Welch Allyn®
Diagnostic Cardiology Suite Resting ECG

User Manual

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

For information about any Welch Allyn product, visit: https://www.welchallyn.com/en/about-us/locations.html

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

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

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901128 CARDIOPULMONARY ECG SYSTEM

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Contents

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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Other Important Information

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Welch Allyn makes no warranty of any kind with regard to this material including, but not limited to, implied warranties of merchantability and fitness for a particular purpose. Welch Allyn assumes no responsibility for any errors or omissions that may appear in this document. Welch Allyn makes no commitment to update or to keep current the information contained in this document.

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** Patient cables intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.

⚠ **WARNING** Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrodes, should not come into contact with other conductive parts including earth ground.

⚠ **WARNING** Do not attempt to clean the patient cables by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. Wipe the exterior surfaces with a warm water and mild detergent solution and then dry with a clean cloth. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device.

⚠ **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** ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation. Electrode materials and ingredients are specified on the packaging or are available from the vendor upon request.

⚠️ **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** Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions. Electrodes are intended for short-term use and should be removed from the patient promptly following testing. Do not mix electrodes made of dissimilar metals.

⚠️ **WARNING** To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.

⚠️ **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** When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.

⚠️ **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** Use only recommended alkaline battery cells with the Welch Allyn Wireless Acquisition Module. Use of other cells may present a risk of fire or explosion.

⚠️ **WARNING** The Welch Allyn Wireless Acquisition Module low battery warning function is designed for alkaline battery cells only. Use of other cells may result in failure of the low battery warning possibly resulting in a malfunction of the device.

⚠️ **WARNING** Test the 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/repaired 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.

FCC Compliance Statement

In the United States use of this device is regulated by the Federal Communications Commission (FCC). The Welch Allyn Wireless Acquisition Module with its antenna complies with FCC's RF exposure limits for general population/uncontrolled exposure.

FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

WAM FCC ID:HJR-WAM2500

UTK FCC ID:HJR-UTK2500

These devices comply with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Cautions

⚠ **CAUTION** Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.

⚠ **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 Welch Allyn Diagnostic Cardiology Suite functionality, Welch Allyn recommends turning automatic Windows update off, and periodically running it manually. A functional test should be executed after update, which includes acquiring a recording, editing and printing a report, as well as importing an order and exporting results, if activated. Compatibility of the 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 resting ECG 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** The Welch Allyn Wireless Acquisition Module will only work with receiving devices that are equipped with the appropriate option.

⚠️ **CAUTION** This Welch Allyn Wireless Acquisition Module is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.

⚠️ **CAUTION** The following equipment may cause interference with the Welch Allyn Wireless Acquisition Module RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.

⚠️ **CAUTION** AA batteries are known to leak their contents when stored in unused equipment. Remove battery from Welch Allyn Wireless Acquisition Module when not used for an extended period of time.

⚠️ **CAUTION** Be careful to insert the correct lead wire into the connector block with the appropriate input connector by matching the lead wire labels to the acquisition lead labels.

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

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   Patient movements may generate excessive artifact that may affect the quality of the ECG traces and the proper analysis performed by the device.

Note   Proper patient preparation is important to application of ECG electrodes and operation of the device.

Note   There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.

Note   If an electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, the display will indicate a lead fault for the lead(s) where the condition is present.

Note   A thick baseline present on the display while using the AM12 may be due to an auto-calibration error. Review the LED indicator on the AM12 to ensure the unit is connected, or disconnect and reconnect to the PC USB port to re-calibrate. If the issue persists, contact technical support.

Note   The Welch Allyn Wireless Acquisition Module has an LED battery indication that will automatically start flashing if the battery has been discharged below its lower threshold of 1.0 volts.

Note   During normal operation, the green LED on the acquisition modules will display continuously.

Note   If the Welch Allyn Wireless Acquisition Module battery cover is opened during transmission, the device will stop transmitting. The battery must be reinserted and the cover fastened to resume operation.

Note   The Welch Allyn Wireless Acquisition Module will automatically turn off (LED off) if the battery has been severely discharged.

Note   The Welch Allyn Wireless Acquisition Module will automatically turn off when the application is closed.

Note   The Welch Allyn Wireless Acquisition Module will automatically turn off after being disconnected from the patient. This will happen regardless of computer battery/AC power state.

Note   A thick baseline present on the display while using the Welch Allyn Wireless Acquisition Module may occur because the device is turned off, has no battery, has not being paired correctly, is operating out of range, or has a calibration error. Review the LED indicator and auditory advisory on the device to ensure the unit is turned on, has proper battery level, is paired correctly, and is within recommended proximity of the UTK, or power cycle (turn off then turn on) the device to re-calibrate.

Note   As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:

- Type CF, defibrillation-proof applied parts.

Note   If not specifically indicated otherwise, personal computer equipment used with the device can be regarded as:

- Class I (if the computer has a three-prong power inlet) or class II (if it has a two-prong inlet)
- Ordinary equipment
- Equipment not suitable for use in the presence of a flammable anesthetic mixture
- Continuous operation

Note   To prevent possible damage to the device during transport and storage
                  (while in original packaging) the following environmental conditions must
                  be adhered to (for ECG accessories, such as electrodes, refer to applicable
                  packaging):

Ambient temperature:	-20° C to 60° C (-4° F to 149° F)
Relative humidity:	10% to 95%, non-condensing

Note   Allow the device and any computer equipment used to stabilize within its
                  intended operating environment for a minimum of two hours prior to use.
                  Refer to the computer equipment user manual for allowable environmental
                  conditions. The allowable environmental conditions for the Welch Allyn
                  wireless and AM12 acquisition modules are as follows:

Ambient temperature:	10° C to 40° C (50° F to 104° F)
Relative humidity:	10% to 95%, non-condensing

Note   The Welch Allyn Wireless Acquisition Module is UL classified:

c (UL) us

E467322

WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS
ONLY IN ACCORDANCE WITH: ANSI/AAMI ES60601-1, CAN/CSA-C22.2
No. 60601-1, IEC 60601-1, IEC 60601-2-25.

Symbols

Documentation symbols

⚠	**WARNING** The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.
⚠	**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. This definition applies to both yellow and black and white symbols.

Miscellaneous symbols

🏭	Manufacturer	🗑	Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements.
welchallyn.com 7d	Follow instructions/directions for use (DFU) -- mandatory action. 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.	⊣♥⊢	Defibrillation-proof Type CF applied parts
⭤	USB	SN	Serial Number
REF	Reorder Number	LOT	Batch Code
#	Model Identifier	GTIN	Global Trade Item Number
ECG 12	Acquire 12 Lead ECG	Rx ONLY	By prescription or order of physician or dentist

MD	Medical Device

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

Package Symbol Delineation

	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

1. Disconnect the power source. Remove cables and lead wires from device before cleaning.
2. For general cleaning of cables and lead wires, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.
3. For disinfecting the exterior surfaces of the device, patient acquisition module, cables, and lead wires, wipe exterior using:

- Clorox Healthcare® Bleach Germicidal Wipes (use according to instructions on product label), or
- a soft, lint-free cloth with a solution of sodium hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants

> ⚠️ **WARNING** Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Never expose cables to strong ultra-violet radiation. Do not sterilize the device or ECG lead wires with Ethylene Oxide (EtO) gas.

⚠️   **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 is intended to provide the user with information about the Welch Allyn Diagnostic Cardiology Suite Resting Electrocardiograph software via the following sections:

- Installing Welch Allyn Diagnostic Cardiology Suite – Resting ECG
- Resting ECG Display Overview
- Customizing the Resting ECG Module
- Recording an ECG
- Viewing a Resting ECG exam
- Interpreting a Resting ECG exam
- Printing a Resting ECG report

This manual supplements the Welch Allyn Diagnostic Cardiology Suite Manager user manual and contains just the information specific to acquiring, editing and analyzing a resting ECG. The Welch Allyn Diagnostic Cardiology Suite Manager manual contains information on the data management aspects of the system. This includes searching for patient data, editing patient and exam information, searching for previously acquired exams, setting system wide settings, etc.

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

Audience

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

Indications for Use

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

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

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

Indications for Welch Allyn Diagnostic Cardiology Suite Resting 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.

Contraindications to Performing ECG

There are no known contraindications.

System Description

The Welch Allyn Diagnostic Cardiology Suite is a multi-lead, diagnostic, computer-based resting electrocardiograph capable of acquiring, viewing, transmitting, printing, and storing ECG data.

The ECG application includes the VERITAS™ resting ECG interpretation algorithm which is capable of specific age and gender interpretation criteria. The VERITAS algorithm provides an over-reading physician with a silent second opinion through diagnostic statements displayed on the ECG report. For additional information on the VERITAS algorithm, please refer to the Physician's Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation.

ECG application is integrated with a patient and exam management system that can schedule exams, manage database storage and maintenance, search exams and patients, print and communicate with external systems and dispatch the modality-dependent acquisition and review functions. For more information see the Welch Allyn Diagnostic Cardiology Suite Manager user manual.

The application supports ECG print formats that include:
- Standard or Cabrera
- 3+1
- 3+3
- 12
- 6+6 channel in automatic mode
- Single channel on one page (60 min of acquired ECG for rhythm strip (full disclosure) printing

The Welch Allyn Diagnostic Cardiology Suite ECG package list includes:
- Acquisition module with lead wire set and accessory starter kit
- Software loaded on USB
- Instructions for use including the Physician's Guide to VERITAS on USB

Acquisition Module Types

Two types of ECG acquisition modules are used with the software, the Welch Allyn Wireless Acquisition Module and the Welch Allyn AM12 Acquisition Module.

Welch Allyn Wireless Acquisition Module with Lead Wires
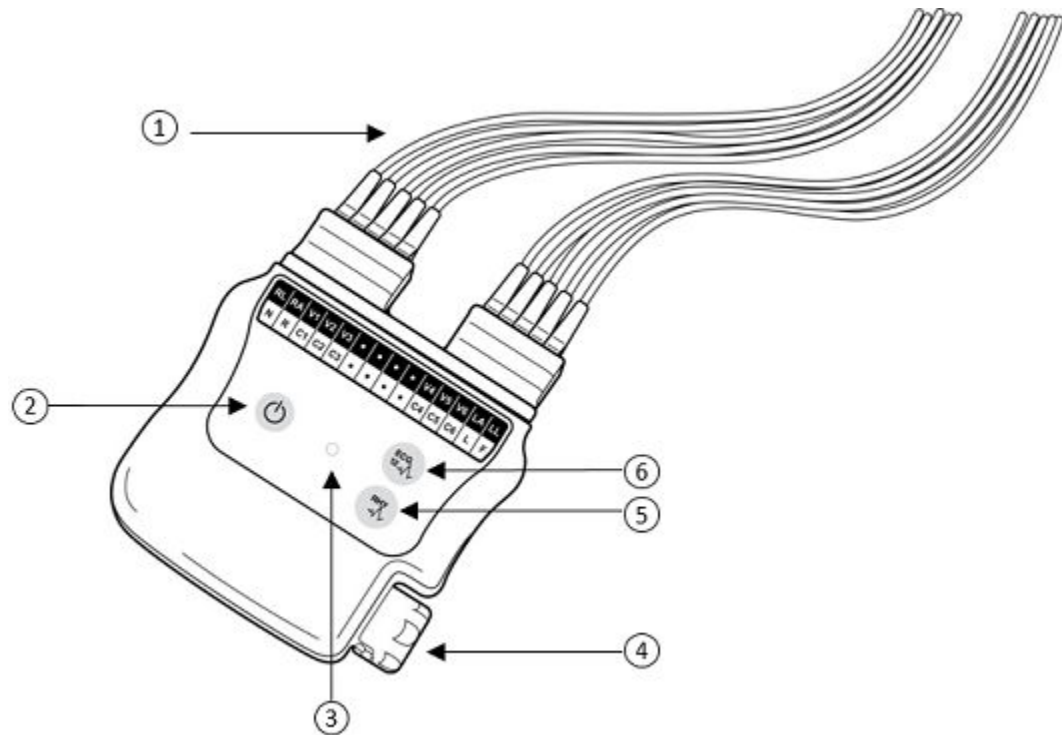
No.	Feature	Description
1	Replaceable lead wires	Connector from the device to the electrode
2	Power On/Off	Push button to turn the device on and off
3	LED indicators	Displays the device status
4	Battery compartment	Houses the alkaline battery
5	Rhythm print	Press to acquire a rhythm print; press again to stop the rhythm print
6	12-lead ECG acquisition	Press the 12-lead ECG acquisition button to complete the acquisition of the 12-lead ECG

The Welch Allyn Wireless Acquisition Module incorporates frequency-hopping technology in the 2500 MHz frequency range with 40,000 Hz ECG acquisition and is operated by two buttons located on the front of the device when used with the Welch Allyn Diagnostic Cardiology Suite:

• Power On/Off

• Acquiring a 12-lead ECG

Note   Rhythm print button is non-functional when used with the Welch Allyn Diagnostic Cardiology Suite.

Battery

The Welch Allyn Wireless Acquisition Module uses one AA alkaline, 1.5V battery for approximately 8-hours of continuous operation.

⚠️   **WARNING** Use of other cells may present a risk of fire or explosion.

USB Transceiver Key (UTK)

The UTK connects to an open USB port on the computer where the Welch Allyn Diagnostic Cardiology Suite is installed and receives ECG signals from the paired Welch Allyn Wireless Acquisition Module. When the UTK is connected to a USB cable from the PC port, it should be positioned in a location with an unobstructed view of the device while in use.

Welch Allyn AM12 Acquisition Module with Lead Wires
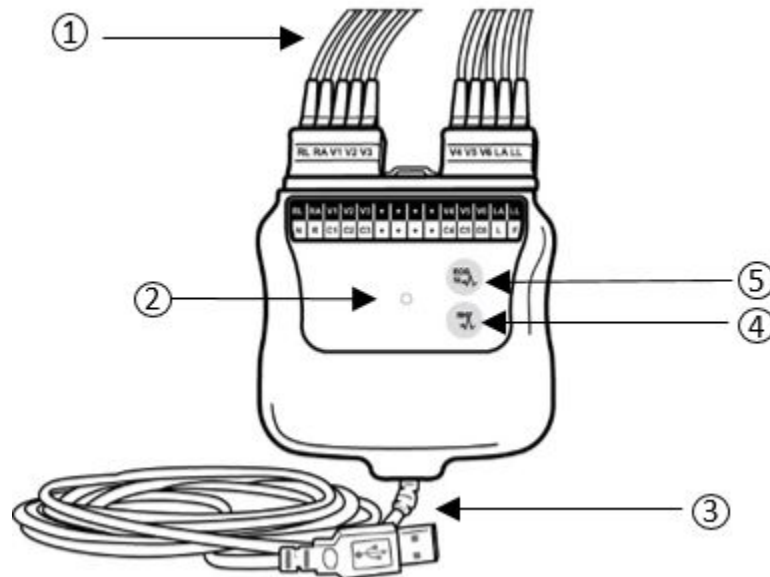
No.	Feature	Description
1	Replaceable Lead Wires	Connector from the device to the electrode
2	LED Indicators	Displays the device status
3	USB Cable	Connect to PC for signal acquisition
4	Rhythm Print	Press to start rhythm print; press again to stop rhythm print
5	12-Lead ECG button	Press the 12-lead ECG acquisition button to acquire an ECG

The Welch Allyn AM12 Acquisition Module is available for a traditional wired connection with direct USB connection and 40,000 Hz ECG acquisition. The 12-Lead ECG button can be used to acquire a 12-lead ECG at the patient's side.

Note   Rhythm print button is non-functional when used with Welch Allyn Diagnostic Cardiology Suite.

Connecting the Acquisition Module

The Welch Allyn AM12 Acquisition Module connects to a USB port on the PC for signal acquisition. The application automatically detects the AM12 once it is connected to the USB port.

The Welch Allyn Wireless Acquisition Module communicates with the Welch Allyn Diagnostic Cardiology Suite ECG application through the UTK (Universal Transmitter/receiver Key) while connected to an active USB port on the PC. The Welch Allyn Wireless Acquisition Module is synchronized with the UTK making them a matched pair. This includes after the Welch Allyn Wireless Acquisition Module has been turned off, after the battery has been changed, or if the UTK is unplugged and used in a different computer.

Pairing the Acquisition Module

Open the Welch Allyn Diagnostic Cardiology Suite ECG application and select Start a Resting Exam. Enter demographic information to go to the real-time display. Connect the UTK to an open USB port on the computer.

1. Select the settings icon in the upper right corner of the real-time display.
2. Select **WAM pairing**.
3. Place the Welch Allyn Wireless Acquisition Module (powered off) near the UTK receiver.
4. Select **Start** and then **Yes**.
5. Power on the acquisition module.

   When the device is successfully paired, a message will display on screen accompanied by 3 beeps.
6. Select **Done**.

   Note   The Welch Allyn Wireless Acquisition Module must be paired to a specific UTK prior to signal acquisition.

   Note   If both AM12 and the UTK are connected simultaneously, the ECG application will default to the AM12 .

   Note   Disconnecting the UTK and connecting the AM12 will automatically cause the ECG application to switch to the AM12. It is not necessary to pair the same Welch Allyn Wireless Acquisition Module with the same UTK to use it again.

Welch Allyn Wireless Acquisition Module LED Indicators

For information on the LED indicators, please see the Welch Allyn Wireless Acquisition Module User Manual

Lead Fail Indication

Lead fail can be observed either by indication in ECG application screen or on the acquisition modules.

In the software, lead failure is represented as a square wave being presented on the lead that has failed. On the acquisition modules lead fail is indicated using LEDs located on the front of the acquisition module. A yellow LED on either of the acquisition modules indicates a lead fail condition on one or more leads and a green LED indicates proper connection. For more information on the LED indicators, please see the Welch Allyn Wireless Acquisition Module User Manual.

Installation

Resting ECG Application Installer

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

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

System Installation

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

Prior to the uninstall:

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

Software Uninstall Steps

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

Resting ECG Display Overview

This section guides you through the various parts of the Welch Allyn Diagnostic Cardiology Suite ECG. The structure of the workspace is similar to the other Welch Allyn Diagnostic Cardiology Suite modules. Once a patient is chosen and the Start Exam button is selected, the Welch Allyn Diagnostic Cardiology Suite will launch the ECG modality.

Display Overview
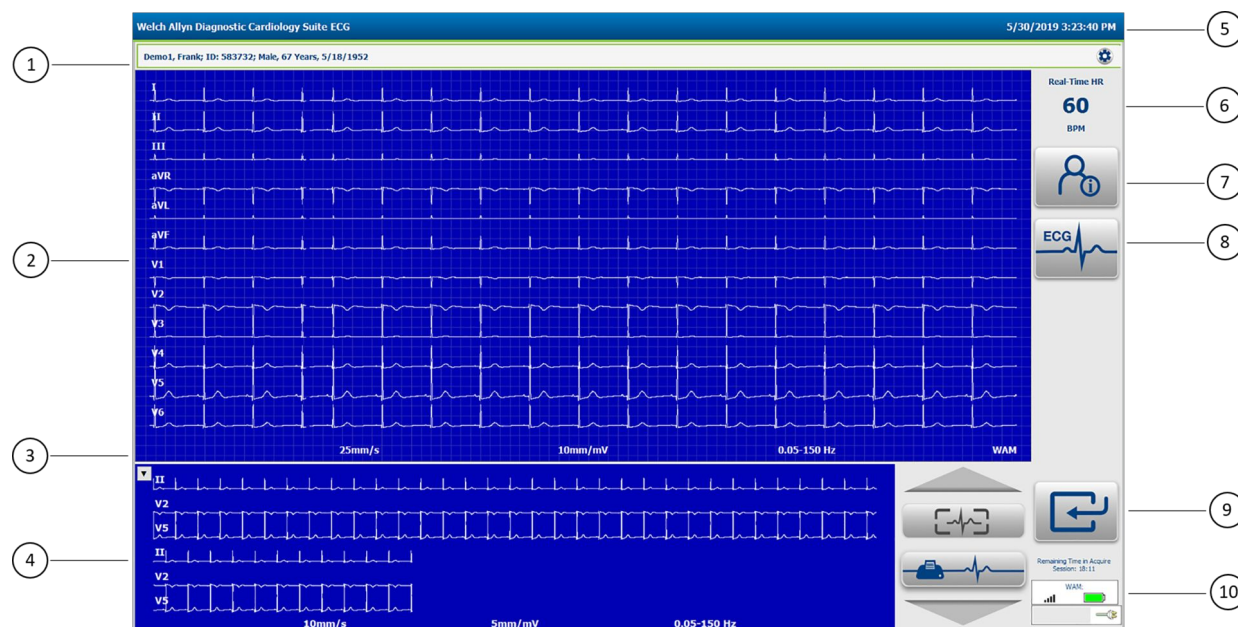
No.	Feature
1	Patient Demographics
2	12-Lead Real-Time ECG View
3	Gain / Speed / Filter
4	Full Disclosure ECG / Full Disclosure Menu Icons
5	Date / Time

No.	Feature
6	Patient Heart Rate
7	Patient Information
8	ECG Acquisition
9	Exit
10	PC Power Status

Menu Selections

Click on the settings button in the upper-right to open the settings menus.

- Select **WAM Pairing** to pair the Welch Allyn Wireless Acquisition Module. (Refer to the Pairing the Welch Allyn Wireless Acquisition Module with Welch Allyn Diagnostic Cardiology Suite section for instructions.)
- Select **ECG Timed Capture** to automatically acquire ECGs at preset time intervals. (Refer to the following section for instructions.)
- Select **About ECG** to view the version of the VERITAS™ resting ECG interpretation algorithm used.

Click the show/hide Full Disclosure ECG section in the lower-left area of the display as desired.

Date / Time

The current date and time are displayed in the upper right corner of the display. The date and time displayed is dependent on the regional settings of the computer being used.

Real-Time Heart Rate

When a patient is connected to the application through an acquisition module, his or her heart rate (HR) is displayed in real time. The HR is the average ventricular rate measured over the patient's last five beats.

Note   If a lead fail occurs, a red message is displayed in red text next to the HR, indicating the wire that is off for both limb lead and chest lead fault conditions.

Timed Capture Status

When timed capture is used, the time remaining until the next capture is indicated in the bottom left corner. Additionally, a count of the ECGs captured and saved can be viewed.

Time to Next Capture: 3:52
ECG Count: 4

Full Disclosure ECG

The Full Disclosure refers to the display of a single lead or three (3) leads of ECG (configurable) that has accumulated over the course of the test. Though only one or three leads are displayed at a time, all twelve (12) leads are accumulated and stored temporarily while the test is in progress. ECGs can be acquired from the Full Disclosure area, else a single lead of the entire Full Disclosure can be printed. The size of accumulation in the Full Disclosure is configurable up to 60 minutes.

Note: Data from the Full Disclosure is only available while a test is in progress. Once an ECG is captured and the test has been completed (test is exited, or ECG is saved, reviewed, or signed), or the patient has been disconnected from the lead wires, the Full Disclosure data is deleted.

ECG Display Menu Icons

Icon	Name	Description
	Patient Information	Allows review of patient and test demographics entered at the start of the exam.
	ECG	Initiates the capture of an ECG at any time the patient is connected.
	Best 10 ECG	10 appears in the place of ECG when Best 10 capture mode is configured; selects the best 10 seconds of the full disclosure as the captured ECG.
	Done	Ends the test and exits the ECG acquisition session.

Full Disclosure Menu Icons

Click within the Full Disclosure ECG area to enable the menu icons.

Icon	Name	Description
	Page Up	Advances the selection window back one page. Page size is determined by the format, speed, and computer screen size.
	Select	Captures 10-second ECG from the selection.
	Print	Initiates the print of a single lead rhythm of the entire full disclosure.
	Page Down	Advances the selection window forward one page. Page size is determined by the format, speed, and computer screen size.

Customizing the Resting ECG Module

This section indicates how to adjust various settings specific to the ECG acquisition and presentation.

To open the Resting ECG settings:

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

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

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

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

Modality settings can be customized for each group. Ensure that the desired group is selected from the drop-down list before proceeding.

Select the tab you wish to modify and click on **Save Changes** to apply or **Discard Changes** to cancel changes before exiting.
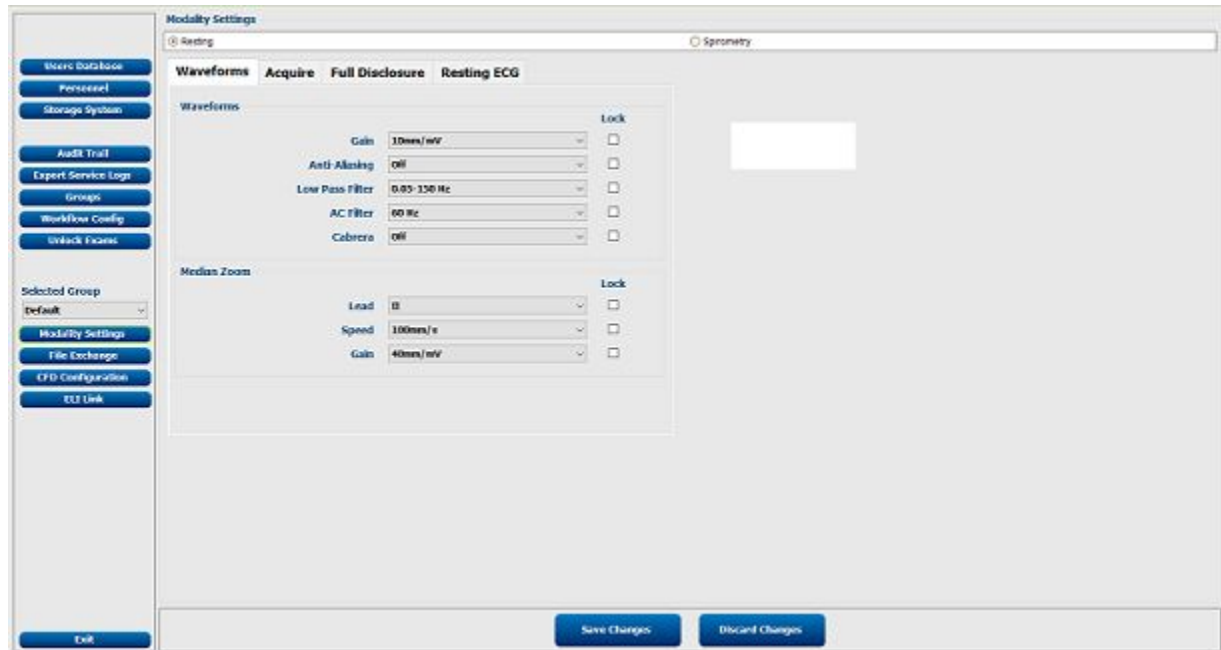
Modality Settings and Default Values

The following tables indicate the Resting ECG Modality settings, and possible values. The default value for each setting is indicated in **bold**.

Waveforms Tab
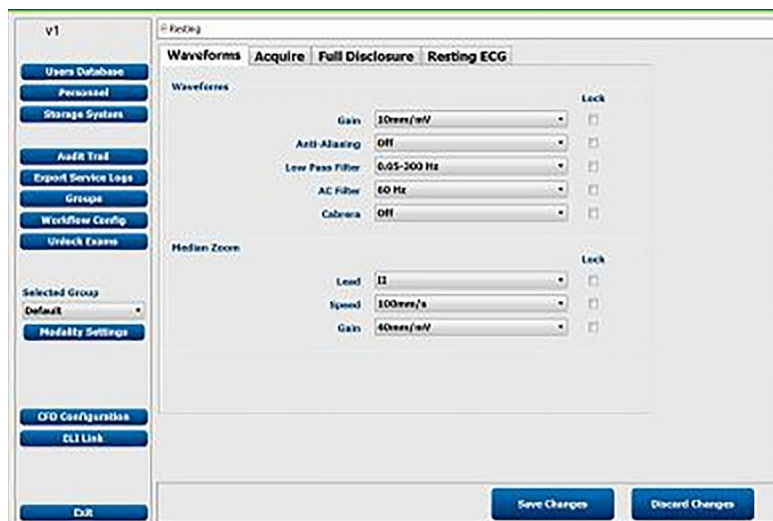
Setting	Notes	Options
Gain	Gain displays and prints at the bottom of the ECG	2.5 mm/mV
		5 mm/mV
		10 mm/mV
		20 mm/mV

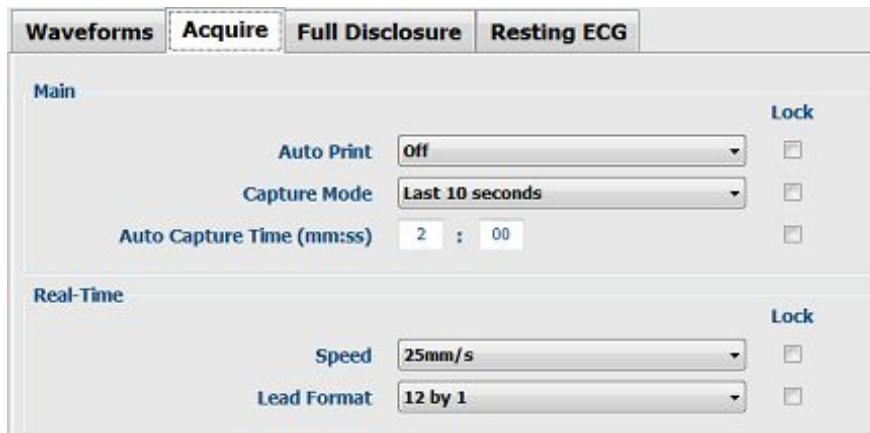| Setting	Notes	Options
Anti-Aliasing	Anti-aliasing reduces slightly the staircase effect due to individual pixels in digital monitors but may put a strain on low performance computers.	**Off**, On
Low Pass Filter	A filter setting lower than 150 Hz will reduce the visibility of fast transients in the ECG like pacemaker spikes or fast notches. For pediatric ECGs a 300 Hz setting is recommended. Filter settings apply only to displayed and printed data. Data is stored in unfiltered format. The High Pass filter (or baseline filter), indicated by the number "0.05" cannot be changed. The application automatically implements a high- performance base line filter that does not distort the ECG waveform. High Pass filters that do distort the ECG waveform are not available.	0.05 – 300 Hz **0.05 – 150 Hz** 0.05 – 40 Hz
AC Filter	The application removes 60 Hz or 50 Hz interference. The setting you select depends on the line frequency in your country. For example, use the 60 Hz setting in the U.S. If the setting is correct but you still see mains interference, check the electrode connections, mains interference sources like transformers or motors close to the patient, and the connection to the safety ground of the computer. Try operating from battery power if needed.	None, 50 Hz, **60 Hz**
Cabrera	Change the default ECG format to Cabrera	**Off**, On
Median Beat Zoom Lead	Change default median ECG lead format display All leads refers to all leads superimposed	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, All Leads
Median Beat Zoom Speed	Change default speed on display	**100 mm/s**, 200 mm/s
Median Beat Zoom Gain	Change default ECG gain	10 mm/mV 20 mm/mV **40 mm/mV** 80 mm/mV

⚠️ **WARNING** When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes and is recommended only if high-frequency noise cannot be reduced by proper procedures.

Note VERITAS calculates by default the QTc with a linear correction method for average RR-interval similar to the Framingham method. In addition, it is possible to display and print the QTc corrected with the Bazett or Fridericia correction methods.

Note Using the lock indicator to the right of this selection can be enabled to hide this choice from the technician, permitting only unlocked choices.

Acquire Tab

This tab is for the default settings of the real time acquisition function.

Setting	Notes	Options
Auto-Print	Defines whether the ECG application will automatically print an unconfirmed ECG after a timed or manual capture. Manual printout is always possible.	**Off**, On
Capture Mode	Defines whether or not the ECG application will automatically capture the 10-second ECG with the lowest noise level from the last 5 minutes of the full disclosure, or the last 10 seconds of data when the ECG button is selected.	**Last 10 Seconds**, Best 10 Seconds
Enable Auto Capture Time (mm:ss)	Defines the time intervals in which the ECG will automatically be acquired once Timed ECG Capture is selected.	Any value from 00:20 to 59:59 in 20 second increments; **default 02:00**
Real-Time Speed	Change default speed on display	5 mm/s 10 mm/s **25 mm/s** 50 mm/s
Real-Time Lead Format	In the real time display only 6+6 and 12 lead formats are available. It is recommended to choose a format that allows at least 10 seconds of real time ECG on the screen during acquisition.	**12 by 1**, 6 by 2

Full Disclosure Tab

This tab is for the default settings of the full disclosure buffer at the bottom of the acquisition screen.

Settings	Notes	Options
Speed	Change default speed on full disclosure display.	5 mm/s **10 mm/s** 25 mm/s 50 mms/
Lead Format	Single lead by 3 displays three lines of ECG data in the full disclosure buffer. Single lead by 6 displays six lines of ECG data in the full disclosure buffer. Three lead displays two groups of three leads in the full disclosure buffer. The amount of data displayed is dependent on the size of the display and the ECG sweep speed selected. The three-lead format requires a lead selection for each of the three leads presented.	Single Lead by 3 Single Lead by 6 **Three Lead**
Single Lead Format – Lead	Active if Lead Format is set to single lead setting	I, **II**, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Three Lead Format – Lead 1	Active if Lead Format is set to three lead setting	I, **II**, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Three Lead Format – Lead 2	Active if Lead Format is set to three lead setting	I, II, III, aVR, aVL, aVF, V1, **V2**, V3, V4, V5, V6
Three Lead Format – Lead 3	Active if Lead Format is set to three lead setting	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, **V5**, V6
Print Lead	Use Print Lead to select the lead printed on full disclosure printouts.	I, **II**, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Buffer Size	Use the Buffer Size to select the total amount of acquisition time permitted in the full disclosure memory. A warning message will display when the selected time limit has been reached, and acquisition terminated.	5, 10, **20**, 30, 45, 60 minutes

Resting ECG Tab

This tab is for the default settings of the captured ECG waveform and printouts.

Setting	Notes	Optional
Speed	Change default speed on Resting ECG display	**25 mm/s**, 50 mm/s
Lead Format	3+3 lead format requires a lead selection for each of the three leads presented	**3 + 1 Lead** 6 Lead 3 + 3 Lead 12 Lead 6 + 6 Lead
3 + 1 Lead Format – Lead	Active if Lead Format is set to 3 + 1 lead setting	I, **II**, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
3 + 3 Lead Format - Lead 1	Active if Lead Format is set to 3 + 3 lead setting	I, **II**, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
3 + 3 Lead Format – Lead 2	Active if Lead Format is set to 3 + 3 lead setting	I, II, III, aVR, aVL, aVF, V1, **V2**, V3, V4, V5, V6
3 + 3 Lead Format – Lead 3	Active if Lead Format is set to 3 + 3 lead setting	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, **V5**, V6
Pace Spike	When Pace Spike is on, pacemaker spikes will be visible on the waveform display and at the bottom of the page on captured ECG printouts.	**Off**, On
Avg. RR	Use this option to display an averaged RR value on the report.	Off, **On**
QTcB	Displays QTc calculation based on Bazett formula	Off **On**
QTcF	Displays QTc calculation based on Fridericia formula	Off, **On**

Setting	Notes	Optional
Print Interpretation	Sets if interpretation is printed on exam report	Off, **On**
Reasons Text	Reasons statements indicate why an interpretive statement was printed. Reasons statements print enclosed in [square brackets] within the interpretive text if the interpretation option is turned on. Turning the reasons statement function on or off does not affect the measurements performed or the interpretive statements selected by the analysis program. For Example: Anteroseptal Infarct [40+ ms Q WAVE IN V1-V4] where Anteroseptal Infarct is the interpretive statement and 40+ ms Q WAVE IN V1-V4 is the reason statement or explanation as to why the interpretive statement was included.	**Off**, On

Record an ECG

Patient Preparation

Before attaching the electrodes, ensure the patient fully understands the procedure and what to expect.

- Privacy is very important in assuring the patient is relaxed.
- Reassure the patient that the procedure is painless and that the electrodes on their skin are all that they will feel.
- Make sure the patient is lying down and is comfortable. If the table is narrow, tuck the patient's hands under his/her buttocks to ensure their muscles are relaxed.
- Once all the electrodes are attached, ask the patient to lie still and to not talk. Explain this will assist you in acquiring a good ECG.

Preparing Patient Skin

Thorough skin preparation is very important. There is natural resistance on the skin surface from various sources such as hair, oil, and dry, dead skin. Skin preparation is intended to reduce resistance and maximize the quality of the ECG signal.
To prepare the skin:

- Clip hair from electrode sites if necessary.
- Wash area with warm, soapy water or alcohol if dirty or oily.
- Dry skin vigorously with a pad such as 2 x 2 or 4 x 4 gauze to remove residue from cleaning, dead skin cells and oil, and to increase capillary blood flow.

Note   *With elderly or frail patients take care to not abrade the skin causing discomfort or bruising.*

Patient Hookup

Correct electrode placement is essential for acquiring a diagnostically valid ECG.

A low resistance highly conductive pathway from the skin surface to the electrocardiograph provides superior noise-free waveforms. Good quality silver-silver chloride (Ag/AgCl) electrodes within their expiration date should be used whenever taking an ECG.

Note   Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly causing reduced adhesion and conductivity, leading to poor trace quality.

Attach the Electrodes

1. Expose the arms and legs of the patient to attach the limb leads.
2. Place the electrodes on flat, fleshy parts of the arms and legs.
3. If a limb site is not available, place the electrodes on a perfused area of the stump.
4. Attach the electrodes to the skin. A good test for firm electrode contact is to slightly tug on the electrode to check adhesion.

   If the electrode moves freely, it needs to be changed. If the electrode does not move easily, a good connection has been obtained.
   For accurate V-lead placement, it is important to locate the 4th intercostal space. Because patients vary with respect to body shape, it is difficult to palpate the 1st intercostal space with accuracy. Thus, locate the 2nd intercostal space by first palpating the little bony prominence called the Angle of Louis, where the body of the sternum joins the manubrium. This rise in the sternum identifies where the second rib is attached, and the space just below it is the 2nd intercostal space. Palpate and count down on the chest until you locate the 4th intercostal space.
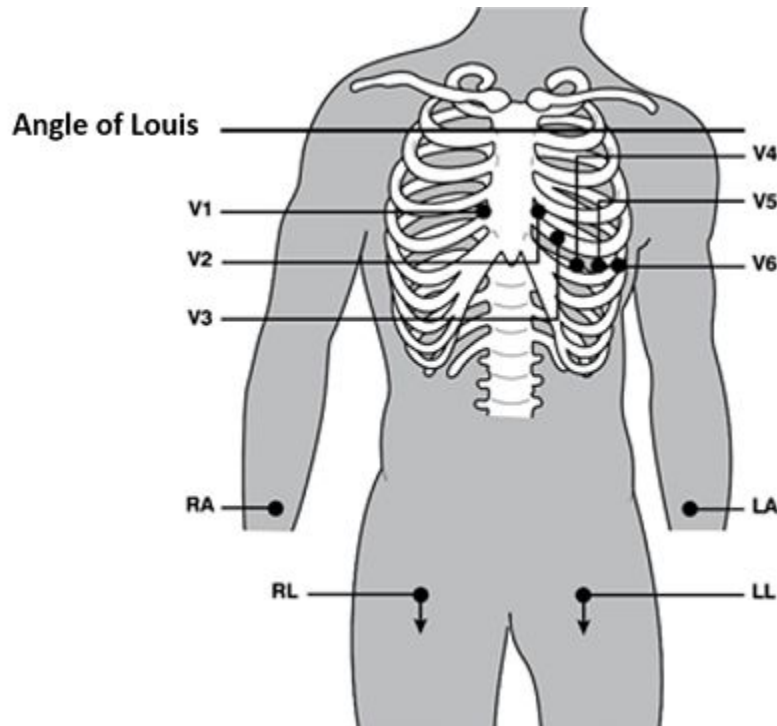
Patient Hookup Summary Table
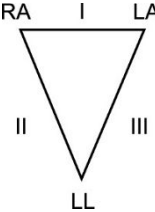
AAMI Lead	IEC Lead	Electrode Position
V1	C1	On the 4th intercostal space at the right sternal border.

AAMI Lead	IEC Lead	Electrode Position
Red	Red	
V2 Yellow	C2 Yellow	On the 4th intercostal space at the left sternal border.
V3 Green	C3 Green	Midway between V2/C2 and V4/C4 electrodes.
V4 Blue	C4 Brown	On the 5th intercostal space at the left midclavicular line.
V5 Orange	C5 Black	Midway between V4/C4 and V6/C6 electrodes.
V6 Violet	C6 Violet	On the left midaxillary line, horizontal with V4/C4 electrode.
LA Black, RA White	L Yellow, R Red	On the deltoid, forearm, or wrist.
LL Red, RL Green	F Green, N Black	On the thigh or ankle.

Acquire ECGs

Examine the display for artifact or baseline drift. Re-prep and replace electrodes if necessary to obtain satisfactory waveforms.

Please refer to the following troubleshooting guide based on Einthoven's Triangle:

	Artifact	Check Electrode
	Lead II and III artifact	Poor LL electrode or left leg tremor
	Lead I and II artifact	Poor RA electrode or right arm tremor
	Lead I and III artifact	Poor LA electrode or left arm tremor
	V Leads	Re-prep site & replace electrode

RA   I   LA

II   III

LL

If a lead fault occurs, square waves appear on the display for that lead and the lead(s) that are faulty will display in the upper left corner of the screen one at a time. After the leads are reattached correctly at least 10 seconds must be acquired before an ECG can be captured.

The program monitors the ECG waveform for unusual configurations that could be caused by misplaced (swapped) electrode positions. If the program detects a high probability of electrode swap, it will display a message like "RA or LA misplaced?" in the same message area as used for lead fault. Check the electrode connections for any misplacement.

Note   Although the majority of lead wire swaps are correctly detected, some real ECG configurations may give rise to an inappropriate "misplaced" message, and some real swaps may not be detected due to patient specific ECG morphologies. The automatic detection helps to prevent lead wire swaps but do not rely completely on the automatic detection.

Manual ECG Capture

To acquire a real-time ECG:

1. Select the ECG button on the display to capture Best 10 **10** or Last 10 **ECG** 12-lead ECG data.

• Best 10 captures the 10-second section of the last 5 minutes of data accumulated in the Full Disclosure with the least artifact

• Last 10 captures the most recently acquired 10-second ECG.

Alternately, press the ECG button   **ECG 12**   on the Welch Allyn Wireless Acquisition

Module or the Welch Allyn AM12 Acquisition Module. The application will capture either the Best or Last 10-seconds of acquired ECG dependent on configuration settings.

Best 10 Seconds Selection

When the Best 10 icon is selected, the resting ECG application automatically selects the best quality10 seconds of acquired data from the last 5 minutes of the Full Disclosure.

ECG acquisition can also be captured by pressing the ECG button on the Welch

Allyn Wireless Acquisition Module or Welch Allyn AM12 Acquisition Module. When Best 10 capture has been configured as the capture mode (see Modality Settings and Default Values for more information). However, this action will always capture the last 10-seconds of acquired ECG.

Capturing ECGs from Full Disclosure

Click anywhere in the full disclosure display at the bottom of the screen to capture an ECG retrospectively from the buffer. To acquire a retrospective ECG:

1. Use a left mouse click anywhere in the full disclosure ECG to highlight 10-seconds of data. Once clicked, the Page Up , Page Down , Select , and Print Full Disclosure buttons become active allowing navigation and ECG selection.
2. Position the 10-second box of highlighted ECG anywhere in the full disclosure ECG using left mouse clicks and the Page Up/Down buttons.
3. Select the ECG button to the right of the full disclosure to capture the highlighted 10-second 12-lead ECG.

Waveform data reviewed on the screen can be selected and printed as a single lead of up to 60 minutes of data, depending on the amount of ECG data that has been acquired.

Note   ECG size and gain will automatically adjust to allow all data to fit on one page.

Note   The full disclosure data cannot be accessed once the acquisition session has ended.

Timed ECG Capture

The application can automatically acquire ECGs at preset time intervals for future review and processing. Automatic acquisition may be as frequent as every 20 seconds or once per a 60-minute period (dependent on the amount of full disclosure time set by the administrator).

To acquire timed ECGs:

1. Prep the patient and place the electrodes in the correct locations (ensuring lead wires are securely attached).
2. Select ECG Timed Capture from the settings icon in the upper right corner of the real-time ECG display.

3. Enter the frequency in the Set Capture Time (mm:ss) window - 20 seconds up to 59-minutes and 59-seconds.
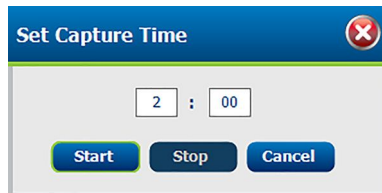
4. Select **Start** to begin automatic ECG collection or **Cancel** to exit the window.
5. Capture the first ECG to begin the timed ECG capture by selecting the ECG button. The time remaining to the next capture and the number of ECGs captured is displayed in the lower right corner of the display.

Note   ECGs are automatically captured for the entire length of the test as defined by the Full Disclosure duration defined by the administrator. ECG capture automatically ends when the duration has been reached. ECGs can also be selected manually at any frequency within the Full Disclosure window. Automatic ECG capture can be manually ended by going back to the Timed Capture menu and selecting Stop or with selection of the Done button.

Note   ECGs that are collected during Timed Capture are saved as individual 10-second ECGs. To review, edit, print, or transmit ECGs when using timed capture exit the ECG modality and return to the main window of the Welch Allyn Diagnostic Cardiology Suite application. Navigate to the exam list to locate the captured ECGs and process as needed.

Rhythm ECG

Occasionally an ECG that is longer than 10 seconds is needed to review the cardiac cycle over a longer period, else it may serve as documentation for another purpose. Collecting, reviewing, and processing ECG data longer than 10 seconds in the same session can be accomplished in the following ways:

Printing the Full Disclosure

When the Full Disclosure is printed, a single lead for the entire time the patient has been connected (depending on configuration, up to 60 minutes) can be printed. To print the Full Disclosure:

1. To change the print lead during the test, see Full Disclosure Print Lead section of this manual.
2. Select the **Print** button in Full Disclosure. The Full Disclosure will print to the default printer for the computer being used.

Note   The amount of data (data collection time) in the Full
                  Disclosure can be configured. The lead that is used for
                  viewing and printing can also be configured by the
                  administrator or chosen during the test. See the Modality
                  Settings and Default Values section for more information.

Note   Although all 12 leads are available choices for view and
                  selection in the Full Disclosure window, only a single lead is
                  used for a printed report.

Note   The data collected in the Full Disclosure is not saved and is
                  only available for viewing, printing, and selection of 10-
                  second ECGs while the test is in progress and the patient
                  connected.

3. Capture multiple 10-second ECGs within the same session by using the Timed-
   Capture feature, which automatically collects ECGs at an increment that is
   configured by the administrator. The minimum time between ECGs is 20 seconds.
4. Collect serial ECGs by using the Full Disclosure to capture and print ECGs
   individually.

Captured ECG Display and Icons

Once captured, the ECG is displayed with global measurements and the Veritas
automatic interpretation. Icon button selections are located at the right of the captured
ECG and actions are described below.

Icon	Name	Description
	Patient Information	ID allows review of patient information.
	Sign	Signs the displayed test. Icon is only available for those logged in with signing authority.
	Review	Mark the displayed ECG as reviewed. Icon is only available for those logged in with permission to edit and review exams. User is prompted to enter the reviewer's name and select OK. Start a Resting Exam is then displayed.
	Save	Save the ECG.

Icon	Name	Description
	Delete	Delete the ECG. User is prompted to select Yes or No and is then returned to the real-time ECG display.
	Print	Sends the ECG as displayed to the default printer for the computer.

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

Note   Print to PDF is not supported.

Median Beats and Median Lead Zoom panels can be shown or hidden by toggling the small arrow buttons in the upper-right corners.

The global measurement and interpretation panels can be shown or hidden by toggling the small arrow button in the upper-left corner.

Measurement parameters can be changed with a double-click in the Median Lead Zoom area and by dragging the cursors to the desired positions. Global measurements are updated upon selection of the OK button. Cancel will undo any changes and revert to the original locations and global values.

For users with editing permission, the interpretation area can be edited by a single-click in the text area. When the user begins to type characters, a scrollable pick-list with commonly used statements that begin with, or contain the characters typed appears allowing quick selection of the desired statement.

An undo icon in the bottom-right corner of the interpretation or measurements area can be selected to revert to the original interpretation or measurements respectively when selected before saving the ECG.
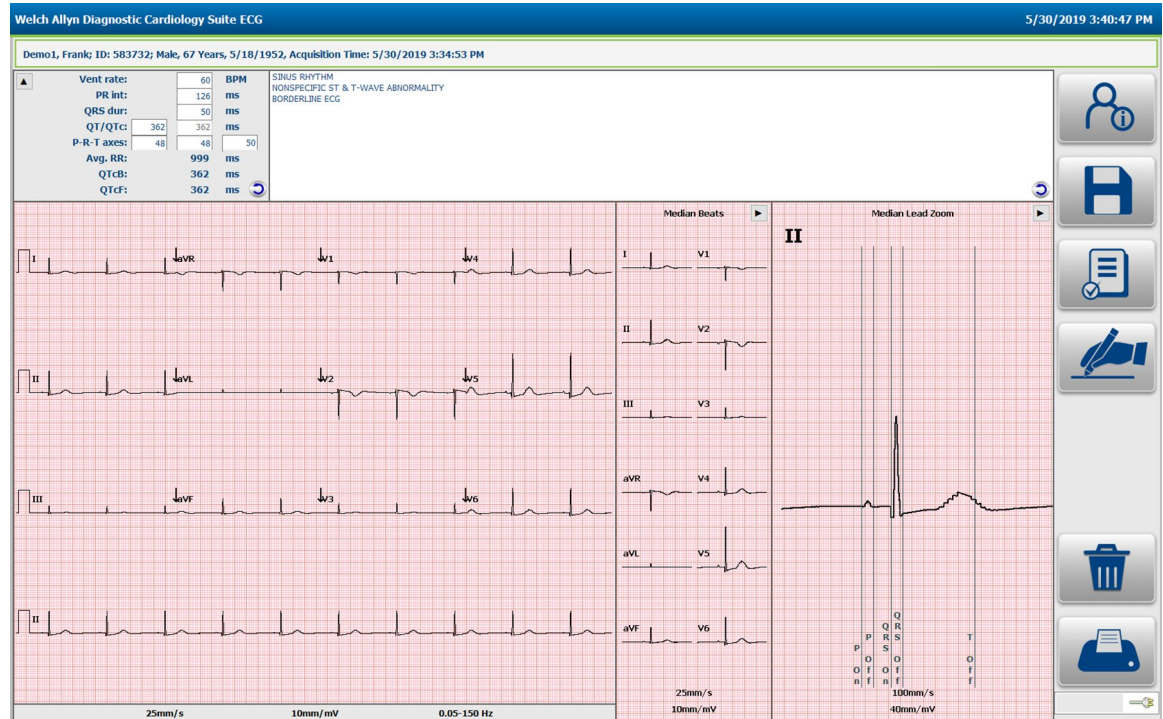
Note   If no patient age is entered prior to acquiring an ECG, the interpretation
                algorithm assumes a 40-year old male. The statement "INTERPRETATION
                BASED ON A DEFAULT AGE OF 40 YEARS" will be added to the
                Interpretation text.

Note   If a patient age of zero (0) is used without the presence of Date of Birth,
                the interpretation algorithm will assume a 6-month old infant. The
                statement "INTERPRETATION BASED ON A DEFAULT AGE OF 6
                MONTHS" will be added to the interpretation text.

Note   Where global measurement values are not available (i.e., rate, interval,
                axis), text such as '- -'or '*' or similar will display/print for the unavailable
                value.

Viewing Resting ECG Exams

Context Menu Settings

Many settings can be changed from the default during a test or review by right clicking on the mouse while the cursor is on the ECG display. A context menu is displayed as seen in the examples below. The context menus may be different depending on the section in which the cursor is located. Some specific context menus are available for display speed, gain, filter settings and lead layout in the area of the window where that parameter is displayed. The context menu is also specific to the display area (e.g. the full disclosure window or the captured ECG window), but where appropriate, the settings may apply to all windows; for example, if you change the gain through the menu in the full disclosure window, the gain in the real time window is also changed. Some context menus activate specific tools, like measurement calipers.

Note   Changes are maintained only for the current sessions. Settings will revert to the default settings with the next exam. Refer to the System Settings section in this manual to change the default settings.

Note   Some of the described menus may not be present if they were locked by the administrator in the Welch Allyn Diagnostic Cardiology Suite configuration settings.

Context Menus in Captured ECG
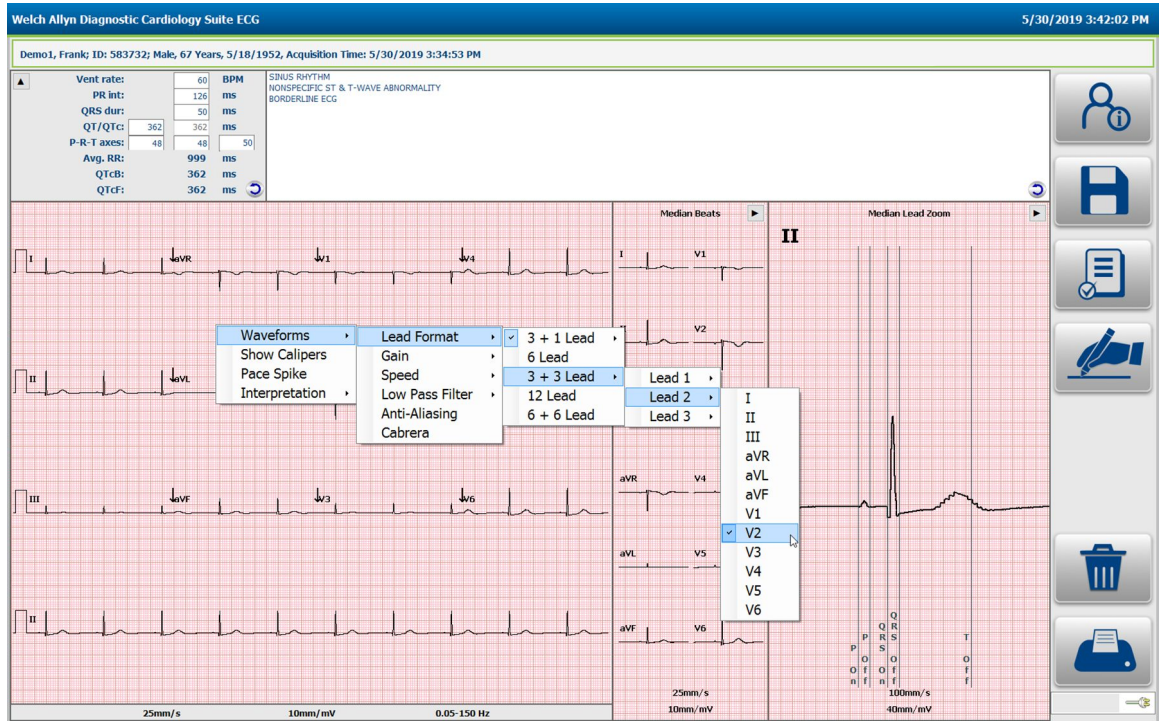
Context Menus in Real-time ECG
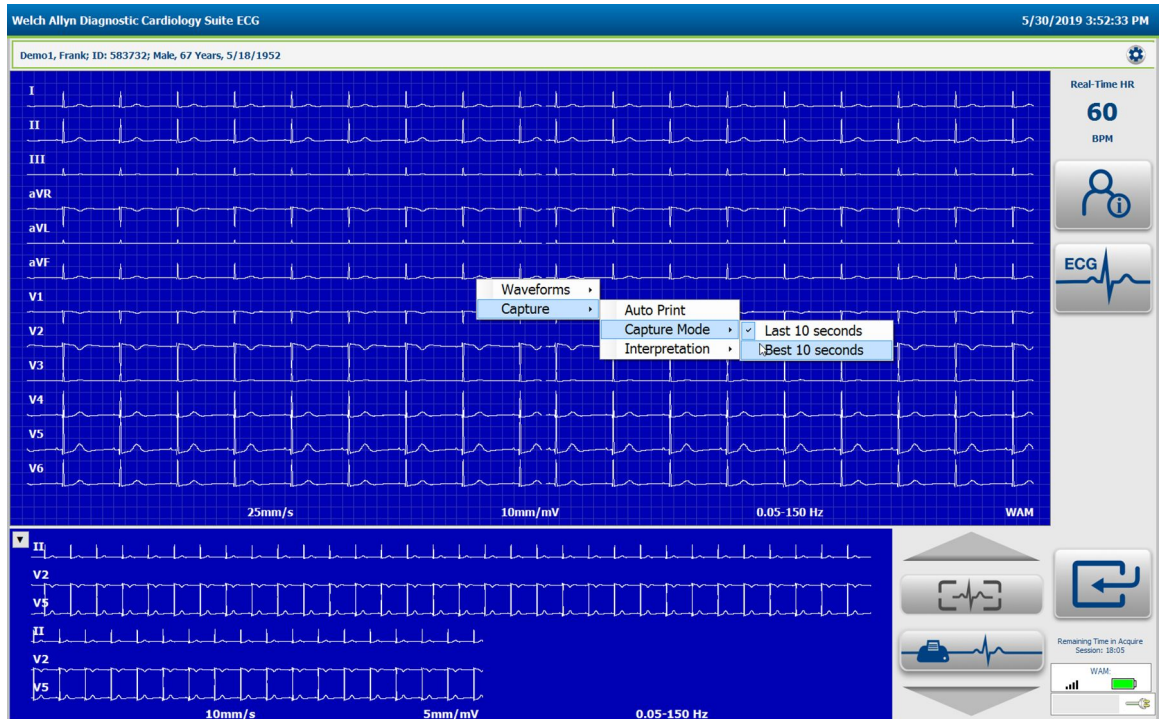
Change Lead Format

1. Right-click while the cursor is over the captured ECG waveform
2. Select **Waveforms**
3. Select **Lead Format**
4. Select from: 3+1, 6, 3+3, 12, or 6+6

   Note   In the real time display only 6+6 and 12 lead formats are
                   available. It is recommended to choose a format that allows
                   at least 10 seconds of real time ECG on the screen during
                   acquisition.

3 + 1 Lead Format – Select Lead

1. Right-click while the cursor is over the captured ECG waveform
2. Select **Waveforms**
3. Select **Lead Format**
4. Select: **3+1**
5. Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

3 + 3 Lead Format – Select Leads

1. Right-click while the cursor is over the captured ECG waveform
2. Select **Waveforms**
3. Select **Lead Format**
4. Select **3+3**
5. Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

   Note   3+3 lead format requires a lead selection for each of the
                   three leads presented.

Full Disclosure Change Lead Format

To change lead format in the full disclosure display:

1. Right-click while the cursor is over the ECG waveform in the Full Disclosure window
2. Select **Waveforms**
3. Select **Lead Format**
4. Select from: single lead by 3, single lead by 6, or 3 lead

   Note   Single lead by 3 displays three lines of ECG data in the full
                   disclosure buffer. Single lead by 6 displays six lines of ECG
                   data in the full disclosure buffer. Three lead displays two
                   groups of three leads in the full disclosure buffer. The
                   amount of data displayed is dependent on the size of the
                   display and the ECG sweep speed selected.

Full Disclosure Single-Lead Format – Change Lead

To change the full disclosure lead to a single-lead format:

1. Right-click while the cursor is over the ECG waveform in the Full Disclosure window
2. Select **Waveforms**
3. Select **Single Lead Format**
4. Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

Full Disclosure Three-Lead Format – Change Lead

To change the full disclosure lead to a three-lead format:

1. Right-click while the cursor is over the ECG waveform in the Full Disclosure window
2. Select **Three Lead Format**
3. Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

   Note   Three-lead format requires a lead selection for each of the
                 three leads presented.

Full Disclosure Change Print Lead

To change the full disclosure print lead:

1. Right-click while the cursor is over the ECG waveform in the Full Disclosure window
2. Select **Print Lead**
3. Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

Change the ECG Presentation Gain

To change the full disclosure lead to a three-lead format:

1. Right-click while the cursor is over the real-time or captured ECG waveform
2. Select **Waveforms**
3. Select **Gain**
4. Select from: 2.5 mm/mV, 5 mm/mV, 10mm/mV, or 20 mm/mV

   Gain displays and prints at the bottom of the ECG

   Note   A shortcut to this menu is available when you right-click on
                 the current gain display of the window. Different gains are
                 available in the median and full disclosure windows.

Change the ECG Presentation Speed

1. Right-click while the cursor is over the real-time or captured ECG waveform
2. Select **Waveforms**
3. Select **Speed**
4. Select from: 5 mm/s, 10 mm/s, 25mm/s, or 50 mm/s (real-time only)

5. Select from: 25mm/s or 50mm/s in the captured ECG waveform

6. Gain displays and prints at the bottom of the ECG

     Note   A shortcut to this menu is available when you right-click on
                     the current speed display of the window. Different speeds
                     are available in the median and full disclosure windows.

Change ECG Low Pass Filter

1. Right-click while the cursor is over the real-time or captured ECG waveform

2. Select **Waveforms**

3. Select **Low Pass Filter**

4. Select from: 0.05 – 40 Hz, 0.05 – 150 Hz, or 0.05 – 300 Hz

     ⚠   **WARNING** When the 40 Hz filter is used, the frequency
              response requirement for diagnostic ECG equipment cannot
              be met. The 40 Hz filter significantly reduces high-frequency
              components of the ECG and pacemaker spike amplitudes,
              and is recommended only if high-frequency noise cannot be
              reduced by proper procedures.

     Note   A filter setting lower than 150 Hz will reduce the visibility of
                     fast transients in the ECG like pacemaker spikes or fast
                     notches. For pediatric ECGs a 300 Hz setting is
                     recommended. Filter settings apply only to displayed and
                     printed data. Data is stored in unfiltered format.

     Note   The High Pass filter (or base line filter), indicated by the
                     number "0.05" cannot be changed. The application
                     automatically implements a high performance base line filter
                     that does not distort the ECG waveform. High Pass filters
                     that do distort the ECG waveform are not available.

Apply Anti-Aliasing to the ECG Display

1. Right-click while the cursor is over the real-time or captured ECG waveform

2. Select **Waveforms**

3. Select **Anti-Aliasing**

     Note   Anti-aliasing reduces slightly the staircase effect due to
                     individual pixels in digital monitors, but may put a strain on
                     low performance computers.

Change AC Filter on the Real-time ECG

1. Right-click while the cursor is over the real time ECG waveform

2. Select **Waveforms**

3. Select **AC Filter**

4. Select from: None, 50 Hz, or 60 Hz

Note   The application removes 60 Hz or 50 Hz interference. The
                    setting you select depends on the line frequency in your
                    country. For example, use the 60 Hz setting in the U.S. If the
                    setting is correct but you still see mains interference, check
                    the electrode connections, mains interference sources like
                    transformers or motors close to the patient, and the
                    connection to the safety ground of the computer. Try
                    operating from battery power if needed.

Change ECG Presentation to or From Cabrera Format

1. Right-click while the cursor is on the ECG waveform
2. Select **Waveforms**
3. Select or unselect

Change Median Zoomed Lead in ECG Review Mode

1. Right-click while the cursor is over the Median Lead Zoom ECG
2. Select **Lead**
3. Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 , or All leads (all 12 leads superimposed)
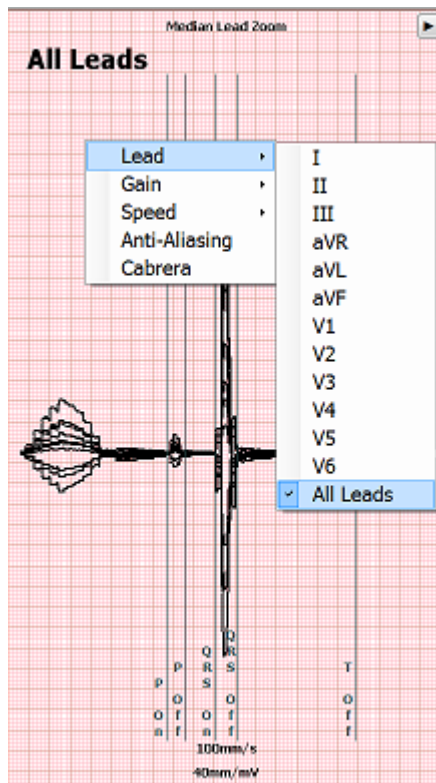
Switch Between Best Ten and Last 10 Seconds Capture in Real-Time ECG Mode

1. Right-click while the cursor is over the real-time ECG waveform
2. Select **Capture**
3. Select **Capture Mode**
4. Select from: Best 10 or Last 10

   Note   Defines whether the ECG application will automatically capture the 10 seconds ECG with the lowest noise level from the full disclosure buffer, or the last 10 seconds of data when the ECG button is selected.

Print Pace Spike Channel

1. Right-click while the cursor is over the acquired ECG waveform
2. Select **Pace Spike** on or off

   Note   When Pacer Spike is selected small tick marks will appear at the bottom of the ECG printout where each pacemaker spike was detected.

Display and Print Average RR Interval

1. Right-click while the cursor is over the acquired the ECG waveform
2. Select **Interpretation**
3. Select **Avg RR** on or off

Display and Print QTcB (Bazett)

1. Right-click while the cursor is over the acquired ECG waveform

2. Select **Interpretation**
3. Select **QTcB** on or off

Display and Print QTcF (Fridericia)

1. Right-click while the cursor is over the acquired ECG waveform
2. Select **Interpretation**
3. Select **QTcF** on or off

   VERITAS Interpretation Algorithm calculates by default the QTc with a linear correction method for average RR-interval similar to the Framingham method. In addition it is possible to display and print the QTc corrected with the Bazett or Fridericia correction methods. For more information on VERITAS, please see the Physician's Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation manual.

Print Automatic Interpretation Text

1. Right-click while the cursor is over the acquired ECG waveform
2. Select **Interpretation**
3. Select **Print Interpretation** on or off

Display and Print Automatic Interpretation Reasons Text

1. Right-click while the cursor is over the real time ECG waveform
2. Select **Capture**
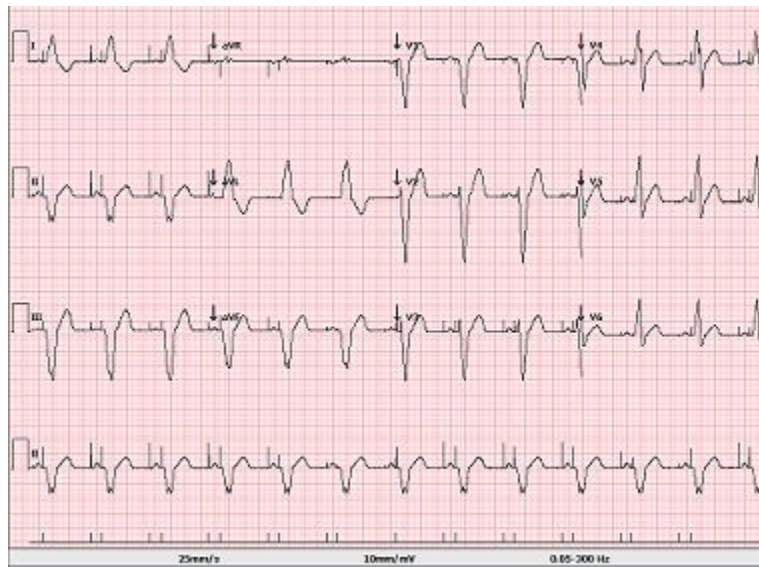3. Select **Interpretation**
4. Select **Reasons Text** on or off

   Note   Reasons statements indicate why a particular interpretive statement was printed. Reasons statements print enclosed in [square brackets] within the interpretive text if the interpretation option is turned on. Turning the reasons statement function on or off does not affect the measurements performed or the interpretive statements selected by the analysis program.

   For example, Anteroseptal Infarct [40+ ms Q WAVE IN V1-V4] where Anteroseptal Infarct is the interpretive statement, and 40+ ms Q WAVE IN V1-V4 is the reason statement or explanation as to why the interpretive statement was printed.

Interpreting a Resting ECG Exam

Edit a Resting ECG Report

When a report is selected from the Exam Search list by a user with review and signing permissions, it is presented on the screen like the one shown below. The Sign and Review button icons are not present for those without permission to perform those actions.

The Save and Review buttons are visible if the administrator has configured the system to make both buttons available.

The Patient Information window can be opened to view the patient and test demographics by selecting the Patient Information button.

If the user agrees with the interpretation statements, the ECG can be saved, marked as reviewed, or signed. After selection of any of these buttons, the user is returned to the Exam Review list.
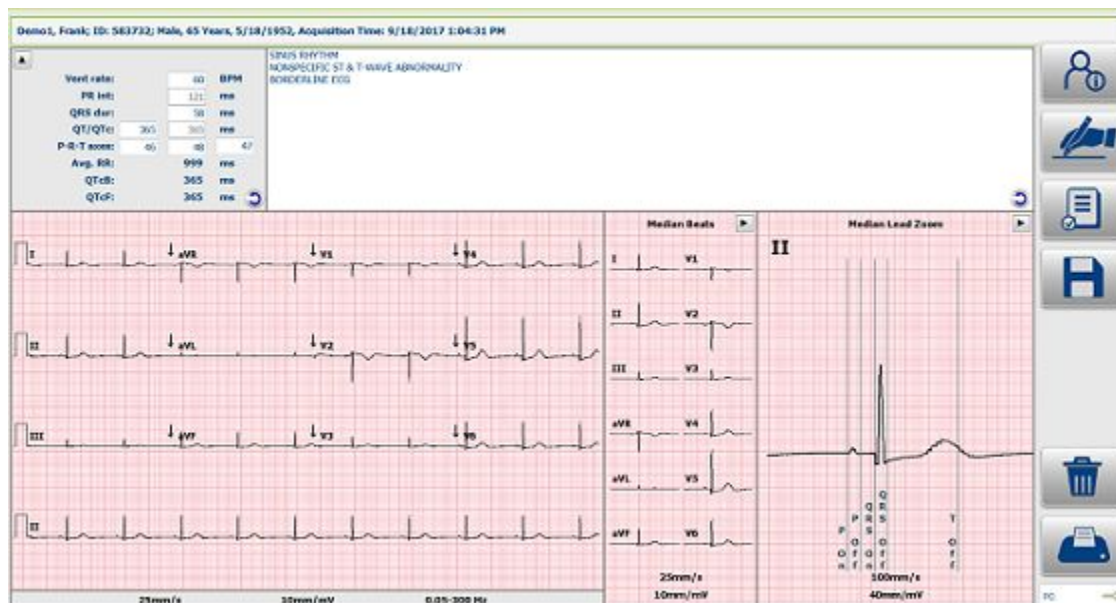
Editing Interpretation

Interpretation statements may be deleted, modified, and new statements added. When adding statements, the application will predict the full statement as characters are typed

and will present statements in a pick-list in order of use frequency. A single-click in the text area allows editing for users with appropriate permissions.
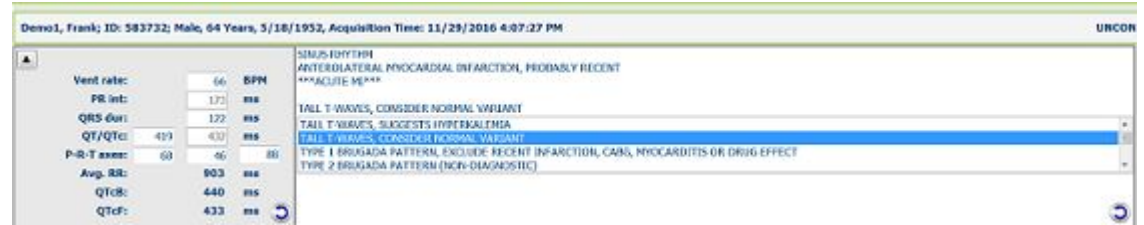
Editing Actions	Description
Down arrow	Moves focus to the statement pick-list
Enter (in statement pick-list)	Adds highlighted statement to the interpretation
Ctrl + L	Deletes the statement text leaving a blank line
Ctrl + L Ctrl + L	Deletes the statement without leaving a blank line
Esc	Closes the statement pick-list

An undo icon in the bottom-right corner of the interpretation area can be selected to revert back to the interpretation before any changes were made.

Note   Each interpretation field line allows up to approximately 65 characters. Additional characters will wrap to the next line.

Note   The interpretation area supports up to 11 lines of text. Additional lines are allowed but may overwrite the ECG waveform.

Editing Measurements

1. Measurement Value Editing
   - Left-click in the value measurement field and enter the desired value.
   - The undo icon in the bottom-right corner of the interpretation area can be selected to revert to the measurement values before any editing changes were made.
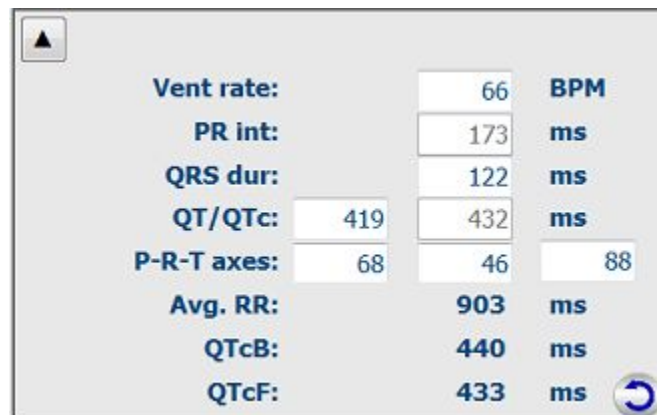
2. Editing interval measurements using the Median Beat Calipers:

- This method can be used for the PR-interval, QRS duration, and QT duration editing.
- Double-click in the Median Lead Zoom window. Measurement calipers are now active in this window.
- Drag the calipers to the desired position. Interval measurements are automatically recalculated.
- Select **Cancel** to leave the editing process without saving.
- Select **OK** to complete the editing process.

To change the lead or presentation of the Median Beat displayed in the Median Lead Zoom area:

- Double-click in the Median Lead Zoom window.
- Right-click within the Median Lead Zoom window.
- Change the lead displayed be selecting from the Lead menu.
- Modify the Gain or Speed by selecting from the respective menus.
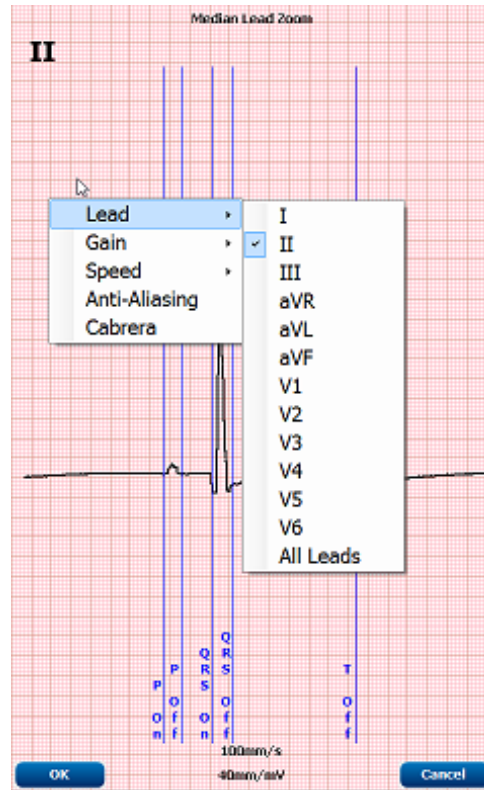
Note	Interval measurements can also be edited using the interval caliper tool.

Settings

Many settings can be changed using context menus. Right click the mouse on any part of the ECG tracing for the following settings:

- Change the waveform presentation
- Print pacemaker spikes
- Print interpretation

Measurement Caliper Tool

A caliper tool is available in the context menus. To use the calipers, right click anywhere in the main ECG window and select **Show Calipers**.

Calipers for amplitude and duration measurements will appear on the waveform.

Hover with the cursor over the caliper area. When the cursor is close to the dotted line, it changes to a cross, after which the calipers can be dragged to the desired position without changing the distance between the calipers. When the cursor is close to the

solid line, it changes to a double arrow, and the distance between the calipers can be modified. Position the cursor over any part of the calipers measuring time and right click to activate additional menus.

March Out

The March Out function applies a duration measurement and associated markers across the entire the ECG. The series or markers can be moved uniformly by hovering over the dotted line in the duration calipers, and clicking and dragging. To deactivate the marched out markers, right click on the calipers and deselect **March Out**.
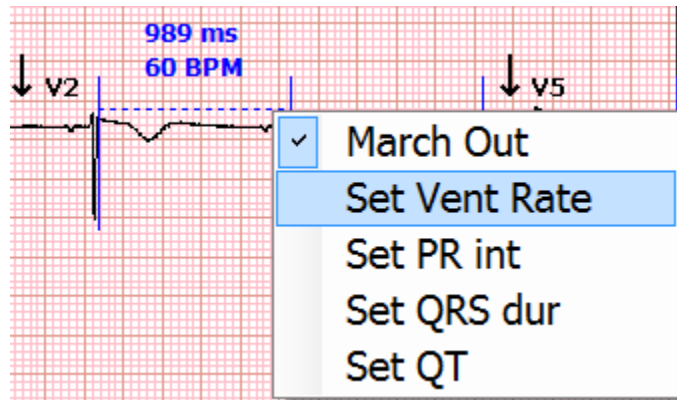
Set Vent Rate

In the calipers menu, select Set Vent Rate to change the vent rate in the measurements section at the top of the ECG. The edited vent rate measurement will have an asterisk (*) next to the measurement to indicate that it has been edited. Select the revert button to revert all global measurements back to those originally calculated by the program.

Set PR int

In the calipers menu, select Set PR int to change the PR interval in the global measurements at the top of the ECG. The edited PR interval will have an asterisk (*) next to the measurement to indicate that it has been edited. Select the revert button to revert all global measurements back to those originally calculated by the program.

Set QRS dur

In the calipers menu, select Set QRS dur to change the QRS duration in the global measurements at the top of the ECG. The edited QRS measurement will have an asterisk (*) next to the measurement to indicate that it has been edited. Select the revert button to revert all global measurements back to those originally calculated by the program.

Set QT

In the calipers menu, select Set QT to change the QT interval in the global measurements at the top of the ECG. The edited QT measurement will have an asterisk (*) next to the measurement to indicate that it has been edited. Select the revert button to revert all global measurements back to those originally calculated by the program.

Viewing Patient Information

 Use the ID button icon to view patient and exam demographic information.

Printing the Report

 Use the Print ECG button icon to print the ECG in the currently displayed format on the default Windows printer.

Note   The state of the exam is not updated when printed immediately upon acquisition, so the previous state of the ECG (e.g. unconfirmed report) will be printed on the resting ECG.

Complete the Editing Process

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

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

Printing Resting ECG Reports

Printing

- If printing is set to "Always" in the System Configuration > Work Flow Config menu, an ECG is printed following ECG capture, both for manual or timed capture.

- For manual printing, select Print ECG. The view on the display is printed to the default printer for the computer being used.

- To change the speed, gain, filter, or print format (regardless of the plot format configuration setting) of the acquired ECG, use a right mouse click over the acquired ECG.

- The complete full disclosure, data can be printed as a single lead by selecting Print Full Disclosure after right-clicking in the Full Disclosure window. Waveform data reviewed on the screen can be selected and printed as a single lead of up to 60 minutes of data, depending on the amount of ECG data that has been acquired.

Report Print Preview

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

Icon Toolbar
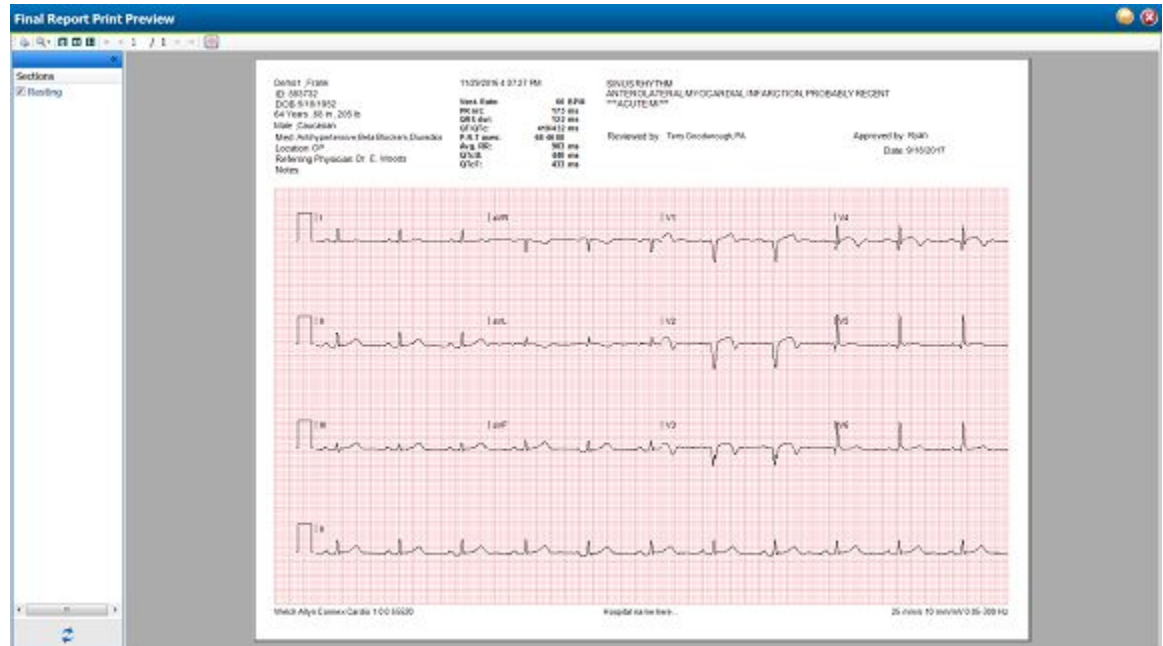
- Use the printer icon to open a Windows' printer dialog and choose defined printers with properties, print range, and number of copies. To print the report, select **OK**.
- Use the magnifying glass icon to choose **Auto** to fit the window or a percentage size for display.
- Use the page icons to select 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. The Resting section will print the predefined 12-lead ECG report with demographic information, measurements, interpretation and signature block.

The Rhythm section prints a 12-lead rhythm strip with summarized patient information and no measurements and interpretation. This section is enabled in the configuration settings by the administrator and may not be present.

Exit the Print Preview

Click on 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:

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

1. To make these customizations open the Windows start menu, navigate to the Hillrom folder and launch the Report Configuration Tool.
2. 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.
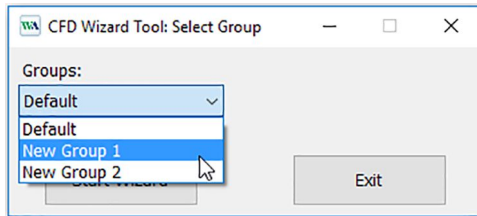
3. Navigate to the Choose a report dropdown and select Spirometry.

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.

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 ensure Run as Administrator is available. Contact Technical Support for assistance.
User prompted for database credentials during Simple installation	Contact Technical Support for assistance.

Accessing 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. If system is setup in a networked configuration, check with the administrator that the Welch Allyn Diagnostic Cardiology Suite server is up and running. Contact the IT administrator to perform the following function: Under Windows Services, ensure the CorScribeGateServer is running. If stopped, start service, and set restart to Automatic if set to Manual. Contact Technical Support for assistance.
Schedule, Exam Search, User Preferences, and Settings icon are grayed out	System is in offline mode. Follow steps above.
Welch Allyn Diagnostic Cardiology Suite was installed as EHR integrated, but is not launching from my EHR.	The interface between Welch Allyn Diagnostic Cardiology Suite and the EHR must be enabled by the EHR. Contact your IT administrator or EHR to ensure the interface is enabled.

Symptom	Resolution
	Contact Technical Support for assistance.

ECG Acquisition

Symptom	Resolution
AM12 is connected to the PC, but no waveforms appear.	Physically inspect the USB port to ensure that it is not damaged.
	Ensure the AM12 is completed seated in the USB port.
	Check the system for compatible software and hardware. From the main screen, select the System Configuration icon. On the top left side of the window that appears, note the software version. If the version is 1.1.0 or later, it must be used with AM12 with a listed reference number as 9293-048-64.
	Contact Technical Support for assistance.
Welch Allyn Wireless Acquisition Module is connected, but no waveforms appear.	Ensure the USB receiver is completed seated in the computer USB port.
	Complete the process to pair the Welch Allyn Wireless Acquisition Module to the USB receiver. Instructions listed under Pairing the Welch Allyn Wireless Acquisition Module to the Welch Allyn Diagnostic Cardiology Suite.
	Check the system for compatible software and hardware. From the main screen, select the System Configuration icon. On the top left side of the window that appears, note the software version. If the version is 1.1.0 or later, it must be used with Welch Allyn Wireless Acquisition Module with a listed reference number as 30012-019-76 and the UTK listed with a PN of 30012-021-60.
Welch Allyn Diagnostic Cardiology Suite is set to Best 10 but Last 10 ECG is captured.	The ECG button on the acquisition module is always set to capture the Last 10 seconds regardless of settings.

ECG Troubleshooting Chart

Symptom	Resolution
Artifact in Lead I and Lead II	Check the RA electrode, re-prep if necessary, and ensure patient is relaxed and muscles are not tense.
Artifact in Lead II and Lead III	Check the LL electrode, re-prep if necessary, and ensure patient is relaxed and muscles are not tense.
Artifact in Lead I and Lead III	Check the LA electrode, re-prep if necessary, and ensure patient is relaxed and muscles are not tense.
High frequency noise in all leads	Adjust low pass filter setting; check proximity to power cables; check that the proper AC filter setting is selected (50 Hz or 60 Hz).
	Remove all portable electronic devices from the vicinity of the patient and the acquisition module.
	Check to see if the patient has an implanted muscle stimulator.
	Ensure patient is relaxed and muscles are not tense.

Symptom	Resolution
	⚠️ **WARNING** When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met.
Excess artifact	Pull the clips off the end of all lead wires (if applicable), visually inspect the connector for corrosion. Inspect the metal portion that comes in contact with the electrode for corrosion. Clean or replace as needed.
	Inspect the lead wires for cracks or breakages.
	Ensure each lead wire is completely seated in the acquisition module.
	If available: Attach a simulator and view the waveforms on screen for artifact. If artifact is present, try another acquisition module. If artifact is still present, contact Technical Support. If no artifact while connected to the simulator, turn off the simulator and gently bend all wires. If artifact is seen, replace applicable lead wire.
No tracings on screen or gaps in the tracings. Screen shows Leads Off.	If using the AM12, the cable between the module and the computer may be damaged or broken. Contact Technical Support for assistance.
	If using the Welch Allyn Wireless Acquisition Module, ensure that the PC where the USB receiver is connected is in range by checking the device signal strength on screen.
	Inspect the battery cap for signs of damage and to ensure it is completely connected.
	Press the power button on the Welch Allyn Wireless Acquisition Module to turn on.
	Ensure the battery is placed in the proper direction in the acquisition module, or replace. Inspect the battery compartment for signs of corrosion.

Data Export

Symptom	Resolution
Exam export not found.	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.
	In the Users Database under System Configurations, ensure that the user logged in has the proper role selected to export exams.
	Contact IT administrator to ensure the interfaces are setup and connected.
	Contact Technical Support for assistance.
Duplicate exams are exported.	Exams are set to automatically export upon completion of configured steps. Under the Workflow Config settings of the System Configuration, check the boxes that are checked under the Manual and Automatic columns. Ensure the appropriate box is checked that matches the step after which the user expects the exam to be exported.
	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.

Software Upgrade

Symptom	Resolution
Installation attempted with the following error: Windows Installer ❌ Another version of this product is already installed. Installation of this version cannot continue. To configure or remove the existing version of this product, use Add/Remove Programs on the Control Panel. [OK]	Browse to the Control Panel to Add/Remove programs. Find and highlight Welch Allyn Diagnostic Cardiology Suite and uninstall. Browse to the new version of software and attempt to install again.
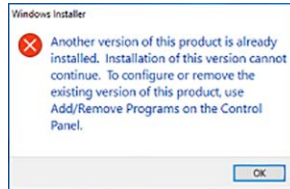
Appendix A: System Specifications

Welch Allyn Diagnostic Cardiology Suite – ECG Specifications

Feature	Specification*
Input Channels	Simultaneous acquisition of all 12 leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
On-Screen Tools	Time and amplitude calipers; 40 Hz and 150 Hz noise filters; various lead layouts and grid
Digital Sampling Rate	40,000 s/sec/channel used for pacemaker spike detection; 1,000 s/sec/channel used for recording and analysis
Gain Setting	2.5, 5, 10, 20 mm/mV
Report Formats	Standard or Cabrera; 3+1, 3+3, 6, 6+6, or 12 channel
Rhythm Print Format	Single lead of up to 60 minutes of data
Frequency Response	Compliant to 60601-2-25 requirements
Filters	High-performance baseline filter; AC interference filter 50/60 Hz; low-pass filters 40 Hz, 150 Hz, 300 Hz

* Specifications subject to change without notice.

Welch Allyn Wireless Acquisition Module Specifications

Feature	Specification*
Instrument Type	12-lead wireless acquisition module for resting ECG
Input Channels	12-lead signal acquisition and transmission
ECG Leads Transmitted	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6

Feature	Specification*
Device Transmission Protocol	Bidirectional and frequency hopping; beacon and response method links a single acquisition module to a single UTK receiver module
Frequency Range	2403.38 MHz to 2479.45 MHz
Channel Spacing	1MHz
RF Output Power	<10dBm
Antenna Type	PCB inverted F
Antenna Gain	-0.33dBi
Modulation	MSK
Receiver Distance	Approximately 10 feet (3 meters)
Lead Set	RA, LA, RL, LL, V1, V2, V3, V4, V5, and V6 (R, L, N, F, C1, C2, C3, C4, C5, and C6) with detachable lead wires
Sampling Rate	40,000 samples/second/channel acquisition; 1,000 samples/second/channel transmitted for analysis
Resolution	1.875 microvolt LSB
User Interface	Two-button operation: ON/OFF and 12-lead ECG acquisition; Rhythm button is non-functional
Defibrillator Protection	Complies with AAMI standards and IEC 60601-2-25
Special Functions	LED indication of power status, operating mode, lead fail, and remaining battery charge
Device Classification	Type CF, battery operated
Weight	6.7 oz. (190 g) with battery
Dimensions	4.45 x 4.25 x 1.1" (11.3 x 10.8 x 2.79 cm)
Battery	1 AA alkaline battery typically powers the device for acquisition of 250 resting ECGs

Specifications subject to change without notice.

UTK Specifications

Feature	Specification*
Frequency Range	2403.38 MHz to 2479.45 MHz
Channel spacing	1MHz
RF output power	<10dBm

Feature	Specification*
Antenna Type	PCB inverted F
Antenna Gain	4.12dBi
Modulation	MSK

*Specifications subject to change without notice.

ECG Acquisition Module Accessories

Part Number	Description
9293-046-07	COMBINER WAM LEADS 10 POS GRAY
9293-046-60	LEAD SET WAM 10 WIRE BANANA AHA GRAY
9293-046-61	LEAD SET WAM 10 WIRE BANANA IEC GRAY
9293-046-62	RPLCE LD SET WAM/AM12 LIMBS BANA AHA GRY
9293-046-63	RPLCE LD SET WAM/AM12 LIMBS BANA IEC GRY
9293-046-64	RPLCE LD SET WAM/AM12 V1-V3 BANA AHA GRY
9293-046-65	RPLCE LD SET WAM/AM12 C1-C3 BANA IEC GRY
9293-046-66	RPLCE LD SET WAM/AM12 V4-V6 BANA AHA GRY
9293-046-67	RPLCE LD SET WAM/AM12 C4-C6 BANA IEC GRY
9293-047-60	LEAD SET WAM 10 WIRE CLIPS AHA GRAY
9293-047-61	LEAD SET WAM 10 WIRE CLIPS IEC GRAY
9293-047-62	RPLCE LD SET WAM/AM12 LIMBS CLIP AHA GRY
9293-047-63	RPLCE LD SET WAM/AM12 LIMBS CLIP IEC GRY
9293-047-64	RPLCE LD SET WAM/AM12 V1-V3 CLIP AHA GRY
9293-047-65	RPLCE LD SET WAM/AM12 C1-C3 CLIP IEC GRY
9293-047-66	RPLCE LD SET WAM/AM12 V4-V6 CLIP AHA GRY
9293-047-67	RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY

Electrodes

Part Number	Description
9300 032 50	ECG MONITORING ELECTRODES CASE 300

Part Number	Description
9300 033 51	ELECTRODE RESTING TAB BOX/500
9300 033 52	ELECTRODE RESTING TAB CASE/5000
042729	CardioSens / Ultra II Electrodes
729295	RESTING TAB ELECTRODE PACK 10 SHEETS
413423	RESTING TAB ELECTRODE BOX/500
413424	RESTING TAB ELECTRODE CASE/500729296 MONITORING SNAP ELECTRODE PK/10
413425	MONITORING SNAP ELECTRODE BOX/300
413426	MONITORING SNAP ELECTRODE CASE/3000

Acquisition Modules

Part Number	Description
9293-048-65	CONNEX CARDIO WIRED PATIENT CABLE (AM12)
30012-019-76	CONNEX CARDIO WIRELESS ACQUISITION MODULE (WAM)
30012-021-60	UTK (Wireless receiver / transceiver)

Manuals

Part Number	Description
9515-001-51-CD	PHYSICIAN'S GUIDE ADULT & PEDIATRIC
80023962	WELCH ALLYN DIAGNOSTIC CARDIOLOGY SUITE MANAGER
80023961	WELCH ALLYN DIAGNOSTIC CARDIOLOGY SUITE RESTING ECG
9515-166-50-CD	ELI LINK USER MANUALS

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

Appendix B: Electromagnetic Compatibility (EMC)

Electromagnetic Compatibility (EMC)

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

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

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

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

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

Emissions and immunity information

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

IEC 61000-3-2

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions test	Compliance	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	
Power frequency(50/60Hz)magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated

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Guidance and Manufacturer's Declaration: Electromagnetic Immunity

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Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$$

$$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$$
80 MHz to 800 MHz

$$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$$
800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].

Interference may occur in the vicinity of equipment marked with the following symbol:

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[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

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

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

Rated max. output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		

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

	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.1m	0.2m
0.1	0.4m	0.7m
1	1.2m	2.3m
10	4.0m	7.0m
100	12.0m	23.0m

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

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

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

Appendix C: Warranty Information

Your Welch Allyn Warranty

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

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

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

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

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

purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence there from relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

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