NEVISENSE EXAM QUICK REFERENCE
Consult Nevisense Instructions for Use for complete device use information, warnings, and precautions

REFERENCE MEASUREMENT

1. Choose suitable reference area and plan your measurement using the coverage tool.

2. Clean the reference skin by rubbing the skin with alcohol prep pad, allow to dry. Soak the reference skin by rubbing the skin 4-5 times with a Salvequick wound cleanser 0.9% saline.

3. Moisten reference area for a minimum of 30 seconds. Remember to apply some pressure against the skin. Tip: Squeeze out the remaining liquid in the swab on the skin at the end.

4. Wipe of all excessive fluid with one firm stroke using a dry compress. Important: Start the measurement within 10 seconds after the wipe off.

5. Measure reference area. Make sure probe is kept stable and 90 degrees to the skin so full contact between skin and electrode is achieved.

6. Clean the lesion by rubbing with alcohol prep pad, allow to dry. Soak the reference skin by rubbing the skin 4-5 times with a Salvequick wound cleanser 0.9% saline.

7. Moisten lesion for a minimum of 30 seconds. Remember to apply some pressure against the skin. Tip: Squeeze out the remaining liquid in the swab on the skin at the end. Moistening must be redone between each measurement.

8. Wipe of all excessive fluid with one firm stroke using a dry compress. Important: Start the measurement within 10 seconds after the wipe off.

9. Measure on the lesion and repeat step 7-9 until lesion is covered. Make sure the lesion has been fully covered before pressing “Done”.

10. Read the Nevisense EIS score.

Warning! Ensure that the preparation of the skin is performed accurately, including both moistening and wipe off. The skin preparation influences the measurement result.

UTILIZATION CONSIDERATIONS

PHYSIOLOGICAL FACTORS:

VARYING SKIN PROPERTIES
Ensure that the reference measurement is performed close to the lesion on normal healthy skin with similar skin properties as the lesion. If the skin property in the area that is evaluated has a big variation, e.g. in the face, the reference and lesion measurement results may show a bigger variation, which most often result in a higher EIS score.

HARD UNDERLYING STRUCTURES
Measurements that are performed on body surface areas with hard underlying structures, such as in the forehead, may have an effect on the EIS score, and may primarily yield a higher EIS score.

VARIATION IN UNDERLYING STRUCTURES
It is important to ensure that the reference measurement is performed on skin with similar underlying structure as the lesion, e.g. skin over tibia, to get a correct reading. If the underlying structures have a big variation, e.g. soft and hard, the results may be affected.

SEBORRHEIC KERATOSIS
Seborrheic Keratosis typically have a high degree of structural changes compared to normal healthy skin and therefore typically generate a high EIS score. It is advised that lesions, if possible, are pre-screened for Seborrheic Keratosis prior to measurement with the Nevisense device since the EIS method is sensitive to the degree of atypia in the tissue.
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.

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;
• lesions not on special anatomic sites (i.e. not for use on acral skin, genitalia, eyes, mucosal areas).

CONTRAINDICATIONS
There are no known contraindications.

WARNING
Do not use on lesions already determined to require biopsy based on clinical evaluation. This device is an adjunct tool for evaluation of lesions prior to the decision to biopsy. There is a potential for Nevisense to classify a melanoma as EIS negative and to miss a melanoma. In the pivotal study results, 4.1% of melanomas (11) pathologically confirmed were classified by Nevisense as negative. In the reader study results, readers without Nevisense missed 22.8% of melanomas, readers with Nevisense as an adjunct missed 16.4% of melanomas, and 3.3% of melanomas were classified as negative by Nevisense.

NOTE: Evaluation with Nevisense should always be initiated by a physician.

PLAN YOUR MEASUREMENT

WARNING! Ensure that a sufficient number of measurements are performed for each lesion, since the degree of atypia may vary within the lesion.

Use the Lesion Coverage Tool to determine the number of measurements needed. One square of the Lesion Coverage Tool is equal to one (1) measurement.

Follow the lesion clockwise to keep track of your measurements and look at the skin marks from the electrode to make sure that the lesion has been fully covered. The inner square of the probe marks the measurement area.

NOTE> When multiple measurements are needed, repeat the moistening procedure before each measurement.

Correctly covered lesions: (better overlap than to risk not covering fully)

Insufficiently covered lesions:

Warning! Ensure that the lesion measurement is performed on the lesion, not outside the lesion. If the measurement is performed outside the lesion, reject the measurement and measure again.