CARDIAC INSIGHT, INC.

CARDEA 20/20 ECG™ Operator's Manual

Resting ECG Analysis System

Model CS-2020

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1 Introduction

1.1 Indications for Use

CARDEA 20/20 ECG records and measures a resting ECG from the adult and pediatric (age ≥ 14) body surface. It provides automatic ECG interpretations which are identified as "Unconfirmed" by the product until they have been over-read and confirmed by a clinician.

CARDEA 20/20 ECG is intended for use on apparently healthy individuals and on symptomatically stable patients with known or potential cardiac conditions.

This device is intended for use under the direct supervision of a licensed health care clinician.

1.2 Clinician's Responsibility

Not all cardiac conditions can be detected by an ECG and many potentially detectable conditions are not always present, or may be transitory and not present in a specific ECG. The symptoms, physical exam, patient / family history and additional information are critical to the clinician's overall assessment of a patient's cardiac health. Such information should not be ignored because an ECG appears normal.

It is the clinician's responsibility to ensure proper ECG collection, review and interpretation and ultimately make a diagnosis of the individual's cardiac health and/or risk of cardiac events.

1.3 Contraindications

- CARDEA 20/20 ECG is not intended for use in acute or emergent care, or in surgical or critical care units, or for monitoring vital signs, or for patients that are unconscious or delirious.
- The Bluetooth radio version of the ECG Transmitter is not intended for use during transport.

1.4 Warnings and Cautions

 **Warning**	**Shock Hazard. Do NOT touch the CARDEA 20/20 ECG system or patient during defibrillation. Death or serious injury may occur from the electrical defibrillator discharge.**
 **Warning**	**Burn Hazard. NEVER position defibrillator pads or paddles close to or in contact with the ECG electrodes. Remove chest leads to allow for correct positioning of the defibrillator pads or paddles. Severe burns may result from incorrect placement of defibrillator pads or paddles. Consult the operating instructions for the defibrillator.**
 **Warning**	**Operator or Patient Injury. Read all instructions for use, including safety procedures, before using CARDEA 20/20 ECG and follow all instructions while using CARDEA 20/20 ECG.**
 **Warning**	**Unattended Use. This device is NOT intended for unattended or continuous patient monitoring. There are NO audible or visible alarms.**
 Caution	**Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.**

1.5 Definitions of Symbols Used

 **Warning**	**Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.**
 Caution	**Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.**
	**Defibrillation-Protected Type CF Equipment.**
	**Battery Status LED**
	**Consult instructions for use.** **ISO 15223-1:2012 Symbol 5.4.3**
	**Power On Button**
	**Direct current medical grade power supply (PS1)**

2 Getting Started

2.1 CARDEA 20/20 ECG Shipping Carton

Your CARDEA 20/20 ECG shipping carton contains:

Quick Start Guide:

- Overview of CARDEA 20/20 ECG
- How to set up your system
- CARDEA 20/20 ECG software download and installation instructions

ECG Transmitter – with patient lead wires. The patient lead wires terminate in clip/snap connectors that attach to user-selected commercially available ECG electrodes (electrodes are not a part of the CARDEA 20/20 ECG System). Two versions of the ECG Transmitter provide communications with the PC via either Bluetooth or USB cable.

PS1 Medical Grade Power Supply to recharge the ECG Transmitter's internal battery or directly power the ECG Transmitter via connection with AC mains power (Bluetooth only). For use outside of North America, use the AC mains adapter provided with the PS1 power supply.

USB Bluetooth Radio (Bluetooth only).

2.2 Device User-Supplied Personal Computer (PC) Requirements

Warning	**Misdiagnosis. Software virus, worms and other forms of malware may compromise the integrity of the PC. The PC should be protected from malware through the use of software and hardware devices as appropriate for the operating environment of the PC. Regular scans of the system to detect malware are strongly recommended.**
Warning	**Misdiagnosis. The PC used in the CARDEA 20/20 ECG system should be properly secured for appropriate user access (password/authenticity verification). Malicious activities of unauthorized users could compromise diagnostic information and/or the analysis software.**

2.2.1 Supported Operating Systems and Associated Components

Windows® 7, 8 and 10

Microsoft .NET Framework 4.5.1 (or higher) and Visual C++ 2013 Runtime library. See:

https://www.microsoft.com/en-us/download/details.aspx?id=40779

and https://www.microsoft.com/en-us/download/details.aspx?id=40784

Warning	**PC Operating System. CARDEA 20/20 ECG has been tested for proper function with the versions of Microsoft Windows specified above. Other versions of the PC operating system should not be used.**

NOTE: Windows® supports user customization of the display characteristics. Using Control Panel\Display to increase text size from the default 100% setting to larger sizes (e.g., Medium or Larger) may prevent the CARDEA 20/20 ECG windows from being fully or correctly displayed.

2.2.2 Hardware Requirements

Windows® compatible personal computer

Disk: 2 GB of free disk space or greater

NOTE: CARDEA 20/20 ECG checks the available disk space for saving patient ECGs and associated information at start-up. If the available disk space is less than 100 Mbytes a warning message will be displayed. On average, a patient ECG and associated images will require less than 1 MByte.

CPU: Intel® Core™2 Duo CPU @1.50 GHz or greater, 32-bit (x86) or 64-bit (x64) processor or equivalent

Display: 1024x768 or higher resolutions

Memory: Minimum 2GB of system memory

Pointing Device: Windows® compatible mouse.

Keyboard: Windows® compatible keyboard

Ports: 1 available USB port

Printer: Microsoft Windows® compatible inkjet or laser printer

⚠ Caution	**Electromagnetic Interference. The selected PC should be compliant with IEC 60601-1-2 standards for radiated emissions and immunity. Use of a PC that is not compliant may interfere with CARDEA 20/20 ECG or other medical equipment operating in the vicinity. Other operating equipment (such as MRI and other imaging devices, other medical devices, microwaves, and cell phones) may degrade or otherwise interfere with the PC function. Never disable other patient monitoring equipment without getting the approval of the attending physician.**

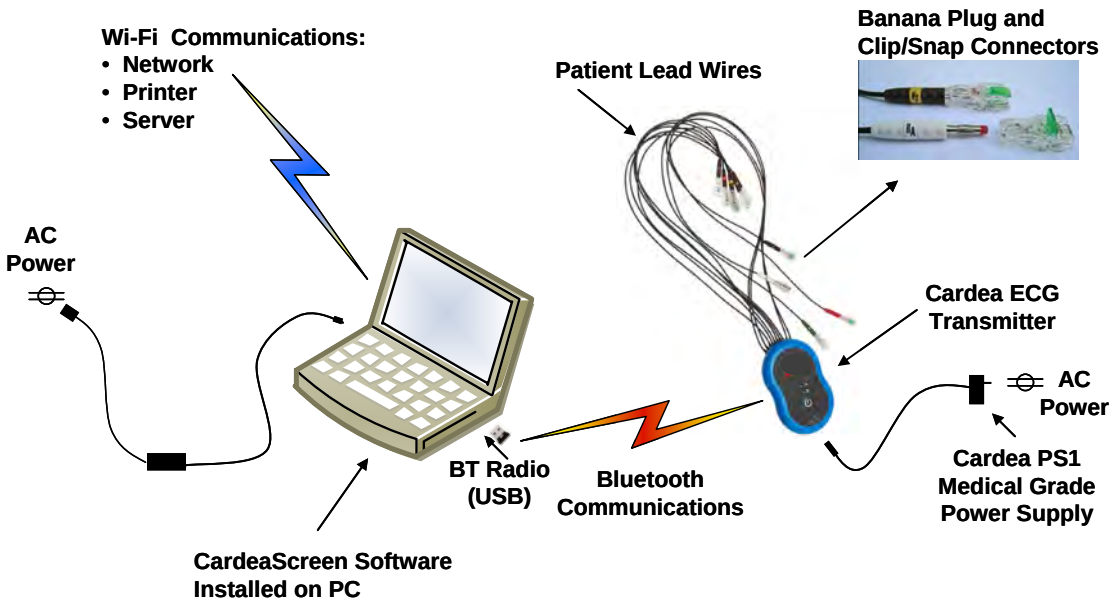
2.2.3 PC Performance Testing

Verifying the overall performance of a PC is an important step for ensuring ECG data collection without data loss. Methods for performance testing your PC are included in the section *ECG Acquisition – Transmission Loss*.

2.3 Hardware Setup

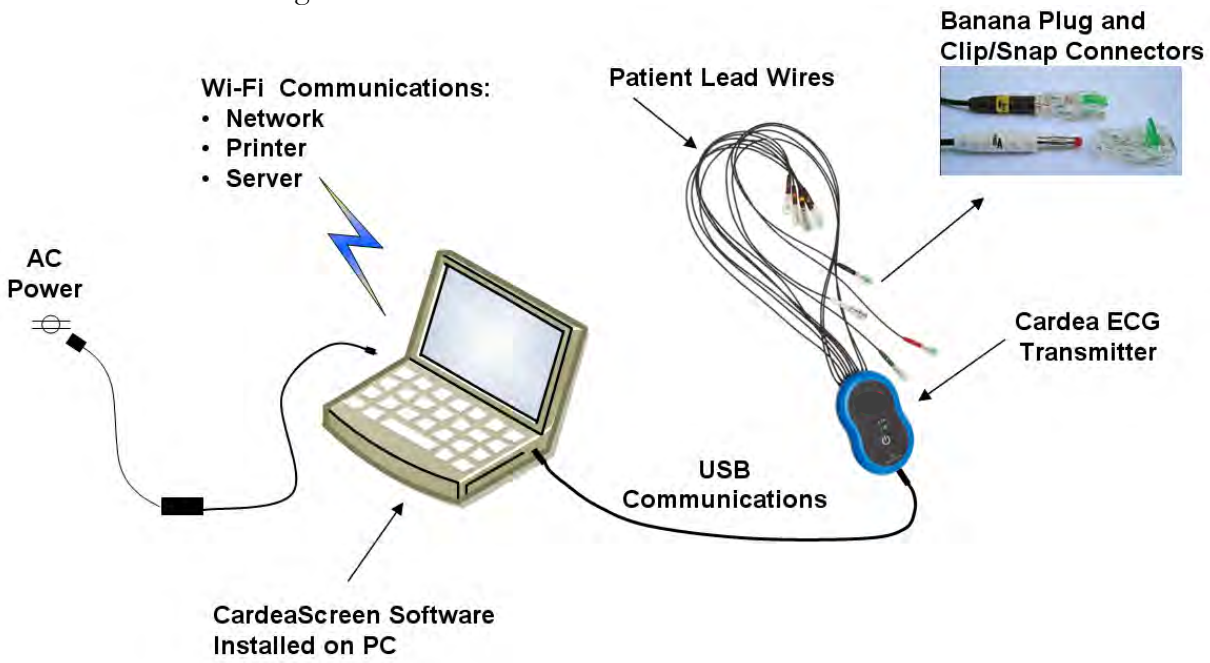
Warning	**Operator or Patient Injury. Never attempt to connect the patient lead wires to an AC outlet. Serious injury or death may result.**
Warning	**Operation of the PC within the patient vicinity (6 feet / 1.83 m surrounding the perimeter of the bed, gurney, examining table, table or chair and 7.5 feet / 2.29 m above the floor) while connected to the AC mains requires use of either a medical grade power supply or medical grade isolation transformer. Only use properly grounded medical grade AC outlets.**
Caution	**Equipment Damage. The CARDEA 20/20 ECG medical grade recharging power supply for the ECG Transmitter must be operated only at the line voltages and frequencies specified.**
Caution	**Data Loss. Unreliable AC power (surges, brown-outs, spikes, and so on) may interrupt the PC function. Surge protectors and Uninterruptible Power Supplies (UPS) should be used for PCs that are not powered by a charged internal battery.**

The CARDEA 20/20 ECG hardware setup is depicted below for the Bluetooth configuration:



The Cardiac Insight provided USB Bluetooth (BT) radio must be plugged into an available USB port. All communication with the ECG Transmitter is via this radio communications link. The ECG Transmitter may be powered from either the internal rechargeable battery or via the PS1 medical grade power supply.

The CARDEA 20/20 ECG hardware setup is depicted below for the wired USB configuration:



Cardiac Insight recommends that PC communication with printers and other network devices and systems be supported via Wi-Fi communications. If the PC is directly connected to other third-party devices, such as a printer, and if the device is within the patient vicinity, then usage of medical grade power supplies is recommended.

The USB connected ECG Transmitter is powered via the PC. Power Requirements: 5V DC +/- 10% 100mAmp maximum.

2.4 CARDEA 20/20 ECG Transmitter Operation

2.4.1 **Bluetooth connected ECG Transmitter**

The Bluetooth ECG Transmitter is shown below:

Battery Status

Power-On and Device Status
(Consult Instructions for Use)

Power-On/Off and BT Device Discovery

5V ⎓ 2A Plug location for the Cardea PS1 Medical Grade Power Supply

The Battery Status LED operation is described in the next section, Rechargeable Battery Operation. The PS1 Medical Grade Power Supply plugs into the end of the ECG Transmitter, as indicated above. Fully charge the ECG Transmitter before initial use.

The Power button supports the following:

Power-On: Depressing the button when the unit is powered-down (LED is off) will power-up the ECG Transmitter. The Power-On and Device Status LED will blink rapidly for about 10 seconds as the Power-On Self-Test (POST) is executed. The LED will turn solid green following a successful POST. If any problem is discovered during the POST the LED will display RED – Contact Cardiac Insight for service support.

Power-Off: Depress and hold the button down until the Power-On and Device Status LED turns off (about 3 seconds). Note: The system will self power-down if the ECG Transmitter is inactive for about 30 minutes.

Discovery Mode: Discovery Mode allows the ECG Transmitter to be recognized by and pair with the PC. With the ECG Transmitter powered-on, depress the button for a few seconds (but less than 3 seconds) and the Power-On and Device Status LED will begin to blink (two flashes/second). The device will stay in Discovery Mode for 60 seconds, then will return to a powered-on state and the LED will be solid green.

Device Status LED – Operational Indications. In addition to the above described functionality of the Power-On and Device Status LED, the Device Status LED will blink slowly when ECG data is being recorded and sent to the PC via the USB Bluetooth radio. If there are any communication problems that prevent the ECG Transmitter from communicating over Bluetooth with the PC, the LED will turn red. Troubleshooting: If this occurs, be sure the patient is within a 10 foot radius of the PC and minimize usage of other wireless devices in the vicinity that operate in the 2.4 GHz ISM band (i.e., wireless Internet, cell phones and some microwaves). Power-down the ECG Transmitter to clear the error. This will reset the LED to green.

⚠ Caution

Infection Control. Do not place the ECG Transmitter on the patient skin. Transfer of patient fluids and/or infectious agents may occur. Use a disposable towel or comparable to cover any areas of the patient skin (e.g. abdomen) where the ECG Transmitter is placed. Frequently clean the patient lead wires and clips – See: *Maintenance and Service – Cleaning*.

Rechargeable Battery Operation

The rechargeable battery in a new ECG Transmitter should support about 8 hours of ECG data acquisition. An average ECG recording session is typically 1-2 minutes – often much less; a new and fully-charged battery should support the recording of about 200 ECGs, depending upon recording duration.

The real-time data acquisition screen displays the current battery charge status (See: *ECG Acquisition*). When the battery charge is getting low, plug in the PS1 charging power supply to recharge. The Battery Status LED charge indicator will blink at the rates below, depending upon charge level:

Battery Charge Level – Battery LED Flash Rate (Flashes/Second)		
< 50 Percent	50 – 99 Percent	100 Percent
1	2	Solid On

A new battery with a charge of less than 10 percent will charge to 90 percent in about four hours. A battery that is fully discharged may trigger a solid on LED condition until the battery recovers from the deep discharge.

See: *Rechargeable Battery* for detailed instructions on the care and maintenance of the ECG Transmitter.

Warning	**Recharging Power Supply. Only use the recharging power supply provided by Cardiac Insight for recharging the battery within the ECG Transmitter. Other recharging units may damage the system and put the patient and operator at risk of electrocution, causing serious injury or death.**

When used with the CARDEA 20/20 ECG PS1 medical grade recharging power supply, the ECG Transmitter is safe for patient use while the battery is being recharged. However, it is more convenient to use the device without the charging cable attached. Cardiac Insight strongly recommends recharging the device when not in use.

2.4.2 USB connected ECG Transmitter

The USB connected ECG Transmitter is similar in operation, except it is powered via the USB cable – there is no Power-on / Off button nor Battery Status charging LED. The ECG Transmitter will execute the Power-On Self-Test function when the USB cable is plugged into a powered-on PC. Following installation of the CARDEA 20/20 ECG software, simply plug the USB connector into a USB socket on your PC. Open the Preferences (**Options / Preferences)** and select the USB option on the System Tab, and Save – you are ready to go.

2.5 Installing the CARDEA 20/20 ECG Software

The ECG Transmitter is not functional without the CARDEA 20/20 ECG software. Instructions for software download and installation onto your PC are as follows.

Close all Windows programs before installing CARDEA 20/20 ECG.

Connect your PC to the Internet, open your Internet Browser, navigate to http://www.cardiacinsightinc.com/software-registration/ and follow the on-screen directions for downloading and installing the CARDEA 20/20 ECG software. You will need to enter your new ECG Transmitter serial number, located on the back of the ECG Transmitter (above the Bar Code, SN: xxxxxxxx), along with your name, address and email address.

Start the installation and follow the on-screen directions to complete your installation. If Windows asks for permission to install drivers, respond Yes.

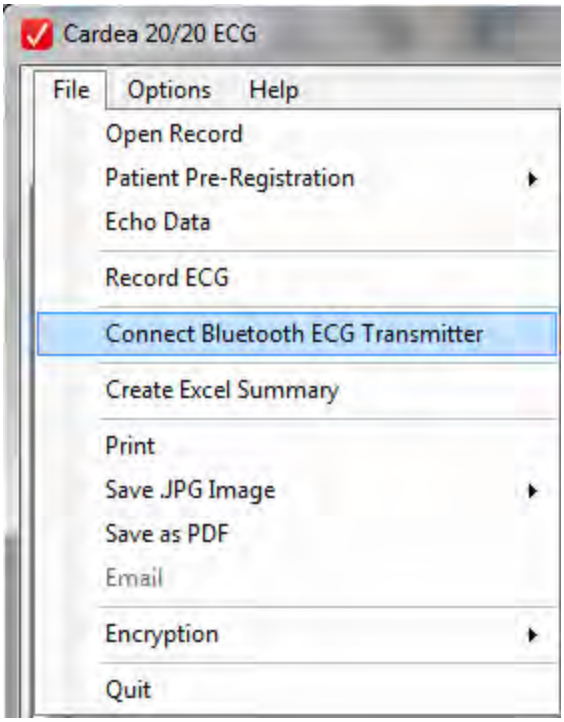
NOTE: The installation program may need to install the Microsoft .Net Framework 4.5.1 if it, or a higher version, is not already present on the PC. The installation program will notify you if .Net Framework 4.5.1 is not installed and provide a link to the Microsoft installation webpage. Following installation of the .Net Framework 4.5.1 you will need to restart the CARDEA 20/20 ECG installation.

2.6 Bluetooth Pairing with Bluetooth ECG Transmitter

Warning	**Misdiagnosis. Bluetooth PC – ECG Transmitter Pairing. Ensure the ECG Transmitter serial number matches the paired serial number displayed during the device pairing and displayed in the "Help / About CARDEA 20/20 ECG" window.**

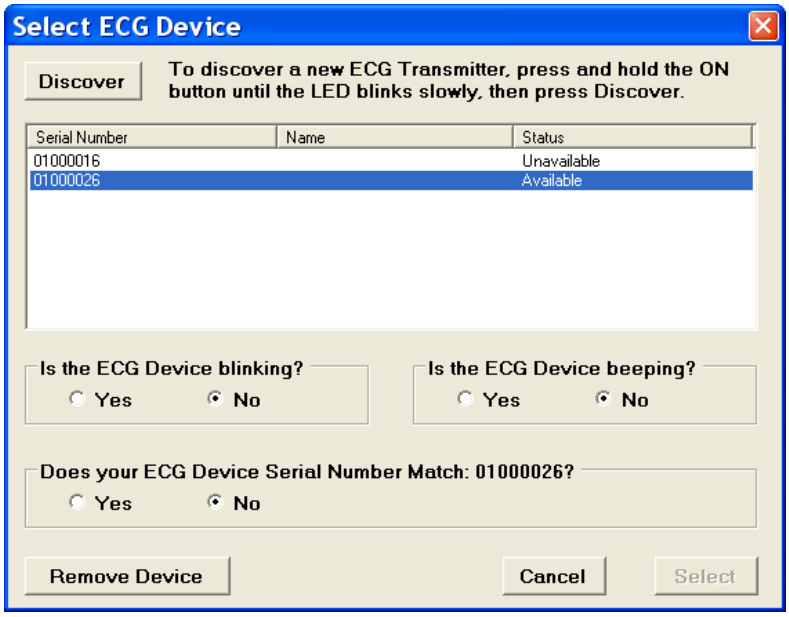
The Bluetooth ECG Transmitter, CARDEA 20/20 ECG software and your PC must be paired before data can be transmitted. Be sure the USB Bluetooth radio has been plugged into your PC and the ECG Transmitter is powered on.

Next, start the CARDEA 20/20 ECG software and select:



If the USB Bluetooth radio is not recognized by Windows an error message will be displayed: "No Local Bluetooth Radios Available." If this occurs, follow the instructions in *Trouble-Shooting* below.

If the Bluetooth radio is recognized the Connection Wizard window will appear:



If your ECG Transmitter's serial number does not appear in the list, with the ECG Transmitter powered on, push the power-on button until the LED begins to blink slowly (See: *CARDEA 20/20 ECG Transmitter Operation)* and then press "**Discover**" on the Wizard (top-left on the above screen). If more than one ECG Transmitter is active in your vicinity, click on the serial number of the device you wish to use. The device will begin to blink the Power-On LED and sound a tone. Click the radio buttons to "**Yes**" to confirm correct operation and device serial number, and then click "**Select"**.

The unique ECG Transmitter Serial Number and associate internal Bluetooth radio MAC address are saved for use in future sessions. Unless you wish to connect to another device or your PC hardware or system software changes, CARDEA 20/20 ECG will automatically reconnect to the selected ECG Transmitter.

NOTE: Removing the USB Bluetooth radio from the PC while CARDEA 20/20 ECG is running will invalidate the Windows radio connection. Power-down the ECG Transmitter and exit the CARDEA 20/20 ECG software. Once the radio has been reinstalled and recognized by Windows, restart the ECG Transmitter and the CARDEA 20/20 ECG software.

If an ECG Transmitter is no longer in use on your system, you can remove it by clicking on the Connection Wizard device serial number and selecting "**Remove Device**".

2.6.1 Trouble-Shooting

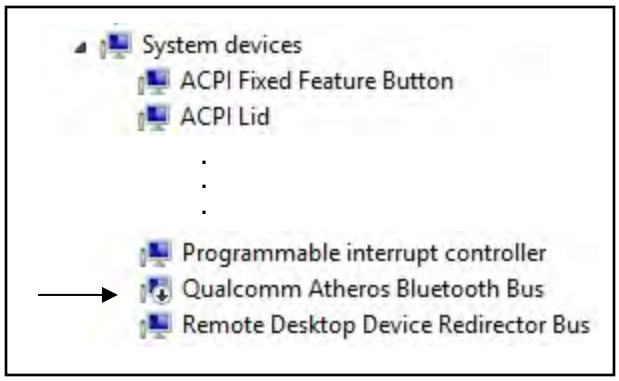
Device Manager: Windows Device Manager is a very helpful utility for diagnosing configuration problems. Open Device Manager as follows:

Right-click on "My Computer" on the Desktop and select "Manage." Under "System Tools" click on "Device Manager."

Or, open the Control Panel and select Device Manager.

No Radio Found: Be sure the USB Bluetooth radio that ships with CARDEA 20/20 ECG is firmly installed. Although Windows should recognize the new hardware when it is plugged in, on some systems it may be necessary in Device Manager to click Action/Scan for hardware changes or, in the worst case, reboot the system.

Qualcomm Atheros Bluetooth Bus: Many PCs are shipping with the manufacturer installed Qualcomm Atheros Bluetooth Bus software, which interferes with the correct operation of the CARDEA 20/20 ECG Bluetooth Radio. In Device Manager, click on the small triangle next to the System Devices entry – you should see something like:



Scroll down this list and verify if the "Qualcomm Atheros Bluetooth Bus" software is installed on your system. If so, right click on the "Qualcomm Atheros Bluetooth Bus" entry in Device Manager and select "Disable". You will be asked to restart the PC.

Internal Bluetooth Radio: Cardiac Insight generally recommends disabling the internal Bluetooth radio, should one be installed, and using the supplied CARDEA 20/20 ECG Bluetooth USB radio. On some PCs, the installed Bluetooth radio and associated software will disable the Generic Bluetooth Radio and/or the Microsoft Bluetooth Enumerator, necessary for CARDEA 20/20 ECG to communicate with the ECG Transmitter. Advanced users may choose to reconfigure the internal radio (right click on the radio and select "Update Driver Software"; Select "Browse my computer for driver software" and then select "Let me pick from a list…"; and finally select "Generic Bluetooth Adapter" – Device Manager should update the driver and enter both the Generic Bluetooth Radio and Microsoft Bluetooth Enumerator under the Bluetooth Radio entry).

To disable the internal radio, open Device Manager. Your Bluetooth Radios section may look like:

For this PC the "Foxconn…" Bluetooth radio was factory-installed within the laptop. Right-click on the built-in radio entry and select "Disable." NOTE: You may need Administrator privileges on your machine to make this change. The "down-arrow" should appear on the entry, as above, when it has been disabled.

Installing the CARDEA 20/20 ECG Bluetooth Radio: With Device Manager open, plug-in the CARDEA 20/20 ECG Bluetooth Radio. Once Device Manager has completed the scan for hardware changes, the "Generic Bluetooth Radio" and the "Microsoft Bluetooth Enumerator" should be added to the listing, per the above, On some systems the manufacturer may have installed additional Bluetooth radio drivers, which may mask the Microsoft "Generic Bluetooth Radio" driver. If you have an entry such as "CSR Bluetooth Radio", right click on the radio and select "Update Driver Software"; Select "Browse my computer for driver software" and then select "Let me pick from a list…"; and finally select "Generic Bluetooth Adapter" – Device Manager should update the driver and enter both the Generic Bluetooth Radio and Microsoft Bluetooth Enumerator under the Bluetooth Radio entry

Device Status Busy, Error or Unavailable: If the ECG Transmitter has been connected to another PC, it will not be available for re-pairing until it has been reset. Exit the CARDEA 20/20 ECG software and power off the ECG Transmitter. Turn on the ECG Transmitter and wait until the rapid flashing LED turns to constant on (end of self-test). Restart the CARDEA 20/20 ECG software and open the Connection Wizard. Hold down the ECG Transmitter power button (about 2 seconds) until the LED begins to blink slowly and then select "**Discover**" in the Connection Wizard (See: *CARDEA 20/20 ECG Transmitter Operation*).

If the Connection Wizard reports "Error" in the Status column, Windows may have been delayed in completing the installation of the driver. Close and re-open the Connection Wizard and click on the ECG Transmitter serial number.

No Device Found: Be sure the device is turned on and closer than 10 feet to the PC. Obstructions (walls, other equipment in the line-of-sight) and interference from other devices may reduce the maximum transmission distance.

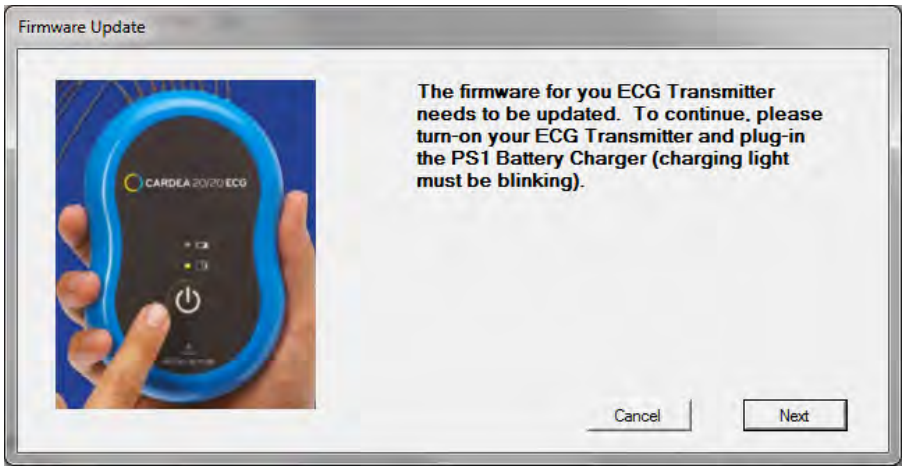
Unplugging the CARDEA 20/20 ECG Bluetooth radio and plugging it into a different USB port may invalidate the Bluetooth pairing. In the CARDEA 20/20 ECG Connection Wizard, select the ECG Transmitter and select "Remove Device", and then re-pair the ECG Transmitter with the PC.

Pairing a PC and ECG Transmitter outside of CARDEA 20/20 ECG: The ECG Transmitter can also be paired with a PC outside of the

CARDEA 20/20 ECG application. Right-click on your toolbar Bluetooth icon and select "Add a Bluetooth Device." Depress the power-on button until the ECG Transmitter blinks slowly (Discovery Mode). The Microsoft Bluetooth Pairing Wizard will ask you for the Bluetooth Passkey. Enter the ECG Transmitter serial number (found on the back label). The ECG Transmitter should now be displayed in the CARDEA 20/20 ECG Connection Wizard – but you must still select the device and confirm correct pairing within CARDEA 20/20 ECG (See: *CARDEA 20/20 ECG Transmitter Operation)*..

2.7 Updating the Bluetooth ECG Transmitter Firmware

The installation process for CARDEA 20/20 ECG includes installing the current release of the ECG Transmitter firmware. When accessing the ECG Transmitter, CARDEA 20/20 ECG verifies the firmware is up-to-date, and if not the following update screen is presented. Please follow the on-screen instructions and update the ECG Transmitter firmware. NOTE: The ECG Transmitter MUST be plugged into the PS1 Battery Charger.



3 Patient Preparation

 **Warning**	**Misdiagnosis. Improperly prepared skin (dirty or otherwise compromised) may cause poor or incorrect readings. Before applying ECG electrodes ensure the skin is properly prepared.**
 **Warning**	**Infection. Lead placement on broken or otherwise compromised skin may lead to infection. Before applying ECG electrodes ensure the skin is clean, unbroken and properly prepared.**
 **Warning**	**Misdiagnosis. The quality of the ECG tracing can be compromised if lead wires and electrodes, or other sources of patient conducted electrical noise from 3rd party devices, are connected to the patient while CARDEA 20/20 ECG is recording ECG signals.**
 **Warning**	**Misdiagnosis. Incorrect electrode placement will degrade or compromise the ECG, resulting in incorrect readings. It is critical that individuals who are applying the ECG electrodes have been properly trained in skin preparation and electrode placement.**
 Caution	**Patient Skin Irritation. Some patients may experience skin irritation with particular electrodes. Monitor the electrode site and, if irritation occurs, use an alternative electrode. Patients with fragile skin can experience skin damage when the electrodes are removed. Do not rip off the electrodes.**

3.1 Skin Preparation

To obtain a high-quality ECG tracing it is important to have good contact between the skin and the electrode. The electrode has only a small area that provides contact. The transmission of the ECG signal is optimized by removing excess hair, dirt, dead skin cells and oil. If there is poor contact between the skin and electrode, the ECG will have distortion and electrical noise, making interpretation difficult.

If there is excessive chest hair present, use a razor to remove it. The Limb leads should be placed on the inner surfaces of the arms and legs, where there is less hair and improved electrode contact. Wipe the target electrode areas with an alcohol pad followed by a rub with a dry gauze pad.

Also note that by removing excess hair, the patient will be less uncomfortable when the electrodes are removed.

3.2 Limb Lead Electrode Placement

Have the patient in a supine, relaxed position with arms at his/her side and legs straight out with no muscular tension required to hold the position. Be careful to not drop the ECG Transmitter onto the patient when positioning the device for patient hook-up.

Place arm limb leads anywhere from upper arm to wrists. Both right and left arm leads should be placed at the same level (upper arm or below elbows). RA (Right Arm) must be on the patient's right side and LA (Left Arm) on the left side. Arm leads placed on the wrong sides reverses ECG waveform. Correct placement of limb leads allows correct axis interpretation and localization of abnormalities.

The right (RL) and left (LL) leg electrodes can be placed anywhere below the navel.

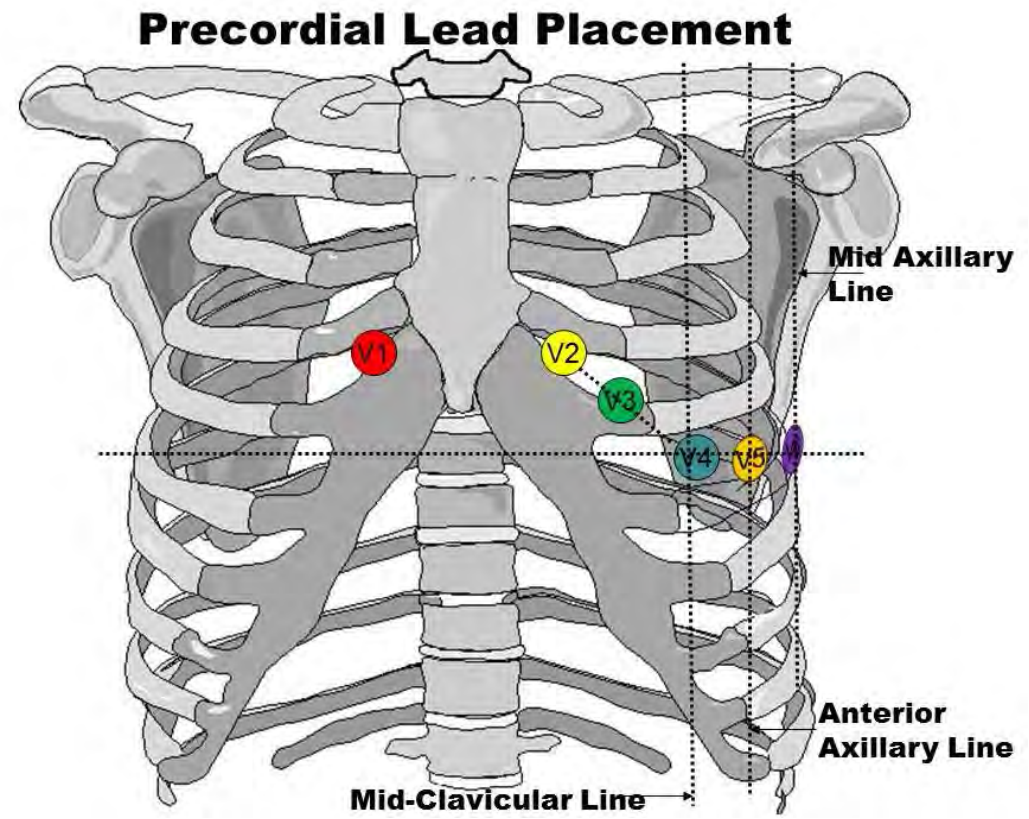
3.3 Precordial or V Electrode Placement

Locating the points for chest electrode placement should be done with the patient in the supine position.

3.3.1 Start with V1 and V2

Find the clavicle by tracing the bone from the shoulder to the neck. Feel for the first space under the clavicle where it connects to the sternum. Then count down three more spaces to reach the 4th intercostal space. This is roughly the first intercostal space above the nipple and two-thirds of the way down the sternum. Place V1 to the immediate right side of the sternum over the 4th intercostal space. Place V2 to the immediate left side of the sternum at the 4th intercostal space.

Incorrect placement (i.e. usually too high) can make the ECG appear to show that a heart attack or other cardiac injury has occurred. Also, the Brugada pattern can be mimicked. Remember that the exact placement is determined by counting the intercostal spaces and being at the lower third of the sternum.



3.3.2 V4 Must Be Next

V4 must be placed next since it determines the placement of V3, V5 and V6. The remaining electrodes cannot be placed correctly without V4 in place first. Find the middle of the left clavicle and then count down to the left 5th Intercostal space. Place V4 in the left 5th intercostal space at the mid clavicular line (mid-point of the clavicle).

3.3.3 V3 Is Next

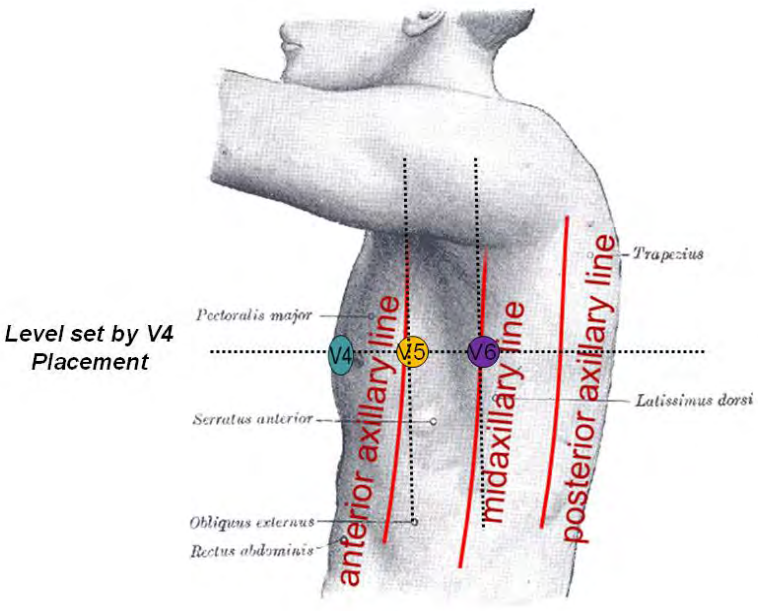
Imagine a diagonal line from V2 to V4. Place V3 in the middle of the diagonal line.

3.3.4 V5 and V6 Are Last

Place V5 and V6 in the same horizontal line position on the chest as V4, as if a belt were placed around the chest wall at the V4 level.

Do not place them in the 5th intercostal space since it curves up.

Find the anterior axillary line and place V5 lateral from V4; find the mid-axillary line and place V6 lateral from V5, both on the level of the belt thru V4.



As a quick check, V1 and V2 are usually at a level just above the nipple and V4, 5 and 6 are just below the nipple. Also, they are at or below the lower third of the sternum.

3.4 Video Training

See: http://www.cardiacinsightinc.com/training/

3.5 Electrode Types

Two types of electrodes can be used: snap or tab. Snap electrodes can be more convenient since they adhere well and are typically low sources of noise. But they are more expensive than tab electrodes.

When applying the tab electrodes it is important to place the electrode clip and wire in a position so that the weight or twist of the lead wire does not slowly peel off the electrode. For example, a tab electrode placed on the arm should have the tab downwards and the lead wire snap resting below the electrode. The reversed configuration, tab upwards with lead wire weight pulling downwards, will result in slow peeling of the electrode and significant high-frequency ECG noise as the adhesive bonds are broken. Be sure the lead wire position and weight or pull on the electrode do not slowly peel off the electrode.

The conductive side for gathering the electrical data is right under the sticky side, so that is what should be placed on the landmark.

Also make sure that the electrode snap connectors are making contact with the conductive side of the electrode; sometimes the connector snaps only have metal on one side.

⚠ Caution	**Mixing Electrode Types. Using dissimilar electrodes on a patient (i.e. different models or manufacturers) may result in the inability to record an ECG.**

3.6 Expired Electrodes

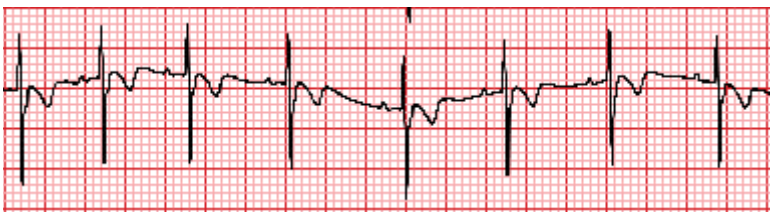
As electrodes age the adhesive materials and conductive gels become less effective, resulting in poor ECG signal quality. Cardiac Insight recommends users read and follow the electrode manufacturer's instructions and discard electrodes that have expired. It is generally good practice to have a reserve of fresh electrodes available for use.

3.7 Troubleshooting ECG Noise

3.7.1 Baseline Wander

A rising and falling of the baseline can be caused by a number of conditions:

- Patient breathing. The post-recording baseline wander filter will generally do a good job of removing wander with a period longer than the duration of 3 beat intervals.
- Body motion. Ask the patient to remain calm and still during the recording and breathe normally.
- Inadequate patient electrode preparation. Be sure the electrodes are firmly applied and the weight of the clip and lead wire are not pulling on the electrode, or peeling off the electrode.
- Old or dried-out electrodes. Check and replace as necessary.

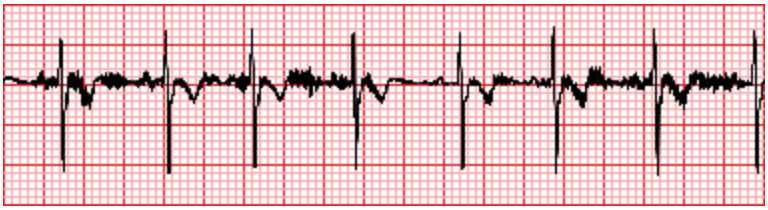


⚠ Caution	**Old/Dated Electrodes. Old or dried-out electrodes will often introduce electrical artifacts that may degrade the ECG quality. Always keep a supply of fresh electrodes available for use.**

3.7.2 Muscle Artifact

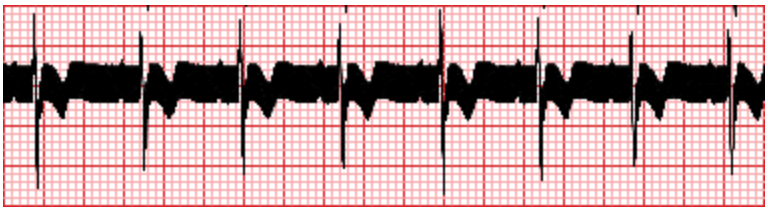
This form of noise is usually caused by muscle tremor or motion. Encourage the patient to relax and lie still.

On occasion, a slowly peeling-off electrode can also introduce random bursts of noise. Be sure the weight of the patient lead is not peeling-off the electrode.



3.7.3 AC line Noise

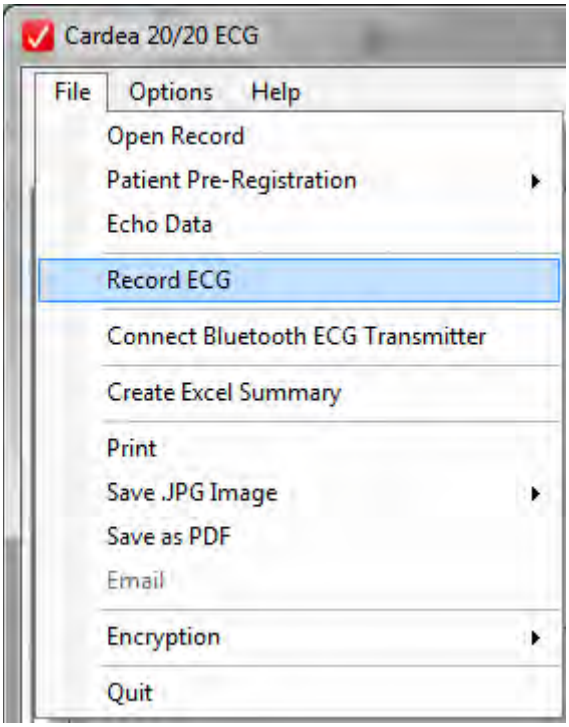
Electrical noise induced from AC power lines introduces an approximately constant amplitude noise. The level of noise may vary from trace to trace. Be sure the line frequency (50 or 60 Hz) is set appropriately for your setting (See: *Data Acquisition and Processing Defaults Tab*).



4 ECG Data Acquisition

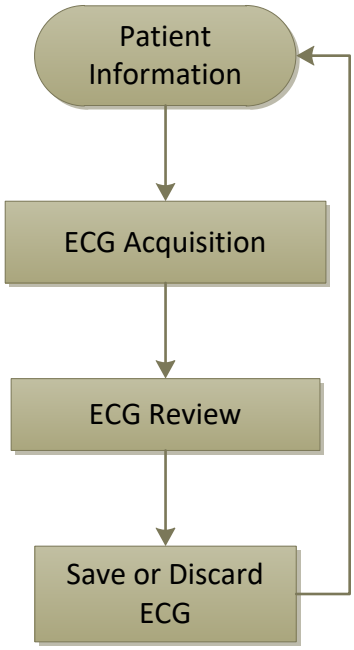
Warning	**Patient Lead Wires. Replace worn or damaged patient lead wires with Cardiac Insight approved lead wires, which include built-in defibrillation protection.**
Warning	**Pre-Check. Before starting an ECG recording session the ECG Transmitter should be cleaned and inspected for damage – See: *Maintenance and Service*.**
Warning	**EXPLOSION HAZARD. Do not use this device in the presence of flammable anesthetics, vapors or liquids.**

Recording patient information and the associated ECG data is accessed by clicking **"Record ECG"**:



The system will transition to acquisition mode and display the Patient Information screen.

The overall workflow for Patient Information entry, ECG data acquisition and ECG review is:



4.1 Patient Information

Warning	**Misdiagnosis. Patient demographic information such as age, gender and ethnicity directly affects the ECG analysis. Additional patient information captured by CARDEA 20/20 ECG may be used by the over reading physician when interpreting the ECG. The over-reading physician should select which elements within the patient demographic data entry screen are required versus optional.**
Warning	**Misdiagnosis. Honest and thorough responses by the patient to the questions posed on the Patient Information screen are critical to establishing cardiovascular risk. Correct entry by the person performing the ECG and the response of the physician to positive responses are also essential. A normal ECG does not negate the potential clinical significance of a positive response to the questions.**

The system supports two patient information screens. The choice of which screen will be displayed, and which parameters are required, is set in Preferences.

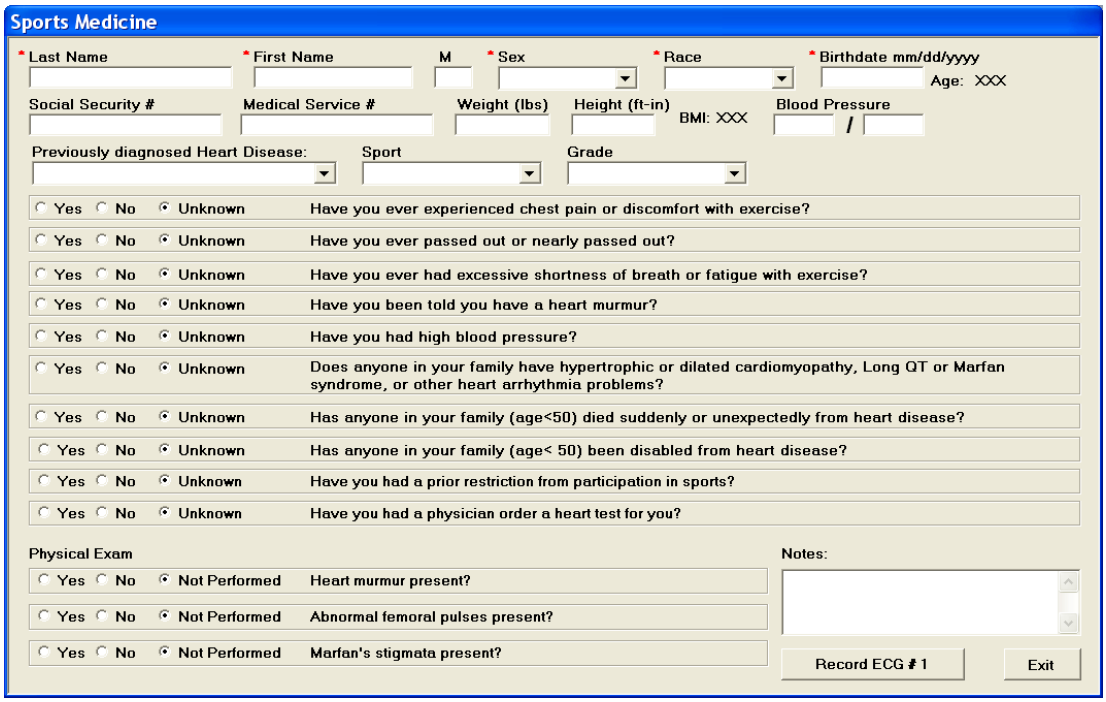
4.1.1 PPE Patient Information Screen

An appropriate physical exam that includes evaluation of the 14-Element American Heart Association Pre-Participation Exam (PPE) questions is important in evaluating cardiovascular risk (See: Maron, B.J., et al. Assessment of the 12-Lead ECG as a Screening Test for Detection of Cardiovascular Disease in Healthy General Populations of Young People (12-25 Years of Age), *Circulation*, 2014; 130). Responses to these questions can strongly influence or override the ECG findings.

About half of the conditions that can lead to an adverse cardiac event can be detected by an ECG. Furthermore, an ECG will only detect those conditions that can be detected about half of the time. Therefore, a "normal" ECG does not rule out the possibility of cardiac risk. This is further complicated by the fact that some of the possible ECG findings that are associated with cardiac risk are transitory and can be missed during a screening. Symptoms, family history, prior events or physical findings should not be ignored simply because the ECG is normal.

Warning	**Misdiagnosis. Information gathered by CARDEA 20/20 ECG requires interpretation and appropriate responses by a trained physician. The physician must be certified/qualified to interpret the ECGs and trained to know the appropriate assessment of positive responses to the AHA questions regarding cardiovascular risk.**

Cardiac Insight recommends careful and complete entry of the requested information on the screen shown below before obtaining an ECG by a trained health care provider:

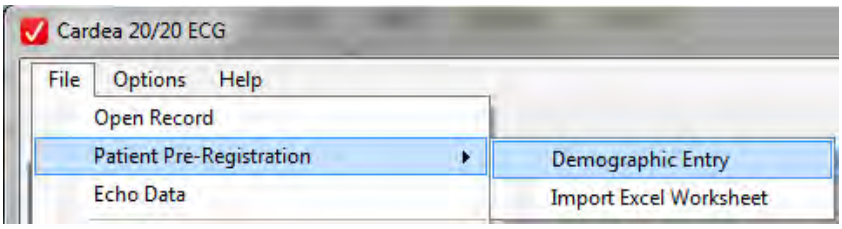


The red "*" preceding fields indicates that the field must be completed (i.e. required input) before the ECG can be recorded (See: *Preferences, Patient Information*). The "**Record ECG**" button will verify that all of the required fields have been completed. If this is the first ECG recorded for this patient encounter, the system will automatically create a Patient Folder. If there is any problem creating the folder (e.g., a network location has been specified and the network is down), the system will report the error and return to this screen. Next the system will start data acquisition. The "# 1" on the Record button indicates that the first ECG will be recorded. A "2" indicates that one record has been recorded and the button push will initiate recording record #2.

Pressing the "**Exit"** button will confirm that you wish to close the encounter with this patient and will redisplay the Patient Information toolbar.

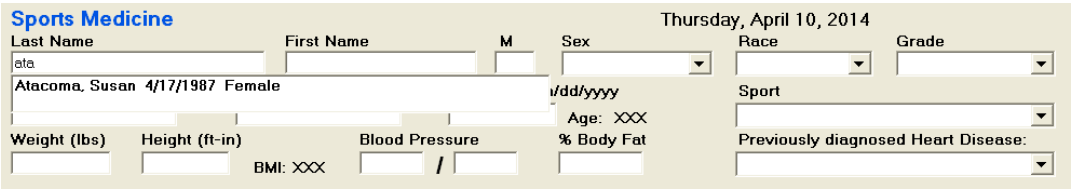
4.1.2 Pre-Registration of Patient Information

For some settings it may be advantageous to pre-register the patient information. Possible cases including large screening events where throughput is important and for those patients that will be returning multiple times for follow-up testing. Clicking as below will present the PPE Patient Information screen shown above.



The labeling on the two buttons is replaced with **"Exit"** and **"Save"**. Enter the patient information and click **"Save"**. The information will be saved to a directory named "Patient Registration" within the overall Patient Data directory set in Preferences (see Section 8.3 – Data Acquisition). Pre-registered patients created on one PC (e.g. administrative) can be moved to the PC hosting ECG storage by moving the contents of the Patient Registration directory.

When using the PPE Patient Information screen, CARDEA 20/20 ECG looks for the Patient Registration directory and matches the last name of the pre-registered patients with the last name being entered. The matching begins after entering three characters and refines the list as each additional character is entered. For two letter last names (e.g. Wu) enter a period following the two characters (i.e. Wu.). The displayed patient list includes last name, first name, birthdate and gender:



Clicking on the patient name will auto-populate the screen with the pre-registered information.

Import Excel Worksheet. CARDEA 20/20 ECG can also import Excel worksheets and create the associated Pre-Registration files. The column headers in Excel MUST match the column headers that CARDEA 20/20 ECG recognizes. The best method to assure full compatibility is to create an example spreadsheet using the function **File/Create Excel Summary** (See: *Database Reporting*). There is no need to have recorded any ECGs – the Excel file "PatientInfo.xls" will be created and all of the possible Patient Info headers enumerated, including any new fields created in Preferences. Delete all of the columns that will not be pre-populated. Column order is not important – CARDEA 20/20 ECG will match the Excel column header with the internal field. Use this resulting Excel file as the template for populating Pre-Registration data.

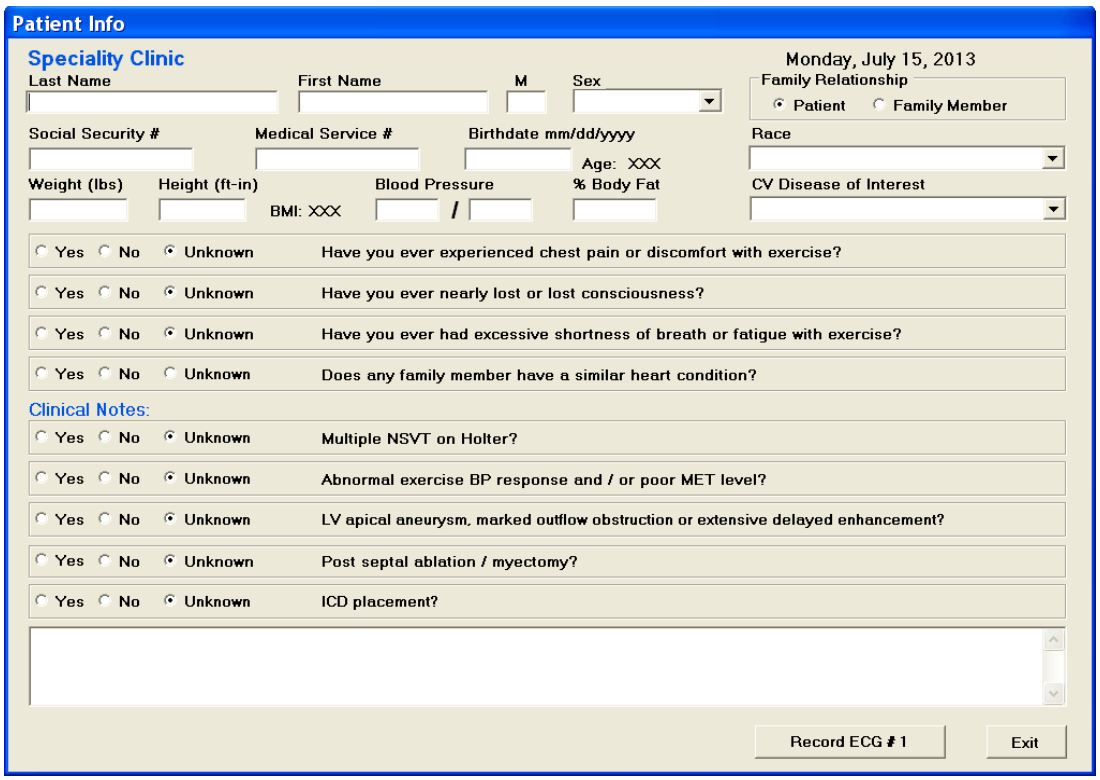
NOTE: CARDEA 20/20 ECG stores weight and height in metric units. Use the header names "Weight" and "Height" to enter patient information in pounds and ft-in (or just inches).

NOTE: Answers to the AHA questions may be entered as:
Yes: "Yes", "Y", or "1"
No: "No", "N", or "0"

NOTE: Excel must be installed on the PC used to create the PatientInfo.xls file.

4.1.3 Clinical Patient Information Screen

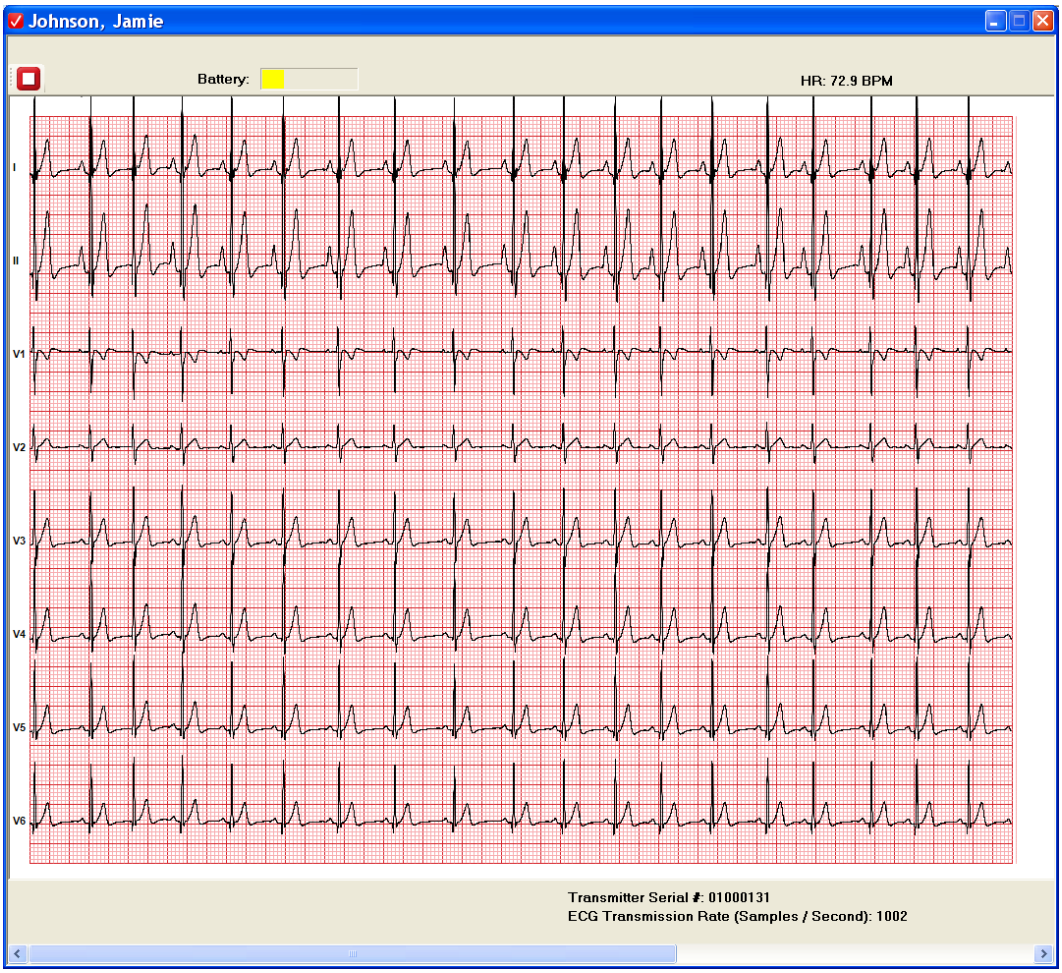
To support clinical use for patients with known cardiovascular risk conditions, a clinical screen has been developed.



All patient Information entered on these two screens is saved to the patient's Diagnostic Chronology file.

4.2 ECG Acquisition

Clicking on the "**Record ECG**" button on the Patient Information screen will begin ECG acquisition. The ECG Transmitter it will blink the Power-On LED, sound a tone and begin ECG transmission and CARDEA 20/20 ECG will begin displaying the real-time ECG:



The displayed recording window is 16 seconds wide and uses a moving wiper display, replacing the oldest section with the most current. The 8 independent ECG leads I, II, and V1-V6 are displayed. Data is collected and saved at a sample rate of 1000 samples/sec and a resolution of ±0.5 µVolt. The data is sub-sampled to 500 samples per second for analysis.

The AC Line Filter selected in Preferences (default is 60 Hz) is always on.

Once the screen is completely filled with stable ECG tracings, click the Stop Acquisition Button:  The recorded ECG data will automatically be processed and analyzed.

NOTE: You must record a full 16 seconds of data before stopping data acquisition, and the display should contain a clean and stable record. For best results, continue running data acquisition until this condition has been met.

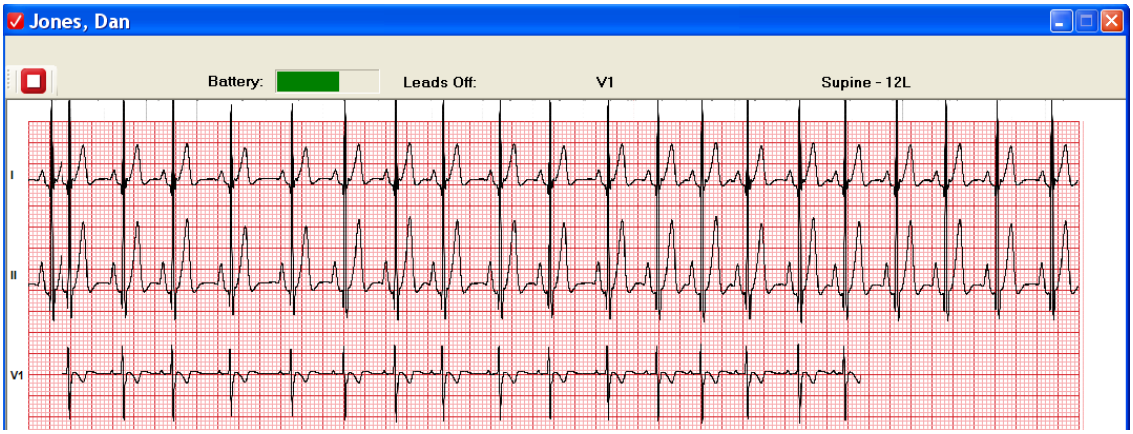
 **Warning**	**Misdiagnosis. Electrostatic discharge (ESD) to the CARDEA 20/20 ECG system may cause transient artifacts that distort the ECG signal. ECGs affected by ESD should NOT be used and should be re-recorded.**
 **Warning**	**Misdiagnosis. The quality of the ECG tracing can be compromised if lead wires and electrodes, or other sources of patient-conducted electrical noise from 3rd party devices, are connected to the patient while CARDEA 20/20 ECG is recording ECG signals.**
 **Warning**	**Patient Lead Wires. Prior to use ensure that the patient lead wires are undamaged and securely connected to the ECG Transmitter.**
 Caution	**Data Loss. Other software applications (e.g., web browsers, down loading applications, and so on) should not be executing while CARDEA 20/20 ECG is collecting ECG data. Possible performance degradation may cause loss of ECG data.**

The data is stored in a circular buffer, and it is not necessary to wait until the wiper reaches the right edge of the screen – click the "**Stop Acquisition Button**" whenever overall quality and stability of the displayed ECG is satisfactory.

NOTE: If more than 25% of any trace is determined to be too noisy for reliable analysis the system will reject the record. Discard the ECG and record again. Exiting Patient Information, when no records have been saved for the patient encounter, will delete the associated empty Patient Folder.

NOTE: The Battery Indicator shows the current status of the rechargeable battery in the ECG Transmitter. In general it is preferable to recharge the battery as needed before using. However, the PS1 battery charger can be plugged into the ECG Transmitter and used while recording ECGs.

NOTE: Lead-Off. The system will detect a lead-off condition and display the offending lead label and draw the trace in red (see below where V1 has been disconnected). Be sure to check the lead, re-attach as necessary (re-clip or replace the electrode) and record a full screen of data before stopping.

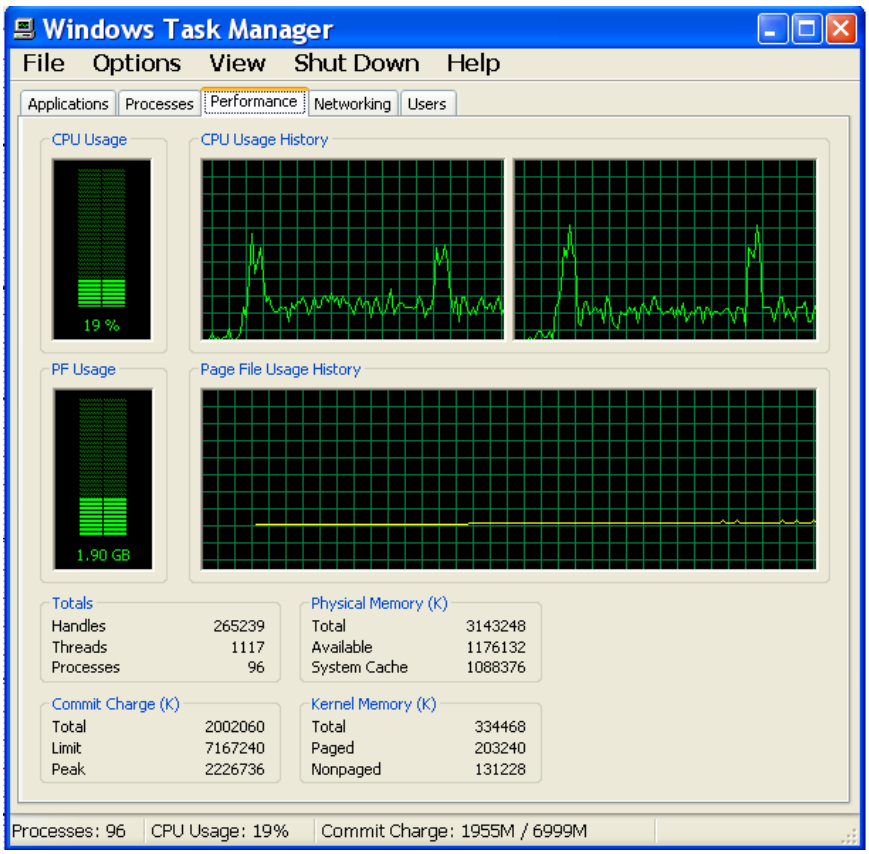


4.3 ECG Acquisition – Transmission Loss

4.3.1 PC Performance Requirements

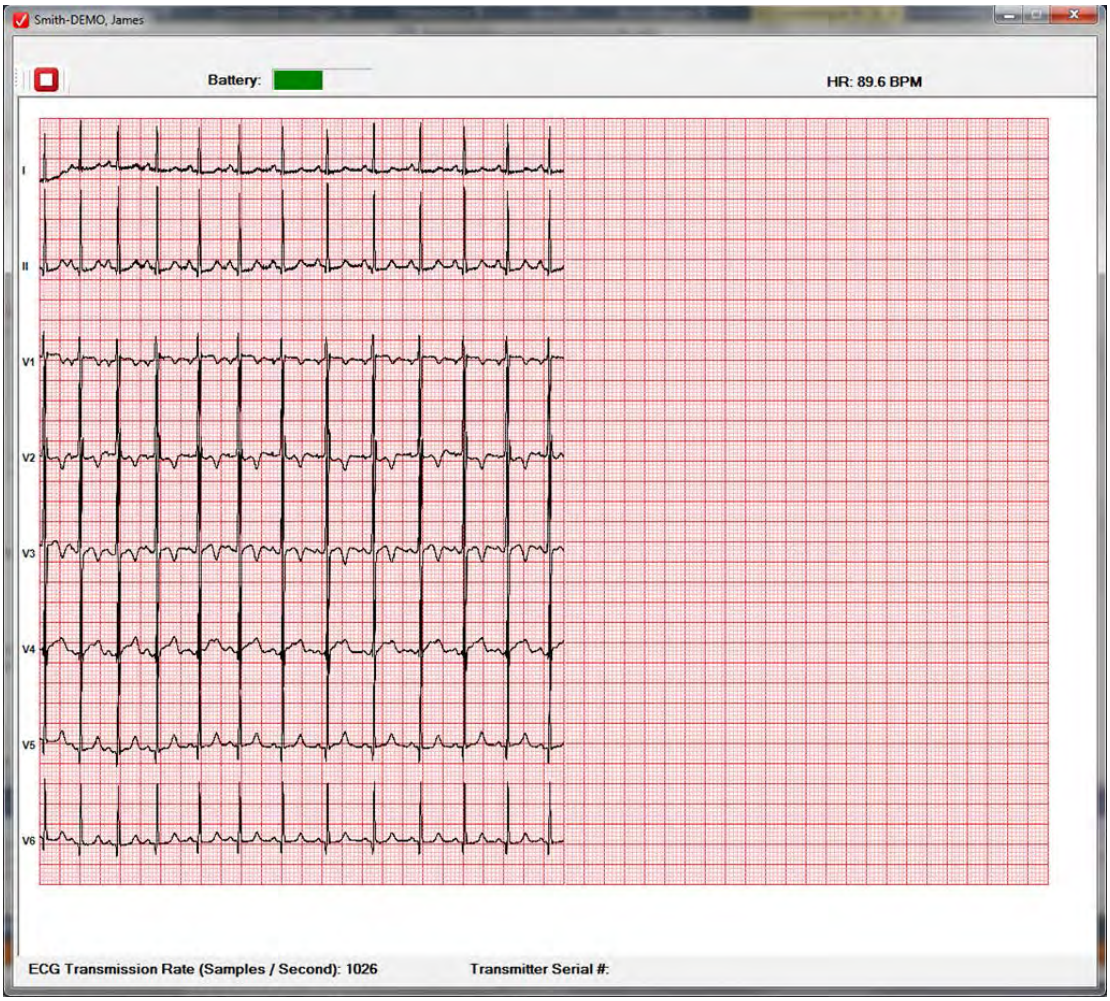
ECG data acquisition can be compromised if the PC does not have adequate system resources and performance to keep up with the demands of the real-time transfer, processing and data display. One good way to test the overall performance of the system is to record an ECG while monitoring the Windows Task Manager.

To open the Task Manager enter the keyboard combination Ctrl+Shift+Esc and select the performance tab. While recording an ECG, your Task Manager screen will look something like:



Average CPU usage should be less than about 75 percent. The hardware PC specifications (See: *Device User-Supplied Personal Computer (PC) Requirements*) will generally consume less than about 25 percent of the available PC. As CPU usage approaches 100 percent the risk of data loss increases. If the CPU meets the hardware specification and CPU usage is high, it is likely associated with inadequate graphical performance necessary to keep up with the real-time screen refresh as the ECG is painted. Occasional CPU pulses, such as the two in the above picture, indicate that other applications may be running on the PC.

During ECG data acquisition the system also reports the ECG data transmission rate, in samples per second (received and drawn – bottom of the screen):

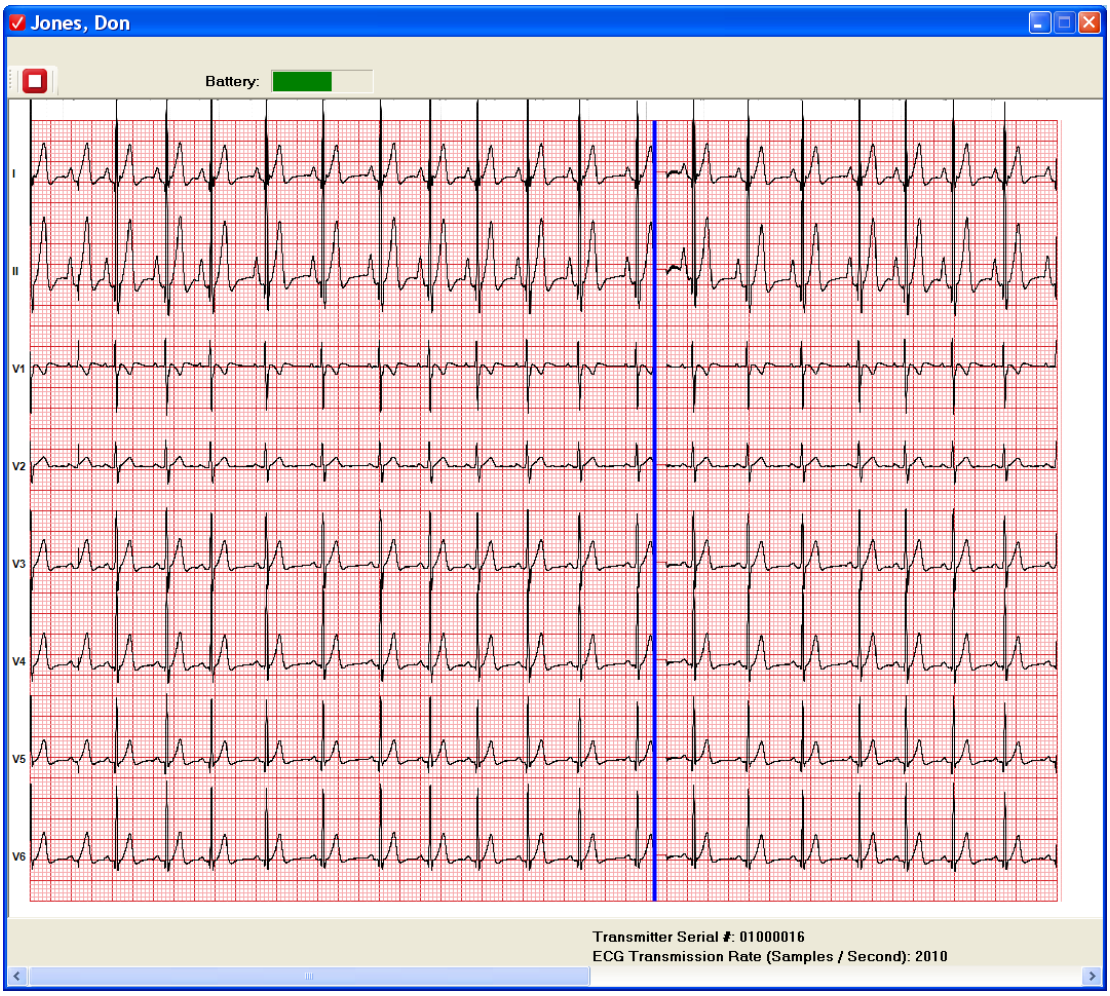


The rate should average around 1000 samples/sec. If the rate is significantly lower than this, the PC is not adequate for the intended use. However, if the rate is usually around 1000 but drops on occasion, then either other software concurrently running on the PC may be using resources, or radio interference from other devices may be lowering the ECG transmission rate. The system will provide visual notification if any data packet is dropped – See: *Bluetooth Data Packet Loss*.

4.3.2 Bluetooth Data Packet Loss

Warning	**Misdiagnosis. The quality of the ECG tracing can be compromised by interference from other devices in the patient vicinity that transmit/radiate in the Bluetooth frequency band (2.4 GHz ISM Band), including Wi-Fi Internet, cell phones, microwaves, and other medical devices. Consult with attending physician(s) before turning off any other device in the vicinity.**
Warning	**Electromagnetic Compatibility. Some electromagnetic fields may interfere with the performance of this device. Ensure that other devices, such as X-Ray and MRI equipment, operated within the vicinity of this device comply with appropriate EMC requirements. ECG artifacts introduced by electromagnetic interference should be assessed by a physician to determine the impact on diagnostic accuracy and treatment. Other devices should not be disabled without the approval of the attending physician.** **CARDEA 20/20 ECG is compliant with IEC 60601-1-2 EMC immunity requirements. See: *EMC Declaration Tables*.**

Within the electronics of the ECG Transmitter, every ECG data sample is sequentially numbered at the time of data acquisition and the sequence number is transmitted along with the 8 channels of ECG data. The transmission protocols provide data integrity and re-try to ensure continuous transmission of data. However, if the environment has heavy Bluetooth or other wireless interference (e.g. wireless Internet – 2.4 GHz ISM Band, cell phones and some microwaves), or should the PC CPU resources saturate such that data services fall behind (See: *PC Performance Requirements*), or if the patient moves beyond the range of the radio USB Bluetooth radio (~10 unobstructed feet), a packet may be dropped. The system will display a bold blue line on the ECG at the point where the packet was lost, and ECG data recorded immediately before and after the loss is excluded from analysis. The blue line on the screen will look like:



The Raw Data display (See: *Raw*) will draw the traces in red around the drop-out, indicating the system has marked the data as invalid.

Data loss should not occur. Cardiac Insight strongly recommends reviewing other Bluetooth transmitters in the vicinity and the CPU usage statistics on your PC and making the appropriate changes to the overall system environment. If a drop-out is a very rare event in your environment, allowing the recording to continue until the screen has rolled over the drop-out is an effective and simple solution.

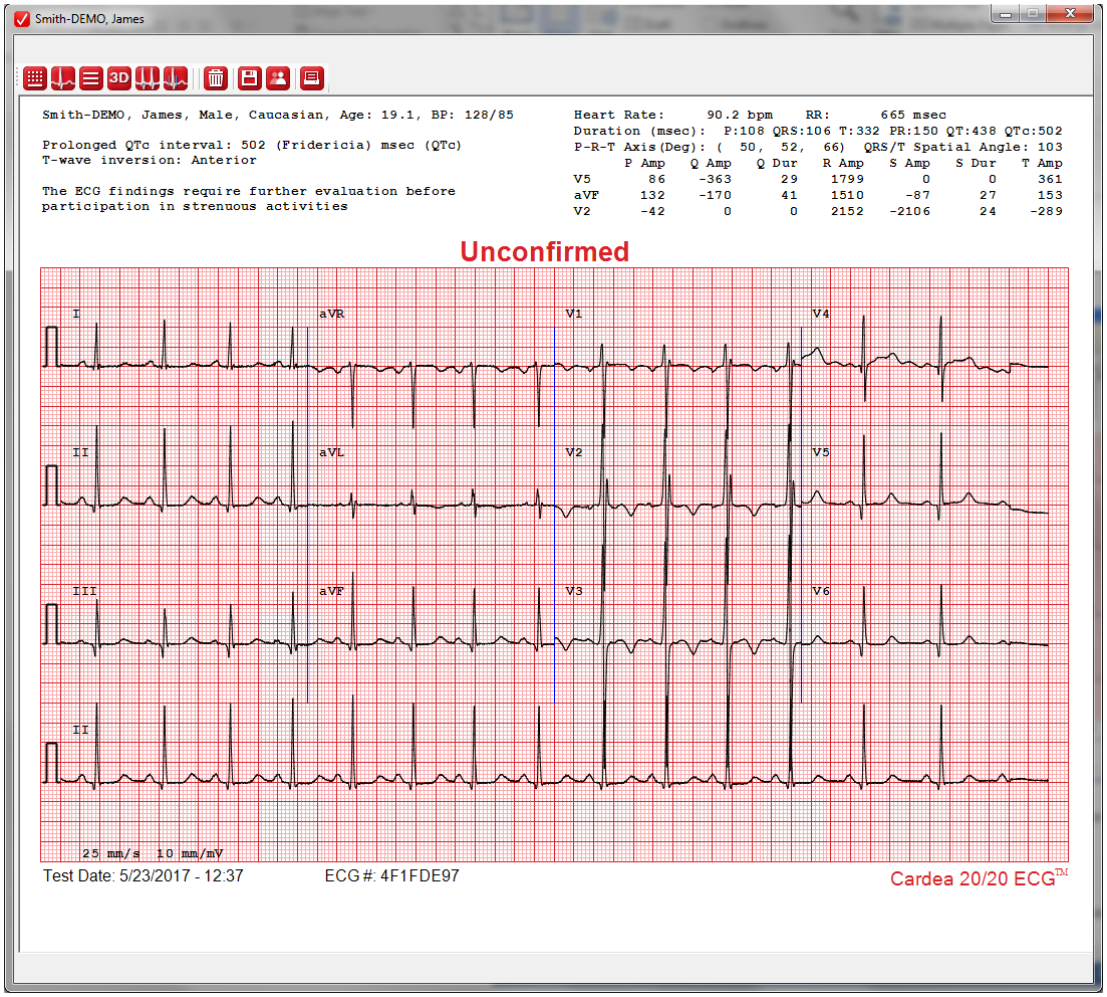
NOTE: Bluetooth shares the 2.5 GHz radio bandwidth with general internet Wi-Fi. In some environments (e.g. school gym with athletes "surfing" the net) it may be necessary to restrict Wi-Fi use.

4.3.3 Communication Failure

In the event of a complete communications failure, such as might occur if the ECG Transmitter power button was cycled to Off during data acquisition, the system will automatically stop data acquisition and post a message box explaining what has happened.

4.4 ECG Review Prior to Saving

The recorded ECG will be analyzed automatically and the associated 12-Lead ECG screen will be displayed:



The first 6 buttons  support the following actions, in sequence:

- 12-Lead display
- Median Beat display
- 16-second display of V5, aVF and V2 (X, Y, and Z – three traces)
- Vector plots (3-Dimensions)
- Raw 16 seconds for all leads with beat classifications and isoelectric points
- Phase Editor for reviewing and adjusting global P-on, P-off, Q, S and end of T fiducial points

More details of these displays are discussed in *ECG Viewing Options*.

NOTE: The system will analyze the ECG for possible Left-Right arm reversal and provide a warning if it appears that the leads may have been reversed. Check the left and right arm electrodes to ensure correct lead placement. If the leads are reversed, discard the ECG, correct the leads and re-record the ECG. Lead reversal is determined by comparison of the QRS waveform in leads I and V5; the two waveforms should have approximately the same overall shape and polarity. If the two leads are nearly mirror images of each other, i.e., one is upside-down relative to the other, then it is likely that the arm leads are reversed.

The next 4 buttons  provide tools for:

- Discard (Trash) the ECG. If the record is of poor quality you may wish to discard the record and record again. This button will return you to the Patient Information screen where you can record another record.
- Save the ECG. This button will save the ECG and return you to the Patient Information screen, where you can either close out the session with the patient or record another ECG.
- Next Patient. This button saves the ECG, confirms that you wish to close the encounter with the current patient, and opens a fresh Patient Information window. If **"Print 12 Lead on ECG Save"** option has been set in Preferences (see **Processing Controls**) a 12 Lead will be printed.
- Print the current screen.

5 Automatic Diagnostic Assessments

 **Warning**	**Interpretation Hazard. A licensed physician must over read all ECG interpretations. Some ECG abnormalities cannot be detected by automated ECG analysis algorithms. Computerized interpretations are only significant when used in conjunction with clinical findings.**
 **Warning**	**Interpretation Hazard. See: *Contraindications*.**
 **Warning**	**Pacemaker. Although the system attempts to detect pacer pulses, and suppresses automatic interpretation when detected, many modern pacemaker pulses are below the detection threshold. Automatic interpretations derived from paced ECGs are NOT valid.**

Diagnostic assessments are automatically determined by the system and are divided into three categories:

1) Diagnostic findings known to be associated with elevated cardiac risk. The ECG status is "Unconfirmed Abnormal", listed as "Unconfirmed_A" in the Patient Selection window (See: *Opening an ECG*). The legend "`The ECG findings require further evaluation before participation in strenuous activities`" is added to the ECG. Note: This legend can be customized for your organization via the Preference settings.

2) Findings of potential interest in the overall health assessment. If none of the abnormalities known to be associated with elevated cardiac risk are detected (See: *Diagnostic Conditions Associated with Elevated Cardiac Risk*), then "`Unconfirmed Normal ECG`" is added to the ECG.

3) Pacemaker Detected. The system does not support ECG analysis for paced patients. Detection of pacer pulses suppresses the automatic interpretation and the legend "`Pacemaker Detected - Automatic Interpretation NOT Valid`" is added to the ECG.

5.1 Diagnostic Conditions Associated with Elevated Cardiac Risk

The diagnostic criteria for individuals with age ≤ 35 follow the recommendations from: "International Recommendations for Electrocardiographic Interpretation in Athletes", JACC 69:8, 2017.

5.1.1 Atrial Abnormalities

Atrial Flutter
Atrial Fibrillation
Low heart rate (< 30 BPM)

5.1.2 Depolarization Abnormalities

Profound Bradycardia (HR < 30 BPM)
Long QRS duration (> 140 msec)
Wide complex ectopy (two or more PVCs in 10 sec)
Polymorphic wide complex ectopy
Gross Congenital Axis Deviation
Left Bundle Branch Block (LBBB)
Wolf–Parkinson–White (WPW) pattern
Pathologic Q waves

- Likely Coronary Artery Disease – Consider MI (Age ≥ 35)
- Possible Hypertrophic Cardiomyopathy (HCM) (Age <35)

5.1.3 Repolarization Abnormalities

ST Depression (Consider MI Age ≥ 35)
ST Elevation (Consider MI Age ≥ 35)
Brugada (Type 1 only)
T-Wave inversions (age, lead, and ethnicity dependent)
Long QT Pattern

NOTE: Heart rate corrected QT (QTc) can be computed using the Bazett, Hodges or Fridericia formulas. See: *Preferences - Data Acquisition and Processing Defaults Tab*. Fridericia is the default setting.

Short QT Syndrome (QTc < 320 msec)

Detection of any of the above conditions will result in the following statement being added to the ECG record:

"The ECG findings require further evaluation before participation in strenuous activities"

5.2 Minor Diagnostic Findings that May be Associated with Elevated Cardiac Risk

Two or more of the following minor findings constitute a Diagnostic Condition associated with Elevated Cardiac Risk – See 5.1 above.

5.2.1 Atrial Abnormalities

Left (LAA) Atrial Abnormalities/Enlargement
Right (RAA) Atrial Abnormalities/Enlargement
Left (LAD) Axis Deviation
Right (RAD) Axis Deviation

5.2.2 Depolarization Abnormalities

Right Bundle Branch Block

5.3 Diagnostics of Potential Interest

5.3.1 Atrial Abnormalities

High heart rate (>95 BPM) – recommend re-test after resting
Coronary Sinus Rhythm
Anomalous PR interval (PR > 300 msec)
Erratic RR intervals, Premature Atrial Contractions (PAC), Atrial Pause
Wandering Pacemaker or Junctional Rhythm

5.3.2 Depolarization Abnormalities

Ectopic beats with QRS <120 msec
Incomplete Right Bundle Branch Block (icRBBB)
Asymmetry: S > R in X (V5) – RV Dilation Pattern
S upstroke duration in V2 > 55 msec and T-wave inversion in V2 – possible Arrhythmogenic Right Ventricular Dysplasia (ARVD)
Low QRS voltage
ST Elevation (Age < 35)
Narrow complex ectopy
Right Ventricular Hypertrophy (RVH)

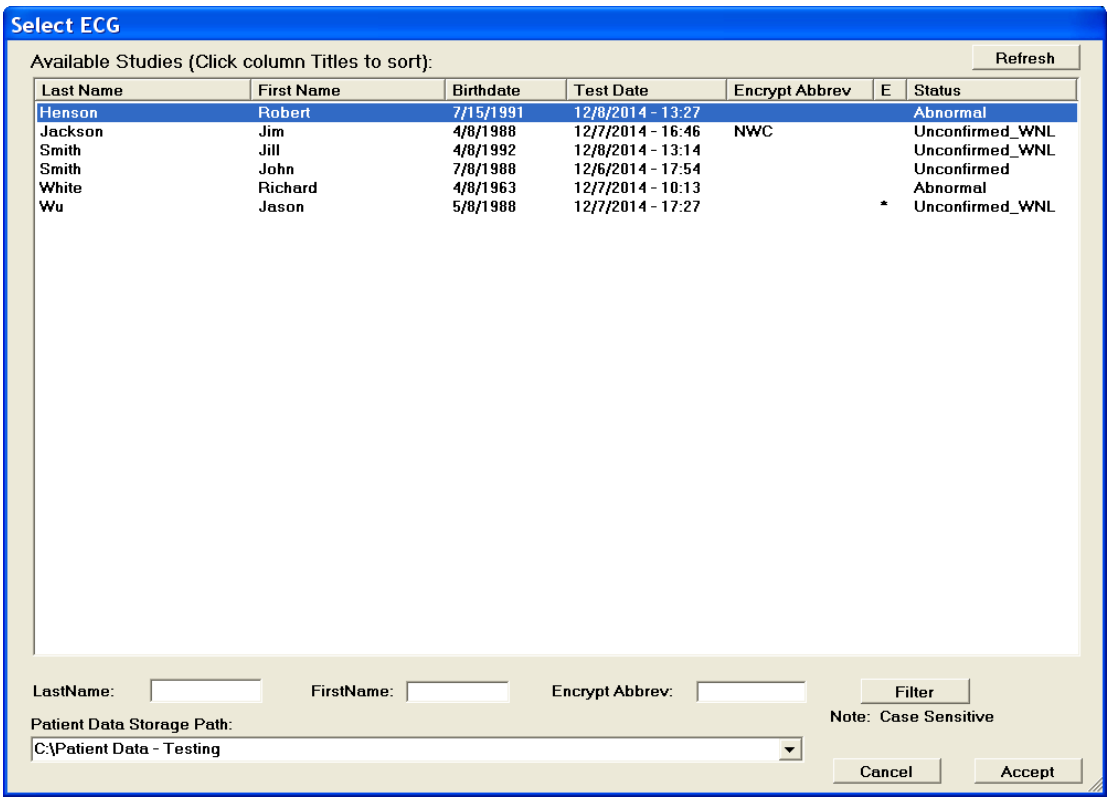
5.3.3 Repolarization Abnormalities

Abnormal ST Elevation (Age < 35)
Possible Long QT Syndrome
Positive T-wave in aVR

6 Reviewing and Over reading ECGs

6.1 Opening an ECG

Selecting **File/Open** will display the list of all Patient Folders in the system:



Click on the patient of interest and click the "**Accept**" button, or just double-click the selected patient to open.

The last column of the top text box highlights the current Status of the patient ECG assessment. When an ECG is recorded, the initial Status is always set to "Unconfirmed.**"** If there is some ECG finding that is Abnormal, the initial status will be set to "Unconfirmed_A." Records with no abnormal findings and that are also Within Normal Limits (WNL) are marked as "Unconfirmed_WNL" (See: *Section 9.4 Within Normal Limits*). As records are reviewed the patient status and Diagnosis can be modified by the authorized reviewer. See: *Dx Review*.

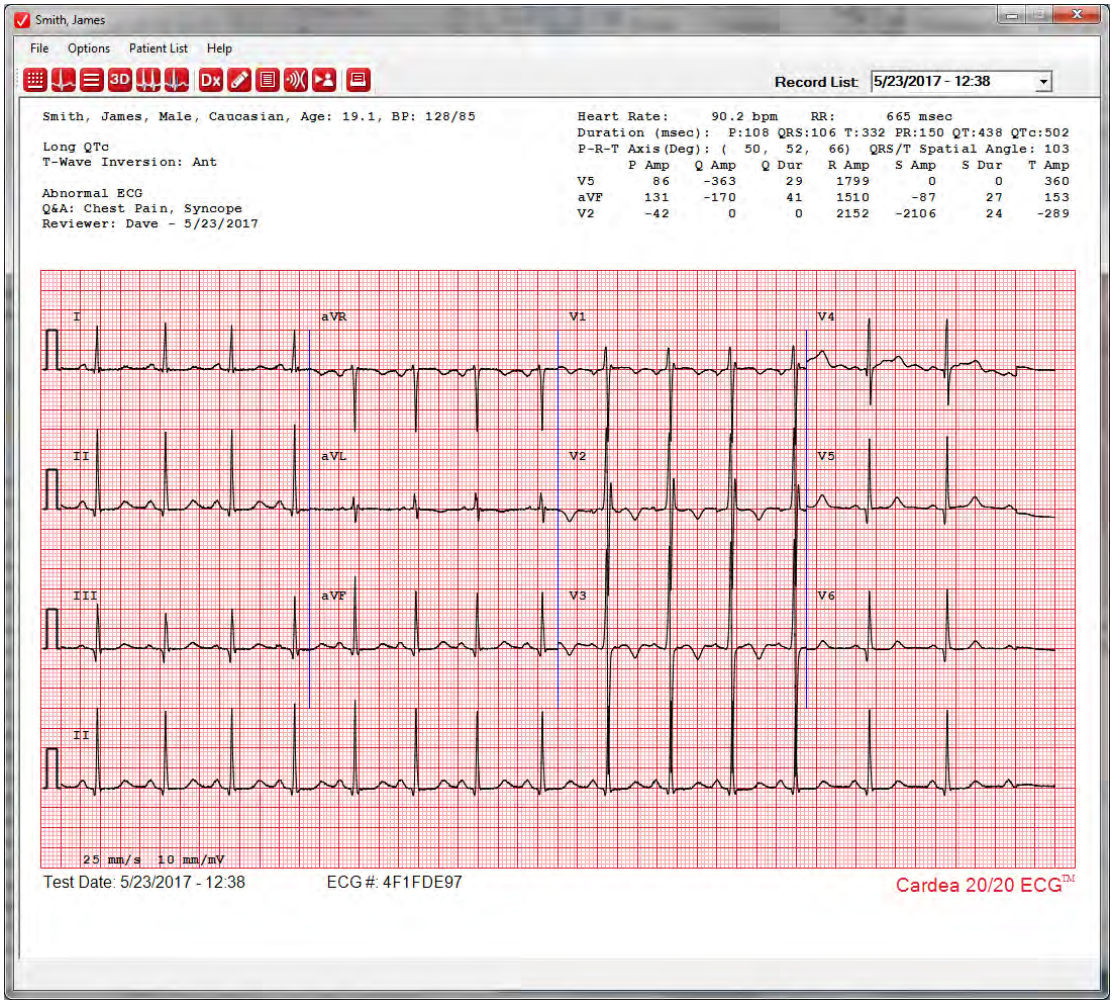
The **Encrypt Abbrev** column indicates the patient record was imported from the encryption account specified in Preferences. The **E** column indicates the patient record has been either encrypted for transmission or emailed via the CARDEA 20/20 ECG email capabilities.

Clicking on a column title will sort the table by that column. Clicking a second time will reverse the order of the sort.

The list of presented patients can be filtered using the filter options. Enter filter text into one or more of the boxes and click **"Filter"**.

If multiple Patient Data directories have been defined in Preferences, the Patient Data drop-down list can be used to quickly move between directories without having to return to Preferences.

The selected record will be displayed:



If there are multiple ECGs available for the patient, the drop-down Record List selection will be added to the top right of the display. Selecting a different record in the list will display the associated ECG.

Note: This ECG has been over read and interpreted as abnormal, noted in the upper left legend "Abnormal ECG." Beneath the ECG Abnormal status on

this record are the AHA questions marked as true on the Patient Information screen. In this case the patient reported chest pain, shortness of breath and previously had been restricted from participation in sports.

Warning	**Misdiagnosis. The CARDEA 20/20 ECG screen images are provided for reference only. On many PC systems the screen resolution is not sufficient for diagnostic quality displays. Use the printout capabilities to ensure accurate diagnostic review.**
Warning	**Misdiagnosis. Verify the patient name displayed in the upper left corner of the ECG is that of the intended patient.**

6.2 ECG Viewing Options

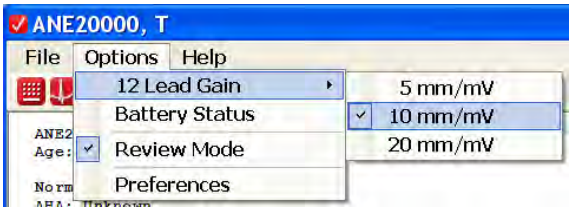
The ECG Viewing and Phase Editing buttons are:

and provide:

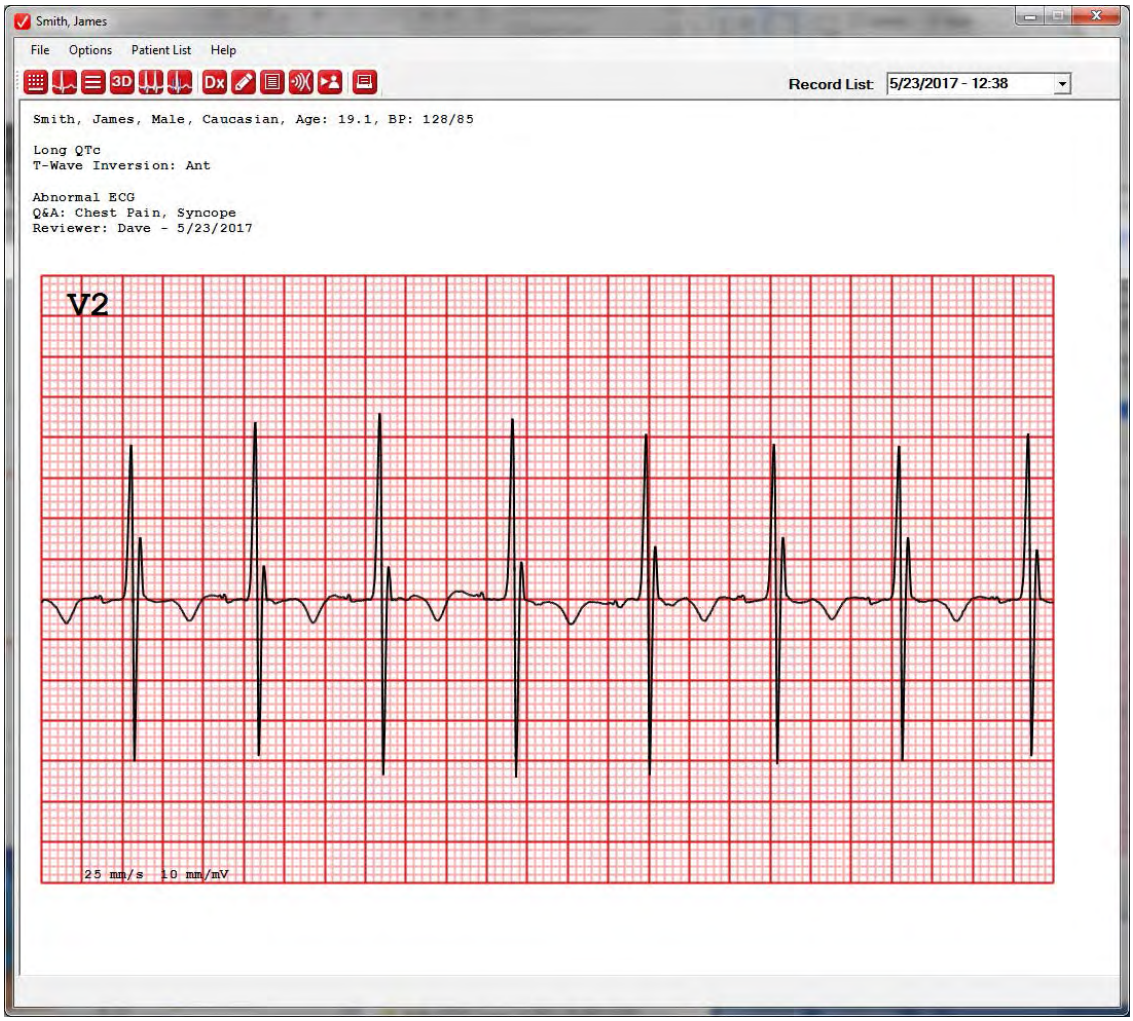
- 12-Lead display
- Median Beat display
- 16-second display of V5, aVF and V2 (X, Y, and Z – three traces)
- Vector plots (3-Dimensions)
- Raw 16 seconds for all leads with beat classifications and isoelectric points
- Phase Editor for reviewing and adjusting global P-on, P-off, Q, S and end of T fiducial points

6.2.1 12-Lead Display

The standard 12-Lead display is shown above. The display gain can be changed by clicking on the **12 Lead Gain** button in the **Options** menu:

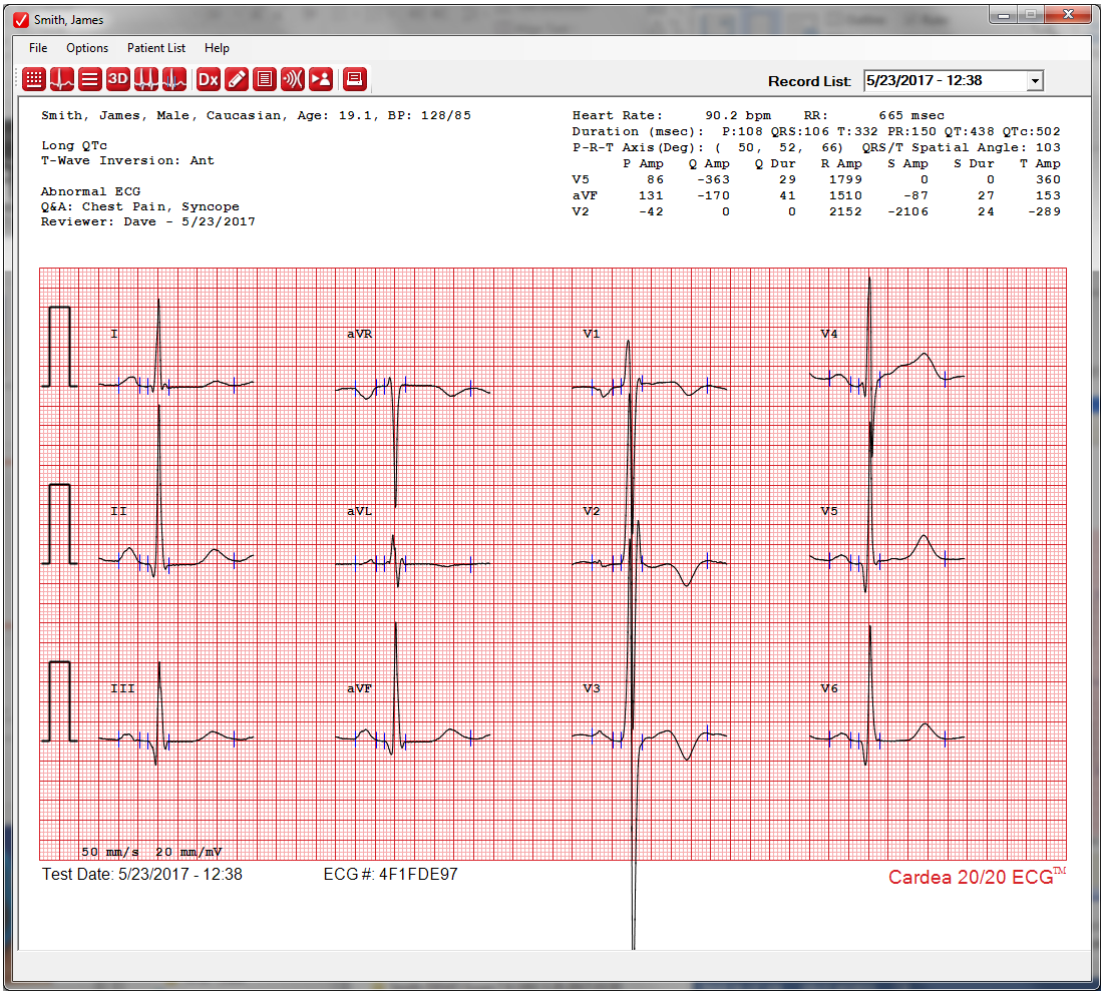


Zoom: Right-clicking a trace and selecting Zoom, or just double-clicking, will display 5 seconds of the selected trace.



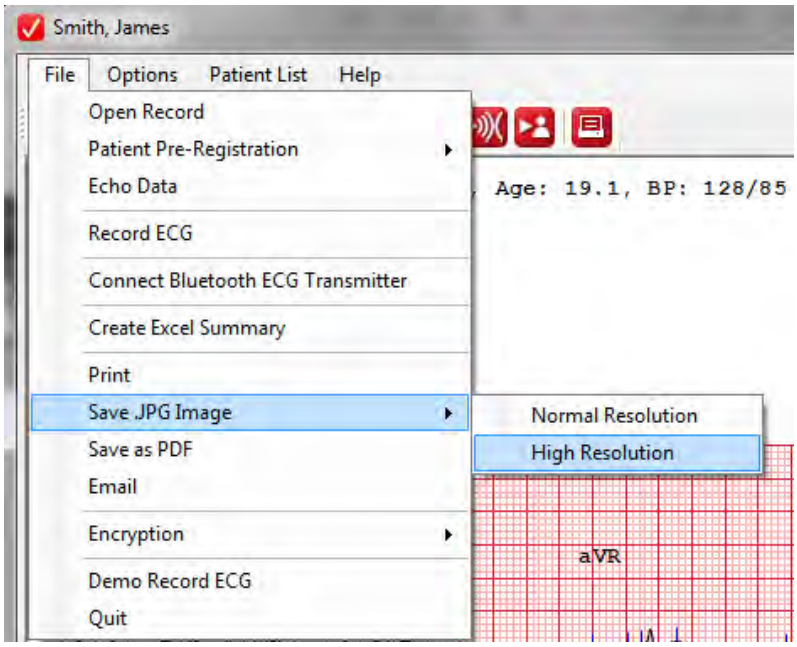
6.2.2 Median Beat Display

Display of the Median beats:



Right-clicking or double-clicking on a median average beat will zoom the display for high resolution viewing:

Screen images can be captured at any time using the Save options:



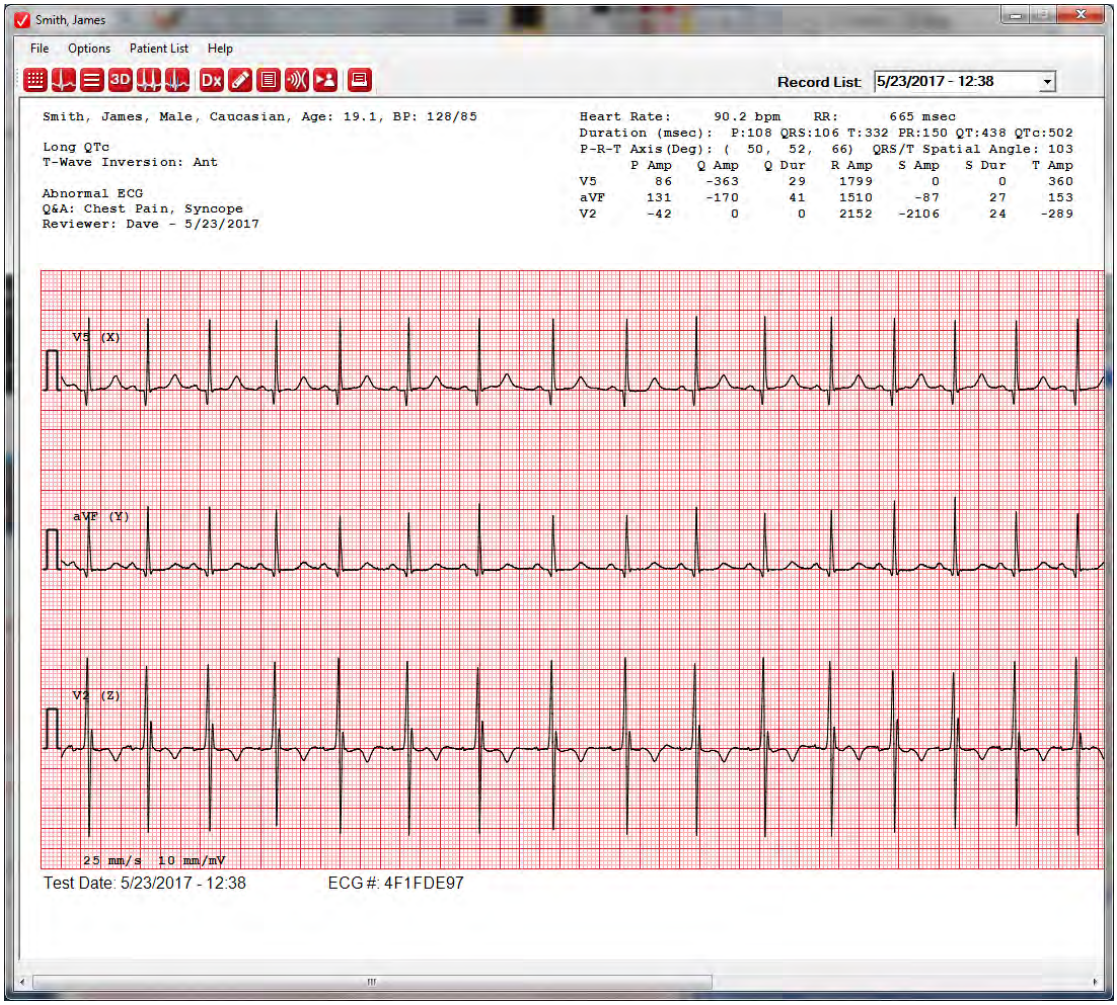
Normal Resolution: Saved at the screen display resolution.

High Resolution: Saved at Printer resolution (3x higher than full screen)

NOTE: The saved images are stored in the patient's folder.

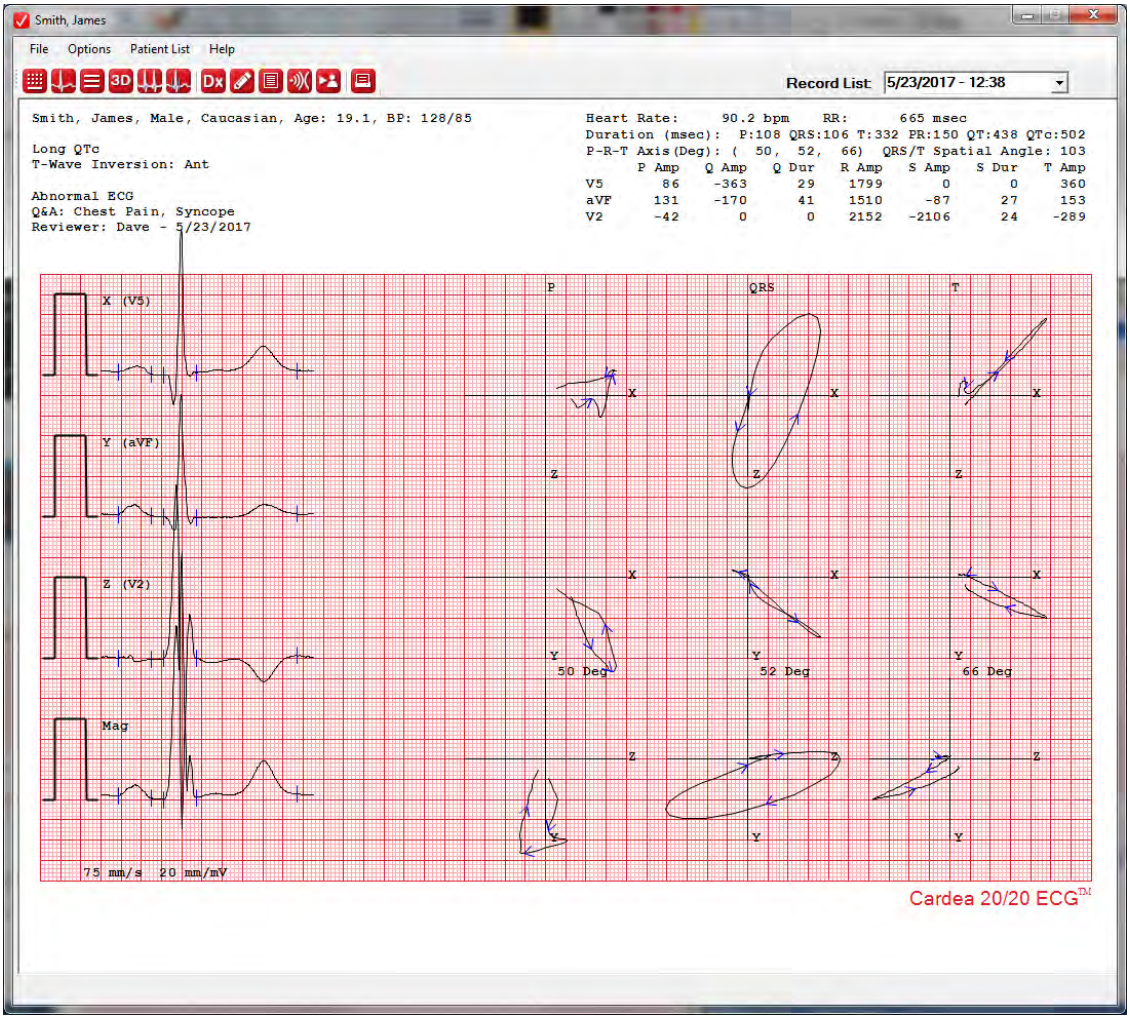
6.2.3 16 Second display

Displays the full 16 seconds of the recorded ECG for leads X (V5), Y (aVF) and Z (V2) leads. Use the scroll bar at the bottom of the window to move the screen display to review the entire record.



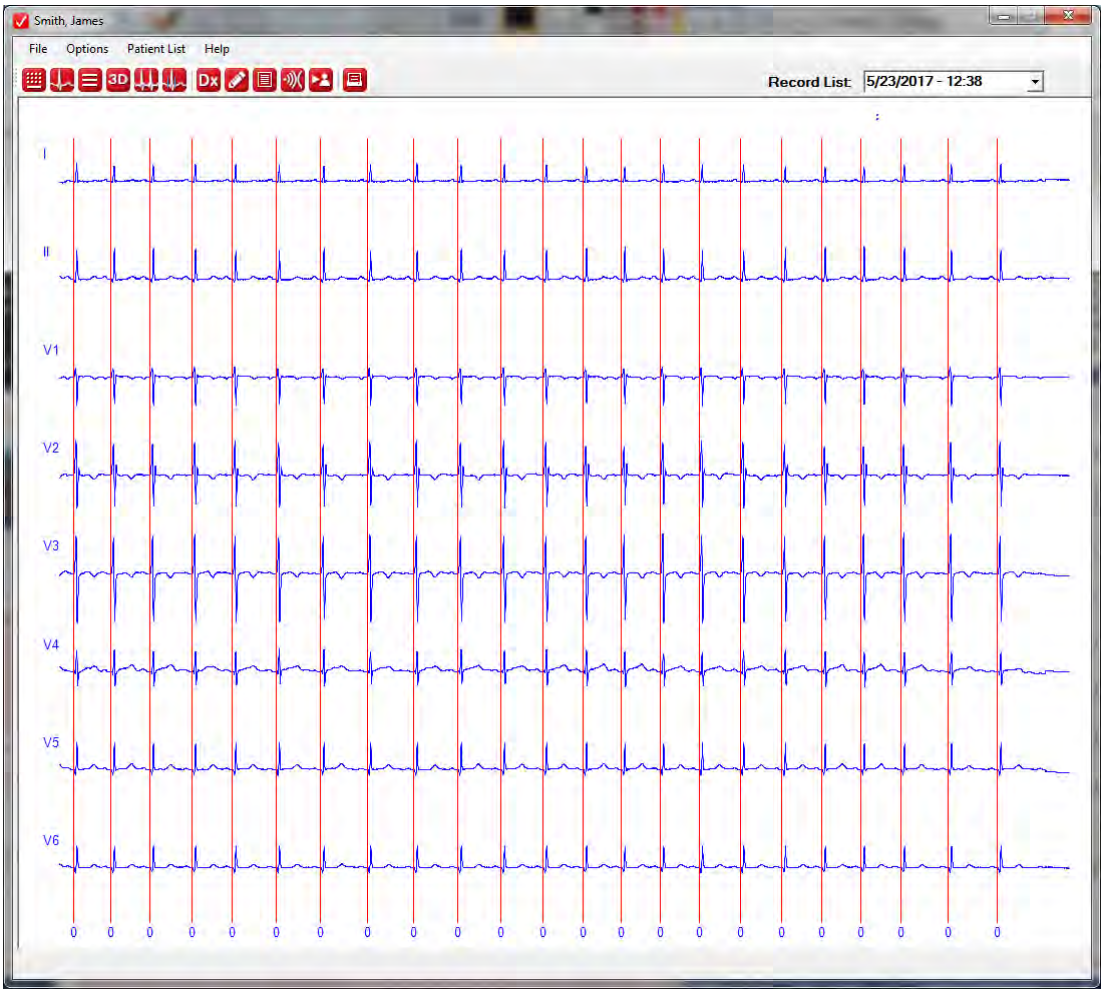
6.2.4 3-D Vector Plot

Displays a vector representation of the ECG data, including the X (V5), Y (aVF) and Z (V2) traces and the P, QRS and T spatial plots:



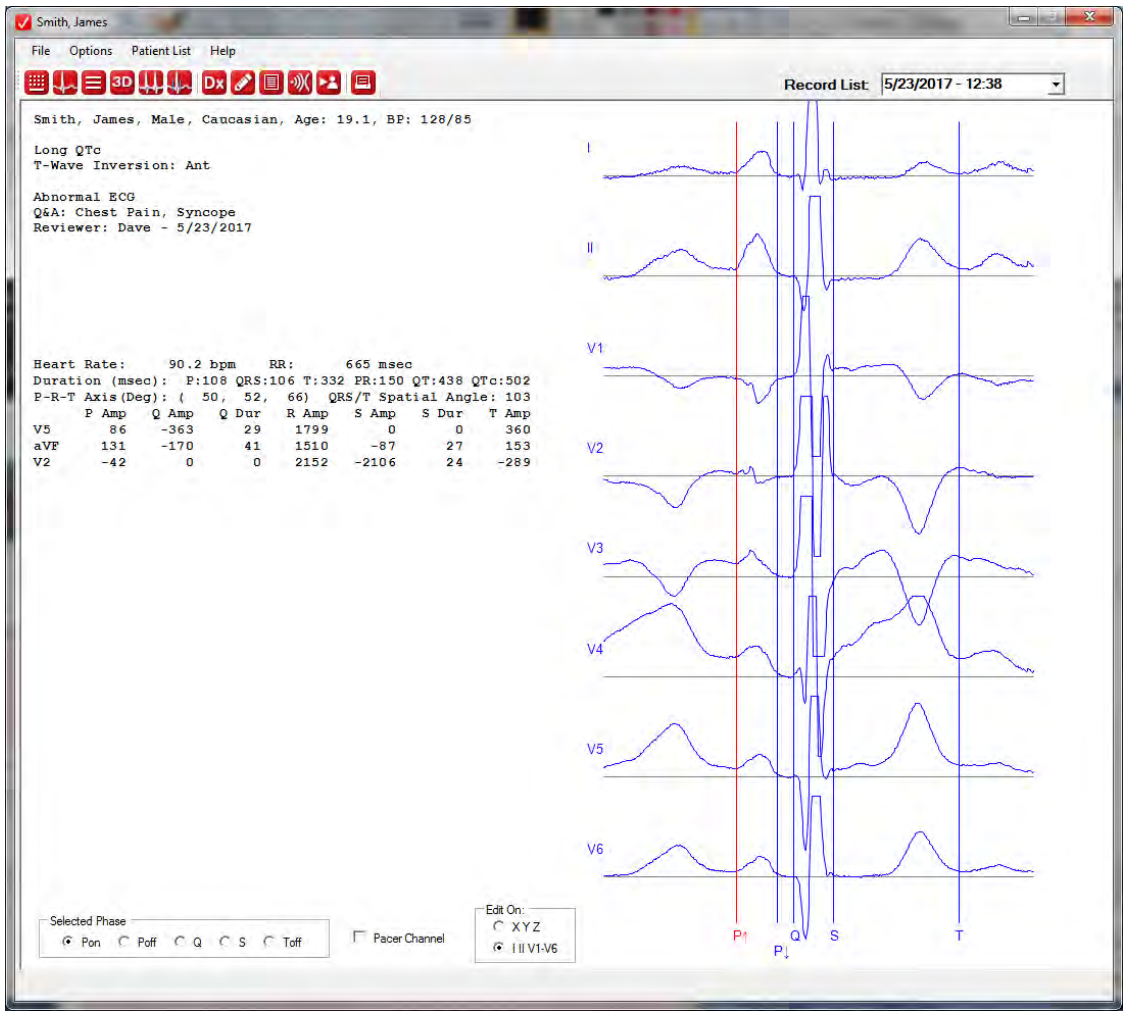
6.2.5 Raw

Displays the baseline corrected data for recorded leads. Each identified beat is marked with a vertical line. Beats with morphologies different from the dominant beat (e.g., Ectopic) will be marked with a different beat family identification number at the bottom of each vertical line. Segments of the ECG trace will be drawn in red if there is a data error, such as a lead-off condition or dropped data packet.



6.2.6 Phase Editing

The Phase Editor provides tools for viewing and adjusting the automatic global phase picks for P-on, P-off, Q onset, end of S and end of T. The isoelectric point is defined as the segment immediately before the onset of Q.



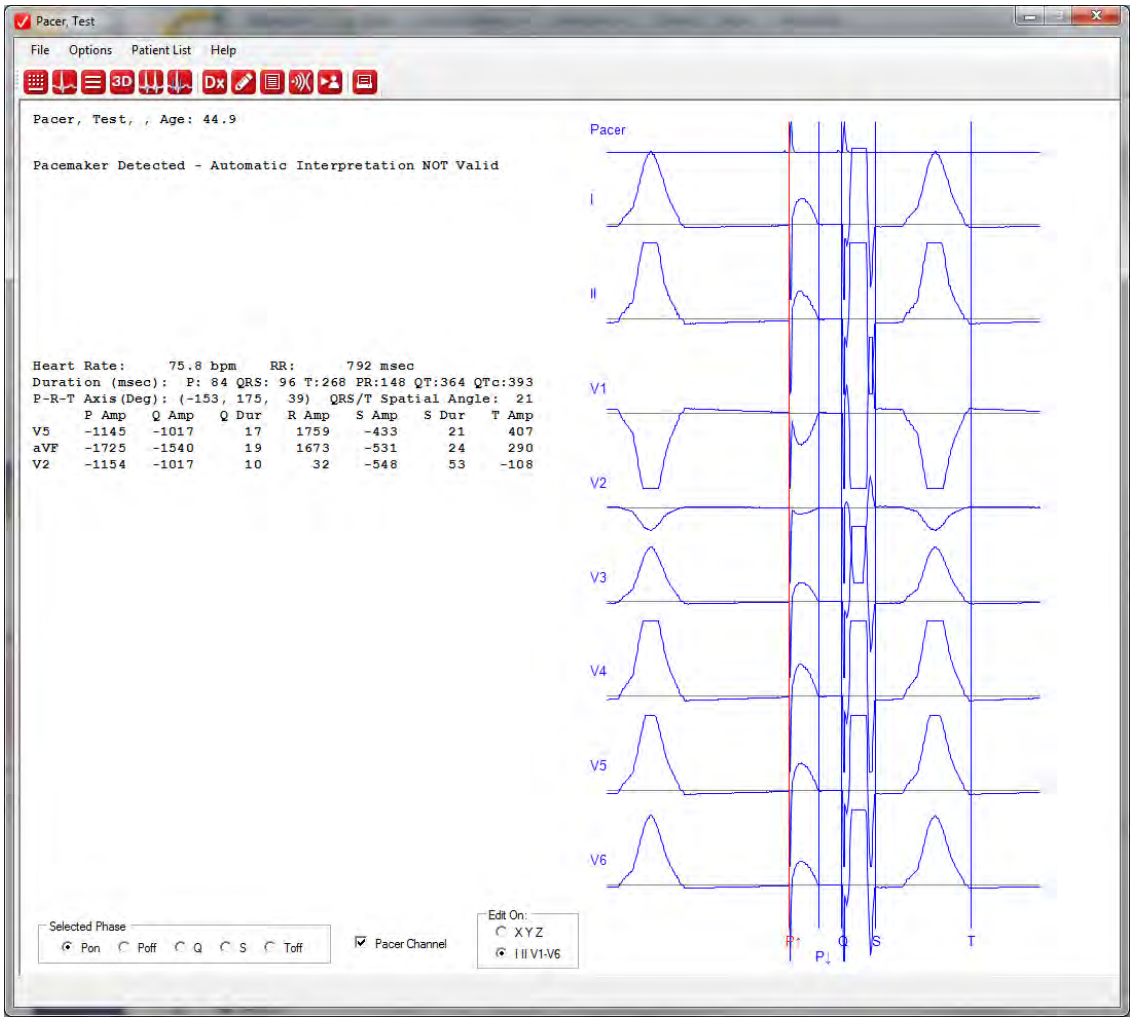
Any of the five phases can be selected for editing by clicking on the "**Selected Phase**" radio buttons, located at the bottom left of the screen. The phase selected for editing will be highlighted in red. Alternatively, a phase can be selected for editing by placing the cursor near the vertical phase line of interest and right-clicking. The radio button will automatically reset to the selected phase, and the line color will change to red. The system will select the nearest phase when right-clicking; it is not necessary to be precisely on the phase. Editing the phase is accomplished by simply clicking on a new time location; the cursor can be placed at any desired vertical location on any trace. Phases can be deleted (e.g., a false

pick on noise when no P is observed) by selecting the phase and clicking "**Delete Phase**." If the system missed picking a phase, such as P, the phase can be added by clicking on the appropriate "**Selected Phase**" radio button and then clicking on the desired location. All edits are saved with the raw data and used in all future displays and analyses.

NOTE: In general, editing a phase will change the diagnostic measurements and interpretation. With each edit the automatic interpretation of the ECG is updated and the status of the ECG is set to "Unconfirmed." If some abnormality is found in the record, the status will be set to "Unconfirmed_A."

6.2.7 Pacemaker Detection Channel

As a patient safety feature, CARDEA 20/20 ECG tests for the presence of a pacemaker. If pacing pulses are found near the onset of P or Q, the interpretation will be suppressed and the following message will be posted: "Pacemaker Detected – Automatic Interpretation NOT Valid." The Pacer Channel can be viewed, time-aligned with the beat waveforms, with the Phase Edit tool:

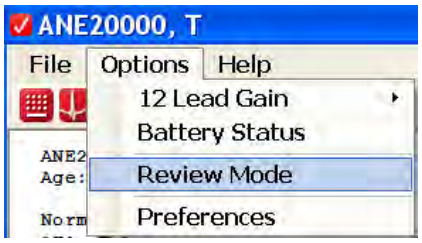


The Pacer channel is on the top; note the two paced pulses. The Pacer channel can be turned on/off using the "**Pacer Channel**" checkbox located at the bottom of the screen, below the "**Delete Phase**" button.

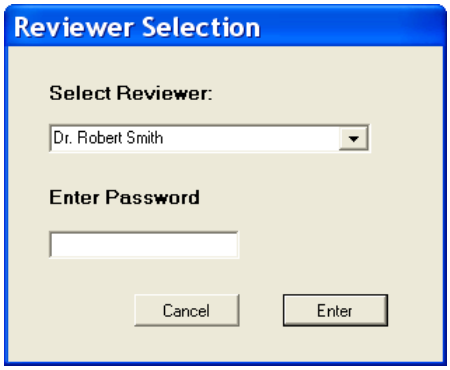
NOTE: If the pacer detection is erroneous, use the Diagnostic Review tool to override the automatic interpretation (See: *Dx Button*).

6.3 Reviewer Login

The over reading, confirmation and review of diagnostic chronology information are controlled and accessible for Reviewers registered in the Preferences (See: *Preferences – Security*). Access for an individual is granted via the Review Mode option:



Reviewers are presented with a login window. If passwords have been set in Preferences the reviewer must enter his/her password:



When an Authorized Reviewer has logged-in, the menu option "**Options/Review Mode**" will show a highlighted checkmark. Clicking a second time on "**Options/Review Mode**" will close Reviewer access.

NOTE: If no Authorized Reviewers have been entered via Preferences the Review Mode menu option will be grayed-out and not available.

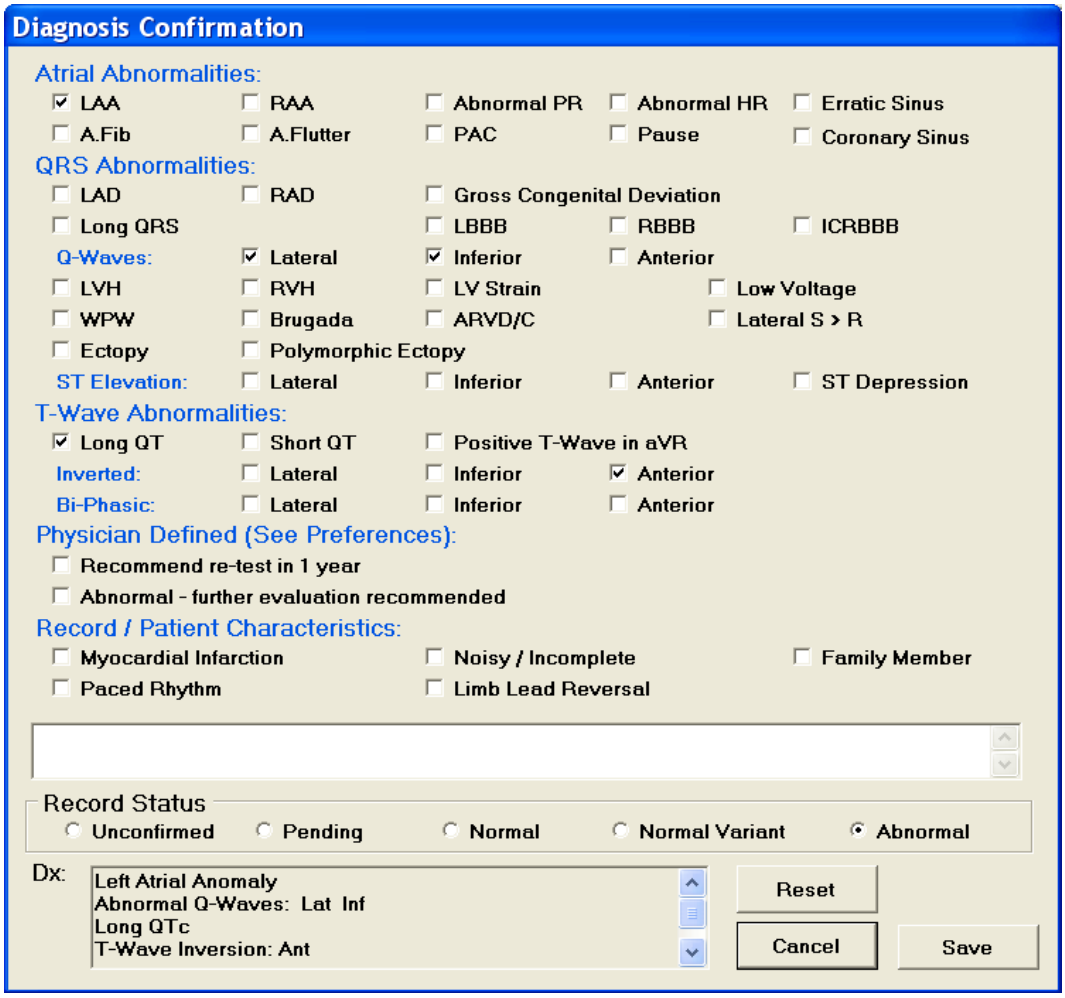
NOTE: Reviewers are urged not to leave a PC enabled for over reading.

6.4 Diagnostic Review

If an Authorized Reviewer has signed in (See: *Preferences – Security)* the ECG display window will include five additional buttons on the task bar:

6.4.1 Dx Button

The Dx button supports the editing of the interpretation. The Dx window is presented:



Clicking any checkbox will add/remove the associated diagnosis. The Diagnostic legend that will be displayed on the ECG is shown in the bottom box labeled Dx:.

The "**Reset**" button will restore the automatically determined interpretation.

Additional ECG notes can be entered into the text box immediately above the Record Status radio buttons. Notes are automatically added to the Diagnostic Chronology file.

Record Status. The ECG can be characterized by five different status indicators:

- Unconfirmed: The automatically interpreted record awaiting over reading
- Pending: Some patients will have a follow-up test before a decision is rendered on the normality of the ECG. The Pending status is commonly used to ensure patients with pending follow-up are not overlooked.
- Normal: Reviewer determined the record is normal.
- Normal Variant: Reviewer determined the record is a normal variant.
- Abnormal. Some significant diagnosis has been found.

For records with status set to Normal, Normal Variant or Abnormal, the "**Save**" button will save the updated diagnosis to the Patient Folder and add the diagnostic information, notes and ECG status to the Diagnostic Chronology file.

NOTE: Records with status set to Unconfirmed or Pending will always reflect the interpretation determined by the CARDEA 20/20 ECG automatic interpretation algorithms. Changes to the ECG interpretation during the over reading that are not associated with a change in status to Normal, Normal Variant, or Abnormal are discarded.

NOTE: Images of confirmed records, 12-Lead and/or Median Beat records and .pdf and/or .jpg, can be saved into a Confirmed Records folder (See Preferences: *Data Acquisition and Processing Defaults Tab*). This provides a simple mechanism for collecting all of the reviewed records for uploading into an Electronic Medical Record system.

Quick Confirm: A record that is over read as Normal can be confirmed to Normal by clicking the F5 key. This automates opening the Dx window, clicking Normal, and clicking Save.

Paced Rhythm. As a patient safety feature, CARDEA 20/20 ECG tests for the presence of a pacemaker. If a pacemaker pulse is detected in the vicinity of the P or Q onset, the "**Paced Rhythm**" checkbox will be checked and any other automatically determined interpretations will be suppressed. If the record status is Unconfirmed, clicking Off the "**Paced Rhythm**" checkbox will reveal the determined interpretations. To view the Pacer channel, See: *Phase Editing.*

NOTE: Not all pacemakers will be detected. Pacemakers with small pacing signals on Lead II, or infrequent demand pacing pulses, may be missed.

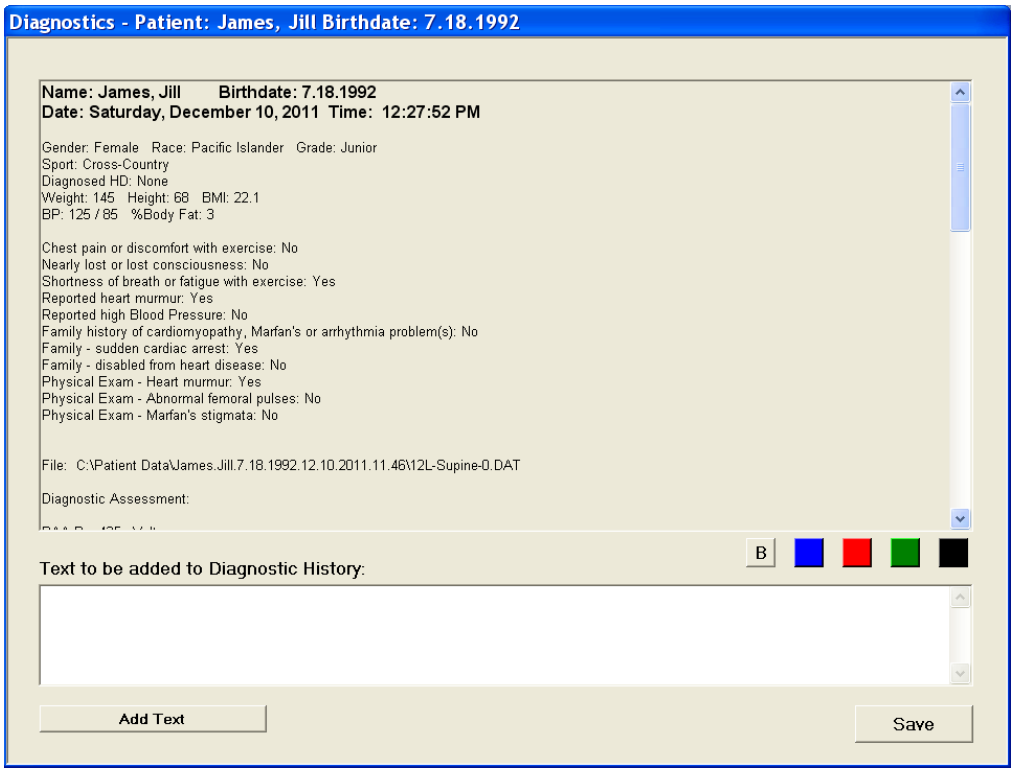
Diagnostic Comments. Statements entered into the text box above the **Record Status** radio buttons will be added to the confirmed ECG.

6.4.2 Edit Patient Information Data

Authorized Reviewers may edit all of the initial patient information entered on the PPI screen. This can be quite helpful for entering late arriving patient information and for correcting data entry errors. Clicking the Edit Demographic button will display the PPE screen. Clicking the **"Save"** button will update the patient information. Changes to the patient name or birth date will result in the creation of a new patient folder; the now obsolete patient folder is moved to an "Obsolete" directory within the Patient Data directory and retains the original patient data. All edits to patient information return the ECG to an "Unconfirmed" state. Edits should be finalized before over reading.

6.4.3 Diagnostic Chronology

 The Diagnostics button will recall the chronology file for the patient encounter and display the following:



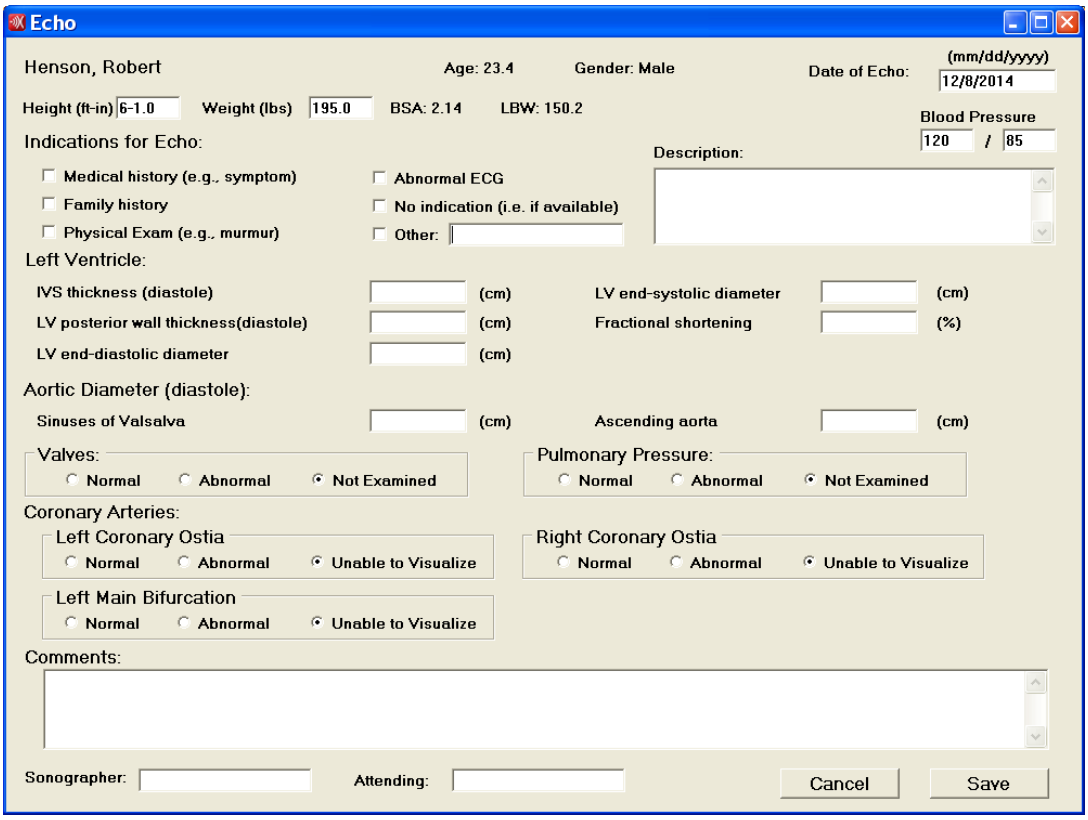
The text in the upper box is a chronological listing of all ECG information that has been gathered for this patient. It includes the date the initial ECG was recorded. All information collected via the Patient Information screen is logged, along with the final Phase Measurement Block, automatically derived Diagnostics and user comments and Windows file pathname to the associated raw ECG data. The date, name of the reviewing physician and updated diagnostic information is also appended to this file. The reviewer can add text to the log by entering the text into the lower text box and selecting "**Add Text**."

Information in the upper box cannot be edited or changed; it represents a chronological history of the patient. However, text can be highlighted (drag cursor over the text of interest with the left mouse button depressed), then Copied (depress keyboard keys Ctrl + C) and Pasted (Ctrl + V) into the lower text box, edited as desired and added to the chronology. Text in the upper box can also be color coded and highlighted with **BOLD** by highlighting the text of interest and clicking on the appropriate color or "**B**" button.

The Diagnostics file is stored in the Patient Folder as a Rich Text Formatted file (.rtf) that also can be viewed using standard tools such as Microsoft Word.

6.4.4 Capturing Echo Measurements

In many environments patients with abnormalities often receive an echo exam. Some of these key measurements can be captured and saved with the patient ECG data. Echo information also can be entered by selecting "**File/Echo Data**." Reviewer log-in is not required. The user will be prompted to select a patient and the following form will be displayed:



The recorded information is saved with the other Patient Information in the Patient Folder and logged into the Diagnostic Chronology file. Selecting Echo Data again will retrieve the data and display the above screen.

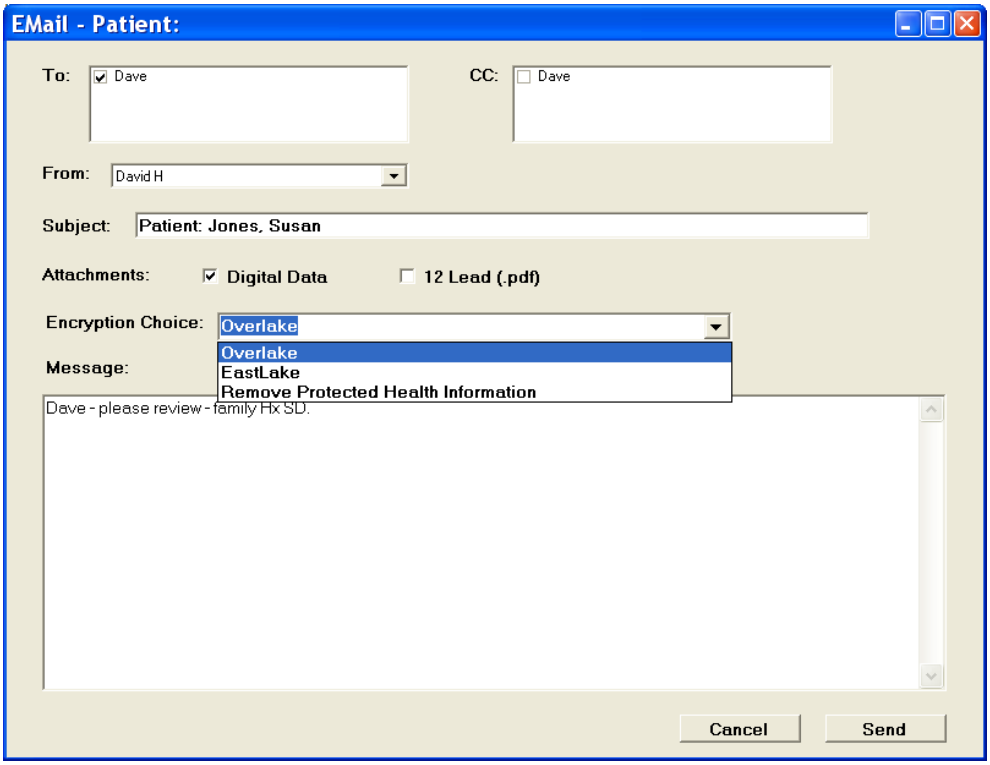
6.4.5 Automating Patient Review

This functionality supports rapid recall of patients who are pending over reading review. Each time the Reviewer clicks this button the system will scan all of the patients and automatically present the next patient who still has an Unconfirmed status.

For patients with multiple ECGs, the Automatic Review Button will show how many additional records are pending for review (beyond the record currently being displayed):  The F6 key will back-up to the previously confirmed ECG. Successive F6 clicks will back-up to previously confirmed ECGs in the reverse order of confirmation. Clicking the F7 key will skip-over the presented ECG and advance to the next unconfirmed record.

6.5 Email

Patient ECG information can be shared via email, enabling easy collaboration with consultants or other medical staff. Email is restricted to accounts established in the Preferences setting; email can ONLY be sent to or from accounts registered in Preferences – See: *Preferences*. When an ECG is displayed, the email functionality is enabled. Selecting "**File/Email**" displays:



Encryption Choice (drop-down menu above): The Health Insurance Portability and Accountability Act (HIPAA) regulations do not allow Protected Health Information (PHI) to be sent over the open Internet. CARDEA 20/20 ECG has been designed to minimize the risk that users might accidentally violate these regulations. Two methods are available for sending ECG data over the open Internet:

A. Remove Protected Health Information. A unique patient encounter 8-character HEX string is created when the first ECG is collected for the patient encounter. The 12-Lead and Median Beat ECG displays include this identifier

below the ECG grid, e.g., "ECG#: 0503E43A." In creating the attachments for the email, all PHI is removed from the digital data and the 12-Lead PDF display. These data may be sent over the open Internet without concern for violating HIPAA regulations.

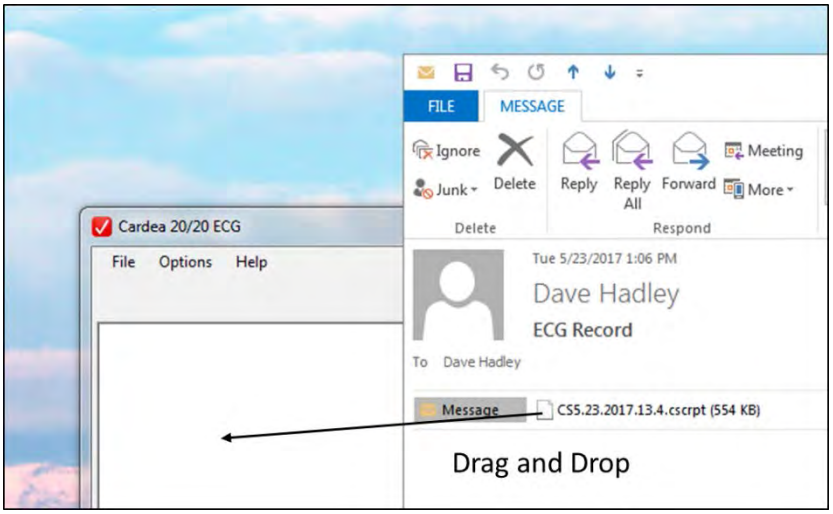
Reminder: The "Directory Database" function (See: *Database Reporting*) builds an Excel file linking patient identifiers, ECG information and the unique HEX code – should you forget which patient record was emailed.

B. Encrypt using one of the Preference Encryption Accounts. See Preferences Security Tab, Encryption / Decryption, and *HIPAA Encryption / Decryption – Secure Transmission of Patient Data* below.

NOTE: The recipient of the email MUST have the same Encryption Account definition as the sender.

The Digital Data and 12 Lead (.pdf) checkboxes all you to select what will be sent as an attachment.

The individual(s) receiving the CARDEA 20/20 ECG email, using Microsoft Outlook, can easily access the data in the file by dragging the file from the email and dropping it on the open CARDEA 20/20 ECG application:

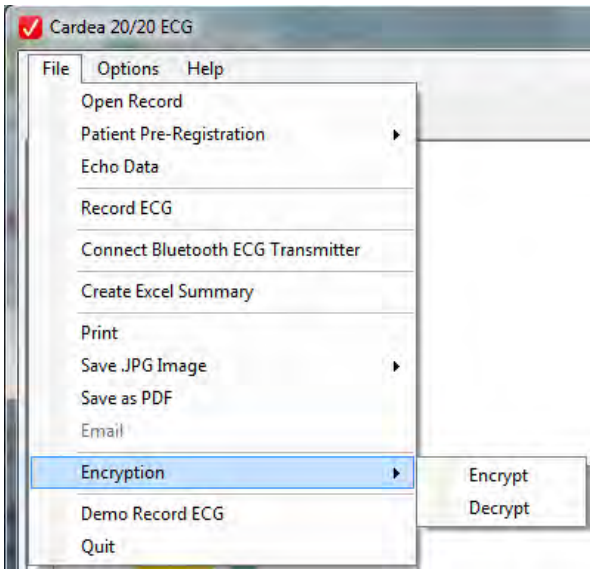


CARDEA 20/20 ECG will move the patient folder to the active patient directory and automatically open the ECG for review. If multiple ECGs have been included in the zip file, all will be moved and the first one will be opened. For non-Microsoft email users, first copy the attachment to a folder or desktop and then drag and drop it on the open CARDEA 20/20 ECG application.

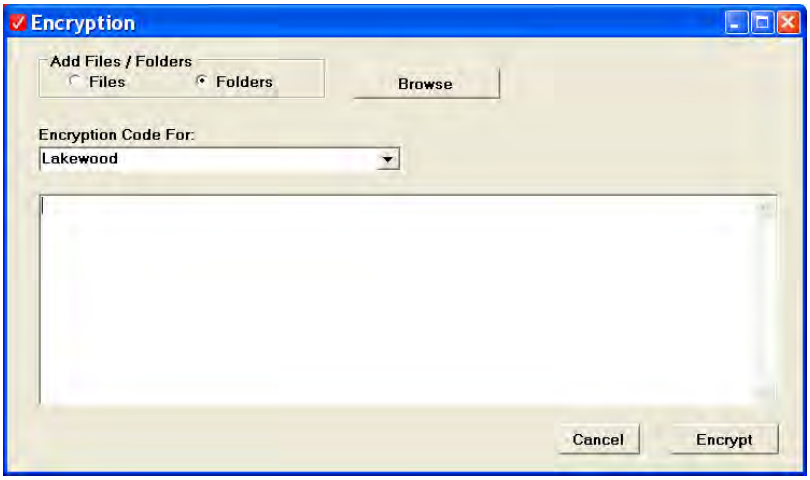
6.6 HIPAA Encryption / Decryption – Secure Transmission of Patient Data

Transmission of Protected Health Information (PHI) over the open Internet is permissible under HIPAA provided the encryption method is suitably secure, such as the 256 bit Advanced Encryption Standard (AES) methodology used in CARDEA 20/20 ECG. Before using these encryption tools for data transmission the encryption keys must first be defined – See Preferences:

Security Tab. Next, select Encrypt to create an encrypted zip file of patient folders and files (e.g. Confirmed PDFs of the ECGs), or Decrypt to access the encrypted information:



Encrypt: Selecting the Encrypt option will display:

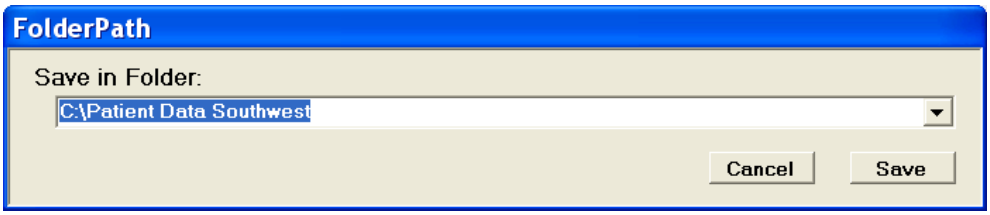


Click "**Browse"** to select Folders (i.e. Patient folders) or individual Files. Holding down the Control or Shift key allows selection of multiple files or

folders. Each cycle through Browse adds files or folders to the text window. Select the Encryption Code for the desired Sender / Receiver relationship. When all of the files and folders of interest have been selected then click **"Encrypt"** and save the encrypted file. CARDEA 20/20 ECG also places the encrypted file onto the Windows Clipboard, so that you can immediately Paste the file into an email for transmission.

NOTE: Many email systems limit the maximum size of the email to about 10 Mbytes, which is approximately 25 patient folders (single ECG per patient and without any PDFs) or 25 ECG PDF files.

Decrypt: The Decrypt function opens a file browser window, supporting navigation and selection of the desired encrypted file. Alternatively, the encrypted file may be dragged and dropped onto the open CARDEA 20/20 ECG main Window. CARDEA 20/20 ECG will display a confirmation window to ensure the data is added to the correct Patient Data directory:



Clicking **"Save"** will decrypt the file, add the data to the designated Directory. If the encrypted file contained patient folders the first patient ECG in the file will be displayed. Individual files (e.g. PDFs of ECGs) are stored in the folder "Files" within the selected Patient Data directory.

Decrypted patient folders are annotated with the Sender / Receiver relationship Abbreviation – See Preferences:

Security Tab, which can be used to filter the list of patients when opening a patient's ECG.

7 Database Reporting

A summary report for all patients in the Patient Data Storage Directory (See: Preferences: *Data Acquisition and Processing Defaults Tab*) can be generated by selecting "**File/Create Excel Summary**". The system will reprocess every record and create a Microsoft Excel file listing all recorded Patient Information, the automatic interpretation and the over read / confirmed interpretations and echo data (if available). The resulting summary information is stored in the Patient Data Storage Directory: "Patient Info.xls."

NOTE: If Microsoft Excel is not installed on the PC, CARDEA 20/20 ECG will create a file "Patient Info.csv" where all values are separated using the character "|". This file can be opened on a PC with Excel and converted to a standard spreadsheet by selecting the first column and using the "Data/Text to Columns…" function.

Column	Meaning:
Patient Information Screen	
LastName	Patient Last Name
FirstName	Patient First Name
MI	Patient Middle Initial
Gender	Male/Female or NA/Other
Race	Asian, etc
Birthdate	MM/DD/YY (honors system settings)
TestDate	MM/DD/YY (honors system settings)
Age	In years
Patient	Patient or Family Member
SSNumber	Social Security Number
MSN	Medical Record Number
PHex	Patient Unique Hex Code
PWeight(kg)	Patient Weight (kg)
PHeight(cm)	Patient Height (cm)
BMI	Body Mass Index
Systolic	BP - Systolic
Diastolic	BP - Diastolic
PercentFat	Percent body fat
Grade	Grade in school
Sport	Primary sport played
PrevHD	Previously diagnosed heart disease
ExPain	Chest pain with Exercise (1=Y, 0=N,-1=Unknown)
Sync	Syncope (1=Y, 0=N,-1=Unknown)
SOB	Shortness of breath (1=Y, 0=N,-1=Unknown)
Murmur	Murmur (1=Y, 0=N,-1=Unknown)
HiBP	High blood pressure (1=Y, 0=N,-1=Unknown)
FamHist	Family history of Heart disease (1=Y, 0=N,-1=Unknown)
SCD	Family sudden death (1=Y, 0=N,-1=Unknown)
FamDisabled	Family member disabled from HD (1=Y, 0=N,-1=Unknown)
PEMurmur	Physical Exam - Murmur (1=Y, 0=N,-1=Not Performed)
PEAbnFemoral	Physical Exam - Abnormal Femoral (1=Y, 0=N,-1=Unknown)
PEMarfanSt	Physical Exam - Marfan (1=Y, 0=N,-1=Unknown)

Column	Meaning:
FamSim	Family member with similar HD (1=Y, 0=N,-1=Unknown)
NSVT	Non-sustained VT on Holter (1=Y, 0=N,-1=Unknown)
AbBP	Abnormal BP with Exercise (1=Y, 0=N,-1=Unknown)
LVAn	LV anatomy abnormalities (1=Y, 0=N,-1=Unknown)
PSeptal	Post septal ablation (1=Y, 0=N,-1=Unknown)
ICD	ICD present (1=Y, 0=N,-1=Unknown)
Notes	Notes
Automatic ECG Analysis - Measurements	
Data_Path	Path to ECG data file
Raw_Status	Unconfirmed ECG Status (Unconfirmed or Unconfirmed_A)
PAmpX1	V5 - P Amp of first deflection
PDurX1	V5 - P duration of first deflection
PAmpX2	V5 - P Amp of second deflection
PDurX2	V5 - P duration of second deflection
PAmpY1	aVF - P Amp of first deflection
PDurY1	aVF - P duration of first deflection
PAmpY2	aVF - P Amp of second deflection
PDurY2	aVF - P duration of second deflection
PAmpZ1	V2 - P Amp of first deflection
PDurZ1	V2 - P duration of first deflection
PAmpZ2	V2 - P Amp of second deflection
PDurZ2	V2 - P duration of second deflection
PAmpVM	P Vector magnitude peak amplitude
PDurVM	P Vector Magnitude duration
QAmpX	V5 - Q wave amplitude
QDurX	V5 - Q-Wave duration
QAreaX	V5 - Q-Wave area
RAmpX	V5 - R-Wave amplitude
RDurX	V5 - R-Wave duration
RAreaX	V5 - R-Wave area
SAmpX	V5 - S-Wave amplitude
SDurX	V5 - S-Wave duration
SAreaX	V5 - S-Wave area
DefX+	V5 - QRS Maximum amplitude
DefX-	V5 - QRS Minimum amplitude
QAmpY	aVF - Q wave amplitude
QDurY	aVF - Q-Wave duration
QAreaY	aVF - Q-Wave area
RAmpY	aVF - R-Wave amplitude
RDurY	aVF - R-Wave duration
RAreaY	aVF - R-Wave area
SAmpY	aVF - S-Wave amplitude
SDurY	aVF - S-Wave duration
SAreaY	aVF - S-Wave area
DefY+	aVF - QRS Maximum amplitude
DefY-	aVF - QRS Minimum amplitude
QAmpZ	V2 - Q wave amplitude
QDurZ	V2 - Q-Wave duration
QAreaZ	V2 - Q-Wave area

Column	Meaning:
RAmpZ	V2 - R-Wave amplitude
RDurZ	V2 - R-Wave duration
RAreaZ	V2 - R-Wave area
SAmpZ	V2 - S-Wave amplitude
SDurZ	V2 - S-Wave duration
SAreaZ	V2 - S-Wave area
DefZ+	V2 - QRS Maximum amplitude
DefZ-	V2 - QRS Minimum amplitude
RVMag	R wave Vector Magnitude
Standing	True if standing
Automatic ECG Interpretation	
HR	Heart Rate
RAA	Right Atrial Anomaly - True/False
LAADef	V1 P-wave maximum deflection of last deflection
LAADur	V1 P-Wave Duration of last deflection
LArea	V1 - P-Wave area of last deflection
LAA	Left Atrial Anomaly - True/False
CorSinus	Coronary Sinus Rhythm
Erratic	Erratic Heart Rate - True/False
PAC	Premature Atrial Contraction - True/False
Pause	Atrial Pause - True/False
AFlut	Atrial Flutter - True/False
AFib	Atrial Fibrillation - True/False
QRSD	QRS Duration
LongQRS	Long QRS - True/False
N-Ectopy	Aberant conduction beat(s) with short QRS duration - True/False
Ectopy	Mono-morphic ectopic beat(s) present with long QRS duration - True/False
PolyEct	Polymorphic ectopic beats present with long QRS duration - True/False
PRAnom	Anomalous PR interval - True/False
AxisP	Axis of the P-Wave
AxisR	Axis of the QRS
AxisT	Axis of the T-wave
SpQRST	3-D Spacial angle between QRS and T
LAD	Left Axis Deviation - True/False
GConD	Gross Congenital Axis Deviation - True/False
RAD	Right Axis Deviation - True/False
LBBB	Left Bundle Branch Block - True/False
RBBB	Right Bundle Branch Block - True/False
ICRBBB	Incomplete Right Bundle Branch Block - True/False
SpatialQRST	Abnormal SpQRST - True/False
WPW	WPW - True/False
DiagQX	V5 - Diagnostic Q-wave - True/False
DiagQY	aVf - Diagnostic Q-wave - True/False
DiagQZ	V2 - Diagnostic Q-wave - True/False
ARVDur	Arrhythmogenic Right Ventricular Dysplasia - V2 S Duration
ARVD	ARVD - True/False
RVH	Right Ventricular Hypertrophy - True/False
LVH	Left Ventricular Hypertrophy (not used)

Column	Meaning:
LowV	Low QRS voltage - True/False
STZAmp	ST Amplitude in V2 at j-point
Brugada	Brugada Type 1 - True/False
STIX	ST Integral in V5
STDep	ST Depression - True/False
STX	ST in V5 (10 msec average starting at the j-point)
STY	ST in aVF (10 msec average starting at the j-point)
STZ	ST in V2 (10 msec average starting at the j-point)
STE	ST Elevation – True/False
QT	QT duration
QTc	QT - Corrected Duration (Bazett)
LQTS	Long QT Syndrome - True/False
SQTS	Short QT Syndrome – True/False
TX	V5 - Peak T-Wave Amplitude
TY	aVF - Peak T-Wave Amplitude
TZ	V2 - Peak T-Wave Amplitude
TM	Peak T-Wave Vector Amplitude
XTInv	V5 - Inverted T-Wave - True/False
YTInv	aVF - Inverted T-Wave - True/False
ZTInv	V2 - Inverted T-Wave - True/False
TaVRM	aVR T-Wave Amplitude
TaVR	Positive T-Wave in aVR - True/False
RLRev	Probable Left Arm - Right Arm reversal- True/False
Rx<Sx	V5 - R-Wave < S-Wave - True/False
MI	Consider MI – True/False
RecCon	Recommend consult - True/False
Global Phase Measurements	
Pon	Onset of P-Wave
Poff	Offset of P-Wave
Q	Onset of Q-Wave
S	Offset of the S-Wave
T	Offset of T-Wave
OverReading Status	
Comment	Overreading comment
Conf_Status	Status - "Normal," etc.
HR	Abnormal Heart Rate - True/False
LAA	Left Atrial Anomaly - True/False
RAA	Right Atrial Anomaly - True/False
CorSinus	Coronary Sinus Rhythm
AFib	Atrial Fibrillation - True/False
AFlut	Atrial Flutter - True/False
PAC	Premature Atrial Contraction - True/False
Pause	Atrial Pause - True/False
Erratic	Erratic Heart Rate - True/False
AnPR	Anomalous PR interval - True/False
LAD	Left Atrial Anomaly - True/False
RAD	Right Atrial Anomaly - True/False
GConD	Gross Congenital Axis Deviation - True/False
SpQRST	Abnormal QRS-T Spatial Angle - True/False

Column	Meaning:
LVH	Left Ventricular Hypertrophy - True/False
RVH	Right Ventricular Hypertrophy - True/False
LVStrain	Left Ventricular Strain - True/False
SxRx	V5 - R-Wave < S-Wave- True/False
LBBB	Left Bundle Branch Block - True/False
RBBB	Right Bundle Branch Block - True/False
ICRBBB	Incomplete Right Bundle Branch Block - True/False
LQRS	Long QT Syndrome - True/False
LVolt	Low QRS voltage - True/False
QLat	V5 - Diagnostic CAD Q-wave - True/False
QInf	aVf - Diagnostic CAD Q-wave - True/False
QAnt	V2 - Diagnostic CAD Q-wave - True/False
WPW	WPW - True/False
ARVD	Arrhythmogenic Right Ventricular Dysplasia - True/False
Brug	Brugada Type 1 - True/False
Ect	Ectopic beat(s) present - True/False
PolyEct	Polymorphic ectopic beats present - True/False
STDep	ST Depression - True/False
STEX	V5 - Abnormal ST Elevation - True/False
STEY	aVF - Abnormal ST Elevation - True/False
STEZ	V2 - Abnormal ST Elevation - True/False
LQTS	Long QT Syndrome - True/False
SQTS	Short QT Syndrome – True/False
XTInv	V5 - Inverted T-Wave - True/False
YTInv	aVF - Inverted T-Wave - True/False
ZTInv	V2 - Inverted T-Wave - True/False
TaVR	Positive T-Wave in aVR- True/False
BiTwX	V5 - Bi-modal T-wave - True/False
BiTwY	aVF - Bimodal T-Wave - True/False
BiTwZ	V2 - Bimodal T-Wave - True/False
Pace	Paced patient - True/False
MI	Myocardial Infarct
RLRev	Probable Left Arm-Right Arm reversal- True/False
Poor	Poor quality ECG - True/False
CPat	Not used
CFMbr	Family Member - True/False
DxNotes	Diagnostic notes
ConfBy	Name of over reading physician
CDate	Date over read
Echo Measurements	
BSA	Body Surface Area
LBW	Lean Body Weight
Date	Echo Date
bMedHist	Indications for Echo - Medical History - True/False
bFamHist	Indications for Echo - Family History - True/False
bPhysEx	Indications for Echo - Physical Exam - True/False
bAbECG	Indications for Echo - Abnormal ECG - True/False
bNoInd	Indications for Echo - None - True/False
bOther	Indications for Echo - Other - True/False

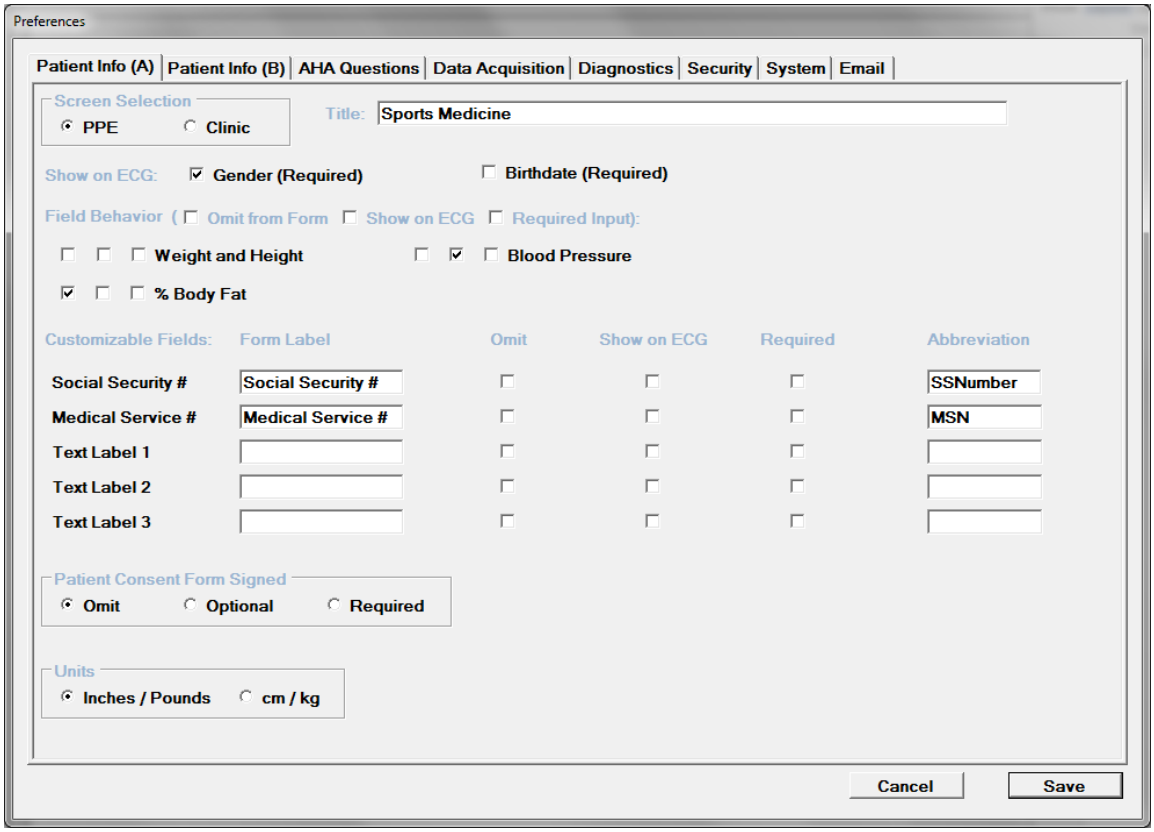
Column	Meaning:
Other	Other - reason for Echo
Desc	Description of concern
IVSThick	IVS Thickness
LVPostW	LV Posterior wall thickness
LVEDDiam	LV End diastolic diameter
LVESDiam	LV End systolic diameter
FShort	Fractional shortening
SinusV	Sinuses of Valsalva Diameter
AscendA	Ascending Aorta Diameter
Valves	Valves - (1=Normal, 0=abnormal, -1=Not Examined)
PPres	Pulmonary Pressure - (1=Normal, 0=abnormal, -1=Not Examined)
LOstia	Left Coronary Ostia - (1=Normal, 0=abnormal, -1=Not Examined)
ROstia	Right Coronary Ostia - (1=Normal, 0=abnormal, -1=Not Examined)
LMainB	Left Main Bifurcation - (1=Normal, 0=abnormal, -1=Not Examined)
Comments	Comments
Sonog	Sonographer name
Attending	Attending name

8 Preferences

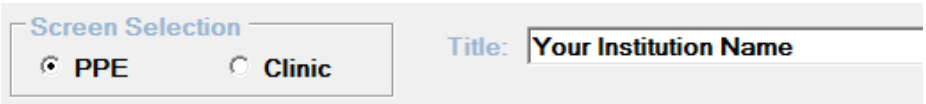
The Preferences subsystem allows users to customize several features and capabilities of CARDEA 20/20 ECG to suit their particular clinical needs. The Preferences screen is set via selecting "**Options/Preferences**." The currently define Preferences will be displayed; if no Preferences have been previously set, then the system default Preferences will be displayed.

8.1 Patient InformationTabs

The first Patient Info (A) Tab screen is:



The system supports two distinct Patient Information data entry screens, one appropriate for patient health screening (PPE) and one for specialty clinics.



The associated radio buttons toggle between the two options, and the title of the Patient Information data entry screen can be customized for your institution.

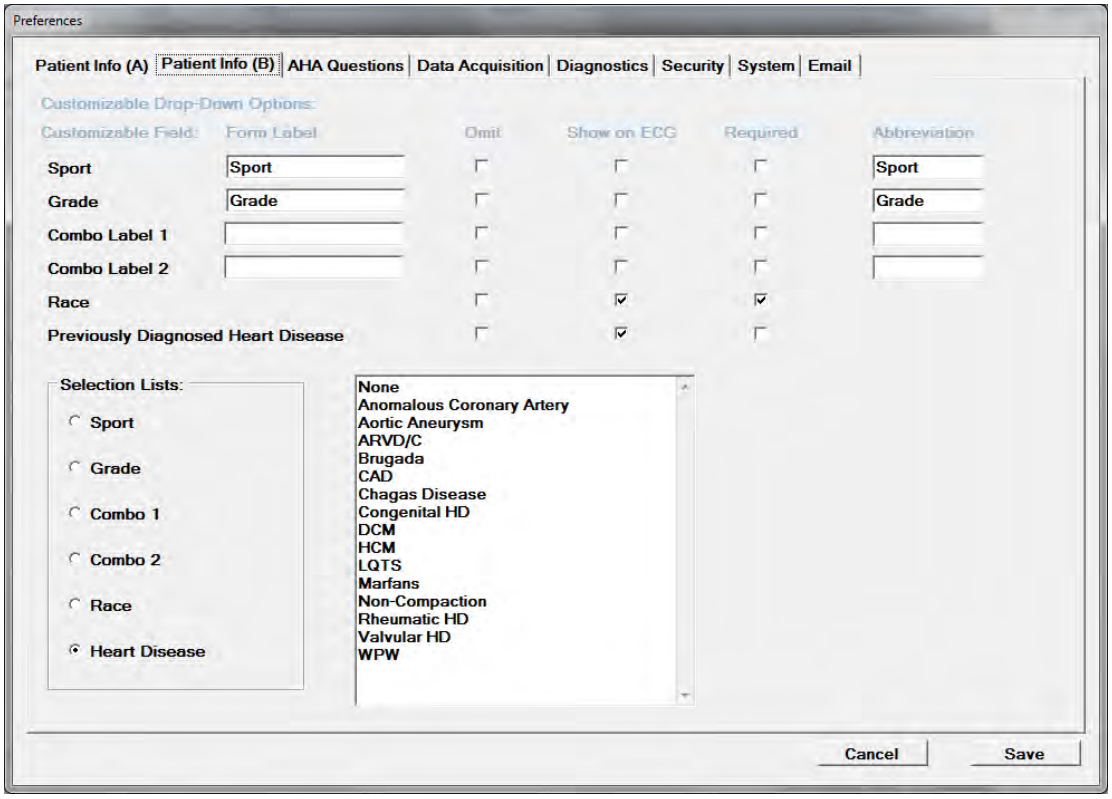
The parameters on the Patient Information screens can be set as "Required Input" (i.e. an ECG cannot be recorded until the required information is entered) by checking the associated box. Patient information collected can be added to the ECG display by checking the "Show on ECG" checkbox. And, fields can be entirely omitted from the Patient Information screen by checking the associated "Omit from Form" checkbox. Note: Birthdate and Gender are required input.

The Customizable Fields support addition of specific fields required by your organization. Social Security number and Medical Service number are provided as a possible default, but can be customized for other use. The "Form Label" is the label that will be displayed on the Patient Information screen and the "Abbreviation" will be used to identify the input information in reports or on the ECG.

Some organizations require tracking patient consent. This option assists users in ensuring that the consent form has been signed before proceeding with the ECG.

Units for Weight and Height can be entered in either Imperial or Metric units.

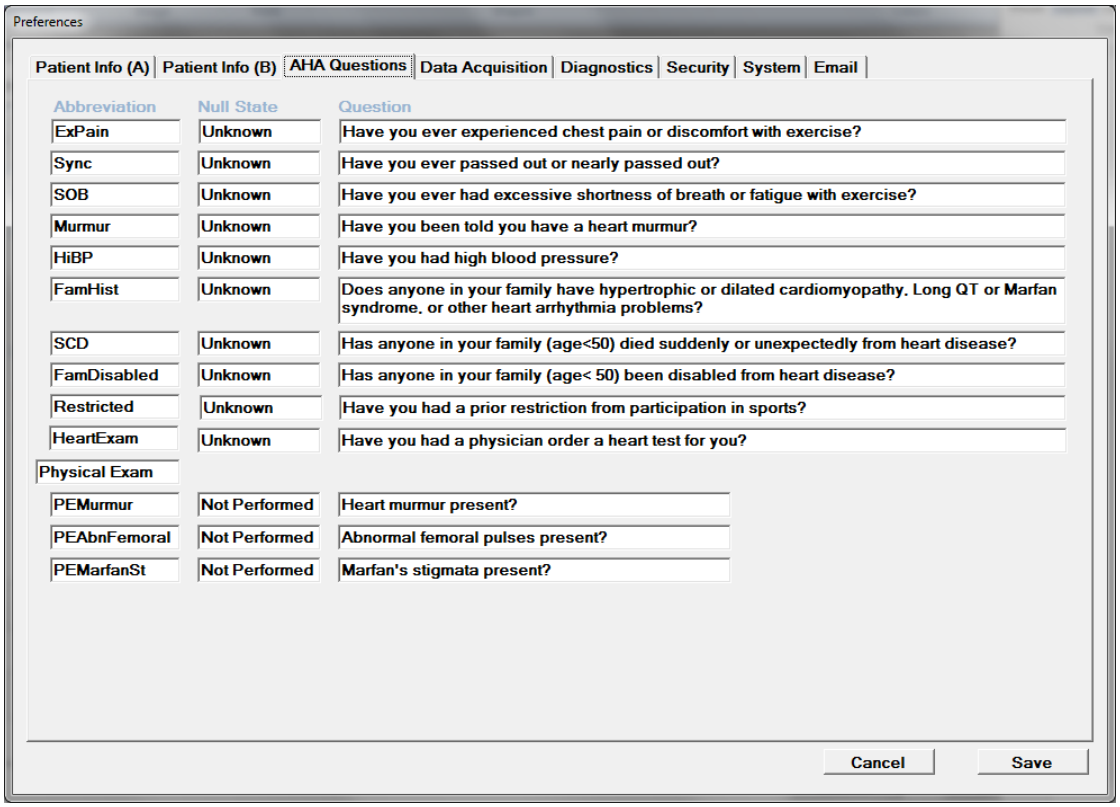
The second Patient Info (B) Tab screen is:



The system is delivered with a standardized selection list for Sport, Grade, Race and Previously diagnosed Heart Disease. However, the list can easily be modified using the lower part of the screen. Two additional selection lists, Combo 1 and 2, can be created for list fields.

8.2 AHA Questions Tab

The Customize Info Tab is:



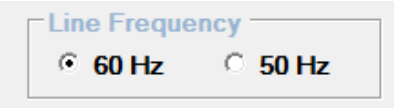
The AHA Questions ("Have you ever…") and the physical exam questions can be customized. To avoid confusion, Cardiac Insight strongly recommends that you change the Abbreviation associated with a changed question. The default abbreviations shown above trigger specific short descriptors for display on the ECG when positive. Changed Abbreviation(s) are used for the short ECG descriptors.

8.3 Data Acquisition and Processing Defaults Tab

8.3.1 Acquisition Controls

The Data Acquisition Tab of the Preferences subsystem controls key preferences used during data acquisition.

The Line filter can be set between 60 and 50 Hz (60 Hz is the standard through out North America, while 50 Hz is often used in other parts of the world):

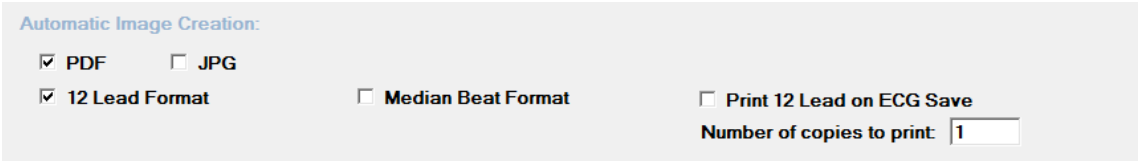


All patient data are stored in individual folders, one for each patient. The storage location for the folder can be set to a convenient Windows Directory. For a deployment of several PC systems, it may be desirable to set the Directory to a networked shared folder, so that all records are stored in a common location. If the storage location does not exist, the system will attempt to create the Directory and will display a Message Error box if it is unable to create the Directory. Following over reading / confirmation of an ECG, the system will automatically save a PDF and/or JPG image of the 12-Lead and/or Median Beat images in the Save Confirmed Record folder. If the Confirmed folder path is blank, no confirmed images will be saved. If the ECG has been marked as Abnormal the record image will be saved to the Abnormal folder. The "*\xxxx" format is interpreted by CARDEA 20/20 ECG to mean create the requested directory in the Patient Data Storage path directory – this can be helpful when managing several distinct Patient Data directories.

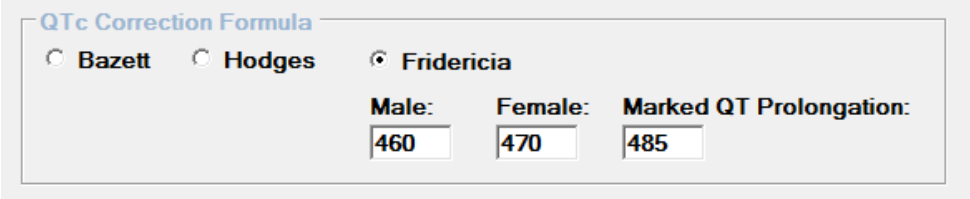
⚠ Caution	**Data Loss. The Patient Data Storage Directory should be archived on a regular or continuous basis. A deleted or otherwise corrupted Patient Folder cannot be recovered.**

8.3.2 Processing Controls

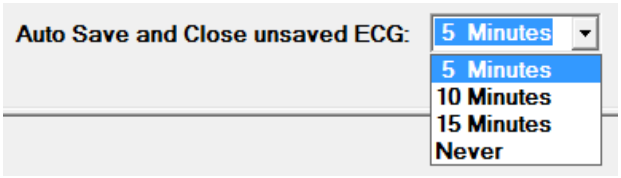
Image Creation. The system can be configured to automatically generate PDF and JPG files for both standard 12-Lead and Median Beat reports. These reports are stored in the associated Patient Folder, located in the Patient Data Storage Path. The user can configure which combinations of images and formats will be created when the ECG is initially saved and subsequently confirmed. Selecting the Print 12 Lead on ECG Save option will automatically print the requested number of 12 Lead ECG copies when the record is initially saved.



QTc Default Selection. The system supports the Bazett, Hodges and Fridericia heart rate corrections for computing QTc. The system default is Fridericia and the associated cut-offs are for "Possible" and "Marked" long QT for Fridericia. The cutoffs for Bazett and Hodges are set to 470/480 msec (male/female, Possible") and 500 msec ("Marked"). Click the radio button associated with the preferred preference.

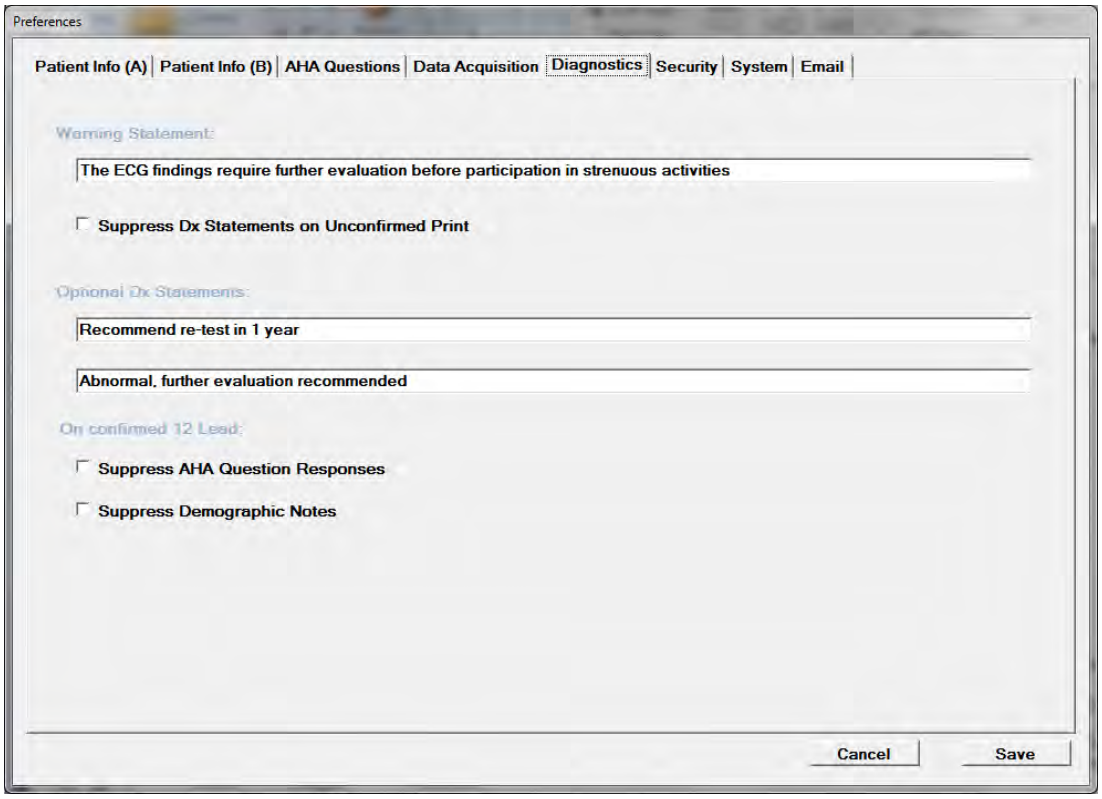


Auto Save and Close. Sometimes ECG recording staff record the ECG but fail to save and close the record and encounter, leaving the patient's data folder in an incomplete state. Cardea 20/20 ECG can be configured to automatically close a pending recorded ECG is there is no Cardea 20/20 ECG user activity for a specified interval, e.g. 5 Minutes. This feature can be disabled by selecting "Never."



8.4 Diagnostics Tab

The Diagnostics Tab is:



The Warning Statement is added to Unconfirmed ECGs that are automatically interpreted as abnormal. This statement can be customized to meet the needs of your organization. And, this statement can be suppressed for Unconfirmed ECGs when printed.

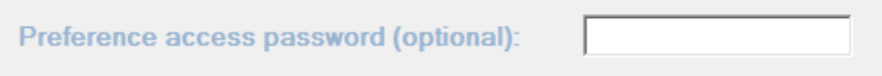
During diagnostic review and over reading, the confirming physician may routinely use a couple of sentences. The Optional Dx Statements provides the opportunity to capture these statements for one-click use during over reading (See: *Diagnostic Review*).

On completion of the over reading and creation of the Confirmed PDF, you can choose to suppress adding to the ECG the responses to the AHA questions and any Demographic notes.

8.5 Security Tab

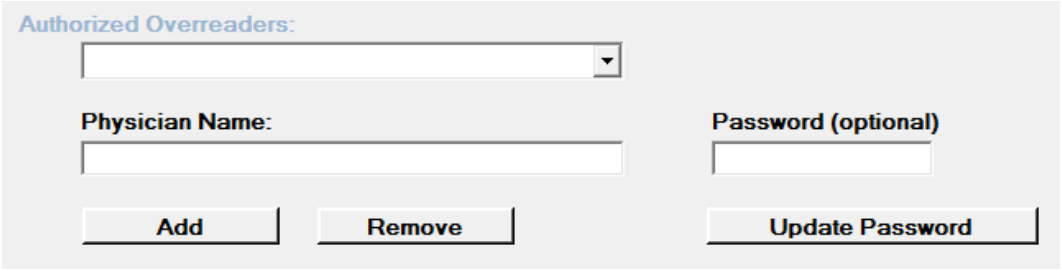
The Security Tab can be used to set several security related attributes.

Access to the Preferences settings can be controlled by setting a Preferences Password:



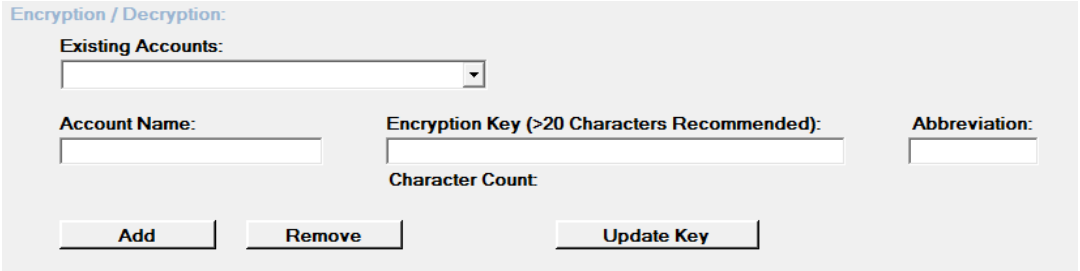
NOTE: There is no "back door" for access to the Preferences. Save your password in a safe place! Cardiac Insight also recommends that you Export the Preferences file without the Password (see below) and save it in a secure location. If you forget your password you can Import the Preferences file and select a new password. If all else fails, the "Factory Default Preferences.dat" file, located in "C:\Program Files (x86)\Cardiac Insight\CARDEA 20/20 ECG\Defaults", can be imported. This will clear all of the set preferences.

The system supports defining of a list of Authorized Over readers (i.e., Reviewers).



If no Authorized Over readers exist, the system will allow unrestricted access to the review mode, but will designate the "Reviewer" as "Unrestricted."

CARDEA 20/20 ECG supports the Encryption / Decryption of patient folders and documents for HIPAA secure transfer over the open internet using 256 bit AES encryption.



The Account Name should describe the Sender / Receiver relationship. For example, an over reading cardiologist might use this field to define each specific primary care or pediatric clinic being supported by entering the name of the clinic (e.g. "Lakeview"). The Encryption Key or phrase should be at least 20 characters in length to ensure adequate HIPAA protection. The Encryption key MUST be entered on each of the Sender and Receiver Systems in exactly the same way, and is CASE sensitive. Finally, a short abbreviation is used to tag patient folders that are transferred, supporting identification of

which patient came from which relationship. The Account Name and Abbreviation should be consistent between the Sender and Receiver.

Access to PDF files can also be password-protected:

Also, you can enable/disable printing of the PDF image(s).

8.6 System Tab

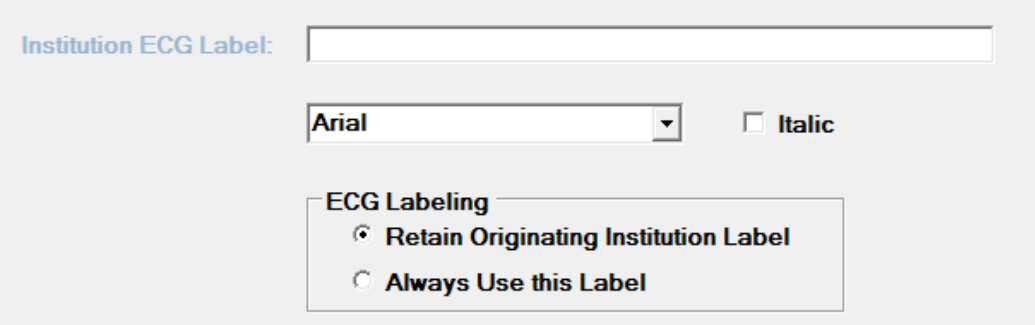
The Preferences subsystem supports the selection of language:

NOTE: At this time only English is supported.

You can also Import and Export all the Preferences settings. This can be very helpful in configuring multiple PC systems to the same settings.

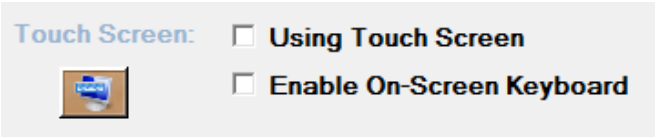
A copy of the factory default settings are installed with the software in the Program Files….\Cardiac Insight\CARDEA 20/20 ECG\Defaults.

You may also set an Institutional Label that will be added to the bottom of the ECG display.

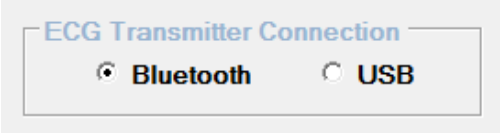


The over reading cardiology service can choose to over-write the originating organizational name with their name, or choose to retain the name of the originating institution.

CARDEA 20/20 ECG has also been designed for use on touch screen devices. Clicking the below check-boxes will enable larger menu and button display, for easier selection, and enable an On-Screen Keyboard for input. After selecting the Touch Screen option and saving the preferences, you must re-start CARDEA 20/20 ECG for the Touch Screen display changes to be in effect.

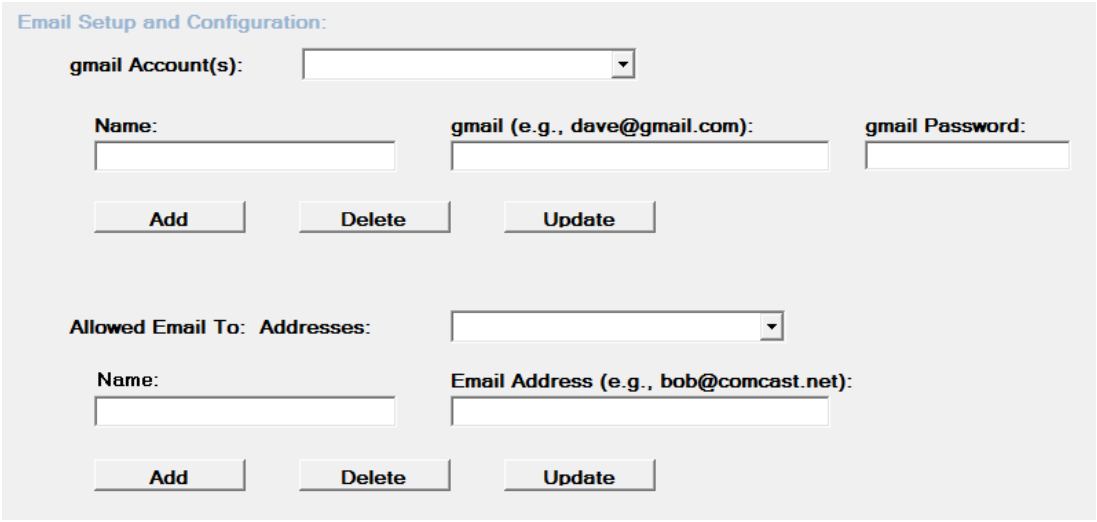


Select the connection technology for the ECG Transmitter, either Bluetooth (default) or USB:



8.7 Email

Email can only be sent from Google Gmail accounts (which are free and easily obtained) and can only be sent to email addresses registered in Preferences. Addresses in the To: directory can also be used for CC. Entry of the email account information is supported via:



NOTE: Email requires a secure socket connection – public wireless connectivity may not work.

NOTE: Google has changed their security standards such that most applications that use a gmail account are considered "less secure" by Google and access is blocked. To overcome this issue, log into your gmail account and then follow this link: https://www.google.com/settings/security/lesssecureapps and enable less secure apps.

8.8 Adding Your Institution's Logo

The CARDEA 20/20 ECG logo filling the ECG display area can be changed to any image by replacing the "Background_Image.jpg" in the CARDEA 20/20 ECG installed directory "C:\Program Files…\Cardiac Insight\CARDEA 20/20 ECG".

9 Physician: System Diagnostic Characteristics

The following information is provided to assist the clinician in understanding the characteristics of the CARDEA 20/20 ECG system that transform electrode potentials into diagnostic statements.

9.1 System Frequency Response

9.1.1 System Bandwidth

The ECG Transmitter digitizes the ECG voltages at 1000 samples/sec at a resolution of 0.6 μVolt. The A/D averages the signal over the duration of a sample interval, thus providing anti-aliasing filtering inherent in the hardware chip design. CARDEA 20/20 ECG applies a digital anti-aliasing filter, corner at 185 Hz, and down-samples the data to 500 samples/sec for subsequent analysis. The A/D hardware imposes no low-frequency filtering – the raw data is flat to DC. At the completion of an ECG recording, the CARDEA 20/20 ECG system removes the average DC offset for each trace, effectively removing any constant voltage bias associated with differing electrode bias.

The nominal system bandwidth is 0 to 150 Hz.

9.1.2 AC Line Filtering

CARDEA 20/20 ECG uses an adaptive filter to estimate and remove the AC line signal, i.e., the amplitude and phase of a pure sine wave that best represents the observed signal. This approach provides a large dynamic range and avoids distortions and limitations associated with narrow notch filters. Three filters are used to remove the fundamental (50 or 60 Hz) and the first two harmonics. The filter adapts slowly, preventing any significant ring associated with abrupt QRS signals.

9.1.3 Baseline Wander

For each ECG trace, the baseline wander filter identifies each isoelectric point for each dominant beat and fits a smooth polynomial through the time-amplitude tuples. The smooth curve is then subtracted from the trace, resulting in an amplitude of zero at each isoelectric point for each beat. The impact of the baseline filter on ST measurements has been assessed following the noise tests in IEC 60601-2-51, Section 50.101.4, wherein 10 biological ECGs are measured without injection of noise and compared to the same records with 1000 μVolt peak-to-valley 0.3 Hz baseline wander. The average ST changes, for ECG traces I, II and V1-V6, was 5.5±8.4 μVolt.

9.1.4 Median Average Beats

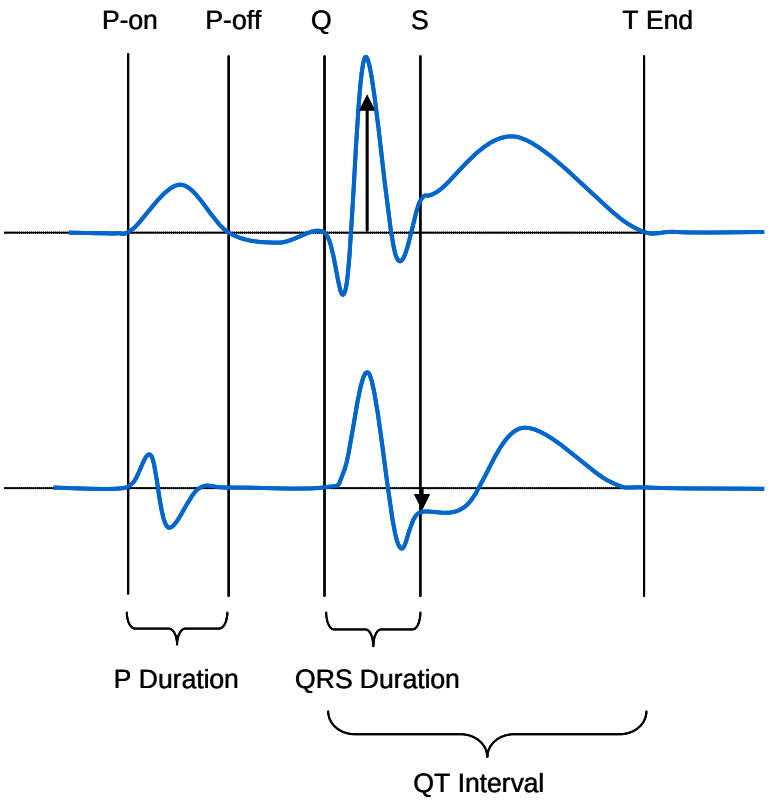
Initially every beat is cross-correlated with every other beat. The beat with the highest average cross-correlation coefficient is selected as the most representative beat, and the maximum correlation times are used to time-align all of the beats. For each time point all of the individual beat

amplitude estimates are ordered largest to smallest and the middle half are averaged to form the estimated amplitude of the beat at that time point. This method is very tolerant of a few noisy beats, as the associated amplitude values are generally outliers and are eliminated by the median element of the method. Averaging of the middle half of the data values provides a robust estimate of the true value, whereas a simple median would be relatively noisier given the low number of beats gathered while recording a rest ECG. All measurements are done on the median averaged beat.

9.2 Phase Amplitude and Duration Measurements

All phase amplitude and duration measurements are done in compliance with "Recommendations for measurement standards in quantitative electrocardiography – The CSE Working Party" E. Heart J. (1985), 6, 815-825.

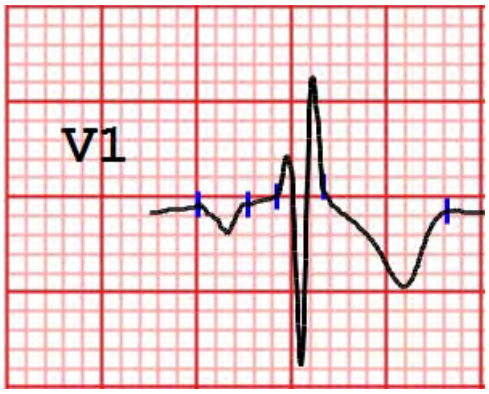
Global phase measurements are made from the earliest onset to the latest offset in the V5 (X), V2 (Y), and aVF (Z) traces:



Following the CSE recommendations, a phase is recognized when it exceeds an amplitude deviation of more than 20 µVolt for a duration of at least 6 msec.

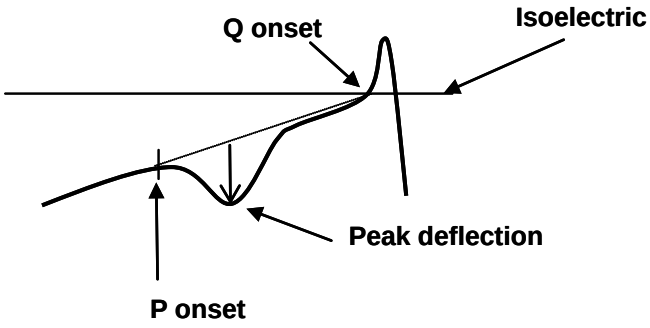
9.2.1 P Wave Amplitude Measurement Convention

Amplitude measurements of the P wave are complicated by the common condition of the trace bias associated with late repolarization trends, such as:



P waves are measured relative to the line formed by connecting the P onset point with the QRS onset point:

P Measurements:

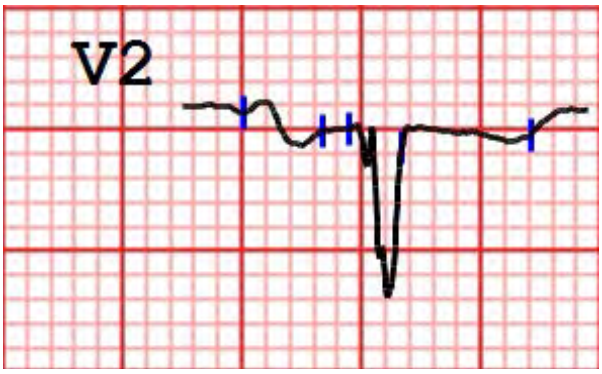


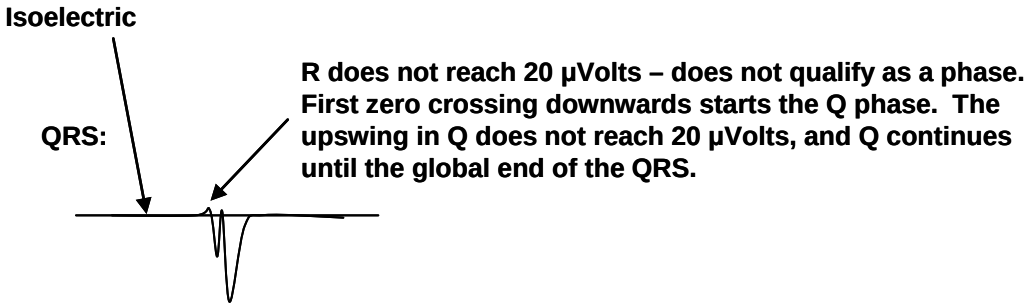
P amplitude and duration measurements are relative to the P onset to Q onset line.

9.2.2 QRS, ST and T-Wave Conventions

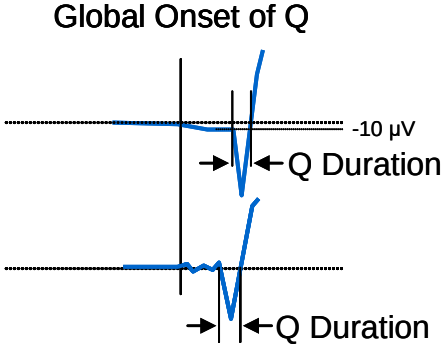
For each trace, all Q, R, S and T measurements are made relative to the isoelectric, defined as the average trace value immediately before the global onset of Q.

Phase Onset: The onset of a phase is defined consistent with the CSE recommendations: deviation of more than 20 µVolt for a duration of at least 6 msec. The following figure illustrates this:



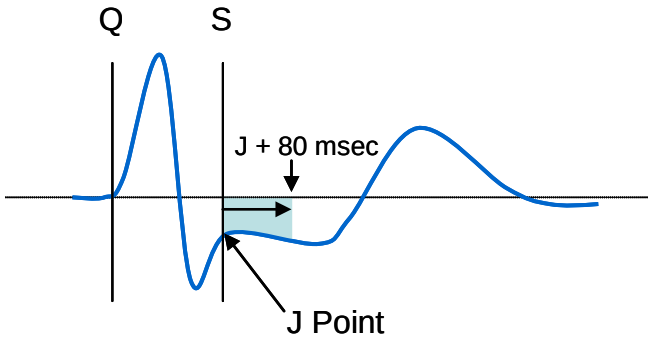


Isoelectric Segment: The Q duration measurement starts at the last positive to negative zero crossing after the global onset of QRS. If there is no zero crossing then the Q duration is measured from the first point following the global onset that deviates from the isoelectric by more than 10 µVolts. This is illustrated in the following figure:



End of the Q phase is defined as the zero crossing associated with the onset of R, or the end of the global QRS, whichever comes first.

ST Segment: ST elevation is measured at the end of the S phase (J Point), relative to the isoelectric point:



ST depression is called if the average trace value from the J point to J + 80 msec is more negative than -50 μVolt.

9.2.3 Automated Measurements on Analytic ECGs

The IEC 60601-2-51 standard, Section 50.101, provides a suite of tests to measure the accuracy of phase amplitude and duration measurements. The tests include both analytic (synthetic) and biological ECGs, representing a wide range of conditions. Following is a brief summary of the results of these tests for the CARDEA 20/20 ECG system.

The standard for amplitude and interval measurements specifies sixteen analytic records for use in testing. Each record type (e.g., CAL20260) is recorded 5 times, and the mean value is compared with the expected values for phase amplitude and duration measurements. All measurements used in the diagnostic assessments were compared to the standards, a total of 608 distinct mean measurements. The standard allows for the exclusion of up to two measurements associated with fiducial (i.e., phase picking) errors – only one phase duration measurement was 1.5 msec longer than the allowed deviation. All amplitude measurements passed without exclusion. The results of the absolute interval and phase duration measurements are:

Measurement	Mean Difference msec	Standard Deviation msec	Acceptable Mean Difference msec	Acceptable Standard Deviation msec	Pass / Fail
P-Duration	3.7	1.4	±10	8	PASS
PQ-Interval	4.0	1.4	±10	8	PASS
QRS-Duration	-1.9	1.1	±6	5	PASS
QT-Interval	0.7	1.6	±12	10	PASS
Q-Duration	-0.1	0.6	±6	5	PASS
R-Duration	-1.1	1.2	±6	5	PASS
S-Duration	-0.1	1.2	±6	5	PASS

9.2.4 Interval Measurements On Biological ECGs

The IEC 60601-2-51 standard, Section 50.101.3.2, uses 100 real ECGs with consensus standard values for global P-Duration, PQ-Interval, QRS-Duration and QT-Interval. Each record has been analyzed using CARDEA 20/20 ECG. To compare the program results with the standard, the standard requires the removal of obvious phase picking errors. None were removed for this test. Next, the standard requires the removal of the 4 largest deviations from the mean (outliers). Finally, the mean and standard deviation for each of the four measurements are compared against the standard:

	P-Duration	**PQ-Interval**	**QRS-Duration**	**QT-Interval**
Mean	0.2 msec	2.1 msec	1.2 msec	-1.1 msec
St.Dev	10.7 msec	8.0 msec	5.1 msec	11.0 msec
Maximum Acceptable Mean and Standard Deviations:				
Mean	± 10 msec	± 10 msec	± 10 msec	± 25 msec
St.Dev	± 15 msec	± 10 msec	± 10 msec	± 30 msec
Conclusion:	PASS	PASS	PASS	PASS

9.2.5 Stability of Measurements Against Noise

The IEC 60601-2-51 standard, Section 50.101.4, requires the disclosure of the phase measurement stability in the presence of:

- Added noise from high-frequency noise (25 μVolt RMS)
- Line (AC) noise of 50 μVolt peak to valley
- Sinusoidal baseline wander (1000 μVolt peak to valley, 0.3 Hz)

These noise conditions are added to every trace of 10 ECGs selected from the 100 records discussed in 50.101.3.2 above. The standard requires the removal of the two largest outliers before computation of the mean and standard deviation. The stability of the measurements, in the presence of these noise conditions, is:

Global Measurement	Type of added Noise	Disclosed differences	
		Mean msec	Standard Deviation msec
P-Duration	High Frequency	1.8	10.1
	Line Frequency	0.0	0.0
	Baseline	1.8	5.3
PQ-Interval	High Frequency	0.75	6.0
	Line Frequency	0.0	0.0
	Baseline	1.3	4.3
QRS-Duration	High Frequency	2.0	2.8
	Line Frequency	0.0	0.0
	Baseline	-0.8	1.5
QT-Interval	High Frequency	-0.5	6.8
	Line Frequency	0.0	0.0
	Baseline	-1.5	3.5

9.3 Diagnostic Algorithm Performance

Existing ECGs were assembled for three study populations and processed using the CARDEA 20/20 ECG algorithms. Each ECG was then over read by a senior cardiologist, and differences between the automatic and over read diagnostic determinations were recorded and tabulated. Sensitivity, Specificity and Positive Predictive Value (PPV) were calculated for each study population and are based upon the agreement or disagreement between the automatic interpretations derived by the CARDEA 20/20 ECG system and the interpretations derived by the senior cardiologist.

The characteristics of the three study populations are detailed below.

Student Population. Existing ECGs collected as part of the pre-participation physical exam for incoming college students were collected for study; 2088 digital ECGs were recorded. The average student age was 18.7±2.3 years and the population was 41% male.

Clinical Population. Existing ECGs collected as part of normal clinical care were collected for study; 957 digital ECGs were recorded. The average patient age was 57.4±15 years and the population was 58 % male.

Military Population. Approximately 43,000 ECGs were collected as part of physical exams for incoming military recruits. Records with left-right arm reversal, high noise and high heart rate (>100 BPM) were excluded from further analysis, resulting in 41,408 ECGs. These were all processed using the CARDEA 20/20 ECG algorithms, resulting in the identification of 1,788 records with significant clinical findings. An additional 1,630 seemingly normal records were selected and randomized with the abnormal records, for a total of 3,418 ECGs for over reading. This cohort is a male population; average age is 19.6±1 years.

The results of these three studies are presented in the following table. The first column in each study, "# Cases," is the prevalence's of the diagnostic condition, as identified by the cardiologist over reader. A case-weighted average for Sensitivity, Specificity and PPV for the three study populations, for each diagnostic condition, is presented in the final columns.

Warning	**Diagnostic algorithm performance is dependent upon many conditions, including record quality, correct lead placement and patient characteristics and history. The following results will not typify all usage scenarios.**
Warning	**A licensed physician must over read all ECG interpretations. Some ECG abnormalities cannot be detected by automated ECG analysis algorithms. Computerized interpretations are only significant when used in conjunction with clinical findings.**

Diagnostic Algorithm Performance:

	Students / Athletes				Clinical				Military				Case Weighted Average			
	# Cases	Sensitivity:	Specificity:	PPV:	# Cases	Sensitivity:	Specificity:	PPV:	# Cases	Sensitivity:	Specificity:	PPV:	# Cases	Sensitivity	Specificity	PPV
LAA	14	100.0%	100.0%	100.0%	8	100.0%	100.0%	100.0%	121	100.0%	100.0%	100.0%	143	100.0%	100.0%	100.0%
RAA	5	100.0%	100.0%	100.0%	6	100.0%	100.0%	100.0%	109	100.0%	100.0%	100.0%	120	100.0%	100.0%	100.0%
AFib	5	100.0%	100.0%	90.9%	38	94.7%	100.0%	94.7%	10	100.0%	100.0%	90.9%	53	96.2%	100.0%	93.7%
AFlut	0		100.0%		5	80.0%	100.0%	80.0%	0		100.0%		5	80.0%	100.0%	80.0%
PAC	0	100.0%	100.0%	100.0%	1	100.0%	100.0%	100.0%	1	100.0%	100.0%	100.0%	2	100.0%	100.0%	100.0%
Pause	7	100.0%	100.0%	100.0%	0		100.0%		19	100.0%	100.0%	100.0%	26	100.0%	100.0%	100.0%
Erratic	58	100.0%	100.0%	100.0%	24	100.0%	100.0%	100.0%	83	100.0%	100.0%	100.0%	165	100.0%	100.0%	100.0%
AnPR	1	91.7%	100.0%	100.0%	4	100.0%	100.0%	100.0%	12	91.7%	100.0%	100.0%	17	93.6%	100.0%	100.0%
LAD	27	100.0%	100.0%	100.0%	53	100.0%	99.9%	98.1%	435	100.0%	100.0%	100.0%	515	100.0%	100.0%	99.8%
RAD	9	99.5%	100.0%	100.0%	5	100.0%	100.0%	100.0%	192	99.5%	100.0%	100.0%	206	99.5%	100.0%	100.0%
GConD	2	100.0%	100.0%	100.0%	1	100.0%	100.0%	100.0%	30	100.0%	100.0%	100.0%	33	100.0%	100.0%	100.0%
RVH	11	100.0%	100.0%	100.0%	0		100.0%		139	100.0%	100.0%	100.0%	150	100.0%	100.0%	100.0%
LBBB	0	100.0%	100.0%	66.7%	40	100.0%	99.9%	97.6%	2	100.0%	100.0%	66.7%	42	100.0%	99.9%	96.1%
RBBB	16	100.0%	100.0%	99.3%	50	98.0%	100.0%	98.0%	138	100.0%	100.0%	99.3%	204	99.5%	100.0%	99.0%
ICRBBB	84	99.7%	100.0%	100.0%	12	100.0%	100.0%	100.0%	297	99.7%	100.0%	100.0%	393	99.7%	100.0%	100.0%
LQRS	7	100.0%	100.0%	100.0%	60	98.3%	99.9%	96.7%	39	100.0%	100.0%	100.0%	106	99.1%	99.9%	98.1%
QLat	64	100.0%	99.9%	99.4%	50	100.0%	99.8%	96.2%	476	100.0%	99.9%	99.4%	590	100.0%	99.9%	99.1%
QInf	35	100.0%	100.0%	99.6%	111	100.0%	99.8%	98.2%	240	100.0%	100.0%	99.6%	386	100.0%	99.9%	99.2%
QAnt	17	100.0%	100.0%	98.3%	44	100.0%	99.9%	97.8%	59	100.0%	100.0%	98.3%	120	100.0%	99.9%	98.1%
WPW	14	94.9%	100.0%	100.0%	5	100.0%	100.0%	100.0%	59	94.9%	100.0%	100.0%	78	95.2%	100.0%	100.0%
ARVD	1	100.0%	100.0%	100.0%	0		100.0%		5	100.0%	100.0%	100.0%	6	100.0%	100.0%	100.0%
Brug	0	100.0%	100.0%	100.0%	1		100.0%		3	100.0%	100.0%	100.0%	4	75.0%	100.0%	75.0%
Ect	23	100.0%	100.0%	100.0%	37	100.0%	100.0%	100.0%	73	100.0%	100.0%	100.0%	133	100.0%	100.0%	100.0%
PolyEct	1	100.0%	100.0%	100.0%	4	100.0%	100.0%	100.0%	1	100.0%	100.0%	100.0%	6	100.0%	100.0%	100.0%
STD	37	100.0%	100.0%	100.0%	50	100.0%	99.8%	96.2%	266	100.0%	100.0%	100.0%	353	100.0%	100.0%	99.5%
STE	23	100.0%	100.0%	100.0%	4	100.0%	100.0%	100.0%	35	100.0%	100.0%	100.0%	62	100.0%	100.0%	100.0%
LQTS	12	100.0%	99.4%	44.1%	24	100.0%	99.7%	88.9%	15	100.0%	99.4%	44.1%	51	100.0%	99.6%	65.2%
XTInv	15	100.0%	99.9%	87.8%	54	100.0%	100.0%	100.0%	36	100.0%	99.9%	87.8%	105	100.0%	99.9%	94.1%
YTInv	15	100.0%	99.9%	96.7%	30	100.0%	100.0%	100.0%	88	100.0%	99.9%	96.7%	133	100.0%	99.9%	97.4%
ZTInv	22	100.0%	99.8%	80.6%	14	100.0%	100.0%	100.0%	25	100.0%	99.8%	80.6%	61	100.0%	99.9%	85.1%
TaVR	2	100.0%	100.0%	100.0%	30	100.0%	100.0%	100.0%	6	100.0%	100.0%	100.0%	38	100.0%	100.0%	100.0%
Rx<Sx	26	100.0%	100.0%	100.0%	20	100.0%	100.0%	100.0%	162	100.0%	100.0%	100.0%	208	100.0%	100.0%	100.0%
Case Weighted Average:		99.8%	100.0%	97.3%		99.2%	99.9%	97.7%		99.8%	100.0%	99.1%		99.7%	100.0%	98.6%
Test Criteria:		> 98%	> 99%	> 95%		> 98%	> 99%	> 95%		> 98%	> 99%	> 95%		> 98%	> 99%	> 95%
Test Status:		**PASS**	**PASS**	**PASS**		**PASS**	**PASS**	**PASS**		**PASS**	**PASS**	**PASS**		**PASS**	**PASS**	**PASS**
# Cases:	553				785				3176				4514			
% Male	41%				58%				100%							
Age	18.7±2.3				57.4±15.0				19.6±1							
n	2088				957				3418				6463			

9.4 Within Normal Limits

For patients less than 35 years old, and with no abnormal findings as defined by the "International Recommendations for Electrocardiographic Interpretation in Athletes", JACC 69:8, 2017, CARDEA 20/20 ECG assesses the likelihood that an ECG is a False Negative finding, relative to the Criteria. The assessment lowers abnormal thresholds with the goal of identifying "Near-Miss" records. For instance, ST Depression is considered abnormal if the ST segment is less than -50 μVolts (-0.5 mm). The ECG will not be considered to be Within Normal Limits (WNL) if the segment is less than -30 μVolts (-0.3 mm). Similar criteria are applied for Q-waves, T-wave inversion, Long QT, WPW, ARVD, Heart Rate, Ectopy, QRS Duration, and QRS Axis. In addition, the record is assessed for both high and low frequency noise, which can degrade the accurate identification of phase onsets and offsets. When all of these elements are negative, and no abnormalities have been found, the record is classified as "Unconfirmed – WNL"

The performance of CARDEA 20/20 ECG to appropriately identifying records as WNL has been tested using a database of ~6,700 ECGs from high school athletes as recorded during Nick-of-Time screening events. All records were over read by Cardiac Insight's Chief Medical Officer. No record subsequently marked as WNL was found to be abnormal on over read, suggesting records so marked have a False Negative rate less than about 1 in 5000. Approximately 80% of the 6,700 ECGs were marked as WNL. Cardiac Insight will continue research in this area to further refine and improve the accurate identification of records that have high likelihood of being true normal.

10 Maintenance and Service

To ensure safe and effective use of the system, Cardiac Insight, Inc. recommends the following maintenance and service procedures:

10.1 Rechargeable Battery

The ECG Transmitter rechargeable battery is sealed within the plastic case and is serviceable ONLY by a trained Cardiac Insight service technician. The battery charge status is reported on the ECG Data Acquisition screen (See: *ECG Acquisition*). The battery should ONLY be recharged using the PS1 recharging unit, which should be unplugged when not in use.

The battery should be replaced when fewer than 50 ECGs can be recorded following an overnight charging cycle. Contact Cardiac Insight to arrange for device service and battery replacement.

 **Warning**	**Opening case. Do not open the ECG Transmitter case. There are no user-serviceable components within the case. Opening the case will invalidate the device warranty and may damage components, resulting in injury or death. The case should be opened only by a Cardiac Insight qualified technician when replacing the battery.**
 **Warning**	**Battery Replacement. The ECG Transmitter rechargeable battery should be replaced only by a Cardiac Insight qualified technician using Cardiac Insight approved batteries. The case should be opened only by a Cardiac Insight qualified technician.**
 **Warning**	**Fire or Explosion. Never attempt to remove the rechargeable battery from the ECG Transmitter to charge using an external battery charger. Fire or explosion may result.**
 **Warning**	**Fire, explosion, or contamination. Properly dispose of batteries in accordance with local regulations. Burning, heating, or improper disposal may cause explosion, fire or contamination.**

10.2 Cleaning

The ECG Transmitter, including clips and patient lead wires, should be cleaned and disinfected after each use session or shift, or more frequently depending upon the number of patients screened.

To clean, dampen a cloth with one of the recommended cleaning/disinfecting agents (listed below), and thoroughly wipe down the ECG Transmitter and patient lead wires and clip/snaps. Dry with a clean soft dry cloth.

 **Warning**	**Fluid Hazard. Do not immerse. Fluids must not be allowed to enter the ECG Transmitter. If fluids have penetrated the device it should be replaced or inspected by a Cardiac Insight qualified technician before use.**
 Caution	**Equipment Damage. Do not use ether, strong bleach, acetone, benzene, or similar solvents to clean the ECG Transmitter.** **Use only the following cleaning agents:** • **Mild detergent and water** • **Chlorine bleach (3% solution in water)** • **Isopropyl alcohol (70% solution in water)** • **Quaternary ammonium compounds, such as Steris Coverage Plus NPD (diluted one part to 255 parts water)**
 Caution	**Equipment Damage. Do not hot sterilize the ECG Transmitter or the patient lead wires.**

10.3 Maintenance

10.3.1 ECG Patient Lead Wires

The ECG patient lead wires comply with ANSI/AAMI EC53:1995 / (R)2001 electrical and safety standards.

The ECG patient lead wires and electrode connectors should be examined periodically for damage. Patient lead wires should ALWAYS be inspected for possible damage following usage in conjunction with a patient defibrillation event.

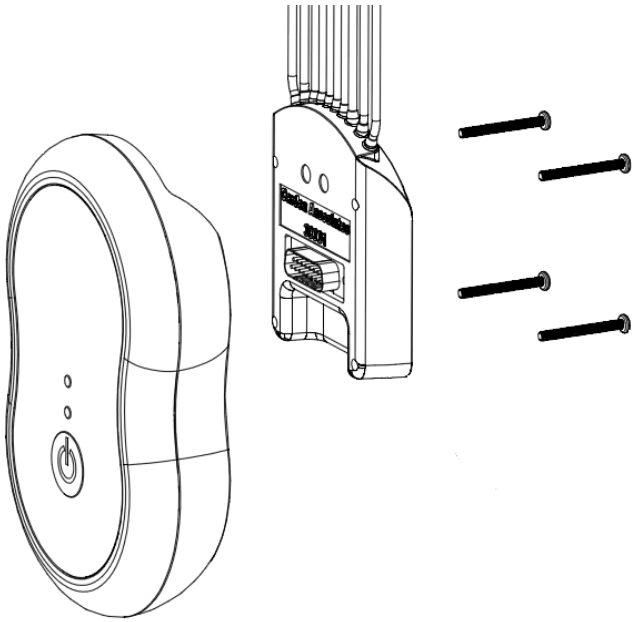
Assuming proper patient preparation and use of quality electrodes, a noisy or intermittent ECG signal may indicate a faulty patient lead wire or loose clip/snap connector. The clip/snap connectors can become damaged by electrode paste or become loosened so they no longer provide a secure connection to the electrodes.

The following procedures are recommended for inspecting the patient lead wires:

- Visually inspect each lead for cracks, pinches or abrasions. Particularly inspect around the strain relief area where the patient lead wire leaves the black lead wire block/transmitter and around the distal end where the lead wire mates with the banana plugs.
- Remove the patient lead wire clip/snap connector and inspect/clean the metallic part of the banana plug. Inspect the patient lead wire clip/snap for damage, particularly looking for incomplete or broken elements of the metallic gripper that connects to the electrode.
- Connect the electrodes to an electronic heart simulator and start recording an ECG. Bend or flex each lead and watch for noisy signals or lead-off indication indicators displayed on the real-time screen.

Damaged or broken patient lead wires are field replaceable using just a standard screwdriver. Remove the four screws holding the lead block in-place and lift off. NOTE: The lead block lifts off in the same direction as the screws – it does not slide out horizontally. See the below figure for disassembly guidance. Place the new lead block into the unit, being sure to carefully mate the electrical connector – see figure below. Insert the screws and tighten, with the same force needed to remove the screws, until the lead block is snugly connected. Do not over-tighten as you may damage the threaded nuts within the plastic.

Contact Cardiac Insight to purchase replacement patient lead wires.



10.3.2 Clip/Snap Connector

The patient lead wire clip/snaps that slide over the banana plug ends of the patient lead wires should be cleaned regularly and inspected for wear or damage. Clip/snaps that have worn to the point of being loose when gripping a snap or tab electrode will introduce ECG noise. Cardiac Insight recommends keeping a small stock of replacement connectors on hand for rapid use in the case of a broken or damaged connector.

Contact Cardiac Insight to purchase replacement electrode connectors.

10.3.3 ECG Transmitter Plastic Case

Periodically inspect the plastic case for damage, particularly if it has been dropped on a hard surface. Cracks in the plastic may allow fluids to enter the electronics compartment and seriously compromise both safety and functionality. See: Fluid Hazard Warning in *Cleaning*.

Warning	**Operator or Patient Injury and Equipment Damage. Never sit or place heavy objects on the ECG Transmitter. Personal injury and/or equipment damage may result.**

If your unit has been damaged, contact Cardiac Insight to arrange for repair or replacement of your patient lead wires.

10.4 Replaceable Components

The following parts may be ordered from Cardiac Insight:

Part Number	Description	Service Notes
PN00173-01 A	10 Lead AHA ECG leadset (Patient Lead Wires)	See: Maintenance – *ECG Patient Lead Wires*
PN00163-02 B	PS1 Medical Grade Power Supply	See: *Hardware Setup*
PN00161-01 A	Clip/Snap Connectors (set of 10)	See: *Hardware Setup*
PN00162-01 A	USB Bluetooth Radio	See: *Hardware Setup*

10.5 Notice to Responsible Service Personnel

Cardiac Insight, Inc. recommends consulting with authorized personnel for all service and repair and using only approved replacement parts. Cardiac Insight DOES NOT assume responsibility for third-party material quality, safety or any consequences, damage or loss, including loss of life or serious injury, that result from use of unapproved parts or activities associated with unauthorized personnel.

This product has been designed, manufactured and tested to achieve a high degree of safety and reliability. However, normal wear and tear will degrade parts and components. Cardiac Insight does not guarantee against failure or deterioration of components due to normal aging and/or use.

10.6 EMC Declaration Tables

CARDEA 20/20 ECG is intended for use in the electromagnetic environment specified below:

10.6.1 Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 2	The CARDEA 20/20 ECG system emits electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	CARDEA 20/20 ECG is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

10.6.2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic 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	Mains power quality should be typical of a commercial or hospital environment.
Surge IEC 61000-4-5	±1kv differential mode ±2 kV common mode	±1kv differential mode ±2 kV common mode	Mains power quality should be typical of a commercial or hospital environment.
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% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycle <5% *U*T (<95% dip in *U*T) for 5 sec	<5% UT (<95% dip in UT) for 0,5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycle <5% *U*T (<95% dip in *U*T) for 5 sec	Mains power quality should be typical of a commercial or hospital environment. If the CARDEA 20/20 ECG user requires continued operation during power mains interruptions, the CARDEA 20/20 ECG PC must be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1: *U*T is the a.c. mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V[c] 3 V/m[c]	Portable and mobile RF communications equipment should be used no closer to any part of CARDEA 20/20 ECG, including patient lead wires, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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: 
NOTE 1: At 80 MHz and 800 MHz, 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.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which CARDEA 20/20 ECG is used exceeds the applicable RF compliance level above, then CARDEA 20/20 ECG should be observed to verify normal operation. If abnormal			

performance is observed, additional measures may be necessary, such as reorienting or relocating CARDEA 20/20 ECG.

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

c. Amplitude modulated at 80% with a modulation frequency of 10 KHz per EN 60601-2-25.

10.6.3 Recommended Separation Distances

The following table provides the recommended separation distances between portable and mobile RF communications equipment and the CARDEA 20/20 ECG system.

The CARDEA 20/20 ECG system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CARDEA 20/20 ECG system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CARDEA 20/20 ECG system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (*P*) of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1: At 80 MHz and 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.

10.6.4 FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

10.7 Operational Environment

Temperature: 10º to 40º C (50 º to 104 º F)

Humidity: 25% to 95% RH (non-condensing)

Atmospheric pressure range: 50kPA to 106kPA

Ingress of Solids and Liquids:

EN 60529:1991, Level IPX2 (Bluetooth ECG Transmitter Model CS-2020-A)
EN 60529:1991, Level IP55 (USB ECG Transmitter Models CS-2020-B, CS-2020-C)

10.8 Shipping and Storage Environment

Temperature: -20º to 70º C (-4 º to 158 º F)

Humidity: 25% to 95% RH (non-condensing)

Atmospheric pressure range: 50kPA to 106kPA