



NEVISENSE

Diagnostic support tool utilizing Electrical Impedance Spectroscopy (EIS), an innovative method providing objective information drawn from atypical lesions. By measuring and analyzing lesions, Nevisense detects changes in cellular structure, cellular orientation, cell sizes and cell types and gives additional and complementary information for melanoma detection.

INTENDED USE

Nevisense is intended for use on cutaneous lesions with one or more clinical or historical characteristics of melanoma. It is designed to be used when a physician chooses to obtain additional information when considering excision. Nevisense should not be used to confirm a clinical diagnosis of melanoma and it is only for use by physicians trained in the clinical diagnosis of skin cancer. The Nevisense result is one element of the overall clinical assessment and the output should be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to excise.



INDICATIONS FOR USE

Nevisense is indicated only for use on primary skin lesions with a diameter between 2 mm and 20 mm; lesions that are accessible by the Nevisense probe; lesions where the skin is intact (i.e. non-ulcerated or non-bleeding lesions); lesions that do not contain a scar or fibrosis consistent with previous trauma; lesions not located in areas of psoriasis, eczema, acute sunburn or similar skin conditions, lesions not in hair-covered areas, lesions which do not contain foreign matter; and, lesions not on special anatomic sites (i.e. not for use on acral skin, genitalia, eyes, mucosal areas).

DESCRIPTION

The Nevisense system consists of a control unit, a probe and a disposable electrode. The control unit is used for user interaction through a touch screen and for signal processing of the impedance measurement signals. The probe unit is used for measuring the impedance by using a disposable electrode on the probe head.

FEATURES

Control unit screen	The control unit has a 12" 800x600 color display with touch screen.
Measurement principle and frequencies	Bioimpedance of the skin is measured micro invasively. Nevisense registers phase and magnitude in four different depths and ten permutations at 35 different frequencies from 1.0 kHz to 2.5 MHz.
System accuracy tests	Nevisense system is equipped with external test impedance tool (also available as accessory) for maintenance purposes. Accuracy tests should be performed monthly, maintenance data will be stored in the control unit.
Battery (optional)	Battery status is indicated on the screen. Additional battery packs for the Nevisense system can be ordered as accessories.
Control unit size	150 mm [h] x 400 mm [w] x 300 mm [d]
System weight	Control unit 3,5kg, probe unit 100g, battery 420g.
Cleaning	Nevisense's exterior surfaces can easily be cleaned with e.g. a soft cloth moistened with water or disinfectant.
Probe design	The probe unit is ergonomic for both left and right handed users.
Electrode lifetime	The disposable electrode is possible to use for 20 consecutive measurements on one patient only. The expiry date is printed on the package.
Operating conditions	Ambient temperature +10°C – +40°C Ambient pressure 700 hPa – 1060 hPa Ambient humidity 30% – 75% (non condensing)
Transportation conditions	Ambient temperature -40 °C – +70°C Ambient pressure 500 hPa – 1060 hPa Ambient humidity 10% – 100%
Product safety	The CE-marked products fulfill the quality and safety regulations according to MDD.
External interfaces	The system is equipped with two USB ports.
Warranty	The warranty of the Nevisense instrument is 12 months from delivery by SciBase AB or SciBase distributor. The warranty is only valid if spare parts are supplied by SciBase AB.

Ordering information:

NEVISENSE COMPLETE, art nr 201-0001

- Nevisense Basic
- Batteri for Nevisense
- NeviFile

NEVISENSE BASIC, art nr 201-0002

- Control unit
- Probe
- Probe cable
- Power cable 2 m
- Test Impedance tool
- Lesion Coverage tool
- USB Flash drive
- Administration and Service Instructions
- Instruction for use
- Training electrode, 8 pcs
- Saline solution swabs
- Nonwoven swabs

CONSUMABLES

- 132-0001 Electrode kit (16 pcs and including saline solution swabs and nonwoven swabs)
132-0002 Training electrode kit (8 pcs and including saline solution swabs and nonwoven swabs)

ACCESSORIES

- 521-0001 Battery for Nevisense
590-0002 Test Impedance tool
590-0001 Lesion Coverage tool
310-0001 Nevisense Training
142-0003 NeviFile

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