

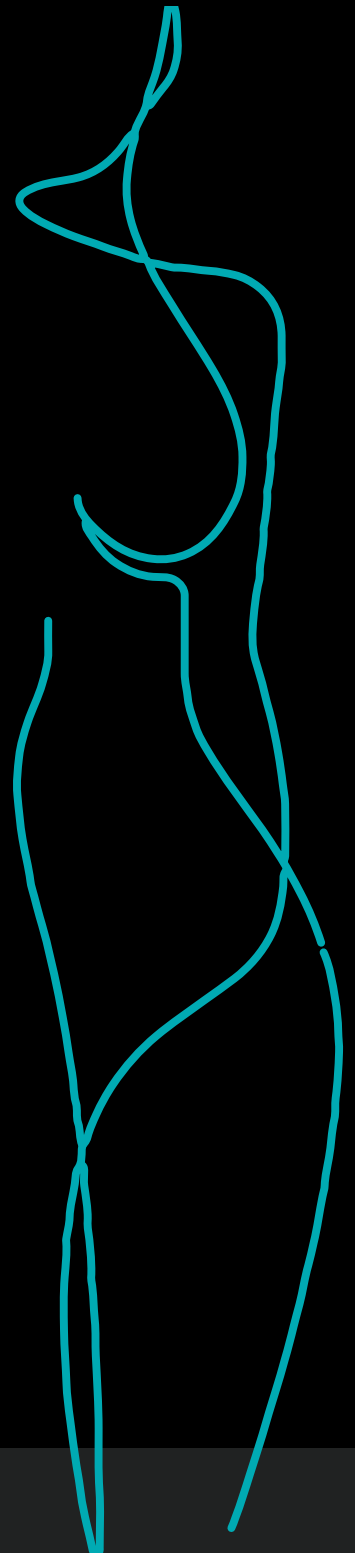


SamanTree
Medical SA

Histolog[®] Scanner

Cancer cells
at your fingertips

BCS brochure - April 2023





The Clinical Need

When surgically excising a tumor, the challenge for the surgeon is to remove all the cancerous tissue while preserving as much healthy surrounding tissue as possible. Intraoperative margin assessment (IOMA) constitutes a crucial part in the decision-making process of surgeons.

In breast conserving surgery, there is no consensual IOMA technique. All current methods present particular benefits and disadvantages, mostly regarding accuracy and time required. Overall, approximately 20% of the patients need to undergo an additional surgery¹⁻².

Unmet medical need :

- Quick & Accurate IOMA
- Minimal tissue removal
- Avoid re-operations

¹R. Jeevan et al., "Reoperation rates after breast conserving surgery for breast cancer among women in England: Retrospective study of hospital episode statistics," *BMJ*, vol. 345, no. 7869, 2012, doi: 10.1136/bmj.e4505

²C. Baliski, L. Hughes, and B. Bakos, "Lowering Re-excision Rates After Breast-Conserving Surgery: Unraveling the Intersection Between Surgeon Case Volumes and Techniques," *Ann. Surg. Oncol.*, vol. 28, no. 2, pp. 894–901, 2021, doi: 10.1245/s10434-020-08731-z.

Our mission

SamanTree Medical aims to be a game changer in the era of clinical workflow digitalization. We are committed to improving the journey of patients suffering from cancer by enabling fresh tissue analysis in real time to drastically reduce delays in establishing and executing the treatment plan.

		1	2	3	
		REDUCE RE-OPERATION RATE	SAVE PRECIOUS TIME AND RESOURCES	ENABLE CLINICAL WORKFLOW DIGITALIZATION	
		Current standard-of-care, such as specimen radiography or ultrasound, lack accuracy to detect microscopic lesions, resulting in a re-operation rate of 15-40% ²⁻³ .	Intraoperative margin assessment often requires resources from different departments, leading to a complex logistic and lengthy procedures. ⁵	Specimens are often sent to other departments for intraoperative assessment, or specialists have to come to the operating room. The need for collaboration with specialists from faraway health centers is quite common.	
	PROBLEM	Absence of relevant tools providing high resolution information in the OR to detect remaining cancer cells.	Current tools not adapted to OR pace and requiring multiple resources	Specimens or specialists required to travel between departments/ hospitals	
	SOLUTION	The gold standard information: tissue morphology. With the Histolog Scanner, the clinician sees the tissue cellular architecture and can immediately visualize cancer lesions (DCIS, IDC, ILC). ³⁻⁴	Whole specimen imaging in minutes. The Histolog Scanner enables fresh tissue assessment, with minimal preparation and 50s imaging time.	An easy-to-use approach providing digital information. With the Histolog Scanner, images travel, not specimens or specialists.	

Our solution The Histolog® Scanner

Global mapping of the breast immediately during surgery

The Histolog® Scanner is a breakthrough medical imaging modality based on a novel ultra-fast confocal microscopy technology invented in 2010.

Its innovative design makes it highly practical for quick assessment during surgery, bringing the clinician one touch-on-the-screen away from visualizing cancerous cells immediately on a surgical specimen.

In BCS, a recent prospective study revealed the potential of the Histolog Scanner, with up to 75% re-operation rate reduction. The device was easily inserted in the clinical workflow and surgeons with no prior experience on morphology information could detect Ductal Carcinoma in situ (DCIS) lesions. More experienced users detected also invasive lobular carcinoma (ILC) and had extrapolated sensitivity up to 70%, while keeping specificity above 80%.³

³Sandor, M. F. et al., 2022 (p. 5)



A cost-efficient technique 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 remote workflows



Result in minutes : 15s for specimen preparation (10s fluorescent dye + 2s 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



Intuitive and user-friendly touch screen

Open top architecture

Easy to handle



QUICK & CLEAN

4-steps procedure for accurate margin assessment immediately in the OR

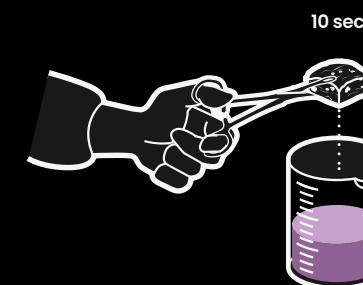
1 Excision

Excise the tumor from the patient.



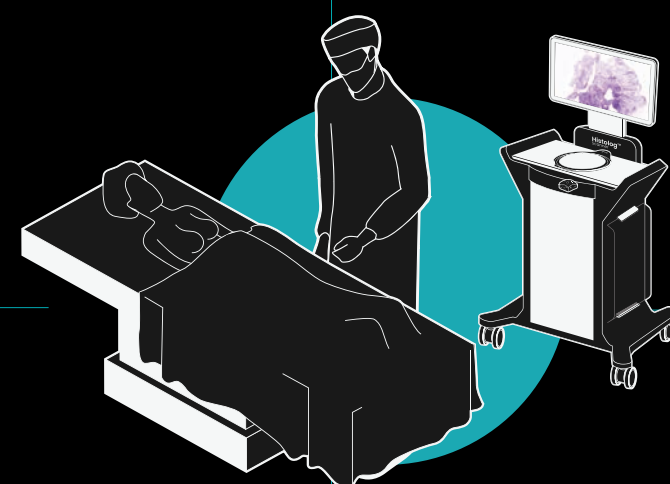
2 Preparation

Immerse the excision in Histolog Dip and rinse it.



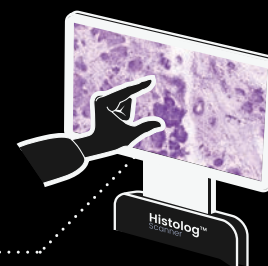
Histolog Dip
Histological stain

10 sec



4 Evaluation

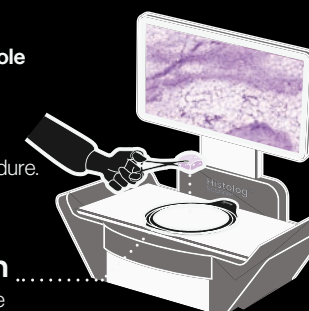
With this additional information, return to patient in confidence.
Excision is sent for standard post-surgical pathology assessment.



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

3 Imaging

Map in minutes the whole excision surface.
Excision remains visible and accessible during the entire imaging procedure.



Histolog Dish
Single use receptacle

Our partners

Clinical partners

In 2019, SamanTree Medical launched an ambitious study with Gustave Roussy Institute and including >180 patients to build a comprehensive atlas of image and evaluate the learning curve of clinicians (surgeons and pathologists) on Histolog® images. The study unraveled the potential of the Histolog Scanner for intraoperative assessment of lumpectomies and showed the universality of the approach with surgeons and pathologists reaching high detection performance.

Built on these promising results, multiple studies were launched to evaluate the performances of the Histolog Scanner for its intraoperative usage. The studies showed a seamless integration in multiple clinical workflows with potential reduction of re-operation rate up to 75%.

The Histolog® Scanner is a CE marked product commercialized in EU and not available for sale in the United States. CAUTION – Investigational device. Limited by U.S. law to investigational use.

Reference centers

**University Hospital
rechts der Isar, Germany**
Dr. Stefan Paepke

**Hopital Cantonal du Valais,
Switzerland**
Dr. Colin Simonson



Clinical evidences

Imaging of lumpectomy surface with large field-of-view confocal laser microscope for intraoperative margin assessment – POLARHIS study

The Breast, 2022

M.-F. Sandor, B. Schwalbach, V. Hofmann, S.-E. Istrate, Z. Schuller, E. Ionescu, S. Heimann, M. Ragazzi, M. P. Lux - St. Vincenz-Krankenhaus, Paderborn, Germany

Evaluation of the Histolog Scanner for the margin assessment of 40 lumpectomy specimens

- Potential re-operation reduction of 75%
- Detection of invasive cancer & DCIS in lumpectomy margins
- Histolog Scanner easily inserted into surgical workflow

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

The Breast, 2023

Togawa R, Hederer J, Ragazzi M, Bruckner T, Fastner S, Gomez C, Hennigs A, Nees J, Pfob A, Riedel F, Schäffgen B, Stieber A, Lux MP, Heil J, Golatta M - Heidelberg University Hospital, Germany

Intraoperative margin assessment performed with the Histolog Scanner and assessed by unexperienced clinicians versus specimen radiography in 50 patients

- Similar performances to current practice without any experience or training on morphology images
- Perspective of significantly higher performances with adequate training and education
- Detection of DCIS, ILC, and IDC

Learn to use Histolog images in no-time

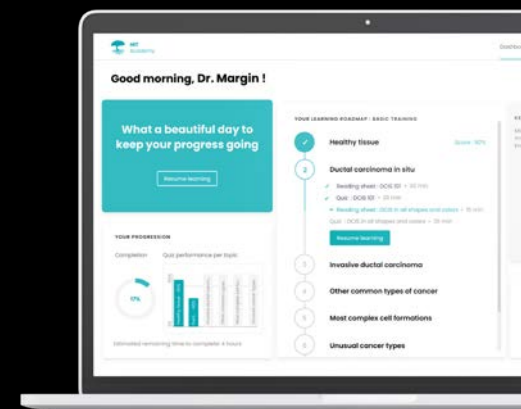
Histolog Image Training program (HIT)

Short. Flexible. Simple.

A learning program designed for clinicians.

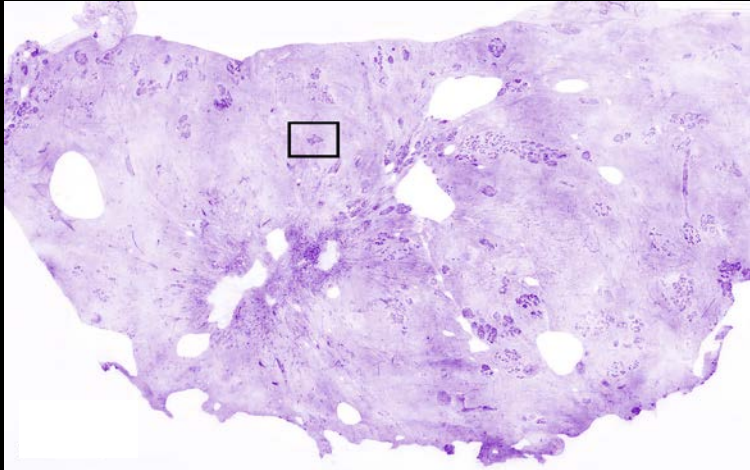
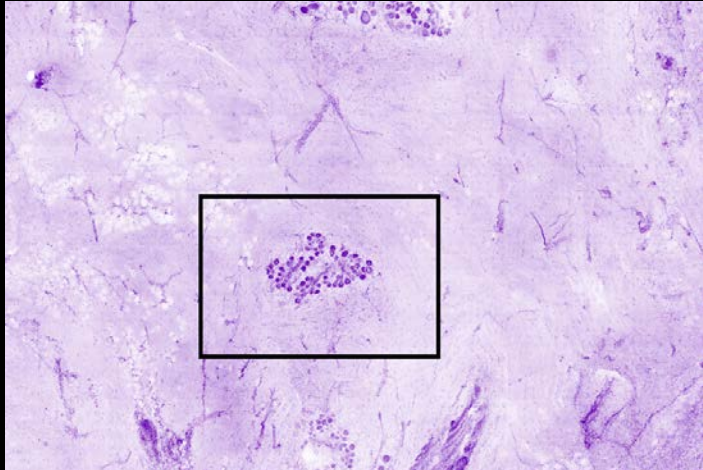
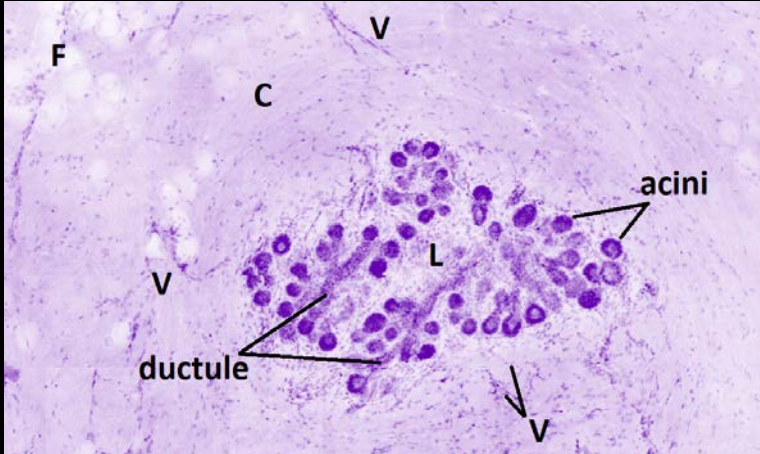
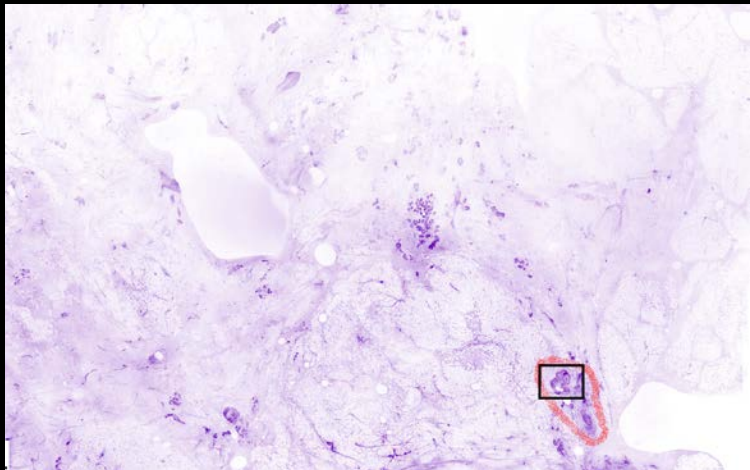
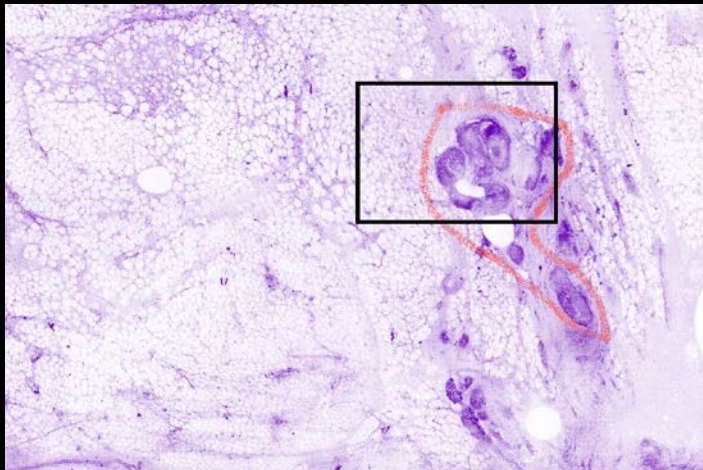
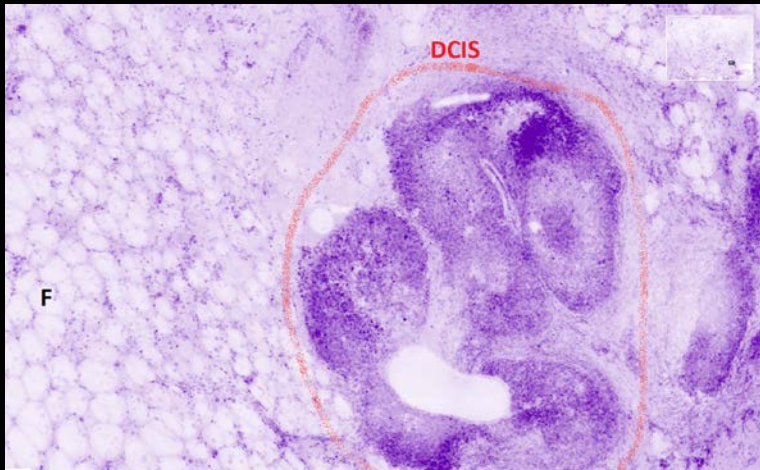
The Histolog Image Training (HIT) was developed with our community of pathologists and experts to provide a simple and efficient way of getting familiar with Histolog image. Designed for both beginners and experienced morphology content readers, the HIT is accessible to all and allows for flexible learning. In and out of the operating theatre, you set the pace and we keep it.

hit.samantree.com



Our images : the gold standard in the OR

Examples of images in breast conserving surgery

	Full Field of View of Histolog Scanner (5% zoom level)	25% Zoom level of the Histolog Scanner	100% Zoom level of the Histolog Scanner
Tissue with Normal Lobules	 <p>The present tissue is notably composed of a large part of connective tissue and normal lobules. Lobules are usually presenting a strong purple coloration. A typical normal lobules is seen inside the selected black frame.</p>	 <p>Normal lobules can be recognized with their shape recalling a bunch of grapes. This structures are usually more colored than connective tissue or fatty tissue. In the black frame, a normal lobule can be seen in the center surrounded by normal connective tissue.</p>	 <p>Lobules are composed of circular structures that may appear empty with purple circular wall. They are the Acini from which the milk is secreted. These beads are organized like a bunch of grapes. All the beads of a lobule are connected together with a branching structure of small pipes called ductules (smaller ducts). Acini (lobules) and ducts are composed of epithelial cells that have generally a strong purple color. The present lobule is surrounded by normal connective tissue (C) with few fatty cells (F). Lobule is closely surrounded with thin linear structures, tiny vessels (V).</p>
Tissue with Ductal Carcinoma In-Situ - DCIS	 <p>A lumpectomy section with a suspicious area at the bottom right is seen. The present lumpectomy is mainly composed of lobules, fatty and connective tissue.</p>	 <p>Within the black frame is seen a roundish pattern that is typical of DCIS. At this magnification, sections of these ducts invaded by DCIS are seen as circular patterns presenting a well-defined border and containing high density of cells strongly colored.</p>	 <p>One large DCIS lesion is seen. It presents a roundish pattern with a well-defined border and a content composed of cancer cells. Here the invaded duct can be figured out as a convoluted duct filled with cancer cells. Some inflammatory cells can also be seen in the DCIS as tiny dots strongly colored. This DCIS is surrounded by fatty tissue (F) that also contains few inflammatory cells.</p>



SamanTree
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Avenue de Provence 12, 1007 Lausanne, Switzerland
contact@samantree.com
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