



WHITE PAPER

3B™ Lumin Bullet®

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Dr. Lehman received his Bachelor's degree in Physics (along with a minor in Mathematics) from Purdue University in 2012. He went on to obtain his PhD in Theoretical High Energy Physics from the University of Notre Dame in 2017. His PhD work was primarily on the mathematical problem of counting operators in effective field theories.

Dr. Williams received her Bachelor's in Biomedical Science and a Doctorate degrees in microbiology from the University of Melbourne. Her concentration is on infectious disease and use of ultraviolet light in disinfection and sterilization processes, technology and sterility assurance.

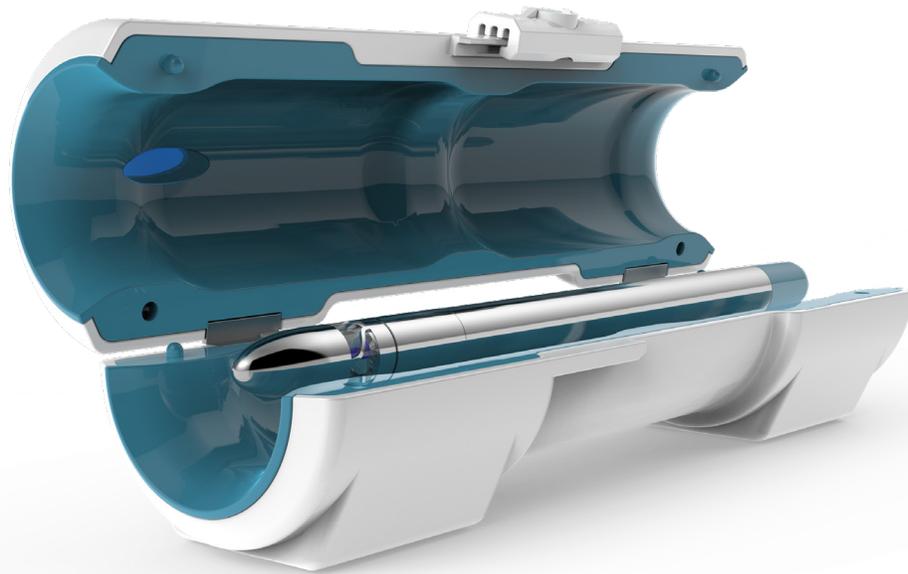


TABLE OF CONTENTS

Part I: Introduction
Irradiance Calculation
Dosage Calculation

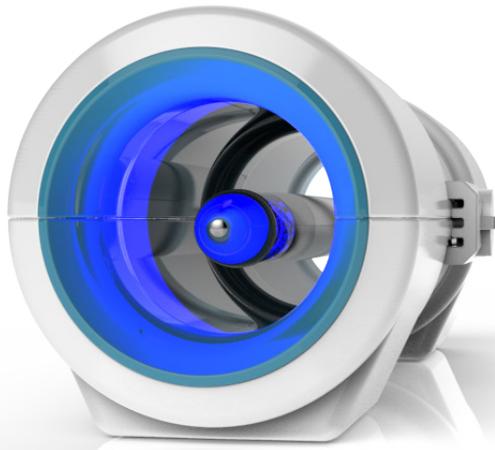
Part 2: Microbiology

Electromagnetic radiation is present all around us in a much larger range of wavelengths than our human eyes can detect. The electromagnetic spectrum ranges from wavelengths of below 1 picometer (gamma rays) to above 1 kilometer (radio waves) and beyond. We humans can only detect wavelengths with our eyes from roughly 400 nanometers to 700 nanometers, corresponding to the visible spectrum.

The wavelength of light has an inverse relationship with the energy of the light: Einstein in the early 1900s proposed that light is made up of photons, and each photon has an energy $E=hc\lambda$, a relationship that has since been experimentally verified. Here h is a constant known as Planck's constant, λ is the wavelength of the light (measured in meters), and $c=3.00 \times 10^8$ m/s is the speed of light. Photons with more energy (shorter wavelengths) can potentially cause more damage to biological

systems.

The ultraviolet part of the electromagnetic spectrum corresponds to light with wavelengths between 100 and 400 nm, too short to be seen by the human eye. Ultraviolet radiation has long been used in medical applications to kill biological microorganisms, such as viruses and bacteria. The Lumin Bullet contains an LED (light-emitting diode) that produces light in the ultraviolet spectrum. Specifically, the peak emission wavelength is 275 nm, with a power output of 20 mW. Directly across from the LED is a polished aluminum reflective cone, that sends more of the LED light towards the outer diameter of the Bullet, and thus towards the inside of the CPAP hose, increasing the effective intensity at the surface of the hose.



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Irradiance Calculation

A source of electromagnetic radiation such as the LED inside the Bullet can in some cases be treated as a point source for the purpose of calculating the irradiance at various distances. This approximation tends to work well when the distance between the source and the detector is greater than five times the largest dimension of the source [1]. For the Bullet, the distance from source to detector (inner surface of a CPAP hose) ranges from about 0.65 cm to 1.13 cm. The UV-emitting LED itself is 3.5 mm square, indicating that the point-source approximation is not sufficient in this case.

Since a square emitting geometry is complicated to deal with theoretically, to get an estimate of the irradiance of the Bullet we will treat the LED as a circle with the same area, hence a radius of 1.97 mm. The fraction of total energy leaving the LED surface that arrives at a patch of the CPAP tube surrounding the Bullet can be calculated via a configuration factor. In this case, the relevant factor is [2]:

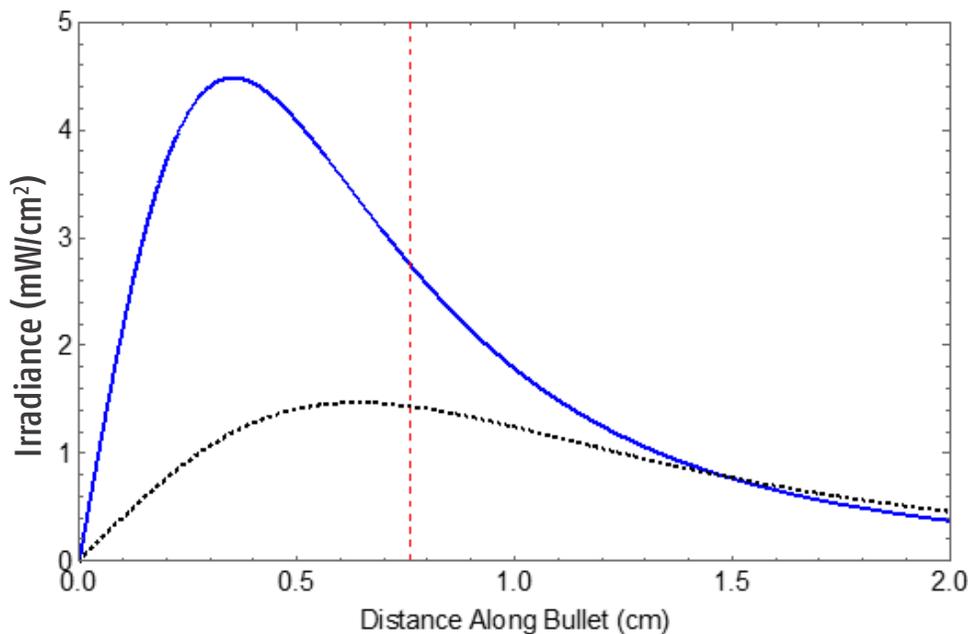
$$\frac{Z}{2} \left[\frac{X}{(X^2 - 4R^2)^{1/2}} - 1 \right]$$

where $X = 1 + Z^2 + R^2$, $Z = z/r_p$, $R = r_2/r_p$, r_1 is the radius of the cylinder (CPAP tube), r_2 is the radius of the source (LED bulb), and z is the perpendicular distance (along the centerline of the Bullet) from the

source to the patch on the tube.

Using the above configuration factor, we can calculate the irradiance for two different distances (values of r_1). The first is $r_1 = 0.65$ cm, and corresponds to the closest distance that the CPAP tube can be from the LED: the radius of the Bullet. The second is $r_1 = 1.13$ cm, and corresponds to the farthest possible distance from the inner surface of the CPAP tube to the LED. The actual irradiance in practice will be somewhere in between these two values. The 1 mm thick doped fused quartz sleeves used in the Bullet transmit 90% of UVC light, so the final values were multiplied by 0.9 in the plot below in order to account for transmission through the quartz.

The irradiance at these two radii are calculated as a function of z (the perpendicular distance along the Bullet) in the plot below. The solid blue line is the closest radius (0.65 cm), and the dotted black line is the farthest radius (1.13 cm). The vertical red dashed line corresponds to the geometrical constraint of reaching the end of the transparent quartz tube (at a value of $z = 0.76$ cm). In actual tests, significant irradiance values are seen beyond this cutoff point, which will be addressed in the discussion following the plot.



In tests performed by 3B™ Medical, significant irradiance values were observed beyond the geometric cutoff point.

The results shown in the plot indicate that there is a distance of about 0.5 cm along the CPAP tube where there is an irradiance of at least 1 mW/cm², with the potential for a much higher irradiance depending on the relative orientation of the Bullet and the tube.

In tests performed by 3B™ Medical, significant irradiance values were observed beyond the geometric cutoff point (for example 1.2 mW/cm² at the “far” radius value). This is because the above calculation gives a very conservative estimate of the Bullet’s irradiance; it has ignored the

polished aluminum reflective cone. Aluminum has a high reflectance in UV wavelengths [3], so the cone increases the observed irradiance and also increases the geometric length (exposure window) along which the inner surface of the CPAP tube is exposed to the UV radiation. The result is to approximately double the exposure window at the “far” radius value: there is an irradiance of 1 mW/cm² for a distance of about 1.0 cm along the CPAP tube.

¹ J. Murdoch. Illumination Engineering – From Edison’s Lamp to the Laser. Collier Macmillan, New York, 1985

² Buschman, Albert Jr. and Pittman, Claud M. “Configuration factors for exchange of radiant energy between axisymmetrical sections of cylinders, cones, and hemispheres and their bases,” NASA TN D-944. 1961.

³ Michael Bass, Guifang Li and Eric Van Stryland (eds). Handbook of Optics, Volume IV: Optical Properties of Materials, Nonlinear Optics, Quantum Optics. Third Edition. McGraw Hill. 2010.

Dosage Calculation

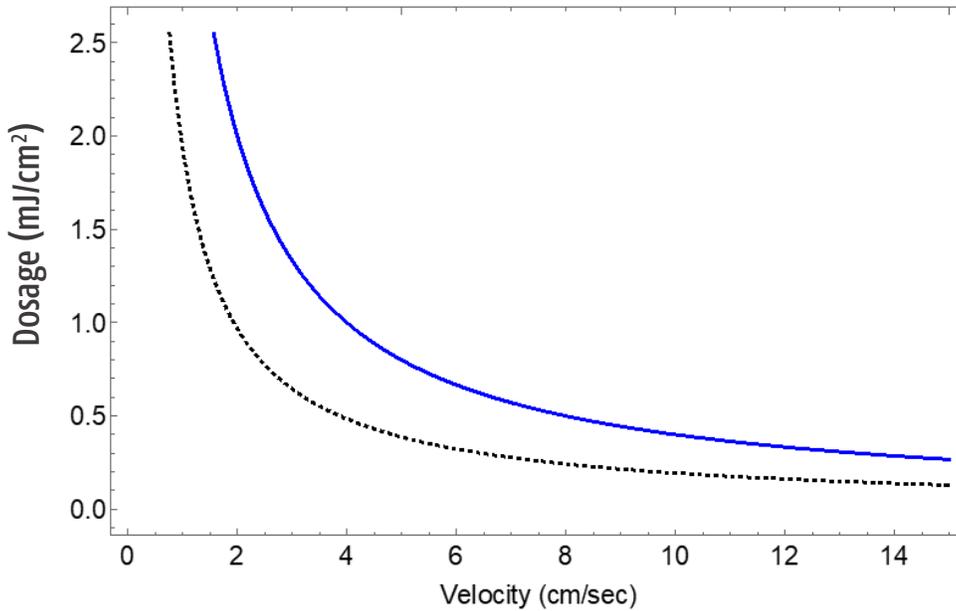
Calculating the dosage is more directly useful for biomedical applications than calculating the irradiance. Since the application of the Bullet involves moving the device along a CPAP tube, we will present the dosage as a function of the velocity between the Bullet and the tube. Moving faster means a lower dosage, and slowing down results in a higher dosage.

The dosage will be calculated for the “near” and “far” radii shown in the irradiance plot above. If the radii r_1 and r_2 are given, then the irradiance is just a function of z (the perpendicular distance along the Bullet): $I(z)$. The dosage is then given by

$$dosage = \int_0^{1.5 \text{ cm}} \frac{I(z)}{v} dz,$$

where v is the velocity measured in centimeters per second. The integral is only taken out to $z=1.5$ cm, because a geometrical constraint is reached near here even with the reflection from the aluminum cone considered, and also because the irradiance decays quickly after this point.

The irradiance $I(z)$ is a complex function of z , but the integral is easily done numerically with a mathematical software program such as Mathematica. The results of the calculation are shown in the following plot:



The upper, blue curve is the “near” radius, corresponding to the inner CPAP tube surface being directly adjacent to the outer quartz tube on the Bullet, and the lower, dashed black curve is the “far” radius, corresponding to the farthest possible distance from the Bullet LED to the inner surface of the CPAP tube.

The above curves correspond to dosages for a single “pass” of the Bullet along the CPAP tube. If the Bullet is taken down and back the tube at a given velocity, then the dosages should be multiplied by a factor of two, and by an additional factor of two for each down and back pass.

Conclusion:

Because the OD of the Lumin Bullet is 13 mm, and the ID of a standard CPAP hose is 19mm, the distance from light source to inside wall of hose is approximately 3mm. At this distance, the strength of UVC output would

be on order of 4.0 mW/cm², or well beyond the necessary kill dose to reach a Log 2 reduction. Biological testing by Mesa Labs confirmed this kill dose and supports efficacy claims.



Continuous Positive Airways Pressure (CPAP) is the standard treatment for Obstructive Sleep Apnea (OSA). A CPAP machine delivers a continuous stream of air to the patient’s airway to splint open the airway and prevent collapse. Regular cleaning and disinfection of the machine is recommended to prevent the growth of microorganisms. Without regular cleaning and disinfection, excess moisture that sits in the tubing or humidifier is at risk of being colonized by bacteria or fungi.

The cleaning recommendations for CPAP users are to wash the mask and empty a humidifier daily, and to bathe the mask and tubing weekly in warm water for 5 minutes with ammonium-free dish detergent⁴. The CPAP tubing, or hose, carries warm air from the therapy device to the mask. It is more difficult to clean the inside surface of the hose than the mask, but without regular disinfection, a layer of microbial growth forms on the inside surface. A recent study involving 66 people diagnosed with OSA who are being treated with CPAP found that only 16.67% (11/66) claim to clean the hose of their apparatus⁵.

Multiple studies have confirmed that both bacteria and fungi

frequently colonize the inside surface of the hose⁵⁻⁷. The most commonly found and abundant bacterium include species of *Staphylococcus*^{6,7}. One study determined bacterial loads of *S. epidermidis*, *S. hominis* and *S. haemolyticus* to be within the range 5.0 – 8.6 x 10³ colony forming units (CFU)/mL, and a number of other vegetative bacteria and yeast species such as *Candida* spp. in smaller populations⁷. Interestingly, the microbial load of a single bacterial species was found to be statistically higher on the inside of the hose than on the mask, possibly due to more frequent cleaning of the mask⁷.

The Lumin Bullet uses a germicidal UV-C light to disinfect the CPAP hose. UV-C light transfers electromagnetic waves to a microbe’s genetic material (DNA or RNA), damaging it and interfering with the cell’s ability to reproduce⁸. The effectiveness of UV-C disinfection is based on both the radiation dosage as well the DNA content of the microorganism. Therefore, different microorganisms have varying degrees of susceptibility to UV-C radiation and require different dosages to achieve a specific log reduction in microbial load (Table 1).

Table 1. Susceptibility of Microorganisms to UV-C Radiation

Susceptibility to UV-C Radiation	Microbial Group	Microbial Group Examples
MOST RESISTANT ↓ MOST SUSCEPTIBLE	Fungal Spores	<i>Apergillus</i> spp, <i>Penicillium</i> spp
	Bacterial Spores	<i>Bacillus</i> spp
	Mycobacteria	<i>Mycobacterium</i> spp
	Fungi	<i>Candida</i> spp
	Vegetative Bacteria	<i>Staphylococcus</i> spp, <i>Micrococcus</i> spp, <i>Pseudomonas</i> spp

The microorganisms with the highest susceptibility to UV-C radiation are vegetative bacteria and fungi such as yeast (Table 1)⁹. This includes all those microbes known to colonize CPAP tubing. Some of the most UV resistant organisms are bacterial spores, particularly of *Bacillus* spp⁹. Spores of *B. pumilus* are highly resistant to UV and ionizing radiation and have long been established as gold standard biological indicator for validating radiation disinfection processes¹⁰. Consequently, the dosage of

UV-C radiation required to kill *B. pumilus* is higher than that required to kill the microbes typically found colonizing the CPAP hose (Table 1).

The following experiments aim to determine the dosage of UV-C radiation, defined by the exposure time (sec), required to kill at least 99% of a microbial population under controlled conditions that simulate the conditions created during typical use of the Lumin Bullet.

⁴ Retrieved 10 September 2019 from <https://www.usa.philips.com/c-e/hs/better-sleep-breathing-blog/better-sleep/keeping-it-clean-cpap.html>
⁵ Mercieca. L, Pullicino. R, Camilleri.K et al, “Continuous Positive Airway Pressure: Is it a route for infection in those with Obstructive Sleep Apnoea?”, Sleep Science, 2017, Vol. 10, No. 1.
⁶ Christopher J. Chin, Charles George, Robert Lannigan et al, “Association of CPAP Bacterial Colonization with Chronic Rhinosinusitis”, Journal of Clinical Sleep Medicine, 2013, Vol. 9, No. 8.
⁷ Todea. D.A, Buzoianu. A.D, Vesa. S.C et al, “Assessment of Respiratory Exposure Risk Due to Continuous Positive Airway Pressure Ventilation in Obstructive Sleep Apnea”, Materiale Plastice, 2017, Vol 54, No.2.
⁸ Walter Harm, “Biological effects of ultraviolet radiation”, Cambridge University Press, 1980, pp 23.
⁹ Retrieved 16 September 2019 <https://www.aetaire.com/what-is-uv-and-how-does-it-clean-the-air-in-my-environment/>
¹⁰ World Health Organisation, “5.8 Methods of Sterilization”, The International Pharmacopoeia, 2019, 9th edition.

Methods

To test the effect of the UV-C radiation dosage on the reduction of bacterial populations, the radiation resistant, bacterial spore of *B. pumilus* was selected. Testing the log reduction of this biological indicator defines the minimum kill rate possible in response to the exposure conditions. It stands to reason then that the same exposure conditions will kill microorganisms with a higher susceptibility to UV-C radiation, such as those known to colonize CPAP tubing, at a higher rate than *B. pumilus*.

Steel discs inoculated with a population of 1×10^3 *B. pumilus* spores (Mesa Labs) were exposed to the germicidal UV-C lamp used in the Lumin Bullet for different lengths of times, representing different dosages of radiation. Discs were exposed for either 0.75, 1.0 or 1.25 sec, each in duplicate. A custom device, the spore shuttle, moved the lamp past the

static discs at the appropriate velocities. All tests were performed at a fixed distance of 3.0 mm from the source. The distance was determined from the average distance between the source and the interior surface of a CPAP hose. There is 6.0 mm of clearance on the inside of the hose, so 3.0 mm in each direction.

Exposed samples, together with an unexposed control disc, were sent to a third-party laboratory (Mesa Labs) for population assay tests. Population assays were carried out by Mesa Labs according to their standard population assay protocol. Upon receipt in the laboratory, each test sample was diluted by 2×10^{-1} and the control sample diluted by 0.5×10^{-1} then plated on duplicate plates. CFU on all plates were counted after incubation at 30–35°C for 48 hours. The detectable limit for this study was 0.5 CFU/mL.

Results & Discussion

The population assay results showed at least a log 2 reduction of *B. pumilus* spores for all dosages tested, compared to the unexposed control. A kill rate greater than 99% was observed for all test samples, with the exception of 1 of 2 plates at the lowest exposure time (0.75 sec), which showed an estimated 98.70% population reduction compared to the control. Therefore, exposure for 1.0 sec is sufficient to kill more than

99% of *B. pumilus* spores under these conditions. Considering the high resistance of *B. pumilus* to UV-C radiation, these results suggest all other microbes that colonize CPAP hoses will respond to the same dose with a greater population reduction than shown here, due to their higher susceptibility to UV-C.

Sample ID	Exposure time(s)	Population <i>B. Pumilus</i> (cfu)	Reduction %
CN1	0.00	1.16×10^3	00.00
A1	0.75	$1.50 \times 10^{1*}$	98.70
A2	0.75	$2.50 \times 10^{0*}$	>99.00
B1	1.00	<1.00 (ND)	>99.00
C1	1.25	$7.50 \times 10^{0*}$	>99.00
C2	1.25	$2.50 \times 10^{0*}$	>99.00

Many of the population assay results reported here are estimated populations. When plate counts are above 0 but less than 20 CFU there is a tendency for greater variability between duplicate plates, leading to less accurate population calculations. Sample B2 was excluded from the analysis due to unacceptable variability between duplicate plates with

low plate counts. Low plate counts could be avoided by exposing a much higher population (e.g. 1.0×10^6), however the population number tested in this study is in the same order as that expected to colonize a CPAP hose (10^3).

Conclusion

This study shows that a 1.0 sec exposure to the germicidal UV-C lamp used in the Lumin Bullet at the average distance between the lamp and the surface of a CPAP hose during use, is sufficient to kill at least 99% of a *B. pumilus* spore population. Considering the high radiation resistance of *B. pumilus* spores, this study describes the minimum kill rate possible for microorganisms that are susceptible to UV-C radiation, such

as vegetative bacteria and fungi, known to colonize the inside surface of CPAP tubing with one “pass” through the CPAP hose.

A double “pass” through the hose and back will double the dosage tested here and have a cumulative effect on disinfection. Therefore, the Lumin Bullet provides a quick application for daily disinfection of the CPAP hose, to prevent or delay colonization by bacteria and fungi.

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