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WHITEPAPER

Three Things Medical Device Designers Need to Know About UVC LEDs

The global infection control market is projected to reach $22 billion by 2022 with disinfection products, which would include UVC devices, representing the largest growth segment. Market growth is propelled by an expanding long lived aging population, ever present Healthcare Associated Infections (HAIs) and the rise in antibiotic resistant pathogens. Acute care facilities remain the largest and fastest growing segment.

Though relatively new compared to other UVC technologies, UVC LEDs offer medical equipment designers an exciting new way to develop hand-held or portable disinfection devices to combat HAIs in a wide range of healthcare applications. Importantly, the design and operating flexibility of UVC LEDs means that these devices could be used during routine daily patient management and not limited to empty terminal room events.

Incorporating UVC LEDs into existing hygiene protocols can greatly enhance HAI prevention—both in healthcare facilities and at home. As a medical device designer, here are the three things to know before you start.

NO. 1

UVC is a proven disinfection method

Ultraviolet (UV) technologies were first introduced in 1904 and since then have proven their ability to effectively disinfect surface, airborne and waterborne pathogens. Starting in the 1950s+, following breakthroughs in personal antibiotics, the use of these devices waned. However, with the rise of antibiotic resistant bacteria and the increased incidence and cost associated with HAI this technology has once again come to the fore.

According to the Centers for Disease Control (CDC), one in 25 people visiting an acute care hospital, ambulatory care ward, outpatient facility, or long term care facility will contract a Healthcare Acquired Infection (HAI).

	2012		2013		2014		AVERAGE HAI/FACILITY			
	FACILITIES REPORTING	OBSERVED HAI	FACILITIES REPORTING	OBSERVED HAI	FACILITIES REPORTING	OBSERVED HAI	2012	2013	2014	TREND
CLABS1	3,516	17,710	3,578	17,799	3,655	17,758	5.04	4.97	4.86	Î
CAUTI	3,597	32,504	3,640	34,627	3,791	35,760	9.04	9.51	9.43	È
Hospital-onset MRSA bacteremia	1,175	2,618	3,827	9,471	3,949	9,230	2.23	2.47	2.34	è
Hospital-onset C. difficile	1,681	40,491	3,924	99,550	3,994	101,074	24.09	25.37	25.31	ì
SSI, Combined SCIP Procedures	3,554	13,770	3,581	14,951	3,618	15,927	3.87	4.18	4.40	ì
		107,093		176,398		179,749				

Here's how it works:

HAIs are caused by a range of common pathogens. Each has a unique radiation absorption "fingerprint," meaning they absorb UV photons differently at different wavelengths based on their physical biology. Absorbing this UVC energy inactivates the pathogen's R/DNA, rendering it unable to reproduce and thus harmless.

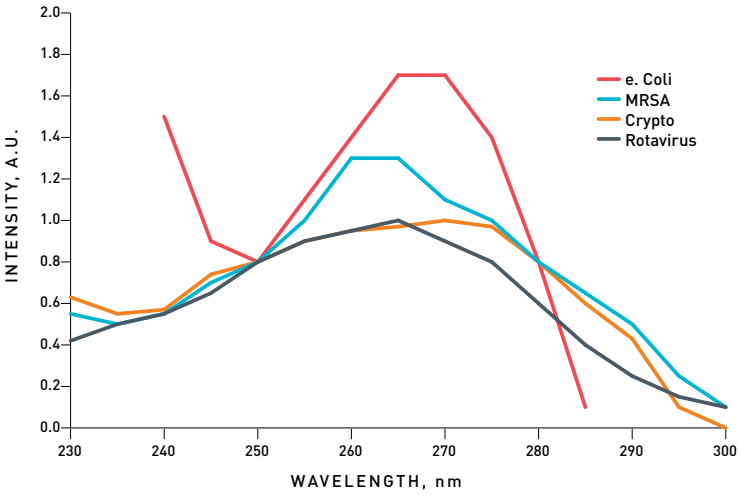
Unlike traditional UV sources, the far more compact UVC LEDs can be produced at specific deep UC wavelengths which match the peak absorption capabilities of targeted microbes, resulting in a much more effective disinfection—ideal for quick disinfection of intricate surgical tools, portable and/or countertop devices, or manual point of care sites.

While individual pathogen absorb radiant energy at different wavelengths, the range between 250-280nm, often referred to as the Germicidal Range, is regarded as the most effective in terms of R/DNA inactivation. LEDs are a polychromatic UVC light source, that is LEDS have a continual emission over a range of wavelengths typically between 250 and 280nm. Based on the microbe spectrum shownin graph below, UVC LED device which has a peak wavelength between 260nm and 270nm would offer the most effective approach, with a 265 nm peak (plus/minus 5 nm) being a sweet spot in terms of maximizing performance across multiple pathogens.

For example, here's the spectral sensitivity for some of the most recognizable pathogens:

> E.Coli and MRSA, which are prokarayotic bacteria
> Crypto, which is Eukaryotic Protozoan
> Rotavirus, which is obviously a virus

FIGURE 1



NO. 2

UVC LEDs offer unmatched design flexibility

We believe hand-held devices equipped with UVC LEDs will soon be used to address a range of HAI-related disinfection issues. That's because in terms of design flexibility, UVC LEDs offer major advantages over other technologies:

> LEDs are powerful yet tiny. At 3.5 mm x 3.5 mm you can put five side by side on a penny and still have room to spare. Their power requirements are equally small, making LEDs ideal for portable, battery powered disinfection devices. For example, an 8 second disinfection dose for a catheter hub with a device equipped with an iPhone battery could provide up to 1,500 doses on a single charge.

> Since no warm-up is required, LEDs are ideal for applications where the radiation must be switched on and off rapidly. As a semiconductor device, an LED can be cycled on/off thousands and thousands of times at any interval—from instantaneous to constantly on. And unlike UV lamp technologies, an LED's service life is long because it's not degraded by frequent on/off cycling.

> LEDs can be placed close to a target surface. While traditional UV sources emit heat and light in a 360-degree pattern around the target, LEDs emit radiant energy in a single direction and shed heat in the other. LED waste heat is removed by thermal conduction from the back of the device—a major advantage in heat sensitive healthcare applications.

> LEDs make it possible to point the UV light exactly where you need it. Designers can use focusing optics or light channels to amplify UV intensity, or transmit disinfection radiance into very tight or hard to reach locations.

NO. 3

UVC LEDs are not as expensive as you think

Like most technologies, early UVC LEDs were expensive.
But now they're mass produced, so LEDs priced at $30 to $40 per milliwatt 18 to 24 months ago now cost one tenth the price and can reach a low as $1 per milliwatt.

BUSINESS CASE:

Examples of how UVC LEDs can help reduce HAIs

Most point of care disinfection applications currently involve manual scrubbing with alcohol. UVC LED devices can automate a range of manual hygiene protocols, and also disinfect high touch devices like iPads and stethoscopes as clinicians move about the facility.

Hand-held or portable devices would also make it easy to log the disinfection activity and even tag it to a specific patient visit. While data logging is not required, it would give infection control staff invaluable data to monitor and reduce HAIs.

Here are some examples of how UVC LEDs can help reduce HAIs.

CLABSI

While the CDC reported a 50 percent decrease in Central Line Associated Blood Stream Infections (CLABSI) between 2008 and 2014, recent improvements have been less dramatic, prompting a review of where steps can be added or enhanced.

It became evident that:

> Disinfecting the hub is a 100% manual process;

> No verifiable means of compliance exists;

> It takes up to 60 seconds when executed properly;

Commonly referred to as scrub the hub, the process relies on friction and time to be effective. If either step is skipped or short changed due to human error, harmful bacteria can be left behind.

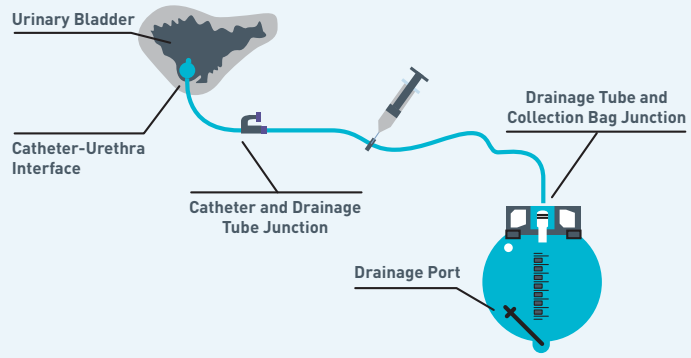
A handheld LED device attached to an infuser could be aimed at the hub and in less than 10 seconds deliver a UVC dose capable of a 6-log reduction of common pathogens like MRSA and c. difficile. The result: a consistent disinfection dose is applied to a common site of pathogen transport in far less time and logged for reporting or analysis.

CATHETER TRACT INFCTIONS

Catheter Associated Urinary Tract infections, or CA-UTIs, are the most common type of nosocomial infection. CA-UTIs account for up to 40 percent of HAIs and have seen little improvement in recent years.

BUSINESS CASE continued

Roughly 15-25% of hospitalized patients receive urinary catheters during their stay. Since 2008 Medicaid has classified these HAIs as preventable and no longer accepts charges for treatment. With high incidence rates and multiple access points for bacteria to enter the body, proper disinfection—especially at home—could bring a paradigm shift in patient care. Using a simple LED-equipped hand held device to administer a quantified disinfection dosage would help prevent intraluminal contamination.



CLOSTRIDIUM DIFFICILE (C-DIFF)

One of the highest reported HAIs is clostridium difficile, or C-Diff. C-Diff. is a remarkably resilient pathogen that can survive for weeks or months if left untreated and is easily transported into the hospital and from room to room on clothing and high contact devices like pagers, laptops, mobile phones, stethoscopes, workstations and diagnostic tools.

Device surfaces are currently cleaned with disinfection wipes that contain a high amount of Isopropyl alcohol, which has an offensive odor, dries out the skin, damages equipment and voids warranties.

A quantified and trackable UVC disinfection dose could be applied using portable or countertop devices, or integrated directly into portable work stations and diagnostic equipment—to disinfect surfaces as hospital staff move between patient rooms.

Summary

The cost of quantifiable disinfection—a determined dose of disinfection that you know is delivered correctly and can be tracked—is miniscule compared to the costs associated with most HAIs. That's why we believe UVC LEDs can and will be used to automate and improve manual tasks in the industry's current hygiene protocol; disinfect high- touch or at-risk devices; and, in instances where an LED device replaces a wipe, log the disinfection activity for reporting and analysis.

While data logging is not required, the advantages are undeniable. Moving from an unverifiable and unquantifiable task—or simply enhancing current protocols with defined disinfection doses—provides a healthcare provider's infection control staff a way to confidently and quantifiably monitor and reduce HAI's. This, in turn, will result in improved patient outcomes and greater clinician safety.

WE INVITE YOU TO LEARN MORE ABOUT OUR UVC LEDs.

Crystal IS™

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