Stratifying the Risk Over 10,000,000 patients are at risk for SCD¹



How do you determine your patient's risk for Sudden Cardiac Death?



Microvolt T-Wave Alternans[™] Test

Stratifying the Risk for Sudden Cardiac Death

The Test

The Microvolt T-Wave Alternans test is a non-invasive, easy-to-perform diagnostic test clinically proven to identify patients at risk of Sudden Cardiac Death. The proprietary Analytic Spectral Method[™] software measures T-wave alternans to a millionth of a volt, then processes the data to determine each patient's risk profile. Multiple prospective clinical trials indicate that patients from broad groups of at risk populations who test MTWA negative will likely live ventricular event-free for 12 to 24 months after their initial MTWA test.



Proprietary multi-segment Micro-V Alternans ™ Sensors minimize noise and artifact to permit data collection of alternans at the microvolt level.

Is Your Patient's Risk High or Low?

A negative MTWA test nearly eliminates your patient's risk of having a sudden cardiac event. Annual follow-up testing in these patients insures continued surveillance should their cardiac risk profile change. Patients who test MTWA positive can be referred to an electrophysiologist for therapeutic treatment.

Over 98% <u>Negative Predictive Value in Ischemic and</u> Non-Ischemic Patients

- High risk patients (MTWA positive) should be referred for electrophysiology consultation
- Low risk patients (MTWA negative) may be managed on optimal medical therapy



MADIT II type patients²

In this study of 177 post-MI patients (MADIT II type), MTWA identified a group of patients not likely to benefit from ICD therapy.

SCD-HeFT type patients³



In this study of 282 patients with dilated nonischemic cardiomyopathy, a negative MTWA test predicted an extremely high 2-year event free survival rate.

Understanding the T-wave

Microvolt T-Wave Alternans is a beat-to-beat fluctuation in the amplitude or morphology of the T-wave at a microvolt level. When detected this indicates the presence of a type of cellular metabolic activity that frequently leads to ventricular tachyarrhythmias. Microvolt T-Wave Alternans has been cleared by the FDA for its ability to predict ventricular tachyarrhythmias and sudden cardiac death.

HearTwave[™] II MTWA System

The Next Generation in MTWA Testing

The HearTwave II system is the next generation Microvolt T-Wave Alternans stand-alone testing platform that simplifies hospital and office-based SCD risk stratification.

- MTWA signal processing/analysis with proprietary Analytic Spectral Method
- Customized patient report generated by Alternans Report Classifier
- Dedicated MTWA Graphic User Interface
- Windows[®] XP operating system powered by Intel[®] Pentium[®] processor
- Real time ECG monitoring built into the proprietary MTWA software
- Large adjustable 15" color LCD display
- Printer options include laser with remote or thermal
- 3000 test storage capacity before archiving to CD-RW, memory key or network
- Test editing in real-time or in review mode
- Compatible with most treadmills
- Optional stress testing capability



Stratifying the risk

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1 AHA Heart & Stroke Statistics Update 2005.

- a Bloomfeld DM, Steinman RC, et al. Microvolt T-Wave Alternans Distinguishes Between Patients Likely and Patients Not Likely to Benefit From Implanted Cardiac Defibrillator Therapy: A Solution to the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II Conundrum. Circulation. 2004; 101:1885-89.
- Costantini 0, et al. Patients With a Nonischemic Cardiomyopathy and a Negative T-Wave Alternans
 Stress Test Are at a Low Risk of Death. AHA 2004 Oral Presentation.

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