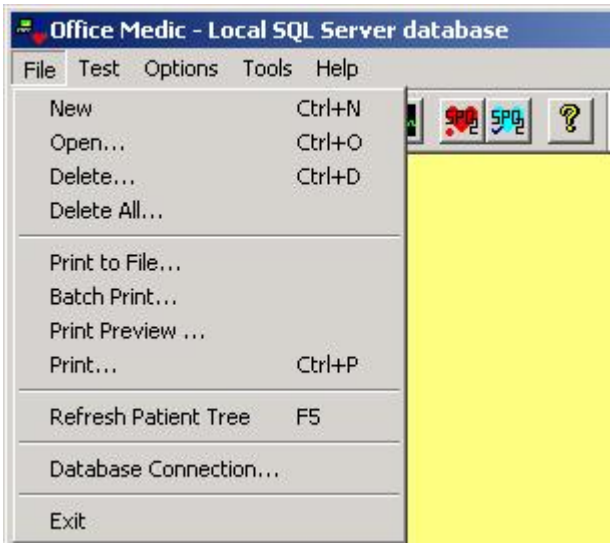
CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

If the host computer does not have a previous synchronization saved with a Pocket PC then the Use the settings from my previous session option is unavailable and the session cannot be initiated.

The user on the host computer can cancel the Automatic MedicSync session. If canceled, the remote computer is notified.

File

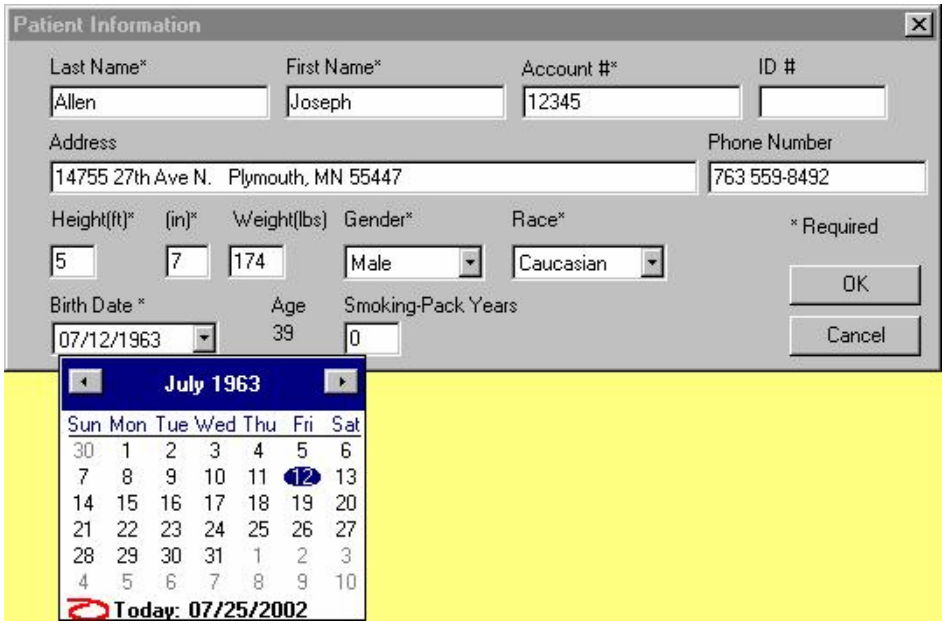
The **File** option displays several choices which provide options for creating and managing patient files, printing, managing the database connection and exiting the program.



New (Ctrl+N) - Selecting **New** will open the Patient Information window.

Enter patient information into the provided fields. Move from field to field with the tab key. Required fields are: **Last Name, First Name, Height, Sex, Race** and **Birth Date**. The **Birth Date** may be selected by selecting the arrow key in the field and using the calendar feature. Opening the calendar feature is an easy way to set the desired date. Select the month, then the year desired. Once you have set those parameters, select the date and close out the calendar. When all the information is entered correctly, select **OK** to save the data.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Smoking-Pack Years is calculated by multiplying the number of cigarette packs smoked per day by the number of years the patient has smoked.

Open (Ctrl+O) - Select a patient and then select **Open** to open the Patient Information window and modify the patient's demographics. Select **OK** when finished to save the information.

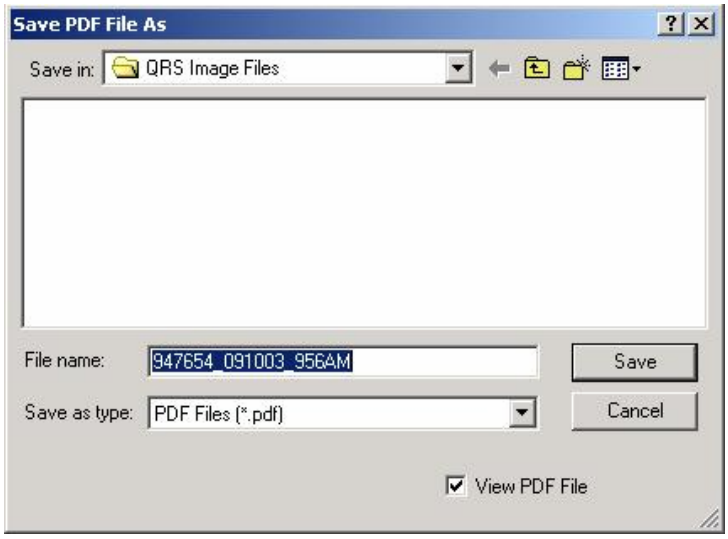
Delete (Ctrl+D) - Select a patient's name and then select **Delete** to delete that patient and all of his/her test sessions. You can also expand the patient tree and delete an entire test session or an individual test by highlighting the session or test you wish to remove and the choosing **Delete**. Warning messages will question you to make sure you want to delete the information. Once deleted the information cannot be recovered.

Delete All - The **Delete All** option deletes the entire database stored on the local computer's hard drive. Using this command will delete all patients, sessions and tests including calibration tests. Once deleted the database cannot be recovered.

Print to File - Creates an image file of an Office Medic report. Highlight the session or test maneuver you wish to image and select this option. The image file is created in the PDF format.

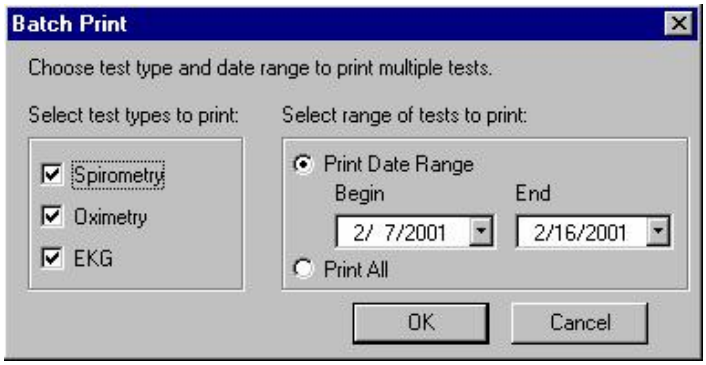
Selecting **Print to File** prompts you to save the file (see illustration).

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



The default location for the image file is "**My Documents\QRS\QRS Image Files**". The default file name reflects the patient's account number and the date and time the session or test maneuver is saved. The default file type is *.PDF. You can change the location and file name at the time of creation (to change the default **Image File Directory** see **Office Medic Options**). The default file type cannot be changed. The PDF report is an image of the report that would have been printed had you selected **File|Print**. Multi-page reports create a single file.

Batch Print - The **Batch Print** option allows for the printing of multiple patient reports, assigned by date (see illustration below), or all patient reports within the database.



Select the check boxes for the type of reports to be printed, and then set a date range. Select **Print All** to print the entire database. Spirometry calibration reports within the date range selected will also be printed. Note that the defaults for the **Batch Print** option is the current date and the last boxes and buttons set from the previous batch print job.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

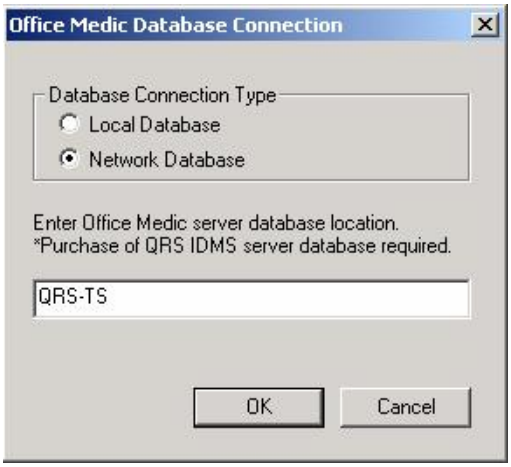
Finally, if tests do not fall within the date range selected, an error message is displayed. Select **OK** and you will be returned to the **Batch Printing** dialog box.

Print Preview - Reports for calibration tests, test sessions or individual tests can be previewed on your computer monitor by selecting the desired item in the patient tree and then selecting **File|Print Preview**. Several options are available when previewing a selected report.

Print (Ctrl+P) - Office Medic software is designed to print to the default printer assigned in the Windows settings. Test reports can be printed using this function. Select the test session or individual test and select **Print** to print a report.

Refresh Patient Tree (F5) - This command is most useful when viewing a networked database. This option automatically refreshes the patient database and allows you to observe any new patients, sessions or tests saved since you opened the database or last refreshed it.

Database Connection... - This option allows you to switch from the network database (located on the server) to your local database (located on your hard drive). Select this option and the following dialog box is displayed.



CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Select database connection type. If connecting to a Network database enter the server name then select **OK**.

Exit - Selecting this option exits the Office Medic program.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

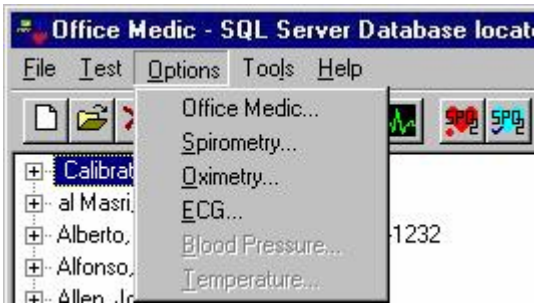
Test

Highlight a patient in the patient directory and select **Test**. Three test types are available:

Select **Spirometry** to start spirometric testing.

Options

Select **Options** from the main menu and choose **Spirometry** option.



Tools

MedicSync

MedicSync allows you to synchronize data between QRS patient databases. This data includes patients as well as test and session data. When synchronizing between an Office Medic (workstation or server) database and a Pocket Medic (handheld) database, MedicSync will automatically launch when you dock your handheld to your PC. MedicSync must be manually launched when transferring data between two Office Medic databases. To manually launch MedicSync choose **Tools|Office Medic|MedicSync** from within Office Medic.

For information about unattended remote synchronization with your Pocket PC see **Office Medic Options**.

Important! You should close all other applications on your PC before beginning a MedicSync session.

MedicSync is designed to work with Microsoft® ActiveSync® version 3.5 or higher. Before using MedicSync you should upgrade ActiveSync if necessary. ActiveSync is a free download from the Microsoft website.

Main Database

When launched MedicSync automatically assigns the Main database to be the currently selected database on your Office Medic workstation software. If your Office Medic workstation has a database connection set to Local Database, the Local Database will be the Main for this session of MedicSync. If your Office Medic workstation has a database connection set to Network Database, the Network Database will be the Main for this session of MedicSync. If you desire to change the Main to a different database, you must exit MedicSync and change the database connection within Office Medic. Select **File|Database Connection** to accomplish this.

Remote Database

In order to exchange data with your Main Database, you must specify a Remote database. The Remote database can be either another Office Medic (desktop or server) database or a Pocket Medic (handheld) database. If you dock your handheld to your PC and MedicSync is set to launch automatically (default), the Remote database is automatically set to the Pocket Medic database on that handheld. When MedicSync is launched manually via the Office Medic Tools

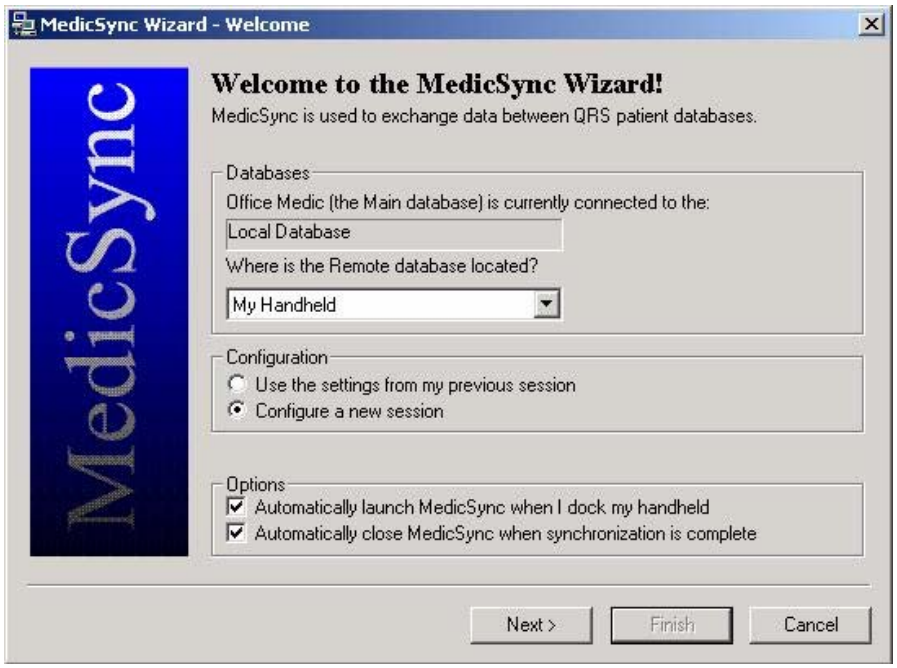
menu, all databases available are listed and you must select which one you want to be the Remote database for this session of MedicSync.

Notes

Before using MedicSync there are several suggestions to make your synchronizations easier. Most customers don't change their settings once they have established a routine for synchronization. The Main database should be the database in which you consistently enter your patient demographic information. This patient data can be sent easily to your Remote database(s). This will establish identical demographic records in both the Main and Remote databases and cut down on potential conflict resolution. Also, if you synchronize often, it will cut down on lengthy synch times and the amount of conflict resolution you will need to perform. For questions about computer compatibility visit
www.qrsdiagnostic.com.com/NewFiles/Hardware.html

First Time Configuration

When used initially MedicSync will walk you through the configuration process. After reading the **Welcome Screen** the initial choices are **Next** or **Cancel**. Choose **Next** to start the configuration process.



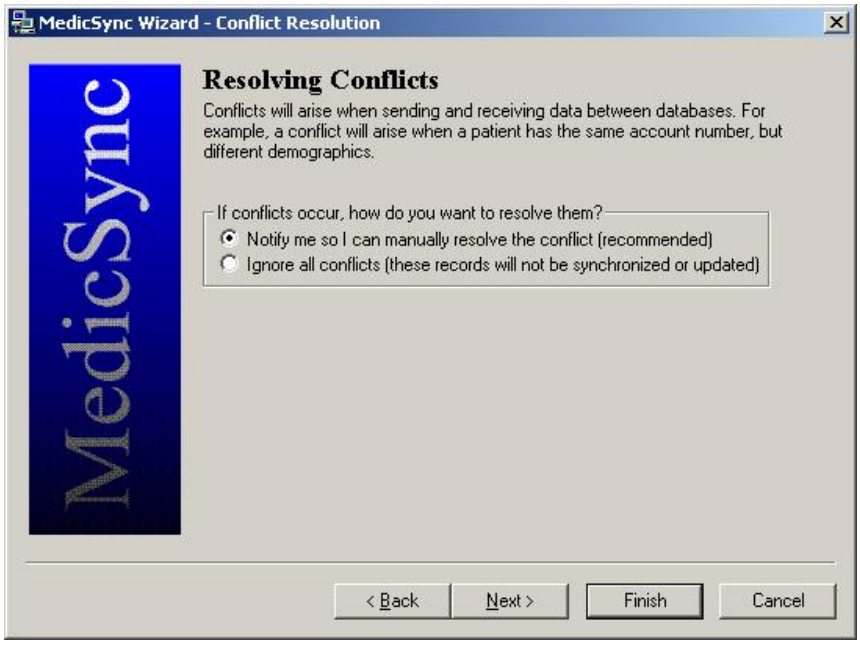
Once configured, the **Finish** button appears as an option and can be used to synchronize the databases using the exact same settings from the previous session, assuming that you are

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

synchronizing the same database types. For example, the **Finish** button will not be available if you are synchronizing any new combination of MedDorna databases.

Steps in the Configuration Process

The first step in the configuration process is to choose a method to resolve conflicts when two records from different databases have the same patient first name, last name and account number, but different demographics. The choices are illustrated below.

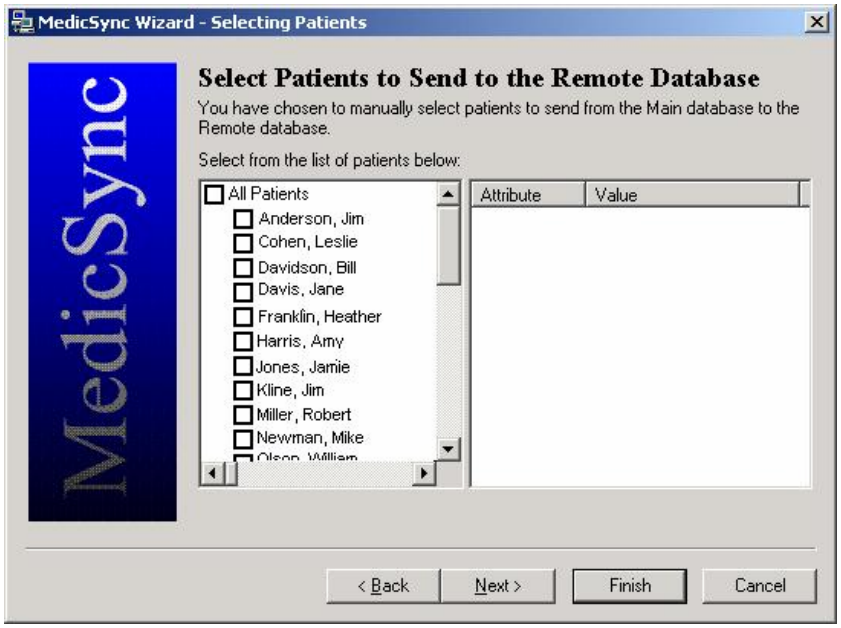


The second step offers the choice of deleting data from the Remote database. You can choose to delete patients and tests, tests only or to not delete any data from the Remote database.

The third step offers the option of sending patient data from the Main to the Remote database. You can choose to not send any patients to the Remote database, to send all the patients or to manually select which patients to send to the Remote database.

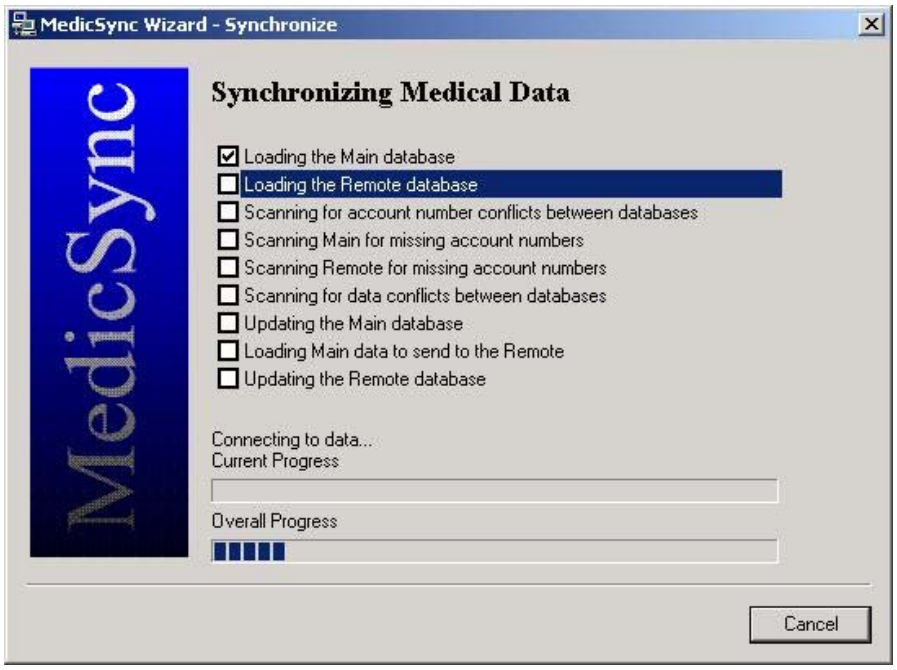
Whether step four is necessary depends on the choice made in step three. If you choose to export all or none of the patients from the Main to the Remote database, then the synchronization process will begin automatically. If you chose to manually select patients to send to the Remote database, then step four will need to be completed before synchronization can begin.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Place a check mark in the boxes next to the patients you wish to export and then select **Finish** to complete step four.

At this point the synchronization of data begins and a progress window is displayed. The steps completed during synchronization are checked off, as they are finished.



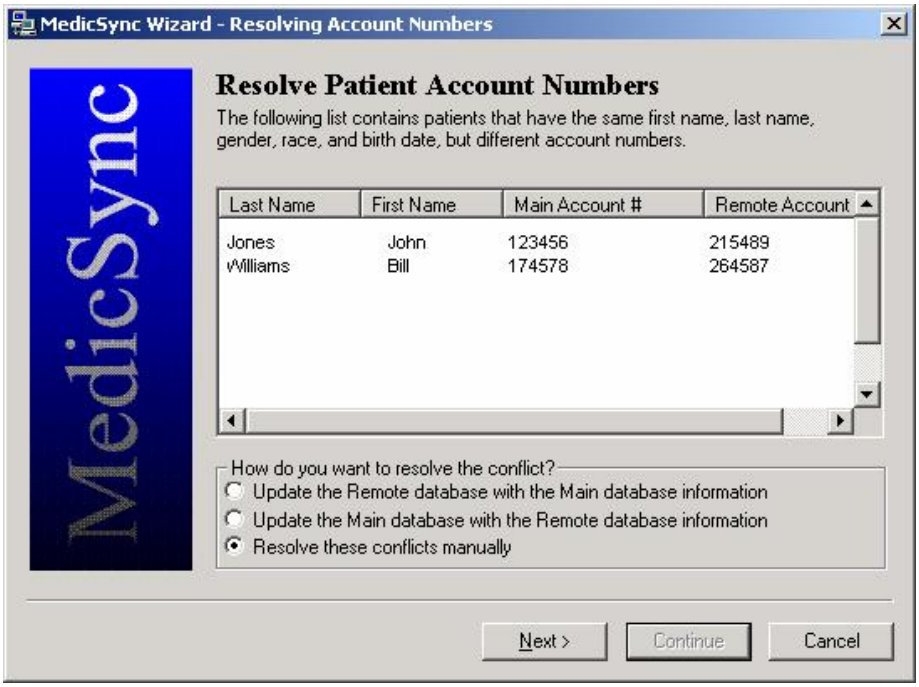
CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Conflict Resolution

MedicSync requires unique account numbers in all databases in order to synchronize patient information and tests. The following conflict resolution screens are displayed if any account numbers are missing or are the same as another patient.

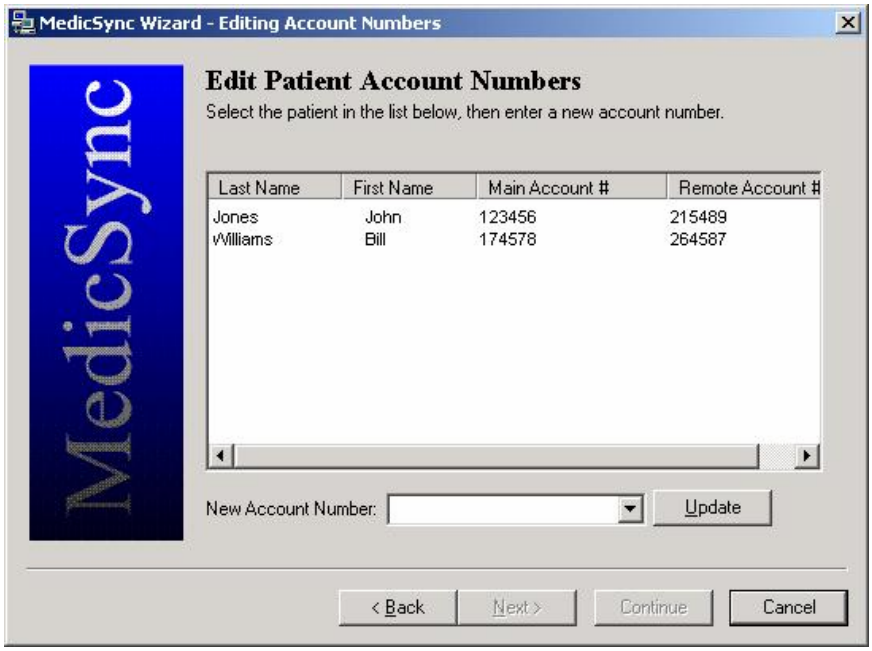
Scanning for Account Number Conflicts

MedicSync scans for patient records that appear in both databases with the same demographic data, but have different account numbers. Should conflicting account numbers be found the following screen is displayed.



Choosing to update the Remote database will send the account numbers from the Main database to the Remote database. Choosing to update the Main database will send the account numbers from the Remote database to the Main database. It is important to note that MedicSync will not update the other database with a blank account number, nor can either of the first two choices be used when both account numbers are blank. In cases such as these the conflicts must be manually reconciled. The screen below is a sample of manually reconciling account numbers.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

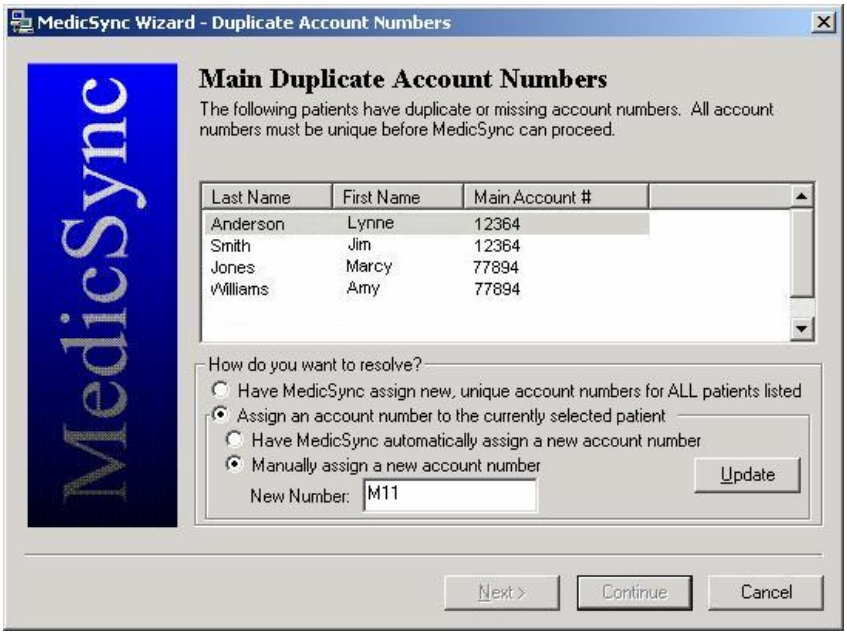


Highlight a record and select the appropriate account number from the drop down menu. For records in which both account numbers are blank, enter an account number. Select Update to then update both records. Select Continue to proceed to the next step.

Scanning Main for Missing Account Numbers

MedicSync scans the Main database for duplicate or missing account numbers. The following screen appears if any records meeting those conditions are found.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



MedicSync can assign unique account numbers to each patient automatically or you can choose to assign account numbers to these patients manually. Highlight the patient's name and enter the account number in the New Number field. Select Update to assign the account number, and select Continue when all patients have been assigned a unique account number.

Scanning Remote for Missing Account Numbers

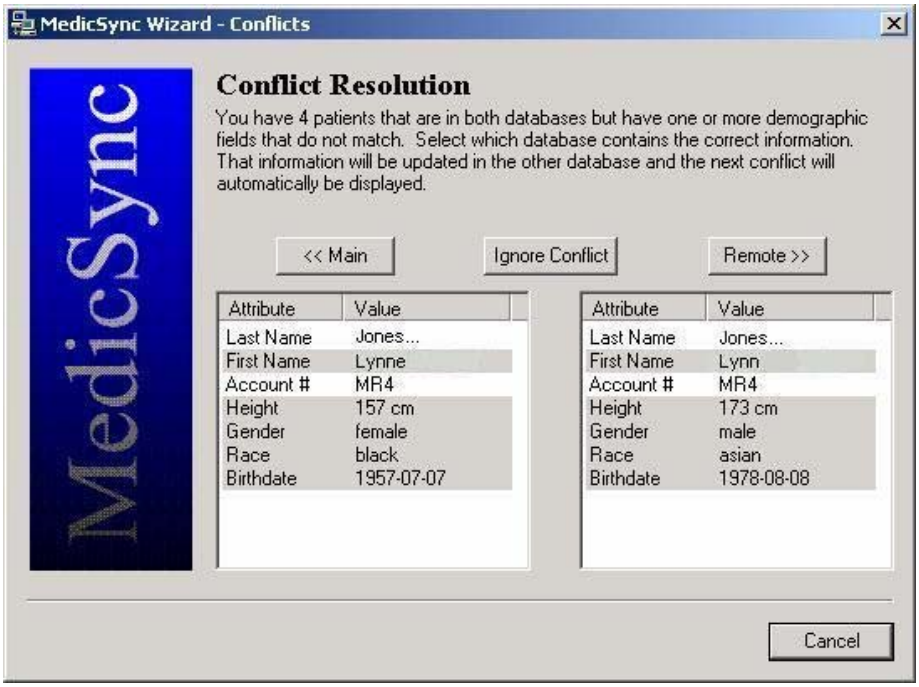
The Remote database is also scanned for duplicate or missing account numbers. Should any be found on the Remote database the same type of screen is displayed as above, and the options and procedures are identical to resolve these conflicts. Select Continue when ready to proceed to the next step.

Scanning for Conflicts

Patients who exist in both databases (identified by having the same account number), but have different demographic data, will display in the Conflict Resolution screen. The differences in the demographics are highlighted.

Important! Should you need to change the demographics from within a test session (see **Getting Started, MedDorna Wireless PRN Spirometer|Session Demographics**). MedicSync will ignore this conflict upon synchronization. Upon synchronization all of the patient data and test data will be synchronized, however the demographics from within the changed test session will be out of sync. Note that the only session information that is continually updated is the Session Comments.

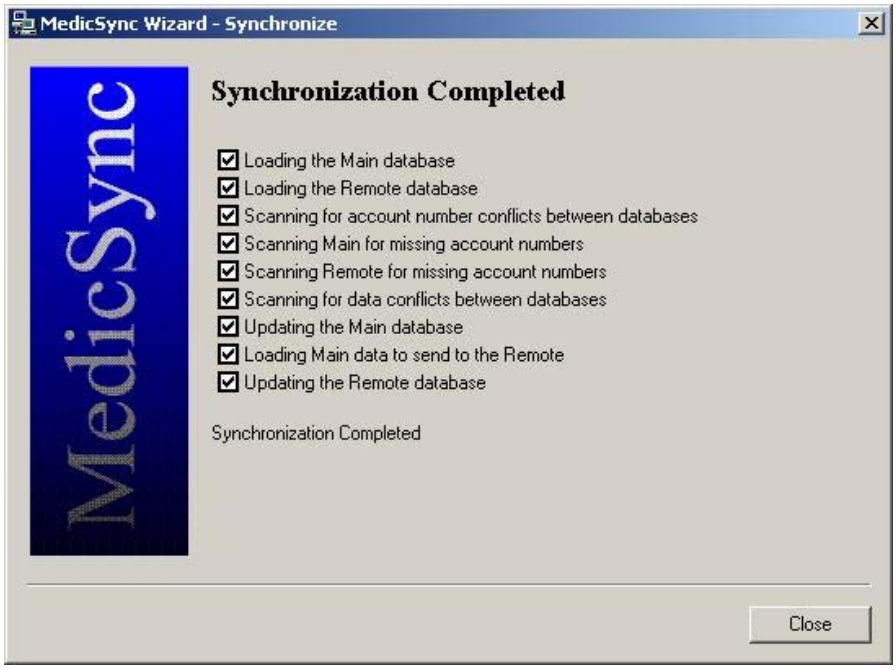
CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Conflicts of this type must be resolved manually by choosing the Main or Remote buttons, which will overwrite the demographic information of the record in the database NOT chosen. Selecting Ignore Conflict results in the record not being synchronized. Each time a conflict is resolved, the number of conflicts refreshes to reflect the current number of conflicts remaining and a new record is displayed. Select Continue when all conflicts have been resolved.

The data will now be synchronized according to the selections made during configuration. When completed the program will display a completion screen. Select Close to close out the MedicSync program.

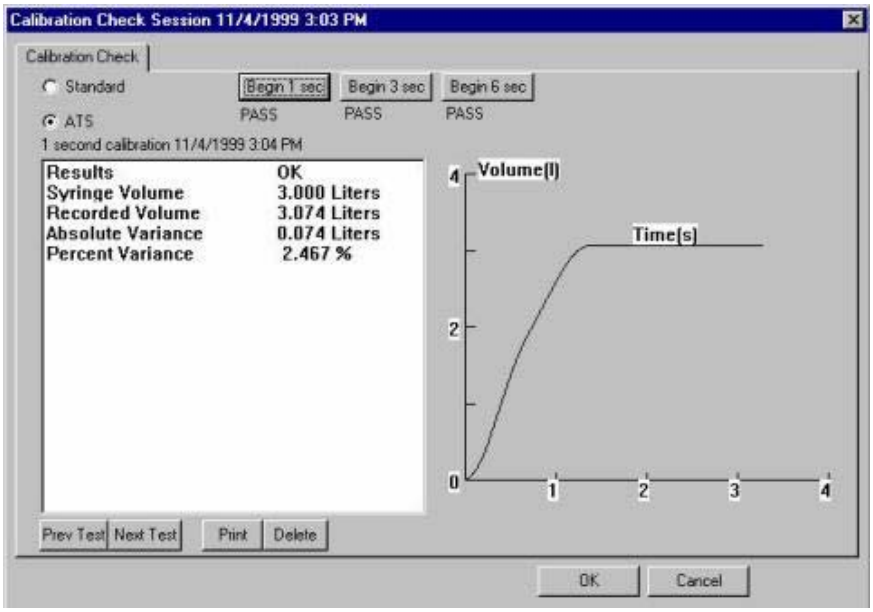
CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Upon return to the database screen the Main Office Medic database will have automatically been refreshed and the new data will be displayed. If the Remote database was displayed during synchronization you will have to manually refresh this database in order to view the most recent data. Select **File|Refresh Patient Tree** or press **F5** to refresh the Remote database.

Select **Tools |Spirometry|Perform Calibration Check** to open the **Calibration Check** window of the Office Medic software. The MedDorna Wireless PRN Spirometer device can have its calibration checked.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Choosing this option for calibration saves the data to the Calibration Data section of the patient directory. See the **MedDorna Wireless PRN Spirometer Calibration** section for specific information about the calibration testing and the calibration feature.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Help

Selecting the Help option opens a pull down menu with four choices.

Contents - This option opens this on-line help guide with the Contents tab selected as the default. This allows you to view the table of contents and select your choice of chapters to view. Index - This option opens this on-line help guide with the Index tab selected as the default. This allows for the topics to be looked up by index entries.

About QRS - Provides information on how to contact QRS by phone, fax and on-line.

About Office Medic - This option displays the version of the Office Medic software.

MedDorna Wireless PRN Spirometer Cautions & Warnings

WARNING:

- Use only MedDorna mouthpieces. These are manufactured to meet the calibration requirements for the MedDorna Wireless PRN Spirometer. Use of other manufacturer's mouthpieces may cause improper Spirometer performance.

CAUTION:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- The MedDorna Wireless PRN Spirometer and the Office Medic/Pocket Medic software are intended for use by a physician or by laboratory personnel under a physician's supervision. It is the physician's responsibility to assure that testing is properly administered, the test data properly evaluated and the patient referred for appropriate treatment. The spirometry test interpretations are intended for the physician's use only. All spirometry numerical and graphical data should be evaluated with respect to the patient's clinical and historical picture.
- Mouthpieces are single patient use only and MUST be replaced for each patient.
- Mouthpieces should not be used on a patient with an injured mouth.
- The opening at the end of the mouthpiece must not be obstructed. Make sure the patient does not obstruct it with his/her fingers. This will result in erroneously high volume and flow results.
- It is the physician's responsibility to properly train individuals using this product in a non-health care setting. In addition the physician must make patients aware of the risks involved with spirometry testing and inform them of the safety measures to implement to minimize those risks.
- FVC and MVV testing can cause fatigue and may be dangerous for some patients. Some patients may be at risk for vertigo, arrhythmia or syncope.
- To reduce the risk of cross contamination the patient should open, handle and dispose of his/her own mouthpiece.
- Caution should be exercised for patients with a history of COPD when doing spirometry.

INDICATIONS FOR USE: Diagnostic Spirometry

- **Patient Population:** Male/Female, Pediatric to Adult
- **Device Functionality:** Diagnostic Spirometry.
- **Spirometric Parameters:** FVC, MVV, SVC, and FEF
- **Environment of Use:** Hospital, Clinical and Home Use

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MedDorna Wireless PRN Spirometer Introduction

Spirometry

Spirometry is a primary pulmonary function test (PFT). This test measures the air flow-rate and volume obtained during a patient's maximum forced exhalation/inhalation effort. It is the most commonly ordered PFT procedure and is practical to perform in any health care setting.

Spirometry is important because it can:

- Identify the presence of lung disease.
- Help the physician assess the severity of a patient's lung disease.
- Identify pulmonary disease symptoms and the degree of disability.
- Assist in the management of patients with lung disease.
- Provide early detection of pulmonary disease.
- Assist in convincing patients to quit smoking.
- Help the physician assess the effects of therapy or medications.

Spirometry can help to identify diseases at very early stages. Without spirometry the patient must usually develop physical symptoms before a pulmonary disease is recognized. By then considerable damage may have occurred.

Getting Started MedDorna Wireless PRN Spirometer

Installation:

The MedDorna Wireless PRN Spirometer device does not have any controls and is operated by the software. Its current status is indicated by two LED on top of the device as follows:

Red LED	Blue LED	Device Status
OFF	OFF	No battery or battery is fully discharged
ON	ANY	Low battery
OFF	Single blink every 10 sec	Standby mode
OFF	Dual blink every 3 sec	Device in use by the software

Make sure your device is in standby mode.

Connect Mouthpiece

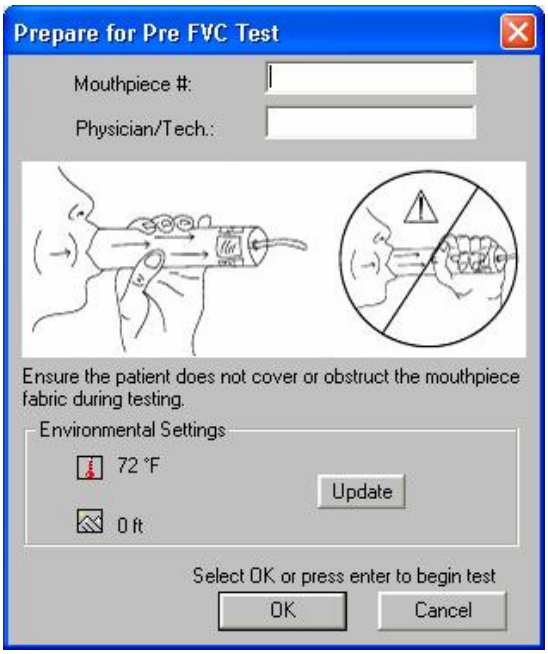
Connect the pressure tube to the luer fitting on the MedDorna Wireless PRN Spirometer device. The pressure tube is what 'transmits' the pressure produced by the mouthpiece to the MedDorna Wireless PRN Spirometer device. Make sure the pressure tube is not kinked or restricted in any way.
Connect the other end of the pressure tube to the disposable mouthpiece. Make sure that the connection is secure.

Performing a Spirometry Test

Once the patient's demographic data is entered or if the patient already exists, select his/her name from the patient tree. Left select **Test|Spirometry** or the icon.

The **Spirometry Test Session** screen will appear. Select one of the highlighted buttons to conduct a Pre-test maneuver. The Post-test options are grayed out until a Pre-test maneuver is performed.

Entering Mouthpiece Number



Each mouthpiece is individually calibrated. Enter the number on the mouthpiece label following the # sign.

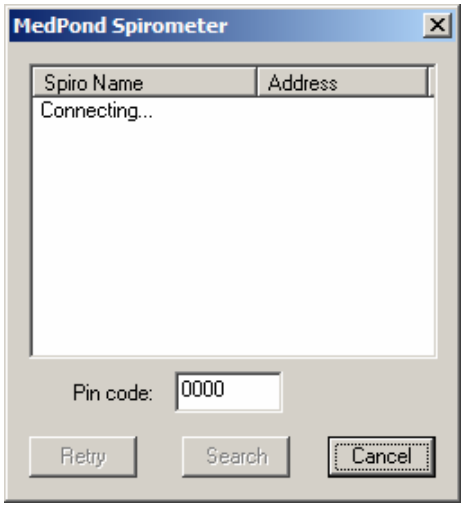
⚠ Mouthpieces are for single patient use.

Performing the Maneuver

After the mouthpiece number and the room temperature range is entered (technician name if desired) select **OK** when ready to test.

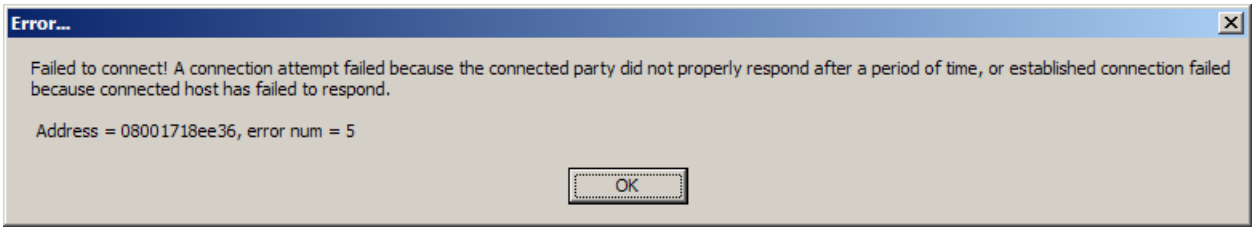
The software attempts to find the spirometer device and connect to it. During this process the following dialog box is displayed:

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

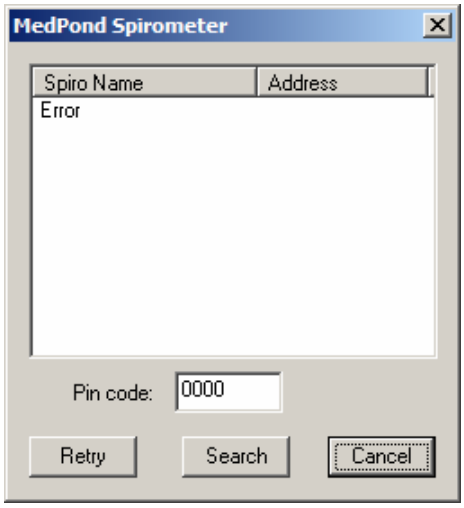


You can click **Cancel** button to terminate the process of device connection and return to previous mode.

If device is successfully found and connected, the software proceeds to testing. If device is not connected, the following message box is displayed:



Click **OK** button, then the following dialog box is displayed:

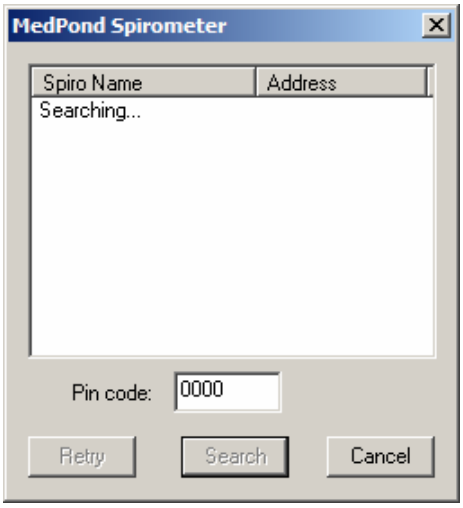


CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

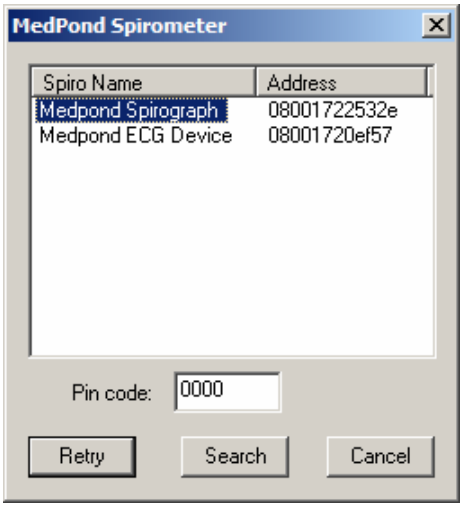
Click **Cancel** button to return to previous mode.

Click **Retry** button to try to connect to the device again.

Click **Search** button to search for any Bluetooth devices around. During the search process the following dialog box is displayed:



Once search is finished the following dialog box is displayed:



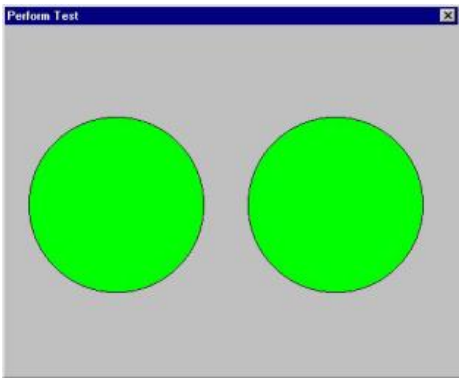
Select spirometer device from the list that has the Bluetooth address matching one on the device label, then enter PIN code and click **Connect** button to complete device connection.

Click **Cancel** to terminate device connection process and return to previous mode.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Two circles will appear flashing red and yellow alternately. The MedDorna Wireless PRN Spirometer is assuring the pressure measured at the mouthpiece is the same as that in the room. Make sure the mouthpiece is not moving or the patient is not breathing into the mouthpiece while the circles are flashing.

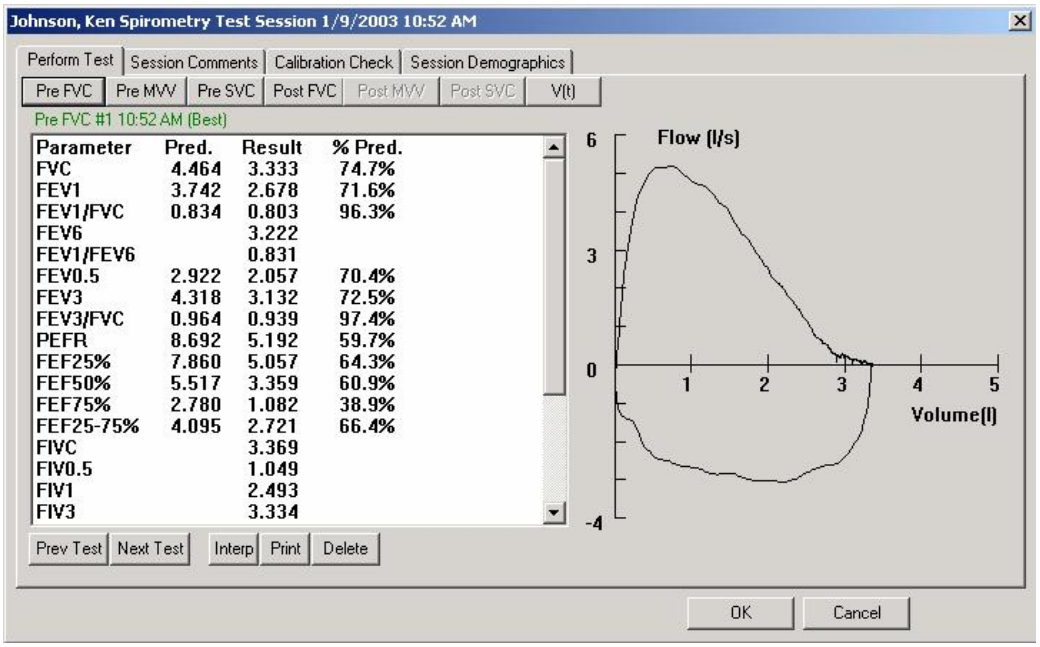
When both circles become green and an audible tone is heard, have the patient begin the maneuver.



Upon completion of the maneuver, the software will ask whether the maneuver was acceptable.

Select **YES** and the results will be displayed.

Select **NO** and you will be returned to the **Spirometry Test Session** screen where the maneuver can be repeated.



CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

To perform another test select one of the test buttons. The mouthpiece number, the technician name and the room temperature settings will default to that of the last maneuver.

Select the **Session Comments** tab to enter any comments relevant to the session. They will print on the report. You may add comments at any time.

When the session is complete, select **OK**, the session will be saved and you will be returned to the patient database screen.

Have the patient discard his/her own mouthpiece after the session is complete.

Menu Buttons on the Test Results Window

The **Prev Test** and **Next Test** buttons allow you to scroll through the tests completed in a single session. These tests appear in the order in which they were completed.

To view interpretations select the **Interp** button on the **Spirometry Test Session** screen after a test has been conducted. Check for age and height limits in the **Predictor Equations** section, no interpretation can be given if the patient falls out of the range of predicted equations.

Source used for Interpretations:

- Office Spirometry: A Practical Guide to the Selection and Use of Spirometers by Paul L..Enright, M.D. Robert E. Hyatt M.D. 1987

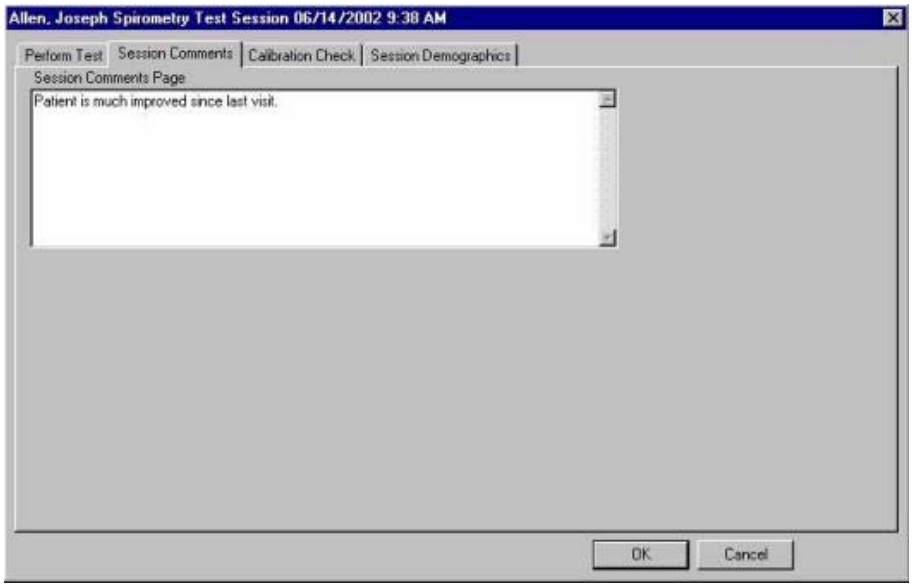
Print allows you to print the individual test you are currently viewing.

Delete allows you to delete the test you are currently viewing.

Tabs

Session Comments - Selecting this tab allows you to enter comments regarding the spirometry test session. These comments can be saved and reviewed at a later date.

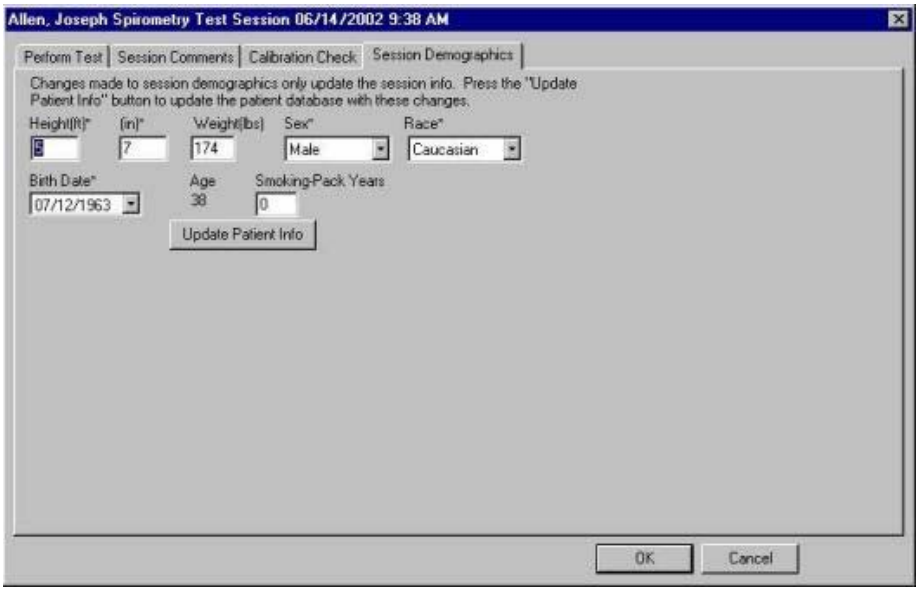
CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Calibration Check - to do a calibration check.

Session Demographics - Select this tab to update patient information from within the test window. Enter the changes and select the U**pdate Patient Info** button to save the changes to the database, this will affect current and future tests only. Previous test sessions must be individually updated.

To have the changes reflected on the current session only, enter the changes and select the **Perform Test** tab to begin testing. The saved session and reports will reflect the demographic changes.

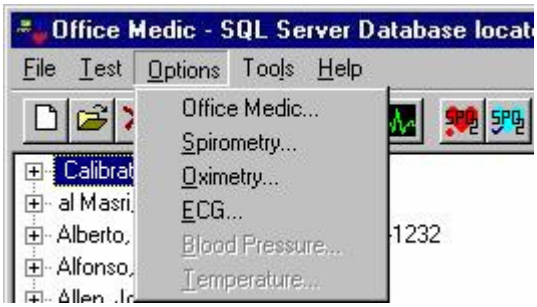


CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

For information on performing specific spirometry maneuvers or to check the calibration of your MedDorna Wireless PRN Spirometer device select one of the buttons below.

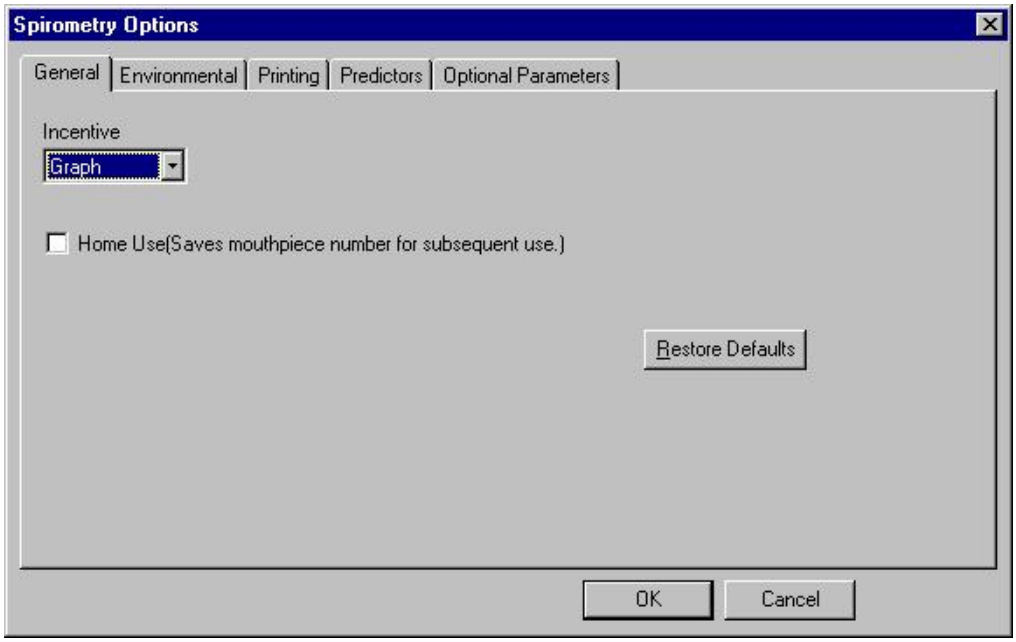
MedDorna Wireless PRN Spirometer Options

Select **Options|Spirometry** from the main menu to view the spirometry options.



The window that opens will feature the spirometry options which can be accessed by selecting one of the five tabs at the top of the window.

Select the **General** tab and you can change or activate the following options.

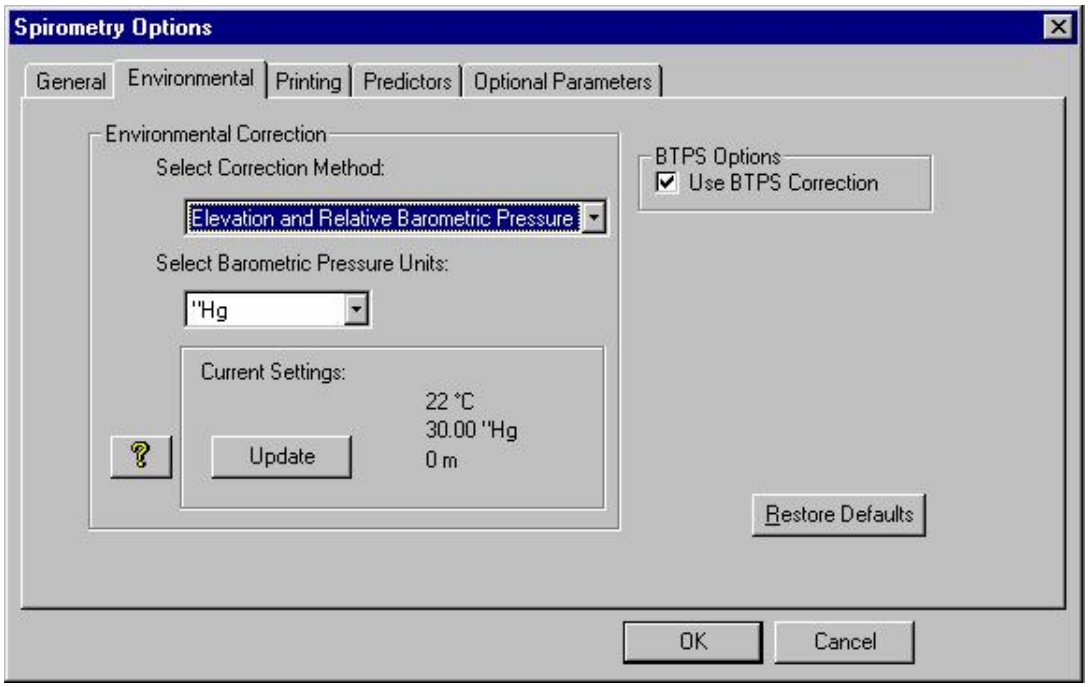


CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Incentives - Using the drop down menu you can change the adult incentive (graph) to one of five pediatric incentives that include a balloon, a ball, a bear, a clown or a pumpkin.

Home Use - Checking this option simplifies mouthpiece number entry for patients testing at home by auto entering the previous day's mouthpiece calibration number.

The **Environmental** tab from the **Spirometry Options** window allows the user to adjust their software based on environmental conditions that may affect test results such as temperature, elevation and barometric pressure.



The pull down menu under **Select Correction Method** allows you to set:

- **Elevation:** Elevation is your altitude above sea level. This is expressed in meters or feet. Use this option if you do not have a barometer.

- **Elevation with Relative Barometric Pressure**: In addition to entering the elevation this option allows you to input the relative barometric pressure. The relative barometric pressure is the measured air pressure in your area and varies from day to day. An on site barometer is one way to determine the barometric pressure. Relative barometric pressure is expressed in inches of Mercury (**"Hg**), millimeters of Mercury (**mmHg**) or millibars hPa (**mb**).

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

The first two options are available for normal office spirometry. Pulmonary laboratories typically utilize the last option.

- **Absolute Barometric Pressure**: Absolute barometric pressure is the true barometric pressure observed at a specific elevation and not corrected for altitude above mean sea level. The measurement of absolute barometric pressure is a site-specific reading usually obtained with precise instrumentation. Absolute barometric pressure is expressed in inches of Mercury (**"Hg**), millimeters of Mercury (**mmHg**) or millibars hPa (**mb**).

Select Barometric Pressure Units - This pull down menu allows you to select the units of barometric pressure in either inches of Mercury (**"Hg**), millimeters of Mercury (**mmHg**) or millibars hPa (**mb**).

Current Settings - Select the **Update** button to enter current data with regard to temperature, barometric pressure and elevation.

- Selecting the will bring you to this Help information.

Other options within the **Environmental** tab include:

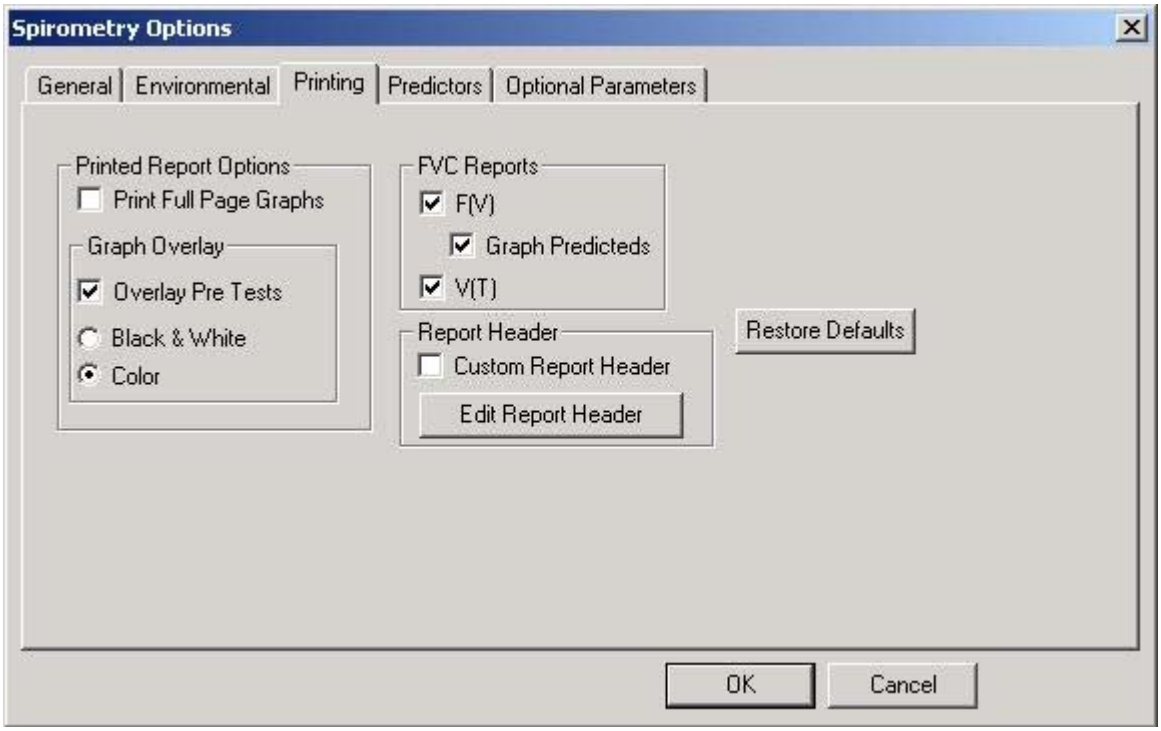
BTPS - The Use BTPS Correction check box should be checked whenever patient testing is performed. When BTPS is selected under the **BTPS Options**, the selected **Room Temperature** will be displayed and can be adjusted by selecting the **Update** button. All values can be entered by selecting the **Update** button and entering current readings. This brings you to the **Current Settings** screen allowing you to adjust the current environmental settings.

Restore Defaults - The **Restore Defaults** button returns the settings to their original factory condition.

Environmental Correction - During testing the mouthpiece dialog box displays an overview of the current environmental settings. The measurement units selected with the **Units** option from the **Options/General** menu (i.e. **English** vs. **Metric**) are reflected in the display. To change the settings select the **Update** button in the dialog box, you are taken to the **Change Settings** window where you can adjust the settings. When performing a calibration test, the mouthpiece dialog box will display the selected environmental settings. Selecting the **Update** button allows for changes in the selected settings. BTPS is automatically turned off for the calibration test and Room Temperature cannot be adjusted.

Select the **Printing** tab and you can change or activate the following options:

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Print Full Page Graphs - Checking this option will put full page graphs into your printed report, usually on the second and third page. Half graphs will still appear at the bottom of the first page.

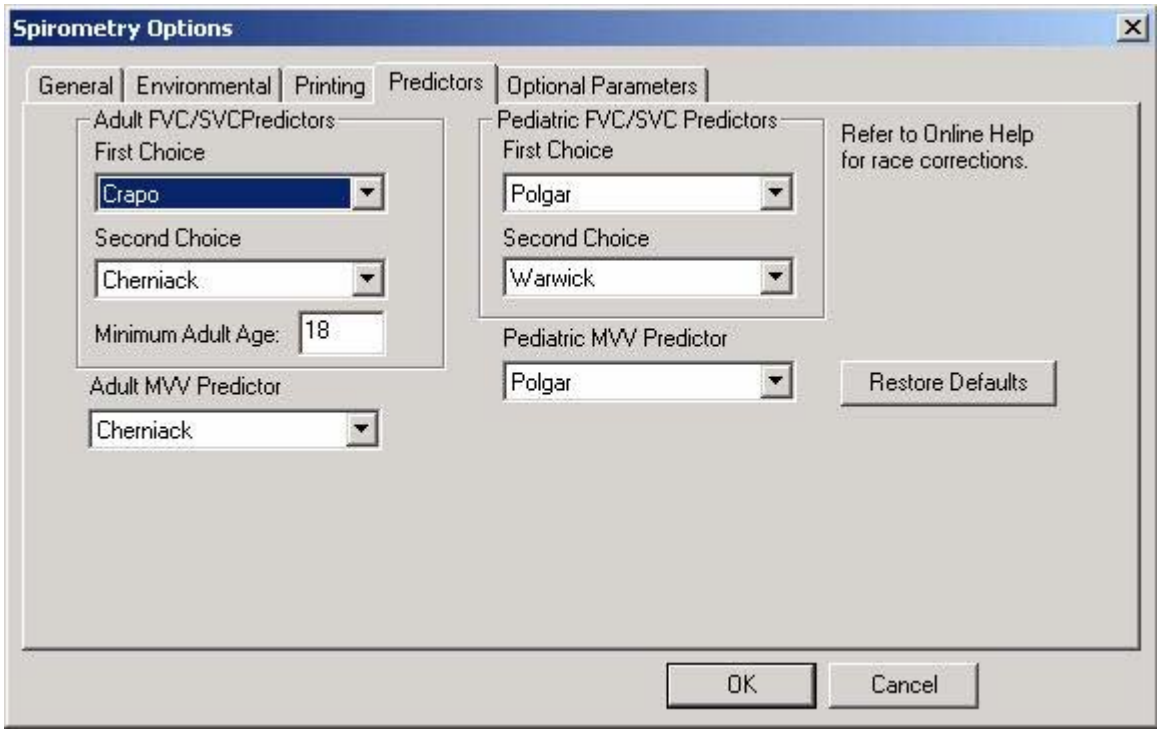
Overlay Pre Tests - Checking this option overlays the graphs of the three best Pre tests on your printed report. If using this option and printing to a color printer the graphs will be overlaid in three different colors. If Post testing is performed in the same session then the best Pre and Post test graphs are overlayed.

Custom Report Header - Select **Edit Report Header** to add a unique heading to your spirometry report. Up to four lines can be added. Check the **Custom Report Header** box to have the header printed on each report.

FVC Reports - Check the box next to the type of graphs you want printed in your reports **F(V)**, **V(T)** and **Predicteds**. You can only graph **Predicteds** if the **F(V)** box is checked. No graphs will be printed if **F(V)** and **V(T)** are unchecked and no **Predicteds** will be graphed if only the **V(T)** option is checked.

Select the **Predictors** tab and you can change or activate the following options.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



Select the predictors to be used in each category (the default predictors are shown above). A first choice and second choice are allowed for adult and pediatric patients. This is useful when a patient falls out of the age or height range of the first choice predictor. The software will use the second choice predictor in this instance. Please note that if the patient falls out of the age or height range of both predictors, no predicted data will be shown. See the **Predictor Equations** section for predictor equations parameters.

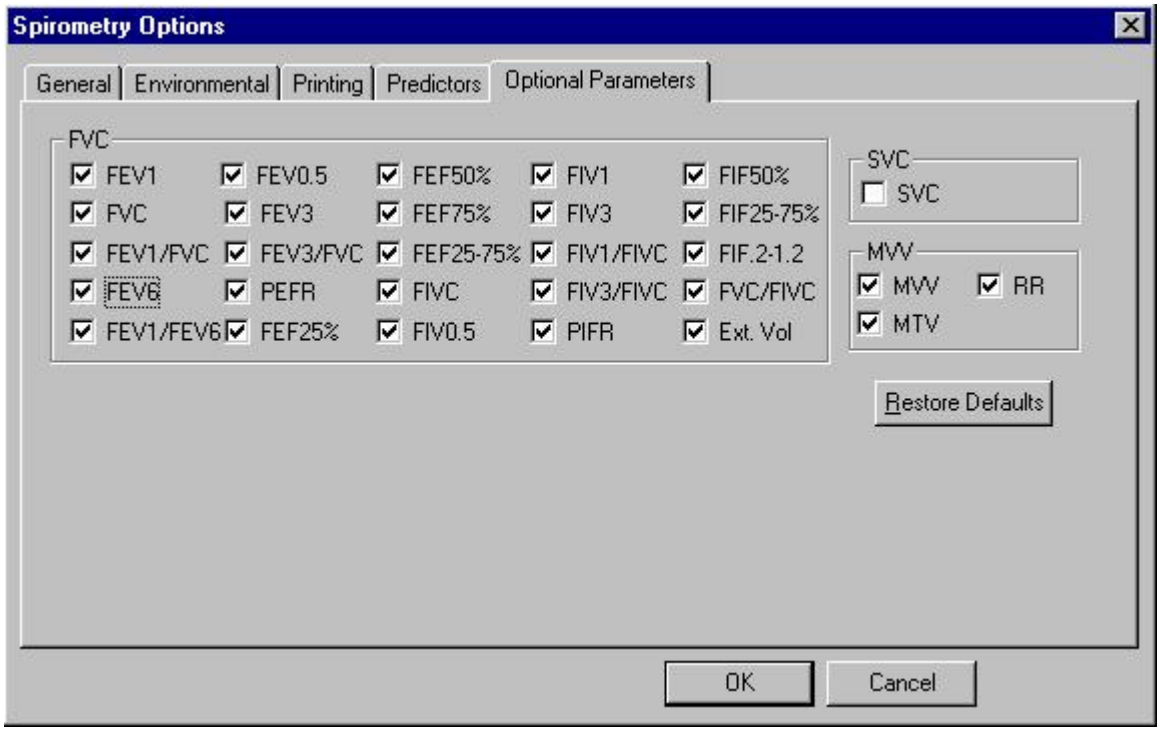
Within the **Adult FVC Predictors** menu you have the option of setting a **Minimum Adult Age**. The default is 18 years old. The **Minimum Adult Age** affects the predicted equations and should only be changed on a physician's order.

Adult and pediatric predictors are also available for MVV.

Race Correction Factors for Predicted Values -- See **Predictor Equations**.

Select the **Optional Parameters** tab to set the following options.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.



There are 25 different optional parameters that you can select to appear in your spirometry report for an FVC maneuver. Two different options appear for an MVV.

All five option tabs have a **Restore Default** button. Selecting this option will restore the choices to their original factory settings for the active tab only.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

FVC

Forced Vital Capacity ⚠ (FVC)

The Forced Vital Capacity (FVC) test measures the volume and the airflow a patient can exhale after filling his or her lungs with the maximum amount of air. By comparing the test results with those of a matched healthy population, the degree of obstruction or restriction present can be evaluated.

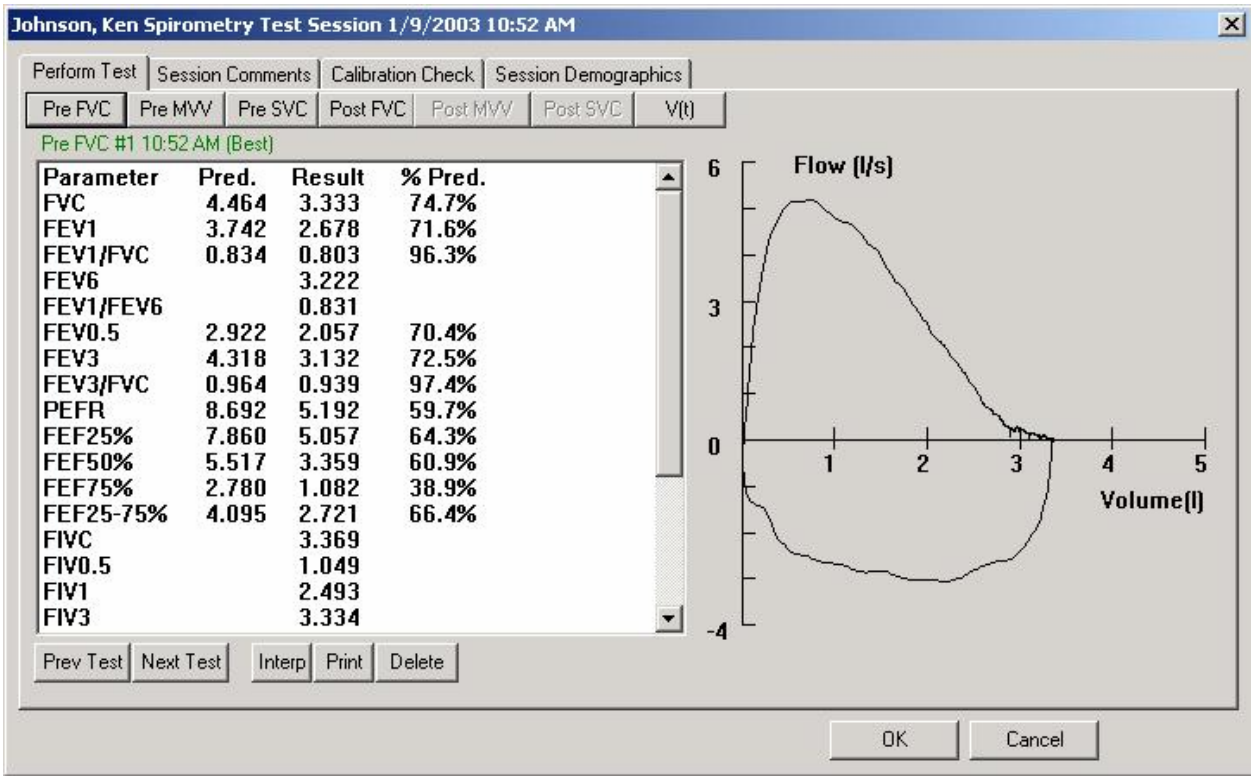
In order to obtain diagnostically reliable results certain testing guidelines should be followed.

Patient preparation for the test:

- Loosen tight clothing (ties, belts, bras).
- Remove patient's dentures.
- Explain the procedure thoroughly to the patient including demonstrating it yourself with your own mouthpiece.
- Make sure the patient has a ⚠ tight seal with his/her lips around the disposable mouthpiece. The patient should not bite the tube or use pursed lips against it.
- Place a disposable nose clip securely on the patient's nose or instruct the patient not to exhale through the nose.

Proper Procedure:

- Before beginning the test the patient should take several slow, deep inhalations/exhalations to feel comfortable.
- Have the patient keep the mouthpiece away from his/her mouth.
- The patient should sit or stand in an upright position during the test. Should you have the patient stand place a chair behind him/her for use should he/she become dizzy.
- Verbally instruct the patient to take the largest possible inhalation, insert the mouthpiece into his/her mouth and, exhale forcefully and completely. Important! Ensure that the patient does not cover or obstruct the fabric at the end of the mouthpiece with his/her hand.
- If a Flow/Volume Loop is desired, verbally instruct the patient to inhale back completely following expiration.
- Enter the mouthpiece number and select OK. When both lights become green and an audible tone is heard the patient can begin testing.
- Make sure that the patient's mouth is tightly closed around the mouthpiece.
- The patient should be instructed to exhale (blow out) as hard and as fast as possible.
- Encourage the patient to keep exhaling as long as possible. It is helpful to coach the patient with verbal commands and physical gestures. A proper expiration should last at least six seconds.
- Have the patient remove the mouthpiece and breathe normally until they have recovered.
- If you accept the test your test result screen should look similar to the illustration below.



Unacceptable tests:

- Insufficient initial inhalation (lungs not completely filled before the test).
- Slow or hesitant start of expiration.
- Leakage around the mouthpiece or nose clip.
- Mouthpiece obstruction by teeth, tongues, or lips.
- Coughing during the test.
- Large variation of FVC or FEV1 between tests.
- Other problems as indicated by test evaluation messages displayed by the software.
- Mouthpiece was obstructed during test. Should this occur the reported volume will be unusually high. The Office Medic software will warn you when the volume is 7.0 liters or greater. Ensure that the patient is not covering the fabric on the mouthpiece and then retest.

Tidal Breathing:

The MedDorna Wireless PRN Spirometer is able to measure FVC test results with a tidal start. This will enable the patient to breathe normally prior to performing the FVC test.

- Once the spirometer unit zeros (the software will display a "**Perform Test**" message), instruct the patient to insert the mouthpiece into his/her mouth and breath normally.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

- When the patient is ready he/she should take a deep breath and exhale forcefully and completely, and (if a Flow/Volume Loop is desired) inhale back completely.
- The Best FVC test results are calculated using the largest Flow/Volume loop. The FVC test results are calculated using the maneuver that was comprised of the highest sum of FVC and FEV1 from the same test.

Click here for information about reproducibility in the FVC results windows.

Reproducibility:

The user will be informed if the patient has met the ATS reproducibility criteria if:

1. Three maneuvers have been accepted and
2. The two highest FVC values from any of the maneuvers are within 200 ml and
3. The two highest FEV1 values from any of the maneuvers are within 200 ml.

You will receive another ATS warning if you perform more than 8 maneuvers on a patient.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MVV

Maximum Voluntary Ventilation ⚠ (MVV)

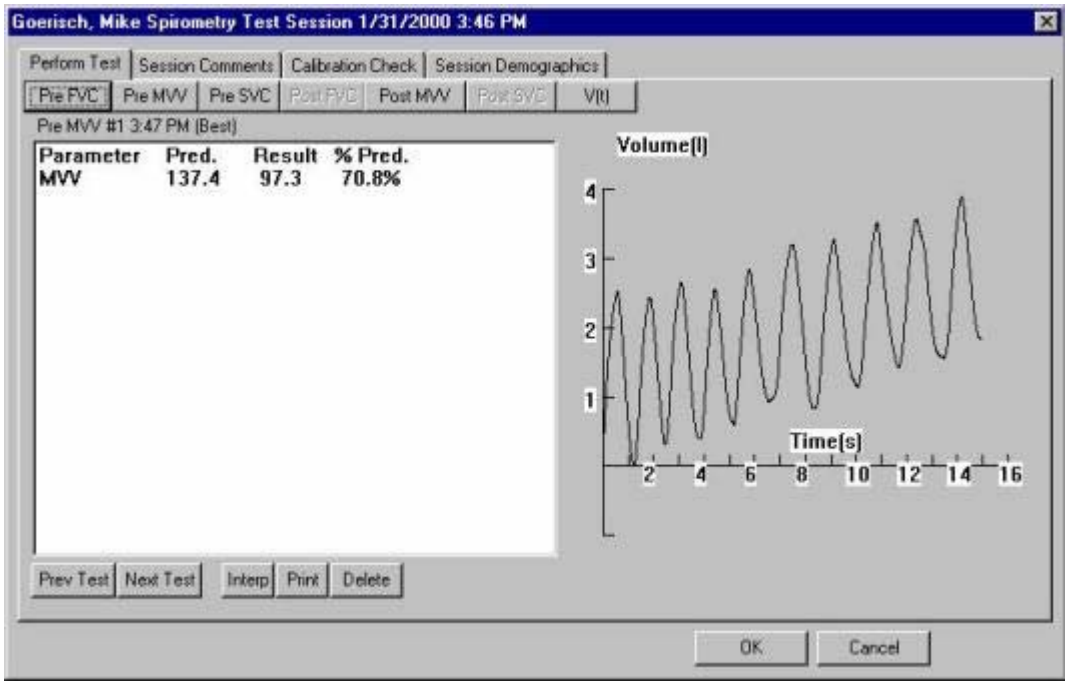
The Maximum Voluntary Ventilation (MVV) test determines the maximum volume of air a patient can exhale over a 12 to 15 second period. During the test the patient repeatedly exhales and inhales as rapidly and forcefully as possible. The test is often difficult to perform for many patients.

The MVV test can be used in:

- Evaluation of disability due to lung disease.
- Testing for environmentally induced lung disease.
- Pneumoconiosis (black lung disease) testing.

Proper procedure:

- Before beginning the test the patient should take several slow, deep inhalations/exhalations to feel comfortable.
- Place a disposable nose clip securely on the patient's nose or instruct the patient not to exhale through the nose.
- The patient should sit or stand in an upright position during the test. Should you have the patient stand place a chair behind him/her for use should he/she become dizzy.
- Have the patient keep the mouthpiece away from his/her mouth and start the test.
- Instruct the patient to breathe as deeply and rapidly as possible for 12 to 15 seconds. Watch to make sure that the mouth is tightly closed around the mouthpiece. **Important! Ensure that the patient does not cover or obstruct the fabric at the end of the mouthpiece with his/her hand.**
- Encourage the patient to keep-up maximum effort. It is helpful to coach the patient with verbal commands and physical gestures.
- At the end of the test the patient should remove the mouthpiece and breathe normally until he or she has recovered.
- If you accept the test your test result screen should look similar to the illustration below.



Unacceptable tests:

- Leakage around the mouthpiece or nose clip.
- Mouthpiece obstructions by teeth, tongue, or lips.
- Poor patient effort.
- Coughing during the test.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

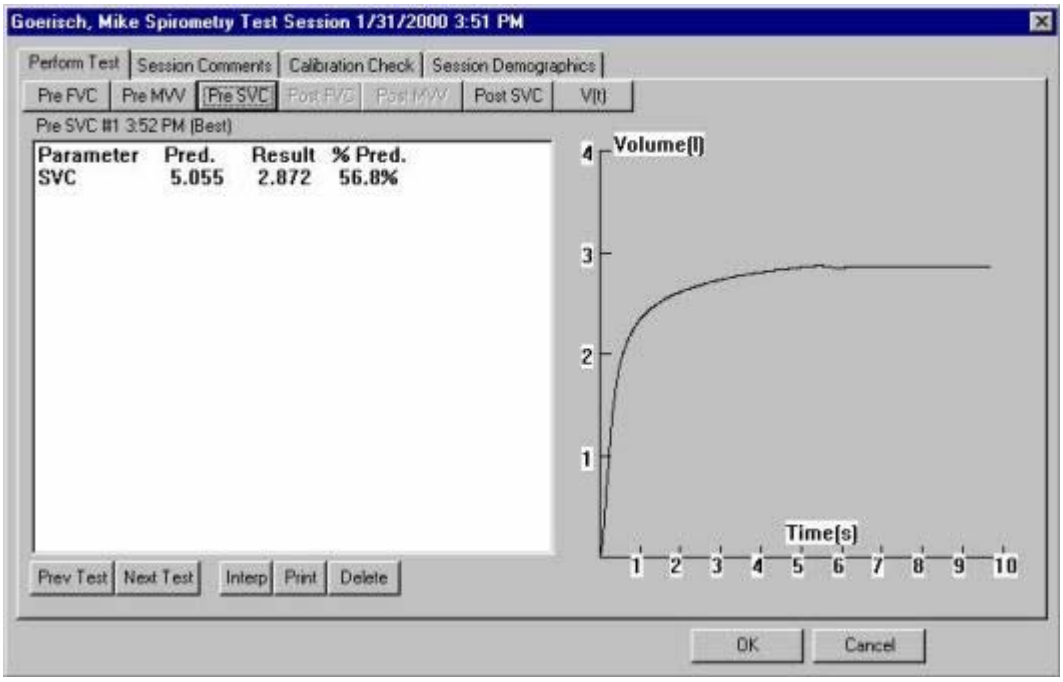
SVC

Slow Vital Capacity (SVC)

The Slow Vital Capacity (SVC) test determines the volume that a patient can slowly exhale after filling his/her lungs with the maximum amount of air.

Proper procedure:

- Before beginning the test the patient should take several slow, deep inhalations/exhalations to feel comfortable.
- Have the patient keep the mouthpiece away from his/her mouth and start the test.
- Place a disposable nose clip securely on the patient's nose or instruct the patient not to exhale through the nose.
- The patient should sit or stand in an upright position during the test. Should you have the patient stand place a chair behind him/her for use should he/she become dizzy.
- Instruct the patient to take the largest possible inhalation, insert the mouthpiece into his/her mouth, and exhale slowly and completely. Make sure that the patient's mouth is tightly closed around the mouthpiece. **Important! Ensure that the patient does not cover or obstruct the fabric at the end of the mouthpiece with his/her hand.**
- Encourage the patient to keep exhaling as long as possible. It is helpful to coach the patient with verbal commands and physical gestures. Have the patient remove the mouthpiece and breathe normally until they have recovered.
- If you accept the test your test result screen should look similar to the illustration below.



Unacceptable tests:

- Insufficient initial inhalation (lungs not completely filled before the test).
- Leakage around the mouthpiece or nose clip.
- Mouthpiece obstructions by teeth, tongue, or lips.
- Coughing during the test.

Tidal Breathing:

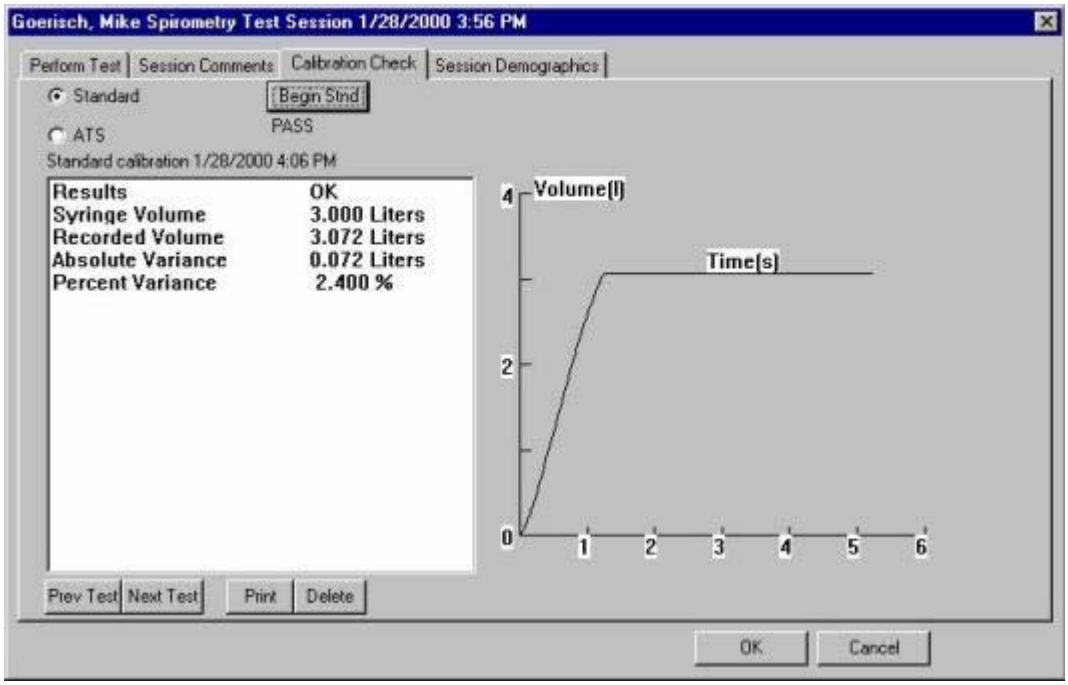
The MedDorna Wireless PRN Spirometer is able to measure SVC test results with a tidal start. This will enable the patient to breathe normally prior to performing the SVC test. Once the spirometer unit zeros (the software will display a "**Perform Test**" message), instruct the patient to insert the mouthpiece into his/her mouth and breath normally. When the patient is ready he/she should take a deep breath and exhale slowly and completely. The SVC test results are calculated from the largest difference between maximum inhalation and maximum exhalation.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MedDorna Wireless PRN Spirometer Calibration

Calibration Check

The calibration function can be accessed through the **Spirometry Test Session** window by selecting the **Calibration Check** tab. This window is identical to the calibration window that can be accessed from the main menu (see **Tools**). The MedDorna Wireless PRN Spirometer can have its calibration checked.



The calibration check is set up for testing by two different methods:

- **Standard** - A single maneuver test
- **ATS** - Designed for testing at three different flow rates to meet the ATS guidelines for calibration.

The calibration check is for verification only. There are no user calibration settings. If the MedDorna Wireless PRN Spirometer is found to be out of calibration try again with a different mouthpiece. If the problem persists, see Service.

Calibration volume for ATS calibration is set to a 3-liter syringe by default and cannot be changed.

To check calibration:

- Select **Calibration Check** from the test session window.
- Connect a syringe to the mouthpiece (recommended, 3 liter syringe).
- Select **Begin Stnd** to begin a standard calibration check. Enter in the mouthpiece number and the syringe volume (range 1 to 10 liters) and select **OK**.
- For an ATS calibration check select **ATS**, select the flow rate and enter the mouthpiece number in the mouthpiece number window (syringe volume is locked at 3-liters for ATS calibration).
- When the MedDorna Wireless PRN Spirometer finishes zeroing and the "**Perform Test**" message appears, push the syringe in (exhale) fully. If it is a Standard calibration maneuver, the flow rate should attempt to mimic an exhalation. If it is an ATS calibration, you must try to match the flow curve on the display to accurately meet the flow requirements of the test. **The MedDorna Wireless PRN Spirometer does not require a calibration check in order to operate!**
- The calibration report will indicate whether you passed or failed. In addition, Syringe Volume, Recorded Volume, Absolute Variance (the difference from the Syringe Volume and the Recorded Volume), and the Percent Variance (the percentage difference of the Recorded Volume to the Syringe Volume) will be displayed.
- If the calibration maneuver was acceptable, select **OK** to complete the calibration check and save the maneuver.
- To print a copy of the calibration report select **Print** at the bottom of the **Calibration Check** window.
- Choosing this option to check calibration saves the data within the patient's test session.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MedDorna Wireless PRN Spirometer Troubleshooting

Question: Do I need to replace the spirometer pressure tube after each patient?

A: No. There is a static pressure column created between the end of the mouthpiece and the pressure transducer inside the MedDorna Wireless PRN Spirometer. The patient's exhalation follows the path of least resistance, the vents on the side of the mouthpiece, thereby preventing moisture from entering the pressure tube.

To illustrate take a pressure tube that can be discarded. Attach the pressure tube to the mouthpiece and cover the opposite end of the pressure tube with your finger. Breathe through the mouthpiece. Notice the lack of moisture in the pressure tube behind the mouthpiece. Now remove your finger from the end of the pressure tube and repeat. Moisture will be present.

This demonstrates that if used properly the pressure tube will not become contaminated. If a patient covers the vents on the mouthpiece or uses the pressure tube when it is not properly connected to the spirometer, the pressure tube must be replaced.

Question: Why do I not get predicted values for spirometry with some patients?

A: Predicted values are most often a determined by a combination of the patient's age and height. If you patient falls outside of the parameters for the particular equations used for prediction, no predictors will be printed. Check the Predictor Equations section for the predicted equation sets and set your predictors accordingly.

Problem: “When I perform a test, the circles keep flashing”

When zeroing, the MedDorna Wireless PRN Spirometer looks for a constant pressure between the room and the mouthpiece. If one of the two pressures is varying, the MedDorna Wireless PRN Spirometer cannot complete the zeroing process. Situations that may cause these variations are:

- Mouthpiece is being moved during zeroing (causes pressure fluctuation)
- Pressure tube is occluded. A block in the tube will show a constant rising pressure
- Room air pressure is changing. The MedDorna Wireless PRN Spirometer will detect room pressure changes if the unit is sitting under a heating/air conditioner vent, a door opening or closing or a high traffic area.

Problem: "Test will not end after patient has completed maneuver"

A test will not end for the same reasons it will not zero (see above)
The MedDorna Wireless PRN Spirometer zeroed at a room pressure that changed during the maneuver and now cannot return to zero.

Problem: **"Test values are too high (intermittent)"**

End of the mouthpiece tube is being covered by the patient's hand causing higher back-pressure and false reading.

Problem: **"Test values are too high (consistently)"**

Pressure tube may be partially occluded. Replace the pressure tube.

Problem: **"Software indicates that no interpretations are available"**

Interpretations require predictor values to do calculations and give an interpretation. If the predictors are set to none for all choices or the patient's height or age falls outside of the predictor equation parameters no predictor values will be given and no interpretation will be available.

Problem: **"Cannot perform maneuvers"**

A Post-test was performed. No more Pre-tests can be performed after a Post-test is conducted.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MedDorna Wireless PRN Spirometer Specifications

Signal type	Air pressure
Number of data channels	2
Sensor type	Air pressure transducer
Sensor models	Channel 1 - CPCL10GFN 10 InH2O
	channel 2 - CPC01GFC 30 InH2O
Input connector type	Air pressure tubing outlet
Measured signal range	Channel 1 - ±6 InH2O
	Channel 2 - +28 InH2O
Frequency range	0 – 25 Hz
Common mode rejection	100 db
ADC resolution	16 bit
Sampling rate	100 Hz
Air flow rate measuring error	Not more than 3%
Battery level measurement	Yes
Interface	Bluetooth
Power supply	Accumulator 1.5 to 8 V
Power consumption	Not more than 0.15 W
Device dimensions	95 mm x 61.5 mm x 27.5 mm
Device weight	100 g
Program	Reporting software is stored on the computer
Environmental Conditions:	
Storage Conditions:	
Ambient Temperature	-15 to 50° C (5 to 122° F)
Relative Humidity	10 to 90% (non-condensing)
Atmospheric Pressure	700 to 1060 hPa
Operating Conditions:	
Ambient Temperature	15 to 40° C (59 to 104° F)
Relative Humidity	10 to 90% (non-condensing)
Atmospheric pressure	700 to 1060 hPa

Measurement Method:	
FLOW	Mouthpiece (US Patent #4,905,709)
VOLUME	flow integration
Range:	
FLOW	+/-14 liters/second
VOLUME	0-8 liters BTPS
Accuracy:	Complies with the American Thoracic Society (ATS) Standards for Spirometry, 1994 Update
FLOW	+/-5% of indication or +/- 200 ml/sec, whichever is greater for FEF 25-75. +/-10% of indication or +/- 400 ml/s whichever is greater for PEF.
VOLUME	+/-3% of indication or +/- 50 ml, whichever is greater for FVC and FEV1. +/-10% of indication or +/-15 L/min, whichever is greater for MVV.
Precision:	
FLOW	5% of indication or 200 ml/sec, whichever is greater for PEF and FEF 25-75
VOLUME	3% of indication or 50 ml, whichever is greater for FVC and FEV1
BTPS Conditions:	
VOLUME	+/- 4.5% of indication or +/- 200 ml, whichever is greater for FVC and FEV1
Calibration	ATS 3-speed or standard calibration check
Predicted Normals	Crapo, Cherniack, Morris, Knudson 1983, Polgar, HSU, Roberts, Warwick, ECCS, NHANES III, Zapletal
Tests Performed	FVC, Pre/Post Testing, Flow Volume Loop, MVV, SVC
Measuring Time	Up to 30 seconds
Printed Scale:	
Flow - Volume	(vertical) .5cm/1L/S, (horizontal) 1cm/1L
Volume - Time	(vertical) 1cm/1L, (horizontal) 1cm/second

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Resolution:	
Flow Rate	2 ml/sec
Volume	1 ml
Limits of Detection:	
Flow Rate	2 ml/sec
Volume	1 ml
Parameters measured	FVC, FEV6, FEV1/FEV6, FEV0.5, FEV1, FEV3, FEV1/FVC, FEV3/FVC, PEFR, FEF25%, FEF50%, FEF75%, FEF25-75%, FIVC, FIV0.5, FIV1, FIV3, FIV1/FIVC, FIV3/FIVC, PIFR, FIF50%, FIF 25-75%, FIF.2-1.2, FVC/FIVC, Extrapolated Volume (Ext. Vol.) MVV, RR, MTV, SVC

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MedDorna Wireless PRN Spirometer Export File Field Order

This is the export file field order for the spirometry data saved as a text file.

Database: Session.txt

Account
Last
First
SessionDate
Height
Weight
Units
Race
Birthdate
Age
Sex
SessionComments
FVCPredVal
FVCPred
FEV05PredVal
FEV05Pred
FEV1PredVal
FEV1Pred
FEV3PredVal
FEV3Pred
FEV1_FVCPredVal
FEV1_FVCPred
PEFPredVal
PEFPred
FEF25PredVal
FEF25Pred
FEF50PredVal
FEF50Pred
FEF75PredVal
FEF75Pred
FEF25_75PredVal
FEF25_75Pred
FIVCPredVal
FIVCPred
MVVPredVal
MVVPred

Database: SpTest.txt

Account
Last
First
SessionDate
TestType
TestSequenceNumber
TestDate
MouthpieceNumber
PhysicianName
FVC
FEV05
FEV1
FEV3
FEV1_FVC
FEV3_FVC
PEFR
FEF25
FEF50
FEF75
FEF25_75
FIVC
FIV05
FIV1
FIV3
FIV1_FIVC
FIV3_FIVC
PIFR
FIF50
FIF25_75
FIF2_1_2
FVC_FIVC
ExtVol
MVV
MTV
RR
SVC
BTPS
Degree

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Database: spGraph.txt

PatientInfo
Sessiondate
TestType
TestDate
NumberOfGraphPoints
Volume- Tab- Flow

Database: SpCalibr.txt

PatientInfo
SessionDate
CalibrationType
CalibrationDate
MouthpieceNumber
SyringeVolume
RecordedVolume

Database: SpCalGr.txt

PatientInfo
SessionDate
CalibrationType
CalibrationDate
NumberOfGraphPoints
Volume-tab-flow

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Predictor Equations

Race Correction: There is a 15% race correction for Asian and Black patients with the exception of NHANESIII, which utilizes the race corrections for Blacks (African-American) and Hispanics (Mexican American) as referenced in John L. Hankinson, John R. Odencrantz, and Kathleen B. Fedan. 1999. "Spirometric Reference Values from a Sample of the General U.S. Population". Am J Respir Crit Care Med Vol 159. pp 179-187.

MORRIS

MALE, 20-90 years, 58.0-80.0 in. (147.3-203.2 cm)

FVC (L) = 0.148 * H[in] - 0.025 * A[yrs] - 4.241
FEV1 (L) = 0.092 * H[in] - 0.032 * A[yrs] - 1.26
FEV1/FVC% (L/sec) = - 0.31180 * H[in] - 0.2422 * A + 107.12
FEF25-75% (L/sec) = 0.047 * H[in] - 0.045 * A[yrs] + 2.513
FEF0.2 -1.2 (L/sec) = 0.10900 * H[in] - 0.0470 * A + 2.01

FEMALE, 20-90 years, 56.0-72.0 in. (142.2-182.9 cm)

FVC = 0.115 * H[in] - 0.024 * A[yrs] - 2.852
FEV1 = 0.089 * H[in] - 0.025 * A[yrs] - 1.932
FEV1/FVC% (L/sec) = - 0.0679 * H[in] - 0.1815 * A + 88.7
FEF25-75 = 0.06 * H[in] - 0.03 * A[yrs] + 0.551
FEF0.2 -1.2 (L/sec) = 0.1450 * H[in] - 0.0360 * A + 2.532

CHERNIACK

MALE, 15-79 years, 35.0-85.0 in. (88.9-215.9 cm)

FVC (L) = 0.12102 * H[in] - 0.01357 * A[yrs] - 3.18373
FEV1 (L) = 0.09107 * H[in] - 0.0232 * A[yrs] - 1.50723
FEF25% (L/sec) = 0.0903 * H[in] - 0.01987 * A[yrs] + 2.72554
FEF50% (L/sec) = 0.06526 * H[in] - 0.03049 * A[yrs] + 2.40337
FEF75% (L/sec) = 0.03583 * H[in] - 0.04142 * A[yrs] + 1.98361
FEF25-75% (L/sec) = 0.05948 * H[in] - 0.037 * A[yrs] + 2.61187
PEFR = 0.14393 * H[in] - 0.02403 * A[yrs] + 0.22544
MVV = 3.02915 * H[in] - 0.81621 * A[yrs] - 37.94893

FEMALE, 15-79 years, 35.0-85.0 in. (88.9-215.9 cm)

FVC (L) = 0.07833 * H[in] - 0.01539 * A[yrs] - 1.04912
FEV1 (L) = 0.06029 * H[in] - 0.01936 * A[yrs] - 0.18693

FEF25% (L/sec) = 0.06876 * H[in] - 0.01926 * A[yrs] + 2.14653
FEF50% (L/sec) = 0.0622 * H[in] - 0.02344 * A[yrs] + 1.4264
FEF75% (L/sec) = 0.02334 * H[in] - 0.0345 * A[yrs] + 2.21596
FEF25-75% (L/sec) = 0.04931 * H[in] - 0.0312 * A[yrs] + 2.2561
PEFR = 0.0913 * H[in] - 0.01776 * A[yrs] + 1.1316
MVV = 2.13844 * H[in] - 0.68503 * A[yrs] - 4.86957

ROBERTS

MALE, 18-86 years, 63.4-77.2 in. (161.0-196.0 cm)

FVC (L) = 0.06628 * H[cm] - 0.028 * A[yrs] - 5.377
FEV1 (L) = 0.03961 * H[cm] - 0.033 * A[yrs] - 1.558
FEV1/FVC% = (-0.21476 * H[cm] - 0.242 * A[yrs] + 126.252)/100
PEFR = 0.05317 * H[cm] - 0.062 * A[yrs] + 3.884
FEF50% (L/sec) = -0.044 * A[yrs] + 6.456

FEMALE, 18-86 years, 57.5-69.7 in. (146.0 - 177.0 cm)

FVC (L) = 0.04321 * H[cm] - 0.023 * A[yrs] - 2.379
FEV1 (L) = 0.03321 * H[cm] - 0.025 * A[yrs] - 1.394
FEV1/FVC% =(-0.172 * A[yrs] + 88.134))/100
PEFR = 0.04087 * H[cm] - 0.05 * A[yrs] + 2.945
FEF50% (L/sec) = -0.038 * A[yrs] + 5.556

KNUDSON (1983)

MALE, 6-11 years, 44.0-61.0 in. (111.8-154.9 cm)

FVC (L) = 0.0409 * H[cm] - 3.3756
FEV1 (L) = 0.0348 * H[cm] - 2.8142
FEF50% (L/sec) = 0.0378 * H[cm] - 2.5454
FEF75% (L/sec) = 0.0171 * H[cm] - 1.0149
FEF25-75% (L/sec) = 0.0338 * H[cm] - 2.3197

MALE, 12-24 years, 55.0-76.0 in. (139.7-193.0 cm)

FVC (L) = 0.059 * H[cm] + 0.0739 * A[yrs] - 6.8865
FEV1 (L) = 0.0519 * H[cm] + 0.0636 * A[yrs] - 6.1181
FEF50% (L/sec) = 0.0543 * H[cm] + 0.115 * A[yrs]-6.3851
FEF75% (L/sec) = 0.0397 * H[cm] - 0.0057 * A[yrs] - 4.2421
FEF25-75% L/sec) = 0.0539 * H[cm] + 0.0749 * A[yrs] - 6.199

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MALE, 25-90 years, 62.0-77.0 in. (157.5-195.6 cm)

FVC (L) = 0.0844 * H[cm] - 0.0298 * A[yrs] - 8.7818
FEV1 (L) = 0.0665 * H[cm] - 0.0292 * A[yrs] - 6.5147
FEF50% (L/sec) = 0.0684 * H[cm] - 0.0366 * A[yrs] - 5.5409
FEF75% (L/sec) = 0.031 * H[cm] - 0.023 * A[yrs] - 2.4827
FEF25-75% (L/sec) = 0.0579 * H[cm] - 0.0363 * A[yrs] - 4.5175

FEMALE, 6-10 years, 42.0-58.0 in. (106.7-147.3 cm)

FVC (L) = 0.043 * H[cm] - 3.7486
FEV1 (L) = 0.0336 * H[cm] - 2.7578
FEF50% (L/sec) = 0.1846 * A[yrs] + 0.7362
FEF75% (L/sec) = 0.0109 * H[cm] - 0.1657
FEF25-75% (L/sec) = 0.022 * H[cm] - 0.8119

FEMALE, 11-19 years, 52.0-72.0 in. (132.1-182.9 cm)

FVC (L) = 0.0416 * H[cm] + 0.0699 * A[yrs] - 4.447
FEV1 (L) = 0.0351 * H[cm] + 0.0694 * A[yrs] - 3.7622
FEF50% (L/sec) = 0.0288 * H[cm] + 0.1111 * A[yrs] - 2.304
FEF75% (L/sec) = 0.0243 * H[cm] + 0.2923 * A[yrs] - 4.4009 - 0.0075 * A[yrs]^2
FEF25-75% (L/sec) = 0.0279 * H[cm] + 0.1275 * A[yrs] - 2.8007

FEMALE, 20-69 years, 58.0-71.0 in. (147.3-180.3 cm)

FVC (L) = 0.0444 * H[cm] - 0.0169 * A[yrs] - 3.1947
FEV1 (L) = 0.0332 * H[cm] - 0.019 * A[yrs] - 1.821
FEF50% (L/sec) = 0.0321 * H[cm] - 0.024 * A[yrs] - 0.4371
FEF75% (L/sec) = 0.0174 * H[cm] - 0.0254 * A[yrs] - 0.1822
FEF25-75% (L/sec) = 0.03 * H[cm] - 0.0309 * A[yrs] - 0.4057
FEMALE, 70-90 years, 58.0-66.0 in. (147.3-167.6 cm)
FVC (L) = 0.0313 * H[cm] - 0.0296 * A[yrs] - 0.1889
FEV1 (L) = 0.0143 * H[cm] - 0.0397 * A[yrs] + 2.6539
FEF50% (L/sec) = 0.0118 * H[cm] - 0.0755 * A[yrs] + 6.2402
FEF75% (L/sec) = -0.0172 * A[yrs] + 1.8894
FEF25-75% (L/sec) = -0.0615 * A[yrs] + 6.3706

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

HSU

MALE, 7-18 years, 43.3-74.8 in. (111.0-190.0 cm)

FVC [ml] = 0.000358 * H[cm]^3.18
FEV1 [ml] = 0.000774 * H[cm]^3
FEV1/FVC = FEV1 pred/FVC pred
PEFR [L/sec] = 0.000005583*H[cm]^2.79
FEF25-75% [L/min] = 0.0000133 * H[cm]^2.46

FEMALE, 7-18 years, 43.3-74.8 in. (111.0-190.0 cm)

FVC [ml] = 0.00257 * H[cm]^2.78
FEV1 [ml] = 0.00379 * H[cm]^2.68
FEV1/FVC = FEV1 pred/FVC pred
PEFR [L/sec] = 0.000043*H[cm]^2.37
FEF25-75% [L/min] = 0.000063167 * H[cm]^2.16

CRAPO

MALE, 15-91 years, 61.8-76.4 in. (157.0-194.0 cm)

FVC (L) = 0.06 * H[cm] - 0.0214 * A[yrs] - 4.65
FEV05 (L) = 0.0327 * H[cm] - 0.0152 * A[yrs] - 1.914
FEV1 (L) = 0.0414 * H[cm] - 0.0244 * A[yrs] - 2.19
FEV3 (L) = 0.0535 * H[cm] - 0.0271 * A[yrs] - 3.512
FEF25-75% (L/sec) = 0.0204 * H[cm] - 0.038 * A[yrs] + 2.133
FEV1/FVC% = -0.13 * H[cm] - 0.152 * A[yrs] + 110.49
FEV3/FVC% = -0.0627 * H[cm] - 0.145 * A[yrs] + 112.09

FEMALE, 17-84 years, 57.5-70.1 in. (146.0-178.0 cm)

FVC (L) = 0.0491 * H[cm] - 0.0216 * A[yrs] - 3.59
FEV05 (L) = 0.0238 * H[cm] - 0.0185 * A[yrs] - 0.809
FEV1 (L) = 0.0342 * H[cm] - 0.0255 * A[yrs] - 1.578
FEV3 (L) = 0.0442 * H[cm] - 0.0257 * A[yrs] - 2.745
FEF25-75% = 0.0154 * H[cm] - 0.046 * A[yrs] + 2.683
FEV1/FVC% = -0.202 * H[cm] - 0.252 * A[yrs] + 126.58
FEV3/FVC% = -0.0937 * H[cm] - 0.163 * A[yrs] + 118.16

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

WARWICK

MALE, 6-18 YEARS, 35.4-74.0 in. (90.0-188.0 cm)

FVC (L) = exp(3.0131 * ln(H[cm]) - 14.0535)
FEV1 (L) = exp(2.7572 * ln(H[cm]) - 12.9007)
FEV1/FVC% = 100 * exp(-0.2679 * ln(H[cm]) + 1.2137)
FEF50% (L/sec) = exp(2.1326 * ln(H[cm]) - 9.3589)
FEF75% (L/sec) = exp(2.1534 * ln(H[cm]) - 10.2213)
PEFR (L/sec)= exp(2.4991 * ln(H[cm]) - 10.7785)

FEMALE, 6-18 YEARS, 35.4-70.1 in. (90.0-178.0 cm)

FVC (L) = exp(2.9446 * ln(H[cm]) - 13.8007)
FEV1 (L) = exp(2.7522 * ln(H[cm]) - 12.921)
FEV1/FVC% = 100 * exp(-0.2126 * ln(H[cm]) + 0.9719)
FEF50% (L/sec) = exp(2.1958 * ln(H[cm]) - 9.6458)
FEF75% (L/sec) = exp(2.2961 * ln(H[cm]) - 10.8666)
PEFR (L/sec) = exp(2.4369 * ln(H[cm]) - 10.535)

POLGAR

MALE, 4-17 years, 43.0-67.0 in. (109.2-170.2 cm)

FVC (L) = 0.0000044 * H[cm]^2.67
FEV1 (L) = 0.0000021 * H[cm]^2.8
FEV1/FVC[%] = 47.73 * H[cm] ^0.13
FEF25-75% (L/sec) = - 3.46167 + 0.0436833 * H[cm]
PEFR (L/sec)= -7.0928567 + 0.08738 * H[cm]
FEV3 = FVC pred * 0.98
MVV = 1.276 * H[cm] - 99.507

FEMALE, 4-17 years, 43.0-67.0 in. (109.2-170.2 cm)

FVC (L) = 0.0000033 * H[cm]^2.72
FEV1 (L) = 0.0000021 * H[cm]^2.8
FEV1/FVC[%] = 63.63 * H[cm] ^0.08
FEF25-75% (L/sec) = - 3.46167 + 0.0436833* H[cm]
PEFR (L/sec)= - 7.0928567 + 0.0873800 * H[cm]
FEV3 = FVC pred * 0.98
MVV = 1.276 * H[cm] - 99.507

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

ECCS

MALE, 25-70 years, (155-195 cm)

FVC (L) = 0.0576 * H[cm] – 0.026*A – 4.34
FEV1 (L) = 0.0430*H[cm] – 0.029*A – 2.49
FEV1/FVC% = (-0.180*A + 87.21)/100
FEF25% (L/sec) = 0.0546 * H[cm] – 0.029 * A – 0.47
FEF50% (L/sec) = 0.0379*H[cm] – 0.031 * A – 0.35
FEF75% (L/sec) = 0.0261 * H[cm] – 0.026 * A – 1.34
FEF25-75% (L/sec) = 0.0194 * H[cm] – 0.043 * A + 2.7
PEFR (L/sec) = .0614 * H[cm] – 0.043 * A + 0.15
FIVC = 0.0610 * H[cm] – 0.028 * A – 4.65

FEMALE, 25-70 years, (145-180 cm)

FVC (L) = 0.0443 * H[cm] – 0.026*A – 2.89
FEV1 (L) = 0.0395*H[cm] – 0.025*A – 2.6
FEV1/FVC% = (-0.190*A + 89.1)/100
FEF25% (L/sec) = 0.0322 * H[cm] – 0.025 * A + 1.6
FEF50% (L/sec) = 0.0245 * H[cm] – 0.025 * A +1.16
FEF75% (L/sec) = 0.0105 * H[cm] – 0.025 * A +1.11
FEF25-75% (L/sec) = 0.0125 * H[cm] – 0.034 * A + 2.92
PEFR (L/sec) = .0550 * H[cm] – 0.030 * A -1.11
FIVC = 0.0466 * H[cm] – 0.024 * A – 3.28

NHANES III (John L. Hankinson)

John L. Hankinson, John R. Odencrantz, and Kathleen B. Fedan. 1999. "Spirometric Reference Values from a Sample of the General U.S. Population". Am J Respir Crit Care Med Vol 159. pp 179-187.

MALE, Caucasian, 8-19 years, 48.0 - 75.6 in. (122 - 192 cm)

FVC (L) = - 0.2584 - 0.20415 * A[yrs] + 0.010133 * A[yrs]2 + 0.00018642 * H[cm]2
FEV1 (L) = - 0.7453 - 0.04106 * A[yrs] + 0.004477 * A[yrs]2 + 0.00014098 * H[cm]2
FEV1/FVC% = (88.066 - 0.2066 * A[yrs])/100
FEV6 (L) = - 0.3119 - 0.18612 * A[yrs] + 0.009717 * A[yrs]2 + 0.00018188 * H[cm]2
FEV1/FEV6% = (87.34 - 0.1382 * A[yrs])/100
FEF25-75% (L/Sec) = - 1.0863 + 0.13939 * A[yrs] + 0.00010345 * H[cm]2
PEF (L/Sec) = - 0.5962 - 0.12357 * A[yrs] + 0.013135 * A[yrs]2 + 0.00024962 * H[cm]2

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

MALE, Caucasian, 20-80 years, 62.2 - 76.4 in. (158 - 194 cm)

FVC (L) = - 0.1933 + 0.00064 * A[yrs] - 0.000269 * A[yrs]2 + 0.00018642 * H[cm]2
FEV1 (L) = 0.5536 - 0.01303 * A[yrs] - 0.000172 * A[yrs]2 + 0.00014098 * H[cm]2
FEV1/FVC% = (88.066 - 0.2066 * A[yrs])/100
FEV6 (L) = 0.1102 - 0.00842 * A[yrs] - 0.000223 * A[yrs]2 + 0.00018188 * H[cm]2
FEV1/FEV6% = (87.34 - 0.1382 * A[yrs])/100
FEF25-75% (L/Sec) = - 1.0863 + 0.13939 * A[yrs] + 0.00010345 * H[cm]2
PEF (L/Sec) = 1.0523 + 0.08272 * A[yrs] - 0.001301 * A[yrs]2 + 0.00024962 * H[cm]2

FEMALE, Caucasian, 8-19 years, 46.5 - 70.1 in. (118 - 178 cm)

FVC (L) = - 1.2082 + 0.05916 * A[yrs] + 0.00014815 * H[cm]2
FEV1 (L) = - 0.8710 + 0.06537 * A[yrs] + 0.00011496 * H[cm]2
FEV1/FVC% = (90.809 - 0.2125 * A[yrs])/100
FEV6 (L) = - 1.1925 + 0.06544 * A[yrs] + 0.00014395 * H[cm]2
FEV1/FEV6% = (90.107 - 0.1563 * A[yrs])/100
FEF25-75% (L/Sec) = - 2.5284 + 0.5249 * A[yrs] - 0.015309 * A[yrs]2 + 0.00006982 * H[cm]2
PEF (L/Sec) = - 3.6181 + 0.60644 * A[yrs] - 0.016846 * A[yrs]2 + 0.00018623 * H[cm]2

FEMALE, Caucasian, 20-80 years, 57.1 - 70.9 in. (145 - 180 cm)

FVC (L) = - 0.356 + 0.0187 * A[yrs] - 0.000382 * A[yrs]2 + 0.00014815 * H[cm]2
FEV1 (L) = 0.4333 - 0.00361 * A[yrs] - 0.000194 * A[yrs]2 + 0.00011496 * H[cm]2
FEV1/FVC% = (90.809 - 0.2125 * A[yrs])/100
FEV6 (L) = - 0.1373 + 0.01317 * A[yrs] - 0.000352 * A[yrs]2 + 0.00014395 * H[cm]2
FEV1/FEV6% = (90.107 - 0.1563 * A[yrs])/100
FEF25-75% (L/Sec) = 2.367 - 0.01904 * A[yrs] - 0.0002 * A[yrs]2 + 0.00006982 * H[cm]2
PEF (L/Sec) = 0.9267 + 0.06929 * A[yrs] - 0.001031 * A[yrs]2 + 0.00018623 * H[cm]2

MALE, Black (African-American), 8-19 years, 48.0 - 76.4 in. (122 - 194 cm)

FVC (L) = - 0.4971 - 0.15497 * A[yrs] + 0.007701 * A[yrs]2 + 0.00016643 * H[cm]2
FEV1 (L) = - 0.7048 - 0.05711 * A[yrs] + 0.004316 * A[yrs]2 + 0.00013194 * H[cm]2
FEV1/FVC% = (89.239 - 0.1828 * A[yrs])/100
FEV6 (L) = - 0.5525 - 0.14107 * A[yrs] + 0.007241 * A[yrs]2 + 0.00016429 * H[cm]2
FEV1/FEV6% = (88.841 - 0.1305 * A[yrs])/100
FEF25-75% (L/Sec) = - 1.1627 + 0.12314 * A[yrs] + 0.00010461 * H[cm]2
PEF (L/Sec) = - 0.2684 - 0.28016 * A[yrs] + 0.018202 * A[yrs]2 + 0.00027333 * H[cm]2

MALE, Black (African-American), 20-80 years, 62.2 - 77.2 in. (158 - 196 cm)

FVC (L) = - 0.1517 - 0.01821 * A[yrs] + 0.00016643 * H[cm]2
FEV1 (L) = 0.3411 - 0.022309 * A[yrs] + 0.00013194 * H[cm]2

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

FEV1/FVC% = (89.239 - 0.1828 * A[yrs])/100
FEV6 (L) = - 0.0547 - 0.02114 * A[yrs] + 0.00016429 * H[cm]2
FEV1/FEV6% = (88.841 - 0.1305 * A[yrs])/100
FEF25-75% (L/Sec) = 2.1477 - 0.04238 * A[yrs] + 0.00010461 * H[cm]2
PEF (L/Sec) = 2.2257 - 0.04082 * A[yrs] + 0.00027333 * H[cm]2

FEMALE, Black (African-American), 8-19 years, 46.5 - 72.4 in. (118 - 184 cm)

FVC (L) = - 0.6166 - 0.04687 * A[yrs] + 0.003602 * A[yrs]2 + 0.00013606 * H[cm]2
FEV1 (L) = - 0.963 + 0.05799 * A[yrs] + 0.00010846 * H[cm]2
FEV1/FVC% =(91.655 - 0.2039 * A[yrs])/100
FEV6 (L) = - 0.637 - 0.04243 * A[yrs] + 0.003508 * A[yrs]2 + 0.00013497 * H[cm]2
FEV1/FEV6% = (91.229 - 0.1558 * A[yrs])/100
FEF25-75% (L/Sec) = - 2.5379 + 0.43755 * A[yrs] - 0.012154 * A[yrs]2 + 0.00008572 * H[cm]2
PEF (L/Sec) = - 1.2398 + 0.16375 * A[yrs] + 0.00019746 * H[cm]2

FEMALE, Black (African-American), 20-80 years, 53.5 - 70.9 in. (136 - 180 cm)

FVC (L) = - 0.3039 + 0.00536 * A[yrs] - 0.000265 * A[yrs]2 + 0.00013606 * H[cm]2
FEV1 (L) = 0.3433 - 0.01283 * A[yrs] - 0.0000974 * A[yrs]2 + 0.00010846 * H[cm]2
FEV1/FVC% = (89.239 - 0.1828 * A[yrs])/100
FEV6 (L) = - 0.1981 + 0.00047 * A[yrs] - 0.00023 * A[yrs]2 + 0.00013497 * H[cm]2
FEV1/FEV6% = (88.841 - 0.1305 * A[yrs])/100
FEF25-75% (L/Sec) = 2.0828 - 0.03793 * A[yrs] + 0.00008572 * H[cm]2
PEF (L/Sec) = 1.3597 + 0.03458 * A[yrs] - 0.000847 * A[yrs]2 + 0.00019746 * H[cm]2

MALE, Hispanic (Mexican-American), 8-19 years, 47.2 - 70.9 in. (120 - 180 cm)

FVC (L) = - 0.7571 - 0.0952 * A[yrs] + 0.006619 * A[yrs]2 + 0.00017823 * H[cm]2
FEV1 (L) = - 0.8218 - 0.04248 * A[yrs] + 0.004291 * A[yrs]2 + 0.00015104 * H[cm]2
FEV1/FVC% = (90.024 - 0.2186 * A[yrs])/100
FEV6 (L) = - 0.6646 - 0.1127 * A[yrs] + 0.007306 * A[yrs]2 + 0.0001784 * H[cm]2
FEV1/FEV6% = (89.388 - 0.1534 * A[yrs])/100
FEF25-75% (L/Sec) = - 1.3592 + 0.10529 * A[yrs] + 0.00014473 * H[cm]2
PEF (L/Sec) = - 0.9537 - 0.19602 * A[yrs] + 0.014497 * A[yrs]2 + 0.00030243 * H[cm]2

MALE, Hispanic (Mexican-American), 20-80 years, 61.4 - 75.6 in. (156 - 192 cm)

FVC (L) = 0.2376 - 0.00891 * A[yrs] - 0.000182 * A[yrs]2 + 0.00017823 * H[cm]2
FEV1 (L) = 0.6306 - 0.02928 * A[yrs] + 0.00015104 * H[cm]2
FEV1/FVC% = (90.024 - 0.2186 * A[yrs])/100
FEV6 (L) = 0.5757 - 0.0286 * A[yrs] + 0.0001784 * H[cm]2
FEV1/FEV6% = (89.388 - 0.1534 * A[yrs])/100

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

FEF25-75% (L/Sec) = 1.7503 - 0.05018 * A[yrs] + 0.00014473 * H[cm]2
PEF (L/Sec) = 0.087 + 0.0658 * A[yrs] - 0.001195 * A[yrs]2 + 0.00030243 * H[cm]2

FEMALE, Hispanic (Mexican-American), 8-19 years, 44.9 - 67.7 in. (114 - 172 cm)

FVC (L) = - 1.2507 + 0.07501 * A[yrs] + 0.00014246 * H[cm]2
FEV1 (L) = - 0.9641 + 0.0649 * A[yrs] + 0.00012154 * H[cm]2
FEV1/FVC% = (91.664 - 0.167 * A[yrs])/100
FEV6 (L) = - 1.241 + 0.07625 * A[yrs] + 0.00014106 * H[cm]2
FEV1/FEV6% =(92.36 - 0.2248 * A[yrs])/100
FEF25-75% (L/Sec) = - 2.1825 + 0.42451 * A[yrs] - 0.012415 * A[yrs]2 + 0.0000961 * H[cm]2
PEF (L/Sec) = - 3.2549 + 0.47495 * A[yrs] - 0.013193 * A[yrs]2 + 0.00022203 * H[cm]2

FEMALE, Hispanic (Mexican-American), 20-80 years, 53.5 - 67.7 in. (136 - 172 cm)

FVC (L) = 0.121 + 0.00307 * A[yrs] - 0.000237 * A[yrs]2 + 0.00014246 * H[cm]2
FEV1 (L) = 0.4529 - 0.01178 * A[yrs] - 0.000113 * A[yrs]2 + 0.00012154 * H[cm]2
FEV1/FVC% = (92.36 - 0.2248 * A[yrs])/100
FEV6 (L) = 0.2033 + 0.0002 * A[yrs] - 0.000232 * A[yrs]2 + 0.00014106 * H[cm]2
FEV1/FEV6% = (91.664 - 0.167 * A[yrs])/100
FEF25-75% (L/Sec) = 1.7456 - 0.01195 * A[yrs] - 0.000291 * A[yrs]2 + 0.0000961 * H[cm]2
PEF (L/Sec) = 0.2401 + 0.06174 * A[yrs] - 0.001023 * A[yrs]2 + 0.00022203 * H[cm]2

ZAPLETAL

Progress of Respiration Research Vol 22 (1987): Lung function in Children and Adolescents; ISBN: 3-8055-4495-2

MALE, 6-18 years, 42.1 - 71.7 in. (107 - 182 cm)

FVC (L) = 10 (-2.9236 + 2.936 * log(H[cm])) / 1000
FEV1 (L) =10 (-2.8652 + 2.8729 * log(H[cm])) / 1000
FEV1/FVC% = (90.6043 - 0.04104 * H[cm])/100
FEF25% (L/Sec) = 10 (-4.0164 + 2.1541 * log(H[cm]))
FEF50% (L/Sec) = 10 (-4.2168 + 2.1771 * log(H[cm]))
FEF75% (L/Sec) =10 (-4.5808 + 2.2116 * log(H[cm]))
FEF25-75% (L/Sec) = 10 (-4.6651 + 2.3588 * log(H[cm]))
PEF (L/Sec) = 10 (-4.3722 + 2.3422 * log(H[cm]))
SVC (L) = 10 (-2.5768 + 2.7799 * log(H[cm])) / 1000
MVV (L/Min) = 10 (-1.9178 + 3.0388 * log(H[cm])) / 1000

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

FEMALE, 6-18 years, 42.1 - 71.7 in. (107 - 182 cm)

FVC (L) = 10 (-2.704 + 2.8181 * log(H[cm])) / 1000
FEV1 (L) =10 (-2.6056 + 2.7413 * log(H[cm])) / 1000
FEV1/FVC% = (90.6043 - 0.04104 * H[cm])/100
FEF25% (L/Sec) = 10 (-4.0164 + 2.1541 * log(H[cm]))
FEF50% (L/Sec) = 10 (-4.2168 + 2.1771 * log(H[cm]))
FEF75% (L/Sec) =10 (-4.5808 + 2.2116 * log(H[cm]))
FEF25-75% (L/Sec) = 10 (-4.6651 + 2.3588 * log(H[cm]))
PEF (L/Sec) = 10 (-4.3722 + 2.3422 * log(H[cm]))
SVC (L) = 10 (-2.297 + 2.6361 * log(H[cm])) / 1000
MVV (L/Min) = 10 (-1.9178 + 3.0388 * log(H[cm])) / 1000

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Care & Maintenance

Care and maintenance is similar for all of MedDorna Wireless devices.

Cleaning - If the device becomes dirty, clean surfaces with a damp cloth using water only. Dry thoroughly. AVOID CLEANING AROUND CONNECTORS. Any moisture in luer could affect operation. To help keep luer port clean from dirt and debris, replace vinyl cap when not in use.

Handling - Avoid contaminating the luer and connectors of the device.

Storage - Store the device in a dry place. Moisture in the device can adversely affect measurements. The card can accept a wide temperature range, but avoid sudden changes in temperature that can cause condensation inside the unit.

Physical Shock - Avoid physical shock to the device. A device that has been dropped should have the spirometry calibration verified before use on a patient.

EMI - The device is not to be used in the proximity of any piece of equipment that has the potential to generate a significantly large electromagnetic field as to interfere in any manner with the operation of the device.

Battery - ????

Disposal - Dispose of the device system components in accordance with the regulations applicable to the country in which it is used. Dispose battery components according to ...

Service

For service please contact the MedDorna service department at (000) 000-0000, fax us at (000) 000-0000 or e-mail us at support@MedDorna.com. Service representatives are available Monday through Friday from 7am to 6 pm CST. In the event that your problem cannot be fixed over the telephone you will be issued a Return Merchandise Authorization (RMA) number. Please have the Spirometer's serial number and BT address available. Please repackage your device in the original packing materials and ship it to:

MedDorna, LLC
9600 Great Hills Trail, Suite 350W
Austin, TX 78759

Normal repairs take three working days and includes static calibration and a stability check.

THE INSTRUMENT MUST BE RETURNED FOR REPAIRS AT THE EXPENSE OF THE PURCHASER. IN-WARRANTY REPAIRED UNITS ARE RETURNED AT THE EXPENSE OF MEDDORNA CORPORATION OR ITS AUTHORIZED AGENT. FOR OUT OF WARRANTY WORK THE CUSTOMER IS RESPONSIBLE FOR ALL FREIGHT CHARGES.

Limited Warranty

All instruments sold and supplied by MedDorna are guaranteed to be free from defects in material and workmanship for a period of 3 years from date of purchase. All supplies and accessories carry a 90-day limited warranty. If in the judgment of MedDorna, LLC the instrument is proven to be defective during the warranty period it will be repaired or replaced with no charge for parts or labor. An extended hardware warranty is available at additional cost.

This warranty does not cover any instrument that has been damaged by accident, misuse, abuse or has been altered or repaired by anyone other than an authorized MedDorna agent. This warranty also does not cover any unit that has had the serial number removed, defaced or rendered illegible.

This warranty is in lieu of all other warranties expressed or implied. Including warranties of merchantability and fitness, and is hereby limited to repair or replacement of instruments found defective during the warranty period.

ALL REPAIRS MUST BE MADE BY AN AUTHORIZED MEDDORNA, LLCAGENT. THE INSTRUMENT MUST BE RETURNED FOR REPAIRS AT THE EXPENSE OF THE PURCHASER. IN-WARRANTY REPAIRED UNITS WILL BE RETURNED AT THE EXPENSE OF MEDDORNA, LLCOR ITS AUTHORIZED AGENT. INSTRUMENTS SENT BY MAIL OR COMMON CARRIER SHOULD BE INSURED AGAINST LOSS OR DAMAGES, AS THEY ARE NOT COVERED BY THIS WARRANTY.

Technical support on software is under warranty for 60 days. A software support package is available after 60 days at an additional cost.

Glossary of Terms

%PRED -- Ratio of patient's actual results compared to predicted normal values, expressed as a percentage. Abnormality is defined by using one standard deviation for each variable rather than any specific percentage below the predicted value. Results above 100% are above average.

ATS -- American Thoracic Society, a scientific medical organization active in pulmonary research and care of patients with lung diseases. The ATS has recommended standards for spirometers.

Back Extrapolation -- A method of determining the start-of-test point as recommended by the ATS.

BF Equipment -- Degree of protection against electrical shock.

Bronchodilator -- A type of drug (i.e. albuterol), usually administered in an aerosol spray, that is used to dilate air passages to reduce any restrictions to air flow. After bronchodilator administration, the spirometry test is repeated to determine reversibility and therapeutic efficacy in obstructed or asthmatic patients.

BTPS -- Body Temperature and Pressure, Saturated: A number, which uniformly expresses all spirometry results at body temperature and pressure, fully saturated with water.

Calibration Syringe -- A large syringe which injects a measured amount of air into the mouthpiece. Many syringes have a stop ring on the plunger, which allows injecting various calibrated amounts of air.

Class II Equipment -- Double insulated equipment

COPD -- Chronic Obstructive Pulmonary Disease.

Demographic Data -- Patient information necessary to predict normal values for a patient - age, height, race and sex.

Dyspnea -- Shortness of breath, sometimes accompanied by pain.

ERS -- European Respiratory Society

EX TIME -- Expiratory Time, expressed in seconds - time elapsed between the beginning and completion of expiration.

FEF 25-75% -- Forced expiratory flow during the middle half (25-75%) of the FVC (formerly called the maximum middle expiratory flow rate), expressed in liters per second. This is the most sensitive measure of small airways obstruction (typically seen in smokers).

FEFxx% -- Forced Expiratory Flow at xx% point of the FVC, expressed in liters per second. See also: Forced Expiratory Flow.

FEV1/FEV6 -- Ratio of FEV6 exhaled in one second. May be used as a surrogate for FEV1/FVC.

FEV6 (L) forced expiratory volume -- Measured six seconds after commencement of expiration. May be used as a surrogate for FVC.

FEVt -- See: Forced Expiratory Volume (timed)

FEVx/FVC% -- The percentage ratio of Forced Expiratory Volume (timed) to Forced Expiratory Vital Capacity, expressed as a percentage.

FIF.2-1.2 -- Forced Inspiratory Flow between 200 ml. and 1200 ml. Flow of inspired air measured after the first 200 ml. And during the next 1000 ml.

FIF 25-75% -- Forced Inspiratory flow during the middle half (25-75%) of the FIVC expressed in liters per second.

FIFxx% -- Forced Inspiratory Flow at xx% point of the FIVC, expressed in liters per second. See also: Forced Inspiratory Flow.

FIVt -- See: Forced Inspiratory Volume (timed)

FIVx/FIC% -- The percentage ratio of Forced Inspiratory Volume (timed) to Forced Inspiratory Vital capacity, expressed as a percentage.

FIVC -- See: Forced Inspiratory Vital Capacity

Flow vs. Volume Curve -- Graph obtained by forced exhalation test, Flow is plotted on the vertical axis and volume on the horizontal axis. It allows easier recognition of unacceptable or poorly reproducible tests when compared with the traditional spirogram. Characteristic shapes and subtle airflow changes are more readily apparent than on standard spirograms or numerical presentations.

Forced Expiratory Flow -- It is the rate of flow, expressed in liters per second, at various points in the volumetric flow, i.e. FEF25%, FEF50%, FEF75%. May be more sensitive than FEV1 in finding a mild airflow limitation.

Forced Expiratory Volume (timed) -- Maximal volume of air, expressed in liters, which can be expelled in specific time in a forced capacity test. For example, FEV1 is the volume of air expelled during the first second of the FVC.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Forced Inspiratory Vital Capacity -- Total volume of air, expressed in liters, which can be inhaled during a rapid forced inhalation after a maximal expiration. Amount may be decreased because of disorders, which cause volume restriction in the lung or airflow limitation causing air trapping.

Forced Inspiratory Flow -- It is the Inspiratory rate of flow, expressed in liters per second, at various points in the volumetric flow, i.e. FIF25%, FIF50%, FIF75%.

Forced Vital Capacity -- Total volume of air, expressed in liters, which can be exhaled during a rapid forced exhalation after a maximal inspiration. Amount may be decreased because of disorders which cause volume restriction in the lung or airflow limitation causing air trapping. May also be caused by poor insinuate or expiratory effort on the part of the patient.

FVC -- See: Forced Vital Capacity.

Lung Age -- Morris JF, Temple W.; Spirometric "lung age" estimation for motivating smoking cessation. Prev Med. 1985 Sep;14(5):655-62. Age Range: 20 - 84

MVV -- Maximum Voluntary Ventilation: The maximum volume of air that can be inhaled and exhaled repeatedly through the lungs over a period of time (usually 12 seconds) and extrapolated to one minute. It is expressed in liters per minute. Note: this is a strenuous test.

MTV -- Mean Tidal Volume: see Tidal Volume (TV).

Obstruction -- Limitation of airflow. It is shown by the FVC test. Low FEV1/FVC% ratio is the main indication of airways obstruction. Reductions in FEV3/FVC% and FEF25-75% best demonstrate obstruction of small airways (e.g. smokers).

PEFR -- Peak Expiratory Flow Rate (FEF max), expressed in liters per second. Maximum instantaneous flow in the FVC test.

PFT -- Pulmonary Function Tests: Group of tests including spirometry, lung volume tests, nitrogen washout, helium dilution, body plethysmography, DLCO, and blood gas analysis.

PIFR -- Peak Inspiratory Flow Rate, expressed in liters per second.

Pred. -- Predicted value according to the "normal" equations used.

Pulmonary Functions Tests -- see PFT.

RR -- Respiratory Rate: the average number of inhalations/exhalations per minute performed during a test.

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.

Slow Vital Capacity – Total volume of air, expressed in liters, which can be exhaled during a slow exhalation after a maximal inspiration. Amount may be decreased because of disorders that cause volume restriction in the lung.

SVC – See Slow Vital Capacity

CONFIDENTIAL: Property of MedDorna, LLC and may not be reproduced without written permission.