Designing Tools for Greater Confidence in Lung Biopsy

**Problem Statement**

The Boston Scientific SCOPE Team researched bronchoscopy tools and procedures and worked with physicians to develop areas of opportunity for Boston Scientific’s pulmonary development team. Boston Scientific asked the team to investigate the problem space of pulmonary lesion identification and diagnosis and develop a solution space.

**Lung Cancer Biopsy Procedures**

- Lung cancer accounts for 14% of cancer diagnoses and 28% of cancer deaths.[1]
- Early detection increases 5-year survival rate to 52%, but only 15% of lung cancer cases are detected at an early stage.[1][2]
- New screening techniques detect lung cancer at an earlier stage, potentially increasing survival rates.
- Even with new screening techniques, current tool designs are insufficient for accurate diagnosis.

**Background: Lung Cancer Biopsy Procedures**

**Pre-Bronchoscopy:** Patients at risk are screened for suspicious lesions (dense tissue), which may be cancer, benign, or an infection.

**Bronchoscopy:** A bronchoscope is fed manually down the patient’s throat. Navigational technologies help locate lesions:
- Video feed on bronchoscope
- Fluoroscopy
- Endobronchial Ultrasound

**Multiple samples are taken** using forceps, needles, or brushes.

**Post-Bronchoscopy:** A cytologist confirms if the sample is cancerous.

**Physician Concerns**

- Tool manipulation in bronchioles
- Obscured bronchoscope vision from bodily fluids
- Excessive sampling due to uncertainty of sampling accuracy
- Inadequate sampling volume

**Giving Physicians Confidence That They Are Sampling the Correct Tissue**

The team researched 5 tissue properties that could be measured and came up with 5 requirements to ensure successful tissue differentiation. The team selected the tissue property that best met the requirements to distinguish between healthy and lesion tissue.

**Areas of opportunity in instrument design for greater physician confidence:**
- precision in manipulation
- higher volume sampling
- higher accuracy in tissue recognition - Boston Scientific’s suggested focus

**Tissue Property:**

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<th>Criteria</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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<tbody>
<tr>
<td>In body confirmation</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4.5</td>
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<tr>
<td>Clear distinction in healthy and lesion tissue values</td>
<td>5</td>
<td>3.5</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Integration with existing biopsy tool</td>
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<td>4</td>
<td>3</td>
<td>3</td>
<td>3.5</td>
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<tr>
<td>No false positives from other tissue and fluids</td>
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<td>3</td>
<td>2.5</td>
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**Weighted totals:**
- **17.95**
- **14.00**
- **13.70**
- **14.80**
- **14.70**

**Tool Design**

The SCOPE Team presented one tool design with a probe measuring property A to Boston Scientific with preliminary validation tests, full system models, and comments on market research, patentability, manufacturability, and scaling.

**References:**


**Acknowledgements:**

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