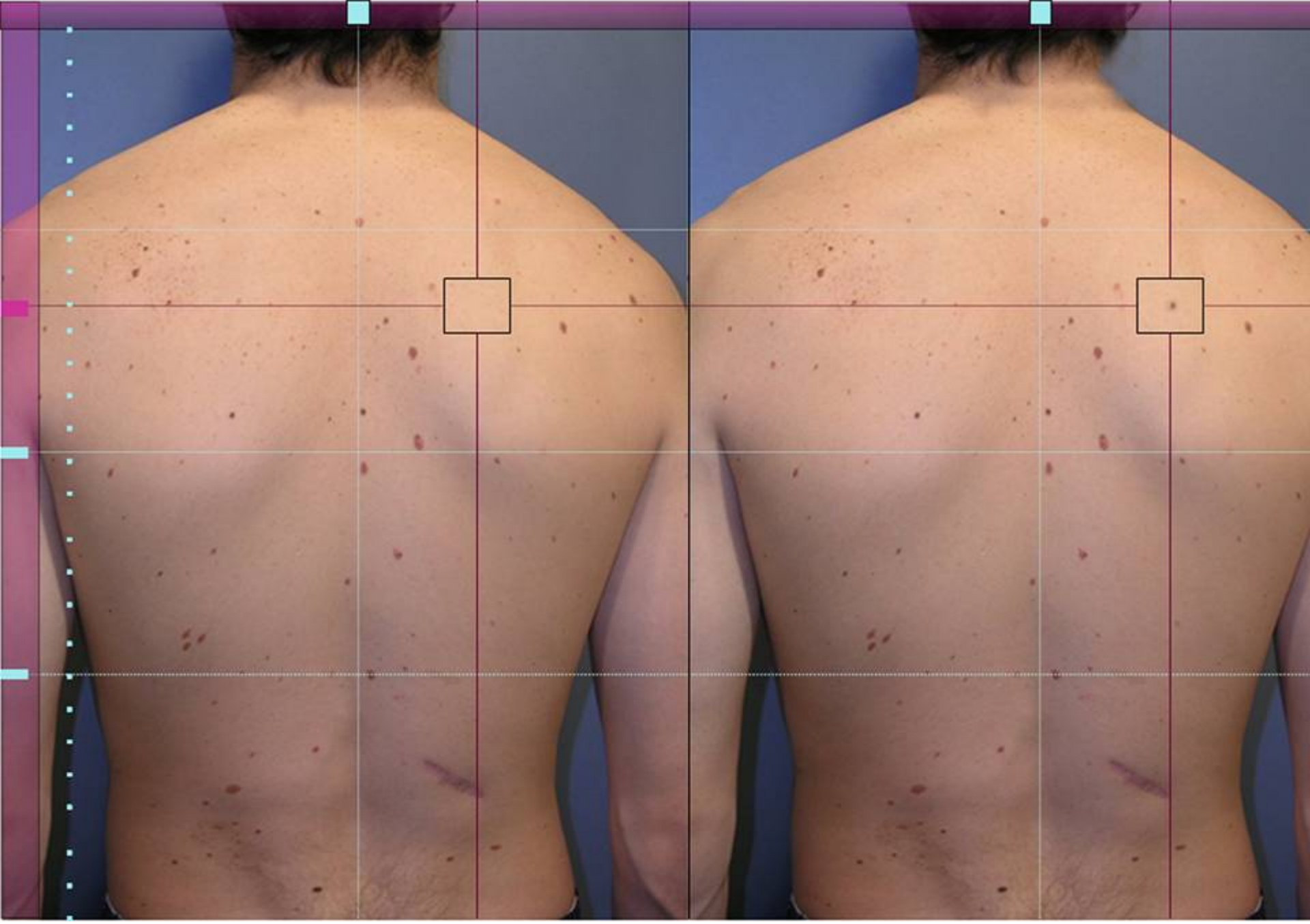
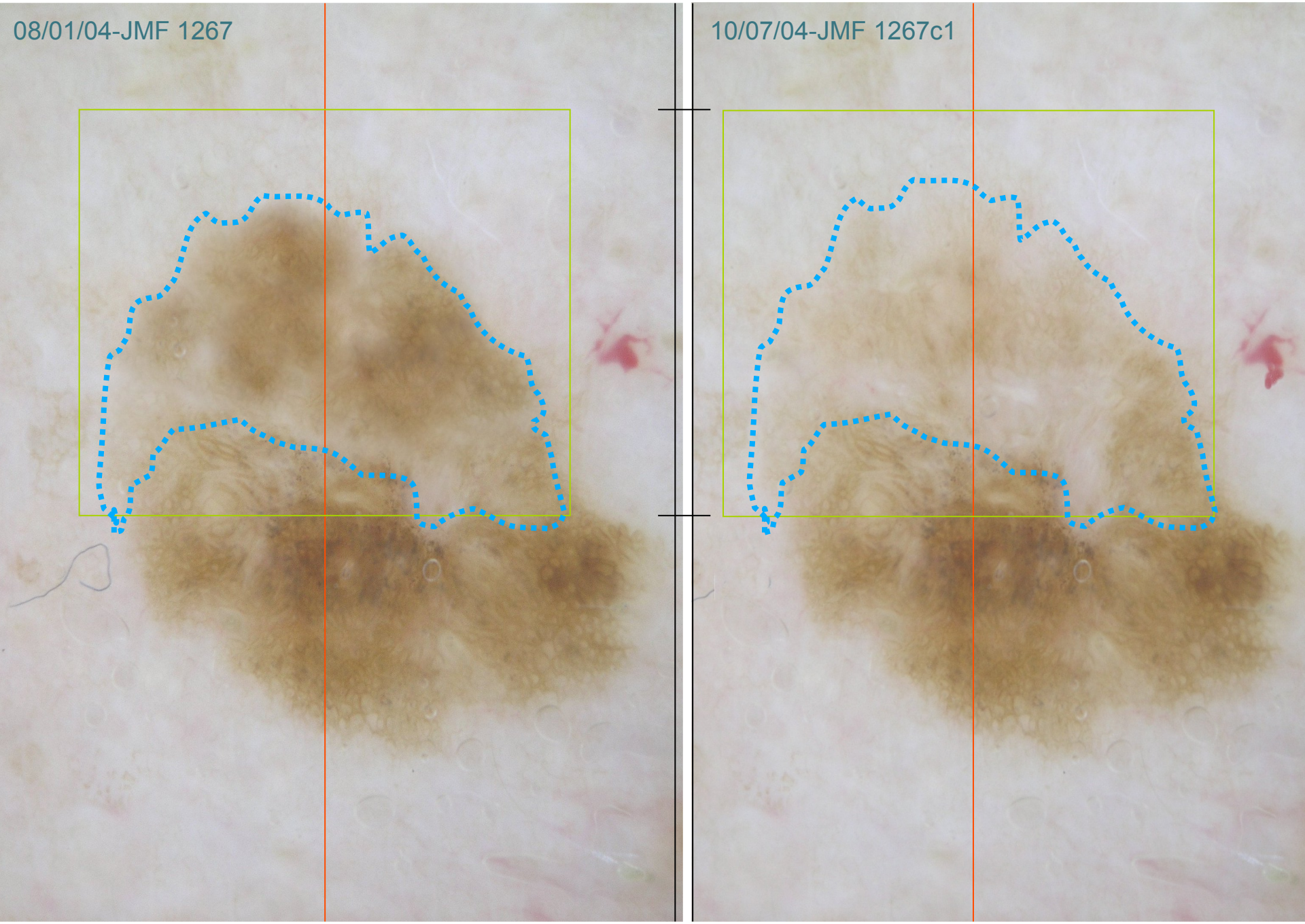
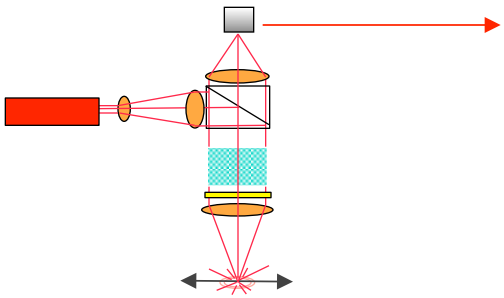

Paciente selec.
ninguno
Última visita
Video en vivo
Datos pacientes
Primera visita
Importar Digital
Informes
MoleMax II
Especial
Historial
Backup
Expertizer
CosMax
SAMSUNG

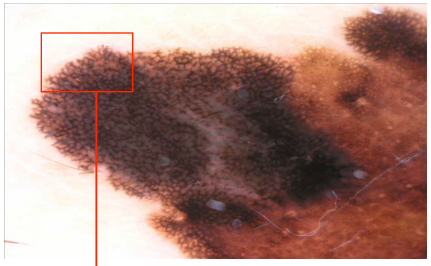

MoleMax
Paciente selec.
ninguno
Datos pacientes
Primera visita
Imágenes
Seguimiento
Mapeo corporal
Historial
Dermatitis
Exploración
Importar
Especial
Backup
Cerrar
SAMSUNG

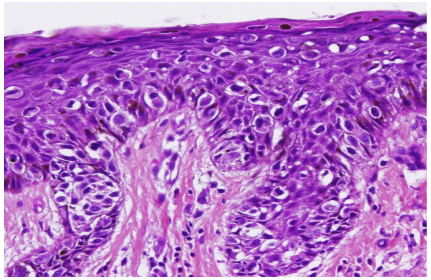


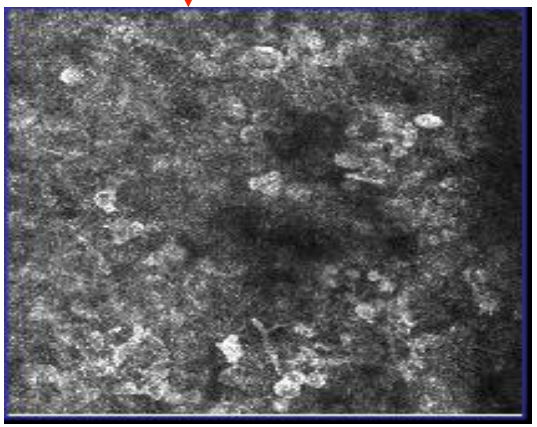

08/01/04-JMF 1267
10/07/04-JMF 1267c1

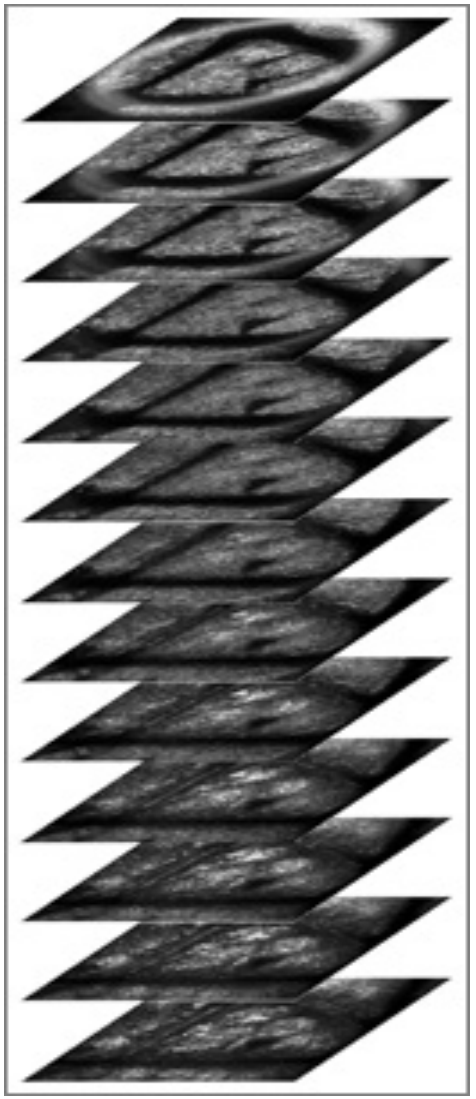
Reflectance confocal microscopy











Hand held RCM

Fast examination (1-5 minutes)
Facial areas


LUCID
REDEFINE

ONLINE FIRST

The Performance of MelaFind

A Prospective Multicenter Study

Gary Monheit, MD; Armand B. Cognetta, MD; Laura Ferris, MD, PhD; Harold Rabinovitz, MD; Kenneth Gross, MD; Mary Martini, MD; James M. Grichnik, MD, PhD; Martin Mihm, MD; Victor G. Prieto, MD, PhD; Paul Googe, MD; Roy King, MD; Alicia Toledano, ScD; Nikolai Kabelev, BCSc; Maciej Wojton, MS; Dina Gutkowicz-Krusin, PhD

Setting: Three academic and 4 community practices in the US

Patients: 1632 lesions (including 127 melanomas—45% in situ—with median Breslow of invasive lesions, 0.36 mm)

Metric	Positive Lesion Set[b]	
	MM, HGDN, AMP, or AMH	MM
Sensitivity	98.3 (172 of 175)	98.4 (125 of 127)
Specificity	10.8 (157 of 1457)	10.5 (158 of 1505)
Positive predictive value	11.7	8.5
Negative predictive value	98.1	98.8
Biopsy ratio	7.6:1	10.8:1

Trial Registration: clinicaltrials.gov Identifier: NCT00434057

Arch Dermatol. 2011;147(2):188-194.

Medical Devices

Products and Medical Procedures

Device Approvals and Clearances

Recently-Approved Devices

2012 Device Approvals
2011 Device Approvals
2010 Device Approvals
2009 Device Approvals
2008 Device Approvals
2007 Device Approvals
2006 Device Approvals
2005 Device Approvals
2004 Device Approvals
2003 Device Approvals
2002 Device Approvals
2001 Device Approvals
2000 Device Approvals

MelaFind® - P090012

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: MelaFind®
PMA Applicant: MELA Sciences, Inc.
Address: 50 South Buckhout Street, Suite 1, Irvington, NY 10533
Approval Date: November 1, 2011
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf9/p090012a.pdf

What is it? An optical imaging and analysis device used in the detection of melanoma among atypical skin lesions.

How does it work? The device uses light to image the skin through a layer of isopropyl alcohol to generate a positive or negative result based on predefined image analysis algorithms.

When is it used? The device is used when a dermatologist chooses to obtain additional information on atypical skin lesions for a decision to biopsy.

What will it accomplish? MelaFind will provide the dermatologist with additional information about atypical skin lesions. This additional information may help a dermatologist find additional melanomas that may not have been found without the use of the device.

When should it not be used? There are no contraindications.

Additional information: Summary of Safety and Effectiveness and labeling will be available online.

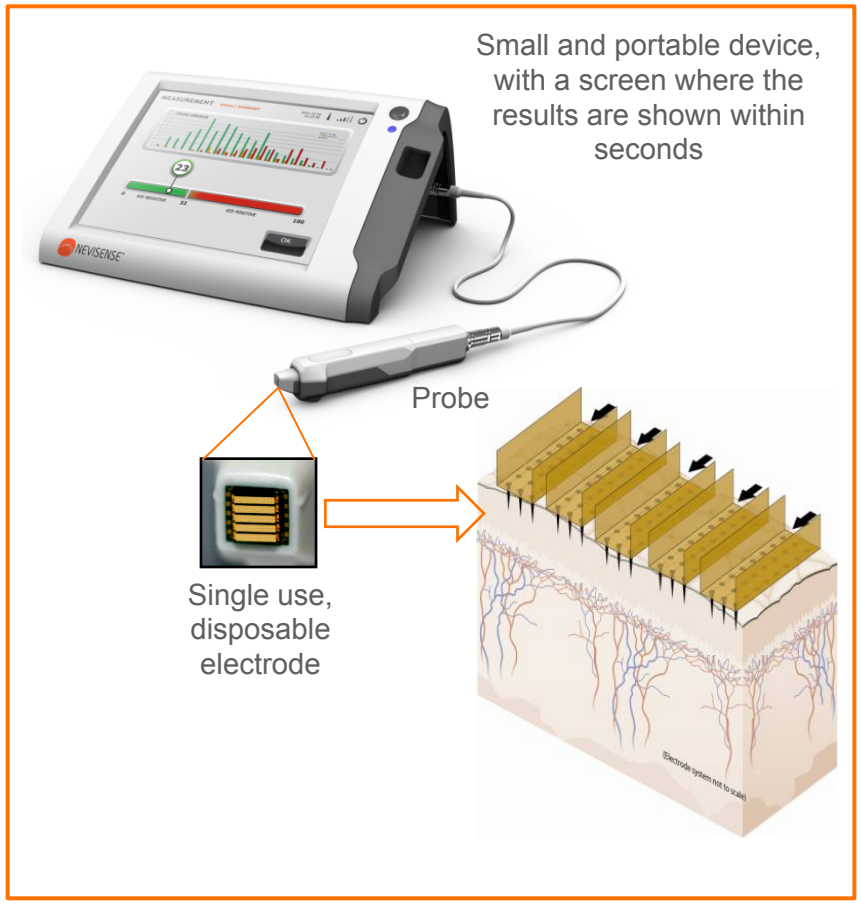
Page Last Updated: 12/04/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Electrical impedance Spectroscopy (EIS)

Technology and method

Overview

- EIS is a measure of the overall resistance within the tissue at alternating currents of various frequencies
- EIS is measured by applying an unnoticeable and harmless alternating electrical current onto the skin and measure the response
- The frequencies used in the applied signal relate to clinically relevant properties, such as composition of intra and extra-cellular environments, cell shape and size and cell membrane composition
- The CE marked technology platform consists of a handheld probe with a disposable electrode connected to a device analysing the signals
  - Aside from the disposable electrode other parts of the device are made of standard components
- Algorithm development based on >4,000 lesions with 500 Malignant Melanoma measurements in International Multicenter Melanoma Training Studies (IMATS)
- The system gives on-screen results within seconds



Luc XIV