

Early identification and follow-up of Autonomic and Small Fiber Neuropathies



Fast

- No patient preparation
- Results in 3 minutes
- Easy-to-read critical data points to help Physicians reach a diagnosis



Accurate

- Highly reproducible quantitative results
- Independent from environmental conditions
- Technology backed by evidence-based research



Simple

- Non-invasive
- Easy to operate
- Advanced touch screen

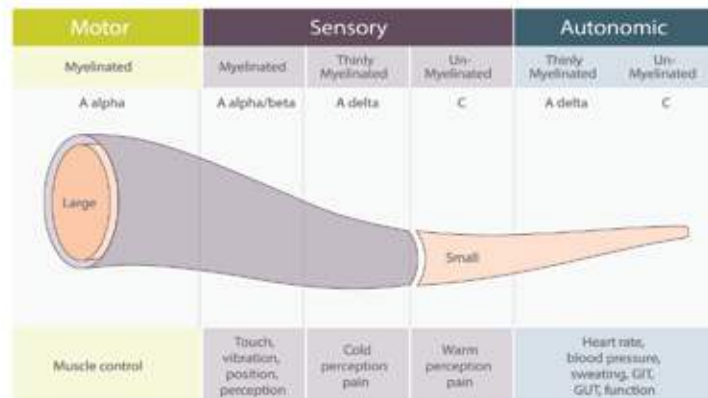
THE SCIENCE

Sweat gland function testing is a reliable indicator for peripheral autonomic neuropathy

Why Test Sweat Gland Function?

Sweat glands are innervated by small sympathetic C-fibers. Sudomotor (sweat) dysfunction can be one of the earliest detectable neurophysiologic abnormalities in distal small fiber neuropathies. Quantitative assessment of sweat response has been proposed as an index of the severity of autonomic failure as well as an early indicator for regeneration of small fibers [1,2,3].

Diabetes has been shown to be the most common identifiable cause of small fiber neuropathy. The American Diabetes Association (ADA) has identified sudomotor (sweat) dysfunction as one of the major clinical manifestations of diabetic autonomic neuropathy. Furthermore, the assessment of autonomic dysfunction may identify patients at high risk for cardiac autonomic neuropathy, which carries a very high rate of morbidity and mortality [4].



The peripheral nervous system is made of large and small fibers. The small, un-myelinated C-fibers are in charge of autonomic functions such as sweating [5].

Simply Put. Less Invasive and More Reliable.

The use of skin biopsy to measure Intraepidermal Nerve Fiber Density (IENFD) or Sweat Gland Nerve Fiber Density (SGNFD) is an accepted surrogate measure of small fiber neuropathy. While skin biopsy is well accepted by the medical community, it has certain limitations such as: invasiveness, risk of infection, bleeding, and a limited number of labs that can process the sample [6].

The Quantitative Sudomotor Axon Reflex Test (QSART) measures sweat response under controlled humidity and temperature conditions. It requires fairly expensive equipment and is available in few centers. SUDOSCAN's diagnostic performance (ESC) is comparable to ENFD/SGNFD and QSART in detecting neuropathy [7].

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"For us to improve nerve function and the quality of life of the individual, we had to do extensive measures: skin biopsy to look at nerve regeneration, nerve conduction studies to show enhancements of nerve conduction and quantitative sensory tests which have a wide variance. These tests are time consuming, laborious and full of error. Now, we have SUDOSCAN that can measure electrical conductance along with sweat gland function in only 2 minutes with instant results that are 75% sensitive, 98% specific and with less than 5% error." [8]

THE TECHNOLOGY

SUDOSCAN enables fast and easy quantification of sudomotor function

How Does it Work?

The degeneration of small nerve fibers reduces sweat gland innervation and alters sudomotor function [9]. Sudoscan measures the concentration of chloride ions produced by sweat gland activity.

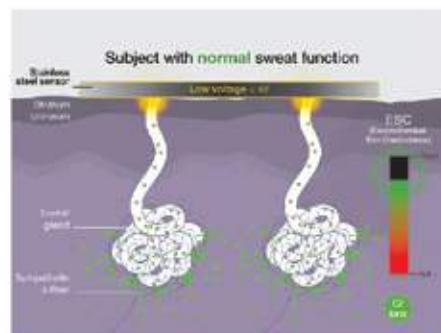
SUDOSCAN provides an accurate evaluation of sudomotor function by measuring the ability of sweat glands to release chloride ions in response to an electrochemical activation on the palm of the hands and soles of the feet, areas with the highest sweat gland density [10].

A low-voltage current (<4V) is applied to the hands and feet through stainless steel sensor electrodes. The applied tension extracts chloride ions from the sweat glands which are densely concentrated on the palms and soles. Since the stratum corneum acts as an isolator, the ions can only pass via the sweat ducts. This ensures that the findings correspond solely to sweat gland function. The chloride ions create a detectable electrochemical reaction with the sensor plates which is measured.

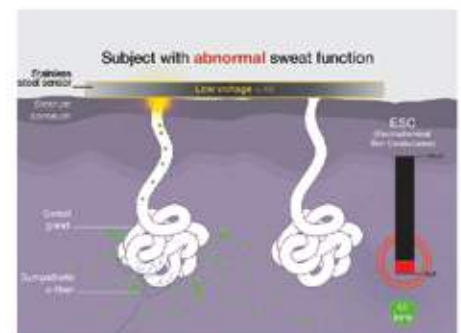


What is Measured?

SUDOSCAN measures the concentration of chloride ions produced by sweat gland activity. SUDOSCAN records the Electrochemical Skin Conductances (ESC) of the hands and feet generated from the current associated with the applied voltage. Loss of sweat glands or loss of their innervations results in reduced ESC [11].



ESC measurement of a subject with normal sweat function



ESC measurement of a subject with abnormal sweat function

THE SOLUTION

Innovations in autonomic function testing

Objective & Reliable Results

1 Simple

Detailed graphics allow for visual representation of the results. Test results range from 0 to 100 microSiemens and displays an easy to interpret color coded risk zones. An immediate quality check ensures reliable results.

2 Quantitative

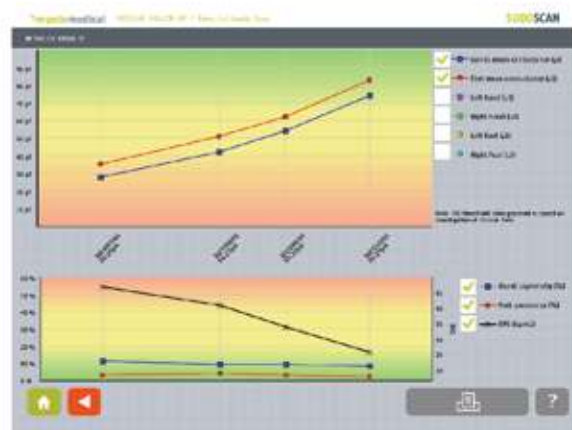
Actual numerical values of the Electrochemical Skin Conductance (ESC) on the hands and feet are displayed. The level of ESC indicates the severity of the neuropathy. Software allows for monitoring of the patient's progression of neuropathy overtime.

3 Symmetry

Measure of symmetry between right and left sides helps identify the type of peripheral neuropathy.



Conductances and asymmetry of hands and feet.

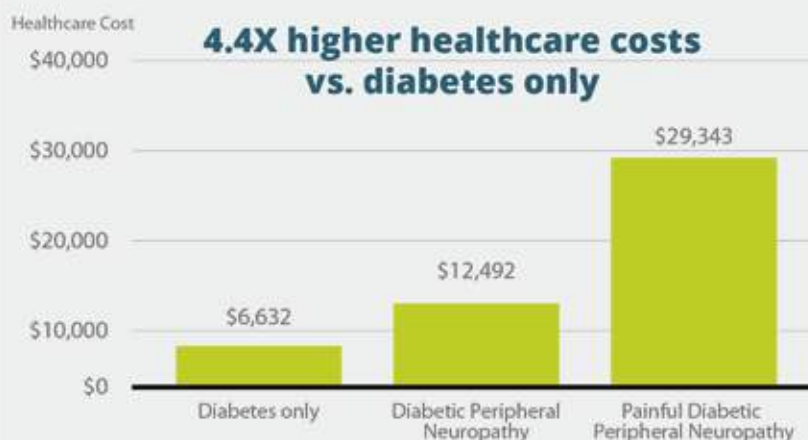


Easy follow-up of the evolution of the neuropathy.



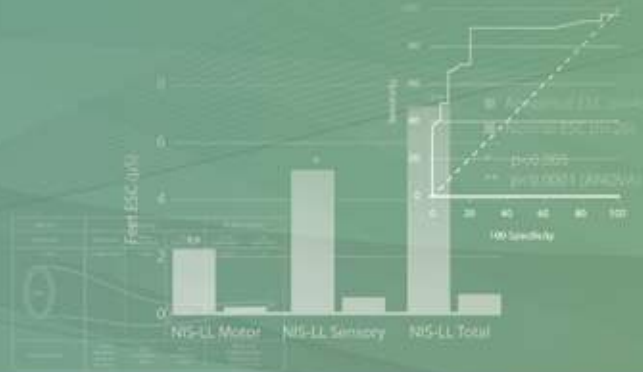
With Early Detection, SUDOSCAN Can Help Reduce Healthcare Costs

Patients with extended diabetes complications have up to 4.4X higher healthcare costs than patients with diabetes only [12].



THE APPLICATIONS

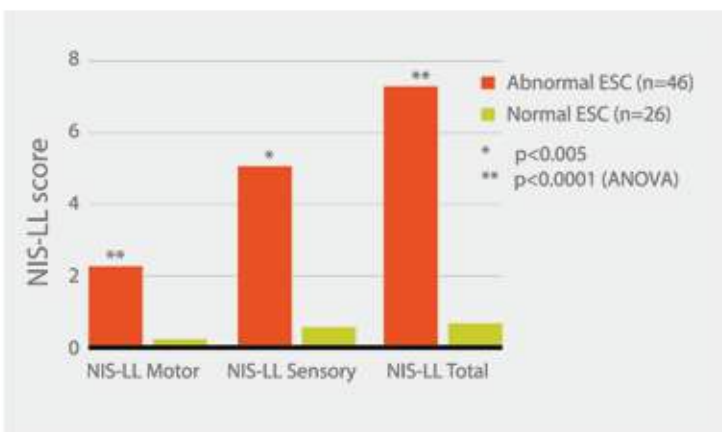
The advantage of early detection for improved patient outcomes and healthcare cost reduction



SUDOSCAN and Type 2 Diabetes

Small nerve fibers are the very first targets of diabetes. For a substantial number of patients, tissue damage (peripheral vascular disease, nephropathy, retinopathy, neuropathy) has already set in at the time of diagnosis [13]. 60-70% of patients with diabetes have neuropathies [14].

Early identification of these complications, which may be asymptomatic in up to 50% of diabetic patients, has the potential to reduce or delay their complications with timely preventative treatment.



Mean Neuropathy Impairment Score within the Lower Limbs (NIS-LL) in diabetes patients with normal vs abnormal feet Electrochemical Skin Conductance (ESC).

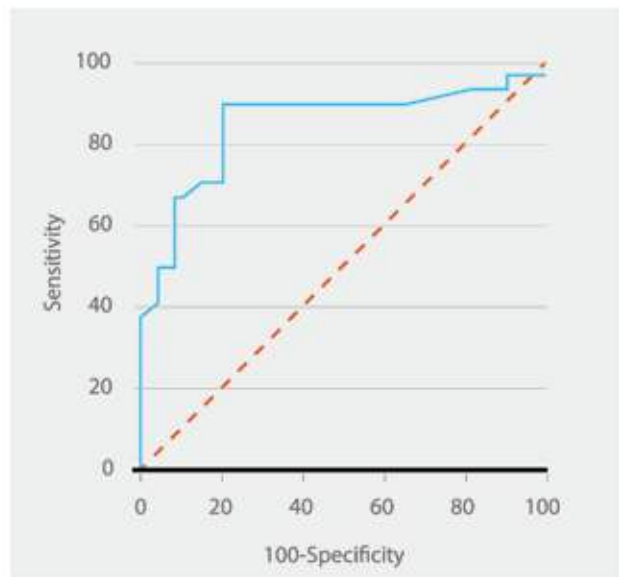


Evaluate Cardiac Autonomic Neuropathy

Cardiac Autonomic Neuropathy (CAN) is a common but often overlooked complication of diabetes. Studies have shown that SUDOSCAN may be used for early evaluation of CAN in everyday clinical practice before resorting to the more sophisticated and specific, but ultimately more time-consuming, Ewing tests [15].

(Pictured right)

Graphic representation of the diagnostic performance of the SUDOSCAN² risk-score, E:I ratio, 30:15 ratio and Blood Pressure (BP) change on standing by Receiver Operating Curve (ROC) analysis, using the low-frequency, power component during moderate activity at a threshold of 90 ms² (first quartile).





ABOUT IMPETO MEDICAL

Impeto Medical is a privately owned medical device company formed in June 2005. With corporate offices in San Diego, U.S., Paris, France and Beijing, China.

Impeto Medical has developed a patented technology that assesses sudomotor function through sweat gland activity. It is non-invasive and analyzes the ability of sweat glands to release chloride ions in response to an electrical stimulus.

Sudoscan is FDA-cleared for use within the U.S.

Patent Numbers:

U.S. Patent No. 8,655,443 | U.S. Patent No. 8,918,170 | U.S. Patent No. 8,934,954



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