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

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

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

VectraCor, Inc.
785 Totowa Rd
Suite 100
Totowa, NJ 07512
Phone – 973-904-0444
# Table of Contents

**GENERAL CAUTIONS & WARNINGS**  
GLOSSARY OF SYMBOLS  
WARNINGS  
CAUTIONS  
ELECTRICAL SAFETY CLASSIFICATIONS  

**Vectraplex ECG BASICS**  
SYSTEM REQUIREMENTS  
INSTALLATION  
BACKING-UP AND RESTORING THE DATABASE  
NAVIGATION  
START-UP SCREEN  
PATIENT DATA AND SESSION SCREEN  
ACQUIRE LIVE ECG  
ECG SESSION SCREEN  
CAPTURE ECG SCREEN  
PREVIEW REPORT SCREEN  
FILE TAB  
SETUP TAB  
WINDOWS TAB  
HELP TAB  
ECG CAUTIONS AND WARNINGS  
INDICATIONS FOR USE  
ECG GETTING STARTED  
PERFORMING AN ECG TEST  
ABOUT THE ACQUISITION WINDOW – DISPLAY ECG SCREEN  
ABOUT THE PREVIEW REPORT SCREEN  
REVIEWING AN ECG  
PRINTING AN ECG  
ECG DEVICE VERIFICATION  
ECG ANALYSIS PROGRAM  
ALARMS  

**SERVICE INFORMATION**  
DEVICE CARE & MAINTENANCE  
TROUBLESHOOTING  
SERVICE  
LIMITED WARRANTY  

**Diagnostic Performance**  

**GLOSSARY OF TERMS**  

**UNIVERSAL ECG SPECIFICATIONS**  

**ADDENDUM C- OFFICE MEDIC SOFTWARE LICENSE AGREEMENT**
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.**


**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 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 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 VectraplexAMI 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 VectraplexAMI Index predominantly remains above 94. If the VectraplexAMI 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 VectraplexAMI 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 VectraplexAMI Index, the ECG tracing should have a relatively flat baseline.
- Do not use the VectraplexAMI Index as the final diagnosis, still need the physician diagnosis. If the VectraplexAMI 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 underestimate 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 VectraplexAMI 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 VectraplexAMI 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

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±8 air</td>
<td>±8 air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient burst</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>±1 kV for input/output lines</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode</td>
<td>±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>±2 kV common mode</td>
<td>±2 kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>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.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% UT (60% dip in UT) for 5 cycles</td>
<td>40% UT (60% dip in UT) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% UT (30% dip in UT) for 25 cycles</td>
<td>70% UT (30% dip in UT) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 KHz to 80 Mhz</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiated RF</th>
<th>3 V/m</th>
<th>3 V/m</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-3</td>
<td>80 MHz to 2.5 GHz</td>
<td></td>
</tr>
</tbody>
</table>

**Recommended separation distance:**

\[
d = \begin{cases} 
1.2 \sqrt{P} & \text{for } 80 \text{ MHz to } 800 \text{ MHz} \\
3.5 \sqrt{P} & \text{for } 800 \text{ MHz to } 2.5 \text{ GHz} 
\end{cases}
\]

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 should be less than the compliance level in each frequency range.

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

- \( \Delta \)

**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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td>( d = 2.3 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>7.3</td>
</tr>
<tr>
<td>100</td>
<td>23</td>
</tr>
</tbody>
</table>

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 VECTACOR/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.
VectraplexECG System Basics

System Requirements

Operating System: Microsoft® Windows® 7 (Professional)
Free Disk Space: minimum of 160 MB
Screen Resolution: 1024x768 (EKG Requirement)

Installation

System is shipped with the VectraplexECG software already installed

A VectraplexECG shortcut will appear on your desktop.

1. Connect the ECG patient cabling (QRS Universal ECG™) to the PC using the USB port (the eSATA 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. Open folder: C:\Users\UserNameGoesHere\AppData\Local\VirtualStore\Program Files\VectraCor\VectraplexECG.
   * UserNameGoesHere is the name of the user you are logged in as
3. Copy the SCPFile folder and paste into a separate secure folder that will be used to store the backup data
4. Open folder: C:\Program Files (x86)\VectraCor\VectraplexECG
5. Copy the VectraplexECG_log (Type = SQL Server Database Transaction Log File) file and paste into the backup folder
6. Copy the VectraplexECG (Type = SQL Server Database Primary Data File) file and paste into the backup folder

**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 all files from the secure backup location into the pathway explained in #2: C:\Users\UserNameGoesHere\AppData\Local\VirtualStore\Program Files\VectraCor\VectraplexECG.
   * UserNameGoesHere is the name of the user you are logged in as
3. Open VectraplexECG.

The database should look exactly as it did on the date of the last back-up.
Navigation
Select the VectraplexECG icon to open the software. The initial screen displays VectraplexECG for 5 seconds and then the Patient list screen appears. The initial screen displays as follows:

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.

1. Before acquiring ECG data make sure you select the SETUP tab to configure your system.
2. Selecting “New Patient” or “Continue” advances to Patient Data and Sessions Screen
**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 “Acquire Live ECG”. Patient ID # must be entered to continue.

There are 2 options for inputting the Date of Birth.

Option 1:
Step 1: To input Date of Birth, highlight the month then enter the 2 digit month.
Step 2: Highlight the day and enter the day of the month (1-31).
Step 3: Lastly, highlight the four digit year and enter the four digit year.

Option 2:
Step 1: Click on the Calendar icon that appears next to the four digit year. This will make the Calendar drop down.
Step 2: Click on the month/year at the top of the calendar (example: January 2012).
Step 3: Click on the year at the top of calendar (example: 2012). This will allow the user to use the arrows to scroll through and select their Year of birth.
Step 4: After Year is selected, the user will be able to then select Month.
Step 5: Lastly, once month is selected, the user will be able to select Day.

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

**Notes:**

1. Must insert Patient ID Number.
2. Smoking-Pack Years is calculated by multiplying the number of cigarette packs smoked per day by the number of years the patient has smoked.
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.
**Acquire Live ECG**

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

**ECG Session 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.

E-mail Feature – If you have Outlook on your system you can e-mail each individual file.

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

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

**Notes:**

1. Must 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. Check the computer’s system clock is accurate before using program.
4. Do not modify SCP files.
5. If no sessions are listed in window, then the only selection is to Acquire Live ECG.
**Capture ECG Screen**

The Capture ECG Screen is the on demand monitoring of the patient. It will display the VectraplexAMI index, Heart Rate and the ECG Leads. 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.

Press START to start acquiring on demand Data. Press Capture to stop and automatically display the Report Preview Screen. To select Capture, you need a Minimum of 10 seconds of Data. At anytime you can enter comments. If you are not in monitoring mode, you can still enter comments, but then you must select Update to save. This will occur after the Report Preview Screen.

**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. In the ECG Sessions screen you will see the saved data with time stamps.

Four Tabs:

- **Interpretation and Comments** – This tab interprets the 12-lead ECG using 10 electrodes only.
- **Patient and Recording** Details – This tab displays the patient info.
- **Detailed Report** – Displays Amplitudes, Slope and Duration of leads.
- **Prompts and Warnings** – Defines the VectraplexAMI index

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

The Preview Report is a 3 page report. 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 Loops.

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

**Page 1**

**Page 2**

**Page 3**

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

**View Patients** – Display the Patient List Screen

**Create Report** – Print Report

**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**

- Input the Comm. Port where the hardware is connected. Click on down arrow and the Comm. Port will be displayed. Click on port.
- SCP File Directory is the Directory the patient ECG data will be saved.
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 Default display for the Monitor Screen to select leads to display.
- **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 longer it will take to refresh the monitoring screen.
Reports Tab

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

Custom Tab

- Select the default leads you want to display in the Display ECG Screen.
Windows Tab

- Lists the window screens that are currently open.
Help Tab


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

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

About  – Displays the software version as shown below.
ECG Cautions and Warnings

**Warnings**

- The 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 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 VectraplexAMI 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 VectraplexAMI Index predominantly remains above 94. If the VectraplexAMI 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 VectraplexAMI 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 VectraplexAMI Index, the ECG tracing should have a relatively flat baseline.
- Do not use the VectraplexAMI Index as the final diagnosis, still need the physician diagnosis. If the VectraplexAMI 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 VectraplexAMI 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 VectraplexAMI 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**

• For diagnostic ECG according to the requirements of the AAMI EC11:1991 standard, use factory default settings. ECG diagnosis should be based on a printed 3x4 report with software filters off, and using a 1:1 scale 300dpi printer.
• The Universal ECG is designed for use with electrodes that comply with AAMI EC12:2000.
• Reseal electrode pouch after opening to prevent dehydrating.
• Suggested maximum electrode duration is 8 hours.
• Do not clean the case with alcohol.
• Do not saturate the case with liquid during cleaning.
• Do not sterilize ECG Device.
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.
**ECG Getting Started**

Connecting the 3 lead (5 electrodes) or 12-Lead (10 electrodes) ECG device to the Laptop:

- **USB**: The VectraplexECG software supports the ECG Device when connecting to a USB port, when using the supplied USB cable.

**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.
10 Electrode Placements (12-Lead ECG)

Limb Leads Above

5 Electrode Placement (3-Lead ECG)

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


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9. Click the Acquire Live ECG button to start the monitoring ECG display.

The acquisition window will appear on the screen and clicking **Start** will display the patient’s on demand ECG.

**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 VectraplexAMI Index. The ECG device is for acquiring resting ECGs and monitoring patients only. The device should not be used for stress testing.

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**About the Acquisition Window – Capture ECG Screen**
<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Leads</strong></td>
<td>Each graph labels which lead is displayed.</td>
</tr>
<tr>
<td><strong>Lead Identifiers</strong></td>
<td>V2</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td><strong>VectraplexAMI</strong></td>
<td>VectraplexAMI 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.</td>
</tr>
<tr>
<td><strong>Heart Rate (bpm)</strong></td>
<td>Displays the active Heart Rate of the patient. Heart Rate is validated from 20-200 BPM.</td>
</tr>
<tr>
<td><strong>Calibration Pulse</strong></td>
<td>Provides a visual indication of the combined sensitivity (1mV vertical height) and speed (100ms horizontal width).</td>
</tr>
<tr>
<td><strong>Speed</strong></td>
<td>Changes the number of millimeters that are passed in one second. The available options are 12.5mm/s, 25mm/s and 50mm/s.</td>
</tr>
<tr>
<td><strong>Sensitivity</strong></td>
<td>Changes the number of millimeters that represent one millivolt. The available options are 5mm/mV, 10mm/mV, and 20mm/mV.</td>
</tr>
<tr>
<td><strong>Muscle Filter</strong></td>
<td>Turns the Muscle filter on and off.</td>
</tr>
<tr>
<td><strong>Power Filter</strong></td>
<td>Turns the Power filter on and off. Note: the default frequency of the Power filter is set in the Setup.</td>
</tr>
</tbody>
</table>
### Leads

The ability to select any of the 15-lead views. A Custom Lead group can be defined in the Setup.

### Electrodes

Select how many electrodes will be placed on the patient. The default can be saved in the Setup. 5 electrodes selection will utilize VectraCor’s proprietary algorithms to derive the additional leads. Both will enable user to compare both methods. Both will display the Vectraplex AMI derived from the 5 electrodes setting and the Computer Interpretation from the 10 electrodes setting.

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

### Stop/Start

Stop ends the recording to modify any of the options. Start resumes recording data.

### Capture/Start

Capture ends the ECG recording and continues to Preview Report screen.

### Preview Report

Preview Report displays up the 3 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 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.
2. Heart Rate and VectraplexAMI display will be refreshed no sooner than approximately every 10 seconds.
**VectraplexAMI Index**
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 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 VectraplexAMI is \( \leq 65 \) as displayed on the device, then the patient may be considered by the clinician to have a normal dipolar cardiac electrical field consistent with non-AMI electrocardiographic lead signals. If the VectraplexAMI is \( \geq 95 \) as displayed on the device, then the patient may be considered by the clinician to have small but significant multipolar force contributions to the cardiac electrical field consistent with AMI electrocardiographic lead signals. If the VectraplexAMI 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.
About the Preview Report Screen

Displays the 15 lead ECG and data screens. By selecting the page up and down arrows, selection between Page 1 – Leads I-V6 12-lead ECG tracing, Page 2 - leads XYZ vectorcardiogram (VCG) tracings and page 3 - the detailed data and vector loops can be shown. Select the Printer icon in the upper left hand corner of the menu bar and it will print the three page report. Select Close and the screen will close and continue to “Capture ECG” window.

6 Printer Icon will print the three page report.

7 Close button will remove the currently displayed window.
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. The user can change the color defaults under the SETUP tab.
Reviewing an ECG

Reviewing an ECG within the “Capture ECG” Window

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

9. Update button – Click the Update button to save changes made during the session.
Details View

The details view shows the interpretation, comments, detailed measurements and patient details of the ECG.

Interpretation and Comments

Note:
1. If physician modifies the interpretation or comment field, the Update button (see above picture) must be selected to save any changes otherwise the changes will be lost.
2. Interpretation field shows the computerized interpretation only if all 10 electrodes are used and 10 electrode mode is selected.

Patient and Recording Details

Detailed Report

Prompts and Warnings

Note: Normal condition – The VectraplexAMI Index is less than 66 and is displayed in green.
Caution Zone – the VectraplexAMI Index is 66-94 and is displayed in orange. Patient requires continued clinical assessment.
Abnormal condition – The VectraplexAMI 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).

⚠️ 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.
**Printing an ECG**

There are two methods to printing a report:

1. Select **File | Create Report**
2. Select the Preview Report button which will display the 3 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.

**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, refer to the accompanying information for instructions on the use of these systems.

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

VectraplexAMI Alarm:

- VectraplexAMI 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).
- VectraplexAMI will be orange when the index is between non-AMI and AMI conditions.
- VectraplexAMI is green when non-AMI.
- To silence the alarm hit “S” for silence or “M” for mute.
  - The unit may take a few seconds to silence after pressing “S” or “M”

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

Note:
1. The user is cautioned that the VectraplexAMI 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
Service Information

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.
<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause of Failure</th>
<th>Possible Solutions</th>
</tr>
</thead>
</table>
| Data inaccessible | 1. Computer Failure  
2. Database on removable or remote storage is inaccessible | 1. Reboot system  
2. Check location of Database and that drive is accessible  
3. Restore back-up |
| Cannot establish communication with QRS hardware (patient cable) | 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 | 1. Make sure QRS hardware-USB cord is connected to USB connection/eSATA 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. Make sure a Comm. Port is configured for the QRS hardware, in SETUP under Configure… in General tab, select appropriate Comm. Port from drop down menu, select OK.  
5. Wait approximately 10 seconds for unit to initialize port before starting |
| ECG graphs look jagged | 1. Insufficient processor resources  
2. Patient movement | 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” |
| Under SETUP > Configure > General tab > Comm. Port drop down menu > No Comm. Port selectable; or none of the displayed Comm. Ports connect to the QRS hardware-USB cord | 1. QRS hardware is not inserted into USB/eSATA port | 1. Ensure the QRS hardware is fully inserted into USB/eSATA port  
2. Disconnect then reconnect QRS hardware into USB/eSATA port  
3. Wait approximately 10 seconds for unit to initialize port before starting |
<p>| Software detects file is in improper format | 1. File corrupted due to hard-drive failure | 1. Restore SCP file from back-up |</p>
<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Possible Causes</th>
<th>Possible Solutions</th>
</tr>
</thead>
</table>
| Software detects file is inaccessible | 1. File moved or deleted  
2. File missing on removable storage | 1. Restore SCP file from back-up |
| System does not run | 1. Program not detected  
2. Program does not run or display Graphs | 1. Check Comm. Port in General tab is set to the correct port.  
2. Re-boot system  
3. Make sure the configuration files in set-up are input correctly.  
4. Call VectraCor’s Service Department |
| 3 Page Report Does Not Print | 1. Printer not available | 1. Make sure printer is installed  
2. Check if printer is online  
3. Check connection from printer to computer |
| Error Message- Lead Off | 1. Electrode is lifting from patient.  
2. Buffer overload. | 1. Check that electrodes are securely connected to patient.  
2. Hit “Stop” acquisition and then select “Start” |
| Data Overload | 1. Data Overload | 1. Reduce the number of leads to display data. |
| Error message “discontinuing Analysis” Under “Prompts and Warnings” “VectraplexAMI is processing” | 1. Electrodes may not be attached  
2. Need 10 seconds of Data | 1. Connect or verify that all electrodes are attached. |
| Unit frozen | 1. Battery power reached end of life  
2. Error during loading of application  
3. Error during initialization of computer  
4. Complication with another program | 1. Plug unit into power outlet  
2. Restart computer (may need to be restarted again if unit shut down due to power loss)  
3. Remove USB then reinsert; a pop up message should appear once device is recognized  
4. Go to SETUP tab and select configure and input COMM PORT  
5. Wait approximately 10 seconds for unit to initialize port before starting |
| "Not Responding" displayed at top of program window | 1. VectraplexECG System work in progress | 1. Wait time may vary depending on the information the program is displaying  
2. Wait approximately 30 seconds for the program to respond  
3. If the program does not respond afterwards close the program and restart the unit |
| "CPU Usage is High" pop-up message | 1. VectraplexECG System work in progress | 1. VectraCor’s software utilizes a large amount of computing power; This is not problematic |
| other | | 1. Call VectraCor’s Service Department |
Service
Contact the VectraCor service department:

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

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

<table>
<thead>
<tr>
<th>ST0 = J point</th>
<th>Parameters</th>
<th>*Actual</th>
<th>*Worst Case</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>EM</strong></td>
<td>Cardiology</td>
<td><strong>EM</strong></td>
</tr>
<tr>
<td>Sensitivity (TPF)</td>
<td>VectraplexAMI (CEB)</td>
<td>93.75%</td>
<td>87.27%</td>
</tr>
<tr>
<td></td>
<td>ST0 (J point evaluation)</td>
<td>70.31%</td>
<td>76.36%</td>
</tr>
<tr>
<td></td>
<td>rTPF (CEB:ST0 Ratio)</td>
<td>1.33</td>
<td>1.143</td>
</tr>
<tr>
<td></td>
<td>95% CI (LL, UL)</td>
<td>(1.155, 1.539)</td>
<td>(0.998, 1.309)</td>
</tr>
<tr>
<td>Specificity (1-Specificity)</td>
<td>VectraplexAMI (CEB)</td>
<td>91.30%</td>
<td>81.50%</td>
</tr>
<tr>
<td></td>
<td>ST0 (J point evaluation)</td>
<td>73.48%</td>
<td>74.02%</td>
</tr>
<tr>
<td></td>
<td>rFPF (CEB:ST0 Ratio)</td>
<td>0.328</td>
<td>0.712</td>
</tr>
<tr>
<td></td>
<td>95% CI (LL, UL)</td>
<td>(0.309, 0.348)</td>
<td>(0.669, 0.758)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>*Actual</th>
<th>*Worst Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EM</strong></td>
<td>Cardiology</td>
<td><strong>EM</strong></td>
</tr>
<tr>
<td>19.0%</td>
<td>17.4%</td>
<td>19.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STSUM = Area under ST segment</th>
<th>Parameters</th>
<th>*Actual</th>
<th>*Worst Case</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>EM</strong></td>
<td>Cardiology</td>
<td><strong>EM</strong></td>
</tr>
<tr>
<td>Sensitivity (TPF)</td>
<td>VectraplexAMI (CEB)</td>
<td>93.8%</td>
<td>87.3%</td>
</tr>
<tr>
<td></td>
<td>STSUM (ST segment)</td>
<td>65.6%</td>
<td>69.1%</td>
</tr>
<tr>
<td></td>
<td>rTPF (CEB:STSUM Ratio)</td>
<td>1.429</td>
<td>1.263</td>
</tr>
<tr>
<td></td>
<td>95% CI (LL, UL)</td>
<td>(1.211, 1.685)</td>
<td>(1.066, 1.497)</td>
</tr>
<tr>
<td>Specificity (1-Specificity)</td>
<td>VectraplexAMI (CEB)</td>
<td>91.30%</td>
<td>81.82%</td>
</tr>
<tr>
<td></td>
<td>STSUM (ST segment)</td>
<td>61.30%</td>
<td>60.47%</td>
</tr>
<tr>
<td></td>
<td>rFPF (CEB:STSUM Ratio)</td>
<td>0.225</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>95% CI (LL, UL)</td>
<td>(0.208, 0.242)</td>
<td>(0.426, 0.497)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>*Actual</th>
<th>*Worst Case</th>
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<td>21.8%</td>
<td>17.9%</td>
<td>21.3%</td>
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## Comparative Diagnostic Performance

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<th>Test Measures</th>
<th>Parameters</th>
<th><em>Actual</em></th>
<th><em>Worst Case</em></th>
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<td>VectorplexAMI (CEB)</td>
<td>93.4%</td>
<td>91.34%</td>
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<td>ECGI (Computer reading)</td>
<td>57.4%</td>
<td>77.2%</td>
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<td>rTPF (CEB:ECGI Ratio)</td>
<td>1.629</td>
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<td></td>
<td>95% CI (LL, UL)</td>
<td>(1.353, 1.960)</td>
<td>(0.374, 0.411)</td>
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<td>VectorplexAMI (CEB)</td>
<td>91.34%</td>
<td>85.1%</td>
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<td>ECGI (Computer reading)</td>
<td>77.92%</td>
<td>75.64%</td>
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<td>rFPF (CEB:ECGI Ratio)</td>
<td>0.392</td>
<td>0.638</td>
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<tr>
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<td>95% CI (LL, UL)</td>
<td>(0.374, 0.411)</td>
<td>(0.607, 0.671)</td>
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<tr>
<td>Negative Predictive Value</td>
<td>VectorplexAMI NPV</td>
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<td>94.1%</td>
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<tr>
<td>Positive Predictive Value</td>
<td>VectorplexAMI PPV</td>
<td>74.0%</td>
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<td>Caution Zone %</td>
<td>No Test %</td>
<td>7.30%</td>
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<td>Utility %</td>
<td>(1-No Test)%</td>
<td>92.7%</td>
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<td>Prevalence</td>
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<td>20.9%</td>
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</table>

*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 (i.e., either a false negative or false positive result)

*CEB = VectorplexAMI® cardiac electrical biomarker

*EM = Emergency Medicine

*ECGI = Computerized Interpretation Software

*ST0 = J point

*STSUM = area under ST segment for ST0-ST80

*LL = Lower limit 95% CI

*UL = Upper limit 95% CI

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

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:

Lead V4

Note: There are graphs that may have cases with identical points around (0,0), which may reflect a lower sample size.
Lead V5

Lead V5 Q Wave
Bland-Altman Plot

Mean: 0.00
Mean ± 2SD: ±0.85

Lead V5 R Wave
Bland-Altman Plot

Mean: 0.69
Mean ± 2SD: ±10.61

Lead V5 S Wave
Bland-Altman Plot

Mean: 1.07
Mean ± 2SD: ±4.37

Lead V5 STG
Bland-Altman Plot

Mean: 0.92
Mean ± 2SD: ±9.44

Lead V5 T Wave
Bland-Altman Plot

Mean: 0.23
Mean ± 2SD: ±2.77

Lead V5 T’ Wave
Bland-Altman Plot

Mean: 0.09
Mean ± 2SD: ±1.33
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 VectraplexECG System. The physician reference standards (Emergency Medicine physician and Cardiologist) were blinded to the measured and derived ECGs, and to each other, when interpreting each ECG.

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>Cardiology OA</th>
<th>Cardiology PPA</th>
<th>Cardiology PNA</th>
<th>EM OA</th>
<th>EM PPA</th>
<th>EM PNA</th>
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</table>

**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

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>VectraplexAMI Index</td>
<td>The VectraplexAMI index is a cardiac electrical biomarker that can detect real time changes in the ECG suggestive of an AMI.</td>
</tr>
<tr>
<td>BF Equipment</td>
<td>Degree of protection against electrical shock.</td>
</tr>
<tr>
<td>AMI</td>
<td>Acute Myocardial Infarction</td>
</tr>
<tr>
<td>CEB</td>
<td>VectraplexAMI index</td>
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<td>AAWMI</td>
<td>Acute Anterior Wall Myocardial Infarction</td>
</tr>
<tr>
<td>AFib</td>
<td>Atrial Fibrillation</td>
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<td>AiWMI</td>
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<td>AMI</td>
<td>Acute Myocardial Infarction</td>
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<tr>
<td>APWMI</td>
<td>Acute Posterior Wall Myocardial Infarction</td>
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<tr>
<td>ASWMI</td>
<td>Acute Septal Wall Myocardial Infarction</td>
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<td>Early Repole</td>
<td>Early Re-polarization</td>
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<td>NSR</td>
<td>Normal Sinus Rhythm</td>
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<td>NSSTT</td>
<td>Non-Specific ST-T Changes</td>
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</tr>
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<td>ILBBB</td>
<td>Incomplete Left Bundle Branch Block</td>
</tr>
<tr>
<td>IRBBB</td>
<td>Incomplete Right Bundle Branch Block</td>
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<td>Abbreviation</td>
<td>Description</td>
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<td>IVCD</td>
<td>Intraventricular conduction delay</td>
</tr>
<tr>
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<td>Left Axis Deviation</td>
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<td>Left Atrial Enlargement</td>
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<td>LBBB</td>
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## Universal ECG Specifications

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<th>Specification</th>
<th>Details</th>
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<td><strong>Hub Weight</strong></td>
<td>280 - 300 grams (0.62 – 0.66 lb) depending on cable options</td>
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<tr>
<td><strong>Hub Dimensions</strong></td>
<td>85mm x 91mm x 20mm (3.3” x 3.6” x 0.8”)</td>
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<td><strong>Patient Leads Length</strong></td>
<td>1 meter (3.3 ft)</td>
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<tr>
<td><strong>PC Connection Length</strong></td>
<td>1-3 meter (3.3 – 9.8 ft), DB9 female connector</td>
</tr>
<tr>
<td><strong>Patient Leads</strong></td>
<td>12-Lead Cable (10 patient electrodes)</td>
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<td><strong>Case Material</strong></td>
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<tr>
<td><strong>Electrode Connections</strong></td>
<td>4 mm Banana plug with &quot;tab&quot; or &quot;snap&quot; connectors</td>
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<tr>
<td><strong>Electrode Labeling</strong></td>
<td>Abbreviations and colors to comply with either IEC or AAMI standards</td>
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<tr>
<td><strong>Display and Operating Console</strong></td>
<td>Dependent on PC (supplied by user)</td>
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<tr>
<td><strong>Gain/Sensitivity</strong></td>
<td>5, 10, 20 mm/mV</td>
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<td><strong>Input Range</strong></td>
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<tr>
<td><strong>Acquisition sample rate</strong></td>
<td>1000 samples per second (compressed to 500Hz with peak picking and averaging algorithm)</td>
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<tr>
<td><strong>Heart Rate Range</strong></td>
<td>20 bpm - 200 bpm</td>
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<td><strong>Frequency Response</strong></td>
<td>0.05 to 175Hz ±3dB</td>
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<td><strong>Defibrillator Protection</strong></td>
<td>Patient leads are isolated from system and operator, with 4kV protection</td>
</tr>
<tr>
<td><strong>Common Mode Rejection</strong></td>
<td>-60dB (minimum)</td>
</tr>
<tr>
<td><strong>Safety Standards</strong></td>
<td>Complies with AAMI EC11, EN60601-1, EN60601-1-2, and EN60601-2-25</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Leads Off Indicators</strong></td>
<td>Connection status for each lead is shown on Acquisition screen</td>
</tr>
<tr>
<td><strong>Power Source</strong></td>
<td>Powered by a PC USB or PS/2 port</td>
</tr>
<tr>
<td><strong>Supply Voltage</strong></td>
<td>4 – 16V DC</td>
</tr>
<tr>
<td>Supply Current</td>
<td>&lt;17mA DC</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Permanent Filters</strong></td>
<td></td>
</tr>
<tr>
<td>High Pass: 0.05Hz 1st order</td>
<td></td>
</tr>
<tr>
<td>Low Pass: 170Hz 1st order</td>
<td></td>
</tr>
<tr>
<td>Baseline Wander: Baseline reset by adaptive zeroing algorithm</td>
<td></td>
</tr>
<tr>
<td><strong>Notch filter (Mains Noise Rejection)</strong></td>
<td></td>
</tr>
<tr>
<td>50Hz 4th order Butterworth, 49.1Hz - 50.9Hz, 60Hz 4th order Butterworth, 59.1Hz - 60.9Hz</td>
<td></td>
</tr>
<tr>
<td><strong>Low pass (Muscle Artifact Filter)</strong></td>
<td></td>
</tr>
<tr>
<td>35Hz 4th order</td>
<td></td>
</tr>
<tr>
<td><strong>Report Capabilities</strong></td>
<td>User selectable Report formats</td>
</tr>
<tr>
<td><strong>Environmental Conditions</strong></td>
<td>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)</td>
</tr>
</tbody>
</table>
ADDENDUM C
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Rev. A