

Figure 1

Figure 2

Figure 1: Normal sweat gland innervation in a healthy control (left). Figure 2: Reduced sweat gland innervation in a patient with diabetes indicates autonomic neuropathy (right). [9]

Peripheral Autonomic Neuropathy Patient Questionnaire

****Please consult with your physician if you have any of the following medical conditions or symptoms:

Medical Condition

- Diabetes
- Cardiovascular Disease
- Genitourinary Disorders
- Renal Impairment
- Digestive Disorders
- Neurological Disorders

Symptoms

- Dizziness or fainting when you stand up
- Abnormal sweating (too much or too little)
- Urinary problems (incontinence, incomplete emptying)
- Sexual difficulties
- Nausea or fullness after eating only a few bites
- Constipation or diarrhea
- Shortness of breath when exercising
- Burning, tingling, or electric shocks in your feet
- Feet that are cold or have dry skin

SUDOSCAN

Impeto Medical is a privately owned medical device company founded in 2005, with US operations based in San Diego, California. Impeto Medical manufactures and markets devices for non-invasive assessment of eccrine sweat gland activity through Galvanic Skin Response.

References

[1] Shy ME. Peripheral Neuropathies. In: Goldman L, Ausiello D, eds. Cecil Medicine. 23rd ed. Philadelphia, Pa: Saunders Elsevier; 2007:chap 446.

[2] Vinik *et al.* Neuropathy: The Crystal Ball for Cardiovascular Disease? Diabetes Care. 2010;33(7):1688-9.

[3] Low PA. Evaluation of Sudomotor Function. Clinical Neurophysiology. 2004;115(7):1506-13.

[4] Gibbons CH *et al.* Capsaicin Induces Degeneration of Cutaneous Autonomic Nerve Fibers. Ann Neurol. 2010;68(6):888-98.

[5] Novak P. Electrochemical skin conductance: a systematic review. Clin Auton Res. 2019;29(1):17-29.

[6] Vinik AI *et al.* Normative Values for Electrochemical Skin Conductances and Impact of Ethnicity on Quantitative Assessment of Sudomotor Function. Diabetes Technol Ther. 2016;18(6):391–8.

[7] Calmet A *et al.* Electrochemical Behavior of Stainless Steels for Sudomotor Dysfunction Applications. Electroanalysis. 2018;30(1):162-9.

[8] Casellini CM *et al.* Sudoscan, a Noninvasive Tool for Detecting Diabetic Small Fiber Neuropathy and Autonomic Dysfunction. Diabetes Technol Ther. 2013;15(11):948–53

[9] Lauria G, Lombardi R. Skin Biopsy: A New Tool for Diagnosing Peripheral Neuropathy. BMJ. 2007;334(7604):1159-62.

SUDOSCAN S medical device is FDA cleared.

`impetomedical

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Are you affected by Peripheral Autonomic Neuropathy?



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Why is it important to identify Peripheral Autonomic Neuropathy?

Peripheral Autonomic Neuropathy (PAN) is a group of symptoms, rather than a specific disease, that occur when there is damage to the nerves that manage everyday body functions. ****Please see Patient Questionnaire (included).

Early assessment of peripheral autonomic dysfunction may identify patients at high risk for cardiac autonomic neuropathy, which may lead to potentially lifethreatening outcomes. [2]

Why test your sweat glands?

Sweat glands are controlled by small nerve fibers within the autonomic nervous system – part of the nervous system that regulates involuntary function. These fibers can be affected at the early stage of different metabolic diseases. "Sweat response may be the most sensitive test in detecting distal small fiber neuropathy". [3] [4]

What is SUDOSCAN S?

SUDOSCAN S evaluates sweat gland function through a process called galvanic skin response. SUDOSCAN S measures the ability of the sweat glands to release chloride in response to a small electrical stimulus on the palms of the hands and soles of the feet. [5]

SUDOSCAN S's focus on the small nerve fibers within the autonomic nervous system, and their ability to quickly regenerate, allows for the monitoring of disease progression and can help gauge if your treatment plan is right for you. [6]



Fast · Non Invasive · Immediate Results

How does it work?

A small electrical current is applied to both hand and foot sensor plates. The chloride ion conductance is quantified and acts as a biomarker to assess the activity of the sweat glands and the small nerve fibers that activate them. [7]

The amount of observed asymmetry between right and left sides helps identify the type of peripheral neuropathy when utilized in conjunction with other testing parameters. [8]

What information does SUDOSCAN S provide?

Patient results will automatically generate after the completion of each scan. Measured conductance values and % asymmetry between right and left sides are quantified. This information is used to determine whether or not a patient's small nerve fibers have been affected.

A follow-up recommendation is provided based upon your SUDOSCAN S results. Your physician can utilize this complementary information to assist with their examination when Peripheral Autonomic Neuropathy is suspected.

SUDOSCAN S Frequently Asked Questions

- **Q:** How long will the scan take?
- A: Less than 3 minutes.

Q: Is the scan painful?

A: No. At most, some patients have experienced a slight tingling sensation on either the palms of their hands or soles of their feet.

Q: Do I need to prepare for the scan?

A: No patient preparation is needed. A patient only has to remove lotion from their hands and/or feet, if applied.

Q: Does age or gender play a factor with my scan results?

A: No.

Q: Do either high or low amounts of sweating affect my scan results?

A: No. SUDOSCAN S measures chloride conductance by an electrochemical reaction. The actual volume of sweat does not impact the test result.

Q: Is SUDOSCAN S the same as a Nerve Conduction Study (NCS)?

A: No. SUDOSCAN S measures the function of the small nerves that activate sweat glands. Nerve conduction studies measure large fiber function.

Q: Will exercise immediately before a scan impact my test results?

A: No. Studies have confirmed that SUDOSCAN S measurements are not affected by exercise and a subsequent increase in sweat rate.

Q: What is the maximum weight that the sensor plates can handle?

A: 199 kg or 440 lbs. A patient may sit and place their feet on the sensor plates if the weight capacity has been exceeded.