A new way to increase accuracy in melanoma detection.

NEVISENSE™
by SCIBASE

THE CHALLENGE OF VISUAL DIAGNOSIS

Until now, the only methods for clinical diagnosis of malignant melanoma have been visual. For advanced melanomas and truly benign lesions, these are procedures that most dermatologists confidently rely on. But for early-stage melanomas and other non-typical lesions, visual examination may be a greater challenge.

In order to reduce the risk of missing a melanoma, many benign lesions are therefore unnecessarily excised. While at the same time, the risk of missed melanomas still remains. In these challenging cases, an additional source of information can help physicians to both improve patient treatment and save lives.

CLINICALLY PROVEN IN THE LARGEST PROSPECTIVE STUDY IN MELANOMA DETECTION*

THE NEVISENSE SOLUTION

Nevisense is the first diagnostic support tool to utilize Electrical Impedance Spectroscopy (EIS), an innovative method that provides objective information drawn from non-typical lesions. By measuring and analyzing lesions, Nevisense detects structural changes in the tissue such as cellular orientation, cell sizes and cell types, which gives physicians a valuable source of additional, complementary information for melanoma detection.

The Nevisense method is safe and painless, and its accuracy is clinically verified in the world's largest prospective study ever conducted in the detection of malignant melanoma. By providing valuable diagnostic information that is unavailable through any other technique, it allows physicians to make more informed decisions in difficult or borderline cases.

** Clinical performance of the Nevisense system in cutaneous melanoma detection: an international, multi-centre, prospective and blinded clinical trial on efficacy and safety, Malvehy J, Hauschild A, Curiel-Lewandrowski C, et al. British Journal of Dermatology. 2014 May 19. DOI: 10.1111/bjd.13121.*

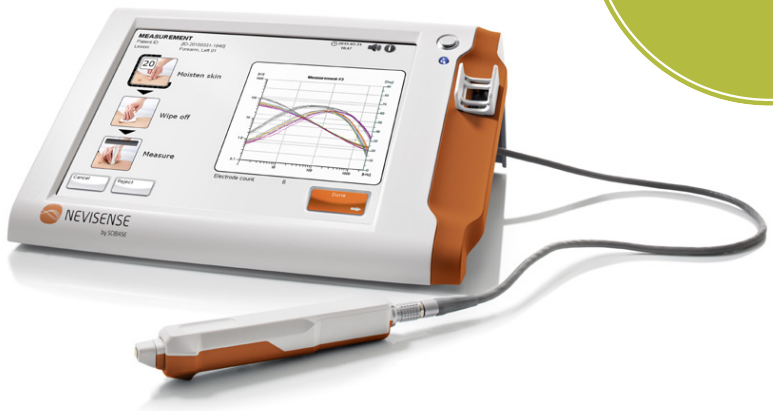
Reliable diagnostic support. When it matters most.

UNIQUE COMPLEMENTARY INFORMATION

FAST AND SIMPLE PROCEDURE

DIAGNOSTIC ACCURACY

OBJECTIVE ANALYSIS



UNIQUE COMPLEMENTARY INFORMATION

In uncertain cases, an EIS analysis provides additional information that complements physicians' visual examinations. Particularly in cases of cutaneous lesions with unclear clinical or historical signs of melanoma, this information helps to support critical decisions regarding whether or not to perform an excision.

FAST AND SIMPLE PROCEDURE

The Nevisense procedure takes just minutes to perform and fits easily within a physician's patient flow. Results are immediate, making it possible to make more optimal treatment selections at the point of care.

DIAGNOSTIC ACCURACY

Nevisense has a proven accuracy in the detection of malignant melanoma – confirmed in three consecutive clinical studies with a total of more than 4,000 lesions. In the final pivotal study, the Nevisense system achieved a sensitivity of 97% in the target population for lesions with a clinical suspicion of malignant melanoma. The system also achieved a 34% specificity, i.e. an increase in specificity over study dermatologists, a figure which represents the potential reduction in unnecessary excisions.

OBJECTIVE ANALYSIS

Visual inspection, whether with dermoscopy or with the naked eye, is inherently subjective. Unlike any other method currently available, Nevisense enables physicians to complement their expertise with an objective, non-visual analysis of cellular characteristics.

Increased diagnostic accuracy. In just a few minutes.

Nevisense is safe and easy to use. The lightweight, portable device can be conveniently placed anywhere, while the procedure itself is fast, simple and effective, integrating easily into the dermatologist's workflow.

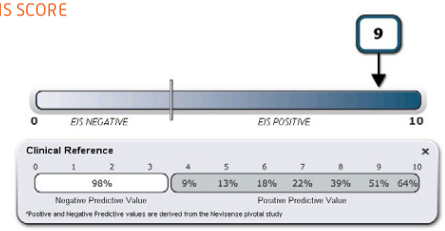
MOISTEN SKIN
Before performing a measurement, moisten the skin with physiological saline solution.

REFERENCE MEASUREMENT
Perform a reference measurement close to the lesion. The measurement takes only 8 seconds to perform.

LESION MEASUREMENT
Repeat the measurement procedure on the lesion to be examined.

Fast, effective analysis with Nevisense.

EIS SCORE



EVALUATE RESULTS
Within seconds, the measurements are analyzed by the Nevisense classifier. The result of the Nevisense measurement is presented on screen as a scale reflecting the degree of atypia, combined with a cut-off marking the 97% sensitivity point for malignant melanoma in the pivotal study.

Negative and Positive Predictive Values indicate the probability of lesion malignancy based on extensive clinical data from the pivotal study. The dermatologist combines the results of the visual evaluation with the added, objective information provided by Nevisense to reach a final, more informed decision.

** compared to study dermatologists. This represents a potential 34% reduction in unnecessary excisions.*

*** predictive values represent the probability that a lesion is benign or malignant, thus providing added value in clinical decision-making.*

Excellent clinical results

Nevisense is proven to deliver effective diagnostic support for all stages of melanoma, with results of the pivotal study showing 97% sensitivity for malignant melanoma.

In addition, the Nevisense method achieved a specificity of 34% for lesions with a clinical suspicion of malignant melanoma, reflecting the potential reduction of unnecessary excisions.

PROTOTYPE DEVICE

1998–2004
Proof of principle

7 studies at Karolinska Institutet
~1,200 patients
~17 confirmed melanomas

2005–2007
Algorithm Training Study I*

12 sites in Europe
673 patients
790 lesions
184 melanomas

FINAL DEVICE

2009–2010
Algorithm Training Study II**

19 sites in Europe
1,134 patients
1,300 lesions
243 melanomas

2010–2012
Pivotal Study***

22 sites in Europe and US
1,951 patients
2,416 lesions
265 melanomas

PROOF OF PRINCIPLE

Beginning in 1998, a Nevisense prototype underwent 6 years of initial studies proving the functionality of the SciBase method. Over the course of 7 studies involving 1,200 patients, the method's success motivated a progression to the next phase: algorithm training for a classifier for malignant melanoma.

ALGORITHM TRAINING FOR THE CLASSIFIER

To develop the classifier, the algorithm was trained on nearly 2,000 patients at 19 sites in Europe.

** Electrical impedance and the diagnostic accuracy for malignant melanoma. Åberg P, Birgersson U, Elsner P, et al. Experimental Dermatology, 2011 Mar 3; 648–652.*

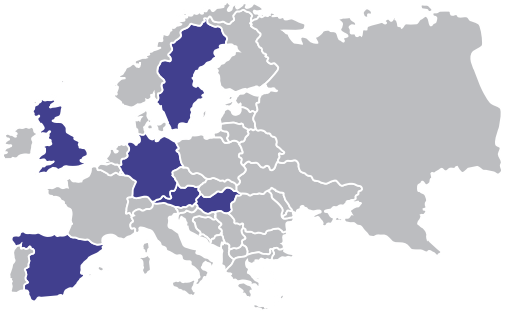
*** Electrical Impedance Spectroscopy as a potential adjunct diagnostic tool for cutaneous melanoma. Mohr P, Birgersson U, Berking C, et al. Skin Research and Technology, 2013; 19:75–83.*

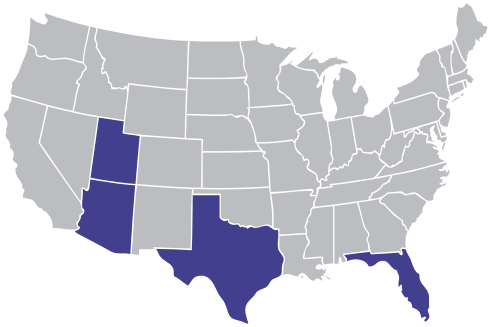
THE PIVOTAL STUDY

The pivotal study was performed in order to provide scientific evidence of the accuracy and safety of Nevisense in detecting malignant melanoma. The study was an international, multicenter, prospective, non-controlled and non-randomized clinical study conducted at both private and academic dermatological centers.

**** Clinical performance of the Nevisense system in cutaneous melanoma detection: an international, multi-centre, prospective and blinded clinical trial on efficacy and safety. Malvehy J, Hauschild A, Curiel-Lewandrowski C, et al. British Journal of Dermatology. 2014 May 19. DOI: 10.1111/bjd.13121.*

The comprehensive pivotal study included 2,400 lesions from 22 participating clinics in the UK, Germany, Sweden, Hungary, Austria, Spain and the US.





Breakthrough diagnostic technology.

SciBase EIS – Electronic Impedance Spectroscopy – is a patented technology developed over 20 years at Karolinska Institutet Stockholm. With its ability to collect and analyze precise data from irregular lesions, EIS represents a technological breakthrough in non-visual detection of malignant melanoma.

DETECTING STRUCTURAL CHANGES

The electrical properties of skin tissues vary under different medical conditions. Normal and non-typical tissue differ, for example, when it comes to cell size, shape, orientation, compactness and structure of cell membranes. All of these changes influence the ability of the cell to conduct and store electricity, a measurable property known as electrical impedance.

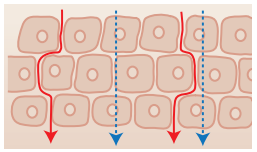
By applying a harmless electrical signal through a skin lesion, EIS can analyze these types of changes to identify a condition such as malignant melanoma. Using an innovative electrode system, it enhances information from multi-depth spectra to detect changes indicating abnormalities in cellular structure, orientation, size, molecular composition and integrity of cell membranes.

EIS measures the overall resistance within the tissue at alternating currents of various frequencies. It works by applying an unnoticeable alternating potential between two electrode bars on the tip of the probe. To cover the lesion in both width and depth, the measurement is performed at 35 frequencies and at four depth settings over the lesion in a total of 10 permutations.

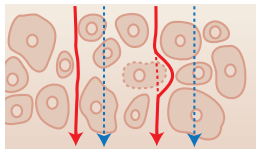
WHAT IT MEASURES

Different frequencies can be used to measure various cellular properties. In general, EIS measurements at low frequencies are affected by the extracellular environment, whereas measurements at higher frequencies are influenced by both the intra- and extracellular environments. The frequencies used by Nevisense (1 kHz – 2.5 MHz) relate to clinically relevant properties, such as composition of intra- and extracellular environments, cell shape and size, and cell membrane composition, all of which are similar to those used by histopathologists to diagnose skin cancer.

NORMAL TISSUE

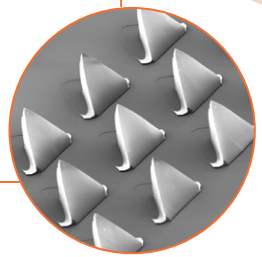


ABNORMAL TISSUE

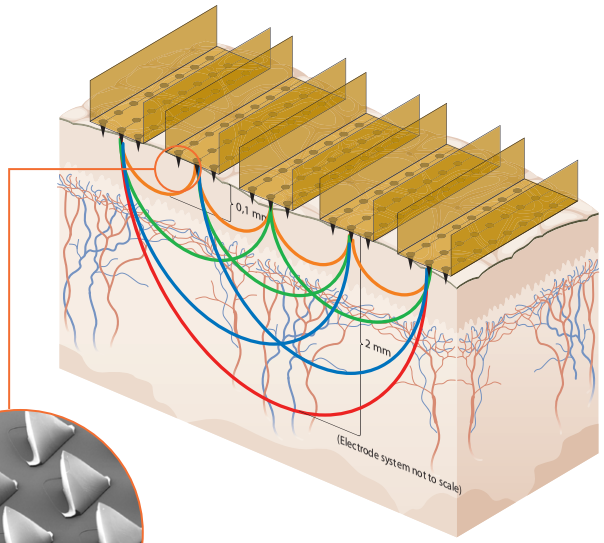


Low frequencies - primarily reflect the extracellular environment

High frequencies - reflects both the intra- and the extracellular environment



Nevisense's advanced algorithm is used to classify the lesion based on measurement data from both the lesion and a reference. Its output then shows a score reflecting the degree of atypia identified. Both the classifier and method of analysis have been developed in several iterations with data from multiple clinical studies.



ELECTRODE SYSTEM

- 45 pins x 5 bars, i.e. a total of 225 pins on a square surface of 5x5 mm
- Pin length: 150 µm
- 10 permutations in one measurement generating 4 depth settings

ABOUT SCIBASE

Founded in 1998, SciBase is a Swedish medical technology company that has developed a unique diagnostic support tool for accurate detection of malignant melanoma. Following 20 years of academic research at Karolinska Institutet Stockholm, the ability of the Nevisense point-of-care device to accurately detect melanoma is now proven in the world's largest prospective study of its kind.

www.scibase.com

Measure what can't be seen.

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NEVISENSE™

by SCIBASE

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