



Protocol: Comparing your Stress Test to HeartTrends®

Objective: Compare the results of your standard treadmill Exercise Stress Test to HeartTrends.

Be aware: Stress Tests are subjectively-interpreted examinations not necessarily reflective of pending heart disease. In the absence of a “gold standard” (e.g., cardiac imaging), correlation with HeartTrends must be viewed accordingly.

Population: For screening of *healthy* individuals without known Coronary Artery Disease (CAD) exhibiting one or more cardiac risk factors. Your success in this comparison depends upon *carefully selecting* the right population.

- **Inclusion criteria: Healthy people or subjects with 1 or more cardiac risk factors:** Including over-age 40, family history, smoking, high blood pressure, diabetes, or cholesterol or those **unable to perform a treadmill test** such as Impaired, elderly, and overweight
- **Exclusionary criteria:** Established CAD, atrial fibrillation or flutter, diagnosis of an acute coronary syndrome or typical angina, presence of a cardiac pacemaker, clinical diagnosis of heart failure, moderate or severe pulmonary disease, acute myocarditis or any presence of cardiomyopathy, known drug or alcohol dependence, presence of left bundle branch block, significant intra-ventricular conduction delay or significant (>1mm) ST deviations at baseline. Beta-blockers should be withheld for at least 24 hours prior to test. Athletes who should use a treadmill to attain true target heart rate measurements. In short, if subjects already have a heart disorder, HeartTrends will not reveal anything new so this test is superfluous.

Testing methodology:

1. First, perform the HeartTrends test on 20-30 subjects for at least 60 minutes on 20-30 subjects. Do *not* reveal the results until after the full set of 20-30 tests.
2. Perform 20-30 stress tests on the same subjects and obtain physician’s diagnosis for each. Do *not* compare the results until completing the full round of 20-30 tests.
3. Compare the results at the end.

Expected results: Assuming a normal healthy population, between 75% - 90% of those tested should correlate nicely. Exercise Stress Tests have been shown to be inherently imprecise and *your comparisons may differ*. Comparing these two tests *without* a gold standard (e.g., imaging), is in itself imprecise but enough to give you a good indication and similarity to a standard stress test. If and when discrepancies occur, consider the following:

- Other risk factors that might indicate the patient might be sick, even though a regular exercise stress test did not detect the disease
- Factors affecting heart rate such as diabetes, Parkinson’s, medication, mental stress & anguish, exertion during the HeartTrends test, etc.

Can I test unhealthy people with HeartTrends? Because HeartTrends is measuring the normal healthy heart rate variability, anything artificially affecting those measurements could affect and yield an inconsistent result. For example:

- Subjects with known heart disease may be taking medication that artificially constrains their heart rate
- Subjects with pacemakers
- Subjects who have undergone a recent intervention which may affect HRV
- Anyone on a treadmill running at a high heart rate self-limits the heart’s variability, hence, affecting the test’s validity.