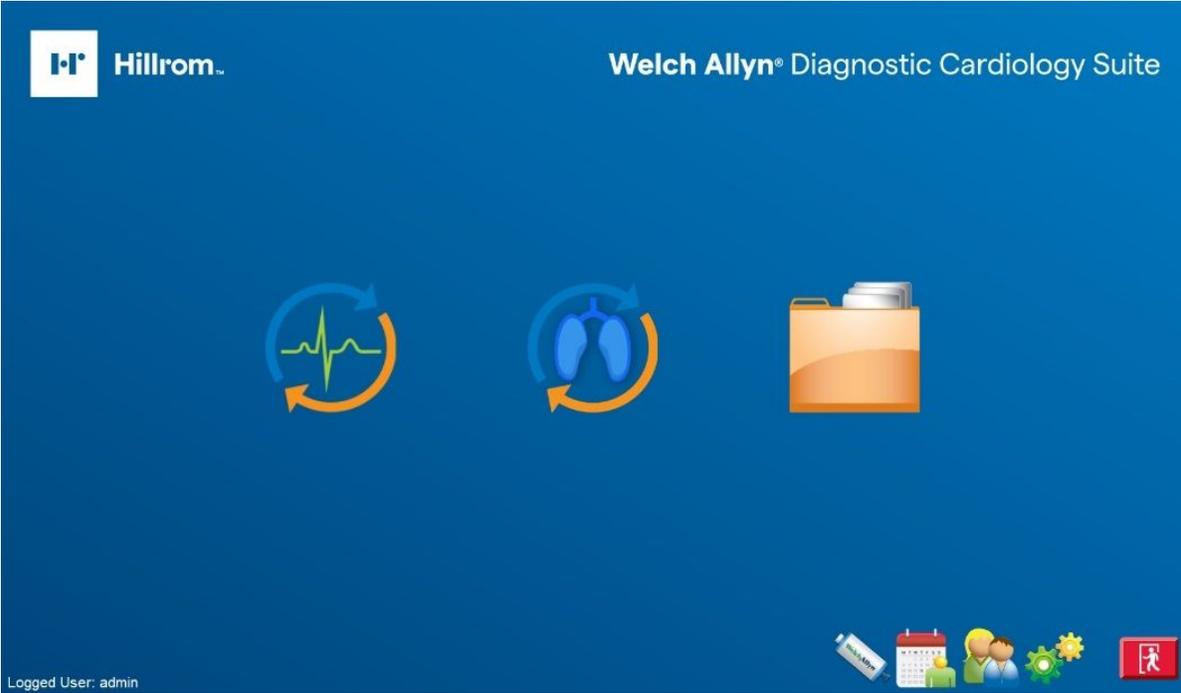




Hillrom™

Welch Allyn® Diagnostic Cardiology Suite Manager User Manual



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

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



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901128 CARDIOPULMONARY ECG SYSTEM



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EC

REP

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Notices

Manufacturer's Responsibility

Welch Allyn 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.
- 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 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 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 IEC 60601-2-25. 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 or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.



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.

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 Windows Server 2016. Although it is unlikely that Windows updates and security patches affect the application's 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 Connection to IT Networks including other equipment could result in previously unidentified risks. The IT Administrator should identify, analyze, evaluate and control any such risks. Changes to the IT network, such as changes in network configuration, connection of additional items, update/upgrade of equipment, could introduce new risks that require additional analysis.

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 application 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** Environmental requirements for operation, transportation and storage of modality specific hardware can be found in the associated user manuals.

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



This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. For more specific disposal information see www.welchallyn.com/weee.



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.

R_x ONLY

By prescription or order of physician or dentist.



USB



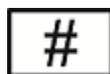
Serial Number



Reorder Number



Batch Code



Model Identifier



Global Trade Item Number

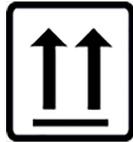


Meets essential requirements of
the European Medical Device
Directive 93/42/EC

Note

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

Package Symbol Delineation



This end up



Fragile



Keep dry



Keep away from heat



Acceptable temperature range

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.

Introduction

Manual Purpose

This manual provides information about the Welch Allyn Diagnostic Cardiology Suite Manager including:

- Installation
- Display screens
- Menu structures
- Navigation tools
- Patient management
- Exam management
- System configuration

For information on the use of specific modalities see the associated Welch Allyn Diagnostic Cardiology Suite modality manuals: Resting ECG, and Spirometry.

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. This manual is also to be referenced by IT administrators responsible for installing and configuring the system.

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.

Indications for Welch Allyn Diagnostic Cardiology Suite ECG range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department.

Welch Allyn Diagnostic Cardiology Suite ECG is indicated for patients of all ages.

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 to Performing ECG

There are no known contraindications.

Contraindications to Performing Spirometry

- 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

The Welch Allyn Diagnostic Cardiology Suite Manager controls the diagnostic modules and performs all non-module specific functions. This includes patient management, exam and order management, system configuration, printing and export of reports. For module-specific information, please refer to the individual module manual.

Note For a description of intended use, indications and contraindications please refer to the appropriate module manual, as these are module specific.

Welch Allyn Diagnostic Cardiology Suite can be configured with bidirectional connectivity and DICOM® protocol support.

The application is integrated with a patient and exam management system that handles the scheduling of exams, database storage and maintenance, exam and patient search, printing, communication with external systems, and dispatches the modality dependent acquisition and review functions. It can be configured for data distribution. When so configured, the database resides on a server supporting a number of networked client workstations.

The Welch Allyn Diagnostic Cardiology Suite offers authorized users the ability to schedule new tests within the application when not linked to an external scheduling system, view reports, enter conclusions, and generate printed or electronic reports for completed exams. The application can also be integrated with supported EMR systems so that the Welch Allyn Diagnostic Cardiology Suite can be launched directly from the EMR software. Exam and order information can be communicated between the Welch Allyn software and the EMR software to support streamlined clinical workflows.

The Welch Allyn Diagnostic Cardiology Suite can be set up as a Citrix® Application Server for remote access from client computers that have Citrix XenApp™ installed. Likewise, the application can be configured to be run using Windows Remote Desktop Protocol.

Installation Process

Important Notes

- If installing the Welch Allyn Diagnostic Cardiology Suite as a distributed system (central database with multiple client PCs connected), the Manager software and any supported modalities must be installed on the Server (database) before the installation of the clients.
- The Welch Allyn Diagnostic Cardiology Suite Manager must be installed prior to installation of the modalities. Once the Manager application is installed, the Manager settings may be edited, but modality configuration settings will not be available until desired modalities are installed. If using the Deployment Tool to distribute software packages, the software must be in a specific staging directory. Please refer to the Deployment Tool addendum manual for further information.
- Prior to beginning the installation, verify the computer, server, or workstation meets the documented specifications.
- The user logged into the computer, server, or workstation, must have administrative permissions to make changes to that system. Failure to have the proper credentials will lead to a failure of the installation.
- Some installation pathways include the reboot of the system on which the software is installed. Best practice is to reboot the system immediately when prompted, therefore it is important to schedule the installation accordingly.
- If the Welch Allyn Diagnostic Cardiology Suite is installed and is to be connected to ELI Link, it is important to note that edited measurements and interpretations only export when connecting to ELI Link version 5.0 and greater. When an earlier version of ELI Link is used, it is advisable to perform reviewing, editing, and signing within the PACS or ECG Management system instead of in the Welch Allyn Diagnostic Cardiology Suite.
- If installing or upgrading the software on a PC with out of date Microsoft certificates, internet connection is required to obtain updated Microsoft certificates.

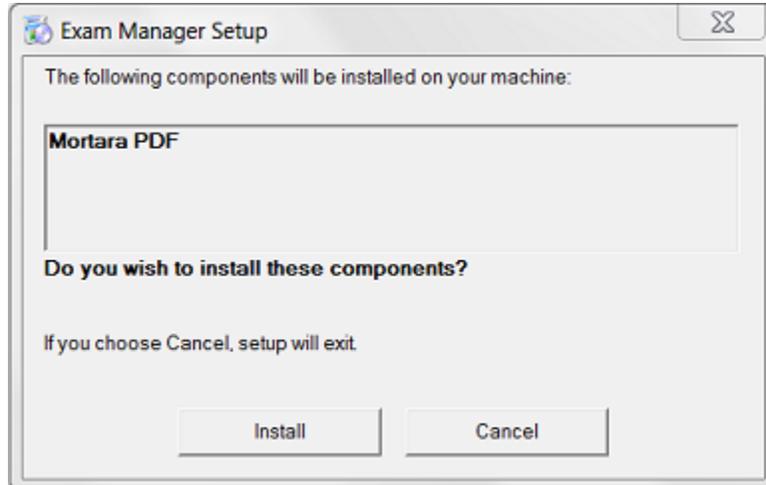
Setup

1. Navigate to the location where the software to be installed is located.

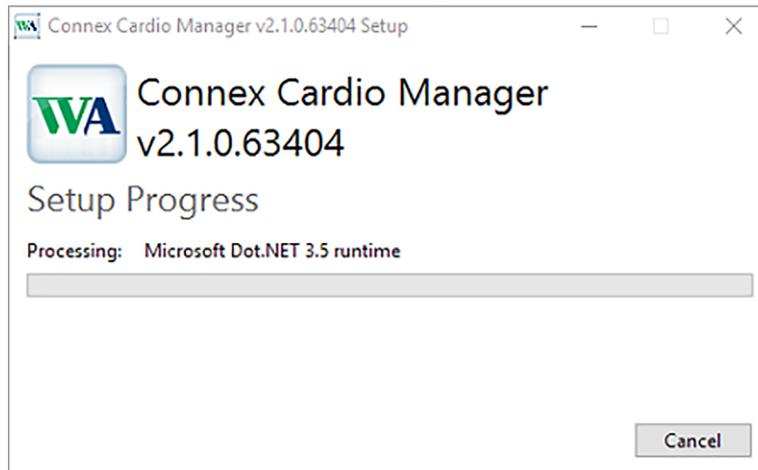
2. Double click **Manager Full Installation.exe**.



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. If the below window appears, click **Install**.

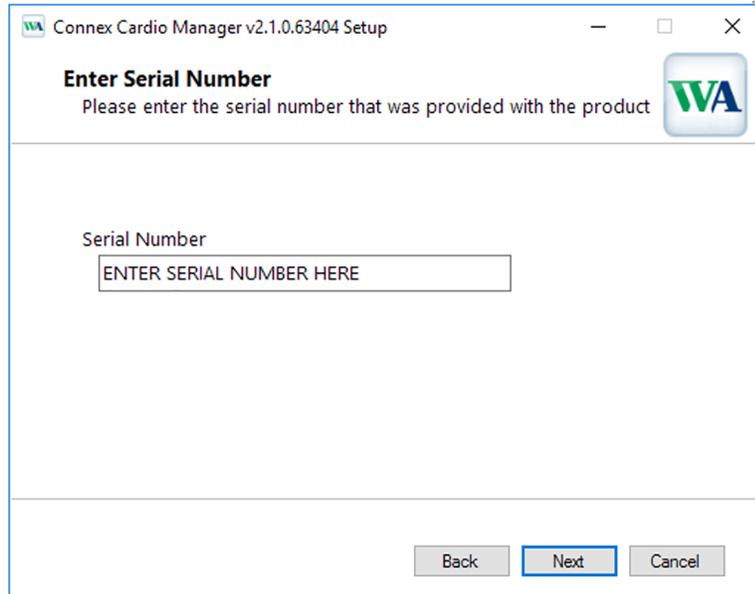


5. Click **Next** to continue.
6. Wait while prerequisite software is installed.



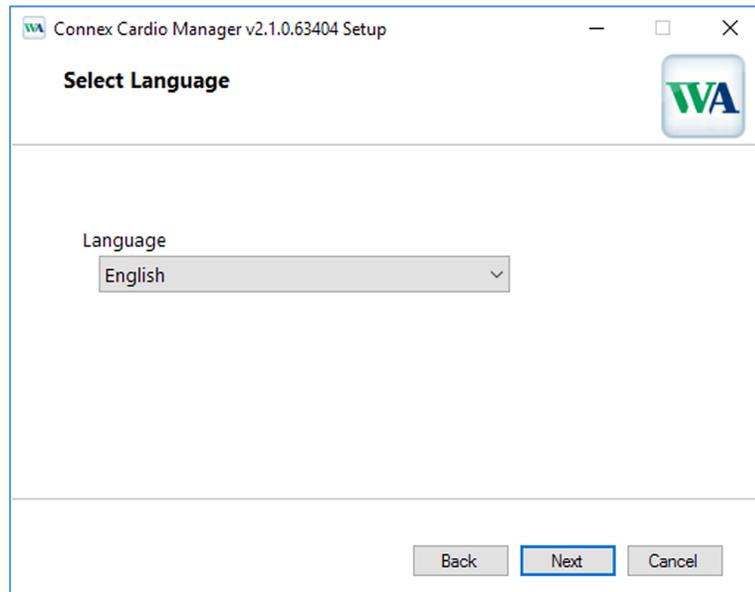
Serial Number

Enter the serial number of your product. This number can be found on the product identification card that is shipped with the software.



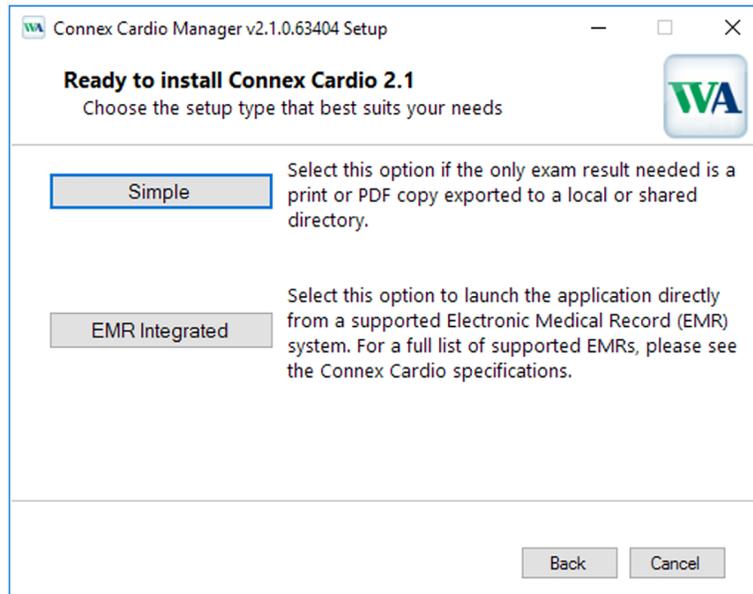
Language

Select the language of the system.



Setup Type

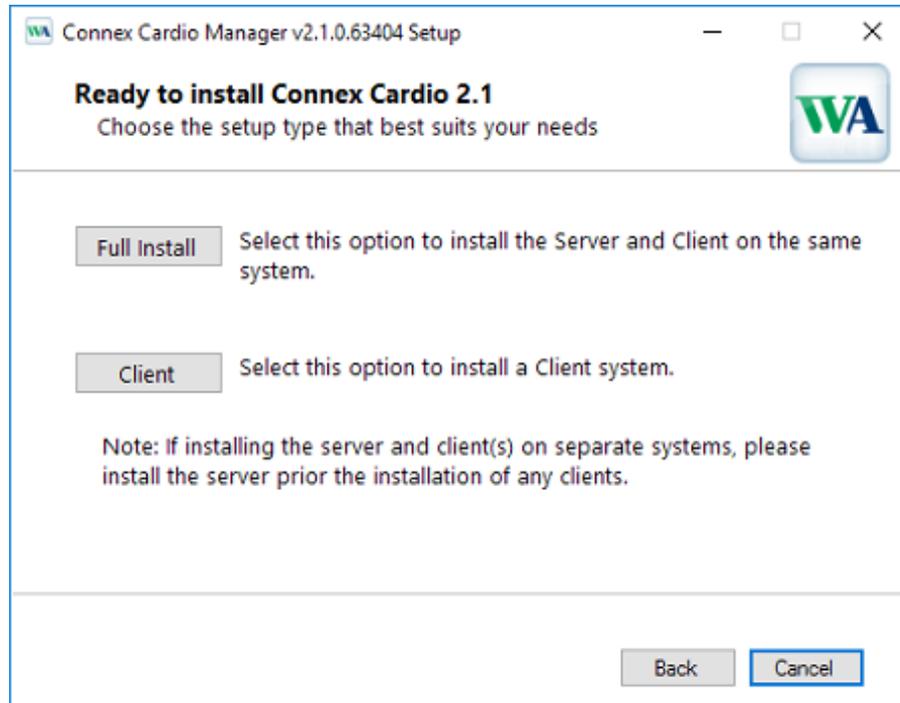
The *Choose Setup Type* window details the setup types that can be selected:



1. **Simple:** Select this option when exam results are obtained and can be saved locally or can be integrated with a 3rd party system other than an EMR, including HL7, DICOM, XML, or PDF. Note: if DICOM connectivity is desired, each system needs to be licensed for DICOM.
2. **EMR Integrated:** Select this option when there is a supported EMR (Electronic Medical Record) system that can integrate with the Welch Allyn Diagnostic Cardiology Suite. The choice *EMR Integrated* installs the necessary components and configures the system to launch from a supported EMR system. The choices of EMRs in the list include: AllScripts, eClinicalWorks, Epic, Nextgen and default.

Simple

Click on *Simple* and a window with the following installation options will be displayed:



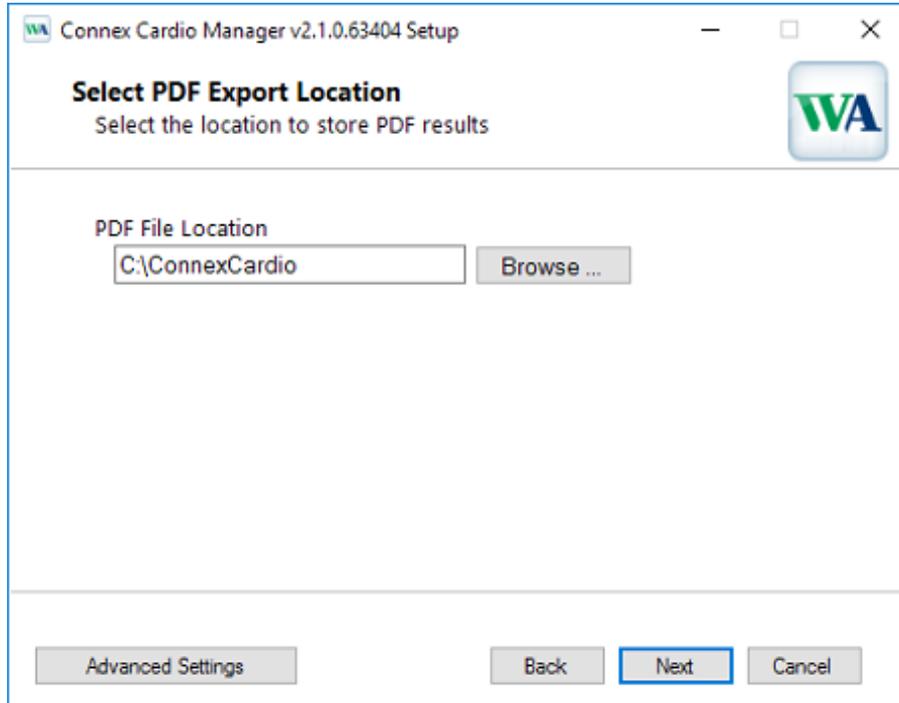
Full Install: Choose this option to install the Server and Client components on the computer. This system can be treated as a standalone device or can be used as a server to which other client PCs running the modalities can network.

Client: Choose this option to install the Welch Allyn Diagnostic Cardiology Suite application on a computer that will be networked to the Database Server functionality on a different computer.

Note If installing a Client system, install the Server system that the client will be connected to first.

The Full Install option:

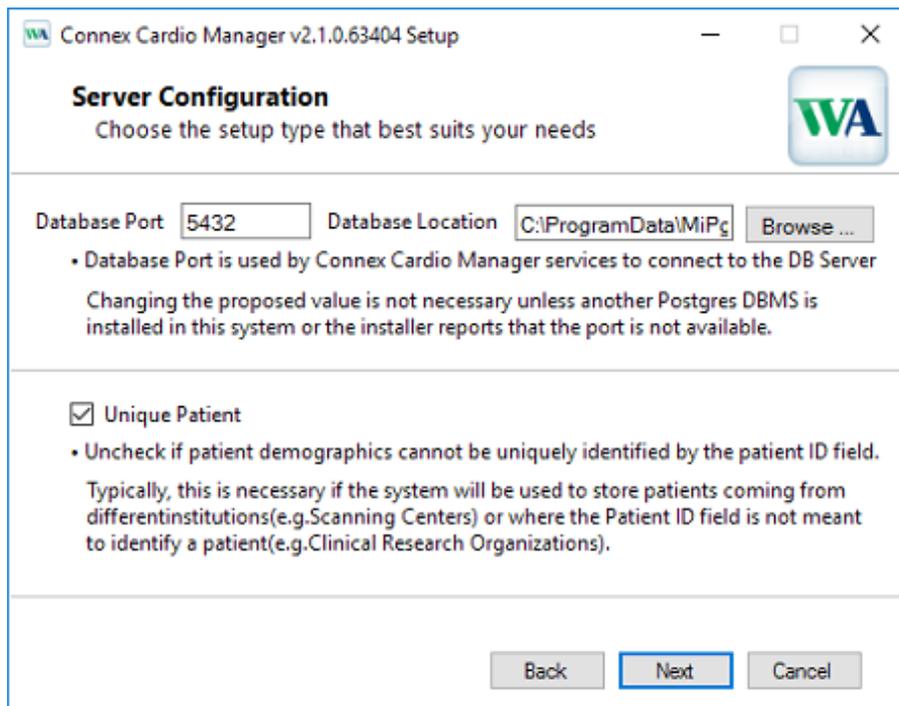
The PDF File Location is where exported exam results will be placed.



To change the export location, click **Browse** and set the desired path.

Upon selecting the location click **Next** to continue to the Port Configuration Window or select Advanced Settings if further configuration is necessary.

If Advanced Settings is selected, the following window will appear.



Database Port: It is recommended to use the default port number for the installation. If the port is already in use, the installation displays an alert that the port is already taken and that a new port number needs to be entered in order to continue.

Unique Patient: This option defaults to an enabled (checked) condition to configure the system to utilize the patient ID field as a unique identifier for patient demographic information. This is the most commonly used system configuration.

The Unique Patient option box can be unchecked to not use the patient ID field as a unique identifier for patient demographics. Choose to uncheck the Unique Patient ID when patients can be entered from different institutions (such as scanning centers) that use different ID schemes. Choose to uncheck the Unique Patient when the patient ID field is not used to identify a patient, such as with clinical research studies.

Set Database Location: Ability to browse to a location for the Welch Allyn Diagnostic Cardiology Suite application and database other than the local default (C:\) directory. This is beneficial when it is necessary to define the application and database locations on a different data drive.

After configuring the settings, click **Next** and continue to the port configuration window.

Connex Cardio Manager v2.1.0.63404 Setup

Server Configuration
Choose the setup type that best suits your needs

LOG Port
• Connex Cardio Manager centralized event log service port. Keep default unless not available

API Port
• Working port of the Connex Cardio Manager service. Keep default unless not available

Calibration Port
• Working port of the Spirometry Calibration service. Keep default unless not available

Back Next Cancel

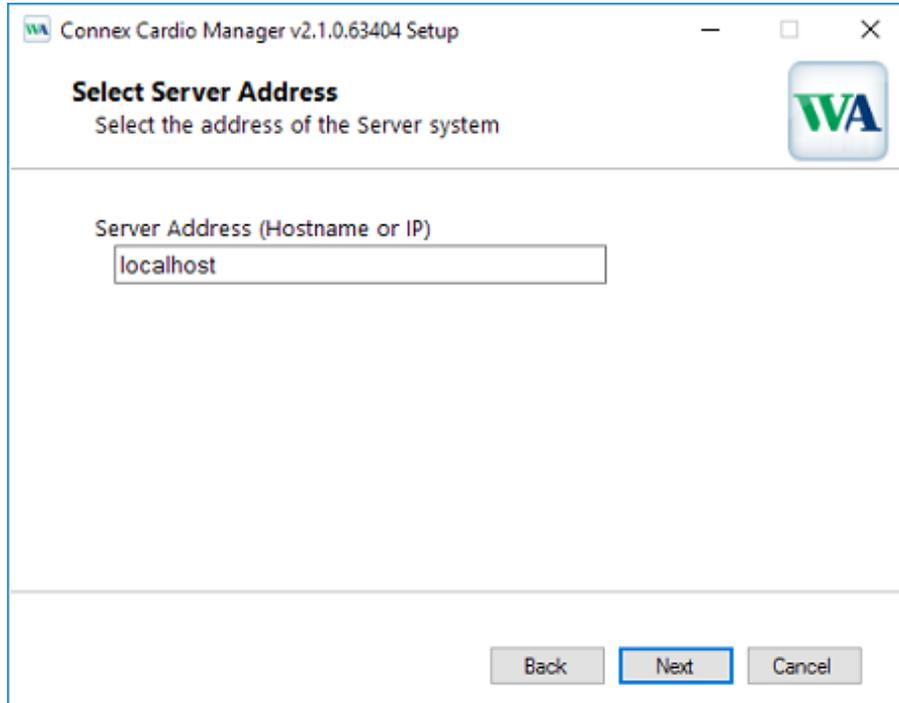
There are three configurable ports used for communication between the server and the client pieces of the application and are described in the installer window. It is recommended to use the default port number for the installation. If the port is already in use, the installation displays an alert that the port is already taken and that a new port number needs to be entered to continue with the installation.

Configure the ports if necessary and click **Next** to be navigated to the final installation window.

The Client option:

The following window containing the information for the Server Address will be displayed.

Upon selecting the server location, click **Next**.



Connex Cardio Manager v2.1.0.63404 Setup

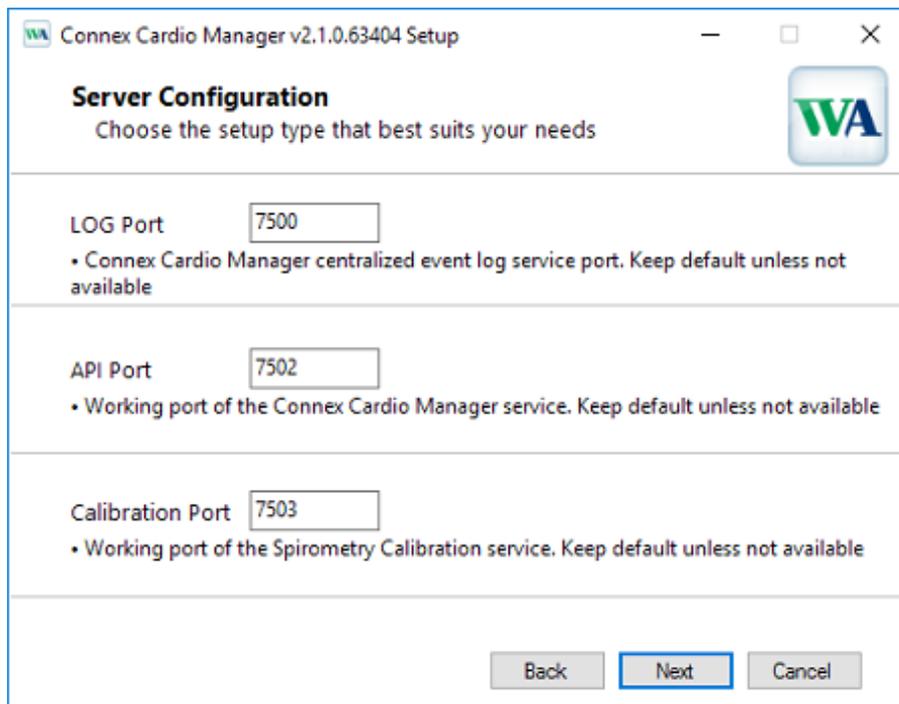
Select Server Address
Select the address of the Server system

Server Address (Hostname or IP)
localhost

Back Next Cancel

The following window containing the information for the port configuration will be displayed.

Select the same port numbers that were set when configuring the server during installation. Click **Next** to be navigated to the final installation window.



Connex Cardio Manager v2.1.0.63404 Setup

Server Configuration
Choose the setup type that best suits your needs

LOG Port 7500
• Connex Cardio Manager centralized event log service port. Keep default unless not available

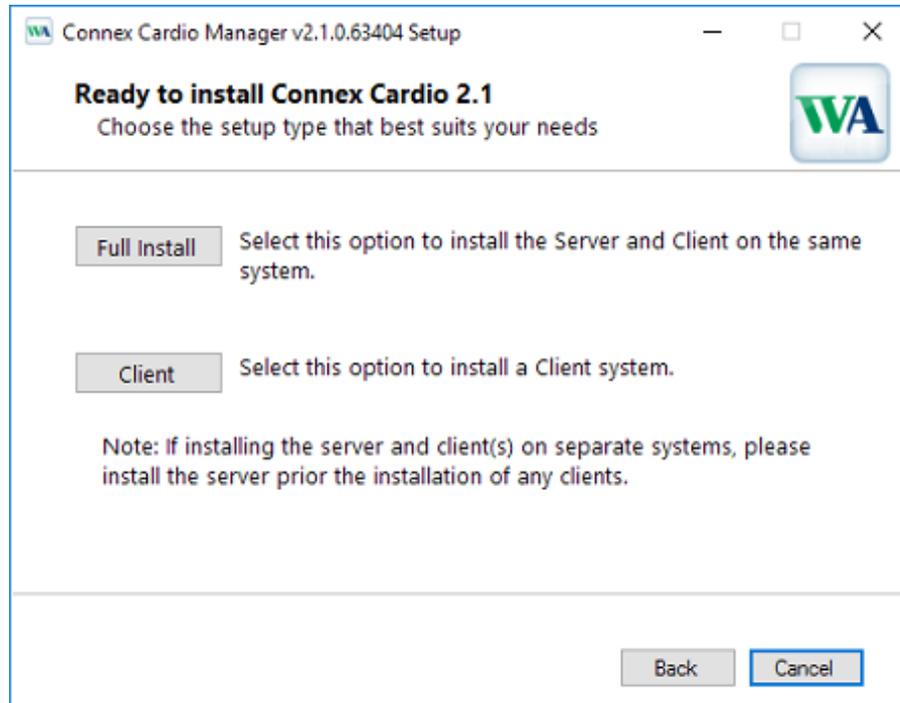
API Port 7502
• Working port of the Connex Cardio Manager service. Keep default unless not available

Calibration Port 7503
• Working port of the Spirometry Calibration service. Keep default unless not available

Back Next Cancel

EMR Integrated

Click on the EMR Integrated choice and a window with the following two installation options will be displayed:



Full Install: Choose this option to install the server and client components on the computer. This system can be treated as a standalone device or can be used as a server to which other client PCs running the modalities can network.

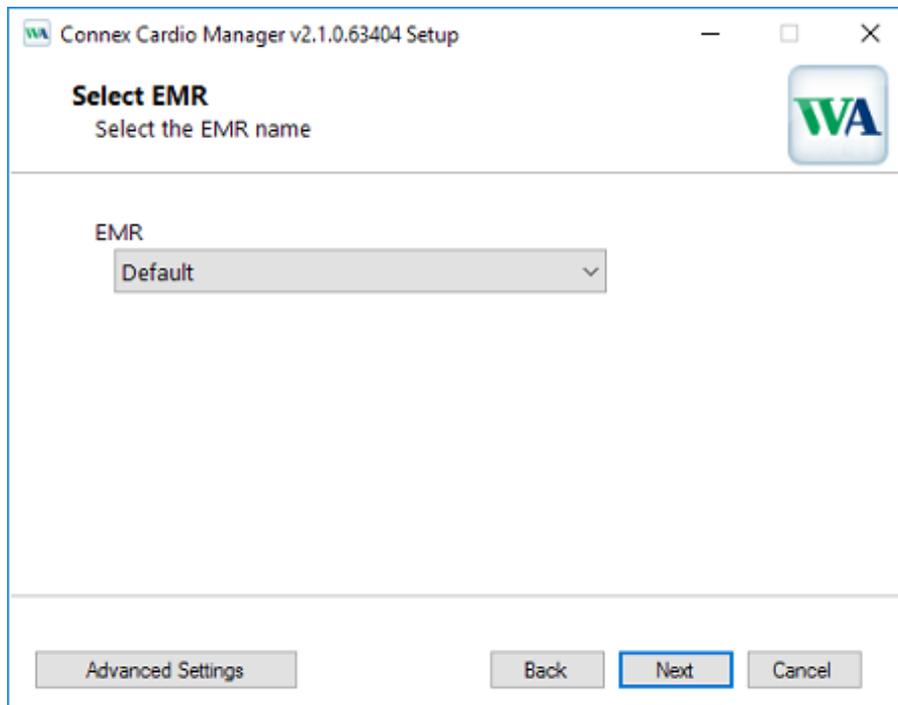
Client: Choose this option to install the Welch Allyn Diagnostic Cardiology Suite application on a computer that will be networked to the Database Server functionality on a different computer.

Note If installing a Client system, install the Server system that the Client will be connected to first.

The Full Install option:

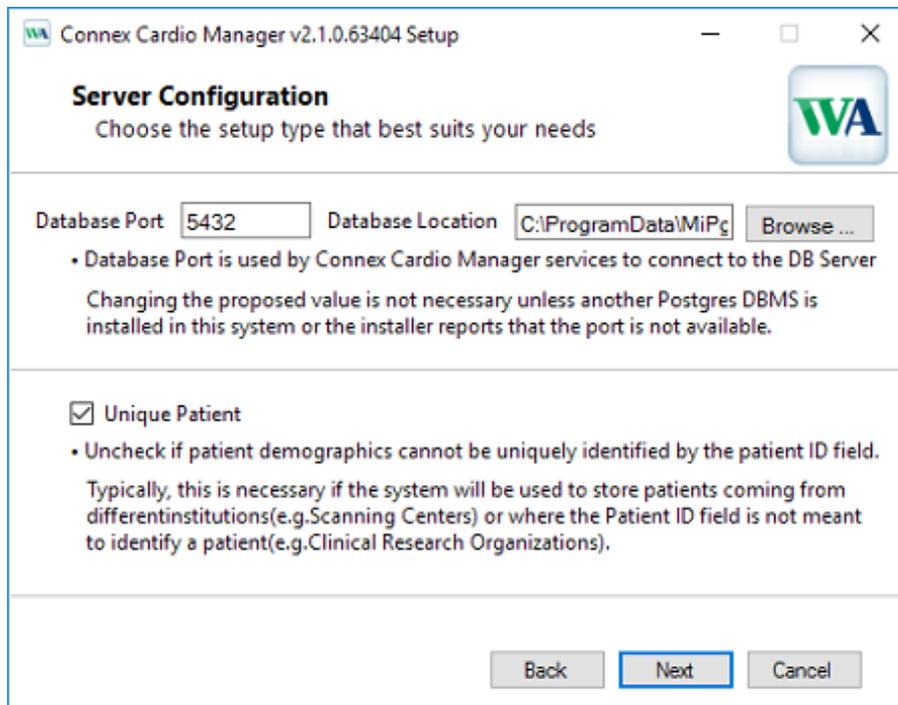
The following window containing the EMR dropdown information will be displayed.

The available options of EMRs in the drop-down menu include Allscripts, eClinicalWorks, Epic, Nextgen and Default.



Upon selecting the EMR click **Next** to continue to the port configuration window or select **Advanced Settings** if further configuration is necessary.

If **Advanced Settings** is selected, the following window will appear.



Database Port: It is recommended to use the default port number for the installation. If the port is already in use, the installation displays an alert that the port is already taken and that a new port number needs to be entered to continue with the installation.

Unique Patient: This option defaults to an enabled (checked) condition to configure the system to utilize the patient ID field as a unique identifier for patient demographic information. This is the most commonly used system configuration.

The Unique Patient option box can be unchecked to not use the patient ID field as a unique identifier for patient demographics. Choose to uncheck the Unique Patient ID when patients can be entered from different institutions (such as scanning centers) that use different ID schemes. Choose to uncheck the Unique Patient when the patient ID field is not used to identify a patient, such as with clinical research studies.

Set Database Location: Ability to browse to a location for the Welch Allyn Diagnostic Cardiology Suite application and database other than the local default (C:\) directory. This is beneficial when it is necessary to define the application and database locations on a different data drive.

After configuring the settings, click **Next** and continue to the port configuration window.

Connex Cardio Manager v2.1.0.63404 Setup

Server Configuration
Choose the setup type that best suits your needs

LOG Port
• Connex Cardio Manager centralized event log service port. Keep default unless not available

API Port
• Working port of the Connex Cardio Manager service. Keep default unless not available

Calibration Port
• Working port of the Spirometry Calibration service. Keep default unless not available

Back Next Cancel

There are three configurable ports used for communication between the server and the client pieces of the application and are described in the installer window. It is recommended to use the default port number for the installation. If the port is already in use, the installation displays an alert that the port is already taken and that a new port number needs to be entered to continue with the installation.

Configure the ports if necessary and click **Next** to be navigated to the final installation window.

The Client option:

The following EMR and Server Address window containing the EMR dropdown options and the field for Server Address (Localhost by default) will be displayed.

Upon selecting the supported EMR and server address, click **Next**.

Connex Cardio Manager v2.1.0.63404 Setup

Select EMR and Server Address
Select the EMR name, and the address of the Server system

Server Address (Hostname or IP)
localhost

EMR
Default

Back Next Cancel

The following window containing the information for the port configuration will be displayed.

Select the same port numbers that were set when configuring the server during installation. Click **Next** to be navigated to the final installation window.

Connex Cardio Manager v2.1.0.63404 Setup

Server Configuration
Choose the setup type that best suits your needs

LOG Port 7500
• Connex Cardio Manager centralized event log service port. Keep default unless not available

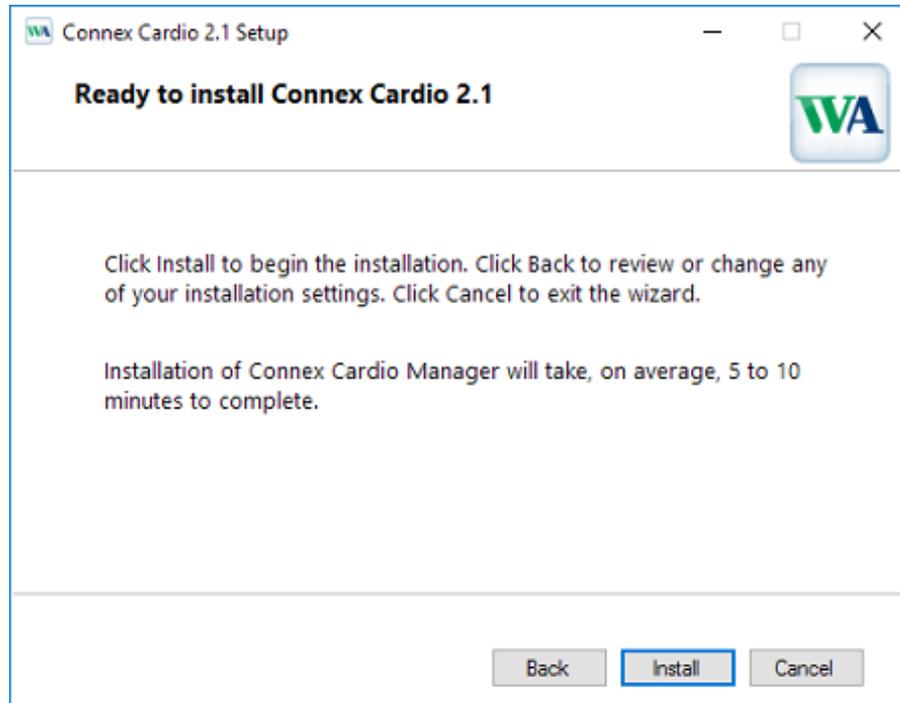
API Port 7502
• Working port of the Connex Cardio Manager service. Keep default unless not available

Calibration Port 7503
• Working port of the Spirometry Calibration service. Keep default unless not available

Back Next Cancel

Final Installation Window

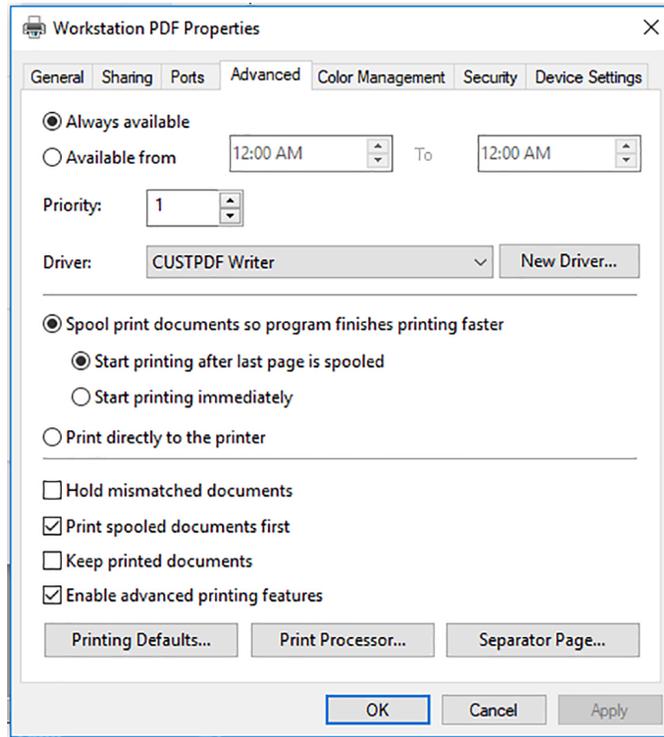
Click **Install** to load the software files to the defined location.



Note: If **Full Install** configuration was selected, Microsoft SQL Server will install automatically on the system. If prompted for permissions, allow the installation. If prompted to restart the system, do so before running the Welch Allyn Diagnostic Cardiology Suite application to ensure proper functionality.

EHR Integrated Installations

After the EMR integrated installation completes, the computer printer settings must be configured. To do so, log in to Windows as an admin user, and go to Windows Devices and Printers settings. Locate the Workstation PDF printer and Workstation File Link printer. Right-click on the printer, select Printer Properties and navigate to the Advanced tab. Configure the tab to match the following for both the Workstation PDF printer and the Workstation File Link printer:



After installing the EMR integrated version of the Welch Allyn Diagnostic Cardiology Suite, steps must be taken by the supported EMR to allow it to launch the Welch Allyn software. The EMR representative should follow the same steps that are taken to integrate with Welch Allyn's CardioPerfect.

Please note, that the component in the EMR to launch the Welch Allyn Diagnostic Cardiology Suite is the same as CardioPerfect and may even be named CardioPerfect.

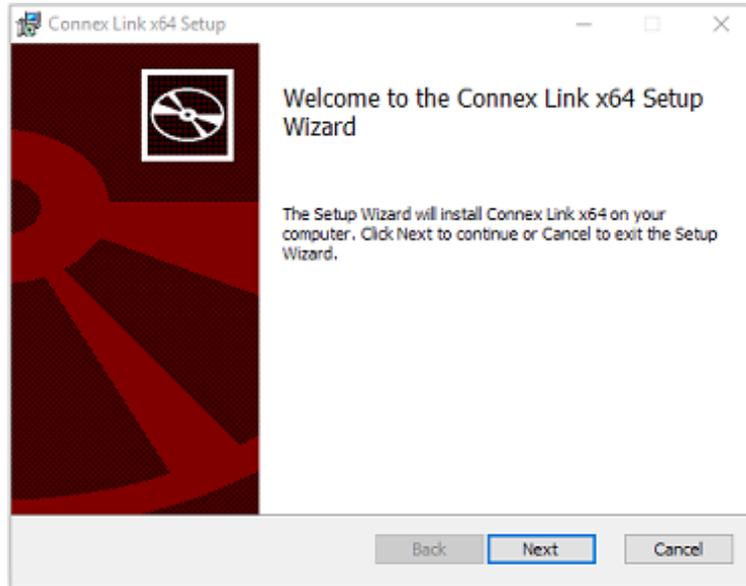
Note If using the eClincialWorks application installed on the PC as opposed to the web based application, a registry setting must be manually configured after installation to ensure Spirometry interpretations appear correctly. For these systems, a DWORD registry key HKLM\SOFTWARE\Mortara Instrument, Inc.\Modality Manager\Config\DisableMDWUrlEncoding should be created and set to 1.

Further instructions on how to operate the Welch Allyn Diagnostic Suite with an integrated EMR can be found in the following sections.

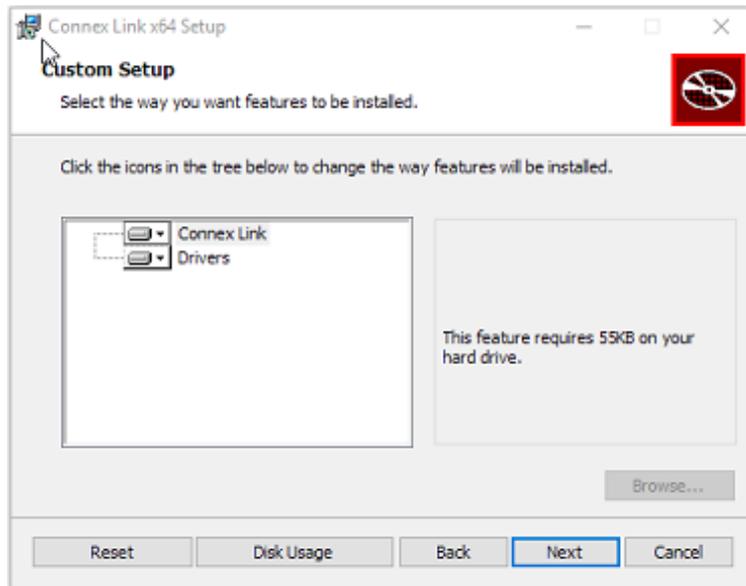
Thin Client Installations

If Welch Allyn Diagnostic Cardiology Suite is being installed on a client that will run Citrix XenApp or Windows Remote Desktop, Connex Link must be installed. The file can be found on the installation media in a folder titled "Connex Link". **It must be installed on every client machine that will acquire spirometry or ECG data.** Connex Link can be installed before or after the client software is installed.

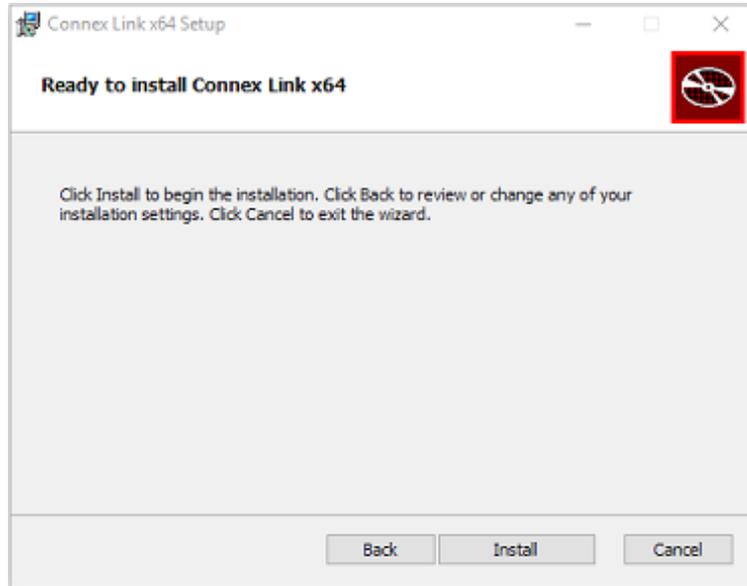
1. After launching the setup, click **Next** to proceed with the installation.



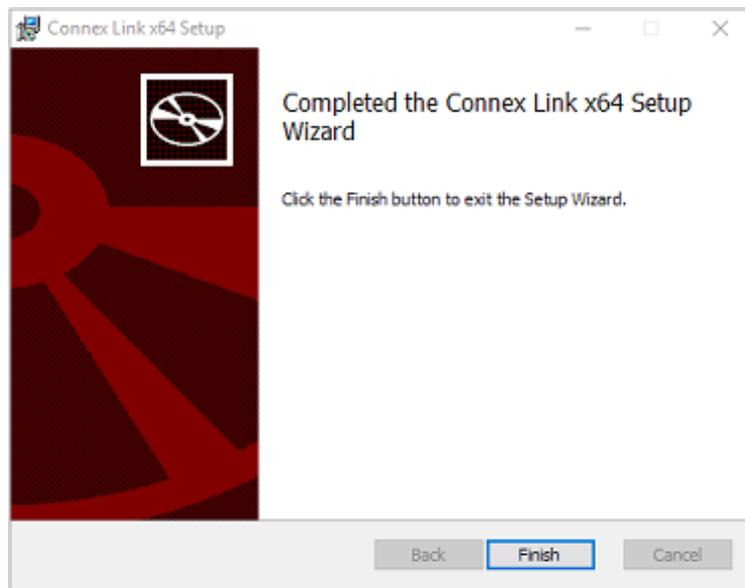
2. Select **Next** unless the system requires extra customization.
 - Disk Usage shows the system drives to ensure storage requirements are met.
 - Clicking Reset will return all changes to default settings.
 - Select **Cancel** to exit the installation process.



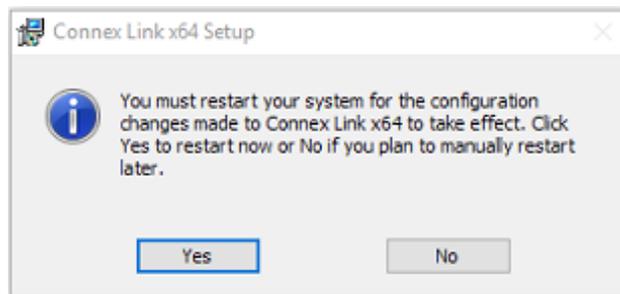
3. Click **Install** to load the software files.



4. Click **Finish** to complete the installation.



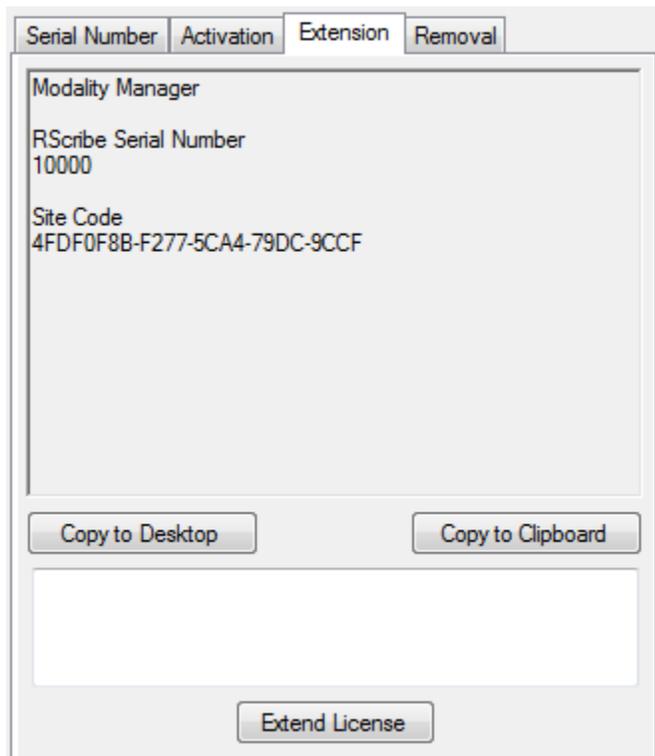
5. Click **Yes** to restart the system or **No** to manually restart the system later. The system must be restarted before using Welch Allyn Diagnostic Cardiology Suite to ensure full functionality.



DICOM Feature Activation

Activation is required to enable DICOM functionality.

1. To prepare for activation, run the Modality Manager Activation Tool accessed from the following menus: **Start Menu > All Programs > Mortara Modality Manager > Modality Manager Activation Tool**
2. Click **Yes** when prompted to allow changes to the computer.
3. To enter your serial number, select the **Serial Number** tab and enter the serial number that appears on the product registration card that was shipped with the product. Since the software can be installed on multiple systems, it is acceptable to use the same serial number for multiple installations. If you no longer have your product registration card and do not know your serial number, please contact Technical Support for assistance.
4. Once your system serial number is entered, this utility generates the site code that is needed for activation by Technical Support personnel. You can click on the **Copy to Desktop** or the **Copy to Clipboard** button to generate a file to be e-mailed Technical Support.
5. Technical Support will return an activation code that can be typed or copied and pasted into the white space above the Extend License button. Select the **Extend License** button to activate the DICOM feature. Contact Technical Support personnel for further information.



Network Operation in a Distributed Configuration

The Welch Allyn Diagnostic Cardiology Suite network capabilities leverage a common database across multiple networked Welch Allyn Diagnostic Cardiology Suite

workstations where exams will be conducted and acquired exams can be reviewed and edited.

A distributed configuration is comprised of a dedicated server and a number of networked client Welch Allyn Diagnostic Cardiology Suite workstations and Welch Allyn Diagnostic Cardiology Suite review stations sharing the same database.

A distributed configuration supports efficient operation for a busy department to:

- Create logins for all users at a single location who can log into any networked station.
- Define system settings at a single location for all networked workstations and review stations.
- Manually schedule exam orders, when no orders interface exists, that are available to all Welch Allyn Diagnostic Cardiology Suite workstations regardless of the lab location.
- Access and update patient information, exam data, and final reports from multiple locations.
- Start exams utilizing scheduled orders received from the institution information system with a single DICOM or HL7 interface to the shared database. Refer to the ELI Link Administrator manual for network interface configuration instructions.
- Selectively search the database to review any completed exam. This includes the ability to edit, sign, print, and export the final report from multiple Welch Allyn Diagnostic Cardiology Suite workstations and review stations on your network, dependent on the user permissions.
- Manage the stored data for all exams with ability to view audit trails, create groups, configure workflow, troubleshoot issues, and archive/restore/delete exams at a single location according to user permissions.

Microsoft Updates

Welch Allyn recommends that all Welch Allyn Diagnostic Cardiology Suite 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. The following guidelines apply for Microsoft updates:

- Customer is responsible for applying updates.
- Configure updates to be manually applied.
 - Turn automatic Windows update off and run it periodically as a manual action.
- Do not install Microsoft updates during active use of the product.
- Run a functional test after any update which includes conducting a test exam as well as importing an order and exporting results (if activated) before running patient exams.

Each Welch Allyn Diagnostic Cardiology Suite product release is tested against the cumulative Microsoft updates at the time of product release. There are no known Microsoft update conflicts with the Welch Allyn Diagnostic Cardiology Suite application. Please contact Technical Support if conflicts are identified.

Anti-Virus Software

Welch Allyn recommends the use of anti-virus (AV) software on computers hosting the Welch Allyn Diagnostic Cardiology Suite application. The following guidelines apply in the use of AV software:

- Customer is responsible for installation and maintenance of AV software.
- AV software updates (software and definition files) should not be applied during active use of the Welch Allyn Diagnostic Cardiology Suite application.
 - AV patch updates and system scans should be scheduled for time periods when the system is not actively in use or should be performed manually.
- AV software must be configured to exclude files/folders as defined in Cautions in User Safety and below:
 - Welch Allyn recommends excluding the Welch Allyn Diagnostic Cardiology Suite database folder (normally C:\ProgramData\MiPgSqlData) from the folders to be scanned.

If a technical support issue is reported, you may be asked to remove the virus scanning software to allow investigation of the issue.

Encrypt Protected Health Information (PHI) Stored in Welch Allyn Diagnostic Cardiology Suite

The Welch Allyn Diagnostic Cardiology Suite database may be configured for Windows Encrypted File System (EFS) for protection of patient data security. EFS encrypts individual files with a key stored with the Windows user account. Only the Windows user that encrypts or creates new files in an EFS-enabled folder can decrypt the files. Additional users can be granted access to individual files by the original account that encrypted the files.

Note The Welch Allyn Diagnostic Cardiology Suite system database must be unencrypted prior to performance of any software upgrades.

Contact technical support if your facility requires this security feature.

System Installation Testing

Once the Welch Allyn Diagnostic Cardiology Suite system 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 system to prevent possibility for excessive touch and leakage currents.

Software Upgrade

When upgrades of Welch Allyn Diagnostic Cardiology Suite Manager 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 Manager software is located.
2. Double-click **Setup.exe**.
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 Manager software must be uninstalled, the following process should be followed.

Prior to the uninstall:

- If uninstalling the full system, the modalities should be uninstalled before the Manager application is uninstalled.
- If the Manager software is uninstalled and reinstalled without uninstalling the modalities, the modalities' installation should be repaired. To repair the installation, select "Repair" from the application list or from the modality 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.

Uninstall steps:

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

Database Backup and Restore

If needed, the Welch Allyn Diagnostic Cardiology Suite database can be copied off to allow for backing up of critical patient data. To do so, complete the following steps:

To copy the database for backup:

1. Navigate to the location where the database is saved. By default the path is C:\ProgramData\MiPgSqlData, but a custom location may have been set during installation.
2. Copy and paste the FDrepo folder and the pgdata folder, as these two folders contain the database. If the database is large, this may take several minutes.
3. Once the folders are copied off they may be stored on a secure location until needed.

To restore the database:

The Welch Allyn Diagnostic Cardiology Suite uses the folders titled "FDrepo" and "pgdata" for the database. By default the location of the database is C:\ProgramData\MiPgSqlData, but a custom location may have been set during installation. If a copied database is to be restored to the system, the current FDrepo and pgdata folders must be removed and the back up must be renamed to match these folders. To do this:

1. The Welch Allyn Diagnostic Cardiology Suite database service must be stopped. To do this go to Control Panel > System and Security > Administrative Tools > Services.
2. Once in the services window find CorScribeDBSvc and select Stop. Stopping this service will also cause the services CorScribeAppServer and CorScribeLogServer to stop.
3. Take the current FDrepo and pgdata folders and rename them so that they are not in use but are stored off in case they must be restored. If needed, the folders can be deleted but doing so will permanently delete all currently stored patient and exam data.
4. Take the previously backed up folders and rename them to "FDrepo" and "pgdata" respectively.
5. Go back to the Services list and start the three services CorScribeDBSvc, CorScribeAppServer, and CorScribeLogServer.
6. Launch the application and see the database has been successfully restored.

Using Welch Allyn Diagnostic Cardiology Suite

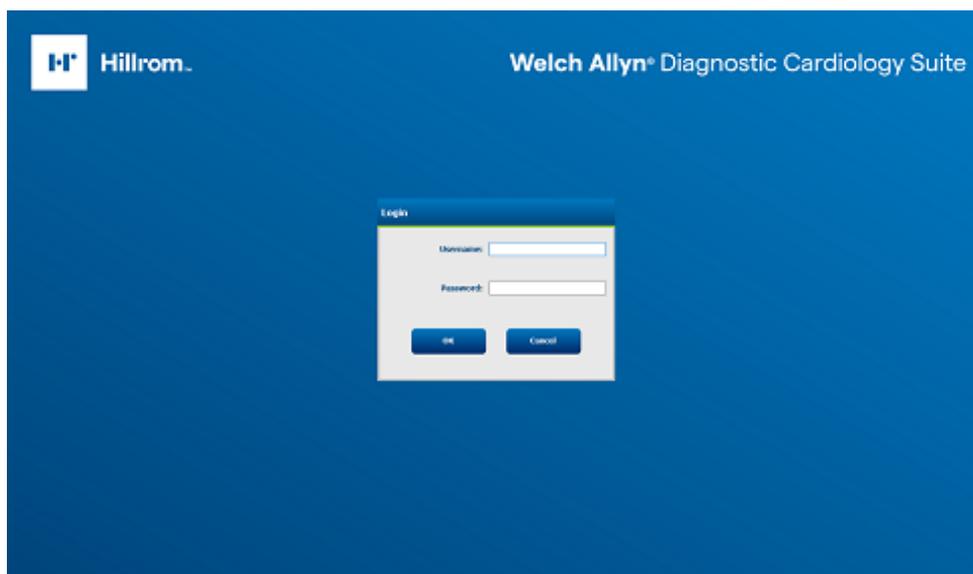
Login and Main Display

1. Use the Welch Allyn Diagnostic Cardiology Suite desktop icon to start the application.
2. If not set up with single sign-on, the application will require user credentials on startup. Enter your username and password and then select **OK** to open the application main menu.

Note The default username and password are "admin" (password is case-sensitive).



WARNING Be sure to change the default password after initial login.

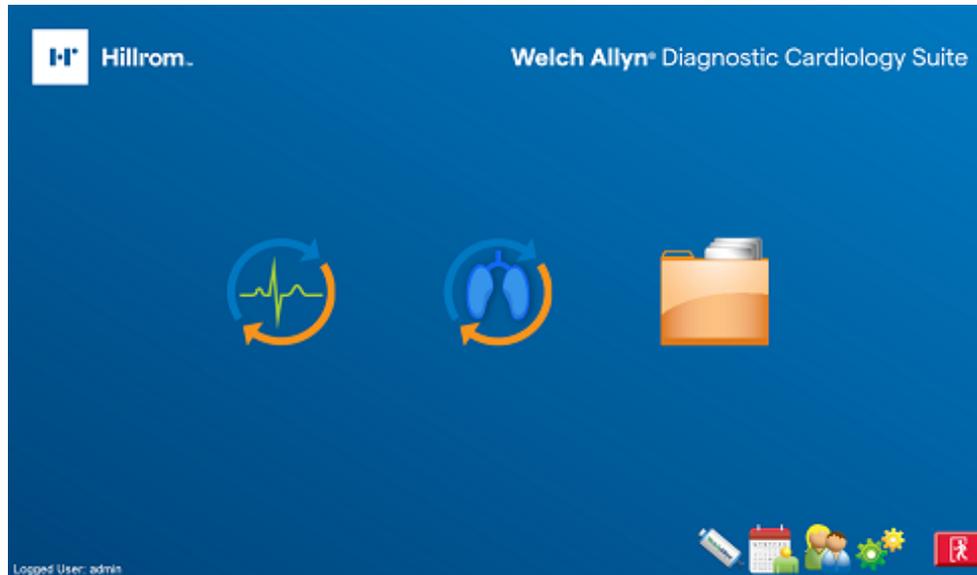


Upon successful login, the application screen will appear displaying the username and software version in the bottom left corner.

The icons in the center of the screen indicate workflow tasks in order, left to right.

3. Click the icon representing the workflow task you wish to perform.

Hover the mouse over an icon to display its function.



Icons and Descriptions

Icon / Name	Description
	<p>Desktop Icon Launches the Welch Allyn Diagnostic Cardiology Suite application.</p>
	<p>MWL Patients Opens a window with two selectable tabs. The MWL (Modality Work List) tab allows exam scheduling (when no orders interface exists) and schedule review. The Patients tab allows addition of new patient information and editing of existing patient information.</p>
	<p>Start a Resting Exam Use to enter exam data and begin real-time ECG acquisition.</p>
	<p>Start a Spirometry Exam Use to enter exam data and begin spirometry acquisition.</p>

Icon / Name	Description
	Spirometry Calibration Use to calibrate the spirometry Flow Sensor.
	Exam Search Use to search for exams in the database using filters.
	User Preferences Use to configure user preferences for the Worklist and to change the password.
	System Configuration For administrative users to configure system settings such as creating/modifying users, changing the default acquisition criteria, defining archive directories, and so on.
	Exit Use to close the application and return to the desktop.
	Toolbar Icons Minimize or exit the application and return to the desktop.

Schedule an Exam

The Schedule an Exam function is used to input patient and scheduled test information when it is known prior to the test and in the absence of an external orders interface.

When an exam is scheduled for a patient; exam data such as referring physician and requested date and time are entered. If the patient does not exist in the database, patient demographic data is entered.

Start an Exam

The patient is ready to begin an exam when he or she is connected to the Welch Allyn Diagnostic Cardiology Suite system via the data acquisition module of the associated modality of the exam. An exam may fulfill an order or be an ad-hoc exam. For an ad-hoc exam, a patient must be selected from the database or a new patient must be created by entering demographic information before starting the exam. Once the data is collected, the operator may edit, print, review, sign or save the exam for future processing and analysis.

Acquiring a STAT ECG Exam

A STAT ECG can be started when there is an immediate need to acquire an ECG without prior demographic data entry. A STAT ECG is acquired by selecting the Start a Resting Exam icon and then selecting Start Exam without entering any patient demographics. The patient is connected to the system via the data acquisition module, data is collected and a 10 second ECG is acquired. If not data was entered before initiating the ECG the exam will be saved to a blank patient. Patient information can be edited after the ECG is saved. These saved exams can be found through exam search and the patient information can be updated in the MWL/Patient window.

Reviewing and Signing an Exam and Printing a Report

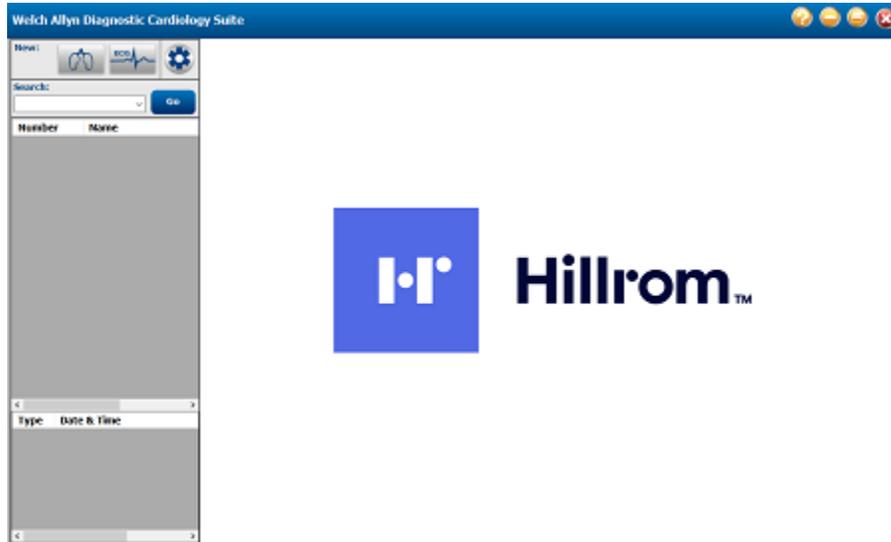
In order to edit an exam and electronically sign it, you must have the necessary permission. Previously acquired exams are saved and can be found through exam search.

Operation without Server Connection

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 to 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.

Use with Integrated EMR

When launching the Welch Allyn Diagnostic Cardiology Suite from an integrated EMR, the workflow is different than if the application was launched from the desktop. Instead of the main screen being displayed, a window similar to the following is displayed upon launching the application:



WARNING When launched from an integrated EMR, if the application is unable to communicate with the database, offline mode is not supported and the application will not be able to launch. If immediate data collection is required, exit then navigate to the start menu. Launch the Welch Allyn Diagnostic Cardiology Suite to acquire the necessary clinical data.

Icon	Name	Description
	Start a Spirometry Exam	Starts a spirometry exam for the selected patient
	Start a Resting Exam	Starts a Resting ECG exam with the selected patient. If no patient is selected, starts a STAT ECG
	Settings	Launches settings if user has local PC administrative privileges
	Toolbar Icons	Access the about screen, minimize, restore, or exit the application window

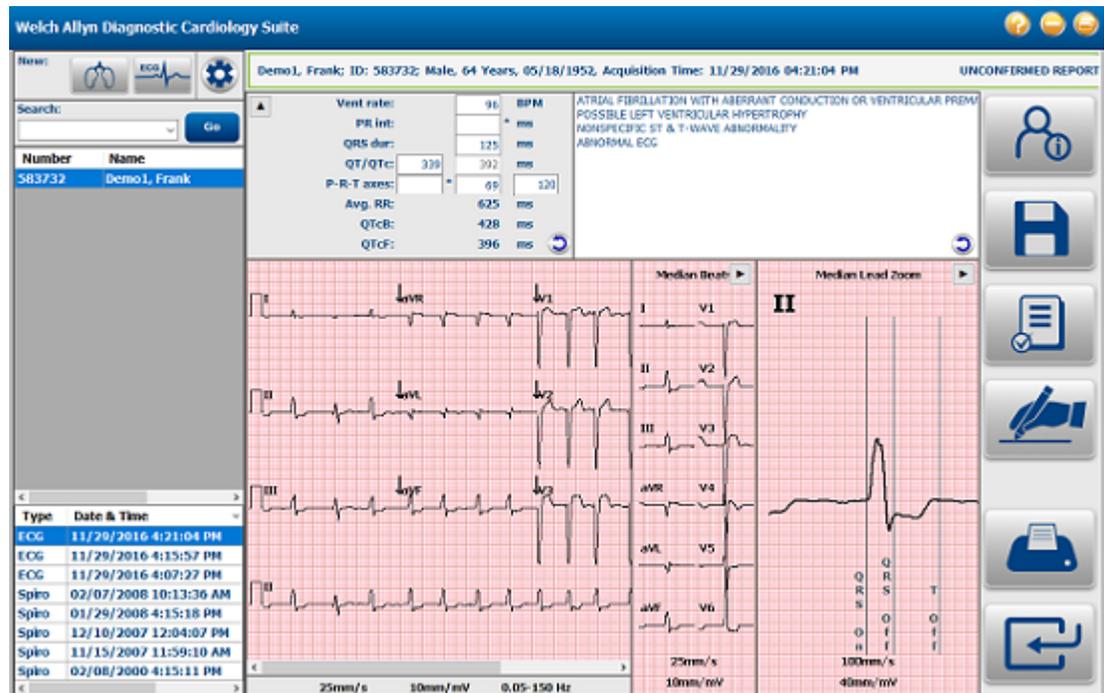
Taking an Exam

When starting an exam from an integrated EMR, depending on the EMR, the user will either immediately enter acquisition for the selected patient in the Welch Allyn Diagnostic Cardiology Suite, or the home screen will be displayed with the selected patient. If the home screen is displayed the user must click the start exam icon corresponding to the exam they are to perform. Specifics on how to perform the exams can be found in the corresponding modality user manuals.

After acquisition is complete and saved, reviewed, or signed, the exam data is sent back to the integrated EMR to allow for future review.

Reviewing an Exam

When an exam is selected to be reviewed in the integrated EMR it will be launched in review mode by the Welch Allyn Diagnostic Cardiology Suite as shown in the example ECG exam below:



The same workflow buttons as described in the section above appear when launched from the EMR integrated configuration as well.

When in review mode, a list of the selected patient's previous exams is displayed in the bottom left of the application window. The type of exam and date of acquisition are displayed, and if the user scrolls the list to the right the exam status is also displayed. Selecting an exam from this list will bring it up in review mode.

User Roles

When an integrated EMR user is created, they are assigned to one of 4 roles: Administrator, Physician, Technician or User. These roles map to roles that exist in the standard desktop version of the Welch Allyn Diagnostic Cardiology Suite in the following way:

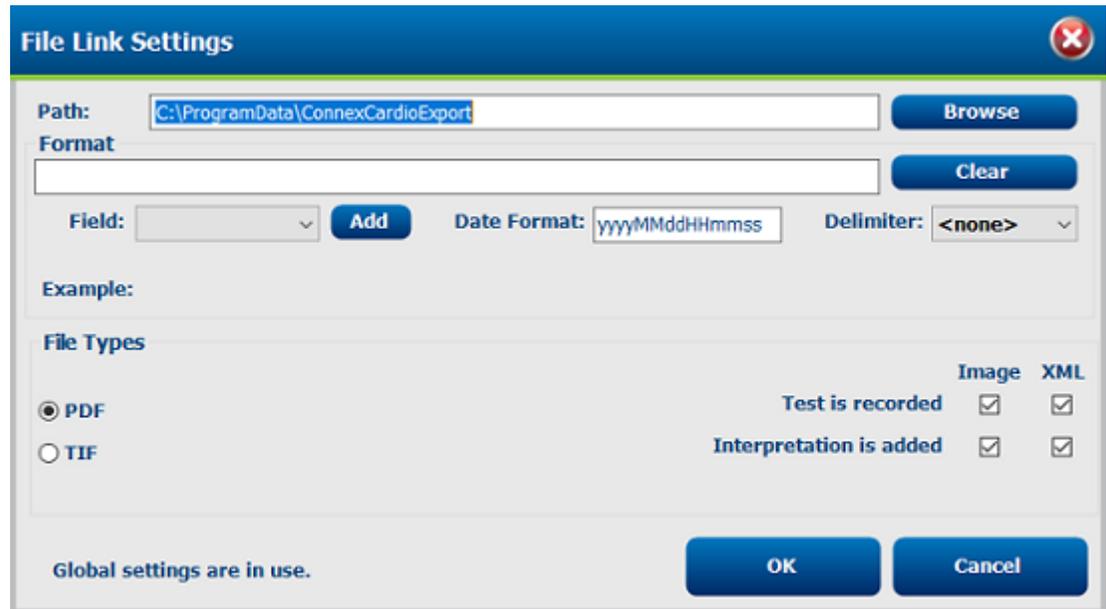
Administrator	<ul style="list-style-type: none"> • It Admin • Schedule Procedure • Prepare Report • Sign Report • Export Report 	<ul style="list-style-type: none"> • Clinical Admin • Patient Hookup • Review & Edit Report • Edit Conclusions • View Exams & Reports
Physician	<ul style="list-style-type: none"> • Clinical Admin • Patient Hookup 	<ul style="list-style-type: none"> • Schedule Procedure • Prepare Report

	<ul style="list-style-type: none"> Review & Edit Report Edit Conclusions 	<ul style="list-style-type: none"> Sign Report Export Report
Technician	<ul style="list-style-type: none"> Patient Hookup Review & Edit Report Export Report 	<ul style="list-style-type: none"> Prepare Report Edit Conclusions View Exams & Reports
User	<ul style="list-style-type: none"> Export Report View Exams & Reports 	

See section below on user roles and permissions for more information about how the roles affect functionality.

Settings

When the settings icon is selected, if the user has administrative privileges on the PC the following settings window is displayed.



Settings are specifically configured upon install based on the integrated EMR selected. Changing the settings could impact the ability of the Welch Allyn Diagnostic Cardiology Suite to communicate with the EMR.

Setting	Description
Path	The path that the Welch Allyn Diagnostic Cardiology Suite saves exam data.
Format	The file name format the data is saved as. Different fields can be added to the format, the presented date format can be edited and a delimiter can be added. An example of the format is displayed.
File Type: Image or XML	The checkboxes at the bottom right of the Preferences screen control when output files are automatically generated, and the type of output.
File Type: PDF or TIF	Sets whether exam reports are exported as PDF or TIF image files.

Setting	Description
Settings Indicator	The bottom left indicates whether the global settings are in use, or if local settings are in use.

Patient and Order Management



The MWL/Patients icon allows you to schedule exams and enter patient demographics information. Select this icon to schedule exams and to view existing schedules.

When the Welch Allyn Diagnostic Cardiology Suite is linked to an external scheduling system, this information arrives from institution entered orders.

When the icon is selected, a split window appears showing two selectable tabs MWL and Patients. Patient or Order Information fields will show on the right.

The screenshot shows a window with two tabs: 'MWL' and 'Patients'. The 'Patients' tab is selected. Below the tabs is a search input field and a blue 'Search' button.

Patients

Text that is entered in the search field will be used to search through the patient demographics in the database to display any patients that start with matching text in the Last Name, First Name, or Patient ID.

Patients columns include Patient ID, Last Name, First Name, and Date of Birth. The list can be sorted by selecting the column headers. A second selection on the same header will reverse the column order.

The screenshot shows the 'Welch Allyn Diagnostic Cardiology Suite' window with the 'MWL/Patients' tab selected. The interface is split into two panes. The left pane shows a table of patients with columns for Patient ID, Last Name, First Name, and Date of Birth. The right pane shows detailed patient information for the selected patient.

Patient ID	Last Name	First Name	Date of Birth
583732	Demo1	Frank	5/18/1952

Patient Information

Last Name: Demo1
 First Name: Frank
 Middle Name: James
 Gender: Male
 DOB: 5/18/1952
 Age: 67 Years
 Height: 68 in
 Weight: 205 lb
 Race: Caucasian
 ID: 583732
 Second ID: 432-35-2832
 Address: 41 North Woods Avenue
 City: Milwaukee
 Postal Code: 53223
 State: WI
 Country: USA
 Home Telephone: 414-252-6893
 Work Telephone: N/A
 Mobile Telephone: N/A
 Email Address: F2D@yahoo.com
 Angina: Typical
 History of MI: No
 Prior Cath: No
 Prior CABG: No

Buttons at the bottom: New Patient, Edit Patient, Delete Patient, Exit, Save Patient, Cancel.

In addition to the default patient ID format, the application also supports custom ID formats for each group through use of ELI Link. Refer to the ELI Link administrator manual, part number 9515-166-50-ENG, for instructions on Custom ID.

Edit Patient

Selecting an entry in the list will display the patient information as read-only. Select **Manage** and then **Edit** to enable and modify the patient demographics fields.

Select **Save Patient** when finished to save changes or **Cancel** to return to read-only demographics without saving changes. When a patient's demographics are changed, the next time an exam that was previously acquired for that patient is opened for review, the patient's demographics for that exam will update to the most recent saved in the database.

New Patient

Selecting **Manage** and then **New Patient** clears any selected patient information allowing the addition of a new patient in the list. The new patient information can be entered in the demographic fields. To save it to the database, click **Save Patient**. Clicking **Cancel** will close the patient information without saving.

The screenshot displays the 'MWL Patients' window. On the left, a table lists patient information:

Patient ID	Last Name	First Name	Date of Birth
583732	Drews1	Frank	5/18/1992

Below the table are buttons for 'New Patient', 'Edit Patient', 'Delete Patient', and 'Exit'. On the right, the 'Patient Information' form contains the following fields:

- Last Name:
- First Name:
- Middle Name:
- Gender:
- DOB:
- Age:
- Height:
- Weight:
- Race:
- ID:
- Second ID:
- Address:
- City:
- Postal Code:
- State:
- Country:
- Home Telephone:
- Work Telephone:
- Mobile Telephone:
- Email Address:
- Angina:
- History of MI:
- Prior Cath:
- Prior CABG:

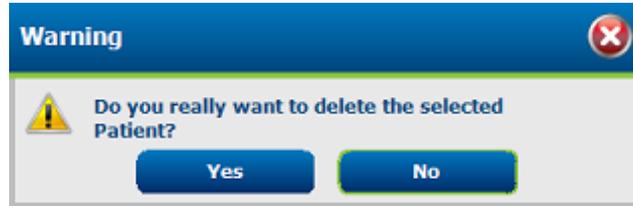
At the bottom right of the form are buttons for 'Save Patient' and 'Cancel'.

Delete Patient

Select **Manage** and then **Delete** to remove patient demographics from the Welch Allyn Diagnostic Cardiology Suite database.

Note *The delete button is disabled when the patient demographics are associated with an existing order or exam. All orders and exams for that patient must first be deleted before the patient demographics can be deleted.*

A delete confirmation warning message will appear. Select **Yes** to delete the patient demographics or **No** to cancel and return to the Patients listing.



Exit MWL/Patient

Select **Exit** when finished to return to the main menu.

MWL

Text that is entered in the search field will be used to search through the Modality Worklist (MWL) to display orders that start with matching text in the Last Name, First Name, or Patient ID.

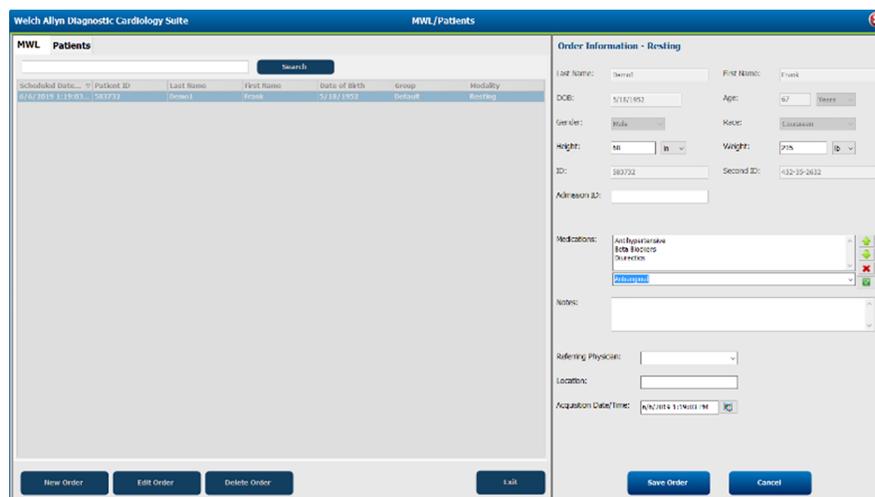
MWL columns include Scheduled Date/Time, Patient ID, Last Name, First Name, Date of Birth, and Group. The list can be sorted by a click on the column headers. A second click on the same header will reverse the column order.

Note Selection of an unavailable order (e.g. in use at another workstation, deleted, or canceled) will result in a refresh of the listed orders.

Edit Order

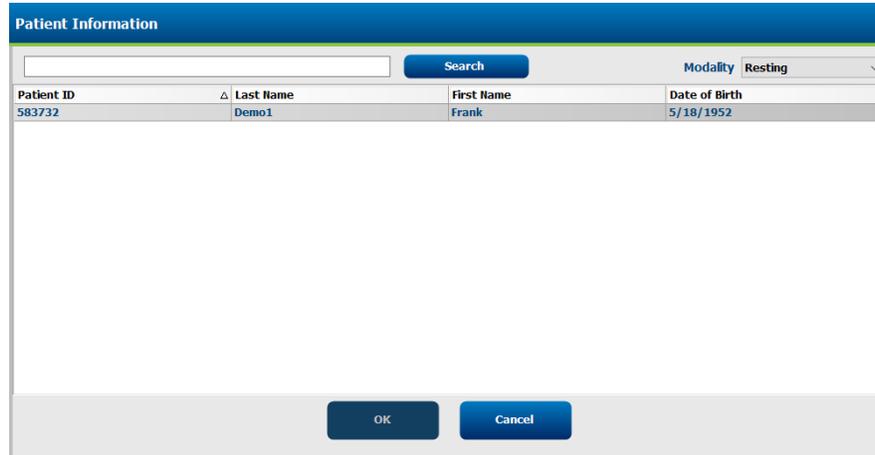
1. Selecting an entry in the list will display the Order Information as read-only. Select **Manage** and click on the item **Edit Order** to modify the order. Select **Save Order** or **Cancel**.

Note This function is not available when an order's interface is enabled.



New Order

The *New Order* button allows a Patient ID or name search of patient information in the database allowing addition of a new order in the MWL list.



The Patient Information dialog box features a search bar at the top with a 'Search' button and a 'Modality' dropdown menu set to 'Resting'. Below this is a table with the following data:

Patient ID	Last Name	First Name	Date of Birth
583732	Demo1	Frank	5/18/1952

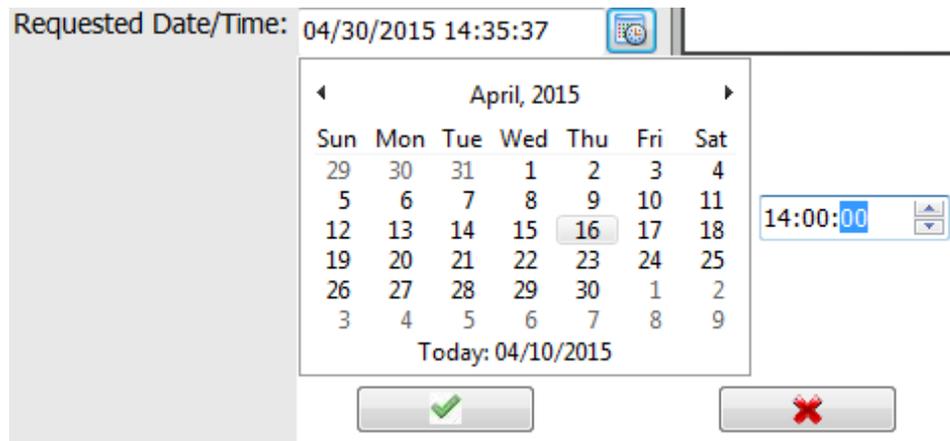
At the bottom of the dialog are 'OK' and 'Cancel' buttons.

When the patient does not exist in the database, cancel the search and select the **Patients** tab to enter a new patient.

The patient information populates the order information at the right of the display. Additional order information can be entered and the order saved. Press **Cancel** to close the order without saving.

When entering an order, use the Group drop-down list to assign the order to a specific group that has been configured in the system settings. This is not necessary when there is no more than one group.

Select the calendar icon in the bottom right corner of the Order Information section to open a calendar to select the scheduled order date and time. Date and time may also be entered by typing in the Requested Date/Time field.



The Requested Date/Time dialog box shows the current date and time as '04/30/2015 14:35:37'. It includes a calendar icon and a calendar view for April 2015. The calendar shows the following dates:

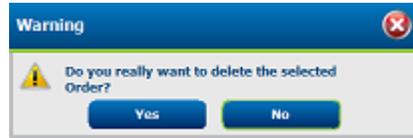
Sun	Mon	Tue	Wed	Thu	Fri	Sat
29	30	31	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	1	2
3	4	5	6	7	8	9

The calendar indicates 'Today: 04/10/2015'. To the right of the calendar is a time selection field showing '14:00:00'. At the bottom are 'OK' (green checkmark) and 'Cancel' (red X) buttons.

Delete an Existing Order

Select an existing patient order by highlighting the line, clicking **Manage**, then **Delete Order**.

A delete confirmation warning message will appear. Select **Yes** to delete the order or **No** to cancel and return to the MWL listing.



Exit MWL/Patients

Select **Exit** when finished to return to the main menu.

Exam Management

Start an Exam

Select any of the installed modalities' **Start an Exam** icon to open the MWL/Patients window.

Scheduled Order(s)

1. When there is an existing order for the patient, highlight the patient in the MWL list. The Exam Information section on the left side of the display is populated by the previously entered patient demographics.

2. Enter any desired exam information on the left panel and select **Start Exam**.

Note Selection of an unavailable order (e.g. in use at another workstation, deleted, or canceled) will result in a refresh of the listed orders.

No Scheduled Order(s)

When no scheduled orders exist, the Patients tab is automatically selected.

1. Search for existing patients in the database by entering a name or ID number, and then select **Search**.
2. When the patient information is not found, enter any desired patient and exam information on the left panel.

Note If the entered ID number already exists in the database, a warning will appear informing you to click OK to continue or Cancel to correct the entered demographics.

Enter date of birth by typing MM/DD/YY or DD-MM-YY according to the computer regional settings, or by clicking on the calendar icon. Select the decade and the year; use the left/right arrows to scroll the year, the month, and the day to populate the field. Age will be automatically calculated.



The application remembers list items such as Indications, Medications, Procedure Type, and Referring Physician as they are entered. The added items will be available for future selection. Enter text or choose items from the drop-down menu and then click on the green checkmark to enter. Use the red X to delete the selected item. When there are multiple entries, items can be moved up or down by using the green arrow keys.

Some fields are not available (grayed) when patient demographics are attached to existing exams in the database or are ordered by an external system.

Exam Data Acquisition, Printing, and Storage

Once the patient is set-up with the acquisition device and the Start Exam button is selected from the Exam Information window, the Welch Allyn Diagnostic Cardiology Suite is ready to collect data. The specifics of data acquisition for each modality can be found in their corresponding user manuals.

Exam Search

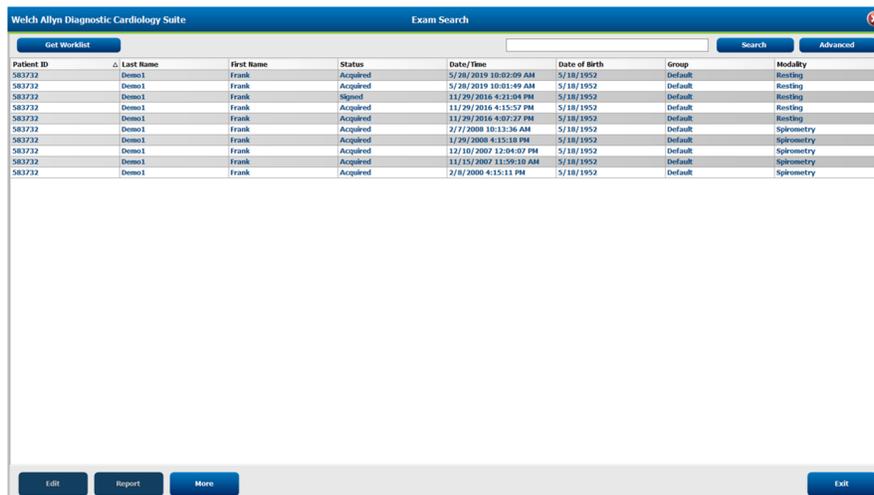
Selecting Reports to Review

The Exam Search icon  is available for users that will edit, review, and sign exams. Click on the icon to view exams according to their status and your role.

Get Worklist will filter the list of exams according to the user preferences for the logged in user.

A search field is available for entry of a patient name or ID number. When you enter one or more alphanumeric characters, all exams that start with those characters are displayed in a list when a search is performed. Listed exams can be sorted by clicking any of the column headers.

When a complete last name, first name, or patient ID is entered in the search field and the Search button is clicked, all matching exams will appear in the list.



Patient ID	Last Name	First Name	Status	Date/Time	Date of Birth	Group	Modality
583732	Demo1	Frank	Acquired	5/28/2019 10:02:09 AM	5/18/1952	Default	Resting
583732	Demo1	Frank	Acquired	5/28/2019 10:01:49 AM	5/18/1952	Default	Resting
583732	Demo1	Frank	Signed	11/28/2016 4:21:04 PM	5/18/1952	Default	Resting
583732	Demo1	Frank	Acquired	11/29/2016 4:15:57 PM	5/18/1952	Default	Resting
583732	Demo1	Frank	Acquired	11/29/2016 4:02:22 PM	5/18/1952	Default	Resting
583732	Demo1	Frank	Acquired	2/7/2008 10:13:36 AM	5/18/1952	Default	Spirometry
583732	Demo1	Frank	Acquired	1/29/2008 4:15:18 PM	5/18/1952	Default	Spirometry
583732	Demo1	Frank	Acquired	12/10/2007 12:04:07 PM	5/18/1952	Default	Spirometry
583732	Demo1	Frank	Acquired	11/15/2007 11:56:10 AM	5/18/1952	Default	Spirometry
583732	Demo1	Frank	Acquired	2/8/2000 4:15:11 PM	5/18/1952	Default	Spirometry

Highlight an exam in the list then click one of the following:

- **Edit** : open the exam for review and editing.
- **Report**: open the final report for review and printing.
- **More**: display advanced selections.
- **Copy Offline**: allows an existing exam to be copied to an external drive using a browser for review at another Welch Allyn Diagnostic Cardiology Suite system.

- **Open Offline:** allows a Welch Allyn Diagnostic Cardiology Suite system user to open an exam from another system by browsing to the location of the copied exam.
- **Transmit:** sends exam results to the ELI Link destination defined in the system configuration settings. This selection is only enabled when the selected exam(s) has the associated export status enabled in the Workflow Config settings.
- **Reconcile:** match an order to an exam that was performed before the order was available, or to correct information after the exam has been completed with incorrect patient demographics.
- **Archive :** move the exam from the database to an external drive for long-term storage purposes.
- **Delete:** permanently remove an exam or an order from the system database. The exam is not recoverable after performing this action.



Note Button actions are dependent on user permissions. Unavailable buttons will appear grayed.

Advanced Search

For more options with exam list filtering, click **Advanced**. The identifier selections are relational to the selected filter and are dependent on your system configuration.

Exams from specific modalities can be searched for by selecting the modality checkboxes. The exam state(s) are selected by checkbox as identifiers. Click **Search** after your filter and identifiers are selected. Click **Clear** to cancel and remove your entries from the search fields.

When finished, click **Done** to exit the advanced search selections and return to the main exam search window.



Exam State Identifiers

Acquired

- Checked if equal to

Edited

- Checked if equal to

Reviewed

- Checked if equal to

Signed

Exam Criteria Identifiers

Patient ID

- Equal to
- Start with

Last Name

- Equal to
- Start with

First Name

- Equal to
- Start with

Group

- Equal to

Exam State Identifiers

- Checked if equal to

Exam Criteria Identifiers

- Blank (All)
- Any defined Group this user can access

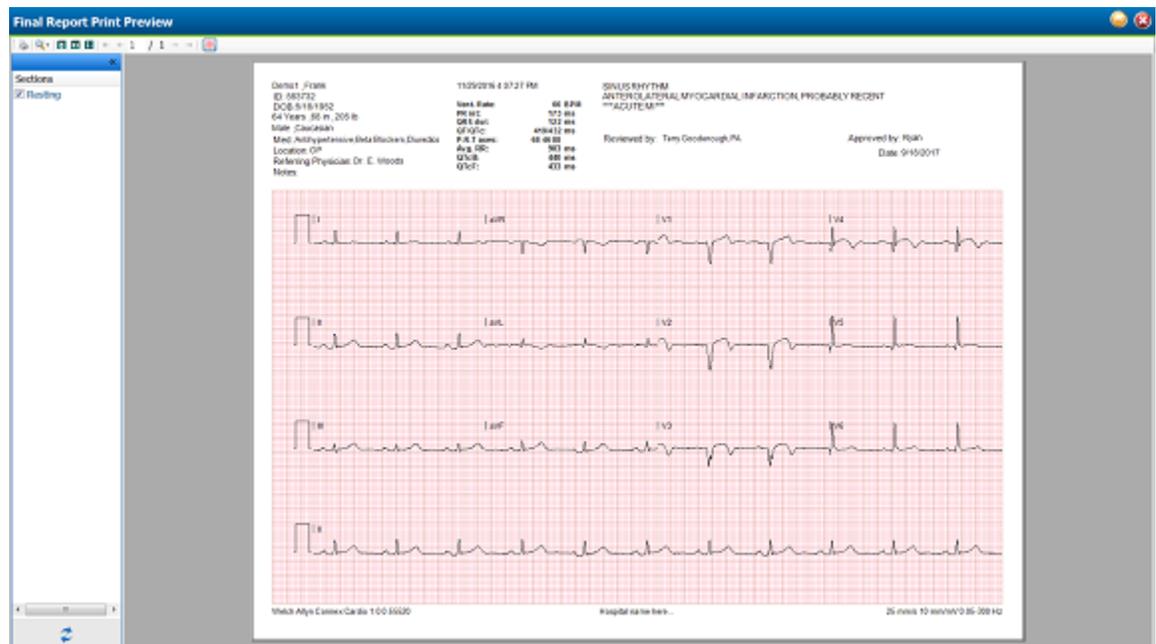
Date / Time

- Equal to
- Prior to
- Later than

Report Print Preview

To open a preview of a report that has been reviewed or signed, select the Report button  in Exam Search. A preview is generated and the report is displayed.

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.

Use the pink grid icon to toggle the ECG grid background on or off. An X appears when the background is off.

Sections

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

Exit the Print Preview

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

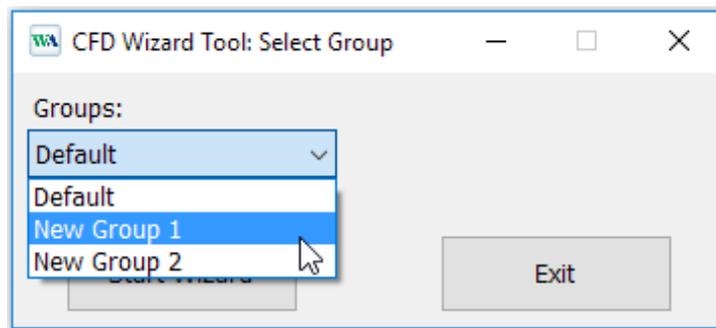
Configure the Report

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

- Adding a custom logo to the report, if supported by the modality
- 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



Some modalities support adding 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.

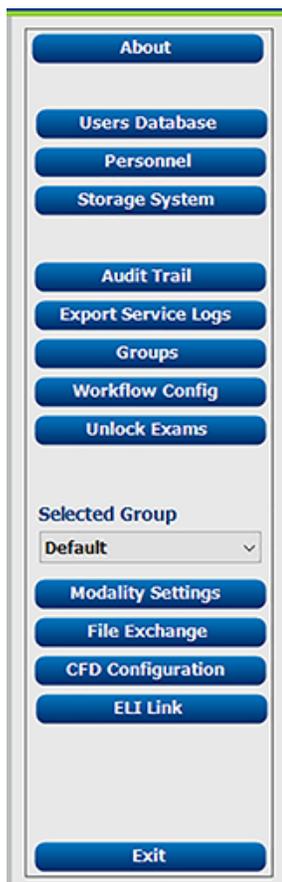
System Settings

Use the System Configuration icon  on the main screen to enter the system configuration menus.

The IT and Clinical Administrator can select the System Configuration icon to enter the administrative functions. All other users can enter this menu to access the Export Service Log task only.

Administrative tasks include:

- View software information such as version and serial number
- Manage User Accounts
- Manage Personnel Lists
- Manage Archived Exams
- View Audit Trail Logs
- Export Service Logs for Troubleshooting
- Manage Groups
- Configure Workflow
- Unlock Exams
- Configure Group Specific Modality Settings
- Configure File Exports
- Configure Patient Demographics Fields
- Configure ELI Link Connectivity



The screenshot displays a vertical menu of system configuration options. At the top is an 'About' button. Below it are buttons for 'Users Database', 'Personnel', and 'Storage System'. A section of buttons follows: 'Audit Trail', 'Export Service Logs', 'Groups', 'Workflow Config', and 'Unlock Exams'. Below these is a 'Selected Group' dropdown menu currently set to 'Default'. Underneath the dropdown are buttons for 'Modality Settings', 'File Exchange', 'CFD Configuration', and 'ELI Link'. At the very bottom of the menu is an 'Exit' button.

Manage User Accounts and Personnel

Users Database

The IT administrator will select Users Database to create new or delete user accounts, reset user passwords, assign roles (permissions) and groups for each user, and assign personnel entries for that user's selection. When a single sign-on is used, no user account and password creation is needed.

Users Database

User ID	Username	Name	Roles
1	admin		IT Administrator, Clinical Admin, Schedule Procedure, Patient Hookup, Prepare Report, Review and Edit Report, Sign Report, Edit
2	Doctor1	Dr. Williamson	Clinical Admin, Prepare Report, Review and Edit Report, Sign Report, Edit Conclusions, Export Report, View Exams/Reports
3	Doctor2	Dr. Fuller	Prepare Report, Review and Edit Report, Sign Report, Edit Conclusions, Export Report, View Exams/Reports
4	Doctor3	Dr. Fredericks	Prepare Report, Review and Edit Report, Sign Report, Edit Conclusions, Export Report, View Exams/Reports
5	RN1	Mary Adams	Clinical Admin, Schedule Procedure, Patient Hookup, Prepare Report, Review and Edit Report, Edit Conclusions, Export Report, View
6	Tech6	Robert Cole, RCVT	Schedule Procedure, Patient Hookup, Prepare Report, View Exams/Reports
7	Tech7	Hannah Esteban, CVT	Patient Hookup, Prepare Report, Export Report, View Exams/Reports
8	Tech8	Norman Kuchar, CCVT	Schedule Procedure, Patient Hookup, Prepare Report, Export Report, View Exams/Reports
9	PA9	Roland Parker, PA	Clinical Admin, Schedule Procedure, Patient Hookup, Prepare Report, Review and Edit Report, Edit Conclusions, Export Report, View
10	NP10	Kathleen Reemer, Nurse Practitioner	IT Administrator, Clinical Admin, Schedule Procedure, Patient Hookup, Prepare Report, Review and Edit Report, Edit Conclusions,

New Edit Delete

Personnel

Personnel is selected to add personnel that will be available in the Patient Information, Summary, and the Finalize Exam Update windows. Listed personnel can be assigned to each user account and will appear as selections for the logged-in user and in the appropriate final report fields.

Personnel

Printed Name	Staff ID#	Enabled	In Reviewer List	In Technician List	In Approver List	In Attending Phys List
Dr. Williamson	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dr. Fuller	2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dr. Fredericks	3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dr. Collins	4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Mary Adams, RN	5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Robert Cole, RCVT	6	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hannah Esteban, CVT	7	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Norman Kuchar, CCVT	8	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Roland Parker, PA	9	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Kathleen Reemer, NP	10	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Save Changes Discard Changes

New User

Selection of the **New** button within the Users Database window will open the New User dialog.

Note It is recommended to complete the personnel list before adding users so they can be selected as new users are added.

The name entered in the Display Name field will appear on the Welch Allyn Diagnostic Cardiology Suite display when that user logs in.

The login password is entered and repeated.

Roles for this user, personnel that will populate drop-down lists for this user, and groups that this user will have access to are checked.

New User through Active Directory

The Welch Allyn Diagnostic Cardiology Suite has the ability to integrate with Active Directory for authentication of users. Activation of Active Directory must be completed by an IT administrator.

To activate Active Directory:

1. Close the application.
2. From the Start menu, browse to All Programs > Hillrom > Connex Cardio Configuration Utility.
3. When prompted that services will stop click **OK**.
4. In the Logon Mode drop-down, select **Active Directory**.
5. To enable single sign-on, check the box below. This is only available when Active Directory is enabled.
6. Click **Save**, then **Exit**.
7. Log in with the local administrator username and password.
8. Click on the gears icon to enter system configurations, then click on the **Users Database** button.
9. To add a new Active Directory user, click **New**.
10. Select the user by using the drop-down list, or typing in the search bar and click **Search**. A list of users and their role is provided by Project Management and added to the onsite form.
11. Select the appropriate roles, personnel, and groups the user should be part of.
12. Click **OK** and repeat for all users.

Note If enabling the Legal Signature setting for signing of exams, additional Windows features must be enabled to use single sign on. Navigate to Windows Features > Internet Information Services > World Wide Web Services > Security. Under Security, make sure Basic Authorization, Request Filtering, and Windows Authentication are all selected.

User Roles and Permissions

The Welch Allyn Diagnostic Cardiology Suite supports a workflow-oriented setup for defining user roles and controlling user access to the various operations. Role assignments are comprised of a set of permissions for each user type (e.g. IT administrator, clinical administrator, technician, and so on).

Each user can be assigned a single role or a combination of roles. Some roles will include permissions assigned to other roles where applicable. After installation, a single user is created, with the role of IT Administrator. Before using the application, this user should log in and create required users and roles.

Roles	Permission Assignment
IT Administrator	Manage user permissions; manage personnel lists; export settings; archive settings; workflow configuration; storage system configuration; unlock exams; view audit trail reports; export service logs; create and modify groups.
Clinical Administrator	Manage database exams (delete, archive, and restore); copy exams offline to share with Welch Allyn personnel or other sites; view audit trail reports; modify modality settings; reconcile; export service logs.
Schedule Procedure	Create new patient orders; associate an order with an existing patient; modify demographics of an existing patient; export service logs. <i>Scheduling and order entry is only available when the application is not linked to an external scheduling system.</i>
Patient Hookup (Start a resting exam)	Ability to start a test using Start a Resting Exam icon. Includes the ability to create a new patient; associate an order with an existing patient; export service logs.
Edit Holter Diary	Not applicable to the Welch Allyn Diagnostic Cardiology Suite application.
View Exams / Reports	Review exams and final reports only. Includes the ability to search exams, view and print reports; export service logs.
Prepare Report	Review and edit exams to move them from an acquired state to the edited state. Includes ability to search exams and view and print reports; export service logs.
Review and Edit Report	Review and edit exams to move them to the reviewed state. Includes ability to search exams and view and print reports; modify and create conclusions; export service logs.
Edit Conclusions	Create and modify conclusions. Includes ability to review exams and final reports only; search exams and view and print reports; export service logs.
Sign Report	Ability to move exams to a signed state. Includes ability to review exams and final reports; search exams and view and print reports; export service logs. May require user authentication.
Export Report	Ability to export a PDF and XML file when features are enabled. Must be assigned in conjunction with another role (e.g. Review, View, or Conclusions).

User Role Assignment Table

Main Screen

	IT Admin	Clinical Admin	Schedule Procedure	Patient Hookup	Prepare Report
Schedule Orders	No	Yes	Yes	No	No
Start an Exam	No	No	No	Yes	No
Exam Search	No	Yes	No	No	Yes
User Preferences	Yes - No Status Filter	Yes - No Status Filter	Yes - No Status Filter	Yes - Filter Acquired only	Yes - Filter Acquired and Edited only
System Configuration	Yes - No Modality Settings, CFD or Report Settings	Yes - Audit Trail, Service Logs, Report Settings, Modality Settings and CFD	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only
Calibrate Spirometer	Yes	Yes	Yes	Yes	Yes

Exam Search

	IT Admin	Clinical Admin	Schedule Procedure	Patient Hookup	Prepare Report
Edit	No	No	No	No	Yes - Acquired and Edited Exams only
Report	No	No	No	No	No
Copy Offline	No	Yes	No	No	No
Open Offline	No	No	No	No	Yes
Export	No	No	No	No	No
Reconcile	No	Yes (Signed only)	No	No	No
Archive	No	Yes	No	No	No
Delete	No	Yes	No	No	No

Editing Permissions

	IT Admin	Clinical Admin	Schedule Procedure	Patient Hookup	Prepare Report
Summary Tables	No	No	No	No	Yes
Conclusions Sections	No	No	No	No	Diagnosis, Reason For End and Technician
Patient Data	No	No	No	Patient and Contact Fields - only after Acquisition	Admission ID, Indications, Referring Physician, Procedure type, Location, Notes, and Technician
Page Review	No	No	No	No	Yes - View/Add/Edit Events and Print
Update Exam State	No	No	No	Acquired only	Edited only

Main Screen

	Review and Edit Report	Sign Report	Edit Conclusions	Export Report	View Exams/ Reports
Schedule / Orders	No	No	No	No	No
Start an Exam	No	No	No	No	No
Exam Search	Yes	Yes	Yes	Yes	Yes
User Preferences	Yes	Yes	Yes - Filter Acquired and Edited only	Yes - No Status Filter	Yes - No Status Filter
System Configuration	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only
Calibrate Spirometer	Yes	Yes	Yes	Yes	Yes

Exam Search

	Review and Edit Report	Sign Report	Edit Conclusions	Export Report	View Exams/ Reports
Edit	Yes - Acquired, Edited, Reviewed Exams only	Yes	Yes - Acquired, Edited, Reviewed Exams only	No	Yes
Report	No	No	No	No	Yes - Reviewed and Signed Exams only
Copy Offline	No	No	No	No	No
Open Offline	Yes	Yes	Yes	No	Yes
Export	No	No	No	Yes - Reviewed and Signed Exams only	No
Reconcile	Yes (Not Signed)	Yes (Not Signed)	No	No	No
Archive	No	No	No	No	No
Delete	No	No	No	No	No

Editing Permissions

	Review and Edit Report	Sign Report	Edit Conclusions	Export Report	View Exams/ Reports
Summary Tables	No	No	No	No	No
Conclusions Section	Symptoms and Conclusions	Symptoms and Conclusions	Symptoms and Conclusions	No	No
Patient Data	No	No	No	No	No
Page Review	Yes - View and Print only	Yes - View and Print only	Yes - View and Print only	No	Yes - View and Print only
Update Exam State	Reviewed only	Signed only	Edited only	No	No - Screen is not shown

Manage Archive Storage

The administrative user will manage storage system disks through selection of **Storage System**.

Add Archive Location

1. Select **New Archive** to define a path to the archive directory destination.

The screenshot shows the 'Storage System' interface with the 'Manage Archives' tab selected. The 'Archive Recovery' sub-tab is active. At the top, there are buttons for 'New Archive' and 'Delete Archive'. Below is a table of existing archives:

Label	Path	Timestamp	Username
External HD Archive	\\ITDomain\FDrive\Data Archive\	11/14/2015 11:24:33 AM	
Network Archive	\\mikedomain\axfer\Network Data Archive\	11/14/2015 11:28:11 AM	mortara\user

Below the table is the 'Archive Editor' section with fields for Label, Path, Username, Password, and Domain. To the right is a 'Drive Name' table showing available drives:

Drive Name	Drive Capacity
Fixed Drives	
C:\	337.4/452 GB
E:\	11.9/232 GB
F:\	909.2/931 GB

Buttons for 'Save Changes' and 'Discard Changes' are at the bottom.

- a. Any external disk (e.g. NAS, USB, etc.) accessible from the Welch Allyn Diagnostic Cardiology Suite central database is a candidate for becoming an archive volume.
 - b. The archive path should be defined as a UNC path such as \\ServerName\ShareName\Directory\
 - c. A Username, Password and Domain may be entered as needed to add the new storage disk to the Archive drive listing.
2. Select **Save Changes** to create the archive location or **Discard Changes** to exit the window without saving changes.

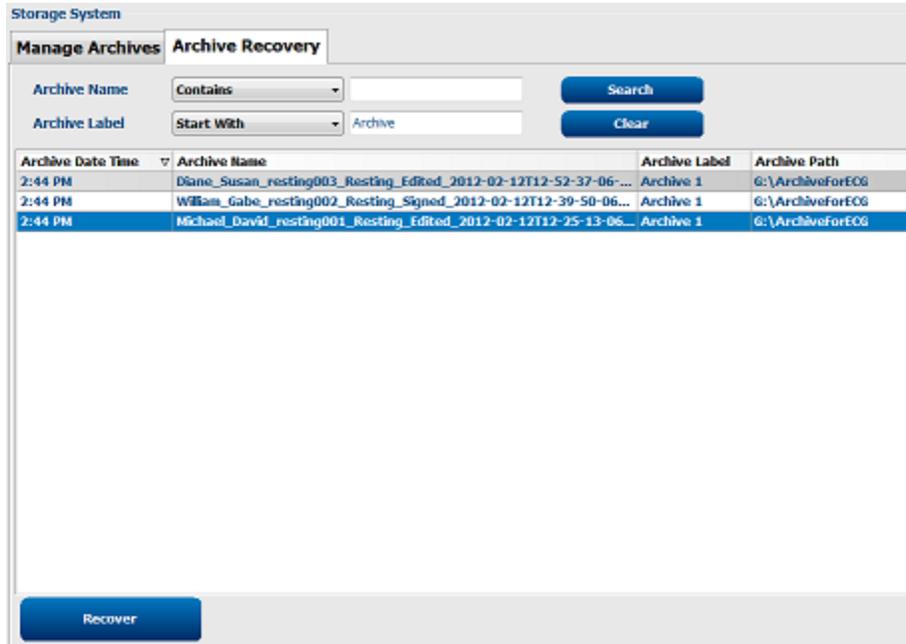
Note **Refresh Drive List** updates the list of available drives.

Note An archive path may also be deleted by highlighting the desired label and selecting **Delete Archive** . All archived exams will remain at the destination until they are manually deleted.

Recover Archived Exams

Administrative users can restore exams from the archive location to the Welch Allyn Diagnostic Cardiology Suite database by using the **Archive Recovery** tab. Once selected, a search can be performed using the Archive Name or the Archive Label.

- To search by Archive Name, a letter or number combination may be entered to show exams that contain the characters.
- To search by Archive Label, the first letter of the label can be entered with the Start With description, or the entire Archive Label can be entered with the Equal To description. Select **Search** when ready.
- Clicking **Clear**, clears all search fields.
- Column headers can be selected to sort listed exams by that item.
- To restore exams, highlight the desired exam(s) in the list and click **Recover**.
- Multiple exams can be restored by selecting to highlight, then clicking **Recover**.



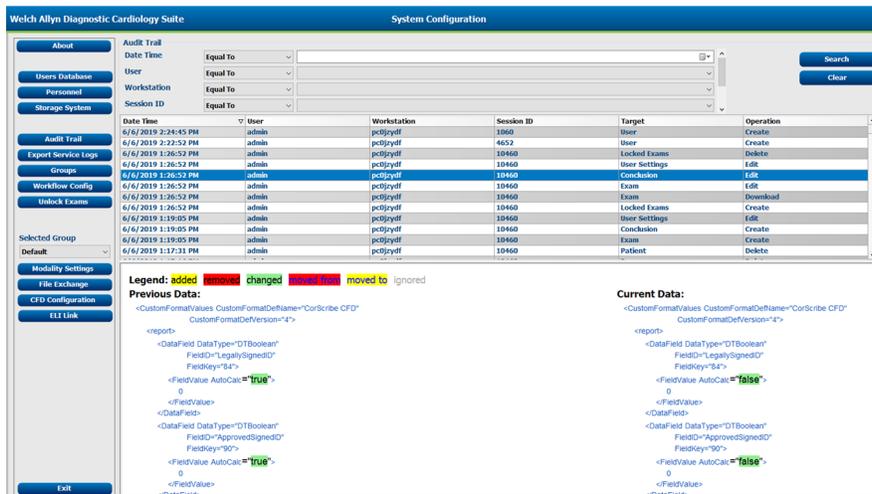
Logs

Audit Trail Logs

The administrative user will select Audit Trail to view the audit trail history. Selections for filter criteria are available to sort the listing by date, user, workstation, operation, or target (e.g. User, Patient, Exam, Conclusion, Locked Exams, User and System Settings). One or more filter criteria can be used to find audit trail information.

Results will display differences by comparing the XML statistics data before and after changes. A legend with colored highlighting will point to added, removed, changed, and moved information.

All configuration information, user information, patient demographic information, exam demographic information, textual conclusions, archive operations, and exam download requests are tracked by the audit trail with a date and time.



Service Logs

All users have access to Export Service Logs. This creates a Win-7 zipped file that can be sent to the desktop containing a copy of the system logged events.

The file named EMSysLog.xml.gz can be e-mailed to a service representative for troubleshooting purposes.

Manage/Create Groups

Groups allow the IT administrator to group exams according to user access, reporting preferences (modality settings) and file exchange preferences. Any user can be assigned to multiple groups. A group definition can be copied and saved with a new name to create a second group, copying all settings and preferences of the existing group.

- Select the **Groups** button to make changes. Any created group can be copied, renamed and modified.
- To create a new group, highlight the group you would like to copy, select **New Group**, and enter the new group name. A new group will be created with the settings of the highlighted group.
- Select the users under the Group User List that may have access to the highlighted group. The Select All and Deselect All options can be used to enable or disable all users.

If you want to rename a group without creating a new one, highlight the group, and enter a group name.

- Select **Save Group** to save your changes.

The default group (first in the list) can only be renamed. An unlimited number of new groups can be created and modified.

The screenshot displays the 'Group Management' window. At the top left, there are two buttons: 'New Group' and 'Delete Group'. Below these is a list box containing 'Cardiology', 'OP Clinic' (which is highlighted in blue), and 'Radiology'. To the right of this list is a text input field labeled 'Group Name:' containing the text 'OP Clinic'. Below the name field is another section labeled 'Group User List:' which includes a checkbox for 'Select All/Deselect All' and a list of users with checkboxes: 'admin' (checked), 'Doctor1', 'Doctor2', 'Doctor3' (checked), 'NP10', 'PA9' (checked), 'RN1', 'Tech6', 'Tech7' (checked), and 'Tech8' (checked). A 'Save Group' button is positioned at the bottom right of the window.

Modality Settings, CFD Configuration, and ELI Link configurations can be uniquely defined for each individual group.

Groups, with exception of the default group, can be deleted. All exams present in the database for the deleted group will be automatically assigned to the default group.

Configure Workflow

The exam states are designed to follow typical user workflow. There are five possibilities:

1. **Ordered:** The exam is either scheduled by a user or an external scheduling system has sent an order.
2. **Acquired:** The exam is completed and is ready for editing.
3. **Edited:** The exam has been analyzed and saved with changes, ready for review by a physician. Interpretation may be edited at this state.
4. **Reviewed:** The exam has been reviewed and confirmed to be accurate by an authorized user (e.g. physician, fellow, clinician, etc.). Interpretation may be edited at this state.
5. **Signed:** The exam is reviewed and electronically signed by an authorized user. No further workflow processing is required. Interpretation may be edited at this state.

Workflow Config

A Legal Signature can be enabled by selecting **Yes** or disabled by selecting **No**. When legal signature is set to Yes, the user is prompted to enter their login password and ID.

Administrative users can configure the workflow to include all, or exclude some states through selection of Modality Status radio buttons.

- Select **All** to enable all five states.
- Select **No REVIEWED** to move the state from EDITED to SIGNED.
- Select **No EDITED/REVIEWED** to move the state from ACQUIRED to SIGNED.

Checkboxes under Export Status allow choices for manual or automatic export of the results when the state moves to Acquired, Edited, Reviewed or Signed. Any combination may be selected.

A default Print Option with the number of automatic copies from 1 to 9 can be defined to:

- **Always** print automatically when moving to the next state
- **Never** print automatically
- Automatically print only **If Signed**

Workflow Config

Modality Status

All

No REVIEWED

No EDITED/REVIEWED

Export Status

	Manual	Automatic
Acquired:	<input type="checkbox"/>	<input type="checkbox"/>
Edited:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reviewed:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Signed:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Legal Signature

Yes

No

Print Option

Always Never If Signed

Copies

Save Changes **Discard Changes**

No Legal Signature

When updating the exam to the signed state, the signature area will show the approver's name with a label of **Approved by:** in the final report.

About the Legal Signature

The legal signature requires user credentials prior to updating an exam to a signed state. When enabled, the user is prompted to authenticate with a username and password when transitioning to the signed state. Authentication can be entered when a different user is logged in. When the correct credentials are not entered, the user will be notified with a message that the "Credentials supplied are not valid."

When the signing physician has been set up as an attending physician under Personnel, the printed name will appear in the final report on the signature line following the **Electronically Signed by:** field label.

Unlock Exams

The Welch Allyn Diagnostic Cardiology Suite internally tracks transitioning exams preventing the same exam to be processed by two or more users. When a second user attempts to access an exam in use, a message displays with notification that the exam is not currently available.

As a measure for recovering locked exams, administrative users can unlock an exam that resides on the same workstation by selecting **Unlock Exams**. Highlight the listed exam(s) and click on **Unlock**.

Modality Settings

Modality Settings define all modality specific default values that do not change on a daily or patient-to-patient basis. Some of these settings can be modified within the modality for a single exam, but most of these default conditions will rarely need to change.

Modality settings and file exchange settings are Group dependent. 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.

Specifics on the settings that can be modified per modality can be found in the corresponding modality user manuals.

File Exchange

The Welch Allyn Diagnostic Cardiology Suite supports the ability to export PDF files to an external system dependent on the system activated features. Export directories for the selected group are defined in the File Exchange Configuration window under the File Export Settings tab.

The file name configuration for XML and PDF results may be customized under the Customize Filename tab. To customize, select the **Clear Filename** button, select the tags in the order you wish them to appear in the name, and then **Save Changes**.

To use a common filename for both PDF and XML files, select the Use Common Filename checkbox.

Note Default Import/Export paths are defined during software installation. PDF files will be exported to C:\ConnexCardio until modified by the administrative user. Access to PDF files are based on user account settings. Permission changes to the file or folder may be required.

Note When DICOM communication is enabled, XML (orders) import selection is grayed to indicate it is not selectable.

File Export Settings:

The screenshot shows the 'File Exchange Configuration' window for the 'Resting' group. It has two tabs: 'File Export Settings' and 'Customize Filename'. The 'File Export Settings' tab is selected and contains the following elements:

- Export Format:** A section with a checked checkbox labeled 'Enable PDF Report Export'.
- Export Directory:** A text box containing the path 'C:\ConnexCardio\RestingReports'.
- User Name:** An empty text input field.
- Password:** An empty text input field.
- Domain:** An empty text input field.

Customize Filename:

The image shows the 'File Exchange Configuration' dialog box. At the top, there are radio buttons for 'Resting' (selected) and 'Spirometry'. Below this, there are two tabs: 'File Export Settings' and 'Customize Filename'. The 'Customize Filename' tab is active, showing a text field for 'PDF Filename' containing a complex string of tags: <Mod>^<DXMGR>^<ExportType>^<OrderUID>_<Group>^<RecID>_<PID>^<LName>^<PName>^<PName>^<PP>. Below the text field is a checkbox for 'Use Common Filename' and two buttons: 'Clear Filename' and 'Restore Default Filename'. A table below lists various data fields and their corresponding tags:

Data	Tag
Patient Demographics	
Patient's ID	<PID>
Patient's Last Name	<PLName>
Patient's First Name	<PFName>
Patient's Middle Name	<PMMName>
Patient's Middle Initial	<PMI>
Patient's Sex (Male, Female, Unknown)	<PSEd>
Patient's Sex (M, F, U)	<PSEX>
Patient's Prefix	<PSPref>
Patient's Suffix	<PSSuff>
Patient's DOB Day (Short)	<DOEDay>
Patient's DOB Day (Long)	<DOEDayL>
Patient's DOB Month (Short)	<DOEMonth>
Patient's DOB Month (Long)	<DOEMonthL>
Patient's DOB Year (4 Digit)	<DOEYear>
Exam Information	
Modality (R, X, H, S)	<Mod>
Group Number	<Group>
Export Type (auto, manual)	<ExportType>
DICOM Accession Number	<AccessID>
DICOM Admission ID	<AdmissID>
Study Instance UID	<StudyUID>

At the bottom of the dialog are two buttons: 'Save Changes' and 'Discard Changes'.

CFD Configuration

A long, custom, or short format for displayed items and report contents can be uniquely defined per group. Select the **CFD Configuration** button to display the Custom Format Definition Template drop-down list. Choose the Long, Custom, or Short template for the selected group and then click Save Changes, or **Discard Changes** to cancel.

The image shows a dropdown menu titled 'Selected Group'. The selected option is 'Cardiology Dept.'.

The Custom format has been created through use of the ELI Link tool. Refer to the administrator manual, part number 9515-166-50-ENG, for information regarding custom IDs.

Note Custom IDs are only available when connected to ELI Link and when an order is used to populate patient demographics. If no order, the Short format is defaulted.

The image shows the 'CFD Configuration' dialog box. It features a dropdown menu for 'Custom Format Definition Template' with three options: 'Custom', 'Short', and 'Long'. The 'Custom' option is currently selected. Below the dropdown are two buttons: 'Save Changes' and 'Discard Changes'.

ELI Link Configuration

The Welch Allyn Diagnostic Cardiology Suite supports the ability to exchange information with DICOM systems, import orders from XML files, and export PDF and XML results to an external system via ELI Link. Available connectivity options are dependent on the system activated features. Refer to the ELI Link administrator manual, part number 9515-166-50-ENG, for information regarding installation and configuration of the ELI Link gateway service.

When using ELI Link connectivity, check the box to enable communication and enter appropriate information into the available fields.

The following table describes the available ELI Link configuration settings:

Item	Description
Host Name or IP	Entry field for the network name or IP address of the networked ELI Link service
Port Number	Entry field for the TCP port number for network communication with the ELI Link service
Site Number	Entry of a number will uniquely identify the Welch Allyn Diagnostic Cardiology Suite system that is communicating with the ELI Link service
Encryption Key	Entry field for use of a secret string shared between the ELI Link service and the Welch Allyn Diagnostic Cardiology Suite

Enter your desired settings and then click **Save Changes**, or click **Discard Changes**, to cancel.

Note If orders are used with the Welch Allyn Diagnostic Cardiology Suite in XML format and setup through ELI Link, XML order refresh must be checked in ELI Link otherwise orders will not appear in the worklist in the Welch Allyn Diagnostic Cardiology Suite.

User Preferences

Select User Preferences to open the window. Set selections define the default criteria for the Get Worklist in the search feature when the particular user is logged into the application.

Set selections can be changed when the user selects the Advanced search selections.

The user can also change the password in this window when the system is not set up with a single sign-on.

All users have access to the User Preferences settings but may not have the search feature available. Those users will only enter this window to change their own password.

There are three possible choices for the worklist exam states that can be enabled or disabled by checkboxes. The choices are dependent on the workflow configuration modality status setting in that Edited or Review may not appear as selections.

1. Acquired
2. Edited
3. Reviewed

There are three choices for the Default Time Filter for worklists.

1. All
2. Today
3. Last week

The user's custom lists can also be modified on this page. Some demographic data entry lists also accept free text which will be automatically added to the list for future use. **My Custom Lists** allows deletion of any list items you do not wish to use in the future.

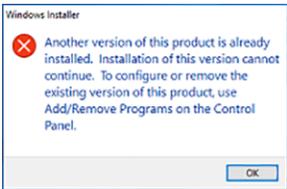
The user can change his password on this page, only if single sign-on is not used.

When finished, select **OK** to save changes or **Cancel** to exit the window without saving changes.

The application will present the default settings on any of the workstations the user logs into.

Troubleshooting

Software Installation

Symptom	Resolution
Software did not install	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 confirm <i>Run as Administrator</i> is available. Ensure there is proper disk space available. Contact Technical Support for assistance.
User prompted for database credentials during Simple installation	Contact Technical Support for assistance.
Installation hangs and then displays an exception error	Microsoft updates may have begun in the background during the application's installation. Allow Microsoft updates to complete and then restart the installation.
Installation attempted with the following error:	Browse to the Control Panel to Add/Remove programs. Find and highlight Connex Cardio and uninstall. Browse to the new version of software and attempt to install again.
	

Accessing the Welch Allyn Diagnostic Cardiology Suite

Symptom	Resolution
Login fails	Ensure the correct username and password are used. 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. If using Active Directory, contact IT administrator for assistance with credentials. Contact Technical Support for assistance.
Server not available message appears	Select Cancel to exit the application and try to login again.

Symptom	Resolution
	<p>If the 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 the service, and set Restart to Automatic if set to Manual.</p> <p>If running Group Policy to force frequent password changes, do not force password changes for the Welch Allyn Diagnostic Cardiology Suite database, PostGres SQL Server 9.6, as this will cause the system to run in offline mode.</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.
The Welch Allyn Diagnostic Cardiology Suite was installed as EHR integrated, but is not launching from my EHR.	<p>The interface between the 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>
XML Validation Exception when attempting to start or review an exam	If using the application as a Client/Server configuration, install any supported modalities on the server.

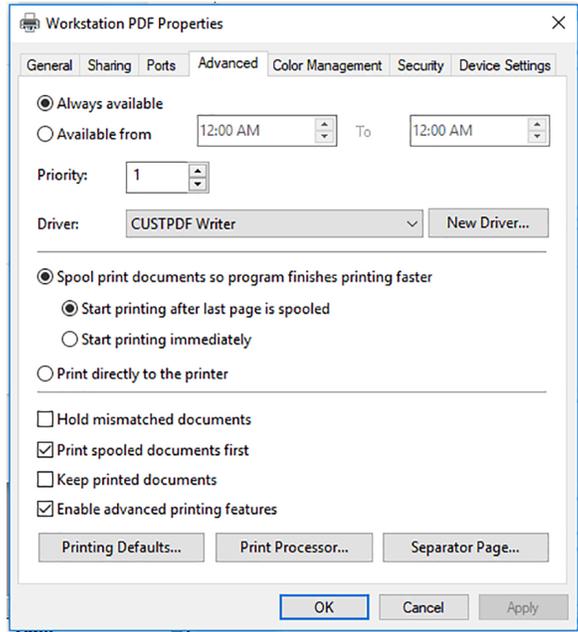
Data Export

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> <p>In the Users' Database under System Configurations, ensure that the user logged in has the proper role selected to export exams.</p> <p>Contact the IT administrator to ensure the interfaces are setup and connected.</p> <p>Contact Technical Support for assistance.</p>
Duplicate exams are exported.	<p>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 selected 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>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>

Symptom**Resolution**

When launched from integrated EMR, saving a test displays error, "Error creating output"

Log in as Windows admin user, go to Windows Devices and Printers settings and change the Workstation PDF printer and Workstation File Link printer advanced printer preferences to match:



Appendices

Appendix A: System Specifications

Welch Allyn Diagnostic Cardiology Suite Standalone/Client Specifications

Feature	Specification*
Waveform Display	Compatible with 1024 x 768, 1366 x 768, 1280 x 800, 1680 x 1050, 1920 x 1080, 1900 x 1200, and 2736 x 1824.
Compatible Operating Systems	Microsoft® Windows® 7 Professional 32 bit and 64-bit and Microsoft® Windows® 10 Pro 64-bit operating systems**
Processor	Performance equivalent or better than an Intel® Core™ i3
RAM	Minimum 4 GB
Hard Drive Capacity	Minimum 250 GB (If client: minimum 160 GB)
Storage Capacity	Unlimited with external archive
Archive	Network or external USB disks (standalone installation)
USB Ports	Requires at least two USB 2.0 ports (acquisition module, external USB drive)
Input devices	Standard keyboard and 2-button scroll mouse
Software Installation	USB
Network	100 Mbps connection or better required for use with server
Printing Device	HP M501dn Windows printer with HPUPD PCL 5 driver or equivalent
Power Requirements	Dependent on computer, 100 – 240 VAC at 50/60 Hz

Note Specifications subject to change without notice.

Note For optimal printing the PCL 5 driver is recommended to be used where possible. This driver is included on the installation media.

Note PDF printers are not supported.

Welch Allyn Diagnostic Cardiology Suite Minimum Server Specifications

Feature	Server Minimum Specifications*
Processor	Performance equivalent to an Intel Xeon class; Quad-core with hyperthreading
Graphics	1024 x 768
RAM	Minimum 4 GB
Operating System	Microsoft® Windows® Server 2012 R2, Windows® Server 2016 *If installing ELI Link with Welch Allyn Diagnostic Cardiology Suite, system requires 64-bit OS to operate both.
System Disk	100 GB for OS and product installation (RAID recommended for data redundancy)
Data Disks	550 GB hard drive space available HD controller with 128 MB read/write cache (RAID recommended for data redundancy)
Archive	Network or external USB drive
Software Installation	USB
Network	100 Mbps connection or better
Input Devices	Standard keyboard and mouse
Multiple Simultaneous Users	Up to 50 simultaneous users without significant performance loss

*Specifications subject to change without notice.

Requirements for Welch Allyn Diagnostic Cardiology Suite deployed via Citrix XenApp

	Requirements
Client Machines that will run Citrix XenApp	Microsoft® Windows® 7 Professional (32-bit and 64-bit) Microsoft® Windows® 10 Professional (64-bit) Citrix Receiver Internet Browser – any that is supported by Citrix
Citrix Desktop Delivery Controller	Citrix XenApp version 7.13 Any operating system supported by Citrix
Citrix App Servers	Microsoft® Windows® 2012 R2 Microsoft® Windows® 2016

Requirements

Citrix Virtual Delivery Agent 7.13
Welch Allyn Diagnostic Cardiology Suite client software

Required for Spirometry and ECG data acquisition Installation of Connex Link – found on installation media

Note A system running in a virtual environment may experience a streaming lag between input and output of the system.

*Requirements subject to change without notice.

Requirements for Welch Allyn Diagnostic Cardiology Suite deployed via Windows Remote Desktop Protocol

Requirements

Client Machines that will run Windows RDP Microsoft® Windows® 7 Professional (32-bit and 64-bit)
Microsoft® Windows® 10 Professional (64-bit)

RDP Servers Microsoft® Windows® 2012 R2
Microsoft® Windows® 2016
Welch Allyn Diagnostic Cardiology Suite Client software

Required for Spirometry and ECG data acquisition Installation of Connex Link – found on installation media

Note A system running in a virtual environment may experience a streaming lag between input and output of the system.

*Requirements subject to change without notice.

Manuals

Part Number	Description
9515-001-51-XXX	Physician's Guide Adult & Pediatric
80023962	Welch Allyn Diagnostic Cardiology Suite Manager
80023961	Welch Allyn Diagnostic Cardiology Suite Resting ECG
80023960	Welch Allyn Diagnostic Cardiology Suite Spirometry
9515-166-50-XXX	ELI Link

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

Appendix B: 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.

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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.

