Efficacy of a Novel Catheter Connector System with UV Sterilization Module

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Introduction/Background

Problem: Catheter related bloodstream infections (CRBSIs) from IV catheters via intraluminal route are particularly difficult to prevent. CRBSIs lead to increased hospital costs and longer patient stays.

Needs: Reduce rate of CRBSIs, caused by recontamination of the lumen. Must continuously sterilize fluid flowing through catheter before it enters the bloodstream. Also must have minimal interference with existing hospital equipment

Market Analysis

IV Catheter* Market Size was USD 8.6 billion in 2022. It is Expected to reach USD 17.8 billion in 2032, with a **CAGR:** 7.5% from 2023 to 2032. **Primary Stakeholders:** Hospital Administration, Doctors, and Nurses

Mission Statement

Reduce the risk of IV catheter related bloodstream infections (CRBSIs).

Lumenous Technologies

Concept

Catheter Connector System Featuring Integrated UV-Sterilization Module, based on Team's Clinical Mentor's patent [1].

Fluid passes through the catheter into the connector system, which uses UV-C radiation to sterilize the fluid before entering the bloodstream, reducing the risk of CRBSIs

Core Features

- UV-C radiation sterilization
- Compact design
- Compatible with standard IV tubing and catheters

Design Specifications

- Dimensions [5cm length and 2.5 cm diameter]
- Weight [59 g or 0.125663 lb.]
- UV-C/UV-A wavelengths [270-280nm & 395-400nm]
- power output [18 W, 3 A & 12V AC]
- Implements Luer lock adapters
- Compliant with all standards and regulations

Technical Model Description	Model Equation
UV-C Sterilization Dosage Model	$(Dosage) = t \cdot (Intensity)$ $(Intensity) = \frac{P_{effective}}{A}$
Power Formulas	$P_{effective} = \frac{T \cdot P_{LED} \cdot A}{\pi(d_{LED} tan(\theta))^2}$ $P_{LED} = P_{electrical} \cdot \eta_{LED}$ $P_{electrical} = IV$
Fluid Flow Model (Poisuille's Law) (Flow Rate Definition)	$Q = \frac{\pi \Delta P r^4}{8\eta l}$ $Q = \frac{V}{t}$
UV-C Transmittance Model	$T = T_{air} \cdot T_{quartz} \cdot T_{fluid}$
Combined Model	$(Dosage) = \frac{8\eta l L R^2 (P_{LED}) T}{\pi^2 r^4 \Delta P (d_{LED} tan(\theta))^2} \geq 12 \frac{mJ}{cm^2}$ In terms of Residence time (t = Volume/Q) $(Dosage) = \frac{\pi R^2 L (P_{LED}) T}{Q (d_{LED} tan(\theta))^2} \geq 12 \frac{mJ}{cm^2}$

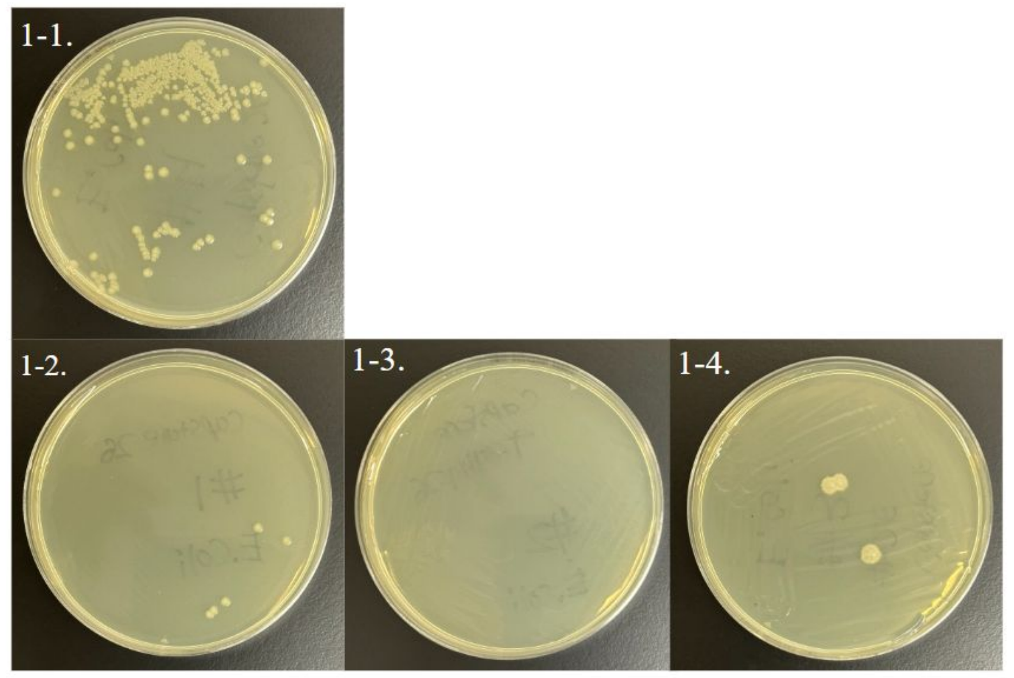
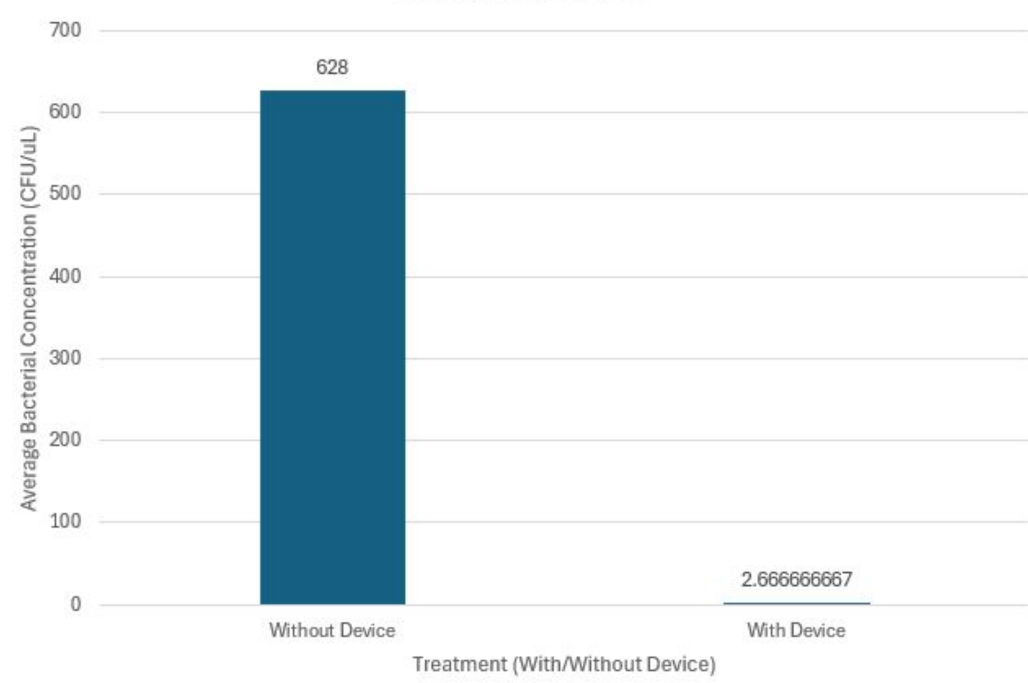
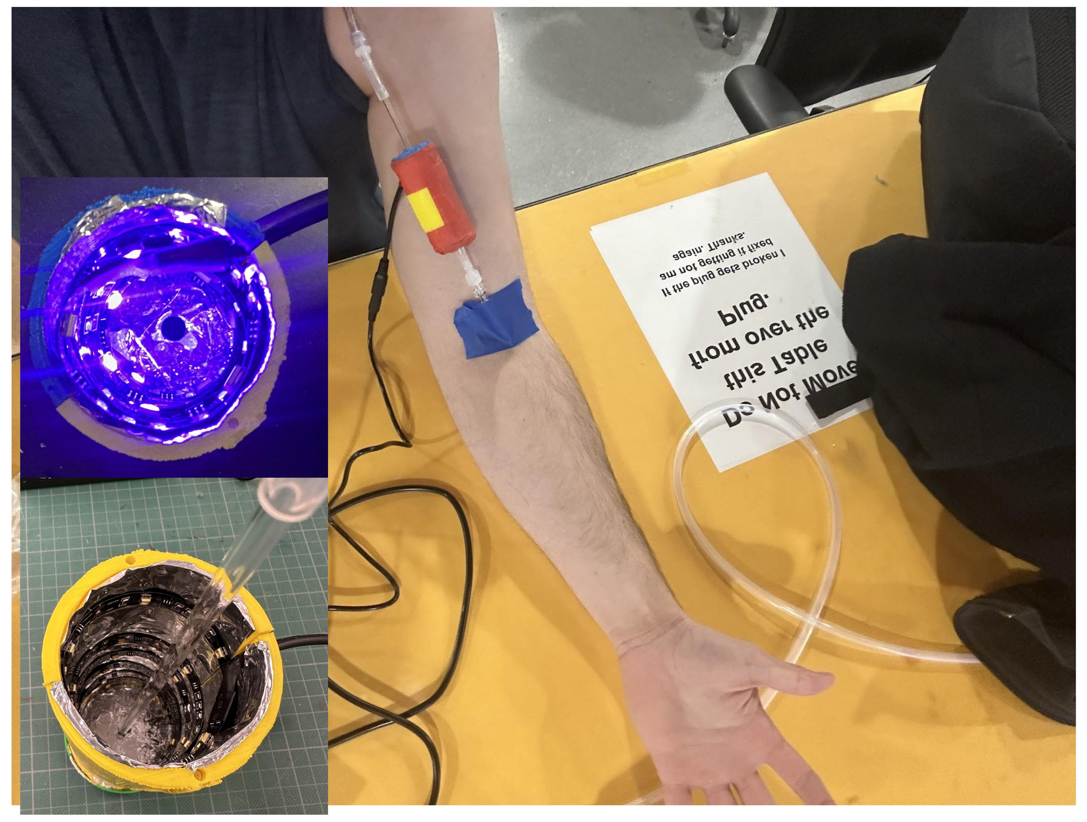


Figure 1: Average Bacterial Concentration in Output IV Fluid With and Without Device





Customer Needs

- Limit hospital acquired infections
- Effective sterilization of fluid flowing into bloodstream via catheter lumen
- Easy to integrate into existing hospital workflows
- Limited UV radiation exposure
- Efficient sterilization procedures

Metrics

UV-C LED Wavelength, LED Efficiency, UV Light Power, Biocompatibility, Sterilization Time, Durability, Weight, Cost per Unit, UV Module Lifespan, Assembly Time

Regulatory Pathway

- Class II Medical device (catheter)
- No definitive predicate device on the market
- De Novo pathway required for UV efficacy
- Special controls testing for UV module

Experimental Procedure

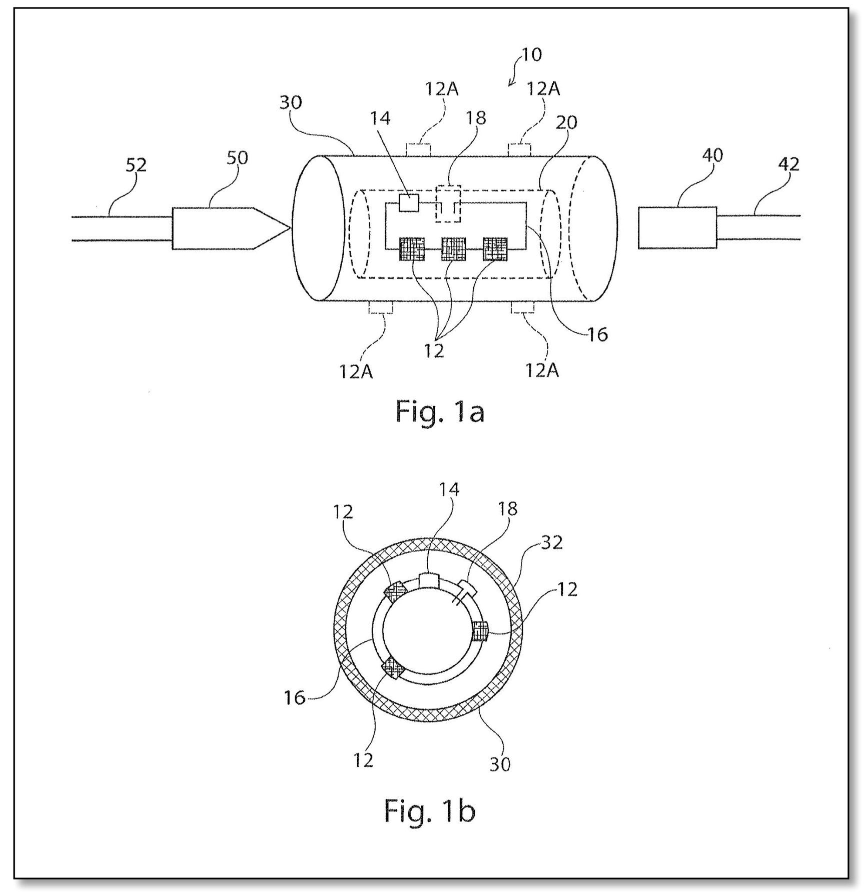
An IV saline bag inoculated with E. coli was connected to the prototype, allowing fluid to flow through the UV-C chamber and into a sterile petri dish via a sterile 20G catheter needle. The control group bypassed the device entirely.

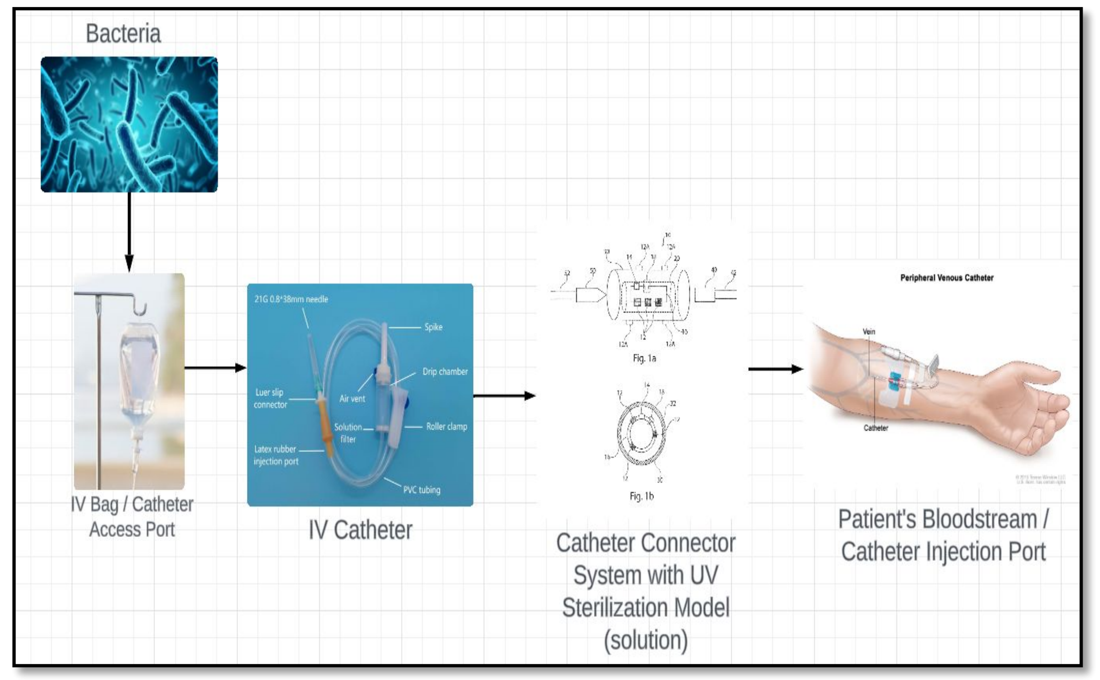
After collecting approximately 20 mL, samples were streaked on agar plates with 1 µL inoculating loops and incubated at 37.5°C for 24 hours. The number of colony-forming units (CFUs) was recorded post-incubation to assess the sterilization effectiveness.

To avoid cross-contamination, all internal tubing and adapters were replaced between trials.

Project Planning/Timeline

✓Research & Development
✓Design & Prototyping
✓Testing & Validation
Manufacturing Preparation
Regulatory Approval & Market Launch





Acknowledgments

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Works Cited

1. Cohen, G. A., & Cohen, M. P. (2019,April 2). UV sterilizing catheters and catheter connectors.