Continuous Environmental Disinfection for Surgical Suites

Don’t Just Clean... Indigo-Clean™

Designed and manufactured in the USA
A Revolutionary New Technology to Continuously Disinfect the Environment

Indigo-Clean, a continuous disinfection technology, is patented and proven to kill harmful bacteria linked to hospital acquired infections (HAIs). Using a combination of 405nm Indigo and White LEDs, Indigo-Clean emits narrow spectrum light that kills bacteria while providing ambient illumination for the space.

Unlike UV light, Indigo-Clean uses safe, visible light to automatically and continuously kill harmful bacteria in the air, and on hard and soft surfaces.
What is Indigo-Clean?

The Problem:
Current environmental disinfection methods are applied at discrete moments in time (i.e. episodically). The results of achieving a "clean room" are short-lived as harmful bacteria re-populate the space.

The Solution:
Indigo-Clean offers a solution that continuously disinfects the environment and bolsters your current infection prevention efforts.

Break the Chain of Infection by Raising Your Standard of Clean

The healthcare environment is a reservoir for pathogens. Indigo-Clean breaks the chain of infection between the environment and an unsuspecting host.

Indigo-Clean, a patented continuous environmental disinfection technology, uses visible light to safely, automatically and continuously kill harmful bacteria, 24/7, in the air and on hard and soft surfaces.

Indigo-Clean bolsters current infection prevention methods and is proven to kill a wide range of harmful bacteria.

Don’t Just Clean... Indigo-Clean™

What Makes Indigo-Clean Unique?

- Continuous environmental disinfection kills bacteria missed during routine cleaning
- Indigo-Clean is NOT UV light... it uses safe 405nm visible light
- Automatically kills bacteria reducing risk of human error
- Kills bacteria in the air, and on hard and soft surfaces
- No special or additional training required
- Light is safe for patients and caregivers
- Products can be applied to balance cost effectiveness and visual preference for your application
- Different modes are used to increase disinfection
How Does Indigo-Clean Work?

How It Works*:

• The 405nm emitted from Indigo-Clean reflects off of walls and surfaces, penetrating harmful micro-organisms
• The 405nm light targets and excites naturally occurring molecules within the bacteria called porphyrins, to produce intra-cellular Reactive Oxygen Species (ROS).
• Similar to bleach, these ROS create an oxidative environment within the organism, inactivating it and preventing it from re-populating the space.

Visible light spectrum showing the active element in Indigo-Clean™

405 nanometers: Peak germicidal activity via photoexcitation of porphyrin molecules

Inactivation of bacteria via visible light absorption

Non-Exposed

Exposed to Indigo-Clean™

ESKAPE Pathogens:
- Enterococcus faecalis
- Staphylococcal Aureus (including MRSA)\textsuperscript{1}
- Klebsiella pneumoniae
- Acinetobacter baumannii
- Pseudomonas aeruginosa
- Enterobacter species

As well as a range of other organisms:
- Aspergillus niger
- E.coli
- Salmonella enteritidis


Clinical testing has shown Indigo-Clean can achieve a continuous 70+ percent reduction of harmful bacteria in the environment. At the same time, recently published studies show that improved cleaning can reduce HAI rates for certain organisms.\textsuperscript{1}

These results, combined with the additional cost per patient due to HAI, suggest that preventing even a single infection would create a positive ROI and drive down costs for healthcare providers.

\textsuperscript{1} Alfa MJ et. al. “Use of a daily disinfectant cleaner instead of a daily cleaner reduced hospital-acquired infection rates”, Am J Infect Control 2015;43:141-146
Indigo-Clean™ Clinical Partnership Results:
Proven Technology Featured at The Medical College of Wisconsin, Froedtert Hospital

Indigo-Clean is currently being evaluated by several institutions across the U.S. including Froedtert & the Medical College of Wisconsin Froedtert Hospital in Milwaukee, WI.

Recently completed studies at the Hospital involved a 450 sq.ft. waiting area in the Gastroenterology (GI) Diagnostic clinic. This allowed the team to evaluate the level of disinfection across a large, clinically relevant area that was difficult to keep continuously clean due to the large number of patients entering and exiting over the course of the day. The results from this study showed a 70%+ continuous reduction of S. aureus throughout the area and were consistent with those from the University of Strathclyde conducted at the Glasgow Royal Infirmary (Glasgow, Scotland).2,3,4

“In this phase of the trial where the lighting deployment was optimized across the room, we were able to improve the bioburden reduction to more than 70%,” said Dr. Nathan Ledeboer, Associate Professor of Pathology at the Medical College of Wisconsin.


Kenall Partners with the University of Strathclyde to Create Indigo-Clean

Kenall proudly partners with the University of Strathclyde’s Robertson Trust Laboratory for Electronic Sterilisation Technologies (ROLEST) to create Indigo-Clean. This technology is a part of the university’s long history of disinfection science dating back to the 1800’s. Kenall has the exclusive North American patent rights to create Narrow Spectrum (HINS) lights proven to kill a wide range of bacteria that are linked to HAI’s.

Professor Scott MacGregor, Vice-Principal at Strathclyde, developed the HINS-light technology with fellow Strathclyde researchers Professor John Anderson, Dr. Michelle Maclean and Professor Gerry Woolsey.

Professor MacGregor said, “Our partnership with Kenall in the United States is an exciting new chapter which will see this innovative technology become a commercially available product. We chose Kenall because of their extensive experience in providing lighting for the most challenging healthcare environments where infection prevention is a key consideration.”

History of Academic Research and Investment in Visible Light Disinfection

| Year | Event Type | Years
|------|------------|-------|
| 2002 | Investment in ROLEST from the Robertson Trust | 2002 – 2004
| 2003 | NHS Research / Medical Charity Funding | 2003 – 2005
| 2006 | Research Funding for other Decontamination Applications | 2006 – 2008
| 2007 | Clinical evaluations started at Glasgow Royal Infirmary | 2007 – 2009
| 2009 | | 2009 – 2011
| 2010 | Indigo-Clean Commercially Available | 2010 – 2014
| 2011 | | 2011 – 2013
| 2013 | | 2013 – 2014
Applications and Configurations

Indigo-Clean can be operated in two different modes:

**White Disinfection Mode**
Provides comfort and visual acuity. Use during procedures and cleaning.

**Indigo Disinfection Mode**
Typically used when room is not in use

**Switching:**
- Manual via wall switch (consult factory for wiring diagram)
- Automatic via control solution (consult factory)

Indigo disinfection mode for increased continuous environmental disinfection

Indigo-Clean (MedMaster M4SEDIC) supports the surgical team, the patient and the surgical suite’s critical environment:

- Continuous environmental disinfection
- Sealed for infection prevention
- IP65 listed per IEC 60598 ensures ingress protection against dust and water
- NSF2 listing supports ease of cleanability
- Antimicrobial finish
- Certified to MIL STD 461F addresses EMI/RFI issues
- High performance LED delivers high visual acuity
- Universal grid-flange mounting provides field installation flexibility
- Lens uniformity reduces glare
- Standard dimming offers flexible light levels

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Indigo-Clean (MedMaster™ M4SEDIC*)

The MedMaster M4SEDIC is a top rated luminaire that delivers superior lumen and color maintenance over time and addresses the current demands for infection prevention, functional reliability and sensitivity to surrounding medical equipment. From concept to completion, every element of the MedMaster M4SEDIC LED luminaire has been carefully engineered to present the ideal solution for today’s surgical suite.

Sealed Housing
- One-piece, seam welded housing construction
- Smooth exterior with gasketed doorframe for cleanability
- Universal housing for both flange and grid installation
- Antimicrobial finish
- Grounded wireway reduces radiated emissions

Internal Components
- Dual Stage Power Factor Correction Driver eliminates flicker
- Standard 0-10V Dimming
- Proprietary mode controller with low voltage input

LED Module Array with Indigo-Clean Technology
- Serviceable white LED array
- High quality ceramic composite mid-power LEDs and high-power 405nm Indigo LEDs
- 80 and 90 CRI

Lens Door/Frame
- Diffused, high-efficiency lens for reduced glare and uniformity
- Smooth exterior doorframe is sealed and gasketed to support infection prevention

Flexibility with Universal Grid/Flange Installation

Flange mounting applications use four adjustable swing-out brackets for fast installation, and ensures a tight seal to the ceiling surface.

Fully sealed housing with closed cell gasketing ensures ingress protection against contaminants. The luminaire is ETL Certified IP65 per IEC 60598

Compact 4” depth housing design allows for reduced plenum intrusion

Inset door provides a flush mount to the ceiling

*Patents Pending
## Performance Data and Safety

<table>
<thead>
<tr>
<th>Size</th>
<th>Mode</th>
<th>Lamp Code</th>
<th>Delivered Lumens (lm)</th>
<th>Input Power (W)</th>
<th>Color Rendering</th>
<th>TM-30 Color Quality</th>
<th>Est. L70 LED Life (Hrs)</th>
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</thead>
<tbody>
<tr>
<td>2'×4'</td>
<td>White Disinfection Mode</td>
<td>150I/100L-40K8</td>
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<td>177</td>
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<td>150I/100L-40K9</td>
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<tr>
<td></td>
<td></td>
<td>75I/50L-50K9</td>
<td>5,811</td>
<td>86</td>
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<td>1'×4'</td>
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### Safety Testing

Indigo-Clean has been evaluated against existing visible light safety standards.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Testing Method</th>
<th>Results</th>
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<tr>
<td>IEC 62471/62778</td>
<td>Independent 3rd Party Laboratory</td>
<td>Pass (Exempt)</td>
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<tr>
<td>ACGIH</td>
<td>Self-Assessment</td>
<td>Pass</td>
</tr>
<tr>
<td>ICNIRP</td>
<td>Self-Assessment</td>
<td>Pass</td>
</tr>
</tbody>
</table>

3. American Conference of Governmental Industrial Hygienists – Threshold Limit Values (TLVs) & Biological Exposure Indices Signature Publications, Cincinnati, 2007
4. International Commission on Non-Ionizing Radiation Protection – Guidelines on limits of exposure to optical radiation from 0.38 to 3.9 nm. Health Physics 73; 539-555; 1997
Create High Visual Acuity while Disinfecting the Environment

Calculations Based on: 26' × 25' Area, 9' Ceiling Height, 90/60/20 Room Reflectance, .80 LLF Fluorescent, .90 LLF LED

Current Lighting Layout

M2 – Fluorescent Lamp (6) F32T8 (10-2'×4') ~or~
Catalog No. M2SEFI24-632-EB-2-120-PAF-2H-MLP-1

M4 – 100W LED (10 – 2'×4')
Catalog No. M4SEDI24-100L40K-DCC-DV-2F-2H-SYM

Indigo-Clean™ Lighting Layout

M4SEDIC – 100W LED (10 – 2'×4')
Catalog No. M4SEDIC24-150/100L40K-DCC-277V-2F-2H-SYM

Average Illuminance

<table>
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<tr>
<th>ZONE 1</th>
<th>ZONE 2</th>
<th>ZONE 3</th>
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</thead>
<tbody>
<tr>
<td>270 fc</td>
<td>209 fc</td>
<td>61 fc</td>
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</table>

System Power Consumption

1890W

Average Illuminance

<table>
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<tr>
<th>ZONE 1</th>
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<tbody>
<tr>
<td>317 fc</td>
<td>232 fc</td>
<td>84 fc</td>
</tr>
</tbody>
</table>

System Power Consumption

1150W

System Power Consumption:
- White Disinfection Mode 1750W
- Indigo Disinfection Mode 1650W

625 Sq. Ft.
Fixtures designed for use in healthcare applications must satisfy a large number of demanding lighting and environmental requirements. Applicable listings are shown below. For the most up-to-date information, please refer to individual product specification sheets at www.kenall.com.

**Listings & Certifications**

**NSF2** — An NSF2 Listing denotes that the luminaire has been evaluated for corrosion resistance, cleanability and the ability of exposed material to withstand normal wear. This supports the infection control standards established by healthcare facilities as it indicates that the luminaire is easy to sanitize.

**IP65** — UL Certified IP65 per IEC 60598 ensures that the enclosure is dust-tight and protected against jet streams of water from any direction without any harmful effects.

**MIL STD 461F** — Military Standards testing measurements cover both radiated and conducted electromagnetic emissions in addition to maximum allowable amounts of emitted energy based on both frequency range and field strength. Luminaires meeting MIL STD 461F pose the lowest possible likelihood of causing EMI-related issues.

**ISO 5** — Suitable for ISO 5, Class 100 Rated Rooms (FED-STD 209E). Measures the number of particles equal to or greater than 0.5 mm in one cubic foot of air. The measurement must not exceed specified particle limits in order for the space to be considered a controlled ‘clean room’ environment.

**UL/CUL Listed** — The UL symbol signifies that Underwriter’s Laboratory (UL) has determined that a manufacturer has demonstrated the ability to produce a product complying with UL’s requirements with respect to specific risk, performance under specific conditions, compliance with regulatory codes and specified standards, or any other conditions as determined by UL.

**ETL** — A product bearing the ETL Listed Mark is determined to have met the minimum requirements of prescribed product safety standards as certified by a Nationally Recognized Testing Laboratory (NTRL). The mark also indicates that the manufacturer’s production site conforms to a range of compliance measures and is subject to periodic follow-up inspections to verify continued conformance.

**ADA Compliant** — Although ADA is not specific to lighting, it does impact fixture design by creating standards for wall sconce projection space and hanging light clearance. Section 4.4 of the ADA states that "objects projecting from walls with their leading edges between 27” and 80” above the finished floor shall protrude no more than 4” into walks, halls, corridors, passageways or aisles."

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**Warranties**

On behalf of our valued customers, Kenall promises to stand behind our medical-grade luminaires. Our commitment to excellence enables us to offer a variety of product warranties including the Kenall exclusive 5-year LED Warranty.

**LED 5-year Warranty**

Kenall’s LED products are warranted by Kenall to be free of defects in workmanship and materials for a period of one (1) year from the date of invoice. Kenall warrants LED lamps and internal power regulation components for a period of five (5) years from the date of invoice against defects in materials and workmanship that result in a fixture depreciation of 30% or greater. Lumen depreciation is compared to the published lumen output of the product on the date of manufacture per IESNA LM-79 reporting procedures. Normal accumulation of particulates on the optical surfaces shall not be factored into the lumen depreciation. Kenall reserves the right to issue credit, repair, or replace the defective merchandise, at its discretion, upon notification and confirmation by its local representative of the defect. Kenall also reserves the right to test and examine the defective product if the defect is questionable, and to deny the warranty herein for any product altered, improperly installed, or installed in applications for which it is not intended. This includes operation in ambient temperatures above stated limits for any length of time. Failure by electrical surge shall not be covered under warranty.

Kenall assumes no responsibility for labor or freight costs incurred in connection with the installation, removal, or replacement of products determined to be defective or any other consequential or incidental damages arising from the use of the product. Kenall’s entire liability on any claim of loss or damage resulting from a defective product is limited to the replacement price of the product.
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