Team F— Surgical UV lighting Ltd.



Luxo, our handheld disinfectant device, safely reduces bacterial infections during prosthetic joint replacement surgery by shining a 222-nm UVC light 30 cm away for 10 seconds at 30 minute intervals. This wavelength effectively inactivates airborne bacteria that "rains down" on the open -wound during the 1-3 hours long surgery. Our device works on a range of bacteria, including superbugs resistant to antibiotics, such as MRSA. Our materials are chosen for their quality and properties like ability to withstand rigorous disinfectant processes as they are highly resistant to harsh chemicals and heat, as well as having a wireless charging system to reduce the risk of tripping and increase ease of use in surgery. With the product only costing £450 per unit and predicted to make profit within 4 years, it would reduce the burden on the NHS, saving them money on re-infection surgeries.

Technical Scope Project Delivery Plan **Security and Assurances**

Eilidh, Harry, Sophie, Isaac, Zhe—Wei, Islay

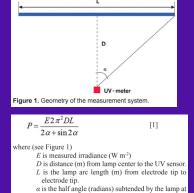


UV SPECIALISTS



Performance data

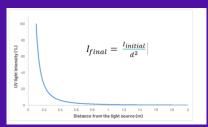
The wireless charging station works by an electrical current passing through coils within, creating an electromagnetic field. When the receiving magnetic plate within the handheld device comes into close range with the charging pad, the magnetic field generates an electrical current within the device and charges it.



the sensor position. That is, $\tan \alpha = L/(2D)$

Using the Keitz formula, we calculated the peak and steady state power output of our device from different distances. We calculated that with a 50W 222-nm UVC light at a distance of 30cm from the surgery site, we could effectively disinfect the air and 400 cm² surface. These conditions would produce an irradiance of 50 W/m² that will inactivate a range of infectious bacteria on the surgery site. To kill MRSA on the implant site, we would need a 520 J/m² dose for less than 5 seconds, however our device will recommend an exposure of 10 seconds to allow for distances of 30-35 cm from the site so that it is still effective in killing 99% of microbes. To ensure that the surface is completely covered we will emit a purple light on the disinfected area.

Recent studies have shown that surgical wound irradiation with UVC lamps have very promising results in reducing prosthetic joint infections. One 19 year study following 5,980 joint replacements showed a three fold reduction of surgical site infection rates (p< 0.0001), compared to unirradiated controls. [study]



Materials Used

Total Weight

 Weight: <1kg (380g lithium-ion battery, 10g fused silica, 120g HDPE, 100g electrical components)

Fused silica

- Fused silica is composed of a non-crystalline silica glass, while quartz is made from crystalline silica. This difference gives fused silica very high transmission in the UV spectrum compared to that of quartz.
- 90% transmission of 222 nm UVC light with thickness of 5mm
- It is resistant to water and strong acids.
- Low resistance to alkali.
- High melting point and a low coefficient of thermal expansion, which makes it resistant to sudden changes in temperature.

High density polyethylene (HDPE)

- HDPE = 970 kg/m3
- 1.106 \$USD/kg (2022)
- HDPE cost per 120g = \$USD 0.132
- Does not form sharp edges when it breaks, one of the top UV resistant plastic on the market, extremely resistant to acids, alcohols and bases. It is also recyclable so can be recycled up to ten times before its quality is compromised.

Battery: lithium ion battery is 250 Wh/kg so is a 25Wh battery. The device will have a charging station that it can stand on. It will use optimisation battery charging to charge the device slowly but does not drain the battery as much as a fast charger would. (supercapacitors). The charger will have a larger battery of 25Wh and the device will have a smaller battery of 1Wh.

Speaker - This allows for the nurse to hear the cue to sanitise the wound again. This means they can hear the sound over the other loud sounds in the operating room. It also means that the nurse does not have to keep track of time and can just listen out for the voice cue.



Material Selection

For the enclosure, we used Ansys Granta Edupack, maximising the cost merit index for a stiffness limited structure, this produced an index line with a gradient of 1.5. We also filtered for materials that were resistant to 10% acetic acid, 10% hydrochloric acid, and ethanol. This shrinked our options to Stainless Steel, PS, PVC, PP and PE We went with PE as it is the most widely recycled material.

Costing

Description	Quantity	Price (£)	Quantity x Price (£)
Fused Silicon (SiO2) Lens (5mm)	1 unit	£30 per unit	30
Li-ion Battery for charging device	1 unit	£25 per unit	25
Li-ion Battery for device	1 unit	£7 per unit	7
HDPE	120g	£0.10 per gram	12
Circuit board	1 unit	£10 per unit	10
222 nm UVC LED	1 unit	£22.94 per unit	22.94
Electrical Wires	1 unit (pack of 22)	£4.73 per unit	4.73
Power Supply Unit	1 unit	£11	11
RGB LED	1 unit (pack of 5)	£0.93	0.93
OLED Screen Display	1 unit	£15.35	15.35
Speaker	1 unit	£5.23	5.23

Materials cost = £ 144.18

Electrical components: Circuit Board, wires, PSU, UV light bulb, RGB LED, OLED Screen Display

Other variable costs

Packaging, shipping and injection moulding

Costs (Estimated)	UV light (£)
Total fixed cost	1,146,100
Unit Selling Price	450
Unit Variable Cost	147.93

Using the manufacturing and labour costs of making barcode scanners, we can estimate the costs associated with our product by using our own material costs.

The total fixed cost will include the rent of the factory used for manufacturing, the employees' salary, utility bills, loan repayments, the price of patents and intellectual property, and insurance. The salary for the factory employees would be around £11 per hour.

Premium price for this product would be higher than market price as there is no market price for this product at the moment. We would sell our product for £450 per device.

How many units to sell to break even = total fixed costs / (unit selling price - unit variable cost)

Units = 1,146,100 / (450 - 147.93) = 3794.153673 units to break even

Therefore, we have worked out that we would need to sell 3795 units to break even.

Feasibility

- It's a small, portable device.
- All the individual components of our product exist already - no new state of the art development is required.
- A single, relatively low, upfront cost with years of reuse and benefit makes our product an attractive purchase.
- It's incredibly easy to use, ensuring our customers are not deterred from introducing our product into their current process.
- With its quick and easy to use nature, our product stands out as an innovative way to reduce the health risks for patients.

Limitations

- Battery won't last forever (despite being rechargeable)
- The HDPE can only be recycled up to ten times before its quality is compromised.
- The Lithium-Ion batteries we are using can fail to operate and may present a fire and/or an explosive hazard.
- The product is relatively cheap but will need funding from stakeholders to get started on the business.

Integration

- Our device has considered inclusive design such as ergonomic and colourblind features that allow NHS staff to easily implement it during prosthetic joint surgeries.
- We outcompete existing technology such as the Phillips UVC disinfection lamp range that employs less safe 254-nm light that is potentially carcinogenic, whereas our 222-nm excimer lamp has undergone rigorous clinical studies testing its safety on human cells and proven harmless.
- We have reduced the burden on NHS staff by making the devise simple yet effective, minimising the learning curve and need for training.

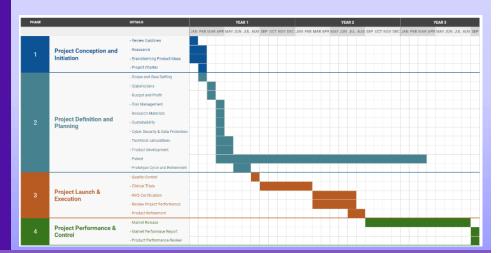
Risk

Risks	Potential consequences of risk	Initial risk level	Control measures	Final risk level
Fire in the building	Lithium battery flammable and potentially explosive	Medium	If there was a fire evacuate the room and remove equipment if safe to do so.	Low
Lithium-ion batteries failing.	Fire and explosive hazard.	Low	The batteries can be easily removed and disposed of safely if they are damaged.	Low
Investors withdrawing from the project	Can't finance the project	Medium	Make sure to continuously update the investors on the progress of the project	Low
Disapproval by key stakeholders	Project shut down	Medium	Make sure to clearly outline the project details so they are informed	Low
Money input < Money output	Bankruptcy	Medium	To carry out lots of research before kick starting the business	Low

Safety

- High Density Polyethylene no sharp edges produced if it breaks
- 222-nm UVC is safe for human cells as it cannot penetrate them and cause harm. The proteins on the surface of human skin absorb the UV-C light and stop it penetrating any further. This ensures it has no carcinogenic properties to humans.
 - ♦ Short exposure
 - More energy and higher frequencies
 - No additional personal protective equipment (PPE) are required for the nurses and surgeons.
 - Our 222-nm irradiance complies with the National Health Commission's recommendations

Project Timeline



Patent and Intellectual property/licencing

Full patent application process: https://www.gov.uk/register-a-design/ print

- During the design IP application, several detailed illustrations of the product will be submitted for intellectual property protection.
- We will state parts of the device that are limitations of the illustration that we want to register. We will disclaim parts of the illustration that we do not want to register as part of the design.
- On average it can take a minimum of a year to process a patent application, with the length of time from filing to approval being about two years. When it has been approved, you can then sue anyone who copies that information.
- The design registration will be renewed every 5 years to keep it protected for a total of 25 years.
- A patent application will be submitted with a description and drawing for our device.

Product plan and life cycle

- Our project will start with initial research and planning.
 We will apply for a patent early on in the project due to the length of approval time.
- We will review project performance near the end of the project to access its market performance.
- The project is estimated to have a duration of 2 years and 9 months.
- Lithium ion battery is recyclable and rechargeable.
 A Lithium-Ion battery's average life span is 2 to 3 years or 300 to 500 charge cycles so whichever comes first.
- The HDPE plastic casing we are using has a lifespan of around 50 years, it is fully recyclable and can be made with recycled plastics.
- 222nm UVC LED typically associated with a lifetime claims of 8000 to 10,000 hours
- RGB LED can work for 50,000 hours

Company cyber security / data protection statement

Importance of Data Protection and Cyber Security

As our product itself has no connection to the internet, there is nothing to secure. However, in its production, we will be hosting a number of clinical trials and storing patient data. This policy will ensure that their data is protected at all times, and confidentiality is maintained throughout, meaning information cannot be accessed by anyone who does not have clearance. If our trials were to lose integrity, by being tampered with to show false positive results, then the treatment could potentially do more harm than good, when treating infections in long joint replacement surgeries.

Managing Access controls

We will be using a Mandatory Access Control (MAC) strategy, where our data security manager will be in charge of data access based on confidentiality and user clearance levels. This means they will also be accountable for vulnerabilities and breaches.

Secure Storage of Data

We will store our data in Amazon Web Services (AWS), which is the world's most comprehensive and broadly adopted cloud service. The patient's data will be encrypted at rest, and we will incorporate two factor authentication and strong password demands for all data access. AWS (the service provider) will also be carrying out all vulnerability scans, to point out weaknesses that can be fixed, allowing us to be confident in the overall protection of the data. In addition to this, AWS has a network firewall which monitors and controls incoming and outgoing network traffic, which is also responsible for intrusion detection and prevention service. Finally, we will provide all patients of the clinical trials with a privacy policy that upholds the General Data Protection Regulation (GDPR) standards on how we use and store their data.

What Information is Collected?

Every patient's forename, surname, email address, weight, height, sex, age, and any relevant medical issues, such as a high sensitivity to light or if they are currently pregnant.

Why do we need this information?

The patient's forename, surname and email address is required for ease of communication about results, and any possible questions. All other information is required as these are control variables that may impact the results of the trial as a whole. Therefore they must be taken into account when producing conclusions about the effectiveness of ultraviolet type C (UVC) light treatment.

How Will we Use This Data?

All patient information will be compared with other patients when drawing out conclusions from the trials. This step will allow us to identify any trends between different control variables, which may affect the results. Their information will never be made public, and will only be shared with authorised employees, decided by our security manager.

Prevention of Attacks

All members of staff carrying out the trials, including those that join part way through, will be sufficiently trained in the understanding of data confidentiality and protection, as well as measures they must take in order to avoid attacks on the sensitive data. This training will be annually renewed in the event that these trails last longer than a year.

Managing Risks and Responding to Attacks

Furthermore, we will hold security audits every 4 months, however, in the event of substantial changes in the organisation, such as people leaving, these may be held more often, this is down to the security manager's discretion. AWS also has services in place for data backup, and disaster recovery. Since all information will be stored on the cloud, in the event of on-site servers going down, potentially due to a cyber security attack, the data will not be lost, and operations can continue as normal from the provider's location, until a fix has been made.

Sustainable Credentials

Outline of our commitment to certain aspects of Sustainability

At LUXO, we are committed to advancing sustainable practices in healthcare by providing innovative solutions that prioritize environmental stewardship, affordability, patient safety, and health, as well as operational efficiency. Our UVC Light handheld device embodies our commitments, offering sustainable alternatives for disinfection in healthcare settings.

Environmental

Our product is designed with energy-efficient technology, complying with Energy Related Products(ErP) for reducing the power consumption compared to a normal UV-related product, in order to minimize the environmental impact. Our materials are highly recyclable, ECO friendly, environmentally responsible, and reduce the waste generation.

Health and Well-Being

The 222 nm UV-C light is a safe and effective electromagnetic approach, to maximizing the performance of disinfection and providing the safest environment for patients and surgical professionals. We put health and safety first.

Economic Sustainability

Our product is offering a reusable and energy efficient alternative to traditional methods of disinfection, it can reduce the operating cost and have a relatively low upfront cost, in order to lower the burden for NHS. We are committed to ensuring the accessibility of our product to facilitate people from different socioeconomic backgrounds.

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Team Profile and responsibilities

Engineer 1: Sophie Leaver	Engineer 2: Islay Maclean	Engineer 3: Eilidh	Engineer 4: Harry Hodges	Engineer 5: Zhe Wei Kho	Engineer 6: Isaac Ho
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Specialism: Bioengineering	Specialism: Bioengineering	Specialism: Mechanical Engineering	Specialism: Computer Science	Specialism: Mechanical Engineering	Specialism: Computer Science
I'm studying bioengineering; my specialised modules on biomaterials and biomanufacturing will aid the project in understanding how the prosthetic material interacts with the body, especially the immune response. I will need to ask questions about topics like robotics systems and electrical components, for these I'm hoping our mechanical and computer science teammates will be able to provide. I believe the most challenging aspect of this project will be creating a novel approach as creating a prosthetic requires a	I'm currently studying Bioengineering and have specialised in modules on mechatronics, electronics, control systems and coding. I learnt a lot of skills from my robotics project that can be applied to prosthetic devices such as the electronics part where I can look at how the device works and whether it is controlled from outside the body or it controls itself. The most challenging aspect of the project may be ensuring a low risk of infection which stream B of Bioengineering knows a lot on.	I am currently studying Mechanical engineering, I have theoretical knowledge in mechanical systems, fluids and thermodynamics. I will be able to apply this knowledge to the project, especially the manufacturing side for our solution will have to be applied on a large scale while being as cost-effective as possible. Furthermore, I can apply my theoretical knowledge to the implant itself and ensure any changes or additions to the standard design won't affect the structural integrity or the dynamics of how it	Computer Science has a key focus on team development projects, as well as the design and implementation of code-based systems. This project may require the interpretation of large datasets, or the use of machines to prevent the risk of human error or skin to skin contact between doctor and patient. Questions I have include: What is our overarching approach? What machines will these use? I can personally contribute an understanding of software systems, cyber security and data protection. I believe a challenge will be to	As a mechanical engineer, I will be able to help the team understand the mechanical interactions and structural health of the product while interacting with the body, for example understanding the manufacturing processes that may be involved. Understanding the thermal characteristics of the materials through empirical analysis by building test rigs is an area I'll also be able to assist on! Should there be experience required from understanding biomechanics, my	I'm studying Computer Science. I have learnt a lot of skills on building a system, a software and web development, mainly on coding. This can be applied to the software side of the prosthetic devices, like making a user interface to analyse the datasets. I will need to ask questions about how the actual design of the device will be and how can it perform on the patient? I believe I can contribute to the software design of the solution. The most challenging aspect of this project is making an affordable and sustainable
comprehensive knowledge on materials, health, and surgery, which all require a lot of research.		moves and functions. The questions I will have to ask is what manufacturing techniques will go into this design and the costs of the solution. The challenge of the design will be creating something that can be practically implicated in real life.	maintain a sensible cost and sustainability whilst reducing the risk. I believe other team members will bring an understanding of machines and their implementations, as well as a knowledge of materials and how they can interact and affect the body when being implanted.	experience of working with anthropometric design and the design of transmissions will help in this area. Overall, I hope I'll be able to help provide a perspective to help turn ideas and turn them into commercial products.	solution. Some aspects I believe my team members will bring out some comprehensive knowledge on medical and materials and the implementations of the design.



AS A TEAM

Where do your disciplines overlap?		The disciplines overlap in mathematics and coding. We all do group projects and have had	
		previous experience in working as a team.	
What has surprised you about the other disciplines?		How different the modules can be in different disciplines but we still learn the same core values.	
	Name	Responsibility	
	Harry Cyber security and data protection statement, Feasibility		

Name	Responsibility	
Harry	Cyber security and data protection statement, Feasibility	
Islay	The costs and the materials needed for the device	
Sophie	Technical calculations, Safety, Project management	
Isaac	Sustainability statement	
Eilidh	Costs and pricing, Design and project management	
Zhe Wei	Materials selection, CAD design, Technical Drawings	