Vectraplex
Central Monitoring System (CMS)
User Manual

VECTRACOR
Diagnosing Better Care

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

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.

Table of Contents

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 B Equipment

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.

CE Mark
Indicates this device is in compliance with MDR (2017/745). 2797 is the Notified Body Number. (Note: This CE mark is in reference to the QRS Diagnostic Universal SmartECG®)
2797

Class II, Electrical Equipment.

REF   **Catalogue or Model Number**

S/N   **Serial Number**

Manufacturer

EC REP   **Authorized representative in the European community.**

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

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

Latex-Free   **Product is Latex-Free**

Upper Limit of Temperature

LOT   **Batch Code**

⚠️ Warnings

- Do not use Vectraplex CMS System in presence of flammable anesthetic mixture.
- Do not operate Vectraplex CMS System in an explosive atmosphere.
- 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 display images will be refreshed about every 5 seconds on a dedicated network connection
- Make sure that virus protection software and firewall software are installed and not disabled.
- If used in a Critical Care setting, have a backup FDA registered device available if current system is down.

⚠️ 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 Vectraplex CMS and VectraplexECG system.

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of VectraplexECG System.
- Universal Smart 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.

Electrical Safety Classifications

- Class II Equipment, Internally Powered.
- Type B Equipment.
- 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

- Vectraplex Central Monitoring System (CMS) is a centralized monitoring system intended to transfer information between networked devices (only VectraplexECG Systems), which include hard-wired or wireless devices via Virtual Private Network (VPN)
- The Central Monitoring System can be used for remote monitor management, printing, viewing or otherwise processing of information from VectraplexECG Systems including remote control
- The device is intended to be used by qualified medical professionals
- The Vectraplex CMS will audibly and visually alarm if the VectraplexECG System's CEB® (VectraplexAMI), Cardiac Electrical Biomarker, reaches an alarm condition.
- The Vectraplex CMS intended use population consists of those patients with certain medical conditions in whom continuous cardiac monitoring is considered to be a medical necessity in the judgment of the ordering healthcare provider.
- The Vectraplex CMS is intended for centralized monitoring of patients through a network in hospitals, Emergency Departments and Surgical Centers, doctor's offices, and urgent care facilities.
- Not for home use

Vectraplex CMS System Basics

Vectraplex Central Monitoring System (CMS) is a remote monitoring system designed for remote monitoring of VectraplexECG software instances from a single computer. The Vectraplex CMS includes three applications: the 'Vectraplex CMS Proxy' application, the 'Vectraplex CMS Monitor' application, and the 'Vectraplex CMS Device' application (pre-installed with the VectraplexECG software).

System Requirements

| Components	Environment
'Vectraplex CMS Monitor' application	- Computer 1 with Windows 10/11 OS - Intranet connection; LAN network speed 100 Mbps. - Minimum 2 GB RAM, 10 GB Hard Disk with dual core processor - Minimum resolution 1920 x 1080 - Minimum recommendation for monitor Screen size is 21 inch.
'Vectraplex CMS Device' application	- Computer 2 with Windows 10/11 OS - Intranet connection; LAN network speed 100 Mbps. - Minimum 2 GB RAM, 10 GB Hard Disk with dual core processor - Minimum resolution 1920 x 1080 (pre-installed with the VectraplexECG software)
'Vectraplex CMS Proxy' application	- Computer 3 with Windows 10/11 OS - Intranet connection; LAN network speed 100 Mbps. - Minimum 2 GB RAM, 10 GB Hard Disk with dual core processor - Minimum resolution 1920 x 1080
Multicast Setup ***Multicast** – One device can be monitored by more than one monitor system**	Up to 16 'Vectraplex CMS Device' application (pre-installed with the VectraplexECG software) and 3 'Vectraplex CMS Monitor' application can use the same 'Vectraplex CMS Proxy' application

System Configuration Recommendations

1. The preferred setup involves deploying the Device and Proxy on dedicated machines within the same LAN (Local Area Network), facilitating necessary firewall rule adjustments for communication, with Vectraplex ECG software installed on the Device.
2. For optimal functionality, the Monitor should be installed on a separate machine, within the same LAN as the proxy. Alternatively, if required, the monitor can be placed on a different network, provided it establishes a VPN connection to the Device/Proxy network with firewall exceptions.
3. Ensure to adjust the PC power settings on the proxy, device, and monitor PCs to disable sleep mode, as continuous network communication and device interaction are critical for intended operation

4. Avoid installing the proxy on the device or monitor PCs to prevent potential system performance issues.
5. Co-installing the Monitor and Proxy on the same machine may result in alarm interference; it's advisable to avoid this configuration.
6. For better resolution, it's recommended to configure Device display resolution to its maximum resolution.

Installation

The Vectraplex CMS includes three integral applications: the 'Vectraplex CMS Proxy' application, the 'Vectraplex CMS Monitor' application, and the 'Vectraplex CMS Device' application with preinstalled VectraplexECG software. To ensure proper functionality of the Vectraplex CMS system, it is essential that all three applications are installed on their designated computers.

1. Download the Vectraplex CMS installation package from the provided source, such as a software download link or removable media.
2. Locate the downloaded file containing the installers for Vectraplex CMS Proxy, Device, and Monitor
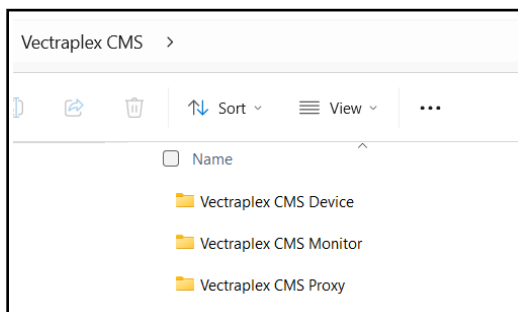
3. Copy the installer file to the respective computers for each software installation:
   - 'Vectraplex CMS Monitor' software: Install on a dedicated Windows computer for monitoring
   - 'Vectraplex CMS Device' software : Install on a Windows **computer with VectraplexECG software pre-installed**, to be monitored
   - 'Vectraplex CMS Proxy' software: Install separately on another Windows computer, preferably a server computer.

Please Note: Avoid installing the proxy on the device or monitor PCs as it can impact system performance. Installing the Monitor and Proxy on the same machine can lead to alarm interference. Therefore, it is advisable to avoid this configuration.
The preferred configuration entails deploying the Device and Proxy on dedicated machines within the same LAN. This setup facilitates necessary adjustments to firewall rules for communication, with VECG installed on the Device.

For optimal functionality, the Monitor should be installed on a separate machine, within the same LAN as the proxy. Alternatively, if required, monitor can be placed on a different network, provided it establishes a VPN connection to the Device/Proxy network with firewall exceptions.

4. Go to the designated application folder (proxy/device/monitor) within the Vectraplex CMS directory. Find the file and double-click to begin installation

5. Follow the on-screen prompts to complete the installation process. Repeat steps 3 to 5 to install all three Vectraplex CMS applications: proxy, device, and monitor, on their respective computers.

6. After successful installation, shortcuts for Vectraplex CMS, including Monitor, Device, and Proxy, will be created on your desktop

    Please note *: a command prompt icon may appear on the taskbar when each application is launched. This icon can be safely ignored or closed by the user without impacting system operation, as it will automatically close when the application is exited.*
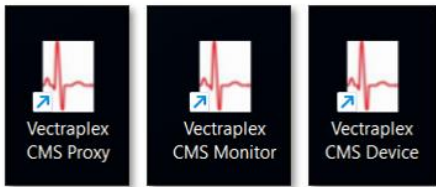
If you wish to upgrade to a more recent version of Vectraplex CMS, please contact VectraCor for assistance. If you encounter any issues during installation or operation, refer to the Trouble Shooting section of the user manual or contact VectraCor support for assistance.

Getting Started - Navigation

The Vectraplex CMS consists of three distinct applications: the 'Vectraplex CMS Proxy' application, the 'Vectraplex CMS Monitor' application, and the 'Vectraplex CMS Device' application (pre-installed with the VectraplexECG software).
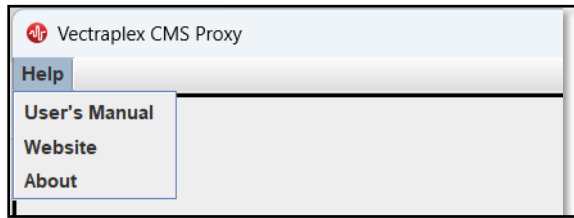
Setup Vectraplex CMS Proxy

The 'Vectraplex CMS Proxy' application serves as the vital link connecting all components of the Central Monitoring System. It acts as the communication bridge between the 'Vectraplex CMS Device' application (pre-installed with the VectraplexECG software) and the 'Vectraplex CMS Monitor' application, making it the initial step in activating Vectraplex CMS. A single 'Vectraplex CMS Proxy' application can support up to 16 VectraplexECG software instances, supported by the 'Vectraplex CMS Device' application, along with 3 instances of the 'Vectraplex CMS Monitor' software.

After installing the Vectraplex CMS Proxy application, double-click on the 'Vectraplex CMS Proxy' icon located on the desktop to open it. This action will bring up a screen showing the automatically generated IP address assigned by the Vectraplex CMS Proxy:
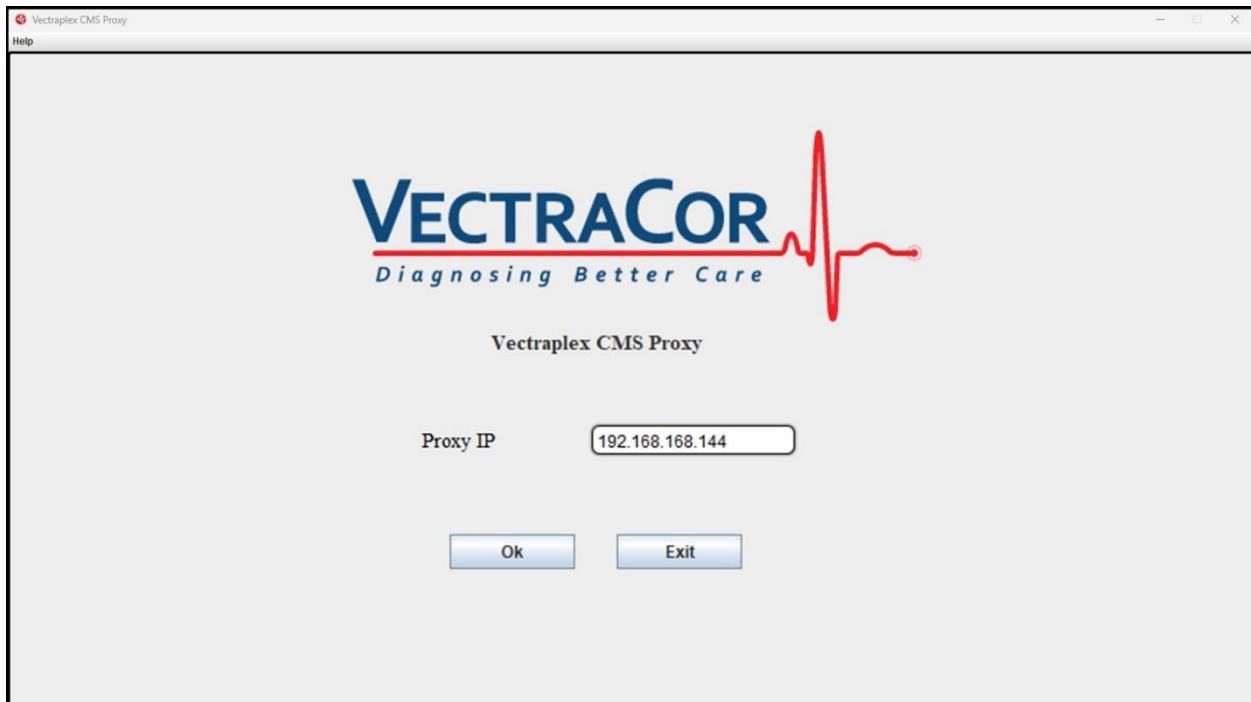
Make sure to take note of this IP address, as it will be utilized by the Vectraplex CMS Device(s) and the Vectraplex CMS Monitor(s) to establish connections with the proxy. Once noted, you can minimize the screen by clicking 'OK.
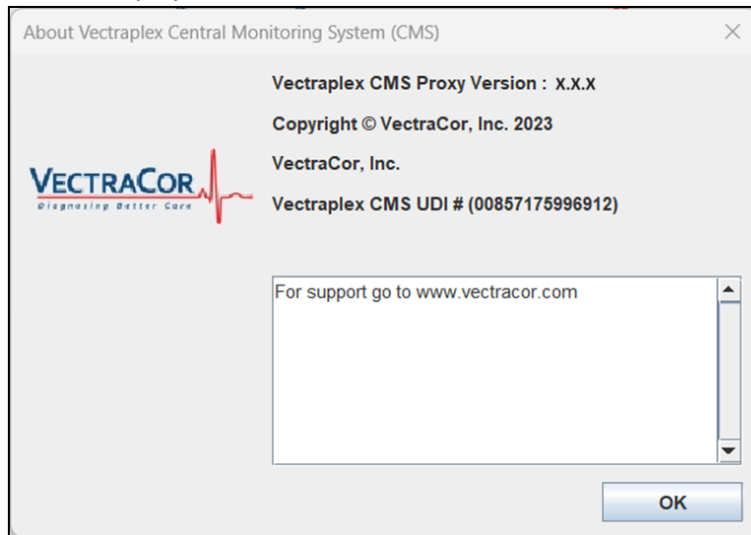
Help Menu

User's Manual - Opens the Vectraplex Central Monitoring System (CMS) User Manual
**Website** – Displays www.vectracor.com (internet connection required)
About - Displays the software version as shown below

Setup Vectraplex CMS Device

The setup of the 'Vectraplex CMS Device' application(pre-installed with VectraplexECG software) is the second step in configuring Vectraplex CMS. This application enables the 'Vectraplex CMS Monitor' application to view and remote control the screen of the device it's installed on. Additionally, the 'Vectraplex CMS Device' application sends information to the 'Vectraplex CMS Monitor' application via the 'Vectraplex CMS Proxy' application, including signals for high CEB alarm conditions when used alongside VectraCor's VectraplexECG software.

After installing the Vectraplex CMS Device application, double-click on the 'Vectraplex CMS Device' icon located on the desktop to open it. The user will be presented with a screen containing options to manually input the proxy-generated IP address, Device Name, and Device Location:
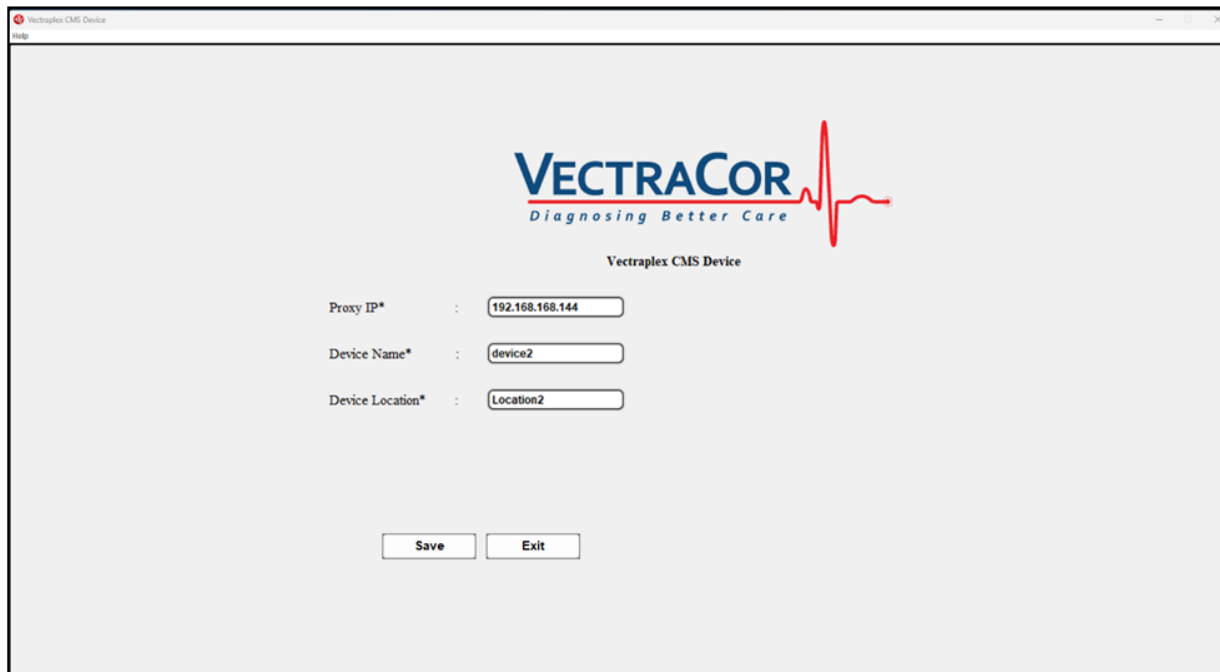
The user must enter the correct IP address (the same IP address shown by the Vectraplex CMS Proxy and used for the Vectraplex CMS Monitor), create a unique Device Name (please note: the system won't accept duplicate device names), and specify a Device Location. Click '**Save**' to establish connection with Proxy application.

The Device Name can be any chosen name, such as "device2", without special characters (e.g., !@#$%). The Device Location can also be user-defined, for example, "Location2". The Device Location can be modified at any time using the Update button (described under the *Update button* section in detail). The Device Name and Location can be different or the same. Once the proxy-to-device connection is established, the Device Name and Proxy IP address cannot be changed. To modify them, exit the device application and restart the program.

*Note: If the central monitor is located at a different facility than the patient, the remote user should contact the patient's healthcare providers at the treating facility for any observed abnormal conditions noted on the central monitor. If a conflict of operation is noted between the remote operator and the bedside operator the remote operator should contact the healthcare providers at the treating facility. The bedside operator should always maintain the right of operation over that of the remote operator.

If the Vectraplex CMS Proxy is not running or if the Vectraplex CMS Device is unable to connect to the proxy, then a pop up window appear:
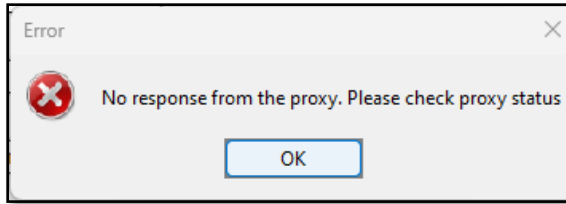
If the entered device name is already registered with the Vectraplex CMS Proxy the user will see the below message:
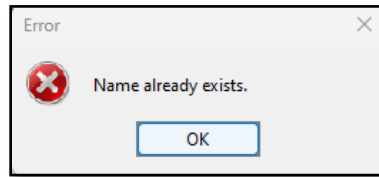
Once the Vectraplex CMS Device successfully connects to the Vectraplex CMS Proxy the user will see the following screen:
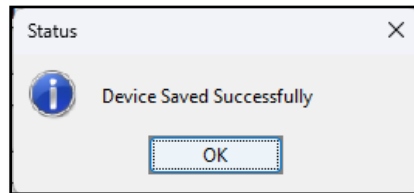

If device communication with the Proxy is lost for more than 5 seconds, presumably because it has been closed or has crashed, any connected Device will notify the user and close itself automatically in order to facilitate reconnection.
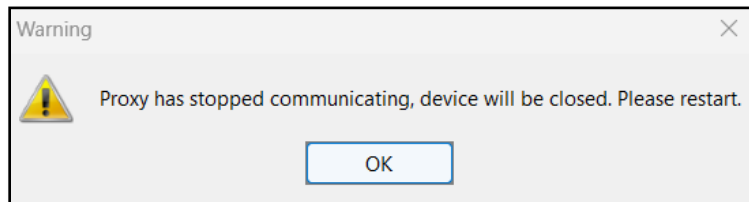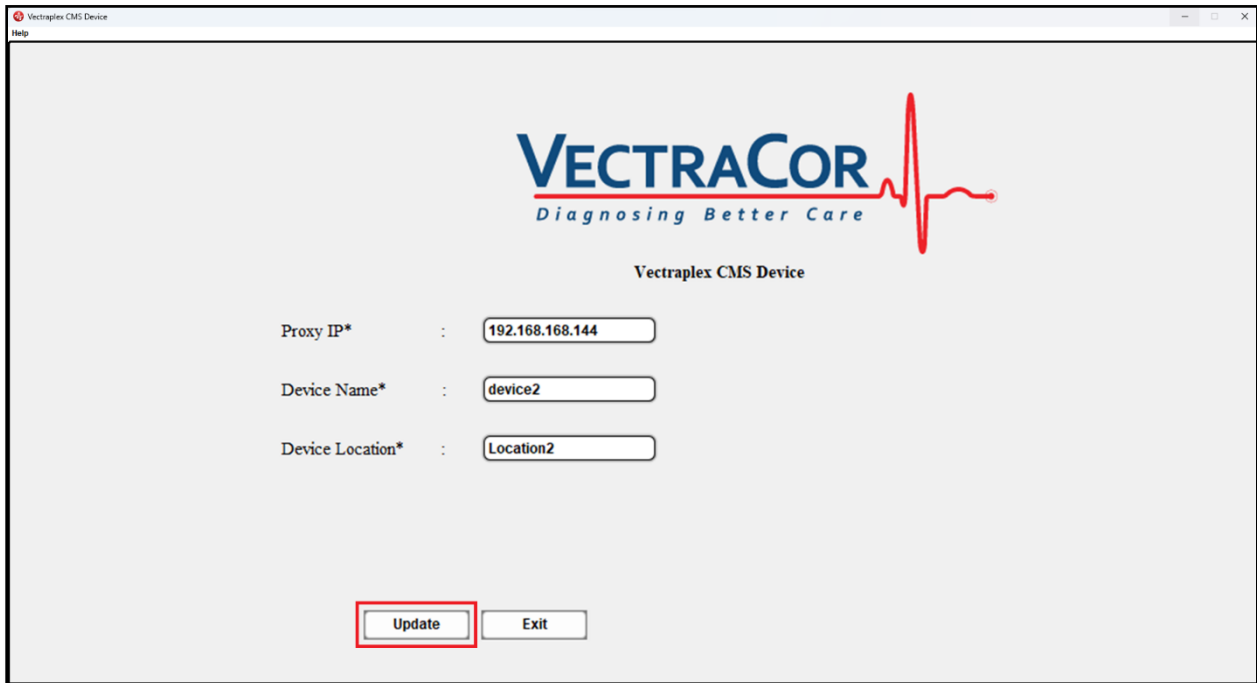

Update Button

Once the information is saved, if the user would like to change the Device Location of a Vectraplex CMS Device the user will need to click on the red icon that can be found on the system tray. The user can go to the system tray by clicking on the up arrow in the lower right corner, , which will bring up a window where the red icon can be found, . Once the red icon is clicked the user will see the following screen:
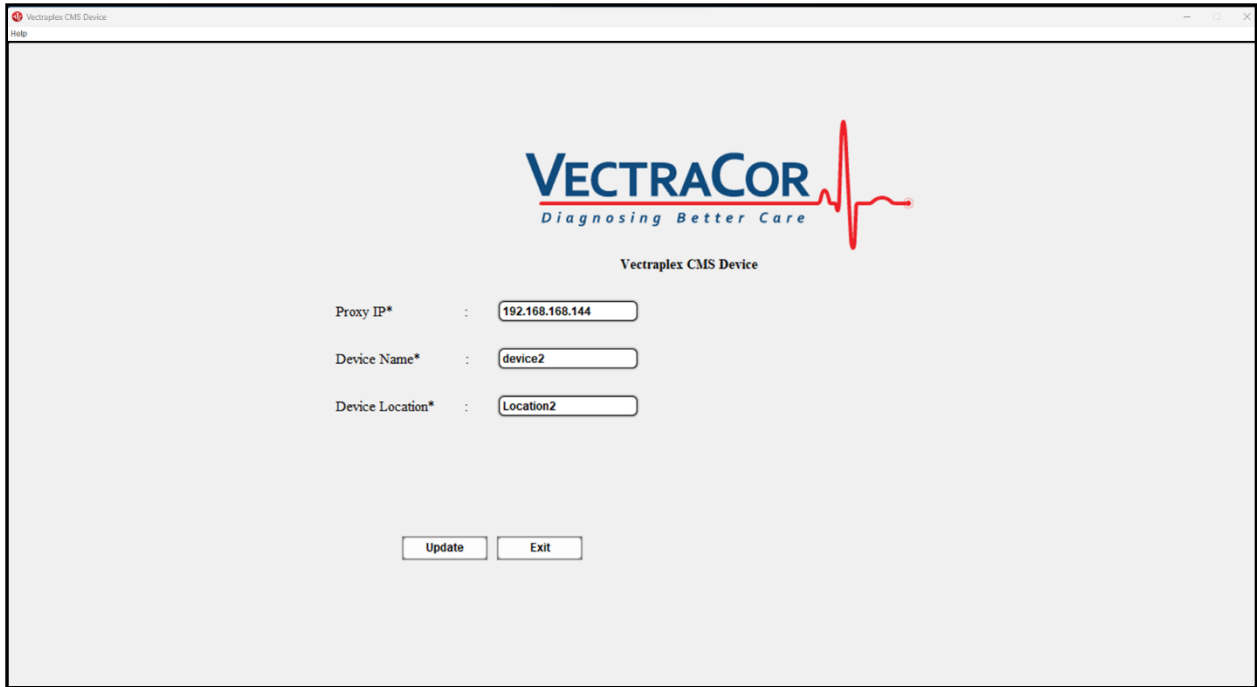
The user can change the Device Location and then click the **Update** button to accept the changes*:

*Note: The Proxy IP address and Device Name cannot be changed using the update button after the device has connected to the Vectraplex CMS Proxy. To change the IP address and/or Device Name, the Vectraplex CMS Device will need to exit from the application to disconnect with the Vectraplex CMS Proxy and reconnect after the changes have been made.

Exit Button

The user can shut down the device connection to the proxy by clicking the **Exit** button. When this button is clicked the user will see the following alert:
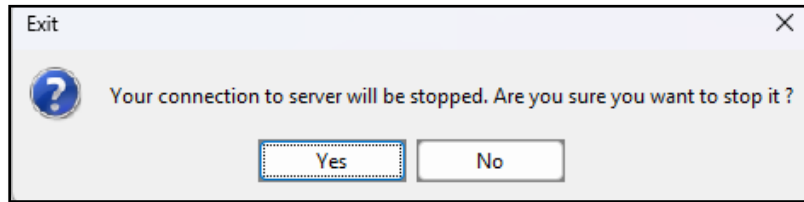
If the user clicks the No button, then the Vectraplex CMS Device will be retained. If the user clicks the Yes button then device loose connection to the proxy, thereby stops transmitting to the Vectraplex CMS Monitor and the program will be closed on the device.
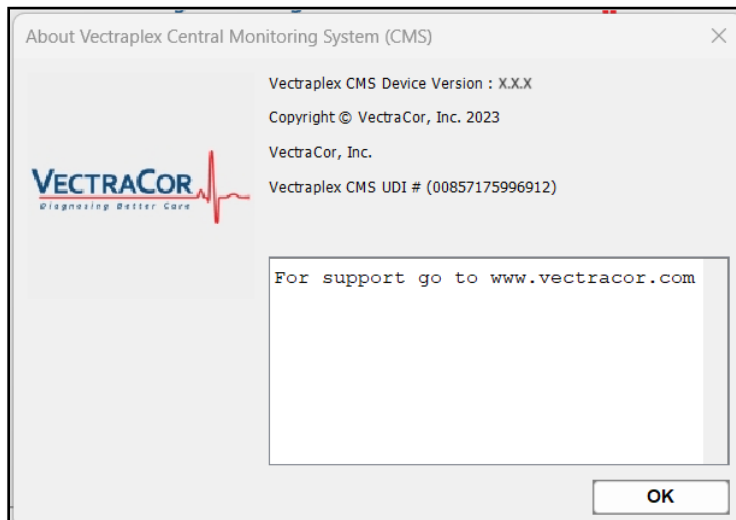
Help Menu
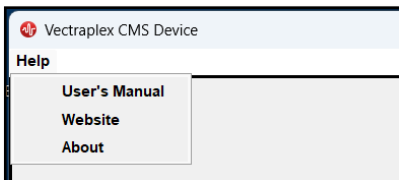
User's Manual - Opens the Vectraplex Central Monitoring System (CMS) User Manual
Website – Displays www.vectracor.com (internet connection required)
About - Displays the software version as shown below

Setup Vectraplex CMS Monitor

The final step in setting up Vectraplex CMS is configuring the 'Vectraplex CMS Monitor' application. This application allows users to simultaneously view up to 8 VectraplexECG software instances (with the support of 'Vectraplex CMS Device' application) on a single monitor screen. If your computer has dual display screens, you can double this capacity to view up to 16 screens. Simply run the monitor application instance twice, enabling you to display 8 screens per monitor and reaching a total of 16 device screens.

Up to three 'Vectraplex CMS Monitor' applications can utilize the same 'Vectraplex CMS Proxy' application to establish connections with the 'Vectraplex CMS Device' (pre-installed with VectraplexECG software), allowing each monitor to display the same device.

Following the installation of the Vectraplex CMS Monitor application, double-click the 'Vectraplex CMS Monitor' icon on the desktop to open it. The user will be prompted to enter the proxy-generated IP Address in the Proxy IP Configuration window.


The user will need to manually enter the IP address generated by the Vectraplex CMS Proxy application and click '**Proceed**'.

If the Vectraplex CMS Proxy is not running or if the Vectraplex CMS Monitor is unable to connect to the proxy, then a pop up window appear:
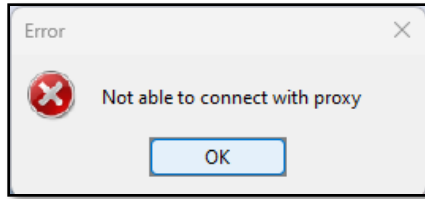
If the Vectraplex CMS Proxy is running and it successfully connects then the Vectraplex CMS monitor window will appear:
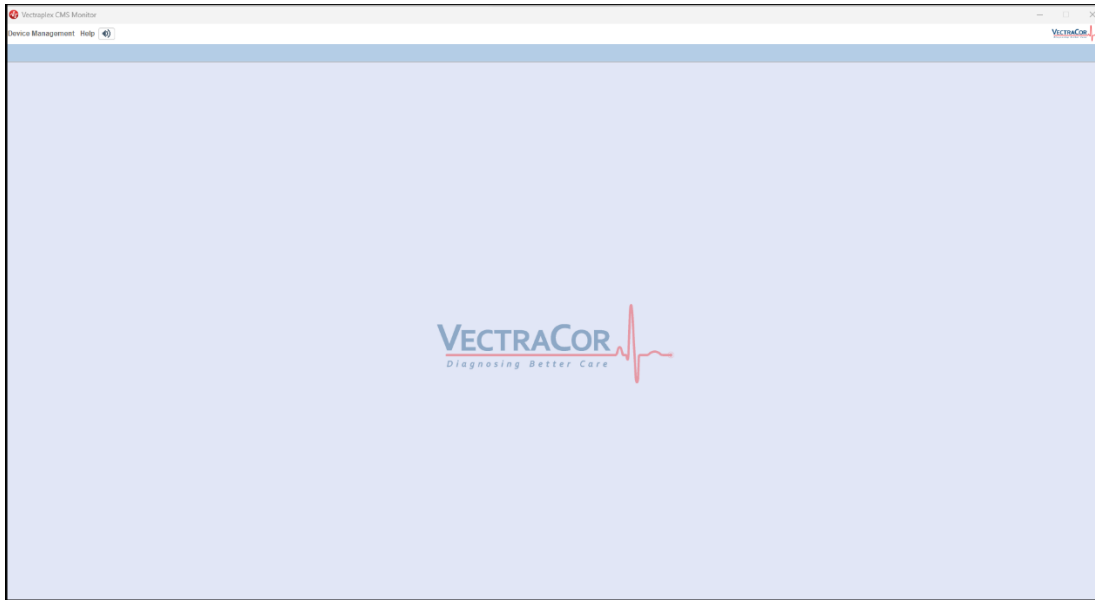

Adding a Device

After successful registration of the monitor with the proxy, the user can add devices by clicking the **Add Device** button found by clicking the **Device Management** button. Please note that before adding a Vectraplex CMS Device, it must first be connected to the Vectraplex CMS Proxy. Only then can it be added to the Vectraplex CMS Monitor.
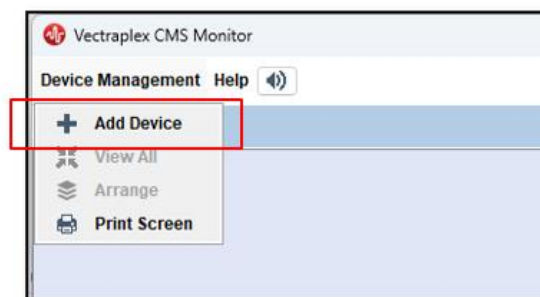
By clicking **Add Device** the user will see a screen which allows them to enter the device name:
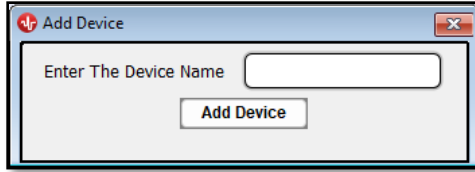
After the user enters the device name exactly as it appears in the device application, simply click the **Add Device** button. The system will check with the Vectraplex CMS Proxy for the device name entered. If the device name has not been registered with the Vectraplex CMS Proxy through a Vectraplex CMS Device, a pop-up message will appear:
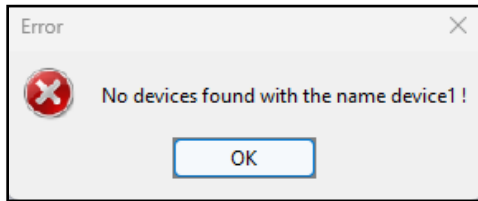

*Please refer to the 'Setup Vectraplex CMS Device' section for assistance with establishing connections and registering a device

If the device is already registered to the Vectraplex CMS Proxy with the name given by the Vectraplex CMS Device, then the connection will be established and a message will appear:
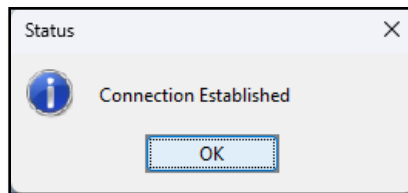
Selecting OK will initiate streaming of the device screen on the monitor application. Follow these steps to add up to 8 device screens per monitor screen

If the Vectraplex CMS Proxy stops after the device begins streaming on the monitor screen, the monitor window will display the following screen:
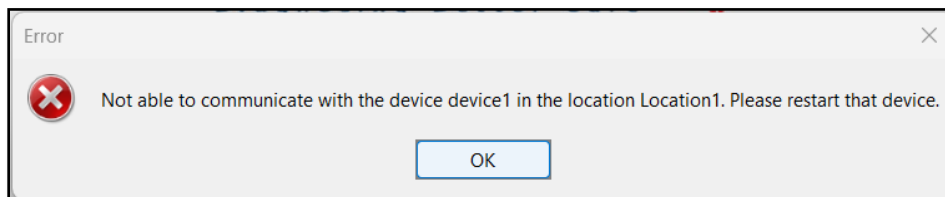
Multicast

Vectraplex CMS provides multicast support, allowing a single device to be monitored by multiple monitor systems simultaneously. The system can accommodate up to three monitoring systems for each device. However, remote operation of a device is limited to monitors where the device screen is maximized to full screen. This restriction is in place to mitigate potential conflicts among multiple monitor users. The user will have full control of the Vectraplex CMS Device(s) from their remote location.

Maximize and View All

Each individual Vectraplex CMS Device can be expanded to full screen on the Vectraplex CMS Monitor by either clicking the maximize button in the top right-hand corner of the window, or by double-clicking on the corresponding device tab. When the device screen is maximized, the **'Add Device'** button will be disabled.

If the user would like to bring the enlarged view back to normal size they can either click the restore button in the top right hand corner of the window, or they can click on the **Device Management** button and select **View All**:
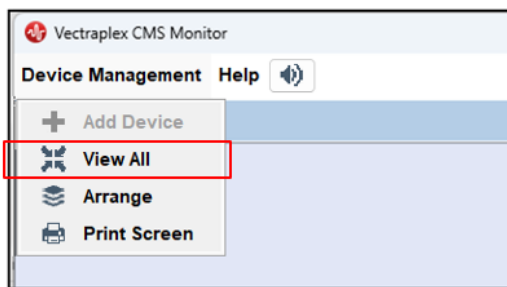
Arrange Device

If there are at least 2 devices connected to the Vectraplex CMS Monitor the user will be able to manage the locations of the individual windows of the device screens on the monitor display. By click on the **Device Management** button a drop down menu will appear with **Arrange** as an option:
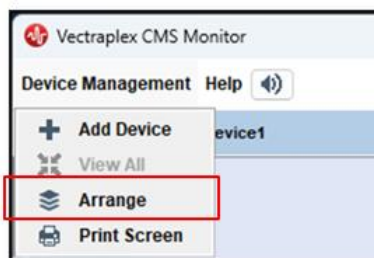
Selecting the Arrange option will cause a window to appear at the right hand side of the monitor screen as well as at the top border next to the device names:

The user will then be able to select the order of the devices displayed based on the device names. The numerical placement will always run from the top left window and continue to the right. This sequence will carry on in the lower windows. Once the user has selected the order they prefer to see the devices in selecting the **Arrange Devices** button will close the **Arrange Devices** window and place the device windows in the specified positions.

Mute

If a device being monitored sends an alarm condition the corresponding window on the monitor will be surrounded in a blinking red border and an audible alarm will sound. If the user wishes to mute the alarm they can click the icon in the upper left hand corner of the Vectraplex CMS Monitor's screen.

Alarm Management Process:
If the CEB at the central monitor displays a positive result an alarm will trigger in order to bring attention to monitoring personnel:

Step 1- Silence alarm (to minimize the distraction)
Step 2- Review CMS for signs of arrhythmia and artifact, and assess derived ECG
Step 3- Notify healthcare provider to immediately evaluate patient at bedside
Step 4- if CEB is True Positive (ECG positive for AMII), follow facility protocols
Step 5- if CEB is positive and ECG is non-diagnostic continue to monitor patient and continue with clinical assessment (obtain and/or await troponin result, obtain frequent ECG's)

It is expected that less than 2 CEB alarms will trigger per day (excluding motion artifact and contraindications for the VectraplexECG System).

Print Screen

To print a screenshot of the viewed devices, users can maximize the device screen and click on the **Device Management** button. Then, they can select **'Print Screen'**.
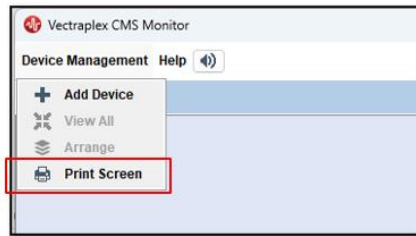
Device Removal

If the user would like to remove a Vectraplex CMS Device from the Vectraplex CMS Monitor they need to click on the CLOSE button, , in the top right corner of the device window. Once this button is clicked the following message will appear:
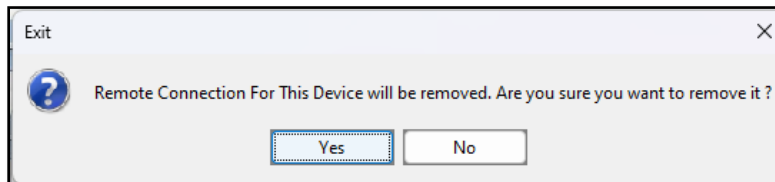
If the user clicks YES then the device window will be removed from the Vectraplex CMS Monitor.

Help Menu
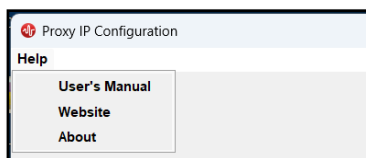
User's Manual - Opens the Vectraplex Central Monitoring System (CMS) User Manual
Website – Displays www.vectracor.com (internet connection required)
About - Displays the software version as shown below

About Vectraplex Central Monitoring System (CMS)   ✕

Vectraplex CMS Monitor Version : x.x.x

Copyright © VectraCor, Inc. 2023

VectraCor, Inc.

Vectraplex CMS UDI # (00857175996912)

For support go to www.vectracor.com

OK

Service Information

Device Care & Maintenance

Cleaning

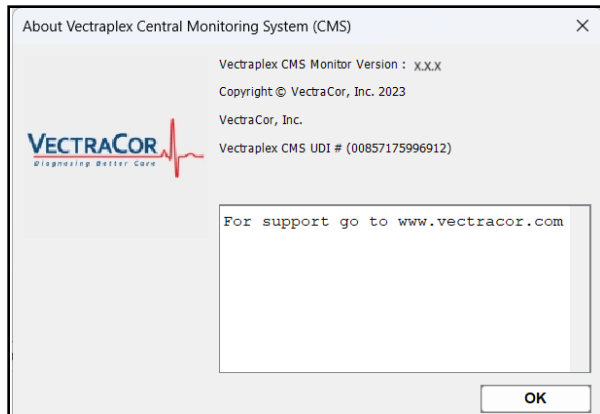Clean surfaces with a damp cloth using water only. Dry thoroughly. AVOID CLEANING AROUND CONNECTORS. Excess moisture in or on the case, cables or air fittings could affect operation.

Clean system as needed and per Hospital/clinic guidelines.

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 for disposal instructions.

Trouble Shooting

Problem	Cause of Failure	Possible Solutions
System Boot Error	The device(s) may have been left without power for a prolonged period of time	1. Make sure the device(s) are plugged into an outlet 2. Reboot the system 3. it may be necessary to dump the memory
Network Disconnection/ Device Communication Interruption	By default, laptops may enter a low-power mode (e.g., "sleep"), which disables network communication and interrupts communication with the Device running on that machine unless configured otherwise	4. Change the sleep mode to 'never'
The Vectraplex CMS Monitor won't accept a Device Name	The Device Name is already in the system	1. Restart the Vectraplex CMS Device and name the device something different 2. Restart the Vectraplex CMS Monitor and the Vectraplex CMS Device and use a different name 3. Restart the Vectraplex CMS Proxy, Vectraplex CMS Monitor, and Vectraplex CMS Device and use a different name
Vectraplex CMS Monitor screen is frozen	Connection to Vectraplex CMS Device or Vectraplex CMS Proxy was interrupted	4. Restart Vectraplex CMS Monitor and connect Vectraplex CMS Devices 5. Restart Vectraplex CMS Monitor and Vectraplex CMS Devices and reconnect

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: qrssupport@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 3-year.