

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^{1,2}
- Traditionally visualized and documented via bulky, costly endoscopy tower

Limited endoscopic capacity in low-resource nations³

- 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



Figure 1: Flexible endoscope⁴

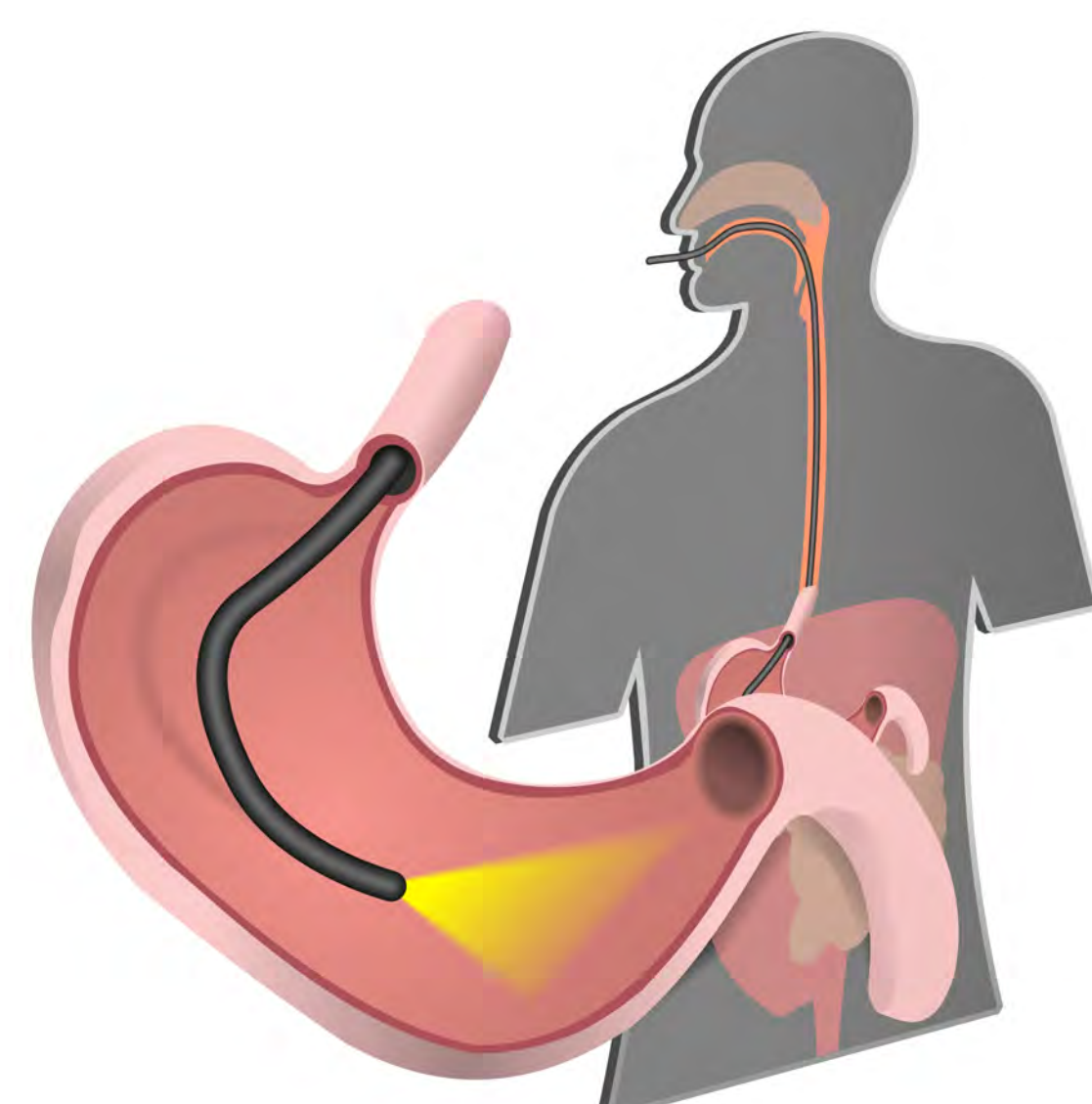


Figure 2: Representative upper GI endoscopy⁵

Market Analysis

Market size and growth⁶

- 2016 global endoscopic device market: ~\$26.9B
- CAGR from 2016 to 2025: 6.12%

Target market

- End users are clinicians such as gastroenterologists, otolaryngologist, and urologists
- Focus: low-resource nations w/ 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 lag⁷
- ClearSCOPE (\$500): mechanical adapter to attach smartphone to endoscope⁸
- Firefly DE1250 (\$1000): wireless camera attached to endoscope that transmits video feed to laptop⁹

Reimbursement:

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

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



Figure 2: EndoView Final Prototype Design

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

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 latency¹⁰
- Results: average lag is 135 ± 31 ms – statistically insignificant difference from 130 ms (lag beyond which adverse clinical effects occur)¹¹

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)

Manufacturing Cost

Item	Cost (\$)
4K Wireless Camera ¹²	26.00
Silicone ¹³	0.0006
Injection Molding (NRE) ¹⁴	0.70
Labor	8.00
Packaging	3.74
Unit Cost	36.44

Regulatory Pathway

- Class I medical device¹⁵
 - Approved several cameras for endoscopic camera
- Exempt from Premarket Approval via 510(k)¹⁵
 - 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

- Peery, A., MD MSCR, et al. (2012). Burden of Gastrointestinal Disease in the United States: 2012 Update. *Gastroenterology*, 143(5). doi:10.1053/gastro.2012.09.012
- Richard, P. (2017, October 4). HOW MUCH DOES UPPER GI ENDOSCOPY COSTS IN USA? Retrieved April 6, 2018, from <https://www.giendoscopypractice.com/blog/how-much-upper-gi-endoscopy-costs-in-usa/>
- Peri, D., Desmond, L., Bizos, D., Veitch, A., N'Dow, J., Bush-Goddard, S., ... Shah, B. (2016). Endoscopic capacity in West Africa. *African Health Science*, 16(1), 329-338. Retrieved April 6, 2018.
- [Flexible endoscopy]. (n.d.). Retrieved May 5, 2018, from <http://www.allteendoscopieservices.com>
- Upper GI Endoscopy]. (n.d.). Retrieved May 5, 2018, from <http://adironackisurgery.com/services/upper-gi-endoscopy/>
- Research, Zion Market. "Global Endoscopy Devices Market Share Expected to Reach USD 41.813.42 million in 2021: Zion Market Research." *GlobeNewswire News Room*, 13 June 2017, <https://www.globenewswire.com/news-release/2017/06/13/1018226/0/en/Global-Endoscopy-Devices-Market-Share-Expected-to-Reach-USD-41-813-42-million-in-2021-Zion-Market-Research.html>
- "Stryker 1488 HD Video Endoscopy Tower System." *Soma Technology Medical Equipment Sales*, www.somatechnology.com/Stryker-1488-HD-Video-Endoscopy-Tower-System-P2475.aspx
- ClearWater ClearSCOPE Endoscopic Imaging Smartphone Endoscope Video Adaptor. (n.d.). Retrieved December 14, 2017, from <https://www.amazon.com/ClearWater-ClearSCOPE-Endoscopic-Smartphone-Endoscope/dp/B01CK6V08W>
- DE1250 Wireless Endoscope Camera. (n.d.). Retrieved December 14, 2017, from <http://fireflyglobal.com/de1250-wireless-endoscope-camera/>
- [Ilektion]. (2016, August 25). How To Measure Input Lag [Video File]. Retrieved from <https://www.youtube.com/watch?v=3x29Ugd78Vc>
- Ranst, W. V., Goedemé, T., & Vennekens, J. (n.d.). Ultra-Low-Latency Automatic Endoscopic Image Orientation Stabilisation (Rep.). Retrieved April 7, 2018, from Katholieke Universiteit Leuven website: <https://iris.kuleuven.be/bitstream/123456789/542799/2/final.pdf>
- Cheap Cube Ultra Hd 4k Wifi Waterproof Sport Action Camera - Buy 4k Waterproof Sport Camera,4k Wifi Waterproof Sport Action Camera,4k Sport Action Camera Product on Alibaba.com. (n.d.). Retrieved from https://www.alibaba.com/product-detail/Cheap-Cube-Ultra-Hd-4k-Wifi_60641523771.html?spm=a2700.7724838.2017115.84.3227792563mtyM&e=p
- Brushable Silicone Rubber For Injection Molding - Buy Silicone Rubber For Injection Molding,Silicone Foam,Brushable Silicon Rubber Product on Alibaba.com. (n.d.). Retrieved from https://www.alibaba.com/product-detail/Brushable-silicone-rubber-for-injection-molding_60389803391.html?spm=a2700.7724838.2017115.65.3227792563mtyM&e=p
- Wholesaler. (n.d.). Retrieved from <https://m.alibaba.com/product/60347496733/Injection-Mold-Silicone-Mold-Plastic-Mold.html?spm=a2706.7843667.1998817009.6.80ZGzw>
- Product Classification. (n.d.). Retrieved March 23, 2018, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?ID=5421>