Nevisense

Instructions for Use

Caution: Federal law restricts this device to sale by or on the order of a physician

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Warranty

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Chapter 1

Introduction

About Nevisense

Nevisense measures electrical impedance of skin lesions and provides an output called the electrical impedance spectroscopy (EIS) score. Electrical impedance is a measure of a material's overall resistance to the flow of alternating electric currents of various frequencies. The principle is that electrical impedance is different in normal versus abnormal tissue.

Indication 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.

Warnings and Precautions

Key warnings and precautions for Nevisense use are listed below. Additional warnings, precautions, notes, and tips related to device operation are provided in Section 3 (Operational Safety) and with the relevant operational steps throughout this manual.

Warnings

- Do not use Nevisense as a screening device. A Nevisense negative reading does not eliminate the possibility that the lesion might be or evolve into a melanoma, see Clinical Studies. The result should always be considered by the physician in conjunction with other clinical parameters.
- 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.
- Do not apply excessive pressure when measuring close to a pacemaker in order not to damage the pacemaker
- If a lesion bleeds, appears ulcerated, or if the skin appears compromised after measurement, change the electrode before conducting additional measurements. This is in order to minimize the risk of transferring possible malignant cells.
- Nevisense safety and effectiveness has not been established in patients age 30 and below. In the pivotal study, there were 296 total lesions in patients 18-30 years old with few (7 lesions, 2.6%) melanomas. The Nevisense sensitivity was 57.1% and specificity was 38.4% for melanomas in patients 18-30 years old compared to patients 31 years and older where the sensitivity was 97.7% and specificity was 29.9%.

Precautions

- Nevisense safety and effectiveness has not been established in patients with Fitzpatrick Skin Type 5 and 6.

- Nevisense may only be used by dermatologists who have successfully completed the Nevisense training.

Potential Adverse Effects

Potential adverse effects of any skin examination for melanoma may include: false negative results, which may lead to delays in diagnosis and treatment of melanoma, potentially increasing morbidity and mortality; and false positive results, which may result in unnecessary medical intervention including more frequent screening and invasive skin biopsy procedures.

Clinical Studies

Two clinical studies, conducted under IDE #G090108 and its Supplements, demonstrate the safety and effectiveness of the Nevisense device for the proposed indication for use: the Pivotal Study, and the Reader Study.

Table 1: Clinical Studies

Clinical Study	Study Design	Objective	Number of Sites	Number of Subjects/Lesions
Pivotal	International, multi-center, prospective, blinded clinical study comparing Nevisense device readings to pathology. Dermatologists were blinded to the Nevisense reading.	To determine the safety and effectiveness of the Nevisense device (Test) designed to distinguish between malignant melanoma and benign lesions, using electrical impedance spectrometry, relative to the histological gold standard.	22	1951/2416
Reader	A Multiple-Reader, Multiple-Case (MRMC) study, in which readers evaluate each case both with and without the aid of the Nevisense output (EIS negative/positive and score).	To assess how Nevisense output is incorporated into dermatologists' considerations when diagnosing melanoma.	41 readers	141 lesion images and EIS scores

Pivotal Study

A. Study Design

The pivotal study was an international, multicenter, prospective, blinded, clinical study conducted at 22 sites with 1951 subjects with 2416 lesions. Nevisense readings were compared to pathology findings. However, dermatologists were blinded to Nevisense readings.

1. Clinical Inclusion and Exclusion Criteria

Pivotal Study Inclusion Criteria:

- Men or women of any ethnic group aged ≥18 years
- Primary lesions (i.e., not metastases or recurrent lesions) that the physicians choose to excise.
- Lesion ≥ 2 mm in diameter and ≤ 20 mm in diameter
- In subjects with multiple skin lesions, all lesions destined for excision must be identified for purposes of study participation. Note: a subject may only be entered into the study once.
- The subject is willing and able to read, understand and sign the study specific informed consent form.

Exclusion Criteria:
- Skin surface not measurable, e.g. lesion on a stalk
- Skin surface not accessible, e.g. inside ears, under nails
- Lesion located on acral skin, e.g. sole or palms.
- Lesion located on areas of scars, crusts, psoriasis, eczema or similar skin conditions.
- Lesion on hair-covered areas, e.g. scalp, beards, moustaches or whiskers.
- Lesion located on genitalia.
- Lesion located in an area that has been previously biopsied or subjected to any kind of surgical intervention or traumatized.
- Lesion located on mucosal surfaces.
- Skin is not intact (measurement area) e.g. bleeding or with clinical noticeable ulceration.
- Lesion with foreign matter, e.g. tattoo, splinter
- Lesion and/or reference located on acute sunburn

2. Follow-up Schedule and Study Sequence

After obtaining informed consent, eligible lesions destined for biopsy were categorized as representing low, mid, or high, suspicion of being melanoma. A photo and dermoscopy image were taken of the lesion, and the lesion was measured with the Nevisense (previously called SciBase III). A second photo of the lesion post measurement was taken, and the lesion was surgically biopsied and subjected to histopathological evaluation. The first analysis was performed by the local pathologist and a second analysis, the reference standard, was performed independently by a panel of three expert pathologists. In case of significant disagreement in the panel, the lesion was sent to the consensus board for additional analysis. The photo and dermoscopy images were also evaluated by a Visual Classification Board for uniform visual classification of all lesions according to established clinical protocols.

Figure 1: Pivotal Study Sequence

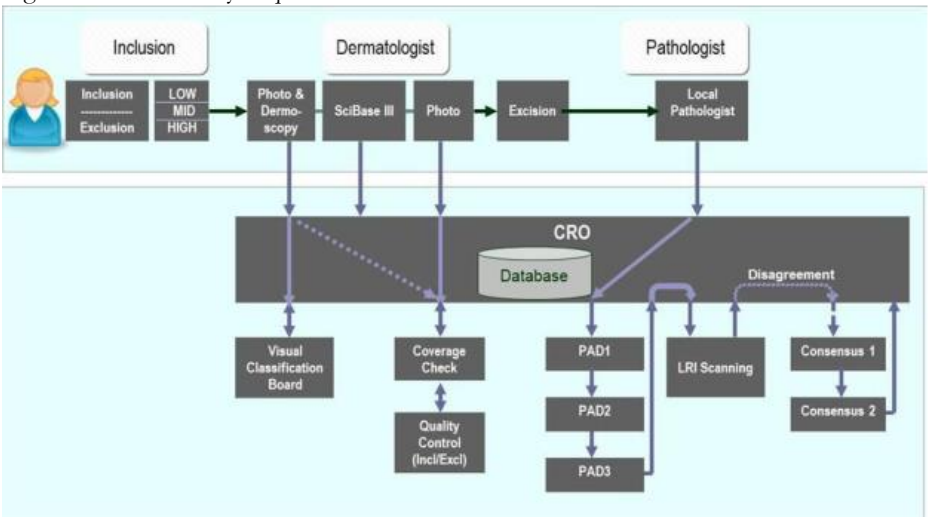


Table 2: Pivotal Study Evaluations and Schedule

Assessment / Visit	Pre-Evaluation	Evaluation	Day 7 +/- 3 days	Post-Evaluation
Informed Consent	X			
Inclusion / Exclusion	X			
Demographic information	X			
Medical History and Physical Examination	X			
Skin Lesion Information		X		
Nevisense Evaluation		X		
Lesion Excision		X		
Histopathology Evaluation				X
Histopathology re-evaluation (PAD board member 1)				X
Histopathology re-evaluation (PAD board member 2)				X
Histopathology re-evaluation (PAD board member 3)				X
Consensus board† (Consensus board member 1)				X
Consensus board† (Consensus board member 2)				X
Visual evaluation board				X
Adverse Event Reporting	X	X	X	

† If significant disagreement among PAD Board evaluations

3. Clinical Endpoints

Safety was evaluated by the occurrence and incidence of all adverse events (AEs) reported for study subjects throughout their participation in the study. The primary safety endpoint was the absence of serious device-related events.

The primary effectiveness endpoint of the study consisted of two co-endpoints aiming to show sensitivity ≥ 0.90 to detect malignant melanoma, and non-randomness. For the primary co-endpoints, a lesion is considered positive according to histology only in cases of malignant melanoma.

The secondary effectiveness endpoints included the same co-endpoints for sensitivity and non-randomness as the primary endpoint; however, for the secondary endpoint, a lesion was considered positive by histology in cases of melanoma, carcinomas (including SCC, BCC, Merkel Cell Carcinoma, and actinic keratosis), and Severe Dysplastic Nevi. The secondary effectiveness endpoints were pre-specified in the pivotal study protocol.

B. Accountability of PMA Cohort

In total, 1951 subjects were recruited into the study. Of 1951 subjects, 1915 (98.2%) were included in the Safety analysis population, and these subjects provided 2372 lesions. Of the 2372 lesions, 1951 (82.3%) were included in the Primary Effectiveness analysis population and 1961 (82.7%) were included in the Secondary Effectiveness analysis population. To be in the primary effectiveness population, a subject/lesion must not have been subject to a major protocol deviation, and the lesion must have had a result for both the test and primary reference diagnoses needed for the primary effectiveness endpoint. To be in the secondary effectiveness population, a subject/lesion must not have been subject to a major protocol deviation, and a lesion must have had a result for both the test and secondary reference diagnoses needed for the secondary effectiveness endpoint. The accountability of subjects/lesions in the PMA cohort is summarized in Table 3 below.

Table 3: Accountability of Subjects/Lesions

	Subjects	Lesions
Recruited	**1951**	**2416**
Excluded from safety[1]	*36*	*44*
Safety Analysis Population	**1915**	**2372**

Excluded from effectiveness populations[2]:	Primary Effectiveness[3]		Secondary Effectiveness[3]	
	Subjects	Lesions	Subjects	Lesions
Patient/Lesion exclusions due to:				
1. Signed informed consent form not present	*0*	*0*	*0*	*0*
2. Withdrawal (patient or investigator)	*10*	*19*	*10*	*19*
3. Inclusion/Exclusion criteria violation	*40*	*53*	*40*	*53*
No valid pathology and/or Nevisense measurement due to:				
4. Measurement failure (due to device malfunction)	*23*	*28*	*23*	*28*
5. No device measurements performed	*7*	*8*	*7*	*8*
6. No reference measurement acquired	*9*	*16*	*9*	*16*
7. Reference measurement failure (≥4 rejected reference measurements)	*59*	*80*	*59*	*80*
8. No lesion measurement acquired	*2*	*2*	*2*	*2*
9. Measurement not performed according to protocol	*10*	*11*	*10*	*11*
10. Insufficient lesion coverage (less than 75% of the lesion was covered with measurements)	*57*	*89*	*57*	*89*
Histopathology, final diagnosis missing or excision not done correctly due to:				
11. Lesion not excised (therefore no histopathology reference)	*3*	*7*	*3*	*7*
12. Excision day >7 days after the measurements were performed	*5*	*6*	*5*	*6*
13. Inability to map histology to excised lesion	*4*	*7*	*4*	*7*
14. Missing lesion histology	*23*	*39*	*23*	*39*
15. Ineligible histopathology (preparation quality)	*7*	*8*	*7*	*8*
16. No Consensus on final diagnosis[4]	*36*	*44*	*32*	*34*
Exclusion due to other reasons:				
17. Other Reason (invalid measurements due to lesion bleeding or suspected mix-up of lesion histology)	*2*	*4*	*2*	*4*
Effectiveness Analysis Populations	**1618**	**1951**	**1622**	**1961**
Excluded due to measurement taken completely outside the lesion (on fully healthy skin)	*7*	*8*	*7*	*8*
Updated Effectiveness Analysis Populations	**1611**	**1943**	**1615**	**1953**

Notes:

1. 36 subjects with 44 lesions were excluded from the safety population. In 34 of these subjects, device use was not initiated. In 2 subjects (from a site which was terminated by the sponsor for lack of GCP), the device use had been initiated, but no adverse events were reported.
2. Subjects/lesions may satisfy more than one exclusion category; however, in this table, each excluded subject/lesion is counted only once according to the first exclusion reason satisfied, using the exclusion hierarchy represented (from 1 – 17). For example, a subject who had insufficient lesion coverage and missing lesion histology would be counted in this table under insufficient lesion coverage.
3. Primary effectiveness endpoint uses reference diagnosis definition where positive = melanoma;
   Secondary effectiveness endpoint uses reference diagnosis definition where positive = melanoma, severe dysplastic nevi, and carcinomas.
4. Because primary and secondary endpoints had different definitions of reference diagnosis, it was possible for consensus to be reached for primary and not secondary, or vice versa.

Italics indicate number of subjects/lesions excluded

C. Study Population Demographics and Baseline Parameters

Table 4.a: Statistics for Age

	N subject	Mean	Std	Min	Median	Max
Age (Years)	1915	50.3	16.8	18.2	48.7	91.2

Table 4.b: Distribution of Gender, Race, Fitzpatrick Scale

Characteristic	**N Subject**	**%**
Gender		
Male	914	47.7
Female	1001	52.3
All	1915	100.0
Race		
White	1867	97.5
Asian	5	0.3
Hispanic	29	1.5

Characteristic	N Subject	%
Black or African American	2	0.1
Other	12	0.6
All	1915	100.0
Fitzpatrick Scale		
1. Always burns easily; never tans	134	7.0
2. Always burns easily; tans minimally	934	48.8
3. Burns moderately; tans gradually	624	32.6
4. Burns minimally; always tans well	191	10.0
5. Rarely burns; tans profusely	28	1.5
6. Never burns; deeply pigmented	1	0.1
Missing	3	0.2
All	1915	100.0

Table 5: Number of Lesions per Subject

	N	Mean	Std	Min	Median	Max
Number of Lesions	1915	1.2	0.7	1.0	1.0	10.0

Table 6: Distribution of Possible Risk Factors for Melanoma

Melanoma Risk Factors	Yes		No		Unknown		Total	
	N	%	N	%	N	%	N	%
History of extensive exposure to ultraviolet radiation	683	35.7	1157	60.4	75	3.9	1915	100.0
History of sunburns, especially during childhood	1136	59.3	588	30.7	191	10.0	1915	100.0
Previous melanoma	511	26.7	1395	72.8	9	0.5	1915	100.0
Previous BCC or SCC	310	16.2	1581	82.6	24	1.3	1915	100.0
Previous Dysplastic Nevi	587	30.7	1260	65.8	68	3.6	1915	100.0
Family history of melanoma	285	14.9	1562	81.6	68	3.6	1915	100.0
Family history of FAM-M syndrome	29	1.5	1742	91.0	144	7.5	1915	100.0

Melanoma Risk Factors	Yes		No		Unknown		Total	
	N	%	N	%	N	%	N	%
Impaired immune system	57	3.0	1845	96.3	13	0.7	1915	100.0
Xeroderma pigmentosum	8	0.4	1899	99.2	8	0.4	1915	100.0

Table 7: Distribution of Risk for Melanoma based on Number of Lesions on Patient

Melanoma Risk Factor	<50		≥50		Total	
	N	%	N	%	N	%
Number of lesions on patient	1021	53.3	894	46.7	1915	100.0

Table 8: Distribution of Site of Lesion

Site of Lesion		Number of Lesions	
		N_{Lesion}	%
Head	Scalp	12	9.6
	Forehead	34	27.2
	Cheek or Nose	64	51.2
	Chin	2	1.6
	Other	13	10.4
	All	125	100.0
Arm	Upper Arm	169	65.0
	Elbow	7	2.7
	Forearm	73	28.1
	Hand	11	4.2
	All	260	100.0
Leg	Upper leg	216	47.4
	Lower leg	176	38.6
	Knee	24	5.3
	Foot	40	8.8
	All	456	100.0
Trunk	Neck	49	3.2

Site of Lesion		Number of Lesions	
		N_{Lesion}	%
	Chest	224	14.7
	Back Upper	596	39.0
	Back Lower	318	20.8
	Abdomen	283	18.5
	Pubic, Inguinal Area	20	1.3
	Buttocks	39	2.6
	All	1529	100.0
All	Head	125	5.3
	Arm	260	11.0
	Leg	456	19.2
	Trunk	1529	64.5
	Missing	2	0.1
	All	2372	100.0

D. Safety and Effectiveness Results

Pivotal Study

Safety Results

28 subjects (1.5% of all subjects) experienced a total of 36 adverse events. No serious adverse event, serious adverse device effect or unanticipated adverse device effect was observed throughout the study. Most AEs were of mild severity (33 of 36). The one severe event (migraine headache) was considered unrelated to the device. Two events of moderate severity (both for wound infection following excision) were considered unlikely to have been related to the device. 12 subjects (0.6% of all subjects) experienced 14 events that were considered by investigators to be possibly, probably, or definitely related to the device. These events involved bleeding during measurement (n=6); itching (n=1) at the measurement site; pain, soreness, or bruising (n=3) or slight tingling sensation (n=2) at the measurement site; and headache (n=2).

Effectiveness Results

1. Primary Effectiveness Analysis (on Primary Effectiveness Population, using Primary Reference Diagnosis (positive = melanoma only))

Co-Primary endpoint 1: Sensitivity of Nevisense for Detecting Melanoma
For the primary effectiveness analysis, in accordance with the primary endpoint definition, disease positive means lesions declared by the histology as melanoma (positive = melanoma only). In the primary effectiveness population, 267 or 13.7% of lesions were by histology, diagnosed as melanoma. The Nevisense device correctly identified 256 melanoma lesions out of 267 melanoma lesions, yielding sensitivity of 95.9%. Of 1,684 lesions that were not melanoma, 527 were diagnosed Negative by Nevisense, yielding specificity of 31.3% (not accounting for dependency between lesions within a subject, which is addressed in the analyses for the co-primary endpoints 1 and 2 below).

Table 9: Frequency Distribution of Nevisense Result by Primary Reference Diagnosis (Positive = melanoma only) – Primary Effectiveness Population

	Reference Positive	Reference Negative
Nevisense Positive	256	1157
Nevisense Negative	11	527

Nevisense observed sensitivity was 95.9%, with a 95% confidence interval lower limit of 93.3% (when using a one-sided interval) and 92.7% (when using a two-sided interval). The observed specificity was 31.1%, with a 95% confidence interval lower limit of 29.2% (one-sided interval) and 28.8% (for the two-sided interval). For sensitivity and specificity, the confidence interval computations were performed using a random effects model, with the following form: Test = Subject ID, with Subject ID treated as a random effect to account for correlated data (i.e. multiple lesions selected from the same set of subjects – about 15% of all lesions in SIMPS come from the same set of subjects – the other 85% are unique lesions from unique individuals). For the computation of sensitivity, the data set includes all positive lesions and excludes all subjects with no positive lesions (i.e., only those lesions declared by the reference method as melanoma were included). For the computation of specificity, the data set includes all negative lesions and excludes all subjects with no negative lesions (i.e., only those lesions declared by the reference method as not melanoma were included).

Co-Primary Endpoint 2: Sensitivity + Specificity > 1 for Melanoma Detection by Nevisense
This endpoint assessed whether the Nevisense is better at detecting melanoma

than randomly flipping a coin to decide whether lesions contain Melanoma. In order to statistically assess this, the odds ratio from statistical logistic regression modelling was used. An odds ratio statistically greater than 1 from this model means that the sum of sensitivity and specificity is also statistically greater than 1. Some of the subjects in the pivotal study contributed multiple lesions (about 15% of all lesions fall in this situation). To account for this, the statistical logistic regression modelling treated subject as a random effect. All lesions were included for this analysis. The results are given in the following table. The odds ratio is 10.5 ($P < 0.0001$), meaning that odds ratio is statistically greater than 1, which means that sum of sensitivity and specificity is statistically greater than 1.

Table 10: Results from mixed logistic model for co-primary endpoint 2

Odds Ratio			
Estimate	Two-Sided 95% Lower CL	Two-Sided 95% Upper CL	P-Value
10.5	5.6	19.5	<.0001

2. Secondary Effectiveness Analysis (on Secondary Effectiveness Population, using Secondary Reference Diagnosis (positive = melanoma, carcinomas, or severe dysplastic nevi))

The secondary effectiveness endpoints included the same co-endpoints for sensitivity and non-randomness as the primary endpoint; however, for the secondary endpoint, a lesion was considered positive (according to histology) in cases of melanoma, carcinomas (including SCC, BCC, Merkel Cell Carcinoma, and actinic keratosis), and Severe Dysplastic Nevi.

Other than the change in definition of positive lesions, the statistical approach for the secondary effectiveness endpoints is the same as the primary effectiveness endpoints. . In the secondary effectiveness analysis, 26.0% of lesions are positive by histology. The Nevisense device correctly identified 472 Positive lesions of the 510 in the sample, yielding a sensitivity of 92.5%. Of 1451 Negative lesions, 500 were diagnosed Negative by Nevisense, yielding specificity of 34.5% (not accounting for dependency between lesions within a subject, which is addressed in the analyses for the co-secondary endpoints 1 and 2 below).

Table 11a: Frequency Distribution of Nevisense Result by Secondary Reference Diagnosis (Positive = melanoma, carcinomas, or severe dysplastic nevi) – Secondary Effectiveness Population

	Reference Positive	Reference Negative

Nevisense Positive	472	951
Nevisense Negative	38	500

Co-Secondary Endpoint 1 (sensitivity >90%)
For the secondary effectiveness analyses, the sensitivity is 92.5%, with 90.4% for lower limit of the one-sided 95% confidence interval and 89.9% for the lower limit of the two-sided 95% confidence interval. The specificity is 34.3%, with 32.2% for the lower limit of the one-sided 95% confidence interval and 31.8% for the lower limit of the two-sided 95% confidence interval.

Co-Secondary Endpoint 2 (non-randomness)

The odds ratio is 6.4, significantly greater than 1 ($P < 0.0001$), indicating, as in the primary effectiveness analysis, that the Nevisense outcome is not random.

Table 11b: Results from mixed logistic model for co-secondary endpoint 2

Odds Ratio			
Estimate	Two-Sided 95% Lower CL	Two-Sided 95% Upper CL	P-Value
6.4	4.5	9.2	<.0001

Exploratory Effectiveness Analyses

The following additional analysis of the primary co-endpoints was conducted in analysis populations not prospectively defined in the Statistical Analysis Plan (SAP)

Primary Effectiveness Endpoints (with Updated Primary Effectiveness Analysis Population)
The primary effectiveness endpoints analyses were repeated on an Updated Primary Effectiveness analysis population, which excluded eight additional lesions due to an invalid measurement procedure (measurements completely outside the border of the lesion on healthy skin), a major protocol deviation, which was discovered after database lock. In this population, which reflects device accuracy for lesions assessed according to device instructions for use:

- Melanoma sensitivity was 96.6% with lower one-sided 95% confidence limit of 94.2%.
- The outcome of Nevisense device remained highly related to the reference outcome ($P<0.0001$), i.e. non-random. The obtained odds ratio of the

device versus reference was 12.9, with a two-sided 95% confidence interval of 6.5 to 25.4.

Therefore, both co-primary hypotheses of this study were also met for the updated primary effectiveness population.

An additional analysis investigating the dependency between accuracy and lesion type was performed using the Updated Primary Effectiveness Analysis population. This analysis excluded the 8 lesions previously mentioned and used for Reference Diagnosis the definition of the secondary confirmatory endpoint. Table 12 presents sensitivity and specificity for different lesion types. As can be seen from this table, the overall sensitivity for melanoma is 96.6%.

The sensitivity for high stage melanoma (thickness T2, T3 and T4) is 100%, and sensitivity for melanoma with thickness T1 is above 98%. Sensitivity for in-situ is, as expected, lowest at 93.8%. Overall specificity is 34.4%, which includes mild to moderate nevi, melanocytic nevi, and other lesions. In this analysis, severe dysplastic nevi, carcinomas, and actinic keratosis are counted as positives. Carcinomas are malignant lesions and are therefore presented as positive. Severe dysplastic nevi are presented in a separate category because they can be considered positive or negative, depending on the clinical conventions adopted in different countries. This analysis was done to help communicate the numbers for lesion subcategories to the clinical community.

Table 12: Updated Primary Effectiveness Analysis Population: Sensitivity and Specificity by Lesion Type

Sensitivity and Specificity Analyses (Assuming Independency)										
Reference Diagnosis (Secondary)	Sensitivity	Specificity	TP	FN	TN	FP	Total N	95% Two-sided LCL	95% Two-sided UCL	95% One-sided LCL
Melanoma (Total)	**96.6**		**256**	**9**			**265**	**93.65**	**98.44**	**94.15**
Melanoma: Tis (In-situ) (= 0mm)	93.8		105	7			112	87.55	97.45	88.58
Melanoma: T1 (0-1 mm)	98.2		111	2			113	93.75	99.78	94.53
Melanoma: T2 (1-2 mm)	100		35	0			35	90	100	91.8
Melanoma: T3 (2-4 mm)	100		4	0			4	39.76	100	47.29

Melanoma: T4 (> 4mm)	100		1	0			1	2.5	100	5
Severe Dysplastic Nevus	**84.1**		**132**	**25**			**157**	**77.4**	**89.42**	**78.48**
Non-MM (BCC+SCC+AK)	**98.4**		**62**	**1**			**63**	**91.47**	**99.96**	**92.69**
Non-MM Excluding AK	100		55	0			55	93.5	100	94.7
BCC	100		48	0			48	92.6	100	93.9
SCC	100		7	0			7	59.0	100	93.5
AK*	87.5		7	1			8	47.3	99.7	52.9
Merkel Cell Carcinoma	**100**		**1**	**0**			**1**	**100**	**N/A**	**N/A**
Mild to Moderate Dysplastic Nevus		**36,1**			**357**	**631**	**988**	**33,13**	**39,22**	**33.6**
Melanocytic Nevus		**36,7**			**131**	**226**	**357**	**31,68**	**41,93**	**32.45**
Other		**11,6**			**13**	**99**	**112**	**6,33**	**19,03**	**7.0**
Overall Specificity		**34,4**			**501**	**956**	**1457**	**31,95**	**36,89**	**32.33**

TP: True Positive, FN: False Negative, TN: True Negative, FP: False Positive, LCL: Lower Confidence Limit, UCL:Upper Confidence Limit

* AK (actinic keratosis) is a precursor lesion to SCC (Squamous Cell Carcinoma), and not an SCC per se.

The negative and positive predictive value (NPV/PPV) will vary depending on the Nevisense score. PPV is the probability that lesions with a positive Nevisense score truly are melanoma, whereas NPV is the probability that lesions with a negative Nevisense score truly are not melanoma. Both PPV and NPV are affected by the prevalence of melanoma in the population. For the pivotal clinical study, the prevalence of melanoma was 13.7%, which may be higher than the prevalence in the intended population at a dermatologist's specific practices. In order to account for the differing levels of prevalence, Table 13 depicts the dependence of the Nevisense PPV and NPV upon prevalence. Table 13 was derived by using the primary endpoint results (sensitivity (95.9%) and specificity (31.3%)) for the overall cohort in the pivotal clinical study and the formulas for adjusting PPV and NPV from Altman, D and Bland, J. BMJ 1994; 309:102.

Table 13 PPV and NPV of Nevisense Adjusted for Prevalence. Last row depicts the PPV and NPV of Nevisense for the Prevalence Observed in the Pivotal Clinical Study

Prevalence	PPV	NPV
3%	4.14%	99.6%

5%	6.84%	99.3%
7%	9.50%	99.0%
9%	12.1%	98.7%
11%	14.7%	98.4%
13%	17.3%	98.1%
13.7%	18.1%	97.9%

Reader Study

A. Study Design

The Reader Study was designed as a Multiple-Reader, Multiple-Case (MRMC), in which readers evaluate each case both with and without the aid of the Nevisense output (EIS negative/positive and score). The study used a subset of images collected during the pivotal study. Each image had a documented reference diagnosis (final diagnosis by the histopathology board) and dermatologist decision. Readers were provided with photographic images and pertinent clinical data; readers did not have access to the dermatoscopic images. The study provided information about the adjunctive use of the device. Readers were not aware of whether the patient whose image is presented was sent out for biopsy/referral, and were not aware of the established lesion diagnosis. None of the dermatologist that participated in the Reader Study participated in the Pivotal study.

B. Eligibility and Accountability

Reader Eligibility Criteria

Readers participating in this study were considered eligible if: 1) he/she was a board certified dermatologist; 2) he/she was a practicing dermatologist in the United States; 3) he/she had not previously participated in the SIMPS trial; 4) at most 1 reader had previously participated in the study from the same site; and 5) he/she completed the survey for at least 60% out of the lesions included in this study within a set timeframe of 4 weeks.

Reader Selection, Enrollment, Accountability

42 board-certified dermatologists (all U.S.) enrolled in in the Reader study, and 41 dermatologists completed the study and contributed the data for the analysis. One dermatologist reviewed only 8 images, and therefore did not meet the reader eligibility criteria requiring that he/she complete the survey for at least 60% of the lesions within a 4 week period. The remaining 41 dermatologists completed the review of the entire dataset. The dataset for

each reviewer consisted of the same set of 141 cases, selected to include both negative (benign) and positive (malignant) lesions from low risk, intermediate risk, and high risk categories.

For each image, the reader completed the following two steps in sequence:

1. Reader reviewed the lesion image with relevant patient clinical information;
2. Reader reviewed the lesion image with relevant patient clinical information, and the EIS score between 0 and 10, and the EIS Negative or Positive

The EIS score provided to the Reader was the same score used in the Pivotal Study, from which the images were provided. After each step, the readers decided whether or not they believed it was a melanoma and whether or not they would biopsy the lesion. This review sequence allows comparison of the use of an EIS score to a dermatologist's assessment of malignancy and whether they would consider excision/referral of a suspected lesion.

The Reader Study had two co-primary endpoints. The first co-primary study hypothesis tests whether dermatologists' sensitivity when diagnosing melanoma is superior with Nevisense information than without Nevisense information. The second co-primary study hypothesis endpoint tests whether the dermatologists' sensitivity + specificity with Nevisense is greater than 1, meaning that the dermatologists' decision with Nevisense's aid is not random. Sensitivity and specificity are derived from the dermatologists' assessments of whether they believe the lesions to be a melanoma, rather than whether or not they would biopsy/refer the lesions. The primary effectiveness analysis was conducted on the population of eligible readers.

C. Reader and Lesion Characteristics

Readers (dermatologists) in the study were 81% male. Readers' ages were about equally distributed in the 10-year intervals from 30 to 59, with few readers in age groups 60-69 (9.5%) or >70 (2.4%). Readers had an average of 15.8 years of experience (range 2 – 41 years). Dermatologists with specialized focus on skin care comprised 40.5% of the readers, and without specialized focus in skin care comprised 57.1%, while the remaining 2.4% reported another specialist focus (described as melanoma and patch testing). The readers' practice settings were private clinic/group practice (52.4%), university clinic (11.9%), combination private and university clinic (2.4%), and private clinic/one person (33.3%). Fifty percent (50%) of readers reported spending >50% of their time per week diagnosing skin lesions suspect for skin cancer. The majority of readers reported being comfortable examining and diagnosing

melanoma using only the naked eye (71.4%), and being comfortable examining and diagnosing melanoma using a dermoscope (76.2%).

The study made use of images collected during the pivotal study. Following the selection scheme presented in this study protocol, 141 lesion images were randomly selected to the reader study, with only one lesion per subject selected. Thus, the number of subjects is the same as the number of lesions. The subjects' average age was 49 years (range 19 to 85), and 45.4% of subjects were male. Most subjects (97.2%) were white. Most subjects were Fitzpatrick scale 2 (57.4%), and 3 (28.4%); and about half the subject (53.9%) had less than 50 lesions.

There were 141 lesions: 81 non-melanoma and 60 melanoma.. The frequency distribution of Nevisense dichotomous outcomes, and the EIS scores for the lesions are summarized in Table 14 and Table 15. The stand-alone Nevisense sensitivity in this subset of lesions is 96.7%, and specificity is 30.9%, which is consistent with accuracy reported in the pivotal study that was based on a greater sample of lesions.

Table 14: Distribution of EIS Dichotomous Outcome

EIS Dichotomous Outcome	Reference Status				All	
	Non-Melanoma		Melanoma			
	N	%	N	%	N	%
Negative	25	30.9	2	3.3	27	19.1
Positive	56	69.1	58	96.7	114	80.9
Total	81	100.0	60	100.0	141	100.0

Table 15: EIS Scores

Reference Status	EIS Score					
	Mean	Standard Deviation	Minimum	Median	Maximum	N
Non-Melanoma	4.5	2.2	0.0	5.0	10.0	81
Melanoma	6.4	2.1	2.0	6.0	10.0	60
Total	5.3	2.3	0.0	5.0	10.0	141

D. Reader Study Safety and Effectiveness Results

The sensitivity of dermatologists in detecting melanoma was 77.2% when using clinical information alone, compared to a sensitivity of 83.6% when dermatologists used the Nevisense plus additional clinical information. The difference (Without – With) was estimated at -6.4%, with two-sided 95% confidence interval of (-9.6%, -3.3%). This improvement was statistically significant with a p-value less than 0.001. Both the p-value and two-sided 95%

confidence interval were derived by using a mixed model. The study succeeded in demonstrating an increase in readers' sensitivity with the aid of Nevisense information. Therefore, the first co-primary hypothesis was met.

With Nevisense aid, the sum of dermatologists' sensitivity and specificity is 1.33 with the two-sided 95% confidence interval (1.24, 1.42), which is significantly greater than 1, as indicated by the confidence interval. This confidence interval was derived by using a mixed model. This result demonstrates that the readers' decision regarding whether a lesion is melanoma or not when using Nevisense device is not random. Therefore, the second co-primary hypothesis was also met.

Dermatologists' sensitivity without Nevisense ranged from 50% to 96.7%, with median sensitivity of 80%. Dermatologists' sensitivity with Nevisense increased and ranged from 51.7% to 98.3%, with median sensitivity of 86.7%. On average, there was an increase of 6.4% in per-reader melanoma sensitivity. The difference in readers' individual sensitivities ranged from 0% (no change) to 20%. Note that sensitivity did not decrease for any reader.

Dermatologists' specificity without Nevisense ranged from 8.6% to 93.8%, with median specificity of 53.1%. Dermatologists' specificity with Nevisense decreased on average by 4%. The difference in readers' individual specificities ranged from -17.3% to 18.5%.

The difference in sensitivity was always positive, whereas the difference in specificity had both positive and negative values (depending on the reader), with an average difference in specificity of -4.0%.

The below tables depict the results when readers were deciding whether or not a lesion was melanoma (primary endpoint).

Table 16: Reader Sensitivity & Specificity for Deciding Whether or Not Melanoma

	Without Nevisense (Standard Deviation)	With Nevisense (Standard Deviation)	Difference (Standard Deviation)
Sensitivity	77.2% (13.6%)	83.6% (13.2%)	6.4% (5.1%)
Specificity	53.1% (21.2%)	49.1% (20.2%)	-4.0% (7.5%)

Table 17: By Reader Sensitivity & Specificity for Deciding Whether or Not Melanoma

	Minimum across	Maximum across	Median

	Readers	Readers	
Sensitivity without Nevisense	50.0%	96.7%	80.0%
Sensitivity with Nevisense	51.7%	98.3%	86.7%
Difference between the above Sensitivities	0.0%	20.0%	6.7%
Specificity without Nevisense	8.6%	93.8%	53.1%
Specificity with Nevisense	17.3%	93.8%	49.4%
Difference between the above Specificities	-17.3%	18.5%	-4.9%

The below tables depict the results when readers were deciding whether or not to biopsy lesions.

Table 18: Reader Sensitivity & Specificity for Deciding Whether or Not to Biopsy

	Without Nevisense (Standard Deviation)	With Nevisense (Standard Deviation)	Difference (Standard Deviation)
Sensitivity	91.4% (7.8%)	96.3% (4.6%)	4.9% (5.0%)
Specificity	26.4% (16.5%)	20.2% (13.1%)	-6.2% (9.2%)

Table 19: By Reader Sensitivity & Specificity for Deciding Whether or Not to Biopsy

	Minimum across Readers	Maximum across Readers	Median
Sensitivity without Nevisense	70.0%	100.0%	93.3%
Sensitivity with Nevisense	75.0%	100.0%	96.7%
Difference between the above Sensitivities	-3.3%	18.3%	3.3%
Specificity without Nevisense	0.0%	65.4%	24.7%
Specificity with Nevisense	2.5%	64.2%	19.8%
Difference between the above Specificities	-21.0%	16.0%	-6.2%

Below are results from the Reader Study for those at or above the age of 30.

Table 20: Reader Sensitivity & Specificity for Deciding Whether or Not Melanoma, Age group ≥ 30

	Without Nevisense (Standard Deviation)	With Nevisense (Standard Deviation)	Difference (Standard Deviation)
Sensitivity	77.5% (13.4%)	84.5% (13.2%)	7.0% (5.1%)
Specificity	52.2% (21.0%)	46.9% (20.6%)	-5.3% (7.3%)

Table 21: By Reader Sensitivity & Specificity for Deciding Whether or Not Melanoma, Age group ≥ 30

	Minimum across Readers	Maximum across Readers	Median
Sensitivity without Nevisense	50.8%	96.6%	81.4%
Sensitivity with Nevisense	52.5%	98.3%	88.1%
Difference between the above Sensitivities	0.0%	20.3%	6.8%
Specificity without Nevisense	10.9%	93.8%	48.4%
Specificity with Nevisense	15.6%	93.8%	46.9%
Difference between the above Specificities	-20.3%	14.1%	-4.7%

Table 22: Reader Sensitivity & Specificity for Deciding Whether or Not to Biopsy, Age group ≥ 30

	Without Nevisense (Standard Deviation)	With Nevisense (Standard Deviation)	Difference (Standard Deviation)
Sensitivity	91.4% (7.6%)	96.9% (4.3%)	5.5% (5.2%)
Specificity	25.5% (16.2%)	18.8% (12.0%)	-6.8% (9.4%)

Table 23: By Reader Sensitivity & Specificity for Deciding Whether or Not to Biopsy, Age group ≥ 30

	Minimum across Readers	Maximum across Readers	Median
Sensitivity without Nevisense	69.5%	100.0%	93.2%
Sensitivity with Nevisense	76.3%	100.0%	93.8%
Difference between the above Sensitivities	-1.7%	18.6%	5.1%

Specificity without Nevisense	0.0%	62.5%	23.4%
Specificity with Nevisense	1.6%	59.4%	17.2%
Difference between the above Specificities	-23.4%	14.1%	-6.3%

Results from the reader study for the melanoma question demonstrated a 6.4% increase in sensitivity with Nevisense and a 4% decrease in specificity with Nevisense. Results from the reader study for the biopsy question demonstrated a 4.9% increase in sensitivity with Nevisense and a 6.2% decrease in specificity with Nevisense.

Below are the total number of readings that changed, across all readers, when deciding whether the lesion was melanoma, and whether they would biopsy lesions.

Change from Not Melanoma to Melanoma for Actual Melanomas: 180
Change from Melanoma to Not Melanoma for Actual Melanomas: 22
Change from Not Melanoma to Melanoma for Non Melanomas: 371
Change from Melanoma to Not Melanoma for Non Melanomas: 239

Change from No Biopsy to Biopsy for Actual Melanomas: 144
Change from Biopsy to No Biopsy For Actual Melanomas: 23
Change from No Biopsy to Biopsy for Non Melanomas: 423
Change from Biopsy to No Biopsy for Non Melanomas: 218

Overall, the device used as an adjunct tool led to 158 more melanoma decisions and 121 more biopsy decisions for actual melanomas.

Subgroup Analyses
The following analyses are conducted on the primary effectiveness population unless otherwise noted.

The sensitivity for each age group was calculated for all melanoma lesions and for the subset of low stage melanoma (thicknesses Tis and T1) in the pivotal study. The results are summarized in Table 24 for the updated primary effectiveness population. Of the 265 lesions that were melanomas in the updated primary effectiveness analysis population, very few (n=7, 2.6%) occurred in subjects 18-30 years of age. The true sensitivity in this age group could not be verified due to the small number of melanoma lesions represented. Therefore, the device labeling warns when assessing Nevisense

output in patients 30 years of age and below, as the safety and effectiveness of Nevisense has not been adequately studied in this subgroup.

Table 24: Sensitivity and Specificity of Nevisense by Age Group and Melanoma Depth (Pivotal Study)

Set of Melanoma Lesions	Age Group	Sensitivity	Specificity
Tis-T4	<= 30	57%	38%
Tis-T4	31-40	97%	38%
Tis-T4	41-50	98%	38%
Tis-T4	51-60	98%	28%
Tis-T4	61-70	97%	19%
Tis-T4	71-80	98%	14%
Tis-T4	> 81	100%	3%
Tis-T1	<= 30	50%	38%
Tis-T1	31-40	96%	38%
Tis-T1	41-50	97%	38%
Tis-T1	51-60	98%	28%
Tis-T1	61-70	96%	19%
Tis-T1	71-80	97%	14%
Tis-T1	> 81	100%	3%

Table 25: Sensitivity and Specificity of Nevisense for Males and Females (Pivotal Study)

Clinical Suspicion of Risk	Sensitivity for Males	Specificity for Males	Sensitivity for Females	Specificity for Females
Overall	97.9%	25.3%	93.5%	36.8%

Sensitivity of Nevisense was evaluated by lesion area quantile. Lesion area is calculated from lesion Length x Width, and lesion quantiles defined by Area (mm^2) as shown below:

- 1st Quantile: Area ≤12
- 2nd Quantile: 12 < Area ≤24
- 3rd Quantile: 24 < Area ≤42
- 4th Quantile: 42 <Area

Table 26: Sensitivity by Lesion Area Quantile (Pivotal Study)

Area Group	Estimate
1st quantile	80.1%
2nd quantile	88.0%
3rd quantile	93.5%
4th quantile	98.9%

A lower sensitivity was observed for Nevisense in the 1st quantile (80.1%) as compared with other quantiles (88.0% – 98.9%). The accuracy of Nevisense relative to other methods used to diagnose the same lesions was explored.

Figure 5 shows the sensitivity by lesion size in the pivotal study primary effectiveness population for Nevisense as compared with assessment by the visual classification board (overall suspicion of malignancy from 0 (benign) to 10 (malignant)), and with each site's local pathologist determination for the same lesions. Nevisense sensitivity was as good as or better than other methods in every lesion size category.

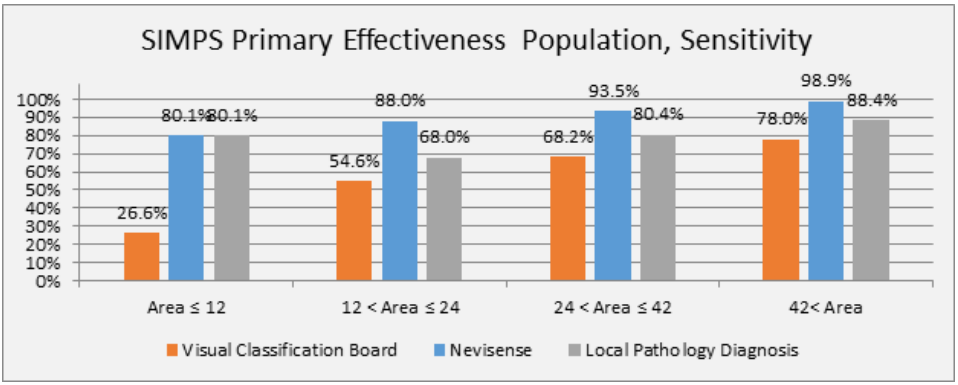


Figure 5: Pivotal Study – Sensitivity by Lesion Size

The Visual Classification Board (VCB) was a panel of dermatologists who evaluated lesion and dermoscopy images according to established clinical protocols (clinical ABCD rule, the dermoscopic ABCD rule, the seven-point checklist, and the overall suspicion of malignancy classified by VCB from 0 (benign) to 10 (malignant)) to ascertain a standardized assessment for study lesions.

Figure 6 shows the sensitivity in the reader study for reader diagnosis of melanoma without (before) having the Nevisense data versus with (after) considering the Nevisense data for the same lesions. In all lesion size categories, Nevisense meaningfully improved physician detection of melanoma. The largest increase in Reader sensitivity was seen in the smallest lesions: Reader sensitivity improved from 37.6% without Nevisense to 50.5% with Nevisense.

Note that Reader diagnosis of *melanoma with Nevisense* is different than stand-alone Nevisense accuracy. Reader diagnosis of *melanoma with Nevisense* is reader accuracy with (after) considering Nevisense output, and should be compared with reader accuracy without (before) considering Nevisense output.

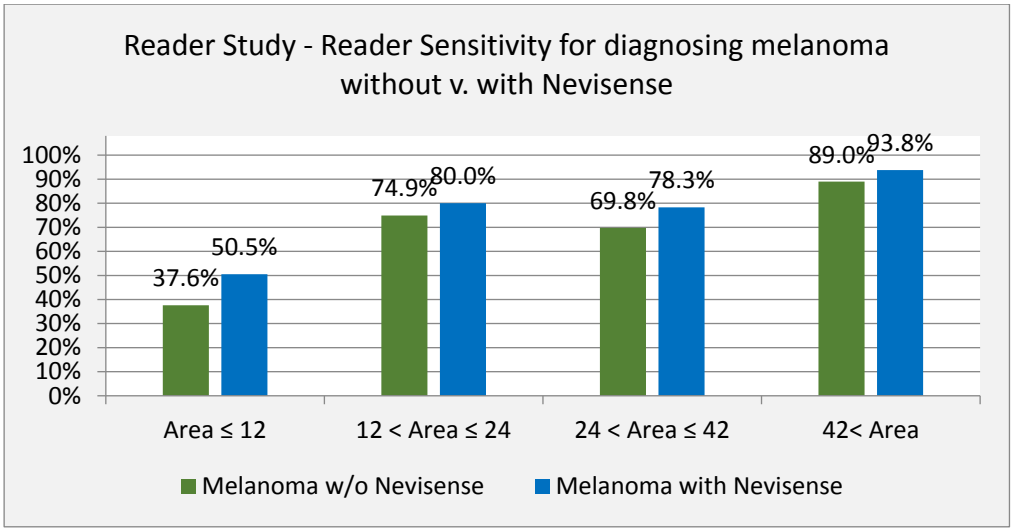


Figure 6: Reader Study, Reader Sensitivity for diagnosis of Melanoma without (before) versus with (after) Nevisense information

Sensitivity for Nevisense in the pivotal study was lower (80.1%) for the smallest lesions. However, sensitivity is also lower for dermatologists for smaller lesions as seen in the VCB group for pivotal study, and in the Reader study. In every lesion size category, sensitivity is as good or better for Nevisense than for the other methods. The largest difference in sensitivity for the pivotal study (Nevisense versus VCB) and the largest improvement in sensitivity for the Reader study (melanoma diagnosis without versus with Nevisense) were observed in the smallest lesions, which may be more difficult

for dermatologists to diagnose, thus supporting the benefit of Nevisense as a diagnostic support tool.

EIS - Electrical Impedance Spectroscopy

Electrical impedance is a measure of a material's overall resistance to the flow of alternating electric currents of various frequencies. The principle is that electrical impedance is different in normal versus abnormal tissue. Electrical impedance of biological materials reflects the clinical status of the tissue under study. Normal and abnormal tissue differ with regards to cell size, shape, orientation, compactness, and structure of cell membranes. These different properties influence the ability of the cells to conduct and store electricity. This means that the properties also will be reflected in an EIS.

A tissue alteration that would be discovered in a microscope during a traditional, histological examination can also be seen as an imprint in the impedance spectrum. In general, impedance at low frequencies is related mainly to the resistive properties of the extra-cellular environments, whereas impedance at high frequencies is related both to the resistive properties of the intra- and extra-cellular environments and the capacitive properties (reactance) of the cell membranes. The measurement outcome of an EIS is magnitude/amplitude and phase shift at each frequency included in the spectrum.

Nevisense evaluation is performed by applying an alternating electrical current onto the skin and measure the response, using an electrode with microscopic pins that penetrates into the stratum corneum.

Examination Procedure

A Nevisense examination should be initiated by a physician when additional information for his clinical decision is preferred. The user of Nevisense should be qualified as a Nevisense user according to the Training and qualification program, see Chapter 5 *Training and Qualification.*

The evaluation consists of at least two measurements; one on healthy skin (reference measurement) in close proximity to the lesion, for comparison to the measurement/s from the lesion. A quality control algorithm evaluates the reference measurement. The measurements will be displayed as graphs of magnitude/amplitude and phase shift. In cases with lesions larger than 5x5 mm it is of importance that multiple lesion measurements are performed in order to cover the entire surface of the lesion. A classifier analyses the measurements and provides an output specifying whether the lesion contains alterations in cell structure.

Measurement Result

Measurement results are presented as EIS positive or EIS negative and a score. It is important that the decision whether to biopsy the lesion or not is taking EIS results, other clinical assessment and patient's medical history into account. With Nevisense, the physician has additional information in which to base clinical decisions.

Nevisense Accuracy

Nevisense Accuracy has been validated through an effectiveness and safety study including 2416 lesions from a total of 1951 subjects. The outcome of the study showed an overall observed sensitivity of 95.9% and specificity of 31.3% in the detection of malignant melanoma.

Caution: Caution is advised when assessing the Nevisense output in patients age 30 and below, as the safety and effectiveness of Nevisense has not been adequately studied. In the pivotal study, there were 296 total lesions in patients 18-30 years old with few (7 lesions, 2.6%) melanomas. The Nevisense sensitivity was 57.1% and specificity was 38.4% for melanomas in patients 18-30 years old compared to patients 31 years and older where the sensitivity was 97.7% and specificity was 29.9%.

Caution: Caution is advised when assessing the Nevisense output in Patients with Fitzpatrick Type 5 and 6, as the safety and effectiveness of Nevisense has not been adequately studied in these groups.

Qualification

Before examining patients with Nevisense you need to perform practical training to become a qualified Nevisense user. For more information, see Chapter 5 *Training and Qualification*.

Chapter 2

Getting Started

About Instructions for Use

The Instructions for Use give information about how to perform examinations using Nevisense, and how to become a qualified Nevisense user.

Before you start using Nevisense it is important that you are familiar with the contents of Instructions for Use.

Notations Used

⚠ Warning! A warning indicates a possible injury to the patient or user.

Caution: A caution indicates possible damage to or malfunction of Nevisense, or loss of data.

Important: An important note provides essential information that you need when using Nevisense.

Note: A note emphasizes information.

Tip: A tip is an advice for more effective use.

Preparing Nevisense for Use

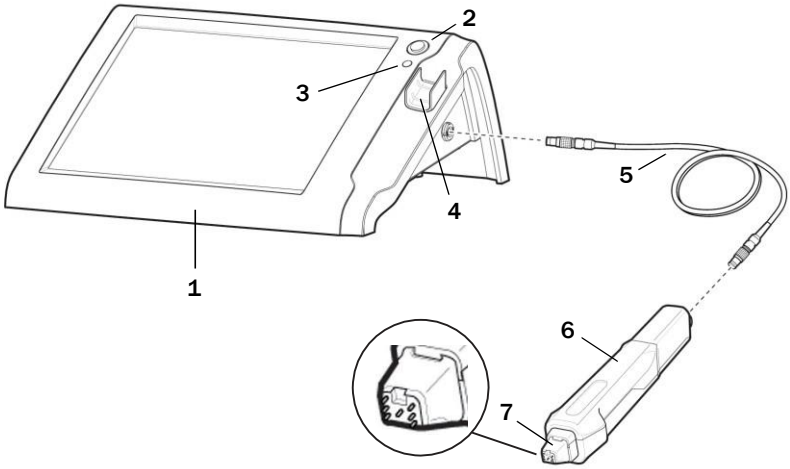
To prepare Nevisense for use:

1. Unpack Nevisense. Verify that the following parts are included and ensure that they are not externally damaged:
   - 1 control unit
   - 1 probe
   - 1 probe cable
   - 1 battery (optional, ordered separately)
   - 1 USB flash drive
   - 1 Test Impedance Tool
   - 1 Lesion Coverage Tool
   - 1 power cord (3 core, unshielded, 2-2.5m)
   - 1 Instructions for Use
   - 1 Administration and Service Instructions
   - 1 Clinical Reference Guide
   - Examination electrodes (grey)
   - Training electrodes (grey with orange package)
2. Wait for 12 hours to let Nevisense adapt to ambient temperature, pressure and humidity.
3. Remove the protective film from the screen.
4. If you will use a battery, connect the battery to the control unit. For more information, see *Administration and Service Instructions*.
5. Connect the probe cable to the probe and the control unit.
6. Connect the power cord to the control unit and the mains outlet.
7. Press the on/off button to turn on Nevisense.

If Nevisense does not work as expected, contact a SciBase representative.

The Nevisense Parts

Control Unit with Probe



1 **Control unit**: Used to navigate Nevisense.

2 **On/off button**: Used to turn on, shut down, log on and log off Nevisense.

3 **Notification LED**: Indicates battery and power status.

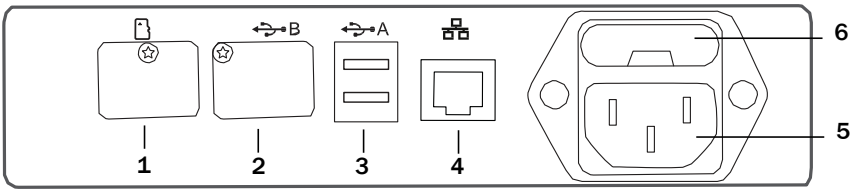
4 **Probe holder**: Holds the probe when it is not used.

5 **Probe cable**: Connects the probe with the control unit.

6 **Probe**: Used to perform lesion examinations on patients, using disposable electrodes attached to the probe.

7 **Probe socket**: Connector for the disposable electrode.

Rear Panel



1 Slot for Micro SD (Secure Digital) memory card, covered. The cover is removed for service purposes only.

2 USB type B port, covered and provided for future use.

3 Two USB type A ports where a USB flash drive can be inserted.

4 10 Mbit Ethernet port, provided for future use, shall only be used with separation device in conformity with IEC/EN 60601-1:2005 paragraph 16.5.

5 Mains power input.

6 Fuse insert.

Electrodes

During a lesion examination a disposable electrode is used. The electrode is easily attached and detached from the probe. For more information, see *Attaching and Detaching Electrodes* on page 60.

The electrode is equipped with microscopic pins. The pins will penetrate into the outermost layer of the skin. A small alternating voltage is applied onto the skin. The responding current is used to evaluate the lesion.

There are two types of electrodes:

Examination electrodes, used when performing measurements on patients. Each electrode can be used up to 20 times for a single patient on several lesions in a single procedure. The examination electrodes are grey, provided in grey containers.

- **Training electrodes**, used for Nevisense training and qualification. Each electrode is to be used only on intact, healthy skin on a single person in a single training session. Each electrode can be used up to 50 times. The reason for the higher number (i.e., 50, as compared with 20 for the examination electrode) is that these electrodes are used for training and qualification purposes only. The training electrodes are provided in orange containers.

Test Impedance Tool

The Test Impedance Tool is used by your system administrator when performing measurement accuracy tests. A measurement accuracy test should be performed once a month, to ensure that all Nevisense examinations will present correct measurement data.

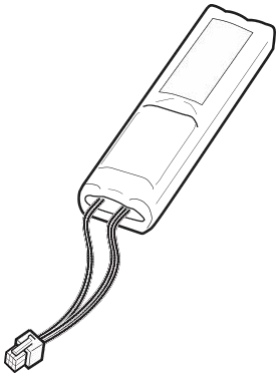
For more information, see *Administration and Service Instructions*.

USB Flash Drive

The USB flash drive is used when archiving and exporting data, and when creating reports. The USB flash drive is inserted to one of the type A USB ports on the rear side of the control unit.

Note: SciBase only guarantees functionality of the USB flash drives provided by SciBase.

Battery



It is possible to order a battery to be used in addition to the power cord. This is useful if Nevisense should be used as a portable device.

For information about how to see the battery status, see *Activity Bar* on page 14.

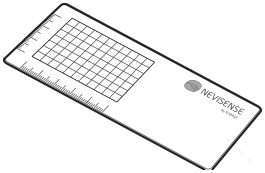
For information about how to insert and remove the battery, see *Administration and Service Instructions*.

⚠ Warning! Only use the battery provided by Sci-

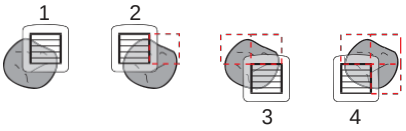
Base, due to the risk of fire and explosion.

Lesion Coverage Tool

The Lesion Coverage Tool is used to determine the number of measurements necessary to cover the entire surface of a lesion.

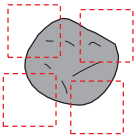


One square of the Lesion Coverage Tool is equal to one (1) measurement.

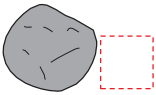


Cover the entire lesion with measurements

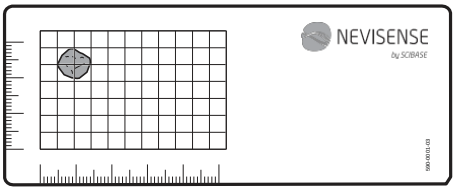
Covered lesion



Insufficiently covered lesion (lesion not completely covered)



Measurement outside lesion (reject the measurement)



This lesion requires a minimum of 4 measurements

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

Getting to Know Nevisense

Notification LED

The notification LED (the blue diode) located on the front panel of the control unit provides information about the Nevisense battery and power status.

LED status	
Steady	The battery is charged. If a battery is not used, the notification LED is a power indicator.
Blinking	The battery level is low. Connect Nevisense to external power.
Fading	The battery is charging. Nevisense is connected to external power.

For more detailed information about battery status, see *Activity Bar* on page 14.

Screen Saver

After five minutes of inactivity the Nevisense screen will go darker to save power. Simply tap the screen to make the screen bright again.

Touchscreen

Nevisense is navigated by a touchscreen.

Simply tap the touchscreen to set the insertion point. Only one insertion point at a time is possible (you cannot tap the screen with two or more fingers).

Caution: Do not use the probe as a pointing device on the screen.

Recurring button	Functionality
Close	Closes the screen.
Cancel	Closes the screen, discarding any changes.
Clear	Removes filled-in data and selections on the screen.
Save	Saves filled-in data and selections on the screen.
Previous	Displays the previous screen.
Next	Displays the next screen.

Touchscreen Keyboard

Keyboard

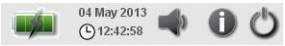
When you tap on an input field on the screen, a keyboard is displayed. Use the keyboard when entering text.

To make the keyboard disappear, tap the **Close** key.

Note: You may have to close the keyboard to access certain buttons or fields.

Key	Functionality
Close	Closes the keyboard.
Shift	Makes the following character uppercase.
Caps	Makes the following characters uppercase, until you tap Caps again.

Activity Bar



Activity bar

The activity bar is located at the top right corner of the screen.

From the activity bar you can see the battery status (if a battery is used), set the date and time, set the volume and view information about Nevisense. You can also log off and shut down Nevisense from here.

Battery status

The battery symbol, displayed if a battery is used, indicates the status of the battery.

Symbol	Status
	The battery is fully loaded. As the battery is used, the four pins displayed will become three pins, and then two pins, and so on, to indicate the battery level.
	25% of the battery remains, i.e. the battery level is low. Connect Nevisense to external power.
	The battery is almost empty, i.e. the battery level is critically low. Connect Nevisense to external power, or Nevisense will shut down within 2 minutes.
	The battery is charging, indicated with a lightning symbol. Nevisense is connected to external power.

To set date and time:

1 In the activity bar, tap

.

2 Tap the part of the date or time to be changed.

3 Tap - or + next to the date/time to increase or decrease the value.

4 Select **OK**.

Warning! Ensure that the correct date is set to make sure that patient age is calculated accurately. The age may influence the measurement result.

To view software version and control unit ID:

1 In the activity bar, tap . The version number of the Nevisense software is displayed.

2 Select **OK**.

To set the volume:

1 In the activity bar, tap . A track bar is displayed.

2 Slide the trackbar to set the volume. Nevisense will beep according to the set volume.

Note: If the volume is set to mute, the symbol is marked with a mute icon .

On/Off Symbol

You can tap to shut down Nevisense, or to log off the current user.
For more information, see the next chapter.

Turning on/Shutting Down Nevisense

An on/off button is located on the front panel. The button is used for turning on Nevisense, shutting down Nevisense, and for logging off the current user.

You can also use in the activity bar to shut down Nevisense or to log off.

Important: Make sure that Nevisense is shut down daily to ensure that the self-test is perfomed every day Nevisense is to be used.

To turn on Nevisense:

1. Ensure that the power cord is connected properly, or that a battery is connected.
2. Ensure that the probe is connected properly.
3. Press the on/off button on the front panel. The login screen will be displayed.

   Caution: Measurement accuracy tests should be performed once a month by your system administrator, to ensure that the cable and probe are functioning correctly. If the tests have not been performed, a notification dialog box will be displayed when turning on Nevisense. If this is the case, contact your system administrator or see *Administration and Service Instructions*.

To shut down Nevisense:

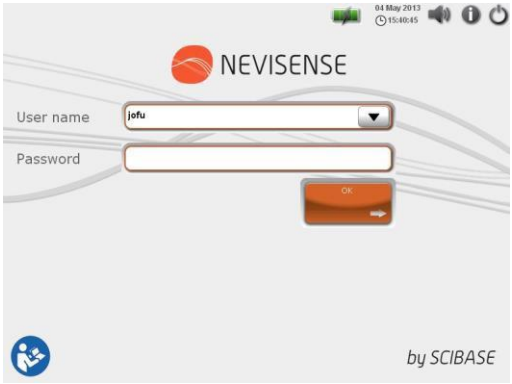
Note: If you are on the **Measurement** screen, select **Done** before shutting down.

1. Press the on/off button on the front panel, or in the activity bar. A dialog box is displayed, asking if you want to shut down or log off.
2. Select **Shut down**.

Logging On/Off

Each Nevisense user should have a personal user account. For more information about user accounts, see *Administration and Service Instructions*.

You must be a qualified user before using Nevisense. As long as you have not completed the Nevisense training and become a qualified Nevisense user, you will be prompted to start the training each time you log on.



Logon screen

To log on:

1. Tap **User name** and select your user name.
2. Tap **Password** and type your password.
3. Select **OK**.
4. If you have not completed the Nevisense training, a dialog box will be displayed asking if you would like to start the training.
   - To start the training, select **Yes**.

   If you select **No**, the dialog box will be displayed again the next time you log on.

   Note: You can at any time select **Training** from the start screen to start the training.

To log off:

Note: If you are on the **Measurement** screen, select **Done** before logging off.

1. Press the on/off button on the front panel, or in the activity bar. A dialog is displayed, asking if you want to shut down or log off.
2. Select **Log off**.

Chapter 3

Operating Safety

General

Various factors may cause inaccurate measurement result. Incorrect usage of Nevisense may also involve risks of injuries to the patient or user.

Observe the following warnings and cautions when using Nevisense.

Usage

⚠ Warning! Nevisense may only be used for purposes stated in Chapter 1 *Introduction*.

⚠ Warning! Nevisense may only be used by users who have successfully completed the Nevisense training. For more information, see Chapter 5 *Training and Qualification*.

Caution: The warranty is only valid if the probe or the control unit has not been opened.

Caution: The warranty is only valid if spare parts, including any associated cables, are supplied by a SciBase representative.

Training and Qualification

⚠ Warning! Always perform training measurements on normal, healthy skin.

Patient Registration

⚠ Warning! Ensure that the correct date of birth is entered when registering a patient. Also ensure that the correct date is set in Nevisense, to make sure that patient age is calculated accurately. The age may influence the measurement result.

Examination

Note: When describing a lesion, ensure that the correct lesion position is selected on the body map. The lesions location on the body may influence how the reference quality control is calculated.

Note: When describing a lesion, ensure that the correct lesion position is selected on the body map. The lesions location on the body may influence how the reference quality control is calculated.

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

Warning! Ensure that a sufficient number of measurements are performed for each lesion, in order to cover the entire lesion. The degree of atypia may vary within the lesion.

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

Control Unit

Warning! Ensure that the air outlet is not covered. Otherwise, the control unit may overheat. The air outlet is at the bottom of the control unit.

Warning! Be careful when touching the metal plate under the control unit since it may be hot.

Warning! Only use the battery provided by SciBase, due to the risk of fire and explosion.

Electrodes

Warning! The disposable electrode is for single person use. It has to be replaced when an examination of a patient is completed, and also whenever Nevisense issues a warning about a used electrode. This in order to minimize the risk of spreading infections and to prevent the electrode spikes from being worn out.

Warning! If a lesion bleeds, appears ulcerated , or if the skin appears compromised after measurement has been performed, change the electrode before conducting additional measurements. This is in order to minimize the risk of transferring possible malignant cells.

Warning! Use Universal Precautions-do not touch the gold electrode tip, and use universal precautions (gloves) when removing and disposing of the electrode.

Caution: Do not touch the gold plated surface of the electrode since the electrode pins are easily damaged.

Caution: Electrodes must not be re-sterilized.

Electrical Safety

⚠ Warning! Mains voltage! The device contains mains voltage circuits. Do not open the covers. There are no user-serviceable parts inside the device. Any repair or maintenance work performed on equipment parts must be carried out by service personnel authorized by SciBase. Failure to observe this rule can be hazardous to human life.

⚠ Warning! Danger of electric shock! Keep the device away from splashing water or liquids, especially the electronic parts. Do not pull on the power cord. In case of emergency, disconnect the mains power supply.

Operating Environment

Nevisense complies with the EMC requirements according to IEC 60601-1-2. For more information regarding EMC and intended electromagnetic environment, see Administration and Service Instructions.

Caution: Radio transmitting equipment, cellular phones, etc, shall not be used in the close proximity of the device since this could influence the performance of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so that for example the HF-cables are not routed on or near the device. If in doubt, contact SciBase.

Cleaning and Disinfection of the Nevisense

Cleaning and disinfection is required after each session of use on each patient, see Chapter 6, Cleaning and Disinfection.

⚠ **WARNING: Incorrect cleaning and/or disinfection of the Nevisense probe can result in contamination and/or biologic risk to the patient and/or device operator.**

Chapter 4

Service and Maintenance

Nevisense Cleaning and Disinfection

Before cleaning or disinfecting, Nevisense should be shut down and disconnected from the mains power supply.

See detailed cleaning and disinfection steps in Chapter 6.

Daily Nevisense Checks

Make sure that the following checks are performed daily:

- Check that the power cord has not been damaged.
- Check that the probe cable has not been damaged.
- Check that the probe and control unit have not been damaged.

If anything is damaged, you must not use Nevisense or any of the associated cables. In this case, contact a SciBase representative for service.

Daily Nevisense Self-Tests

Each time Nevisense is turned on, a self-test is performed. This includes:

- calibration of the measurement system
- check of storage space

If an error is discovered a notification message will be displayed. The notification message will inform you about how the problem can be solved.

Monthly Maintenance Tests

The four measurement accuracy tests must be performed once a month by the system administrator. The tests are made to ensure that the cable and the probe are working properly, in order to present correct measurement result at examinations. See *Nevisense Administration and Service Instructions* for more information.

Chapter 5

Training and Qualification

About Training and Qualification

Before examining patients with Nevisense you need to perform practical training to become a qualified Nevisense user. The training will both give you detailed information about examinations and give you the possibility to train measurements as many times as needed. The training takes about an hour to complete.

Training is necessary to acquire a coherent routine throughout the complete examination, including skin preparation. Training is also important to get experience of measuring with the probe, in order to get consistent measurement results.

It is recommended that you practice measurements on another person (not on yourself).

The training consists of the following steps:

1 Examination overview

2 Measurement training

3 Qualification

Note: During training the training electrodes are used. The training electrodes are provided in orange containers. They are to be used only on normal, intact, healthy skin on a single person in a single training session.

Note: Qualification needs to be done on each Nevisense device to be used. However, if settings are imported from another Nevisense device the qualification result is also transferred. For more information, see *Administration and Service Instructions*.

⚠ Warning! The examination and training electrodes are for single person use.

⚠ Warning! Always perform training measurements on normal, healthy skin.

Starting the Training

As long as you have not completed the training and become a qualified Nevisense user, a dialog box will be displayed at login asking if you would like to start the training.

- To start the training, select **Yes**.

If you select **No**, the dialog box will be displayed again the next time you log on.

Note: You can at any time select **Training** from the start screen to start the training.

Step 1: Examination Overview (Screens 1 to 9)

Introduction screen

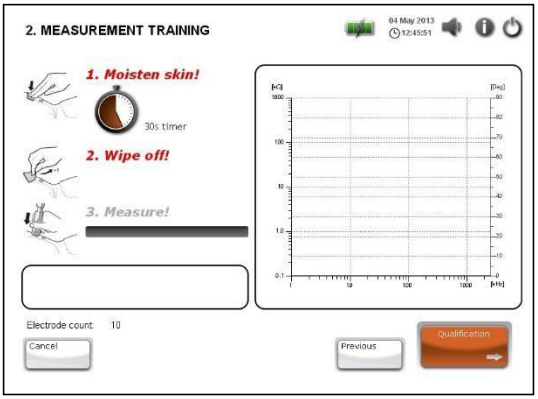
Screens number 1 to 9 will give you an introduction to the training and an overview of the lesion examination process. It will also give you a walkthrough of the Nevisense measurement procedure.

Read the information on the screens in Nevisense attentively.

To move on to the next step and start training:

- When you have read the overview, select **Training**.

Step 2: Measurement Training



Measurement training screen

On the **Measurement training** screen you can train measurements, as many times as desired, using the training electrodes (provided in orange package). The measurement result is displayed on the screen after each measurement.

The measurement was approved.

The measurement was not approved.

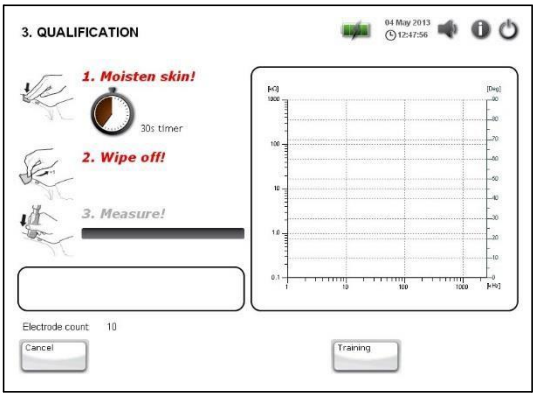
Train until the entire measurement procedure, including the skin preparation, is performed with stability. When the majority of the training measurements are approved you can move on with the qualification procedure.

Note: If you need to refresh your knowledge about the measurement procedure, select **Previous** to go back to the examination overview. For more detailed information, see also Chapter 6 *Performing an Examination*.

To move on to the next step and start the qualification:

- When you are finished training measurements, select **Qualification**.

Step 3: Qualification



Qualification screen

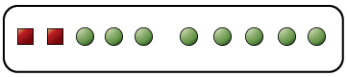
On the **Qualification** screen measurements are performed until you become a qualified user. As during the training, you will be notified after each measurement if it was approved or not approved.

Note: If you need additional measurement training, select **Previous** to go back to the **Training** screen.

To become a qualified user:

- On the **Qualification** screen, perform measurements **until 8 out of 10** measurementsare are approved. A dialog box is displayed, informing that the qualification is successful.

Note: It is the **10 latest measurements** that will be assessed. For example, if you have not achieved 8 approved measurements after 10 measurements, continue to measure and the result will be assessed from the second measurement that was performed (counting measurements 2-11).



8 out of 10 measurements approved

Qualification is successfully performed

As a qualified user you will still have access to the training (by selecting **Train- ing** on the start screen), if you would like to perform additional training.

Chapter 6

Performing an Examination

About Examining

Before performing examinations you need to be a qualified Nevisense user. For more information, see Chapter 5 *Training and Qualification*.

All patients to be examined need to be registered in Nevisense before the examination.

For more information about the measurement method and how to interpret the examination result, see Chapter 1 *Introduction*.

Examination Procedure

The following steps are included in the examination procedure:

1. A patient is either registered or selected, depending on whether the patient is new or already registered.
2. The lesion is described.
3. The patient's skin is prepared for examination.
4. The lesion is examined.
5. The result is analyzed.

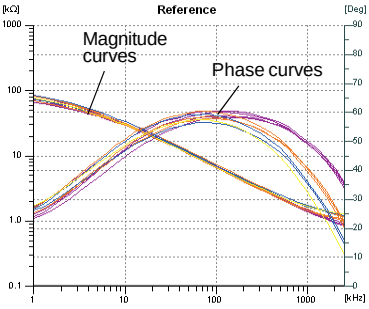
Steps 3-5 are repeated for each new measurement on the lesion.

Reference Measurements

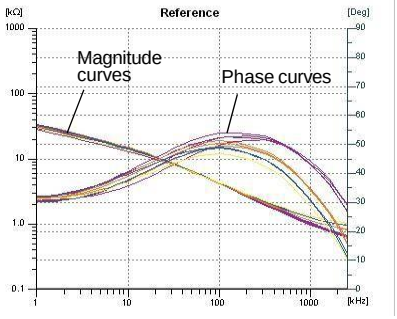
To be approved the measurement needs to be performed on properly cleaned and soaked, healthy skin.

A reference measurement of good quality is distinguished by magnitude curves that are parallel and fairly straight. The shape of the phase shift curves may differ due to skin properties, but the peak is around 100 kHz.

For information about rejected measurements, see *Rejection of Measurements* on page 69.



An approved forearm reference measurement



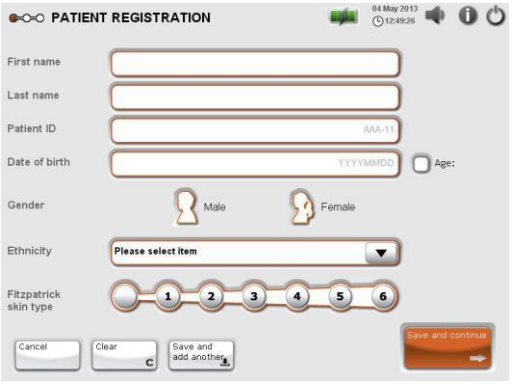
An approved forehead reference measurement

Registering a New Patient

If the patient is not already registered in Nevisense you need to make a registration before starting the examination.

Note: All fields described may not be present on your screen. The fields are set by your system administrator.

Important: Patients should be archived and deleted from Nevisense regularly, to free storage space. For more information, see *Deleting Patient Data* on page 56.



Patient registration screen

To register a new patient:

1 From the start screen, select **New Patient**.

2 Tap **First name** and enter the patient's first name.

3 Tap **Last name** and enter the patient's last name.

4 Tap **Patient ID** and enter the patient's ID. Which format to be used is displayed to the right in the field.

Note: The patient ID is a unique ID which identifies the patient. The format of the ID is set by your system administrator.

5 Tap **Date of birth** and enter the patient's date of birth. Which format to be used is displayed to the right in the field. The patient's age is calculated in **Age**.

6 Tap **Age** to confirm the patient's age. The confirmation is needed since the patient's age may influence the measurement result.

7 Select the gender of the patient by tapping **Male** or **Female** next to **Gender**.

8 Tap **Ethnicity** and select the ethnicity of the patient.

9 Select the patient's **Fitzpatrick Skin Type** by tapping the correlating number on the scale. An explanation of the selected Fitzpatrick Skin Type is displayed to the right of the scale.

10 Select one of the following:

- Select **Save and continue** to save the information and continue to the **Lesion Description** screen.
- Select **Save and add another** to register another patient.

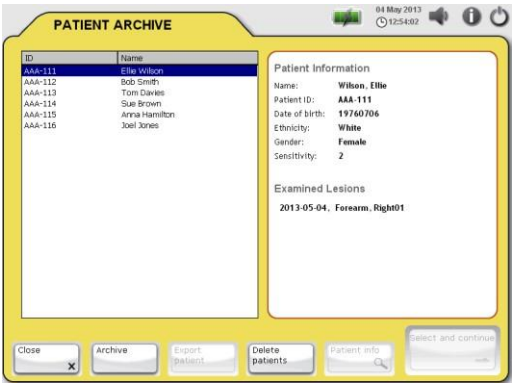
Note: If all required content is not completed, a notification message is displayed. The missing content is highlighted. Make sure all required content is completed and select **Save and continue** or **Save and add another** again.

It is not possible to register a **Patient ID** that is already in use. If you try to register an already registered patient ID, a notification message is displayed.

⚠ Warning! Ensure that the correct date of birth is entered. The age may influence the measurement result.

Selecting a Previously Registered Patient

If the patient to be examined is already registered, the patient is selected from the patient archive.



Patient archive screen

To select a previously registered patient:

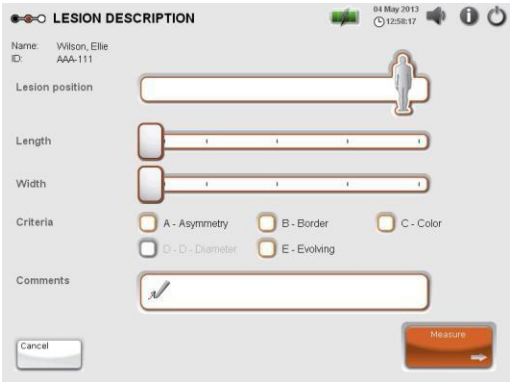
1. From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.
2. Tap the patient in the patient list.

   Tip: Tap **Name** to sort the patients by names, or tap **ID** to sort by ID.
3. Select **Select and continue**. The **Lesion description** screen is displayed.

Describing a Lesion

Before measuring, data about the lesion is registered on the **Lesion Description** screen.

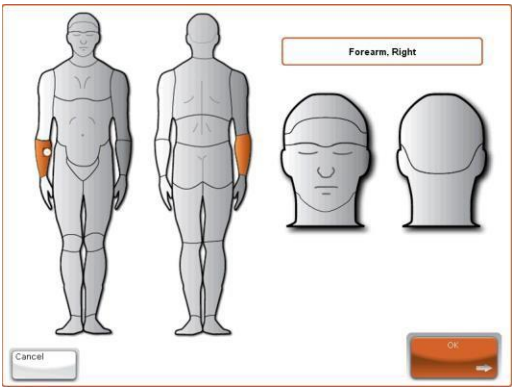
Note: All fields described may not be present on your screen. The fields are set by your system administrator.



Lesion description screen

To describe a new lesion:

1. Select the patient from the patient archive, or register the patient if it is a new patient.
2. Tap **Lesion position**. A body map is displayed.



Body map

3 Select the position of the lesion by tapping the corresponding body part. You can then tap with your finger to move the position within the selected body area.

Note: When you have tapped a lesion position and selected **OK**, a lesion ID will be generated (for example **Forearm, Left01**). If multiple lesions on the same position are examined on the same date, the lesions will be separated by consecutive numbering, for example **Forearm, Left01** and **Forearm, Left 02**.

4 Move the **Length** and **Width** slide bars to specify the size of the lesion. You can also tap at any position on the slide bar to set the size. The size should range from 2x2 mm to 20x20 mm.

5 Select the characteristics of the lesion by tapping the appropriate **Criteria** checkboxes.

Note: The **Diameter** checkbox is preselected when the lesion is larger than 5 mm.

6 Tap **Comments** to enter additional information about the lesion, if any. Enter the information in the dialog box that is displayed and then select **OK**. 180 characters can be entered at a maximum.

7 Attach a new electrode on the probe. For more information, see *Changing Electrodes* on page 60.

8 Select **Measure** to save the information and display the **Measurement** screen.

Note: If all required content is not completed, a notification message is displayed. The missing content is highlighted. Make sure all required content is completed and select **Measure** again.

If the current electrode is already used, not attached correctly or of the wrong type, a notification message will also be displayed. Make any corrections and select **Measure** again.

⚠ Warning! Ensure that the correct lesion position is selected on the body map. The body position may influence the measurement result.

⚠ Warning! The examination and training electrodes are for single person use.

⚠ Warning! Use Universal Precautions-do not touch the gold electrode tip, and use universal precautions (gloves) when removing and disposing of the electrode.

Caution: Do not touch the gold plated surface of the electrode since the pins are easily damaged.

Cleaning and disinfection is required after each session of use on each patient.

⚠WARNING: Incorrect cleaning and/or disinfection of the Nevisense probe can result in contamination and/or biologic risk to the patient and/or device operator.

Performing an Examination

Performing an examination means that you make at least two measurements:

1 **Reference measurement**: One measurement is made on a reference skin area, used for comparison with the lesion skin area. Reference skin is healthy skin located approximately 2 cm from the lesion. The location is important since the skin properties of the areas to be compared must be the same. If the reference area is located too far from the lesion, the measurements may deviate too much. If the reference area is located too close to the lesion, both the reference and the lesion may contain a malignancy.

2 **Lesion measurement**: One or more measurements are performed on the lesion, depending on the size of the lesion.

For more information about the measurement method and how to interpret the examination result, see Chapter 1 *Introduction*.

For information about error messages or problems that may arise, see Chapter 8 *Troubleshooting*.

For information about rejected measurements, see *Examples of rejected reference measurements* on page 70.

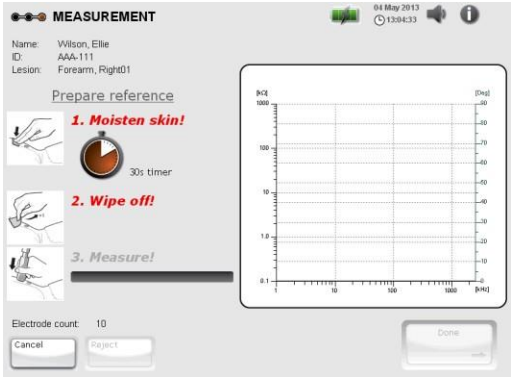
⚠ Warning! Ensure that a sufficient number of measurements are performed for each lesion, in order to cover the entire lesion. The degree of atypia may vary within the lesion.

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

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

To perform an examination:

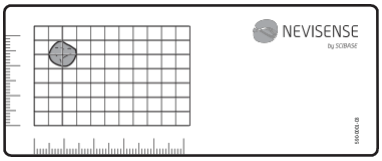
1 When the lesion has been described, select **Measure**. The **Measurement** screen is displayed.



Measurement screen

2 Position the patient on an examination bed or similar.

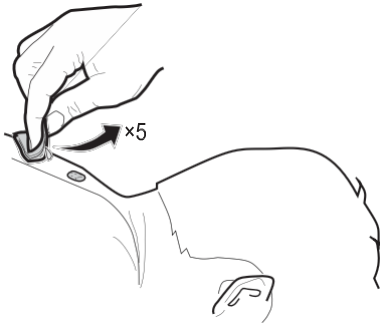
3 Use the **Lesion Coverage Tool** to determine the number of measurements needed to cover the entire lesion.



This lesion requires a minimum of 4 measurements

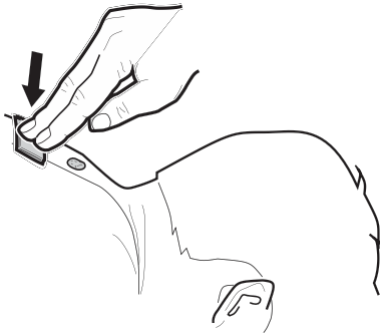
Note: One square of the Lesion Coverage Tool is equal to one (1) measurement.

4 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.



Important: Always start to measure the reference skin. The reference skin should be an ipsi-lateral skin area located 2 cm from the lesion. If this is not possible, for example if the lesion is located on the side of the nose, you must use a contra-lateral reference skin area instead.

5 Moisten the reference skin by holding the wet Salvequick compress against the skin for **30 seconds**.

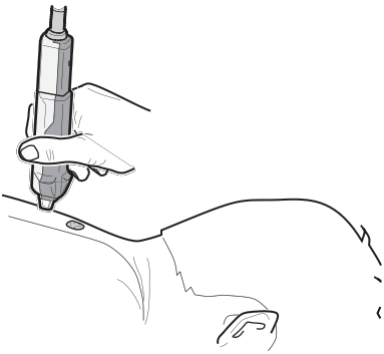


Tip: Use the 30-second timer in Nevisense. Reset the timer by tapping it.

6 Wipe off excess fluid with one firm stroke using a clean and dry compress.

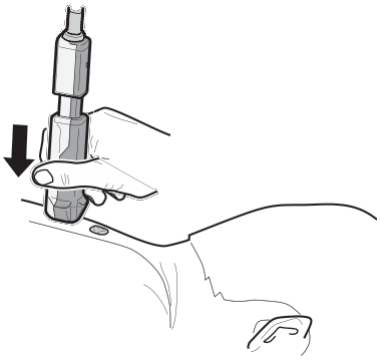
Important: Start the measurement within 10 seconds after the wipe off.

7 Hold the probe in a vertical position against the moistened skin.



8 Start the measurement by pressing down the movable probe housing. Keep the probe still and maintain the same pressure throughout the measurement. This takes about 8 seconds. When the measurement is done, remove the probe from the skin.

Note: A progress bar is displayed during the measurement, and a beep will indicate when the measurement starts and stops.

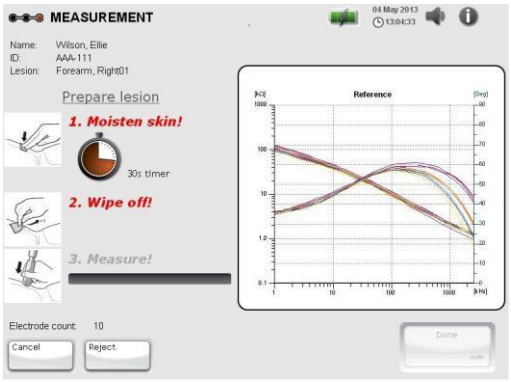


9 The measurement data is processed. This takes about 3 seconds. A progress bar is displayed during the processing.

Note: During the data processing the reference measurement is evaluated to be approved or not approved. If the measurement is not approved (because of, for example, too dry skin), Nevisense will display a warning and request a new measurement.

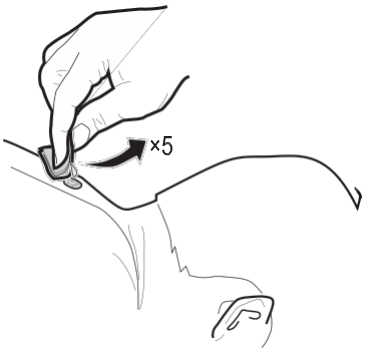
The measurement can be manually rejected if you for some reason wish to redo the measurement. Select **Reject**, moisten the skin again and perform a new measurement.

10 The measurement is shown in the **Reference** graph. You are now done measuring the reference skin.



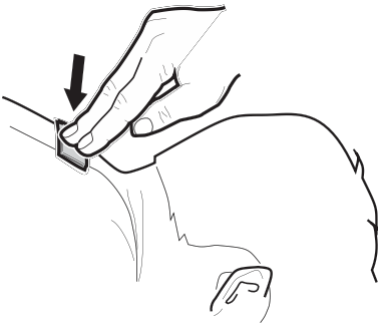
Measurement screen, displaying an impedance graph of a reference measurement

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



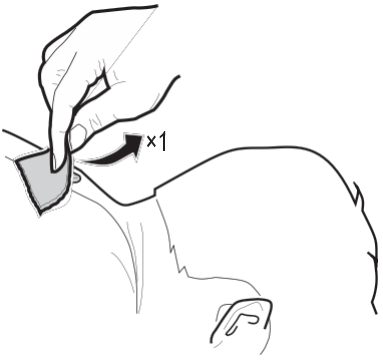
12 Moisten the lesion by holding the Salvequick wet compress against it for **30 seconds**.

Tip: Use the 30-second timer in Nevisense. Reset the timer by tapping it.

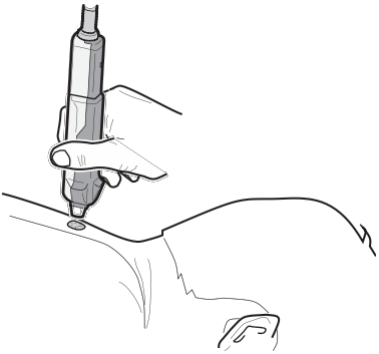


13 Wipe off excess fluid with one firm stroke using a clean and dry compress.

Important: Start the measurement within 10 seconds after the wipe off.

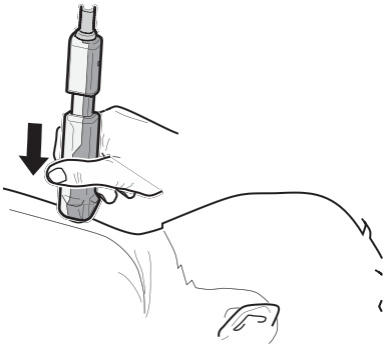


14 Hold the probe in a vertical position against the skin. Ensure that the gold plated surface is placed on the lesion.



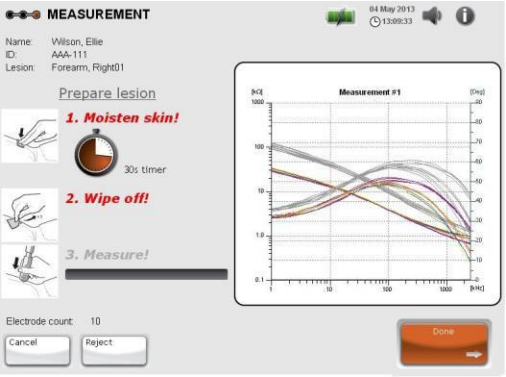
15 Start the measurement by pressing down the movable probe housing. Keep the probe still and maintain the same pressure throughout the measurement. This takes about 8 seconds. When the measurement is done, remove the probe from the lesion.

Note: A progress bar is displayed during the measurement, and a beep will indicate when the measurement starts and stops.



16 The measurement data is processed. This takes about 3 seconds. A progress bar is displayed during the processing.

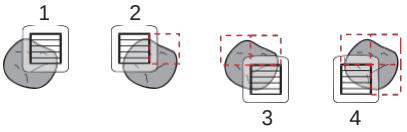
17 The measurement is shown together with the greyed out reference measurement in the **Measurement** graph. The measurement graph will be updated for every new measurement on the lesion. However, the reference graph will remain the same throughout the examination.



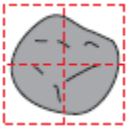
Measurement screen, displaying an impedance graph of a lesion measurement. The reference graph is still displayed, in grey.

Note: The latest measurement can be manually rejected if you for some reason wish to redo the measurement. Select **Reject**, moisten the skin again and perform a new measurement.

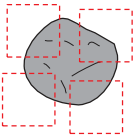
18 Ensure that you cover the entire lesion with measurements. Covering the entire lesion is very important since the degree of atypia may vary within the lesion. Use the Lesion Coverage Tool to determine the number of measurements needed.



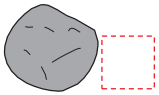
Cover the entire lesion with measurements



Covered lesion



Insufficiently covered lesion (lesion not completely covered)



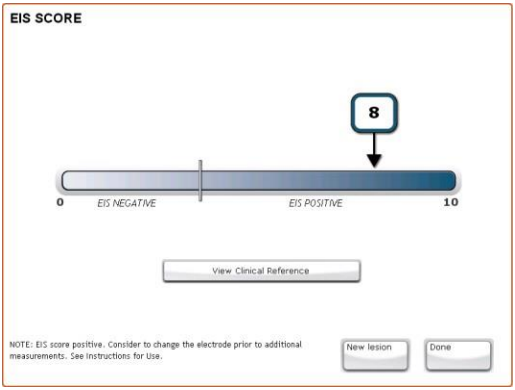
Measurement outside lesion (reject the measurement)

Important: When multiple measurements are needed, repeat the cleaning and moistening procedure of the lesion before each measurement.

19 Repeat step 11-17 until you have covered the entire lesion.

20 Select **Done** to finalize the examination and save all examination data. A dialog box with the summarized result of the lesion examination will open.

Important: For information about how to interpret the measurement result, see Chapter 1 *Introduction*.



Measurement result

For clinical reference and additional clinical information view the Clinical Reference Guide.

21 Select one of the following:

- Select **New lesion** to go to the **Lesion Description** screen and continue to examine additional lesions on this patient. Select **Done** to return to the start screen.

Note: If **Done** is selected before a sufficient number of measurements have been performed in order to cover the entire lesion, a warning is displayed.

⚠ Warning! If a lesion bleeds, appears ulcerated, or if the skin appears compromised after measurement has been performed, change the electrode before conducting additional measurements. This is in order to minimize the risk of transferring possible malignant cells.

22 When the examination is finished, remove the electrode. For more information, see *Changing Electrodes* on page 60.

To cancel the current examination:

- Select **Cancel** on the **Measurement** screen.
  - If no measurement has been performed yet, the **Lesion description** screen is displayed.
  - If a measurement has been performed, a dialog box is displayed. Select **New Lesion** to make a new lesion description, or **Start screen** to go back to the start screen. Selecting **Continue** will discard the cancellation.

Important: When cancelling, the examination will be completely deleted. No examination data will be saved.

Changing Electrodes

When performing examinations the probe must have an examination electrode attached.

The examination electrode must be replaced in the following situations:

- After finishing an examination of a patient.
- When the electrode has been used 20 times, including rejected measurements, on a single patient. This is because the electrode pins will be worn out.

When a measurement with a positive score has been performed, and if the lesion is ulcerated, consider changing the electrode.

For more information about the electrodes, see *Electrodes* on page 9.

Note: Nevisense will warn you and prohibit usage if you try to examine a patient with a used electrode, or when the electrode has been used 20 times for a single patient on several lesions in a single procedure.

⚠ Warning! The electrodes are for single person use.

Attaching and Detaching Electrodes

Each electrode is individually packaged in a container that allows you to attach and detach the electrode without having to touch it. This means less risk to accidentally damage or contact the electrode.

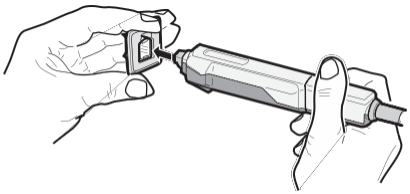
Tip: Do not discard the empty container. Save it and use it for detaching the electrode when you have finished the examination. Always grasp the probe and align the probe with the electrode container as shown on the following page.

Caution: Do not touch the gold plated surface to the electrode since the electrode pins are easily damaged.

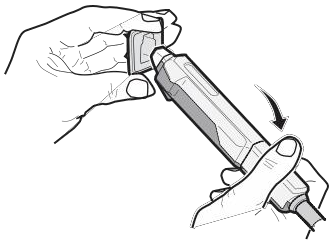
⚠ Warning! Use Universal Precautions-do not touch the gold electrode tip, and use universal precautions (gloves) when removing and disposing of the electrode.

To attach an electrode:

1 Remove the protective film from the electrode container.

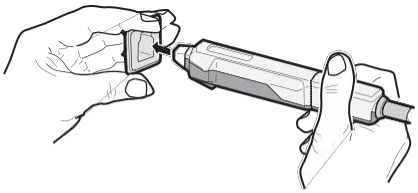


2 Grasp probe at the stationary portion of the probe body near the cable connection. Firmly press the probe into the container as shown until you hear a click. The click indicates that the electrode is attached to the probe.

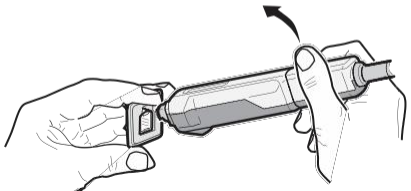


3 To detach the container, angle the probe downwards.

To detach an electrode:



1 Holding the probe as shown, press the electrode into an empty container until you hear a click. The click indicates that the electrode has snapped back into the container.



2 To detach the probe, angle the probe upwards.

Discard the used electrode according to local guidelines.

Nevisense Cleaning and Disinfection

Cleaning and disinfection is required after each session of use on each patient.

The probe unit and lesion coverage tool are validated for intermediate level disinfection. The control unit, probe cable, and mains cable are validated for low level disinfection

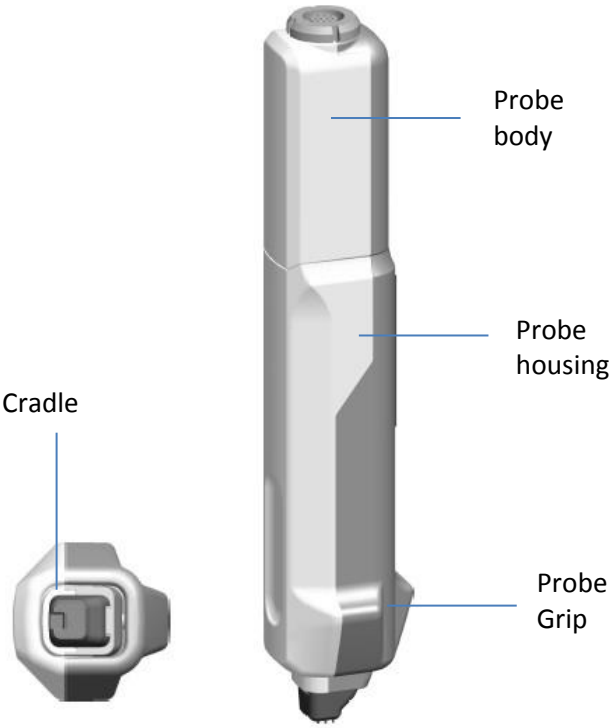
General Cleaning Probe Unit

⚠**WARNING: Do not use solvents and/or inorganic acids. Avoid disinfectants that are very oxidizing such as the sodium hypochlorite (NaClO).**

⚠**WARNING: Incorrect cleaning and/or disinfection of the Nevisense probe can result in contamination and/or biologic risk to the patient and/or device operator.**

⚠**WARNING: Shutdown the device according to Nevisense Instructions for Use, and disconnect from Mains power supply before cleaning and disinfecting.**

Step	Instructions -
Materials needed:	• Lint-free Soft-cloth • Soft-bristled brush (size: medium, i.e. generic toothbrush) • Cotton swab • 70% Isopropyl Alcohol (IPA) • ENZOL Enzymatic Cleaning solution • Critical Water (DI / RO / Distilled) approximately 68°F/20°C (room temperature)§
Personal Protection:	• Disposable gloves • Safety glasses • (optional) protective coat or apron
Glossary	***Dampened cloth****- A cloth wet with cleaning solution but not to the point of dripping.* ***Soaked cloth-*** *A cloth wet with cleaning solution so that excess liquid is coming off of it.* ***Critical Water****- Either deionized, reverse osmosis, or distilled water*
Precaution	Disconnect the probe from its cable before cleaning. Visually inspect the probe under adequate lighting conditions (and magnification if needed) to confirm that the cleaning process has not damaged the components. Inspect for surface wear, discoloration, corrosion, or cracking.

Step	Instructions -
⚠ **WARNING:**	If soiled, DO NOT allow the soil on the control unit and probe to dry. Clean immediately after exposure. Allowing soil to dry could diminish the effectiveness of this validated cleaning procedure. Incorrect cleaning and/or disinfection of the Nevisense probe can result in contamination and/or biologic risk to the patient and/or device operator.
Component Identification:	
1	Make sure that the disposable electrode on the tip of the probe has been removed and properly discarded. Remove disposable electrode according to Nevisense Instructions for Use.
2	Soak a soft-cloth with enzymatic cleaner. Paying particular attention to the ridges along the probe grip and the cable connector, and the probe cradle wipe down the body and housing of the probe for at least one (1) minute.

Step	Instructions -
3	Inspect the probe for visible debris. If visible debris is present remove it with a soft bristle brush, cotton swab, or soaked soft-cloth depending on the location of the soil. Ensure no soil remains, paying particular attention to the Cradle. This includes the interior end of the housing that surrounds the tip.
4	Soak a soft-cloth with critical water. Paying particular attention to the ridges along the probe grip and the cable connector, wipe down the body and housing of the probe for at least one (1) minute.
5	Inspect the probe again and repeat step 2 thru 4 if soil persists.
6	Wipe the probe down with a soft-cloth dampened with 70% IPA to help remove moisture.
7	Allow the probe to air dry completely before the next use (minimum 3 minutes).
⚠ **WARNING:**	Soiled towelettes/cloth and gloves should be disposed of as biohazard material in accordance with federal, state and local regulations.

General Cleaning Control Unit / Probe Cable / Mains Cable / Lesion Coverage Tool

⚠**WARNING: Do not use solvents and/or inorganic acids. Avoid disinfectants that are very oxidizing such as the sodium hypochlorite (NaCIO).**

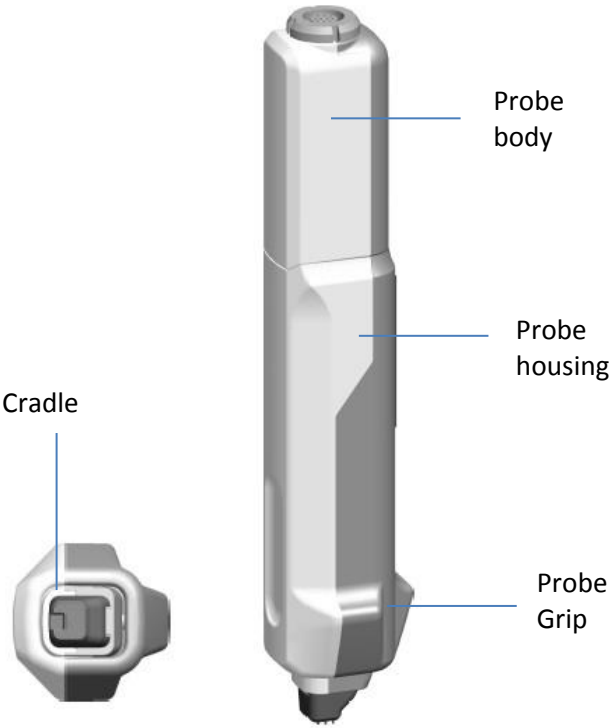
Step	Instructions -
Materials needed:	• Lint-free Soft-cloth • Soft-bristled brush (size: medium, i.e. generic toothbrush) • 70% Isopropyl Alcohol (IPA) • ENZOL Enzymatic Cleaning solution • Critical Water (DI / RO / Distilled) approximately 68°F/20°C (room temperature)
Personal Protection:	• Disposable gloves • Safety glasses • (optional) protective coat or apron
Glossary	***Dampened cloth****- A cloth wet with cleaning solution but not to the point of dripping.* ***Soaked cloth-*** *A cloth wet with cleaning solution so that excess liquid is coming off of it.* ***Critical Water****- Either deionized, reverse osmosis, or distilled water*

Step	Instructions -
Precaution	Disconnect the probe cable and power cable from the Control Unit before cleaning. Visually inspect the control unit and accessories under adequate lighting conditions (and magnification if needed) to confirm that the cleaning process has not damaged the components. Inspect for surface wear, discoloration, corrosion, or cracking.
⚠ **WARNING:**	If soiled, DO NOT allow the soil on the control unit, cables and lesion coverage tool to dry. Clean immediately after exposure. Allowing soil to dry could diminished the effectiveness of this validated cleaning procedure. Incorrect cleaning and/or disinfection of the Nevisense control unit and accessories can result in contamination and/or biologic risk to the patient and/or device operator.
Component Identification:	
1	Soak a soft-cloth with enzymatic cleaner and wipe down the upper surface of the device including touchscreen and outer edged of the curved upper surface of the device.
2	Using a soft-bristled brush soaked in cleaner, brush around the edges of the power button and indicator light until visually free of gross soil.
3	Using a soft-bristled brush soaked in cleaner, brush the edges of the touchscreen for at least one (1) minute . Ensure that the bristles stick into the lip around the edge of the screen. Use moderate excessing liquid to ensure that the brushing flushes out any soil built up inside the lip.
4	Using a soft-bristled brush soaked in cleaner, brush within the probe rest for at least one (1) minute.

Step	Instructions -
5	Soak a soft-cloth with critical water and wipe down the upper surface of the device including touchscreen and outer edged of the curved upper surface of the device to remove loose soil and cleaner residue. Wipe areas for at least one (1) minute.
6	Wipe off excess water from the surfaces of the device with a dry, clean soft-cloth.
7	Inspect the device for evidence of debris. In the case of debris, repeat the cleaning procedure focusing attention on the site of interest.
8	Allow all surfaces to air dry completely before next use (minimum 3 minutes).
9	Wipe down the cables for at least one (1) minute with a soft-cloth dampened with enzymatic cleaner to remove gross debris.
10	Wipe down the cables with a soft-cloth dampened with critical water to remove cleaner residue for at least one (1) minute.
11	Inspect the cables. Repeat cleaning steps 9 and 10 if soil remains.
12	Allow the cables to air dry completely (minimum 3 minutes).
13	Wipe the Lesion coverage Tool for one (1) minute with a dampened soft-cloth to remove gross debris.
14	Wipe the Lesion Coverage Tool with a soft-cloth dampened with critical water for 30 seconds to remove residue. Allow to air dry completely (minimum 3 minutes).
⚠ **WARNING:**	Soiled towelettes/cloth and gloves should be disposed of as biohazard material in accordance with federal, state and local regulations.

General Disinfection Probe Unit

Step	Instructions
Materials needed:	• Lint-free Soft-cloth • Cotton swab • 70% Isopropyl Alcohol (IPA) • Cavicide Spray • Critical Water (DI / RO / Distilled) approximately 68°F/20°C (room temperature)
Personal Protection:	• Disposable gloves • Safety glasses • (optional) protective coat or apron
Glossary	***Dampened cloth****- A cloth wet with cleaner (or such) but not to the point of dripping.*

Step	Instructions
	Soaked cloth- *A cloth wet with cleaner (or such) so that excess liquid is coming off of it.* ***Critical Water***- *Either deionized, reverse osmosis, or distilled water*
⚠ **WARNING:**	If soiled, DO NOT allow the soil on the probe to dry. Clean immediately after exposure. Allowing soil to dry could diminished the effectiveness of this validated cleaning procedure. Do not use Cavicide on skin.
Component Identification:	
1	Damp a soft-cloth with Cavicide spray and wipe down the exterior of the probe for one (1) minute at approximately 68°F/20°C (room temperature).
2	Sliding the probe housing up toward the tip of the probe, exposing the interior of the cradle. Wipe down the probe cradle for one (1) minute at approximately 68°F/20°C (room temperature). Inspect the inside edge of the cradle for debris. Soak a soft-cloth, brush, or cotton swab with enzymatic cleaning

Step	Instructions
	solution and wet the interior surfaces with the soaked tool and let sit wet for a minimum of three (3) minutes at approximately 68°F/20°C (room temperature).
3	Manually remove the debris (if present) with the desired tool.
4	With a soaked soft-cloth, wipe down the surfaces of the cradle/probe housing to remove any loosened debris.
5	Spray the interior of the probe housing with 70% IPA to remove disinfectant residue (use enough IPA to cover all surfaces with a liquid coating.
6	Wipe down the exterior of the probe with a soft-cloth dampened with 70% IPA
7	Allow all surfaces to air dry completely (minimum 3 minutes) before next use.
⚠ **WARNING:**	Soiled towelettes/cloth and gloves should be disposed of as biohazard material in accordance with federal, state and local regulations.

General Disinfection Control Unit / Probe Cable / Mains Cable / Lesion Coverage Tool

Step	Instructions
Materials needed:	• Lint free Soft-cloth • 70% Isopropyl Alcohol (IPA) • Cavicide Spray • Critical Water (DI / RO / Distilled) approximately 68°F/20°C (room temperature)
Personal Protection:	• Disposable gloves • Safety glasses • (optional) protective coat or apron
Glossary	***Dampened cloth****- A cloth wet with cleaner (or such) but not to the point of dripping.* ***Soaked cloth-*** *A cloth wet with cleaner (or such) so that excess liquid is coming off of it.* ***Critical Water****- Either deionized, reverse osmosis, or distilled water* ***Upper Surface****- curved housing that makes up the primary exposed surface area of the unit.*
⚠ **WARNING:**	If soiled, DO NOT allow the soil on the control unit, cables or lesion coverage tool to dry. Clean immediately after exposure. Allowing soil to dry could diminished the effectiveness of this validated cleaning procedure. Do not use Cavicide on skin.

Step	Instructions
Component Identification:	
1	Spray the exterior of the control unit with Cavicide spray ensuring complete coverage of the upper surface of the device. Use moderate excess along the edges of the touchscreen to flush out any debris that might be trapped under the lip of the screen.
2	Using a soft-cloth dampened with Cavicide wipe down the upper surface of the control unit. Pay particular attention to the edges of the touchscreen, power button and indicator light, and the probe rest.
3	Let the control unit sit wet for a minimum of three (3) minutes at approximately 68°F/20°C (room temperature).
4	Wipe away any excess disinfectant with a dry soft-cloth.
5	Wipe down the exterior of the control unit with a soft-cloth dampened with 70% IPA
6	Allow all surfaces to air dry completely (minimum 3 minutes) before next use.
7	Wipe down the cables with a soft-cloth dampened with Cavicide.
8	Let the cables sit wet for a minimum of three (3) minutes at approximately 68°F/20°C (room temperature).
9	Wipe down the cables with a soft-cloth dampened with critical water to remove disinfectant residue.
10	Inspect the cables. Repeat cleaning if soil remains.
11	Wipe the Lesion Coverage Tool with a soft-cloth dampened with Cavicide for one (1) minute.
12	Let the Lesion Coverage Tool sit wet for a minimum of three (3) minutes at approximately 68°F/20°C (room temperature).
13	Wipe the Lesion Coverage Tool with a soft-cloth dampened with 70% IPA for 30 seconds to remove any residue.

Step	Instructions
⚠ **WARNING**	Soiled towelettes/cloth and gloves should be disposed of as biohazard material in accordance with federal, state and local regulations.

Visual inspection

Visually inspect the probe cable, power cord, Control Unit, Probe Unit and Lesion Coverage Tool under adequate lighting conditions (and magnification if needed) to confirm that the cleaning process has not damaged the components. Inspect for remaining soil, surface wear, discoloration, corrosion, or cracking.

If any component damage occurs during the cleaning or disinfection process, contact Scibase immediately. Do not attempt to use the Nevisense until the device has been inspected and repaired by authorized Scibase personnel.

Contact information

For Questions regarding Nevisense Cleaning and Disinfection contact:

Scibase AB
Kammakargatan 22
SE - 111 40 Sweden

Phone: + 46 (0) 8 410 620 00
E-post: info@scibase.com

Chapter 7

Managing Patient Data

Editing Patient Data

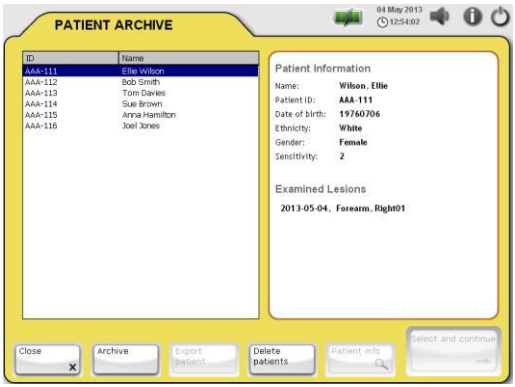
Data for a registered patient can be edited. This may be needed if you accidently entered incorrect data, or if your system administrator has added more required fields after the patient was registered.

To edit patient data:

1 From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.

2 In the patient list, tap the patient.

Tip: Tap **Name** to sort the patients by name, or tap **ID** to sort by ID.

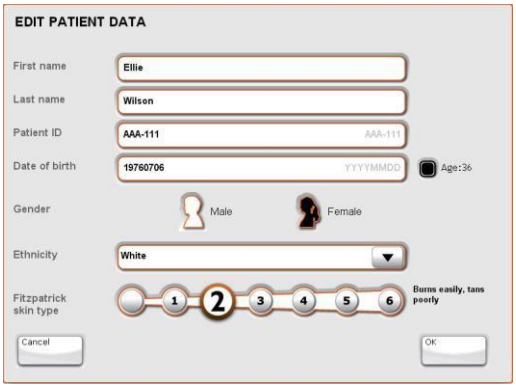


3 Select **Patient info**. The screen with detailed information about the patient is displayed.

4 Select **Edit patient**. The **Edit patient data** screen is displayed, showing information about the selected patient.

5 Make the changes in the fields.

Note: **Patient ID** changes have to be confirmed in a dialog box. It is not possible to register a patient ID that is already in use. When a patient ID is changed, the old patient ID will be deleted.



Note: If changing **Date of birth**, **Age** also has to be confirmed. The confirmation is needed since the patient's age may influence the measurement result.

6 Select **OK** to save your changes. The **Patient archive** screen is displayed.

⚠ Warning! Ensure that the correct date of birth is entered. The age may influence the measurement result.

To edit lesion description data:

1 From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.

2 In the patient list, tap the patient.

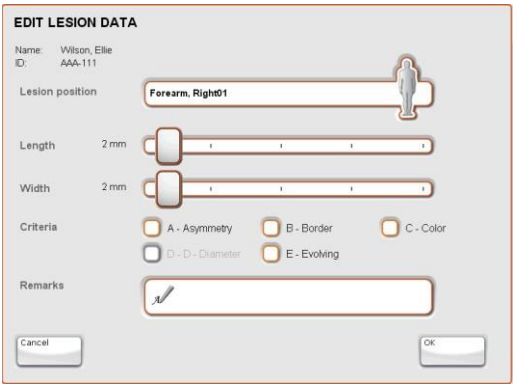
Tip: Tap **Name** to sort the patients by name, or tap **ID** to sort by ID.

3 Select **Patient info**. The screen with detailed information about the patient is displayed.

4 Tap the lesion in the **Examined Lesions** list to select the lesion.

Note: If more than five lesions are registered, a scrollbar is displayed. Drag the scrollbar button downwards to view more lesions in the list.

5 Select **Edit lesion**. The **Edit lesion data** screen is displayed, showing information about the selected lesion.



6 Make the changes in the fields.

Note: **Lesion position** changes have to be confirmed in a dialog box.

7 Select **OK** to save your changes. The **Patient archive** screen is displayed.

Note: When describing a lesion, ensure that the correct lesion position is selected on the body map. The lesions location on the body may influence how the reference quality control is calculated.

Deleting Patient Data

Patient data can be deleted from Nevisense. It is possible to delete one single patient, multiple patients, and lesions (one lesion at a time).

Caution: Before deleting patient data, make sure to archive any data that should be saved. For more information, see *Archiving and Exporting Patient Data* on page 58.

To delete all patients up until a certain date:

1. From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.
2. Select **Delete patients**. A dialog box with a date is displayed.
3. Tap the part of the date to be changed.
4. Tap **-** or **+** next to the date to increase or decrease the value.
5. Select **Delete**. The patients are deleted, and the **Patient archive** screen is displayed.

To delete a single patient:

1. From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.
2. In the patient list, tap the patient.

   Tip: Tap **Name** to sort the patients by name, or tap **ID** to sort by ID.
3. Select **Patient info**. The screen with detailed information about the patient is displayed.
4. Select **Delete patient**. A confirmation dialog box is displayed.
5. Select **Yes** to delete the patient. The **Patient archive** screen is displayed.

To delete a lesion:

1. From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.
2. In the patient list, tap the patient.

   Tip: Tap **Name** to sort the patients by name, or tap **ID** to sort by ID.
3. Select **Patient info**. The screen with detailed information about the patient is displayed.
4. Tap the lesion in the **Examined Lesions** list to select the lesion.

   Note: If more than five lesions are registered, a scrollbar is displayed. Drag the scrollbar button downwards to view more lesions in the list.
5. Select **Delete lesion**. A confirmation dialog box is displayed.
6. Select **Yes** to delete the lesion.The **Patient archive** screen is displayed.

   Note: If you delete a lesion and there are no more lesion measurements for that particular examination date, the examination date will be deleted as well.

Patient Data Storage

Patient and examination data will be stored internally on Nevisense.

Nevisense will save the following information during an examination:

- Patient data
- Lesion description data
- Examination data

Important: Data should be archived to a USB flash drive regularly, to free storage space. If more than 250 patients have been registered, a message is displayed requesting archiving.

Archiving and Exporting Patient Data

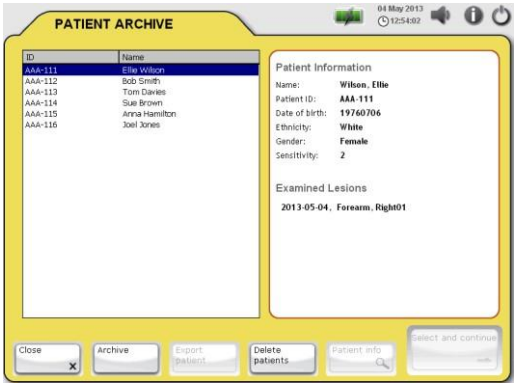
It is possible to archive data for all registered patients, and to export data for one single patient or lesion. The following table describes the export and archive functions.

	Archive	Export
Functionality	Exports all patient data to a USB flash drive.	Exports data for a selected patient to a USB flash drive.
Purpose	To regularly archive all patient data, for future reference and to free storage space.	To export data for one patient. The data can be sent to SciBase for investigation if a problem has occured.
Storage format	Compressed files in a .zip archive called *NevisenseArchive_[Date]_[Time].zip* on the USB flash drive.	Files with suffix .xml in the *Patient* folder on the USB flash drive.

To archive all patient data:

1 Insert the USB flash drive in the USB A port .

2 From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.



3 Select **Archive**. A dialog box is displayed.

4 Tap the checkbox in the dialog box if you want to delete all patient data from the archive when archiving is completed.

5 Select **Yes** to start archiving.

Note: If the USB flash drive is missing, not inserted correctly or faulty, a dialog box is displayed. Select **OK**, insert the USB flash drive properly and select **Archive** again.

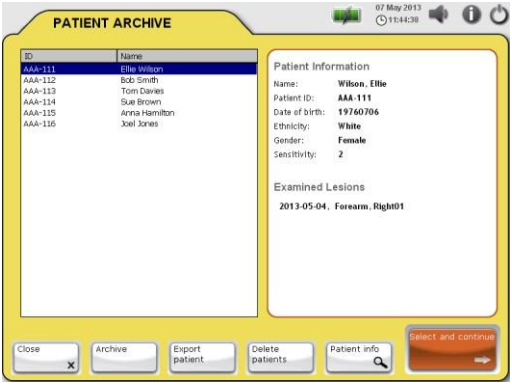
6 The patient data is archived. This may take several minutes, depending on the size of the internal data. The data is saved in the file **NevisenseArchive_[Date]_[Time].zip** on the USB flash drive.

7 Remove the USB flash drive.

To export data for a selected patient:

1 Insert the USB flash drive in the USB type A port.

2 From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.



3 In the patient list, tap the patient.

Tip: Tap **Name** to sort the patients by name, or tap **ID** to sort by ID.

4 Select **Export patient**. A dialog box is displayed.

Note: The **Export patient** button is only active when a USB flash drive is inserted.

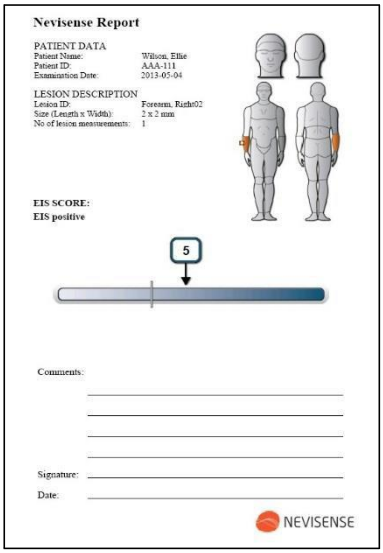
5 Select **Yes** to export all data for the selected patient to the USB flash drive.

6 The data is exported and saved in the folder **Patients** on the USB flash drive.

7 Remove the USB flash drive.

Creating Reports with Patient Data

Reports containing examination data for a selected patient can be created and saved to a USB flash drive. The reports will be in PDF format, to be viewed on a computer or printed.


Nevisense Report

PATIENT DATA
Patient Name: Wilson, Ellie
Patient ID: AAA-111
Examination Date: 2013-05-04

LESION DESCRIPTION
Lesion ID: Forearm, Right02
Size (Length x Width): 2 x 2 mm
No of lesion measurements: 1

EIS SCORE:
EIS positive

5

Comments:

Signature:

Date:

NEVISENSE

Example of a report

To create a report:

1. Insert the USB flash drive in the USB A port.
2. From the start screen, select **Browse archive**. The **Patient archive** screen is displayed, showing all registered patients.
3. In the patient list, tap the patient.

   Tip: Tap **Name** to sort the patients by name, or tap **ID** to sort by ID.
4. Select **Patient info**. The screen with detailed information about the patient is displayed.

5 Tap the lesion in the **Examined Lesions** list to select the lesion.

Note: If more than five lesions are registered, a scrollbar is displayed. Drag the scrollbar button downwards to view more lesions in the list.

6 Select **Create report**. The report is generated. When the generation is finished, a dialog box is displayed showing the file name of the report.

7 Select **OK** and remove the USB flash drive.

Chapter 8

Troubleshooting

Error Messages in Dialog Boxes

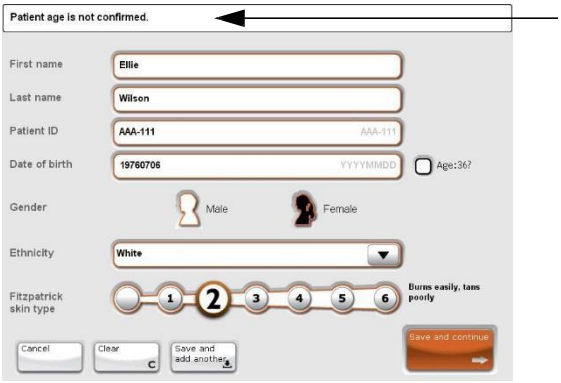
Error message	Explanation
Measurement out of bounds Prepare the skin according to Instructions for Use and redo the measurement.	Measurement was interrupted due to too high impedance. Possible cause: • The skin is too dry. • Inadequate contact between the probe and the electrode. • The electrode might be faulty. Redo the preparation of the skin and perform the measurement again. If the problem persists, try attaching a new electrode.
Measurement error Redo the measurement.	As above.
Reference measurement not approved Ensure that the preparation of the skin has been performed accurately, including both moistening and wipe off. Redo the reference measurement.	The quality of the reference measurement was insufficient. Possible cause: • The skin is too dry or too wet. • The stratum cornum is thick, for example palm or sole (acral skin). • The electrode was not held in a vertical position against the skin. • The electrode might be faulty. Redo the preparation of the skin and perform the measurement again. If the problem persists, try attaching a new electrode.
Reference measurement not approved See Instructions for Use for a detailed description of the measurement procedure and troubleshooting.	As above. This message is displayed when 3 not approved reference measurements have been performed.
Probe connection failed Make sure the probe is accurately connected and redo the measurement.	Possible cause: • The probe cable is not properly connected to the control unit. • The probe cable is not properly connected to the probe.

Error message	Explanation
Inconsistent probe pressure Redo and maintain probe pressure throughout the entire measurement.	No measurement has been performed since the pressure on the probe was not constant. Redo the preparation of the skin and perform the measurement again.
Used electrode The attached electrode has been previously used. Replace the electrode and try again.	The current electrode must be discarded and a new electrode attached. Possible cause: • The electrode was used on another patient. • The electrode has been used 20 times on a single patient. Redo the preparation of the skin and perform the measurement again.
Electrode not attached Attach an electrode and try again.	Possible cause: • The electrode is not properly attached to the probe socket. • The probe cable is not properly attached to the probe or the control unit. Redo the preparation of the skin and perform the measurement again.
Incorrect electrode A training electrode is attached. Attach an examination electrode.	An incorrect electrode type is used. Remove the current electrode and attach an examination electrode to be able to continue. Redo the preparation of the skin and perform the measurement again.
Attach electrode. Attach a training electrode.	No electrode is attached, or an incorrect electrode type is used. Attach a training electrode to be able to continue. Redo the preparation of the skin and perform the measurement again.
Archiving recommended There is a large amount of patient and measurement data that has not been archived. Insert USB flash drive and select OK to archive.	Archiving is needed. The message is displayed when more than 250 patients have been registered.

Error message	Explanation
Failed to archive data Ensure that the USB flash drive is OK.	Possible cause: • The USB flash drive was removed during archiving. Insert the USB flash drive properly and archive again. • The USB flash drive is not working properly.
Export failed Check USB flash drive and try again.	Possible cause: • The USB flash drive is full. Free storage space, insert the USB flash drive again and make a new export. • The USB flash drive was removed during the export. Insert the USB flash drive again and make a new export. • The USB flash drive is broken. If the problem persists, contact a SciBase representative.
No USB flash drive available.	The USB flash drive was not inserted properly. Insert the USB flash drive.
Internal hardware error	This message may be displayed after logging on, if the system calibration fails. Restart Nevisense. If the problem persists, contact a SciBase representative.
Faulty micro SD memory card Contact your SciBase representative.	This message may be displayed when the patient and examination data cannot be saved. The error will prevent further use. Contact a SciBase representative.
Storage space for patient data is full Delete patient data to free storage space.	This will prevent further measurements. Delete patient data to free storage space, and to be able to perform measurements.
Power failure Wait 60 seconds for Nevisense to recover and redo measurement.	Wait 60 seconds for Nevisense to recover and then redo the measurement. Moistening the skin for 30 seconds is required to ensure measurement quality. Remoisten the skin.

Status Messages

Status messages are displayed at the top of the screen, providing different types of status information.



Example of a status message, displayed when Age has not been confirmed

Problems

Problem	Possible cause	Solution
User name or password is wrong.	The logon is case sensitive. Your user name or password may contain uppercase letters.	Try to log on again, using capital letters where needed. If the problem persists, contact your system administrator or see *Administration and Service Instructions*.
The touchscreen does not work as expected.	The touchscreen is not calibrated.	Contact your system administrator or see *Administration and Service Instructions*.
Nevisense does not respond, or the touchscreen does not work at all.	There is a software or hardware problem.	Press and hold down the on/off button on the front panel for about 7 seconds, until Nevisense shuts down. Then restart Nevisense. If the problem persists, contact a SciBase representative.
The instrument is not starting or the battery is not charging despite Nevisense being connected to external power.	The fuse has blown.	The blown fuse must be replaced. Contact your system administrator or see *Administration and Service Instructions*.

Reporting Errors

If Nevisense does not work as expected, contact a SciBase representative.

Provide the ID of the control unit and the probe, and the software version.

The probe ID is displayed on the probe. For information about how to view software version and control unit ID, see *Activity Bar* on page 14.

If needed, also provide the electrode serial number. For more information, see *Administration and Service Instructions*.

Rejection of Measurements

In some cases, a measurement will give results that Nevisense interprets as erroneous, for example if the skin is too dry, or if there is inadequate contact between the probe and the skin. In these cases, an error message is displayed and you must redo the measurement.

In the table below, examples of parameters in the measurements are shown which correlate with factors that form the basis for rejection of reference measurements.

Cause of error	Explanation
High magnitude of the impedance	Too dry skin, tilted probe, loose connectors, thick stratum corneum for example palm or sole (acral skin)
Low magnitude of the impedance	Too wet skin, shortcut between bars/connectors, measurement too close to a (malignant) lesion
Separated permutations	Too wet skin, tilted probe, shortcut between bars/connectors, motion (during the measurement)
Deformed shape of the phase of the impedance	Faulty pins in the electrode, oily skin (due to lotions, moisturizer etc)
Abnormal position of maximum phase	Too dry skin, thick stratum corneum for example palm or sole (acral skin)
Spikes in the magnitude/phase curves	Electrical interference

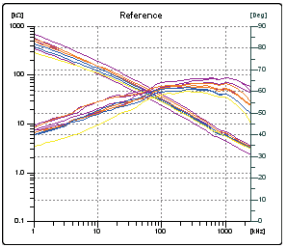
Rejected Reference Measurements

Graphs for rejected reference measurements often show separated and distorted magnitude and phase shift curves.

Nevisense automatically rejects reference measurements that do not fulfil internal quality control criteria.

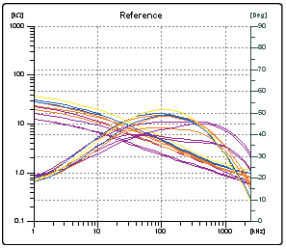
Examples of rejected reference measurements

Possible cause:



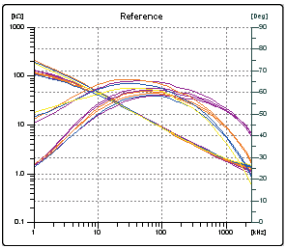
- The skin is too dry, causing inadequate contact between the probe and the skin. Make sure to start the measurement within 10 seconds from the wipe off, and that the electrode is placed on the area that was moistened.
- The reference skin area is located on skin with high impedance, for example on sole.
- The electrode is faulty.

Possible cause:



- The skin is too wet, causing inadequate contact between the probe and the skin.
- The skin is not wiped off properly, causing inadequate contact between the probe and the skin.
- The reference skin area is located too far from, or too close to, the lesion skin area.
- The skin is not intact or not healthy.
- Moist from a previous measurement remains on the electrode.
- The electrode is faulty.

Possible cause:

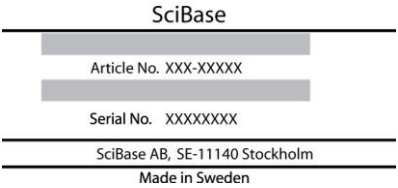


- The contact between probe socket pins and electrode is inadequate. Make sure the pins on the probe socket are clean and not depressed.
- The electrode is faulty.
- The probe is not held in a vertical position against the skin, causing inadequate contact between the electrode surface and the skin. The entire electrode surface must be be in contact with the skin during the measurement.

Chapter 9

Symbols and Labels

Symbols and Labels

Symbol/Label	Explanation
	USB port.
	Ethernet port.
	Safety classification type BF (Body Floating) of applied part, providing a particular degree of protection of electric shock. (In Nevisense the applied part is the probe.)
	Article No. is a number identifying Nevisense. Serial No. is a number identifying this specific control unit or probe. SciBase AB is the name of the manufacturer.
	Do not discard Nevisense with the trash. For more information, see Chapter 10 *Waste Disposal*.
	Follow instructions for use.
	Single use. An examination electrode may be used up to 20 times for a single patient on several lesions in a single procedure. A training electrode may be used up to 50 times, on a single person in a single training session.
	CE approved according to Medical Device Directive 93/42/EEC.

Chapter 10

Waste Disposal

Waste Disposal

When the product lifetime of Nevisense ends you may contact a SciBase representative to return it, for environmentally sound recycling.

For local recycling, refer to the table below.

Component	Materials
Packing material	Packing material follows the standard SS-EN 13430:2004 regarding recyclable material.
Electrode	Electrodes consist of: • Plastic material • Metal • Electronic components, such as a printed circuit board (PCB).
Electrode container	Electrode containers consist of: • Plastic material
Control unit	The control unit contains: • Plastic material • Metal • Glass • Electronic components, such as printed circuit board (PCB) and display.
Probe	The probe contains: • Plastic material • Metal • Electronic components

CE 0123

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