

VECGWEB Application
With
CEB (Cardiac Electrical Biomarker)

User Manual

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General Cautions & Warnings

Important Information Regarding Instruction for Use

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



Warnings

- The CEB® index has only been tested in comparison to physician interpretation of standard 12-lead ECGs in patients presenting to an acute care setting, and not in comparison to additional clinical data documenting the presence of acute myocardial infarction.
- Do not use the 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 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.
- Make sure that virus protection software and firewall software are installed on the PC hosting the VECGWEB application and are not disabled.



Cautions

- Federal (USA) law restricts this product 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.

Security precautions:

- User is responsible for protection of the login credentials/ access controls used to access the PC hosting the VECGWEB application and SCP files.
- User is responsible for equipping the PC hosting the VECGWEB application and SCP files with necessary protection against external attacks (virus, malware etc.) and protection configuration.
- VectraCor strongly recommends the user utilize credible antivirus, malware protection, firewall, etc. software on each piece of equipment where patient information is stored.
- VECGWEB stores log information pertaining to any runtime errors encountered during program execution for each day as a .log file. Log files are created and stored in the same directory as the VECGWEB application. The log file is named in the format “VECGWEB_YYYYMMDD”. User is responsible for the security permissions/access control of the log files.
- User is responsible for SCP files and patient medical data. VectraCor will not receive or maintain any patient identifiable data.
- User is responsible for the integrity of the VECGWEB software and its components residing on the Host PC.

Indications for Use

The VECGWEB application is intended for use by healthcare professionals in a healthcare setting. It is a windows-based program which operates as follows:

- The application is run from a simple command-line interface.
- The application accepts a single command-line parameter, the name of a SCP file located in the same directory as the application.
- The application supports Web-SCP file format only.
- The data in the SCP file must have been acquired from adult patients (18+ years).
- Multiple instances of the application may be run concurrently.
- The SCP input file will remain unchanged.
- The application is intended to be used by healthcare professionals, or trained personnel.

Application Specification

Medical Indication:	Processing of SCP file data to be used in the diagnosis of cardiovascular conditions/diseases
User Profile:	Trained professional
Patient Population:	Adult Male/Female (18+)
Environment of Use:	Hospital and Clinical Use
Tissue Type of Device Interaction:	None
Conditions of Use:	Continuous use
Operating Principle:	Software application running on a Windows Server.

VECGWEB System Basics

System Requirements

Operating System: Windows Server 16 or 19

Free Disk Space: 400 MB

Screen Resolution: N/A

Co-Installed Software:

- License Key: A license key must be entered into the system during installation to activate the VECGWEB application software. The VECGWEB application will not run without a valid license key.

Installation

1. Ensure you are logged in to a Windows Server 16 or 19 with Administrator rights.
2. Unzip VECGWEB_Installer.zip.
3. Run setup.exe as Administrator.
4. The VECGWEB splash screen, shown below, is displayed. Click Next.
5. Select a language. Click Next.
6. The Welcome screen for the InstallShield Wizard for VECGWEB is displayed. Click Next.
7. Choose a destination folder for the install. Click Next.
8. Select United States. Click Next.
9. InstallShield Wizard Complete is displayed. Click Finish.
10. The application requires licensing information to be entered.
To enter licensing information later, click Exit. Then go to step 16.
To enter licensing information now, click Activate VECGWEB.
11. If you already have a License ID/Password, click Activate VECGWEB Online. Otherwise, follow the steps to obtain the license information.
12. Follow the prompts to enter the License ID and Password.
13. Click Continue.
14. The software should be activated successfully.
15. Click Continue.
16. Important: You must now close the Windows command window to complete the installation.

If licensing information is not entered during the initial installation, it may be entered later by opening a Windows command window with Administrator privileges and entering the command `vecgweb` without specifying a SCP filename. In this case, a dialog box will appear requesting license information.

Running the Application

The application can be run from a Windows command window.

1. Open a Windows command window as an administrator.
2. Copy the SCP input file into the installation directory.

3. Enter the command: `cd C:\<folder name>` to navigate to the installation directory.
4. Enter the command: `vecgweb <SCP filename>`
5. An output file with a similar name will be created in the installation directory.
For example, SCP input filename of `patient.scp` will produce a SCP output filename of `patient.vecg.scp`.

Splash Screen



SCP Input File

The VECGWEB application takes a SCP file named with a .scp extension as input.

- The application supports the following SCP file format: Web-SCP.
- A Web-SCP file is defined as follows:
 - Contains Rhythm data for at least leads I, II, and V2
 - Contains Section 1 Tags 14 (Machine ID Acquiring Device), 25 (Date of Acquisition), and 26 (Time of Acquisition)
 - The Rhythm data must consist of raw, unencoded values and be of the same length, with the same start and end indices

SCP Output File

The VECGWEB application processes the specified SCP input file, and creates an augmented SCP output file as follows:

- The SCP output file will contain all of the data from the SCP input file in the same format.
- The application extracts the lead data for leads I, II, and V2, and computes the CEB based on this data.
- If the lead data in the input file is such that it cannot be processed to provide corresponding reference beats for leads I, II, or V2, the CEB will be given as 10000 (0x2710); otherwise, it will contain the result of the CEB calculation.
- The CEB is inserted in Section 1 in custom Tag 233 of the output file.
- The application derives lead data for the missing leads and adds the data to Section 6 (Rhythm Data), updating the Section 3 lead descriptors accordingly.
- Section 5 data (Reference Beats) is optional in the SCP input. If it is present in the input file, then Section 5 data will also be added to the SCP output file for the missing leads.
- The SCP output file contains data for the following 15 leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, X, Y, Z.
- The SCP output file is created in the same directory as the application.
- The output filename is based on the input filename, i.e., if the input file is patient.scp, the output filename will be patient.vecg.scp.

Cardiac Electrical Biomarker (CEB®) Index Number

The output file generated by the VECGWEB application contains CEB index in custom Tag 233.

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

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

If the CEB® is ≤ 65 , 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 , 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, 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.

Service Information

Troubleshooting

Problem	Cause of Failure	Possible Solutions
Application does not run	License information not found or invalid. SCP filename not specified on command line. Command window is not in proper directory.	Verify valid license information was entered into the system. Verify command line input contains SCP filename. Change directory to where VECGWEB.exe file is located.
Application detects input file is in improper format	SCP input file is not in a supported file format. SCP input file is corrupted	Copy a Web-SCP file into installation directory
Application detects input file is inaccessible	File not present in installation directory	Copy a Web-SCP file into installation directory
Other		Call VectraCor's Service Department

Service

Contact the VectraCor service department:

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

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

email: support@vectracor.com

Limited Warranty

DISCLAIMER OF WARRANTY

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The performance of the Software varies with various manufacturers' equipment with which it is used. VectraCor, Inc. does not warrant the level of performance of the Software.

Glossary of Terms

CEB® Index	The CEB® Index is a cardiac electrical biomarker that can detect real time changes in the ECG suggestive of an AMII, including AMI.
AMII	Acute Myocardial Ischemic Injury
AMI	Acute Myocardial Infarction
CEB	CEB® Index
Paced	Pacemaker rhythm
PVC	Premature Ventricular Contraction
Extrapolated lead data	Lead data calculated from leads I, II, and V2 using the lead extrapolation algorithm created by VectraCor
SCP	Standard Communications Protocol, which is an abbreviation for SCP-ECG
SCP-ECG	Standard Communications Protocol for Computerized Electrocardiography
Web-SCP	The SCP format for input data supported by this application