MARQUETTE 12SL ALGORITHM

Connected Clinical Excellence

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CLINICAL DECISION SUPPORT FOR YOUR ECG

Since its introduction in 1980 the Marquette™ 12SL ECG analysis program has been consistently refined and improved in order to offer our customers the best possible clinically validated decision support to help achieve faster accurate diagnosis.

- Exceeds current standards[1] for 12- and 15-lead measurements and analysis
- Provides accurate, validated measurements of heart rate, axis, intervals, and durations
- Offers automated second opinion minimizing time spent over-reading ECGs
- Offers ECG analysis including those for atrial arrhythmias, pace detection, and QT measurement
- Offers quick quality check of ECGs (Hookup Advisor™)
- Offers gender and age-driven criteria for acute MI to identify clinically significant changes and expedite patient care in time-critical situations
- Dedicated pediatric criteria
- Supporting decisions on ECG across the care continuum

Timeline

- **1980** — 12SL PROGRAM
- **1984** — Serial Comparison
- **1987** — Pediatric Analysis
- **2000** — Gender-specific criteria
- **2003** — QT Algorithm
- **2004** — Hookup Advisor
- **2006** — Right Ventricular Involvement
- **2011** — Pace Statements Acute Coronary Syndrome
- **2015** — Updated criteria for left ventricular hypertrophy (LVH)

Serial Comparison

The Marquette Serial Comparison Program indicates changes in the ECG from the previous ECG of the same patient. It utilizes interpretive statements, ECG measurements and waveform comparison techniques to maximize accuracy in the detection of clinically significant changes. Serial comparison requires the MUSE™ ECG management system.

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Benefit:

Consistent validated[1] analysis and comparison ensures reproducibility and objectivity for increased efficiency in the process.
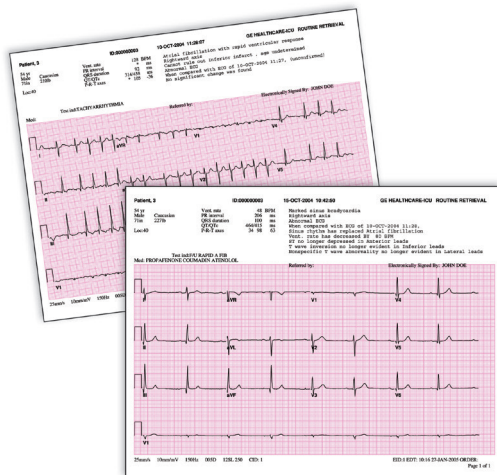
Pediatric Analysis

12 Age groups applied to ECG analysis
Less than one day old
At least a day old but not more than 2 days
3 to 6 days old
1 to 3 weeks old
1 to 2 months old
3 to 5 months old
6 to 11 months old
1 to 2 years old
3 to 4 years old
5 to 7 years old
8 to 11 years old
12 to 15 years old

Children are not the same as adults and neither are their ECGs. Increased right ventricular size, increased heart rate and narrower complexes would lead to different interpretation in an adult ECG. To take this into account, if an age of less than 16 years is entered the Marquette 12SL program employs pediatric criteria.

In addition the possibility to apply 15 leads allows different positions to cater for the differences in pediatric anatomy.

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Benefit:

Accurate pediatric specific measurement and interpretation validated by independent study with over 1,100 pediatric ECGs.[1]

● **2000**
Gender-specific criteria

Just like children, adult men and women are also different and this difference extends to the ECG. Marquette 12SL with Gender- Specific interpretation applies criteria for evaluating the ST segment and T-wave of the ECG waveform, improving sensitivity to acute myocardial infarction in women and enhancing diagnostic confidence.

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Benefit:

- Improves the sensitivity for detection of acute anterior MI from 42% to 48% in women under 60 years of age.[2]
- 25% relative improvement in detection of acute inferior MI in women under 60 years of age without sacrificing the high specificity already maintained by the program.[3]

● **2003**
QT Algorithm

It is well recognized that the identification of prolonged QT is important as the condition can result in serious arrhythmia and Sudden Cardiac Death.[4] However, it can be difficult to measure QT accurately due to factors such as ECG noise, difficulty defining the end of the T wave, and requiring corrections for heart rate. GE has concentrated its efforts in helping to minimize these challenges through the Marquette 12SL program. The QT is measured from a median complex reducing the influence of noise, it is also measured from global fiducial points from all 12 simultaneous leads.
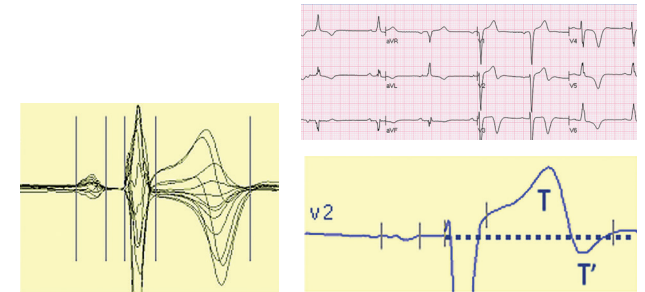
By using all leads of the median complex to define the end of ventricular repolarization, Marquette 12SL offers accuracy and consistency in QT measurement.

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Benefit:

- Consistent, reproducable and accurate measurement and interpretation
- Offers multiple QT correction factors including Bazett, Framingham, and Fridericia STEMI / ACS.

2004
Hookup Advisor

Marquette Hookup Advisor™ enables high quality ECGs by measuring impedance plus the signal quality of the ECG leads.

- The easy to understand red-yellow-green signal indicates the quality of the ECG.
- The Hookup advisor not only takes skin contact through impedance into consideration, but also looks at the ECG signal and electrode motion or noise coming from movement, AC or muscle tremor.

Benefit:
The system indicates the cause of interference, so that the root cause can be eliminated without using higher filters.
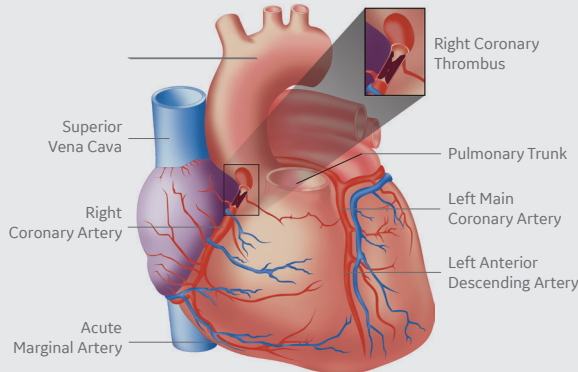

2006
Right Ventricular Involvement (RVI)

Right Ventricular Involvement (RVI) is associated with a significantly greater risk of in-hospital mortality and major in-hospital complications.[5] Following the AHA/ACC standards[6] Marquette 12SL will call out from the regular 12-lead ECG that RV involvement should be considered.

Benefit:
- Reduced risk of death, shock and arrythmias through improved diagnosis on the 15-lead ECG on the basis of an ST-segment elevation in the right precordial leads (e.g. lead V4R)[7]
- Marquette 12SL is assisting the user on when to consider RVI and apply 15-leads
- Validated on a multi-site database of over 1.300 chest pain ECGs[1]

Superior Vena Cava

Right Coronary Artery

Acute Marginal Artery

Right Coronary Thrombus

Pulmonary Trunk

Left Main Coronary Artery

Left Anterior Descending Artery

Treatment of infarction may vary with right ventricular involvement, therefore recording of additional right-sided precordial leads during acute inferior wall, left ventricular infarction is recommended. Routine recording of these leads, in the absence of acute inferior infarction, is not recommended. (Circulation 2007).[8]

2011

Pace Statements

Bipolar pacing has lead to a reduction of pulse amplitudes and width.[9] Therefore it is necessary to detect pacemaker pulses at a sampling rate that is much greater than is required for conventional ECG analysis. In conjunction with MAC VU360™, the Marquette 12SL program is able to identify a biventricular paced rhythm.

• The pacemaker annotation channel will then be displayed on the ECG printout and on the MUSE ECG management system
• Validation of pacemaker detection in three independent studies[1]

Benefit:

Marquette 12SL provides analysis for detecting bi-ventricular pacemakers, identifying the underlying rhythm, in addition to the chamber(s) being paced.

Acute Coronary Syndrome (ACS) Tool

The Marquette 12SL ACS tool* increases sensitivity for ST-Elevated MI or Acute Ischemia in patients suspected of having an acute cardiac event. The tool heavily weighs the finding of ST elevation with reciprocal ST depression. This is a very important and highly-specific indicator of STEMI and ACS that has been found to "identify patients who stand to benefit most from early interventional strategies."[10] A study evaluated on over 1,900 clinically correlated ECGs[1] from patients suspected of having ACS showed that the ACS tool:

Benefit:

• Improved the sensitivity of emergency physicians' interpretation of acute myocardial infarction by 50% and cardiologists' interpretations by 26%, with no loss of specificity[11]
• Improved the sensitivity of emergency physicians' acute ischemic syndrome interpretation by 53% while maintaining a specificity of 91%[11]

2015

Updated criteria for left ventricular hypertrophy (LVH)

Marquette 12SL directly incorporates four commonly-used criteria for (LVH) that have been extensively studied and validated in the literature:

• R wave amplitude in lead aVL[12]
• Sokolow-Lyon criteria (SV1 + max(RV5, RV6))[12]
• Cornell voltage*duration product [13, 14]
• Romhilt-Estes criteria[15]

If any of these criteria are positive they will be listed in parentheses in the interpretation with the applicable LVH statement.

Benefit:

As more criteria are listed in the interpretation, the physician will be able to have a higher level of confidence in the assessment of the LVH.

ECG RECORDING - WHY QUALITY MATTERS...

The outcome of the ECG measurement and interpretation improve with the quality of the ECG recording and processing. Therefore the AHA/ACC established ECG standards and recommendations to improve the accuracy and usefulness of the ECG in practice.[16]

Recommendations for electrode positioning

Electrodes must be positioned in accordance with AHA recommendations. If any of the electrodes need to be sited in non-standard positions the recording must be labelled with this information to avoid misinterpretation of altered ECG waveforms.[16,17,18]

Mid-clavicular line
V1 V2 V3 V4 V5 V6
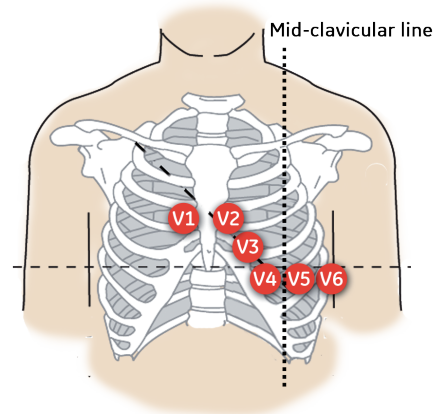
Filtering recommendations

- To avoid distortion of the ST segment the low-frequency cut-off should be no higher than 0.67 Hz in "auto" mode, or 0.05Hz in "manual" mode.[8]
- To prevent the loss of high frequency information the high frequency cutoff should be no lower than 150 Hz in adults and adolescents.[8]

Daily
>1.5 M ECG's
performed globally.[19]

The ECG is a quick, non-invasive procedure that many patients undergo as the first test!

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Benefit:
- Suspect arm lead reversals are indicated, but not considered in the interpretation

CLINICALLY VALIDATED ECG MEASUREMENT AND INTERPRETATION

The IEC Standard 60601-2-25:2011[20] defines the validation requirements:

Measurement accuracy

• Rhythm interpretation accuracy must be tested on at least 1,500 ECGs, 100 with Afib

Diagnostic interpretation accuracy

• Accuracy must be validated via non-ECG data
• Performance information shall be disclosed in accompanying documents and readily available to customers who want to know the information

The Marquette 12SL ECG analysis program is continually refined through the following processes[1]:

• Regular clinical input – continuous input is gathered from some of the world's top consulting cardiologists and physicians.

• Clinically correlated databases – GE utilizes different databases during the development and validation processes to enhance program accuracy.

• Beyond clinically-correlated databases GE measures its analysis program performance on a large database of ECGs (>50,000).
This process challenges the program with multiple diseases and varying degrees of abnormality. ECGs with changed analysis results due to program modification can be further investigated with expert confirmation.

Benefit:
Improved program accuracy, which helps clinicians to improve patient care.

Disclosure of Accuracy/ Confirmation[1]	Marquette 12SL
ICE 60601-2-51 in product specification-performance standard for ECG analysis	✓
Measurement Accuracy via CSE database	✓
Stabiliy of measurements in presence of noise - CSE recordings	✓
Rhythm interpretation accuracy on over 1.500 ECGs by cardio-logist, includes at least 100 ECGs with artrial fibrillation	✓
Accuracy of conduction abnormalities by cardiologist	✓
Accuracy of LVH, RVH, old infarction via CSE database (NEJM 1991)	✓
STEMI confirmed by cardiac enzymes & clinical outcome	✓
Acute ischemia via longitudinal clinical outcome	✓
Accuracy of QT measurement by core lab and drug dosage	✓
Independent evaluation: articles where inventor/vendor is not an author	**>30**

CONNECTED CLINICAL EXCELLENCE

MUSE NX ECG Management System

CardioSoft™

12SL PROGRAM

MAC 5

MAC VU360

CARESCAPE™

MAC 7

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* The 12SL ACS algorithm is not available in all GE Healthcare ECG devices.
 MAC VU360 is not available in all markets.
 Contact your GE Healthcare Representative for more details.

www.gehealthcare.com

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care.

Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost.

In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.