

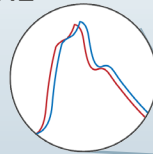


EARLY DETECTION OF DIABETES AND ITS COMPLICATIONS

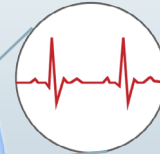
AUTONOMIC NERVES AND VASCULAR ASSESSEMENTS

BRACHIAL BLOOD PRESSURE AND CENTRAL AORTIC SYSTOLIC PRESSURE

Monitoring and Treatment Management of Hypertension



HEART RATE VARIABILITY (HRV)
Fitness and early stage of Autonomic dysfunction



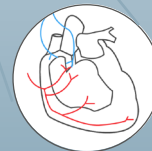
PHOTOPLETHYSMOGRAPHY

Patented Endothelial function and Insulin resistance markers with high specificity and sensitivity comparing to the gold standard



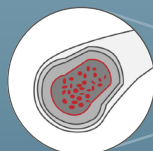
CARDIAC AUTONOMIC REFLEX TESTS (CARTs)

Cardiac Autonomic Neuropathy Assessment



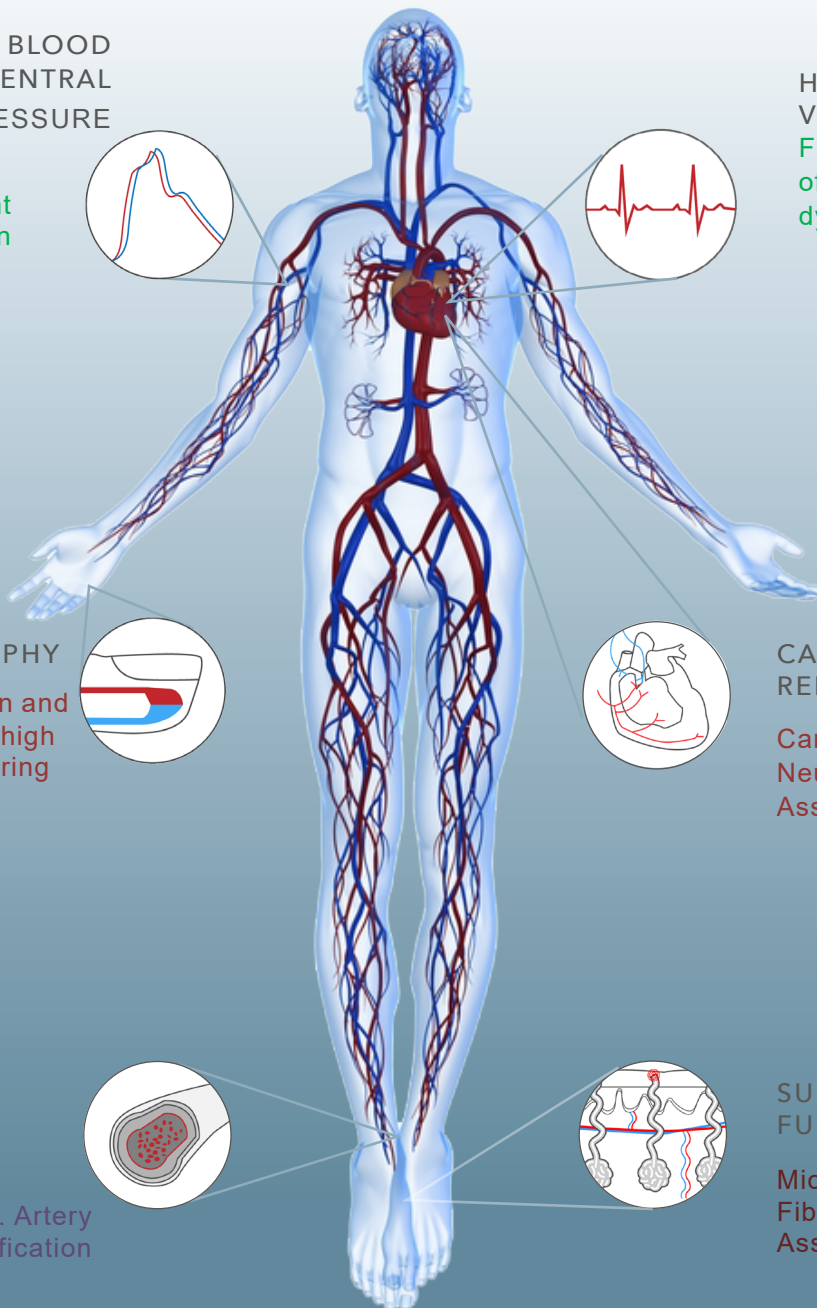
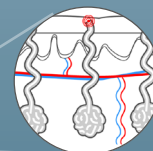
ANKLE BRACHIAL INDEX

Peripheral Artery Disease. Artery Blood Flow blockage or Calcification



SUDOMOTOR FUNCTION TESTS

Microcirculation and Small Fiber Neuropathy Assessments



MAIN SYMPTOMS OF AUTONOMIC NEUROPATHY AND VASCULAR DYSFUNCTION

- Fatigue
- Headache
- Dizziness
- Exercise Intolerance
- Fainting
- Tingling in the Toes or Fingers
- Claudication
- Painful muscle cramping in the hips, thighs or calves when walking, climbing stairs or exercising

POPULATIONS THAT SHOULD BE TESTED WITH LD PRODUCTS

Autonomic neuropathy and vascular dysfunction risk group in the USA

50+

Population over 50 years old
with cardiovascular risk factors
(Hypertensive, Overweight, Smoker, Diabetic)

70+

Everyone older than 70

OVER 45 MILLION PEOPLE

**EVERYONE IN THE RISK GROUP
SHOULD BE MEASURED
WITH LD PRODUCTS**

TM-FLOW

VASCULAR / AUTONOMIC NERVES

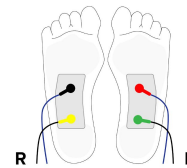
FULL ASSESSMENT

TM-FLOW IS A MEDICAL DEVICE DATA SYSTEM INTEGRATING 4 TECHNOLOGIES



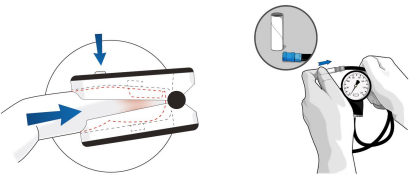
SWEATC

1. GALVANIC SKIN RESPONSE
2. BIOIMPEDANCE ANALYSIS



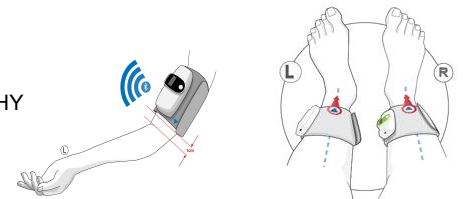
LD-OXI

3. PHOTOPLETHYSMOGRAPHY

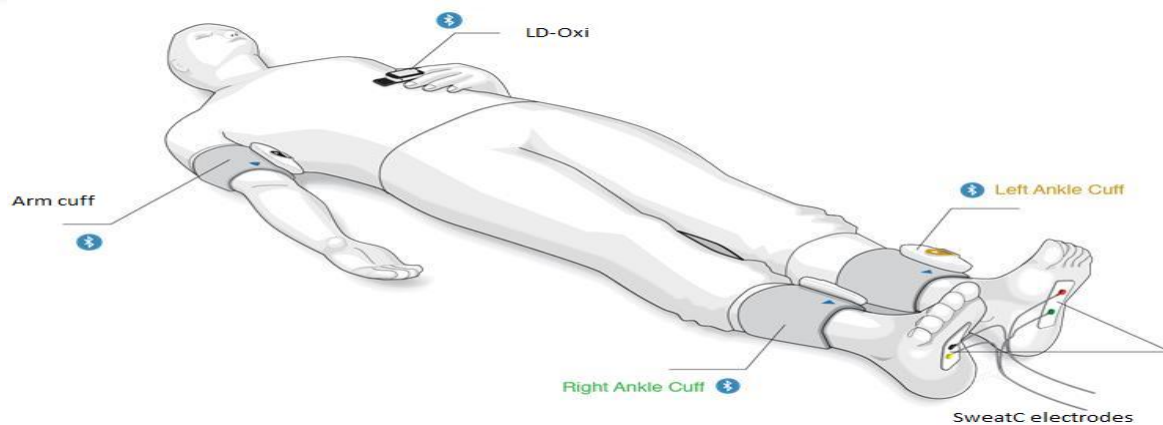


TBL-ABI

4. BRACHIAL AND ANKLES' VOLUME PLETHYSMOGRAPHY



PATIENT SETUP



TM-FLOW ASSESSMENTS

ARTERY ASSESSMENT :

Photoplethysmography (PTG)

Endothelial function assessment:

- Second derivative PTG
- Stress Index
- PTGVLF Index
- PTG Index

Insulin Resistance assessment:

- PTG-TP

Volume Plethysmography Analysis

Large artery Assessment:

- Pulse Wave Velocity (PWV)
- Peripheral Augmentation Index (pAIx)
- Central Aortic Systolic Pressure (CASP)
- Ankle Brachial Indices (ABI)

ANS ASSESSMENT :

Galvanic Skin response (GSR)

Sudomotor function:

- Micro circulation
- C-Fiber density

Cardiac Autonomic Reflex Tests (CARTs)

Heart Rate Variability at rest:

- Total Power
- SDANN
- LF/HF

Heart Rate Variability during challenges:

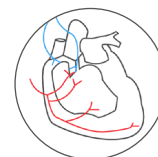
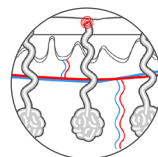
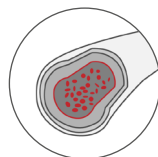
- Valsalva Ratio
- E/I Ratio
- K30/15 Ratio and
- Systolic Pressure Response difference while standing

ENDOTHELIAL DYSFUNCTION
INSULIN RESISTANCE

X LARGE ARTERY DISEASE

X SUDOMOTOR DYSFUNCTION

X CARDIAC AUTONOMIC NEUROPATHY



TM-FLOW SYSTEM OUTCOMES



No Human Error



Clear report



Accurate Results



(Simultaneous measurements)
7-10 min



ANS and vascular Overview
Combination of Technologies

TM-FLOW is the only available medical device for assessing the Autonomic Nervous and vascular systems in one exam.

TM-FLOW helps the physician to distinguish the cause of neuropathic or vascular symptoms.

Moreover, since Autonomic Neuropathy, insulin resistance and vascular dysfunctions are the early signs and main complications of chronic metabolic diseases, in adjunct with the blood tests,

TM-FLOW enhances the early detection and treatment management of those diseases.

TM-FLOW performs accurate, simultaneous measurements that are based on established medical guidelines without any extrapolation of the results.

TBL-ABI

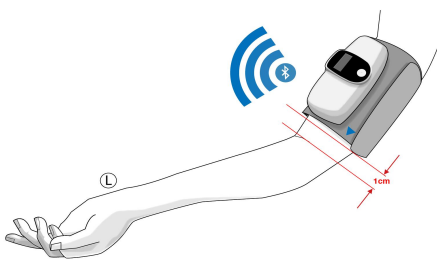
VASCULAR

PERIPHERAL ARTERY DISEASE ASSESSMENT AND HYPERTENSION MANAGEMENT



The TBL-ABI is the first valuable automated **wireless** system based on pulse volume plethysmography for measuring blood pressure, ankle brachial index, arterial stiffness and central aortic Pressure.

PATIENT SETUP



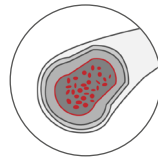
TBL-ABI ASSESSMENT

VASCULAR MARKERS:

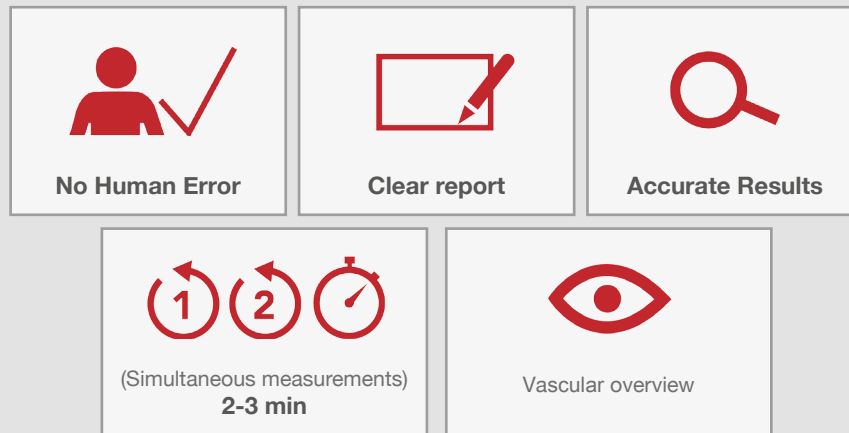
Volume plethysmography analysis:

- Arm and Ankles Blood Pressure
- Pulse Wave Velocity (PWV)
- Peripheral Augmentation Index (pAIx)
- Central Aortic Systolic Pressure (CASP)
- Ankle Brachial Indices (ABI)

PERIPHERAL ARTERY DISEASE X LARGE ARTERY STIFFNESS



TBL-ABI OUTCOMES



TBL-ABI detects the markers of hypertension in addition to the Brachial Blood Pressure. The device provides Brachial and Ankle Arterial Stiffness and Central Aortic Systolic Pressure.

ALLOWS NEW AND EFFECTIVE TREATMENT MANAGEMENT OF HYPERTENSION

- Best method to assess peripheral artery disease using:
- Synchronization of the measurements arm-ankles
 - Wireless Blood pressure measurement using Pulse volume plethysmography

ANS-1

AUTONOMIC NERVES/ENDOTHELIAL FUNCTION

AUTONOMIC NERVOUS SYSTEM AND ENDOTHELIAL FUNCTION ASSESSMENT



ANS-1 IS A MEDICAL DEVICE INTEGRATING 3 TECHNOLOGIES

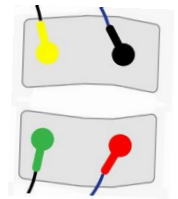
BLOOD PRESSURE DEVICE



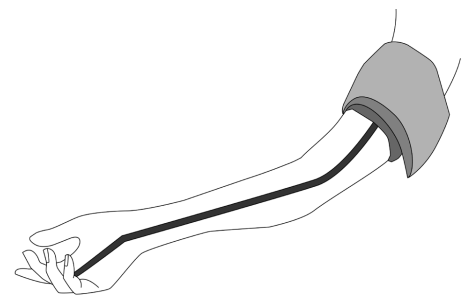
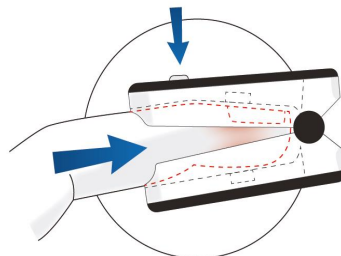
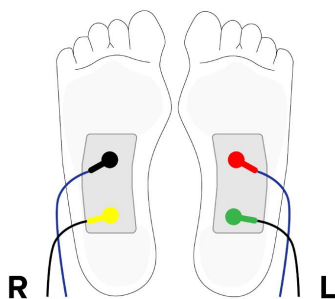
LD-OXI



GALVANIC SKIN RESPONSE



PATIENT SETUP



ANS-1 MARKERS

VASCULAR ASSESSMENT

Photoplethysmography (PTG)

Endothelial function assessment:

- Second derivative PTG
- Stress Index
- PTGVLF Index
- PTG Index

Insulin Resistance assessment:

- PTG-TP

Large artery Assessment:

- Peripheral Augmentation Index (pAIx) -
- Central Aortic Systolic Pressure (CASP)

ANS ASSESSMENT :

Galvanic Skin response (GSR)

Sudomotor function:

- Micro circulation
- C-Fiber density

Cardiac Autonomic Reflex Tests (CARTs)

Heart Rate Variability at rest:

- Total Power
- SDANN
- LF/HF

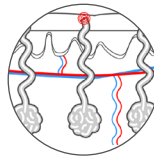
Heart Rate Variability during challenges:

- Valsalva Ratio
- E/I Ratio
- K30/15 Ratio and
- Systolic Pressure Response difference while standing

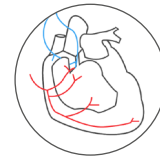
ENDOTHELIAL DYSFUNCTION X
INSULIN RESISTANCE



SUDOMOTOR DYSFUNCTION X



CARDIAC AUTONOMIC NEUROPATHY



ANS-1 OUTCOMES



No Human Error



Clear report



Accurate Results



(Simultaneous measurements)

7-10 min



Overview

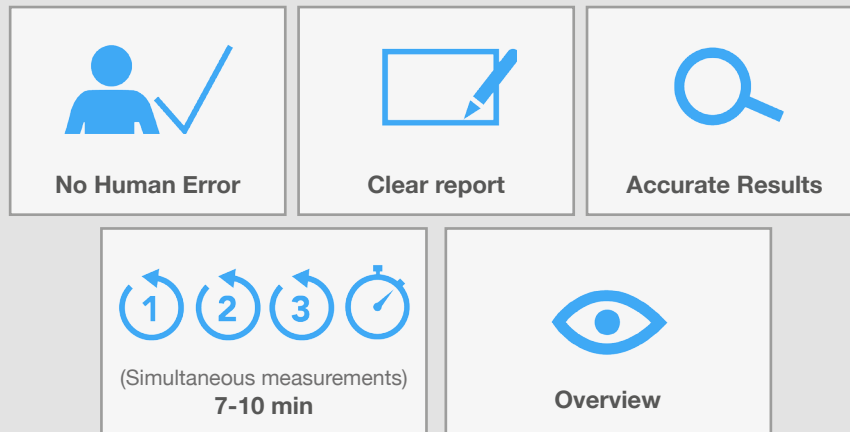
Autonomic testing is recommended for all patients with type 2 diabetes at the time of the diagnosis, and 5 years after diagnosis in individuals with type 1 diabetes. (Boulton et al., 2005; Tesfaye et al., 2010; Spallone et al., 2011; Bernardi et al., 2011.)

Since Autonomic Neuropathy, insulin resistance and endothelial dysfunction are the early signs and main complications of chronic metabolic diseases, in adjunct with the blood tests, ANS-1 enhances the early detection and treatment management of those diseases.

WMS ASSESSMENT



WMS OUTCOMES



WMS analyzes the markers of photoplethysmography, bioimpedance, interstitial fluid and autonomic nervous system to provides the best personalized wellness program for each patient.

The accuracy of the WMS markers are supported by several published clinical studies.

TECHNICAL SPECIFICATIONS

SWEATC	
Measuring principle	Galvanic skin response
Measuring Range	
Voltage	Maximum 1.28 V
Intensity	Maximum 200 mA
Measuring Accuracy	
The max mean deviation	± 3%
Power requirements	
Supply voltage	5V via USB port

SWEATC
Galvanic Skin Response related to the sweat gland function.

510k # k152216

TBL-ABI	
Measuring types	Ankle Brachial pressure index using volume plethysmography method for measuring systolic and diastolic pressure at arm and ankles.
Measuring ranges	Pressure: 0 to 299 mmhg Heart rate 30 to 199 per min.

TBL-ABI
Plethysmography Analysis for assessing symptomatic peripheral artery disease.

510k # k179636

LD-OXY	
SpO ₂ Parameter Specification	
Measuring range	0%~100% (the resolution is 1%)
Measuring range	Photoplethysmography resolution: 100 ms
Pulse Parameter Specification	
Measuring ranges	30 bpm ~ 250 bpm, (the resolution is 1bpm)
Accuracy	± 2bpm during the pulse rate range of 30 ~ 99bpm and 2% during pulse rate range of 100 ~ 250bpm

LD-OXY
Photoplethysmography analysis, HRV and CARTs analysis.

510k # k160956

ANS-1
Photoplethysmography analysis, HRV and CARTs analysis and blood pressure.

510k # # k140412



LD TECHNOLOGY ISO 13485

FDA OWNER/OPERATOR NUMBER: 9097859

FDA ESTABLISHMENT REGISTRATION NUMBER: 3006146787

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