

PD2i Analyzer™

Vicor Technologies, Inc.

The Science Behind Heart Rate Variability (HRV) Measurement

- The PD2i Analyzer™ has FDA 510K clearance for HRV measurement.
- HRV has been an accepted measure of autonomic nervous system (ANS) function for 20 years.**
- The PD2i Analyzer™ measures HRV during 3 safe and simple physical challenges.
- The computer generated results are compared against known normal values based on age and sex.
- HRV failure and somatosensory failure occur independently.

Benefit to the Patient

- The PD2i Analyzer™ brings research level technology into the clinic to improve patient care.
- Symptoms of autonomic neuropathy tend to occur when nerve damage is advanced and difficult to treat. Early diagnosis is now possible in the clinic setting by the physician's interpretation of the PD2i Analyzer™ test results.
- The ADA has recommended annual screening for autonomic neuropathy in diabetics.

Why Seek to Diagnose ANS Disease in Diabetic Patients? They have:

- Increased operative risk
- More Hypoglycemic unawareness
- More visual impairment
- More gastroparesis
- 2x rate of silent MI with 2x mortality
- More orthostatic hypotension
- Need for guided exercise programs
- More prone to heat stroke

- The provider can identify opportunities to optimize medications.
- One can use an abnormal result to motivate the patient to obtain better glucose control and begin an exercise program as intense diabetic therapy delays the progression of ANS dysfunction and exercise increases vagal tone.
- ICD 337.9 is autonomic dysfunction—If a patient has abnormal HRV testing, then one should note this in the patient's diagnosis list so that these at risk patients will be properly treated in future medical encounters.

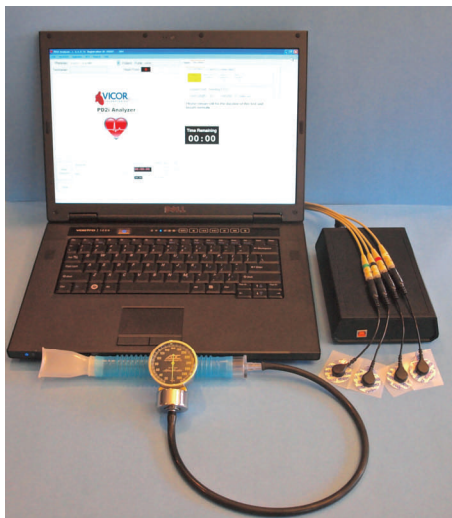
Possible Management When Testing the Diabetic Patient

Test Normal —> Repeat in 1 year.

Test Abnormal —>

1. Chart the diagnosis of Autonomic Dysfunction (337.9) in the patient's diagnosis/problem list.
2. Begin an exercise program which can improve vagal tone. Consider stress test.
3. Press for better DM control which will delay the progression of ANS dysfunction. Use the abnormal test as a motivator.
4. Check to see if patient is on medications that might depress the ANS like B-blockers, alpha-blockers, clonidine, TCA, Benzos?
 - No —> Repeat in 1 year for trending.
 - Yes —> Inquire for symptoms of ANS dysfunction like fatigue, depression, sexual dysfunction, diarrhea, constipation, orthostasis, heat intolerance, or wheezing.
 - Absent —> No medication changes.
 - Present —> Consider dose reduction or a change of suspected medications and retest in 3 months.

The Device



The PD2i Analyzer™ is comprised of:

- A Wi-Fi enabled PC with the PD2i® data collection software
- ECG signal box
- ECG leads
- Valsalva device

The PD2i Analyzer™ also performs 12 lead ECGs (\$2,500 value).

Testing Population

- The ADA has recommended annual screening for autonomic dysfunction in your diabetic population.
- Other Medicare covered diagnoses include Hypertension (HTN), Myocardial Infarction (MI), Angina, Cardiomyopathy (CM), Congestive Heart Failure (CHF), Renal Failure (RF), Asthma, Chronic Obstructive Pulmonary Disease (COPD).

Financials

- 24 million diabetic patients in the United States.
- New area of practice revenue.
- Extremely low start up cost for a piece of medical equipment, \$6,500.
- No test volume commitment.
- Test fee payment waived for any documented payment denials so you may provide excellent patient care without non-payment concerns.
- Minimal cost of consumables—4 ECG patches, one mouthpiece (<\$2/test).
- Very profitable—\$90/test with excellent insurance coverage.
- 4 tests/day can generate >\$85,000 profit/year.
- CPT codes 95921, 95922-52, 93040, 99211 (your representative can provide a customized revenue projection based on your payer mix).
- A new model for medical device placement—Minimal initial cost with payment for the technology through a per test fee.
- Excellent support (U.S. based) with overnight equipment replacement.
- Excellent insurance coverage—Medicare, Medicaid (managed also), BC/BS, Cigna, United Healthcare, Blue Choice, Carolinas Care Plan, Humana, Care Improvement, Tricare (See posted remittances*).

Testing Personnel and Time

- This test can be administered by non-medical personnel in 30 minutes.

Interpretation

- The test is simple to interpret.
- Learn the basics in just 30 minutes online at your convenience by viewing the tutorials* along with the PD2i® Resource Manual or your representative will put you in contact with a physician advisor.

Contact Information

VF Medical (www.vfmedical.com) is the Authorized Distributor of the PD2i Analyzer™ by Vicor Technologies, Inc. (www.vicortech.com).

*www.vfmedical.com

**PD2i® Educational Resource Manual

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