VectraplexECG System
With
CEB (Cardiac Electrical Biomarker)

User Manual

VectraCor Document #: 630001

VECTRACOR
Diagnosing Better Care

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Caution: Federal US law restricts sale of the device identified in this manual to, or on the order of, a licensed physician.

VectraCor assumes no responsibility for any injury, or for any illegal or improper use of the product, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or indications for use published in this manual.

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For information about any VectraCor product, please call VectraCor Technical Support:

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Suite 100
Totowa, NJ 07512
Phone – 973-904-0444
www.vectracor.com

Note: VectraplexAMI is VectraCor's Cardiac Electrical Biomarker (CEB).
VectraplexAMI and CEB are synonymous. VectraCor is moving forward with their brand name CEB as the Cardiac Electrical Biomarker. References to VectraplexAMI still exist.

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General Cautions & Warnings

Before conducting tests read the General Caution & Warnings and the specific Cautions & Warnings pertaining to your particular medical device. If you need further assistance see Service.

Glossary of Symbols

Consult Instructions for Use

Caution/Warnings
Consult Instruction's for Use for important cautionary information

Defibrillator proof type CF equipment
Defibrillator proof type CF equipment complying with IEC Publication 60601.

CE Mark
Indicates this device is in compliance with MDD 93/42/ECC. 0086 is the Notified Body Number. (Note: This CE mark is in reference to the QRS Diagnostic Universal ECG®)

Underwriters Laboratories
Canadian and United States with respect to electric shock, fire and mechanical hazards only in accordance with UL2601-1 and CAN/CSA C22.2 no.601.1 Control number 52FM.

Do not reuse.

Class II, Electrical Equipment.

REF Catalogue or Model Number

S/N Serial Number

Manufacturer

Authorized representative in the European community.

Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment.

Rx only Federal (USA) law restricts this device to sale by or on the order of a physician.

Latex-Free Product is Latex-Free

Upper Limit of Temperature

Batch Code

Important Information Regarding Instruction for Use

- Instruction for use are only provided in electronic format and are provided in all Member States of the EU where product is available.
- Customers can request a hard copy of the instruction for use by contacting VectraCor within 30 days of receiving equipment at no additional cost.
- Any request for a hard copy of the instruction for use after 30 days upon receiving the equipment can be provided at a cost.
- Customers can contact VectraCor either by phone or email to request a hard copy of the instruction for use.
- When a hard copy of the instruction for use are requested, a hard copy will be provided with 7 days of receiving the request.
- Current and previous revisions of instruction for use are available on www.VectraCor.com.

⚠ Warnings

- The CEB® index has only been tested in comparison to physician interpretation of standard 12-lead ECGs in patients presenting to an acute care setting, and not in comparison to additional clinical data documenting the presence of acute myocardial infarction.
- Do not use the VectraplexECG System in presence of flammable anesthetic mixture.
- Do not operate VectraplexECG System in an explosive atmosphere.
- Use of accessory equipment not complying with EN60601-1 and/or UL2601-1 or equivalent safety standard may lead to a reduced level of safety of the resulting system.
- Computers and printers used with VectraplexECG System should be evaluated to EN 60950-1, EN60601-1 or equivalent safety standard to maintain the safety of VectraplexECG System.
- Do not use any VectraplexECG System on children or vulnerable adults without proper supervision.
- Ensure patient cabling or tubing is carefully routed on all VectraplexECG System to reduce the possibility of patient entanglement or strangulation.
- Turn off filters if you are going to use for diagnostic purposes.
- If the CEB® index displays a value greater than 94, make sure the patient is in a resting position with no movement and monitor patient to determine if the CEB® index predominantly remains above 94. If the CEB® Index falls below 95, while the patient is in a resting position (no movement), then continue to monitor patient.
- Consider immobilizing electrode wire movement by securing the wires to the patient (example: with tape).
- Avoid patient movement to reduce artifact and potential increase or decrease in CEB® index. The ECG Device is for acquiring resting ECGs and monitoring patients only. The Device should not be used for stress testing.
- In calculating the CEB® index, the ECG tracing should have a relatively flat baseline.
- Do not use the CEB® index as the final diagnosis, still need the physician diagnosis. If the CEB® index displays an AMI condition, the physician needs to connect all 10 electrodes to obtain a diagnostic quality ECG and use the print out for actual diagnosis.
- The dECG may under-estimate the mECG when the mECG is at high voltages for leads V4-V6.
- The computerized interpretation is only valid when used in conjunction with clinical findings. All computer generated tracings and interpretations must be confirmed by a qualified physician. Test interpretations are intended for the physician's use only. The computerized interpretation is for the 12-lead ECG only using 10 electrodes.
- All ECG numerical, graphical and interpretive data should be evaluated with respect to the patient's clinical and historical picture.
- Physicians should compare the Heart Rate display to ECG graphs for accuracy.
- The displays for CEB® and Heart Rate are refreshed approximately every 12-18 seconds depending on the configuration of the system.
- Do not interpret the accessory leads (XYZ) as shown on page 2 of the report, or the vector loops on page 3 of the report, without having the 12-lead ECG available for concomitant interpretation.
- The CEB® Index is accurate if the 10 seconds of derived ECG data does not include the following:
    - Wandering baseline, Noise, Premature Ventricular Contractions (PVCs) Paced Beats, improper placement of electrodes, missing leads (disconnected leads), patients younger than 18 years old, and Bundle Branch Block.
- Though false positive errors will intentionally outnumber false negative errors, both will occur, thus the necessity for over reading by a qualified physician of any computer-interpreted ECG. The computer interpretation does not produce a definitive diagnosis.

- Restoring the database erases all of the data located in the VectraplexECG System software and replaces it with the data contained in the back-up file. Data that was acquired after the date of the last back-up will be lost and cannot be recovered.
- The ECG does not provide means to protect the patient against burns when used with HF surgical equipment.
- The ECG is protected against malfunction caused by electrosurgery.
- Loss of ECG signal may occur during high frequency electrosurgery. Signal should re-establish within 10 seconds of removal of the high-frequency source. No other conditions of use must be met to operate the device in a high frequency electrosurgery environment. Indications for use are the same as stated above.
- If signal quality is lost due to electromagnetic disturbances, the ECG signal may be affected which can lead to incorrect diagnosis.
- Make sure that virus protection software and firewall software are installed and not disabled.
- Once deleted, data can only be recovered from the date of your last back-up. Maintain regular back-ups to ensure data is not lost.
- If used in a Critical Care setting, have a backup FDA registered device available if current system is down.
- The ECG Device is not intended for use in a sterile environment. Do not use for direct cardiac application.
- The ECG Device is reusable.
- Do not attempt to insert the ECG device (including patient cables) into an electrical outlet.

- Ensure electrodes are connected only to patient.
- Conductive parts of electrodes and connectors, including neutral electrode, should not contact other conductive parts including earth.
- Select a three lead view during defibrillation to ensure signals are clearly separated following electrode polarization.
- Isoelectric segments within the QRS are excluded from the Q-, R-, or S- waves.
- Defibrillator warnings:
  - Do not touch the patient during defibrillation.
  - Do not touch the defibrillator's paddle-electrode surface when discharging the defibrillator.
  - Keep defibrillation electrodes well clear of other electrodes or metal parts in contact with the patient.
  - Do not touch the patient, bed, or any conductive material in contact with the patient during defibrillation.
  - When defibrillation discharge is applied, the ECG may be overloaded with voltage, but will recover normal function within 5 seconds.
  - Only use electrodes that comply with AAMI EC12:2000.

⚠ Cautions

Disposal Instructions: Due to the potential presence of hazardous substances in electrical or electronic equipment, DO NOT dispose of medical devices with municipal waste. Improper disposal could have an adverse effect on the environment and human health.

For VectraCor's products not marked with please contact your local municipal waste company for proper disposal instructions.

For VectraCor's product marked with please contact your local sales representative (from whom you purchased the product) or your local municipal waste company for proper disposal instructions.

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- All VectraCor's products are intended for use by a physician or by trained personnel under a physician's supervision. Read all instructions for use and specifications provided prior to use.

⚠ **Important! VectraCor's products are intended for use in the electromagnetic environment(s) specified below. Users of this equipment should ensure that it is used in such environment(s).**

Attention should be paid to the following EMC information prior to installing or using VectraplexECG system.

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of VectraplexECG System. RF equipment should only be used no closer than 30 cm (12 inches to any part of the VectraplexECG system.
- The Universal SmartECG is designed for use with electrodes that comply with AAMI EC12:2000.
- Universal SmartECG has been tested and found to comply with IEC/EN 60601-1-2.
- Computers, cables and accessories not tested to 60601-1-2 may result in increased emissions or decreased immunity of VectraCor devices.
- Verify normal operation if utilizing VectraCor medical devices adjacent to or stacked with other electrical equipment.
- Leakage current of device is increased when several items of the device are interconnected. However, leakage current is tested to be within acceptable levels.
- No specific filter settings were used to pass the distortion test.

Guidance and manufacturer's declaration - electromagnetic emissions and immunity		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	VectraCor equipment uses RF energy only for its internal function. Therefore, its RF emissions are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	VectraCor medical devices are suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment Guidance
	Universal SmartECG		
Electrostatic Discharge (ESD)	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	✓	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	✓	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	✓	Portable and mobile RF Communications equipment should be used no closer to any part of VectraCor medical devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ 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] Interface may occur in the vicinity of equipment marked with the following symbol:

NOTE: 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 VectraCor medical devices are used exceeds the applicable RF compliance level above, VectraCor medical devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating VectraCor medical devices. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and VectraCor medical devices.

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

Rated maximum output power 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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Security precautions:

- User is responsible for protection of the login credentials/ access controls used to access the PC hosting VectraplexECG and patient database. VectraCor will not be able to give access to any user who has lost their access to their host PC.
- User is responsible for equipping the PC hosting VectraplexECG and patient database with necessary protection against external attacks (virus, malware etc.) and protection configuration.
- VectraCor strongly recommends the user utilize credible antivirus, malware protection, firewall, etc. software on each piece of equipment where patient information is stored. Please keep in mind that VectraCor software will need to be given appropriate permissions to operate properly.
- User is responsible for creating/maintaining logs of login or VectraplexECG usage information. VectraplexECG inherently stores log/audit information for each day as a .txt file. Log files are created and stored in 'logs' folder located at "C:\Vectraplex\logs". The log file is named in the format "VectraplexECG_YYYYMMDD". User is responsible for the security permissions/access control of the 'logs' folder storing VectraplexECG log files.
- User is responsible for patient database including patient demographic information and patient medical data. VectraCor will not receive or maintain any patient identifiable data.
- User is responsible for scheduled backup of the database to prevent data loss due to

unforeseen circumstances. Refer BACKING UP AND RESTORING DATABASE section for instructions.

- User is responsible for the integrity of VectraplexECG software and its components residing in the PC.
- VectraCor does not access, store or modify the patient demographic and medical data stored in the VectraplexECG database residing in the user's PC.
- Use of other equipment that connects to the network may result in unidentified risks to patients, operators or third parties. The User is responsible for identifying, evaluating, and controlling these risks.
- Changes to the network (including, but no limited to changes in network configuration, connection of additional items, disconnection of items, update of equipment, or upgrade of equipment) may introduce new risks that requires additional analysis.

Electrical Safety Classifications

Note: These classifications currently apply only to VECTRACOR/QRS Medical Devices.

- Class II Equipment, Internally Powered.
- Type CF Equipment. Note: Universal ECG/VectraplexECG is Type CF with defibrillator-proof applied part.
- IPXO - Ordinary Equipment.
- Continuous Operation.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Accessories

Tab Electrodes

- Gel: Adhesive Gel
- Chloride Content: 4%
- Substrate: Synthetic Paper or Vinyl
- Sensor: Ag/AgCl
- Shape/Size: Rectangle, 1" x 7/8"
- Adhesive Performance: Usable up to 1 hour
- Shelf Life: 2 years, when stored between 10-32°C

Wet Gel Electrodes

- Superior Conductivity
- Up to 72 hours of continuous use
- Better Skin Contact
- Recommended for VectraplexECG System

Snap Electrode Adaptors

- Universal Adapter fits both snap and tab electrodes: Fits 3 mm to 4 mm pin leads
- Latch Lock System: Securely locks on electrodes, leads won't detach
- Secure Connection: Reduces false alarms
- Re-usable: Adapters can be cleaned/sterilized and re-used

Indications for Use

The Vectraplex ECG system with CEB is intended for use by healthcare professionals in a healthcare setting where ECG monitoring/acquisition is indicated for adult (18+) patients. Specific indications include the following:

- The System is intended to derive, display and print a derived 12 lead ECG as well as the X, Y, Z leads from the acquisition of just 3 leads (5 electrodes). The System also has the capability to acquire the standard 12 lead ECG using the standard 10 electrodes and convert the ECG signal into a digital format.
- The 12 lead interpretive software is a windows-based program intended to interpret electrocardiograms. The software receives, displays and stores a single, three or standard 12 lead simultaneous ECG recording, which is transmitted either locally or transtelephonically from an ECG monitor using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze and interpret the 12 lead ECG signal only.
- In 5 electrode mode, the System analyzes data from 3 leads (5 electrodes) and produces visual and audible alarms for ECG changes that may be consistent with 12-lead ECG signs of Acute Myocardial Ischemic Injury, including Acute Myocardial Infarction. This mode is not intended to be a sole means of diagnosis, but prompts the user to acquire a standard 12 lead ECG (using 10 electrodes) for interpretation by a physician when the CEB is 95 or greater. Monitoring patients with a CEB is only indicated for patients presenting with chest pain or other presumed anginal equivalents.
- The interpretation software is only available for the standard 12 lead ECG utilizing the standard 10 electrodes.
- The System is intended to be used by healthcare professionals, or trained personnel.
- The System can be used within electrosurgical environments.
- Device is for Adult use.

Application Specification

Medical Indication:	Diagnosis of cardiovascular conditions/diseases
User Profile:	Trained professional
Patient Population:	Adult Male/Female (18+)
Environment of Use:	Hospital and Clinical Use
Tissue Type of Device Interaction:	Patient Skin
Conditions of Use:	Single patient, non-sterile, single-use electrodes, non-invasive, resting ECGs, continuous use, portable
Operating Principle:	[Physical Method] Electrodes are attached to the patient to acquire the ECG (electrocardiogram) with software application. [Mechanism] The attached electrodes records the ECG signal. The software application starts and stops the recording of the ECG. Then, the software can display or print a hard copy of the ECG report.

VectraplexECG System Basics

System Requirements

Operating System:	Windows 7 or 10
Free Disk Space:	minimum of 1 GB
Screen Resolution:	minimum 1024x768 (EKG Requirement)
ECG Devices:	Universal ECG, Universal SmartECG

IT-Network information:

- Purpose of networking: Networked databases can be accessed by multiple computers and integrate of Office Medic test sessions to an EMR/HER
- Required characteristics: Windows NT Client/Server domain.
- Required configuration: Windows NT Active Directory
- Technical specifications: Microsoft SQL trusted connect string
- Intended information flow: The Office Medic software utilizes a Software Developer Kit (SDK) and calls Office Medic to perform tests and return test data.

Co-Installed Software:

- bioPDF: This is installed by VectraCor and *should not be removed*.
- Vectraplex Information System (VIS): This is optional software that must be installed in order to use the Electronic Medical Record (EMR/EHR) export feature.
- License Key: A license key has been entered into the system to activate the VectraplexECG Software. If there are any problems a dialog box may appear requesting license information. If this is seen contact VectraCor.
- Adobe Acrobat: This is installed by VectraCor and *should not be removed*.

Installation

For VectraplexECG 4.0.0 or later (previous versions come pre-installed):

1. Ensure you are logged in with Administrator rights.
2. Remove all QRS devices from the computer.
3. Log out and close all programs.
4. Insert the VectraplexECG/OM installer media.
5. Select a language. (Will only affect Office Medic)
6. Click Next.
7. You will be given a choice to install either VectraplexECG only or VectraplexECG and Office Medic together. Click Next.
8. Choose a destination folder. Click Next.

9. You will be given a choice to install a local or network database. The Network option requires an Office Medic Network Database formally called IDMS database. To learn more about obtaining a Network database, and networking VectraplexECG/Office Medic, contact Customer Care at VectraCor.

⚠ Attention! In order to review or modify ECG (SCP) files with a network database, the SCP files directory should reside on a shared network folder where all VectraplexECG instances have read/write access to the contents. Refer to General Tab under VectraplexECG Configuration menu for more details regarding changing the SCP files directory.

10. You will be given a choice to set the default units. Click Next.

11. The setup will proceed with the installation process. The setup may install programs and drivers that are not present in the system.

12. Click Finish. VectraplexECG will open automatically after the installation finishes.

1. Connect the ECG patient cable to the PC using the USB port.

2. Once plugged, the ECG device will notify its status via an LED light on the device:

LED Light Status	ECG Status
Off	ECG is not powered
On	ECG is powered
Blinking Continuously	ECG is receiving and sending data

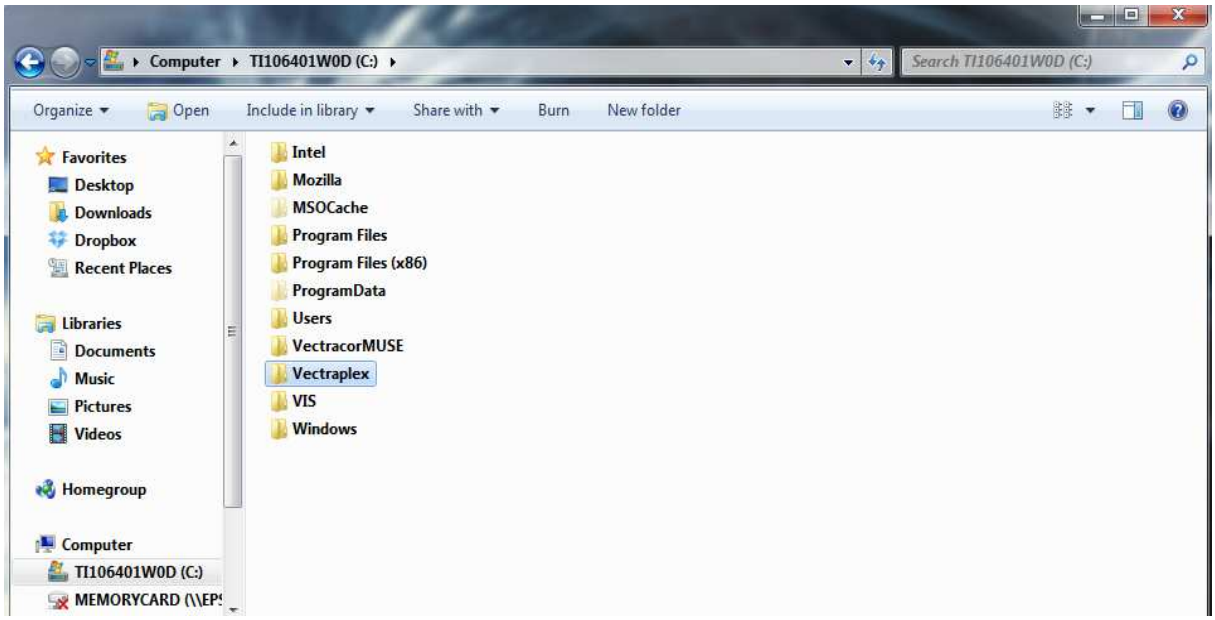
Backing-up and Restoring the Database

Database Back-up Instructions

Backing-up your database protects you from losing your patient data should a catastrophic event occur. Regular back-ups of the database should be maintained. Follow the steps below to back-up the database:

1. Close VectraplexECG System.
2. Copy the Vectraplex folder- C:\Vectraplex.

3. Paste the Vectraplex folder in a secure location and rename the folder with the title of “backup” and the current date.



Database Restore Instructions

⚠ Warning! Restoring the database erases all of the data located in VectraplexECG and replaces it with the data contained in the back-up file. Data that was acquired after the date of the last back-up will be lost and cannot be recovered.

Follow the steps below to restore the database:

1. Close VectraplexECG.
2. Copy and paste the latest backup folder from the secure backup location to the C drive.
3. Rename the folder to “VectraplexECG”
    a. This should remove the title “backup” and the date the backup occurred.
4. Open VectraplexECG.

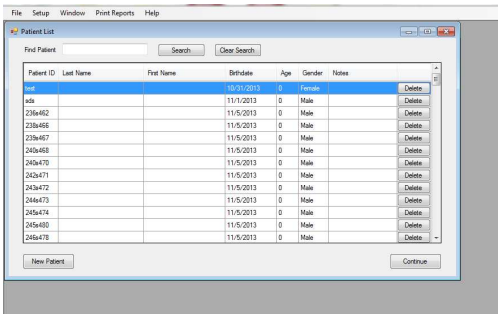
The database should look exactly as it did on the date of the last back-up.

Getting Started - Navigation

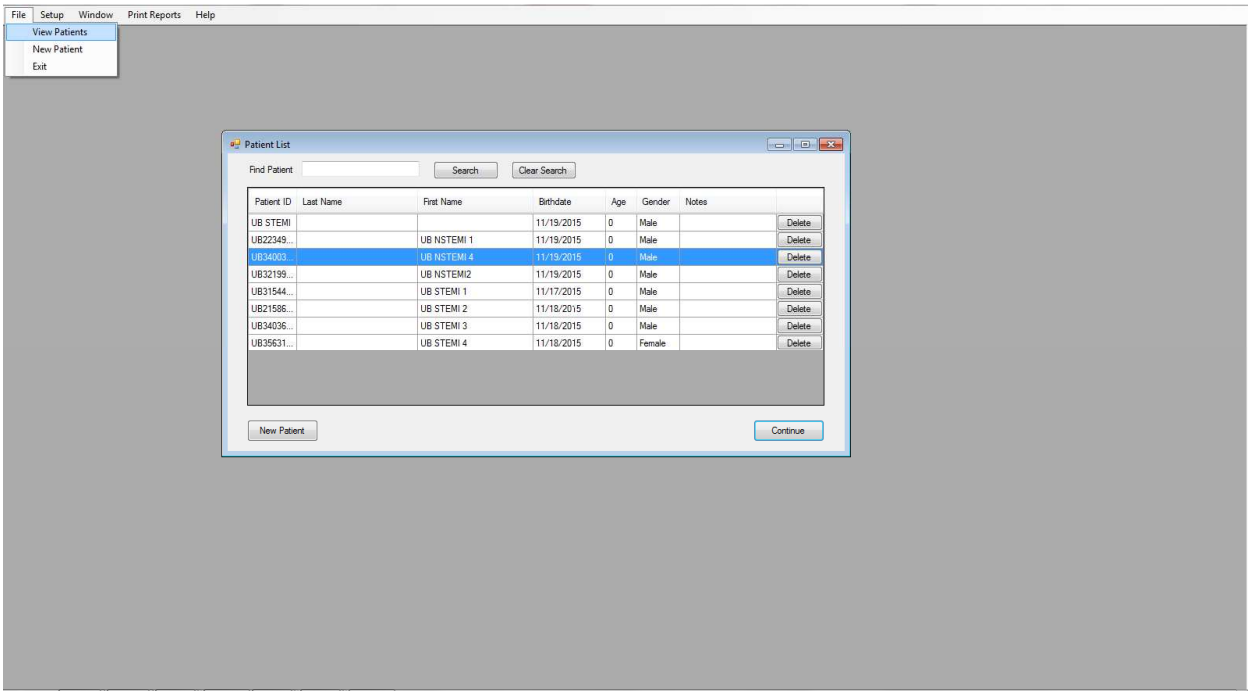
Select the VectraplexECG icon, on your desktop, on your taskbar, or in the Start menu, to run the software. The initial screen displays VectraplexECG (splash screen) for 5 seconds and then the home screen appears. The initial screen displays as follows:

Splash Screen

Home Screen



File Tab

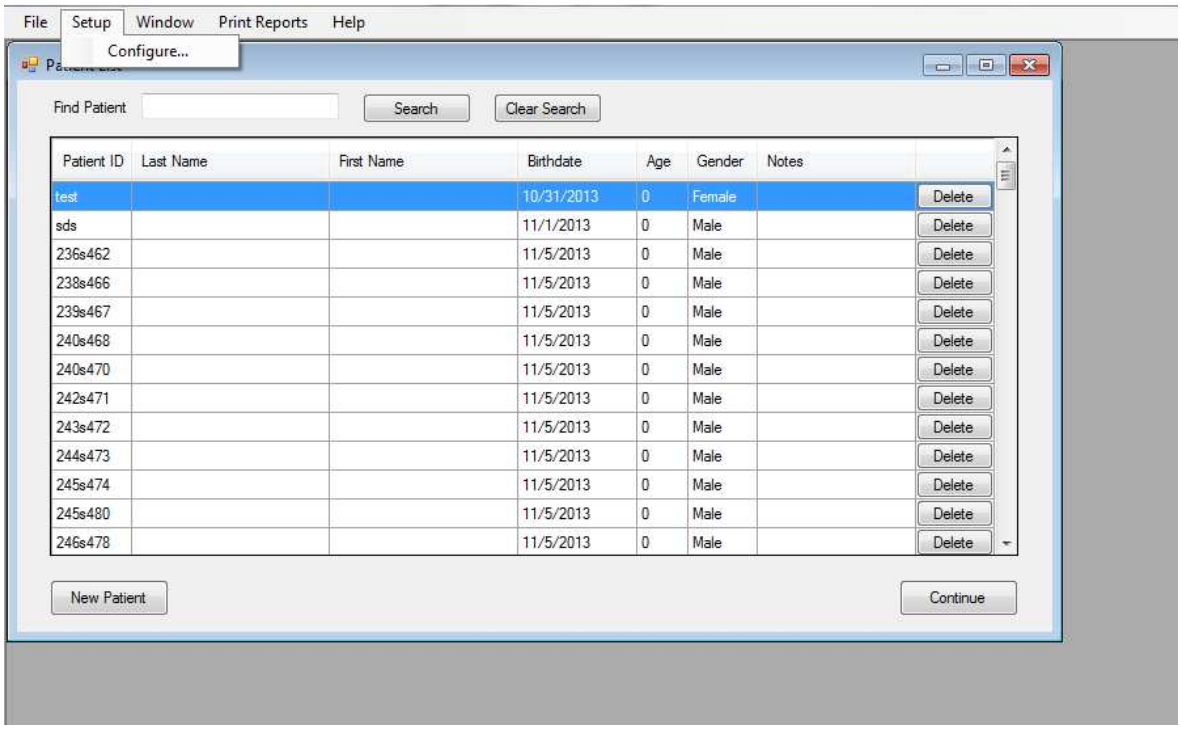


View Patients – Display the Patient List Screen

New Patient – New Patient will bring up the New Patient window, the same as the New Patient button on the Patient List window.

Exit – Exit will exit the VectraplexECG program. Select VectraplexECG Shortcut Icon to start again.

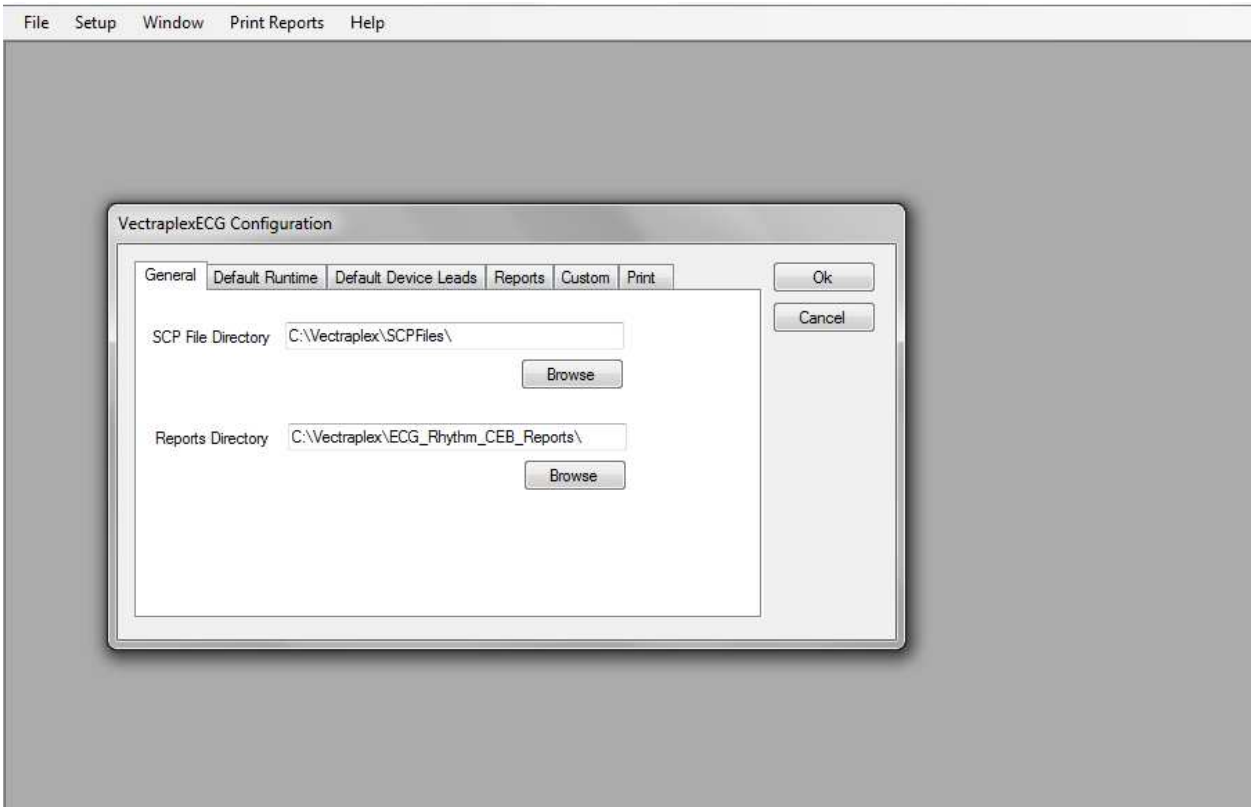
Setup Tab – VectraplexECG Configuration Menu



Select Setup to change program settings.

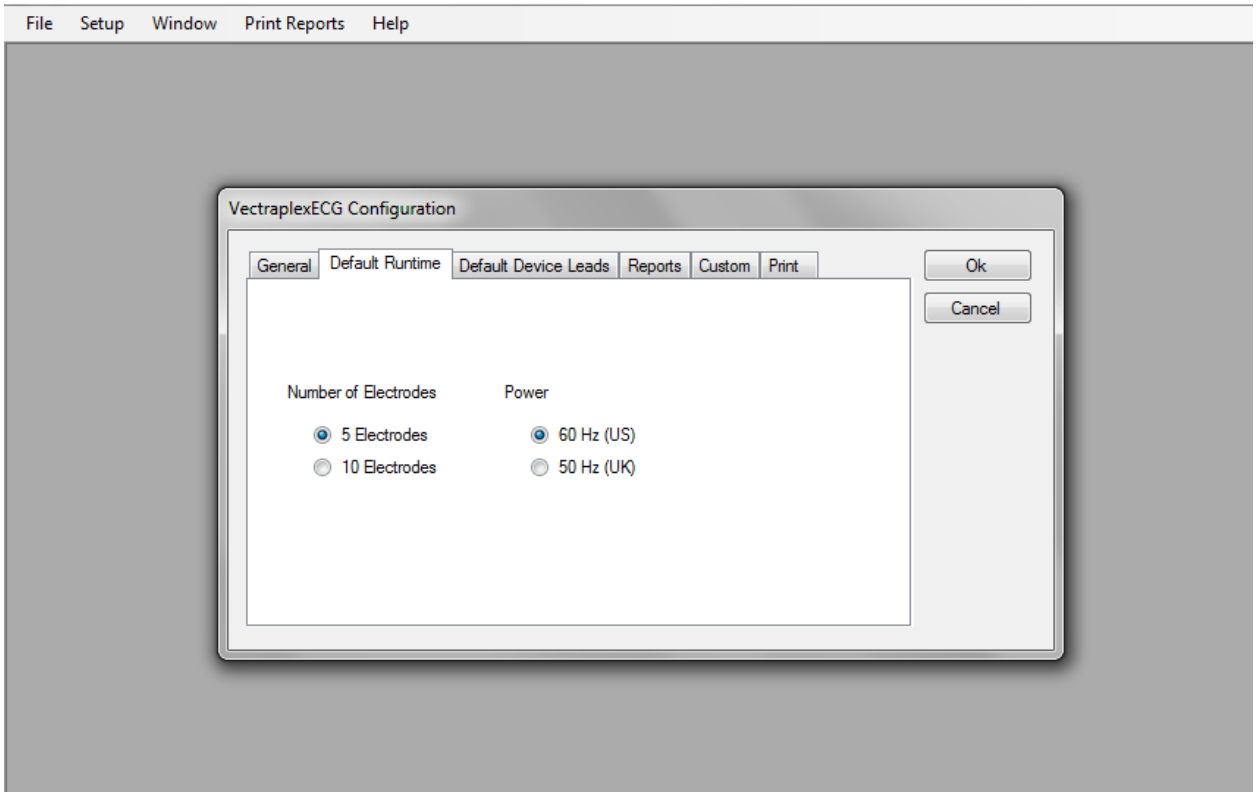
General Tab

- SCP File Directory is the location the patient ECG data will be saved. The default location is “C:\Vectraplex\SCPFiles”.
- Reports Directory is the location a PDF copy of the reports from the Print Reports tab will be saved. The default location is “C:\Vectraplex\ECG_Rhythm_CEB_Reports\



Default Runtime Tab

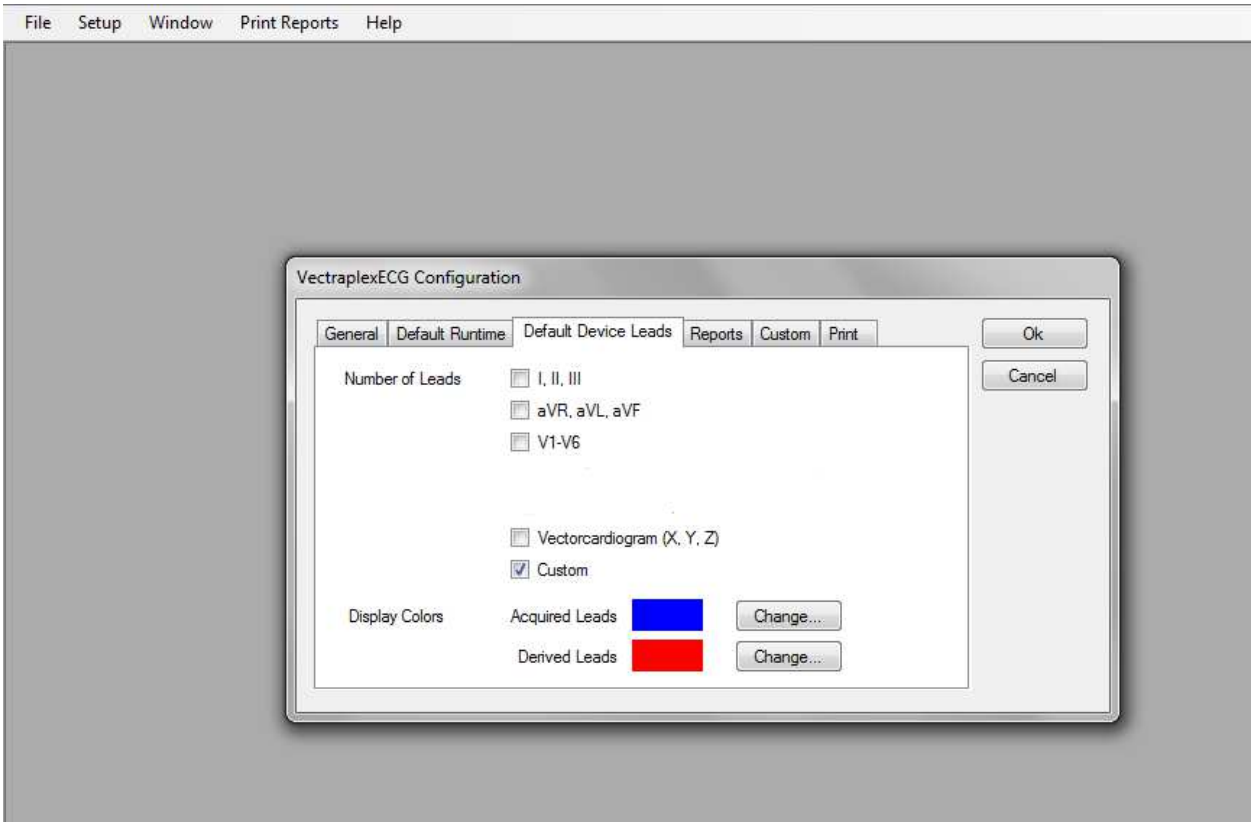
- **Number of Electrodes** – Select the button for the number of electrodes you will use on the Patient. Selecting 5 or 10 electrodes will always produce the 12-lead and XYZ lead ECG.
- **Power** – Select the Power requirement for your location



Default Device Leads Tab

This is the selected defualt display for the Monitor Screen during Live Acquisition.

- **Display colors** – This diplays the color of the leads on the screen.
- **Acquired Leads** – measured; Blue is default
- **Derived Leads** - Red is default

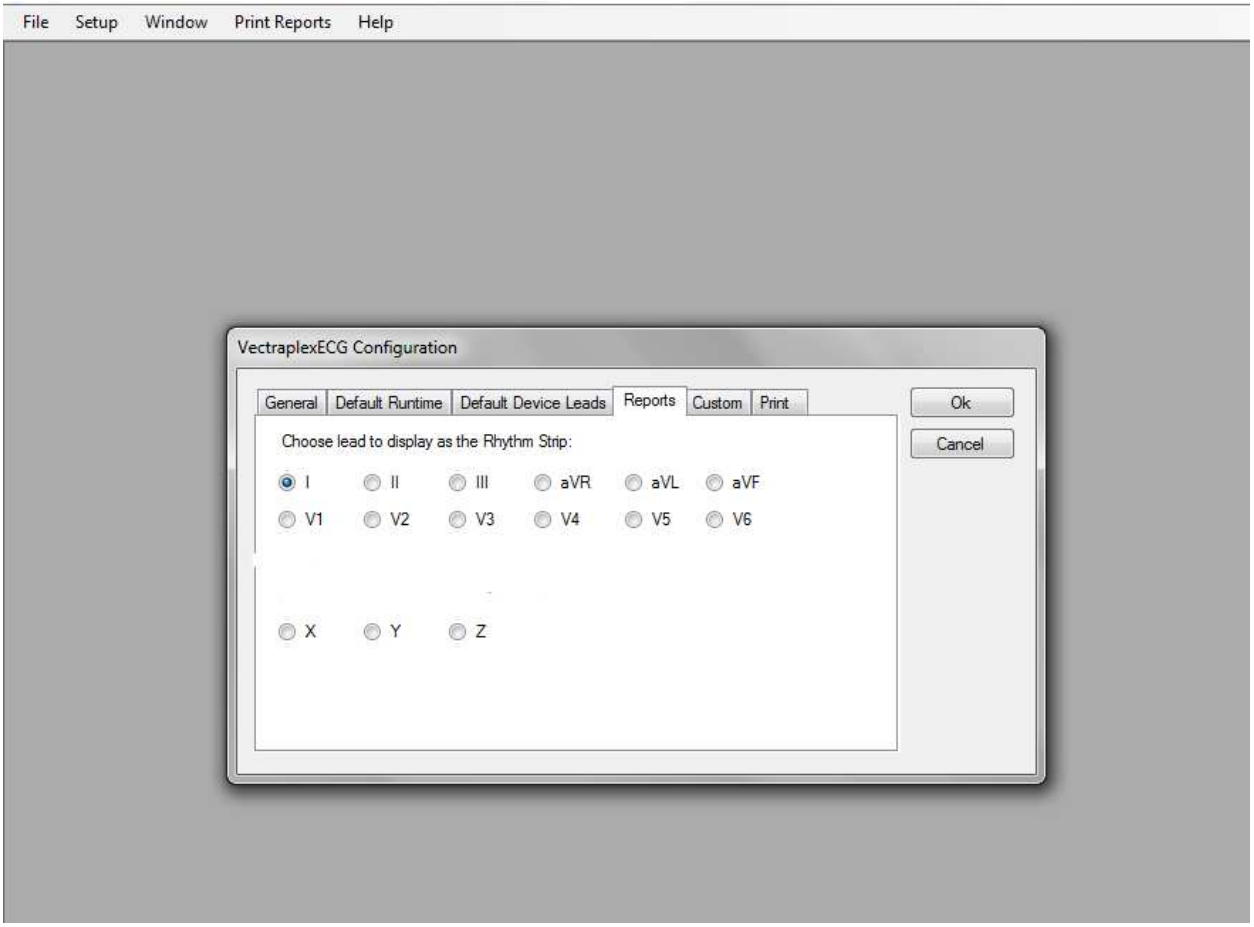


Note:

1. The more leads selected to display on demand, the slower the refresh on the monitoring screen.
2. The default setting is to display leads I, II, and V2.

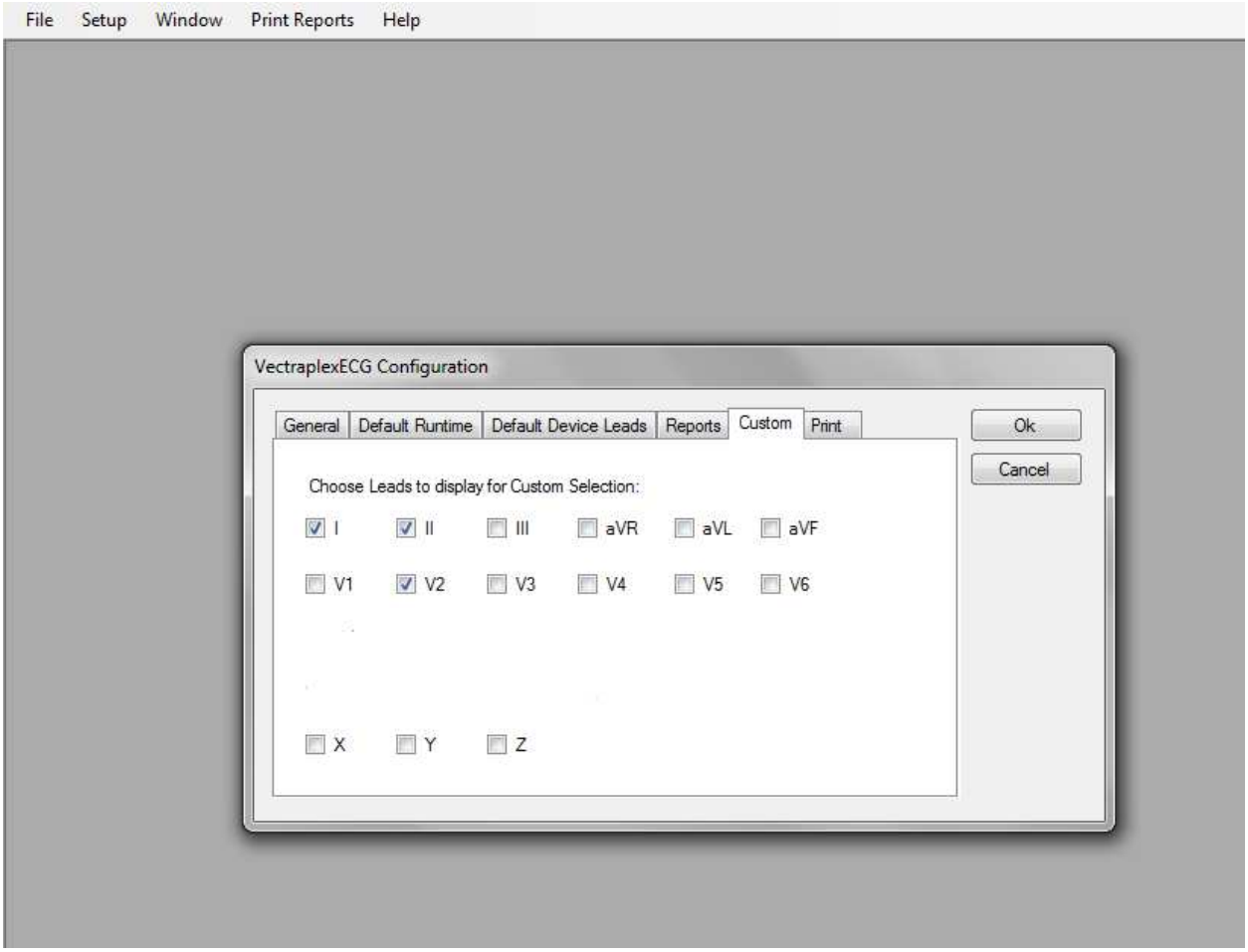
Reports Tab

Select the lead you want to display in the Report and Report Preview Screen as the rhythm strip.



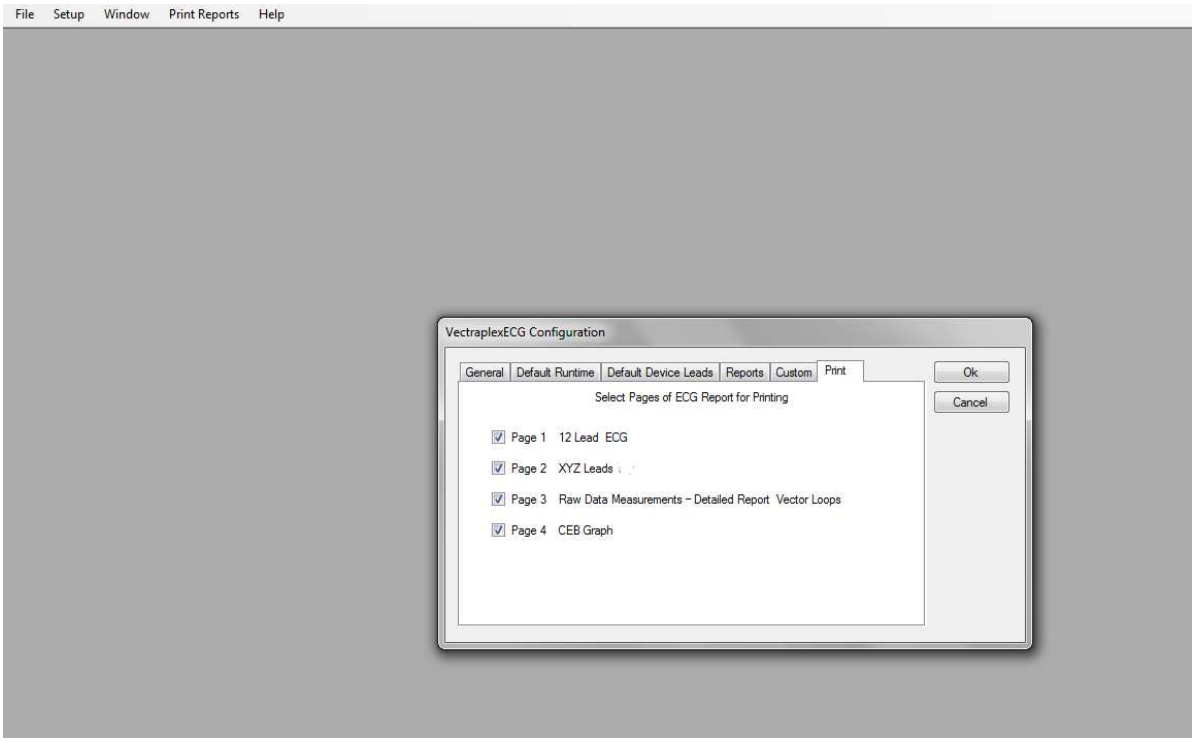
Custom Tab

Select the leads you want to display when using the “Custom” lead group selection in the Display ECG and Capture ECG Screen.



Print Tab

The Print tab is used to select the default pages to display and print for the ECG Report. This selection will also affect the pages that can be viewed during print preview. This setting is defaulted to all pages.

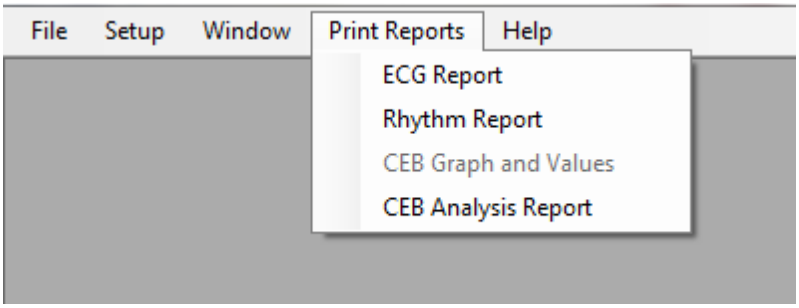


Note: Selecting “OK” exits the user from the configuration window.

Windows Tab

Lists the window screens that are currently open. Click on the listed window to bring it to the front of the open windows.

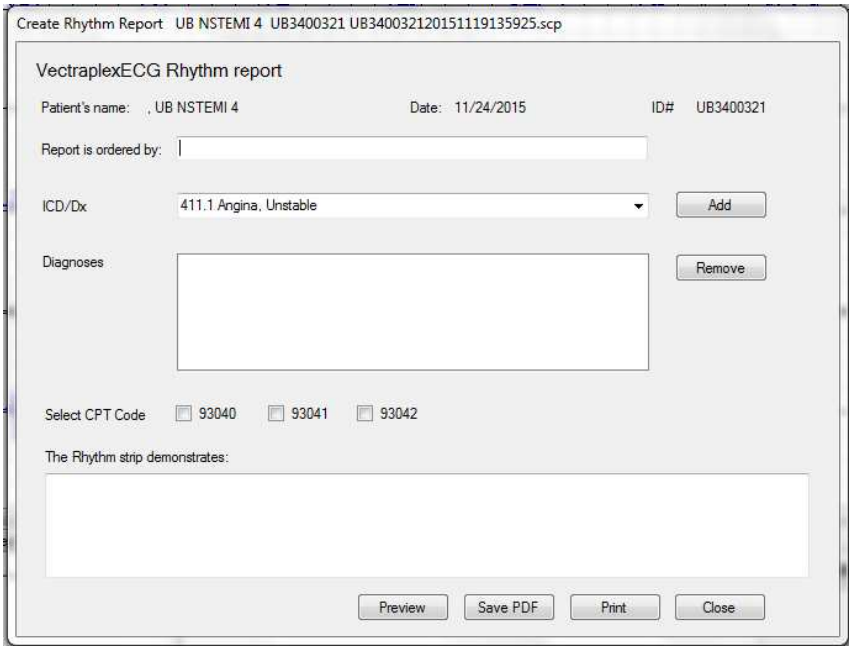
Print Reports



ECG Report – This will print an ECG Report. This option is available from a Capture ECG screen. This will bring the user directly to printer options, without reviewing the scalar graphs. The user can choose to print a range or specified pages of the ECG scalar graphs, only from this menu. If the user would like to see the scalar graphs, prior to printing, select Preview Report button.

Rhythm Report – This will print a Rhythm Report. This option is only available from a Capture ECG screen.

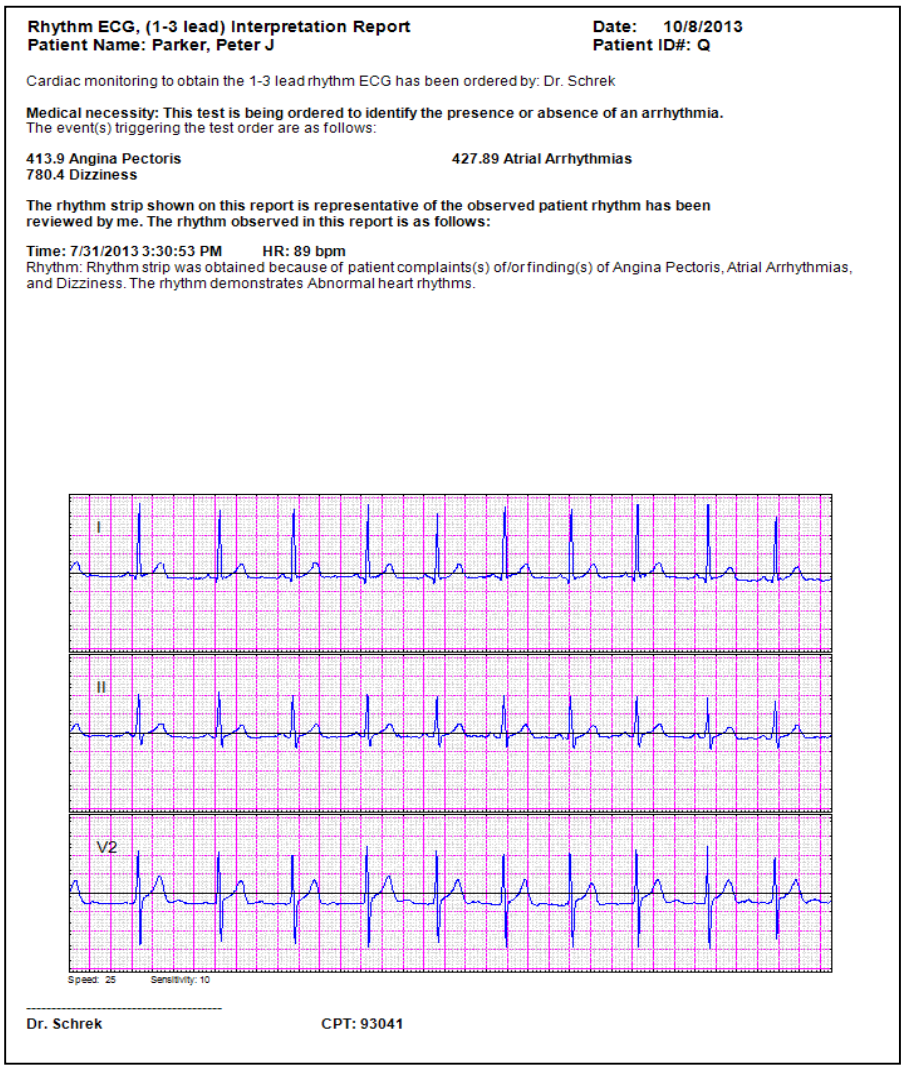
The Rhythm Report can be either previewed or printed by selecting the Print Reports > Rhythm Report menu item. A dialog will be presented to allow the user to enter *Report is ordered by*, *ICD/Dx*, *CPT Code(s),* and interpretation for *the Rhythm strip demonstrates* section.



Rhythm Report Setup items:

Report is ordered by - enter the Interpreting Physician's name.
ICD/Dx – select the patient symptoms from this drop-down list. Once a selection is made, click Add to include it in the Diagnoses list. Multiple items can be added to the list. New items can also be typed in to add to the list.
CPT Code – select a CPT Code checkbox for each Rhythm Report to be printed. Reports will be identical except for the CPT Code.
The Rhythm strip demonstrates – enter any further comments about the interpretation of the rhythm here.
Print – send the report(s) directly to the printer.
Save PDF- save a copy of the report to the Reports Directory, location specified under the Setup > Configure > Reports Directory
Preview – show the report(s) in a preview window.

A sample Rhythm Report is shown below. Each page of the report displays the information entered in the Rhythm Report Setup Screen, as well as three-lead strips. The selected CPT Code is displayed in the footer. Each CPT Code checked will generate its own page in the report.



Rhythm ECG, (1-3 lead) Interpretation Report **Date: 10/8/2013**
Patient Name: Parker, Peter J **Patient ID#: Q**

Cardiac monitoring to obtain the 1-3 lead rhythm ECG has been ordered by: Dr. Schrek

Medical necessity: This test is being ordered to identify the presence or absence of an arrhythmia.
The event(s) triggering the test order are as follows:

413.9 Angina Pectoris **427.89 Atrial Arrhythmias**
780.4 Dizziness

The rhythm strip shown on this report is representative of the observed patient rhythm has been reviewed by me. The rhythm observed in this report is as follows:

Time: 7/31/2013 3:30:53 PM **HR: 89 bpm**
Rhythm: Rhythm strip was obtained because of patient complaints(s) of/or finding(s) of Angina Pectoris, Atrial Arrhythmias, and Dizziness. The rhythm demonstrates Abnormal heart rhythms.

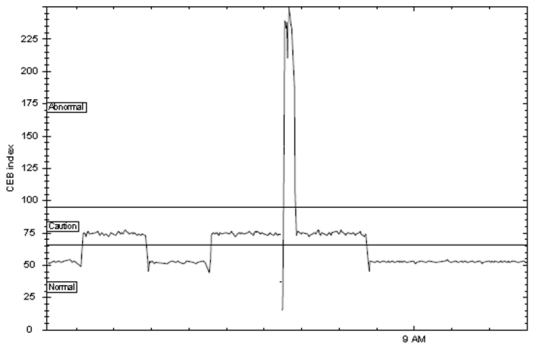
Dr. Schrek **CPT: 93041**

CEB Graph and Values – This will print a report with a CEB graph and values displayed. This option is only available from a Display CEB screen.

The CEB Graph and Values can be printed by clicking the Print button on the Display CEB screen or selecting the Print Reports > CEB Graph and Values menu item when the Display CEB screen is active. The first page of this report displays the CEB® graph and the beginning of the table of CEB® values, formatted into three columns. Subsequent pages show the remainder of the CEB® table. If this report follows an ECG Report then the portion of the graph corresponding to the capture is indicated by vertical lines.

Note: Since an ECG Report only consists of 10 seconds of data, this may appear as only a single vertical line, depending on the length of the acquisition session.

Patient ID: 1234 CEB® Graph and Data



Session Started Thursday, September 05, 2013 8:11:02 AM (hours)
Session Ended Thursday, September 05, 2013 9:15:01 AM

Date/Time	CEB Value	Date/Time	CEB Value	Date/Time	CEB Value
9/5/2013 8:11:02 AM	----	9/5/2013 8:18:43 AM	73.00	9/5/2013 8:24:55 AM	52.00
9/5/2013 8:11:20 AM	52.00	9/5/2013 8:18:59 AM	74.00	9/5/2013 8:25:10 AM	53.00
9/5/2013 8:11:28 AM	51.00	9/5/2013 8:19:21 AM	72.00	9/5/2013 8:25:18 AM	52.00
9/5/2013 8:11:43 AM	52.00	9/5/2013 8:19:29 AM	73.00	9/5/2013 8:25:26 AM	51.00
9/5/2013 8:12:07 AM	53.00	9/5/2013 8:19:37 AM	75.00	9/5/2013 8:25:34 AM	52.00
9/5/2013 8:12:14 AM	52.00	9/5/2013 8:19:52 AM	74.00	9/5/2013 8:27:14 AM	51.00
9/5/2013 8:12:45 AM	53.00	9/5/2013 8:20:16 AM	73.00	9/5/2013 8:27:22 AM	52.00
9/5/2013 8:13:01 AM	52.00	9/5/2013 8:20:39 AM	76.00	9/5/2013 8:27:46 AM	53.00
9/5/2013 8:13:25 AM	53.00	9/5/2013 8:20:55 AM	74.00	9/5/2013 8:28:18 AM	52.00
9/5/2013 8:14:13 AM	54.00	9/5/2013 8:21:02 AM	75.00	9/5/2013 8:28:33 AM	53.00
9/5/2013 8:14:22 AM	53.00	9/5/2013 8:21:18 AM	74.00	9/5/2013 8:28:48 AM	52.00
9/5/2013 8:14:30 AM	52.00	9/5/2013 8:21:26 AM	76.00	9/5/2013 8:29:19 AM	51.00
9/5/2013 8:14:45 AM	53.00	9/5/2013 8:21:33 AM	77.00	9/5/2013 8:29:36 AM	52.00
9/5/2013 8:15:40 AM	49.00	9/5/2013 8:21:41 AM	76.00	9/5/2013 8:29:44 AM	53.00
9/5/2013 8:15:47 AM	59.00	9/5/2013 8:21:57 AM	75.00	9/5/2013 8:30:36 AM	52.00
9/5/2013 8:15:55 AM	74.00	9/5/2013 8:22:05 AM	74.00	9/5/2013 8:31:01 AM	51.00
9/5/2013 8:16:03 AM	75.00	9/5/2013 8:22:28 AM	75.00	9/5/2013 8:31:10 AM	52.00
9/5/2013 8:16:11 AM	74.00	9/5/2013 8:22:35 AM	74.00	9/5/2013 8:31:54 AM	53.00
9/5/2013 8:16:18 AM	72.00	9/5/2013 8:22:43 AM	75.00	9/5/2013 8:32:11 AM	52.00
9/5/2013 8:16:26 AM	74.00	9/5/2013 8:22:59 AM	74.00	9/5/2013 8:32:45 AM	44.00
9/5/2013 8:16:34 AM	76.00	9/5/2013 8:23:06 AM	73.00	9/5/2013 8:32:53 AM	54.00
9/5/2013 8:16:41 AM	75.00	9/5/2013 8:23:22 AM	74.00	9/5/2013 8:33:01 AM	73.00
9/5/2013 8:16:49 AM	74.00	9/5/2013 8:23:37 AM	73.00	9/5/2013 8:33:09 AM	74.00
9/5/2013 8:17:44 AM	75.00	9/5/2013 8:23:45 AM	74.00	9/5/2013 8:33:17 AM	75.00
9/5/2013 8:17:52 AM	76.00	9/5/2013 8:24:16 AM	73.00	9/5/2013 8:33:26 AM	74.00
9/5/2013 8:18:00 AM	75.00	9/5/2013 8:24:32 AM	55.00	9/5/2013 8:33:45 AM	75.00
9/5/2013 8:18:08 AM	73.00	9/5/2013 8:24:39 AM	45.00	9/5/2013 8:33:53 AM	74.00
9/5/2013 8:18:27 AM	75.00	9/5/2013 8:24:47 AM	53.00	9/5/2013 8:34:01 AM	73.00

Patient ID: 1234 CEB® Graph and Data

Date/Time	CEB Value	Date/Time	CEB Value	Date/Time	CEB Value
9/5/2013 8:34:09 AM	75.00	9/5/2013 8:46:09 AM	73.00	9/5/2013 9:04:12 AM	53.00
9/5/2013 8:34:25 AM	74.00	9/5/2013 8:46:32 AM	74.00	9/5/2013 9:04:27 AM	54.00
9/5/2013 8:34:55 AM	75.00	9/5/2013 8:46:47 AM	75.00	9/5/2013 9:04:35 AM	53.00
9/5/2013 8:35:26 AM	74.00	9/5/2013 8:46:55 AM	74.00	9/5/2013 9:04:58 AM	52.00
9/5/2013 8:35:34 AM	75.00	9/5/2013 8:47:10 AM	76.00	9/5/2013 9:05:37 AM	53.00
9/5/2013 8:35:42 AM	76.00	9/5/2013 8:47:18 AM	77.00	9/5/2013 9:05:53 AM	52.00
9/5/2013 8:35:49 AM	75.00	9/5/2013 8:47:26 AM	74.00	9/5/2013 9:06:24 AM	53.00
9/5/2013 8:35:57 AM	74.00	9/5/2013 8:47:34 AM	73.00	9/5/2013 9:06:31 AM	52.00
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9/5/2013 8:36:13 AM	72.00	9/5/2013 8:48:04 AM	74.00	9/5/2013 9:07:10 AM	52.00
9/5/2013 8:36:20 AM	73.00	9/5/2013 8:48:28 AM	73.00	9/5/2013 9:07:40 AM	53.00
9/5/2013 8:36:29 AM	74.00	9/5/2013 8:48:43 AM	75.00	9/5/2013 9:08:04 AM	52.00
9/5/2013 8:36:44 AM	75.00	9/5/2013 8:48:51 AM	74.00	9/5/2013 9:08:42 AM	53.00
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9/5/2013 8:38:12 AM	75.00	9/5/2013 8:50:08 AM	75.00	9/5/2013 9:10:23 AM	53.00
9/5/2013 8:38:29 AM	74.00	9/5/2013 8:50:16 AM	77.00	9/5/2013 9:10:39 AM	52.00
9/5/2013 8:38:38 AM	73.00	9/5/2013 8:50:24 AM	76.00	9/5/2013 9:10:45 AM	53.00
9/5/2013 8:38:45 AM	75.00	9/5/2013 8:50:31 AM	75.00	9/5/2013 9:11:17 AM	52.00
9/5/2013 8:38:53 AM	76.00	9/5/2013 8:50:47 AM	74.00	9/5/2013 9:11:32 AM	53.00
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9/5/2013 8:39:09 AM	76.00	9/5/2013 8:51:02 AM	74.00	9/5/2013 9:12:03 AM	53.00
9/5/2013 8:39:24 AM	75.00	9/5/2013 8:51:10 AM	75.00	9/5/2013 9:12:26 AM	52.00
9/5/2013 8:39:31 AM	74.00	9/5/2013 8:51:41 AM	74.00	9/5/2013 9:12:34 AM	53.00
9/5/2013 8:39:47 AM	75.00	9/5/2013 8:51:56 AM	75.00	9/5/2013 9:12:42 AM	52.00
9/5/2013 8:40:03 AM	74.00	9/5/2013 8:52:12 AM	73.00	9/5/2013 9:13:13 AM	53.00
9/5/2013 8:40:33 AM	73.00	9/5/2013 8:52:20 AM	74.00	9/5/2013 9:13:51 AM	52.00
9/5/2013 8:40:41 AM	74.00	9/5/2013 8:52:43 AM	75.00	9/5/2013 9:14:38 AM	53.00
9/5/2013 8:40:49 AM	75.00	9/5/2013 8:52:51 AM	76.00	9/5/2013 9:14:54 AM	52.00
9/5/2013 8:40:57 AM	74.00	9/5/2013 8:52:59 AM	74.00	9/5/2013 9:15:01 AM	52.00
9/5/2013 8:41:20 AM	73.00	9/5/2013 8:53:14 AM	73.00	9/5/2013 9:15:01 AM	----
9/5/2013 8:41:35 AM	75.00	9/5/2013 8:53:22 AM	72.00		
9/5/2013 8:41:43 AM	74.00	9/5/2013 8:53:29 AM	73.00		
9/5/2013 8:41:51 AM	73.00	9/5/2013 8:53:37 AM	74.00		
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9/5/2013 8:42:25 AM	15.00	9/5/2013 8:55:26 AM	52.00		
9/5/2013 8:42:33 AM	16.00	9/5/2013 8:55:57 AM	53.00		
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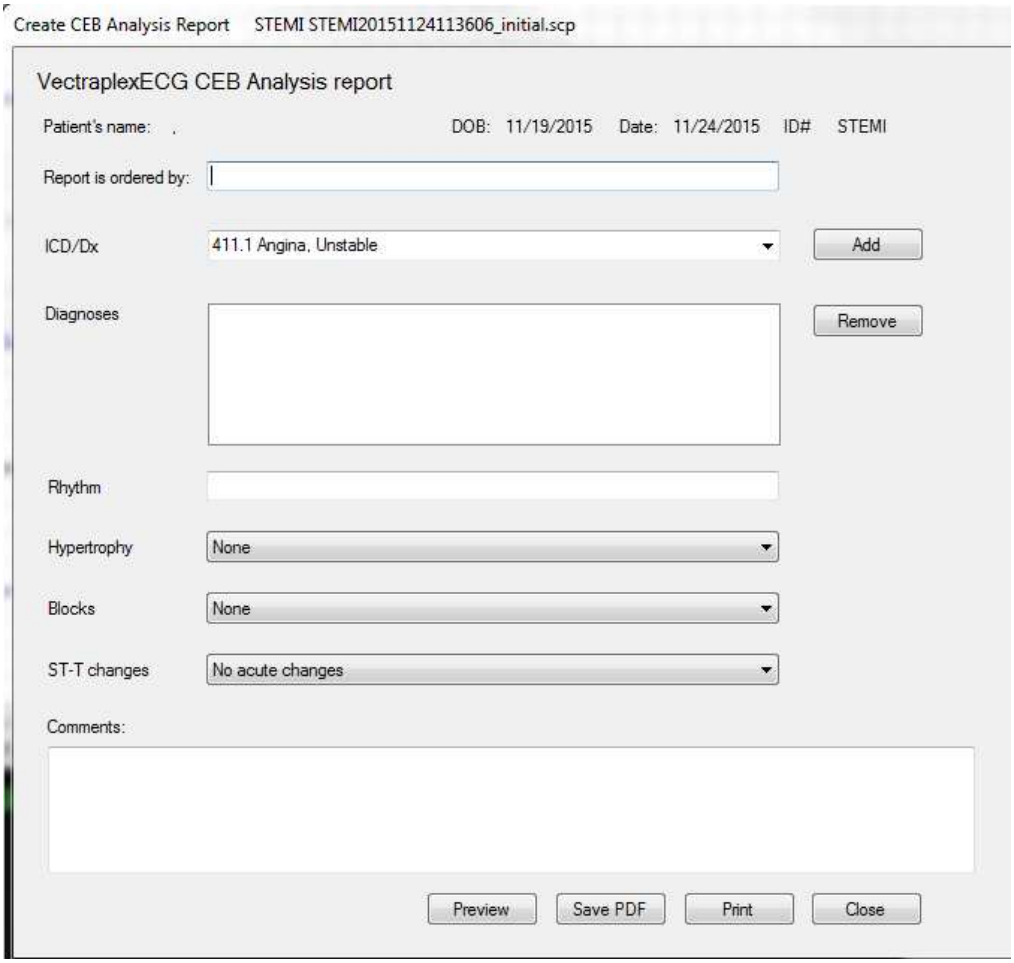
9/5/2013 8:42:57 AM	233.00	9/5/2013 8:56:43 AM	52.00		
9/5/2013 8:43:04 AM	238.00	9/5/2013 8:57:14 AM	53.00		
9/5/2013 8:43:12 AM	210.00	9/5/2013 8:57:21 AM	52.00		
9/5/2013 8:43:20 AM	250.00	9/5/2013 8:58:00 AM	53.00		
9/5/2013 8:43:28 AM	246.00	9/5/2013 8:58:08 AM	52.00		
9/5/2013 8:43:36 AM	235.00	9/5/2013 8:58:15 AM	53.00		
9/5/2013 8:43:43 AM	234.00	9/5/2013 8:58:31 AM	52.00		
9/5/2013 8:43:51 AM	222.00	9/5/2013 8:58:38 AM	53.00		
9/5/2013 8:44:04 AM	188.00	9/5/2013 8:59:02 AM	52.00		
9/5/2013 8:44:12 AM	104.00	9/5/2013 8:59:56 AM	53.00		
9/5/2013 8:44:19 AM	73.00	9/5/2013 9:00:04 AM	52.00		
9/5/2013 8:44:27 AM	75.00	9/5/2013 9:00:12 AM	51.00		
9/5/2013 8:44:35 AM	76.00	9/5/2013 9:00:19 AM	52.00		
9/5/2013 8:44:59 AM	74.00	9/5/2013 9:00:58 AM	53.00		
9/5/2013 8:45:06 AM	75.00	9/5/2013 9:01:37 AM	52.00		
9/5/2013 8:45:53 AM	74.00	9/5/2013 9:02:00 AM	53.00		
9/5/2013 8:46:00 AM	72.00	9/5/2013 9:02:54 AM	52.00		

CEB Analysis Report

– This will print a CEB Report which formats a report of the data over time for the doctor to interpret. This option is only available from a Capture ECG screen.

The CEB Analysis Report can be either previewed or printed by selecting the Print Reports > CEB Analysis Report menu item. A dialog will be presented to allow the user to enter diagnosis, medical codes and interpretation for the report.



CEB Analysis Report Setup items:

Report is ordered by - enter the Interpreting Physician's name.
ICD/Dx – select the patient symptoms from this drop-down list. Once a selection is made, click Add to include it in the Diagnoses list. Multiple items can be added to the list. New items can also be typed in to add to the list.
Rhythm – enter any comments on the patient's current heart rhythm. This is required to move forward.
Hypertrophy, Blocks, ST-T changes – select one of the items from each of these drop-down lists, if applicable.

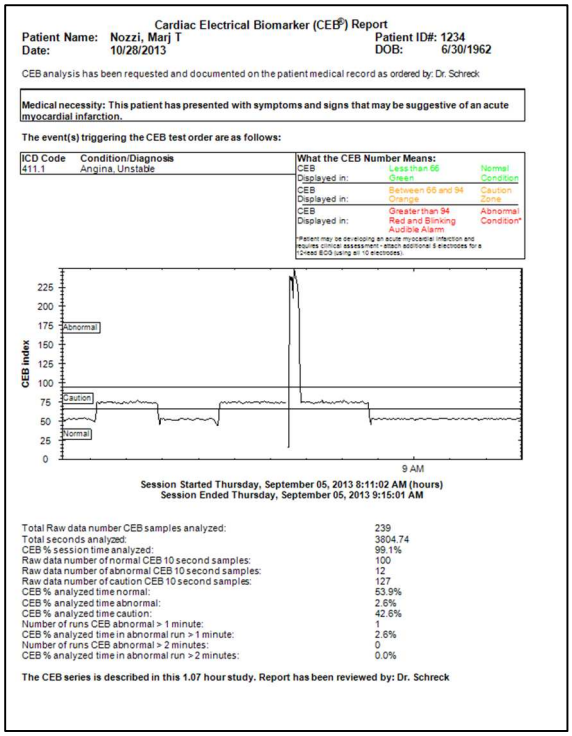
Comments – enter any further comments about the diagnoses here. This is required to move forward.
Print – send the report(s) directly to the printer.

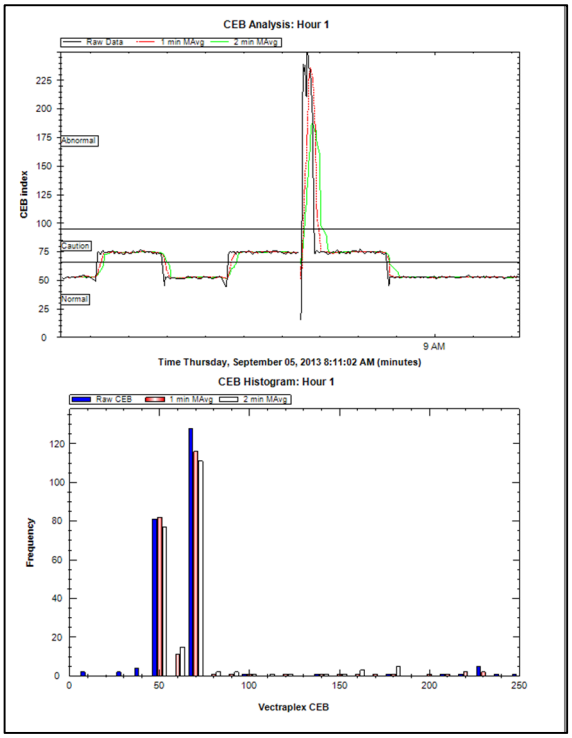
Note: After printing, you will return to this screen, in case you need to print the same report to multiple printers, such as a PDF printer, as well as a standard printer.

Save PDF- save a copy of the report to the Reports Directory, location specified under the Setup > Configure > Reports Directory
Preview – show the report(s) in a preview window.

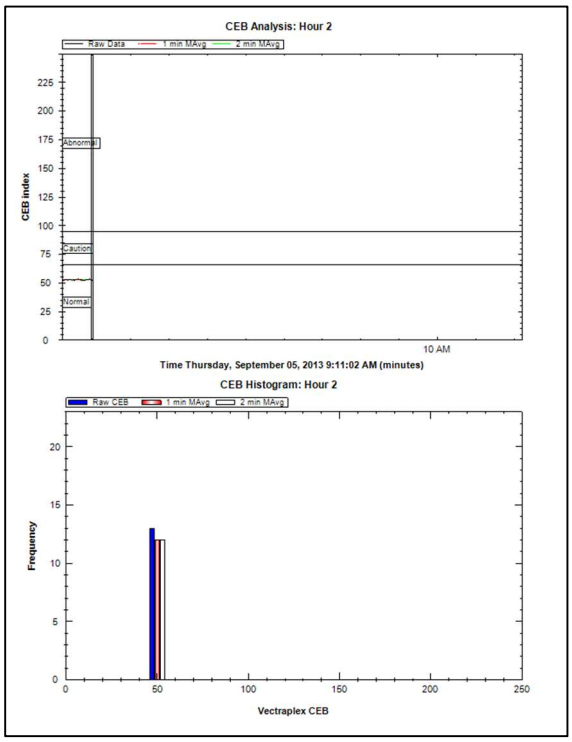
Note: You may Preview and then return to this screen to fill in the Comments before printing by closing the Preview screen.

The CEB Analysis Report contains an introductory summary page, then a page for each hour the CEB data was collected, and then 2 conclusion pages at the end. The last page contains the results from an FDA non-inferiority study. This is not specific to the patient, but gives the user some background information on the study of the CEB. Each hourly page shows a graph of the CEB data for that hour and a histogram of the same data.

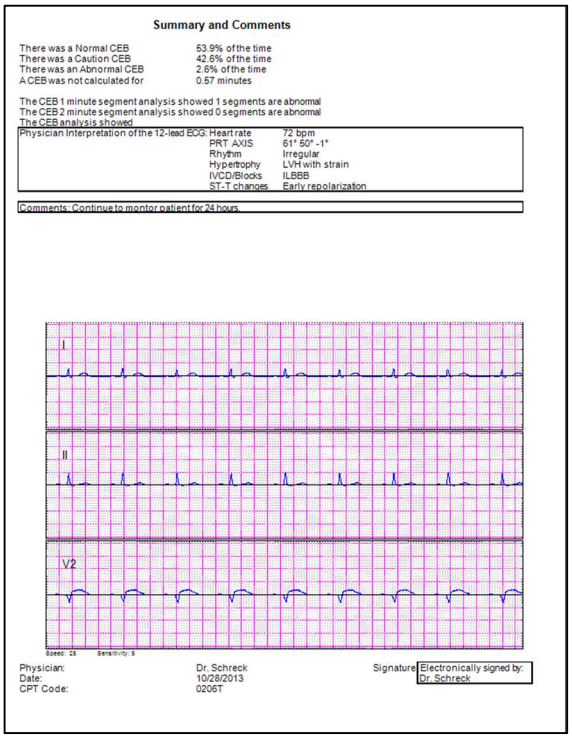




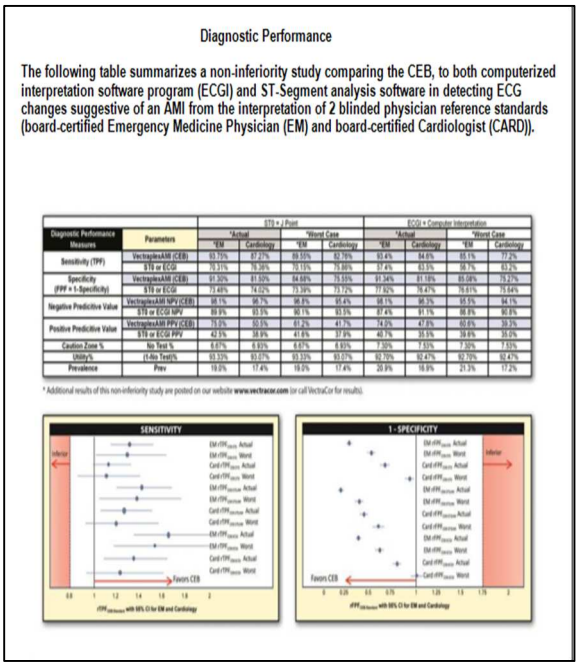
Page 1 **Page 2**



Page 3



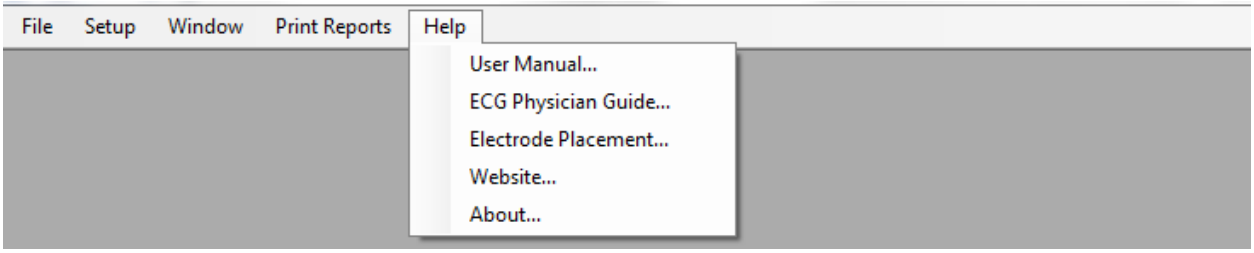
Page 4



Page 5

Note: Page Numbers will depend on how long the test was performed

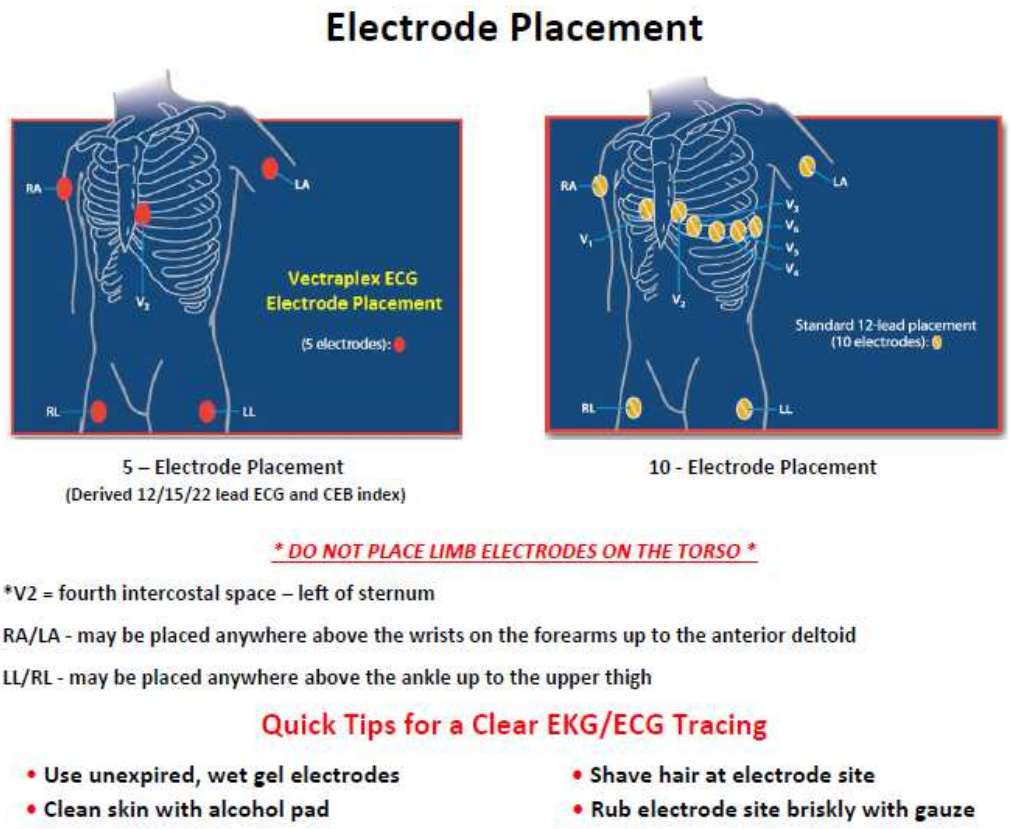
Help Tab



User Manual – Displays the User Manual

ECG Physician Guide – Displays the Physician's Guide for the ECG interpretation algorithm. The computerized interpretation algorithm only interprets the 12-lead ECG.

Electrode Placement- Displays a PDF with instructions and tips on proper location to place electrodes on a patient.



Website – Displays www.vectracor.com (internet connection required)

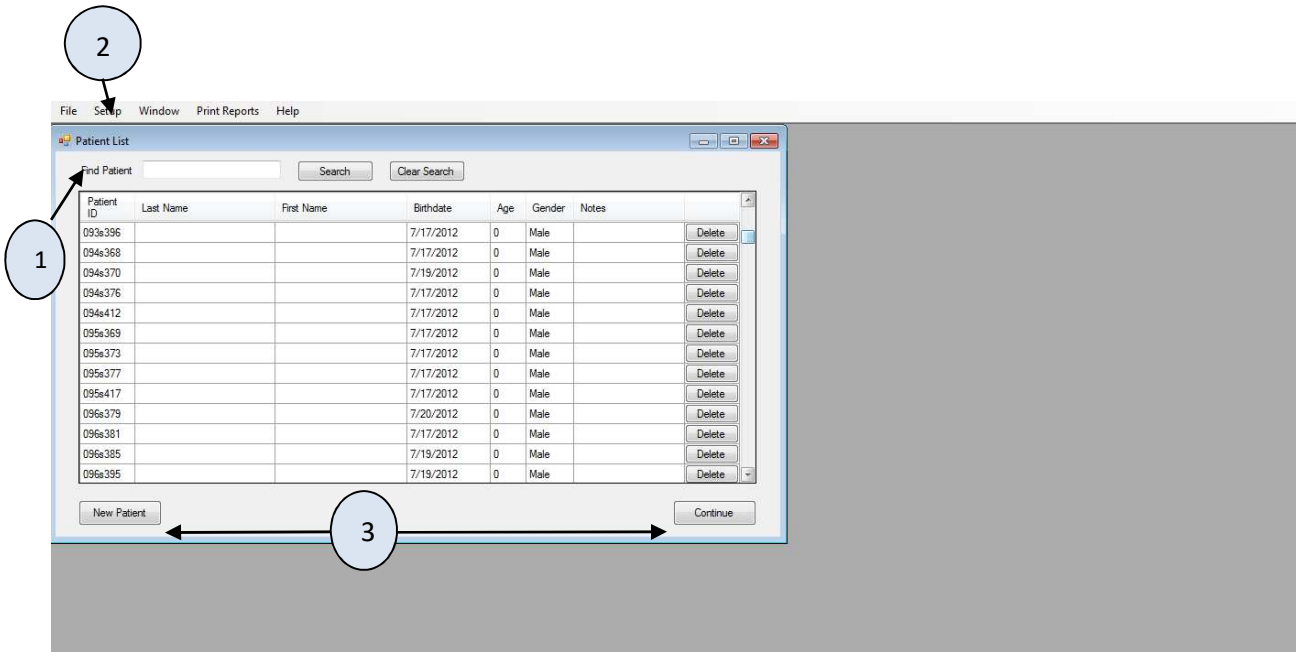
About – Displays the software version as shown below.

About VectraplexECG System with CEB
VectraplexECG with CEB
VectraplexECG System with CEB
Version 4.0.3.0 T (EU) QRS Device 1.0.0
Copyright © VectraCor, Inc. 2018
VectraCor, Inc.
UDI # (00857175006029)
For support go to www.vectracor.com
OK

Start-up Screen – Patient List Screen

Patient List Screen displays all the patients saved on disk. If a patient does not exist press "New Patient" button to enter patient information. To start, select a patient or click the new patient and enter fields.

Note: Any open windows associated with another patient's record will be automatically closed.



1 The Patient List is automatically displayed when the VectraplexECG program is opened.

2 Before acquiring ECG data make sure you select the **SETUP** tab to configure your system.

3 Selecting "New Patient" or "Continue" advances to Patient Data and Sessions Screen.

Note: A unique patient ID and Gender must be selected for each new patient.

Patient Data and Sessions Screen

After inputting the patient fields, click the save button. The save button will then toggle to edit. To start a session, click “Continue” or “New Session”. A unique patient ID # and gender must be entered to continue.

There are 2 options for inputting the Date of Birth.

Option 1:

Step 1: To input Date of Birth, highlight the month then enter the 2 digit month.

Step 2: Highlight the day and enter the day of the month (1-31).

Step 3: Lastly, highlight the four digit year and enter the four digit year.

Option 2:

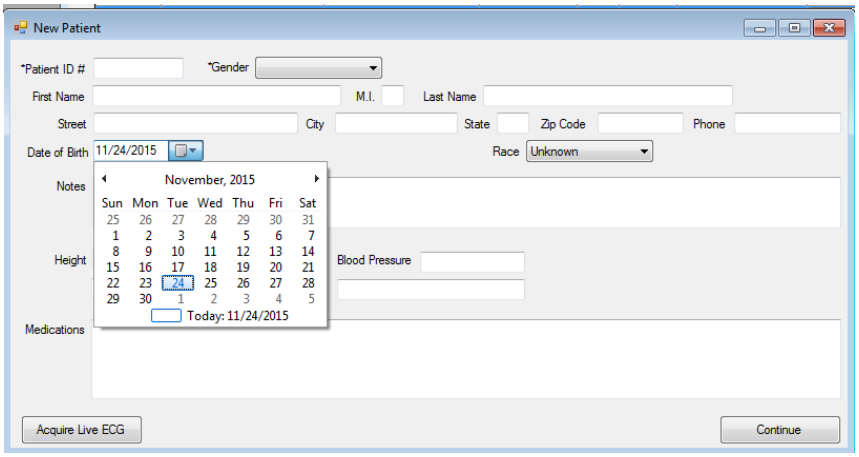
Step 1: Click on the Calendar icon that appears next to the four digit year. This will make the Calendar drop down.

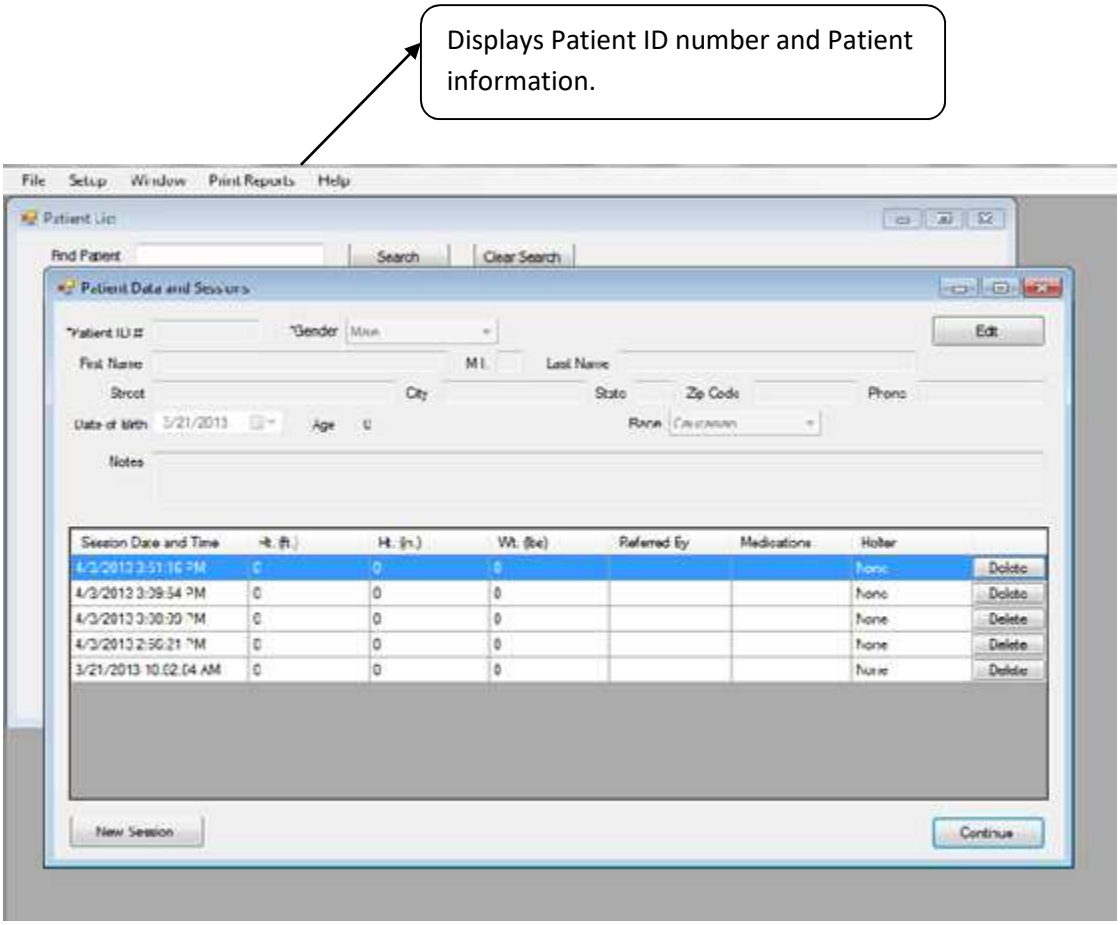
Step 2: Click on the month/year at the top of the calendar (example: ***January 2012***).

Step 3: Click on the year at the top of calendar (example: ***2012***). This will allow the user to use the arrows to scroll through and select their **Year** of birth.

Step 4: After Year is selected, the user will be able to then select **Month**.

Step 5: Lastly, once month is selected, the user will be able to select **Day**.





By pressing the Continue button at the bottom right the user can go to a screen with additional information (height, weight, blood pressure, medications, packs/day, referring physician).

Notes:

1. Must insert Patient ID # and Gender.
2. Packs/day is how many cigarette packs the patient smokes in a 24 hour period.
3. "Notes" field in the screen does not transfer to the printed or display report and should not be used to store any data relevant to a diagnosis on a specific ECG session, since it will not be included in the printed or display report
4. Once a patient's information is saved the "Save" button will toggle to "Edit"

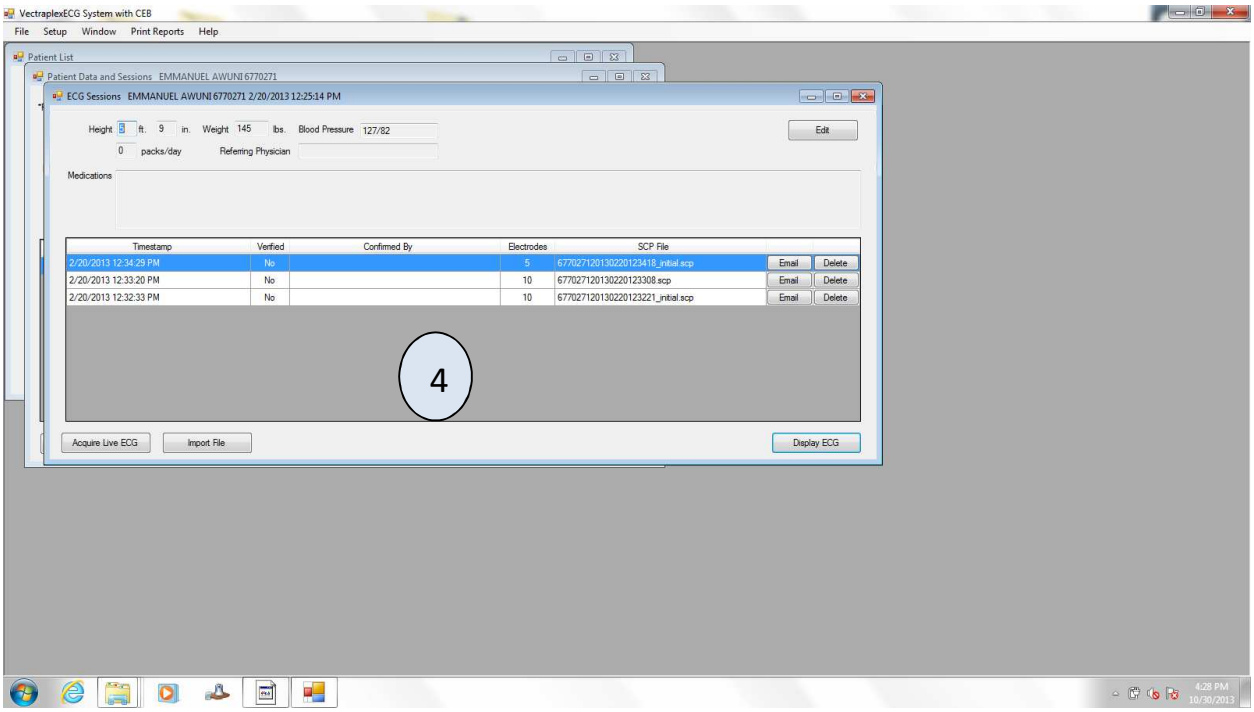
Acquire Live ECG

Select a Patient and input the required fields. Then select Save, the button will toggle to Edit after the save. Then select the Continue button. The ECG Session Screen will appear with the patients ID number followed by the session date and time.

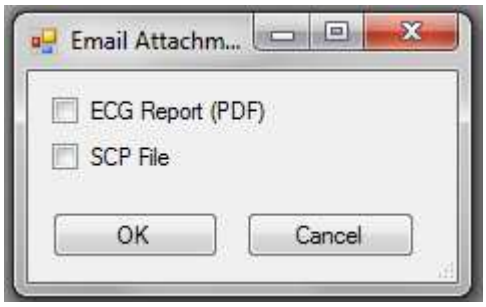
4

ECG Sessions Screen

Input patient fields and select save. Button will toggle to edit after save is clicked. Then select a session or start a new acquisition by clicking “Acquire Live ECG”. The ECG Session screen stores all the saved SCP files for a patient. There is a timestamp to let you know the day and time. Each SCP file holds 10 seconds of data.



Email– The system has the ability to email both a PDF of the 4-page report and the .scp file (raw data file), .ceb files cannot be emailed. When the “Email” button is clicked, a screen will come up that gives the user the option to select either “SCP File” or “ECG Report” (PDF). Click the desired box (both can be selected, if desired) and click “OK”. A progress bar will then appear letting the user know the program is working, and the default e-mail client (i.e. Windows Live Mail) will appear with the desired file (.scp or PDF) as an attachment. If an account has not been setup, follow the steps to do so with Windows Live mail.



.

Delete - Clicking “Delete” will remove a particular ECG from the ECG Session list.

Display ECG - Clicking “Display ECG” will display the session you have highlighted.

Import File - Clicking “Import File” will allow you to import a patient “scp” file and display the ECG.

Notes:

1. Input patients Height and Weight otherwise they will default to 0
2. Do not reset the system clock, since patient SCP files are time stamped.
3. SCP file time stamps are accurate to the second
4. Check the computer’s system clock is accurate before using program.
5. Smoking Packs Years is calculated by multiplying the number of cigarette packs smoked per day by the number of years the patient has smoked.
6. Do not modify SCP files.
7. If no sessions are listed in window, then the only selection is to Acquire Live ECG.
8. The “Notes” field on the ECG Sessions screen does not transfer to the printed or displayed report and should not be used to store any data relevant to a diagnosis on a specific ECG session.

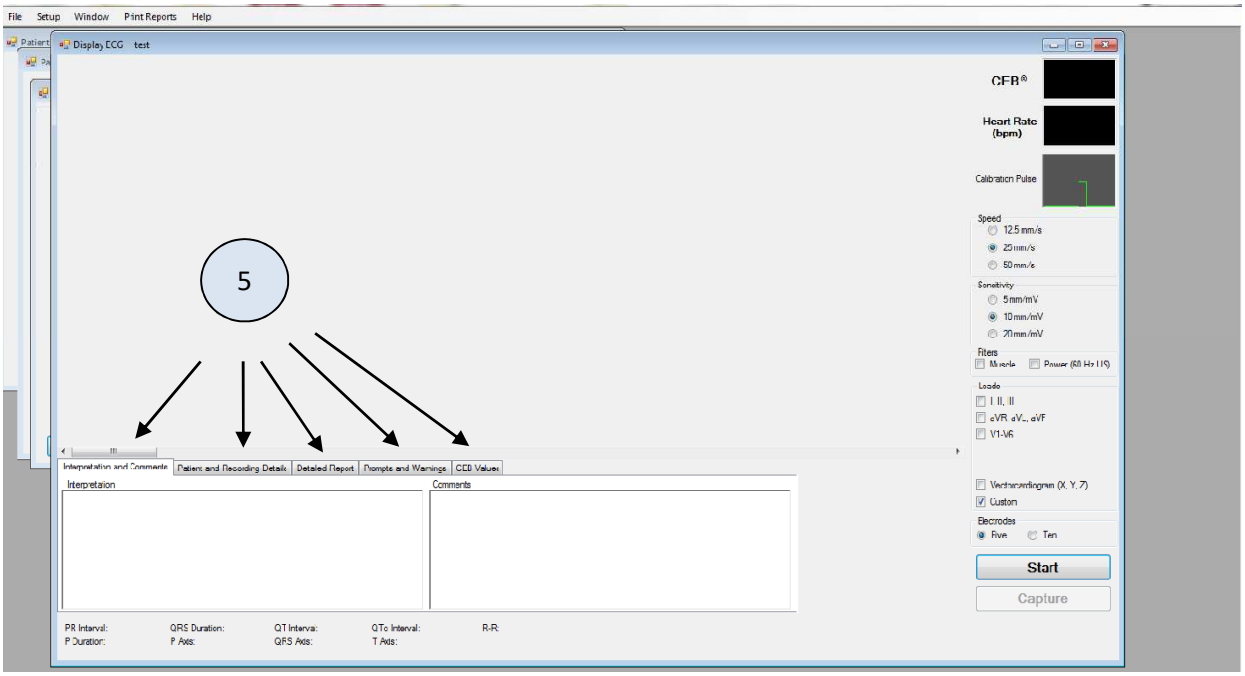
Acquiring a Live ECG and the Display ECG Screen

When the Acquire Live ECG button is selected the Display ECG Screen will appear. The Display ECG Screen is for on-demand and real-time monitoring of the patient. It will display the CEB®, Heart Rate and the ECG Leads that have been selected to be viewed. Toggle the buttons to select the leads you want to display. The custom lead button can be configured in the "Setup" menu. Select your speed and sensitivity. Also, select muscle and power filters, if needed. Go to the Capture ECG Screen for more information.

Make sure the ECG patient cable is plugged in. Press the Start button to begin acquiring on demand data. Press the Stop button to halt the recording of data. If the Start button is pressed again the previously acquired data will disappear and a new recording will begin on the same screen. Press Capture to stop and automatically display the ECG Report screen. To select Capture, you need a Minimum of 10 seconds of data. At any time you can enter comments. If you are not in monitoring mode, you can still enter comments, but then you must select Update to save.

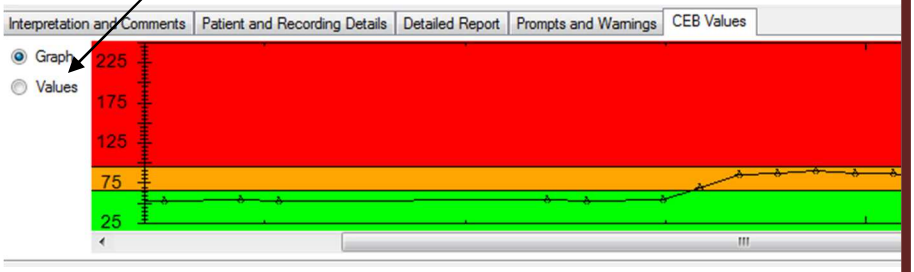
Note:

1. The system will automatically save the first 10 seconds of data to an SCP file.
2. The system will save 10 seconds of Data to an SCP file every 8 hours.
3. If any preferences are changed in the "Setup" menu while a Display ECG Screen is open, the Display ECG Screen will need to be close and reopened for the changes to be seen.
4. In the ECG Sessions screen you will see the saved data with time stamps.
5. Changing the acquisition settings after stopping a live acquisition can refresh the collected data. Capture required data before changing acquisition settings.
6. Do not edit or create a new/existing patient during acquisition.



5 Five Tabs:

- **Interpretation and Comments** – This tab interprets the 12-lead ECG using 10 electrodes only.
- **Patient and Recording** Details – This tab displays the patient info.
- **Detailed Report** – Displays Amplitudes, Slope and Duration of leads.
- **Prompts and Warnings** – Notifies user of current CEB zone (Normal, Caution, Abnormal)
- **CEB Values- Displays previous CEB values in numerical and graphical form.**
  - **This tab will only be displayed while acquiring live data in 5 electrode mode**
  - **To view values, click "Values" radial button**
  - **To view graph , click "Graph" radial button**



User should check signal quality prior to using the raw lead data for diagnostic purposes.

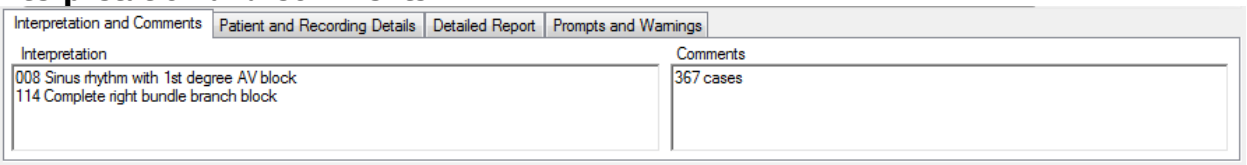
*** After each capture during a recording session, a temporary file containing the CEB® values will be saved. When the DisplayECG screen is closed or the Electrode setting is changed, this file will appear with the readings in the ECG Sessions screen with a**

.ceb extension. When the Electrode setting is changed, all data will be cleared from the graph, in preparation for a new acquisition.

Information Tabs

The Information Tabs show the interpretation, comments, detailed measurements and patient details of the ECG. The follow sections can be found in the Acquire Live ECG, Capture ECG, and Display ECG Screen sections.

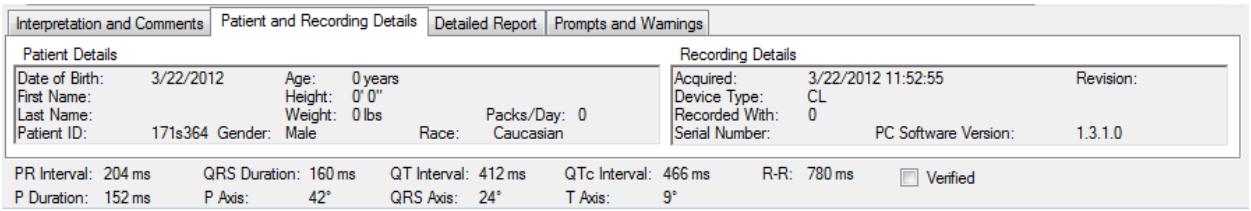
Interpretation and Comments



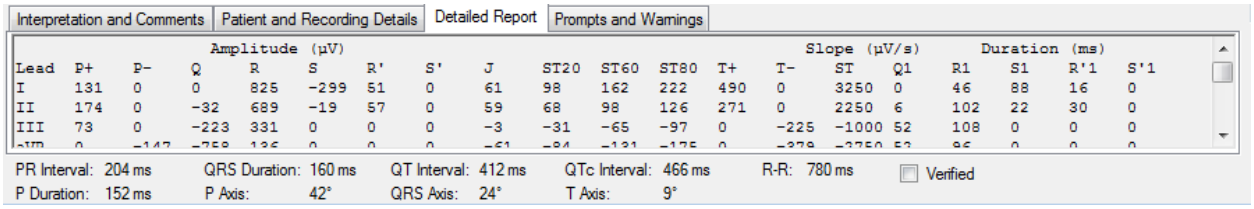
Note:

1. If physician modifies the interpretation, the state of the Verified checkbox, or comment field, the **Update** button (see above picture) must be selected to save any changes otherwise the changes will be lost.
2. When a reading is updated, the old SCP file will be saved to a "backup", i.e., replacing the .scp extension with .BAK.*n*, where *n* is the number of backups to that reading.
3. Interpretation field shows the computerized interpretation only if all 10 electrodes are used and 10 electrode mode is selected.
4. The Medication and Comments fields have no input character limitation in the program. However, the PDF report truncates the information at 35 characters to accommodate important information.

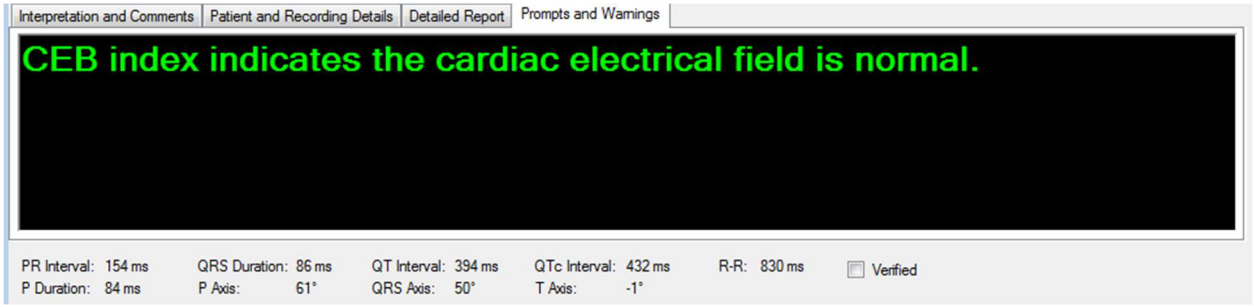
Patient and Recording Details



Detailed Report



Prompts and Warnings

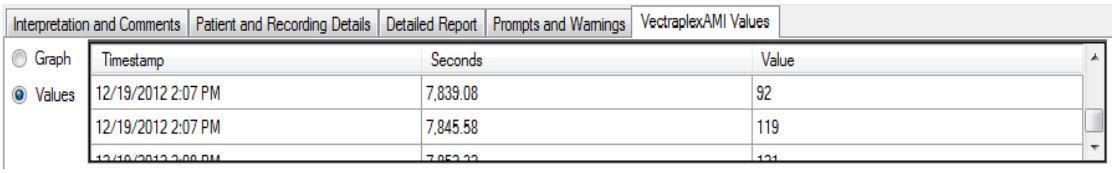


Note: **Normal condition** – The CEB Index is less than 66 and is displayed in green.

Caution Zone – the CEB Index is 66-94 and is displayed in orange. Patient requires continued clinical assessment.

Abnormal condition– The CEB Index is greater than 94 and is displayed blinking and in red. Patient may be developing an acute myocardial infarction and requires continued clinical assessment –attach additional 5 electrodes for a 12-lead ECG (using all 10 electrodes).

CEB Values (Values Radial Button)

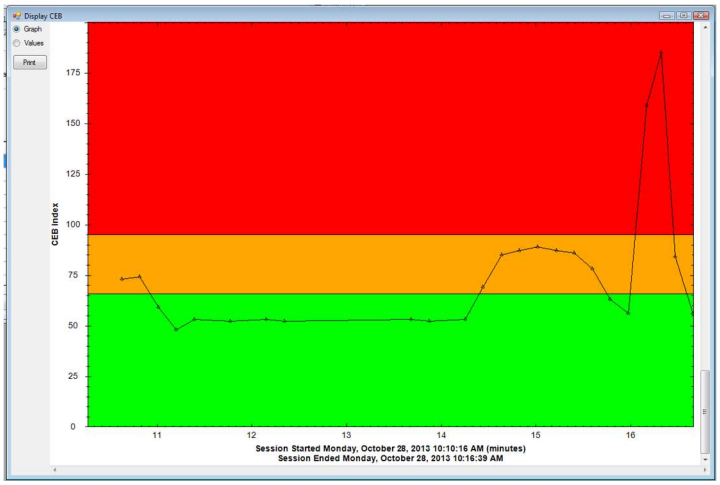


CEB Values (Graph Radial Button)

⚠ Warning! The computerized interpretation provided by the VectraplexECG software is only for the 12-lead tracings (using 10 electrodes) and valid when used in conjunction with clinical findings. All computer generated tracings and interpretations must be confirmed by a qualified physician.

Display CEB Screen

The Display CEB screen is reached when "Display Record" is selected for a previously recorded .ceb file in the ECG Sessions window. The screen is originally sized relative to the range of CEB values in the file.



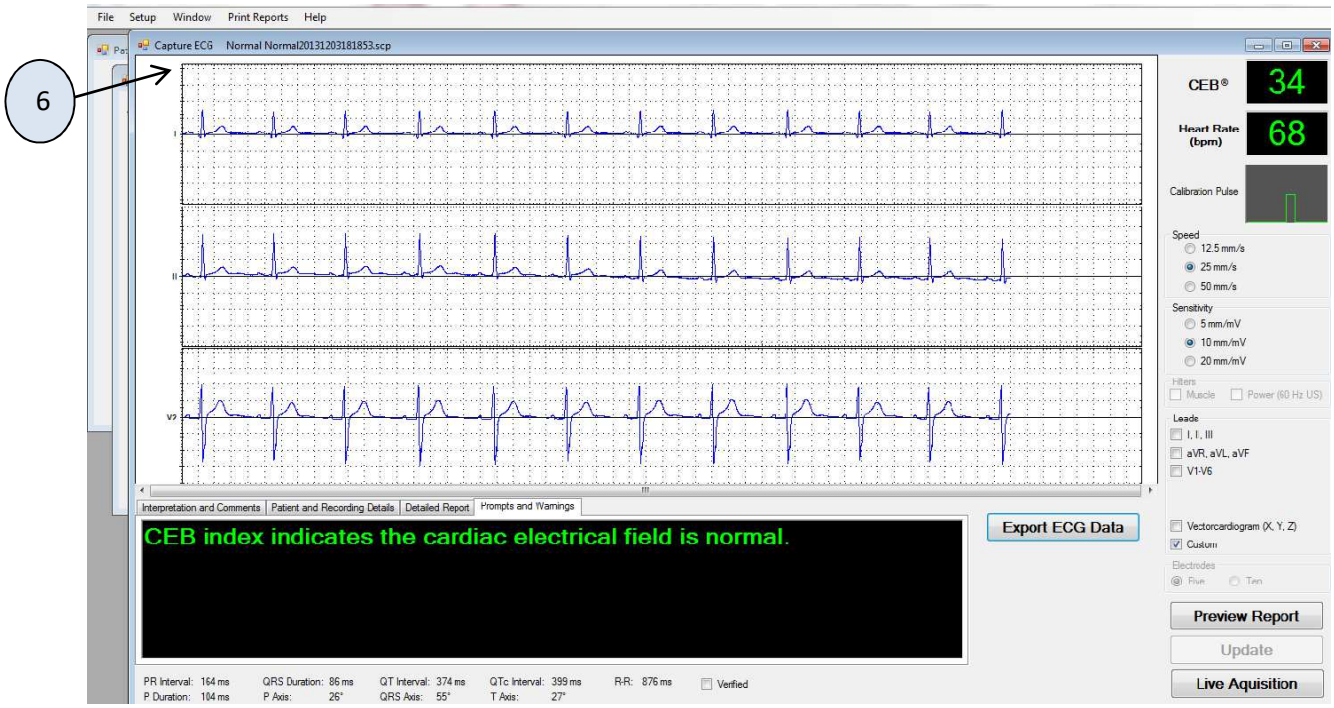
Double-clicking on this tab will cause the graph to pop-up in its own window; closing this window will restore the graph to its original position in this tab control; if the graph window becomes hidden behind other screens, double-clicking again on the tab will bring the CEB graph window to the front

The y-axis ticks are in 5 unit increments with labels every 25 units. The x-axis labels will depend on the amount of data collected, displaying minutes, hours, and days. Mousing over a data point will display the coordinates of the point. By clicking and dragging to select a given rectangular region, one may zoom in on a particular set of points. Right-clicking, will bring up a context-menu with options to “Un-Zoom” and “Undo all Zoom and Pan” to restore the graph to its original scale.

6 Capture ECG Screen

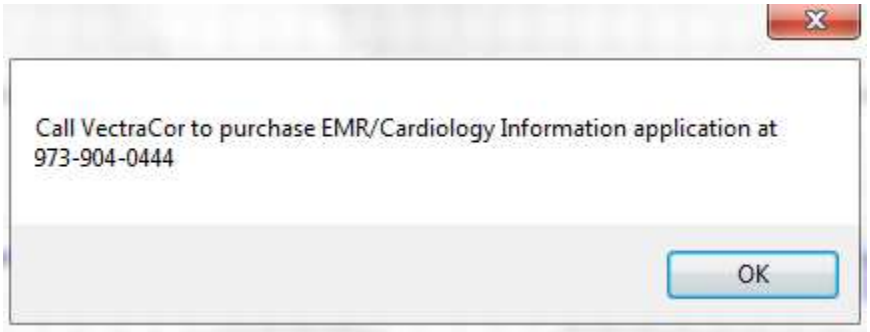
The Capture ECG screen will appear either after “Display Record” is selected for a previously recorded .scp file in the ECG Sessions window or when “Capture” is selected in Live Acquisition Mode from the Display ECG screen, behind the ECG Report. This screen is very similar to the Display ECG screen, except for the available buttons.

From this screen you can view the 4-page report by clicking the “Preview Report” button, go back to acquiring a live ECG by clicking the “Live Acquisition” button, or send the ECG record to an EMR/EHR system using the “Export” button.



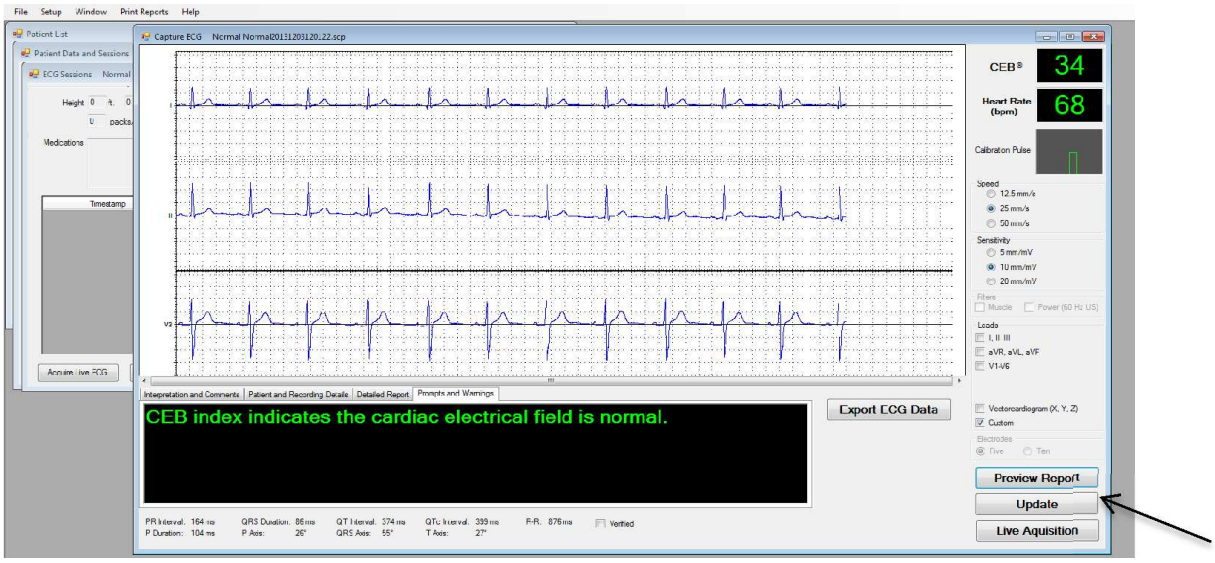
Comments can be entered in the box at the bottom of the screen. To save these comments select the “Update” button on the bottom, right.

If the Vectraplex Information System (VIS) is installed, pressing the “Export ECG Data” will cause the displayed reading to be sent to an EMR management system (both the SCP file and PDF of the associated printed report). Otherwise, the user will be advised how to obtain the VIS from VectraCor with the following screen:



Note: Patient sessions prior to revision 3.0 of the VectraplexECG System will not have the 4th page of the ECG Report, consisting of the CEB Graph, or .ceb files.

Preview Report button- Will display the ECG Report.



ECG Report

A 4-page ECG Report may be created from any .scp file reading. The first page is the 12-lead ECG. The second page displays the X, Y, Z leads. The third page displays the detailed data and the Vector Loop/Vectorcardiogram graphs. The fourth page displays the CEB Graph.

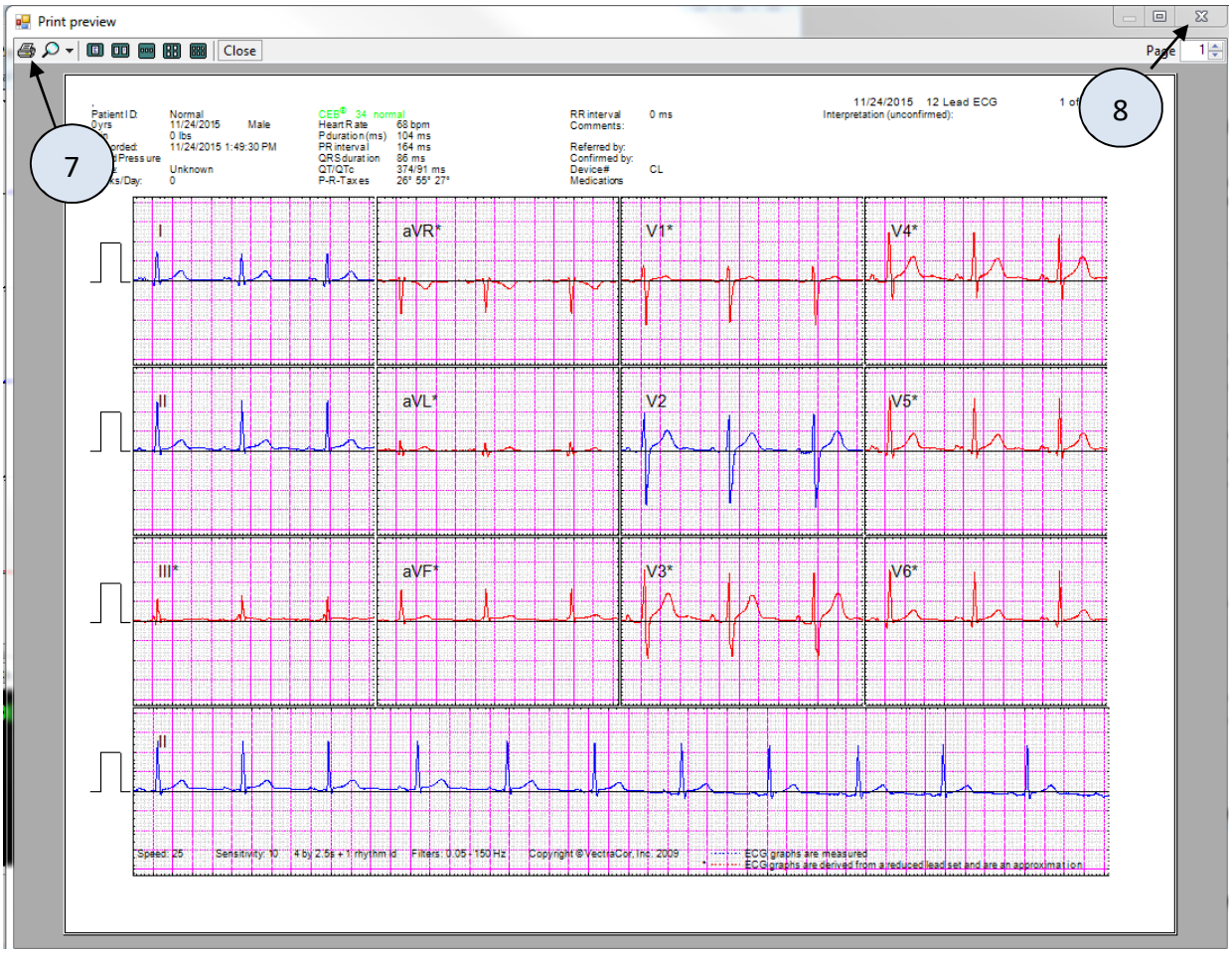
With the ECG reading displayed in a Capture ECG screen, the report may either be sent directly to a selected printer, by selecting Print Reports > ECG Report, or previewed in a Preview Report Screen, by clicking the "Preview Report" button, then selecting the printer icon in the top left corner.

Note: When selecting a printer, one may also select a range of one or more pages to print (e.g. pages 1-2; page 1 only etc.) only if the ECG Report is selected from the Print Reports tab. Each of these pages also displays the configured report lead strip (see the "Setup Tab – VectraplexECG Configuration Menu" section).

Select "Close" button or X and it will return to the Capture ECG Screen, but not in monitoring mode.

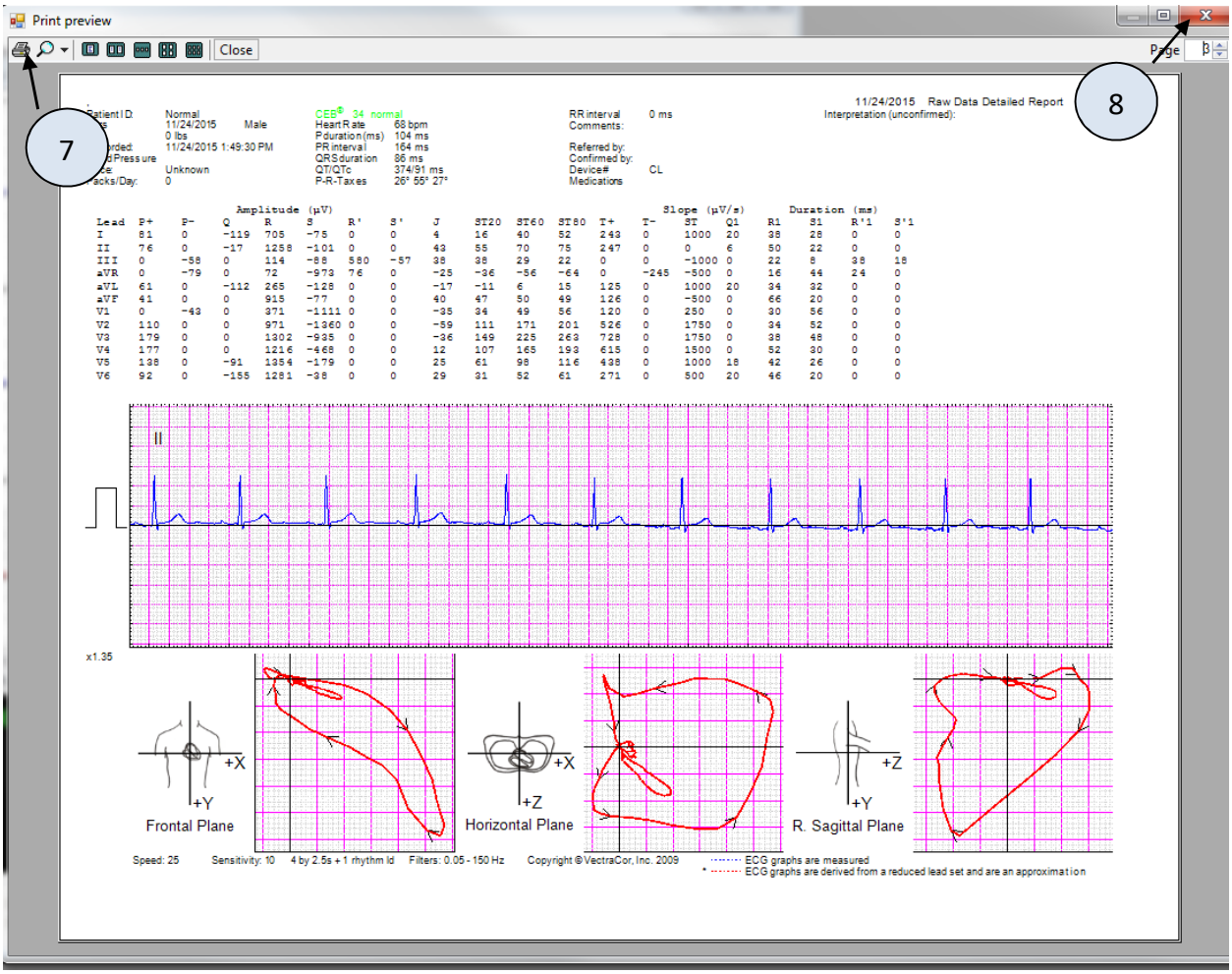
7 Printer Icon will print the four page report if selected.

8 Close button will remove the currently displayed window.

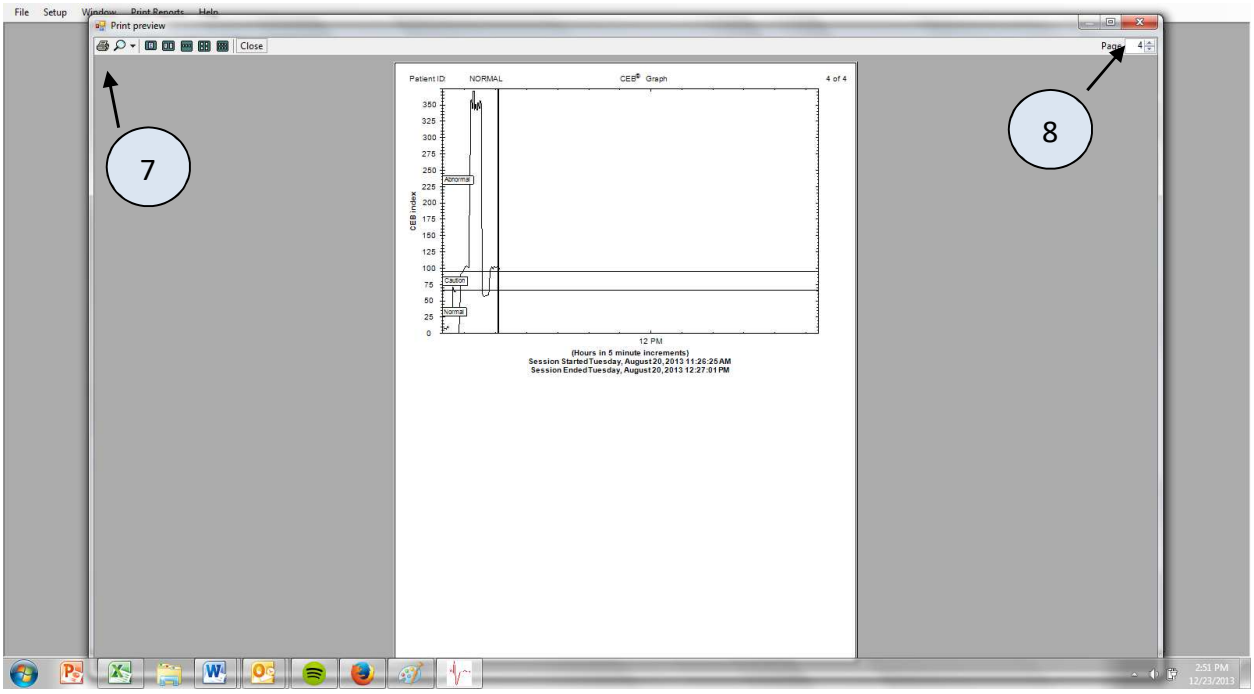

Print preview
Close
Page 1
7
8
11/24/2015 12 Lead ECG
Interpretation (unconfirmed):
I
aVR*
V1*
V4*
II
aVL*
V2
V5*
III*
aVF*
V3*
V6*
II
Speed: 25
Sensitivity: 10
4 by 2.5s + 1 rhythm ld
Filters: 0.05 - 150 Hz
Copyright © VectraCor, Inc. 2009
ECG graphs are measured
ECG graphs are derived from a reduced lead set and are an approximation

12 Lead ECG

XYZ Leads


Print preview
Close
Page
7
8
11/24/2015 Raw Data Detailed Report
Interpretation (unconfirmed):
Normal
11/24/2015 Male
0 lbs
11/24/2015 1:49:30 PM
Unknown
0
CEB® 34 normal
Heart Rate 68 bpm
P duration (ms) 104 ms
PR interval 164 ms
QRS duration 86 ms
QT/QTc 374/91 ms
P-R-Taxes 26° 55° 27°
RR interval 0 ms
Comments:
Referred by:
Confirmed by:
Device# CL
Medications
Amplitude (µV) Slope (µV/s) Duration (ms)
Lead P+ P- Q R S R' S' J ST20 ST60 ST80 T+ T- ST Q1 R1 S1 R'1 S'1
I 81 0 -119 705 -75 0 0 4 16 40 52 243 0 1000 20 38 28 0 0
II 76 0 -17 1258 -101 0 0 43 55 70 75 247 0 0 6 50 22 0 0
III 0 -58 0 114 -88 580 -57 38 38 29 22 0 0 -1000 0 22 8 38 18
aVR 0 -79 0 72 -973 76 0 -25 -36 -56 -64 0 -245 -500 0 16 44 24 0
aVL 61 0 -112 265 -128 0 0 -17 -11 6 15 125 0 1000 20 34 32 0 0
aVF 41 0 0 915 -77 0 0 40 47 50 49 126 0 -500 0 66 20 0 0
V1 0 -43 0 371 -1111 0 0 -35 34 49 56 120 0 250 0 30 56 0 0
V2 110 0 0 971 -1360 0 0 -59 111 171 201 526 0 1750 0 34 52 0 0
V3 179 0 0 1302 -935 0 0 -36 149 225 263 728 0 1750 0 38 48 0 0
V4 177 0 0 1216 -468 0 0 12 107 165 193 615 0 1500 0 52 30 0 0
V5 138 0 -91 1354 -179 0 0 25 61 98 116 438 0 1000 18 42 26 0 0
V6 92 0 -155 1281 -38 0 0 29 31 52 61 271 0 500 20 46 20 0 0
II
x1.35
+X
+Y
Frontal Plane
+X
+Z
Horizontal Plane
+Z
+Y
R. Sagittal Plane
Speed: 25 Sensitivity: 10 4 by 2.5s + 1 rhythm ld Filters: 0.05 - 150 Hz
Copyright ©VectraCor, Inc. 2009
ECG graphs are measured
* ECG graphs are derived from a reduced lead set and are an approximation

Page 3 VCG



Page 4 CEB Graph

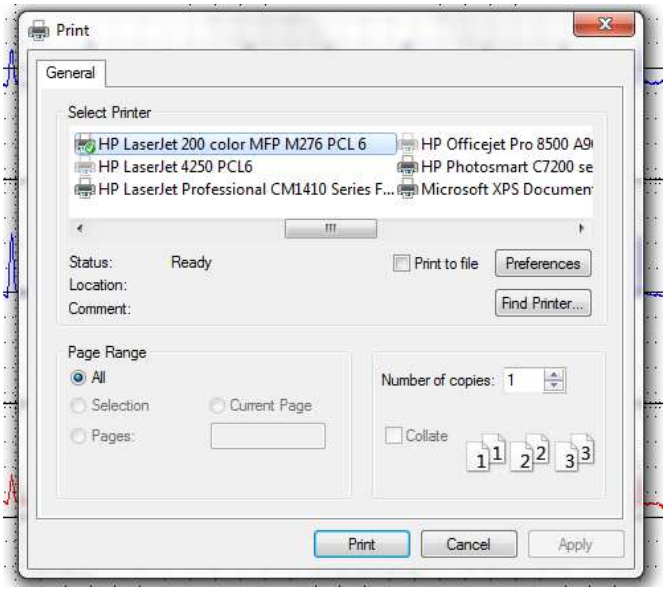
Note:
Blue (default) tracings are acquired/measured ECG tracings.
Red (default) tracings are derived ECG tracings and will also have an asterisk.

1. In Setup, you can select the color of the measured leads and the derived leads. In the above example, the measured leads are in blue and the derived leads are in red. This is the default from the factory.
2. The derived leads are also denoted by an asterisk.
3. The derived leads and the detailed data associated with each lead is an approximation to the conventional 12-lead ECG system.
4. Physician interpretation should only be based on unfiltered lead data and the ECG print out.
5. Physician should inspect the measured lead graphs to confirm they are reasonable and confirm diagnosis.
6. Verify that the patient name and ID are correctly entered on the report.
7. Interpretation of the ECG is only displayed using the 10 electrode mode. If the CEB index indicates an AMI, it is recommended that you add the additional 5 electrodes to obtain an ECG using 10 electrodes.
8. The accessory leads should only be utilized by those clinicians who are skilled in their interpretation.
9. An ECG must have been captured in order to use the Printed Reports menu.

Printing an ECG

There are three methods to printing an ECG report:

1. Select **Print Reports** > **ECG Report** when viewing a captured ECG
    a. A window will appear with the default printer selected
    b. Press Print button



2. Select Capture during a Live Acquisition, which will then display the ECG Report Print Preview.
    a. Select the printer icon in the upper left hand corner of the screen.
3. Select the **Preview Report** button from a previously captured patient session, which will display the 4 page report. Then select the printer icon in the upper left hand corner of the screen.

Note:

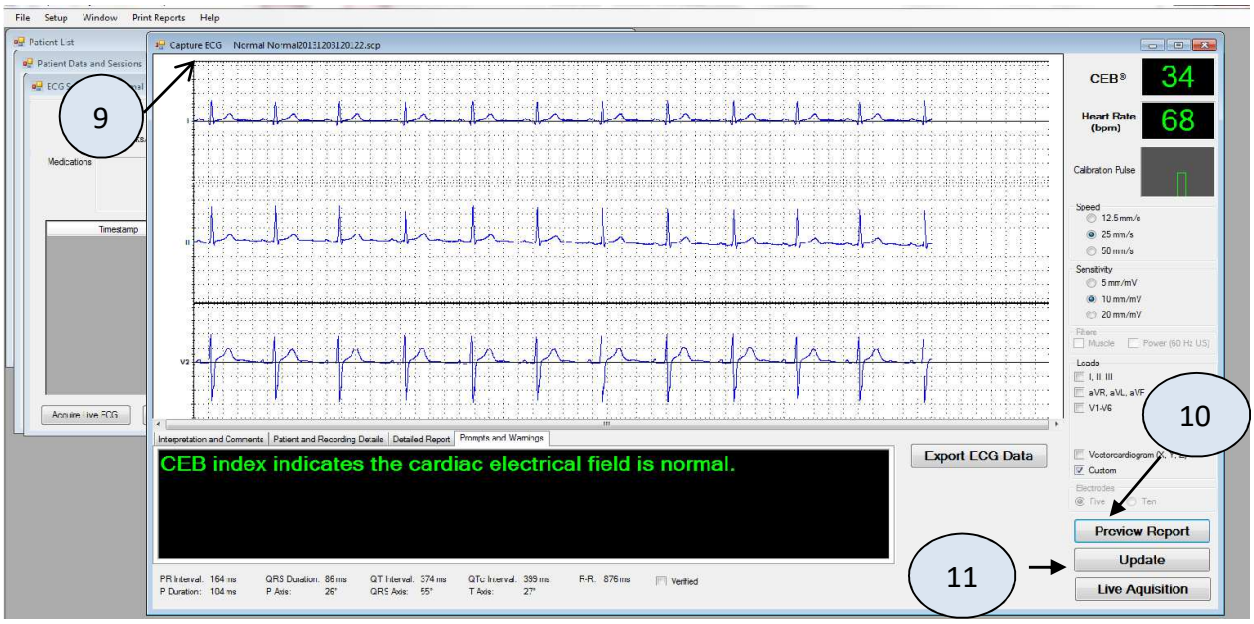
1. Install printer that is compatible with a Windows 7 or 10 Professional operating system and follow the directions for installation that are included with printer.

Reviewing an ECG

9 Reviewing an ECG within the “Capture ECG” Window

10 Click the Preview Report button to go to the report screen.

11 Update button – Click the Update button to save changes made during the session.



Note: The P-R-T axes may display 999. This represents times when the ECG amplifier cannot calculate the axes.

ECG - Getting Started

Connecting the 5 electrodes or 10 electrodes ECG device to the Laptop:

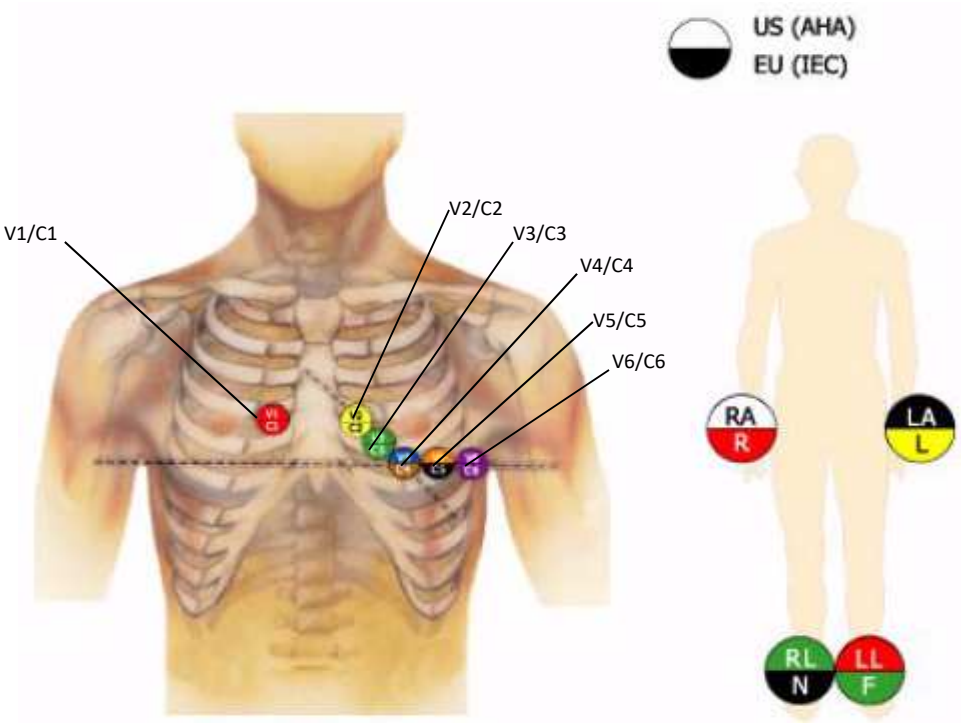
The VectraplexECG software supports the ECG Device when connected to a USB port.

Use electrodes that are 510k cleared only. Please reference the FDA registered electrode supplier for length of attachment.

Performing an ECG Test

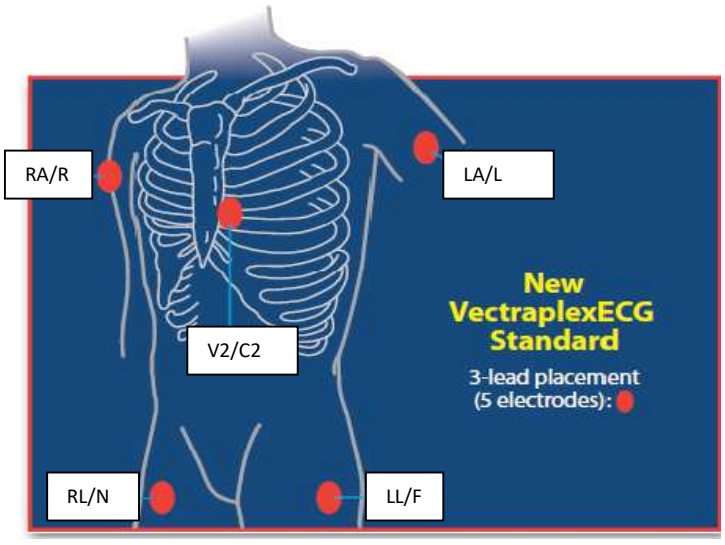
1. Connect the ECG device to the PC via the USB port.
2. Select a patient from the Patient Directory or add new patient.
3. Shave electrode sites if necessary. Thoroughly clean the area and let dry.
4. Prep skin by briskly rubbing with gauze, being careful not to break or damage the skin.
5. Remove electrodes from backing.
6. Apply each electrode, adhesive side down to desired site.
7. For positive electrode contact, start from outer edge and run your finger around the electrode several times, working toward the center.
8. Connect the lead wires to the patient ensuring correct lead placement. Excess movement can cause artifact. Patient should be directed to remain still during ECG acquisition.
9. Click the Acquire Live ECG button to start the monitoring ECG display.

10 Electrode Placements (12-Lead ECG)



Limb Leads Above

5 Electrode Placement (3-Lead ECG)



Note: Only need to place V2/C2 and limb leads

Do not **place electrodes V1/C1, V3/C3, V4/C4, V5/C5, and V6/C6 for 5 electrode**

placement.

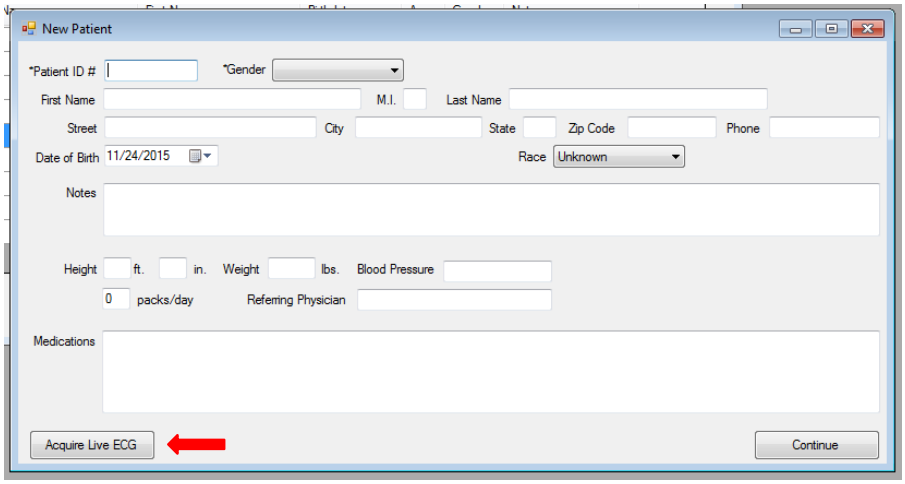
Note:

1. System can be used by trained healthcare professionals in the use of ECG equipment. No other training is needed.

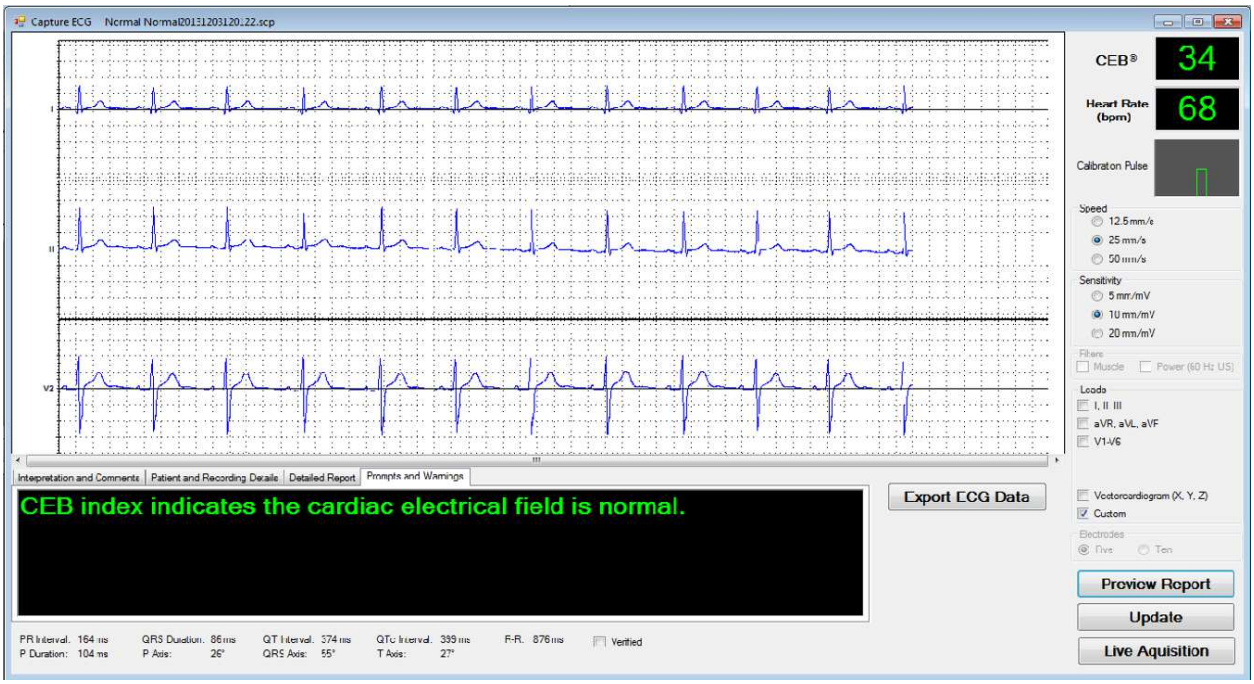
⚠ Warning: Avoid patient movement to reduce artifact and potential increase or decrease in CEB® (VectraplexAMI®) index. The ECG device is for acquiring resting ECGs and monitoring patients only. The device should not be used for stress testing.

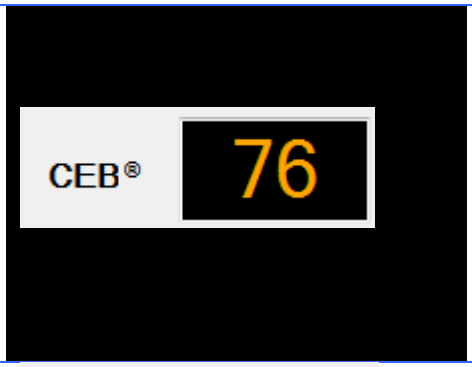
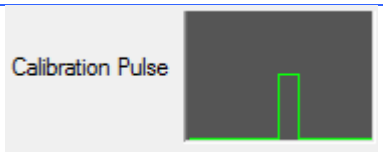
Fast ECG Acquisition for New Patient

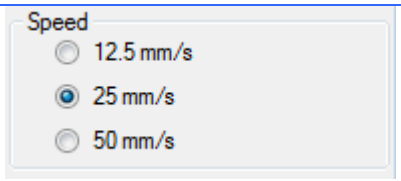
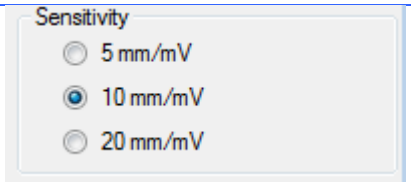
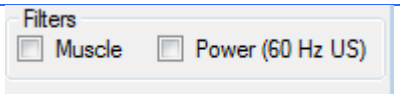
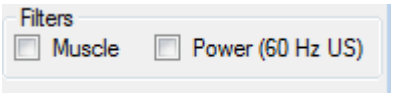
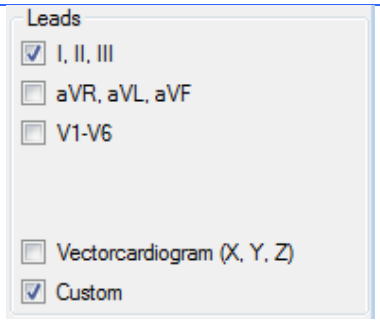
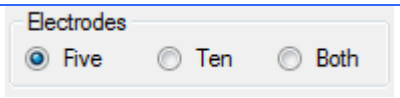
1. Either select ”New Patient” from the File drop down menu or the “New Patient” button at the bottom left corner of the Patient List
2. The New Patient screen will appear
3. Input Patient ID and gender
    4. These are the only two fields required to move forward. Additional information can be added based on preference.
5. Click the Acquire Live ECG button at the bottom left of the New Patient screen
    6. This will begin acquiring an ECG

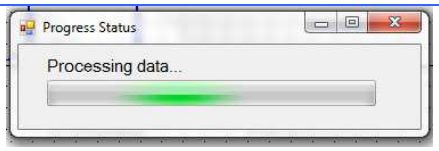


About the Acquisition Window – Capture ECG Screen



Leads		Each graph labels which lead is displayed
Lead Identifiers	I, II, (etc.)	Identifies each of the 15 leads. If a lead is disconnected (leads off) then a red circle with a diagonal line is placed over the lead identifier.
CEB®		CEB® is an index that will alarm if the patient is having an ECG change that may be indicative of an acute myocardial infarction. Patient is considered normal if Index is lower than 66. Patient is considered abnormal if the index is greater than 94. Patient is considered to be in a "caution zone" if between 66-94 and needs continued monitoring.
Heart Rate (bpm)		Displays the active Heart Rate of the patient. Heart Rate is validated from 20-200 BPM.
Calibration Pulse		Provides a visual indication of the combined sensitivity (1mV vertical height) and speed (100ms horizontal width).

Speed		Changes the number of millimeters that are passed in one second. The available options are 12.5mm/s, 25mm/s and 50mm/s.
Sensitivity		Changes the number of millimeters that represent one millivolt. The available options are 5mm/mV, 10mm/mV, and 20mm/mV.
Muscle Filter		Turns the **Muscle** filter on and off.
Power Filter		Turns the **Power** filter on and off. Note: the default frequency of the **Power** filter is set in the Setup.
Leads		The ability to select any of the 15-lead views. A Custom Lead group can be defined in the Setup.
Electrodes		Select how many electrodes will be placed on the patient. The default can be saved in the Setup. 5 electrodes selection will utilize VectraCor's proprietary algorithms to derive the additional leads. **Both** will enable user to compare both methods. **Both** will display the Vectraplex AMI derived from the 5 electrodes setting and the Computer Interpretation from the 10 electrodes setting. Note: the EU version (CE Mark) will give a Computer Interpretation for the 5 electrode setting, but not in the US version.
Stop/Start		**Stop** ends the recording to modify any of the options. **Start** begins recording new data.

Capture/Start		**Capture** ends the ECG recording and continues to Capture ECG screen.
Preview Report		**Preview Report** displays up the 4 page report.
Update		**Update** saves changes that have been made during the session.
Live Acquisition		**Live Acquisition** displays the Display ECG screen to acquire a live ECG.
Status Bar		Signifies that the VectraplexECG System is processing.

Note:

1. The CEB® index has only been tested in comparison to physician interpretation of standard 12-lead ECGs in patients presenting to an acute care setting, and not in comparison to additional clinical data documenting the presence of acute myocardial infarction.
2. Heart Rate and CEB® display will be refreshed no sooner than approximately every 10 seconds.

Cardiac Electrical Biomarker (CEB) Index Number

The CEB index is a Cardiac Electrical Biomarker (CEB) for the real-time detection of ECG changes suggestive of an Acute Myocardial Infarction (AMI).

"The CEB index has been shown to be non-inferior when tested against accepted standards of ST segment voltage-time deviations that may be suggestive of an AMI in the appropriate clinical setting."

If the CEB is $\leq$ 65 as displayed on the device, then the patient may be considered by the clinician to have a normal dipolar cardiac electrical field consistent with non-AMI electrocardiographic lead signals. If the CEB is $\geq$ 95 as displayed on the device, then the patient may be considered by the clinician to have small but significant multipolar force contributions to the cardiac electrical field consistent with AMI electrocardiographic lead signals. If the CEB is between 66 and 94 as displayed on the device, then the patient may be considered by the clinician to be in a "no test" caution zone indicating that the clinician should be aware that the cardiac electrical field may be changing and the patient requires diligent monitoring for clinical changes that may progress to AMI.

Note:

1. Although the VectraplexECG System is able to detect and interpret arrhythmias using the interpretative software, the device does not alarm in the presence of a new arrhythmia.

ECG Analysis Program

VectraplexECG System provides analysis and interpretation of 12-Lead ECG only. This is based on

algorithms developed by Cardionics S.A. For further information consult the ECG Physician's Guide.

What to expect from the analysis program

The ECG analysis program provides a computerized analysis of the amplitudes, duration, and morphologies of the ECG waveform. The analysis is based upon standards of interpretation of these parameters and calculations of the electrical axis and relationship between leads.

The interpreted ECG is a tool to assist the physician in making a clinical diagnosis, and is not a substitute for the physician's knowledge, the patient's history, and results of the physical exam, the ECG tracing or other findings.

Alarms

CEB®Alarm:

- CEB Alarm is an audible and visual alarm. The visual alarm will be red and blink when the patient is having an ST deviation that may be indicative of an acute myocardial infarction (AMI).
- CEB will be orange when the index is between non-AMI and AMI conditions.
- CEB is green when non-AMI.
- To silence the alarm hit “S” for silence or “M” for mute.

Note:

1. If the CEB Index displays an AMI condition, connect the additional 5 electrodes to obtain a diagnostic quality ECG using all 10 electrodes attached to the patient.

2. The user is cautioned that the CEB Index is accurate if the 10 seconds of ECG data does not include the following:
    - Wandering baseline
    - Noise
    - Premature Ventricular Contractions (PVCs)
    - Paced Beats
    - Improper placement of electrodes
    - Missing leads (disconnected leads)
    - Patients less than 18 years old
    - Bundle Branch Block

Interactions with Office Medic

For VectraplexECG 4.0.0 or later:

If Office Medic was installed with VectraplexECG, VectraplexECG may be selected as the default ECG viewer whenever an ECG test is made with Office Medic.

To set VectraplexECG as the default ECG program in Office Medic:

1. In Office Medic, go to Options > General…
2. Select VectraplexECG as the Default ECG Program.
3. Now whenever an ECG test is to be performed in Office Medic, VectraplexECG will automatically open.

Note: The last program that make changes to the patient will be the program that will be used to edit patient information.

Service Information

Device Care & Maintenance

Cleaning

Clean system as needed and per Hospital/clinic guidelines.

To clean the ECG device wipe the surfaces of the case with a clean cloth moistened in water only. To disinfect the ECG device wipe the case with a hospital grade disinfectant.

Storage

Store the Device in a dry place. Avoid sudden changes in temperature.

Physical Shock

Avoid physical shock.

Inspection

Inspect device for damage initially and before each use. Do not use devices that show visual signs of damage. Contact the VectraCor Service department with questions related to device damage and repair.

Disposal Instructions

Reference the PC supplier and electrode supplier for disposal instructions.

ECG Device Calibration

User calibration is not necessary. But, a periodic check of the ECG system with an ECG simulator is recommended. Intervals for these checks can be set at the discretion of your equipment quality assurance director or equivalent personnel. There are commercially available ECG simulators which may be used for this purpose.

For further information on device verification, contact VectraCor at www.VECTRACOR.com.

Training

Contact VectraCor for training on VectraplexECG and the Universal SmartECG.

Troubleshooting

Problem	Cause of Failure	Possible Solutions
Data inaccessible No data exists	1. Computer Failure 2. Database on removable or remote storage is inaccessible	1. Reboot system 2. Check location of Database and that drive is accessible 3. Restore back-up
Cannot establish communication with VectraplexECG patient cable Error Message- “Cannot establish communication with VectraplexECG patient cable; Auto-detect of comm. Port [COM1] failed. Error finding NxtGen device	1. Device not connected to USB Port 2. Need time to have system boot up and establish connection	1. Make sure VectraCor hardware-USB cord is connected to USB port 2. If VectraCor hardware-USB cord is plugged in, remove from computer. Then plug in VectraCor hardware-USB connector into PC. 3. Close the Display window and select ECG acquisition tab and hit start again. 4. Ensure the device drivers have installed for the ECG device. 5. Wait approximately 10 seconds for unit to initialize port before starting
ECG graphs look jagged/noisy	1. Insufficient processor resources 2. Patient movement 3. Power/electrical interference	1. Make sure no other applications are running 2. Capture the data and re-start 3. Display fewer leads 4. Ask patient to minimize movement 5. Select “Stop” and Hit “Start” 6. Make sure lead wires are not close to a power source 7. Make sure the patient is prepared to accept electrodes according to guidelines
Software detects file is in improper format	1. File corrupted due to hard-drive failure	1. Restore SCP file from back-up
Software detects file is inaccessible	1. File moved or deleted 2. File missing on removable storage	1. Restore SCP file from back-up
System does not run	1. Program not detected 2. Program does not run or display Graphs	1. Re-boot system 2. Make sure the configuration files in set-up are input correctly. 3. Call VectraCor’s Service Department

Report Does Not Print	1. Printer not available	1. Make sure printer is installed 2. Check if printer is online 3. Check connection from printer to computer
Error Message- Lead Off	1. Electrode is lifting from patient. 2. Buffer overload.	1. Check that electrodes are securely connected to patient. 2. Hit “Stop” acquisition and then select “Start”
Data Overload	1. Data Overload	1. Reduce the number of leads to display data.
Error message “ discontinuing Analysis”	1. Data Overload	1. Reduce the number of leads to display data.
Under “Prompts and Warnings” “CEB is processing”	1. Electrodes may not be attached 2. Need 10 seconds of Data	1. Connect or verify that all electrodes are attached.
Unit frozen	1. Battery power reached end of life 2. Error during loading of application 3. Error during initialization of computer 4. Complication with another program	1. Plug unit into power outlet 2. Restart computer (may need to be restarted again if unit shut down due to power loss) 3. Remove USB then reinsert; a pop up message should appear once device is recognized 4. Wait approximately 10 seconds for unit to initialize port before starting

“Not Responding” displayed at top of program window	1. VectraplexECG System work in progress	1. Wait time may vary depending on the information the program is displaying 2. Wait approximately 30 seconds for the program to respond 3. If the program does not respond afterwards close the program and restart the unit
“CPU Usage is High” pop-up message	1. VectraplexECG System work in progress	1. VectraCor’s software utilizes a large amount of computing power; This is not problematic
‘Cannot update SCP file’ pop up message	1. .ceb files cannot be confirmed	1. The system is working properly; click ‘OK’ and proceed
Dialogue box appears ‘Unlock by Phone’	1. Missing or corrupted license file to activate VectraplexECG System	1. Call VectraCor, 973-904-0444, to receive code to unlock VectraplexECG System
‘Email of this record type is not supported’	1. User attempted to email an unsupported file structure (ex. .ceb file)	1. The system is working properly; click ‘OK’ and proceed
Pop up message ‘Database May Be Corrupt. The following database fields are inconsistent with corresponding data in this file for this patient:’	1. Patient information has been changed after a session(s) has been created	1. Check to make sure the patient information is correct. If so, the system is working properly, click ‘Yes’
Other		1. Call VectraCor’s Service Department

Service

Contact the VectraCor service department:

VectraCor, Inc
785 Totowa Rd
Suite 100
Totowa, NJ 07512

Monday through Friday
9am to 6pm EST
Phone: 973-904-0444

email: support@vectracor.com

A Return Merchandise Authorization (RMA) number will be issued for repairs

THE INSTRUMENT MUST BE RETURNED FOR REPAIRS AT THE EXPENSE OF THE PURCHASER. IN-WARRANTY REPAIRED UNITS ARE RETURNED AT THE EXPENSE OF VECTRACOR OR ITS AUTHORIZED AGENT. FOR OUT OF WARRANTY WORK THE CUSTOMER IS RESPONSIBLE FOR ALL FREIGHT CHARGES.

Limited Warranty

- All instruments sold and supplied by VectraCor are guaranteed to be free from defects in material and workmanship for a period of 1 year from date of purchase. All supplies and accessories carry a 90-day limited warranty. If in the judgment of VectraCor the instrument is proven to be defective during the warranty period it will be repaired or replaced with no charge for parts or labor.
- This warranty does not cover any instrument that has been damaged by accident, misuse, abuse or has been altered or repaired by anyone other than an authorized VectraCor agent. This warranty also does not cover any unit that has had the serial number removed, defaced or rendered illegible.
- **THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS AND IS HEREBY LIMITED TO REPAIR OR REPLACEMENT OF INSTRUMENTS FOUND DEFECTIVE DURING THE WARRANTY PERIOD. AN AUTHORIZED VECTRACOR AGENT MUST MAKE ALL REPAIRS. INSTRUMENTS SENT BY MAIL OR COMMON CARRIER SHOULD BE INSURED AGAINST LOSS OR DAMAGES, AS THEY ARE NOT COVERED BY THIS WARRANTY.**
- Technical support on software is under warranty for 1-year. This includes ECG lead wires. A software support package is available after 1-year at an additional cost.

Diagnostic Performance

The following table summarizes a non-inferiority study comparing the VectraplexAMI index (CEB, Cardiac Electrical Biomarker) to both a computerized interpretation software program (ECGI) and ST segment analysis software in detecting ECG changes suggestive of an AMI from the interpretation of 2 blinded physician reference standards (board-certified Emergency Medicine Physician (EM) and board-certified Cardiologist (CARD)).

Comparative Test	Diagnostic Performance Measures	Parameters	*Actual		*Worst Case	
			*EM	Cardiology	*EM	Cardiology
ST0 = J point	Sensitivity (TPF)	VectraplexAMI (CEB)	93.75%	87.27%	89.55%	82.76%
		ST0 (J point evaluation)	70.31%	76.36%	70.15%	75.86%
		rTPF (CEB:ST0 Ratio)	1.33	1.143	1.277	1.091
		95% CI (LL, UL)	(1.155,1.539)	(0.998, 1.309)	(1.007,1.618)	(0.854, 1.394)
	Specificity (FPF = 1-Specificity)	VectraplexAMI (CEB)	91.30%	81.50%	84.68%	75.55%
		ST0 (J point evaluation)	73.48%	74.02%	73.39%	73.72%
		rFPF (CEB:ST0 Ratio)	0.328	0.712	0.576	0.93
		95% CI (LL, UL)	(0.309, 0.348)	(0.669, 0.758)	(0.542, 0.612)	(0.872, 0.993)
	Negative Predicitive Value	VectraplexAMI NPV	98.1%	96.7%	96.8%	95.4%
		ST0 NPV	89.9%	93.5%	90.1%	93.5%
	Positive Predicitive Value	VectraplexAMI PPV	75.0%	50.5%	61.2%	41.7%
		ST0 PPV	42.5%	38.9%	41.6%	37.9%
	Caution Zone %	No Test %	6.67%	6.93%	6.67%	6.93%
	Utility%	(1-No Test)%	93.33%	93.07%	93.33%	93.07%
	Prevalence	Prev	19.0%	17.4%	19.0%	17.4%

Comparative Test	Diagnostic Performance Measures	Parameters	*Actual		*Worst Case	
			*EM	Cardiology	*EM	Cardiology
STSUM = Area under ST segment	Sensitivity (TPF)	VectraplexAMI (CEB)	93.8%	87.3%	89.6%	81.4%
		STSUM (ST segment)	65.6%	69.1%	65.7%	67.8%
		rTPF (CEB:STSUM Ratio)	1.429	1.263	1.364	1.2
		95% CI (LL, UL)	(1.211, 1.685)	(1.066, 1.497)	(1.067, 1.742)	(0.928, 1.551)
	Specificity (FPF = 1-Specificity)	VectraplexAMI (CEB)	91.30%	81.82%	84.68%	75.82%
		STSUM (ST segment)	61.30%	60.47%	62.10%	61.17%
		rFPF (CEB:STSUM Ratio)	0.225	0.46	0.404	0.623
		95% CI (LL, UL)	(0.208, 0.242)	(0.426, 0.497)	(0.374, 0.436)	(0.575, 0.674)
	Negative Predicitive Value	VectraplexAMI NPV	98.1%	96.7%	96.8%	95.0%
		STSUM NPV	86.5%	90.0%	87.0%	89.8%
	Positive Predicitive Value	VectraplexAMI PPV	75.0%	51.1%	61.2%	42.1%
		STSUM PPV	32.1%	27.5%	31.9%	27.4%
	Caution Zone %	No Test %	6.67%	7.23%	6.67%	7.23%
	Utility%	(1-No Test)%	93.33%	92.77%	93.33%	92.77%
	Prevalence	Prev	21.8%	17.9%	21.3%	17.8%

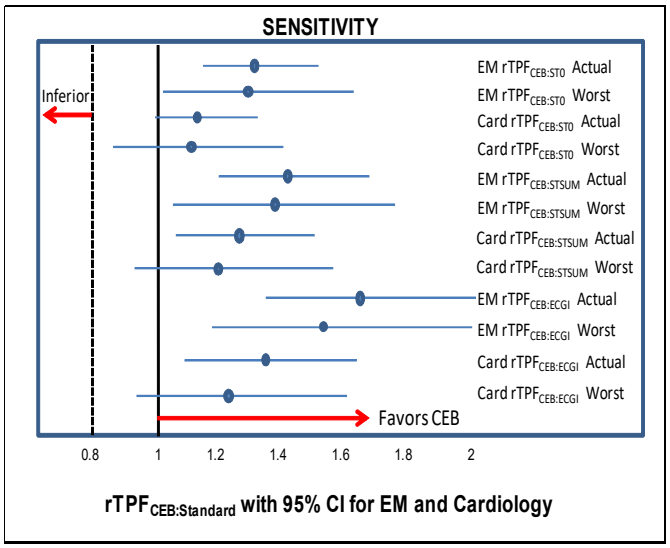
Comparative Test	Diagnostic Performance Measures	Parameters	*Actual		*Worst Case	
			*EM	Cardiology	*EM	Cardiology
ECGI = Computer Interpretation	Sensitivity (TPF)	VectraplexAMI (CEB)	93.4%	84.6%	85.1%	77.2%
		ECGI (Computer reading)	57.4%	63.5%	56.7%	63.2%
		rTPF (CEB:ECGI Ratio)	1.629	1.333	1.500	1.222
		95% CI (LL, UL)	(1.353, 1.960)	(1.097, 1.621)	(1.153, 1.952)	(0.932, 1.602)
	Specificity (FPF = 1-Specificity)	VectraplexAMI (CEB)	91.34%	81.18%	85.08%	75.27%
		ECGI (Computer reading)	77.92%	76.47%	76.61%	75.64%
		rFPF (CEB:ECGI Ratio)	0.392	0.800	0.638	1.015
		95% CI (LL, UL)	(0.374, 0.411)	(0.761, 0.841)	(0.607, 0.671)	(0.963, 1.070)
	Negative Predicitive Value	VectraplexAMI NPV	98.1%	96.3%	95.5%	94.1%
		ECGI NPV	87.4%	91.1%	86.8%	90.8%
	Positive Predicitive Value	VectraplexAMI PPV	74.0%	47.8%	60.6%	39.3%
		ECGI PPV	40.7%	35.5%	39.6%	35.0%
	Caution Zone %	No Test %	7.30%	7.53%	7.30%	7.53%
	Utility%	(1-No Test)%	92.70%	92.47%	92.70%	92.47%
	Prevalence	Prev	20.9%	16.9%	21.3%	17.2%

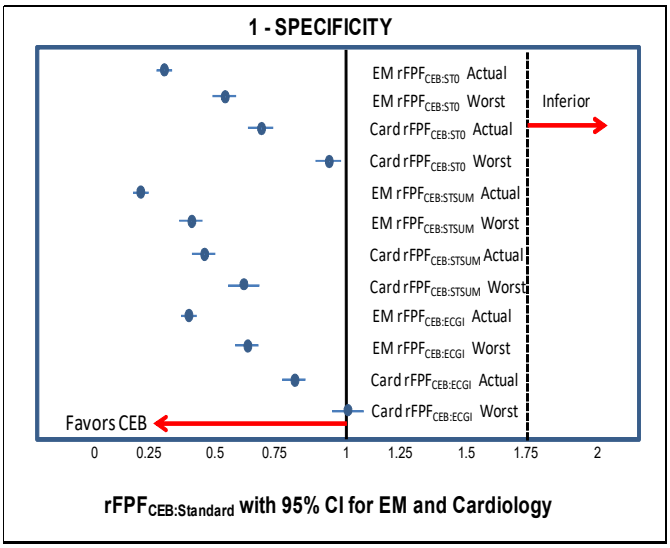
***Actual = Diagnostic performance excluding cases that displayed a "NO TEST" ("Caution Zone") result**
***Worst Case = Diagnostic performance utilizing all cases (including "NO TEST" ("Caution Zone") cases).**
The "NO TEST" cases are all considered to be a misdiagnosis (ie, either a false negative or false positive result)
***CEB = VeactraplexAMI® cardiac electrical biomarker**
***ECGI = Computerized Interpretation Software**
***ST0 = J point**
***STSUM = area under ST segment for ST0-ST80**
***EM = Emergency Medicine**
***CI = 95% Confidence Interval**
***TPF = True positive fraction = Sensitivity = (True Positives)/(True Postives + False Negatives)**
***FPF = False positive fraction = 1 - Specificity, where Specificity = (True Negatives)/(True Negatives + False Positives)**
***LL = Lower limit 95% CI**
***UL = Upper limit 95% CI**

Standard = ST0 (J point), or STSUM, or ECGI analysis
***rTPF = CEB_{TPF}:$Standard_{TPF}$= ratio of the CEB to Standard Test TPF (sensitivity ratio)**
If rTPF = 1, then CEB TPF = Standard TPF; If rTPF > 1, then rTPF favors CEB; If rTPF <1, then rTPF favors Standard Test
If LL rTPR > 0.8, then the CEB sensitivity is non-inferior to Standard Test;
If rTPF > 1 and LL rTPF >1, then CEB sensitivity is superior and non-inferior to the Standard Test
***rFPF = $CEBF_{PF}$:$StandardF_{PF}$= ratio of the CEB to Standard FPF (1-specificity ratio)**
If rFPF = 1, then CEB FPF = Standard FPF (specificities are equal); If rFPF > 1, then rFPF favors CEB;
If rFPF < 1, then rFPF favors Standard Test
If UL rFPF < 1.75, then CEB specificity is non-inferior to Standard Test;
If UL rFPF < 1.75 and rFPF < 1 , then CEB specificity is superior and non-inferior to Standard Test

The statistical evaluation with confidence intervals of rTPF and rFPF is described by Alonzo, et al:

Alonzo TA, Pepe MS, Moskow otz CS: Sample size calculations for comparative studies of medical tests for detecting presence of disease. Statist. Med. 2002;21:835-852.

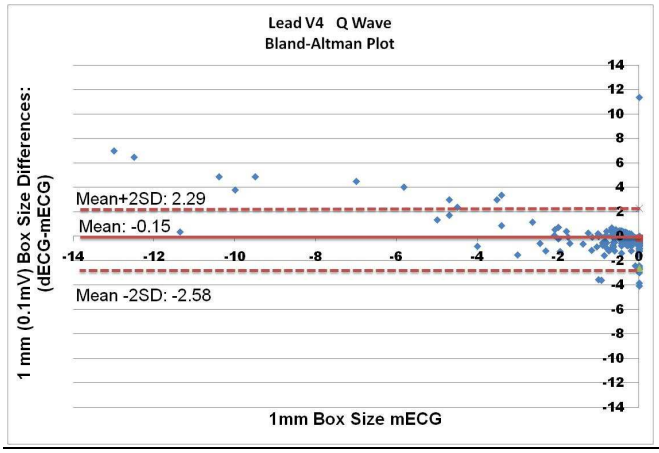

SENSITIVITY
Inferior
EM rTPF CEB:ST0 Actual
EM rTPF CEB:ST0 Worst
Card rTPF CEB:ST0 Actual
Card rTPF CEB:ST0 Worst
EM rTPF CEB:STSUM Actual
EM rTPF CEB:STSUM Worst
Card rTPF CEB:STSUM Actual
Card rTPF CEB:STSUM Worst
EM rTPF CEB:ECGI Actual
EM rTPF CEB:ECGI Worst
Card rTPF CEB:ECGI Actual
Card rTPF CEB:ECGI Worst
Favors CEB
0.8
1
1.2
1.4
1.6
1.8
2
rTPF CEB:Standard with 95% CI for EM and Cardiology

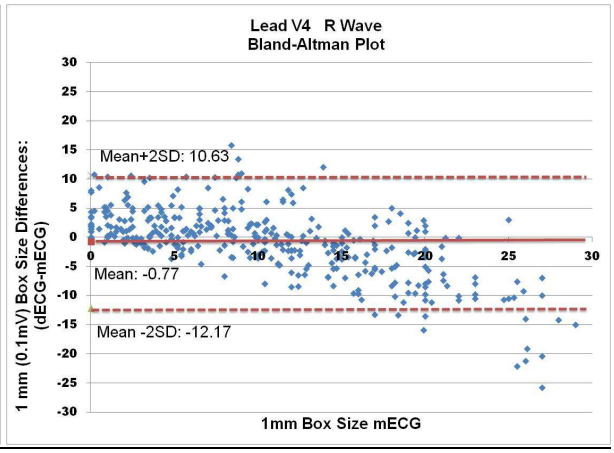

1 - SPECIFICITY
EM rFPF CEB:ST0 Actual
EM rFPF CEB:ST0 Worst
Card rFPF CEB:ST0 Actual
Card rFPF CEB:ST0 Worst
EM rFPF CEB:STSUM Actual
EM rFPF CEB:STSUM Worst
Card rFPF CEB:STSUM Actual
Card rFPF CEB:STSUM Worst
EM rFPF CEB:ECGI Actual
EM rFPF CEB:ECGI Worst
Card rFPF CEB:ECGI Actual
Card rFPF CEB:ECGI Worst
Inferior
Favors CEB
0
0.25
0.5
0.75
1
1.25
1.5
1.75
2
rFPF CEB:Standard with 95% CI for EM and Cardiology

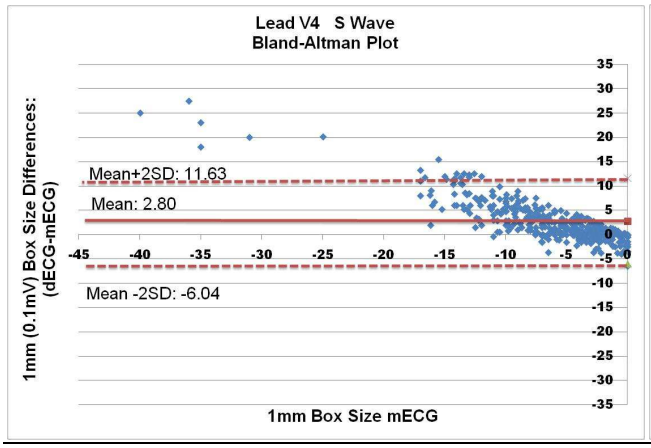
The following data are Bland-Altman plots of the (dECG-mECG) voltages on the y axis and the mECG on the x Axis (1mm box =0.1mV). The dECG may under-estimate the voltage of the mECG when the mECG is at high voltages for leads V4-V6. The Bland-Altman plots are as follows:

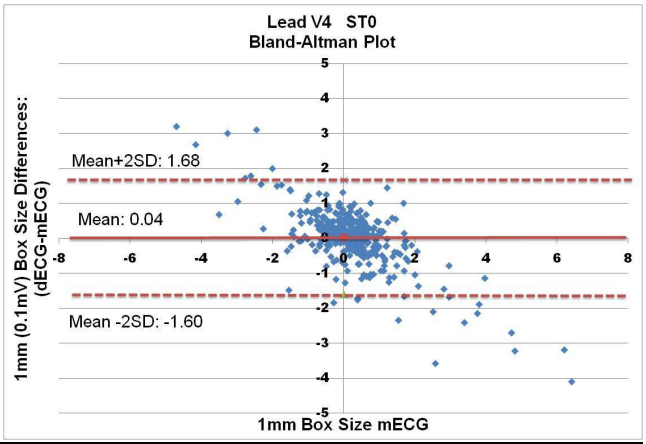
Note: There are graphs that may have cases with identical points around (0,0), which may reflect a lower sample size.

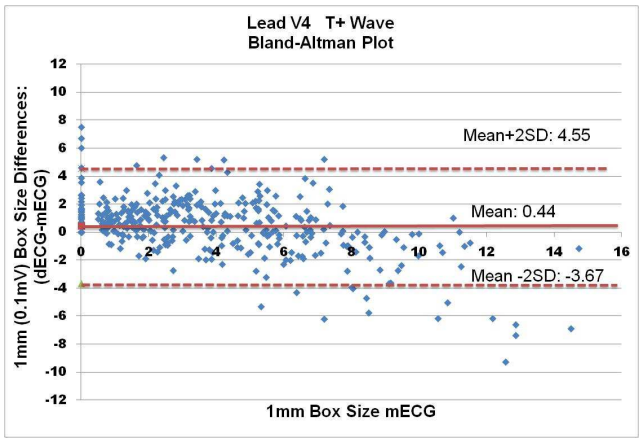
Lead V4

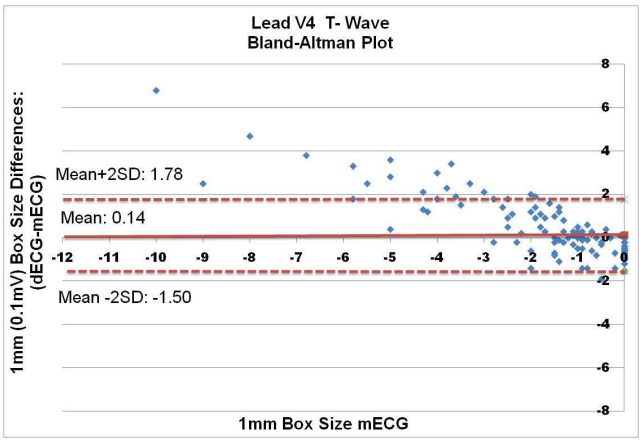




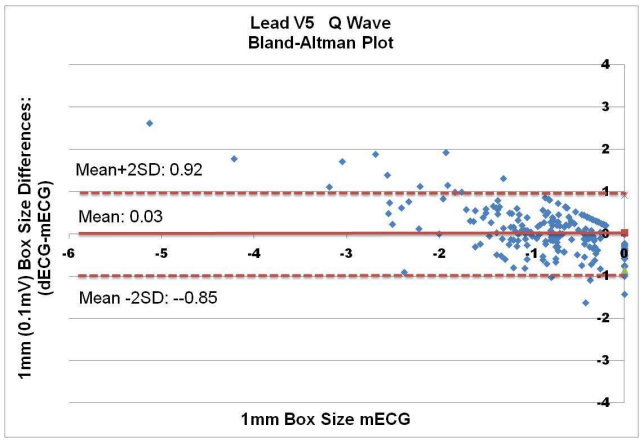


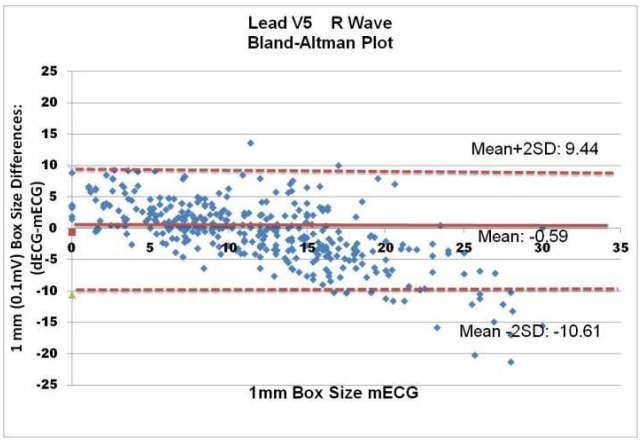


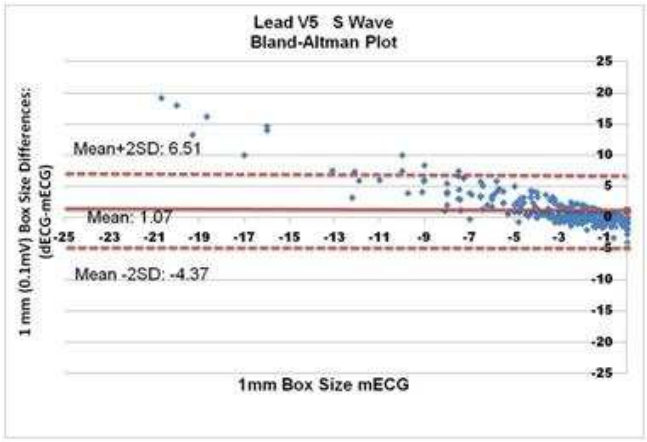


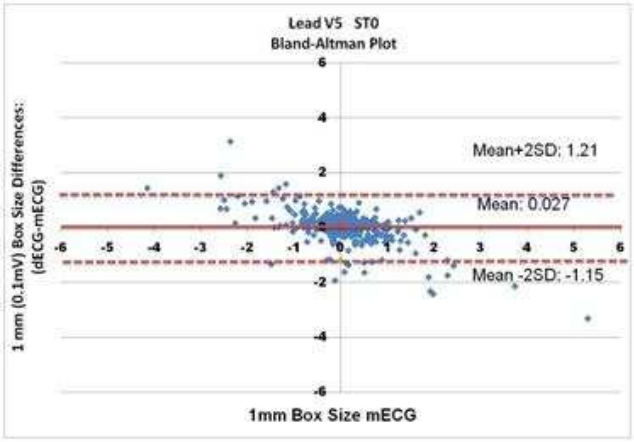


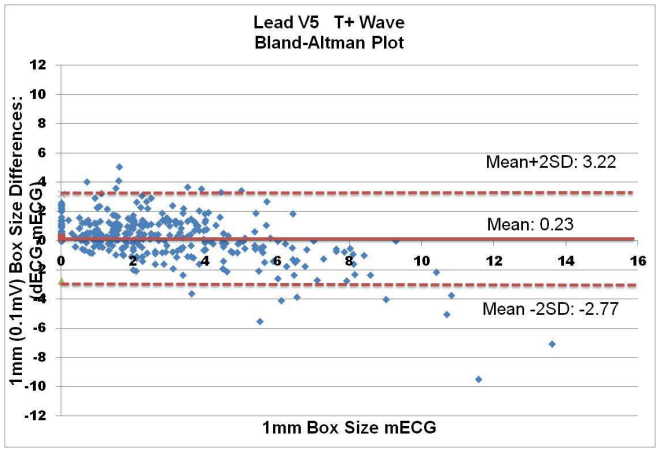
Lead V5

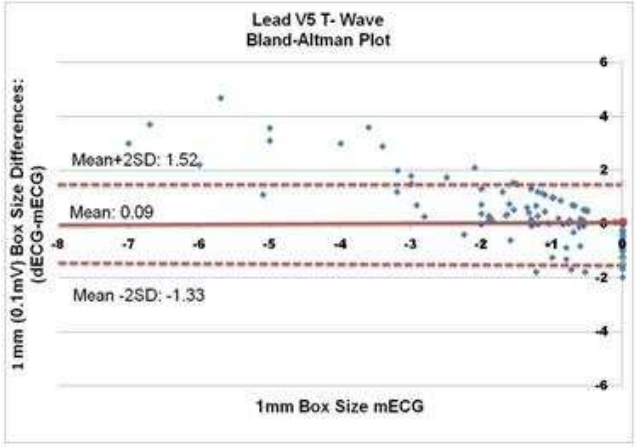

Lead V5 Q Wave
Bland-Altman Plot
Mean+2SD: 0.92
Mean: 0.03
Mean -2SD: --0.85
1mm (0.1mV) Box Size Differences: (dECG-mECG)
1mm Box Size mECG


Lead V5 R Wave
Bland-Altman Plot
Mean+2SD: 9.44
Mean: -0.59
Mean -2SD: -10.61
1 mm (0.1mV) Box Size Differences: (dECG-mECG)
1mm Box Size mECG

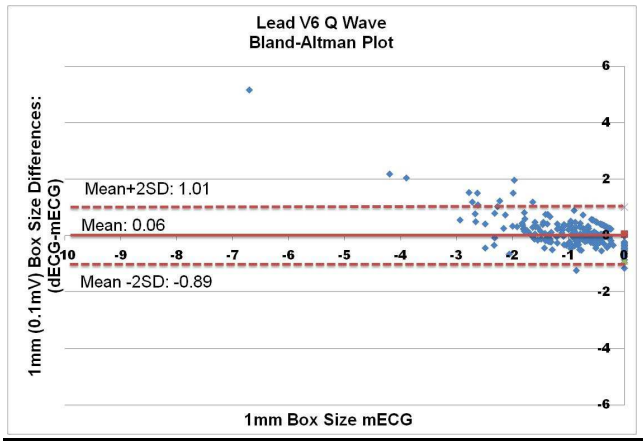

Lead V5 S Wave
Bland-Altman Plot
Mean+2SD: 6.51
Mean: 1.07
Mean -2SD: -4.37
1 mm (0.1mV) Box Size Differences: (dECG-mECG)
1mm Box Size mECG

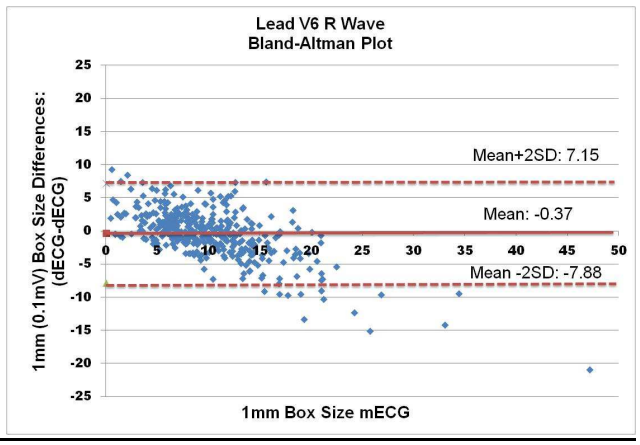

Lead V5 ST0
Bland-Altman Plot
Mean+2SD: 1.21
Mean: 0.027
Mean -2SD: -1.15
1 mm (0.1mV) Box Size Differences: (dECG-mECG)
1mm Box Size mECG

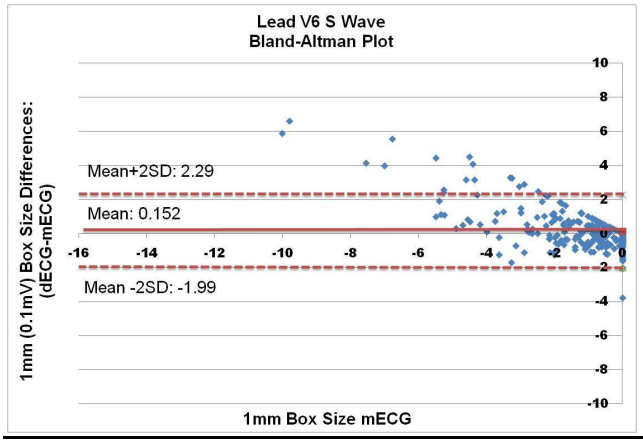

Lead V5 T+ Wave
Bland-Altman Plot
Mean+2SD: 3.22
Mean: 0.23
Mean -2SD: -2.77
1mm (0.1mV) Box Size Differences: (dECG-mECG)
1mm Box Size mECG

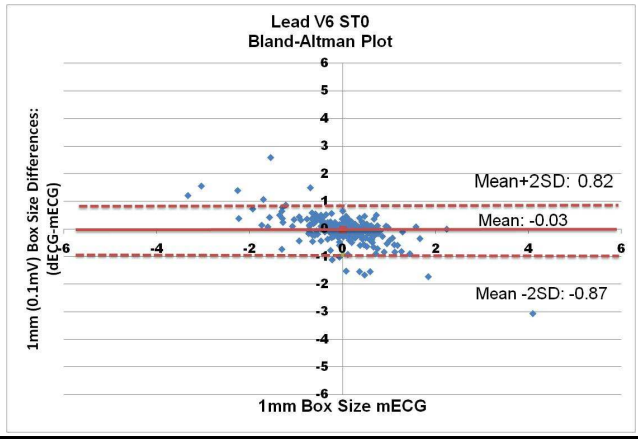

Lead V5 T- Wave
Bland-Altman Plot
Mean+2SD: 1.52
Mean: 0.09
Mean -2SD: -1.33
1mm (0.1mV) Box Size Differences: (dECG-mECG)
1mm Box Size mECG

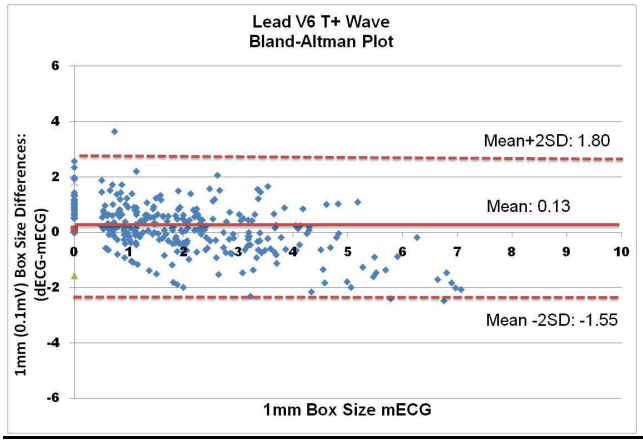
Lead V6

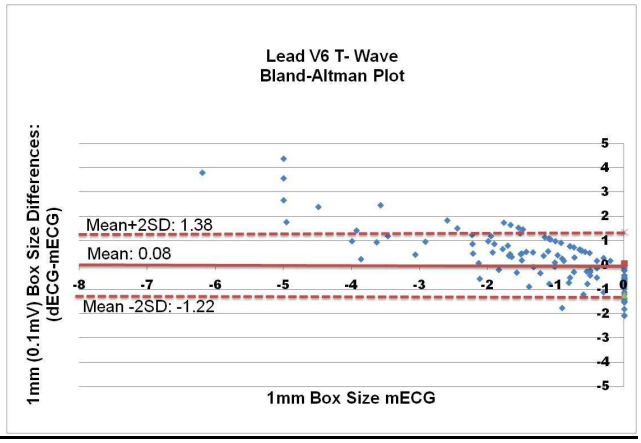

Lead V6 Q Wave
Bland-Altman Plot
1mm (0.1mV) Box Size Differences: (dECG-mECG)
Mean+2SD: 1.01
Mean: 0.06
Mean -2SD: -0.89
1mm Box Size mECG


Lead V6 R Wave
Bland-Altman Plot
1mm (0.1mV) Box Size Differences: (dECG-dECG)
Mean+2SD: 7.15
Mean: -0.37
Mean -2SD: -7.88
1mm Box Size mECG


Lead V6 S Wave
Bland-Altman Plot
1mm (0.1mV) Box Size Differences: (dECG-mECG)
Mean+2SD: 2.29
Mean: 0.152
Mean -2SD: -1.99
1mm Box Size mECG


Lead V6 ST0
Bland-Altman Plot
1mm (0.1mV) Box Size Differences: (dECG-mECG)
Mean+2SD: 0.82
Mean: -0.03
Mean -2SD: -0.87
1mm Box Size mECG


Lead V6 T+ Wave
Bland-Altman Plot
1mm (0.1mV) Box Size Differences: (dECG-mECG)
Mean+2SD: 1.80
Mean: 0.13
Mean -2SD: -1.55
1mm Box Size mECG


Lead V6 T- Wave
Bland-Altman Plot
1mm (0.1mV) Box Size Differences: (dECG-mECG)
Mean+2SD: 1.38
Mean: 0.08
Mean -2SD: -1.22
1mm Box Size mECG

The following table describes the performance agreements for various clinical conditions for the physician reference standards in comparing the measured ECG to the derived ECG using the VectraplexECG System. The physician reference standards (Emergency Medicine physician and Cardiologist) were blinded to the measured and derived ECGs, and to each other, when interpreting each ECG.

		Cardiology	EM			Cardiology	EM
1st Degree AV Block	n	52	47	NSR	n	242	225
	OA	100.0%	100.0%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
AAWMI	n	28	30	NSSTT	n	82	74
	OA	98.8%	98.1%		OA	100.0%	100.0%
	PPA	92.3%	92.3%		PPA	100.0%	100.0%
	PNA	99.3%	98.6%		PNA	100.0%	100.0%
Afib	n	14	17	NSTEMI	n	9	7
	OA	100.0%	100.0%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
AIWMI	n	22	35	NSTEMI AWMI	n	7	13
	OA	100.0%	100.0%		OA	99.7%	100.0%
	PPA	100.0%	100.0%		PPA	85.7%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
ALWMI	n	11	20	NSTEMI IWMI	n	4	8
	OA	99.4%	99.1%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	99.4%	99.0%		PNA	100.0%	100.0%
AMI	n	58	68	NSTEMI LWMI	n	6	20
	OA	99.4%	100.0%		OA	100.0%	100.0%
	PPA	98.2%	100.0%		PPA	100.0%	100.0%
	PNA	99.6%	100.0%		PNA	100.0%	100.0%
APWMI	n	6	15	NSTEMI SWMI	n	1	9
	OA	100.0%	99.1%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	99.0%		PNA	100.0%	100.0%
Arrythmia	n	84	89	Paced	n	4	4
	OA	100.0%	100.0%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
ASWMI	n	21	28	PAWMI	n	50	33
	OA	100.0%	98.7%		OA	99.4%	99.1%
	PPA	100.0%	88.9%		PPA	100.0%	93.8%
	PNA	100.0%	99.7%		PNA	99.3%	99.6%
Bradycardia	n	52	56	PIWMI	n	56	63
	OA	100.0%	100.0%		OA	99.7%	99.7%
	PPA	100.0%	100.0%		PPA	100.0%	98.4%
	PNA	100.0%	100.0%		PNA	99.6%	100.0%
Early Repole	n	27	27	PLWMI	n	5	28
	OA	100.0%	100.0%		OA	99.7%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	99.7%	100.0%

		Cardiology	EM			Cardiology	EM
ILBBB	n	3	3	PSWMI	n	53	28
	OA	100.0%	100.0%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
IRBBB	n	4	17	PVC	n	11	11
	OA	100.0%	99.1%		OA	100.0%	100.0%
	PPA	100.0%	82.4%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
IVCD	n	34	39	RAD	n	7	5
	OA	100.0%	100.0%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
LAD	n	32	32	RAE	n	3	1
	OA	100.0%	100.0%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
LAE	n	59	101	RBBB	n	14	12
	OA	99.7%	99.7%		OA	100.0%	100.0%
	PPA	98.3%	99.0%		PPA	100.0%	100.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
LAFB	n	9	25	RVH	n	2	1
	OA	99.7%	100.0%		OA	100.0%	99.7%
	PPA	88.9%	100.0%		PPA	100.0%	0.0%
	PNA	100.0%	100.0%		PNA	100.0%	100.0%
LBBB	n	18	16	STEMI	n	49	61
	OA	100.0%	100.0%		OA	99.4%	99.7%
	PPA	100.0%	100.0%		PPA	97.9%	98.4%
	PNA	100.0%	100.0%		PNA	99.6%	100.0%
LVH	n	32	27	Tachycardia	n	19	19
	OA	99.7%	99.7%		OA	100.0%	100.0%
	PPA	100.0%	100.0%		PPA	100.0%	100.0%
	PNA	99.7%	99.7%		PNA	100.0%	100.0%
Norm Axis	n	289	279				
	OA	100.0%	100.0%				
	PPA	100.0%	100.0%				
	PNA	100.0%	100.0%				

Note:

1. n= sample size
2. Total sample size for Cardiologist is 328
3. Total sample size for Emergency Physician is 316
4. Total sample size for Adjudication is 316
5. OA = Overall Agreement
6. PPA = Percent Positive Agreement
7. PNA = Percent Negative Agreement

Glossary of Terms

CEB® Index	The CEB® Index is a cardiac electrical biomarker that can detect real time changes in the ECG suggestive of an AMII, including AMI.
BF Equipment	Degree of protection against electrical shock.
AMII	Acute Myocardial Ischemic Injury
AMI	Acute Myocardial Infarction
CEB	CEB® Index
AAWMI	Acute Anterior Wall Myocardial Infarction
AFib	Atrial Fibrillation
AIWMI	Acute Inferior Wall Myocardial Infarction
ALWMI	Acute Lateral Wall Myocardial Infarction
APWMI	Acute Posterior Wall Myocardial Infarction
ASWMI	Acute Septal Wall Myocardial Infarction
Early Repole	Early Re-polarization
NSR	Normal Sinus Rhythm
NSSTT	Non-Specific ST-T Changes
NSTEMI	Non-ST Elevation Myocardial Infarction
NSTEMI AWMI	Non- STEMI Anterior Wall Myocardial Infarction
NSTEMI IWMI	Non- STEMI Inferior Wall Myocardial Infarction
NSTEMI LWMI	Non-STEMI Lateral Wall Myocardial Infarction
NSTEMI SWMI	Non-STEMI Septal Wall Myocardial Infarction
Paced	Pacemaker rhythm
PAWMI	Prior Anterior Wall Myocardial Infarction
PIWMI	Prior Inferior Wall Myocardial Infarction
PLWMI	Prior Lateral Wall Myocardial Infarction
ILBBB	Incomplete Left Bundle Branch Block

IRBBB	Incomplete Right Bundle Branch Block
IVCD	Intraventricular conduction delay
LAD	Left Axis Deviation
LAE	Left Atrial Enlargement
LAFB	Left Anterior Fascicular Block
LBBB	Left Bundle Branch Block
LVH	Left Ventricular Hypertrophy
Norm Axis	Normal Axis
PSWMI	Prior Septal Wall Myocardial Infarction
PVC	Premature Ventricular Contraction
RAD	Right Axis Deviation
RAE	Right Atrial Enlargement
RBBB	Right Bundle Branch Block
RVH	Right Ventricular Hypertrophy
STEMI	ST Elevation Myocardial Infarction

Universal SmartECG Specifications

Hub Weight	280 - 335 grams (0.62 – 0.66 lb)
Hub Dimensions	85mm x 91mm x 20mm (3.3” x 3.6” x 0.8”)
Patient Leads Length	1.0 meter (3.3 ft) for limb leads 0.6 meter (2.0 ft) for chest leads
PC Connection Length	1.8 meter (5.9 ft) USB cable
Patient Leads	12-Lead Cable (10 patient electrodes)
Case Material	ABS Plastic
Electrode Connections	4 mm Banana plug with "tab" or "snap" connectors
Electrode Labeling	Abbreviations and colors to comply with either IEC or AAMI standards
Display and Operating Console	Dependent on PC (supplied by user)
Gain/Sensitivity	5, 10, 20 mm/mV
Input Range	±5mV
Acquisition sample rate	1000 samples per second (compressed to 500Hz with peak picking and averaging algorithm)
Heart Rate Range	30 bpm - 200 bpm
Frequency Response	0.05 to 175Hz ±3dB
Defibrillator Protection	Patient leads are isolated from system and operator, with 5kV protection
Common Mode Rejection	-60dB (minimum)
Safety Standards	Complies with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-25
Accuracy	Accurate to IEC 60601-2-25 essential performance requirements
Leads Off Indicators	Connection status for each lead is shown on Acquisition screen
Power Source	Powered by a PC via USB interface
Supply Voltage	5V DC
Supply Current	<17mA DC

Permanent Filters	High Pass: 0.05Hz 2nd order Low Pass: 175Hz 2nd order Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (Mains Noise Rejection)	50Hz 4th order Butterworth, 60Hz 4th order Butterworth,
Low pass (Muscle Artifact Filter)	35Hz 4th order
Report Capabilities	User selectable Report formats
Environmental Conditions	Operating Temperature: 10 to 35° C (50 to 95° F) Storage Temperature: -20 to 70° C (-4 to 158° F) Operating Relative Humidity: 20% -85% (non-condensing) Storage Relative Humidity: 10% -85% (non-condensing) Atmospheric Pressure: 70 kPA – 106 kPA