

UV Disinfection Device for Central Line Hubs

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PROBLEM AND NEED

- Central Line-Associated Bloodstream Infections (CLABSI's) occur when bacteria enter the bloodstream via a central line [1].
- Nurses have techniques to prevent central line infections, including the industry-standard Scrub-the-Hub technique (Figure 2) [2].
- Infections result from lack of compliance in Scrub-the-Hub due to human error and poor adherence to workflow protocols.
- 40,000 CLABSI's occur annually, costing hospitals ~\$1.9B in costs each year [3].
- 65-70% of CLABSI's are completely preventable with proper disinfection procedure [3].

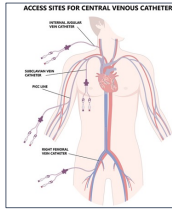


Figure 1: Central Line Access Ports [1]

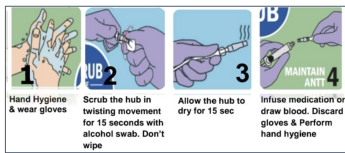


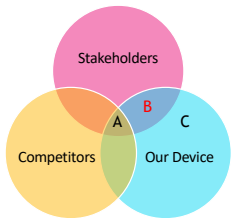
Figure 2: Scrub-the-Hub Technique Protocol

Need Statement

Hospital nurses need a quick, reliable, and user-friendly system to disinfect central lines to maintain adherence to proper protocols and reduce infection risk in patients.

DESIGN INPUTS & VALUE PROPOSITION

Functional Requirements	Design Constraints
Thoroughly and properly disinfects central lines	Does not cause undue harm to patients or users
4-log reduction (EPA OCSPP 810.2200)	$<400 \mu\text{W}/\text{cm}^2$ of exposure over 15s (ISO 15858:2016)
Indicates proper central line disinfection	Does not impede hospital workflows
	Able to be handheld
	Affordable for purchase



- A: Points of Parity
- Disinfects central lines
- B: Points of Difference
- System functions in under 30 seconds
 - System is easily reusable between patients
- C: Points of Irrelevance
- Monitoring system for completion of disinfection

FINAL SOLUTION

Why UV-C Disinfection?

- We are using UV-C LEDs for their efficacy in disinfection.
- DNA and RNA strongly absorb 260nm (UV-C) incident light.
- The high-energy light creates nitrogenous base lesions, distorting the helix structure and blocking transcription and translation.

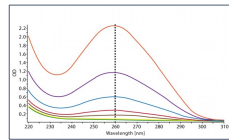


Figure 3: UV-C Absorption at Different Frequencies [4]

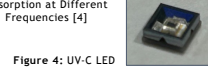


Figure 4: UV-C LED

Electrical Design

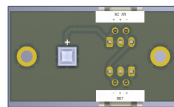


Figure 5: UV-C LED PCB

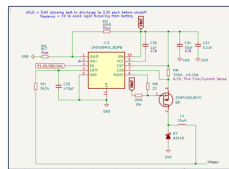


Figure 6: Schematic of UV-C Driver

- UV-C LED PCB Board
Proper powering, safety and maneuverability of LED's
- nRF54L15 MCU
- Current-limiting Elements
Protect UV-C LED's from excess power
- Buzzer
Auditory notification to nurses



Figure 7: Assembled PCB Boards

Mechanical Design

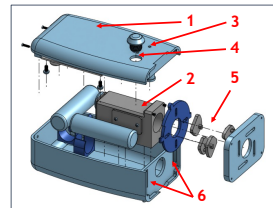


Figure 8: Exploded View of Mechanical Assembly

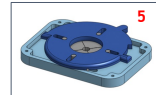


Figure 9: Opening Aperture Assembly

- Resin-Printed Casing
Prevents UV-C light leakage
- Disinfection Chamber
Catheter Inserted Here
- RGB LED
Flashes different colors during sanitation and errors
- Activation Button
- Opening Aperture
Seats around Catheter to prevent light leakage
- Safety Interlocks
Prevent light leakage in case of premature opening

Assembled Device



Figures 10-12: Final Assembled Prototype in Open (without catheter) and Closed (with catheter) States

TESTING

Functional Requirement - Germicidal Effectiveness

DH5α bacteria was incubated, seeded, and adhered to catheter hubs at room temperature. Hubs (n=3 replicates per group) were irradiated with UV-C or room light at 0 hours, 2 hours, and 4 hours to quantify UV-C disinfection capacity. Catheter hubs were vortexed to retrieve bacteria, and CFU counts were determined by 10-fold serial dilution and incubation: measuring an overall 4-log reduction.

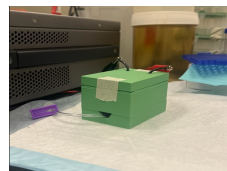


Figure 14: Enclosure for UV-C LED Irradiation of Catheter Hub

Constraint - UV Light Safety

Based on the aperture size, LED optical power, and ISO 15858, a safe shutoff time of 450 ms was determined for the interlocks. Ten (n=10) trials of initiating the device, forcing an error state, and slow-motion frame capture determined a mean shutoff time of 17 ms, successfully satisfying and exceeding the constraint.

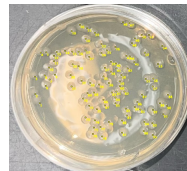


Figure 15: ImageJ CFU count of Serially Diluted LB Agar Plate

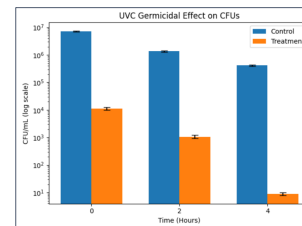
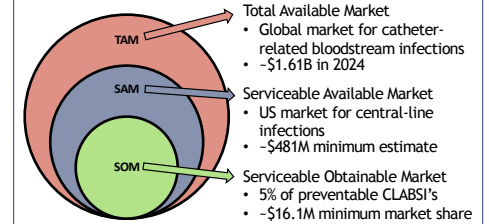


Figure 13: Germicidal Effectiveness of UV-C LED

Table 1: Prototype Testing Quantitative Values

Pertinent Quantity	Value
Device Weight	204 g
UV-C LED Optical Power	2.49 ± 0.047 mW
UV-C LED Bandwidth	262.9 - 273.2 nm
Rapid Shutoff Time	17 ± 2 ms (<450 ms)
Germicidal CFU Reduction	4-log Reduction

MARKET AND REGULATORY PATHWAYS



The CLAB-Free device will be classified as a CLASS-II device with the FDA due to the inherent risk with ultraviolet light and the nature of catheters being in the body.

510(k) - Preferred

If determined to be similar enough to UV-surface-disinfecting devices, the CLAB-Free could undergo a 510(k) pathway to become FDA approved.

De Novo

If the use of disinfection through catheter tubing causes a novel use case, the CLAB-Free could undergo a "De Novo" pathway to become FDA approved.

CONCLUSION AND FUTURE STEPS

- Our device is successfully able to disinfect central line hubs using UV-C light in the germicidal range at a proper intensity and time range.
- It prioritizes patient safety, turning off if not properly closed to prevent unwanted exposure to UV-C light.
- Our device is incredibly portable and able to be operated with one hand, increasing ease of use for nurses.

Next steps include nurse usability testing, creation of docking stations for recharging and ease of location, redesign of the device chamber to be autoclavable, and testing of the device disinfection against Scrub-the-Hub practices, both proper and improper.

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- [1] Cambridge Vascular Access. (n.d.). What is a central venous line? <https://cambridgevascularaccess.com/what-is-a-central-venous-line.php>
- [2] Centers for Disease Control and Prevention. (2013). Hemodialysis central venous catheter (CVC) scrub-the-hub protocol. <https://www.cdc.gov/dialysis-safety/media/pdfs/Hemodialysis-Central-Venous-Catheter-STH-Protocol-P.pdf>
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- [4] BMG LABTECH. (2014, December). UV absorbance DNA quantitation. <https://www.bmglabtech.com/en/application-notes/uv-absorbance-dna-quantitation/>