midmark®

Midmark Digital Spirometer

Version 11.0

Operation Manual

56-78-0001 Rev. CA1

Notice

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Part number for this Operation Manual - English: 56-78-0001 Rev. CA1

RxOnly	Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Table of Contents

Important Information

Safety Symbols

	**Warning** *Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.*
	**Caution** *Indicates a potentially hazardous situation that may result in minor or moderate injury. It may also be used to alert against unsafe practices.*
	**NOTICE** *Indicates practices not related to physical injury.*

Physician's Responsibility

The interpretations provided by the Midmark 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 (U.S.A.) 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 Midmark Digital Spirometer:

- *IQmanager® Software Operation Manual (Part number: 62-78-0001)*
- *Quick Reference Guide – Midmark Digital Spirometer – General - English (Part number: 003-10242-00)*
- *Quick Reference Guide – Midmark Digital Spirometer – PCP Mode - English (Part number: 003-10243-00)*
- *Setup Manual: Midmark Products over Thin Client using IQpath™ or COM port mapping (Part number: 61-78-0001)*

French translations of this Operation Manual and the Quick Reference Guides listed above are available on the product page at: midmark.com/technical-library/medical.

- *Midmark Digital Spirometer Operation Manual – French (Part number: 56-78-0002)*
- *Quick Reference Guide – Midmark Digital Spirometer – General - French (Part number: 003-10242-02)*
- *Quick Reference Guide – Midmark Digital Spirometer – PCP Mode - French (Part number: 003-10243-02)*

All product Operation Manuals can also be downloaded from midmark.com. For additional information contact Midmark Technical Service.

Precautions

Read and observe the following precautions to ensure proper operation of the Midmark Digital Spirometer.

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 administrating spirometry tests to a patient by an organization that is certified by a recognized agency.
3. Keep the device away from splashing liquids, significant or extreme changes in humidity, ventilation, direct sunlight, 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 Midmark Digital Spirometer handle. Refer servicing to qualified service personnel.
13. The USB cable must be arranged such that it does not present a tripping hazard to the patient or clinician.

	***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 Midmark Digital Spirometer near any type of liquids.*

	***Caution*** *The Midmark Digital Spirometer, 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 device is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark Digital Spirometer 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, and hand-washing after touching them.*

Warnings

The Midmark Digital Spirometer 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 hazards may lead to complications when using the Midmark Diagnostic Spirometer:

1. Infection or injury due to the use of a non-sterile mouthpiece over open wounds
2. Infection or injury due to the re-use of the mouthpiece or improper cleaning of parts
3. Skin or mucous membrane abrasion caused by prolonged rubbing or excessive use of the mouthpiece (not related to biocompatibility issues)
4. Nasal, oral, or dental pain
5. Congestion or irritation of Eustachian tubes
6. Hyperventilation, dizziness, and possible fall due to patient overexertion
7. Choking hazard due to aspiration of broken components, parts (including packaging material), or secretions
8. Incorrect spirometer test results due to the following:
    - Operator is inadequately trained in the use of the device,
    - Device exposure to environmental factors (such as particulates, chemicals, fluid/humidity, sunlight, or extreme heat),
    - Not appropriately calibrating the device,
    - Incorrect data entry of patient RASH values,
    - Improper patient positioning

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 Observation Notes).

Contents Checklist

The Midmark Digital Spirometer 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 for replacement.

Quantity Each	Description
1	Midmark Digital Spirometer
1	10-pack Midmark Disposable Spirometer Mouthpieces
1	10-pack Disposable Nose Clips
1	Mouse Pad
1	Operation Manual CD
1	Quick Reference Guide – Midmark Digital Spirometer – General - English
1	Quick Reference Guide – Midmark Digital Spirometer – PCP Mode - English

1	Warranty Registration Card
1	Carrying Case

General Information

Introduction

The Midmark 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.
A Pulmonary Function Test (PFT) is a widely used term for spirometry. The Midmark Digital Spirometer maybe be referred 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 Digital Spirometer device and its operation.

This manual describes how to use the various Midmark Digital Spirometer 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 should 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. Therefore, many of the features are interconnected and can be accessed from more than one screen.

Before conducting any spirometry testing, install IQmanager® (or equivalent software) on a Windows-compatible computer. Once IQmanager® has been installed connect the Midmark Digital Spirometer device to the computer via a USB port. Together with IQmanager®, the Midmark Digital Spirometer makes it easy to record, interpret, and archive spirometry efforts for future reference.

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

Model	Connection	Device Part Number	Kit Part Number
Midmark Digital Spirometer (Gray)	USB	1-100-1235	4-000-0028 w/syringe
			4-000-0027

Model	Connection	Device Part Number	Kit Part Number
Midmark IQspiro® (Blue)	USB	1-100-1225*	4-000-0026 w/syringe
			4-000-0025

**No longer in production*

Note

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

Caution

The Midmark Digital Spirometer, 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 device is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark Digital Spirometer mouthpiece, including but not limited to the use of an adapter or filter, is considered an alteration to the design of the product.

Indications for Use

The Midmark Digital Spirometer is intended for prescription-use only by physicians and professional medical personnel to conduct diagnostic spirometry testing of adults and pediatric patients, 5 years and older, in hospitals and physician/clinician offices.

Contraindications

The disposable mouthpieces 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 Midmark Digital Spirometer conforms to the following standards:

- Industry Standards: ATS/ERS 2005, NLHEP, NIOSH, SSD, OSHA, ECCS
- Quality System Regulations: FDA QSR, SOR 98/282, ISO 13485:2016
- Product Testing Standards: IEC 60601-1-1, IEC 601-1, IEC 60601-1-2, ISO 10993-5, ISO 10993-10, EN 60601-1-2, CAN/CSA STD C22.2 No. 60601-1:08

Necessary Computer Skills

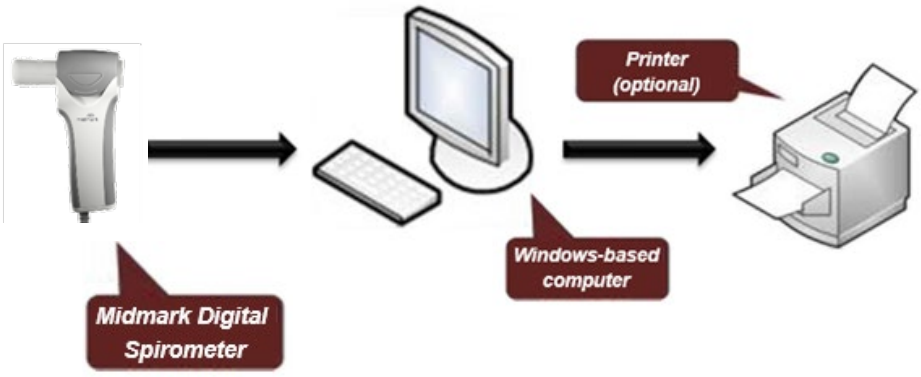
This manual is intended for a user capable of using Microsoft® Windows® applications, who has some understanding of PC operations, and who is familiar with the basic operations of Windows®.

This Operation Manual is designed as a comprehensive guide, and designed to educate the user on the operation and functions of the Midmark Digital Spirometer device. The information in this manual includes options currently available with the Midmark Digital Spirometer.

Configurations

Typical PC Configuration

The following block diagram illustrates the standard configuration of the Midmark Digital Spirometer system. The primary components are a Windows based PC, a printer, and the Spirometer acquisition module. A portable computer is recommended if mobility is a consideration. Please refer to this diagram when setting up the Midmark Digital Spirometer system.



Thin Client Configurations

Install the software on the Terminal Server and operate the Midmark Digital Spirometer through a thin client terminal when operating in a thin client environment.

IQmanager® supports the IQpath™ Software Solution. IQpath™ works with the USB port version of the Midmark Digital Spirometer in high-latency, limited-bandwidth network configurations with Windows-based PC clients.

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

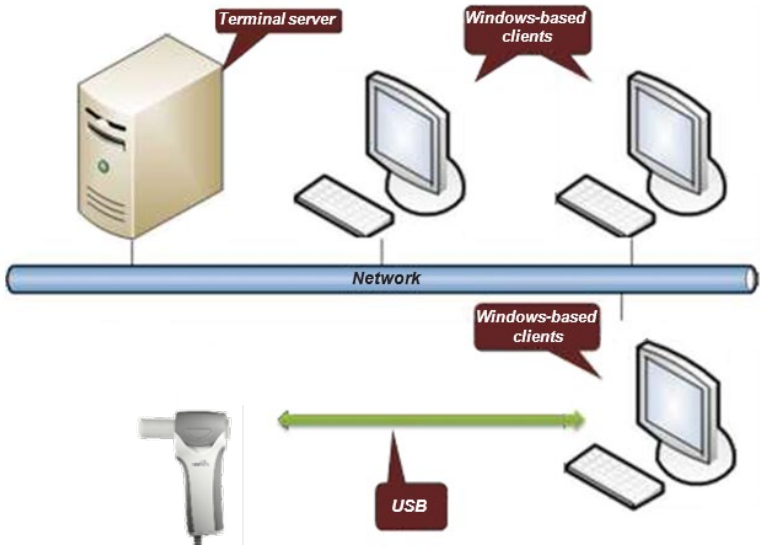
Thin Client Using the IQpath™ Software Solution

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

- Improved operation over 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 Midmark Digital Spirometer 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, 8.1, or 7:



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

- **IQpath™ for Microsoft Terminal Services:** If using Microsoft Terminal Services (Microsoft RDP).
- **IQpath™ for Citrix ICA:** If using Citrix® software on the 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.

Once the software is installed on the client server network and computers, IQmanager® must be configured for thin client operation as described in Connecting the Midmark Digital Spirometer Module and Configuring the Midmark Digital Spirometer, or refer to the IQmanager® Operation Manual, Configuring Client Server Networks.

System Specifications

The following are the physical and performance specifications for the:

Midmark Digital Spirometer Performance Specifications	
Category	**Specification**
Intended Use	A prescription-use-only clinical diagnostic spirometer for pulmonary function evaluation and data management.
Dimensions	7.75" x 2.5" x 1.75" (197 x 64 x 44mm)
Device style	USB
Weight	9.0 oz.
Connection	USB port
Anatomical Sites	Non-invasive device
Patient Contact	Disposable mouthpiece (DM)
Safety Parameters	Double-insulated handle

Midmark Digital Spirometer Performance Specifications	
Category	**Specification**
Spirometry Acquisition	• Fleisch Pneumotach: Differential pressure reading of flow with a disposable mouthpiece • Volume determined by flow integration
Ranges	• Flow: +/- 14 L/s • Volume: +/- 8 L
Operating Conditions	• Temperature: 50°F (10°C) to 104°F (40°C) • Relative humidity between 15% to 90%, non-condensing • Atmospheric pressure: -500 ft to 10,000 ft (-152 m to 3,048 m)
Storage Conditions	• Temperature: -4°F (-20°C) to 122°F (50°C) • Relative humidity between 15% to 95%, non-condensing • Atmospheric pressure: -500 ft to 16,000 ft (-152 m to 4,876 m)
Body Temperature and Ambient Pressure Saturated (BTPS)	• Automatic BTPS Correction
Analysis & Measurement	• Automatic Back Extrapolation calculation • Automatic spirometry parameter calculation • Automatic comparison to published spirometry predicted equations (Reference Values) • Automatic interpretation of test results
Parameters Measured	• See Appendix G – Spirometry Measurement Parameters
Reference Values Sets	• See Appendix D – Reference Values – Adult and Appendix E – Reference Values – Pediatric
Interpretations	• ATS (1991): See Appendix B – Interpretation – ATS • NHANES III (NLHEP 1999): See Appendix C – Interpretation – NHANES III
Printer	• Windows® compatible inkjet or laser printer
Paper	• 8.5" x 11" (Letter size) or 210mm x 297mm (A4 size)

System Installation

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

Minimum Computer Requirements

Refer to the Minimum Computer Requirements document at http://www.midmark.com, or contact Midmark Technical Service.
The Minimum Computer Requirements document 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 that you always refer to the most recent Minimum Computer Requirements document at www.midmark.com, or contact Midmark Technical Service 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.*

The Minimum Computer Requirements are the specifications for operating the Midmark Digital Spirometer through IQmanager®. A faster CPU and/or more memory may be required if you planning to operate the Midmark Digital Spirometer through an EMR or install additional software.

Software Installation

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

The medical diagnostic application Midmark Digital Spirometer uses IQmanager® to manage patient records. When installing or upgrading the Midmark Digital Spirometer, IQmanager® may also need to be installed or upgraded accordingly (refer to the *IQmanager® Operation Manual* for further information).

Other Midmark products can also be accessed from IQmanager®, such as, IQholter®, IQecg®, Midmark Digital Vital Signs Device, IQvitals® Zone, 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 to understand and carry out task described on the following pages:

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.

Screensaver

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 care. Refer to the computer or software manual for these settings.

Important Computer Date Information

The Midmark Digital Spirometer 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 Midmark Digital Spirometer 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.

Installation Steps for IQmanager®

> ***Note***
> *The Midmark Digital Spirometer requires software to operate. The following instructions use the IQmanager® software. Please contact Midmark Technical Service to purchase the required software license.*

> ***Note***
> *Close all Windows® programs before running this software installation. Do not interrupt the installation program while it is running.*

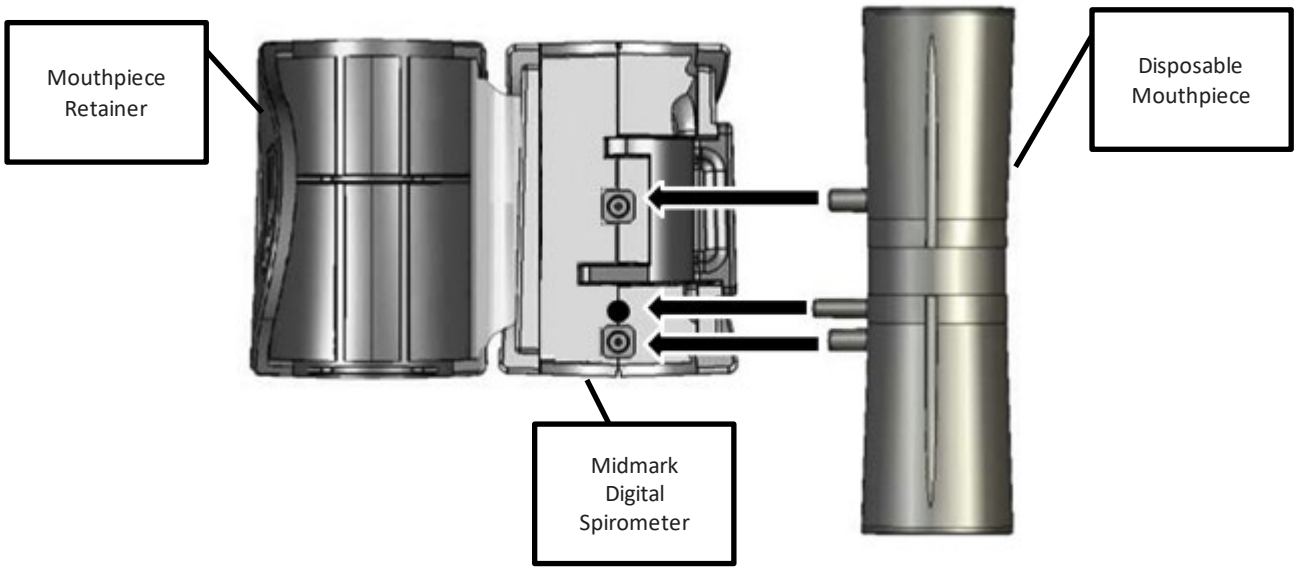
> ***Note***
> *Do not connect any devices to the computer before running the software installation.*

For any questions on the installation please refer to the IQmanager® Operation Manual.

Connecting the Midmark Digital Spirometer Module

Inserting a Disposable Mouthpiece in the Midmark Digital Spirometer

- Open the Mouthpiece Retainer by unlatching it from the side of the spirometer, and use the index finger to hold it opened with one hand.
- The following diagram shows the three ports in the top of the Midmark Digital Spirometer. Line the pins of the disposable mouthpiece up with the ports of the Midmark Digital Spirometer and firmly press the disposable mouthpiece in place, making sure it is securely anchored in the ports. Close and latch the Mouthpiece Retainer.

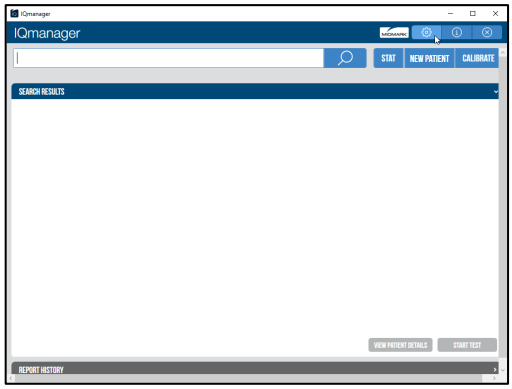


Note
The disposable mouthpiece must be firmly pressed into place to ensure a proper seal. If the disposable mouthpiece is not correctly pressed into place it may not seat flush against the Midmark Digital Spirometer cradle.

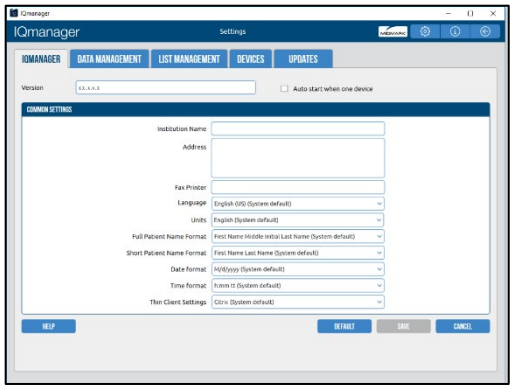
Configuring the Midmark Digital Spirometer

IQmanager® and the Midmark Digital Spirometer can be customized by using the configuration settings. To access the

Configuration Settings click on the  in the upper right side of the IQmanager® opening screen.



The *IQmanager Configuration Settings* dialog box appears:

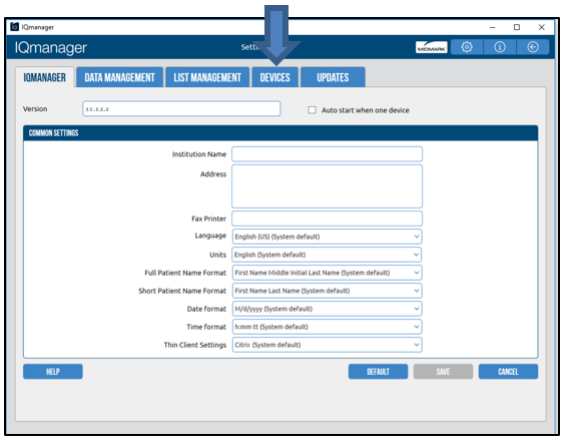


Complete the ***Institution Name*** and ***Institution Address*** boxes with information about the medical practice. This information will also be displayed on printed reports. Enter a name that describes the practice/location to enable other medical personnel to recognize the origin of the reports, and *Save* the information.

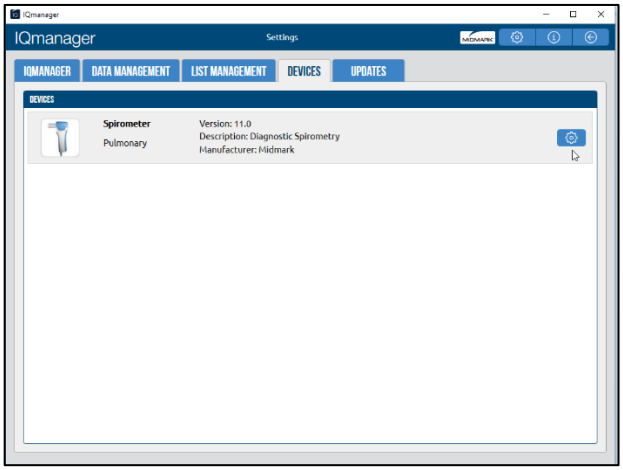
Choose between Metric and English units of measurement, 24- and 12-hour time standard. When done, press *Save*.

All information saved in this screen will apply to all devices.

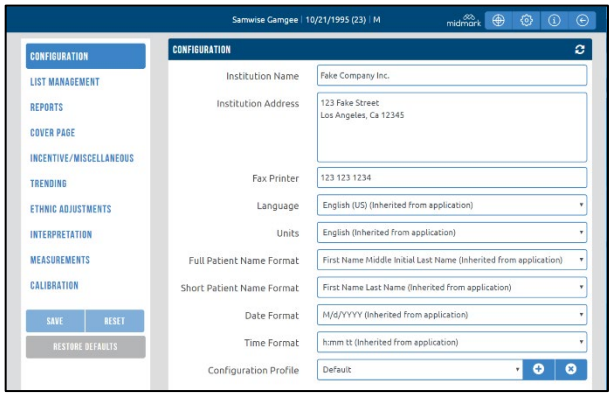
Select the *Devices* tab from the IQmanager Configuration Settings dialog box:



Access the **Midmark Digital Spirometer Configuration Settings** by selecting the  button on the right side of the device information section.



The Midmark Digital Spirometer Configuration screen opens:



Note

Most of the settings on this screen are inherited from the IQmanager Configuration Settings and can be overridden. To change back and inherit from IQmanager, select the option that states "inherited from application"

in the drop-down menu. Changes to these settings can be made from either screen.

Midmark Digital Spirometer Configuration Screen

Customize how the Software will display information on the screen and reports by editing the following options:

- **CONFIGURATION**
- **LIST MANAGEMENT**
- **REPORTS**
- **COVER PAGE**
- **INCENTIVE/MISCELLANEOUS**
- **TRENDING**
- **ETHNIC ADJUSTMENTS**
- **INTERPRETATION**
- **MEASUREMENTS**
- **CALIBRATION**

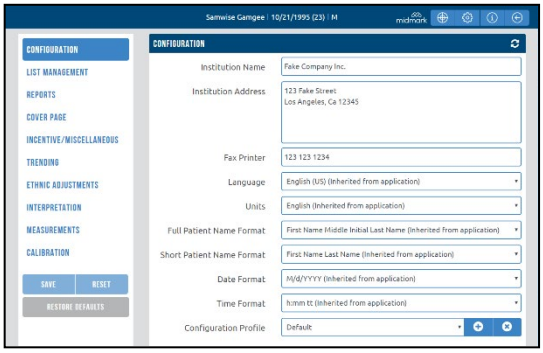
Saving Configuration Changes

Once the information on the Configuration screen tabs have been customized, select one of the options from the bottom left of the configuration screen to save the changes to the current profile:

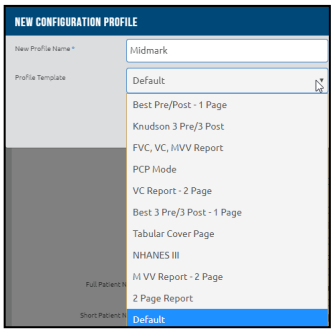
- ***SAVE***: Saves the changes applied to the configuration settings.
- ***RESET***: Resets all the configuration sections to the last saved changes.
- ***RESTORE DEFAULTS***: Restores the current configuration profile to the system defaults.

Note
All changes applied to the tabs in the Configuration window will be saved to the profile selected on the CONFIGURATION tab.

Configuration changes can also be saved by selecting the button  at the bottom of the screen to save the customized changes to a new, existing, or default profiles.

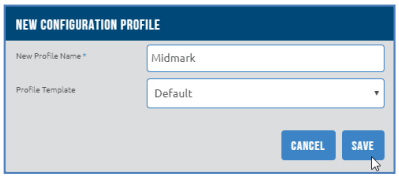


Enter a *New Profile Name,* and select where the customized information detail will appear by clicking on one of the options from the drop down menu in the Profile Template box.

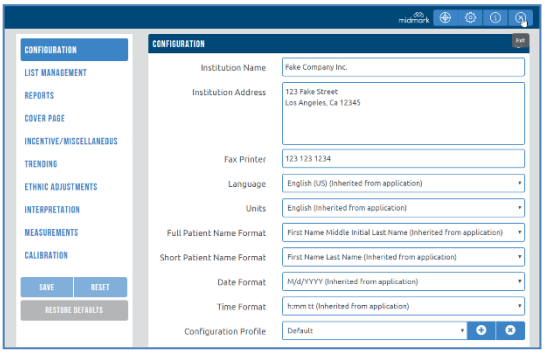


Select *Default* to apply the default settings to the New Profile created.

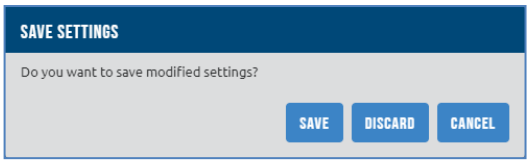
Select *SAVE*.



Select the Exit button at the top of the CONFIGURATION screen to exit the configuration screen:



If there are any unsaved changes, the Software will prompt the user to either SAVE, DISCARD, or CANCEL upon attempting to exit the Configuration screen without saving the changes applied:

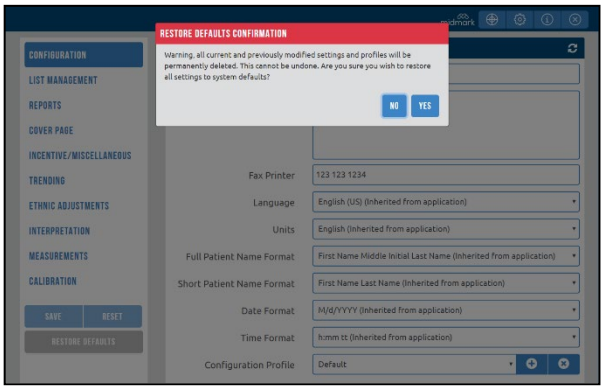


- ***SAVE***: Saves the customized profile.
- ***DISCARD***: Disregards all edits and uses the last saved Configuration Profile settings.
- ***CANCEL***: Takes the user back to the CONFIGURATION screen to continue editing.

Reset Configurations to System Default

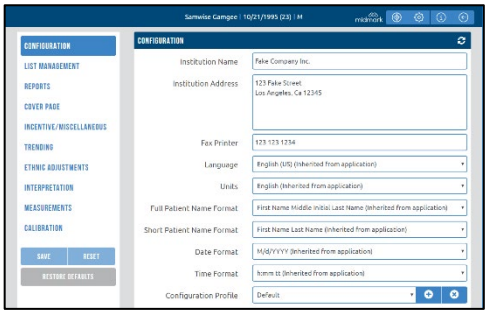
The option located on the title bars can be used to restore that specific configuration section to the system defaults. To restore all the configuration sections use the RESET button at the bottom of the left panel.

A RESTORE DEFAULTS CONFIRMATION window appears when the user selects the reset option:



- ***YES***: Restores the configuration section to system defaults.
- ***NO***: Returns to the screen last accessed.

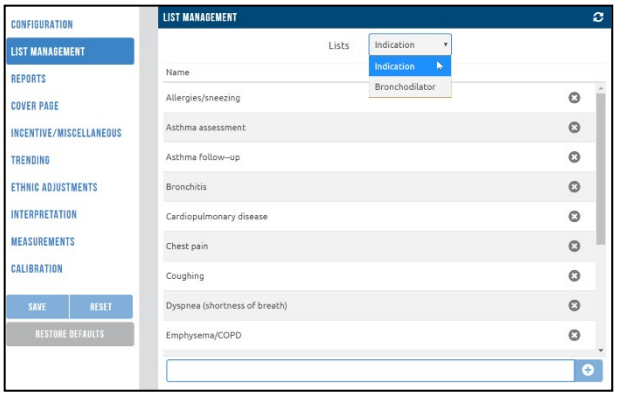
Configuration



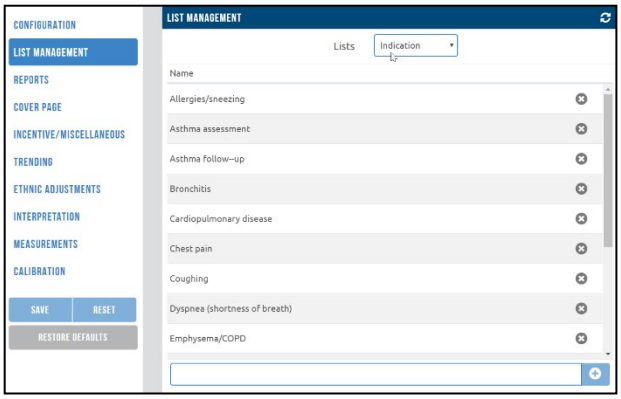
Customize how patient and Institution information is displayed and printed by entering the corresponding information into the labelled boxes or selecting the options from the drop down menus (access the menus by selecting the drop down arrows).

List Management

The Midmark Digital Spirometer Software contains two default Lists: Indication and Bronchodilator. The LIST MANAGEMENT windows opens the Indication list by default, and the Bronchodilator List can be accessed by selecting the drop down arrow inside the Lists box:

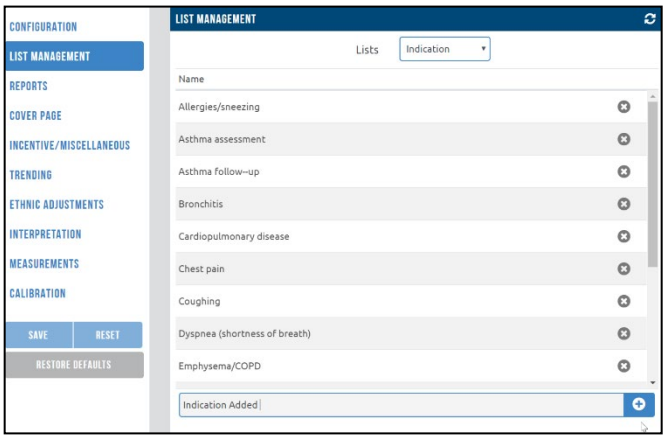


The Indication List contains the system default list of possible Indications.

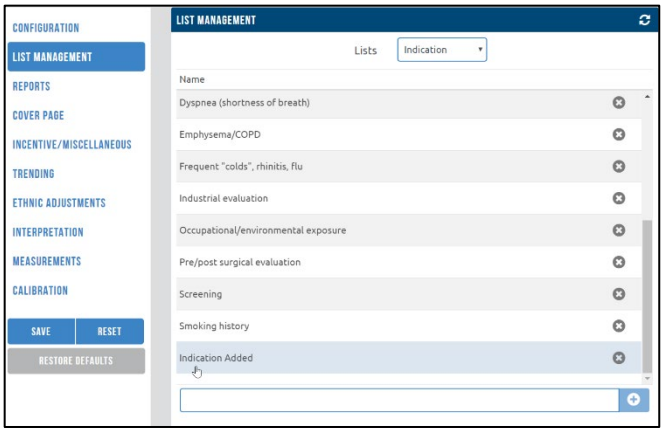


Indications Names can be customized by either adding new Indications or deleting items from the default Indication List.

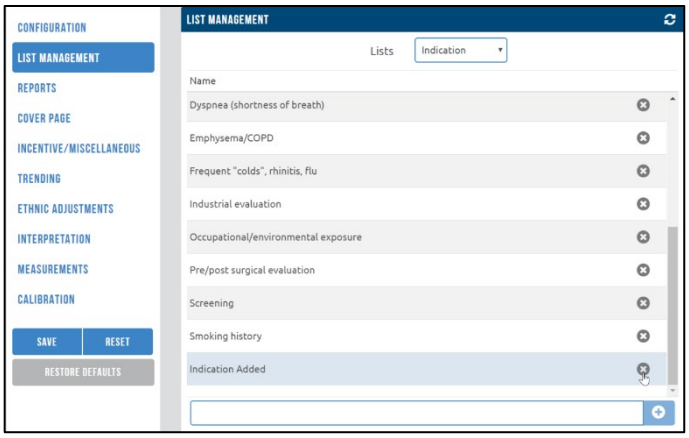
In order to add new Indications, type the name of the Indication in the empty box at the bottom of the window and select the option with the plus sign ( ) as this button becomes available when a new Indication is typed into the box.



The Name of the new Indication will display at the bottom of the list:



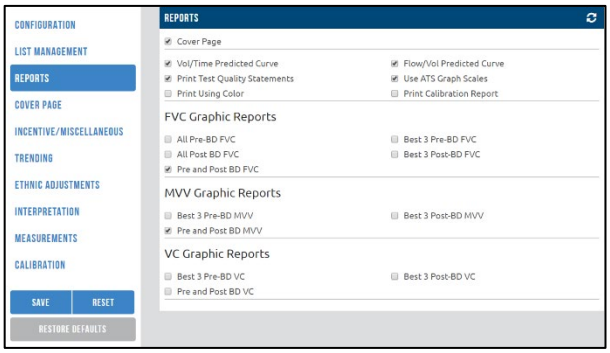
In order to delete Indications, select the delete option ( ) as seen below, and the Indication Name will be removed from the list:



Access the Bronchodilator List by selecting Bronchodilator from the Lists drop down menu:

Reports

⚠	**Caution** For printed or PDF reports, due to size constraints: • Observations Notes might not appear completely, • Interpretation Notes over 310 characters (including spaces) might not appear completely It is recommended to refer to the digital report in the software when reviewing Observation Notes.



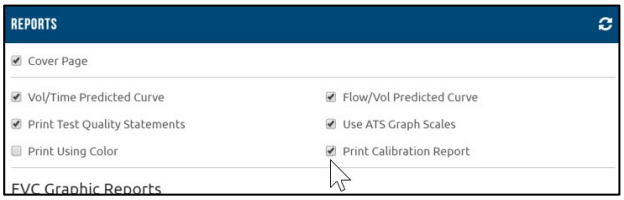
The REPORTS tab settings manage which reports will be printed when the Print icon ( ) is clicked.

Printed reports will include a page for each box checked in this configuration settings.

If the Cover Page box is selected, and no boxes within the Reports area are selected, only a one-page 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):

In this example, if a test session only contains Pre-BD FVC tests, clicking **Print** will print a three page report. The first page will be the Cover Page, the second page will be the Best 3 Pre-BD FVC tests performed and the third page will be the best Pre-BD test. 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 also select to print 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 along with the report. This is helpful if proof of calibration is required.

There are five other options within this section of the REPORTS tab:

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

For instance, 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.

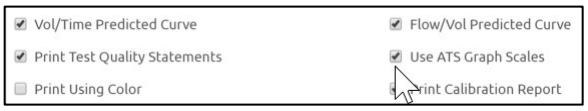
The *Cover Page Settings* tab has separate selections for *COPD Risk*, *Smoking History, Lung Age,* and *Test Quality Statements*. See Configuring Midmark Digital Spirometer for additional information about the cover page.

• *ATS Recommended Graph Size*

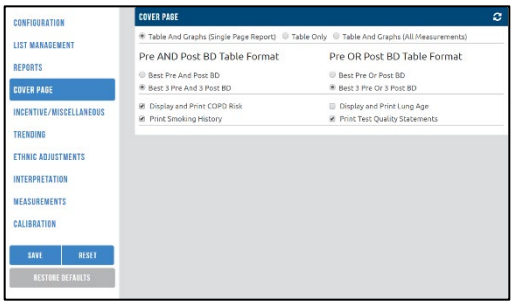
The ATS recommends that a Volume Time graph be at least 20 mm per second and 10 mm per liter when hand measurements are required. Some government agencies and insurance carriers require this for reimbursement.

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

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



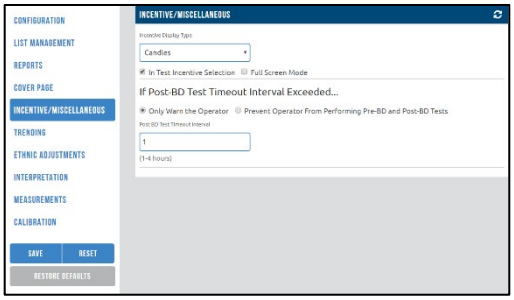
Cover Page



The COVER PAGE *Settings* tab enables the user to customize the cover page on the printed report. Selections on this tab only change the look of the cover page - they do not affect the report pages.

- ***Table and Graphs (Single Page Report)***: The printed report will consist of a single page if this option is selected. The Single Page Report contains a table (predicted values, efforts) and graphs (Flow/Vol and Vol/Time graphs). This report can only display up to 10 measurements.
- ***Table only***: Only Table (Measurements) are included on the Cover Page if this option is selected.
- ***Table and Graphs (All Measurements)***: All selected measurements with the volume-time and flow volume graphs can be printed if this option is selected.
- ***Pre AND Post BD Table Format***: These 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.
- ***Pre OR Post BD Table Format***: These selections will take effect if the patient has performed only Pre or Post BD tests,
- ***Display and Print COPD Risk, Print Smoking History, Display and Print Lung Age,*** and ***Print Test Quality Statements***: *determine the additional information to appear in the patient demographics field and graph section of the cover page.*

Incentive/Miscellaneous



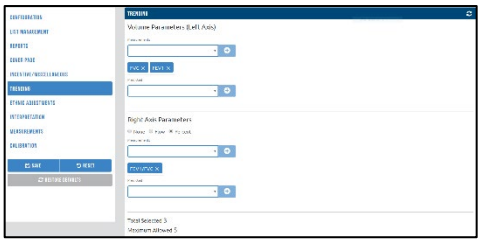
The INCENTIVE/MISCELLANEOUS tab enables the user to customize the pictorial representation settings of the incentive that the patient will see when performing a test.

- ***Incentive Display Type***: 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. Click on the drown arrow to open the Incentive Display Type Menu to select one of the following options.
    - Candles
    - Dandelion
    - Tree, Leaves and Monkeys
    - Boat Races
    - Thermometer

- None: The incentive selection portion of the test screen will not appear if this option is selected.

- ***In Test Incentive Selection***: The user can select any of the incentives (for display) on the Incentive screen if this option is selected.
- ***Full Screen Mode***: The Incentive graphics image is maximized and displays as the full screen (graphs pane are replaced with the Incentive image) if this option is selected.
- ***Only Warn the Operator***: An alert message displays when the selected interval times out if this option is selected. However, the Post-BD test can still be performed.
- ***Prevent Operator From Performing Post-BD Tests***: An alert message displays when the selected interval times out if this option is selected, and the Post-BD Test cannot be performed.
- ***Post BD Test Timeout Interval***: This option consists of the Post-BD test timeout interval, and can be customized with an entry of 1, 2, 3, or 4 hours.

Trending



- ***Selecting Parameters to Trend***

The user can select up to 5 measurements from the following trending parameters in the *Trending* tab on the *Spirometry Configurations* screen:

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

> ***Note***
> *All five measurements will be displayed on the graph together, but only the first three measurements will be displayed in the effort grid of the trending screen. To view the other two measurements, click on the Expand Effort grid button.*

- ***Axis Parameters***

The left axis and right axis trending 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.

- Click on the ⊕ sign after selecting a measurement from the drop down menu to add it:

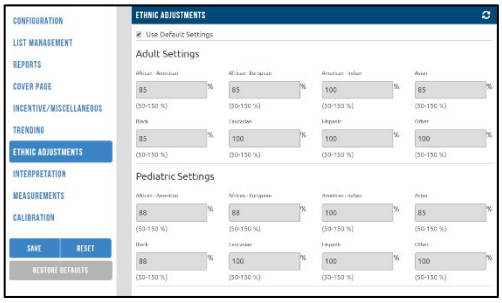
- Click on the ⊠ sign next to the measurement to remove it from the trending selection.

- ***Volume Parameters (Left Axis)***

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

- ***Flow and Percentage Parameters (Right Axis)***
  - ***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.

Ethnic Adjustments

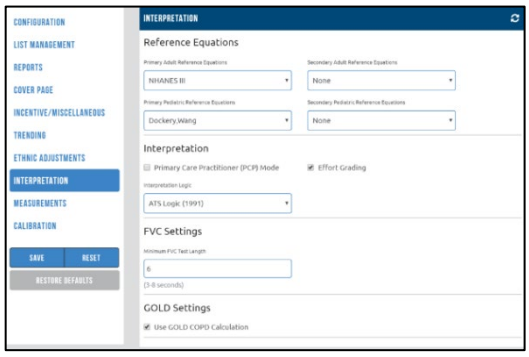


The *Ethnic Adjustments* tab enables the user to view what the predicted value equations are adjusted to when testing a specific ethnic group. The user can also adjust or change the predicted values.

When the *Use Default Settings* box is checked, the program will set the percentages to the default. When the *Use Default Settings* box is not checked, the values may be adjusted. See Appendix F - Adjustments to Reference Values Equations for the default values and additional information.

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

Interpretation



⚠	**Caution** For printed or PDF reports, Interpretation Notes over 310 characters (including spaces) might not appear completely due to size constraints. It is recommended to refer to the digital report in the software when reviewing Observation Notes.

- ***Reference Equations***

The default *Reference Equations* set for Adults and Pediatrics tests can be selected from the INTERPRETATION tab.

Not every spirometry measurement (FVC, FEV, 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 FEF_{25}, 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, select **None** in the *Interpretation Logic* dropdown 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 3 seconds for patients < 10 years old and 6 seconds for patients > 10 years old.

See Appendix D – Reference Values – Adult or Appendix E – Reference Values – Pediatric for more information on the reference equations.

- ***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 Midmark Digital Spirometer 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 VC and MVV test selection.

> ***Note***
> *In the PCP mode, the Midmark Digital Spirometer measures the FEV6 but on all reports and displays it is labeled as the FVC.*

- ***Grading***

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. Two acceptable tests are required for the software to display *Good Test Session*, according to the criteria listed on the table below.

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 FEV1 measurements that match between 101 and 150 ml.
C	At least two acceptable maneuvers with FEV1 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 FEV_6 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.

- ***FVC Settings***

The minimum FVC test length can be set by entering the desired number of seconds in the *Minimum FVC Test Length* box.

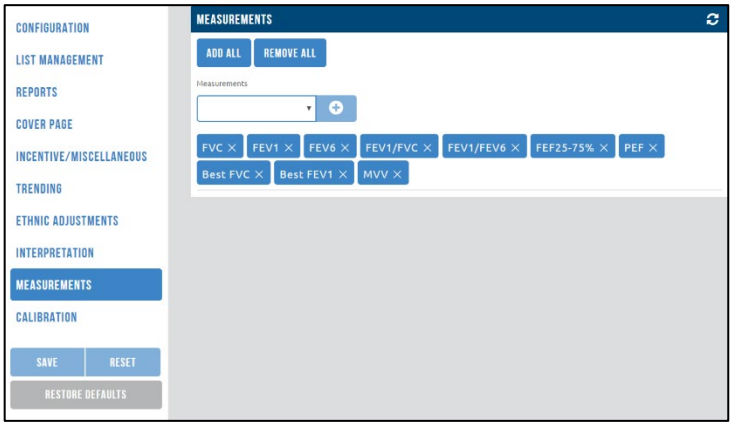
The minimum value allowed for the FVC test Length is 3 seconds and the maximum allowed value is 8 seconds. For example, if the user selects 4 then the length of the FVC test (inhale/exhale) shall be at least 4 seconds.

- ***Gold Settings***

The Gold settings can be enabled by checking the *Use GOLD COPD Calculation* option.

If this option is selected it becomes available on the patient information screen. (See Gold Assessment for additional information).

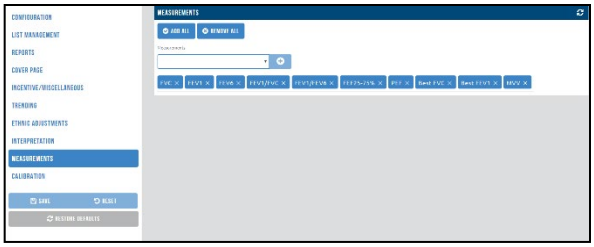
Measurements



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

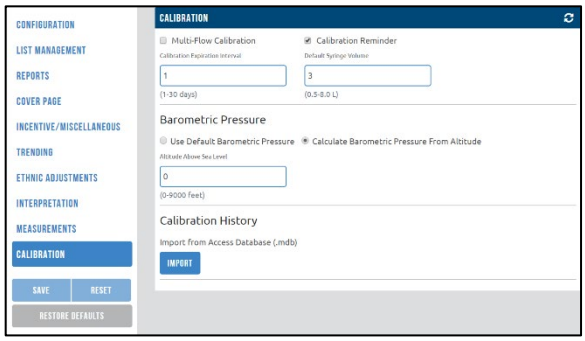
If the user has selected the *Tables and Graphs* setting for the Cover Page, only the first 10 measurements selected will be displayed on the Cover Page. If the *Only Table* setting is selected, up to 28 measurements can be displayed.

- ***ADD ALL*:** Adds all measurements from drop down menu.
- ***REMOVE ALL*:** Removes all measurements from drop down menu.



The measurements can also be added by selecting each of them individually from the drop down menu and adding to the list.

Calibration



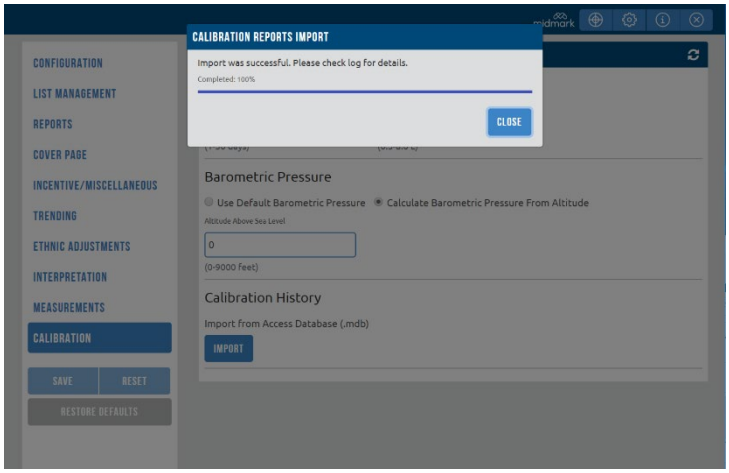
NOTICE	**NOTICE** *The American Thoracic Society highly recommends daily calibration checks be performed on spirometers. (See reference 12)*

- ***Multi-Flow Calibration***: This option can be checked to ***allow*** the user to perform 4 flow tests.
- ***Calibration Reminder***: Check this box to get a reminder when the device's Calibration has expired. If unchecked, no Calibration Expiration notification will be generated.
- ***Calibration Expiration Interval***: Enter the Calibration expiration interval (between 1 to 30 days).
- ***Default Syringe Volume***: Enter the Syringe Calibration volume (between 0.5 L to 8.0 L).
- ***Barometric Pressure***:
    - ***Use Default Barometric Pressure***: The default Barometric Pressure will be used if this option is selected.
    - ***Calculate Barometric Pressure From Altiture***: Select this option if the barometric pressure is not known, 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 check.*

- ***Calibration History:*** Import Access Database (.mdb) Calibration records from IQmanager version 8.6.1.
    - ***Import***: This option allows the user to select an Access Database file (.mdb) to be imported. Follow the steps below to import Calibration files from IQmanager version 8.6.1.

1. Click on the Import Button.
2. Locate to the folder containing the .mdb files to be imported.
3. Select the .mdb file to be imported.
4. Click Import.
5. Observe the following pop up screen after the file is imported successfully.



6. Click on the Calibration Icon to access the calibration screen.
7. Click on the History tab.
8. The Calibration files from IQmanager version 8.6.1 will be available in the Calibration History.

Note
*If the Calibration files are not imported successfully a message "**Import has failed**" will appear. Check the Calibration Log file for additional information.*

Operation

Pre-Test Preparation

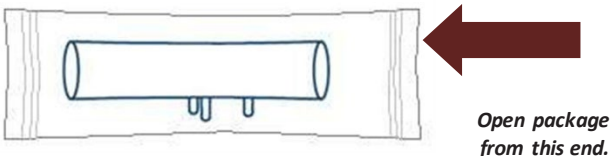
⚠	**Caution** The Midmark Digital Spirometer, when used with specific Midmark disposable mouthpieces, is designed and tested to meet regulatory and industry standards. Midmark can only warrant product performance and accuracy if the device is used as intended in its unaltered form, and when recommended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

1. Calibrate the Midmark Digital Spirometer daily before use.
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. Obtain a new, un-opened disposable mouthpiece.

NOTICE	**NOTICE** *The disposable mouthpiece to be used with the Midmark Digital Spirometer is intended for one use, or for use on a single patient during a single procedure.*

NOTICE	**NOTICE** *Inspect the nose clips thoroughly for any signs of damage or missing pads prior to use.*

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).



Open package from this end.

9. Remove the plastic wrapper from the mouthpiece and discard. Inspect the mouthpiece to assure no plastic remains.
10. Avoid cross-contamination by disposing each used disposable mouthpiece and replacing it with a new one for each patient.
11. Explain to the patient that they will be performing a minimum of three and a maximum of eight testing maneuvers.

Operation of Midmark Digital Spirometer with IQmanager®

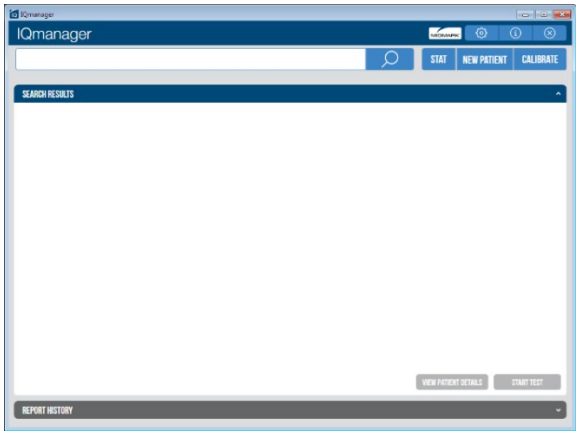
Starting the Program

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

Midmark IQmanager®

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.

Calibration

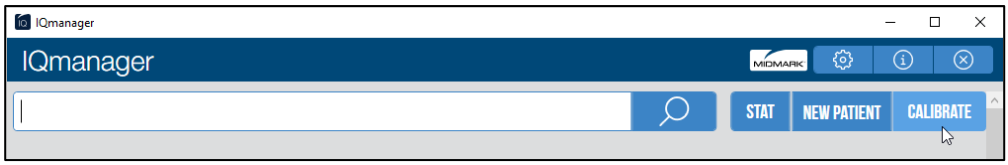
NOTICE	**NOTICE** *The American Thoracic Society highly recommends daily calibration checks be performed on spirometers. More frequent calibration checks may be needed if conducting testing on large numbers of patients or in cases where the ambient temperature will be changing (see reference 12).*

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

Performing a calibration check for the Midmark Digital Spirometer requires a 3-Liter syringe. Midmark strongly recommends using the Midmark Spirometer Calibration Syringe with the Midmark Syringe Adapter.

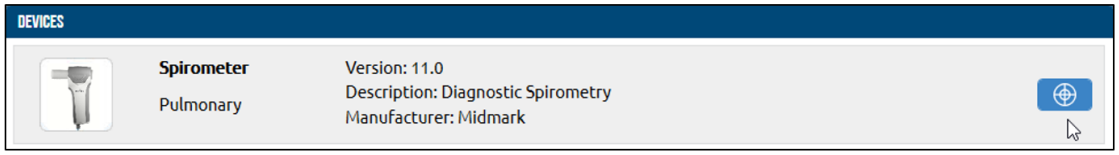
Note
The Midmark Digital Spirometer must be calibrated with a disposable mouthpiece; the device must be calibrated with a syringe adapter that fits over the outside diameter of the disposable mouthpiece. Never calibrate the device with a syringe that fits inside the disposable mouthpiece.

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



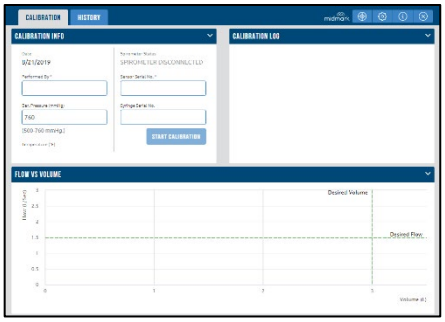
2. A list of devices that support calibration is shown. Select Spirometer from the list by choosing the calibration

   ( ) icon on the right.



Note
Place the disposable mouthpiece into the Midmark Digital Spirometer before opening the Calibration or Test screens. See Connecting the Midmark Digital Spirometer.

3. The following calibration screen is shown:



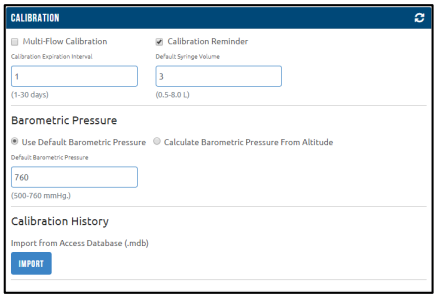
4. Check to see if *Spirometer Connected* is displayed in the upper-right corner of the Calibration Info window.
5. Select *START CALIBRATION* to calibrate the Midmark Digital Spirometer device.
6. To print calibration reports for a device, select the **Print n ( )** on the appropriate row on the Calibration Log window.
7. To print a Calibration log for a device, click on the History tab, select a range (*All, Last Month, Last Year*) from the drop down option by click the **icon ( )** on the device row.

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.

1. Click on **Settings** to open the *Spirometry Settings* dialog box.
2. 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 in the *Altitude Above Sea Level* text box. 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.*



If the *Calibration Reminder* option is checked, the software reminds the user when the Midmark Digital Spirometer has not been calibrated for the interval set in the *Calibration Expiration Interval* box.

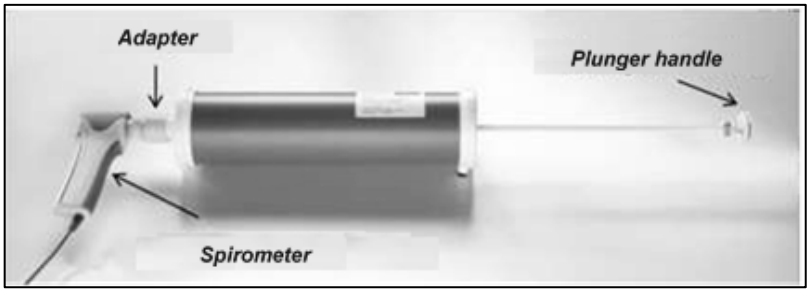
Starting a New Calibration

1. Attach the Midmark Digital Spirometer to the computer via USB and open the Calibration screen, see **Calibration** section above for steps.

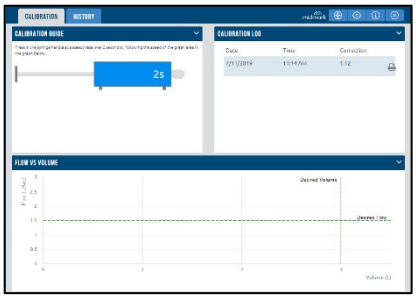
> ***Note***

When illuminated, the green LED light on the Spirometer indicates the spirometer is connected to the Spirometry Software on the computer for a spirometry maneuver or 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 disposable mouthpiece.



3. Check that the disposable mouthpiece is properly attached to the Midmark Digital Spirometer.
4. The first time the Midmark Digital Spirometer is calibrated; the serial numbers for the syringe and the spirometer handle need to be entered in the appropriate boxes.
5. Click **Start Calibration** once the device is detected. The sensor will zero itself and then the software will be ready for calibration.



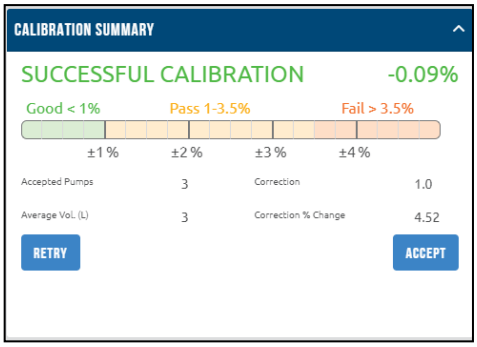
6. Follow the instructions. Use the dotted line and/or the green progress bar on the **Flow vs Time** graph as a target flow rate. The Blue line is the current flow going through the device. Try to inject the air from the syringe at a rate close to that of the green progress bar.
7. The plunger handle 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 green progress bar to start. If it does, wait for the green progress bar 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 American Thoracic Society 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. See reference 12.

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.



11. After accepting the verification, the system automatically saves the calibration. To print the calibration report, click the **Print icon** on the appropriate row in Calibration Log and select *Print*. To view the calibration report, click **Print**.
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*. If this option is checked, the spirometer must be calibrated 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 line or keep the blue bar moving at the same speed as the green progress bar on the Flow vs Time graph.

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 an OSHA representative for additional details about occupational testing.

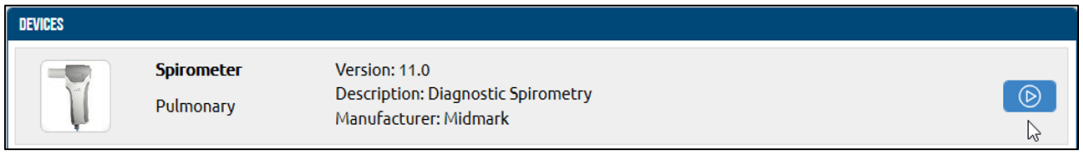
Testing a Patient

Spirometer Acquisition Screen

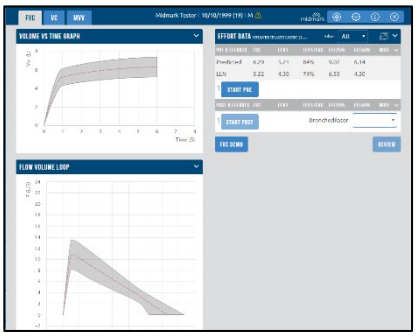
FVC Testing

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 Midmark Digital Spirometer, the user can perform a FVC or FVC Loop by selecting FVC.

1. To start a test, click **New Test** from the Patient Data screen, then click on the play icon next to the Midmark Digital Spirometer:



2. If desired, type the Technician's name and the name of the Physician who requested the test 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.
3. Click on New **Test** to open the test acquisition screen. The *Spirometry Data Acquisition (Test)* screen appears:

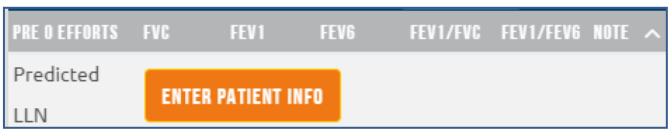


4. **FVC** will be selected by default. For a Pre-BD test, select **START PRE**.
5. Once **Start Pre** is selected, an incentive selection screen appears. Select the desired incentive.
6. Do not click on **Start** until the patient is ready.

Missing Patient Information

When opening the spirometry screen with missing patient information (such as Race, Age, Sex, Height (RASH), or Smoking History), an alert messages will appear.

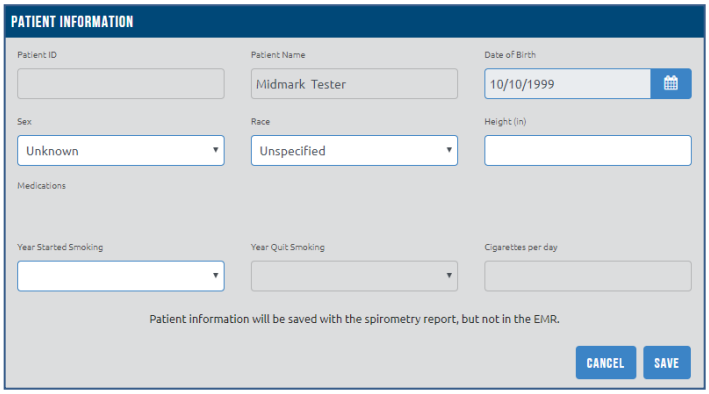
The *Enter Patient Info* button appears where the predicted and LLN values would normally appear when the RASH values are missing.



The alert symbol ( ) appears next to the patient information on the title bar when the RASH values or Smoking History is missing.

1. Select the **Enter Patient Info** button in the EFFORT GRID, or select the **alert symbol** near the patient information on the title bar.
2. Once the Patient Information window appears, enter the RASH values and Smoking History information.
3. Press **Save** after the missing information is filled out.

> ***Note***
> *Patient information edited during the spirometry test will be saved with the report, but not in the EMR. Information saved in the report may be used in subsequent spirometry tests.*



Selecting accurate patient demographics are important as the predicted values, LLN, various calculations, and interpretation all rely on the patient's Race, Age, Sex, and Height.

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 demonstrates the correct way to perform the test.

- The purpose of the FVC test 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 disposable mouthpiece in their mouth with the tongue under the disposable mouthpiece, teeth and lips around it, sealing the lips around the disposable mouthpiece, blast out as hard and fast as possible.

> ***Note***
> *The patient should not block the opening of the disposable mouthpiece 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 disposable mouthpiece 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** The Midmark Digital Spirometer, 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 device is used as intended in its unaltered form, and when recommended practice guidelines are followed. Any modification to the Midmark Digital Spirometer mouthpiece, including but not limited to the use of an adapter or filter, is considered an alteration to the design of the product.

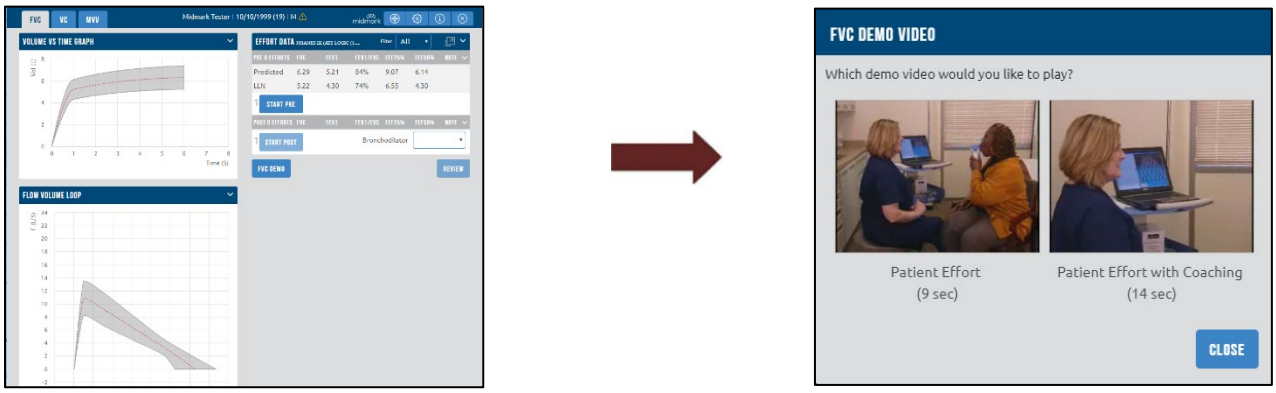
- The use of nose clips helps ensure that no air leaks out through the nose during testing. Air leakage through the nose can affect the test results.
- The technician will demonstrate the FVC maneuver with the use of a disposable mouthpiece.
  - To emphasize the maneuvers to the patient, have the technician 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 disposable mouthpiece 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.

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

Demo Videos for FVC Test Instructions

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.*

The FVC Test screen contains a link to two Demo Videos that can help with instructing the patients on how to execute the test. Access the link by clicking on the FVC DEMO button on the test screen, as seen below.



Select either the *Patient Effort,* or the *Patient Effort with Coaching* to access the Demo Videos contents. Using these videos will help maintain a consistent coaching message throughout the organization

Click on the *CLOSE* button to exit the *FVC DEMO VIDEO* screen.

Acquisition Effort Review

After every effort, the technician will be presented with a review screen. It will look similar to the following:

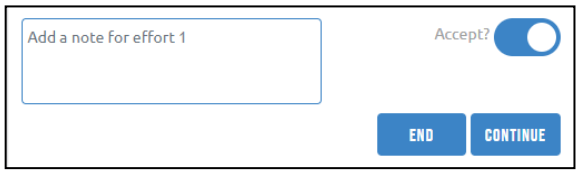
The software will display a digital coaching message above the values, which will have a green or orange background. The technician will use their training, the patient's effort, and values displayed to decide which effort will be accepted or rejected. If an effort is to be rejected, click the **Accept?** slider so the slider is off (gray). If an effort is to be accepted, ensure the **Accept?** slider is on (blue).

To stop gathering efforts, select **END**. To continue gathering efforts select **CONTINUE**.

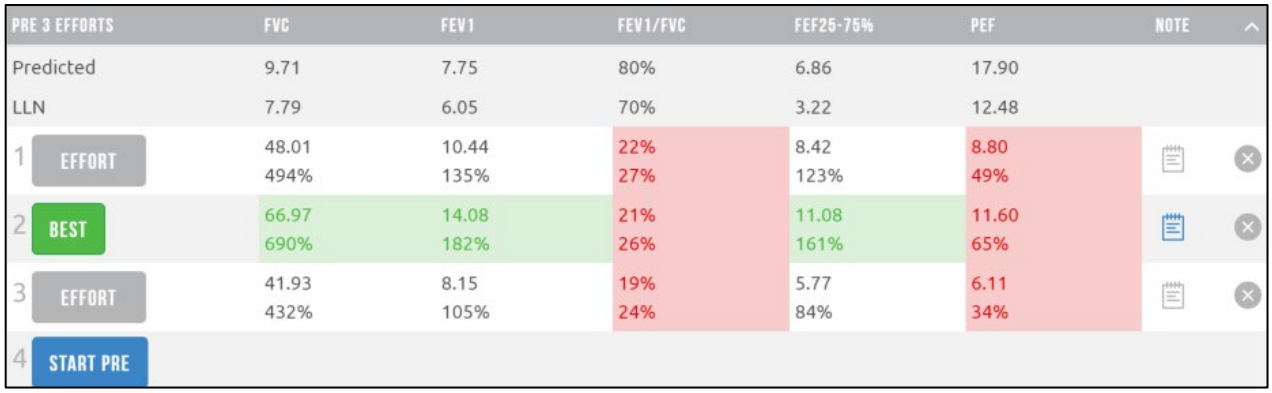
Observation Notes

⚠	**Caution** For printed or PDF reports, Observations Notes might not appear completely due to size constraints. It is recommended to refer to the digital report in the software when reviewing Observation Notes.

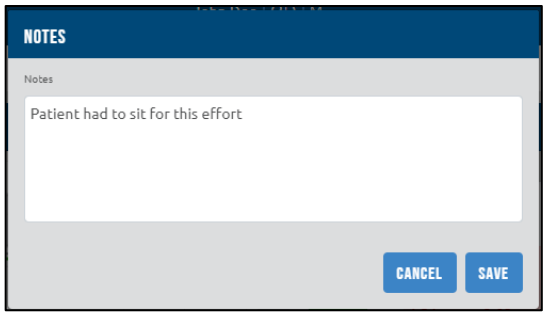
Observation Notes may be added during the Acquisition Effort Review screen here:



Observation Notes can also be added after efforts are collected via the **Notes** icon shown on the effort line in the acquisition and review screen. To add it while on the acquisition or review screen, select the blue or gray colored **Notes** icon and type in the desired operation notes in the input box that appears, select **Save**.



In order to edit any observation notes, select the blue colored **Notes** icon on the acquisition or review screen. Edit the text that appears in the input box, select **Save**.



Post-Bronchodilator Test

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

> ***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.*

From the Acquisition screen or the Report Review screen, select **START POST** to perform a Post-BD test. Ensure a bronchodilator is selected from the pull-down list before returning to the review screen. Post-BD FVC tests are performed the same way as Pre-BD FVC tests.

> ***Note***
> *Once a Post-BD test has been performed. No more Pre-BD tests can be acquired.*

Step-by-Step Spirometer Instructions

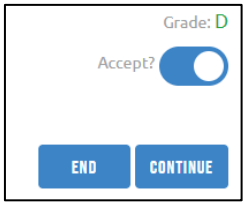
1. Insert a new disposable mouthpiece in the Midmark Digital Spirometer. See Connecting the Midmark Digital Spirometer.
2. Instruct the patient to hold the Midmark Digital Spirometer in either hand and then hold the device up and to the side of their face, as illustrated in the photo below.

3. On the *Patient Testing* screen click **Start Pre**. Select the appropriate incentive and click **Start**.
4. The device will zero itself. ***Be sure that no air is traveling through the mouthpiece during zeroing.***
5. Once the zeroing is done, an incentive display appears, if one has been chosen.
6. Instruct the patient to take a maximal inhalation.
7. Instruct the patient to quickly put the disposable mouthpiece in their mouth, with their tongue under the disposable mouthpiece, teeth and lips around it, sealing the lips around the disposable mouthpiece. 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 disposable mouthpiece.

Note
When explaining the maneuver to the patient, instruct them to use the ridges on the top and bottom of the disposable mouthpiece *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.*

8. 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 disposable mouthpiece 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:



13. After each completed test, the *Accepted* section appears with **Accept** marked as on (accept) or off (reject) automatically selected. After a test is accepted or rejected, click **Continue** to perform another test or **End** to stop testing.

Note
The acceptability statements are intended as recommendations or guidelines and are not mandatory actions. The software selection can be overridden, and 'Accept' or 'Reject' can be chosen for each test.

Acceptability Statements Seen During FVC Testing	
Statement	**Criteria**
Good Effort	Meets all the FVC Testing acceptability criteria.
Hesitation Detected. Blast Out Faster; Blast Out Harder	If V Ext. > 5% of the FVC value. If FVC is under .15, then V Ext. > .15.
Exhale Longer	If under 10 years old and blows less than 3 seconds or if user is over 10 and blows less than 6 seconds.
Poor Effort. Blast Out Faster; Blast Out Harder	If PEFT > 120msec.
Unsmooth Blow Detected. Blast Without Cough	Cough or interruption detected.
Don't Hesitate*	If V Ext. > 5% of the FVC value. If FVC is under .15, then V Ext. > .15.
Blow Out Longer	If FVC < Predicted Fvc and ExpTime < minimum Fvc Length from settings.
Blast Out Completely	If max volume – min volume > .05
Inhale Deeper Before Starting the Test	If Fivc > 1.1 * Fvc
Inhale Completely at the End of the Test	If Fvc > 1.1 * Fivc
Unable to Perform Automatic Interpretation because: Predicted Fev1/FVC is not available or valid	No Predicted Values are set
Volume Too Low	If Fvc < .500
Blast out Faster*	If user blows too slowly.
Blast out Harder*	If Best Test Pef Value > Current Test Pef + 1
Deeper Breath*	If Best Test Fev6 Value > Current Test Fev6 + .15
Blow Out Longer*	If test is less than 6 seconds and the change in volume in the last half a second is greater than 100ml

**Statements will only be shown in PCP Mode.*

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

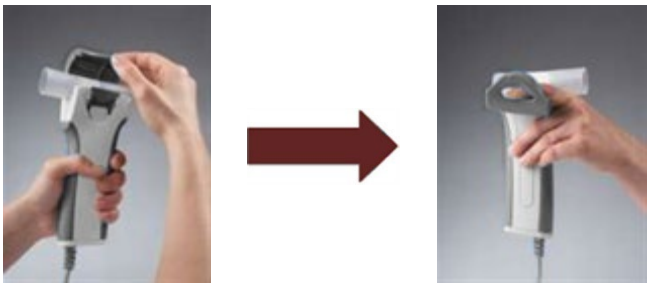
Note
Only one error message is displayed.

14. If medication is needed, administer as per manufacture's guidelines. Select appropriate medication for BD dropdown. Repeat steps 3-13 for the Post test. See **Post-Bronchodilator Test** for more information.
15. After the patient has completed the number of required tests, click **Review** in the lower-right corner of the test screen. This will display the *View Report* screen. To save the report, select **Save** from the Review screen.

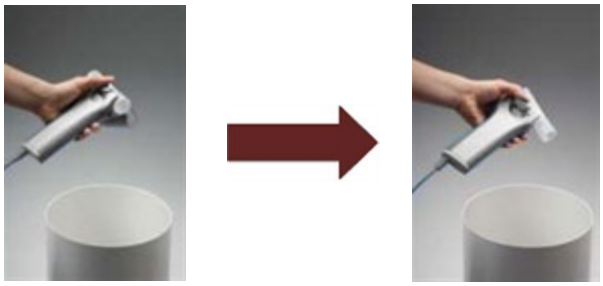
See Reviewing Patient Reports information about the *View Report* screen.

Ejecting the disposable mouthpiece from the Midmark Digital Spirometer

The Midmark Digital Spirometer eliminates the need to handle the used disposable mouthpiece to eject the disposable mouthpiece from the device:



1. Open the Midmark Digital Spirometer door and hold open with index finger.
2. Hold the device over trash receptacle and use the thumb to push down on the eject lever.



3. The used disposable mouthpiece will eject into the trash receptacle.

Quality of Test Results

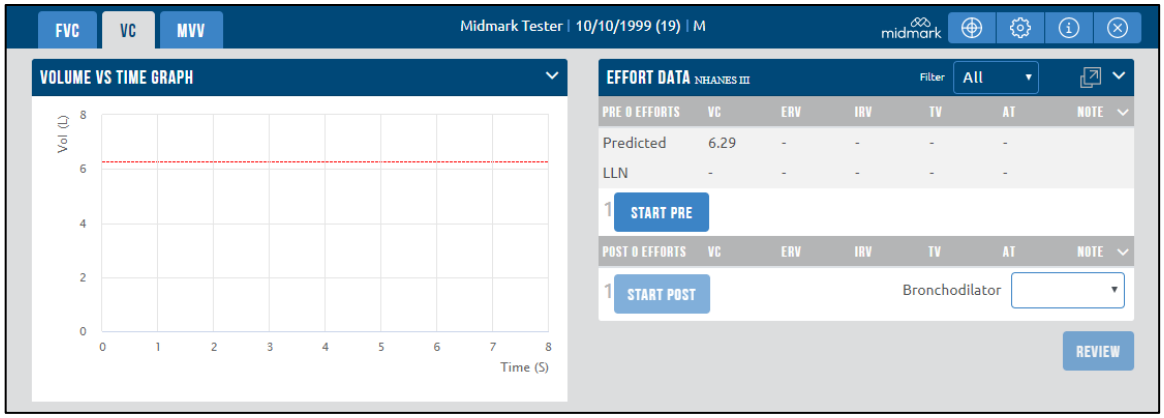
Having the patient inhale at the end of the test provides measures to ensure that the patient inhaled fully before they started the test and expired fully during the test. If a patient performs a FVL, the results of their expiratory volume and their inspiratory volume should be within 10% of each other.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

VC Testing

Vital capacity (VC) 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.

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

1. Click on the **VC** tab on the Midmark Digital Spirometer test screen. Do not click START PRE or START POST until the patient is ready to perform the test.



2. When ready, click on either START PRE or START POST to start the test. Select the incentive and press start.
3. 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 disposable mouthpiece. Have the patient take a couple tidal breathes.
4. After the tidal breathes, have the patient inhale as deeply as possible, until a plateau is observed at the bottom of the graph on the computer screen.
5. Have the patient exhale slowly and evenly until a plateau is observed at the top of the graph on the computer screen, or the device signals that the end of the test criteria has been met. The patient must exhale at a faster rate during the blow out phase than during the tidal breaths.
6. Stop the test by clicking on **STOP** or pressing **Enter**.
7. Click on END to end the test, or on CONTINUE to continue test sessions.
8. Remove the mouthpiece.
9. If medication is needed, administer as per manufacture's guidelines. Select appropriate medication for BD dropdown. Repeat steps 1-8 for the Post test. See **Post-Bronchodilator Test** for more information.
10. Click on **REVIEW** then on **SAVE** to save the test after the patient has completed the number of tests required.

MVV Testing

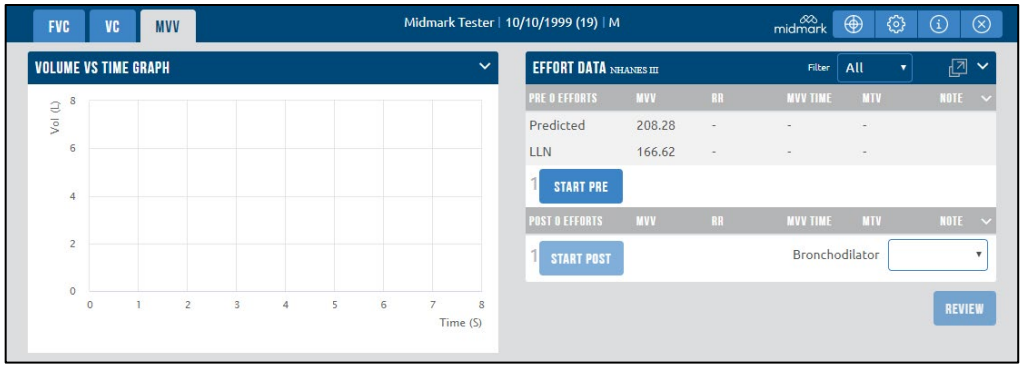
The Maximum Voluntary Ventilation (MVV) is the measurement of a patient's breathing when the patient inhales and exhales maximally and rapidly for 12 to 15 seconds. The software takes this result and extrapolates the results for a period of one minute. MVV is expressed in Vol/Time.

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.

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

1. Click on the **MVV** tab in the Midmark Digital Spirometer test screen. Do not click START PRE or START POST until the patient is ready to perform the test.



2. When ready, click on either START PRE or START POST to start the test. Select the incentive and press start.
3. Instruct the patient to put disposable mouthpiece in their mouth, with their tongue under the disposable mouthpiece and lips sealed around it. Instruct the patient to inhale and exhale maximally and as quickly as possible for 12 to 15 seconds. Coach and encourage the patient until the test time exceeds 12 seconds.
4. Have the patient remove the disposable mouthpiece from their mouth and allow them to rest.
5. Click on END to end the test after the patient has completed the number of tests required, or on CONTINUE to continue test sessions.
6. If medication is needed, administer as per manufacture's guidelines. Select appropriate medication for BD dropdown. Repeat steps 1-8 for the Post test. See **Post-Bronchodilator Test** for more information.
7. Click on **REVIEW** then on **SAVE** to save the test after the patient has completed the number of tests required.

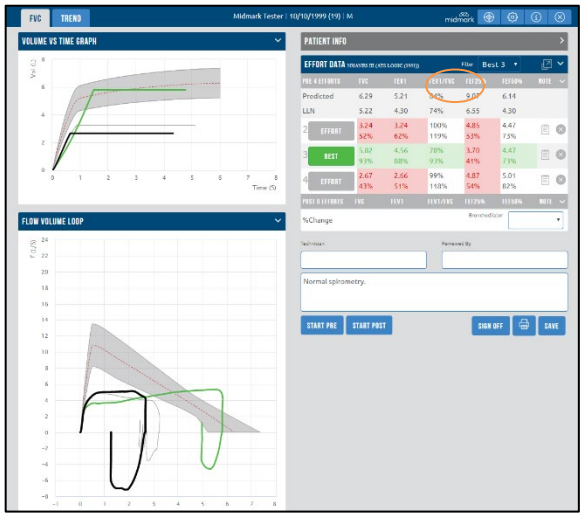
Reviewing Patient Reports

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.

Spirometer Review Screen

Once the spirometry session is completed, click on the REVIEW button at the bottom of the screen, and note the following:

- The *Technician*, *Reviewed By*, and *Interpretation* boxes appear.
- The filter for the effort data is changed from All to Best 3.
- Patient Info panel appears and is collapsed.



Effort Data Grid

- Click on the button on the EFFORT DATA header to display the expanded EFFORT DATA grid:

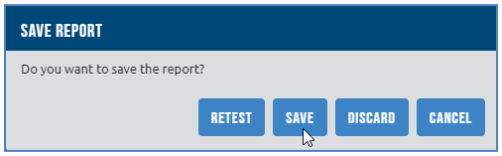
- The expanded EFFORT DATA grid header displays the predicted values generated using the Reference Equation on the title bar in read-only mode for all the applicable measurements.

- The PRE-EFFORTS section information includes the number of efforts (PRE *X* EFFORTS), Predicted and LLN measurement data.
- The POST-EFFORTS section information includes the number of efforts (POST *X* EFFORTS), and the measurements data.
- Click CLOSE to exit the EFFORT DATA grid.

Sign Off a Report

- Enter the Reviewed By and Interpretation information to the report to be able to sign off.
- Click on the *SIGN OFF* button on the test review screen:

- Click on the *SAVE* button on the SAVE REPORT box that opens.



- The *SIGN OFF* button will change to *UNLOCK* and a signed date and time stamp will appear next to it. The report will change to read-only.
- Use the UNLOCK button to change the report from read-only if it needs to be edited again after being signed off:

- Click on the UNLOCK button to make the report's review information editable again, make the required changes, SAVE the report, and SIGN OFF once again.

Reject/Delete an Effort

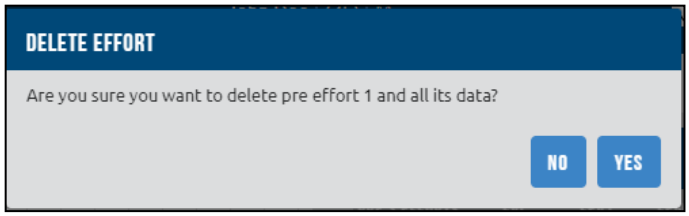
On the *Effort Data* table, select the **X** icon to reject an effort.

Once rejected, the effort or best button will show Rejected, the notes icon will turn to an Undo icon and the X icon will now delete a test.

To restore a rejected test, set the Filter to **All**, and click the **Undo** icon.

The effort will then look like it did before it was rejected.

Select the **X** icon of the REJECTED Effort again, then select *Yes* at the prompt to permanently delete the effort.



The test will be removed, but the numbering will continue. If effort #2 was deleted in a four efforts test, the tests will be numbered 1, 3, 4 – allowing the reviewer to understand the context of the report.

⚠	***Caution*** *When an effort it deleted, it is permanent – it cannot be recovered.*

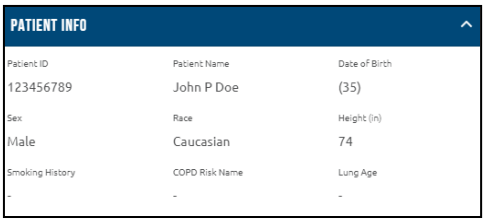
Note
A rejected test will be hidden if the 'Best 3' filter is set. Change the filter option to 'All' in order to view, restore, or delete rejected tests.

Observation Notes
See Observation Notes under the Testing a Patient section for instructions on adding and editing notes.

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.

COPD Risk can be located under the *Patient Info* section of the *Review Screen*.

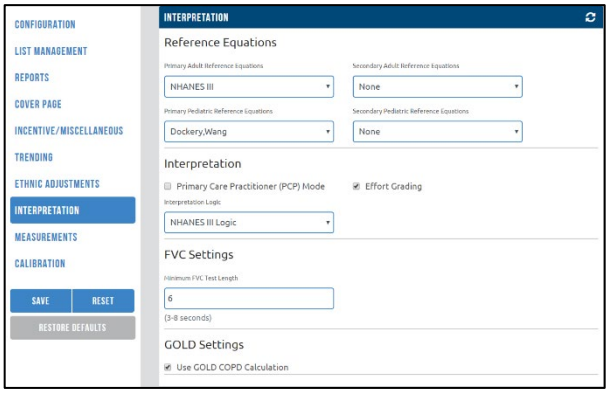


See Appendix H – COPD Risk Assessment Calculation for additional information.

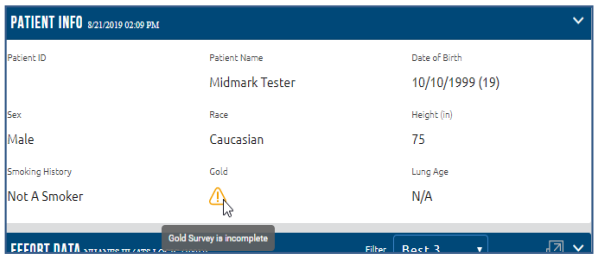
GOLD Assessment

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) assessment aids in the characterization of the severity of COPD.

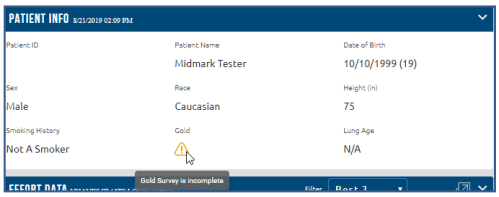
This feature can be enabled in *Settings* by selecting the *GOLD Settings* check box *(Use GOLD COPD Calculation)* at the bottom of the Interpretation screen, as seen below:



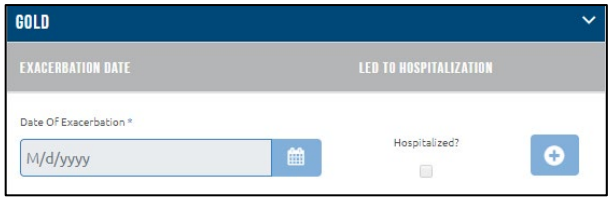
The patient information necessary for the GOLD assessment needs to be entered to generate a GOLD classification, otherwise the software will notify the user that the *Gold Survey is incomplete*.



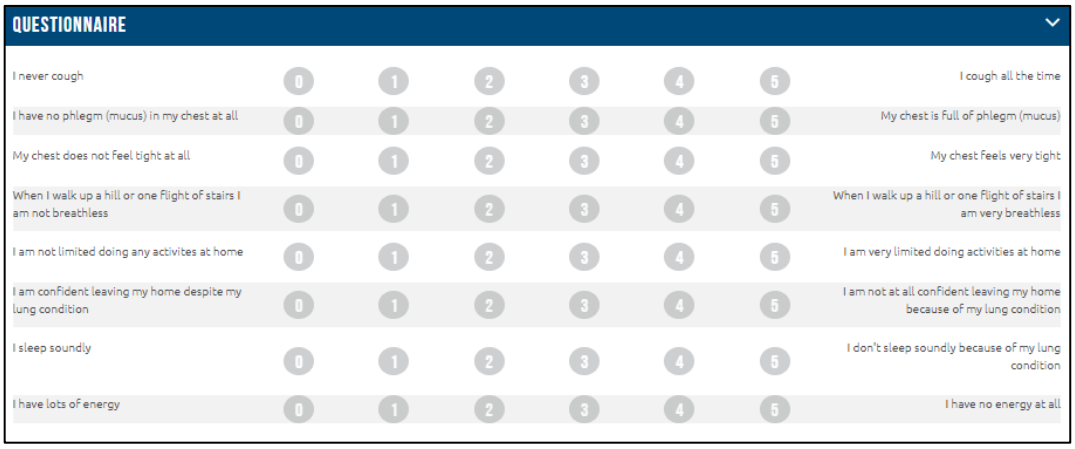
To fill in the missing information, click on the yellow triangle.



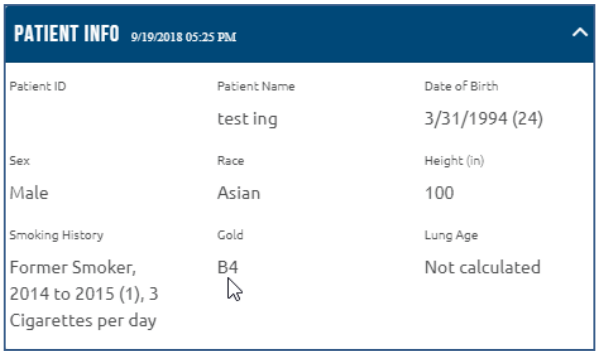
Fill in any exacerbations that occurred over the past year, by selected the date icon and choosing the date of the exacerbation. If the exacerbation lead to a hospitalization, check *Hospitalization* on the right side of the section.



Answer the QUESTIONNAIRE per the patient's symptoms, and select OK to save the questionnaire and exacerbation list.



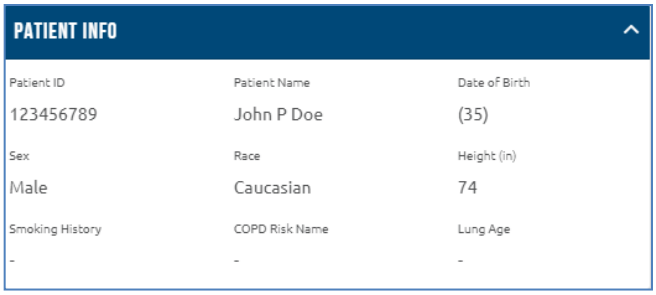
After the GOLD information is completed and if the patient's Best Post-BD FEV_1/FVC ratio is below 70%, a GOLD classification will appear.



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 FEV_1. Lung age is calculated only for patients who have been identified as current or former smokers, from 20 to 84 and will never have 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 J – Lung Age Calculation for additional information.

Note
The calculated GOLD grade uses the test's Best Post-BD FEV_1 and FVC value, Exacerbation List, and the Total Score of the Questionnaire answers. If a date appears next to the GOLD grade, it indicates the Exacerbation List and Questionnaire have been imported from a previous test and has not been reviewed. Click on the GOLD grade to edit or confirm the imported values, doing so will remove the date caveat. Please note, the FEV_1 and FVC values used in the calculation will never come from a previous test.



Trending

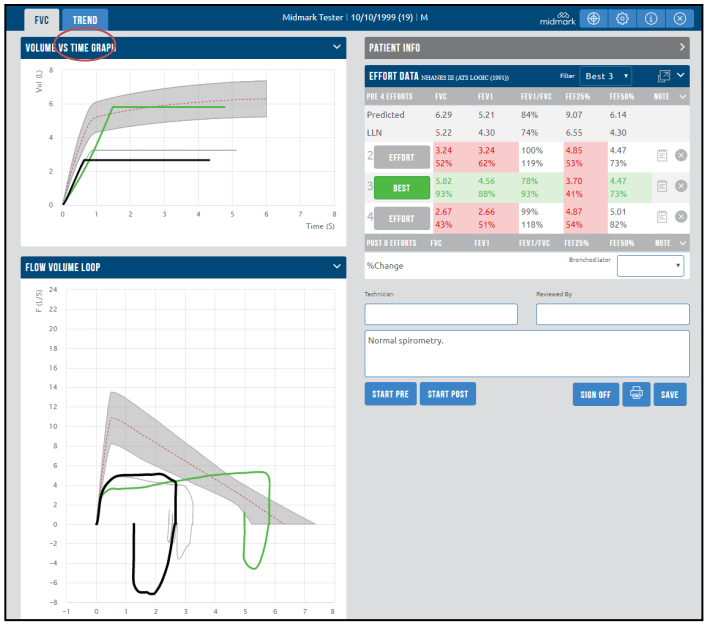
Trending enables the comparison of two or more '*Best Tests*' measurements of the same patient's spirometry sessions over time. Trending facilitates the visualization of the changes in a patient's condition by displaying the tests measurements in graphical and tabular forms.

The following features are standard in the Trending software:

- Date of each test performed is displayed
- Select up to five 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 10 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 format.

> ***Note***
> *See the Configurations Section to change the measurements that are being trended.*

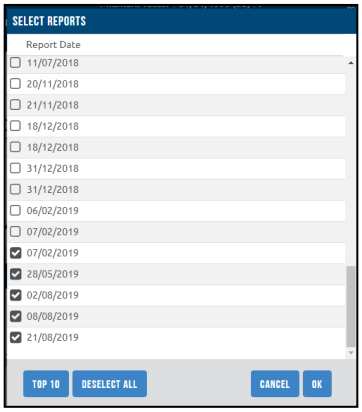
The TRENDING tab is located at the top right of the test review screen:



Selecting Reports to Trend

After clicking on the **TRENDING** tab on the Test Review Screen, the results are automatically selected and trended.

Click on the SELECT REPORTS button to change the trending reports selection:

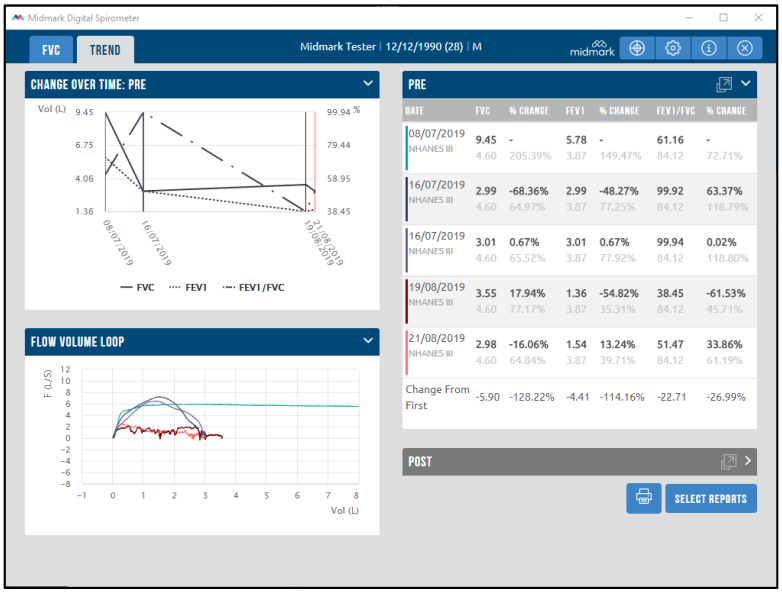


Trending Reports Selection Options

Click on two or more of the checkboxes next to the reports dates to compare the reports selected or use the buttons at the bottom of the window.

- *TOP (X)*: Compare up to 10 reports in the list. The X indicated how many reports could be trended from the list.
- *DESELECT ALL*: Unchecks all reports dates' boxes.
- *OK*: Confirms the selection of reports data to trend, and displays the trending data window.
- *CANCEL*: Cancels the SELECT REPORT option and returns to previous screen.

Trending Display Screen



The *Trending* screen is the main screen of the spirometry trending control. Each parameter trended is a data series and is built from the values from the best Pre-BD or best Post-BD tests of the spirometry sessions selected.

The *Trending* screen consists of graphical charts, a tabular measurement grid, print and SELECT REPORTS buttons.

- The print button sends the trending report to the default printer.
- The SELECT REPORTS button enables changes to the selection of reports to trend.
- Clicking on the grid row of a given report listed on the table highlights its graphical representation on the chart. The graph created for each F/V Loop is represented by a different color line.
- 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 oldest session to the newest session.

Accessories and Supplies

The following table shows the accessories and supplies approved by Midmark for use with the Midmark Digital Spirometer.

Item	Part Number
Midmark Digital Spirometer Disposable Mouthpieces (box of 25)	2-100-1205
Midmark Digital Spirometer Disposable Mouthpieces (case - 4 boxes of 25)	2-100-1206
Midmark Digital Spirometer Disposable Mouthpieces (box of 500)	2-100-1207
Disposable Nose Clips (box of 25)	2-244-0001
Midmark 3-Liter Spirometer Calibration Syringe	1-100-0007

Appendices

Appendix A – Troubleshooting the Midmark Digital Spirometer

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

Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
MODULE NOT RESPONDING! or SENSOR NOT RESPONDING! Message appears after starting a new test. No waveform is displayed on the screen.	The Midmark Digital Spirometer cannot communicate with the computer because it is not connected. • Verify that the USB cable is connected securely into a USB port on the computer.
FVC Test Starts for no apparent reason.	The minimum flow required to start a test has been exceeded or excessive electromagnetic interference is affecting the instrument. • Instruct the patient not to move the Spirometer abruptly, as it can cause air to flow through the disposable mouthpiece 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** 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.
Incorrect diagnostic interpretation.	• Check Patient's Date of Birth, Height, Sex, and other information to ensure it is accurately entered. • Check which FVC test is selected as the best test. • Check which Interpretation logic is selected.
Predicted FEV_1/FVC is not available or valid.	Check the patient's demographics. Race, Age, Sex, and Height (R.A.S.H.) must be entered to calculate a Predicted Value.

Software Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
Volume numbers appear too high or too low.	Ambient air pressure or temperature has changed since the last calibration or the current disposable mouthpiece lot is slightly different from the last one. • Perform Calibration Leak Test (see Midmark Spirometer Calibration Syringe Leak Test for additional information). • Calibrate the Midmark Digital Spirometer.
No PDF report appears when pressing the print icon within the Spirometer review screen.	When working with multiple windows open, PDF reports may open in the background. • Check taskbar for PDF report Icon. • Use Alt+Tab keys to cycle through all open windows to locate PDF report.
Cannot install disposable mouthpiece into Midmark Digital Spirometer	Leur fitting (pressure port) plugged with plastic from last disposable mouthpiece. Carefully remove plastic from Leur fitting.
Cannot zero the spirometer sensor.	Air is flowing through the disposable mouthpiece while the software is attempting to zero the Midmark Digital Spirometer or excessive electromagnetic interference is affecting the instrument. • Hold the spirometry sensor handle steady and ensure there is no air flowing through it. • Instruct the patient to hold the Spirometer next to their cheek prior to starting the test and to blow after zeroing is complete. • Select a different location or find and correct the source of the interference. Contact Midmark Technical Service for additional assistance.
LED on the Midmark Digital Spirometer will not turn on.	The Spirometer LED only turns on during a Pre/Post maneuver or calibration. • LED is defective if it does not turn on during a Pre/Post maneuver but the unit functions as intended. Contact Midmark Technical Service for additional assistance.

Appendix B – 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 Midmark Digital Spirometer software displays the statement *Normal Spirometry* if the FVC and the FEV_1/FVC ratio are within the normal range (i.e., above the LLN).

Airway Obstruction

If the FEV_1/FVC ratio is below the LLN, the software displays one of the following statements regarding obstruction:

Statement (*Obstruction may be a:*)	Criteria
Physiological variant	FEV_1 >= 100% Pred. FEV_1
Mild airway obstruction	70% Pred. FEV_1 <= FEV_1 < 100% Pred. FEV_1
Moderate airway 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 airway 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 1.11	1.05 to 1.11
Not improved	< 1.05	< 1.05

Lower Limit of Normal (LLN)

The LLN 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:

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

MVV LLN

The LLN for MVV is calculated as follows:

$$MVV\ LLN = MVV*0.80$$

Appendix C – 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 (see Configuring the Midmark Digital Spirometer). It determines results as follows:

The software displays a statement that reads Normal Spirometry if the FEV_1 and the FEV_1/FEV_6 ratio are within the normal range (i.e. above the LLN).

If the FEV_1/FEV_6 ratio and the FEV_1 are below the LLN, the software will display one of the following statements regarding obstruction.

Statement	Criteria
Mild airway obstruction	FEV_1 >= 60% Pred. FEV_1
Moderate airway obstruction	40% Pred. FEV_1 <= FEV_1 < 60% Pred. FEV_1
Severe airway obstruction	FEV_1 < 40% Pred. FEV_1

In addition, if the FEV_1/FEV_6 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*

Appendix D – Reference Values – Adult

The Midmark Digital Spirometer 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
- GLI

Note
Please note that, when there are multiple age ranges for the same patient race and sex, the left age value is inclusive and the right age value is exclusive for all ranges except the last, where both are inclusive.

Crapo – Adult

H = Height in centimeters
A = Age in years

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI95%	Source
VC	All	All	All	Predicted VC = Predicted FVC			
FVC	M	W	15 -91	0.06H - 0.0214A - 4.650	0 .644	1.115	Ref. 1
	F	W	17 -84	0.0491H - 0.0216A - 3.590	0.393	0.676	Ref. 1
$FEV_{0.5}$	M	W	15-91	0.0327H – 0.0152A – 1.914	0.414	0.708	Ref. 1
	F	W	17 -84	0.0238H – 0.0185A – 0.809	0.294	0.506	Ref. 1
FEV_1	M	W	15 -91	0.0414H - 0.0244A - 2.190	0.486	0.842	Ref. 1
	F	W	17 -84	0.0342H - 0.0255A - 1.578	0.326	0.561	Ref. 1
FEV_3	M	W	15 -91	0.0535H - 0.0271A - 3.512	0.587	1.017	Ref. 1
	F	W	17 -84	0.0442H - 0.0257A - 2.745	0.360	0.62	Ref. 1
FEV_1/FVC%	M	W	15 -91	-0.13H - 0.152A + 110.49	4.78	8.28	Ref. 1
	F	W	17 -84	-0.202H - 0.252A + 126.58	5.26	9.06	Ref. 1
FEV_3/FVC%	M	W	15-91	-0.0627H - 0.145A + 112.09	2.68	4.64	Ref. 1
	F	W	17 -84	-0.0937H – 0.163A + 118.16	3.11	5.36	Ref. 1
$FEF_{25-75\%}$	M	W	15 -91	0.0204H - 0.038A + 2.133	0.962	1.666	Ref. 1
	F	W	17 –84	0.0154H - 0.046A + 2.683	0.792	1.363	Ref. 1
PEF	M	W	15-25	0.078H + 0.1660A - 8.060	1.653	2.72	Ref. 3
	M	W	25-85	0.0940H - 0.0350A - 5.993	2.078	3.42	Ref. 3
	F	W	17-20	0.0490H + 0.157A - 3.916	1.339	2.20	Ref. 3
	F	W	20-87	0.0490H - 0.0250A - 0.735	1.605	2.64	Ref. 3
$FEF_{25\%}$ ($MEF_{75\%}$)	M	W	15-25	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 3
	M	W	25-85	0.0880H - 0.0350A - 5.618	2.012	3.31	Ref. 3
	F	W	17-20	0.0440H + 0.1440A - 3.365	1.290	2.12	Ref. 3
	F	W	20-87	0.0430H - 0.0250A - 0.132	1.53	2.52	Ref. 3
$FEF_{50\%}$ ($MEF_{50\%}$)	M	W	15-25	0.0543H + 0.1150A - 6.3851	1.1196	1.84	Ref. 2
	M	W	25-85	0.0684H - 0.0366A - 5.5409	1.2915	2.12	Ref. 2
	F	W	17-20	0.0288H + 0.1111A - 2.3040	0.9585	1.58	Ref. 2
	F	W	20-70	0.0321H - 0.0240A - 0.4371	0.9778	1.61	Ref. 2
	F	W	70-87	0.0118H - 0.0755A + 6.2402	0.7569	1.25	Ref. 2
$FEF_{75\%}$ ($MEF_{25\%}$)	M	W	15-25	0.0397H - 0.0057A - 4.2421	0.7551	1.24	Ref. 2
	M	W	25-85	0.0310H - 0.0230A - 2.4827	0.6917	1.14	Ref. 2
	F	W	17-20	$0.0243H + 0.2923A - 4.4009 - 0.0075A^2$	0.7202	1.18	Ref. 2
	F	W	20-70	0.0174H - 0.0254A - 0.1822	0.6612	1.09	Ref. 2
	F	W	70-90	-0.0172A + 1.8894	0.2409	0.396	Ref. 2
MVV				$FEV_1 * 40$			Ref. 12
MVV LLN				MVV * 0.8			Ref. 12

Knudson – Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	$CI_{95\%}$	Source
VC	All	W	All	Predicted VC = Predicted FVC			
FVC	M	W	18-25	0.0590H + 0.0739A - 6.8865	0.4708	0.775	Ref. 2
	M	W	25-85	0.0844H - 0.0298A – 8.7818	0.6384	1.05	Ref. 2
	F	W	20-70	0.0444H - 0.0169A – 3.1947	0.4831	0.795	Ref. 2
	F	W	70-90	0.0313H – 0.0296A –0.1889	0.5745	0.945	Ref. 2
$FEV_{0.5}$	M	W	18-25	0.030H + 0.043A – 3.0540	0.425	0.699	Ref. 3
	M	W	25-85	0.037H – 0.017A – 2.746	0.474	0.779	Ref. 3
	F	W	20-87	0.019H – 0.014A – 0.406	0.388	0.638	Ref. 3
FEV_1	M	W	18-25	0.0519H + 0.0636A - 6.1181	0.4458	0.734	Ref. 2
	M	W	25-85	0.0665H - 0.0292A - 6.5147	0.5241	0.862	Ref. 2
	F	W	20-70	0.0332H - 0.0190A - 1.8210	0.3903	0.642	Ref. 2
	F	W	70-90	0.0143H – 0.0397A + 2.6539	0.3758	0.618	Ref. 2
FEV_3	M	W	18-25	0.052H + 0.066A – 5.531	0.589	0.969	Ref. 3
	M	W	25-85	0.063H – 0.031A – 5.245	0.575	0.946	Ref. 3
	F	W	20-87	0.035H – 0.023A – 1.633	0.496	0.816	Ref. 3
FEV_1/FVC%	M	W	18-25	-0.0813H + 100.4389	6.5752	10.82	Ref. 2
	M	W	25-85	-0.105A + 86.6862	6.2691	10.31	Ref. 2
	F	W	20-89	-0.1852H - 0.1896A + 121.6777	7.5702	12.45	Ref. 2
$FEF_{25-75\%}$	M	W	18-25	0.0539H + 0.0749A - 6.1990	0.9861	1.62	Ref. 3
	M	W	25-85	0.0579H - 0.0363A - 4.5175	1.0825	1.78	Ref. 3
	F	W	20-70	0.0300H - 0.0309A - 0.4057	0.8539	1.40	Ref. 3
	F	W	70-90	-0.0615A + 6.3706	0.7210	1.19	Ref. 3
PEF	M	W	18-25	0.0780H + 0.1660A - 8.060	1.653	2.72	Ref. 2
	M	W	25-85	0.0940H - 0.0350A - 5.993	2.078	3.42	Ref. 2
	F	W	20-87	0.0490H - 0.0250A - 0.735	1.605	2.64	Ref. 2
$FEF_{25\%}$ ($MEF_{75\%}$)	M	W	18-25	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 3
	M	W	25-85	0.0880H - 0.0350A - 5.618	2.012	3.31	Ref. 3
	F	W	20-87	0.0430H - 0.0250A - 0.132	1.53	2.52	Ref. 3
$FEF_{50\%}$ ($MEF_{50\%}$)	M	W	18-25	0.0543H + 0.1150A - 6.3851	1.1196	1.84	Ref. 2
	M	W	25-85	0.0684H - 0.0366A - 5.5409	1.2915	2.12	Ref. 2
	F	W	20-70	0.0321H - 0.0240A - 0.4371	0.9778	1.61	Ref. 2
	F	W	70-87	0.0118H - 0.0755A + 6.2402	0.7569	1.25	Ref. 2
$FEF_{75\%}$ ($MEF_{25\%}$)	M	W	18-25	0.0397H - 0.0057A - 4.2421	0.7551	1.24	Ref. 2
	M	W	25-85	0.0310H - 0.0230A - 2.4827	0.6917	1.14	Ref. 2
	F	W	20-70	0.0174H - 0.0254A - 0.1822	0.6612	1.09	Ref. 2
	F	W	70-90	-0.0172A + 1.8894	0.2409	0.396	Ref. 2
MVV				FEV_1 * 40			Ref. 12
MVV LLN				MVV * 0.8			Ref. 12

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)
Male	18-25	139.7-195.6
Male	25-85	157.5-195.6
Female	20-70	147.3-180.3
Female	70-90	147.3-167.3

5. LLN = Predicted Value – $CI_{95\%}$

European Community for Coal and Steel (ECCS) – Adult

Height (H) is in meters.
Age (A) is 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
IVC	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/VC%	M	W	18-70	-0.18A + 87.21	7.17	11.79
	F	W	18-70	-0.19A + 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				FEV_1 * 40		
MVV LLN				MVV * 0.8		

Notes:

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

See reference 6.

See reference 12 for MVV and MVV LLN.

NHANES III (Hankinson, NLHEP) – Adult

Male age range : ≥ 20 years
Female age range: ≥ 18 years

Parameter	Sex	Race	Intercept	Age	Age^2	Ht_{prd} $(cm)^2$	Ht_{lln} $(cm)^2$
			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	-0.02114	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	-0.000847	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
	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
MVV				FEV_1 * 40			
MVV LLN				MVV * 0.8			

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 Ht_{lln} 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	$Intercept_{prd}$	Age	$Intercept_{lln}$
			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 MVV measurement.

$$MVV = 40*FEV_1$$

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

$$LFP=b_0 + b_1 * Age$$

Use the b_0 coefficient from the $Intercept_{prd}$ column to calculate the predicted value. Use the b_0 coefficient from the $Intercept_{lln}$ column to calculate the lower limit of normal.

The following default predicted equations are be used to calculate the following measurements:

Default Equation Set	
Knudson	**ECCS**
$FEV_{0.5}$	FEF_{25}
FEV_3	FEF_{50}
FEF_{25}	FEF_{75}
FEF_{50}	MVV
FEF_{75}	
MVV	

If the patient's race is not white, black or Hispanic, the software uses the equations for the patient race of white and applies the race correction factors for the following measurements.

1. FVC
2. FEV_1
3. FEV_6
4. FEV_1/FEV_6
5. FEV_1/FVC
6. FVC LLN
7. FEV_1 LLN
8. FEV_6 LLN
9. FEV_1/FEV_6 LLN
10. FEV_1/FVC LLN
11. $FEV_{0.5}$ (if patient is not black or white and using the Knudson default equation set)
12. FEV_3 (if patient is not black or white if using the Knudson default equation set)
13. FEV_3 LLN
14. $FEV_{0.5}$ LLN

Morris – Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	$CI_{95\%}$	Source
FVC	M	W	20-84	.0583H – 0.025A – 4.241	0.74	1.22	Ref. 5
	F	W	20-84	.0453H – 0.024A – 2.852	0.52	0.855	Ref. 5
FEV_1	M	W	20-84	.0362H – 0.032A – 1.26	0.55	0.905	Ref. 5
	F	W	20-84	.0350H – 0.025A – 1.932	0.47	0.773	Ref. 5
$FEF_{200-1200}$	M	W	20-84	0.0429H – 0.047A + 2.01	0.74	1.22	Ref. 5
	F	W	20-84	0.0571H – 0.036A – 2.532	1.19	1.96	Ref. 5
$FEF_{25-75\%}$	M	W	20-84	0.0185H – 0.045A + 2.513	1.12	1.84	Ref. 5
	F	W	20-84	0.0236H – 0.030A + 0.551	0.80	1.316	Ref. 5
MVV				FEV_1 * 40			Ref.12
MVV LLN				MVV * 0.8			Ref. 12

Notes:

The height ranges are as follows:

Sex	Age Range	Height Range (cm)
Male	20-84	147.3-203.2
Female	20-84	142.2-182.9

The following default predicted equations are used to calculate the following measurements:

Default Equation Set	
Knudson	**ECCS**
$FEV_{0.5}$	FEV_1/FVC
FEV_3	FEV_1/FVC LLN
FEV_1/FVC	FEF_{25}
FEV_1/FVC LLN	FEF_{50}
FEF_{25}	FEF_{75}
FEF_{50}	MVV
FEF_{75}	
MVV	

See Reference 5.

Roca – Adult

Parameter	Sex	Race	Age Range	Predicted Equation (W = Weight in Kilograms)	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
$FEF_{25\%}$ ($MEF_{75\%}$)	M	W	20-69	MEF75% = ALOG(2.113Log(H) – 0.01A – 4.136)	0.146	0.240
	F	W	20-69	MEF75% = ALOG(1.209Log(H) – 0.006A – 0.001W – 2.003) - 1	0.073	0.120
$FEF_{50\%}$ ($MEF_{50\%}$)	M	W	20-69	0.0517H – 0.0397A – 2.4	1.3	2.14
	F	W	20-69	0.0242H – 0.0418A + 1.6151	0.925	1.52
MVV				FEV_1 * 40		
MVV LLN				MVV * 0.8		

The following default predicted equations are used to calculate the following measurements:

Default Equation Set	
Knudson	ECCS
$FEV_{0.5}$	FEF_{25}
FEV_3	MVV
FEF_{25}	
MVV	

See reference 6.

See reference 12 for MVV and MVV LLN.

GLI – Adult

Parameter	Sex	Race	Age Range	Predicted Equation	Source
FVC	M/F	ALL	3-95	Exponent (mu + height Coefficient * Log(H) + Age Coefficient * Log(A) + Ethnicity Coefficient + Spline)	Ref. 14 Ref. 15
FEV_1	M/F	ALL	3-95	Exponent (mu + height Coefficient * Log(H) + Age Coefficient * Log(A) + Ethnicity Coefficient + Spline)	Ref. 14 Ref. 15
FEF_{75}	M/F	ALL	3-90	Exponent (mu + height Coefficient * Log(H) + Age Coefficient * Log(A) + Ethnicity Coefficient + Spline)	Ref. 14 Ref. 15
FEV_1/FVC%	M/F	ALL	3–95	Exponent (mu + height Coefficient * Log(H) + Age Coefficient * Log(A) + Ethnicity Coefficient + Spline)	Ref. 14 Ref. 15
$FEF_{25-75\%}$	M/F	ALL	3–90	Exponent (mu + height Coefficient * Log(H) + Age Coefficient * Log(A) + Ethnicity Coefficient + Spline)	Ref. 14 Ref. 15
MVV				FEV_1*40	Ref. 12
VC	M/F	ALL	3-95	Predicted VC = Predicted FVC	

Notes:

1. Age (A) is in years.
2. Height (H) is in centimeters.
3. Mu is a lookup value for patients based on their gender, age and measurement.
4. Height Coefficient is a lookup value for patients based on their gender, age & measurement.
5. Age Coefficient is a lookup value for patients based on their gender, age & measurement.
6. Ethnicity Coefficient is a lookup value for patients based on their gender, age & measurement.
7. Spline is obtained by linear interpolation of the lookup value. As an example, a 12.2 year old patient would have two values to choose from 12 (lower bound) and 12.25 (upper bound).

See references 12, 14, and 15.

Appendix E – Reference Values – Pediatric

The Midmark Digital Spirometer software provides the following sets of reference equations for pediatric patients:

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

Note
Please note, when there are multiple age ranges for the same patient race and sex, the left age value is inclusive and the right age value is exclusive for all ranges except the last, where both are inclusive.

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%		82.3%		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: $\ln(PF) = \alpha + \beta \ln(Ht)$, where PF is FVC (L), FEV_1 (L), FEV_1/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.

Use the following equation to calculate the MVV measurement:

$$MVV = 40 * FEV_1$$

See reference 10.

See reference 12 for MVV and MVV LLN.

Knudson – Pediatric

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	95% CI	Source
VC	All		All	Predicted VC = Predicted FVC			
FVC	M	W	6 -12	0.0409H - 3.3756	0.3503	0.576	Ref. 2
	M	W	12- 18	0.0590H + 0.0739A - 6.8865	0.4708	0.774	Ref. 2
	F	W	6 –11	0.0430H - 3.7486	0.3728	0.613	Ref. 2
	F	W	11-20	0.0416H + 0.0699A - 4.4470	0.4973	0.818	Ref. 2
$FEV_{0.5}$	M	W	6-18	0.030H + 0.043A –3.054	0.425	0.699	Ref. 3
	F	W	6-18	0.019H + 0.061A – 1.738	0.364	0.599	Ref. 3
FEV_1	M		6 – 12	0.0348H - 2.8142	0.2734	0.449	Ref. 2
	M		12 – 18	0.0519H + 0.0636A - 6.1181	0.4458	0.733	Ref. 2
	F		6 – 11	0.0336H - 2.7578	0.2697	0.444	Ref. 2
	F		11 - 20	0.0351H + 0.0694A - 3.7622	0.4223	0.695	Ref. 2
FEV_1/FVC%	M		6 - 18	-0.0813H + 100.4389	6.5752	10.82	Ref. 2
	F		6 - 20	-0.1909H + 0.6655A + 109.9739	7.8385	12.89	Ref. 2
$FEF_{25-75\%}$	M		6 - 12	0.0338H - 2.3197	0.6263	1.03	Ref. 2
	M		12 - 18	0.0539H + 0.0749A - 6.1990	0.9861	1.62	Ref. 2
	F		6 - 11	0.0220H - 0.8119	0.6568	1.08	Ref. 2
	F		11 - 20	0.0279H + 0.1275A - 2.8007	0.8653	1.42	Ref. 2
PEF	M		6 - 18	0.078H + 0.1660A - 8.060	1.653	2.72	Ref. 3
	F		6 - 20	0.0490H + 0.157A - 3.916	1.339	2.20	Ref. 3
$FEF_{25\%}$ ($MEF_{75\%}$)	M		6 - 18	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 3
	F		6 - 20	0.0440H + 0.1440A - 3.365	1.290	2.12	Ref. 3
$FEF_{50\%}$ ($MEF_{50\%}$)	M		6 - 12	0.0378H - 2.5454	0.6538	1.08	Ref. 3
	M		12 - 18	0.0543H + 0.1150A - 6.3851	1.1196	1.84	Ref. 3
	F		6 - 11	0.1846A + 0.7362	0.6689	1.10	Ref. 3
	F		11 - 20	0.0288H + 0.1111A - 2.3040	0.9585	1.58	Ref. 3
$FEF_{75\%}$ ($MEF_{25\%}$)	M		6 – 12	0.0171H - 1.0149	0.5037	0.829	Ref. 3
	M		12 - 18	0.0397H - 0.0057A - 4.2421	0.7551	1.24	Ref. 3
	F		6 - 11	0.0109H - 0.1657	0.4999	0.822	Ref. 3
	F		11 - 20	$0.0243H + 0.2923A - 4.4009 - 0.0075A^2$	0.7202	1.18	Ref. 3
MVV				$FEV_1 * 40$			Ref. 12
MVV LLN				MVV * 0.8			Ref. 12

Note:

The height ranges are as follows:

Sex	Age Range (years)	Height Range (cm)
Male	6-12	111.8-154.9
Male	12-18	139.7-193.0
Female	6-11	106.7-147.3
Female	11-20	132.1-182.9

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	$FVC_{pred} * 0.98$	
	F	W	4-17	$FVC_{pred} * 0.98$	
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	M	W	4-17	$0.08738 * H - 7.0929$	12.8
	F	W	4-17	$0.08738 * H - 7.0929$	12.8
MVV				$FEV_1 * 40$	
MVV LLN				MVV * 0.8	

The following measurements are calculated from the Knudson Pediatric table if Knudson Pediatric is the default reference set:

1. $FEF_{0.5}$
2. FEF_{25}
3. FEF_{50}
4. FEF_{75}

See reference 7.

See reference 12 for MVV and MVV LLN.

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. 11
	M	B	7-20	$1.07 \times 10^{-6} \times H^{2.93}$	17	Ref. 11
	M	H	7-20	$1.06 \times 10^{-6} \times H^{2.97}$	13	Ref. 11
	F	W	7-20	$2.57 \times 10^{-6} \times H^{2.78}$	14	Ref. 11
	F	B	7-20	$8.34 \times 10^{-7} \times H^{2.98}$	15	Ref. 11
	F	H	7-20	$1.25 \times 10^{-6} \times H^{2.92}$	14	Ref. 11
FEV_1	M	W	7-20	$7.74 \times 10^{-7} \times H^{3.00}$	13	Ref. 11
	M	B	7-20	$1.03 \times 10^{-6} \times H^{2.92}$	17	Ref. 11
	M	H	7-20	$1.73 \times 10^{-6} \times H^{2.85}$	13	Ref. 11
	F	W	7-20	$3.79 \times 10^{-6} \times H^{2.68}$	14	Ref. 11
	F	B	7-20	$1.14 \times 10^{-6} \times H^{2.89}$	15	Ref. 11
	F	H	7-20	$1.61 \times 10^{-6} \times H^{2.85}$	14	Ref. 11
$FEF_{25-75\%}$	M	W	7-20	$7.98 \times 10^{-4} \times H^{2.46} / 60$	26	Ref. 11
	M	B	7-20	$3.61 \times 10^{-4} \times H^{2.60} / 60$	36	Ref. 11
	M	H	7-20	$9.13 \times 10^{-4} \times H^{2.45} / 60$	25	Ref. 11
	F	W	7-20	$3.79 \times 10^{-3} \times H^{2.16} / 60$	28	Ref. 11
	F	B	7-20	$1.45 \times 10^{-3} \times H^{2.34} / 60$	30	Ref. 11
	F	H	7-20	$1.20 \times 10^{-3} \times H^{2.40} / 60$	24	Ref. 11
PEF	M	W	7-20	$3.35 \times 10^{-4} \times H^{2.79} / 60$	18	Ref. 11
	M	B	7-20	$1.74 \times 10^{-4} \times H^{2.92} / 60$	22	Ref. 11
	M	H	7-20	$7.69 \times 10^{-4} \times H^{2.63} / 60$	17	Ref. 11
	F	W	7-20	$2.58 \times 10^{-3} \times H^{2.37} / 60$	18	Ref. 11
	F	B	7-20	$5.51 \times 10^{-4} \times H^{2.68} / 60$	20	Ref. 11
	F	H	7-20	$6.97 \times 10^{-4} \times H^{2.64} / 60$	18	Ref. 11
MVV				FEV1 * 40		Ref. 12
MVV LLN				MVV * 0.8		Ref. 12

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.
4. The following measurements are calculated from the Knudson Pediatric table if Knudson Pediatric is the default reference set:

    - $FEF_{0.5}$
    - FEF_{25}
    - FEF_{50}
    - FEF_{75}
    - FEV_1/FVC
    - FEV_1/FVC LLN

See reference 11.

See reference 12 for MVV and MVV LLN.

NHANES III (Hankison, NLHEP) – Pediatric

Parameter	Sex	Race	Intercept	Age	Age²	Ht_{prd} (cm)²	Ht_{lln} (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
PEF	M	W	-0.5962	-0.12357	0.013135	0.00024962	0.00017635
	M	B	-0.2684	-0.28016	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
MVV				FEV_1 * 40			
MVV LLN				MVV * 0.8			

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

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

Parameter	Sex	Race	$Intercept_{prd}$	Age	$Intercept_{lln}$
			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
$FEV_{1.0}$/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 $Intercept_{lln}$ column to calculate the lower limit of normal.

Use the following equation to calculate the MVV measurement.

$$MVV = 40*FEV_1$$

The following measurements are calculated from the Knudson Pediatric table if Knudson Pediatric is the default reference set:

1. $FEV_{0.5}$
2. FEF_{25}
3. FEF_{50}
4. FEF_{75}
5. $FEV_{0.5}$ LLN
6. FEF_{25} LLN
7. FEF_{50} LLN
8. FEF_{75} LLN
9. MVV

If the patient's race is not white, black, or hispanic, the software uses the equations for the patient race of white and applies the race correction factors for the following measurements:

1. FVC
2. FEV_1
3. FEV_6
4. FEV_1/FEV_6
5. FEV_1/FVC
6. FVC LLN
7. FEV_1 LLN
8. FEV_6 LLN
9. FEV_1/FEV_6 LLN
10. FEV_1/FVC LLN
11. $FEV_{0.5}$ (if patient is not black or white and using the Knudson default equation set)
12. FEV_3 (if patient is not black or white if using the Knudson default equation set)
13. $FEV_{0.5}$ LLN
14. FEV_3 LLN

See reference 13.

See reference 12 for MVV and MVV LLN.

Zapletal – Pediatric

Age range is from 6 to 18 years.
H = Height is 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	$0.1694 – 0.01217 \times H + 0.000189 \times H^2$		
$FEV_{1.0}$	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	$-5.3794 + 0.06594 \times H$		
MVV			$FEV_1 * 40$		
MVV LLN			MVV * 0.8		

The following measurements are calculated from the Knudson Pediatric table if Knudson Pediatric is the default reference set:

1. $FEF_{0.5}$
2. FVC LLN
3. FEV_1/FVC
4. FEV_1/FVC LLN

See reference 8.

See reference 12 for MVV and MVV LLN.

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 (a)	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
MVV	FEV_1 * 40			
MVV LLN	MVV * 0.8			

Notes:

1. The FEV_1/FVC predicted equation generates a fraction instead of a percentage so the software converts this number to a percentage.
2. The FEV_1/FVC predicted equation generates a fraction instead of a percentage so the $CI_{95\%}$ value has been converted to a percentage value.
3. Patient gender was not considered in the regression analysis. The Knudson Pediatric predicted equations is not 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.

See reference 9.

See reference 12 for MVV and MVV LLN.

GLI – Pediatric

The GLI formula is the same for adult and pediatric, see GLI – Adult for the reference equations.

Appendix F – Adjustments to Reference Values Equations

According to the ATS recommendations specified in Reference 4, Black and Asian adults have FVC and FEV_1 values that are approximately 15% below that of Caucasians. Black children have FVC and FEV_1 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 for 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 paper by Korotzer et al (Am. J. Respir. Crit. Care Med. 2000 161: 1101-1108) suggests a 0.93 correction for Asian-American.

Appendix G – 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)

Appendix H – COPD Risk Assessment Calculation

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

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

Male:

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

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

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

Female:

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

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

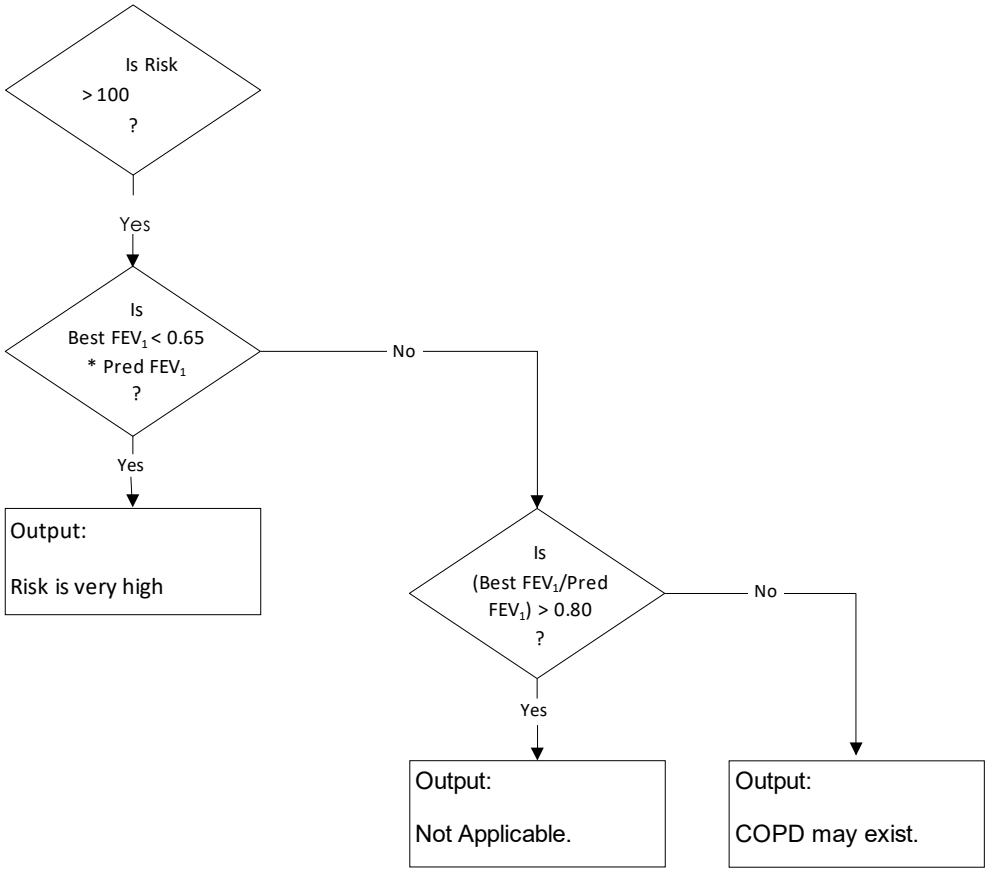
$$x_{quit} = x + cigs * 0.0506$$ ***Equation 5***

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

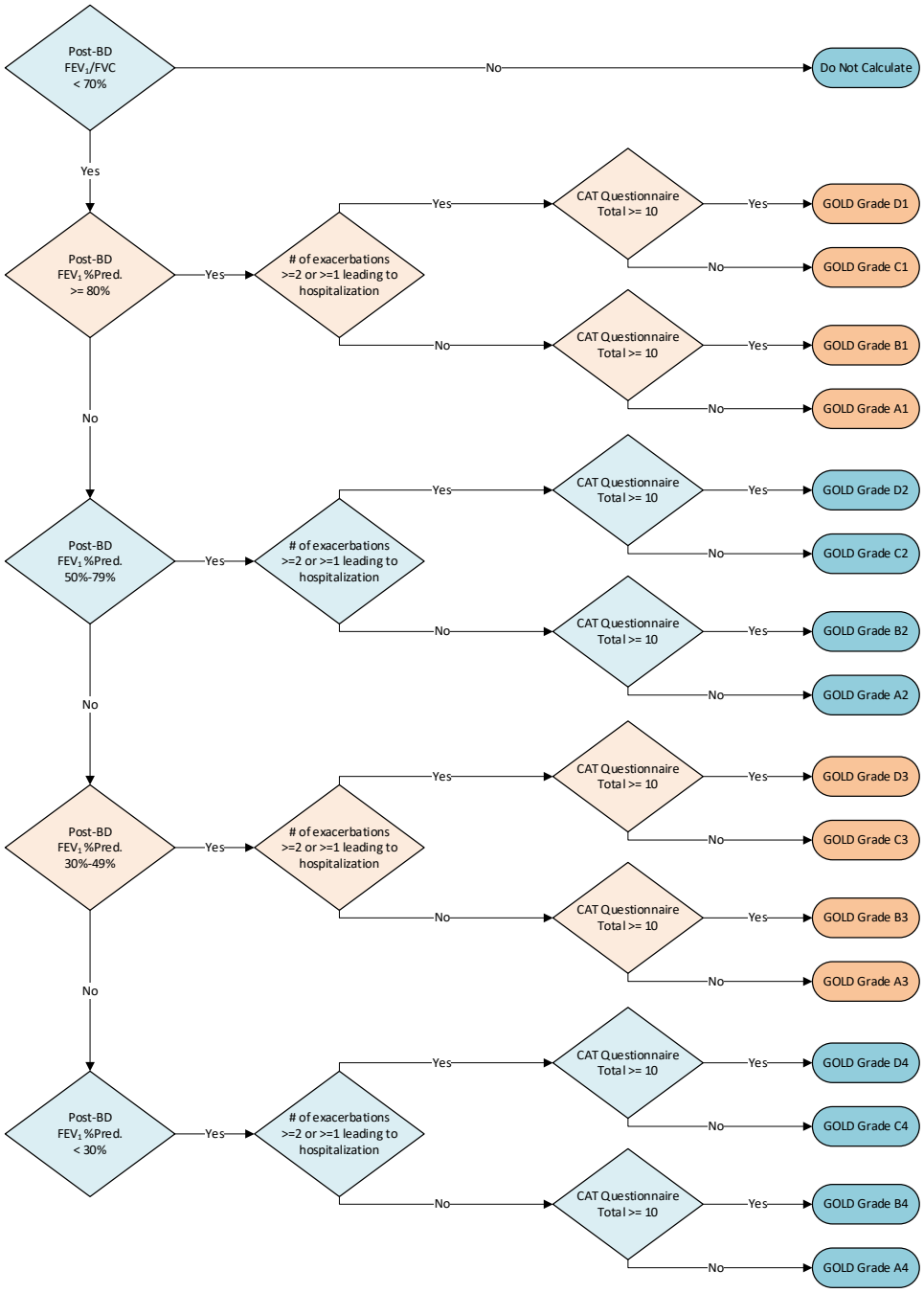
COPD Risk Statement Criteria

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.



Appendix I – GOLD Calculation



See reference 16.

Appendix J – Lung Age Calculation

Reference 4 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 Midmark Digital Spirometer program automatically calculates the estimated lung age provided that the following information is available.

1. Best FEV_1 from the FVC tests
2. Patient height in inches
3. Patient sex

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

$$L_{AGE} = 2.87 * H - 31.25 * BestFEV_1 - 39.375$$

For **female** patients, the estimated lung age is calculated as follows:

$$L_{AGE} = 3.56 * H - 40.0 * BestFEV_1 - 77.28$$

L_{AGE} is the estimated lung age in years. H is the patient height in inches.

The Midmark Digital Spirometer program uses the following table to print the lung age statement:

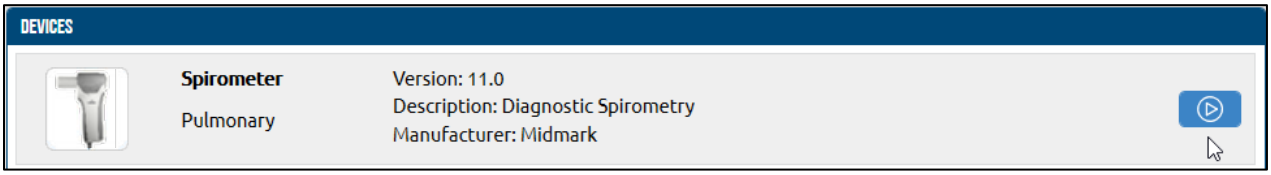
Criteria	Lung Age Statement
(Patient's Age < 20) or (Patient's Age > 84)	N/A
Lung Age > 84	> 84 years
Lung Age < Patient's Age	< #Patient's Age years
Otherwise	#Lung Age years

Appendix K – Performing a Pre/Post FVC Test - Quick Reference User's Guide

A condensed guide to using the Midmark Digital Spirometer.

> ***Note***
> *Midmark recommends daily calibration checks and an annual calibration certification of the Midmark Digital Spirometer and Midmark Spirometer Calibration Syringe.*

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.
   c. 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.**
5. Click on the play icon next to the Midmark Digital Spirometer:



6. Prepare the patient for the spirometry test.
   d. Explain the procedure to the patient.
   e. Demonstrate the procedure to the patient. Use FVC demo videos.
   f. Insert a new disposable mouthpiece into the Midmark Digital Spirometer.
   g. Instruct the patient to place the disposable mouthpiece on top of their tongue, with their teeth and lips around the mouthpiece, sealing their lips around the disposable mouthpiece. Let the patient get used to the feeling of breathing with the disposable mouthpiece in their mouth.
7. The type of test selected is displayed in the selected tab in the top left corner of the screen. If this is not the type of test required, select the required test by clicking the appropriate tab (**FVC**, **VC**, **MVV**).
8. When the patient is ready, instruct the patient to hold the Midmark Digital Spirometer up and to the side of their face.
9. Click **Start Pre** and select an incentive. Press **Start.** - wait for the zeroing process. ***Do not allow airflow to pass through the sensor during this process.***
10. When the incentive appears, instruct the patient to perform a full inspiration and then to place the disposable mouthpiece in their mouth.
11. Instruct the patient to exhale forcibly. 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.
    h. If a flow volume loop is required, have the patient inhale at the end of the expiration.
12. Click **Stop** or press **Enter** to conclude the test.
13. **Accept** or **Reject** the test based on the patient's effort.
14. Repeat steps 9 through 13 until the appropriate number of tests has been performed. If a Post test is needed, administer medication as per manufacture's guidelines. Select appropriate medication for BD dropdown. Repeat steps 9-13, selecting **Start Post** instead of Start Pre. Performing more than 8 FVC tests in

one sitting will usually return diminished results.

15. Remove and discard the used disposable mouthpiece after all tests are completed.
16. Click **Review** and use the review screen to review, edit and/or print the results.
17. Click **Save** to save the efforts.

Appendix L – Maintenance and Storage

NOTICE	**NOTICE** *The American Thoracic Society highly recommends daily calibration checks be performed on spirometers. More frequent calibration checks may be needed if conducting testing on large numbers of patients or in cases where the ambient temperature will be changing. (See reference 12)*

Note *Midmark recommends daily calibration checks and an annual calibration certification of the Midmark Digital Spirometer and Midmark Spirometer Calibration Syringe.*

- **DO NOT REUSE DISPOSABLE MOUTHPIECES**.
- Inspect the Midmark Digital Spirometer and Midmark Spirometer Calibration Syringe regularly for damages.
- Contact Midmark for annual calibration certifications for both the Midmark Digital Spirometer and the Midmark Spirometer Calibration Syringe.

The Midmark Digital Spirometer 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. Calibration Certification provides peace of mind that the device continues to work within our factory specifications. Calibration Certifications can be purchased directly from Midmark for both the Midmark Digital Spirometer and the Midmark Spirometer Calibration Syringe.

The Calibration Syringe has a "Use By" date of 2 years from the manufacturing date. It is best practice that it be serviced at the end of 2 years to increase the warranty an additional year.
Please contact Midmark Technical Service with any questions or to make arrangements for the certification of the Midmark Digital Spirometer device or the Calibratin Syringe.

Midmark Spirometer Calibration Syringe Leak Test

In the event the Calibration Syringe volume numbers appear too high or too low, perform the following steps to test it for possible leaks:

1. With the plunger handle pulled all the way out, shut off air flow to the syringe by placing the palm of your hand tightly over the outlet port or by placing the supplied plug in the outlet port.
2. Attempt to push the plunger in while shutting off air flow and, at the same time, place your ear close to the syringe end plate and listen for any hissing sounds that may indicate a leak:
    a. If there is no movement in the plunger and no hissing sounds, there are no leaks in the syringe.
    b. If the syringe plunger is able to be pushed in or you hear hissing sounds, you most likely have a leak in the syringe and need to contact Midmark for return authorization and repair.
3. Midmark recommends that the calibration syringe be tested for leaks daily, before calibrating a spirometer.

Preventative Cleaning

⚠	**Caution** Do not use aromatic hydrocarbons, rubbing alcohol, or solvents for cleaning the Midmark Digital Spirometer.

Clean the outside of the Midmark Digital Spirometer with a mild solution of detergent and water with a soft cloth. If necessary, use a mild sterilizing detergent with low alcohol content generally used in hospitals.

- Do **not** use an excessive amount of solution.
- Do **not** wet the ports on the top of the Spirometer.
- **Verify that all equipment, including accessories, is completely dry before using.**

Preventative Inspection

NOTICE	**NOTICE** *USB ports/contacts can become worn with repeated use. The Midmark Digital Spirometer test may not function with a worn USB port.*

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 Midmark Digital Spirometer 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.

Storage Conditions	• Temperature: -4°F (-20°C) to 122°F (50°C) • Relative humidity between 15% to 95%, non-condensing • -500 ft to 16,000 ft (-152 m to 4,876 m)

⚠	**Caution** Electronic devices can be damaged by exposure to liquids. Do not use or store the Midmark Digital Spirometer near any type of liquids.

Appendix M – EMC Requirements for the Midmark 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 Digital Spirometer is an electrical medical equipment.

The Midmark Digital Spirometer models comply with the EMC Standard IEC 60601-1-2

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

Electromagnetic Interference

This product is designed and built to minimize electromagnetic interference with other devices and does not have essential performance. However, if interference is noticed between another device and this product:

- Remove interfering device from room
- Plug chair into isolated circuit
- Increase separation between chair and interfering device
- Contact Midmark Corporation if interference persists.

Table 1 – Guidance and manufacturer's declaration – electromagnetic emissions – for the Midmark Digital Spirometer

The emissions characteristics of this equipment make it suiable for use in industrial areas and hospitals (CISPR 11 class
A). If it is used in a residential enviroment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. Ther user might need to take mitigation measures, such as -relocation or re-orienting the equipment.

Emission tests	IEC60601-1-2 Compliance Test Level
Conducted and Radiated RF Emissions	CISPR 11 Group 1, Class A

Table 2 – Guidance and manufacturer's declaration – electromagnetic immunity – for the Midmark Digital Spirometer

Guidance and manufacturer's declaration – electromagnetic immunity	
The Midmark Digital Spirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Midmark Digital Spirometer should assure that it is used in such an environment.	
Immunity test	**Immunity Test Level**
Electrostatic Discharge	± 8 kV Contact, ±15 kV Air
Radiated RF EM Fields	3V/m 80MHz-2.7 GHz 80% AM at 1kHz
Rated Power Frequency Magnetic Fields	30 A/m
Proximity fields from RF wireless communications equipment	27 V/m at 385 MHz 28 V/m at 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz, 9 V/m at 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785 MHz
Electrical Fast Transients	±2 kV at 100kHz repetition frequency ±1 kV at 100kHz repetition frequency ±0.5 kV at 100kHz repetition frequency ±0.25 kV at 100kHz repetition frequency
Surges	Line to Neutral ±0.5 kV Line to Neutral ±1 kV Neutral to Ground ±0.5 kV Neutral to Ground ±1 kV Neutral to Ground ±2 kV Line to Ground: ±0.5 kV Line to Ground: ±1 kV Line to Ground: ±2 kV
Conducted RF	3V: 0.15MHz -80MHz , 80% AM at 1KHz 6V in ISM Bands between 0.15MHz - 80MHz 80% AM at 1kHz
Voltage Dips	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle at 0° 70 % UT; 30 cycles at 0°
Voltage Interruptions	0 % UT; 300 cycle
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.	

Appendix N – Safety and International Symbols

The following symbols are associated with the Midmark Digital Spirometer and cleared accessories and supplies.

Symbol	Description
	Refer to instruction manual/booklet
	Do not dispose of this product as unsorted municipal waste For more disposal information see Disposal
	Type BF applied part
	Manufacturer
	Date of Manufacture
IPX0	Ordinary Equipment
	DC VOLTAGE – (USB CONNECTION DEVICES) This device uses 5 Volt power and consumes 80mA when in use
	Warning
	Caution
	Non-sterile
	[1]Single use only
RxOnly	Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician
	Batch code
	Catalogue (model) number

Symbol	Description
	Serial Number
	Temperature limits to which the medical device can be safely exposed
	Range of humidity to which the medical device can be safely exposed
	Consult instructions for use
	Keep dry
	Shipping Direction
	Do not use if package is damaged
	Keep away from sunlight

[1]The disposable mouthpiece to be used with the Midmark Digital Spirometer is intended for one use, or for use on a single patient during a single procedure. The Midmark Digital Spirometer device is reusable.

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Customer Support and Warranty Information

Warranty

Midmark warrants the Midmark Digital Spirometer to be free from manufacturing and material defects for 12 months from the date of purchase. Accessories for the Midmark Digital Spirometer 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 used. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for an RMA number. It is ultimately 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.

Contact Information

Technical Support is available Monday through Friday (except holidays), 6:00 am to 4:00 pm Pacific Standard Time.

Midmark Corporation
60 Vista Drive
Versailles, OH 45380 USA
Email: techsupport@midmark.com
T: 844.856.1230, option 2
Fax: 310.516.6517
midmark.com
kb.midmark.com (Knowledge Base)

Disposal

The disposal of Midmark Diagnostic Devices and their accessories should be carried out according to local medical waste disposal policies and procedures. Do not discard these items in unsorted municipal waste. Contact your local waste disposal agency for guidance on proper recycling or disposal.

Certain items contain electronic circuit boards or lithium ion batteries that should not be incinerated, crushed, disassembled or exposed to extreme heat. Do not put the lithium ion battery in a refuse container. Lithium batteries and electronic components should be recycled appropriately.

Midmark Corporation
60 Vista Drive
Versailles, OH 45380 USA
T: 844.856.1230, option 2
Fax: 310.516.6517

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