MCG Report

Example Patient

Summary Report

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Contents

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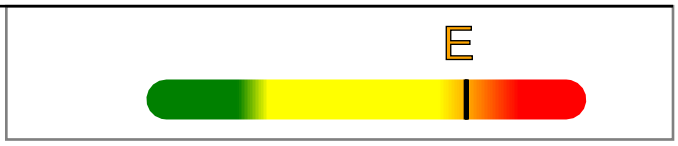
Example Patient
Gender: M, Age: 41
ID: 123-45-6789
MCG Patient: 2856
MCG Session: 41666

MCG Summary

Category E (High Dysfunction)



MCG Analysis points to serious cardiovascular system dysfunction.

Ischemia Results

ECG Sample	Testing Date	ECG Tracing Quality	Local	Global	Severity
32399617	2011-03-15 10:42	undescribed (ATQ: N/A)	Present	Absent	5.0
31531521	2011-03-15 10:42	good (ATQ: N/A)	Present	Absent	5.0
32130049	2011-03-15 10:42	undescribed (ATQ: N/A)	Present	Absent	5.0
32400129	2011-03-15 10:42	undescribed (ATQ: N/A)	Present	Absent	5.0
31531265	2011-03-15 10:41	marginal (ATQ: N/A)	Present	Absent	4.0

Signature: _____

MCG Suggestions

Pathological Conditions:

	Cardiomyopathy	Potential Fibrillation	Atrial Fibrillation	Incipient Ventricular Fibrillation	Atrial-Ventricular Fibrillation	Incipient Arrhythmia	Ventricular Arrhythmia	Myocardial Damage	Myocarditis	Pulmonary Heart Disease	Rheumatic Heart Disease	Congenital Heart Disease	Ventricular Hypertrophy
32399617	+	-	-	+	-	-	+	+	-	-	+	-	-
31531521	+	-	-	+	-	-	+	+	-	-	+	-	-
32130049	+	-	-	+	-	-	+	+	-	-	+	-	-
32400129	+	-	-	+	-	-	+	+	-	-	+	-	-
31531265	+	-	+	-	-	+	-	+	-	-	+	-	+

Physiopathological Conditions:

	Myocardial Remodeling	Decreased myocardial compliance	Increased myocardial compliance	Decreased ejection fraction	Bradycardia	Tachycardia	Acute Power Failure	Global asynchrony (II < V5)	Global asynchrony (V5 < II)	Localized Asynchrony	Local asynchrony (II < V5)	Local asynchrony (V5 < II)
32399617	+	-	+	-	+	-	+	-	-	-	-	-
31531521	+	-	+	-	+	-	+	-	-	-	-	-
32130049	+	-	+	-	+	-	+	-	-	-	-	-
32400129	+	-	+	-	+	-	+	-	-	-	-	-
31531265	+	-	+	-	+	-	+	-	-	-	-	-

Unlike the primary diagnosis of the presence or absence of local or global ischemia the secondary pathological and physiopathological findings of each test should be considered as a reference for physician consideration and evaluation rather than a definitive diagnosis. Premier Heart does not provide medical advice, and MCG analysis is not a substitute for physician judgment, diagnosis, or treatment. The ultimate diagnosis and treatment decisions are left to the reviewing and treating physician.

Interpreting This Report

Unlike conventional ECG tools which operate in the time domain - millivolts over milliseconds - MCG analysis is primarily performed in the frequency domain, using the principles of systems analysis to examine the relationship of multiple leads through auto power spectrum and its variations: Phase shift, impulse response, coherence, cross-correlation and amplitude histogram. Indexes derived from these functions are statistically matched against a population of thousands of healthy people as well as tens of thousands with various cardiac conditions collected over decades of clinical research. This allows MCG to draw inferences about overall cardiac function from a diverse range of causes including obstructive or functional ischemia, metabolic issues, or structural anomalies.

The results of the MCG analysis are summarized in this report to aid physicians in quickly assessing a patient, developing treatment plans, and monitoring the effectiveness of interventions.

Interpreting MCG Categories

MCG Categorization may be performed on sessions with at least three (3) ECG samples, and provides a general overview of cardiac dysfunction based on other information presented in the report. It is designed to assist with rapid clinical decisionmaking by medical professionals.
MCG Categorization assesses cardiac dysfunction due to obstructive causes (e.g. CAD), nonobstructive causes (e.g. vasospasm), or metabolic causes (e.g. hypo/hyperthyroid, hyperinsulinemia, pre-diabetes, or diabetes) as well as possible underlying pathological and physiological conditions.

Category N (True Normal)

MCG analysis has produced no significant findings for this patient.

Category A (Clinical Normal)

MCG analysis points to potential signs of early or subclinical cardiovascular system dysfunction and/or incipient cardiac conditions.

Category B (Low Dysfunction)

MCG Analysis points to minor cardiovascular system dysfunction.

Category C (Recovered Dysfunction)

MCG Analysis points to cardiovascular system dysfunction, with indications that this dysfunction may be residual or due to recovery from a prior condition (for example after interventional procedures, or due to collateral circulation around an obstructed vessel).

Category D (Moderate Dysfunction)

MCG Analysis points to moderate cardiovascular system dysfunction.

Category E (High Dysfunction)

MCG Analysis points to serious cardiovascular system dysfunction.

Category F (Severe Dysfunction)

MCG analysis points to severe cardiovascular system dysfunction.
Patients in this category are at high risk of developing heart failure.

Category G (Extreme Dysfunction)

MCG Analysis points to extreme cardiovascular system dysfunction.
Patients in this category are at high risk of sudden cardiac death.

Interpreting MCG Severity

MCG Severity Scores represent an accumulation of functional anomalies detected by the MCG analysis software. Higher severity scores are correlated with increased ischemic burden from both obstructive and functional causes, as well as other conditions leading to cardiac supply/demand imbalances.

Interpreting MCG Ischemia Results

MCG analysis distinguishes between two categories of ischemia - Local and Global - either may be described as absent (MCG analysis found no evidence in the ECG data), present (MCG analysis found strong indications in the ECG data), or borderline. It is important to note that MCG's detection of ischemia is based on functional (electrophysiological) measurements, and may include ischemia from obstructive causes (e.g. due to coronary artery disease), functional obstruction (e.g. vasospasm), or metabolic conditions (e.g. hypo/hyperthyroid, hyperinsulinemia, pre-diabetes, or diabetes).

Local Ischemia

Regional or patchy myocardial ischemia of the kind often caused by mid-or distal single or double vessel coronary artery disease.

Global Ischemia

Diffuse ischemia affecting the entire myocardium, of the kind often caused by proximal large vessel coronary artery disease (usually two or more vessels are pathological) and/or microvascular disease.

Interpreting Pathological and Physiopathological Condition Suggestions

MCG analysis seeks to detect anomalies in ECG data which are correlated with certain pathological or physiopathological conditions. Definitive diagnosis for many of these conditions typically requires the use of other diagnostic modalities, therefore they are reported in a "Suggestions" section for physician consideration and evaluation.

Interpreting ECG Tracings On This Report

ECG tracings presented on this report are intended for assessment of tracing quality only. While gross time-domain ECG anomalies (arrhythmias) may be visible on these tracings the tracings are not scaled for time-domain analysis and should not be used for traditional ECG time domain judgments. A standard 12-lead ECG or 12-lead MCG with scaled lead reporting should be performed for this purpose.

The report summary presents two evaluations of tracing quality: A subjective asessment (Good, Marginal, Poor) set by the technician in the MCG Clinical Client software or by the reviewing physician in the web based reporting application, and an algorithmic tracing quality (ATQ) score between 0 and 100 set by the MCG analysis software.

* ATQ scores above 70 are typically 'good' tracings suitable for MCG analysis
* ATQ scores from 41-70 are typically 'marginal' and may affect the accuracy of MCG results
* ATQ scores below 40 are typically 'poor' tracings unacceptable for MCG analysis

Algorithmic categorization is not perfect and the ATQ score is included for reference only.
Human review of tracing quality is an essential part of MCG analysis, and MCG defers to the human (subjective) assessment if there is a conflict.

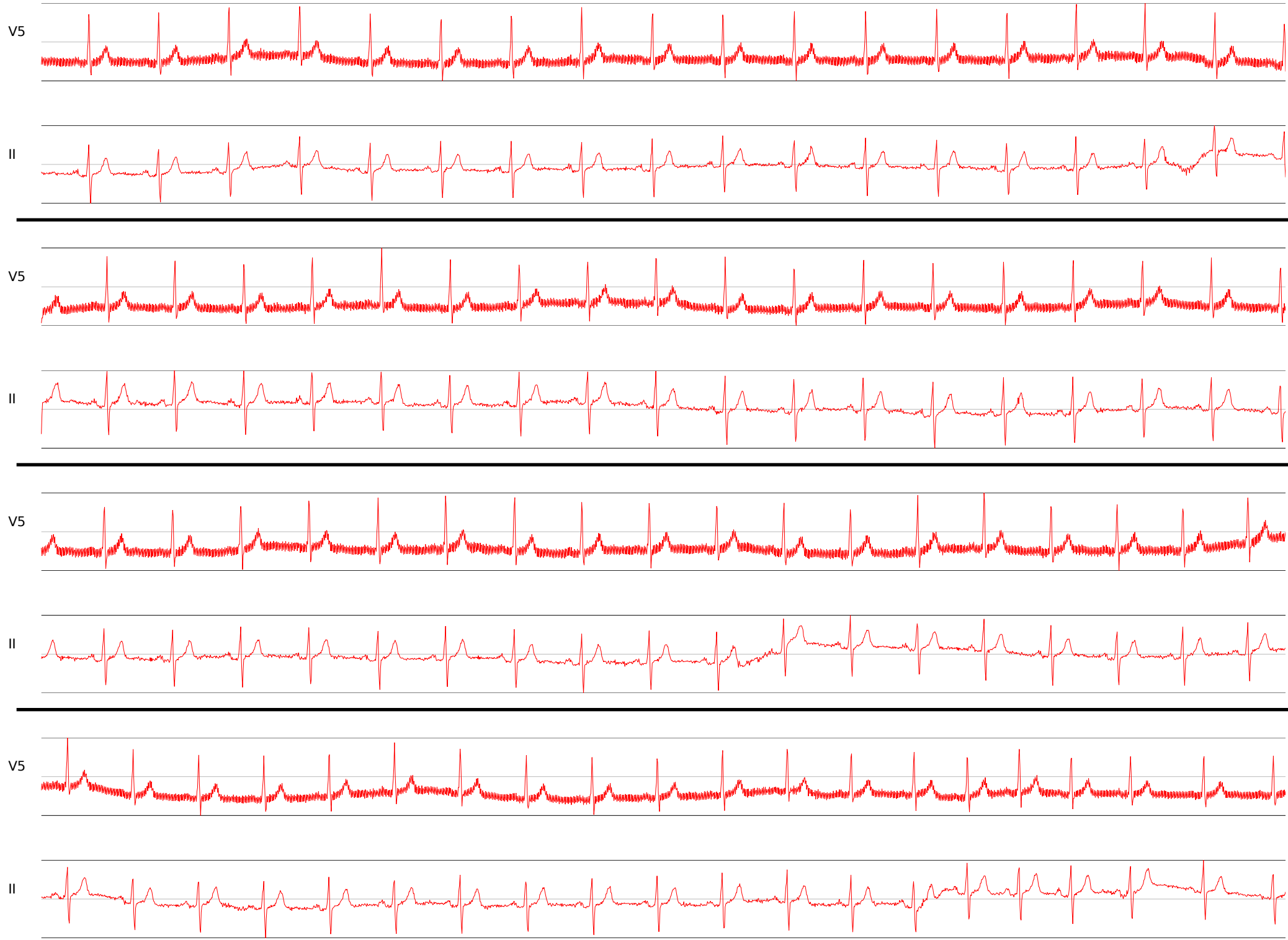
Interpreting DSP Colorstrips

The DSP colorstrips provided in this report are a 'top down' view of the various transformations used by MCG in evaluating the ECG data. They are useful for identifying significant anomalies in individual ECG samples, or repeating patterns in the frequency domain data which may indicate intermittent disease observable in part of a session (e.g. vasospasms). Additionally the comparison of DSP heatmaps between sessions can provide insight into cardiac changes over time. Each ECG tracing sample is presented as a row in the heatmap, sessions with more samples will have shorter rows compressed to fit the data.

Physician Judgment

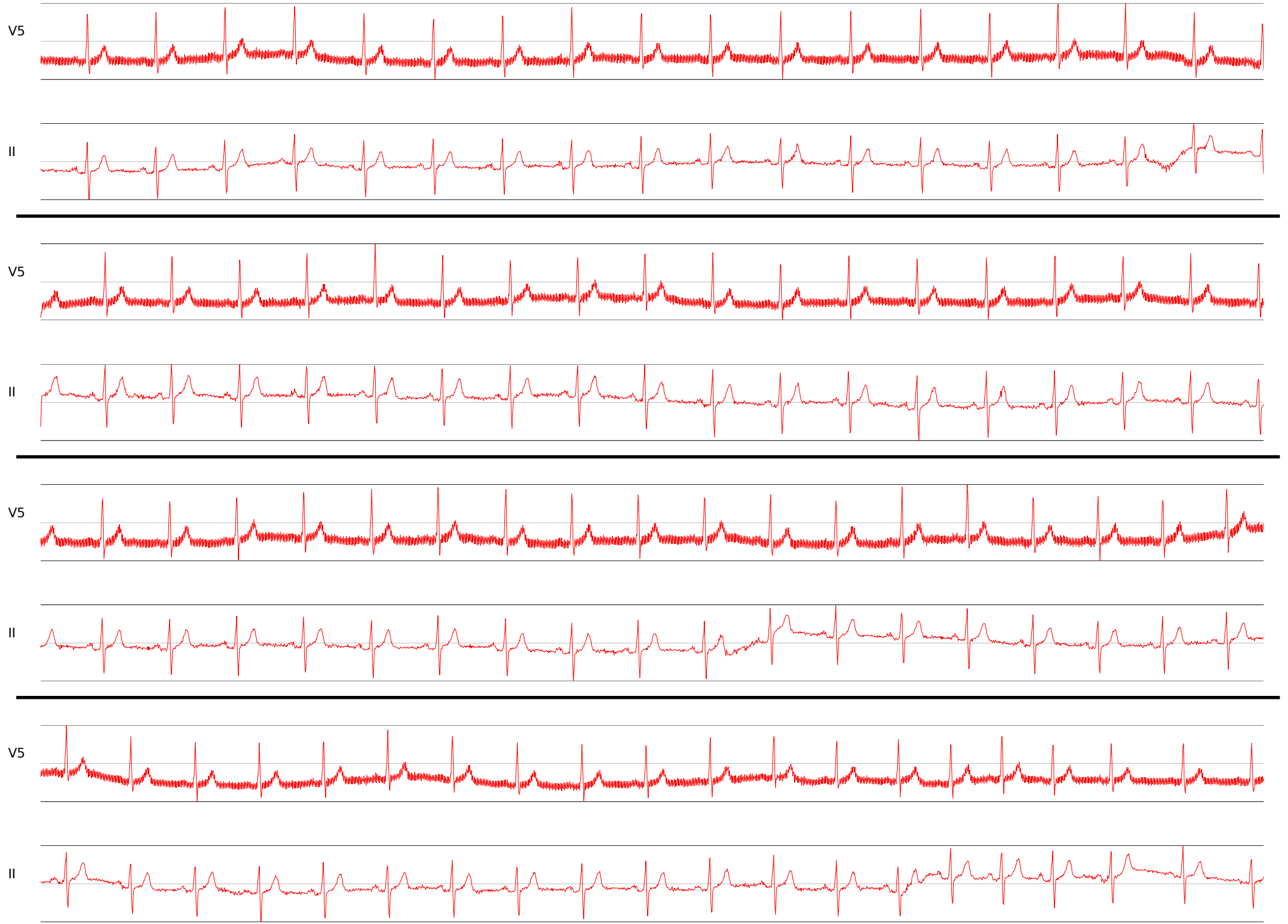
MCG analysis is a diagnostic tool which may assist physicians in arriving at a timely and accurate diagnosis for cardiac ischemia, coronary artery disease (CAD), and other pathological or physiopathological conditions. The results presented in this report do not replace expert evaluation by a physician.

In considering the contents of this MCG report you should bear in mind the potential false-positive and false-negative scenarios identified in the MCG disclaimer, and also consider the patient's case history and symptom presentation. To assist clinical users in interpreting the MCG results Premier Heart maintains a medical support team which can be contacted using the Request Assistance buttons in the reporting application, via telephone (US: (888) 380-8338, International: +1 (516) 883-3383, option 3), or via email (medsupport@premierheart.com). If contacting Premier Heart via telephone or email please provide the MCG Patient ID (2856) and Session ID (41666) from this report.



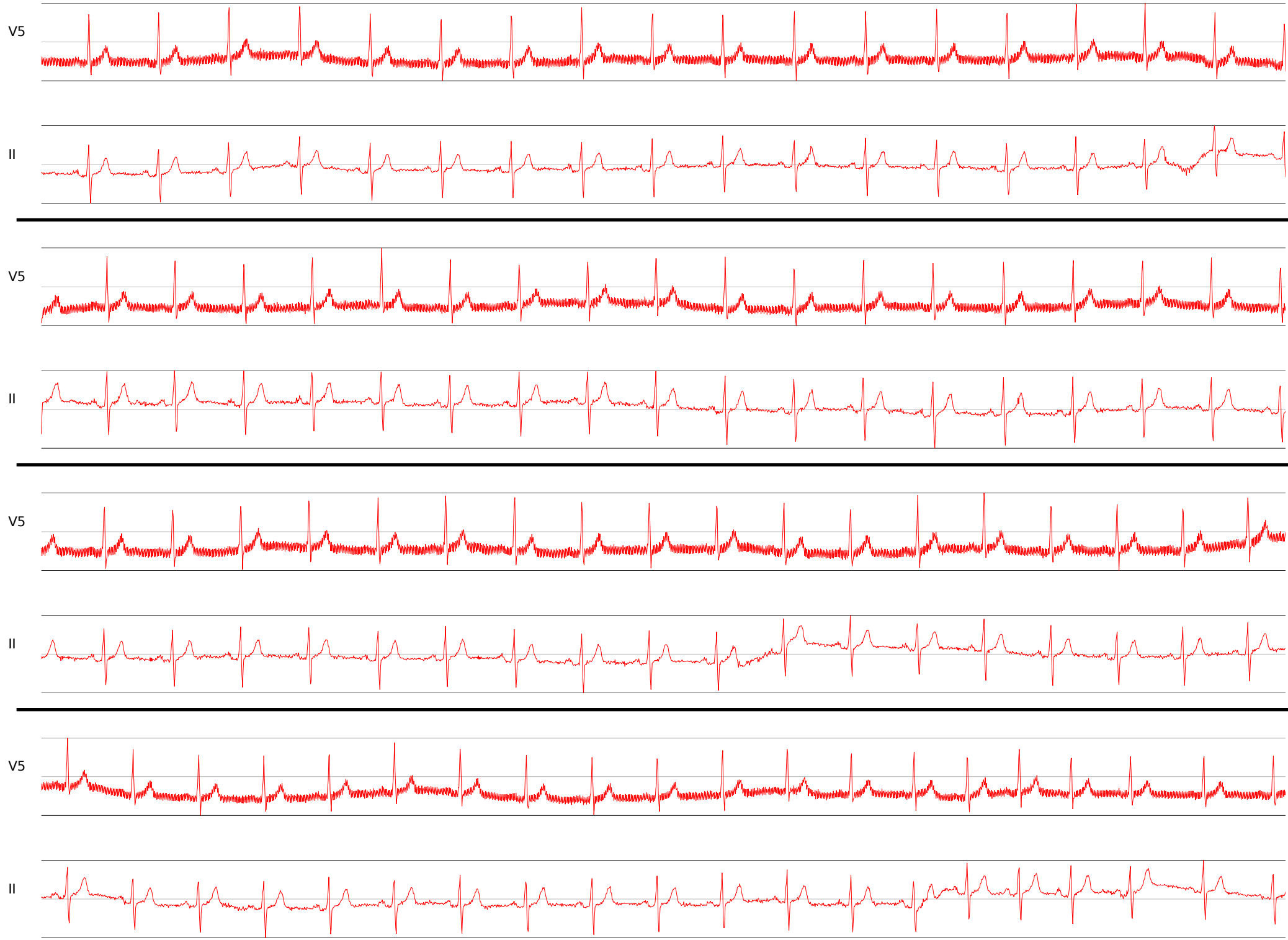
ECG Sample 32399617

Example Patient MCG Session: 41666 @ 2011-03-15 14:41



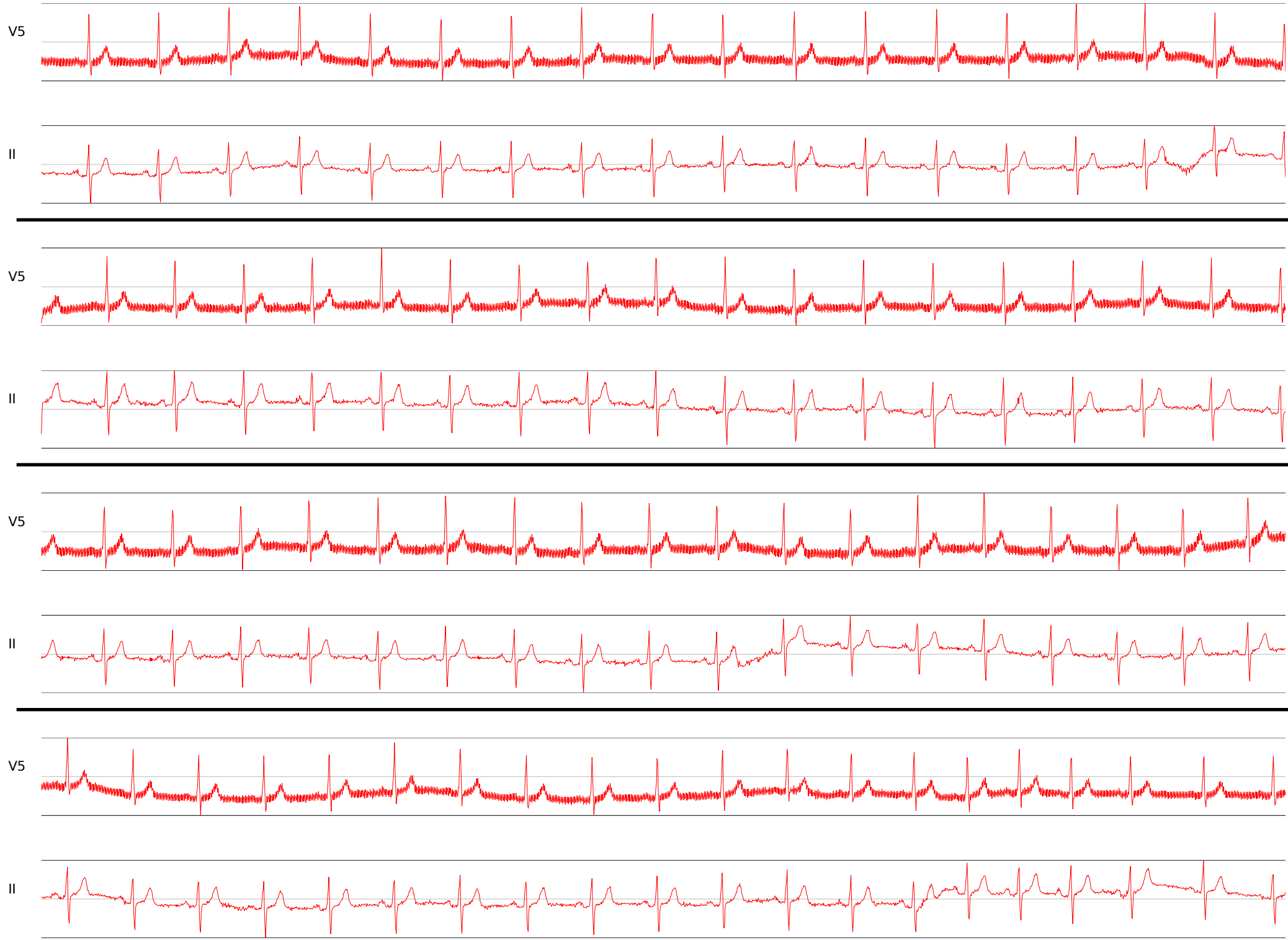
ECG Sample 31531521

Example Patient MCG Session: 41666 @ 2011-03-15 14:41



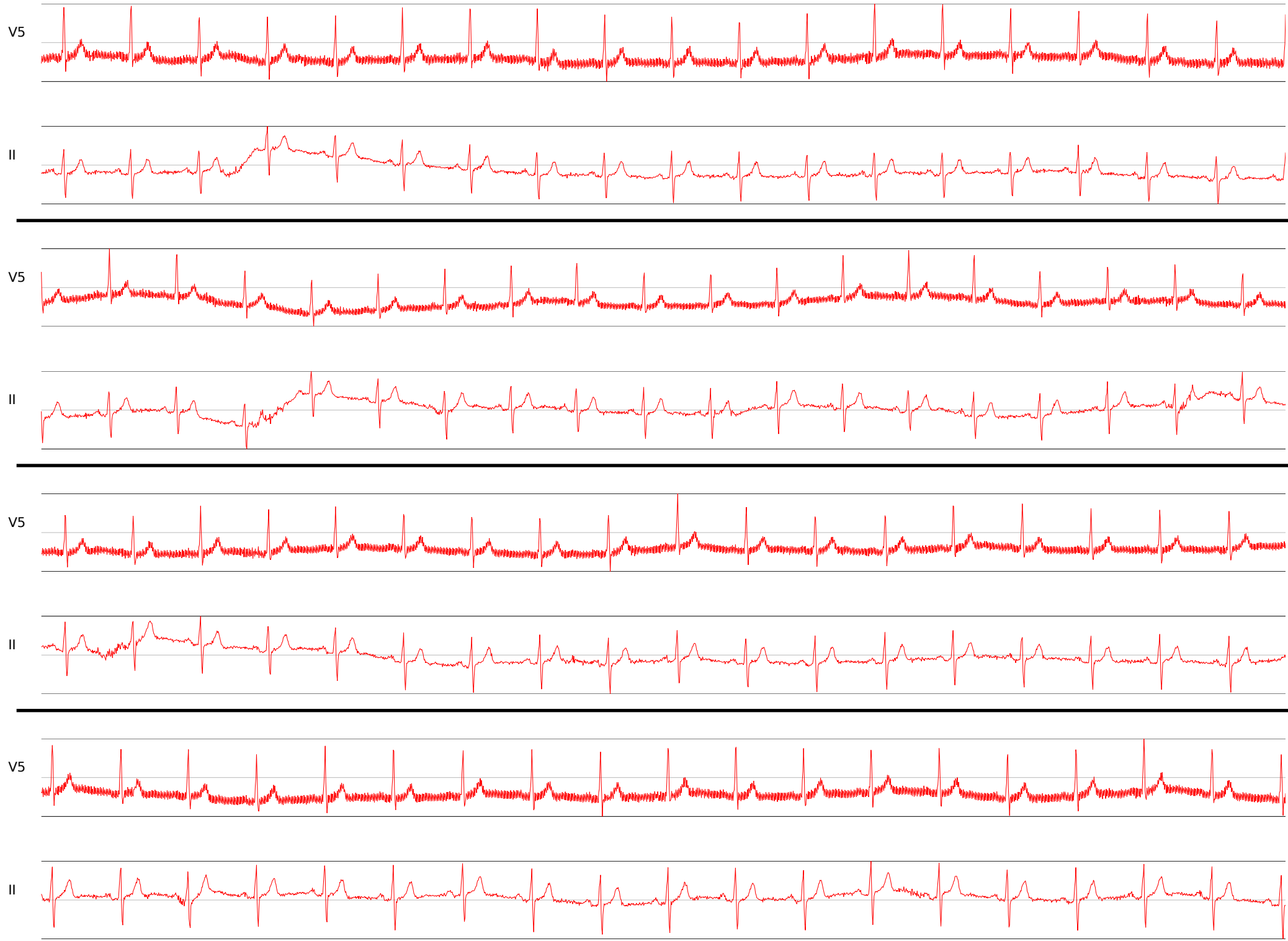
ECG Sample 32130049

Example Patient MCG Session: 41666 @ 2011-03-15 14:41



ECG Sample 32400129

Example Patient MCG Session: 41666 @ 2011-03-15 14:41



ECG Sample 31531265

Example Patient MCG Session: 41666 @ 2011-03-15 14:41

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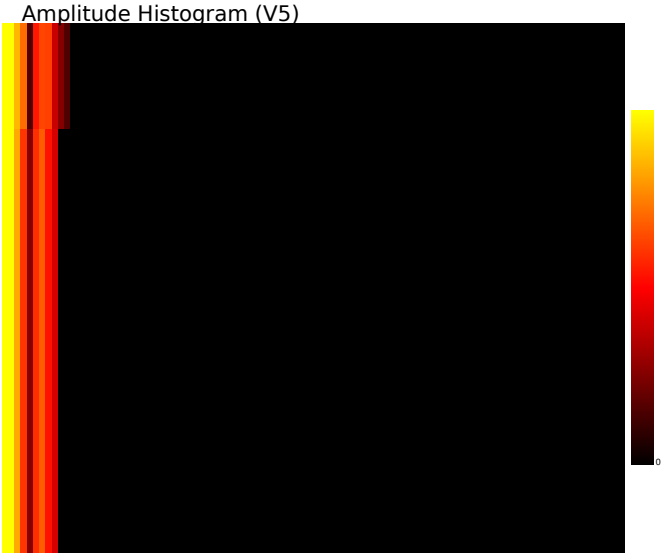
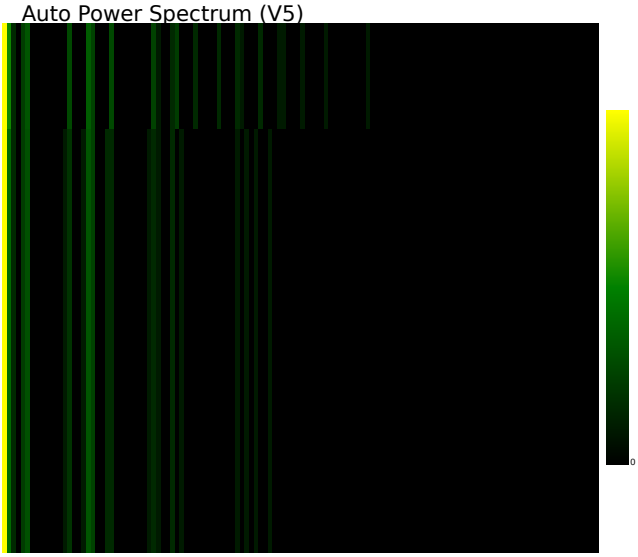
DSP Heatmaps

Amplitude Histogram (V5)

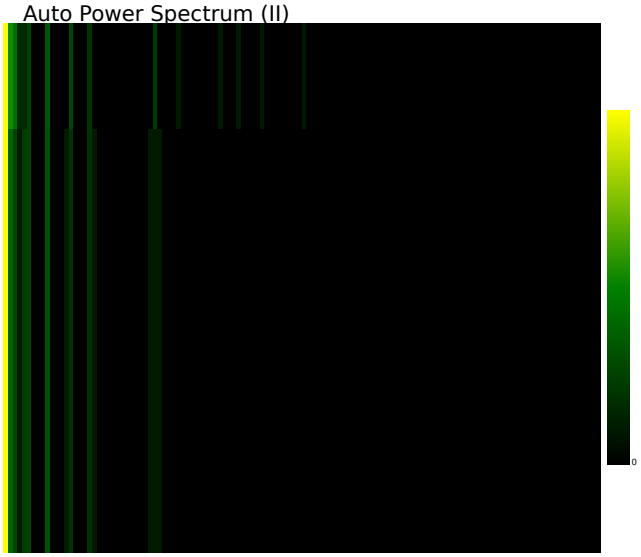


Amplitude Histogram (V5)

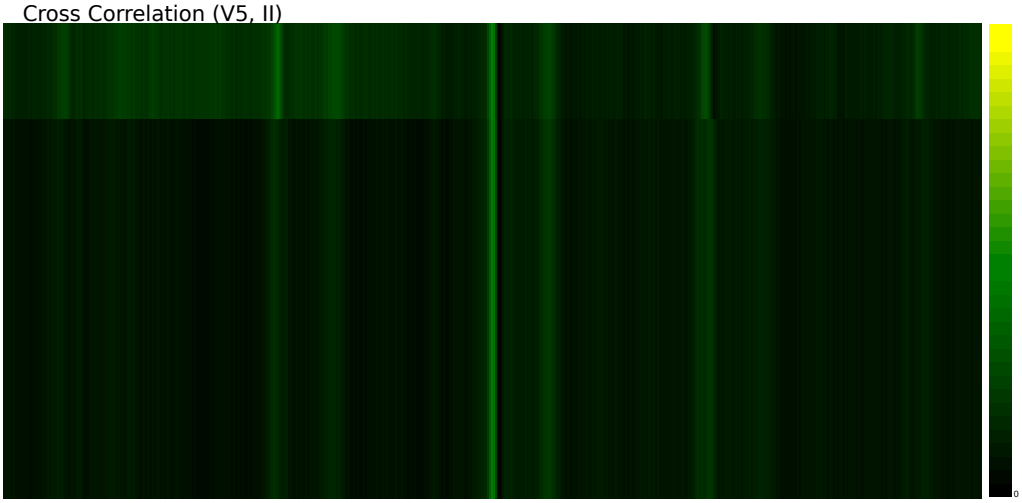
Auto Power Spectrum (V5)



Auto Power Spectrum (II)

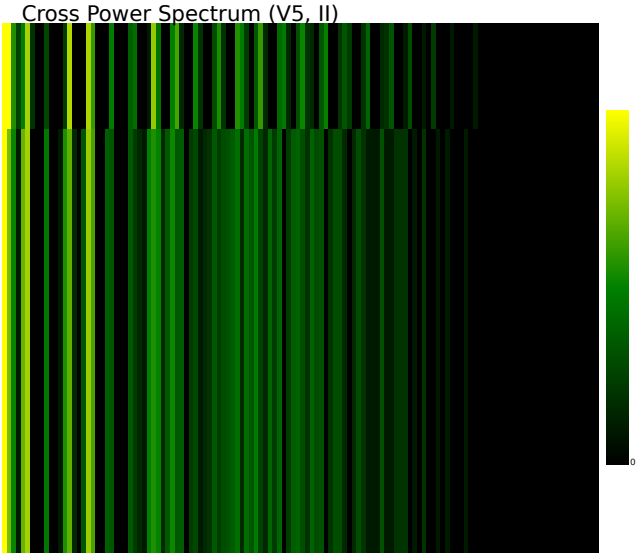


Cross Correlation (V5, II)

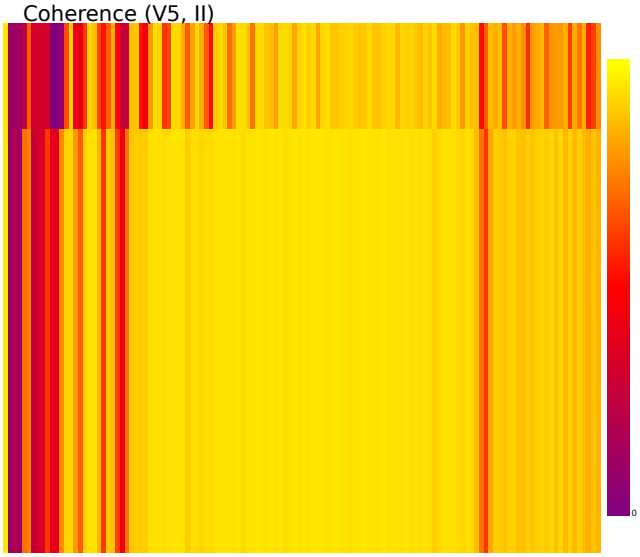


DSP Heatmaps

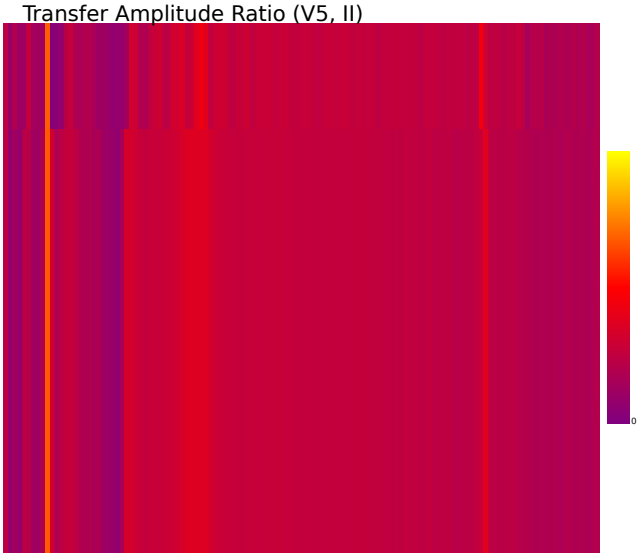
Cross Power Spectrum (V5, II)



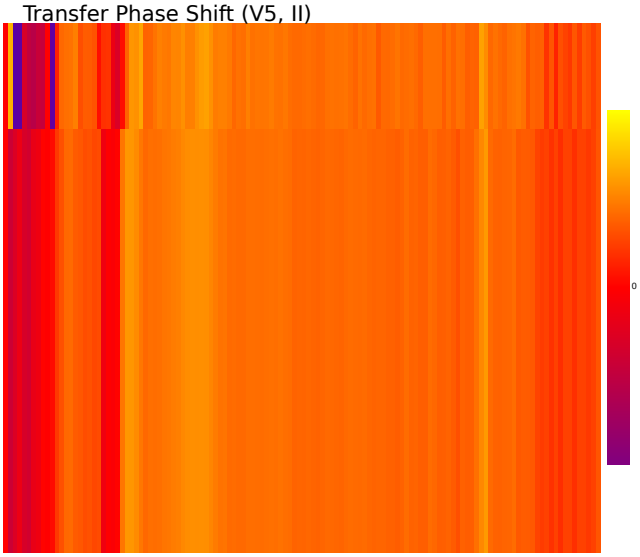
Coherence (V5, II)



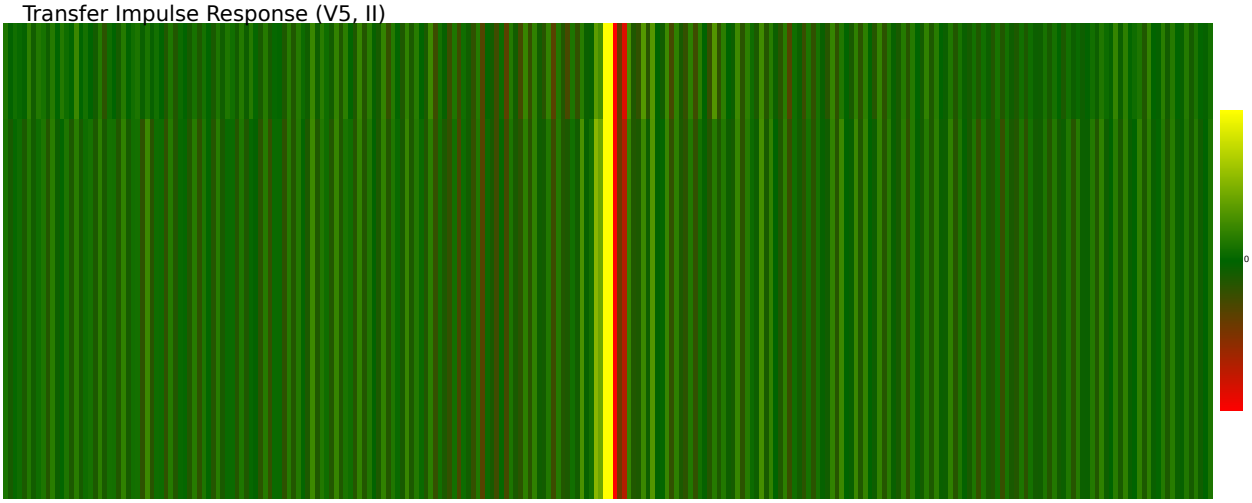
Transfer Amplitude Ratio (V5, II)



Transfer Phase Shift (V5, II)



Transfer Impulse Response (V5, II)



MCG Disclaimers

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MCG Ischemia Detection Rates and Accuracy

In clinical studies MCG has shown a sensitivity of >90% with a specificity of >85% in detecting obstructive coronary ischemia due to obstructive coronary artery disease (>50% luminal encroachment in the Left Main Coronary Artery, and/or >70% luminal encroachment in other large coronary arteries e.g. LAD or L. Circumflex) in patients without established collateral circulation when compared to coronary angiography.
As MCG's detection of ischemia is based on functional (electrophysiological) measurements MCG ischemia results may differ from anatomic assessments. A positive ischemia result does not guarantee that the patient has obstructive CAD, and a negative ischemia result does not guarantee that the patient is free from obstructive CAD.

The MCG false positive rate is 15±3% when compared to coronary angiography, causes include:

* Coronary artery vasospasms
* Microvascular disease
* Metabolic diseases (diabetes, hypo/hyperthyroid)
* Aortic stenosis & regurgitation
* Hypertensive heart disease
* Untreated/undertreated anemia
* Renal disease
* Stimulant medications / substance abuse
* Poor quality ECG tracings

The MCG false negative rate is 7±2% when compared to coronary angiography, causes include:

* Well-established coronary collateral circulation
* Visually poor angiography results (counter to FFR / intravascular ultrasound)
* Patients with pharmacologically reversible obstructive disease receiving vasodialator therapy
* Poor quality ECG tracings

The MCG detection rates and accuracy noted above are unaffected by gender, age or race. All statistics have been derived from multiple controlled and double-blind prospective studies published in peer-reviewed journals. Supporting articles are available from the Premier Heart website, or upon request from Premier Heart.

MCG assumes that the subject has normal complete blood count (CBC) and comprehensive metabolic panel (CMP) results, including normal serum electrolyte chemistry. It also assumes that metabolic disorders (e.g. diabetes) are well controlled, and the subject has no structural anomalies of the myocardium.
If these assumptions are not correct at the time of testing MCG accuracy may be affected.

Pathological and Physiopathological Conditions

Unlike the primary diagnosis of the presence or absence of local or global ischemia the secondary pathological and physiopathological findings of each test should be considered as a reference for physician consideration and evaluation rather than a definitive diagnosis. Premier Heart does not provide medical advice, and MCG analysis is not a substitute for physician judgment, diagnosis, or treatment. The ultimate diagnosis and treatment decisions are left to the reviewing and treating physician.

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