VivaScope® Systems
Confocal Laser Scanning Microscopy – Innovation for Analysis, Diagnosis and Therapeutic Monitoring
Tradition and Innovation

MAVIG GmbH, a family owned and operated company founded in 1921 and headquartered in Munich, is a quality and innovation leader in the field of X-ray protection. Lucid, Inc., operating as Caliber Imaging & Diagnostics Inc., based in Rochester, New York (USA), is manufacturer of the VivaScope products. In 2006 MAVIG assumed the confocal laser technology distribution rights for Europe, Russia, the Middle East, and North Africa. Both companies work hand in hand concerning R&D in the field of laser scanning microscopy.

Content

Competitive Edge in Research and Competency .......... page 2/3
A Window into the Skin ........................................... page 4/5
In Vivo and Ex Vivo Findings ........................................ page 6/7
The entire imaging chain ........................................ page 8/9
Learning from the Best ............................................ page 10/11
Publications and References .................................... page 12/13
Overview of all VivaScope® Products ....................... page 14/15
Competitive Edge in Research and Competency.

Optical Skin Biopsy in Real-Time
Confocal laser scanning microscopy opens a „window into the skin“. This innovative imaging process provides for the first time a non-invasive view into epidermis and dermis down to the superficial stratum reticulare – in a pain free, uncomplicated, and quick manner.

Leading in Service and Consultation
MAVIG’s product portfolio not only includes devices and software for confocal laser scanning microscopy – in vivo and ex vivo. The company also provides comprehensive workshops and training opportunities as well as training materials for independent study. Users are able to expand and improve their application skills during a supervised online training session.

Microscopically Accurate and Non-Invasive
Traditional methods are only the first step of mostly invasive and time-consuming diagnostic procedures. Confocal laser scanning microscopes offered by MAVIG, however, make it possible to depict different skin structures step by step horizontally with microscopic accuracy and in cellular resolution.

MAVIG offers different confocal laser scanning microscopes for in vivo use – on living tissue – as well as the associated imaging software.

H&E section  Skin model  Optical cross section of single skin layers from the surface down into the deepness of the skin.
What is Confocal Laser Scanning Microscopy?

Microscopic examinations and analyses of glass slides are considered the gold standard for assessing pathogenic tissue changes. Traditional dermatoscopes, however, do not penetrate the skin very deeply. An exact diagnosis usually requires an invasive and time-consuming procedure. Confocal laser scanning microscopy, in contrast, makes it possible to differentiate between pathogenic and healthy tissue quickly and non-invasively. This method is used with in vivo and ex vivo medical applications as well as therapeutic monitoring and is facilitated by technology that optimizes the diagnosis of various skin diseases. New applications are described in the medical literature all the time.
A Window into the Skin.

Layer by Layer: Journey through the Skin

In vivo examinations using confocal laser scanning microscopy allow for an optical biopsy using a non-invasive procedure. Cellular microstructures of skin can thereby be depicted cell by cell in clearly defined horizontal „optical cross-sections“ with a thickness of less than 5.0 µm.

To generate confocal images, a laser beam in the near infrared range (standard device) is directed through an interconnected lens system and a beamsplitter onto the area of skin to be examined. The light is reflected by the different components of the tissue and captured by the microscope to make an image. The image focus plane – the illuminated spot in the tissue – and the aperture of the detector are on optically conjugated focal planes.
In Vivo and Ex Vivo Findings: Surprisingly Quick and Easy.

What are the indications of confocal laser scanning microscopy?

Confocal laser scanning microscopy can be used in countless applications and research areas. Laser scanning microscopy is especially well suited for screening examinations and diagnoses in case of skin cancer or early forms of skin cancer (carcinoma in situ). This technology is also applied in cases of burns, wound healing, inflammatory diseases and cosmetics industry research.

Prompt Findings in many screening and Diagnostic Areas

In vivo skin cancer screenings benefit greatly from distinguishing a harmless nevus from the malignant variety.

Confocal images taken with the VivaScope 1500 and the VivaScope 3000 meet the requirements needed to diagnose basal cell carcinomas promptly, non-invasively, and accurately.

Dermatoscopic image of a melanoma.

Confocal mosaic of a melanoma without ulceration at the dermo-epidermal junction (VivaBlock®).

Dermatoscopic image (taken with the VivaCam®) of a superficial basal cell carcinoma.

The confocal image of the same superficial basal cell carcinoma at the level of the stratum granulosum shows elongated, polarizing cells.

© Prof. G. Pellacani, Universität Modena und Reggio Emilia, Italy

© Dr. M. Ulrich, Charité Berlin, Germany
In vivo:
A look into living tissue

In vivo examination with confocal laser scanning microscopy is a non-invasive and time-saving procedure. Patients do not have to undergo a painful and potentially unnecessary tissue extraction when examined with the VivaScope. And almost more importantly, results are available within minutes without external contrasting agents. This means diagnostic processes are no longer dependent on tissue samples. The examined skin regions remain unchanged and are available for subsequent standard histological methods. In addition to the standard reflectance imaging devices, a special multilaser model can be added for especially complex research, which combines reflectance with fluorescence confocal laser scanning microscopy.

Examples for in vivo applications

- Melanocytic lesions: pigmented skin cancer and its early forms
- Non-melanocytic lesions: non-pigmented skin cancer and its early forms
- Inflammatory diseases
- Wound healing/burns

The use of the VivaScope 1500 and the VivaScope 3000 makes it possible to distinguish qualitatively and quantitatively between superficial burns (second degree) and severe wounds on the verge of third degree burns and therefore requiring immediate medical treatment.

Ex vivo:
Analyzing Biopsied Tissue in only 9 minutes

Although confocal laser scanning microscopy makes it possible to avoid a biopsy in many cases, ex vivo tissue samples are still very important. Confocal laser scanning microscopy allows for the analysis of sampled tissue with minimal preparation. The prompt assessment of the excised tissue in precisely defined optical cross-sections is therefore possible immediately after excision of the tissue sample. Such an analysis performed during surgery to control the margins between pathogenic and healthy tissue may help avoid a second operation, for example, in cases of breast cancer or within the scope of Mohs surgery.

Examples for ex vivo applications

- Mohs surgery
- Pathological tissue (for example colon cancer)

Within the scope of Mohs surgery, the need for cryosections could be avoided when using confocal laser scanning microscopy since freshly extracted tissue samples are quickly and accurately analyzed with minimal preparation. Excised tissue samples do not need to be frozen or cross-sectioned when using the VivaScope 2500 Multilaser.

The confocal image at the level of the demo-epidermal junction depicts a superficial second degree burn with the partially preserved basal cell layer (light, reflecting rings). These wounds usually exhibit a good healing tendency without scarring.

Basal cell carcinoma:
Confocal ex vivo image (here a VivaBlock with one single frame corresponding with 750 µm x 750 µm).

H&E section of same tumor

© Dr. M. A. Altintas, Medizinische Hochschule Hannover, Germany
© Dr. Caterina Longo, University of Modena and Reggio Emilia, Italy
The examination process and documentation are managed with the use of one software surface only. Due to the integration of total body mapping, clinical imaging with dermoscopy and confocal microscopy, a quick and smooth dermatological examination process is possible.

Standardized Total Body Mapping Documentation
with the microDERM® SkinMap Plus of Visiomed AG.

The Entire Imaging Chain. Efficient and Easy.

- Networking of the practice-/clinic server and the imaging devices, archiving
- Direct diagnosis on reading workstations by the physician (internal)
Imaging of clinical and dermoscopic features is possible with one device only, the VivaCam.

Quick and easy: the confocal examination.

All confocal laser scanning microscopes are developed and produced specifically for daily practical use. Within the scope of their intended usage, they are robust devices suitable for a variety of applications. Confocal images can be generated and analyzed in just a few steps.

Examination process:
The tissue window is placed onto the skin and is used as an adapter for VivaCam and VivaScope in order to provide a correlation between the dermoscopic and confocal image.

The dermoscopic image is taken with the VivaCam and may be used to navigate the laser in the lesion.

The laser tube of the VivaScope 1500 is affixed to the tissue ring.

Different sets of confocal images can be acquired as desired.

Direct diagnosis by the experienced dermatologist, or external assessment by the specially trained dermatopathologist.

- Teledermatology Service with external VivaNet Server for encrypted storage, retrieval and transfer of patient data
- Prompt assessment by specialists (external)
Learning from the Best.

Service and Support from the Start. With the help of the free training options offered by MAVIG, handling and use of the VivaScope devices is quickly and easily learned. An ingenious and comprehensive confocal laser scanning microscopy training program creates the optimal prerequisites for analyzing and diagnosing confocal images quickly and – most importantly – reliably.
1. Introductory Training On-Site

Training lasting one to two days offered, after the installation of the device, and provides dermatologists or pathologists with basic knowledge and skills necessary to start using VivaScope devices without further delay. Presentations, manuals, imaging guidelines, and studies provide additional support and assistance.

2. Independent study with textbook

The image textbook prepared by four leading experts in the field of confocal laser scanning microscopy is especially well suited for the independent study of image interpretation. This hands-on guide is generously illustrated with numerous confocal images. It provides schematic drawings of the tumor criteria and a chapter specifically devoted to bridging the gap between dermoscopy, RCM, and histopathology.

3. Expert Training

Advanced VivaScope users have the opportunity to expand and solidify their knowledge of the many different confocal laser scanning microscopy options in a clinical setting. At the University of Modena and Reggio Emilia, VivaScope users can attend an advanced training on the diagnosis of pigmented lesions and non-pigmented lesions, inflammatory skin diseases, and cosmetology. The training is held by Prof. Giovanni Pellacani in collaboration with Dr. Marco Ardigo (Rome), Dr. Caterina Longo (Reggio Emilia) and Dr. Martina Ulrich (Berlin). At the University of Barcelona (Hospital Clinic), users of Ex-Vivo as well as those interested can deepen their knowledge. The training will be organized by Dr. Susana Puig, Dr. Josep Malvehy and Dr. Toni Benassar.

4. Online Training

Within the scope of intensive continuous training, VivaScope users are able to review numerous sample cases posted at www.confocaltraining.com. This expert training was devised by Prof. Giovanni Pellacani and consists of levels that build on one another. The foundation courses of the University of Modena are the basis for this online training.

5. Online Expert Tutorial

For difficult cases, VivaScope users can get a “second opinion” from confocal experts with years of experience. This training module will allow readers of confocal images to expand their own expertise and increase their ability to diagnose even problematic lesions with a high degree of reliability and accuracy. The Online Expert Tutorial is not intended as clinical second opinion for any case, but rather as an educational tool.

Independent International Circle of Experts

The International Confocal Group (ICG) has been meeting regularly since the beginning of 2008. More than 200 physicians of different disciplines ensure the interdisciplinary information exchange is lively and valuable. Establishing confocal laser scanning microscopy as the standard in dermatological diagnosis and the expansion of the range of medical indications and uses are the goal of the ICG. National and international interested VivaScope users can join the ICG. The confocal experts also meet regularly at national meetings.
Publications

Approx. 550 publications in medical journals as well as feature articles testify to the diverse application possibilities of the VivaScope devices. The number of recognized indications is continuously increasing with the associated studies usually determining a very high sensitivity and specificity. Here are some relevant studies:

On www.vivascope-pub.com you can find the Online Collection Booklet
Confocal Microscopy – Fundamentals, Reviews and Perspectives

- **Melanocytic Lesions**

- **Non-Melanocytic Lesions**

- **Inflammatory Diseases**
Proven method – Official S1 guideline for confocal laser scanning microscopy

The German AWMF S1 guideline covers the complete spectrum of applications and the methodology.


Guideline „Basal Cell Carcinoma“ of the European Dermatology Forum:

All addresses of Dermatological Health Centers, Physicians’ Offices and Clinics in Europe using VivaScope Devices you can find here:

Competency Centers using VivaScope Devices in Clinics and Physicians’ Offices

Numerous university clinics and established dermatologists worldwide are already working with VivaScope devices. These clinics, physicians’ offices, and centers offer consulting services and screenings with VivaScope devices and at the same time continue to discover and develop new application possibilities and innovative indications.

The VivaScope 1500 especially is a favorite tool of established dermatologists. Physician and medical personnel are trained effectively so that exams and screenings are carried out quickly and efficiently and patients can benefit from rapid diagnosis and further treatment. University clinics increasingly rely on VivaScope devices for everyday tasks. They are also heavily used in research and development.
Overview of all VivaScope® Products.

Devices for in vivo use

**VivaScope® 1500**: The non-invasive VivaScope 1500 provides a view into the epidermis down to the upper reticular dermis. Black and white images of the individual skin layers are generated.

**VivaScope® 1500 Multilaser**: The VivaScope 1500 Multilaser combines reflectance with fluorescence confocal laser scanning microscopy. The device makes use of wavelengths of 785 nm, 658 nm, or 488 nm.

**VivaScope® 3000**: The VivaScope 3000 is the manual model of the VivaScope series of products. Due to its compact design and low weight, it is especially well suited for a wide variety of applications and simplifies examining difficult to access skin regions.

**VivaCam®**: The digital dermatoscopic camera VivaCam is an accessory of the in vivo devices and complements the confocal imaging technology by supplying dermatoscopic images of the skin surface.

**microDERM® SkinMap Plus**: The system of Visiomed AG allows you to create a standardized total body mapping documentation in a minimal period of time and with the highest degree of detail. The software quickly and intuitively leads the user through the scanning process and automatically captures images of predefined skin areas from head to toe. During the imaging process, the user is supported in the detection of newly developed nevi.

Devices for ex vivo use

**VivaScope® 2500 Multilaser**: The VivaScope 2500 Multilaser makes it possible to subject large specimens of freshly sampled tissue to pathological analyses at cellular resolution and in approx. 9 minutes. Imaging requires little to no prior preparation and is realized in exactly defined optical cross-sections.

Software and IT solutions

**VivaScan®**: VivaScan is the imaging application software (Windows) for the VivaScope devices. This user-friendly software features an overview menu from which all confocal image and patient data can be depicted, processed, edited, and archived.

The extended VivaScan-Version provides the management of patient data of the entire imaging chain (standardized total body mapping documentation, clinical image, dermoscopy and confocal microscopy) with the help of only one software surface. Thus an efficient and easy examination process is possible.

**VivaLAN**: VivaLAN is a networked VivaScope solution. This system is intended to facilitate and coordinate the scheduling, imaging and reviewing of images within a practice, clinic or research facility where multiple VivaScopes and/or viewing workstations can be in use. VivaLAN is configured to archive and store clinical, dermatoscopic and confocal images centrally on a powerful server in order to provide an efficient workflow.

**VivaNet®**: VivaNet is a DICOM-compliant service for the storage, retrieval and transfer of VivaScope images. When using VivaNet, the dermatologist first compiles the patient’s confocal images and then sends these to the VivaNet server via an encrypted private network through the Internet. The responsible dermatopathologist is able to retrieve the images immediately and return his or her assessment.

**ConfoScan**: ConfoScan is an image quantification utility. The quantification parameters of the confocal images can be digitized and the image values can then be depicted numerically.

Technical specifications are subject to change without notice. Status: 08/2015
Please visit www.vivascope.eu for additional information.