

# Marquette T-Wave Alternans analysis program

A tool for risk classification of Sudden Cardiac Death<sup>1</sup>

*"T-Wave Alternans Algorithm measurements have been found to be predictive of arrhythmic death and can be used for the purpose of risk stratification"<sup>1</sup>*

## The clinical challenge

Each year, Sudden Cardiac Death (SCD) claims the lives of 300,000 Americans – with 80-90% of those deaths caused by ventricular fibrillation.<sup>2</sup> Repolarization Alternans is manifested in the ST-segment and T-wave portions of the ECG waveform. T-Wave Alternans (TWA) is defined as a beat-to-beat fluctuation in the morphology (amplitude and shape) of the ECG waveform. It must present with an every-other-beat, repeating ABABABtype pattern, and when present, is seen as a precursor of SCD. Use of the Marquette TWA analysis program allows clinicians the ability to quickly identify patients who are at risk for SCD, in order to initiate treatment sooner. The absence of T-wave Alternans indicates minimal risk, which may minimize the need for an implantable defibrillator.

## The clinical solution

The amplitude and duration of TWA episodes from the Marquette TWA analysis program have been correlated with SCD<sup>4</sup>. The analysis program detects and measures TWA at any heart rate, over short exercise intervals: two essential components for patients at high risk. The Marquette TWA Analysis Program detects, measures, and allows for visual validation of subtle, commonly missed ECG variations in real waveforms, at an accuracy and resolution of 1-microvolt. The outcome: Clinicians can quickly identify ST/T wave variations that have been found to be predictive of SCD.



# Advantages of GE's Marquette TWA Analysis Program

Although other devices have been available, GE's advanced time-domain method of measuring TWA has several advantages for clinicians including:

- Provides immediate, visual assessment of TWA presence, amplitude and variation to physician
- Only requires one-time patient testing: Stress testing and TWA are conducted in the same test
- No proprietary electrodes are required
- No minimum heart rate requirement
- No minimum exercise time required
- Robust measurements provided, even in the presence of noise and artifact
- No special protocols are needed: In fact, user can customize individual protocols
- Two sets of results can be secured (ST and TWA) from one test in a patient visit using the same ST segment analysis tools
- Trend plots and superimposed beats are used in diagnosing and creating final reports
- Lead-by-lead basis analysis allows for greater, more accurate localization



Visual verification in median beats and ventricular tachycardia. TWA can be overlooked until computer detected.

# Research and validation

The patented algorithm for the time-domain method of detecting TWA<sup>5</sup> was developed by Dr. Richard L. Verrier and Bruce D. Nearing of Beth Israel Deaconess Medical Center, Harvard Medical School, and was evaluated for the prediction of ventricular fibrillation,<sup>6</sup> for application to both stress testing and ambulatory recordings. TWA describes an electrocardiographic (ECG) pattern that exhibits different ST/T-wave morphologies on alternating beats in an ABABAB pattern. The algorithm classifies alternate beats in the stream of ECG data as either “A” or “B”. It then, via incremental averaging, generates representative “A” and “B” complexes.

Advanced signal processing techniques are required for removing artifact before the representative complexes are generated.<sup>8</sup> Measurement of TWA below 10 microvolts has been objectively evaluated in the face of various artifacts, and has been analyzed against a measurement database.<sup>9</sup> Much of our research has been based on ambulatory databases, which are an excellent source of validation for the algorithm,<sup>7</sup> since so many databases already have been correlated with SCD. For additional technical information and abstracts, refer to the T-Wave Alternans Physician Guide – available through your local GE representative.

# Accurate and easy to use

GE’s TWA Analysis Program utilizes the well-known Marquette algorithms, which minimize artifact, and enable the measurement of T-Wave alternans. At the root of functionality, these robust algorithms use the patented, proprietary Incremental Median Updating, where ECG templates are created and continually updated throughout the test. As a result, the analysis program allows for noise elimination while maintaining the integrity of the ST and TWA.

Additionally, the analysis is performed on all existing leads on an individual lead-by-lead basis. The program will run simultaneously in the background of the test program if selected by the user before the testing has begun. And it can be used as an adjunct to the patient’s clinical history and the results of other non-invasive and/or invasive tests, supporting other ECG data obtained during testing of patients.

“Among the most compelling challenges facing the cardiologists today is the identification of which patients are at highest risk for sudden death.”<sup>3</sup>

# Frequently asked questions

1. How reliable and accurate is the Marquette TWA analysis program? T-Wave Alternans (TWA) exhibits different ST/Twave morphologies on alternating beats at an accuracy and resolution of 1-microvolt, demonstrated even in the presence of noise.
2. Is the analysis program easy to run? Yes. Users simply check a box at the beginning of the test to activate the TWA analysis program. There are no special protocols or electrodes required, and the user can configure the upper and lower heart rate limits for when TWA is reported by the system.
3. How does the TWA analysis handle noise and artifact? The Marquette TWA analysis program removes baseline sway via the Marquette Cubic Spline analysis program. Muscle artifact is removed via incremental averaging. Instead of just one average beat, the Marquette TWA program generates two beats: one to represent the odd beats, the other for the even beats which are then displayed and superimposed. Patented cubic spline alignment of the medians enables more accurate comparison and T-Wave Alternans measurement. Furthermore, if the system detects too much artifact, it provides the user with immediate visual feedback as to the validity of the data.
4. For which patients is this application appropriate? The test can be applied to any patient, but is typically used for the risk stratification of high-risk patients and used for the prediction of Sudden Cardiac Death (SCD). Local Medical Review Policies often provide indications of use for this test (see CPT 93025).
5. What should be done when the TWA test results are "positive"? The presence of TWA is just another diagnostic value for the physician to consider when assessing the patient. In addition to a report, the system also allows the user to find ECG tracings that reveal TWA patterns. These reports and tracings are useful in the assessment of a patient's risk for sudden cardiac death (SCD). If positive, patients should be referred to an electrophysiologist for further analysis.
6. How does GE's Marquette TWA Analysis Program differ from other programs? Although both systems can measure TWA to 1 microvolt, the key difference for the user is that GE measures peak-to-peak TWA and displays the associated waveform for this measurement. Other systems cannot show the ECG alternans waveform and measures the mean TWA value, a much smaller value than the peak-to-peak measurement.
7. How often should the test be performed? There is no information yet available on how often the test should be performed. Serial trending of TWA is still an area of research.
8. What extra equipment is needed to perform the test and what additional supply cost should the user expect? There is no need for additional equipment, supplies or electrodes to run the Marquette TWA analysis program.
9. Is this test reimbursable for the clinician and/or facility? Reimbursement varies upon location, so check with your carrier and Local Medical Review Policy (LMRP). They will want to know that the algorithm performs the measurement of this variation at an accuracy and resolution of 1 micro volt and that the measurements generated by GE's algorithm have been found to be predictive of arrhythmic Death and can be used for the purposes of risk stratification. (see CPT 93025)

For additional details, please refer to the TWA physician's guide, part number 2020044-067, Rev A.

**The Marquette T-Wave Alternans Analysis Program: assessing risk of sudden cardiac death, one beat at a time!**

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<sup>1</sup> 510(k) Premarket Notification Database 510(k) Number: K032513.

<sup>2</sup> Moss AJ, Cannom DS, Daubert JP, et al, for the MADIT II Investigators. Multicenter Automatic Defibrillator Implantation Trial II (MADIT II): design and clinical protocol. *Ann Noninvasive Electrocardiol.* 1999;4:83-91.

<sup>3</sup> Gregory Engel, MD, James G. Beckerman, MD, Victor F. Froelicher, MD, Takuya Yamazaki, MD, Henry A. Chen, MD, Electrocardiographic Arrhythmia Risk Testing *Curr Probl Cardiol*, July 2004.

<sup>4</sup> Verrier RL et. al., Noninvasive Sudden Death Risk Stratification by Ambulatory ECG-Based T-Wave Alternans Analysis: Evidence and Methodological Guidelines *The Annals of Noninvasive Electrocardiology* Volume 10 Issue 1 Page 110 – January 2005.

<sup>5</sup> Bruce D. Nearing and Richard L. Verrier. System and method for quantifying alternation in an electrocardiogram signal. Patent No.: US 6,169,919 B1, Jan. 2, 2001.

<sup>6</sup> Nearing, B.D., and Verrier, R L "Modified Moving Average Analysis of T-Wave Alternans to Predict Ventricular Fibrillation with High Accuracy." *J Appl Physiol.* 92(2)(Feb 2002): 541-549.

<sup>7</sup> Verrier, R.L., et.al. for the ATRAMI Investigators. "Ambulatory ECG-Based Tracking of T-Wave Alternans in Post-Myocardial Infarction Patients to Assess Risk of Cardiac Arrest or Arrhythmic Death." *J Cardiovasc Electrophysiol.* 14 (7)(July 2003): 705-711.

<sup>8</sup> Kaiser W. et. al. Improving T-Wave Alternans Measurement Quality by Reducing Noise and Artifacts *Computers in Cardiology* 2004.

<sup>9</sup> Xue JQ et. al. Effect of Noise on the Frequency and Time Domain Methods of T Wave Alternans *Computers in Cardiology* 2004.

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GE Medical Systems Information Technologies GmbH  
Munzinger Strasse 3  
79111 Freiburg, Germany  
Tel. +49 761 4543 0 • Fax +49 761 4543 233

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