nexus ANS+

ANS & Arterial Assessment Device
Training Manual

nexus ANS+
PATIENTS
SETTINGS
MANUAL
SUPPORT
SIGN OUT
ARTERY ASSESSMENT
ARTERIAL RISK ASSESSMENT
AUTONOMIC NERVOUS SYSTEM ASSESSMENT
ANS RISK ASSESSMENT
ARTERIAL STIFFNESS
PERIPHERAL ARTERY DISEASE
PHYSICIAN QUICK GUIDE
MONITORING OF CMR *
SYMBOL LEGEND:
nexus ANS+
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INTRODUCTION

Nexus ANS+ is a neurovascular analysis device that performs a series of fast, non-invasive tests on your nerves and arteries.

Nexus ANS+ assesses the Autonomic Nervous System and the arteries. The **Autonomic Nervous System (ANS)** is the part of the nervous system that regulates key involuntary functions of the body, including the activity of the heart, the smooth muscles (including the muscles of the intestinal tract), and the glands. The ANS has two divisions: the **Sympathetic Nervous System**, which accelerates the heart rate, constricts blood vessels, and raises blood pressure, and the **Parasympathetic Nervous System**, which slows the heart rate, increases intestinal and gland activity, and relaxes sphincter muscles.

Nexus ANS+ aids in the identification and early detection of ANS and arterial dysfunction related to disorders and disease complications. Autonomic Nerve and artery dysfunction or damage are the most frequent complications of **Chronic Metabolic Diseases (CMD)**, such as diabetes, kidney disease, hepatitis, thyroid failure, and aging.

Autonomic Neuropathy occurs when the nerves that control involuntary bodily functions are damaged. This may affect blood pressure, temperature control, digestion, bladder function and even sexual function. The nerve damage interferes with the messages sent between the brain and other organs and areas of the Autonomic Nervous System, such as the heart, blood vessels and sweat glands.

Arterial Disease is a general term that refers to a number of diseases that affect the blood vessels that distribute oxygenated blood throughout the body. Arterial Disease can hinder the body's ability to transport blood to affected body region(s). Depending on the type and severity of the disease, it can result in limb amputation and even death.

Although the symptoms may imitate each other, it is imperative to distinguish between Autonomic Neuropathy and Arterial Disease because the treatments are quite different. Nexus ANS+ gives healthcare providers the infomation necessary to make this distiction and improve patient treatment outcomes with early detection and accurate assessment.

Nexus ANS+ performs non-invasive tests to assess the patient's risk of autonomic nervous system & arterial dysfunction related to disorders and disease complications.

Arterial Risk Assessment

- Skin Microcirculatory Disorder
- Arterial Stiffness
- Peripheral Artery Disease

ANS Risk Assessment

- Sudomotor Function
- Autonomic Regulation
- Cardiac Autonomic Neuropathy

Skin Microcirculation, the circulation of blood to the smallest blood vessels in the skin, is altered in patients with hypertension, diabetes, and obstructive arterial disease. Furthermore, abnormalities of microcirculation are generally accepted as early changes associated with diabetes. Eventual manifestations of altered microcirculation, such as neuropathy, are related to the duration and severity of diabetes. Nexus ANS+ gathers information to evaluate risk of Skin Microcirculatory Disorder using the non-invasive Galvanic Skin Response (GSR) test.

Arterial Stiffness occurs as a consequence of biological aging and Arteriosclerosis, which occurs when arteries become thick and stiff, sometimes restricting blood flow to your organs and tissues. Arterial Stiffness is associated with an increased risk of cardiovascular events such as heart attack and stroke, the two leading causes of death in the developed world. Depending on the cause, Arterial Stiffness may be treated and prevented. Nexus ANS+ evaluates Aterial Stiffness using Pulse Wave Velocity (PWV), Peripheral augmentation index (pAIx), and Central aortic Systolic Pressure (CASP).

Peripheral Artery Disease (PAD) is a common manifestation of atherosclerotic vascular disease where the arteries in your legs or arms are narrowed or blocked. Its incidence increases with age and in the presence of known cardiovascular risk factors (e.g., smoking and diabetes). People with PAD are at an increased risk of heart attack, stroke, poor circulation and leg pain. Nexus ANS+ evaluates PAD using the Ankle Brachial Index (ABI). The ABI compares your systolic blood pressure measured at your ankle with your systolic blood pressure measured at your arm. A low ABI can be a strong indicator of PAD and risk of circulatory problems.

Sudomotor (or sweat motor) Function is related to the nerve fibers controlling the activity of the sweat glands (the post sympathetic cholinergic nerve fibers or C-fibers). Sudomotor dysfunction (sweat dysfunction) is an early indicator of small fiber neuropathy. Traditional neurophysiologic measurements of sudomotor function include invasive testing such ast hermoregulatory sweat testing (TST), quantitative sudomotor axon reflex testing (QSART), silicone impressions. Nexus ANS+ uses Galvanic Skin Response (GSR) to test Sudomotor Function, which is a non-invasive test.

Autonomic Regulation is the body's ability to maintain homeostasis (stability and balance) during internal and external stimuli. Autonomic Regulation is always functioning and we are often unaware of the important tasks it is performing. When the nerves that control Autonomic Regulation are damaged, Autonomic Dysfunction can develop. Autonomic Dysfunction can be temporary or chronic. Diabetes and Parkinson's disease are two examples of chronic conditions that can lead to Autonomic Dysfunction. Nexus ANS+ tests Autonomic Regulation through a combination of Heart Rate Variability (HRV) Assessment and Cardiac Autonomic Reflex Tests (CARTs).

Cardiovascular Autonomic Neuropathy (CAN) is a common form of autonomic neuropathy, causing abnormalities in heart rate control and central/peripheral vascular dynamics. CAN has a strong link to diabetes and can contribute to the development of a variety of severe conditions resulting in a multitude of complications and higher mortality risk. Like the Autonomic Regulation Assessment, Nexus ANS+ evaluates the Sympathetic and Parasympathetic Nervous Systems using CARTs to identify CAN risk factors.

TEST PROCEDURE

Nexus ANS+ provides fast, accurate, and clear results. Easy to learn and operate, the tests can be administered by any staff member.

Testing with the Nexus ANS+ is performed in roughly 7 minutes and is completely non-invasive.

The recording includes a baseline phase where the patient is relaxed and a testing phase where the patient is asked to perform basic breathing exercises and one active postural change. Scores are calculated based on several recorded parameters and allow for the fast and intuitive interpretation of color coded results.

1. Set up the patient.

Input the patient's information into the Nexus ANS+ System.

2. Connect Nexus ANS+ to Patient.

With the patient laying supine:

- Place disposable electrodes on the soles of the feet
- Place blood pressure cuffs on the arm and legs
- Place pulse oximeter on the finger

3. Collect Baseline Data.

First the device will collect baseline information while the patient is relaxed.

- BP Pulse Volume Analysis
- Ankle Brachial Index (ABI)
- Galvanic Skin Response & Metaboreflex Analysis
- Heart Rate Variability (HRV) Analysis

4. Perform Cardiac Autonomic Reflex Tests (CARTs).

First the device will collect baseline information while the patient is relaxed.

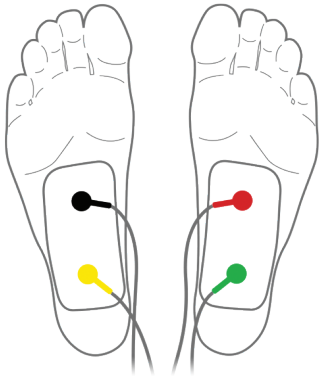
- Valsalva Maneuver – patient bears down and attempts to exhale with mouth and nostrils closed
- Deep Breathing – patient performs a deep breathing exercise
- Change in Posture – patient stands up from a seated position

5. Test is Complete.

Collected data is placed through a series of algorithms that produce scores that indicate risk levels for a variety of ANS and Artery related diseases and conditions.

TEST METHODS

Nexus ANS+ performs 4 non-invasive tests in 7 minutes. Results can aid in the early detection of Autonomic Nervous System and Arterial conditions.



Sudomotor Test

Used to assess risk of Small Fiber Neuroptathy & Skin Microcirculatory Disorder

The Nexus ANS+ uses the galvanic skin response method which is based on the induced sudomotor axon reflex stimulations of the cholinergic sympathetic system using:

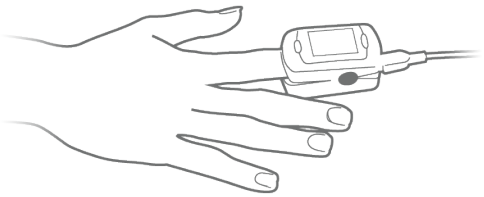
- Direct Current at a constant voltage
- Metaboreflex following the inflation of the ankle cuffs

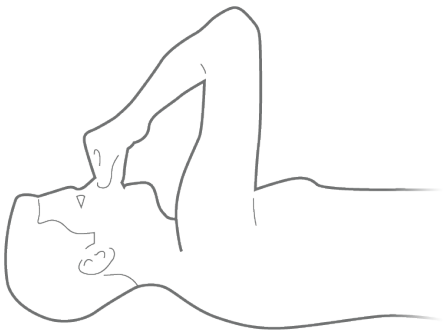
It provides quantitative evaluation of the sweat response measured on disposable electrodes.

Photoplethysmography (PTG)

Used to assess risk of Arterial Stiffness & Autonomic Dysregulation

Nexus ANS+ uses Photoplethysmography (PTG) analysis derived from the pulse oximeter. PTG is an optical measurement technique using red and infrared light to measure peripheral blood volume changes. PTG uses the time domain and spectral analysis of the waveform recording during 2 minutes of the test to retrieve information regarding artery (capillaries) stiffness, and Heart Rate Variability (HRV) Analysis.





Cardiac Autonomic Reflex Tests (CARTs)

Used to assess risk of Cardiac Autonomic Neuropathy

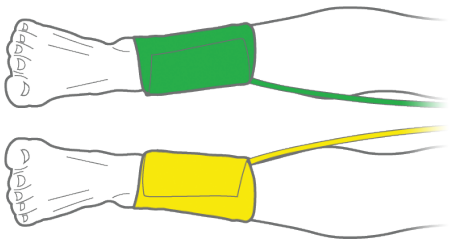
After a Baseline ANS Evaluation is completed by assessing the Heart Rate Variability (HRV) analysis, the Cardiac Autonomic Reflex Tests (CARTs) are performed. CARTs consist of 3 tests to assess the autonomic functions of the Sympathetic and Parasympathetic Systems. The tests are as follows:

- Valsalva Maneuver
- Deep Breathing
- Change in Posture

Ankle Brachial Measurement (ABI)

Used to assess risk of Peripheral Artery Disease

The Ankle-Brachial Index (ABI) is the ratio of the blood pressure at the ankle to the blood pressure in the upper arm. Compared to the arm, lower blood pressure in the leg is an indication of blocked arteries due to arterial disease. The ABI is calculated by dividing the systolic blood pressure at the ankle by the systolic blood pressure in the arm.



WHO SHOULD BE TESTED

Over 45,000,000 Americans have symptoms or risk factors that would justify testing with the Nexus ANS+.

Symptom-Based

Any patient suffering any one of the following symptoms could be a candidate for the test:

- Pain, numbness, tingling, or burning in the feet
- Leg pain after effort, claudication
- Dizziness, Syncope

Age/Health-Based

Any patient above the age of 50 that has been diagnosed with any one of the following health conditions could be a candidate for the test:

- Hypertensive
- Smoker
- Overweight
- Diabetic

Age-Based

Any patient above the age of 70 could be a candidate for a test.

40% of adults age 50 and older are obese.

1 in 6 Americans aged 45-64 is a smoker.

Over 60% of Americans over the age of 55 have high blood pressure.

12 million Americans suffer from Lower Extremity Disease.

15-20% of people over 60 years old have Atery and ANS damage.

The CDC projects that 1 in 3 adults could have diabetes by 2050.

CONTRAINDICATIONS

General Contraindications

The devices should not be used in association with or presence of defibrillators, cardiac pacemakers, patients connected to electronic life support devices, or any implanted electronic device.

Any blood pressure recording can be affected by the position of the subject, his or her physiologic condition, and other factors such as:

- Taking the blood pressure measurement:
  - » Less than 1 hour after meals
  - » After drinking alcohol or coffee
  - » Less than 1 hour after smoking
  - » After exercise or sporting activity
  - » After bathing
- White-Coat Hypertension (anxiety)
- Factors during Readings: Something as simple as moving the arm while blood pressure is being taken can affect the reading. If the sleeves of a shirt fit too tightly over the cuff, or if the cuff size is wrong, the readings could be inaccurate.
- Features: When the blood pressure reading is being taken, patient should be lying in a comfortable position.
- Considerations: Other factors include age, race, temperature, medication, emotional state, stress, exercise, smoking, and medical conditions such as diabetes, obesity, cardiovascular disease, irregular heartbeat, pregnancy and alcoholism. These factors need to be taken into account to determine an accurate measurement of blood pressure.
  - » The accuracy of the blood pressure device should be verified, and we recommend that a calibration is performed annually.
  - » The blood pressure device might not meet its performance specifications if stored or used outside of the temperature and humidity range.
  - » Blood pressure measurements determined with this device are equivalent to those obtained by an intra-arterial blood pressure measurement device within the limits prescribed by the American National Standard for manual, electronic, or automated sphygmomanometers.
  - » Cardiac arrhythmia may cause an irregular heartbeat, and may increase the measurement time.
  - » If the patient is on a Heart-Lung machine, the measurement may not be possible.
  - » Rapid pressure changes may not be possible to record.
  - » Severe shock or hypothermia may give unreliable results since reduced blood flow to the peripheries will reduce pulsation of arteries

Electrode Contraindications

- Dermatological lesions or calluses in contact with the electrodes, or excessive perspiration.
- Metal pins or prostheses on the level of the extremities or the joints.
- This device should not be used on pregnant women.
- An absence of one or more limbs.

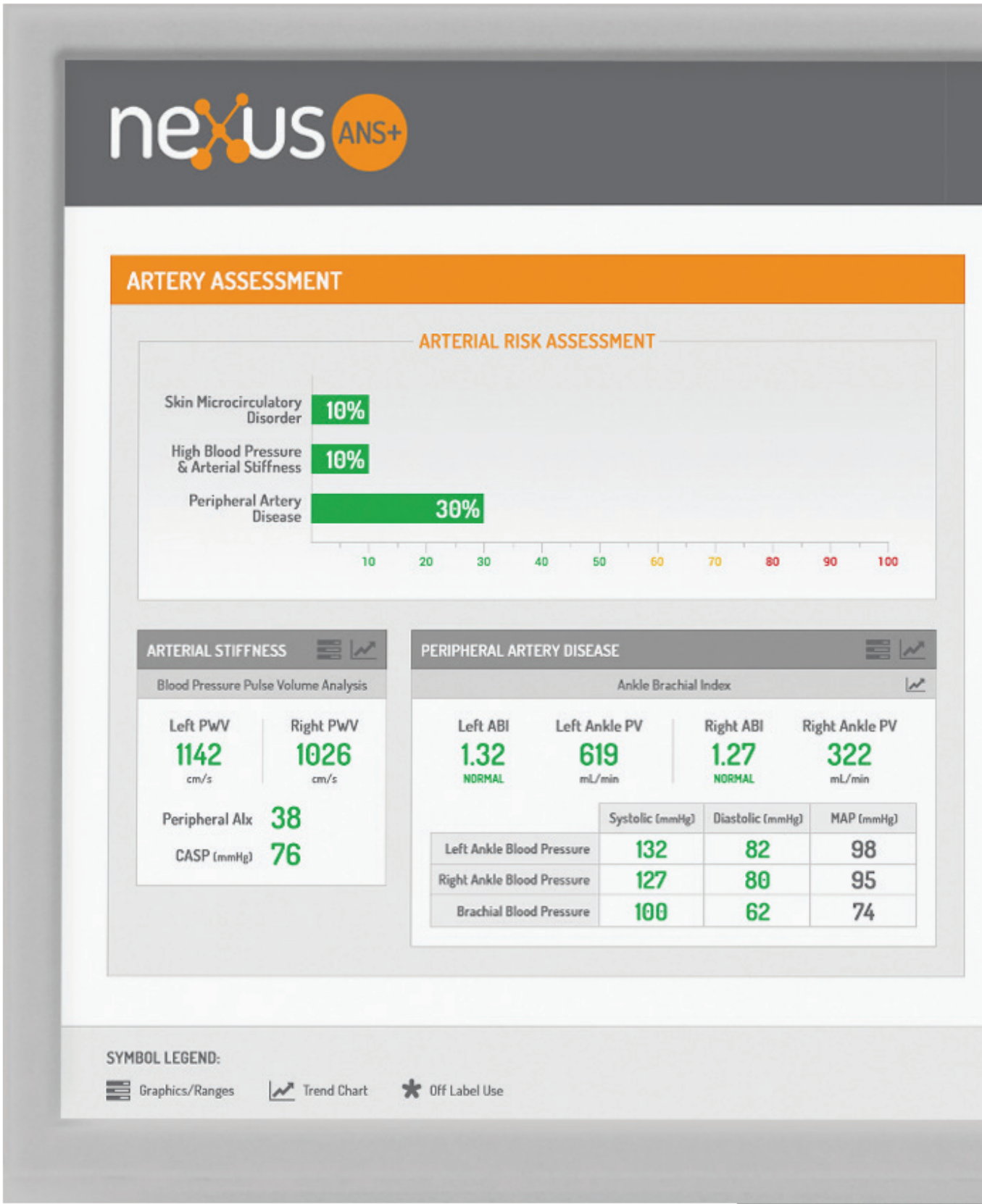
ABI Contraindications

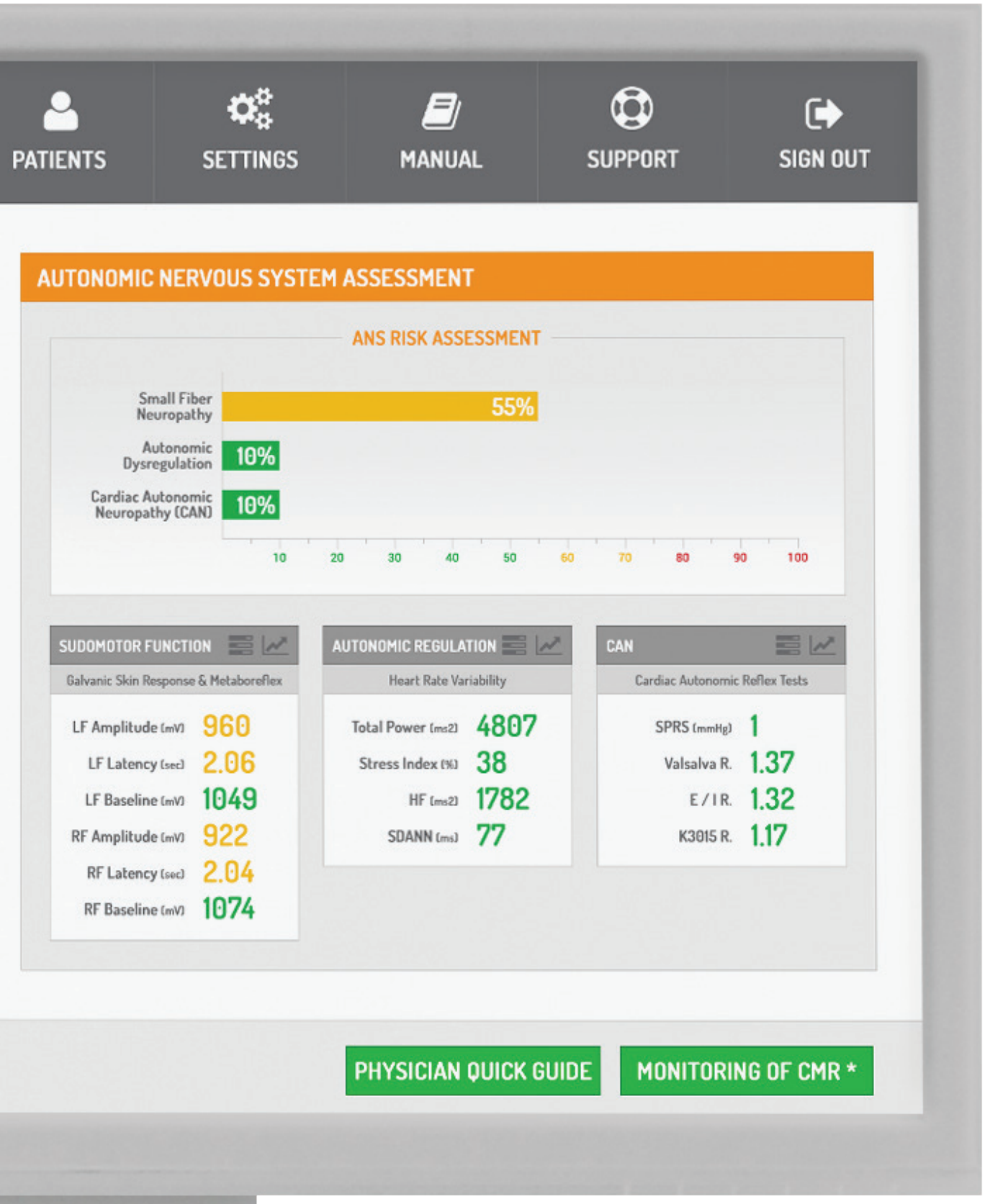
- Arterial catheter, AV fistula, or pressure dressing.
- Venous pulsations may cause erroneous readings in blood pressure (e.g. tricuspid valve regurgitation).
- Bilateral mastectomy

Oximeter Contraindications

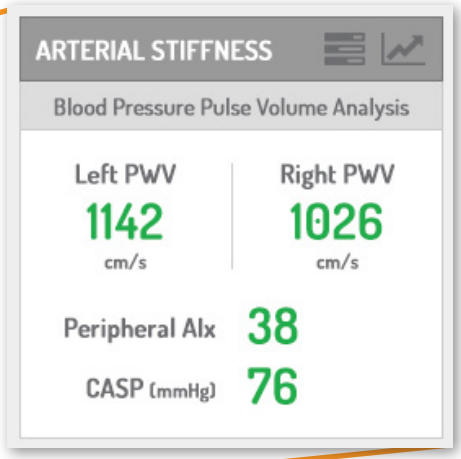
- When using the oximeter probe, use the finger of the arm not in use with the blood pressure cuff, arterial catheter, or having an AV fistula or pressure dressing.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein.
- Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO2 measurement.
- Any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO2 readings.
- For elderly patients or subjects with a weak pulse due to shock, low ambient/body temperature, major bleeding, or use of a vascular contracting drug, the SpO2 waveform will be decreased or absent.
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.
- Venous pulsations may cause erroneous readings in blood pressure (e.g. tricuspid valve regurgitation).
- Be careful with low perfused patients. Using the blood pressure device may cause skin erosion and/or pressure necrosis.
- Valsalva maneuver should not be performed on persons:Undergoing procedures with proliferative retinopathy.
- Systolic Blood pressure of 160mmHg or higher.
- Anyone who's had laser treatment for retinopathy within the past three months.

RESULTS


nexus ANS+
ARTERY ASSESSMENT
ARTERIAL RISK ASSESSMENT
Skin Microcirculatory Disorder
10%
High Blood Pressure & Arterial Stiffness
10%
Peripheral Artery Disease
30%
10 20 30 40 50 60 70 80 90 100
ARTERIAL STIFFNESS
Blood Pressure Pulse Volume Analysis
Left PWV
1142
cm/s
Right PWV
1026
cm/s
Peripheral AIx
38
CASP (mmHg)
76
PERIPHERAL ARTERY DISEASE
Ankle Brachial Index
Left ABI
1.32
NORMAL
Left Ankle PV
619
mL/min
Right ABI
1.27
NORMAL
Right Ankle PV
322
mL/min
Systolic (mmHg)
Diastolic (mmHg)
MAP (mmHg)
Left Ankle Blood Pressure
132
82
98
Right Ankle Blood Pressure
127
80
95
Brachial Blood Pressure
100
62
74
SYMBOL LEGEND:
Graphics/Ranges
Trend Chart
Off Label Use


PATIENTS
SETTINGS
MANUAL
SUPPORT
SIGN OUT
AUTONOMIC NERVOUS SYSTEM ASSESSMENT
ANS RISK ASSESSMENT
Small Fiber Neuropathy
55%
Autonomic Dysregulation
10%
Cardiac Autonomic Neuropathy (CAN)
10%
10 20 30 40 50 60 70 80 90 100
SUDOMOTOR FUNCTION
Galvanic Skin Response & Metaboreflex
LF Amplitude (mV) 960
LF Latency (sec) 2.06
LF Baseline (mV) 1049
RF Amplitude (mV) 922
RF Latency (sec) 2.04
RF Baseline (mV) 1074
AUTONOMIC REGULATION
Heart Rate Variability
Total Power (ms2) 4807
Stress Index (%) 38
HF (ms2) 1782
SDANN (ms) 77
CAN
Cardiac Autonomic Reflex Tests
SPRS (mmHg) 1
Valsalva R. 1.37
E / I R. 1.32
K3015 R. 1.17
PHYSICIAN QUICK GUIDE
MONITORING OF CMR *

ARTERIAL STIFFNESS – RESULTS



Description

Arterial Stiffness occurs as a consequence of biological aging and Arteriosclerosis, which occurs when arteries become thick and stiff, sometimes restricting blood flow to your organs and tissues. Arterial Stiffness is associated with an increased risk of cardiovascular events such as heart attack and stroke, the two leading causes of death in the developed world. Depending on the cause, Arterial Stiffness may be treated and prevented. Nexus ANS+ evaluates Aterial Stiffness using Pulse Wave Velocity (PWV), Peripheral augmentation index (pAIx), and Central aortic Systolic Pressure (CASP).

Relevant Definitions

Arteriosclerosis occurs when the blood vessels that carry oxygen and nutrients from your heart to the rest of your body (arteries) become thick and stiff — sometimes restricting blood flow to your organs and tissues. Healthy arteries are flexible and elastic, but over time, the walls in your arteries can harden, a condition commonly called hardening of the arteries.

Atherosclerosis is a specific type of arteriosclerosis, but the terms are sometimes used interchangeably. Atherosclerosis refers to the buildup of fats, cholesterol and other substances in and on your artery walls (plaques), which can restrict blood flow. These plaques can burst, triggering a blood clot. Although atherosclerosis is often considered a heart problem, it can affect arteries anywhere in your body. Atherosclerosis may be preventable and is treatable.

Arterial Stiffness - Key Measurements

Pulse Wave Velocity

Pulse Wave Velocity (PWV) is a measure of arterial stiffness, or the rate at which pressure waves move down the vessel.

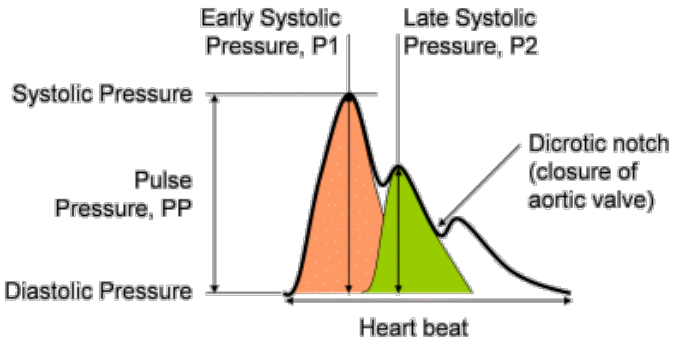
$$\mathbf{PWV} = \frac{D\ (meters)}{\Delta T\ (seconds)}$$

A = Right Brachial Pulse pressure waveform
B = Right Ankle Pulse pressure waveform
ΔT = Delta Time between the 2 waves
D = Estimated distance from arm to ankle based on patient total height

Peripheral Augmentation Index

The Peripheral Augmentation Index (pAIx) is a ratio calculated from the blood pressure waveform, it is a measure of wave reflection and arterial stiffness. Peripheral Augmentation index is commonly accepted as a measure of the enhancement (augmentation) of central aortic pressure by a reflected pulse wave.

$$\mathbf{pAIx} = \frac{P1}{P2} * 100$$



Pulse Pressure

Pulse Pressure (PP) is the difference between the systolic and diastolic pressure readings.

$$\mathbf{PP} = SP - DP$$

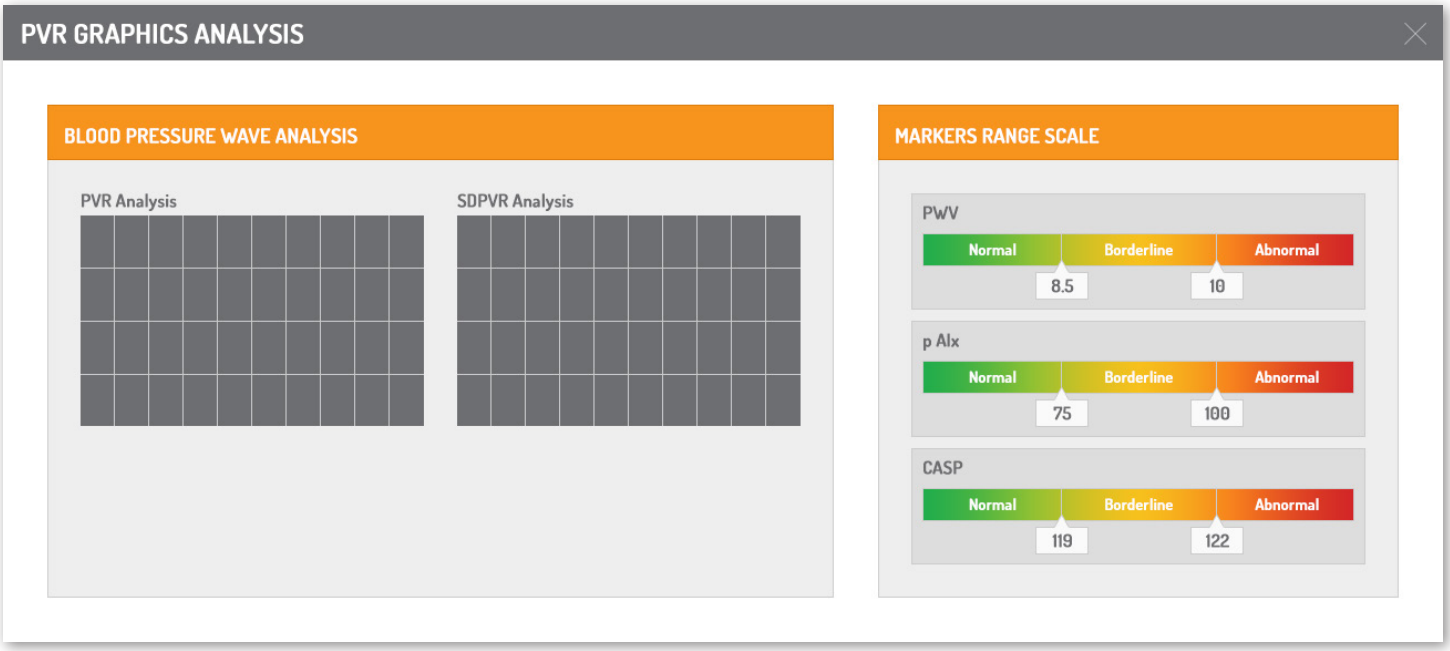
SP = Systolic Pressure
DP = Diastolic Pressure

Central Aortic Systolic Pressure (CASP)

Central Aortic Systolic Pressure (CASP) is the blood pressure at the root of the aorta. It has been shown in many studies to be the strongest independent risk factor for stroke, heart attacks and the likelihood of survival after such an event.

$$\mathbf{CASP} = DP + \frac{(pAIx * PP)}{100}$$

Arterial Stiffness - Graphics & Ranges



Measurement Ranges

PWV below 8.5m/s and/or AIx below 75%	PWV from 8.5 to 10m/s and/or AIx from 75 to 100%	PWV above 10m/s and/or AIx above 100 %
NORMAL: Suggests that the patient does not have arterial stiffness.	**BORDERLINE:** Suggests condition could be reversed by a lifestyle change.	**ABNORMAL:** Suggests moderate to severe arterial stiffness.

Clinical Data

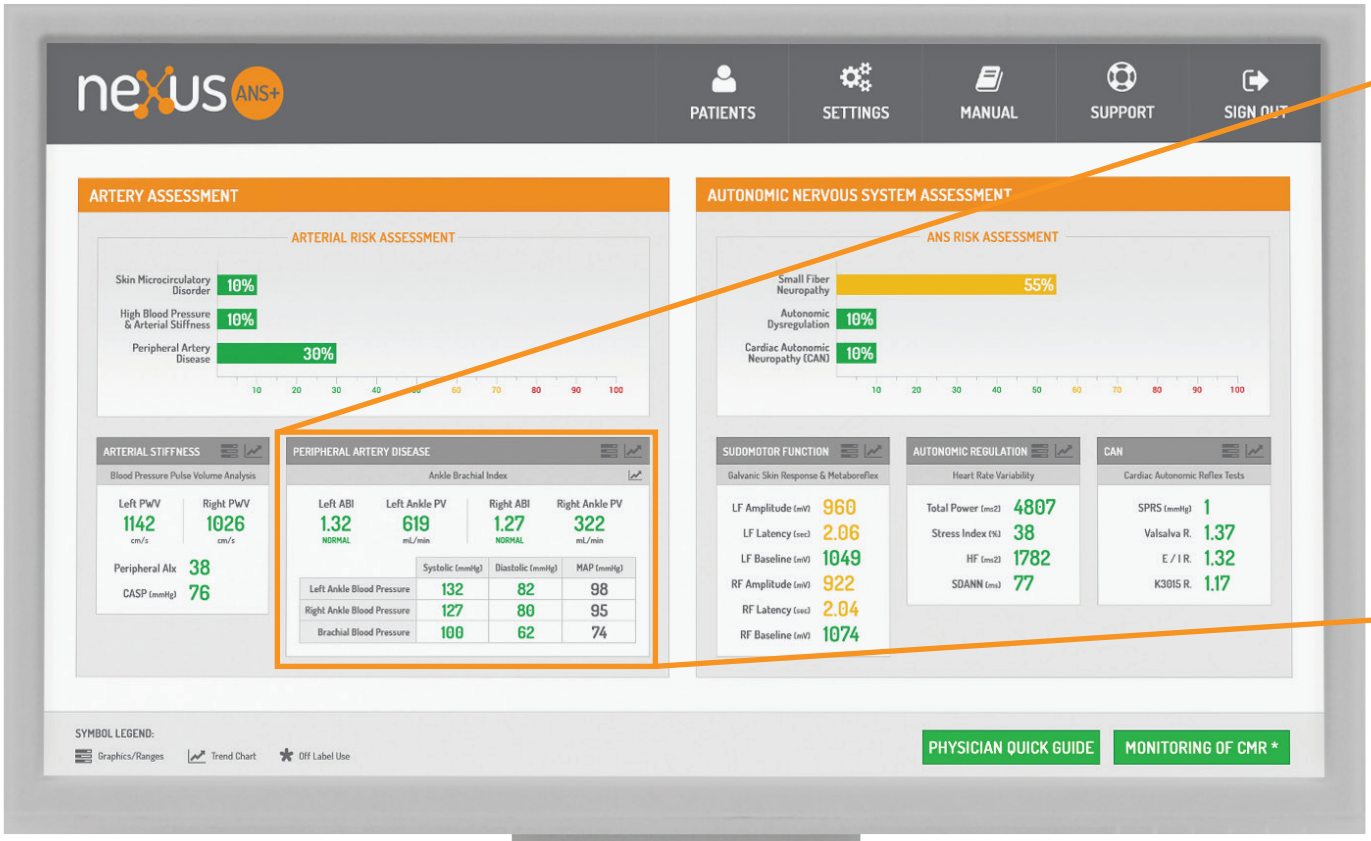
Pressure measured with a cuff in the brachial artery is accepted as an important predictor of future cardiovascular risk. However, systolic pressure varies throughout the arterial tree, such that aortic (central) systolic pressure is actually lower than corresponding brachial values, although this difference is highly variable between individuals. Emerging evidence now suggests that central pressure is better related to future cardiovascular events than is brachial pressure. Moreover, anti-hypertensive drugs can exert differential effects on brachial and central pressure. Therefore, basing treatment decisions on central, rather than brachial pressure, is likely to have important implications for the future diagnosis and management of hypertension. Such a paradigm shift will, however, require further, direct evidence that selectively targeting central pressure, brings added benefit, over and above that already provided by brachial artery pressure. (McEniery C.M etal.2014)

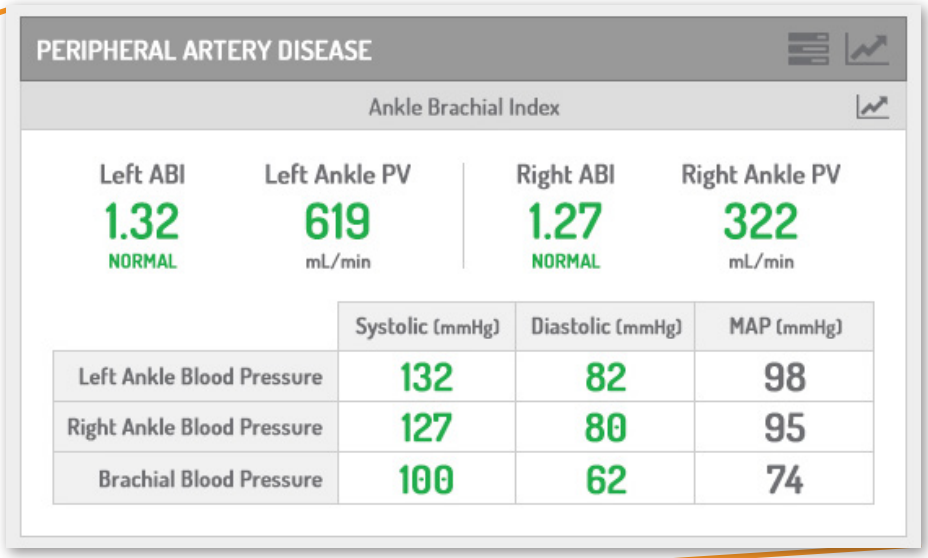
Educational Reading

Determination of age-related increases in large artery stiffness by digital pulse contour analysis.
Department of Clinical Pharmacology, St. Thomas' Hospital, Centre for Cardiovascular Biology and Medicine, King's College London, Lambeth Palace Road, London SE1 7EH, UK.
http://www.ncbi.nlm.nih.gov/pubmed/12241535

M. Span1, G. Gersak2, M. Meza3, A. Kosir4
https://asiakas.kotisivukone.com/files/terveystekniikka.palvelee.fi/Tutkimukset_artikkelit/mesi_clinical_study.pdf

PERIPHERAL ARTERY DISEASE (PAD) – RESULTS





Description

Peripheral Artery Disease (PAD) is a common manifestation of atherosclerotic vascular disease where the arteries in your legs or arms are narrowed or blocked. Its incidence increases with age and in the presence of known cardiovascular risk factors (e.g., smoking and diabetes). People with PAD are at an increased risk of heart attack, stroke, poor circulation and leg pain. Nexus ANS+ evaluates PAD using the Ankle Brachial Index (ABI). The ABI compares your systolic blood pressure measured at your ankle with your systolic blood pressure measured at your arm. A low ABI can be a strong indicator of PAD and risk of circulatory problems.

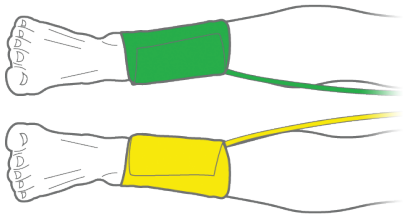
Peripheral Artery Disease (PAD) - Key Measurements

Ankle Brachial Index (ABI) is the ratio of the systolic pressure of the ankle divided by the arm systolic pressure.

Pulse Volume Velocity (PVV) reflects the return of the blood volume over time after inflation and occlusion.

Mean Arterial Pressure (MAP) is the average pressure in the arteries during one cardiac cycle.

Ankle Brachial Index (ABI)



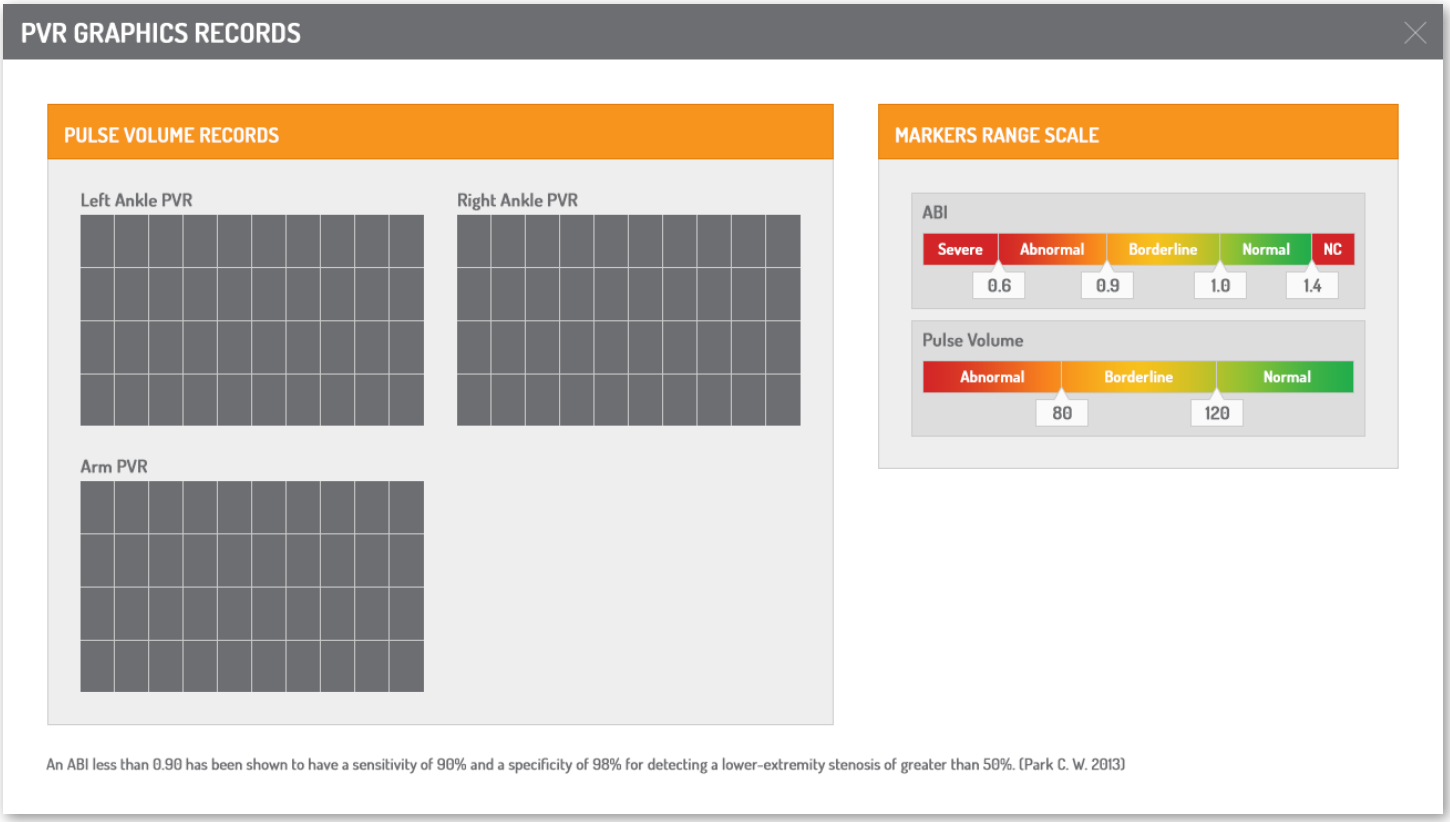
The ankle-brachial index test is a quick, noninvasive way to check your risk of peripheral artery disease (PAD). Peripheral artery disease is a condition in which the arteries in your legs or arms are narrowed or blocked. People with peripheral artery disease are at an increased risk of heart attack, stroke, poor circulation and leg pain.

The ankle-brachial index test compares your systolic blood pressure measured at your ankle with your systolic blood pressure measured at your arm. A low ankle-brachial index number can indicate narrowing or blockage of the arteries in your legs, increasing your risk of circulatory problems, and possibly causing heart disease or stroke.

The Ankle Brachial Index (ABI) was initially proposed for the noninvasive diagnosis of lower-extremity peripheral artery disease (PAD) (Carter 1967). However, it was later shown that the ABI is also an indicator of atherosclerosis at other vascular sites, and it can serve as a prognostic marker for cardiovascular events and functional impairment, even in the absence of symptoms of PAD (Criqui et al. 1992).

The ABI results interpretation come from the "Guidelines for the Management of Patients with Peripheral Artery Disease" published by the Journal of the American College of Cardiology.

Peripheral Artery Disease (PAD) - Graphics & Ranges



Measurement Ranges

ABPI less than 0.6	ABPI from 0.6 to 0.9	ABPI from 0.9 to 0.99	ABPI from 1.0 to 1.3	ABPI from 1.31 to 1.39	ABPI more than 1.4
SEVERE: Blockage in ankle and leg arteries may be severe.	**ABNORMAL:** Blockage in ankle and leg arteries may be fairly significant.	**BORDERLINE:** Ankle and leg arteries may be narrowing.	**NORMAL:** Ankle and leg arteries are likely normal.	**BORDERLINE:** Ankle and leg arteries may be borderline rigid.	**ABNORMAL:** Ankle and leg arteries may be rigid and do not compress.

PVR Max less than 50 mL	PVR Max from 50 to 79 mL	PVR Max from 80 to 119 mL	PVR Max more than 120 mL
Severe reduction in blood flow of the foot.	**Moderate** reduction in blood flow of the foot.	**Borderline** reduction in blood flow of the foot.	**Normal** blood flow of the foot.

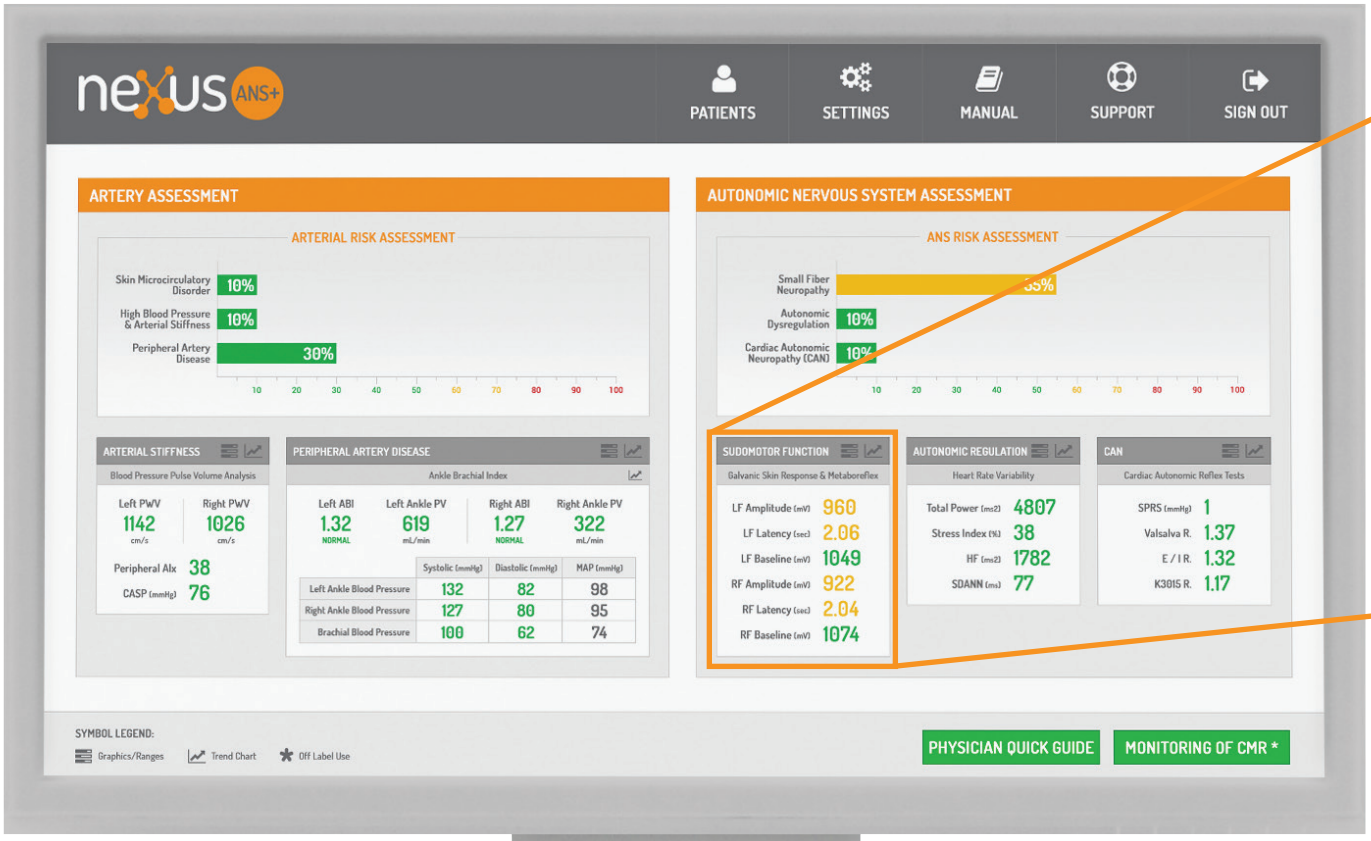
Clinical Data

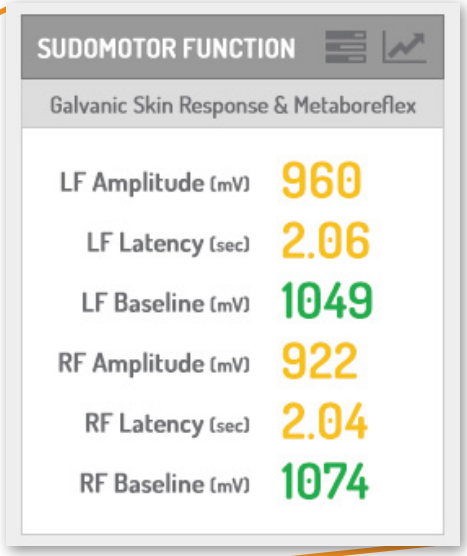
When comparing ABI measurement results obtained by oscillometric measurements vs. Doppler probe measurements, it was evident that the oscillometric measurements were more precise than Doppler probe measurements; 17% vs.19% respectively. Bland Altman plot showed bias of +0.06 and scatter diagram showed good correlation (slope: 0.75). In the oscillometric method analysis percentage error was 0.26. Furthermore, assessment of the concordance index revealed a very good agreement between both methods in terms of clinical relevance: concordance index of 0.88 (95% CI: from 0.76 to 0.97). Oscillometric measurements were completed three times faster than Doppler probe measurements.

Educational Reading

Comparison of Doppler probe method and oscillometric method in determining ankle brachial index
M. Span1, G. Gersak2, M. Meza3, A. Kosir4
https://asiakas.kotisivukone.com/files/terveystekniikka.palvelee.fi/Tutkimukset_artikkelit/mesi_clinical_study.pdf

SUDOMOTOR FUNCTION – RESULTS





Description

Sudomotor (or sweat motor) Function is related to the nerve fibers controlling the activity of the sweat glands (the post sympathetic cholinergic nerve fibers or C-fibers). Sudomotor dysfunction (sweat dysfunction) is an early indicator of small fiber neuropathy. Traditional neurophysiologic measurements of sudomotor function include invasive testing such ast hermoregulatory sweat testing (TST), quantitative sudomotor axon reflex testing (QSART), silicone impressions. Nexus ANS+ uses Galvanic Skin Response (GSR) to test Sudomotor Function, which is a non-invasive test.

Relevant Definitions

Sudomotor (from Latin sudor, 'sweat' and motor) describes anything that stimulates the sweat glands.

Peripheral Neuropathy (PN) is damage to or disease affecting nerves, which may impair sensation, movement, gland or organ function, or other aspects of health, depending on the type of nerve affected.

Small Fiber Peripheral Neuropathy is a type of peripheral neuropathy that occurs from damage to the small unmyelinated peripheral nerve fibers. These fibers, categorized as C fibers, are present in skin, peripheral nerves, and organs. The role of these nerves is to innervate the skin (somatic fibers) and help control autonomic function(autonomic fibers). It is estimated that 15-20 million people in the United States suffer from some form of peripheral neuropathy.

Afferent nerves from skeletal muscle are stimulated by contraction, leading to increased ventilation and increased efferent sympathetic nerve activity. This reflex arc is called the muscle chemoreflex or **Metaboreflex**.

Galvanic Skin Response (GSR) is the phenomenon that the skin momentarily becomes a better conductor of electricity when either external or internal stimuli occur that are physiologically arousing.

Sudomotor Function - Key Measurements

Left/Right Foot Amplitude (L/RF Amplitude) reflects the sudomotor response to electrical and muscle metaboreflex stimulation if the sympathetic system. The response is proportionate to the active sweat gland density and skin microcirculation response. This is the main marker of sudomotor function.

Left/Right Foot Latency (L/RF Latency) reflects the time of sudomotor response after stimulation related to the skin thermoreceptor (A Delta Fiber).

Left/Right Foot Baseline (L/RF Baseline) is a marker of the left foot skin microcirculation.

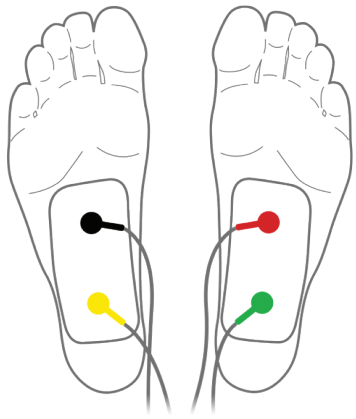
Galvanic Skin Response (GSR)

The Nexus ANS + performs **galvanic skin response** based on the sympathetic skin response method and induced sudomotor axon reflex of the cholinergic sympathetic system using double stimulation:

1) DC electricity at a constant voltage

2) Metaboreflex following the inflation of the ankle pressure cuffs.

It provides a quantitative evaluation of the sweat response or sudomotor function measured via disposable electrodes. The quantitative induced sweat response is expressed by waveform amplitude from the skin voltage responses (in mV) and latency (in seconds).



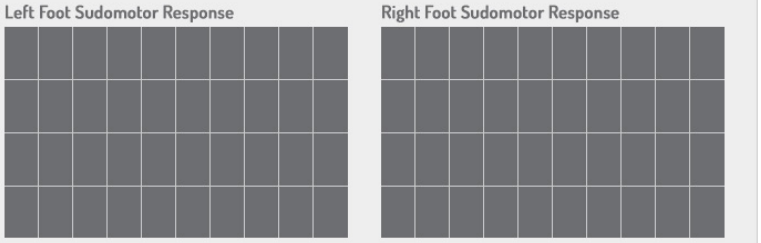
The skin voltage responses reflect the absorption of the induced sweat on the bulk of the cloth electrodes, and latency reflects the time of response from stimulation to the peak of waveform amplitude. The measurement is performed at the soles of the right and left foot, which have the highest density of eccrine sweat glands and C-fibers that travel the furthest from the brain and spinal cord.

As perspiration increases, more sweat glands are stimulated which increase the voltage waveform amplitude in a given area of skin covered by the disposable cloth electrodes.

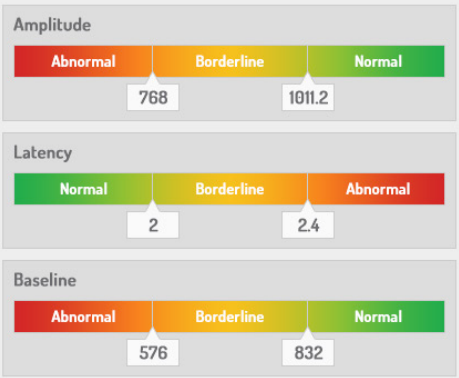
Sudomotor Function - Graphics & Ranges

GRAPHICS OF SUDOMOTOR RESPONSE RECORDS

SUDOMOTOR RESPONSE RECORDS



MARKERS RANGE SCALE



The Sudomotor testing clinical data suggest it may be the most sensitive means to detect peripheral small fiber neuropathy (Low, et al., 2006).

Clinical Data

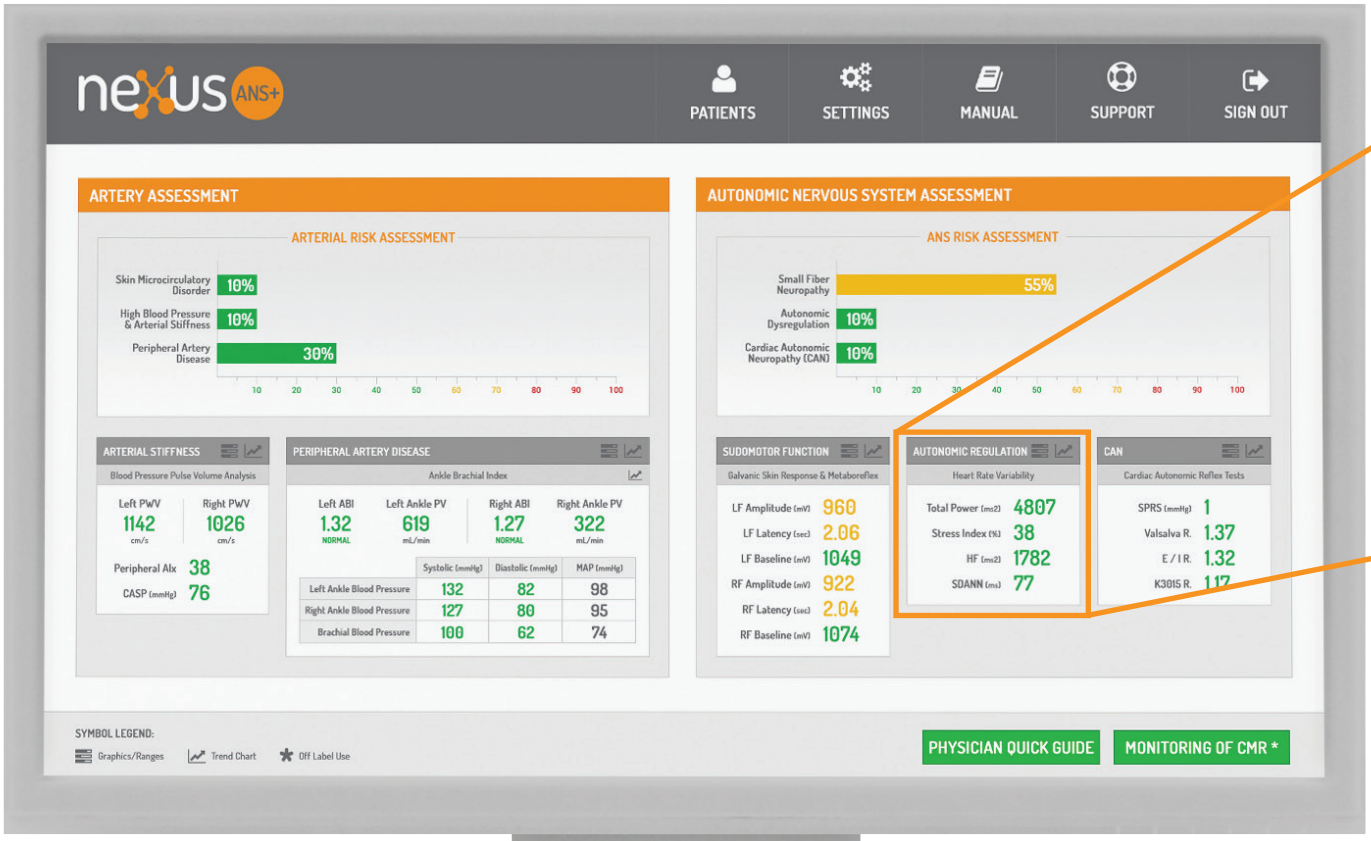
Sudomotor response (SMR) score. SMR score is based on highest score between the right and left foot. SMR Score had a sensitivity of 91.4% and specificity of 79.1% to detect peripheral distal neuropathy symptoms (Gandhi et al. 2015). The sudomotor testing clinical data suggests it may be the most sensitive means to detect peripheral small fiber neuropathy (Low et al. 2006). Amplitude response reflects the C-Fiber density, Baseline response reflects the skin microcirculation state and latency response reflects the small myelinated thermal fiber (A delta fiber) state following the induced sudomotor axon reflex stimulations of the cholinergic sympathetic system by electrical stimulation and metaboreflex.

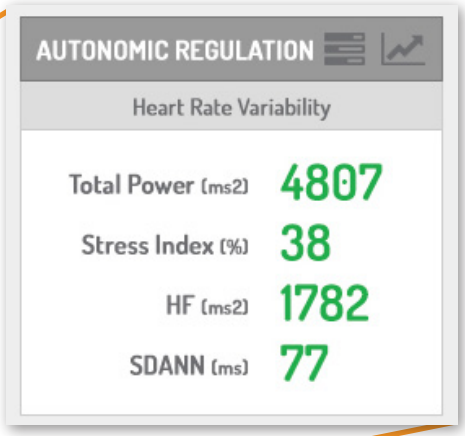
Educational Reading

Detection of neuropathy using a sudomotor test in type 2 diabetes
Gandhi PG, Rao GHR
https://www.dovepress.com/articles.php?article_id=19898

Cardiac autonomic neuropathy in patients with diabetes mellitus
Gerasimos Dimitropoulos, Abd A Tahrani, and Martin J Stevens
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3932425/

RESULTS – AUTONOMIC REGULATION





Description

Autonomic Regulation is the body's ability to maintain homeostasis (stability and balance) during internal and external stimuli. Autonomic Regulation is always functioning and we are often unaware of the important tasks it is performing. When the nerves that control Autonomic Regulation are damaged, Autonomic Dysfunction can develop. Autonomic Dysfunction can be temporary or chronic. Diabetes and Parkinson's disease are two examples of chronic conditions that can lead to Autonomic Dysfunction. Nexus ANS+ tests Autonomic Regulation through a combination of Heart Rate Variability (HRV) Assessment and Cardiac Autonomic Reflex Tests (CARTs).

Autonomic Regulation - Key Measurement Details

Total Power is the main indicator of ANS activity at rest. In peer reviews, Total Power is used to define the total HRV Score.

High Frequency (HF) of the RR Intervals spectral analysis. It reflects Parasympathetic activities at rest.

Stress Index reflects the sympathetic system's effect on peripheral circulation. Sympathetic effect of peripheral small fiber.

Standard Deviation Average of all Normal to Normal (SDANN) is an indicator of both sympathetic and parasympathetic regulation at rest, and is a marker of V02 max.

Heart Rate Variability (HRV)

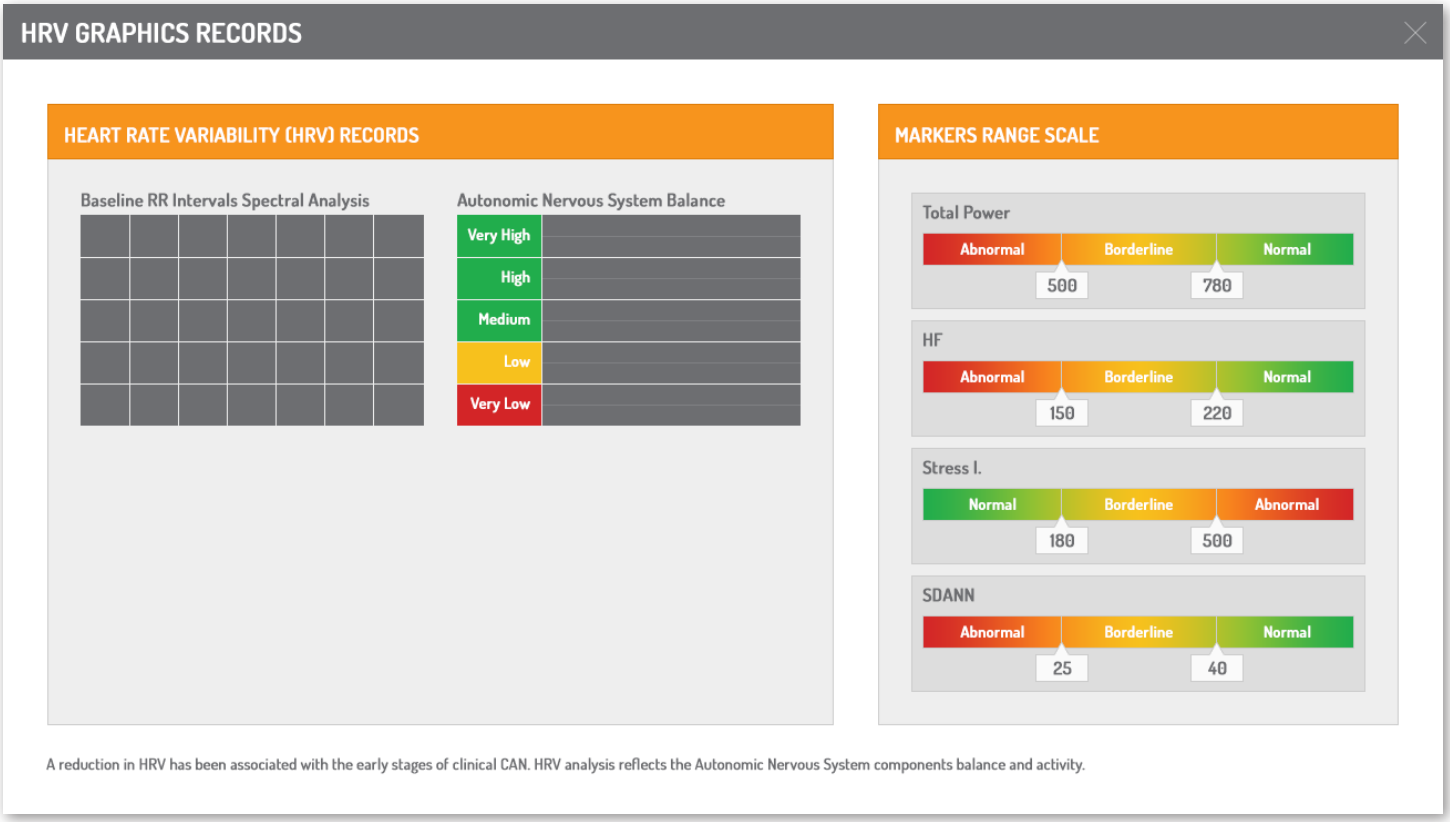
Heart Rate Variability (HRV) is the variation in the time interval between heartbeats. It is measured by the variation in the beat-to-beat intervals. It's measured in milliseconds. The Autonomic Nervous System plays a central role in HRV. Depressed or reduced HRV primarily means a lowered ability of the ANS regulatory function to keep homeostasis, cope with internal and external stressors (stress provoking agents), resist disease and/or recover in proper time.

Photoplethysmography (PTG)

Photoplethysmography (PTG) is an optical measurement technique using red and infrared light to measure peripheral blood volume obtained with the pulse oximeter.

- Is reflective of blood movement in cutaneous vessels and synchronous cardiovascular events.
- The signal contains information regarding the heart rate and variability, vessel dilation and contraction.

Autonomic Regulation - Graphics & Ranges



Clinical Data

A reduction of HRV and High score of Autonomic Regulation Score have been associated with the early stages of Cardiac Autonomic Neuropathy (CAN). HRV analysis reflects the autonomic nervous system components balance and activity. HRV results could be improved by lifestyle change.

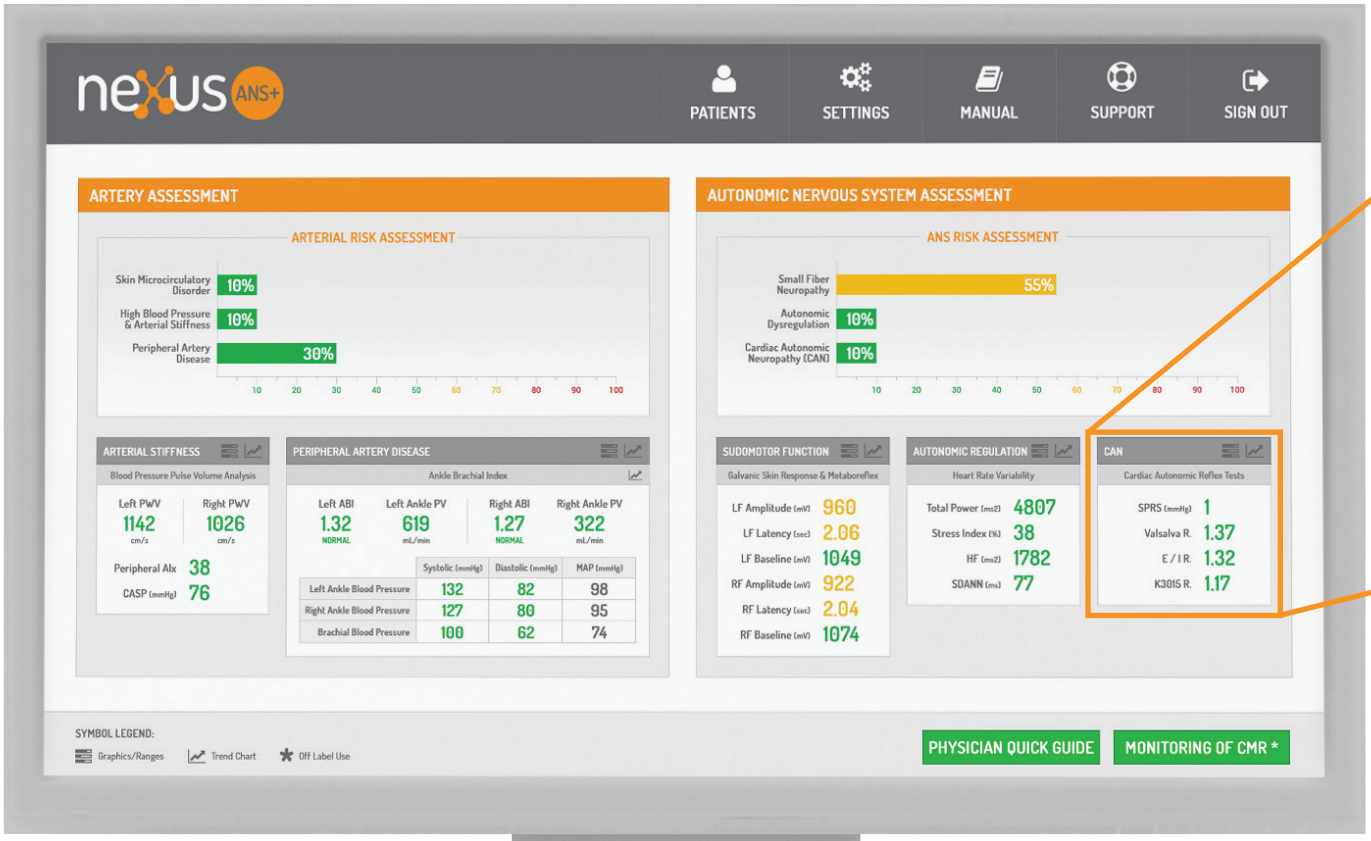
Educational Reading

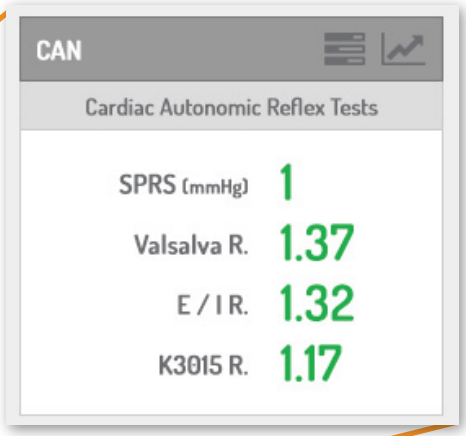
Heart rate variability: Standards of measurement, physiological interpretation, and clinical use: Task Force of The European Society of Cardiology and The North American Society of Pacing and Electrophysiology (Membership of the Task Force listed in the Appendix)
https://www.escardio.org/static_file/Escardio/Guidelines/Scientific-Statements/guidelines-Heart-Rate-Variability-FT-1996.pdf

Impact of reduced heart rate variability on risk for cardiac events. The Framingham Heart Study.
Hisako Tsuji, MD; Martin G. Larson, ScD; Ferdinand J. Venditti, Jr, MD; Emily S. Manders,
BS; Jane C. Evans, MPH; Charles L. Feldman, ScD; Daniel Levy, MD
http://www.ncbi.nlm.nih.gov/pubmed/8941112

Photoplethysmography and its application in clinical physiological measurement.
Regional Medical Physics Department, Freeman Hospital, Newcastle upon Tyne, UK. john.allen@nuth.nhs.uk
http://www.ncbi.nlm.nih.gov/pubmed/17322588

RESULTS – CARDIAC AUTONOMIC NEUROPATHY (CAN)





Description

Cardiovascular Autonomic Neuropathy (CAN) is a common form of autonomic neuropathy, causing abnormalities in heart rate control and central/peripheral vascular dynamics. CAN has a strong link to diabetes and can contribute to the development of a variety of severe conditions resulting in a multitude of complications and higher mortality risk. Like the Autonomic Regulation Assessment, Nexus ANS+ evaluates the Sympathetic and Parasympathetic Nervous Systems using CARTs to identify CAN risk factors.

Autonomic Regulation (CAN) - Key Measurements

Systolic Pressure Response to Standing (SPRV) is the difference between the sitting systolic pressure minus the standing systolic pressure. It reflects the Sympathetic adrenergic response.

Valsalva Ratio (VALS. R) is the subsequent tachycardia/bradycardia during the Valsalva maneuver are baro receptor mediated.

Expiration and Inspiration Ratio (E/I R) is calculated by the longest RR or NN Interval divided by the shortest RR Interval during the deep breathing test. It reflects the parasympathetic system's cardio-vagal response during breathing challenge.

K3015 R is the maximum RR intervals at 30 seconds divided by the minimum RR intervals at 15 seconds after standing up. It reflects the parasympathetic system cardiovagal response to the changes of posture. It is considered an index of cardiovascular function.

Cardiac Autonomic Reflex Tests (CARTs)

After a Baseline ANS Evaluation is completed by assessing the Heart Rate Variability (HRV) analysis, the **Cardiac Autonomic Reflex Tests (CARTs)** are performed. CARTs consist of 3 tests to assess the autonomic functions of the Sympathetic and Parasympathetic Systems. The tests are as follows:

- **Valsalva Maneuver** – patient bears down and attempts to exhale with mouth and nostrils closed
- **Deep Breathing** – patient performs a deep breathing exercise
- **Change in Posture** – patient stands up from a seated position

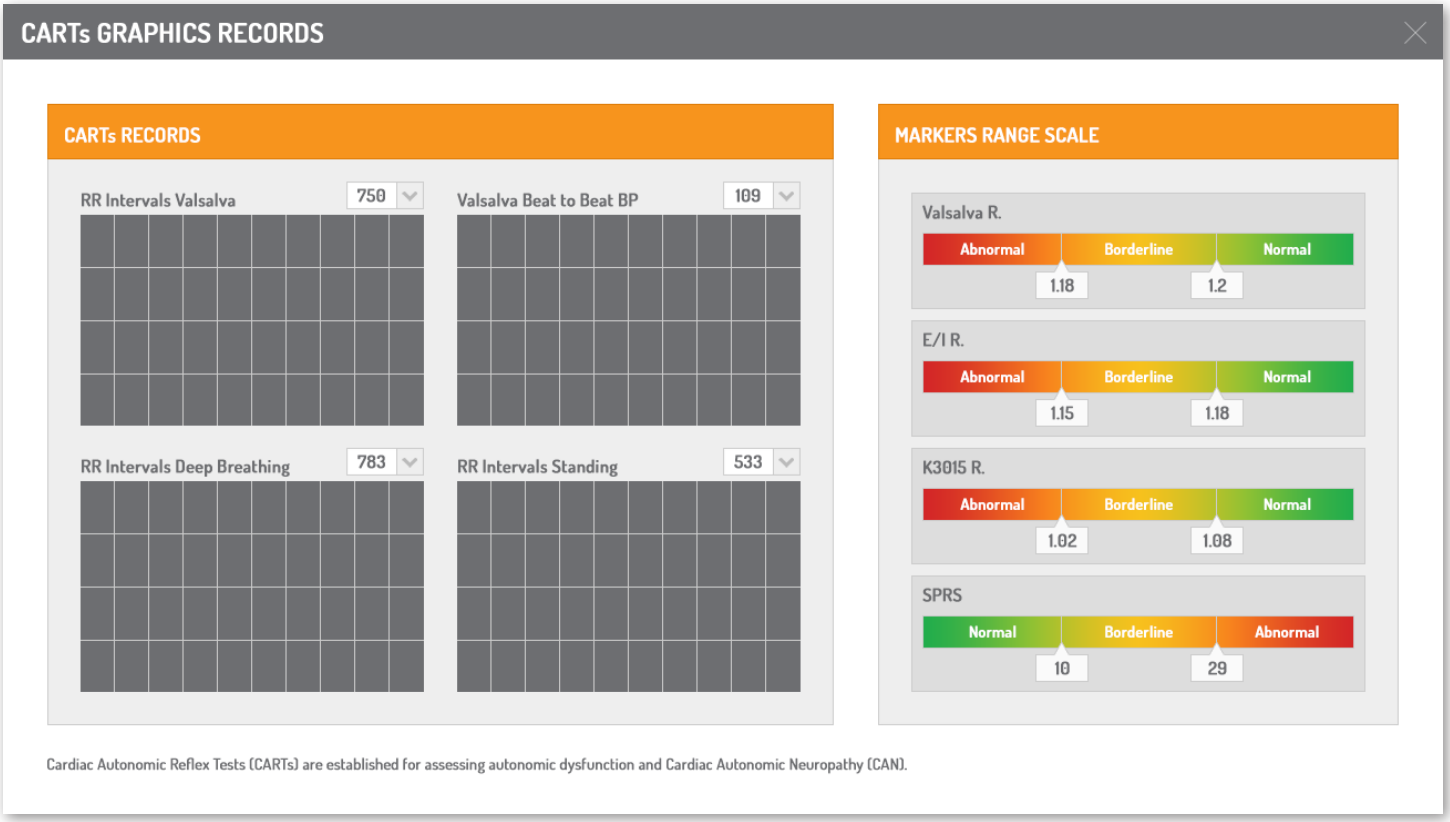
Cardiac Autonomic Reflex Tests (CARTs) are recognized in order to diagnose Cardiac Autonomic Neuropathy (CAN) by the guidance of the Cardiac Autonomic Neuropathy (CAN) Subcommittee of the Toronto Consensus Panel on Diabetic Neuropathy and American Academy of Neurology. Cardiac Autonomic neuropathy occurs when the nerves that control involuntary bodily functions are damaged. This may affect blood pressure, temperature control, digestion, bladder function and even sexual function.

Cardiovagal (Parasympathetic) Evaluation with Valsalva ratio: this is the ratio of heart rate phase IV/heart rate phase II, and is essentially a measure of vagal function. The normal response is an increase in heart rate during phase II (SPVR2) in responsetothe fall in blood pressure, and the baroreflex response to the blood pressure overshoot in phase IV (SPRV4) is transient bradycardia. In dysautonomia patients, there is typically a loss of both the blood pressure overshoot and the reflex bradycardia. Age-adjusted normal Valsalva ratios are used as controls for the Valsalva ratio.

Adrenergic (Sympathetic) Evaluation with Beat-to-beat blood pressure response to the Valsalva maneuver:phase II may be divided into early and late phases. In early phase II, reduced preload and stroke volume lead to a fall in cardiac output despite the tachycardia caused by decreased vagal activity. Total peripheral resistance increases due to increased sympathetic discharge (nucleus tractus solitarius) and an increase in plasma epinephrine concentration. The fall in blood pressure is thus arrested, and is termed "late phase II"; in normal patients there is actually a rise in blood pressure just before release. Interestingly, this phasecan be blocked with alpha-antagonists (e.g., phentolamine) while phase IV can be blocked with beta-blockers. Patients with peripheral adrenergic failure due to involvement of autonomic fibers will have absent late phase II and in fact can have such dramatic drops in blood pressure during forced expiration that syncope may occur.

Deep Breathing tests cardiac parasympathetic functions. Because the heart responses to deep breathing are mediated by the vagal nerve, the test is also referred to as cardiovagal testing. Duringinspiration, intra thoracic pressure is reduced, which will decrease venous return from the pulmonary circulation to the left atrium of the heart and decrease preload; heart ratewill therefore increase slightly to compensate and maintain the same cardiac output. The opposite happens during expiration; intra thoracic pressure rises, increasing pulmonary venous return (and therefore preload), so heart rate will decrease to maintain constant cardiac output. The results is expressed as E/I Ratio (expiration/Inspiration Ratio).

Cardiac Autonomic Neuropathy (CAN) - Graphics & Ranges



Educational Reading

1. Cardiovascular Autonomic Neuropathy in Diabetes: clinical impact, assessment, diagnosis, and management
Spallone v, Ziegler o. Freeman R. Bernardi L. Frontonl s. Pop-Busul R, Stevens M, Kempler P. Hilsted J, Testaye s. Low P, vatensl P; Toronto Consensus Panel on Diabetic Neuropathy. Diabetes Metab Res Rev. 2011 Oc~27(7):639·53. doi: 10.1002/dmrr.1239.

Diagnosis and management of diabetic autonomic neuropathy
"D J EWING, B F CLARKE 1982 BRITISH MEDICAL JOURNAL VOLUME 285"

nexus ANS+

SYMPTOM WORKSHEET

PATIENT INFORMATION

Name: _____ **Date of Birth:** _____ **Gender:** ☐ Male ☐ Female

Height: _____ **Weight:** _____ **Activity Level:** ☐ None ☐ Light ☐ Moderate ☐ Frequent ☐ Heavy

Have you experienced any of the following in the last 14 days?

			FOR OFFICE USE ONLY	
			ANS	Vascular
Frequent Urination	☐ Yes	☐ No		
Nausea	☐ Yes	☐ No		
Numbness in Hands & Feet	☐ Yes	☐ No		
Vomiting	☐ Yes	☐ No		
Burning Sensation	☐ Yes	☐ No		
Difficulty Digesting Food	☐ Yes	☐ No		
Sweat Abnormalities	☐ Yes	☐ No		
Sexual Difficulties	☐ Yes	☐ No		
Tingling in Hands & Feet	☐ Yes	☐ No		
Urinary Problems	☐ Yes	☐ No		
Cold, Clammy, Pale Skin	☐ Yes	☐ No		
Depression	☐ Yes	☐ No		
Fainting	☐ Yes	☐ No		
Lack of Concentration	☐ Yes	☐ No		
Lack of Energy	☐ Yes	☐ No		
Rapid Shallow Breathing	☐ Yes	☐ No		
Exercise Intolerance	☐ Yes	☐ No		
Painful Contact with Sock or Bed	☐ Yes	☐ No		
Pebble or Sand-like Sensation in Shoes	☐ Yes	☐ No		
Stabbing or Electrical Shock Sensation	☐ Yes	☐ No		
Pins & Needles in Feet	☐ Yes	☐ No		
Blurred Vision	☐ Yes	☐ No		
Elevated Blood Sugar	☐ Yes	☐ No		
Extreme Thirst	☐ Yes	☐ No		
Fatigue	☐ Yes	☐ No		
Increased Hunger	☐ Yes	☐ No		
Heartburn	☐ Yes	☐ No		
Pain In Calves	☐ Yes	☐ No		
Angina	☐ Yes	☐ No		
Chest Pain that Goes Away with Rest	☐ Yes	☐ No		
Shortness of Breath	☐ Yes	☐ No		
TIA (Mini Stroke)	☐ Yes	☐ No		
Blood Clot in a Vein	☐ Yes	☐ No		
Heart Attack	☐ Yes	☐ No		
Irregular Heartbeat (Too Fast/Slow)	☐ Yes	☐ No		
Stroke	☐ Yes	☐ No		

nexus ANS+

SUPER BILL

Patient Name: _____

Gender: ☐ Male ☐ Female Date of Birth: _____

CODING INFORMATION AND SUGGESTED BILLING AMOUNTS

CODES & MODIFIERS

95923 - $325.00 **95921** - $150.00

93922 - $180.00 **Modifier:** XU or 59

- CPT codes 95921 and 95943 CANNOT be used together.
- Use the 76 modifier if the physician has the need to repeat the test.
- Physicians can bill an E/M code along with these services. List E/M with a 25 Modifier then list test performed.
- Bill 1 unit for each CPT code
- Modifiers XU or 59 must be used on secondary CPT codes. Medicare allows modifier XU and 59 for Commercial payers.

CODES SPECIFIC TO 95921 AND 95923

☐ **E08.40**	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified	☐ **E85.0**	Non-neuropathic heredofamilial amyloidosis
☐ **E08.41**	Diabetes mellitus due to underlying condition with diabetic mononeuropathy	☐ **E85.1**	Neuropathic heredofamilial amyloidosis
☐ **E08.42**	Diabetes mellitus due to underlying condition with diabetic polyneuropathy	☐ **E85.2**	Heredofamilial amyloidosis, unspecified
☐ **E08.43**	Diabetes mellitus due to underlying condition with diabetic autonomic	☐ **E85.3**	Secondary systemic amyloidosis
☐ **E08.44**	Diabetes mellitus due to underlying condition with diabetic amyotrophy	☐ **E85.4**	Organ-limited amyloidosis
☐ **E08.49**	Diabetes mellitus due to underlying condition with other diabetic neurological complication	☐ **E85.8**	Other amyloidosis
☐ **E08.610**	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy	☐ **E85.9**	Amyloidosis, unspecified
☐ **E08.65**	Diabetes mellitus due to underlying condition with hyperglycemia	☐ **G90.1**	Disorders of autonomic nervous system, Familial dysautonomia
☐ **E10.40**	Type 1 diabetes mellitus with diabetic neuropathy, unspecified	☐ **G90.2**	Horner's syndrome
☐ **E10.41**	Type 1 diabetes mellitus with diabetic mononeuropathy	☐ **G90.3**	Multi-system degeneration of the autonomic nervous system
☐ **E10.42**	Type 1 diabetes mellitus with diabetic polyneuropathy	☐ **G90.4**	Autonomic dysreflexia
☐ **E10.43**	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	☐ **G90.50**	Complex regional pain syndrome I, unspecified
☐ **E10.44**	Type 1 diabetes mellitus with diabetic amyotrophy	☐ **G90.511**	Complex regional pain syndrome I of right upper limb
☐ **E10.49**	Type 1 diabetes mellitus with other diabetic neurological complication	☐ **G90.512**	Complex regional pain syndrome I of left upper limb
☐ **E10.610**	Type 1 diabetes mellitus with diabetic neuropathic arthropathy	☐ **G90.513**	Complex regional pain syndrome I of upper limb, bilateral
☐ **E10.65**	Type 1 diabetes mellitus with hyperglycemia	☐ **G90.519**	Complex regional pain syndrome I of unspecified upper limb
☐ **E13.40**	Other specified diabetes mellitus with diabetic neuropathy, unspecified	☐ **G90.521**	Complex regional pain syndrome I of right lower limb
☐ **E13.41**	Other specified diabetes mellitus with diabetic mononeuropathy	☐ **G90.522**	Complex regional pain syndrome I of left lower limb
☐ **E13.42**	Other specified diabetes mellitus with diabetic polyneuropathy	☐ **G90.523**	Complex regional pain syndrome I of lower limb, bilateral
☐ **E13.43**	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy	☐ **G90.529**	Complex regional pain syndrome I of unspecified lower limb
☐ **E13.44**	Other specified diabetes mellitus with diabetic amyotrophy	☐ **G90.59**	Complex regional pain syndrome I of other specified site
☐ **E13.49**	Other specified diabetes mellitus with other diabetic neurological complication	☐ **G90.8**	Other disorders of autonomic nervous system
☐ **E11.40**	Type 2 diabetes mellitus with diabetic neuropathy, unspecified	☐ **G90.9**	Disorder of the autonomic nervous system, unspecified
☐ **E11.41**	Type 2 diabetes mellitus with diabetic mononeuropathy	☐ **G60.0**	Hereditary motor and sensory neuropathy
☐ **E11.42**	Type 2 diabetes mellitus with diabetic polyneuropathy	☐ **G60.1**	Refsum's disease
☐ **E11.43**	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	☐ **G60.2**	Neuropathy in association with hereditary ataxia
☐ **E11.44**	Type 2 diabetes mellitus with diabetic amyotrophy	☐ **G60.3**	Idiopathic progressive neuropathy
☐ **E11.49**	Type 2 diabetes mellitus with other diabetic neurological complication	☐ **G60.8**	Other hereditary and idiopathic neuropathies
☐ **E11.610**	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	☐ **G60.9**	Hereditary and idiopathic neuropathy, unspecified
☐ **E11.65**	Type 2 diabetes mellitus with hyperglycemia	☐ **G61.81**	Chronic inflammatory demyelinating polyneuritis
☐ **E13.610**	Other specified diabetes mellitus with diabetic neuropathic arthropathy	☐ **G63**	Polyneuropathy in deseases classified elsewhere
☐ **R55**	Syncope and collapse	☐ **I49.8**	Other specified cardiac arrhythmias
☐ **R00.0**	Tachycardia, unspecified		

CODES SPECIFIC TO 93922

☐ **I72.4**	Aneursym Of Artery Of Lower Extremity.	☐ **E10.65**	Diabetes Mellitus W/ P Circ Disorders I Uncontrolled
☐ **I72.1**	Aneurysm Of Artery Iliac Crest	☐ **E11.51**	Diabetes Mellitus W/ P Circ Disorders II Not Stated As Uncontrolled.
☐ **I72.3**	Aneurysm Of Artery Upper Extremity.	☐ **E11.65**	Diabetes Mellitus W/ P Circ Disorders, Ii Unspecif Type Uncontrolled.
☐ **I70.209**	Atherosclerosis Native Arteries Extremites Unspecified.	☐ **E08.51**	Diabetes mellitus due to underlying condition W/ diabetic peripheral angiopathy W/O gangrene
☐ **I70.229**	Atherosclerosis Native Arteries Extremites With Rest Pain.	☐ **E08.52**	Diabetes mellitus due to underlying condition W/ diabetic peripheral angiopathy W/ gangrene
☐ **I70.269**	Atherosclerosis Native Arteries W/ Gangrene	☐ **E09.51**	Drug or chemical induced diabetes mellitus W/ diabetic peripheral angiopathy W/O gangrene
☐ **I70.219**	Atherosclerosis Native Arteries W/ Intermittent Claudication.	☐ **E09.52**	Drug or chemical induced diabetes mellitus W/ diabetic peripheral angiopathy W/ gangrene
☐ **I70.25**	Atherosclerosis Native Arteries W/Ulceration.	☐ **E10.51**	Type 1 diabetes mellitus W/ diabetic peripheral angiopathy W/O gangrene
☐ **I70.599**	Atherosclerosis Non Autologous Biological Bypass Graft Extremities.	☐ **E10.52**	Type 1 diabetes mellitus W/ diabetic peripheral angiopathy W/ gangrene
☐ **I70.0**	Atherosclerosis Of Aorta	☐ **E11.52**	Type 2 diabetes mellitus W/ diabetic peripheral angiopathy W/ gangrene
☐ **I70.499**	Atherosclerosis Of Autologous Vein Bypass Graft Extremites.	☐ **E13.52**	Other specified diabetes mellitus W/ diabetic peripheral angiopathy W/ gangrene
☐ **I70.399**	Atherosclerosis Of Bypass Graft Extremites	☐ **I10**	Hypertension Unspecified
☐ **I77.71**	Dissection of carotid artery	☐ **I30.9**	Acute pericarditis, unspecified
☐ **I77.72**	Dissection of iliac artery	☐ **I40.0**	Infective myocarditis
☐ **I77.73**	Dissection of renal artery	☐ **I40.1**	Isolated myocarditis
☐ **I77.74**	Dissection of vertebral artery	☐ **I48.0**	Paroxysmal atrial fibrillation
☐ **I67.0**	Dissection of cerebral arteries, nonruptured	☐ **I48.1**	Persistent atrial fibrillatio
☐ **I96**	Gangrene, not elsewhere classified	☐ **I48.2**	Chronic atrial fibrillation
☐ **I73.9**	Pheripheral Vascular Disease, Unspecified	☐ **I48.91**	Unspecified atrial fibrillation
☐ **I73.00**	Raynaud's symdrome without gangrene	☐ **Z13.9**	Screening For Hypertension
☐ **I73.01**	Raynaud's syndrome with gangrene	☐ **G54.0**	Brachial plexus disorders
☐ **I73.1**	Thromboangiitis obliterans (Buerger's disease)	☐ **I74.01**	Saddle embolus of abdominal aorta

Ordering Physician: _____ Signature: _____ Date: _____

* The information contained in this template superbill is intended as general information only. It is not intended to serve as a substitute for professional advice of a physician or medical coding professional. Final determination should be made by the treating physician. CODES SPECIFIC TO 93922, 95921 & 95923. * Physicians can bill an E/M code along with these services.

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