



N95 Filtering Facepiece Respirator Ultraviolet Germicidal Irradiation (UVGI) Process for Decontamination and Reuse

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Substantially based upon:

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Introduction

Rationale and Method

The ongoing pandemic of SARS-CoV-2 resulting in COVID-19 has severely stressed the worldwide healthcare system and has created dangerous shortages of personal protective equipment (PPE) including N95 filtering facepiece respirators (FFR). To extend the stockpile of FFRs and reduce risks associated with reuse of untreated, contaminated FFRs, we have developed a device and procedure for surface decontamination using ultraviolet germicidal irradiation (UVGI) to decontaminate used FFRs.

The evidence base supporting this program includes:

- UVGI has been shown to effectively inactivate a wide range of human pathogens including coronaviruses and other human respiratory viruses
- UVGI has been demonstrated to inactivate human respiratory viruses, including coronaviruses, on various models of N95 FFRs
- Levels of UVGI needed to inactivate human respiratory viruses are well below the level of irradiation that adversely affects the fit and filtration characteristics of N95 FFRs
- UVGI can be safely administered when appropriate safeguards are in place.

Literature supports UVGI exposures of 1 J/cm^2 are capable of decontaminating influenza virus on N95 FFRs and exposures as low as of $2\text{-}5 \text{ mJ/cm}^2$ are capable inactivating coronaviruses on surfaces (1-2). Thus, the UVGI exposure chosen exceeds by several fold the amount of exposure needed to inactivate SARS-CoV-2 and provides a wide margin of safety for surface decontamination.

The UVGI Sterilization Chamber contains four 30W UV-C 254 nm bulbs two on each side and each set within 5 inches of each side of the masks. The chamber operates when the lever on safety switch on the left side is down (which happens when the cover is in place) and when the timer value is non-zero. As documented on the face of the timer, the chamber timing is set by turning the timer knob past the minimum setting value. The delivered UV energy is monitored using a handheld monitor at periodic intervals either with or without masks in the chamber.

Roles

In this procedure, four roles are referenced:

- Healthcare Professional (HCP)
- UVGI Associate – Pre-Disinfection (Pre)
- UVGI Associate – Post-Disinfection (Post)
- Staff Associate

Both UVGI Associates, Pre and Post, work together to load and unload the cabinet.

Zones

There are two zones and areas within those zones required as part of this process:

1. Soiled utility space: This is the location where the soiled masks are stored, bagged and ready for later disinfection.
2. Clean area: A large area containing the prep for disinfection, the UV-C disinfection cabinet, and an area remote from the area surrounding the disinfection cabinet where processed masks can be re-bagged for delivery back to HCPs.

Healthcare Professional (HCP)

Use of FFR by HCP

1. This step would typically be handled as part of the overall FFR management protocol, whether the technology used in vaporized hydrogen peroxide or UV-C light.

Using a black ink permanent marker, HCP writes the date of first use.



2. HCP uses FFR following local institution guidelines.
3. HCP doffing will be handled per general decontamination guidelines.
4. HCP will deliver the soiled mask to the appropriate location, soiled utility space, and in the manner defined by the decontamination guidelines.
5. HCP will notice a tally mark has been added, by the UVGI associate, after disinfection process, to track the number of times a mask has gone through the disinfection. Once the maximum number of disinfection cycles has been reached, which is up to 20, the FFR will be discarded and the HCP will be required to obtain a new FFR.

UVGI Associates Management and Decontamination of Masks

1. UCGI-Pre acknowledges receipt of used respirators from courier in soiled utility space.
2. UVGI-Pre dons PPE (gown, gloves, procedural mask) for contact precautions.
3. UVGI-Pre transfers the cart with soiled FFRs, to the Decontamination Location, which is in the clean area.
4. FFR are removed from each bag one at a time. The number of decontamination cycle marks are reviewed, and any FFR with too many marks is to be discarded properly. UVGI Pre inspects for any material damage to FFR or straps. Verify that no soiling/stains are visible on mask. Discard any masks that have damage or soiling apparent.
5. Secure the frame. Before each mask is loaded on the frame, UVGI Pre cleans the rubber straps with a sterilizing wipe.
6. UVGI-Pre then loads the soiled masks into the frame, delicately blooming FFR exposing as much outer surface as possible while preserving structure integrity. Do not turn masks inside out. Masks should not overlap each other. Do not touch the straps when hanging the masks if your hands have touched the mask body.
7. When the frame is fully loaded with masks by UVGI-Pre, UVGI-Post opens the cabinet.
8. UVGI-Pre then loads the frame in the cabinet, secures it with the Velcro straps. UVGI-Pre then wipes the top of the frame, handle and Velcro straps with a sterilizing wipe.



9. Then UVGI-Post closes the cover and sets the timer to the value “10” for 10 minutes of timer operation.

Important! The UV light in the chamber at the high levels necessary to inactive pathogens will damage human tissue. There is a safety switch that disables the UV light but DO NOT open the cover when the UV light is on (cover on and mechanical timer operating). DO NOT force the mechanical timer dial.



10. UVGI-Pre changes gloves and wipes/disinfects the exterior of the cabinet and the cart used to deliver the soiled FFRs.
11. When the time cycle is complete, UVGI-Post removes the frame to a far location in the clean area close to the exit, removes the masks, and delivers the frame to UVGI-Pre for loading and the disinfection cycle repeats.
12. A staff associate at the far location in the clean area loads in the masks into bags per the disinfection procedure and exits the room with the bagged masks for delivery back to the HCP.

13. with the frame in place. Setup the UV sensor so it is facing the rear of the chamber, close the lid and set the timer for the minimum operating setting for the timer, taking a reading close at 30 seconds or longer into the timer cycle. At the end of the cycle, move the UV sensor so it is facing the front of the chamber, close the lid, set the timer again and take a reading at about 30 seconds into the cycle. The 30 second timing is not critical; we want to allow some time for the bulb light output to stabilize.

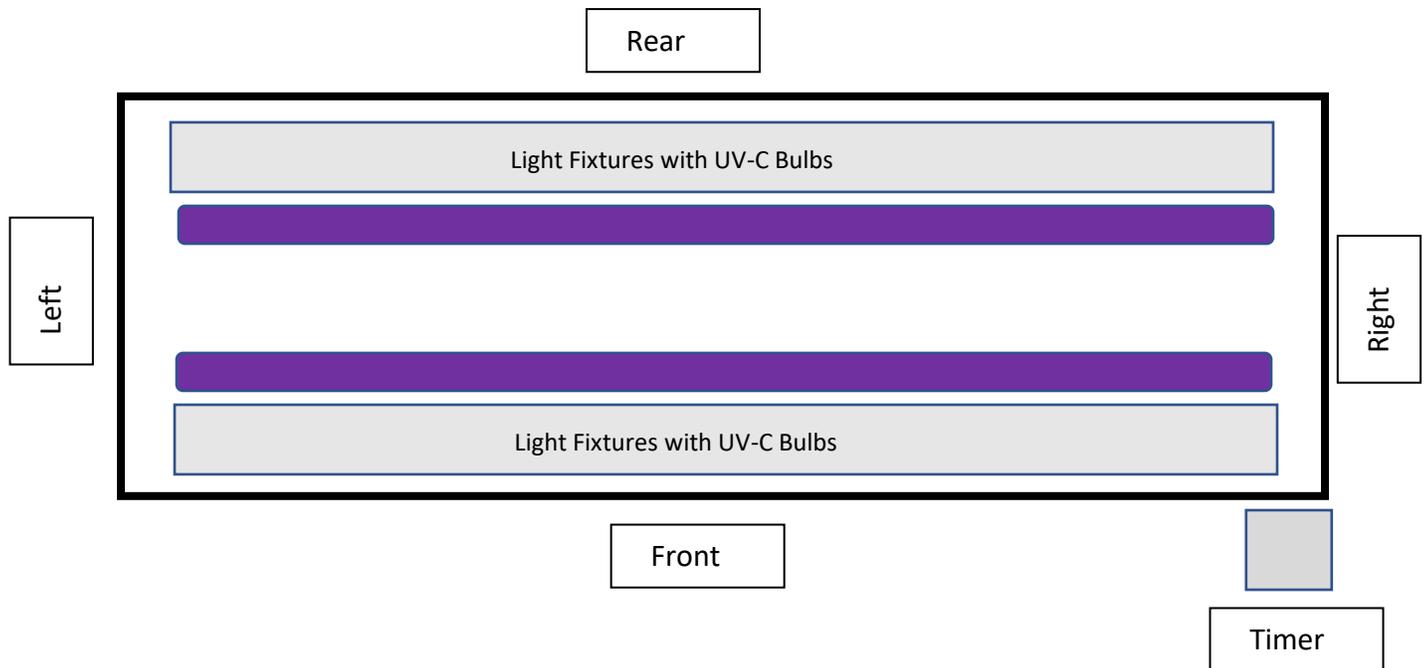
Important! Both readings MUST be greater than 3000 uW/cm². If they are not, then the chamber should not be used and the masks since the last check were not adequately disinfected



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UV Test Data – for reference only
Second unit in black container, 07Apr2020 and 08Apr2020

Top View of Chamber, Cover Open



Test Name: Back of Mask UV Light Level

1. Procedure is to take an N95, cut a hole in the rear of the mask and using gaffer's tape secure the UV meter sensor so it measures the UV level at the rear of the mask as closely as possible.
2. Perform a two-minute warm up for the bulbs.
3. Move the mask to each position in the fixture and set the timer for one minute. Take a reading near the end of the 1-minute period from the meter and log in the table.
4. Take one set of readings with the mask/sensor facing the rear of the cabinet and a second set of reading with the mask/sensor facing the front of the cabinet.



Front/Rear Facing	Position Number	Sensor Reading $\mu\text{W}/\text{cm}^2$
Rear	6	2988
Rear	5	3366
Rear	4	3752
Rear	3	3528
Rear	2	3189
Rear	1	2161
Front	6	2927
Front	5	3374
Front	4	3793
Front	3	4067
Front	2	3610
Front	1	1905

Test Name: UV Across the Chamber

Procedure is to mount the sensor at one side of the chamber with VHB attached to the bulbs, pointing across the chamber at the UV bulbs on the opposite side with no masks in between.

Facing Rear with the sensor on the Front bulbs = 3619 uW/cm²

Facing Front with the sensor on the Rear bulbs = 3352 uW/cm²

Test Name: Left and Right Mask Shadowing

1. Procedure is to cut a hole into one side of an N95 and secure it using clamps in the approximate position it would have if no sensor was present, in order to measure the UV light energy arriving in the shadowed area of the mask.
2. The lamps had a 2-minute warm up and each test had a 1-minute cycle with a reading taken toward the end of each cycle.
3. All readings were taken with the mask pointed toward the rear of the chamber.

Sensor on Right or Left	Position Number	Sensor Reading uW/cm ²
Right	6	2380
Right	5	2545
Right	4	2639
Right	3	1473
Right	2	1052
Right	1	434
Left	6	865
Left	5	2105
Left	4	2135
Left	3	2274
Left	2	2143
Left	1	2076

Sterilizer Bulb Testing

28Mar2020, Room Temperature about 30% RH

uW/cm² taken using General UV512C probe pointed at pair of bulbs; whether other bulbs are present behind the sensor has been informally determined to not substantially impact the target reading. To be clear, readings can only be taken when the device is powered. Timer should always be allowed to run down, do not force it.

Bulb	Conditions	Low uW/cm ²	High uW/cm ²
Both Philips	2-minute (mech timer) warmup, first of day		1728
	+2 more minutes		2157
	+2 more minutes		2256
	Off 25s, cover on, operate one minute	2053	2211
	Off 1-minute cover on, operate one minute	1891	2173
GE A and B	From the first/opened box of bulbs 2-minute warmup, first time these bulbs powered	2323	2802
	Off and cover off 30s, cover on operate one minute	2711	2832
GE C and D	2-minute warmup, first time these bulbs powered	1852	2767
	Off and cover off 30s, cover on operate one minute	2722	2848
GE E and F	2-minute warmup, first time these bulbs powered	1976	2710
	Off and cover off 30s, cover on operate one minute		2712
GE G and H, and J and K	4 new GE bulbs, replaced Philips that were not targeted From the second box of bulbs, which were at ~50F	1351	2318
	One more minute, cover on		2613
	One more minute, cover on		2676

	Off and cover off 30s, cover on operate one-minute, adjusted position of sensor		2815
	Sit with cover off 15 minutes, unpowered		
	Operate one minute	2070	2543
	30s off and cover off, operate one minute	2603	2769
	30s off and cover off, operate one minute	2793	2937
	30s off and cover off, operate one minute	2878	2982
	30s off and cover on operate one minute	2962	3047
	30s off and cover on operate one minute	2942	3074
	30s off and cover on operate one minute	3048	3114
	Cover on, run three minutes to check temps; fixtures (near sheet metal covering ballast) were 88F and 86F, metal rings at edges of bulbs were 88F and 92F		

Disclaimer

This documentation is provided for informational and educational purposes only. It is intended to document our own efforts and provide guidance for anyone who wishes to reproduce our results. Adherence to any recommendations included may not ensure successful results in every situation. Furthermore, these recommendations should not be interpreted as setting a standard of use, or be deemed inclusive of all proper methods of use nor exclusive of other methods of use reasonably directed to obtaining the same results.

This documentation and its conclusions and recommendations reflect the best available information at the time the documentation was prepared. The results of future studies may necessitate revisions to the instructions in this documentation to reflect new data. It is the responsibility of the entity implementing this unit and the associated processes to evaluate their use against current information.