# Can a Consumer Ultraviolet Disinfection Device be Repurposed for N95 Mask Decontamination during the COVID-19 pandemic?

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# Abstract.

The reuse of N95 masks has been forced on small community-based hospitals, dentists, nursing, and care homes, amongst others, due to the desperate shortage of personal protective equipment globally during the COVID-19 pandemic. The CDC issued guidance on the reuse of N95 masks due to this shortage. However, large scale ultraviolet disinfection equipment would not be practical in these circumstances, we, therefore, investigated the efficacy of a small, mobile, benchtop device with the potential to disinfect N95 masks from SARS-CoV-2 using ultraviolet irradiation. The device tested was the Lumin LM3000 System manufactured by 3B Medical. We found the Lumin LM3000 to be effective against enveloped viruses, including coronavirus, non-enveloped viruses, gram-negative and gram-positive bacteria and spores with reductions greater than 99.9 per cent.


# Introduction;

On the 12th of December 2019, a case of unidentified pneumonia was reported in Wuhan, Hubei Province, People's Republic of China (PRC) [1]. Its clinical characteristics were very similar to those of viral pneumonia. It spread rapidly, and COVID-19 is now causing the worst pandemic for a century.

As of the 28th of July 2020, global deaths from the SARS-CoV-2 virus was 655,084, with 148,295 deaths in the U.S. alone [2]. Certain countries have dealt with the outbreak better than others introducing lockdowns and civil rights restrictions to prevent the spread of the virus. It is yet unclear as to the most effective methodology to either slow or contain the virus' spread. What is certain, however, is that the use of personal protective equipment (PPE) does protect those in high-risk environments where the viral titre is especially high [3-6]. The pandemic has caused a surge in demand for the supply of PPE and shortages around the globe. Small community-based setting such as hospitals, clinics, nursing homes and primary care offices have found it particularly difficult to obtain sufficient PPE and reuse, with its inherent dangers, has become commonplace [7-9].

To help mitigate this the U.S. Center for Disease Control (CDC) issued guidance on the reuse of PPE and in particular the NP95 face mask [10], they also advised on the further use of face shields to prevent soilage of the mask and that the use of a single mask be restricted to one person.

As the strains on supplies of PPE continue and in particular in the hardest-hit counties in the world including; the USA, Brazil and India, we investigated, with guidance from the FDA a small desktop ultraviolet disinfection device for the treatment of N95 masks. The intent was to be to build upon the guidance of the CDC as to whether such as device would be suitable for small scale decontamination and safe reuse of N95 masks in community settings, such as local doctors and dentists, plus care and rest homes. There are, of course, undoubted environmental advantages also. The FDA issued guidance on the 20th of May 2020 "Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 2019 (COVID19)". These recommendations stated that one of the three criteria should be satisfied.

1. *≥ 3-log reduction of a non-enveloped virus,* ***or***
2. *≥ 3-log reduction of two gram-positive and two gram-negative vegetative bacteria* ***or***
3. *Other evidence demonstrating that the bioburden reduction system will reliably achieve ≥ 3-log reduction in non-enveloped virus or vegetative bacteria, which could include, where appropriate, published scientific literature, and scientific and engineering studies.*

Large scale equipment is not practical in small community settings. Accordingly, we investigated the use of a widely available consumer ultraviolet disinfection device, the Lumin LM3000, see Figure 1.

The Lumin LM3000 is manufactured by 3B Medical, Inc. Approximately the size of a toaster it was originally designed to disinfect CPAP (Continuous positive airway pressure) accessories. These were used to treat people with sleep apnoea by pumping air into the airways to overcome obstructions and stimulate normal breathing.

The human eye can detect electromagnetic radiation in the visible spectrum, which ranges from wavelengths of 400 nm (violet) to 700 nm (red). Ultraviolet radiation is defined as radiation with a wavelength of less than 400 nm and greater than 100 nm, below the visible spectrum and thus not detectable by the human eye. Ultraviolet radiation is split into three subdivisions, as shown in Table 1.

UVA is used in tanning beds and black lights, and 97% of ultraviolet radiation that reaches the Earth's surface is in this category. UVB causes sunburns and accounts for 3% of the ultraviolet radiation at the Earth's surface. UVC radiation is naturally blocked by the Earth's atmosphere, specifically the ozone layer [11].

Ultraviolet radiation is harmful to biological microorganisms, such as viruses and bacteria. It disrupts base pairing in their DNA and RNA and thus prevents replication. Ultraviolet radiation has been used in medicine since the work of Niels Finsen in the late 1800s. The Nobel Prize in Medicine and Physiology was awarded to Finsen in 1903 [12]. It has been known since 1937 that for germicidal applications, the wavelength of maximum effectiveness is near 260 nm [13-15].

Conveniently, low-pressure mercury vapour lamps have an emission spectrum peaking at 254 nm, so these lamps have been used in germicidal applications for many decades. The mechanism behind this type of lamp is ionized mercury vapour allowing an electrical arc to pass between two electrodes. The lamp used in the Lumin is a low-pressure mercury vapour lamp with a power of 2.3 W in the UVC range, concentrated at a wavelength of 254 nm. The is made using quartz glass for the bulb, which allows UVC radiation to pass through.

The Lumin device is an aluminium lined chamber with a mercury-arc lamp that generates an irradiance output between 1,500 mJ/cm$^2$ up to 2,400 mJ/UVC depending on the exact point of impact on the mask.

The need to re-use PPE during a pandemic was explored following the influenza pandemic in 2009 when several studies examined various methodologies including UVC irradiation which concluded that results from such a methodology were encouraging [16].

The CDC concluded that most of the consumer UVC devices on the market are too weakly powered to repurpose for N95 respirator decontamination. To be effective for this application, scientific consensus seems to suggest a suitable UVC dose would be in the range of 500 to 900 mJ/cm$^2$ [17]. It is now widely accepted that a dose of approximately 1,000 mJ/cm$^2$ should be the target irradiance dose for a device that claims efficacy with SARS-CoV-2 . Malayeri et al. [18] published a table of UVC irradiation doses by log reduction for a variety of pathogens which indicates that the effective dose for most pathogens, including SARS-CoV-1, generally fall below 200 mJ/cm$^2$.

There are several variables to be considered:

- Does the device emit the appropriate wavelength?
- Does the device UVC output exceed 1,000 mJ/cm$^2$.
- Brand, make and construction of N95 mask
- UVC exposure (i.e. cycle time)

# Methods

The efficacy of the Lumin device was determined in a series of experiments which are described in detail in the Supplementary Materials, which include each of the study reports and their standard methodologies. The study reports are summarised in Table 1, with the appropriate standards against which the testing was conducted.

In collaboration with the FDA, 3B Medical developed a protocol for N95 decontamination that involves running Lumin for two cycles per mask and flipping the mask over in between cycles. Figure 1 shows how the Lumin device could be used in the community-based setting in conjunction with the CDC guidelines.

We tested the Lumin device using two enveloped viruses, influenza and a coronavirus, plus two gram-positive (Stearothermophilus and S. aureus) and two gram-negative bacteria (K.Pneumoniae and E . Coli). We also tested three non-enveloped (naked) viruses: Poliovirus, Reovirus, and Adenovirus, the latter being a UVC resistant challenge strain.

In addition, the device was tested with a viral inoculum on 4 brands of masks: the Petragon 305050 N95, the Xiantao ZYB-11, the 3M 1860 and the 3M 8511 with varying results.

Additionally, the physical UVC irradiation dose of a single cycle was measured using the ILT2400-UVGI-NB Germicidal/Disinfection Light Measurement System, for both the surface of an N95 and one-layer deep from the second interior layer of the 3M 1860 N95 (Figure 2).

# Results.

Irradiance Dose measurements are shown in Table 2 and ranged from a 1,381 mJ/cm$^2$ to 2,253 mJ/cm$^2$ based on sensor location on 5 different areas of the mask, see Figure 2.

A summary of the results of all the experiments conducted at the independent laboratories are shown in Table 3 and the final reports for each test are available as supplementary information.

# Discussion

When considering the recommendations of the FDA for the emergency use licensure of bioburden reduction as outlined on the 20$^{th}$ of May, the Lumin device satisfied the requirements of greater than 3 logs (99.9%) reduction in titre of enveloped viruses, gram-positive and gram-negative bacteria. At the request of the FDA, we also tested the device against a non-enveloped virus, namely adenovirus 2 and bacterial spores, which are known to be highly resistant against both of which it was also equally effective.

The single most significant variable impacting results are the brand and model of N95 respirator. Both the Reovirus and Poliovirus were inoculated on the Petragon masks. The outer surfaces of the Petragon are not water-repellant. They are absorbent, allowing the inoculum to penetrate past the top layer of the mask and absorb into what is presumably a thicker absorbent cotton layer. Testing results fell shy of the 3 Log reduction with results reported of 99.1-99.4% on the absorbent Petragon mask. While this is still a significant result, it does not meet the threshold established by FDA for Emergency Use Approval (EUA). By contrast, testing with the 3M 1860 (Adenovirus), 3M 8511 (Influenza H1N1), and Xiantao XYB-11 (Human Coronavirus) all achieved greater than a 3 Log (>99.9%)

reduction. These results allow us to deduce that Lumin works best, and meets or exceeds the FDA recommendations for a Tier 3 N95 Bioburden Reduction System when used with moulded hydrophobic N95 respirators such as the 3M 1860, 3M 8511 and Xiantao XYB-11. Lumin is still useful, but not quite as effective (i.e. > Log 2 reduction) with other makes and models of masks that may not have the same hydrophobic properties as the three we tested successfully.

Additionally, the sensor was subsequently placed beneath the top layer of the 3M 1860 N95 mask to measure UVC irradiance dose penetrating the first layer of the mask and reaching the second layer. Dose measurement of the UVGI dose at the second interior layer of the mask was recorded in the 300 to 400 mJ/cm2 range, sufficient to kill or inactivate the majority of virus and bacteria that might penetrate the first layer of an N95 respirator

# Conclusion

Our testing of Lumin device with different viruses and N95 respirators; the 3M 1860 with Human Adenovirus 2, the 3M 8511 with Influenza H1N1 and Xiantao ZYB-11 with Human Coronavirus N95 showed greater than a 3 Log reduction (>99.9%).

Additional irradiance dose testing also evidences that > 300 mJ/cm$^2$ at the secondary interior layer of the N95 (3M 1860). Although on N95 respirators similar to the ones tested, an aerosolized viral load will sit on the surface of the mask and would not ordinarily penetrate the repellent top layer of a molded hydrophobic mask.

We conclude that that, for specific mask types, the Lumin device is capable of meeting the criteria for emergency use, of decontaminating N95 masks, when PPE is in short supply.

# Tables and Figures.

*Table 1 Classification of ultraviolet radiation by wavelength.*

| Classification | Wavelengths |
|---|---|
| Ultraviolet A (UVA) | 400nm – 315nm |
| Ultraviolet B (UVB) | 315nm – 280nm |
| Ultraviolet C (UVC) | 280nm – 100nm |

*Table 2 Irradiance Dose measurements at sensor locations shown in Figure 2.*

| Sensor location | UV-C dose measurements mj/cm$^2$ |
|---|---|
| 1 | 2,063 |
| 2 | 1,430 |
| 3 | 1,548 |
| 4 | 1,381 |
| 5 | 2,253 |

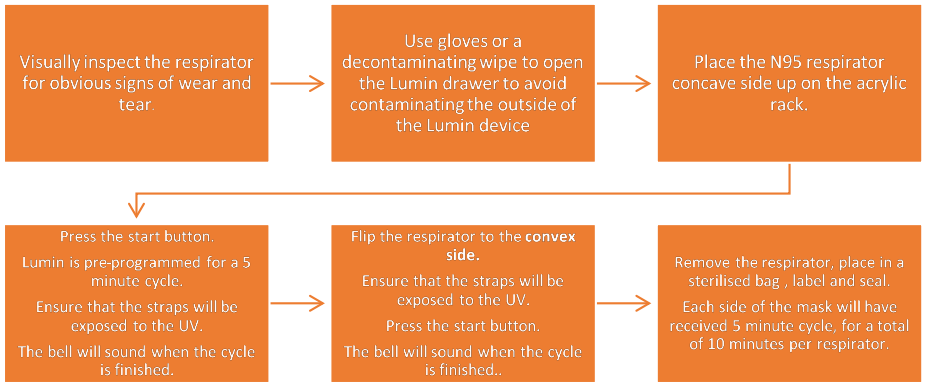
*Table 3 Reduction in Bioburden using the Lumin device.*

| Virus | File name (Supplementary data) | Title of report | Laboratory | Test Standard | % reduction |
|---|---|---|---|---|---|
| **Enveloped** | | | | | |
| **Corononavirus 229E** | Supplementary A: Human Coronavirus on N95 Microchem ASTM E1053 Report NG14983V2 | Modified ASTM E1053 Virucidal Efficacy of a UV Test Device on an N95 Respirator | Microchem Laboratory | Modified ASTM E1053 | >99.9 |
| **Influenza H1N1** | Supplementary B: Lumin Influenza H1N1 Study | Modified ASTM E1053 Method Virucidal Efficacy of a UV Device | Microchem Laboratory | Modified ASTM E1053 [Carriers with simulated soil] | >99.99 |
| **Non Enveloped** | | | | | |
| **Adenovirus** | Supplementary C: 3B products Lumin Mask Study Adenovirus 2 0704 20 BCS ID 2006241r | Lumin LM 3000 Adenovirus 2 Bioburden Reduction Testing on Inoculated Facemask Device Performance Validation study | BCS Laboratories | Modified ASTM E3135 (Carriers with simulated soil) | >99.94 |
| **Bacteria** | | | | | |
| **Gram-positive** | | | | | |
| **Stearothermophilus** | Supplementary D: Stearothermophilus CPAP Accessories | Lumin Disinfection Validation Study Design | Microchem Lab/Kristi Jones | In house SOPs | >99.99 |
| **S. aureus** | Supplementary E: Microchem- S aureus K pneumoiae -NG14592 | Antibacterial Activity and Efficacy of 3B Medical Lumin CPAP UV Sanitizer Device | Microchem Laboratory | Modified ASTM E1153 Method | >99.99 |
| **Gram-Negative** | | | | | |
| **K.Pneumoniae** | Supplementary F: Microchem- S aureus K pneumoiae -NG14592 | Antibacterial Activity and Efficacy of 3B Medical Lumin CPAP UV Sanitizer Device | Microchem Laboratory | Modified ASTM E1153 Method | >99.99 |
| **E . Coli** | Supplementary G: APP 2 Microchem- E Coli -NG14813-V1 | Antibacterial Activity and Efficacy of 3B Medical Lumin CPAP UV Sanitizer Device | Microchem Laboratory | Moodified ASTM E1153 Method | >99.99 |
| **S. Enterica G** | Supplementary H: APP 3 Microchem- S. Enterica-NG14813-V2-SE10708 | Antibacterial Activity and Efficacy of 3B Medical Lumin CPAP UV Sanitizer Device | Microchem Laboratory | Custom Device Study Based on: ASTM E1153 Method | >99.99 |
| **Spores:** | | | | | |
| **Gram-Negative** | | | | | |
| **B pumilus** | Supplementary I: Mesa- CPAP Accessories B pumilus | Population Analysis Report #593-193 - Study 3 | MesaLabs | Population assay based lab SOPs. | >99.9 |

## Lumin Device Output : 1381 – 2253 mJ/cm2

**Dimensions: 12”x 8”x 7.25”**
**Weight: 8 lbs**
**Does it plug into a regular socket? Yes**
**Any other special requirements? No**
**Recommended cleaning procedure?**
**After each use**
**[Check for physical debris or water spots. If present, wipe with a microfiber cloth.**
**Servicing and testing requirements N/A**
**Length of life of lamp at suitable output. 9,000hrs**
**Cycle Time: 5 Minutes**
**Number of Cycles Approximately 100K**


**Simplified Flow Chart of Instructions for Use.**




Notes:

- **Each respirator to be reused should be used with a face shield to prevent soiling as per CDC guidelines.**
- **Each respirator to be reused should only be used by the same person per CDC guidelines.**
- **Each respirator received 5 minutes of up to 2253 mJ/cm$^2$.**
- **Respirators are discarded if they have shown any wear or tear that may affect their integrity.**
- **If integrity is in doubt the respirator is discarded.**
- **The respiratory is not used for more than ten runs (total of 20 cycles).**

*Figure 1. The Lumin device and operating instructions*

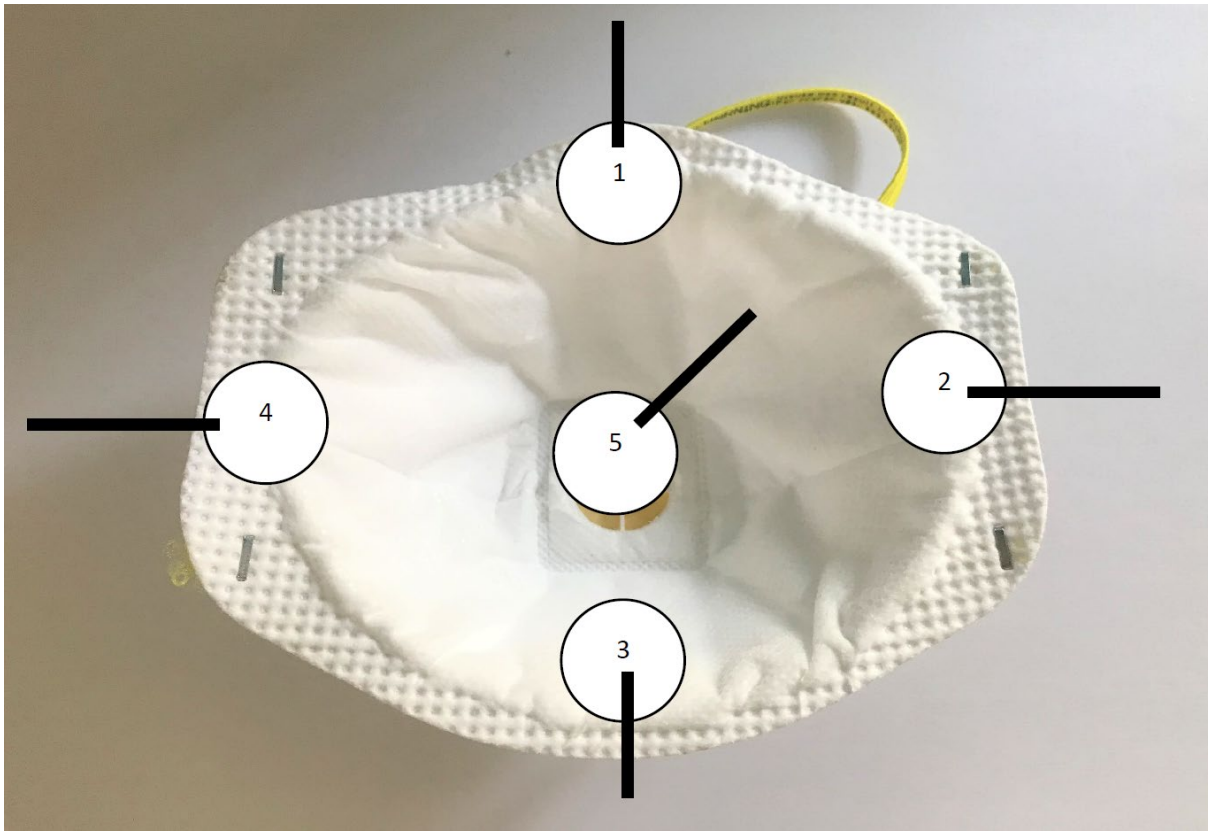



*Figure 2. Sensor location on five different areas of the mask.*

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