Prostate HistoScanning™
Visual Reassurance for Decision Making and True Targeting
Prostate HistoScanning™ TT is a unique Tissue Characterisation technology, specifically developed to detect, visualise and pinpoint the tissues under suspicion of harbouring cancer. It gives clinicians an immediate and clear view with accurate identification, location and volume of differentiated tissues in the prostate.

Prostate HistoScanning™ TT complements Tissue Characterisation with True Targeting functionality, enabling real-time guided biopsy in the same patient session. Prostate HistoScanning™ and Prostate HistoScanning™ TT will guide clinicians in making immediate, independent and informed decisions for each particular patient in their daily diagnostic routine, and open up the options for least-invasive treatment.

Prostate HistoScanning™ is a unique Tissue Characterisation technology, specifically developed to provide comprehensive in Prostate cancer care.

**Diagnostic**
- **Detection & Diagnosis**
- **Treatment planning**
- **Treatment guidance**
- **Surveillance**

**Unique Technology**
- 3D whole volume Tissue Characterisation
- Native Bark Field Frequency (NRF) data
- Real-time biopsy guidance
- Location and volume of suspect tissues
- Developed and validated on real prostate
- Intrinsically multi-parametric

**Patient-focused**
- One point of care:
  - High-precision Production line
  - Production line
  - True Targeting
  - Real-time Guidance
  - Accurate and effective workflow

**Health Economics Proof**
- Cost-effective procedure
- Ability to reduce costs and reduce clinical trial data suggests it is feasible.

**My centre was one of the first to start working with Prostate HistoScanning™ which in my opinion is an ideal imaging tool in hands of urologists to diagnose prostate cancer. I'm convinced of the benefits of the guided biopsy system for all of us.**

PD Dr. med. Jürgen Zumbé
Klinikum Leverkusen, Germany

Contact your local representative for more clinical case studies; our library includes among others, cases of patients on active surveillance, cases of patients monitored after high-intensity focused ultrasound treatment.
"When the patient arrives prepared, the examination with Ultrasound, Tissue Characterisation and the Guided biopsy procedure are perfectly feasible in one session!"

Dr. Johan G. Braeckman
Universitair Ziekenhuis Brussel (UZB), Belgium

“I have been using Prostate HistoScanning™ within a research setting and in my practice. My data on its accuracy in detecting prostate cancer before radical prostatectomy are very promising. This makes it an interesting tool for planning and aiding decision-making before radical prostatectomy. I also see future benefits for targeted biopsies or for active surveillance of selected patients without the need for repeat biopsy.”

Petr Macek, MD PhD
General University Hospital and First Faculty of Medicine Charles University Prague, Czech Republic

In cooperation with Institut Mutualiste Montsouris, Paris, France

True Targeting comprises:

- One accessible examination session with Tissue Characterisation and guided biopsy ensuring a fast and easy workflow for optimising your biopsies.
- Taking informed decisions on where to biopsy and how to select your targets: either your standard biopsy scheme, or your individual targets within or outside the differentiated areas.
- Real-time guidance with easy navigation of the transducer towards the selected targets and providing live visual reassurance that the needle hits the intended spot.
- A quick quality check of the performed biopsies with the video report of the needle path.

See www.histoscanning.com for demonstration videos of Tissue Characterisation and True Targeting.

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Typical workflow of a Tissue Characterisation procedure

Acquire 3D NRF data

Contour the prostate

Automatic processing with algorithms

Clinical interpretation

Report and plan next steps

Raise your standards with True Targeting

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Multiple studies have thoroughly validated the ability of Prostate HistoScanning™ to identify and characterise cancer foci with histology results from radical prostatectomy specimens as reference test. The exploratory proof-of-concept study PHS-01 demonstrated high concordance between Prostate HistoScanning™ and histology results: [2, 3]

- A strong correlation in diameter of index tumour (r=0.95, P<0.001);
- 100% concordance in attribution of multifocality and laterality;
- A strong correlation in lesion volumes (r=0.99, P<0.001) and total cancer volume (r=0.98, P<0.001);
- Prostate HistoScanning™ performed well in detecting cancer foci bigger than 0.50 mL on histology as illustrated in Table 1.

The multi-centre, European study PHS-02 examined the diagnostic accuracy of Prostate HistoScanning™ to locate a cancer focus of at least 0.20 mL or 0.50 mL in a sextant in patients with organ-confined prostate cancer and scheduled for radical prostatectomy. Prostate HistoScanning™ showed 90% sensitivity and 70% to 72% specificity and histology results: [2, 3]

<table>
<thead>
<tr>
<th>Volume threshold</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foci ≥ 0.50 mL</td>
<td>100%</td>
<td>81%</td>
<td>80%</td>
<td>100%</td>
</tr>
<tr>
<td>Foci ≥ 0.20 mL</td>
<td>90% (79/88)</td>
<td>70% (35/50)</td>
<td>84% (79/94)</td>
<td>80% (35/44)</td>
</tr>
</tbody>
</table>

PPV: positive predictive value; NPV: negative predictive value

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**Spectrum of clinical benefit**

- **Detection and Diagnosis**
  - Multiple users show in independent studies that Prostate HistoScanning™ provides key support to make informed decisions throughout prostate cancer treatment to provide optimal patient care, including:
    - determining the need for biopsy or surveillance
    - prediction of biopsy outcome and improved targeting of biopsies
    - guidance in treatment planning and execution
    - aid in monitoring of patients after treatment

- **Treatment planning**
- **Treatment guidance**
- **Surveillance**

Ask your local representative for the latest Clinical Studies Summary
Bibliography


Disclaimer
Prostate HistoScanning™ and Prostate HistoScanning™ TT are CE Marked under the European Medical Device directive (MDD) 03/42/EEC as amended by 1007/47/EC.
Prostate HistoScanning™ and Prostate HistoScanning™ TT are not yet commercially available in the United States of America. R-Action recommends consulting your local regulatory agency to comply with local ordinances.
Integration of society guidelines or clinical protocols, as well as any form of automation, reporting and networking are under the user’s responsibility.
The functionalities are depending on product configuration and availability. Currently supported ultrasound devices compatibility you find listed at www.histoscanning.com.