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## Executive Summary

Approximately 1.7 million hospital-associated infections are acquired each year. Currently, there is no accurate and rapid method for the early detection of infection. Our proposal is the invention a lab-on-a-chip PCT level detection device that displays results in under 15 minutes. The motivation for this project stems from the difficulty in inducing swift, inexpensive, and adequate mixing of immunoassay reagents on the micro scale. Ultimately this product will inform physicians when infections are present or eradicated, and will limit the use of antibiotics to cases of actual infection.

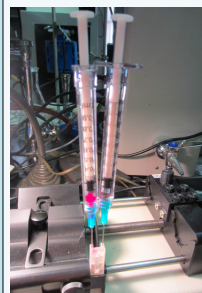
## Clinical Need

PCT is a good marker of bacterial infection that has recently been introduced into clinical practice in the U.S. It is currently measured in the hospital central laboratory, usually once per day. This practice commonly misses the early stage of infection, allowing rapid worsening prior to therapy. PCT levels can differentiate between inflammation, post-surgical response, and infection. Lab-on-a-chip devices at the bedside have the potential of continuously monitoring for new infections as well as the resolution of prior ones.

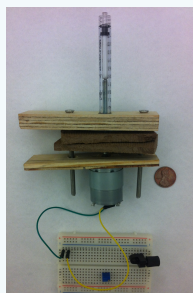
## Description of Market

- Health care associated infections lead to 99,000 deaths in the United States annually.
- \$28-\$45 billion medical cost from health care associated diseases annually.
- Surgical site infections cause about 17% of all hospital acquired infections. After discharge this number increases to 47%-84%.
- 75,000 patients suffer from sepsis in the United States each year and 20% die from health associated infections (HAI).

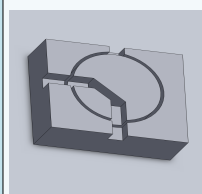
## Description of Design



The mixing chamber



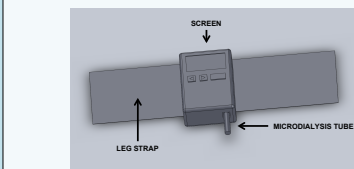
The Pumps



The Switches



LED & Photodiode



Overall Device

### The mixing chamber

- Maximizes the turbulence of the flow
- Has small cross-sections along the detection channel that allow the mixer to maximize the amount of fluidic "shuffling"
- Disposable
- Symmetric, which allows for easier manufacturing

### LED & Photodiode with fiber optics

- High intensity for easy detection of fluorescence
- Embedded in mixer or separate detector
- LED / photodiode and embedded system controller obtain measurements

### Pump

- Larger syringe-pumps
- A screw that drives the plunger of the syringe into and out of the syringe tube
- Low power, cost effective
- 3 $\mu$ L accuracy, could be enhanced

### Liquid storage containers & connecting tubes

- Storage for reagents
- Can be removed & replaced

### Switches

- Switch between the storage containers and the mixer-detector setup

## Novelty of Concept

Our device is novel because there is no such device that adequately and quickly mixes fluids at the micro level, has the ability to perform multi-stage, repetitive mixing, and is able to adjust mixing volumes.

This device prevents the contents of the fluid from getting damaged, and provides a mixing chamber that is removable and replaceable. Additionally, it is easy and cheap to manufacture.

## Estimated Cost

Current Medicare Reimbursement (per use): \$28.30

Non-disposable	Disposable (30 uses)
1ml syringe: \$0.15 * 2 = \$0.30	Single use:
Motor: \$ 0.20 * 2 = \$0.40	Glass capillary tube: \$0.10
Tubing: 10cm * \$0.01/cm = \$0.10	Mixing Chamber: \$0.02
Internal Reflective tubing: 10cm * \$2.00/cm = \$20.00	Multiple use:
Blue LED: \$0.05	Reagent 1 of Assay: \$100.00
Photodiode: \$0.01	Reagent 2 of Assay: \$100.00
Printed Circuit Board: \$2.00	Cleaning Materials: \$5.00
Screen: \$1.20	
Plastic Casing: \$2.00	
PCB Support Screws: \$0.01 * 4 = \$0.04	
Internal Support Screws: \$0.01 * 10 = \$0.10	
Wall Wiring: 1m * \$0.20/m = \$0.20	
Wiring: 10cm * \$0.01/cm = \$0.10	
Manufacturing (extrusion, building, etc.) = \$4.00	
<b>Subtotal: \$32.59</b>	<b>Cost per use: \$6.95</b>

## Anticipated Regulatory Pathway



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