Clinical Need

What is an endoscopy?
- Endoscopy: non-surgical medical visualization to diagnose, treat, & monitor diseases such as esophageal and stomach cancer (Fig. 1 & Fig. 2)
- 18.4M endoscopies in 2009 in USA costing ~$2,700
- Traditionally visualized and documented via bulky, costly endoscopy tower

Limited endoscopic capacity in low-resource nations
- Cumulative death rates due to liver disease, esophageal cancer, & stomach cancer / 100K people:
  - 41.35 in Nigeria vs 15.15 in USA
- Gastroenterologists / 100K people:
  - 0.04 in Nigeria vs 3.9 in USA

Low-cost, ergonomic & adjustable endoscope visualizer to replace costly endoscopy towers

Final EndoView Prototype Design

Idea: Wi-Fi camera aligned with endoscope lens via silicone case transmits video feed in real-time to smartphone

Final design (Figure 3)
- Camera/smartphone app
  - 4K video quality suitable for disease diagnosis
  - Connects to smartphone app via camera’s personal Wi-Fi
- Silicone case
  - Stiffness of phone case to keep camera and endoscope lenses aligned
  - Flexible enough so that endoscope and camera are easily removable
  - Safe-to-use in medical environment
  - Undergoes minimal hysteresis over time to reduce loosening

Design novelties
- Camera over smartphone: reduces bulkiness and improved ergonomics compared to ClearSCOPE
- Silicone case over metal adapter: reduces cost and bulkiness compared to ClearSCOPE
- Camera’s Wi-Fi capability: wider range of usable smartphones/tablets and no need to update for new sizes

Manufacturing Cost

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4K Wireless Camera</td>
<td>26.00</td>
</tr>
<tr>
<td>Silicone</td>
<td>0.0006</td>
</tr>
<tr>
<td>Injection Molding (NRE)</td>
<td>0.70</td>
</tr>
<tr>
<td>Labor</td>
<td>8.00</td>
</tr>
<tr>
<td>Packaging</td>
<td>3.74</td>
</tr>
<tr>
<td><strong>Unit Cost</strong></td>
<td><strong>36.44</strong></td>
</tr>
</tbody>
</table>

Regulatory Pathway

- Class I medical device
- Approved several cameras for endoscopic camera
- Exempt from Premarket Approval via 510(K)
- Substantially equivalent to existing devices
- Silicone used will be of non-implantable class because only in contact with clinician’s hands

Future Work

- Improve silicone molding process
- Compatibility with modern flexible endoscopes
- Compatibility with laptops
- Add maneuverability, insufflation, and suctioning capabilities

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References

4. Final EndoView Prototype Design

Market Analysis

Market size and growth
- 2016 global endoscopic device market: ~$26.9B
- CAGR from 2016 to 2025: 6.12%

Target market
- End users are clinicians such as gastroenterologists, otolaryngologists, and urologists
- Focus: low-resource nations with limited endoscopic capacity such as Nigeria, Gambia, Senegal, & Malawi

Competition:
- Endoscopy tower ($50,000+): A/V tower wired to endoscope that visualizes and records procedure with high quality and low lag
- ClearSCOPE ($500): mechanical adapter to attach smartphone to endoscope
- Firefly DE250 ($1000): wireless camera attached to endoscope that transmits video feed to laptop

Reimbursement:
- Not applicable to Medicare or Medicaid because device used by clinician, not patient

Product Testing

1. Ergonomics: comfort and ease-of-use key for clinicians
   - Test plan: hands-on clinical feedback
   - Results: Positive feedback from Director of Endoscopy at AHN

2. Silicone case fit: camera-endoscope alignment must be fixed
   - Test plan: shake device semi-vigorously 10 times
   - Results: alignment changed due to lack of stiffness of silicone case, contributable to imperfect molding procedure

3. Video lag: lag disrupts clinician’s hand-eye coordination
   - Test plan: image of camera taking video of stopwatch on laptop to measure exact latency
   - Results: average lag is 135 ± 31 ms – statistically insignificant difference from 130 ms (lag beyond which adverse clinical effects occur)

4. Video quality: minute details crucial for accurate diagnoses
   - Test plan: attach “secret words” with varying font sizes onto ear model and determined lowest font size users could read
   - Results: lower readable font size is 3 point (4 pixels tall)