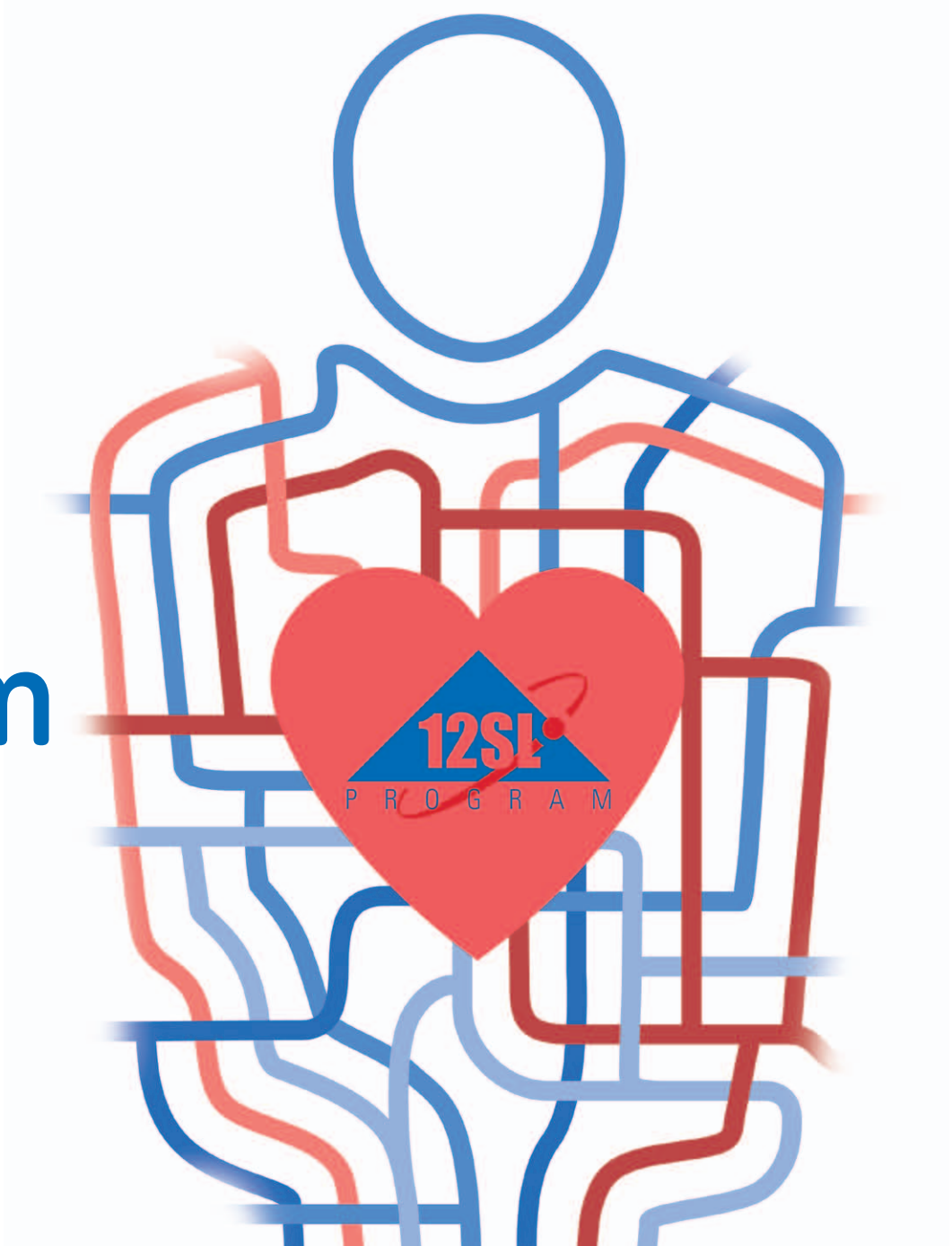
Marquette™ 12SL Algorithm

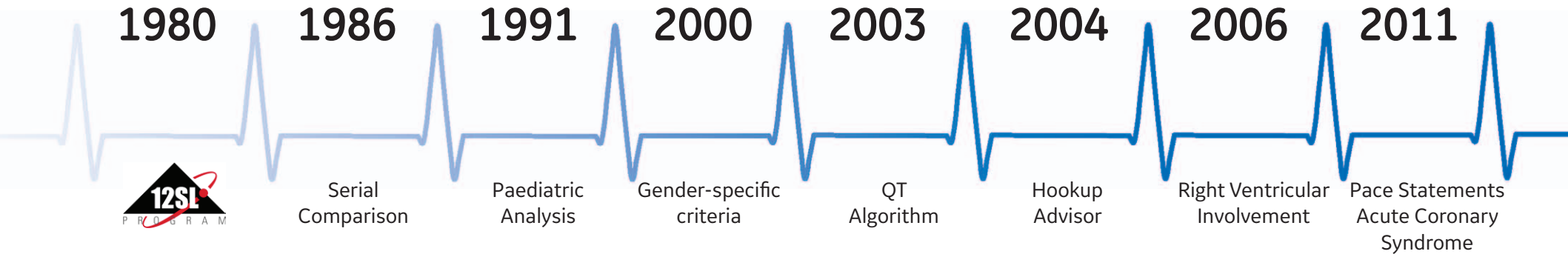
Connected Clinical Excellence



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 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 (Hook-up advisor)
- Offers gender and age-driven criteria for acute MI; utilized in pre-hospital defibrillators to identify clinically significant changes and expedite patient care in time-critical environments
- Dedicated paediatric criteria
- Supporting decisions on ECG across the care continuum



1980 1986 1991

12SL PROGRAM

Serial Comparison

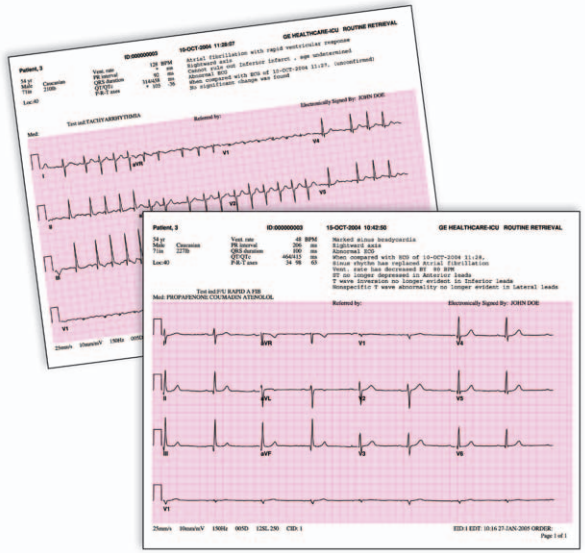
Paediatric Analysis

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.

Benefit:

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



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

Benefit:

- Accurate paediatric specific measurement and interpretation validated by independent study with over 1.100 paediatric ECGs.[1]

2000 2003

Gender-specific criteria

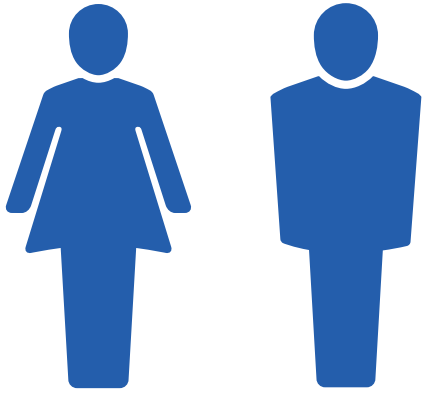
QT Algorithm

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.

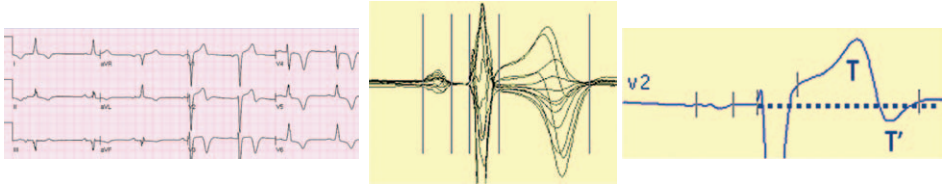
Benefit:

- 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]



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

Benefit:

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

2004 2006

Hookup Advisor

Right Ventricular Involvement

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.

Right Ventricular Involvement (RVI)

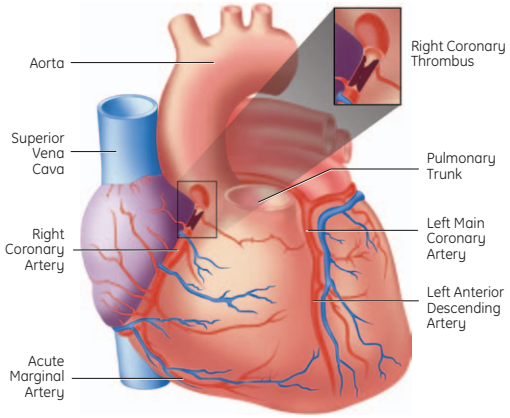
Right Ventricular Involvement (RVI) is associated with a significantly greater risk of in-hospital mortality and major in-hospital complications.[5] Following the AHA/ACC standards[6] Marquette 12SL will call out from the regular 12-lead ECG that RV involvement should be considered.

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 12 SL is guiding the user on when to consider RVI and apply 15-leads

- Validated on a multi-site database of over 1.300 chest pain ECGs.



Because treatment of infarction may vary with right ventricular involvement, 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]

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 the CAM HD, GE's high-definition ECG acquisition module, the Marquette 12SL program is able to identify a biventricular paced rhythm.

- The pacemaker annotation channel will then be shown in the MUSE™ ECG management system
- Validation of pacemaker detection in three different 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:

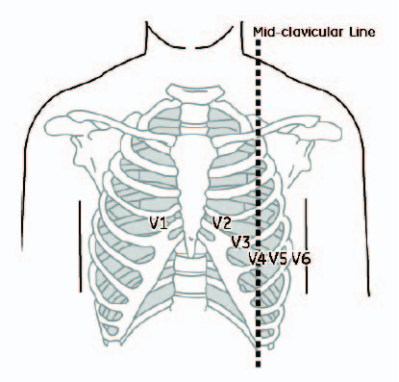
- Improved the sensitivity of emergency physicians' interpretation of acute myocardial infarction by 50% and cardiologists' interpretations by 26%, with no loss of specificity[11]
- Improved the sensitivity of emergency physicians' acute ischemic syndrome interpretation by 53% while maintaining a specificity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

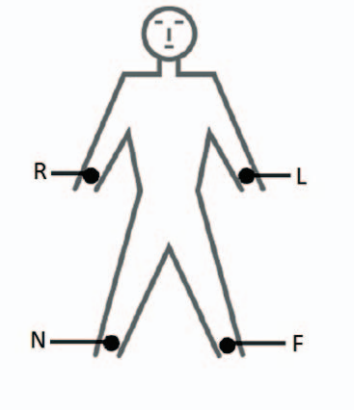
ECG Recording - why quality matters...

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.[12]

Recommendations on electrode positioning

- Electrodes must be positioned in accordance with AHA recommendations. If any of the electrode need to be sited in non-standard positions the recording must be labelled with this information to avoid misinterpretation of altered ECG waveforms.[12,13,14]





More than

300,000,000

ECGs are recorded in Europe every year.[15]

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

Benefit:

- Hook-up advisor indicates the quality of the ECG with an easy-to-understand red-yellow-green signal
- Suspect arm lead reversals are indicated, but not considered in the interpretation
- Tools and training materials support correct positioning

Recommendations of filtering

- 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]

Benefit:

- Hookup Advisor will list the cause of interference is indicated to remove root-cause potentially avoiding the need of filtering
- Flexible filter settings allow permanent and ad-hock changes to filter if needed

Clinically validated ECG measurement and interpretation

The IEC Standard 60601-2-25:2011[16] 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]:

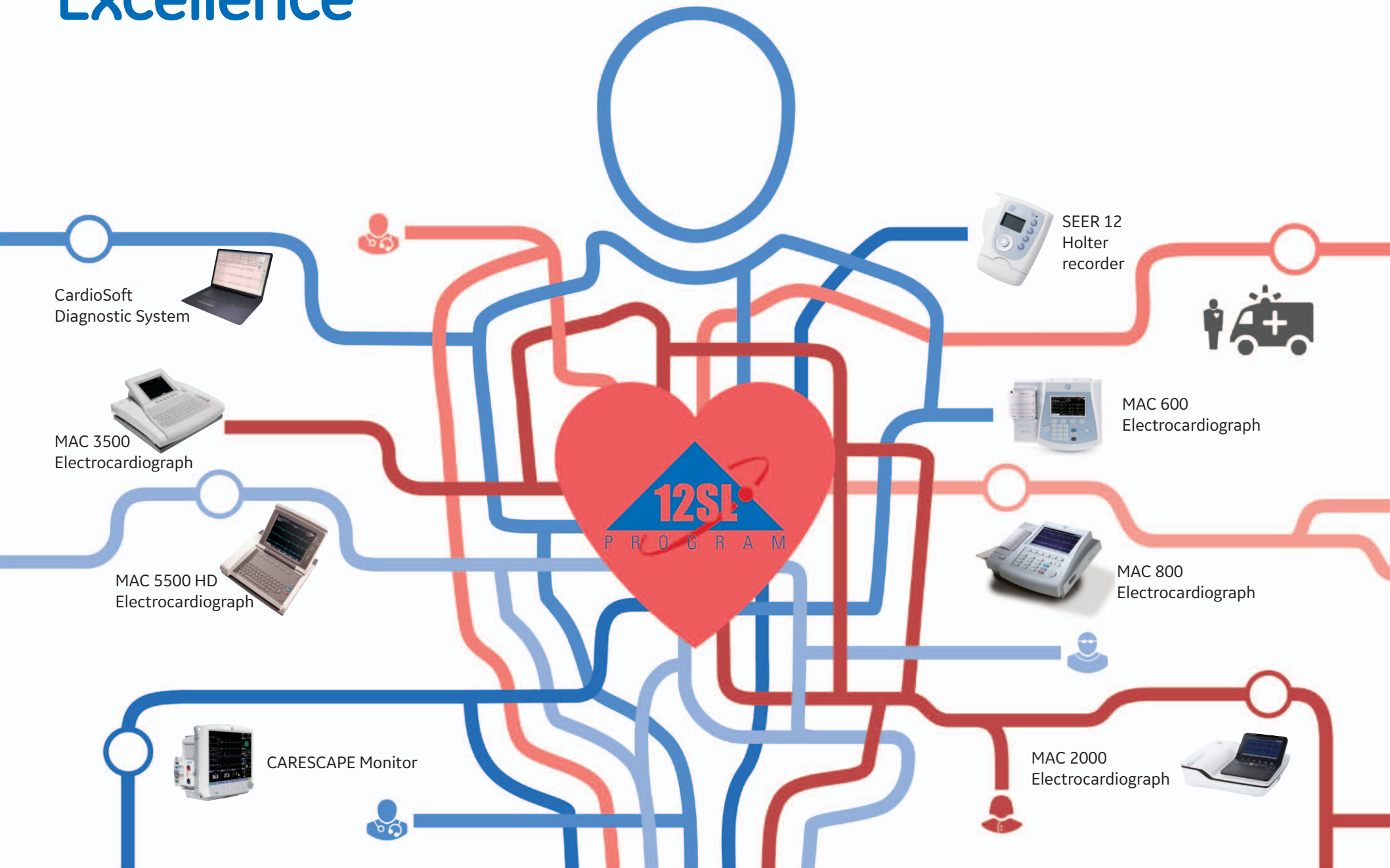
- Regular clinical input – continuous input is gathered from some of the world's top consulting cardiologists and physicians.
- Clinically correlated databases – GE utilizes different databases during the development and validation processes to enhance program accuracy.
- Beyond clinically-correlated 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



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.

Imagination at work

GE Healthcare
P.O. Box 900,
FIN-00031 GE, Finland
GE Direct United Kingdom: +44 (0) 800 0329201

JB39052XE 04/2016

References:

1 Marquette™ 12SL™ ECG Analysis Program Physician's Guide 2036070-006 Revision C, 2010, 2012 General Electric Company

2 Wright, R.S., et.al. "Women with Acute Anterior Myocardial Infarction Have Less Precordial ST Elevation Than Men Independent of Age of Presentation." J Am Coll Cardiol. 37(2001): 361A.

3 Xue, J., et.al. "A New Method to Incorporate Age and Gender Into the Criteria for the Detection of Acute Inferior Myocardial Infarction." J Electrocardiol. 34(4) (Part 2) (Oct 2001): 229-234.

4 Al-Khatib SM, et. al., What Clinicians Should Know About the QT Intervall, Jama 2003; 289(16):2120-2127.

5 Zehender, M., et al. (1993). "Right ventricular infarction as an independent predictor of prognosis after acute inferior myocardial infarction." N Engl J Med

6 Antman EM, Anbe DT, Armstrong PW, Bates ER, Green LA, Hand M, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation. 2004; Aug 31;110(9):e82-292.

7 "Patients with inferior MI who also have RV myocardial involvement are at increased risk of death, shock and arrhythmias." Mehta, S. R., et al. (2001).
"Impact of right ventricular involvement on mortality and morbidity in patients with inferior myocardial infarction." J Am Coll Cardiol

8 Kligfield P, Gettes LS, Bailey JJ, Childers R, Deal BJ, Hancock EW, et al. Recommendations for the Standardization and Interpretation of the Electrocardiogram. Part I: The Electrocardiogram and Its Technology. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology. Circulation. 2007 Feb 23.

9 Improved pacemaker pluse detection: clinical evaluation of a new high-bandwith electrocardiographic system. J Electrocardiol, 2011.

10 Otto, L.A. and T.P. Aufderheide, Evaluation of ST segment elevation criteria for the prehospital electrocardiographic diagnosis fo acute myocardial infarction.
Ann Emerg Med, 1994. 23(1): p. 17-24.

11 Xue, J., et al., Added value of new acute coronary syndrome computer algorithm for interpretation of prehospital electrocardiograms. J Electrocardiol, 2004. 37 Suppl: p. 233-9.

12 Recommendations for the Standardization and Interpretation of the Electrocardiogram, Paul Kligfield, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC; James J. Bailey, MD; Rory Childers, MD; Barbara J. Deal, MD, FACC; E. William Hancock, MD, FACC; Gerard van Herpen, MD, PhD; Jan A. Kors, PhD; Peter Macfarlane, DSc; David M. Mirvis, MD, FAHA; Olle Pahlm, MD, PhD; Pentti Rautaharju, MD, PhD; Galen S. Wagner, MD, 2007 by the American Heart Association, Inc., the American College of Cardiology Foundation, and the Heart Rhythm Society

13 Kossman CE, Brody DA, Burch GE, Hecht H, Johnston FD, Kay C, Lepeschkin E, Pipberger HV, Baule G, Berson AS, Briller SA, Geselowitz DB, Horan LG, Schmitt OH. Recommendations for standardization of leads and of specifications for instruments in electrocardiography and vectorcardiography. Circulation 1967; 35:583-601.

14 Pipberger HE, Arzbaecher RC, Berson AS. American Heart Association Committee on Electrocardiography: recommendations for standardization of leads and of specifications for instruments in electrocardiography and vectorcardiography. Circulation 1975; 52:11-31.

15 World Health Organisation (1981) Regional Office for Europe. Uses of the Electrocardiogram. Report on a WHO study; Copenhagen EURO Reports and Studies 37 (project ICP/ATH 003). WHO, Geneva

16 IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

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