SUDOSCAN
WHAT IS SUDOSCAN?

- Medical device for the detection and follow-up of peripheral and autonomic neuropathies
- Developed and manufactured by Impeto Medical
- Patented technology based on dynamic assessment of sweat function
THE SWEAT FUNCTION IS CONTROLLED BY THE PERIPHERAL AUTONOMIC NERVES (SMALL NERVE FIBERS)

Vinik AJ et al. Nature Clinical Practice Endocrinol Metab. 2006;2:269-281
As the sweat glands are innervated by peripheral nerves, their dysfunction is a marker of peripheral neuropathy.

Gibbons et al. showed that in healthy subjects, the peripheral autonomic nerves can regenerate quickly.

**Method:** 32 healthy subjects applied a cream containing capsaicin 0.1% (or placebo) on the forearm for 48 hours. Subjects were followed for 6 months with a series of evaluation functions sweat, vasomotor and sensory pilomotrice in parallel with a skin biopsy to assess the status of small fibers.

**Publication:** Gibbons et al. Capsaicin Induces Degeneration of Cutaneous Autonomic Nerve Fibers. ANNALS of Neurology December, 2010 Volume 68, No. 6
SUDOSCAN evaluates neuropathies by measuring the ability of the sweat glands to release chloride ions following a stimulation.

1. Low voltage (<4V) applied to the skin (hands and feet) through stainless steel electrodes.
2. Chloride ions attracted to the electrodes.
3. Electrochemical reaction between the electrodes and chloride ions.
4. Conductance recording:
   - **High conductance**: no malfunction of the sweat and therefore no function neuropathy
   - **Low conductance**: dysfunction of the sweat function and presence of neuropathy
The measurement is easy, fast and quantitative...

At a glance

- Non-invasive
- Less than 3 minutes
- Easy to use
- Immediate and quantitative results
- Compact, ergonomic
Symmetry

Conductances measured on feet and hands

Cardiac autonomic score
SUDOSCAN HAS BEEN COMPARED TO REFERENCE TESTS

- Skin biopsy
- QSART
- Biothesiometer
- NIS-LL score
SUDOSCAN DETECTS NEUROPATHIES WITH COMPARABLE RESULTS TO THE SKIN BIOPSY AND QSART

SUDOSCAN shows diagnostic performance comparable to IENFD (skin biopsy) and QSART.

**Method:**
- The study investigated patients with suspected DSP: 55 general neurology clinic patients with DSP (22 DM, 2 pre-DM, 31 idiopathic) (DM : Diabetes mellitus)
- 42 healthy controls
- Tests: SUDOSCAN: sudomotor function assessment evaluated by Electrochemical Skin Conductance (ESC)
- UENS: Utah Early Neuropathy Scale (a clinical exam of large and small nerve fibers)
- IENFD: skin biopsy for intraepidermal nerve fiber density
- QSART: Quantitative Sudomotor Axon Reflex Testing
- NCS: Nerve conduction studies

SUDOSCAN EVALUATES NEUROPATHIES WITH MORE OBJECTIVITY AND REPRODUCIBILITY THAN THE VIBRATION PERCEPTION THRESHOLD

The SUDOSCAN values are more symmetrical than biothesiometer as shown in diabetic patients.

Method:
- 265 Type 2 diabetes patients
- Tests: SUDOSCAN: sudomotor function assessment evaluated by Electrochemical Sweat Conductance (ESC) on hands and feet. Lower ESC is suggestive of sudomotor dysfunction Michigan neuropathy screening instrument (MNSI) A and B: Assessment of symptoms (MNSI A) and clinical signs (MNSI B) of neuropathy, Biothesiometer: test of peripheral somatic neuropathy using vibration perception on the feet. Score is positive for Vibration Perception Threshold (VPT) ≥ 15 V

Publication: Quick and simple evaluation of sudomotor function for screening of diabetic neuropathy. CS. Yajnik, V. Kantikar, AJ.Pande, JP.Deslypere. ISRN Endocrinology. doi:10.5402/2012/103714
SUDOSCAN PROVIDES THE RESULTS OF THE DETECTION OF DIABETIC NEUROPATHY CORRELATED WITH SCORE NIS-LL

Patients with neuropathy, assessed by the NIS-LL score have SUDOSCAN values degraded. The sensitivity and specificity for detecting SUDOSCAN diabetic neuropathy are 78 and 92%.

**SUDOSCAN measurements in diabetics with and without neuropathy**

The ESC values of the feet and hands were significantly better in healthy subjects and diabetics without neuropathy compared with those with neuropathy.

**SUDOSCAN according to neuropathy NIS-LL score**

Patients with abnormal values of ESC had increased NIS-LL scores of motor neuropathy, sensory and total NIS-LL.


**Method**
- 62 type 2 diabetes patients and 21 type 1 diabetes patients
- Neurological Assessment: measuring neuropathy score with NIS-LL (Neuropathy Impairment Score in the Lower Limbs)
- Test of heat, cold and touch: quantitative sensory evaluations (QST)
- Symptomatic pain: visual analog scale
- Measurement of sweat function: SUDOSCAN (ESC Electrochemical Skin Conductance)
SUDOSCAN HAS BEEN TESTED IN SEVERAL DISEASES

Published data
- Diabetes
  - Microvascular complications of diabetes
  - Peripheral autonomic neuropathy
  - Cardiac autonomic neuropathy
- Idiopathic Neuropathy
- Familial amyloid polyneuropathie

On-going
- Fabry disease
- Parkinson
- Chemotherapy induced neuropathy
- Prediabetes (ePREDICE)
SUDOSCAN, ENABLES TO DETECT PERIPHERAL NEUROPATHY IN DIABETES

In diabetes, SUDOSCAN measurements are correlated to NIS-LL score.

Patients with abnormal values of ESC had increased NIS-LL scores of motor neuropathy, sensory and total NIS-LL.


Method
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• Measurement of sweat function: SUDOSCAN (ESC Electrochemical Skin Conductance)
SUDOSCAN, BY QUANTITATIVE DATA, ENABLES TO FOLLOW THE TREATMENT IN DIABETES

SUDOSCAN can follow the evolution of neuropathy during treatment intervention.

SUDOSCAN measurement follow-up during treatment intervention

SUDOSCAN measurement are better in insulin patient after one year of treatment.


Method:
• 52 type 1 diabetes patients et 115 type 2 diabetes patients (69 under insulin).
• Evaluation of sweat function with SUDOSCAN at t0 and one year after.
SUDOSCAN DETECTS A CARDIAC AUTONOMIC NEUROPATHY

SUDOSCAN can be used as a screening test for cardiac autonomic neuropathy before performing more specific tests.

SUDOSCAN showed better performance than the standard tests Ewing.

Reference used: low frequency component at moderate activity at a threshold of 90ms \(^2\) (1st quartile)


Method:
- 232 diabetic patients: 52±9 y; BMI 26±4 kg/m\(^2\); HbA1C 8.5±1.8 %; Diabetes duration: 9±7 y
- Heart rate variability: LF power during moderate activity (stair climbing)
- Ewing tests: E/I ratio; 30/15 ratio; Orthostatic hypotension
- Hand and foot Electrochemical skin conductances (ESC) and SUDOSCAN risk score
SUDOSCAN ENABLES TO DETECT AND DIFFERENTIATE IDIOPATHIC NEUROPATHIES

SUDOSCAN results are correlated to UENS score in patients with different forms of neuropathies.

The ESC values measured on the feet and hands with SUDOSCAN were significantly lower in subjects with peripheral neuropathy. ESC has a very high negative predictive value (83%), making it a valuable and quick tool to exclude neuropathy in patients with sensory symptoms.


Method:
• 55 patients with neuropathy (22 with diabetic neuropathy and 31 with idiopathic neuropathy), 42 control subjects.
• Tests: Sweat function with SUDOSCAN (ESC, Electrochemical Skin Conductance), Michigan Neuropathy Screening Instrument (MNSI), Utah Early Neuropathy Score (UENS), nerve conduction studies (NCS), quantitative sudomotor axon reflex testing (QSART), intraepidermal nerve fiber density (IENFD)
SUDOSCAN HAS BEEN TESTED IN AMYLOSE

SUDOSCAN can detect and follow the nerve damage in Familial amyloid neuropathy (FAP).

ESC on hands and feet in FAP patients with or without MET30TTR mutation

SUDOSCAN values are considerably reduced in patients with symptomatic neuropathy compared to asymptomatic patients.

Publication: Poster. Sudomotor function assessment by SUDOSCAN in FAP patients : the NNERF experience by D. Adams et al. PNS 2013

Method:
- Patients with familial amyloid neuropathy (FAP), with or without Met30TTR mutation, with or without symptomatic polyneuropathy
- Clinical exams/ Sequencing of the gene TTR/ Biopsie cutanée/ Electromyographie
- Sudomotor function with SUDOSCAN (ESC, Electrochemical Skin Conductance)
SUDOSCAN, AN INTERNATIONAL CLINICAL DEVELOPMENT

- Clinical studies in France, USA, UK, Netherlands, Germany, Sweden, Finland, India, China, Hong-Kong, Australia, Colombia
- 34 published articles (6 in reviewing)
- More than 20,000 patients tested in clinical studies
SUDOSCAN, PATENTED AND RECOGNIZED INNOVATION FOR THE DETECTION OF PERIPHERAL AND AUTONOMIC NEUROPATHIES

**Patents**
- Holds 17 international patents in Europe, the USA, China, Japan and Korea

**Regulation**
- CE marqued (FR12/01324)
- Cleared by FDA (USA), CFDA (Chine), Cofepris (Mexique) etc.

**Clinical studies**
- 34 published studies
- More than 20 000 patients tested in clinical studies
- SUDOSCAN used as endpoint in the study ePREDICE (Early Prevention of Diabetes Complications in Europe): financed by EU, 15 centres

**Commercialization**
- US, Chine, Europe
- More than 1500 machines sold
- 5 000 000 tests per year in the world
- After Sales Service and Production in France