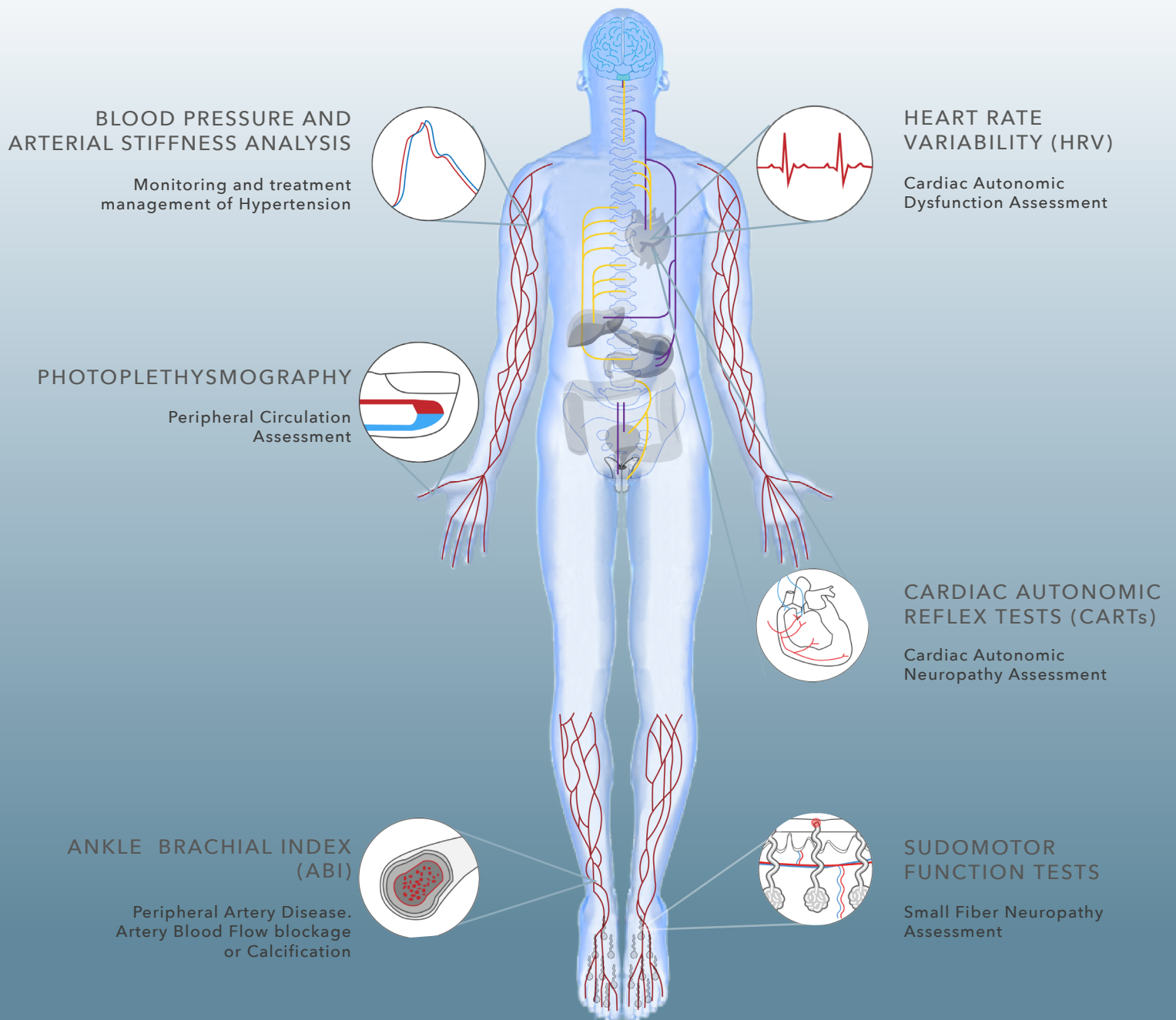




EARLY DETECTION OF DIABETES COMPLICATIONS

AUTONOMIC NERVOUS SYSTEM AND VASCULAR FUNCTION 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 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 SYSTEM

VASCULAR FUNCTION AND AUTONOMIC NERVOUS SYSTEM ASSESSMENTS

EARLY DETECTION AND MONITORING OF NEUROPATHIC AND VASCULAR COMPLICATIONS



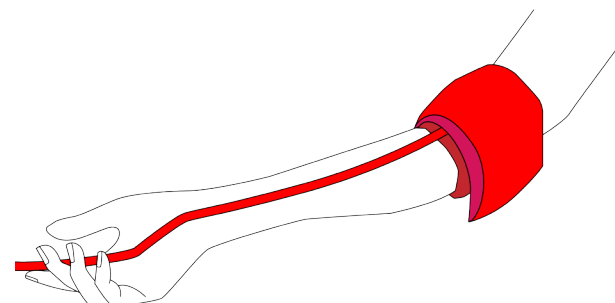
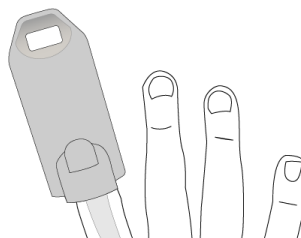
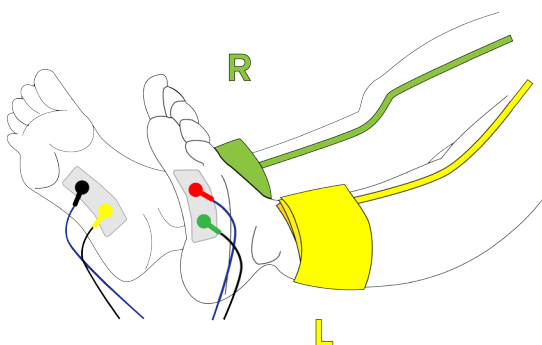
OXIMETER



FOOT ELECTRODES

TM-Flow System is focused on the Autonomic Nervous System and Vascular System for the early detection and monitoring of complications resulting from chronic diseases, such as Diabetes.

PATIENT SETUP



TM-FLOW SYSTEM MARKERS

VASCULAR ASSESSMENT :

Peripheral Circulation Markers

Photoplethysmography analysis

Segmental Vascular Assessment:

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

ANS ASSESSMENT :

Sudomotor Markers

Sympathetic Skin Response

Heart Rate Variability Analysis (HRV)

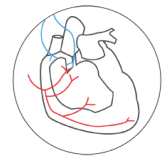
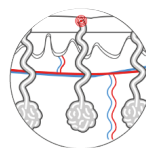
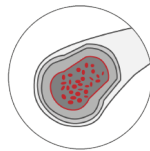
Total Power, SDANN, LF, HF and LF/HF

Cardiac Autonomic Reflex Tests (CARTs)

Valsalva Ratio, E/I Ratio and K30/15 Ratio

INCREASED PERFORMANCE BY ADDING TECHNOLOGIES

PERIPHERAL CIRCULATION + PERIPHERAL ARTERY DISEASE + SUDOMOTOR DYSFUNCTION + CARDIAC AUTONOMIC NEUROPATHY



BENEFITS OF TM-FLOW SYSTEM



No Human Error



Clear report



Accurate Results



(Simultaneous measurements)
7-10 min



ANS and vascular function
Overview

«If there is no early diagnosis,
then there is no timely treatment»

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

TM-FLOW SYSTEM TECHNOLOGY SPECIFICATIONS

TM-FLOW System is a Medical Device Data System (MDDS) which manages the SweatC, TM-ABI and LD-OXY Systems. FDA product code: OUG.

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

SWEATC
Galvanic Skin Response
related to the sweat gland
function.

510k # k152216

TM-ABI	
Measuring types	Segmental Volume Plethysmography method for calculating Ankle Brachial Indices (ABI) and Arterial Stiffness
Measuring ranges	Pressure: 0 to 299 mmHg
Measuring Accuracy	
Blood Pressure accuracy	± 3 mmHg
ABI accuracy	± 0.01

TM-ABI
Volume Plethysmography
for assessing symptomatic
Peripheral Artery Disease.

510k # k143152

LD-OXY	
Measuring range	
SpO2 % range	0%~100%
Photoplethysmography resolution	# 100 ms
Heart Rate range	30 bpm ~ 250 bpm
Measuring Accuracy	
Pulse Rate	± 2 bpm
SpO2 %	± 2 % in the range 70 -100 %

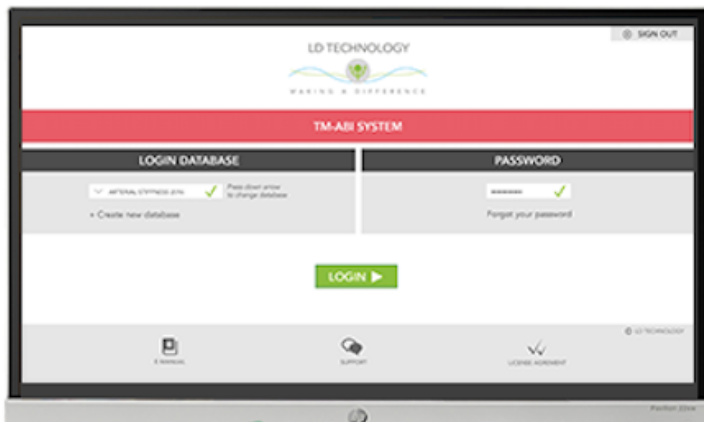
LD-OXY
Photoplethysmography,
HRV and CARTs analysis.

510k # k160956

LEDA SYSTEM

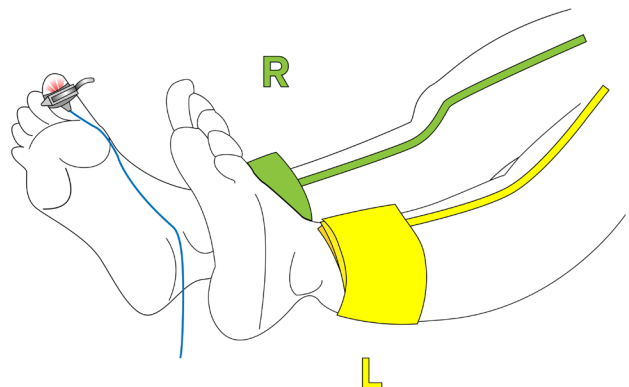
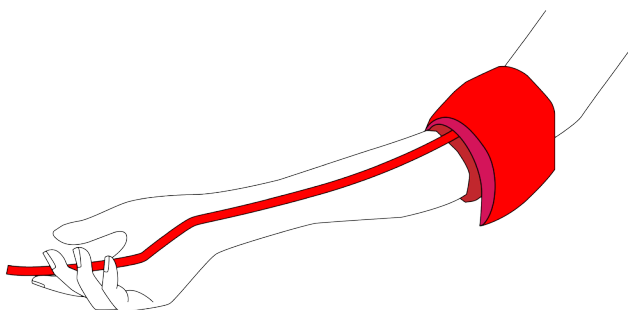
VASCULAR FUNCTION ASSESSMENT

PERIPHERAL ARTERY DISEASE AND HYPERTENSION TREATMENT MANAGEMENT



LEDA SYSTEM is the first valuable automated ankle-brachial index measuring system based on volume plethysmography for measuring blood pressure, ankle brachial and toe brachial index, arterial stiffness and central aortic Pressure.

PATIENT SETUP

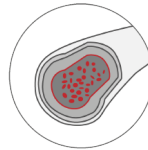


LEDA SYSTEM MARKERS

SEGMENTAL 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)
Toe Brachial Index (TBI)

PERIPHERAL ARTERY DISEASE



BENEFITS OF LEDA SYSTEM



No Human Error



Clear report



Accurate Results



(Simultaneous measurements)
2-3 min



Vascular function Overview

LEDA System detects all 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
- Blood pressure measurement from Photoplethysmography
- Toe Brachial Index is a requirement to assess PAD in cases of ABI results ≥ 1.4

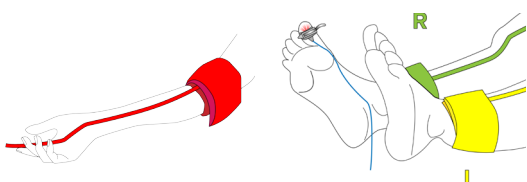
OPTION TO UPGRADE LEDA SYSTEM

START WITH LEDA BASIC SYSTEM



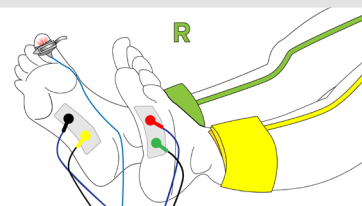
THEN, ADD SWEATC TECHNOLOGY

LEDA SYSTEM
Vascular assessment



+

Sudomotor function assesment



LEDA SYSTEM TECHNOLOGY SPECIFICATIONS

LEDA SYSTEM is a Medical Device Data System (MDDS) which manages the TM-ABI and LD-OXY Systems.
FDA product code: OUG.

TM-ABI	
Measuring types	Segmental Volume Plethysmography method for calculating Ankle Brachial Indices (ABI) and Arterial Stiffness
Measuring ranges	Pressure: 0 to 299 mmHg
Measuring Accuracy	
Blood Pressure accuracy	± 3 mmHg
ABI accuracy	± 0.01

TM-ABI
Volume Plethysmography
for assessing symptomatic
Peripheral Artery Disease.

510k # k143152

LD-OXY	
Measuring range	
SpO2 % range	0%~100%
Photoplethysmography resolution	# 100 ms
Heart Rate range	30 bpm ~ 250 bpm
Measuring Accuracy	
Pulse Rate	± 2 bpm
SpO2 %	± 2 % in the range 70 -100 %

LD-OXY
Photoplethysmography,
HRV and CARTs analysis.

510k # k160956

ANS-1 SYSTEM

AUTONOMIC NERVOUS SYSTEM ASSESSMENT

EARLY DETECTION AND MONITORING OF NEUROPATHIC
AND PERIPHERAL CIRCULATION COMPLICATIONS



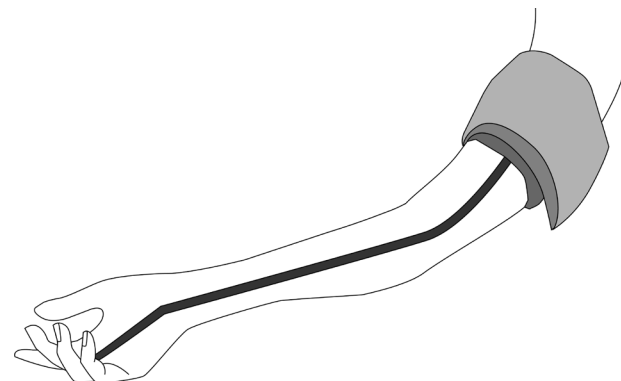
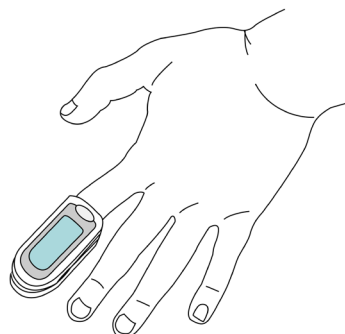
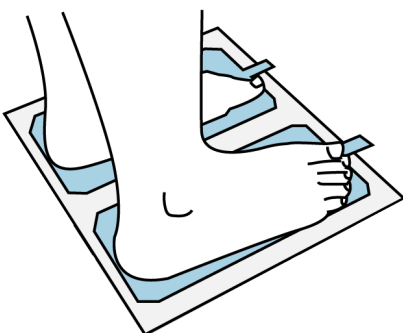
OXIMETER



FOOT ELECTRODES

ANS-1 System manages the Peripheral Circulation, Sudomotor test, Heart Rate Variability (HRV) Analysis at rest and during the Ewings tests in order to provide an overview of Automic Nervous System.

PATIENT SETUP



ANS-1 SYSTEM MARKERS

VASCULAR ASSESSMENT :

Peripheral Circulation markers

Photoplethysmography analysis

Brachial Blood Pressure

ANS ASSESSMENT :

Sudomotor markers

Sympathetic Skin response

Heart Rate Variability Analysis (HRV)

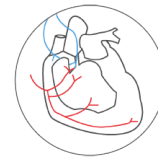
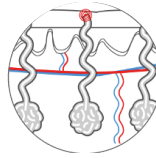
Total Power, SDANN, LF, HF and LF/HF

Cardiac Autonomic Reflex Tests (CARTs)

Valsalva Ratio, E/I Ratio and K30/15 Ratio

INCREASED PERFORMANCE BY ADDING TECHNOLOGIES

PERIPHERAL CIRCULATION + SUDOMOTOR DYSFUNCTION + CARDIAC AUTONOMIC NEUROPATHY



BENEFITS OF ANS-1 SYSTEM



No Human Error



Clear report



Accurate Results



(Simultaneous measurements)
7-10 min



Integrated Technologies

ANS-1 System manages the Autonomic Nervous System battery of tests recommended by the American Academy of Neurology since 1996, and the Cardiovascular Autonomic Neuropathy Subcommittee of the Toronto Consensus Panel on Diabetic Neuropathy, for assessing the Autonomic Nervous System.

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.)

ANS-1 SYSTEM TECHNOLOGY SPECIFICATIONS

ANS-1 System manages a Galvanic Skin response device, an oximeter and non-invasive blood pressure device. FDA product code: DXN, DQA, GZO and MNW.

GALVANIC SKIN RESPONSE	
Measuring principle	Galvanic skin response
Measuring Range	
Voltage	Maximum 1.28 V
Intensity	Maximum 200 mA
Measuring Accuracy	
The max mean deviation	$\pm 3\%$
Power requirements	
Supply voltage	5V via USB port

BLOOD PRESSURE DEVICE	
Measuring types	Brachial pressure index using oscillometric method.
Measuring ranges	Pressure: 0 to 299 mmHg.
Measuring Accuracy	
Blood Pressure accuracy	± 3 mmHg

OXIMETER	
Measuring range	
SpO2 % range	0%~100%
Photoplethysmography resolution	# 100 ms
Heart Rate range	30 bpm ~ 250 bpm
Measuring Accuracy	
Pulse Rate	± 2 bpm
SpO2 %	± 2 % in the range 70 -100 %

ANS-1 SYSTEM
Sudomotor function, HRV
and CARTs Analysis and
Photoplethysmography

510k # k140412



LD TECHNOLOGY
ISO 13485-2003 - CAMCAS

FDA OWNER/OPERATOR NUMBER: 9097859

FDA ESTABLISHMENT REGISTRATION NUMBER: 3006146787

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