



IQspiro®
Version 10.0



Operation Manual

3-100-1120 Rev. E

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Part number for this Operation Manual: 3-100-1120 Rev. E



Caution

Federal Law restricts this device to sale by or on order of a physician or properly licensed practitioner.

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Physician's Responsibility

The interpretations provided by the Midmark IQspiro® Digital Spirometer are for the exclusive use of licensed physicians or personnel under their direct supervision. The suggested interpretation, including numerical and graphical results, should be examined with respect to the patient's overall clinical condition. Final analysis should always be determined and verified by a physician.

Spirometry is an effort-dependent test. It is the responsibility of the physician to ensure proper administration of the test, making a diagnosis, obtaining expert opinions on the results, and instituting the correct treatment, if indicated.



Caution

Federal Law restricts this device to sale by or on the order of a physician.

Related Documents

The following documents may be needed in order to operate Midmark diagnostic devices and software products with the IQspiro® Digital Spirometer:

- *IQmanager® Software Operation Manual* (Part number: 62-78-0001)
- *Setup Manual: Midmark Products over Thin Client using IQpath™ or COM port mapping* (Part number: 61-78-0001)

All documents referenced above are located on the Midmark Operation Manuals CD (part number: 3-100-2000), included with every device. All product Operation Manuals can also be downloaded from midmark.com. For additional information contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2.

Precautions

Read and observe the following precautions to ensure proper operation of the IQspiro®.

1. Become familiar with the operations and procedures of the instrument prior to use.
2. It is recommended that the user be trained in the methods of administering spirometry tests to a patient by an organization that is certified by a recognized agency.
3. Installation location and maintenance of the device:
 - Avoid installing the device in direct sunlight.
 - Install and keep the device away from splashing fluids.
 - Do not install the device where it may be affected by significant or extreme changes in humidity, ventilation, airborne particles containing dust, salt, sulfur, etc.
4. Prepare the device for operation according to instructions in this operation manual.
5. Observe the patient closely while using the device. If any abnormality is observed, proper action, which may include stopping the test, should be taken immediately.
6. The software turns off the device power according to programmed procedures.
7. Keep the device clean at all times to ensure trouble-free operation.
8. In case of a malfunction, call Midmark Technical Service and be prepared to describe the problem precisely.
9. Perform routine inspections on the device.
10. Keep all items in a clean environment.
11. Do not make any modifications to the device; any modifications made will void the warranty.
12. Do not attempt to open the IQspiro® handle. Refer servicing to qualified service personnel.

**Caution**

To ensure accurate patient testing, only use the accessories recommended by Midmark for this product.

**Caution**

Electronic devices can be damaged by exposure to liquids. Do not use or store the IQspiro® near any type of liquids.

**Caution**

Midmark IQspiro®, when used with specific Midmark disposable mouthpieces, is designed and tested to meet regulatory and industry standards. Midmark can only warrant product performance and accuracy if the IQspiro® is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark IQspiro® mouthpiece, including but not limited to the use of an adapter or filter, is considered an alteration to the design of the product.

**Caution**

The American Thoracic Society (ATS) Standardization of Spirometry recommends the use of gloves when replacing disposable mouthpieces (DMs), and hand-washing after touching DMs.

Adverse Reactions

The IQspiro® is a non-invasive device and is safe in both construction and use. This has been confirmed by the performance of Verification and Validation Testing, Biocompatibility Testing, Risk Assessment Analysis, and ATS testing.

The following minor complications can occur with all diagnostic Spirometers:

1. Infection or injury due to the use of a non-sterile mouthpiece over open wounds,
2. Skin or mucous membrane abrasion caused by prolonged rubbing or excessive use of the mouthpiece (not related to biocompatibility issues),
3. Nasal, oral, or dental pain,
4. Drying of oral or pharyngeal mucosa,
5. Congestion or irritation of Eustachian tubes,
6. Gastric distention or flatulence from ingested air,
7. Slight discomfort during test procedures,
8. Decreased secretion clearance during test procedures,
9. Aspiration of secretions,
10. Hyperventilation and possible dizziness.

A sitting position is recommended during testing as it may be safer for the patient if they experience syncope or dizziness while performing the forced expiratory maneuver. Should the patient wish to stand for a maneuver place a sturdy chair behind them in case they should become dizzy or lightheaded.

If prior testing took place with the patient standing, a new test can be performed with the patient sitting, just be sure to make a note of the change (see [Section III-F, Observation Notes](#)).

Contents Checklist

The IQspiro® shipping box contains the items listed below. Open the package and account for each item prior to set up. Inspect all items for signs of damage such as dents, cracks, tears or scratches. If an item is missing or damaged, contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2, for replacement.

Quantity Each	Description
1	IQspiro® Digital Spirometer
1	10-pack Disposable Spirometer Mouthpieces
1	10-pack Disposable Nose Clips
1	Mouse Pad
1	Operation Manual CD
1	Quick Reference Guide – IQspiro®
1	Quick Reference Guide – PCP Mode
1	Warranty Registration Card
1	Carrying Case

I. General Information

A. Introduction



The information in this Operation Manual is provided for users of Spirometer models Midmark IQspiro® Digital Spirometer. Future reference of IQspiro® in this document may include the following part numbers:

Model	Connection Type	Device Part Number	Kit Part Number
Midmark IQspiro®	USB	1-100-1225	4-000-0026 w/syringe
			4-000-0025
	Serial*	1-100-1205*	4-000-0021* w/syringe
			4-000-0020*

**No longer in production.*

The IQspiro® Digital Spirometer is intended for use as a prescription-use-only clinical diagnostic spirometer for pulmonary function evaluation and data management. The IQspiro® is for use in hospitals and physician/clinician offices by individuals that have received instruction or training in the administration of spirometry tests. The IQspiro® operates with a Windows-compatible computer using a serial or USB port connection and the IQmanager® Software.



Caution

Midmark IQspiro®, when used with specific Midmark disposable mouthpieces, is designed and tested to meet regulatory and industry standards. Midmark can only warrant product performance and accuracy if the IQspiro® is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark IQspiro® mouthpiece, including but not limited to the use of an adapter or filter, is considered an alteration to the design of the product.

The IQspiro® is indicated for use with male and female adult and pediatric patients to evaluate, assess, describe, measure or monitor:

- Symptoms, signs or abnormal laboratory tests.
- Effects of disease on pulmonary function.
- Individuals at risk for pulmonary disease.
- Preoperative risk.
- Post-surgical prognosis.
- Pre-treatment health status.
- Therapeutic interventions.
- The course of disease affecting lung function.
- Persons exposed to pollutants.
- Adverse reactions to drugs with known pulmonary toxicity.
- Rehabilitation programs.
- Risks as part of an insurance evaluation.
- Individuals for legal reasons.
- Epidemiological surveys.
- Derivation of reference equations.

Note

This list of indications is taken from: American Thoracic Society. 1995. Standardization of Spirometry 1994 Update. Am. J. Respiratory Crit. Care Med. 152:1108.

Contraindications

The disposable mouthpieces (DMs) are clean but not sterile and should not be placed over open wounds that are prone to infection. There are no other known medical contraindications other than the physical limitations of the patient.

Conformance to Standards

The IQspiro® conforms to the following standards:

- Industry Standards: ATS/ERS 2005, NLHEP, NIOSH, SSD, OSHA, ECCS
- Quality System Regulations: FDA QSR, ISO 10993-5, ISO 10993-10, EN 60601-1-2, CAN/CSA STD C22.2 601.1-M90
- Product Testing Regulations: IEC 60601-1-1, IEC 601-1, IEC 60601-1-2

B. Description

Note

This manual is intended for IQmanager® Diagnostic Workstation software users. If using the IQspiro® through an EMR, please contact Midmark Technical Service for assistance with installation, setup and operation.

The IQspiro® Digital Spirometer is a portable device that performs Forced Vital Capacity (FVC), Vital Capacity (VC) and Maximal Voluntary Ventilation (MVV) testing. It provides real-time display of flow volume curves as well as inspiratory and expiratory measurements.

Together with IQmanager®, the IQspiro® makes it easy to record, interpret, and archive spirometry efforts for future reference.

This manual describes how to use the various IQspiro® features and the operational sequence most users will follow. This does not mean that a user is restricted to following this particular sequence. There are certain sequences that must always be followed, such as entering a patient's medical data prior to performing a spirometry test. However, this program is designed to be both user-friendly and flexible.

Many of the features are interconnected and can be accessed from more than one screen. The bottom or right side of each screen has a menu bar that lists other screens that may be accessed. To visit any of these screens, click the appropriate button.

C. Product Overview

Before conducting any spirometry testing, install IQmanager® on a Windows-compatible computer. Once IQmanager® has been installed connect the IQspiro® device to the computer via the COM or USB port, depending on which version is being used.

A Pulmonary Function Test (PFT) is a widely used term for spirometry. People may refer to the IQspiro® as a PFT machine. A spirometer is a device used by a patient to perform a PFT. In this manual, the words spirometer and spirometry are used when referring to the Midmark IQspiro® device and its operation.

D. Necessary Computer Skills

This manual is intended for a user capable of using Microsoft® Windows® applications, has some understanding of PC operations, and is familiar with the basic operations of Windows®.

This Operation Manual is designed as a comprehensive guide, designed to educate the user on the operation and functions of the IQspiro® device. The information in this manual includes all options that are available with IQspiro®.

E. Configurations

Typical PC Configuration

The block diagram below (see **Figure 1-1**) illustrates the standard configuration of the IQspiro® system. The primary components are a Windows®-based PC, a printer, and the IQspiro® acquisition module. A portable computer is recommended if mobility is a consideration. Please refer to this block diagram when setting up the IQspiro® system:

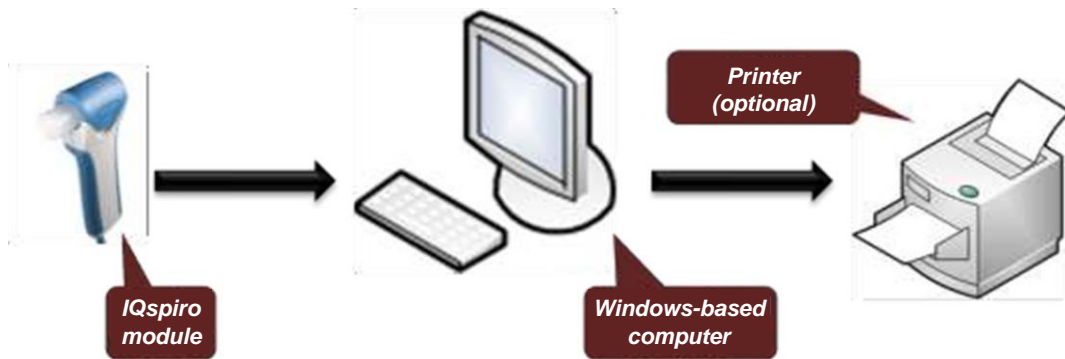


Figure 1-1

F. Thin Client Configurations

If working in a thin client environment, install the IQmanager® software on the Terminal Server and operate the IQspiro® through a thin client terminal.

IQspiro® supports two thin client configurations:

- IQpath™ Software Solution, and
- COM port mapping.

IQpath™ works with either USB or serial port versions of the IQspiro® in high-latency, limited bandwidth network configurations with Windows-based PC clients. For non-Windows thin client devices on low-latency high-speed networks, use the serial port versions of the IQspiro® and connect to client devices via COM port mapping.

Setting up any application in a network environment typically requires special access rights and knowledge of the network. Please have a system administrator install and configure IQmanager® to the office environment.

Thin Client Using the IQpath™ Software Solution

IQpath™ utilizes a dedicated flow control scheme to provide the following advantages over COM port mapping:

- Improved performance on high-latency, low-bandwidth, high-loss networks.
 - Microsoft Terminal Services: Improvement is approximately 10-to-1 in latency tolerance.
 - VMware VDI: Improvement is approximately 10-to-1 in latency tolerance.
 - Citrix® ICA® protocol: Improvement is approximately 40-to-1 in latency tolerance.
- No COM port mapping is required.
- The USB version of the IQspiro® module is compatible.
- Improved device auto-configuration and diagnostics.

Note

IQpath™ has specific requirements for computer hardware, software and network performance. System administrators should read Setup Manual: Midmark Products over Thin Client using IQpath™ or COM port mapping before installing, configuring and using this software in a thin client environment.

The following block diagram describes IQpath™. In this thin client environment, the client computers must be running Windows® 10, 8, and 7:

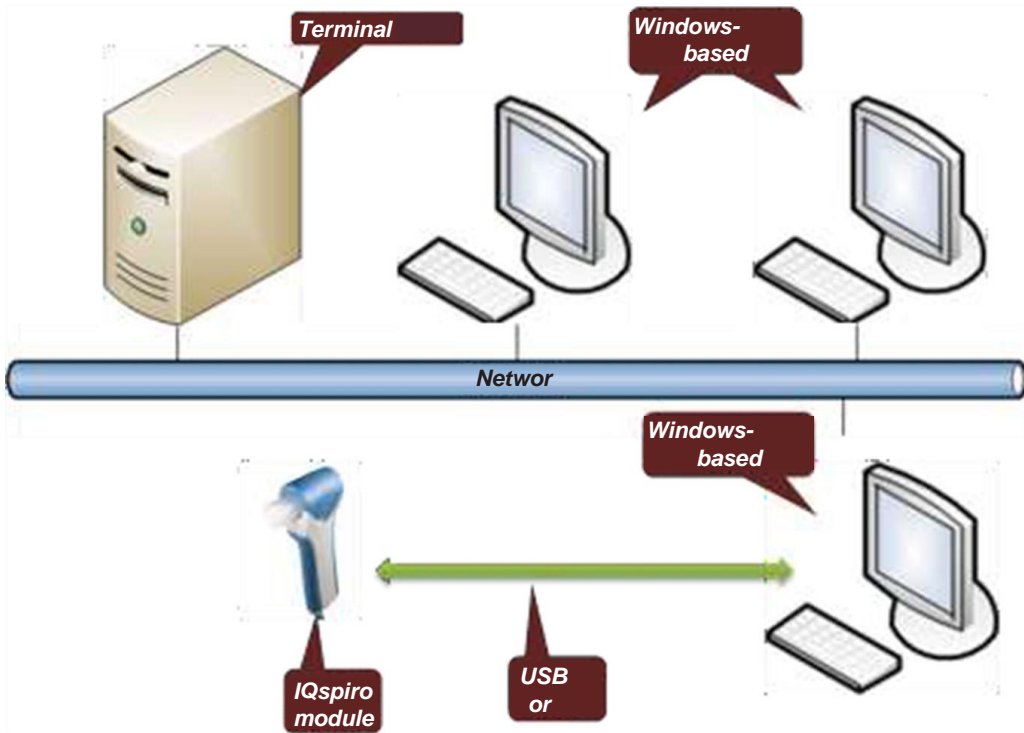


Figure 1-2

To use IQpath™, load IQmanager® or equivalent software on the terminal server and install one of the following software components on each client PC that will be used for data acquisition:

- **IQpath™ for Microsoft Terminal Services:** if using Microsoft Terminal Services (Microsoft RDP).
- **IQpath™ for Citrix ICA protocol:** if using Citrix software on your clients and servers.
- **IQpath™ for VMware:** If using VMware VDI software on the clients and servers.

These software products are provided separately and may be obtained by contacting Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2.

Once the software is installed on the client server network and PCs, IQmanager® must be configured as described in [Section II-D, Hardware Setup](#) and [Section II-E, Configuring IQspiro®](#), or refer to the IQmanager Operation Manual, Section VI-F, *Configuring Client Server Networks*.

Thin Client Using COM Port Mapping

COM port mapping refers to a configuration in which the IQspiro® connects to a serial port of the client and the server is configured so that logical COM ports on the terminal server are mapped to the physical COM ports of the client.

If using non-Windows®-based thin client terminal devices on a low-latency, high-speed network, use the serial port versions of the IQspiro® and configure the thin client server for COM port mapping.

Note

*In order to use the COM port mapping solution in a thin client environment, the computer hardware and software as well as the network must meet stringent performance requirements. System administrators must read the document *Setup Manual: Midmark Products over Thin Client using IQpath™ or COM port mapping* before installing, configuring and using this software in a thin client environment using COM port mapping.*

The following block diagram illustrates the use of the IQspiro® in a thin client environment using COM port mapping:

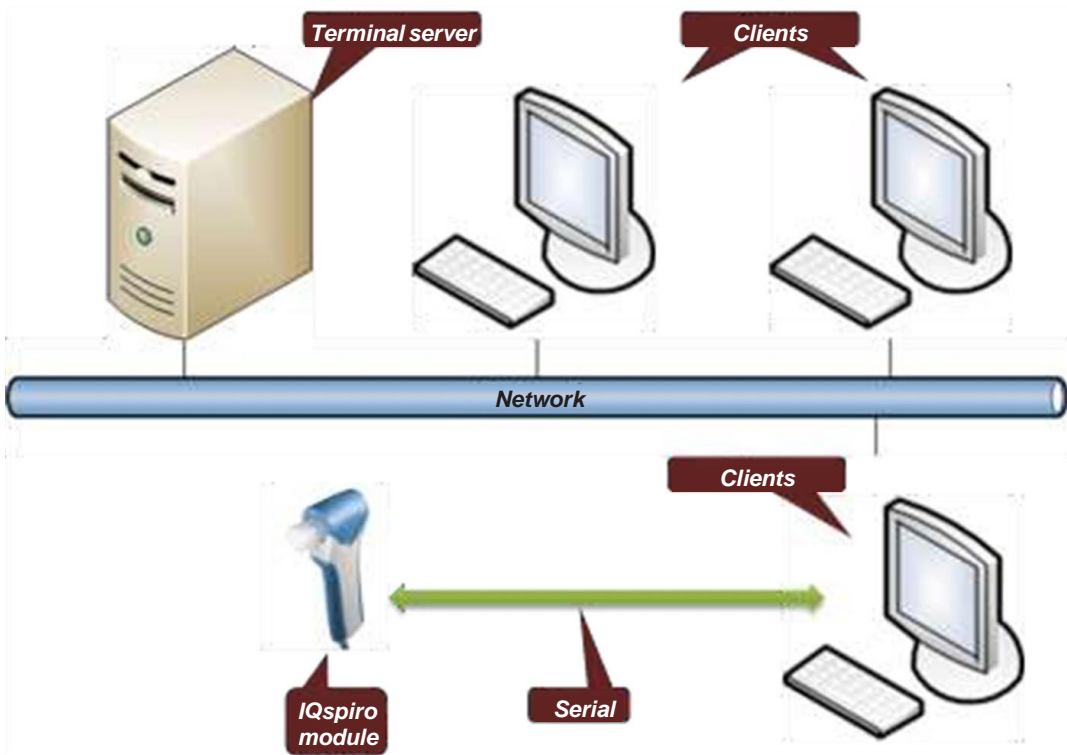


Figure 1-3

To use the IQspiro® in this configuration, install IQmanager® on the terminal server and configure the server to map to the COM port on the client terminal.

System administrators should configure the terminal server for COM port mapping as described in the document entitled *Setup Manual: Midmark Products over Thin Client using IQpath™ or COM port mapping*.

G. System Specifications

IQspiro® Performance Specifications		
Category	Specification	
Intended Use	To provide diagnostic spirometry results that a licensed practitioner can use to interpret the current condition of a patient's lungs.	
Dimensions	7.75" x 2.5" x 1.75" (191 x 64 x 44mm)	
Device style	RS232 (serial port)	USB
Weight	9.5 oz.	9.0 oz.
Batteries	Two 1.5V AAA alkaline	N/A
Connection	Standard serial port (DB9 or DB25 w/ adapter)	USB port
Anatomical Sites	Non-invasive device	
Patient Contact	Disposable mouthpiece (DM)	
Safety Parameters	Double-insulated handle	
Spirometry Acquisition	<ul style="list-style-type: none"> Fleisch Pneumotach: Differential pressure reading of flow with aDM Volume determined by flow integration 	
Ranges	<ul style="list-style-type: none"> Flow: +/- 14 L/s Volume: +/- 8 L 	
Environmental Conditions (temperature and humidity)	<ul style="list-style-type: none"> Temperature: 15°C to 40°C Humidity, non-condensing: 10% to 90% 	
BTPS	<ul style="list-style-type: none"> Automatic BTPS Correction 	
Analysis & Measurement	<ul style="list-style-type: none"> Automatic Back Extrapolation calculation Automatic spirometry parameter calculation Automatic comparison to published spirometry predicted equations (Reference Values) Automatic interpretation of test results 	
Parameters Measured	<ul style="list-style-type: none"> See Appendix I - Spirometry Measurement Parameters 	
Reference Values Sets	<ul style="list-style-type: none"> See Appendix F - Reference Values - Adult and Appendix G - Reference Values - Pediatric 	
Interpretations	<ul style="list-style-type: none"> ATS (1991): (See Appendix D - Interpretation – ATS) NHANES III (NLHEP 1999): (See Appendix E - Interpretation – NHANES III) 	
Printer	<ul style="list-style-type: none"> Windows® compatible inkjet or laser printer 	
Paper	<ul style="list-style-type: none"> 8.5" x 11" (Letter size) or 210mm x 297mm (A4 size) 	

II. System Installation

Note

Contact Midmark Technical Service before installing and setting up the IQspiro®. Computers today are more complex with more software and hardware options than before, making each computer almost unique. Midmark wants to make sure that your IQspiro® device is installed and configured as quickly and easily as possible.

Midmark Technical Service can be reached at (800) 624-8950 or (844) 856-1230, option 2.

A. Minimum Computer Requirements

This section describes the minimum computer resources and hardware components needed when using new Midmark devices and software. As is the nature of technology to change often, these requirements will be evaluated and modified periodically. We suggest always referring to the most recent *Minimum Computer Requirements* document at www.midmark.com, or contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2, for additional information.

Note

If updating existing computer systems currently being used with older Midmark devices and software, please contact Midmark Technical Service before doing so.

IQspiro® Minimum Computer Requirements	
Item	Requirement
Operating Systems	Windows® 10, Professional and Enterprise, 32-bit and 64-bit Windows® 8, Professional and Enterprise, 32-bit and 64-bit Windows® 7, 32-bit and 64-bit
Hardware Requirements	Windows® compatible personal computer.
CPU	Intel® Core™ 2 Duo Processor E4300 (2M Cache, 1.80 GHz, 800 MHz FSB) (x86) or 64-bit (x64) processor or faster
Disk	2 GB of free disk space or greater
Memory	Minimum 2GB of system memory
Input/Output Ports	One (1) USB port or one (1) serial port: • One Universal Serial Bus (USB) port if using USB version of the IQ product Or • One RS-232 Serial Port if using serial port version of IQproduct. The above computer port is required for new test acquisitions. It is not required to review and/or edit a test. Additional USB ports as needed for keyboard, mouse, printer, etc.

IQspiro® Minimum Computer Requirements	
Item	Requirement
Pointing Device	Windows® compatible mouse.
Keyboard	Windows® compatible keyboard.
Display	1024x768 or higher resolutions for the real time acquisition screen. 16-bit color. Wide-screen (1680x1050) is highly recommended.
Printer	Microsoft Windows® compatible inkjet or laser printer.
Surge Protector	One (1) hospital-grade power surge protector for the computer system.

Note

The above is the minimum computer requirement specification for operating the IQspiro® through IQmanager®. A faster CPU and/or more memory may be required if planning to operate the IQspiro® through an EMR or install additional software.

Note

USB ports/contacts can become worn with repeated use. The IQspiro® may not function with a worn USB port.

B. Software Installation

Note

The following software installation information refers to IQmanager® only. If using the IQspiro® through an EMR, please contact Midmark Technical Service for assistance with installation and setup.

IQspiro® uses the IQmanager® software to manage patient records. Other Midmark products can also be accessed from IQmanager®, such as, IQecg®, IQholter®, IQvitals®, IQvitals® PC and Weight/Scale Interfaces. Contact the Midmark Sales Department for the latest information on available Midmark products or visit midmark.com.

Note

If IQmanager® is already installed on the computer and the user is now either upgrading or adding a new Midmark product, please skip this section and refer to the IQmanager® Operation Manual for installation information.

Before installing IQmanager® on a computer, it is important that the user understand and carry out the following tasks:

Windows Taskbar

IQmanager® is designed to run as a full-screen program. For best results, the Windows Taskbar should not be displayed in order to provide maximum display area. Place the mouse pointer on the blank portion of the Taskbar on the bottom of the screen, then right-click and select **Properties**. Check the *Auto-hide* the taskbar box to hide the taskbar when it is not in use; to display the taskbar when it is hidden, move the mouse cursor over the area where the taskbar is normally set, and it will reappear.

Screen Saver

If a screen saver or any energy saving feature is enabled on the computer, make sure that it does not activate and interfere with data acquisition during patient testing. Refer to the user's computer or software manual for these settings.

Important Computer Date Information

The IQspiro® uses the current date from the computer and the patient's birth date as entered by the user to calculate the patient's age. Since the IQspiro® equations and interpretive analysis use the patient's age to produce appropriate diagnostic statements, it is important that the computer's current date is accurate. Contact the system administrator if the computer's date is incorrect.

C. Installation Steps for IQmanager®

Note

Close all Windows programs before running this software installation. *Do not interrupt the installation program while it is running. The installation should take less than five minutes.*

Note

The Midmark IQspiro® requires software to operate. The following instructions use the IQmanager® software. Please contact Midmark at 1-800-624-8950 to purchase the required software license.

1. Do not connect any devices to the computer before running the software installation.
2. Double-click the IQmanager® setup file. The installation starts automatically.
3. Follow the instructions on the screen. For detailed installation, setup and detailed operation instructions, please refer to the IQmanager® Operation Manual.
4. Once installation is complete connect the IQspiro® module to the computer with the steps outlined in the following section.
5. If there are any new licenses, add them to the licensing server. For any questions on adding licenses please refer to the IQmanager® operation manual.

D. Hardware Setup

Connecting the Serial-Type IQspiro® Module

If using the serial-type IQspiro®, attach the female end of the 9-pin communication cable to an available serial port. You may also use a 9-pin to 25-pin adapter as necessary. Secure the connections with the thumbscrews. Do not over-tighten.

Note

If using a 25-pin serial port, connect the 25-pin (female) to 9-pin (male) adapter to the port on back of the computer. Then connect the female end of the 9-pin connector on the communication cable to the 9-pin port on the adapter.

Battery Installation for Serial (RS232)

- The battery compartment is located at the bottom of the IQspiro®. Hold the IQspiro® upside down so that the cable is aiming up.
- Press down on the battery door and slide it out until the cover pops up when released.
- Insert two (2) AAA batteries into the battery holder, according to the icon.
- Close the battery compartment door by holding it down while sliding it back in place.

Note

If using a USB version of the IQspiro®, no batteries are needed and there will be no battery door at the bottom of the unit.

Low Battery Sensor

The low battery detection circuit monitors the battery voltage and alerts the micro controller when the energy in the batteries is low. The micro controller causes the LED on the IQspiro® to glow RED and sends a LOW BATTERY message that is displayed on the screen by IQmanager®. The user can complete the current testing session with confidence but should replace the batteries before starting a new test.

Connecting the USB IQspiro Module

DO NOT plug the USB IQspiro® into the computer until IQmanager® has been installed. Once the software is installed, plug the USB connector into any available USB port and the software will automatically detect the device.

Inserting a Disposable Mouthpiece in the IQspiro®

- Open the IQspiro® door by unlatching the door at the side of the spirometer and hold the door open with one hand, using your index finger.

- The following diagram shows the three ports in the top of the IQspiro®. Line the pins of the DM up with the ports of the IQspiro® and firmly press the DM in place, making sure that the DM is securely anchored in the ports. Close and latch the IQspiro® door.

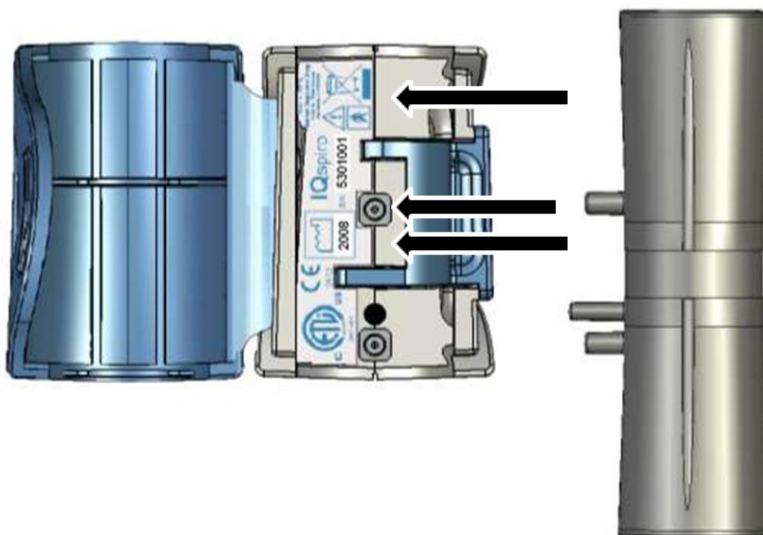


Figure 3-1 Inserting the IQspiro® disposable mouthpiece

Note

The DM must be firmly pressed into place to ensure a proper seal. The DM is not correctly pressed into place it may not seat flush against the IQspiro® cradle.

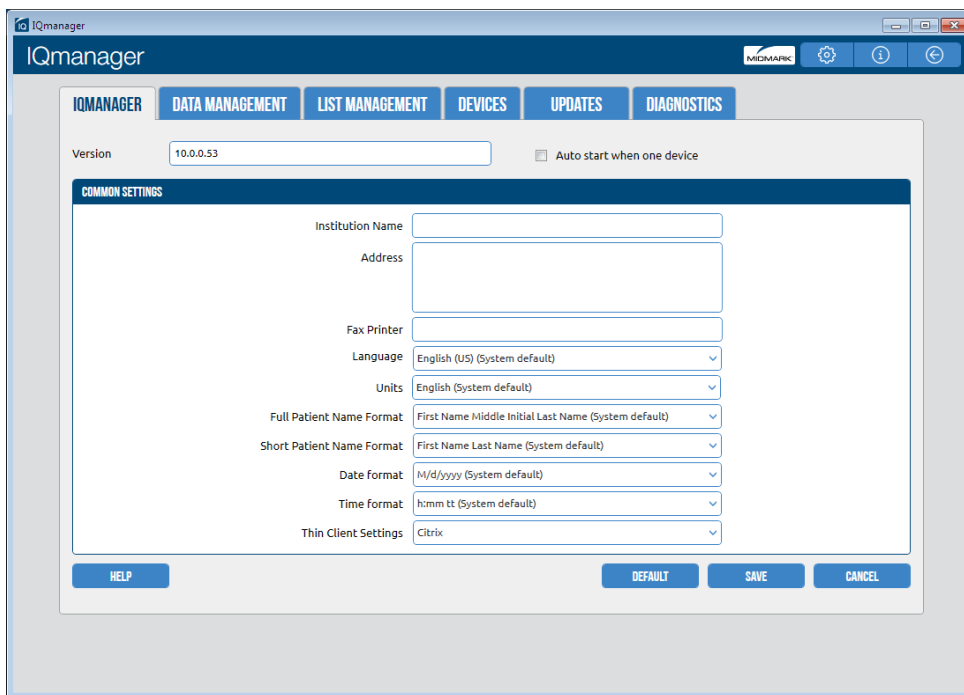
E. Configuring IQspiro®

IQmanager® and the IQspiro® can be customized by using the configuration settings. Access the **Configuration Settings** by using the following steps:

Click on the **SETTINGS** button in the upper right side of the IQmanager® opening screen



The *IQmanager* Settings window appears:



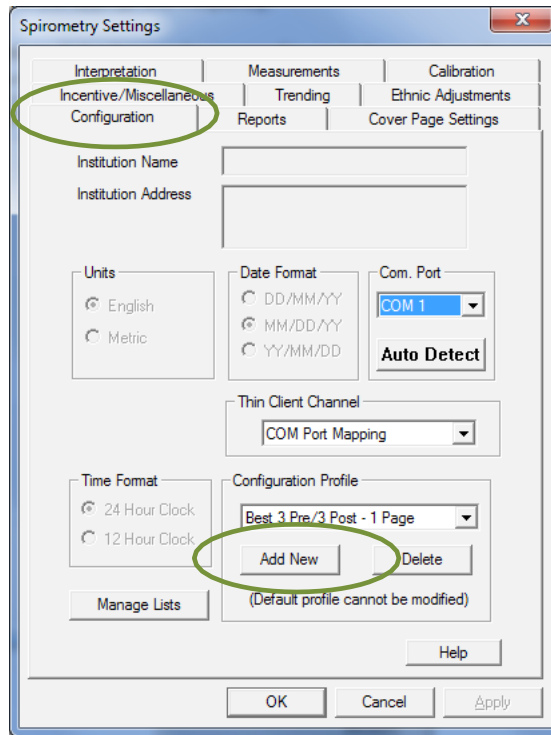
Complete the *Institution Name* and *Address* boxes with information about the user's medical practice. IQmanager® will display your institution name on each of the procedure screens and on printed reports. Enter a name that describes your practice or operation to enable other medical personnel to identify your reports.

Choose between Metric and English units of measurement, 24- and 12-hour time standard. When done, press **Save**.

The **Spirometry Settings** dialog box can be accessed in several ways: it can be accessed by selecting the spirometer settings button from the *Devices* tab of the IQmanager Settings;



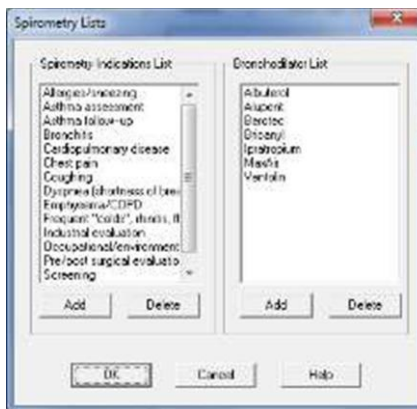
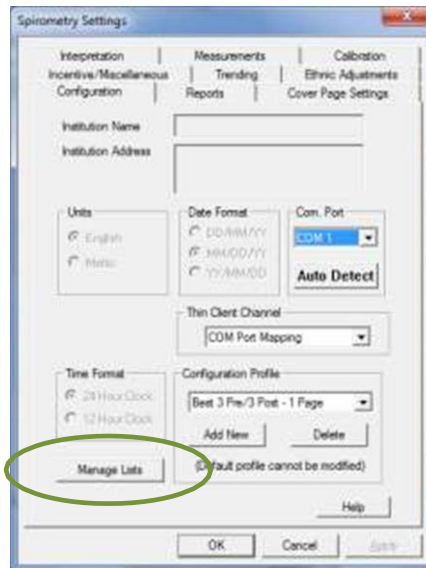
or by clicking **Settings** in the *New Test* or *Spirometry Review and Edit* screens within IQmanager®. The following configuration menu will appear:



Configuration Tab

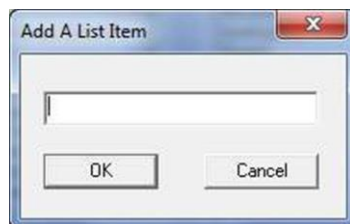
If the profile listed in the *Configuration Profile* box is *Default*, highlight *Default* and click **Add New**. Create a new name for the profile and click **OK**. The Default profile cannot be modified. Global settings (Institution Name, etc.) must be set in the IQmanager® Configuration program.

Manage Lists enables the user to modify the *Spirometry Indications List* and the *Bronchodilator List*. Add or delete items from either list.



Spirometry Lists Dialog Box

- To add to a list, click **Add** under the appropriate list box and type a new item.



- To delete an item, highlight the item in the list box and click **Delete**.

For example, if a doctor uses only Albuterol for a bronchodilator, this list can be modified so that Albuterol is the only selection available. The list always appears in alphabetical order.

Note

The indication list in the spirometry settings are no longer used. Instead the indications are stored in IQmanager. Refer to the IQmanager operation manual for details.

Note

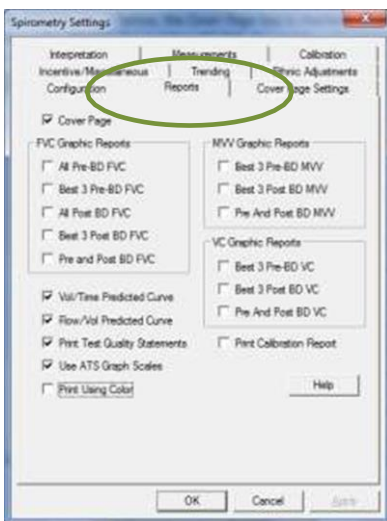
For the recommended wait time between bronchodilator administration and postspirometer testing, refer to the manufacturer's package insert.

Reports Tab

Select which reports will be printed when **Print** is clicked from the *Reports* tab. For each box checked in any of the *Reports* areas, the printed report will include a page for that report.

If the *Cover Page* box is selected and no boxes within the Reports area are selected, only a onepage report will print because no additional *Reports* boxes are selected.

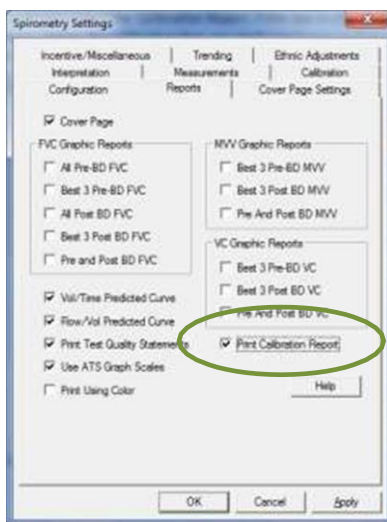
For example, in the *Reports* tab shown below, the *Cover Page* box is checked and three report boxes are selected (*Best 3 Pre-BD FVC*; *Pre and Post BD FVC*; *Pre and Post BD MVV*). If a test session only contains Pre-BD FVC tests, clicking **Print** will print a three page report. The first page is the Cover Page, the second page is the Best 3 Pre-BD FVC tests performed and the third page is the best Pre-BD test.



Spirometry Settings – Reports Tab

If the patient has Pre- and Post-Bronchodilator, FVC, VC and MVV tests saved, all applicable selected reports will print when **Print** is clicked.

From this tab the user may select the *Calibration Report*. If this box is checked, every time the user prints a patient's report, the calibration that was performed prior to that test is printed with the report. This is helpful if proof of calibration is required.



There are five options at the left of this tab:

- *Vol/Time Predicted Curve*,
- *Flow/Vol Predicted Curve*,
- *Use ATS Graph Scales*,
- *Print Test Quality Statements* (only affects the printed reports but not the Cover Page), and
- *Print Using Color* (affects all reports, including the Cover Page)

For example, if the *Predicted Curve* boxes are selected, the predicted Volume/Time and predicted Flow/Volume graphs for the patient are printed on the secondary report pages and will also print on the cover page graphs.

The *Cover Page Settings* tab has separate selections for *Smoking History*, *COPD Risk*, *Lung Age* and *Test Quality Statements*. See [Section II-E, Configuring IQspiro®](#) for additional information about the cover page.



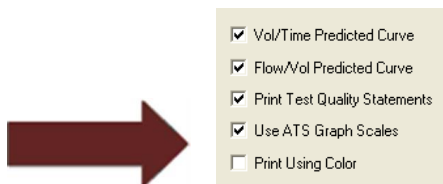
Cover Page, Best 3 Pre and Best 3 Post Selected

ATS Recommended Graph Size

The ATS recommends that a Volume Time graph be at least 20 mm per second and 10 mm per liter when hand measurements are required. Some government agencies and insurance carriers require this for reimbursement.

In order to create a one page report, all Cover Page graphs will not print to this scale size. However, all reports from the *Reports* tab will if *Use ATS Graph Scales* is selected here. These graphs will print on the pages following the cover page.

Use this setting if requested from the user's carrier or for government agencies.



- ☒ Vol/Time Predicted Curve
- ☒ Flow/Vol Predicted Curve
- ☒ Print Test Quality Statements
- ☒ Use ATS Graph Scales
- ☐ Print Using Color

Enable ATS Graph Scales

Cover Page Settings Tab

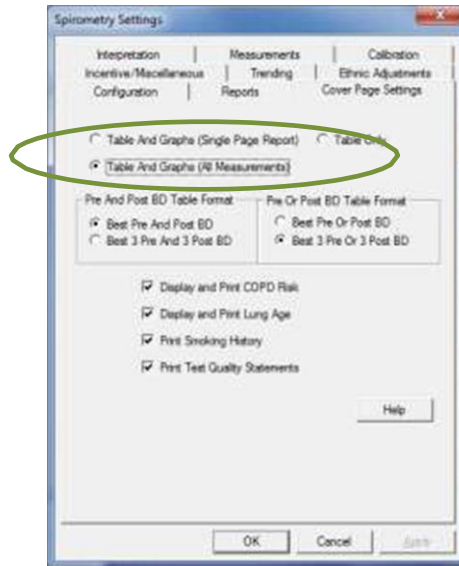
The *Cover Page Settings* tab enables the user to customize the cover page. Selections on this tab only change the look of the cover page: they do not affect the report pages. The first selection determines whether the volume-time and flow-volume graphs are printed on this page.

When the check box is selected that states "*Table and Graphs (All Measurements)*" the user can print out all selected measurements with the volume-time and flow volume graphs.

The *Pre and Post BD Table Format* selections determine whether the report includes only the Best Pre and Best Post BD test or the Best 3 Pre and Best 3 Post BD tests. This option is available when both Pre and Post BD tests have been saved.

If the patient has performed only Pre or only Post BD tests, the *Pre Or Post BD Table Format* selections will take effect.

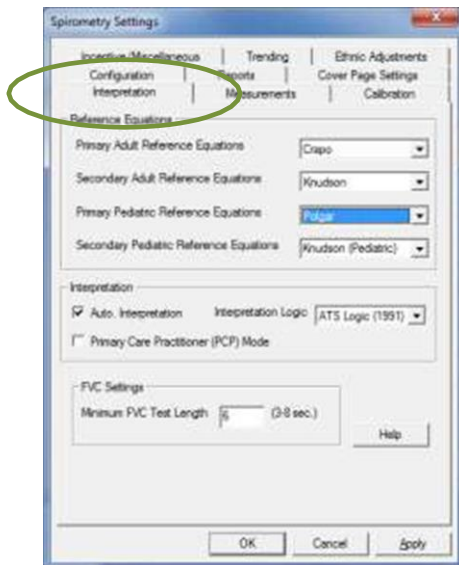
The check box selections at the bottom of this tab (*Print Smoking History*, *Print COPD Risk*, *Print Lung Age*, *Print Test Quality Statements*) determine the additional information to appear in the patient demographics field and graph section of the cover page.



Spirometry Settings – Cover Page Settings Tab

Interpretation Tab

Select which *Reference Equations* set to use as the default for Adults and Pediatrics from the *Interpretation* tab. Not every spirometry measurement (FVC, FEV₁, etc) is available in every reference equation. The secondary reference equations can be used to complete missing measurements. For example, if the user's primary reference equation does not have an equation for FEF₂₅, select a secondary reference equation that does to complete the report.



The user can control the *Auto. Interpretation* feature from this tab, which allows the user to select the *ATS Logic* or the *NHANES III* logic. If the user does not wish to have the software automatically interpret the spirometry tests, clear the *Auto. Interpretation* box. The *Primary Care Practitioner (PCP) Mode* overrides *Reference Equation* and *Interpretation* selections, as discussed below.

The *FVC Settings* enable the user to define the acceptable length of test required. Reducing this number will affect the length of test acceptability error code. The ATS recommends that the minimum length of test be set to 6 seconds.

Primary Care Practitioner (PCP) Mode

The *PCP Mode* automatically selects the NHANES III reference equations and interpretation logic and modifies the test acquisition screen, the test review screen and the printed reports. To set the IQspiro® into PCP Mode, click on the *Configuration* tab. Select *PCP Mode* from the pull-down list In the *Configuration Profile* dialog box and click **OK**.

As recommended by the National Lung Health Education Program (NLHEP), this mode simplifies the test procedure, measurements displayed and report options. For the test procedure, it eliminates the inhalation side of the flow volume loop and stops the test at 6 seconds of exhalation. It also eliminates the VC and MVV test selection.

Note

In the PCP mode, the IQspiro® measures the FEV₆ but on all reports and displays it is labeled as the FVC.

After each test maneuver is performed, the software will give a quality control grade for the test session. The quality control grade displayed will be A, B, C, D or F. A test session must be graded A, B or C to generate an interpretation and the results of Pre-FVC and Post-FVC tests are only compared if both the Pre and Post sessions are graded A, B or C. To have the software display *Good Test Session*, you must acquire two acceptable tests that match, according to the criteria listed here.

QC Grade	Criteria
A	At least two acceptable maneuvers with the largest FEV ₁ values matching within 100 ml and the largest two FEV ₆ values matching within 100 ml.
B	At least two acceptable maneuvers with FEV ₁ measurements that match between 101 and 150 ml.
C	At least two acceptable maneuvers with FEV ₁ measurements that match between 151 and 200 ml.
D	Only one acceptable maneuver or more than one acceptable maneuver, but the FEV ₁ values don't match within 200 ml.
F	No acceptable maneuvers

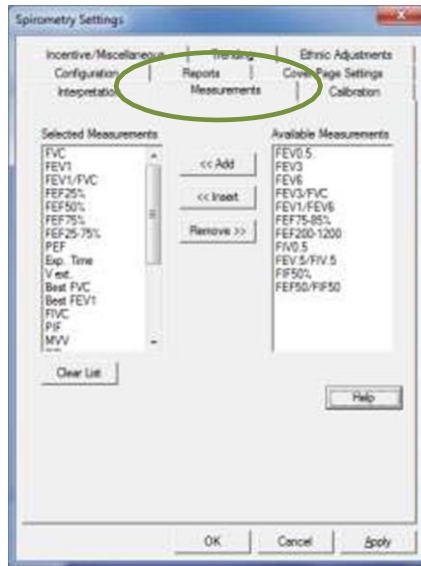
If the FVC maneuver is less than 6 seconds because the operator ended the test, but the end of test volume is less than 100 ml during the last 0.5 seconds, then the software will set the FEV₆ value equal to the FVC value, if the FVC measurement is valid.

Checking the *Primary Care Practitioner (PCP) Mode* box with a profile other than *PCP Mode* selected on the *Configuration* tab will enable test grading and remove VC and MVV from the test screen, but will not limit the measurement parameters displayed. This allows the user to customize the report. To remain in PCP Mode without customization, select *PCP Mode* from the *Configuration Profile* box.

Measurements Tab

The *Measurements* tab enables the user to customize which measurements to appear on the cover page, the test screen and the review screen. At least one measurement must be selected.

If the user has selected the *Tables and Graphs* setting for the Cover Page, only the first 9 measurements selected will be displayed on the Cover Page. If the *Only Table* setting is selected, up to 28 measurements can be displayed.



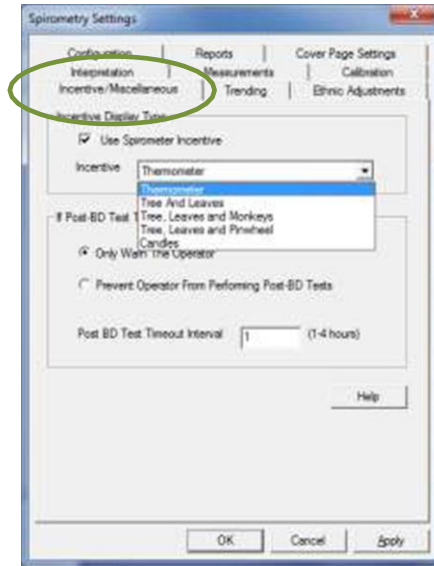
Spirometry Settings – Measurement Tab

Measurements can be placed in any order by clicking **Add**, **Insert**, **Remove** or **Clear List**. Highlight the measurement and choose the desired function:

- **Add:** Move the selected item from the *Available Measurements* list to the bottom of the *Selected Measurements* list.
- **Insert:** Move the selected item from the *Available Measurements* list above the highlighted item in the *Selected Measurements* list.
- **Remove:** Moves the selected item from the *Selected Measurements* list to the *Available Measurements* list.
- **Clear List:** Moves all of the items from the *Selected Measurements* list to the *Available Measurements* list.

Incentive/Miscellaneous Tab

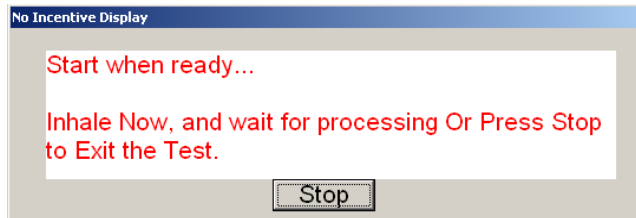
The *Incentive/Miscellaneous* tab enables the user to customize the incentive that the patient will see when performing a test. The default selection is Candles. Since spirometry is a patient effort-dependent test, these incentives help some patients complete their exhalation and perform the test properly.



The user can select from the following choices:

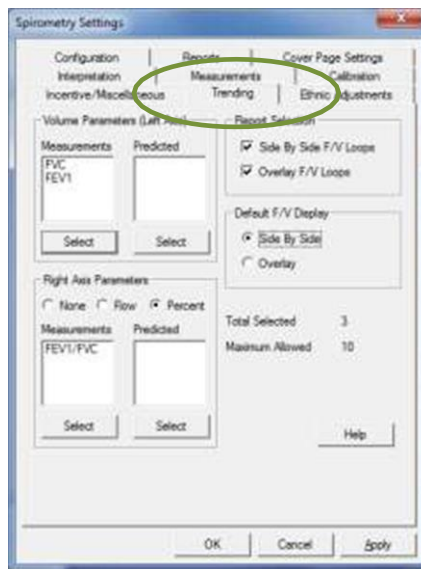
- Thermometer
- Tree and Leaves
- Tree, Leaves and Monkeys
- Tree, Leaves and Pinwheel
- Candles
- No incentive (see below)

If the user prefers that no incentive appear during a patient test, un-check the box marked “Use Spirometer Incentive”. No graphic incentive will display during the test maneuver, however, the following dialog box will be displayed.



Trending Tab

The *Trending* tab enables you to customize the Trending report. Select which volume, flow and/ or percent parameters to display. For additional information on this feature, see [Section IV-C, Trending](#).



Spirometry Settings – Trending Tab

Ethnic Adjustments Tab

The *Ethnic Adjustments* tab enables the user to set what the predicted value equations are adjusted to when testing a specific ethnic code. When the *Use Default Settings* box is checked, the program will set the percentages to the default; when the box is clear, the values may be adjusted. See [Appendix H - Adjustments to Reference Values Equations](#) for the default values and additional information.



Spirometry Settings – Ethnic Adjustments Tab

It is highly recommended to use the default ethnic settings for testing.

F. Calibration

Midmark recommends calibrating all spirometers daily before use. The IQspiro® automates this process for quick and accurate calibration of the instrument.

Calibrating the IQspiro® requires a 3-Liter syringe. Midmark strongly recommends using the Midmark 3-Liter syringe with the Midmark Syringe Adapter.

Note

*The IQspiro® must be calibrated with a DM; the DM must be calibrated with a syringe adapter that fits over the outside diameter of the DM. **Never calibrate the device with a syringe that fits inside the DM.***

1. Access the **Calibration** screen from the IQmanager® Opening Screen by selecting the Calibrate



button

2. A list of devices that support calibration is shown. Select Spirometer from the list by choosing the calibration icon on the right.



IQspiro
Pulmonary

Version: 10.0.0.22
Description: Midmark Spirometry device
Manufacturer: Midmark



Spirometry Calibration Utility Screen

Note

Place the DM into the IQspiro® before opening the Calibration or Test screens. See [Section II-D, Hardware Setup](#).

3. The following calibration screen is shown:



Calibration Screen

4. Check to see if *Sensor: Ready* is displayed in the upper-right corner of the graph window. To print the calibration report, select **Print** in the bottom left.

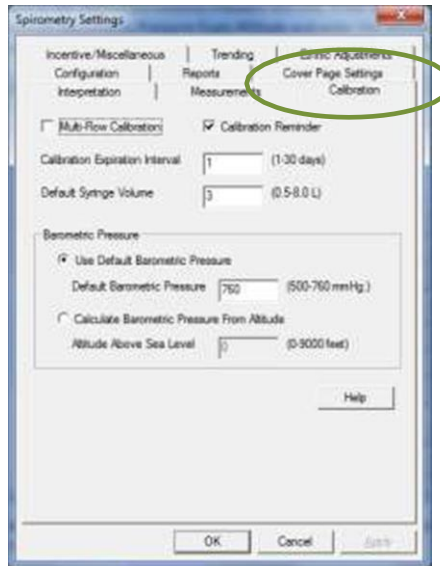
Barometric Pressure

The barometric pressure must be set prior to the first time the system is calibrated. It must be changed only if the location of the instrument is changed and/or the altitude changes.

Click **Settings** to open the *Spirometry Settings* dialog box. Select the *Calibration* tab and enter the barometric pressure in the *Default Barometric Pressure* text box. If the barometric pressure is not known, select *Calculate Barometric Pressure From Altitude* and enter the altitude. The software will automatically calculate and store the usual barometric pressure for that altitude.

Note

The proper barometric pressure or altitude **MUST** be entered to assure a proper calibration.



Spirometry Settings – Calibration Tab

Check the *Calibration Reminder* box to remind the user when the IQspiro® has not been calibrated for the interval set in the *Calibration Expiration Interval* box.

G. Starting a New Calibration

1. Click **New Cal** on the *Calibration* screen to begin a new calibration.
2. Attach the 3-Liter syringe to the large end of the syringe adapter then attach the small end of the adapter to the DM.

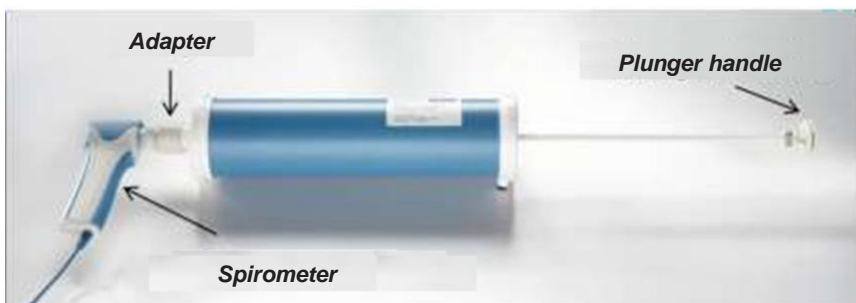
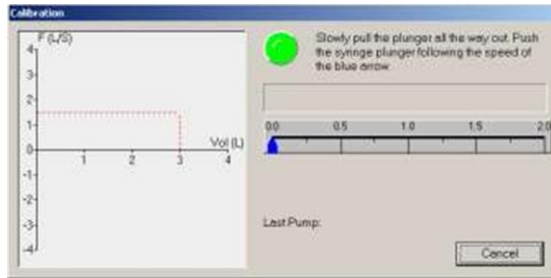


Figure 3-1 IQspiro® with a 3-Liter syringe attached

3. Check that the DM is properly attached to the IQspiro®.
4. The first time the IQspiro® is calibrated; the serial numbers for the syringe and the spirometer handle need to be entered in the appropriate boxes.
5. Click **Start Cal**. The sensor will zero itself and then the *Calibration Pump* screen appears:



6. Follow the instructions. Use the red dotted line and/or the blue timer arrow as a target flow rate. Try to inject the air from the syringe at a rate close to that of the red line.
7. The plunger handle must be pulled all the way out before proceeding. Once the handle is all the way out, inject the air from the syringe until the handle is all the way in.

Note

Push the handle in and draw the handle out smoothly; try not to “bang” the plunger as you perform the maneuver. Banging the plunger can cause the timer arrow to start to count. If it does, wait for the timer to reset and inject the plunger. This will not affect the calibration results.

8. If the calibration is performed correctly, the system will prompt to begin a second injection. Repeat the process, injecting all of the air from the syringe through the spirometer. If the injection is not performed correctly, the system will discard the attempt and prompt to inject again.
9. After three correctly performed calibrations, the system will automatically calculate a correction factor and prompt to perform a verification pump. **Always verify the calibration.** After a verification injection, the software will display the measured volume and the percentage difference from 3.0 Liters.

Note

The ATS recommends that the verified volume should be between 2.89 and 3.10 (+/- 3.5%) to be accepted. Be sure to check these numbers before accepting the verification.

10. The verification acceptance dialog box will display those numbers for comparison. Click Yes if the verification flow is within the recommended parameters. If the flow is not within the parameters, click No and repeat the verification flow.



Verification Acceptance Dialog Box

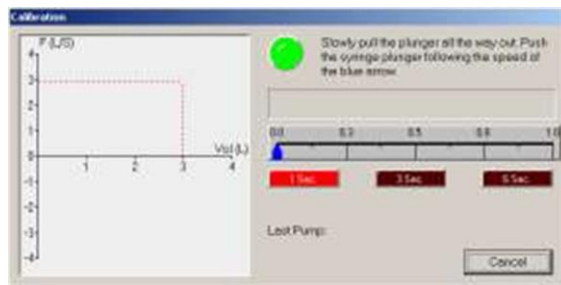
11. After accepting the verification, the system automatically saves the calibration. To print the calibration report, click **Print** and select *Print*. To view the calibration report, click **Print** and select *Print Preview*.
12. After printing or reviewing the calibration report, click **Exit** to start testing.

Social Security Disability – 3 Flow Calibration

SSD and OSHA require a calibration at three different flow rates. Midmark has incorporated a feature that requires calibration at 0.5 L/s, 1 L/s and 3.0 L/s.

On the *Calibration* tab of the *Spirometry Settings* screen, there is an option for *Multi-Flow Calibration*; when checked, you must calibrate at three different flow rates. The program will display the *Multi-Flow Calibration* dialog box and will measure the flow rates as the user injects the 3 liters. If the flow is too fast or too slow, the program will reject the injection and ask the user to try again.

When injecting the 3 liters, try to keep the graph on the left hand side in line with the dotted red line, or, on the right hand side, try to keep the bar moving at the same speed as the blue arrow.



Multi-Flow Calibration Window

OSHA Regulations

OSHA regulations are outlined in the Recommended Standardized Procedures for Pulmonary Function Testing, published in the Federal Register. At a minimum, OSHA requires:

- Calibration with both spirometer and syringe at the same temperature.
- Proper calibration of the spirometer daily (three different flow rates).
- Calibration for volume and time or flow and time (we provide volume and time).
- Calibration before each shift.
- Calibration whenever the spirometer is transported.
- Calibration after every thirty tests or sooner (2-3 hours) under field test conditions.

Please refer to the Federal Register or your OSHA representative for additional details about occupational testing.

III. Operation

A. Starting IQmanager®

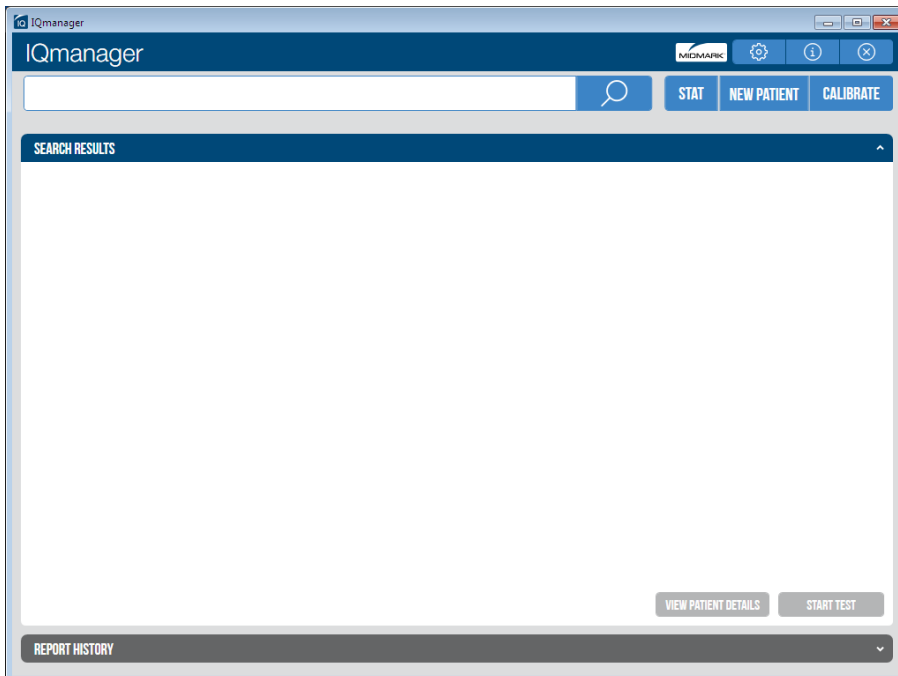
The software application for operating the IQspiro® is called IQmanager® and is located on the computer desktop as a shortcut icon. Double-click on this icon to start IQmanager®.












Midmark IQmanager®

B. Opening Screen

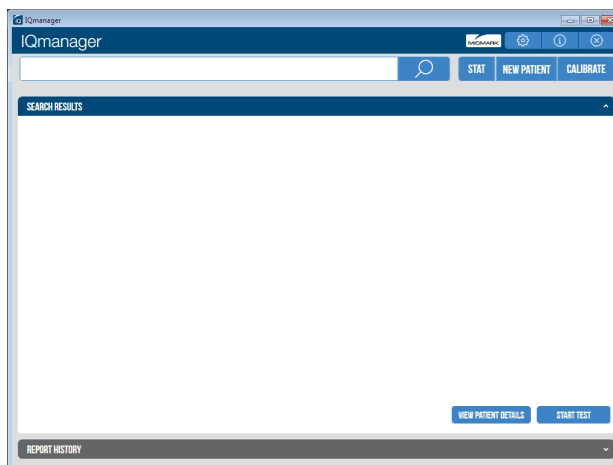
When starting IQmanager®, the opening screen will appear:



Opening Screen Functions	
Button	Function
	Search for patients previously entered into the database; selecting a patient from the list allows access to, edit, add and delete data from that patient's records and view data from previous tests.
	Acquire any STAT test before entering patient demographics or selecting a patient.
	Register a New Patient . Refer to the appropriate device Operation Manual for a description of the patient details required for specific tests.
	Calibrate a Midmark device.
	View patient details from a patient selected from the Search Results screen.
	Go directly to the test selection screen for the selected patient, bypassing the Patient Data screen.
	Enable users to configure the program to meet their needs. (See “Configuring IQmanager” for more information).
	Receive assistance regarding the use, operation and troubleshooting of IQmanager® and other Midmark products.
	Exits the program and returns to the Windows desktop.

C. Creating a New Patient Profile

To create a new patient file, click the **New Patient** icon on the *Opening screen*. This opens the *Patient Details* screen to enter the patient's specific data.



Opening Screen

Note

A patient name and DOB must be entered to start a new test. It is highly recommended to enter all information available, including patient ID.

Click in any text box or press the Tab key on the computer keyboard to enter information and move from field to field. This information may not be essential for every test performed, however, it is important to complete each of these fields as accurately as possible. Each diagnostic test has its own patient data requirements, which may affect the computer-generated interpretation of the test; it is important to refer to each device's Operation Manual when completing this screen.

Important Computer Date Information

The IQspiro® uses the current date from the computer and the patient's birth date (entered by the user) to calculate the patient's age. Since the IQspiro® equations and interpretive analysis use the patient's age to produce appropriate diagnostic statements, it is important that computer's current date is accurate. Contact the system administrator if your computer's date is incorrect.

The following table provides a brief description of the function for each field. Fields that play a diagnostic role in the interpretive program are noted.

Patient Data Fields		
Field	Diagnostic Role	Description
Patient Information		
<ul style="list-style-type: none">• First Name• Middle Name• Last Name	Required (except Middle Name)	Used for identification purposes. Letters and numbers may be used.
Date of Birth Format: MM/DD/YYYY	Required for ECG and Spirometry	Used for information and diagnostic purposes in ECG and Spirometry. IQmanager® uses this data to calculate the age of the patient. Format may be changed in the <i>Configuration Settings</i> .
Gender	Required for ECG and Spirometry	Used for identification and diagnostic purposes in ECG and Spirometry.
Race	Required for Spirometry	Used for information and diagnostic purposes in Spirometry. Select from the pull-down menu one of the following: Unspecified, Caucasian, Black, Asian, American Indian, Hispanic, African- American, or African-European. If the patient's race is not listed, not known, or the patient is of multiracial origin, select the race as identified by the patient.
ID #	Recommended	Used for identification purposes. Letters and numbers may be used.
Contact Information		
Address	(Contact Info tab)	Used for identification and/or contacting purposes. Letters and numbers may be used.
Home Phone		
Cell Phone		
Work Phone		
Email		
Smoking History		
Year Start Smoking	Recommended for Spirometry (Smoking History tab)	For diagnostic purposes in Spirometry. Enables the operator to enter smoking history.
Year Quit Smoking		
Cigarette/Day		
Risk Factors		
History of Angina	(Risk Factors tab)	Used for informational and diagnostic purposes when interpreting test results. The information entered in this tab appears in the Patient Data Report.
Physical Activity		
Resting ECG Status		
<ul style="list-style-type: none">• Hypertension• High Cholesterol• Obesity• Diabetes		
Medical History		

Patient Data Fields		
Field	Diagnostic Role	Description
Pacemaker	(History tab)	Used for information purposes.
Physician		
Referred By		
Facility		
Medication(s)		
<ul style="list-style-type: none">• Medications• Dosage• Schedule	Recommended for Resting ECG and Spirometry (Medications tab)	May be used as a diagnostic tool when interpreting test results.

Click **Save** to store the data entered or edited in the *New Patient* screen in the database.

Click **Clear** to refresh the *New Patient* screen and remove all existing information entered or edited.

Click **Cancel** to exit the *New Patient* screen without saving any changes.

Upon completion of the Patient Data screen, review all information to ensure that everything is accurate and up-to-date. Once accuracy is confirmed, proceed with a new patient test.

Vitals

The Vitals drop-down provides a composite of the patient's most recent day of data. If no vital signs have been entered, the title of the control group title reads *Vital Signs* and each field is blank. If vital signs have been previously entered, the control group title will read Vital Signs as of *mm/dd/yy hh:mm:ss* indicating the date and time of data entry, and boxes will be read only. To edit vitals, click **New Vitals** to overwrite the data. Additional information about the *Vitals* section can be found in the *IQmanage® Operation Manual*.

Smoking History Drop-down

Smoking History N ▼

Year Started Smoking

2010 ▼ ✕

Year Quit Smoking

▼ ✕

Cigarettes per day

» Save | » Cancel

- Select the year the patient started smoking from the *Year Start Smoking* drop-down.
- If the patient has quit smoking, select the year the patient quit from the *Year Quit Smoking* drop-down. If the patient has not quit smoking, select *Have Not Quit* from the drop-down.
- Enter the number of cigarettes the patient smokes per day in the *Cigarettes/Day* field.

Medications Drop-down

The *Medications* drop-down displays the current medications assigned to the patient. The available actions are to add, edit or delete medications from the patient's profile.

Medications 1 ▼

Medications

Metaprolol ▼

Dosage

10mg

Frequency

4/day ✕

▼

+

» Save | » Cancel

Contact Info Drop-down

The *Contact Info* drop-down provides the patient's address, phone numbers and email address.

Contact Information1

Address

Home Phone

Cell Phone

555-123-5678

Work Phone

Email

» Save | » Cancel

Medical History Drop-down

Selecting the *History* drop-down on the *Patient Details* screen enables the operator to select from a number of common conditions that may play a role in the physician's final diagnosis.

Medical History0

Pacemaker

Physician :

Referred By :

Hospital

» Save | » Cancel

Risk Factors Drop-down

The Risk Factors drop-down lists possible diagnostic factors for the physician's use including *History of Angina*, *Physical Activity*, *Resting ECG Status*, *Hypertension*, *High Cholesterol*, *Obesity* and *Diabetes*. The data is informational only and will not affect the program's diagnostic results.

Risk Factors3

History of Angina

None

Physical Activity

Sedentary

Resting ECG Status

Risk Factors

☒Hypertention

☐High Cholesterol

☐Obesity

☐Diabetes

» Save

|

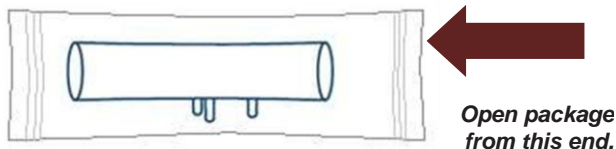
» Cancel

D. Pre-Test Preparation

1. Calibrate the IQspiro® daily before use for accuracy.
2. Measure the patient's height. If the patient can't stand, measure their arm span from fingertip to fingertip with arms outstretched against a wall.
3. Wash your hands.
4. Explain to the patient that they will be sitting for the test. If prior testing took place with the patient standing, have them sit, but make a note of the change or have them continue to stand while being tested.
5. Ask the patient to loosen any restrictive clothing.
6. Have the patient place loose dentures in a cup.
7. Use of a nose clip is highly suggested during the testing procedure.
8. Avoid cross-contamination by disposing of the DM and replacing it with a new one for each patient.

Note

Always open the package from the end closest to the single pin on the mouthpiece. This is the exhalation side of the mouthpiece and is safe to handle. (See figure below).



9. Explain to the patient that they will be performing a minimum of three and a maximum of eight testing maneuvers.



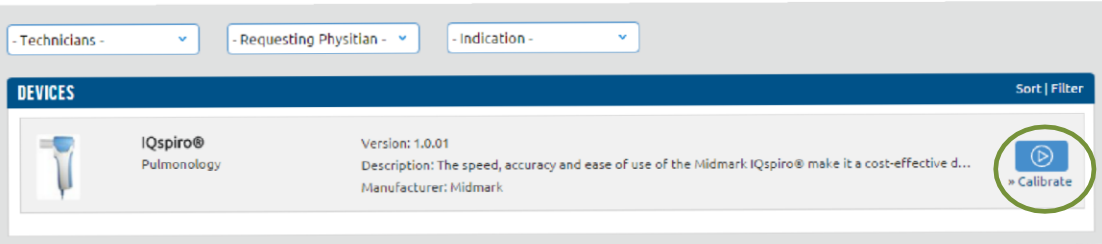
Caution

Midmark IQspiro®, when used with specific Midmark disposable mouthpieces, is designed and tested to meet regulatory and industry standards. Midmark can only warrant product performance and accuracy if the IQspiro® is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark IQspiro® mouthpiece, including but not limited to the use of an adapter or filter, is considered an alteration to the design of the product.

E. Performing an FVC or FVC Loop

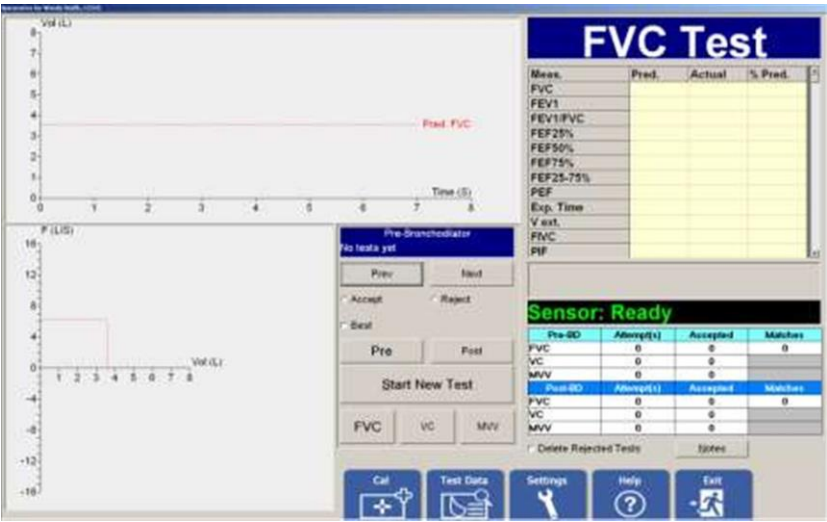
The FVC test is usually the first spirometry test prescribed. Traditionally, the FVC test measures expiratory flow only; the FVC Loop is a FVC test with the inspiratory portion of the test included. However, a full expiratory and inspiratory loop is often referred to as a Flow Volume Loop, an FVC Loop or occasionally, an FVC test. With IQspiro®, the user can perform a FVC or FVC Loop by selecting FVC.

To start a test, click **New Test** from the *Patient Data* screen. Click on the play icon next to IQspiro.



If desired, type the Technician's name and the Physician's name or select them from the pull-down list. The reason for testing the patient can also be selected from the *Indication* list as shown in the *New Test Selection* Screen.

Click on **OK** to open the test acquisition screen. The *Spirometry Data Acquisition (Test)* screen appears:



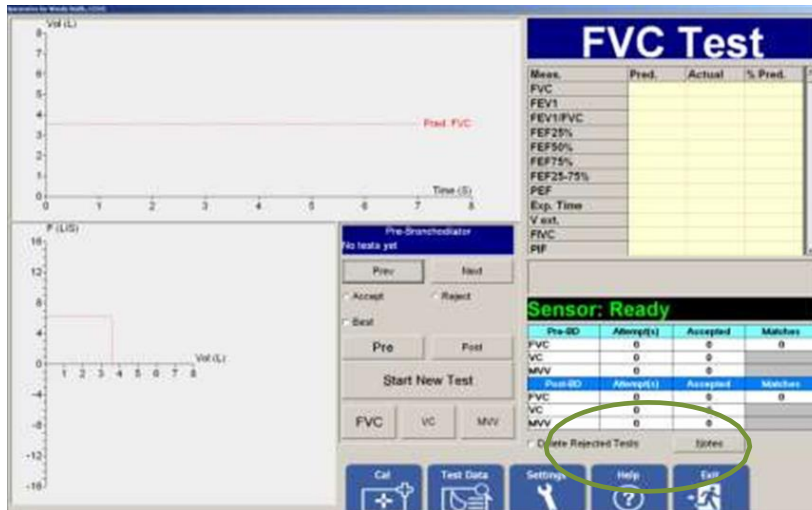
By default, **FVC** will be selected. For a Pre-BD test, make sure the words *Pre-Bronchodilator* appear in the blue box in the middle of the screen. Also notice that **Pre** and **FVC** are bold. Do not click **Start New Test** until the patient is ready.

F. Observation Notes

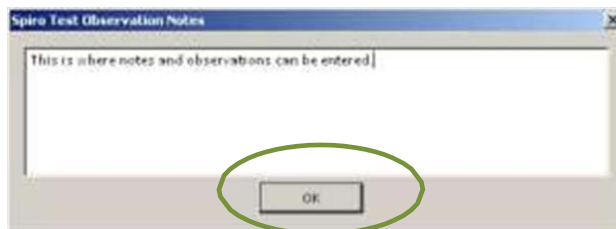
Observation notes may be added in this section before or right after the patient maneuver. Be sure the information entered is accurate as once the report screen is clicked, notes and observations cannot be changed.

To add notes and observations before or right after a test maneuver:

1. Click on the **Notes** button in the *Spirometry Data Acquisition (Test)* screen.



2. Enter notes and observations here.



3. Click **OK** when done.

The observation notes entered can be viewed in the report screen and will appear on the printed report.

ECG RR Variability Holter Spirometry Stress Vitals

1-04/30/12 10:02:24 Report 1 of 1 Trending

Technician: Bill Marks Review Date:

Reviewed By: Predicted: Crapo Bronchodilator: ipratropium

Summary | FVC Graphs | M/V Graphs | VC Graphs

	Units	Predicted	Pre Actual	Pre % Pred.	Post Actual	Post % Pred.	% Change
FVC	L	6.29	1.97	30 %			
FEV1	L	5.20	1.40	27 %			
FEV1/FVC	%	84 %	75 %	90 %			
FEF25%	L/S	8.46	3.65	43 %			
FEF50%	L/S	5.66	1.34	24 %			
FEF75%	L/S	3.13	0.54	17 %			
FEF25-75%	L/S	5.36	1.08	20 %			
PFF	L/S	9.29	1.49	16 %			

Age: 16 years Lung Age: N/A Pre-BD FVC: 3 attempted, 2 accepted, 0 matches.
 Sex: Male Post-BD FVC: 0 attempted, 0 accepted, 0 matches.
 Height: 74 inches Smoker: No.
 Race: Caucasian

Interpretation:
 Moderately severe obstruction.

Observation Notes:

File Print New Patient Patient List Patient Data New Test Help Exit

Note

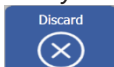
Text entered in the Observation Notes can only be edited while in the live testing screen. Observation notes cannot be edited once the test screen has been exited.

Note

The Sign check box allows users to electronically sign the report after the report has been reviewed and saved. This feature prevents any changes to be made to the signed report.

Note

During the initial acquisition/edit of the spirometry test, the results can be discarded by selecting the **Discard** button.



G. Patient Instructions

The accuracy of spirometry testing depends on proper patient instruction and coaching. Therefore, the technician or nurse is a critical factor in achieving good spirometry results. After patient instruction is given, it is essential that the clinician demonstrate the correct way to perform the test.

- The purpose of spirometry is to determine how much air the patient can inhale into their lungs and how hard and fast the patient can blow out that air for at least six seconds. It should be like blowing out candles on a birthday cake, until there is no air left to exhale.
- The patient should inhale as deeply as possible; when the lungs are completely full, have them quickly put the DM in their mouth with the tongue under the DM, teeth and lips around it, sealing the lips around the DM, blast out as hard and fast as possible.

Note

The patient should not block the opening of the DM with their tongue or teeth.

Note

When explaining the maneuver to the patient, instruct them to use the ridges on the top and bottom of the DM as a guide for how far to insert the mouthpiece into their mouth. Good practice is for the patient to rest their teeth gently between the ridges.



Caution

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- The use of nose clips helps ensure that no air leaks out through the nose during testing. Air leakage through the nose can affect the test results.
- The technician will demonstrate the FVC maneuver with the use of a DM.
 - To emphasize to the maneuvers to patient have the technician do the following:
 - Take a very deep breath, and throw the shoulders back, widen their eyes and stand on their toes.
 - The technician should then stick out their tongue, place the DM on top of their tongue and seal their lips around it.
 - The technician will then **Blast** out as hard and fast as possible for at least six seconds. A vigorous demonstration will help produce a good spirometry test for the patient.
- Explain to the patient that the correct posture during testing is to have the shoulders back, chin up and do not lean forward during exhalation.

Note

Most patients have a normal tendency to lean forward while exhaling forcefully. Ask the patient for permission to place a hand on their shoulder during the test. If they start to lean forward during the maneuver gently help correct their posture.

Have the patient visually focus on an incentive screen or an object at eye level to help keep the chin up and posture straight.

For pediatric patients with small hands, instruct them to hold the spirometer with both hands, versus one hand.

H. Step-by-Step Spirometry Instructions

1. Insert a new DM in the IQspiro®. See [Section II-D, Hardware Setup](#).

- Instruct the patient to hold the IQspiro® in either hand and then hold the device up and to the side of their face, as illustrated in the photo below.



- On the *Patient Testing* screen click **Start New Test**.
- The device will zero itself. **Be sure that no air is traveling through the mouthpiece during zeroing.** The following box will appear while the IQspiro® is zeroing:



- Once the zeroing is done, an incentive display appears, if one has been chosen.
- Instruct the patient to take a maximal inhalation.
- Instruct the patient to quickly put the DM in their mouth, with their tongue under the DM, teeth and lips around it, sealing the lips around the DM. Have them *Blast* out as hard and fast as possible.

Note

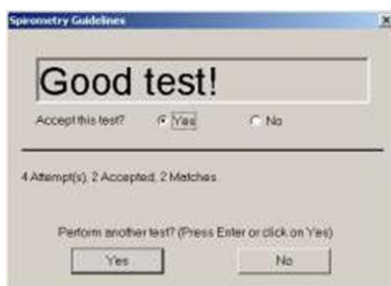
The patient's tongue or teeth should not be blocking the opening of the DM.

Note

When explaining the maneuver to the patient, instruct them to use the ridges on the top and bottom of the DM as a guide for how far to insert the mouthpiece into their mouth. Good practice is for the patient to rest their teeth gently between the ridges.

- Encourage the patient to keep blowing out for six seconds, until no air is left to exhale.
 - Optional: Have patient then forcefully inhale until lungs are full.

9. Stop the test and instruct the patient to remove DM from their mouth.
10. If necessary, instruct the patient on how to correct any technique problems.
11. Obtain three good maneuvers and two matches. Do not exceed eight maneuvers in one testing session.
12. The program automatically assigns a quality grade to the test.



Test Accepted Dialog Box

13. After each completed test, the *Test Accepted* dialog box appears with either **Yes** or **No** automatically selected. After a test is accepted or rejected, click **Yes** to perform another test or **No** to stop testing.

Note

The acceptability statements are intended as recommendations or guidelines and are not mandatory actions. You can override the software selection and choose Accept or Reject for each test.

Acceptability Statements Seen During FVC Testing		
Acceptability Statement	Criteria	Comment Displayed
Good test	Meets all the criteria listed below	Good test!
Hesitating start	If BEV >150mL	Don't Hesitate
Test too short	If FET <6.0 sec and EOTV >40 mL (invalid FEV ₀)	Blow out longer
Poor effort	If PEF match >1.0 L/s	Blast out harder
Poor effort in 1 st second	If FEV ₆ match >150mL	Deeper breath
Achieve two matches	After two acceptable maneuvers match	Good test session
Poor effort on PEFT	If PEFT >120msec	Blast out faster
Interrupted flow	Cough or interruption detected	Blast out smoothly
Abrupt stop	No plateau of duration of at least one second in which there is less than 0.050 liters of volume change	Blast out completely
Inhalation volume is greater than the Exhalation Volume	Inhale > 1.1 * exhalation if inhalation performed	Inhale deeper before starting the test

Acceptability Statements Seen During FVC Testing		
Acceptability Statement	Criteria	Comment Displayed
Exhalation volume is greater than the Inhalation Volume	Exhale > 1.1 * inhalation if inhalation performed	Inhale completely at the end of the test
This acceptability statement was added by Midmark	Volume less than 0.50 Liters	Volume Too Low

Note

Only one error message is displayed.

Note

Use best judgment when deciding to accept or reject a test.

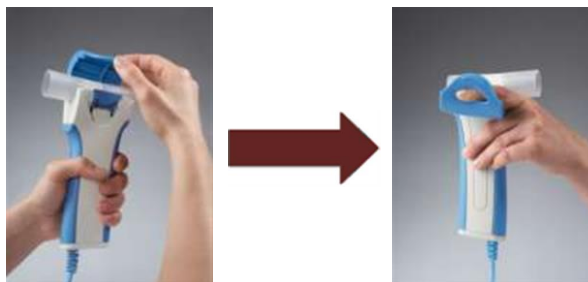
- After the patient has completed the number of required tests, click **Save Review** in the lower-right corner of the test screen. This will automatically save the test session and display the *View Report* screen.

See [Section IV, Reviewing Patient Reports](#) for more information about the *View Report* screen.

Ejecting the DM from the IQspiro®

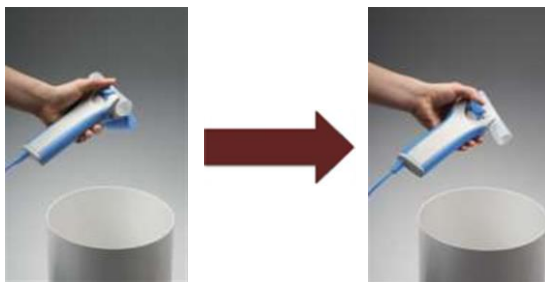
The IQspiro® eliminates the need to handle the used DM

To eject the DM from the IQspiro®:



- Open the IQspiro® door and hold open with indexfinger.

2. Hold IQspiro® over trash receptacle and use your thumb to push down on the eject lever.



3. The used DM will eject into the trash receptacle.

Quality of Test Results

Having the patient inhale at the end of the test provides measures to ensure that the patient inhaled fully before they started the test and expired fully during the test. If a patient performs a FVL, the results of their expiratory volume and their inspiratory volume should be within 10% of each other. If they are not, the appropriate acceptability statement will display after the test is completed.

Post-Bronchodilator Test

The following instructions assume the Pre-BD test has been done on the patient and the bronchodilator has been administered.

Note

To assure validity of the Post-BD test, ample time should be allowed for the medication to take effect. Refer to manufacturer's package insert for further information.

Post-Bronchodilator Testing a Patient

From the View Report screen, select a bronchodilator from the pull-down list then click **Post-BD** to return to the testing screen and perform the test. Post-BD FVC tests are performed the same way as Pre-BD FVC tests. See [Appendix L - Performing a Pre/Post FVC Test - Quick Reference User's Guide](#).

Vital Capacity or Slow Vital Capacity Tests

Vital capacity (VC) or slow vital capacity (SVC) tests can determine if a patient's lungs are trapping air during a FVC test. Air trapping can be an indication of airway obstruction and can also be seen in older patients. This is a very slow and deliberate test. The patient takes two or three normal tidal breaths then a slow, deep breath, and then a slow, full exhale.

Click **VC**, which will be bolded. If this is a Pre-BD test, make sure the *Pre-Bronchodilator* message is displayed in the blue box in the middle of the test screen. Do not click **Start New Test** until the patient is ready to perform the test.

To perform a VC test, the patient must perform the following:

1. Inhale completely before placing the flow sensor mouthpiece into the mouth.
2. Instruct the patient to place the mouthpiece on top of their tongue, with their teeth and lips around the mouthpiece. The patient must seal their lips around the DM. Let the patient get used to the feeling of breathing with the DM in their mouth.
3. Inhale as deeply as possible, until the technician observes a plateau at the bottom of the graph.
4. Exhale slowly and evenly until the technician observes a plateau at the top of the graph or the device signals that the end of test criteria has been met.
5. The technician should stop the test by clicking **Stop** or pressing **Enter**.
6. Remove the mouthpiece when instructed by the technician.

The patient must exhale at a faster rate during the blow out phase than during the tidal breaths. After the patient has completed the number of tests required, click **Save Review** and click **Yes** to save the test efforts.

Maximum Voluntary Ventilation

The Maximum Voluntary Ventilation (MVV), is the measurement of a patient's breathing when the patient inhales and exhales maximally and rapidly for 12 to 15 seconds. The software takes this result and extrapolates the results for a period of one minute. MVV is expressed in liters per minute (L/min). This is a very demanding test and patients must be allowed to rest between efforts. The MVV test is required to qualify some patients for Social Security Disability benefits.

Click **MVV**, which will now be bolded. For a Pre-BD test, make sure the *Pre-Bronchodilator* message is displayed in the blue box in the middle of the test screen. Do not click **Start New Test** until the patient is ready to perform the test.

To perform the MVV test, the patient must perform the following:

1. Instruct the patient to put DM in their mouth, with their tongue under the DM and lips sealed around it. Take at least three normal tidal breaths.
2. Inhale and exhale maximally as quickly as possible for 12 to 15 seconds.

Coach and encourage the patient until the test time exceeds 12 seconds. Have the patient remove the DM from their mouth and allow them to rest.

After the patient has completed the number of tests you require, click **Save Review** and click **Yes** to save the test efforts.

IV. Reviewing Patient Reports

IQmanager® allows for the storage of additional patient diagnostic tests including ECG and Holter data. If the components are being utilized refer to the appropriate manual for information about those devices.

A. Review Spirometry Reports

Once the spirometry session is completed and the test screen has been exited, the *View Report Summary* screen appears:

ECG RR Variability Holter Spirometry Stress Vitals

1 - 04/30/12 10:02:24 Report 1 of 1 Trending

Technician: Bill Marks Review Date:

Reviewed By: ☒ Sign Predicted: Crapo

Summary | P/V Graphs | MVV Graphs | VC Graphs

	Units	Predicted	Pre Actual	Pre % Pred	Post Actual	Post % Pred	% Change
FVC	L	6.29	1.87	30 %			
FEV1	L	5.20	1.40	27 %			
FEV1/FVC	%	84 %	75 %	90 %			
FEF25%	L/S	8.46	3.65	43 %			
FEF50%	L/S	5.86	1.34	24 %			
FEF75%	L/S	3.13	0.54	17 %			
FEF25-75%	L/S	5.36	1.08	20 %			
PFF	L/S	9.26	1.40	16 %			

Age: 16 years Lung Age: N/A Pre-BD P/V: 3 attempted, 2 accepted, 0 matches.
Sex: Male Post-BD P/V: 0 attempted, 0 accepted, 0 matches.
Height: 74 inches Smoker: No.
Race: Caucasian

Interpretation: Moderately severe obstruction.

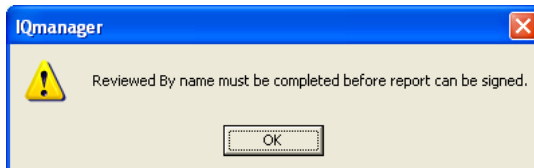
Observation Notes:

File Print New Patient Patient List Patient Data New Test Help Exit

Spirometry View Report Screen - Summary

The test results are displayed in the middle of the display area with other useful information displayed in the upper sections.

The *Sign* checkbox is used for signing off the report. If the *Sign* checkbox is unchecked, it indicates the report has not been signed and can still be edited. If the *Reviewed By* box is filled in with a name and the *Sign* checkbox is checked and saved when the review screen is exited, the report becomes read-only. If the user tries to check the *Sign* checkbox without first typing the reviewer's name in the *Reviewed By* box, a warning message will pop up as follows:

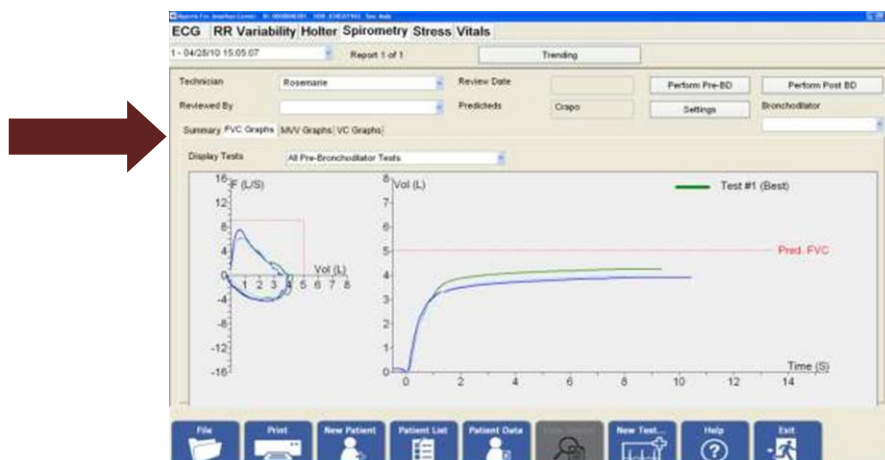


Click **Settings** to select which reports to print; every report checked will be included when the print function is selected.

In addition to the test results, the *Summary* tab includes the following information:

- Patient information: Age, Sex, Height, Race, Smoking History
- Lung age
- COPD (Chronic Obstructive Pulmonary Disease) risk
- Pre and Post FVC test session statement (Attempted, Accepted, Matches)

Click on the *FVC Graphs*, *MVV Graphs* or *VC Graphs* tab to view other data for this patient. Remember that only the information stored is available for viewing.



Spirometry View Report Screen – FVC Graphs

B. Spirometry Analysis and Reports

Printed reports display patient demographics, test date and time, measurements, graphs, interpretations, observation notes and additional analysis of the spirometry test results.

COPD Risk Assessment

The COPD Risk Assessment uses the Tecumseh Index. It is helpful in smoking cessation programs. If the patient is a current smoker and that fact is entered into the *Patient Data* screen, the printed report will indicate the current COPD risk and the reduced COPD risk to the patient if they quit smoking. The COPD risk statements are: Low, Moderate, High. See [Appendix J – COPD Risk Assessment Calculation](#) for additional information.

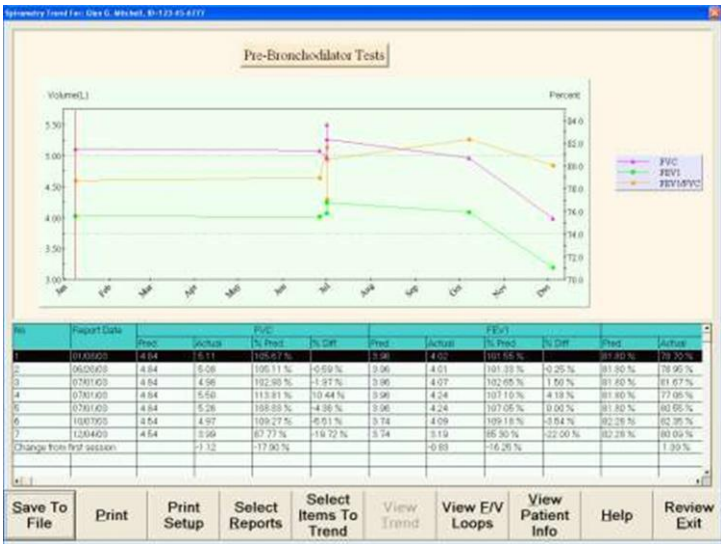
Lung Age

Lung age is a smoking cessation tool that, if enabled, appears on the summary screen and provides an indication of the health of the patient's lungs. The program automatically calculates the lung age of the

patient from the patient's sex, height and FEV₁. Lung age is calculated only for patients who have been identified as current or former smokers, from 20 to 84 and will never a value of 25 or less than the patient's actual age. It should be emphasized that the lung age parameter is intended to be used solely as a smoking cessation tool and not as a diagnostic measurement. See [Appendix K - Lung Age Calculation](#) for additional information.

C. Trending

Trending enables the comparison of the best test measurements from two or more of a patient's spirometry sessions.



Trending - Main Screen

Use trending to compare different spirometry measurements over time. The changes in a patient's condition can be more easily seen in graphical and tabular form.

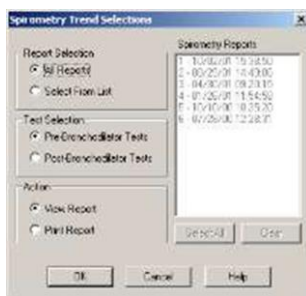
The following features are standard in the Trending software:

- Date and time of each test performed is displayed
- Select one to ten different spirometry measurements to trend at one time.
- Select the length of time to compare, from a minimum of two sessions to a maximum of all test sessions stored for that patient.
- Compare two individual tests, e.g., the best test in one session against the best test in another session.
- Compare actual and predicted measurements.

- View changes over a selected period of time, e.g., the oldest test session against the latest test session.
- Compare Pre-Bronchodilator tests only or Post-Bronchodilator tests only.
- Display tabular and graphical results for easy comparison.
- Display color-coded graphic results for easy identification.
- Print and display trend measurement in tabular format.
- Print and display graphical Flow/Volume (F/V) reports in overlay or side-by-side formats.

Selecting Reports to Trend

Click **Trending** from the *View Report* screen and the *Spirometry Trend Selection* dialog box appears:



Spirometry Trend Selection Dialog Box

Report Selection

- *All Reports* (default): View all the reports in the list.
- *Select From List*: Select individual reports for trending.

Test Selection

- *Pre-Bronchodilator* (default): All trended values are taken from the best Pre-BD test of the session.
- *Post-Bronchodilator*: All trended values are taken from the best Post-BD test of the session.

Action

- *View Report* (default): Display the *Trending* screen, from which the user can choose to print the trending reports.
- *Print Report*: Click **OK** to print the trending report to the default printer. The *Trending* screen displays briefly then returns to the *View Reports* screen.

Spirometry Settings, Trending Tab



Spirometry Settings - Trending

The following actions can be accessed in the *Trending* tab on the *Spirometry Settings*:

- Select the parameters to trend,
- Select the type of Flow Volume Loop report to print, and
- Select the default Flow Volume Loop to display

Report Selection

Select which type of Flow Volume Loops to print with the trend report:

- *Side By Side F/V Loops*: F/V Loops are displayed and printed side-by-side.
- *Overlay F/V Loops*: F/V Loops are displayed and printed overlaid.

Default F/V Display

Select which type of Flow Volume Loops to review the trend report:

- **Side By Side**: Click **View F/V Loops** in the *Trending* screen to display the *Side By Side F/V Loop* screen as the default.
- **Overlay**: Click **View F/V Loops** in the *Trending* screen to display the *Overlay F/V Loop* screen as the default.
- **Total Selected**: Displays the number of parameters selected for printing.
- **Maximum Allowed**: Displays the maximum number of parameters allowed.

Axis Parameters

The left axis and right axis scales are independent of each other. The left axis always displays volume parameters in liters. The right axis displays either percentage parameters or flow parameters.

Volume Parameters

- **Measurements:** Lists volume measurements selected for the left axis.
- **Predicted:** Lists predicted values for volume measurements for the left axis.

Flow and Percentage Parameters

- **None:** Disables the right axis trend.
- **Flow:** The right axis is for trending flow measurements.
- **Percent:** The right axis is for trending percentage measurements.
- **Measurements:** Lists flow or percentage measurements selected for the right axis.
- **Predicted:** Lists predicted values for flow or percentage measurements for the right axis.

Selecting Parameters to Trend

From the *Trending* tab on the *Spirometry Settings* screen, click **Select** under one of the *Measurements* list boxes. The *Spirometry Trend Parameters Selections* dialog box appears, where the user selects which parameters to trend. There are six possible sets of parameters:

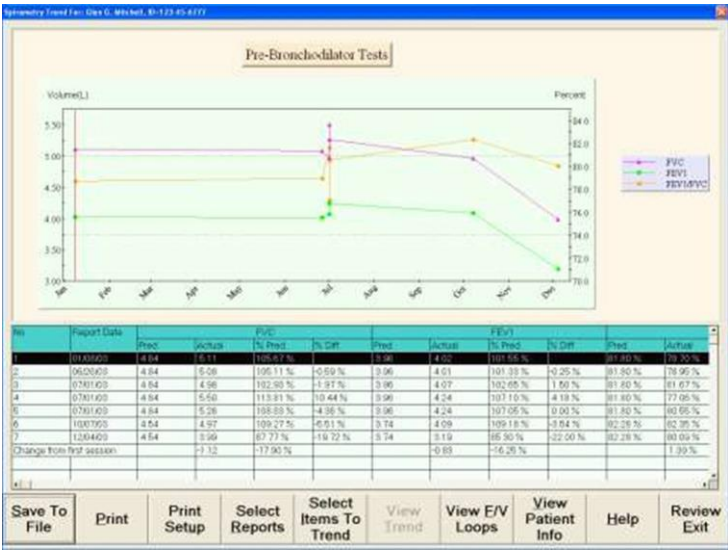
- Volume measurements
- Volume predicted values
- Percentage measurements
- Percentage predicted values
- Flow measurements
- Flow predicted values



Spirometry Trend Parameter Selection

- **Add:** Highlight an item in the *Available* list and click **Add**. This will place the new item at the bottom of the *Selected* list.
- **Insert:** Highlight an item in the *Selected* list. The new item will be inserted above this item. Highlight an item in the *Available* list and click **Insert**. This will place the new item above the highlighted item in the *Selected* list.
- **Remove:** Highlight an item in the *Selected* list and click **Remove**. This will remove that item from the *Selected* list and place it on the *Available* list.
- **Clear List:** Removes all the items in the *Selected* list and places them on the *Available* list.

Trend Display Screen



Trending - Main Screen

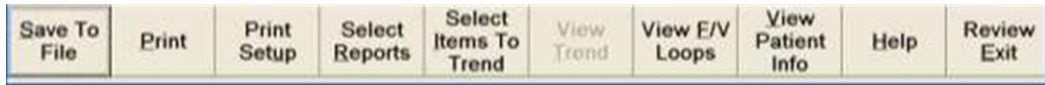
The *Trending* screen is the main screen of the spirometry trending control. It consists of a graphical chart, a tabular measurement grid, and trending button bar.

The graphical chart plots volume parameters on the left axis. The right axis is optional and can display either percentage parameters or flow parameters, depending on the settings. The horizontal axis represents time, spanning from the earliest session to the latest session.

Each parameter trended is a data series and is built from the values from the best Pre-BD or best Post-BD test of the spirometry sessions selected. The graph created for each parameter is represented by a different color line.

A vertical marker on the display moves left or right as the cursor is moved from left to right. The software automatically scrolls the grid and highlights the report to which the current marker points. If on a grid row is clicked on, the software moves the vertical marker to the data corresponding to the selected report.

Trending Buttons



Trending Button Bar

- **Save To File:** Click to open the *File Save* dialog box. Enter a valid filename and click **OK** to save the information in the grid in Microsoft Excel file format (*.xls).
- **Print:** Click to print the trend report to the currently selected printer.
- **Print Setup:** Click to display the *Print Setup* dialog box.
- **Select Reports:** Click to close this screen and return to the *Spirometry Trend Selection* screen.
- **Select Items To Trend:** Click to display the *Trending* tab from *Spirometry Settings*.
- **View F/V Loops:** Click to display the Flow/Volume loops using the default screen format or the last screen format used.
- **View Patient Info:** Click to display the patient's information for the current highlighted test.

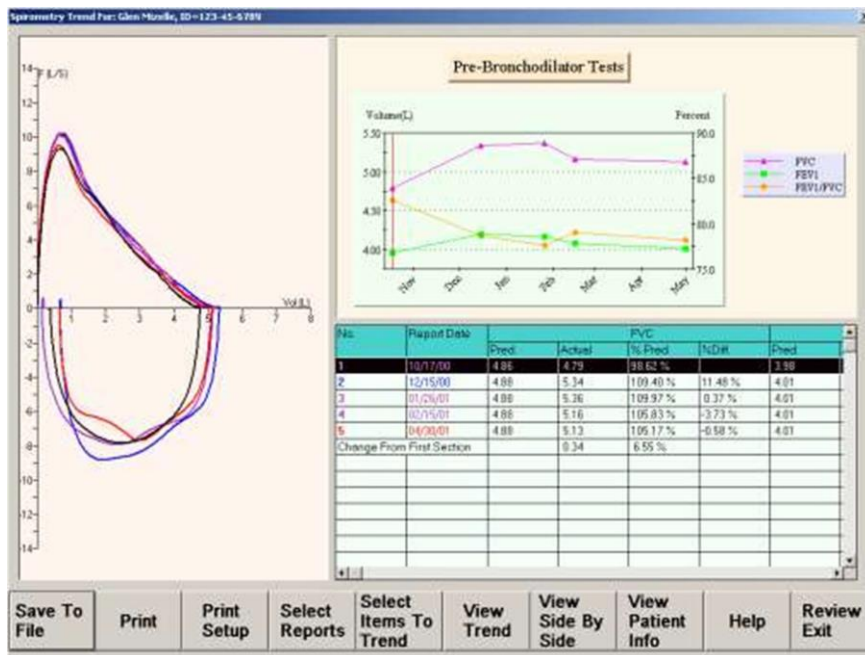
A dialog box titled 'Patient Information' with a blue header bar and a red close button. It contains several input fields: 'Name' (Glen G. Mitchell), 'Sex' (Male), 'ID' (123-45-6777), 'Race' (Caucasian), 'Report Date' (6 - 10/07/03), 'Age' (42 Years), 'Height' (68 inches), 'Weight' (162.4 lbs.), 'Smoker' (No.), and a large 'Medications' text area. An 'OK' button is at the bottom right.

Patient Information

- **Help:** Click to open the Help file.
- **Review/Exit:** Click to exit this screen and return to the *View Report* screen.

Overlay F/V Loops

The *Overlay F/V Loop* screen consists of a single F/V graphical display of the best FVC loop from each trended session, a chart showing the trended plots, and a tabular grid showing the parameters trended.



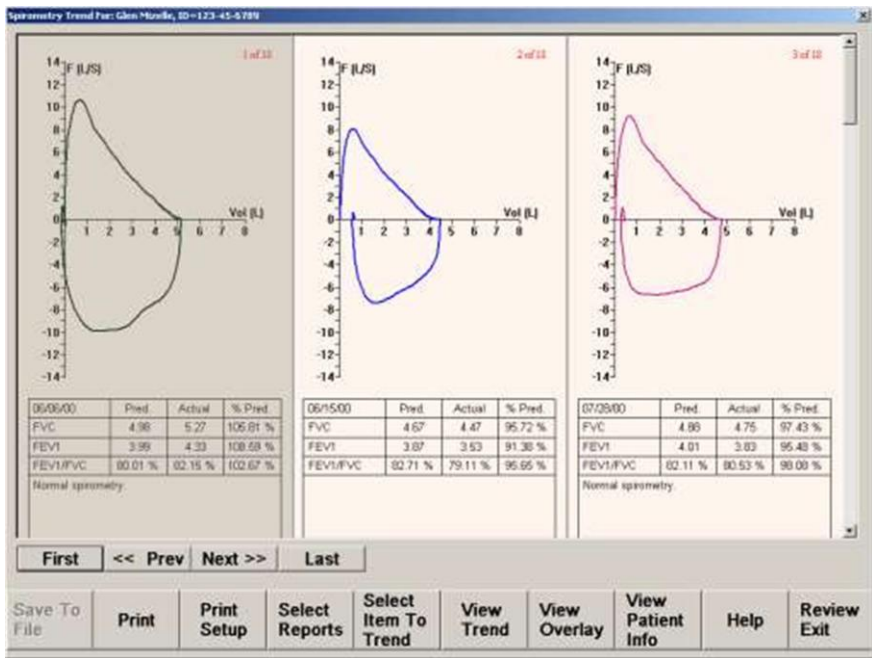
Overlay Screen

The F/V loops are displayed in up to ten different colors. If the number of F/V loops exceeds ten, the control reuses colors. The same color scheme is used in the grid, showing the session number and report date in the color that matches the associated F/V loop.

When the vertical marker is moved to a date or a point in the grid is selected, the software highlights the F/V loop corresponding to that report (if one exists) by drawing the loop in a black. The loop returns to its previous color when you select another report.

Side by Side F/V Loops

From the *Trending* screen, click *View Side by Side*. This screen shows three F/V loops ordered chronologically, starting with the top left loop, to the bottom right loop. Note that in this screen, **View Side by Side** will change to **View Overlay**.



Side By Side Screen

Immediately below the display are buttons that provide fast navigation:



- **First:** Display the first, second, and third F/V loops.
- **Prev:** Shift the display to show the previous series of F/V loops.
- **Next:** Shift the display to show the next series of F/V loops.
- **Last:** Display the last F/V loops.

Click **View Overlay** to display the F/V loops in an overlay format. Click **View Trend** to return to the main *Trending* screen.

V. Maintenance and Storage

Note

For the greatest accuracy, Midmark recommends daily calibration of the IQspiro® frequently.

- **DO NOT REUSE DISPOSABLE MOUTHPIECES.**
- For serial devices: Replace the batteries when the device LED turns red or the computer screen displays the *Low Battery* message.
- Inspect the IQspiro® and calibration syringe regularly for accuracy.
- Contact Midmark for your annual calibration certifications.

The IQspiro® Digital Spirometer product is designed to operate without adjustment for the lifetime of the device.

However, electronic equipment can be subject to wear and damage that can cause malfunctions. A certification policy is the responsibility of the end user and is subject to the end users' business practices which may require it. Certification provides peace of mind that the device continues to work within our factory specifications. Certifications can be purchased directly from Midmark.

Please contact Technical Service at (800) 624-8950 or (844) 856-1230, option 2, with any questions or to make arrangements for the certification of your IQspiro® Digital Spirometer device.

Cleaning



Caution

Do not use aromatic hydrocarbons, rubbing alcohol, or solvents for cleaning the IQspiro®.

Preventative Cleaning

Because the IQspiro® uses disposable single-patient use mouthpieces, there is no need to routinely clean or sterilize any part of the spirometer or cable. To clean the outside of the IQspiro®, use a mild solution of detergent and water with a soft cloth. Do not use an excessive amount of solution. Be sure not to wet the ports on the top of the IQspiro® or the battery compartment at the bottom (if applicable). If necessary, use a mild sterilizing detergent with low alcohol content generally used in hospitals. **Verify that all equipment, including accessories, is completely dry before using.**

Preventative Inspection

A preventative inspection should be done prior to each use to verify that there is no visible damage to the unit that may cause it to malfunction. The visual inspection should include the IQspiro® and the cable for signs of damage and deterioration, including but not limited to cracks, cuts, discoloration, or oxidation. If a cable or other accessory exhibits any of these symptoms, call Midmark Technical Service.

Storage

Avoid extreme humidity and heat during storage.

For serial connection devices: To prevent damage to the IQspiro® handle due to battery leakage or oxidation, remove all batteries if the device will not be used for a long period of time.



Caution

Electronic devices can be damaged by exposure to liquids. Do not use or store the IQspiro® near any type of liquids.

Radio and Television Interference

This equipment does not generate or use radio frequency energy. It will not cause interference to radio or television reception. This equipment has been tested and proved to be in compliance with the limits for a medical device in accordance with the IEC 60601 rules, which are designed to provide reasonable protection against such interference in a medical or hospital environment.

VI. Appendices

A. Appendix A - Screen Summary

Summary of Screens		
Screen Name	Screen Summary	Main Functions
Opening	Access the main functions of IQmanager®.	<ul style="list-style-type: none"> • Access <i>New Patient</i> screen. • Access <i>Search Results</i>. • Configure IQmanager® • Access <i>Help</i>. • Exit to desktop. • Run a STAT test (If IQecg® or IQvitals® is installed)
Patient Data	Enter patient information, including name, ID, vital signs, medications, smoking and medical history.	<ul style="list-style-type: none"> • Enter new patient data. • Edit data for an existing patient • Initiate a test for a patient • Access a previously saved test for review.
Spirometry Test	Used to acquire spirometry tests. Also used to accept or reject tests and assign the best test of a session.	<ul style="list-style-type: none"> • Acquires FVC, VC and MVV tests. • Automatically "grades" tests based on the ATS recommendations. • Compares accepted tests for reproducibility. • Enables the user to change the settings for the IQspiro®.
Spirometry Review	Shows the interpretation for the best Pre-FVC test. Allows the user to confirm the test interpretation.	<ul style="list-style-type: none"> • View and analyze the spirometry test numeric and graphic results. • Enables the user to print preview the test report. • Enables the user to edit the interpretation. • Enables the user to change the settings for the IQspiro®.
Trending	Compares the best test measurements from two or more spirometry sessions.	<ul style="list-style-type: none"> • Select the trending parameters. • Compare individual tests, Pre-BD or Post-BD tests only, actual and predicted measurements or changes over a period of time. • Display and/or print tabular or graphic results.

B. Appendix B – Troubleshooting IQspiro® and IQmanager®

This *Troubleshooting Guide* provides a list of solutions or recommendations to problems that may be encountered with the IQspiro® and IQmanager®. Before calling Midmark Technical Service, please refer to the following table for help. Error messages are displayed at the center or at the bottom-right corner of the screen.





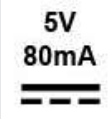
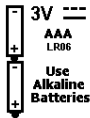


Software Troubleshooting Guide	
Error Message or Problem	Solution or Recommendation
<p>FAILED TO CREATE EMPTY DOCUMENT</p> <p>Message appears immediately after initial software installation and after each attempt to start IQmanager®.</p>	<p>All Windows programs must be closed before installing IQmanager®.</p> <ul style="list-style-type: none"> Uninstall IQmanager®, restart computer and reinstall IQmanager® (refer to the <i>IQmanager® Operation Manual</i>).
<p>FVC Test Starts for no apparent reason.</p>	<p>The minimum flow required to start a test has been exceeded or excessive electromagnetic interference is affecting the instrument.</p> <ul style="list-style-type: none"> Instruct the patient not to move the IQspiro® abruptly, as it can cause air to flow through the DM and start a test. Turn off fans, close heating and air conditioning vents near the test area and close doors or windows. Delay clicking Start New Test until just prior to beginning the maneuver. Select a different location or find and correct the source of the interference. Contact Midmark Technical Service for additional assistance.
<p>Incorrect diagnostic interpretation.</p>	<ul style="list-style-type: none"> Check Patient's Date of Birth, Height, Sex, and other information to ensure it is accurately entered. Check which Pre-FVC test is selected as the best test. Check which Interpretation logic is selected.
<p>MODULE NOT RESPONDING! or SENSOR NOT RESPONDING!</p> <p>Message appears after starting a new test. No waveform is displayed on the screen.</p>	<p>The IQspiro® cannot communicate with the computer because it is not connected, it is connected to the wrong serial port, or the batteries are dead or installed incorrectly.</p> <ul style="list-style-type: none"> Verify the cable is connected to a serial port and that it corresponds with what is selected in the Configuration Settings. Check the battery orientation. Install new batteries.

Software Troubleshooting Guide	
Error Message or Problem	Solution or Recommendation
Other operation problems	<ul style="list-style-type: none"> Access the online help by clicking Help on any screen. Contact Midmark Technical Service. See Section VII, Customer Support and Warranty Information.
Predicted FEV1/FVC is not available or valid.	<ul style="list-style-type: none"> Check the patient's demographics. Race, Age, Sex, and Height (R.A.S.H.) must be entered to calculate a Predicted Value.
<p>The [test] report dated [test date] for [patient name] is in use by [network computer name]</p> <p>Message appears when trying to open a test report.</p>	<p>The Report Locking feature prevents multiple users from accessing a report simultaneously in a LAN environment where multiple workstations share a central database.</p> <p>Report Locking can also be caused by improperly exiting the patient report.</p> <ul style="list-style-type: none"> Close the test report at the [network computer name] workstation by clicking Review Exit.
<p>This patient's record is in use by: [network computer name]</p> <p>Message appears when trying to open a specific Patient Data screen.</p>	<p>The Record Locking feature prevents multiple users from accessing a patient record simultaneously in a LAN environment where multiple workstations share a central database. Record Locking can also be caused by improperly exiting the patient record.</p> <ul style="list-style-type: none"> Close the <i>Patient Data</i> screen at the [network computer name] workstation using Opening Screen.
<p>Unable to create big button</p> <p>Message appears when attempting to launch/start IQmanager®.</p>	<ul style="list-style-type: none"> Exit IQmanager®. Start MS-DOS Prompt. Change directory to c:\windows\system. Type <i>regsvr32 threed32.ocx</i> and press Enter. Exit MS-DOS Prompt and start IQmanager®.
View Report screen does not work	<ol style="list-style-type: none"> Exit IQmanager®. Start MS-DOS Prompt (command). Change directory to c:\windows\system. Type <i>regsvr32 msflxgrd.ocx</i> and press Enter. Type <i>regsvr32 oleaut32.dll</i> and press Enter. Exit MS-DOS Prompt and re-start IQmanager®.
Volume numbers appear too high or too low	<p>Ambient air pressure or temperature has changed since the last calibration, the current DM lot is slightly different from the last one, or the <i>Use Dry Air Conditions</i> option is checked.</p> <ul style="list-style-type: none"> Calibrate the IQspiro®. Deselect the <i>Use Dry Air Conditions</i> option when performing patient tests. This option disables the BTPS corrections.

Software Troubleshooting Guide	
Error Message or Problem	Solution or Recommendation
Battery door will not close	<p>Battery contact damaged.</p> <ul style="list-style-type: none"> • Call Midmark for RMA; repair IQspiro®.
Cannot install DM into IQspiro®	<p>Leur fitting (pressure port) plugged with plastic from last DM.</p> <ul style="list-style-type: none"> • Carefully remove plastic from Leur fitting
Cannot zero IQspiro®	<p>Air is flowing through the DM while the software is attempting to zero the IQspiro® or excessive electromagnetic interference is affecting the instrument.</p> <p>A. Instruct the patient to hold the IQspiro® next to their cheek prior to starting the test and to blow after zeroing is complete.</p> <p>B. Select a different location or find and correct the source of the interference.</p> <p>C. Contact Midmark Technical Service for additional assistance.</p>
LED on the IQspiro® glows or flashes red	<p>Batteries are low, the COM port is not communicating, or the IQspiro® is defective.</p> <ul style="list-style-type: none"> • Replace with new batteries. • Configure the COM port. • Repair computer COM port. • Call for RMA. Repair IQspiro®.
LED on the IQspiro® will not turn OFF but unit functions correctly otherwise.	<p>The COM port is defective or not compatible with IQspiro®; the installed USB-to-serial port converter is not compatible with the IQspiro®.</p> <ul style="list-style-type: none"> • Repair COM port • Install USB COM Port. • Install different USB to Serial Port converter. • Contact Midmark Technical Service.
LED on the IQspiro® will not turn on.	<p>There are no batteries in the IQspiro®, the IQspiro® is not plugged into an available COM port, the COM port is not talking with the IQspiro®, or the IQspiro® is defective.</p> <ul style="list-style-type: none"> • Install new batteries • Plug IQspiro® into an available COM port. • Configure the COM port. • Call Midmark for RMA; repair IQspiro®.
LED will not turn ON, unit functions correctly.	<p>Defective LED</p> <ul style="list-style-type: none"> • Call Midmark for RMA; repair IQspiro®.

C. Appendix C - Safety and International Symbols

The following symbols are used on Midmark products. Refer to this directory for details concerning the symbols used on equipment.

Symbol	Description
	Follow instructions for use.
	Date of manufacture.
	Do Not Use for More than One Patient – Single-Patient-Use Only, however, multiple tests can be performed on the same patient with a single mouthpiece.
	IEC 601-1 Medical Electric Equipment - Type BF Equipment Equipment displaying this symbol provides the patient protection by providing isolation from earthed parts and other accessible parts of the equipment.
	DC VOLTAGE – (USB CONNECTION DEVICES) This device uses 5 Volt power and consumes 80mA when in use.
	DC VOLTAGE AND BATTERY ORIENTATION– (SERIAL CONNECTION DEVICES) This device uses 3 Volt power and consumes 70mA. Battery orientation, battery type, and power requirements.
	ETL Listing Mark Equipment displaying this symbol has been tested to comply with the following safety standards: <ul style="list-style-type: none"> • Conforms to UL Std60601-1; • Certified to CAN/CSA Std C22.2 No. 601.1
	DISPOSAL Do not dispose of this product as unsorted municipal waste. Dispose this product in accordance with national requirements per EC Directive 2002/96.

D. Appendix D - Interpretation – ATS

The American Thoracic Society (ATS) created recommendations for the interpretation of spirometry tests. Measurements are compared to the Lower Limit of Normal (LLN).

The IQspiro® software displays the statement *Normal Spirometry* if the FVC and the FEV₁/FVC ratio are within the normal range (i.e., above the LLN).

Airway Obstruction

If the FEV₁/FVC ratio is below the LLN, the software displays one of the following statements regarding obstruction:

Statement (<i>Obstruction may be a:</i>)	Criteria
Physiological variant	FEV ₁ ≥ 100% Pred. FEV ₁
Mild obstruction	70% Pred. FEV ₁ ≤ FEV ₁ < 100% Pred. FEV ₁
Moderate obstruction	60% Pred. FEV ₁ ≤ FEV ₁ < 70% Pred. FEV ₁
Moderately severe obstruction	50% Pred. FEV ₁ ≤ FEV ₁ < 60% Pred. FEV ₁
Severe obstruction	34% Pred. FEV ₁ ≤ FEV ₁ < 50% Pred. FEV ₁
Very severe obstruction	FEV ₁ < 34% Pred. FEV ₁

If the FVC is below the LLN, the software will add, “with low vital capacity” to the above obstruction statements.

Lung Restriction

If there is no suggested airway obstruction, the program displays one of the following statements pertaining to lung restriction:

Statement	Criteria
Mild restriction	70% Pred. FVC ≤ FVC < LLN
Moderate restriction	60% Pred. FVC ≤ FVC < 70% Pred. FVC
Moderately severe restriction	50% Pred. FVC ≤ FVC < 60% Pred. FVC
Severe restriction	34% Pred. FVC ≤ FVC < 50% Pred. FVC
Very severe restriction	FVC < 34% Pred. FVC

Pre/Post Bronchodilator Comparison

If both pre and post bronchodilator tests have been performed, the software performs and reports automatic interpretation for both sets of test data.

Statement	Ratio of Post-BD / Pre-BD (Post/Pre)	
	Post FVC/Pre FVC	Post FEV ₁ /Pre FEV ₁
Markedly improved	>= 1.25	>= 1.25
Improved	1.15 to 1.24	1.12 to 1.24
Not clearly improved	1.05 to 1.14	1.05 to 1.11
Not improved	< 1.05	< 1.05

Lower Limit of Normal (LLN)

The LLN for FVC, FEV₁ and FEV₁/FVC is calculated as follows:

$$LLN = Value_{pred} - CI_{95\%}$$

The Value_{pred} is the predicted value provided by the reference equations. The CI_{95%} is the 95% confidence interval for the predicted value. If the CI_{95%} is not reported for the predicted value, and the Standard Error of the Estimate (SEE) is, then the CI_{95%} shall be calculated as follows:

$$CI_{95\%} = 1.645 \times SEE$$

If the SEE is not reported and the SD% (Standard Deviation of the error) is, then the software shall calculate the LLN as follows:

$$LLN = Value_{pred} \times \left(1 - \left(\frac{SD\%}{100} \right)^2 \right)$$

E. Appendix E - Interpretation – NHANES III

The 3rd National Health and Nutrition Examination Survey (NHANES III) created a number of medical recommendations including some directed at spirometry. A new set of predicted equations as well as new calculations for LLN were developed from data collected and we have labeled these equations as NHANES III.

The NLHEP published an interpretation table using NHANES III. We have labeled this interpretation logic as NHANES III (or by selecting PCP Mode as the Configuration Profile, see [Section II-E, Configuring IQspiro®](#)). It determines results as follows:

The software displays a statement that reads Normal Spirometry if the FEV₁ and the FEV₁/FEV₆ ratio are within the normal range (i.e. above the LLN).

If the FEV₁/FEV₆ ratio and the FEV₁ are below the LLN, the software will display one of the following statements regarding obstruction.

Statement	Criteria
Mild obstruction	FEV ₁ >= 60% Pred. FEV ₁
Moderate obstruction	40% Pred. FEV ₁ <= FEV ₁ < 60% Pred. FEV ₁
Severe obstruction	FEV ₁ < 40% Pred. FEV ₁

In addition, if the FEV₁/FEV₆ ratio is above the LLN but the FEV6 measurement is below the LLN, the software will output the statement: *Low vital capacity, perhaps due to restriction of lung volumes*

F. Appendix F - Reference Values - Adult

IQspiro® provides the following sets of reference equations for adult patients:

- Crapo (Crapo/Knudson compilation, aka ITS, ATS)
- Knudson (1976 & 1983 compilation)
- European Community For Coal And Steel (ECCS) (1993)
- NHANES III (aka NLHEP, Hankinson)
- Morris
- Roca

Crapo - Adult

H = Height in centimeters.

A = Age in years.

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
VC	M/F	W	All	Predicted VC = Predicted FVC			
FVC	M	W	15–91	0.06H - 0.0214A - 4.650	0.644	1.115	Ref. 4
	F	W	15–91	0.0491H - 0.0216A - 3.590	0.393	0.676	Ref. 4
FEV _{0.5}	M	W	15–91	0.0327H - 0.0152A - 1.914	0.414	0.708	Ref. 4
	F	W	15–91	0.0238H - 0.0185A - 0.809	0.294	0.506	Ref. 4
FEV ₁	M	W	15–91	0.0414H - 0.0244A - 2.190	0.486	0.842	Ref. 4
	F	W	15–91	0.0342H - 0.0255A - 1.578	0.326	0.561	Ref. 4
FEV ₃	M	W	15–91	0.0535H - 0.0271A - 3.512	0.587	1.017	Ref. 4
	F	W	15–91	0.0442H - 0.0257A - 2.745	0.360	0.620	Ref. 4
FEV ₁ /FVC%	M	W	15–91	-0.13H - 0.152A + 110.49	4.78	8.28	Ref. 4
	F	W	15–91	-0.202H - 0.252A + 126.58	5.26	9.06	Ref. 4
FEV ₃ /FVC%	M	W	15–91	-0.0627 - 0.145A + 112.09	2.68	4.64	Ref. 4
	F	W	15–91	-0.0937H - 0.163A + 118.16	3.11	5.36	Ref. 4
FEF _{25-75%}	M	W	15–91	0.0204H - 0.038A + 2.133	0.962	1.666	Ref. 4
	F	W	15–91	0.0154H - 0.046A + 2.683	0.792	1.363	Ref. 4

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
PEF	M	W	18-25	0.0780H + 0.1660A - 8.060	1.653	2.72	Ref. 14
	M	W	25-85	0.0940H - 0.0350A - 5.993	2.078	3.42	"
	F	W	20-87	0.0490H - 0.0250A - 0.735	1.605	2.64	"
FEF _{25%} (MEF _{75%})	M	W	18-25	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 14
	M	W	25-85	0.0880H - 0.0350A - 5.618	2.012	3.31	"
	F	W	20-87	0.0430H - 0.0250A - 0.132	1.53	2.52	"
FEF _{50%} (MEF _{50%})	M	W	18-24	0.0543H + 0.1150A - 6.3851	1.1196	1.184	Ref. 13
	M	W	25-85	0.0684H - 0.0366A - 5.5409	1.2915	2.12	"
	F	W	20-70	0.0321H - 0.0240A - 0.4371	0.9778	1.61	"
	F	W	70-87	0.0118H - 0.0755A + 6.2402	0.7569	1.25	"
FEF _{75%} (MEF _{25%})	M	W	18-25	0.0397H - 0.0057A - 4.2421	0.7551	1.24	Ref. 13
	M	W	25-85	0.0310H - 0.0230A - 2.4827	0.6917	1.14	"
	F	W	20-70	0.0174H - 0.0254A - 0.1822	0.6612	1.09	"
	F	W	70-90	-0.0172A + 1.8894	0.2409	0.396	"
MVV	M	W	18-25	1.840H + 1.800A - 192.3			K3
	M	W	25-85	2.080H - 1.0800A - 168.1			K3
	F	W	20-87	1.090H - 0.840A - 31.8			K3

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	15 – 91	157 – 194	62 – 76
Female	17 – 84	146 – 178	57 – 70

Knudson - Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
VC	M/F	W	All	Predicted VC = Predicted FVC			
FVC	M	W	18-25	0.0590H + 0.0739A - 6.8865	0.4708	0.775	Ref. 13
	M	W	25-85	0.0844H - 0.0298A - 8.7818	0.6384	1.05	"
	F	W	20-70	0.0444H - 0.0169A - 3.1947	0.4831	0.795	"
	F	W	70-90	0.0313H - 0.0296A - 0.1889	0.5745	0.945	"
FEV _{0.5}	M	W	18-25	0.030H + 0.043A - 3.0540	0.425	0.699	Ref. 14
	M	W	25-85	0.037H - 0.017A - 2.746	0.474	0.779	"
	F	W	20-87	0.019H - 0.014A - 0.406	0.388	0.638	"
FEV ₁	M	W	18-25	0.0519H + 0.0636H - 6.1181	0.4458	0.734	Ref. 13
	M	W	25-85	0.0665H - 0.0292A - 6.5147	0.5241	0.862	"
	F	W	20-70	0.0332H - 0.0190A - 1.8210	0.3903	0.642	"
	F	W	70-90	0.143H - 0.0397A + 2.6539	0.3758	0.618	"
FEV ₃	M	W	18-25	0.052H + 0.066A - 5.531	0.589	0.969	Ref. 14
	M	W	25-85	0.063H - 0.031A - 5.245	0.575	0.946	"
	F	W	20-87	0.035H - 0.023A - 1.633	0.496	0.816	"
FEV ₁ /FVC%	M	W	18-25	-0.0813H + 100.4389	6.5752	10.82	Ref. 13
	M	W	25-85	-0.105A + 86.6862	6.2691	10.31	"
	F	W	20-89	-0.1852H - 0.1896A + 121.6777	7.5702	12.45	"
FEF _{25-75%}	M	W	18-25	0.0539H + 0.0749A - 6.1990	0.9861	1.62	Ref. 14
	M	W	25-85	0.0579H - 0.0363A - 4.5175	1.0825	1.78	"
	F	W	20-70	0.0300H - 0.0309A - 0.4057	0.8539	1.40	"
	F	W	70-90	-0.0615A + 6.3706	0.7210	1.19	"
PEF	M	W	18-25	0.0780H + 0.1660A - 8.060	1.653	2.72	Ref. 14
	M	W	25-85	0.0940H - 0.0350A - 5.993	2.078	3.42	"
	F	W	20-87	0.0490H - 0.0250A - 0.735	1.605	2.64	"

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
FEF _{75%} (MEF _{75%})	M	W	18-25	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 14
	M	W	25-85	0.0880H - 0.0350A - 5.618	2.012	3.31	"
	F	W	20-87	0.0430H - 0.0250A - 0.132	1.53	2.52	"
FEF _{50%} (MEF _{50%})	M	W	18-24	0.0543H + 0.1150A - 6.3851	1.1196	1.184	Ref. 13
	M	W	25-85	0.0684H - 0.0366A - 5.5409	1.2915	2.12	"
	F	W	20-70	0.0321H - 0.0240A - 0.4371	0.9778	1.61	"
	F	W	70-87	0.0118H - 0.0755A + 6.2402	0.7569	1.25	"
FEF _{25%} (MEF _{25%})	M	W	18-25	0.0397H - 0.0057A - 4.2421	0.7551	1.24	Ref. 13
	M	W	25-85	0.0310H - 0.0230A - 2.4827	0.6917	1.14	"
	F	W	20-70	0.0174H - 0.0254A - 0.1822	0.6612	1.09	"
	F	W	70-90	-0.0172A + 1.8894	0.2409	0.396	"
MVV	M	W	18-25	1.840H + 1.800A - 192.3			K3
	M	W	25-85	2.080H - 1.0800A - 168.1			K3
	F	W	20-87	1.090H - 0.840A - 31.8			K3

Notes:

1. CI_{95%} calculated using the equation CI_{95%} = 1.645 * SEE.
2. Race: W = white. Sex: M = male, F = female.
3. A = age in years. H = height in centimeters.
4. Height ranges are as follows

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	18-25	139.7-195.6	55-77
Male	25-85	157.5-195.6	62-77
Female	20-70	147.3-180.3	58-71
Female	70-90	147.3-167.3	58-66

European Community For Coal And Steel (ECCS) - Adult

H = Height in meters. A = Age in years.

Parameter	Sex	Race	Age See Note 1	Predicted Equation	RSD	CI _{95%} See Note 2
VC	M	W	18-70	$6.10H - 0.028A - 4.65$	0.56	0.92
	F	W	18-70	$4.66H - 0.026A - 3.28$	0.42	0.69
FVC	M	W	18-70	$5.76H - 0.026A - 4.34$	0.61	1.00
	F	W	18-70	$4.43H - 0.026A - 2.89$	0.43	0.707
FEV ₁	M	W	18-70	$4.30H - 0.029A - 2.49$	0.51	0.839
	F	W	18-70	$3.95H - 0.025A - 2.60$	0.38	0.625
FEV ₁ /FVC%	M	W	18-70	$-0.18A + 87.21$	7.17	11.79
	F	W	18-70	$-0.192A + 89.10$	6.51	10.7
FEF _{25-75%}	M	W	18-70	$1.94H - 0.043A + 2.70$	1.04	1.71
	F	W	18-70	$1.25H - 0.034A + 2.92$	0.85	1.398
PEF	M	W	18-70	$6.14H - 0.043A + 0.15$	1.21	1.99
	F	W	18-70	$5.50H - 0.030A - 1.11$	0.90	1.48
FEF _{25%}	M	W	18-70	$5.46H - 0.029A - 0.470$	1.71	2.81
(MEF _{75%})	F	W	18-70	$3.22H - 0.025A + 1.60$	1.35	2.22
FEF _{50%}	M	W	18-70	$3.79H - 0.031A - 0.35$	1.32	2.17
(MEF _{50%})	F	W	18-70	$2.45H - 0.025A + 1.16$	1.10	1.81
FEF _{75%}	M	W	18-70	$2.61H - 0.026A - 1.34$	0.78	1.28
(MEF _{25%})	F	W	18-70	$1.050H - 0.025A + 1.11$	0.69	1.14
MVV	M	W	18-70	$1.34H \times 100 - 1.26A - 21.40$		Kory
	F	W	18-70	$0.807H \times 100 - 0.57A - 5.50$		Lindall

Notes:

1. If the patient age is between 18 and 25, the program shall use the equation for age = 25.
2. CI_{95%} calculated using the equation $CI_{95\%} = 1.645 \times RSD$.

NHANES III (Hankinson, NLHEP) - Adult

Male age range : >= 18 years

Female age range: >= 20 years

Parameter	Sex	Race	Intercept	Age	Age ²	Ht _{... (cm)} ₂	Ht _{... (cm)} ₂
			b ₀	b ₁	b ₂	b ₃	b ₃
FVC	M	W	-0.1933	0.00064	-0.000269	0.00018642	0.00015695
	M	B	-0.1517	-0.01821	0	0.00016643	0.00013670
	M	H	0.2376	-0.00891	-0.000182	0.00017823	0.00014947
	F	W	-0.3560	0.01870	-0.000382	0.00014815	0.00012198
	F	B	-0.3039	0.00536	-0.000265	0.00013606	0.00010916
	F	H	0.1210	0.00307	-0.000237	0.00014246	0.00011570
FEV ₁	M	W	0.5536	-0.01303	-0.000172	0.00014098	0.00011607
	M	B	0.3411	-0.02309	0	0.00013194	0.00010561
	M	H	0.6306	-0.02928	0	0.00015104	0.00012670
	F	W	0.4333	-0.00361	-0.000194	0.00011496	0.00009283
	F	B	0.3433	-0.01283	-0.000097	0.00010846	0.00008546
	F	H	0.4529	-0.01178	-0.000113	0.00012154	0.00009890
FEV ₆	M	W	0.1102	-0.00842	-0.000223	0.00018188	0.00015323
	M	B	-0.0547	-0.02144	0	0.00016429	0.00013499
	M	H	0.5757	-0.02860	0	0.00017840	0.00015029
	F	W	-0.1373	0.01317	-0.000352	0.00014395	0.00011827
	F	B	-0.1981	0.00047	-0.000230	0.00013497	0.00010848
	F	H	0.2033	0.00020	-0.000232	0.00014106	0.00011480
PEF	M	W	1.0523	0.08272	-0.001301	0.00024962	0.00017635
	M	B	2.2257	-0.04082	0	0.00027333	0.00018938
	M	H	0.0870	0.06580	-0.001195	0.00030243	0.00021833
	F	W	0.9267	0.06929	-0.001031	0.00018623	0.00012148
	F	B	1.3597	0.03458	-0.00847	0.00019746	0.00012160
	F	H	0.2401	0.06174	-0.001023	0.00022203	0.00014611
FEF ₂₅₋₇₅	M	W	2.7006	-0.04995	0	0.00010345	0.00005294

Parameter	Sex	Race	Intercept	Age	Age ²	Ht _{pr} (cm) ₂	Ht _{ln} (cm) ₂
			b ₀	b ₁	b ₂	b ₃	b ₃
	M	B	2.1477	-0.04238	0	0.00010461	0.00004819
	M	H	1.7503	-0.05018	0	0.00014473	0.00009020
	F	W	2.3670	-0.01904	-0.000200	0.00006982	0.00002302
	F	B	2.0828	-0.03793	0	0.00008572	0.00003380
	F	H	1.7456	-0.01195	-0.000291	0.00009610	0.00004594

Use the following equation to calculate the predicted value for a lung function parameter (LFP).

$$LFP = b_0 + b_1 * Age + b_2 * Age^2 + b_3 * Height^2$$

Height is in centimeters and age is in years. Use b₃ coefficient from the Ht_{pr} column for the predicted value calculation. Use the b₃ coefficient from the Ht_{ln} column to calculate the LLN.

The following table presents the predicted values for FEV_{1.0}/FEV_{6.0}% and FEV_{1.0}/FVC%

Parameter	Sex	Race	Intercept _{pr}	Age	Intercept _{ln}
			B ₀	b ₁	b ₀
FEV _{1.0} /FEV _{6.0} %	M	W	87.340	-0.1382	78.372
	M	B	88.841	-0.1305	78.979
	M	H	89.388	-0.1534	80.810
	F	W	90.107	-0.1563	81.307
	F	B	91.229	-0.1558	81.396
	F	H	91.664	-0.1670	83.034
FEV ₁ /FVC%	M	W	88.066	-0.2066	78.388
	M	B	89.239	-0.1828	78.822
	M	H	90.024	-0.2186	80.925
	F	W	90.809	-0.2125	81.015
	F	B	91.655	-0.2039	80.978
	F	H	92.360	-0.2248	83.044

Use the following equation to calculate the lung function parameter (LFP).

$$LFP = b_0 + b_1 * Age$$

Use the b₁ coefficient from the Intercept_{pr} column to calculate the predicted value. Use the b₁ coefficient from the Intercept_{ln} column to calculate the lower limit of normal.

Morris - Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
FVC	M	W	20-84	.0583H – 0.025A – 4.24	0.74	1.22	Ref. 12
	F	W	20-84	.0453H – 0.024A – 2.85	0.52	0.855	Ref. 12
FEV ₁	M	W	20-84	.0362H – 0.032A – 1.265	0.55	0.905	Ref. 12
	F	W	20-84	.0350H – 0.025A – 1.93	0.47	0.773	Ref. 12
FEF _{25-75%}	M	W	20-84	0.0185H – 0.045A + 2.513	1.12	1.84	Ref. 12
	F	W	20-84	0.0236H – 0.030A + 0.551	0.80	1.316	Ref. 12

Notes:

1. The height ranges are as follows:

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	20-84	147.3-203.2	58-80
Female	20-84	142.2-182.9	56-72

Roca - Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}
FVC	M	W	20-69	$0.0678H - 0.0147A - 6.0548$	0.53	0.872
	F	W	20-69	$0.0454H - 0.0211A - 2.8253$	0.403	0.663
FEV ₁	M	W	20-69	$0.0499H - 0.0211A - 3.837$	0.44	0.724
	F	W	20-69	$0.0317H - 0.025A - 1.2324$	0.307	0.505
FEV ₁ /FVC%	M	W	20-69	$-0.1902A + 85.58$	5.36	8.82
	F	W	20-69	$-0.224A - 0.1126W + 94.88$	5.31	8.73
FEF _{25-75%}	M	W	20-69	$0.0392H - 0.043A - 1.1574$	1.0	1.645
	F	W	20-69	$0.023H - 0.0456A + 1.1055$	0.68	1.12
PEF	M	W	20-69	$0.0945H - 0.0209A - 5.7732$	1.47	2.42
	F	W	20-69	$0.0448H - 0.0304A + 0.3496$	1.04	1.71
FEF _{75%}	M	W	20-69	$MEF_{75\%} = A \log(2.113 \log(H) - 0.01A - 4.136)$	0.146	0.240
FEF _{75%}	F	W	20-69	$MEF_{75\%} = A \log(1.209 \log(H) - 0.006A - 0.001W - 2.003) - 1$	0.073	0.120
FEF _{50%}	M	W	20-69	$0.0517H - 0.0397A - 2.4$	1.3	2.14
(MEF _{50%})	F	W	20-69	$0.0242H - 0.0418A + 1.6151$	0.925	1.52

G. Appendix G - Reference Values - Pediatric

The IQspiro® software provides the following sets of reference equations for pediatric patients:

- Wang (1993)
- Knudson (1976 & 1983 compilation)
- Polgar (1971)
- Hsu
- NHANES III
- Zapletal
- Eigen

Wang – Pediatric

Race/ Sex	Age (years)	lnFVC		lnFEV ₁		lnFEV ₁ /FVC		lnFEF _{25.75%}	
		α	β	α	β	α	β	α	β
White Boys	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
	MSE	0.0121		0.0129		0.0044		0.0502	
	LLN	83.0%		82.5%		89.0%		67.9%	
White Girls	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
	MSE	0.0131		0.0132		0.0040		0.0504	
	LLN	82.2%		82.2%		89.5%		67.9%	

Race/ Sex	Age (years)	lnFVC		lnFEV ₁		lnFEV ₁ /FVC		lnFEF _{25-75%}	
		α	β	α	β	α	β	α	β
Black Boys	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
	MSE	0.0150		0.0157		0.0047		0.0625	
	LLN	81.9%		81.2%		89.0%		66.8%	
Black Girls	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
	MSE	0.0160		0.0166		0.0038		0.0621	
	LLN	81.3%		81.0%		90.0%		67.0%	

Model: $\ln(\text{PF}) = \alpha + \beta \ln(\text{Ht})$, where PF is FVC (L), FEV₁ (L), FEV₁/FVC, or FEF_{25-75%} (L/s), and Ht is height (m). MSE, means squared error; LLN, lower limit of normal defined as the percent predicted corresponding to the 5th percentile

See reference 21.

Knudson – Pediatric

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
VC	M/F	W	All	Predicted VC = Predicted FVC			
FVC	M	W	6 - 12	0.0409H - 3.3756	0.3503	0.576	Ref. 13
	M	W	12 - 18	0.0590H + 0.0739A - 6.8865	0.4708	0.774	"
	F	W	6 - 11	0.0430H - 3.7486	0.3728	0.613	"
	F	W	11- 20	0.0416H + 0.0699A - 4.4470	0.4973	0.818	"
FEV _{0.5}	M	W	6 - 18	0.030H + 0.043A - 3.054	0.425	0.699	Ref. 14
	F	W	6 - 18	0.019H + 0.061A - 1.738	0.364	0.599	"
FEV ₁	M		6 - 12	0.0348H - 2.8142	0.2734	0.449	Ref. 13
	M		12 - 18	0.0519H + 0.0636A - 6.1181	0.4458	0.733	"
	F		6 - 11	0.0336H - 2.7578	0.2697	0.444	"
	F		11- 20	0.0351H + 0.0694A - 3.7622	0.4223	0.695	"
FEV ₁ /FVC%	M		6 - 18	-0.0813H + 100.4389	6.5752	10.82	Ref. 13
	F		6 - 20	-0.1909H + 0.6655A + 109.9739	7.8385	12.89	"
FEF _{25-75%}	M		6 - 12	0.0338H - 2.3197	0.6263	1.03	Ref. 13
	M		12 - 18	0.0539H + 0.0749A - 6.1990	0.9861	1.62	"
	F		6 - 11	0.0220H - 0.8119	0.6568	1.08	"
	F		11- 20	0.0279H + 0.1275A - 2.8007	0.8653	1.42	"
PEF	M		6 - 18	0.078H + 0.1660A - 8.060	1.653	2.72	Ref. 14
	F		6 - 20	0.0490H + 0.157A - 3.916	1.339	2.20	"
FEF _{25%} (MEF _{75%})	M		6 - 18	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 14
	F		6 - 20	0.0440H + 0.1440A - 3.365	1.290	2.12	"
FEF _{50%} (MEF _{50%})	M		6 - 12	0.0378H - 2.5454	0.6538	1.08	Ref. 13
	M		12 - 18	0.0543H + 0.1150A - 6.3851	1.1196	1.84	"
	F		6 - 11	0.1846A + 0.7362	0.6689	1.10	"
	F		11- 20	0.0288H + 0.1111A - 2.3040	0.9585	1.58	"
FEF _{75%} (MEF _{25%})	M		6 - 12	0.0171H - 1.0149	0.5037	0.829	Ref. 13

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
	M		12 - 18	0.0397H - 0.0057A - 4.2421	0.7551	1.24	"
	F		6 - 11	0.0109H - 0.1657	0.4999	0.822	"
	F		11- 20	0.0243H + 0.2923A - 4.4009 - 0.0075A ²	0.7202	1.18	"
MVV	M		6 - 18	1.840H + 1.800A - 192.3			K3
	F		6 - 19	1.090H + 3.40A - 108.1			K3

Notes:

1. The height ranges are as follows:

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	6-12	111.8-154.9	44.01 – 60.98
Male	12-18	139.7-193.0	55.00 – 75.98
Female	6-11	106.7-147.3	42.00 – 57.99
Female	11-20	132.1-182.9	52.00 – 72.00

Polgar – Pediatric

H = Height in centimeters.

Parameter	Sex	Race	Age Range	Predicted Equation	SD%
FVC	M	W	4-17	$0.0000044 \times H^{2.67}$	13
	F	W	4-17	$0.0000033 \times H^{2.72}$	13
FEV _{1.0}	M	W	4-17	$0.0000021 \times H^{2.80}$	10
	F	W	4-17	$0.0000021 \times H^{2.80}$	10
FEV _{3.0}	M	W	4-17	$FVC_{pred} \times 0.98$	
	F	W	4-17	$FVC_{pred} \times 0.98$	
FEV ₁ /FVC%	M	W	4-17	$47.73 \times H^{0.13}$	7
	F	W	4-17	$63.63 \times H^{0.08}$	7
FEF _{25-75%}	M	W	4-17	$0.0437 \times H - 3.4616$	
	F	W	4-17	$0.0437 \times H - 3.4616$	
PEF (L/s)	M	W	4-17	$0.08738 \times H - 7.0929$	12.8
	F	W	4-17	$0.08738 \times H - 7.0929$	12.8
MVV (L/min)	M	W	4-17	$1.276 \times H - 99.507$	
	F	W	4-17	$1.276 \times H - 99.507$	

See Reference 19.

Hsu – Pediatric

Parameter	Sex	Race	Age Range	Predicted Equation	SD%	Source
FVC	M	W	7-20	$3.58 \times 10^{-7} \times H^{3.18}$	13	Ref. 15
	M	B	7-20	$1.07 \times 10^{-6} \times H^{2.93}$	17	"
	M	H	7-20	$1.06 \times 10^{-6} \times H^{2.97}$	13	"
	F	W	7-20	$2.57 \times 10^{-6} \times H^{2.78}$	14	"
	F	B	7-20	$8.34 \times 10^{-7} \times H^{2.98}$	15	"
	F	H	7-20	$1.25 \times 10^{-6} \times H^{2.92}$	14	"
FEV ₁	M	W	7-20	$7.74 \times 10^{-7} \times H^{3.00}$	13	"
	M	B	7-20	$1.03 \times 10^{-6} \times H^{2.92}$	17	"
	M	H	7-20	$1.73 \times 10^{-6} \times H^{2.85}$	13	"
	F	W	7-20	$3.79 \times 10^{-6} \times H^{2.68}$	14	"
	F	B	7-20	$1.14 \times 10^{-6} \times H^{2.89}$	15	"
	F	H	7-20	$1.61 \times 10^{-6} \times H^{2.85}$	14	"
FEF _{25-75%}	M	W	7-20	$7.98 \times 10^{-7} \times H^{2.46}$	26	"
	M	B	7-20	$3.61 \times 10^{-7} \times H^{2.60}$	36	"
	M	H	7-20	$9.13 \times 10^{-7} \times H^{2.45}$	25	"
	F	W	7-20	$3.79 \times 10^{-6} \times H^{2.16}$	28	"
	F	B	7-20	$1.45 \times 10^{-6} \times H^{2.34}$	30	"
	F	H	7-20	$1.20 \times 10^{-6} \times H^{2.40}$	24	"
PEF	M	W	7-20	$3.35 \times 10^{-7} \times H^{2.79}$	18	"
	M	B	7-20	$1.74 \times 10^{-7} \times H^{2.92}$	22	"
	M	H	7-20	$7.69 \times 10^{-7} \times H^{2.63}$	17	"
	F	W	7-20	$2.58 \times 10^{-6} \times H^{2.37}$	18	"
	F	B	7-20	$5.51 \times 10^{-7} \times H^{2.68}$	20	"
	F	H	7-20	$6.97 \times 10^{-7} \times H^{2.64}$	18	"

Notes:

1. Race: W = white, B = black, H = Hispanic or Mexican-American
2. The original equations provide volume in milliliters and flow in milliliters per second. The above equations are a modification of the original equations and provide volume in liters and flow in liters per second.
3. Height (H) range is from 110.0 to 190.0 cm for male and 110.0 to 180.0 for female.

NHANES III (Hankinson, NLHEP) – Pediatric

Parameter	Sex	Race	Intercept	Age	Age ²	Ht... (cm) ₂	Ht... (cm) ₂
			b ₀	b ₁	b ₂	b ₃	b ₃
FVC	M	W	-0.2584	-0.20415	0.010133	0.00018642	0.00015695
	M	B	-0.4971	-0.15497	0.007701	0.00016643	0.00013670
	M	H	-0.7571	-0.09520	0.006619	0.00017823	0.00014947
	F	W	-1.2082	0.05916	0	0.00014815	0.00012198
	F	B	-0.6166	-0.04687	0.003602	0.00013606	0.00010916
	F	H	-1.2507	0.07501	0	0.00014246	0.00011570
FEV _{1.0}	M	W	-0.7453	-0.04106	0.004477	0.00014098	0.00011607
	M	B	-0.7048	-0.05711	0.004316	0.00013194	0.00010561
	M	H	-0.8218	-0.04248	0.004291	0.00015104	0.00012670
	F	W	-0.8710	0.06537	0	0.00011496	0.00009283
	F	B	-0.9630	0.05799	0	0.00010846	0.00008546
	F	H	-0.9641	0.06490	0	0.00012154	0.00009890
FEV _{6.0}	M	W	-0.3119	-0.18612	0.009717	0.00018188	0.00015323
	M	B	-0.5525	-0.14107	0.007241	0.00016429	0.00013499
	M	H	-0.6646	-0.11270	0.007306	0.00017840	0.00015029
	F	W	-1.1925	0.06544	0	0.00014395	0.00011827
	F	B	-0.6370	-0.04243	0.003508	0.00013497	0.00010848
	F	H	-1.2410	0.07625	0	0.00014106	0.00011480

Parameter	Sex	Race	Intercept	Age	Age ²	Ht....(cm) ₂	Ht....(cm) ₂
			b ₀	b ₁	b ₂	b ₃	b ₃
PEF	M	W	-0.5962	-0.12357	0.013135	0.00024962	0.00017635
	M	B	-0.2684	-0.08016	0.018202	0.00027333	0.00018938
	M	H	-0.9537	-0.19602	0.014497	0.00030243	0.00021833
	F	W	-3.6181	0.60644	-0.016846	0.00018623	0.00012148
	F	B	-1.2398	0.16375	0	0.00019746	0.00012160
	F	H	-3.2549	0.47495	-0.013193	0.00022203	0.00014611
FEF ₂₅₋₇₅	M	W	-1.0863	0.13939	0	0.00010345	0.00005294
	M	B	-1.1627	0.12314	0	0.00010461	0.00004819
	M	H	-1.3592	0.10529	0	0.00014473	0.00009020
	F	W	-2.5284	0.52490	-0.015309	0.00006982	0.00002302
	F	B	-2.5379	0.43755	-0.012154	0.00008572	0.00003380
	F	H	-2.1825	0.42451	-0.012415	0.00009610	0.00004594

Use the following equation to calculate the predicted value for a lung function parameter (LFP).

$$LFP=b_0 + b_1 * Age + b_2 * Age^2 + b_3 * Height^2$$

Height is in centimeters and age is in years. Use b_3 coefficient from the Ht_{prd} column for the predicted value calculation. Use the b_3 coefficient from the $Htlin$ column to calculate the lower limit of normal.

The following table presents the predicted values for $FEV_{1.0}/FEV_{6.0}\%$ and $FEV_1/FVC\%$

Parameter	Sex	Race	Intercept _{prd}	Age	Intercept _{lin}
			B_0	b_1	b_0
$FEV_{1.0}/FEV_{6.0}\%$	M	W	87.340	-0.1382	78.372
	M	B	88.841	-0.1305	78.979
	M	H	89.388	-0.1534	80.810
	F	W	90.107	-0.1563	81.307
	F	B	91.229	-0.1558	81.396
	F	H	91.664	-0.1670	83.034
$FEV_1/FVC\%$	M	W	88.066	-0.2066	78.388
	M	B	89.239	-0.1828	78.822
	M	H	90.024	-0.2186	80.925
	F	W	90.809	-0.2125	81.015
	F	B	91.655	-0.2039	80.978
	F	H	92.360	-0.2248	83.044

Use the following equation to calculate the lung function parameter (LFP).

$$LFP=b_0 + b_1 * Age$$

Use the b_1 coefficient from the Intercept_{prd} column to calculate the predicted value. Use the b_1 coefficient from the Intercept_{lin} column to calculate the lower limit of normal.

Zapletal – Pediatric

Age range is from 6 to 18 years.

H = Height in centimeters.

Parameter	Sex	Race	Predicted Equation	SEE	CI _{95%}
FVC	M	W	$7.9942 - 0.12509 \times H + 0.000605 \times H^2$		
	F	W	$0.1694 - 0.01217 \times H + 0.000605 \times H^2$		
FEV _{1.0}	M	W	$6.6314 - 0.10261 \times H + 0.000499 \times H^2$		
	F	W	$-3.0378 + 0.03640 \times H$		
FEF _{25%}	M	W	$-2.3069 + 0.02817 \times H$		
	F	W	$-1.8576 + 0.02483 \times H$		
FEF _{50%}	M	W	$-4.5848 + 0.05430 \times H$		
	F	W	$-3.3655 + 0.04477 \times H$		
FEF _{75%}	M	W	$-6.822 + 0.07811 \times H$		
	F	W	$-5.1934 + 0.06367 \times H$		
PEF	M	W	$-6.9865 + 0.08060 \times H$		
	F	W	$-5.3794 + 0.06594 \times H$		

Eigen – Pediatric

The age range is from 3-6 years and the height range is 87-127 cm (34.3 to 50 inches).

Parameter	Intercept (α)	Slope (β)	SEE	CI _{95%}
FVC	-13.63	2.95	0.1167	0.192
FEV ₁	-12.26	2.63	0.1124	0.185
FEF ₂₅₋₇₅	-8.13	1.81	0.2393	0.394
FEV ₁ /FVC (see Note 1)	1.37	-0.31	0.0608	10.0 (see Note 2)
PEF	-10.99	2.54	0.1509	0.248

Notes: 1. The FEV₁/FVC predicted equation generates a fraction instead of a percentage so the software must convert this number to a percentage. 2. The FEV₁/FVC predicted equation generates a fraction instead of a percentage so the CI_{95%} value has been converted to a percentage value

Patient gender was not considered in the regression analysis. The Knudson Pediatric predicted equations will not be used for missing parameters because that study does not cover children less than 6 years old. In addition, the Eigen equations should not be used as the default pediatric equations because of the limited age range.

H. Appendix H - Adjustments to Reference Values Equations

According to the ATS recommendations specified in Reference 2 and studies cited by Enright (Reference 23), Black and Asian adults have FVC and FEV₁ values that are approximately 15% below that of Caucasians. Black children have FVC and FEV₁ values that are approximately 12% lower than Caucasian children's values.

The software makes the following adjustments to the reference values for Asian and Black patients if the reference equations are only for a white patient population.

Correction of Reference Values for Blacks And Asians	
Measurement	Scale Factor
FEV ₁	0.85
FVC	0.85
FEV ₁ /FVC%	None

Correction of Reference Values Black Children	
Measurement	Scale Factor
FEV ₁	0.88
FVC	0.88
FEV ₁ /FVC%	None

The software does not use the above correction factors if the reference equations in use include the patient's race, e.g., Hankinson.

Not all race scale factors have been documented. At the time of this printing, many races have had some published recommendations. The latest recommendations are as follows:

1.00 - American Indian, Caucasian, Eskimo, European-American, Hawaiian, Hispanic, Indian, Italian, Iranian, Jordanian, Polynesian, Saudi Arabian, South American, Spanish,

0.85 - Asian, African, African-American, Black, Cambodian, Chinese, East Indian Pakistani, Filipino, Jamaican, Japanese, Korean, Laotian, Vietnamese

However, a recent paper by Korotzer et al (Am. J. Respir. Crit. Care Med. 2000 161: 1101-1108) suggests a 0.93 correction for Asian-American.

I. Appendix I - Spirometry Measurement Parameters

FVC	FEV _{0.5}	FEV _{1.0}	FEV _{3.0}	FEV _{6.0}	FEV _{1.0} /FVC	FEV _{3.0} /FVC	FEV _{1.0} /FEV _{6.0}
FEV _{25%}	FEV _{50%}	FEV _{75%}	FEV _{25-75%}	FEV _{75-85%}	FEV ₂₀₀₋₁₂₀₀		FEV _{0.5} /FIV _{0.5}
PEF	FIVC	FIV _{0.5}	FIF _{50%}	PIF	Exp Time	V ext.	MVV
MTV	RR	AT	AT%	VC	ERV	IRV	TV

Unless otherwise noted: Volumes (capacity) are expressed in Liters BTPS (L) Flows are expressed in Liters per second BTPS (L/s)

J. Appendix J – COPD Risk Assessment Calculation

The IQspiro® program calculates the assessment of the likelihood of the patient developing COPD in the next ten years using the Techumseh Index as follows.

$$Risk = 1000 * \left(\frac{1}{1 + 10^x} \right) \quad \text{Equation 1}$$

Male:

$$x = -2.1316 + \left(\frac{bestFEV_1}{predFEV_1} \right) * 10.78 - Age * 0.0914 - cigs * 0.0594 \quad \text{Equation 2}$$

If the **male** patient were to quit smoking...

$$x_{quit} = x + cigs * 0.0297 \quad \text{Equation 3}$$

Female:

$$x = \left(\frac{bestFEV_1}{predFEV_1} \right) * 12.81 - 2.98 - Age * 0.0944 - cigs * 0.1065 \quad \text{Equation 4}$$

If **female** patient were to quit smoking...

$$x_{quit} = x + cigs * 0.0506 \quad \text{Equation 5}$$

The program calculates the Risk factor and then uses the criteria shown in the following table to produce a COPD risk statement.

COPD Risk Statement Criteria

Criteria	COPD Risk Statement
If Risk <= 10	Low
If Male and 10 < Risk <= 70	Moderate
If Female and 10 < Risk <= 30	Moderate
If Male and 70 < Risk <= 100	High
If Female and 30 < Risk <= 100	High
If Risk > 100	See Figure 1 below

If the patient is currently smoking, the software will calculate the factor called x_{quit} using Equation 3 or 5 and calculates the risk using Equation 1. The software then generates a statement indicating the reduced risk if the patient quits smoking.

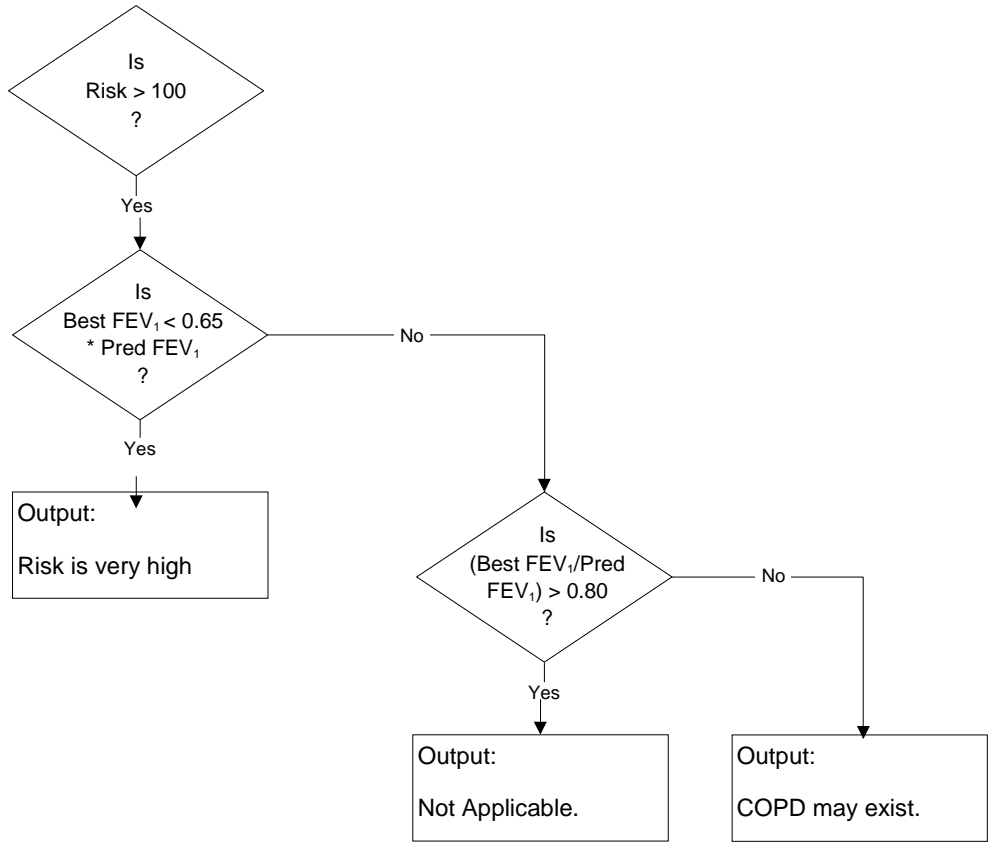


Figure 1 COPD Risk Greater Than 100

K. Appendix K - Lung Age Calculation

Reference #18 describes the method to be used for calculating estimated lung age. If the patient is twenty years old or older but less than eighty-four years old, the IQspiro® program automatically calculates the estimated lung age provided that the following information is available.

- 1. Best FEV₁ from the FVC tests
- 2. Patient height in inches
- 3. Patient sex

For **male** patients, the estimated lung age shall be calculated as follows:

$$LAGE = 2.87 * H - 31.5 * BestFEV_1 - 39.375$$

For **female** patients...

$$LAGE = 3.56 * H - 40.0 * BestFEV_1 - 77.28$$

LAGE is the estimated lung age in years. H is the patient height in inches.

The IQspiro® program uses the following table to print the lung age statement:

Criteria	Lung Age Statement
(Patient's Age < 20) or (Patient's Age > 84)	N/A
Lung Age > 84	> 84 years
Lung Age < Patient's Age	< #Patient's Age years
Otherwise	#Lung Age years

See reference 18.

L. Appendix L - Performing a Pre/Post FVC Test - Quick Reference User's Guide

A condensed guide to using the IQspiro® Digital Spirometer.

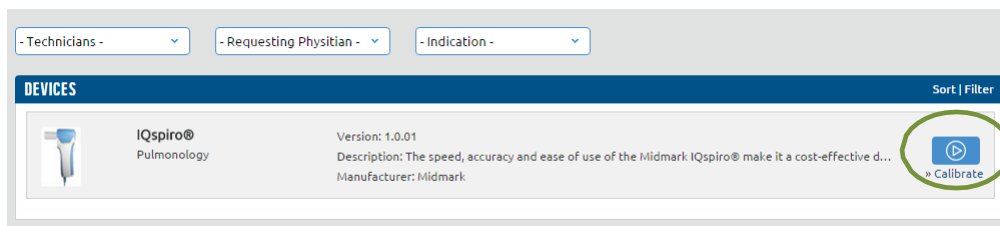
Note

The ATS recommends that calibration be performed daily before testing is started.

1. Start IQmanager®.
2. Select the patient:
 - a. Search for a patient from the *Opening Screen* and double-click the patient name, or
 - b. Click **New Patient** from the *Opening Screen*.
3. Check the patient data fields to ensure *Name, Date of Birth, Weight, Height, Sex* and *Race* fields have been entered on the *Patient Data* screen.
 - a. The R.A.S.H. (Race; Age; Sex; Height) must be entered for each patient to obtain predicted values and interpretations.
4. When the *Patient Data* screen is complete, select **New Test**.



Click on the play icon next to IQspiro.



5. Prepare the patient for the spirometry test.
 - a. Explain the procedure to the patient.
 - b. Demonstrate the procedure to the patient.
 - c. Insert a new disposable mouthpiece (DM) into the IQspiro®.
 - d. Instruct the patient to place the DM on top of their tongue, with their teeth and lips around the mouthpiece, sealing their lips around the DM. Let the patient get used to the feeling of breathing with the DM in their mouth.

6. The type of test selected is displayed in bold in the upper-right corner of the screen. If this is not the type of test required, select the required test by clicking the appropriate button (**FVC**, **VC**, **MVV**) and either **Pre** or **Post**.
7. When the patient is ready, instruct the patient to hold the IQspiro® up and to the side of their face.
8. Click **Start New Test** - wait for the zeroing process. ***Do not allow airflow to pass through the sensor during this process.***
9. When the incentive box displays *Start When Ready*, instruct the patient to perform a full inspiration and then to place the DM in their mouth.
10. Instruct the patient to blast out the air. Encourage the patient with verbal and body language to blast out fast and blast out long. Ask the patient to continue to blow out until a plateau is reached on the volume-time curve.
 - a. If a flow volume loop is required, have the patient inhale at the end of the expiration.
11. Click **Stop** or press **Enter** to conclude the test.
12. **Accept** or **Reject** the test based on the patient's effort.
13. Repeat steps 8 through 11 until the appropriate number of tests has been performed. Performing more than 8 FVC tests in one sitting will usually return diminished results.
14. Remove and discard the used DM after all tests are completed.
15. Click **Save/Review** to save the efforts.
16. Use the review screen to review, edit and/or print the results.

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VII. Customer Support and Warranty Information

For immediate help diagnosing problems with this product, refer to the online *Help* or [Appendix B – Troubleshooting IQspiro® and IQmanager®](#).

For help diagnosing problems by phone with this product, contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2, Monday to Friday 5:00 am to 5:00 pm, Pacific Time.

To contact Midmark Technical Service via email: techsupport@midmark.com

Self-help knowledge base and live chat can be accessed at: kb.midmark.com

Warranty

Midmark warrants IQspiro® to be free from manufacturing and material defects for 12 months from the date of purchase. Accessories for IQspiro® are warranted for 90 days. Any misuse or abuse of a Midmark product voids all applicable warranties.

Please refer to midmark.com for the full and current Warranty Terms and Conditions.

Return Materials Authorization

To return any product for repair, a Return Materials Authorization (RMA) number must be obtained from Midmark Technical Service. This RMA number should be referenced on the package(s) containing the items to be returned and in any correspondence regarding the return.

Shipping

Before shipping any unit to Midmark, be certain that an RMA number has been issued and that all guidelines regarding this authorization are followed. We highly recommend following all guidelines for the shipment of medical products set forth by the shipping company you choose to use. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for your RMA number. It is the responsibility of the customer when shipping a product to ensure that all packages and their contents get to Midmark safely. Midmark will not assume responsibility for damage due to improper packaging, shipment or product use. Such actions will void all applicable warranties.

Midmark Corporation
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VIII. *EMC Requirements for the IQspiro® Digital Spirometer*

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Appendix.

Portable and mobile RF communications equipment can affect the operation of medical electrical equipment. The Midmark IQspiro® are medical electrical equipment.

The IQspiro® models comply with sections 36.201 and 36.202 of the EMC Standard EIC60601-1-2 (E).

Use of cables, cable extensions or accessories other than those specified, with the exception of cables and accessories sold by the manufacturer of the IQspiro® as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the IQspiro®.

Table 1 – Guidance and manufacturer’s declaration – electromagnetic emissions – for the IQspiro® Digital Spirometer

Guidance and manufacturer’s declaration – electromagnetic emissions		
The IQspiro® is intended for use in the electromagnetic environment specified below. The customer or the user of the IQspiro® should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The IQspiro® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class B	The IQspiro® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	Battery-operated device
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	Battery-operated device

Table 2 – Guidance and manufacturer’s declaration – electromagnetic immunity – for the IQspiro® Digital Spirometer

Guidance and manufacturer’s declaration – electromagnetic immunity			
The IQspiro® is intended for use in the electromagnetic environment specified below. The customer or the user of the IQspiro® should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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 materials, 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	N/A ±1 kV for input/output lines	Battery operated device
Surge IEC 61000-4-5	±1 kV differential mode	N/A	Battery operated device
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	N/A	Battery operated device
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. mains voltage prior to application of the test level.			

Table 3 – Guidance and manufacturer’s declaration – electromagnetic immunity – for the IQspiro® Digital Spirometer


Guidance and manufacturer’s declaration – electromagnetic immunity			
The IQspiro® is intended for use in the electromagnetic environment specified below. The customer or the user of the IQspiro® should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
 <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms</p> <p>150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF Communications equipment should be used no closer to any part of the IQspiro®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from the fixed RF transmitters, as determined by an electromagnetic site survey, ^ashould be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^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 the IQspiro® is used exceeds the applicable RF Compliance level above, the IQspiro® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the IQspiro®.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 4 – Recommended separation distances between portable and mobile RF communications and the IQspiro® Digital Spirometer

Recommended separation distances between Portable and mobile RF communications equipment and the IQspiro® Digital Spirometer			
The IQspiro® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IQspiro® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IQspiro® as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 to 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.			

IX. Contact Information

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