



Melanoma detection  
with objective analysis

INFORMATION FOR PATIENTS

 NEVISENSE™  
by SCIBASE

## Nevisense helps your doctor evaluate your moles

Nevisense is an advanced diagnostic device used during a skin exam or mole check to provide your doctor with a simple and immediate method of detecting signs of the skin cancer known as malignant melanoma.



## I have an irregular mole. How do I know if it's melanoma?

### 1. Visual examination

When doctors examine a mole, they can normally identify whether there are signs of melanoma. A visual examination is often enough to determine whether further investigation is necessary.

### 2. Measurement with Nevisense

In other cases, additional information may be needed.

Nevisense supports your doctor in determining the likelihood that your mole is melanoma by providing:

- A proven method, tested in the world's largest melanoma detection study<sup>1</sup>
- Objective diagnostic information evaluating the risk that a lesion is malignant melanoma
- Immediate results

### 3. Mole removal?

If any signs of melanoma are detected in these first two steps, your mole may need to be removed by performing a biopsy. The irregular mole is surgically removed and your doctor can then send it to a laboratory to check for malignant melanoma.

<sup>1</sup>Clinical performance of the Nevisense system in cutaneous melanoma detection: an international, multi-centre, prospective and blinded clinical trial on efficacy and safety. Malvey J, Hauschild A, Curiel-Lewandrowski C, et al. British Journal of Dermatology. 2014 May 19. DOI: 10.1111/bjd.13121.

## Is Nevisense right for me?

### Benefits of Nevisense

Nevisense is intended for use on irregular moles. In difficult cases, when a mole looks unusual but lacks obvious signs of melanoma, doctors may use Nevisense after visual examination to obtain additional information that helps determine whether a biopsy is needed.

### Nevisense provides unique diagnostic information

Nevisense provides objective diagnostic data that is not available through any other method. This additional information, in combination with your medical history and the visual examination, helps your doctor decide whether to remove the mole for biopsy.

The results of clinical studies suggest that Nevisense can aid dermatologists in detecting melanoma.

### Risks

*It is not possible to know whether the use of Nevisense by your doctor will directly benefit you. Possible risks of any skin check or test for melanoma include incorrect results.*

- A false negative result means a mole is melanoma but the test says it is not, or says that it has a low risk of being a melanoma. A false negative may delay treatment melanoma. This can lead to increased illness or death.*
- A false positive is when a mole is not melanoma but the test wrongly says it is, or says it has a high risk of being melanoma. A false positive may result in removing a mole that is not melanoma.*

*For more information, please see Patient Labeling at [nevisense.com](http://nevisense.com)*

Early melanoma  
detection is critical.  
Nevisense can help your  
doctor ensure timely  
treatment.



## How Nevisense works

The Nevisense test is simple and is typically painless. The device sends small electrical impulses into the skin's surface – impulses so small that they cannot be felt when the measurement is taken. The only thing you are likely to feel is the handpiece touching your skin.

Nevisense measures skin properties that cannot be seen, such as cell structure, shape and size.

The result of the Nevisense test provides additional information to your doctor. Used in combination with other data such as your mole's appearance, your medical history and other risk factors, it helps to decide whether the mole should be removed.



THE TEST IS SIMPLE AND PRECISE

## What happens next?

1. If your doctor decides that the mole is benign, be sure to follow your doctor's recommendations and continuously monitor your moles for changes in size, color or shape.
2. If your doctor decides that further investigation is needed, removal of the mole will be planned as soon as possible. The removed mole tissue will be sent to a lab for analysis.



Measure what can't be seen.

#### ABOUT SCIBASE

Founded in 1998, SciBase is a Swedish medical technology company that has developed a unique diagnostic support tool for accurate detection of 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.<sup>2</sup>

For more information, visit [nevisense.com](http://nevisense.com)

<sup>2</sup> 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.

**INDICATIONS FOR USE** Nevisense is indicated for use on cutaneous lesions with one or more clinical or historical characteristics of melanoma, when a dermatologist chooses to obtain additional information when considering biopsy. Nevisense should not be used on clinically obvious melanoma. The Nevisense result is one element of the overall clinical assessment. The output of Nevisense should be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to biopsy.