NEVISENSE™
by SCIBASE

"The device's unique design and its advanced signal-processing capabilities make it a highly desirable system for the early detection of multiple forms of skin cancers."

- Frost & Sullivan Research Analyst Sangeetha Prabakar

SciBase's unique EIS technology was awarded the 2011 Frost & Sullivan Europe Technology Innovation Award in Skin Cancer Diagnosis.

FROST & SULLIVAN

2011 BEST PRACTICES AWARD

European Technology Award in Skin Cancer Diagnosis

Now there's a way to measure what can't be seen.

Nevisense is the world's first non-visual diagnostic support tool for malignant melanoma.

Until now, the only methods of diagnosis have been visual – e.g. examination, hand-held dermascopes and pathology. Nevisense aims to change this. By accurately measuring structural changes under the skin's surface, it gives physicians the objective information they need to make more confident decisions. Rather than only examine and diagnose, it is now possible to objectively measure and verify conclusions. For the first time.

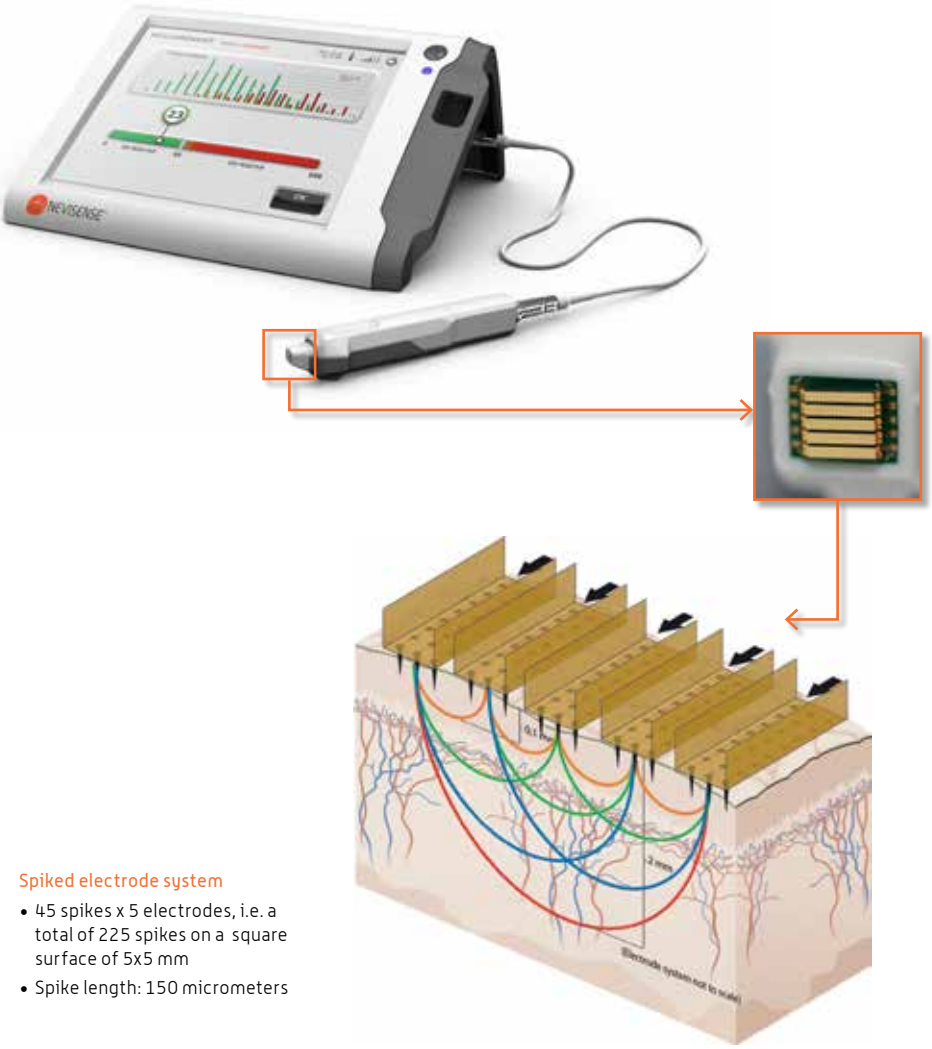
The technology – how it works

SciBase has developed a novel method for detection of malignant melanoma. The patented method, originally developed at Karolinska Institutet, Sweden, utilizes Electrical Impedance Spectroscopy (EIS) applied to the skin as small electrical signals. The procedure is complementary to physicians' regular visual inspections, serving as a decision support tool for difficult or borderline cases.

EIS is sensitive to changes in cellular structure, cellular orientation, cell sizes and cell types – i.e. the same criteria on which a histopathologist would base his or her diagnosis. Depending on the measured frequency range, EIS is also sensitive to molecular composition and integrity of cell membranes.

Nevisense applies a new methodology that enhances information extraction from multi-depth spectra, as well as an innovative micro-invasive electrode system that facilitates precise data collection from abnormal lesions at an early stage.

With Nevisense, EIS is applied as a reliable diagnostic decision support tool for malignant melanoma. In addition to helping to save lives, the method can significantly reduce the time and money spent on unnecessary excisions, as suspicious lesions can be scientifically evaluated prior to excision.



Spiked electrode system

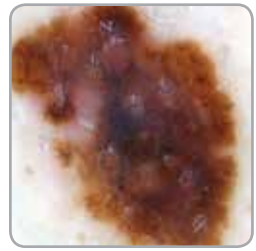
- 45 spikes x 5 electrodes, i.e. a total of 225 spikes on a square surface of 5x5 mm
- Spike length: 150 micrometers

Positive Clinical Results

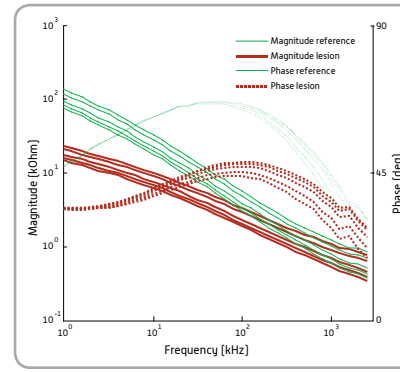
Three consecutive and comprehensive clinical studies have been performed to date with consistent clinical results and more than 4,000 lesions confirming Nevisense's ability to increase accuracy in melanoma detection. The final pivotal study, SIMPS (SciBase International Multi-center Pivotal Study), was performed with the objective to provide scientific evidence of the accuracy of Nevisense in detecting malignant melanoma. 22 clinics across Europe and the US participated in the blinded study, which was conducted under an IDE approval from the FDA. The study included 2,400 skin lesions from 1,900 patients and 260 melanomas,

Malignant melanoma (SSM)

Visual photo



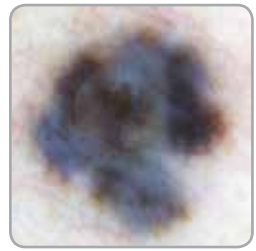
Dermoscopy



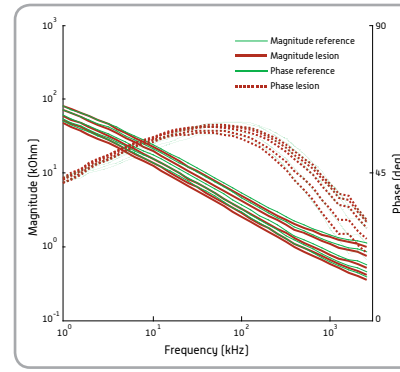
SciBase measurement

Benign pigmented nevus

Visual photo



Dermoscopy



SciBase measurement

making this the largest prospective study ever conducted in melanoma detection. Top-line results show that Nevisense achieved a sensitivity of 98% (with 100% sensitivity on all stages of invasive melanomas) and a specificity of 33% (more than 20 percentage points higher than that of the study dermatologists). Data from the pivotal study will provide the basis for market launch in Europe and Australia, all of which are planned for Q1 2013, as well as for the regulatory process for approval in the US.

About Scibase

SciBase AB is a Swedish medical technology company founded in 1998 to commercialize and develop the SciBase method for measurements on skin and mucous membranes. The patented system, which consists of a handheld probe connected to a computer, was invented by Associate Professor Stig Ollmar of Karolinska Institutet.

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