AUTONOMIC NERVOUS SYSTEM AND VASCULAR FUNCTION ASSESSMENT

BLOOD PRESSURE AND ARTERIAL STIFFNESS ANALYSIS
Monitoring and Treatment Management of Hypertension

PHOTOPLETHYSMOGRAPHY
Mathematical Analysis of the pulse Ox waveform and Vital signs

ANKLE BRAKIAL INDEX (ABI)
Peripheral Artery Disease (PAD) Blood Flow Blockage or Calcification

HEART RATE VARIABILITY (HRV)
Cardiac Autonomic Dysfunction and Fitness Assessment

CARDIAC AUTONOMIC REFLEX TESTs (CARTs)
Cardiac Autonomic Neuropathy Assessment

SUDOMOTOR FUNCTION TESTs
Skin Microcirculation and Small Fiber 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.

POPLULATION 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

ANYONE THAT FALLS IN THE RISK GROUP SHOULD BE MEASURED WITH LD PRODUCTS

VISION

Our vision is to provide physicians with new tools that simplify complex procedures, such as Ankle Brachial Index (ABI) and Autonomic Nervous Systems Assessments, recommended by US and International Medical Associations. Our most recent innovation includes wireless transmission to increase patient and technician comfort. Our products offer a better, faster and easier approach to detect diabetes complications early.

MISSION

LD Technology’s mission is to help physicians

1. Evaluate the cardiometabolic risk using a scoring system
2. Distinguish the cause of symptoms
3. improves the early detection and treatment management of vascular and autonomic nervous system complications resulting from diabetes and/or other chronic diseases, aging, and/or an unhealthy lifestyle. If there is no early diagnosis, then there is no timely treatment.
**TM FLOW**

**EARLY DETECTION OF DIABETES COMPLICATIONS**

TM Flow is a medical device data system integrating 3 technologies:

**TBL-ABI + SWEATC + LD-OXY**

Models C001 A001 and D001

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**TM FLOW INTENDED USE:**

- Measurement of **Ankle Brachial Indices** for the screening of Peripheral Artery Disease.
- Measurement of the Galvanic Skin response related to the **sudomotor function**.
- Mathematical Analysis of the Photoplethysmography for assessing:
  - The autonomic nervous system via **Heart Rate Variability Analysis at the rest and during the Ewing Tests**.
  - The **Endothelial function** via the Photoplethysmography (PTG) Analysis.

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**TM FLOW MAIN MARKERS:**

**VASCULAR FUNCTION ASSESSMENT**

- Arterial stiffness and Ankle Brachial Indices from the Volume plethysmography analysis.
- Endothelial Function Patented markers from mathematical analysis of the photoplethysmography spectral analysis. (Off label use).

**AUTONOMIC NERVOUS SYSTEM ASSESSMENT**

- Sudomotor Function Markers.
- Heart rate variability Analysis (HRV).
- Cardiac Autonomic Reflex Tests:
  - Valsalva Ratio,
  - E/I Ratio,
  - K30/15 Ratio and
  - Systolic Pressure Response to Standing.

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**TM FLOW PATIENT SETUP:**
PAD SERIES
ADAPTED TO HEALTH PROFESSIONAL NEEDS

**NEUROLOGY**
Autonomic Nervous System Assessment
Sudomotor test & Cardiac Autonomic Neuropathy

**CARDIOLOGY**
Vascular Assessment
Small and peripheral artery Blood Pressure Analysis & Ankle Brachial Indices

**PODIATRY**
Lower Extremity Assessment
Sudomotor test & Ankle brachial Indices
ANS-1 SYSTEM
AUTONOMIC NERVOUS SYSTEM ASSESSMENT

ANS-1 system integrates 3 technologies to assess the Autonomic Nervous System and Peripheral circulation:

GALVANIC SKIN RESPONSE + OSCILLOMETRY + PHOTOPLETHYSMOGRAPHY

ANS-1 Software manages 2 hardware’s:

SweatC Model A001 and TM-Oxi Model B001

No Human Error  Clear report  Accurate results  ANS and Artery overview  Simultaneous measurements (7-10 min)

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.

PATIENT SETUP:
TBL-ABI Model C001
Volume Plethysmography: PERIPHERAL ARTERIAL DISEASE (PAD)

The TBL-ABI system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).

TBL-ABI system is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR)/volume plethysmography in adults.

It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy.

The ankle-brachial index (ABI) is the ratio of the systolic blood pressure measured at the ankle to that measured at the brachial artery.

ADVANTAGES OF TBL-ABI:

- Improvement of the patient comfort: No tube or wire on the body.
- Reduction of the technician errors when preparing the patient for taking a measurement:
  - In addition to the color code of the cuffs, the devices are labelled "ARM", LEFT ANKLE" and "RIGHT ANKLE".
  - All the cuffs are labelled with a blue arrow "DOWN", and therefore, the technician doesn't have to take care about the direction of the tubes.
- 60 to 100 measurements per full charge.
- Charging dock that stops automatically when the battery is fully charged.

PATIENT SETUP:

Right and Left Dorsalis Pedis (DP) Artery Pressure
Left and Right Posterior Tibial (PT) Artery Pressure
Right Brachial Artery Pressure
Left Brachial Artery Pressure
LD-OXY INTENDED USE:

1. To analyze the pulse waveform (Photoelectrical plethysmography or PTG).
2. To analyze the basic rhythms of the NN or RR intervals in heart rate. Both in the time domain and in the frequency domain.

The PTG analyses the peripheral circulation and detection of the beat to beat heart rate. PTG uses transmitted infrared and red light to measure oxygen saturation and relative blood volume in the fingertip. PTG waveform are reflective of blood movement in cutaneous vessels and can be used to identify synchronous depolarization of cardiovascular tissue.

FEATURES:

- Photoplethysmography (PTG) analysis to assess the peripheral circulation.
- HRV (Heart Rate Variability) analysis both in the time domain and frequency domain to assess early ANS dysfunction.
- Ewing Tests analysis (Valsalva maneuver, deep breathing and K30/15 tests) to assess cardiovagal failure.

ADVANTAGES:

- **Accuracy of the heart rate detection:**
  Comparing our algorithm using the first derivative of the photoplethysmography to EKG, the coefficient of correlation $r=0.99$.
- **Accuracy of the HRV analysis:**
  According to the standard ANSI/AAMI EC57, our results follow the Input MIT-BIH database.
- **Research and development i.e. clinical studies:**
  The PTG spectral analysis using LD-Oxy is patented. Results are Off label Use.
The SweatC is a galvanic skin response technology related to the sweat gland function. It uses the sympathetic skin response (SSR) method to assess the sudomotor function via foot skin disposable electrodes following a predetermined electrical stimulations and specific sequence of measurement.

The SweatC measures the absorption of the induced sweat on the bulk of the cloth electrodes. As perspiration increases, more sweat glands are stimulated which increases the voltage amplitude in a given area of skin covered by the disposable cloth electrodes.

*The test is performed in the supine position on an exam table and the patient needs to be relaxed at least 5 minutes.

ELECTRODE PLACEMENT

REVIEW OF THE SUDOMOTOR TEST SWEATC:

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

Sudomotor function is controlled by part of the sympathetic nervous system (post sympathetic cholinergic fiber) and it relates to skin microcirculation and small demyelinated nerve fibers (C-Fibers).

Microcirculatory disorders and Small fiber neuropathy could be the earliest stages of peripheral distal neuropathy in diabetic patients.

In addition, sudomotor dysfunction has been found in different diseases or as medication side effects such as cancer treatment, antihypertensive treatment (in particular beta and alpha blockers and calcium antagonists), metformin treatment, vitamin deficiency, Parkinson's disease, AIDS, amyotrophic lateral sclerosis, hypothyroidism, kidney and liver diseases, alcoholism, Alzheimer's disease and Guillain-Barre syndrome.

Traditional and recognized neurophysiologic measurements of sudomotor function include thermoregulatory sweat testing (TST), quantitative sudomotor axon reflex testing (QSART), silicone impressions and sympathetic skin response (SSR).

Sudomotor dysfunction is used to define a decreased sudomotor activity. Impaired response of autonomic C-Fiber (low level or absence or acetylcholine production) or of capillaries vasodilation (low or absence of response to Nitric Oxide) lead to sudomotor dysfunction.

The autonomic C-fiber response (Sweat Peak) is measured at the positive electrode. The vasodilation response (NO Peak) is measured at the negative electrode.

DISPOSABLE ELECTRODE ADVANTGES:
- No disinfection and no maintenance.
- Increased reproducibility (no ageing of the electrodes)
- Prevent cross contamination
- Prevent biased measurement from the temperature
- Prevent biased measurement from the size of the feet
LD TECHNOLOGY
ISO 13485-2016

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- SweatC A001 K152216
- LD-Oxy D001 K160956
- TM-Oxi System B001 K130056
- TBL-ABI C001 K173696

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