

6.2 billion/yr.



HeartTrends®

Early cardiac screening for healthy individuals



Exclusive: Early Ischemia Detection



HEART DISEASE: #1 CAUSE OF DEATH IN THE WORLD*

- ❑ 90% of ischemic heart disease may be **preventable** with *early detection***



* - www.WHO.int (2017)

** - Preventing Heart Disease in the 21st Century. [Circulation 2008 117:1216](#)

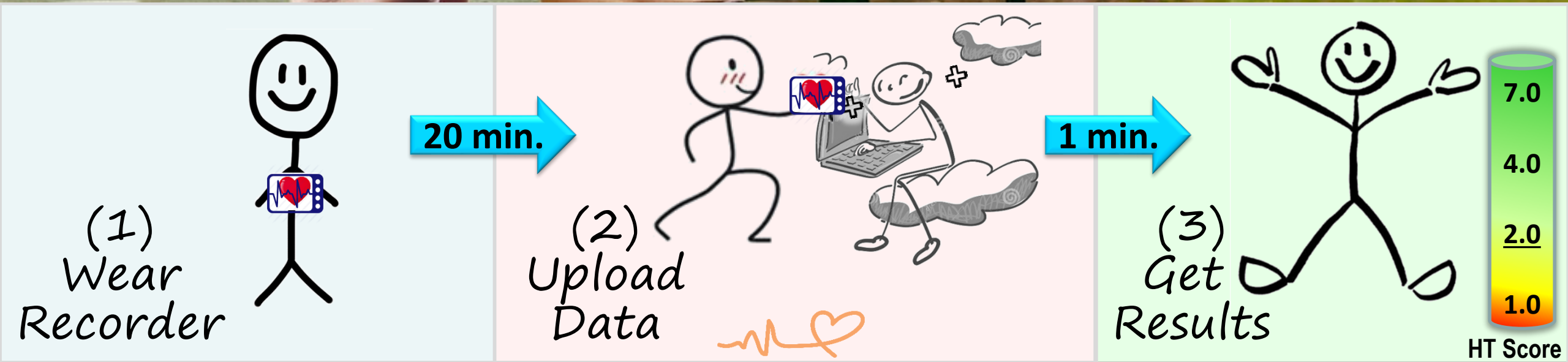




SaaS

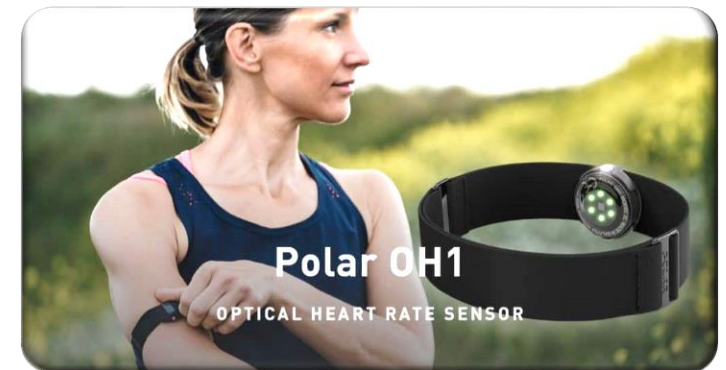
Device-agnostic

HeartTrends®



What?

- ❑ **Reliable Cardiac Screening**
 - Similar to Exercise Stress Test
- ❑ **No stressful maneuvers**
- ❑ **Only 20 minutes** of recording needed
 - Analyze heart rate from any device
- ❑ **Instant results** using cloud-analysis
- ❑ **Fraction of the cost**
- ❑ **Clinically proven:** 42,000 tests performed
- ❑ **CE-approved; FDA-cleared** algorithm, Patented
 - Pending: Cofepris (Mexico), Anvisa (Brazil)



Who?

Early ischemia detection test for:

- ❑ **Healthy people** with one or more risk factors
 - *Smoking, family history, high blood pressure, cholesterol, diabetes, or age >40 yr.*
- ❑ **Treadmill-challenged**
 - *Elderly, overweight, handicapped – 30% of population*
- ❑ **Chest Pain Syndrome** (reflux, heartburn, etc.)



Peer-Reviewed
THE CLINICAL EVIDENCE



SUBJECTS

451*



1,043*



*- Gold Standard: Echo Stress or MPI



MAYO CLINIC - WORLD'S LARGEST PROSPECTIVE CLINICAL STUDY - 1,043 SUBJECTS



HT vs. EST	HeartTrends®	EST
Sensitivity	71%	33%
NPV	97%	94%

J. American Heart Assoc. (2019)

EST: **E**xercise **S**tress **T**est
NPV: **N**egative **P**redictive **V**alue



www.ahajournals.org/doi/pdf/10.1161/JAHA.119.014540

HEARTTRENDS® OUTPERFORMS EXERCISE STRESS TEST (EST) COMPARED TO MYOCARDIAL PERFUSION IMAGING

Clinical Study on 451 Subjects; Important Noninvasive Technique for
Early Detection of Myocardial Ischemia (Goldenberg, et al)

The
American Journal
of Cardiology

Am. J. Cardiol. 115:1518 (2015)

	HeartTrends®	EST
Sensitivity *	77%	27%
NPV **	98%	94%

EARLY DETECTION (6-MONTH FOLLOW-UP)
73% had angiographically-detected Coronary Artery Disease

* Sensitivity: % of Positive (sick) patients identified by test (HeartTrends or EST) out of the **truly** Positive results

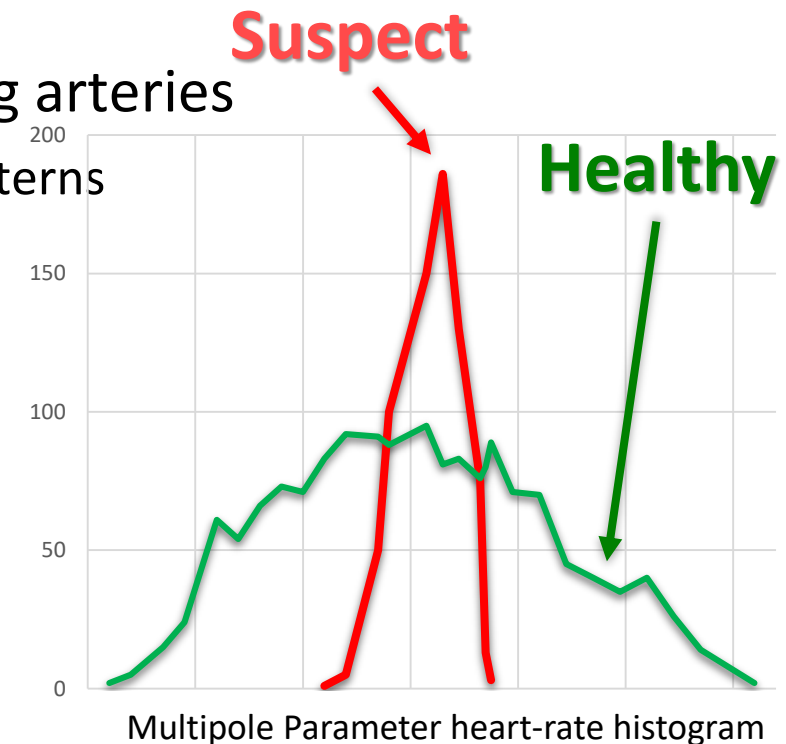
** Negative Predictive Value: % of **truly** Negative (healthy) patients, compared to Gold Standard, out of **entire** Negative results. Individual results may vary and even be lower



Science behind HeartTrends®

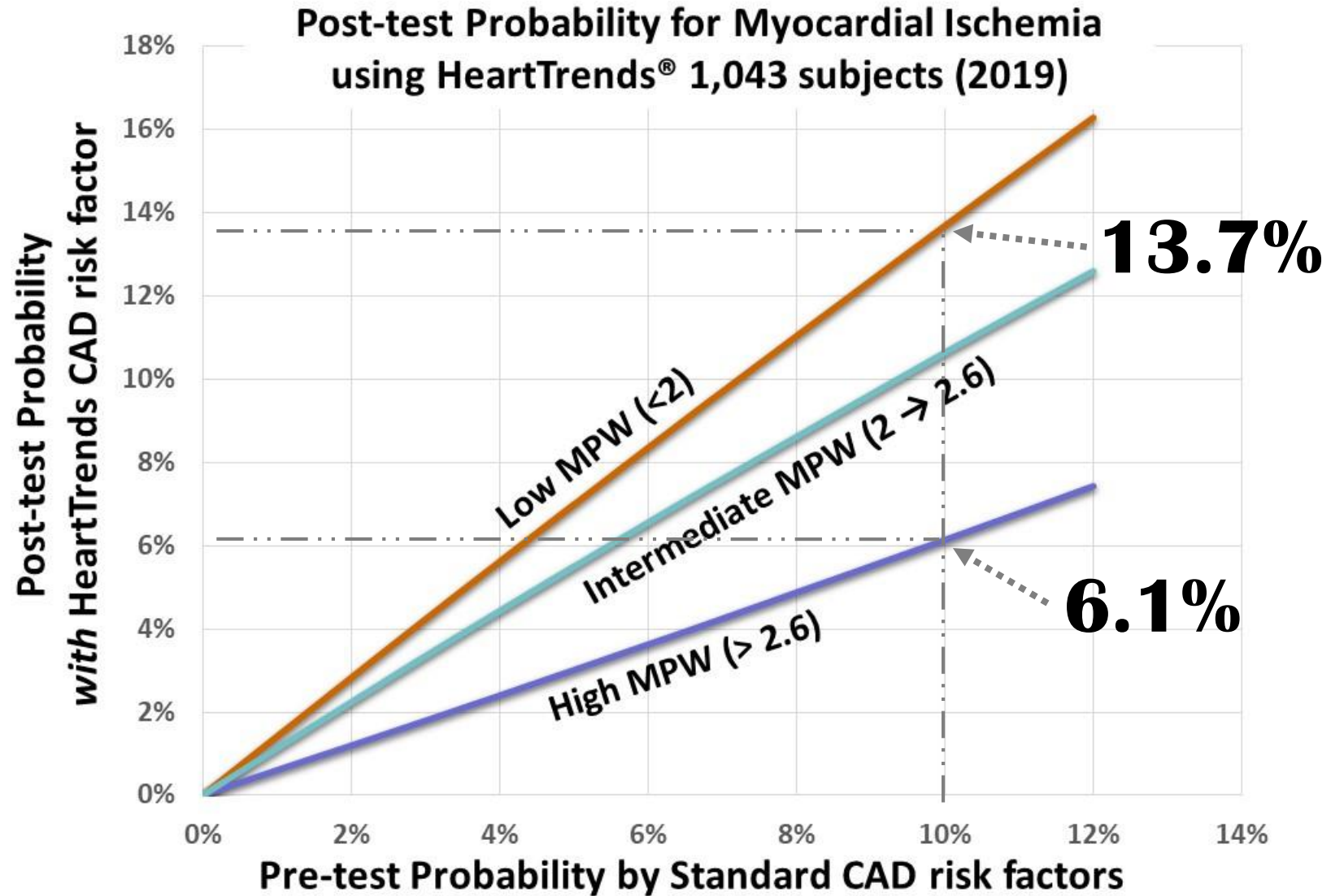
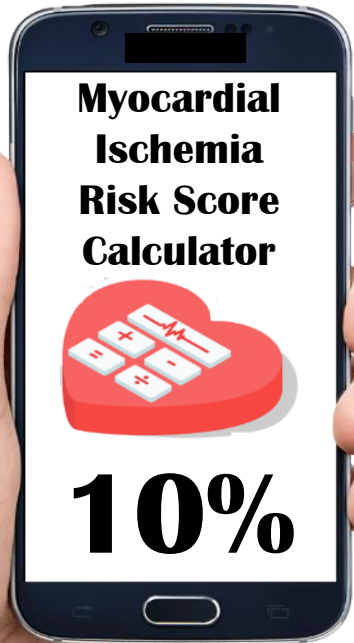
Autonomic Nervous System (ANS) functionality

- ❑ “Decreased HRV associated with coronary artery disease likely for early detection of myocardial ischemia”
 - Framingham Heart Study (*Circulation*. 1996; 94:2850)
 - Other ANS effects on Diabetes and Parkinson’s
- ❑ HeartTrends monitors ANS instead of artificially stress testing arteries
 - As ischemia develops, ANS “compensates” by altering heartbeat patterns
 - As ischemia intensifies, the feedback “swings” attenuate
- ❑ HeartTrends® **Multipole Parameter Weight (MPW) Analysis**
 - Utilizing **Non-linear** physics’ **Chaos** Theory ... not simplistic HRV
- ❑ HeartTrends MPW calculates 3 dimensions:
 1. **Time**
 2. **Frequency**
 3. **Randomness**



Using The New CAD Risk Factor -- in Action

(Actuarial table for Life Insurance, et al)





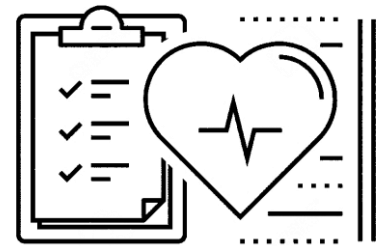
Go-To Market Strategy

RISK REDUCTION



Life Insurance

HEALTH



Checkups

AUTO



Automotive Health

MILITARY



Soldiers/Police

FITNESS



Digital Health SmartWatch

MEDICAL



Chest Pain Syndrome



HeartTrends[®] Market Strategy



Life Insurance

Life Insurance: 90M new policies/yr. worldwide^{1,2}



“Swiss Re has investigated the HeartTrends test as an alternative for the traditional exercise stress test for underwriting.
Swiss Re recognizes HeartTrends as an alternative, non-invasive test for the **early detection of cardiac ischaemia** when assessing underwriting risk of potential **life insurance applicants...**”



1. www.statista.com/statistics/207651/us-life-insurance-policies-in-force
2. Swiss Re.com



HeartTrends® Market Strategy



Checkups

- World's Healthy Population¹ 6.2 billion (84%)**
- US Cardiac Treadmill Tests² 3.8M annual (\$433M/yr.)**
 - Health Checkups (US)³ 193M annual (\$19.6B/yr.)** (ISR, BRZ, MEX)
 - US Military⁴ 2.1M active/reserves; 17M eligible** (US AF bid)
 - Civil Aviation Pilots⁵ 650,000 worldwide** (EUR, S. Afr)
 - China mandatory annual health checkup 1.5B tests/yr** (in progress)
 - India: 60% world's cardiac ischemia 1B tests/yr**
 - Pre-diabetes detection** (research Denmark)

1. *Worldpopulationreview.com; JAMA. 2015; 314(18):1905 (non-cardiac disease)*

2. *NIH: Annals Internal Med. 161:482–490 2014 & Circulation. 131:e29–322 2015*

3. *National Ambulatory Medical Care Survey, 2014*

4. [Selective Service System, 2018](#)

5. www.faa.gov/data_research/aviation_data_statistics/civil_airmen_statistics/

Chest Pain Syndrome: for *non-cardiac* chest pain (Heartburn, Reflux, Anxiety etc.)

- ❑ **Second Leading Cause** of Emergency Room (ER) Visits¹
 - 76% of chest pains are *Non-Cardiac*²
- ❑ HeartTrends for **differential diagnosis** of Chest Pain Syndrome

Conditions for Use:

1. Individuals *without* known CAD
2. Some risk factors
3. Presenting with *non-anginal* chest pain + clean ECG

Exclusion Criteria:

1. Subjects with chest pain who already have known CAD
2. Typical chest pain
3. ECG with pathologic ischemic changes and/or positive troponin



Chest Pain Syndrome

1. www.cdc.gov/nchs/fastats/emergency-department.htm

2. [J. Am. Col. Cardiol. \(JACC\) 71:617 2018](#)



Lev-EL Personnel



Dr. Dov Rubin, CEO, expert in non-invasive medical technologies. Prior to his position as CEO of Lev-EL Diagnostics producing an effortless stress test alternative for early detection of cardiac ischemia, he was Pres. & CEO of Itamar-Medical (TASE) for early detection of heart disease & sleep apnea & acquired by Zoll for \$583M. He was also Sr. VP at HealthWatch creating textile ECG-sensing garments communicating to smartphones for around-the-clock personal monitoring. Dov was co-founder of NDS (NASDAQ), the leading supplier of secure digital Pay-TV delivery to over 350 million worldwide viewers which he started in 1988 along with News Corporation's Rupert Murdoch earning annual revenues of \$850M and ultimately acquired by Cisco for \$5B.



Prof. Jacob Levitan, CTO, internationally known physicist, Professor at the University Center of Ariel, and the University of Bar Ilan. Prof. Levitan is responsible for research projects with the Technical University in Lundtofte, Denmark and published widely in the areas of nonlinear physics & chaos theory.



Prof. Ilan Goldenberg, MD, Chief Cardiologist, Director of Clinical Cardiovascular Research at the University of Rochester Medical Center. He was Director of the Dept. of Cardiology at Sheba Medical Center, Tel Aviv. Prof. Goldenberg is the associate editor of Annals of Noninvasive Electrocardiography. He has published over 300 articles in cardiology including myocardial ischemia.



Dr. Ilan Gur MD, Chief Medical Officer, Vice President Medical Management in Bikur Rofe, the leading private company in Israel for primary and emergency medical services. He was Director of the Neonatal Department (2003) and NICU (1998) in Bikur-Cholim Hospital.



6.2 billion/yr.



The Effortless Stress Test Alternative

Early cardiac screening for healthy individuals

Fitness



Medical

Health

Stress Testing

with  out Stress

