

Step-by-Step Protocols for Decontamination Techniques for the Reuse of N95 Respirators

N95/PPE Working Group Report

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Step-by-Step Protocols for Decontamination for the Reuse of N95 Respirators

Note: This report is a follow-up to the March 29, 2020, document titled "[Evaluation of Decontamination Techniques for the Reuse of N95 Respirators](#)," released on the COVID-19 Healthcare Coalition (C19HCC) website (<https://c19hcc.org>). The Coalition has researched and collated the current best methods for decontamination and reuse (i.e., recharging, recycling) of N95 respirators.

Summary

In this paper, we provide specifics details needed to follow the methods listed below, in terms of materials, equipment, and protocols.

- Vaporized Hydrogen Peroxide (VHP) (Page 2)
- Ultraviolet Germicidal Irradiation (UVGI or UV-C) (Page 5)
- Moist Heating (Page 8)
- Dry Heating (Page 9)

Each decontamination method carries caveats, and users should consider these caveats before and during implementation of recharging treatments. We do not yet have data on the number of treatment iterations N95 respirators can undergo before impact on performance.

It is important to note that effectiveness of the listed decontamination techniques assumes proper fitting of the N95 filtering facepiece respirators (FFRs). A poorly fitted N95 FFR permits leakage of contaminants into the breathing zone by introducing gaps in the interface region between the face and the respirator seal. Therefore, it is imperative that users take into consideration proper fitting of the FFR prior to reuse, regardless of decontamination treatment.

The protocols described herein were derived from peer-reviewed publications, as well as studies performed by fellow academic and research institutions. The COVID-19 Healthcare Coalition does not endorse one method or option, but rather leaves it to users to determine the most appropriate decontamination method for their purposes, which may be dependent on available infrastructure and resources.

Vaporized Hydrogen Peroxide (VHP)

Basic Requirements

To effectively use VHP as a decontamination process, the following parameters should be followed.

- Use of 30% H₂O₂
- Minimum Process requirements: VHP room concentration = 8 g/m³, 15 min dwell, 125 min total cycle time.
- Use of a VHP generator as required

Option 1: Whole Room VHP Materials and Protocol¹

- Room Bio-Decontamination Service (RBDS™, BIOQUELL UK Ltd, Andover, UK) consisting of:
 - Clarus® R HPV generator (utilizing 30% H₂O₂)



- Clarus R20 aeration unit
 - Instrumentation module (to measure VHP concentration, temperature, and relative humidity)
 - Control computer
1. Prior to implementing decontamination treatment:
 - a. The Clarus® R was placed in a room (64 m³).
 - b. The VHP concentration, temperature and relative humidity within the room were measured by the instrumentation module and monitored by a control computer situated outside the room.
 - c. VHP room concentration = 8 g/m³, 15 min dwell, 125 min total cycle time.
 2. Upon testing, FFRs were hung on a string stretching across the length of room.
 3. According to manufacturer instructions, the Clarus® R HPV is placed in a room that is conditioned to 8 g/m³ prior to initiating decontamination cycle (15 min dwell, 125 min total cycle).
 4. Following HPV exposure, the Clarus R20 aeration unit was run overnight inside the room to catalytically convert the VHP into oxygen and water vapor.
 5. The treatments were performed on three consecutive days (one treatment per day).

Option 2: Mail-away Materials and Protocol²

- STERRAD 100S H₂O₂ Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA, USA)



- Mylar/Tyvek self-seal pouches



1. FFRs and a chemical indicator are placed in an individual Mylar/Tyvek self-seal pouch.
2. FFRs were shipped to and from a commercial facility specializing in low-temperature sterilization methods and were tested within 72 hours of receipt.
3. Self-seal pouches were placed in a STERRAD 100S H₂O₂ Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA, USA) and processed using the single 55-minute standard cycle.

Option 3: VHP Procedure Developed by Duke Health and Battelle^{3,4}

- For materials, procedures, and healthcare professional roles in the implementation of vaporized hydrogen peroxide (VHP) for the decontamination of N95 respirators, please refer to the following documentation: https://www.safety.duke.edu/sites/default/files/N-95_VHP-Decon-Re-Use.pdf (Duke Health) and <https://www.fda.gov/media/136386/download> (Battelle).
- An animated video of the Battelle Decontamination system can be found at the following link: <https://www.battelle.org/inb/battelle-critical-care-decontamination-system-for-covid19>.



Inside the VHP chamber for PPE decontamination using Battelle's design. Image from: <https://news.stonybrook.edu/newsroom/battelle-ccds-critical-care-decontamination-system-arrives-at-stony-brook-university/>.

Duke Procedure:

1. The Duke BSL3 facility contains a room specifically designed to use VHP to decontaminate laboratory equipment and utilizes a Bioquell Clarus™ system with a 35% hydrogen peroxide solution and distribution system to uniformly disperse VHP into the room.
2. N95 masks were collected and hung from stainless steel wire racks in VHP processing room. This process consisted of five stages: Conditioning, Pre-gassing, Gassing, Gassing Dwell, and Aeration.
3. Existing VHP SOP was employed and required a concentration of 480+ ppm of VHP with a “Gassing” time of 25 minutes and a “Gassing Dwell” time of 20 minutes.
4. At the end of a cycle, during the aeration stage, fresh air is introduced into the room to increase the rate of catalytic conversion of hydrogen peroxide vapor into oxygen and water. This procedure leaves no residue other than water.
5. A PortaSens II™ sensor is used to ensure hydrogen peroxide levels were below the OSHA PEL of 1.0 ppm.
6. After four hours of aeration, the VHP levels decreased below the PortaSens II™ level of detection (0 ppm).
7. After aeration, place respirators into quantitative fit test to ensure continued performance.

Battelle Procedure:

1. HPV exposure was conducted with the Bioquell Clarus C system.
2. Four steps were employed: Conditions, gassing, dwell (or contact time), and aeration.
3. The chamber used was a static glove-box (Model No 830-ABC, Plas-Labs, Inc., Lansing, MI) with dimensions of 71 cm x 59 cm x 74 cm and an internal volume of about 310 L.
4. A conditioning time of 10 minutes was used.
5. A gassing time of 20 minutes was employed with a VHP gas injection rate of 2.0 g/min.
6. A dwell time of 120 minutes is recommended for complete decontamination.
7. During the aeration phase a low-level hydrogen peroxide monitor was used (Portasens II, International, Inc. DeMotte, IN). The sensor has a range of 0 to 10 ppm in increments of 0.1 ppm. Five hours of aeration was required to achieve a non-detect for hydrogen peroxide.

8. This approach is intended to decontaminate FFRs in bulk at the end of a work shift.
9. FFRs underwent 50 decontamination cycles with no drop in collection efficiency; however, after 20 cycles, there was sufficient strap degradation such that fit tests were unable to be performed.

Ultraviolet Germicidal Irradiation (UVGI)

Basic Requirements

To effectively use UVGI as a decontamination process, the following parameters should be followed.

- Lamp with bulbs that emit UV-C wavelength (~ 254nm)
- UV Meter to monitor the dosage of light administered to the masks
- Total UV-C dosage amounts greater than 3mJ/cm² to less than 1000mJ/cm²
 - a. Average has been between 60 – 300 mJ/cm², but at least 160 mJ/cm² is recommended⁷
- Time duration is based on the wattage of the bulb to achieve the desired UV exposure
- Proper eye wear protection (if around or in contact with the light source)
- UV-reflective paint for the chamber or room (optional)
- Ensure that geometry provides uniform exposure with no shadowing and that both surfaces are exposed

Option 1: Benchtop UVGI Materials and Protocol¹

- UV Bench Lamp (UV-C, 254 nm, 40 W), Model XX-40S (UVP, LLC, Upland, CA)



- UVX Digital Radiometer, UVX-25 Sensor (254 nm filter) (UVP, LLC, Upland, CA)



- Laboratory chemical fume hood
1. A UV Bench Lamp (UV-C, 254 nm, 40 W), Model XX-40S (UVP, LLC, Upland, CA) was used for this decontamination procedure.
 2. The experimental conditions were as follows:
 - a. Test tube racks were placed beneath both ends of the lamp to lift the lamp ~25 cm from the working surface of a laboratory hood.
 - b. The UV intensity was reported as the mean of 27 measurements over the rectangular area used at the surface of the hood using a UVX Digital Radiometer with a model UVX-25 Sensor (254 nm filter) (UVP, LLC, Upland, CA).
 3. Only the exteriors of the FFRs were exposed. The duck bill and flat fold style FFRs were placed over standard beakers to facilitate exposure to the FFR surface.
 4. The exteriors of the FFRs were exposed for 45 minutes at 1.8 mW/cm² (note: one 45-minute continuous exposure constitutes the 3X cycle).

Option 2: Flow Cabinet Materials and Protocol²

- Sterilgard III laminar flow cabinet (The Baker Company, Sanford, ME, USA)



- UV-C lamp capable of providing 40W at intensity range 0.18 – 0.20 mW/cm²
1. FFRs are placed on the working surface of a Sterilgard III laminar flow cabinet (The Baker Company, Sanford, ME, USA) fitted with a 40W UV-C light (average UV intensity experimentally measured to range from 0.18 – 0.20 mW/cm²).

2. FFRs are exposed for 15 minutes on each side (outer and inner), totaling a UV dosage of 176 – 181 mJ/cm² exposure to each side of the FFR.

Option 3: University of Nebraska Medical Center⁵

- For materials, procedures, and healthcare professional roles in the implementation of a scalable UVGI decontamination and reuse of N95 FFRs, please refer to the following documentation: <https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf>. Of note, Nebraska Medical Center lined the experiment chamber (i.e., full-sized room) with UV-reflective paint to amplify signal and reached a measurement of >100mJ (but 60mJ is believed to be sufficient).
 - University of Nebraska Medical Center based their technique on a joint FDA and Applied Research Associates (ARA) study published on Sept 30, 2019, and showed respirators could undertake 20 cycles of UVGI decontamination at doses upward of 1J/cm² with limited impact on overall performance.⁸
 - N95 FFRs were subjected to UVGI at a room exposure of 300mJ/cm² total exposure. Based upon the bulbs used the duration of time to achieve that dosage was approximately 5 minutes.
1. In the decontamination process the N95 FFRs are subjected to a room exposure of 300 mJ/cm². This exposure is measured for one of the two UVGI sources and from a location that receives the lowest UVGI dose---this does not represent the dose on the surface of each N95 FFR. Exposure mapping of the system indicated N95 FFR received a dose of double the measured dose from each side of the N95 FFR.
 2. Respirators are secured on wires that are strung across a room with two UVGI towers (ClorDiSys UVGI Light System, <https://www.clordisys.com/products.php>) on either side.
 3. Each of the two UVGI towers are equipped with eight 254 nm bulbs; these bulbs are routinely used in biosafety cabinets and produce 200 μw/cm² at 10 feet distance for a dosage of 12 mJ/minute.
 4. We monitor the delivered UVGI exposure dose with a room UVGI meter that can be initiated and monitored from outside the room to verify that the desired exposure has been achieved. Prior to initiating the decontamination program, the walls and ceiling were covered with a UV-4 reflective coating (<https://lumaccept.com>).

Option 4: Stanford UVGI Procedure

1. The UVGI sterilization cabinet here provides UV-C light centered at 254 nm with intensity of 8 W (considering the internal area of 475 cm², the total light intensity is 17 mW/cm²).
2. The treatment time is 30 minutes per cycle, resulting in an estimated fluence of all radiation in the chamber at ~30 J/cm² per cycle (Note that this is far above the necessary radiation to inactivate SARS-CoV (~3.6 J/cm²). By 20 cycles, the filtration slightly drops to ~93%, making it unsuitable for N95-grade FFRs by itself.
3. The UVGI (254 nm, 17 mW/cm²) sterilizer cabinet used in these tests does not have enough dose to damage the respirators within a reasonable number of treatment cycles and may be considered for disinfection, with doses smaller than 1000 J/cm².

4. FFRs underwent 10 decontamination cycles before seeing slight drops in filtration efficiency.

Moist Heating (~80% RH)

Basic Requirements

To effectively use Moist Heating as a decontamination process, the following parameters should be followed.

- Laboratory Incubator or equivalent method of heating device
- Water vessel to increase the Relative Humidity (RH) to $\geq 80\%$
- Temperature must remain between 60-75°C, as anything greater will affect the integrity of the mask
- It has been shown that a safer threshold for SARS-CoV-1 inactivation in culture media should be set to at least 75°C for at least 30 minutes⁷; other work has indicated that filter effectiveness is not affected up to 20 decontamination cycles at 75°C for 30 minutes⁶

Option 1: Laboratory-grade Incubator Materials and Protocol¹

- Caron model 6010 laboratory incubator (Marietta, OH)



1. According to manufacturer instruction, FFRs are incubated for 30 minutes at 60°C, 80% relative humidity (RH) in a Caron model 6010 laboratory incubator (Marietta, OH).
2. Following the first incubation, the samples were removed from the incubator and air-dried overnight. Following the second and third incubations, samples were removed from the incubator and air-dried for 30 min with the aid of a fan.

Dry Heating (~30% RH)

Basic Requirements

To effectively use Dry Heating as a decontamination process, the following parameters should be followed.

- Laboratory Incubator or equivalent method of heating device (e.g., laboratory-grade oven)
- Lowest humidity setting possible approaching relative humidity (RH) ~30%
- Temperature must remain between 80-100°C; heating temperatures must remain below 100°C to avoid changes to filtration properties and above 75°C to enable viral inactivation⁷
- It has been shown that a safer threshold for SARS-CoV-1 inactivation in culture media should be set to at least 75°C for at least 30 minutes⁷; other work has indicated that filter effectiveness is not affected up to 50 decontamination cycles at 75°C for 30 minutes⁶

Option 1: Laboratory-grade Oven Materials and Protocol⁶

- Fisher Scientific Isotemp 500 Series laboratory oven (Fisher Scientific, Pittsburgh, PA, USA)



Stanford Procedure

1. FFRs were placed in a Fisher Scientific Isotemp 500 Series laboratory oven (Fisher Scientific, Pittsburgh, PA, USA) for 1 hour at temperatures ranging from 80 to 100°C at lowest humidity settings (~30% RH). These parameters result in the minimal change in filter efficiency while maintaining mechanical robustness of respirator components.
2. The temperature of 75°C is selected as application of this temperature to the N95 masks for 50 cycles did not change the filtration efficiency of the meltblown fabric's (present within the mask).

References

- [1] Bergman, M. S., Viscusi, D. J., Heimbuch, B. K., Wander, J. D., Sambol, A. R., & Shaffer, R. E. (2010). Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators. *Journal of Engineered Fibers and Fabrics*. <https://doi.org/10.1177/155892501000500405>.
- [2] Viscusi, Dennis J., Bergman, Michael S., Eimer, Benjamin C., Shaffer, Ronald E. (2009). Evaluation of Five Decontamination Methods for Filtering Facepiece Respirators. *The Annals of Occupational Hygiene*. 53: 815-827. <https://doi.org/10.1093/annhyg/mep070>.
- [3] Schwartz, A. et al. (2020). Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor to Address Worldwide Personal Protective Equipment Shortages During the SARS-CoV-2 (COVID-19) Pandemic. Retrieved March 31, 2020, from: https://www.safety.duke.edu/sites/default/files/N-95_VHP-Decon-Re-Use.pdf.
- [4] Final Report for the Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination for Reuse of N95 Respirators. Prepared by Battelle Columbus, Ohio. Prepared under Contract No. HHSF223201400098C. Study Number 3245. Prepared for the FDA. July 2016. Accessed, March 31, 2020 <https://www.fda.gov/media/136386/download>.
- [5] Lowe, John J. et al. (2020). N95 Filtering Facepiece Respirator Ultraviolet Germicidal Irradiation (UVGI) Process for Decontamination and Reuse. Retrieved March 25, 2020, from: <https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf>.
- [6] Liao, L., Xiao, W., Zhao, M., Yu, X., Wang, H., Wang, Q., Chu, S., Cui, Y. (2020) Can N95 respirators be reused after disinfection? And for how many times? Retrieved from April 1, 2020 email correspondence.
- [7] Duan, S. et al. (2003) Stability of SARS Coronavirus in Human Specimens and Environment and Its Sensitivity to Heating and UV Irradiation. *Biomedical and Environmental Sciences*. 16: 246-255. https://www.researchgate.net/publication/8995908_Stability_of_SARS_Coronavirus_in_Human_Specimens_and_Environment_and_Its_Sensitivity_to_Heating_and_UV_Irradiation.
- [8] Heinbuch et al. (2019) Research to Mitigate a Shortage of Respiratory Protection Devices During Public Health Emergencies. Contract number: HHSF223201400158C. Applied Research Associates in the Engineering and Science Division.