

Memo

Date: May 5, 2020

Re: AirClean® Systems UV Light Box

To Whom It May Concern:

Best practice is to use new N95s. Decontamination does not solve the PPE shortage crisis, and is an emergency practice to be considered during the COVID-19 pandemic. Efficacy and safety of N95 decontamination has not been fully characterized.

The AirClean® Systems UV light box is not a medical device, it is a piece of laboratory equipment. The UV light box was not a previously cleared medical device by the FDA and does not qualify for an Emergency Use Authorization to change an existing product to sterilize N95 masks. The UV light box was designed to meet all the latest scientific data from many hospitals, research organizations, and the consortium named [N95decon](#) to help in the COVID-19 pandemic and PPE shortage.

Data for Ultraviolet germicidal irradiation (UVGI) light decontamination of N95 FFRs is also backed up by the [CDC](#) and [NIH](#)

N95DECON has put a value of at least 1.0 J/cm² of UV-C radiation to decontaminate N95 FFRs.

The AirClean Systems UV light box can provide 1.0 J/cm² of UV-C radiation if all N95s are placed directly below the UV-C bulbs, have 30 minutes exposure on each side, and the UV bulbs are still within their life according to the UV light box counter.

Things to keep in mind about the N95 integrity:

N95 keeps fit and filter performance after 10-20 cycles of 1.0–1.2 J/cm² of UV-C. However each don/doff can reduce N95 fit; some models fit unacceptably after 5 don/doff cycles.

Key considerations to follow:

- Ensure accurate UV-C dose on all surfaces of N95
- Measure dose at N95 surface with UV-C specific sensor
- Return N95s to original users and ensure handling minimizes cross-contamination
- Perform user seal check before each reuse
- Be aware that data from tests on specific N95 models may not apply to other models

Risks:

- UV-C may not decontaminate N95 straps or eliminate risk of bacterial co-infection
- Cosmetics and sunscreen on N95 may reduce decontamination efficacy
- Validate each UV-C source and protocol with a UV-C sensor to ensure adequate dose for decontamination at the N95 surface.

If implemented properly using sensors to ensure $\geq 1.0 \text{ J/cm}^2$ UV-C dose to the N95, this method likely inactivates SARS-CoV-2; however, this has not yet been confirmed directly with SARS-CoV-2. This method may protect against some bacterial co-infection risks but not all.

References:

<https://www.n95decon.org>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

<https://www.nih.gov/news-events/news-releases/nih-study-validates-decontamination-methods-re-use-n95-respirators>

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Validation of the AirClean Systems UV Light Box to provide ≥ 1.0 J/cm² of UV-C Radiation

DOCUMENT NUMBER EDD-0107

Revision	Date	COMMENTS
A	05.13.2020	Initial Release

Approvals:

	Name/Title: Signature	Date
Prepared By	Kendall Ashe	05.13.2020
Approved By	Dawn Kusy	05.13.2020

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1. Goal

The goal of this validation was to ensure that the AirClean® Systems UV Light Box provided ≥ 1.0 J/cm² of UV-C radiation. This study proved, that when the directions are followed, the UV Light Box does provide ≥ 1.0 J/cm² of UV-C radiation in 30 minutes.

2. Background

The UV Light Box was designed to meet all the latest scientific data from many hospitals, research organizations, and the consortium named N95decon to help in the COVID-19 pandemic and specifically N95 FFR shortage.

Best practice is to use new N95s. Decontamination does not solve the PPE shortage crisis, and is an emergency practice to be considered during the COVID-19 pandemic. Efficacy and safety of N95 decontamination has not been fully characterized.

The AirClean Systems UV Light Box is not a medical device, it is a piece of laboratory equipment. The UV Light Box was not a previously cleared medical device by the FDA and does not qualify for an Emergency Use Authorization to change an existing product to sterilize the single-use N95 FFRs. The UV Light Box decontaminates N95 FFRs per N95DECON's requirement of ≥ 1.0 J/cm² of UV-C radiation at 254nm with non-ozone producing bulbs.

It is important that the dose of UVGI is measured with a UV-C specific sensor, that the N95s are returned to the original users, and that any handling minimizes cross-contamination. The user must perform a seal check before each reuse. Also the facility must implement a robust industrial hygiene workflow for transporting masks to and from the UV Light Box. It is also important to understand that UV-C may not decontaminate N95 straps or eliminate risk of bacterial co-infection. Also any blood, debris, cosmetics, or sunscreen on N95s may reduce decontamination efficacy.

3. Testing Summary

This validation tested 3 UV Light Boxes of each model (ACUVLB24 - 24" model; ACUVLB42 - 42" model). This testing was done with three of each model to ensure no variation between units. Measurements were taken with a calibrated UV-C sensor. Measurements were taken with UV bulbs turned-off before and after the study to ensure there was no UV-C radiation in the background. All values were recorded to three decimal places in mW/cm². Measurements were taken around the UV light and under the UV light in the first hood and subsequent hoods taken directly under the UV light. Below in Table 1 is all the equipment used for this validation.

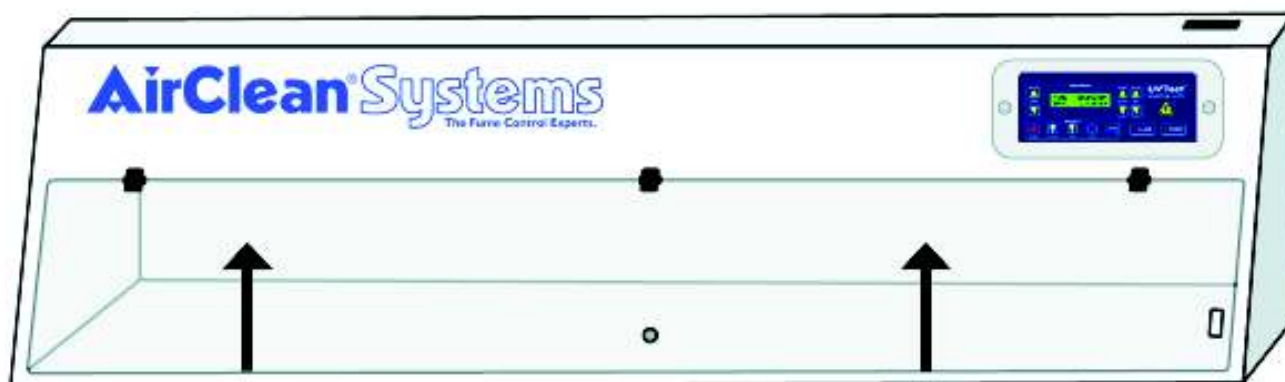
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Equipment	Manufacturer / Model	Serial Number
UV-C Light Sensor	GENERAL / UV254SD	SN:Q614526 Cal due 10-29-2020
24" UV Light Box	ACS / ACUVLB24	ACUVLB24-815
24" UV Light Box	ACS / ACUVLB24	ACUVLB24-816
24" UV Light Box	ACS / ACUVLB24	ACUVLB24-817
42" UV Light Box	ACS / ACUVLB42	ACUVLB42-822
42" UV Light Box	ACS / ACUVLB42	ACUVLB42-823
42" UV Light Box	ACS / ACUVLB42	ACUVLB42-824

Table 1

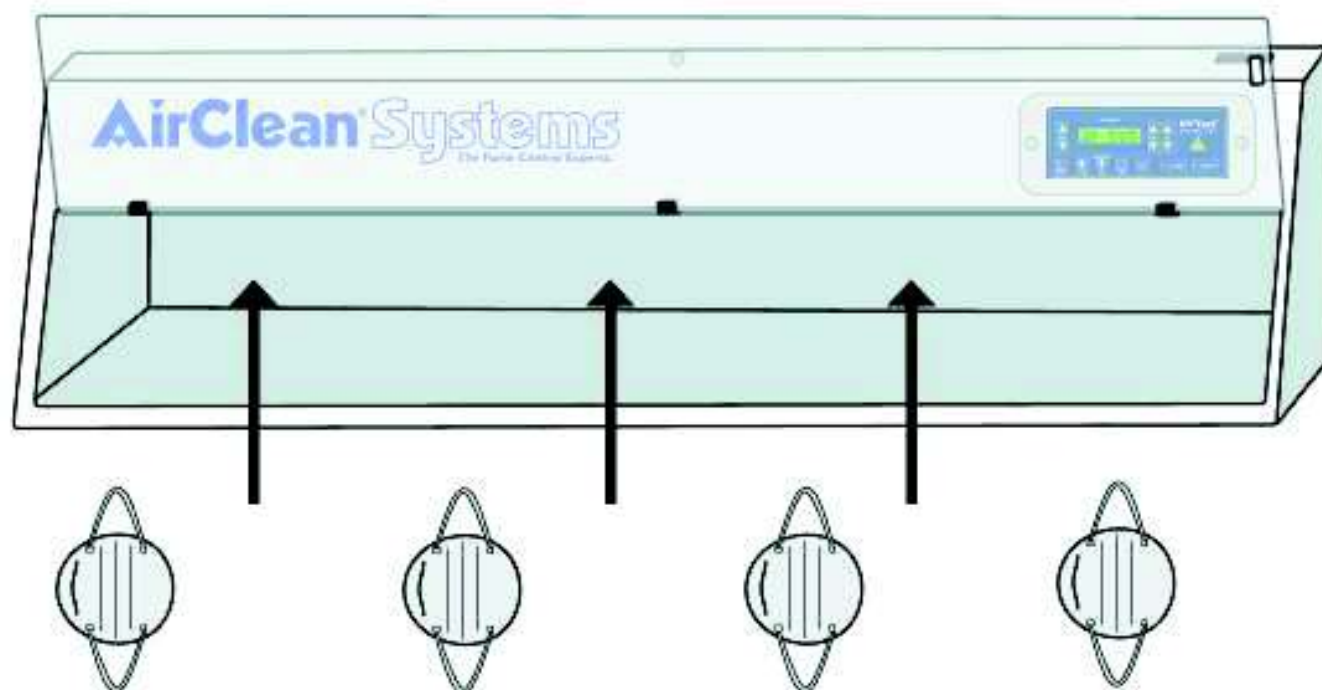
Directions for Use of UV Light Box

1. Chemically disinfect the straps of the mask with an EPA registered disinfectant for emerging pathogens, such as Solucide®.
2. Open the unit by lifting the chamber door upward, resting it on the head assembly of the unit.

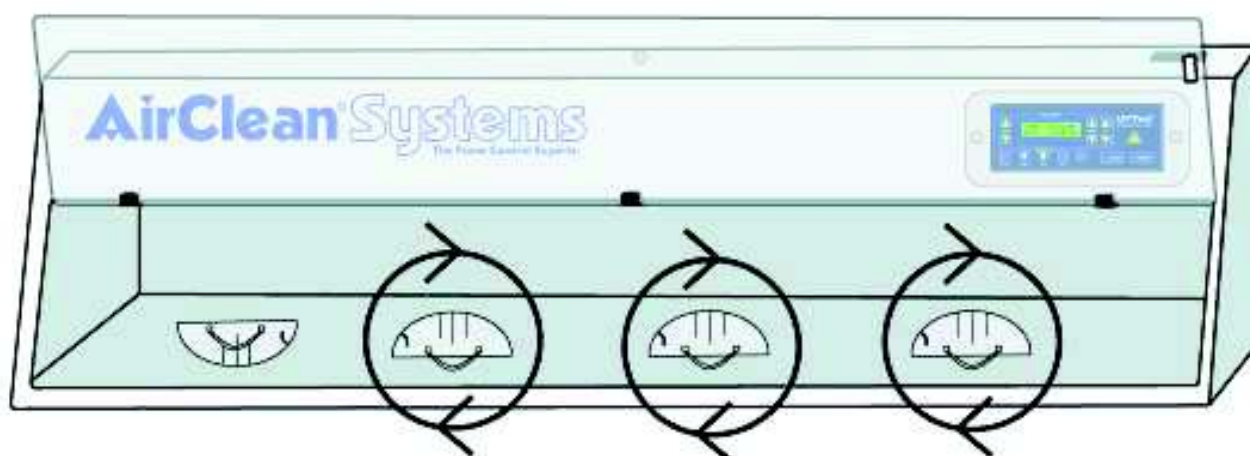


3. Place potentially contaminated mask in the chamber directly underneath the UV-C bulbs and close the door to the chamber. Ensure there is no mask overlap; we recommend a one-inch minimum between masks positioned in the chamber.
4. Set the timer on the UVTect™ microprocessor controller to 30 minutes and engage the UV-C light bulbs by pressing the “UV LIGHT” button.

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5. Once 30 minutes have elapsed and the timer has ended, flip the mask(s) within the chamber, keeping them directly under the UV-C bulbs.



6. Close the door to the chamber and press the “UV LIGHT” button, engaging the timer for an additional 30 minutes.

7. Once the timer has elapsed, the N95 masks can be removed and reused.

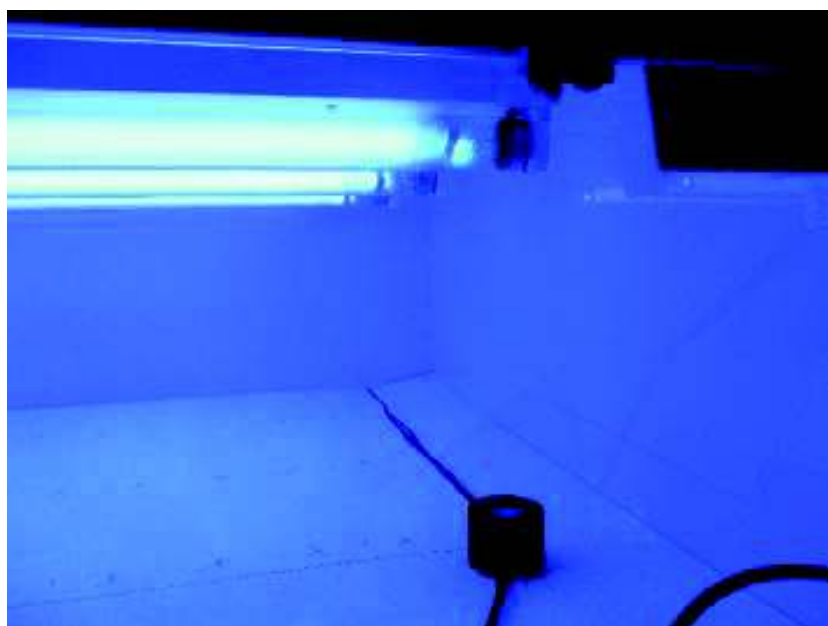
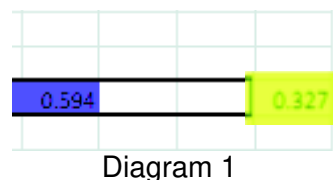
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N95 Masks are viable for 5 decontamination cycles only. Reusing beyond 5 cycles may cause masks to degrade, resulting in exposure to the user. N95 masks should be labeled for individual use and users should use the same mask. If implemented properly using sensors to ensure $\geq 1.0 \text{ J/cm}^2$ UV-C dose to the N95, this method likely inactivates SARS-CoV-2; however, this has not yet been confirmed directly against SARS-CoV-2. This method may protect against some bacterial co-infection risks, but not all.

4. Results

Below are the results of measurements (recorded in mW/cm^2) found in three 24" UV Light Boxes and three 42" UV Light Boxes. Each cell in the images on the following pages represent a 1 inch by 1 inch square at the bottom of the UV light box. The first UV Light Box was used to determine limits. All raw data was analyzed and converted to number of minutes need to achieve $\geq 1.0 \text{ J/cm}^2$ of UV-C Radiation in section 5. *Analysis*.

To better understand the raw data in the section below, the yellow cell highlighted in Diagram 1 is right below the non UVC light emitting part of the bulb. The cell in purple are measurements taken directly below the UVC emitting part of the bulb. Picture 1 corresponds with the yellow highlighted cell.



Picture 1

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0.212		0.425		0.718		0.638		0.624		0.413		0.205
0.448		0.763		0.969		1.055		0.792		0.594		0.327
0.373		0.701		0.991		1.140		0.991		0.744		0.394
0.625		1.007		1.167		1.223		1.086		0.702		0.342
0.450		0.870		1.084		1.058		0.957		0.657		0.316
0.438		0.856		1.094		1.109		0.960		0.977		0.315
0.257		0.537		0.713		0.804		0.493		0.413		0.225

Serial Number ACUVLB24-815

0.579		0.830		1.011		1.092		1.122		1.086		0.887		0.636		0.323
0.621		0.958		1.177		1.305		1.331		1.287		1.109		0.833		0.458
0.548		0.796		1.009		1.115		1.137		1.118		0.984		0.714		0.444

Serial Number: ACUVLB24-816

0.550		0.838		1.054		1.163		1.181		1.133		0.976		0.700		0.381
0.608		0.918		1.183		1.294		1.315		1.275		1.113		0.822		0.473
0.577		0.875		1.108		1.208		1.223		1.186		1.014		0.759		0.476

Serial Number: ACULVB24-817

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0.428	0.685	0.869	1.009	1.010	1.015	1.037	1.047	1.052	1.078	1.039	0.998	1.033	0.999	0.940	0.815	0.585
0.568	0.884	1.144	1.295	1.319	1.330	1.342	1.333	1.336	1.335	1.324	1.324	1.317	1.286	1.202	1.043	0.734
0.529	0.814	1.004	1.093	1.114	1.141	1.155	1.147	1.155	1.145	1.139	1.140	1.113	1.080	1.015	0.826	0.612

Serial Number: ACUVLB42-822

0.437	0.581	0.804	0.908	0.933	0.952	0.976	0.982	1.030	1.031	1.022	1.033	1.016	0.981	0.921	0.811	0.576
0.560	0.962	1.186	1.341	1.365	1.380	1.372	1.378	1.386	1.390	1.384	1.381	1.370	1.333	1.240	1.086	0.767
0.599	0.898	1.115	1.225	1.244	1.262	1.255	1.260	1.256	1.245	1.232	1.237	1.231	1.198	1.102	0.931	0.677

Serial Number: ACUVLB42-823

0.447	0.674	0.888	0.999	1.044	1.053	1.107	1.072	1.038	1.057	1.045	1.024	1.011	1.023	0.933	0.765	0.578
0.566	0.890	1.158	1.265	1.321	1.329	1.345	1.350	1.345	1.336	1.330	1.316	1.300	1.268	1.206	1.041	0.709
0.519	0.805	1.027	1.200	1.237	1.237	1.228	1.223	1.236	1.240	1.237	1.224	1.203	1.170	1.086	0.933	0.659

Serial Number: ACUVLB42-824

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5. Analysis

In this section, the raw data recorded was converted from mW/cm² to the minutes need to achieve 1.0 J/cm² of UV-C radiation energy.

78.62		39.22		23.21		26.12		26.71		40.36		81.30
37.20		21.84		17.20		15.80		21.04		28.06		50.97
44.68		23.78		16.82		14.62		16.82		22.40		42.30
26.67		16.55		14.28		13.63		15.35		23.74		48.73
37.04		19.16		15.38		15.75		17.42		25.37		52.74
38.05		19.47		15.23		15.03		17.36		17.06		52.91
64.85		31.04		23.38		20.73		33.81		40.36		74.07

Serial Number ACUVLB24-815

28.79		20.08		16.49		15.26		14.85		15.35		18.79		26.21		51.60
26.84		17.40		14.16		12.77		12.52		12.95		15.03		20.01		36.39
30.41		20.94		16.52		14.95		14.66		14.91		16.94		23.34		37.54

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30.30	19.89	15.81	14.33	14.11	14.71	17.08	23.81	43.74
27.41	18.16	14.09	12.88	12.67	13.07	14.97	20.28	35.24
28.89	19.05	15.04	13.80	13.63	14.05	16.44	21.96	35.01

Serial Number ACUVLB24-817

38.94	24.33	19.18	16.52	16.50	16.42	16.07	15.92	15.84	15.46	16.04	16.70	16.13	16.68	17.73	20.45	28.49
29.34	18.85	14.57	12.87	12.64	12.53	12.42	12.50	12.48	12.48	12.59	12.59	12.66	12.96	13.87	15.98	22.71
31.51	20.48	16.60	15.25	14.96	14.61	14.43	14.53	14.43	14.56	14.63	14.62	14.97	15.43	16.42	20.18	27.23

Serial Number ACUVLB42-822

38.14	28.69	20.73	18.36	17.86	17.51	17.08	16.97	16.18	16.17	16.31	16.13	16.40	16.99	18.10	20.55	28.94
29.76	17.33	14.05	12.43	12.21	12.08	12.15	12.09	12.03	11.99	12.04	12.07	12.17	12.50	13.44	15.35	21.73
27.82	18.56	14.95	13.61	13.40	13.21	13.28	13.23	13.27	13.39	13.53	13.47	13.54	13.91	15.12	17.90	24.62

Serial Number ACUVLB24-823

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37.29	24.73	18.77	16.68	15.96	15.83	15.06	15.55	16.06	15.77	15.95	16.28	16.49	16.29	17.86	21.79	28.84
29.45	18.73	14.39	13.18	12.62	12.54	12.39	12.35	12.39	12.48	12.53	12.66	12.82	13.14	13.82	16.01	23.51
32.11	20.70	16.23	13.89	13.47	13.47	13.57	13.63	13.48	13.44	13.47	13.62	13.85	14.25	15.35	17.86	25.29

Serial Number ACUVLB24-824

6. Conclusions

These results and analysis show that the AirClean® Systems UV Light Box can achieve ≥ 1.0 J/cm² of UV-C radiation in 30 minutes, therefore validating the directions for use.

7. References

1. <https://www.n95decon.org>
2. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>
3. <https://www.nih.gov/news-events/news-releases/nih-study-validates-decontamination-methods-re-use-n95-respirators>
4. Heimbuch, B.K. and D. Harnish. *Research to Mitigate a Shortage of Respiratory Protection Devices During Public Health Emergencies*. 2019
5. Fisher, E.M. and R.E. Shaffer, *A method to determine the available UV-C dose for the decontamination of filtering facepiece respirators*. Journal of Applied Microbiology, 2011. 110(1): p. 287-295.
6. Mills, D., et al., *Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators*. American Journal of Infection Control, 2018. 46(7): p. e49-e55.
7. Heimbuch, B.K., et al., *A pandemic influenza preparedness study: use of energetic methods to decontaminate filtering facepiece respirators contaminated with H1N1 aerosols and droplets*. American Journal of Infection Control, 2011. 39(1): p. e1-e9.