



Introducing the FDA approved TM-Flow

5 FDA clearances

- **Scientifically validated** our class 2 analytical medical device performs a complete patient health risk analysis.
- This exam is covered and reimbursed by most insurance.





“Think ANS First”

This will become your practice’s standard test for every patient.
This cutting edge medicine giving doctors significant insights into patient health.



- ■ The **TM-Flow ANS testing medical device** is a highly comprehensive, user-friendly, **non-invasive tool** that focuses on **early detection of over 20 disease states**. This is done through the **autonomic nervous system & vascular system** by measuring 8 health risk areas within the body.
- ■ This **ANS testing medical device** effectively measures the state of a patient’s health by screening for hidden causes of disease and chronic diseases such as diabetes and other cardiometabolic risks.



Assessment of health risks

Our ANS scan aims to offer physicians the necessary tools to assess health risks and potential for complications in the autonomous nervous system. The data within our test results are based on essential functions within the body.

FUNCTIONS INCLUDE

- Body temperature
- Heart-rate
- Digestion
- Rate of breathing
- Sensations

Our ANS scan monitors these functions to determine risk factors for a large variety of disease complications.



Bio-data analysis and reimbursement

The TM-Flow medical exam is reimbursable by Medicare and most private insurance. Practices can expect anywhere from \$300 - \$500 in reimbursements per exam.

- ■ ----- **Autonomic Nervous System**
- ■ ----- **Macro-vascular system**
- ■ ----- **Micro-vascular system**

This medical device validates over 120 bio-markers with specified CPT and ICD-10 codes reimbursable through most insurance carriers.

The codes this device use are 95923-95943-95921 and also use cardiometabolic code: 93923-93922



“Think ANS First”

8 out of 10 patients (on average) qualify to take this test

SYMPTOMS INCLUDE

- Blurred vision
- Elevated blood sugar
- Extreme thirst
- Frequent urination
- Fatigue (tiredness)
- Heartburn
- Increased hunger
- Nausea
- Numbness & tingling in hands or feet
- Vomiting
- Angina (severe chest pain, often spreading to shoulder, arm, back, neck, or jaw),
- Chest pain that goes away with rest
- Pain in calves
- Shortness of breath
- Stroke
- TIA (mini-stroke)
- Burning sensations
- Painful contact with socks or bed sheets
- Pebble or sand-like sensation in shoes
- Stabbing or electrical shock sensation
- Stabbing or electrical shock sensation
- Blood-clot in a vein (venous thrombosis)
- Heart-attack
- Irregular heartbeat, too fast/slow (atrial fibrillation)
- Difficulty digesting food
- Dizziness or fainting
- Exercise intolerance
- Sexual difficulties
- Sweat abnormalities
- Urinary problems
- Headache
- Swelling of ankles
- Cold, clammy, pale skin
- Depression
- Lightheadedness
- Lack of concentration
- Lack of energy
- Rapid shallow breathing





“Think ANS First”

Disease complications detected through the ANS analysis of our test:

This is good medicine for both patient and doctor, aiding in the early detection of over 20 disease complications while also validating critical next-step treatment and testing! Our medical device programs have medical markers for all of the following:

- Heart attack
- Heart rate variability issues
- Cardiac output to body surface area
- Abnormal LDL cholesterol
- High levels of insulin resistance
- Diabetes with complications
- Physical and mental stress, anxiety and fatigue
- Stroke
- Angiotensin activity
- Atherosclerosis
- Peripheral vascular disease
- Hyper-drosis and hyperhidrosis
- Impaired glucose intolerance
- Nerve damage
- Obesity
- Amyloid neuropathy
- Asthma
- Cardiovascular associated diseases
- Idiopathic neuropathy
- Multiple system dystrophy
- Postpartum dysfunctions
- Psychological conditions
- Pure autonomic failure
- Sjogren's syndrome



The TM-Flow system markers

The markers for the TM-Flow system include:

ANS assessment markers

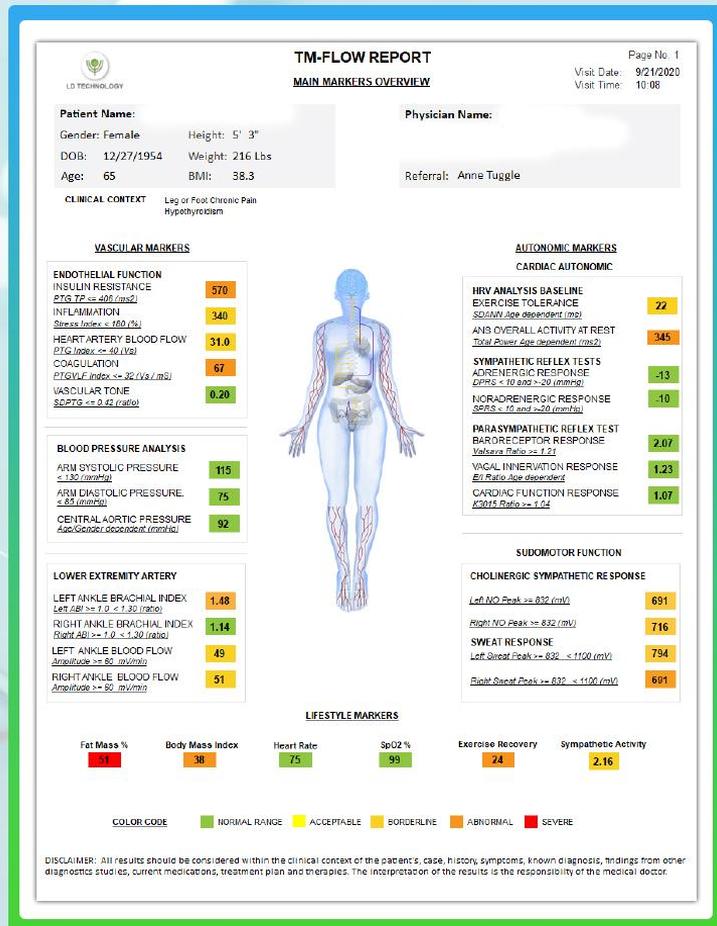
- Sudomotor markers
- Cardiac autonomic reflex tests (CARTS)
- Heart rate variability (HRV)

Vascular assessment markers

- Peripheral circulation markers
- Segmental vascular assessment

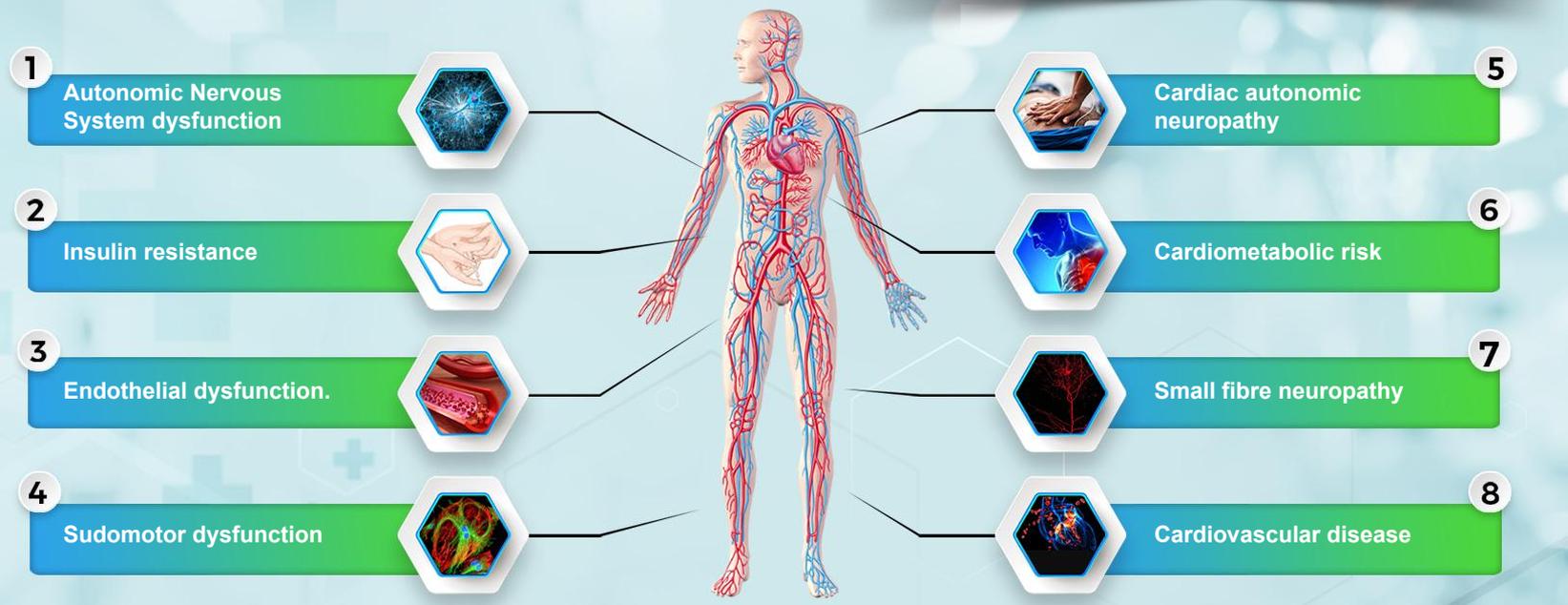
Additional marker

- Lifestyle marker





The 8 risk factor areas examined



Please reference the sample patient exam and the science report for a deeper dive into the clinical applications.



Health risk factors defined

Here is a quick review of the health risk factors that the PECE medical device platform report is based on.

1. Autonomous nervous system dysfunction risk - ANSD

Problems with the ANS can range from mild to life-threatening. Sometimes, only one part of the nervous system is affected. In other cases, the entire ANS is affected. Some conditions are temporary and can be reversed, while others are chronic and will continue to worsen over time. Diseases such as diabetes or Parkinson's disease can cause irregularities with ANS. Problems with ANS regulation often involve organ failure, or the failure of the nerves to transmit a necessary signal.

Endothelial dysfunction risk - EndoD

Current evidence suggests that endothelial function is an integrative marker of the net effects of damage from traditional and emerging risk factors on the arterial wall and its intrinsic capacity for repair. Endothelial dysfunction, detected as the presence of reduced vasodilating response to endothelial stimuli, has been observed to be associated with major cardiovascular risk factors, such as aging, hyperhomocysteinemia, post menopause state, smoking, diabetes, hypercholesterolemia, and hypertension.

2. Sudomotor dysfunction risk - SudoD

Sudomotor dysfunction testing may indicate to physicians a patient's peripheral nerve and cardiac sympathetic dysfunction. Neuropathy is a common complication in diabetes mellitus (DM), with 60%-70% of patients affected over their lifetime. Symptoms of neuropathy is more common than clinical neuropathy. Neuropathy may remain undetected, and progress over time leading to serious complications. The most common associated clinical condition is peripheral neuropathy, affecting the feet. Autonomic nerve involvement is common but probably the most undiagnosed. Low scores in the sudomotor may lead a medical provider to look at clinical neuropathy.

4. Insulin resistance risk - IR

Insulin resistance is defined clinically as the inability of a known quantity of exogenous or endogenous insulin to increase glucose uptake and utilization in an individual as much as it does in a normal population. Insulin resistance occurs as part of a cluster of cardiovascular metabolic abnormalities commonly referred to as "The Insulin resistance syndrome" or "The metabolic syndrome". This cluster of abnormalities may lead to the development of type 2 diabetes, accelerated atherosclerosis, hypertension or polycystic ovarian syndrome depending on the genetic background of the individual developing the insulin resistance.



Health risk factors defined

Here is a quick review of the health risk factors that the PECE medical device platform report is based on.

5. Cardiometabolic risk - CMR

The specific factors that can cause this increased risk include: obesity (particularly central), hyperglycemia, hypertension, insulin resistance and dyslipoproteinemia. When patients have one or more risk factors and are physically inactive or smoke, the cardiometabolic risk is increased even more. Medical conditions that often share the above characteristics, such as type 2 diabetes, can also increase cardiometabolic risk. The primary focus of cardiometabolic risk treatment is management of each high risk factor, including dyslipoproteinemia, hypertension, and diabetes. The management of these subjects is based principally on lifestyle measures, but various antihypertensive, lipid-lowering, insulin sensitizing, anti-obesity and antiplatelet drugs could be helpful in reducing cardiometabolic risk.

7. Plethysmography cardiovascular Disease risk - PTG CVD

The PTG CVD risk factor is the combined total of the other seven risk factors assessments. It takes into consideration the cardiovascular as well as the autonomic nervous system (ANS) measurements.

7. Cardiac autonomic neuropathy risk - CAN

High blood glucose levels over a period of years may cause a condition called autonomic neuropathy. This is damage to the nerves that control the regulation of involuntary function. When the nerve damage affects the heart, it is called cardiac autonomic neuropathy (CAN). CAN encompasses damage to the autonomic nerve fibers that innervate the heart and blood vessels, resulting in abnormalities in heart rate control, vascular dynamics and the body's ability to adjust blood pressure. CAN is a significant cause of morbidity and mortality associated with a high risk of cardiac arrhythmias and sudden death.

8. Small fiber neuropathy risk - SFN

A small fiber neuropathy occurs when damage to the peripheral nerves predominantly or entirely affects the small myelinated fibers or unmyelinated C fibers. The specific fiber types involved in this process include both small somatic and autonomic fibers. The sensory functions of these fibers include thermal perception and nociception. These fibers are involved in many autonomic and enteric functions.



Assessment of the autonomic nervous system

TM – Flow technology

- ■ The accurate detection of the **beat-to-beat heart rate** (RR-intervals) is analyzed by the TM-Flow medical device scan, through the **photoplethysmography (PTG) waveform**.
- ■ While lying and standing, the blood pressure is measured by **oscillometry** (TM-Flow) or by **volume plethysmography**.
- ■ The **sudomotor function** is assessed by a **galvanic skin response** device either using **metal plates** following the **electrical stimulation** of the **sweat glands (ANS-1)** or **disposable cloth electrodes** and **pressure cuffs** placed on the **ankles** following a **double stimulation** - the **metaboreflex** and the **electrical stimulation of the sweat glands** (TM-Flow).



Assessment of the micro and macro vascular systems

TM – Flow technology

- The TM-Flow device analyzes the **volume plethysmography** recordings from **segmental pressures** of **both extremities**. The **large artery blood flow** is recorded through the **decibels plethysmography**.
- Our **volume plethysmography** analysis provides markers of **arterial stiffness**, measured by the **brachial-ankle pulse wave velocity**, peripheral augmentation Index, and **central aortic systolic pressure**. This allows Calculate **ankle-brachial indexes** to diagnose **PAD** through **segmental pressures** of **both extremities**.
- **PTG** is a technique that records the **peripheral circulation** using **infrared light** with our **pulse oximeter**.





Vascular function is measured by sound and accurate technologies including.

- Carotid artery ultrasound
- Peripheral artery ultrasound
- Volume plethysmography recordings
- Photoplethysmography recordings
- Segmental pressures of the upper and lower extremities
- TCP02 testing





TM-Flow and diabetes

- ■ **This device aims to provide physicians with new technology and a better approach to detect and treat diabetes and its complications.** Diabetes damages the autonomic nerves and micro/macrovascular systems and we are able to assess the damage earlier than the gold standard.
- ■ Unfortunately, the current laboratory system fails to provide effective treatment results for the early detection of diabetes and its complications. Our ANS device platform offers a better solution to improve a patient's health conditions with high levels of specificity.



The TM-Flow medical device is faster and more comprehensive.

- The assessment of **Autonomic Nervous System** and the **vascular system** requires several different diagnostic tools, which may be expensive and time-consuming.
- Our TM Flow device, with its advanced technology, helps physicians to detect ANS and vascular function health and disease states through only one exam. This saves valuable time over other technologies needed to perform these measurements.
- Sometimes it is difficult for Physicians to differentiate vascular from neuropathic disorders. **TM Flow will help the physician to distinguish between autonomic neuropathy and vascular dysfunction symptoms.**
- Without a **comprehensive test** such as ours a-symptomatic problems are harder to assess especially those with early signs. TM Flow offers physicians a better tool for early detection of chronic disease and **more complete and comprehensive treatment options.**

