

Office Medic™ User's Manual

For use with: SpiroCard $^{\otimes}$ • SpirOxCard $^{\otimes}$ • Orbit $^{\text{\tiny TM}}$ • Universal ECG $^{\text{\tiny TM}}$







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General Cautions & Warnings

Before conducting tests read the General Caution & Warnings and the specific Cautions & Warnings pertaining to your particular medical device.

If you need further assistance see **Service**.

Glossary of Symbols



Attention

Consult Accompanying Documents



Consult Instructions For Use

Consult Accompanying Documents



Consult Instructions For Use

Consult Accompanying Documents



Type BF Equipment

Type B equipment with an F-type applied part (patient isolation from electric shock).



Defibrillator proof type BF equipment

Defibrillator proof type BF equipment complying with IEC Publication 601.



CE Mark

Indicates this device is in compliance with MDD 93/42/ECC. 0086 is the Notified Body Number.



Do not reuse.



Class II, Electrical Equipment.

KEF

Catalogue or Model Number

S/N

Serial Number



Manufacturer



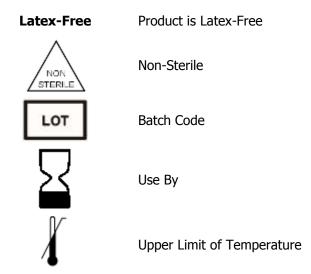
Authorized representative in the European community.



Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment.

Rx only

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



Warnings

- Do not use ORS Medical Devices in presence of flammable anesthetic mixture.
- Do not operate QRS Medical Devices in an explosive atmosphere.
- Use of accessory equipment not complying with EN60601-1 and/or UL2601-1 or equivalent safety standard may lead to a reduced level of safety of the resulting system.
- Computers and printers used with QRS Medical Devices should be evaluated to EN 60950-1, EN60601-1 or equivalent safety standard to maintain the safety of QRS Medical Devices.
- Do not use any QRS Medical Device on children or vulnerable adults without proper supervision.
- Ensure patient cabling or tubing is carefully routed on all QRS Medical Devices to reduce the possibility of patient entanglement or strangulation.
- All numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.
- Do not attempt to insert any QRS Medical Device (including patient cables) directly into an electrical outlet.



- Restoring the database erases all of the data located in Office Medic and replaces it with the data contained in the back-up file. Data that was acquired after the date of the last back-up will be lost and cannot be recovered.
- Once deleted, data can only be recovered from the date of your last back-up. Maintain regular back-ups to ensure data is not lost.
- The computer regulates the battery and will provide a warning message to inform the user that the battery is low in order to prevent data loss.
- Do not load any other manufacturer's SCP files. The Office Medic program is designed to work only with QRS Diagnostic SCP files.
- Do not use 3rd party applications to review or analyze QRS Diagnostic SCP files.
- Use only QRS approved accessories with QRS devices.

Cautions

Disposal Instructions:

Due to the potential presence of hazardous substances in electrical or electronic equipment, DO NOT dispose of QRS Diagnostic medical devices with municipal waste. Improper disposal could have an adverse effect on the environment and human health.

For QRS Diagnostic products NOT marked with please contact your local municipal waste company for proper disposal instructions.

For QRS Diagnostic products MARKED with please contact your local sales representative (from whom you purchased the product) or your local municipal waste company for proper disposal instructions.

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- All QRS Devices are intended for use by a physician or by trained personnel under a physician's supervision. Read all instructions for use and specifications provided prior to use.

Important! QRS Diagnostic medical devices are intended for use in the electromagnetic environment(s) specified below. Users of this equipment should ensure that it is used in such environment(s).

Attention should be paid to the following EMC information prior to installing or using QRS Diagnostic medical devices.

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of QRS Diagnostic medical devices.
- QRS Diagnostic medical devices have been tested and found to comply with IEC/EN 60601-1-2.
- Computers, cables and accessories not tested to 60601-1-2 may result in increased emissions or decreased immunity of QRS devices.
- Verify normal operation if utilizing QRS Diagnostic medical devices adjacent to or stacked with other electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions and immunity		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	QRS Diagnostic equipment uses RF energy only for its internal function. Therefore, its RF emissions are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	QRS Diagnostic medical devices are
Harmonic emissions IEC 61000-3-2	Not applicable for QRS Devices other than Universal ECG. Class A for Universal ECG Cable	suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supplies buildings
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not applicable	used for domestic purposes.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of QRS medical devices requires continued operation during power mains interruptions, it is recommended that the computer to be used is powered by an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note UT is the a.c. mair	ns voltage prior to application	on of the test level	

Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 Mz	3 Vrms	Portable and mobile RF Communications equipment should be used no closer to any part of QRS Diagnostic medical devices, including cables, than
Radiated RF	3 V/m	3 V/m	the recommended separation distance calculated
IEC 61000-4-3	80 MHz to 2.5 GHz		from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
			80 MHz to 800 MHz
			800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range. ^b
			Interface may occur in the vicinity of equipment marked with the following symbol:
			((·(·))

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

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

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which QRS medical devices are used exceeds the applicable RF compliance level above, QRS medical devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating QRS medical devices.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and QRS Diagnostic medical devices.

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

Rated maximum output	Separation distance according to frequency of transmitter		
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Electrical Safety Classifications

Note: These classifications currently apply only to QRS Medical Devices.

- Class II Equipment
- Type BF Equipment. Note: Universal ECG is Type BF with defibrillator-proof applied part.
- IPXO Ordinary Equipment.
- Continuous Operation.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Office Medic Basics

System Requirements

Operating System: Microsoft® Windows®:

*XP sp3 , Vista, 7, 8

Free Disk Space: 600MB

Internet Requirements: Internet Explorer 6.0 SP1 or later

RAM: 512 MB or higher

Processor: x86 1.0 GHz or x64 1.4 Ghz Screen Resolution: 1024x768 (EKG Requirement)

Interface: Available USB port

Media: A CD/DVD drive or access to the internet to download the software.

Contact Customer care for download instructions and details.

Installation

Important! Do not connect the medical device to the PC prior to installing the software. The device drivers (step #8) must be installed prior to testing.

- 1. Ensure you are logged in with Administrator rights.
- 2. Remove all QRS devices from the computer.
- 3. Log out and close all programs.
- Insert the Office Medic CD-ROM.
 - If the autorun feature on your computer is disabled go to the next instruction. If not follow the on screen prompts.
- 5. On the lower Windows toolbar select **Start** | **Run** or simultaneously press the Windows logo and R key. Type d:\setup.exe in the Open dialog box. Note: substitute the letter of your CD/DVD-ROM drive if it is different from d:.
- 6. Select a language.

Note: If you need to change the language, you will need to uninstall Office Medic. To do this go to your control panel, click on "Programs and Features" and then find the "Programs" and select "Uninstall a program. Find Office Medic on the list and uninstall. Finally, reinstall Office Medic using the setup program and select the correct language. Any data that was recorded will be preserved because uninstallation doesn't delete data.

7. Follow the on-screen instructions.

^{*}Note XP installation upgrade only. Previous version of Office Medic 5.X or higher must be installed first. Contact Customer Care for additional details.

^{**}Recommended system specifications: PC running Windows 7, Dual core CPU, 2 gigs of RAM, 300 gig HDD or better with an available USB port.

Note: You will be given a choice to install a local or network database. The Network option requires an Office Medic Network Database formally called IDMS database. To learn more about obtaining a Network database, and networking Office Medic, contact Customer Care.

An Office Medic shortcut will appear on your desktop when the installation is complete.



8. Once the installation is complete, connect the medical device to the PC with the CD-ROM still inserted. Follow the software prompts for installing the device driver.

Backing-up and Restoring the Database

Database Back-up Instructions

Backing-up your database protects you from losing your patient data should a catastrophic event occur. Regular back-ups of the database should be maintained. Follow the steps below to back-up the database:

- 1. Close Office Medic.
- 2. Open folder: C:\Program Files\Microsoft SQL Server\MSSQL.1\MSSQL\Data.
- 3. Copy the two files OfficeMedic_Data.MDF and OfficeMedic_Log.LDF to a secure location. This is the back-up copy of your Office Medic database. Copy these files as often as needed to maintain a current back-up file.

Database Restore Instructions

Warning! Restoring the database erases all of the data located in Office Medic and replaces it with the data contained in the back-up file. Data that was acquired after the date of the last back-up will be lost and cannot be recovered.

Follow the steps below to restore the database:

- 1. Close Office Medic.
- 2. Copy and paste the two back-up files into the following location: C:\Program Files\Microsoft SQL Server\MSSQL.1\MSSQL\Data.
- 3. Open Office Medic.

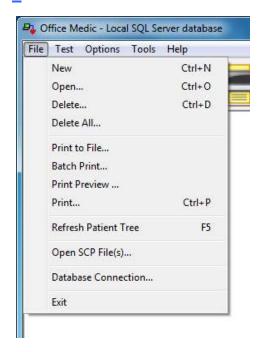
The database should look exactly as it did on the date of the last back-up.

Navigation

Select the Office Medic icon to open the software. The initial screen displays the directory of patients, sessions and tests. Contact QRS Technical Support for instructions on how to hide patient names.

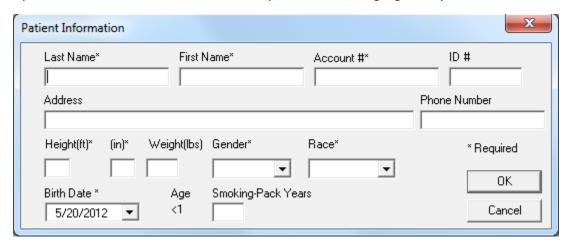


File Menu



New (Ctrl+N)

Opens the Patient Information window. Required fields are highlighted by an asterisk.



Note: 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, session or test and then select **Open** to view the selected data.

Delete (Ctrl+D)

Select a patient, session or test and then select **Delete** to delete the selected data.

Delete All

The Delete All option deletes the entire database.

Warning! Once deleted, data can only be recovered from the date of your last back-up. Maintain regular back-ups to ensure data is not lost.

Print to File

Creates an image file (either JPEG, TIFF, or PDF) of an Office Medic report. Highlight the session or test in the patient tree and select this option.

Note: The default location for image files is My Documents\Diagnostic Test Data\Image Files.

Batch Print

The Batch Print option allows for the printing of multiple patient reports.

Print Preview

Reports can be previewed by selecting the desired session or test and then select **File | Print Preview**.

Print (Ctrl+P)

Select a patient, session or test and select **File** | **Print** to print a report.

Refresh Patient Tree (F5)

Select to refresh the patient database.

Database Connection...

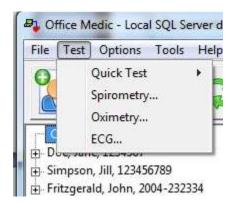
Select to switch between local and network databases.

E<u>x</u>it

Exits the Office Medic program.

Test Menu

Select a patient and then select the desired test from the $\underline{\mathbf{Test}}$ menu to begin testing.



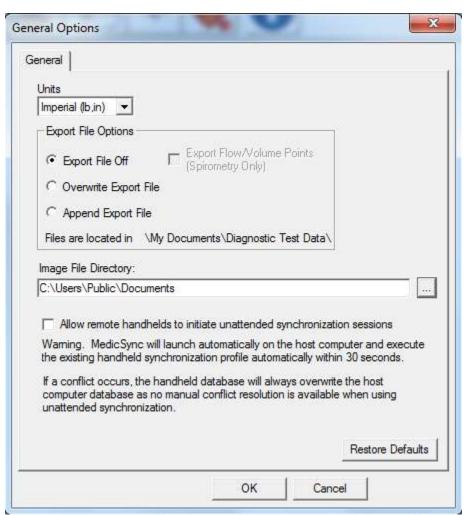
For details on spirometry testing see <u>Performing a Spirometry Test</u>
For details on oximetry testing see <u>Performing an Oximetry Test</u>
For details on ECG testing see <u>Performing an ECG Test</u>

Options Menu

Select **Options** to change program settings.



General Options



Units

Select **Imperial** or **Metric**.

Export File

Creates tab delimited ASCII text files: Session.txt, SpTest.txt, SpCalibr.txt, OxiSess.txt and OxiTest.txt. The Export Flow/Volume Points feature creates two files called SpGraph.txt and SpCalGr.txt.

Image File Directory:

Select the browse button to change the default path where image files are saved.

Allow remote handhelds to initiate unattended synchronization sessions:

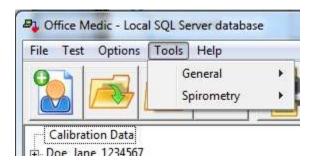
MedicSync will launch automatically on the host computer and execute the existing handheld synchronization profile automatically within 30 seconds.

If a conflict occurs, the handheld database will always overwrite the host computer database as no manual conflict resolution is available when using unattended synchronization.

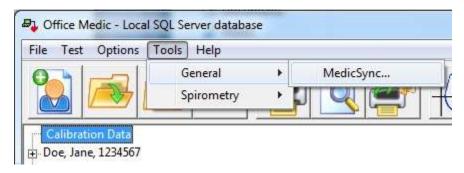
Note: If the host computer is set to delete data from the remote, then data will be deleted from the remote during an automatic synchronization.

For details on changing the spirometry options see <u>Spirometry Options</u>
For details on changing the oximetry options see <u>Oximetry Options</u>
For details on changing the ECG options see <u>ECG Options</u>

Too<u>l</u>s Menu



General Tools



MedicSync

MedicSync synchronizes data between QRS patient databases. For information about unattended remote synchronization with your Pocket PC see the <u>General Options</u> section.

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.

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

For details on the spirometry tools see **Spirometry Tools**

Help Menu



User's Manual

Opens the Office Medic User Manual.

ECG Physician's Guide

Opens the Physician's Guide for the ECG interpretation algorithm.

About QRS

Provides information for contacting QRS Diagnostic.

About Office Medic

Displays the version of Office Medic and statistics about any connected device.

Spirometry

Note: The information in this chapter applies to spirometry tests acquired using an Orbit Portable Spirometer, SpiroCard or SpirOxCard.

Spirometry Cautions & Warnings

Warnings

- Use only QRS mouthpieces manufactured to meet calibration requirements for the QRS Orbit Portable Spirometer, SpiroCard or SpirOxCard.
- Mouthpieces are single patient use only and MUST be replaced for each patient.
- Exercise caution when performing spirometry testing on patients with a history of COPD.
- Do not use mouthpieces on a patient with an injured mouth.
- Do not obstruct the opening at the end of the mouthpiece. Obstruction may result in erroneous results.
- FVC and MVV testing can cause fatigue and some patients may be at risk for vertigo, arrhythmia or syncope.
- Patients should open, handle and dispose of his/her own mouthpiece to reduce the risk of cross contamination.
- If condensation forms inside the pressure tube or the pressure tube becomes visibly kinked it must be replaced.

Warning! The ATS/ERS Task Force: Standardisation of Lung Function Testing recommends daily calibration checks.

Cautions

- Physicians must properly train individuals, under their care, in the use of this product.
- All tests must be evaluated by a qualified physician.

Indications for Use: Diagnostic Spirometry

Patient Population: Male/Female, Pediatric to Adult

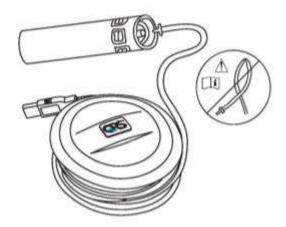
Device Functionality: Diagnostic Spirometry Spirometric Parameters: FVC, MVV, SVC, and FEF

Environment of Use: Hospital, Clinical and Home Use

Spirometry Getting Started

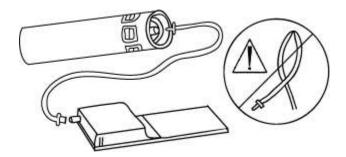
For the Orbit Portable Spirometer

- 1. Insert the USB cable into an available USB Port on your PC.
- 2. Connect the pressure tube to the Luer fitting. Ensure the pressure tube is not kinked or restricted in any way.
- 3. Connect the other end of the pressure tube to the disposable mouthpiece.



For the SpiroCard or SpirOxCard

- 1. Insert the PC Card into the PC Card Reader.
- 2. Connect the pressure tube to the Luer fitting. Ensure the pressure tube is not kinked or restricted in any way.
- 3. Connect the other end of the pressure tube to the disposable mouthpiece.



Warning! Ensure pressure tube is properly connected. If condensation forms inside the pressure tube or the pressure tube becomes visibly kinked it must be replaced.

Proper Patient Preparation

To obtain diagnostically reliable results:

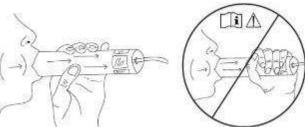
- Loosen tight clothing (ties, belts, bras).
- Remove patient's dentures.
- Explain the procedure thoroughly, including demonstrating it yourself with your own mouthpiece.
- Have the patient sit or stand in an upright position during the test. When standing, place a chair behind them in case they become dizzy.
- Before beginning the test have the patient take several slow, deep inhalations/exhalations to feel comfortable.

Proper Testing Procedure

To obtain diagnostically reliable results proper testing procedures must be followed:

- When the equipment is zeroing (two circles flashing) have the patient keep the mouthpiece away from their mouth.
- When testing ensure the patient has a tight seal with their lips around the mouthpiece. The patient should not bite the tube or have pursed lips.
- Place a disposable nose clip securely on the patient's nose or instruct the patient not to exhale through the nose.
- Verbally instruct the patient on properly performing the procedure:
 - FVC instruct the patient to take the largest possible inhalation, insert the mouthpiece into their mouth and exhale forcefully and completely. If a Flow/Volume Loop is desired, verbally instruct the patient to inhale after completely exhaling.
 - SVC instruct the patient to take the largest possible inhalation, insert the mouthpiece into their mouth, and exhale slowly and completely.
 - MVV instruct the patient to breathe as deeply and rapidly for 12 to 15 seconds into the mouthpiece. This test is often difficult to perform for many patients.

Important! Ensure the patient has a tight seal around the mouthpiece and is not covering or obstructing the fabric at the end of the mouthpiece with their hand.



- 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.
- Once finished, have the patient remove the mouthpiece and breathe normally until they have recovered.

Important! Using the mouthpiece more than 20 times, or for more than 10 consecutive days, may generate inaccurate results. Use a new mouthpiece after 20 attempts and/or 10 days to get the most accurate results.

Effort Quality Messages for Adult Subjects

Warning Message	Criteria
"Don't hesitate."	BEV (Ext. Vol) > 150 mL or 5% of the FVC
"Blast out faster."	PEFT > 120 msec
"Blow out longer."	${\sf FET}$ < 6.0 s for subjects aged 10 years and older or ${\sf FET}$ < 3 s for subjects aged less than 10 years, and ${\sf EOTV}$ > 40 mL
"Blast out harder."	PEF values do not match within 1.0 L/s
"Deeper breath."	FEV6 values do not match within 150 mL
Warning message does not appear.	Effort meets above criteria.
"Good test session."	Two acceptable efforts meet the repeatability requirements.

Test Session Grades

Each test session is given a grade which indicates the degree of confidence in the results.

Grade	Criteria
Α	At least 2 maneuvers with the largest two FEV1 values matching within 100mL and the largest two FEV6 values matching better than 100mL.
В	At least 2 maneuvers with FEV1 values matching between 101 and 150 mL.
С	At least 2 maneuvers with FEV1 values matching between 151 and 200 mL.
D	Only one maneuver, or more than one, but the FEV1 values match > 200mL.

Unacceptable Spirometry Tests

A spirometry test is considered unacceptable when:

- 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. Obstruction can cause the volume to be unusually high.

Repeatability

You will be informed when the patient has met the ATS/ERS 2005 repeatability criteria when:

- Three maneuvers have been accepted and
- The two highest FVC values from any of the maneuvers are within 150ml and the two highest FEV1 values from any of the maneuvers are within 150ml. For tests with an FVC of ≤ 100ml both of these values are 100ml.

An ATS/ERS 2005 warning will be displayed if more than 8 maneuvers are performed on a patient.

You will be informed when the patient has met the BTS-NICE (2004-05) repeatability criteria when:

- Three maneuvers have been accepted and
- The two highest FVC values from any of the maneuvers are within 100ml (or 5%) and the two highest FEV1 values from any of the maneuvers are within 100ml (or 5%).

Performing a Spirometry Test

- 1. Prepare the patient as described in the **Proper Patient Preparation** section.
- 2. Select the patient and then select **Test** | **Spirometry** or the icon

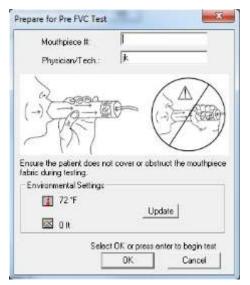


The Spirometry Test Session screen will appear. Select one of the test buttons to conduct a maneuver.



Important! Ensure correct patient is selected.

3. Enter the Mouthpiece Number.

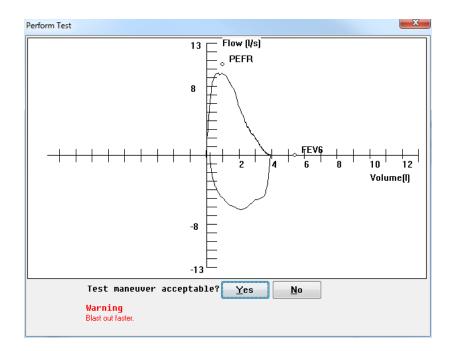


Enter the number on the mouthpiece label following the # sign.

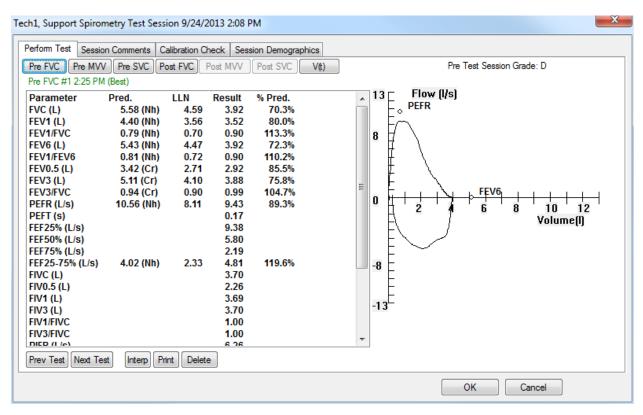
4. Perform the Maneuver.

After the mouthpiece number is entered, select **OK** when ready to test. Two circles will flash red and yellow. When both circles become green instruct the patient to begin the maneuver. Ensure proper testing procedures are being followed as described in the <u>Proper Testing Procedure</u> section.

Important! Ensure the patient does not cover the fabric at the end of the mouthpiece.



5. Select **YES** to save the test and display the results. Select **NO** to delete the test and return to Spirometry Test Session window.

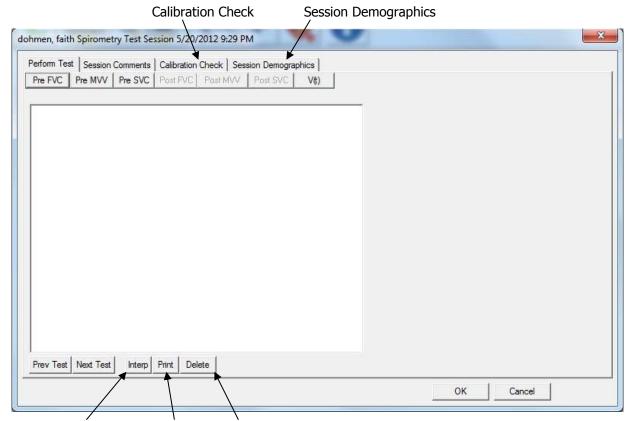


Select another test button to perform additional maneuver.

Pre FVC Pre MVV Pre SVC Post FVC Post MVV Post SVC V(t)

Select **Session Comments** to enter text relevant to the session.

About the Spirometry Test Session Window



Interp Button Print Button Delete Button

Interp Button

Provides an interpretation for the test visible in the test session window. For additional information see the <u>Spirometry Interpretation</u> section.

Print Button

Prints the individual test visible in the test session window.

Delete Button

Deletes the individual test visible in the test session window.

Calibration Check Tab

Checks the calibration of the Spirometer and appends the results to the patient's spirometry report. For instructions on performing a calibration check see the <u>Spirometry Calibration Check</u> section.

Session Demographics Tab

Select **Session Demographics** to update patient information. This will affect current and future tests only.

When the session is complete, select **OK** to save the session and return to the patient database.

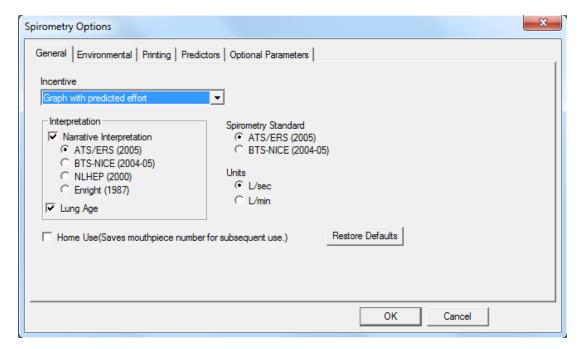
Spirometry Options

Select **Options** | **Spirometry** from the menu bar.



General Tab

Select **General** to change the graphical incentive displayed.



Interpretation

Turn the **Narrative Interpretation** and **Lung Age** options ON and OFF. For details on the interpretation criteria see the <u>Spirometry Interpretation</u> section. For details on the Lung Age calculation see the <u>Lung Age Calculation</u> section.

Spirometry Standard

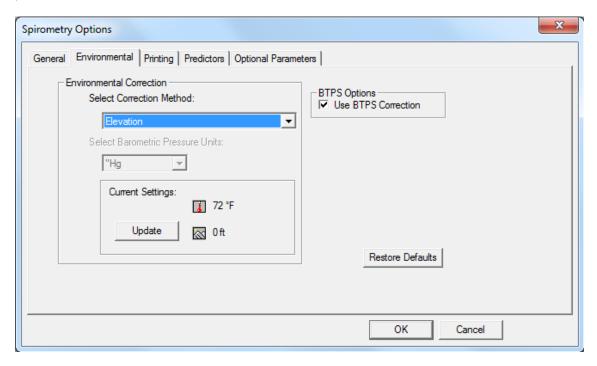
Select between the ATS/ERS (2005) and the BTS-NICE (2004-05) standard.

Units

Select to have results displayed in Liters per second (L/sec) or Liters per minute (L/min).

Environmental Tab

Select **Environmental** to adjust environmental conditions such as temperature, elevation and barometric pressure.



- Elevation: Elevation is your altitude above sea level. Use this option if you do not have a barometer.
- Elevation with Relative Barometric Pressure: The relative barometric pressure is the measured air pressure in your area and varies from day to day.
- 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.

Select Barometric Pressure Units

Select the units of barometric pressure in either inches of Mercury ("Hg), millimeters of Mercury (mmHg) or millibars hPa (mb).

Current Settings

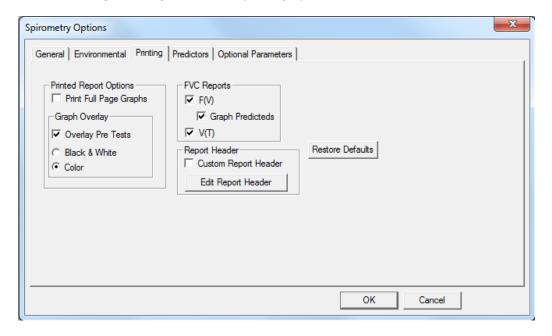
Select the **Update** button to change temperature, barometric pressure and elevation data.

BTPS Options

Use BTPS Correction should be turned on when testing patients. For calibration testing BTPS is automatically turned off and Room Temperature cannot be adjusted.

Printing Tab

Select **Printing** to change or activate printing options:



Print Full Page Graphs

Prints two additional pages, containing full page F(V) and V(T) graphs, in the report.

Overlay Pre Tests

Overlays the best three Pretests in Color or Black & White.

Note: When a Post test is performed the report will overlay the best Pre and best Post test. Once a Post test is performed, the best three Pretests will not overlay on the report.

Custom Report Header

Select **Edit Report Header** to create or edit a custom header. Select the **Custom Report Header** checkbox to activate the custom report header.

Note: Report headers contain patient demographics.

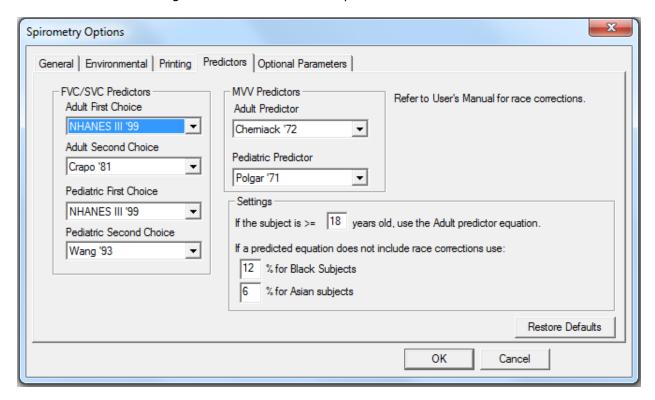
FVC Reports

Prints the F(V) and/or V(T) graphs at the bottom of the report. Select the **Graph Predicteds** options to have the predicted values plot on the F(V) report.

Note: Predicteds will not plot on V(T) graphs.

Predictors Tab

Select **Predictors** to change or activate the Predictor options.



Predictors

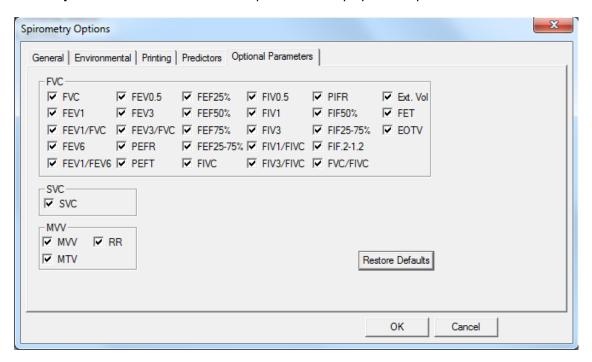
A first and second Predictor choice is allowed. Should a patient fall out of the age or height range of the first choice predictor, the second predictor will be used. If the patient falls out of range of both predictors, no predicted data will be shown. See the Predicted Value Equations section for equation parameters.

Settings

Sets a race correction for Blacks and Asians. The correction is applied to the predicted value and predicted value LLN. The software default is 12% for Blacks and 6% for Asians. Enter 0% if you do not want to correct for race.

Optional Parameters Tab

Select **Optional Parameters** to set the parameters displayed on reports.

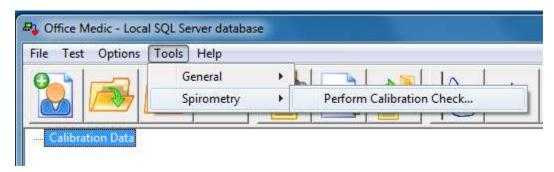


Spirometry Tools

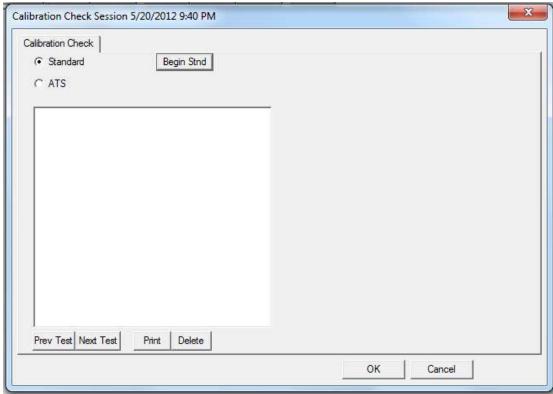
Spirometry Calibration Check

There are two methods for accessing and storing the Calibration test:

1. Select **Tools** | **Spirometry** | **Perform Calibration Check**. This method stores the calibration report chronologically under **Calibration Data** in the Patient Directory window.



2. Select **Calibration Check** within a test session window. This method appends the calibration results to the patient's spirometry test report.



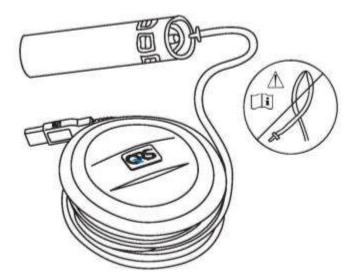
There are two methods of calibration:

- Standard A single volumetric test.
- ATS ATS 3-speed flow and volume test.

Note: The Spirometer does not require a calibration check in order to operate.

To check calibration: Orbit Portable Spirometer

- 1. Insert the USB cable into the USB port.
- 2. Connect the pressure tube to the Luer fitting.
- 3. Connect the pressure tube to the mouthpiece.



4. Connect a syringe to the mouthpiece (recommended 3-liter syringe).

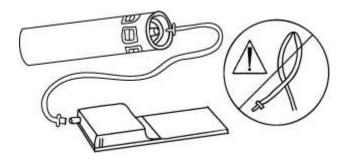
Note: The calibration syringe must form a tight seal around the mouthpiece. If you are unable to get a tight seal contact Technical Support for more information.

- 5. Select the desired calibration check:
 - For standard calibration select **Begin Stnd**, enter the mouthpiece number and the syringe volume (1 to 10 liters) and select **OK**.
 - For ATS/ERS 2005 calibration select ATS and enter the mouthpiece number and select
 OK. A 3-liter syringe must be used.
- 6. When both circles stop flashing and turn green push the syringe in fully.

Note: The calibration check is for verification only. If the spirometer is found to be out of calibration, repeat with a different mouthpiece. If the problem persists, see <u>Service</u>.

To check calibration: SpiroCard or SpirOxCard

- 1. Insert the PC Card into the PC Card Slot.
- 2. Connect the pressure tube to the Luer fitting.
- 3. Connect the pressure tube to the mouthpiece.



4. Connect a syringe to the mouthpiece (recommended 3-liter syringe).

Note: The calibration syringe must form a tight seal around the mouthpiece. If you are unable to get a tight seal contact Technical Support for more information.

- 5. Select the desired calibration check:
 - For standard calibration select **Begin Stnd**, enter the mouthpiece number and the syringe volume (1 to 10 liters) and select **OK**.
 - For ATS/ERS 2005 calibration select **ATS** and enter the mouthpiece number and select **OK**. A 3-liter syringe must be used.
- 6. When both circles stop flashing and turn green push the syringe in fully.

Note: The calibration check is for verification only. If the spirometer is found to be out of calibration, repeat with a different mouthpiece. If the problem persists, see <u>Service</u>.

Predicted Value Equations Predicted Study Summary Table

Reference	Abbreviation	Gender	Age Range [yrs]	Height Range	Caucasian	Black	Mexican - American	Asian	FVC	FEV1	FEV1/FVC	FEV6	FEV1/FEV6	FEF25-75%	PEFR	FEF25%	FEF50%	FEF75%	MVV	SVC	FEV0.5	FEV3	FEV3/FVC	FET	FIVC					
		М	8–19	48-75.6 in (122-192 cm)	Х				Χ	Х	Х	Χ	Х	Χ																
		М	8–19	48-76.4 in (122-194 cm)		X			Х	Х		X		Х				ļ		ļ										
		М	8–19	47.2-70.9 in (120-180 cm)			Χ		Χ	Х		Χ		X																
		М	20–80	62.2-76.4 in (158-194 cm)	Χ				Χ	Χ		Χ			Χ															
		М	20–80	62.2-77.2 in (158-196 cm)		Χ			Χ	Χ	Χ	Χ	X	Х	X															
NHANES III	R	М	20–80	61.4-75.6 in (156-192 cm)			Χ		Χ	Χ	Χ	Χ	Χ	Χ	Χ															
(1999)	Z	F	8–17	46.5-70.1 in (118-178 cm)	Χ				Χ	Χ	Χ	Χ	Χ	Χ	Χ															
		F	8–17	46.5-72.4 in (118-184 cm)		Χ			Χ	Χ	Χ	Χ	Χ	Χ	Χ															
		F	8–17	44.9-67.7 in (114-172 cm)			Χ		Χ	Χ	Χ	Χ	Χ	Χ	Χ															
		F	18–80	57.1–70.9 in (145–180 cm)	Χ				Χ	Χ	Χ	Χ	Χ	Χ	Χ															
		F	18–80	53.5-70.9 in (136-180 cm)		Χ			Χ	Χ	Χ	Х	Χ	Х	Χ															
		F	18–80	53.5–67.7 in (136–172 cm)			Х		Χ	Χ	Χ	Х	Χ	Х	Χ															
ECCS/ERS		М	18–70	61- 76.8 in (155-195 cm)	Х				Χ	Χ	Χ			Х		Χ	Χ	Х							Χ					
(Quanjer 1993)		F	18–70	57.1–70.9 in (145–180 cm)	Х				Х	Х	Х			Х	Х	Х	Х	Х		-					Х					
, , ,		М	6–18	43.3–74.8 in (110–190 cm)	Х				Χ	Х	X			Х																
(4000)	D	М	6–18	47.2–74.8 in (120–190 cm)		Χ			Χ	Χ	Χ			Х						İ										
Wang (1993)	Wg	F	6–18	43.3–70.9 in (110–180 cm)	Χ				Χ	Χ	Χ			Χ																
	F	6–18	47.2–70.9 in (120–180 cm)		Χ			Χ	Χ	Χ			Х																	
0 : (4005)	п	М	6–18	43.3-80.7 in (110-205 cm)	Χ				Χ	Χ	Χ																			
Quanjer (1995)	Qu	F	6–18	43.3-72.8 in (110-185 cm)	Х				Χ	Χ	Χ																			
7 1 1 (4007)	æ	æ	m	ď	æ	a	М	6–18	42.1-71.7 in (107-182 cm)	Χ				Χ	Χ	Χ			Χ	Χ	Χ	Χ	Χ	Χ	Χ					
Zapletal (1987)	Za	F	6–18	42.1-71.7 in (107-182 cm)	Χ				Χ	Χ	Χ			Χ	Χ	Χ	Χ	Χ	Х	Χ										
		М	20–90	58-80 in (147.3-203.2 cm)	Х				X	Χ				Х																
	0	М	20–79	58-80 in (147.3-203.2 cm)	Χ						Χ																			
Morris (1971/73)	Mo	F	20–90	56-72 in (142.2-182.9 cm)	Χ				Χ	Χ				Χ																
		F	20–79	56-72 in (142.2-182.9 cm)	Χ						Χ																			
Cherniack	h	М	15–79	35-85 in (88.9-215.9 cm)	Χ				Χ	Χ				Χ	Χ	Χ	Χ	Χ	Х											
(1972)	Ch	F	15–79	35-85 in (88.9-215.9 cm)	Χ				Χ	Χ				Χ	Χ	Χ	Χ	Χ	Χ											
Daharia (4004)	0	М	18–86	63.4-77.2 in (161-196 cm)	Χ				Χ	Χ	Χ				Χ		Χ													
Roberts (1991)	Ro	F	18–86	57.5-69.7 in (146-177 cm)	Χ				Χ	Χ	Χ				Χ		Χ													
		М	6–11	44-61 in (111.8-154.9 cm)	Х				Χ	Χ	X			Χ			Χ	Χ												
		М	12–24	55-76 in (139.7-193 cm)	Χ				Χ	Χ	Χ			Х			Х	Χ												
		М	25 +	62-77 in (157.5-195.6 cm)	Χ				Χ	Χ				Χ			X	Χ												
		М	25–85	62-77 in (157.5-195.6 cm)	Χ						Χ																			
Knudson (1983) 5	F	6–10	42-58 in (106.7-147.3 cm)	Χ				Χ		Χ			Х				Х	E												
	F	11–19	52-72 in (132.1-182.9 cm)	Χ				Χ		X			Χ				X	E												
		F	20–69	58-71 in (147.3-180.3 cm)	Χ				Χ	Χ				Х			X	X												
		F	20–88	58-71 in (147.3-180.3 cm)	Χ						X																			
		F	70 +	58–66 in (147.3–167.6 cm)	X				X	X				X			X	X												
		M	7–20	43.7–74.8 in (111–190 cm)	Χ				X	X					X				<u> </u>											
		M	7–20	43.7–74.8 in (111–190 cm)		Х	.,		X		X				X			<u> </u>		-										
Hsu (1979)	Η̈́S	М	7–20	43.7–74.8 in (111–190 cm)	· · ·		Х		X		X				X			ļ				ļ								
	_	F	7–18	43.7–74.8 in (111–190 cm)	Х				X	X					X				ļ											
		F	7–18	43.7–74.8 in (111–190 cm)		X	V		X						X			ļ		-										
		F	7–18	43.7–74.8 in (111–190 cm)			Х		Χ	Х	Х			Х	X															

Cron - (4004)	ب	М	15–91	61.8-76.4 in (157-194 cm)	X	X	Χ	X	X					X	X	
Crapo (1981) ර	F	17–84	57.5-70.1 in (146-178 cm)	X	Х	Χ	Х	Χ					X	Χ		
	ď	М	< 18	35.4-74 in (90-188 cm)	X	Х	Χ	Х		X	Х	Χ				Х
Warwick (1977)	F	< 18	35.4-70.1 in (90-178 cm)	X	Х	Χ	Х		Χ	Χ	Χ				Х	
Dalaar (4074)	0	М	4–17	43.3-67 in (110-170 cm)	X	Х	X	X	Х	Х			Х			
Polgar (1971)	Ъ	F	4–17	43.3-67 in (110-170 cm)	X	Х	Х	Χ	Х	Х			Х			
Chadad IIN av	siloble															

MORRIS (1971/1973)

Morris, James F., et. Al.: Spirometric Standards for Healthy Non-smoking Adults. American Review of Respiratory Disease 1971; vol 103(1): 57–67.

Morris, James F, et al.: Normal values for the ratio of one-second forced expiratory volume to forced vital capacity. American Review of Respiratory Disease 1973 Vol 108: 1000–1003.

MALE	FVC (L) = $0.148 * H[in] - 0.025 * A[yrs] - 4.241$
20–90 years,	FEV1 (L) = $0.092 * H[in] - 0.032 * A[yrs] - 1.26$
58–80 in. (147.3–203.2 cm)	FEF25-75% (L/sec) = $0.047 * H[in] - 0.045 * A[yrs] + 2.513$
	MALE, 20-79 years FEV1/FVC (L/sec) = (-0.3118 * H[in] - 0.2422 * A[yrs] + 107.12)/100
FEMALE	FVC = 0.115 * H[in] - 0.024 * A[yrs] - 2.852
20–90 years,	FEV1 = 0.089 * H[in] - 0.025 * A[yrs] - 1.932
56–72 in. (142.2–182.9 cm)	FEF25-75% = 0.06 * H[in] - 0.03 * A[yrs] + 0.551
	FEMALE, 20–79 years FEV1/FVC (L/sec) = (-0.0679 * H[in] - 0.1815 * A[yrs] + 88.7)/100

CHERNIACK (1972)

Cherniack, RM and Raber, MB: Normal Standards for Ventilatory Function Using an Automatic Wedge Spirometer American Review of Respiratory Disease 1972; Vol 106(1), p38–46.

MALE 15–79 years, 35–85 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, 35–85 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 (1991)

Roberts, Michael C. et. al: Reference values and prediction equations for normal lung function in non-smoking white

urban population. Thorax 1991; 4	6: 643–650
MALE 18–86 years, 63.4–77.2 in. (161–196 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. (146–177 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)	
	e in the Normal Maximum Expiratory Flow-Volume Curve with Growth and Aging. Disease 1983; 127(5–6): 725–734.
MALE 6–11 years, 44–61 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) = $0.0338 * H[cm] - 2.3197$ FEV1/FVC = $100.4389 - 0.0813 * H[cm]$
MALE 12–24 years, 55–76 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 FEV1/FVC = 100.4389 - 0.0813 * H[cm]
MALE 25+ years, 62–77 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) = $0.0579 * H[cm] - 0.0363 * A[yrs] - 4.5175$ MALE ≥ 25 and < 85 years FEV1/FVC = $86.6862 - 0.105 * A[yrs]$
FEMALE 6–10 years, 42–58 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 FEV1/FVC = 109.9739 - 0.1909 * H[cm] + 0.6655 * A[yrs]
FEMALE 11–19 years, 52–72 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) = $0.0279 * H[cm] + 0.1275 * A[yrs] - 2.8007$ FEV1/FVC = $109.9739 - 0.1909 * H[cm] + 0.6655 * A[yrs]$
FEMALE 20–69 years, 58–71 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 \geq 20 and $<$ 88 years FEV1/FVC = $121.6777 - 0.1852 * H[cm] - 0.1896 * A[yrs]$
FEMALE 70+ years, 58–66 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

HSU (1979)

Hsu, Katharine, et. al.: Ventilatory Functions of Normal Children and Young Adults – Mexican American, White and Black. J Pediatr 1979; 95: 14–23.

To determine the Predicted FEV1/FVC value for this predicted set QRS software uses: Pred FEV1/Pred FVC

MALE, White 7–20 years, 43.7–74.8 in. (111–190 cm)	FVC [L] = $(0.000358 * H[cm]^{3.18})/1000$ FEV1 [L] = $(0.000774 * H[cm]^{3})/1000$ PEFR [L/min] = $0.000335 * H[cm]^{2.79}$ FEF25-75% [L/min] = $0.000798 * H[cm]^{2.46}$
MALE, Black 7–20 years, 43.7–74.8 in. (111–190 cm)	FVC [L] = $(0.00107 * H[cm]^{2.93})/1000$ FEV1 [L] = $(0.00103 * H[cm]^{2.92})/1000$ PEFR [L/min] = $0.000174 * H[cm]^{2.92}$ FEF25-75% [L/min] = $0.000361 * H[cm]^{2.60}$
MALE, Mexican-American 7–20 years, 43.7–74.8 in. (111–190 cm)	FVC [L] = $(0.00106 * H[cm]^{2.97})/1000$ FEV1 [L] = $(0.00173 * H[cm]^{2.85})/1000$ PEFR [L/min] = $0.000769 * H[cm]^{2.63}$ FEF25-75% [L/min] = $0.000913 * H[cm]^{2.45}$
FEMALE, White 7–18 years, 43.7–74.8 in. (111–190 cm)	FVC [L] = $(0.00257 * H[cm]^{2.78})/1000$ FEV1 [L] = $(0.00379 * H[cm]^{2.68})/1000$ PEFR [L/min] = $0.00258 * H[cm]^{2.37}$ FEF25-75% [L/min] = $0.00379 * H[cm]^{2.16}$
FEMALE, Black 7–18 years, 43.7–74.8 in. (111–190 cm)	FVC [L] = $(0.000834 * H[cm]^{2.98})/1000$ FEV1 [L] = $(0.00114 * H[cm]^{2.89})/1000$ PEFR [L/min] = $0.000551 * H[cm]^{2.68}$ FEF25-75% [L/min] = $0.00145 * H[cm]^{2.34}$
FEMALE, Mexican-American 7–18 years, 43.7–74.8 in. (111–190 cm)	FVC [L] = $(0.00125 * H[cm]^{2.92})/1000$ FEV1 [L] = $(0.00161 * H[cm]^{2.85})/1000$ PEFR [L/min] = $0.000697 * H[cm]^{2.64}$ FEF25-75% [L/min] = $0.00120 * H[cm]^{2.40}$

CRAPO (1981)

Crapo, et. al: Reference Spirometric Values using Techniques and Equipment that Meet ATS Recommendations. American Review of Respiratory Disease 1981; 123: 659–664.

MALE	FVC(L) = 0.06 * H[cm] - 0.0214 * A[yrs] - 4.65
15–91 years,	FEV05 (L) = 0.0327 * H[cm] - 0.0152 * A[yrs] - 1.914
61.8–76.4 in. (157–194 cm)	FEV1 (L) = 0.0414 * H[cm] - 0.0244 * A[yrs] - 2.19
(20. 20. 00.)	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 = $(-0.13 * H[cm] - 0.152 * A[yrs] + 110.49)/100$ FEV3/FVC = $(-0.0627 * H[cm] - 0.145 * A[yrs] + 112.09)/100$
FEMALE 17–84 years, 57.5–70.1 in. (146–178 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)/100 FEV3/FVC = (-0.0937 * H[cm] - 0.163 * A[yrs] + 118.16)/100

WARWICK (1977/80)

Warwick, WJ: Pulmonary Function in Healthy Minnesota Children. Minnesota Medicine 1977; Supplement 60: 435–440. Warwick, WJ: Pulmonary Function in Healthy Minnesota Children. Minnesota Medicine March 1980; 191–195.

MALE < 18 YEARS, 35.4–74 in. (90–188 cm)	LnFVC (L) = 3.0131 * ln(H[cm]) - 14.0535 LnFEV1 (L) = 2.7572 * ln(H[cm]) - 12.9007 LnFEV1/FVC = -0.2679 * ln(H[cm]) + 1.2137 LnFEF50% (L/sec) = 2.1326 * ln(H[cm]) - 9.3589 LnFEF75% (L/sec) = 2.1534 * ln(H[cm]) - 10.2213 LnPEFR (L/sec)= 2.4991 * ln(H[cm]) - 10.7785 LnFET (s) = 1.6208 * ln(H[cm]) - 7.2327
FEMALE < 18 YEARS, 35.4–70.1 in. (90–178 cm)	LnFVC (L) = 2.9446 * ln(H[cm]) - 13.8007 LnFEV1 (L) = 2.7522 * ln(H[cm]) - 12.921 LnFEV1/FVC = -0.2126 * ln(H[cm]) + 0.9719 LnFEF50% (L/sec) = 2.1958 * ln(H[cm]) - 9.6458 LnFEF75% (L/sec) = 2.2961 * ln(H[cm]) - 10.8666 LnPEFR (L/sec) = 2.4369 * ln(H[cm]) - 10.535 LnFET (s) = 1.2423 * ln(H[cm] - 5.3288

POLGAR (1971)

Polgar and Promadhat: Pulmonary Function Testing in Children: Techniques and Standards 1971.

To determine the Predicted FEV1/FVC value for this predicted set QRS software uses: Pred FEV1/Pred FVC

MALE 4–17 years, 43.3–67 in. (110–170 cm)	FVC (L) = $0.0000044 * H[cm]^{2.67}$ FEV1 (L) = $0.0000021 * H[cm]^{2.8}$ FEF25–75% (L/min) = $-207.70 + 2.621 * H[cm]$ PEFR (L/min)= $-425.5714 + 5.2428 * H[cm]$ MVV = $1.276 * H[cm] - 99.507$
FEMALE 4–17 years, 43.3–67 in. (110–170 cm)	FVC (L) = $0.0000033 * H[cm]^{2.72}$ FEV1 (L) = $0.0000021 * H[cm]^{2.8}$ FEF25-75% (L/min) = $-207.70 + 2.621 * H[cm]$ PEFR (L/min)= $-425.5714 + 5.2428 * H[cm]$ MVV = $1.276 * H[cm] - 99.507$

ECCS/ERS (Quanjer 1993)

Quanjer, Ph.H, et. al: Lung Volumes and Ventilatory Flows: Official Statement of the European Respiratory Society. European Respiratory Journal 1992–1993; Supplement 15–16: 5–40.

MALE	FVC (L) = $0.0576 * H[cm] - 0.026*A[yrs] - 4.34$
18–70 years,	FEV1 (L) = $0.0430*H[cm] - 0.029*A[yrs] - 2.49$
61–76.8 in. (155–195 cm)	FEV1/FVC = (-0.180*A[yrs] + 87.21)/100 FEF25% (L/sec) = 0.0546 * H[cm] - 0.029 * A[yrs] - 0.47 FEF50% (L/sec) = 0.0379*H[cm] - 0.031 * A[yrs] - 0.35

For subjects aged 18–25 years the predicted mean is the same as for subjects 25 year.	FEF75% (L/sec) = $0.0261 * H[cm] - 0.026 * A[yrs] - 1.34$ FEF25-75% (L/sec) = $0.0194 * H[cm] - 0.043 * A[yrs] + 2.7$ PEFR (L/sec) = $.0614 * H[cm] - 0.043 * A[yrs] + 0.15$ FIVC = $0.0610 * H[cm] - 0.028 * A[yrs] - 4.65$
FEMALE 18–70 years, 57.1–70.9 in. (145–180 cm) For subjects aged 18–25 years the predicted mean is the same as for subjects 25 year.	FVC (L) = 0.0443 * H[cm] - 0.026*A[yrs] - 2.89 FEV1 (L) = 0.0395*H[cm] - 0.025*A[yrs] - 2.6 FEV1/FVC = (-0.190*A[yrs] + 89.1)/100 FEF25% (L/sec) = 0.0322 * H[cm] - 0.025 * A[yrs] + 1.6 FEF50% (L/sec) = 0.0245 * H[cm] - 0.025 * A[yrs] +1.16 FEF75% (L/sec) = 0.0105 * H[cm] - 0.025 * A[yrs] +1.11 FEF25-75% (L/sec) = 0.0125 * H[cm] - 0.034 * A[yrs] + 2.92 PEFR (L/sec) = .0550 * H[cm] - 0.030 * A[yrs] -1.11 FIVC = 0.0466 * H[cm] - 0.026 * A[yrs] - 3.28

NHANES III (1999)

Hankinson, John L., Odencrantz, John R., Fedan, Kathleen B.. Spirometric Reference Values from a Sample of the General U.S. Population. Am J Respir Crit Care Med 1999; Vol 159: 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) = $-0.5962 - 0.12357 * A[yrs] + 0.013135 * A[yrs]^2 + 0.00024962 * H[cm]^2$
MALE Caucasian 20–80 years, 62.2–76.4 in. (158– 194 cm)	$ \begin{aligned} & \text{FVC (L)} = -0.1933 + 0.00064 * \text{A[yrs]} - 0.000269 * \text{A[yrs]}^2 + 0.00018642 * \text{H[cm]}^2 \\ & \text{FEV1 (L)} = 0.5536 - 0.01303 * \text{A[yrs]} - 0.000172 * \text{A[yrs]}^2 + 0.00014098 * \text{H[cm]}^2 \\ & \text{FEV1/FVC} = (88.066 - 0.2066 * \text{A[yrs]})/100 \\ & \text{FEV6 (L)} = 0.1102 - 0.00842 * \text{A[yrs]} - 0.000223 * \text{A[yrs]}^2 + 0.00018188 * \text{H[cm]}^2 \\ & \text{FEV1/FEV6} = (87.34 - 0.1382 * \text{A[yrs]})/100 \\ & \text{FEF25-75\% (L/Sec)} = 2.7006 - 0.04995 * \text{A[yrs]} + 0.00010345 * \text{H[cm]}^2 \\ & \text{PEF (L/Sec)} = 1.0523 + 0.08272 * \text{A[yrs]} - 0.001301 * \text{A[yrs]}^2 + 0.00024962 * \\ & \text{H[cm]}^2 \end{aligned} $
FEMALE Caucasian 8–17 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 18–80 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)	$ \begin{aligned} & \text{FVC (L)} = -0.4971 - 0.15497 * \text{A[yrs]} + 0.007701 * \text{A[yrs]}^2 + 0.00016643 * \text{H[cm]}^2 \\ & \text{FEV1 (L)} = -0.7048 - 0.05711 * \text{A[yrs]} + 0.004316 * \text{A[yrs]}^2 + 0.00013194 * \\ & \text{H[cm]}^2 \\ & \text{FEV1/FVC} = (89.239 - 0.1828 * \text{A[yrs]})/100 \\ & \text{FEV6 (L)} = -0.5525 - 0.14107 * \text{A[yrs]} + 0.007241 * \text{A[yrs]}^2 + 0.00016429 * \\ & \text{H[cm]}^2 \\ & \text{FEV1/FEV6} = (88.841 - 0.1305 * \text{A[yrs]})/100 \\ & \text{FEF25-75\% (L/Sec)} = -1.1627 + 0.12314 * \text{A[yrs]} + 0.00010461 * \text{H[cm]}^2 \\ & \text{PEF (L/Sec)} = -0.2684 - 0.28016 * \text{A[yrs]} + 0.018202 * \text{A[yrs]}^2 + 0.00027333 * \\ & \text{H[cm]}^2 \end{aligned} $
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 - 0.02309 * A[yrs] + 0.00013194 * H[cm] ² 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) 8–17 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) 18–80 years, 53.5–70.9 in. (136–180 cm)	$ \begin{aligned} & \text{FVC (L)} = -0.3039 + 0.00536 * \text{A[yrs]} - 0.000265 * \text{A[yrs]}^2 + 0.00013606 * \text{H[cm]}^2 \\ & \text{FEV1 (L)} = 0.3433 - 0.01283 * \text{A[yrs]} - 0.000097 * \text{A[yrs]}^2 + 0.00010846 * \text{H[cm]}^2 \\ & \text{FEV1/FVC} = (91.655 - 0.2039 * \text{A[yrs]})/100 \\ & \text{FEV6 (L)} = -0.1981 + 0.00047 * \text{A[yrs]} - 0.00023 * \text{A[yrs]}^2 + 0.00013497 * \text{H[cm]}^2 \\ & \text{FEV1/FEV6} = (91.229 - 0.1558 * \text{A[yrs]})/100 \\ & \text{FEF25-75\% (L/Sec)} = 2.0828 - 0.03793 * \text{A[yrs]} + 0.00008572 * \text{H[cm]}^2 \\ & \text{PEF (L/Sec)} = 1.3597 + 0.03458 * \text{A[yrs]} - 0.000847 * \text{A[yrs]}^2 + 0.00019746 * \\ & \text{H[cm]}^2 \end{aligned} $
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 = $(89.388 - 0.1534 * A[yrs])/100$

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FEF25-75\% (L/Sec) = 1.7503 - 0.05018 * A[yrs] + 0.00014473 * H[cm]<sup>2</sup>
                                    PEF (L/Sec) = 0.087 + 0.0658 * A[yrs] - 0.001195 * A[yrs]^2 + 0.00030243 *
                                    H[cm]<sup>2</sup>
                                    FVC(L) = -1.2507 + 0.07501 * A[yrs] + 0.00014246 * H[cm]^{2}
FEMALE, Hispanic (Mexican-
                                    FEV1 (L) = -0.9641 + 0.0649 * A[yrs] + 0.00012154 * H[cm]^2
American)
                                    FEV1/FVC = (92.360 - 0.2248 * A[yrs])/100
8-17 years, 44.9-67.7 in. (114-
                                    FEV6 (L) = -1.241 + 0.07625 * A[yrs] + 0.00014106 * H[cm]^2
172 cm)
                                    FEV1/FEV6 = (91.644 - 0.1670 * A[yrs])/100
                                    FEF25-75\% (L/Sec) = -2.1825 + 0.42451 * A[yrs] - 0.012415 * A[yrs]<sup>2</sup> +
                                    0.0000961 * H[cm]^2
                                    PEF (L/Sec) = -3.2549 + 0.47495 * A[yrs] - 0.013193 * A[yrs]^2 + 0.00022203 *
                                    H[cm]<sup>2</sup>
FEMALE, Hispanic (Mexican-
                                    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
American)
                                    FEV1/FVC = (92.36 - 0.2248 * A[yrs])/100
18-80 years, 53.5-67.7 in. (136-
                                    FEV6 (L) = 0.2033 + 0.0002 * A[yrs] - 0.000232 * A[yrs]^2 + 0.00014106 * H[cm]^2
172 cm)
                                    FEV1/FEV6 = (91.664 - 0.167 * A[yrs])/100
                                    FEF25-75\% (L/Sec) = 1.7456 - 0.01195 * A[yrs] - 0.000291 * A[yrs]<sup>2</sup> + 0.0000961
                                    * H[cm]<sup>2</sup>
                                    PEF (L/Sec) = 0.2401 + 0.06174 * A[yrs] - 0.001023 * A[yrs]^2 + 0.00022203 *
                                    H[cm]<sup>2</sup>
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ZAPLETAL (1987)

Zapletal, A.: Lung Function in Children and Adolescents. Methods, Reference Values. Progress in Respiration Research Vol 22 (1987)

MALE 6–18 years, 42.1–71.7 in. (107–182 cm)	$ \begin{aligned} & \text{FVC (L)} = 10^{\left(-2.9236 + 2.936 * \log(\text{H[cm]})\right)} / 1000 \\ $
FEMALE 6–18 years, 42.1–71.7 in. (107–182 cm)	$ \begin{aligned} & \text{FVC (L)} = 10 ^{(-2.704 + 2.8181 * \log(\text{H[cm]}))} / 1000 \\ $

QUANJER (1995)

Quanjer, PhH, et. al.: Spirometric Values for White European Children and Adolescents: Polgar Revisited, Pediatric Pulmonology 1995, 19: 135–142.

MALE	LnFVC[I] = -1.2782 + [1.3731 + 0.0164 * A[yrs]] * H[m]
6–18 years,	LnFEV1[I] = -1.2933 + [1.2669 + 0.0174 * A[yrs]] * H[m]

43.3–80.7 in. (110–205 cm)	FEV1/FVC = 86.2
FEMALE 6–18 years,	LnFVC [I] = $-1.4507 + [1.4800 + 0.0127 * A[yrs]] * H[m]$ LnFEV1 [I] = $-1.5974 + [1.5016 + 0.0119 * A[yrs]] * H[m]$
43.3–72.8 in. (110–185 cm)	FEV1/FVC = 88.9

WANG (1993)

Wang, Xiaobin, et.al,: Pulmonary Function Between 6 and 18 Years of Age. Pediatric Pulmonology 1993; 15: 75–88.

 MALE, White
 LnFVC(L) = a + β*InHt[m]

 6–18 years,
 LnFEV1(L) = a + β*InHt[m]

 43.3–74.8 in. (110–190 cm)
 LnFEV1/FVC(L) = a + β*InHt[m]

 LnFEF25–75%(L/s) = a + β*InHt[m]

MALE, Black

6–18 years, Refer to the Wang look-up tables for α and β . 47.2–74.8 in. (120–190 cm)

FEMALE, White

6–18 years, 43.3–70.9 in. (110–180 cm)

FEMALE, Black

6–18 years,

47.2-70.9 in. (120-180 cm)

Wang look-up tables:

MALE, White, 6–18 years

Age [years]	<u>FVC</u>		FEV1		FEV1/FVC		FEF25-75%	
	а	β	а	β	а	β	а	β
6	-0.024	2.470	-0.109	2.252	-0.078	-0.248	-	-
7	-0.018	2.489	-0.104	2.270	-0.086	-0.220	-	-
8	0.005	2.443	-0.089	2.257	-0.091	-0.199	0.264	1.505
9	0.017	2.426	-0.063	2.197	-0.086	-0.206	0.308	1.443
10	0.030	2.407	-0.057	2.212	-0.081	-0.209	0.290	1.557
11	0.009	2.468	-0.093	2.324	-0.101	-0.147	0.242	1.738
12	-0.061	2.649	-0.161	2.512	-0.101	-0.133	0.165	1.982
13	-0.175	2.924	-0.292	2.843	-0.116	-0.085	0.007	2.396
14	-0.219	3.060	-0.329	2.983	-0.106	-0.087	0.014	2.483
15	-0.079	2.859	-0.141	2.709	-0.060	-0.155	0.241	2.163
16	0.104	2.591	0.062	2.409	-0.045	-0.178	0.503	1.764
17	0.253	2.374	0.262	2.099	0.008	-0.272	0.762	1.368
18	0.296	2.316	0.251	2.129	-0.054	-0.170	0.678	1.528

MALE, Black, 6–18 years

Age [years]	FVC		FEV1		FEV1/FVC		FEF25-75%	
	а	β	а	β	а	β	а	β
6	-0.088	1.961	-0.166	1.723	-0.091	-0.152	-	-
7	-0.040	2.040	-0.122	1.846	-0.091	-0.153	-	-
8	-0.094	2.323	-0.225	2.271	-0.118	-0.104	0.097	1.544
9	-0.074	2.308	-0.142	2.059	-0.079	-0.218	0.255	1.248
10	-0.110	2.417	-0.157	2.117	-0.047	-0.303	0.230	1.428
11	-0.138	2.453	-0.176	2.166	-0.048	-0.263	0.256	1.438
12	-0.224	2.710	-0.307	2.548	-0.084	-0.162	0.085	1.936
13	-0.342	2.975	-0.486	2.962	-0.141	-0.018	-0.121	2.476
14	-0.337	3.035	-0.472	3.010	-0.123	-0.050	-0.115	2.536
15	-0.226	2.889	-0.318	2.789	-0.070	-0.140	0.170	2.120
16	0.058	2.425	0.074	2.140	0.018	-0.289	0.663	1.299
17	0.148	2.310	0.053	2.223	-0.095	-0.087	0.505	1.618
18	0.152	2.341	0.130	2.121	-0.041	-0.190	0.859	1.053

FEMALE, White, 6–18 years

Age [years]	<u>FVC</u>		FEV1		FEV1/FVC		FEF25-75%	
	а	β	а	β	а	β	а	β
6	-0.013	2.007	-0.109	1.949	-0.097	-0.055	-	-
7	0.062	2.385	-0.144	2.243	-0.084	-0.132	-	-
8	-0.055	2.381	-0.137	2.239	-0.079	-0.152	0.247	1.668
9	-0.039	2.351	-0.123	2.222	-0.084	-0.128	0.254	1.710
10	-0.068	2.458	-0.161	2.364	-0.092	-0.097	0.195	1.933
11	-0.120	2.617	-0.223	2.558	-0.102	-0.061	0.161	2.091
12	-0.174	2.776	-0.264	2.709	-0.090	-0.067	0.185	2.120
13	-0.061	2.576	-0.153	2.535	-0.093	-0.040	0.294	1.976
14	0.139	2.208	0.046	2.178	-0.096	-0.026	0.450	1.711
15	0.210	2.099	0.148	2.008	-0.062	-0.093	0.581	1.486
16	0.226	2.097	0.181	1.972	-0.048	-0.120	0.654	1.366
17	0.214	2.146	0.176	1.992	-0.038	-0.154	0.688	1.290
18	0.195	2.179	0.152	2.031	-0.069	-0.096	0.520	1.622

FEMALE, Black, 6-18 years

Age [years]	<u>FVC</u>		FEV1		FEV1/FVC		FEF25-75%	
	а	β	а	β	а	β	а	β
6	-0.172	2.117	-0.288	2.182	-0.109	0.059	-	-
7	-0.135	2.132	-0.250	2.158	-0.104	-0.030	-	-
8	-0.176	2.362	-0.276	2.295	-0.103	-0.066	-0.283	2.990
9	-0.200	2.452	-0.294	2.330	-0.097	-0.104	0.025	2.062
10	-0.230	2.571	-0.344	2.507	-0.120	-0.043	0.051	2.028
11	-0.204	2.526	-0.308	2.460	-0.089	-0.105	0.078	2.006
12	-0.107	2.342	-0.219	2.312	-0.115	-0.021	0.225	1.804
13	-0.042	2.294	-0.117	2.196	-0.051	-0.148	0.418	1.504
14	0.105	2.021	0.041	1.920	-0.063	-0.103	0.574	1.257
15	0.253	1.787	0.203	1.662	-0.043	-0.139	0.599	1.281
16	0.111	2.098	0.129	1.824	-0.022	-0.188	0.653	1.175
17	0.205	1.930	0.273	1.547	0.048	-0.342	0.713	1.067
18	-0.042	2.423	-0.084	2.259	-0.197	0.145	-0.209	2.896

Lung Age Calculation

Lung age is calculated for patients 20-84 years old. *Lung age is equal to the predicted FEV1 that matches the patient's actual FEV1.

For example:

Predicted equation: Crapo

Patient demographics: Height: 5ft 10in

Age: 46 years
Gender: Male
Race: Caucasian
Actual FEV1: 4.49L
Predicted FEV1: 4.05L

Patient's Lung Age: 28 years

Based on Crapo's predicted equation, the patient's actual FEV1 (4.49L) is equal to the predicted FEV1 of a 28 year old. Therefore, the patient's lung age is 28 years old.

Note: Lung age may differ based on the predicted equation selected.

* Morris JF, Temple W.; Spirometric "lung age" estimation for motivating smoking cessation. Prev Med. 1985 Sep: 14)5):655-62.

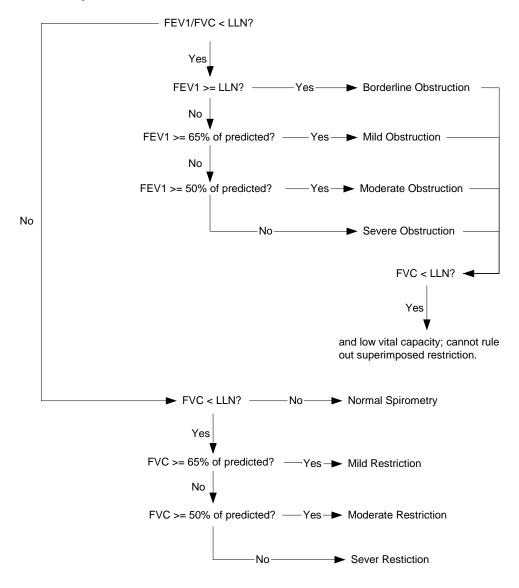
Note: "Lung age not available" dialog box may appear when certain predictors and ages are selected because they are not supported for this function.

Spirometry Interpretation

Note: A disclaimer is provided on all spirometry reports: "All test results should be evaluated by a qualified physician."

Enright (1997)

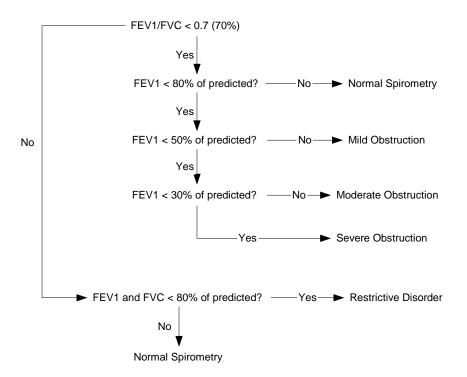
Office Spirometry: A Practical Guide to the Selection and Use of Spirometers by Paul L. Enright, M.D. Robert E. Hyatt M.D. 1987



BTS-NICE (2004-05)

The British Thoracic Society (BTS) COPD Consortium: Spirometry in Practice: A Practical Guide to Using Spirometry in Primary Care. Second Edition. April 2005.

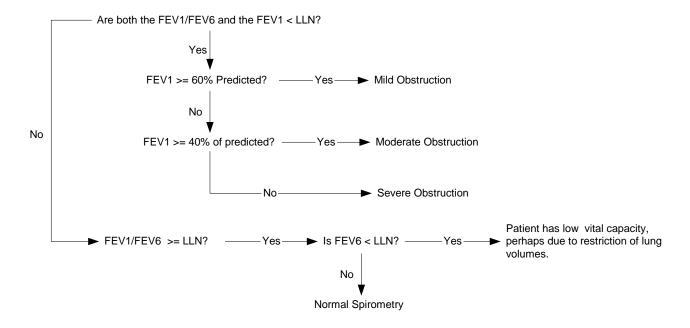
National Institute for Clinical Excellence (NICE): Chronic obstructive pulmonary disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care. Clinical Guideline 12. February 2004. Developed by the National Collaborating Centre for Chronic Conditions.



NLHEP (2000)

Ferguson GT, et. al.: Office Spirometry for Lung Health Assessment in Adults. A Consensus Statement from the National Lung Health Education Program (NLHEP). Chest April 2000; Volume 117: 1146–1161.

FVC is used in place of FEV6 when the predicted study does not provide an FEV6 predicted value/LLN.



ATS/ERS (2005)

ATS/ERS Task Force: Interpretive strategies for lung function tests. Standardisation of spirometry. Eur. Respir. J., Nov 2005; 26: 948-968.



Oximetry

Note: the information in this chapter applies to oximetry tests acquired using a SpirOxCard.

Oximetry Cautions & Warnings

Warnings

- The Oximeter is intended as an adjunct in patient assessment. It must be used with respect to the patient's clinical and historical picture.
- Do NOT use the Oximeter as an apnea monitor.
- Use only sensors provided by QRS Diagnostic with QRS SpirOxCard. Use of other manufacturer's sensors may adversely affect device performance. Check sensor application site frequently to determine circulation, positioning, and skin sensitivity. Tissue damage can result from incorrect application of the sensor.
- Do not use QRS SpirOxCard as a continuous monitoring device. There are no visual or audible alarms. Readings are for Spot Check and Record purposes only.
- To avoid the risk of cross contamination the sensor must be cleaned between patient uses with isopropyl alcohol. All tape residues must also be removed.
- Do not use the SpirOxCard during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The SpirOxCard may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- An Oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
- External dyes (fingernail polish, paint, etc.) may reduce light transmission and thereby affect SpO2 accuracy.
- The SpirOxCard is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhaemoglobin or methemoglobin may affect the accuracy of the measurement.
- The following factors may degrade pulse SpirOxCard performance: Excessive ambient light, incorrect sensor type, excessive motion, poor pulse quality, electrosurgical interference, venous pulsations, arterial catheters, blood pressure cuffs, infusion lines, moisture in the sensor, improperly attached sensor, sensor not at heart level, anemia or low hemoglobin concentrations.
- Cardiogreen and other intravascular dyes, depending on the concentration, may affect the accuracy of the SpO2 measurement.
- Confirm the accuracy of real-time clock settings each time the SpirOxCard is used to collect patient trend data.
- The SpirOxCard may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).

Cautions

- The SpirOxCard must record an accurate pulse before SpO2 readings can be deemed accurate.
- If you are unable to achieve stable readings discontinue use.
- Optimally the index, middle or ring finger of the left hand should be used for Oximetry testing. Keep the fingernail facing the light source and ensure that long fingernails are not interfering with proper finger position. The finger clip should fit securely onto the finger.
- Carefully read the instructional insert, if provided, with the sensor before use.
- The SpirOxCard must be repaired by trained personnel only.
- Do not immerse the SpirOxCard or sensors in liquid to clean.
- Do not use abrasive or caustic cleaning agents on the sensors.
- Do not sterilize sensors.

Oximetry Indications for Use

Patient Population: Male/Female, Patient's weighing greater than 30kg or 66lb

Device Functionality: Oximetry

Oximetry Parameters: %SpO2 and Pulse Rate (bpm) Environment of Use: Hospital, Clinical and Home Use

Oximetry Getting Started

- 1. Insert the SpirOxCard into the PC Card Reader.
- 2. Connect Finger Clip Attach the data end of the finger clip connector to the 9 Pin connector on the PC Card. Insert a finger (preferably the index, middle or ring finger of the left hand) into the finger clip sensor until the end of the finger reaches the finger stop.

Performing an Oximetry Test

Select patient and then select:

- Test | Quick Test | Oximetry Displays pulse and %SpO2.
- **Test | Oximetry** Displays and optionally records pulse and %SpO2 for up to 24 hours.

Quick Test

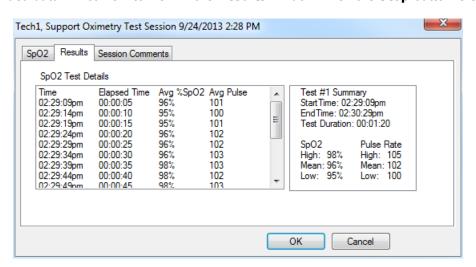
- 1. Insert the patient's finger into the clip sensor until the end of the finger reaches the finger stop.
- 2. Place the patient in a relaxed position.
- 3. Select **Test** | **Quick Test** | **Oximetry**
- 4. Select **OK** to end the test.

Standard Test

- 1. Insert the patient's finger into the clip sensor until the end of the finger reaches the finger stop.
- 2. Place the patient in a relaxed position.
- 3. A patient must be selected.



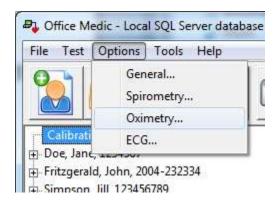
- 4. Select **Test | Oximetry** or the icon
- 5. Select the **Record** button to begin recording. Data will be saved at the interval chosen in **Options** | **Oximetry** | **General**.
- 6. Recorded data will come into view in the **Results** window when the **Stop** button is engaged.



Select **Session Comments** to enter text relevant to the session. Select **SpO2** to view real-time data or select **OK** to end session. Select **Cancel** to end session without saving data.

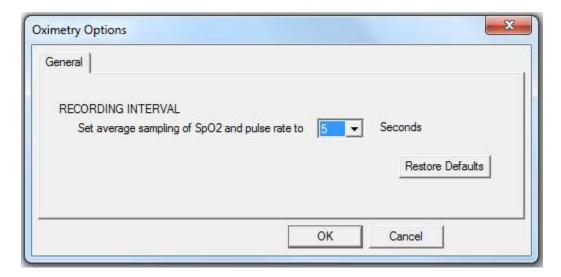
Oximetry Options

Select **Options** | **Oximetry** from the menu bar.



Recording Interval

Used to save the %SpO2 and pulse rate data to the database. This can be set at 5, 10, 30 or 60-second increments.



Oximeter Calibration

The SpirOxCard sensors are calibrated during manufacturing. To determine the calibration status contact QRS Technical Support.

Electrocardiography

ECG Cautions and Warnings

Warnings

- The computerized interpretation is only valid when used in conjunction with clinical findings. All computer generated tracings and interpretations must be confirmed by a qualified physician. Test interpretations are intended for the physician's use only. All ECG numerical and graphical data should be evaluated with respect to the patient's clinical and historical picture.
- The ECG Device is not intended for use in a sterile environment. Do not use for direct cardiac application.
- The ECG device is reusable.
- Do not attempt to insert the ECG device (including patient cables) into an electrical outlet.



- Avoid patient movement to reduce artifact. The ECG Device is for acquiring resting ECGs only. The device should not be used for stress testing.
- Though false positive errors will intentionally outnumber false negative errors, both will occur, thus the necessity for over reading by a qualified physician of any computer-interpreted ECG. The computer interpretation does not produce a definitive diagnosis.
- Ensure electrodes are connected only to patient.
- Conductive parts of electrodes and connectors, including neutral electrode, should not contact other conductive parts including earth.
- Select a three lead view during defibrillation to ensure signals are clearly separated following electrode polarization.
- Defibrillator warnings:
 - Do not touch the patient during defibrillation.
 - Do not touch the defibrillator's paddle-electrode surface when discharging the defibrillator.
 - Keep defibrillation electrodes well clear of other electrodes or metal parts in contact with the patient.
 - Do not touch the patient, bed, or any conductive material in contact with the patient during defibrillation.

Cautions

- For diagnostic ECG according to the requirements of the AAMI EC11:1991 standard, use factory
 default settings. ECG diagnosis should be based on a printed 3x4 report with software filters off,
 and using a 1:1 scale 300dpi printer.
- The Universal ECG is designed for use with electrodes that comply with AAMI EC12:2000.



- Reseal electrode pouch after opening to prevent dehydrating.
- Suggested maximum electrode duration is 8 hours.
- Do not clean the case with alcohol.
- Do not saturate or immerse the case with liquid during cleaning.
- Do not sterilize ECG device.

ECG Indications for Use: Receipt, Storage, Viewing, Printing and Interpretive Analysis of 12 channel simultaneous ECGs

Patient Population: Adult Male/Female

Environment of Use: Hospital, Clinical and Home Use

ECG Getting Started

Connecting the 6 or 12 Channel ECG device to your PC:



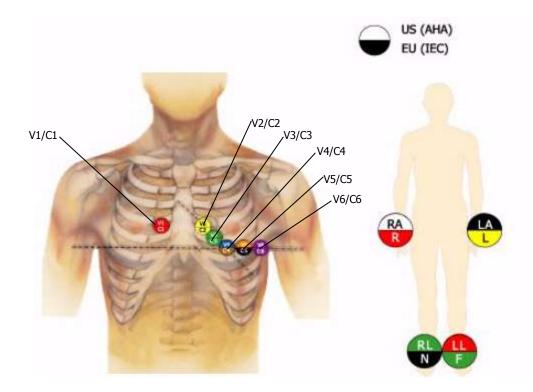
There are three methods for connecting the ECG device to the PC:

- **Compact Flash (CF) Card (optional):** Connect the serial connector of the ECG device to the CF Card. Insert the CF Card into the CF to PC Card adapter and then insert into the PC Card Reader of your PC.
- **RS232 Serial Port:** You must have an RS232 port with a 128-byte minimum FIFO buffer.
- **USB:** The Office Medic software supports the ECG Device when connecting to a USB port, when using the supplied USB/Serial Converter or using a Universal ECG with a direct USB connection.

Note: Supplementary Power: Some serial ports do not provide enough power for the Universal ECG. In this situation we recommend you use the supplied USB-DC power boost cable (P/N 5000-1914) or the PS/2-DC power boost cable (P/N 5000-1897) to supplement the power supplied to the Universal ECG. These cables connect from a USB, keyboard or mouse port to a socket on the Universal ECG's Serial (DB9) connector.

Performing an ECG Test

- 1. Connect the ECG device to the PC.
- 2. Select a patient from the Patient Directory.
- 3. Shave electrode sites if necessary. Thoroughly clean the area and let dry.
- 4. Prep skin by briskly rubbing with gauze, being careful not to break or damage the skin.
- 5. Remove electrodes from backing.
- 6. Apply each electrode, adhesive side down to desired site.
- 7. For positive electrode contact, start from outer edge and run your finger around the electrode several times, working toward the center.
- 8. Connect the lead wires to the patient ensuring correct lead placement. Excess movement can cause artifact. Patient should be stable.





9. Click the ECG icon

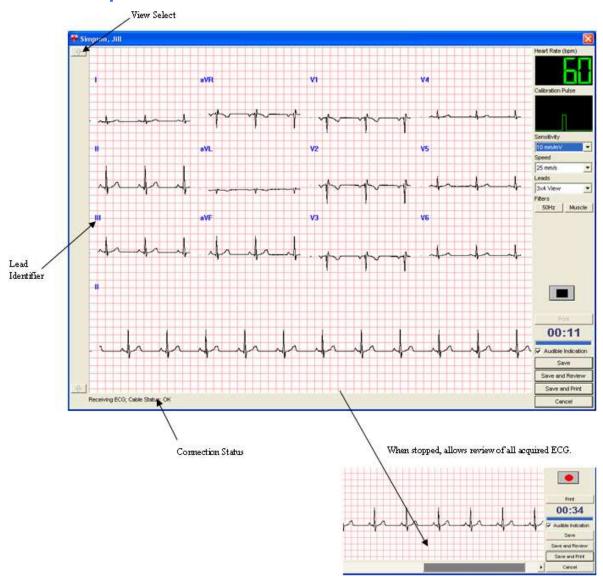
on the Toolbar, or select **Test** | **ECG**.



The acquisition window will appear on the screen with the patients real-time ECG displayed.

Warning: Avoid patient movement to reduce artifact. The ECG Device is for acquiring resting ECGs only. The device should not be used for stress testing.

About the Acquisition Window

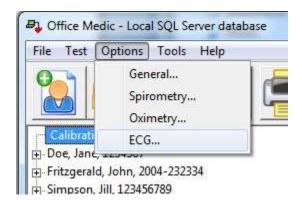


View Select		Scrolls through the different leads when you view the 3 or 6 lead sets.
Lead Identifiers		Identifies each of the 12 leads. If a lead is disconnected (leads off) then a red circle with a diagonal line is placed over the lead identifier.
Connection Status		Displays the status of the connected ECG cable.
Heart Rate (bpm)	Heart Rate (bpm)	Displays the active Heart Rate of the patient.

Provides a visual indication of the combined sensitivity (1mV vertical height) and speed (100ms horizontal width). Sensitivity Changes the number of millimeters that represent one millivolt. The available options are 5mm/mV, 10mm/mV, and 20mm/mV. Speed 25 mm/s Changes the number of millimeters that are passed in one second. The available options are 12.5mm/s, 25mm/s and 50mm/s. Leads 3x4 View View 3, 6 or 12 leads, or 3x4 view. The ability to select between the Limb leads and the Chest leads is also available when viewing 3 or 6 leads at a time. A Custom Lead group can be defined in the ECG Options. Power Filter 60Hz Turns the Main filter on and off. Note: the default frequency of the Main filter is set in the ECG Options. Print Stop Stops the real time recording to view the previous 15 minutes of ECG. The user can select the desired 10 seconds of ECG and select Save to save and exit the test. Record Resumes recording data. Once selected, all paused data will no longer be available. Print Allows you to print all or a selected portion of the stopped ECG. This printed report is not intended for diagnostic use, or as a patient record - for that purpose print from the review window, or use "Save and Print." Status Bar Represents whether 10 seconds of valid ECG data has been received. When the status bar is full, the Save button is activated and data can then be saved. Audible Indication Save Save Save Save Save Save Saves the test and alunches a review of the results. Save and Print Save the test and automatically prints a report or PDF (optional). Cancel Closes the test without saving.			
The available options are 5mm/mV, 10mm/mV, and 20mm/mV. Speed 25 mm/s Chages the number of millimeters that are passed in one second. The available options are 12.5mm/s, 25mm/s and 50mm/s. Leads 3x4 View View 3, 6 or 12 leads, or 3x4 view. The ability to select between the Limb leads and the Chest leads is also available when viewing 3 or 6 leads at a time. A Custom Lead group can be defined in the ECG Options. Power Filter 60Hz Turns the Main filter on and off. Note: the default frequency of the Main filter is set in the ECG Options. Muscle Filter Muscle Turns the Muscle filter on and off. Stop Stops the real time recording to view the previous 15 minutes of ECG. The user can select the desired 10 seconds of ECG and select Save to save and exit the test. Record Resumes recording data. Once selected, all paused data will no longer be available. Print Allows you to print all or a selected portion of the stopped ECG. This printed report is not intended for diagnostic use, or as a patient record - for that purpose print from the review window, or use "Save and Print." Elapsed Time Ou:11 Minutes and seconds of current ECG acquisition. Status Bar Represents whether 10 seconds of valid ECG data has been received. When the status bar is full, the Save button is activated and data can then be saved. Audible Indication Audibly indicates a "leads off" status or QRS detection as selected in "options." Save Save Save Save Saves the test and closes the window. Save and Print Save and Print Save and Print Save and Print Saves the test and launches a review of the results.			, ,
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Indication Print Print Print Allows you to print all or a selected portion of the stopped ECG. This printed report is not intended for diagnostic use, or as a patient record - for that purpose print from the review window, or use "Save and Print." Elapsed Time O0:11 Minutes and seconds of current ECG acquisition. Represents whether 10 seconds of valid ECG data has been received. When the status bar is full, the Save button is activated and data can then be saved. Audible Indication Audibly indicates a "leads off" status or QRS detection as selected in "options." Save Save Save Save and Review Save and Print Save steetest and automatically prints a report or PDF (optional).	Stop		ECG. The user can select the desired 10 seconds of ECG and
This printed report is not intended for diagnostic use, or as a patient record - for that purpose print from the review window, or use "Save and Print." Minutes and seconds of current ECG acquisition. Represents whether 10 seconds of valid ECG data has been received. When the status bar is full, the Save button is activated and data can then be saved. Audible Indication Audible Indication Save Save Save Save Save Save Save Saves the test and closes the window. Save and Review Save and Print Save and Print Save and Print Save sthe test and automatically prints a report or PDF (optional). Class the test without assistance.	Record		- · · · · · · · · · · · · · · · · · · ·
Represents whether 10 seconds of valid ECG data has been received. When the status bar is full, the Save button is activated and data can then be saved. Audible Indication Audibly indicates a "leads off" status or QRS detection as selected in "options." Save Save Save Saves the test and closes the window. Save and Review Saves the test and launches a review of the results. Save and Print Save and Print Saves the test and automatically prints a report or PDF (optional).	Print	Print	This printed report is not intended for diagnostic use, or as a patient record - for that purpose print from the review window,
received. When the status bar is full, the Save button is activated and data can then be saved. Audible Indication Audibly indicates a "leads off" status or QRS detection as selected in "options." Save Save Save Save Save Saves the test and closes the window. Save and Review Save and Review Saves the test and launches a review of the results. Save and Print Save and Print Saves the test and automatically prints a report or PDF (optional).	Elapsed Time	00:11	Minutes and seconds of current ECG acquisition.
Indication selected in "options." Save Save Save and Review Save and Review Save and Print Saves the test and launches a review of the results. Save and Print Saves the test and automatically prints a report or PDF (optional).	Status Bar		received. When the status bar is full, the Save button is
Save and Review Save and Print		✓ Audible Indication	
Save and Print Save and Print Save and Print Saves the test and automatically prints a report or PDF (optional). Saves the test without available.	Save	Save	Saves the test and closes the window.
(optional).		Save and Review	Saves the test and launches a review of the results.
Cancel Closes the test without saving.	Save and Print	Save and Print	
	Cancel	Cancel	Closes the test without saving.

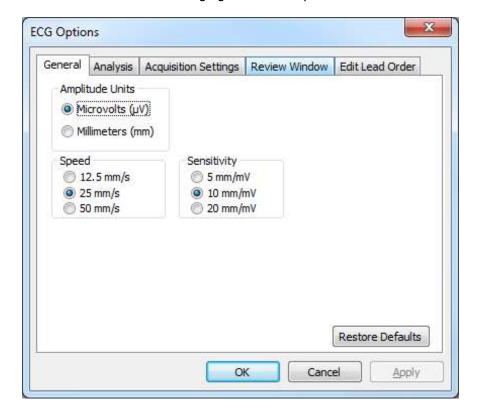
ECG Options

Select **Options** | **ECG**.



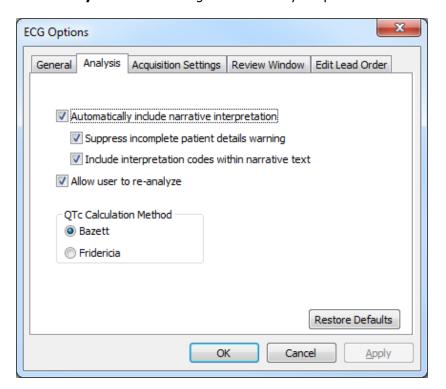
General Tab

Select **General** to set or change general ECG Options.



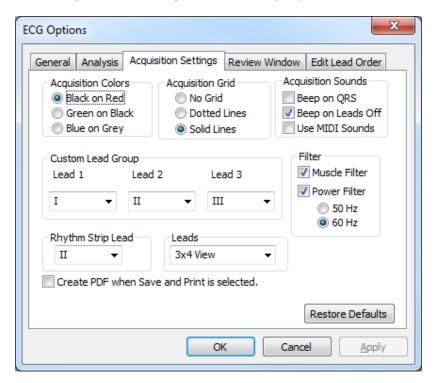
Analysis Tab

Select **Analysis** to set or change the ECG analysis options.



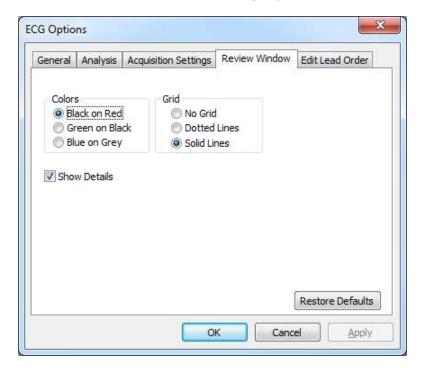
Acquisition Settings Tab

Select **Acquisition Settings** to set or change options available for the acquisition window.



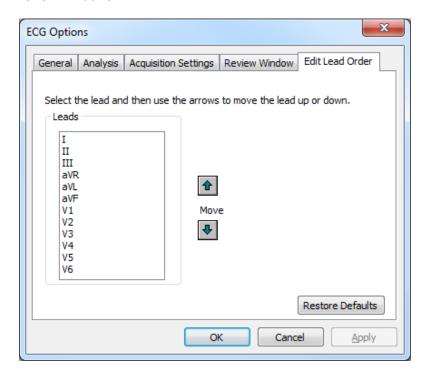
Review Window Tab

Select **Review Window** to set or change options available for the ECG Review Window.



Edit Lead Order Tab

Select **Edit Lead Order** to change the lead order. Note, the setting applies to both the acquisition and review windows.



Reviewing an ECG

Reviewing an ECG within the ECG Review Window

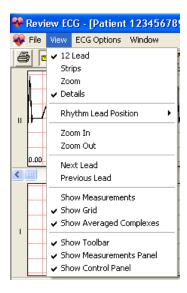


File Menu



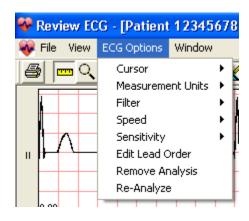
Menu Item	Icon	Function
Save	NA	Saves changes.
Printer Setup	NA	Opens the print setup window for the default printer.
Print		Prints the ECG test.
Print Preview	NA	Previews the hardcopy report.
Print to File	NA	Creates an image file (JPEG, TIFF, or PDF) of the hardcopy report.
Close	NA	Closes open tests without closing the review window.
Exit	NA	Closes open tests and exits the review window.

View Menu



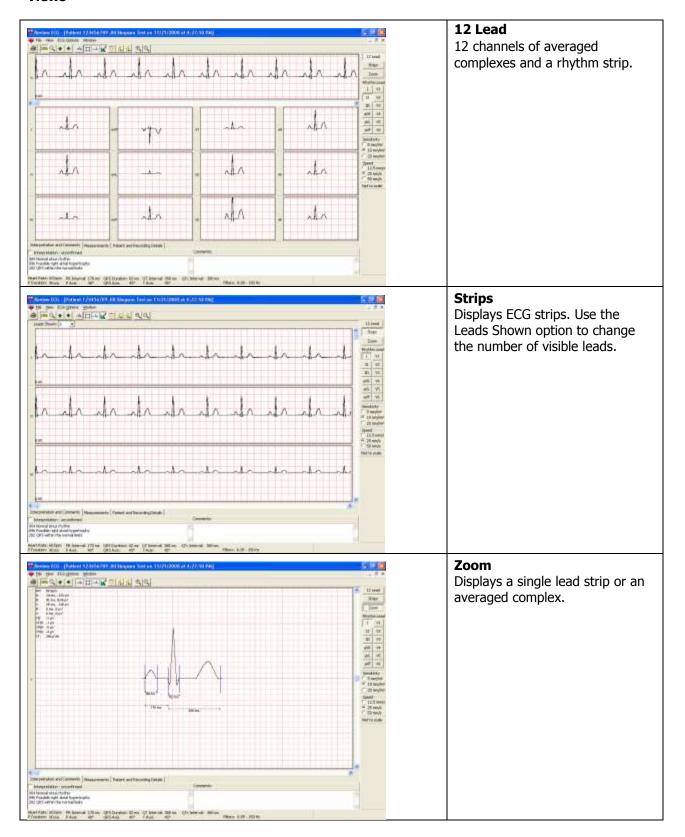
Menu Item	Icon	Function
12 Lead	12 Lead	Selects the 12 lead view of the ECG. See $\frac{12 \text{ Lead View}}{12 \text{ Lead View}}$ for an example.
Strips	Strips	Selects the three lead strip view of the ECG. See <u>ECG</u> <u>Strips View</u> for an example.
Zoom	Zoom	Selects the zoom view of the ECG. See <u>Zoom View</u> for an example.
Details		Displays the interpretation, comments, and detailed measurements. See <u>Details View</u> for an example.
Rhythm Lead Position	NA	Toggles the Rhythm Lead to the top or the bottom of the screen (12 Lead view only).
Zoom In	⊕(Enlarges the ECG.
Zoom Out	્	Reduces the ECG.
Next Lead/ Previous Lead	4 +	Scrolls through recorded leads.
Show Measurements	~+h	Turns the averaged complex's measurements On and OFF.
Show Grid	<u> </u>	Turns the grid lines on and off.
Show Averaged Complexes	N	Switches between averaged complexes and 10 second lead strip displays.
Show Toolbar	NA	Displays or removes the toolbar.
Show Measurements Panel	NA	Displays or removes the summary measurements panel.
Show Control Panel	NA	Displays or removes the Control Panel.

ECG Options Menu



Menu Item	Icon	Function
Cursor	or 🔍	Toggles the cursor between the Zoom tool used to increase or decrease the ECG display or the Measure tool used for on-screen calipers.
Measurement Units	NA	Selects Millimeters or MicroVolts
Filter	<u> </u>	Muscle Filter Activates the Muscle Filter.
		Power Filter
	<u>\$</u> 50	Activates the Mains Filter. The Hz are set in the ECG Options .
Speed	☐ 12.5 mm/s	Changes the number of millimeters that are passed in one second. The available options are 12.5mm/s, 25mm/s and 50mm/s.
Sensitivity		Changes the number of millimeters that represent one millivolt. The available options are 5mm/mV, 10mm/mV, and 20mm/mV.
Edit Lead Order	NA	Select Edit Lead Order to change the lead order.
Remove Analysis	NA	Removes the detailed measurements. The narrative interpretation and comments remain unchanged.
Re-analyze	NA	Resets the interpretation to its original state and removes all changes made by the user to the narrative interpretation.

Views



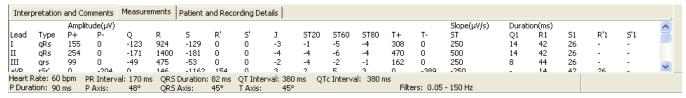
Details View

The details view shows the interpretation, comments, detailed measurements and patient details of the ECG.

Interpretation and Comments



Measurements



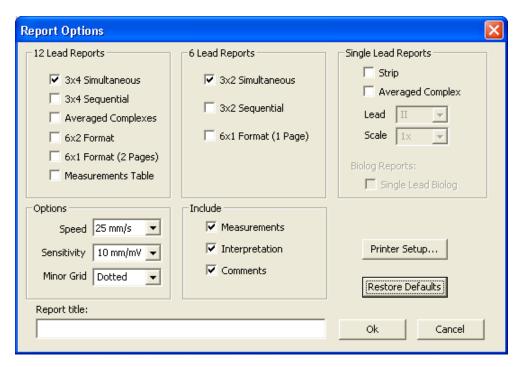
Patient and Recording Details



Warning! The computerized interpretation provided by the Office Medic software is only valid when used in conjunction with clinical findings. All computer generated tracings and interpretations must be confirmed by a qualified physician.

Printing an ECG

Select **File** | **Print** or the print icon.



Single Lead Report Prints a single strip or averaged complex with scale options: 1x, 2x, 4x, 8, 16x). 3X4 Simultaneous Prints 2.5 second segments of all twelve channels displayed at the same point in time along with a 10 second single channel rhythm strip. 3X4 Sequential Report Prints 2.5 second segments of all twelve channels displayed at the same point in time progressing in four sequential columns along with a 10 second single channel rhythm strip. Average Complexes Print an average QRS complex for all 12 channels along with a 10 second single channel rhythm strip. 6X1 Format, 2 Page Prints a ten second trace of each channel (2 page report). 6X2 Format, 1 Page Prints a five second trace of each channel (1 page report). Measurements table Prints a chart with amplitude, slope and duration data for all twelve channels. Include Allows you to select whether to include Measurements, Interpretation, and/or Comments in the report(s).	Print Options	Description
in time along with a 10 second single channel rhythm strip. 3X4 Sequential Report Prints 2.5 second segments of all twelve channels displayed at the same point in time progressing in four sequential columns along with a 10 second single channel rhythm strip. Average Complexes Print an average QRS complex for all 12 channels along with a 10 second single channel rhythm strip. 6X1 Format, 2 Page Prints a ten second trace of each channel (2 page report). 6X2 Format, 1 Page Prints a five second trace of each channel (1 page report). Measurements table Prints a chart with amplitude, slope and duration data for all twelve channels. Allows you to select whether to include Measurements, Interpretation, and/or	Single Lead Report	
in time progressing in four sequential columns along with a 10 second single channel rhythm strip. Average Complexes Print an average QRS complex for all 12 channels along with a 10 second single channel rhythm strip. 6X1 Format, 2 Page Prints a ten second trace of each channel (2 page report). 6X2 Format, 1 Page Prints a five second trace of each channel (1 page report). Measurements table Prints a chart with amplitude, slope and duration data for all twelve channels. Include Allows you to select whether to include Measurements, Interpretation, and/or	3X4 <u>S</u> imultaneous	· · ·
single channel rhythm strip. 6X1 Format, 2 Page Prints a ten second trace of each channel (2 page report). 6X2 Format, 1 Page Prints a five second trace of each channel (1 page report). Measurements table Prints a chart with amplitude, slope and duration data for all twelve channels. Include Allows you to select whether to include Measurements, Interpretation, and/or	3X4 Seguential Report	in time progressing in four sequential columns along with a 10 second single
6X2 Format, <u>1</u> Page Prints a five second trace of each channel (1 page report). Measurements <u>table</u> Prints a chart with amplitude, slope and duration data for all twelve channels. Include Allows you to select whether to include Measurements, Interpretation, and/or	<u>A</u> verage Complexes	· · · · · · · · · · · · · · · · · ·
Measurements <u>table</u> Include Prints a chart with amplitude, slope and duration data for all twelve channels. Allows you to select whether to include Measurements, Interpretation, and/or	6X1 Format, <u>2</u> Page	Prints a ten second trace of each channel (2 page report).
Include Allows you to select whether to include Measurements, Interpretation, and/or	6X2 Format, <u>1</u> Page	Prints a five second trace of each channel (1 page report).
,	Measurements <u>t</u> able	Prints a chart with amplitude, slope and duration data for all twelve channels.
	Include	, , , , , , , , , , , , , , , , , , , ,
Speed and Sensitivity Allows you to select the Speed (12.5, 25, or 50mm/s) and Sensitivity (5, 10, or 20 mm/mV) of the ECG reports.	Speed and Sensitivity	
Minor grid Allows you to select the minor grid: Lines, Dots, or None.	Minor grid	Allows you to select the minor grid: Lines, Dots, or None.

Note: when printing to a low resolution printer select Dots or None for the minor grid.

ECG Device Verification

A periodic check of the ECG system with an ECG simulator is recommended. Intervals for these checks can be set at the discretion of your Medical Director. There are commercially available ECG simulators which may be used for this purpose, refer to the accompanying information for instructions on the use of these.

For further information on device verification, contact QRS Diagnostic at www.QRSdiagnostic.com.

ECG Analysis Program

Office Medic provides analysis and interpretation of 12 channel ECGs. This is based on algorithms developed by Cardionics S.A. For further information consult the ECG Physician's Guide.

What to expect from the analysis program

The ECG Analysis Program provides an analysis of the amplitudes, duration, and morphologies of the ECG waveform. The analysis is based upon standards of interpretation of these parameters and calculations of the electrical axis and relationship between leads.

The interpreted ECG is a tool to assist the physician in making a clinical diagnosis, and is not a substitute for the physician's knowledge, the patient's history, results of the physical exam, the ECG tracing or other findings.

Service Information

Device Care & Maintenance

Cleaning

Clean surfaces with a damp cloth using water only. Dry thoroughly. AVOID CLEANING AROUND CONNECTORS. Excess moisture in or on the case, cables or air fittings could affect operation. Replace vinyl cap when not in use.

To clean the ECG device wipe the surfaces of the case with a clean cloth moistened in water only. To disinfect the ECG device wipe the case with a hospital grade disinfectant.

Handling

Do not insert a "dirty" PC Card into a PC Card slot. Do not insert a dirty USB cable into the USB port. Avoid contaminating the Luer connector and connectors of the PC Card.

Storage

Store the Device in a dry place. Avoid sudden changes in temperature.

Physical Shock

Avoid physical shock, a card that has been dropped should have the calibration verified before use on a patient.

Inspection

Inspect device for damage initially and before each use. Do not use devices that show visual signs of damage. Contact the QRS Diagnostic Service department with questions related to device damage and repair.

Service Information 75

Service

Contact the QRS Diagnostic service department:

VectraCor, Inc. 785 Totowa Road Suite 100 Totowa, NJ 07512 USA

Monday through Friday 8am to 6pm EST Phone: 973-904-0444 www.vectracor.com

A Return Merchandise Authorization (RMA) number will be issued for repairs

THE INSTRUMENT MUST BE RETURNED FOR REPAIRS AT THE EXPENSE OF THE PURCHASER. IN-WARRANTY REPAIRED UNITS ARE RETURNED AT THE EXPENSE OF QRS 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 QRS Diagnostic are guaranteed to be free from defects in
 material and workmanship for a period of 1 year from date of purchase. All supplies and
 accessories carry a 90-day limited warranty. This includes oximetry sensors. If in the judgment of
 QRS Diagnostic the instrument is proven to be defective during the warranty period it will be
 repaired or replaced with no charge for parts or labor.
- 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 QRS Diagnostic 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. AN AUTHORIZED QRS DIAGNOSTIC AGENT, MUST MAKE ALL REPAIRS. 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 1-year. This includes ECG lead wires. A software support package is available after 1-year at an additional cost.

Service Information 76

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.

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 airflow.

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.

EOTV End-of-test volume.

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.

FET Forced Expiratory Time.

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.

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 200ml. and 1200ml. Flow of inspired air

measured after the first 200ml. And during the next 1000ml.

Glossary of Terms 77

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.

FIVx/FIC% The percentage ratio of Forced Inspiratory Volume (timed) to Forced Inspiratory

Vital capacity, expressed as a percentage.

Flow vs. Volume

Curve

Graph obtained by forced exhalation test, Flow is plotted on the vertical axis and volume on the horizontal axis.

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%.

Forced Expiratory Volume (timed), (FEV(t))

Maximal volume of air, expressed in liters, which can be expelled in specific time in a forced capacity test.

Forced Inspiratory Vital Capacity, (FIVC)

Total volume of air, expressed in liters, which can be inhaled during a rapid forced inhalation after a maximal expiration.

Forced Inspiratory Flow

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

Forced Vital Capacity (FVC) Total volume of air, expressed in liters, which can be exhaled during a rapid forced exhalation after a maximal inspiration.

LLN Lower limit of normal.

Maximum Voluntary Ventilation (MVV)

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.

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.

PC Card

Also known as a PCMCIA card. A standard 68-pin computer card designed to add modular hardware to computers.

Perfusion

Display indicating if the pulse waveform signal is of good quality and the SpO2 data is accurate.

Peak Expiratory Flow Rate (PEFR) Maximum instantaneous flow in the FVC test.

PFT Pulmonary Function Test. Peak Expiratory Flow Time. **PEFT**

PIFR Peak Inspiratory Flow Rate, expressed in liters per second. Predicted value according to the "normal" equations used. **Predictor**

Pulmonary Functions Tests see PFT

Pulse Rate Heart rate measured in beats per minute (bpm).

Glossary of Terms 78 RR Respiratory Rate: the average number of inhalations/exhalations per minute

performed during a test.

Signal Intensity Indication displaying the patient's pulse.

Slow Vital Capacity Total

(SVC)

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.

Sp02 Approximate percentage of oxygen saturation in hemoglobin.

Glossary of Terms 79

SpiroCard Specifica	tions	
Weight	57 – 60 grams (0.13 lb)	
Height WxDxH	53mm x 140mm x 16-27mm (2.1" x 5.5" x 0.6-1"), extended housing	
Housing	PCMCIA Type II PC Card with extended housing	
Program	Reporting software is stored on the computer	
Environmental Conditions	Storage Conditions: Ambient Temperature: -15 to 50° C (5 to 122° F) Relative Humidity: < 90% (non-condensing) Atmospheric Pressure: 700 to 1060 hPa	
Power Supply	Internal: 5Vdc, less than 80 mA. Supplied by the PCMCIA slot	
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 (BTPS)	FLOW: ±14 liters/second VOLUME: 0.5 - 8 liters	
Accuracy (BTPS)	FLOW: ±5% of indication or ±200 ml/sec, whichever is greater for FEF 25-75 and ±10% of indication or ±300 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 (BTPS)	FLOW: 5% of indication or 150 ml/sec, whichever is greater for PEF VOLUME: 3% of indication or 50 ml, whichever is greater for FVC and FEV1	
Calibration	ATS 3-speed or standard calibration check	
Predicted Normals	Crapo (1981), Cherniack (1972), Morris (1971/73), Knudson (1983), Polgar (1971), HSU (1979), Roberts (1991), Warwick (1977), ECCS/ERS/Quanjer (1993), NHANES III (1999), Zapletal (1987), Wang (1993), Quanjer (1995)	
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	
Sample Rate	100 samples/sec	
Resolution	Flow Rate: 2ml/sec Volume: 1ml	
Limits of Detection	Flow Rate: 2ml/sec Volume: 1ml	
Parameters Measured	FVC, FEV0.5, FEV1, FEV6, FEV1/FEV6, FEV3, FEV1/FVC, FEV3/FVC, PEFR, PEFT, 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. BEV), EOTV, FET, MVV, RR, MTV, SVC	

SpirOxCard Specific	ations
Weight	85 grams (0.19 lb)
Height WxDxH	53mm x 140mm x 26mm (2.1" x 5.5" x 1.0"), extended housing
Housing	PCMCIA Type II PC Card with extended housing
Program	Reporting software is stored on the computer
Environmental Conditions	Storage Conditions: Ambient Temperature: -15 to 50° C (5 to 122° F) Relative Humidity: < 90% (non-condensing) Atmospheric Pressure: 700 to 1060 hPa
Power Supply	Internal: 5Vdc, less than 80mA. Supplied by the PCMCIA slot
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	Spirometry: FLOW: Mouthpiece (US Patent #4,905,709). VOLUME: flow integration
Range (BTPS)	Spirometry: FLOW: ±14 liters/second. VOLUME: 0.5 - 8 liters Oximetry: % Saturation: 0-100%. Pulse Rate: 18 to 300 pulses per minute
Accuracy (BTPS)	Spirometry: FLOW: ±5% of indication or ±200 ml/sec, whichever is greater for FEF 25-75 and ±10% of indication or ±300 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 Oximetry: SpO2: 70-100% ±2% of full scale (±1 S.D.)* Pulse Rate: ±3% (± 1 digit)
Precision (BTPS)	Spirometry: FLOW: 5% of indication or 150 ml/sec, whichever is greater for PEF. VOLUME: 3% of indication or 50 ml, whichever is greater for FVC and FEV1
Calibration	Spirometry: ATS 3-speed or standard calibration check
Predicted Normals	Spirometry: Crapo (1981), Cherniack (1972), Morris (1971/73), Knudson (1983), Polgar (1971), HSU (1979), Roberts (1991), Warwick (1977), ECCS/ERS/Quanjer (1993), NHANES III (1999), Zapletal (1987), Wang (1993), Quanjer (1995)
Tests Performed	Spirometry: FVC, Pre/Post Testing, Flow Volume Loop, MVV, SVC
Measuring Time	Spirometry: Up to 30 seconds
Printed Scale	Spirometry: Flow Volume: (vertical) .5cm/1L/S, (horizontal) 1cm/1L Volume Time: (vertical) 1cm/1L, (horizontal) 1cm/second
Sample Rate	Spirometry: 100 samples/sec
Resolution	Spirometry: Flow Rate: 2ml/sec. Volume: 1ml
Limits of Detection	Spirometry: Flow Rate: 2ml/sec. Volume: 1ml
Parameters Measured	Spirometry: FVC, FEV0.5, FEV1, FEV6, FEV1/FEV6, FEV3, FEV1/FVC, FEV3/FVC, PEFR, PEFT, 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., BEV), EOTV, FET, MVV, RR, MTV, SVC

Hub Weight	280 - 335 grams (0.62 – 0.66 lb) depending on cable options
Hub Dimensions	
	85mm x 91mm x 20mm (3.3" x 3.6" x 0.8")
Patient Leads Length	1 meter (3.3 ft) .6 meter for chest leads
PC Connection Length	1-3 meter (3.3 $-$ 9.8 ft), DB9 female connector or USB connector. 1.8 meter USI A type connector for USB version
Patient Leads	6 Lead Cable (4 patient leads) 12 Lead Cable (10 patient leads)
Case Material	ABS Plastic
Electrode Connections	4 mm Banana plug with "tab" or "snap" connectors
Electrode Labeling	Abbreviations and colors to comply with either IEC or AAMI (AHA) standards
Display and Operating Console	Dependent on PC (supplied by user)
Gain/Sensitivity	5, 10, 20 mm/mV
Input Range	±6mV
Acquisition sample rate	1000 samples per second (compressed to 500Hz with peak picking and averaging algorithm)
Heart Rate Range	30 bpm - 170 bpm
Frequency Response	0.05 to 175Hz ±3dB
Defibrillator Protection	Patient leads are isolated from system and operator, with 4kV protection
Common Mode Rejection	-60dB (minimum)
Safety Standards	Complies with AAMI EC11, EN60601-1, EN60601-1-2, and EN60601-2-25
Accuracy	Accurate to AAMI EC11:1991 requirements, based on printed 3x4 report with software filters off, and using 1:1 scale 300dpi printer. Frequency and impulse response have been evaluated according to methods A, B and C of EC11:1991, 3.2.7.2/4.2.7.2.
Leads Off Indicators	Connection status for each lead is shown on Acquisition screen
Power Source	Can be powered by the PC Serial port control lines in most cases, depending on the PC being used. Can draw extra power if necessary from a PC PS/2 port or USB Port for the serial version. For the USB version, it is powered from the USB interface
Supply Voltage	4 – 16V DC
Supply Current	<17mA DC
Permanent Filters	High Pass: 0.05Hz 1st order Low Pass: 170Hz 1st order Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (Mains Noise Rejection)	50Hz 4th order Butterworth, 49.1Hz - 50.9Hz, 60Hz 4th order Butterworth, 59.1Hz - 60.9Hz
Low pass (Muscle Artifact Filter)	35Hz 4th order
Report Capabilities	User selectable Report formats
Environmental Conditions	Operating Temperature: 0 to 40° C (32 to 104° F) Storage Temperature: -20 to 70° C (-4 to 158° F) Humidity < 85% (non-condensing)

Orbit Portable Spiro	meter Specifications
Weight	226.8 grams (0.5 lb.)
Dimensions	109.2 mm x 94.0 mm x 43.2 mm (4.3" x 3.7" x 1.7")
Communication Port	USB
Software Compatibility	Office Medic Version 5.5 (or later)
Storage Conditions	Temperature: -15 to 50° C (5 to 122° F) Relative Humidity: < 90% (non-condensing) Atmospheric Pressure: 700 to 1060 hPa
Power Supply	5 Vdc ±5% 100 mA or less from the host PC USB Port
Operating Conditions	Temperature: 15 to 40° C (59 to 104° F) Relative Humidity: 10 to 90% (non-condensing) Atmospheric Pressure: 700-1060 hPa
Spirometry Measurement Principle	The pressure is converted to flow. Volume measurement by flow integration.
Measurement Time	FVC - 60 sec.; SVC - 60 sec.; MVV - 15 sec.
Sampling Rate	125 Hz
Range (BTPS)	FLOW: ±14 liters/second VOLUME: 0.5 – 8.0 liters
Accuracy (BTPS)	 FEF 25-75: ±5% of indication or ±200 ml/sec, whichever is greater PEF: ±10% of indication or ±300 ml/sec, whichever is greater VOLUME: ±3% of indication or ±50 ml, whichever is greater for FVC and FEV1 FVC and FEV1: ±3% of indication or ±50 ml, whichever is greater MVV: ±10% of indication or ±15 L/min, whichever is greater
Precision (BTPS)	FLOW: PEF: ±5% of indication or 150 ml/sec, whichever is greater VOLUME: FVC and FEV1: ±3% or 50 ml, whichever is greater
Minimum Tracing Size	FLOW VOLUME: Flow (vertical): 5 mm/L/S; Volume (horizontal): 10 mm/L VOLUME TIME: Volume (vertical): 10 mm/L; Time (horizontal): 20 mm/S
Calibration	ATS 3-speed or standard calibration check
Predicted Normals	ADULT FVC: Crapo (1981), Cherniack (1972), Morris (1971/73), Knudson (1983), Roberts (1991), ECCS/ERS/Quanjer (1993), NHANES III (1999) PEDIATRIC FVC: Hsu (1979), Knudson (1983), Polgar (1971), Warwick (1977), NHANES III (1999), Zapletal (1987), Wang (1993), Quanjer (1995) ADULT MVV: Cherniack (1972) PEDIATRIC MVV: Polgar (1971), Zapletal (1987)
Interpretation	ATS/ERS 2005, BTS-NICE 2004-2005, NLHEP 2000, Enright 1987
Report Format	Pre-test overlay with full page graphs Pre/Post test overlay with full page graphs
Parameters Measured	FVC, FEV0.5, FEV1, FEV6, FEV1/FEV6, FEV3, FEV1/FVC, FEV3/FVC, PEFR, PEFT, 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. BEV), EOTV, FET, MVV, RR, MTV, SVC