INOVISE 12L INTERPRETIVE ALGORITHM PHYSICIAN'S GUIDE

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Preface

Intended Use

This manual is intended for use by medical practitioners who perform electrocardiography (ECG) and similar tests, and for physicians who interpret ECG data.

The Inovise 12L Interpretive Algorithm provides automated detection and advanced identification of myocardial infarction (MI) and left ventricular hypertrophy (LVH) and standard interpretation of other types of rhythms and morphologies.

While the 12L Interpretive Algorithm's enhanced MI/LVH sensitivity should generally improve the clinical decision process, no diagnostic test has perfect sensitivity and specificity.

The 12L Interpretive Algorithm's interpretive statements are designed to enhance the diagnostic process. They are no substitute for the qualified judgment of a properly trained, supervised clinician. As with any diagnostic test, always give consideration to patient symptoms, history and other relevant factors.

12L Interpretive Algorithm testing is indicated for patients who present with cardiac symptoms, including shortness of breath, and for patients who are at risk for heart disease.

12L Interpretive Algorithm testing is indicated only for patients 18 years of age or older. 12L Interpretive Algorithm analyses are not valid for patients under 18 years of age.

If a patient has one or more particular underlying heart conditions, the 12L Interpretive Algorithm might not analyze ECG abnormalities excluded by the particular underlying conditions. If any of these conditions occur, the unit displays a detailed message in its *Analysis Results*.

Warnings

Inovise 12L Interpretive Algorithm analyses are not valid for patients under 18 years of age.

Ensure qualified clinicians carefully review Inovise 12L charts from patients with implanted pacemakers. Implanted pacemakers can affect the Inovise 12L Interpretive Algorithm ECG analysis. The 12L Interpretive Algorithm incorporates pacemaker detection technology, but it might not detect all pacemakers.

Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove ECG electrodes from the chest area in order to prevent patient burns.

Enter the correct age and gender for each patient before performing ECG analysis using the Inovise 12L Interpretive Algorithm. This enables the 12L Interpretive Algorithm to analyze patient data correctly. By default, the 12L Interpretive Algorithm is configured to test an 18+ year-old male.

Related Publications and Materials

X Series Operator's Guide (9650-001355-01)

X Series Quick Reference Guide (96-000391-01)

How to Use This Manual

The Inovise 12L Interpretive Algorithm Physician's Guide provides information operators need for the safe and effective use and care of the unit. It is important that all persons using this device read and understand all the information contained within.

Please read thoroughly the safety considerations and warnings section in this guide.

Physician's Guide Updates

An issue or revision date for this Physician's Guide is shown on the inside cover. If more than three years have elapsed since this date, contact ZOLL Medical Corporation to determine if additional product information updates are available.

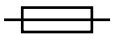
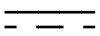
All users should carefully review each manual update to understand its significance and then file it in its appropriate section within this manual for subsequent reference.

Product documentation is available through the ZOLL website at www.zoll.com. From the Products menu, choose Product Manuals.

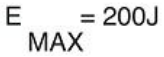
Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:

Symbol	Description
	Dangerous voltage.
	Attention, consult accompanying documents.
	Fragile, handle with care.
	Keep dry.
	This end up.

Symbol	Description
	Temperature limitation.
	**Conformité Européenne** Complies with medical device directive 93/42/EEC.
	Type B patient connection.
	Type BF patient connection.
	Type CF patient connection.
	Defibrillator-proof type BF patient connection.
	Defibrillator-proof type CF patient connection.
	Fusible link.
	Equipotentiality.
	Alternating current (ac).
	Direct current (dc).
	Contains lithium. Recycle or dispose of properly.
	Keep away from open flame and high heat.
	Do not open, disassemble, or intentionally damage.
	Do not crush.

Symbol	Description
	Do not discard in trash. Recycle or dispose of properly.
	Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash.
	Date of manufacture.
	Use by.
	Latex-free.
	Do not reuse.
	Do not fold.
	Not sterile.
	Nonionizing electromagnetic radiation.
	Manufacturer.
	Authorized representative in the European Community.
	Serial Number.
	Catalogue number.
	Consult instructions for use.

Symbol	Description
	Prescription only.
	Maximum energy.
	Test port.

Conventions

This guide uses the following conventions:

Within text, the names and labels for the unit's physical buttons and softkeys appear in **boldface** type (for example, "Press the **SHOCK** button or the **Code Marker** softkey").

This guide uses uppercase italics for the unit's audible prompts and for text messages displayed on the screen (for example, *Acute Anterior Infarct*).

WARNING! **Warning statements alert you to conditions or actions that can result in personal injury or death.**

Caution Caution statements alert you to conditions or actions that can result in damage to the unit.

Chapter 1
Introduction

This chapter provides an overview of the Inovise 12L Interpretive Algorithm (Inovise algorithm) and the interpretive statements provided from its analysis of a 12-lead ECG.

Algorithm Overview

The Inovise algorithm surpasses the traditional 12-lead ECG by providing an advanced analysis of 12-lead, resting ECG data.

The Inovise algorithm uses advanced algorithms to extract data from the ECG criteria in order to create a detailed analysis of heart conditions. The unit provides a screen display of the Inovise algorithm findings on Analysis Pages 1 and 2. The unit can also print the Inovise algorithm findings on a strip chart with the ECG traces. This makes it easier for practitioners to understand the results and to educate patients about heart conditions.

Inovise 12L Interpretive Analysis Information

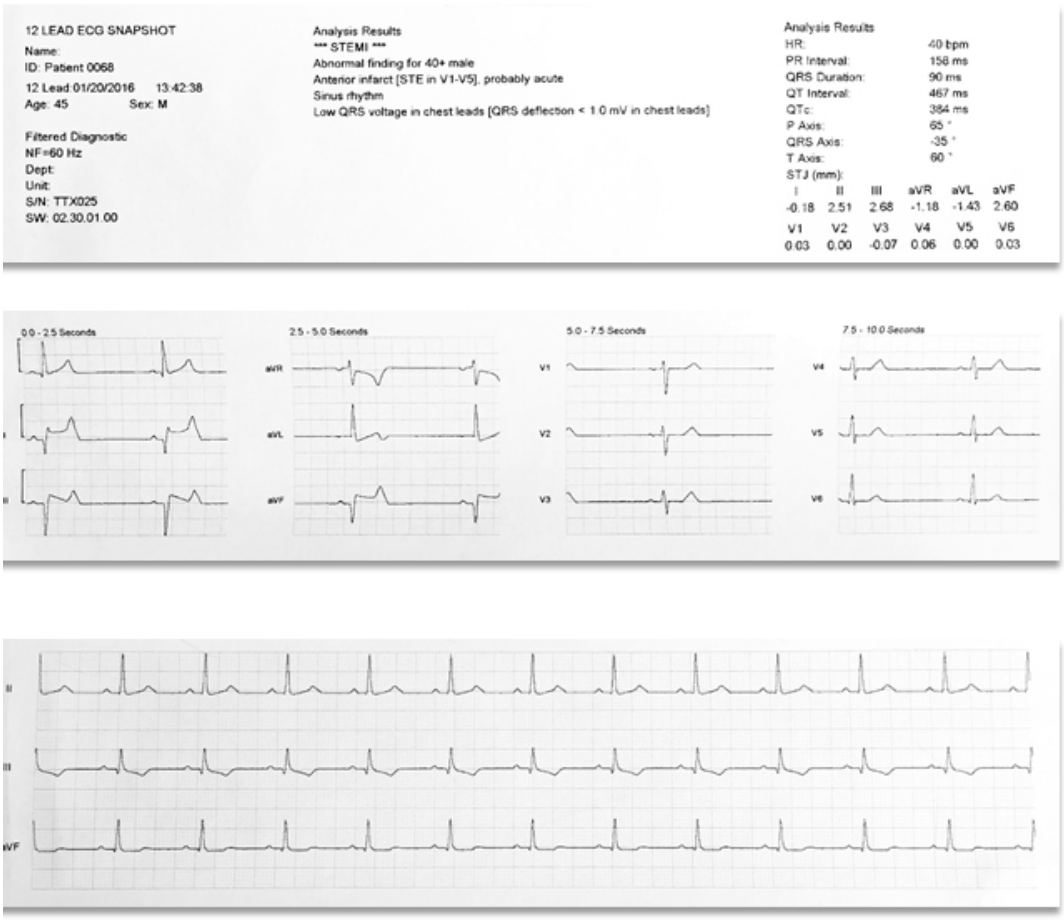
The Inovise algorithm's strip chart and screen display (*Analysis Page* 1 and 2) consolidates conventional ECG traces with advanced analysis statements to provide a concise report on the condition of the patient's heart. The Inovise algorithm displays and prints the following information:

- Patient demographics and rescue department/unit information.
- Analysis results, summarized by Inovise algorithm's **Analysis Statements**, which we describe in detail in Chapters 2 and 3.
- Basic measurements. This includes the patient's ventricular heart rate, PR interval, QRS duration, QT interval, and so on.
- ECG traces

Information provided by Inovise algorithm includes the following fields:

12L Analysis Information Field	Indicates
Name:	Patient name.
ID:	Alphanumeric code used to identify patient.
12 Lead:	Date and time during which 12 Lead data was acquired.
Age:	Patient's age.
Sex:	Patient's gender.
Filtered Diagnostic	Indicates that the diagnostic filter was applied to the ECG sample.
NF=OFF	Indicates that the ECG notch filter is OFF.
Dept:	Alphanumeric label to identify rescue department.
Unit:	Alphanumeric label to identify unit in rescue department.
S/N	Serial Number of the unit used in rescue.
SW:	Software revision installed in the unit.
Analysis Results	Heading identifying the Analysis Statements and ECG measurements produced by the Inovise algorithm.
HR:	Patient's heart rate in Beats Per Minute (bpm).
PR Interval:	Average duration of the 12 Lead sample's PR interval in milliseconds (ms).
QRS Duration:	Average duration of the12 Lead sample's QRS complex in milliseconds (ms).
QT Interval:	Average width of the 12 Lead sample's QT Interval in milliseconds (ms).
QTc:	Average width of the 12 Lead sample's QTc (QT Interval *Corrected*) in milliseconds (ms). The formula that the Inovise algorithm uses to derive QTc is as follows: $\frac{QT}{\sqrt{RR}}$ where *QT* is the QT interval, and *RR* is the RR interval in seconds. The formula that the Inovise algorithm uses to derive *RR* is as follows: $\frac{60}{HR}$ where *HR* is the heart rate in Beats Per Minute (BPM).
P Axis:	Axis of P wave in degrees.
QRS Axis	Axis of R wave in degrees.
T Axis:	Axis of T wave in degrees.
STJ (mm)	Lead-by-Lead deviation of the ST segment in mm, measured at the J-point

The following strip chart sections provide an example of what the unit prints after the Inovise algorithm has determined the occurrence of an ST-Elevation Myocardial Infarction (*** *STEMI****):



Chapter 2
Interpreting Myocardial Infarction

This chapter describes the analysis statements that the Inovise 12L Interpretive Analysis Algorithm (Inovise algorithm) provides for the interpretation of myocardial infarction. For each analysis statement, this chapter provides the criteria and the rationale from which the Inovise algorithm derives the analysis statement.

STEMI and Acute Myocardial Infarction: Clinical Focus

Electrocardiographic (ECG) evaluation for acute ischemic heart disease plays a central role in defining hospital-based STEMI protocols and it is crucial for reducing door-to-balloon time for STEMI cases.

The Inovise algorithm is aligned with these clinical goals and validated retrospectively using very large databases of 12-lead ECGs in which the clinical status of the subjects was established through the following inputs:

- Patient history
- Patient physical examination,
- Cardiac biomarker findings
- Hospital discharge diagnosis.

Validation of the Inovise algorithm MI interpretation also included comparison with cardiac angiography imaging findings and reperfusion therapy results.

Definitions

Term	Definition
Acute Myocardial Infarction (AMI)	AMI is broadly defined to be myocardial ischemia severe enough that if unresolved will result in myocardial tissue necrosis.
ST Elevation Acute Myocardial Infarction (STEMI)	STEMI is considered a subcategory of AMI caused by a 100% blockage of one coronary artery.
Non-ST Elevation Acute MI (nSTEMI)	nSTEMI may be defined as an AMI caused by a severely narrowed, but not completely blocked, coronary artery.
STEMI Equivalent	STEMI Equivalent is may be defined by: • STEMI ECG evidence in the presence of Left Bundle Branch Block (LBBB), • Isolated STEMI ECG evidence for the posterior wall • Left main occlusion. **Note:** An alternate definition for STEMI Equivalent is to associate it with high-grade left main coronary artery (LMCA) disease.

STEMI

STEMI (ST Elevation Acute Myocardial Infarction) is a subcategory of AMI usually caused by a 100% blockage of one of the coronary arteries. An ECG interpretation of STEMI is based upon evaluating cardio-electric signals captured at the skin surface from specific locations on the patient's torso and limbs. A clinical workup for STEMI would typically include interpretation of the ECG and evaluation of patient presentation and history, cardiac biomarker and imaging study results, and inputs derived from other methods. As a result, ECG interpretation of STEMI is distinct from a clinical diagnosis of STEMI, though ECG results are an important input to the clinical diagnosis.

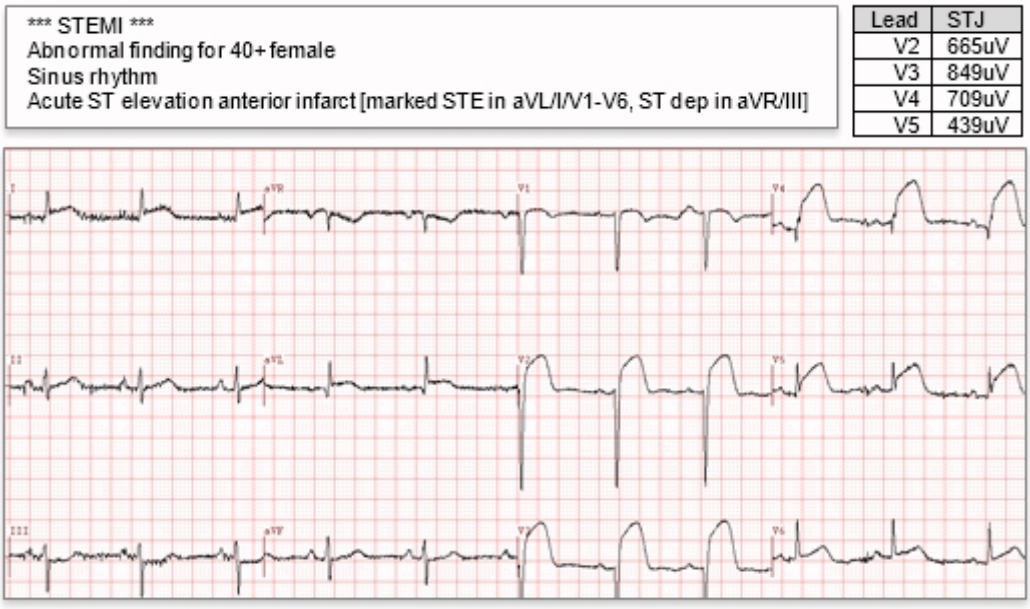
The definitional differences between a clinical workup versus ECG interpretation for STEMI can create confusion when deciding the role of ECG findings for activation of STEMI protocols. This confusion can be partially, but not wholly, eliminated by applying published guidelines for interpreting ECG evidence for STEMI.

Guidelines for the interpretation of STEMI can be found in the document, "AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part VI: Acute Ischemia/Infarction: A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society: Endorsed by the International Society for Computerized Electrocardiology".

The examples that follow show representative samples of information delivered when the Inovise algorithm interprets the occurrence of STEMI, nSTEMI, and STEMI Equivalent.

STEMI Example #1

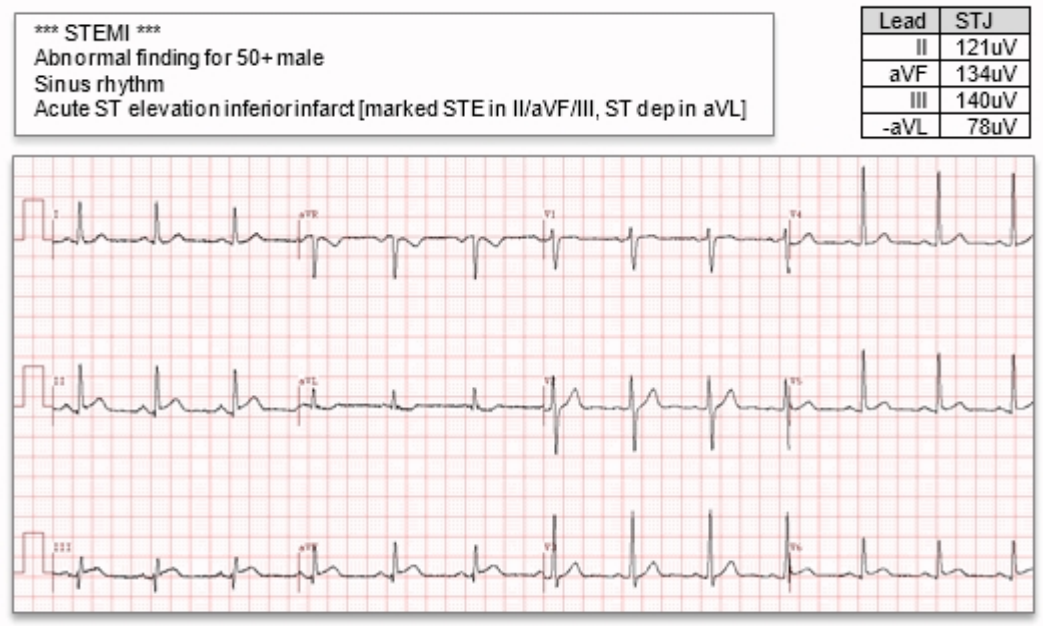
Below is the hospital admitting ECG with Inovise algorithm interpretation for a 67 year old female suffering from chest pain. The ECG exhibits prominent ST elevation in leads V2-V5 consistent with anterior wall STEMI. Cardiac biomarker results for the patient were positive for AMI. Angiography imaging results confirmed a proximal high-grade lesion of the LAD.



STEMI Example #2

Below is the hospital admitting ECG with Inovise algorithm interpretation for a 50 year old male suffering from chest pain. The ECG exhibits ST elevation in the inferior leads that meets established STEMI criteria.

The clinical workup for this patient included a 12-Lead ECG, cardiac enzymes and angiographic imaging. The admitting CK-MB was negative at 1 ng/ml. The angiogram revealed a 95% occlusion of the mid RCA which was subsequently resolved via PCI. The post-PCI CK-MB was highly positive for myocardial injury at 23.1 ng/ml.



nSTEMI

nSTEMI may be defined as an AMI caused by a severely narrowed, but not completely blocked, coronary artery.

Similar to the STEMI circumstance, an ECG interpretation of nSTEMI is distinct from a clinical diagnosis of nSTEMI. However, there are additional considerations for an nSTEMI diagnosis for these reasons:

- An absence of a universally agreed upon definition for ECG evidence for nSTEMI.
- An absence of clinical guidelines for treating nSTEMI that include a quantitative ECG definition for nSTEMI.

One accepted definition for nSTEMI is *myocardial infarction without ECG evidence of ST elevation.* With this definition, the nSTEMI ECG is described as exhibiting widespread ST depression.

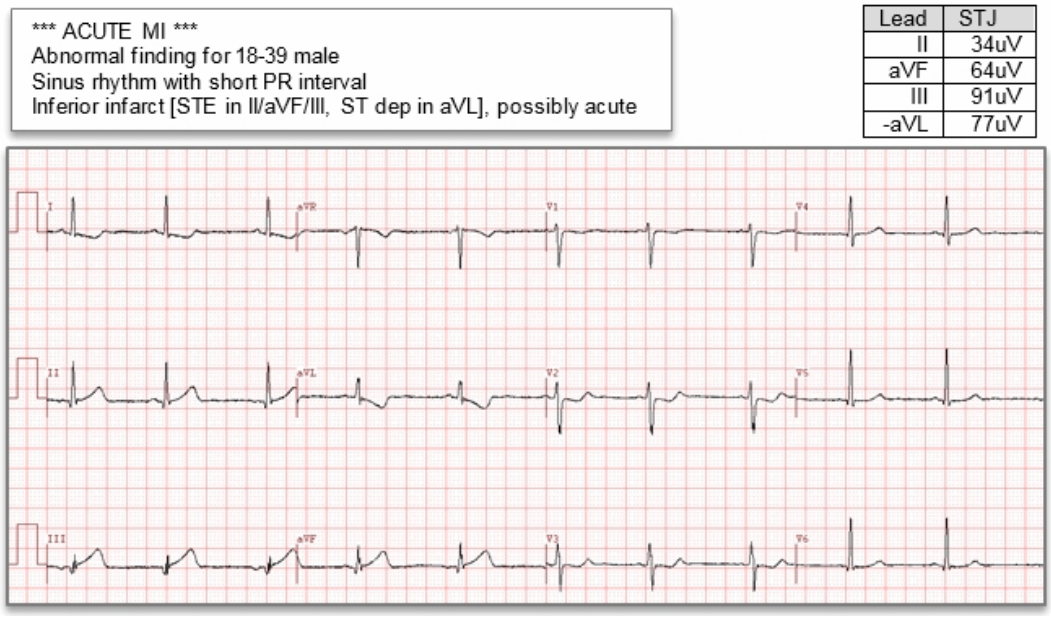
However, a crucial deficiency with this definition is that it does not identify or categorize a significant group of AMI positive subjects where ST elevation is present, but insufficient to meet STEMI criteria.

Note: See the STEMI Equivalent section in this chapter for a description of how the Inovise algorithm interprets marked ST depression.

Clinical workup for these subjects often reveals high-grade coronary artery disease (CAD) or total occlusions of a coronary artery, suggesting the importance of considering interventional strategies for these cases that is comparable to that pursued when STEMI criteria are met. In order to address this potentially under-served population, the Inovise algorithm uses an alternate definition for nSTEMI that entails identifying AMI when there is a pattern of ST elevation present in the ECG that localizes to the coronary anatomy but is insufficient to meet established STEMI criteria. The Inovise algorithm accompanies this type of AMI finding with the annotation ***ACUTE MI***.

nSTEMI Example

Below is the hospital admitting ECG with Inovise algorithm interpretation for a 38 year old male suffering from chest pain. While the ECG exhibits ST elevation in the inferior leads, the magnitude is insufficient to meet established STEMI criteria, which requires 100uV in two anatomically contiguous leads. The clinical workup for this patient included a 12-Lead ECG, cardiac enzymes and angiographic imaging. The admitting CK-MB was negative at 1.9 ng/ml. The angiogram revealed a 95% occlusion of the distal RCA which was subsequently resolved via PCI. The post-PCI CK-MB was highly positive for myocardial injury at 91.5 ng/ml.



STEMI Equivalent

STEMI Equivalent also represents an important risk category for interventional consideration. There are two definitional conventions for STEMI Equivalent that may be considered.

The first convention for STEM Equivalent includes:

1. STEMI ECG evidence in the presence of Left Bundle Branch Block (LBBB).
2. Isolated STEMI ECG evidence for the posterior wall.
3. Left main occlusion.

The Inovise algorithm employs an alternate definition for the first two of these three clinical scenarios.

- For the case of STEMI evidence in the presence of LBBB and other primary STT confounding conditions, such as Right Bundle Branch Block (RBBB) or Left Ventricular Hypertrophy (LVH), the Inovise algorithm annotates these as ***STEMI***. The AMI interpretive statement includes an equivocation of the form “Probable Acute ST Elevation Infarct” due to the uncertainties introduced by the presence of a confounding condition.
- For the case of STEMI evidence for posterior wall AMI, the Inovise algorithm considers these as “***STEMI***”, consistent with published guidelines for the identification of posterior wall STEMI.

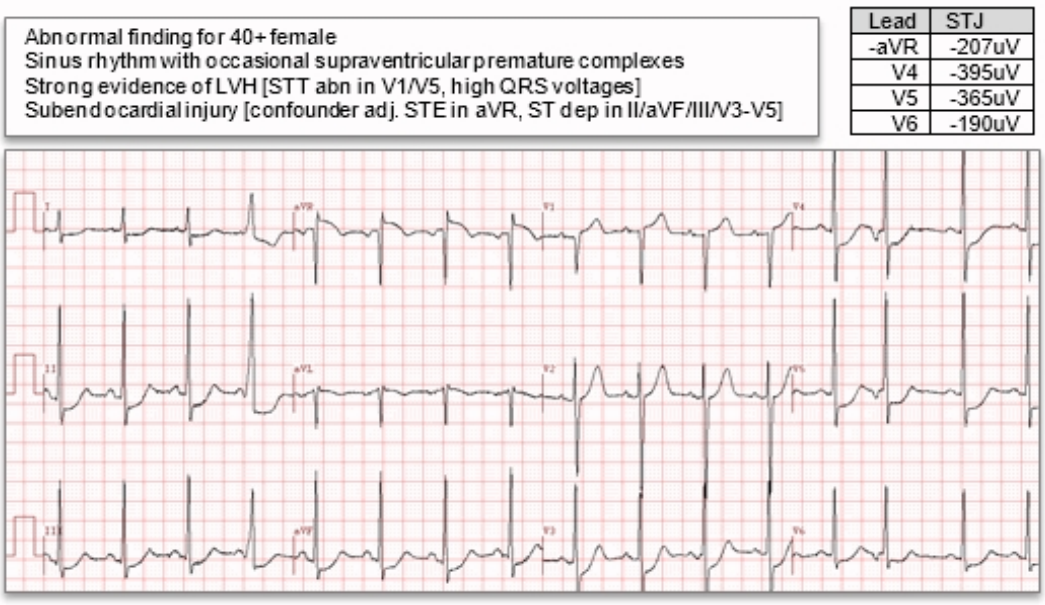
The second definitional convention for STEMI Equivalent is to associate it with high-grade left main coronary artery (LMCA) disease, a very high-risk pathology. Acute LMCA disease manifests in the ECG as widespread, apically directed ST depression.

A challenge with applying this ECG interpretation lies with differentiating LMCA from acutely severe three-vessel disease, which can produce a similar ECG. To address this challenge, the Inovise algorithm provides a finding of “subendocardial injury” as the ECG interpretation that covers both of these underlying pathologies.

STEMI Equivalent Example

Below is the hospital admitting ECG with Inovise algorithm interpretation for a 76 year old male suffering from chest pain and dyspnea. The ECG does not exhibit a localizing pattern of ST elevation and does not meet any STEMI criteria but does show marked, widespread ST depression directed toward the apex. The ECG also shows strong evidence for LVH. STJ normalized for the effects of LVH is sufficient to support a finding of subendocardial injury.

The clinical workup for this patient included a 12-Lead ECG, cardiac enzymes and angiographic imaging. The admitting CK-MB was negative with a reading of 2.9 ng/ml. The angiogram revealed severe left main disease. Peak CK-MB was positive at 53.5 ng/ml.



AHA/ACCF/HRS STEMI Guidelines

Published guidelines from an AHA/ACCF/HRS working group standardize ECG interpretation for STEMI. The guideline STEMI definition relies upon ST elevation measurements taken in pairs of anatomically contiguous ECG leads with ST elevation thresholds uniform at 100uV for limb lead measurements and for precordial leads V4-V6. The thresholds for precordial leads V1-V3 are nominally set at 200uV.

The Inovise algorithm AMI finding includes the annotation ***STEMI*** whenever the ECG ST measurements meet the criteria as described in the guidelines document, “AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part VI: Acute Ischemia/Infarction: A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society: Endorsed by the International Society for Computerized Electrocardiology”.

This document is available from the websites of the following organizations:

Organization	URL
American Heart Association	http://my.americanheart.org
American College of Cardiology Foundation	http://www.acc.org
Heart Rhythm Society	http://www.hrsonline.org

Guideline Limitations

Limitations to the guidelines for a STEMI diagnosis emerge with the consideration of gender and age and with STT confounding conditions.

Currently, the AHA/ACCF/HRS guidelines offer only limited criteria adjustments for the following patient groups:

- Female
- Young Male (under 40 years)
- LBBB patients

The Inovise algorithm incorporates the existing AHA/ACCF/HRS guideline criteria adjustments and specifies additional adjustments, based on very large databases of ECGs clinically correlated to be AMI positive or AMI negative for females and on a broader category of STT confounding conditions other than LBBB.

As a result, the Inovise algorithm will annotate some ECGs as ***STEMI*** that are not identified as such by the guideline criteria for STEMI.

These criteria adjustments and extensions enable the Inovise algorithm to have an improved sensitivity for STEMI while maintaining very high specificity.

Gender and Age Considerations

The STEMI guideline threshold adjustments that account for gender and age differences are limited to the lead pair V2-V3.

- For females, the guidelines decrease the threshold from 200uV to 150uV.
- For males under 40 years, the guidelines increase the threshold from 200uV to 250uV.

As a result of the study of extensive databases of clinically correlated ECGs, the Inovise algorithm uses a proprietary method to make further gender and age adjustments for STEMI and nSTEMI/AMI determination. These adjustments result in improved overall accuracy for STEMI, and for nSTEMI/AMI.

Confounding Condition Considerations

The AHA/ACCF/HRS guidelines recognize LBBB as a primary confounder for interpreting ST elevation for STEMI.

The Inovise algorithm supports the guideline by employing specific STEMI criteria in the presence of LBBB. It also surpasses the guideline through additional criteria for other ECG conditions known to perturb the STT and confound the interpretation of ST deviation for AMI.

The Inovise algorithm does this by employing a proprietary method for quantifying the effect on STT measurements due to these confounding conditions. With this method, the algorithm mathematically removes the quantified effect of these confounders, effectively normalizing the STJ in such a manner that STEMI thresholds, consistent with guideline definitions, can be applied.

See the section below entitled “Confounding Conditions” for a list and further discussion of confounders and Inovise algorithm findings in the presences of these confounders.

QRS Changes Associated with Evolving and Acute MI

The early stages of AMI (STEMI, nSTEMI, and STEMI Equivalent) are accompanied by STT changes. As an AMI evolves from its early stages, QRS changes emerge, that indicate depolarization and repolarization abnormalities which result from hibernating or necrotic myocardial cells.

With this understanding of AMI evolution, a relationship emerges between the time of AMI onset, the timing of reperfusion intervention, and the degree of myocardial salvage that can be accomplished with such interventions.

Understanding this relationship is crucial to the STEMI protocol objective to minimize door-to-balloon time to less than one hour for many hospitals.

The Inovise algorithm is optimized to have the highest possible accuracy for detection of early-stage AMI. The algorithm then differentiates early AMI from evolving AMI and chronic MI through evaluation of QRS changes. The algorithm relies the Selvester QRS Score as a means to quantify the degree of myocardial scar present within the left ventricle. This information is incorporated into the AMI assessment as follows:

1. If AMI STT abnormalities are prominent, and QRS changes are minor or modest, the Inovise algorithm produces an AMI finding of the form “MI, probably acute”, indicating the AMI is actively evolving but is no longer in the earliest stage.

2. If AMI STT abnormalities are modest and QRS changes are modest, the Inovise algorithm produces an AMI finding of the form “MI, possibly acute”, indicating the AMI has likely undergone significant evolution, but may still be considered actively acute.
3. If AMI STT abnormalities are modest or have resolved and QRS changes are prominent, the Inovise algorithm produces a finding of “MI, age undetermined”, indicating the MI has likely completely evolved and therefore may be considered chronic.

This aspect of the Inovise algorithm is intended to aid the clinician’s decision to pursue interventional therapies considerate of both patient risk and the potential opportunity to salvage myocardium.

Acute MI: Categories of Findings

Findings for the acute portion of the Inovise algorithm are divided into six categories that are discussed in this section.

Category 1: “Acute ST Elevation {location} Infarct”

This finding is reported when no STT confounding conditions are present, and when ST levels measured meet the published guideline definition for STEMI. This statement is accompanied by a ***STEMI*** annotation.

Statement Location Variants
Acute ST Elevation Anterior Infarct
Acute ST Elevation Posterior Infarct
Acute ST Elevation Inferior Infarct
Acute ST Elevation Apical Infarct
Acute ST Elevation Anterolateral Infarct
Acute ST Elevation Anterior-Inferior Infarct
Acute ST Elevation Inferior Infarct w/ Posterior Extension
Acute ST Elevation Posterior Infarct w/ Inferior Extension
Acute ST Elevation Posterior-Anterolateral Infarct
Acute ST Elevation Inferoapical Infarct

Category 2: “Probable Acute ST Elevation {location} Infarct”

This finding is reported when no significant STT abnormalities specific for Acute MI are present and when ST levels do not quite meet the guideline definitions for STEMI. This can occur, for example, as a result of STEMI gender adjustments. This statement form is also presented when STEMI criteria are met but are accompanied by STT confounding conditions that introduce some uncertainty with the quantitative evaluation of ST level. This statement is accompanied by a ***STEMI*** annotation.

Statement Location Variants
Probable Acute ST Elevation Anterior Infarct
Probable Acute ST Elevation Posterior Infarct
Probable Acute ST Elevation Inferior Infarct
Probable Acute ST Elevation Apical Infarct
Probable Acute ST Elevation Anterolateral Infarct
Probable Acute ST Elevation Anterior-Inferior Infarct
Probable Acute ST Elevation Inferior Infarct w/ Posterior Extension
Probable Acute ST Elevation Posterior w/ Inferior Extension
Probable Acute ST Elevation Posterior-Anterolateral Infarct
Probable Acute ST Elevation Inferoapical Infarct

Category 3: “Acute Anterior Infarct”

This finding is reported when a pattern of STJ depression in anterior leads V1-V3 is present, accompanied by tall, symmetric T-Waves in those same leads. This finding identifies a very early stage AMI sometimes referred to as a “hyperacute” MI.. This statement is accompanied by a ***ACUTE MI*** annotation.

Statement
Acute Anterior Infarct

Category 4: “{location} infarct, probably acute”

This finding is reported when STT abnormalities specific for AMI are present, but are accompanied by QRS abnormalities that indicate the infarction is no longer in the earliest phase of evolution. This finding is also reported when no QRS abnormalities are present and when ST levels indicate an AMI is probably underway. If ST levels meet STEMI guideline criteria, this statement is accompanied by a ***STEMI*** annotation. Otherwise, the ***ACUTE MI*** annotation will appear.

Statement Location Variants
Anterior Infarct, Probably Acute
Posterior Infarct, Probably Acute
Inferior Infarct, Probably Acute
Apical Infarct, Probably Acute
Anterolateral Infarct, Probably Acute
Anterior-Inferior Infarct, Probably Acute
Inferior Infarct w/ Posterior Extension, Probably Acute
Posterior Infarct w/ Inferior Extension, Probably Acute
Posterior-Anterolateral Infarct, Probably Acute
Inferoapical Infarct, Probably Acute

Category 5: "{location} infarct, possibly acute"

This finding is reported when STT abnormalities specific for AMI are present, but are accompanied by significant QRS abnormalities consistent with a highly evolved AMI. This finding is also reported when no QRS abnormalities are present and when ST levels indicate there is a possibility for the presence of AMI. If ST levels meet STEMI guideline criteria, this statement is accompanied by a ***STEMI*** annotation. Otherwise, the ***ACUTE MI*** annotation will appear.

Statement Location Variants
Anterior Infarct, Possibly Acute
Posterior Infarct, Possibly Acute
Inferior Infarct, Possibly Acute
Apical Infarct, Possibly Acute
Anterolateral Infarct, Possibly Acute
Anterior-Inferior Infarct, Possibly Acute
Inferior Infarct w/ Posterior Extension, Possibly Acute
Posterior Infarct w/ Inferior Extension, Possibly Acute
Posterior-Anterolateral Infarct, Possibly Acute
Inferoapical Infarct, Possibly Acute

Category 6: “Probable subendocardial injury”

This finding is reported when the STT abnormality appears as marked ST depression in a combination of limb and precordial leads, the mean vector of which points toward the apex.

Statement Variants
Possible Subendocardial Injury
Probable Subendocardial Injury
Subendocardial Injury

Reasons Associated with Acute MI Findings

The acute portion of the Inovise algorithm presents the statements of rationale listed in the following table, in concert with statements of findings, as applicable, under Analysis Results.

Statement
[Borderline STE in {ECG Lead Designation}]
[Borderline ST DEP in {ECG Lead Designation}]
[Confounder ADJ. STE {ECG Lead Designation}]
[Confounder ADJ. ST DEP {ECG Lead Designation}]
[Marked STE in {ECG Lead Designation}]
[Marked ST DEP in {ECG Lead Designation}]
[STE in {ECG Lead Designation}]
[STJ DEP w/ Tall T-Waves {ECG Lead Designation}]
[ST DEP in {ECG Lead Designation}]
Key to Abbreviations • *S: S-Wave* • *ST: ST segment (end of S-Wave, or J point, to beginning of T-Wave)* • *ST DEP: ST segment depression (ST deviation below the baseline)* • *STE: ST segment elevation (ST deviation above the baseline)* • *T: T-wave*

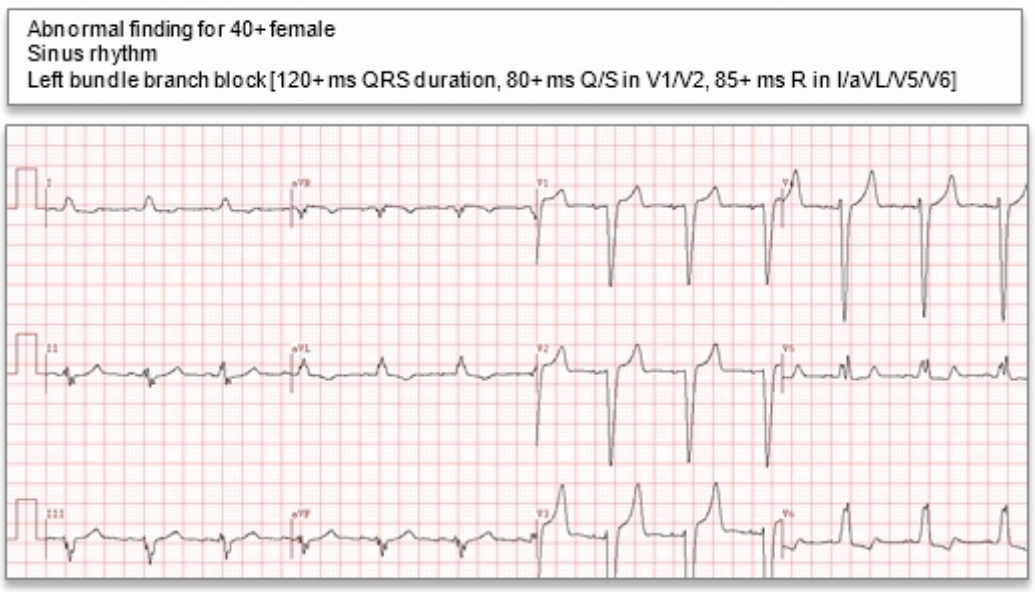
Confounding Conditions

Confounding conditions are clinical conditions that, when present, complicate straightforward ECG evaluation. Confounders include those in the table that follows.

Confounder	Abbreviation	Impact to AMI Interpretation
Left Bundle Branch Block	LBBB	Primary confounder for identification of anterior AMI due to the significant repolarization abnormalities accompanying the highly abnormal terminal depolarization forces in leads V1-V3.
Right Bundle Branch Block	RBBB	Primary confounder for interpreting posterior AMI due to prominent STT abnormalities in leads V1-V3 resulting from delayed activation of right ventricle. Significant adjustments are made to baseline measurements in these leads. Some baseline adjustments are made to the remaining precordial leads and to limb leads to account for the impact to the STT resulting from abnormal terminal left ventricular activation.
Intraventricular Conduction Delay	IVCD	Primary confounder for identification of anterior and inferior AMI due to STT abnormalities that can have wide ranging manifestations.
Left Anterior Fascicular Block	LAFB	Minor adjustments are made to the baseline limb lead measurements to account for the repolarization effects arising from the conduction abnormality.
Left Ventricular Hypertrophy	LVH	Adjustments are made to both limb and precordial lead STJ measurements proportional to the severity of hypertrophy effect as evidenced by the amplitudes of R-waves and S-waves.
Right Ventricular Hypertrophy	RVH	
Bi-Ventricular Hypertrophy	BVH	
Right Atrial Enlargement	RAE	Adjustments are made to the baseline limb lead measurements to account for the effect RAE has in the isoelectric point preceding the QRS onset. The degree of adjustment is proportional to the P-wave amplitude in the inferior limb lead.

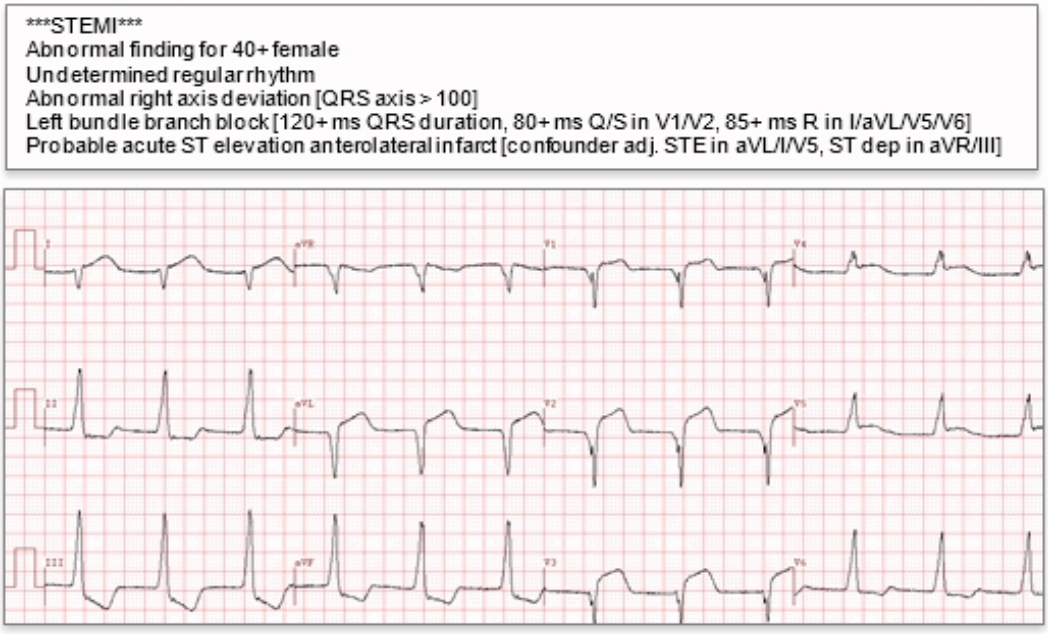
LBBB Reference Example: AMI Negative

Clinical Workup	ECG Interpretation
Negative cardiac enzymes and negative angiographic findings.	ST elevation in leads V1-V3 meets STEMI guideline thresholds. However, confounder adjustments to STJ measurements reveals this abnormal ST elevation to result from LBBB rather than from anterior AMI, thereby preventing a false positive AMI finding.



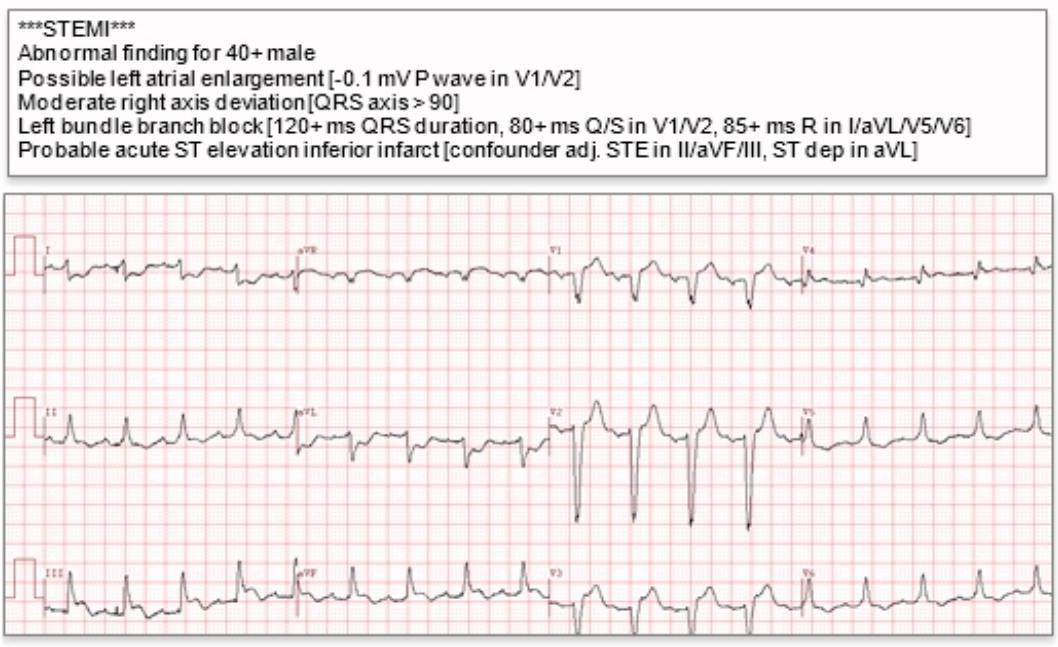
LBBB STEMI Example #1: Anterolateral AMI

Clinical Workup	ECG Interpretation
Positive cardiac enzymes and angiographic finding of LAD occlusion.	ST elevation in leads V2-V5 and leads aVL/I meet STEMI guideline thresholds. However, confounder adjustments to STJ measurements resulted in highest confidence that STE in the anterolateral leads was due to AMI rather than LBBB and that STE in septal leads V2-V3 may or may not be due to AMI.



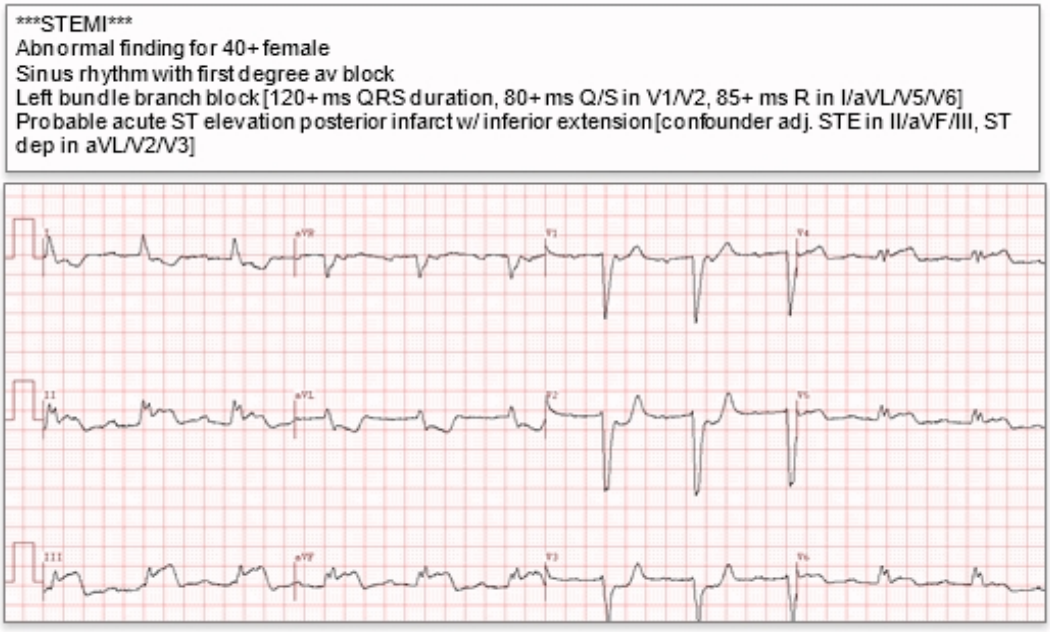
LBBB STEMI Example #2: Inferior AMI

Clinical Workup	ECG Interpretation
Positive cardiac enzymes and angiographic finding of RCA occlusion.	ST elevation in leads V1-V3 meets STEMI guideline thresholds but confounder adjustments reveals this STE to be due to LBBB and not AMI. ST Elevation in the inferior leads also meets STEMI thresholds. Since the ST segment is expected to deflect opposite from the larger of R or S waves, confounder adjustments in this instance increases the inferior lead STE and increases confidence that the abnormal STE is due to inferior AMI.



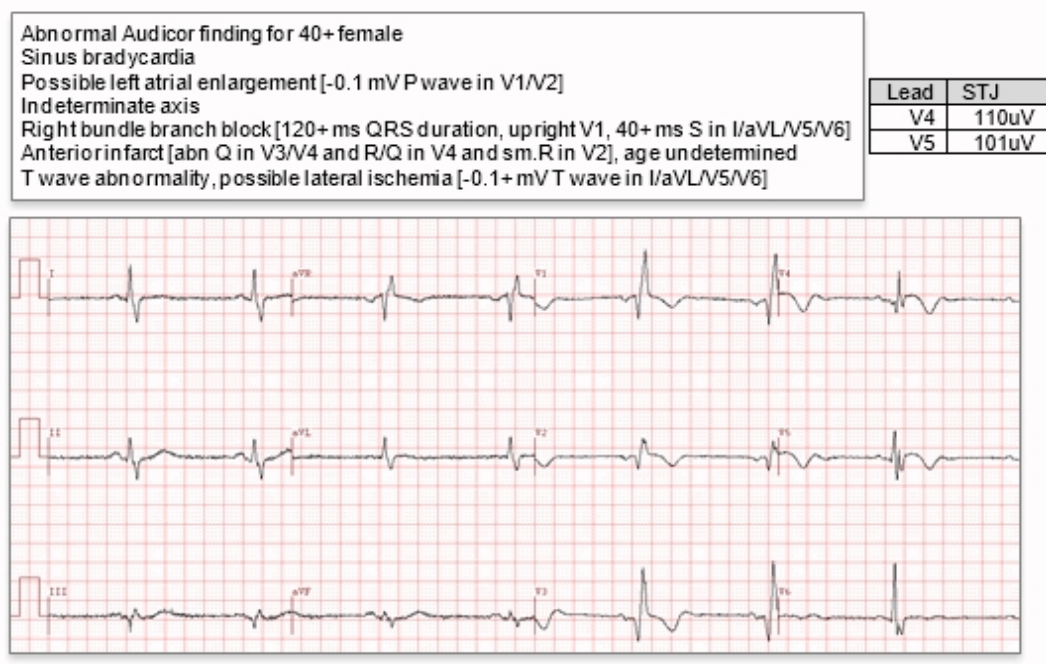
LBBB STEMI Example #3: Posterior-Inferior AMI

Clinical Workup	ECG Interpretation
AMI confirmed by abnormal cardiac enzyme levels and discharge diagnosis.	There is clear evidence for STEMI in the inferior leads. In addition, the ST depression in leads V2-V3 meets criteria for posterior wall STEMI. Since LBBB is associated with ST elevation in those leads, ST depression increases confidence of posterior wall AMI.



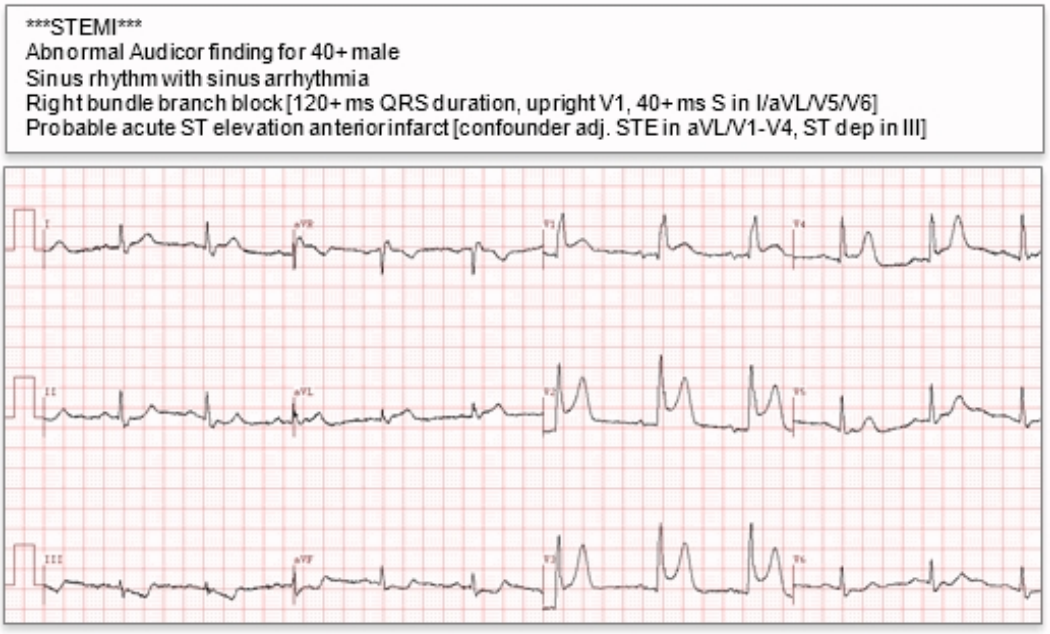
RBBB Reference Example: AMI Negative

Clinical Workup	ECG Interpretation
Negative cardiac enzymes and positive history for chronic MI.	ST elevation in leads V4-V5 meets STEMI guideline thresholds. However, confounder adjustments to these measurements reduces the magnitude, resulting in no AMI interpretation being produced, preventing a false positive AMI finding.



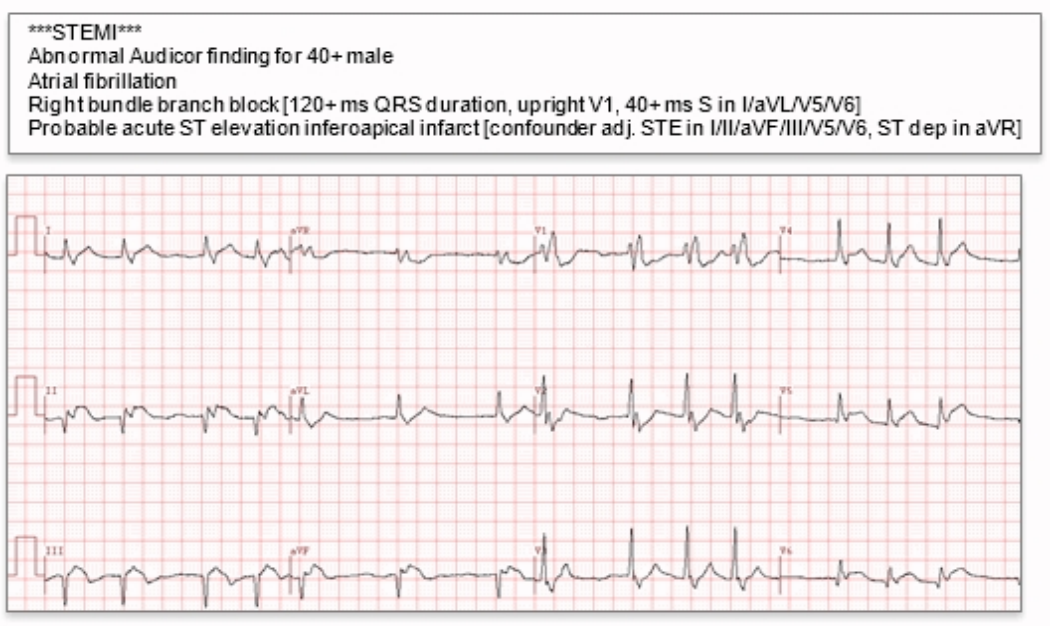
RBBB STEMI Example #1: Anterior AMI

Clinical Workup	ECG Interpretation
Positive cardiac enzymes and angiographic finding of severe 3-vessel disease.	ST elevation in leads V2-V4 meet STEMI guideline criteria. Since RBBB is associated with ST depression in these leads, confounder adjustments increase the magnitude of STJ measurements, thereby confirming the anterior AMI interpretation.



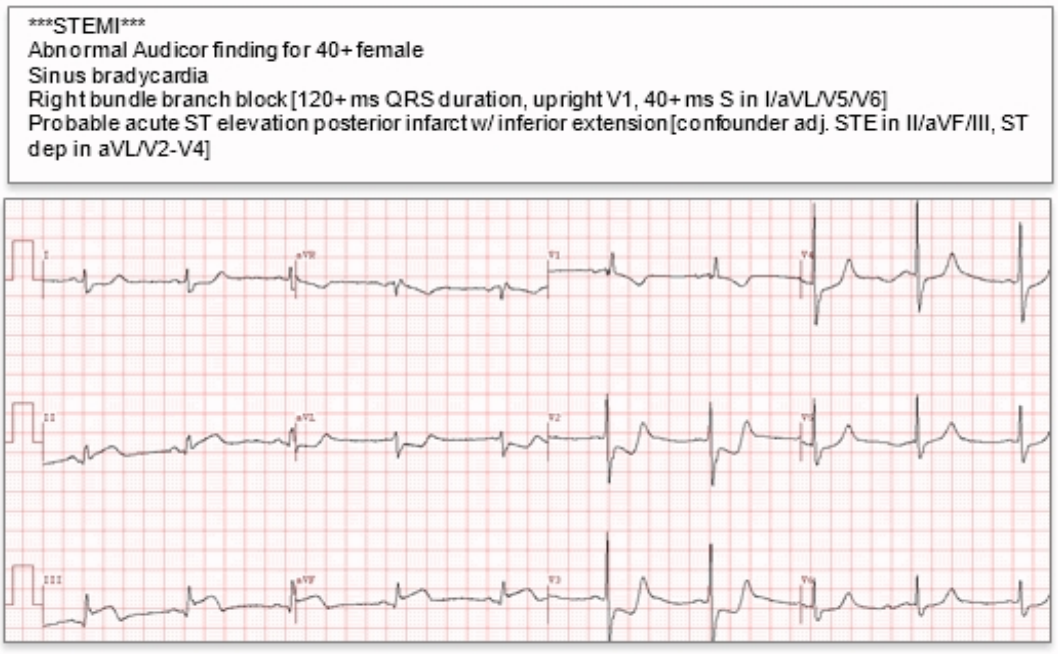
RBBB STEMI Example #2: Inferior AMI

Clinical Workup	ECG Interpretation
Positive cardiac enzymes and angiographic finding of RCA occlusion.	Confounder-adjusted inferior lead STE remains sufficient to meet STEMI thresholds. This results in the Inovise algorithm interpreting an inferior wall AMI.



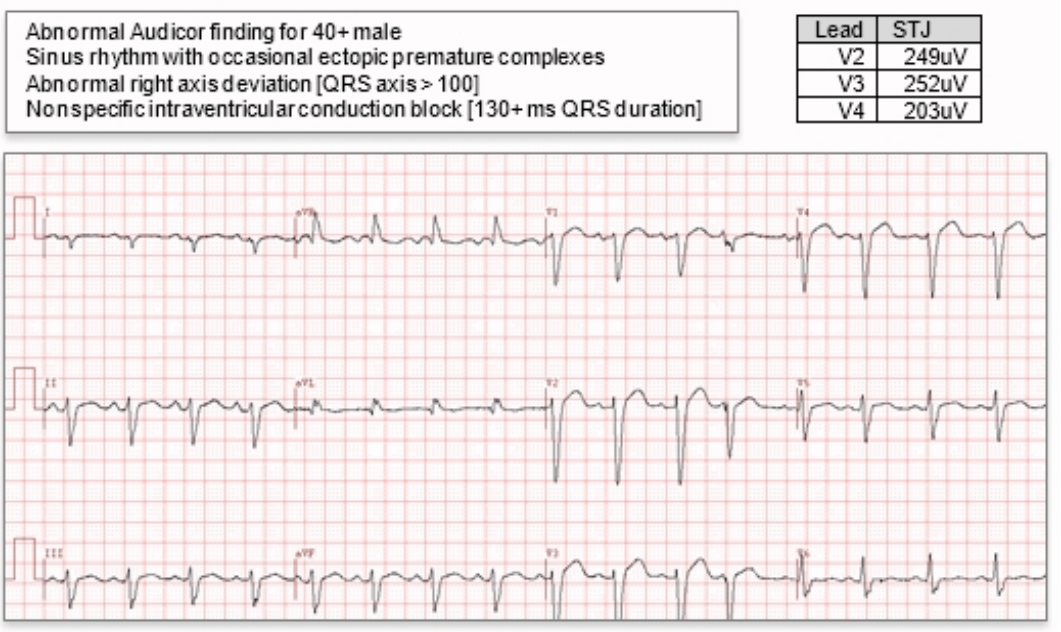
RBBB STEMI Example #3: Posterior-Inferior AMI

Clinical Workup	ECG Interpretation
AMI confirmed by positive cardiac enzymes.	Inferior and posterior ST elevation meets STEMI guideline thresholds. The posterior STE resulting from RBBB is normalized, leaving STE sufficient for interpreting AMI. Confounder adjusted STE in the inferior leads also meets STEMI thresholds resulting in an AMI interpretation that includes both posterior and inferior walls.



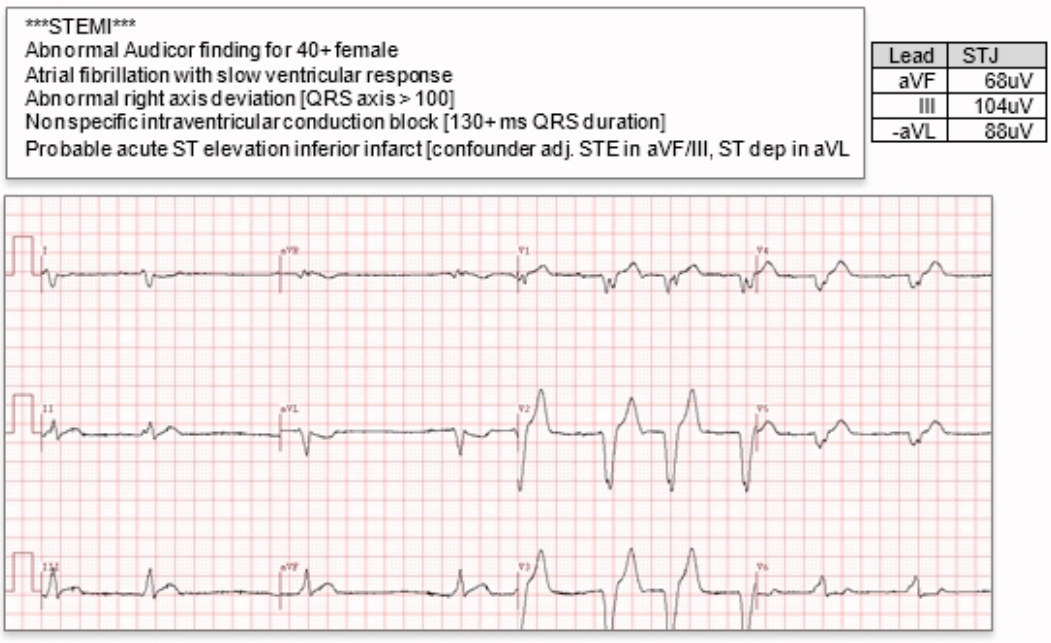
IVCD Reference Example: AMI Negative

Clinical Workup	ECG Interpretation
Negative cardiac enzymes and negative history for MI.	ST elevation in leads V2-V4 meets STEMI guideline thresholds. However, the Inovise algorithm normalized these measurements to account for the effect of the conduction abnormality, preventing a false positive STEMI interpretation.



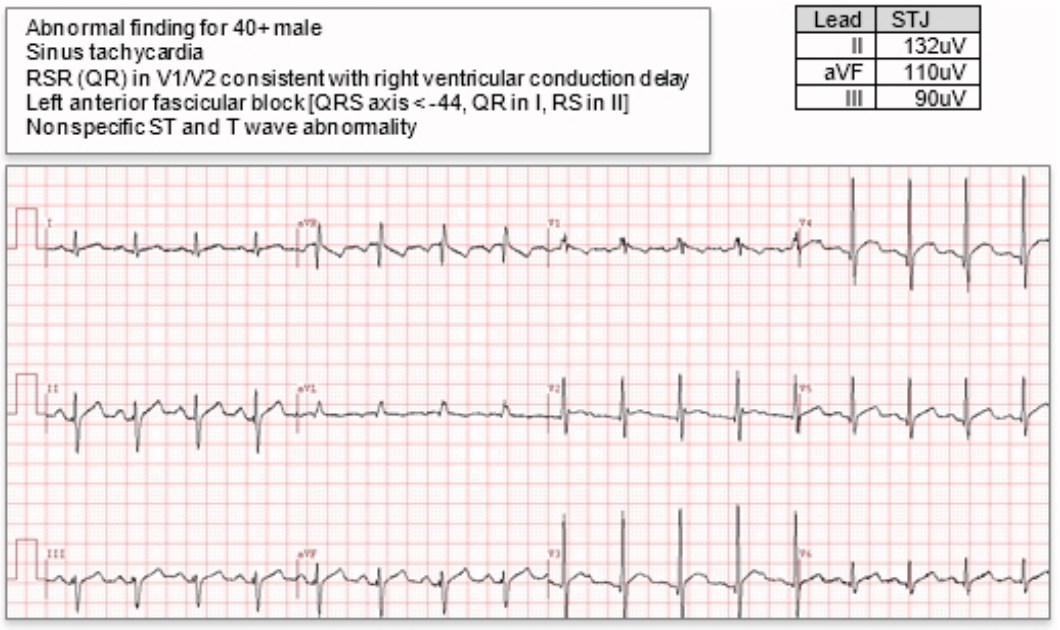
IVCD STEMI Example: Inferior AMI

Clinical Workup	ECG Interpretation
Positive cardiac enzymes and angiographic finding of RCA occlusion.	Anterior STE in leads V2-V3 meets STEMI guideline thresholds. However, much of this STE is a consequence of IVCD. Once the effect of IVCD is accounted for, there remains no evidence for anterior AMI. Inferior lead STE does not meet STEMI thresholds. However, normalized STJ measurements in those leads were of a larger magnitude, resulting in an Inferior STEMI interpretation.



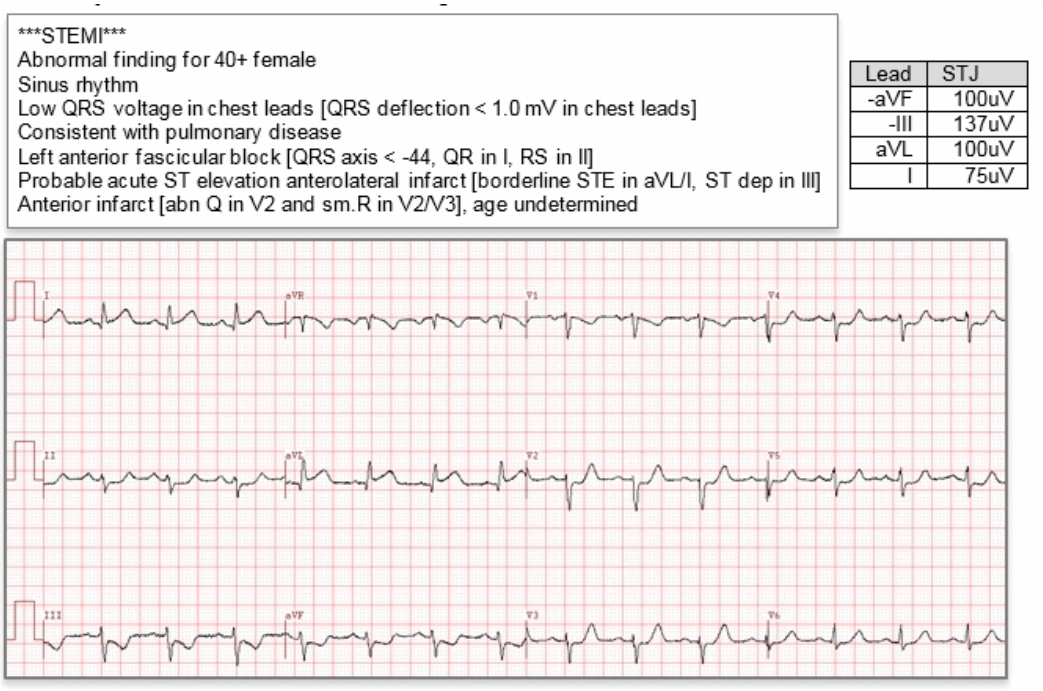
LAFB Reference Example: AMI Negative

Clinical Workup	ECG Interpretation
Negative cardiac enzymes and negative history for MI.	ST elevation in the inferior leads meets STEMI guideline thresholds. However, the Inovise algorithm's normalized ST measurements result in no AMI interpretation, preventing a false positive STEMI.



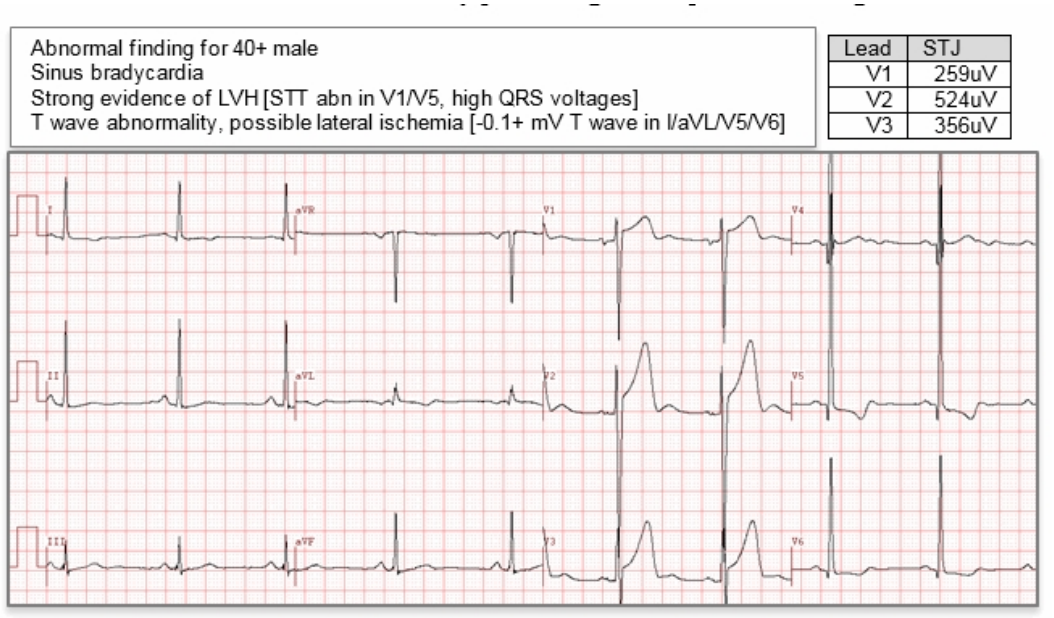
LAFB STEMI Example: Anterior AMI

Clinical Workup	ECG Interpretation
Positive cardiac enzymes and angiographic finding of occluded 1st diagonal branch of the LAD.	ST elevation in anterolateral leads –III/aVL just meets STEMI guideline thresholds. Normalized STJ measurements in these leads increases the ST elevation raising the certainty of the anterolateral AMI interpretation.



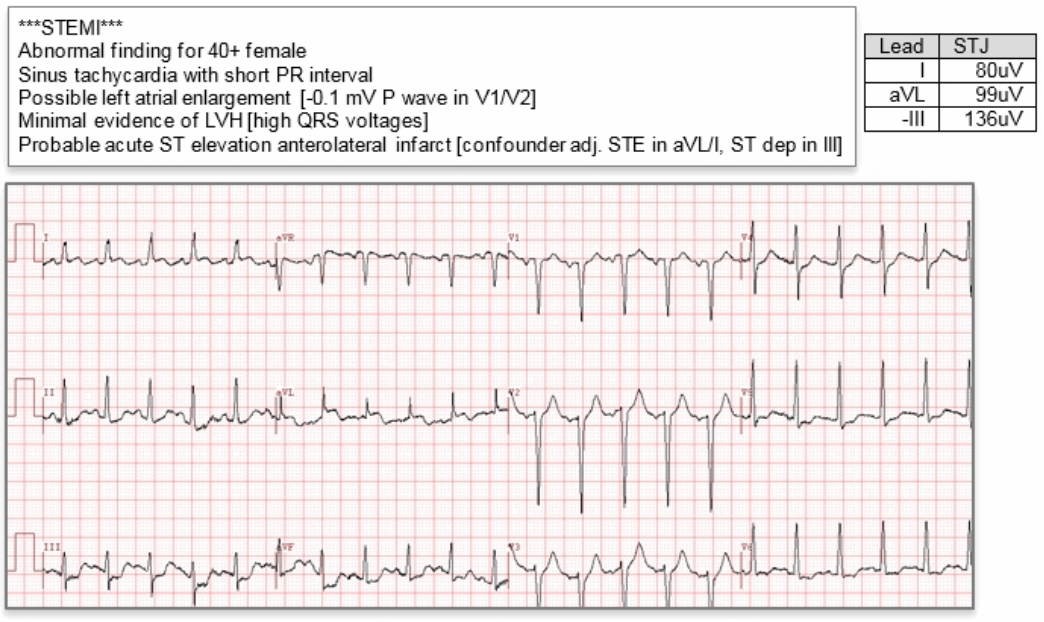
LVH Reference Example: AMI Negative

Clinical Status	ECG Interpretation
Ambulatory normal without chest pain or history of MI.	STJ in anterior leads V1-V3 meets guideline thresholds for STEMI. However, the very strong ECG evidence for LVH suggests this anterior STE is more likely attributable to LVH than to AMI. The Inovise algorithm's normalized ST measurements were insufficient to make an AMI call, thereby preventing a false positive finding.



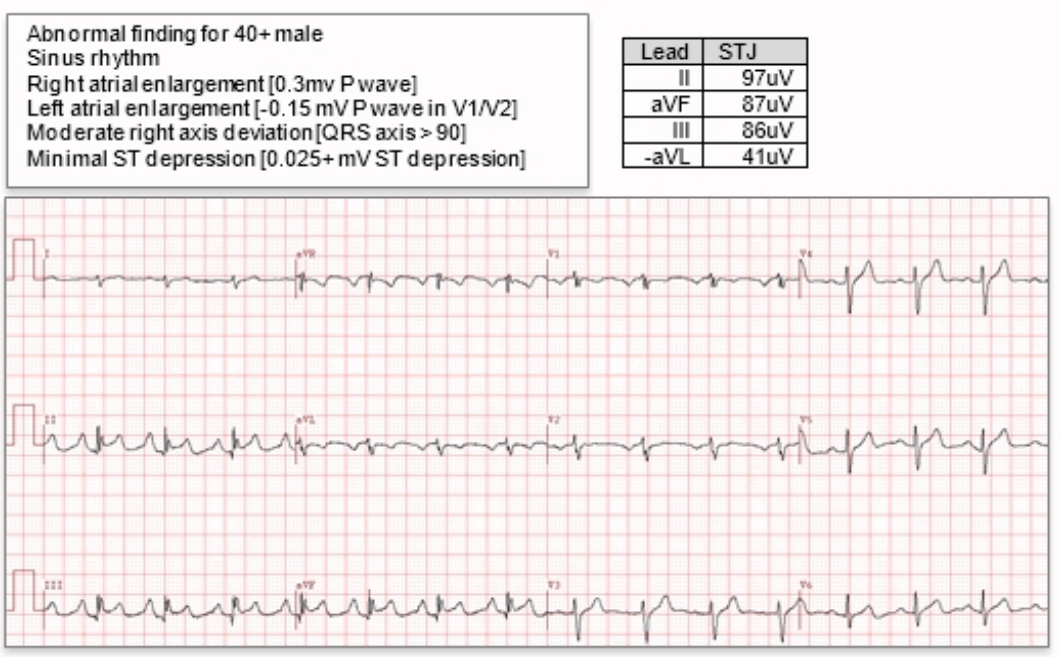
LVH STEMI Example: Anterolateral AMI

Clinical Status	ECG Interpretation
Positive cardiac enzymes and angiographic finding total occlusion of the 1st diagonal branch of the LAD.	There is insufficient STE in leads V1-V3 to lead to an AMI interpretation. However, leads aVL & I exhibit STE where the effects of LVH generally produces ST depression. As a result of normalizing ST measurements for LVH, STE in these leads, combined with ST depression in lead III, resulted in an anterolateral AMI interpretation.



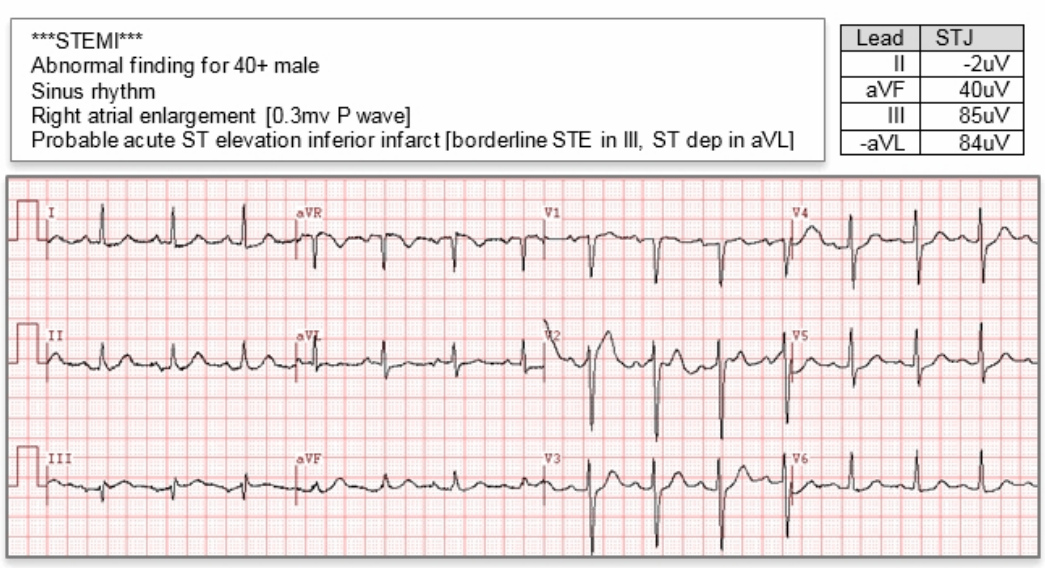
RAE Reference Example: AMI Negative

Clinical Status	ECG Interpretation
Negative cardiac enzymes and negative angiographic findings for ischemic heart disease.	STJ measurements in the inferior leads describe a localizing pattern of ST elevation that nearly meets STEMI criteria, suggesting “probable AMI”. However, the isoelectric point (zero point for measuring ST elevation) of the inferior leads is deflected downward in response to the very large amplitude P-waves, thereby resulting in exaggerated STJ elevation measurements. When confounder adjustments are applied, the normalized STJ is insufficient to produce an AMI interpretation, preventing a false positive finding.



RAE STEMI Example: Inferior AMI

Clinical Status	ECG Interpretation
Positive cardiac enzymes and discharge diagnosis confirm AMI status.	While the ECG meets criteria for RAE, there is insufficient P-wave amplitude to have a measurable effect on the isoelectric point. As a result, the measured STJ is very close to STEMI thresholds, resulting in an appropriate finding of probable STEMI.



Chronic Myocardial Infarction

The Inovise algorithm produces a finding “infarct, age-undetermined” for the clinical case of chronic MI. The reasoning for this phrasing is that it is algorithmically difficult, with high accuracy, to distinguish between sub-acute MI (3-5 days post CP onset), recent MI (5 days-2 weeks), and old MI (> 2 weeks). When there is quantitative ECG evidence that the infarcted region of the left ventricle exceeds 25%, a size qualifier of “large” is added to the interpretive statement. A number of research-validated clinical and angiographic databases of patients confirmed for status of acute and/or chronic myocardial infarction were used in the development and validation of the Inovise algorithm.* Criteria were constructed on the basis of clinical understandings of the anatomy and pathophysiology of myocardial infarction.

The Inovise algorithm evaluates patterns of QRS and ST-T abnormalities through computerized measurements of digitized resting 12SL waveforms. The age-undetermined portion of the Inovise algorithm combines scalarcardiographic QRS criteria derived from the Selvester QRS Scoring System** with additional scalarcardiographic QRS criteria, T-wave criteria and vectorcardiographic QRS criteria. Parameters for the Inovise algorithm include variants and combinations of R-wave amplitudes, R-wave to Q-wave amplitude ratios, R-wave to S-wave amplitude ratios, Short R-wave duration, Long R-wave duration, and Q-wave then R-wave pattern.

Database sources include university-affiliated institutions renowned in the field of cardiovascular research, including: Long Beach Memorial Medical Center, Wake Forest University – Bowman Gray School of Medicine, Medical College of Virginia, and Rancho Los Amigos Medical Center.

The Selvester QRS Scoring System is based on the documented spread of electrical activation through normal human hearts and the effects of infarcts in the distributions of the three major coronary arteries. It utilizes measurements of diagnostically relevant portions of the QRS complex in various leads of the scalar ECG to identify infarcts in one or more portions of the left ventricle, and incorporates a method for estimating location and size. The System was developed using computer simulations and validated using quantitative pathoanatomical studies.

Categories of Findings, Age-Undetermined MI (AUMI)

An Inovise algorithm finding of age-undetermined MI appears when there are QRS abnormalities consistent with MI, but insufficient STT abnormalities to indicate that the MI is in an acute, evolving stage. An age-undetermined MI could be an MI that is at the end-stages of evolution or one which has already evolved to be a chronic, healed MI.

Findings for the age-undetermined portion of the Inovise algorithm are divided into two categories: infarcts of unspecified size, and infarcts of large size.

- Age-undetermined MI, Category 1: Infarcts of unspecified size.

  This is an age-undetermined infarct with QRS abnormalities consistent with less than 25% involvement of the left ventricle.

- Age-undetermined MI, Category 2: Infarcts of large size.

  This is an age-undetermined infarct with QRS abnormalities consistent with more than 25% involvement of the left ventricle.

Category 1 – Infarcts of Unspecified Size

These are age-undetermined infarcts with less than 25% infarction of the left ventricle. Statements of findings for Category 1, Infarcts of Unspecified Size, are reported in the following general format :< {Location} Infarct, Age Undetermined >

Statement
Anterior Infarct, Age Undetermined
Posterior Infarct, Age Undetermined
Inferior Infarct, Age Undetermined
Apical Infarct, Age Undetermined
Anterolateral Infarct, Age Undetermined
Anteroapical Infarct, Age Undetermined
Anterior-Posterior Infarct, Age Undetermined
Anterior-Interior Infarct, Age Undetermined
Inferior Infarct w/ Posterior Extension, Age Undetermined
Posterior Infarct w/ Inferior Extension, Age Undetermined
Anterior-Interior Infarct w/ with Posterior Extension, Age Undetermined
Inferoapical Infarct, Age Undetermined
Posterior-Anterolateral Infarct, Age Undetermined

Category 2 – Infarcts of Large Size

These are age-undetermined infarcts with more than 25% infarction of the left ventricle. Statements of findings for Category 2, Infarcts of Large Size, are reported in the following general format: < Large {Location} Infarct, Age Undetermined >

Statement
Large Inferior Infarct, Age Undetermined
Large Anterior-Posterior Infarct, Age Undetermined
Large Anterior-Inferior Infarct, Age Undetermined
Large Anteroapical Infarct, Age Undetermined
Large Posterior Infarct w/ Inferior Extension, Age Undetermined
Large Inferior Infarct w/ Posterior Extension, Age Undetermined
Large Anterior-Interior Infarct with Posterior Extension, Age Undetermined
Large Inferoapical Infarct, Age Undetermined

Reasons Associated with Age-Undetermined MI

Reasons for the age-undetermined findings are printed in parentheses, following the relevant statements for MI.

The age-undetermined portion of the Inovise algorithm presents the statements of rationale listed in the following table, in concert with statements of findings, as applicable, under Analysis Results in the ECG strip chart. There may be more than one reason for a particular finding of age-undetermined MI.

Statements of Rationale for Age-Undetermined MI

Statement	
[ABN LG.R/S in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Narrow R in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Notched R in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Q in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Q,R/Q in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Q-R in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN R/Q in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN SM.Q&S in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN SM.R in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN SM.R/S in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Wide R in {ECG Lead Designation}	*<with {Location] Ischemic T>]*
[ABN Minimal Initial Anterior Vector	
[ABN Inferior Q's	

Key to Abbreviations:

- *ABN*: Abnormal
- *Ischemic T*: T-wave abnormality indicative of residual ischemia in same location as infarct
- *LG*: Large
- *Q*: Q-wave duration
- *Q-R*: Pattern of Q-wave followed by R-wave
- *Q&S*: Q-wave amplitude and S-wave amplitude
- *R*: R-wave
- *R/Q*: Ratio of R-wave amplitude to Q-wave amplitude
- *R/S*: Ratio of R-wave amplitude to S-wave amplitude
- *S*: S-wave
- *SM*: Small

Excluding and Error Conditions for MI Analysis

The Inovise algorithm aborts its analysis if excluding or error conditions for MI analysis are present. The Inovise algorithm displays any excluding or confounding conditions under Analysis Results.

Excluding Conditions for MI Analysis

The Inovise algorithm aborts its analysis if one of the following excluding conditions for MI analysis are present:

Excluding Condition	Abbreviation
Arm Leads Reversed	*ALR*
Atrial Flutter	*AFLUT (Acute MI only)*
Left Bundle Branch Block	*CLBBB (AUMI only)*
Dextrocardia	*DXT*
Heart Rate >200 bpm	*HR>200*
QRS Duration < 50 ms	*QRSD<50*
PR Interval < 120 ms	*SHPR*
Possible Ventricular Pacemaker	*PossVP*
Ventricular Pacing	*VP*
Ventricular Rhythm	*VR*
Ventricular Tachycardia	*VT*
Wolff Parkinson White Syndrome	*WPW*

Error Conditions for MI Analysis

The Inovise algorithm aborts its analysis if one of the following error conditions for MI analysis are present:

Error Condition	Meaning
Data quality limits analysis	Electrical (ECG) signal is insufficient (a lead is not well connected to an electrode, or the signal quality is poor) to perform acute age-undetermined MI analysis.
No data available due to insufficient ECG data from lead fault or invalid cable type	

Chapter 3
Non-Myocardial Infarction Analysis Statements

This chapter describes the non-myocardial infarction analysis statements that the Inovise 12L Interpretive Analysis Algorithm (Inovise algorithm) provides, gives the criteria to which the ECG data must conform to generate the statements, and provides the rationale from which each statement derived.

Arm Lead Reversal and Dextrocardia

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for Arm Lead Reversal and Dextrocardia.:

If	Then
No Q in lead I and R amplitude < 150uV in lead I or Q amplitude > 0 in lead I and P axis > 90 and PR duration >= 110 ms and QRS axis > 90	DISPLAY/PRINT: Arm leads reversed REASON: Inverted P & QRS in lead I
If above criteria are met and R amplitude < 500 uV in lead V6 and Maximum S amplitude > Maximum R amplitude in lead V6 and P amplitude < 20 uV in lead V6 and P' amplitude < -20 uV in lead	DISPLAY/PRINT: *Dextrocardia* REASON: Inverted P & QRS in V6

Rationale

Simultaneously negative P and QRS contours in lead I are unlikely in a properly recorded ECG. If, in addition, the QRS has a Qr (or rSr') configuration, the most probable explanation is that the arm leads are reversed or dextrocardia is present. If lead V6 has a typical upright configuration, arm lead reversal is more likely: otherwise, dextrocardia is the remaining plausible explanation.

Although the reason statement for both lead reversal and dextrocardia mentions only the inverted P & QRS, the requirement of a Qr/rSr' morphology is important to distinguish these cases from pulmonary disease and right ventricular hypertrophy patterns, where rS configurations are the norm. (Further separation from the latter is ensured by the requirement of an inverted P.).

Wolff-Parkinson-White

The Inovise algorithm will only present a Wolff-Parkinson-White Analysis Statement if the following criteria is not met:

Skip This Test If
The test for coupled P wave to QRS is negative
or PR duration > 170 ms
or QRS duration < 100 ms
or Heart rate > 120 BPM
or QRS duration > 200 ms
or PR duration > 100 ms and QRS duration > 160 ms

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for Wolff-Parkinson-White:

If	Then
PR duration < 140 ms and Delta wave is present in 2 leads	DISPLAY/PRINT: *Atypical Wolff-Parkinson-White Pattern*
Delta wave is present in 2 leads and R amplitude > S amplitude in V1	DISPLAYPRINT: *Type A Wolff-Parkinson-White Pattern*
QRS area ratio >= 0.6 in 2 leads of I/V5/V6 and R duration > 30 ms in V2 or Delta wave is present in 2 leads and PR duration is < 140 ms and R amplitude <= S amplitude in V1	DISPLAYPRINT: *Type B Wolff-Parkinson-White Pattern*

Atrial Enlargement

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for atrial enlargement:

If	Then
Heart rate < 120 and P amplitude > 250 uV in any 1of leads II/III/aVF/V1/V2	DISPLAY/PRINT: *Possible right atrial enlargement* REASON: 0.25 mV P wave
Heart rate < 120 and P amplitude > 300 uV in any 1 of leads II/III /aVF/V1/V2	DISPLAY/PRINT *Right atrial enlargement* REASON: 0.3 mV P wave
P' amplitude < -100 uV in V1 or V2 and negative P wave area >= 400 uV/ms in the same lead	DISPLAY/PRINT: *Possible left atrial enlargement* REASON: -0.1 mV P wave in V1/V2
P' amplitude < -150 uV in V1 or V2 and negative P wave area >= 600 uV/ms in the same lead	DISPLAY/PRINT: *Left atrial enlargement* REASON: -0.15 mV P wave in V1/V2

Rationale

The criteria are the customary ones. For those records meeting only minimal criteria, the qualifier "possible" is used to convey this information. Right atrial enlargement is not "read" for rates of 120 or above, because it is unclear whether increased P amplitude at elevated rates should be attributed to enlargement.

Axis Deviation

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for QRS axis deviation:

If	Then
QRS axis < -20	DISPLAY/PRINT: *Moderate Left axis deviation* REASON: QRS axis < -20
QRS axis < -30	DISPLAY/PRINT: *Abnormal Left axis deviation* REASON: QRS axis < -30
QRS axis > 90	DISPLAY/PRINT: *Moderate Right axis deviation* REASON: QRS axis > 90
QRS axis >100	DISPLAY/PRINT: *Moderate Right axis deviation* REASON: QRS axis > 90
The total net QRS amplitude in leads I, II, and III is < 33% of the total QRS deflection in leads I, II, and III.	DISPLAY/PRINT: *Indeterminate axis*

Rationale

The criteria are more or less conventional. Borderline cases are characterized by the use of the term “moderate.” (Axis deviation statements are omitted when subsequently identified diagnostic categories may be regarded as the probable cause of the axis deviation.)

Whenever the net amplitude is a small fraction of the total QRS deflection in each lead, the measurement of axis is lacking in meaning. The term “indeterminate axis” is used to convey this information.

Low Voltage

The Inovise algorithm will only present a Low Voltage Analysis Statement if the following criteria is not met:

Skip This Test If
QRS duration >= 120 ms

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for low voltage in the heart:

If	Then
Total QRS deflection < 500 uV in all limb leads	DISPLAY/PRINT: *Low QRS voltage in limb leads* REASON: QRS deflection < 0.5 mV in limb leads
Total QRS deflection < 1000 uV in all V leads	DISPLAY/PRINT: *Low QRS voltage in chest leads* REASON: QRS deflection < 1.0 mV in chest leads
If both of the above are true	DISPLAY/PRINT: *Low QRS voltage* REASON: QRS deflection < 0.5/1.0 mV in limb/chest leads

S1-S2-S3 Pattern

The statement *S1-S2-S3 Pattern* refers specifically to prominent S waves in leads I, II, & III of the electrocardiogram.

Note: This should not be confused with the statement *S3 detected*.

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for S2-S2-S3 pattern:

If	Then
S amplitude > 300 uV in I and S amplitude > 400 uV in II and S amplitude > 700 uV in III or S amplitude > R amplitude in leads I, II & III and S amplitude > 200 uV in leads I, II & III and the test for R' is negative in any of these leads and age > 15	DISPLAY/PRINT: *S1-S2-S3 pattern, consistent with pulmonary disease, RVH, or normal variant*

Pulmonary Disease

The Inovise algorithm will only present a Pulmonary Disease Analysis Statement if the following criteria is not met:

Skip This Test If
QRS duration >= 120 ms

Criteria

The test for pulmonary disease is based on counting how many of its typical characteristics are present.

One point is awarded for each of

- Right atrial enlargement
- RRS axis < -30
- QRS axis > 90
- QRS axis is indeterminate
- S1-S2-S3 pattern
- Low voltage in limb leads
- Low voltage in chest leads

Three points are awarded if QRS net amplitude is negative in lead V5 and the R (and R') amplitude in V6 < 500 uV.

If	Then
Cumulative points > 3	DISPLAY/PRINT: *Consistent with pulmonary disease*

Rationale

There is room to doubt whether sufficient ECG criteria exist to diagnose pulmonary disease. However, if at least 4 (from a list of 8 distinct) features common to pulmonary disease are present, then the comment "consistent with" seems prudent.

Right Bundle Conduction

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for defects in conduction in the right ventricle:

If	Then
R amplitude > 100 uV in V1 & V2 and R duration > 20 ms in V1 and V2 and no S in V1 or V2 or R' amplitude > 100 uV in V1 & V2 and R' duration > 20 ms in V1 & V2 and no S' in V1 or V2	DISPLAY/PRINT: *RsR' (QR) in V1/V2 consistent with right ventricular conduction delay*
Either of the above is true and QRS duration > 90 ms and QRS duration < 120 ms and S duration >= 40 ms in any 2 leads of I/aVL/V4/V5/V6	DISPLAY/PRINT: *Incomplete right bundle branch block* REASON: 90+ ms QRS duration, terminal R in V1/V2, 40+ ms S in I/aVL/V4/V5/V6
QRS duration >= 120 ms and S duration >= 40 ms in any 2 leads of I/aVL/V4/V5/V6 and R duration < 100 ms in any 4 leads of I/aVL/V4/V5/V6 and QRS area > 0 in V1 and V1 does not terminate in S or S' or QRS duration > 105 ms and S duration >= 60 ms in any 3 leads of I/aVL/V4/V5/V6 and R duration > 60 ms in V1 and QRS area > 0 in V1	DISPLAY/PRINT: Right bundle branch block REASON: 120+ ms QRS duration, upright V1, 40+ ms S in I/aVL/V4/V5/V6
The test for right bundle branch block is positive and R amplitude > 1500 uV in V1 and QRS axis > 110	DISPLAY/PRINT: *Right bundle branch block plus possible Right Ventricular Hypertrophy* REASON: RBBB, 1.5 mV R in V1, RAD

Rationale

Right bundle branch conduction abnormalities exhibit anterior and rightward-directed terminal forces. The rightward force should be noticeably prolonged. Thus, in addition to QRS conducting time criteria, tests are included for a widened terminal R wave in V1 and widened terminal S waves in at least two of the lateral leads.

Conventional criteria require QRS widths in excess of 0.12 seconds for bundle branch block. However, very wide lateral S waves, a wide R in an upright V1, and a QRS duration > 105 ms will also be read as right bundle branch block by most interpreters.

This is the basis of the second portion of the complete right bundle branch block test. Specific criteria for right bundle branch block + right ventricular hypertrophy are also included.

Left Bundle Conduction

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for defects in conduction in the left ventricle:

If	Then
QRS duration > 105 ms and QRS net amplitude < 0 in V1 & V2 S duration >= 80 ms in V1 & V2 and no Q is present in 2 leads of I/V5/V6 and R duration >= 60 ms in 2 leads of I/aVL/V5/V6	DISPLAY/PRINT: *Incomplete left bundle branch block* REASON: 105+ ms QRS duration, 80+ ms Q/S in V1/V2 no Q and 60+ ms R in I/aVL/V5/V6
QRS axis < = -45 and R amplitude > Q amplitude in I & aVL and a Q is present in I and S or S' amplitude > R amplitude in II	DISPLAY/PRINT: *Left anterior fascicular block* REASON: QRS axis < -45, QR in I, RS in II
The test for S1-S2-S3 is negative, and the test for Pulmonary Disease is negative and QRS axis >= 110 and R amplitude > Q amplitude in III & aVF and a Q is present in III & aVF	DISPLAY/PRINT: *Left posterior fascicular block* REASON: QRS axis > 109, inferior Q
The test for Incomplete Left Bundle Branch Block is positive and QRS area ratio > 0.25 in I or V6 and R duration >=100 ms in 1 lead of I/aVL/V6 and QRS duration >= 160 ms or QRS duration >= 140 ms and the average R duration > 85 ms in I/aVL/V6 or QRS duration >= 120 ms and the average R duration > 85 ms in I/aVL/V6 and QRS area ratio > 0.4 in 2 leads of I/aVL/V6	DISPLAY/PRINT: *Left bundle branch block* REASON: 120+ ms QRS duration, 80+ ms Q/S in V1/V2, 85+ ms R in I/aVL/V6

Rationale

The meaning of incomplete left bundle branch block beyond describing an ECG pattern is unknown. For this reason the criteria for this statement are narrowly defined, and whenever a specific label such as left anterior fascicular block is available, the term incomplete left bundle branch block is suppressed.

The test for left bundle branch block introduces a measurement called the “QRS area ratio,” which is defined as the ratio of the QRS area (algebraic) to the area of a rectangle defined by QRS onset and offset and the peak positive amplitude. The area ratio is large whenever the QRS is upright and has a wide or notched R wave peak. The thresholds used in the above left bundle branch block tests are empirically determined to correlate with typical left bundle branch block patterns. The area ratio is used in lieu of R duration in order to better discriminate between true left bundle branch block and a monophasic (upright) QRS with nonspecific terminal slurring of the R wave leading to increased QRS duration.

Strict criteria for fascicular blocks are used. This should be noted by readers who use simple axis deviation tests.

Non-Specific Conduction Abnormality

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for defects in conduction within the heart:

If	Then
The test for Right Bundle Branch Block is negative and The test for Incomplete Right Bundle Branch Block is negative and The test for Left Bundle Branch Block is negative and The test for Incomplete Left Bundle Branch Block is negative and The test for left anterior fascicular block is negative and The test for left posterior fascicular block is negative and The test for RSR Pattern is negative and QRS duration > 110 ms	DISPLAY/PRINT: *Nonspecific intraventricular conduction delay* REASON: 110+ ms QRS duration
The test for Right Bundle Branch Block is negative and The test for Left Bundle Branch Block is negative and QRS duration > 130 ms	DISPLAY/PRINT: *Nonspecific intraventricular conduction block* REASON: 130+ ms QRS duration

Rationale

Intraventricular conduction delay is used to connote QRS widening which does not fit any previously defined pattern, and is not so great as to be considered block.

Right Ventricular Hypertrophy

The Inovise algorithm will only present a Right Ventricular Hypertrophy Analysis Statement if the following criteria is not met:

Skip This Test If
The test for Right Bundle Branch Block is positive
or the test for Left Bundle Branch Block is positive
or S amplitude < 250 uV in I
or S amplitude > 1000 uV in V1
or QRS axis < 60
or QRS duration > 140 ms and net QRS amplitude < 0 in V1
or Q amplitude > S amplitude and R exists in I

Criteria

The test for right ventricular hypertrophy is based on counting how many of (or in what degree) its common characteristics are present.

One point is awarded for each of:

- R/R' amplitude > 500 uV in V1
- Net QRS amplitude > 0 in V1
- Net QRS amplitude > 500 uV in V1
- Net QRS amplitude < 0 and S amplitude > 500 uV in V5 or V6
- QRS axis >= 90
- QRS axis >= 100
- QRS axis >= 110
- Possible right atrial enlargement has been called
- S1, S2, S3 is present
- Age > 30

If Indeterminate Axis is true, no points are given for QRS axis.

If	Then
Cumulative points > 3	DISPLAY/PRINT: *Possible right ventricular hypertrophy* REASON: Some/all of: prominent R in V1, late transition, RAD, RAE, SSS
Cumulative points > 5	DISPLAY/PRINT: *Right ventricular hypertrophy* REASON: Some/all of: prominent R in V1, late transition, RAD, RAE, SSS
The test for possible right ventricular hypertrophy is positive and STJ > STM > STE or one of (STM, STE, and T) < -100 uV in V1, V2, and V3 and QRS duration < 120 ms	DISPLAY/PRINT: *Right ventricular hypertrophy with repolarization abnormality* REASON: Some/all of: prominent R in V1, late transition, RAD, RAE, SSS, right precordial ST depression

Note: STJ = ST segment amplitude at QRS offset; STM = ST segment amplitude at ST segment midpoint; STE = ST segment amplitude at ST segment endpoint; T = peak of the T wave.

Left Ventricular Hypertrophy

While most ECG criteria for detection of Left Ventricular Hypertrophy (LVH) are based primarily on high QRS voltages in precordial leads V1, V5, V6, and aVL, the Inovise algorithm also incorporates criteria such as STT abnormalities and QRS duration. The Inovise algorithm's LVH algorithm uses a gender-specific linear regression formula to produce a value proportional to the left ventricular mass. Evidence of LVH (reported as minimal, moderate, or strong) is then determined on the basis of the linear regression output relative to certain thresholds, and is thereafter adjusted, as applicable, on the basis of other factors (e.g., positive T wave in V4) and confounding conditions.

The Inovise algorithm's LVH algorithm was developed using several research-validated clinical databases, all with an echocardiogram M-mode (Penn convention) gold standard, some with an additional cardiac magnetic resonance imaging confirmation of LVH, and all with significant female patient populations.

Note: Database sources include university-affiliated institutions renowned in the field of cardiovascular research, including: Cornell University Medical Center, Long Beach Memorial Medical Center, University of California - San Francisco and Beth Israel Medical Center.

Findings for LVH

The LVH algorithm presents the following statements of findings, as applicable, under *Analysis Results*.

Statement of Findings for LVH
Minimal Evidence of LVH
Moderate Evidence of LVH
Strong Evidence of LVH
High QRS Voltages in one of R(aVL), S(V1), R(V5), R(V5/V6)+S(V1), May be Normal Variant

Reasons behind Findings for Evidence of LVH

Reasons for the LVH findings are displayed within brackets, following the statement for LVH.

Reasons are gender specific. Also, there may be more than one reason for a particular finding of evidence of LVH.

Statements of Rationale for Men

Statement of Rationale for Men
[Increased QRS Area]
[STT ABN in V1]
[STT ABN in V5]
[STT ABN in V1/V5]
[High QRS Voltages]
[QRS Widening]

Statements of Rationale for Women

Statement of Rationale for Women
[Increased QRS Area]
[STT ABN in I]
[STT ABN in V6]
[STT ABN in I/V6]
[High QRS Voltages]
[QRS Widening]

Excluding Conditions for LVH

The Inovise algorithm's LVH algorithm aborts its analysis if excluding conditions for LVH are present. The LVH algorithm adjusts its analysis if any confounding conditions for LVH are present.

Excluding Condition	Abbreviation
QRS duration > 140 ms	*QRSD>140*
Left bundle branch block	*CLBBB*
Right bundle branch block	*RBBB*
Arm leads reversed	*ALR*
QRS duration < 50 ms	*QRSD<50*
Dextrocardia	*DXT*
Heart rate > 200 bpm	*HR>200*
PR interval < 120 ms	*SHPR*
Ventricular rhythm	*VR*
Ventricular tachycardia	*VT*
Wolff Parkinson White Syndrome	*WPW*
Ventricular pacing	*VP*
Possible Ventricular Pacemaker	*PossVP*

Early Repolarization

The Inovise algorithm will only present a Early Repolarization Analysis Statement if the following criteria is not met:

Skip This Test If
Corrected QT interval $> \left(450 - \frac{(1000 - RR)}{7}\right)\sqrt{\frac{1000}{RR}}$ ms where *RR* is the RR interval.
Either myocardial infarct, right bundle branch block, left bundle branch block, intraventricular conduction block is present and the left ventricular hypertrophy flag is not set

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for Early Repolarization:

If	Then
Count of leads V1-V6 for which STJ and STM amplitude > 75 uV plus count of leads I, II, III, aVL, aVF for which STJ & STM > 50 uV exceeds 2 and sum of STJ amplitudes > 450 uV for leads passing above test	DISPLAY/PRINT: *ST elevation, consistent with epicardial injury, pericarditis, or early repolarization* REASON: ST elevation w/o normally inflected T wave
ST elevation is present, per the above conditions and more than 1/2 of the leads passing ST elevation test above also have well-inflected T waves	DISPLAY/PRINT: *ST elevation, probably early repolarization* REASON: ST elevation with normally inflected T wave
Above count > 5 and sum > 450 uV	DISPLAY/PRINT: *Early repolarization* REASON: ST elevation with normally inflected T wave

Pericarditis

The Inovise algorithm will only present a Pericarditis Analysis Statement if the following criteria is not met:

Skip This Test If
The test for myocardial infarct, right bundle branch block, left bundle branch block, intraventricular conduction block, left ventricular hypertrophy is positive

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for Pericarditis:

If	Then
4 times STJ & T amplitude & T amplitude > 0 in at least 4 leads of I, II, V4-V6 and STJ and STM amplitude > -100 uV in all leads except aVR and count of leads I, II, aVF with STJ and STM amplitude > 75 uV plus count of leads V2-V6 with STJ and STM amplitude > 90 uV is >= to 5	DISPLAY/PRINT: *Possible acute pericarditis* REASON: Marked ST elevation w/o normally inflected T wave
Possible acute pericarditis is present and count of leads I, II, aVF with STJ and STM amplitude > 90 uV plus count of leads V2-V6 with STJ and STM amplitude > 110 uV is >= to 5	DISPLAY/PRINT: *Acute pericarditis* REASON: Marked ST elevation w/o normally inflected T wave

ST Depression

The Inovise algorithm will only present a ST Depression Analysis Statement if the following criteria is not met:

Skip This Test If
The test for left bundle branch block, intraventricular conduction block, left ventricular hypertrophy with repolarization, or pericarditis is positive

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for ST Depression:

If	Then
The tests for right ventricular hypertrophy with repolarization, ST elevation and right bundle branch block are negativeand STJ amplitude < -100 uV and STE amplitude >= 0 in 2 Leads (except aVR and III)	DISPLAY/PRINT: *Junctional depression, probably normal* **REASON:** 0.1+ mV junctional ST depression
The tests for right ventricular hypertrophy with repolarization, ST elevation, and right bundle branch block are negative and STJ < -100 uV and STE < 0 and STE >= STJ/2 in 2 leads (except aVR and III)	DISPLAY/PRINT: *Abnormal Junctional depression* **REASON:** Junctional depression with weak upslope
The tests for right ventricular hypertrophy with repolarization, ST elevation, and right bundle branch block are negative and STM or STE < both STJ and -50 uV in 2 leads (except aVR and III)	DISPLAY/PRINT: *ST depression, possible digitalis effect* **REASON:** Downsloping or coved ST depression
The tests for right ventricular hypertrophy with repolarization, ST elevation, and right bundle branch block are negative and STJ/STM/STE all < -25 uV in 2 leads (except aVR and III)	DISPLAY/PRINT: *Minimal ST depression* **REASON:** *0.025+ mV ST depression*
The tests for right ventricular hypertrophy with repolarization, ST elevation and right bundle branch block are negative and STM < -50 uV and STE < 0 or STE < all of STJ/ STM -50 uV in 2 leads (except aVR and III)	DISPLAY/PRINT: *Moderate ST depression* **REASON:** 0.05+ mV ST depression
The test for atrial fibrillation is positive and either minimal or moderate ST depression is present or “marked” ST depression w/o .1 + mV ST depression	Append *probably digitalis effect*
The test for atrial fibrillation is positive and there is “marked” ST depression w/o .2 + mV ST depression	Append *or digitalis effect*

ST Segment Elevation

The Inovise algorithm will only present a ST Segment Elevation Analysis Statement if the following criteria is not met:

Skip This Test If
The test for either right bundle branch block, left bundle branch block, intraventricular conduction block, myocardial infarct or left ventricular hypertrophy with repolarization is positive

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for ST Segment Elevation:

If	Then
STJ/STM/STE all >= 50 uV and T is not upward inflected in 2 leads of I, II, III, aVF, V3-V6	DISPLAY/PRINT: *Nonspecific ST elevation* **REASON:** *0.05+ mV ST elevation*

T Wave Abnormality, Ischemia

The Inovise algorithm will only present a T Wave Abnormality, Ischemia Analysis Statement if the following criteria is not met:

Skip This Test If
Left bundle branch block, intraventricular conduction block, left ventricular hypertrophy with repolarization, right ventricular hypertrophy with repolarization, subendocardial injury, ST elevation or pericarditis is (are) true

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for T wave abnormality by Ischemia:

If	Then
The test for anteroseptal infarct is negative and the test for right ventricular hypertrophy with repolarization is negative and Alternate T amplitude <= -100 uV in 2 leads of V2/V3/V4 (excluding V2 if right bundle branch block is present)	DISPLAY/PRINT: *T wave abnormality, possible anterior ischemia* REASON: -0.1+ mV T wave in V3/V4
The test for anterior ischemia is positive and Alternate T amplitude < -500 uV in 1 lead of V2/V3/V4 (excluding V2 if right bundle branch block is present)	DISPLAY/PRINT: *T wave abnormality, consistent with anterior ischemia* REASON: -0.5+ mV T wave in V3/V4
The test for lateral infarct is negative and Alternate T amplitude < -100 uV in 2 leads of I/aVL/V4/V5/V6 (excluding aVL if R(aVL) <= 500 uV)	DISPLAY/PRINT: *T wave abnormality, possible lateral ischemia* REASON: -0.1+ mV T wave in I/aVL/V5/V6
The test for lateral ischemia is positive and Alternate T amplitude =< -500 uV in 1 lead of I/aVL/V5/V6 (excluding aVL if R(aVL) =< 500 uV)	DISPLAY/PRINT: *T wave abnormality, consistent with lateral ischemia* REASON: -0.5+ mV T wave in I/aVL/V5/V6
The tests for both possible anterior and lateral ischemia are positive and the tests for anterior infarct and lateral infarct are positive	DISPLAY/PRINT: *T wave abnormality, possible anterolateral ischemia* REASON: -0.1+ mV T wave in V3-V6
The test for possible anterolateral ischemia is positive and the tests for anteroseptal infarct or a lateral infarct are positive	DISPLAY/PRINT: *T wave abnormality, consistent with anterolateral ischemia* REASON: -0.5+ mV T wave in I/aVL/V3-V6
Continued...	

Continued...	
If	**Then**
The test for nonspecific ST abnormalities is positive and the test for possible anterior ischemia and/or possible lateral ischemia is positive	Prefix *ST & t*o the T wave abnormality statement
The test for atrial fibrillation is positive and the tests for possible anterior ischemia and/or possible lateral ischemia are positive	Append *or digitalis effect*
The test for inferior infarct is negative and alternate T amplitude < -100 uV in II or aVF (excluding aVF if net QRS amplitude < 0) and alternate T amplitude < 0 in II and aVF	DISPLAY/PRINT: *T wave abnormality, possible inferior ischemia* REASON: -0.1+ mV T wave in II/aVF
The test for inferior ischemia is positive and non-specific ST abnormalities are present	Prefix *ST &* T wave abnormality, possible inferior ischemia
T wave abnormality is present and the test for possible inferior ischemia is positive and the test for possible atrial fibrillation is positive	Append *or digitalis effect* to the T wave abnormality statement
The test for possible inferior ischemia is positive and Alternate T amplitude < -500 uV in II or aVF (excluding aVF if net QRS amplitude < 0)	DISPLAY/PRINT: *T wave abnormality, consistent with inferior ischemia* REASON: -0.5+ mV T wave in II/aVF

T Wave Abnormality, Nonspecific

The Inovise algorithm will only present a T Wave Abnormality, Nonspecific Analysis Statement if the following criteria is not met:

Skip Test (except test Short QT) If
left bundle branch block, intraventricular conduction block, left ventricular hypertrophy with repolarization, right ventricular hypertrophy with repolarization, subendocardial injury, ST elevation, pericarditis, myocardial infarct, right bundle branch block, possible anterior ischemia, possible lateral ischemia or possible inferior ischemia exist

Below is the mathematical definition for the following variable:

Define
TMIN= 1. 25 uV = net QRS amplitude/20 if net amplitude > 0 2. 25 uV if net amplitude < 0

Criteria

The following criteria is what ECG data must conform to in order to generate an Analysis Statement for nonspecific T wave abnormality:

If	Then
QRS axis - T axis > 60 and T axis < 0 or QRS - T axis < -60 and T axis > 90	PRINT/DISPLAY: *Abnormal QRS-T angle* REASON: QRS-T axis difference > 60
Count of I/II/aVL/aVF/V3-V6 with alternate T amplitude < TMIN and R amplitude > 500 uV is >= 2	PRINT/DISPLAY: *Nonspecific T wave abnormality*
Nonspecific ST abnormalities and nonspecific T-wave abnormalities exist and the test for tall T waves is negative	PRINT/DISPLAY: *Nonspecific ST & T wave abnormality*
The test for atrial fibrillation is positive and the test for either nonspecific T wave or ST abnormalities is positive	Append *probably digitalis effect*
T amplitude > 1000 uV and T amplitude > 1/2 R amplitude in 3 leads of I/II/V1-V6	PRINT/DISPLAY: *Tall T waves, possible hyperkalemia*
QTc < $>\left(450-\frac{(1000-RR)}{7}\right)\sqrt{\frac{1000}{RR}}$ ms and heart rate < 140	PRINT/DISPLAY: *Short QT interval*
QTc > $>\left(450-\frac{(1000-RR)}{7}\right)\sqrt{\frac{1000}{RR}}$ ms	PRINT/DISPLAY: *Long QT interval*

Rhythm Statements

Rhythm Statements and Modifiers

Rhythm statements describe the predominant rhythm in the 10 seconds of analyzed data. A modifier, listed after the rhythm statements, may also be added to more accurately describe the type of rhythm.

Rhythm Statements
Sinus Tachycardia Sinus Rhythm Sinus Bradycardia
Atrial Tachycardia(abnormal P axis) Atrial Rhythm Atrial Bradycardia
Junctional Tachycardia(superior P axis and Short PR) Junctional Rhythm Junctional Bradycardia
Supraventricular Tachycardia(narrow QRS, regular RR, no P) Supraventricular Rhythm Supraventricular Bradycardia
Undetermined (regular) rhythm
Atrial fibrillation Atrial flutter
Electronic ventricular pacemaker
Modifiers
...with (marked) sinus arrhythmia ...with first degree AV block ...with short PR interval ...with second degree AV block, Mobitz Type (I, II) ...with (occasional/frequent) ventricular premature complexes ...with (occasional/frequent) ectopic premature complexes ...with (occasional/frequent) atrial premature complexes ...with (occasional/frequent) supraventricular premature complexes ...in a pattern of bigeminy ...with marked rhythm irregularity, possible non-conducted PAC, SA block, AV block, or sinus pause.
Modifiers Used With Atrial Fribrillation
...with (rapid/slow) ventricular response ...with AV block
Modifiers Used With Atrial Flutter
...with aberrant conduction or ventricular premature complexes ...cannot rule out atrial flutter (Regular rate near 150) ...electronic (atrial/ventricular) pacemaker ...contour analysis based on intrinsic rhythm ...intermittent Wolff-Parkinson-White pattern

Chapter 4 Glossary

Term	Definition
ACCF	American College of Cardiology Foundation
Acute Myocardial Infarction (AMI)	A myocardial infarction that, as analyzed by the Inovise algorithm, is currently in an acutely evolving phase, usually within 24 hours of the onset of chest pain.
Age-Undetermined Myocardial Infarction (AUMI)	A myocardial infarction of which the Inovise algorithm cannot determine the age. An age-undetermined MI finding can appear when an acute MI has occurred in the recent past, usually within a few days, or when an MI is in a healed, chronic phase.
Age<18	Age less than 18 years. An excluding condition for the Inovise algorithm analyses of acute MI, age-undetermined MI, and LVH.
AHA	American Heart Association
Bradycardia	A slow heart rate, usually defined as less than 60 (< 60) beats per minute.
Bi-Ventricular Hypertrophy (BVH)	A confounding condition for acute and age-undetermined MI.
confounding condition	A clinical condition that causes the Inovise algorithm to adjust its analysis of acute MI, age-undetermined MI, or LVH. For example, bi-ventricular hypertrophy (BVH) is a confounding condition for both acute and age-undetermined MI. When the Inovise algorithm identifies BVH, the system considers that condition in its analysis for MI and displays that information under the Inovise algorithm's analysis results.
ECG	Electrocardiogram or electrocardiograph.

Term	Definition
Excluding Condition	A condition for which the Inovise algorithm cannot provide a detailed analysis for acute MI, age-undetermined MI,or LVH. For example, atrial flutter is an excluding condition that prevents the Inovise algorithm from analyzing for Acute MI.
HR	Heart rate (pulse).
HRS	Heart Rhythm Society
Infarct	Myocardial infarction. The Inovise algorithm can detect and analyze the following two types of MI: • Acute Myocardial Infarction (AMI) • Age-Undetermined Myocardial Infarction (AUMI).
Ischemia	Condition in which the blood flow within a coronary artery is limited to the point where the oxygen needs of the heart muscle cannot be met (hypoxia).
J point	The J point is the junction between the QRS complex termination and the ST segment start.
Left ventricular hypertrophy (LVH)	A confounding condition for acute and age-undetermined MI.
Myocardial Infarction (MI)	The Inovise algorithm can detect and analyze two types of MI: • Acute MI • Age-undetermined MI.
Non-ST Elevation Acute MI (nSTEMI)	nSTEMI may be defined as an AMI caused by a severely narrowed, but not completely blocked, coronary artery.
P wave	The deflection used to identify atrial depolarization. It is the first wave of a complex or beat.
PR Interval	That interval of time that occupies the space between the beginning of the P wave and the beginning of the QRS complex.
Q wave	The first negative wave of the QRS complex.
QRS complex	The wave complex represented by ventricular depolarization. It may consist of individual or multiple waves in succession, which may appear in any combination: the Q wave, R wave, and S wave.

Term	Definition
QRS interval	The interval of time occupied by the QRS complex. (i.e., The elapsed time from the beginning of the Q wave to the end of the S wave.)
QT interval	The interval of time represented by the space from the beginning of the QRS complex to the end of the T wave (which can vary with heart rate).
QTc interval	The QT interval, corrected mathematically for the heart rate.
R Wave	The first positive wave of the QRS complex.
S	S wave
S wave	The second negative wave of the QRS complex.
ST Elevation Acute Myocardial Infarction (STEMI)	STEMI is considered a subcategory of AMI caused by a 100% blockage of one coronary artery.
ST segment (ST)	The end of the S-wave (J point) to the beginning of the T wave.
ST segment depression (ST DEP)	ST deviation below the baseline.
ST segment elevation (STE)	ST deviation above the baseline.
STEMI Equivalent	STEMI Equivalent is may be defined by: • STEMI evidence in the presence of Left Bundle Branch Block (LBBB) • Isolated STEMI ECG evidence for the posterior wall • Left main occlusion. **Note:** An alternate definition for STEMI Equivalent is to associate it with high-grade left main coronary artery (LMCA) disease.
STJ	Lead-by-Lead deviation of the ST segment in mm, measured at the J-point
T	T-wave.
T wave	The wave that represents ventricular re-polarization.
Tachycardia	A rapid heart rate, usually defined as greater than 100 (> 100) beats per minute.
Trace	A waveform of the electrical data recorded by a tab electrode

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