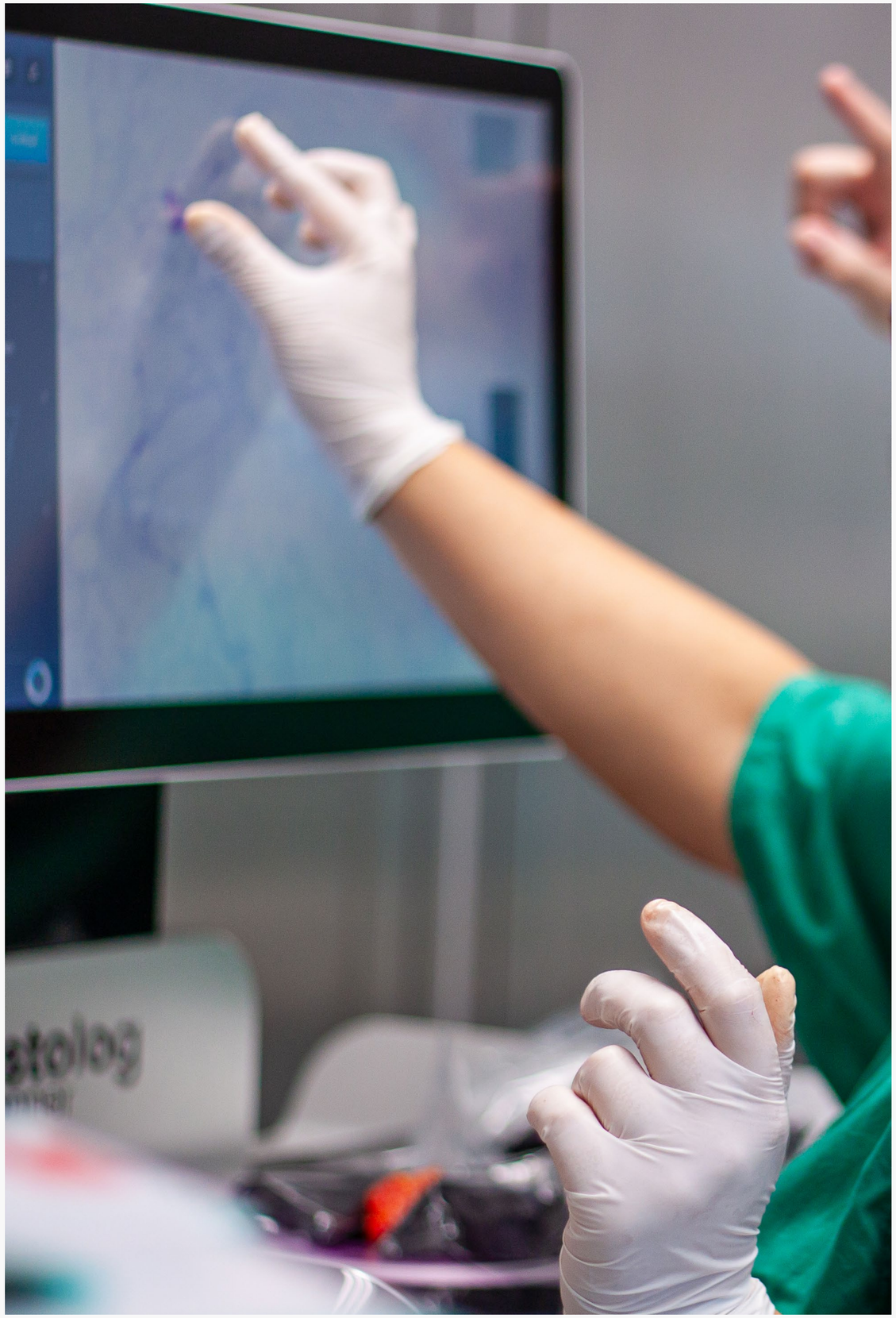
SamanTree Medical SA

Histolog® Scanner

Real-time assessment of fresh tissue

Histolog Scanner brochure - August 2024



Spot cancer cells when every minute counts

From biopsy taking to surgical diagnosis, tissue assessment is a key component to efficient and straightforward cancer treatment. The challenge is to obtain high-resolution results in a timely manner. The Histolog Scanner changes the game by bringing cancer cells to the fingertips of clinicians. It is a confocal microscopy device intended for imaging the surface of excised human tissue specimens to visualize morphological micro-structures. Easy-to-read images are available immediately, providing decision-making support at the point-of-care.

The Histolog Scanner

Real-time global mapping of fresh specimen

The Histolog Scanner is an in vitro diagnostic (IVD) device with CE marking, built on a breakthrough medical imaging modality. This innovative approach is based on a novel ultrafast confocal microscopy technology invented in Switzerland.

Its innovative design makes it highly practical for quick assessment at the point of care, bringing the clinician one touch-on-the-screen away from visualizing cancerous cells immediately on a fresh specimen.

- A cost-efficient alternative to frozen section analysis (FSA) that provides real-time morphology information
- Easy-to-use platform: plug and play device with quick learning, usable by clinicians or OR staff
- Digital images, enabling digital and remote workflows
- Result in minutes : 15s for specimen preparation (10s fluorescent dye + 5s rinsing in saline solution) and ~50s for full-resolution image (large field of view 4.8cm x 3.6cm)
- A dedicated team and network to support you in the implementation

QUICK & CLEAN

4-steps procedure for morphology assessment within 5 minutes.

Watch how

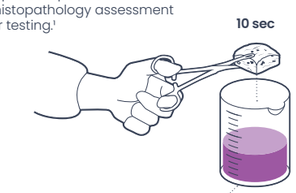
1 Excision

Excise the tumor from the patient.

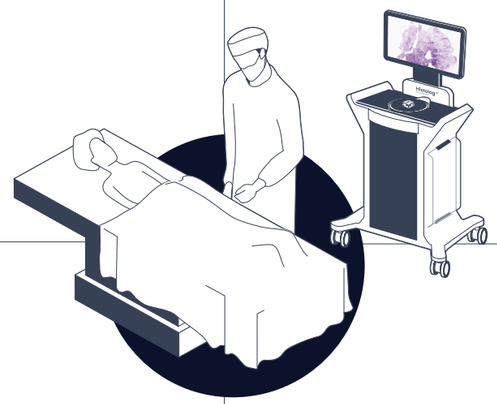
2 Preparation

Immerse the specimen in Histolog Dip and rinse it in saline solution.

The Histolog Dip is compatible with downstream histopathology assessment and molecular testing.[1]



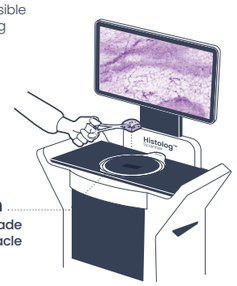
Histolog Dip
Histological stain



3 Imaging

Map the whole specimen surface in minutes.

Specimen remains visible and accessible during the entire imaging procedure.

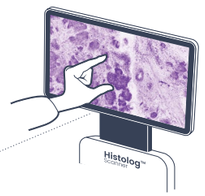


Histolog Dish
Single-use optical-grade receptacle

4 Evaluation

Assess the images on the device or remotely

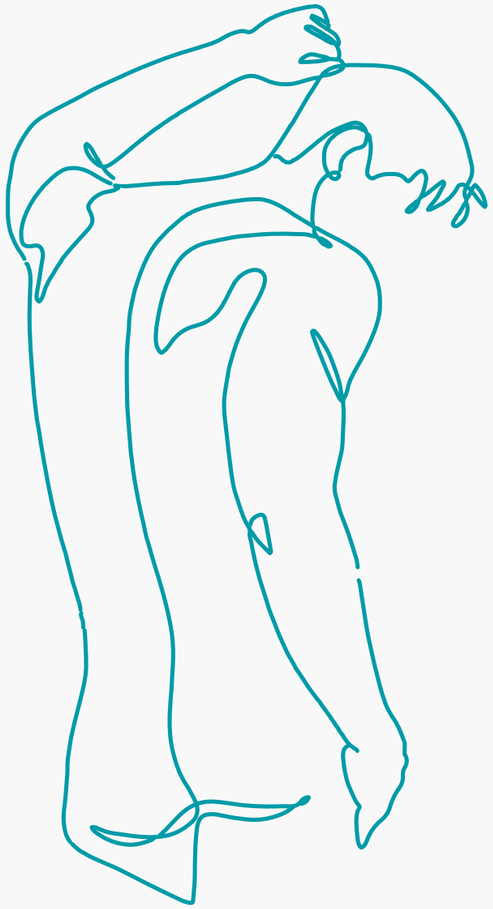
Specimen is preserved and the routine histopathological assessment can be performed.



Touchscreen interface
Instant access to special features such as reporting & annotation tools

[1] AH Nguyen et al. 2023
DOI: 10.55920/IJCIMR.2023.04.001150

Radical prostatectomy



Whole specimen scanning during robot-assisted radical prostatectomy (RARP)

Preserving the nerves adjacent to the prostate increases the risk of leaving cancer behind, and current intraoperative margin assessments (IOMA) require substantial resources and take up to 1 hour, preventing its adoption in the Standard-of-Care procedures.

To standardize a conserving approach with a low positive margins rate, there is a need for IOMA to meet the following criteria:

- High accuracy: cellular morphology
- Ultra-fast: whole prostate scanning in <10 min
- Remote collaboration: possibility to send digital images to pathology laboratory

By fulfilling these needs, the Histolog Scanner aims to reduce positive margins, saving precious time and resources to enable the standardization of the nerve-sparing approach.

CLINICAL DATA HIGHLIGHTS

High performance with sensitivity of >90% and specificity of >90%[2]

Assessment in <10 min (versus >50 minutes with NeuroSAFE)[1]

Easy to use procedure compatible with whole specimen scanning[1]

The Histolog Scanner fits your clinical workflow

IN OR IMAGING

Histolog images can be easily generated in the OR under the supervision of the surgical team and then either assessed directly or assessed remotely by pathologists via remote connectivity.

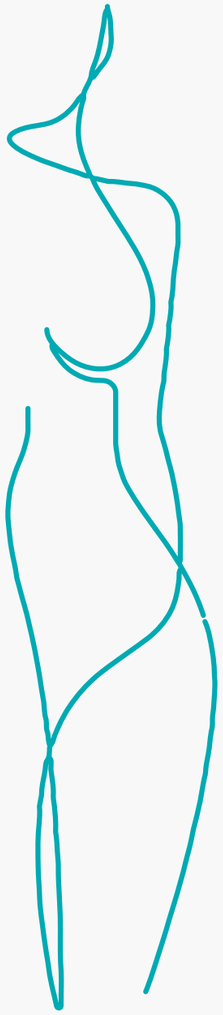
IN LAB IMAGING

When the workflow is optimized for efficiently transporting fresh specimens to a nearby pathology department, the Histolog Scanner can be stationed there to offer real-time information within the lab.

[1]Baas, D. J. H., Vreuls, W., Sedelaar, J. P. M., Vrijhof, H. J. E. J., Hoekstra, R. J., Zomer, S. F., van Leenders, G. J. L. H., van Basten, J. P. A., & Somford, D. M. (2022). Confocal laser microscopy for assessment of surgical margins during radical prostatectomy. BJU International, 1–7. https://doi.org/10.1111/bju.15938

[2]Almeida-Magana R, Au M, Al-Hammouri T, Dinneen K, Haider A, Freeman A, Shaw G. Improving fluorescence confocal microscopy for margin assessment during robot-assisted radical prostatectomy: The LaserSAFE technique. BJU Int. 2024 Jun;133(6):677-679. doi: 10.1111/bju.16239. Epub 2023 Dec 14. PMID: 38009389.

Breast conserving surgery



Preserving healthy tissue with accuracy to avoid re-operations

The Histolog Scanner has been designed to fit seamlessly into the surgical workflow and help surgeons to ensure complete tumor removal at primary surgery.

In order to completely remove the tumor while keeping as much healthy tissue as possible, a few prerequisites are absolute must-haves for efficient IOMA:

- High-resolution to spot ductal carcinoma in situ (DCIS), invasive ductal carcinoma (IDC) and invasive lobular carcinoma (ILC)
- Fast imaging that fits the OR pace and doesn't require heavy specimen preparation
- Easy-to-use approach for the clinician (no additional resources)

By addressing these needs, the Histolog Scanner aims to promote a conserving approach while keeping re-operation rates at a minimum. It integrates smoothly into clinical workflows, and enables clinical practice digitalization.

CLINICAL DATA HIGHLIGHTS

Up to 75% reduction of re-operation rate[1]

High performance to detect most common cancer lesions (DCIS, IDC, ILC) with sensitivity and specificity >90%[2]

Compatibility with multi-ple clinical workflows for results in minutes[1,3]

The Histolog Scanner fits your clinical workflow

USE BY SURGEONS

Histolog images can be assessed directly by surgeons who can reach high performance thanks to the dedicated Histolog Image Training platform (HIT Academy) that provides a quick training to interpret images from the Histolog Scanner.

USE BY PATHOLOGISTS

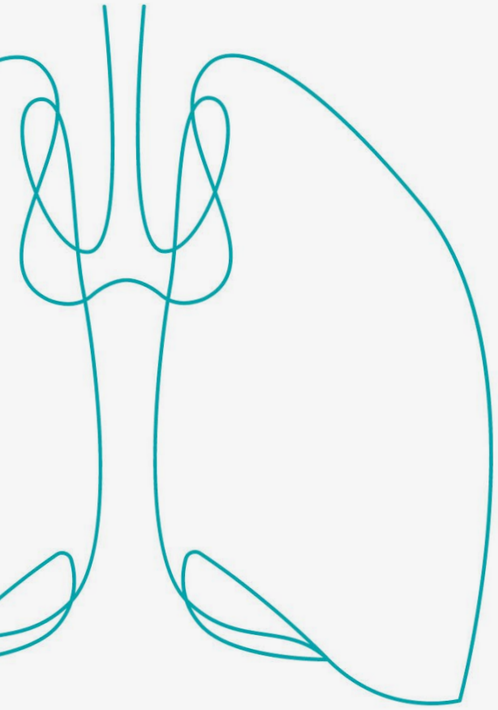
When a pathologist is available for IOMA, interpreting images isn't an issue due to the shared morphological standard[2]. Pathologists can access images remotely, or use the device in the pathology lab.

[1]Sandor, M. F., Schwalbach, B., Hofmann, V., Istrate, S. E., Schuller, Z., Ionescu, E., Heimann, S., Ragazzi, M., & Lux, M. P. (2022). Imaging of lumpectomy surface with large field-of-view confocal laser scanning microscope for intraoperative margin assessment - POLARHIS study. Breast, 66(June), 118–125. https://doi.org/10.1016/j.breast.2022.10.003

[2]Angelica Conversano, Muriel Abbaci, Paul van Diest, Aurélie Roulot, Giuseppe Falco, Malek Ferchiou, Saverio Coiro, Milan Richir, Pierre- Michel Genolet, Carine Clement, Odile Casiraghi, Aicha Ben Lahkdar, Nizard Labaied, Moira Ragazzi, Marie-Christine Mathieu, Breast carcinoma detection in ex vivo fresh human breast surgical specimens using a fast slide-free confocal microscopy scanner: HIBISCUSS project, BJS Open, Volume 7, Issue 3, June 2023, zrad046, https://doi.org/10.1093/bjsopen/zrad046

[3]Togawa, R., Hederer, J., Ragazzi, M., Bruckner, T., Fastner, S., Gomez, C., Hennigs, A., Nees, J., Pfob, A., Riedel, F., Schäfgen, B., Stieber, A., Lux, M. P., Heil, J., & Golatta, M. (2023). Imaging of lumpectomy surface with large field-of-view confocal laser scanning microscopy 'Histolog® scanner' for breast margin assessment in comparison with conventional specimen radiography. Breast, 68(February), 194–200. https://doi.org/10.1016/j.breast.2023.02.010

Thoracic surgery



Faster diagnosis and conservative practice

The Histolog Scanner has been designed to integrate into both biopsy procedures and surgical workflows. In biopsy settings, it aids in ensuring adequate cellularity, streamlining the process to proceed to molecular testing. During lung surgeries, it serves as a critical tool for surgeons to verify that no traces of cancer are left behind.

To ensure optimal patient outcomes, several criteria are paramount for effective treatment:

- High-resolution imaging to detect cancer cells
- Swift imaging in line with the OR and biopsy rhythm, eliminating the need for re-admissions
- A user-friendly interface for clinicians that doesn't necessitate supplementary resources

By addressing these requirements, the Histolog Scanner aspires to speed up biopsy taking, improve cancer surgery outcomes, while saving vital time and resources.

HIGHLIGHTS: BIOPSIES CLINICAL DATA

- Identification of high cellularity tumor area in <10 minutes[1]
- Synergy with real-time PCR to get biopsy results in 2-6 hours instead of 5-7 days[1]

[1]F. Schmitt : PS-20-012 Virchows Archiv (2023) 483 (Suppl 1):S121-122

Other applications - Ongoing work

LUNG WEDGES

Real-time assessment of lung wedges to ensure no cancer cells are left behind

BRONCHI

Detect bronchial invasion to avoid additional surgeries

PLEURA

Detect potential pleural invasion

Mohs and slow Mohs surgery

No need for slide preparation, suitable for a variety of specimens

In the context of Mohs or slow Mohs surgery, frozen section analysis provides an accurate method to examine the surgical specimen. However, slide preparation takes time and requires a complex organization and workflow.

In order to make Mohs and slow Mohs more comfortable and accessible for the patient, as well as to optimize the clinical workflow, the following requirements must be met:

- Fast IOMA
- Imaging method compatible with diverse specimens
- Simplified organizational procedure

By fulfilling these needs, the Histolog Scanner aims at simplifying Mohs and slow Mohs surgeries.

CLINICAL DATA HIGHLIGHTS

High performances to detect basal cell carcinoma (BCC) with sensitivity and specificity of 80% and 100%, respectively.[1,3]

Compatibility with diverse specimens such as giant BCC[2]

Easy specimen preparation and positioning[1,3]

By enabling clinicians to evaluate fresh specimens during surgery, our objective is to significantly enhance patient comfort during skin cancer surgery: eliminating the need for slide preparation avoids them to endure long waiting times with an open wound. The specimen undergoes staining in approximately 10 seconds, and in an additional 50 seconds the image is obtained. The morphology image can be directly examined by the clinician to determine the need for any further resection. This innovation further empowers dermatologists to accommodate a greater number of surgeries within their daily schedule.

[1]Grizzetti, L., & Kuonen, F. (2022). Ex vivo confocal microscopy for surgical margin assessment: A histology- compared study on 109 specimens. Skin Health and Disease, September 2021, 1–8. https://doi.org/10.1002/ski2.91

[2]Kechrid, N., Tonellotto, L., Monnier, S., Rossi, S. A., Ulrich, F., & Kuonen, F. (2022). Ex vivo confocal microscopy for the intraoperative assessment of deep margins in giant basal cell carcinoma. JAAD Case Reports, 27, 41–45. https://doi.org/10.1016/j.jdcr.2022.07.008

[3]Peters, N., Schubert, M., Metzler, G., Geppert, J. P., & Moehrle, M. (2019). Diagnostic accuracy of a new ex vivo confocal laser scanning microscope compared to H&E-stained paraffin slides for micrographic surgery of basal cell carcinoma. Journal of the European Academy of Dermatology and Venereology, 33(2), 298–304. https://doi.org/10.1111/jdv.15243

Other indications

The Histolog Scanner is a highly versatile and adaptable technology that can be used in a wide range of applications. With its advanced imaging abilities, it is capable of providing high-resolution images of tissues, allowing for more precise diagnosis and treatment planning in various medical specialties.

Brain

Feasibility study on the Histolog Scanner for real-time intraoperative brain tumor diagnosis on 50 patients: results showed a fast and simple process (under 5 min to get image) and high agreement with final pathology.

The Leeds Teaching Hospitals, UK, 2022

Kidney

Exploratory use of the Histolog Scanner to assess surgical margins during robot-assisted partial nephrectomy on 6 patients: results showed easy & fast assessment, plus improved diagnostic resolution compared to current solutions.

Canisius-Wilhelmina Ziekenhuis, Netherlands, 2022

ENT

Evaluation of the Histolog Scanner imaging of cervical lymph nodes on 44 patients with squamous cell carcinoma showed 93% agreement with conventional histology.

Gustave Roussy Institute, France, 2022
Guy's and St Thomas' NHS Trust, UK, 2023

GI

Exploratory use in GI surgeries, where residual cancerous tissue can lead to recurrence, while unnecessarily wide resections can compromise the organ's functionality and the patient's quality of life.

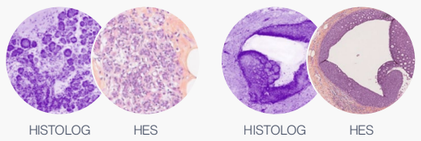
Valais Hospital, Switzerland, 2023

Morphological images in minutes

Gold standard information, minus the waiting

The Histolog Scanner provides morphological images immediately during surgery.

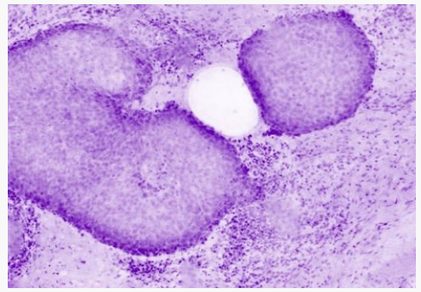
Same morphological criteria defined in histopathology such as tissue architecture and cell features can be applied to describe Histolog images[1]. This opens the perspective to make the Histolog Scanner universally compatible across all clinical indications.



[1]Angelica Conversano, Muriel Abbaci, Paul van Diest, Aurélie Roulot, Giuseppe Falco, Malek Ferchiou, Saverio Coiro, Milan Richir, Pierre- Michel Genolet, Carine Clement, Odile Casiraghi, Aicha Ben Lahkdar, Nizard Labaied, Moira Ragazzi, Marie-Christine Mathieu, Breast carcinoma detection in ex vivo fresh human breast surgical specimens using a fast slide-free confocal microscopy scanner: HIBISCUSS project, BJS Open, Volume 7, Issue 3, June 2023, zrad046, https://doi.org/10.1093/bjsopen/zrad046

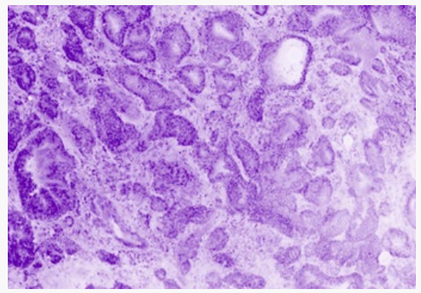
Breast

DCIS



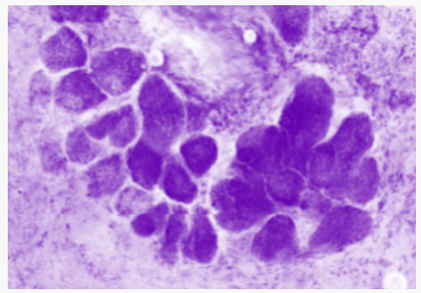
Prostate

CANCEROUS GLAND



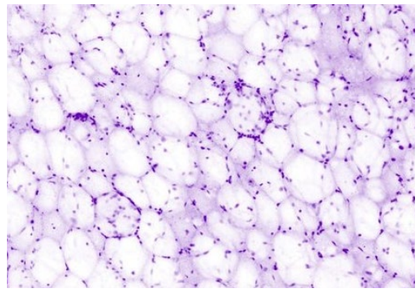
Skin

BCC



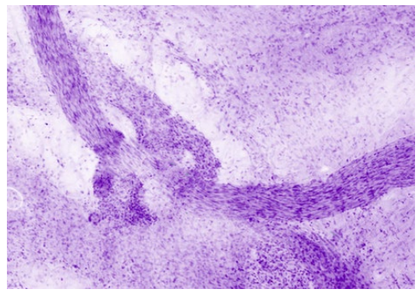
Breast

FATTY TISSUE



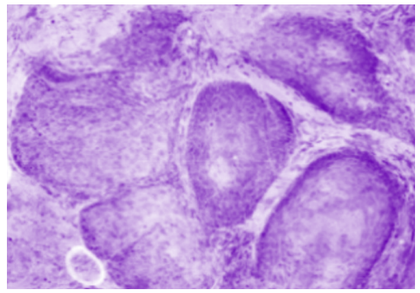
Prostate

NERVE



Skin

SEBACEOUS GLAND



Dedicated support

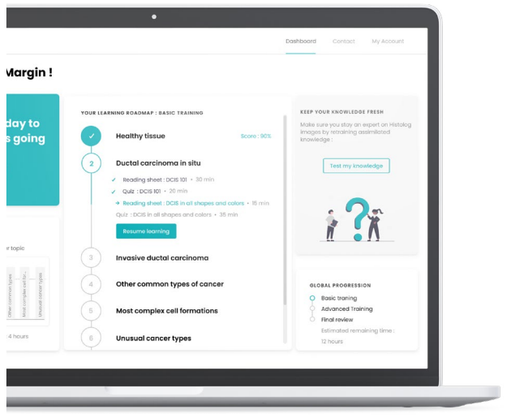
Working hand in hand with clinicians

At SamanTree Medical, we believe that the key to creating impactful medical technologies is through close collaboration with clinicians. By working together with healthcare professionals, we gain valuable insights into their needs and are better able to develop solutions that truly make a difference in patients' lives. Our main references centers include :

- Fribourg Cantonal Hospital, Switzerland with Dr. Benedetta Guani (breast)
- Valais Hospital in Sion, Switzerland with Dr. Colin Simonson (breast)
- OLV Hospital in Aalst, Belgium with Prof. Dr. Alex Mottrie (prostate)
- University College Hospital London, UK, with Prof. Dr. Greg Shaw (prostate)

These partnerships combined with our innovative thinking ensure that we remain at the forefront of the medical imaging industry, supplying cutting-edge solutions that enable clinicians to provide the best possible care for their patients.

To streamline the integration of our solutions into clinical workflows, our dedicated product specialists and distribution network offer crucial support, connecting our technologies seamlessly with healthcare systems across Europe.



Histolog images training: the HIT Academy

To ensure that clinicians are not only equipped with our cutting-edge technology but are also adept at interpreting Histolog images effectively, we have developed the HIT Academy with our community of pathologists and experts to provide a simple and efficient way of getting familiar with the images.

Designed for both beginners and experienced morphology content readers, the HIT is accessible to all and allows for flexible learning. Users will be ready to interpret morphology images in just a few hours of training.

hit.samantree.com

ISO certification

The medical ISO certification is a crucial component of our commitment to quality, safety, and excellence in all aspects of our operations, from research and development to manufacturing and distribution. It is a symbol of our dedication to meeting the needs of our customers, the healthcare industry, and the patients who rely on our products and services.

Certificate:
EN ISO 13485:2016
(MD 671824)

Our partners

Clinical partners

From the start, we've collaborated with renowned European centers on clinical studies to evaluate the Histolog Digital Solution in diverse clinical settings, showing promising results in improving intraoperative assessment and reducing re-operations.

In breast cancer, studies across Europe involving over 500 patients resulted in an atlas of 300+ images, showcasing the Histolog Scanner's effectiveness in assessing lumpectomies. These studies confirmed its ability to integrate seamlessly into clinical workflows, potentially reducing re-operation rates by up to 75%.

In prostate surgery, a feasibility study at Canisius Wilhelmina Hospital showed the Histolog Scanner performs similarly to NeuroSAFE but with 80% time savings. It's now under evaluation in the NeuroSAFE PROOF trial at University College London and was incorporated into Orsi Academy's curriculum in February 2024, enhancing training in minimally invasive surgery.

The Histolog Scanner is also under evaluation for other indications and continues to expand geographically.

Training & reference centers

ORSI Academy, Belgium

OLV Hospital Aalst, Belgium

University College London, UK

Fribourg Cantonal Hospital Switzerland

Valais Hospital, Sion Switzerland

SamanTree
Medical SA

Avenue de Provence 12, 1007 Lausanne, Switzerland
Rue des Bergères 2, 1331 Rosières, Belgium
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