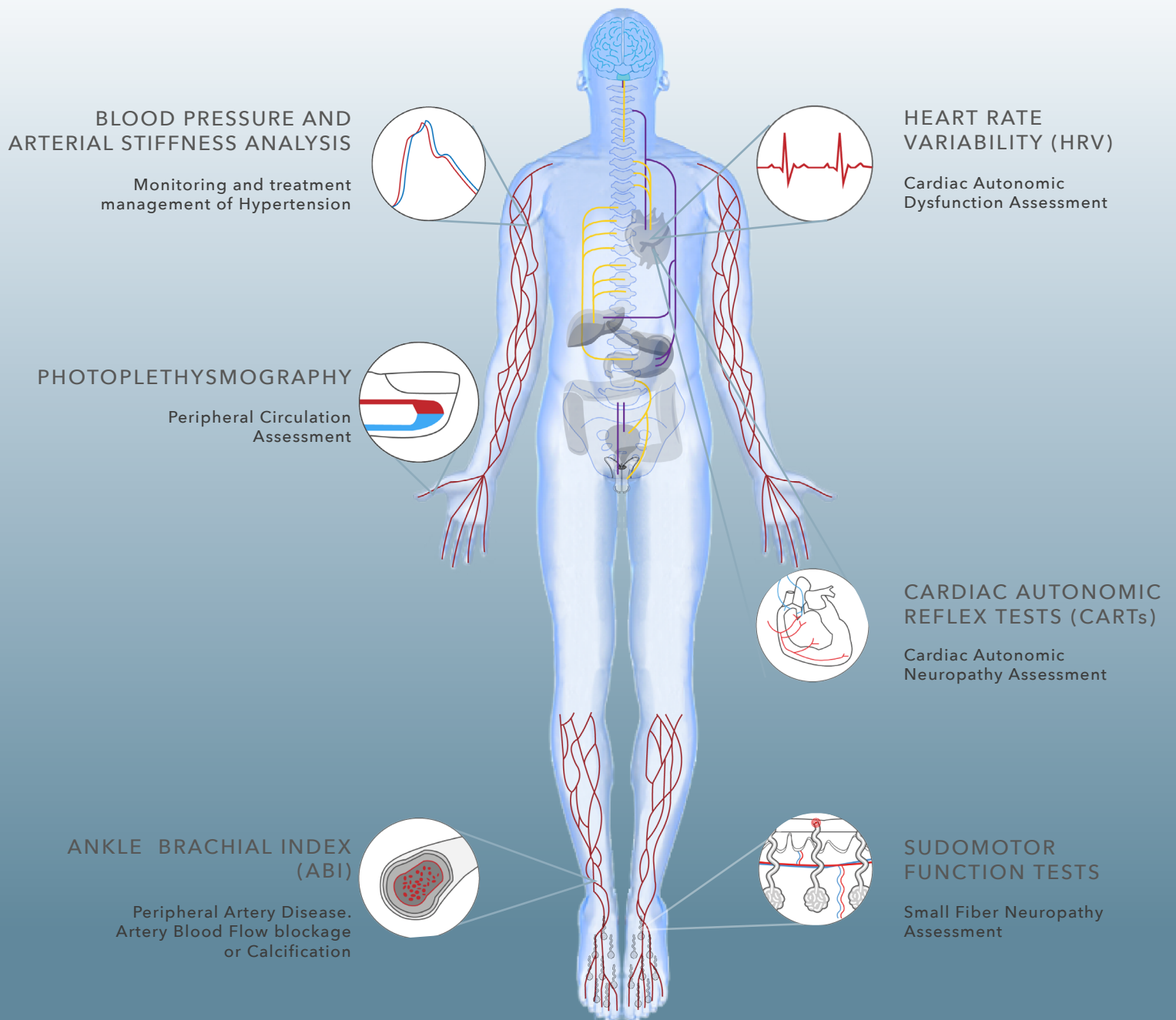




## EARLY DETECTION OF DIABETES COMPLICATIONS

### 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



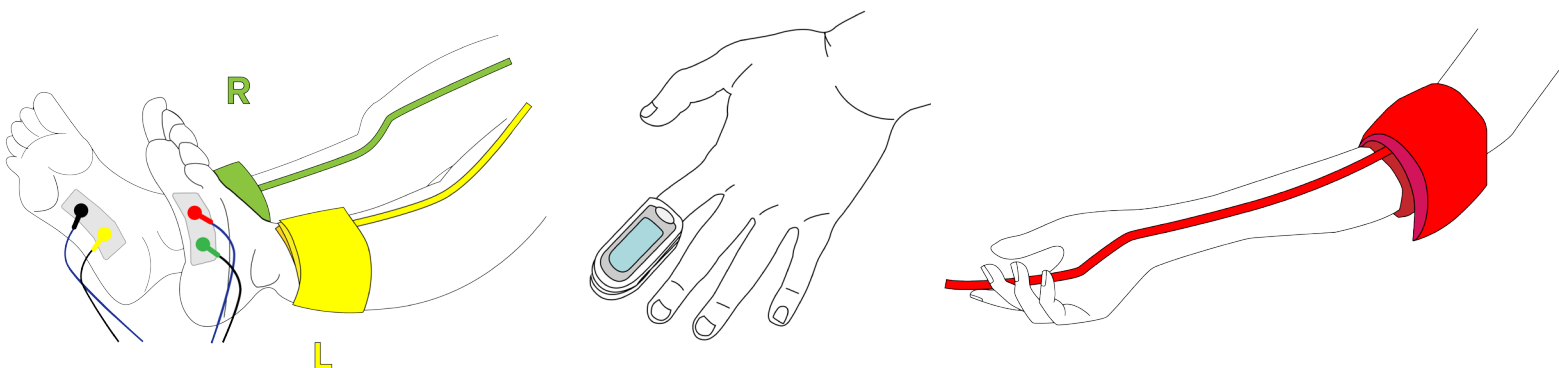
OXIMETER



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)

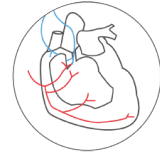
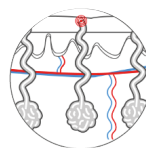
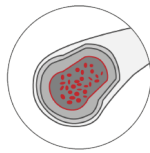
Total Power, SDANN, LF, HF and LF/HF

### 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	$\pm 3$ mmHg
ABI accuracy	$\pm 0.01$

**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	$\pm 2$ bpm
SpO2 %	$\pm 2$ % in the range 70 -100 %

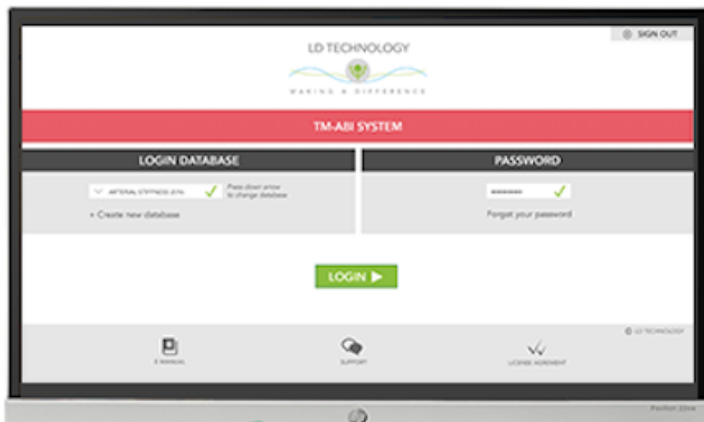
**LD-OXY**  
Photoplethysmography,  
HRV and CARTs analysis.

**510k # k160956**

# LEDA SYSTEM

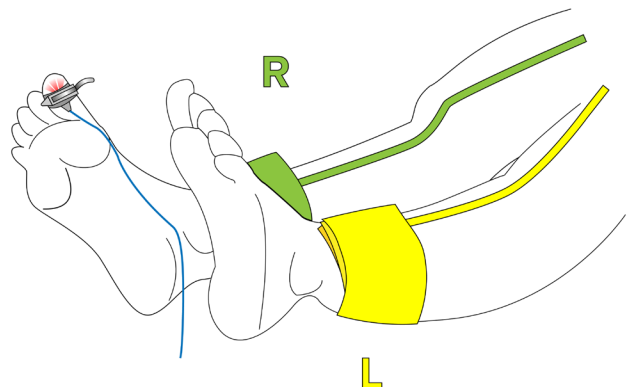
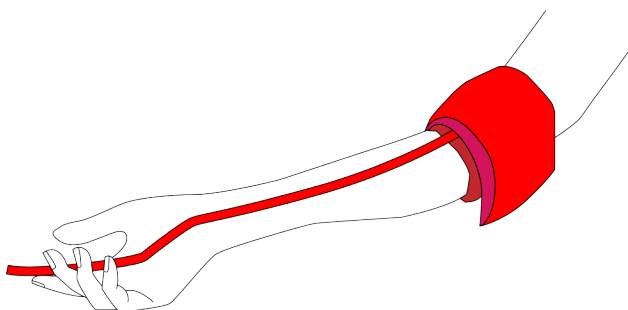
## VASCULAR FUNCTION ASSESSMENT

### 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

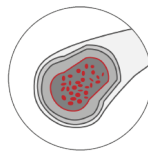


# LEDA SYSTEM MARKERS

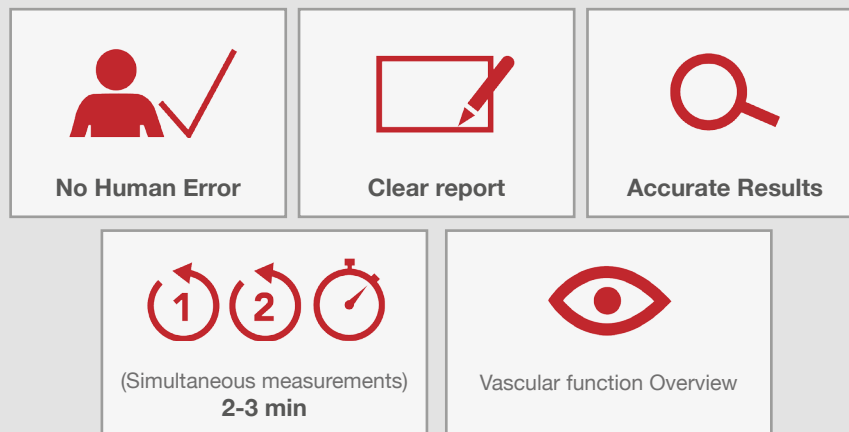
## SEGMENTAL VOLUME PLETHYSMOGRAPHY ANALYSIS:

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



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  $\geq 1.4$

# 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	$\pm 3$ mmHg
ABI accuracy	$\pm 0.01$

**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	$\pm 2$ bpm
SpO2 %	$\pm 2$ % 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



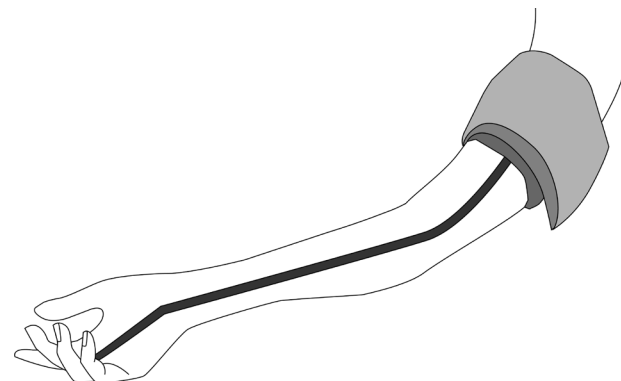
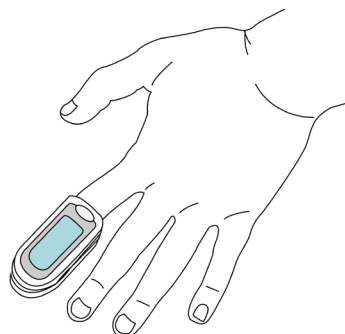
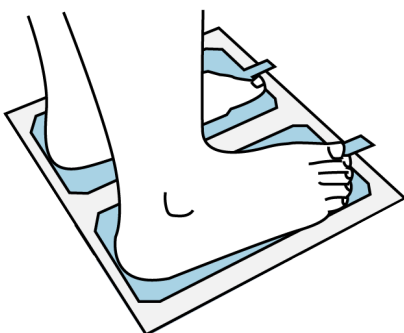
OXIMETER



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 Autonomic 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)

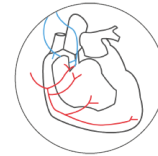
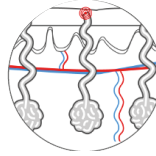
Total Power, SDANN, LF, HF and LF/HF

### 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	$\pm 3$ mmHg

OXIMETER	
Measuring range	
SpO2 % range	0%~100%
Photoplethysmography resolution	# 100 ms
Heart Rate range	30 bpm ~ 250 bpm
Measuring Accuracy	
Pulse Rate	$\pm 2$ bpm
SpO2 %	$\pm 2$ % 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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