



1

# AUTONOMIC, VASCULAR AND CARDIO RISK ASSESSMENTS

A NEW TESTING TOOL FOR  
DIAGNOSING HIDDEN  
ILLNESSES



# Millions of Americans Have Chronic Disease That Goes Undiagnosed.



NEARLY 1 IN 4 FOUR ADULTS LIVING WITH DIABETES – 7.2 MILLION AMERICANS – DON'T KNOW THEY HAVE THE CONDITION<sup>1</sup>.



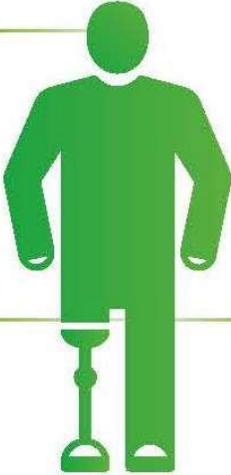
50% OF PEOPLE WITH PERIPHERAL ARTERY DISEASE (PAD) ARE ASYMPTOMATIC<sup>2</sup>

1. More than 29 million Americans have diabetes; 1 in 4 doesn't know. (2014, June 10). Retrieved from <https://www.cdc.gov/media/releases/2014/p0610-diabetes-report.html>.
2. Frequency of asymptomatic peripheral arterial disease in patients (2004., May). Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/15224456>



# Undiagnosed Disease Has Serious Health Consequences

**PAD**  
often goes undiagnosed by healthcare professionals



Left untreated PAD can lead to **GANGRENE & AMPUTATION**



People with PAD have **4X to 5X GREATER RISK** for heart attack or stroke



# When Symptoms Do Appear, They Can Often Be Complex and Hard to Diagnose:

## Scenario 1:

A Patient comes in complaining of unexplained fainting, dizziness or fluttering heart rate.

*✓ How can the physician quickly assess if the patient is suffering from chronic vascular disease?*

## Scenario 2:

A Patient comes in complaining of sharp pains in the legs or feet.

*✓ How can the physician tell if the pains are due to underlying metabolic illness such as diabetes?*





**Philip A. Mongelluzzo, Jr., M.D., CMO**

**Board Certified Internal Medicine**

**One of the foremost authorities in this space.**

Could no longer solely rely on the Gold Standard EKG to give enough information

## **Certifications:**

American Board of Internal Medicine Subspecialty Sleep Medicine  
Medical Education

Creighton University School of Medicine  
Residency

Atlanta Medical Center

Yale Primary Care Internal Medicine Residency

Dr. Mongelluzzo received his medical degree from Creighton University School of Medicine, followed by residencies at Atlanta Medical Center and Yale University. He has maintained a primary care practice in Waterbury for many years, providing comprehensive, patient-centered care for men and women.

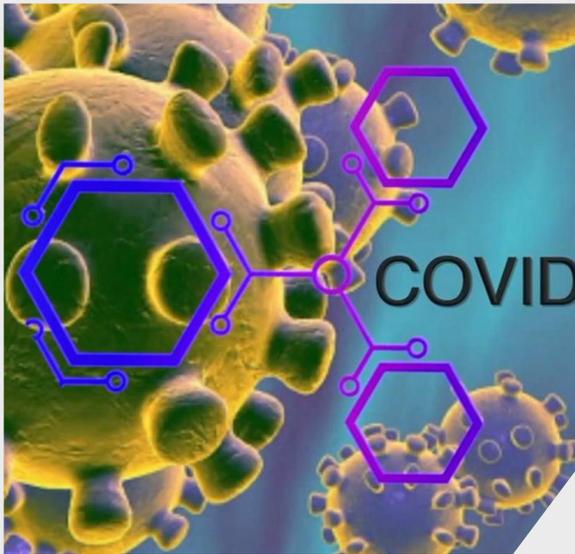
Dr. Mongelluzzo is focused on helping his patients achieve and maintain optimal health and wellness at every age.

His areas of clinical interest include asthma, diabetes, hypertension, fibromyalgia and neuropathy.

**3.5 Minute Brief Intro <https://bit.ly/2Zqai21>**

# COVID-19

## WHAT YOU NEED TO KNOW:



- ▶ Uncover underlying asymptomatic conditions related to COVID-19
- ▶ Comorbidities greatly affect the recovery rate
- ▶ Much more than a pulmonary disease.
- ▶ Total body inflammation process.
- ▶ Journal of American College of Cardiology
  - ▶ “COVID may predispose to thrombotic disease, both in the venous and arterial circulations, due to excessive inflammation, platelet activation, endothelial dysfunction and stasis“.
- ▶ American College of Cardiology:
  - ▶ “Cardiovascular comorbidities are common with COVID-19 “.



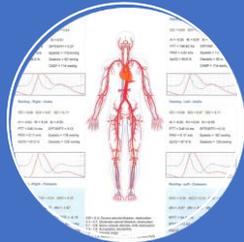
What if the physician could quickly evaluate the patient for several types of chronic illnesses right from the office without having to refer out?





### Technology

- FDA Cleared Type II Medical Device
- Small-office footprint
- Portable mobile cart



### Medical Reports

- Instant easy-to-interpret 3 page report based on our Proprietary Algorithm
- 40-Page archived report via secure cloud-based database hipaa compliant



### Medical Technician & Account Manager

- Employees of Pulse 4 Pulse
- Screens Patients
- Performs Test
- Schedules Patient's Follow-up



### Billing

- Determine insurance eligibility
- Submit claims
- Resolve disputes

**Turnkey System**  
**Seamless Integration into Practice**

**All-In-One Fee-for-Service**



**We believe that Early Detection or Early Detection Medicine (EDM) is the key to successful treatment.**

**Our Mission:**

To empower the physician to proactively identify disease indicators in asymptomatic patients by utilizing cutting edge preventative screenings and technologies while improving the overall patient experience.



# 3 Main Tests to Identify Asymptomatic Diseases

- We report the heart-rate variability with beat-to-beat blood pressure in the patient after deep-breathing, head-tilt and Valsalva maneuver tests and compare to base-line.
- Many diseases of the nervous system identified

## 1. Autonomic Nervous System (ANS)



- Device stimulates the patient's sweat glands by emitting a low voltage through a glass plate.
- Results for this tests helps physician determine if the patient is going to be at risk of vascular disease or neuropathy.

## 2. Sudomotor Test



- A measurement of the ratio of blood pressure of the upper and lower body
- Indicates if the patient is suffering from vascular disease.
- Ability to test the vascular system at the micro-level

## 3. Ankle-Brachial Index Test (ABI)



# Uncover Possible Major Illness & Other Hidden Diseases

Peripheral Artery Disease

Complex Pain Disorders

Atherosclerosis

Sleep Apnea

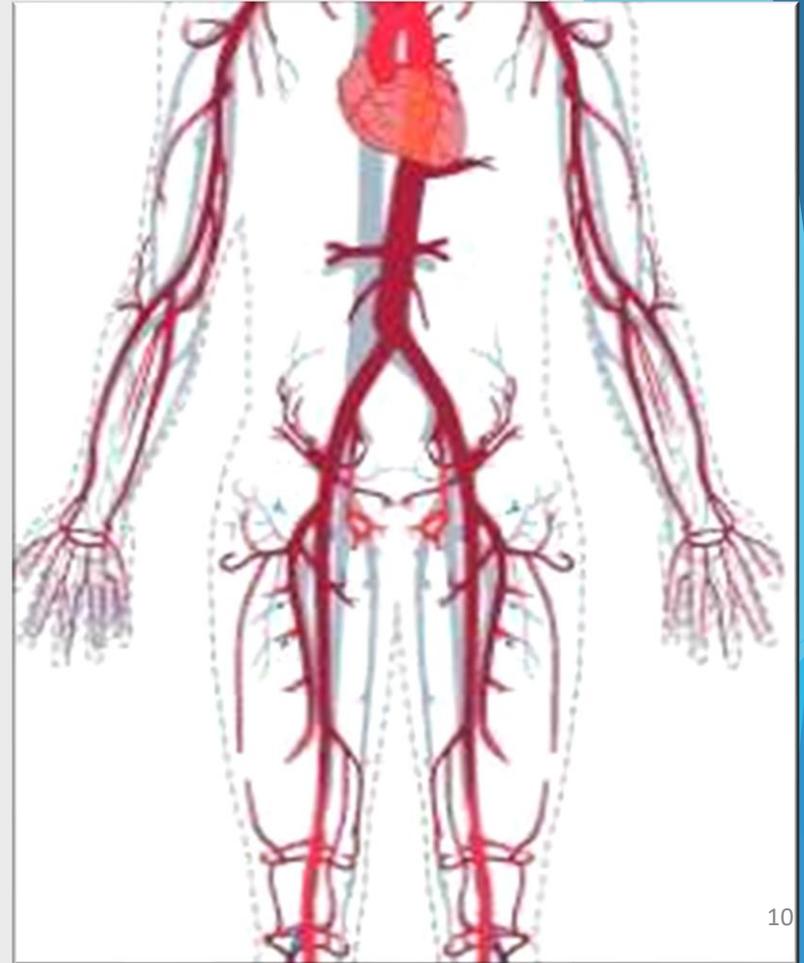
Hypertension

Diabetic Neuropathy

Cardiac Autonomic Neuropathy

Vascular Abnormalities

Type 2 Diabetes



## What is a screening?

Pulse 4 Pulse preventive health screening services are designed to identify risk factors that can lead to heart disease, stroke and other serious illnesses.

We use three non-invasive methods to get you real time accurate results and recommendations you can review with your doctor.

## What to expect as a Patient:

- Simple screening questionnaire in your medical provider's office
- If eligible medical assistant will perform the non-invasive test conveniently in your medical provider's office
- Results & recommendations immediately sent to your doctor
- Your medical provider will discuss the findings with you
- Follow your medical provider's recommendation
- If necessary, schedule follow up test to monitor any changes



## **Peripheral Artery Disease Screening**

Peripheral Arterial Disease (PAD), more commonly known as hardening of the arteries. PAD is a condition in which the large and medium-sized arteries supplying blood to the legs become narrow or clogged, constricting the flow of blood.

### **Who Qualifies for this Screening?**

- Anyone with risk factors

### **Ages**

- 18+

### **Frequency**

- Up to 4 times per year

## **Risk Factors**

- Family history of cardiovascular disease or stroke
- Tobacco usage, past or present
- High cholesterol
- Diabetes
- Obesity
- High blood pressure

## **Screening Details**

A quick and non-invasive procedure, PAD screening is done by using the ankle-brachial index (ABI). The ABI vascular test compares the blood pressure in your legs to your arms. After removing your socks and shoes, you will have pressure cuffs placed around your upper arms and ankles. A small ultrasound device will then measure the systolic blood pressure in your limbs.



## Atrial Fibrillation Screening

Atrial Fibrillation is an irregular heartbeat and can affect the heart's ability to pump blood. Afib increases the risk of stroke by 5 times.

### Who is this screening for?

Atrial fibrillation screenings are recommended for anyone with risk factors for stroke or carotid artery disease

### Ages

- 50+

### Frequency

- Up to 4 times per year

## Risk Factors for Afib

- Diabetes
- High Blood Pressure
- Coronary artery disease
- Smoking
- Overactive Thyroid
- Heavy alcohol or caffeine consumption
- Obesity
- Sleep apnea

## Screening Details

Atrial Fibrillation screening is painless, non-invasive, and does not require the removal of any clothing. While you are lying on your back, the technician will attach EKG electrodes to your arms and wrists and take readings.



# Practice Types-We Work With:

Solo-Medical Practices

Diabetic Medicine

Internal Medicine

Nephrology

Multi-Specialty Medical  
Groups

Endocrinology

Neurology

Weight  
Management

Hospital and Healthcare  
Groups

Family Practice

Neurosurgery & Spine

Wound Care

Cardiology

Gastroenterologist

Ophthalmology

Urology

Geriatric Medicine

General Practice

Orthopedic

OB  
Gynecology

Integrative Practice

Pain Management



# Billing Codes

## Up To 5 Billable Diagnostic Tests

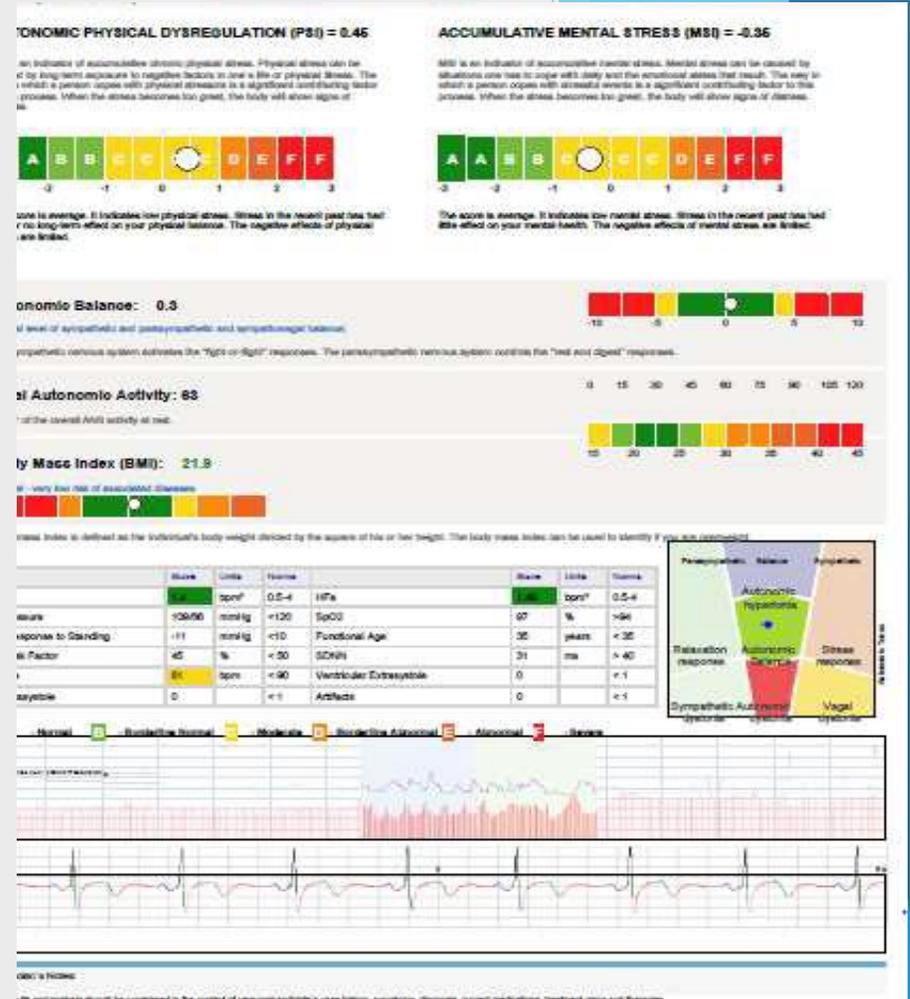
- Ankle Brachial Test (93923)
- Autonomic Function Test (95921)
- Sudomotor Test (95923)
- Electrocardiogram (93040)
- Pulse Oximetry (94761)

## Additional Billing Code

- Follow-up Office Visit (99213, 99214)

**Follow-up visits can also be done by Telemedicine**

The codes are the same as the normal follow up visits 99213 or 99214 for example. Together with a modifier depending on the payor like GT, 95, or POS 02 (place of service)



**Instantly Available Easy-to-interpret Report**



# Proven Care Standards

- Testing of the ***autonomic nervous system (ANS)*** is recommended standard of care by the American Diabetes Association for patients with Type 1 and Type 2 diabetes.
- The American Heart Association Practice Guidelines for the management of patients with peripheral artery disease include the ***measurements of ankle-brachial index (ABI)*** in adults over 50 years old with a history of smoking, diabetes, or circulation problems, and all adults over 70 years old.



# Proven Care Standards

**ANS** analysis measures neuro-cardiac function which reflects heart-brain interactions and autonomic nervous system dynamics. The ***autonomic nervous system*** is involved in the function of virtually every organ system and clinical manifestations of ***autonomic dysfunction*** are involved in just about every disease.

Measures of ***autonomic nervous system*** activity and lower urinary tract symptoms



The American Board of Neurological Surgery®  
Member Board of the American Board of Medical Specialties



American  
Urological  
Association

Advancing Urology™



# How It Works

1. Patient completes simple patient questionnaire.
2. Pulse 4 Pulse Medical Technician explains test to the patient and performs the Test during office visit.
3. Pulse 4 Pulse Technician provides "Real Time" results to the Practice
4. Pulse 4 Pulse Technician schedules Patients for follow up visits for Downstream Revenue for the Practice.
5. Pulse 4 Pulse bills insurance on behalf of physician.
6. Physician receives full remittances directly to their Practice.
7. Pulse 4 Pulse invoices practice
8. Testing allowed up to 4 times a year by Medicare/Medicaid & Private Insurance



✓ Portable, streamlined Mobile Cart offers mobility for testing service

✓ Small office space footprint

✓ FDA Cleared Device

14



# Medical Necessity is Determined By Answering “Yes” to Only One of These Questions

## Patient Questionnaire

1. Have you been diagnosed with COVID-19 or have been exposed?
2. Do you have diabetes?
3. Do you have high blood pressure?
4. Do you have high cholesterol?
5. Do you have sleep apnea?
6. Do you have erectile dysfunction?
7. Do you have chronic kidney disease?
8. Do you have heart disease?
9. Do you smoke?
10. Do you ever get pain or numbness in your fingers, hands, toes or feet or do they ever feel cold?
11. Do you ever get pain in your legs when you walk?



**60% of patients qualify**



# Billing

## Two Options

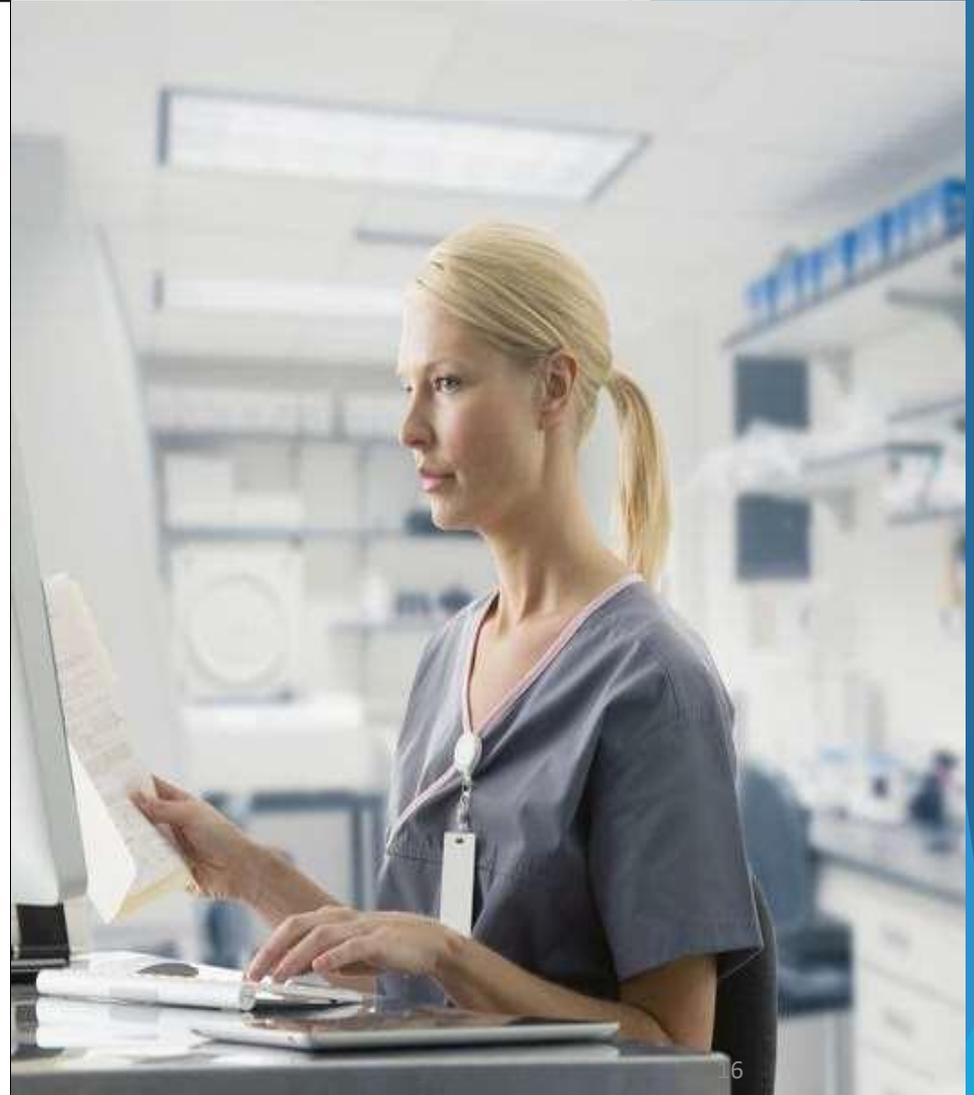
### Option 1:

- Billing provided by Pulse4Pulse team via national platform AdvancedMD.
- *6-week lead time to setup in clearing house.*

### Option 2:

- Practice bills through their existing system
- Pulse4Pulse provides expert billing liaison.
- *2-week lead time.*

***Full Reimbursements Paid Directly to the Practice***



# Finances and Revenue

After Pulse 4 Pulse, LLC fees for services provided, the average net to the practice per patient screening is in the range of **\$160-170 per patient\***

**Additional revenue** is generated from follow up **99213, 99214** office visit codes **(not included in this estimate)**

Screenings Per Day	Per Month	Per Year	Estimated Revenue Per Year
5	100	1200	\$200,000
10	200	2400	\$400,000
15	300	3600	\$600,000

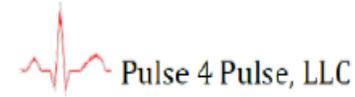
\* Actual revenue may vary based on location, successful implementation of protocol and payer.

\* Based on Medicare's National Average



# New Practice Submission Form (NPS)

- Required to provide Pulse4Pulse with necessary account information to start backend process internally
- Practice details for Pulse4Pulse to determine profitability for practice.
- Please complete as quickly as possible



## New Practice Submission Form

Representative: \_\_\_\_\_ DATE: \_\_\_\_\_

### PRACTICE INFORMATION

Legal Name of Practice: \_\_\_\_\_

Practice Type: \_\_\_\_\_

Practice Primary Address: \_\_\_\_\_

Additional Locations: \_\_\_\_\_

Main Phone: \_\_\_\_\_ FAX: \_\_\_\_\_

Number of Locations: \_\_\_\_\_ Number of Doctors: \_\_\_\_\_

Patient Volume per Month: \_\_\_\_\_ Expected number of tests per month: \_\_\_\_\_

Practice Days / Hours: \_\_\_\_\_

Payer Mix: \_\_\_\_\_

All Practicing Doctors Name and Specialties: \_\_\_\_\_

### PRIMARY CONTACT (Physician/Owner):

PRIMARY NAME \_\_\_\_\_ TITLE \_\_\_\_\_

PHONE \_\_\_\_\_ EMAIL \_\_\_\_\_

### OFFICE MANAGER CONTACT INFORMATION:

PRIMARY NAME \_\_\_\_\_ TITLE \_\_\_\_\_

PHONE \_\_\_\_\_ EMAIL \_\_\_\_\_

### BILLING MANAGER CONTACT INFORMATION:

PRIMARY NAME \_\_\_\_\_ TITLE \_\_\_\_\_

PHONE \_\_\_\_\_ EMAIL \_\_\_\_\_



# In Summary

## Better Patient Care

- Identify asymptomatic patients
- Diagnose at the micro-level
- Increased compliance with treatments
- Help patients prevent disease

## Increased Revenue

- \$200k per provider (full-time equivalent)
- Increased office visits by 15-20%
- Downstream revenue for multi-specialty groups

## Zero Start-Up Costs

- No capital expenditure
- No training of clinical staff
- No burden to billing staff



By systematically screening for chronic diseases in asymptomatic patients, our in-office diagnostic tests allows the physician to help patients prevent costly and invasive interventions later on...



# Getting Started



**Complete NPS Form**

**How many clients are seen per month?**

**What is the payer mix of practice?**



**Receive proforma report estimating revenue projection**



**Sign contract**



**Implementation within 2-6 weeks of signed contract**



# Frequently Asked Questions

# FAQ's 1

- ***I already have a diagnostic department in my medical group/hospital. Why would I need your service?***
  - ✓ Physicians typically refer patients to diagnostic departments when trying to diagnose patients with presenting symptoms. Our service screens for asymptomatic patients right in the doctor's office during the patients scheduled visit.
- ***I already use the ABI test, why would I use your service and lose the full reimbursement?***
  - ✓ Many physicians currently use the ABI Test during a yearly physical or when symptoms of vascular disease appear. We are screening all patients who pass through the office and who are potentially asymptomatic. With that said, we can do partial-tests that include everything but the ABI.
- ***My office would prefer to do the billing. Is that allowed?***
  - ✓ While we prefer to do the billing because of our experience with these specific codes we do let clients who request it do their own billing.

## FAQ's 2

### ***I don't have an extra room to dedicate to this.***

- ✓ The testing device is placed on a mobile cart for easy transportation and storage and requires a very small footprint.

### ***I don't have enough patients to justify your service.***

- ✓ We require at least 5 tests a day to justify a full-time 5-day-a-week onsite medical technician. With offices that see less than 20 patients a day a medical technician can stack patients to ensure that the minimum number of tests a day is met for a few days a week.

### ***Can the medical technician schedule the test with patients?***

- ✓ Yes

## FAQ's 3

### ***Can a patient be tested more than once?***

- ✓ Medicare approves the test up to 4 times a year.
- ✓ Repeat testing may also be ordered if there is a change in treatment and this is documented.
- ✓ Serial testing may be ordered every 4-6 months to ensure good patient care.

# Clinical Studies

ABI, ANS, and Sudomotor

## Selected Articles (ABI)

- ▶ Carol Davila. The Role of Ankle-Brachial Index for Predicting Peripheral Arterial Disease. *MEDICA -A Journal of Clinical Medicine* 2014;9(3):295-302.
- ▶ Ammar Ahor et al. Effects of Exercise Modalities on Arterial Stiffness and Wave Reflection: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Plos One* 2014;9(10):1-15
- ▶ Ziemssen, Tijalf and Siepmann, Timo. The Investigation of the Cardiovascular and Sudomotor Autonomic Nervous System -A Review. *Frontiers In Neurology*. 2019:10:53

## Selected Articles (ANS and Sudomotor)

- ▶ *The Investigation of the Cardiovascular and Sudomotor Autonomic Nervous System A Review. Ziemssen, Tijalf and Siepmann, Timo.*
- ▶ *Frontiers In Neurology. 2019:10:53*
- ▶ *Non-invasive, Quantitative, Measurements of Autonomic Nervous System Activity Levels: III. Improved ANS Balance Improves Clinical Outcomes, Ramesh K Adiraju, MD, FACC1; Joseph Colombo, Ph.D.2, Submitted To Clinical Autonomic Research*
- ▶ *Autonomic Nerve Testing Predicts the Development of Complications, Diabetes Care, Volume 30, Number 1, January 2007*

















