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 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), VectraplexAMI index, for the real-time detection of ECG changes suggestive of an AMI (using only 5 electrodes)
- Derives a total of 15 ECG leads (12-lead ECG, XYZ vectorcardiogram 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

Implemented results show surprising new methods for detecting AMI:
- Non-invasive detection of ECG changes suggestive of an AMI (using only 5 electrodes)
- Real-time monitoring, including patient status updates automatically
- Does NOT require an additional ECG machine
- VectraplexECG is a stand-alone ECG machine and cardiac monitor all in one

According to Cautions and Warnings:
- The computerized interpretation provided by the VectraplexECG software is only for the 12-lead ECG and their measurements are approximations to conventional 12-lead ECGs and should not be used for final diagnostic interpretations.
- The VectraplexAMI index has been studied against ST segment analysis (ST0) and an ECG computer interpretation (ECGI) program.

The VectraplexAMI index (CEB) 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:

| Study | Results
|-------|--------|
| ST0 vs ECGI | Non-inferiority

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

The VectraplexAMI index (CEB) 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:

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References
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 to come back.

**New VectraplexECG Standard**

1. Attach only 5 electrodes* to patient.
2. Displays CEP® and heart rate.
3. Normal results within seconds.

**VERSUS**

• Real-time, continuous, non-invasive detection of ECG changes that may be indicative of an AMI, along with heart rate and rhythm monitoring, and 15-lead dECG with vector loops—all in 1 device

How VectraplexAMI works: quantifying the cardiac electrical field changes suggestive of an AMI

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

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

- The VectraplexECG System requires only 5 electrodes to derive 15-lead dECG leads, compared to the standard practice of acquiring a 15-lead mECG with the placement of approximately 14 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.
- A 2008 study showed that lead V1 was incorrectly placed by 51% of nurses—and by 46% of physicians including cardiologists—so by 84% of cardiologists (p<0.001 for inter-group differences).
- The VectraplexAMI System requires less 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 nurses—and by 46% of physicians including cardiologists—so by 84% of cardiologists (p<0.001 for inter-group differences).
- The VectraplexAMI System quantifies the dipole forces in the cardiac electrical field suggestive of an AMI.

The VectraplexAMI index which is continuously displayed in real-time

- An audible alarm will sound if the potential for faster patient treatment.
- This could free up space in the Emergency Department and potentially increase patient flow/bed turnover.

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.

**What the VectraplexAMI Number Means:**

<table>
<thead>
<tr>
<th>Measured mECG</th>
<th>VectraplexECG Derived dECG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than 94 Abnormal</td>
<td><strong>Orange</strong></td>
</tr>
<tr>
<td>Between 66 and 94 Caution</td>
<td><strong>Green</strong></td>
</tr>
<tr>
<td>Less than 66 Normal</td>
<td><strong>No display</strong></td>
</tr>
</tbody>
</table>

*Patient may be developing an acute myocardial infarction and requires clinical assessment—attach additional 5 electrodes for a 15-lead ECG (using all 10 electrodes).

Monitoring Screen STEMI Case

- Orange Condition
- Red and Blinks Condition
- Green Condition

Three Page Report

- Page 1 – Leads
- Page 2 – XYZ leads
- Page 3 – VCG Loops and Lead voltage data

**Current Practice**

- Requires clinical assessment—attach additional 5 electrodes for a 15-lead ECG (using all 10 electrodes).

**New VectraplexECG Standard**

- Provides the simplicity of continuous monitoring.
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 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 12 lead ECG patient tracings (using 10 electrodes) 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
- 5-page printout with the appropriate labeling of all leads, thus reducing the risk of mislabeling
- Non-invasive
- EMR Connectivity
- 12-lead ECG Patient Cable

The VectraplexAMI index (CEB) 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

- Estimated 10% increase in positive diagnosis of AMI
- 30% decrease in false positives

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 infarction (AMI) plus the capability to derive a 15-lead ECG

Provides continuous, non-invasive detection of ECG changes suggestive of an AMI
Because Every Second Counts

Cardiovascular disease (CVD), a problem of staggering proportions, CVD is the #1 killer in the United States and the rest of the world—killing over 17 million people worldwide, and over 811,000 Americans annually.¹⁻³ According to the American Heart Association, in 2009 an estimated 74.5 million adults in the United States had CVD, with over 40 million in this group aged 60 or older.¹ A growing “baby boom” population threatens to increase this number. To avoid increasing the cost and pressure on healthcare systems already challenged.

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.

New VectraplexECG System with VectraplexAMI

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

- The VectraplexECG System requires only 5 electrodes to derive 22-lead mECG, compared to the standard practice of acquiring a 22-lead mECG with the placement of approximately 31 electrodes.
- No extra training is required for electrode placement—the 5 electrodes used are the safest to place and are a subset of the standard measured 12-lead mECG.
- The VectraCor electrode set has less variability and fewer electrodes, which reduce the potential of errors in lead placement.²⁻⁴
- A 2008 study showed that lead V1 was incorrectly placed by 51% of nurses—²—and by: 84% of cardiologists (p<0.001 for inter-group differences)²⁻⁴
- 69% of physicians (excluding cardiologists)⁴

Current Practice

- Workup (ER) for AMI detection
- Standard 12-lead mECG and by administering a blood draw (which could be virtually NO continuous monitoring of serum markers when sent to the lab.
- The VectraCor electrode set has the least variability and fewer electrodes, which reduce the potential of errors in lead placement.²⁻⁴
- A 2008 study showed that lead V1 was incorrectly placed by 51% of nurses—²—and by: 84% of cardiologists (p<0.001 for inter-group differences)²⁻⁴
- 69% of physicians (excluding cardiologists)⁴

New VectraplexAMI

- The VectraCor electrode set has the least variability and fewer electrodes, which reduce the potential of errors in lead placement.
- A 2008 study showed that lead V1 was incorrectly placed by 51% of nurses—²—and by: 84% of cardiologists (p<0.001 for inter-group differences)
- 69% of physicians (excluding cardiologists)⁴

How VectraplexAMI works: quantifying the cardiac electrical field suggestive of an AMI

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

What the VectraplexAMI Number Means:

- Greater than 94 Abnormal
- Between 66 and 94 Caution
- Less than 66 Normal

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.

Please see back cover for Important Safety Information.
Cardiovascular disease (CVD) is a problem of staggering proportions. CVD is the #1 killer in the United States and the rest of the world—killing over 17 million people worldwide, and over 811,000 Americans annually.1-3 According to the American Heart Association, in 2009 an estimated 74,130,000 patients received cardiovascular operations and procedures were performed in the United States, while approximately 62.0 million Americans have one or more forms of CVD, with over 40 million in this group aged 60 or older. A growing "baby boom" population threatens to add increasing time and cost pressures on the healthcare system already challenged. It is in this area of a disruptive disease faster, and help make timely intervention possible, that 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.

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

The VectraplexECG System requires only 5 electrodes to derive 15-lead ECG, compared to the standard practice of acquiring a 15-lead ECG with the placement of approximately 14 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.

TheVectraplexECG System quantifies the dipolar forces in the CEB®. Using advanced mathematical modeling, the VectraplexECG System quantifies the dipolar forces in the cardiac electrical field suggestive of an 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.

Real-time, continuous, non-invasive detection of ECG changes that may be indicative of an acute myocardial ischemic injury (AMI), including AMI along with heart rate and rhythm monitoring, and 22-lead ECG 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 AMI. In general, the more multipolar (less dipole) forces in the cardiac electrical field, the greater the potential for an AMI.

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 ECG (using all 10 electrodes). Three Page Report
• Page 1 – 12 leads
• Page 2 – VCG Loops and lead voltage data
• Page 3 – VCG Loops and lead voltage data

What the CEB® Number Means:
- Normal
- Less than 66
- Greater than 66
- Between 66 and 94
- Abnormal
- Caution
- Zone

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.

**Patient may be developing an acute myocardial infarction and require clinical assessment—attach additional 5 electrodes for a 15-lead ECG using all 10 electrodes.**

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. Send blood to lab for detection of serum cardiac markers indicative of an AMI.
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

New VectraplexECG Standard

1. Attach only 5 electrodes* to patient.
2. Displays VectraplexAMI index and heart rate, and monitors up to 15 derived ECG (dECG) leads within seconds
3. Utilizes advanced mathematical modeling to compute the standard measured 12-lead mECG
4. Requires clinical assessment—attach additional 5 electrodes for a 15-lead ECG (mECG)
5.VectraplexECG provides the simplicity of continuous monitoring

Current Practice

Standard 12-lead ECG (using all 10 electrodes).

New VectraplexECG Standard

1. Attachelectrodes 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.
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Non-STEMI Measured mECG Non-STEMI VectraplexECG Derived dECG

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<td>mECG</td>
<td>VectraplexECG Dered dECG</td>
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The device provides the simplicity of continuous monitoring along with heart rate and rhythm monitoring, and 22-lead ECG with vector loops—all in 1 device.

What is the CEB® Number Meanings:
- Normal
- Less than 66
- Greater than 66
- Between 66 and 94
- Abnormal
- Caution
- Zone

*Patient may be developing an acute myocardial infarction and require clinical assessment—attach additional 5 electrodes for a 15-lead ECG using all 10 electrodes.

Monitoring Screen

| Red and Blinking Condition*
| Orange
| Green

Displayed in:

Celestial®:

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Please see back cover for Important Safety Information.
**The Science of AMI, Redefined**

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

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**The 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:

- Positive Predictive Value: 95.4%
- Negative Predictive Value: 98.0%
- Sensitivity: 93.0%
- Specificity: 98.0%

The measured 12-lead ECG is the cornerstone diagnostic tool for detecting ECG changes suggestive of an AMI. It is the only ECG device that provides all of the following benefits:

- Displays a Cardio Electrical Biomarker (CEB), VectraplexAMI index, for the real-time detection of ECG changes suggestive of an AMI (using only 5 electrodes)
- Derives a total of 15 ECG leads (12-lead ECG, XYZ vectorcardiogram 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 cardi monitor all in one
- Provides constant ECG monitoring (selectable between 1 to 15 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-diagnosed information
- Capability of e-mailing patient data
- 3 page printout with the appropriate labeling of all leads, thus reducing the risk of mislabeling
- Is non-invasive

**Important Safety Information**

- The only system with a Cardio Electrical Biomarker for the real-time detection of ECG changes suggestive of an acute myocardial infarction (AMI) plus the capability to derive a 15-lead ECG
- Provides continuous, non-invasive detection of ECG changes suggestive of an AMI

**References**

1. Data on file, VectraCor, Inc., Totowa, NJ.
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.
5. Data on file, VectraCor, Inc., Totowa, NJ.