

Introducing the New SmartECG

VectraplexECG System with CEB®

Innovative
Technology
Designated
Product

vizient
Awarded Supplier



Because Every Second Counts

The *only* system with a **Cardiac Electrical Biomarker** for the real-time detection of ECG changes suggestive of an acute myocardial ischemic injury (AMI), including AMI, plus the capability to derive a 22-lead ECG

Provides continuous, non-invasive detection of ECG changes suggestive of an AMI

VECTRACOR
Diagnosing Better Care

VectraplexECG System with CEB®

According to an American Heart Association Report, 121.5 million adults in the U.S. – 48 percent based on 2016 figures – have cardiovascular disease.

Cardiovascular disease is the leading global cause of death, accounting for more than 17.9 million deaths per year in 2015, a number that is expected to grow to more than 23.6 million by 2030.

Cardiovascular diseases claim more lives each year than all forms of cancer and Chronic Lower Respiratory Disease combined.

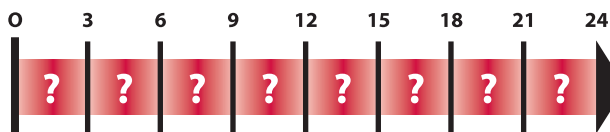
To assist the physician in diagnosing disease faster, and help make timely intervention possible, VectraCor has developed a technology that, in real-time, detects ECG changes that may be indicative of an AMI, thus potentially saving heart muscle—and lives.

Because Every Second Counts

Compare the typical chest pain/acute coronary syndrome workup with the potential time-saving utilization of the VectraplexECG System:

Current Practice Workup (ER)

1. Attach 10 electrodes to acquire the measured 12-lead ECG (mECG).
2. Attach 3 to 5 additional electrodes to patient to monitor heart rhythm, utilizing an additional device.
3. Draw blood to measure serum cardiac markers.
4. Send blood to lab for detection of serum cardiac markers indicative of an AMI.
5. Wait approximately 1 hour or longer for results when sent to the lab.
6. Repeat every 3 to 6 hours for 24 hours to check for increase in serum cardiac markers indicative of an AMI.



No continuous monitoring of serum markers for AMI detection

versus

New VectraplexECG Standard

1. Attach only 5 electrodes* to patient.
 - Displays CEB® index and heart rate, and monitors up to 22 derived ECG (dECG) leads within seconds
2. The 5 electrodes (V2 and limb electrodes) are a subset of the standard 10-electrode placement.



VectraplexECG

VectraplexECG provides the simplicity of continuous monitoring

VectraplexECG System with CEB®

The Science of AMI, Redefined

Advanced mathematics allow real-time detection of ECG changes that may be indicative of an AMI

While ECG technology has improved considerably since Willem Einthoven recorded the first electrocardiogram in 1903, the voltage-time PQRST graph remains the same. The measured 12-lead ECG is the cornerstone diagnostic test for every CVD patient. The gold standard for detecting AMI includes the 12-lead ECG and drawing blood to measure serum cardiac markers. Along with being invasive, the problem with testing for serum cardiac markers is that blood is typically drawn every 3 to 6 hours and it is not practical to draw blood more often or continuously.

But now, using proprietary mathematical algorithms, the VectraplexECG System with CEB® revolutionizes the detection of ECG changes suggestive of an AMI. It is the **only** ECG device that provides all of the following benefits:

- Displays a Cardiac Electrical Biomarker (CEB®), for real-time detection of ECG changes suggestive of an AMI (using only 5 electrodes)
- Derives a total of 22 - ECG leads = 12-Lead, right heart, posterior and Vectorcardiogram / XYZ leads and vector loops from the placement of only 5 electrodes
- Displays results within seconds and provides continuous real-time status updates automatically
- Does NOT require an additional ECG machine
 - VectraplexECG is a stand-alone ECG machine and cardiac monitor all in one
 - Provides constant ECG monitoring (selectable between 1 to 22 leads)
- Provides 12-lead measured ECG interpretation software (10 electrodes attached to patient)
- Incorporates a patient database
- Report editor feature allows inclusion of additional physician diagnoses
- Capability of e-mailing patient data
- 3-page printout with the appropriate labeling of all leads, thus reducing the risk of mislabeling
- Non-invasive
- EMR Connectivity



12-lead ECG Patient Cable



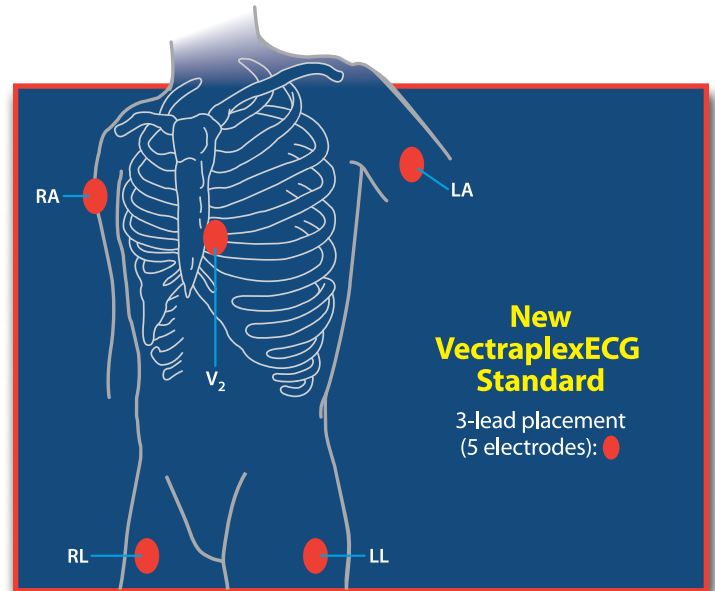
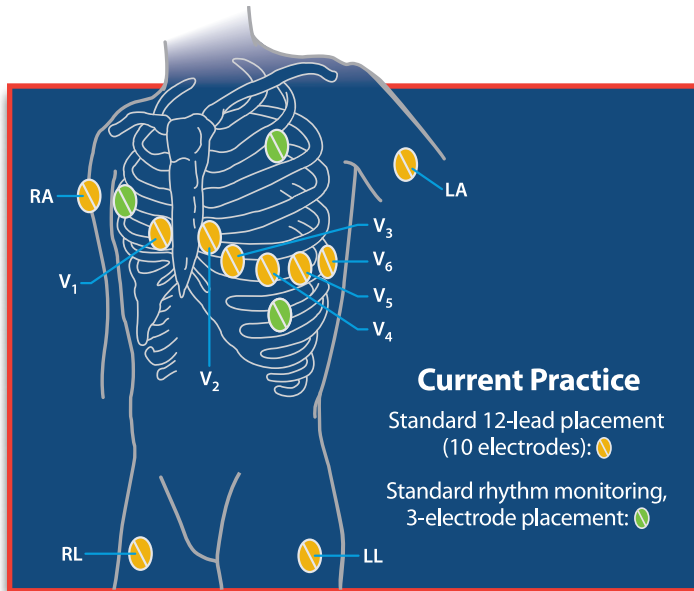
Hospital Unit
(#V1009001)



Physician's Office Unit
(#V1001001)

Now get the critical cardiac data you need...using only 5 standard electrodes

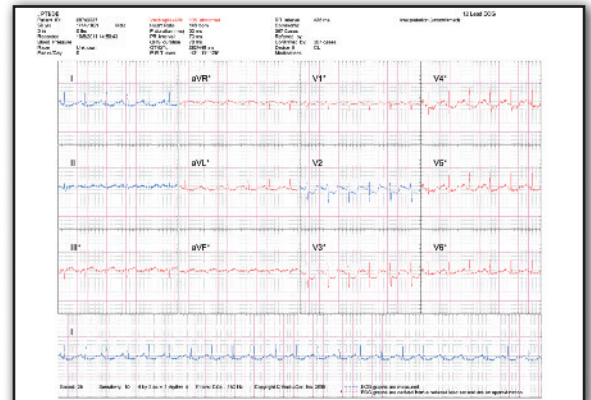
- The VectraplexECG System requires **only 5 electrodes** to derive 22 dECG leads, compared to the standard practice of acquiring a 22-lead mECG with the placement of approximately 23 electrodes
- **No extra training is required for electrode placement**—the 5 electrodes used are the easiest to place and are a subset of the standard measured 12-lead mECG
- The VectraCor electrode set has the least variability and fewer electrodes, which reduce the possibility of errors in lead placement
 - A 2008 study showed that lead V1 was **incorrectly placed** by 51% of nurses⁴—and by:
 - 69% of physicians (excluding cardiologists)⁴
 - 84% of cardiologists ($p < 0.001$ for inter-group differences)⁴



Non-STEMI Measured mECG



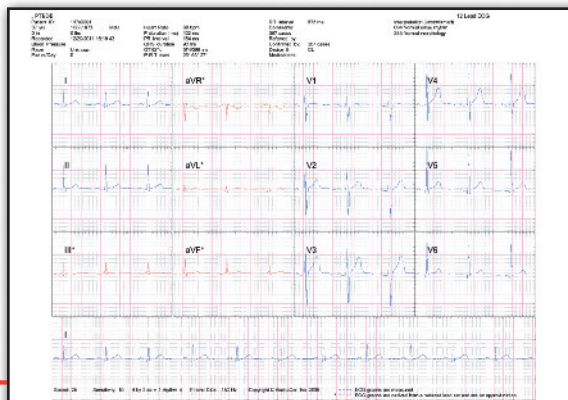
Non-STEMI VectraplexECG Derived dECG



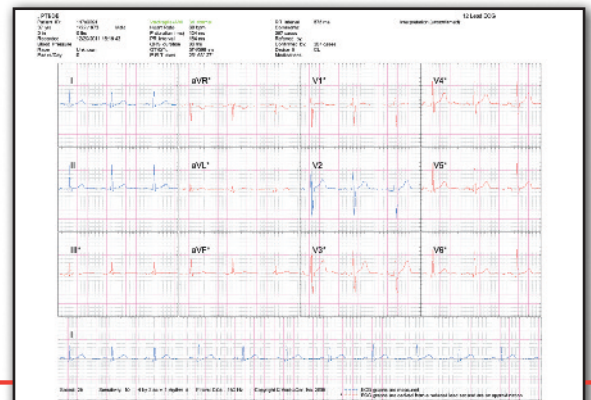
A standard measured mECG vs. a VectraplexECG derived dECG... *can you tell the difference?*

There are **virtually NO clinically significant differences** between mECG vs. dECG.⁵

Normal Measured mECG



Normal VectraplexECG Derived dECG



Real-time, continuous, non-invasive detection of ECG changes that may be indicative of an acute myocardial ischemic injury (AMII), including AMI along with heart rate and rhythm monitoring, and 22-lead dECG with vector loops—*all in 1 device*

How the CEB® works: quantifying the cardiac electrical field to detect ECG changes suggestive of an AMI

- Using advanced mathematical modeling, the VectraplexECG System quantifies the dipolar forces in the cardiac electrical field suggestive of an AMII/AMI
 - In general, the more multipolar (less dipole) forces in the cardiac electrical field, the greater the potential for an AMI
- VectraplexECG then continuously analyzes these data points resulting in the CEB® index which is continuously displayed in real-time

What the CEB® Number Means:

CEB®:	Less than 66	Normal Condition
Displayed in:	Green	
CEB®:	Between 66 and 94	Caution Zone
Displayed in:	Orange	
CEB®:	Greater than 94	Abnormal Condition*
Displayed in:	Red and Blinking Audible Alarm	

*Patient may be developing an acute myocardial infarction and requires clinical assessment—attach additional 5 electrodes for a 12-lead ECG (using all 10 electrodes).

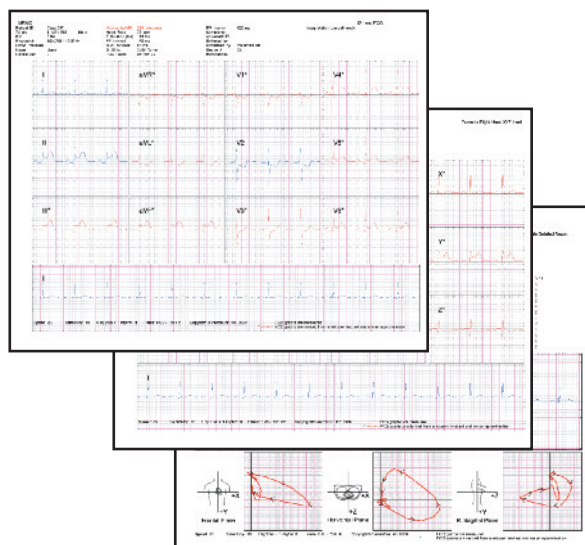
Monitoring Screen

STEMI Case



Three Page Report

- Page 1 – 12 leads
- Page 2 – right heart, posterior, XYZ leads
- Page 3 – VCG Loops and lead voltage data



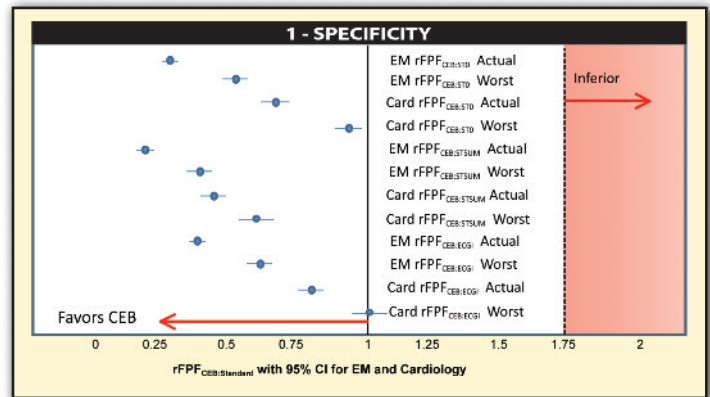
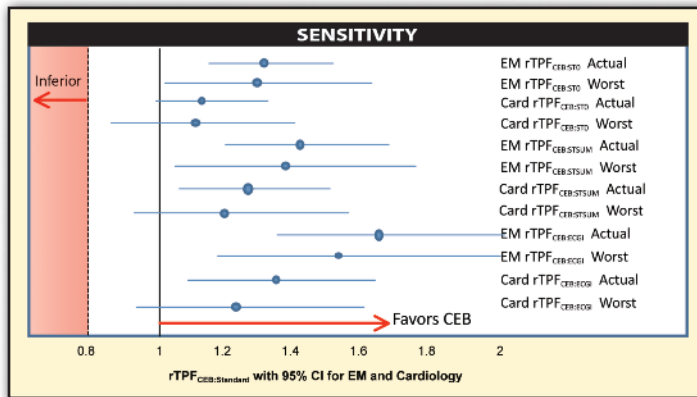
*If the VectraplexECG System does detect ECG changes that may be indicative of an AMI, the clinician can verify findings by acquiring a 12-lead mECG and by administering a blood draw (which could be sooner than current hospital protocols for measuring serum cardiac markers), resulting in the **potential for faster patient treatment**. This could free up space in the Emergency Department and potentially increase patient flow/bed turnover.*

VectraplexECG System with VectraplexAMI

The CEB® index has been studied against ST segment analysis (ST0) and an ECG computer interpretation (ECGI) program. The results of a non-inferiority study are as follows*5:

Diagnostic Performance Measures	Parameters	ST0 = J Point				ECGI = Computer Interpretation			
		*Actual		*Worst Case		*Actual		*Worst Case	
		*EM	Cardiology	*EM	Cardiology	*EM	Cardiology	*EM	Cardiology
Sensitivity (TPF)	VectraplexAMI (CEB)	93.75%	87.27%	89.55%	82.76%	93.4%	84.6%	85.1%	77.2%
	ST0 or ECGI	70.31%	76.36%	70.15%	75.86%	57.4%	63.5%	56.7%	63.2%
Specificity (FPF = 1-Specificity)	VectraplexAMI (CEB)	91.30%	81.50%	84.68%	75.55%	91.34%	81.18%	85.08%	75.27%
	ST0 or ECGI	73.48%	74.02%	73.39%	73.72%	77.92%	76.47%	76.61%	75.64%
Negative Predictive Value	VectraplexAMI NPV (CEB)	98.1%	96.7%	96.8%	95.4%	98.1%	96.3%	95.5%	94.1%
	ST0 or ECGI NPV	89.9%	93.5%	90.1%	93.5%	87.4%	91.1%	86.8%	90.8%
Positive Predictive Value	VectraplexAMI PPV (CEB)	75.0%	50.5%	61.2%	41.7%	74.0%	47.8%	60.6%	39.3%
	ST0 or ECGI PPV	42.5%	38.9%	41.6%	37.9%	40.7%	35.5%	39.6%	35.0%
Caution Zone %	No Test %	6.67%	6.93%	6.67%	6.93%	7.30%	7.53%	7.30%	7.53%
Utility%	(1-No Test)%	93.33%	93.07%	93.33%	93.07%	92.70%	92.47%	92.70%	92.47%
Prevalence	Prev	19.0%	17.4%	19.0%	17.4%	20.9%	16.9%	21.3%	17.2%

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



References

1. 121.5 million adults in the U.S. – 48 percent based on 2016 figures – have cardiovascular disease. Available at: <https://healthmetrics.heart.org/wp-content/uploads/2018/02/At-A-Glance-Heart-Disease-and-Stroke-Statistics-2018.pdf>. Accessed October 18, 2019.
2. Cardiovascular disease is the leading global cause of death, accounting for more than 17.9 million deaths per year in 2015, a number that is expected to grow to more than 23.6 million by 2030. Available at: <https://healthmetrics.heart.org/wp-content/uploads/2018/02/At-A-Glance-Heart-Disease-and-Stroke-Statistics-2018.pdf>. Accessed October 18, 2019.
3. Cardiovascular diseases claim more lives each year than all forms of cancer and Chronic Lower Respiratory Disease combined. Available at: <https://healthmetrics.heart.org/wp-content/uploads/2018/02/At-A-Glance-Heart-Disease-and-Stroke-Statistics-2018.pdf>. Accessed October 18, 2019.
4. Rajaganesan R, Ludlam CL, Francis DP, Parasramka SV, Sutton R. Accuracy in ECG lead placement among technicians, nurses, general physicians, and cardiologists. Int J Clin Pract. 2008;62(1):65-70.
5. Data on file, VectraCor, Inc., Totowa, NJ.

IMPORTANT SAFETY INFORMATION

The significance of the ST segment changes and CEB® require physician interpretation. If the CEB® indicates a potential AMI, the user should acquire a 12-lead ECG using 10 electrodes.

The CEB® index has 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.

Derived 15-lead ECGs and their measurements are approximations to conventional 12-lead ECGs and should not be used for final diagnostic interpretations.

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.

Catalog Numbers

V1000011	Universal SmartECG patient cable (with VectraplexECG software)
V1000021	VectraplexECG Software
V1001001	VectraplexECG System with CEB® (Includes Monitor, 12-Lead ECG Patient Cable and Rolling Stand)
V1001101	VectraplexECG Wall Unit with CEB®
V1003001	Vectraplex Monitoring ECG Electrodes
V1009001	VectraplexECG System with CEB® (Hospital Unit)

VectraCor also has a Spirometry/Lung Function device
The Orbit™ Portable Spirometer Z-7000-0101

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Please contact VectraCor for additional information, including Cautions and Warnings.

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