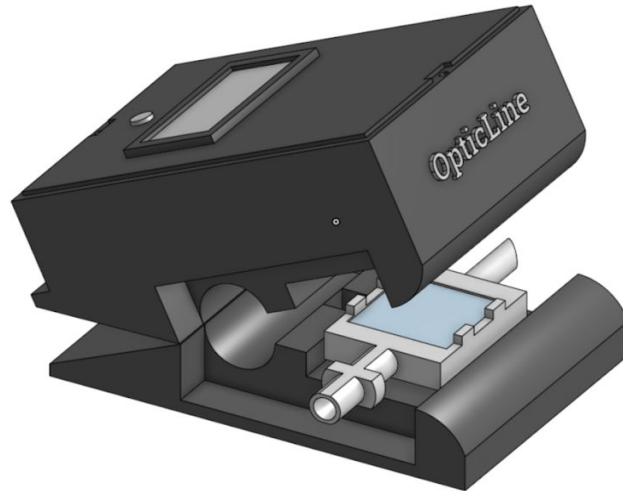


# OpticLine

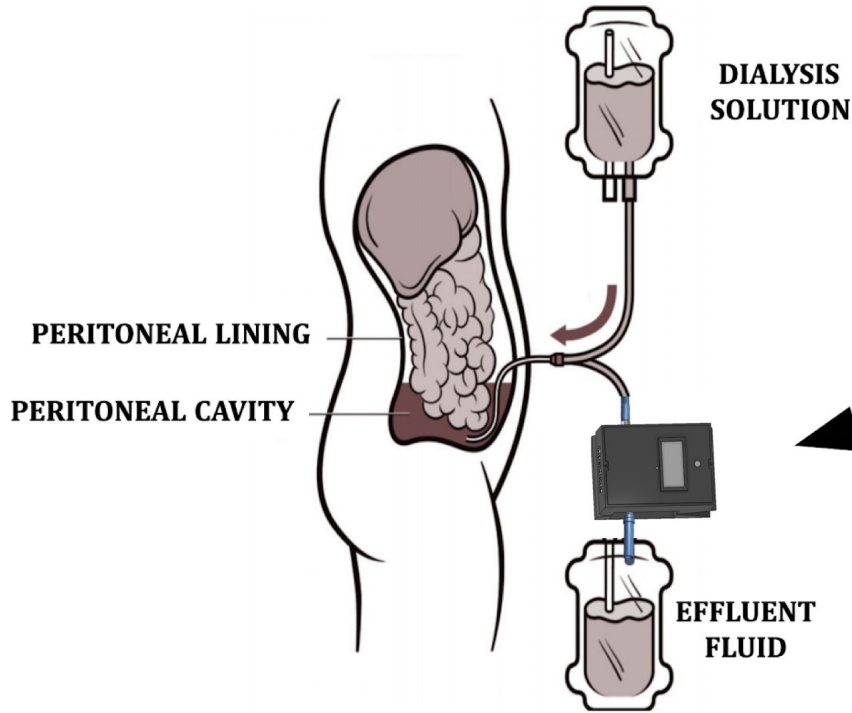
Alisha Birk B.S.H. '19; Mark Buckup B.S.H. '19;  
Eleanor Glockner B.S. '21; Janelle Kaneda B.S.H. '19, M.S. '21  
Stanford University, Department of Bioengineering



# Introduction

- 195,000 PD patients worldwide<sup>1</sup> → continuing to rise
- At home methods allow patients to have flexible and more consistent dialysis sessions...
- But also leads to peritonitis (infection of the peritoneum)
  - Hospitalization costs are \$100 USD million annually<sup>1-3</sup>
  - 4-10 days to begin treatment<sup>4-5</sup>
  - Longevity decreases from 10 years to 2 years<sup>6-7</sup>

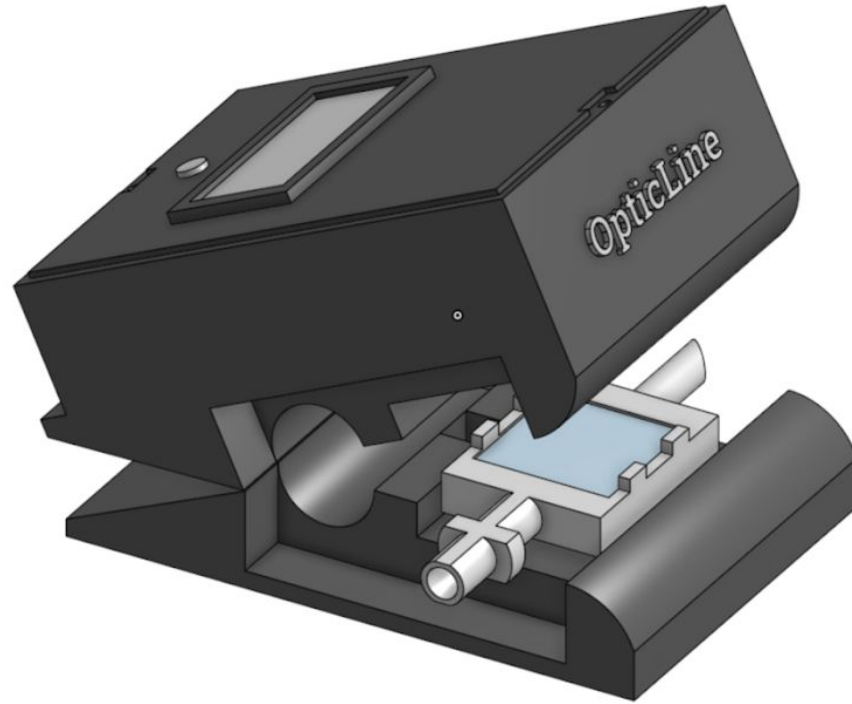
# Device Overview



# OpticLine

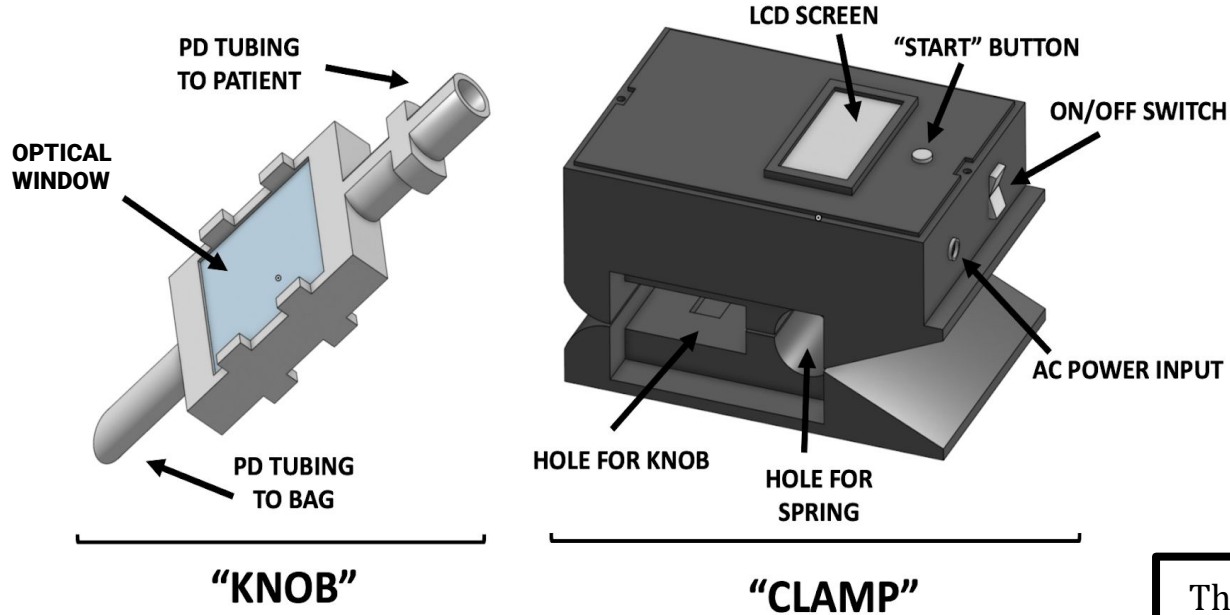
OpticLine uses a noninvasive optical method to detect early indicators of infection in peritoneal dialysis effluent fluid.

# Device Overview



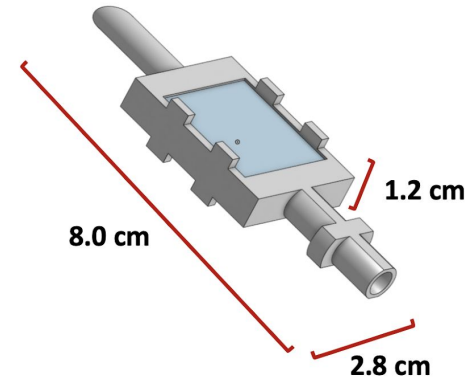
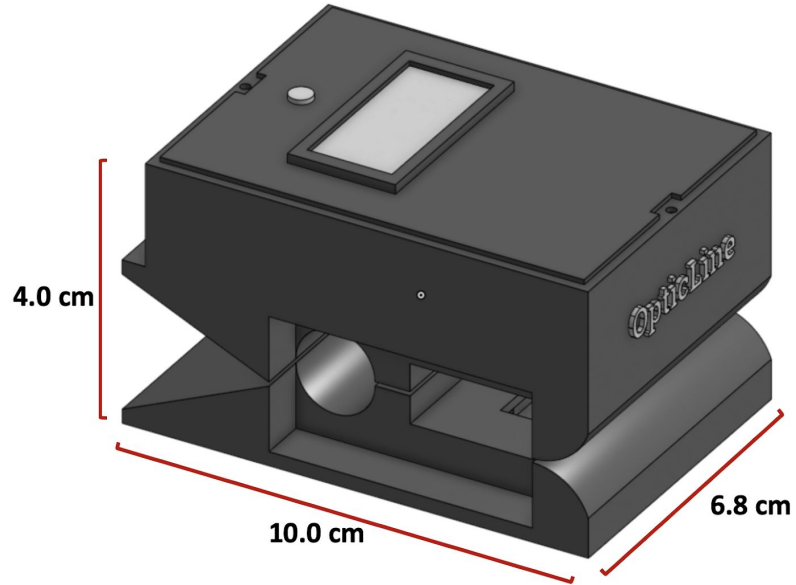
The “knob” fits in line with the drain line using existing male/female connectors, and the “clamp” clamps externally over the knob.

# Device Components



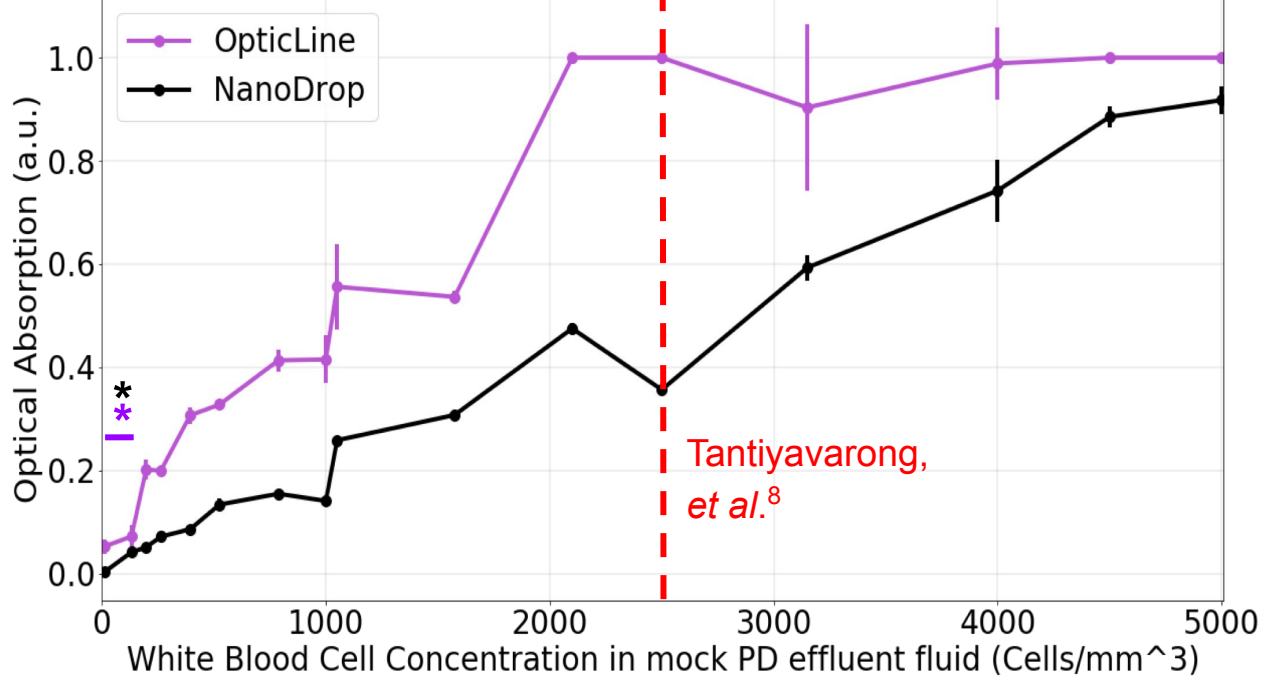
The "knob" fits in line with the drain line using existing male/female connectors, and the "clamp" clamps externally over the knob.

# Device Dimensions



# Optical Absorption Data: Mock Effluent Fluid

Comparing Optical Absorption of OpticLine prototype and NanoDrop 2000



Our initial testing showed that the OpticLine had comparable absorbance detection to the NanoDrop, the current standard for optical absorbance measurements. Both were able to detect a significant difference between normal and infected samples in mock PD effluent fluid.

# Existing Solutions



Cost

PERiPLEX<sup>®</sup>

**OpticLine**

**OpticLine**

Patient Compliance



# Go-to-Market Strategy & Business Model

- Provisional patent (US S19-158)
- Using a licensing model
  - Potential partners/investors from KidneyX connections & beyond
- Target market: Medicare
  - New legislation: Patient Access to ESRD New Innovative Devices Act (H.R. 2710)



# Regulatory Pathway

**Class II**

**510(k)**

# Key Stakeholders



PATIENTS



HOSPITALS



INSURANCE

# Timeline

OCT 2019

**IRB Protocol  
Approved**

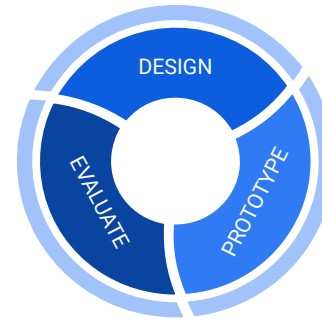
JAN 30, 2020

**Kidney X Phase II  
Submitted**

*Ongoing*

**Continue to  
iterate prototype**

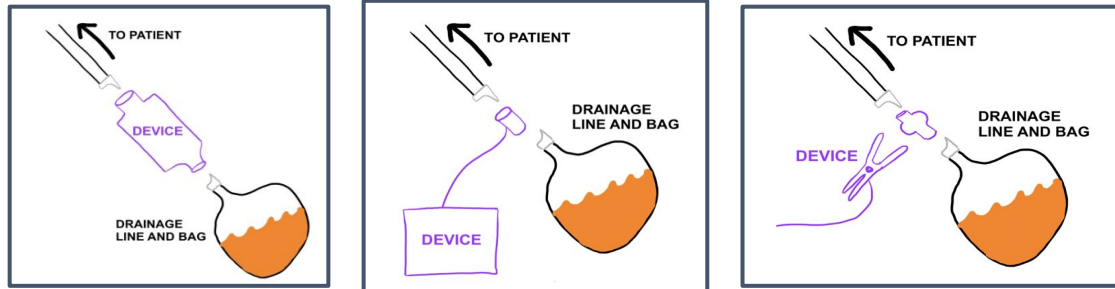
**Connect with  
potential licensees  
& partners**



# Human Factor Study of Peritoneal Dialysis Patients for Device Design

## *IRB Approved*

- For current/past PD patients/caretakers, nephrologists, nurses, etc.
- General questions about PD experience
- 3 prototypes:



- For PD patients at LPCH: shown how to connect, then timed on own
- Virtually: asked how willing to use



<https://forms.gle/2JfPKLWf1inkYzQL>

6

# References

1. ([J Am Soc Nephrol](#)) Jain, et al., J Am Soc Nephrol. 2012 Mar; 23(3): 533–544.
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3. [Becker's Hospital CFO Report](#): “Average cost per inpatient day across 50 states”
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7. [National Kidney Federation](#): “How Long Can I Remain on PD?”
8. ([NCBI](#)) Tantiyavarong, et al., Int J Nephrol. 2016; 6217135.