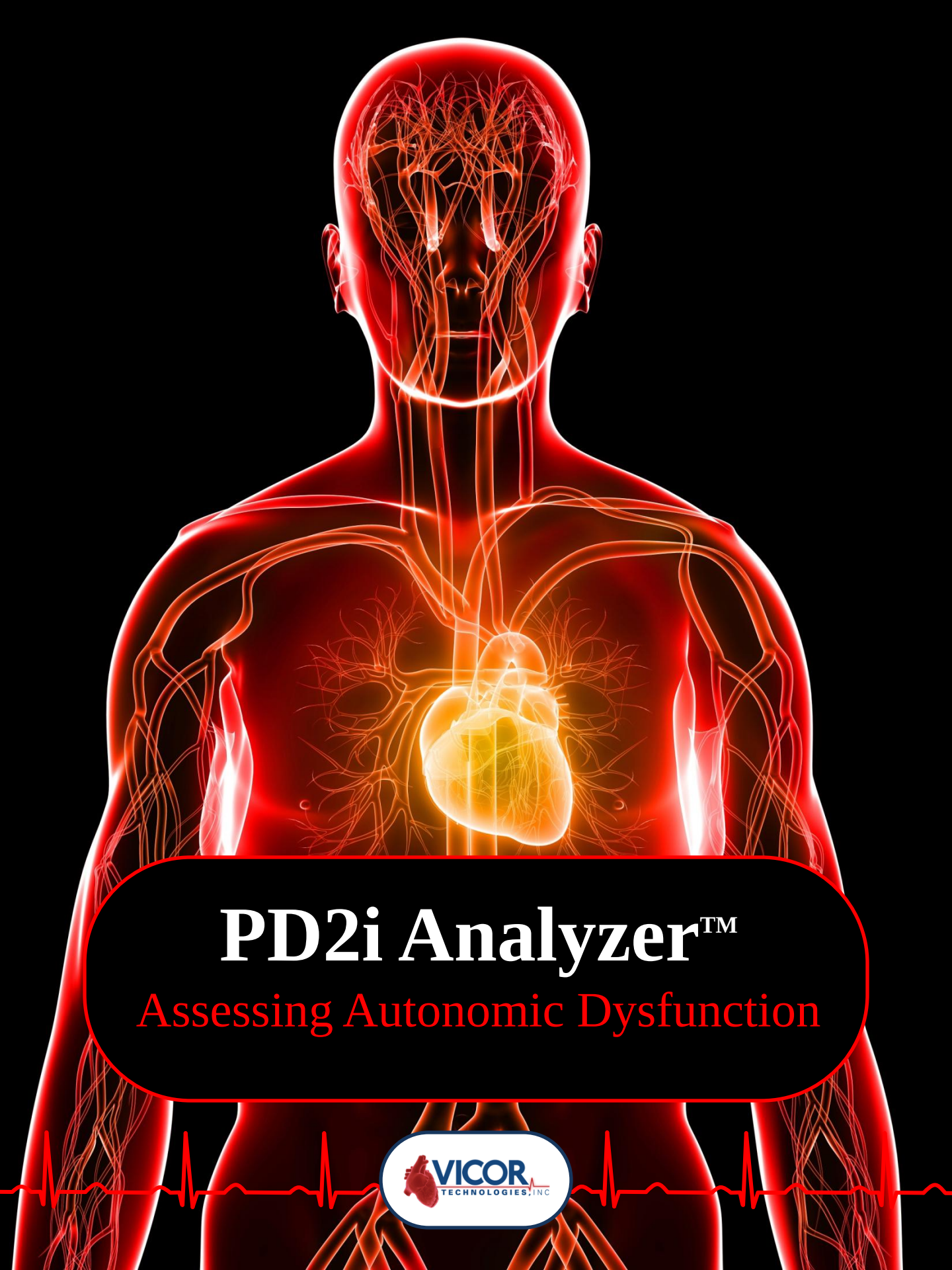

PD2i Analyzer™

Assessing Autonomic Dysfunction

VICOR TECHNOLOGIES, INC

Detecting the 'Silent Killer' Cardiac Autonomic Neuropathy

An estimated 60% of people with diabetes have some form of nerve damage or neuropathy. While diabetic neuropathy rarely involves the nerves of the brain or spine, signaling to and from other parts of the body can be impaired.

Nerves control everything from heartbeats to balance. The brain-to-heart signal processing forms a complex network which needs to accommodate for changes in activity and other bodily functions. Heart Rate Variability is a valid measure of Autonomic Nervous System health.

The PD2i Analyzer™ readily allows for this assessment in the office setting.

Cardiac Autonomic Neuropathy in diabetes has been called a "silent killer", because so few patients realize that they suffer from it and yet its effect can be lethal.

Early detection of Cardiac Autonomic Neuropathy and intervention are of prime importance for risk stratification in preventing life threatening cardiac events. Analyzing Heart Rate Variability is a valuable tool in detecting autonomic neuropathy.

Cardiac Autonomic Neuropathy occurs in 22% of Type 2 diabetics, and in 17% of Type 1 diabetics[1]. 25–50% of patients exhibiting symptomatic autonomic neuropathy die within 5-10 years[2]

Symptoms | **Autonomic Disorders** | **Conditions**

- Depression
- Fatigue
- Orthostatic Hypotension
- Sexual Dysfunction

- Diabetes
- Hypertension
- Heart Failure
- Ischemia

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[1]American Diabetes Association www.diabetes.org
[2]The DiaCAN Multicenter Study Group. Diabetes Metabolism 1993
[3]Diabetes Mellitus Manual, S. Inzucchi 2005

VICOR's PD2i Analyzer™ enables you to comply with the American Diabetic Association's recommendation for detecting Cardiac Autonomic Dysfunction by evaluating precise R-R changes to simple physiological challenges. These critical tests can be performed in your office using the 4-step PD2i Analyzer™.

The ADA recommends testing for Cardiac Autonomic Neuropathy at the time of initial diagnosis for Type 2 diabetics and 5 years after diagnosis for Type 1 diabetics.[3]

PD2i ®– Tim's Story

Tim is a 60 year old hypertensive diabetic with coronary arterial bypass surgery 3 years prior. He was seeking clearance for knee surgery. His history was negative for angina, orthopnea and palpitations but positive for mild depression, fatigue and erectile dysfunction.

Tim was tested with the PD2i Analyzer™. The Valsalva and orthostatic components revealed Autonomic Nervous System (ANS) Dysfunction. The ECG from the PD2i® showed normal sinus rhythm, no evidence of old or acute injury. Chest x-ray and labs were unremarkable except for an elevated HbA1c.

Interventions:

1) Nuclear stress test performed due to known increased incidence for silent MI and mortality in diabetic patients with ANS Dysfunction. The result indicated no reversible ischemia.
2) Metoprolol dosage was reduced resulting in marked improvement in fatigue and erectile dysfunction.
3) Tim was approved for surgery with anesthesia alerted about hypothermia and hypotension risk.
4) Patient education with regard to heat and exercise precautions as well as instructions about glucose control to inhibit further autonomic nerve damage.

"The PD2i Analyzer™ has allowed me a new window into the physiologic health of my diabetic patients, and this information influences my daily medical decision making. "

Dr. Paul Freel, Dillon, SC

4 Stages of PD2i Analyzer™ Testing

The PD2i Analyzer™ provides results for 3 standardized physical challenges of the Autonomic Nervous System

12 Minute Resting Baseline	Metronomic Breathing	Valsalva Maneuver	Orthostatic Challenge
Gathers EKG data to produce the PD2i® score	**Detects the effect of paced respiration on Heart Rate Variability**	**Detects the effect of forced exhalation on Heart Rate Variability**	**Detects the effect of postural changes on Heart Rate Variability**

PD2i Analyzer ™ – Results in Minutes

- ✓ Packaged complete with the following:
  - EKG signal box
  - Adjoined blood pressure cuffs
  - Paired to private label computer
  - Proprietary algorithm and software
  - Valsalva mouthpiece
  - Internet connection
- ✓ Menu driven prompts
- ✓ 18 minute procedure
- ✓ Full analysis and interpretive reporting
- ✓ Also acts as a resting ECG unit
- ✓ Toll free support available

STATEMENT OF INTENDED USE: The Vicor PD2i Analyzer™ is intended to display and analyze electrocardiographic information and to measure heart rate variability (HRV) in patients at rest and in response to controlled exercise and paced respiration. These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

CPT CODE	DESCRIPTION	2010 NATIONAL REIMBURSEMENT AVERAGE	SUBMITTAL REQUEST
95921	Parasympathetic Nervous System Testing	$79.84	$150
95922	Sympathetic Nervous System Testing	$98.53	$150
93000	Routine ECG with at least 12 leads; with interpretation and report	$19.71	$25
93040	3 lead ECG rhythm strip with report	$13.25	$17

Sympathetic and Parasympathetic testing (95921 & 95922) are separate and distinct procedures. A -59 or -52 modifier may be required. These rates are not a guarantee of payment. Please refer to your billing resource for specific state and payor rates and rules.

VICOR TECHNOLOGIES, INC

2300 NW Corporate Boulevard Boca Raton, FL 33431
877.528-PD2i (7324) info@vicortech.com