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SU DOSCAN ACTIVE SKIN CONDUCTANCE TEST



SUDOSCAN APPROACH



A QUICK LOOK AT SUDOSCAN

No patient preparation

Easy to use

Fast

Immediate results

Quantitative

Reproducible

Principle

> What we know

The degeneration of small nerve fibers reduces sweat gland innervation and alters sudomotor function [3].

> What is stimulated

Low voltage is applied to nickel electrodes in contact with the hands and feet, areas with the highest sweat gland density. The voltage extracts ions (CI⁻, H⁺) which reach the electrodes, passing solely via the sweat gland ducts. At low voltage, the stratum corneum acts as a capacitor and only the sweat ducts allow the transmission of ions from the skin. This ensures that the measurements taken correspond solely to the sweat gland function.

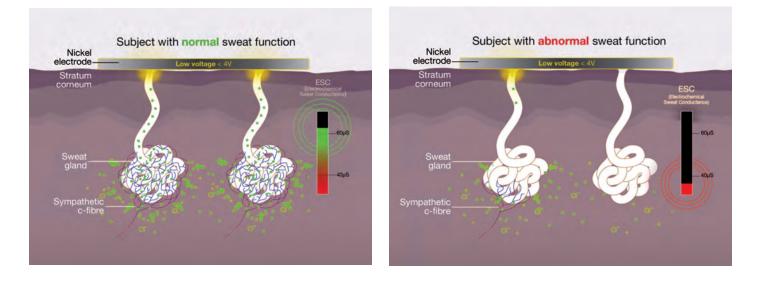
> What is the reaction

There is an observable electrochemical reaction between:

- > the Cl⁻ ions and the anode,
- > and the H^+ ions and the cathode [10].

> What is measured

The device records electrochemical conductances related to the pH and concentration of the chloride ions supplied from the sweat glands and detected by the electrodes (on the hands and feet) [11].



SMALL FIBERS AND PERIPHERAL NEUROPATHIES

Why test small fibers? What is the link between small fibers and sweat?

Sweat glands are innervated by small sympathetic C-fibers. Sudomotor (sweat) dysfunction is 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 and distribution of autonomic failure as well as an early indicator for regeneration of small fibers [1, 2, 3].

Diabetes is shown to be the primary cause of small fiber neuropathy. The American Diabetes Association recommends including sudomotor function assessment of small fiber in the current panel of diagnostic tests for the detection of peripheral neuropathies. Early identification of these complications, which may be asymptomatic in up to 50% of diabetes patients, has the potential to reduce or delay their disease progression with timely preventative treatment [4].

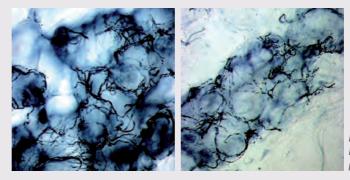
Peripheral neuropathies and sudomotor function

Studies have shown that assessment of sweat gland innervation through sudomotor function testing can be useful to evaluate neuropathies early.

Small nerve fibers are impaired at an early stage of peripheral neuropathies.

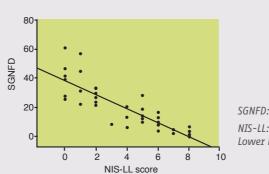
"Intraepidermal nerve fiber (IENF) density is significantly reduced in patients with normal Nerve Conduction, suggesting early damage to small nerve fibers (...). Additionally, IENF density is lower in diabetic patients with painful-compared with painless-early neuropathy" [4].

Sweat gland nerve fiber density diminishes early with peripheral neuropathy.



Left: normal patient Right: patient with peripheral neuropathy

Figure 1 : Sweat glands [5]



A strong correlation exists between sweat gland nerve fiber density and peripheral neuropathy.

SGNFD: Sweat Gland Nerve Fiber Density NIS-LL: Neuropathy Impairment Score in the Lower Limbs

Figure 2: Relationship between sweat gland nerve fiber density and neuropathy impairment score [6]

These results suggest that measuring sudomotor function in relation to sweat gland innervation can be useful in evaluating peripheral neuropathies.

A NEW SOLUTION

SUDOSCAN: a potential test for early and non-invasive detection of small nerve peripheral neuropathy

> A need for a quick test

Small fibers are difficult to assess. Skin biopsy, the gold standard used to evaluate small fibers is invasive and is not commonly available.

SUDOSCAN is a new test that provides an accurate evaluation of sweat gland function through galvanic skin response. SUDOSCAN measures the ability of the 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. It is a dynamic test equivalent to a stress test in cardiology [7].

SUDOSCAN is:

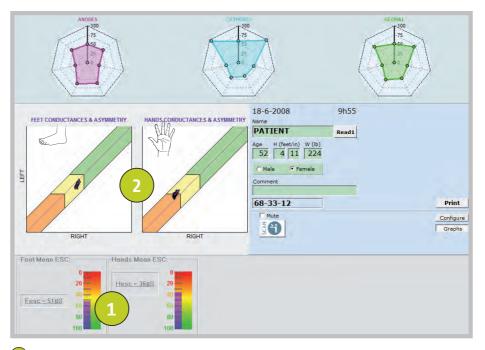
> Fast:

2 min test with no patient preparation

- > Easy to use: requires no specialist training
- > Patient friendly: non-invasive and painless

Once an abnormality is suspected or confirmed, additional evaluation by the physician with specialized tests are recommended to pinpoint the underlying cause.

Instant results and test report

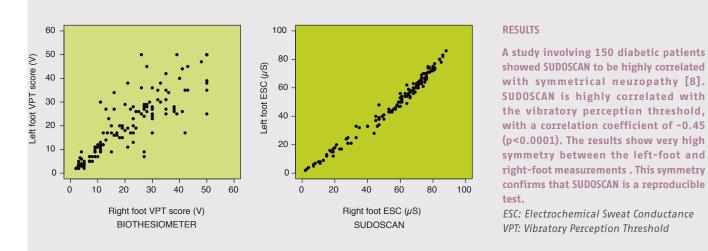


Provides a quantitative measure of the sweat conductance on the hands and feet (in units of micro-siemens). This measure can be used to compare with later test results to follow-up patients on the effect of treatment or other prescribed interventions.

2 Evaluates symmetry (left side vs right side of hands and feet). In addition to providing information about skin conductance measurements from palms and soles of feet, SUDOSCAN also compares the levels between right versus left-hand side.

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Test reports are generated instantly after completion of the test. Reports help the physician to interpret the test results by examining the measurements in more detail, and to document the patients' findings for future follow-up.



> High correlation with symmetrical neuropathies

Figure 3: Correlation between SUDOSCAN and symmetrical neuropathies

> Higher sensitivity than Biothesiometer

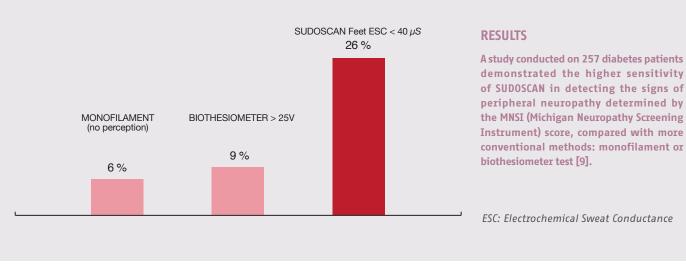


Figure 4 : Comparison of Monofilament, Biothesiometer and SUDOSCAN

Clinical studies

Clinical studies are currently conducted in multiple countries. For more information on our research and results, you can consult our website.

www.impeto-medical.com

About Impeto Medical

Impeto Medical is a medical device company, with the US operations based in San Diego, California.

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