Central Line-associated Bloodstream Infections (CLABSI) Prevention Device

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Table of Contents

1. Problem Definition

1.1. Background

Central-line-associated bloodstream infections (CLABSI’s) are infections associated with central lines. Central lines are critical in most patients to quickly and effectively deliver medications. However, through failures and lack of sterility in either the insertion of a central line, sterilization of a hub connection, contamination of a central line dressing, or prolonged use of the device, infection can be introduced.

1.2. Consequences

CLABSI’s can cause severe infections in otherwise completely healthy patients, putting undue burden on them and their families and prolonging their hospital visit more than necessary. This can also put financial strain on the families. Many of the caused infections are also life-threatening with high mortality rates. The hospitals themselves also have to commit resources to treat these preventable illnesses, causing strain on staff and affecting the regulatory

scores and metrics of the hospital itself. CLABSI's, because they are preventable, directly impact quality metrics of a hospital.

1.3. Statistics

A 2009 study reports that roughly 40,000 CLABSI's occur annually in the United States (Zimlichman 2013), and CLABSI's are estimated to cost hospitals $1.9 billion annually (Larsen 2019). Mortality among patients diagnosed with CLABSI is also high, with extra attributable mortality estimated between 14% and 16% (Larsen 2019). Among these CLABSI's, it is estimated that 65-70% of the infections are preventable with proper precautions (Larsen 2019).

1.4. Deficit

Currently, the problem is known, but workflow barriers, lack of time in emergencies, and human error cause a lack of adherence to the proper protocol of sterilization. Efforts have been made to bundle central lines together, and the technique of scrubbing and drying for thirty seconds is in place, but nurses report that that technique is very long, and such a technique lacks the proper accountability measures to ensure it happens every time.

2. Need Statement

Medical professionals need a quick, reliable, and user-friendly system to properly sterilize central lines to maintain adherence to proper protocols and reduce infection risk in patients.

3. Disease State Fundamentals

3.1. Anatomy (Form)

Central venous access is notably obtained via the internal jugular, subclavian, and femoral veins.

The internal jugular vein collected blood from the head, face, neck to the superior vena cava. It travels with the common carotid artery and vagus nerve within a carotid sheath. The right internal jugular vein is preferred for central venous access because it makes a straight line from the brachiocephalic vein to the superior vena cava; however, the left internal jugular vein is still usable because it follows a more acute angel as it joins the left innominate and again as the innominate joins the superior vena cava. The mean diameter of the vein is 10 mm with a range between 5 and 35 mm. The Trendelenberg position can increase the size of the internal jugular to facilitate cannulation. The internal jugular is easily accessed at the apex of the Sedillot triangle (shown below).

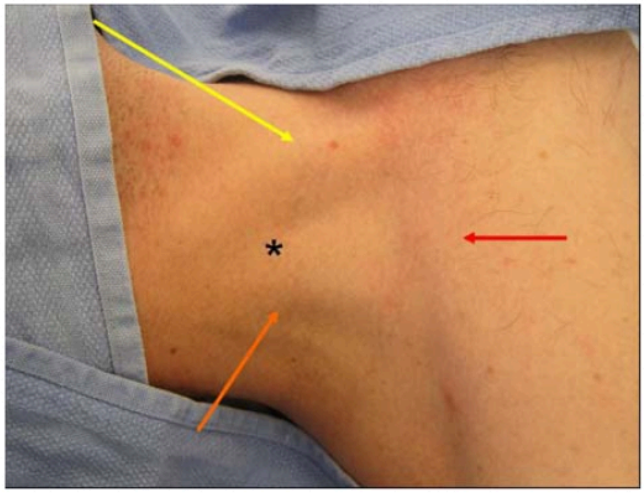


Figure 1: Sedillot Triangle and IJ cannulation site (Bannon, 2011).

The subclavian vein is a large, paired vein responsible for draining the blood from the bilateral upper extremities. It joins the internal jugular vein to form the innominate (brachiocephalic) vein. The Trendelenburg position also facilitates cannulation by increasing the diameter and by minimizing the risk of venous embolus formation. It is accessed 1 to 2 cm inferiolateral to the clavicular transition point (the flat later two-thirds of the clavicle). The danger with this site is the risk of puncturing the pleura and subclavian artery.

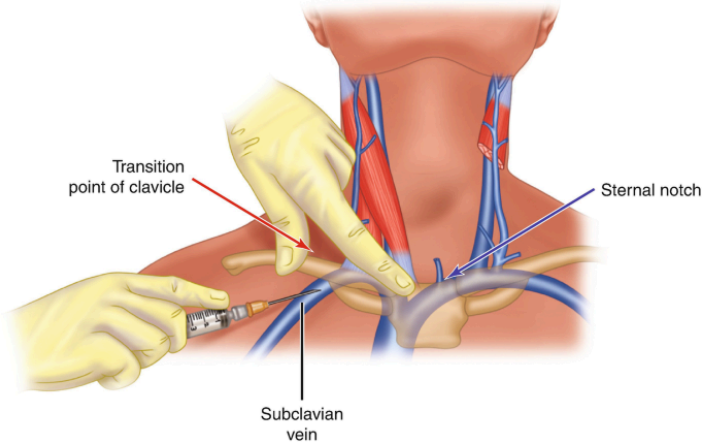


Figure 2: Subclavian access (Amankwah, 2015).

The femoral vein is also a large, paired vein that drains the lower extremities. It travels medial to the femoral artery in the femoral sheath. The femoral vein continues from the popliteal vein and begins at the adductor hiatus muscle within the adductor magnus muscle. Access for central venous catchers occurs at the common femoral vein, located halfway between the anterior superior iliac spine and pubic symphysis. This site is favored during emergent placement, especially during CPR and intubation. Femoral access has been associated with a higher risk of CLABSI.

3.2. Physiology (Function)

The bloodstream is a sterile compartment. Microbial protection primarily depends on the skin barrier and the innate immune system. Pathogenic colonization is prevented by the following: keratinized epidermis, antimicrobial peptides in the dermal layer, and flora on the skin surface.

The innate immune response includes neutrophils, macrophages, the complement system, and cytokines. The introduction of a catheter alters the immune response however as phagocytes, cytokines, and relevant compounds cannot easily enter the biofilm which develops on a catheter. Within minutes of insertion, plasma proteins bind to the catheter materials (silicone, polyurethane) and facilitate microbial adherence (Donlan, 2001).

In normal cases, blood clots in response to damage to endothelial cells lining the blood vessels. However, blood clots can also occur in cases of turbulent flow and blood stasis which can be seen in improperly placed catheters that damage the blood vessel lining or alter blood flow to flow below physiological levels and form a thrombus.

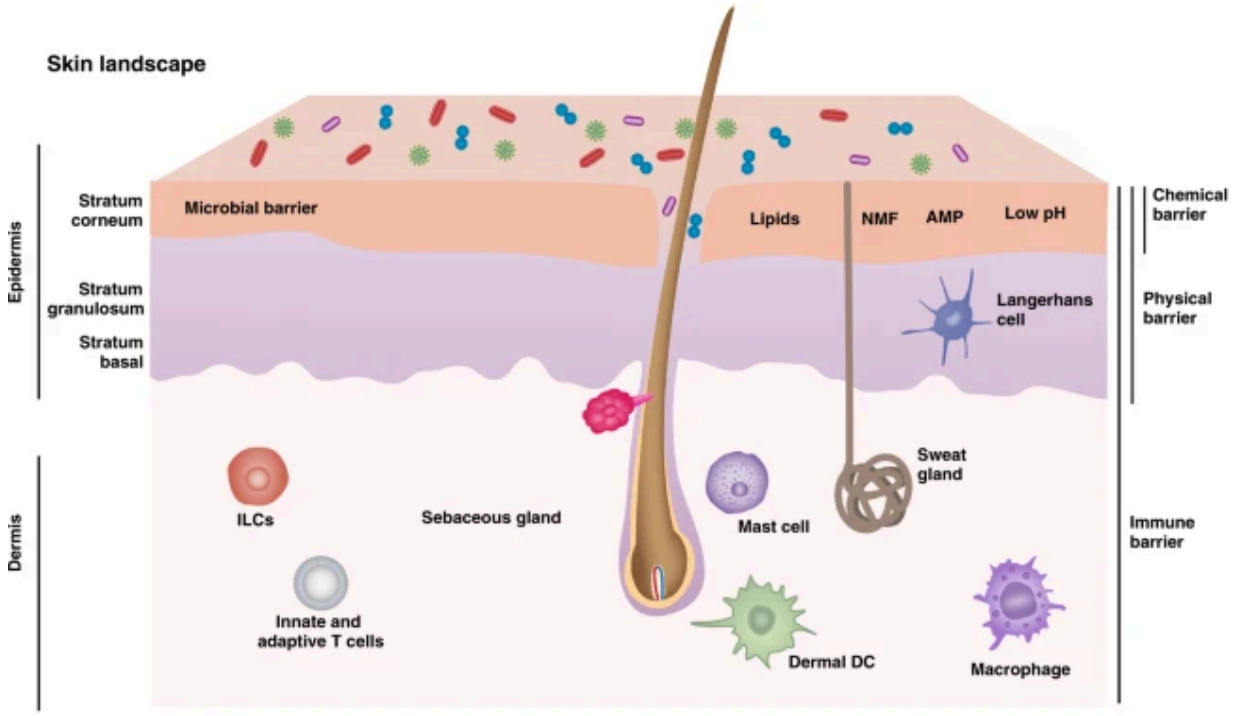


Figure 3: Skin immunity (Zhang, 2022).

3.3. Pathophysiology (Failure Modes)

CLABSIs arise from extraluminal spread, intraluminal spread, contaminated infusates, and hematogenous spread. The dominant route of infection is extraluminal spread. Contaminated infusate and hematogenous spread are rare events (Safdar, 2004).

Extraluminal spread denotes the migration of organisms from the skin insertion site along the external catheter surface, exacerbated by compromised dressing and securement. Extraluminal spread can be mitigated by tunneled central venous catheters (CVCs) and is also responsible for immediate infections (on the scale of 0-10 days relative to the insertion date).

Intraluminal spread occurs when the internal lumen of the catheter becomes contaminated, often as a result of improper handling or inadequate hub disinfection. This pathway is more frequently responsible for infections that develop after 10 days of catheter use. Strict adherence to hub disinfection protocols and aseptic technique during line access are key preventive measures to minimize intraluminal contamination.

Contaminated infusates represent another potential source of CLABSI. This mechanism involves the introduction of pathogens through contaminated intravenous fluids, parenteral nutrition, or other infused substances. Although relatively rare in high-resource healthcare

settings, this route of infection is more commonly observed in lower-income regions where sterility assurance and supply chain oversight may be limited.

Hematogenous spread occurs when an existing bloodstream infection in another part of the body seeds the catheter, allowing organisms to colonize the internal or external surfaces of the line. This mechanism highlights the bidirectional relationship between systemic infection and central line colonization, underscoring the importance of vigilant infection control practices throughout a patient's clinical course.

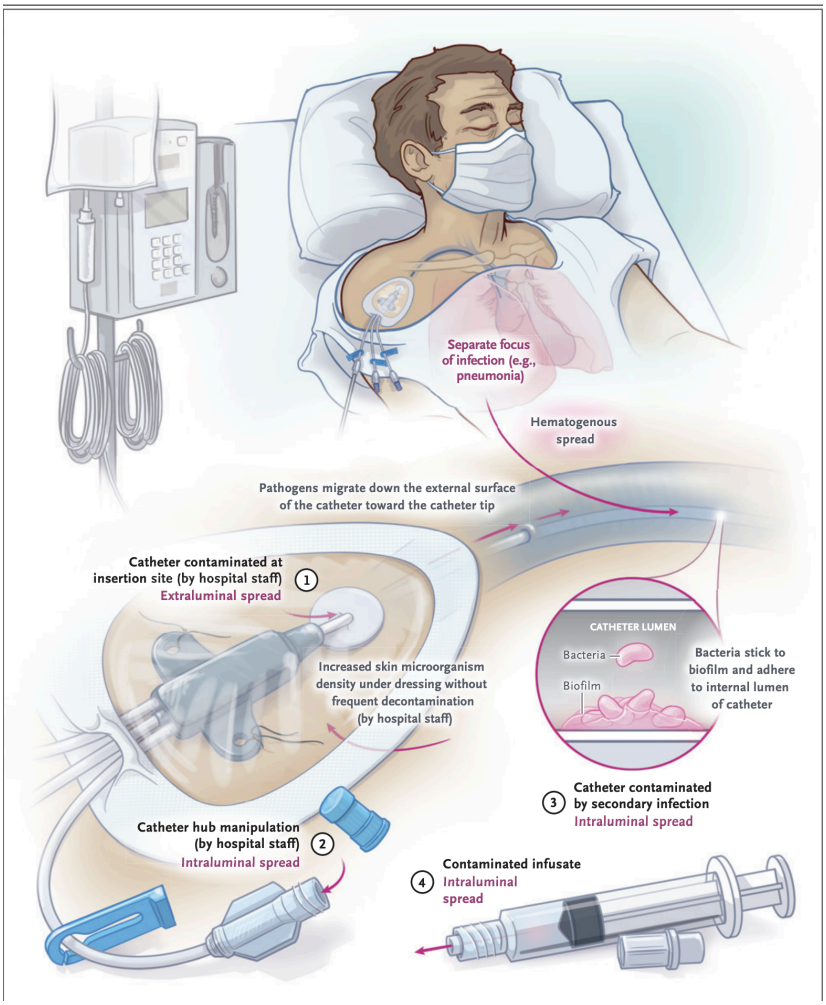


Figure 4: Infection Methods for CLABSI (O'Grady, 2023).

A critical feature of CLABSI development is biofilm formation. After insertion, catheters develop a fibrin-protein matrix that promotes microbial colonization by facilitating adhesion.

(Mehall, 2002). Biofilms are resistant to antimicrobials, making infections difficult to treat and often necessitating catheter removal. Biofilms render microbes more resistant to antimicrobials

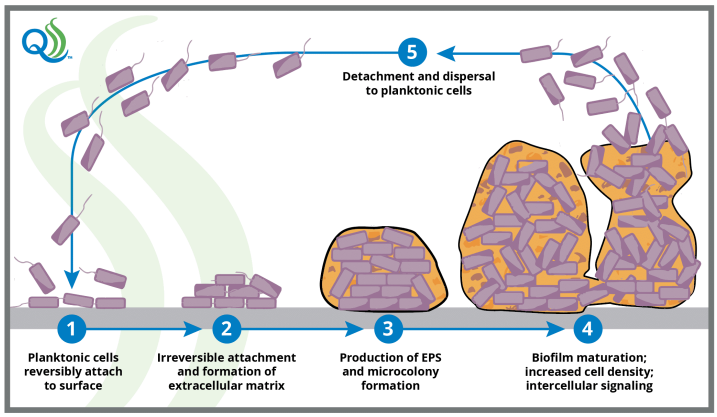


Figure 5: Biofilm formation process (QualiTru Sampling Systems, 2025)

The most common pathogens in CLABSI cases are bacterial or fungal and are as follows:

1. Gram-positive bacteria: *Coagulase-negative staphylococci (34.1%), Enterococci (16%), Staphylococcus aureus (9.9%)*.

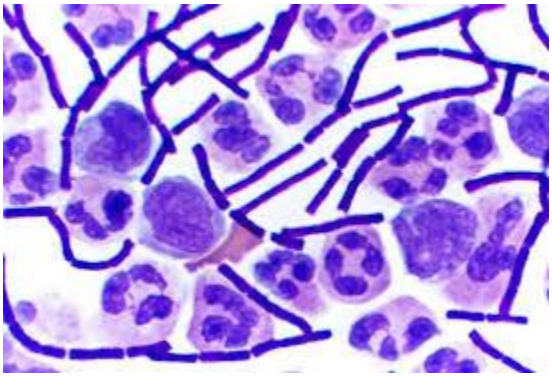


Figure 6: Gram-positive bacteria (Sizar, 2023).

2. Gram-negative bacteria: *Klebsiella (5.8%), Enterobacter (3.9%), Pseudomonas (3.1%), E. coli (2.7%), Acinetobacter (2.2%)*.

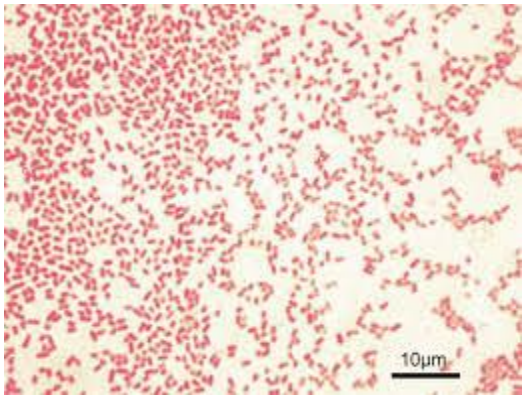


Figure 7: Gram-negative bacteria (Freda 2025).

3. Fungal pathogens: *Candida spp.* account for ~11.8%.

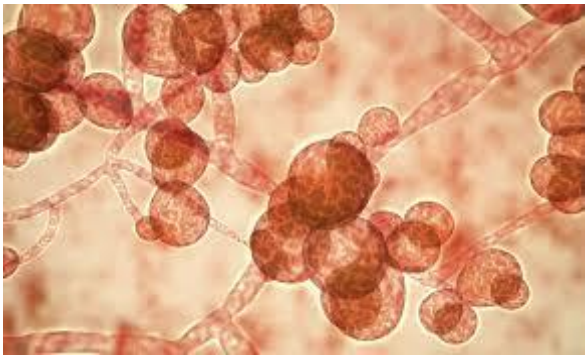


Figure 8: *Candida spp.* (Soliman, 2023)

4. Organisms such as *MRSA* and *Pseudomonas* are associated with high virulence and resistance (Haddadin et al., 2022).

3.4. Risk Factors

The likelihood of developing a central line–associated bloodstream infection (CLABSI) is influenced by a variety of clinical, procedural, and patient-related factors. These risk factors encompass both controllable elements—such as the technique, site, and maintenance practices used during catheter insertion—and intrinsic patient characteristics, including immune status and underlying comorbidities. Understanding these variables is essential for reducing infection incidence, optimizing care protocols, and guiding preventive strategies.

The risk factors we determined were:emergency

- Emergency vs. elective insertion
- Clinician skill and experience
- Insertion site
    - subclavian < jugular < femoral for risk
- Skin antisepsis quality
    - chlorhexidine preferred (possible carcinogen)
- Catheter lumens
    - single-lumen safer
- Duration of catheterization
    - Longer = Greater risk
- Barrier precautions during insertion
- Ongoing maintenance and hub care
- Immune compromised patient & presence of comorbidities in patient

3.5.Presentation (Signs of Failure)

CLABSI typically presents with clinical signs of infection such as fever, chills, altered mental status, and hypotension. However, a diagnosis of CLABSI must be confirmed through a laboratory bloodstream infection assessment and must meet specific criteria, including the presence of a central line for more than two consecutive calendar days and the identification of an organism not related to an infection at another site (CDC, 2025).

Sensory assessment of the central line involves both visual and tactile evaluation (Herrera, 2024). Visually, the clinician compares the skin around the central line to nonimpacted skin, identifying subtle differences such as erythema, shine, or tautness. Through palpation, the clinician assesses the texture, firmness, warmth, and tenderness of the affected area and compares it to unaffected skin to detect abnormalities.

Once an adequate blood culture sample from the central line has been obtained and localized signs of infection are observed, as indicated in the sensory assessment, the next steps involve either removal of the central line or initiation of empiric antimicrobial therapy, such as vancomycin (Mermel, 2009).

Removal of the central line is considered when the patient exhibits severe sepsis, endocarditis, a bloodstream infection that persists despite more than 72 hours of appropriate antimicrobial therapy, or infections caused by gram-negative bacilli or *Staphylococcus aureus*. Removal becomes necessary when infections are due to mycobacterial or fungal pathogens, when a tunnel site infection with erythema and purulent drainage is present, or in cases of suppurative thrombophlebitis, which involves infection of a blood clot accompanied by inflammation and pus formation.

3.6. Clinical Outcomes (Consequences)

CLABSIs lead to prolonged hospitalization, increased risk of rehospitalization, decreased quality of life, substantial morbidity and mortality, and sequelae (negative long-term effects from a disease or condition occurrence). The outcomes are dependent on the infection-causing pathogen, patient, catheter characteristics, and delay around infection, diagnosis, and intervention. Additionally, CLABSIs drive antibiotic use and thus antimicrobial resistance, especially due to the inclusion of pathogens such as MRSA (multidrug-resistant Gram-negative bacilli) and VRE (vancomycin-resistant enterococci) (Sievert, 2013). Furthermore, fungal CLABSIs, notably *C. auris*, are major threats that increase patient and hospital burden due to its high resistance to strong antifungals like azoles and echinocandins (Bidaud, 2018).

Hospital stays for CLABSIs were prolonged to an average of 10 days with a range of 7 to 15 days, placing a significant burden on patients and hospitals. A subset of these CLABSIs which were caused by MRSA prolonged hospital stay to an average of 16 days with a range of 8 to 37 days (Zimlichman, 2013).

3.7. Epidemiology (Stats)

- "Although a 46% decrease in CLABSIs has occurred in hospitals across the U.S. from 2008-2013, an estimated 30,100 central line-associated bloodstream infections (CLABSI) still occur in ICUs and wards of U.S. acute care facilities each year" (CDC, 2025).
- 9.8/1000 central-line days rate for CLABSI in medical/surgical ICUs and (Hung, 2018).
- Estimated 67% of CLABSIs were preventable. (Hsueh, 2022).
- At-Risk Populations: ICU patients, neonates, oncology patients, hemodialysis patients, and those with emergent ED-inserted lines face the highest risks, patients with comorbidities

Table 2. Epidemiology of Health Care–Associated Infections Among US Adult Inpatients (Including ICUs) at Acute Care Hospitals, 2009[a]

Health Care-Associated Infection Type	Incidence Rate	Population at Risk	Cumulative Incidence
Surgical site infections	1.98[b]	8 020 658	158 639
MRSA	0.29[b]	8 020 658	23 417
Central line-associated bloodstream infections	1.27[c]	31 695 922	40 411
MRSA	0.21[c]	31 695 922	6638
Catheter-associated urinary tract infections	1.87[c]	41 115 000	77 079
Ventilator-associated pneumonia	1.33[c]	23 392 785	31 130
Clostridium difficile infections	3.85[d]	34 716 079	133 657
Total health care-associated infections	NA	NA	440 916

Figure 9: Incidence Rate of Health Care-Associated Infections (Zimlichman, 2013).

3.8. Market Analysis and Economic Impact

The TAM (Total Addressable Market) was taken to be the global treatment market for all catheter-related bloodstream infections. This market was valued at $1.61 billion in 2024 and is projected to reach ~$2.65 billion by 2034. (Precedence Statistics, 2024).

The SAM (Serviceable Available Market) can then be narrowed down to the market for central-line-associated infections in just the United States. With an estimated number of 30,100 CLABSI's occurring in the US every year and each adding an estimated $16,000-$45,000 in direct hospital costs (Zimlichman et al., 2013), a minimum estimate of the SAM is $481.6 million per year for the United States.

Of this market, an estimated 67% of CLABSI's are preventable. Within this range of preventable CLABSI's, several other companies exist in the space, such as 3M, Becton Dickinson, Citius Pharmaceuticals (Mino-Lok®), CorMedix, TauroPharm, Fresenius Medical Care, and Baxter International. Given the wide range of potential device functions, we could aim for 5% of the market share for CLABSI prevention devices, which would result in a SOM (Serviceable Obtainable Market) of $16.13 million.

In additional costs, CLABSI rates are a CMS quality metric, influencing Medicare/Medicaid reimbursement and accreditation. As of 2014, hospitals in the top quartile for HAI rates face a 1% payment reduction (CMS, 2014).

Outside of CLABSI's, future markets worth exploring would be catheter markets as a whole. The antimicrobial catheter market was valued at 1.5 billion USD in 2025 with projections of 2.76 billion USD in 2034 with a CAGR of 6.9% (Business Research Insights, 2025). For both the central line market and the catheter market, growth is driven by rising catheter use in ICUs, oncology, and dialysis, and regulatory emphasis on infection prevention, especially due to the growing age of population and need for long-term care and management of increasing chronic diseases (Towards Healthcare, 2025).

4. Treatment Overview

The current prevention of CLABSI relies on three main approaches: central line bundles, cap and hub maintenance, and antimicrobial devices and dressings. These strategies work to prevent microbial entry during insertion and maintenance but infection rates continue because of workflow restrictions and inconsistent staff adherence.

4.1. Central Line Bundles

The healthcare industry uses standardized evidence-based central line bundles to decrease the risk of infections that occur during catheter insertion and maintenance procedures. The bundle consists of:

1. Hand hygiene before and after line handling
2. Maximal sterile barrier precautions such as masks, gowns, and gloves
3. Chlorhexidine skin antisepsis at the insertion site
4. Optimal cather site selection
5. Regular review of line necessity and prompt removal when no longer needed

The implementation of the central line bundle decreases the risk of CLABSI but this success is highly reliant on both staff training and consistent adherence. Research indicates that any failure to follow any one of the bundle elements will lead to substantial rise in infection probabilities. The central line bundles create fundamental protection against infections but they fail to prevent post-insertion contamination especially when the line is regularly accessed.

4.2. Cap and Hub Maintenance

The catheter hub functions as the main entry point through which microorganisms can enter the central line. To address this, the "Scrub the Hub" technique has become the standard for hub disinfection. The procedure requires healthcare providers to clean the catheter access port thoroughly with an alcohol or chlorhexidine swab for 15 seconds before allowing it to dry for 5–10 seconds before each access attempt.

The "Scrub the Hub" technique depends on mechanical friction and chemical disinfection to eliminate microbes and stop bacterial penetration into the lumen. However, the combination of short work periods, heavy workload, and insufficient training leads healthcare staff to reduce their scrubbing duration or skip cleaning steps. Furthermore, the process of scrubbing fails to remove all microorganisms from internal surfaces because it does not reach microorganisms that reside in microgrooves or biofilms.

4.3. Antimicrobial Devices and Dressings

Antimicrobial technologies provide continuous protection against bacterial colonization on central lines. Catheters and dressings pre-loaded with agents such as chlorhexidine-silver sulfadiazine (CHG-SSD) and minocycline-rifampin form localized antiseptic barriers that reduce biofilm formation. Products like ARROWg+ard Blue® and Cook Spectrum® catheters, as well as Tegaderm™ CHG and Biopatch® dressings, have been shown to significantly lower CLABSI rates in clinical use (Darouiche et al., 1999; Maki et al., 2011; Timsit et al., 2012).

Passive disinfection caps, such as Curos™ and SwabCap®, contain 70% isopropyl alcohol and continuously disinfect catheter hubs between uses. These caps have been linked to over 50% reductions in CLABSI incidence when used consistently (Sweet et al., 2012). However, their protection is time-limited and dependent on proper application, emphasizing the need for longer-lasting, user-independent disinfection solutions.

5. Gap Analysis

5.1. Insertion Bundles

Compliance is often inconsistent in clinical settings due to emergencies, time pressures, human error, and the financial strength of the medical center (Zhou, 2025). Results of real-world use do not always match those of clinical trials (Odada, 2023).

5.2. Maintenance and hub disinfection

These processes require a lot of labor and depend on healthcare professionals to be consistent in execution. However, this is not always possible due to workflow pressures, staff shortages, and time constraints resulting in skipped steps or inadequate performance. For example the study performed by McBeth and Cheryl in 2020 showed that routine audits following Scrub-The-Hub re-education showed variability in technique and hub disinfection (McBeth, 2020).

5.3. Antimicrobial/Antiseptic-Impregnated Catheters and Dressings

These devices usually cost a lot, hindering widespread use particularly in low-income regions. There are also still concerns with regard to the efficacy of these devices due to the possibility of microbes developing antimicrobial resistance (Milstone, 2020).

5.4. Passive Disinfection Caps

The cost of disinfection caps can add up especially in high-volume facilities. Their effectiveness also relies on healthcare professionals to be consistent in applications and after every access. And they do not completely replace manual scrubbing (Gillis et al., 2023).

5.5. Automated Sterilization Devices

These devices are largely experimental and in early stages of adoption. While devices like the one developed by Fourkas show potential for reducing CLABSI, widespread adoption by healthcare facilities may be slow due to a lengthy certification process (Fourkas et al., 2024).

5.6. AI-Driven Prevention Techniques

Currently in early developmental stages, AI-driven prevention techniques are not yet widely available. Due to their experimental nature, these AI solutions are primarily utilized for diagnostic purposes. A notable risk associated with their use is the potential for false positives, which could lead to excessive interventions and increase the workload for healthcare professionals (Obama et al., 2025).

6. Design Inputs

6.1. Value Proposition

POP: Points of Parity

- Central line is properly disinfected

POD: Points of Difference

- System functions without a wait time or drying time of over 30 seconds
- System is easily reusable between different uses and patients

POI: Points of Irrelevance

- Monitoring system alerts doctors to completion of sterilization

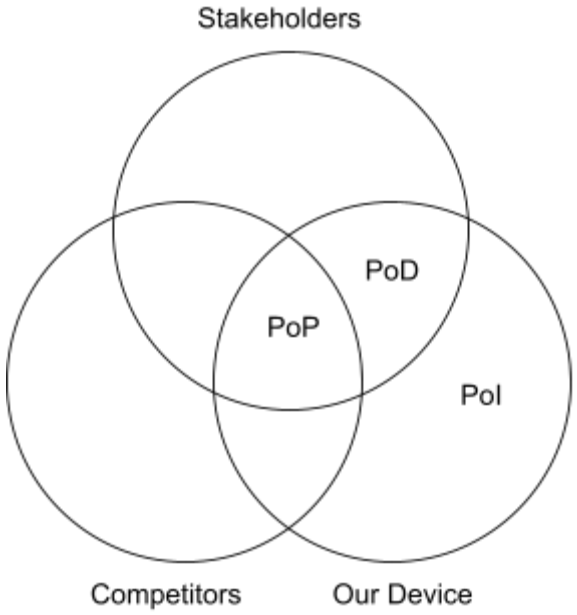


Figure 10: Value Proposition Diagram

6.2. Stakeholders

The following table lists the key stakeholders associated with the presented need statement.

Table 1: Stakeholders and their Interest in CLABSI's

Stakeholder	**Interaction with Problem**
Nurses and Doctors who access central lines	Responsible for disinfecting central lines multiple times a day before lines are accessed. Interested in the efficiency of devices used.
Internal Medicine Physicians and Infectious Disease Specialists	Responsible for the treatment of any central line infections that occur from poor practice.
Doctors with patients who have central lines	The primary healthcare providers of patients who could develop CLABSI's.
Patients receiving central lines	Patients with central lines that need regular accessing. These patients risk CLABSI development and could incur further illness and prolonged hospital stays. Examples include ICU patients, oncology patients, and surgery inpatients and outpatients.

Patient friends and family	Invested in the patient's wellbeing and provide support to the patient.
Hospitals	Institutions that pay for treatment of CLABSI's and incur the reduction of compliance scores.
Insurance Companies	Institutions that help pay for CLABSI treatments and reduce support of hospitals with increased HAI rates.
Companies responsible for central line production	Companies that have a vested interest in the reduction of infections through their devices.
Companies responsible for alcohol wipe production.	Companies that provide the current solution with an interest in new potential technology.

6.3. Cycle of Care Diagram

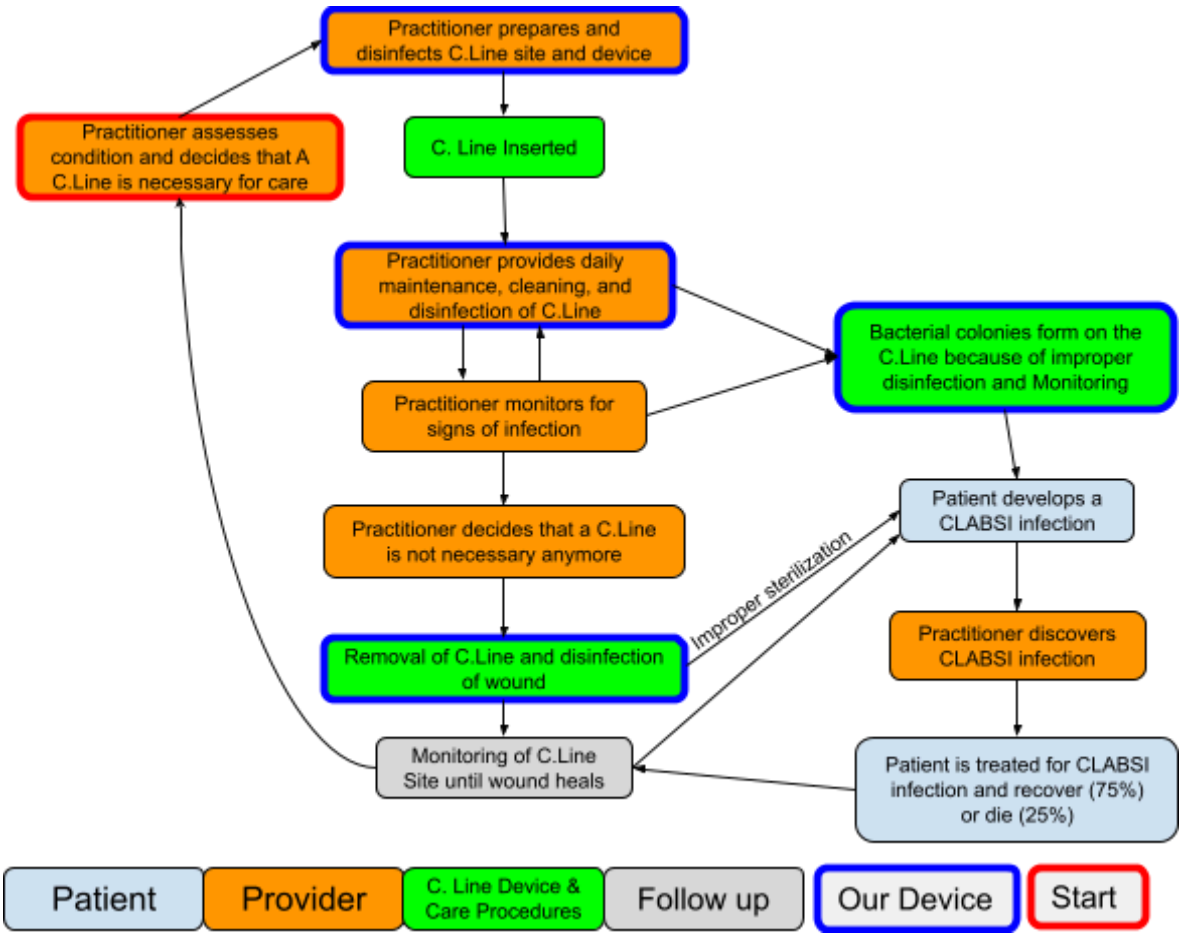


Figure 11: Cycle of Care Diagram

This cycle of care diagram illustrates how our device integrates into the clinical workflow to reduce the risk of central line–associated bloodstream infections (CLABSIs). By mapping each step in the patient care process—from the initial assessment and insertion of the central line to ongoing maintenance, monitoring, and eventual removal—we identified multiple points where our device could enhance safety and efficiency. Specifically, our device can support practitioners in ensuring proper disinfection, maintenance, and infection surveillance, thereby minimizing opportunities for bacterial contamination and infection.

6.4. Functional Requirements (Ranked)

1. Thoroughly and properly disinfects central lines:
    - Central lines necessitate proper disinfection to prevent CLABSI infections, which is the most critical requirement for this device.

2. Indicates proper disinfection:
    - Our device should indicate when a central line has been properly disinfected after hospital staff have followed our device's protocols correctly.

6.5. Constraints

- Does not cause patient undue harm:
    - Our device must not unduly affect the patient's stay in the hospital or cause discomfort.
- Does not impede current hospital workflows:
    - Our device must seamlessly integrate with existing hospital equipment and protocols. Our solution should not interfere with treatments and should not significantly delay time to treatment.
- Is of small enough size and weight to be able to be handheld by nurses:
    - Our device should be portable so that nurses are not burdened by its consistent use on patients throughout the day.
- Does not significantly increase the cost of care to a patient and is affordable to hospitals:
    - Our device should be cost-effective to prevent increasing the financial burden on patients and healthcare systems.

7. Idea Generation

After completing some initial design research, we brainstormed various ideas for our device. Then we further organized our ideas into categories representing functionality and design, assigning each idea with a group and several categories codes to facilitate an easier transition into research and application of design constraint, as shown below in Table 2.

Table 2: List of Solution Categories

(A) Alerts	(DS) Data Synthesis	(MD) Material Design	(RL) Risk Location
(AB) Antibacterial Surfaces	(DT) Data Trends	(ML) Machine Learning	(SC) Self-Cleaning Coating
(AF) Antifungal Surfaces	(EV) Ethanol Vapor	(NM) Nanomaterials	(SFS) Shear Force Sensing

(AI) Artificial Intelligence	(FL) Filtration	(OM) Ozone Methods	(SHA) Skin Health Assessment
(AM) Antimicrobial	(FS) Forces Sensors	(MD) Material Design	(SM) Shape Memory Materials
(AR) Augmented Reality	(HY) Hydrogels	(P) Pain	(SR) Self Regenerating Surfaces
(BI) Biofilm Inhibition	(HZ) Hybrid Zones	(PH) pH Responsive System	(T) Thermistors
(C) Capacitance	(IM) Implantable Techniques	(PO) Position Optimization	(TR) Temperature Regulation
(CC) Color Change	(IN) Integration	(PZ) Piezoelectrics	(UV) Ultraviolet Sterilization
(DR) Drug Delivery	(LoM) Lack of Motion	(RF) RFID Tracking	(WS) Wearable Sterilization

7.1 Chemical Sterilization Kit

7.1.1: **Chemical Soak System**: Combined tank system that holds sterilizing chemicals like ethanol and antiseptics like chlorhexidine that hold antimicrobial properties. (EV), (AM)

7.1.2: **Multi-mode alcohol sterilization kit**: Combined system which integrates wipes, sprays and chemical components into a singular unit, enabling clinicians to choose in the kit which chemical approaches depending on the device or hub.(EV), (AM), (IN)

7.1.3: **Pressurized alcohol spray:** A sealed spray canister which will deliver alcohol in order to get even coverage or surfaces, reducing manual handling and speeding up sterilization (EV), (PO)

7.1.4: **Enzmatic Spray/Mist Sterilizer:** A spray which contains a mixture of enzymes that breaks down organic residues w/ disinfectant, improving chemical sterilant effectiveness by removing biofilm and debris. (BI), (AM), (NM)

7.1.5: **Relay-controlled Ethanol Vapor Station:** Relay system which times the delivery and production of ethanol release through a chamber, automating the sterilant exposure to maintain sterility passively between workups (EV), (DS), (IN)

7.1.6 **Automated Disinfectant Backflush the line with disinfectants**: Using pumps and valves to periodically push disinfectant through the IV lumen to flush microbes away, treating internal biofilms and pathogen building. (BI), (IM), (AM)

7.1.7 **Addition of antibacterial/antifungal medium into IV drip:** Using a low concentration medium mixed into the IV fluid to provide internal disinfection and suppress microbial growth in the fluid path without harming patient tissues outside (AB), (AF), (IM)

7.1.8 **Combination method: Alcohol flush + Pressurized air (multiple chambers):** Chamber system where alcohol is used to clean, then removed with pressured air to dry. Hybrid method that kills microbes and removes residual moisture to present regrowth again (EV), (IN), (OM)

7.1.9 **Slow-Release Iodine Polymer Liner:** A surface coating with iodine polymer which will release antiseptic over time. This can provide continuous antimicrobial protection for catheter interiors and tubes (SR), (AB), (AF), (MD)

7.1.10 **Electro-activated disinfectant Mist:** Mechanical system that creates a mist of sterilizant directly activated by piezoelectric or electrostatics at the hub, which can maximize surface contact (PZ), (AM), (IN)

7.1.11 **Microfluid "disinfectant injector" valve in line:** Iteration of #8, a tiny valve in the fluid path to precisely release micro-doses of sterilant when triggered during cap removal. Can be used for localized disinfection and saves chemical volume long term. (IN), (MD), (DR)

7.1.12 **Self-Refilling Chemical Spray Cartridge built in IV pole**: Module which would be mounted on an IV pole, to hold a reservoir of disinfectant and automatically pumps to spray surfaces on demand. (IN), (EV), (WS)

7.2 Radiation Sterilization

7.2.1 **UV sterilization cabinet:** A closed UV-C chamber that sterilizes catheters, hubs, or small devices before use. Provides fast, non-contact sterilization but only works on surfaces directly exposed to light. (UV), (IN)

7.2.2 **Sterilizing light for outside of dressing**: A low-dose UV-C source continuously irradiates the catheter exit site that reduces microbial growth while also harming skin. (UV), (WS), (RL)

7.2.3 **Mini microwave/dielectric sterilization box**: A compact dielectric heating unit sterilizes tubing and small components quickly. This is useful for equipment prep, but there is a risk of plastic damage and uneven heating. (TR), (OM), (MD)

7.2.4 **Thermo-based sterilization (Heater / hair dryer / air dryer):** A hot-air blower or dryer that directs sterile heat at catheter surfaces. This is inexpensive and easy but unlikely to reach microbicidal temperatures safely at the bedside. (TR), (LoM)

7.2.5 **Autoclave-like bedside sterilizer box:** A portable steam-pressure unit for bedside sterilization of small equipment. Functionally, it replicates autoclave principles on a smaller scale to deliver proven sterilization at the point of care. (TR), (MD), (IN)

7.2.6 **Mobile iRobot sterilizer (heat/light sterilization microwave):** An autonomous robotic helper or platform that sterilizes patient rooms with light, heat, or microwave radiation, reducing environmental contamination and lowering infection risks indirectly. (UV), (IN), (RL), (AI)

7.2.7 **Cold plasma jet sterilizer**: A handheld or mounted probe that delivers a focused plasma stream or blast to disinfect catheter hubs or dressings, enabling targeted sterilization at critical points with precision control. (BI), (NM), (IN)

7.2.8 **Low-power infrared diode ring:** A small ring fitted with IR diode that generates gently heating around the catheter hub for continuous, low-level sterilization in a portable and reusable format. (TR), (WS)

7.2.9 **Phase-change heating patch**: A disposable patch containing phase-change materials that release controlled heat when activated. This can sterilize the entry zone without electronics or power through contact heating. (TR), (SM), (WS)

7.2.10 **Rotating UV-C ring clamp for line disinfection:** A clamp-on ring that rotates around a hub and emits UV-C light in all directions, providing full 360 sterilization coverage at high risk connection points without manual cleaning. (UV), (PO), (WS)

7.2.11 **Wearable IR sterilization cuff:** A wrap-around cuff that emits controlled infrared heat at the catheter entry site, delivering localized heating that can inactivate growth of

microbes while being comfortable for the patient during the process. (TR), (WS), (SHA)

7.3 Caps, Hubs, Connectors

7.3.1: **Pre-sterilization wall unit:** a pre-sterilization wall unit that connects to the central line hub to have the port sterile prior to use. (AM)

7.3.2: **Sterilizing Hub:** a sterilizing cap that actively disinfects the access surface prior to connect through a chemical, gel, or alcohol vapor. (AM), (EV)

7.3.3: **Antimicrobial alloy matrix hub**: A sterilizing cap that passively disinfects hub surface through an antimicrobial alloy matrix such as copper, silver, or magnesium-zinc. (AM), (MD)

7.3.4 **Photocatalytic TiO2 hub coating:** A sterilizing coating on the hub that activates under light, breaking down microbes to reduce infection risk. (AM), (MD)

7.3.5. **Chitosan hydrogel ring @ hub:** A sterilizing chitosan hydrogel ring that surrounds the hub, passively releasing antimicrobial agents to reduce infection risk. (AM), (HY), (DD)

7.3.6 **Shape-memory polymer caps:** A polymer cap that strongly conforms to hub geometry, forming an air-tight seal that reduces infection risk by maintaining sterility after disconnection. (MD)

7.3.7. **Ozone micro-chamber cap:** A cap that releases controlled doses of ozone gas to the hub surface to maintain sterility. (AM), (DD), (OZ)

7.3.8: **Nanopore filtration hub:** A hub with nanoscale channels to physically block microbes from proliferating on the hub. (MD)

7.3.9: **Single-use cleaning caps:** A disposable cleaning cap that contains antimicrobial agents to sterilize the hub prior to pushing medication. (MD)

7.3.10: **Multi-layer “Russian nesting doll” hubs, tearable components:** Disposable layers of the hub that allows for immediate sterilization of the hub by tearing away the contaminated, thin surface layer prior to pushing medication. (MD)

7.3.11**: Spring-loaded mechanical scrubber caps:** A sterilizing mechanism by scrubbing the surface automatically for the technician to ensure adherence. (MD)

7.3.12: **Magnetic self-aligning hub with sterilant reservoir:** A redesigned hub that connects magnetically to isolate the component with an integrated antimicrobial to maintain sterility. (AM), (MD)

7.4 Surface Coatings, Material Design

7.4.1: **Antimicrobial coating on catheter coating**: A specialized surface layer applied to catheters to continuously suppress bacterial growth and prevent infection risks. (AM), (AB), (BI), (MD), (IM)

7.4.2: Nano-sphere coating: Nanoscale spheres embedded on catheter surfaces gradually release antimicrobial compounds for extended protection. (AM), (AB), (DR), (NM), (MD)

7.4.3: Texture Change (Bio-inspired sharkskin): Micro-patterned surface inspired by sharkskin that physically resists bacterial adhesion and biofilm formation. (BI), (AB), (SC), (MD)

7.4.3: Antifungal coating: A catheter surface layer engineered to inhibit fungal growth and lower the risk of fungal-associated infections. (AF), (AM), (MD), (IM)

7.4.4: Plasma-coated catheter lines: Plasma-modified catheter surfaces incorporate antimicrobial functionality at the molecular level to block colonization. (AM), (AB), (MD), (IM), (SC)

7.4.5:Permanent hydrogel with disinfectant coating (dressing, CLine, needle): Durable hydrogel matrix infused with disinfectant ensures ongoing antimicrobial protection at device contact points. (HY), (AM), (AB), (DR), (IM)

7.4.6: Moisture-activated antiseptic release barrier: Smart coating that releases antiseptic agents only when exposed to moisture or body fluids. (AM), (AB), (DR), (BI), (MD)

7.4.7: pH-responsive surface (acidic on contamination): Coating that becomes acidic when contamination occurs, creating an environment hostile to microbes. (PH), (AM), (AB), (BI), (MD)

7.4.8: **Dual-action coating: antifouling + antibacterial nano-spheres:** Hybrid approach combining antifouling textures with antibacterial nano-sphere release. (AM), (AB), (BI), (NM), (MD), (SC)

7.4.9: **Magnetically activated particle coating** : Antimicrobial nanoparticles activated by external magnetic fields for on-demand sterilization. (AM), (AB), (DR), (NM), (MD)

7.4.10: **Biodegradable polymer catheter with embedded silver nanoparticles:** Slowly degrading catheter polymer releases silver ions for long-term antimicrobial defense. (AM), (AB), (DR), (NM), (MD), (IM)

7.4.11: **Electrically conductive polymer coating:** Conductive polymer surface disrupts microbial survival by interfering with bacterial activity through electric fields. (AM), (AB), (BI), (MD), (NM), (IM)

7.5 Dressing Modifications

7.5.1 **Temperature-sensitive dressing:** A dressing designed to monitor, maintain, and change temperature to prevent infections from occurring, whether it be through materials or through electrical components. (BI), (TR), (MD)

7.5.2: **Moisture-wicking dressing:** Gore-Tex dressing (keep dry) A dressing made of moisture-wicking material such as Gore-Tex to keep the area around the central line dry and prevent the type of environment bacteria grow in. (BI), (MD)

7.5.3: **Sterilizing light embedded dressing**: A dressing with embedded UV lights woven in a circle around the central line access port that shine at predetermined intensities and intervals to prevent bacterial migration across the circle. (UV), (WS)

7.5.4: **RFID tags to track dressing changes:** Each dressing is tagged with an RFID tag that can track how long the dressing has stayed in place. When dressings are changed, the tag is scanned and updates doctors on frequency of dressing changes. (RF), (DT)

7.5.5: **Barcodes to track dressing changes:** Each dressing for a central line has a barcode placed on it. When the dressing is changed, the barcode of the old dressing is scanned to aid doctors in tracking dressing changes. (DT)

7.5.6: **Smart dressing + hospital dashboard:** Dressings that track themselves and send updates to a monitor in the hospital so that physicians can track all dressings from one spot and know when to change each. (DS), (A), (IN)

7.5.7: **Dashboard-connected dressing with microbiome monitoring patch:** A dressing that is connected to a hospital monitor that contains a microbiome detector. In the presence of microbes or bacteria, the detector sends a signal to the dashboard to alert

physicians to change the dressing. (A), (BI), (SHA)

7.5.8: **Dressing-changing robot or automated reminder:** An automated robot that performs the task of changing dressings on a predetermined cycle for the doctors to maintain sterility. (AI), (ML)

7.5.9: **Motorized retractable dressing flap:** A dressing flap connected to a motor that, at the press of a button from a physician, can mechanically remove the first dressing and replace it. (SC)

7.5.10: **Electrical heating dressing (Sterilizes periodically)**: A dressing connected to a heating source that is powered on a timer. This source heats the pad to a temperature that kills microbes and sterilizes the dressing, removing the need to change dressings. (WS), (TR)

7.6 Sterilization Device

7.6.1: **Portable sterilizing docking station (UV + chemical mist):** A device next to the patient that sterilizes the hub while docked on standby with UV light and a mist of chemical disinfectant. (AM), (UV)

7.6.2: **Portable ozone gas sterilizer** A device next to the patient that sterilizes the hub with controlled doses of ozone gas. (AM), (OZ)

7.6.3**: Electrolyzed water spray pen:** A handheld device that flushes the hub on-demand with an antimicrobial solution prior to hub access. (AM)

7.6.4: **Auto-clean and flush system built into line:** A sterilizing device integrated into the fluid line that automatically rinses and disinfects the line between uses. (AM), (BI), (IN)

7.6.5: **Battery-powered handheld sterilizer:** A low power device that enables handheld sterilization of the hub surface using UV, heat, or controlled chemical release. (AM), (UV)

7.6.6: **Bed-integrated sterilization port:** A device integrated into the bed to facilitate sterilization of catheter hubs without a detached device using UV, heat, or controlled chemical release. (AM), (IN), (UV)

7.6.7: **Ultrasonic oscillation modules (anti-biofilm):** A modular device that delivers high-frequency mechanical pulses to break up biofilms before they become an infection risk that naturally form on the catheter line. (BI)

7.6.8: **Self-sterilizing catheter pump module:** A device that integrates heating and fluid flushing to continuously disinfect the catheter channel during and in the absence of hub access. (AM), (BI)

7.6.9: **Cather sterilization carousel:** A multi-hub docking device that automatically allows for sequential sterilization of the hub through ethanol, chemical treatment, heat, and UV prior to use. (AM), (BI), (UV), (IN)

7.7 Indicators, Sensing, Monitoring

7.7.1: Sterility Indicator caps (color change, glow, buzz when unsafe): Smart catheter caps that signal contamination risk using visual or sensory alerts. (A), (CC), (MD), (RL)

7.7.2: Fluorescent biosenor patch: Wearable patch that fluoresces in response to microbial contamination for quick detection. (A), (MD), (SC), (BI)

7.7.3: Electrochemical biosensor hub: Hub-integrated biosensor detecting pathogens through electrochemical signals. (A), (MD), (FS), (BI)

7.7.4: Timestamped hub caps logging every access: Catheter hub caps that digitally record each access to ensure traceability and accountability. (A), (DS), (RL), (RF)

7.7.5: Accelerometer or Haptic wristband for scrub motion feedback: Wearable device providing feedback on hand-scrubbing technique to reinforce proper sterilization. (A), (FS), (LoM), (SHA)

7.7.6: Skin microbiome monitoring patch: Patch that tracks skin microbial balance to detect early infection risks. (A), (SHA), (BI), (MD)

7.7.7: AR glasses overlaying bacterial growth hotspots: Augmented reality glasses projecting real-time bacterial contamination zones. (AR), (A), (RL), (BI)

7.7.8: AI camera tracking sterilization technique: Intelligent vision system analyzing and giving feedback on sterilization practices. (AI), (A), (ML), (RL)

7.7.9: Hospital dashboard with infection heatmap: Centralized data visualization

platform mapping infection hotspots across wards. (A), (DS), (DT), (RL)

7.7.10: Blockchain-logged catheter access history: Secure blockchain system ensuring tamper-proof records of catheter interactions. (A), (DS), (IN), (RL)

7.7.11: Capacitive sensor detecting moisture contamination: Embedded capacitive sensors detecting liquid breaches or contamination near the hub. (A), (C), (MD), (RL)

7.7.12: Micro-thermal metabolic sensors: Miniaturized thermal sensors detecting microbial metabolism through subtle heat changes. (A), (T), (BI), (MD)

7.7.13: Smartphone clip-on scanner for hub sterility check: Portable smartphone accessory enabling quick sterility checks of catheter hubs. (A), (MD), (SC), (RL)

7.8 Process Management

7.8.1: Standardized digital checklists with automated alerts: Creating a uniform checklist for doctors and nurses to follow that updates practitioners throughout the procedure on steps they have completed. This management system can also be implemented in parallel with other devices. (A)

7.8.2: VR/AR-based training with microbial spread animations: Using virtual reality to simulate common central-line actions. This VR would track physician practices and use AI to simulate infections and spread in the virtual environment based on physician actions. (AI), (AR), (RL)

7.8.3: Dashcam for regulatory oversight: Using a dashcam or other camera system mounted on a wall to allow regulatory officials to oversee a physician's actions during central line treatments and point out unsafe practices before they can cause harm. (RL)

7.8.4: Meta glasses for ensuring proper technique: Physicians wear artificially-enhanced glasses during procedures which watch actions and decision-making. These glasses display techniques and alert physicians to take proper precautions and maintain the proper level of adherence to central line bundles. (AI), (RL)

7.8.5: Digital twin simulation for infection control: Taking information and data from a patient to make a digital recreation of said patient. This allows doctors to monitor central line components for infections in the simulation and act to prevent them in the patient themselves. (AI), (DS), (DT), (RL)

8. Idea Selection

8.1 Screening Table

7.1.1	7.1.2	7.1.3	7.1.4	7.1.5	7.1.6	7.1.7	7.1.8	7.1.9	7.1.10	7.1.11	7.1.12	
7.2.1	7.2.2	7.2.3	7.2.4	7.2.5	7.2.6	7.2.7	7.2.8	7.2.9	7.2.10	7.2.11		
7.3.1	7.3.2	7.3.3	7.3.4	7.3.5	7.3.6	7.3.7	7.3.8	7.3.9	7.3.10	7.3.11	7.3.12	
7.4.1	7.4.2	7.4.3	7.4.4	7.4.5	7.4.6	7.4.7	7.4.8	7.4.9	7.4.10	7.4.11		
7.5.1	7.5.2	7.5.3	7.5.4	7.5.5	7.5.6	7.5.7	7.5.8	7.5.9	7.5.10			
7.6.1	7.6.2	7.6.3	7.6.4	7.6.5	7.6.6	7.6.7	7.6.8	7.6.9				
7.7.1	7.7.2	7.7.3	7.7.4	7.7.5	7.7.6	7.7.7	7.7.8	7.7.9	7.7.10	7.7.11	7.7.12	7.7.13
7.8.1	7.8.2	7.8.3	7.8.4	7.8.5								

In order to break down our total of 85 ideas, we brainstormed 8 design criteria that our intended device must have, these being (1) Addressing Core Need, (2) Sustainability, (3) Feasibility, (4) Safety, (5) Infection Reduction, (6) Designer Interest, (7) Innovation, and (8) Workflow Fit. We then created a system to screen the ideas, if we believed the idea occupied all 8 ideas, then it received a green mark, if the idea only hit 5-7 design criteria, then it received an orange mark, and if the idea hit less than 5 of our design criteria, it received a red mark. This screening system brought our initial 85 ideas down to 24 ideas.

8.2 Scamper Method

Next we used the scamper method learned in EGR 101, to combine and modify our favorite ideas into a smaller subset seen below:

1) Bio-Inhibition Hub & Smart Dressing
(Derived from: 7.3.2, 7.3.5, 7.4.5, 7.5.6, 7.5.7)
The Bio-Inhibition Hub & Smart Dressing integrates chemical, hydrogel, and digital systems to provide continuous protection around catheter entry sites. The hub utilizes antimicrobial and hydrogel coatings to prevent bacterial adhesion, while a smart hydrogel dressing infused with disinfectant maintains a moist but sterile interface. Embedded sensors track microbial signals and communicate to a hospital dashboard (7.5.6–7.5.7), alerting clinicians when contamination begins or dressing changes are required. This hybrid of biological inhibition and smart data connectivity transforms passive dressing care into active, responsive infection control, maintaining sterility at the line–skin interface in real time.

2) **Handheld Multi-Mode Sterilization Device**
(Derived from: 7.1.2, 7.1.4, 7.1.10, 7.6.5)
The Handheld Multi-Mode Sterilization Device combines chemical, enzymatic, and UV sterilization within a single portable unit. Clinicians can switch between alcohol spray, enzyme-based mist, and UV disinfection depending on the surface or hub type. Compact and battery-powered (7.6.5), it ensures precise, even sterilant coverage without overuse or contamination risk. This device allows bedside sterilization on demand, improving procedural flexibility and safety while reducing chemical waste. Its adaptive design addresses diverse sterilization needs in both inpatient and emergency settings, providing quick, controlled, and contact-free disinfection.

3) **Bedside / Machine Sterilization Chamber**
(Derived from: 7.2.5, 7.6.1, 7.6.6)
The Bedside Sterilization Chamber acts as a miniaturized autoclave for small medical components like hubs and tubing. Combining UV-C light, pressurized steam, and chemical mist sterilization in a sealed, bedside enclosure, it provides automatic sterilization cycles between procedures without requiring central reprocessing. Integrated into the bed frame or patient workstation (7.6.6), it ensures that all reusable items remain sterile until the moment of use. This system mirrors the reliability of a full-scale autoclave in a portable, smart format, enabling immediate, verifiable sterilization at the point of care, minimizing cross-contamination in high-risk hospital zones.

4) **AutoClean Infusion Network (ACIN)**
(Derived from: 7.1.6, 7.1.9, 7.6.4, 7.6.9, 7.3.12)
The AutoClean Infusion Network is a closed-loop, self-sterilizing IV system designed to maintain sterility internally and externally. It utilizes a slow-release iodine polymer liner (7.1.9) to provide ongoing antimicrobial activity within the tubing and a pump-driven disinfectant backflush (7.1.6) that automatically clears biofilm formation. When not in use, the line docks into a sterilization carousel (7.6.9) that applies ethanol mist and UV light before reactivation. The magnetic self-aligning hub (7.3.12) ensures a sterile seal at every connection point. Together, these mechanisms create a hands-free disinfection loop, dramatically reducing infection rates and human handling errors in IV therapy.

5) **SteriSphere Mobile Robot**
(Derived from: 7.2.6, 7.2.7, 7.2.10, 7.2.11, 7.4.8)
The SteriSphere Mobile Robot is an autonomous sterilization assistant that uses multiple physical and chemical modalities to sanitize both devices and surroundings. Equipped with rotating UV-C rings, plasma jets, and infrared cuffs, it can move around patient beds or sterile zones, delivering focused or ambient sterilization. As it operates, it deploys a dual-action

antifouling and antibacterial nano-coating mist (7.4.8) that provides lingering antimicrobial protection on treated surfaces. AI-guided mapping and sensors ensure targeted coverage while avoiding patients and staff. SteriSphere redefines environmental hygiene by combining autonomous navigation with precision multi-mode sterilization, keeping hospital spaces continuously disinfected.

6) SmartSense Sterility Monitoring Ecosystem

(Derived from: 7.7.1, 7.7.2, 7.7.7, 7.7.8, 7.8.1–7.8.4)

SmartSense is a real-time monitoring network that merges sensing, augmented reality, and AI feedback for sterilization assurance. Catheter caps and biosensor patches (7.7.1–7.7.2) detect microbial contamination and provide instant color or signal alerts. AR glasses (7.7.7, 7.8.4) overlay bacterial growth hotspots in the clinician's field of view, while AI-assisted cameras (7.7.8) analyze procedural technique. A digital checklist platform (7.8.1) synchronizes all data, tracking compliance and generating automatic reminders. Together, these components form a closed feedback ecosystem that enhances sterility adherence, supports clinician training, and prevents infection through proactive guidance and digital oversight.

7) Adaptive Antimicrobial Catheter System (AACS)

(Derived from: 7.4.1, 7.4.6, 7.4.7, 7.4.10, 7.5.7)

The Adaptive Antimicrobial Catheter System is a self-responding catheter that combines smart materials and biosensing. Built from a biodegradable polymer embedded with silver nanoparticles (7.4.10), it offers long-term antimicrobial defense while minimizing toxicity. A moisture-activated antiseptic barrier (7.4.6) and pH-responsive acidic surface (7.4.7) automatically release disinfectant when microbial contamination or fluid exposure is detected. The accompanying dashboard-connected dressing with microbiome sensor (7.5.7) tracks early microbial changes and alerts clinicians before infection develops. This innovation transforms a standard catheter into a living antimicrobial system, capable of sensing, adapting, and protecting the patient autonomously.

8.3 Scoring Matrix

Design Criteria	Weight %	Idea 1	Idea 2	Idea 3	Idea 4	Idea 5	Idea 6	Idea 7
Addressing Core Need	0.2	5	5	5	4	4	4	5
Sustainability	0.1	4	4	4	4	3	3	3
Feasibility	0.15	4	5	4	3	3	4	3
Safety	0.15	5	4	5	4	4	4	4
Infection Reduction	0.1	5	4	5	5	4	4	5
Designer Interest	0.05	4	5	4	4	5	4	4
Innovation	0.15	5	5	4	5	5	5	5
Workflow Fit	0.1	4	5	4	3	4	4	4
Total		4.7	4.6	4.5	4.3	4.2	4.1	4.0

After assigning weights to each design criteria, we further scored our newly formed 7 ideas with the top 3 ideas being 1) Bio-inhibition Hub with a top score of 4.7, 2) Handheld Multi-Mode Sterilization Device with a score of 4.6, and 3) Bedside / Machine Sterilization Chamber with a score of 4.5. We will now complete research into each of these different ideas, further breaking them down by principle of operation, functionality, design parameters, and more.

9. Idea Research

9.1. Bio-Inhibition Hub and Smart Dressing

9.1.1. Principle of Operation (PoO)

The Bio-Inhibition Hub will be designed to provide continuous antimicrobial protection internally (lumen) and externally (catheter surface). This device will be 5 major components: (1) The inner lumen would be coated with a polymer matrix that contains an iodine complex which is slowly released at a controlled rate, maintaining local antiseptic concentration to prevent biofilms. (2) The exterior would have a micro-pattern with hydrophilic/hydrophobic properties that reduces bacterial adhesion and fouling. This passive disinfection will contrast the active counterpart occurring in the (3) hub, which will be modified to hold a reserve of disinfectant and a controlled injection mechanism. (4) To close the system, the cap will contain a chemical colorimetric indicator which will respond to the presence of microbial colonies. When a

successful disinfection cycle reaches a threshold, the indicator changes color to give practicans a visible confirmation that the hub is sterile. Finally, we will add a low-power microcontroller which will manage scheduled flush cycles and log disinfection events for efficient organization of the system. The microcontroller will have an output that may be sent to a program which medical nurses may observe all the condition patients virtually, saving workforce load and time.

9.1.2. Block Diagram

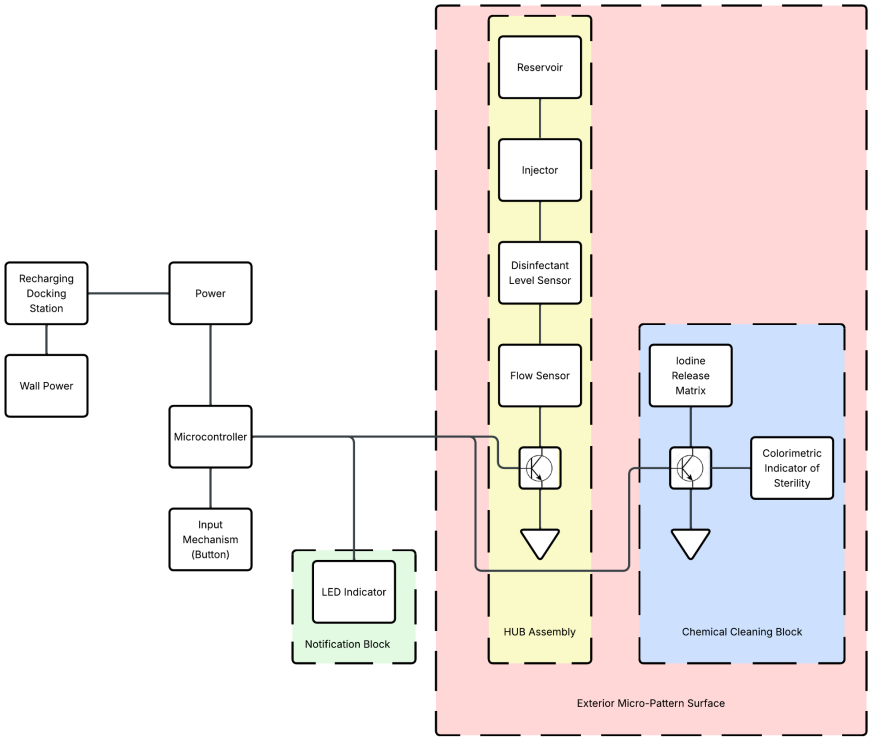


Figure 12: Block Diagram for Biofilm Inhibition Hub

9.1.3. Flowchart

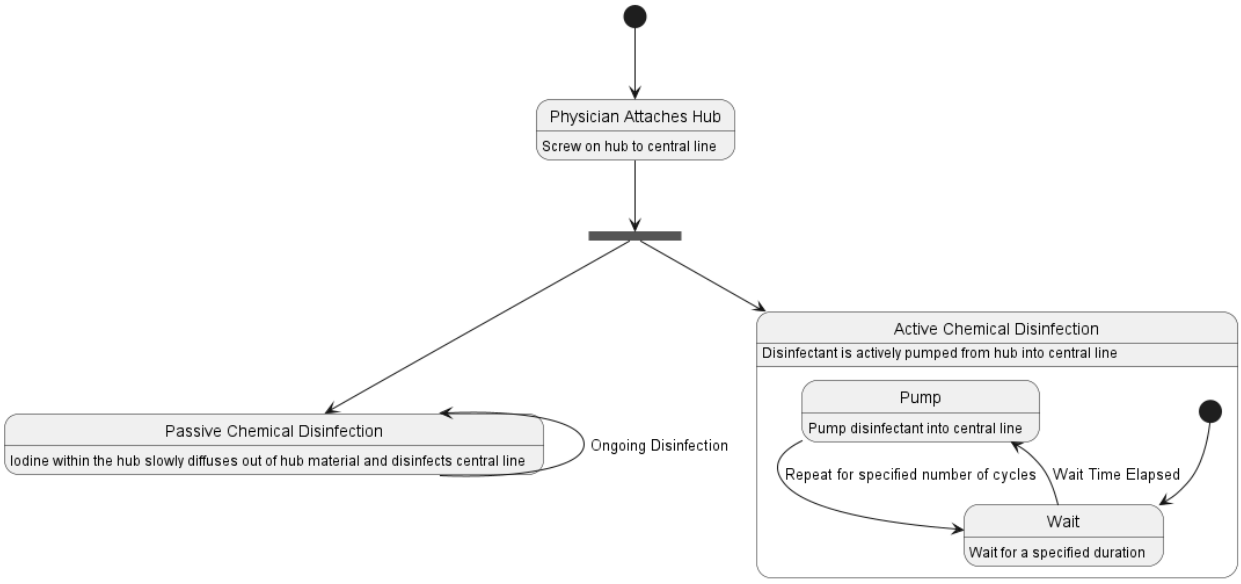


Figure 13: Flowchart for Biofilm Inhibition Hub

9.1.4. Prior Art Search

9.1.4.1. US10709819B2 - Method for coating catheters with a layer of antimicrobial agent **(Active)**

This patent discloses a catheter having a polymeric coating/layered structure that incorporates an iodine complex within one or more polymer matrices. Its purpose is to provide controlled, sustained release of free iodine from the catheter surface over time, thereby inhibiting microbial colonization, biofilm formation, and device-associated infections (urinary tract, bloodstream, respiratory) adjacent to the catheter. The coating is applied in one or more organic solution layers onto an elastomeric substrate; by adjusting layering, composition, pH, thickness, and placement of "antitoxic agents," the rate and potency of iodine delivery can be tailored.

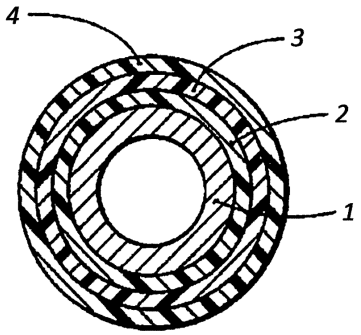


Figure 14: Depiction of multiple layers of antimicrobial film and structures

9.1.4.2 US20240173538 A1 - Medical disinfection device with visible disinfection indicator **(Pending)**

This patent application describes a disinfection cap or cleaning device that fits over medical connectors (e.g., vascular access device ports) and includes a visual colorimetric indicator that changes color when sufficient scrubbing or disinfection has been achieved. The form includes an external housing with a disinfectant-impregnated sponge or medium and a rotatable collar that moves the sponge against the connector surface to scrub it. Within the cap is a visualization chamber holding two isolated colored fluids; as the collar is rotated, the fluids mix, producing a third color visible externally, which signals to a clinician that adequate disinfection has occurred.

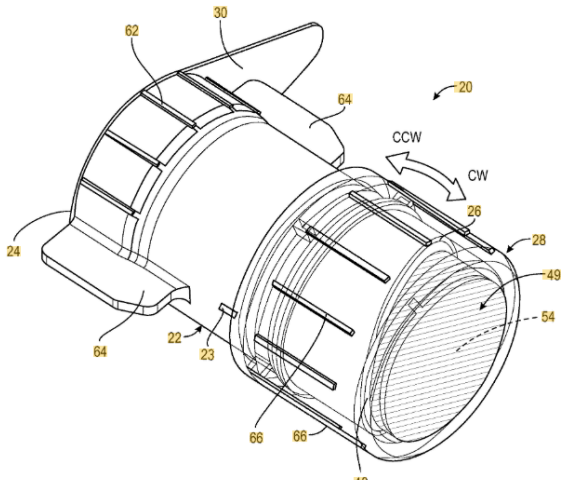


Figure 15: Color-changing chamber

9.1.4.3 US10946168 B1 - Smart Urinary Catheter **(Active)**

In this patent, a catheter or infusion line is augmented with a sensor or indicator integrated within the fluid pathway used for drug delivery. The sensor—based on an electrolytic or impedance-sensing element composed of a wicking substrate and paired electrodes—detects the passage of fluids with specific electrical or chemical characteristics. When a drug solution flows through the line, the circuit activates, recording the event or transmitting a signal to a microcontroller or remote monitoring system. By correlating flow events and fluid composition, the device could log dosage, timing, and frequency of drug administration, providing clinicians with an automated record of therapy compliance and helping detect infusion interruptions or incorrect dosing in real time.

9.2. Automatic Handheld Disinfection Device

9.2.1. Principle of Operation (PoO)

The Automatic Handheld Disinfection Device was designed to be a portable disinfection device that could be placed on central line hubs to quickly disinfect them. The device would be stored in a docking station near the central line access ports for easy use. It would be able to fit in a nurse's hand and be placed over the central line hub, with a circular opening on the bottom that the hub would fit into snugly. This fit would ensure the hub is fully contained and able to be properly disinfected. The nurse then would be able to press a button to commence the disinfection sequence.

The device would consist of a twofold disinfection sequence: first, it would perform a chemical disinfection, and second, it would perform a UV disinfection. For the chemical disinfection, a cleaning agent such as ethanol would be released as a vapor to kill any potential bacteria on the hub. The ethanol would release as a vapor to ensure it can be dried more quickly. Then, after the chemical disinfection, UV lights built into the hub container would be illuminated. These UV lights would dry the ethanol vapor and provide further disinfection. This light is flashed for under 5 seconds. After the lights turn off, the device would have an outward-facing green LED that would flash to signal completion of disinfection. Once this light is flashed, the nurse removes the device from the hub.

9.2.2. Block Diagram

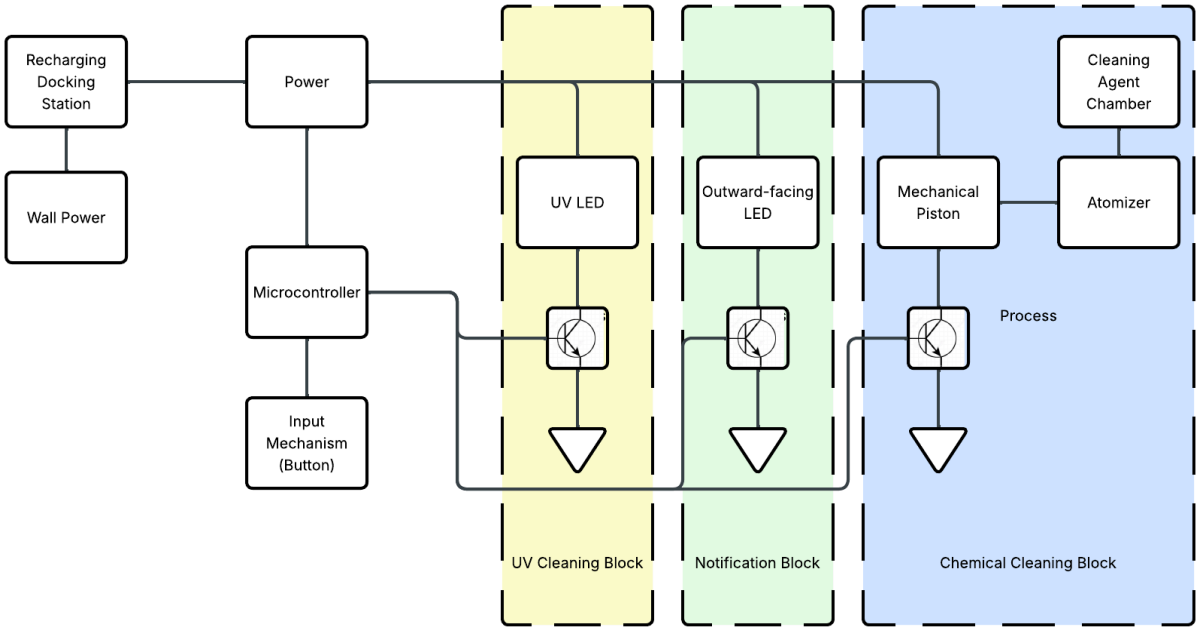


Figure 16: Block Diagram for Automatic Handheld Disinfection Device

9.2.3. Flowchart

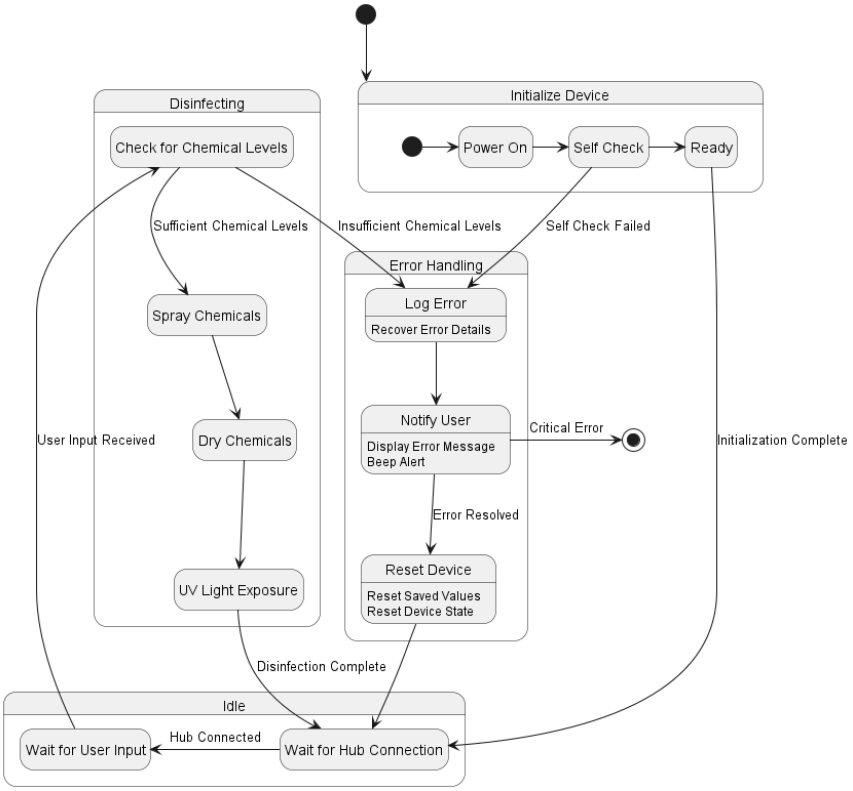


Figure 17: Flowchart for Automatic Handheld Disinfection Device

9.2.4. Prior Art Search

9.2.4.1. US11071799B2 - Portable and disposable UV device **(Active)**

The patent describes a portable device that takes a user input to shine UVC light onto an object to sanitize a surface and the air around it. A user grips the rectangular base, which has sensors attached to it to detect pressure, and pulls off the cap. The input powers a UVC light source focused onto a surface and a visible light that identifies the surface being disinfected.

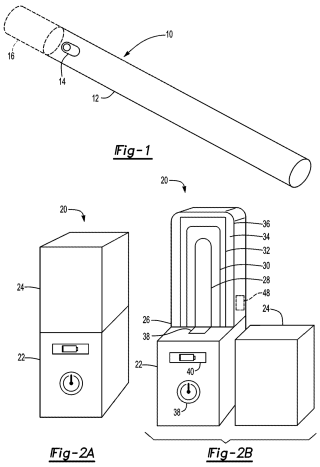


Figure 18: Isometric view of device with both cap on and cap off.

9.2.4.2. US20160082138A1 - Ultraviolet Disinfection Unit **(Expired)**
This patent describes an ultraviolet disinfection unit for disinfecting catheter line connections. It consists of a body with a trough and a recess to properly position both the catheter lines and connection in the device and a lid to cover the connection. Then, the device shines UV light to disinfect the connection.

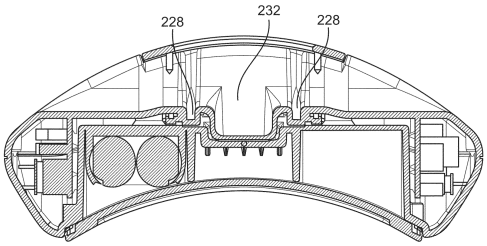


FIG. 3C

Figure 19: Top and Side view of disinfection unit, with the trough specified at number 232.

9.2.4.3. US20250058003A1 - Point of care ultraviolet disinfection system **(Pending)**
This patent describes a handheld, portable disinfection device that, off of a user input, shines UV light in a focused direction toward a target to disinfect a surface. The device is specifically designed to disinfect an indwelling catheter.

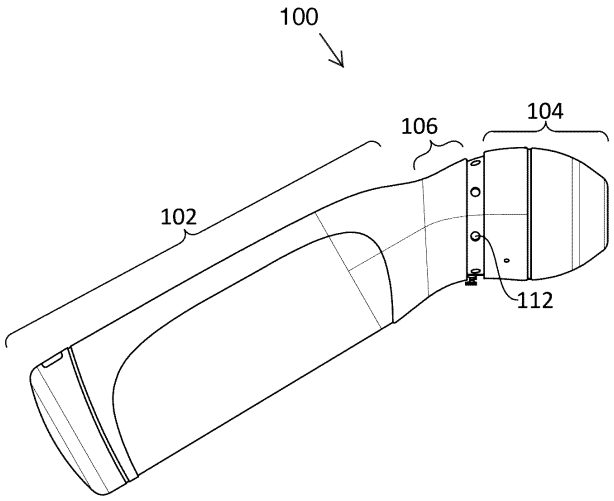


Figure 20: Side View of disinfection device.

9.3. Multiple Chamber Device

9.3.1 Principle of Operation (PoO)

The Multiple Chamber Device is designed to disinfect central lines placed on limbs, including Midline, PICC, and Femoral central lines. Roughly the size of a microwave, the device will be battery-operated and rest on a docking station within ICU rooms when not in use. It will be placed around a patient's extremity to surround and seal an un-dressed central line. Using both chemical and ultraviolet light disinfection methods, the device will disinfect the skin beneath the dressing and the central line itself, preventing both intra- and extra-luminal bacterial spread.

The device operates in several steps. First, an inner apparatus is attached to the hub, and the outer shell is secured around the extremity. A chemical disinfectant is then applied inside and outside the hub, as well as to the surrounding skin. The chemical is dried using medical air, followed by a short UV-C disinfection cycle to ensure complete sterilization. Once the process is complete, the apparatus is removed, and new sterile dressings are applied to the central line.

9.3.2. Block Diagram

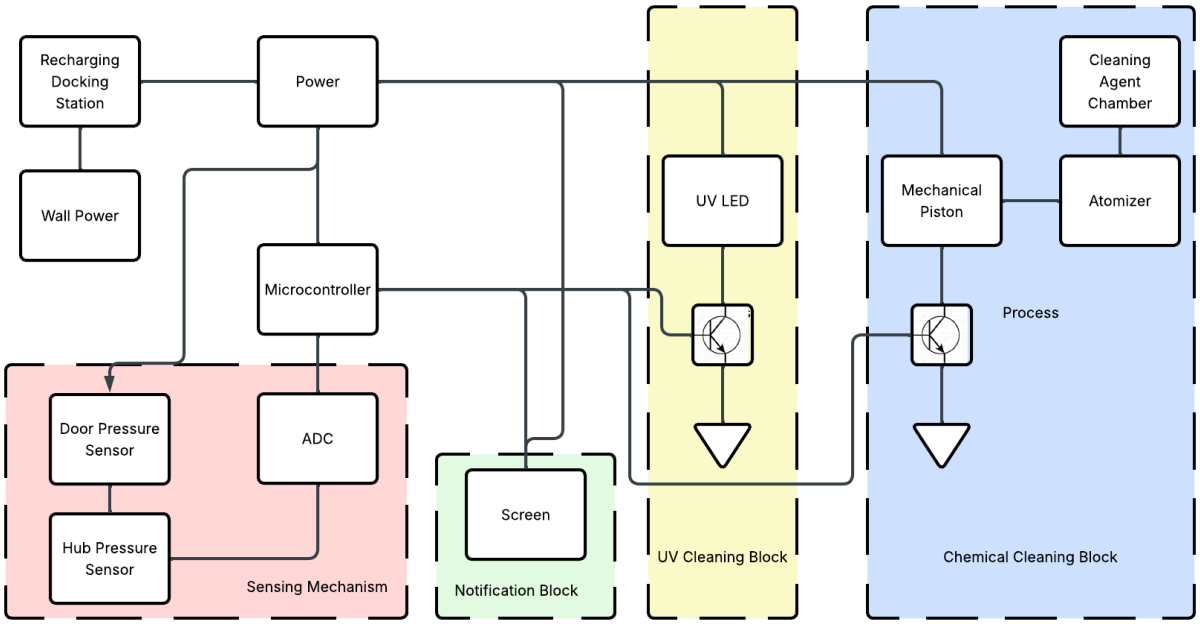


Figure 21: Block Diagram of Multiple Chamber Device

9.3.3. Flowchart

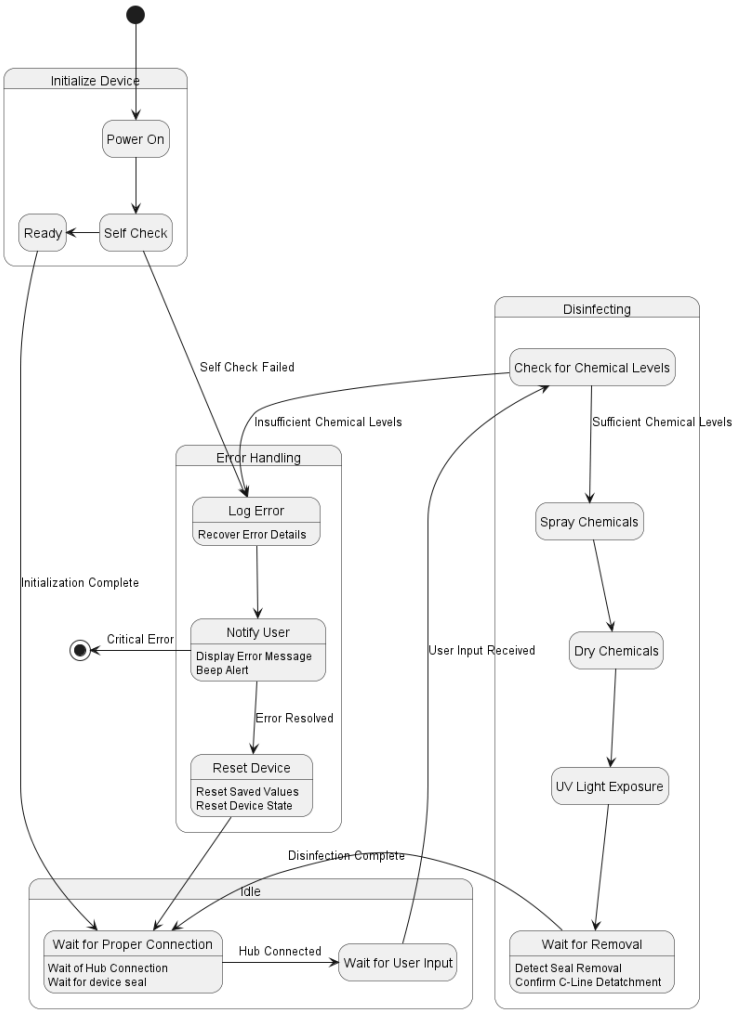


Figure 22: Flowchart for Multiple Chamber Device

9.3.4. Prior Art Search

9.3.4.1. US7713473B2 — Sterilization system and vaporizer therefor **(Expired)**

This patent describes a device that uses a vaporizer in its sterilization system. The device pumps liquid sterilant into a chamber with sloped surfaces to allow maximum coverage of the surface. The surface is then heated to vaporize the sterilizing agent, which is then directed into the sterilizing chamber to sanitize an object.

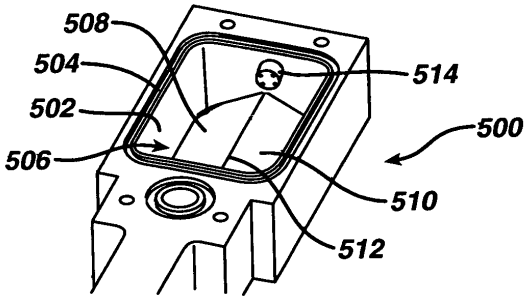


Figure 23: Isotropic view of sterilization device with vaporizing chamber and its sloped surfaces.

9.3.4.2 US9045358B2 — UV disinfecting device **(Expired)**
This patent describes a device that acts as a container for an object or liquid. As the object is placed in the container, the side walls and end cover are replaced, and a dielectric barrier discharge lamp provides UV light into the chamber to sterilize all surfaces of the device.

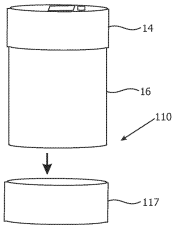


FIG. 5

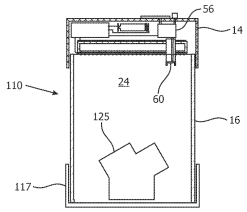


FIG. 6

Figure 24: Outer isotropic view and inner side view of container.

9.3.4.3. WO2016179193A1 — UV-C based skin sterilization device **(Active)**
This patent describes a UV light-based sterilizing device. It contains a console connected to a delivery system and a display screen to alter the effective dose of UV light generated in the device. The UV light is produced either from an LED array or from xenon lamps, and the dosing system uses a negative feedback loop with a camera, light absorption sensor, and distance sensor

to change the intensity of UV light generated. It also creates a 3D map of the treatment area and shows it on the display screen for the user.

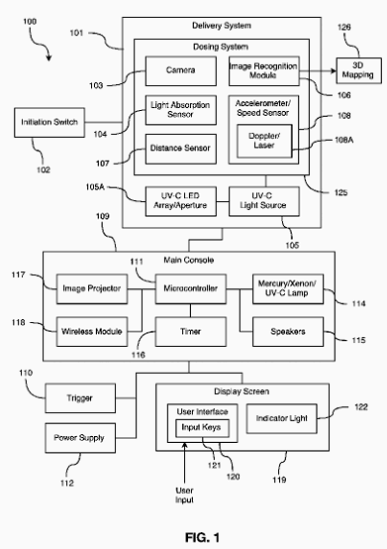


Figure 25: Block Diagram of UV sterilizing device with negative feedback loop.

10. Idea Visualization

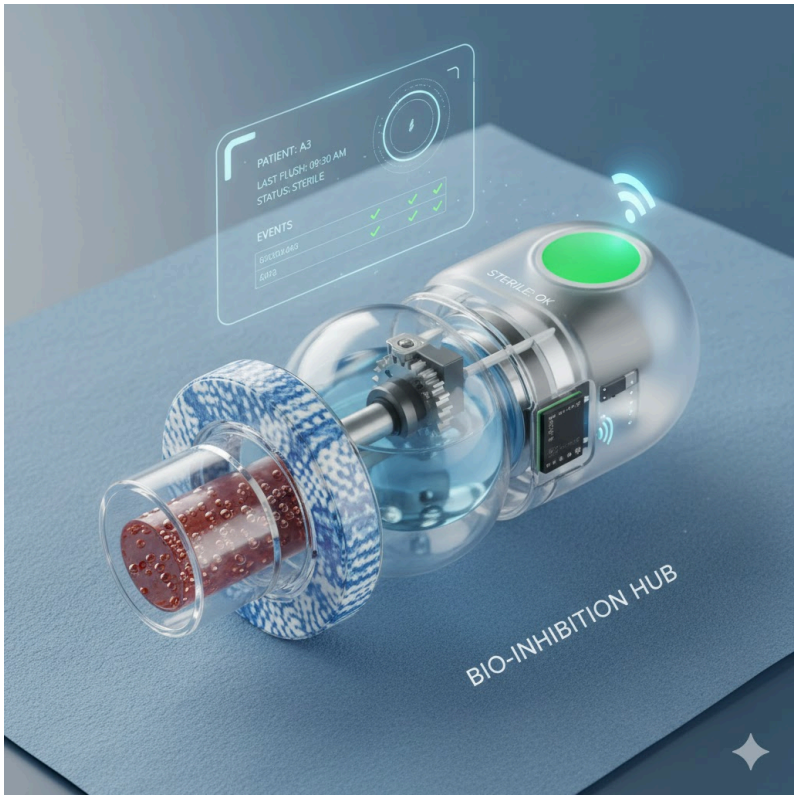


Figure 26: Visualization of Bio-Inhibition Hub

The device is small and is designed to provide a seamless fit around the catheter, both internally and externally. The inner surface is coated in a polymer complex that is meant to be slowly released. The device also contains a bright LED that indicates when disinfection procedures are completed.

Figure 27: Visualization of Automatic Handheld Disinfection Device

This device is a handheld disinfection apparatus. It is placed completely around the catheter and provides both chemical disinfection from a vapor and UV disinfection from UV lights inside the device.

Figure 28: Visualization of Multiple Chamber Device

The device is a portable device meant to be placed on a cart next to the extremities of a patient. There is a larger circular chamber for the extremity to be placed in, and there is a smaller chamber inside the device for the central line hub to be placed in. Pressure sensors exist in the device to register the connections, and a touchscreen controls the device and signals both chemical and, subsequently, UV radiation. The device also rests on a charging bank so that the device itself is portable.

11. Stakeholder Interviews

11.1 Interview #1: Cardiac Intensive Care Unit Field Notes
Role: Patients/Beneficiaries | Interviewers: David Bearden, Forest Rudd
Date of contact: 10/3/25 by email | Date of interview: 10/9/25 in person in Cardiac ICU
Key Takeaways:

- Not enough time was spent on proper central line disinfection techniques, even with college students specifically watching the process.
- Rushes during the day prevent proper checks for dressing changes and inspections of patient hubs.
- Scrub the Hub improvements are relevant to more than central lines: use also in urine hubs, PIV hubs, arterial hubs

Scrub the Hub Timings
Nurse #1: 6 seconds of scrubbing
6 seconds of scrubbing with an ethanol wipe, 2 seconds of transition between setting down the ethanol wipe and picking up the saline before pushing it into the line.

Nurse #2: 15 seconds of scrubbing, with full intent on showing theoretical Scrub the Hub
0:00 Access cabinet to get saline syringes and alcohol wipes
0:29 Walk to Pt and set down equipment on nearby cart
0:40 Scrub Hub of left IJ central line
0:55 Finished scrubbing and immediately inserted, following blood return and then flushing

Nurse #3: 3 seconds of scrubbing
3 seconds of scrubbing with an ethanol wipe, 2 seconds of transition between setting down the ethanol wipe and picking up the saline before flushing the line.

Nurse #4: 5 seconds of scrubbing
5 seconds of scrubbing with an ethanol wipe and then setting down wipe and mimicking inserting and flushing the line.

Paraphrased Field Questions and Answers

Q: How often are hubs actually checked despite the protocol to check every 4 hours?
A: Competency of lines are checked once a shift but during rush times they are only checked once in the morning.

Q: Should a central line be removed due to indications of infection (elevated WBCs, erythema) how long does it take to insert a new one?
A: The times vary by the skill level. It takes several minutes to set up a sterile field and bring in an ultrasound. A resident takes between 60 to 90 minutes. An attending takes between 15 to 20 minutes.

Empirical Findings

Multiple lumens are often inserted when a line is started. It's rare for a single lumen, if ever, to be placed. Triple lumen central lines are standard in intensive care. An infection risk is present with a single lumen so a triple lumen is easily justifiable.

A full panel blood sample is taken once every 24 hours. Elevated WBC counts are flagged as a central line infection risk and the line is thoroughly assessed for erythema or unadherent dressing or fever.

Hub sanitization practice (Scrub the Hub) is employed for every hub used in urine collection, blood collection, flushing, medication pushing, etc. for a variety of lines (e.g. arterial, peripheral, central, urine).

Dressing changes are not prioritized and neglected unless apparently faulty, as evidenced by questioning. The standard of 7 days for dressings and 24 hours for gauze is rarely followed.

Some patients have hub accesses every 60-90 minutes to push meds.

<u>11.2 Interview #2: Kimberly Coston and Timothy Matusz, Cardiac ICU Nurses</u>
Role: Healthcare Provider | Interviewers: Daniel Chong, Forest Rudd
Date of contact: 10/3/25 by email | Date of interview: 10/9/25 over Zoom
Key Takeaways:

- Handheld devices would have more universal applications but be less specialized towards potential ICU uses.
- Stick with the handheld on-and-off use case instead of considering switching to a permanently-on use case.
- Thought needs to be put into physical removal of potential soilings and physical remains of bacteria.

Transcript:
Intro: We have two groups working on this project, we thought if you had any insight of how our projects could have some differences since we're both leaning towards a disinfection device using UV light. So what we were thinking was a device where instead of scrubbing the hub right before you go to draw blood or administer IVs or like whenever you need to clean the device, instead of using scrub the hub, our device is like a cylinder that you could place on here on top of the hub, and then it would shine a light that would disinfect it for five seconds and then you would take it off and proceed. So it's essentially a replacement for the scrub the hub technique using UV disinfection.

Q: What would the different circumstances be for like good use cases for each of our devices?
Kim: Yeah. Forrest, I think with y'alls, it's sounds like it'd be more universal. So when you came in and you saw like the different applications, like with an A-line or cleaning the head of like those certain medications with I think that's the biggest use case. And James, for yours, it's just that it's always there. Of course, it's only applicable to central lines, but central lines is where we see the highest risk of infection anyways. So yeah, the utility in that.
Tim: I agree. I think that you guys are coming at it from two different angles, having something like you said that is portable and small and just kind of as needed. So like you put it on there while the nurse is preparing the medications and it can be doing a thing in the background while you're preparing instead of taking up. It's only 30 seconds, but just sitting there for 30 seconds seems to be a barrier, I think, in people actually doing it. So we hook it up, go prepare your stuff and you come back to it and the hub is ready to go. I think that's awesome. And then as well, James, what you're saying was something that's there. I think that's also good because a lot of the problems we have too with it is The central line, especially the ones coming out of the neck, they're coming in from an angle here and then all the lines are pulling down. So it's pulling it down and away from the body. So if you find a way to secure it and also secure the hubs at the same time, all the weight of all those lines that are just constantly tugging on there would also help prevent, you know, the dressing being pulled away from the body and exposing that for, you know, for infections.

Q: A quick follow-up, Tim, on that aspect. Are there tools or methods that are being used right now to ensure it doesn't hang down and pull away at the dressing?
Tim: They've had solutions coming up over the past few years. I want to say there's at least a couple that have come up that I've seen. And most of them are just different anchors that are adhesive anchors that go onto the skin and then lock that hub to it. So if you can imagine, it's almost like a band-aid here, and then the line goes in there, and then there's usually something that tapes it down to it and holds it there. But a lot of times the problem is that the lines when they're going in, you got the hairline right there. So if it's a guy with a beard that's growing in,

you're having to shave every few days and get that dressing to stick. And so there's definitely limitations to what we have right now.

Q: Yeah. And then are the lines connected to something like an IV drift that is like a standalone thing next to the bed or where do they usually go?
Tim: Yeah, I wish I had a picture of it, but so typically like what we see in ICU or in my ICU, and I'm sure Kim sees it as well, most of the time we have a line going into the neck that's three different ports to it. Two of them are, you know, the IV scrub the hub ones. And then the third one can be used like that, or it could float a swan through it, or we can transduce it for like a central venous pressure. So basically, it's like 3 access points coming out. Typically, one of those will have what we call a train, but basically it's just an IV line with hubs all the way down it. So you could put in multiple different medications and have them all flowing through the same line. And you guys might have seen an example of that. So if you imagine that line coming out and, you know, sometimes a patient might be on 10, 12 different IV medications all going in through that line. So now you got a dozen lines all pulling down on that. Easy to get snagged on stuff and it's just in general a lot of weight pulling down on it.

Q: So I have a question because I think I didn't explain it very well, but I also, you brought up a really great point. So you said for like handheld, for the handheld version, You were talking about putting it on, leaving it and going to prepare meds and then taking it off. I think our vision was you put it on and then you hold it there for five seconds, kind of the same way that you would scrub the hub and then you take it off and you don't have to worry about it while you prepare meds. Being able to have it be something that attaches on and you leave it for 10 seconds while you prepare the meds, would that be more beneficial? official or like, are there pros or cons to either one of those that y'all can think of in your time, like actually administering medications?
Kim: I would err on the side of what you guys are already doing. I think the whole going back and forth for nurses would make them not want to use it. Tim, I don't know if you have a different perspective.
Tim: I think, if it's like a five second deal, you're already cutting down that 30 second, like time spending on it. So I think that like just goes into the natural process that we already have and just cuts down that process time, which is like the big issue instead of changing the process, which is all the behavior change that I think would. Deter them.

Tim: Yeah, I think that's definitely a good point. All right. I had one question for you with the one that you're saying you just put on there and you take it off. Does it, if it's physically soiled, so a lot of our patients, you know, sometimes it might be incontinent or just, you know, fluids there in the bed. Does it? Will it remove like gross contamination as well? Generally our lines, like if we see something like, you know, get soiled on that we're going to clean it at that point.

We're not going to wait till the next time that we're accessing that. So I don't know if it would be a huge, you know, thing to focus on or not.
A: I'm not sure yet.

Q: Do y'all have any experience with using UV lights for disinfection in the hospital? And if you do, kind of what are some of the, I guess, pitfalls you've seen? And I was also wondering if you know if there are any hospital codes that regulate what wavelengths of light might be required?
Kim: The only thing that I've seen in the hospital are the UV lights that clean after patients. They're called like True D, True Dash D. I don't know what it's. Tim, I literally can't think of the word.
Tim: Yeah, it's just like for disinfecting a patient that's on like contact precautions after they've been discharged from a room. It's, I guess, powerful UV lights. And I don't know if it works on like ionizing, like creating ozone. I'm not 100% sure, but in my head, I feel like that's how it works is by creating ozone in the space. But not a whole lot of experience with it other than smelling it after they're done.
Kim: Yeah, I attached the link in the chat that talks about like the Trudy thing. I guess that's our environmental services staff that comes and brings those in maybe or a separate staff. So it's not us as nurses directly using it, but that's the closest to UVC light I could think of that we use.

Q: I was just wondering if Kim and Tim, do y'all have any questions for us?
Tim: No, I think I just kind of asked a couple along the way about, you know, like the gross decontamination and how does that. Do you guys? Just curious, like when do you guys anticipate having like a, I guess like a testing model or a prototype?
Interviewer: So our goal for the end of the semester is to get through our like proof of principle prototyping, which is just to make sure that we know that what we're trying to do will actually work. But once that's done by the end of the semester, our goal is to have full, I believe, full developed prototypes by like early to mid-February. that we could bring in and show. And then we'll also have, we'll also have like mockups probably earlier than that as well. But the, I mean, the goal, the goal is obviously by, by April, by like early April, it's like done and tested and like iterated on with, with y'all's feedback. Obviously, like we will definitely be continuing to bring y'all stuff over the next few months.

<u>11.3 Interview #3: Alice Bremer, CLABSI/CAUTI Regulatory Committee Nurse</u>
Role: Other (Regulatory) | Interviewers: Forest Rudd
Date of contact: 11/14/25 by email | Date of interview: 11/21/25 over Zoom
Key Takeaways:

- Central line techniques are audited every week.
- Even a nurse on the CLABSI/CAUTI committee thinks the required time for bundles is not followed.

- Dressings often caused more problems than caps did.
- Time of disinfection and size are the most important factors to the device.
- Other units outside of the Cardiac ICU could be more affected by CLABSI's, such as step-down units.

Transcript:

Q: What is your background on what you know about central lines and what the book tells you to do with central lines?

A: Right. So I worked in the cardiac ICU at Duke. And I feel like in ICUs, there's a big emphasis on, because we do deal with a lot of central lines, and like catheters and things, CAUTIs and CLABSIs. And so we had pretty strict guidelines about what to do every shift with the central lines, like every, if you were dealing with like a lipid-based substance every 12 hours, you had to change the cap of the central line or every seven days you had to change the central line dressing. And then like you had to scrub the patient down with CHG every 24 hours as well. And then there were, we did a lot of like peers, observing peers of changing central line dressings, changing the caps, making sure people were adhering to all the guidelines. So I was on the CAUTI CLABSI committee and we would audit, I think somebody audited it every week actually, and would go make sure all the dressings were up to date, all the caps, and like all the tube, I don't think you all really care about that, but all the tubing and everything. And so I do feel like, I do think things were definitely missed, especially with, I know you all are focusing on like scrubbing the hub of the central line, right? I think that, I feel like in nursing there's, like sometimes you don't have time to do a lot of things and that's obviously ideally not the thing to miss. But I don't, unless you're being watched, I feel like the full 15 seconds probably wasn't. happening all the time, then letting it dry for the appropriate amount of time, too. I think those probably were things that got compromised when time kind of ran out. But I do feel like people did a decent job and were pretty aware of the importance and risks of central line infections.

Q: Could you talk a little bit more about your time on the committee itself? Kind of like, what did y'all do? How did y'all go about that?

A: Right. So we, I think there were like five of us. And so pretty much everybody once a month would audit and we would go through the chart and 1st and look at every patient. First we would make sure like they had orders for all these central lines. So like central lines weren't just staying in and using them without an order. Then we would look at the date that the dressing was changed. And for these like chlorhexidine dressings, they're supposed to be changed every seven days or unless they're like saturated or have blood outside the chlorhexidine square. So we look at the date of that. We would look at the date of the caps, which is supposed to be, it was recently changed to seven days as well. It used to be 4. And then like look how the nurse is charting the dressing, like if it's clean, dry, intact, or saturated, where it should be changed. And then an indication for the order, like if they're on vasopressors where you need a central line versus somebody with a central line who really has no indication, like isn't even getting an IV infusion, then we would talk to the nurse to then talk to the provider about getting the central line out. But

so we would go through, we would do like kind of a deep chart review first. And then obviously too, like a IJ, like a internal jugular versus a femoral line, we would look at that because ideally in the ICU, like you don't want to have It's going to happen, but femoral lines are much more prone to infection, I'm sure you all know, just because they're in a dirtier area. So we look at all of those factors and then actually go in to all the patients' rooms and physically look at the central line itself, making sure what was charted is actually true, and then look at the IV tubing, those dates, it has to be 7 days for non-lipid. Substances, so we would look at those and then talk with the nurse. And also in the chart review, we would look at making sure they're like chlorhexidine baths were up to date, so 24 hours. And then every Wednesday or every other Wednesday, the infectious disease nurse would come, like of the hospital, there was like an adult and a pediatric one, and she would round with us. And so we would already have gone into the rooms to look at all the lines, and then she would also come in too to kind of be like a second eye and offer any tips from someone who's in the role. But it was pretty in-depth. And obviously if something were wrong, then we would help, we would do the dressing change if the nurse were busy or just like offer that advice.

Q: So I've noticed you're talking a lot about the caps and the dressing. I guess this might be a little hard to be able to place without doing lab work, but if you were to guess, do you know which one, if you were to also like throw the central line hub in there, which one usually causes the most infections in your unit?

A: I feel like that is a little tough, but so our... caps for the central lines. They were actually, I don't know if you all have like physically seen them, but they're the gray caps that are, that have chlorhexanine inside of them. So they're like antimicrobial caps. So I feel like that was a good, like obviously you're supposed to scrub for 15 seconds regardless, but they kind of had that safety feature. I feel like more so the dressings. Some of our patients who are waiting for like heart transplants were more mobile. And I think the biggest one, I feel like that we had trouble with dressings were these pulmonary artery catheters in the neck. They're just really like hefty, hefty lines. The patient's moving around a lot. They're always like popping up. So I feel like, I feel like when I would come on to the shift, the biggest thing I would notice is the dressings just not being like adhesive or clean. The caps, I think it's fairly straightforward. Like you change them every seven days. They stay on the patient. You're supposed to scrub them. I feel like the dressings get a little tricky. So obviously I don't have an exact answer, but that would be my guess.

Q: What kind of qualities do you think we would need to have for nurses to actually want to use and adopt our device?

A: I think the time is something, although like nurses should be scrubbing the hub for a full 15 seconds. I feel like that could be something that could kind of impact it. I think the size, I don't know what like the size of whatever you're thinking about, but I think that's something like I feel

like you're already kind of, your pockets are stuffed during the shift. So I'm, again, I'm not sure like exactly what this device would be, but if you have to carry this around, I think, or like if there was one for every room, obviously that would be ideal that you didn't have to carry it. I'm trying to think what else. I think it would be a good idea. We did this on the Cottie Clabsy committee. We did a, activity. It used, I guess it used UV light called glow germ. And it was, we had the nurse, we like, I don't know, have you heard of this? Yeah. It's like, we would go around to the nurses and then put this like glow germ on and then have them scrub for however long they thought was appropriate. And it should be 15 seconds, obviously. Or we had them do like 3 seconds versus 15 and then put like a flashlight on it. And then obviously much more like green germ was appearing after the three seconds versus 15. Sorry, that's just something I remembered too that we did. But I feel like that was a good like visual for the nurses that, hey, like these germs actually stay on here. Like this is a problem. So, but no, I think the, I feel like in the medical field and nursing, like introducing something new. There's always, like I even felt this when I was in the position. It's just like, oh my gosh, like you're so used to a routine and change sometimes doesn't feel the best. But I mean, if it's the best for the patients, I feel like people would be willing to do it.

Q: Do you think that you're at the point right now in which people would think that this is still enough of a problem that they would want to adopt it? Or do you think they would be like, oh, we're good with how things are?
A: No, I think, I mean, I think there's always, like, there are always CLABSIs happening. I still, I don't, I'm in like full-time school now, but I still get the emails from our unit that'll be like this many CLABSIs. And like we had a unit goal for how many in like the year. And I think we did well this year, but there have been years where we really exceeded the goal. And sometimes there are obviously patient factors that you can't really control, like a central line, a femoral central line where the patient's having a lot of like incontinence or like bowel movements, like that's going to be tricky to avoid. But no, I do think, I think central line infections are always an issue. And I like, I don't know if it's different in the ICUs versus the step down force. But I know in the ICUs at least, or in my ICU, we paid a lot of attention to central line care and CLABSI prevention. But honestly, somewhere like a step-down unit where they have 4 patients that are running around, it might be good for that because I'm sure things also get overlooked there as well. So I see, like intensive care, you have one to two critically ill patients. And then once, I mean, they might be admitted directly into, it's like a lower acuity floor. Like you don't need to be in the intensive care unit anymore. So once you don't need to be in the ICU or you never need to be in the ICU to begin with, you could go to a step down unit, like a Gen. med, if you've ever heard of that. And they have, they're like lower acuity there. So they have typically three to four patients. Not as many central lines, I feel like in general on some floors versus like oncology where you have a lot of ports and things like you will have a lot of lines. But, and we would float there sometimes like they would send us there if they needed help. And I do think things definitely get overlooked just because of the balance. Like you have four people that constantly

need things, you're running around. So I feel like somewhere like that could also be really helpful. I mean, in the ICU, absolutely. But somewhere where it's just very time constraining, that could be a good implication.

11.4 Interview #4: David Lai, Cardiac ICU Nurse
Role: Healthcare Provider | Interviewers: Forest Rudd
Date of contact: 11/19/25 by email | Date of interview: 12/4/25 over phone
Key Takeaways:

- CLABSI's often come from poor dressing changes and poor awareness on nurse's parts.
- There is not enough time to check for CLABSI's in ICU's.
- Full replacement systems would be preferred to just additions to the scrub-the-hub process.
- One of the hardest aspects to making the device viable will be the orientation process and having older nurses buy in to the system.

Transcript:
Q: In your experience, how do CLABSI's usually occur?
A: I think it's just like, I mean, probably why they occur is a lot of people being too sloppy. Um, I mean, and then also just not, I think, doing the wipe down right or the proper, like using chlorohexadine to be in the scrubbing for a long time after doing addressing changes. But, um, also if a patient's been in the hospital for a long, long time. I know the longer lines are in, like the more, the more risk it is for a, a line infection. So yeah.

Q: I know there are a few different ways that CLABSIs can occur. Like we know that they can come from hubs or dressing contaminations or a few different methods. What do you think is the most common method of failure that you see?
A: Probably my guess is people forgetting, especially like on floor. Is this a specific ICU or a floor thing, or is it like a hospital wide issue?
Interviewer: Ideally it's a hospital-wide issue, but obviously you can speak better to your experience.
A: I think, yeah, the dressing - letting dressings sit for longer than they should be. A lot of times when I float to floors that the dressings that have been on for while, more than a week, maybe it's because people forgot to change it or they were too lazy to change it. So for a lot of times the dressing, even if it's been less than a week, it's falling off halfway. But people have a lot of stuff to do. So and like in their mind, the dressing chain is one of the. last thing to do. Others like giving meds, ambulating, going to procedures, stuff like that.

Q: How do you typically do central line techniques when you are in the ICU?
A: At Duke, which I work primarily, we do centralized wipe downs, I believe. I can do it on my shift. I think it's supposedly once a day, but that's kind of our protocol.

Q: How often do you get caught up in helping with other patients? Like, are there certain times of day where you find it a lot harder to be able to fully do wipe downs?
A: Definitely during the beginning of rounds on day shift. The morning is always super busy, I would say, from like 8 am to 12 pm. And then same thing on night shift, more likely from 8 pm to 12 pm. You have 4 things that are going on.

Q: If you had to pinpoint one area kind of for the greatest room for improvement in CLABSI prevention, what would you consider that one area to be?
A: Like honestly, like there probably needs to be more rounds when it comes to looking for dressing and I know that's really difficult on the board but I know that like if I know that there's somebody that's on the CAUTI Classic Committee that's working that day like I always make sure that my dressing and everything looks good because unfortunately it could not take you know, someone being, you know, a snitch or something, you know, for for you to actually do it, I believe.

Q: Would it be easier for y'all to properly decontaminate if that process were just a quicker process overall, so you didn't have to spend as much time doing it?
A: I think it depends on having to scrub for a minute every time. If there was something that made it easier, I would definitely welcome it 100%.

Q: In designing that device, would you prefer for it to be a complete replacement for a technique like Scrub the Hub, or would you prefer for it to be something that accompanied it?
A: Everybody does it differently, right? And everybody says they do it per minute, but nobody does it per minute. They're like, they're very rare, very, very rare, right? Because you have stuff to do, patients already on the whole time, they're moving, they're saying it's thing. So there's something that completely 100%, you know that if you do it and it does the job for you, I would 100% hope that.

Q: So yeah, replacement over like an additional system, I guess.
A:No, I would rather just replace it. Yeah, because if it was just, if it was just an addition, then I would just stick to my normal habits. I think everybody is hard, especially in the hospital system. It's very difficult to break habits.

Q: For something like a device like this, what kind of features would you want on it that would help you as a nurse to do your job best?
A: Features maybe like if it just covers up the entire port where you would scrub right, then don't you have to worry about it getting dirty inherently, right? Our biggest fear when we try to scrub

and do dressing cages is that uh it's going to get contaminated before we put the sterile dressing on. Yeah I mean that would be my biggest thing.

Q: And my last question is, for a device like that, what what kind of challenges do you think you would have to overcome for it to be successful?
A: Orientation process. I think getting a lot of the older nurses like myself to buy in because I am a cynic too. Let's see. I really think it's probably cost, right? I mean, to have one in every room would be difficult, you know, I don't know how much that would cost. So, yeah, I mean, that's all.

11.5 Interview #5 Harry Owusu-Dapaah Medical Provider/Anesthesiologist
Role: Anesthesiologist | Interviewers: Nathan Tweneboa-Kodua
Date of contact: 12/11/25 by phone | Date of interview: 12/12/25 over phone
Key Takeways:

- CLABSI most result from contamination during handling, not just placement.
- Insertion site selection strongly influences infection risk.
- ICU work and patient transfers are high-risk moments.
- Certain patient populations are inherently higher risk.
- Current prevention relies heavily on maintenance and monitoring visual cues, in need of a sensing mechanism.

Q: How do CLABSIs usually occur in your experience?
Harry: Yeah, Nathan, that's a great question. From what I've seen, CLABSIs for us, happen because of contamination at some point—either when the line is first placed, during the routine maintenance, or just from frequent handling of the line. The risk really goes up when there are a lot of people interacting with the patient. In the operating room, when it is done, the placement of the central line, because we can't put a peripheral IV. Usually I place sterile caps after to make sure they are clean. Transfers are a big one, like moving a patient from the operating room to the ICU, and then once they're in the ICU, you've got multiple providers at the bedside throughout the day. A lot of it comes down to transference, hands, equipment, the patient's own skin…And then patient factors matter too. Not all patients are created equal. If someone is a frequent flyer in the hospital, on dialysis three times a week, like there are diabetic and need to be exposed to certain environments more than people like you and me, they're most likely at a higher risk just because they can be exposed to so many different microorganisms over time. Maybe you want to make your device that can deal with those different scenarios and environments.

Q: That makes sense. I guess building on that, what would you say is the most common method of failure that leads to CLABSIs?

Harry : The biggest one I see is not using ultrasound consistently when placing the line. If an ultrasound isn't used, you can end up with multiple puncture attempts. Those attempts and wounds can create new sites for infection. Those extra wounds can cause more tissue damage, and that definitely increases infection risk. On top of that, you have issues like breaks in sterile technique, or nurses accessing the line more often than necessary creating new cases for infection. Patients are usually bed bound mostly so this can cause a lot of sweat and debris build up over time, which is another problem. One more thing, lines can also clot off. We flush them with heparin if this happens, but every time you access the line, that's another opportunity for contamination.

Q. What are the main things you personally do to try to avoid CLABSIs?
Harry: A lot of it starts with site selection. There are 3 main places we will use or chose. Either the intrajugular which is near the neck, femoral vein, and subclavian area. Like I said, ultrasound guidance is huge cause it helps avoid multiple punctures and vessel damage. We actually avoid the femoral vein cause we see that as the highest rate of infection, since the intrajugular is close to the mouth and ear, highest risk of microorganisms being introduced, we'll try the subclavian area as our main method, typically keeping the dressing clean, no obvious redding on the dress. We're very strict during placement to avoid any case of new introduction. After that, it's all about maintenance which is less of my field.However I can say that checking that the dressing is clean, dry, and intact, changing dressings regularly, and watching closely for signs of infection like redness or pus is normal.

Q:I guess a follow up to what you said about your job in the operating room, what role does the operating room and ICU transfer play in CLABSI risk?
Harry: So actually central lines are often placed in the operating room, which is great. Potentially the best time for someone like me to use a device like that, would be once the patient is transferred to the ICU, that's where risk starts to increase. Transport alone introduces more handling, more hands, and more people. In the ICU, you've got nurses, physicians, respiratory therapists—all at the foot of the bed. The more people involved, the more opportunities there are for transference and contamination.

Q: What is the greatest room for improvement in preventing CLABSIs?
Harry: Central line setups shouldn't be bulky, especially for groin lines. Ideally, they'd be lightweight, attached securely to the central line, and positioned far away from high-contamination areas. Maybe we should make a harness or something to clamp onto the skin…..Having visible indicators of infection—like early signs of pus—and designs that reduce clotting would also help. Right now, we rely a lot on dressing changes, but it all also depends on different medications and products that the lines are used for.

12. Design Ethics

12.1 Current Ethical Concern

Patients with central venous catheters are directly affected by CLABSI risk, especially those in intensive care units who are often immunocompromised and have limited ability to advocate for themselves. Breaches in non-maleficence occur when preventable infections develop due to suboptimal catheter care or delayed diagnosis. Autonomy may also be compromised as patients often depend on healthcare providers to implement infection prevention and timely intervention. The principle of justice is challenged when infection control resources vary by hospital or patient socioeconomic status, potentially leading to higher CLABSI rates in under-resourced settings or marginalized populations (CDC, 2023; Zimlichman et al., 2013).

Example Case #1
Real-time electronic monitoring systems for catheter care show potential to improve patient safety through their ability to detect infection signs before symptoms appear (Choudhuri et al., 2011). These monitoring systems would decrease the need for human judgment in patient assessments while allowing doctors to start treatments sooner which could lead to better results and reduced medical expenses. The expensive nature of these systems together along with requirements for advanced staff training create major obstacles for their implementation in settings with limited resources. Furthermore, the implementation of these innovative technologies faces challenges because resource-constrained hospitals lack the ability to maintain them which worsens existing healthcare inequalities.

Example Case #2
The combination of patient-centered education with shared decision-making for central line maintenance allows patients and their families to actively participate in infection prevention through correct hygiene practices (Buetti et al., 2022). Patients who participate in decision-making about their care practices show better adherence which produces superior health results. However, healthcare providers and caregivers also need to perform additional ethical responsibilities because critically ill patients cannot decide about infection prevention measures, and healthcare organizations must maintain elevated standards of care regardless of patient involvement in decision-making processes.

Example Case #3
The use of standardized central line bundles for both insertion and maintenance has shown to significantly reduce the incidence rate of central-line infections by promoting uniform, evidence-based practices of care (Provonost, et al., 2006). These central-line bundles support ethical forms of beneficence by acting to minimize patient harm. However, at the same time, strict adherence to bundles could conflict with potential individualized care practices, especially

in cases where deviation from the central line bundle could be clinically justified. Furthermore, understaffed locations may have a harder time ethically implementing these bundles properly, which could raise concerns about fairness and accountability.

Approach to Addressing Concern
Our project will solve these ethical problems through sensor-based monitoring of central line sites which uses low-cost technology to track temperature and humidity levels and detect early infection symptoms. The system depends on continuous objective data collection instead of depending on clinical staff observations to minimize both diagnostic delays and observer prejudices. The system promotes justice through its affordable design and user-friendly interface which enables CLABSI prevention in various healthcare facilities regardless of their resource levels while protecting patient safety and upholding ethical values of beneficence and non-maleficence and autonomy and justice.

12.2 Regulatory Pathways

The most common device-based treatment of CLABSI's is the use of antimicrobial catheters, specifically those containing as an antimicrobial agent (Buetti et al., 2022). This device is considered a medical device, as it is used for the treatment and mitigation of a disease (CLABSI's) and interfaces directly with the bloodstream, thereby affecting the structure of the body. The device is FDA-approved under 21 CFR 880.5200 - Intravascular Catheter, and the antimicrobial-impregnated catheters are considered a Class II medical device (FDA, 2025). Antimicrobial catheters are considered a Class II device due to the need for efficacy and safety validation. They are also under regulation in the EU under the CE Mark and MDR as a Class IIb medical device due to their invasive nature (European Union, 2017).

The regulatory pathway for this type of device first starts by classifying the device as a Class II device. Since this device is not exempt, it must submit a 510(k) to show that it is substantially equivalent to other previously approved antimicrobial catheters in both efficacy and safety (FDA, 2022). After performance and safety testing is complete, the device must be cleared by the FDA. As part of the regulation of the device, post-market surveillance of the device must occur, and manufacturers must also maintain Good Manufacturing Practice (GMP). In the EU, manufacturers would also have to compile a technical file subject to documentation guidelines in Annex II and III, and applicants would have to submit a Declaration of Conformity to be eligible to use the CE Mark (Emergo, 2025).

However, a different course of action with a UV-C emitting portable device is available. Currently, there are no such devices used to treat CLABSI's, but any UV-based device for the surface disinfection of equipment would fall under 21 CFR 880.6600 as a Class II device (FDA, 2025). Due to the unique interface of our product with the catheter hub, the device could fall

under 510(k) restrictions to show substantial equivalence, or it could be required to go down the "De Novo" pathway as a new product classification (US FDA, 2024). This would require submitting a De Novo request including intended use, risk analysis, and testing, and the FDA would approve the device as a Class II device.

13. Midterm Design

13.1. Handheld UV-C Light Emission Device

13.1.1 Principle of Operation (PoO)

The disinfection device operates by harnessing the well-established germicidal properties of UV-C radiation, specifically within the 254–265 nm wavelength range. The molecular bonds of nucleic acids including DNA and RNA become accessible to UV-C photon energy because these acids show their maximum absorption at 260 nm (Ganske, 2014). This absorption induces a series of photochemical reactions, including the formation of uracil and cytosine dimers in RNA, single- and double-strand breaks, and cross-linking that disrupts proper replication and denatures the DNA and RNA strands (Thomas, 1993). The mechanisms operate at high speed to disable microorganisms including bacteria and fungi and viruses by blocking the genetic material transcription and replication processes.

The device is optimized for ease of use in clinical workflows, particularly for disinfecting central line hubs. The nurse places the handheld device above the hub to achieve complete coverage through its circular design which provides a tight seal to block all light from escaping. The device starts its operation when the button on top is pressed which leads to automatic centering and sealing of the hub before it begins a 5-second UV-C exposure period. The high-intensity UV-C LEDs create a uniform light field which covers the entire enclosed area to achieve complete disinfection of the entire hub structure. The hub displays a green indicator which flashes to show that the system has reached a safe state for immediate entry. The docking station of the device which sits near line access points provides continuous power supply and easy access and fast deployment capabilities which enable staff to maintain consistent disinfection protocols that minimize contamination risks and enhance clinical operational efficiency.

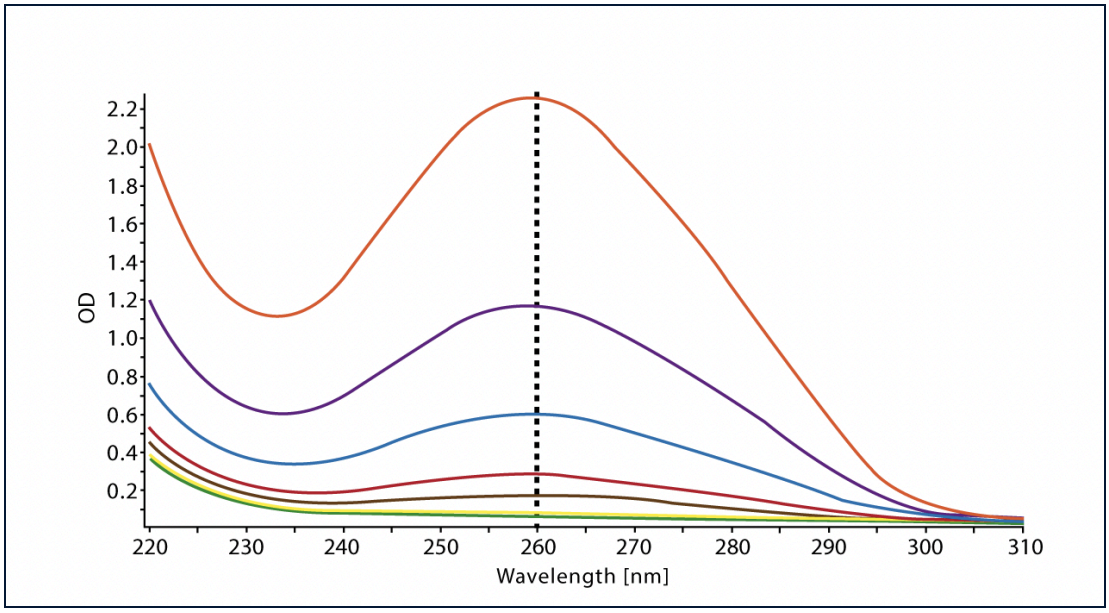


Figure 29: Absorbance spectrum of different concentrations of calf thymus DNA recorded on a BMG LABTECH microplate reader. Detection range is between 220 and 310 nm and resolution was set at 1 nm (Lee, 2018).

13.1.2 Block Diagram

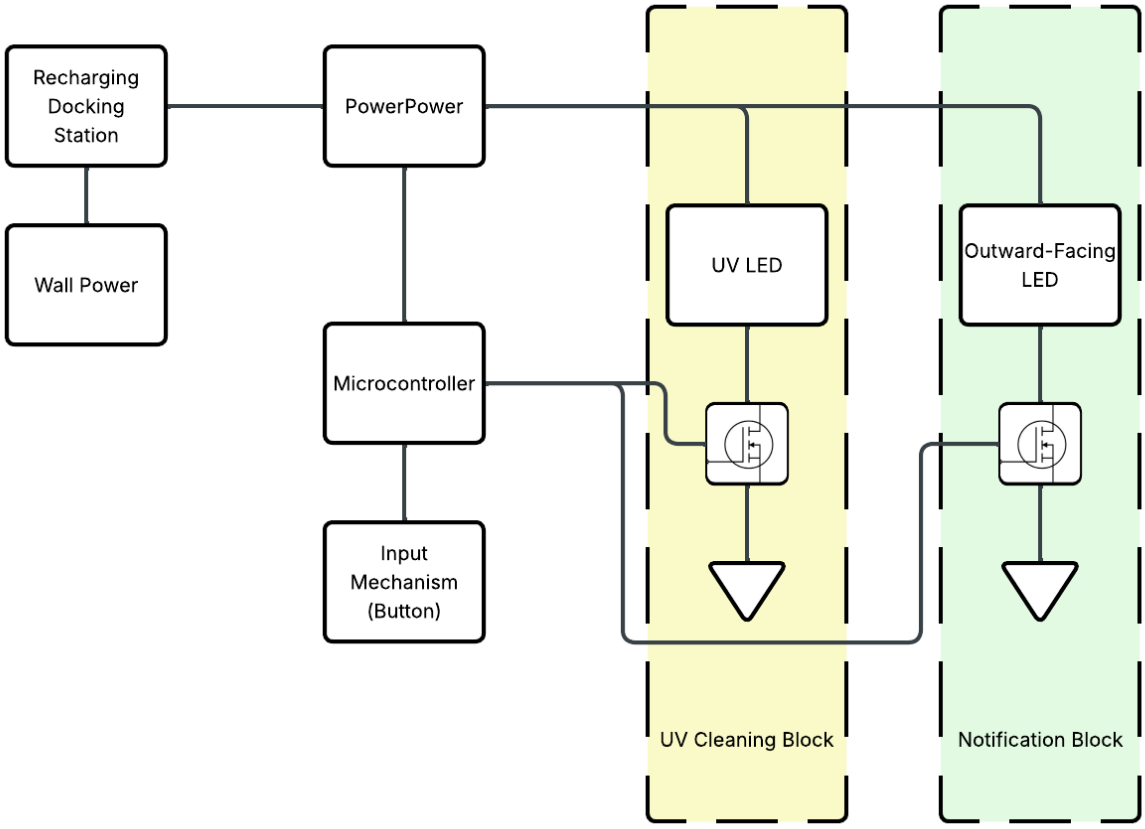


Figure 30: Block Diagram of Handheld UV-C Light Emission Device

13.1.3. Flowchart

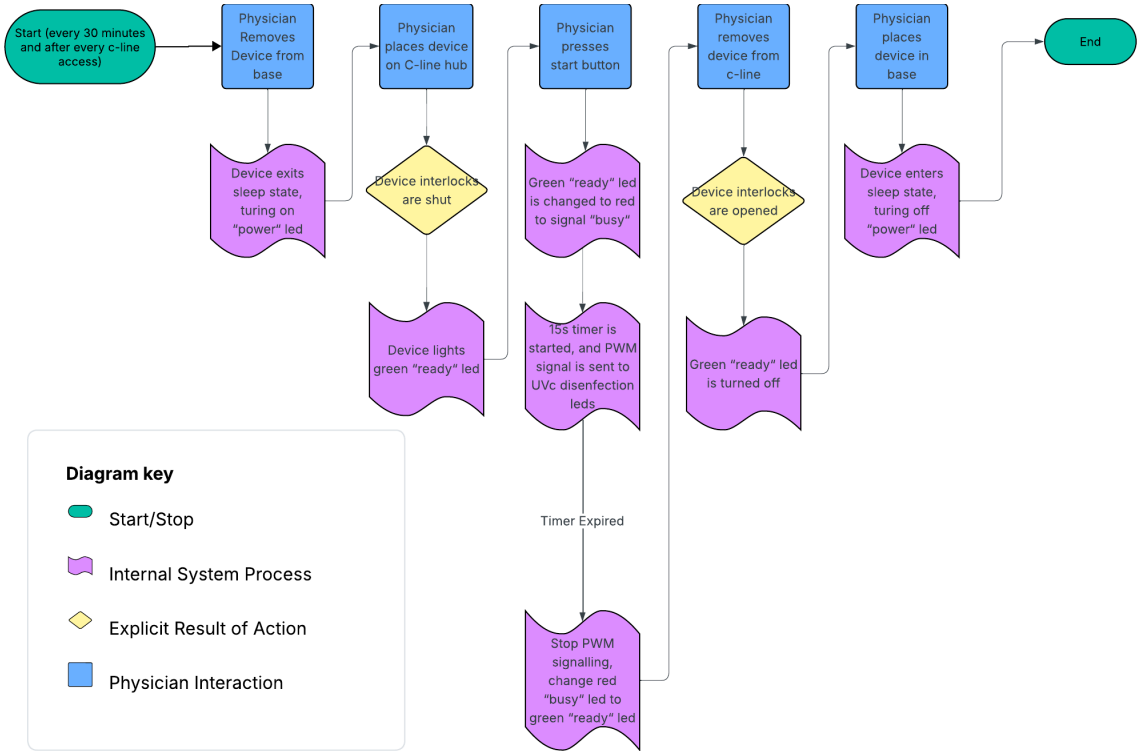


Figure 31: Flowchart for Handheld UV-C Light Emission Device

13.1.4. CAD Rendering

The CAD rendering illustrates the compact form factor and functional layout of the handheld UV-C light emission device. The model shows the device's ergonomic cylindrical design which includes an integrated power button interface and its UV-C LED array that runs through the circular aperture which surrounds a central line hub. The inside of the device has a placement feature for both the docking station for charging and for lining up central line hubs in the device. The views show how outside design elements connect with inside structural components which both protect the seal and produce equal lighting and support medical procedures.

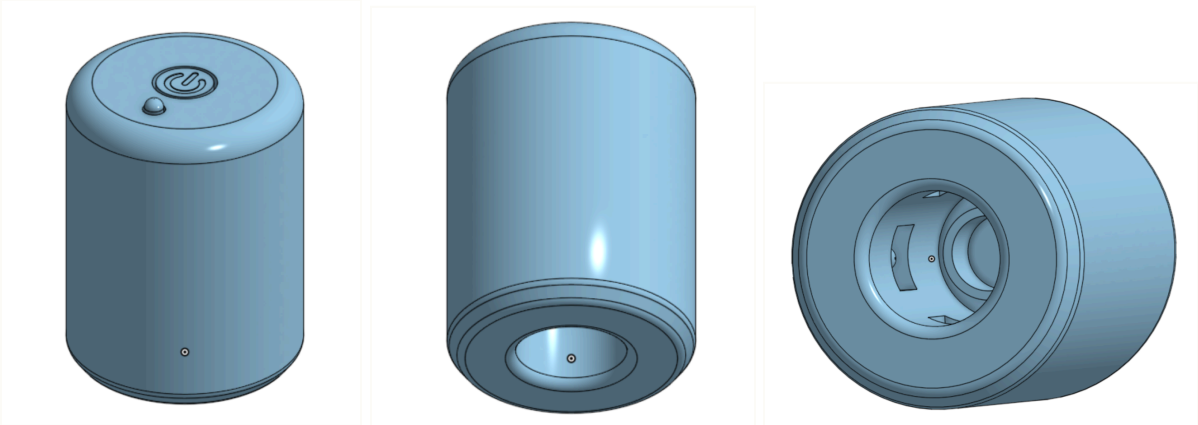


Figure 32: CAD Rendering of Handheld UV-C Light Emission Device

14. Proof of Principle Testing

Proof of Principle Testing was split into two sections: UV Characterization Testing and Bacterial Irradiation Testing. UV characterization testing was performed to assess the light source itself, while bacterial testing was used to test its efficacy in eliminating bacterial spread. In these tests, two light sources were tested - a UV Antiviral Light Bolt from Amazon, and a 254nm UV LED from Digikey.

14.1 UV Characterization Testing

UV Characterization testing was split into two separate tests: optical power testing to test the output of the LED and spectral characterization to test the bandwidth of the light source. The objective of these tests was to empirically test the optical output of the light to assess whether or not the light would be effective in bacterial irradiation.

14.1.1 Optical Power Testing

Materials:
THORLabs PM400K5 Optical Power Meter

Necessary UV LED's
DukeLabs voltage supply
3D-printed safety casing
UV-protective safety glasses
Personal Protective Equipment

Methods:

1. Put on safety equipment and place UV LED in protective casing.
2. Perform test in a dark room to limit ambient light.
3. Place LED directly over optical power meter at a distance five times the LED width (Ryer, 1997).
4. Turn on and zero optical power meter.
5. on LED for fifteen seconds at a voltage of 9V and a current of 30 mA.
6. Record optical power.
7. Turn off LED and rezero optical power meter.
8. Repeat this trial 9 more times for a total of 10 trials.
9. Repeat steps 4-8 with voltages of 10V, 11V, and 12V.
10. Repeat steps 3-9 with second LED.

14.1.2 Spectral Characterization

1. UV LED in protective casing.
2. Place LED in line with optical diffuser connected to spectrometer at a distance five times the LED bulb width.
3. Turn on spectrometer.
4. Turn on LED at a voltage of 9V and a current of 30mA.
5. Take a recording of spectrometer data to import into a csv.
6. Turn off LED.
7. Repeat this trial 9 more times for a total of 10 trials.
8. Repeat steps 3-8 with voltages of 10V, 11V, and 12V.

14.2 Bacterial UV-C Irradiation Testing

The objective of the bacterial testing is to validate a significant reduction in bacterial colony forming units (CFUs) of 95% by UV-C irradiation over the target surface at a specified duration and intensity. Three treatment groups are used: control, UV-C irradiation at time t=0 hours (T0), UV-C irradiation at time t=12 hours (T12). T0 assesses immediate UV-C potency at reducing CFUs while T12 assesses UV-C potency after a 12-hour duration of no catheter hub accesses overnight until the morning. As morning hospital rounds involve accessing hubs to ensure lines are still valid and not blocked in the case of emergent access. The output of the experiment will be three CFU counts within each bacterial dilution for each treatment condition. Only three

samples were used to balance ensuring statistical significance and minimizing the number of agar plates used due to the need of serial dilution to avoid saturation of the plate.

The used bacteria was the DH5-alpha *E. coli* strain from ThermoFisher. *E. coli* was selected for its low virulence factor, availability in the lab, and high safety profile suitable for proof of principle testing. Duration was selected at 5 seconds because field notes found a median time of 5 seconds from beginning to scrub the hub to pushing medication on the IV line; thus, a significant result at 5 seconds would facilitate substitution of the ethanol scrubbing with the target UV-C device. Intensity was selected at 12V.

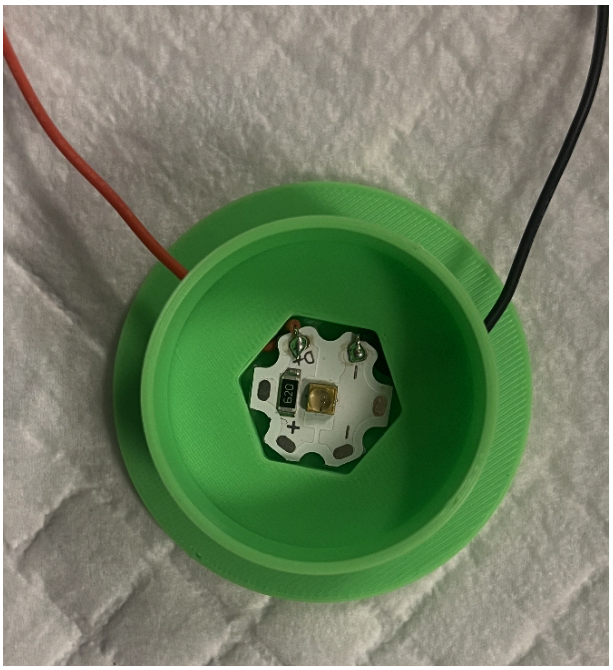


Figure 33: Proof of Principle UV-C LED Enclosure for 35 mm petri dishes. The petri dish sits within the enclosure during irradiance. DC power supply not included in image.

The following procedure was followed in a Biosafety Level 2 certified laboratory (Duke University, Teer P05 Lab):

Day 1.1: Expand seed culture

1. Wear appropriate PPE.
2. Pour 10 mL sterilized LB broth in a 14 mL culture tube.
3. Thaw a microcentrifuge tube of DH5-alpha *E. coli* on wet ice.
4. Mix and aliquot 20 µL of DH5-alpha into the 14 mL culture tube.
5. Place the culture tube in the shaking incubator (37 ºC) overnight.

Day 1.2: Prepare LB agar plates

6. Measure and mix 7.5 grams LB broth (Lennox) and 4.5 grams agarose in 300 mL of deionized water.
7. Autoclave LB agar mix.
8. Pour sterilized 5 mL LB agar into 35 mm petri dishes (9X per concentration tested)
9. Once agar plates are solid, store upside down in the refrigerator overnight

Day 2: Serial Dilution and Initial Testing

10. Get and label 7X 5 mL culture tubes from E-1 to E-7.
11. Pipette 900 µL of DPBS into each 5mL culture tube.
12. Vortex the incubated DH5-alpha 14 mL culture tube and pipette 100 µL of the bacterial suspension into the 10E-1 tube.
13. Vortex the E-1 tube and pipette 100 µL of the diluted bacterial suspension into the E-2 tube. Continue the serial dilution until the final E-7 tube, being sure to vortex each tube prior to pipetting.
14. Retrieve agar plates from refrigerator and label for each dilution and three replicates for each treatment group (control, T0: irradiation after spreading, T12: irradiation 12 hours after spreading)
15. Vortex the appropriate dilution tube and pipette 90 µL onto the center of each agar plate and spread by shaking north-south, east-west, diagonals, and figure-eights.

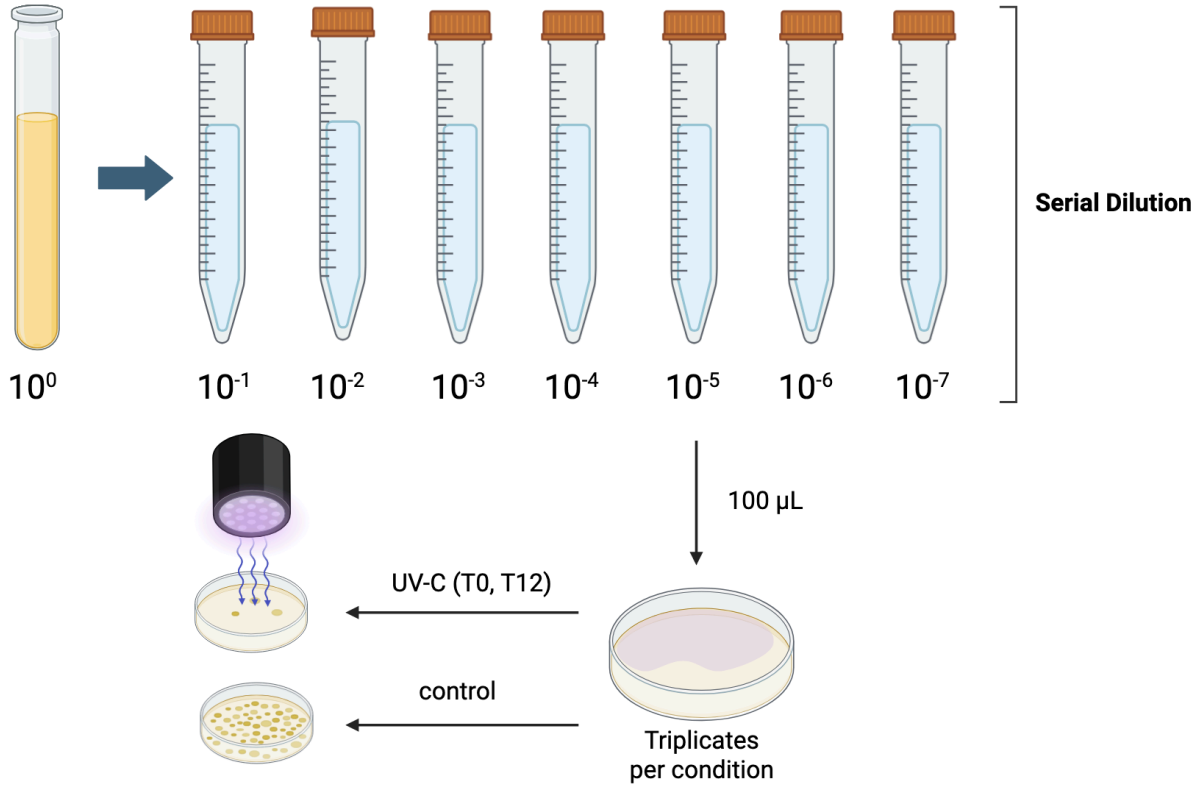


Figure 34: Serial Dilution and Experimental Testing Process.

16. Irradiate each T0 agar plate for 5 seconds at 12V, 100mA with the target UV-C LED setup
17. Incubate plates upside down overnight.

Day 3: Final Testing

18. Inspect each dilution plate and select a dilution to continue with final testing. Selection should be based on clear distinct and countable CFUs below 100.
19. Irradiate each T12 agar plate for the selected dilutions as done in step 16.
20. Place plates back in the incubator upside down overnight.

Day 4: Measurement

21. Take plates out of the incubator, and count CFUs for each treatment group and selected dilutions using ImageJ.
22. Image control and T12 CFUs with 40X phase microscopy by pipetting 20 µL of sterile distilled water on a microscope slide and mixing one distinct colony onto water. Let water air dry then stain with crystal violet for one minute and then rinse with water.

15. Proof of Principle Outcomes

15.1 UV Characterization Testing

Testing was performed with two LED's - a UV Antiviral Light Bolt from Amazon, and a 254nm UV LED from Digikey. The Antiviral Light Bolt was powered at 30mA of current, while the 254nm LED was powered at 100mA of current according to the safety documentation with each LED.

15.1.1 Optical Power Testing

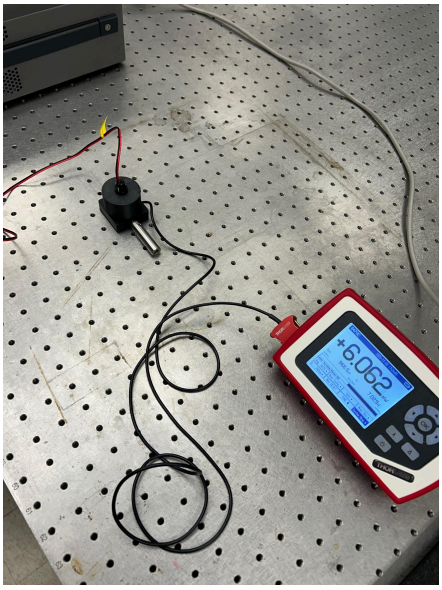


Figure 35: Optical Power Meter Testing Setup

For UV characterization testing, we have two sets of data. First, we obtained optical power data from the optical power meter. This data is displayed in the figures and table below:

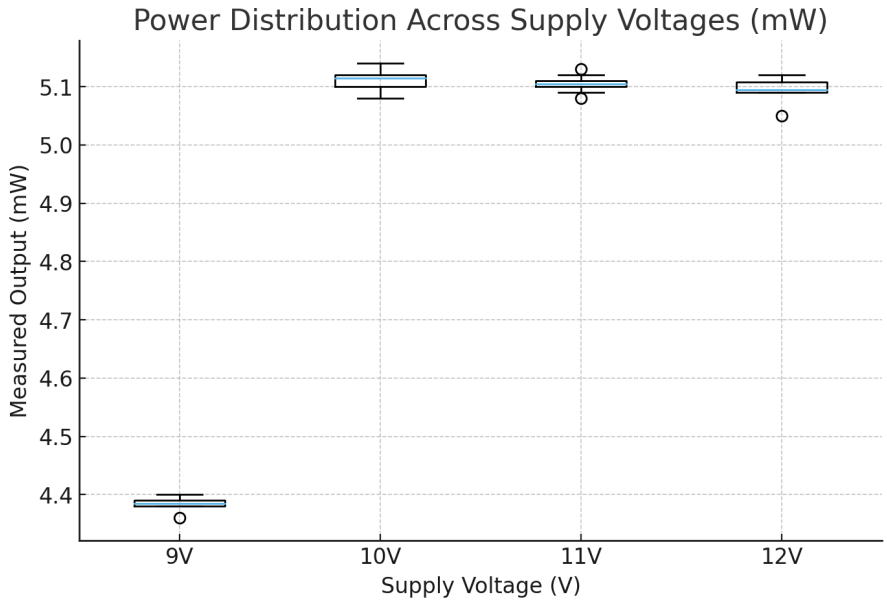


Figure 36: Optical Power Output of LED over 9V, 10V, 11V, and 12V. Box-whisker plots show the measured output distribution with a shared scale for meaningful comparisons.

Table 3: Optical power of UV Antiviral Light Bolt at Different Voltages

Supply Voltage (V)	Average Output (mW)
9	4.39 ± 0.12
10	5.11 ± 0.19
11	5.11 ± 0.14
12	5.10 ± 0.19

When analyzing this data, the first trend to note is that power greatly increases between 9V and 10V. There is a 17.1% increase in optical power when increasing voltage from 9V to 10V. However, at 10 volts and above, the optical power stabilizes at around 5.1 volts and draws 9.15 volts.

Statistical analysis was performed through means of a one-way ANOVA followed by multiple t-tests when comparing power output over different voltage levels. The ANOVA returned a p-value of 4.27E-47, so we can conclude that there is a statistical difference between at least two sets of voltage outputs. When comparing individual groups, output from 9V is significantly different from outputs at 10V, 11V, and 12V, with p-values of 3.29E-23, 6.06E-27, and 1.14E-22, respectively. However, there is no significant statistical difference between the power measured at 10V, 11V, and 12V. The p-values for those t-tests are 0.42 for 10V and 11V, 0.07 for 10V and 12V, and 0.20 for 11V and 12V.

The 254nm UV LED was only tested at 12V of power and 100 mA of current. This was done to increase the quickness of our testing procedures. We thought that this analysis was appropriate, as we set the power as high as feasible for a potential device to test for efficacy in bacterial experiments. This supply produced an optical power of **3.67 ± 0.08 mW** through ten trials. When comparing this value to the first LED being powered at 12V, there is a -28.0% decrease from the first LED to the second LED. When performing a t-test to analyze the statistical difference between these outputs, there is a p-value of 2.7E-11, showing a statistically significant difference between the samples.

15.1.2 Spectral Characterization

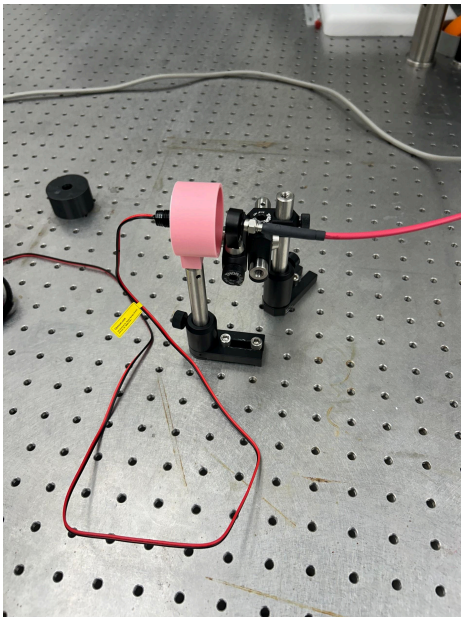


Figure 37: Spectrometer Testing Setup

In our other set of characterization testing, we have spectrometer data, which characterizes the wavelength output of our LED. For our Antiviral Bolt Light LED, much of the optical power comes from the blue light spectrum instead of the UV spectrum. While the UV spectrum does have a peak, in order to detect it we have to completely saturate the blue light spectrum.

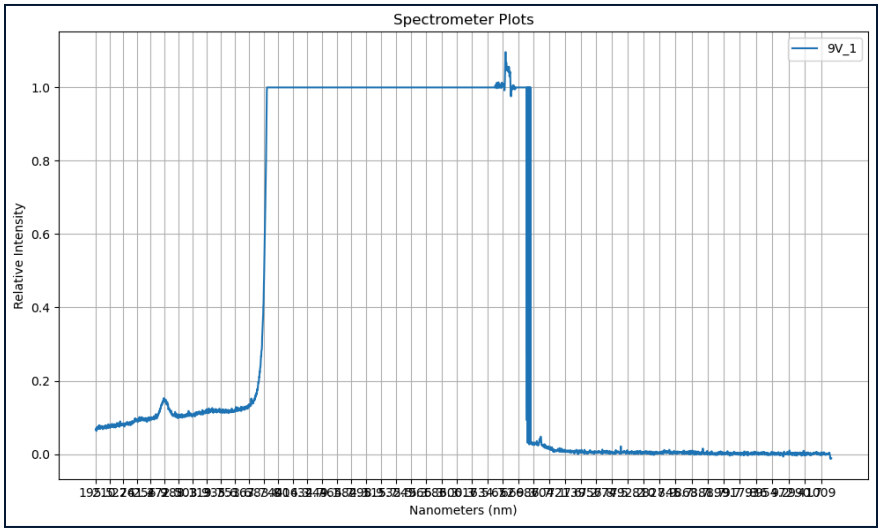


Figure 38: Full wavelength spectrum of Antiviral Bolt Light.

Despite this saturation, a UV peak does appear and is worth analyzing. When plotting all spectra together and focusing solely on the UV band, a peak is formed. This peak occurs with a

maximum relative intensity value at a wavelength of 272 nm. This relative intensity value depends on the voltage provided to the LED. The relative intensity of our Antiviral Light Bolt occurs at 0.16. Furthermore, based on this data, we can determine the UV band that is given off as a result of this peak. We determine the band by taking the half-max of light intensity between the peak and the average baseline intensity. The band spans from 268.1 to 277.2 nm, which does not the crucial value of 260 nm.

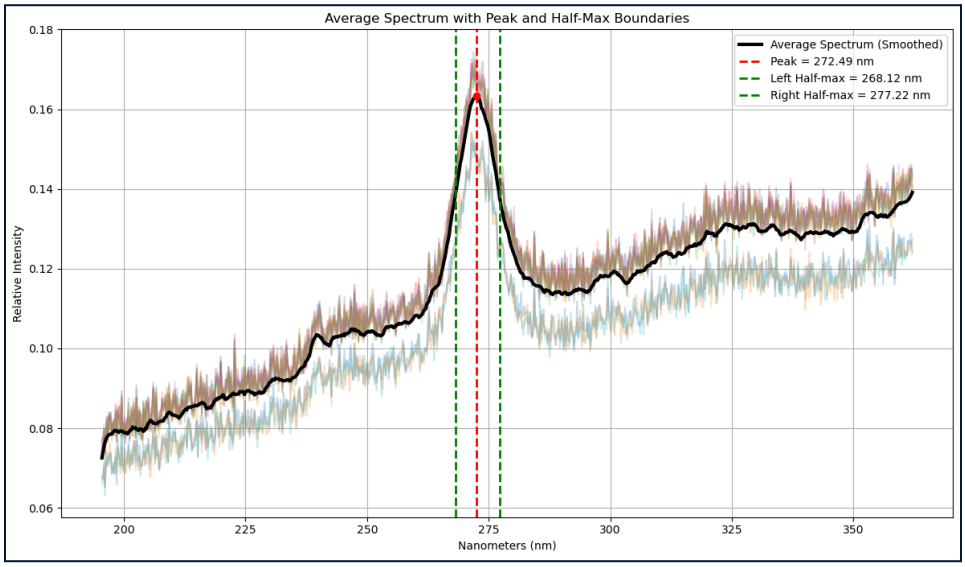


Figure 39: Average UV wavelength spectrum of Antiviral Bolt Light with peak at 272.5 nm.

When looking at our 254nm LED, a much clearer spectrum emerges. This spectrum has a peak at a wavelength of 259.2 nm with a relative intensity of 0.31. Furthermore, we can determine the UV band that is given off as a result of this light. Using the same technique as before, the UV band for the 254nm LED spans from 253.6 to 264.7 nm, which does contain the crucial value of 260 nm.

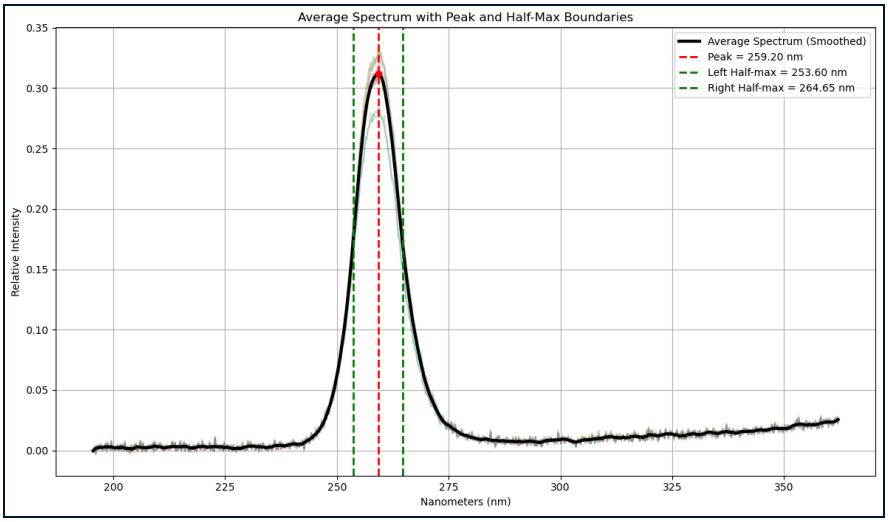


Figure 40: Average light wavelength spectrum of 254nm UV LED with peak intensity at 259.2 nm.

15.1.3 UV Characterization Analysis

When looking initially at the optical power testing the Antiviral Light Bolt seems like the correct LED choice. The bulb produces 28% more power than the 254nm LED at the same voltage and specified current draws, for which the Bolt Light in fact draws less current. Furthermore, the Antiviral Bolt Light stabilizes its optical power at a voltage of 10V, which would be the power required to provide maximum output. However, when analyzing the spectral data of the two LED's, it is worth noting that a majority of the optical power for the first LED comes from its broadband blue light LED power. In fact, those wavelengths had to be fully saturated before UV peaks started appearing on the spectrometer. Furthermore, for the Antiviral Bolt Light LED, the UV spectrum does not contain the crucial wavelength of 260 nm. Thus, it would be a bad choice for an LED.

In comparison, the second LED, while giving off a lower optical power, has a higher relative intensity of its UV peak by 93.8%. Furthermore, its peak is 259.2 nm, not even 1 nm away from the ideal, and its narrowband spectrum of 253.6 to 264.7 nm gives a total bandwidth of 11.1 nm, small enough to be focused on the ideal wavelengths for eliminating bacterial reproduction.

To give the proper dose of radiation for a three-long bacterial reduction on a surface, a dosage of 6.6 mJ/cm^2/nm needs to be provided (Malayeri et al., 2016). To calculate this value, the spectral irradiance of the LED needs to be calculated with equation (1) and multiplied by exposure time to calculate the dosage. The Antiviral Light Bolt LED cannot have its spectral irradiance calculated due to its broadband light source, but the 254nm LED can have its irradiance calculated. The detector area is 5.07 cm^2 according to the document specifications, and the LED

outputs 3.67 mW of power over an 11.1 nm bandwidth. Thus, the irradiance value for the 254nm UV LED is 0.065 mW/cm^2/nm, and therefore needs to be powered for 101 seconds to give a proper dose of UV light. It is very worth noting, however, that this formula is purely based on units, so true bacterial testing is needed to determine whether our UV light actually emits the proper dose to eliminate bacterial reproduction.

(1) $$Irradiance = \frac{Optical\ Power}{Detector\ Area\ (Narrowband\ Wavelength)}$$

15.2 Bacterial Testing

15.2.1 Dilution Selection

Testing continued with a dilution of E-5 (10^{-5}) relative to incubated inoculum. Lower concentrations (E-4, E-3, E-2) had uncountable colonies upon inspection as seen in Figure 42 or expectedly uncountable colonies after another day of incubation due to high density as seen in Figure 41. Higher concentrations (E-6, E-7) had no visible or significant growth as seen in Figure 43.

Several factors impact the selected dilution; however, the notable factors are the starting inoculum, the time of incubation, and pipetted amounts. For reproducibility of this experiment and target dilution, it must be asserted that 20 µL was aliquotted from the thawed seed culture and incubated in 10 mL of LB broth. Additionally, incubation persisted for 36 hours, specifically in this experiment, prior to dilution. Furthermore, 90 µL of the dilution was pipetted into the center of a 35 mm agar plate. Changes to the aforementioned values may alter the selected dilution.

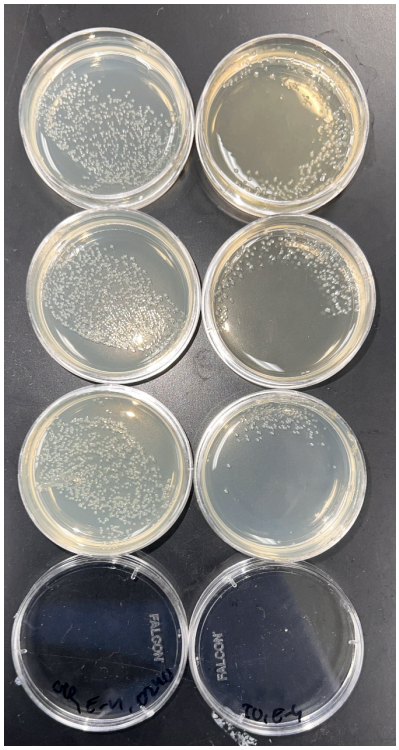


Figure 41: E-4 plating of Control and T0. Notable area of no growth in T0 relative to control. High density in control colonies.

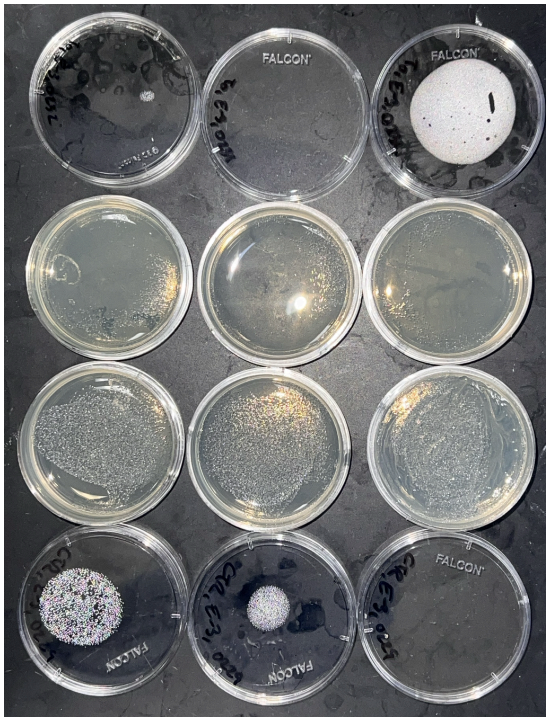


Figure 42: E-3 Plating of Control and T0. Uncountable colonies in the control plate (third row of plates).

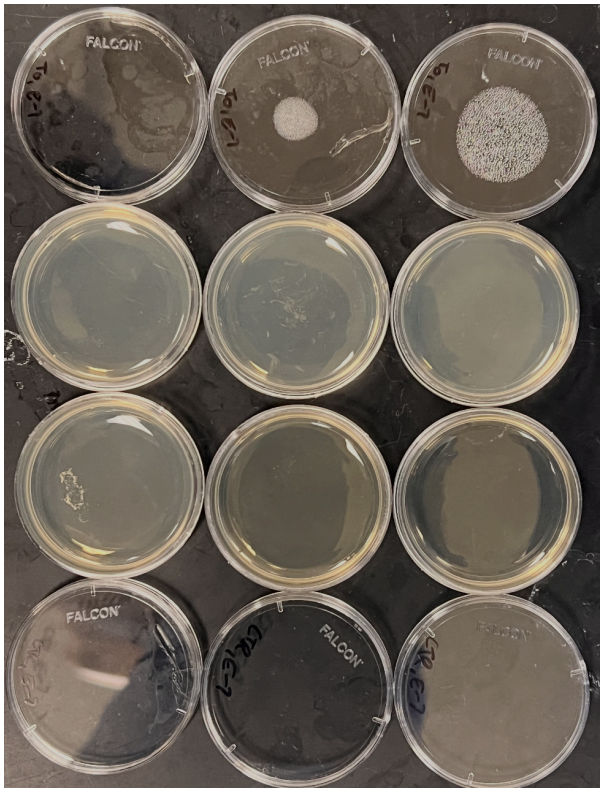


Figure 43: E-7 Plating of Control and T0. No visible colonies in control (third row of plates).

15.2.2 CFU Counts

The selected E-5 dilution was measured on Day 4 of the procedure. A clear area of no growth is seen at T0, slightly greater than the area of the used LED PCB but smaller than the 35mm petri dish surface. An area of stunted growth is seen at T12, smaller than the area of the used LED PCB and smaller than the area of no growth in T0.

Testing has validated the proof of principle that UV-C can indeed kill bacteria on a surface; however, the presence of an area of dead bacteria as opposed to total eradication of the surface motivates spatial tuning of the device. Device improvements will need to ensure adequate coverage of the contaminated surface by an arrangement of LEDs to ensure exceeding the necessary lethal dose at all points of the surface, especially considering directionally of UV-C emission such as the hemispherical dome focusing beams forward. Additionally, height parameters will need to be assessed and calculated with optical intensity equations on a catheter hub model. Height, intensity, durations and UV-C emitting source arrangements need to be considered in various configurations while accounting for early and late bacterial growth as seen in T0 and T12, respectively.

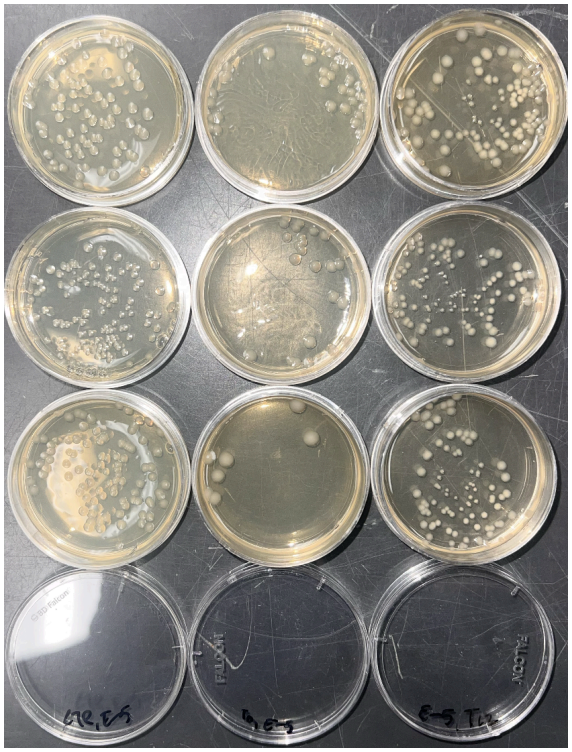


Figure 44: E-5 Plates on Day 4. Area of no growth in T0 relative to Control. Smaller area of stunted growth in T12 relative to Control. Bacterial growth in T0 seen at the edges.

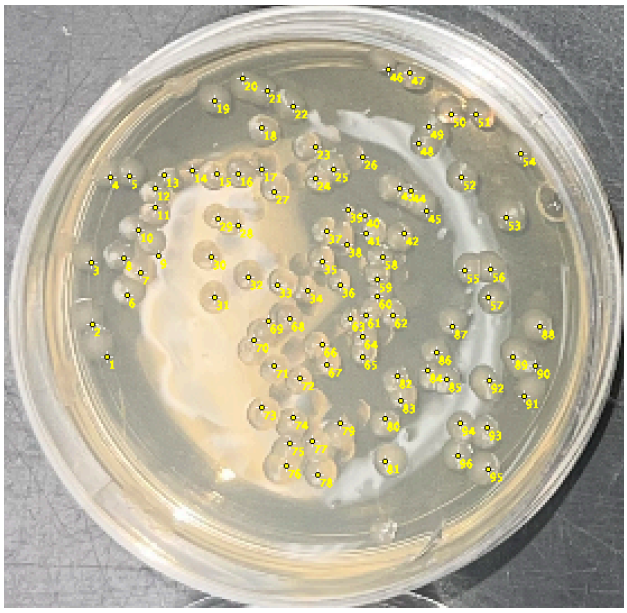


Figure 45: ImageJ counting of a Control E-5 Plate imaged on Day 4. Total count of 96 CFUs.

TABLE 4: CFU Counts for Treatment Conditions (Control, T0, T12). T12' included to account for stunted CFUs (equal CFU size prior to treatment and 12 hours after incubation)

Control	T0	T12	T12'
96	7	97	80
110	22	102	53
89	31	87	57

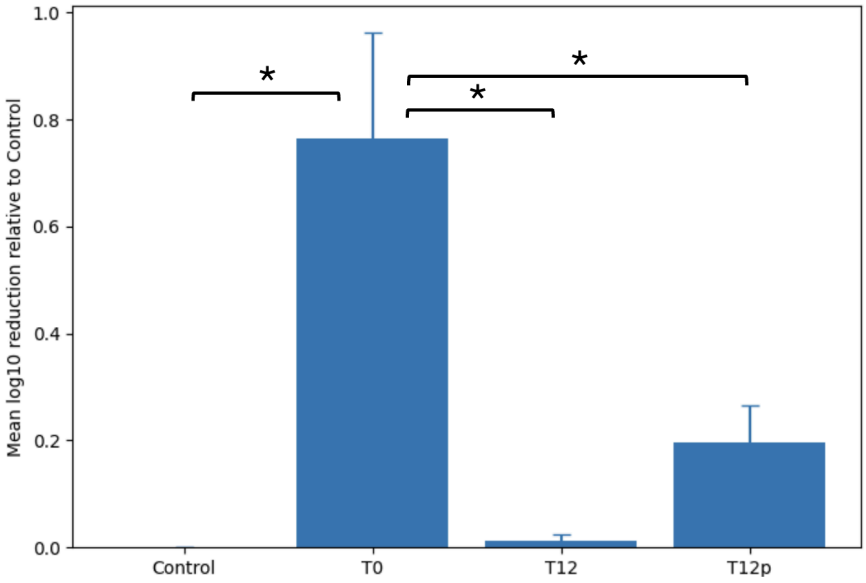


Figure 46: Log(CFU) Reductions of Treatments Relative to Control. * denotes statistical significance by $p < 0.05$ with one-way ANOVA and Tukey post-hoc testing.

15.2.3 Qualification of T12 versus Control

The lack of live/dead bacterial assays due to cost constraints motivated qualification of the visibly stunted CFUs on the T12 plate relative to the control plate. A colony from the center of the control and T12 plate was heat adhered to a microscope slide and stained with crystal violet for visualization. As shown in Figure 47, the control CFU had near 100% confluency; whereas, the stunted T12 CFU had about 30% confluency as shown in Figure 48. Despite a similar CFU count in T12 relative to control, bacteria was killed as evidenced by the lack of colony growth after a day of incubation (by visual overlay with an image a day prior) and the low confluency of 30% of the T12 CFU relative to 100% confluency of the control CFU.

Future quantification efforts will need funding for a fluorescent live/dead bacterial assay or a cheaper metabolic equivalent live/dead bacterial assay to quantify viability before and after UV-C irradiation. Bacterial testing did not achieve the target reduction of 95% or a log(CFU) reduction of 1.301; however, UV-C is a promising method of bacterial eradication as seen in a

significant result in CFU counts for T0 relative to control and qualification of stunted T12 CFU relative to control CFU by confluency measures. Future improvements will need to be made to the irradiation setup as elucidated in *15.2.2.*

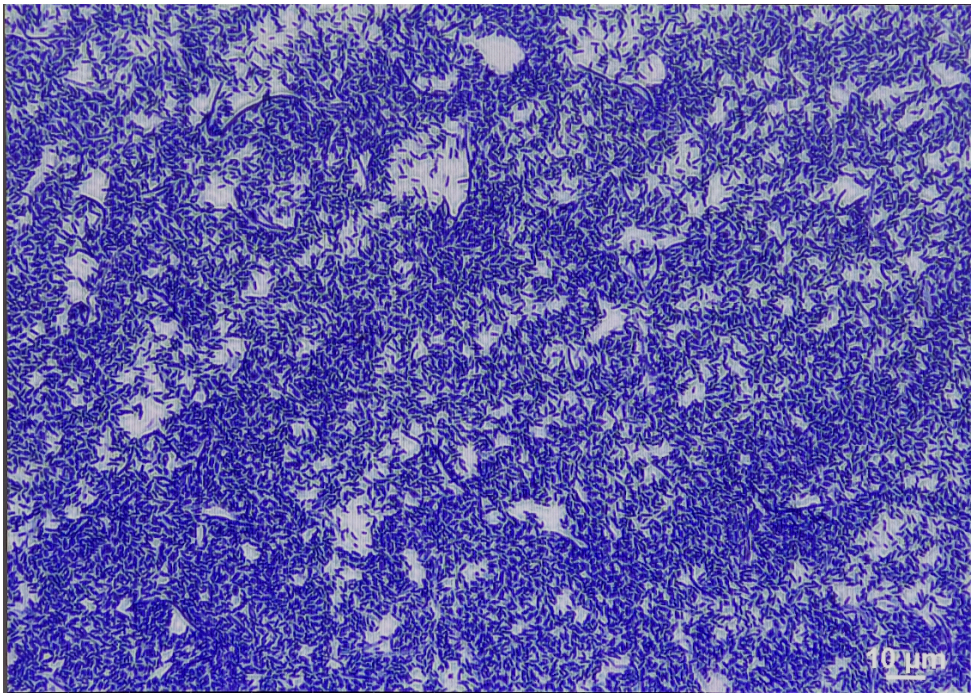


Figure 47: Control CFU Imaged with 40X Phase Microscopy after Crystal Violet Stain. *E. Coli* at near 100% confluency.

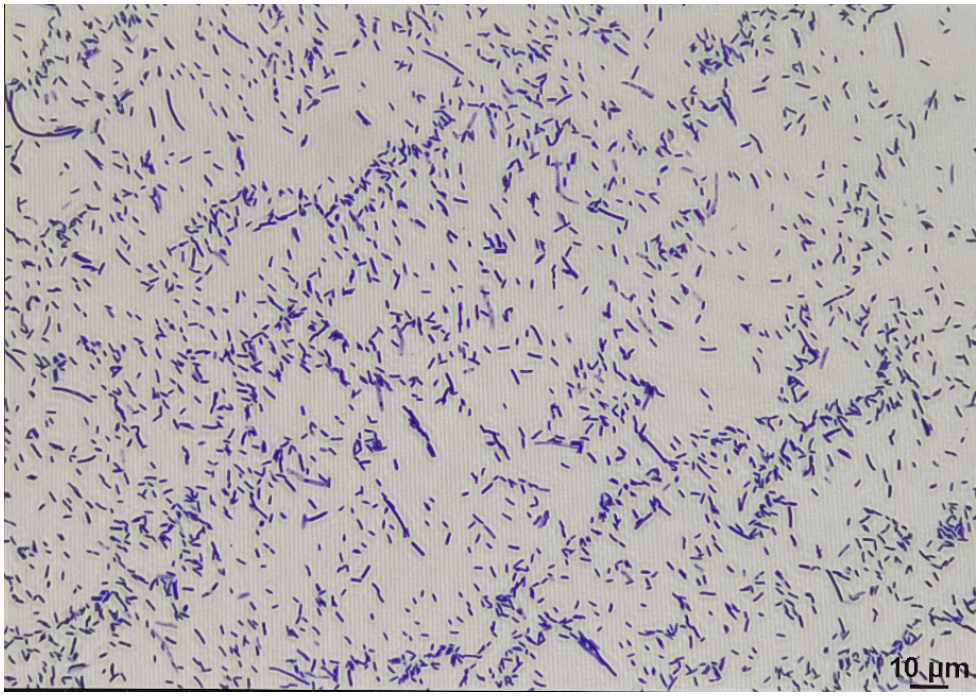


Figure 48: T12 CFU Imaged with 40X Phase Microscopy after Crystal Violet Stain. *E. Coli* at near 30% confluency.

15. Design Review Meeting Agendas

15.1 DRM #1

Agenda Info:
Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Meeting Lead: Daniel Chong
Meeting Scribe: Forest Rudd

Recap:

Semester 1 Feedback Review:

- Field notes comment - the notes were primarily from observation - Forest and David surveyed and observed a range of nurses performing procedures.
- Importance of anesthesiologist - the team wanted to interview other physicians who primarily handle central lines and their maintenance, so they reached out to an anesthesiologist to try to better understand if CLABSI's were an issue in the ICU alone or if they affected other areas of the hospital, such as surgical suites.
- Noted that for future presentations and papers, better image presentation will make our results clearer and easier to understand.
- The goal reduction level for effective disinfection was 2-log reduction, to be verified with standards.

Week's Activities:

Completed work:
Ranked blocks

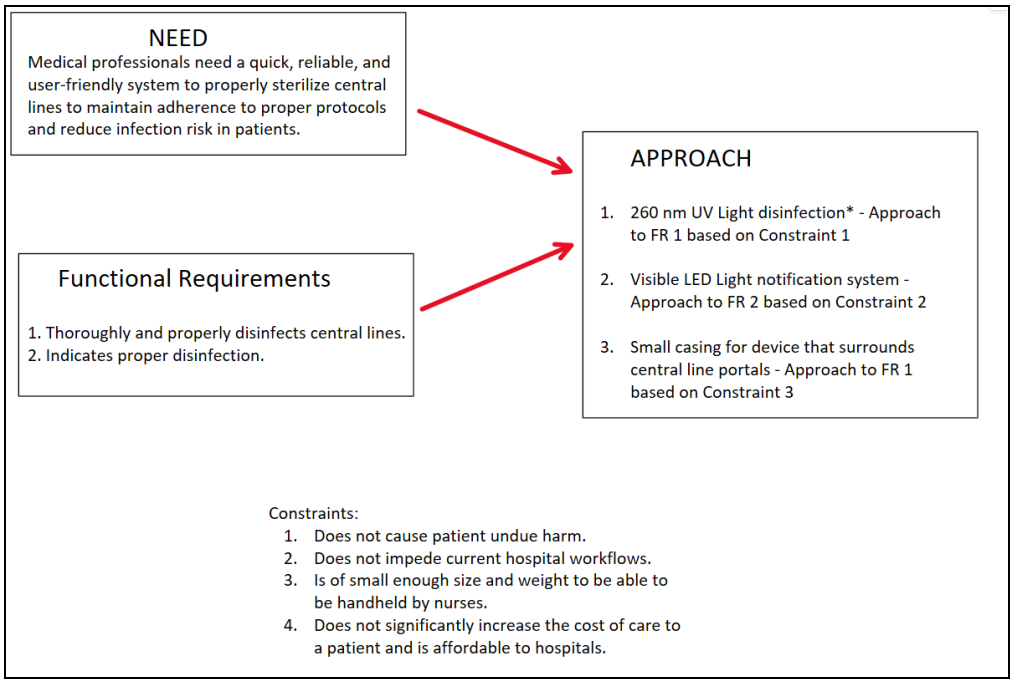


Figure 49: Ranked Blocks Graphic

The team started the semester by decomposing their problem into several design blocks based on the client need and the team's prior specified functional requirements and constraints. Using the top constraint and functional requirement, the team's primary design block is a 260-nm UV light for disinfection. The team also created secondary blocks to be able to identify a design block for the notification system of the device without imposing on the nurses' workload or workflow, and a block for the casing that addresses fully encompassing the central line hub for disinfection while remaining portable enough for nurses to carry.

Specifications and Standards

*** All specifications and standards are accessed through and used in accordance with Accuris' licensing policy. Information below should not be reproduced.***

BS EN ISO 15858:2016 (UV-C Devices — Safety information — Permissible human exposure)
BS EN ISO 15858:2016; **5.2 - Maximum permissible UVC exposure**

This International Standard adopts the REL[9] maximum permissible UVC exposure values, and the maximum permissible UVC exposure shall not exceed the ACGIH TLV and NIOSH REL[9] of 6,0 mJ/cm^2 for an 8 h day, 40 h work week exposure to UV radiation at 254 nm.[8][10]

Table 1 — Maximum permissible UVC exposure for radiation at 254 nm

Permissible exposure time	Effective irradiance μW/cm^2
24 h	0,07
18 h	0,09
12 h	0,14
10 h	0,17
8 h	0,2
4 h	0,4
2 h	0,8
1 h	1,7
30 min	3,3
15 min	6,7
10 min	10
5 min	20
1 min	100
30 s	200
15 s	400
5 s	1 200
1 s	6 000
NOTE This table is based on NIOSH/ACGIH maximum UV exposure times.	

Threshold Limit Value® (TLV®) consideration should be based on real-time occupancy of spaces treated by UVGI.[10] This recommendation is supported by recent UV monitoring data from First and colleagues,[11] who found that peak meter readings poorly predict actual exposure of room occupants.

BS EN ISO 15858:2016; **5.3 - Personal protective equipment**

Exposures exceeding the levels listed in Table 1 require that workers use personal protective equipment (PPE). PPE shall consist of the following:

a) UV-resistant eyewear, such as goggles, face shields, and safety glasses; selecting a suitable eye protector shall comply with EN 170;
b) Clothing known to be non-transparent to UVC penetration, which covers exposed skin

BS ISO 15727:2020 (UV-C Devices: Measurement of the output of a UV-C Lamp)

Discusses how to properly quantify output of a UV-C device to compare against other standards.

BSI BS EN 16489-1 (Professional indoor UV exposure services Part 1: Requirements for the provision of training)

Waiting for approval from libraries.

BSI BS 8628 (Disinfection using ultraviolet radiation - Methods for quantitative testing of automated ultraviolet disinfection activities by direct illumination - Determination of bactericidal, mycobactericidal, sporicidal, yeasticidal, fungicidal, virucidal and phagocidal activities)

Waiting for approval from libraries.

IES RP-44 (RECOMMENDED PRACTICE: ULTRAVIOLET GERMICIDAL IRRADIATION (UVGI))

Waiting for approval from libraries.

ASHRAE HVAC APPLICATIONS SI CH 62 (ULTRAVIOLET AIR AND SURFACE TREATMENT)

Waiting for approval from libraries.

ANSI/HSI 2000-2023 (Healthcare UV Germicidal Light Whole-Room Surface Disinfection)

Waiting for approval from libraries.

The team obtained standards for permissible exposure to properly quantify our top constraint of not harming patients or healthcare practitioners. The team also is exploring standards for quantifying proper bacterial disinfection, with a particular emphasis on the ANSI/HSI 2000-2023 standard.

Data:
N/A

Next steps:
Milestones:

Share Documentation

- ☐ Share OnShape with Dr. Kyle
- ☐ Share Github with Dr. Kyle

Final Design Definition

- ☐ Defined Principle of Operation effectively after receiving initial comments
- ☐ Complete block diagram, flowchart, and CAD rendering
- ☐ Locked core system architecture (UV-C emitter, handheld form decision)

Proof of Principle Testing Started

- ☐ Verified UV-C spectral output and optical power
- ☐ Demonstrated bacterial CFU reduction under controlled exposure
- ☐ Identified experimental limitations like the fixed exposure region and incomplete sweeping (lights were shown on one area of the petri dish, not swept)

Goals:

1) Refining Proof of Principle Testing
    a) Implementing swept exposure testing
    b) Defining a quantitative log-reduction target
    c) Requesting the use of testing differing representative CLABSI pathogens)

2) Human Factors
    a) Attempt to simulate ICU use scenarios
    b) Validate the use of a one-handed operation and intuitive use

3) Safety Characterization

a) UV leakage testing
b) Skin exposure risk analysis
c) Initial IEC 62471 UV photobiological safety alignment

Breakdown of work:

- Nick
    1. Setup GitHub (https://github.com/Nick-Trigger/CLABSI/)
        i. Create filestructure and READMEs
        ii. Create initialized west workspace for Zephyr ROTS development
        iii. Add documentation on how to start development (KiCad & Zephyr/West)
        iv. Create KiCad Documents and Project Files
        v. Add Custom Kicad Libraries
        vi. Share with team
    2. Create OnShape workspace and share with team
    3. Research Zephyr ROTS compatible microcontrollers and propose suitable solutions
    4. Order Microcontrollers x2 and UVc Leds x 3
- Forest
    1. Set up initial Trello sign in for teammates
    2. Contributed to development of ranked blocks for design blocks and requested standards from the Engineering Workbench for quantification of specifications
    3. Reviewed feedback on Final DHF
- Nathan
    1. Contributed to preparation of agenda and requesting of standards
- Daniel
    1. Contributed to preparation of agenda and development of ranked blocks
- David
    1. Contributed to development of ranked blocks

15.2 DRM #2

Agenda Info:
Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Meeting Lead: Nick Trigger
Meeting Scribe: David Bearden

Recap:
The first Design Review Meeting of the semester was primarily focused on planning and adjustment.

- Recommendation to decompose the Design Block into more clearly segmented design blocks
    - Avoid group blocks in a way that implies simultaneous or tightly coupled development
    - Improve clarity by mapping the overall approach into distinct sub-systems
- Initial testing was conducted using LEDs from Jame's team
    - POP will be conducted using newly ordered OSRAM UV-C LEDs
    - Planned testing include bacterial exposure, UV-C illumination, and post exposure swabbing on petri dishes

- Next steps
    - Coordinate with Colton to redo POP testing
    - Continue system quantification with emphasis on permissible UV exposure and PPE requirements
- Initial concept was cylindrical
    - Discussed alternative forms such as “gun-style” holder
    - Start with simple design and scale up
    - Explore pressure switch mechanism for detecting proper hub placement
- Develop clear visualizations to share with stakeholders
    - Gather feedback without bias and allow visualization development to proceed

Week’s Activities:

Completed work:
Breadboarding on Tinkercad

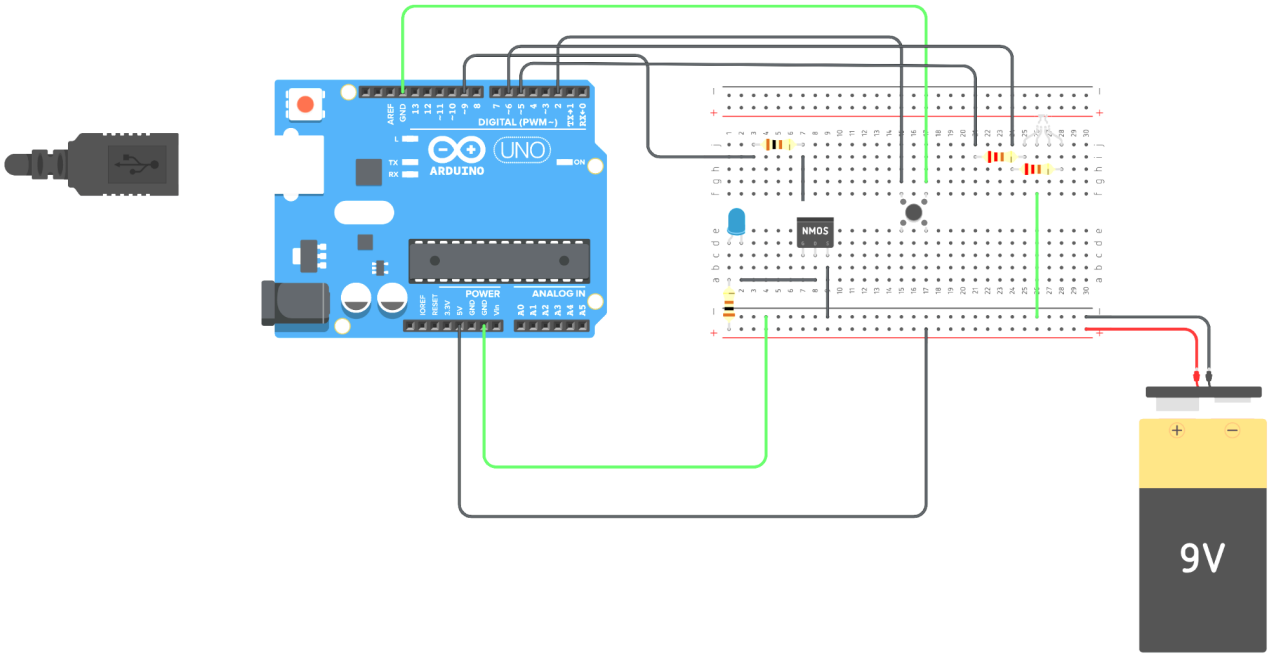


Figure 50: Breadboard Prototype on Tinkercad

When the pushbutton is pressed, the Arduino drives the MOSFET gate high, allowing current from a separate 9 V supply to power the UVC LED for a fixed duration. While the UVC LED is active, an RGB indicator LED lights yellow, and when the timer expires and the MOSFET turns off, the indicator changes to green to show the system is idle. Pull-down and current-limiting resistors ensure stable operation and protect the components. The circuit has also been developed on a breadboard in real life.

```
const int buttonPin = 2;
const int gatePin   = 9;
const int redPin    = 5;
const int greenPin  = 6;

const unsigned long ON_TIME = 10000;

bool running = false;
unsigned long startTime = 0;

void setup() {
  pinMode(buttonPin, INPUT_PULLUP);
  pinMode(gatePin, OUTPUT);
  pinMode(redPin, OUTPUT);
  pinMode(greenPin, OUTPUT);

  digitalWrite(gatePin, LOW);
  updateRGB(false);
}

void loop() {
  if (!running && digitalRead(buttonPin) == LOW) {
    running = true;
    startTime = millis();
    digitalWrite(gatePin, HIGH);
    updateRGB(true);
    delay(50);
  }

  if (running && (millis() - startTime >= ON_TIME)) {
    digitalWrite(gatePin, LOW);
    updateRGB(false);
    running = false;

    while (digitalRead(buttonPin) == LOW) {
      delay(10);
    }
  }
}

void updateRGB(bool ledOn) {
  if (ledOn) {
    digitalWrite(redPin, HIGH);
    digitalWrite(greenPin, HIGH);
  } else {
    digitalWrite(redPin, LOW);
    digitalWrite(greenPin, HIGH);
  }
}
```

Figure 51: Functional C++ Code on Tinkercad

Form Factor Development in OnShape

After the MCAD workshop, development of multiple models for CAD housing were created to be showed to our clients to review form factor. Brainstormed designs included both methods of gripping and methods of closing the device around a central line portal. Ideated designs included:

Table 1: CAD Designs

Gripping and Form Factor Mechanisms	Closing Mechanisms
Simple cylindrical enclosure	Camera shutter aperture
"Gun" / handled enclosure	Hinge mechanism
Wand enclosure	Drawstring mechanism

Data:

N/A

Next steps:

- Meet with Tim and Kim to discuss form factor considerations
    - Based on their recommendation, iterate on the CAD model to bring it to proper standards
- Test upgraded bacterial protocol based on the central line portal itself
- When new lights come in, reproduce optical and bacterial testing to verify results
- Continue Zephyr code (disinfection, communication, error state functionality)

Breakdown of work:

- Nick
    1. device overlay for demo board, setup (threads, SMF, handlers, hardware structs, workqueues, timers)
- Forest
    1. Reached out to Tim and Kim about future meetings
    2. Ideated and developed Onshape models
    3. Discussed with Colton preliminary access to his lab to re-perform UV testing in his lab for new lights
- Nathan
    1. Organized Kanban to better reflect future developments
- Daniel
    1. Built Tinkercad model
    2. Working on physical breadboard
- David
    1. Initial SMF functionality (idle, init) and hardware init (gpio, pwm, adc, trigger ISR)

– – – – SCRIBED Meeting Notes

SUPPLIES ARE IN! Microcontroller and 3X SMD UVC-LEDS

Actionables for upcoming week

1. Laser cut stencil for SMD solder paste (use KiCad)

1. Friday (tomorrow) SMD and soldering
2. Monday/Tuesday optical validation of UV-C LED
3. Present 3D Printed handheld options (vertical, angled, gun) to stakeholders and iterate on feedback for ergonomics and form factor

Contingency Plan
- Order a presoldered UVC-LED board/array in case of UVC-LED blowout and issues with soldering (esp. Bc of impact from reflow oven, copper area, etc.)

Qualifiers on 3D Printing
- Extremely low infill

Mechanisms to Clasp catheter
- Camera shutter aperture,
- Hinge joint,

Mechanisms Feedback and Dialogue
- Why not clasp hinge joint over tube to maximize no leakage?
- Compression spring to open and close on its own

Form Factor Feedback:
- Favor cylindrical form factor (familiarity with pulse ox and small enough to fit in pocket) over other factors like gun or angled handle

Firmware and Hardware Feedback:
- Safety interlocks and watchdog timers
-

15.3 DRM #3

Agenda Info:

Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Meeting Lead: David Bearden
Meeting Scribe: Nathan Kodua

Recap:

- Completed breadboard prototype in Tinkercad and physically built circuit
    - Arduino controls MOSFET to power UVC LED for fixed duration
    - RGB LED indicates status: yellow = active, green = idle
    - Implemented functional C++ timing and control code in Tinkercad
- Developed multiple CAD housing concepts in OnShape (cylindrical, handled, wand)
    - Explored closing mechanisms (aperture, hinge, drawstring)
- Received supplies: microcontroller + 3x SMD UVC LEDs
    - Planned SMD soldering, optical validation, and continued Zephyr firmware work
- Chose driving circuitry for UVc Leds and RGB leds over I2C

Week's Activities:

Firmware Development

In the meeting with the client, the team learned that the client would like both a notification light and a buzzer that sounds off at the completion of a disinfection cycle. Code was further developed in Zephyr, and the decision to place two independent safety switches in the device in compliance with ISO 14119 (Safety of machinery — Interlocking devices associated with guards — Principles for design and selection).

Onshape Form Factor and Client Meeting

Models for various methods of holding the device and attaching said device to a lumen were printed and brought to clients for review. Initial client choice of device was for an angled handle with a camera shutter-esque aperture at the front to seal off any scattered UV light. This device has been started to be further developed in OnShape with more attention paid to ergonomics and sizing, along with a requested stand for the device to sit on.

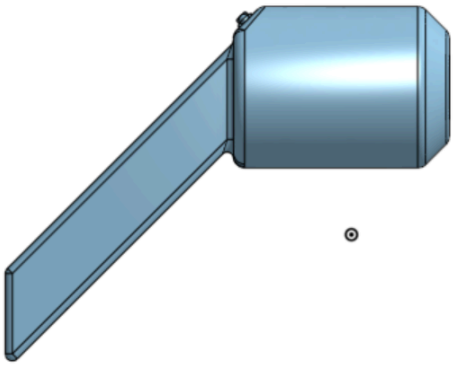


Figure 52: Current Outer Shell Prototype for Device with Angled Handle

UV Light Testing

With the UV LED's arriving, the team was able to start optical testing of the LED's. This included milling of a PCB

During actual testing, the team decided on using an LED driver to help control the power to the UV LED's with a current limit of 350 mA per LED. Using this current and the required 6.2V per LED, optical characterization testing was completed, including both optical power and UV spectral testing (see results in Data section).

Bacterial Testing

Bacterial cultures were seeded over the weekend of 2/7 to be able to be properly plated for testing by classtime on 2/12 after optical testing has been completed.

Data:

With a voltage of 6.2V and a current of 350mA (the intended conditions for lights in our device), the optical power of one LED based on ten trials was 2.49 ± 0.047 mW. With an allowed effective exposure

of 400 microWatts/cm^2 per second for 15 seconds of shining a 254-nm LED on skin, we need to ensure our device will properly close around the hub in order to ensure this exposure limit is not reached.

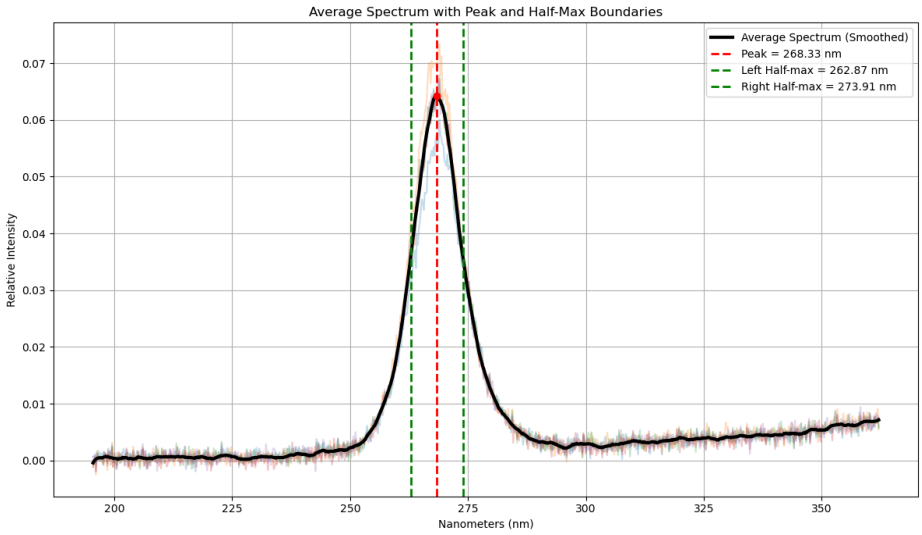


Figure 53: Spectral Distribution of Radiant Intensity of New LED

From our data, our new LED has a peak intensity range from 262-274 nm, with a peak at 268 nm. This is slightly right-shifted and less than ideal for pathogenic efficacy at the wavelength of 260nm, but because it is still within 10 nm of 260 nm and the general germicidal range, we feel confident in proceeding with germicidal testing.

Next steps:

- Further develop 3D models, especially for the aperture and take back to clients for another round of review with more nurses for more data points
- Obtain bacterial testing data with our light

Breakdown of work:

- Nick
    1. Chose ICs for driving UVc Leds, Rgb leds, and lipo battery charging
    2. Implemented ICs in kicad
    3. Recreated XIAO nRF54L15 Kicad Schematic, and modified for our board
    4. Tested LED in both optical power and spectroscopy testing
    5. Implemented and researched ISO 14119
    6. Finished implementation of power circuitry
- Forest
    1. Printed 3D models for clients
        i. Met with clients to discuss form factor and decided on preliminary final design
    2. Tested LED in both optical power and spectroscopy testing
- Nathan
    1. Develop 3D models, and research into the addition of the aperture lens and take it back to clients for another round of review.
        i. Met with clients to discuss form factor and decided on preliminary final design

2. Began to seeding cell culture and design a two-phase testing with the agar plate irradiation and a realistic test bed case test.

- Daniel
    1. Continued working on Breadboard
- David
    1. Continued implementation of Zephyr firmware
        i. Began to seeding cell culture and design a bacterial testing protocol.

15.4 DRM #4

Agenda Info:

Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Meeting Lead: Forest Rudd
Meeting Scribe: David Bearden

Recap:

- Bacterial testing done on glass slides, awaiting incubation for CFU results
- Circular PCB design for initial two-handed housing

Aesthetic and Functional Refinement

Sketch idea of Refinement

- One-handed design by extending a knob on aperture to actuate directly
- Increased space for PCB
- Professional housing, facilitating placing in pocket and carrying as needed

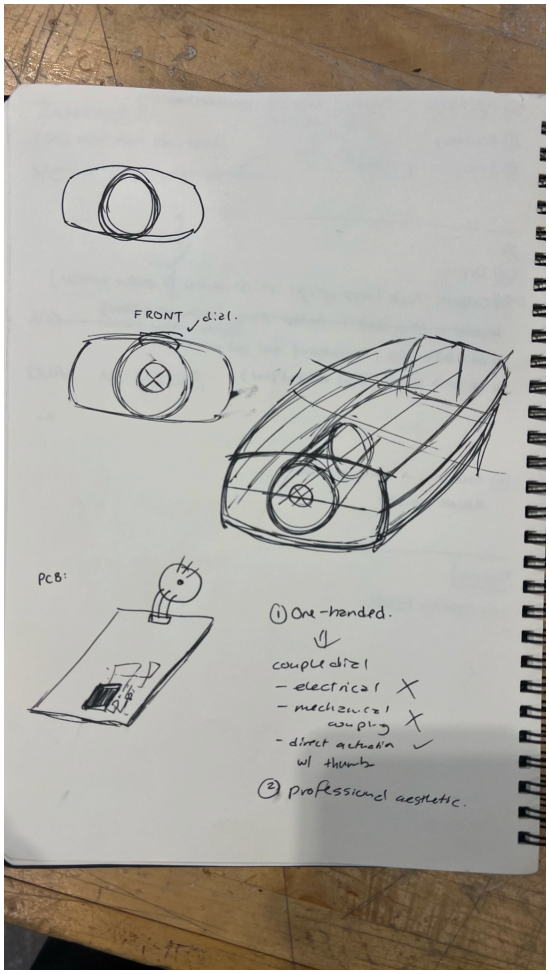


Figure 54: 3D Rendering to be shown at meeting by Forest Rudd

FMEA

Design Block	Failure Mode	Failure Effect
Disinfection (Block#1)	Insufficient UV dose delivered	Inadequate disinfection which could lead to infection risk
Disinfection (Block#1)	Uneven UV exposure due to LED placement	Inadequate disinfection which could lead to infection risk
Disinfection (Block#1)	UV LEDs fail to turn on	Device deemed unsafe or ineffective
Disinfection (Block#1)	UV exposure exceeds safety limits	Patient or clincian UV-C exposure
Notification/Firmware (Block #2)	Device activates in the wrong state	Incomplete or excessive disinfection // Loss of User Trust
Notification/Firmware (Block #2)	Abort/Error does not shut off the light	Excessive UV-C exposure, skin health
Notification/Firmware (Block #2)	Button press not registered	Loss of User Trust
Notification/Firmware (Block #2)	Incorrect state transtitions	Unsafe UV-C exposure when not needed or incomplete disinfection
Notification/Firmware (Block #2)	Incorrect LED color/state	Loss of User Trust, Lower Hospital Compliance
Notification/Firmware (Block #2)	Buzzer too quiet, absent, not working	Lower Compliance
Mechanical/Housing (Block #3)	Iris or aperature does not close	UV leakage = safety hazard, excessive UV-C exposure
Mechanical/Housing (Block #3)	Mechanical misalignment of shutters due to prin	Wear over time, failure to enclose on the
Mechanical/Housing (Block #3)	Device does not fit all catheter lines or hubs	Non-complicance to hospital protocols, incomplete disinfection
Mechanical/Housing (Block #3)	Cracks, misformed, low quality prints	UV leakage = safety hazard, excessive UV-C exposure
Power/Battery (Block #4)	Battery drains too quickly / fails to hold charge	Device dies during disinfection, leading to incomplete cycle
Disinfection (Block #1	Chamber becomes dirty or degraded	Reduced UV transmission, inadequate disinfection
Power/Battery (Block #4)	Battery overheats during charging or operation	Thermal hazard to user or patient; device damage

Severity (S, 1-10)	Detection (D, 1-10)	Occurrence (O, 1-10)	RPN (SxD xO)	Action to Reduce Occurrence or Increase Detection
9	7	3	189	Follower circuit to ensure consistent power delivery
8	7	2	112	Optimize LED array design using optical simulation of hub
9	2	3	54	Init function to put device in ERROR state if needed
7	8	2	112	Implement hardware cutoff and redundant optical safety features
7	6	3	126	Add state-checking logic before activation; implement watchdog timer.
9	7	3	189	Hardwire abort button to power interrupt (hardware override).
4	1	2	8	Use high-reliability tactile switches; add debouncing in firmware.
9	5	5	200	Implement state machine validation and unit testing for firmware.
5	1	3	15	Use RGB LEDs with diagnostic color-check at startup.
4	2	3	24	Select louder buzzer; add volume test
8	2	4	64	Add limit switches to detect shutter position; lubricate mechanism.
7	2	2	28	Tighten 3D printing tolerances or injection mold; use more rigid material (e.g., PC/ABS).
9	2	2	36	Redesign adapter with flexible silicone seal or mechanism; test with multiple hub brands.
8	3	3	72	Switch to injection molding and visually inspect (QA)
5	4	4	80	Low-battery warning indicator and failure to proceed; Li-ion cells.
5	5	3	75	Use UV-resistant coating and autoclavable material
9	2	2	36	Include thermal fuse

Initial Verification Planning

Focus on mitigating the highest-risk failure modes identified in the FMEA, specifically those related to safety and critical functionality.

Disinfection Block

- **Test:** UV Dose Delivery and Safety Shutoff
  - **How:** Verify consistent power delivery using the follower circuit. Test the hardware cutoff and redundant safety features. Verify that the hardwired abort button instantly interrupts power.
  - **Data:** UV output remains within target range with low variability. Hardware cutoff prevents UV exposure above safety limits. Abort button successfully shuts off UV light via hardware override.
- **Test:** UV Exposure Uniformity
  - **How:** Test the optimized LED array design to ensure even UV distribution across the sterilization hub.
  - **Data:** Even UV exposure (e.g., within reasonable variation) to prevent inadequate disinfection.

Notification/Firmware Block

- **Test:** State Machine Validation and Error Handling
  - **How:** Unit testing on firmware to validate state machine transitions and prevent incorrect activation. Implement and test watchdog timer logic.
  - **Data:** All state transitions function as intended; device cannot activate UV exposure unless in the proper state. Watchdog timer successfully resets/errors the device if logic hangs in loop or timeout.

Mechanical/Housing Block

- **Test:** Catheter Line/Hub Fit and UV Sealing
  - **How:** Test the chamber with multiple brands of catheter lines and hubs. Test the iris/aperture closure using interlocks to detect closure.
  - **Data:** Device successfully fits all tested hub brands without physical interference. Interlock switches correctly detect when the shutter is fully closed to ensure no UV leakage.

Next steps:

- Integrate housing, PCB design, and firmware.
- Conduct device testing on expected catheter hubs
- User feedback with client of device

Breakdown of work:

- Nick
    1. Finalizing PCB and boards to mount components within device housing
- Forest
    1. Finalizing one-handed design housing
- Nathan
    1. Ideation on motor actuation of aperture
    2. Ethnography
- Daniel
    1. Resin printing components and iterating on handle design
- David
    1. Finalizing firmware
    2. Device germicidal protocol testing

15.5 DRM #5

Agenda Info (04/09): Team CLABSI
Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger

Meeting Lead: Daniel Chong
Meeting Scribe: Nick Trigger

Week's Activities:
Form Factor for Device

- Iterated design printed
    - Iris printed using FormLabs 3B+ (White Resin V4.1)
        - Clearance necessary for comfortable fit
            - Too much clearance was made (between design and sanding away material)
            - Reduce amount of clearance
        - Slight warping noticed around areas where supports were attached
            - Prints will be done without supports
        - Small stubs left behind from supports
            - Can be sanded away
    - Main casing printed using Prusa Core (PLA)
        - Cannot rely on printer for final prototype
            - Warped areas and rough edges

        - Rounded areas were printed incorrectly
    - Mates well with laser print
    - Size feels comfortable to hold
        - Finalized design 85% complete

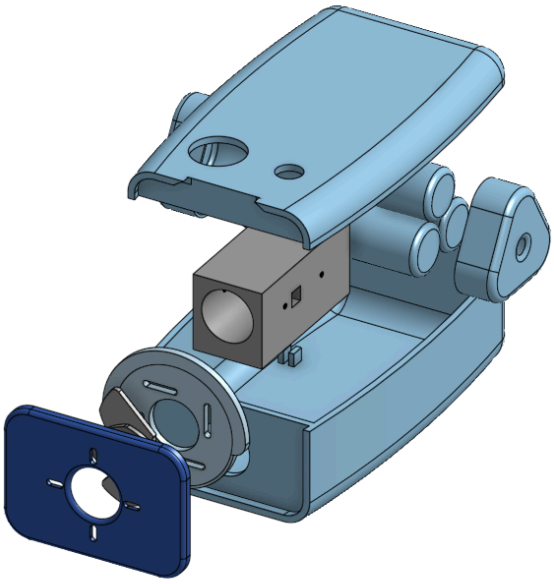


Figure 55

- Mechanical Iris **may be** printed with Bambu instead of FormLabs
- Casing will be printed with SLS printer to compare fidelity (may be final version)

Firmware Development

- Ordered updated PCB boards for integration testing
- Continued development of state-based control logic for UVC operation
- Began integrating firmware with planned hardware layout (pins, drivers, and sensors)
- Preparing codebase for transition from breadboard prototype to PCB implementation
- Initial testing plan outlined for validating illumination control and safety interlocks

Power Source Discussion

- 4 3.3V LiPo batteries arrived
    - Need to verify that current output is sufficient

Next steps

1. Refine design based on fit and clearance adjustments
2. Print final prototype iteration
3. Attach circuitry to housing
4. Order M2 screws and heat-set inserts for assembly

Breakdown of work:

Daniel:

- Ordered resin for resin printer
- Iterated on iris printing and tolerances for resin printer
- Redesigned housing to be one-handed model

David:

- Finalized code for firmware to work with Nick's PCB design
- Material accrual for bacterial final device testing

Forest:

- Redesigned housing to be one-handed model
    - Added details to CAD including safety switches, bosses, holes for buttons and lights, etc.

Nathan:

-

Nick:

- Redesigned PCBs to fit in new housing
    - Changed physical components to larger size (0201 -> 0805) so that they are easier to handsolder.
    - Created New BOM and ibom
        - Referenced BOM to Digikey parts list:
            - https://www.digikey.com/en/mylists/list/K8YR1YC0QL
            - PW: Bme474L!
        - IBOM
        - BOM
    - Ordered PCBs and Stencil

16. Progress Reports

16.1 Progress Report 1

BME 474 PROTOTYPE PROGRESS REPORT – FEB 2, 2026

Team Name: CLAB-FREE
Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Kanban Board Link: https://trello.com/b/GRZ18QqD/kanban-board

Project Health:

On Track	*Issues*	*Delayed/At Risk*
• *The project remains on track with clear progress across all three technical blocks. Core risks—particularly*	• *May run into issues soldering the UV-C light to board.*	• *If all three lights break or the PCB is soldered incorrectly, it would take a*

around UV-C safety and effective bacterial reduction—have been identified early and are being actively mitigated through standards review and iterative proof-of-principle testing. While some testing must be repeated with newly ordered UV-C LEDs, this delay is expected and built into the project timeline.	• *Lack of resources has set back the amount of prototyping with UV LED's, leading to a slight time crunch.* • *The UV-LED's need to be properly retested to ensure that they hold up to the standard set by the LED's tested last semester.*	*large amount of time to reorder parts.*

Summary:
This reporting period focused on initial prototyping and laying the basis for prototype testing for a UV-C–based CLABSI prevention device. The team decomposed the system into ranked design blocks and defined safety and performance constraints using relevant standards. Parallel progress was made in firmware development and form factor ideation, ensuring that technical feasibility and clinical usability advance together.

Progress with Respect to Design Blocks:

Design Block #1: 260-nm disinfection
Design Block 1 revolves around our disinfection mechanism, ultraviolet radiation at 260 nm. The team ordered UV-C LED's early in January and milled a PCB for LED testing. The lights have now come in and the team has been able to schedule a meeting with Colton McGarraugh in order to repeat spectral analysis and optical testing and then revisit the bacterial protocol. Further progress is scheduled but remains slightly halted due to the necessity of ensuring the LED's fit the needed specifications.

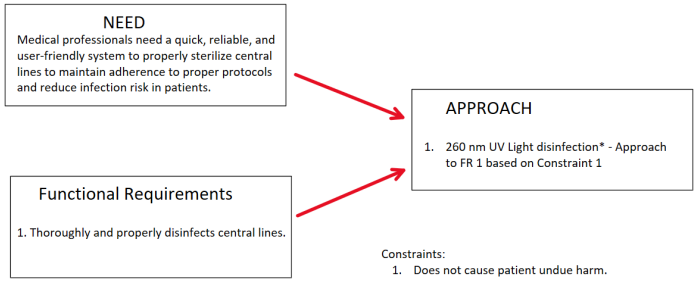


Figure 56: Top ranked design block based on highest-priority Functional Requirement and Constraint.

To ensure our Design Block meets the proper criteria, several specifications were set out pertaining to this top functional requirement and constraint. In order to properly disinfect a surface, the CDC requires a hospital-level disinfection (HLD), which is a 6-log reduction in bacterial presence on a surface (Recommendations for Disinfection and Sterilization in Healthcare Facilities | Infection Control | CDC).

Design Block #2: Visible LED Light Notification System

Our second design block is the notification system for nurses. This currently has been prototyped to include a notification light that shines green when ready to use and yellow when in use, along with a buzzer system to indicate use. These notifications will be shown to the nurses in the meeting the week of February 2nd so that they can verify the system's effectiveness. An ECAD model is in the process of being developed based on this system so that a PCB may be milled and fitted into the overall container system as well.

Design Block #3: Printed portable casing for device that surrounds central line portals

Design Block 3 revolves around the housing for the CLAB-free device. Progress on this design block came in two large sections: ideation and rapid model development. The goal of this design block currently is to assess what form factor the nurses who would be using the device would prefer the most. Thus, quick ideation occurred for two different aspects of the casing: how the casing would be held and how the casing would be shut. Ideas were narrowed down to four main holding methods and two main closing methods, and examples of each have been printed to be able to display to nurses. ISO 15858 "UV-C Devices — Safety information — Permissible human exposure" contains information on how to safely handle UVc radiation and permissible human exposure to UVc light. Specifically our device should avoid using quartz glass, sodium barium glass, or PTFE as a UVc blocking material. The standard also gives the maximum permissible exposure to UVc light at different exposure lengths, measured from 6-7 feet away (shown in table below).

5.2 Maximum permissible UVC exposure

This International Standard adopts the REL[9] maximum permissible UVC exposure values, and the maximum permissible UVC exposure shall not exceed the ACGIH TLV and NIOSH REL[9] of 6,0 mJ/cm^2 for an 8 h day, 40 h work week exposure to UV radiation at 254 nm.[8][10]

Table 1 — Maximum permissible UVC exposure for radiation at 254 nm

Permissible exposure time	Effective irradiance μW/cm^2
24 h	0,07
18 h	0,09
12 h	0,14
10 h	0,17
8 h	0,2
4 h	0,4
2 h	0,8
1 h	1,7
30 min	3,3
15 min	6,7
10 min	10
5 min	20
1 min	100
30 *s*	200
15 *s*	400
5 *s*	1 200
1 *s*	6 000
NOTE This table is based on NIOSH/ACGIH maximum UV exposure times.	

Threshold Limit Value® (TLV®) consideration should be based on real-time occupancy of spaces treated by UVGI.[10] This recommendation is supported by recent UV monitoring data from First and colleagues,[11] who found that peak meter readings poorly predict actual exposure of room occupants.

Demo Video:

The following demo video shows our initial firmware prototype functioning as intended, creating a solution to both design blocks 1 and 2.
https://youtube.com/shorts/V8jeDzfoGqs?feature=share

Issues/Challenges:
One clerical issue is our lack of updating Kanban, which leads into lapses of unproductivity while we focus on one or two design blocks while setting aside the rest. By working to better keep our Kanban updated and on track, we aim to be able to split ourselves up more effectively and work in parallel on multiple goals at the same time. Furthermore, considering our worry about the UV-C LED's, we plan to go ahead and pre-order more of them so that if our current three break or don't function, we are not set back further.

Next Steps:
Our next steps for each of our design blocks are as follows:
Block 1: Repeat optical testing and bacterial testing to ensure the LED is of the right power and wavelength for our purposes.
Block 2: Verify with nurses how they want their notification light setup and design a PCB to connect our notification LED's and UV LED. Furthermore, reconfigure code to work in Zephyr with our new microcontroller.
Block 3: Show nurses our designs and get feedback to proceed with functional prototyping to move into more rigorous MCAD design.
Expectations: All these next steps can easily be, and should be, completed by EOD Friday. Meetings with nurses and Colton are confirmed for this week. Furthermore, all team members should report progress in groupchats and log progress on Kanban.

16.2 Progress Report 2

BME 474 PROTOTYPE PROGRESS REPORT – 2/16/2026

Team Name: CLAB-Free
Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Kanban Board Link: https://trello.com/b/GRZ18QqD/kanban-board

Project Health:

On Track	*Issues*	*Delayed/At Risk*
• *Form factor for device and closing mechanism have been verified by clients.* • *LED's have been retrieved and characteristically tested and give promising results.* • *Circuitry has been prototyped and has started to be transferred into an ECAD.* • *Bacterial testing of LED's is in progress.*	• *The testing protocol for testing LED's in the testbed, while based on standards, is largely unknown to the team and could result in longer than expected test times if improperly done.* • *The team has focused on one size of central line hub, while multiple exist, forcing a slight pivot in terms of closing mechanisms.*	• *The largest risk is if the LED's do not properly eradicate bacteria, despite the positive results last semester. This would set back the project greatly until better LED's could be retrieved.*

Summary:
Most of the progress this period came in the testing of the UV-C LED and the further development of the form factor and mechanical design. The UV-C LED was tested for optical power and spectral distribution, which both gave promising results. Furthermore, bacterial testing was started for the original petri dish experiment, and the testbed for testing central line disinfection was written and set up according to previous disinfection experiment standards. The final design of the housing was also designed, with iterations on holding form factor and closing mechanism developed.

Progress with Respect to Design Blocks:

Design Block #1: 260-nm disinfection
The LED's were delivered and tested for characteristic optical power and spectral distribution. They were properly soldered to the PCB test plateDuring testing, it was discovered that the LED's need specifically 350mA and 6.2V for powering, so the team decided to use an LED driver for that specific current value to limit fluctuations. The optical power of one LED was 2.49 ± 0.047 mW.

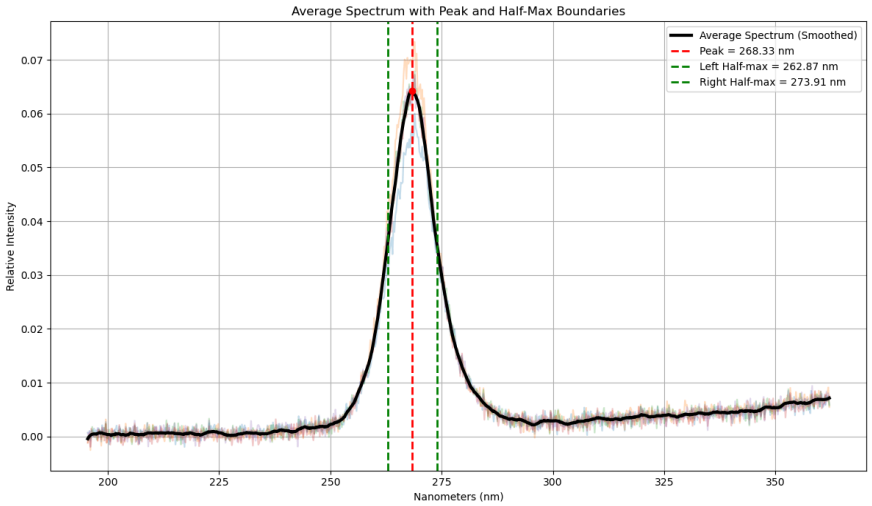


Figure 57: Spectral Distribution of Radiant Intensity of New LED

Furthermore, from spectral testing, the LED has a peak intensity range from 262-274 nm, with a peak at 268 nm, which is within the germicidal range and validates the LED choice (Figure 1). Given positive results from the characterization testing, the team proceeded with bacterial testing and data is in the process of being collected for both the standard and the testbed case.

Design Block #2: Visible LED Light Notification System
The notification system was verified by the clinicians. They requested a slight change in the notification system, so the light now turns blue during the disinfection cycle and turns green at the end. Furthermore, a buzzer now sounds at the end of the cycle to provide auditory stimulus. Code has been developed in Zephyr, and an ECAD electrical diagram has been created. A rechargeable battery system has also been implemented into the ECAD in order to power the system.

Design Block #3: Printed portable casing for device

Progress on Design Block 3 started with a meeting with the team's clients, where the angled handle form factor and an iris aperture closing mechanism were chosen as the client's preferred casing option. The decision to split the casing down the middle and join it together with screws was also made for ease of assembly and access to electronics. The aperture was chosen with a linear rotation motion to prevent failure and friction areas, with four leaves to cut down on parts and potential failure points (Figures 2 and 3). A hole was made in the aperture dimensioned to fit the standard cardiac ICU central line hub, and the team decided that future prototypes will have two independent safety press switches at the front of different aperture slots to ensure full closing from the nurse in line with ISO standards.

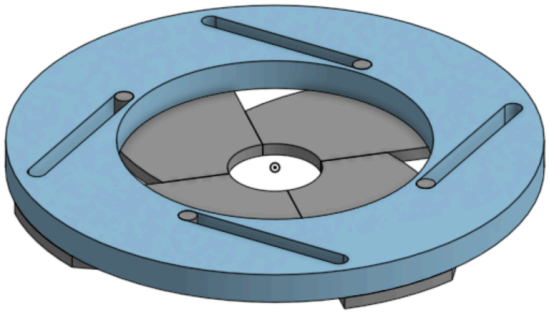


Figure 58: Assembly View of Mechanical Iris First Prototype

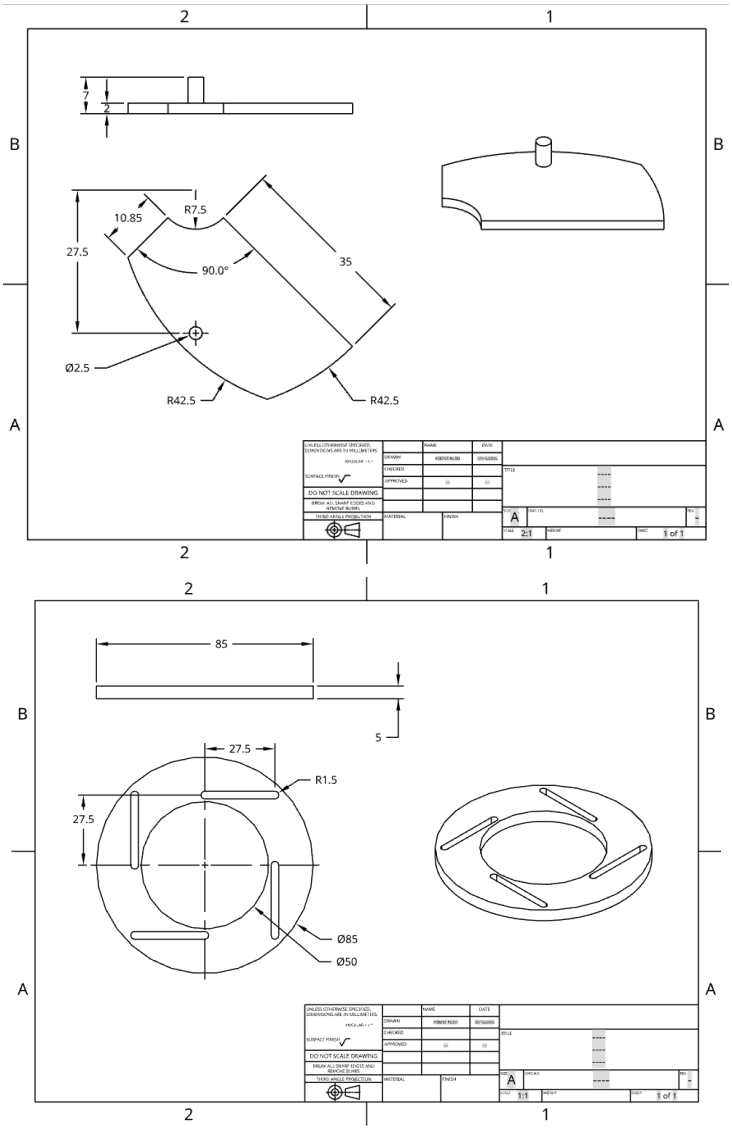


Figure 59: Mechanical Drawings of Mechanical Iris First Prototype

Further development on the aperture is underway to make the aperture fully opaque. Furthermore, the design of the angled handle is being made more ergonomic to better fit into a nurse's hands.

Issues/Challenges:

The team is still lacking in proper documentation on Kanban. Furthermore, bacterial testing requires a large amount of setup and time to run the experiment. The petri dish experiment was run over the weekend, and the team is in the process of setting up a calendar for each team member to go and assist in checking and disinfecting with the light system in order to ensure that the experiments can be run throughout the week. The team plans on presenting a fully realized MCAD and 3D-printed housing for midterm, which presents an issue if different printers create different tolerances and error in actual printing. However, to combat this, the team set up a member's club Bambu printer to try to expedite the printing process and ensure that each print is uniform in its tolerances.

Next Steps
The next steps for the team are as follows:

Block 1: Finish bacterial testing in both petri dishes and testbeds to ensure the LED has the proper germicidal properties for our device. Develop PCB boards to be able to solder other LED's onto the PCB.
Block 2: Further develop ECAD to be able to print a PCB over spring break.
Block 3: Continue prototyping, printing, and modifying the housing and closing apertures to function smoothly, close completely, and be completely defined in mechanical drawings by Midterm Report.

16.3 Progress Report 3

BME 474 PROTOTYPE PROGRESS REPORT – 3/30/2026

Team Name: CLAB-Free
Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger
Kanban Board Link: https://trello.com/b/GRZ18QqD/kanban-board

Project Health:

On Track	*Issues*	*Delayed/At Risk*
• *Bacterial Testing of LED's was successful and yielded the proper reduction for germicidal effect.* • *The housing has been redesigned and iterated for a one-handed fit, along with the PCB being redesigned to both be larger and fit in the new device.*	• *Resin Printing tolerances are different from 3D printing tolerances, so any work tested with typical layer-by-layer 3D printing will need to be resized and re-toleranced for resin printing. We also have a lack of the material, so properly sizing parts needs to be accurate very quickly.*	• *PCB schematic had an incorrect charging circuit. This will need to be redesigned.*

Summary:

Most of the progress this period came in the testing of the UV-C LED and the further development of the form factor and mechanical design. The UV-C LED was tested for optical power and spectral distribution, which both gave promising results. Furthermore, bacterial testing was started for the original petri dish experiment, and the testbed for testing central line disinfection was written and set up according to previous disinfection experiment standards. The final design of the housing was also designed, with iterations on holding form factor and closing mechanism developed.

Functional Refinement by FMEA:

After identifying the device's highest risk priority numbers (RPNs) were associated with potential inadequate UVC exposure and harmful exposure to the patient or user, functional refinements were implemented to mitigate said high-failure risks. The highest risks came in two main forms: UV light

efficacy and safety. Our first main concern was the amount of light the UV LED's would put out. Despite our bacterial tests being successful, there is still a risk of the LED's not putting out enough power to properly irradiate the hub, which is also very hard to notice. This can also factor in light placements, which, if off, could adversely affect the device. Second is the unsafe exposure limits, which we are mitigating through a series of safety switches.

Design Block	Failure Mode	Failure Effect	Severity (S, 1-10)	Detection (D, 1-10)	Occurrence (O, 1-10)	RPN (SxD xO)	Action to Reduce Occurrence or Increase Detection
Disinfection (Block#1)	Insufficient UV dose delivered	Inadequate disinfection which could lead to infection risk	9	7	3	189	Follower circuit to ensure consistent power delivery
Disinfection (Block#1)	Uneven UV exposure due to LED placement	Inadequate disinfection which could lead to infection risk	8	7	2	112	Optimize LED array design using optical simulation of hub
Disinfection (Block#1)	UV LEDs fail to turn on	Device deemed unsafe or ineffective	9	2	3	54	Init function to put device in ERROR state if needed
Disinfection (Block#1)	UV exposure exceeds safety limits	Patient or clincian UV-C exposure	7	8	2	112	Implement hardware cutoff and redundant optical safety features
Notification/Firmware (Block #2)	Device activates in the wrong state	Incomplete or excessive disinfection // Loss of User Trust	7	6	3	126	Add state-checking logic before activation; implement watchdog timer.
Notification/Firmware (Block #2)	Abort/Error does not shut off the light	Excessive UV-C exposure, skin health	9	7	3	189	Hardwire abort button to power interrupt (hardware override).
Notification/Firmware (Block #2)	Button press not registered	Loss of User Trust	4	1	2	8	Use high-reliability tactile switches; add debouncing in firmware.
Notification/Firmware (Block #2)	Incorrect state transtitions	Unsafe UV-C exposure when not needed or incomplete disinfection	9	5	5	200	Implement state machine validation and unit testing for firmware.
Notification/Firmware (Block #2)	Incorrect LED color/state	Loss of User Trust, Lower Hospital Compliance	5	1	3	15	Use RGB LEDs with diagnostic color-check at startup.
Notification/Firmware (Block #2)	Buzzer too quiet, absent, not working	Lower Compliance	4	2	3	24	Select louder buzzer; add volume test
Mechanical/Housing (Block #3)	Iris or aperature does not close	UV leakage = safety hazard, excessive UV-C exposure	8	2	4	64	Add limit switches to detect shutter position; lubricate mechanism.
Mechanical/Housing (Block #3)	Mechanical misalignment of shutters due to prin	Wear over time, failure to enclose on the	7	2	2	28	Tighten 3D printing tolerances or injection mold; use more rigid material (e.g., PC/ABS).
Mechanical/Housing (Block #3)	Device does not fit all catheter lines or hubs	Non-complicance to hospital protocols, incomplete disinfection	9	2	2	36	Redesign adapter with flexible silicone seal or mechanism; test with multiple hub brands.
Mechanical/Housing (Block #3)	Cracks, misformed, low quality prints	UV leakage = safety hazard, excessive UV-C exposure	8	3	3	72	Switch to injection molding and visually inspect (QA)
Power/Battery (Block #4)	Battery drains too quickly / fails to hold charge	Device dies during disinfection, leading to incomplete cycle	5	4	4	80	Low-battery warning indicator and failure to proceed; Li-ion cells.
Disinfection (Block #1	Chamber becomes dirty or degraded	Reduced UV transmission, inadequate disinfection	5	5	3	75	Use UV-resistant coating and autoclavable material
Power/Battery (Block #4)	Battery overheats during charging or operation	Thermal hazard to user or patient; device damage	9	2	2	36	Include thermal fuse

Figure 60: FMEA spreadsheet by design block, failure mode, failure effect, scores, and actions

To address adequate UVC exposure, mechanical design of the chamber and aperture were refined to ensure proper alignment and distance of the hub from the UVC LEDs. The chamber and aperture were designed so that the catheter hub must be inserted at the proper depth within the chamber for the aperture to close over the central line lumen and enable UVC power. The geometrical design constraint ensures reliable UVC disinfection to the hub surface by mitigating intensity fall-off inversely proportional to distance squared in the case of improper alignment or hub insertion.

Firmware additions were added to continuously monitor hardware safety interlocks to immediately disable the UVC PWM controller using an interrupt service routine if an unsafe condition is detected, notably if the aperture is opened. The addition ensures UVC emission does not exceed permissible human exposure through a max 10 ms delay from detection of the unsafe condition to power cut-off from the UVC LED. The hardware safety interlocks are wired in two parallel arms and interface with a DPDT switch to further hardware disable the UVC LED power as a firmware failure failsafe.

Progress with Respect to Design Blocks:

Design Block #1: Bacterial Testing Data

Germicidal Effect:

Bacterial testing was executed using the UVC LED on glass slides. The target organism of *E. coli* was adhered to glass slides following culture in LB broth on a shaking incubator overnight. Three replicates of control and treatment slides were subjected to control (no UVC irradiation) or treatment (UVC irradiation) at room temperature. CFUs were recovered by washing and vortexing in DBPS followed by serial dilution on LB agar plates. Plates were incubated overnight before CFU counting and determination of CFUs/mL to determine the germicidal effect (Figure 5). The third UVC treatment at 4 hours reached a 4-log reduction in CFUs which exceeded the team's goal of a 3-log reduction by UVC disinfection.

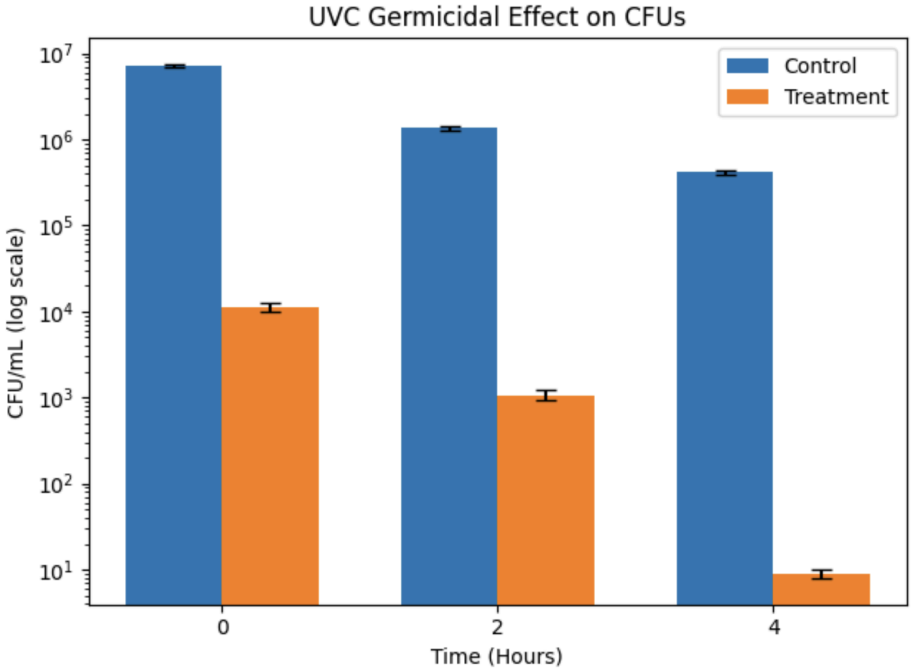


Figure 61: UVC Germicidal Effect on CFUs of E. Coli.

Design Block #3: Revised portable casing

The initial design iteration featured an angled, pistol-style handle intended to improve ergonomics and enable one-handed operation. While this approach provided a familiar grip and clear directional use, it introduced several practical limitations. The form factor made the device bulkier than necessary, reducing portability and making it less suitable for quick storage in clinical settings. Additionally, the separation between the handle and the main UV chamber created an uneven weight distribution, which affected balance during use. The iris aperture mechanism, although conceptually effective for controlled exposure, proved difficult to manufacture and assemble reliably, with noticeable friction and alignment issues between the leaves. These challenges motivated our next design.

The updated design adopts a more compact, streamlined form factor similar in size and shape to a smartphone, significantly improving portability and ease of handling. The new design can be operated

entirely with one hand. By integrating flat lithium-polymer batteries, the internal layout becomes more efficient, allowing the device to be slimmer without sacrificing functionality. The casing is simplified into a split-body design secured with screws, making assembly and maintenance more straightforward while improving structural consistency. The aperture system is also more cleanly integrated into the front face, reducing mechanical complexity and improving alignment compared to the previous exposed iris configuration.

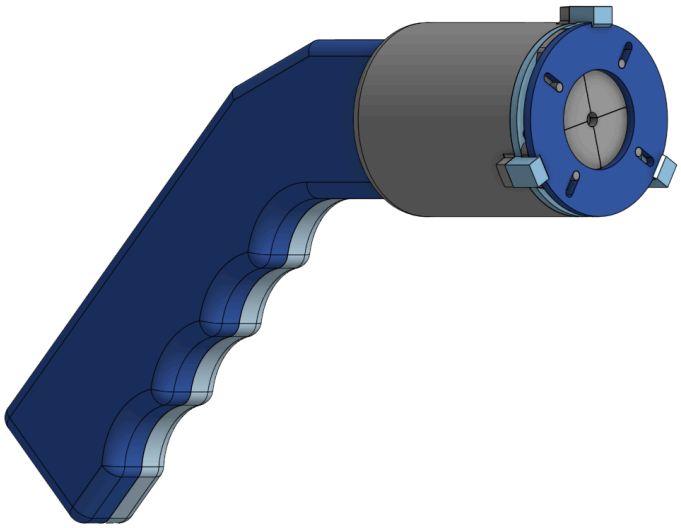


Figure 62: Assembly View of UV Disinfectant v.1

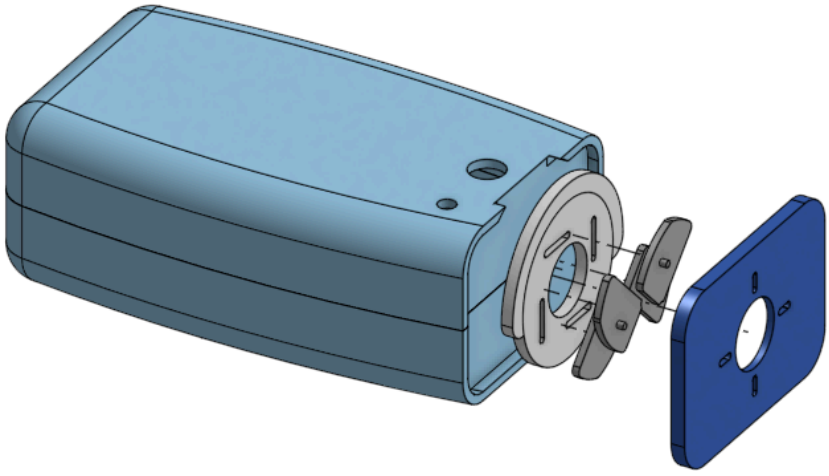
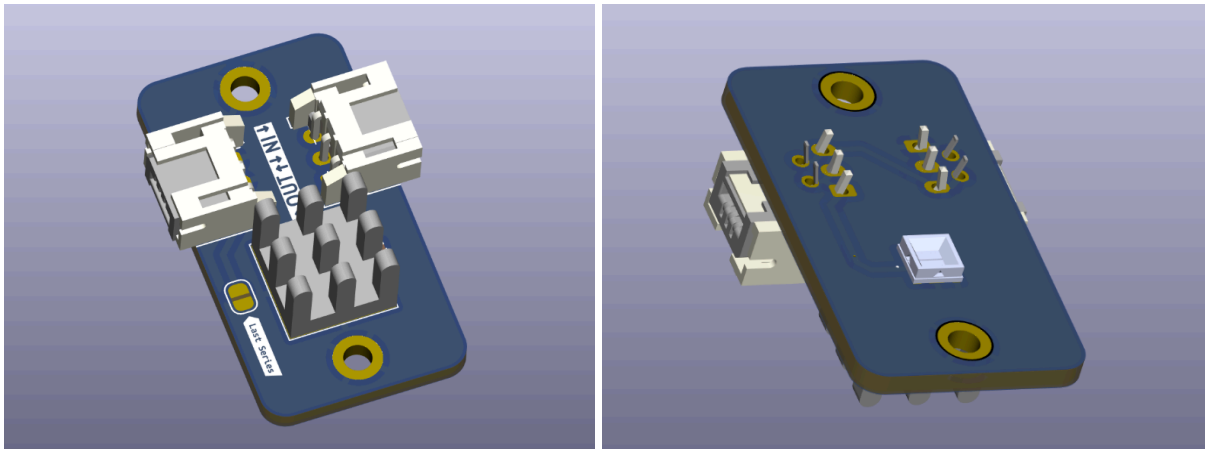


Figure 63: Assembly View of UV Disinfectant v.2

Design Block #2: PCB Design/Electronics

An error was identified in the battery charging block of the electrical schematic. The battery charging circuitry is not correct for our use-case. The circuitry only has the ability to charge and discharge the batteries as a series, not balance the batteries. This will be fixed.

A daughter PCB has been designed to hold the UVc leds in the housing (Figure 4). The PCB was designed as either a FFC connector or JST connector to allow for different mounting positions. The board is designed so that they can be chained in series with a terminating jumper on the last board so that multiple different boards did not have to be created.



BACK FRONT

Figure 64: LED PCB

Issues/Challenges:

While the team is confident about the aesthetic redesign, and while it doesn't impact any of the key functionalities of the device, it does mean that the PCB layout and MCAD did have to be completely redesigned for the new model. The team feels confident in stepping up to the challenge, but it will require significant work and further prototyping to ensure proper sizing and fit of pieces.

Next Steps

The next steps for the team are as follows:

- Fix BMS schematic and design PCB.
- Continue to iterate on MCAD designs (specifically tolerances, and ensuring ergonomic use)
- Integrate PCB into final prototype
- Test for UVC light leakage in final prototype

16.4 Progress Report 4

BME 474 PROTOTYPE PROGRESS REPORT 4 – 04/08/26

CLAB-Free

Daniel Chong, David Bearden, Forest Rudd, Nathan Kodua, Nick Trigger

Kanban Board Link: https://trello.com/b/GRZ18QqD/kanban-board

Project Health:

On Track	*Issues*	*Delayed/At Risk*
• *Bacterial testing protocols are in good shape and properly working, so once prototypes are complete the test is ready to run.* • *Housing has been iterated and the design is finalized and has been printed.* • *The electronics design and firmware is finalized and complete, so implementing it should be a fairly simple process.*	• *The housing design needs to be printed several times to ensure no warping and proper tolerances in the resin print. These prints take up some time, so it is imperative the team stays engaged with printing to be able to iterate quickly.*	• *Because of delays in ordering the PCBs, the resulting backlog has created a significant risk that they will not arrive in time for upcoming demonstrations. To mitigate this risk, the team is developing a protoboard as an interim solution.*

Summary:

Progress focused on iterating the mechanical design for manufacturability, furthering firmware development, and preparing for integration. The device housing underwent multiple iterations, validating ergonomics and one-handed usability. However, resin printing introduced new tolerancing challenges, requiring adjustments to clearances and printing strategies. On the electrical side, updated PCBs were ordered, and firmware development progressed toward a state-based control system with integrated safety interlocks. Preparation for final bacterial testing is ongoing but remains dependent on material availability. Overall, the project continues to make steady progress, with key risks centered around fabrication and testing dependencies.

Progress with Respect to Design Blocks:

Design Block #1: Bacterial Testing Data

Work toward final bacterial validation is ongoing; however, testing is currently limited by delays in material acquisition. Experimental protocols and test methods remain unchanged from previously validated procedures and are ready for execution once materials are available.

Design Block #2: PCB Design / Electronics

PCB designs were updated to fit within the revised compact housing geometry. Component sizes were increased (0201 → 0805) to improve manufacturability and hand assembly reliability. A new BOM and iBOM were created and linked to supplier parts for procurement. Updated PCBs and stencils have been ordered and will be used for integration testing.

Firmware development progressed significantly, including implementation of state-based control logic for UVC operation and early integration with the planned hardware layout (pins, drivers, and sensors). The system is being prepared for transition from breadboard prototyping to PCB-based implementation. Additionally, four 3.3V LiPo batteries were received, and validation of their current output capabilities is pending.

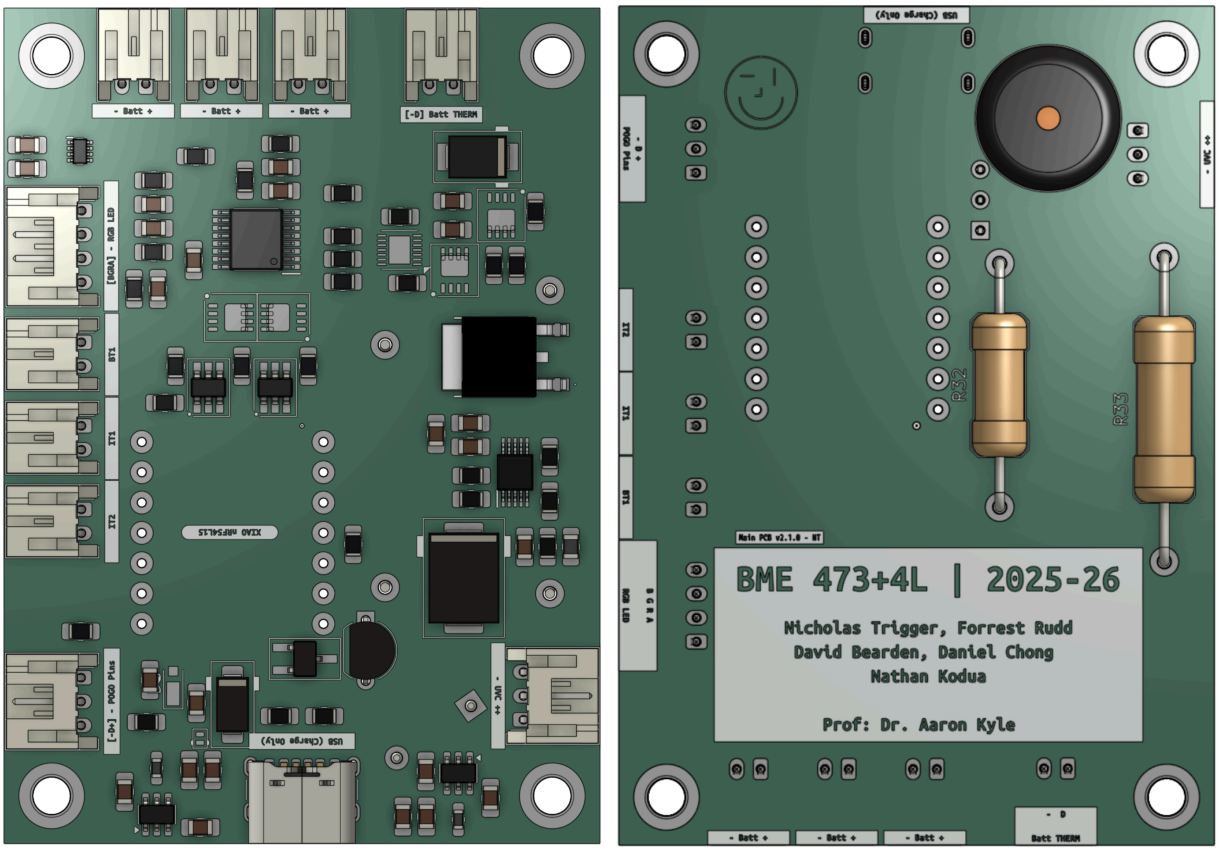


Figure 65: Assembly View of UV Disinfectant PCB Board

Design Block #3: Housing / Mechanical Design

Significant progress was made in refining the housing and overall form factor. The device has been redesigned into a compact, one-handed form, with ergonomics validated through physical prototypes.

Iris mechanisms were fabricated using a FormLabs 3B+ resin printer. Testing revealed that excessive clearance, compounded by sanding, reduced mechanical precision. Future iterations will reduce clearance and minimize support structures to prevent warping and surface defects. Alternative fabrication methods, including Bambu printing for the iris and SLS printing for the casing, are being explored to improve dimensional accuracy and surface quality.

The main casing was also printed using PLA on an FDM printer; however, print quality limitations (warping, rough edges, and poor curved feature resolution) make it unsuitable for final prototypes.

Despite this, fit and ergonomics were validated, and compatibility with laser-cut components was confirmed.

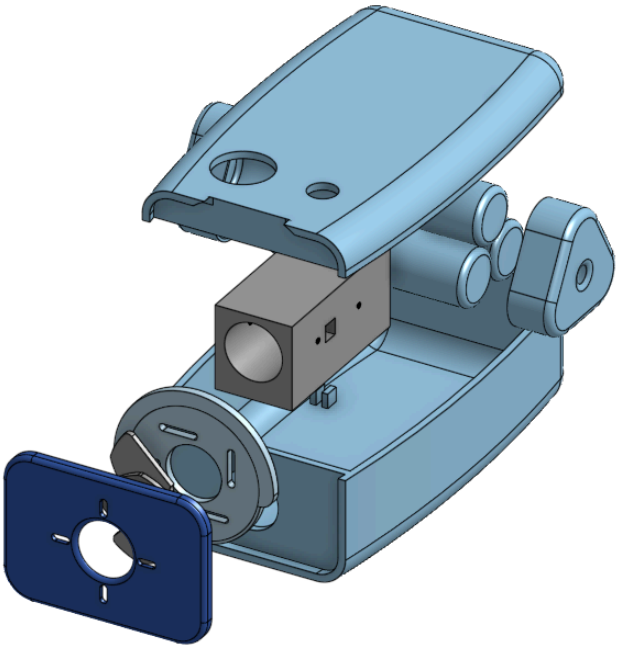


Figure 66: Assembly View of UV Disinfectant v.2.1

Demo Video:
Create a short (1-3 minute) video showing your prototype in action. Share a YouTube link in this section.
https://drive.google.com/file/d/1r6FdJgS5B-92FW6JdzneBJiP0pkc_cmn/view?usp=drive_link

Issues/Challenges:

Resin printing variability has required multiple design iterations, particularly for the iris mechanism where clearance and warping significantly affect performance. PCB integration is also dependent on resolving schematic issues and receiving manufactured boards quickly.

Additional Notes or Highlights:
The transition to a compact, one-handed device represents a major milestone in usability and design maturity. Improved coordination between mechanical, electrical, and firmware subsystems has enabled more efficient integration planning. The project is nearing full prototype readiness pending final fabrication and testing steps.

Next Steps

Internal Expectations (Team):

- Refine housing tolerances and finalize mechanical design
- Print final prototype iteration using improved fabrication methods (SLS, Bambu)
- Validate LiPo battery performance and power system capability
- Receive and assemble PCBs, then integrate with housing
- Complete firmware-hardware integration and system testing
- Conduct final bacterial testing and validate UVC performance with assembled prototype

External Expectations (Teaching Team):

- Provide feedback on final design manufacturability and integration readiness
- Support or guidance for resolving bacterial testing material delays
- Review system-level testing approach and safety validation

17. Experimental Protocols and Testing Data

17.1 Optical Power Testing

For the New UV-C lights received this semester, optical power testing was required to be redone to test the efficacy of the new LED. Protocols were followed as laid out in Section 15.1, but with a voltage of 6.2 V and a current of 350 mA. This testing resulted in an optical power of 2.49 ± 0.047 mW and the following spectral characterization.

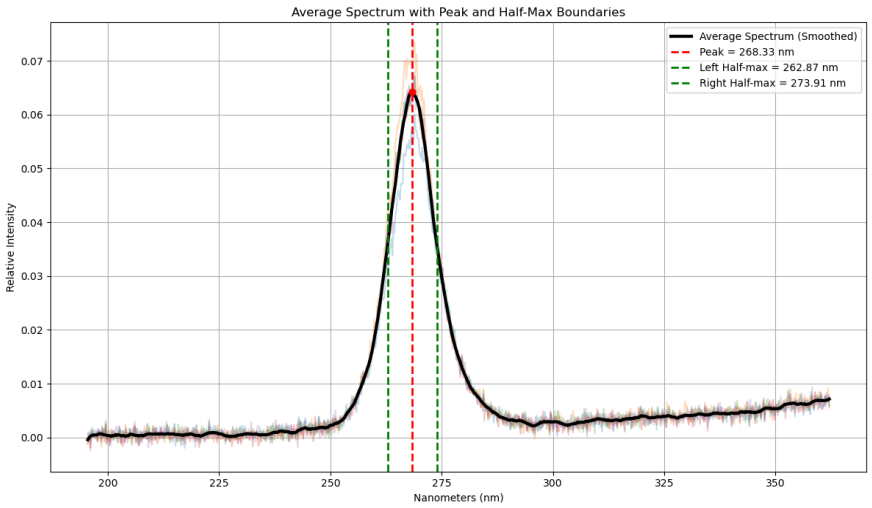


Figure 67: Spectral Output of UV-C LED

This spectral characterization confirmed that the UV-C LED works effectively in the germicidal range, as its half-max bandwidth spans from 262.9-273.9 nm inside the germicidal range and right on the cusp of the 260-nm mark. Further bacterial testing showed the proper disinfection range.

17.2 Bacterial Testing: Catheter Hub

The objective of the catheter-adhered bacterial testing is to validate that UV-C irradiation achieves a significant reduction in bacterial CFUs on the target surface for the device, extending the proof-of-principle results from section 14.2 to clinically relevant surfaces. Biofilm and surface-adhered bacteria present a greater challenge to sterilization than bacteria spread on LB agar, as the catheter hub material may attenuate UV-C penetration and surface topology may create shadowing effects from the porous material. The same treatment groups are used: control and UV-C irradiation. For this experiment, irradiation occurs on three events at time t=0 hours, t=2 hours, and t=4 hours.

Standard needleless catheter hubs (InVisionPlus) were selected as the target substrate due to their clinical prevalence in central venous access and their documented role as a primary site of intraluminal contamination. The same DH5-alpha E. coli strain from ThermoFisher was used for consistency. Irradiation duration and intensity were held constant at 5 seconds and 12V respectively, consistent with the parameters established in section 14.2.

The following procedure was followed in a Biosafety Level 2 certified laboratory (Duke University, Teer P05 Lab):

Day 1.1: Expand Seed Culture

1. Wear appropriate PPE.
2. Pour 10 mL sterilized LB broth in a 14 mL culture tube.
3. Thaw a microcentrifuge tube of DH5-alpha E. coli on wet ice.
4. Mix and aliquot 20 µL of DH5-alpha into the 14 mL culture tube.
5. Place the culture tube in the shaking incubator (37 ºC) overnight.

Day 1.2: Prepare LB Agar Plates for Serial Dilution

1. Measure and mix 7.5 grams LB broth (Lennox) and 4.5 grams agarose in 300 mL of deionized water.
2. Autoclave LB agar mix.
3. Pour sterilized 5 mL LB agar into 35 mm petri dishes (9X per concentration tested).
4. Once agar plates are solid, store upside down in the refrigerator overnight.

Day 2: Catheter Hub Inoculation and Irradiation

1. Get and measure OD600 of the incubated culture by coding for the following sequential operations on a spectrophotometer and plating each of 3 wells with 200 µL of the cultured bacterial suspension: Shaker – Shake, ABS (P) – EndPoint at 600 nm.

2. Using an OD600-CFU estimation curve for *E. coli*, calculate the dilution factor needed to dilute (in LB Broth) to 2E7 CFUs/mL in 1 mL of volume.
3. Perform the CFU dilution using LB Broth.
4. Label catheter hubs for each treatment group (control-T0, T0, control-T2, T2, control-T4, T4) with three replicates per group.
5. Pipette 20 µL of bacterial suspension at the selected dilution onto the surface of each catheter hub placed on a rack upright. Ensure the catheter hubs are perpendicular to the table. Wait 30 minutes for bacteria to dry.
6. Irradiate each T# catheter hub for 5 seconds at 6.2V, 350 mA using the UV-C LED enclosure, positioning the hub face-up and flush against the irradiation aperture.
7. A minute following irradiation, collect each control and appropriate T catheter hub (e.g. control-T0 and T0 at time t=0 hours) and begin the recollection and plating procedure.
8. Begin recollection by removing the catheter hub from the IV line and vortex at the maximum setting in 5mL DBPS for 5 minutes.
9. Remove the catheter hub and plate the recovered bacteria suspended in DBPS on agar plates, following the procedure from 14.2 for serial dilution up to E-7. Label each plate
10. Incubate all plates upside down overnight at 37 ºC.
11. Repeat step 5 after each 2 hour interval until T4 hubs are recovered and plated.

Table 5: Empirical OD600 to CFU Estimate

OD600 Measured (n=3)	**CFU Estimate**
0.638 ± 0.9	4.8E8 CFUs/mL

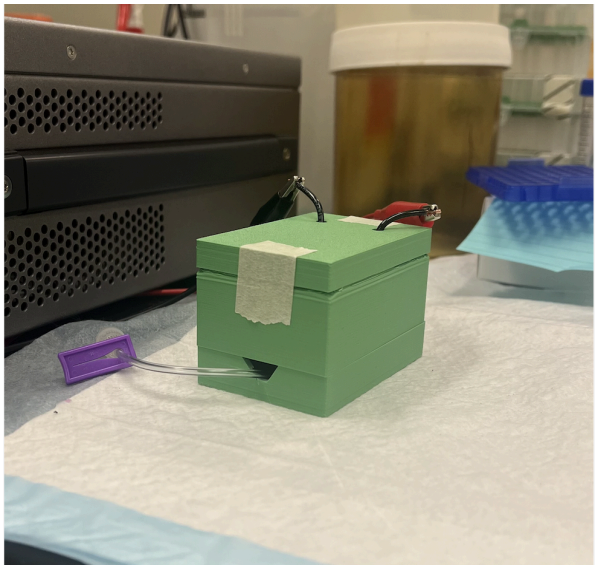


Figure 68: UVC Irradiation Setup of Catheter Hubs using Digital PSU

Day 3: Final Testing

1. Inspect control serial dilution plates and ensure proper recovery occurred.
2. Now, count and tabulate CFU results for each of the six groups of serially diluted plates with three replicates each.

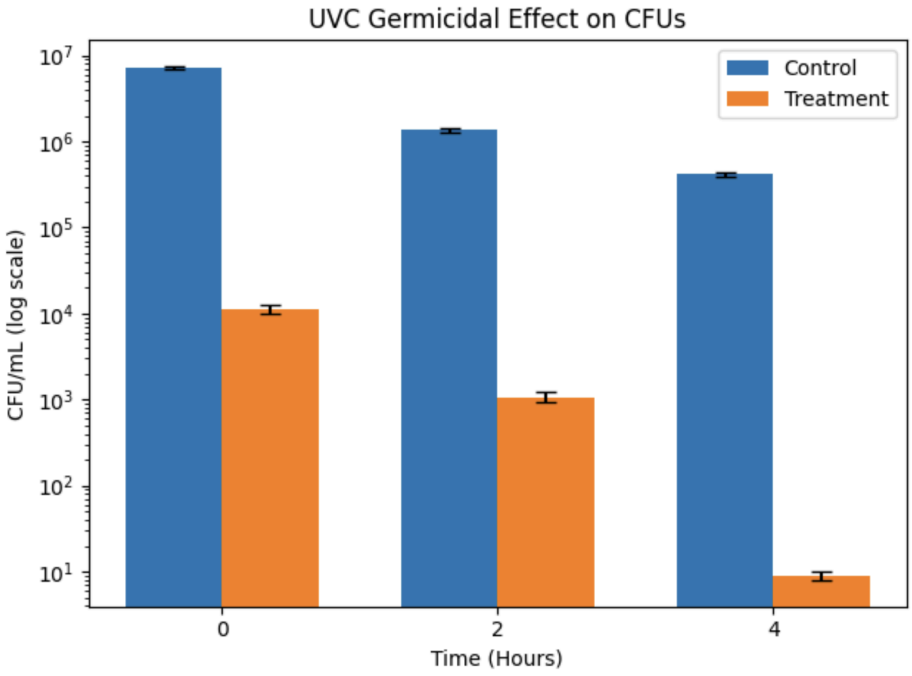


Figure 69: *E. Coli* CFUs/mL Counted per Experimental Group. Blue bars show CFUs/mL of control bacteria on catheter hubs at room temperature. Orange bars show catheter hubs with UVC treatment at two hour intervals, starting at time *t*=0 hours, until recovery and measurement at time *t*=N hours reported on the x-axis. 4-log reduction target exceeded after three irradiations at time *t*=4 hours.

17.3 Safety Testing

Safety Testing took place to ensure the device met the proper safety protocols. Based on the safe exposure limit of under 400µW/cm2 of exposure over 15s (ISO 15858:2016), a safe exposure cutoff time of 450 ms was calculated using the opening of the disinfection hub to calculate area and the optical power of the device to find the necessary time. After this, the following procedure was completed using blue LED's to properly track timing on the phone camera:

Materials:

CLAB-Free Device
- 2x Reed Switches
- 1x Rotating Iris
- 3x Blue LED's

iPhone Slow-Motion Camera

Methods:

1. Set up CLAB-Free device lying horizontally on table.
2. Set up phone camera in slow motion to record.
3. Close device.
4. Turn device on with blue lights set up inside chamber.
5. Turn on recording.
6. Open device suddenly during disinfection cycle.
7. End recording.
8. Count number of frames between first touch of rotating iris and shutoff of blue light.
9. Divide number by 1024 fps to find timing.
10. Repeat steps 3-9 seven more times.

After 8 tests were completed, the results were tabulated, and an average and standard deviation were found. The cutoff time for the CLAB-Free device was 17 ± 2 ms, well under the 450 ms threshold needed for proper safety protocols.

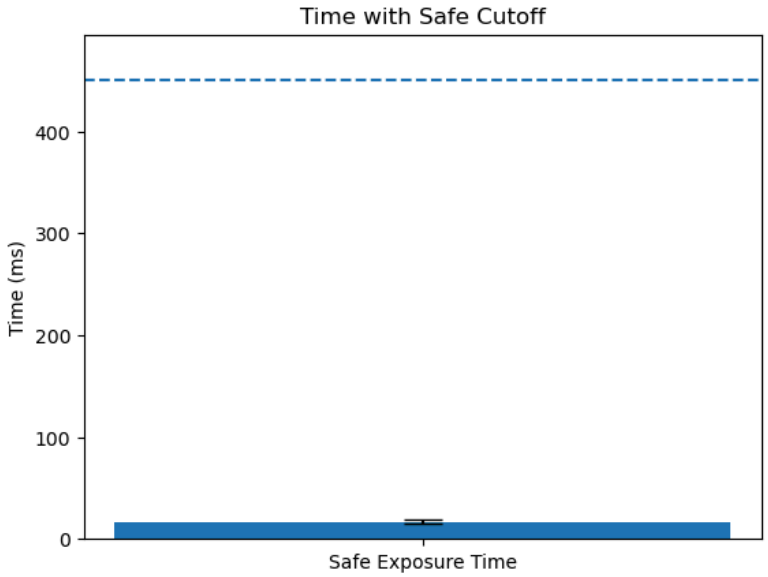


Figure 70: CLAB-Free Safe Exposure Time

17.4 Overall Testing Data

Table 6: 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 Exposure	17 ± 2 ms (<450 ms)
Germicidal CFU Reduction	4-log Reduction

In addition to the other tests described in more detail, one constraint of the device was to be portable. By weighing the device on a scale, its weight was found to be 204 g, well under the 2 kg requested by the nurses.

18. MCAD Representation of Device

18.1 Device Housing MCAD

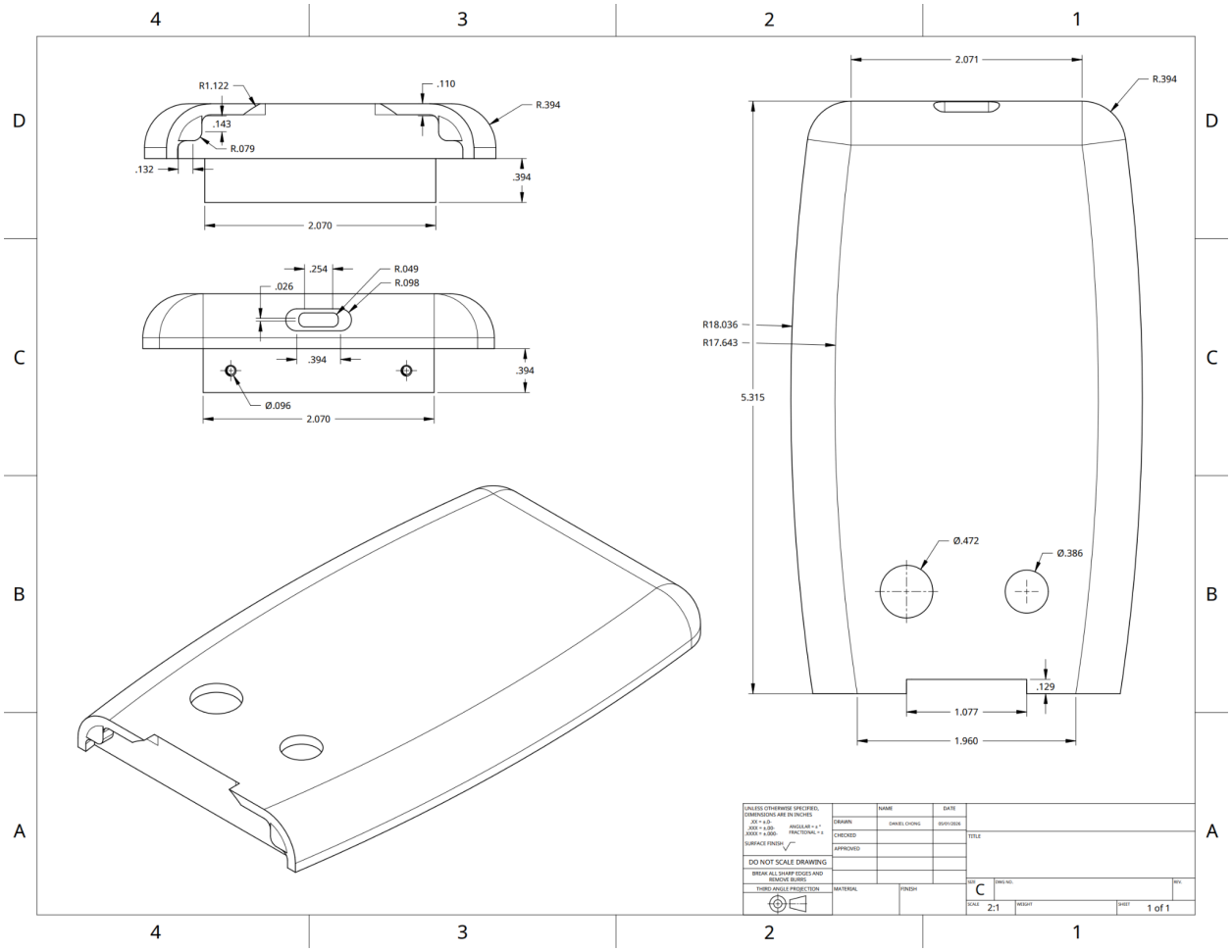


Figure 71: Assembly Drawing of Top Shell

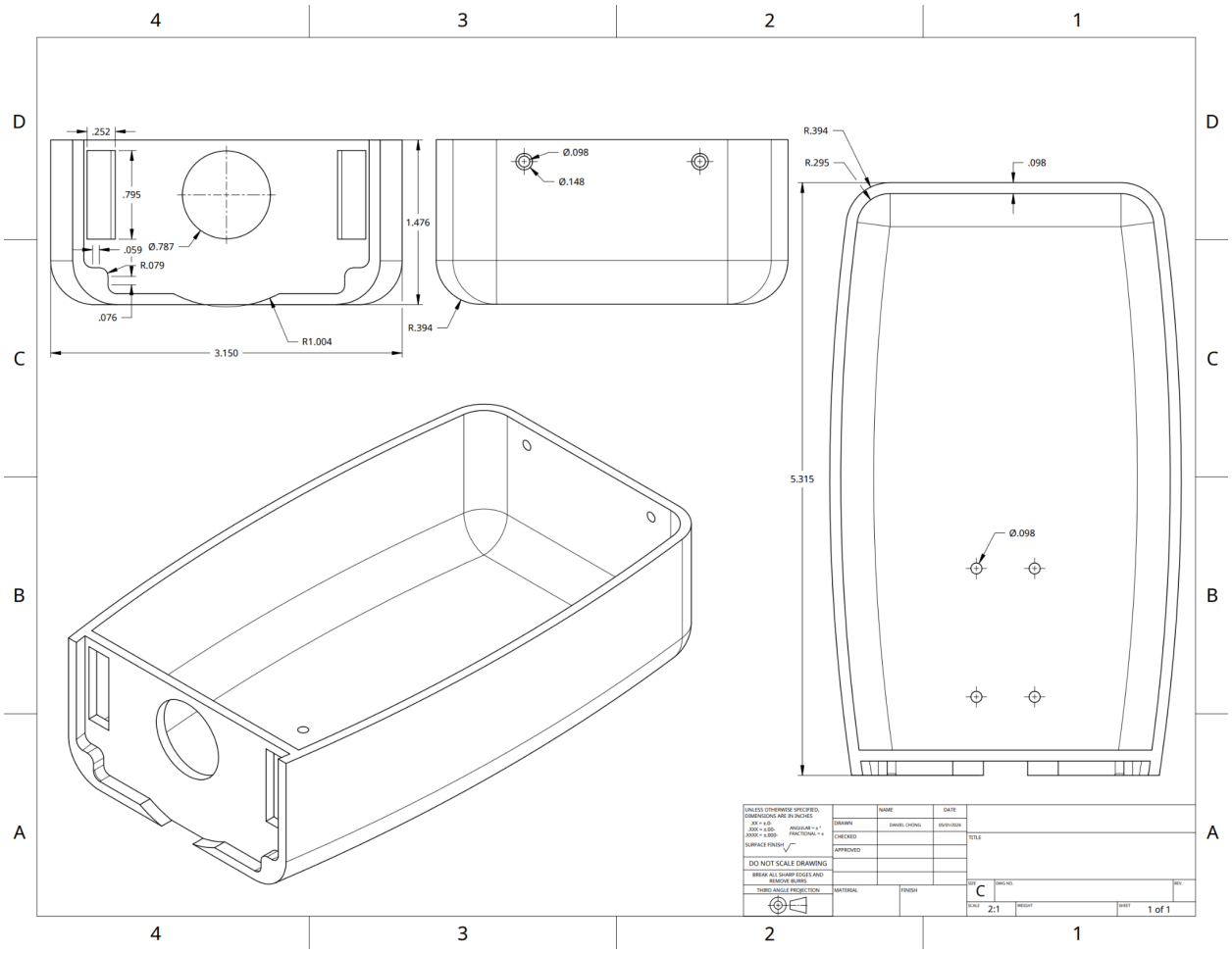


Figure 72: Assembly Drawing of Bottom Shell

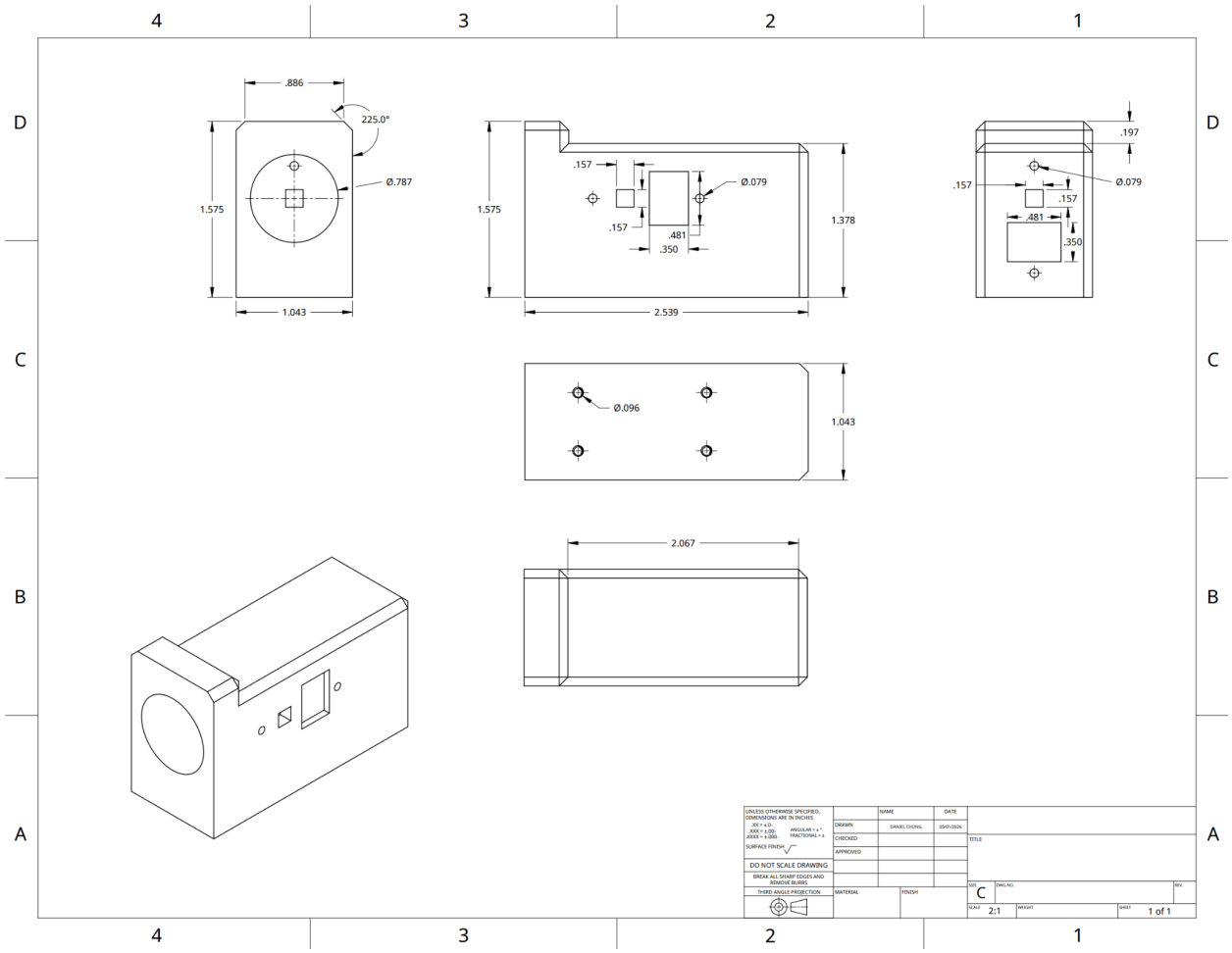


Figure 73: Assembly Drawing of LED Holder

18.1 Mechanical Iris MCAD

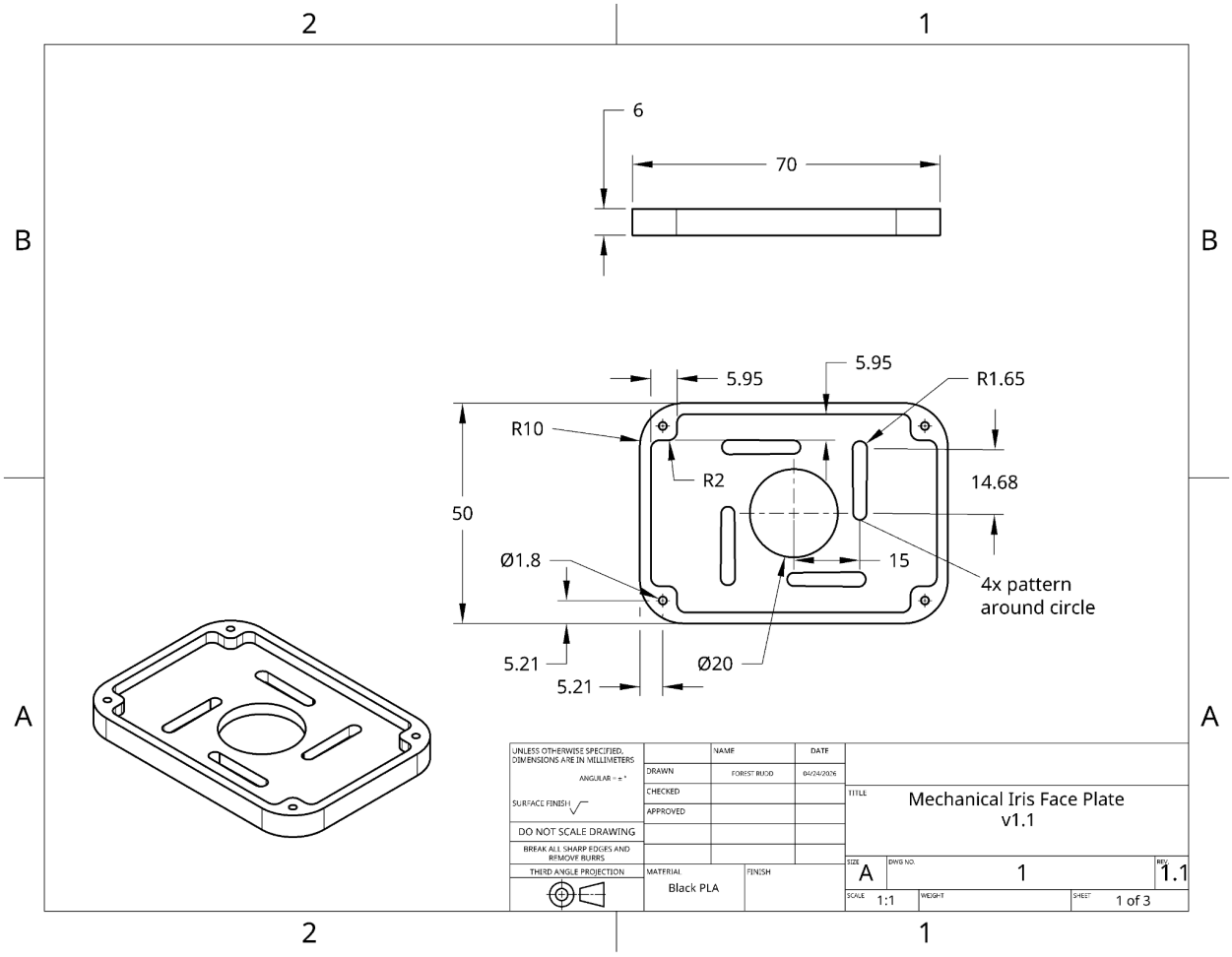


Figure 74: Assembly Drawing of Front Plate

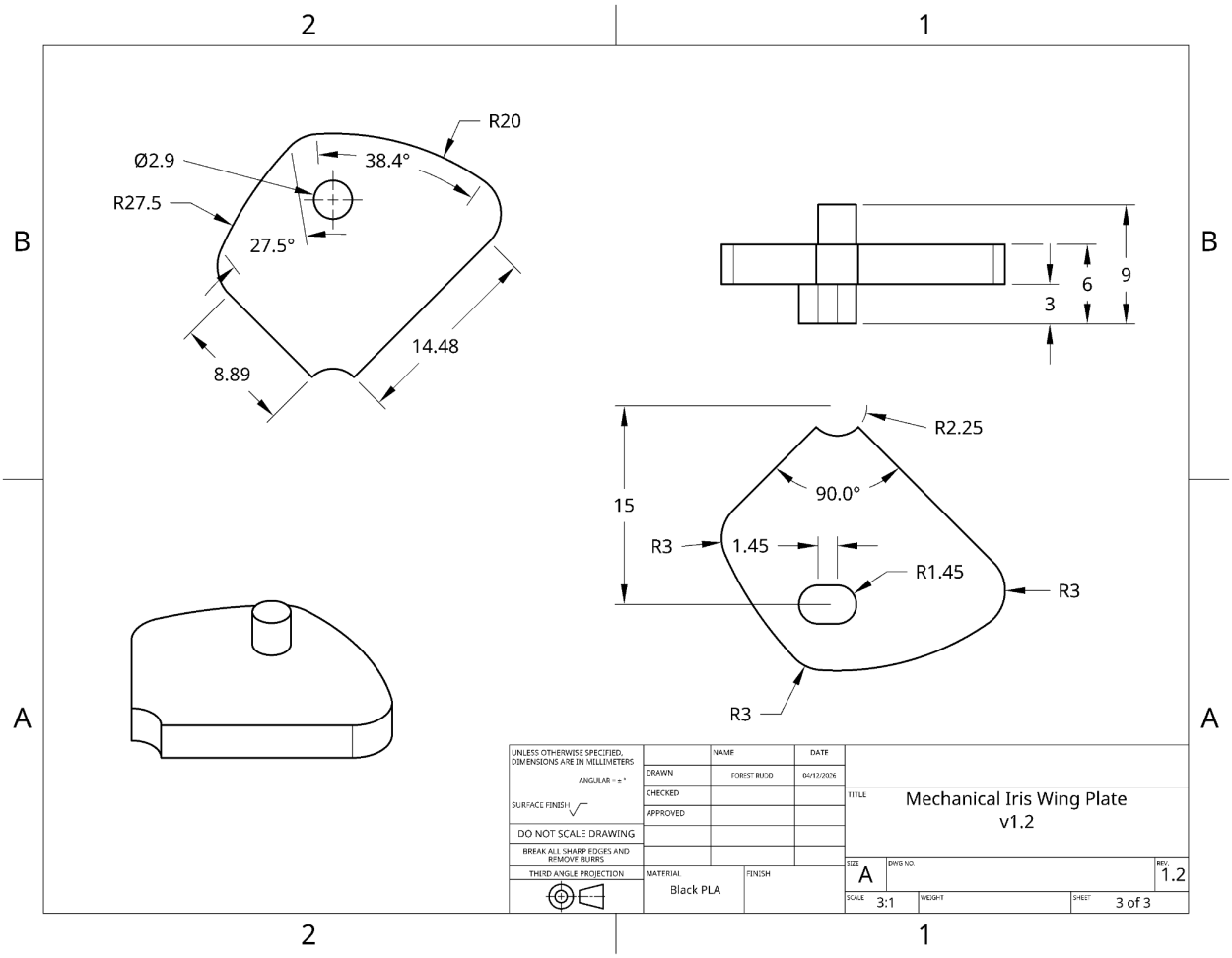


Figure 75: Assembly Drawing of Iris Wing

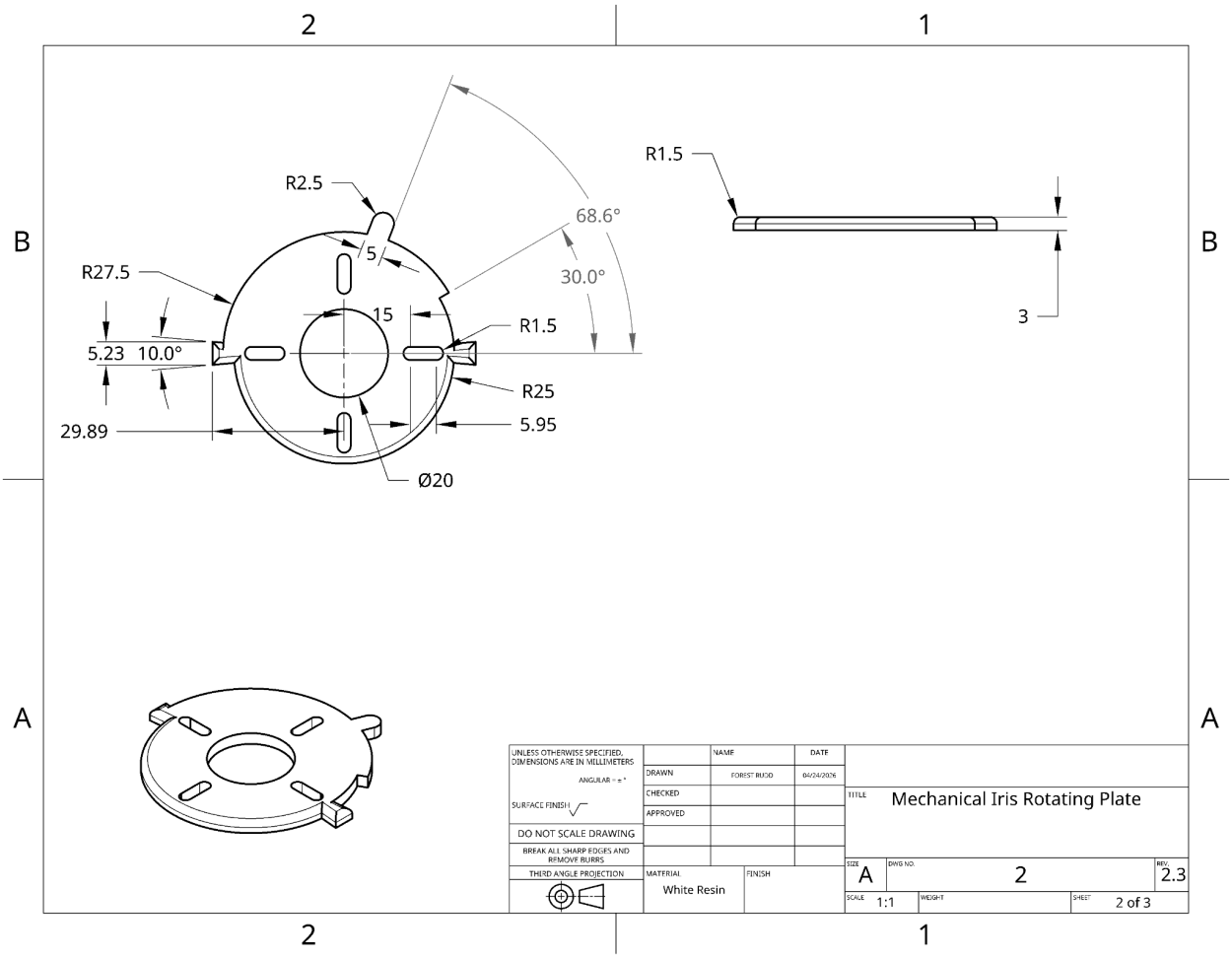


Figure 76: Assembly Drawing of Rotator

18.3 Exploded View MCAD

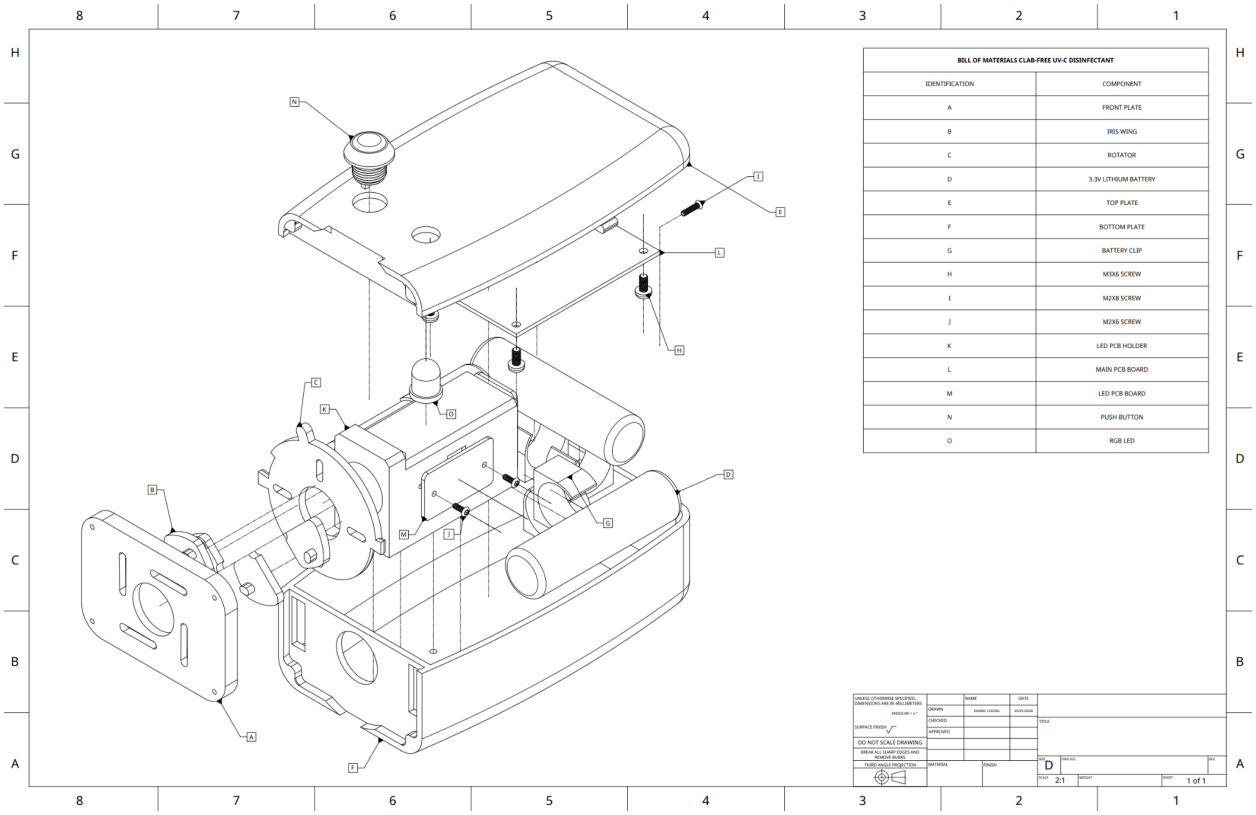


Figure 77: Assembly Drawing of Exploded View of CLAB-Free UV-C disinfectant

19. ECAD Representation of Device

19.1 ECAD Overview

The ECAD design consists of several design blocks:

1) Control System (MCU)
2) Battery Management System (BMS) and reporting systems
3) Inputs and Interlocks
4) RGB Led & Buzzer
5) UVc Led

19.2 ECAD Design Considerations and Choices

19.1.1 Control System

The function of the electrical design is driven by a Microcontroller Unit (MCU) in this case a XIAO nRF54L15 was used. This MCU has several features that are useful for this design.

1) The nRF54L15 has a ultra-low power mode where internal circuitry is physically disconnected to reduce power consumption
2) It contains two watchdog timers that are used to verify proper function of the overall device
3) It can output PWM signal (used to control UVc leds)
4) It can be programmed using Zephyr RTOS

19.1.2 Battery BMS Charging/Discharging Circuity + Battery Level Notification Design

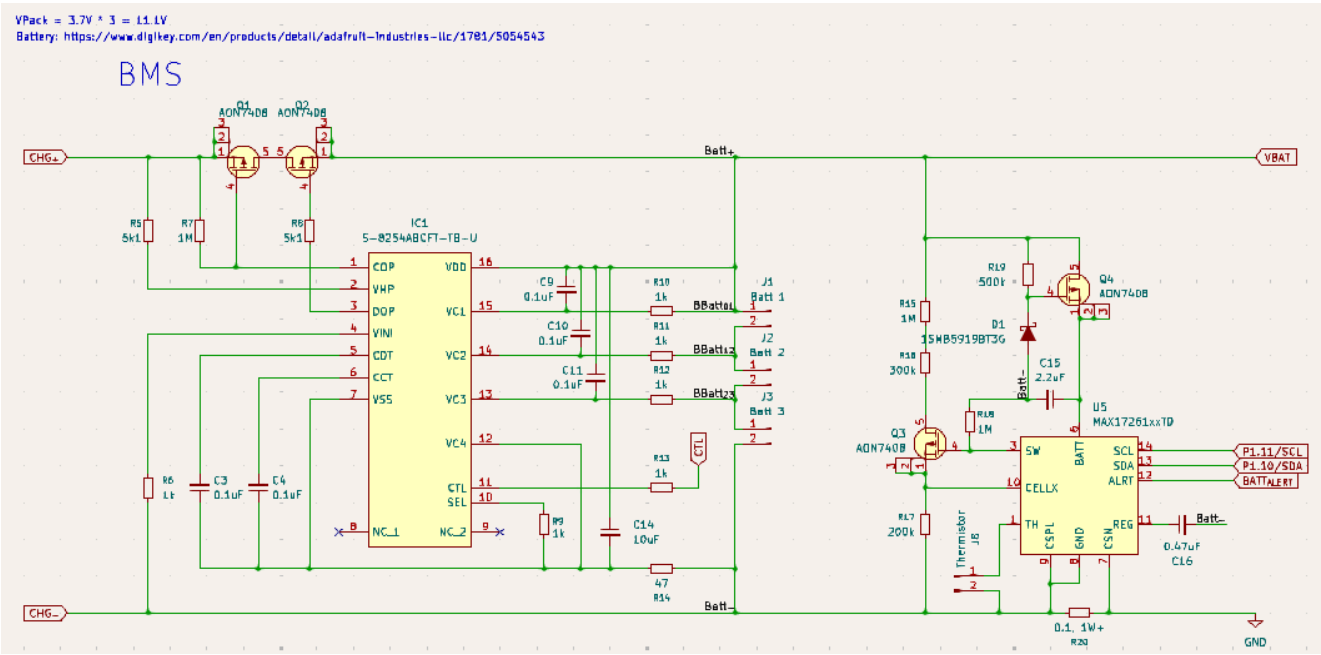


Figure 78: BMS Schematic

The BMS was designed to protect and detect the device from component failure and shorting. The overall device was calculated to pull a maximum of ~1.5A under normal operating conditions. From this a 33% range of error was used to determine the shutoff current of the device, this translates to a shutoff current of >2A. Knowing this and following the datasheet for the S-8254 BMS IC, several resistor and capacitor values were chosen to set current. The current is measured over R20, a low-resistance current-sensing resistor.

The S-8254 BMS IC was chosen for several reasons:

1) It is cheap and readily available
2) It does not require external control from a management MCU and therefore does not use any IO from the XIAO nRF54L15
3) It can handle 3-5s lipo

To monitor the state of the S-8254 BMS and the state of the associated battery cells a MAX17261 fuel gauge IC was used. The MAX 17261 has several useful features for our use:

1) It monitors the voltage and current draw (also through R20) of the batteries
2) It can shut off the power supplied to the whole system from an I2C signal sent by the XIAO nRF54L15
3) It can read the voltage of the battery pack and report that value to the XIAO nRF54L15 over I2C

Both ICs can independently isolate the battery pack from the rest of the system by controlling the AON7408 mosfets.

19.1.3 Inputs and Interlocks

There is one main user input in the form of a button on the final device. There are two internal interlocks that are in the form of limit switches actuated by the aperture on the front of the device. All of these switches are setup in the same way following IEC 60204-1: pull up with falling edge detection.

In practice this was implemented using the internal pull-up resistors in the nRF54L15 and using device interrupts when a change in state was detected.

19.1.4 RGB Led & Buzzer

Both the RGB Led and buzzer are used to alert the user of the device status, the status signals are listed below in **Table 7.**

Table 7: Buzzer and Led Alert State Table

State	Led	Buzzer
Idle (Full Battery)	-	-
Idle (Medium Battery)	Solid Yellow	-
Idle (Low Battery)	Fading Red	Buzz at 440 hz twice a minute for 2 seconds
Idle (Critically Low Battery)	Rapid Flash Red	Buzz at 880 hz at 1 hz intervals
Error	Blinking Red	Buzzing at 880 hz at 1 hz intervals
Disinfecting	Solid Purple	Buzzing constantly at 440 hz
Successful Disinfection	Flash Green twice then return to correct Idle state	Stop disinfecting buzz, buzz twice quickly then return to correct Idle state

The buzzer is controlled by a PWM controlled n-channel mosfet in the drain configuration, see Figure 79.

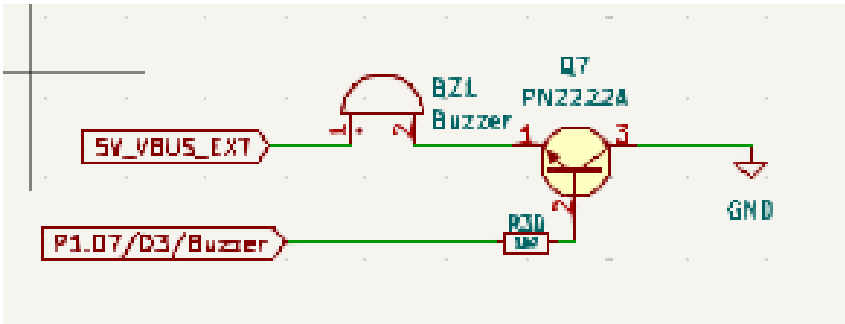


Figure 79: Buzzer Circuitry

The RGB led is controlled by a LP5185 IC. This IC communicates with the MCU over I2C to set the color of the LED while also being able to independently control LED lighting patterns. This IC was used for two main reasons: 1) since the IC can independently light the LED using pre-programmed lighting patterns the burden of sending these commands are taken away from the already busy MCU. 2) The IC communicates with the MCU over I2C which frees up GPIO pins for other purposes. See the RGB led circuit in Figure 80.

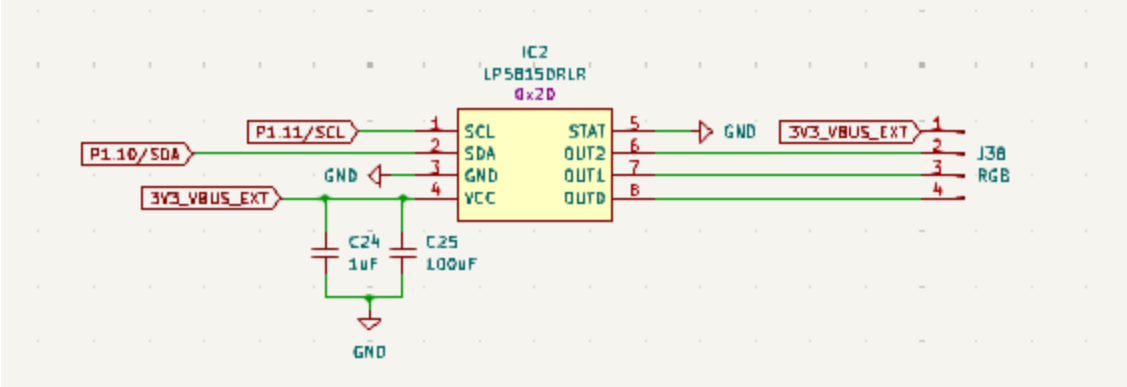


Figure 80: RGB Led Circuitry

19.1.5 UVc Led

The design of the UVc circuitry can be split into two distinct units: the first is the actual driver circuitry, and the second are the UVc led daughterboards.

The UVc driver circuitry is based on the LM3409 IC. This IC creates an analog current-controlled voltage based on the spacing of this PWM signal. It was chosen for a few reasons:

1) The current-controlled nature of the driver circuitry does not allow for overcurrent across the leds, making it more difficult to burn them out
2) Since it is PWM controlled the IC only needs one dedicated GPIO to operate
3) The IC falls within spec for our leds (can deliver 11.1V at 1050 mA)
4) The IC can detect and report led faults to the MCU

The UVc driver was configured using resistor and capacitor networks as described in the LM3409 datasheet. It was configured with a shutoff current of 1500 mA and a UVLO of 9.6V. Since the high current leds draw a substantial amount of power when initially switched on they can cause a drop in battery pack voltage, if this voltage drops below UVLO the leds will not try to reactivate. This is done to avoid a situation where the leds cannot turn on due to low pack voltage.

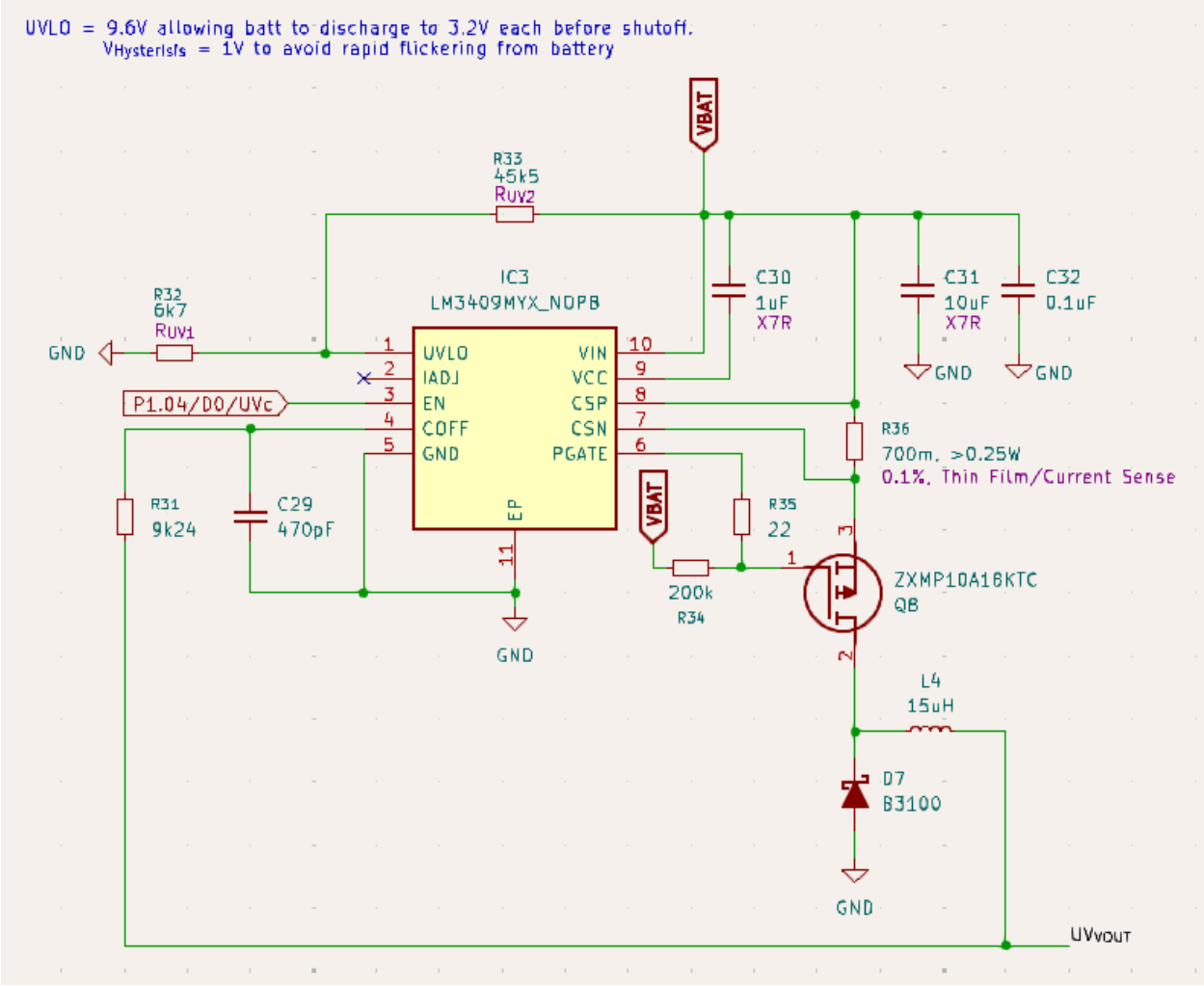


Figure 81: UVc Led Circuitry

The UVc leds are physically mounted to small daughterboards that can be mounted inside the mechanical chassis of the device. These boards have several design considerations:

1) The boards can use either a FPC or JST connector without any redesign
2) They all have the exact same electrical layout
3) They all contain heat sinks for thermal energy dissipation

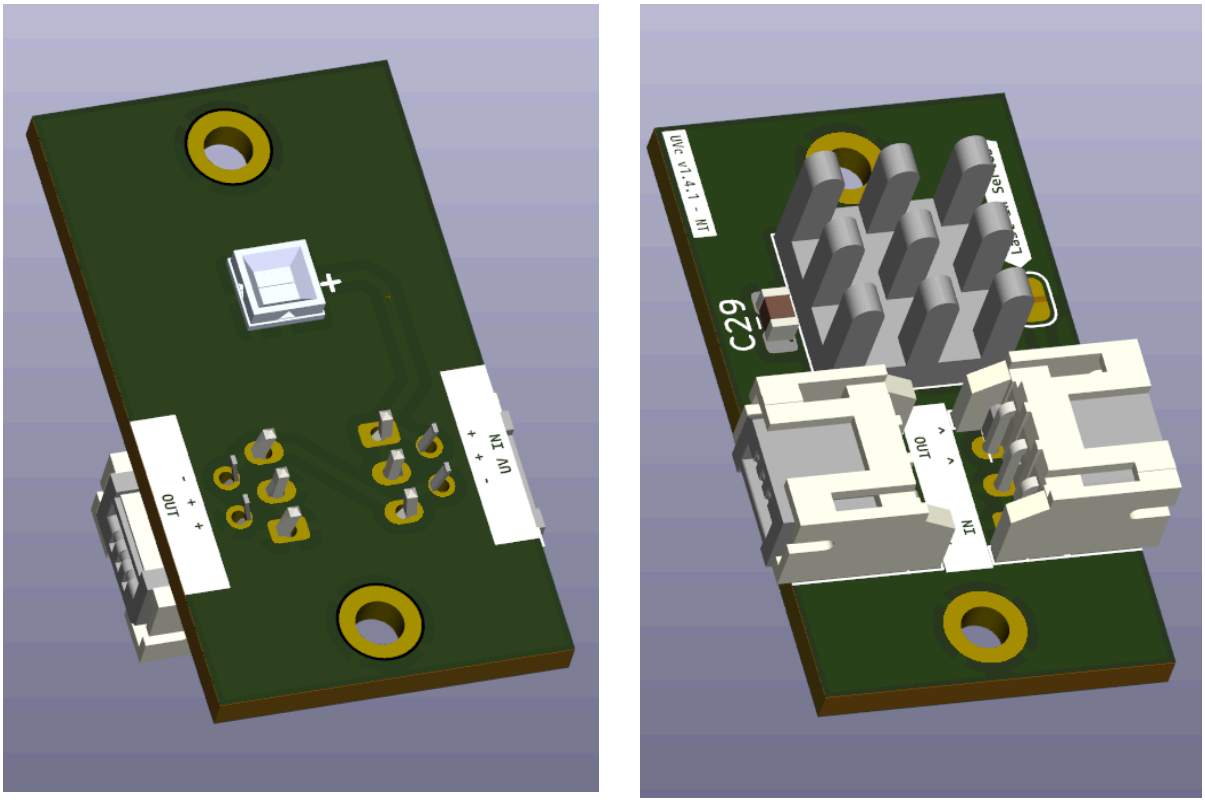


Figure 82: UVc Led Daughterboard (Left: Front - Led Side, Right: Back - Connection Side)

20. FMEA

Design Block	Failure Mode
Disinfection (Block#1)	Insufficient UV dose delivered
Disinfection (Block#1)	Uneven UV exposure due to LED placement
Disinfection (Block#1)	UV LEDs fail to turn on
Disinfection (Block#1)	UV exposure exceeds safety limits
Notification/Firmware (Block #2)	Device activates in the wrong state
Notification/Firmware (Block #2)	Abort/Error does not shut off the light
Notification/Firmware (Block #2)	Button press not registered
Notification/Firmware (Block #2)	Incorrect state transtitions
Notification/Firmware (Block #2)	Incorrect LED color/state
Notification/Firmware (Block #2)	Buzzer too quiet, absent, not working
Mechanical/Housing (Block #3)	Iris or aperature does not close
Mechanical/Housing (Block #3)	Mechanical misalignment of shutters due to print
Mechanical/Housing (Block #3)	Device does not fit all catheter lines or hubs
Mechanical/Housing (Block #3)	Cracks, misformed, low quality prints
Power/Battery (Block #4)	Battery drains too quickly / fails to hold charge
Disinfection (Block #1	Chamber becomes dirty or degraded
Power/Battery (Block #4)	Battery overheats during charging or operation

Failure Effect	Severity (S, 1-10)	Detection (D, 1-10)	Occurrence (O, 1-10)	RPN (SxDxO)
Inadequate disinfection which could lead to infection risk	9	7	3	189
Inadequate disinfection which could lead to infection risk	8	7	2	112
Device deemed unsafe or ineffective	9	2	3	54
Patient or clincian UV-C exposure	7	8	2	112
Incomplete or excessive disinfection // Loss of User Trust	7	6	3	126
Excessive UV-C exposure, skin health	9	7	3	189
Loss of User Trust	4	1	2	8
Unsafe UV-C exposure when not needed or incomplete disinfection	9	5	5	200
Loss of User Trust, Lower Hospital Compliance	5	1	3	15
Lower Compliance	4	2	3	24
UV leakage = safety hazard, excessive UV-C exposure	8	2	4	64
Wear over time, failure to enclose on the	7	2	2	28
Non-complicance to hospital protocols, incomplete disinfection	9	2	2	36
UV leakage = safety hazard, excessive UV-C exposure	8	3	3	72
Device dies during disinfection, leading to incomplete cycle	5	4	4	80
Reduced UV transmission, inadequate disinfection	5	5	3	75
Thermal hazard to user or patient; device damage	9	2	2	36

Figure 83: FMEA Analysis

The RPN = Severity (S) x Detection (D) x Occurrence (O), each scored 1-10

- Severity: How harmful is the failure to the patient
- Occurence: How frequently is this failure likely to happen.
- Detection: How hard is it to catch the failure before it occurs.

A high RPN means the failure is serious. Our highest RPN is originates from the Notification Design Block #2 detailing the effect of if “abor/error does not shut off the light”. This effect would cause unsafe UV-C exposure when not need or incomplete disinfection which is a core

requirement for our model. The second and third highest shared at 189 detailing the Disinfection (Block #1) showing that insufficient UV dose delivery can severely undermine the effectiveness of our model as well as Notification/Firmware (Block #2) - “UV exposure exceeds safety limits” as excessive UV-C exposure can cause future medical aid for skin health.

FMEA Analysis matters as our device is the intersection of firmware, mechanical, and optical systems working to deliver precise UV-C dose safely. The firmware is the brain of our device. If state transitions are wrong or if the abort signal doesn’t propagate to hardware, we lose both trust in our users and safety of our patients. In order to mitigate this, we included state machine validation and hardware-level power interrupt on booty. Finally the Disinfection Block #1 is crucial as UV-C efficacy is the entire clinical value proposition. An insufficient dose means the device is no longer useful in disinfection, ultimately unable to provide CLABSI which is the value of our device.

21. Business Aspects: Market and Value

Despite the form factor of the device changing quite drastically, the overall market potential and value propositions from the first semester are relatively unchanged.

21.1 Market Potential

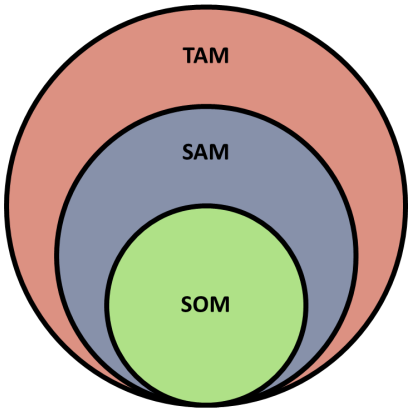


Figure 84: Market Potential Breakdown

The market potential for the CLAB-Free is sizable, given the costs of central line-associated infections annually. Since that number is around $2 billion USD, preventing even a small amount of that cost could be invaluable and drive the demand for the device substantially.

For the CLAB-Free, the TAM, or Total Addressible Market, was taken to be the global market for all catheter-related bloodstream infections. This market was valued at $1.61 billion in 2024 and is projected to reach ~$2.65 billion by 2034. (Precedence Statistics, 2024).

Following that, the SAM, or Serviceable Available Market, can then be narrowed down to the market for central-line-associated infections in just the United States. With an estimated number of 30,100 CLABSI's occurring in the US every year and each adding an estimated $16,000-$45,000 in direct hospital costs (Zimlichman et al., 2013), a minimum estimate of the SAM is $481.6 million per year for the United States.

To find the SOM, or Serviceable Obtainable Market, the team must look at the gainable market share of the SAM. Of this market, an estimated 67% of CLABSI's are preventable. Within this range of preventable CLABSI's, several other companies exist in the space, such as 3M, Becton Dickinson, and others. We could aim for 5% of the market share for CLABSI prevention devices, which would result in a SOM of $16.13 million.

21.2 Value Proposition

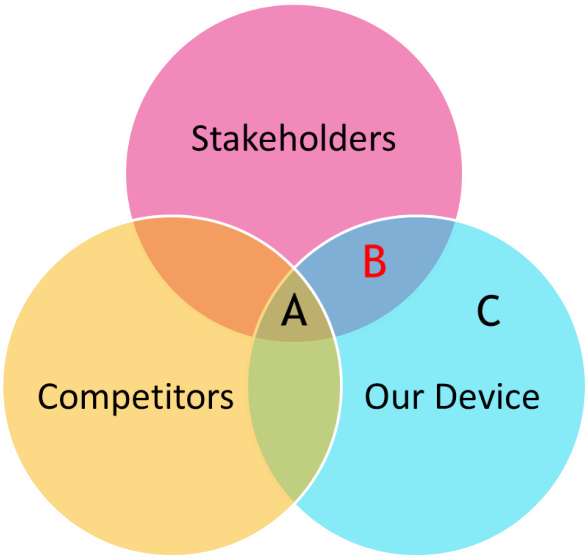


Figure 85: Value Proposition of CLAB-Free

Based on the final design of CLAB-Free, the device has Points of Parity (A), Points of Difference (B), and Points of Irrelevance (C).

The Points of Parity of the device are the common disinfection of central lines from different methods and techniques. When used properly, these methods and techniques all follow the EPA regulation of a 4-log reduction.

The Points of Difference of the device are what make the device unique and stand out from other similar devices or methods. CLAB-Free has several points of difference compared to other

devices. First, the device is able to be operated in under 30 seconds, as compared to the proper Scrub-the-Hub technique. Second, unlike the current method, which requires waste of alcohol pads, the CLAB-Free device is able to be easily switched and used between multiple patients and is easily reusable. The device's resin casing, which protects the nurses and patients from UV-C light, is another key point of difference. One final point of difference exists in the one-handed nature of our device, which allows nurses to use it much more efficiently than other two-handed devices.

The Points of Irrelevance of the device are aspects that, while helpful, are not necessities for the stakeholders. The point of irrelevance of our device is the notification system, which alerts nurses to the completion of a disinfection procedure. While an important aspect, it is not completely critical to the nurses' use of the device

22. Regulatory Pathways

The CLAB-Free would be considered a Class-II device under the FDA. This classification comes from the inherent risk associated with low-wavelength UV-C light, its damaging properties to patients, and the nature of catheters being directly inserted into the human body. This direct access to the bloodstream assists in the Class-II designation. As a Class-II device, the CLAB-Free has two potential pathways to gain FDA approval.

22.1 510(k) Exemption

Since the CLAB-Free is not exempt, it must submit a 510(k) to show that it is substantially equivalent to other previously approved UV-C disinfection devices in both efficacy and safety (FDA, 2022). After completing performance and safety evaluations, the device must be cleared by the FDA. As part of the regulation of the device, post-market surveillance of the device must occur, and manufacturers must also maintain Good Manufacturing Practice (GMP).

22.2 "De Novo" Classification

However, a different course of action with a UV-C emitting portable device is available. Currently, there are no such devices used to treat CLABSI's, but any UV-based device for the surface disinfection of equipment would fall under 21 CFR 880.6600 as a Class II device (FDA, 2025). Due to the unique interface of our product with the catheter hub, it could be required to go down the "De Novo" pathway as a new product classification (US FDA, 2024). This would require submitting a De Novo request including intended use, risk analysis, and testing, and the FDA would approve the device as a Class II device.

23. Design Ethics II

23.1 Ethical Approach Through our Final Solution

Several groups may be affected by the use of a UV-C central line hub disinfection device. Patients with central venous catheters are the most directly affected because they face the risk of central line-associated bloodstream infections (CLABSIs) if disinfection is performed incorrectly or inconsistently. Many of these patients are critically ill or immunocompromised, which could mean that even small failure in infection prevention can lead to severe complications. Healthcare workers, particularly nurses responsible for catheter maintenance, are also affected because they interact directly with the device during routine care. If the device is misused or safety features fail, clinicians could be exposed to UV-C radiation or may unknowingly provide inadequate disinfection. Hospitals and healthcare systems are also stakeholders, as failures in infection prevention increase patient harm, healthcare costs, and institutional liability. Ethical principles of beneficence, non-maleficence, autonomy, and justice apply to all of these groups because the device must both protect patients from infection and avoid introducing new risks.

23.2 Example Case #1: Improper Hub Preparation

A potential ethical failure could occur if a nurse relies entirely on the UV-C device without properly preparing the catheter hub before disinfection. For example, if visible debris or biofilm remains on the hub surface, UV-C light may not fully penetrate and sterilize the area. In this scenario, the device may appear to complete a successful disinfection cycle, but microbial contamination could remain, potentially leading to infection. This situation raises concerns about negligence and overreliance on technology. While the device is intended to improve infection prevention, it should not replace proper clinical protocols such as visual inspection and cleaning of the catheter hub prior to use.

23.3 Example Case #2: Accidental UV-C Exposure

Another ethical concern involves the risk of accidental UV-C radiation exposure. If the device were activated without being fully sealed around the catheter hub, or if a user attempted to bypass safety mechanisms, harmful UV-C radiation could reach skin or eyes. UV-C exposure can cause skin irritation, burns, or eye injury. This situation would represent a conflict between beneficence and non-maleficence: the technology is designed to prevent infection, but improper use could introduce new health risks to patients or healthcare workers. Even with safeguards, human error or device malfunction must be considered when designing medical technologies that emit potentially harmful radiation.

23.4 Example Case #3: Device Failure due to Battery Depletion

A final example case could occur if the device fails during use due to battery depletion or internal malfunction. For example, if the battery is too low to complete a full disinfection cycle but the clinician is unaware, the hub may receive only partial UV exposure. This could result in ineffective sterilization while the clinicians believe the procedure was completed successfully. In high-pressure clinical settings, failure could occur during emergencies when time is limited.

23.5 Approach to Addressing Failures in Practice

The device incorporates several safeguards to reduce ethical risks during clinical use. A mechanical iris housing with safety interlocks ensures that the UV-C LEDs can only activate when the device is fully sealed around the catheter hub, preventing accidental radiation exposure. A notification system using LED indicators and an audible buzzer clearly communicates device status: blue during the disinfection cycle, green upon successful completion, and red to indicate errors such as improper placement or malfunction.

Battery monitoring also prevents the device from operating if insufficient power is available to complete a full disinfection cycle. In addition to these engineering controls, proper training and adherence to clinical protocols remain essential. Healthcare workers must continue to visually inspect and clean catheter hubs prior to using the device. Together, these safeguards help minimize risks related to human error, device malfunction, and UV-C exposure while supporting safe and effective infection prevention.

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