NOTE: The information contained in this physician's guide refers specifically to 12SL versions 17 through 21 unless otherwise noted. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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Contents

1 Introduction
   Revision History .................................................. 1-3
   Purpose .................................................................. 1-4
   Overview .............................................................. 1-6
   References .......................................................... 1-7

2 Acquisition
   Patient Information .................................................. 2-3
   Simultaneous 12-Lead Acquisition .............................. 2-4
   Digitization/Sampling Rates ...................................... 2-6
   Eliminating Noise .................................................... 2-7
   Pre-Acquisition ....................................................... 2-9
   Gain Setting .......................................................... 2-10
   References .......................................................... 2-11

3 Measurement
   Introduction .......................................................... 3-3
   QRS Detection ....................................................... 3-4
   Ventricular Rate Calculation .................................... 3-8
   Median Formation .................................................. 3-9
   Onsets/Offsets and Intervals ...................................... 3-11
   Wave Measurement ................................................ 3-12
   P Wave Detection ................................................... 3-15
   References .......................................................... 3-16

4 Diagnosis
   Introduction .......................................................... 4-3
   Computer Interpretation/Development Process ............... 4-5
References ................................................................. 4-7

5

Rhythm Criteria
Introduction ............................................................... 5-3

Criteria for Predominant Rhythms ................................. 5-6
- Electronic Artificial Pacing ........................................ 5-6
- Atrial Flutter ......................................................... 5-7
- Ectopic Atrial Rhythm ............................................. 5-7
- Sinus Rhythm ....................................................... 5-8
- Junctional Rhythm ................................................. 5-9
- Atrial Fibrillation .................................................. 5-10
- Undetermined Rhythm ............................................ 5-10

Criteria for Rhythm Modifiers .................................. 5-13
- Sinus Arrhythmia .................................................. 5-14
- First Degree AV Block — Long PR .............................. 5-14
- Short PR ............................................................ 5-14
- Ectopy ............................................................... 5-15
- AV Block ............................................................ 5-18
- Irregular Rhythm .................................................. 5-21
- AV Block (for Flutter) ............................................ 5-21
- Ectopy (for Flutter/Fibrillation) ................................. 5-23
- AV Block (for Fibrillation) ...................................... 5-23

6

Adult Contour Criteria
Overview ................................................................. 6-3
- Wolff-Parkinson-White ........................................... 6-5
- Atrial Enlargement ............................................... 6-5
- QRS Axis ............................................................ 6-5
- Low Voltage QRS ................................................ 6-6
- Pulmonary Disease Pattern ...................................... 6-6
- Conduction Abnormalities ...................................... 6-7
- Ventricular Hypertrophies ....................................... 6-9
- Infarction ............................................................ 6-12
- ST Elevation Abnormalities .................................... 6-15
- ST Depression Abnormalities .................................. 6-18
- T Wave Abnormalities .......................................... 6-22

Details ................................................................. 6-26
- Suspect Arm Lead Electrode Reversal ......................... 6-26
- WPW ................................................................. 6-26
- Atrial Enlargement ............................................... 6-27
- Frontal Plane Axis Deviation .................................. 6-28
- Low Voltage and Lung Disease ................................. 6-29
- Conduction Defects .............................................. 6-31
- Ventricular Hypertrophy ...................................... 6-37
- Infarction ............................................................ 6-41
- ST Abnormality (Elevation) .................................... 6-54
- ST Abnormality (Depression) .................................. 6-63
Pediatric Contour Criteria

Overview ................................................. 7-3
Wolff-Parkinson-White .................................. 7-5
Dextrocardia .............................................. 7-5
Atrial Enlargement ...................................... 7-6
QRS Axis ................................................. 7-6
Low Voltage QRS ......................................... 7-6
Conduction Abnormalities ................................ 7-7
Ventricular Hypertrophies ................................ 7-9
Infarct .................................................... 7-14
ST Abnormalities ......................................... 7-15
ST Elevation Abnormalities .............................. 7-16
ST Depression Abnormalities ............................ 7-18
T Wave Abnormalities .................................... 7-22

Details ..................................................... 7-25
WPW ......................................................... 7-25
Dextrocardia .............................................. 7-25
Atrial Enlargement ...................................... 7-26
Frontal Plane Axis Deviation ............................ 7-27
Low Voltage and Lung Disease ......................... 7-28
Conduction Defects ..................................... 7-29
Ventricular Hypertrophy ................................ 7-36
Infarction ................................................ 7-40
ST Abnormality (Elevation) ............................. 7-41
ST Abnormality (Depression) ............................ 7-47
T Wave Abnormality ..................................... 7-51

ECG Classification

Overview .................................................. 8-3

Serial Comparison

Introduction .............................................. 9-3

Overview of Serial Comparison Analysis ............... 9-4
Rhythm Analysis ......................................... 9-4
QRS Analysis ............................................ 9-4
ST-T Analysis ........................................... 9-4

Details of Serial Comparison Analysis ................ 9-5
Rhythm Comparison ...................................... 9-5
QRS Comparison ......................................... 9-5
Repolarization Comparison ............................. 9-6
Miscellaneous Comparisons ............................ 9-7
References ........................................................................................................ 9-8

A Statement Library by Acronym

B Statement Library by Statement Number

C Pediatric Tables
  Overview ........................................................................................................ C-3
  References ...................................................................................................... C-3
  Less Than One Day Old .................................................................................... C-4
  At Least a Day Old but not More Than 2 Days ............................................... C-5
  3 to 6 Days Old ............................................................................................... C-6
  1 to 3 Weeks Old ............................................................................................ C-7
  1 to 2 Months Old ......................................................................................... C-8
  3 to 5 Months Old .......................................................................................... C-9
  6 to 11 Months Old ....................................................................................... C-10
  1 to 2 Years Old ............................................................................................ C-11
  3 to 4 Years Old ............................................................................................ C-12
  5 to 7 Years Old ............................................................................................. C-13
  8 to 11 Years Old ........................................................................................... C-14
  12 to 15 Years Old ......................................................................................... C-15

D Standardization of Terminology and Interpretation
  Overview ........................................................................................................ D-3
  Type A Statements ........................................................................................ D-3
  Type B Statements ......................................................................................... D-3
  Type C Statements ........................................................................................ D-3

E 12SL Version Identification
  Introduction .................................................................................................... E-3
F

Screening Criteria

Introduction ........................................ F-3

Suppressed Statements ............................. F-4

G

Statement of Validation and Accuracy

Introduction ........................................ G-3

Document Purpose ................................. G-3

The Marquette 12SL ECG Analysis Program: A Brief History ................. G-3

Intended Use of GE’s Marquette 12SL Analysis Program ......................... G-5

Overall Impact of Computerized ECG: Assisting the Physician ................ G-6

Development and Validation Process of the Program ......................... G-8

Reanalysis of Stored ECGs ................................ G-8

Initiating a Change in the Program .................................. G-8


12SL Analysis Program Structure: Measurements Before Interpretation .... G-13

Detection and Measurement ........................................ G-14

The Digital ECG: Data Content and Fidelity ................................ G-14

Median Beat/Signal Averaging ...................................... G-17

QRS Onset / Offset and Determination of Global Intervals ............... G-19

Definition and Measurement of Waves ................................ G-20

Measurement Accuracy: Reported Results ................................. G-23

Common Standards for Electrocardiography (CSE) Database ................. G-23

Independent Assessments of 12SL Measurements .......................... G-27

Accuracy of Interpretive Statements: Reported Results ..................... G-32

Purpose of Reported Results ........................................... G-32

Definition of Sensitivity, Specificity, and Other Performance Metrics .... G-33

Description of Table Format for Reporting Interpretation Metrics ....... G-34

Bayes Theorem and Intended Use: Understanding Performance Metrics .... G-35

Interpretation of Rhythm: Reported Results ................................ G-36

Asynchronous P-Wave Detection via QRS Subtraction ....................... G-36

QRS Subtraction / MAC-RHYTHM: Prospective Study on 10,761 ECGs .... G-36

Enhancements to QRS Subtraction, Tested on 69,957 ECGs .................. G-38

Subsequent Evaluations of Rhythm Interpretation Yield Similar Results .... G-39

Paced Rhythms .............................................. G-41

Pediatric Rhythm Interpretation ........................................ G-43

Interpretation of P-wave Abnormalities: Reported Results .................. G-45
1 Introduction
For your notes
About the Manual

Revision History

The document’s part number and revision appear at the bottom of each page. The revision is incremented with each release of the document. The revision history of this document is summarized in the table below.

<table>
<thead>
<tr>
<th>Revision</th>
<th>Date</th>
<th>Comment</th>
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<tbody>
<tr>
<td>A</td>
<td>14 November 2000</td>
<td>Initial release of document.</td>
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<tr>
<td>C</td>
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<td>Added information for version 21.</td>
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<tr>
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<td>28 July 2008</td>
<td>Revised clinical test information in “Statement of Validation and Accuracy”, updated graphics throughout the manual, and corrected a few minor errors.</td>
</tr>
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Intended Audience

This manual is intended for qualified health care professionals using the 12SL ECG Analysis Program in hospitals, doctor’s offices, or other clinical environments.

Manual Purpose

The intent of this physicians’ guide is to provide a logical approach to computerized ECG analysis. The information is first presented in a generalized format, followed by a more detailed one. Our primary objective is to present the Marquette 12SL ECG analysis program in a succinct manner for the novice user as well as a detailed display for the more advanced user.

The following “rules and examples” will facilitate the use of this guide:

- Understanding the flow of the program is essential before the details of a specific criteria will make any sense.
- Drawings and/or logic symbols are included with the presentation of the criteria to help you understand how the program works.
- The flow of the program can be comprehended by viewing the drawings from top to bottom.
Introduction: About the Manual

- The logic symbols are used to indicate tests that cause the program to proceed forward or to suppress statements that the program has already made. For example:

  Proceed forward…

  ![Symbol showing LBBB with Yes and Skip AMI]

  Suppress statements…

  ![Symbol showing LBBB with Yes and Suppress LAD]

**NOTE**

The use of LBBB as opposed to “Left Bundle Branch Block” mnemonic abbreviations are used for brevity.

- Most of the acronyms are obvious, but if they are not, consult the library tables in the appendixes.
- Diagnostic statements are made by the 12SL analysis program by utilizing a set of rules and thresholds (presented throughout this guide), which are applied to the measurements obtained from the 12-lead electrocardiogram.
- A concise overview will be presented at the beginning of most sections. Refer to the table of contents for a listing of each section.
- Detailed sections and ECG samples are located following the interpretive section.

The sections include our attempt in visually portraying the 12SL criteria. We hope you will find this to be a useful tool in understanding computerized ECG analysis.

**NOTE**

Despite the fact that the Marquette 12SL analysis program has a high level of accuracy, it will occasionally not correctly interpret an ECG. The ECG tracing is significant only when interpreted in conjunction with clinical findings. Thus, it is critical that a physician utilizes his/her best clinical judgement when reviewing the ECG interpretation.

A Statement of Validation and Accuracy for the Marquette 12SL ECG analysis program is available upon request.
Introduction: About the Manual

Hazard Information

The terms Danger, Warning, and Caution are used throughout this manual to point out hazards, and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

Hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Additional safety messages that provide appropriate safe operation information may be found throughout this manual.

Warnings

WARNING
INTERPRETATION HAZARD: 12SL analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and or invasive tests.

12SL analyses must be reviewed by a qualified physician.
Introduction: About the Product

About the Product

Overview

The first human electrocardiogram was taken over a hundred years ago, and computerized electrocardiography has been in existence since the late 1950's. In spite of its widespread use, long history, and the voluminous amount of literature regarding the scientific aspects of this technology, there is little written that directly addresses the intent of computerized electrocardiography.

The pioneers of this technology had motivations which ranged from the esoteric goal of proving that a computer could mimic human activity to the basic requirement of efficiently recording artifact free tracings. Some of the favorable developments which resulted from the evolution of this technology were hardly imagined at its inception. Consider, for example, work patterns at facilities which provide ECG services; they have been greatly streamlined. Additionally, computerization has resulted in two practical advantages for the overreading physician. First, the computer can serve as an additional expert opinion. Second, cardiologists have found that it is possible for them to overread computer analyzed tracings in half the time required for conventional, non-analyzed ECGs.

The computer, therefore, is not only used to efficiently record, store, transmit, and present the ECG; but it is also used to assist the physician in overreading an ECG. Consequently, developers inherit a certain responsibility. GE Healthcare has accepted this serious challenge.

It should be made clear that a computerized analysis is not a substitute for human interpretation. There are two reasons for this. First, statements of accuracy need to be viewed from a statistical perspective. Although accuracy levels may be high, outliers can and will exist. Second, a computer does not have the ability to include the entire clinical picture of the patient. A person with organic heart disease can exhibit an ECG within normal limits. Conversely, a normal individual can have an abnormal appearing ECG. The ECG, therefore, must always be reviewed in light of the surrounding clinical circumstances.

Intended Use

The 12SL ECG Analysis Program assists the physician in interpreting resting 12-lead EGGs for rhythms and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patient's homes.
Prescription Device

**CAUTION**
United States federal law restricts this device to sale by, or on the order of, a physician.
References


2 Acquisition
For your notes
Patient Information

Entering patient information is the first step in taking a 12-lead ECG. Age is important because the Marquette 12SL analysis program contains age specific criteria. Age, in particular, is necessary for accurate pediatric analysis.

**NOTE**
This version of the 12SL analysis program contains gender-specific criteria therefore it is important to enter the age and sex of the patient in order to activate these performance enhancing criteria.
Simultaneous 12-Lead Acquisition

All 12 leads of the ECG are simultaneously acquired. Eight of the leads are acquired directly (I, II, and V1 through V6). The remaining four (III, aVR, aVL, and aVF) are derived via Einthoven's law.

Because of the inherent relationship of the standard limb leads to each other, Einthoven stated that at any given instant during the cardiac cycle, the sum of the potentials of leads I and III equals the potential of lead II. (This complies with the American Heart Association recommendations.)

Most formats show only a portion of the 12-lead, 10-second data. An example of this is the standard 12-lead presentation which displays only 2.5 seconds from each of the 4 lead groups.
Regardless of the data that you see, the complete data is always acquired. This is used by the 12SL analysis program for precise waveform measurement. It also allows you to choose from a multiple set of formats for accurate rhythm and contour diagnosis.
Digitization/Sampling Rates

The incoming analog electrical signals are digitized. For resting electrocardiography, the device digitizes the analog potential into 4.88-μV units at a rate of 4 kHz. This fast sampling rate allows for superior reproduction of pacemaker artifact.

The 12SL analysis program requires data that has been acquired at the rate of 500 samples per second as per AHA guidelines. This sampling rate represents a value every 0.05 mm on a chart that is moving with the standard speed of 25 mm/s. The device obtains this rate, from the data above, by averaging ten consecutive digital values together.
Eliminating Noise

To acquire cardiac waveforms accurately, we have taken great care to design our electrocardiographs to exclude noise from the 12SL data set. Our resting ECG analysis systems employ several noise excluding mechanisms.

Let us first discuss the noise that is generated by signals that originate outside the patient’s body. That is, in addition to the small voltages that are generated by the heart, the ECG equipment is receiving signals that are coming from electrical equipment outside the body. These signals are called common mode signals because all of the leads on the body see these signals; it is common to all of them. A common mode signal can be many times greater than the ECG. Therefore, it is important to eliminate it.

The ability of the electrocardiograph to reject that signal, so that it does not appear in the ECG tracing, is called common mode rejection. Due to practical limitations, it is not possible to entirely eliminate the common mode signal, but we are able to reduce it. The amount of reduction is called the common mode rejection ratio.

Despite all of the methods used to reject common mode signals, power line interference — which is often referred to as 50/60-Hz “buzz”—will continue to be part of the acquired signal. This is because magnetic fields induce differential signals in the loops formed by the lead connections to the body. Since digitization takes place at the patient, the effective leadwire length is very short; thus, these signals are minimized. Nevertheless, a line frequency filter is used for taking out any remaining 50/60-Hz buzz. This filter must know what the line frequency is; you can specify it in the setup options.

Besides reducing the noise due to electrical interference, we must also address the artifact that is caused by the patient. This artifact falls generally into two broad categories, low frequency and high frequency noise.

Below is an example of a low frequency wave. Notice that it does not change quickly. Low frequency noise typically results from patient respiration or the slowly changing potentials caused by the electrode-electrolyte-skin interface. This is often referred to as baseline sway which generally occurs at less than 1 Hz in the signal frequency spectrum. Good skin preparation and the use of quality electrodes will reduce the contribution from this source.
Below is an example of a high frequency wave. It has sharp edges and it changes quickly. High frequency noise is usually caused by the activity of the skeletal muscles. If the patient relaxes, the artifact should be reduced.

**High Frequency**

A baseline filter is used to remove baseline sway. The filter works by subtracting a portion of the difference of the signal and the mid-channel potential. The longer the signal strays away from the middle, the greater the portion of the difference subtracted. The result of this processing is that it will remove baseline sway. However, a higher frequency waveform—such as that caused by a QRS—is not altered.
Pre-Acquisition

Pre-acquisition is another option. When pre-acquisition is selected, your device sends digitized ECG data to a buffer in its computer memory whenever there are incoming signals. When the buffer is full, new data constantly displaces the older data; it will always have the latest 10 seconds available for analysis. If the buffer is not full, the analysis program pauses until it is full. If pre-acquisition is not on, the device begins acquiring 10 seconds of data when you initiate 12-lead acquisition.

One particularly noteworthy advantage to pre-acquisition is that it allows you to capture a 12-lead ECG on a relatively infrequent event. For instance, if you observe an arrhythmia on the display, you have 10 seconds to capture a 12-lead ECG. With pre-acquisition on, the arrhythmic episode will be part of the 10 seconds of data in the buffer and will be analyzed.
Gain Setting

The standard gain, or sensitivity, setting is 10 mm/mV. The setting is indicated by the 1 mV high calibration pulse at the beginning of each trace. At the standard setting, the calibration pulse is 10 mm high. At one-half sensitivity, the pulse is 5 mm high.

**NOTE**

Adjusting the gain affects only output traces. Data for the 12SL analysis program are always measured at the standard 10-mm/mV setting.
References

1. Pipberger, HV. et al.

2. D.I. Tayler and R. Vincent,
For your notes
3 Measurement
For your notes
Introduction

Following acquisition, the program measures the electrocardiogram. This process can be broken down into six basic steps:

1. **QRS detection** – Identifies and groups, by shape, the QRS complexes in the ECG record. (See “QRS Detection” on page 3-4 for more information.)

2. **Ventricular rate calculation** – The ventricular rate is determined by the number of QRS complexes detected. (See “Ventricular Rate Calculation” on page 3-8 for more information.)

3. **Median formation** – Beats of the same shape are combined into an accurate, representative cycle. Noise is dramatically reduced by this process. (See “Median Formation” on page 3-9 for more information.)

4. **Onsets/offsets and Intervals** – All 12 leads are used to demarcate the P, QRS, and T. (See “Onsets/Offsets and Intervals” on page 3-11 for more information.)

5. **Wave measurement** – The program generates a measurement matrix that identifies all the waves evident in each lead. (See “Wave Measurement” on page 3-12 for more information.)

6. **P wave detection** – The raw rhythm tracings are examined for P waves. (See “P Wave Detection” on page 3-15 for more information.)
QRS Detection

The first step in computerized ECG analysis is the identification of each QRS complex. This step is vital. If it is done incorrectly, all subsequent steps in the analysis will be in error. Since all 12 leads are available to the 12SL program, correct identification is maximized. Even when individual leads have low voltage complexes, the program can use all signals from all leads to properly identify each QRS.

Before the QRS detector can scan the signal data for something that resembles a QRS, it must first remove any pacemaker artifact. This is because pacemaker signals can be large in amplitude and they could fool the detector. The program identifies pacemaker artifact through two independent methods. Separately, the 12SL analysis program identifies pacemaker artifact in the ECG data by finding either large amplitude spikes (greater than 1000 μV) or lower amplitude spikes (greater than 250 μV) that pass further scrutiny, so as not to be deceived by muscle artifact. Regardless of how the spikes are detected, the 12SL program remembers their height and position and then removes them. When the program is finished, it replaces these spikes.

After the pacemaker spikes are removed, the QRS detector filters the data. It attenuates both low frequency and high frequency waves, leaving untouched the mid-band frequencies that are usually evident in the QRS. This may sound complicated but it is ultimately reduced to the adding and subtracting of samples. High frequencies are attenuated by adding samples together while low frequencies are attenuated by subtracting samples. See the following examples.

![Image](M5264-14)
Measurement: QRS Detection

Eliminate low frequencies by subtracting

This filter makes the QRS detector more resilient in the presence of noise. It also decreases the probability of a false detection due to T waves. Following is a diagram of the frequency response of the QRS detector.

The output of this filter is summed across all 12 leads. Once the summed output crosses a specific threshold, a QRS is considered to be detected. In order to avoid the following T wave, the threshold is increased for a short period of time (200 ms).
Once a QRS is detected, the 12SL analysis program makes a template of it for each lead.

![QRS detection template](image)

From this point on, the QRS detector looks for the same shape. If it finds a match, the program classifies it as another QRS detection. Furthermore, it slides the waveforms past one another looking for the optimal match. This sample time will be used later when we form a composite cycle.

![Optimal match](image)

If the filter output exceeds thresholds, but there is no match, it is assumed that a different beat type has been detected and an additional set of lead templates is made for further matching tests.
In summary, the QRS detector uses a filter and template matching techniques to both detect and group, by shape, the QRS complexes which occur in the ECG record. The QRS detector also defines the points in the ECG record that can be used to align in time, with maximum correlation, the respective beats of a beat type.
Measurement: Ventricular Rate Calculation

Ventricular Rate Calculation

After all QRS complexes have been detected, the ventricular rate is computed by counting the number of beats detected and dividing by the time difference between the first and last beats.

\[
\text{rate} = \frac{(\text{number of QRSs} - 1) \text{ beats}}{(\text{time difference between first and last QRS}) \text{ msec}} \times 60000 \text{ msec/min}
\]

The number of R-R intervals (number of QRS complexes minus one) is divided by the time difference between the first and last beats, and the result is converted to units of beats per minute.

**NOTE**

The interpretations of Sinus bradycardia, Sinus rhythm, and Sinus tachycardia are based on the atrial rate, not the ventricular rate. The atrial rate is determined from the P wave detections. Of course, the atrial rate will equal the ventricular rate for the majority of ECGs. In cases of 2nd or 3rd degree AV blocks, for example, the atrial rate may legitimately differ from the ventricular rate.
Median Formation

Before any further signal processing takes place, the program must determine which beat type will be used for the morphology measurements. The program uses the RR intervals and the location of any pacer spikes in order to decide which beat type has the highest level of origin in the conduction system. This selection is not dependent upon the number of beats per beat type. Rather, the beat type which is most informative for analysis is the one sought after and any beat type with three or more complexes can qualify.

The beat type that the computer considers to be most informative of normal conduction is often referred to as the “primary beat.” Later in this guide you will see the rhythm criteria refer to “a normally shaped beat.” This is a QRS complex with the same shape as the primary beat.

After a primary beat type has been chosen, each of its associated beats is used in generating a representative (median) complex for each lead. This is done using the sample times that were generated by the QRS detector. These times not only indicate the occurrence of a QRS, but they also indicate when the QRSs for a specific beat type are optimally matched. The representative complex is then generated with the median voltages from this aligned group of beats; that is, it is formed by taking, at each sample time, the middle voltage of the superimposed beats.

This process has several advantages. As opposed to other analysis programs, the alignment is done in all channels simultaneously. The problem of reconciling data from different lead groups is eliminated. Secondly, this technique is excellent for diminishing noise. A median is better than an average. It disregards the contributions that could be made by outliers. The net result is the most artifact-free picture of the electromotive forces generated by the heart cycle.
Consider, for example, the set of five voltages given below. The median is defined as the value at which half of the samples are above this value and half of the samples are below this value. For this example, the median is 10 (two samples are greater than 10 and two samples are less than 10). On the other hand, the average is 26. The average was greatly biased by the outlier value of 100, whereas the outlier did not unduly bias the median.

**Median**

| 0 | 5 | 10 | 15 | 100 | Median is 10 |

**Average**

| 0 | 5 | 10 | 15 | 100 | Average is 26 |
Onsets/Offsets and Intervals

At this point, the median for the primary cycle has been established for each of the 12 leads. Since all leads were sampled synchronously, and time aligned synchronously, the median complexes are also synchronous. Since noise has been eliminated, the accuracy of the identification of wave onset/offset has been increased and the process simplified.

The onsets and offsets of the P, QRS, and T are found in a specific order. QRS onset is detected first. This is because it is the easiest to find; the slope change is usually very rapid and in great contrast to the other slopes in the median. This is followed by QRS offset and T offset. Next, the representative complex is searched for a P wave. A P wave will be found in the representative complex only if P waves are present and are synchronous with the QRS complexes. For example, junctional rhythms may not have a P wave and the P waves of Mobitz I (Wenckebach) second degree AV block will not have a constant PR interval and are asynchronous with QRS complexes. Finally, if a P wave is found, the onset and offset of the P wave are delineated.

The onsets and offsets are determined by an analysis of the simultaneous slopes in all 12 leads. Onsets are defined as the earliest deflection in any lead, and offsets are defined as the latest deflection in any lead. Thus, the QRS duration is measured from the earliest onset in any lead to the latest deflection in any lead. Similarly, the QT interval is measured from the earliest detection of depolarization in any lead to the latest detection of repolarization in any lead. The PR interval is measured from the earliest detection of atrial depolarization in any lead to the earliest detection of ventricular depolarization in any lead (the QRS onset). A PR interval is reported only if synchronous P waves are detected (i.e. P waves are detected and have a constant PR interval for each beat).

The QT interval is corrected for heart rate (QTc) using Bazett’s formula\(^1\):

\[
QTc = QT \sqrt{\frac{HR}{60}}
\]

where HR is the ventricular rate in beats per minute, which is calculated as described previously in this chapter.

**NOTE**

By definition, the QTc will equal the QT interval for a heart rate of 60 beats per minute.
Wave Measurement

After the P, QRS, and T complexes have been demarcated in the median complex, the waves for each complex are identified. This is done separately for each lead. The program finds the points at which the signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal to 160 μV • ms, the wave is considered to be significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave.

The measurement matrix contains the amplitudes (with respect to QRS onset) and durations of all of these individual waves.

The median complex is shifted so that the voltage at the QRS onset is 0 by definition. All amplitudes and ST levels are voltages in μV with respect to the voltage at the QRS onset. The P, P', T, and T' amplitudes and the STJ, STM, and STE voltages may be positive or negative values, depending on whether the values are greater than or less than 0. However, because the Q, S, and S' waves are always defined as negative deflections, their amplitudes are represented as positive values with the implicit understanding that they are negative deflections.

STJ is defined as the ST level (with respect to QRS onset) at the QRS offset (commonly referred to as the “J point”). STM is the ST level at the QRS offset plus 1/16 of the average RR interval. STE is the ST level at the QRS offset plus 1/8 of the average RR interval.
In addition to the individual wave durations and amplitudes defined on in the previous paragraph, the following quantities are also defined for each lead:

**Maximum R amplitude** = maximum of the R or R’
This is the maximum positive deflection.

**Maximum S amplitude** = maximum of the Q, S, or S’
This is the maximum negative deflection. (a positive value)

**QRS balance** = maximum R amplitude – maximum S amplitude
Will be positive if the QRS is predominately positive. Will be negative if the QRS is predominately negative.

**QRS deflection** = maximum R amplitude + maximum S amplitude
The maximum peak-to-peak deflection.

**Minimum ST amplitude** = minimum of STJ or STM

**Special T amplitude** = the minimum of either T amplitude or the T amplitude – STE
This value reflects the T amplitude without ST segment effects.

If the T' amplitude is negative, then the special T amplitude = T' amplitude

If T amplitude >-70 μV and T' amplitude is 4 times greater than the T amplitude and the T' amplitude is positive, the special T amplitude is = T' amplitude

There is an exception to this if the T' is a small deflection. Specifically, if the wave is less than 70 μV and the positive wave is at least 4 times bigger than the negative deflection, it ignores the small negative deflection.
If \( T' = 0 \) and \( T \) amplitude is negative, then special \( T \) amplitude = minimum of either, minimum of \( T \) amplitude, or \( T \) amplitude – STE, or \( T \) amplitude – amplitude at \( T \) offset.
P Wave Detection

In addition to P wave detection in the median complex, the raw rhythm data is also analyzed for atrial activity following the QRS detection and median formation. All leads are first examined for the greatest probability of proper P wave detection. One of leads I and II is selected and one precordial lead (V1 - V6) is selected. The QRST portion of the median complexes of the two selected leads are subtracted from the corresponding QRST locations in the rhythm data. Then, atrial waves (P, fibrillatory, or flutter waves) are detected from a composite signal of the two leads using a threshold based on the maximum values in the regions between the QRS complexes. Onsets and offsets of the detected atrial waves are delineated using a second threshold based on the baseline activity. Each detected atrial wave is assigned a confidence score based on how closely its measurements resemble those of the majority of the detected waves. Next, contextual analysis is applied to the measurements of the detected atrial waves, their confidence scores, and their temporal relations to each other and to QRS complexes. This is intended to exclude erroneously detected P waves and to perform a second search, using lower thresholds, for P waves that are suspected to be missing. For more information on P wave detection, see references 2 through 5 found on page 3-16.
References


4 Diagnosis
For your notes
Introduction

The interpretive section determines which diagnostic statements will be made by the 12SL analysis program. The following sections present the rules and thresholds (i.e., the criteria) that are used by the program.

Keep the following items in mind as you use this manual:

- Understanding the flow of the program is essential before the details of a specific criteria will make any sense.
- Drawings and logic symbols are included with the presentation of the criteria. This should help you understand the flow of the program.
- The flow of the program can be comprehended by viewing the drawings from top to bottom and left to right.
- The logic symbols are used to indicate tests that cause the program to proceed forward or to suppress statements that the program has already made.
- Most of the acronyms are obvious, but if they are not, consult the library tables in the appendices.
- Detailed sections and ECG samples are located following the presentation of the flow of the program.

The rhythm criteria is presented first since it is analyzed before the morphology of the waveforms. This sequence is required because information regarding the rhythm is needed for proper morphology interpretation.

A pediatric or an adult interpretation is available with the 12SL program; that is, if an age of less than 16 years is entered, the program employs pediatric as opposed to adult criteria. Age can also adjust thresholds within these two main bodies of criteria, as in the characterization of left ventricular hypertrophy. If age is not entered, the program enters a default adult age.

NOTE

This version of 12SL contains gender specific criteria; therefore, it is important to enter the age and sex of the patient in order to activate these performance enhancing criteria.
Age is used by the rhythm criteria but in very limited ways; for example, age is used to define normal sinus rates for pediatric ages. Therefore, the rhythm criteria for both pediatric and adult analysis is presented as a single unit.

Following the documentation of rhythm, the morphology criteria are presented. Morphology analysis cannot be presented as one set of criteria since pediatric analysis is not possible through simple adjustments of adult thresholds. A whole other approach is required. The morphology criteria for pediatrics and adults are presented separately, with the adult criteria presented first.
Computer Interpretation/Development Process

The Marquette 12SL Program was introduced in 1980. All improvements to the program have been accomplished via a systematic, logical, and controlled methodology. A major aspect of this methodology benefits from the use of stored ECGs.

ECGs are stored in such a fashion that they can be re-analyzed by the 12SL Program.\(^1,2\) In other words, the fidelity of the stored ECG is such that it can be used as if it was newly acquired. This allows access to large volumes of stored ECGs for the purposes of either training or testing the program.

Any change to the program requires a great deal of research. This effort can be instigated by a variety of sources. The constant pursuit of clinically correlated databases can yield statistics that indicate whether a change should be considered. New criteria published in the literature can be evaluated and sometimes incorporated into the program. Consultations with cardiologists also stimulate investigations. This is especially true when they have stored ECGs whose interpretation has been verified by other, non-ECG data.

Before a change can be instituted, it must always be evaluated in relation to the current performance of the program. This validation process is facilitated by a set of research tools developed specifically for this purpose. These tools are then used in conjunction with our reanalysis capability. As an ECG is re-analyzed, a score pertaining to the item under investigation is stored and collated by the computer. Later, after many ECG records have been scored, the computer can generate statistics on the entire set of ECGs that it reanalyzed and scored. To determine ECGs that might be affected by a program change, the entire ECG set is reanalyzed twice: once with the change and once without. After this is done, the computer automatically calls out and plots any ECGs that scored differently between the two versions of the program. This work has resulted in an efficient set of research tools that allows an automatic determination of how a change might affect program performance on a large database.\(^3\)

Given these sophisticated tools, the next issue relevant to the development process is the selection of an appropriate database. Appendix B contains a list of “gold standard” databases that Marquette has used in program validation. These databases are extremely valuable, because they are time consuming and expensive to obtain. Nevertheless, they are an essential ingredient. Without an objective yardstick, the program will not excel since the target for performance will be vaguely and inconsistently defined by the “consensus cardiologist”.\(^4\)

It should also be noted that different databases are used during the development and validation process. This precludes us from developing a program that works beautifully on the training set but cannot be applied, with the same success, to other populations.\(^5,6\)

During the training phase, we use a database that has been correlated with a “gold standard”. The choice of the “gold standard” depends upon
the problem being investigated. For criteria that references a particular patho-physiologic state (like myocardial infarction), we use a database that is correlated with other non-ECG evidence (like, cardiac catheterization, echocardiography, autopsy, cardiac enzymes, patient history, etc.). For measurements, or arrhythmia statements that can be confirmed by the ECG itself, we use the ECG in conjunction with expert opinion.

During the test phase, not only is an independent “gold standard” database used, but other databases are also used. This is prudent because “gold standard” databases have some limitations. Examples include the following: 7

- The “gold standard” may not be representative of the disease in the clinical setting. For example, an ECG database which contains autopsy proven myocardial infarctions (MI) may not be indicative of what typical MI looks like since many patients survive a MI.
- “Gold standard” databases often contain only one, isolated disease. For example, a database may only contain MIs and normals. The program, however, must also operate in the presence of ischemia, LVH, drug effects, etc.
- There may be a systematic bias when selecting patients for a “gold standard” test. “CATH proven normals” often receive the test because they were symptomatic.
- A “gold standard” database may only contain extremes of normal versus abnormal. ECG analysis programs don’t operate in a black and white world.
- And finally, a “gold standard” cannot be considered perfect: every test comes with its own inherent level of inaccuracy.

Given these aforementioned limitations, testing must go beyond the use of “gold standard” databases. The program must be tested with a wider spectrum of data. This is accomplished by measuring the program’s performance on a large database (>150,000 ECGs). This process, which the computer can do in less than a few hours, presents the program with multiple diseases and varying degrees of abnormality. ECGs that changed their analysis results due to program modification can be further investigated with either confirmation from medical records and/or expert opinion.

Only after this retrospective testing is complete, can we finally incorporate the change into 12-lead ECG device and evaluate its performance at a clinical site. If this last test is successful, the change is incorporated into the program for general release.
References


2. Reddy et. al., 1991. *Data compression for storage of resting ECGs digitized at 500 samples per second*. Association for the Advancement of Medical Instrumentation Meeting


For your notes
5 Rhythm Criteria
For your notes
Introduction

The rhythm criteria first determines the origin of the predominant rhythm in the 10 seconds of analyzed data. The program chooses from the following major categories:

- Electronic artificial pacing
- Atrial flutter
- Ectopic atrial rhythm
- Sinus rhythm
- Junctional rhythm
- Atrial fibrillation

A set of statements exists for each of these categories; for example, sinus rhythm includes sinus tachycardia, normal sinus rhythm, sinus bradycardia, and marked sinus bradycardia.

If the program is not able to choose a rhythm that is described by one of the above categories, it defaults to the undetermined rhythm category. This category includes such statements as wide QRS tachycardia and supraventricular tachycardia; these describe the overall rhythm, but refrain from defining the mechanism. If the rhythm cannot be labeled by these descriptive statements, the program states “Undetermined Rhythm.”

After the program states the predominant rhythm, several rhythm modifier statements can be appended for abnormalities of conduction and/or ectopy. Some of the modifier statements are only used for particular predominant rhythms. For example, the statement “with rapid ventricular response” is used only in conjunction with atrial fibrillation.

The following figure graphically portrays the criteria for selecting the predominant rhythm. Notice that if the program does not find a match in the first six categories, it defaults to the undetermined rhythm category.

Since the use of the rhythm modifiers are dependent upon the stated predominate rhythm, the document will first describe the criteria that is used for determining the predominant rhythm.
Rhythm Criteria: Introduction

Electronic Pacing?

No

Demand Pacing?

Yes

State demand pacer and continue processing

No

Atrial Flutter?

No

Atrial Spikes

Ventricular Spikes

Atrial-Ventricular Spikes

Spike on Non-dominant Beat

Atrial Rate >250 bpm

Next Page
Rhythm Criteria: Introduction

From Previous Page

Ectopic atrial rhythm?

No

Sinus rhythm:

P waves, unusual P axis

No

Junctional rhythm?

P waves, normal P axis

Short PR

No detected P waves
Regular RR

No P detected, irregularly irregular RR

Atrial fibrillation?

Undetermined rhythm.

No

Fibrillation-flutter waves detected with slow or irregular rate
Criteria for Predominant Rhythms

There are seven categories of predominant rhythm statements.
- Electronic artificial pacing
- Atrial flutter
- Ectopic atrial rhythm
- Sinus rhythm
- Junctional rhythm
- Atrial fibrillation
- Undetermined rhythm

Each of these categories is presented with its associated statements. Each statement is shown in its actual wording, followed by the statement acronym, and any specific criteria associated with that statement.

Electronic Artificial Pacing

This category requires that the predominant rhythm be artificially paced. Three statements are included in this category; they delineate the origin of the artificial pacing.
- “Electronic Ventricular Pacemaker” — $PCK$
- “Electronic Atrial Pacemaker” — $APCK$
- “AV Sequential or Dual Chamber Electronic Pacemaker” — $AVPCK$

If artificial pacer spikes are detected before beats that are not the primary beats, then a demand pacemaker statement is issued.

Demand Pacemaker; Interpretation is Based on Intrinsic Rhythm

Acronym: $DPCK$

Requires
- No pacer spikes preceding the primary beats, and
- Pacer spikes preceding the secondary beats.

Rhythm analysis continues after this statement is issued. Therefore, the predominant rhythm of the ECG is still chosen after a demand pacemaker is cited.

Atrial Flutter

Acronym: $FLUT$

The program must detect an atrial rate from 200 to 350 bpm (for pediatrics, requires atrial rate to be 300 to 350 bpm).
Ectopic Atrial Rhythm

This category is chosen if a P wave, with an abnormal axis, is found before the primary beats.

Specifically, this category requires:
- Rigidly coupled P wave detected for primary beat, and
- no flutter or second degree AV block, and
- P axis less than -30 or greater than 120. (For pediatrics, P axis less than -20 or greater than 100.)

For adults the ectopic atrial rhythm statements are rate dependent.

Unusual P axis, possible ectopic atrial bradycardia

Acronym: \textit{EABRAD}
Requires
- Atrial rate less than 60 bpm.

Unusual P axis, possible ectopic atrial rhythm

Acronym: \textit{EAR}
Requires
- atrial rate from 60 to 100 bpm.

Unusual P axis, possible ectopic atrial tachycardia

Acronym: \textit{EATACH}
Requires
- Atrial rate greater than 100 bpm.

For pediatrics, the ectopic atrial rhythm statements are dependent on both rate and origin of impulse. If low right atrial rhythm is stated, the P axis is greater than 100 degrees. A left atrial rhythm is stated if the P axis is less than -20. Rate thresholds are age dependent. (Refer to Appendix C for pediatric ages.)
- Low Right Atrial Bradycardia — \textit{RABRAD}
- Low Right Atrial Tachycardia — \textit{RATACH}
- Left Atrial Bradycardia — \textit{LABRAD}
- Left Atrial Tachycardia — \textit{LATACH}
- Low Right Atrial Rhythm — \textit{RAR}
- Left Atrial Rhythm — \textit{LAR}
Sinus Rhythm

This category requires the program to detect P waves with a normal axis. Specifically, it requires.
  - Rigidly coupled P wave detected for primary beat, and
  - normal P axis.

  or

  - P waves detected at a regular rate and not associated with primary beat.

Sinus rhythm statements are rate and age dependent (refer to Appendix C for pediatric ages). “Marked Sinus Bradycardia” is stated for both adults and pediatrics at a rate below 50 bpm.

NOTE

The determination of sinus bradycardia, sinus rhythm, or sinus tachycardia is based on the atrial rate, not the ventricular rate. This is because it is the atrial rate that reflects the rate of the sinus node. While these two rates will be identical for the vast majority of sinus rhythms, they may differ in cases such as 2nd or 3rd degree AV block. For example, an ECG with complete heart block and an atrial (sinus) rate of 115 bpm and a ventricular rate of 55 beats per minute would be interpreted as “Sinus tachycardia with complete heart block” even though the ventricular response might normally be thought of as bradycardia.

Sinus bradycardia

Acronym: SBRAD
Requires atrial rate from 50 to 59 bpm.

Normal sinus rhythm

Acronym: NSR
Requires atrial rate from 60 to 100 bpm and no rhythm modifiers appended or only “with sinus arrhythmia” appended.

Sinus rhythm

Acronym: SRTH
Requires atrial rate from 60 to 100 bpm and any rhythm modifiers appended beyond “with sinus arrhythmia”.

Sinus tachycardia

Acronym: STACH
Requires atrial rate over 100 bpm.

Marked sinus bradycardia

Acronym: MSBRAD
Requires Atrial rate less than 50 bpm.
Junctional Rhythm

Two sets of criteria are used for this category. One set of criteria is applicable to those junctional rhythms that have a P wave which precedes the QRS. The other criteria is for when the P wave is submerged in the QRS or T.

If the P wave precedes the QRS, it must be ectopic in shape with a short PR interval. Pediatric patients exhibit shorter time intervals before the onset of ventricular activation. As a result, they rarely exhibit AV nodal rhythms with a short PR interval. Therefore, pediatric analysis leaves this rhythm categorized as ectopic atrial rhythm.

Specifically, if P waves are visible before the QRS then the criteria requires:
- Rigidly coupled P wave detected for primary beats, and
- no flutter or second degree AV block, and
- PR interval less than 140 ms, and
- P wave axis outside of -60 to 240 degrees, and
- an adult age.

The statements for this criteria are rate dependent.

Unusual P axis and short PR, probable junctional bradycardia

Acronym: JBRAD
Requires ventricular rate less than 50 bpm.

Unusual P axis and short PR, probable junctional rhythm

Acronym: JR
Requires ventricular rate from 50 to 75 bpm.

Unusual P axis and short PR, probable junctional tachycardia

Acronym: JTACH
Requires:
- Ventricular rate greater than 75 bpm.

If P waves are not visible, then the program requires a very regular, narrow QRS rhythm.

Specifically it requires:
- No P waves found, and
- a regular RR interval (that is, a range of RR intervals that is less than 10% of the average RR interval), and
- a narrow primary beat (<120 ms for QRS duration, for pediatric ages refer to Appendix C), and
- a ventricular rate less than 90 bpm.

Junctional rhythm statements are rate dependent. The rate thresholds are the same for both pediatric and adult analyses.
Rhythm Criteria: Criteria for Predominant Rhythms

Junctional bradycardia

Acronym: JUNBRAD
Requires rate less than 45 bpm.

Junctional rhythm

Acronym: JUNCT-R
Requires rate from 45 to 65 bpm.

Accelerated

Acronym: ACCEL
This statement precedes Junctional Rhythm when the rate is greater than 65 bpm.

Atrial Fibrillation

If none of the other aforementioned categories has been chosen, the program tests for atrial fibrillation. Generally, the program looks for an irregular rhythm or fibrillatory waves in the presence of a slow heart rate. Specifically, it requires test 1 or test 2 to be true.

Test 1 requires:
- An irregularly irregular rhythm (range of RR intervals more than 15% of average RR interval and RR intervals not organized) and
- no regular atrial rhythm detected.

Test 2 requires:
- Atrial rate >400

Only one statement is generated for this category. The rhythm can be further defined by rhythm modifier statements. (Refer to next section.)

Atrial Fibrillation — AFIB

Atrial fibrillation occurs so rarely in pediatric individuals that the program requires an adult age for this diagnosis.

Undetermined Rhythm

This category is chosen if none of the other previously mentioned categories fits the description of the measurements extracted from the ECG.

Some descriptive statements can be issued from this category without specifying the mechanism.
Ideoventricular Rhythm

Acronym: *IVR*
Requires:
- A slow ventricular rate (<= 40 bpm for adult and pediatric).
- A wide QRS (QRS duration > 120 ms; refer to Appendix C for pediatric ages).
- A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).

Wide QRS Rhythm

Acronym: *WQR*
Requires:
- Ventricular rate between 40 and 120 bpm; refer to Appendix C for upper rate limit for pediatric.
- A wide QRS (QRS duration > 120 ms; refer to Appendix C for pediatric ages).
- A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).

Wide QRS tachycardia

Acronym: *WQTACH*
Requires:
- A fast ventricular rate (>120 bpm; refer to Appendix C for pediatric).
- A wide QRS (QRS duration > 120 ms; refer to Appendix C for pediatric ages).
- A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).

Supraventricular tachycardia

Acronym: *SVT*
Requires:
- A fast ventricular rate (>140 bpm; >220 bpm for pediatric).
- A narrow QRS (QRS duration <120 ms; refer to Appendix C for pediatric).
- A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Narrow QRS tachycardia

Acronym: \textit{NQTACH}
Requires:
- Pediatric age
- Same criteria as described for supraventricular tachycardia, but allows rates below 220 bpm that are still above the fast heart rate for age.

Undetermined rhythm

If the criteria cannot be met for these descriptive statements, then the program will state Undetermined rhythm (acronym: UR).
Criteria for Rhythm Modifiers

The rhythm criteria first determines the predominant rhythm for the 10-second record. Rhythm modifiers are then appended for a complete interpretation of the rhythm.

After the predominant rhythm is stated, the program can append phrases that further define the rhythm.

For a sinus rhythm, the program has a variety of rhythm modifiers to choose from. These can be classified into six groups.

### Sinus Rhythm
- Ectopy (Example: Premature Ventricular Complexes)
- AV Block (Example: With Complete Heart Block)
- PR Interval (Example: With 1st Degree AV Block)
- Sinus Arrhythmia (Example: With Marked Sinus Arrhythmia)

Ectopy is the only group of sinus rhythm modifiers that is used by other predominant rhythms: namely, ectopic atrial rhythm and junctional rhythm.

### Ectopic Atrial Rhythm and Junctional Rhythm
- Ectopy

Ectopy or conduction abnormalities are stated for the rhythms, but with phrases that are more appropriate for the non-sinus predominant rhythm.

For example, ectopy can occur with atrial fibrillation or flutter, but the origin of it is harder to define. That is why atrial fibrillation and atrial flutter have a tailored set of ectopy statements.

### Atrial Fibrillation and Atrial Flutter
- Ectopy (tailored for fibrillation/flutter), Example: With Premature Ventricular or Aberrantly Conducted Complexes

Similarly, AV block can occur with atrial fibrillation or atrial flutter, but it is more clearly expressed with a different set of modifiers.

### Atrial Flutter — AV Block (tailored for flutter)
- Example: With 4:1 AV Conduction

### Atrial Fibrillation — AV Block (tailored for atrial fibrillation)
- Example: With Slow Ventricular Response

Immediately following is an explanation of each of these groups, including specific criteria and statements.
Sinus Arrhythmia

This group is only used for sinus rhythms. It requires a rigidly coupled P wave detected for the primary beat and no premature supraventricular beats (normal shape but without P wave) or premature ectopic beats (shape other than primary beat).

Sinus arrhythmia is stated if the range of RR intervals exceeds a particular limit. The limits are much higher for the pediatric population which has much more sinus arrhythmia. Specifically:

with sinus arrhythmia

Acronym: SAR
Requires range of RR intervals 20 to 39% (greater than 40% for pediatrics) of average RR interval.

with marked sinus arrhythmia

Acronym: MSAR
Requires range of RR intervals 40% or greater of average RR interval (not used for pediatric ages).

First Degree AV Block — Long PR

Sinus rhythm and ectopic atrial rhythms use this category. This statement is made if the PR interval is long for age.

with 1st degree AV block

Acronym: FAV
Requires PR interval of 210 ms or longer (for pediatrics, it is the 98th percentile plus 20 ms; refer to Appendix C for pediatric).

Short PR

Sinus rhythm is required. Short PR is stated if the PR interval is short for age. Obviously, if WPW is detected (see contour criteria) this statement is suppressed.

with short PR

Acronym: SPR
Requires PR interval 110 ms or less (for pediatrics, it must be less than the 2nd percentile for age. Refer to Appendix C for pediatric).
Ectopy

This group of modifiers can be used by the program if sinus rhythm, ectopic atrial rhythm, or junctional rhythm is stated.

The ectopy group can be further subdivided. It contains statements that pertain to premature beats, fusion beats, or escape beats.

Modifiers that are associated with premature beats are always preceded by a phrase that indicates how often the beats occur. Specifically:

with occasional

Acronym: OCC
Requires 1 or 2 beats.

with frequent

Acronym: FREQ
Requires greater than 2 beats.

**NOTE**
If ectopic shaped beats appear as at least one consecutive pair, then not only is the frequency of the beats commented on, but the consecutive nature of the beats is also indicated.

and consecutive

Acronym: CSEC
Requires:
- At least one pair of beats, and
- these beats
  - are separated by less than 600 ms for rates lower than 85 bpm, or
  - are at least 100 ms premature for rates over 85 bpm.

Listed below are the various premature beat modifier statements that follow the aforementioned prefixes.

Premature supraventricular complexes

Acronym: PSVC
Requires:
- No AV block, Mobitz I or II, and
- no AV dissociation, and
- at least one QRS that is premature, normally shaped, and
- no P wave found before this QRS.
Rhythm Criteria: Criteria for Rhythm Modifiers

Premature atrial complexes

Acronym: PAC
Requires:
- No AV block, Mobitz I or II, and
- no AV dissociation, and
- at least one QRS that is premature, normally shaped, and
- one or more P waves found preceding this QRS, and
- one of the following:
  - no rigidly coupled P for this beat and more than one preceding P,
  or
  - an organized bimodal or trimodal distribution of RR intervals.

Premature ventricular complexes

Acronym: PVC
Requires:
- At least one QRS that is premature, ectopic shaped, and
- has a QRS duration greater than 120 ms (for pediatrics, wide for age; refer to Appendix C), and
- no fusion beats detected.

Premature ventricular and fusion complexes

Acronym: PVCF
Requires:
- At least one QRS that is premature, ectopic shaped, and
- has a QRS duration greater than 120 ms (for pediatrics, wide for age; refer to Appendix C), and
- at least one fusion beat.

Premature ectopic complexes

Acronym: PEC
Requires:
- At least one QRS that is premature, ectopic shaped, and
- no PVCs.

A suffix can also be added to these statements if a pattern of bigeminy is evident.
in a pattern of bigeminy

Acronym: BIGEM
Requires:
- A strict 10-second pattern of alternating premature and not premature beats, and
- one of the following:
  - at least one QRS that is premature, ectopic shaped, or
  - at least one premature atrial or supraventricular beat.

Statements that specifically deal with fusion beats or escape beats are not conjugated with the phrase “With Occasional” etc. Listed below are these statements.

with junctional escape complexes

Acronym: JESC
Requires:
- No AV block, Mobitz I or II, and
- at least one beat that follows an RR interval which is longer than 1.4 times the longer of the previous RR or the median RR, and
- no P wave preceding that beat, and
- follows a normally shaped beat.

with ventricular escape complexes

Acronym: VESC
Requires:
- At least one beat that is ectopic shaped, and
- has a QRS duration greater than 120 ms, (for pediatrics, wide for age; refer to Appendix C) and
- follows an RR interval of more than 1200 ms, and
- follows a normally shaped beat.
with fusion or intermittent ventricular pre-excitation (WPW)

Acronym: ALTWPW
Requires:
- Fusion beats, and
- no premature ectopic shaped beats, and
- delta waves in three or more leads of the fusion beat.

A fusion beat requires:
- A QRS that is not premature but ectopic shaped, and
- not the first QRS of the 10-second strip, and
- within 100 ms of the expected RR interval.

with retrograde conduction

**NOTE**
This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Acronym: RETC
Requires:
- Junctional bradycardia, junctional rhythm, or accelerated junctional rhythm stated, and
- no AV dissociation or complete heart block, and
- regular atrial rhythm detected, and
- number of P waves detected < number of QRSs plus 5, and
- short RP interval

**AV Block**

Either sinus rhythm or ectopic atrial rhythm is required as the predominant rhythm before any of these modifiers can be used. This section lists the statements that express 2nd and 3rd degree AV block.

with 2nd degree AV block (Mobitz I)

Acronym: MBZI
Requires:
- At least one beat that follows an RR interval which is longer than 1.4 times the longer of the previous RR or the median RR, and
- no rigidly coupled P wave for this beat, and
- two P waves preceding that beat, and
- PR interval for this beat is shorter than average, and
- this beat follows a normally shaped beat.
with 2nd degree AV block (Mobitz II)

Acronym: MBZII
Requires:
- Two or more P waves preceding a beat, and
- that beat follows a normally shaped beat, and
- that beat follows an RR interval which is longer than one of the following:
  - 2.2 times the longer of the previous RR or the median RR, or
  - 1.8 times the longer of the previous RR or the median RR and
    there is a rigidly coupled P wave for this beat.

with 2:1 AV conduction

For MBZI and MBZII

NOTE
This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Acronym: W2T1
Requires:
- Synchronous blocked P wave identified in the median complex in
  addition to synchronous conducted P wave, or
- Pattern of blocked P, conducted P, blocked P, conducted P detected
  somewhere in the rhythm analysis.

with 2nd degree AV block

Acronym: SAV
Requires:
- Rigidly coupled P wave detected for primary beats, and
- atrial rate less than 200 bpm, and
- the atrial rate is less than 10 bpm different than twice the
  ventricular rate.

with 2:1 AV conduction

For SAV
Acronym: W2T1
Requires:
- Synchronous blocked P wave identified in the median complex in
  addition to synchronous conducted P wave, or
- Pattern of blocked P, conducted P, blocked P, conducted P detected
  somewhere in the rhythm analysis, or
- Atrial rate is within 5 bpm of 2 times the ventricular rate.
with 3:1 AV conduction

For SAV
Acronym: W3T1
Requires: Atrial rate is within 10 bpm of 3 times the ventricular rate.

with 4:1 AV conduction

For SAV
Acronym: W4T1
Requires atrial rate is within 15 bpm of 4 times the ventricular rate.

with complete heart block

Acronym: CHB
Requires:
- No AV Block (Mobitz I or II), and
- regular atrial rhythm detected, and
- no rigidly coupled P wave detected for primary beats, and
- range of RR intervals less than 3% of average RR interval, and
- atrial rate more than 6 bpm faster than ventricular rate, and
- one of the following:
  - PR variance greater than 200 ms, or
  - atrial rate more than 25 bpm faster than ventricular rate.

with AV dissociation

Acronym: AVDIS
Requires:
- No AV Block (Mobitz I or II), and
- no flutter, and
- regular atrial rhythm detected, and
- no rigidly coupled P wave detected for primary beats, and
- one of the following:
  - atrial rate more than 25 bpm faster than ventricular rate, or
  - PR variance greater than 200 ms.

**NOTE**
If “with complete heart block” or “with AV dissociation” is stated, then additional statements regarding the ventricular activity will follow. The presence of an atrioventricular dyssynchrony requires that both the atrial and the ventricular activity be specified. The ventricular activity will be stated as one of the otherwise predominant rhythm statements of: “Junctional rhythm”, “Junctional bradycardia”, “Ideoventricular rhythm”, “Wide QRS rhythm”, or “Wide QRS tachycardia”. 
Irregular Rhythm

Ectopic atrial rhythm and junctional rhythm use this category. It is analogous to the sinus arrhythmia category for sinus rhythms. If the program did not detect any ectopy and if the rhythm is irregular, the program will describe the condition with the following statements.

For adult ages, it will append:

with undetermined rhythm irregularity

**NOTE**

This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Acronym: **IRREG**
Requires range of RR intervals greater than 20% of average RR interval.

For pediatric ages, it will precede the predominant rhythm statement with:

irregular

Acronym: **IRR**
Requires range of RR intervals greater than 20% of average RR interval.

AV Block (for Flutter)

AV block for atrial flutter is described by this group of modifiers.

with variable AV block

Acronym: **VAVB**
Requires range of RR intervals is 10% or more of average RR interval.

with 2:1 AV conduction

**NOTE**

This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Acronym: **W2T1**
Requires:
- Range of RR intervals less than 10% of average RR interval, and
- atrial rate is within 10 bpm of 2 times the ventricular rate.
with 3:1 AV conduction

**NOTE**
This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Acronym: **W3T1**
Requires:
- Range of RR intervals less than 10% of average RR interval, and
- Atrial rate is within 10 bpm of 3 times the ventricular rate.

with 4:1 AV conduction

**NOTE**
This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Acronym: **W4T1**
Requires:
- Range of RR intervals less than 10% of average RR interval, and
- Atrial rate is within 10 bpm of 4 times the ventricular rate.

with 5:1 AV conduction

**NOTE**
This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Acronym: **W5T1**
Requires:
- Range of RR intervals less than 10% of average RR interval, and
- Atrial rate is within 10 bpm of 5 times the ventricular rate.

If the ventricular rate is regular (that is, the range of RR intervals is less than 10% of the average RR interval) and the atrial rate is not within some multiple of the ventricular rate, then the program will suggest a competing junctional pacemaker.
Ectopy (for Flutter/Fibrillation)

In the presence of atrial fibrillation or atrial flutter it is difficult to define the origin of ectopic shaped beats. The following statement is used for this purpose.

with premature ventricular or aberrantly conducted complexes

Acronym: ABER
Requires Test 1 or Test 2 to be true.

Test 1 requires:
- Flutter, and
- range of RR intervals is 10% or more of average RR interval, and
- one or more premature ectopic shaped beats.

Test 2 requires:
- Atrial fibrillation, and
- one or more premature ectopic shaped beats.

AV Block (for Fibrillation)

The following statements are used to indicate the degree of AV block in the presence of atrial fibrillation.

with rapid ventricular response

NOTE
This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Acronym: RVR
Requires ventricular rate higher than 100 bpm.

with slow ventricular response

NOTE
This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Acronym: SVR
Requires ventricular rate lower than 60 bpm.
with a competing junctional pacemaker

**NOTE**
This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Acronym: **CJP**
Requires:
- No electronic pacer spikes detected, and
- one of the following:
  - range of RR intervals less than 5% of average RR, or
  - the 3 longest RR intervals are longer than 800 ms and within 40 ms of each other.
6 Adult Contour Criteria
Overview

The morphology interpretation consists of two separate bodies of criteria: one for adults, the other for pediatrics. If an adult age is entered (16 years or older) or if no age is entered, an adult analysis is performed.

The 12SL analysis program has adult age and gender-specific contour criteria. These criteria are invoked if an adult age is entered and if the patient’s sex is entered. If age and sex are not entered, 12SL returns to conventional criteria.

The categories of abnormalities that the program always examines for are listed in the following table. This outline is expanded upon in succeeding figures which describe, in very simplistic terms, the basic flow and logic of the program. Note that the order of the steps is important since information obtained from tests, performed earlier in the sequence, are applied to subsequent tests.

Following the presentation of the basic flow of the program are more detailed explanations of each step. This includes specific thresholds, sample tracings, and additional figures. This section will address those questions regarding particular criteria, as opposed to revealing the overall approach used by the program to interpret the morphology.

Refer to Chapter 3 for definitions of the wave measurements used in this chapter.

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Subcategory</th>
<th>Acronyms/Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wolff-Parkinson-White</td>
<td>WPWA</td>
<td>WPWB</td>
</tr>
<tr>
<td>Atrial Hypertrophy</td>
<td>RAE, Right Atrial Enlargement</td>
<td>LAE, Left Atrial Enlargement</td>
</tr>
<tr>
<td>QRS Abnormalities</td>
<td>LOWV</td>
<td>PULD</td>
</tr>
<tr>
<td>QRS Pulmonary Disease Pattern</td>
<td>RAD, Right Axis Deviation</td>
<td>LAD, Left Axis Deviation</td>
</tr>
<tr>
<td>QRS Axis</td>
<td>RSAD, Right Superior Axis Deviation</td>
<td>RBBB, Right Bundle Branch Block</td>
</tr>
<tr>
<td>Conduction Abnormalities</td>
<td>LBBB, Left Bundle Branch Block</td>
<td>IRBBB, Incomplete Right Bundle Branch Block</td>
</tr>
<tr>
<td>Ventricular Hypertrophy</td>
<td>ILB BBB, Incomplete Left Bundle Branch Block</td>
<td>RSR, RSR Pattern In V1</td>
</tr>
<tr>
<td></td>
<td>IVCB, Intraventricular Conduction Block</td>
<td>IVCD, Intraventricular Conduction Delay</td>
</tr>
<tr>
<td></td>
<td>AFB, Left Anterior Fascicular Block</td>
<td>PFB, Left Posterior Fascicular Block</td>
</tr>
<tr>
<td></td>
<td>LVH, Left Ventricular Hypertrophy</td>
<td>RVH, Right Ventricular Hypertrophy</td>
</tr>
<tr>
<td></td>
<td>BIVH, Biventricular Hypertrophy</td>
<td>RVE+, Plus Right Ventricular Hypertrophy</td>
</tr>
<tr>
<td></td>
<td>QRSW, With QRS Widening</td>
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</table>
**Table 1. Adult Contour Criteria Summary (Continued)**

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Subcategory</th>
<th>Acronyms/Statements</th>
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<tbody>
<tr>
<td>QRS Abnormalities (continued)</td>
<td>Infarction</td>
<td>MI, Myocardial Infarction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AMI, Anterior</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMI, Septal</td>
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<tr>
<td></td>
<td></td>
<td>LMI, Lateral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IMI, Inferior</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PXT, With Posterior Extension</td>
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<tr>
<td>ST Abnormalities—QRS Related</td>
<td>ST + T abnormality with</td>
<td>2ST, With Repolarization Abnormality</td>
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<tr>
<td></td>
<td>Ventricular Hypertrophy</td>
<td>AC, Possibly Acute</td>
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<tr>
<td></td>
<td>Dating Infarcts</td>
<td>AU, Age Undetermined</td>
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<tr>
<td>ST Abnormalities—QRS Related</td>
<td>Epicardial Injury</td>
<td>INJ, Injury</td>
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<td></td>
<td></td>
<td>LINJ, Lateral</td>
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<td></td>
<td></td>
<td>IINJ, Inferior</td>
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<td></td>
<td>Pericarditis</td>
<td>PCARD, Acute Pericarditis</td>
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<tr>
<td></td>
<td>Early Repolarization</td>
<td>REPOL, Early Repolarization</td>
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<tr>
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<td>Undefined ST Elevation</td>
<td>STEL, ST Elevation Consider Early Repolarization, Injury or</td>
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<td></td>
<td></td>
<td>Acute Pericarditis</td>
</tr>
<tr>
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<td>Nonspecific</td>
<td>NST, Nonspecific ST Abnormality</td>
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<tr>
<td>ST Depression Abnormalities</td>
<td>Subendocardial Injury</td>
<td>SBINJ, Subendocardial Injury</td>
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<td></td>
<td>SSBINJ, Septal</td>
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<td>LSBINJ, Lateral</td>
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<td></td>
<td>ISBINJ, Inferior</td>
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<td></td>
<td>Undefined ST Depression</td>
<td>STDEP, ST Depression, Consider Subendocardial Injury or</td>
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<td>Digitalis Effect</td>
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<td>Digitalis Effect</td>
<td>PDIG, Probably Digitalis Effect</td>
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<td>STDIG, ST Abnormality, Possible Digitalis Effect</td>
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<td>Junctional ST Depression</td>
<td>JST, Junctional ST Depression Probably Abnormal</td>
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<td></td>
<td>JSTN, Junctional ST Depression, Probably Normal</td>
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<td>Nonspecific</td>
<td>NST, Nonspecific ST Abnormality</td>
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<tr>
<td>T Wave Abnormalities</td>
<td>Ischemia</td>
<td>T Ischemia</td>
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<td>AT, Anterior</td>
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<tr>
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<td></td>
<td>IT, Inferior</td>
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<tr>
<td></td>
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<td>LT, Lateral</td>
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<td></td>
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<td>MT, Marked Ischemia</td>
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<td>MAT, Anterior</td>
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<td></td>
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<td>MIT, Inferior</td>
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<td></td>
<td>MLT, Lateral</td>
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<td>Nonspecific</td>
<td>NT, Nonspecific T Wave Abnormality</td>
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<td></td>
<td>QRS-T Angle</td>
<td>AQRST, Abnormal QRS-T Angle, Consider Primary T Wave</td>
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<tr>
<td></td>
<td></td>
<td>Abnormality</td>
</tr>
<tr>
<td></td>
<td>QT Interval</td>
<td>LNGQT, Prolonged QT</td>
</tr>
</tbody>
</table>
Wolff-Parkinson-White

Atrial Enlargement

Skip the test if it is not a sinus rhythm.

![Heart rate graphs](image)

BAE - Both RAE and LAE are true

QRS Axis

![QRS Axis diagrams](image)
**Low Voltage QRS**

Standard requirement of limb leads less than 500 μV. However, if horizontal plane exhibits low voltage and the limb lead have voltage close to the standard requirement, state *low voltage QRS*.

![Low Voltage QRS Diagram](image)

**Pulmonary Disease Pattern**

*PULD* — check for several attributes, states if at least a few are present.

![Pulmonary Disease Pattern Diagram](image)

If *PULD* is true, do not redundantly state *LOWV*.
Conduction Abnormalities

Major Blocks

If \( RBBB \) is true, suppress \( RAD \) and \( RSAD \).

If \( RBBB \) is true, skip further conduction tests and go to ventricular hypertrophy tests.

If \( LBBB \) is true, skip further analysis.
If QRS is wide and not RBBB or LBBB, state IVCB.

If IVCB is true, go to ventricular hypertrophy tests. If not true, test for incomplete blocks.

Incomplete Blocks

Hemiblocks
Adult Contour Criteria: Overview

If AFB is true, suppress ILBBB and LAD.

If PFB is true, suppress RAD.

If RBBB is also true, append BIFB.

IVCD
If no conduction abnormality is stated and QRS duration is greater than 105 ms, state IVCD.

Ventricular Hypertrophies

Right Ventricular Hypertrophy

If RBBB is true, use a separate set of criteria for RVH.

If these conditions exist, the program looks for other characteristics. If at least a few of these exist, it states RVH.
Adult Contour Criteria: Overview

RVH-2ST
If the program finds a repolarization abnormality that is also indicative of RVH, it will upgrade any RVH call to right ventricular hypertrophy with repolarization abnormality.

Left Ventricular Hypertrophy

First evaluate voltage.

If just over the threshold, the program states minimal voltage criteria for left ventricular hypertrophy, may be normal variant. Larger voltages, which exceed the thresholds by several hundred microvolts, are defined by the program as moderate voltage criteria or voltage criteria for left ventricular hypertrophy.
The program states left ventricular hypertrophy without the phase 
_voltage criteria_ for which the program finds additional indications of 
hypertrophy, namely: repolarization changes, increased ventricular 
activation time, or left atrial hypertrophy.

**Biventricular Hypertrophy**

If both _RVH_ and _LVH_ are true, then state _BVH_.

It is also possible to call _BIVH_ based upon other tests.

If _BIVH_ is stated, the program will not also state _LVH_ and/or _RVH_.
Infarction

Septal Myocardial Infarction

Degree of confidence is based on repolarization. If the ST is elevated, with terminal or complete T wave in version, SMI is stated without qualification, otherwise it is preceded by cannot rule out.

Anterior Myocardial Infarction

Narrow and shallow Q waves will be qualified as cannot rule out or possible.
Lateral Myocardial Infarction

*LMI*  
At least two lateral leads have wide and deep Q waves that have significant Q:R ratios.

If the criteria detected significant Q waves, it states an unqualified *LMI*; otherwise it would prefix *possible*.

If *LMI* is true, suppress statements concerning right axis deviation (*RAD*, *RSAD*)

If *AMI* or *LMI* is true, the program will suppress *PULD*.

At this point the program will issue conjunctions of the different MIs it detected in the horizontal plane. For example:
Inferior Myocardial Infarction

Acronym: IMI
Significant Q:R ratio is the main component of this test.

The significance of the Q:R ratio is evaluated in conjunction with other parameters, namely: Q amplitude, Q duration, QRS axis, and presence of Q in lead II.

If the IMI is true, then inspect posterior involvement.

The qualification of the infarct is based upon the QRS and repolarization. Small Qs in aVF will be qualified as cannot rule out or possible unless there are ST-T changes commensurate with infarction.
ST Elevation Abnormalities

Epicardial Injury

All leads are inspected for ST elevation. Anteroseptal leads are tested with a higher threshold than the other leads.

The thresholds are also adjusted for repolarization abnormalities that can occur with LVH and/or conduction abnormalities.

If any lead is over threshold, the program then applies several additional tests. As the ST:T ratio gets larger, the program considers the character of the STT to be more like injury.

All of the leads are analyzed for reciprocal depression. If it is present, the ST elevation is considered to be more like injury.
These three items: degree of ST elevation, ST:T ratio, and reciprocal changes are used for stating injury.

Injury is stated for those lead groups where it is most pronounced. If an MI has already been cited for that lead group, then the program does not state injury, it qualifies the MI as acute.

If injury has been stated, do no further analysis of ST elevation abnormalities.

The program has three choices
(1) pericarditis,
(2) early repolarization, or
(3) unknown origin.
Early Repolarization

Early repolarization is stated if the ST:T ratio is low and the repolarization character appears normal (that is, T waves are upright in appropriate leads and ST aligned with T).

![Diagram of early repolarization](image)

Acute Pericarditis

Pericarditis has similar criteria to early repolarization except more ST elevation is required.

ST Elevation, Mechanism Unknown

If pericarditis or early repolarization cannot be stated, the program identifies the ST elevation and suggests the three aforementioned mechanisms.

Acronym: **STEL**
ST elevation, consider early repolarization, pericarditis, or injury

If **PCARD**, **REPOL**, or **STEL** is stated, skip further ST elevation analysis.
Nonspecific ST Abnormalities

Nonspecific ST elevation abnormality is detected using the same methods as outlined above. The difference is that the threshold for elevation is twice as sensitive. Furthermore, the program only states the elevation as a nonspecific abnormality if it has characteristics that meet the criteria outlined for injury.

ST Depression Abnormalities

If the QRS is wide, do not test for ST depression abnormalities.

If injury has been called and the ST elevation is larger than the depression, do not test for any ST depression abnormality.
Subendocardial Injury

If all of these items are true, call subendocardial injury.

If subendocardial injury is true, skip further analysis.

If any repolarization abnormality has been stated, in association with hypertrophy, do no further ST depression analysis. Also, avoid RBBB.

If a nonspecific ST elevation abnormality has already been found from ST elevation, test ST depression analysis.
Adult Contour Criteria: Overview

Now analyze ST segments as was done for SUBNJ, only with more sensitivity. If true, state ST depression, consider subendocardial injury or digitalis effect (STDEP). Also skip further ST depression analysis.

Nonspecific ST Abnormality

Again, analyze the ST segment with even more sensitivity.

If this occurs in at least two leads, state NST. If AFIB is present, append PRDIG.
Digitalis Effect

Now inspect for digitalis effect.

- STDIG
  - T wave must be above ST segment.
  - Middle or end of ST segment depressed and below J point.
  - OR -
  - End or middle of ST must be depressed.
  - End of ST must be below STJ.

If digitalis is stated, do no further ST depression analysis.

Junctional ST Depression

- End of ST is positive
  - Upward sloping ST segment

If true, state: Junctional ST depression, probably normal.

- End of ST below baseline
  - Upward sloping ST segment

If true, state: Junctional ST depression, probably abnormal.
T Wave Abnormalities

Ischemia

If any injury statement has been made, do not test for ischemia.

Likewise, if LVH with repolarization abnormality is stated, do not test for ischemia.

Additional restrictions are applied to anterior leads in order to avoid calling anterior ischemia in the presence of RBBB or RVH-2ST.

T wave abnormalities are also not tested in lead groups where infarction is stated.
If ischemia is stated and a nonspecific ST abnormality was previously detected, make one statement as opposed to two.

If atrial fibrillation is present, append or digitalis effect.

If ischemia is called, skip further analysis of T waves.
If infarction is present, skip further analysis of T waves.

Nonspecific T Wave Abnormality

Acronym: NT
Small T waves or shallow T wave inversion are found in at least two leads

If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two.

If atrial fibrillation is present, append probably digitalis effect.
Abnormal QRS-T Angle

Acronym: *AQRST*
Do not test for abnormal QRS-T angle if any other T wave abnormality has already been stated.

Prolonged QT

QT interval is corrected for rate using Bazett’s formula. (See “Onsets/Offsets and Intervals” on page 3-11 for more information about Bazett’s formula.) As the ventricular rate increases, the corrected QT increases.

LNGQT -- if QTc >460 ms and rate <100 bpm, stage LNGQT.
Details

Suspect Arm Lead Electrode Reversal

Stop test if ventricular pacemaker.
Statement is made if:
either QRS axis is between 90 and 270 degrees and P axis is between 90 and 210 degrees
or QRS axis is between 130 and 270 degrees and P axis is not measurable and Q amplitude > R amplitude in lead I
Then say suspect arm lead reversal.

WPW

Skip test WPW if:
Atrial flutter or atrial fibrillation is present
or No P wave is present.
Statement is made if:
- Delta wave is present in three or more of 12 leads
- PR interval is not = 0
- P axis is >-30 degrees and <120 degrees
- P amplitude + P' amplitude in lead aVF >–50 μV
- either QRS area is positive in lead V1 and PR interval <180 ms
- or QRS area is positive in lead V2 and PR interval <160 ms
- or QRS area is negative in lead V1 and PR interval <140 ms

If QRS area is positive (R amplitude >80% of the total deflection) in lead V1, then say: Ventricular pre-excitation, WPW pattern type A.

If QRS area is negative (S amplitude >80% of the total deflection) in lead V1, then say: Ventricular pre-excitation, WPW pattern type B.

If not, say: Wolff-Parkinson-White.

If test WPW passed, then suppress with short PR.

**Atrial Enlargement**

Skip all atrial enlargement tests if:
- Test WPW passed
- Ventricular rate >150 bpm
- PR interval = 0
- No sinus rhythm or atrial pacemaker present.
- P axis is <0 degrees or >100 degrees.

**Right Atrial Enlargement**

Statement is made if:
- P wave amplitude >250 μV in any lead: II, III, aVF, V1, or V2

Then say right atrial enlargement.
Left Atrial Enlargement

Statement is made if in lead V1 or V2, P or P’:
   Amplitude $<-100 \, \mu V$
and   Duration $\geq 60$ ms
and   Amplitude area $\geq 4000 \, \mu V \times ms$ (one small box)

Then say: possible left atrial enlargement. *

If test for possible LAE passed
and   P or P’ amplitude $<-200 \, \mu V$ in lead V1 or V2.

Then say left atrial enlargement.
* This statement will not appear if screening criteria is turned on.  
  See Appendix F for more information.

Biatrial Enlargement

Statement is made if:
   Test left atrial enlargement passed
and   Test right atrial enlargement passed

Then say biatrial enlargement.

Frontal Plane Axis Deviation

Skip all frontal plane axis deviation tests if:
   Test WPW passed.

Left Axis Deviation

Statement is made if:
   QRS axis between -30 and -89 degrees

Then say left axis deviation.
Right Axis Deviation

Statement is made if:
QRS axis between 90 and 109 degrees

Then say rightward axis.*

If:
QRS axis between 110 and 180 degrees

Then say right axis deviation.*

If:
QRS axis between 181 and 269 degrees

Then say right superior axis deviation.*

* These statements will not appear if screening criteria is turned on.
See Appendix F for more information.

Indeterminate Axis

Statement is made if:
R amplitude minus S amplitude <50 μV or ≤10% of the total QRS deflection in leads I, II, and III

Then say indeterminate axis.

Low Voltage and Lung Disease

Skip test low voltage and lung disease if:
Test WPW passed
or QRS duration >120 ms.

Low Voltage

Statement is made if:
QRS deflection <1000 μV in all leads
or QRS deflection <500 μV in all frontal leads
Then say low voltage QRS.
Pulmonary Disease

Statement is made by point scoring technique
Test S1, S2, and S3 pattern used  1 point

Test passed if:
R amplitude < (4 × S amplitude) in any two of leads I, II, and III
or
S amplitude > 200 μV with no R' in leads I, II, and III
and
No R' wave is present in leads I, II, and III
or
S amplitude > 200 μV in leads I, II, and III
and
No R' wave present in leads I, II, and III
and
S amplitude in lead I > 300 μV
and
S amplitude in lead II > 400 μV
and
S amplitude in lead III > 700 μV

QRS deflection < 500 μV in all frontal leads  1 point
P axis > 80 degrees and < 270 degrees  1 point
QRS axis ≤ –30 or > 90 degrees or indetermined axis passed  1 point
R amplitude in lead V5 < S amplitude in lead V5
or
R amplitude in lead V6 < S amplitude in lead V6  1 point

If cumulative points are ≥ 3 points, then say pulmonary disease pattern.*

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Conduction Defects

Skip all tests for conduction defect if:
Test WPW passed.

RSR' or QR Pattern

Statement is made if in lead V1:
either
Q wave is >0 ms
and R wave duration >20 ms
and R wave amplitude -STJ >200 μV
and No S wave is present
or
R' wave duration >20 ms
and R' wave amplitude -STJ >200 μV
and No S' wave is present

Then say RSR' or QR pattern in V1 suggests possible right ventricular conduction delay.
* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Incomplete Right Bundle Branch Block

Statement is made if:
QRS duration is between 91 and 120 ms
and S wave duration >40 ms in any two of leads I, aVL, V4, V5, and V6
and In lead V1 or V2
either
R wave duration ≥30 ms
and R wave amplitude >100 μV
and No S wave is present
or
R' wave duration ≥30 ms
and R' wave amplitude >100 μV
and No S' wave is present

Then say incomplete right bundle branch block.
* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Incomplete Right Bundle Plus Right Ventricular Hypertrophy

Statement is made if:

- Test for IRBBB passed and
- R or R’ amplitude >1000 μV in lead V1
- QRS axis >110 degrees

Then say **incomplete right bundle branch block plus right ventricular hypertrophy.**

and

Suppress RVH.

Right Bundle Branch Block

Statement is made if:

**Test 1:**

- QRS duration ≥120 ms
- In any two of leads I, aVL, V4, V5, and V6, S wave duration >40 ms
- QRS area in lead V1 is positive
- either
  - No terminal S wave is present in lead V1
  - S amplitude + minimum STJ or STM <100 μV and <R amplitude in lead V1
  - S amplitude + minimum STJ or STM-to-R amplitude ratio <30% in lead V1
  - S amplitude + minimum STJ or STM-to-R amplitude ratio <50% in lead V1
- QRS >130 ms
- QRS axis <100 degrees

**Test 2:**

- QRS duration ≥108 ms
- QRS area is positive in lead V1
- R or R’ duration >60 ms in lead V1
- In any three of leads I, aVL, V4, V5, and V6: S wave duration >60 ms
or, if

**Test 3:**

- QRS duration >130 ms
- QRS area is positive in lead V2
- In two or more of leads I, aVL, V4, V5, and V6: S duration >40 ms
- R or R’ wave present in lead V1 and no terminal S wave

Then say **right bundle branch block**.

If test **RBBB** passed, then suppress all right axis deviation.

**RBBB Plus Right Ventricular Hypertrophy**

Statement is made if:

- Test right bundle branch block passed
- either R or R’ amplitude >1500 μV in lead V1
- QRS axis >110 degrees

Then say **right bundle branch block, plus right ventricular hypertrophy**

and suppress **right ventricular hypertrophy**.

* This statement will not appear if screening criteria is turned on.

See Appendix F for more information.

**Incomplete Left Bundle Branch Block**

Statement is made if:

- QRS duration ≥105 and ≤120 ms
- In leads V1 and V2, QRS amplitude is negative
- In leads V1 and V2, Q or S wave duration ≥80 ms
- In any two of leads I, V5, and V6, no Q wave is present
- In any two of leads I, aVL, V5, and V6, R duration >60 ms

Then say incomplete **left bundle branch block**.
Left Bundle Branch Block

Statement is made if:

- QRS duration > 120 ms
- QRS area > 1/4 of (QRS duration x maximum R amplitude) in lead I or V6. That is, the area of lead I or V6 is at least half the area of a right triangle with height h and base b.

![Diagram](image)

- h = maximum R amplitude
- b = QRS duration
- Area = 1/2 bh

- QRS balance is negative in leads V1 and V2
- In leads V1 and V2, Q or S duration ≥ 80 ms
- In any two of leads I, V5, and V6, no Q wave is present
- In any one of lead I, V5, or V6, R duration + R' duration ≥ 100 ms
- Either QRS duration ≥ 160 ms
  - or QRS duration ≥ 140 ms
    - and Over leads I, aVL, and V6, the sum of R duration and R' duration totals > 240 ms
    - or QRS duration > 120 ms
      - and Over leads I, aVL, and V6, the sum of R duration and R' duration totals > 240 ms
      - and QRS area > 1/2.5 times (QRS duration x maximum R wave amplitude) in any two of leads I, aVL, and V6

Then say left bundle branch block.

If test LBBB passed, then suppress left anterior fascicular block and left posterior fascicular block.

If LBBB not stated, but QRS balance is negative in lead V1, QRS duration > 140 ms, and RBBB test did not pass, then remember this ECG has passed as complete LBBB for internal logic purposes. This is not printed on the analysis report, but the ECG will be treated as complete LBBB in the analysis program logic.
Left Anterior Fascicular Block

Statement is made if:

- QRS axis is <-45 degrees and no indeterminate axis present
- R amplitude >Q amplitude in leads I and aVL
- Any Q wave is present in lead I
- either S or S’ is of greater amplitude than both R and R’ in lead II

Then say left anterior fascicular block.

If test left anterior fascicular block passed, then suppress all left axis deviation and ILBBB.

Left Posterior Fascicular Block

Statement is made if age >30 years:

and Test S1, S2, and S3 pattern failed
and Test pulmonary disease failed
and QRS axis between 110 and 180 degrees
and Indetermined axis not present
and R amplitude >Q amplitude in leads III and aVF
and Any Q wave is present in leads III and aVF

Then say left posterior fascicular block.

If test left posterior fascicular block passed, then suppress all right axis deviation.

Bifascicular Block

Statement is made if:

- Test RBBB passed
  - and Test left anterior fascicular block passed
- or Test RBBB passed
  - and Test left posterior fascicular block passed

Then say bifascicular block.
Nonspecific Intraventricular Conduction Delay

Statement is made if:
QRS duration is $\geq 118 \text{ ms}$ and $\leq 124 \text{ ms}$
and Tests $RBBB$ and complete LBBB failed
and Tests $IRBBB$, $ILBBB$, fascicular blocks, and $RSR$ failed

Then say *nonspecific intraventricular conduction delay.*

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Nonspecific Intraventricular Conduction Block

Statement is made if:
QRS duration $\geq 125 \text{ ms}$
and Test $RBBB$ and $LBBB$ failed

Then say *nonspecific intraventricular conduction block.*

If test nonspecific intraventricular conduction block passed, then suppress *left anterior fascicular block*, *left posterior fascicular block*, and $RSR$ or $QR$ pattern.
Ventricular Hypertrophy

Right Ventricular Hypertrophy

Skip test right ventricular hypertrophy if:
  Test WPW passed
or  Test RBBB passed
or  QRS is negative in lead V1
or  S amplitude >1000 μV in lead V1
or  QRS axis <60 degrees

Statement is made by point scoring technique:

either  R or R' amplitude >500 μV in lead V1
Add one point for every 500 μV increment up to 1500 μV
  1 point
QRS amplitude is negative and
S amplitude >500 μV in lead V5 or V6
  1 point
QRS amplitude is negative and
S amplitude >500 μV in lead V5 or V6
  1 point
QRS amplitude is negative and
S amplitude >500 μV in lead V5 or V6
  1 point
Test right atrial enlargement passed
  1 point
Patient is ≥30 years old
  1 point
Add one point for every 10 degrees increment up to maximum of 110 degrees
  1 point
Test S1, S2, and S3 pattern passed
  1 point

If cumulative RVH points are ≥ 3 points, then say possible right ventricular hypertrophy. *

If cumulative RVH points are ≥ 5 points, then say right ventricular hypertrophy.

Suppress RAD, LPFB, LOWV, RSR, and IVCD.

* This statement will not appear if screening criteria is turned on. See Appendix F for more information.
RVH with Repolarization Abnormality

Statement is made if:

Test possible RVH passed
and QRS duration ≤120 ms
and In all leads V1, V2, and V3
   either STJ > STM or STJ > STE
   or STM or STE or T amplitude ≤-100 μV
   and In no more than one lead of leads V4, V5, and V6
       STM or STE or T amplitude < -100 μV

Then say right ventricular hypertrophy with repolarization abnormality.

Left Ventricular Hypertrophy

Skip test if:

Test WPW passed
or LBBB was stated

Statement is made by point scoring technique.
Some amplitude indices are based on the patient’s age. All values are in μV. A value of XXX indicates that any test using that index will not pass.

<table>
<thead>
<tr>
<th>Index</th>
<th>under 20</th>
<th>20 to 29</th>
<th>30 to 39</th>
<th>over 39</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead V1</td>
<td>XXX</td>
<td>3000</td>
<td>2400</td>
<td>2400</td>
</tr>
<tr>
<td>Lead V5</td>
<td>XXX</td>
<td>3000</td>
<td>2600</td>
<td>2600</td>
</tr>
<tr>
<td>Leads V1 and V5/V6</td>
<td>XXX</td>
<td>4500</td>
<td>4000</td>
<td>3500</td>
</tr>
</tbody>
</table>
With QRS Widening

Statement is made if:
- Cumulative LVH points ≥ 1
- QRS duration ≥ 115 ms
- test RBBB failed *

Then say left ventricular hypertrophy with QRS widening.

If test QRS widening passed, then suppress IRBBB, IVCD, IVCB, and ILBBB.

* This condition is applicable with version 21 or higher of the 12SL analysis program.
With Repolarization Abnormality

Statement is made if any of leads I, aVL, V4, V5, or V6 have:

- STJ > STM or STJ > STE
- STE < -50 μV
- R amplitude ≥ 1100 μV
- Test atrial fibrillation failed
- LVH point logic ≥ 1

Then say LVH with repolarization abnormality.

LVH with QRS Widening and Repolarization Abnormality

Statement is made if:

- Test QRS widening test and repolarization abnormality passed

Then say LVH with QRS widening and repolarization abnormality.

Biventricular Hypertrophy

Skip test of biventricular hypertrophy if:

- Test WPW passed
- If test RBBB passed

Statement is made if:

- Test RVH passed and cumulative LVH points were ≥ 1
- Patient's age ≥ 30 years
- QRS axis > 90 degrees
- R or R' amplitude ≥ 2600 μV in lead V5 or V6
- Q, S, and S' amplitudes < 500 μV in lead V1
- R or R' amplitude > 2600 μV in lead V6

Then say biventricular hypertrophy.

Suppress all LVH and RVH statements.

If test QRS widening passed, then append with QRS widening.

If test repolarization passed, then append with repolarization abnormality.

If test QRS widening and test repolarization passed, then say with QRS widening and repolarization abnormality.
Infarction

Anterior Infarction Tests

Skip tests if WPW passed or LBBB stated:

**Test 1**

Q duration in lead V3 >30 ms and Q amplitude is ≥75 μV

**Test 2**

Q duration in lead V4 > Q threshold duration and
Q amplitude ≥75 μV

Establish Q duration threshold via the following criteria:

If QRS duration <120 ms
and R amplitude in lead V4 >1200 μV, then for every 100 μV over
1200 μV (from lead V4 R amplitude) add 1 ms to the default lead
V4 Q duration of 30 ms up to maximum of 40 ms
or If QRS duration ≥120 ms
and If R amplitude in lead V4 >800 μV, then Q duration
threshold in lead V4 = 35 ms
and If RS in lead V1 is present
and R duration in lead V1 >35 ms, then lead V4 duration
threshold = R duration in lead V1 + 3 ms up to a
maximum of 45 ms

**Test 3**

Q amplitude in lead V3 ≥100 μV
and QRS balance is negative in lead V3

**Test 4**

Q amplitude in lead V4 ≥100 μV
and QRS balance is negative in lead V4

**Test 5**

Q duration in leads V2 and V3 >20 ms
and Q amplitude in leads V2 and V3 > 200 μV

Skip tests 6 and 7 if the QRS deflection (maximum R amplitude +
maximum S amplitude) in lead V3 ≤ 50 μV.

**Test 6**

*LVH* is not passed and balance in leads V1 and V2 is negative
and Maximum R or R' in lead V3 <200 μV
and Maximum R amplitude in lead V3 + 25 μV ≤ R amplitude
in lead V2
and Q + R + S duration in lead V3 ≤ 50 ms
or LVH not passed and balance in leads V1 and V2 is negative
and R amplitude in lead V3 < 200 μV
and R amplitude in lead V3 + 25 $\mu$V $\leq$ R in lead V2
and Q + R + S duration in lead V3 $\geq$ 50 ms

Test 7

$LVH$ is not passed and QRS duration $\leq$ 120 ms and
Q amplitude in lead V2 is 0 $\mu$V
and Maximum R or R’ amplitude in lead V3 $<$ 100 $\mu$V
and Q + R + S duration in lead V3 $\leq$ 50 ms

or $LVH$ does not pass and QRS duration $\leq$ 120 ms and Q
amplitude in lead V2 is 0 $\mu$V
and R amplitude in lead V3 $<$ 100 $\mu$V
and Q + R + S duration in lead V3 $\geq$ 50 ms

SKIP TEST 8 IF THE QRS DEFLECTION (maximum R amplitude +
maximum S amplitude) in lead V4 $<$ 50 $\mu$V.

Test 8

Q + R + S duration $\leq$ 50 ms
and No $LVH$ passed
and QRS balance in leads V1 and V2 is negative.
and Maximum R amplitude in lead V4 + 25 $\mu$V $\leq$ R amplitude in lead V3

or Q + R + S duration in lead V4 $\geq$ 50 ms
and R amplitude in lead V4 $<$ 200 $\mu$V
and R amplitude in lead V4 + 25 $\mu$V $\leq$ R amplitude in lead V3
and No $LVH$ passed
and Balance in leads V1 and V2 is negative

Cannot Rule Out Anterior Infarction

If any $AMI$ tests passed, then say cannot rule out anterior infarction.*

* This statement will not appear if screening criteria is turned on.

See Appendix F for more information.

Possible Anterior Infarction

Statement is made if:

Any of AMI tests passed
and Low voltage did not pass and IVCB did not pass
and In lead V3 the R duration $<$ 30 ms, the Q
duration = 0 ms, and the S duration $>$ 40 ms or
In lead V3 the Q duration $>$ 30 ms

and In lead V4 the R duration $<$ 45 ms, the Q duration
= 0 ms, and the S duration $>$ 40 ms or
In lead V4 the Q duration $>$ 35 ms

or In lead V3 the R duration $<$ 20 ms, S duration $>$ 40 ms,
and Q duration = 0 ms

or In lead V3 the Q duration $>$ 35 ms
Adult Contour Criteria: Details

or In lead V4 the R duration <25 ms, S duration >40 ms, and Q duration = 0 ms
or In lead V4 the Q duration >40 ms

Then say possible anterior infarction.*
* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Anterior Infarction

Statement is made if:
Any of AMI tests passed
and No low voltage passed and no IVCB passed
and In lead V3 the R duration ≤25 ms, the Q duration = 0 ms, and the S duration >40 ms, or
In lead V3 the Q duration >30 ms
and In lead V4 the R duration ≤30 ms, the Q duration = 0 ms, and the S duration >40 ms, or
In lead V4 the Q duration >40 ms
or In lead V3 the R duration <15 ms, S duration >40 ms, and Q duration = 0 ms
or In lead V3 the Q duration >40 ms
or In lead V4 the R duration <20 ms, S duration >40 ms, and Q duration = 0 ms
or In lead V4 the Q duration >50 ms
or Any anterior injury test passed or the special T amplitude in lead V3 < -150 μV

Then say anterior infarction.

If LBBB statement not stated, QRS duration >145 ms, QRS balance in lead V1 is negative, and RBBB is not stated:
and In any leads V1 through V6, the QRS balance is positive and Q duration >30 ms, Q amplitude >100 μV, and any anterior infarction test 1 through 5 passed

Then If “possible anterior infarction” test passed, then state possible anterior infarction.

or If anterior infarction passed, then state anterior infarction.

Determine age of infarct:
If anterior injury is present

Then append, possibly acute.

Otherwise append, age undetermined.
Septal Infarction Tests

Skip septal infarction tests if:
- Test WPW passed
- or Tests complete LBBB passed

**Test 1**
- QR is present in lead V1
- Q duration in lead V2 ≥ 30 ms

**Test 2**
- Q duration ≥ 30 ms in lead V2

**Test 3**
- Q amplitude ≥ 100 μV in lead V2
- and QRS balance is negative in lead V2 or test RBBB passed

**Test 4**
- If no Q present in lead V1, test if R amplitude in lead V2 < R amplitude in lead V1 by more than 50 μV, R amplitude in lead V2 ≤ 200 μV, AMI did not pass, and QRS deflection in lead V2 > 50 μV

Cannot Rule Out Septal Infarct

Statement is made if:
- Any SMI test passed

Then say *cannot rule out septal infarct.*

* This statement will not appear if screening criteria is turned on.
  
  See Appendix F for more information.

Septal Infarct

Statement is made if:
- Any SMI test passed
  - and either STM > 50 μV and T and T' are negative in lead V2
  - or Test IVCB failed and LVH is not present

Then say *septal infarct.*

Determine age of infarct:
- If anterior injury present
  - Then append, *possibly acute.*

Otherwise append, *age undetermined.*
Possible Lateral Infarct

If WPW, then skip all tests for lateral infarct.

**Test 1**

If AMI tests 1, 2, 3, 4, and 5 did not pass

and

In lead V5 the Q + R + S duration ≤50 ms and
QRS deflection >50 μV and maximum
R or R' amplitude in lead V5 <100 μV

or

In lead V5 the Q + R + S duration >50 ms and
R amplitude <100 μV

2 points

**Test 2**

In lead V6 if maximum R or R' amplitude <100 μV and
Q + R + S duration ≤50 ms and QRS deflection >50 μV

or

In lead V6 if Q + R + S duration >50 ms and R amplitude <100 μV

2 points

**Test 3**

Test for the following conditions in leads I, V5, V6, and aVL,
1 point each lead

- Q duration >25 ms
- Q amplitude >75 μV
- 5 times Q amplitude >R amplitude: when lead V5 or V6
- 4 times Q amplitude >R amplitude: when lead I or aVL

1 point

If cumulative point value >2 points, then say possible lateral infarct*

* This statement will not appear if screening criteria is turned on.

See Appendix F for more information.

Lateral Infarct

Statement is made if in two or more of leads I, aVL, V5, and V6:

- Q duration >30 ms
- Q amplitude >75 μV
- 5 times Q amplitude >R amplitude in lead V5 or V6
- 4 times Q amplitude >R amplitude in lead I or aVL

or

Test for possible lateral infarction passed and test for lateral injury passed

Then say lateral infarct

If test any lateral infarct passed, then suppress all right axis deviation.

If no Q wave is present and R amplitude >200 μV in lead V3, then suppress all anterior infarct. If left anterior fascicular block is not passed, then suppress left posterior fascicular block and bifascicular block.
Determine age of infarct:
   If lateral injury present
      Then append, possibly acute

Otherwise append, age undetermined

**Anteroseptal Infarct**

Statement is made if:
   Any AMI tests passed
   and Any SMI test passed
   and LMI failed

Then say anteroseptal infarct

If cannot rule out or possible anterior infarction passes in the presence of
   septal infarction, then say possible anteroseptal infarct* or cannot rule
   out anteroseptal infarct.

   * This statement will not appear if screening criteria is turned on.

   See Appendix F for more information.

   Suppress AMI
   Suppress SMI
   Suppress ILBBB
   Suppress IVCD
   Suppress PULD

Determine age of infarct:
   If any were labeled acute, append, possibly acute
   Otherwise append, age undetermined

**Anterolateral Infarct**

Statement is made if:
   Any AMI tests passed
   and Any LMI test passed

Then say anterolateral infarct

If cannot rule out or possible anterior infarct passes and possible lateral
   infarct passes, then say possible anterolateral infarct*.

If LMI passed in the presence of cannot rule out or possible anterior
   infarct or if AMI passed in the presence of possible lateral infarct, then
   say anterolateral infarct

   Suppress SMI
   Suppress AMI
   Suppress LMI
   Suppress PULD
   Suppress ILBBB
   Suppress IVCD
Determine age of infarct:
   If any were labeled acute, append, *possibly acute*
   Otherwise append, *age undetermined*

**Inferior Infarct**

Skip test inferior infarct if:
   Test *WPW* passed
or  *LBBB* printed

**INFERIOR INFARCT TESTS**

**Test 1:** Test for normal repolarization.

   Test repolarization abnormalities
   (refer to *STELE*, *STDEP*, and T wave abnormality details)
   Normal repolarization = test 1 passes

**Test 2:** Test for normal QRS and T.

   If the QRS axis and T axis <30 degrees apart, use T amplitude
   threshold of 50 μV
else  use T amplitude threshold of 100 μV
If   T amplitude in leads aVF and V3 through V6 >T amplitude
and  Maximum ST amplitude in leads aVF and V3 through V6 >-20 μV
and  Minimum ST amplitude in lead aVF <50 μV
and  Minimum ST amplitude in leads V3 through V6 <200 μV
and  R amplitude in lead II >500 μV and Q:R ratio in lead II
     <1.5 (20%)
o    R amplitude in lead aVF >500 μV
and  QRS balance in lead V5 is positive

   and  QRS axis >0 degrees
   and  QRS axis and T axis is <45 degrees apart

then pass Test 2

**Test 3:** Test for normal repolarization and QRS axis and duration

   if   Test 1 passed
and  QRS axis >10 degrees
and  QRS duration < 120 ms
then pass Test 3
Test 4: Test for Q wave amplitude in lead aVF

Skip Test 4 if test 3 fail
Results of Test 2 are used to adjust for Q wave thresholds
Test 2 pass uses less sensitive Q wave threshold criteria
Test 2 fail uses more sensitive Q wave threshold criteria (in parentheses)

if
QRS duration < 100 ms
and Q amplitude in lead aVF ≥100 μV
and Q duration ≥40 (30) ms in lead aVF
and Q:R duration >1:5 in lead aVF
or Q amplitude ≥100 μV in lead aVF
and Q duration in lead aVF ≥40 ms
or Q amplitude >75 μV in lead aVF
and Q duration >40 ms in lead aVF
and Q:R ratio in lead aVF ≥1:5
or QRS duration ≥100 ms and <120 ms
and Q amplitude in lead aVF ≥75 μV
and Q duration in lead aVF ≥40 (35) ms
or Q duration in lead aVF ≥40 (25) ms and Q:R ratio in lead aVF ≥1:5 (20%)
or QRS duration < 120 ms
and Q amplitude in lead aVF >200 μV
and Q duration in lead aVF ≥30 ms
and Q:R duration in lead aVF >1:3

then pass Test 4

If Test 3 passed and Test 4 failed (normal QRS axis and duration and no repolarization abnormalities and no significant Q wave in aVF), then stop and do not execute any further IMI tests.

Cannot Rule Out Inferior Infarct (Masked by Left Anterior Fascicular Block?)

Statement is made if:
Q duration + R duration <20 ms in lead aVF
and R amplitude in lead aVF <50 μV
and Test left anterior fascicular block passed

Then say cannot rule out inferior infarct (masked by left anterior fascicular block?) *

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Cannot Rule Out Inferior Infarct

Statement is made if:
In lead II or aVF:
Q amplitude $>50$ μV
and Q duration $\geq 25$ ms
and Q amplitude minus the minimum of T or T’ $>1/5$ of R amplitude

or
If Q amplitude $>50$ μV
and Q duration $\geq 20$ ms
and either QRS axis $\leq 45$ degrees
or QRS axis $>240$ degrees
and Maximum R amplitude in aVF $<100$ μV

Then say cannot rule out inferior infarct *

* This statement will not appear if screening criteria is turned on. See Appendix F for more information.
Possible Inferior Infarct

In lead II or aVF:
- Q amplitude $>75 \, \mu V$
- Q duration $\geq 35$ ms
- Q wave minus the minimum of T amplitude or T' amplitude is $>1/5$ R amplitude

or In lead II or aVF:
- Q amplitude $>75 \, \mu V$
- Q duration $\geq 30$ ms
- Q wave minus the minimum of T amplitude or T' amplitude is $>1/4$ R amplitude

or In lead II or aVF:
- Q amplitude $>75 \, \mu V$
- Q duration $\geq 25$ ms
- Q wave minus the minimum of T amplitude or T' amplitude is $>1/3$ R amplitude

or In lead II or aVF:
- Q amplitude $>75 \, \mu V$
- Q duration $\geq 20$ ms
- Both STJ and STM are $\geq 50 \, \mu V$
- Special T amplitude $<-50 \, \mu V$

or In lead II or aVF:
- Q amplitude $>100 \, \mu V$
- Q duration $\geq 40$ ms
- Q amplitude minus the minimum of T amplitude or T' amplitude $>1/4$ R amplitude

or In lead II or aVF:
- STJ $>100 \, \mu V$ or special T amplitude $- STE < -200 \, \mu V$

Then say possible inferior infarct
* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Inferior Infarct

Statement is made if:
- Cannot rule out IMI passed or possible IMI passed and IINJ passed
or
- Any possible inferior infarct test passed

and In lead II or aVF:
- STJ $>100 \, \mu V$ or special T amplitude $- STE < -200 \, \mu V$

or In lead II or aVF:
- Q amplitude $>100 \, \mu V$
- Q duration $\geq 40$ ms
- Q amplitude minus the minimum of T amplitude or T' amplitude $>1/4$ R amplitude

or In lead II or aVF:
- Q amplitude $>100 \, \mu V$
- Q duration $\geq 35$ ms
Adult Contour Criteria: Details

and Q amplitude minus the minimum of T amplitude or T' amplitude >1/3 R amplitude
or In lead II or aVF:
   Q amplitude >100 μV
   Q duration ≥30 ms
   and Q amplitude minus the minimum of T amplitude or T' amplitude >1/2 R amplitude

Then say inferior infarct

If inferior injury passed and extra lead V4r is present, test for right ventricular involvement:
   If STM in lead V4r > 100 μV
   or STM in lead V4r > 50 μV and 2nd or 3rd degree AV block and
   STM in lead III > STM in lead II
Then append with right ventricular involvement *
* This statement is made by version 21 or higher of the 12SL analysis program.

Determine age of infarct:
   If inferior injury passed
Then append , possibly acute
Otherwise append , age undetermined

Inferior-Posterior Infarct

Skip test with posterior extension if:
   Test WPW passed

Statement is made if:
   Any inferior infarct test passed
   and No Q wave is present in leads V1 and V2,
   and QRS duration <120 ms
   and Test complete RBBB, failed
   and either R duration ≥35 ms in leads V1 and V2,
     and QRS balance in leads V1 and V2 is positive
     or QRS balance in lead V2 is positive
     or Maximum ST amplitude < -50 μV in lead V2
     or R duration in lead V1 or V2 > 40 ms
     and R amplitude in lead V1 or V2 > 200 μV
     and Maximum ST amplitude in lead V1 or V2 < -100 μV
     or Balance in lead V3 is positive
     and Maximum ST amplitude in lead V3 < -100 μV
     and Maximum ST amplitude in lead V2 < -50 μV
     or Maximum ST amplitude in lead V1 < -50 μV
     and Maximum ST amplitude in lead V2 < -50 μV
     and Maximum ST amplitude in lead V3 < -50 μV

Then say inferior-posterior infarct
Suppress all RVH, IRBBB, BVH, and IMI statements
If possibly acute (see immediately below) and extra lead V4r is present, test for right ventricular involvement:
   If STM in lead V4r > 100 μV
   or STM in lead V4r > 50 μV and 2nd or 3rd degree AV block and
   STM in lead III > STM in lead II
Then append *right ventricular involvement*

* This statement is made by version 21 or higher of the 12SL analysis program.

Determine age of infarct:
   If inferior injury present or maximum ST amplitude in
   lead V2 < -100 μV
   Then append: , possibly acute
   Otherwise, append: , age undetermined

**Posterior Infarct**

Skip test if inferior-posterior infarct or WPW passed

Requires:
   Age > 30 years
   and QRS duration < 120 ms
   and No RBBB, IRBBB, or RVH passed

**Test 1**
   R amplitude in leads V2 and V3 > 700 μV
   and R amplitude in leads V2 and V3 > 3 times S amplitude

**Test 2**
   QRS balance in leads V1 and V2 is positive
   or QRS balance in leads V2 and V3 is positive

**Test 3**
   Maximum ST in lead V1 or V2 < -100 μV

**Test 4**
   T amplitude in lead V1 or V2 is > 0 μV

**Test PMI 1**
   TEST FOR R:S RATIO IN LEAD V1
   If test 2 or tests 1 and 4
   and If test 3 failed
   and If R:S ratio in lead V1 ≥ 1:2
   and R amplitude in lead V1 > 100 μV
   and R duration in lead V1 > 20 ms
   or R:S ratio ≥ 1:3 in lead V1
   and R amplitude in lead V1 > 100 μV
   and R duration in lead V1 ≥ 40 ms
   and If T amplitude in V1 ≥ 0 μV
   and T amplitude in lead V2 > 200 μV
Adult Contour Criteria: Details

and T amplitude in lead V3 >200 μV
and LVH test failed

**Test PMI 2** TEST TRUE POSTERIOR INFARCT
Tests 2, 3, and 4 passed

Statement is made if:
- Test PMI 2 passed and any IMI test passed
- PMI 1 passed, PMI 2 failed, and IMI passed

Then say inferior-posterior infarct and suppress IMI statement

If test PMI 2 passed and IMI failed, then say posterior infarct

If PMI 1 passed, PMI 2 failed, and IMI failed, then say *increased R/S ratio in V1, consider early transition, or posterior infarct*

Determine age of infarct if IMI and PMI or PMI is stated:
- If test PMI 2 passed
  - IMI is acute
- Maximum ST amplitude in lead V2 < -50 μV

Then append, *possibly acute*
Otherwise append, *age undetermined*

If PMI 1 or PMI 2 passed then suppress RSR’ pattern statement
**ST Abnormality (Elevation)**

Skip test *ST abnormality (elevation)* if:
- Test WPW passed
- or Heart rate >120 bpm and test *RBBB* passed
- or Test *LBBB* passed

**Nonspecific ST Abnormality (Elevation)**

Statement is made if:
- All tests of infarct failed
- and Test *RBBB* failed
- and QRS duration <120 ms
- and In any 2 of leads I, II, III, aVF, and V3 through V6 STJ, STM, and STE are all $\geq 50 \, \mu V$
- and The slope from QRS onset to J point $\geq$ slope of ST segment
- and T is not tall

Then say *nonspecific ST abnormality*

**Repolarization Tests**

Skip statement if:
- QRS $>140$ ms, or *LBBB, RBBB, or MI* is present

Continue all early repolarization tests if:
- Corrected Q-T interval is between 370 and 460 ms
- and Any test infarct failed
- and Test *IRBBB* failed
- and Test *ILBBB* failed
- and Test *RBBB* failed
- and Test *RVH* failed
- and *LVH* failed
- and QRS duration <120 ms
- or If any ST elevation $\geq 200 \, \mu V$ in the precordial leads
- and $\geq 100 \, \mu V$ in the limb leads (other than leads aVR and V1)
- and The QRS balance is positive

*** REPOLARIZATION TEST 1 ***

Count leads from leads V1 through V6 with a QRS balance $>0$ in which both STJ and STM are $\geq 75 \, \mu V$

plus The number of leads from I, II, III, aVL, and aVF with a QRS balance $>0$ in which ST amplitude $\geq 50 \, \mu V$

also Compute the sum of the amplitudes of the smaller of STJ and STM for each lead which passes

*** REPOLARIZATION TEST 2 ***

Count the number of leads with tall T waves which passed repolarization test 1
ST Elevation, Early Repolarization, Pericarditis or Injury

Skip statement if QRS >140 ms, or LBBB, RBBB, or MI is present.

Statement is made if:
- Three or more leads pass repolarization test 1
- The sum from repolarization test 1 ≥450 μV
- Any ST elevation >200 μV in the precordial leads
- ≥100 μV in the limb leads (other than leads aVR and V1)
- QRS balance is positive
- * In at least one lead of I, II, aVF, and V3 through V6, the T amplitude is negative or T' amplitude < -50 μV
- * If in lead aVL the T or T' amplitude < -100 μV and either QRS axis < 50 degrees or in any leads II, III, and aVF, the minimum ST amplitude > 100 μV and in lead V5 or V6 the minimum ST amplitude < 50 μV
- * If in at least two leads (other than leads aVR and V1) minimum ST amplitude < 0 μV
- * If in at least one lead (other than leads aVR and V1) minimum ST amplitude < -50 μV and in at least two leads (other than leads aVR and V1) minimum ST amplitude < 20 μV

Then say ST elevation, consider early repolarization, pericarditis or injury †

* If tests marked with "*" pass under any condition, skip to pericarditis tests.
† This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

ST Elevation, Probably Due to Early Repolarization

Statement is made if:
- Test ST elevation, consider early repolarization, pericarditis, or injury passed
- In more than half of the leads passing repolarization test 1, T is also tall

Then say ST elevation, probably due to early repolarization *

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Early Repolarization

Statement is made if:
More than five leads pass early repolarization test 1 and
T wave is tall in five or more leads
and The sum calculated in early repolarization test 1 ≥500 μV

Then say early repolarization *

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information

Possible Acute Pericarditis

Skip test acute pericarditis if:
Any test infarct passed
or QRS duration ≥120 ms

Count leads from leads I, II, and aVF in which both STJ and STM are ≥75 μV
plus The count of leads (V2 through V6) in which both
STJ and STM are ≥90 μV

Statement is made if:
The total count is at least five
and In any four of leads I, II, V4, V5, and V6 T amplitude is >0 μV
and STJ >1/4 of the T amplitude
and In all leads, except leads aVR and V1, both STJ and STM
are >-100 μV and T amplitude >0 μV.

Then say possible acute pericarditis *

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Acute Pericarditis

Statement is made if possible pericarditis is made and
Count the number of leads (leads I, II, and aVF) in which both
STJ and STM are ≥90 μV plus count the number of leads
(V2 through V6) in which both STJ and STM are ≥110 μV

If count ≥5, then say acute pericarditis
Injury Pattern Tests

Skip test all injuries if:
   Any tests pericarditis passed

(Done on all 12 leads individually)

Test 1:
Inspect QRS balance:
   Count the number of leads in frontal plane where QRS balance
   is <1000 \( \mu V \) and in the precordium where the QRS balance
   <2000 \( \mu V \). Test 1 passes if count = 12.

Test 2:
Test at all 12 leads (except leads aVR and V1) for ST elevation:
   (Skip lead groups with infarct present)
   If AMI skip leads V2, V3, and V4
   If SMI skip lead V2
   If IMI skip leads II, III, and aVF
   If LMI skip leads I, aVL, V5, and V6
For this test and subsequent tests, the parameter ST LIMIT is set for
each lead:
   *ST LIMIT = 200 \( \mu V \) unless,
   If frontal lead (I, II, III, aVR, aVL, and aVF)
   or If in leads V5 and V6 (R-S) \( \geq 0 \) \( \mu V \) then = 100 \( \mu V \)
If lead is elevated
   and QRS balance is positive
   or In precordial leads QRS deflection <1500 \( \mu V \)
   or In frontal plane QRS deflection <1000 \( \mu V \)
   or If QRS balance is negative and ratio of maximum S
       amplitude to QRS deflection <75%
then Test 2 passes

Test 3:
Look for ST elevation based on QRS duration (except leads V1 and aVR)
   SKIP LEAD GROUPS WITH MI PRESENT
   *Apply ST LIMIT as above
   If lead is elevated
   and QRS duration is \( \geq 120 \) but <130 ms and QRS balance is
       positive
   and Ratio of QRS balance to QRS deflection must be >15%
   or QRS duration \( \geq 130 \) but <150 ms
   or Ratio of QRS balance to QRS deflection must be >25%
   or QRS duration \( \geq 150 \) ms
   and Ratio of QRS balance to QRS deflection must be >50%
   or QRS duration <120 ms and QRS balance is negative or
       positive
   and If minimum STJ and STM \( >100 \) \( \mu V \) in frontal leads
   and If minimum STJ and STM \( >200 \) \( \mu V \) in precordial leads
**Test 3: (Continued)**

If any of the leads meet the above criteria, then inspect further for that lead group.

*Apply ST LIMIT as above for specific lead group

If Test 1 passed

and If in precordial leads minimal STJ and STM >300 μV = set injury flag

or If in precordial leads maximum R + maximum S <1000 μV

and Minimal STJ and STM >200 μV = set injury flag

or If in frontal lead minimum STJ and STM >200 μV = set injury flag

or If frontal lead maximum R + maximum S <750 μV

and Minimal STJ and STM >100 μV = set injury flag

or In any lead the minimal STJ and STM >½ T amplitude = set injury flag

else If test 2 passed

*Apply ST LIMIT as above

and If precordial lead, ST elevation >300 μV = set injury flag

or If frontal lead, ST elevation >200 μV = set injury flag

or If in any lead, the minimal STJ and STM >1/2 T amplitude

or If in any lead T' amplitude < -150 μV and T' amplitude (absolute value) > 1/8 of T amplitude for inspected lead that is elevated

or If T amplitude is negative = set injury flag

**Test 4:**

If Test 3 passed:

and If in precordial leads, STJ and STM >100 μV

or If in frontal leads, STJ and STM >50 μV

and If in elevated lead T' amplitude < -150 μV

and T' amplitude (absolute value) > 1/8 of T amplitude = set injury flag

or If T amplitude is negative = set injury flag

**Test 5:**

If Test 1 or Test 2 passed, look for reciprocal changes:

and Excluding leads aVR and V1, count the number of leads where:

Test 5a: Maximal STJ and STM < -100 μV in any lead

Test 5b: Maximal STJ and STM < -50 μV in any lead

Test 5c: Maximal STJ and STM < 0 μV in any lead

and If Test 5a count > 0

or Test 5b count ≥ 2

or Test 5b count ≥ 1 and Test 5c count ≥ 3 set injury flag
Test 6:
If Test 5 fails and injury flag is set:
and No MIs passed
and QRSV passed
and No LVHR present
Then state ST elevation, early repolarization, pericarditis or injury
If LVH with repolarization is present, the injury flag is clear and no statement is made.

Anterior Injury

Statement is made if:
In any lead V2, V3, or V4 criteria for ST elevation and any injury flag set

Then say ST elevation, consider anterior injury or acute infarct

If there is no evidence of LVH, RBBB, IRBBB, LBBB, IVCB and the QRS duration is less than 140 msec and the ventricular rate less than 100 bpm and the age of the patient is greater than or equal to 30 years old then use the following more sensitive criteria for Anterior Injury.

This Anterior Injury Criteria relies on the use of “Concomitant repolarization” information, (i.e. leads V2 - V4 are inspected for ST elevation and the inferior leads II, III, AVF are inspected for concomitant repolarization changes). The concomitant repolarization changes consist of depressed ST segments, which are weighted more heavily if they are down sloping, and T wave inversion. In this criteria the concept of setting or adapting the ST elevation thresholds based on QRS balance is used. This allows for increased sensitivity by allowing lower ST elevation thresholds to be used to call Anterior Injury but retains high specificity by requiring the presence of other repolarization changes in the inferior leads.

Inspection of the Inferior leads for repolarization changes.

T wave inversion is present if in leads II or AVF the T wave amplitude or T' amplitude is less than -100 μV.

ST depression is present if in leads II, III, AVF the STJ, STM or STE point is depressed more than -20 μV. In addition if the ST segment is depressed and STE is depressed more than the STM point and the STM point is depressed more than the STJ point (down sloping from STJ to STM to STE) then the ST segment is considered to be “down sloping”.

The ST elevation thresholds for V2, V3, and V4 are set according to the following:
If the QRS deflection (R+S) is less than or equal to 500 μV the ST threshold is 100 μV.
If the QRS deflection (R+S) is less than or equal to 1000 μV the ST threshold is 150 μV.
If the QRS deflection (R+S) is less than or equal to 1500 μV the ST threshold is 200 μV.
If the QRS deflection (R+S) is less than or equal to 2000 \( \mu \text{V} \) the ST threshold is 250 \( \mu \text{V} \).

If the QRS deflection (R+S) is greater than 2000 \( \mu \text{V} \) the ST threshold is 300 \( \mu \text{V} \).

If inferior ST depression and T wave inversion and down sloping ST segments are all present, then the Anterior ST elevation threshold is decreased by 25 \( \mu \text{V} \).

The ST elevation in V2, V3 and V4 is established by a point scoring system. For each lead, if the minimum of the STJ and the STM point are greater than the set threshold 1 point is awarded. If two of the inferior leads have depressed and downsloping ST segments with T wave inversion an additional point is awarded. In the case where the QRS deflection is less than 500 \( \mu \text{V} \) if the minimum of the STJ and the STM point is elevated by more than 200 \( \mu \text{V} \) an additional point is awarded. If the ST threshold is less than 250 and the minimum of the STJ and the STM point is greater than 300 \( \mu \text{V} \) an additional point is awarded. Thus a single lead could accrue a maximum point score of 4.

For Anterior Injury to be called the point score for the three leads V2, V3, V4 must be greater than or equal to 2 points and at least one inferior lead must have ST depression and or T wave inversion.

For the case where a Q wave Anterior or Septal MI has been called, the MI is dated as acute if for the Anterior MI the minimum of the STJ and the STM point is greater than 200 \( \mu \text{V} \) and the T wave is upright (positive) and the STE point is less than the T wave amplitude in V2 or V3 or V4. For the Septal MI the same criteria is used but only for lead V2.

For the special case where there is a Q wave in V3 that is greater than 100 \( \mu \text{V} \) in amplitude and greater than 25 msec in duration. If the points awarded in the ST elevation section are 2 or more and the Anterior Elevation Flag is set, the Anterior MI is dated as Acute.

In addition to the previously described criteria additional Anterior injury criteria was added below and also is used when “dating” a Q wave MI as acute.

Part 1 focuses in on the ST segment in the leads V2 and V3 for ST elevation, and takes into account the T wave amplitude in the leads being inspected for elevation. This enhancement is focusing on the Septal and Antero-Septal manifestations of injury patterns. The Concomitant repolarization changes are confined to leads AVF, I, and V6 in this criteria.

Part 2 uses the ST and T wave data to “date” a Q wave MI which occurs in leads V2 – V4.

**NOTE**

ECGs in this criteria are included in the analysis if they have no evidence of LVH, RBBB, IRBBB, LBBB, IVCB and have a QRS duration less than 140 msec with a ventricular rate less than 100 bpm and the age of the patient is greater than or equal to 30 years old.
Part 1 criteria are outlined in three steps.

**Step 1:** Look for ST elevation in V2 and V3.

The ST elevation criteria is met if in any of V2 or V3 either the STJ point is elevated by more than 150 $\mu$V or the STM point is elevated by more than 250 $\mu$V with the requirement that the T wave amplitude in that lead be more than 1200 $\mu$V.

**Step 2:** Look for ST and T wave repolarization changes in leads AVF, V6, I.

The ST criteria require that the STJ point be depressed (i.e. less than 0 $\mu$V) and the STM point be depressed by more than -50 $\mu$V and the T or T' amplitude in that lead be greater than 100 $\mu$V.

**Step 3:** Look for large deflections in V2 and V3. If this pattern is found then do not call Injury.

If the Maximum of either the Q wave or the S wave in leads V2 or V3 exceeds 2000 $\mu$V then no injury will be called.

If the Criteria in steps 1 and 2 are met and the criteria for step 3 is not present, then call Anterior Injury.

Part 2 of the Anterior Injury Criteria looks in detail at “dating” a Q wave Anterior Infarct as Acute.

Four ST and T wave criteria tests are applied to the leads V1 – V4.

**NOTE**

The following tests are performed only if the ECG shows no evidence of LVH, IVCB, ILBBB, LBBB, IRBBB, RBBB, and has a QRS duration less than 116 msec, a ventricular rate less than 100 bpm, the patients age is greater than 30 years old and the ECG shows evidence of either a non acute septal, anterior or inferior MI.

Test 1: requires the STM point to be elevated by at least 100 $\mu$V and also requires the T amplitude be greater than 150 $\mu$V with a T' amplitude being less than -150 $\mu$V.

Test 2: requires the STM point be elevated by at least 150 $\mu$V and also requires the T amplitude to be greater than 250 $\mu$V with a T' amplitude less than -50 $\mu$V.

Test 3: requires the STM point to be elevated more than 250 $\mu$V and in addition requires the T amplitude to be greater than 1200 $\mu$V.

Test 4: requires the STM point to be elevated more than 200 $\mu$V and requires the T amplitude to be greater than 500 $\mu$V and in addition requires that the T amplitude is greater than the QRS deflection in that particular lead.

If the Maximum of either the Q wave or the S wave in leads V2 or V3 exceeds 2000 $\mu$V, then no injury will be called.

If the above test is not met then if test 1 and 2 are met or test 3 and 4 are met or test 4 alone is met, then call Anterior Injury.
Lateral Injury

Statement is made if:
   In any lead I, aVL, V5, or V6 criteria for ST elevation
   and   Injury test passed

Then say ST elevation, consider lateral injury or acute infarct

Inferior Injury

Statement is made if:
   In any lead II or aVF criteria for ST elevation
   and   Any injury test passed

Then say \textit{ST elevation, consider inferior injury or acute infarct}

If anterior injury, lateral injury, and inferior injury present, then say
\textit{ST elevation, consider anterolateral injury or acute infarct}
\textit{ST elevation, consider inferior injury or acute infarct}

If anterior and lateral injury present, then say \textit{ST elevation, consider anterolateral injury or acute infarct}

If inferior and lateral injury present, then say \textit{ST elevation, consider inferolateral injury or acute infarct}

If inferior injury present and extra lead V4r is present, test for right ventricular involvement:
   If STM in lead V4r > 100 \, \mu V
or   STM in lead V4r > 50 \, \mu V and 2nd or 3rd degree AV block and
   STM in lead III > STM in lead II

Then append \textit{with right ventricular involvement} *

* This statement is made by version 21 or higher of the 12SL analysis program.
Adult Contour Criteria: Details

ST Abnormality (Depression)

Skip ST abnormality (depression) if:
  Test WPW passed
or  Test LBBB passed
or  QRS duration >125 ms
or  Heart rate >120 bpm and RBBB passed

Statement not made if:
  Acute MI or injury stated
  and  If ST elevation is > depression

ABNORMALITY TEST

Condition for skipping applies to all ST tests.

Junctional ST Depression, Probably Normal

Skip test if:
  Test LVH secondary repolarization passed
or  Test RVH with secondary repolarization passed
or  Test nonspecific ST abnormality (elevation) passed
or  Test RBBB passed
or  Any acute infarct or injury test passed
or  Any MI test passed

Statement is made if:
  In any two of all leads, except lead aVR, STJ < -100 μV,
  and STE > 0

Then say junctional ST depression, probably normal *

* This statement will not appear if screening criteria is turned on.
  See Appendix F for more information.
Junctional ST Depression, Probably Abnormal

Skip test if:
   Test LVH and RVH with secondary repolarization passed
or Test nonspecific ST abnormality (elevation) passed
or Test RBBB passed
or Test MI passed

Statement is made if:
   STJ < -100 μV
and STE > 1/2 STJ in any two of all leads except aVR

Then say *junctional ST depression, probably abnormal*

* This statement will not appear if screening criteria is turned on.
  See Appendix F for more information.
Adult Contour Criteria: Details

ST Abnormality Probably Digitalis Effect

Skip test if:
- Test LVH and RVH with secondary repolarization passed
- Test nonspecific ST abnormality (elevation) passed
- Test RBBB passed
- Any MI present

Statement is made if:
either
- In any two of leads I, II, aVL, and V2 through V6:
  - Minimum of STM or STE < minimum of STJ or \(-50 \mu V\)
- Heart rate \(<100\) bpm
  and
- PR interval \(<200\) ms
  and
- In any two of leads I, II, aVL, and V2 through V6:
  - Minimum of STM or STE < minimum of STJ,
  - P onset amplitude \(-50 \mu V\), or \(-25 \mu V\)
  and
  - T amplitude > STM +100 \mu V

Then say \textit{ST abnormality probably digitalis effect}

Nonspecific ST Abnormality

Skip test if:
- Test LVH or RVH with secondary repolarization passed
- Test nonspecific ST abnormality (elevation) passed
- Test RBBB passed

Statement is made if in any two of leads I, II, aVL, aVF, V4, V5, and V6:
- STJ < \(-50 \mu V\) and STE < \(0 \mu V\)
- STE \(<\) minimum (STJ and STM) \(-25 \mu V\)

Then say \textit{nonspecific ST abnormality}

If test atrial fibrillation passed simultaneously, then append \textit{probably digitalis effect}

If MI present, suppress all ST abnormality statements.
**Adult Contour Criteria: Details**

**ST Depression Consider Subendocardial Injury or Digitalis Effect**

Skip test if:
- Test LVH or RVH secondary repolarization passed

Statement is made if:
- In any two of leads I, II, aVL, aVF, and V2 through V6 STJ and STM are \( \leq 100 \) μV
  
(If test RBBB passed, then do not test leads V2, V3, and V4)

Then say *ST abnormality and possible subendocardial injury or digitalis effect*

Suppress nonspecific ST statements.

**Septal Subendocardial Injury**

Statement is made if:
- Test septal and posterior infarct failed
- In lead V1 or V2, STJ and STM are \( \leq 200 \) μV

Then say *marked ST abnormality possible septal subendocardial injury*

**Anterior Subendocardial Injury**

Statement is made if:
- Test anterior and posterior infarct failed
- Tests LVH with repolarization abnormality failed
- In lead V3 or V4, STJ and STM are \( \leq 200 \) μV

Then say *marked ST abnormality possible anterior subendocardial injury*

**Lateral Subendocardial Injury**

Statement is made if:
- Test lateral infarct failed
- Test LVH with repolarization abnormality (LVHR) failed
- Test LVH with repolarization abnormality (LVHR) failed

Then say *marked ST abnormality possible lateral subendocardial injury*
**Inferior Subendocardial Injury**

Statement is made if:

- Test *inferior infarct* failed
- Test LVH with repolarization abnormality failed
- In lead II or aVF, STJ and STM are $\leq -100 \ \mu V$

Then say *marked ST abnormality possible inferior subendocardial injury*

If any tests *subendocardial injury* passed, then suppress *nonspecific ST abnormality, junctional ST depressions, and ST depression consider digitalis effect.*

If inferior myocardial infarction and lead III has STJ >100 $\mu V$, suppress lateral subendocardial injury statement.

If anterior and lateral subendocardial injury present but no septal subendocardial injury present, then say *Marked ST abnormality possible anterolateral subendocardial injury*

If inferior and lateral subendocardial injury present but no septal and no anterior subendocardial injury present, then say *Marked ST abnormality possible inferolateral subendocardial injury*

If septal and anterior subendocardial injury present, then say *Marked ST abnormality possible anteroseptal subendocardial injury*

**Special LVHR and anterior subendocardial criteria**

If *LVHR* present:
- No *LBBB* or *RBBB*
- No *subendocardial injury* tests passed
- No *ST elevation* test passed
- No *ST depression abnormalities* tests passed
- QRS duration $<150$ ms
- No *posterior infarct* passed
- No *acute MIs* passed

Statement is made if:

- In two or more of leads V2, V3, or V4
  - QRS balance is positive and ratio of maximum R amplitude to QRS deflection $<75$
  - QRS balance is negative
  - Maximum ST amplitude $<-100 \ \mu V$ and QRS balance is negative
  - Maximum ST amplitude $<-100 \ \mu V$ and QRS balance is positive and T amplitude $>0 \ \mu V$
  - QRS balance is positive and maximum ST amplitude $<0 \ \mu V$
  - T amplitude is positive and $T' = 0$ and minimum ST amplitude $<-150 \ \mu V$

Then say *Marked ST abnormality, possible anterior subendocardial injury*
T Wave Abnormality

Skip test if:

- Test WPW passed
- Test LVH with repolarization abnormality passed
- Any injury test passed
- Test complete LBBB passed
- Test subendocardial injury passed

Conditions for skipping test applies to all T wave tests.

Abnormal QRS-T Angle, Consider Primary T Wave Abnormality

Skip test if:

- Any test infarct passed
- Test RBBB passed

Statement is made if:

- QRS axis - T axis ≥ 60 degrees
  and  T axis < 0 degrees
- QRS axis - T axis ≤ -60 degrees
  and  T axis > 90 degrees

Then say **abnormal QRS-T angle, consider primary T wave abnormality**

*This statement will not appear if screening criteria is turned on.

See Appendix F for more information.
Nonspecific T Wave Abnormality

Skip test if:
   Any test infarct passed
or   Test RBBB passed

**NONSPECIFIC T ABNORMALITY TEST**

For each lead to be tested:
   Set test limit
   If QRS amplitude is positive, limit value is 1/20 QRS amplitude + 25 μV
or If QRS amplitude is negative, limit value is 25 μV
   Then Count lead as passing test if special T Amplitude < the test limit and (special T <0 or TA <200 μV)

Test leads as follows:
   First test lead V6 to V3
   If lead V3 passed test, then test lead V2; then test leads I, II, and aVL
   If special T amplitude exceeds 150 μV in leads I, II, and aVL, do not test
   and If QRS balance is negative, do not test lead aVL

If more than two leads pass this test, then say nonspecific T wave abnormality

If test atrial fibrillation passed simultaneously, then append , probably digitalis effect

Anterior Ischemia

Statement is made if:
   AMI, RBBB, or RVHR PMI passed
   In any two of leads V2, V3, and V4, special T amplitude ≤-100 μV

Then say T wave abnormality, consider anterior ischemia

If test atrial fibrillation passed simultaneously, then append or digitalis effect

If test nonspecific ST abnormality passed simultaneously, then prefix ST &
Marked T Wave Abnormality Consider Anterior Ischemia

Statement is made if:

- AMI, RBBB, or RVH passed, skip test
- In two leads V2, V3, and V4, special T amplitude \( \leq -500 \text{ mV} \)

Then say marked T wave abnormality, consider anterior ischemia

If test nonspecific ST abnormality passed simultaneously, then prefix ST &

Lateral Ischemia

Statement is made if:

- Test lateral infarct failed
- In any two of leads I, aVL, V4, V5, and V6, special T amplitude \( \leq 100 \text{ \mu V} \)
  (Do not test aVL if QRS balance is negative.)

Then say T wave abnormality, consider lateral ischemia

If test atrial fibrillation passed simultaneously, then append or digitalis effect

If test nonspecific ST abnormality simultaneously passed, then prefix ST &

Marked T Wave Abnormality Consider Lateral Ischemia

Statement is made if:

- Test lateral infarct failed
- Any of leads I, aVL, V5, and V6, special T amplitude \( \leq -500 \text{ \mu V} \)
  (Do not test aVL if QRS balance is negative.)

Then say marked T wave abnormality, consider lateral ischemia

If test nonspecific ST abnormality simultaneously passed, then prefix ST &
Anterolateral Ischemia

Statement is made if:

- Test T wave abnormality, consider anterior ischemia passed
- Test T wave abnormality, consider lateral ischemia passed

Then say *T wave abnormality, consider anterolateral ischemia*

If test atrial fibrillation passed, simultaneously then append
*or digitalis effect*

If test nonspecific ST abnormality simultaneously passed, then prefix
*ST &*

Marked T Wave Abnormality Consider Anterolateral Ischemia

Statement is made if:

- Test T abnormality consider anterior ischemia passed
- Test marked T abnormality consider lateral ischemia passed

Then say *marked T wave abnormality, consider anterolateral ischemia*

If test nonspecific ST abnormality simultaneously passed, then prefix
*ST &*

T Wave Abnormality Consider Inferior Ischemia

Statement is made if:

- Any test *inferior infarct* failed
- Special T amplitude <-100 μV in lead II or aVF
  (Test lead aVF only when QRS amplitude is positive.)

Then say *T wave abnormality, consider inferior ischemia*

If test atrial fibrillation passed simultaneously, append
*or digitalis effect*

If test nonspecific ST abnormality passed simultaneously, then prefix
*ST &*
Marked T Wave Abnormality Consider Inferior Ischemia

Statement is made if:
- Special T amplitude ≤ 500 μV in lead II or aVF
  (Test lead aVF only when QRS amplitude is positive.)

Then say *marked T wave abnormality, consider inferior ischemia*

If test nonspecific ST abnormality passed simultaneously, then prefix *ST &*

T Wave Abnormality Consider Inferolateral Ischemia

Statement is made if:
- Test T wave abnormality consider inferior ischemia passed
  and Test T wave abnormality consider lateral ischemia passed
  and Test T wave abnormality consider anterior ischemia failed

Then say *T wave abnormality consider inferolateral ischemia*

If marked T wave abnormality passed with above statements, upgrade the statement to *Marked T wave abnormality consider inferolateral ischemia*

If any ischemia tests pass, suppress *STEREP* and *EREP*.

If any test ischemia pass, suppress *NST*, *STJD1*, *STJD2*, *STDIG*, *NT*, *AQRST*, and *STD*.

Nonspecific ST and T Abnormality

Statement is made if:
- Any specific ischemia tests failed
  and Pericarditis test failed
  and ST depression test failed
  and Test nonspecific ST abnormalities passed
  and Test nonspecific T abnormality passed

Then say *nonspecific ST & T abnormality*

If test *atrial fibrillation* passed, simultaneously append *probably digitalis effect*

If test *NSTT* passed, suppress *NST*, *STJD1*, *STJD2*, *STDIG*, *NT*, *AQRST*, and *STD*. 
Prolonged QT

Skip test prolonged QT if:
   Test WPW passed

Statement is made if:
   Ventricular rate <100 bpm
   and IVCB not present
   and RBBB not present
   and LBBB not present
   and QRS duration <120 ms
   and * QTC ≥460 ms
   and Test for nonspecific T wave abnormality passed
   or * QTc ≥480 ms
   and T wave abnormalities not present
   and Any infarction not present
   and Any ischemia not present
   or * QTc ≥500 ms
   and Either infarction or ischemia present

Then say Prolonged QT

Suppress EREP and STEREP.

* An additional 10 ms is added to the above thresholds for female patients over 60 years old.

Acute MI

Statement made if:
   Any injury pattern is cited
   and Any MI labeled age undetermined
or
   Infarct statement is labeled as possibly acute.

Then say ** ** ** ** * Acute MI * ** ** ** **
Consider Right Ventricular Involvement

Skip test if lead V4r present in 15-lead ECG
(see test with right ventricular involvement instead)

Statement made if:
- Test Acute MI passed
- Inferior injury pattern or inferior infarct labeled as possibly acute (including inferolateral injury or inferior-posterior infarct)
- STM in lead III > STM in lead II
- or 2nd or 3rd degree AV block present

Then say Consider right ventricular involvement in acute inferior infarct

* This statement is made by version 21 or higher of the 12SL analysis program.
7 Pediatric Contour Criteria
For your notes
Overview

If an age of 15 years or less is entered, a pediatric analysis is performed.

Pediatric analysis employs a set of tables which contain the normal values for 12 different age groups. QRS duration limits are important in the diagnosis of conduction blocks. Amplitude limits are used in the diagnosis of ventricular hypertrophy. These tables are included in appendix C for your perusal.

Listed below are the categories of abnormalities that the pediatric analysis program always checks for. This outline is expanded upon in succeeding figures which describe, in very simplistic terms, the basic flow and logic of the pediatric criteria. Note that the order of the steps is important since information obtained from tests performed earlier in the sequence are applied to subsequent tests. Refer to Chapter 3 for definitions of the wave measurements used in this chapter.

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Subcategory</th>
<th>Acronyms/Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrocardia</td>
<td></td>
<td>DEXTRO</td>
</tr>
<tr>
<td>Wolff-Parkinson-White</td>
<td></td>
<td>WPW</td>
</tr>
<tr>
<td>Atrial Hypertrophy</td>
<td></td>
<td>RAE, Right Atrial Enlargement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LAE, Left Atrial Enlargement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BAE, Biatrial Enlargement</td>
</tr>
<tr>
<td>QRS Abnormalities</td>
<td>Low Voltage QRS</td>
<td>LOWV</td>
</tr>
<tr>
<td></td>
<td>QRS Axis</td>
<td>RAD, Right Axis Deviation</td>
</tr>
<tr>
<td></td>
<td>Conduction Abnormalities</td>
<td>LAD, Left Axis Deviation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NWA, North West Axis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RBBB, Right Bundle Branch Block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RBBRVH, Right Bundle Branch Block or Right Ventricular Hypertrophy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBB, Left Bundle Branch Block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IRBBB, Incomplete Right Bundle Branch Block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ILBBB, Incomplete Left Bundle Branch Block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IVCB, Intraventricular Conduction Block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IVCD, Intraventricular Conduction Delay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LVH, Left Ventricular Hypertrophy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RVH, Right Ventricular Hypertrophy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BIVH, Biventricular Hypertrophy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>QRSW, With QRS Widening</td>
</tr>
<tr>
<td></td>
<td>Infarction</td>
<td>MI, Myocardial Infarction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LMI, Lateral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IMI, Inferior</td>
</tr>
<tr>
<td>ST Abnormalities—QRS Related</td>
<td>ST + T abnormality with Ventricular Hypertrophy Dating Infarcts</td>
<td>2ST, With Repolarization Abnormality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WSTR, With Strain Pattern</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AC, Possibly Acute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU, Age Undetermined</td>
</tr>
</tbody>
</table>
# Pediatric Contour Criteria: Overview

## Table 1. Pediatric Contour Criteria Summary (Continued)

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Subcategory</th>
<th>Acronyms/Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ST Elevation Abnormalities</strong></td>
<td>Marked ST Elevation</td>
<td>STELIN, ST Elevation In</td>
</tr>
<tr>
<td></td>
<td>Pericarditis</td>
<td>PCARD, Acute Pericarditis</td>
</tr>
<tr>
<td></td>
<td>Early Repolarization</td>
<td>REPOL, Early Repolarization</td>
</tr>
<tr>
<td></td>
<td>Undefined ST Elevation</td>
<td>STEL, ST Elevation Probably Due to Repolarization, Injury or Acute Pericarditis</td>
</tr>
<tr>
<td></td>
<td>Nonspecific</td>
<td>NST, Nonspecific ST Abnormality</td>
</tr>
<tr>
<td><strong>ST Depression Abnormalities</strong></td>
<td>Marked ST Depression</td>
<td>STDEPIN, ST Depression In</td>
</tr>
<tr>
<td></td>
<td>Undefined ST Depression</td>
<td>STDEP, ST Depression, Consider Subendocardial Injury or Digitalis Effect</td>
</tr>
<tr>
<td></td>
<td>Digitalis Effect</td>
<td>PDIG, Probably Digitalis Effect</td>
</tr>
<tr>
<td></td>
<td>Junctional ST Depression</td>
<td>JST, Junctional ST Depression Probably Abnormal</td>
</tr>
<tr>
<td></td>
<td>Nonspecific</td>
<td>JSTN, Junctional ST Depression, Probably Normal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NST, Nonspecific ST Abnormality</td>
</tr>
<tr>
<td><strong>T Wave Abnormalities</strong></td>
<td>T Wave Inversion</td>
<td>TINVIN, T Wave Inversion In</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INF, Inferior Leads</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LAT, Lateral Leads</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IFLAT, Inferolateral Leads</td>
</tr>
<tr>
<td></td>
<td>Nonspecific</td>
<td>NT, Nonspecific T Wave Abnormality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NSTT, Nonspecific ST and T Wave Abnormality</td>
</tr>
<tr>
<td></td>
<td>QRS-T Angle</td>
<td>AQRST, Abnormal QRS-T Angle</td>
</tr>
<tr>
<td></td>
<td>QT Interval</td>
<td>LNGQT, Prolonged QT</td>
</tr>
</tbody>
</table>
Pediatric Contour Criteria: Overview

Wolff-Parkinson-White

![Wolff-Parkinson-White Diagram]

Dextrocardia

**DEXTRO**

QRS deflection much greater in right precordial leads as opposed to left lateral leads.

![Dextrocardia Diagram]

If dextrocardia is stated, do no further analysis.
Atrial Enlargement

Skip the test if it is not a sinus rhythm.

- **IF**
  - OR -
  
- **RAE**
  - Any Lead
  - Tall P wave

- **LAE**
  - V1 or V2
  - Significant terminal P wave inversion
  - OR -
  - Long P Duration

- **BAE**
  - Both RAE and LAE are true.

QRS Axis

- **RAD**
  - Right axis for age

- **NWA**
  - aVF
  - If Q in II or aVF and not laterally, then refer to as RAD.

- **LAD**
  - Left axis for age
  - If Q in II or aVL and not inferiorly, then refer to as LAD.

Low Voltage QRS

- **LOWV**
  - Less than 500 μV
  - I, II, III

Standard requirement of limb leads less than 500 μV. However, if horizontal plane exhibits low voltage for age and the limb leads have voltage close to the standard requirement, state low voltage QRS.
Conduction Abnormalities

Right Bundle Branch Block

It is sometimes difficult to discriminate among RBBB, RVH, or normal variants. Therefore, the pediatric criteria for RBBB is the most complicated of the conduction abnormalities.

If the QRS is very wide, the program tests for terminal slowing on the right. As the QRS gets narrower, the tests for terminal slowing on the right become increasingly more difficult to pass.

If RBBB is true, suppress all statements concerning right axis deviation and do not test for hypertrophy.
**RBBRVH**
If the QRS is wide for age, and it has some of the components of RBBB which do not quite meet the criteria, the program will state: “Right bundle branch block or right ventricular hypertrophy.”

QRS is wide. Although the terminal force is towards the right, there is no evidence of terminal conduction delay. This could be due to RVH or RBBB. If RBBRVH is called, bypass hypertrophy tests.

**IRBBB**
IRBBB is called if the QRS has some of the attributes of RBBB, but the rightward terminal slowing is not evident enough for the criteria to state a complete block.

**Left Bundle Branch Block**

**ILBBB**
Same criteria as LBBB but QRS is slightly prolonged for age, as opposed to wide.
If a conduction abnormality has not been cited, and the QRS is wide for age, a nonspecific conduction delay or block will be cited.

Ventricular Hypertrophies

If any complete block has been stated, do not test for ventricular hypertrophy.

Right Ventricular Hypertrophy

RVH
If IRBBB has been stated, use special criteria for RVH, avoid the standard criteria.
Pediatric Contour Criteria: Overview

There are several ways in which RVH can be diagnosed via the standard criteria. Possible RVH is stated if any of these tests are true.

If the R amplitude in V1 is large for age, or there is a QR pattern in V1, the program states RVH without the prefix possible. If RVH is stated, suppress IVCD.

When RVH is stated, the repolarization of the right precordial leads is inspected.
Pediatric Contour Criteria: Overview

If the ST-T meets these requirements, but is not typical of RVH with strain, the program will state: *With repolarization abnormality.*

If the ST-T is typical of RVH with strain, the program will state: *With strain pattern.*

Left Ventricular Hypertrophy

*LVH*

The criteria first tests the voltage in leads V1 and V6.

If either of these criteria are true, the program will state possible *LVH*. If the voltage significantly exceeds this criteria, the program will state *LVH* without any qualifier.

Repolarization in the lateral leads is the next item tested.

If this repolarization abnormality is found in conjunction with voltage criteria for *LVH*, the program will state: *Left ventricular hypertrophy with repolarization abnormality.*
If the repolarization abnormality is more typical of a strain pattern, the program will modify the statement by using *with strain pattern*.

T wave inversion in the lateral leads is abnormal for all ages. If a repolarization abnormality is detected in the lateral leads and the ECG exhibited voltage that was close to the aforementioned criteria, the program would upgrade the diagnosis to *LVH*.

If *LVH* is cited, suppress the statement nonspecific interventricular conduction delay.
Biventricular Hypertrophy

**BVH**
The way in which the program detects BVH is dependent upon what hypertrophy has already been detected by the program.

If both LVH and LVM have already been detected by the program, the program will state LVH.

If neither LVH or LVM have been detected, then inspect mid-precordial leads.

If total QRS deflection is large for age, state BVH.

If definite LVH has been detected, then see if there are some indications of RVH.

If R amplitude (V1) or S amplitude (V6) is significantly beyond the mean for age, state possible BVH and suppress RVH.
If definite \( RVH \) has been detected, then see if there are some indications of \( LVH \).

![Diagram](image.png)

**Infarct**

**Septal Myocardial Infarct**

\( SMI \)

Not diagnosed by pediatric program.

**Anterior Myocardial Infarct**

\( AMI \)

Not diagnosed by pediatric program.

**Lateral Myocardial Infarct**

\( LMI \)

Criteria for lateral MI is very specific. Deep, wide Q waves with a large Q:R ratio are required for diagnosis. This criteria is used to avoid the deep Q waves that occur normally in the pediatric ages.

![Diagram](image.png)

If there are deep Q waves for age, that do not meet the criteria for \( LMI \), and LVH was not stated, the program will state: *Deep Q wave in V6, possible LVH.*
Inferior Myocardial Infarct

*IMI*
Do not execute if RBBB or any hypertrophy is detected.

Criteria for inferior MI is very specific. Deep, wide Q waves with a large Q:R ratio are required for diagnosis. This criteria is used in order to avoid the large Q waves that occur normally in the pediatric ages.

*AC:* Possibly acute
*AU:* Age undetermined
statements for the dating of MIs are not used by the pediatric program.

**ST Abnormalities**

Inspection of the ST segment is dependent upon what was found in the QRS.

---

**Revision E**
**Marquette™ 12SL™ ECG Analysis Program**
**7-15**
**416791-004**
If repolarization abnormality has already been stated with RVH, LVH, or BVH, do not inspect the ST segment.

**ST Elevation Abnormalities**

The number of leads inspected for ST elevation is dependent on age.

If any ST segment is over threshold, then several other tests are applied. An injury character is suspected the larger the ST elevation and ST:T ratio. Reciprocal depression is also considered to be an indicator of injury.

ST elevation that has an injury-like character is descriptively stated; for example: ST elevation in anterior leads.
Once it is stated, no further ST elevation analysis is done.

**Early Repolarization**

Early repolarization is stated if the ST elevation has low ST:T ratio and a repolarization character that appears normal (that is, T waves upright in appropriate leads and ST aligned with T).

**Acute Pericarditis**

Acute pericarditis has similar criteria except more ST elevation is required.

**ST Elevation, Mechanism Unknown**

If pericarditis or early repolarization cannot be stated, the program identifies the ST elevation and suggests the three aforementioned mechanisms.

**STEL**

ST elevation, consider early repolarization, pericarditis, or injury

If PCARD, REPOL, or STEL is stated, do no further ST elevation analysis.
Nonspecific ST Elevation

NST
Nonspecific ST elevation abnormality is detected using the same methods as outlined above. The difference is that the threshold for elevation is twice as sensitive. Furthermore, the program only states the elevation as a nonspecific abnormality if it has characteristics that meet the criteria outlined for injury.

ST Depression Abnormalities

If injury has been called and the ST elevation is larger than the depression, do not test for any ST depression abnormality.

Inspect all leads for ST segment depression. The anteroseptal leads are not inspected if the age is less than 12 years.
Compare ST segments to threshold. The threshold for anterior leads is less sensitive.

Avoid upward sloping ST segments.

Avoid anterolateral lead groups when LVH, 2ST is stated.

Avoid leads with stated infarction.

If all of these items are true, state ST depression in specific lead group.

If ST depression is true, skip further analysis.
If a nonspecific ST elevation abnormality has already been found (from NST elevation tests), do no further ST depression analysis.

Now look for ST depression as before but with more sensitivity. If true, state *ST depression, consider subendocardial injury or digitalis effect.* Also skip further ST depression analysis.

**Nonspecific ST Abnormality**

Again, analyze the ST segment with even more sensitivity.

If this occurs in at least two leads, state *NST.* If atrial fibrillation is present, append *PRDIG.*
Digitalis Effect

Now inspect for digitalis effect.

If digitalis is stated, do no further ST depression analysis.

Junctional ST Depression

If true, state: *Junctional ST depression, probably normal.*

If true, state: *Junctional ST depression, probably abnormal.*
T Wave Abnormalities

If LVH with a repolarization abnormality has already been stated, do not test T waves. Likewise, if an MI has been cited, skip T wave analysis in respective lead group.

Avoid inspection of leads V1–V4. T wave inversion in this lead group is normal for age.

If RVH with strain pattern was noted, also avoid inspection of inferior leads.

If T waves are inverted, then state descriptively as opposed to stating ischemia.

If a nonspecific ST abnormality was previously detected, make one statement as opposed to two.
If atrial fibrillation is present, append *or digitalis effect*.

If T wave inversion is stated, skip further analysis of T waves.

If infarction is present, skip further analysis.

**Nonspecific T Wave Abnormality**

*NT*
Small T waves or shallow T wave inversion are found in at least two leads.

If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two.
If atrial fibrillation is present, append *probably digitalis effect*.

**Abnormal QRS-T Angle**

*AQRS*T
Do not test for abnormal QRS-T angle if any other T wave abnormality has already been stated.

**Prolonged QT**

QT interval is corrected for rate. As the ventricular rate increases, the corrected QT increases.

*LNGQT*
If QTc >460 ms and rate <100 bpm, stage LNGQT.

If QTc >450 ms, say borderline prolonged QT.

If any hypertrophy or incomplete block is cited, append: *May be secondary to QRS abnormality.*
Details

WPW

Skip test WPW if:
- Atrial flutter or atrial fibrillation is present
- No P wave is present

Statement is made if:
- Delta wave is present in three or more of 12 leads
- PR interval is not = 0 ms
- P axis is >-30 degrees and <120 ms
- PR interval ≤ mean PR interval for age
- PR interval ≤ mean PR interval for age + 25 ms
- QRS onset <12 ms after P offset
- There are ≥5 delta waves present

Then say Ventricular pre excitation WPW.

If test WPW passed, then suppress short PR and skip any contour tests.

Dextrocardia

Skip test if WPW present

Statement is made if:
- QRS deflection in lead V1 ≥ QRS deflection in lead V5 times 1.9
- QRS deflection in lead V1 ≥ QRS deflection in lead V6 times 1.9
- QRS duration < IVCB QRS duration for age
- In two of leads I, aVL, V5, and V6
- Either Q amplitude > 1/4 the QRS deflection and R amplitude > 100 μV
- Or RSR' pattern present where R amplitude < 50 μV and R' amplitude > 100 μV and S amplitude > 1/4 the QRS deflection

Then say dextrocardia.

If dextrocardia present, then skip any contour tests.
Atrial Enlargement

Skip all atrial enlargement tests if:
- Test WPW passed
- PR interval = 0 ms
- No sinus rhythm or atrial pacemaker present
- P axis is < the upper limit for right atrial rhythm for age
- P axis is > the upper limit for left atrial rhythm for age

Right Atrial Enlargement

Statement is made if:
- P wave amplitude >250 μV in any lead

Then say Right atrial enlargement.

Left Atrial Enlargement

Statement is made if:
- P duration in lead II >125 ms and P amplitude >100 μV
- or P amplitude in lead V1 >40 ms and P' amplitude < -100 μV and P' duration >60 ms
- or P amplitude in lead V1 >40 ms and P' amplitude < -125 μV and P' duration >50 ms
- or P amplitude in lead V1 >40 ms and P' amplitude < -150 μV and P' duration >40 ms

Then say Possible left atrial enlargement.*

If
- Any test for possible LAE passed
- and P' amplitude in lead V1 < -200 μV
- or P duration in lead II >140 ms and P' amplitude in lead V1 < -100 μV

Then say Left atrial enlargement.

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Biatrial Enlargement

Statement is made if:
- Test left atrial enlargement passed
- and Test right atrial enlargement passed

Then say biatrial enlargement.
Frontal Plane Axis Deviation

Skip test frontal plane axis deviation if:
Test WPW passed and dextrocardia passed.

Left Axis Deviation

Statement is made if:
QRS axis is ≤LAD lower limit for age
or
QRS axis is > superior NWA limit for age
and
Q amplitude >40 μV in lead I or aVL
and
Q amplitude ≤40 μV in leads II, III, and aVF

Then say Left axis deviation.

Right Axis Deviation

Statement is made if:
QRS axis is ≥RAD upper limit for age
or
QRS axis is ≥NWA upper limit for age
and
Q amplitude in leads I and aVL ≤40 μV
and
Q amplitude in lead II, III, or aVF >40 μV

Then say Right axis deviation.*

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

North West Axis

Statement is made if:
QRS axis is > superior NWA limit for age
and
Q amplitude in lead I or aVL >40 μV
and
Q amplitude in lead II, III, or aVF >40 μV
or
No Q wave in leads I, aVL, II, III, and aVF

Then say North WestAxis.*

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Pediatric Contour Criteria: Details

Indeterminate Axis

Statement is made if:
- R amplitude minus S amplitude ≤50 μV in leads I, II, and III
- The QRS balance in leads I, II, and III is <10% of the QRS deflection

Then say *Indeterminate* axis.

Low Voltage and Lung Disease

Skip test low voltage and lung disease if:
- Test WPW or dextrocardia passed
- QRS duration >120 ms

Low Voltage QRS

Statement is made if:
- Total QRS deflection <500 μV in all frontal leads
- QRS deflection <1500 μV in all precordial leads
- QRS deflection <1000 μV in all frontal leads

Then say *Low voltage QRS.*
Conduction Defects

Skip all tests for conduction defect if:
Test WPW or dextrocardia passed.

Incomplete Right Bundle Branch Block

Statement is made if:
- QRS duration >= upper QRS duration for age 98% confidence level
- QRS area is positive in lead V1
- Test RBBB 1 passed
- if any of the following are true:

**Test 1**
- RBBB criteria 1-8 failed (see below criteria)
- QRS duration <90 ms
- R' amplitude in lead V1 not = 0 μV
- S' amplitude in lead V1 <100 μV
- R amplitude in lead V1 >100 μV

**Test 2**
- RBBB criteria 1-10 failed (see below criteria)
- IRBBB test 1 failed
- RBBB test 6 failed
- R' duration in lead V1 > R duration in lead V1 times 1.3
- S duration in lead V6 > R duration in lead V6 times 1.5
- QRS duration < maximum QRS duration for age for block
- R amplitude in lead V1 >100 μV

**Test 3**
- RBBB criteria 1-12 failed (see below criteria)
- IRBBB tests 1 and 2 failed
- RBBB test 6 failed
- R amplitude in lead V1 >100 μV
- R' amplitude in lead V1 >100 μV
- S amplitude in lead V1 >100 μV
- S duration in lead V6 > maximum QRS duration for age block divided by two
- QRS duration > IVCB QRS duration for age – 20 ms
- QRS duration < IVCB QRS duration for age

Then say *Incomplete right bundle branch block.*

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Right Bundle Branch Block Tests

**Test 1**
R or R' (with no S or S') is present in lead V1

**Test 2**
If test 1 fails:
and QRS duration > maximum QRS duration for age for block
and In any two leads I, aVL, V4, V5, and V6
  S duration >1/3 QRS maximum duration for age
and QRS area in lead V1 is positive
and S amplitude + minimum STJ or STM <100 μV and <R amplitude in lead V1
  or S amplitude + minimum STJ or STM to R amplitude
    Ratio <30% in lead V1
  or S amplitude + minimum STJ or STM to R amplitude
    Ratio <50% in lead V1 and QRS >130 ms
  or S' amplitude + minimum STJ or STM <100 μV and <R' amplitude in lead V1
  or S' amplitude + minimum STJ or STM to R' amplitude
    Ratio <30% in lead V1
  or S' amplitude + minimum STJ or STM to R' amplitude
    Ratio <50% in lead V1 and QRS >130 ms

**Test 3**
R' wave present in lead V1 with duration >40 ms
(To obtain R' duration, subtract from the measured QRS duration the Q duration + R duration + S duration + R' duration + S' duration)

**Test 4**
R' duration in lead V1 > duration variable lead V1 times two
and S duration in lead V6 > duration variable lead V6 times two
Duration variable lead V1 Add Q duration + R duration + S duration in lead V1
Duration variable lead V6 Add Q duration + R duration in lead V6

**Test 5A**
QRS area is positive in lead V1
Notch present in lead V1 (after peak of R wave)
Notch depth ≥200 μV

**Test 5B**
QRS area is present in lead V1
Notch present in lead V1 (after peak of R wave)
Notch depth ≥100 μV

**Test 6A**
QRS duration <90 ms
and RBBB criteria 1-8 failed (see below criteria)
and Criteria for IRBBB test 1 failed
Test 6B

All RBBB criteria 1-12 failed
and IRBBB test failed
and RBBB test 6A failed
and QRS duration ≤ maximum QRS duration for age for block + 20 ms
and S duration in lead V6 < R duration in lead V6 times 1.4

Right Bundle Branch Block

Statement is made if:

QRS duration > upper QRS duration for age
and QRS area is positive in lead V1
and Test RBBB 1 passed
or Test RBBB 2 passed
or Test RBBB 3 passed

And any of the following criteria are met:

Criteria 1:

Test RBBB 4 passed

Criteria 2:

QRS duration ≥ 120 ms
and S duration in lead V6 > R duration in lead V6 times two

Criteria 3:

R' duration in lead V1 > duration variable lead V1 + 10 ms
and S duration in lead V6 > R duration in lead V6 times two
and S duration in lead V6 > duration variable lead V6 times 1.5
or Q amplitude in lead V6 < 200 μV

Criteria 4:

S duration in lead V6 > R duration in lead V6 times three
or S duration in lead V5 > R duration in lead V5 times five

Criteria 5:

R' in lead V1 > duration variable in lead V1 times 1.5
and QRS duration ≥ 130 ms

Criteria 6:

R' amplitude in lead V1 = 0 μV
and S amplitude in lead I < 100 μV
and RBBB test 5 passed
and S duration in lead V6 > R duration in lead V6 times two
and S duration in lead V6 > duration variable in lead V6 times 1.5
or Q amplitude in lead V6 < 200 μV
Criteria 7:
- R amplitude in lead V1 >100 μV
- R’ amplitude in lead V1 >100 μV
- R’ duration in lead V1 >R duration in lead V1 times two
- R’ duration in lead V1 >R + S duration in lead V1
- S duration in lead V6 >R duration in lead V6 times two
- S duration in lead V6 > duration variable in lead V6 times 1.5
- or
- Q amplitude in lead V6 <200 μV

Criteria 8:
- QRS duration > maximum QRS duration for age for block
- S duration in lead V6 >R duration in lead V6 times 2.5
- S duration in lead V7 > duration variable in lead V6 times 1.5

Criteria 9:
- QRS duration >140 ms
- At lead one lead of I, aVL, V4, V5, or V6 has
  - S duration >60 ms
  - or
  - R’ duration in lead V6 = 0 ms
  - or
  - R’ duration in lead V6 not = 0 ms
  - and
  - S’ duration in lead V6 >60 ms

Criteria 10:
- QRS duration >130 ms
- In more than one lead of I, aVL, V4, V5, and V6
  - S duration >70 ms
  - or
  - R’ duration in lead V6 = 0 ms
  - or
  - R’ duration in lead V6 not = 0 ms
  - and
  - S’ duration in lead V6 >70 ms

Criteria 11:
  - IRBBB test 1 failed
  - Test RBBB 6 passed
  - Criteria 1-10 failed
  - R’ duration in lead V1 >R duration in lead V1 times 1.3
  - S duration in lead V6 >R duration in lead V6 times 1.5
  - and
  - QRS duration > maximum QRS duration for age for block

Criteria 12:
  - IRBBB tests 1 and 2 failed
  - Test RBBB 6 failed
  - Criteria 1-11 failed
  - R amplitude in lead V1 >100 μV
  - R’ amplitude in lead V1 >100 μV
  - and
  - S amplitude in lead V1 >100 μV
and S duration in lead V6 > maximum QRS duration for age for block divided by two
and QRS duration > maximum QRS duration for age for block + 20 ms

Then say Right bundle branch block

If test RBBB passed, then suppress all right axis deviation.

Right Bundle Branch Block or Right Ventricular Hypertrophy

Statement is made if any of the following:

Test 1:
If QRS area in V1 > 0 μV
and Test 1 or 2 passed
and All RBBB criteria 1-12 failed (see above criteria)
and All IRBBB tests failed
and RBBB test 6A failed
and RBBB test 6B failed
and QRS duration > maximum QRS duration for age for block + 20 ms
and S duration in lead V6 not = 0 ms
and R' not present in lead V6

Test 2:
If QRS area in V1 > 0 μV
and Test 1 or 2 passed
and All RBBB criteria 1-12 failed (see above criteria)
and All IRBBB tests failed
and RBBB test 6A and 6B failed
and S duration in lead V6 > R duration in lead V6 + 10 ms
and RBBB test 5B passed

Then say Right bundle branch block or right ventricular hypertrophy

If IRBBB test passed and RBBB criteria 1-12 failed, then say Incomplete right bundle branch block
If Age is < 1 year
and Maximum R amplitude in V1 > 1000 μV
or Age ≥ 1 year
and Maximum R amplitude in lead V1 > 1500 μV

Then say Incomplete right bundle branch block plus right ventricular hypertrophy *

If any RBBB statement made, suppress any RAD statements.

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
Incomplete Left Bundle Branch Block

Statement is made if:

- QRS duration > ILBBB QRS duration for age and < maximum QRS duration for age for block
- In leads V1 and V2, QRS balance is negative
- In leads V1 and V2, Q or S wave duration ≥ 2/3 maximum QRS duration for age for block
- In any two of leads I, V5, and V6, no Q wave is present
- In any two of leads I, aVL, V5, and V6, ≥ 1/2 maximum QRS for age for block

Then say Incomplete left bundle branch block

If test ILBBB passed, then suppress leftward axis.

Left Bundle Branch Block

Statement is made if:

- Two x QRS area > 1/40 of (QRS duration x maximum R amplitude) in lead V1 or V6
- QRS balance is negative in leads V1 and V2
- In leads V1 and V2, Q or S duration ≥ 1/6 QRS duration for age for block
- In any two of leads I, V5, and V6, no Q wave is present
- In any one of lead I, V5, or V6, R duration + R’ duration ≥ maximum QRS duration for age for block - 20 ms
- either QRS duration ≥ maximum QRS duration for age for block times 1.3
  or QRS duration ≥ maximum QRS duration for age for block (+ 1/6 of this value)
  - Over leads I, aVL, and V6 the sum of R duration
  - R’ duration totals > maximum QRS duration for age for block times two
  or QRS duration ≥ maximum QRS duration for age for block
  - Over leads I, aVL, and V6, the sum of R duration total > maximum QRS duration for age for block times two
  - Five x QRS area > 1/10 times (QRS duration x maximum R wave amplitude) in any two of leads I, aVL, and V6

Then say Left bundle branch block

* If LBBB not stated, but QRS balance is negative in lead V1, QRS duration > QRS duration for age for block (plus 1/6 of this value), then remember this ECG has passed as complete LBBB. This is not printed on the analysis report, but the ECG will be treated as complete LBBB in the analysis program logic.
Nonspecific Intraventricular Conduction Delay

Statement is made if:

1. QRS duration is >QRS duration for age for block minus 7 ms
2. QRS duration is <QRS duration for age for block
3. Tests RBBB and complete LBBB failed
4. Tests IRBBB and ILBBB failed

Then say *Nonspecific intraventricular conduction delay*

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

Nonspecific Intraventricular Conduction Block

Statement is made if:

1. QRS duration >QRS duration for age for block
2. Test RBBB and LBBB failed

Then say *Nonspecific intraventricular conduction block*
Ventricular Hypertrophy

Right Ventricular Hypertrophy

Skip test right ventricular hypertrophy if:
- Test WPW or dextrocardia passed
- Test IRBBB, RBBRVH, IRBBB + RVH, and LBBB passed

Statement is made if:
- Maximum S or S' amplitude in lead V6 > Large S in lead V6 for age + 200 μV
  and Maximum S or S' amplitude in lead V6 >1/4 QRS deflection in lead V6
  or S amplitude in lead V6 not = 0 μV
  and Ratio of maximum R amplitude in lead V6 to maximum S amplitude in lead V6 < low R to S ratio in lead V6
  or S amplitude in lead V1 is not = 0 μV
  and Maximum R amplitude to S amplitude ratio in lead V1 > high R/s ratio for age in lead V1
  or Age <8 years and >0 years
  and T amplitude in lead V1 >100 μV and T' amplitude in lead V1 = 0 μV
  and STE in lead V6 >0 and special T amplitude in leads V5 and V6 >50 μV
  or Q amplitude in lead V1 >20 μV and maximum R amplitude in lead V1 >500 μV

Then say Possible right ventricular hypertrophy
- Maximum R amplitude in lead V1 > large R in lead V1 for age
  or Q amplitude in lead V1 >20 μV and maximum R amplitude in lead V1 >750 μV

Then say Right ventricular hypertrophy

If RVH present, suppress IVCD and LOWV.
RVH with Repolarization Abnormality

Statement is made if:

- Test RVH passed
- No IRBBB test passed
- In all leads V1, V2, and V3
  - either $\text{STJ} > \text{STM}$ or $\text{STJ} > \text{STE}$
  - or $\text{STM}$ or $\text{STE}$ or $\text{T}$ amplitude $\leq 100 \mu V$
  - and In no more than one lead of leads V4, V5, and V6
    - STM or STE or T amplitude $<-100 \mu V$

Then say Right ventricular hypertrophy with repolarization abnormality

Right Ventricular Hypertrophy with Strain Pattern

Statement is made if:

- In two or more leads V1, V2, and V3 the STM $>$ STE and STE $>$ T amplitude
- T amplitude $<-200 \mu V$

Then say Right ventricular hypertrophy with strain pattern

If RVH2REP and RVHWSTER both pass, only append with strain pattern
Left Ventricular Hypertrophy

Skip test if:
  Test WPW dextrocardia passed
or  Test complete LBBB passed
or  Test RBBB passed

Statement is made if:
  Maximum S amplitude in lead V1 > large S in lead V1 for age
  and  Maximum S amplitude in lead V1 ≥ 1/4 QRS deflection in lead V1
  or  Maximum R amplitude in lead V6 > large R in lead V6 for age

Then say possible left ventricular hypertrophy *

If test for possible LVH passed:
  and  Maximum R amplitude in lead V6 + maximum S amplitude in lead V1 > top deflection in horizontal plane for age
  or  Maximum S amplitude in lead V1 > large S in lead V1 for age + 500 μV
  and  Maximum R amplitude in lead V6 > large R in lead V6 for age + 500 μV

Then say Left ventricular hypertrophy

* This statement will not appear if screening criteria is turned on.
  See Appendix F for more information.

With Repolarization Abnormality

Statement is made if any of leads I, aVL, V4, V5, and V6 have:
  STJ > STM or STJ > STE
  and  STE < -50 μV
  and  R amplitude ≥ 1100 μV
  and  Possible LVH passed or LVH passed or maximum R amplitude in lead V6 > large in lead V6 for age -200 μV

Then say left ventricular hypertrophy with repolarization abnormality
With Strain Pattern

Statement is made if:
Test for LVH with repolarization abnormality passed
and In at least two of leads I, aVL, V4, V5, and V6 QRS balance is positive
and STM > STE and STE > T amplitude and T amplitude <-200 μV

Then say left ventricular hypertrophy with strain pattern

If any LVH passed, then suppress IVCD and LOWV.

If tests for possible LVH, LVH, or LVH2REP failed and the Q amplitude in lead V6 > the deep Q in lead V6 for age + 200 μV, then say Deep Q wave in lead V6, possible left ventricular hypertrophy

Biventricular Hypertrophy

Skip test of biventricular hypertrophy if:
Test WPW or dextrocardia passed
or If any test RBBB passed
or Test LBBB passed

Statement is made if:

Test 1: LVH passed
and Maximum R amplitude in lead V1 ≥ mean R amplitude in lead V1 for age + 300 μV
or Maximum S amplitude in lead V6 > mean S amplitude in lead V6 for age + 300 μV

Test 2: LVH failed and RVH passed
and Maximum S amplitude in lead V1 > mean S amplitude in lead V1 for age + 300 μV
or Maximum R amplitude in lead V6 > mean R amplitude in lead V6 for age + 300 μV

Test 3: LVH failed and RVH failed
and Lead V4 ratio of QRS deflection <35%
and Lead QRS deflection > R amplitude + S amplitude in lead V4 for age

Then say possible biventricular hypertrophy *

If BVH test 3 passed, then say prominent midprecordial voltage, possible biventricular hypertrophy *
If LVH and RVH passed and LVH2REP or RVH2REP passed, then say
BVH with secondary repolarization abnormality

If LVH and RVH passed and LVHWSTR or RVHWSTR passed, then say
biventricular hypertrophy with strain pattern

If LVH and RVH passed with no 2REP or WSTR, then say biventricular
hypertrophy

If BVH, suppress RVH and LVH statements.

If PMDPV and possible BVH passed, then suppress QV6.
* This statement will not appear if screening criteria is turned on.
  See Appendix F for more information.

Infarction

Possible Lateral Infarct

Statement is made if:
  Test LBBB failed
  and In at least three of leads I, aVL, V4, V5, and V6 Q amplitude
     >100 μV
  and Q duration >24 ms
  and Q/R ratio >40%

Then say possible lateral infarct

Suppress QV6

Possible Inferior Infarct

Statement is made if:
  Tests for RVH, BVH, LVH, and RBBB failed
  and Q duration in lead aVF >30 ms
  and Q amplitude in lead aVF >100 μV
  and Q/R ratio in aVF >35%

Then say possible inferior infarct

Then suppress QV6
ST Abnormality (Elevation)

Skip all test ST abnormality (elevations) if:
- Test WPW or dextrocardia passed
- Heart rate >120 bpm and RBBB passed
- Test LBBB passed

Nonspecific ST Abnormality (Elevation)

Statement is made if:
- All tests of infarct failed
- Test RBBB failed
- QRS duration <120 ms
- In any two of leads I, II, III, aVF, and V3 through V6 (if age <12 years skip lead V3) Minimum STJ, STM, and STE are all ≥50 μV
- The slope from QRS onset to J point ≥ slope of ST segment
- T is not tall

Then say nonspecific ST abnormality

Repolarization Tests

Skip statement if:
- QRS >140 ms, or LBBB, RBBB, or MI is present

Continue all early repolarization tests if:
- Corrected Q-T interval is between 370 and 460 ms
- Any test infarct failed
- Test IRBBB failed
- Test ILBBB failed
- Test RBBB failed
- Test RVH failed
- Test LVH failed
- QRS duration <120 ms
- If any ST elevation >200 μV in the precordial leads
- ≥100 μV in the limb leads (other than leads aVR and V1)
- The QRS balance is positive

*** REPOLARIZATION TEST 1 ***
Count leads from leads V1 through V6 with a QRS balance >0 in which both STJ and STM are >75 μV

plus The number of leads from I, II, III, aVL, and aVF with a QRS balance >0 in which ST amplitude ≥50 μV

also Compute the sum of the amplitudes of the smaller of STJ and STM for each lead which passes

*** REPOLARIZATION TEST 2 ***
Count the number of leads with tall T waves which passed repolarization test 1
ST Elevation, Early Repolarization, Pericarditis or Injury

Skip statement if QRS >140 ms, or LBBB, RBBB, or MI is present. Statement is made if:

- Three or more leads pass repolarization test 1 and
- The sum from repolarization test 1 ≥450 μV
- Any ST elevation >200 μV in the precordial leads and
- ≥100 μV in the limb leads (other than leads aVR and V1)
- QRS balance is positive

or either

- In at least one lead of I, II, aVF, and V3 through V6 (skip lead V3 if age <12 years) the T amplitude is negative or T' amplitude < -50 μV
- If in lead aVL the T or T' amplitude < -100 μV and
- QRS axis < 50 degrees
- Any lead II, III, and aVF the minimum ST amplitude ≥100 μV and Lead V5 or V6 the minimum ST amplitude <50 μV
- If in at least two leads (other than leads aVR, V1, V2, and V3 if age <12 years) minimum ST amplitude < 0 μV
- If in at least one lead (other than leads aVR, V1, V2, or V3 if age <12 years) minimum ST amplitude < -50 μV and if in at least two leads (other than lead aVR, V1, V2, or V3 if age <12 years) minimum ST amplitude < 20 μV

Then say **ST elevation consider early repolarization, pericarditis or injury** †

* If tests marked with asterisk pass under any condition, skip to pericarditis tests.
† This statement will not appear if screening criteria is turned on.
See Appendix F for more information.
ST Elevation, Probably Due to Repolarization

Statement is made if:
   Test ST elevation, consider early repolarization, pericarditis, or injury not stated
   and In more than half of the leads passing repolarization test 1, T is also tall

Then say *ST elevation, probably due to repolarization*

* This statement will not appear if screening criteria is turned on.
   See Appendix F for more information.

Early Repolarization

Statement is made if:
   More than five leads pass early repolarization test 1 and T wave is tall in five or more leads
   and The sum calculated in early repolarization test 1 ≥500 μV

Then say *early repolarization*

* This statement will not appear if screening criteria is turned on.
   See Appendix F for more information.

Possible Acute Pericarditis

Skip test acute pericarditis if:
   Any test infarct passed
or QRS duration >120 ms
   Count leads from leads I, II, and aVF in which both STJ and STM are ≥75 μV
   plus The count of leads (leads V2 through V6 and skip leads V2 and V3 if age <12 years) in which both STJ and STM are ≥90 μV

Statement is made if:
   The total count is at least five
   and In any of leads I, II, V4, V5, and V6 T amplitude minus the minimum (STJ or STM) is positive and STJ minus (STJ or STM) >T amplitude minus the minimum (STJ or STM)
   and In all leads (other than leads aVR and V1 and skip leads V2 and V3 if age <12 years) both STJ and STM are ≥100 μV or T or T' ≥0 μV

Then say *possible acute pericarditis*

* This statement will not appear if screening criteria is turned on.
   See Appendix F for more information.
Acute Pericarditis

Statement is made if possible pericarditis is made and:

The count of leads (lead I, II, or aVF) in which both STJ and STM are \( \geq 90 \mu V \) plus the count of leads (leads V2 through V6 and skip leads V2 and V3 if age <12 years) in which both STJ and STM are \( \geq 110 \mu V \) \( \geq 5 \mu V \)

Then say acute pericarditis

Injury Pattern Tests

Skip test all injuries if:

Any tests pericarditis passed

(Done on all 12 leads individually)

For all of the following INJURY tests, if age <12 years skip testing leads V1, V2, and V3.

Test 1:
Inspect QRS balance:
Count the number of leads in frontal plane where QRS balance is \( <1000 \mu V \) and in the precordium where the QRS balance \( <2000 \mu V \). Test 1 passes if count = 12.

Test 2:
Test at all 12 leads (except leads aVR and V1) for ST elevation. Skip lead groups with infarct present.
For this test and subsequent tests, the parameter ST limit is set for each lead:

\*ST LIMIT = 200 \( \mu V \) unless,
If frontal leads (I, II, III, aVR, aVL, and aVF)
or
If in leads V5 and V6 (R-S) \( \geq 0 \mu V \) then = 100 \( \mu V \)
If lead is elevated
and QRS balance is positive
or
In precordial leads maximum R + maximum S \( <1500 \mu V \)
or
In frontal plane maximum R + maximum S \( <1000 \mu V \)
or
If QRS balance is negative and ratio of maximum S amplitude to maximum R + maximum S \( <75\% \)
then
Test 2 passes

Test 3:
Look for ST elevation based on QRS duration (except leads V1 and aVR)
Skip lead groups with MI present

\*Apply ST LIMIT as above
If lead is elevated
and QRS duration is 120 to 130 ms and QRS balance is positive
and Ratio of QRS balance to QRS deflection must be >15%
or
QRS duration \( \geq 130 \) but <150 ms
Pediatric Contour Criteria: Details

- Ratio of QRS balance to QRS deflection must be >25%
- QRS duration ≥150 ms
- Ratio of QRS balance to QRS deflection must be >50%
- QRS duration <120 ms and QRS balance is negative or positive

If any of the leads meet the above criteria, then inspect further for that lead group.

*Apply ST LIMIT as above for specific lead group

- If test 1 passed
  - and If in precordial leads minimal STJ and STM >300 μV = set injury flag
  - or If in precordial leads maximum R + maximum S <1000 μV
    - and Minimal STJ and STM >200 μV = set injury flag
  - or If in frontal lead minimum STJ and STM >200 μV = set injury flag
  - or If frontal lead maximum R + maximum S <750 μV
    - and Minimal STJ and STM >100 μV = set injury flag
  - or In any lead the minimal STJ and STM >1/2 T amplitude = set injury flag

else

- If test 2 passed
  - *Apply ST LIMIT as above
  - and If precordial lead, ST elevation >300 μV = set injury flag
  - or If frontal lead, ST elevation >200 μV = set injury flag
  - or If in any lead, the minimal STJ and STM >1/2 T amplitude
    - or If in any lead T' amplitude < -150 μV
      - and T' amplitude (absolute value) >1/8 of T amplitude for inspected lead that is elevated
  - or If T amplitude is negative = set injury flag

**Test 4**
If test 3 passes:

- and If in precordial leads, STJ and STM >100 μV
- or If in frontal leads, STJ and STM >50 μV
  - and If in elevated lead T' amplitude < -150 μV
  - and T' amplitude (absolute value) >1/8 of T amplitude = set injury flag
  - or If T amplitude is negative = set injury flag

**Test 5**
If test 1 or 2 passed, look for reciprocal changes:

- and Count the number of leads where:
  - Test 1 minimal STJ and STM < -100 μV in any lead
  - Test 2 minimal STJ and STM < -50 μV in any lead
  - Test 3 minimal STJ and STM <0 μV in any lead
  - and If Test 1 count >0
  - or If Test 2 count ≥2
  - or If Test 2 count ≥1 and test 3 count ≥3 set injury flag
**Test 6**
If test 5 fails and injury flag is set:
and  No MIs passed
and  QRSV passed
and  No LVHR present

Then state *ST elevation, early repolarization, pericarditis or injury*

If *LVH* with repolarization is present, the injury flag is clear and no statement is made.

**ST Elevation in Anterior Leads**

Statement is made if:
- In any lead V2, V3, or V4 criteria for ST elevation
- Any injury test passed

Then say *ST elevation in anterior leads*

**ST Elevation in Lateral Leads**

Statement is made if:
- In any lead I, aVL, V5, or V6 criteria for ST elevation
- Any Injury test passed

Then say *ST elevation in lateral leads*

**ST Elevation in Inferior Leads**

Statement is made if:
- In any lead II or aVF criteria for ST elevation
- Any injury test passed

Then say *ST elevation in inferior leads*

If anterior injury, lateral injury, and inferior injury present, then say *ST elevation in anterolateral leads* *ST elevation in inferior leads*

If anterior and lateral injury present, then say *ST elevation in anterolateral leads*

If inferior and lateral injury present, then say *ST elevation in inferolateral leads*
ST Abnormality (Depression)

Skip ST abnormality (depression) if:
- Test WPW or dextrocardia passed
- Test LBBB passed
- QRS duration >100 ms
- Test RBBB passed
- Test LVH2REP passed
- Test RVH2REP passed

Statement is made if:
- Acute MI or injury present
- Any precordial leads and acute anterior infarct present
- Anterior injury present
- Acute septal infarct present
- In lateral leads (leads I, aVL, V5 and V6) and lateral injury present or acute lateral infarct present
- In inferior leads (leads II, III, and aVF) and inferior injury present or acute inferior infarct
- If the largest of (STJ and STM minimum value greater than 0 μV) in any lead > the smallest of the absolute value of (STJ, STM, or STE maximum value <-100 μV) in any lead except lead aVR

Then SKIP ST ABNORMALITY TEST

Condition for skipping applies to all ST tests and if age <12 years skip testing leads V1, V2, and V3.

Junctional ST Depression Probably Normal

Skip test if:
- Test LVH secondary repolarization passed
- Test RVH with secondary repolarization passed
- Test nonspecific ST abnormality (elevation) passed
- Test RBBB passed
- Any acute infarct or injury test passed

Statement is made if:
- In any two of all leads, except lead aVR, STJ <-100 μV and STE >0 μV

Then say junctional ST depression probably normal *

* This statement will not appear if screening criteria is turned on.
  See Appendix F for more information.
Junctional ST Depression Probably Abnormal

Skip test if:
- Test $LVH$ and $RVH$ with secondary repolarization passed
- Test nonspecific $ST$ abnormality (elevation) passed
- Test $RBBB$ passed
- Test $MI$ passed

Statement is made if:
- $STJ < -100 \, \mu V$
- $STE > 1/2 \, STJ$ in any two of all leads except aVR

Then say junctional $ST$ depression probably abnormal *

* This statement will not appear if screening criteria is turned on.
See Appendix F for more information.

ST Abnormality Probably Digitalis Effect

Skip test if:
- Test $LVH$ or $RVH$ secondary repolarization passed
- Test nonspecific $ST$ abnormality (elevation) passed
- Test $RBBB$ passed

Statement is made if:
either
- In any two of leads I, II, aVL, V4, V5, and V6:
  - Minimum STM or STE < minimum STJ and also $-50 \, \mu V$
  - Heart rate $\leq 100 \, \text{bpm}$
  - PR interval $< 200 \, \text{ms}$
  - In any two of leads I, II, aVL, and V1 through V6:
    - Minimum STM or STE < minimum STJ
    - P onset amplitude $-50 \, \mu V$
    - $-25 \, \mu V$
    - T amplitude $> STM + 100 \, \mu V$

Then say $ST$ abnormality probably digitalis effect
Nonspecific ST Abnormality

Skip test if:
- Test LVH or RVH with secondary repolarization passed
- Test nonspecific ST abnormality (elevation) passed
- Test RBBB passed

Statement is made if in any two of leads I, II, aVL, aVF, V4, V5, and V6:
- STJ ≤ -50 μV and STE < 0 μV
- STE ≤ minimum (STJ and STM) -25 μV

Then say nonspecific ST abnormality

If test atrial fibrillation passed simultaneously, then append probably digitalis effect

If MI present, suppress all ST abnormality statements.

ST Depression Consider Subendocardial Injury or Digitalis Effect

Skip test if:
- Test LVH or RVH secondary repolarization passed

Statement is made if:
- In any two of leads I, II, aVL, aVF, and V2 through V6 STJ and STM are < -100 μV (If test RBBB passed, then do not test leads V2, V3, and V4)

Then say ST abnormality consider subendocardial injury or digitalis effect

Suppress nonspecific ST statements.

ST Depression in Septal Leads

Statement is made if:
- Test septal and posterior infarct failed
- In lead V1 or V2, STJ and STM are ≤ -200 μV

Then say ST depression in septal leads
ST Depression in Anterior Leads

Statement is made if:
- Test anterior and posterior infarct failed
- Tests LVH with repolarization abnormality failed
- In lead V3 or V4, STJ and STM are ≤-200 μV

Then say *ST depression in anterior leads*

ST Depression in Lateral Leads

Statement is made if:
- Test lateral infarct failed
- Test LVH with repolarization abnormality failed
- Lead V5 or V6, STJ and STM are ≤200μV
- In lead I or aVL, STJ and STM are ≤100μV

Then say *ST depression in lateral leads*

ST Depression in Inferior Leads

Statement is made if:
- Test inferior infarct failed
- Test LVH with repolarization abnormality failed
- In lead II or aVF, STJ and STM are ≤-100 μV

Then say *ST depression in inferior leads*

If any tests subendocardial injury passed, then suppress nonspecific ST abnormality, junctional ST depressions, and ST depression consider digitalis effect.

If inferior myocardial infarction and lead III has STJ >100 μV, suppress ST depression in lateral leads statement.

If ST depression in anterior and lateral leads present but no ST depression in septal leads present, then say *ST depression in anterolateral leads*

If ST depression in inferior and lateral leads present but no ST depression in septal and anterior leads present, then say *ST depression in inferolateral leads*

If ST depression in septal and anterior leads present, then say *ST depression in anteroseptal leads*
T Wave Abnormality

Skip test if:
- Test WPW or dextrocardia passed
- Test LVH with repolarization abnormality passed
- Test complete RBBB passed
- Test complete LBBB passed

Conditions for skipping test applies to all T wave tests.

Abnormal QRS-T Angle, Consider Primary T Wave Abnormality

Skip test if:
- Any test infarct passed
- Test RBBB passed

Statement is made if:
- QRS axis – T axis ≥ 60 degrees
  and T axis < 0 degrees
- QRS axis – T axis ≤ -60 degrees
  and T axis > 90 degrees

Then say abnormal QRS-T angle, consider primary T wave abnormality

* This statement will not appear if screening criteria is turned on. See Appendix F for more information.

Nonspecific T Wave Abnormality

Skip test if:
- Any test infarct passed
- Test RBBB passed

For age < 16 years skip testing leads V1 through V4.

**NONSPECIFIC T ABNORMALITY TEST**

For each lead to be tested:
- Set test limit
  - If QRS amplitude is positive, limit value is 1/20 QRS amplitude + 25 μV
  - If QRS amplitude is negative, limit value is 25 mV
- Then Count lead as passing test if special T Amplitude ≤ the test limit and (special T < 0 or TA < 200 μV)
Test leads as follows:
   First test lead V3 through V6
   If lead V3 passed test, then test lead V2; then test leads I, II, and aVL
   If special T amplitude exceeds 150 μV in leads I, II, and aVL
do not test
and If QRS balance minus special T <0 μV in aVL, or if QRS balance is negative, do not test aVL

If more than two leads pass this test, then say nonspecific T wave abnormality

If test atrial fibrillation passed simultaneously, then append probably digitalis effect

T Wave Inversion in Lateral Leads

Statement is made if:
   Test lateral infarct failed
   and In any two of leads I, aVL, V5, and V6,
special T amplitude ≤100 μV
   (Do not test aVL if QRS balance is negative.)

Then say T wave inversion in lateral leads

If test atrial fibrillation passed simultaneously, then append or digitalis effect

If test nonspecific ST abnormality simultaneously passed, then prefix ST&

T Wave Inversion in Inferior Leads

Statement is made if:
   Any test inferior infarct failed
   and Special T amplitude ≤-100 μV in lead II or aVF (Test lead aVF only when QRS amplitude is positive.)

Then say T wave inversion in inferior leads

If test atrial fibrillation passed simultaneously, append or digitalis effect

If test nonspecific ST abnormality simultaneously passed, then prefix ST&
T Wave Inversion in Inferolateral Leads

Statement is made if:
   Test T wave abnormality consider inferior ischemia passed
and   Test T wave abnormality consider lateral ischemia passed

Then say *T wave inversion in inferolateral leads*

If any T wave inversion tests pass, suppress *STEREP and EREP*.

If any T wave inversion tests pass, suppress *NST, STJD1, STJD2, STDIG, NT, AQRST, and STD*.

Nonspecific ST and T Abnormality

Statement is made if:
   Any specific T wave inversion tests failed
and   Pericarditis test failed
and   ST depression test failed
and   Test nonspecific ST abnormalities passed
and   Test nonspecific T abnormality passed

Then say *nonspecific ST & T abnormality*

If test atrial fibrillation passed, simultaneously append probably digitalis effect

If test NSTT passed, suppress *NST, STJD1, STJD2, STDIG, NT, AQRST, and STD*. 
**QT Abnormalities**

Skip test prolonged QT if:
- Test WPW or dextrocardia passed

Statement is made if:
- QTc $\geq$ High QT for age
- Ventricular rate $\leq$ 100 bpm
- IVCB not present
- RBBB not present
- LBBB not present
- QRS duration <120 ms

Then say *Borderline prolonged QT*

Suppress EREP and STEREPE.

If LVH or RVH, BVH or IVCD, or IRBBB or ILBBB append, *may be secondary to QRS abnormality*
8 ECG Classification
Overview

Unless generation of ECG Classification is suppressed in a particular platform’s setup, each ECG is assigned one of the following classifications by the 12SL analysis program (listed in order of increasing severity):

- Normal ECG (N)
- Otherwise normal ECG (O)
- Borderline ECG (B)
- Abnormal ECG (A)

Most statements generated by 12SL have a classification associated with them. Some statements are informative only and do not have an associated classification. These are typically statements that are appended or prepended to a primary statement. The classification of each 12SL statement is given in Appendix B – “Statement Library by Number”. The overall ECG classification is made based on the most severe single statement in the 12SL diagnosis.

As a very simple example, say an ECG contained the single 12SL statement: “Normal Sinus Rhythm”. The classification for this statement is “N”. The overall classification for this ECG would be “Normal ECG”.

As another example, say 12SL generated the following statements for an ECG (the classification of each single statement is shown in parentheses):

- Sinus bradycardia (O)
- with frequent (none)
- premature ventricular complexes (O)
- in a pattern of bigeminy (O)
- Left ventricular hypertrophy (A).

In this case, the most severe single statement is “Left ventricular hypertrophy”, with a classification of “A”, which would result in an ECG classification of “Abnormal ECG”.

For your notes
9 Serial Comparison
Introduction

In clinical settings the general practice of providing a complete interpretation of an ECG requires a comparison of the current ECG to a previous ECG. The technique of comparing the current ECG to the previous ECG of a patient is termed serial electrocardiography. Serial electrocardiography is used to identify changes in the patient’s electrocardiogram. More importantly, it is used to detect “clinically significant changes” in a patient’s electrocardiogram and to determine if an ECG abnormality is new, old, or unchanged. Serial ECGs have been shown to be most helpful in the detection of acute infarction. Studies have shown that a physician’s accuracy in diagnosing acute myocardial infarction rose from 51% to 83% when serial ECG tracings were used, and in some cases was the sole factor in the detection of infarction. Additionally, research has shown that the number of statements that are edited or changed by overreading physicians can be reduced by as much as 76% when a computerized serial comparison program is used. When previously edited changes on the ECGs are used by the serial comparison program, the number of statements needing changes can be reduced by 84%.

GE Healthcare’s Marquette 12SL Serial ECG Comparison Program has been developed to emulate the techniques used by trained electrocardiographers in the comparison of serial electrocardiograms and is designed to take advantage of the Marquette 12SL ECG analysis program’s interpretation and measurements. The Marquette 12SL ECG serial comparison program was developed to use statements, ECG measurements, and waveform comparison techniques to maximize performance and accuracy in the detection of clinically significant changes in rhythm, P, QRS, ST and T waves. The MUSE system, which stores electrocardiograms with physician edited interpretations to both individual ECGs and serial comparisons, in unison with the serial comparison program, allows for accurate and expedient processing of a patient’s ECG data.

Although the 12SL analysis is completed at the cardiograph at the time of the ECG acquisition, the serial comparison analysis is done at the MUSE when the MUSE receives the ECGs. This is transparent to the electrocardiographer who reads the ECGs printed from the MUSE workstation, and because of the integration of the programs, the serial comparison interpretation is appended to the original 12SL interpretation.
Overview of Serial Comparison Analysis

Rhythm Analysis

- Dominant rhythms compared first (sinus, ventricular, atrial fibrillation, etc.) via statements
- Rhythm modifiers compared second only if dominant rhythm does not change

QRS Analysis

- QRS comparison is done via statements, measurements, and waveform analysis
- Aim is to detect changes in conduction and/or infarction
- Changes in axis and voltage (amplitude) are also detected
- Looks for the first occurrence of an infarct and labels it on the ECG
- For infarction (if acute) more sensitive criteria is used
- Time between ECGs is used to adapt criteria sensitivity

ST-T Analysis

- Looks for the presence/absence of acute infarction or ischemia
- Looks for evolution of the ST-T changes in an acute MI
- Uses MI age categories to “adapt sensitivity of detection”
- < 4 days old

**NOTE**

The serial comparison program looks for significant changes in the waveforms when doing the contour comparisons. It is not unusual to have an ECG that may have narrowly met the criteria for a particular 12SL statement and have another ECG that just missed the criteria thresholds, yet there are no significant differences in the waveforms themselves. In such a case, the first ECG would have a statement that would be absent from the second, and could possibly even have a different overall ECG classification. However, if the serial comparison program does not discern a significant difference in the actual waveforms, it will simply state that “no significant changes have occurred.”
Details of Serial Comparison Analysis

Rhythm Comparison

Rhythm comparison is done via statements. (Edited rhythm statements may be used by the program if they are from the original MUSE system library and are not user added statements or free text.) However, actual Marquette 12SL program measurements are compared to assist in the detection of significant changes for first degree AV block and short PR interval. If a major rhythm change occurs, it is stated without reference to changes that occur in the rhythm modifier statements. Major rhythm changes are stated without reference to rate. For example, the statement “sinus rhythm has replaced junctional rhythm” is made instead of “sinus tachycardia has replaced unusual P axis and short PR, probable junctional bradycardia.” Only when the basic rhythm is the same, does the program mention changes that occur in the rhythm modifier statements (e.g., PVCs, PACs, 1st degree AV Block, etc.).

Clustering of rhythm modifier changes is used. The program “clusters” modifier statements regarding ectopic beats as either premature ventricular or premature supraventricular. Other rhythm modifiers that are also clustered are (complete heart block and AV dissociation), (sinus pause and second degree SA block Mobitz I and II), (second degree AV block Mobitz I and II). Certain rhythm modifier statements such as second degree AV block, complete heart block or AV dissociation are given a higher priority than other rhythm modifier statements. For example, if the previous ECG has complete heart block and the current ECG has first degree AV block, then no statement is made about the PR interval for first degree AV block, but complete heart block is stated to be no longer present.

Rate dependent and PR interval calls are checked against the measurements before statements about change are made. Rate change statements are made at a more sensitive level if both ECGs contain electronic ventricular pacemakers. If a rhythm change (i.e. WPW or electronic pacing) results in a QRS change, the QRS-ST-T comparison is suppressed. If either of the ECGs being compared has “undetermined rhythm” then no rhythm comparison is performed.

QRS Comparison

QRS comparison uses statements, measurements and waveforms. The emphasis is in detecting conduction and infarction changes. However, changes concerning axis and/or voltage are also stated but with less sensitive criteria to take into account “normal variability” in the ECG and changes that may be caused by inaccurate and inconsistent lead placement.

When WPW is stated in either the current or the previous ECG interpretation, then further QRS and repolarization comparisons are inhibited.
For conduction, measurement comparison and waveform correlation are used to determine whether the change is large enough to warrant the program stating it. If a major conduction change occurs, comparison of the repolarization is suppressed (skipped) since these are considered secondary changes.

Comparison concerning infarction is the most complicated and sophisticated analysis scheme in the program. Once a statement concerning infarction occurs in either of the ECGs being compared, then parameters related to infarction along with waveform correlation techniques and measurements are used to detect “clinically significant” change. The program will also search all of a patient’s previous records and inform the user as to when the infarction first appeared in the series of ECGs.

If both ECGs have definite evidence of infarction (or if a lesser degree of infarction evidence is unchanged, i.e. the ECG waveform data in the leads exhibiting the infarction “look very similar”), then the program states “no significant change has occurred.” If a “clinically significant” waveform change is evident, then the program will state it appropriately as “(specific location) MI now present” or “criteria for (specific location) MI no longer present” or if subtle changes in the Q-waves (initial part of the QRS) have been detected, the program will state “questionable change in initial forces of (specific location).”

This approach is used until repolarization changes or injury (ST-elevation) is evident in either of the ECGs. Upon development of a significant repolarization change in the presence of myocardial infarction evidence (QRS changes), the program becomes much more sensitive to changes in the QRS-ST-T. When there are ST-T wave changes detected by the program, the comparison becomes much more detailed. Sensitivity for detection of “clinically significant changes” changes with respect to the time difference between the two ECGs. Sensitivity and program statements will change depending on the following time differences between the acquisition dates of the ECGs: same day to 3 days, 4 days to 21 days, 22 days to 365 days and more than 365 days (1 year). When the ST-T wave changes occur within the first 3 days, the changes will be labeled as new or acute or as “serial changes of an evolving myocardial infarction.” ST-T wave changes occurring between 4 days to 1 year which are becoming less severe (ST-T becoming more normal) will be described as “serial changes of myocardial infarction.” If at any time the repolarization (ST-T) become more abnormal, the program will state that there are new changes present.

**Repolarization Comparison**

The ST segments and T waves are compared via the 12SL measurements. When significant changes are detected, they are indicated using “descriptive statements.” For example, the program will state that the “T wave amplitude in (specific lead group) has increased or decreased.” The same is done for ST segment elevation and depression. If there is T wave inversion, the comparison will indicate the extent of the T wave inversion by making the statement “T wave inversion in (specific lead group) is more evident, less evident, now evident or no longer evident.” When the T wave abnormality is “non-specific,” then the
program will indicate whether the nonspecific T wave abnormality is worse or improved in (specific lead group).

**Miscellaneous Comparisons**

Pediatric ECGs are not compared but the previous ECGs date and time are indicated by the program.

The Serial Comparison program tracks the length of the total interpretation. This includes the original ECG as well as the serial comparison interpretation. If more than 10 lines of text occurs and the serial comparison interpretation is more than 6 full lines of text, then the serial comparison program will suppress the comparison interpretation and simply state “significant changes have occurred.” This is done to prevent the use of an additional page for the printing of the ECG.

If all of the previous ECGs are on an archive volume that is not “on-line” then the serial comparison program informs the user with the statement “manual comparison required data is off line and on volume#.” If all previous ECGs are analog ECGs, then the program states “manual comparison required, analog tracing.”
References


A  Statement Library by Acronym
For your notes
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<thead>
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<th>Acronym</th>
<th>Statement</th>
</tr>
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<td>ST ELEVATION CONSIDER ANTERIOR INJURY OR ACUTE INFARCT</td>
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<td>ABNORMAL LEFT AXIS DEVIATION</td>
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<td>ANTEROLATERAL INFARCT</td>
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<td>T WAVE ABNORMALITY, CONSIDER ANTEROLATERAL ISCHEMIA</td>
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</tr>
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<td>AV SEQUENTIAL OR DUAL CHAMBER ELECTRONIC PACEMAKER</td>
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### Statement Library by Acronym:

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<td>T WAVE ABNORMALITY, CONSIDER INFERIOR ISCHEMIA</td>
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<td>LEFT VENTRICULAR HYPERTROPHY</td>
</tr>
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For your notes
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<td>WITH A-V DISSOCIATION</td>
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<td>ATRIAL FLUTTER</td>
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<td>COARSE</td>
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<td>164</td>
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<td>171</td>
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<td>172</td>
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<td>174</td>
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<td>WITH UNDETERMINED RHYTHM IRREGULARITY</td>
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<td>O</td>
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<td>PREMATURE VENTRICULAR AND FUSION COMPLEXES</td>
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<td>, AND CONSECUTIVE</td>
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### Statement Library by Statement Number:

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<th>Statement</th>
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<th>Classification</th>
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<td>AV SEQUENTIAL OR DUAL CHAMBER ELECTRONIC PACemaker</td>
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<td>UNDETERMINED RHYTHM</td>
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### Statement Library by Statement Number:

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<td>INDETERMINATE AXIS</td>
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<td>NORTHWEST AXIS</td>
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<td>S1S2S3</td>
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<td>WITH QRS WIDENING AND REPOLARIZATION ABNORMALITY</td>
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<td>DEEP Q-WAVE IN LEAD V6</td>
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<td>573</td>
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### Statement Library by Statement Number:

<table>
<thead>
<tr>
<th>Acronym</th>
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KEY: N = NORMAL ECG  
A = ABNORMAL ECG  
B = BORDERLINE ECG  
O = OTHERWISE NORMAL ECG  
* = STATEMENT NOT USED BY 12SL ANALYSIS PROGRAM  
NA = NOT APPLICABLE - DESCRIPTIVE STATEMENT
C Pediatric Tables
For your notes
Overview

The normal values included in this appendix, and used by the pediatric analysis program, are those collected and published by Davignon et al. This data is based on more than 2000 children who were found to have a normal physical examination. The total population was divided into 12 age groups, with 7 age groups in the first year of life in order to reflect the greater changes in the ECG during this time.

References

Davignon A., Rautaharju P., Boisselle E., et al.,
## Pediatric Tables: Less Than One Day Old

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Amplitude in microvolts; Duration in milliseconds
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Amplitude in microvolts; Duration in milliseconds
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Amplitude in microvolts; Duration in milliseconds
### Pediatric Tables: 1 to 3 Weeks Old

#### 1 to 3 Weeks Old

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Amplitude in microvolts; Duration in milliseconds
# Pediatric Tables: 1 to 2 Months Old

## 1 to 2 Months Old

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Amplitude in microvolts; Duration in milliseconds
## 3 to 5 Months Old

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<td><strong>QRS Duration</strong></td>
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Amplitude in microvolts; Duration in milliseconds
# 6 to 11 Months Old

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<td>V6 R amplitude + V1 S amplitude in horizontal plane</td>
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<td>QT Interval</td>
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Amplitude in microvolts; Duration in milliseconds
## Pediatric Tables: 1 to 2 Years Old

### 1 to 2 Years Old

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<tr>
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<td>QRS Duration</td>
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Amplitude in microvolts; Duration in milliseconds
## Pediatric Tables: 3 to 4 Years Old

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Amplitude in microvolts; Duration in milliseconds
# 5 to 7 Years Old

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Amplitude in microvolts; Duration in milliseconds
# 8 to 11 Years Old

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Amplitude in microvolts; Duration in milliseconds
## 12 to 15 Years Old

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Amplitude in microvolts; Duration in milliseconds
Pediatric Tables: 12 to 15 Years Old

For your notes
D Standardization of Terminology and Interpretation
For your notes
Overview

The 12SL Analysis Program interpretive statements are consistent with the terminology and interpretation classifications recommended by the 10th Bethesda conference on Optimal Electrocardiography (1978). The interpretive statements, classified as type A, B, or C are defined as follows:

Type A Statements

Refer to an anatomic lesion or pathophysiologic state which is verifiable by nonelectrocardiographic means. Examples include statements about hypertrophy and infarction.

Type B Statements

Refer to an anatomic or functional disturbance that is detectable by the ECG itself. Examples include statements about arrhythmias and conduction disturbances.

Type C Statements

Refer to descriptive ECG features that do not fit into type A or B categories. Examples include statements about electrical axis, nonspecific T wave abnormalities and unusual voltage.

Criteria for each statement was developed from a variety of sources including cardiologist experts, World Health Organization standards and Common Standards for Quantitative Electrocardiography.

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<th>Category</th>
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<td>Anterior infarct, Left ventricular hypertrophy</td>
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<tr>
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<td>Diagnosis of electrophysiologic changes</td>
<td>Atrial fibrillation, Right bundle branch block</td>
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<tr>
<td>C</td>
<td>Descriptive ECG features</td>
<td>Nonspecific ST abnormality, Flat T waves</td>
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For your notes
E 12SL Version Identification
For your notes
Introduction

The 12SL analysis program has continually evolved since it was first introduced in 1980. Each released version of the program contains one or more changes to it and is associated with a unique version number. A version number appears on the ECG report printed by an electrocardiograph or a MUSE system; encoded within this number are the actual 12SL version number and information about the specific platform on which the ECG was acquired.

The following table can be used to convert the value displayed on the ECG report to the actual 12SL version number. Some values are reserved for future use. This table lists all possible values which may appear on the ECG report; not all of these values have been (or ever will be) used.
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<td>reserved</td>
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<td>227</td>
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<table>
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<th>Version on Report</th>
<th>Actual 12SL version</th>
</tr>
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<td>228</td>
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</tr>
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<td>244</td>
<td>10</td>
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<td>245</td>
<td>reserved</td>
</tr>
<tr>
<td>246</td>
<td>11</td>
</tr>
<tr>
<td>247</td>
<td>reserved</td>
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<tr>
<td>248</td>
<td>12</td>
</tr>
<tr>
<td>249</td>
<td>reserved</td>
</tr>
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<td>250</td>
<td>13</td>
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<td>251</td>
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<td>252</td>
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<td>254</td>
<td>15</td>
</tr>
<tr>
<td>255</td>
<td>reserved</td>
</tr>
</tbody>
</table>
For your notes
F Screening Criteria
For your notes
Introduction

With Screening Criteria turned at the electrocardiograph (also referred to as Hi-Spec, or High Specificity mode) certain lower-acuity 12SL statements are suppressed from appearing on the report. By suppressing these statements when Screening Criteria is turned on, 12SL is placed in a higher specificity mode; that is, fewer interpretive statements will be generated. Most statements that are suppressed are either of lower clinical acuity, such as “incomplete right bundle branch block”, or represent lower confidence levels of abnormalities, such as those prefixed with “cannot rule out” or “possible”.

Note that not all platforms offer the screening mode as a user-configurable choice. Screening mode is turned off by default (i.e., statements are not suppressed).

**NOTE**

Running 12SL with the Screening Criteria turned on can affect the ECG classification. For example, an ECG with the diagnosis “Normal sinus rhythm; Right axis deviation”, will be classified as an Abnormal ECG when Screening mode is off. However, if Screening mode is on, “right axis deviation” will not be stated and the ECG will be classified as a Normal ECG. Refer to Chapter 8, “ECG Classification” for details on classification of ECGs.
## Suppressed Statements

The following table lists all statements that are suppressed when Screening mode is turned on.

<table>
<thead>
<tr>
<th>Statement Text</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td>... with undetermined rhythm irregularity</td>
<td>IRREG</td>
</tr>
<tr>
<td>... with rapid ventricular response</td>
<td>RVR</td>
</tr>
<tr>
<td>... with slow ventricular response</td>
<td>SVR</td>
</tr>
<tr>
<td>... with a competing junctional pacemaker</td>
<td>CJP</td>
</tr>
<tr>
<td>... with x:1 AV conduction (x=2,3,4,5)</td>
<td>W2T1, W3T1, W4T1, W5T1</td>
</tr>
<tr>
<td>... with retrograde conduction</td>
<td>RETC</td>
</tr>
<tr>
<td>... [and/with] possible premature atrial complexes with aberrant conduction</td>
<td>[AND/WITH] + PO + PAC + WITH + ABCOND</td>
</tr>
</tbody>
</table>

### Table 1. Statements Suppressed When Screening Criteria Turned On

<table>
<thead>
<tr>
<th>Statement Text</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rightward axis</td>
<td>RAD</td>
</tr>
<tr>
<td>Right axis deviation</td>
<td>RAD4</td>
</tr>
<tr>
<td>Northwest axis *</td>
<td>NWA</td>
</tr>
<tr>
<td>Right superior axis deviation</td>
<td>RAD5</td>
</tr>
<tr>
<td>Pulmonary disease pattern</td>
<td>PULD</td>
</tr>
</tbody>
</table>

### Axis / Voltage

<table>
<thead>
<tr>
<th>Statement Text</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSR’ or QR pattern in V1 suggests right ventricular conduction delay</td>
<td>RSR</td>
</tr>
<tr>
<td>Incomplete right bundle branch block</td>
<td>IRBBB</td>
</tr>
<tr>
<td>Nonspecific intraventricular conduction delay</td>
<td>IVCD</td>
</tr>
</tbody>
</table>

### Ventricular conduction

<table>
<thead>
<tr>
<th>Statement Text</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal voltage criteria for LVH, may be normal variant</td>
<td>QRSV</td>
</tr>
<tr>
<td>Moderate voltage criteria for LVH, may be normal variant</td>
<td>LVH3</td>
</tr>
<tr>
<td>Possible right ventricular hypertrophy</td>
<td>PO + RVH</td>
</tr>
<tr>
<td>... plus right ventricular hypertrophy</td>
<td>RVE+</td>
</tr>
<tr>
<td>Possible left atrial enlargement</td>
<td>PO + LAE</td>
</tr>
<tr>
<td>Possible left ventricular hypertrophy *</td>
<td>PO + LVH</td>
</tr>
<tr>
<td>Deep Q wave in lead V6, possible left ventricular hypertrophy *</td>
<td>QV6 + PO + LVH</td>
</tr>
<tr>
<td>Possible biventricular hypertrophy *</td>
<td>PO + BIVH</td>
</tr>
<tr>
<td>Statement Text</td>
<td>Acronym</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Prominent mid-precordial voltage, possible biventricular hypertrophy *</td>
<td>PMDPV + PO + BIVH</td>
</tr>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td></td>
</tr>
<tr>
<td>Cannot rule out septal infarct</td>
<td>CRO + SMI</td>
</tr>
<tr>
<td>Cannot rule out anteroseptal infarct</td>
<td>CRO + ASMI</td>
</tr>
<tr>
<td>Cannot rule out anterior infarct</td>
<td>CRO + AMI</td>
</tr>
<tr>
<td>Cannot rule out inferior infarct</td>
<td>CRO + IMI</td>
</tr>
<tr>
<td>Cannot rule out inferior infarct (masked by fascicular block?)</td>
<td>CRO + IMI + MAFB</td>
</tr>
<tr>
<td>Possible anteroseptal infarct</td>
<td>PO + ASMI</td>
</tr>
<tr>
<td>Possible anterior infarct</td>
<td>PO + AMI</td>
</tr>
<tr>
<td>Possible anterolateral infarct</td>
<td>PO + ALMI</td>
</tr>
<tr>
<td>Possible lateral infarct</td>
<td>PO + LMI</td>
</tr>
<tr>
<td>Possible inferior infarct</td>
<td>PO + IMI</td>
</tr>
<tr>
<td><strong>ST - T</strong></td>
<td></td>
</tr>
<tr>
<td>ST elevation, consider early repolarization, pericarditis, or injury</td>
<td>SERYR1</td>
</tr>
<tr>
<td>ST elevation, probably due to early repolarization</td>
<td>SERYR2</td>
</tr>
<tr>
<td>Early repolarization</td>
<td>REPOL</td>
</tr>
<tr>
<td>Possible acute pericarditis</td>
<td>PO + PCARD</td>
</tr>
<tr>
<td>Junctional ST depression, probably normal</td>
<td>JSTN</td>
</tr>
<tr>
<td>Junctional ST depression, probably abnormal</td>
<td>JST</td>
</tr>
<tr>
<td>Abnormal QRS-T angle, consider primary T wave abnormality</td>
<td>QRST</td>
</tr>
</tbody>
</table>

* Statements marked with asterisk are statements that are only made when doing pediatric ECG analysis (age < 16 years).
For your notes
G Statement of Validation and Accuracy
For your notes
Introduction

Document Purpose

This appendix reviews the validation and accuracy of GE Healthcare’s Marquette 12SL ECG analysis program. Accuracy levels, as well as the overall clinical impact of the 12SL analysis program, are supplied from independent assessments reported in the scientific literature. For a more complete description of how the 12SL analysis program processes the electrocardiogram (ECG), please see the 12SL Physician’s Guide (PN 416791-004).

The Marquette 12SL ECG Analysis Program: A Brief History

The Marquette 12SL analysis program was first developed in 1980. It was the first commercially available ECG program to analyze all 12 leads, simultaneously recorded for 10 seconds. In 1982, the 12SL analysis program was embedded into a computerized electrocardiograph, known as the MAC-II. It was the first of its kind, generating a 12-lead interpretation at the bedside in less than 10 seconds.[1]

Since its inception, GE Healthcare has continued to evolve the Marquette 12SL analysis program. Furthermore, the Marquette 12SL analysis program has been validated on a variety of platforms beyond the diagnostic electrocardiograph, including bedside monitors, stress-testing systems, pre-hospital defibrillators, Holter recorders, and PC-based systems.

The timeline in Table 1, “ECG Analysis / 12SL Timeline,” on page 4 provides is a summary of the significant advancements related to GE Healthcare’s Marquette 12SL analysis program.
## Table 1. ECG Analysis / 12SL Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Advancement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>12SL ECG analysis program introduced on the MUSE system[1]</td>
</tr>
<tr>
<td>1982</td>
<td>12SL incorporated into a computerized electrocardiograph: MAC-II[1]</td>
</tr>
<tr>
<td>1984</td>
<td>12SL Serial Comparison program is introduced on MUSE[2]</td>
</tr>
<tr>
<td>1986</td>
<td>Automated testing of 12SL using non-ECG, gold-standard databases[3]</td>
</tr>
<tr>
<td>1987</td>
<td>Pediatric analysis, based on Davignon tables, incorporated into 12SL[4]</td>
</tr>
<tr>
<td>1988</td>
<td>Analysis of extra leads, generating vector loops at an electrocardiograph</td>
</tr>
<tr>
<td>1989</td>
<td>Recognition of ST-elevated acute myocardial infarction (MI) in pre-hospital setting[5]</td>
</tr>
<tr>
<td>1991</td>
<td>12SL in a pre-hospital defibrillator equipped with 12-lead ECG[6]</td>
</tr>
<tr>
<td>1992</td>
<td>500 samples per second analysis, compression, and storage[7]</td>
</tr>
<tr>
<td>1993</td>
<td>12SL in a bedside monitor, equipped with 12-lead ECG[8]</td>
</tr>
<tr>
<td>1995</td>
<td>ACI-TIPI integrated into 12SL for prediction of acute cardiac ischemia[9]</td>
</tr>
<tr>
<td>1997</td>
<td>Automated QT dispersion and T-wave principal component analysis[10]</td>
</tr>
<tr>
<td>1999</td>
<td>MAC-RHYTHM: 12SL incorporates asynchronous P wave detector based on QRS subtraction[14]</td>
</tr>
<tr>
<td>2000</td>
<td>Gender specific acute MI criteria[15]; Improved pacemaker detection based on 4KHz sampling[16]</td>
</tr>
<tr>
<td>2002</td>
<td>12SL in a Holter recorder, equipped with 12 lead ECG[17-19]</td>
</tr>
<tr>
<td>2004</td>
<td>Hookup Advisor in 12SL[21]</td>
</tr>
<tr>
<td>2005</td>
<td>12SL cleared for measurement and trending of 12-lead ambulatory recordings[22]</td>
</tr>
<tr>
<td>2006</td>
<td>Recognition of acute right ventricular infarction via analysis of V4R[23]</td>
</tr>
</tbody>
</table>
Intended Use of the Marquette 12SL Analysis Program

GE Healthcare’s Marquette 12SL analysis program assists the physician in interpreting and measuring the resting 12-lead ECG. All computer generated measurements and interpretations should be overread by a physician. All ECG interpretations are identified as being “unconfirmed” until they have been edited by a physician.

12SL Outputs

GE Healthcare’s Marquette 12SL analysis program is intended for use in the general population, ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The program can select different ECG criteria based on age and gender. The program has ECG criteria intended for all patient ages, including neonatal, pediatric, and adult.

The 12SL analysis program is intended for all clinical care environments that require a resting 12 lead ECG, as prescribed by a physician. This includes all departments within small or large hospitals as well as out-of-hospital environments, such as outpatient clinics, physician offices, ambulances, nursing care facilities, and home-based care.

Population-based research groups also use the 12SL analysis program for generating measurements, since it can improve their effectiveness and consistency.[24-26]

Note that the Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC) require manufacturers to provide an “intended use” for medical devices.[27] This disclosure is filed with the respective regulatory agency and used for certification and clearance of the medical device. Note that the aforementioned “intended use” for the 12SL analysis program also applies to all devices that use the 12SL analysis program and provide the capabilities of an analyzing electrocardiograph. (See IEC 60601-2-51 clause 50.102.2).
Overall Impact of Computerized ECG: Assisting the Physician

When computerized electrocardiography is used in conjunction with a physician, it can improve both the speed and accuracy of reviewing ECGs, as determined via the following clinical studies:

- "Combined cardiologist and program results demonstrated the highest accuracy, i.e., respectively 78.7% and 76.1%, higher than the result of any individual reader or program. These findings demonstrate that the combination of expert knowledge of computer programs can, similar to panel review and group analysis in clinical practice, enhance diagnostic accuracy."[28]
- "The quality of computer-assisted ECG interpretation was comparable to that of review provided by a cardiology service. Furthermore, computerized interpretation may be clinically more useful because it is immediately available."[29]
- "Computer ECG systems provide a valuable function for ECG analysis, storage, retrieval, and serial comparison. The current systems can provide quality control of technician performance, acquisition equipment, and physician over reading. Its overall acceptability and clinical usefulness is documented in a clinical practice setting with a 90.4% computer-physician agreement in more than 20,000 ECGs. Computerized ECG systems have demonstrated their clinical usefulness in patient care."[30]
- "The impact of computer assisted interpretation on cardiologists’ readings of ECGs is demonstrably beneficial: the main empirical conclusion of this study is that, compared with conventional interpretation, the use of computer assisted interpretation of ECGs cuts physician time by an average of 28% and significantly improves the concordance of the physician’s interpretation with the expert benchmark, without increasing the false-positive rate."[31]
- "In summary, this study has confirmed that junior doctors have a high error rate in reporting ECGs. Computer generated reports did not significantly improve this, even though the machine achieved a low major error rate compared with the junior doctors. Computer generated reports may have a role in prompting junior doctors to query their own ECG interpretation but should not replace experienced medical support."[32]

Despite the documented benefits of a computerized ECG system, it should be made clear that a computerized analysis is not a substitute for human interpretation. There are two reasons for this:

- First, statements of accuracy need to be viewed from a statistical perspective. Although accuracy levels may be high, outliers can and will exist. The computer will make mistakes, especially in the presence of artifact. As one author cautioned: "Computer decision support systems can generally improve the interpretive accuracy of internal medicine residents in reading EKGs. However, subjects were influenced significantly by incorrect advice, which tempers the overall usefulness of computer-generated advice."[33]
Second, a computer does not have the ability to include the entire clinical picture of the patient. The ECG tracing is significant only when interpreted in conjunction with the other clinical findings associated with the patient. As quoted in the literature: “Given that computers alone cannot perform the task of cardiovascular diagnosis, and that cardiologists' ECG interpretations are greatly enhanced by ubiquitous computer assisted interpretation, it appears that the best approach is one that combines person and machine.”[31]
GE Healthcare’s Marquette 12SL analysis program was introduced in 1980. All improvements to the program have been accomplished via a systematic, logical, controlled methodology. A major aspect of this methodology benefits from the use of stored ECGs.

Reanalysis of Stored ECGs

All historical ECGs analyzed by the 12SL analysis program and stored on the MUSE cardiology information system, can be reanalyzed for the purposes of validating or improving the program. This is because the median QRS complex generated by the program has always been compressed and stored via a lossless Huffman encoding method. The first implementation of this methodology has been described in the literature, was later enhanced by GE Healthcare for ECGs stored at 500 samples per second (sps), and ultimately served as the basis of a new international standard. This standard includes data fidelity requirements for compressed ECGs; these requirements are surpassed by the data compression/decompression methods currently employed by GE Healthcare. For those who desire additional fidelity in the decompressed ECG, GE Healthcare provides another option (known as Digital View Storage DVS), which uses lossless compression on all of the raw ECG data.

Initiating a Change in the Program

Any change to the program requires a great deal of research. This effort can be instigated by a variety of sources:

- The constant pursuit of clinically correlated databases can yield statistics that indicate whether a change should be considered.
- New criteria published in the scientific literature can be evaluated and sometimes incorporated into the program.
- Consultations with cardiologists also stimulate investigations. This is especially true when they have stored ECGs that reveal a particular error.
- GE Healthcare also documents customer complaints. Although complaints are typically documented from customer interactions with GE Healthcare Service, Sales, or the Call Center personnel, any GE Healthcare employee who is aware of a complaint must document it. The Engineering department then tracks these complaints. Some times the complaint can be resolved by providing the customer further documentation or clarification as to how the program functions.
Measuring the Impact: Evaluation via a Library of Databases

Before a change can be instituted, it must always be evaluated in relation to the current program performance. Stored ECGs are reanalyzed and any difference due to the enhancement is scored and tracked. After this is done, the validation system automatically culls out any ECGs that scored differently between the two versions of the program. This results in an efficient method to automatically determine how a change might affect program performance.[3, 11]

An Appropriate Gold-Standard Database for Type A, B, or C Statements

In the 12SL physician's guide, each 12SL interpretive statement has been identified as either Type A, B, or C, a classification methodology approved at the Tenth Bethesda Conference on Optimal Electrocardiography.[37]

Type A statements refer to the diagnosis of anatomic lesion or pathophysiologic state, such as myocardial infarction or hypertrophy. The accuracy of these statements can be determined by non-ECG evidence such as cardiac catheterization (CATH), echocardiography (ECHO), cardiac enzymes, clinical outcome, etc. These statements are evaluated with databases that have been clinically correlated with non-ECG data. The non-ECG data acts as the “gold standard”.

Type B statements cover statements referring to the diagnosis of electrophysiologic changes and are therefore detected primarily by the ECG itself. This includes arrhythmias and conduction disturbances. Although intracardiac recording can be used to validate the diagnostic conclusions determined via the surface ECG, this is often not practical. As a result, a database of ECGs with the physician’s interpretation is used as the reference.

Type C statements refer to purely descriptive ECG features that usually cannot be documented by any other means. Examples of such statements include “non-specific ST-T abnormality” and “left axis deviation”. Again, a database of ECGs with the physician’s interpretation is used as the reference.

Type A Statements: Reliance on Non-ECG Correlates is Not Enough

Databases that have been correlated with non-ECG data are critical for the development and validation of Type A statements. But these databases have their limitations. Reasons include the following:

- The use of a particular “gold standard”, non-ECG correlate may force the database to contain a population that is not representative of the disease in the actual clinical setting. For example, an autopsy-proven myocardial infarction (MI) database may not be indicative of what a typical MI looks like, since many patients survive an MI. Another example would be “CATH proven normals”. In this case, the patient often receives the CATH because they were symptomatic or the ECG was “abnormal”. As a result, the ECGs from such a database may actually not be from true “normal” patients.

- Databases from most published clinical investigations have already removed the “confounding influence” of ECGs with conduction defects, etc. However, this is not the case in the real world. The algorithm must operate in the presence of ischemia, conduction defects, drug effects, etc.

- A non-ECG value may indicate the presence of an abnormality but this does not mean that the abnormality is revealed in the surface ECG. For example, an
Statement of Validation and Accuracy: Development and Validation Process of the Program

ECG can often appear “normal” even when it is clearly established that it is from a patient with an acute myocardial infarction. It is important to not force the program to identify these ECGs as positive, if the abnormality is not revealed in the signal. Otherwise, the program will overcall the abnormality in other environments.

- The database may only contain the extreme cases of normal versus abnormal. Algorithms do not operate in a black and white world.
- And finally, non-ECG data cannot be considered perfect: every test comes with its own inherent level of inaccuracy.

Thus, even when an abnormality can only be positively determined via a non-ECG correlate, a physician’s interpretation is critical as an additional check. Therefore, during development and testing, databases based on a physician’s interpretation are used in conjunction with databases that have been correlated with non-ECG data.

As an additional check, GE Healthcare uses large databases that have been gathered as part of routine care. In this case, there may be little quality control of the physician interpretation. Nevertheless, these large databases, available via a MUSE system, are useful for determining the rate at which a change in the program will generate a change in an interpretation across an entire institution. Reanalysis on over 100,000 ECGs can be done in a matter of minutes and it confronts the algorithm with multiple kinds of waveforms and varying degrees of abnormality. ECGs that changed their analysis can be further investigated with either confirmation from medical records and/or another expert opinion.

Training versus Test / Validation Sets

Different databases are used for development versus validation. This precludes us from overtraining an algorithm so that it works beautifully on the training set but cannot be applied, with the same success, to other populations. This is an important requirement for reliable pattern recognition.[38] In this document, all reported results for interpretation performance are from independent validation sets.

Porting 12SL to Multiple Platforms: Verification Process

GE Healthcare’s Marquette 12SL analysis program has been implemented on a variety of platforms, including Holter recorders and pre-hospital defibrillators. In order to accomplish this, the program must be completely tested in its target environment. The use of analog ECGs to test every logic path in the target environment is not feasible. Thousands of ECGs would have to be recorded and the results manually compared. A digital solution is required. GE Healthcare invented a program for this purpose, known as EZSIM.
EZSIM Background

EZSIM is a program that generates simulated ECGs with the intent of thoroughly exercising the 12SL analysis program. After 12SL processes an ECG made by EZSIM, a checksum is computed across the complete IO12SL data structure (this data structure contains all inputs, the complete analysis output of 12SL, and many intermediate results that never get displayed on a report). Checksum mismatches indicate that 12SL produced a different output than expected on the target platform. A target implementation is only considered successful when over 70,000 ECGs have been analyzed by the target platform without any differences detected in the checksums.

EZSIM: ECGs with Variety of Shapes and Rhythms

EZSIM simulates ECGs with a vast variety of shapes and rhythms, covering all categories identified by the program. Each ECG is generated algorithmically and can run as long as samples are drawn from the simulator. ECGs are not restricted to 10 seconds or even 24 hours.

The simulator has two parts: the initialization routine and the running routine. The initialization routine uses about 109 random numbers to create a basic P wave pattern, a basic QRS pattern, a basic PVC pattern, a basic PP interval, an amount of PP variability, a basic PR interval, an amount and frequency of muscle tremor noise and an amount and frequency of baseline sway noise. The running routine uses up to 4 random numbers per sample to determine the noise, 3 random numbers per QRS or unconducted P-wave to determine when the next P-wave, QRS, or PVC will occur.

The simulator is able to overlap one QRS cycle with the next so that the P-waves at higher heart rates can creep into the T-wave of the previous cycle.

Although constructed using random numbers, these ECGs are exactly reproducible given a starting point in the random number sequence. That starting point is called the random number seed. That seed is all that is needed to reconstruct that ECG of unlimited length.

Any number can be used as the random number generator seed. All the numbers from 0 to 65535 produce different sequences of random numbers and therefore different ECGs. The simulator algorithm is the equivalent of a database but as opposed to conventional databases that retrieve stored ECGs, this database requires only about 3 kilobytes of code and no storage for the actual ECGs.
Some of the Rhythm ECG FeaturesSupported by EZSIM

- unconducted P-waves
- modulated coupling intervals, P-P
- random occurrence of ectopy, blocked AV conduction
- dual synthesis of patterns allows overlap, P onto T, or R onto T
- atrial fibrillation - irregular with fibrillatory waves
- atrial flutter - fast, less irregularity, no fibrillatory waves
- ventricular tachycardia
- torsades, ventricular pattern is rotated gradually
- ventricular fibrillation
- muscle tremor noise, electrode motion noise, baseline sway
12SL Analysis Program Structure: Measurements Before Interpretation

The following illustration is a simple block diagram of GE Healthcare’s Marquette 12SL analysis program. Note that all the interpretative statements are generated following the measurement portion of the program.

All measurements generated by the program are stored in a measurement matrix, which are then later accessed by the interpretive portions of the program. Criteria used by the program are fully described in the 12SL physician’s guide. Note that these criteria never directly measure the ECG. Rather, the criteria use only the values from the measurement matrix. For any given ECG, the measurement matrix can be printed at the interpreting electrocardiograph or MUSE system.
Detection and Measurement

Since the interpretive portions of the program are based on measurements, it is critical that the ECG measurements be as robust and as accurate as possible.[39] The following sections address the necessary elements for generating quality measurements, with associated references to substantiate this quality.

The Digital ECG: Data Content and Fidelity

In addition to resting electrocardiographs, the 12SL analysis program operates in a variety of products, from bedside monitors to pre-hospital defibrillators. As a result, the 12SL analysis program has been designed to be configurable for different environments.

All 12 leads, simultaneously recorded for 10 seconds, is the minimum data set required by GE Healthcare’s Marquette 12SL analysis program (specifically leads I,II and V1-V6; leads III, aVR, aVL, and aVF are calculated via Einthoven’s law). In some applications, the 12SL analysis program analyzes more than 10 seconds or more than 12 leads.

In 1979, GE Healthcare introduced simultaneous recording so that the computer could use all signals from all 12 leads to properly detect and classify each QRS complex. The Common Standards for Electrocardiography independently verified the advantage of this technique:

“Conclusion: The simultaneous recording and analysis of all 12 standard leads ... is certainly an improvement over the conventional recording of three leads at a time. Similarly ... multi-lead programs proved to be more stable than those obtained by conventional programs analyzing three leads at a time ...”[40]

All resting electrocardiographs currently sold by GE Healthcare analyze the waveform at 500 samples per second (sps). In some GE Healthcare resting electrocardiographs, the ECG is sampled at a much higher rate, such as 4,000 sps. This is referred to as over-sampling and it used by the device to generate an average, cleaner signal at 500 sps. Specifications for electrocardiographs, across the industry, often cite the raw sample rate (e.g. 4K sps) without clarifying that the ECG analysis and measurement software actually executes on data with a lower sample rate. Current guidelines for resting ECG analysis cite 500 sps,[41] which is the sample rate executed by 12SL in a resting electrocardiograph.

Before the physiological data is sampled, analog filtering is applied. These filters attenuate high-frequency electrical noise that is not part of the physiological signal. If these analog filters were not present in the device, high-frequency signals could be digitized by the device and appear as low frequency noise, inter-mixed with the physiological cardiac signal. To eliminate this possible source of contamination, GE Healthcare applies an analog filter, known as an anti-aliasing filter. See the 12SL physician’s guide (PN 416791-004) for further discussion on anti-alias filters.
Specialized Hardware and Software Algorithm for Cardiac Pacemaker Detection

Recent advances in pacemaker technology have adversely affected the accuracy of pacemaker detection by computerized ECG analysis systems, particularly those relying solely on detecting pacemaker pulses from the digitized surface ECG. Improvements in pulse generators and lead design and the increasing use of bipolar pacing have lead to the reduction of pulse amplitudes and widths observable on the digitized surface ECG. Consequently, paced ECGs are often misinterpreted. In addition, today's pacemakers offer a wide range of operating modes and programmability options that place limitations on the inferences that can be made regarding the timing relations of pacemaker pulses.

To overcome these limitations, it is necessary to reliably detect pacemaker pulses prior to digitization of the ECG and to efficiently relay that information to the interpretation software. Therefore, in addition to sampling the physiological signal, all GE Healthcare resting electrocardiographs equipped with an active, digitizing patient cable have a parallel channel specifically designed for sampling pacemaker activity. See the following representative schematic.

![Parallel channel schematic](image)

This parallel channel measures signals with a center frequency on the order of 2KHz, as opposed to the frequencies inherent in the physiological cardiac signal that are below 250Hz.[42] In addition to the hardware detection circuit, a software algorithm contextually analyzes these high-frequency detections in relation to the physiologically recorded signal.[16] This capability reduces falsely detected pulses in high frequency noise situations. Accuracy for the detection of pacemakers is covered under the rhythm interpretation section of this document.

Signal Conditioning

It has been shown that both the physician and the 12SL analysis program are prone to make more ECG interpretation errors when presented poor-quality tracings.[43] As opposed to other applications of the ECG (like Holter or Stress), where the skin is aggressively prepared before the test, the resting ECG is typically done with little or no preparation of the skin. Therefore, it is in the best interest of the overreading physician to insist that ECGs be taken with good-quality electrodes and that the patient be kept supine, calm, and warm during the procedure in order to minimize artifacts. Nevertheless digital filters can be applied to the ECG to improve ECG quality. This process is often referred to as signal conditioning.

The 12SL analysis program automatically removes A/C interference by generating a model of the interference and then subtracting it from the raw waveform.[44] It has been demonstrated that the 50/60Hz-learning filter in the 12SL analysis program can easily remove over 1mV of 50/60Hz noise, without distortion of the physiological signal. In some developing countries, there is no power grid. As a result, A/C interference is not locked to a specific 50 or 60Hz frequency. For the removal of AC
interference in these environments, GE Healthcare has developed a “Hunting Filter”.[45]

In order to remove baseline sway, the 12SL analysis program employs a high-pass filter that has a linear phase response.[46] It has been known for many years that ST segments can be faithfully reproduced with a higher filter setting if the phase response is linear.[42] This recognition led to new recommendations in the AAMI standards (EC11 1991) allowing the filter setting to be up to 0.67 Hz with an additional test to be sure the ST segment is not distorted.[41] It has been demonstrated that the 12SL program can high-pass filter the ECG at 0.32Hz without distortion of low frequency components of the ECG, such as the ST or T wave.[22]

Other sources of noise in the ECG include muscle tremor or electrode-motion artifact. Most electrocardiographs have various low-pass filter settings, including 40Hz, 100Hz, or 150Hz. The lower the filter setting, the more aggressively the filter removes high frequency signals, which include muscle tremor or electrode-motion artifact. However, these low-pass filters also operate on the entire ECG signal and attenuate all high frequency elements of the ECG signal, such as the QRS complex and pacemaker artifacts. Therefore, in order to consistently measure the resting ECG and capture the proper QRS amplitude, the 12SL program always analyzes the ECG at the AHA / AAMI recommended full bandwidth of 150Hz,[41, 42] regardless of the low-pass filter setting. As a result, these settings are sometimes referred to as “writer settings”, since they do not affect the ECG interpretation.

It should be noted that all filter settings travel with the ECG. That is, the MUSE system can be configured to either portray the ECG signal as it was acquired at the electrocardiograph or at another specified filter setting. Note that over-reliance on aggressive, low-pass filtering implies that the 12SL program is subjected to more high-frequency noise than the physician sees in a filtered ECG tracing.

Detection and Measurement of Signal Quality

ECG devices often measure the impedance across the skin-electrode interface. When this impedance exceeds 600K ohms, a GE Healthcare resting electrocardiograph informs the user that a lead is off and provides no signal for that particular lead. The reason the device no longer provides a signal for a “lead-off” condition is because a dangling lead would result in extreme noise, obscuring the rest of the ECG report and making it difficult for both the analysis program and the human to interpret the ECG.

Throughout the ECG industry, impedance across the electrode-skin interface is often used as a surrogate for lead quality. However, normal skin impedance, especially without any skin preparation, can vary dramatically, from 10 to 300K ohms.[47]
Furthermore, it can be readily demonstrated that good quality resting ECGs can be obtained throughout this range, since the large impedance values exist due to the nature of the patient's skin rather than the electrode-skin interface. Stating poor signal quality below 300K ohms simply results in false-positive calls and great frustration upon the person taking the ECG. Furthermore, it has been shown that skin impedance has a poor correlation with artifacts associated with poor electrodes or a poor electrode-skin interface.[48]

As a result, GE Healthcare has adopted an alternative approach for detecting signal quality, which directly analyzes the ECG signal for muscle tremor, AC power interference, electrode motion, or baseline shifts. This software algorithm for detecting these artifacts has previously been described and is referred to as the Hookup Advisor.[21]

The Hookup Advisor assigns an ECG lead quality level of green, yellow, or red, which is also indicated on the user interface of the electrocardiograph. This was tested on a large database of over 120,000 ECGs. Lead quality distributions and rhythm interpretation discordance rates between the physician and GE Healthcare’s Marquette 12SL analysis program are reported in Table 3.

<table>
<thead>
<tr>
<th>Lead quality</th>
<th>N</th>
<th>Percent of total</th>
<th>Discordance rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>115128</td>
<td>95.39%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Yellow</td>
<td>5170</td>
<td>4.28%</td>
<td>7.4%</td>
</tr>
<tr>
<td>Red</td>
<td>400</td>
<td>0.33%</td>
<td>12.1%</td>
</tr>
</tbody>
</table>

Overall, 95.4% of all ECGs were categorized as green (good) lead quality, 4.3% were assessed as yellow (marginal) lead quality, and 0.3% as red (poor) lead quality. As the primary rhythm from the 12SL reanalysis was compared to the primary rhythm in the confirmed ECG, the discordance of these two interpretations increased sharply, from 3.9% to 7.4% to 12.1% as the lead quality degraded from green to yellow to red.

Lead quality indicators can be stored on the MUSE system and used to monitor and continuously improve the quality of ECG acquisition across an institution.

**Median Beat/Signal Averaging**

In addition to filtering or signal conditioning, there is another method that is employed to eliminate noise from the cardiac cycle: that is, signal averaging. Instead of analyzing a single, raw QRS complex, the GE Healthcare’s Marquette 12SL analysis program generates a median complex. In other words, all QRSs of the same shape are aligned in time. Next, the algorithm generates a representative QRS complex from the median voltages that are found at each successive sample time. Although more complicated than creating an average, the method results in a cleaner signal than an average.
The following figure is an example of the formation of a median from a 12-lead Holter recording.[22]

The following illustration is an even closer look at the median. It shows the median complex displayed along with the raw complexes used to form the median complex. Note the noise in the raw signal versus the median complex.

Willems et. al.[49] independently verified the value of this technique. Without the technique, onsets and offsets were shifted outward in the presence of noise. As quoted from the literature: “Increasing levels of high-frequency noise shifted the onsets and offsets of most programs outward. Programs analyzing an averaged beat showed significantly less variability than programs, which measure every complex or a selected beat. On the basis of the findings of the present study, a measurement strategy based on selective averaging is recommended for diagnostic ECG computer programs.”

Results by Zywietz[50] also showed that programs analyzing an averaged beat exhibited less variability than programs that measure every complex or a selected beat. Subsequently, Zywietz also confirmed that median beats had less noise and generated more accurate measurements than an analysis of raw beats.[51]

Farrell[52] also demonstrated the effectiveness of the median by testing 12SL on 90,000 “noisy” ECGs. This test used a repeatable methodology for the creation of “noisy” ECGs, which can be applied for industry-wide assessment of robustness of computerized measurements.
Statement of Validation and Accuracy: Detection and Measurement

QRS Onset / Offset and Determination of Global Intervals

Good ECG measurements depend upon the proper identification of the fiducial points such as QRS onset and offset. Consistent with the signal-processing portion of the program as well as the physiological definitions for cardiac depolarization and repolarization, these fiducial points are determined by an analysis of the slopes in all 12 simultaneous leads. As a result, each fiducial point refers to the same sample-time in all of the time-aligned median complexes. Since these fiducial points are applied across all 12 median complexes, they are often referred to as “global” versus “lead-specific”.

P onset and P offset are also determined via the median complexes, unless the computer detects asynchronous P wave activity or an inconsistent PR coupling interval in the rhythm data. In this case, P onset and P offset remain undefined.

As opposed to the human reader, which may only inspect the QRS duration in any single lead of the ECG, the computer measures the QRS duration as a global interval. That is, it measures the QRS duration from the earliest detection of depolarization in any lead (QRS onset) to the latest detection of depolarization in any lead (QRS offset). Similarly, the QT interval is measured as global interval: that is, from the earliest detection of depolarization in any lead (QRS onset) to the latest detection of repolarization in any lead (T offset). See the following diagrams.

Basic ECG Nomenclature
Definition and Measurement of Waves

After the global fiducial points (P onset/offset, QRS onset/offset and T offset) have been determined, the waves within each complex are measured according to published standards.[53] This is done separately for each lead. Different ECG analysis programs treat waves within the QRS complex in different ways; as a result, the IEC standard requires that this wave identification process be fully disclosed, as provided below. (See IEC 60601-2-51 clauses 50.101.2-4).[27]

Starting at QRS onset, the program finds the points at which the ECG signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal to 160 µV-ms, the wave is considered to be significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave. Sections of the complex that do not exceed the minimum wave criteria of 160 µV-ms are combined with the adjacent significant wave.

Since the wave of depolarization is a spatial entity, the onset of the wave will not be evident in all leads at the same time. Isoelectric sections starting at QRS onset of the complex are treated as part of the subsequent significant wave. Likewise, isoelectric sections at the end of the QRS will be incorporated into the preceding significant wave.
Statement of Validation and Accuracy: Detection and Measurement

Definition of Waves Within Complex

Amplitudes of significant waves within the QRS as well as the T wave are measured with respect to QRS onset. Deviation of the ST segment is also measured in relation to QRS onset. STJ is defined as QRS offset. Further definition of the ST segment is defined by STM and STE, which are two additional points along the ST segment that are 1/16 and 1/8 of the average RR-interval from STJ. See the following figure.

Amplitudes of QRS and ST-T Measured in Relation to QRS Onset

Amplitudes of significant waves within the P wave are measured with respect to a baseline level that is interpolated from P onset to P offset. This accommodates the phenomena of PR segment depression. See the following diagram.
These amplitudes and durations result in a measurement matrix containing more than 800 values. Measurements are then passed onto the criteria portion of the program so that it can generate an interpretation.
Measurement Accuracy: Reported Results

Common Standards for Electrocardiography (CSE) Database

In an effort to standardize and evaluate the performance of ECG computer measurement programs, a 12-lead ECG reference database was developed.[40] Typically referred to as the Common Standards for Electrocardiography (CSE) database,[54] it contains a set of 250 electrocardiograms (ECGs), with selected abnormalities, which were measured by five cardiologists. Attention was focused on the exact determination of the onsets and offsets of P, QRS, and T waves. As quoted from the literature:

“The cardiologists performed their task on highly amplified, selected complexes from the library in a two round process. With use of a modified Delphi approach, individual outlying point estimates were eliminated in four successive rounds. In this way final referee estimates were obtained that proved to be highly reproducible and precise.”[55]

All ECG waveforms in the CSE database are available to the industry. However, only one-half of these ECGs contain the measurements from the CSE referee committee. The other half does not contain these manual measurements. In other words, one-half has published measurements; the other half has unpublished referee measurements. As a result, the ECGs that contain the published referee measurements can be used by the industry for the self-assessment and reporting of measurement performance. The other 125 ECGs are unavailable for self-assessment.

Independent Evaluation Using CSE Database

The Marquette 12SL analysis program was tested using all the CSE ECGs (that is, including those without the published CSE measurements). This independent evaluation was done when the program only operated on data sampled at 250 sps. The data in the CSE database was originally acquired at 500 sps. In order to re-analyze this data at 250 sps, the ECG was down-sampled to generate data at 250 sps. The results of this independent evaluation are presented in Table 4, including the mean difference from the manual measurements and the standard deviation of the mean difference.

| Table 3. Complete CSE Database Evaluation, Including Unpublished Referee Annotations[40] |
|---------------------------------|-------|-----------------|-----------------|
| Interval Measurement            | N     | Mean difference (ms) | Standard Deviation (ms) |
| P duration                      | 218   | -0.4             | 9.0              |
| PR interval                     | 218   | -0.6             | 5.8              |
| QRS duration                    | 240   | -0.6             | 5.4              |
| QT interval                     | 238   | 0.9              | 12.2             |
Statement of Validation and Accuracy: Measurement Accuracy: Reported Results

IEC 60601-2-51/ Reporting of Measurement Performance via CSE Database

The International Electrotechnical Commission (IEC) has issued particular requirements for recording and analyzing electrocardiographs (see 60601-2-51(c) IEC 2003)[27]. For measurement performance assessment and acceptance testing, the standard uses ECGs from the CSE database that contain the published referee measurements. As a result, this is a self-assessment, self-reporting measurement performance test.

In addition to biological ECGs, the CSE database contains analytical and calibration ECGs. These are used to evaluate the accuracy of the global interval measurements and the accuracy of amplitude and wave duration measurements within each complex of each lead. GE Healthcare’s Marquette 12SL analysis program has been evaluated with these analytical and calibration ECGs. With regards to amplitude measurements, no ECGs were excluded due to fiducial point errors; the program passed all of the amplitude measurement requirements as defined in IEC 60601-2-51 clause 50.101.2. With regards to global interval and wave duration measurements, one ECG was excluded from QRS duration and the S duration measurements due to a QRS offset fiducial point error. All global interval measurements were within acceptable limits. For the per-lead measurements all results are reported in the following table. No exclusions were made. All per-lead measurements were within the acceptable limits as required in IEC 60601-2-51 clause 50.101.3.1.

In addition to the calibration ECGs, the IEC requires testing on 100 biological ECGs from the 125 ECGs that contain the CSE measurements. In the performance reporting of the 100 ECGs, the IEC standard allows exclusion of up to four measurements with “obvious fiducial point errors”. No obvious fiducial point errors were observed via GE Healthcare’s Marquette 12SL analysis program. Thus no ECGs were excluded for this reason. The standard then allows exclusion of the “four largest deviations from the mean (outliers) for each measurement”. As a result, the following table contains the global interval results for 96 ECGs, analyzed at 500 sps. Included in the table are the mean difference from the CSE manual measurements, the standard deviation of the mean difference, and the IEC pass / fail criteria. The global interval measurements are well within accepted limits and pass the test. (See IEC 60601-2-51 clause 50.101.3.2).

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Mean difference (msec)</th>
<th>Standard deviation (msec)</th>
<th>Acceptable mean difference (msec)</th>
<th>Acceptable standard deviation (msec)</th>
<th>Pass / Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>P duration</td>
<td>-8.6</td>
<td>1.5</td>
<td>+10</td>
<td>8</td>
<td>Pass</td>
</tr>
<tr>
<td>PR interval</td>
<td>-6.0</td>
<td>1.6</td>
<td>+10</td>
<td>8</td>
<td>Pass</td>
</tr>
<tr>
<td>QRS duration</td>
<td>0.0</td>
<td>1.6</td>
<td>+6</td>
<td>5</td>
<td>Pass</td>
</tr>
<tr>
<td>QT interval</td>
<td>1.4</td>
<td>3.8</td>
<td>+12</td>
<td>10</td>
<td>Pass</td>
</tr>
<tr>
<td>Q duration</td>
<td>-0.8</td>
<td>2.8</td>
<td>+6</td>
<td>5</td>
<td>Pass</td>
</tr>
<tr>
<td>R duration</td>
<td>-0.7</td>
<td>2.2</td>
<td>+6</td>
<td>5</td>
<td>Pass</td>
</tr>
<tr>
<td>S duration</td>
<td>-0.9</td>
<td>2.7</td>
<td>+6</td>
<td>5</td>
<td>Pass</td>
</tr>
</tbody>
</table>

In addition to the calibration ECGs, the IEC requires testing on 100 biological ECGs from the 125 ECGs that contain the CSE measurements. In the performance reporting of the 100 ECGs, the IEC standard allows exclusion of up to four measurements with “obvious fiducial point errors”. No obvious fiducial point errors were observed via GE Healthcare’s Marquette 12SL analysis program. Thus no ECGs were excluded for this reason. The standard then allows exclusion of the “four largest deviations from the mean (outliers) for each measurement”. As a result, the following table contains the global interval results for 96 ECGs, analyzed at 500 sps. Included in the table are the mean difference from the CSE manual measurements, the standard deviation of the mean difference, and the IEC pass / fail criteria. The global interval measurements are well within accepted limits and pass the test. (See IEC 60601-2-51 clause 50.101.3.2).
Statement of Validation and Accuracy: Measurement Accuracy: Reported Results

Another test includes only 10 ECGs from the CSE database that contains the published referee measurements. These 10 ECGs were analyzed by the 12SL analysis program, first without noise added and then with each of the noise types specified: 25 µV RMS high frequency muscle artifact noise, 50 µV peak-to-valley 60 Hz line frequency noise, and 1 mV peak-to-valley 0.3 Hz sinusoidal baseline noise.

For each noise type, the interval measurements were recorded and compared against the measurements of the noise-free ECGs. For each of the interval measurements of each noise type, the mean of the ten differences from the noise-free measurements was calculated. As specified by the IEC standard, two of the largest deviations from the mean were excluded from the final reported mean and standard deviation of the differences. (See IEC 60601-2-51 clause 50.101.4).

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Mean difference (msec)</th>
<th>Standard deviation (msec)</th>
<th>Acceptable mean difference (msec)</th>
<th>Acceptable standard deviation (msec)</th>
<th>Pass / Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>P duration</td>
<td>-6.7</td>
<td>9.0</td>
<td>+10</td>
<td>15</td>
<td>Pass</td>
</tr>
<tr>
<td>PR interval</td>
<td>-1.5</td>
<td>5.5</td>
<td>+10</td>
<td>10</td>
<td>Pass</td>
</tr>
<tr>
<td>QRS duration</td>
<td>-5.2</td>
<td>5.2</td>
<td>+10</td>
<td>10</td>
<td>Pass</td>
</tr>
<tr>
<td>QT interval</td>
<td>+1.0</td>
<td>8.9</td>
<td>+25</td>
<td>30</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Table 6. IEC 60601-2-51, Clause 50.101.4
Mean Difference From Recordings Without Noise

<table>
<thead>
<tr>
<th>Global Measurement</th>
<th>Type of Added Noise</th>
<th>Mean Difference (ms)</th>
<th>Standard Deviation (ms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P duration</td>
<td>high frequency</td>
<td>-43.5</td>
<td>9.9</td>
</tr>
<tr>
<td></td>
<td>line frequency</td>
<td>-2.8</td>
<td>6.7</td>
</tr>
<tr>
<td></td>
<td>baseline</td>
<td>1.5</td>
<td>3.7</td>
</tr>
<tr>
<td>PR interval</td>
<td>high frequency</td>
<td>-18.5</td>
<td>11.0</td>
</tr>
<tr>
<td></td>
<td>line frequency</td>
<td>-1.5</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td>baseline</td>
<td>0.3</td>
<td>1.3</td>
</tr>
<tr>
<td>QRS duration</td>
<td>high frequency</td>
<td>-7.8</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td>line frequency</td>
<td>-1.3</td>
<td>4.7</td>
</tr>
<tr>
<td></td>
<td>baseline</td>
<td>-0.3</td>
<td>1.7</td>
</tr>
<tr>
<td>QT interval</td>
<td>high frequency</td>
<td>-1.3</td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>line frequency</td>
<td>1.5</td>
<td>3.7</td>
</tr>
<tr>
<td></td>
<td>baseline</td>
<td>-0.3</td>
<td>3.5</td>
</tr>
</tbody>
</table>
Interval Measurement Noise Immunity: Evaluation with MIT-NST & CSE Database

The 125 ECGs of the CSE (containing the published referee measurements) were merged with records from the MIT Noise Stress Test database (MIT-NST).[56] For each CSE ECG, 720 unique noise ECGs were created, for a total of 90,000 noisy ECGs. Computerized measurements from the noisy ECGs were compared to the original ECG measurements. The repeatability of the measurements was assessed as a function of a lead quality score.

The repeatability of the measurements was found to be in excellent agreement with the original ECG measurements when the noise level was no worse than that of the original ECGs. Noise did not introduce any bias to the measurements, although not surprisingly, the variation of the errors increased as the lead quality degraded.[52]

An example of an ECG generated by the combination of the CSE and MIT-NST databases is shown in the following illustration. The MIT-NST database consists of three 30-minute 2-channel noise records and is specified for the analysis of the robustness of ambulatory ECG analysis by the AAMI standard EC38.[57] The noise recordings were made using physically active volunteers and standard ECG recorders, leads, and electrodes; the electrodes were placed on the limbs in positions in which the subjects’ cardiac generated signal was not visible.

![Example of CSE ECG combined with MIT-NST Record](image)

For each ECG, interval measurement differences versus the CSE annotations were obtained. These differences were grouped against the Hookup Advisor indicators[21] and the ranges of the values reported in the following figure.[52] The reported PR interval tended to shorten as the noise level increased. The mean difference of the QRS duration was relatively unaffected by noise, changing by less than 2ms. Likewise, the median difference of the QT interval was 0 ms for both lead quality levels, while the standard deviation (SD) of the QT differences went from 20.5 to 39 ms and the interquartile range went from 8 to 18ms.
Statement of Validation and Accuracy: Measurement Accuracy: Reported Results

**Independent Assessments of 12SL Measurements**

There have been several independent assessments of the measurements generated by GE Healthcare’s Marquette 12SL ECG analysis program, ranging from an evaluation for routine clinical use[58, 59] through to an assessment as to whether the measurements are appropriate for large clinical trials or epidemiology studies.[60]

**Independent Assessment of QRS Duration**

Based on the QRS duration measurement made by GE Healthcare’s Marquette 12SL program, several studies have explored whether QRS duration can predict death[61] or indicate the presence of congestive heart failure.[62] QRS duration has also been investigated as an indicator for patients that benefit most from cardiac resynchronization therapy.[63-65] Following are some quotes from the scientific literature with regards to GE Healthcare’s automated QRS duration measurement:

- “The widest QRS duration on each ECG was manually measured after magnification. ... Compared with computer measurements of QRS duration, the correlation coefficient (r) was 0.95, with a SE of 0.06, p < 0.0001”[66]
“Of the 4,033 patients, 252 died during a median follow-up of 3 years. The QRS duration was univariately associated with an increased risk of death (relative risk 8.5, 95% confidence interval CI 4.4 to 16.4, p <0.0001) ... A QRS duration >105 ms best identified patients at increased risk. In conclusion, QRS duration is associated with an increased risk of death, even after adjustment for clinical factors, exercise capacity, left ventricular function, and exercise-induced myocardial ischemia.”[67]

“Prolonged QRS was associated with a significant increase in mortality (49.3% vs 34.0%, P = .0001) and sudden death (24.8% vs 17.4%, P = .0004).”[68]

“A target population of 3,471 had .... ECG data obtained from automated sources during the first year of diagnosis. .... Among the heart failure population, 20.8% of the subjects had a QRS duration > 120 ms. A total of 425 men (24.7%) and 296 women (16.9%) had a prolonged QRS duration (p < 0.01). There was a linear relationship between increased QRS duration and decreased ejection fraction (p < 0.01). A prolonged QRS duration of 120 to 149 ms demonstrated increased mortality at 60 months (p = 0.001), when adjusted for age, sex, and race (p = 0.001). Systolic dysfunction was associated with graded increases in mortality across ascending levels of QRS prolongation.”[69]

“Analyses were performed on the first electrocardiogram digitally recorded on 46,933 consecutive patients.” Using computer generated QRS durations from 12SL, the following conclusion was made: “QRS duration provides a simple method to stratify patients as to their risk of cardiovascular (CV) death. In a general medical sample, without BBB or paced rhythms, those with a QRS duration greater than 130 ms experience nearly twice the risk of cardiovascular death compared with those with a QRS duration of 110 ms or less. Similarly in patients with LBBB and RBBB, QRS duration greater than 150 ms is associated with greater risk of CV death.”[70]
Independent Assessment of ST Deviations

Quoting from the literature, here are some assessments of ST measurements made by the 12SL program:

- “The predictive value of nonspecific ST depression as determined by visual and computerized Minnesota Code (MC) codes 4.2 or 4.3 was compared with computer-measured ST depression > or = 50 microvolts in 2,127 American Indian participants in the first Strong Heart Study examination. ... Conclusions: Computer analysis of the ECG, using computerized MC and computer-measured ST depression, provides independent and additive risk stratification for cardiovascular and all-cause mortality, and improves risk stratification compared with visual MC.” [71]

- In this study, computerized ST measurements were correlated with the presence of left ventricular hypertrophy (LVH). ECGs and echocardiograms (ECHO) were done on a total of 1,595 American Indian participants without evident coronary disease.[72] “The absolute magnitude of ST segment deviation above or below isoelectric baseline was measured by computer in leads V(5) and V(6), and participants were grouped according to gender-specific quartiles of maximal STdep. Left ventricular hypertrophy was defined by indexed LV mass >49.2 g/m(2.7) in men and >46.7 g/m(2.7) in women. ... After controlling for clinical differences, increasing STdep remained strongly associated with increased prevalence of LVH (p = 0.0001). Conclusions: In the absence of evidence of coronary disease, increasing STdep in the lateral precordial leads is associated with increasing LV mass and increased prevalence of anatomic LVH.”

- ST deviations were evaluated in 69 consecutive patients suspected of an acute coronary syndrome.[73] Bland-Altman analysis demonstrated clinically acceptable limits of agreement comparing measurements of the J point and the T wave, but clinically inadequate limits of agreement with respect to ST-segment deviation, between the electrocardiographer and the computer. But as quoted from the study: “The difference between these two methods is mainly caused by different measurement points. There is no common agreement on what time point to use to measure ST amplitude. In this study, it was measured at 80 ms after the J point by manual measurement, while the computer selected a displacement at the midpoint of the ST segment.” This measurement is known as STM, which is 1/8th of the average RR interval after the J point.

Independent Assessment of QT Measurements

The assessment of automated QT measurements has undergone a great deal of scrutiny due to the challenge of consistent measurement of small changes (<6ms) for drug-induced trials.[74] Automated measurements are desirable since the reduction of effort in performing manual measurements may result in a lower sample size and overall cost of a trial.[75]

One drug-induced QT study concluded: “Manual and automated measurements generated similar numerical results in these 3 studies in healthy volunteers, which all included a positive control. There is little evidence to suggest that manual methods have advantages over automated methods in measuring QT, and the clinical interpretations remain the same.” [76]

In another study, which evaluated normals and patients with hypertrophic cardiomyopathy, the automatic QT measurements made by GE Healthcare’s Marquette 12SL analysis program were “more stable and reproducible than the manual measurements”. [25]
The stability and consistency of the 12SL analysis program was recently leveraged in for the measurement of QT in a large epidemiology study, because the QT variability of the 12SL Program “was smaller than that of the Dalhousie program.”[77] This study derived normal limits from percentile distributions for QT as well as QT and T-wave subintervals in 22,311 participants in the Women’s Health Initiative (WHI). This study advised considerable revision of the currently used limits for prolonged QT in women, with an additional race-specific adjustment in Asian women. The study also recommended that Bazett’s formula is inappropriate for testing new drugs or other applications.

Similar normative values were established in another study, which was conducted on a large drug-induced trial patient population using 12SL Program measurements and medians, available for review by a cardiologist.[78] The analysis was performed on baseline (drug-free) ECG data. The final analysis population included 13,039 baseline ECG recordings from 13,039 patients. Reference ranges from the study are stratified by important prognostic factors: age, sex, and overall ECG evaluation at baseline (normal or abnormal). From this study, proposed reference ranges may be useful for patient management and data analyses in clinical drug development, in addition, the article provides a QT correction formula to correct the QT interval for heart rate. This QT correction formula was shown to be superior to the Bazett and Fridericia corrections in a clinical trial population in the ability to minimize the correlation between QT and RR.

In 2006, a large independent study evaluated the new QT algorithm for the 12SL analysis program, which was released in 2003 and is now available in all current GE Healthcare electrocardiographs. Evaluation of computerized QT measurements from 12SL was done on over 45,000 resting ECGs obtained from two clinical trials, labeled as set “A” and “B”. Set “A” (n=15,194 ECGs) exhibited substantially better signal quality than set “B” (n=29,866 ECGs). In recording set A, 95.9% of ECGs were measured automatically within 10 ms of the manual measurement. In recording set B, 83.9% of the automated measurements were within 10ms. “The study shows that (a) compared to the “old” version of the 12SL algorithm, the QT interval measurement by the “new” version implemented in the most recent GE Healthcare ECG equipment is significantly better, and (b) the precision of automatic measurement by the 12SL algorithm is substantially dependent on the quality of processed ECG recordings. The improved accuracy of the “new” 12SL analysis program makes it feasible to use modern ECG equipment without any manual intervention in selected parts of drug-development program.”[20]

<table>
<thead>
<tr>
<th>Absolute measurement error</th>
<th>ECG Set A</th>
<th>ECG Set B</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 5 ms</td>
<td>73.7</td>
<td>47.8</td>
</tr>
<tr>
<td>≤ 10 ms</td>
<td>95.9</td>
<td>76.6</td>
</tr>
<tr>
<td>≤ 15 ms</td>
<td>99.3</td>
<td>91.7</td>
</tr>
</tbody>
</table>

Table 8 shows percentages of ECG tracings in which the error of automatic QT interval measurement was below the given threshold. For example, with a given threshold of 10ms, 95.9% of the ECGs in set A were within 10 ms of the manual measurement as opposed to only 76.6% of the ECGs with the “old” 12SL measurement algorithm.
Furthermore, GE Healthcare’s computerized QT / T wave measurements,[12, 13, 79] including QT dispersion and principal component analysis, have been correlated with overall mortality[26, 80-83] as well as acute ischemia.[10, 84-87]

Despite these positive statistics, it is important to note that outliers do occur in an automated interpretation. Furthermore, congenital QT abnormalities provide their own unique challenges to the program accuracy, as identified in the literature.[88, 89] Given this new established performance of the 12SL program in drug-induced trials,[20] GE Healthcare is currently re-evaluating the performance of 12SL on databases specifically developed for the management of congenital long QT syndromes.
Accuracy of Interpretive Statements: Reported Results

Purpose of Reported Results

The Statement of Validation and Accuracy is considered official product labeling and is reviewed by the Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC). This document primarily serves as a disclosure of the accuracy of the interpretive statements generated by GE Healthcare’s Marquette 12SL analysis program. This is in contrast to a description of how interpretive statements are generated by the program; that is the purpose of another document, known as the 12SL physician’s guide.

In 1991, the FDA recommended that such a document as The Statement of Validation and Accuracy be generated for the clearance of a 1500 Series Prehospital Defibrillator[6] that incorporated GE Healthcare’s Marquette 12SL Program and was the first prehospital defibrillator to provide automated analysis of the prehospital 12-lead ECG.[5] Since 1991, The Statement of Validation and Accuracy has periodically been updated to keep abreast of the latest scientific findings regarding the 12SL Program. In 2003, the IEC issued a similar request for all manufacturers of ECG analysis equipment: that is, the IEC asked the manufacturers of ECG analysis programs and equipment to report the sensitivity, specificity, and positive predictive accuracy of the interpretive statements for each of the major diagnostic categories (see 60601-2-51(c) IEC 2003).[27] Like the FDA, the IEC also requested that these results be published and available to the consumer. This Statement of Validation and Accuracy fulfills this requirement.

The Marquette 12SL analysis program has continually evolved since it was first introduced in 1980. Each released version of the program contains one or more changes to it and is associated with a unique version number. This number appears on the ECG report printed by the analyzing electrocardiograph. The number is also printed on each ECG from the MUSE system. Encoded within this number are two elements: the actual 12SL version number and a product specific code, which refers to the type of product used for the analysis. The 12SL Physician’s Guide (PN 416791-004) contains a table that clarifies these codes and identifies the related 12SL version numbers.

The Marquette 12SL analysis program has continually evolved since it was first introduced; however, only portions of the program are changed for any one particular software version. The rest of the executable is tested to insure that it generates the same results as the last version (see the previous description of the development and validation process for 12SL). Based on the 12SL version number, the state of revision of each portion of the program can be determined.

Scientific references and results presented in this document span a variety of dates. Portions of the program that have not been recently changed can rely on reported results that are older, and yet remain representative of the current state of that portion of the program. Sections of the program that have recently been enhanced require more recent publications. Depending upon which portion of the program is used for a particular diagnostic statement, different results reported in the literature can be used to characterize the performance of that particular statement as long as the results were generated subsequent to any substantial change to that portion of the program. Care has been taken to insure that results from the literature and presented in this document are representative of the current version of the 12SL analysis program.
Although scientific references and results presented in this document reflect the current performance of the 12SL analysis program, it would be unwise to directly extrapolate these to what will occur in a particular clinical environment. Furthermore, these are statistical measures, not the performance that one should expect for a particular patient.

**Definition of Sensitivity, Specificity, and Other Performance Metrics**

For the purpose of this document, four key accuracy measures are explained in this section.

It is assumed that the true diagnosis for a patient is known (that is, the “truth”). The ECG interpretation (classification) is called a “Test”. The following designations are applied to characterize the performance of a test:

- “Normal” correctly classified as “Normal” is called “True normal” (TN)
- “Normal” incorrectly classified as “Pathologic” is called “False pathologic” (FP)
- “Pathologic” incorrectly classified as “Normal” is called “False normal” (FN)
- “Pathologic” correctly classified as “Pathologic” is called “True pathologic” (TP)

The following equations are calculated from a two- (or multi-) category test:

1. **Sensitivity**: probability that a “True pathologic” would be classified as “Pathologic”
   
   \[
   \text{Sensitivity} = \frac{TP}{(TP+FN)} \times 100\%
   \]

<table>
<thead>
<tr>
<th>Reference</th>
<th>Test</th>
<th>“Normal”</th>
<th>“Pathologic”</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Normal”</td>
<td>TN</td>
<td></td>
<td>FP</td>
</tr>
<tr>
<td>“Pathologic”</td>
<td>FN</td>
<td></td>
<td>TP</td>
</tr>
</tbody>
</table>
Statement of Validation and Accuracy: Accuracy of Interpretive Statements: Reported Results

2. Specificity:
   probability that a “True normal” would be classified as “Normal”.

   \[ \text{Specificity} = \frac{\text{TN}}{\text{TN} + \text{FP}} \times 100\% \]

3. Positive predictive value (PPV):
   probability that a classified “Pathologic” is a “True pathologic”.

   \[ \text{PPV} = \frac{\text{TP}}{\text{TP} + \text{FP}} \times 100\% \]

   **NOTE**
   The previous explanation can be made general by substituting “Negative” for “Normal” and “Positive” for “Pathologic”.

4. Negative predictive value (NPV):
   probability that a classified “Normal” is a “True normal”.

   \[ \text{NPV} = \frac{\text{TN}}{\text{TN} + \text{FN}} \times 100\% \]

**Description of Table Format for Reporting Interpretation Metrics**

In order to present the performance metrics for GE Healthcare’s Marquette 12SL program, each study reported in this document uses one of the tables as presented in the following example. Note that the overall description of the study is presented in the header of the table, including the total number of ECGs for the particular study, the representative population or care environment where the ECGs were acquired for the study, and the independent scientific method used for verifying the disease or pathology. (See IEC 60601-2-51 clauses 50.102.3.1 and 50.102.3.2.)

In the following example, 110 ECGs were collected in an emergency department from patients with chest pain of unknown origin. Each patient was tested for cardiac Troponin, a very sensitive and specific indicator of an acute myocardial infarction (AMI). Such details of the study and the method used to verify the diagnosis can be pursued via the bibliography reference associated with the title of the table. (See “Bibliography” on page 69.) In this example, only 10 patients were positive for Troponin. As a result, under the column labeled “N”, the number “10” appears in the row labeled as acute myocardial infarction. Therefore, “N” has to do with the number of patients who have been verified for a particular diagnosis, “N” has nothing to do with number of ECGs that were positive or negative for the recognition of AMI. In this specific example, the program correctly identified 4 of the 10 patients as having an AMI. As a result, the sensitivity for the program is listed as 40%. Note: this does not necessarily mean that the program made an ECG interpretation error on the other 6 patients. Rather, it could mean that the ECG did not reveal any ST elevation. From the remaining 100 patients that were negative for Troponin, the program falsely recognized 1 as being an AMI. As a result, the specificity is listed as 99%. Since a total of 5 patients were called AMI by the program, but only 4 were correct, the positive predictive value is 80%.
Bayes Theorem and Intended Use: Understanding Performance Metrics

The tables in this document report sensitivity, specificity, positive predictive value (PPV) and, sometimes, negative predictive value (NPV). Depending on the distribution and prevalence of disease in a particular population, a high-level of specificity may be more important than a high level of sensitivity. In the above example, there are only 10 individuals with the disease out of a population of 110. A 10-point drop in specificity would lead to many more mistakes (10% of 100 results in 10 mistakes) as opposed a 10-point drop in sensitivity (10% of 10, results in one mistake). However, it may be important to find every sick individual if a particular therapy can be applied that cures the disease but is not detrimental to the healthy individual. In this case, a high sensitivity, which typically results in a loss in specificity, may be warranted if there is no risk for treating a false positive, healthy individual. These issues are beyond the scope of this document but are discussed in the literature.[90, 91]
Interpretation of Rhythm: Reported Results

This section provides performance metrics as reported in the literature regarding rhythm interpretations generated by GE Healthcare’s Marquette 12SL Program. Results are reported for the following major rhythms: sinus, ectopic atrial rhythm, atrial tachycardia, atrial fibrillation, atrial flutter, junctional rhythm, and artificially paced. In addition, results are reported for the following rhythm modifiers: 1st degree AV block, 2nd AV block, 3rd AV block, and premature atrial / ventricular beats. The IEC also requires manufacturers to disclose rhythms, without reported results, due to their low rate of prevalence. (See IEC 60601-2-51 clause 50.102.4.1.) These include idioventricular rhythm, ventricular tachycardia, ventricular fibrillation, and wandering atrial pacemaker as well as statements regarding escape or fusion beats. Also, no reported results exist for interpretations regarding the rate or character of AV conduction during atrial fibrillation or atrial flutter.

Asynchronous P-Wave Detection via QRS Subtraction

Interpretation of cardiac rhythms is highly dependent on accurate detection of atrial activity. As a result, improved P wave detection has been a major pursuit of GE Healthcare.[92-94] Since 1998, a sophisticated tool, called MAC-RHYTHM, was incorporated into GE Healthcare’s Marquette 12SL ECG analysis program for the detection of asynchronous P waves, hidden within the QRS or T wave.[95]

Previous versions of the program, which did not incorporate the QRS subtraction tool for P-wave detection, have been evaluated for rhythm interpretation accuracy and reported in the literature.[96, 97] The metrics in all of the following tables are from the later versions of the program, which incorporated MAC-RHYTHM.

QRS Subtraction / MAC-RHYTHM: Prospective Study on 10,761 ECGs

The value of the QRS subtraction tool was prospectively tested on 10,761 ECGs.[14] Quoting from the study:

“For three of the abnormal rhythms, namely, atrial fibrillation, junctional rhythms, and second degree atrioventricular blocks, MAC-RHYTHM gave significantly higher sensitivity in both prospective (87.5%, 92.2%, and 80.8%, respectively) and retrospective (82.0%, 81.2%, and 79.6% respectively) testing than the [old program] (65.0%, 39.6%, and 12.0% respectively). Similarly, for sinus rhythms, MAC-RHYTHM had significantly higher specificity (prospective, 91.0% and retrospective, 91.7%) than the [old program] (86.5%). The specificity for the abnormal rhythms remained very high with MAC-RHYTHM (prospective, 99.4% to 99.7% and retrospective, 99.1% to 99.7%) compared to the [old program] (99.0% to 99.9%).”
Table 10. Prospective Study Using MAC-RHYTHM[14]

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>NPV (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus rhythms</td>
<td>9,324</td>
<td>98.7</td>
<td>91.0</td>
<td>91.5</td>
<td>98.6</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>832</td>
<td>87.5</td>
<td>99.4</td>
<td>99.0</td>
<td>92.4</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>106</td>
<td>76.4</td>
<td>99.7</td>
<td>99.8</td>
<td>71.7</td>
</tr>
<tr>
<td>Junctional</td>
<td>64</td>
<td>92.2</td>
<td>99.5</td>
<td>100.0</td>
<td>52.7, (72.8)*</td>
</tr>
<tr>
<td>2nd-degree AV blocks</td>
<td>26</td>
<td>80.8</td>
<td>99.6</td>
<td>100.0</td>
<td>32.8</td>
</tr>
</tbody>
</table>

*After excluding paced ECGs with failed pace detection.
Enhancements to QRS Subtraction, Tested on 69,957 ECGs

Since the addition of the QRS subtraction tool, several enhancements were made to the P wave detector. This included spectral analysis for the detection of atrial flutter; optimal lead selection for P wave detection; and T wave alignment to reduce subtraction artifact in the residual signals used to create a P wave detection function.[98]

As published in the literature:

“Performance was assessed using a test set of 69,957 confirmed ECGs from four hospitals. The rhythm interpretation in the confirmed ECG was compared to the rhythm interpretations from the previous and new versions of the program. The rate of disagreements between the confirmed rhythm and the computerized interpretation decreased from 6.9% to 4.1%. Sensitivity improved for sinus, atrial fibrillation, atrial flutter, and junctional rhythms, while specificity and positive predictive value improved for all arrhythmias.”[98]

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus</td>
<td>62397</td>
<td>98.2</td>
<td>85.5</td>
<td>98.3</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>5163</td>
<td>89.0</td>
<td>99.4</td>
<td>91.9</td>
</tr>
<tr>
<td>Ectopic atrial rhythm</td>
<td>1066</td>
<td>35.2</td>
<td>99.7</td>
<td>63.4</td>
</tr>
<tr>
<td>No P waves</td>
<td>635</td>
<td>63.1</td>
<td>99.1</td>
<td>38.1</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>576</td>
<td>55.0</td>
<td>99.6</td>
<td>50.7</td>
</tr>
<tr>
<td>2nd/3rd degree AVB</td>
<td>120</td>
<td>49.1</td>
<td>99.6</td>
<td>18.1</td>
</tr>
</tbody>
</table>
Subsequent Evaluations of Rhythm Interpretation Yield Similar Results

Recently, Poon[99] analyzed the interpretation performance for rhythm on 3,954 non-paced ECGs analyzed by the 12SL analysis program. As quoted from the literature: “Our findings differ only modestly from the corresponding performance characteristics for sinus rhythm, atrial fibrillation, and atrial flutter recently reported by Farrell et al.”

<table>
<thead>
<tr>
<th>Table 12. Evaluation Done in 2005 at NY Presbyterian Hospital [99]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Representative test population . . . . . . . . University Hospital</strong></td>
</tr>
<tr>
<td>Additional demographic data . . . . . . . . . Consecutive inpatient and outpatient ECGs over a 3 week period.</td>
</tr>
<tr>
<td>Specific ages, gender, and race are unavailable.</td>
</tr>
<tr>
<td><strong>Total number of test ECGs . . . . . . . . 4297</strong></td>
</tr>
<tr>
<td><strong>Method(s) used to verify diagnosis . . . . . . . . Confirmation by 2 cardiologists</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rhythm Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Rhythms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinus</td>
<td>3579</td>
<td>98.7</td>
<td>90.1</td>
<td>99.0</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>250</td>
<td>90.8</td>
<td>98.9</td>
<td>84.7</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>41</td>
<td>61.0</td>
<td>99.9</td>
<td>83.3</td>
</tr>
<tr>
<td>Atrial tachycardia</td>
<td>360</td>
<td>2.8</td>
<td>99.9</td>
<td>25.0</td>
</tr>
<tr>
<td><strong>Rhythm Modifiers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premature atrial complexes</td>
<td>212</td>
<td>64.2</td>
<td>99.5</td>
<td>87.2</td>
</tr>
<tr>
<td>Premature ventricular complexes</td>
<td>162</td>
<td>82.7</td>
<td>99.1</td>
<td>80.2</td>
</tr>
</tbody>
</table>

In another study, a total of 2194 consecutive ECGs from 1856 patients were collected from a tertiary care VA Hospital from both inpatients and outpatients. The results for rhythm analysis are summarized in the following table. Not all rhythms, for example sinus rhythms, were reported in the study.
In another study, ECGs were acquired from symptomatic patients with isolated pulmonary hypertension. The blinded and un-blinded cardiologist and computer program analysis agreed regarding the rate and rhythm in each case (n=64). Sinus rhythm was present in 96.9% of patients; one patient had an ectopic atrial rhythm and one had a junctional rhythm. The heart rate averaged 84.1 ± 15.5 b/min. Sinus bradycardia was present in 5, sinus tachycardia in 6, and first degree atrioventricular block in 7 patients; 2 patients had a complete right bundle branch block.

Table 13. Evaluation of Rhythm Analysis Done in 2006 at Tertiary Care, VA Hospital

<table>
<thead>
<tr>
<th>Rhythm Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Rhythms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>67</td>
<td>76.1</td>
<td>99.6</td>
<td>85.0</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>41</td>
<td>65.9</td>
<td>99.9</td>
<td>93.1</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>56</td>
<td>73.2</td>
<td>99.9</td>
<td>93.2</td>
</tr>
<tr>
<td>2nd degree AV block</td>
<td>1</td>
<td>100</td>
<td>99.7</td>
<td>14.3</td>
</tr>
<tr>
<td>Rhythm Modifiers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st degree AV block</td>
<td>138</td>
<td>97.8</td>
<td>99.7</td>
<td>95.7</td>
</tr>
<tr>
<td>Premature ventricular complexes</td>
<td>150</td>
<td>94.0</td>
<td>99.5</td>
<td>94.0</td>
</tr>
<tr>
<td>Premature atrial complexes</td>
<td>94</td>
<td>66.0</td>
<td>99.5</td>
<td>86.1</td>
</tr>
</tbody>
</table>

Table 14. ECGs from Symptomatic Patients With Pulmonary Hypertension

<table>
<thead>
<tr>
<th>Rhythm Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Rhythms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinus</td>
<td>62</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Ectopic atrial rhythm</td>
<td>1</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Junctional Rhythm</td>
<td>1</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Rhythm Modifiers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st degree AV block</td>
<td>7</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>RBBB</td>
<td>2</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
Statement of Validation and Accuracy: Interpretation of Rhythm: Reported Results

Note that the aforementioned studies yield similar results, despite the different locations and environments. This increases the confidence that these results will be reproducible in other populations.

In addition to these aforementioned studies, an evaluation of the clinical consequences of misdiagnosed atrial fibrillation by a computer was performed at Henry Ford Hospital in Detroit, Michigan. A total of 2298 ECGs were identified with a computerized diagnosis of atrial fibrillation by GE Healthcare’s Marquette 12SL analysis program. Of these 2298 ECGs, 442 (or 19%) from 382 (35%) of the 1085 patients had been incorrectly interpreted as atrial fibrillation. The paper did not report the total number of true atrial fibrillation ECGs across the entire sampled population, only the number of “true positives” and “false positives” from the computerized interpretation. Therefore only the positive predictive value may be calculated. In 92 patients (that is, 24% of the inaccurate computerized interpretations), the physician ordering the ECG, failed to correct the inaccurate interpretation. Clinical consequences of this misdiagnosis are presented in the paper. The conclusion of this work is that greater efforts should be directed toward educating physicians about the electrocardiographic appearance of atrial dysrhythmias and the recognition of confounding artifacts.

This value of 81% for the positive predictive accuracy for the computerized recognition of atrial fibrillation is lower but comparable to the other studies presented here. Noise in the ECG tracing is certainly a confounding factor in this study. Note that 38% of the misinterpretations by both the computer and physician were due to artifact.

<table>
<thead>
<tr>
<th>Table 15. Evaluation of Misdiagnosis of Atrial Fibrillation by Computer[43]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Representative test population</strong> . . . . . . Large, university hospital</td>
</tr>
<tr>
<td><strong>Additional demographic data</strong> . . . . . . Mean age of these 382 patients is 74 ± 14 yr. 49% (188) were men.</td>
</tr>
<tr>
<td>Only a minority of patients complained of palpitations (22) or dizziness (44) at the time of the index ECG. The remaining patients were asymptomatic.</td>
</tr>
<tr>
<td>31% (120) had a prior history of atrial fibrillation. Race is unavailable.</td>
</tr>
<tr>
<td><strong>Total number of test ECGs</strong> . . . . . . 2298</td>
</tr>
<tr>
<td><strong>Method(s) used to verify diagnosis</strong> . . . Patient chart and follow-up</td>
</tr>
<tr>
<td><strong>Rhythm Category</strong></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
</tr>
</tbody>
</table>

Paced Rhythms

Improvements in electronic pacemaker pulse generators and lead design as well as the increasing use of bipolar pacing have led to the reduction of pulse amplitudes and widths observable on the digitized surface ECG.

In 1983, a prospective evaluation study in one hospital published by Swiryn and Jenkins reported pacemaker detection sensitivity for the GE Healthcare’s Marquette 12SL Program to be 87.5%.[97] By 1998, a prospective analysis of more than 10,000 ECGs analyzed by essentially the same detection algorithm in one hospital had a corresponding sensitivity of only 71.5%. Specificity in both samples was very high at 99.9%.[14] This reduction of 16% in sensitivity is most likely due to the advent of low energy pacemaker artifacts. In 2000, GE Healthcare enhanced the
Software that operates with the pacemaker detection circuitry in order to improve sensitivity while maintaining specificity.[16]

In 2001, this software was evaluated on 100 of 103 consecutive patients seen in a device clinic who were asked to participate in the study. Two consecutive paced ECGs were recorded from each patient with pacemaker amplitudes and pulse widths at arrival or discharge settings. In 86 patients, two additional consecutive ECGs with underlying non-paced rhythm were recorded by lowering the pacemaker rate thresholds. The implanted devices included 44 single and 56 dual chamber devices (41 ICDs; 59 pacemakers; 92 bipolar leads). Pulse width settings ranged between 0.3 ms and 3.0 ms and voltage settings ranged between 0.9 and 6.0 V. Sensitivity for detecting paced rhythms using the new method was 87% compared to 41% using the old method ($x^2=45.9, p < 0.0005$). For both methods, specificity was 100% for this data set.

<table>
<thead>
<tr>
<th>Rhythm Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paced</td>
<td>200</td>
<td>87</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Similarly, in 2002, a prospective trial was done at a different institution on 100 pacemaker clinic patients. ECGs were obtained from all patients in the clinic. At least two paced ECGs, and whenever possible, two non-paced ECGs were obtained from each patient. A total of 389 ECGs were collected and analyzed; 235 ECGs were paced and 154 were non-paced. Both the new and old algorithms had high specificity for pacemaker detection (>99.4%). The new algorithm had a sensitivity of 87% versus 30% for the old algorithm.

<table>
<thead>
<tr>
<th>Rhythm Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paced</td>
<td>235</td>
<td>87</td>
<td>99.4</td>
<td>99.5</td>
</tr>
</tbody>
</table>

In 2006, a large study was conducted that solely focused on pacemaker recognition and rhythm interpretation in the presence of electronic pacemakers. Of the 7834 consecutive ECGs screened, a pacemaker (PM) was identified by the computer, the cardiologists, or both in 205 ECGs. The cardiologists detected an electronic pacemaker in 201 tracings, whereas the computer detected one in 168 tracings. In 4 ECGs that were read as having an electronic pacemaker by computer, no pacemaker was present according to both cardiologists. Therefore, in 164 of 205 ECGs
(80.0%), both computer and cardiologists agreed upon the presence of an electronic pacemaker. The sensitivity of recognizing a pacemaker by computer was 82.0%, and the specificity was 99.9%. In 37 cases, the algorithm failed to recognize the presence of a pacemaker. A common error was missing the ventricular spike (16 cases). Other errors included missing both the atrial and ventricular spikes (10 cases) and, rarely, the atrial spikes alone (4 cases)."[105]

The article concludes that: “Automated computer ECG reading algorithms are useful tools for ECG interpretation, but they need further refinement in recognition of electronic pacemakers (PM). In 61.3% of ECGs with electronic PM, computer-drawn interpretation required revision by cardiologists. In 18.4% of cases, the ECG reading algorithm failed to recognize the presence of a PM. Misinterpretation of paced beats as intrinsic beats led to multiple secondary errors, including myocardial infarctions in varying localizations. The most common error in computer reading of ECGs with PMs is the failure to identify an underlying rhythm.”[105]

Poon reported similar results for the analysis of paced tracings. Quoting from the article: “The most common errors were related to interpretive statements involving patients with pacemakers: of 343 ECGs with pacemaker activity comprising 8.0% of the study ECGs, 75.2% (258/343) required revision, so that 45.7% of all inaccurate rhythm statements in this population occurred in patients with pacemakers. Overall, 13.2% (565/4297) of computer-based rhythm statements required revision, but excluding tracings with pacemakers, the revision rate was 7.8% (307/3954).”[99]

### Pediatric Rhythm Interpretation

Recently, two studies have evaluated pediatric populations. The first was in an emergency department (ED); the other was across a large pediatric hospital.

In the first study, a total 294 cases were evaluated.[89] The patients ranged in age from 5 days to 21 years. The ED physicians interpreting the ECGs were directly involved in the patients' care and were familiar with the presenting complaint, past medical history, and physical examination. Physicians were allowed to use whatever means available to aid with ECG interpretation. The physicians were blinded to the computer interpretations. The reference standard was the ECG interpretation by a pediatric electrophysiologist.

Each electrocardiographic diagnosis, as well as the ECG as a whole, was assigned to one of the following predetermined classes: I, normal sinus rhythm; II, minimal clinical significance; III, indeterminate clinical significance; IV, those of definite clinical significance.

Both the computer and ED physician correctly interpreted all normal (class I) ECGs correctly (that is, normal sinus rhythm / normal ECG). The computer correctly
diagnosed class II ECGs 82% of the time as compared to 67% by the ED physicians (p<0.001). The computer was also significantly more accurate than the ED physicians with regard to the class III diagnoses, correctly interpreting 73% compared to 30% by the physicians (p<0.001). With regard to the individual class IV ECG diagnoses, the ED physicians were more accurate than the computer (28% vs 14%), but this difference did not reach significance (p>0.3).

Pediatric rhythm interpretation resulted in a majority of computer errors in this study. Quoting this work: “Despite its superior ability to accurately interpret many of the simple rhythm disturbances, the computer was less accurate than the ED physicians with regards to interpreting ECGs with abnormal Supraventricular rhythms. Specifically, the computer failed to identify all 4 ECGs with junctional rhythm, 2 of 4 with supraventricular tachycardia, and 2 with intraatrial reentry tachycardia.”[89]

This study did not assess specificity. “The over interpretation of ECGs by either the computer or ED physicians was not evaluated in this study.”[89] As a result, the results of this study cannot be represented in the table recommended by the IEC.[27]

The second study evaluated 56,149 pediatric ECGs.[106] From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure balanced representation in terms of age, sex, etc. This resulted in a sample size of 1,147 ECGs. The reported results for rhythm are presented in Table 20.

<table>
<thead>
<tr>
<th>Rhythm Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus Rhythm in presence of Heart Disease</td>
<td>399</td>
<td>95.5</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>Sinus Rhythm in normal group</td>
<td>390</td>
<td>98.5</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Sinus Arrhythmia in presence of Heart Disease</td>
<td>31</td>
<td>87</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Sinus Arrhythmia in normal group</td>
<td>51</td>
<td>88</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Sinus Rhythm with Ectopy in Heart Disease group</td>
<td>10</td>
<td>100</td>
<td>98.5</td>
<td>56</td>
</tr>
<tr>
<td>Sinus Rhythm with Ectopy in normal group</td>
<td>22</td>
<td>100</td>
<td>98</td>
<td>69</td>
</tr>
</tbody>
</table>
Interpretation of P-wave Abnormalities: Reported Results

This section provides performance metrics, as reported in the literature, for interpretation of right and left atrial abnormalities.

<table>
<thead>
<tr>
<th>P Wave Abnormality</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>29</td>
<td>100</td>
<td>99.9</td>
<td>97</td>
</tr>
<tr>
<td>Left</td>
<td>97</td>
<td>95.5</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
Interpretation of QRS Abnormalities: Reported Results

This section provides performance metrics, as reported in the literature, for the computerized interpretation of QRS abnormalities. These include: right bundle branch block (RBBB), left bundle branch block (LBBB), left ventricular hypertrophy (LVH), right ventricular hypertrophy (RVH) as well as healed anterior and inferior myocardial infarction. The IEC also requires manufacturers to disclose those QRS abnormalities without reported results. (See IEC 60601-2-51 clause 50.102.3.1). These include the following statement categories:

- Wolff-Parkinson-White (WPW),
- QRS axis deviation abnormalities,
- hemi-blocks,
- low-voltage QRS, and
- pulmonary disease pattern.

In addition, isolated lateral or posterior myocardial infarctions have no reported results; instead, these statements are grouped with inferior or anterior myocardial infarctions.

Conduction

At Mount Sinai Medical Center in New York City, over 39,000 ECGs were reviewed for computer accuracy. The cardiologist was used as the reference, since interpretative statements regarding conduction are Type B statements.

A detailed inspection of the data from the Mount Sinai study showed that the cardiologist often changed the computer diagnosis to LBBB (n=97) from another conduction abnormality already stated by the program (like ILBBB or nonspecific intraventricular conduction block). If these other conduction abnormalities were included as part of the analysis, the sensitivity would increase from 78% to 88%.

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBBB</td>
<td>1661</td>
<td>90</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>LBBB</td>
<td>860</td>
<td>78</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>LBBB (grouped w/ ILBBB, IVCB)</td>
<td>860</td>
<td>88</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
At the Mayo clinic, the 12SL program was evaluated to determine whether it could replace an ECG program, based on XYZ Leads, with the 12SL program, which is based on the scalar 12-lead ECG.[108] In a similar fashion as the aforementioned study, over 12,000 ECGs were evaluated at the Mayo Clinic. See Table 22, “Independent Assessment of Conduction Abnormalities[109],” on page 47.

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBBB</td>
<td>391</td>
<td>91</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>LBBB</td>
<td>248</td>
<td>87</td>
<td>99.9</td>
<td>99.9</td>
</tr>
</tbody>
</table>

In another study,[100] ECGs were collected in a tertiary care facility from inpatients (36.4%), outpatients (47.6%), and emergency room patients (16.0%). There were 2194 consecutive ECGs recorded on 1856 patients. Two cardiologists read the ECGs. Of the 2,194 tracings, 122 were excluded from analysis because of a disagreement between the cardiologists’ interpretations. Out of 2072 remaining cases, 776 (37.5%) the computer interpreted as normal and 1296 as abnormal. In 206 cases, there were discordances between the computer and cardiologists’ interpretation (9.9%). There were no discordances in the ECGs interpreted as normal by the computer. Therefore, the discordances occurred in 15.9 % of all ECGs read as abnormal.

Conduction abnormalities were evaluated as part of this study. The results are reported in the following table:

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBBB</td>
<td>118</td>
<td>93.2</td>
<td>99.8</td>
<td>96.5</td>
</tr>
<tr>
<td>LBBB</td>
<td>33</td>
<td>90.9</td>
<td>99.9</td>
<td>90.9</td>
</tr>
</tbody>
</table>
Assessment of RBBB in a Pediatric Population

RBBB in a pediatric population is exhibited in a narrow QRS. This diagnosis was evaluated at a pediatric hospital using 56,149 ECGs stored on a MUSE system. From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure a balanced representation. This resulted in a sample size of 1,147 ECGs. RBBB is a Type B statement and can thus be validated by a pediatric cardiologist.

<table>
<thead>
<tr>
<th>Table 24. Assessment of RBBB in Pediatric Population[106]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Representative test population.</strong> Hospital, all departments</td>
</tr>
<tr>
<td><strong>Additional demographic data.</strong> Median age at the time of ECG was 3.0 yrs in the heart disease group and 6.0 years in the group without heart disease. Race and gender are unavailable.</td>
</tr>
<tr>
<td><strong>Total number of test ECGs.</strong> 1,147</td>
</tr>
<tr>
<td><strong>Method(s) used to verify diagnosis.</strong> Confirmation by 2 pediatric cardiologists</td>
</tr>
<tr>
<td>Verified Diagnosis</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>RBBB</td>
</tr>
</tbody>
</table>

Hypertrophy

Two independent studies have evaluated the performance of our 12SL analysis program for *left ventricular hypertrophy* (LVH) using echocardiography (ECHO).

At the Mayo Clinic, an ECHO test was performed within 30 days of the ECG. ECGs demonstrating WPW syndrome, paced rhythm, or LBBB were excluded from the study. ECHO studies were excluded for patients who were less than 21 years of age. All two dimensional and M-mode ECHO studies were technically adequate and required clear delineation of interventricular septal thickness (IVST), posterior wall thickness (PWT), and left ventricular internal dimension (LVID). Patients with IVST/PWT>1.5, segmental wall motion abnormalities, pericardial effusion, or infiltrative cardiomyopathy were excluded from the study. This resulted in a test population of 4,300 patients.

ECHO measurements were made according to the American Society of Echocardiography. ECHO studies revealed LVH in 1,029 patients. LVH was defined as:

\[
\text{ECHO LV mass} > 265g \\
\text{LV mass} = 1.04 ((\text{LVID} + \text{PWT} + \text{IVST})^3 - (\text{LVID})^3) - 13.6g
\]

The 12SL analysis program correctly identified 328 patients with LVH and 3,010 patients without LVH. The program was scored as stating LVH for the full breadth of statements that refer to the abnormality; including “minimal (and moderate) voltage criteria for LVH, may be normal.” Table 25, “LVH by ECG and Cross Correlation with ECHO[108],” on page 49 summarizes the program’s performance.
In addition to the Mayo Clinic study, a large international study evaluated program performance for hypertrophy.\[110\] In this study there were a total of 1220 patients, 382 controls and 838 with cardiac disorders that were collected across five European centers. ECGs showing complete Left Bundle Branch Block (LBBB), Right Bundle Branch Block (RBBB) or other major intraventricular conduction defects were excluded; otherwise there were no other criteria for excluding ECGs. A normal individual (n=286) was defined as being free of significant cardiopulmonary disease on the basis of a health screening examination (negative history, normal physical exam, normal chest X-ray) or invasive cardiac study (n=96). Invasive studies usually entailed cardiac catheterization (CATH) for atypical chest pain or ST/T abnormalities evident at rest or during exercise. LVH was based on CATH or ECHO or both. Specific details regarding the population are contained in the article.\[110\]

In another study, patients with pulmonary hypertension due to pulmonary vascular occlusive disease were evaluated in the Pulmonary Hypertension Clinic at the University of Michigan. Each underwent a thorough history, physical exam, ECG, echocardiogram, pulmonary function testing, and right heart catheterization. Symptoms (type and duration), effort tolerance, and New York Heart Association (NYHA) functional class were recorded during the initial visit. Pulmonary hypertension was defined as a mean pulmonary artery pressure >25 mmHg. Patients were excluded if they presented with evidence of chronic lung disease, left

---

**Table 25. LVH by ECG and Cross Correlation with ECHO[108]**

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVH</td>
<td>1,029</td>
<td>31.9</td>
<td>92</td>
<td>57</td>
</tr>
</tbody>
</table>

**Table 26. Performance of LVH and RVH by ECG, Validated by CATH and ECHO[110]**

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertrophy, all kinds</td>
<td>291</td>
<td>61.1</td>
<td>91.2</td>
<td>85</td>
</tr>
<tr>
<td>LVH</td>
<td>183</td>
<td>76.2</td>
<td>91.2</td>
<td>82</td>
</tr>
<tr>
<td>RVH</td>
<td>55</td>
<td>29.1</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
ventricular hypertrophy, mitral or aortic valve disease, congenital heart disease, coronary artery disease or cardiomyopathy.[101]

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVH</td>
<td>64</td>
<td>39.1</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Right Atrial Enlargement</td>
<td>13</td>
<td>46</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

The blinded cardiologist and computer program diagnosed RVH in 43.8 and 39.1% of patients, respectively; this is substantially lower than the 78.1%, as determined by the un-blinded reader that was provided the age and clinical parameters (i.e. symptoms associated with possible pulmonary hypertension). Right ventricular strain was present in 71.9% of patients, and was most often characterized by the blinded cardiologist and the computer program as non-specific or inferior/ anterior-lateral ischemia. The most common errors by the computer and blinded cardiologist were the diagnosis of an anterior-septal infarction based on the presence of a qR in V1 (10.9%), and of an inferior-posterior myocardial infarction because of the presence of a “pathologic” Q wave in II, III and aVF associated with a prominent R in V1 (6.2%)

The study concluded that the ECG does have a high specificity for the detection of RVH in symptomatic patients with pulmonary hypertension and that correlation with the clinical parameters is essential to optimize the usefulness of the ECG. Without the clinical parameters, the computer program and blinded cardiologist often suggested myocardial infarction/ischemia.

In another study, two cardiologists were considered as the gold standard. As expected, performance metrics for the program are much higher when they are based on this human standard.

<table>
<thead>
<tr>
<th>Hypertrophy Category</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Ventricle (RVH)</td>
<td>15</td>
<td>100</td>
<td>99.9</td>
<td>66.7</td>
</tr>
<tr>
<td>Left Ventricle (LVH)</td>
<td>399</td>
<td>98.7</td>
<td>99.5</td>
<td>98</td>
</tr>
</tbody>
</table>

In addition to the evaluation of accuracy, GE Healthcare’s Marquette 12SL interpretation of LVH has been evaluated in terms of its prognostic value on 26,734 male and 3,737 female veterans.[81] The computerized interpretation was used
without modification. Computer detected abnormalities associated with the lowest survival rates are presented in the following illustration. Note that LVH with strain is the most predictive and that a normal ECG as defined by the 12SL program “is associated with extremely good survival”.[81]

![Graph showing survival rates for different ECG abnormalities.](image)

Assessment of RVH in a Pediatric Population

Criteria for RVH, in a pediatric patient, are defined by 16 different age categories.[4, 111] This diagnosis was evaluated at a pediatric hospital using 56,149 ECGs stored on a MUSE system. From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure balanced representation. This resulted in a sample size of 1,147 ECGs.

Note that RVH is a Type A statement: that it typically requires non-ECG data for a reference gold-standard. However, in this case, the authors used the opinion of 2 pediatric cardiologists.

### Table 29. Assessment of RVH in a Pediatric Population[106]

<table>
<thead>
<tr>
<th>Represented test population</th>
<th>Hospital, all departments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional demographic data</td>
<td>Median age at the time of ECG was 3.0 yrs in the heart disease group and 6.0 yrs in the group without heart disease. Race and gender are unavailable.</td>
</tr>
<tr>
<td>Total number of test ECGs</td>
<td>1,147</td>
</tr>
<tr>
<td>Method(s) used to verify diagnosis</td>
<td>Confirmed by 2 pediatric cardiologists</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVH</td>
<td>93</td>
<td>91.3</td>
<td>99.8</td>
<td>99</td>
</tr>
</tbody>
</table>
Myocardial Infarction

There are several independent studies that have evaluated the performance of GE Healthcare’s Marquette 12SL analysis program to recognize healed myocardial infarction (MI).[112] The term “healed myocardial infarction” implies that this section is reporting results on the ability of the program to detect QRS abnormalities (like abnormal Q-waves) associated with necrosis. Computerized interpretation of a myocardial infarction is a Type A statement, requiring independent validation from non-ECG data.

CATH as the Reference

The first series of evaluations of the 12SL program were done on ECGs from subjects that were selected from consecutive patients undergoing cardiac catheterization.[113, 114] The presence of an MI was determined via wall motion abnormalities associated with a 75% or greater obstruction of the relevant coronary artery. Patients with pulmonary disease, valvular disease, a history of previous MI, LV wall motion abnormalities suggesting multiple MIs, and patients with a history of previous cardiac surgery were excluded. Normals were defined as having normal LV motion and coronary arteries. This resulted in a study population of 734 patients with an MI and 406 patients defined as normal. The infarction group consisted of 84% males with an average age of 55 years. The average age of the 121 female patients was 57 years. ECGs selected for analysis were obtained on average 3 days before the CATH in 92% of the infarction group patients. The remaining 8% were done within 30 days following the CATH procedure. The normal group consisted of 41% males with an average age of 46 years. The average age of the 238 female patients was 52 years. ECGs were obtained, on average, within 4 days before the CATH in 99% of the normal patients.

The results for the performance of the program versus CATH are presented in Table 31. Note that the physician had a similar level of sensitivity (69%) but maintained a higher level of specificity (97%).

<table>
<thead>
<tr>
<th>Table 30. Performance of MI: Group All Statements Indicating MI[113]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verified Diagnosis: Myocardial Infarction</td>
</tr>
<tr>
<td>N</td>
</tr>
<tr>
<td>Specificity (%)</td>
</tr>
<tr>
<td>PPV (%)</td>
</tr>
</tbody>
</table>
Influence of Modifiers “Cannot Rule Out”, “Possible”

This same study also evaluated the performance of statements that were preceded by the modifiers cannot rule out and/or possible. When these statements were not considered diagnostic for MI, the sensitivity was reduced to 54% while the specificity improved to 98%.

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction</td>
<td>734</td>
<td>54</td>
<td>98</td>
<td>98</td>
</tr>
</tbody>
</table>

Inferior Myocardial Infarction

Using the same aforementioned source of data, an evaluation of inferior MI was conducted,[114] which demonstrated that the 12SL program had a sensitivity of 76% and a specificity of 95% while the physician had a lower sensitivity (75%) but a higher specificity (97%) than the computer.

Anterior Myocardial Infarction

In a separate study conducted at a Veterans Administration hospital, 137 patients were evaluated via cardiac catheterization using similar methods for data acquisition and analysis as the aforementioned study but, in this case, the focus was anterior myocardial infarction. Patients who had significant valvular heart disease, left bundle branch block or paced rhythm were excluded. However, no attempt was made to identify and exclude patients with either left ventricular enlargement or chronic obstructive pulmonary disease, conditions that can reduce the specificity of ECG criteria for anterior myocardial infarction. All the ECGs were obtained on or near the day of each patient's catheterization. Of the 137 patients, the normal group consisted of 82 patients and the anterior MI group consisted of 55 patients. Following are the reported results for the 12SL analysis program:

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior MI</td>
<td>55</td>
<td>64</td>
<td>99</td>
<td>99</td>
</tr>
</tbody>
</table>
Evaluation of Both Inferior and Anterior Myocardial Infarction via Cath

Another large international study also used CATH as the reference but relied solely on the assessment of wall motion abnormalities, not including coronary obstruction. The results are presented in Table 34:

| Table 33. Performance of Anterior and Inferior MI by ECG, validated by CATH [110] |
|---------------------------------|-----------------|-------------|-------------|-------------|
| Verified Diagnosis               | N               | Sensitivity (%) | Specificity (%) | PPV (%)     |
| Anterior MI                     | 170             | 66           | 98           | 84          |
| Inferior MI                     | 273             | 65           | 97           | 86          |

Evaluation of Old Myocardial Infarctions Based on Cardiologist Opinion

In another study, two cardiologists were defined as the standard. As expected, the performance metrics of the program are markedly higher using this human standard.

| Table 34. Evaluation of Ventricular Hypertrophy at Tertiary Care, VA Hospital[100] |
|---------------------------------|-----------------|-------------|-------------|-------------|
| Category                        | N               | Sensitivity (%) | Specificity (%) | PPV (%)     |
| Old myocardial infarctions      | 399             | 98.8         | 99.5         | 97.4        |
MI Sizing / Electrocardiographic Damage Scores

There are several electrocardiographic damage scores, which are used to predict the size or severity of the myocardial infarction. These scores primarily rely on an analysis of QRS abnormalities, such as Q waves. Based on measurements generated by GE Healthcare’s Marquette 12SL analysis program, the following damage scores have been evaluated: Selvester Score,[116] Simplified Selvester Score,[117] and Cardiac Infarction Injury Score (CIIS).[118]

A fully automated version of the Selvester Score was validated versus manual measurements and the results demonstrated that it “had a high correlation with manual application (r = 0.94) and was superior regarding time, training, reader bias, reproducibility and precision of measurement.”[119] This automated version evaluated ECGs from 1,344 normal subjects, 706 patients with a single myocardial infarction (366 with inferior infarction, 277 with anterior infarction and 63 with posterolateral infarction), and 131 patients with combined inferior and anterior infarction.[120] The presence and location were determined by CATH criteria, similar to the other aforementioned study done by Haisty.[114] A score greater than 4 yielded a sensitivity of 67% for anterior infarction, 41% for inferior infarction, 32% for posterolateral infarction and 72% for multiple infarcts. However, 7 of 32 criteria failed to achieve 95% specificity and 10 of 35 criteria in criteria sets had a sensitivity that was even lower than their false positive rate. Quoting from the literature: “the automated Selvester QRS scoring system currently has limitations that are attributable to development of the original manual system, which used manual scoring techniques and established criteria limits from middle-aged men”. [120] Note that the sensitivity and specificity of the Selvester Score are all less than the reported results of the standard interpretation of myocardial infarction by the 12SL analysis program, even though the score is often used as a reference.[121, 122]

In a more recent study, ECGs from 46,933 patients were used to evaluate the prognostic value of these electrocardiographic damage scores.[123] The Simplified Selvester Score, the Cardiac Infarction Injury Score (CIIS), and a Q-wave score were calculated based on the computerized measurements generated by the 12SL program. The main outcome was cardiovascular mortality. During a mean follow-up of 6 years, the CIIS outperformed all other ECG classifications in determining prognosis.

There is renewed interest in MI-sizing via a QRS score, due to advances in cardiovascular magnetic resonance as a new reference for myocardial size[124, 125] and the possible implications that MI size could have on prophylactic ICD therapy.[126] However, more work needs to be done on this promising technology.[127]
Repolarization Abnormalities: Reported Results

Repolarization abnormality computerized interpretations are composed of Type A and C statements. Recall that Type C statements refer to purely descriptive ECG features that usually cannot be documented by any other means. Examples of such statements include non-specific ST-T abnormality. This document will primarily be reporting results of the Type A statements, which are verified by non-ECG data such as cardiac enzymes, patient outcomes, etc.

This document reports results for ST-elevated acute myocardial infarction (STEMI). Other statements associated with ST elevation, namely early repolarization and acute pericarditis are not directly reported. However, these other ST elevation interpretations are analyzed appropriately as part of the assessment of STEMI: that is, they would be classified as FN (false normal) or TN (true normal) with respect to the enzyme data. In addition to STEMI, ST segment depression and T wave abnormalities associated with the interpretation of ischemia are presented.

The IEC requires manufacturers to disclose those interpretative repolarization statements that have no reported results in the literature. (See IEC 60601-2-51 clause 50.102.3.1). These include interpretations regarding subendocardial injury, an abnormal QRS-T angle, non-specific ST or T-wave abnormality and digitalis effect. In addition, repolarization abnormalities interpreted as part of old infarctions or hypertrophies are not reported separately from the commensurate QRS abnormality. In this document, the interpretation of prolonged QT has been included under the assessment of the automated QT measurement.

ST Elevated Acute Myocardial Infarction

The recognition of ST-elevated acute myocardial infarction (STEMI) has been a major focus of GE Healthcare. This is because the ECG is so vital in selecting an appropriate treatment path for acute myocardial infarction[128] as well as reducing time-to-treatment for STEMI.[129]

Prehospital Electrocardiography

GE Healthcare was the first to introduce a prehospital diagnostic 12 lead ECG as a small, compact unit for the ambulance that could acquire and transmit the ECG digitally so that there would be no distortion of the ST/T waveform.[130] This led to several studies that demonstrated that a prehospital ECGs can be practically acquired,[131] significantly cuts total time-to-treatment,[132-134] and has “the potential to significantly increase the diagnostic accuracy in chest pain patients.”[135]

Based on data collected from the prehospital environment,[136] GE Healthcare’s Marquette 12SL analysis program was modified to recognize earlier forms of STEMI, using reciprocal depression as the primary discriminating characteristic to discern STEMI versus early repolarization.[5] This approach, combined with enhancements, allowed the sensitivity to double without a loss of specificity.[137, 138] Several tests have since verified that reciprocal depression is a highly specific marker of STEMI.[139-141]

GE Healthcare’s Marquette 12SL analysis program (Version 14) is used in prehospital defibrillators currently offered by other vendors (Medtronic-
PhysioControl, Zoll).[142, 143] GE Healthcare’s resting electrocardiographs use a later version that includes such features as gender and age-specific criteria for the recognition of STEMI[144] and the detection of right ventricular involvement in the presence of an acute inferior infarction.[23] As a result, the following reported results for STEMI are presented in two groups: one that applies to the results of the program in the prehospital defibrillator and one for the results of the program in GE Healthcare’s resting ECG equipment. Note that both versions of the program analyze data of the same fidelity and content, generating fiducial points and medians at 500 sps.[7]

**STEMI - Reported Results, Prehospital ECGs**

The following series of reported results are from prehospital ECGs and are representative of version 14 of the 12SL analysis program.

In Australia, a GE Healthcare portable prehospital electrocardiograph[145] was used for the automatic diagnosis of acute myocardial infarction via GE Healthcare’s Marquette 12SL analysis program. “This automated program diagnosed acute evolving Q wave myocardial infarction with 71% sensitivity and 98% specificity. Specificity was 100% when patients with a known previous Q wave myocardial infarction were excluded.”[141, 146]

As part of the NIH sponsored Myocardial Infarction Triage and Intervention (MITI) Project,[147] the 12SL analysis program accuracy for recognizing STEMI was evaluated. This was a large prehospital study (n=1,189) that acquired ECGs from patients within 6 hours of the onset of chest pain. This study used cardiac enzymes as the “gold standard”. Their conclusion: “the positive predictive value of the computer- and physician-interpreted ECG was, respectively, 94% and 86% and the negative predictive value was 81% and 85%.”[148] The authors also stated: “The present algorithm is clearly adequate for first line screening of patients with chest pain by paramedics or in the emergency department. Its sensitivity is no worse than that of the emergency physician and its specificity is superior to the trained electrocardiographer. ... Although more sensitive, the electrocardiographer had an overall incidence of a 5% false positive diagnosis, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation. In contrast, the computer was nearly perfect at excluding patients without acute myocardial infarction, but did so at the expense of diminished sensitivity.” The raw numbers for algorithm performance are given in the following Table 37.

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute MI</td>
<td>Unknown</td>
<td>71</td>
<td>98</td>
<td>Unknown</td>
</tr>
<tr>
<td>Acute MI, no previous MI</td>
<td>Unknown</td>
<td>71</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
Statement of Validation and Accuracy: Repolarization Abnormalities: Reported Results

The results of the MITI trial were also analyzed for the recognition of STEMI as opposed to solely using cardiac enzymes as the reference. That is, an analysis was done as to whether or not ST elevation was present along with the positive cardiac enzyme result. In this case, the program achieved a sensitivity of 71%. As stated in the literature: “The computer algorithm was developed to help differentiate early repolarization and nonspecific ECG changes from those of acute injury and, unlike the electrocardiographer, did not presume that ST elevation in a patient with chest pain was more likely than not to indicate acute infarction. Although more sensitive, the electrocardiographer has an overall incidence of 5% false positive diagnoses, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation.”[148]

In another study, clinical data and ECG findings on 264 consecutive patients admitted to a coronary care unit with suspected acute myocardial infarction were prospectively evaluated with the same portable prehospital electrocardiograph as in the aforementioned prehospital studies. Eighty-six (86) patients (32.5%) had confirmed acute infarction and of these 85% had some form of ST elevation on their initial ECG. The area under the receiver operator curve (ROC) of the interpretations made by the 12SL analysis program was 83.9%.[139]

In a recent survey of 365 hospitals in the United States, found that hospitals that used the results of prehospital “electrocardiography, that were called in or transmitted by emergency medical services to activate the catheterization laboratory while the patient was still en route to the hospital, had significantly faster door-to-balloon times than did hospitals that waited for the patient to arrive before activating the catheterization laboratory (P = 0.001).”[149] Furthermore, this survey found that “false alarms were reported to be infrequent.”[149] The authors also stated that the perception “about the number of false alarms are probably as important” in determining “whether non-cardiologists are permitted to activate the catheterization laboratory”. [149]

### Table 36. Results from the MITI Trial Based on Cardiac Enzymes[148]

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute MI</td>
<td>391</td>
<td>52</td>
<td>98.5</td>
<td>94</td>
</tr>
</tbody>
</table>

### Table 37. Results from the MITI Trial Based on Cardiac Enzymes and Presence of ST Elevation[148]

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>286</td>
<td>71</td>
<td>98.5</td>
<td>94</td>
</tr>
</tbody>
</table>

The results of the MITI trial were also analyzed for the recognition of STEMI as opposed to solely using cardiac enzymes as the reference. That is, an analysis was done as to whether or not ST elevation was present along with the positive cardiac enzyme result. In this case, the program achieved a sensitivity of 71%. As stated in the literature: “The computer algorithm was developed to help differentiate early repolarization and nonspecific ECG changes from those of acute injury and, unlike the electrocardiographer, did not presume that ST elevation in a patient with chest pain was more likely than not to indicate acute infarction. Although more sensitive, the electrocardiographer has an overall incidence of 5% false positive diagnoses, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation.”[148]
STEMI - Reported Results for Resting Electrocardiographs

The following series of reported results are representative of the current version of the 12SL analysis program.

In the following study, body surface mapping (80 leads) was compared with GE Healthcare’s Marquette 12SL analysis program for the recognition of acute myocardial infarction on ECGs taken over a 3-month period from 103 chest pain patients in the ED.[150] Of these, 53 had an acute myocardial infarction as defined by positive enzymes. Only 24 met ECG criteria for STEMI.

The purpose of this study was to not only detect STEMI but to detect non-ST elevated acute myocardial infarction. The motivation of the study was to reveal that body surface mapping is superior because it can detect non-ST elevated acute myocardial infarction. Note that the 12SL analysis program is designed not to detect non-ST elevated acute myocardial infarction; rather it will indicate ST depression or T wave inversion. Based on the severity of these abnormalities, the current program will state, *marked ST depression, consider subendocardial injury or marked T wave abnormality, consider ischemia*. It remains controversial as to whether the ECG can diagnose non-ST elevated acute myocardial infarction: this diagnosis is currently the sole domain of cardiac enzyme data.[151]

See the reported results of this study in the following tables. The admitting physician correctly diagnosed 24 patients with AMI (sensitivity 45%, specificity 94%). Of the 24 patients correctly diagnosed, 20 received thrombolytic therapy. According to care guidelines, thrombolytic therapy should only be applied in the case of a STEMI.[128] The automated analysis program correctly diagnosed 17 patients with STEMI (sensitivity 32%, specificity 98%).

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute MI</td>
<td>53</td>
<td>32</td>
<td>98</td>
<td>98</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>24</td>
<td>71</td>
<td>98</td>
<td>98</td>
</tr>
</tbody>
</table>

In the next study, 75 electrocardiograms were interpreted. “Two criteria were compared for thrombolysis eligibility: (1) measurement of ≥1 mm ST-segment elevation in 2 contiguous leads (measured) and (2) criterion 1 plus the subjective opinion that the changes represented acute transmural injury (interpretive). The
Statement of Validation and Accuracy: Repolarization Abnormalities: Reported Results

Results were compared with computerized interpretations by the Marquette 12SL system.\[152\]

The ECGs for this study\[152\] were manually selected in a CCU and were roughly evenly divided among (1) normal, (2) those showing evidence of acute transmural injury, and (3) those showing other ST-segment or T-wave abnormalities (such as early repolarization, acute pericarditis, etc.) Note: this distribution of patient abnormalities is not representative of an ED, CCU, or emergency medical service that typically has a much lower incidence of acute transmural injury (that is, on the order of 10-15\%).\[153\]

This paper states that “strict reliance on measured electrocardiographic criteria alone would have resulted in overuse of thrombolysis among all 3 raters. Based on the consensus opinion, the absolute overuse of thrombolysis would have been approximately 15\% (P < .0034).” In contrast, the computer had 100\% specificity.

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>26</td>
<td>61.5</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

STEMI - Gender Specific Criteria in GE Healthcare Resting Electrocardiographs

GE Healthcare has done considerable research in gender specific differences in the ECG. Testing was done via data collected at the Mayo Clinic and the Medical College of Wisconsin. Results of testing, and an analysis of the ECG differences based on gender, have been broken down by location of myocardial infarction: that is, anterior versus inferior.

For acute inferior MI patients under age 60, women had lower ST elevation than men (lead II STJ average: 57\(\mu\)V for 99 females versus 86\(\mu\)V for 340 males, P value <.02). The opposite was true for patients over age 60. In the older patient population, women had larger ST elevation than men (lead AVF STJ average: 102\(\mu\)V for 378 females versus 84\(\mu\)V for 522 males, P value < .04). [15]

For acute anterior MI patients under age 60, women had lower ST elevations than men (lead V2 STE average, 307\(\mu\)V for females versus 432\(\mu\)V for males, P value < .007). Over age 60 years, this difference becomes less pronounced (lead V2 STE average, 336\(\mu\)V for females versus 421\(\mu\)V for males, P value < .009). The figure displays a comparison of the results between the two program versions for the recognition of acute anterior myocardial infarction in women less than 60 years of age.[154]
Test results show that the program is more sensitive for the recognition of acute myocardial infarction in women less than 60 years of age. For ages 60 and over, the program performance is the same as in previously published studies.

<table>
<thead>
<tr>
<th>Table 41. Results for STEMI from prehospital and ED patients with new onset chest pain of unknown origin[154]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Representative test population</strong></td>
</tr>
<tr>
<td><strong>Additional demographic data</strong></td>
</tr>
<tr>
<td><strong>Total number of test ECGs</strong></td>
</tr>
<tr>
<td><strong>Method(s) used to verify diagnosis</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Verified Diagnosis</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Anterior MI</td>
<td>1,159</td>
<td>48</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
AHA / ACC guidelines recommend that patients with inferior STEMI and hemodynamic compromise should be assessed with a right precordial lead V4r to detect ST segment elevation to screen for right ventricular (RV) infarction.[128] This is a class I recommendation, meaning that there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective. RV involvement in acute inferior infarction may be accompanied by significant hemodynamic consequences including a lowering of cardiac output and systemic blood pressure.[155] In addition, the in-hospital mortality of an acute inferior infarct is worsened when complicated by RV involvement.[156]

The 12SL ECG analysis program uses a threshold of 100 µV in lead V4r in interpreting all cases of right ventricular involvement, except under very specific circumstances.[23] Specifically, the program reduces the threshold to 50 µV in the presence of an acute inferior STEMI with high-degree AV block and a rightward ST vector (i.e., STE in III > II).[157-159] The prevalence of high-degree AV block (i.e., 2nd or 3rd degree AV block) in the general population is extremely rare and a person with an acute inferior STEMI and concomitant high-degree AV block is more than twice as likely to have RV involvement than not.[160]

ST elevation of 100 µV in lead V4r is a highly specific indicator of right ventricular involvement in the presence of acute inferior infarction. A threshold of 100 µV has been reported to have sensitivities of 57% - 100% and specificities of 68% - 100%, depending on the gold standard used (post-mortem examination, hemodynamic measures, angiography, etc).[161] A threshold of 50 µV has been reported to have sensitivities of 76% - 100% and specificities of 40% - 86%, again depending on the gold standard.[161, 162] Morgera[163] analyzed both thresholds in the same study with the same patient population and reported a specificity increase from 86% to 100% as the threshold went from 50 to 100 µV, with a sensitivity decrease from 76% to 57%. However, one should note that the diagnostic accuracy of right ventricular involvement statements have not been assessed in patients with certain conditions such as chronic lung disease and pericardial disease.

Although the lower ST elevation threshold in lead V4r will increase sensitivity and decrease specificity, this decreased specificity is offset by the requirement of concomitant ST elevation in lead III exceeding ST elevation in lead II and high-degree AV block, both of which are associated with right ventricular involvement. Using only the criteria of ST in III > II, Saw[157] reported a sensitivity of 97% and a specificity of 56% for the detection of right ventricular involvement in the presence of an acute inferior infarction. The reported incidence of high degree AV block in patients with RV involvement is 43%, compared to only 13% in patients with acute inferior infarction without RV involvement.[160]

GE Healthcare developed a 16-lead ECG database in conjunction with several chest-pain centers. A total of 1,343 16-lead ECGs were acquired and analyzed from 712 chest-pain patients. Each ECG record contained the standard 12-lead ECG, simultaneously acquired with leads V4r, V7, V8, and V9. GE Healthcare, in conjunction with the contributing investigators, analyzed and reported on the characteristics of the additional leads in relation to acute myocardial infarction and outcome.[164-166] The interpretation of GE Healthcare’s Marquette 12SL analysis program was compared to patient outcomes, as registered in this 16-lead ECG database. An acute STEMI was detected in 143 ECGs. Of these, 101 were diagnosed as being an acute inferior STEMI (including inferolateral and inferior-posterior). When V4r was withheld from the analysis, consider RVI was stated in 84
of the 101 IMI ECGs. When V4r was included in the analysis, the with RVI modifier was added in 34 of the 101 IMI ECGs. With one exception, all 12-lead ECGs that stated consider RVI also stated with RVI when V4r was added.

The sensitivity of the consider RVI statement for predicting positive ST elevation in V4r was 97% (33 / 34), while the positive predictive accuracy was 39% (33 / 84). The result here of 34% (34 / 101) of all acute inferior STEMI having RVI is consistent with the percentages of 30 - 50% reported in the literature.[167].

Repolarization Abnormalities Associated with Acute Cardiac Ischemia

ACI-TIPI[168] uses the measurements of GE Healthcare’s Marquette 12SL program. Based on the presence of pathologic Q waves and/or the presence of repolarization abnormalities, the ACI-TIPI algorithm reports the probability of acute cardiac ischemia. The logistic regression formula used by ACI-TIPI[169] was implemented in all GE Healthcare electrocardiographs and tested in the emergency department (ED)[170] as well as the prehospital environment.[9]

A large prospective trial was accomplished across 10 different emergency departments, with 30-day follow-up of clinical outcomes. A total of 10,689 patients were evaluated: 8150 were not ischemic, 673 had stable angina, and 1866 had acute cardiac ischemia (that is, unstable angina or an acute myocardial infarction. Quoting from the literature:[171]

“Reductions in admissions for patients without acute cardiac ischemia were greater among patients with ACI-TIPI-predicted ischemia probabilities in the lower ranges, reflecting a greater effect with stronger probabilistic advice not to admit (that is, a dose-response effect). Of note, in settings in which use of the ACI-TIPI reduced unnecessary admissions, appropriate hospital and CCU admission did not deteriorate for patients with true acute ischemia (unstable angina or acute infarction). Given these results of this ‘effectiveness’ trial ACI-TIPI seems to be safe and effective for general use.”

ACI-TIPI had a larger impact when the attending physician was inexperienced (that is, an unsupervised resident). In this case, “use of ACI-TIPI was associated with a reduction in CCU admissions from 14% to 10%, a change of -32% (CI, -55% to 3%); a reduction in telemetry unit admissions from 39% to 31%, a change of -20% (CI, -34% to -2%) and an increase in discharges to home from 45% to 56%, a change of 25% (CI, 8% to 45%; overall P = 0.008).”

The purpose of this study was to measure the impact of care based on whether ACI-TIPI was available or not available. Within the same ED, ACI-TIPI was available on alternate months. The effect of improved triage with ACI-TIPI was reproducible, even after the physician had several months of experience with the device.
Repolarization Abnormalities Stated as Ischemia

Using two cardiologists as the reference, the following results were reported for the interpretations of ischemia by computer:

<table>
<thead>
<tr>
<th>ST/T Abnormality</th>
<th>N</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemia</td>
<td>199</td>
<td>100</td>
<td>99.8</td>
<td>98</td>
</tr>
</tbody>
</table>

Table 42. Evaluation of ST/T abnormalities stated as ischemia at tertiary care, VA Hospital[100]
Overall Classification: Reported Results

Several studies have addressed the issue of whether or not the computer can reliably classify the ECG as either normal or abnormal. The following studies reported the following:

- “the program is reliable in diagnosing normality: even the disagreements are arguable.”[59]
- “From a practical point of view, the eventual consensus opinion of the cardiologists was that only one tracing reported as normal by the system definitely should have been reported as abnormal to a family doctor, resulting in a negative predictive value of 98.4%. In view of the cardiologists inter-observer variation with regard to what is normal, this may well be higher than an individual cardiologist’s negative predictive value and suggests that the system examined may safely be used to exclude major abnormalities which would affect clinical management”.[59]
- “A total of 39,238 electrocardiograms were reviewed ... The program placed the ECG into the following diagnostic classifications: normal 22%, otherwise normal 6%, borderline 5%, abnormal 66%. The reviewing physician agreed with this classification in 96.3% of all cases ... The most striking information shows the agreement of the physicians with the computer diagnosis of an abnormal electrocardiogram in 97.7% of the 25,295 tracings. In only 204 records out of 25,987 tracings (.8%), the physicians edited a computer-called abnormal electrocardiogram and changed it to normal. Likewise, in only 63 of 8,632 (.7%) tracings of which the computer called normal did the physicians edit this tracing to read abnormal.”[107]
- As tested on 26,734 male and 3,737 female veterans, a classification of a normal ECG by the 12SL analysis program “is associated with extremely good survival”.[81]
- “Three ECG computer programs–Hewlett Packard analog program (HP), Telemed analog program (T) and Marquette 12SL digital program (MAC)–were evaluated and their accuracy of ECG reading compared with the reading of 4 experienced interpreters on 140 ECGs of patients with various clinical abnormalities. Major disagreement with effect on patient management, and minor disagreement were defined at a joint session with a senior (consensus). The computers identified all normal ECGs correctly (sensitivity 100%). The percentage of major agreements (full agreements and minor disagreements) between consensus and computer was 79% for HP, 90% for T and 93% for MAC.”[172]

<table>
<thead>
<tr>
<th>Table 43. Overall Classification via Large Database[107]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Representative test population.</strong> Large hospital</td>
</tr>
<tr>
<td><strong>Additional demographic data</strong>  Age, gender, and race are unavailable.</td>
</tr>
<tr>
<td><strong>Total number of test ECGs</strong> 39,238</td>
</tr>
<tr>
<td><strong>Method(s) used to verify diagnosis</strong> Physician diagnosis</td>
</tr>
<tr>
<td><strong>Verified Diagnosis</strong></td>
</tr>
<tr>
<td>Normal ECG</td>
</tr>
<tr>
<td>Abnormal ECG</td>
</tr>
</tbody>
</table>
“A total of 2194 ECGs were included for analysis in the study. One hundred twenty two ECGs with a disagreement between the two cardiologists were excluded from analysis. Out of 2072 remaining cases, 776 (37.5%) were read by the computer as normal ... There were no discordances in the ECGs read as normal.” [100]

The computer correctly interpreted all normal ECGs. [89]

“The quality of computer-assisted ECG interpretation was comparable to that of review provided by a cardiology service.” [29] As a result, the overall result of the computerized interpretation is comparable in performance to the average cardiologist. (See IEC 60601-2-51 clause 50.102.)
Serial Comparison

The Serial Comparison program compares ECGs over time, appending interpretive statements to the report generated by GE Healthcare’s Marquette 12SL analysis program. The Serial Comparison program is only available via the MUSE system and is described in the 12SL physician’s guide.

The Serial Comparison program compares statements, measurements and waveforms.[2] The purpose of the program is to detect a significant clinical change and describe the change in terminology familiar to the cardiologist. Note that interpretive statements can change across serial ECGs, even though there is no significant clinical change in the ECGs. In this case, the program will not state a change.

The Serial Comparison program will compare ECGs that are analyzed by different versions of the 12SL program. This is because the Serial Comparison program re-analyzes historical ECGs. Furthermore, it compares the actual waveforms of the stored median complexes. However, it is critical this comparison be done on medians and fiducial point measurements generated by the same signal processing 12SL methodology, otherwise there will be a poor superimposition of the waveforms. This is important if an institution is going to compare and evaluate repolarization changes throughout the continuum of care, as recently demonstrated in a study that used 12SL measurements and waveforms to measure the potential significance of spontaneous and interventional ST-changes in patients transferred for primary percutaneous coronary intervention.[173]

GE Healthcare has developed specialized tools[85, 86, 174-178] for the collection, trending and comparison of serial 12-lead ECGs analyzed by the 12SL analysis program for the assessment of the acute coronary syndrome patient as they migrate from the prehospital setting through to intervention and the CCU.
Conclusion

This document has presented the performance of GE Healthcare’s Marquette 12SL analysis program. The evidence came from the scientific literature and it is, indeed, extensive. Nevertheless, gold standard data continues to be collected and the performance of the program evaluated.

Collection of data is an unending pursuit, for several reasons. The first, and most obvious, is that the program needs to be tested as improvements are made to it. However, equally important, is that new gold standards become available that can fundamentally change our understanding of the ECG. Sometimes, ECG criteria that are well accepted and have been used for decades can be rejected, as recently demonstrated for atrial enlargement.[179] In addition, changes in clinical practice, can change the meaning of a gold standard, as in the case of evaluating Q-waves in an environment of aggressive treatment for STEMI. Clinical practice can also alter the use of the ECG or generate new manifestations of the ECG, as in the case of artificial pacing. The challenge is to keep abreast of these changes and, yet, have an interpretive program that is understandable to the practicing physician.

GE Healthcare is committed to continuous improvement of the program and obtaining the highest performance in the industry. GE Healthcare recognizes that data collection is key to this improvement and, as a result, collaborates across the globe with several centers in the collecting of ECGs correlated with gold standard data or other clinical input. Given the capabilities of the MUSE system, most centers can investigate the performance of the program in a systematic fashion. GE Healthcare welcomes this activity and is interested in collaborating with those who are equally committed to the advancement of computerized electrocardiography. Feel free to contact us with your comments and insights.
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