Institution: University of Strathclyde		
Unit of Assessment: B12 - Engineering		
Title of case study: Innovative lighting system in healthcare settings reduces infection and benefits patients		
Period when the underpinning research was undertaken: 2005-2016		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Prof Scott MacGregor	Professor	01/06/1986 – present
Dr Michelle MacLean	Senior Lecturer	01/10/2015 – present
Prof John Anderson	Professor; Research Fellow	01/11/1971-04/01/2008; 01/05/2008 – present
Period when the claimed impact occurred: 2015 – December 2020		
Is this case study continued from a case study submitted in 2014? No		

1. Summary of the impact

Research at Strathclyde led to the development and commercialisation of a pioneering lighting system that can kill bacteria, fungi, and, under certain circumstances, viruses on surfaces and in the air. 'Whole-room' environmental decontamination is achieved with high-intensity narrow-spectrum violet-blue light, which is safe for patients and staff, material and equipment, and can be continuously operated without the need for trained staff, or time consuming and potentially hazardous manual cleaning protocols. Licensees of the technology include two major US manufacturers, with implementation in over 300 healthcare facilities to date, with benefits to patient health, cost savings for hospitals, and economic benefits to commercial suppliers.

2. Underpinning research

Hospital-acquired infections are a worldwide problem, and the increasing emergence of multi-drug resistant microbes presents both a major risk to public health and a significant economic burden on the global healthcare system. Environmental contamination is a significant source of infection transmission, with potential sources of cross-infection being contact from contaminated surfaces, the hands of medical staff or equipment, and through the air. In the fight against healthcare infection, Strathclyde researchers developed an antimicrobial high-intensity narrow-spectrum (HINS) violet-blue (indigo) light system, through highly interdisciplinary research at The Robertson Trust Laboratory for Electronic Sterilisation Technologies (ROLEST) involving engineers, microbiologists, optical physicists and statisticians, in collaboration with clinicians from Glasgow Royal Infirmary and at Addenbrooke's Hospital, Cambridge.

Initial work involved fundamental investigation of the microbial sensitivity to narrow bandwidths of near-UV and visible light, using broad-spectrum light sources and a series of optical filters, identified a peak of antimicrobial activity in the region of 405nm. Further investigation led to development of 405nm narrow-band light emitting diode (LED) array systems as suitable sources for improved optical and energy efficiency. Irradiance and dose experiments using 405nm sources established broad antimicrobial efficacy against bacteria, endospores, fungi and, under certain conditions, viruses [**R1**]. The team conducted a detailed safety analysis of these antimicrobial wavelengths against international standards (International Committee on Non-Ionising Radiation Protection (ICNIRP) and the American Conference of Governmental Industrial Hygienists (ACGIH)). This established the safety of these wavelengths, and enabled identification of optical irradiance levels, which could be utilised for safe, continuous exposure of humans [**R2**] – a major safety advantage over UV light. The advantage of being able to utilise 405nm violet-blue light in the presence of humans led to the concept of developing an antimicrobial technology which could provide safe, continuous environmental decontamination, in occupied environments, as a novel infection control strategy [**R2**, **R3**, **R4**].

A Scottish Enterprise Proof of Concept Award to the ROLEST research team at Strathclyde led to the technical development of a 405nm High-Intensity Narrow-Spectrum Light Environmental Decontamination System (HINS-light EDS). The objective of this project was to advance from the use of single small-scale light sources to the development of a large-scale, ceiling-mounted, blended white light system which had appropriate optical output to provide continuous decontamination efficacy over large 'whole room' areas, whilst being within the acceptable human safety limits. Significant technological challenges were involved in this, including: identification of appropriate light sources for antimicrobial effectiveness; integration of optical components for a blended white-light output; irradiance profiling to ensure optimal optical output; thermal management of the optical components; power and energy efficiency requirements to ensure the system was in line with standard lighting systems; and antimicrobial testing against a range of microbes to ensure decontamination efficacy [**R3**, **R4**, **R5**]. The decontamination source also required optical blending in order to produce a lighting system which had an overall 'white' optical output similar to standard room lighting, in order to ensure usability and acceptability of the final prototype [**R2**]. A range of custom-build prototype and demonstration units for laboratory, clinical and industrial use have been designed and developed, with specifications fit for end user applications. Overall, there is a significant body of underpinning research conducted at Strathclyde into this antimicrobial technology covering aspects including: energy efficiency, germicidal efficacy and synergy, microbial resistance, material degradation, pulsed efficacy and safety [**R2**, **R5**, **R6**].

3. References to the research (Strathclyde affiliated authors in **bold**)

R1 **Maclean, M.**, **MacGregor, S.J.**, **Anderson, J.G.**, & **Woolsey, G.** (2009). Inactivation of bacterial pathogens following exposure to light from a 405-nm LED array. *Applied and Environmental Microbiology*, *75(7)*, 1932-1937. https://doi.org/10.1128/AEM.01892-08 [REF2 in 2014]

R2 **Anderson, J.G.**, **Maclean, M.**, **Woolsey, G.**, & **MacGregor, S.J.** Optical Device for the Environmental Control of Pathogenic Bacteria. US Patent No. 8,398,264, Granted 2013; European Patent No. 2211914, Granted 2014. https://bit.ly/3fbOwb6

R3 **Maclean, M.**, **MacGregor, S.J.**, **Anderson, J.G.**, **Woolsey, G.**, Coia, J.E., Hamilton, K., Taggart, I., Watson, S.B., Thakker, B., & **Gettinby, G.** (2010). Environmental decontamination of a hospital isolation room using high-intensity narrow-spectrum light. *Journal of Hospital Infections*, *76(3)*, 247-251. https://doi.org/10.1016/j.jhin.2010.07.010 [REF2 in 2014]

R4 Bache, S.E., **Maclean, M.**, **Gettinby, G.** **Anderson, J.G.**, **MacGregor, S.J.**, & Taggart, I. (2018) Universal decontamination of hospital surfaces in an occupied inpatient room with a continuous 405 nm light source. *Journal of Hospital Infections*, *98(1)*, 67-73. https://doi.org/10.1016/j.jhin.2017.07.010 [REF2]

R5 **Dougall, L.R.**, **Anderson, J.G.**, **Timoshkin, I.V.**, **MacGregor, S.J.**, & **Maclean, M.** Efficacy of antimicrobial 405 nm blue-light for inactivation of airborne bacteria. *Proceedings SPIE 10479, Light-Based Diagnosis and Treatment of Infectious Diseases*, 104791G (8 Feb 2018). https://doi.org/10.1117/12.2289987

R6 **Gillespie, J.B.**, **Maclean, M.**, **Wilson, M.P.**, **Given, M.J.**, & **MacGregor, S.J.** Development of an antimicrobial blended white LED system containing pulsed 405nm LEDs for decontamination applications. *Proceedings SPIE 10056, Design and Quality for Biomedical Technologies X*, 100560Y (14 Mar, 2017); https://doi.org/10.1117/12.2250539

Notes on the quality of research: All references journal articles and conference papers were peer-reviewed ahead of publication. The underpinning research to develop the prototype was supported by a Scottish Enterprise Proof of Concept Award (MacGregor & Anderson. POC7 HINS-light system for the control of MRSA. Scottish Enterprise, 02/10/2006 – 31/05/2009, GBP457,000) and was awarded Research Project of the Year 2011 by Times Higher Education. The research has been patented and has led to four licensing agreements.

4. Details of the impact

Clinical evaluation of the HINS-light system provided validation of the decontamination efficacy of the technology and external recognition of the research, with isolation rooms found to be cleaner (up to 90% less environmental contamination) when the system was used in conjunction with standard cleaning and infection control procedures [**R3**]. The IP for the technology is protected by two families of patents (Process and Device patents e.g. [**R2**]) with patents granted in the UK, Europe, USA, Canada, China, Australia and Japan. Through licensing this technology, the Strathclyde research has:

- Enabled commercialisation of the HINS-light technology, leading to the growth of two major US manufacturers,
- Established a safer and more effective decontamination method;
- Supported decontamination in hospitals, resulting in improved cleanliness and infection control;
- Reduced surgical-site infections and improved patient health, resulting in cost savings through improved patient treatment and mitigation against hospital penalties.

Enabling commercialisation of HINS-light technology

Underpinning research led to IP generation [**R2**], and the subsequent licensing of the technology to two major US lighting manufacturers: Kenall Lighting in June 2015 [**S1**, **S2**], and Hubbell Lighting Corporation in April 2018 [**S3**]. These licensing agreements have generated a royalty income to the University of Strathclyde of nearly GBP1,000,000 from 2015 to date. Kenall Lighting, who are licensees for the healthcare field, have developed and commercialised the technology under the brand name *Indigo-Clean.* The establishment of this dedicated branch within Kenall Lighting has resulted in a significant increase in income [Text removed for publication] and the creation of 5 jobs directly related to Sales & Marketing of the products [**S2**]. In addition, the technology '*has had a key impact on the company's future as it was a large factor in its recent acquisition by Legrand, a multi-billion dollar French company specializing in the building environment*' [**S2**]. [Text removed for publication] Hubbell Lighting Corporation are licensees of the technology for applications outwith the healthcare industry, and have commercialised the technology under the brand name *SpectraClean.* [Text removed for publication] Their products have won a number of awards including a 2019 US Vision Award which '*honor innovation and excellence in products that contribute to the efficient and profitable operations and management of institutional and commercial buildings in the United States'* [**S4**]. Recent licensing developments have been sub-licensing of the patents by Kenall to Pinnacle Lighting (May 2020) [**S5**], and a first European license to Linea Light of Italy (November 2020). Announcing the sub-licence, the President of Kenall stated: '*Kenall is moving into our next phase of championing disinfection using safe wavelengths of visible light. Sublicensing Strathclyde's core patent using the Indigo-Clean brand will further expand the use of this unique, life-saving technology*' [**S5**].

Establishing a safer and more effective decontamination method

Cleaning and disinfection play a major role in reducing hospital-acquired infection, but are dependent upon staff competence and compliance with protocols. In this context, the clinical research partner and previous Head of Microbiological Services for NHS Greater Glasgow & Clyde highlights: '*It is well known that these may be compromised, particularly in busy institutions with high bed occupancy rates, or where there are shortages of appropriately trained staff*' [**S6**]. The key advantage of this technology is that it can be operated without the need for trained staff, as it is a simple light switch, and is safe for continuous operation in occupied environments:

> *'Some of the more potent chemical disinfectants e.g. formaldehyde gas or vapour have been used in recent years for terminal disinfection of ward areas affected by outbreaks of multi-resistant or hypervirulent strains of "superbugs", as has UV irradiation. However, because of their hazardous and toxic effects, they cannot be used while patients and staff are present, hence are unsuitable for routine environmental decontamination. Against this background, the discovery by these researchers that High Intensity Narrow Spectrum*

405nm light (HINS-light) had broad-spectrum antimicrobial activity, even at levels of irradiance that do not pose a hazard to humans, was a major breakthrough.' [S6]

In addition to the Strathclyde research demonstrating the efficacy of the technology against a wide range of superbugs, including MRSA and C. difficile [R3, R4], a range of independent studies has validated the benefits of the technology. At IDWeek Conference 2016 (USA), data was presented to show the efficacy of the system against a range of microbial pathogens on surfaces, with successful inactivation of three key problematic bacteria (MRSA, VRE, MDRA) on surfaces (>80% reduction in 24-hr) [S7]. At the same conference, other clinicians presented on the effective use of the technology within an intensive care unit for environmental decontamination and confirmed its efficacy as a complementary strategy in the fight against hospital environmental contamination, with the levels of environmental staphylococcal contamination reduced by 99.4% after 2 weeks use [S7]. In 2016, another independent UK study highlighted clinical use of the technology in an NHS specialist burns unit as part of an infection-control bundle to help control environmental contamination from multi-drug resistant bacteria, and prevent transmission to other patients [S7].

Supporting decontamination in hospitals, with improved cleanliness and infection control

Kenall Lighting's *Indigo-Clean* technology has been adopted in more than 300 US healthcare facilities in just 5 years since commercial launch, which *'highlights how strongly the value of the technology resonates with healthcare providers*' [S2]. The CEO and Managing Director of Henderson Hospital, stated: '*We currently have Indigo-Clean disinfectant lights in all of our inpatient and outpatient surgical suites and emergency department patient bays….Indigo-Clean has been a great partner in our fight to maintain a safe, clean environment for our patients. There are many disinfectant technologies available, but we feel Indigo-Clean is the right tool to help keep our patients safe*' [S1]. Medical Director, New Century Spine and Outpatient Surgical Institute, noted the benefits for them: '*We chose to invest in Indigo-Clean for our operating room lighting not only because of the proven high antimicrobic rates, but we appreciated the ease of use, and the ability to continuously disinfect our operating rooms without any downtime. That translates into more procedures and more revenue for us*.' [S1]. In 2019, Kenall Lighting announced a partnership with SLD Technology, Inc. to incorporate the technology into a fully-integrated, modular ceiling system that combines the HINS-light disinfection with ventilation, electrical, filtration, ambient light, that is easily installed into operating rooms [S1]. Kenall Lighting *'have a vision for this technology in which it becomes the "standard" light fixture within healthcare institutions worldwide*', and due to the current pandemic *'the opportunities for HINS technology have grown dramatically'* [S2]. In April 2020, in response to the urgent need for lighting in temporary hospitals during the pandemic, Kenall introduced portable Indigo-Clean fixtures which *'provide generous ambient light while safely and continuously killing harmful bacteria, bolstering existing cleaning and infection prevention protocols, and reducing harmful bacteria when used as recommended'* [S8].

Reducing surgical-site infections and improved patient health, resulting in additional cost savings in penalties and expenses for hospitals

Annually, in the USA, approximately 2,000,000 patients suffer from a healthcare-associated infection, and an estimated 90,000 of these patients die. Data published in 2019 demonstrates that use of the *Indigo-Clean* environmental decontamination lighting system during surgical procedures resulted in a 73% reduction in surgical-site infections [S9]**.** This publication by US clinicians is major independent validation of the technologies ability to not only reduce environmental contamination, but to significantly reduce surgical site infections during its use. '*The significance of this…finding should not be underestimated, as there are exceedingly few decontamination/disinfection technologies that have been able to demonstrate clinically-proven reduction in rates of infection as opposed to mere efficacy of decontamination.'* [S6]. Looking specifically at how this impacted the hospital in which the study was conducted, there was '*a reduction of 14 infections in just one year within only 2 rooms saving the hospital approximately 300,000 USD in penalties and excess costs*' [S2]. The technology was also part of a clinical study

at the NHS St Andrew's Centre for Plastic Surgery and Burns, Chelmsford, UK, where it was used as part of a successful infection control bundle for control of multi-drug resistant infections [**S7**]. Since the study, the systems have been retained and '*they have continued to provide infection control support for our patients'* [**S10**]. Based on the reductions in infection rate achieved by use of the installed lighting system, and the published costs associated with SSIs, Indigo-Clean estimates that use of the antimicrobial lighting systems will result in each hospital facility saving USD197,400 (11-2020) per operating room per year [**S1**].

This technology is also supporting health beyond hospitals. Kenall's Indigo-Clean products have application in the wider healthcare field, and have been used in nurse's facilities in schools and therapy/rehab centres and in athletic training facilities: '*We chose to install the Indigo-Clean Technology in our athletic training room and adjacent areas. These high-traffic areas are an opportune environment for bacteria to hide.*' Co-Head Coach, University of Utah, Dumke Gymnastics Center [**S1**]. On a wider scale, Hubbell Lighting's SpectraClean products have been applied to food manufacturing [Text removed for publication] general office environments and health club/athletic venues, where provision of a cleaner environment will provide public health benefits [**S3**].

5. Sources to corroborate the impact

S1 Collated webpages from Kenall Lighting 'Indigo-Clean' product website:

a. Application Case Study: Henderson Hospital https://bit.ly/36Lvp1E
b. Application Case Study: New Century Spine and Outpatient Surgical Institute https://bit.ly/2IQIbDv
c. Indigo-Clean Announces Partnership with SLD Technologies https://bit.ly/35IqBL7
d. Financial Benefits. https://bit.ly/38SZpv7
e. Application Case Study: University of Utah. https://bit.ly/2IOdMGc

S2 Supporting statement from Director of Clinical Affairs, Kenall Lighting, dated 16 May 2020.

S3 Supporting statement from Senior Product Manager, Hubbell Lighting, dated 22 August 2020.

S4 Hubbell Lighting, Inc. Webpage. SpectraClearn Wins Vision Award. https://bit.ly/3rJA8JR

S5 Cision PRWeb Webpage. Kenall Licenses Disinfection Lighting Patents to Pinnacle. 18 May 2020. https://bit.ly/3q8A0TP

S6 Supporting statement from Previous Head of Microbiological Services, NHS Greater Glasgow & Clyde. Current Position: Chief Microbiologist, Hospital South West Jutland, University Hospital of Southern Denmark, received August 2020.

S7 Independent studies demonstrating the effectiveness of HINS light:

a. Rutala *et al.*, (2016) Antimicrobial Activity of a Continuous Visible Light Disinfection System. https://bit.ly/36L7CPj
b. Sandhu *et al.*, (2016) Environmental Decontamination of Medical ICU Suites Using High-Intensity Narrow-Spectrum Light. https://bit.ly/2KluXj5
c. Teare *et al.* (2016). Prevention and control of carbapenemase-producing organisms at a regional burns centre. *Journal of Hospital Infection*, 93(2); p141-144. DOI: 10.1016/j.jhin.2016.03.002

S8 LEDs Magazine. New Portable Lighting for Temporary Hospitals Kills Bacteria Safely & Continuously. 3 April 2020. https://bit.ly/36F9yIY

S9 Murrell *et al.* (2019). Influence of a visible-light continuous environmental disinfection system on microbial contamination and surgical site infections in an orthopedic operating room. *American Journal of Infection Control*; 47:804-810. DOI: 10.1016/j.ajic.2018.12.002.

S10 Supporting statement from Consultant Plastic and Reconstructive Surgeon, St Andrew's Burns and Plastics Centre, Mid Essex Hospital Services NHS Trust, received August 2020.