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.

Population 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 is a medical device data system integrating 3 technologies:

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

Models C001 A001 and D001

**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.

**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.

**TM FLOW PATIENT SETUP:**

Price under request for distributors or users
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

Price under request for distributors or users
LD-OXY INTENDED USE:

1. To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate.

2. To analyze the pulse waveform (Photoplethysmography or PTG) provided by the oximeter. It only provides mathematical analysis of the input of the PTG using the first and second derivatives of the PTG values related to the microvascular condition.

3. To analyze the basic rhythms of the NN or RR intervals in heart rate from the PTG, both in the time domain and in the frequency domain (short time 5 minutes). It only provides mathematical analysis of the heart rate variability values related to the autonomic nervous system function.

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.

BENEFITS:

- **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-Oxi is patented. Results are Off label Use.

Price under request for distributors or users
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 stimulation and specific sequence of measurement. *The test is performed in the supine position on an exam table and the patient needs to be relaxed at least 5 minutes.*

Pain might be caused by any dysfunction or damage of:
- Peripheral nerve (motor nerve) and/or Aα fiber (large fiber) and / or Aδ (sensory nerve) and/or C-Fiber (Autonomic cholinergic sympathetic fiber controlling the sudomotor function)

Used diagnostic tools:
1. The vibration tests are using to detect the Aα fiber dysfunction
2. The mono filament tests are using to detect the Aδ fiber dysfunction.
3. The nerve conduction velocity studies are using to detect the Peripheral nerve dysfunction
4. The sudomotor tests are using to detect the C-Fiber dysfunction.

The C-Fibers are unmyelinated. Therefore, they are not protected and usually should be the first one to be affected before the other myelinated nerves.

**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 BENEFITS:**

- Increased reproducibility (no ageing of the electrodes)
- Prevent cross contamination
- No disinfection and low maintenance.
- Prevent biased measurement from the temperature
- Prevent biased measurement from the size of the feet

Price under request for distributors or users
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

Price under request for distributors or users
**NEURO PAIN CARE**
Near Infrared Device

**INTENDED AND INDICATION FOR USE**

The Near Infrared Device (NID) is intended for use for Pain relief by improving micro-circulation.
Our Neuro Pain Care (NPC) System combines the use of our diagnostic SweatC technology, to identify and monitor sudomotor dysfunction with Near infrared Device improve a patient's symptoms and condition.

**SPECIFICATIONS**

- Wave length : 890 nm.
- Penetration : 5 cm

**CONTRAINDICATIONS**

- Cancer
- Pregnancy
- Children

**NIT FEATURES**

Nld device was developed according to the discovery using wavelength near-infrared light source stimulates the tissue to release Nitric Oxide and therefore it provides blood dilation and micro circulation improvement.

Price under request for distributors or users
Lifeprobes kiosk integrates 6 technologies to assess a patient pre-consultation.

**BLOOD PRESSURE + OXIMETER + BIOIMPEDANCE + HEIGHT SENSOR + WEIGHT SCALE + THERMOMETER**

BP-BT Kiosk + Oxi_W + JUMPER infrared thermometer + SONKA Sensors

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**LIFEPROBES FEATURES**

Lifeprobes Kiosk provides the following:
- Patient registration online and QR code identification
- Clinical context and current treatment
- Height and weight,
- Temperature,
- Blood pressure,
- Oxygen saturation percent
- Heart rate,
- Estimate body composition
- Markers related to autonomic nervous system (stress level) and fitness
- Marker of vascular aging.
- Customized micro-nutrition and diet under the MD supervision.

The report is sent automatically to the assigned MD and can be uploaded to any EMR/EHR.

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**LIFEPROBES BENEFITS**

- Improved patient flow in medical offices, clinics, and hospitals
- It saves time for nurses and other employees to focus on other tasks
- Triage in ER according to the vital signs
- Triage and monitoring for cardiometabolic risk

Price under request for distributors or users
COVID-19 Products

Masks / UV-C Sterilizer

**SURGICAL MASKS**

A protection mask is a loose-fitting disposable mask that protects the wearer's nose and mouth from contact with droplets, splashes and sprays that may contain germs. A protection mask also filters out large particles in the air. Protection masks may protect others by reducing exposure to the saliva and respiratory secretions of the mask wearer. The KN95 masks have a filtering effect: 95% + Particle, Bacterial and Virus Filtration Efficiency.

**MIS: Mini Instant Sterilizer**

The MIS UV-C is a small flash key connected to your phone (IOS or android) that turns on instantly, and it is the perfect way to control your environment and to be safe not only for home, office, car, but also for travel; Put the germicidal light into your pockets, and experience the bacteria defender anywhere you need. UV-C refers to ultraviolet light with wavelengths between 200 – 280 nanometers (nm) that is Safe for Humans but Bad for Bacteria and Viruses. ... The research team found that continuous low doses of UV-C light can kill airborne flu viruses without harming human tissues. It can be used for fast disinfecting (only 5 to 10 s) houseware, tableware, makeup tools, toothbrush, baby toys or nipple, small package food products water surfaces, computer microorganisms in air minor wounds pc, pda, camera purses and wallets keys masks cash, credit cards

**HOW DOES UVC DISINFECTION WORK?**

As evident by multiple research studies and reports, when biological organisms are exposed to deep UV light it is absorbed by DNA, RNA, and proteins. Absorption by proteins can lead to rupture of cell walls and death of the organism replication process is disrupted, and the cell cannot replicate. CELLS THAT CANNOT REPLICATE, CANNOT INFECT.
LD TECHNOLOGY

ISO 13485-2016

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SweatC A001 K152216
LD-Oxy D001 K160956
TBL-ABI C001 K173696
Oxi_W E001 K200141
BP-BT Kiosk F001 K200287

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