



Hillrom™

Welch Allyn® Diagnostic Cardiology Suite Spirometry

User Manual



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Customer Service and Technical Support: <https://www.welchallyn.com/en/other/contact-us.html> 1.888.667.8272, mor_tech.support@hillrom.com

For patent information, please visit www.welchallyn.com/patents.

This manual applies to the  901128 CARDIOPULMONARY ECG SYSTEM and the  901051 SPIROMETER.



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Notices

Manufacturer's Responsibility

Welch Allyn, Inc. is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Welch Allyn, Inc.
- The device is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

Welch Allyn, Inc. equipment is identified by a serial and reference number on the back of the device. Care should be taken so that these numbers are not defaced. Software equipment is accompanied by an identification card; carefully store this card as the information is needed for activation, upgrade and customer service. This information can be entered at the time of installation to help ensure the information is not lost.

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User Safety



WARNING Means there is the possibility of personal injury to you or others.



CAUTION Means there is the possibility of damage to the device.

Note Provides information to further assist in the use of the device.

This manual may contain screen shots and pictures. Any screen shots and pictures are provided for reference only. Consult the actual screen in the host language for specific wording.

Warnings



WARNING This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.



WARNING The personal computer (non-medical electrical equipment) shall be situated outside the patient environment (reference IEC 60601-1). The personal computer used should adhere to the appropriate safety standard for non-medical electrical equipment (IEC 60950, or its national variants), and use of an isolation transformer is recommended. The personal computer used should adhere to the appropriate electromagnetic compatibility (EMC) standard for non-medical electrical equipment (CISPR 22/24 - FCC Part 15 - CE, or related national variants). If it is required for the personal computer to be situated within the patient environment, it is the responsibility of the user to ensure that the system provides a level of safety in compliance with IEC 60601-1. To ensure the safety of the patient it must not be possible for the operator to touch the patient and the computer at the same time. In general, at least 1.5 meters (5') of open area must surround the patient to achieve this.



WARNING Device captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.



WARNING Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact service for additional training options.



WARNING To minimize chances of a misdiagnosis, it is the physician's responsibility to assure that spirometry tests are properly administered, evaluated, and interpreted.



WARNING To maintain designed operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact must be in compliance with UL 60601-1, IEC 60601-1, and ISO 26782. Only use parts and accessories supplied with the device and available through Welch Allyn. Equipment relying only on basic insulation for protection against electric shock should not be used in the system.



WARNING The device is part of an integral personal computer-based diagnostic system. The user must adhere to all warnings in order to ensure safe and reliable performance.



WARNING If operated on AC (~) power, the personal computer must be connected with its original power cable to an electrical installation that complies with applicable regulations for environments where patients are treated.



WARNING If the personal computer is situated within the patient environment, to maintain designed operator and patient safety when a LAN network connection is being used, the network cable must be connected to the device through an Ethernet isolator module that complies with IEC 60601-1-1 (available from Welch Allyn).



WARNING To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device.



WARNING To avoid potential for spread of disease or infection, single-use disposable components (e.g., flow transducers) must not be reused.



WARNING A possible explosion hazard exists. Do not use the device in the presence of flammable anesthetic mixture.



WARNING Possible malfunction risks may be present when installing third-party software. Welch Allyn cannot verify the compatibility of all possible hardware/software combinations.



WARNING The device has not been designed for use with high-frequency (HF) surgical equipment and does not provide a protective means against hazards to the patient.



WARNING The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillation and ultrasound machines.



WARNING Test Welch Allyn Diagnostic Cardiology Suite functions after each Microsoft critical and security update with a simulator prior to patient use.



WARNING Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repared by qualified service personnel prior to continued use.



WARNING To prevent emission of substances that may damage the environment, dispose of the device, its components and accessories and/or packing materials that are past the shelf life in accordance with local regulations.



WARNING Proper functioning backup items such as, display monitor, and other equipment are recommended on hand to prevent delayed treatment due to an inoperable device.



WARNING A color printer and a color printout are recommended for printing spirometry reports. Printing these reports with a monochrome printer or in black and white can lead to confusion as it is not easy to identify which curve is a Pre and which is a Post effort.



WARNING Do not perform spirometry test if any of the following conditions apply to the patient:

- hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition);
- pneumothorax;
- unstable cardiovascular status (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus;
- thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure);
- recent eye surgery (e.g., cataract);
- presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting);
- recent surgery of thorax or abdomen.



WARNING People may become light-headed, dizzy, or even faint during a spirometry effort. Watch patients closely. If they choose to stand during testing, keep a chair immediately behind them. If there is any reason for concern, stop the test and take appropriate action.



WARNING To prevent cross-contamination, do not try to clean the flow transducers and nose clips. Discard these items after a single patient use.



WARNING The American Thoracic Society (ATS) recommends using gloves when replacing disposable flow transducers, and washing hands after touching them.



WARNING No modification of this equipment is allowed.



WARNING Fire and explosion hazard. Do not operate the spirometer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen-enriched environments; or in any other potentially explosive environment.



WARNING The performance of the spirometer can be affected by the patient spitting or coughing into the spirometer during expiration.

Cautions



CAUTION Windows compatibility, updates and anti-virus policy: The Welch Allyn Diagnostic Cardiology Suite software has been fully tested with Windows 7 (32-bit and 64-bit) Professional Service Pack 1, and Windows 10 Pro (64-bit) operating systems. The Welch Allyn Diagnostic Cardiology Suite software has also been tested with Windows Server 2012 R2 and Server 2016. Although it is unlikely that Windows updates and security patches affect Welch Allyn Diagnostic Cardiology Suite functionality, Welch Allyn recommends turning automatic Windows update off, and periodically running it manually. A functional test should be executed after update, which includes acquiring a recording, editing and printing a report, as well as importing an order and exporting results, if activated. Compatibility of Welch Allyn Diagnostic Cardiology Suite with corporate anti-virus software packages has been evaluated. Welch Allyn recommends excluding the Welch Allyn Diagnostic Cardiology Suite database folder (normally C:\ProgramData\MiPgSqlData on a stand-alone system or the server) from the folders to be scanned. In addition, anti-virus patch updates and system scans should be scheduled for time periods when the system is not actively in use or performed manually.



CAUTION No other non-recommended PC application software should be running while the Welch Allyn Diagnostic Cardiology Suite application is being used.



CAUTION It is recommended that all workstations and review stations be periodically updated with Microsoft critical and security updates to protect from malware attacks and to fix critical Microsoft software issues.



CAUTION To prevent delivery of malware into the system Welch Allyn recommends that institution operating procedures are written to prevent malware to be transmitted into the system from removable media.



CAUTION Test information should be backed up to prevent loss of critical data as a result of a malware attack or system failure.



CAUTION Use only parts and accessories supplied with the device and available through Welch Allyn . The use of accessories other than those specified may result in degraded performance of the device.



CAUTION When putting the spirometer away, store the pressure tubing in a basket or drawer or somewhere that prevents compression or kinking.



CAUTION Avoid installing the spirometer in direct sunlight or in a location where it may be affected by significant changes in humidity, ventilation, or airborne particles containing dust, salt or sulfur.

Note(s)

- Note** Local Administrator permissions are required for software installation, and application configuration. Local User privileges are required for application users. Roaming and temporary accounts are not supported.
- Note** The application times out automatically after 8 hours of inactivity. Any operation (e.g. Exam Search, Patient Search, editing exams, starting an exam, etc.) will reset the timeout start time. When returning to the application after the timeout, the user is prompted to enter login credentials.
- Note** When the server is unavailable in a distributed configuration, the client workstation will notify the user with a prompt to proceed in Offline Mode or cancel. In Offline Mode, scheduled orders are not available. An exam can be conducted with manually entered demographics and will be stored locally. When the server becomes available, the user is prompted with a list of unsent exams and a selection to send exams to the server database.
- Note** If not specifically indicated otherwise, personal computer equipment used with the device can be regarded as:
- Class I (if the computer has a three-prong power inlet) or class II (if it has a two-prong inlet)
 - Ordinary equipment.
 - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
 - Continuous operation.
- Note** To prevent possible damage to the device during transport and storage (while in original packaging) the following environmental conditions must be adhered to:
- | | |
|----------------------|-----------------------------------|
| Ambient temperature: | -20° C to 60° C (-4° F to 149° F) |
| Relative humidity: | 10% to 95%, non-condensing |
- Note** The compatible spirometer flow sensor, mouthpiece and disposable accessories are manufactured by Medikro Oy, Finland and Distributed by Welch Allyn. Medikro's spirometer accessories are CE marked :



Symbols

Documentation symbols



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables. Warning symbols will appear with a grey background in a black and white document.



CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

Miscellaneous symbols



Manufacturer



Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements.



Consult directions for use (DFU). A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.



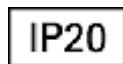
Not made with natural rubber latex



USB



Single Use - Do Not Reuse



Protected against the ingress of solid foreign objects ≥ 12.5 mm diameter, not protected against the ingress of water.



Serial Number



Reorder Number



Batch Code



Model Identifier



Global Trade Item Number



Expiration Date



To identify a type BF applied part complying with IEC 60601-1.



Meets essential requirements of the European Medical Device Directive 93/42/EC
-Applies to spirometer hardware



Canadian Standards Association mark of conformity

R_x ONLY

By prescription or order of physician or dentist

Note

Refer to the manual(s) accompanying the device that pertain to the computer hardware for additional definitions of symbols that may be present.

Package Symbol Delineation



Fragile



Keep dry



Keep away from heat / sunlight



Temperature limit



Atmospheric pressure limitation



Humidity limitation

General Care

Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia based solutions, alcohol, or abrasive cleaning agents which may damage equipment surfaces.

Inspection

Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.

- Verify that all cords and connectors are securely seated.
- Check the case and chassis for any visible damage.
- Inspect cords and connectors for any visible damage.
- Inspect keys and controls for proper function and appearance.

Cleaning and Disinfecting

Note To clean the PC or any PC accessories, consult the manufacturer's recommendation for cleaning procedures.



WARNING Use of unspecified cleaning/disinfecting agents or failure to follow recommended procedures could result in increased risk of harm to users, patients and bystanders, or damage to the device.



CAUTION Do not clean the pressure tubing or sensor. Trapped moisture could affect their accuracy. Replace the pressure tubing if it becomes visibly soiled, is known to be contaminated with blood or sputum, or after 100 uses, whichever comes first. After replacing the used pressure tube, discard it. Replace the sensor when it becomes faulty.



CAUTION You cannot clean the spirometer or any of its components.



CAUTION If you choose to clean the calibrations syringe, clean the outer surface of the syringe with only the following solutions or wipes:

- Solution of dish soap and water, ½ tsp per cup of water
- Solution of bleach and water, 1 part bleach (6% sodium hypochlorite) with 9 parts water
- Isopropyl alcohol and water, 70% by volume
- PDI Sani-Cloth Plus wipes (14.85% Isopropanol)
- Cavi-Wipes (17.2% Isopropanol)



CAUTION Keep the spirometer away from splashing fluids.

Introduction

Manual Purpose

This manual provides information about the Welch Allyn Diagnostic Cardiology Suite Spirometry software:

- Installing Welch Allyn Diagnostic Cardiology Suite Spirometry
- Spirometry Display Overview
- Customizing the Spirometry Module
- Ambient Settings
- Calibration of the Flow Sensor
- Recording Spirometry Tests
- Viewing Spirometry Tests
- Interpreting Spirometry Tests
- Printing Spirometry Reports
- Prediction Norms
- Maintaining the Spirometer

This manual supplements the Welch Allyn Diagnostic Cardiology Suite Manager manual. For information on the shared components of the Manager and the Spirometry applications — for example, searching for patient data, setting system wide settings — see the Welch Allyn Diagnostic Cardiology Suite Manager manual .

Note This manual contains screen images that are for illustration, and might be different in the actual product. Consult the actual screen in the host language for specific wording.

Audience

This manual is written for clinical professionals with a working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

Indications for Use

The Welch Allyn Diagnostic Cardiology Suite is a prescription device intended for use by physicians, other licensed health care practitioners, and trained personnel who are acting on the orders of a physician. Welch Allyn Diagnostic Cardiology Suite is intended for use in medical clinics, physician offices and hospital settings to acquire, analyze, display,

transmit and print certain physiological signals identified below and provide the data for consideration by a physician.

Welch Allyn Diagnostic Cardiology Suite utilizes a software platform to support 12-lead diagnostic resting ECG and diagnostic spirometry applications and is designed to operate within the inherent capabilities of an off-the-shelf laptop or PC Windows operating system. Welch Allyn Diagnostic Cardiology Suite also provides functions related to patient data management including communication with electronic medical records systems. Welch Allyn Diagnostic Cardiology Suite Resting ECGs are intended to be taken with the patient in the supine position and offer VERITAS™ resting ECG algorithm to generate measurements and advisory statements for review and interpretation by the physician.

Welch Allyn Diagnostic Cardiology Suite is not intended to be used as a physiological vital signs monitor, not intended to be used in a mobile medical environment (e.g. ambulance, helicopter), in magnetic resonance (MR) environments, in operating theaters, nor in conjunction with high frequency surgical equipment.

Welch Allyn Diagnostic Cardiology Suite Spirometry is indicated for pulmonary function testing, providing forced expiratory flow-volume and time measurements. The device is intended to be a general assessment tool assisting the clinician in the diagnosis of pulmonary function. These devices are commonly used on patients with occupational exposure to dust or chemicals; presenting with symptoms such as chronic cough, shortness of breath and wheezing; disorders such as interstitial lung disease, bronchitis, asthma, and COPD; or other patients where the clinician determines these pulmonary function measurements are needed.

Welch Allyn Diagnostic Cardiology Suite Spirometry is indicated for adult and pediatric patients age 6 years and older and should only be used with patients able to understand the instructions for performing the test.

Contraindications

Contraindications to performing spirometry are:

- Hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition);
- Pneumothorax;
- Unstable cardiovascular status (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus; thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure);
- Recent eye surgery (e.g., cataract);
- Presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting);
- Recent surgery of thorax or abdomen.

System Description

Welcome

Welch Allyn Diagnostic Cardiology Suite Spirometry is a computer-based program used to record, view and interpret spirometric tests. It can also be used to print and transmit spirometry tests in various formats.

The spirometry module meets the requirements of ISO 26782, Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans.

This manual contains specific information about the spirometry module of the Welch Allyn Diagnostic Cardiology Suite . For all general information about the data management software, please refer to the Manager manual, which describes:

- Creating and editing patients
- Scheduling exams
- Setting preferences
- Managing users

Welch Allyn Diagnostic Cardiology Suite Spirometry performs FVC, SVC and MVV testing, including pre-post testing. It instantly displays flow-volume curves and depicts inspiratory and expiratory measurements.

Product Overview

The Spirometry module contains the components required to record spirometry efforts. These include the following:



Disposable Flow Transducer

Mouth piece used by the patient while performing tests. This is a single patient use only item to minimize the risk of cross contamination.

**Pressure Tubing**

Connects the flow transducers to the spirometer sensor.

**Spirometer Sensor with USB cable**

Connects to the USB port of your PC.
Converts pressure to airflow.

**Reusable Patient Handle**

Connects to the disposable flow transducer and pressure tubing for the patient to hold while performing efforts.

**Assembled Spirometer**

Consists of: disposable flow transducer, handle, pressure tubing, and USB sensor.

**Nose Clip**

It is highly recommended for patients to use a nose clip during testing to avoid air leaks. The nose clip should be used unless a medical condition makes it uncomfortable or impractical, in which case, the clinician should record that the nose clip was not used. This is a single-use only component.

**3-liter Calibration Syringe**

For daily use to calibrate the spirometer for accuracy. Note: this item is only included with the product if specifically ordered.

Features

- Automatic interpretation and comparison to best pre-bronchodilator.
- Real-time flow/volume and volume/time graphs.
- Incentive graphic for pediatric patient coaching.
- Multiple predicted norms.
- Multiple report formats.
- Validated to meet the ISO 26782 spirometry accuracy standards for both ambient and BTPS humidified air.
- Instant quality and variability check for proper test performance.
- Single-stroke and multiple-stroke calibration protocols.
- Reduced risk of cross contamination with Welch Allyn single-use, disposable flow transducers.
- Meets all industry standards, including ISO 26782, ATS, OSHA and Social Security.

Important Considerations

The spirometer should not be used if any of the following conditions exist or are thought to exist:

- The spirometer is not regularly calibrated.
- The maintenance instructions listed are not satisfactorily completed.
- Any part of the equipment or system is known, or suspected, to be defective.

Installation

Spirometry Application Installer

Before installing the Spirometry software, the Welch Allyn Diagnostic Cardiology Suite Manager software must first be installed. For information on the Welch Allyn Diagnostic Cardiology Suite software installation and upgrade processes, please refer to the Welch Allyn Diagnostic Cardiology Suite Manager user manual.

Note If installing the Spirometry software on Windows 7 32-bit or Windows 7 64-bit operating systems, it is required to install Flash Player in order to take a spirometry test. A copy of Flash Player can be found on the installation media.

Note If installing the Spirometry software on a supported Windows Server operating system, the desktop experience Windows setting must be enabled in order to run the Spirometry modality.

To begin installation:

1. Navigate to the location where the software to be installed is located.
2. Double click the application **SpirometryInstallation.msi** file.
3. If prompted by a User Account Control window, allow the program to make changes to the computer by clicking **Yes**. Note: User must have Administrator access to complete the installation.
4. The application installation window will appear. Select **Next**.
5. Enter the serial number of your product. This number can be found on the product identification card that is shipped with the software. Select **Next** to finish the installation.

System Installation

Once the Welch Allyn Diagnostic Cardiology Suite has been fully installed – including PC connected to power supply, software installed, and any associated accessories or equipment attached – the system must be tested for electrical safety. Because the PC and other related non-medical equipment is sourced by the user, it is the responsibility of the user to ensure the completed system provides a level of safety that is compliant with IEC 60601-1. The user should perform system level safety tests as defined by Clause 16 of IEC 60601-1 to ensure the final installation configuration of the system is compliant. It is recommended that non-medical equipment should be powered through a medical grade isolation transformer of sufficient capacity to facilitate compliance.



WARNING Multiple socket-outlet or extension cord not to be connected to the Welch Allyn Diagnostic Cardiology Suite to prevent possibility for excessive touch and leakage currents.

Software Upgrade

When upgrades of the Welch Allyn Diagnostic Cardiology Suite Spirometry software versions become available, the following process should be followed:

Prior to the upgrade:

- Always review specifications for the specific version being installed prior to upgrading the software.
- For networked installations, upgrade the software on the server prior to upgrading software on the clients.
- Upgrades should be scheduled while Welch Allyn Diagnostic Cardiology Suite is not in use. The software on the server must not be modified during data acquisition on any of the clients.
- The user logged in and performing the upgrade must have administrator privileges.

Software Upgrade Steps

1. Browse to the location where the Welch Allyn Diagnostic Cardiology Suite Spirometry software is located.
2. Double-click the **setup.exe** file.
3. If prompted to allow the program to make changes to the computer, select **Yes**.
4. When the Setup Wizard appears, select **Next**.
5. Select **Install** to move forward with the upgrade.

Software Uninstallation

When the Welch Allyn Diagnostic Cardiology Suite Spirometry software must be uninstalled, the following process should be followed:

Prior to the uninstall:

- If the Manager software is uninstalled and reinstalled without uninstalling the Spirometry application, the Spirometry application installation should be repaired. To repair the installation, select **Repair** from the application list or from the spirometry installer.
- Uninstall should be completed while Welch Allyn Diagnostic Cardiology Suite is not in use.
- The user logged in and performing the uninstall must have administrator privileges.

Software Uninstall Steps

1. Navigate to the Control Panel in the system settings and select **Uninstall a Program**.
2. The Welch Allyn Diagnostic Cardiology Suite Spirometry application will appear in the list as Connex Cardio Spirometry.
3. Select the application and choose **Uninstall**.
4. When the Setup Wizard appears, select **Uninstall** to remove the application from the computer.

Spirometer Setup

The Welch Allyn Diagnostic Cardiology Suite Spirometry module consists of two elements: the spirometry sensor, and the software that runs on the computer to which the sensor is connected.

Two spirometers are supported, the Welch Allyn Diagnostic Cardiology Suite spirometer, and SpiroPerfect spirometer. To prepare the spirometer for use, follow the steps:

Welch Allyn Diagnostic Cardiology Suite spirometer:

1. Connect the USB cable to the spirometer sensor.
2. Connect the pressure tubing to the spirometer sensor ensuring the tubing is fully seated.
3. Connect the USB cable to the computer on which the software has been installed.

The assembled spirometer setup can be viewed below (with handle attached):

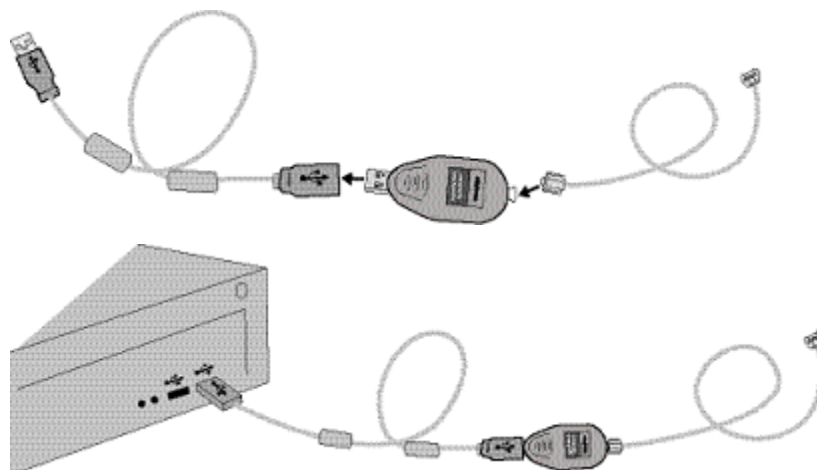


SpiroPerfect spirometer:

1. Connect the USB extension cable to the SpiroPerfect sensor.
2. Connect the pressure tubing to the SpiroPerfect spirometer.
3. Connect the SpiroPerfect spirometer to the computer on which the software has been installed.



CAUTION If using the SpiroPerfect spirometer: Always use the USB extension cable. The USB extension cable prevents damage to the spirometer.



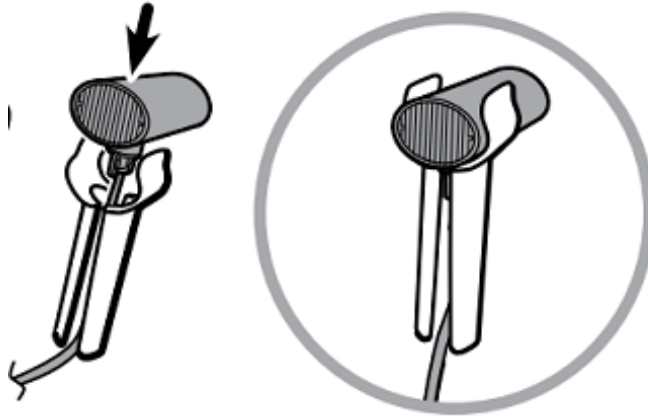
Warm up the spirometer

After connecting the device, it is recommended to let the spirometer warm up.

Setup the spirometer for a new patient

Once the device is connected to the PC and a patient is ready to begin a spirometry test, prepare the sensor for use.

1. Connect a new flow transducer to the tubing, ensuring it is properly seated.
2. Attach the tubing and flow transducer to the handle for the patient to hold.



WARNING Keep the reusable patient handle clean. Patient contact with contaminated equipment can spread infection.

Note Clean the patient handle after each patient use.

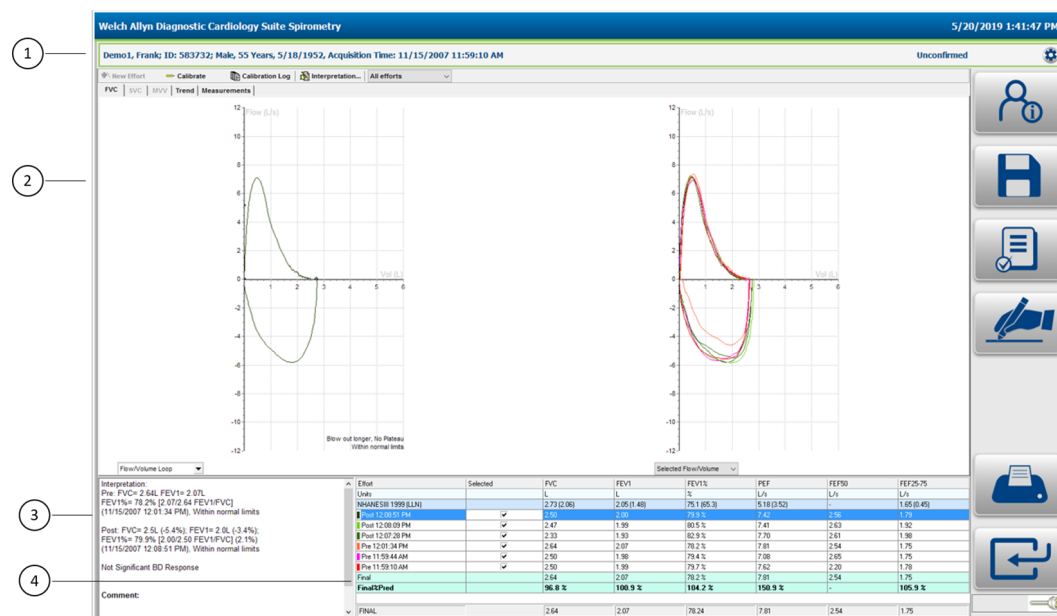
3. Open the spirometry module.

Note If using the SpiroPerfect sensor, the sensor starts to warm up as soon as the module is opened. Allow it to warm up for 5 minutes if it was just started.

Spirometry Display Overview

This section is a guide to the various parts of the Welch Allyn Diagnostic Cardiology Suite Spirometry application. There are two ways to launch the application:

1. **If using Welch Allyn Diagnostic Cardiology Suite as a desktop application:**
 - To start a test, select a scheduled test or order from available list or type the patient information manually. After the Start Exam button is selected, the spirometry application launches.
2. **If using Welch Allyn Diagnostic Cardiology Suite launching within an EMR:**
 - To start a test, follow the EMR-specific workflow to find the patient or order and launch the spirometry application from within the EMR.



Screen Areas

1. Toolbar

The toolbar contains the Calibrate, Calibration Log, Interpretation buttons and Effort Selection.

2. Graph Area

This area displays spirometry and flow curves.


3. Interpretation Area

The interpretation area displays the automatic or confirmed interpretation for the test, lung age and ATS reproducibility data.

4. Parameters Area

The parameters area displays each effort and up to 6 user-defined measured parameters.

Menu Selections

Click on the **Settings Menu** button  in the upper-right area of the display to open the menu for deleting an effort, recalculating the prediction norm and reanalyzing the test.



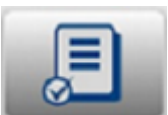
Set Selected Effort As Best Effort
Delete Selected Effort
Recalculate Prediction Norm
Reanalyze Test




- Select **Set Selected Effort As Best Effort** to overwrite the selection of best effort and set the currently selected effort as the Best Effort.
- Select **Delete Selected Effort** to delete the currently highlighted effort
 - Refer to previous section for instructions
- Select **Recalculate Prediction Norm** to select a new prediction norm to compare the patient's values against.
 - Refer to previous section for instructions
- Select **Reanalyze Test** to perform the reanalyze function on the test data.
 - Refer to previous section for instructions

Date / Time

Current date/time according to the computer regional settings is displayed in the upper right-hand corner of the display.

Spirometry Display Screen Icons

Icon	Name	Description
	Patient Information	Allows review of patient and test demographics entered at the start of the exam.
	Sign	Sign the displayed test. This icon is only available for those logged in with signing authority.
	Review	Mark the displayed ECG as <i>Reviewed</i> . This icon is only available for those logged in with permission to edit and review exams.

Icon	Name	Description
	Save	Saves the test and assigns an <i>acquired</i> status, or <i>edited</i> status if changes have been made after initial acquisition.
	Done	Ends and exits the data acquisition session.
	Print Preview	Prompts a <i>Print Preview</i> to select the report sections then send to the default printer for the computer.

Note The Review button may not be shown based on system configurations. View the Workflow Config section for further details.

Customizing the Spirometry Module

This section indicates how to adjust various settings like selecting prediction schemes, determining which parameters to view, and set various display options.

Customize features in the Spirometry settings.

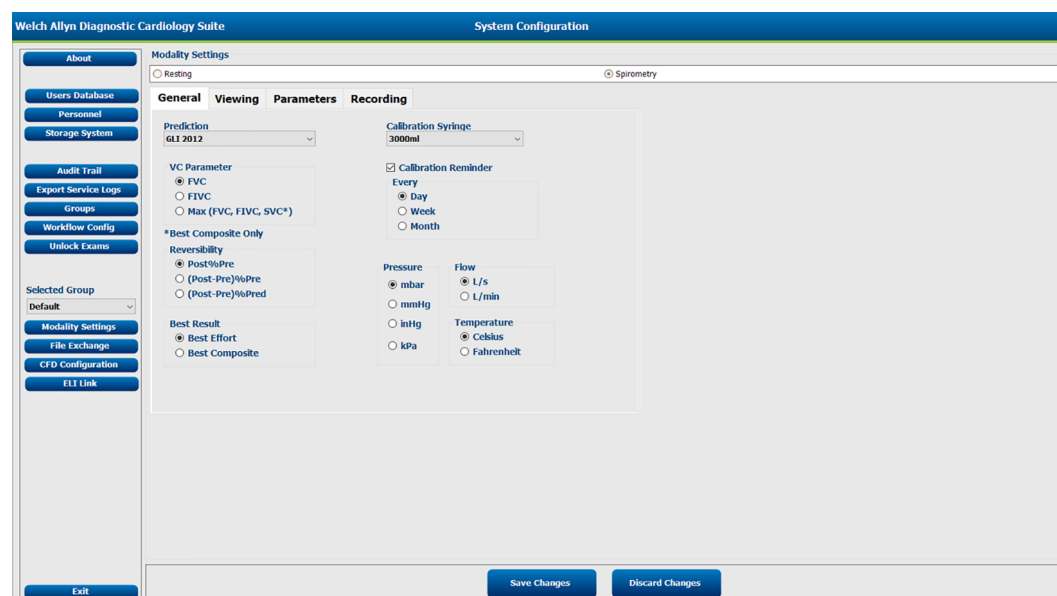
To open the Spirometry settings:

1. Open Welch Allyn Diagnostic Cardiology Suite from the desktop.

Note If using the Welch Allyn Diagnostic Cardiology Suite by launching from within an EMR, the System Configuration menu is still accessed through the desktop application. The desktop application can be accessed by browsing to the application in the Start Menu.

2. Select **System Configuration > Modality Settings > Spirometry**

The following screen appears:



Modality Settings define all modality-specific default values that do not change on a daily or patient-to-patient basis. Most of these settings can be modified within the modality for a single exam, but most of these default conditions will rarely need to change. The modality settings may be locked by the administrator, meaning that the setting cannot be changed during an exam per patient. Use the *Lock* checkbox to the right of each setting to exclude it from the settings available from within the modality.

Modality settings can be customized for each group. Ensure that the desired group is selected from the drop-down list before proceeding. Select the tab you wish to modify and click on **Save Changes** to apply or **Discard Changes** to cancel changes before exiting.

Modality Settings and Default Values

The following table indicates the Spirometry Modality settings, and possible values. The default value for each setting is indicated in **bold**.

General Tab

The screenshot shows the 'General' tab of a software interface with the following settings:

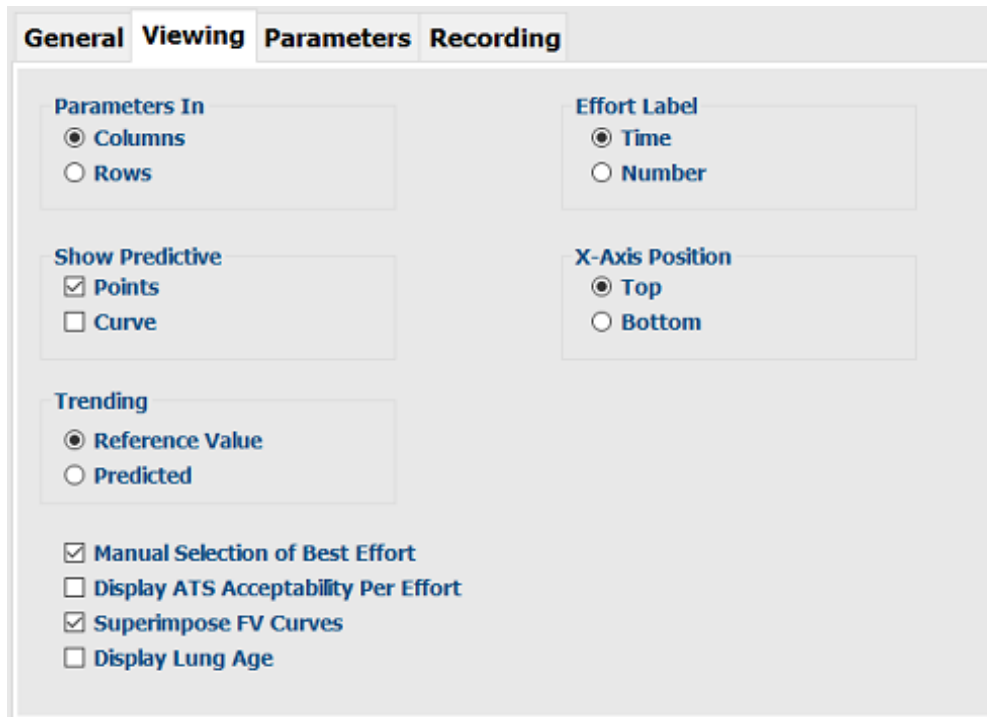
- Prediction:** GLI 2012
- Calibration Syringe:** 3000ml
- VC Parameter:**
 - FVC
 - FIVC
 - Max (FVC, FIVC, SVC*)
- *Best Composite Only**
- Reversibility:**
 - Post%Pre
 - (Post-Pre)%Pre
 - (Post-Pre)%Pred
- Best Result:**
 - Best Effort
 - Best Composite
- Calibration Reminder:**
 - Every:**
 - Day
 - Week
 - Month
- Pressure:**
 - mbar
 - mmHg
 - inHg
 - kPa
- Flow:**
 - L/s
 - L/min
- Temperature:**
 - Celsius
 - Fahrenheit

Setting	Notes	Options
Prediction	Sets the default prediction norm presented to the user as an option at the start of a spirometry test.	Berglund 1963 Composite Crapo 1981 Dockery 1983 ECCS / Quanjer 1993 ECCS / Solymar ECCS / Zapletal Falaschetti 2004

Setting	Notes	Options
		Forche II 1988 GLI 2012 Hedenström 1986 Hedenström / Solymar Hibbert 1989 Hsu 1979 Knudson 1976 Knudson 1983 Koillinen 1998 Kory 1961 Langhammer 2001 Morris 1971 NHANESIII 1999 Polgar 1971 Roca 1986 Schoenberg 1978 Solymar 1980 Viljanen 1981 Wang 1993 Zapletal 1969
VC Parameter	<p>The VC Parameter sets the FEV1% formula, which determines the calculation method for the FEV1% value and therefore affects the automatic interpretation. The formula contains two components – the numerator, which is always the best effort FEV1 value, and the denominator, which varies depending on the formula. The formula for each choice is indicated below:</p> <ul style="list-style-type: none"> • FVC (FEV1% = FEV1/FVC) • FIVC (FEV1% = FEV1/FIVC) • Max (FVC, FIVC, SVC*) (FEV1% = FEV1/FVC or FIVC or SVC, the largest) 	<p>FVC FIVC Max (FVC, FIVC, SVC*)</p>
Note	<p>The SVC parameter is only included if Final Result is set to Best composite.</p>	
Reversibility	<p>Reversibility is the percentage difference between pre-bronchodilation and post-bronchodilation data. This measurement indicates the effect of medication on lung function. The reversibility calculation selected applies to each parameter separately. The nomenclature of X%Y is equivalent to (X/Y)*100</p>	<p>Post%Pre (Post-Pre)%Pre (Post-Pre)%Pred</p>
Best Result	<p>A patient’s best effort is a measurement calculated from a set of efforts. To determine the method in which best effort is calculated, choose from these options:</p> <p>Best Effort: Defined as the single best effort in a set of efforts per effort type (best FVC-pre, best FVC post, best SVC). This ATS-recommended method uses the effort with</p>	<p>Best Effort Best Composite</p>

Setting	Notes	Options
	<p>the highest sum of FVC + FEV1, or the effort with the highest SVC value.</p> <p>Best Complete: Defined as a composite of the highest parameter values across all selected efforts.</p>	
Calibration Syringe	Configures the value for the volume of the calibration syringe.	1000 ml 2000 ml 3000 ml 4000 ml 5000 ml 6000 ml 7000 ml
Calibration Reminder	<p>Sets whether users are presented a reminder to calibrate the spirometer and the frequency in which the reminders are presented.</p> <p>The system default is to remind the user of the need to calibrate.</p>	Day Week Month
Pressure	Indicates the unit of measure for pressure.	mbar mmHg inHg kPa
Flow	Indicates the unit of measure for flow	L/s L/min
Temperature	Indicates the unit of measure for temperature	Celsius Fahrenheit

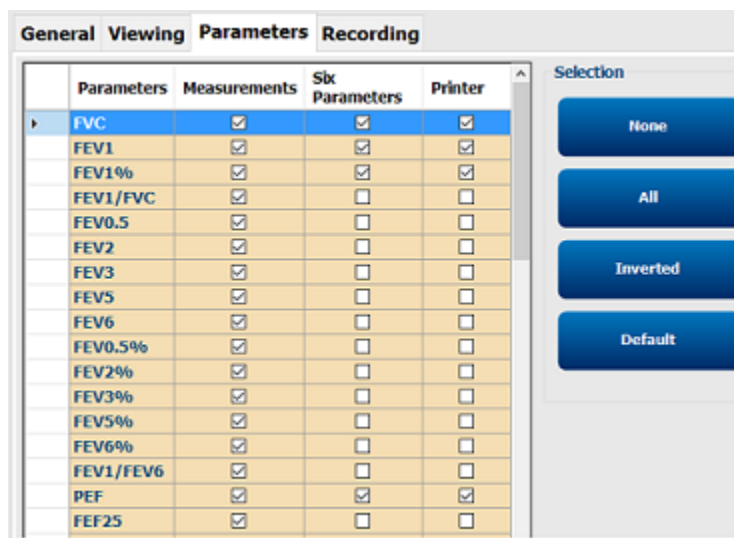
Viewing Tab



Setting	Notes	Options
Parameters In	Sets the layout of the six-parameter table	Columns Rows
Show Predictive	If Points is checked, predictive points display and print in the FVC graph. If Curve is selected a prediction curve will be displayed in the FVC graph.	Points Curve
Trending	When Reference Value is selected, parameter values are graphed as a percentage of the selected reference value. When Predicted is selected, parameters will trend as a percentage of predictive values. Note: The printed report will always show the parameters trending as a percentage of predictive values.	Reference Value Predicted
Manual Selection of Best Effort	If selected, you are allowed to manually select the best effort, when the final result is set to Best Effort.	Selected
Display ATS Acceptability per Effort	If selected, a row or column appears in the Parameter and Measurement tables displaying whether or not each individual effort meets the ATS 2005 acceptability criteria.	Not selected
Superimpose FV Curves	If selected, curves are offset on the graph. If unchecked, all curves are superimposed.	Selected


Setting	Notes	Options
Display Lung Age	If selected, the estimated lung age will be shown while viewing a test and in the printed reports for patients 20 years or older.	Not selected
Effort Label	If Time is selected, each effort is labeled with the time it was recorded. If Number is selected, each effort is labeled with a number and stage. For example, FVC Pre3 means it is the 3rd effort of a FVC test.	Time Number
X Axis Position	If Bottom is selected, spiroms are displayed with the horizontal axis at the bottom of the graph. If Top is selected spiroms are displayed with the horizontal axis at the top of the graph.	Bottom Top

Parameters Tab



Setting	Notes	Options
Measurements	Parameters selected in the Measurements column are displayed in the Measurements tab of the spirometry module.	All parameters selected
Six Parameters	Parameters selected in the Six Parameters column are displayed in the Six Parameters table of the parameter area (see Display Area for a visual). A maximum of six parameters can be selected per test type. For FVC, a minimum of three parameters is required	FVC FEV1 FEV1% PEF FEF50 FEF25-75 SVC VT-svc IC ERV IRV

Setting	Notes	Options
		Tin/Tex MVV VTmw BFmw MVmvv DFRC Time

Printer	Parameters selected in the Printer column are printed on the reports.	Default selections in Six Parameters setting
	 WARNING Selecting more than 15 parameters for printing may result in the list of printed parameters being truncated on all but the Best FVC report.	

Parameters Measured FVC Testing

FVC	FIVC	FIV1	FIV1%	FEV0.5	FEV1
FEV2	FEV3	FEV5	FEV6 FEV3%	FIV0.5	FEV0.5%
FEV1%	FEV1/FVC	FEV2%	FEF75	FEV5%	FEV6%
PEF	FEF25	FEF50	FEF50/FIF50	FEF0.2-1.2	FEF25-75
FEF75-85	PIF	FIF50		FEV1/FEV6	FET
MEF25	MEF50	MEF75			

SVC Testing

SVC	ERV	IRV	VT	IC	BF
MV	Tin	Tex	Tin/Tex		

MVV Testing

MVV	MV	VT	BF	DFRC	
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Selection

None	Blanks all previously selected parameters boxes in the Measurements and Printer columns. It does not affect the Six Parameters column.
All	Selects all parameters in the Measurements and Printer columns. It does not affect the Six Parameters column.
Inverted	Deselects the selected parameters, and selects the parameters that are not for the Measurements and Printer columns. It does not affect the Six Parameters column.
Default	Selects factory default parameter selections for the Measurements, Six Parameters and Printer columns.

Recording Tab

Setting	Notes	Options
Calibration Protocol	Select the Single Stroke calibration protocol (recommended for Welch Allyn Spiro Perfect) or Select Three Stroke calibration protocol (1, 2 and 3 seconds flow)	Single Stroke Three Stroke
ATS Sound Notification	Enables or disables sound notification after the completion of an effort.	Selected
Calibration Error Tolerance	Select Social Security (1%) for increased accuracy required by US Social Security Administration guidelines or Standard (3%)	Social Security Standard

Customize the spiro.txt File

The Medications and Interpretation lists that are available in the Interpretation and Comment editor are customizable.

To customize the statements:

1. As a default, this file is located in <install. dir> \modules\resources\<language code>*.txt. Use Notepad to open the file.
2. Edit, add and delete the statements according to your own preferences.

The *.txt files consist of statements that are grouped in categories. The statements are listed under the category name to which they belong. Statements indent one position. In the Medications list, the items that are immediately followed by an asterisk (*) appear in the Medications dropdown list in the modality.

To create a new category:

1. Type the name of the new category on the first position of a new line.
2. Enter the statements you want to add to this category on new lines, making sure that each statement indents one character.

Ambient Settings

When using the Welch Allyn Diagnostic Cardiology Suite spirometer, the flow sensor's ambient settings are automatically calculated and input. If the SpiroPerfect flow sensor is used, the ambient settings must be input manually.

Adjust the ambient settings (the temperature, humidity and air pressure) before calibrating the flow sensor.



CAUTION

- Adjust ambient settings before calibrating the flow sensor. If the ambient settings are not adjusted before calibration, the device will not be properly calibrated and could give false readings.
- You must recalibrate if there is a significant change in the ambient settings.
- If using the SpiroPerfect spirometer: ambient settings are stored locally by the program and passed on to the flow sensor before each measurement. This means that when using different PCs with the same flow sensor you have to set the ambient settings on each PC before starting the measurements. Also, when another person logs in to the PC, he/she needs to enter the ambient settings.

Ambient Setting Information

Ambient settings information is necessary for calculating the Ambient Temperature Pressure Saturation (ATPS) to Body Temperature Pressure Saturation (BTPS) correction in the flow sensor.

When to Adjust the Ambient Settings if using the SpiroPerfect sensor

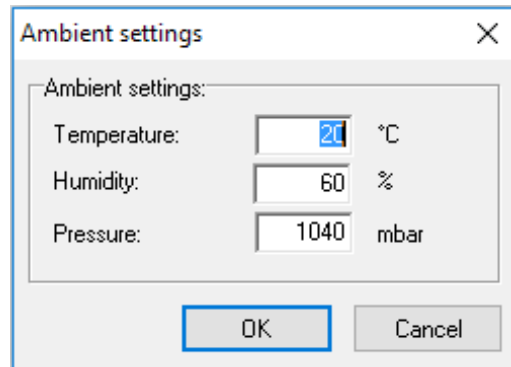
- Daily, the first time logging into the spirometry module.
- When ambient settings have changed significantly during the day.
- When the same flow sensor is used on different computers. In this case, adjust the ambient settings on each computer.
- Before a calibration takes place, in the pre-calibration window.

Adjusting the Ambient Settings

The Ambient settings can be accessed in two locations.

- During calibration in the pre-calibration window (see Calibration Process section for more information)
- At the beginning of a spirometry test (see Record a Spirometry Test for more information on how to prompt this action)

1. When starting a new spirometry test, select the Ambient settings button in the new spirometry test window.
2. Enter the Temperature value. (The value for the ambient temperature.)
3. Enter the Humidity value. (The value for the ambient air humidity.)
4. Enter the Pressure value. (The value for the ambient barometric pressure.)



The image shows a dialog box titled "Ambient settings" with a close button (X) in the top right corner. Inside the dialog, there is a section labeled "Ambient settings:" containing three input fields. The first field is labeled "Temperature:" and contains the value "20" followed by the unit "°C". The second field is labeled "Humidity:" and contains the value "60" followed by the unit "%". The third field is labeled "Pressure:" and contains the value "1040" followed by the unit "mbar". At the bottom of the dialog, there are two buttons: "OK" and "Cancel".

Note The unit of measure for ambient settings can be changed in the System Configuration. See Modality Settings and Default Values under the General Tab for more information.

Calibration of Flow Sensor



CAUTION The American Thoracic Society and Welch Allyn recommend calibrating spirometers every day before use

Welch Allyn guarantees accurate calibration only with the use of a Welch Allyn 3L calibration syringe. Although the Welch Allyn Diagnostic Cardiology Suite Spirometry application provides other calibration syringe volumes for use, Welch Allyn is not responsible for the system's accuracy if these syringes are used.

Flow Transducers

Flow transducers are manufactured to high precision and it is not necessary to calibrate the spirometer system with each flow transducer separately.



CAUTION Perform a new calibration when using a new lot of flow transducers.

Preparing Calibration

Calibration Protocol

Welch Allyn Diagnostic Cardiology Suite with Spirometry supports two calibration protocols:

- Single Stroke Calibration
- Three Stroke Calibration

The calibration protocol can be set on the Recording tab in the spirometry modality settings. For information on how to change the calibration protocol, see Modality Settings and Default Values under the Recording Tab for more information.

To calibrate the flow sensor it is strongly recommended to use the *Single Stroke Calibration Protocol*. This method will increase the accuracy of the flow sensor. The protocol can be changed in the spirometry settings.

Warm up the SpiroPerfect Spirometer

If using the SpiroPerfect spirometer, it is recommended to let the spirometer warm up prior to calibration. If the spirometer has already been used shortly before calibration, this warm up period is not needed.

1. Connect the spirometer to the computer.
2. Open the spirometry module. The sensor starts to warm up as soon as the spirometer module is opened.
3. Wait at least 5 minutes before starting the calibration process.

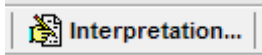
The Calibration Process

There are three ways to prompt calibration of the spirometer:

- If using Welch Allyn Diagnostic Cardiology Suite as a desktop application, select the syringe icon at the bottom of the screen.



- Regardless of setup type, if calibration reminders are on and the system has not been calibrated yet, a pop-up appears at the start of a test to give the opportunity to calibrate.
- Regardless of setup type, calibration can also be done while reviewing a test by selecting the icon in the toolbar.



Once the spirometer USB cable is connected to an open port on the computer, complete the following steps to calibrate the device.

1. To start the calibration, select the Calibrate button located on the toolbar or on the Welch Allyn Diagnostic Cardiology Suite main screen.
2. Fill in the following parameters:
 - Lot Code
 - Calibration Code

Pre-calibration
✕

Selected Flow Sensor: **SpiroPerfect Spirometer**

Lot Code

Calibration Code

Syringe Volume [Liter]


Current Calibration Factor

Calibration Error Tolerance: Social Security (1 %)
 Standard (3 %)

Temperature: °C

Humidity: %

Pressure: mbar

Setting	Description
Lot Code	Enter the lot code for the flow transducers located on the transducers box.
Calibration Code	<p>Enter the calibration code for the flow transducers located on the transducers box. See example of a schematic cutout of the label from the flow transducers box below where # are the numbers to be entered.</p> <p style="text-align: center;">CALIBRATION CODE #####</p> <p style="text-align: center;">LOT ## QTY 100</p> <p style="text-align: center;"></p> <p style="text-align: center;">##</p>
Syringe Volume	Select the appropriate syringe volume.
Current Calibration Factor	This value cannot be changed and indicates the correction factor applied to the calibration data from the previous session. Once the calibration is performed, this value will be updated. The factor displayed is the average of the inspiration and expiration calibration factor.
Calibration Error Tolerance	Select the measured calibration accuracy to be within 1% or 3% of the syringe volume.
Temperature	The ambient temperature.

Setting	Description
Humidity	The ambient humidity.
Pressure	The ambient pressure.



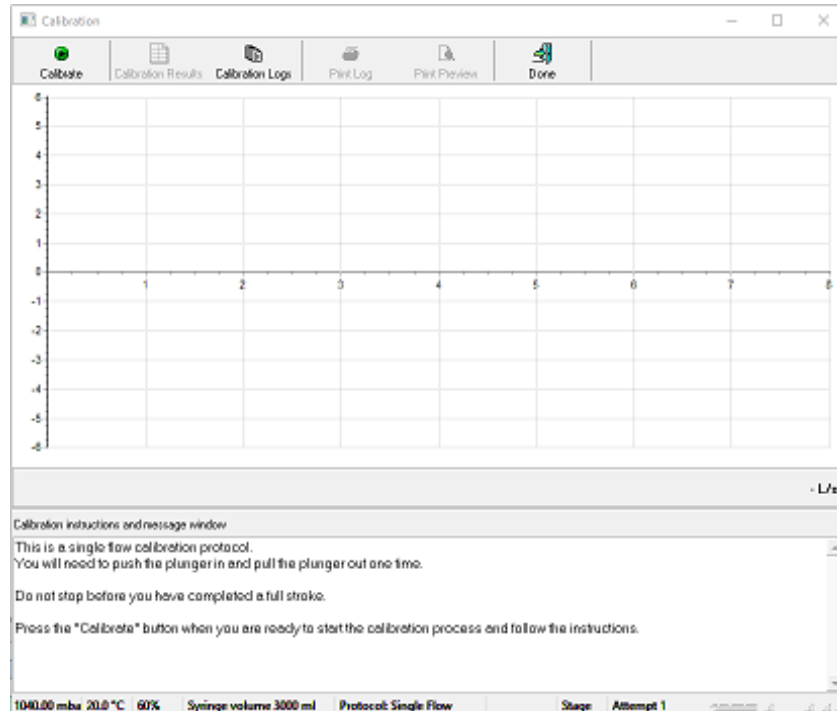
WARNING For the ambient settings pressure field please enter the pressure as given by a barometer in the immediate vicinity.

Do not enter the normalized sea-level pressure as commonly listed on internet sites on meteorological data resources.

3. Press **Next**.

Calibration instructions and message window is displayed below the Calibration window.

Note Please check the calibration and lot code if you cannot continue to the Calibration window.



4. Connect the syringe to the new flow transducer.

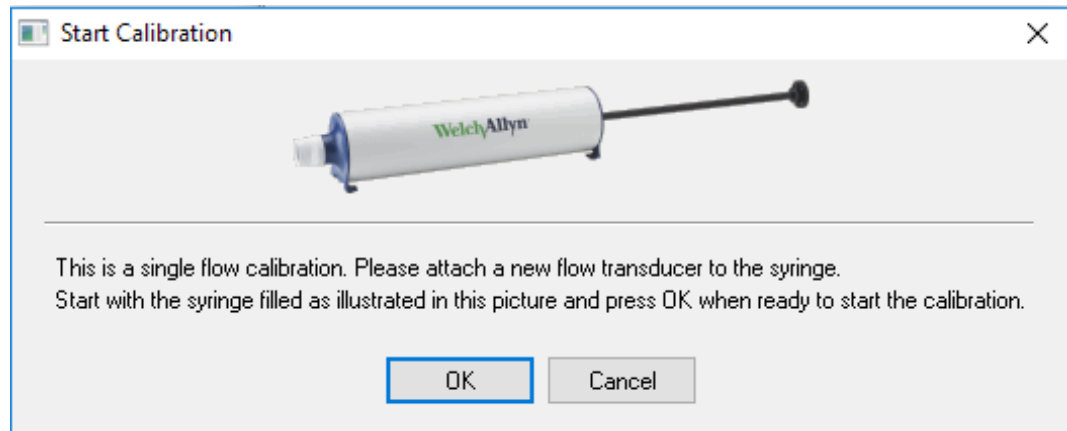
5. Fill the syringe by pulling the plunger completely out.

6. Press **Calibrate**.

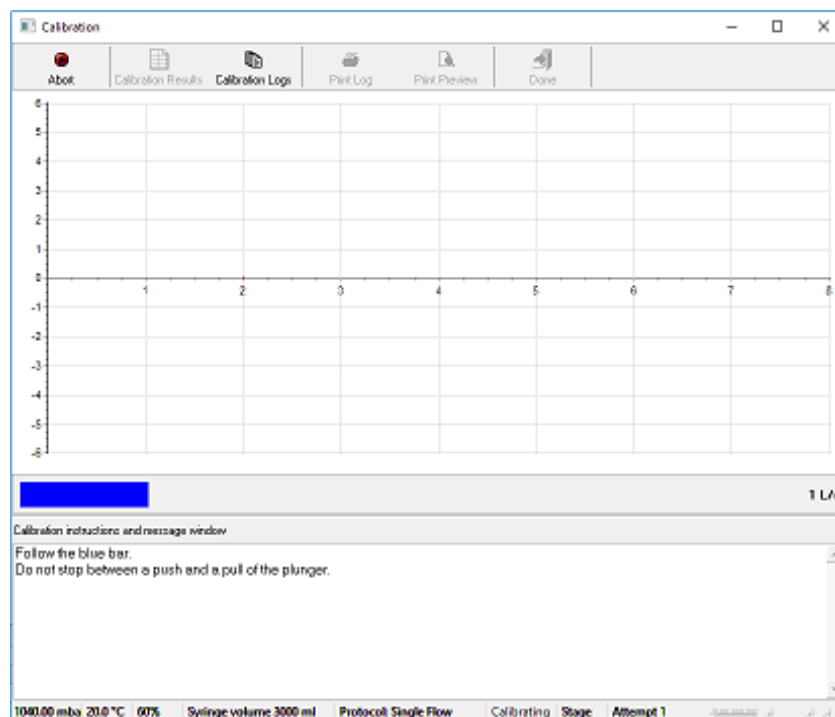
7. Wait until the messages: **Initializing sensor. Opening sensor, please wait...** disappears.

8. Verify the handle on the syringe is completely pulled out, as shown in the Start Calibration window, and press **OK**.

Note If the plunger is pushed in before calibration, the **No valid stroke recorded** message will appear.



9. Follow the on-screen instructions. The blue calibration bar is a guideline that indicates the speed at which to push the plunger.

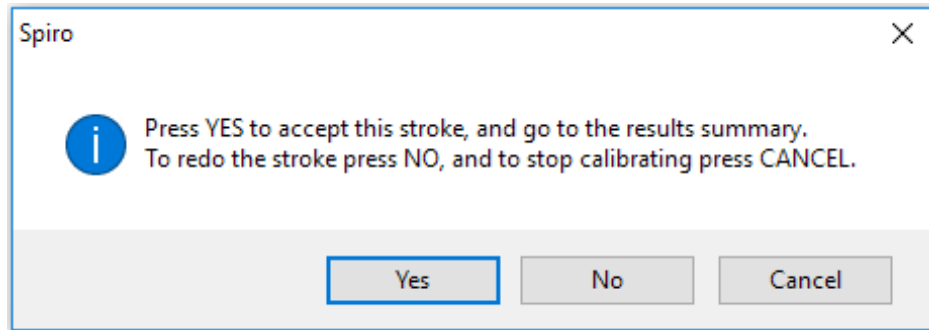


For a single flow calibration protocol: Push the plunger entirely in and pull the plunger out as far as possible, while following the blue bar as closely as possible. The calibration procedure will stop automatically, and inform you of the results.

For multiple-stroke calibrations: Push the plunger entirely in and pull the plunger out as far as possible, three times, while following the blue bar as closely as possible.

10. At the end of each stroke, choose to accept or redo the stroke.

Note If the selected standard (1% or 3%) has not been met you must redo.



Note If recalibrating, after pressing **Recalibrate**, press **Repeat Calibration** in the Calibration window and follow the instructions above.

If there is trouble getting the results within the Calibration Error Tolerance try:

- waiting 1 second between emptying and filling the syringe
- selecting the Reset Calibration icon to reset the calibration factors to factory default
- performing a single flow calibration before the three flow calibration, if the three flow calibration is unsuccessful

View Calibration Results

After calibration the Verify Calibration Results window will appear.

$(|Exp.\%| + |Insp.\%|)/2 = Abs.Avg.\%$

Stroke Nt.	L/s	Exp.Vol	Exp.%	Insp.Vol	Insp.%	Avg.Vol	Abs.Avg.%
1.	1	2951	-1.63	2938	-2.07	2944	1.85
Averages		2951	-1.63	2938	-2.07	2944	1.85

Note:
 Abs.Avg% should be:
 - <1% to meet the social security standard
 - <3% to meet ATS standard

ATS standard has been met (< 3%)

Each row provides the result of a stroke, the last row displays the averages. The bottom of the window informs the user whether or not the error tolerance has been met and if therefore calibration was successful.

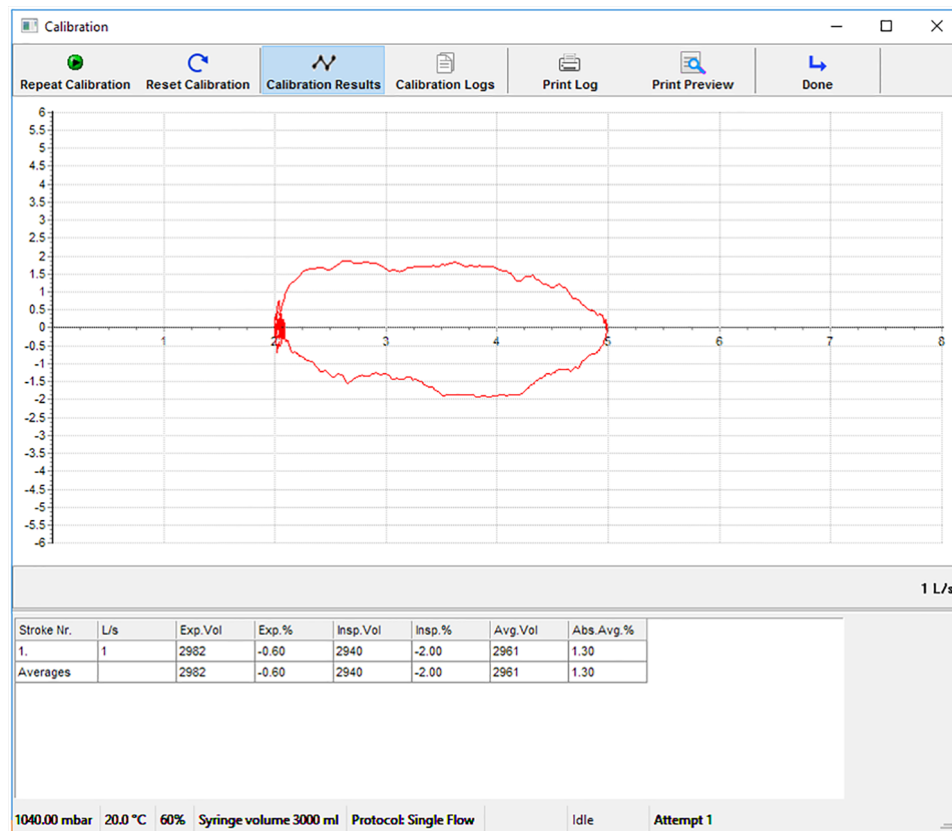
L/s	Results per stroke: The speed in the L/s plunger should be moved, as indicated by the blue calibration bar during the strokes.
Exp. Vol	The expiration volume reached by pushing in the plunger.
Exp. %	The expiration deviation from the actual volume in percent.
Insp. Vol	The inspiration volume reached by pulling out the plunger.

Insp. %	The inspiration deviation percentage.
Avg. Vol	The averages of inspiration volume and expiration volume.
Abs. Avg. %	The absolute average deviation percentage between inspiration volume and expiration volume.

The average volume should match as close as possible to the volume of the syringe that is being used to calibrate the sensor. Noticing a value that is much different than the expected volume of the syringe is an indicator of a bad calibration.

The Averages row gives the averages reached for all strokes. Please refer to this row for improving the calibration results.

After you have accepted the results you can view these values in the table below the graph by selecting the Calibrate Results button.

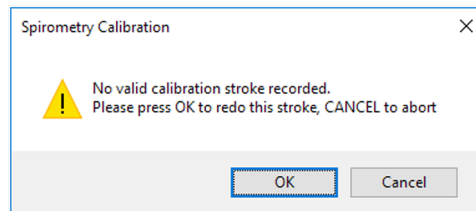


Calibrated Results Table

Selection	Description
Calibrate	Press Calibrate when you are ready to start the calibration process. After one calibration, the icon label changes to Repeat Calibration. It is recommended to repeat the calibration more than once.
Calibration Results	Press Calibration Results to view the results of the calibration. This can only be viewed between calibration attempts.

Selection	Description
Calibration Logs	Press Calibration Logs to view previous calibration attempts.
Print Log	Press Print log to print the currently selected or displayed log.
Print Preview	Press OK on the Print dialog box to view the calibration results before printing.
Done	Press Done to exit the calibration window.

Error Messages Associated with Failed Calibration



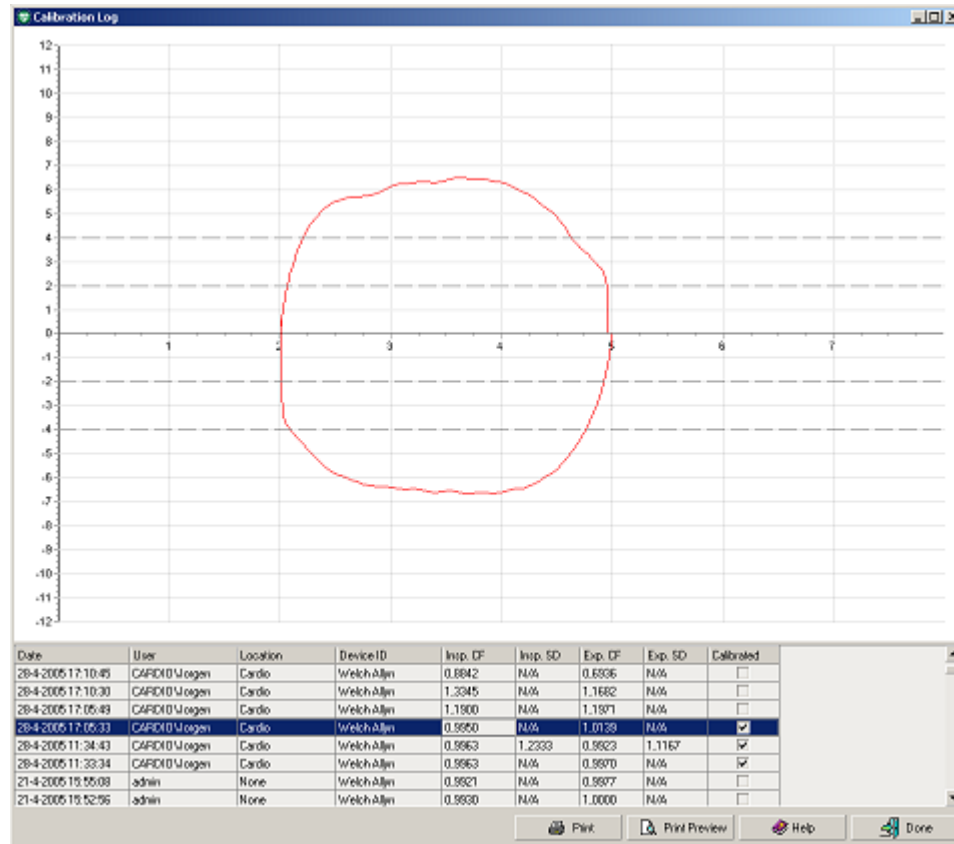
When the calibration attempt was not valid or if the volume read back by the sensor is not within 35% of the selected syringe volume, the calibration fails.

This message also appears if the calibration attempt was performed in the wrong order, first emptying the syringe instead of filling it before starting the calibration.



CAUTION It is the user's responsibility to determine whether to accept or reject failed calibration data. If the device does not pass calibration it could provide false readings.

Calibration Log



Use the calibration log to view calibration information of current and previous calibration efforts. Each time the sensor is calibrated, results are stored in the calibration log. The 100 most recent calibrations are stored. Select a calibration effort from the list to see the curve that belongs to it.

Calibration Log

Selection	Description
Date & Time	Date and time of calibration
User	Name of the user that performed the calibration
Location	Location specified in the general settings
Device ID	The spirometry sensor hardware used
Insp. CF	The Calibration Factor of the inspiratory strokes
Insp. SD	The stroke difference between the inspiratory strokes
Exp. CF	The Calibration Factor of the expiratory strokes
Exp. SD	The stroke difference between the expiratory strokes

Selection	Description
Calibrated	A check mark shows if the sensor was actually calibrated (yes) or only a log entry was saved (no)

To view the calibration log:

1. From the main screen select **Start Spirometry Calibration**, select **Calibration Log** in the calibration window.
2. In the spirometry application select Calibration Log

Note If printing the calibration logs on a printer using a PCL 5 driver, the Flow/Volume and Volume/Time graphs will not be printed.

Recording Spirometry Tests

The following types of efforts can be recorded with the spirometry module:

- **FVC:** Forced Vital Capacity - the volume delivered during an expiration made as forcefully and completely as possible starting from full inspiration.
- **MVV:** Maximum Voluntary Ventilation - the volume moved in and out of the lungs in a timed interval with voluntary effort.
- **SVC:** Slow Vital Capacity - volume of air expired after a maximal inspiration without forced effort.

The following tags can be assigned to each effort:

- **Pre:** Use to label efforts that are done before a bronchodilator is administered or for all other tests that do not include administration of a bronchodilator.
- **Post:** Use to label efforts that are done after administration of a bronchodilator.

When recording a post stage effort, the medication administered to the patient can be entered.

Start a Test Using the Desktop Application

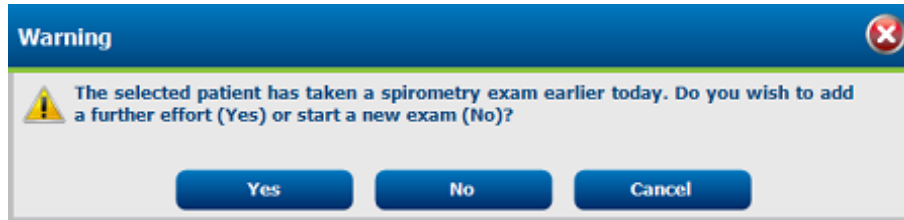
1. Connect the spirometer USB cable to an open port on the computer.
2. From the Welch Allyn Diagnostic Cardiology Suite main screen select **Start a Spirometry Exam**.
3. Select a patient, order, or enter patient and test demographics manually.
For further information on starting an exam see the Welch Allyn Diagnostic Cardiology Suite Manager user's manual.
4. Continue to Step 4 below.

Start a Test from within the EMR

Note This workflow is only available when the Welch Allyn Diagnostic Cardiology Suite has been setup to be integrated with and launched from an EMR. Contact your administrator for questions on your installation type.

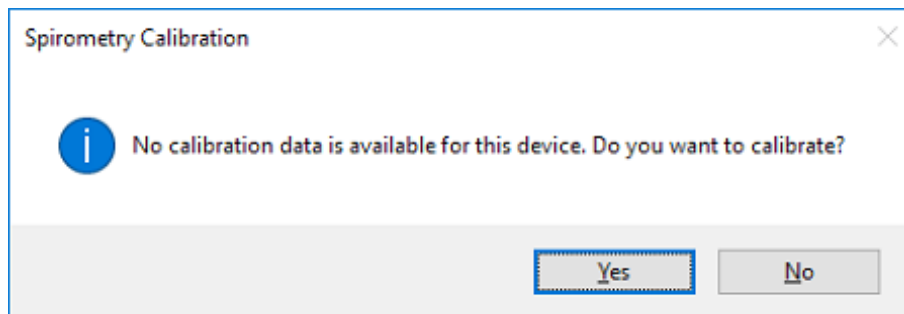
1. Connect the spirometer USB cable to an open port on the computer.
2. Follow your EMR-specific workflow to select a patient and associated demographics or order.
3. Launch the spirometry application from the EMR.

Note The following screen appears if a new effort or test is done on a patient that has performed a test within 24 hours. To add additional efforts (pre or post) select **Add New Effort**. To start a new test, select **Create New Test**, else cancel to return to the **Start a Spirometry Exam** window.



CAUTION Use numerals only to set the date format. Alpha characters cannot be used in the date field.

Note If automatic calibration reminders are enabled and the system is not yet calibrated, a reminder may be presented. Select **Yes** to calibrate the spirometer immediately. Select **No** to use the previous calibration data and continue with the test.



- Complete patient information fields in the **New spirometry test** window. Check the **Smoker** and/or **Asthmatic** boxes if applicable.

 A "New spirometry test" window with a close button (X) in the top right. It is divided into two sections: "Patient information" and "Test information".

Patient information:

Height: 68 inches	Weight: 205.0 lbs	Birth date: M/d/yyyy: 5/18/1952
Gender: Male	Race: Caucasian	
<input type="checkbox"/> Smoker	<input type="checkbox"/> Asthmatic	

Test information:

Prediction norm: GLI 2012

Ambient settings button

Buttons: Cancel, Next >

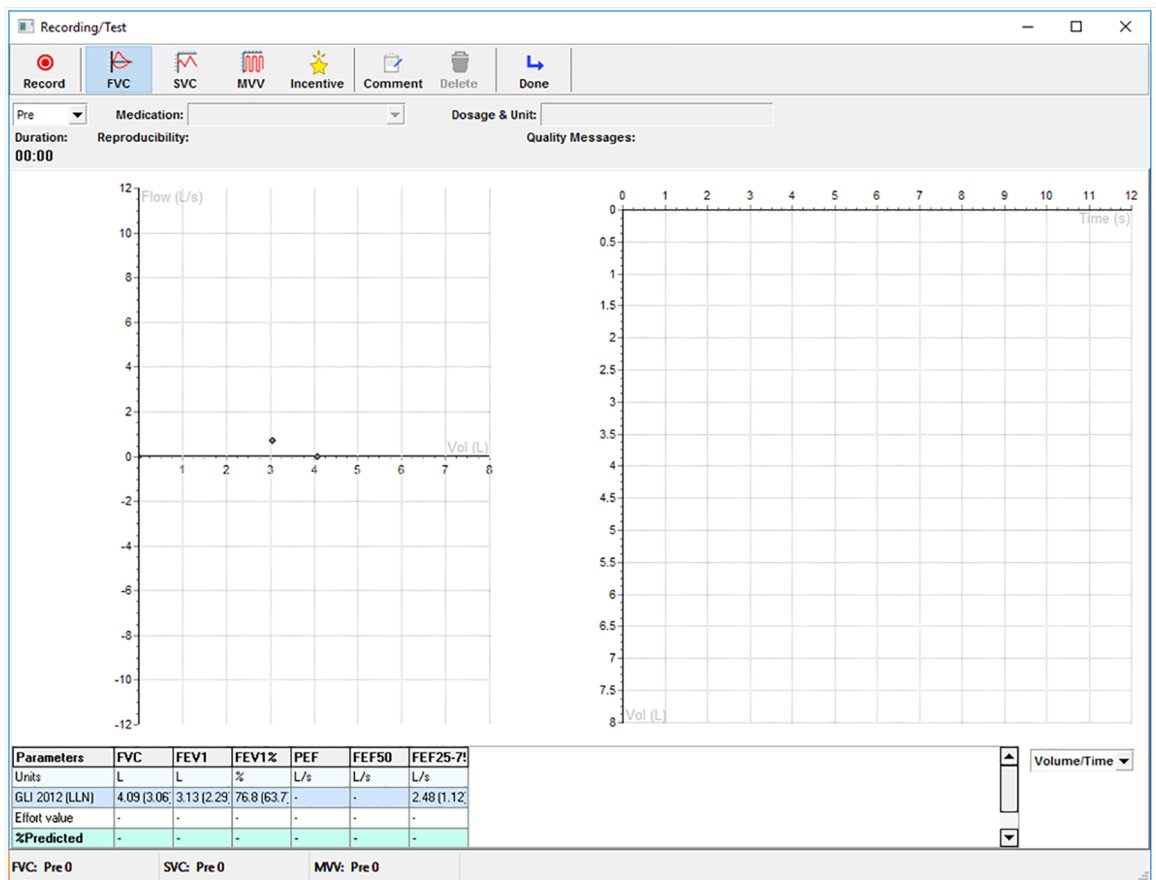
- Select the desired **Prediction Norm** if different from the default. To modify the default prediction norm, see Modality Settings and Default Values section of this manual.



CAUTION To obtain predictive values for certain parameters, the patient’s age, gender, race and height must be entered into the window, otherwise no predictive data is reported.

Note If required data is missing, the parameter labels are displayed red in the **New spirometry test** window. You must fill in the required fields to continue. The Norm Profiles indicate valid demographic ranges for each norm.

6. If the humidity, temperature or pressure have changed since the last calibration, select **Ambient Settings** and adjust as necessary.
7. Select **Next**



Note To expand the window to full screen, double click on the title bar, or again to reduce size.

8. Select the effort type to perform by selecting the **FVC, SVC** or **MVV**. To use an incentive screen with the FVC test, select the **Incentive** option
9. Select the effort stage.
 - a. **Pre** is automatically selected for all new tests. Additionally, select Pre to add efforts to the pre-bronchodilation portion of a test.
 - b. Select **Post** to add efforts after the administration of a bronchodilator. Post efforts can only be added to existing exams that have completed Pre efforts within the last 24 hours.

10. If you have selected Post, enter the medication dosage and unit.
The medication and dosage fields are only active if a post-effort is selected.
11. Modify the type of curve presented from the drop-down menu located at the bottom of the right graph (Volume/Time, Flow/Time, or Incentive)
12. Instruct the patient to hold the sensor still.
Make sure the rear of the flow-tube is not blocked. The extra resistance will result in faulty measurements.
13. Select **Record** to start recording.
14. Ask the patient to perform the effort according to the appropriate procedures. See the Patient Procedures section below for addition information.
15. When the patient has completed the test, select **Done**. The recording window closes and the main view displays all efforts of the recorded effort stage (Pre/Post).
The effort along with six corresponding parameter values are displayed in the parameters area.
16. The status bar above the graphs displays ATS acceptability criteria met, duration of the effort, number of FVC, SVC and MVV efforts completed in a test and if the reproducibility criteria are met.
17. When the patient finishes testing, select **Done**. The spirometry view appears displaying all the efforts with the ability to print, save, review or sign.

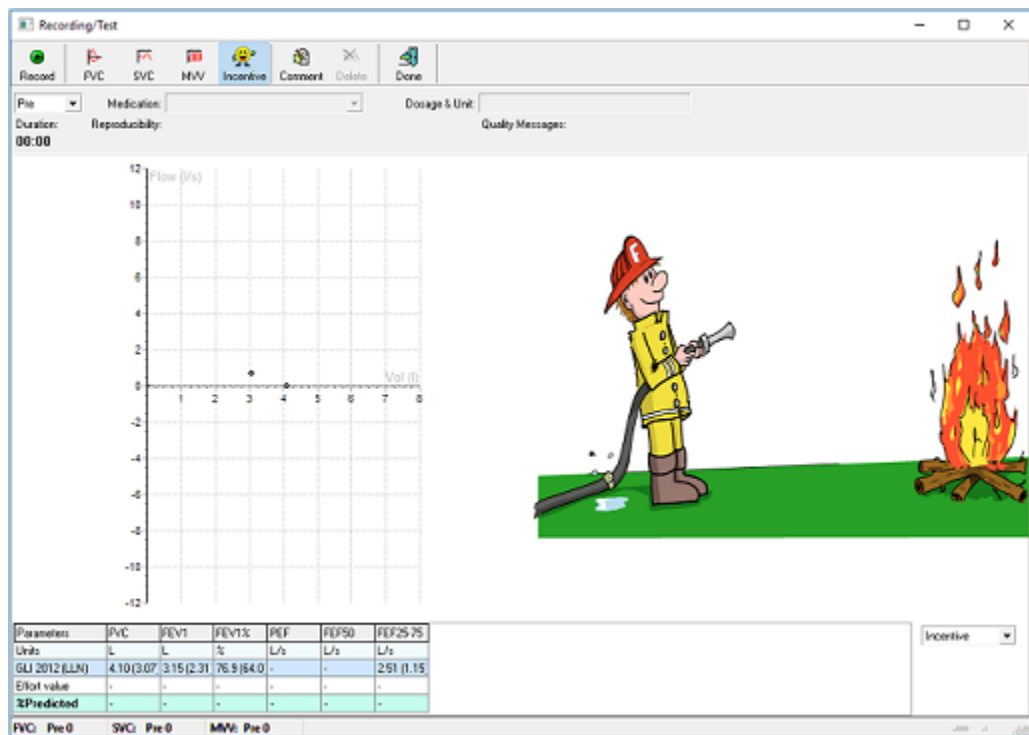
Incentive Screen

The incentive screen is used to guide patients through the effort and encourage them to blow into the flow transducer the best they can.

Note If the patient's demographics are outside of the prediction norm demographics no prediction values will be calculated. The incentive screen will not operate without predicted values.

1. Select **Incentive** from the Recording/Test toolbar or select **Incentive** from the Type of Curve drop-down menu

The fireman extinguishes the fire if the patient's effort reaches 80% of the predicted for PEF & FVC values. If the patient's effort is below 80%, the fire is not extinguished.



2. To remove the incentive screen, select **Volume/Time** from the Type of Curve drop-down menu or select the **FVC**, **SVC**, or **MVV** button.

Patient Procedures



WARNING Patients may become faint, light-headed, dizzy, or short of breath during spirometry testing. Watch patients closely. If they choose to stand during testing, keep a chair immediately behind them. If there is any reason for concern, stop the test and take proper action.

Recommendation:

Practice the procedure with the patient before recording the effort. American Thoracic Society recommends ending recording after eight successful FVC efforts to avoid fainting.

To prepare patients for any spirometry test, explain the entire procedure for the type of effort you want them to perform. Remind patients that the test is painless. Demonstrate at least one effort for the patient.

The accuracy of a spirometry test is highly dependent on the patient's understanding and cooperation. Be prepared to coach and encourage the patient with your body language and your words.

Instruct the patients to do the following:

- Loosen any tight articles of clothing that might constrict lung function, for example, a tight belt, tie, vest, or undergarment.
- Remove any foreign objects from the mouth, including loose dentures.
- The use of a nose clip is highly recommended. If used, check for proper fit.
- Place lips and teeth around a new flow transducer, sealing their lips tightly around the transducer. Grip slightly with teeth in the groove.
- Keep tongue away from the flow transducer to avoid blocking it.
- Keep the rear of the Flow sensor free.
- Keep chin up so as not to restrict the airway.



WARNING Always check the interior of the flow transducer to ensure that no foreign objects are present.

Once the patient has the flow transducer in place, ask him or her to perform the effort using the guide below for the patient's predicted performance effort breathing instructions.

For an FVC effort, instruct the patient to:

1. Breathe in (until the Total Lung Capacity is reached).
2. Blow out forcefully (until the Residual Volume is reached). The ATS sound notification will let the patient know the effort is complete.

For an FVC loop, instruct the patient to:

1. Breathe in (until the Total Lung Capacity is reached).
2. Exhale forcefully (until the Residual Volume is reached)
3. Breathe in forcefully (until the Total Lung Capacity is reached). Allow sufficient time.

or

1. Start normal breathing (tidal breathing).
2. Breathe out (until the Residual Volume is reached).
3. Breathe in forcefully (until the Residual Volume is reached). Allow sufficient time.
4. Exhale forcefully (until the Total Lung Capacity is reached).

For an SVC effort, instruct the patient to:

1. Start normal breathing (tidal breathing).
2. Breathe in calmly, (until the Total Lung Capacity is reached).
3. Exhale calmly, (until the Residual Volume is reached). Allow sufficient time.
4. If necessary, repeat steps 3 and 4.

Steps 3 & 4 can be reversed, meaning: a maximum expiration followed by a maximum inspiration.

For an MVV effort, instruct the patient to:

Breathe in and out forcefully at a pace of approximate 30 breaths per minute (2 seconds per complete breath) for 15 seconds (the program automatically stops gathering data after 15 seconds).

About quality feedback

The spirometer provides effort-quality messages as described in the following sections.

About effort-quality messages

One of the following effort-quality messages appears on the screen after each effort is completed. These messages indicate whether an effort was acceptable, and if not, what the patient needs to do differently.

Effort-Quality Message	Criteria
Do not hesitate	Back Extrapolated Volume (BEV) is > 150 mL
Blast out faster	PEF time > 120 ms.
Blow out longer, No plateau	FET < 6 seconds (3 pediatrics) and no plateau
Good effort	FET < 6 seconds (3 pediatrics) and has plateau or FET is > 6 seconds (3 seconds pediatrics)

Delete an Effort

While performing or reviewing a test, it is possible to delete efforts so they are no longer part of the test and will not appear in the test report. Possible reasons this may be desired is if an effort was started or stopped prematurely, or the effort was of very poor quality.

Option 1:

When in the Recording/Test window, immediately after acquiring an effort select **Delete**, then **OK** on the Confirmation window.

Option 2:

While viewing the test click on an effort in the Parameters area to highlight it. The Parameters area is located in the lower right side of the workspace window.

1. Select **Settings > Delete Selected Effort**, the confirmation dialog box appears.
2. Select **OK**. Once an effort has been deleted, it cannot be recovered.

Add or change information in the Comment editor

When creating a new spirometry test, the Welch Allyn Diagnostic Cardiology Suite offers a space for adding or changing comments, while recording.

To add or change comments:

1. Select the **Comment** button from the toolbar.
2. Type comments or select canned statements from the interpretations or medication from the statement tree in the left pane of the Comment editor.

3. Select **Save**.

The Comment editor is also available after recording.

Viewing Spirometry Tests

To view a spirometry test when using the desktop application:

1. From the Welch Allyn Diagnostic Cardiology Suite main screen select **Exam Search**.
2. Double click to select a patient and open the associated spirometry test
3. Use the tabs and the Effort selector (in the toolbar) for selecting information to view.
For more information on how to search and sort records in the Exam Search window, see the Welch Allyn Diagnostic Cardiology Suite Manager manual.

To view a spirometry test when the product is launched from the EMR:

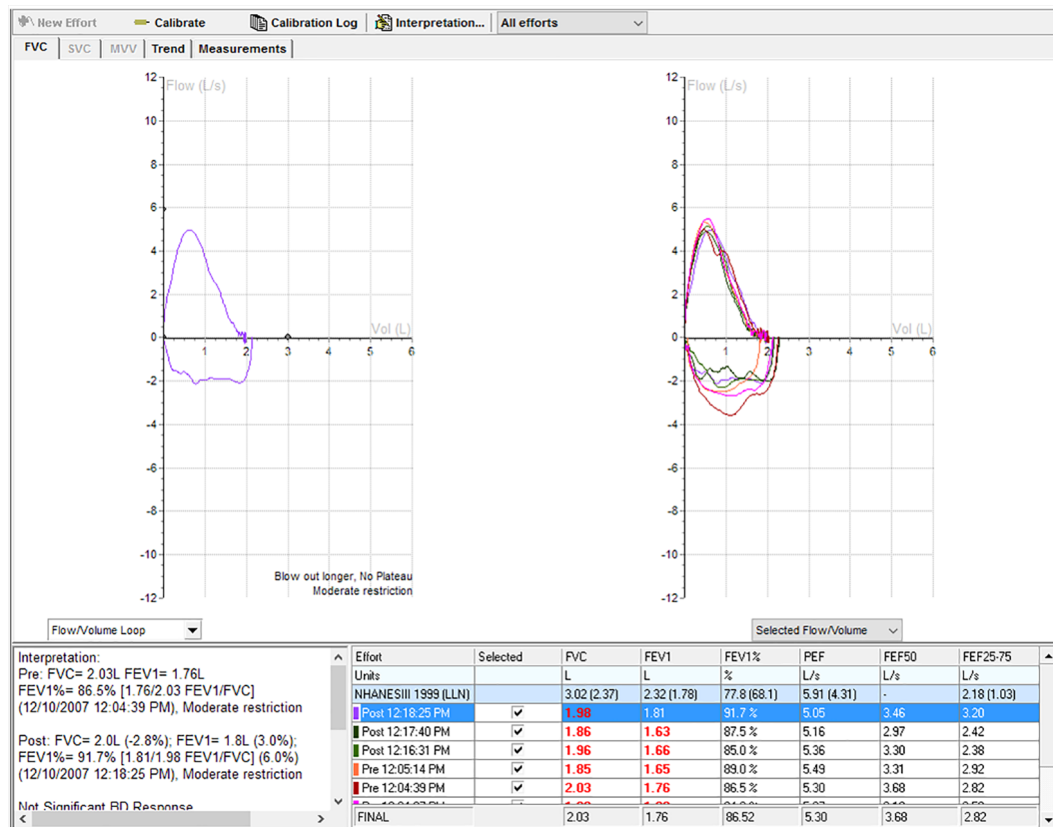
1. Use your EMR-specific workflow to find a patient and open a test.
For more information on the specific steps to find patients and tests within the EMR, contact your administrator.

Test Modes and Tabs

FVC	SVC	MVV	Trend	Measurements
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Tab	Description
FVC	Select to view only the currently selected FVC efforts A flow/volume curve of the current FVC effort and the flow/volume curves of all selected FVC efforts. The dotted line marks the predicted values.
SVC	Select to view only the currently selected SVC efforts. A spirogram for the current SVC effort.
MVV	Select to view only the currently selected MVV efforts. A spirogram for the current MVV effort.
Trend	Select to view only the trends to a maximum of six parameters. Trends of the FVC effort of the test.
Measurements	Select to view all the parameters calculated of all effort types. All parameters values based on user settings for each stage and effort.

Common Features for each Tab



View multiple flow/volume curves of one test

It is possible to view and compare multiple efforts previously recorded in one test. The right hand side of the window displays a flow curve of all selected efforts. The left hand side of the window displays the flow curve of the currently selected effort.

To view multiple efforts in one flow/volume graph:

1. In the spirometer window, move the mouse arrow to the Parameters table.
2. Check the box of each effort to view in the selected row/column.
3. Uncheck the boxes of each effort to hide it from view.

Parameters Area

Effort	Units	GLI 2012 (LLN)	Pre 2.	Pre 1.	Final	FinalSPred (z)
ATS	-	-	No	Yes	-	-
Selected			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
FVC	L	5.71 (4.58)	5.60	5.13	5.80	98 % (-0.16)
FEV1	L	4.85 (3.70)	4.70	4.34	4.70	101 % (0.08)
FEV1/FVC	%	82 (71)	84 %	85 %	84 %	102 % (0.35)
PEF6	L	-	5.60	5.13	5.80	-
PEF	L/s	-	11.14	10.96	11.14	-
FEF25-75	L/s	4.61 (2.82)	5.06	4.94	5.06	110 % (0.36)

Selection	Description
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Parameters Area

The parameters area holds the Parameters table. It is displayed under the FVC, SVC MVV and Trend tabs.

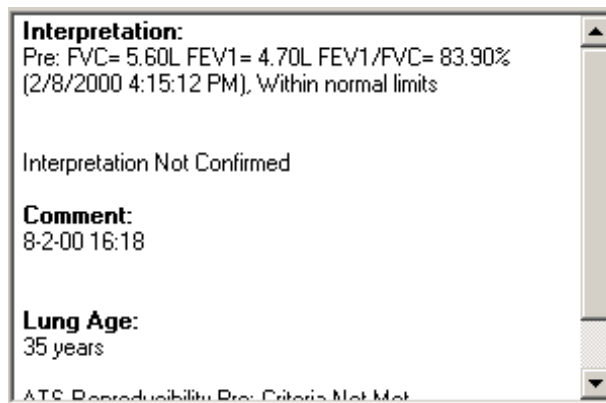
The Parameters table lists up to six user-defined parameters.

The following information is displayed in the table:

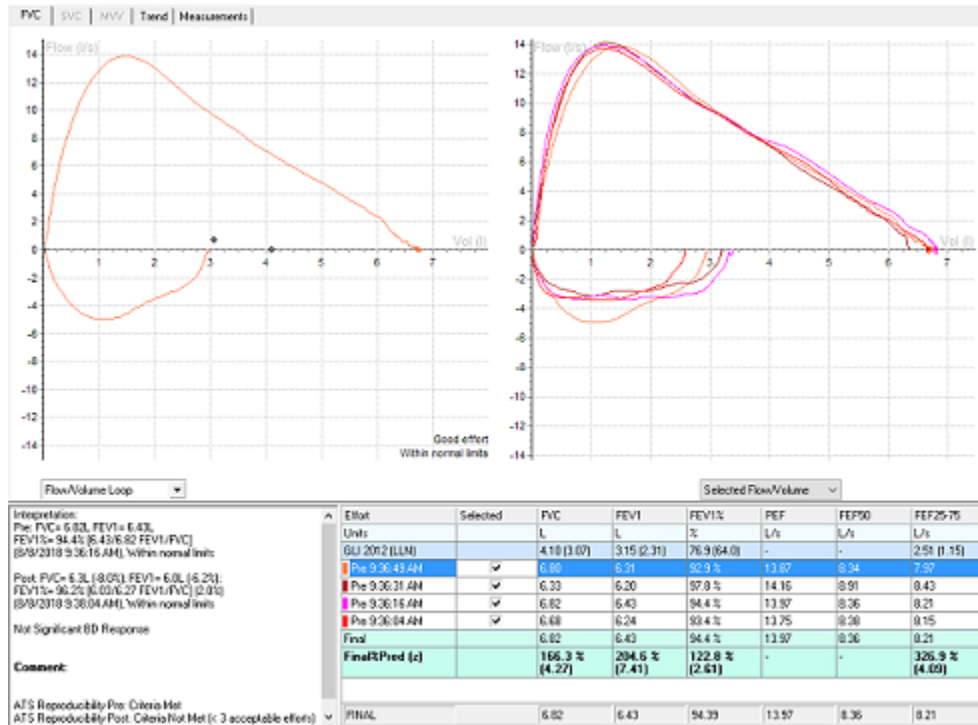
Selection	Description
	<ul style="list-style-type: none"> • predictive norm • ATS acceptability criteria • predictive values per parameter, followed by the lower limit of normal in parentheses • effort stage & parameter value • final result parameter values • % predictive, followed by the z-score in parentheses for the norms that support z-score • % change (in "All efforts" and "Post "view)
Effort	<p>The color in front of the effort name corresponds to the color of the curve in the graph.</p> <p>Select the check box in the selected row or column and the curve is displayed in the graph. You can select to show the parameters in rows or columns in the settings.</p> <p>Deselect a check box and the curve is hidden.</p>

Interpretation Area

The interpretation area displays automatic or confirmed interpretation, medications, comments, lung age (if enabled in the settings), and reproducibility information.

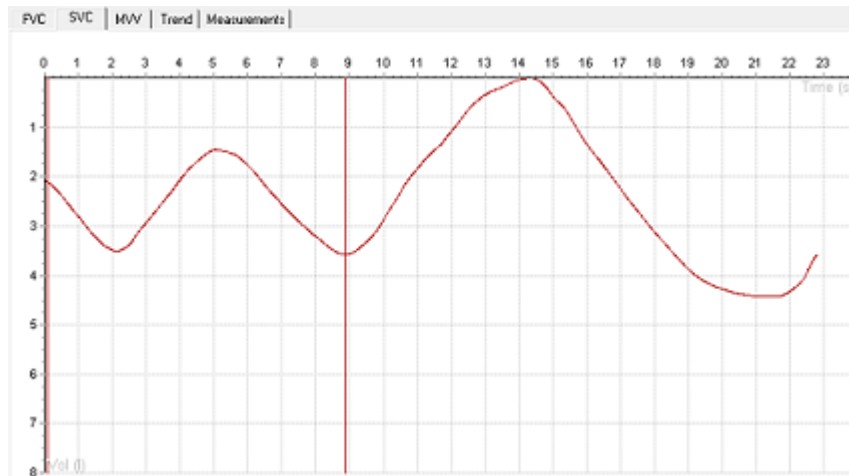


FVC Tab



Selection	Description
Left Graph	The left graph always represents the selected effort in the parameters table as a flow volume loop or as tidal volume.
Right Graph	The right graph displays curves all efforts selected for a particular stage. Different curve views are selected from the drop down menu: <ul style="list-style-type: none"> • Flow/Volume • Volume/Time • Flow/Time
Axes	In a flow volume graph, the flow is plotted against the volume. In a volume/time graph, the volume is plotted against time.
Units	<ul style="list-style-type: none"> • Volume is expressed in liters. • Time is expressed in seconds. • Flow is expressed in liters per second, or liters per minute based on settings.

SVC Tab



SVC test

Review results under the SVC tab.

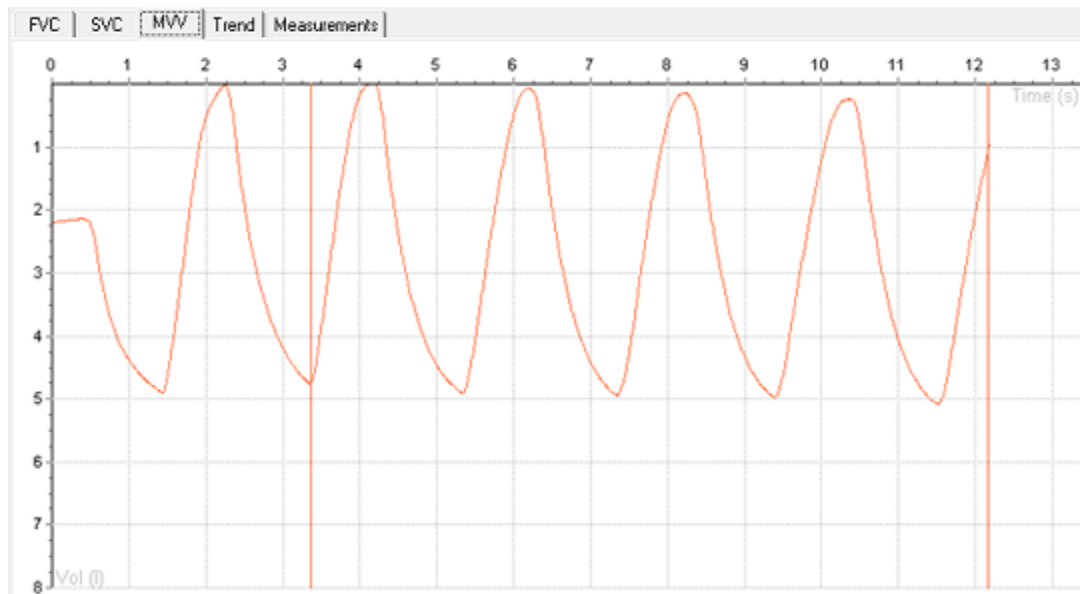
Only volume/time (spirogram) graphs are displayed along with six SVC parameters.

Calipers mark the beginning and the end of the tidal area. Each effort line displayed on the graph has a different color.

Note Calipers can be manually adjusted. If so, affected parameters will automatically be recalculated.

If no SVC test is performed, the SVC tab is disabled.

MVV Tab



MVV test

Review results under the MVV tab.

Only volume/time (spirogram) graphs are displayed along with six MVV parameters.

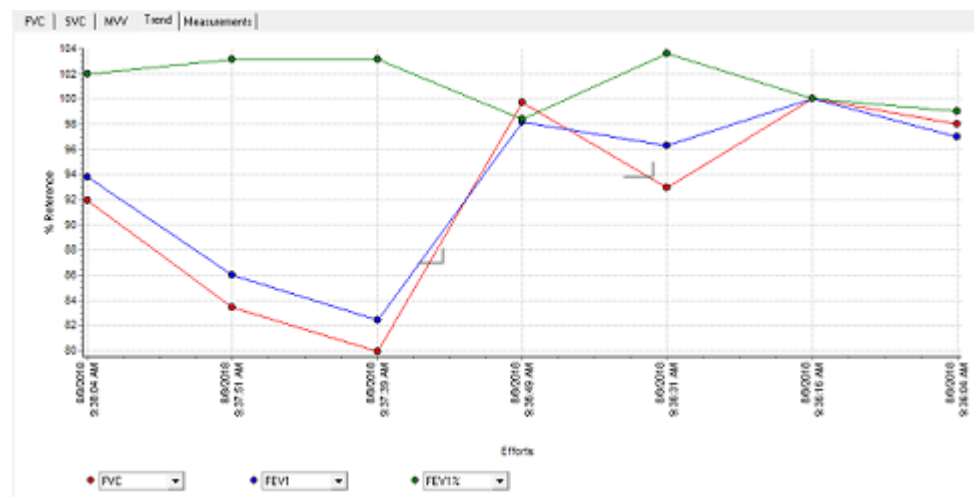
Calipers (vertical lines) mark the beginning and the end of the ventilation volume (not the tidal area).

Note Calipers can be manually adjusted. If so, affected parameters will automatically be recalculated.

[tip:] **Tip** You can select or deselect a curve in the parameters table.

If no MVV test is performed, the MVV tab is disabled.

Trend Tab

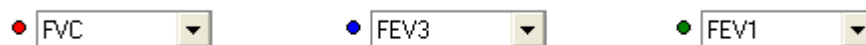


The Trends tab displays trends of:

- the FVC efforts of the test or
- the best pre and best post efforts of the several different tests of the same patient.

There is no limit to the number of tests that you can trend. You can simultaneously view three parameters and see how the parameters evolve during the test.

The interpretation area shows the interpretation of the most recent test.



Selection	Description
Parameters	Three parameters are always trended. The choice of parameters trended depends on the selected parameters in the settings.
Axes	<p>The horizontal axis displays the date & time of the efforts.</p> <p>The vertical axis displays the parameter values:</p> <ul style="list-style-type: none"> • As a % of Predictive (effort x/pred value) x 100. • As a percentage of a reference value. The value of the parameters is a relative value. It depends on the currently selected effort. For example, if a test has three efforts and effort 1 is selected, all parameter values for effort 1 are set to 100%. The values for other efforts are expressed as

Selection	Description
	lower or higher percentages in relation to effort 1. (Effort x / Effort 1) x 100.

Example with Effort 1 selected

	Effort 1	Effort 2	Effort 3	Effort 4
Real value of FEV 1%	3.49	3.70	3.77	3.46
Relative value of FEV 1% as displayed in trends	100%	106%	108%	99%

To view trends:

1. Select three parameters from the drop down menus located beneath the Trends graph. The curve for these parameters is displayed in the Trends graph.
2. Select or deselect efforts by checking the boxes beneath the efforts listed in the parameters area. The efforts are added or removed from the Trends graph.
3. Select which effort is used as the reference point, by clicking on one of the efforts located in the parameters area. The parameter value of this effort is set to 100% in the graph, and the parameter values of all other efforts are expressed as a percentage proportional to the reference value. The percentage of deviation is given in the parameters area.
4. You can select a line from the Trends graph by clicking on one of the points in the line. The percentage deviation for each point is shown when you move the mouse over a point in the line. By clicking on a different colored point you select the line of that color and the percentage deviation for that line is displayed when moving over the points of that line.

Effort	ATS	Selected	FVC	FEV1	FEV1%	FEV3	FEV6	PEF
Units	-		L	L	%	L	L	L/s
ECCS/Quanjer 1993	-		4.73	3.90	80 %	-	-	0.00
Post 10:19:33 AM Albuterol, 5 kg	No	<input checked="" type="checkbox"/>	2.98	2.82	95 %	2.98	2.98	8.79
% Change			-	-	-	-	-	-
Pre 10:18:27 AM	No	<input checked="" type="checkbox"/>	2.99	2.47	83 %	2.99	2.99	6.78
% Change			0.4 %	-12.5 %	-12.9 %	0.4 %	0.4 %	-22.9 %
Pre 10:18:11 AM	No	<input checked="" type="checkbox"/>	2.97	2.58	87 %	2.97	2.97	10.50
% Change			-0.1 %	-8.8 %	-8.7 %	-0.1 %	-0.1 %	19.4 %
Pre 10:17:51 AM	No	<input checked="" type="checkbox"/>	2.94	2.94	100.00	2.94	2.94	11.24
% Change			-1.1 %	4.2 %	5.3 %	-1.1 %	-1.1 %	27.8 %
Pre 10:17:34 AM	No	<input checked="" type="checkbox"/>	2.99	2.63	87.84	2.99	2.99	3.62
% Change			0.5 %	-7.0 %	-7.5 %	0.5 %	0.5 %	-58.8 %
Final	-		2.94	2.94	100.00	2.94	2.94	11.24
Final%Pred	-		62 %	75 %	125 %	-	-	122 %

Measurements Tab

FVC	SVC	MVV	Trend	Measurements	FVC Pre 1	FVC Pre 2	FVC Pre 3	FVC Pre 4	FVC Post 1	FVC Post 2	FVC Post 3	SVC Post 5	MVV Post 7	Final
Efforts	Units	GLJ 2012 (LLN)												
FVC	L	4.10(3.07)			6.68	6.82	6.33	6.80	5.45	5.69	6.27	-	-	6.62
FEV1	L	3.15(2.31)			6.24	6.43	6.20	6.31	5.30	5.53	6.03	-	-	6.43
FEV1%	%	76.9(64.0)			93.4%	94.4%	97.8%	92.9%	97.4%	97.3%	96.2%	-	-	94.4%
FEV1/FVC	%	76.9(64.0)			93.4%	94.4%	97.8%	92.9%	97.4%	97.3%	96.2%	-	-	94.4%
FEV0.5	L	-			4.87	4.91	4.82	4.89	4.38	4.57	4.77	-	-	4.91
FEV2	L	-			6.67	6.80	6.33	6.70	5.40	5.67	6.23	-	-	6.60
FEV3	L	-			6.67	6.82	6.33	6.73	5.41	5.67	6.24	-	-	6.62
FEV5	L	-			6.67	6.82	6.33	6.74	5.43	5.68	6.26	-	-	6.62
FEV6	L	-			6.68	6.82	6.33	6.75	5.44	5.68	6.27	-	-	6.62
FEV0.5%	%	-			72.9%	72.0%	76.1%	72.0%	80.4%	80.4%	76.1%	-	-	72.0%
FEV2%	%	-			99.8%	99.8%	100.0%	98.6%	99.1%	98.8%	99.4%	-	-	99.6%
FEV3%	%	-			99.9%	100.0%	100.0%	99.1%	99.2%	98.8%	99.6%	-	-	100.0%
FEV5%	%	-			99.9%	100.0%	100.0%	99.2%	99.7%	99.9%	99.9%	-	-	100.0%
FEV6%	%	-			100.0%	100.0%	100.0%	99.3%	99.6%	100.0%	100.0%	-	-	100.0%
FEV1/FEV6	%	-			93.4%	94.4%	97.8%	93.5%	97.5%	97.4%	96.2%	-	-	94.4%
PEF	L/s	-			13.75	13.97	14.16	13.87	14.13	13.65	13.15	-	-	13.87
PEF25	L/s	-			12.77	12.89	13.16	13.43	13.75	13.19	13.15	-	-	12.89
PEF50	L/s	-			8.36	8.36	8.91	8.34	9.19	9.73	8.60	-	-	8.36
PEF75	L/s	-			0.71 (0.27)	4.56	4.76	4.79	4.40	3.91	4.54	4.67	-	4.76
MEF25	L/s	-			0.71 (0.27)	4.56	4.76	4.79	4.40	3.91	4.54	4.67	-	4.76

The Measurements Tab contains a number of parameter values for each FVC, SVC and MVV efforts. Each effort is represented by a separate column.

- The measurement table only displays the efforts belonging to the selected stage. It only lists the parameters selected in the settings.
- Information on test reproducibility is displayed in the reproducibility table that is placed below the measurements table. In particular, the FVC and FEV1 absolute value variance (difference) between the best effort and the second best effort is analyzed for both pre and post tests.
- When a value is in bold red text, that value is below the lower prediction limit.

Interpreting Spirometry Tests

The spirometry module can automatically interpret FVC efforts by offering interpretations based on testing parameters.



WARNING A computer generated interpretation cannot replace sound medical reasoning by a trained professional. Therefore, a physician should always review the interpretation.

Editing and Confirming an Interpretation

To open the interpretation editor, select **Interpretation** on the toolbar of the review window.

Save Cancel Clear Date/time Best Effort FVC Interpretation Comment	
<ul style="list-style-type: none"> Medications Interpretation 	<p>Pre: FVC= 2.03L FEV1= 1.76L FEV1%= 86.5% [1.76/2.03 FEV1/FVC] (12/10/2007 12:04:39 PM), Moderate restriction</p> <p>Post: FVC= 2.0L (-2.8%); FEV1= 1.8L (3.0%); FEV1%= 91.7% [1.81/1.98 FEV1/FVC] (6.0%) (12/10/2007 12:18:25 PM), Moderate restriction</p> <p>Comment: PNEUMONITIS</p>

In the Interpretation editor, text or interpretation statements can be added to the interpretation area.

Automatically Generated Interpretation:

- The generated interpretation is shown in the interpretation editor automatically. You can keep this interpretation, add text to it, or replace it. The automatic interpretation statements can be inserted by clicking the Best Effort FVC Interpretation button.

To add comments to the interpretation, click in the comment pane and start typing the comment.

To add text to the interpretation edit area, click in the interpretation edit area and start typing the text.

Adding an interpretation statement to the interpretation edit area using the statement tree:

1. Select a category to display the statements.
2. In the statement tree look up the statement to include in the interpretation.
3. Click on the statement to add it to the interpretation edit area.

To delete an interpretation statement from the interpretation edit area, select the statement text and press Backspace or DEL.

To delete a comment from the comment pane, select the comment and press Backspace or DEL.

Tips for Editing and Confirming an Interpretation

- Automatically insert the current date and time by selecting the **Date/time** button.
- Clear the interpretation editor by selecting the **Clear** button.
- The statement tree can be changed. Please consult your system administrator or local dealer for new or changed statements.

Automatic Interpretation

The spirometer module automatically calculates interpretive results as described in the document noted in reference 2.

The automatic interpretation is shown in the interpretation area if the interpretation is not confirmed. If the interpretation is confirmed it is shown in the interpretation area.

Reanalyze a Spirometry Test

Retrieve overwritten automatic interpretations by reanalyzing the spirometry test.

To Reanalyze a Spirometry Test:

- In the spirometry application go to the Settings Menu
- Select **Reanalyze test**.

Reanalyzing the test will result in the following:

- All user entered text in the interpretation area is deleted.
- The automatic interpretation statements are replaced with the original interpretation.

Recalculate Prediction

To recalculate a prediction:

1. In the spirometry application go to the Settings menu
2. Select **Recalculate Prediction**.
3. Select the preferred prediction norm from the list.
4. Press **OK**.

Complete the Editing Process

Once analysis and editing is complete, the exam can be saved to the database. The system can be configured to automatically export results or print reports based on the status of the exam – Acquired, Edited, Reviewed or Signed. Refer to the Welch Allyn Diagnostic Cardiology Suite Manager user manual for more information.

- Select **Save** to complete the editing process and return to the Exam Review list
 - The exam is saved with an Acquired status if not previously marked as reviewed or signed.
 - The exam is saved with an Edited status if any changes have been made after data acquisition, such as editing the interpretation.
- Select **Review** to mark the ECG status as reviewed and return to the Exam Review list.
 - User is prompted to enter the reviewer's name.
- Select **Sign** to mark the ECG status as signed and return to the Exam Review list.
 - User is prompted to enter signer's name or signer's credentials if legal signature is enabled.

Printing Spirometry Reports

Report Viewer

To print a test report, select the print icon from the spirometry display screen, or select an exam in the Exam Search and select **Print**.

Report Viewer

Report Type

- All Plus Best Efforts
- Social Security
- Measurements PVC
- Measurements SVC
- Best FVC
- Best SVC
- Best MVV
- Best Three FVC
- Trend

Connex Cardio
Demo1, Frank
12/10/2007 12:04:07 PM
Best FVC

Patient Information

First Name: Frank Last Name: Demo1
 Patient ID: 98972
 Gender: Male Race: Caucasian
 DOB: 5/18/1952 Age: 55 Years
 Height: 66 in Weight: 255 lb
 Smoking: No Asthma: No
 Cooperation: ---

Test Information

Pre Time: 12:04
 Post Time: 12:16
 Protocol Ref: IMANES03 1999

Quality Messages:
 Pre: 3-Blow out longer, No Plateau
 Post: 8-Blast out faster

Test Result

FEV1 %Pred: 76%
 FEV1 %: 86.52 %
 Improvement: FVC 97%, FEV1: 103% (Post / Pre) * 100

FEV1 Pre / PostVar: 95 ml (5 %) / 149 ml (8 %)
 FVC Pre / PostVar: 73 ml (4 %) / 19 ml (1 %)
 ATS Reproducibility:
 Pre: ---
 Post: ---

Test Interpretation

UNCONFIRMED REPORT
 Pre: FVC > 2.0L, FEV1 > 1.7L,
 FEV1% > 80.5% (1.755 L) FEV1/FVC
 (12/10/2007 12:04:39 PM), Moderate restriction
 Post: FVC > 2.0L (> 2.8%), FEV1 > 1.8L (3.0%),
 FEV1% > 91.7% (1.915 L) FEV1/FVC (6.0%),
 (12/10/2007 12:10:25 PM), Moderate restriction

Text Comment

PNEUMONITIS

Spirometry Summary

Parameter	Units	Pred (LLN)	Best Effort		%Change
			3Pre	3Post	
FVC	(L)	3.02 (2.37)	2.57	1.97	65%
FEV1	(L)	2.12 (1.70)	1.70	1.81	10%
FEV1%	(%)	73 (86)	86.52	91.7	11%
PEF	(L/s)	5.91 (4.81)	5.3	5.06	8%
FEF50	(L/s)	-	3.68	3.46	-
FEF25%	(L/s)	2.18 (1.50)	2.82	2.2	14%

UNCONFIRMED REPORT. See notes, CPDS. Page 1 of 2
 Last Calibration: 12/10/2007 7:46:40 AM

Icon toolbar

Use the printer icon to open a Windows printer dialog and choose defined printers with properties, print range, and number of copies. To print the report, select **OK**.

Use the magnifying glass icon to choose Auto to fit the window or a percentage size for display.

Use the page icons to select a single-page or two-page preview.

The number of report pages is shown as xx / xx (displayed page number per total pages). The red arrow keys allow you to preview the next page or the previous page, as well as move to the last page or the first page.

Print report formats

Use the checkboxes at the left of the display to choose report formats for inclusion or exclusion in the final printout. Select the arrows in the bottom left corner of the display to refresh the displayed report after a change is made.

The spirometry module prints the following report formats:

- All plus best effort FVC
- Best FVC
- Best MVV
- Best SVC
- Best Three FVC
- Measurements MVV
- Measurements SVC
- Measurements FVC
- Social Security
- Trend


Each format contains the patient's personal information, test information, interpretation, and parameter table. All but the measurement report contains a graphs section.

Exit the Print Preview

Click on the red X to close the report preview and return to the previous display.

Print Report Details

Example Report



Connex Cardio
Demo1, Frank

Best FVC
12/10/2007 12:04:07 PM

Patient Information

First Name: Frank Last Name: Demo1
 Patient ID: 583732
 Gender: Male Race: Caucasian
 DoB: 5/18/1952 Age: 55 Years
 Height: 68 in Weight: 205 lb
 Smoking: No Asthma: No
 Cooperation: ---

Test Information

Pre Time: 12:04
 Post Time: 12:16
 Predicted Ref: NHANESIII 1999

Quality Messages:
 Pre: 3-Blow out longer, No Plateau
 Post: 8-Blast out faster

Test Result

FEV1 %Pred: 76%
 FEV1%: 86.52 %
 Improvement: FVC: 97%, FEV1: 103% (Post / Pre) * 100

FEV1 Pre / Post Var: 95 ml (5 %) / 149 ml (8 %)
 FVC Pre / Post Var: 73 ml (4 %) / 19 ml (1 %)
 ATS Reproducibility:
 Pre: ---
 Post: ---

Test Interpretation

UNCONFIRMED REPORT
 Pre: FVC= 2.03L FEV1= 1.76L
 FEV1%= 86.5% [1.76/2.03 FEV1/FVC]
 (12/10/2007 12:04:39 PM), Moderate restriction

Post: FVC= 2.0L (-2.8%); FEV1= 1.8L (3.0%);
 FEV1%= 91.7% [1.81/1.98 FEV1/FVC] (6.0%)
 (12/10/2007 12:18:25 PM), Moderate restriction

Test Comment

PNEUMONITIS

Spirometry Summary

Parameter	Units	Pred (LLN)	Best Effort				%Change
			1.Pre	%Pred	2.Post	%Pred	
FVC	(L)	3.02 (2.37)	2.03*	67%	1.98*	66%	97% (-0.06)
FEV1	(L)	2.32 (1.78)	1.76*	76%	1.81	78%	103% (0.05)
FEV1%	(%)	78 (68)	86.52	111%	91.7	115%	106% (5.18)
PEF	(L/s)	5.91 (4.31)	5.3	90%	5.05	85%	95% (-0.25)
PEF50	(L/s)	-	3.68	-	3.46	-	94% (-0.22)
PEF25-75	(L/s)	2.18 (1.03)	2.82	129%	3.2	147%	113% (0.38)

(*) Means below LLN

UNCONFIRMED REPORT

Last Calibration: 12/10/2007 7:45:40 AM Hospital name here...

Device info: CP200

Page 1 of 2

Report Area

- Date and time of Pre and Post efforts.
- Norm profile used to calculate predicted values.

Test Information:

Pre Time: 11:59 AM
 Post time: 12:07 PM
 Norm Reference: NHANESIII 1999

- For each selected Pre and Post effort, this section provides quality indication regarding individual effort acceptability.

Quality Messages:

Pre: 4-Blow out longer, 2-Blow out longer, 1-Blow out longer,
 Post: 7-Blow out longer, 6-Blow out longer, 5-Blow out longer,

- Variance of best FVC and FEV1 in Pre and Post phases. ATS standards require this variance to be <150 mL.
- Indication of Pre and Post effort repeatability being met.
- If criteria is not met, the reason why is provided.

FEV1 Pre / Post Var: 79 ml (4 %) / 10 ml (0 %)
 FVC Pre / Post Var: 138 ml (5 %) / 32 ml (1 %)
 ATS Reproducibility:
 Pre: NOT MET (< 3 acceptable efforts)
 Post: NOT MET (< 3 acceptable efforts)

- Main results of the spirometry test.
- Settings influence the amount of information shown here.

Test Results:

Lung age: 63 years
 FEV1%Pred: 101 %
 FEV1%: 77%
 Improvement: FVC: 95%, FEV1: 97% (Post / Pre) * 100
 Not Significant BD Response

- Spirometry interpretation area.

Test interpretation: UNCONFIRMED REPORT

Pre: FVC= 2.64L FEV1= 2.07L
 FEV1%= 77.5% 2.07/2.67 FEV1/Max(FVC, FIVC, SVC)
 (11/15/2007 12:01:34 PM), Within normal limits

Post: FVC= 2.5L (-5.4%); FEV1= 2.0L (-3.5%); FEV1%= 71.0% (-8.4%)
 (11/15/2007 12:08:51 PM), Within normal limits

- Tabular presentation of a subset of measurement data.

Parameter	Units	Pred (LLN)	Best Effort				%Change
			4. Pre	%Pred (z)	7. Post	%Pred (z)	
FVC	(L)	2.62 (1.88)	2.64	101% (0.04)	2.50	95% (-0.27)	-5% (-0.14)
FEV1	(L)	2.02 (1.45)	2.07	102% (0.13)	1.99	99% (-0.08)	-3% (-0.07)
FEV1/FVC	(%)	78 (64)	78	101% (0.06)	80	103% (0.27)	2% (2)
FEV6	(L)	-	2.64	-	2.50	-	-5% (-0.14)
PEF	(L/s)	-	7.81	-	7.13	-	-9% (-0.69)
FEF25-75	(L/s)	1.69 (0.75)	1.75	103% (0.08)	1.75	104% (0.09)	0% (0.01)

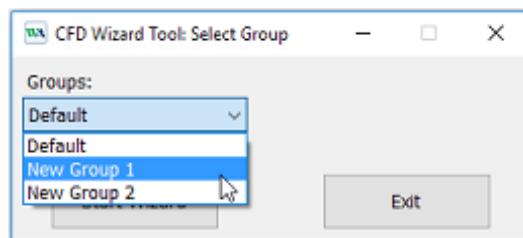
Configure the Report

It is possible to make minor customizations to reports. This includes:

- Adding a custom logo to the report
- Enabling and disabling report sections
- Adding a practice name to the report

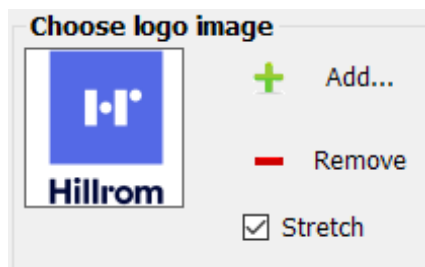
To make these customizations open the Windows start menu, navigate to the Hillrom folder and launch the Report Configuration Tool.

From the Groups dropdown, select which group of patients and orders the customizations will apply to. Note: For more information on user group configuration refer to the Manager user manual.



Navigate to the **Choose a report** dropdown and select **Spirometry**.

Add a Custom Logo to the Report



The default logo on the report is the Hillrom logo. To add a custom logo select **Add** and navigate to the image that is to be used. Select **Stretch** to scale the selected image to fit the area. Select **Remove** to remove any image from the report.

Enabling and Disabling Report Sections

Each report section is listed in the Report Configuration Tool. To prevent any of these sections from appearing in the Report Viewer select the checkbox in the Hide column next to the report section. After selecting this, when the report is generated by the Spirometry modality it will not be possible to select this report section.

Add Practice Name

Filling in the Practice Name field will cause the entered test to appear on a generated report.

Select **Next** and **Finish** when done customizing the report.

Predictions

Norm Profiles

Each predictive norm supports a particular subset of parameters and covers a specific population, as detailed in the profile charts below.

		Norm Name													
		Berglund 1963	Crapo 1981	Dockery 1983	ECCS/Quanjer 1993	ECCS/Solymar (1993/1980)	ECCS/Zapletal (1993/1967)	Falaschetti	Forche II 1988**	GLI 2012	Langhammer 2001	Hedenstrom 1986	Hedenstrom/Solymar (1986/1980)	Hibbert 1989	Hsu 1979
Parameters Studied	FVC	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	FEV1	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	FEV1%	X	X		X	X*	X*	X	X	X	X	X	X*	X	X
	FEV0.5		X												
	FEV3		X												
	FEV3%		X												
	FEV6														
	FEV1/FEV6														
	PEF				X	X	X		X		X	X	X	X	X
	FEF25-75		X		X	X*	X*		X		X	X	X	X	X
	FEF75				X	X	X		X			X	X	X	X
	FEF50				X	X	X		X			X	X	X	X
	FEF25				X	X	X		X			X	X	X	X
	FEF0.2-1.2														
	FEV0.5%														
	MVV														
SVC											X	X			
Gender	Male	X	X	X	X	X	X	X		X	X	X	X	X	X
	Female	X	X	X	X	X	X	X		X	X	X	X	X	X
Age	Pediatric		No	6-11	No	7-18	6-18	No	M: 5-17 F: 5-15		No	No	7-18	8-19	7-20
	Adult	≤ 70	M: 15-81 F: 17-84	No	18-70	19-70	19-70	16-75	M: 18-80 F: 18-80	FVC: ≤ 95 FEV1: ≤ 95 FEF: ≤ 90	20-80	20-70	20-70	No	No
Height (cm)			M: 157-194 F: 146-178	110-160	M: 155-195 F: 145-180	M*: 155-195 F*: 145-180	Mchild: 118-181 Madult: 155-195 Fchild: 107-173 Fadult: 145-180		Mchild: 109-196 Madult: 144-200 Fchild: 110-182 Fadult: 140-190			M: 160-196 F: 146-183	M*: 160-196 F*: 146-183	M: 120-190 F: 120-176	M: 111-200 F: 111-180
Weight (kg)			M: 60-111 F: 44-105									M: 55-109 F: 45-94	M*: 55-109 F*: 45-94		
Race	Caucasian	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	Black			X	X	X*	X*			X					X
	Hispanic														
	Asian				X	X*	X*			X					X
	Native American														

*adult population only

**Caution: Pediatric use in the US ≥ 12 years old

		Norm Name													
		Knudson 1976	Knudson 1983	Koillinen 1998	Kory 1961	Morris 1971	NHANES III 1999	Polgar 1971**	Roca 1986	Schoenberg 1978	Solymar 1980	Viljanen 1981	Wang 1993	Zapletal 1969	Composite
Parameters Studied	FVC	X	X	X	X	X	X	X	X	X	X	X	X	X	
	FEV1	X	X	X	X	X	X	X	X	X	X	X	X	X	
	FEV1%	X	X	X			X		X	X	X	X		X	
	FEV0.5			X	X									X	
	FEV3													X	
	FEV3%													X	
	FEV6						X							X	
	FEV1/FEV6						X							X	
	PEF	X		X			X	X	X	X	X	X		X	X
	FEF25-75	X	X			X	X	X	X	X	X		X		X
	FEF75	X	X						X	X	X	X		X	X
	FEF50	X	X	X					X	X	X	X		X	X
	FEF25	X								X				X	X
	FEF0.2-1.2					X									X
	FEV0.5%			X											
MVV				X											
Gender	Male	X	X	X	X	X	X	X	X	X	X	X	X	X	
	Female	X	X	X	No	X	X	X	X	X	X	X	X	X	
Age	Pediatric	≥8	≥6	6-16	No	No	≥8	3-19	No	M: 7-17 F: 7-14	7-18	No	6-18	6-18	No
	Adult	≤90	M: <85 F: ≤88	No	18-66	20-84	≤80	No	20-70	M: 18-99 F: 15-99	No	18-65	No	No	M: 20-70 F: 20-70
Height (cm)			M: 112-196 F: 107-183					110-170						M: 118-181 F: 107-173	M: 155-195 F: 145-180
Weight (kg)															
Race	Caucasian	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	Black						X		X			X			
	Hispanic						X								
	Asian														
	Native American														

**Caution: Pediatric use in the US ≥ 12 years old

Norm-Related Clinical Studies

Each of the following studies provides expected values for various spirometric parameters by measuring significant samples of a specific population.

Berglund 1963	Spirometric Studies in Normal Subjects. I. Forced Expirograms in Subjects 7-70 Years of Age, Berglund E., et. al., Acta Medica Scandinavica, vol. 173(2): 185-192, 1963.
Crapo 1981	Reference Spirometric Values using Techniques and Equipment that Meet ATS Recommendations, Crapo RO, et. al., American Review of Respiratory Disease 1981, 123:659-664.
Dockery 1983	Distribution of Forced Vital Capacity and Forced Expiratory Volume in One Second in Children 6-11 Years of Age, Dockery DW, et. al., American Review of Respiratory Disease 1983, 128:405-412.
ECCS/Quanjer 1993	Lung Volumes and Forced Ventilatory Flows: Official Statement of the European Respiratory Society, Quanjer Ph. H., et. al., European Respiratory Journal, 1993, vol. 6, Suppl. 16: 5-40.
Falaszchetti 2004	Prediction equations for normal and low lung function from the Health Survey for England, Falaszchetti E., et.al., European Respiratory Journal, 2004, 23: 456-463
Forche II 1988	Neue spirometrische Bezugswerte für Kinder, Jugendliche und Erwachsene; Forche G., Harnoncourt K., Stadlober E.; Österreichische Ärztezeitung 43, 15-16, 1988.
GLI 2012	Multi-ethnic reference values for spirometry for the 3-95 year age range: the global lung function 2012 equations. Quanjer, P.H., Stanojevic, S., Cole, T.J., Baur, X., Hall, G.L., Enright, P.L., Hankinson, J.L., Ip, M.S., Zheng, J., Stocks, J. on behalf of the ERS Global Lung Function Initiative. (2012), European Respiratory Journal, 2012; 40: 1324–1343.
Langhammer 2001	Forced Spirometry Reference Values for Norwegian Adults: The Bronchial Obstruction in Nord-Trøndelag Study, Langhammer A., Gulsvik A., et. al., European Respiratory Journal 2001, 18: 770-779.
Hedenström 1986	Reference Values for Lung Function Tests in Men: Regression Equations With Smoking Variables, Hedenström, H. et. al., Upsala Journal of Medicine Science 91:299-310, 1986. Reference Values for Lung Function Tests in Females: Regression Equations With Smoking Variables, Hedenström, H. et. al., Bull. Eur. Physiopathol. Respir. 1985, 21, 551-557.
Hibbert 1989	Lung function values from a longitudinal study of healthy children and adolescents. Hibbert ME, Lanigan A., Landau LI, Phelan PD, Pediatric pulmonology, 7:101-109, 1989.
Hsu 1979	Ventilatory Functions of Normal Children and Young Adults—Mexican-American, White and Black. I. Spirometry, Katharine HK Hsu, et. al., The Journal of Pediatrics; volume 95(1):14-23, July 1979.
Knudson 1976	The Maximal Expiratory Flow-Volume Curve. Normal Standards, Variability, and Effects of Age, Ronald J. Knudson, Ronald C. Slatin, Michael D. Lebowitz, and Benjamin Burrows. American Review of Respiratory Disease, volume 113: 587-600, 1976.
Knudson 1983	Changes in the Normal Maximal Expiratory Flow-Volume Curve With Growth and Aging, Ronald J. Knudson, et. al., American Review of Respiratory Disease 1983 127: 725-734.

Koillinen 1998	Terveiden suomalaislasten spirometrian ja uloshengityksen huippuvirtauksen viitearvot, Hannele Koillinen, et. al., Suomen Laakarilehti, 1998, 5 vsk 53, p. 395-402.
Kory 1961	The Veterans Administration-Army Cooperative Study of Pulmonary Function. I. Clinical Spirometry in Normal Men, Kory RC, et. al., American Journal of Medicine, February 1961, 243-258.
Morris 1971	Spirometric Standards for Healthy Nonsmoking Adults, James F. Morris, et. al., American Review of Respiratory Disease, 103: 57-67, 1971.
NHANES III 1999	Spirometric Reference Values from a Sample of the General U.S. Population, John L. Hankinson, John R. Odencrantz, and Kathleen B. Fedan, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Morgantown, West Virginia, 1999. The Third National Health And Nutrition Examination Survey (NHANES III). Am J Respir Crit Care Med Jan 1999; 159:179-187.
Polgar 1971	Pulmonary Function Testing in Children: Techniques and Standards, Polgar G. and Promadhat V. Philadelphia, WB Saunders, 1971.
Roca 1986	Spirometric Reference values from a Mediterranean population, J. Roca, J. Sanchis, A. Agusti-Vidal, F. Segarra, D. Navajas, R. Rodriguez-Roisin, P. Casan, S. Sans. Bull. Eur. Physiopathol. Respir. 1986, 22, 217-224
Schoenberg 1978	Growth and Decay of Pulmonary Function in Healthy Blacks and Whites, Janet B. Schoenberg, Gerald J. Beck, and Arend Bouhuys, Respiration Physiology, 1978, 33, 367-393.
Solymer 1980	Nitrogen Single Breath Test, Flow-Volume Curves and Spirometry in Healthy Children, 7 -18 Years of Age, L. Solymer, P. H. Aronsson, B. Bake, and J. Bjure. European Journal of Respir. Dis. 1980, 61:275-286.
Viljanen 1981	Spirometric Studies in Non-smoking, Healthy Adults, AA Viljanen, et. al., The Scandinavian Journal of Clinical Lab Investigation, 41 supplement 159, 5-20, 1981.
Wang 1993	Wang X, Dockery DW, Wypij D, Fay ME, Ferris BG Jr., Pulmonary function between 6 and 18 years of age. Pediatric Pulmonology 1993; 15: 75-88.
Zapletal 1969	Maximum Expiratory Flow-Volume Curves and Airway Conductance in Children and Adolescents, A Zapletal, EK Motoyama, KP Van De Woestijne, VR Hunt and A. Bouhuys, Journal of Applied Physiology, vol. 26, no. 3:308-316, March 1969.

Norm Extrapolation

Extrapolation is the practice of applying a norm's formula to a patient whose profile doesn't fit that norm's profile. For example, if you were testing an 88-year-old man, and the primary (selected) norm was based on males 85 or younger, the predicted values are extrapolated values.

- When it takes place, extrapolation is indicated in the test record.
- Pediatric norms do not provide any age, weight, or height extrapolation.
- Adult norms allow extrapolation of age up, but not down.
- Adult norms allow extrapolation of height, weight, up and down.

Composite Norm Values

When the composite norm is selected, predictive parameter values are filled in from one of the alternative (composite) norm sources listed here.

NHANESIII	FVC, FEV1, FEV1%, FEV6, FEV1/FEV6, FEV6/FVC, PEF, FEF25-75
Crapo 1981	FEV0.5, FEV3, FEV3/FVC
Morris 1971	FEF0.2-1.2
ECCS/Quanjer 1993	FEF25, FEF50, FEF75

Note If an adult norm is selected but pediatric patient data is used – no prediction value will be calculated and displayed.

The following combinations of norms are supported:

Prediction Norm	Age Range	Composite Norm
Solymer	7-18	ECCS/Solymer
ECCS	19-70	
Zapletal	6-18	ECCS/Zapletal
ECCS	19-70	
Solymer	7-18	Hedenström/Solymer*
Hedenström	20-70	

*The Composite of Hedenstrom/Solymer cannot be used for age 19

For a listing of the parameters included in each norm, see Norm Profiles.

Lung Age

Lung age is a calculated value based on a patient's demographics and spirometric performance. This provides a relative indication of the health of the patient's lungs. This value is used primarily to encourage smoking cessation.

The spirometer calculates lung age values according to the document cited in Reference 4 (Morris, 1985). For single-effort tests, lung age is based on the current effort. Otherwise, it is based on the patient's best pre effort as defined in the settings.

Lung age calculations are provided only for patients 20 and older. For patients older than 84 years the lung age is extrapolated. This limitation is derived from the subject population on which Morris based his research. The lung age is one floating point number in years: the average of the 4 formulas in the Morris article (FVC, FEV1, FEF25-75%, and FEF0.2-1.2). Specifically, lung age is calculated as follows:

Gender Lung Age Formula

Men	$[5.920 (\text{height}) - 40.000 (\text{FVC}) - 169.640 +$
-----	--

Gender Lung Age Formula

$$\begin{aligned} &2.870 (\text{height}) - 31.250 (\text{FEV1}) - 39.375 + \\ &2.319 (\text{height}) - 21.277 (\text{FEF200-1200}) + 42.766 + \\ &1.044 (\text{height}) - 22.222 (\text{FEF25\%-75\%}) + 55.844] / 4 \end{aligned}$$

Women

$$\begin{aligned} &[4.792 (\text{height}) - 41.667 (\text{FVC}) - 118.833 + \\ &3.560 (\text{height}) - 40.000 (\text{FEV1}) - 77.280 + \\ &4.028 (\text{height}) - 27.778 (\text{FEF200-1200}) - 70.333 + \\ &2.000 (\text{height}) - 33.333 (\text{FEF25\%-75\%}) + 18.367] / 4 \end{aligned}$$

Note height in inches

Ethnic Group Correction

Studies have demonstrated that expected values for certain spirometric parameters can vary significantly from one ethnic group to another. Some norm studies include separate regression equations for different races but most others do not.

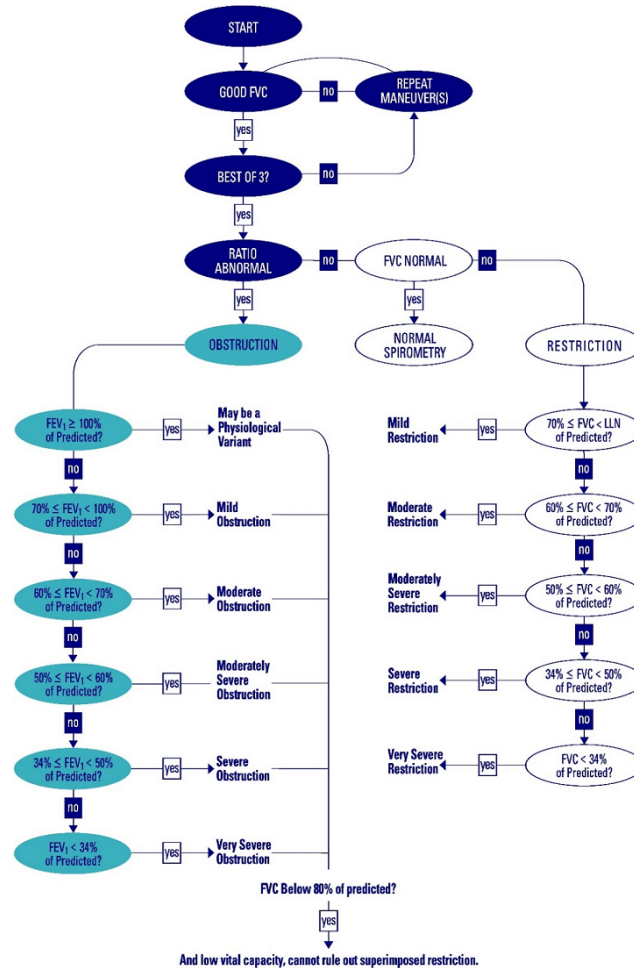
In the latter case Welch Allyn CardioPerfect applies ethnic group correction to all non-Caucasian adult patients in the prediction formulas. The interpretation area will state if the norm values are extrapolated. The ATS (for blacks) or NIOSH (for Asians) recommendations will be used for extrapolation.

Race Choices	FVC & FEV1	Recommendation Source
Caucasian	No adjustment	-
Black	88%	ATS
Asian	94%	NIOSH
Hispanic	No adjustment	None found
Native American	No adjustment	None found

Note Race adjustment applies for adults only and applies to all supported parameters within the norm study. If a race adjustment percentage is used, the same adjustment is applied to the LLN value.

Understanding Interpretation Results

The following diagram illustrates the process of collecting and interpreting spirometry data.



Acceptability of an Effort

An individual effort is deemed acceptable by the Spirometry software when:

The effort has a good start:

- extrapolated volume <5% of FVC or 150 mL, whichever is greater.

If this criterion is not met, the effort-quality message "Don't hesitate" or "Blast out faster" displays.

The effort exhibits satisfactory exhalation:

- duration ≥ 6 seconds (≥ 3 seconds for children under 10 years of age), OR
- a 1 second plateau in the volume-time curve occurs

If this criterion is not met, then the effort-quality message "Blow out longer, No plateau" displays.

See the Effort-Quality Message table below for further detail.

Effort - Quality Message	Criteria
Don't hesitate	Back Extrapolated Volume (BEV) is > 150 mL
Blast out faster	PEF time > 120 ms.
Blow out longer, No plateau	FET < 6 seconds (3 pediatrics) and no plateau
Good effort	FET < 6 seconds (3 pediatrics) and has plateau or FET is > 6 seconds (3 seconds pediatrics)

In addition, the clinician administering the test should assess the effort for signs of:

- cough during the initial second
- glottis closure
- early termination
- effort that is not maximal throughout
- leak
- obstructed mouthpiece

Refer to the effort acceptability poster that shipped with your product for examples of efforts that are acceptable. The poster also contains examples of inaccurate results. Delete any efforts exhibiting signs of inaccurate results.

Reproducibility of a Test Stage

Within a test stage, (i.e. either Pre or Post medication), an assessment will be made of the acceptability and reproducibility of the overall test stage. The test stage will be deemed by the software to be acceptable if:

- there are at least 3 acceptable efforts

and reproducible if:

- within the 3 acceptable efforts, the best two FVC measurements and the best two FEV1 measurements are within 150 mL

Reversibility (Bronchodilator Response)

For any spirometry test that has Pre and Post efforts, significance of the BD response will be shown in the interpretation text area, stating either "Not Significant BD Response" or "Significant BD Response" as appropriate.

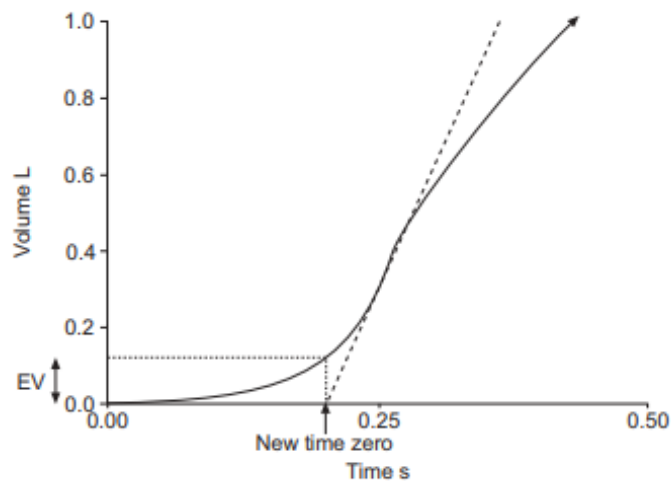
The Spirometry software will deem the bronchodilator response to be significant if either FVC or FEV1:

- Show an increase from Pre to Post of 12% or more, AND
- Have an absolute increase from Pre to Post of 200 mL or more.

Time Zero Calculation

Time zero is the point of intersection on the time axis of a line drawn on the volume time trace through the point of peak expiratory flow (PEF) with a slope equal to the peak

expiratory flow. The Spirometry application finds time zero by taking the largest slope averaged over an 80-ms period at the beginning of an effort, and extrapolation the slope to find the x-intercept, which equals time zero.



Z-score

For norms that support calculation of the z-score, this value will be shown together with the % Predicted values.

References

1. Disability Evaluation Under Social Security (the "blue book"), Social Security Administration SSA publication number 64-039, Office of Disability Programs ICN 468600, January 2003. See in particular the calibration and reporting sections of this document.
2. Lung Function Testing: Selection of Reference Values and Interpretive Results, American Thoracic Society, March 1991. This document describes the methods of selecting the reference values and the algorithm for interpretive results.
3. National Occupational Respiratory Mortality System, National Institute for Occupational Safety and Health (NIOSH).
4. Short Report Spirometric "Lung Age" Estimation for Motivating Smoking Cessation, James F. Morris, M.D., and William Temple, Preventive Medicine 14, 655-662, 1985.
5. ATS/ERS Task Force: Standardisation of Lung Function Testing, European Respiratory Journal, Volume 26 Number 2, 319-338, 2005. This document describes the methods of acquiring the output parameters and the required accuracy. For details on ATS/ERS acceptability criteria, see these sections:
 - a. "Start of Test Criteria," page 324
 - b. "Manoeuvre repeatability," page 325
6. Standardized Lung Function Testing, European Respiratory Journal, volume 26, supplement number 16, April 2005.
7. U.S. Pulmonary Function Standards for Cotton Dust Standard, 29 CFR 1910.1043, Appendix D.
8. Lung Function Testing: Selection of reference values and interpretive strategies. American Thoracic Society, American Review of Respiratory Disease, 144:1202-1218 (1991).

9. Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans, EN ISO 26782:2009, NSAI Standards, 2009.

Maintaining the Spirometer

Maintaining the sensor

The spirometer sensor needs little maintenance to stay in good working condition.



WARNING Change the flow transducer for each patient.



CAUTION Perform the following inspections daily:

- Check that all connections are properly aligned and tight.
- Visually check the pressure tubing for leaks and kinks.
- Check for irreversible bending or compression of the pressure tubing between flow transducers and device.

Ensure the spirometer is calibrated and that the proper lot code and calibration code is used. The lot code and calibration code can be found on the flow transducer package. For more information please refer to the calibration section of this manual.



CAUTION Avoid placing the spirometer and any of its components in direct sunlight or in a dusty environment. To make reliable recordings, calibrate the sensor on a daily basis. Keep track of the calibrations in the calibration log.

Cleaning the spirometer





WARNING Satisfactory maintenance procedures must be implemented, or equipment failure and health hazards may result. Only qualified service personnel should repair the equipment. To prevent cross-contamination, do not try to clean the flow transducers and nose clips. Discard these items after a single patient use. Wear gloves when replacing flow transducers, and wash hands after touching them.



CAUTION

- Do not clean the pressure tubing or sensor. Trapped moisture could affect accuracy.
- Do not use aromatic hydrocarbons, rubbing alcohol, or solvents on the spirometer.
- Replace the pressure tubing if it becomes visibly soiled, is known to be contaminated with blood or sputum, or after 100 uses, whichever comes first. After replacing the used pressure tube, discard it. Recalibrate after replacement.
- Replace the sensor when it becomes faulty.

Cleaning the calibration syringe

Clean the outer surface of the syringe with any of the following solutions or wipes:

- Solution of dish soap and water, ½ tsp per cup of water
- Solution of bleach and water, 1 part bleach (6% sodium hypochlorite) with 9 parts water
- Isopropyl alcohol and water, 70% by volume
- PDI Sani-Cloth Plus wipes (14.85% Isopropanol)
- Cavi-Wipes (17.2% Isopropanol)

Cleaning the patient handle



WARNING Keep the reusable patient handle clean. Patient contact with contaminated equipment can spread infection.

Note Clean the patient handle after each patient use.

Clean on a routine basis according to your facility's protocols and standards or local regulations.

The following agents are compatible with the patient handle:

- 70 percent isopropyl alcohol
- 10 percent chlorine bleach solution



CAUTION When cleaning the patient handle, avoid using cloths or solutions that include quaternary ammonium compounds (ammonium chlorides) or glutaraldehyde-based disinfectants.

Discarding the equipment



Dispose of this product and its accessories according to local regulations. Do not dispose of as unsorted municipal waste.

For more specific disposal or compliance information, go to www.welchallyn.com/weee or contact Welch Allyn Technical Support at www.welchallyn.com/about/company/locations.htm.

Ordering Information for Replacement Parts

The following parts must be replaced as noted:

- Flow transducers & nose clips – replace for each new patient.
- Pressure tubing – replace when soiled or after use life limit.
- Sensor – replace when faulty.

To order parts, call the Welch Allyn Technical Support Center.



WARNING Discard all spirometry components according to local regulations.

Use of components other than those recommended by Welch Allyn may compromise product performance. The Welch Allyn warranty can only be honored if you use Welch Allyn approved components and replacement parts.

Troubleshooting

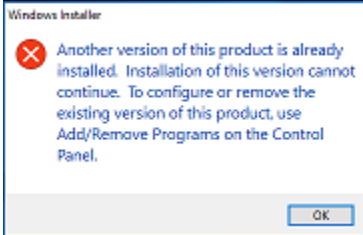
Spirometry Errors

Symptom	Resolution
The device (sensor) is not responding	<p>Disconnect and reconnect the sensor.</p> <p>Check if the port settings in the settings menu correspond with the used COM-port.</p>
Measured values are incorrect	<p>Verify LOT number and perform a verification test.</p> <p>Check the flow transducer for potential obstruction.</p> <p>Do a volume calibration to check the gain-factor and to recalibrate the device if necessary.</p> <p>Check to ensure that the patient's lips form a tight seal around the flow transducer.</p> <p>Use a nose clip on the patient.</p>
Values are too high (intermittent)	<p>Retest with fingers positioned properly around the flow transducer. Do not block the end of the flow transducer with your fingers or hand.</p> <p>Check the flow transducer for obstruction caused by patient saliva or phlegm. Replace the flow transducer.</p> <p>Check to ensure that the patient's airways are not restricted by excessive bending. Correct the patient's posture.</p>
Flow data is out of range (measured flow has exceeded the allowable limits)	<p>Recalibrate with a 3-liter syringe.</p>
The program does not predict values or the values appear incorrect	<p>Verify that the date of birth, gender, race and the height of the patient are correctly entered in the patient card; these are needed for the calculation of the predicted values. For some prediction norms the patient's weight is also obligatory.</p>
Unable to calibrate	<p>Verify sensor calibration information.</p> <p>Check the connection between flow transducer and sensor.</p> <p>Replace the flow transducer.</p> <p>Check that the connection between the syringe and the flow transducer is tight and without leaks.</p>

Symptom	Resolution
	<p>Select the Reset Calibration icon to reset the calibration factors to factory default.</p> <p>Use even strokes in calibration.</p>
<p>Error message: No valid stroke recorded.</p>	<p>Wait with pushing the plunger in until the blue calibration bar starts moving.</p> <p>Pull the plunger completely out before pressing the OK button on the start calibration window.</p>
Report does not print parameters or graphs	Check print and parameters settings.
Indistinguishable Pre and Post curves on printed reports	A color printer and a color printout are recommended for printing spirometry reports. Printing these reports with a monochrome printer or in black and white can lead to confusion as it is not easy to identify which curve is a Pre and which is a Post effort.
Patient test values differ from values expected by physician	<p>Verify sensor calibration information.</p> <p>Verify the barometric pressure.</p> <p>Recalibrate.</p> <p>Replace transducer.</p> <p>Verify the patient data. The norm selection is dependent upon accurate input of patient data in the database.</p> <p>Eliminate any leaks in the pressure tubing.</p> <p>Replace the sensor if damaged.</p> <p>Make sure the patient remains still during recording.</p>
The flow sensor has been dropped	Recalibrate.
Loss of network connection during spirometry test	Reconnect to database and tests taken while offline will be resynchronized upon login. This only applies for client/server configurations.

Software Installation

Symptom	Resolution
Software did not install.	<p>Ensure that the user logged in at the time of installation has administrative privileges. To check if a user has administrative privileges, right click on the setup.exe file and ensure "Run as Administrator" is available.</p> <p>Contact Technical Support for assistance</p>
User prompted for database credentials during Simple installation	Contact Technical Support for assistance
Installation attempted with the following error:	<p>Browse to the Control Panel to Add/Remove programs. Find and highlight Welch Allyn Diagnostic Cardiology Suite and uninstall.</p> <p>Browse to the new version of software and attempt to install again.</p>

Symptom	Resolution
 <p>A screenshot of a Windows Installer error dialog box. The title bar reads 'Windows Installer'. The main text says: 'Another version of this product is already installed. Installation of this version cannot continue. To configure or remove the existing version of this product, use Add/Remove Programs on the Control Panel.' There is a red 'X' icon in a circle on the left and an 'OK' button at the bottom right.</p>	

Accessing Welch Allyn Diagnostic Cardiology Suite

Symptom	Resolution
Login fails.	<p>Ensure the correct username and password are used.</p> <p>Contact administrator of Welch Allyn Diagnostic Cardiology Suite to ensure the username being used is registered in the Users Database section of the system configuration.</p> <p>If using Active Directory, contact IT administrator for assistance with credentials.</p> <p>Contact Technical Support for assistance</p>
Server not available message appears.	<p>Select Cancel to exit the application and try to login again.</p> <p>If system is setup in a networked configuration, check with the administrator that the Welch Allyn Diagnostic Cardiology Suite server is up and running.</p> <p>Contact the IT Administrator to perform the following function: Under Windows Services, ensure the CorScribeGateServer is running. If stopped, start service, and set restart to Automatic if set to Manual.</p> <p>Contact Technical Support for assistance.</p>
Schedule, Exam Search, User Preferences, and Settings icon are grayed out	System is in offline mode. Follow steps above.
Welch Allyn Diagnostic Cardiology Suite was installed as EHR integrated, but is not launching from my EHR.	<p>The interface between Welch Allyn Diagnostic Cardiology Suite and the EHR must be enabled by the EHR. Contact your IT administrator or EHR to ensure the interface is enabled.</p> <p>Contact Technical Support for assistance</p>

Data Export

Symptom	Resolution
Exam export not found.	<p>Exams are set to automatically export upon completion of the configured steps. Under the Workflow Config settings of the System Configuration, check the boxes that are checked under the Manual and Automatic columns. Ensure the appropriate box is checked that matches the step after which the user expects the exam to be exported.</p>

Symptom	Resolution
Duplicate exams are exported.	<p data-bbox="906 289 1422 365">In the Users Database under System Configurations, ensure that the user logged in has the proper role selected to export exams.</p> <p data-bbox="906 380 1422 428">Contact IT administrator to ensure the interfaces are setup and connected.</p> <p data-bbox="906 443 1370 470">Contact Welch Allyn Technical Support for assistance</p> <p data-bbox="906 516 1422 674">Exams are set to automatically export upon completion of configured steps. Under the Workflow Config settings of the System Configuration, check the boxes that are checked under the Manual and Automatic columns. Ensure the appropriate box is checked that matches the step after which the user expects the exam to be exported.</p> <p data-bbox="906 688 1422 785">If multiple boxes are checked, the exam will export each time the step is completed. Ensure that only the steps after which the exam should be exported are checked automatically.</p>

Appendix A : System Specifications

Spirometry Software Specifications

For minimum specifications for client and server PCs, see the Modality Manager user's manual.

Feature	Specification*
Tests	FVC, SVC, MVV, Pre- and Post- bronchodilator
Sensor Type	Pneumotach
Power Equipment	None, obtained from USB port
Current consumption	50 mA Max (30 mA typical)
Accuracy	Compliant with ATS/ERS 2005 guidelines Compliant with ISO 26782 guidelines Error is less than the largest of either 0.05L or 3% of reading
Reproducibility	Compliant with ATS/ERS 2005 guidelines Compliant with ISO 26782 guidelines Variability is less than the largest of either 0.05L or 3% of reading
Flow Range	14 L/sec
Volume Range	0 - 14 L
Resistance	Compliant with ATS/ERS 2005 guidelines Compliant with ISO 26782 guidelines Impedance does not exceed 0.15kPa/(L/s) with flows up to 14 L/s
Predictive Norms	For Predictive Norms included, see above Predictions section. Additional predictive norms may be added upon customer request.
Interpretation	1991 ATS Interpretation Standards. Lung Age calculation can be enabled or disabled. Automatic interpretation can be enabled or disabled.

Feature	Specification*
	User-defined interpretation statements are also available to be added manually.
Reports	FVC - Volume / Time FVC - Flow / Volume FVC - Both – Volume / Time and Flow / Volume SVC – Volume / Time MVV – Volume / Time
Incentive graphic	Fireman
Parameters	FVC, FIVC, FIV1, FIV1%, FEV0.5, FEV1, FEV2, FEV3, FEV5, FEV6, FEV0.5, FEV0.5%, FEV1%, FEV1/FVC, FEV2%, FEV3%, FEV5%, FEV6%, PEF, FEF25, FEF50, FEF75, FEF0.2-1.2, FEF25-75, FEF75-85, PIF, FIF50, FEF50/FIF50, FEV1/FEV6, FET, MEF25, MEF50, MEF75 SVC, ERV, IRV, VT, IC, BF, MV, Tin, Tex, Tin/Tex MVV, MV, VT, BF, DFRC
Quality Checks	ATS Acceptability and ATS Reproducibility checks Effort-quality messages Audio and visual incentive for assistance in coaching patients
Connectivity	Compatible with Welch Allyn Diagnostic Cardiology Suite
Spirometer protection against ingress of water, per IEC 60529	IP20
Storage and Environment	Temperatures between –20 °C (-4 °F) and 50 °C (122 °F). Relative humidity between 10 and 95% (non-condensing). Atmospheric Pressure of 700 hPa (mbar) to 1,060 hPa (mbar).
Operation Environment	Temperatures between 10 °C (50 °F) and 40 °C (104 °F), Relative humidity between 15% and 95% (non-condensing), Atmospheric Pressure of 700 hPa (mbar) to 1,060 hPa (mbar)

Note * Specifications subject to change without notice.

Spirometer and Accessories

Part Number	Description
410857	Welch Allyn Diagnostic Cardiology Suite Spirometer Kit manufactured by Medikro
720725 – 25 /pack 720706 – 100 /pack	Disposable Flow Transducers. Package includes Lot code and Calibration code.
410370	Pressure Tubing

Part Number	Description
100680	Nose Clip
703480	3L Calibration Syringe
BASIC-LVL-CAL BASIC-LVL2-CAL	Syringe Calibration service

Manuals

Part Number	Description
9515-001-51-CD	Physician's Guide Adult & Pediatric User Manual
80023962	Welch Allyn Diagnostic Cardiology Suite Modality Manager User Manual
80023960	Welch Allyn Diagnostic Cardiology Suite Spirometry User Manual
9515-166-50-CD	ELI Link User Manual

Contact your dealer or go to www.welchallyn.com for more information.

Appendix B: Electromagnetic Compatibility (EMC)

Electromagnetic Compatibility (EMC)

The following information on Electromagnetic Compatibility applies to the USB Spirometry flow sensor.

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See the appropriate EMC table for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers, and cables other than those specified by Welch Allyn may result in increased emissions or decreased immunity of the equipment.



CAUTION The Medikro spirometers needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided. Portable and mobile RF communications equipment can affect the Medikro spirometers.

Emissions and immunity information

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometers should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Medikro spirometers uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Medikro spirometers are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity


The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8 kV contact ± ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-to-line ± 0.5 kV, ± 1 kV Line-to-ground ± 0.5 kV, ± 1 kV, ± 2 kV	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	Dips 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Interruptions 0 % UT; 250/300 cycle	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Medikro spirometers requires continued operation during power mains interruptions, it is recommended that the Medikro spirometers be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the AC Mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V	3 V	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 Medikro spirometer unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol:
	0,15 MHz – 80 MHz	0,15 MHz – 80 MHz	
	6 V in ISM bands between 0,15 MHz and 80 MHz	6 V in ISM bands between 0,15 MHz and 80 MHz	
	80 % AM at 1 kHz	80 % AM at 1 kHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz	10 V/m 80 MHz to 2700 MHz	
RF wireless communication	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz and 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz and 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz	

Recommended separation distances between portable and mobile RF communications equipment and the equipment

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

Rated max. output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.1m	0.2m
0.1	0.4m	0.7m
1	1.2m	2.3m
10	4.0m	7.0m
100	12.0m	23.0m

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

Note 1: At 800 MHz, the separation distance for the higher frequency range applies.

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

Appendix C: Warranty Information

Your Welch Allyn Warranty

Welch Allyn, Inc. (hereafter referred to as “Welch Allyn”) warrants that components within Welch Allyn products (hereafter referred to as “Product/s”) will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Welch Allyn, or if not otherwise noted, for a period of thirteen (13) months from the date of shipment.

Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

Reusable product such as, but not limited to, BATTERIES, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, TRANSDUCER CABLES, Y-CABLES, PATIENT CABLES, LEAD WIRES, MAGNETIC STORAGE MEDIUMS, CARRY CASES or MOUNTS, are warranted to be free from defects in workmanship and materials for a period of 90 days. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

1. Freight damage;
2. Parts and/or accessories of the Product/s not obtained from or approved by Welch Allyn;
3. Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;
4. Accident; a disaster affecting the Product/s;
5. Alterations and/or modifications to the Product/s not authorized by Welch Allyn;
6. Other events outside of Welch Allyn’s reasonable control or not arising under normal operating conditions.

THE REMEDY UNDER THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT WITHOUT CHARGE FOR LABOR OR MATERIALS, OR ANY PRODUCT/S FOUND UPON EXAMINATION BY WELCH ALLYN TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Welch Allyn of any alleged defects promptly after discovery thereof within the warranty period. Welch Allyn’s obligations under the foregoing warranty will further be conditioned upon the assumption by the purchaser of the Product/s (i) of all carrier charges with respect to any Product/s returned to Welch Allyn’s principal place or any other place as specifically designated by Welch Allyn or an authorized distributor or representative of Welch Allyn, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Welch Allyn is limited and that Welch Allyn does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm,

or damage due directly or indirectly to an occurrence or consequence there from relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER'S SOLE EXCLUSIVE REMEDY AGAINST WELCH ALLYN FOR CLAIMS RELATING TO THE PRODUCT/S FOR ANY AND ALL LOSSES AND DAMAGES RESULTING FROM ANY CAUSE SHALL BE THE REPAIR OR REPLACEMENT OF DEFECTIVE PRODUCT/S TO THE EXTENT THAT THE DEFECT IS NOTICED AND WELCH ALLYN IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL WELCH ALLYN BE LIABLE FOR INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS, DAMAGE, OR EXPENSE OF ANY KIND, INCLUDING LOSS OF PROFITS, WHETHER UNDER TORT, NEGLIGENCE OR STRICT LIABILITY THEORIES OF LAW, OR OTHERWISE. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

