

VectraplexECG System
With
VectraplexAMI

User Manual

11/24/2015

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

VectraCor, Inc.
785 Totowa Rd
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

	Attention Consult Accompanying Documents
	Type BF Equipment Type B equipment with an F-type applied part (patient isolation from electric shock).
	Defibrillator proof type BF equipment Defibrillator proof type BF equipment complying with IEC Publication 601.
	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

Warnings

- The CEB® (VectraplexAMI®) 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.
- 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.
- 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.


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.
- Universal ECG 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.

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 for VECTRACOR Devices other than Universal ECG. Class A for Universal ECG Cable	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 air	±6 kV contact ±8 air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of VECTRACOR medical devices requires continued operation during power mains interruptions, it is recommended that the computer to be used is powered by an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note UT is the a.c. mains voltage prior to application of the test level			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: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 3.5\sqrt{P}$ 800MHz 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: 
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 Mhz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Electrical Safety Classifications

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

- Class II Equipment, Internally Powered.
- Type BF Equipment. Note: Universal ECG/VectraplexECG is Type BF 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.

Indications for Use

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

- VectraCor's VectraplexECG System with VectraplexAMI 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 infarction. The device does not provide a diagnosis of acute myocardial infarction, but prompts the user to acquire a standard 12-lead ECG (using 10 electrodes) for interpretation by a physician. Monitoring patients with VectraplexAMI is only indicated for patients presenting with chest pain or other presumed anginal equivalents.
- The VectraplexECG 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. The interpretation software is only available for the standard 12-lead ECG utilizing the standard 10 electrodes.
- VectraplexECG is intended to be used by healthcare professionals, i.e. Physicians, Nurses, Technicians, and Physician Assistants, where 12-lead and X, Y, Z leads are indicated for Hospitals and/or Clinics.
- 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.
- Device is for Adult use.

VectraplexECG System Basics

System Requirements

Operating System: Microsoft® Windows® 7 (Professional), Windows 8, Windows 10

Free Disk Space: minimum of 1 GB

Screen Resolution: minimum 1024x768 (EKG Requirement)

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

The system is shipped with the VectraplexECG software already installed. If you wish to upgrade to a more recent version please contact VectraCor.

A VectraplexECG shortcut will appear on your desktop.



Warning

- 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.
1. Connect the ECG patient cable (QRS Universal ECG™) to the PC using the USB port.

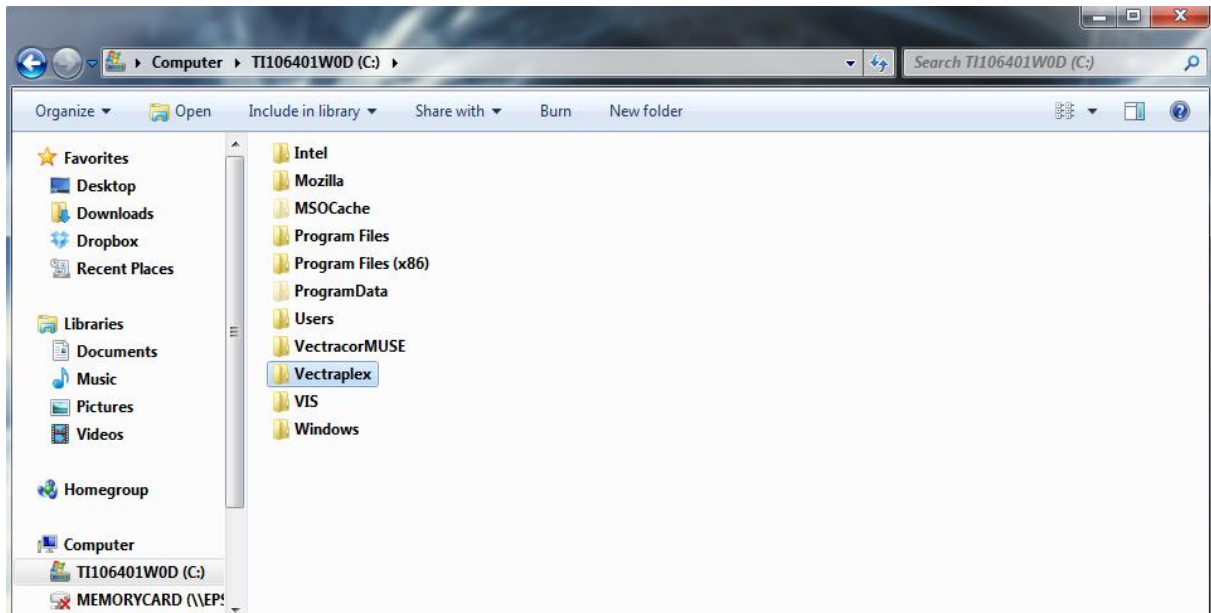


Backing-up and Restoring the Database

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.

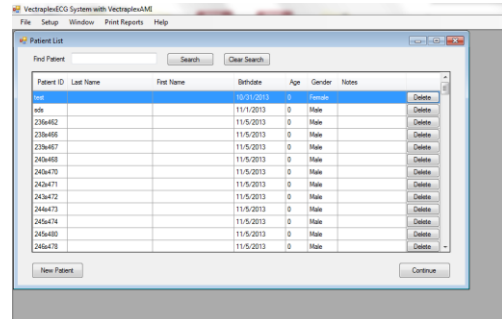
Getting Started - Navigation

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:

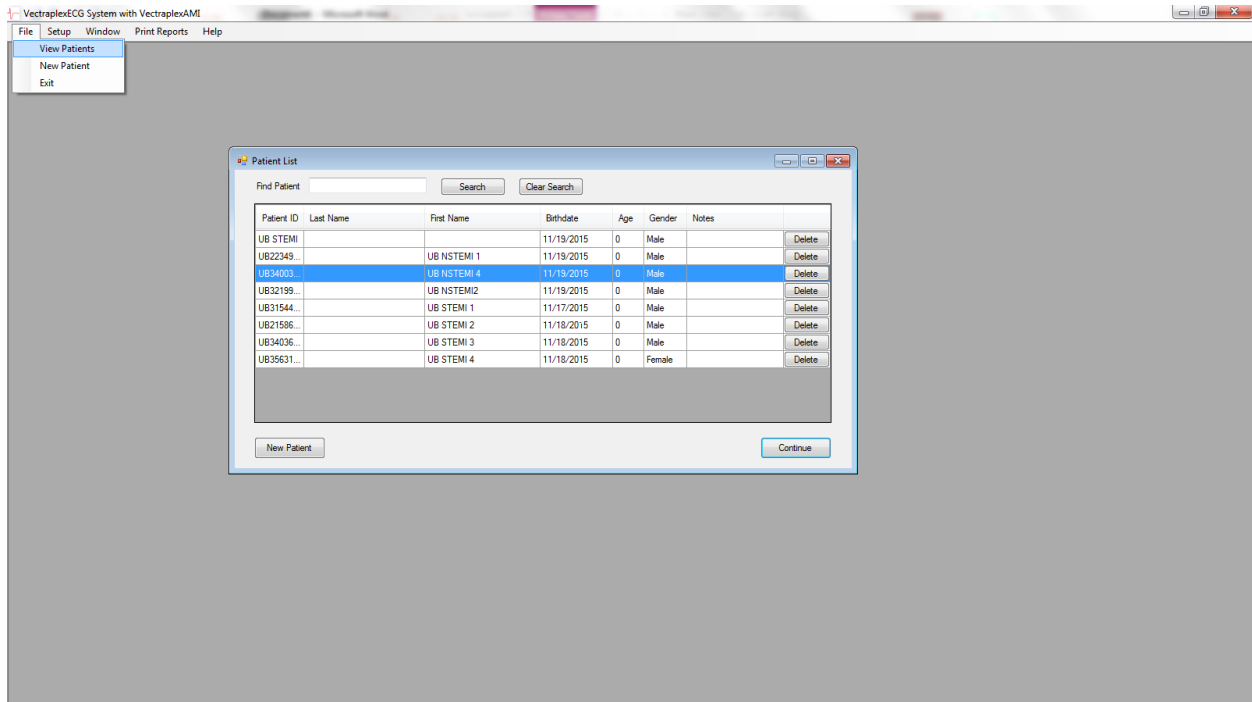
Splash Screen



Home Screen



File Tab

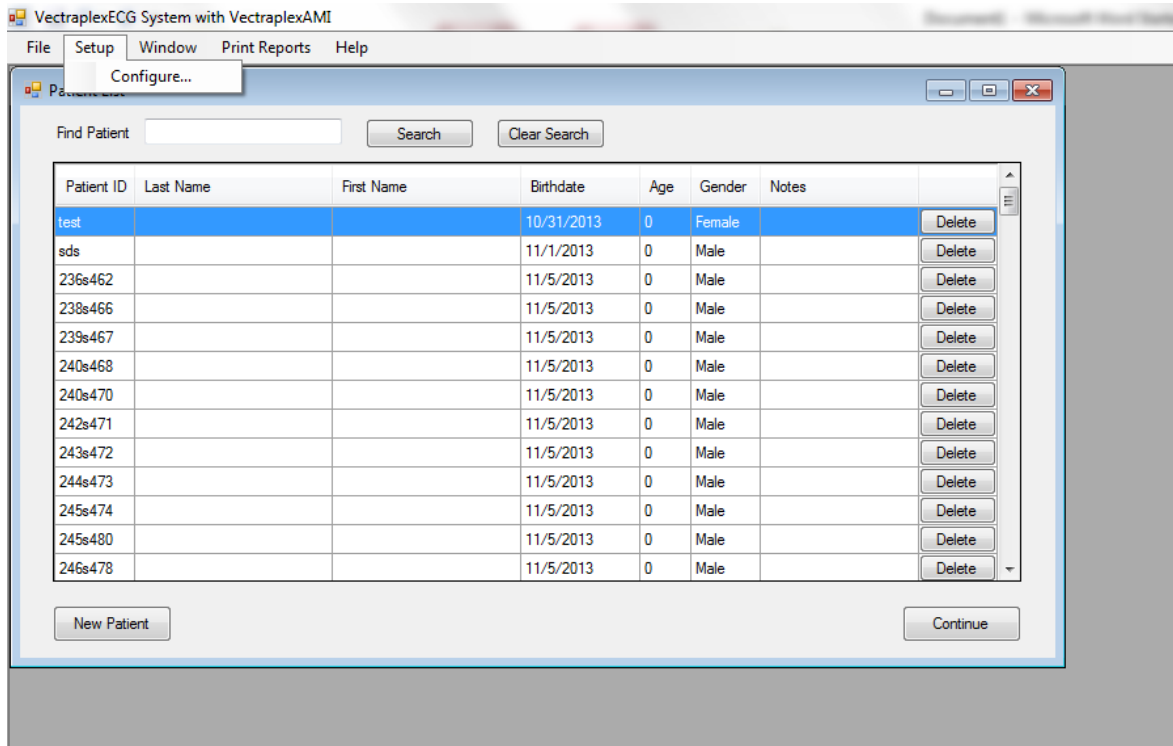


View Patients – Display the Patient List Screen

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.

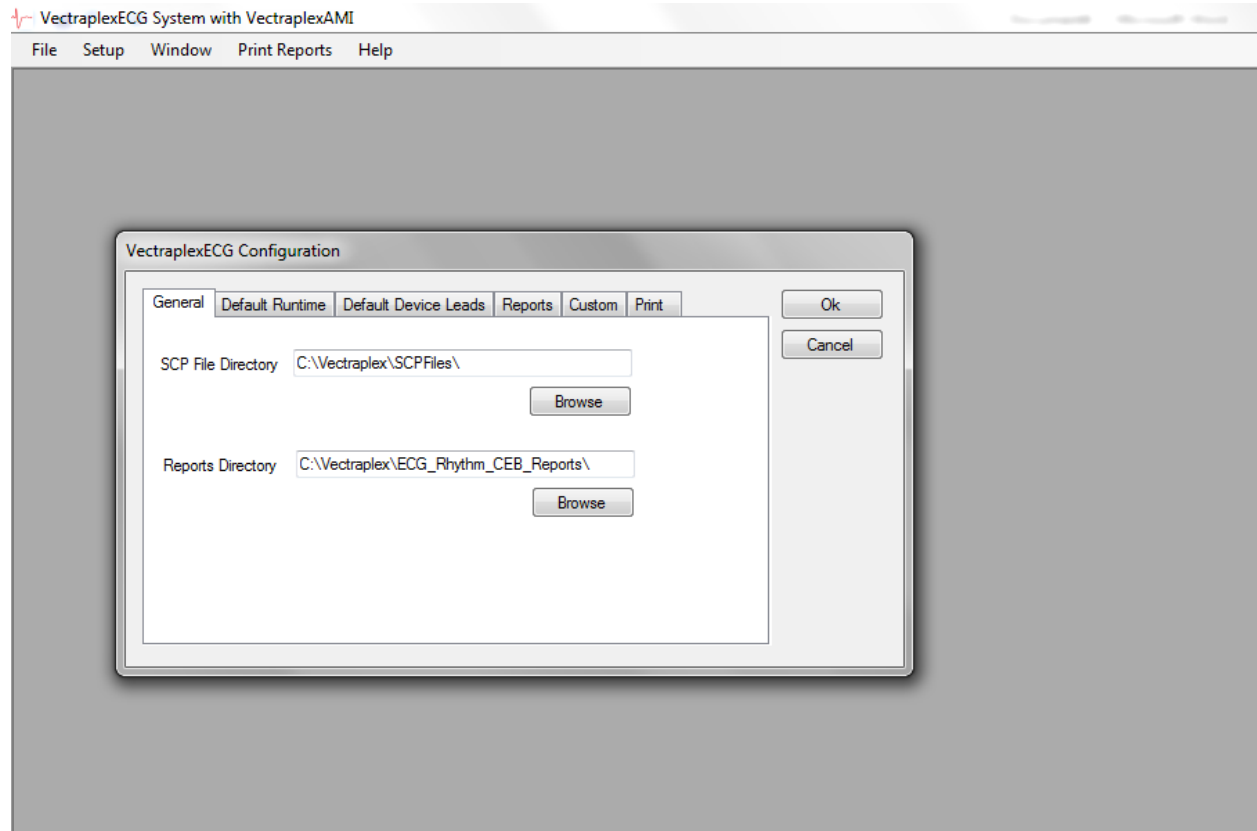
Setup Tab – VectraplexECG Configuration Menu



Select Setup to change program settings.

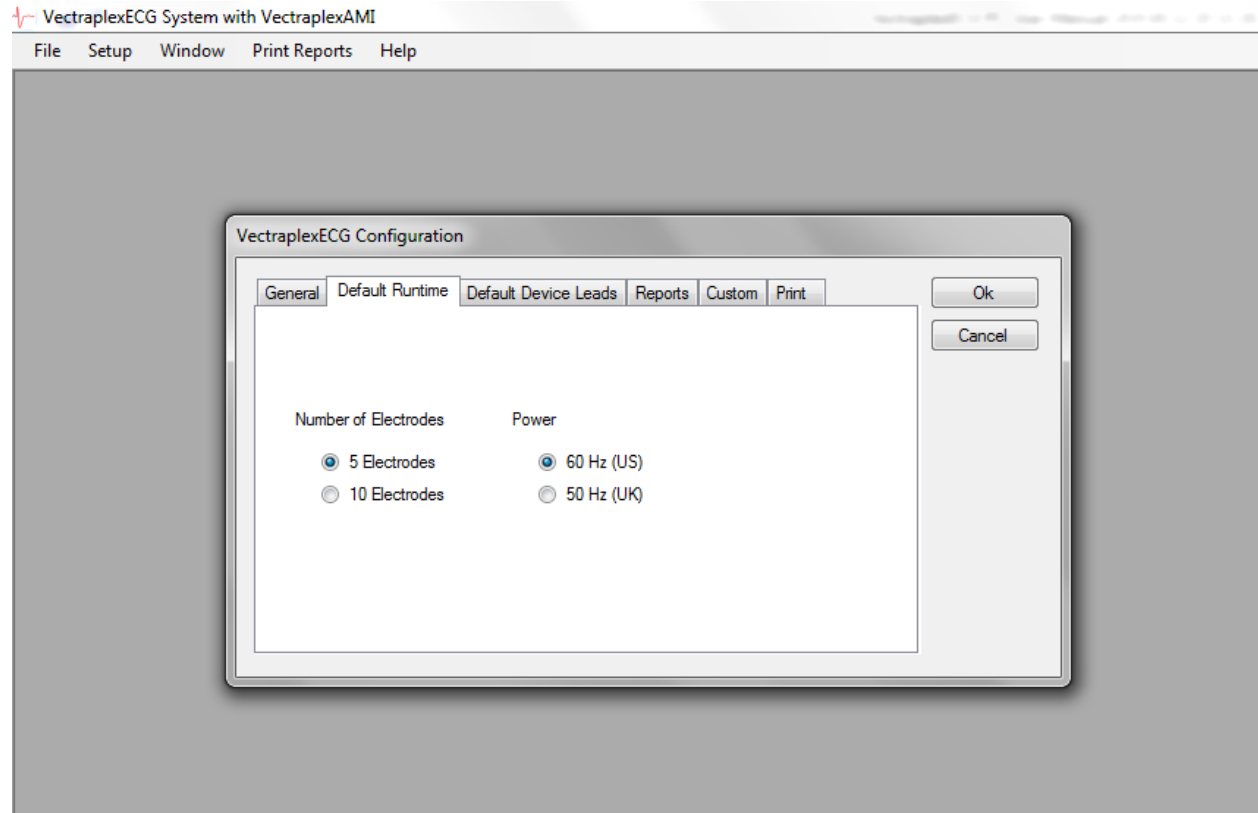
General Tab

- 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\”



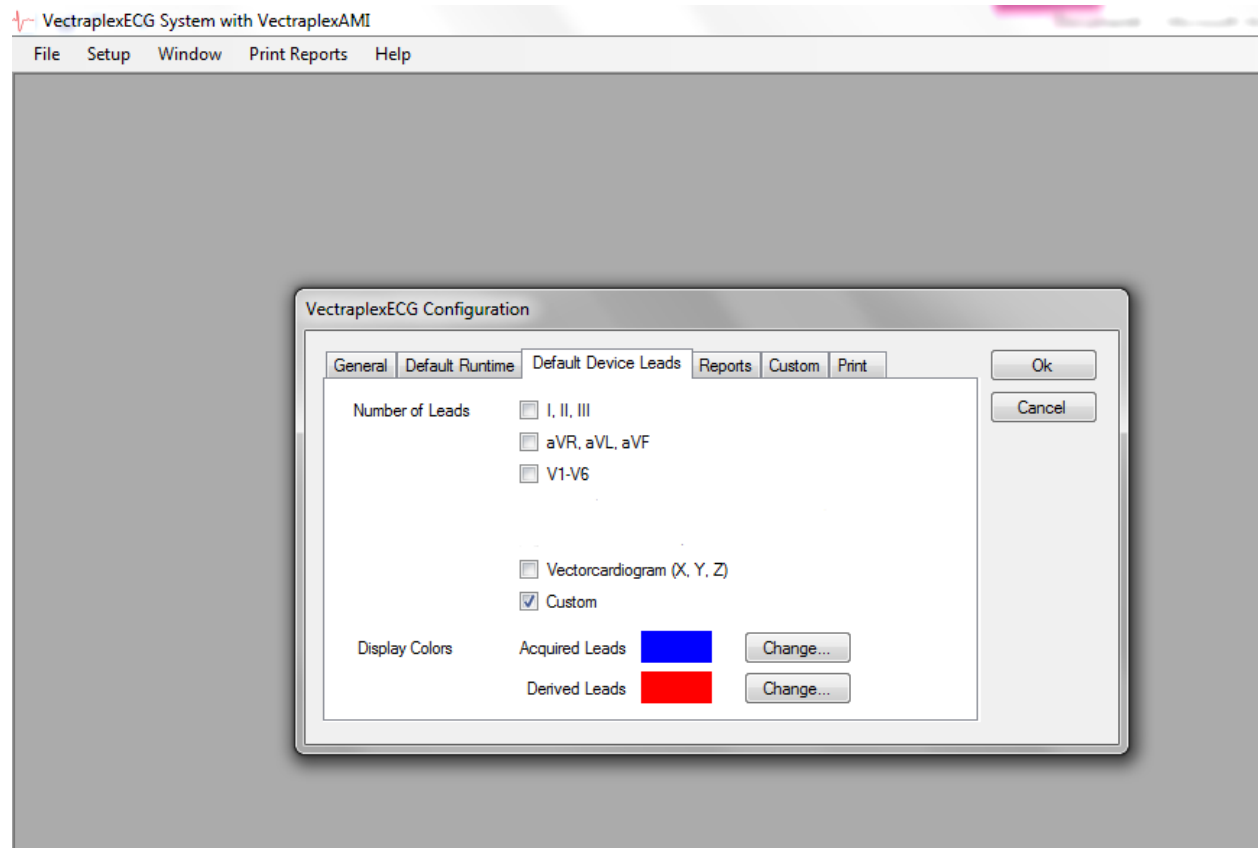
Default Runtime Tab

- **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 default display for the Monitor Screen during Live Acquisition.
- **Display colors** – This displays the color of the leads on the screen.
 - **Acquired Leads** – measured; Blue is default
 - **Derived Leads** - Red is default

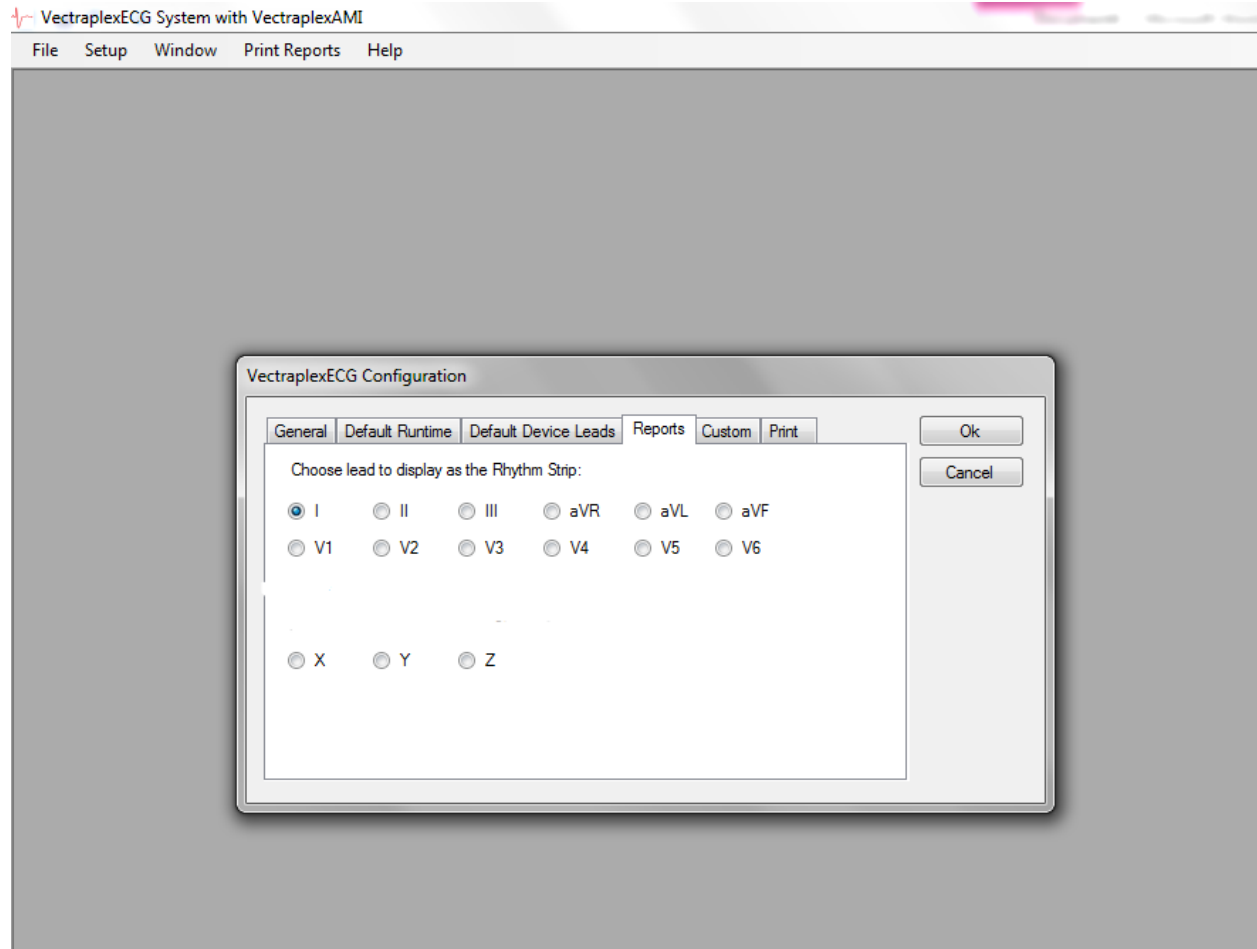


Note:

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.

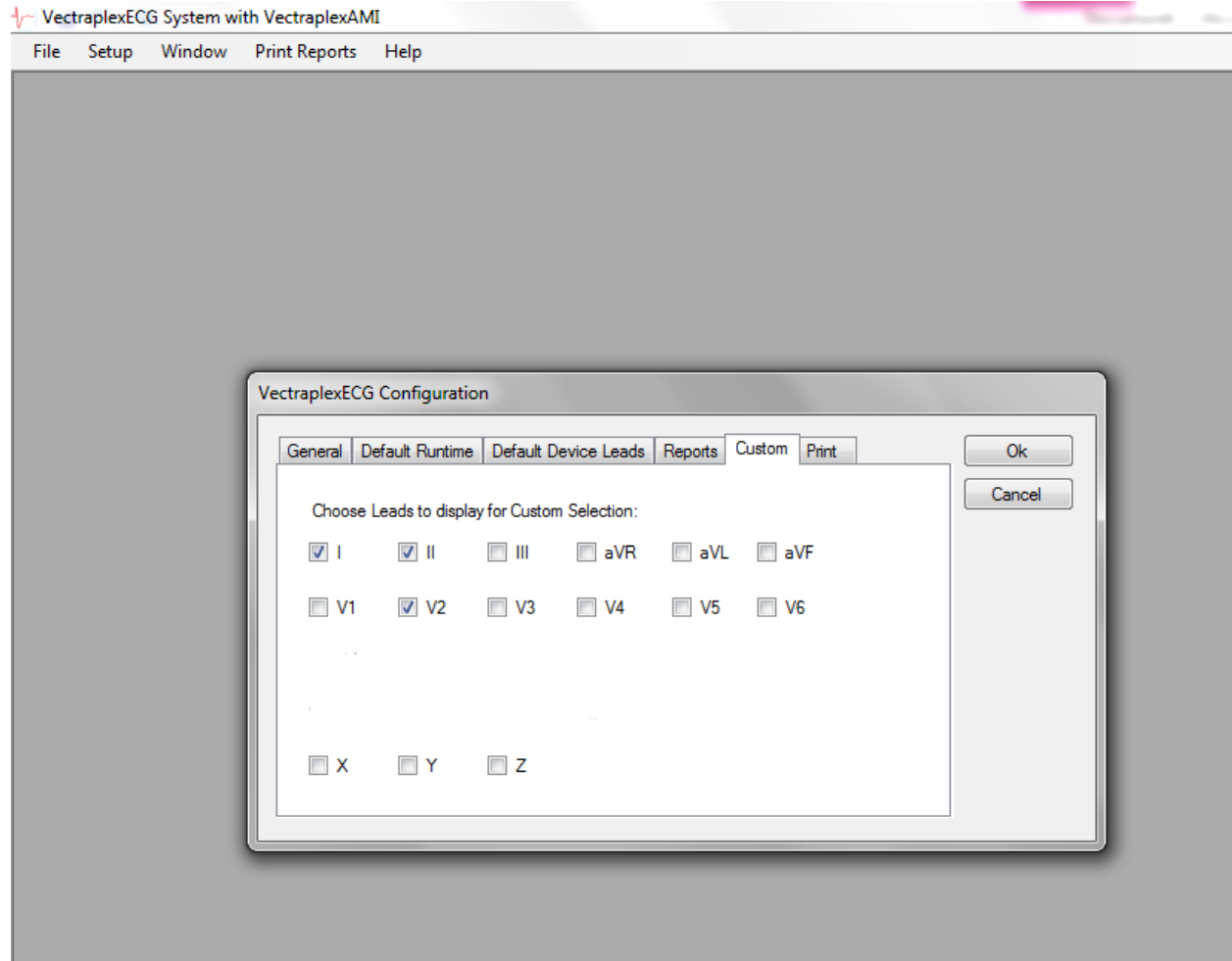
Reports Tab

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



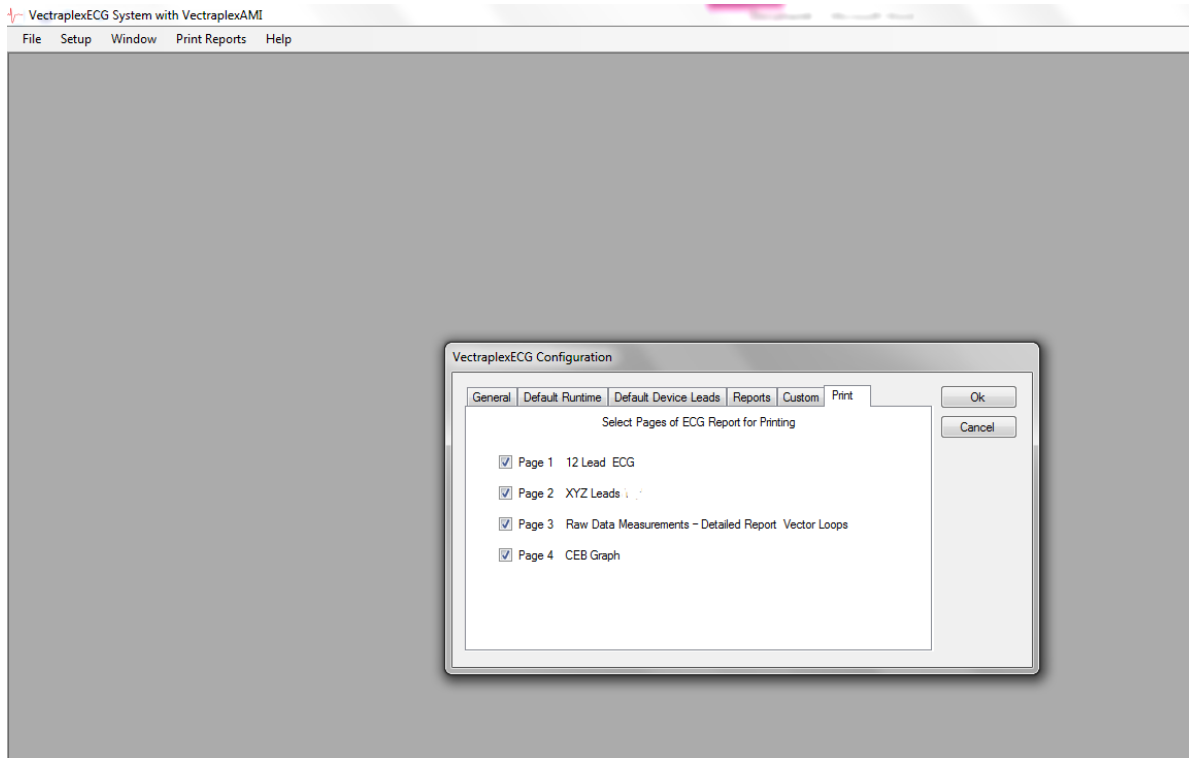
Custom Tab

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



Print Tab

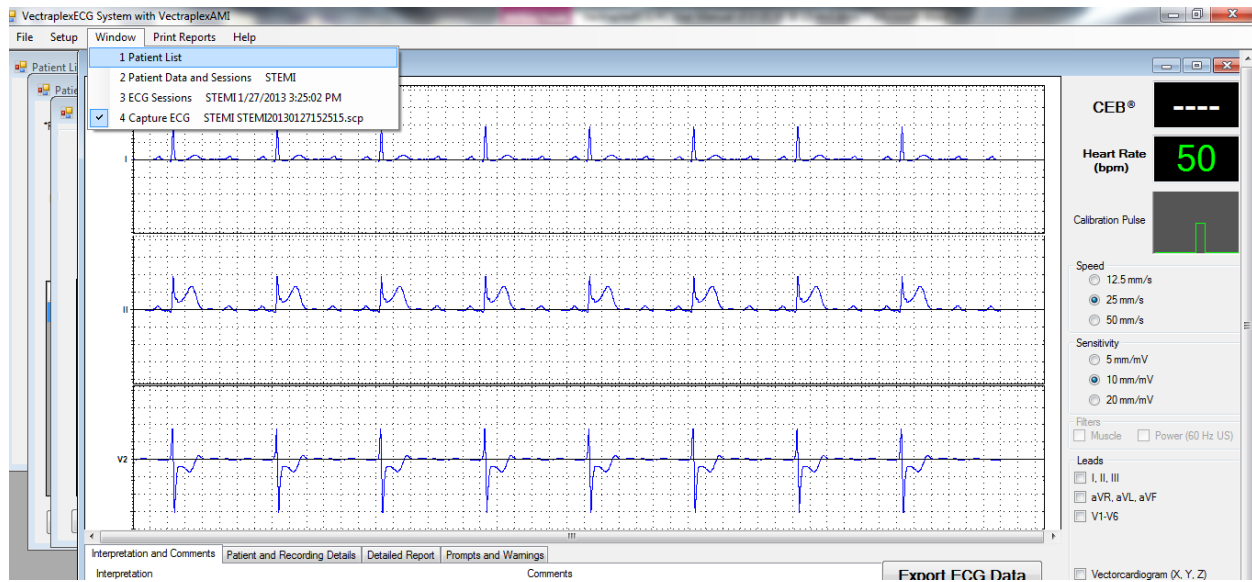
The Print tab is used to select the default pages to display and print for the ECG Report. This selection will also affect the pages that can be viewed during print preview. This setting is defaulted to all pages.



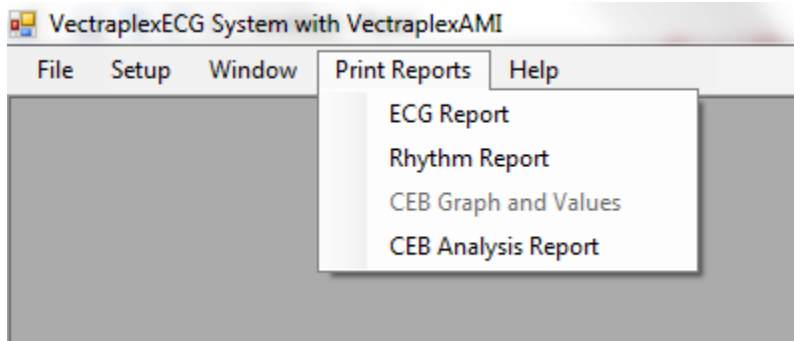
Note: Selecting “OK” exits the user from the configuration window.

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.

The image shows a screenshot of the 'Create Rhythm Report' dialog box. The title bar reads 'Create Rhythm Report UB NSTEMI 4 UB3400321 UB340032120151119135925.scp'. The dialog has a light grey background and contains the following fields and controls:

- VectraplexECG Rhythm report** (Section Header)
- Patient's name:** UB NSTEMI 4
- Date:** 11/24/2015
- ID#:** UB3400321
- Report is ordered by:** A text input field.
- ICD/Dx:** A dropdown menu showing '411.1 Angina, Unstable' with an 'Add' button to its right.
- Diagnoses:** A large text area with a 'Remove' button to its right.
- Select CPT Code:** Three checkboxes labeled '93040', '93041', and '93042'.
- The Rhythm strip demonstrates:** A large text area.
- Buttons:** 'Preview', 'Save PDF', 'Print', and 'Close' are located at the bottom of the dialog.

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

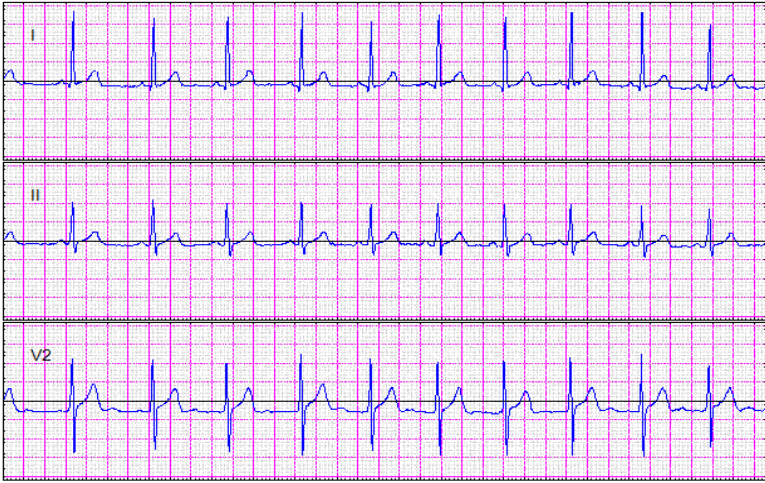
Cardiac monitoring to obtain the 1-3 lead rhythm ECG has been ordered by: Dr. Schrek

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.



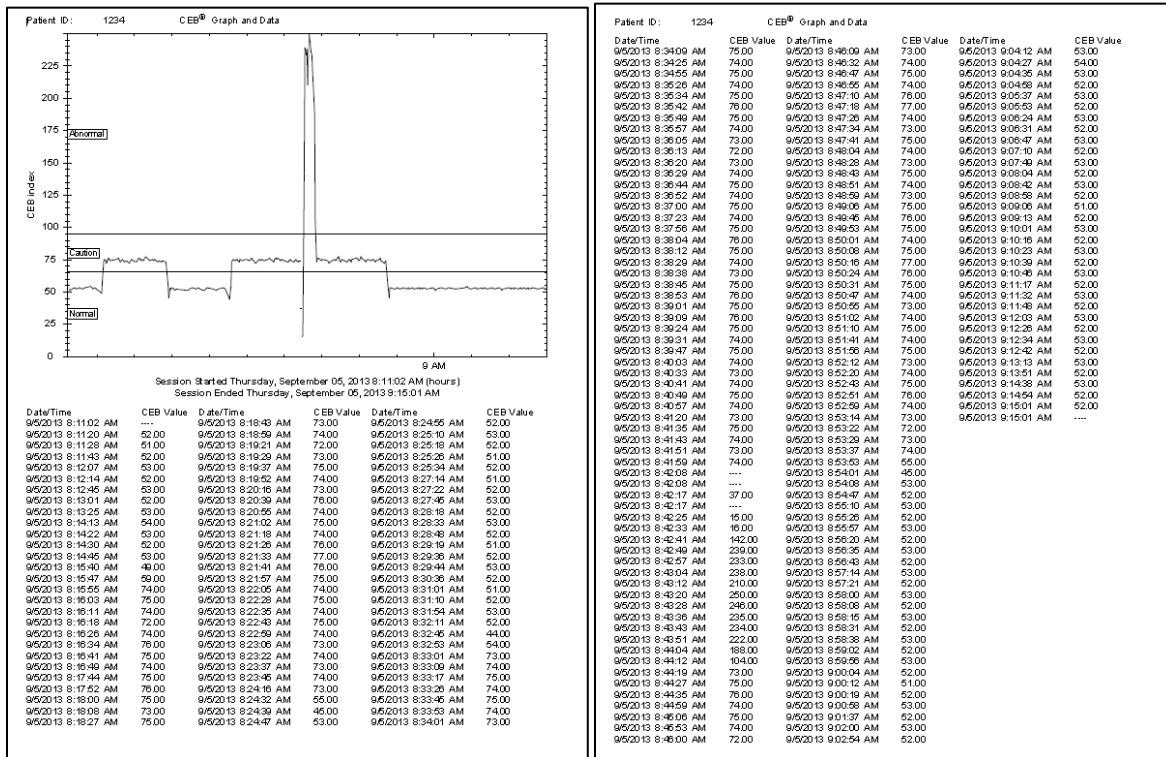
Speed: 25 Sensitivity: 10

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.

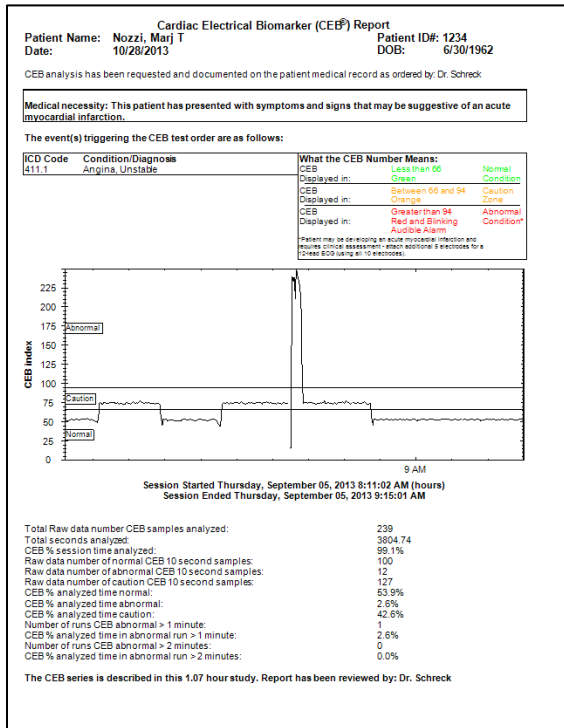


CEB Analysis Report – This will print a CEB Report which formats a report of the data over time for the doctor to interpret. This option is only available from a Capture ECG screen.

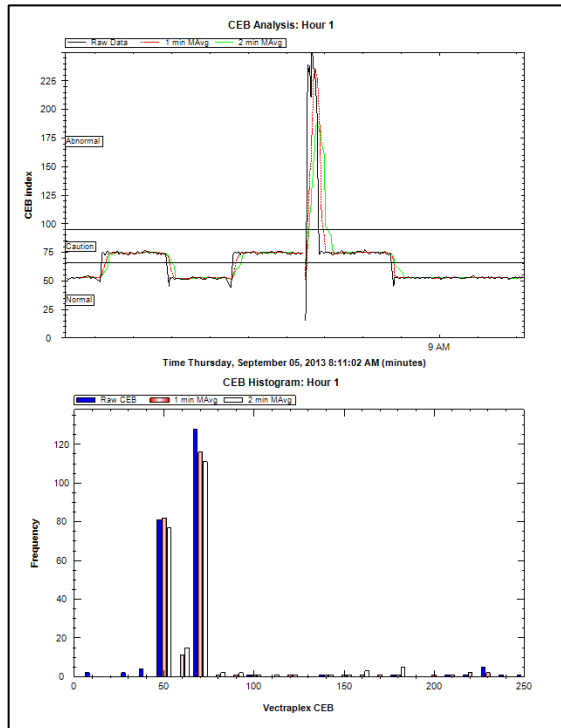
The CEB Analysis Report can be either previewed or printed by selecting the Print Reports > CEB Analysis Report menu item. A dialog will be presented to allow the user to enter diagnosis, medical codes and interpretation for the report.

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

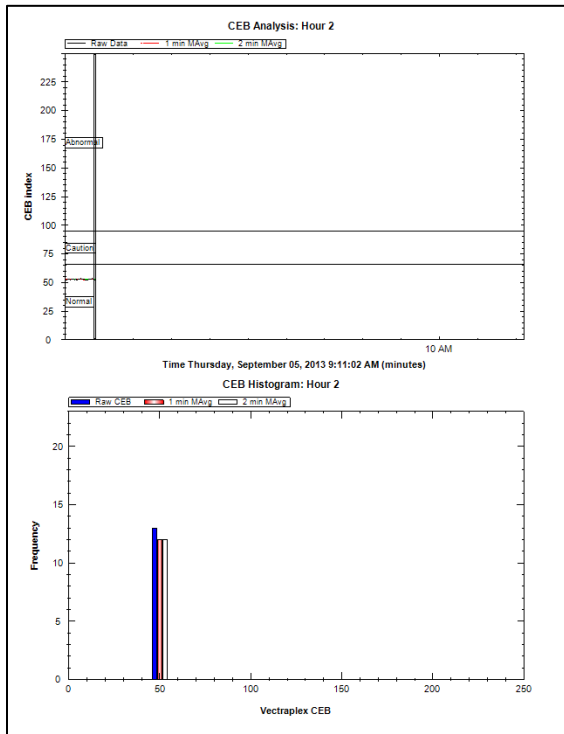
The CEB Analysis Report contains an introductory summary page, then a page for each hour the CEB data was collected, and then 2 conclusion pages at the end. The last page contains the results from an FDA non-inferiority study. This is not specific to the patient, but gives the user some background information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

Summary and Comments

There was a Normal CEB 53.9% of the time
 There was a Caution CEB 42.6% of the time
 There was an Abnormal CEB 2.6% of the time
 A CEB was not calculated for 0.57 minutes

The CEB 1 minute segment analysis showed 1 segments are abnormal
 The CEB 2 minute segment analysis showed 0 segments are abnormal
 The CEB analysis showed:

Physician interpretation of the 12-lead ECG:	Heart rate: 72 bpm
	PRT AXIS: 61° 50' -1°
	Rhythm: Irregular
	Hypertrophy: LHF with strain
	IVCD/IBlocks: ILBBB
	ST-T changes: Early repolarization

Comments: Continue to monitor patient for 24 hours.

Physician: Dr. Schreck
 Date: 10/2/2013
 CPT Code: 0206T

Signature: Electronically signed by: Dr. Schreck

Page 4

Diagnostic Performance

The following table summarizes a non-inferiority study comparing the CEB, to both computerized interpretation software program (ECG) 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)).

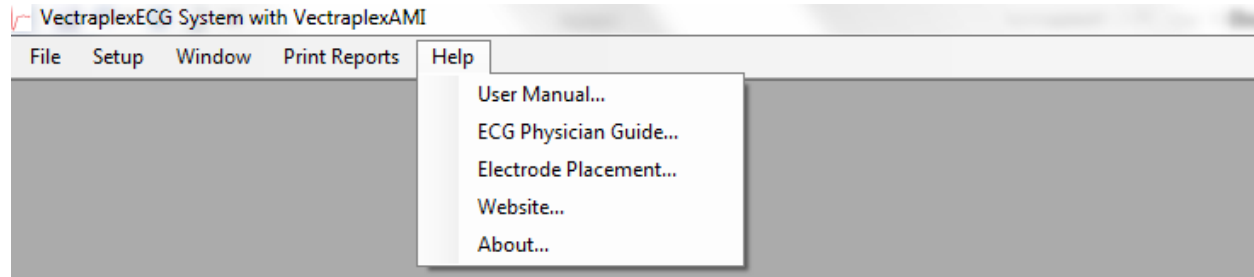
Diagnostic Performance Measure	Parameter	ST-S + Point				ECG + Computer Interpretation			
		"Ideal"		"Worst Case"		"Ideal"		"Worst Case"	
		EM	Cardiologist	EM	Cardiologist	EM	Cardiologist	EM	Cardiologist
Sensitivity (TPP)	Vectraplex/AMI CEB	83.7%	87.2%	80.5%	82.7%	81.4%	84.6%	85.1%	77.2%
	ST-S or ECG	83.1%	79.3%	70.1%	70.8%	87.4%	83.3%	88.7%	83.2%
Specificity	Vectraplex/AMI CEB	81.3%	81.5%	84.8%	78.5%	81.3%	81.1%	88.2%	78.2%
	ST-S or ECG	74.6%	74.6%	73.3%	73.7%	77.5%	78.4%	79.1%	76.6%
Negative Predictive Value	Vectraplex/AMI CEB	88.1%	88.7%	88.4%	88.4%	88.1%	88.1%	88.1%	84.1%
	ST-S or ECG	88.9%	88.1%	88.1%	87.4%	87.4%	87.4%	88.8%	80.8%
Positive Predictive Value	Vectraplex/AMI CEB	77.2%	81.1%	81.2%	81.7%	74.5%	81.8%	82.1%	78.3%
	ST-S or ECG	82.1%	80.9%	81.8%	81.8%	80.7%	80.5%	78.8%	80.8%
Caution Zone %	No Test %	8.67%	8.93%	8.93%	8.93%	7.32%	7.93%	7.32%	7.93%
	1-lead Test %	81.3%	81.5%	81.3%	81.5%	82.7%	82.4%	82.7%	84.4%
Prevalence	True	18.3%	17.4%	18.8%	17.4%	20.8%	18.8%	20.8%	17.2%

*Additional results of this non-inferiority study are posted on our website www.vectracor.com or call VectraCor for results.

Page 5

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

Help Tab

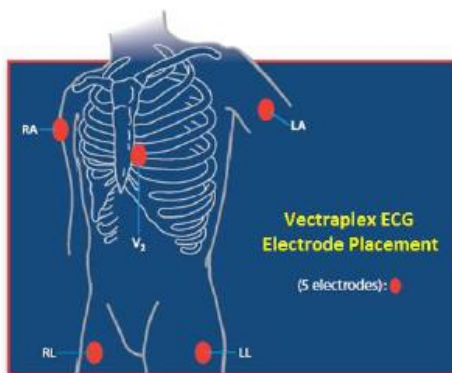


User Manual – Displays the User Manual

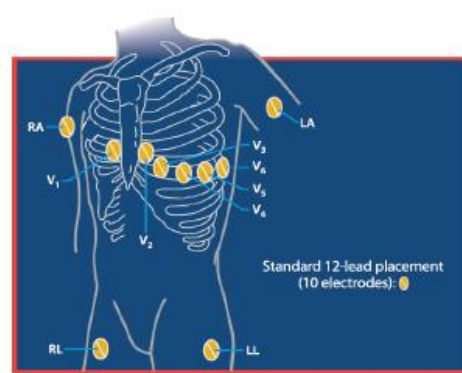
ECG Physician Guide – Displays the Physician’s Guide for the ECG interpretation algorithm. The computerized interpretation algorithm only interprets the 12-lead ECG.

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

Electrode Placement



5 – Electrode Placement
(Derived 12/15/22 lead ECG and CEB index)



10 - Electrode Placement

**** DO NOT PLACE LIMB ELECTRODES ON THE TORSO ****

*V2 = fourth intercostal space – left of sternum

RA/LA - may be placed anywhere above the wrists on the forearms up to the anterior deltoid

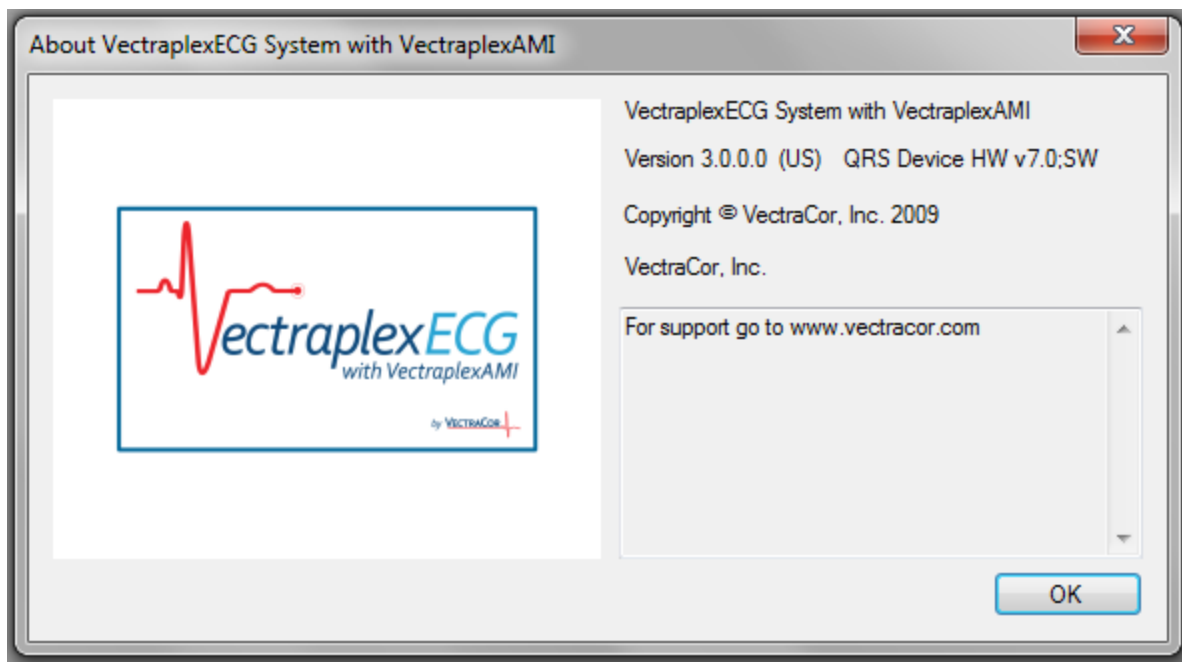
LL/RL - may be placed anywhere above the ankle up to the upper thigh

Quick Tips for a Clear EKG/ECG Tracing

- Use unexpired, wet gel electrodes
- Shave hair at electrode site
- Clean skin with alcohol pad
- Rub electrode site briskly with gauze

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

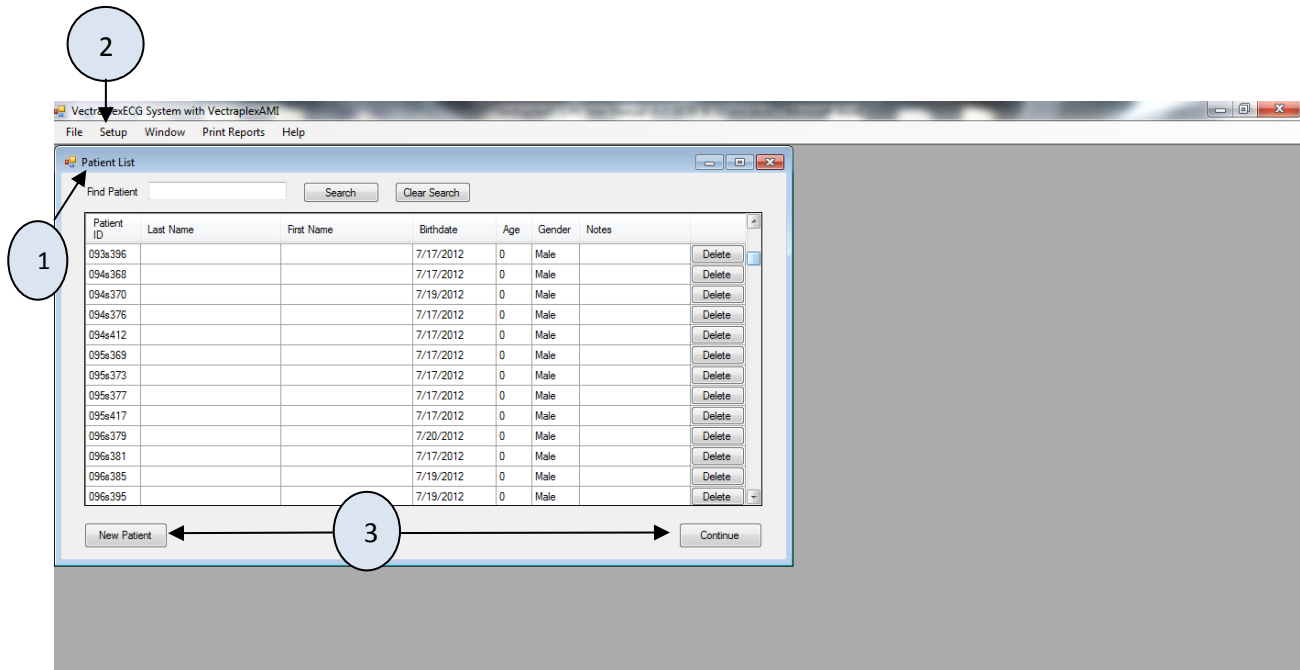
About – Displays the software version as shown below.



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:

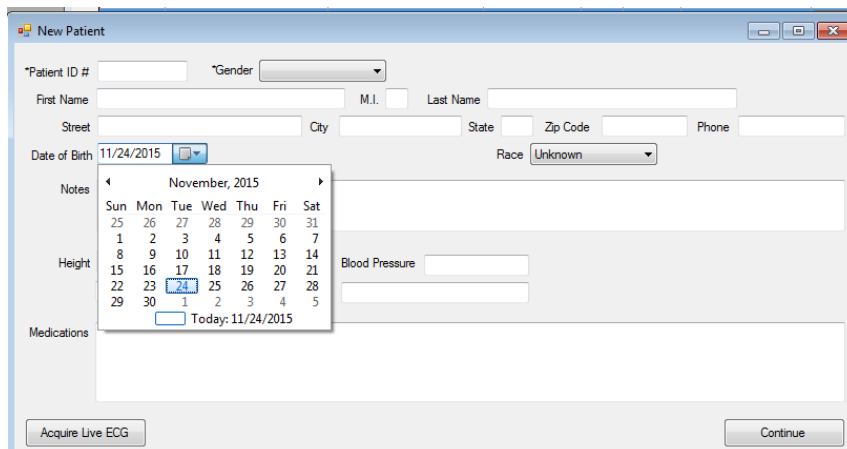
Step 1: Click on the Calendar icon that appears next to the four digit year. This will make the Calendar drop down.

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**.



The screenshot shows a web-based form titled "New Patient". The form includes fields for Patient ID #, Gender, First Name, M.I., Last Name, Street, City, State, Zip Code, Phone, Date of Birth, Race, Notes, Height, Blood Pressure, and Medications. The Date of Birth field is currently set to 11/24/2015. A calendar dropdown is open, showing the month of November 2015. The calendar grid shows the days of the week (Sun through Sat) and the dates from 1 to 31. The date 24 is highlighted in blue. Below the calendar, there is a checkbox labeled "Today: 11/24/2015". At the bottom of the form, there are two buttons: "Acquire Live ECG" and "Continue".

Displays Patient ID number and Patient information.

Session Date and Time	Ht. (ft.)	Ht. (in.)	Wt. (lb)	Referred By	Medications	Holler	Delete
4/3/2013 3:51:16 PM	0	0	0			None	Delete
4/3/2013 3:09:54 PM	0	0	0			None	Delete
4/3/2013 3:00:00 PM	0	0	0			None	Delete
4/3/2013 2:50:21 PM	0	0	0			None	Delete
3/21/2013 10:02:04 AM	0	0	0			None	Delete

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

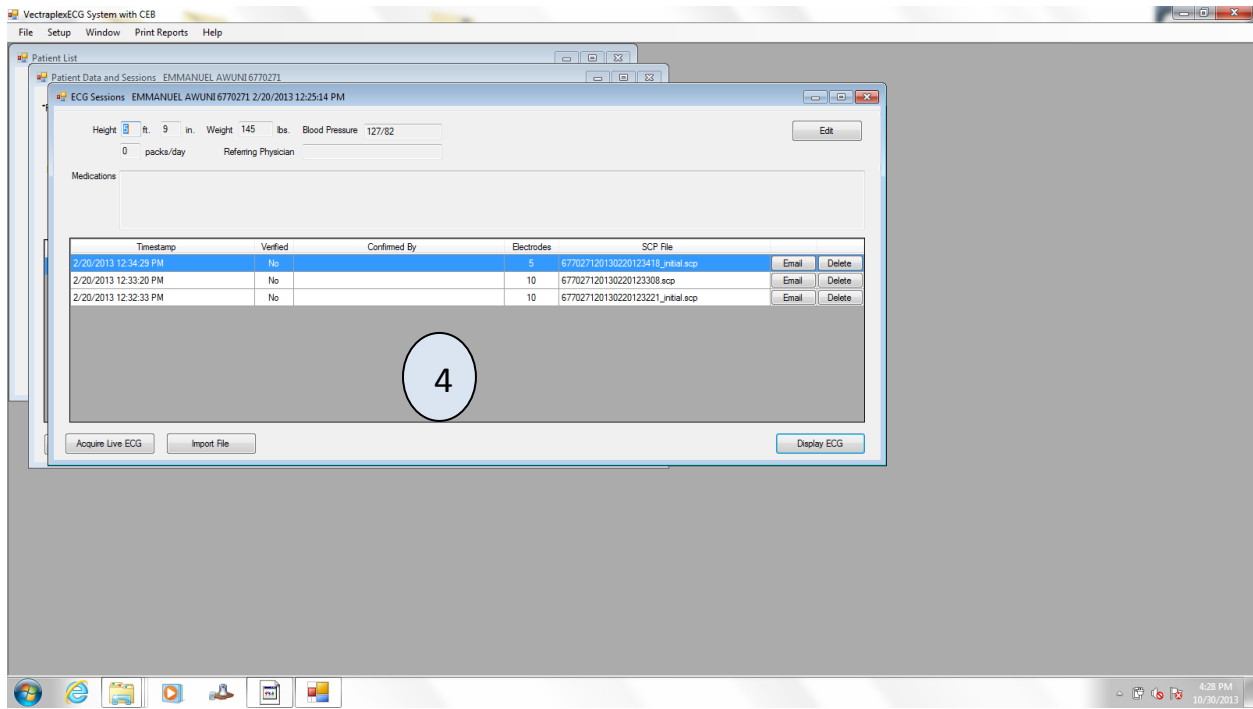
Select a Patient and input the required fields. Then select Save, the button will toggle to Edit after the save. Then select the Continue button. The ECG Session Screen will appear with the patients ID number followed by the session date and time.

4

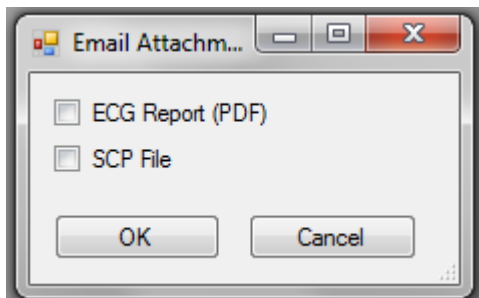
ECG Sessions Screen

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.

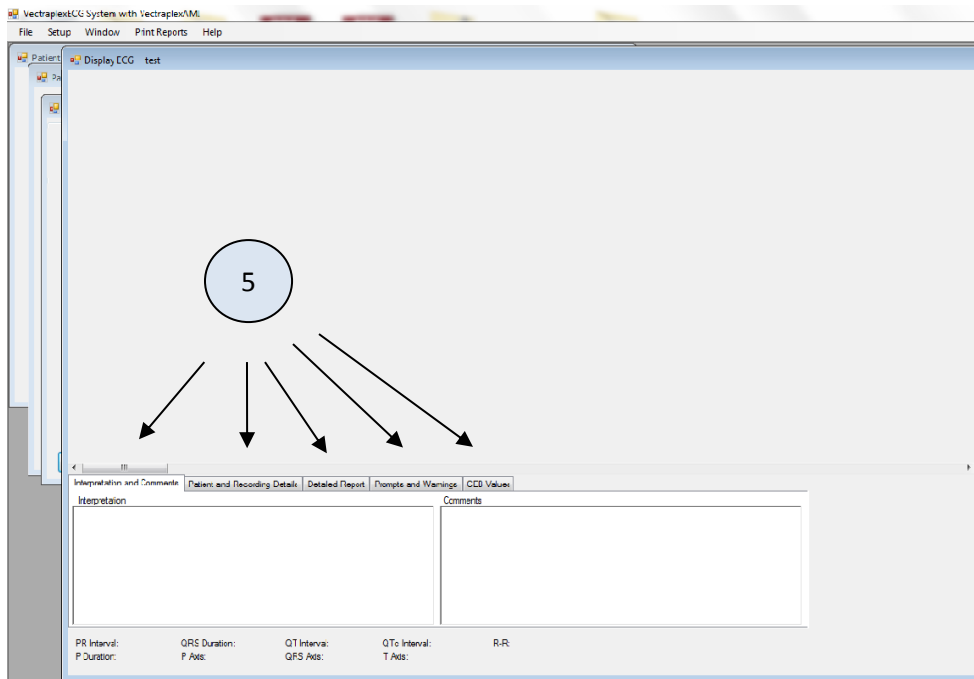
Acquiring a Live ECG and the Display ECG Screen

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.

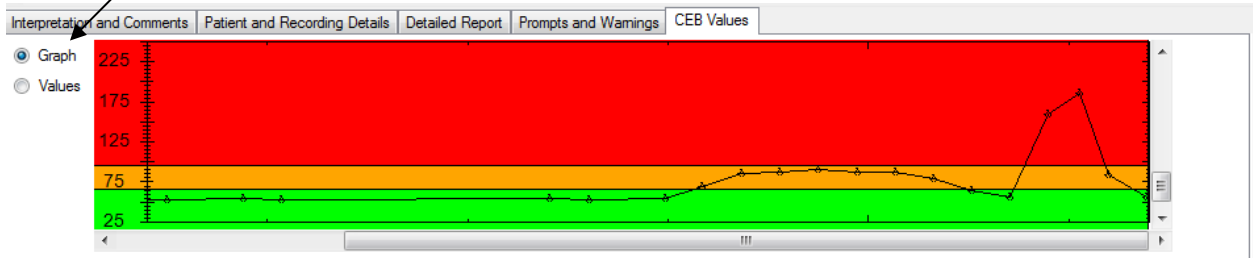
Note:

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.



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

- **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



* 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

Interpretation and Comments	Patient and Recording Details	Detailed Report	Prompts and Warnings
Interpretation 008 Sinus rhythm with 1st degree AV block 114 Complete right bundle branch block		Comments 367 cases	

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.

Patient and Recording Details

Interpretation and Comments		Patient and Recording Details		Detailed Report		Prompts and Warnings	
Patient Details				Recording Details			
Date of Birth:	3/22/2012	Age:	0 years	Acquired:	3/22/2012 11:52:55	Revision:	
First Name:		Height:	0' 0"	Device Type:	CL	Recorded With:	0
Last Name:		Weight:	0 lbs	Packs/Day:	0	Serial Number:	PC Software Version: 1.3.1.0
Patient ID:	171s364	Gender:	Male	Race:	Caucasian		
PR Interval:	204 ms	QRS Duration:	160 ms	QT Interval:	412 ms	QTc Interval:	466 ms
P Duration:	152 ms	P Axis:	42°	QRS Axis:	24°	T Axis:	9°
				R-R:	780 ms	<input type="checkbox"/>	Verified

Detailed Report

Interpretation and Comments		Patient and Recording Details		Detailed Report		Prompts and Warnings														
		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	131	0	0	825	-299	51	0	61	98	162	222	490	0	3250	0	46	88	16	0	
II	174	0	-32	689	-19	57	0	59	68	98	126	271	0	2250	6	102	22	30	0	
III	73	0	-223	331	0	0	0	-3	-31	-65	-97	0	-225	-1000	52	108	0	0	0	
AVM	0	-147	-788	136	0	0	0	-61	-84	-131	-175	0	-278	-2750	52	86	0	0	0	
PR Interval:	204 ms	QRS Duration:	160 ms	QT Interval:	412 ms	QTc Interval:	466 ms	R-R:	780 ms	<input type="checkbox"/>	Verified									
P Duration:	152 ms	P Axis:	42°	QRS Axis:	24°	T Axis:	9°													

Prompts and Warnings

Interpretation and Comments		Patient and Recording Details		Detailed Report		Prompts and Warnings	
CEB index indicates the cardiac electrical field is normal.							
PR Interval:	154 ms	QRS Duration:	86 ms	QT Interval:	394 ms	QTc Interval:	432 ms
P Duration:	84 ms	P Axis:	61°	QRS Axis:	50°	T Axis:	-1°
				R-R:	830 ms	<input type="checkbox"/>	Verified

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

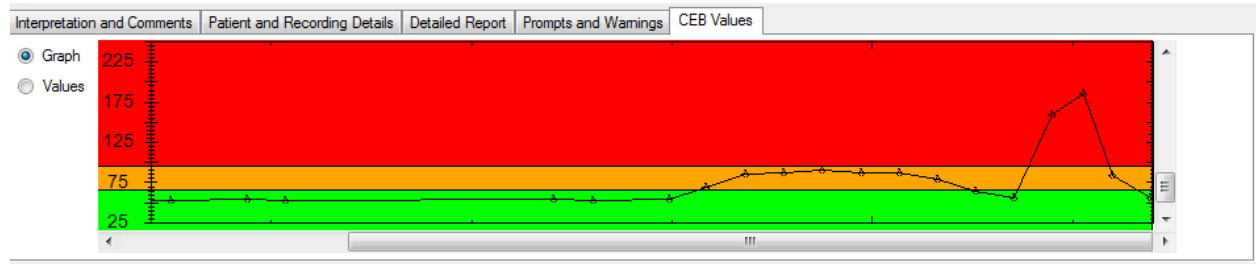
Caution Zone – the CEB Index is 66-94 and is displayed in orange. Patient requires continued clinical assessment.

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)

Interpretation and Comments		Patient and Recording Details		Detailed Report		Prompts and Warnings		VectraplexAMI Values	
<input type="radio"/>	Graph	Timestamp	Seconds	Value					
<input checked="" type="radio"/>	Values	12/19/2012 2:07 PM	7,839.08	92					
		12/19/2012 2:07 PM	7,845.58	119					
		12/19/2012 2:08 PM	7,852.22	131					

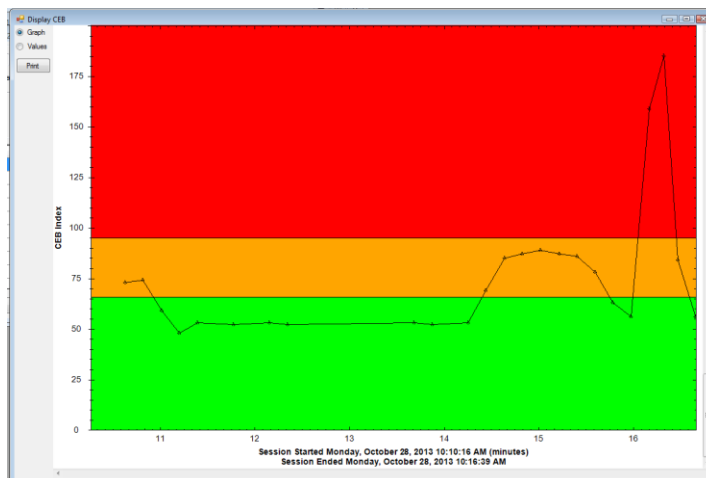
CEB Values (Graph Radial Button)



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



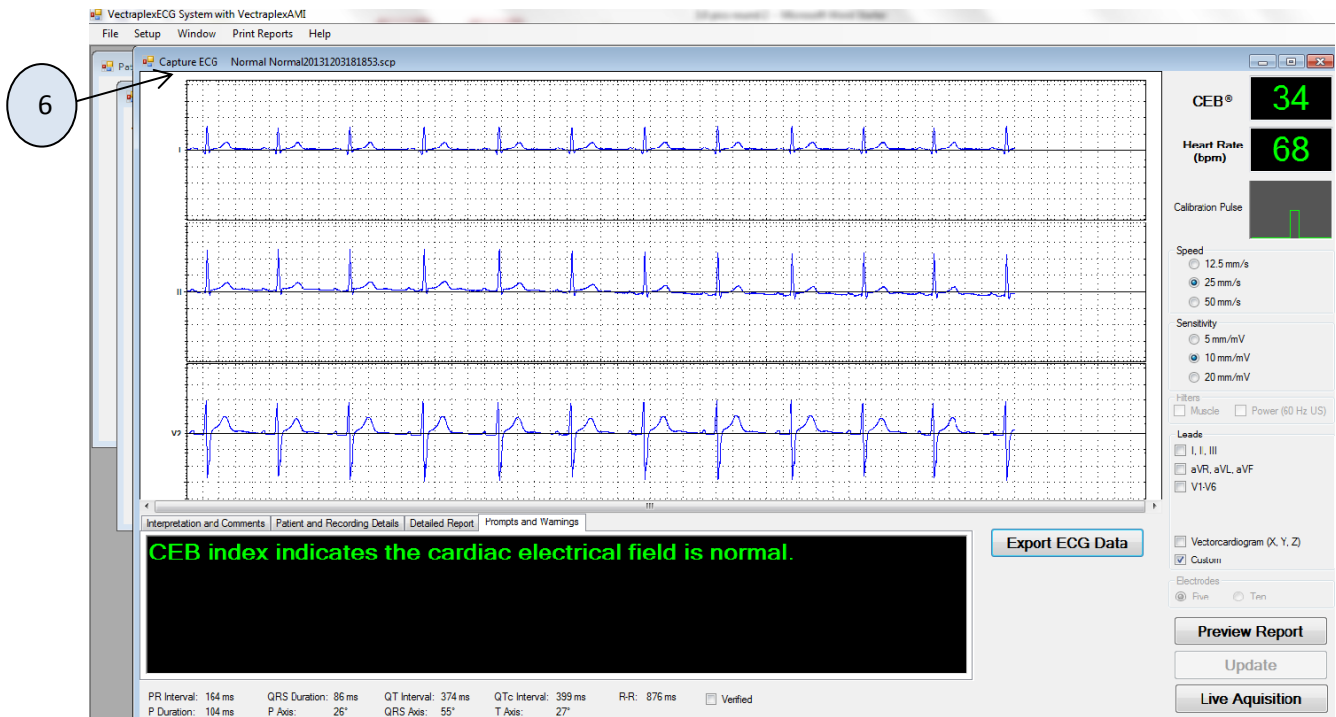
The y-axis ticks are in 5 unit increments with labels every 25 units. The x-axis labels will depend on the amount of data collected, displaying minutes, hours, and days. Mousing over a data point will display the coordinates of the point. By clicking and dragging to select a given rectangular region, 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.

Capture ECG Screen

6

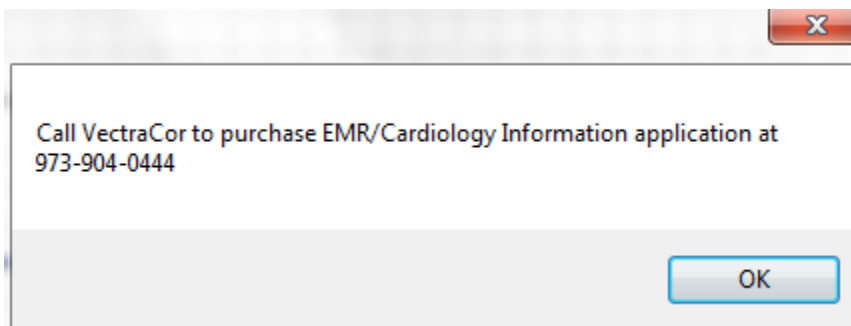
The Capture ECG screen will appear either after “Display Record” is selected for a previously recorded .scp file in the ECG Sessions window or when “Capture” is selected in Live Acquisition Mode from the Display ECG screen, behind the ECG Report. This screen is very similar to the Display ECG screen,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



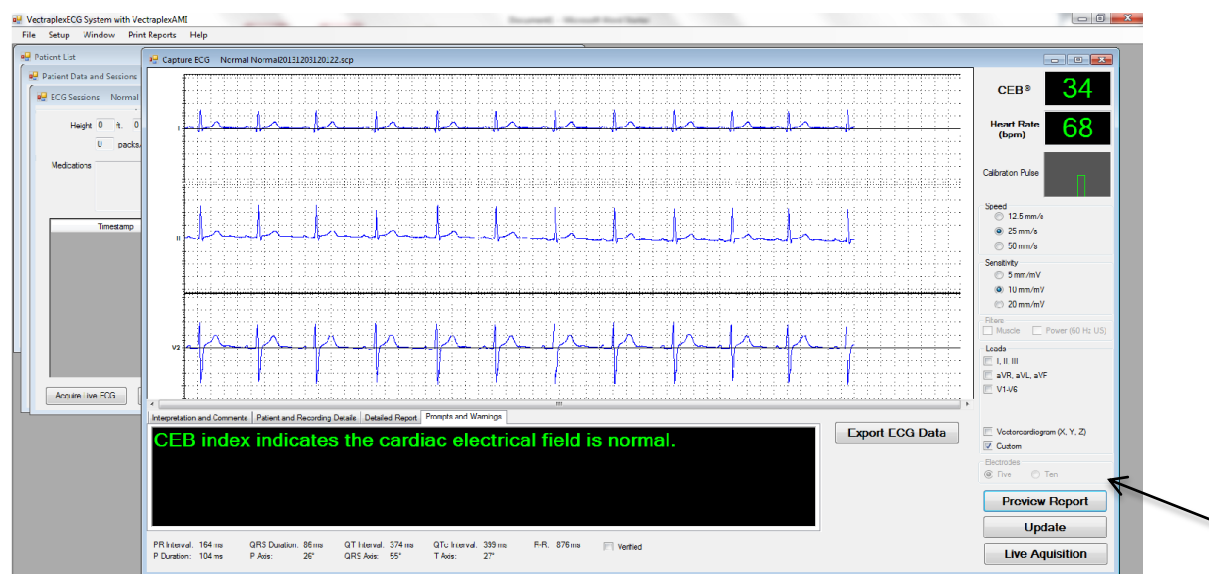
Comments can be entered in the box at the bottom of the screen. To save these comments select the “Update” button on the bottom, right.

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 Vectraplex ECG 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 “**Error! Reference source not found.**” section).

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

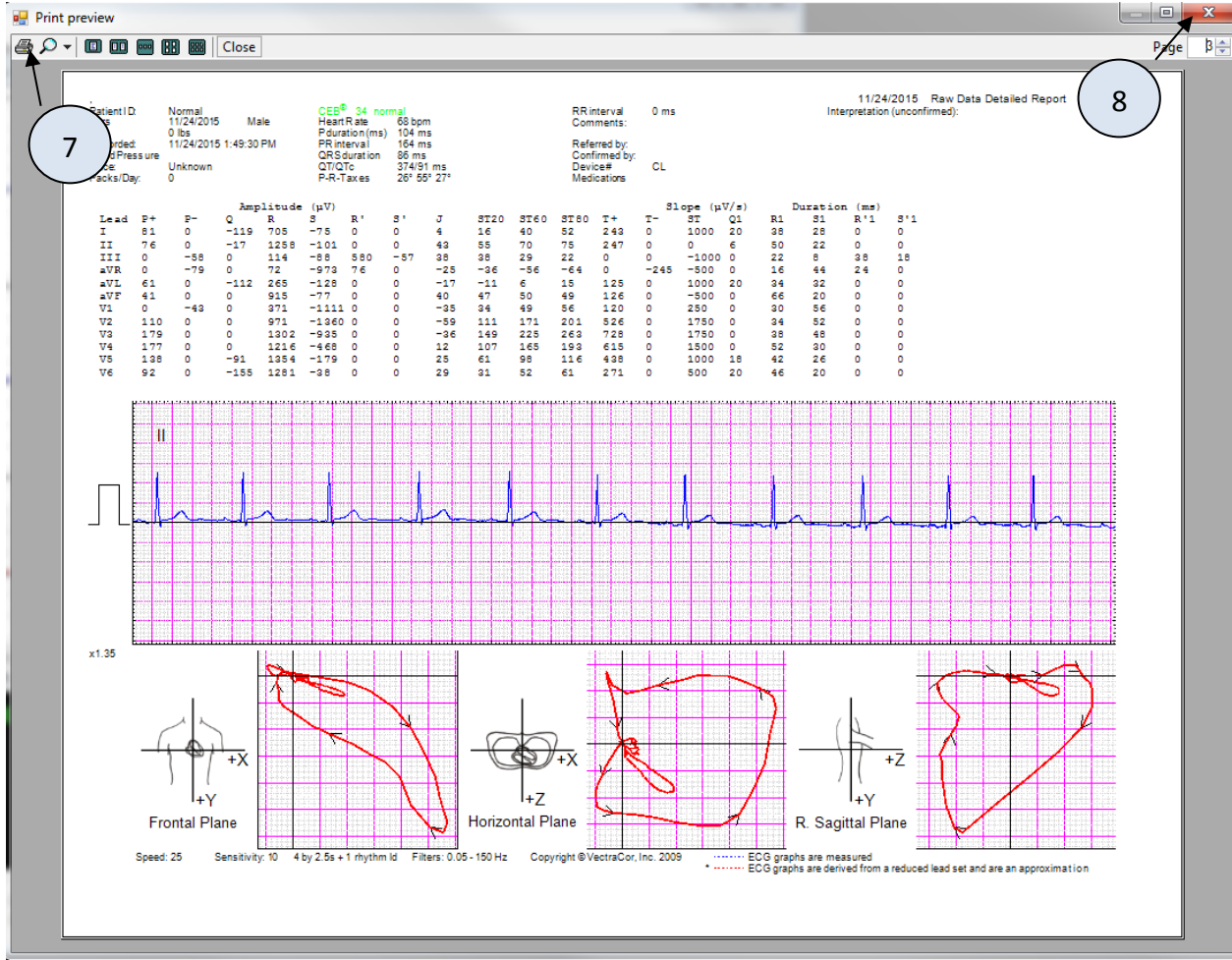
- 7 Printer Icon will print the four page report if selected.
- 8 Close button will remove the currently displayed window.

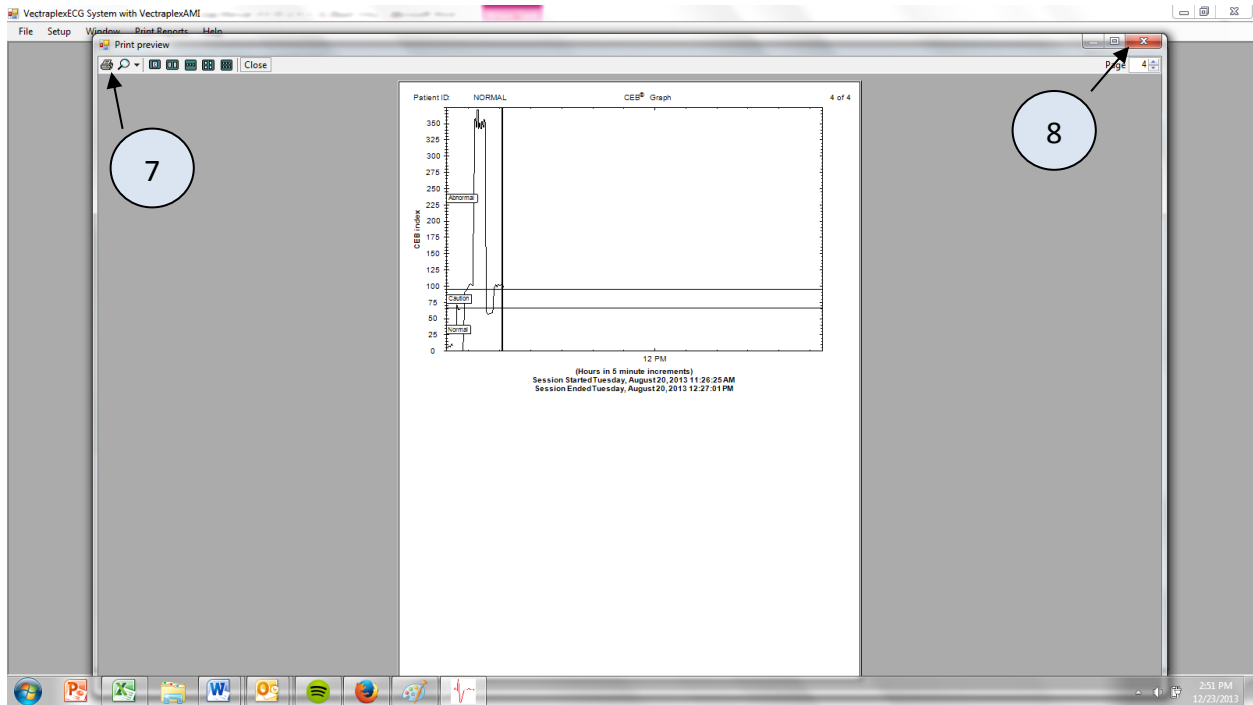


12 Lead ECG



XYZ Leads





Page 4 CEB Graph

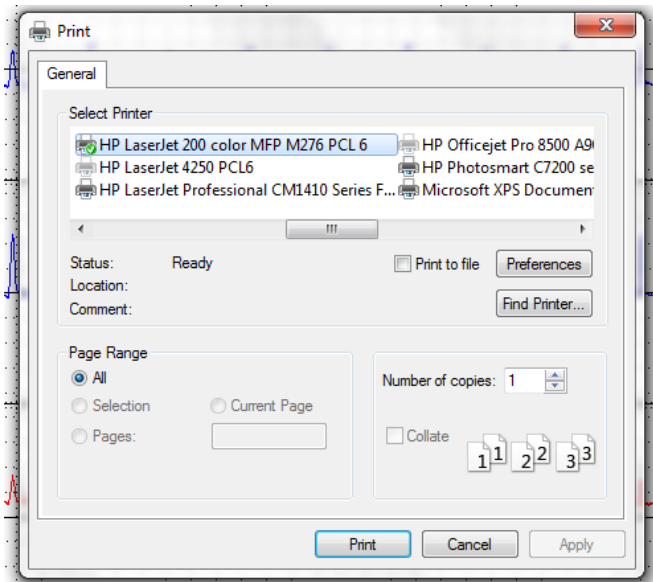
Note:

1. Blue (default) tracings are acquired/measured ECG tracings.
2. Red (default) tracings are derived ECG tracings and will also have an asterisk.
3. 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.
4. The derived leads are also denoted by an asterisk.
5. The derived leads and the detailed data associated with each lead is an approximation to the conventional 12-lead ECG system.
6. Physician interpretation should only be based on unfiltered lead data and the ECG print out.
7. Physician should inspect the measured lead graphs to confirm they are reasonable and confirm diagnosis.
8. Verify that the patient name and ID are correctly entered on the report.
9. 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.
10. The accessory leads should only be utilized by those clinicians who are skilled in their interpretation.
11. 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 Professional operating system and follow the directions for installation that are included with printer.

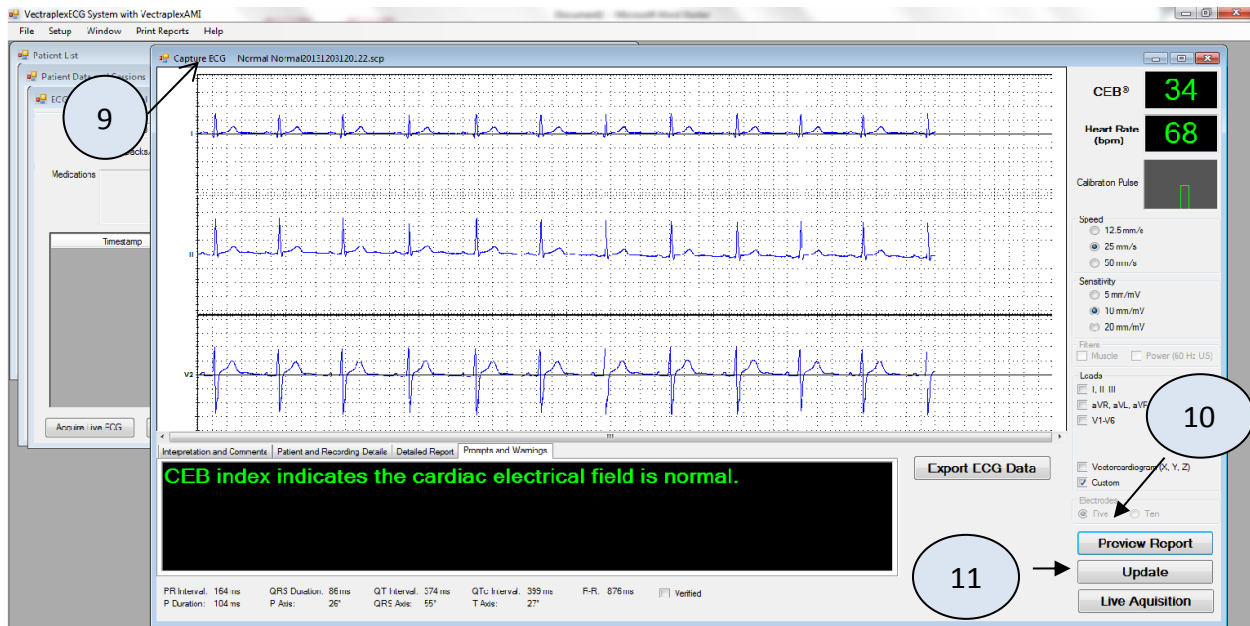
Reviewing an ECG

Reviewing an ECG within the “Capture ECG” Window

9

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:



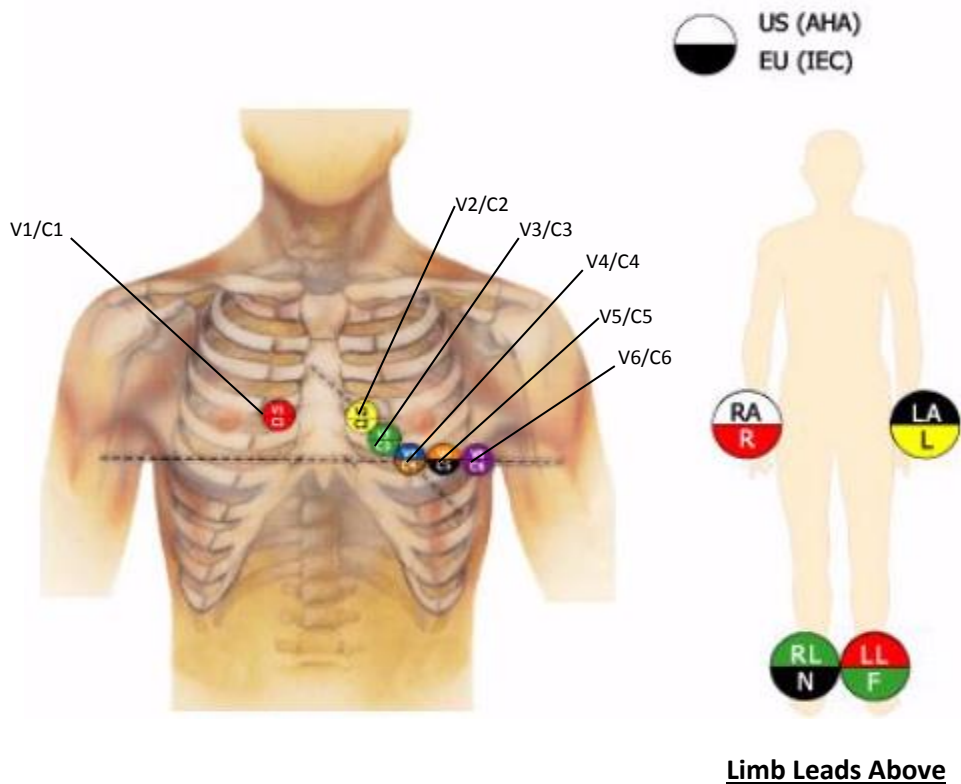
Use electrodes that are 510k cleared only. Please reference the FDA registered electrode supplier for length of attachment.

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

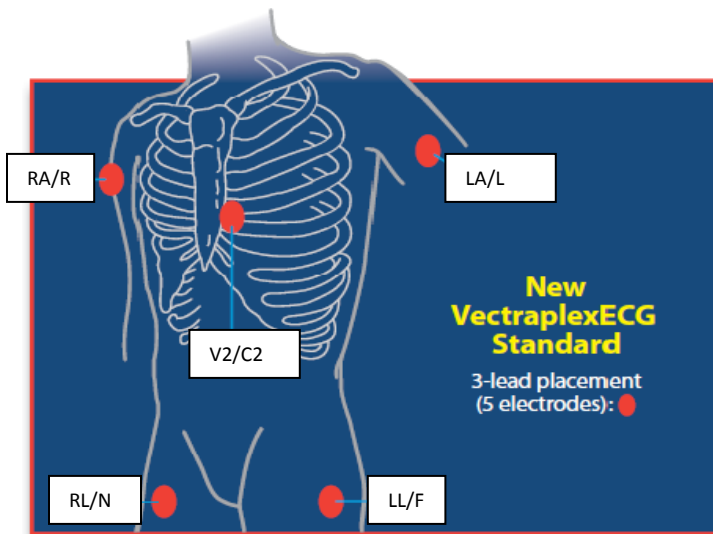
Performing an ECG Test

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)



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.

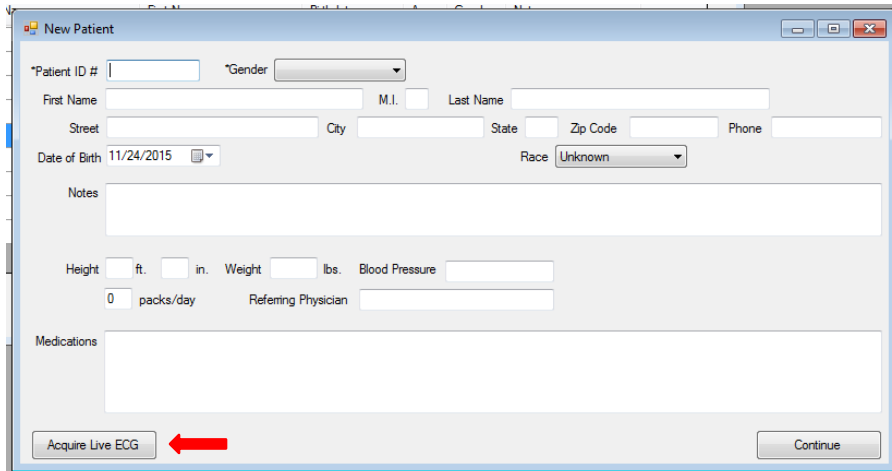
Note:

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

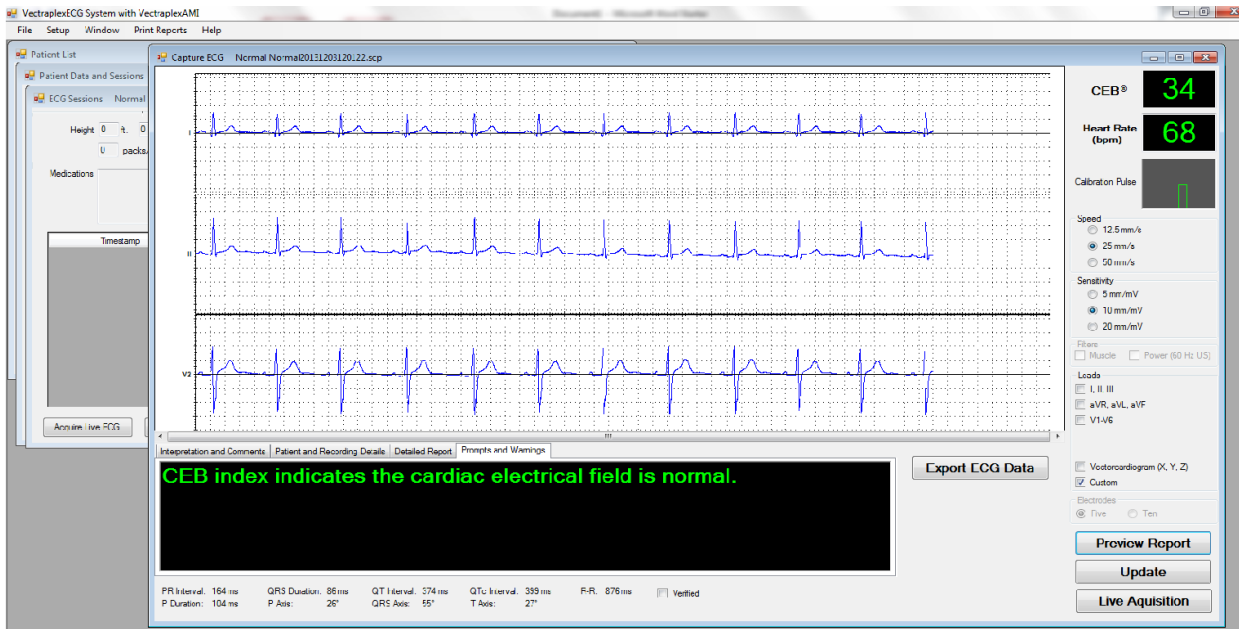


The screenshot shows a "New Patient" form with the following fields and values:

- *Patient ID #: [Empty]
- *Gender: [Dropdown]
- First Name: [Empty]
- M.I.: [Empty]
- Last Name: [Empty]
- Street: [Empty]
- City: [Empty]
- State: [Empty]
- Zip Code: [Empty]
- Phone: [Empty]
- Date of Birth: 11/24/2015
- Race: Unknown
- Notes: [Text Area]
- Height: [Empty] ft. [Empty] in.
- Weight: [Empty] lbs.
- Blood Pressure: [Empty]
- 0 packs/day
- Referring Physician: [Empty]
- Medications: [Text Area]

At the bottom left, there is a button labeled "Acquire Live ECG" with a red arrow pointing to it. At the bottom right, there is a "Continue" button.

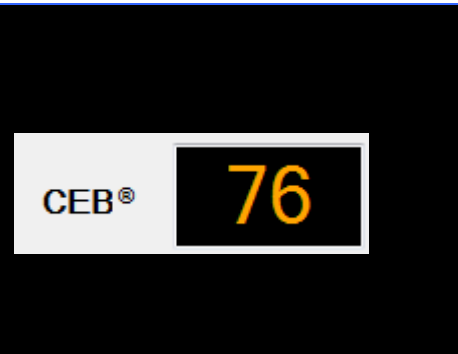
About the Acquisition Window – Capture ECG Screen



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


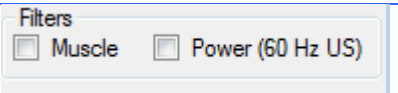
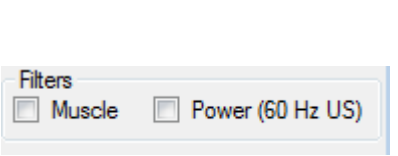
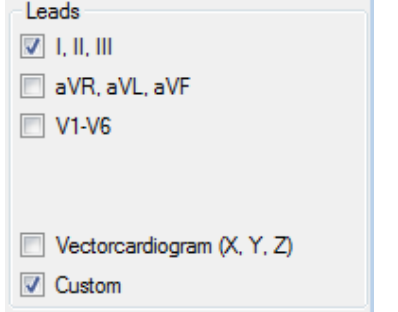
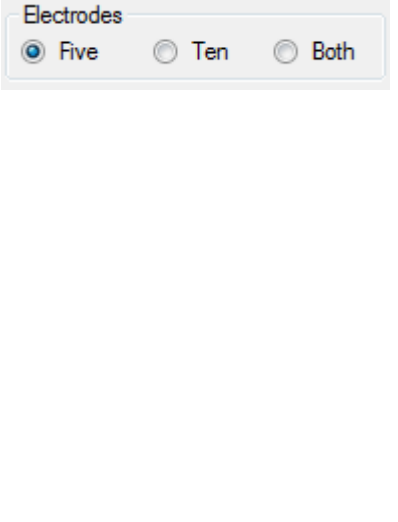
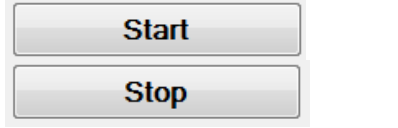






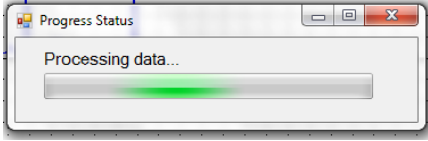
Provides a visual indication of the combined sensitivity (1mV vertical height) and speed (100ms horizontal width).

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		<p>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.</p> <p>Note: the EU version (CE Mark) will give a Computer Interpretation for the 5 electrode setting, but not in the US version.</p>
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.

VectraplexAMI Index (CEB)

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

“The VectraplexAMI (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 ≤ 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 ≥ 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 Device Verification

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.

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

Device Care & Maintenance

Cleaning

Clean surfaces with a damp cloth using water only. Dry thoroughly. AVOID CLEANING AROUND CONNECTORS. Excess moisture in or on the case, cables or air fittings could affect operation. Replace vinyl cap when not in use.

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.

TROUBLESHOOTING

Problem	Cause of Failure	Possible Solutions
Data inaccessible No data exists	<ol style="list-style-type: none"> 1. Computer Failure 2. Database on removable or remote storage is inaccessible 	<ol style="list-style-type: none"> 1. Reboot system 2. Check location of Database and that drive is accessible 3. Restore back-up
Cannot establish communication with QRS hardware (patient cable) Error Message- "Cannot establish communication with QRS Hardware; Cannot get recording parameters- StartDATA; Cannot get ReOpen port- driver busy.	<ol style="list-style-type: none"> 1. Device not connected to USB Port 2. Need time to have system boot up and establish connection 3. Set-up tab was not configured for correct port 	<ol style="list-style-type: none"> 1. Make sure QRS hardware-USB cord is connected to USB port 2. If QRS hardware-USB cord is plugged in, remove from computer. Then plug in QRS 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	<ol style="list-style-type: none"> 1. Insufficient processor resources 2. Patient movement 3. Power/electrical interference 	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. File corrupted due to hard-drive failure 	<ol style="list-style-type: none"> 1. Restore SCP file from back-up
Software detects file is inaccessible	<ol style="list-style-type: none"> 1. File moved or deleted 2. File missing on removable storage 	<ol style="list-style-type: none"> 1. Restore SCP file from back-up
System does not run	<ol style="list-style-type: none"> 1. Program not detected 2. Program does not run or display Graphs 	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Printer not available 	<ol style="list-style-type: none"> 1. Make sure printer is installed 2. Check if printer is online 3. Check connection from printer to computer
Error Message- Lead Off	<ol style="list-style-type: none"> 1. Electrode is lifting from patient. 2. Buffer overload. 	<ol style="list-style-type: none"> 1. Check that electrodes are securely connected to patient. 2. Hit "Stop" acquisition and then select "Start"
Data Overload	<ol style="list-style-type: none"> 1. Data Overload 	<ol style="list-style-type: none"> 1. Reduce the number of leads to display data.
Error message " discontinuing Analysis"	<ol style="list-style-type: none"> 1. Data Overload 	<ol style="list-style-type: none"> 1. Reduce the number of leads to display data.
Under "Prompts and Warnings" "CEB is processing"	<ol style="list-style-type: none"> 1. Electrodes may not be attached 2. Need 10 seconds of Data 	<ol style="list-style-type: none"> 1. Connect or verify that all electrodes are attached.
Unit frozen	<ol style="list-style-type: none"> 1. Battery power reached end of life 2. Error during loading of application 3. Error during initialization of computer 4. Complication with another program 	<ol style="list-style-type: none"> 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

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

Service

Contact the VectraCor service department:

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

Monday through Friday
9am to 6pm EST
Phone: 973-768-0402

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)).

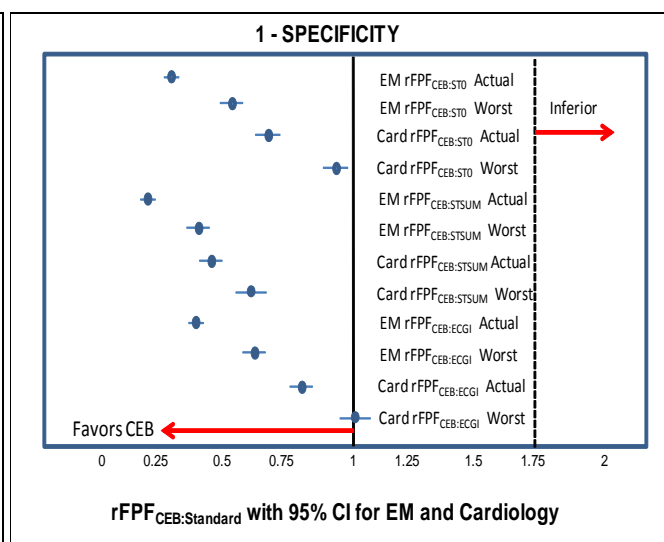
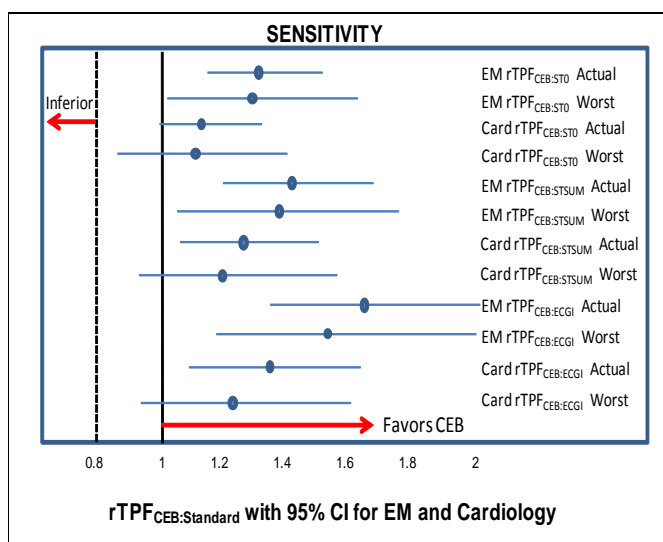
Comparative Test	Diagnostic Performance Measures	Parameters	*Actual		*Worst Case	
			*EM	Cardiology	*EM	Cardiology
ST0 = J point	Sensitivity (TPF)	VectraplexAMI (CEB)	93.75%	87.27%	89.55%	82.76%
		ST0 (J point evaluation)	70.31%	76.36%	70.15%	75.86%
		rTPF (CEB:ST0 Ratio)	1.33	1.143	1.277	1.091
		95% 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 Predictive Value	VectraplexAMI NPV	98.1%	96.7%	96.8%	95.4%
		ST0 NPV	89.9%	93.5%	90.1%	93.5%
	Positive Predictive 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%
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 Predictive Value	VectraplexAMI NPV	98.1%	96.7%	96.8%	95.0%
		STSUM NPV	86.5%	90.0%	87.0%	89.8%
	Positive Predictive 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 Predictive Value	VectraplexAMI NPV	98.1%	96.3%	95.5%	94.1%
		ECGI NPV	87.4%	91.1%	86.8%	90.8%
	Positive Predictive 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 = VectraplexAMI[®] 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 Positives + 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 rTPF > 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 = $CEB_{FPF} : Standard_{FPF}$ = 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

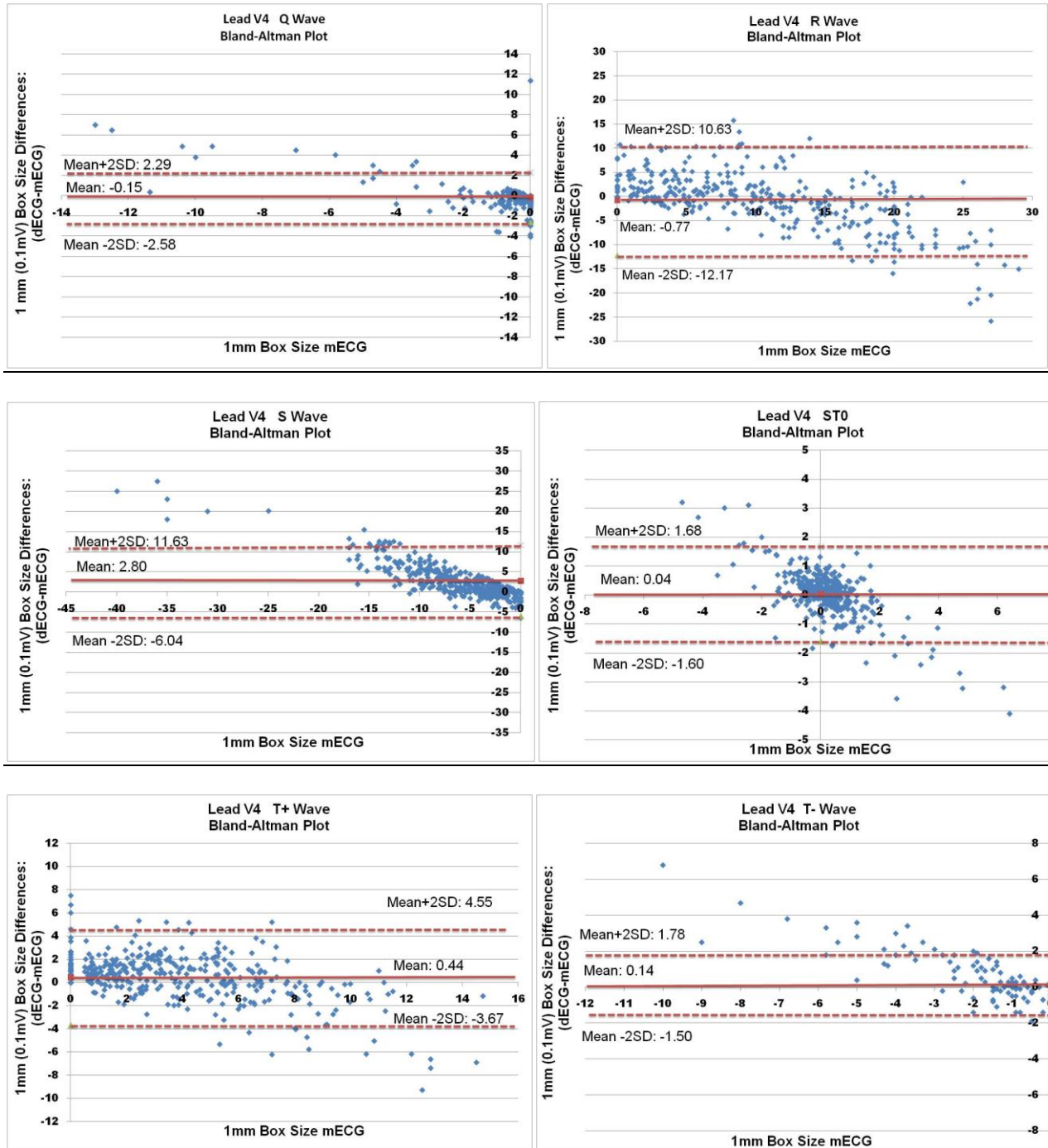
The statistical evaluation with confidence intervals of rTPF and rFPF is described by Alonzo, et al:
Alonzo TA, Pepe MS, Moskow otz CS: Sample size calculations for comparative studies of medical tests for detecting presence of disease. Statist. Med. 2002;21:835-852.



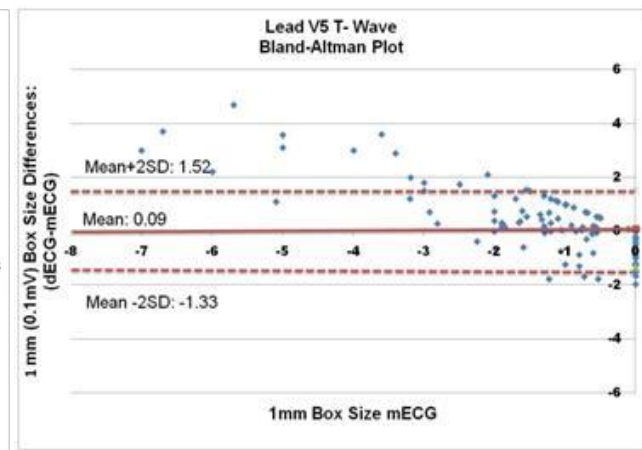
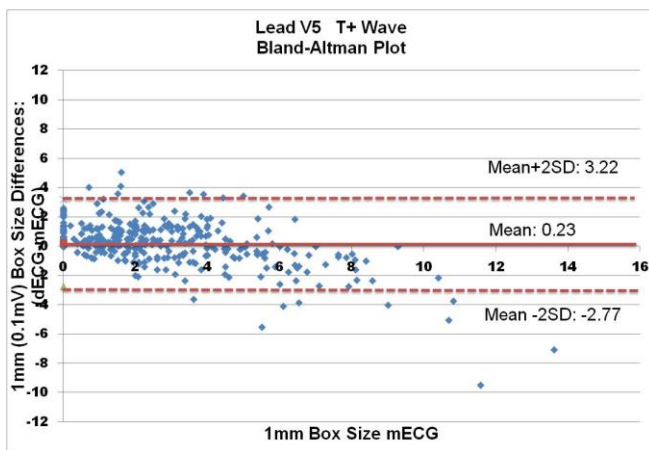
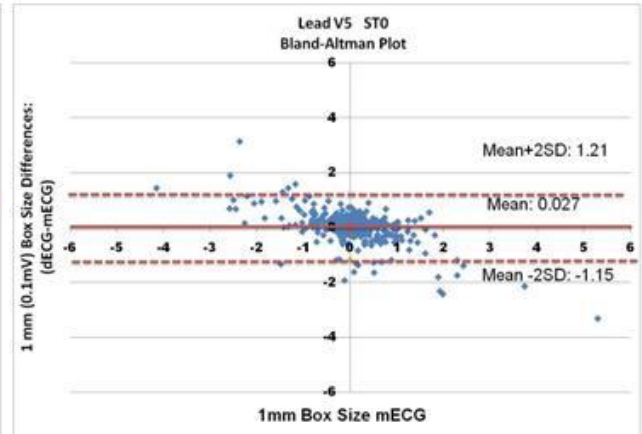
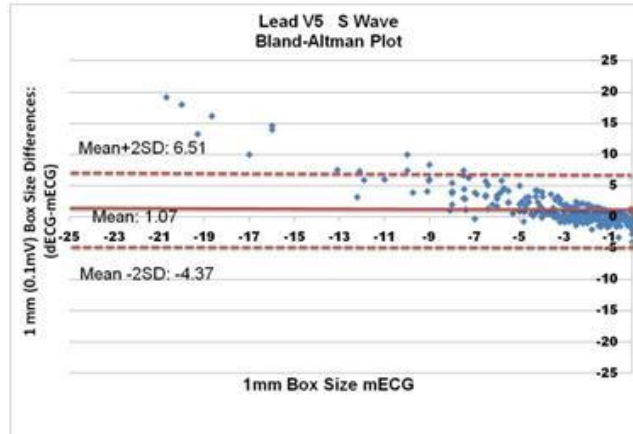
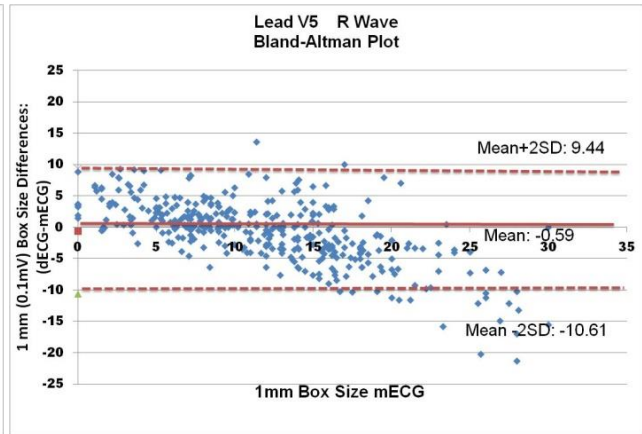
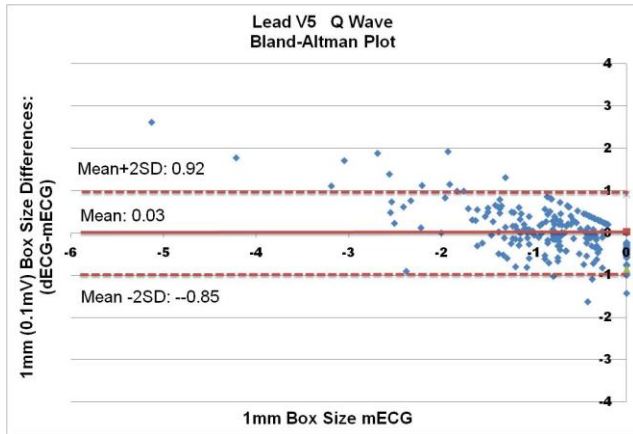
The following data are Bland-Altman plots of the (dECG-mECG) voltages on the y axis and the mECG on the x Axis (1mm box =0.1mV). The dECG may under-estimate the voltage of the mECG when the mECG is at high voltages for leads V4-V6. The Bland-Altman plots are as follows:

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

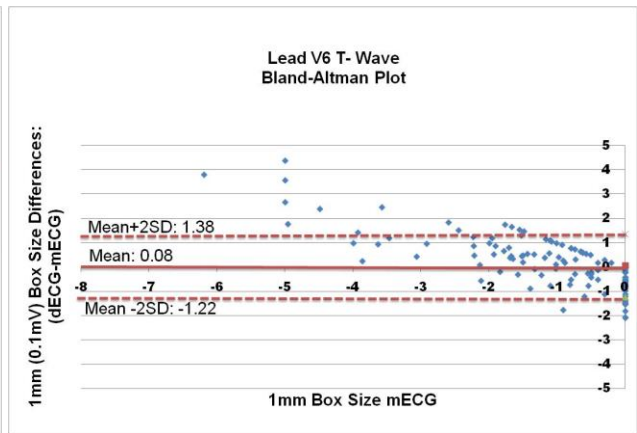
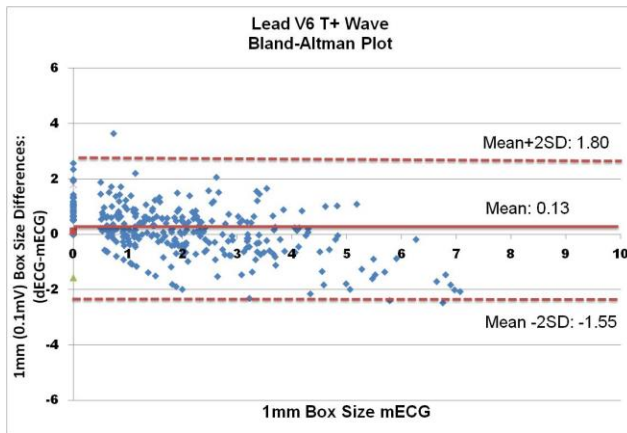
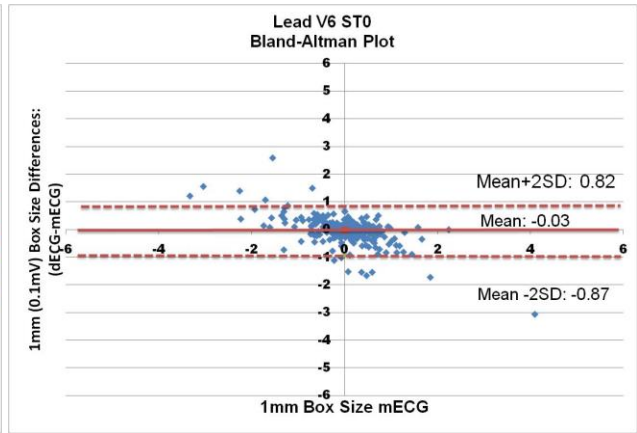
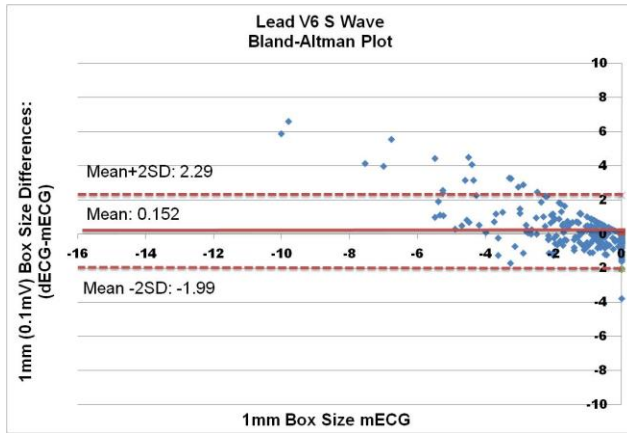
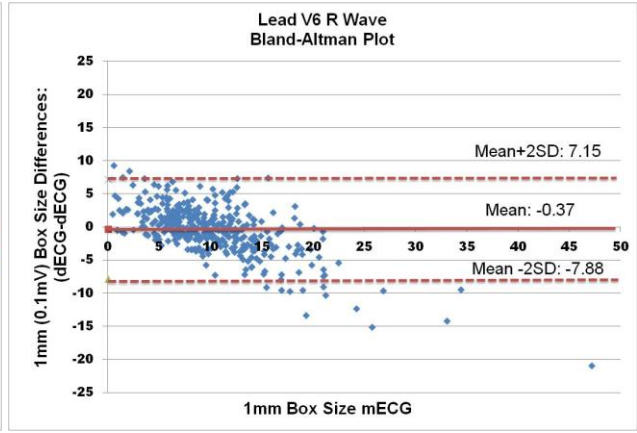
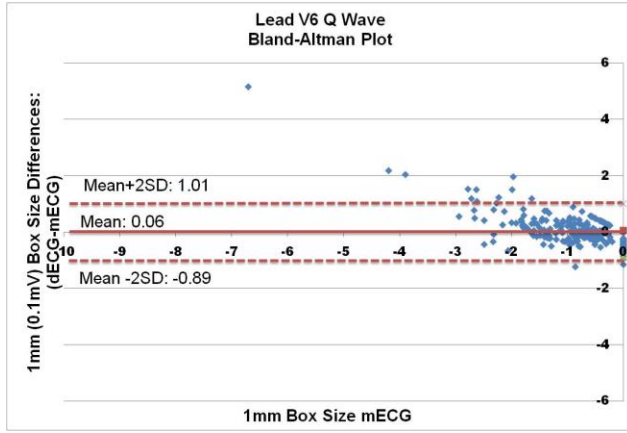
Lead V4



Lead V5



Lead V6



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 Vectraplex ECG 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%	
Arrhythmia	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%	PPA	100.0%	100.0%	PNA	100.0%	100.0%		
	OA	100.0%	100.0%		OA	100.0%	100.0%		PPA	100.0%		100.0%	PPA		100.0%	100.0%		
	PPA	100.0%	100.0%		PPA	100.0%	100.0%		PNA	100.0%		100.0%	PNA		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%	100.0%	PPA	100.0%	100.0%	PNA	100.0%	100.0%		
	OA	100.0%	99.1%		OA	100.0%	100.0%		PPA	100.0%		100.0%	PPA		100.0%	100.0%		
	PPA	100.0%	82.4%		PPA	100.0%	100.0%		PNA	100.0%		100.0%	PNA		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%	PPA	100.0%	100.0%	PNA	100.0%	100.0%		
	OA	100.0%	100.0%		OA	100.0%	100.0%		PPA	100.0%		100.0%	PPA		100.0%	100.0%		
	PPA	100.0%	100.0%		PPA	100.0%	100.0%		PNA	100.0%		100.0%	PNA		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%	PPA	100.0%	100.0%	PNA	100.0%	100.0%		
	OA	100.0%	100.0%		OA	100.0%	100.0%		PPA	100.0%		100.0%	PPA		100.0%	100.0%		
	PPA	100.0%	100.0%		PPA	100.0%	100.0%		PNA	100.0%		100.0%	PNA		100.0%	100.0%		
	PNA	100.0%	100.0%		PNA	100.0%	100.0%											
LAE	n	59	101	RBBB	n	14	12	OA	100.0%	100.0%	PPA	100.0%	100.0%	PNA	100.0%	100.0%		
	OA	99.7%	99.7%		OA	100.0%	100.0%		PPA	100.0%		100.0%	PPA		100.0%	100.0%		
	PPA	98.3%	99.0%		PPA	100.0%	100.0%		PNA	100.0%		100.0%	PNA		100.0%	100.0%		
	PNA	100.0%	100.0%		PNA	100.0%	100.0%											
LAFB	n	9	25	RVH	n	2	1	OA	100.0%	99.7%	PPA	100.0%	0.0%	PNA	100.0%	100.0%		
	OA	99.7%	100.0%		OA	100.0%	99.7%		PPA	100.0%		0.0%	PPA		100.0%	0.0%		
	PPA	88.9%	100.0%		PPA	100.0%	0.0%		PNA	100.0%		100.0%	PNA		100.0%	100.0%		
	PNA	100.0%	100.0%		PNA	100.0%	100.0%											
LBBB	n	18	16	STEMI	n	49	61	OA	99.4%	99.7%	PPA	97.9%	98.4%	PNA	99.6%	100.0%		
	OA	100.0%	100.0%		OA	99.4%	99.7%		PPA	97.9%		98.4%	PPA		97.9%	98.4%		
	PPA	100.0%	100.0%		PPA	97.9%	98.4%		PNA	99.6%		100.0%	PNA		99.6%	100.0%		
	PNA	100.0%	100.0%		PNA	99.6%	100.0%											
LVH	n	32	27	Tachycardia	n	19	19	OA	100.0%	100.0%	PPA	100.0%	100.0%	PNA	100.0%	100.0%		
	OA	99.7%	99.7%		OA	100.0%	100.0%		PPA	100.0%		100.0%	PPA		100.0%	100.0%		
	PPA	100.0%	100.0%		PPA	100.0%	100.0%		PNA	100.0%		100.0%	PNA		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%		
	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%						

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 AMI.
BF Equipment	Degree of protection against electrical shock.
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
AMI	Acute 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 ECG Specifications Using VectraplexECG

Hub Weight	280 - 300 grams (0.62 – 0.66 lb) depending on cable options
Hub Dimensions	85mm x 91mm x 20mm (3.3" x 3.6" x 0.8")
Patient Leads Length	1 meter (3.3 ft)
PC Connection Length	1-3 meter (3.3 – 9.8 ft), DB9 female connector
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	±6mV
Acquisition sample rate	1000 samples per second (compressed to 500Hz with peak picking and averaging algorithm)
Heart Rate Range	20 bpm - 200 bpm
Frequency Response	0.05 to 175Hz ±3dB
Defibrillator Protection	Patient leads are isolated from system and operator, with 4kV protection
Common Mode Rejection	-60dB (minimum)
Safety Standards	Complies with AAMI EC11, EN60601-1, EN60601-1-2, and EN60601-2-25
Accuracy	Accurate to AAMI EC11:1991 requirements, based on printed 3x4 report with software filters off, and using 1:1 scale 300dpi printer. Frequency and impulse response have been evaluated according to methods A, B and C of EC11:1991, 3.2.7.2/4.2.7.2.
Leads Off Indicators	Connection status for each lead is shown on Acquisition screen
Power Source	Powered by a PC USB or PS/2 port
Supply Voltage	4 – 16V DC

Supply Current	<17mA DC
Permanent Filters	High Pass: 0.05Hz 1st order Low Pass: 170Hz 1st order Baseline Wander: Baseline reset by adaptive zeroing algorithm
Notch filter (Mains Noise Rejection)	50Hz 4th order Butterworth, 49.1Hz - 50.9Hz, 60Hz 4th order Butterworth, 59.1Hz - 60.9Hz
Low pass (Muscle Artifact Filter)	35Hz 4th order
Report Capabilities	User selectable Report formats
Environmental Conditions	Operating Temperature: 0 to 40° C (32 to 104° F) Storage Temperature: -20 to 70° C (-4 to 158° F) Humidity 5% -85% (non-condensing)

ADDENDUM C

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