Pan American Health Organization
World Health Organization
Regional Office for the Americas

PAHO

Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages

10 June 2020

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Objectives

- This document presents issues related to the extended use, reuse, and reprocessing of N95 and equivalent respirators by health services during shortages of this personal protective equipment (PPE).
- It summarizes the available evidence on existing methods for reprocessing N95 and equivalent respirators.
- Its audience is health facility managers, health authorities, and others involved in decision-making on the use and prioritization of PPE.*
- These are interim recommendations subject to review as new evidence becomes available.†

Summary

- N95 or equivalent respirators are single-use personal protective equipment (PPE) designed for use by health workers that provide direct care to patients with diseases transmitted by aerosols or during aerosol generating procedures (AGP) for patients with acute respiratory disease, as is the case of COVID-19 *(1)*.
- Given the current shortage of N95 and equivalent respirators, the World Health Organization (WHO) has suggested the possibility of their extended use by the same individual for up to 6 hours or the reprocessing of respirators when necessary *(2)*.
- During shortages of N95 and equivalent respirators, stopgap measures for optimizing their use may be considered, among them extended use and reuse. Since risks are associated with these measures, special criteria and precautions should be used when adopting them, confining their use to situations where they are indispensable.
- Extended use is recommended over reuse, because the latter requires a controlled procedure in the health services and implies that the staff performing it will come into contact with contaminated respirators, increasing the risk of occupational exposure.
- During critical respirator shortages, reprocessing can be considered. Although saturated steam, UVC radiation, and gas plasma or vaporized hydrogen peroxide sterilization are the respirator reprocessing methods with the most evidence of efficacy to date, no method can be adopted without prior local validation testing in the health facility. A written protocol for the procedure should be also prepared and health workers trained in the proper use of the reprocessed respirators. Respirator reprocessing should be regulated by the regulatory authority with jurisdiction over these medical devices.
- The method selected by a health facility will depend on its infrastructure and ability to prepare and implement operating protocols that guarantee the efficacy and safety of the respirators after reprocessing.

Glossary

- **Disinfection:** A process to reduce the number of viable microorganisms to a less harmful level. This process may not inactivate bacterial spores, prions, and some viruses *(3)*.
- **Sterilization:** A validated process used to render an object free of viable microorganisms, including viruses and bacterial spores, but not prions *(3)*.
- **Medical mask:** Masks used in surgery and other clinical procedures. They can be flat or pleated (some are shaped like cups) and secured to the head with straps. They are tested using a series of standard methods (ASTM F2100, EN 14683 or equivalent) that aim to balance high filtration, adequate breathability, and optionally, fluid penetration resistance *(2,4)*.
- **Fit test:** Use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator for an individual to determine whether there is leakage and the respirator is not filtering adequately. This test is necessary for selecting the most appropriate type and size of respirator for an individual. Each individual should use only the specific respirator that yielded satisfactory results when subjected to the fit test. Testing should be done at least annually, and every time that new respirator is introduced in a facility or a physical change is detected in the user that could alter the balance between the type and size of the respirator and the user's face *(5)*.
- **Seal check:** This test should be performed prior to each use of the respirator to ensure it is working properly before the health worker's contact with the patient. If not performed, there is no guarantee that the respirator is doing its job of filtering the inhaled air, and the protective effect would be equivalent to that of a mask *(5)*.

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* Click on this link for more information on WHO advice on the use of masks in the community in general.

† Up-to-date information on COVID-19 is available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019.

- **Respirator:** A protective device designed to achieve very tight facial fit and highly efficient filtration of airborne particles *(6)*. The choice of respirator will depend on the contaminants to which the worker is exposed *(7)*.

N95 and equivalent respirators

- N95 respirators are a type of filtering facepiece respirator (FFR) that is not resistant to oil or solvents (N) and blocks at least 95% of airborne particles greater than 0.3µm in size. These devices are designed to fit around the user's nose and mouth, creating an airtight seal with the face*(8)*. N95 respirators are made of several layers of non-woven synthetic material treated to sustain an electrostatic charge. In addition to creating a mechanical barrier against aerosols, they retain charged particles, such as bacteria, and adequately protect against most airborne pathogens in a health care setting. The majority of N95 respirators are intended as disposable, single-use devices, but reusable models are available *(8)*.
- In the United States, N95 respirators are subject to performance testing and certification by the National Institute for Occupational Safety and Health (NIOSH).
- In Europe, the nearest equivalent to N95 respirators is FFP2 devices, which are required to eliminate 94% of particles greater than 0.6 µm in size *(8)*.
- According to the PAHO List of Priority Medical Devices in the context of COVID-19 *(9)*, N95 respirators should meet the following specifications and quality criteria:
    - N95 or FFP2-grade (or higher) respirator that permits good breathability and has a design that does not collapse against the mouth.
    - Compliance with:
        - Regulation EU PFP 2016/425 Category III, CE Mark and certification by Notifying Body
        - EU MDD (directive) 93/42/EEC Class I; or
        - FDA Class 2
        - Minimum "N95" respirator according to CDC NIOSH 42 CFR 84; or
        - Minimum "FFP2" according to EN 149
- Table 1 presents some performance standards and product classifications for respirators with filtration efficiency and protection similar to that of N95 respirators (which meet the CDC NIOSH 42 CFR 84 standard) and whose use is authorized by the United States Food and Drug Administration (USFDA), through an emergency use authorization (EUA), as equivalent to N95 respirators in the context of the of COVID-19[‡] pandemic *(10)*.

Table 1. Performance standards and product classifications approved by the USFDA as equivalent to N95 during the COVID-19 pandemic.

Jurisdiction	Performance standard	Acceptable product classification	Standards/Guidance documents	Protection factor ≥10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715: 2009	Yes
Brazil	ABNT/NBR 13698:2011	FFP3, FFP2	Fundacentro CDU 614.894	Yes
Europe	EN 149 – 2001	FFP3, FFP2	EN 529:2005	Yes
Japan	JMHL, W-2000	DS/DL3 DS/DL2	JIS T8150:2006	Yes
South Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	Yes
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	Yes

Source: FDA Combating COVID-19 with Medical Devices (11).

[‡] The USFDA also considers disposable respirators with marketing authorization in the one of the following regulatory jurisdictions to be equivalent: European CE Marking, Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada License, Japan Pharmaceuticals and Medical Device (PMDA) / Ministry of Health, Labor, and Welfare (MHLW) *(11)*.

- The USFDA has issued an EUA *(12)* for a series of disposable respirator models manufactured in China, unapproved by NIOSH, that it considers to meet the N95 filtration standard. The respirator models included in this EUA are reviewed periodically, and can be viewed at this link.
- On June 7, 2020, the USFDA has revised the relevant EUAs for respirator decontamination systems, so that they are no longer authorized to decontaminate respirators manufactured in China. According to CDC NIOSH testing, respirators manufactured in China may vary in their design and performance and the available information does not support the decontamination of these respirators *(13)*.
- Additionally, according to the USFDA EUAs revised on June 6, 2020, respirators with exhalation valves should not be decontaminated and are no longer authorized to be decontaminated by any authorized decontamination systems *(13)*.

Optimization of respirator use during shortages

- Respirator availability can be seriously affected during epidemics of infectious respiratory diseases, as in the current COVID-19 pandemic. WHO has published recommendations on rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages *(14)*. Multiple strategies can be employed to increase the availability of these devices, among them:
    - **Minimize the need for respirators in health care settings –** for example, keep confirmed COVID-19 patients without coinfection with other transmissible microorganisms in the same room to streamline the workflow and facilitate extended use of the respirators.
    - **Reserve respirators for health personnel** that perform AGP.
    - **Coordinate mechanisms for respirator supply chain management** *(14)*.

Considerations on decision-making during respirator shortages

- When **respirator shortages** occur despite use of the aforementioned strategies, other **stopgap measures** should be considered. It is important to note that such measures are only temporary and should be limited to the fewest possible situations *(14)***.**
- The following stopgap measures can be used in isolation or in combination, depending on the local situation:
    1. Use of alternatives to respirators. These include other classes of respirators with a filtration mask, halfpiece and fullpiece elastomeric air purifying respirators, and powered air purifying respirators *(15)*. All of these alternatives provide equivalent or greater protection than improperly used respirators *(16)*. Click on this link to find CDC recommendations on the use of elastomeric respirators *(17)*.
    2. Use of respirators beyond the manufacturer's expiration date *(18)*.
    3. Use of respirators for periods longer than indicated in the standards, such as the 6 hours suggested by WHO.
    4. Reprocessing and subsequent reuse (after cleaning or disinfection/sterilization) of reusable or disposable respirators.

Extended use of respirators

- Single-use respirators should be discarded after each use in a procedure or encounter with a patient for whom they are required, since potentially hazardous waste is involved. However, during shortages, N95s can be used for up to 6 hours, as long as the seal between the respirator and the face remains airtight and the mask is not wet or damaged *(8)*.
- **Extended use** refers to the practice of using the same respirator for the care of several patients without removing it between patient encounters. While this is easier to do when the patients are together in dedicated wards, it can be done in other situations. It is recommended that these respirators be used for no more than 6 hours *(14)*.

Risks associated with the extended use of respirators

- **Extended use** of respirators can increase the chance of health workers touching the mask or having inadvertent under-mask touches; if the mask is touched/adjusted, hand hygiene must be performed immediately *(14)*.
- Extended use of respirators can cause facial dermatitis, respiratory fatigue, impaired work capacity, increased oxygen debt, early exhaustion at lighter workloads, elevated CO_2 levels, and increased non-compliance with best practices while wearing the respirator *(14).*
- Extended use may clog the filtration media, leading to increased breathing resistance *(14)*.

Precautions for reuse of respirators

- If the respirator becomes wet, soiled, degraded, or difficult to breathe through.
- If exposed to splashes of chemicals, infectious substances, or bodily fluids.
- If displaced from the face for any reason.
- If the front of the respirator is touched to adjust it, the safe removal procedure should be followed without touching the front *(14)*.
- **Extended use is recommended over reuse**, because the latter requires use of a controlled procedure in the health services and implies that health workers will come into contact with contaminated respirators, increasing the risk of occupational exposure.

Reuse of respirators

- **Reuse** refers to the practice of using the same respirator for multiple patient encounters but removing it after every encounter *(18)*. The respirator is stored between encounters and may or may not be reprocessed before it is donned again for the next patient encounter. **Reprocessing** is understood as the decontamination of a respirator using disinfection or sterilization methods *(14)*.
- A reuse strategy recommended by the Centers for Disease Control and Prevention (CDC) of the United States to reduce the risk of transmitting pathogens from the respirator to the user is to provide all health workers who perform AGP with as many N95 respirators as the number of days they work per week, enabling them to use a respirator, properly store it, and reuse it up to seven days later *(18)*.

Precautions for respirator reuse

- The following **precautions** should be taken to ensure safer reuse of respirators:
    - Use a face shield over the respirator whenever possible to reduce the likelihood of contaminating the surface of the respirator.
    - Put respirators in a designated storage area and keep them in clean, breathable containers, such as a paper bag.
    - The containers should be clearly marked and kept separate, in addition to being discarded regularly.
    - Health workers should clean their hands with soap and water or alcohol-based hand sanitizer whenever they handle the respirator: when putting it on, taking it off, and adjusting it *(18).*

Risks associated with respirator reuse

The Table 2 describes the risks associated with respirator reuse.

Table 2. Risks associated with respirator reuse

Risk	Remarks
Loss of fit	Respirators are secured with metal clips or elastic bands that are not designed to last, and breakage with reuse is common. It is recommended that respirators be closely inspected before reuse, that proper donning techniques be employed, and that the seal be checked. The manufacturer's instructions should be followed, and the number of reuses limited to no more than five *(18)*.
Loss of filtration efficiency	Reuse without reprocessing does not pose a great risk; however, decontamination procedures can damage the filter, depending on the method and materials and the respirator's design *(18)*.
Risk of spreading the infection	Respirator surfaces can be contaminated when filtering the air inhaled by the user during exposure to aerosols containing pathogens. Pathogens in the filter materials can be transferred to the user by touching the respirator when adjusting it, improperly removing it, or checking the seal of a previously used respirator. A study evaluating the persistence of SARS-CoV-2 on plastic, stainless steel, and cardboard surfaces showed that the virus can survive for up to 72 hours *(19)*.

Reprocessing of respirators

- If supplies are even scarcer, it may be necessary to reprocess respirators between uses. **Reprocessing** is understood as the decontamination of a respirator using disinfection or sterilization methods *(14)*.
- It is important to consider three issues before deciding to reprocess respirators:

  1) Local regulations governing the reprocessing of medical devices,
  2) The availability of sterilization methods of proven efficacy for respirator reprocessing,
  3) The existence of validated local protocols for respirator reprocessing.

- The principal methods for reprocessing respirators are described below. Since there are no standardized and consolidated respirator reprocessing methods, **this possibility should be considered only during critical shortages or the absence of respirators.**
- The main factors in considering a reprocessing method acceptable are:

  1) the efficacy of the equipment disinfection/sterilization method;
  2) maintenance of the respirator's filtration efficiency;
  3) retention of the respirator's shape and therefore its fit;
  4) safety of the respirator's user (for example, toxicity after the reprocessing) *(14)*.

- Current evidence on the efficacy of the methods for decontaminating a respirator specifically against SARS-CoV-2 is still limited and constantly evolving. It is important to use this information with caution, since in some cases, it has not yet been peer-reviewed. It should also be borne in mind that other pathogens may be present in reprocessed respirators; health workers should therefore handle reprocessed respirators with extreme caution.
- Health workers should take the following precautions when using a reprocessed respirator:
  - Avoid touching the inside of the respirator, and clean hands with soap and water or alcohol-based hand sanitizer before and after touching the respirator.
  - Visually inspect the respirator to determine whether its integrity has been compromised. Check that the straps, nose bridge, and nose foam material are not degraded, as this can affect the quality of the fit and seal.

  - Perform a seal check immediately after donning each respirator, and do not use a respirator without an adequate seal.
  - If the integrity of any part of the respirator is compromised, or if a successful user seal check cannot be performed, discard the respirator *(20).*

- For more information on the precautions to take when handling reprocessed FFRs, visit Prevention and Control of Healthcare-associated infections *(4)*.

Criteria for discarding or reprocessing respirators and precautions

- After a predetermined number of reuses, respirators should be discarded in an adequate, closed container following local directives or policies.
- After the respirator is removed, it should immediately be placed in a specific container for reprocessing, marked with the name of its original user.
- The respirator should be returned to its original user after every reprocessing cycle.
- When reprocessing respirators, the human resources, equipment, procurement of consumables, and health worker safety should be considered.

Regulation of respirator reprocessing

- **Any N95 reprocessing method that is going to be adopted must be regulated by the competent local regulatory authority**. Health authorities should require health facilities to perform **local validation testing** before adopting a respirator reprocessing method to ensure that the shape and fit are preserved once the process is completed and to determine the maximum number of reprocessing cycles. They should also require facilities to produce a written protocol for the process and guarantee that health workers will be trained in the proper use of the reprocessed respirators.
- National regulatory authorities (NRA) in the Region of the Americas were asked to participate in the preparation of this document by providing information on regulations and making recommendations for the reprocessing of respirators. As of its publication date, such regulations are limited. When the competent jurisdiction has no regulations on respirator reprocessing, NRAs can avail themselves of the regulatory decisions and information from other NRAs to inform their own regulations *(21,22)*.
- The regulatory agency of the United States, USFDA, and the Canadian agency, *Health Canada (23),* have issued regulations for the authorization of equipment and reprocessing procedures. The USFDA has issued a compulsory compliance policy *(24)* stipulating the minimum information that should be provided to it and the basic requirements that a decontamination process should meet before submitting the EUA request. *Health Canada* aligned itself with the USFDA criteria for the emission of its Interim Orders. The main features of this policy are summarized below:
- **Minimum information that producers should provide to the regulatory agency (*USFDA or Health Canada*)** *(23,24).*
  - A description of the reprocessing process, including the scientific rationale.
  - Microbial testing that validates the reduction/disinfection of the pathogen burden.
  - A description of the chain of custody and safeguards to prevent inadvertent exposure.
  - Compatibility of the respirator material with the reprocessing process
  - Performance testing, including t filtration performance, fit test data (airflow resistance, exhalation valve leakage)
  - Adequate labeling of the reprocessed device that includes the maximum number of times the device can be reprocessed, and the method for tracking the number of times it has been reprocessed.

- *Health Canada* has identified the **minimum requirements and essential information** for N95 reprocessing processes in the current context:
  - Reduce pathogen burden:

        - **Bacterial sporicidal testing,** biological indicators for the different sterilization methods.
        - **Viral inactivation testing** (for example, SARS-CoV-2, MERS-CoV, SARS-CoV, H1N1, influenza A/PR/8/34), including the use of surrogates. Risk Group 2 bacteria or viruses or other microorganisms not required to be handled in biosafety level 3 laboratories can be used as surrogates.
        - Use of the **disinfectant parameters** specified in the labeling of the reprocessing equipment.
        - **Sterility indications**: A sterility assurance level (SAL) of 10^{-6} is usually accepted for sterilization procedures.
    - Maintain performance:
        - **Particle filtration efficiency**: breathability and valve leak tests (where applicable) and respirator fit testing. The maximum number of suggested reprocessing cycles should be indicated and adequate performance demonstrated once the maximum number of cycles has been reached.
        - **Fit tests**: alternative fit tests can be considered and demonstrated. It will be necessary to inform users whether an acceptable fit can be achieved with the reprocessed respirators or alternative uses for them are recommended.
        - **Tracking and recording reprocessing cycles**: a method for tracking the number of times a specific respirator has been reprocessed should be indicated. Respirators can be marked directly (on the elastic, for example).
- Not pose a residual chemical risk:
    - **Measurement and assessment of residual chemicals**, or scientific rationale in its place.
- Provide users/reprocessors with adequate labeling, including:
    - **Validated reprocessing methods and conditions** (for example, temperature, disinfectant concentration, contact time, density).
    - **Notices** that include any **performance or safety testing** that has not been validated.

- ANVISA, the Brazilian regulatory agency, has issued a technical note for the health services on prevention and control measures to adopt when caring for suspected or confirmed cases of SARS-CoV-2 [in Portuguese only]. It requires health services and research institutions that reprocess respirators to develop a protocol to guide health workers on the use, removal, packing, integrity assessment, use time, and criteria for discarding respirators. It also contains guidelines on the extended use and reuse of respirators *(25)*.

Respirator reprocessing methods

- Multiple respirator decontamination or sterilization methods have been evaluated. Based on the current evidence, the paragraphs below provide a more detailed description of the most promising reprocessing methods, due to their efficacy in guaranteeing sterilization/decontamination, preservation of the respirator's filter capacity and fit, and user safety. These methods involve the use of **saturated steam**, **UVC radiation**, and **gas plasma or vaporized hydrogen peroxide**
- Methods that damage respirators, are not effective sterilization methods, or result in toxicity or loss of filtration efficiency should be avoided. Some of these include washing, saturated steam sterilization at 134° C, disinfection with bleach/sodium hypochlorite or alcohol, and irradiation in microwave ovens and sterilization with ethylene oxide *(14)(20)*.

Gas plasma or vaporized hydrogen peroxide (HPV)

- **Gas plasma or vaporized hydrogen peroxide** is regularly used to sterilize thermosensitive medical materials *(26)*. **Hydrogen peroxide gas plasma** (HPGP, STERRAD) and **ionized hydrogen peroxide** (iHP, SteraMist) systems use ionization to accelerate the generation of hydroxyl radicals and rapidly eliminate the condensed peroxide *(27)*.

- The USFDA, the regulatory authority of the United States, has issued EUAs to five hydrogen peroxide decontamination processes.
- Table 3 presents the hydrogen peroxide decontamination processes approved in the United States for N95 respirators.

Table 3. Hydrogen peroxide decontamination processes approved in the U.S. for N95 respirators

System	Specifications	EUA Reference
Battelle *"Critical Care Decontamination System™" of VHP-GPHP (CCDS)*	Available at only 6 locations in the U.S. Maximum of 20 reprocessing cycles.	28 March 2020 *(28)*
STERIS VHPTM (V-PRO, maX and maX2)	Maximum of 10 reprocessing cycles.	9 April 2020 *(29)*
ASP STERRAD (100S, NX, 100NX)	Maximum of 2 reprocessing cycles.	11 April 2020 *(30)*
Sterilucent HC 80TT Hydrogen Peroxide Sterilizer	Maximum of 10 reprocessing cycles.	20 April 2020 *(31)*
Duke Decontamination System	Maximum of 10 reprocessing cycles.	7 May 2020 *(32)*

- In the Batelle system, available only in the United States, a hospital or health center mails a batch of masks for decontamination to one of the company's six decontamination centers. In the other four processes (Steris, STERRAD, Sterizone, Sterilucent), the procedure takes place in hospitals and requires specific protocols and dedicated staff, as well as a system for labeling masks with the user's identification and number of decontamination cycles.
- Multiple studies have demonstrated the **efficacy** of the gas plasma or vaporized hydrogen peroxide methods for sterilizing N95 respirators contaminated with aerosols or droplets containing the spores of highly resistant microorganisms, such as *G. stearothermophilus*, showing more than a 99.9% reduction. More recent, non-peer-reviewed studies have also demonstrated their efficacy in decontaminating N95 respirators inoculated with the SARS-CoV-2 virus, showing more than a 99.9% reduction *(32–34).*
- The respirators' **filtration efficiency** did not decline until 50 VHP decontamination cycles. Nevertheless, by the 20th cycle, the respirators straps showed degradation and were permanently deformed when stretched *(27).*
- It is important to bear in mind that hydrogen peroxide systems are not compatible with cellulose, which, though not a component of most respirators, may be present in some *(27).*
- Multiple types of systems administer hydrogen peroxide, varying in humidity, temperature, hydrogen peroxide concentration, and duration of the exposure, depending on whether the hydrogen peroxide is administered as steam, aerosol, or ionized gas.
- It is particularly important for hospitals to ensure that the correct protocol for decontaminating N95 respirators is compatible with the available equipment *(25, 26)*.

Saturated steam

- Saturated steam under pressure is a method often used for sterilizing medical items in the health services. Inexpensive and available in hospitals and health centers, it includes technologies as autoclaving.
- To date, no regulatory agency in the Region of the Americas has authorized the sterilization of respirators using saturated steam under pressure or dry heat.
- The most **efficacious conditions** for the inactivation of SARS-CoV-2 in N95 respirators are **temperatures of 70-85° C at a relative humidity of more than 50% for 60 minutes or more**. Higher temperatures or longer exposure times would lead to greater disinfection efficacy, provided that they preserve the integrity of the mask *(35–37)*.Under laboratory conditions, temperatures of 70° C in dry heat for 60 minutes have inactivated SARS-CoV-2 in respirators *(35)*. Another recent publication suggests that **N95 respirators contaminated with SARS-CoV-2 can be decontaminated after a 15-minute standard autoclave cycle at 121° C**, though it was found that some respirator models failed the fit test after one cycle under these conditions *(33)*.
- The presence of saliva and mucus can protect the virus from inactivation and may require more time and higher temperature or humidity to achieve inactivation *(38–40)*. It is important to point out that moist heat does not

necessarily inactivate all microorganisms potentially present in respirators *(42)*. Autoclaving can be an effective SARS-CoV-2 decontamination method for certain pleated and layered respirators but with molded models can fail after one or two cycles *(33)*.

- The various respirator models have different susceptibilities at high temperatures. The durability results for one model do not necessarily extend to other models, and the integrity of filtration efficiency can be affected to varying degrees. Any protocol adopted should be tested with the respirator models used locally *(43)*.

Ultraviolet radiation (UVC)

- Ultraviolet radiation inactivates pathogens by damaging their genomic material. UVC has been widely used for the decontamination of air, water, and surfaces and the inactivation of pathogens, such as the TB bacillus, in hospitals *(44)*. Its efficacy is critically dependent on the ultraviolet (UV) wavelength, achieving maximum efficacy in inactivating pathogens with UVC ~ 260 SL light at a dose of UVC (1.2J / cm^2). The dose is the product of irradiance (W/cm^2) and exposure time *(45)*.
- To date, no national regulatory agency has authorized the reprocessing of respirators with UVC.
- To date, there is no direct evidence that it inactivates the SARS-CoV-2 virus. Nevertheless, **inactivation efficacy** of more than 99.9% has been seen with viruses analogous to SARS-CoV-2, using a ≥1.0 J / cm^2 dose of UVC radiation at a maximum wavelength of 254 SL for most respirators. It should be noted, however, that **respirator straps require an additional decontamination method** *(46, 47)*. It should also be noted that **higher doses may be required to inactivate other classes of pathogens**, such as unwrapped viruses, bacteria, and bacterial spores and fungi. At these UVC doses, it is estimated that **fit** and **filtration efficiency** are retained for at least 10 cycles *(48)*. However, with repeated use, some respirators begin to fail after five cycles *(49)*.
- UVC light is attenuated as it passes through the respirator's layers, resulting in lower values at the center of the respirator filter than on the surface *(50)*. Shadows also reduce the dose of radiation received by the respirator. To mitigate this, both sides of the respirator must be irradiated, or the respirator should be turned over, ensuring that there is no obstruction between the UVC source and the respirator *(51)*.
- For all new UVC decontamination processes, the following points should be validated before moving ahead with respirator reprocessing:
    - Efficacy of the decontamination process (viral inactivation)
    - Subsequent respirator reuse capacity (filtration, fit)
- **The UVC dose should reach or exceed 1.0 J/cm^2** for the entire surface of the respirator and ideally should be validated with each cycle, or at least periodically. It is critical to measure the wavelength and irradiance of the UVC sources with specific UVC sensors to guarantee that the sources emit radiation within the UVC germicidal range *(45)*.
- Direct exposure to UVC radiation is hazardous to health. Proper controls should be place before using UVC systems to ensure that all users are adequately protected. The majority of UV medium-pressure lamps emit around 185 SL UV and, as a result, will generate ozone *(52)*. UVC sources that emit minimal or no ozone should be selected, and/or adequate ventilation should be confirmed to minimize the ozone risk.

Limitations and risks of respirator reprocessing

- Given the circumstances of the COVID-19 pandemic, it should be borne in mind that the evidence on the efficacy of the reprocessing methods described is very new (and in some cases has not been peer-reviewed) and constantly evolving. Protocols that will guarantee respirator efficacy and integrity after reprocessing have yet to be developed.
- The shelf-life of reprocessed respirators is unknown; however, degradation of the filter material or elastic bands after one or more sterilization cycles affects the respirator's fit to the face.
- Changes in the respirator's shape due to reprocessing can affect its fit and protective properties.
- The maximum number of reprocessing cycles varies widely, depending on the reprocessing method.

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