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Technical Bulletin

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# Reusable Respirator FAQ: Healthcare — United States

## Description

This is a general document for healthcare workers that is not specific to any particular airborne contaminant, including viruses and bacteria. When respiratory protection is required or recommended for healthcare professionals to help reduce their exposures to airborne particles, including bacteria and viruses that may cause disease, most often the requirement is for them to use a respirator that provides an "N95, FFP2 or similar" filtering performance. One style of respiratory protection that may be considered is an elastomeric respirator with a filter. The following are generalized responses to some frequently asked questions about elastomeric respirators.

It is important to note that guidance for healthcare professionals from all applicable occupational health authorities, such as the World Health Organization (WHO), United States Occupational Safety and Health Administration (OSHA), United States National Institute for Occupational Safety and Health (NIOSH), United States Centers for Disease Control and Prevention (CDC), the United States Environmental Protection Agency (EPA), and your local health authority, should be followed in any health emergency and that this document is not a substitute for that guidance.

**My reusable elastomeric respirator has an exhalation valve. Should a respirator with a valve be used by healthcare workers as source control?**

At times, healthcare workers may require both respiratory protection and source control. In their guidance titled Personal Protection Equipment: Questions and Answers, CDC says, "Wear a respirator without an exhalation valve when both source control and respiratory protection are required".

Additionally, in their guidance, the CDC says, "If only a respirator with an exhalation valve is available and source control is needed, cover the exhalation valve with a surgical mask, procedure mask, or a cloth face covering that does not interfere with respirator fit".

3M has not evaluated the practice of wearing surgical masks or other coverings over respirator exhalation valves. Due to the variability in design of source control masks and face coverings, it is not known how this practice might impact the respiratory protection performance of 3M respirators. It is important that the above guidance is recognized and then that each facility determine where respirators with exhalation valves are appropriate for use.

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

**How often do I need to change the filters used on my elastomeric respirator?**

3M particulate filters are constructed with electrostatically charged fibers to help trap particulates within the filter media. As particles are collected on the filter media, the respirator will eventually become more difficult to breathe through comfortably.

Replace 3M™ Particulate Filters when:

- It becomes difficult to breathe comfortably (this will vary from individual to individual).
- The filter becomes dirty or physical damage occurs.

- The filter is wet or submerged.
- Per facility's infection control policy.

3M does not recommend cleaning or disinfection of filter media (e.g., disc-style filters and pre-filter pads). However, some 3M filter products have a hard-plastic case surrounding the filter media, e.g., 3M part number 7093, filter adapter 603 and filter retainer 501. This hard case can be cleaned by wiping the outside surface with a damp cloth soaked in disinfecting solution.

**Does an elastomeric respirator need to be cleaned and/or disinfected after standard use in Healthcare?**

Per 3M Product User Instructions for the 6000 Series half facepiece respirator, cleaning is recommended after each use[1]. The OSHA Respiratory Protection Standard 29 CFR 1910.134 includes cleaning and disinfection guidance within the standard and in Appendix B-2, which involves immersion of the respirator facepiece (filters/cartridges removed). OSHA 29 CFR 1910.134 includes the following requirements-

1910.134 (h)(1)(i) Respirators issued for the exclusive use of an employee shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition;

1910.134 (h)(1)(ii) Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals;

1910.134 (h)(1)(iv) Respirators used in fit testing and training shall be cleaned and disinfected after each use"[3].

OSHA also states that "the use of individually wrapped cleaning towelettes may be appropriate as an interim method in the cleaning schedule for individually assigned respirators, but they must not be the only method in place"[4]. Facilities should review the complete OSHA Respiratory Protection Standard and Appendix B-2 for cleaning and disinfection requirements applicable to their specific situation. This guidance from OSHA, in addition to a facility's infection prevention policy, will inform the frequency at which each of these methods occur.

1. 3M™ 6000 Series User Instructions: https://multimedia.3m.com/mws/media/967510/3m-6000-series-half-facepiece-respirator-user-instructions.pdf
2. OSHA Cleaning Procedures: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppB2
3. OSHA 29 CFR Respiratory Protection Standard: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134
4. OSHA Instruction-Directive CPL 02-00-158 Inspection Procedures for the Respiratory Protection Standard: https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-00-158.pdf

**What can I use to clean and disinfect my elastomeric respirator and the exterior of certain filters and cartridges?**

For cleaning, soap and water or other neutral detergent can be considered.

For disinfecting, there are numerous disinfectants that can be considered. Please see this 3M Technical Data Bulletin for the most current list of options: 3M™ Technical Bulletin Cleaning and Disinfecting 3M Reusable Elastomeric Half and Full Facepiece Respirators following Potential Exposure to Coronaviruses: https://multimedia.3m.com/mws/media/1793959O/cleaning-and-disinfecting-3m-reusable-respirators-following-potential-exposure-to-coronaviruses.pdf

We have not tested every disinfectant with each respirator, as the list is exhaustive, however harsher chemicals and more frequent cleaning may lead to earlier degradation of the respirator. Therefore, performing a water wipe down after disinfectant contact time and performing a thorough inspection before donning to ensure the respirator is in good, safe working order are critical. Replace any parts as needed.

**How do I know how to use my selected disinfectant? For example, I need help with dilution instructions, contact time, etc.**

The EPA label of a registered disinfectant will provide detailed guidance on:

- Cleaning (sometimes called pre-cleaning) requirements
- Dilution instructions (if applicable)
- Antimicrobial claims and their relevant contact times
- Other important information

You can search by EPA registration number to access the EPA label for your selected disinfectant. Use this link to search by EPA registration number: https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1

**What decontamination methods are acceptable for my reusable elastomeric respirator?**

Many decontamination methods are likely not appropriate for use with 3M reusable respirators due to potential for product degradation or damage. 3M has not evaluated and so DOES NOT recommend the following for use on reusable elastomeric facepieces or their filters/cartridges:

- Ethylene oxide or formalydehyde
- Ionizing Radiation
- Microwave
- High Temperatures above 75°C, such as Autoclave or Steam
- Ozone
- Vaporized Hydrogen Peroxide (VHP)

**Can I share my elastomeric respirator facepiece and/or cartridges and filters?**

Yes, you can consider sharing reusable respirators, but 29 CFR 1910.134 OSHA Respiratory Protection Standard states that "Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals"[1].

More detailed cleaning and disinfection guidance can be found here: https://multimedia.3m.com/mws/media/1793959O/cleaning-and-disinfecting-3m-reusable-respirators-following-potential-exposure-to-coronaviruses.pdf

1. OSHA Respiratory Protection Standard: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

**How often do I need to clean the filters used on my reusable respirator?**

Per the CDC, on an emergency basis during contingency and crisis capacity emergency use:

- Filters (except for unprotected disc type, i.e., pancake style) may be used for an extended period, if the filter housing of cartridge types is disinfected after each patient interaction provided the disinfectant or cleaning agent does not come in contact with the filter media.
- Filters, even cartridge types, must not be dipped or immersed in a cleaning or disinfection solution because this may damage or render the filter material ineffective. When using a cleaning or disinfectant wipe on the external surface of a filter cartridge, users should avoid contact with the filter media on the inside of the cartridge.

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html

**Is a user seal check the same as fit testing?**

No, a user seal check and fit test are different procedures.

A user seal check is performed by the respirator wearer to determine if the respirator is being properly worn before each use. Employees required to wear tight-fitting respiratory protection in the workplace must perform a user seal check each time they put on their respirator as required by OSHA regulations[1]. Air will take the path of least resistance, so if the seal is improperly maintained, there may be leak paths that allow the air to flow around the facepiece seal rather than through the filter(s) and therefore compromise the respiratory protection afforded to the user. A user seal check is only applicable when a respirator has already been successfully fit tested on the individual.

Here is an example Wear it Right poster to visualize the process of donning and performing a seal check: https://multimedia.3m.com/mws/media/1477510/wear-it-right-7500-series-respirator-english.pdf

A fit test helps ensure that the respirator is able to fit the wearer and provide a secure seal. Per OSHA's Respiratory Protection standard, 29 CFR 1910.134, every employee using a tight-fitting facepiece respirator must be fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter.

Here is an example of a qualitative fit testing method, using 3M fit testing kits: https://multimedia.3m.com/mws/media/1658130O/quick-reference-guidequalitative-fit-testing.pdf

1. Occupational Safety and Health Administration. (2014). Regulations (Standards-29 CFR)-Table of Contents.?US Department of Labor. Retrieved from https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards
2. 3M™ Wear It Right: Putting on Your Respirator Brochure: https://multimedia.3m.com/mws/media/1448498O/wear-it-right-putting-on-your-respirator.pdf

**Are reusable respirators compatible with faceshields?**

Yes, certain models of 3M half-facepiece reusable respirators, such as the 6000 series and 6500 series, have a low profile design that is intended to be compatible with many faceshield options.

Selecting a slim profile filter, such as the 7093 or 5N11 assembly, will help in optimizing compatibility.

**What is the average weight of 3M reusable respirator?**

It depends on the product model and specific filter and/or cartridge combination.

| | 6200 facepiece | 6500 facepiece | 7500 facepiece | 5N11 | 7093 | 2091 |
|---|---|---|---|---|---|---|
| Approximate Weight | 82 g | 100 g | 135 g | 6 g | 18 g | 21 g |

**Does my elastomeric respirator contain latex?**

The 3M™ 6000 Series Half Facepiece (6100,6200, 6300), 6500 Series (6501, 6502, 6503), 7500 Series (7501, 7502, 7503), 6000 Series Full Facepiece (6700, 6800, 6900) and FF-400 Series (FF-401, FF-402, FF-403) respirators contain no components made from natural rubber latex.

**What is the shelf life of the elastomeric respirator?**

There is no established shelf life on 3M elastomeric respirators. Determination for use depends on inspection and verification that the respirator is in good condition.

**What is the shelf life of the filter cartridge?**

It depends on the filter or cartridge in use.

7093: 5 year shelf life when stored in original packaging and within recommended storage conditions.

2091: 5 year shelf life when stored in original packaging and within recommended storage conditions.

6000 Series Filters: 5 year shelf life when stored in original packaging and within recommended storage conditions.

5N11 filter: No shelf life established. Rely on inspection to determine suitability for use.

**Which fit testing methods can I use for elastomeric respirators?**

Both qualitative and quantitative fit testing can be performed on reusable elastomeric respirators. If quantitative fit testing is being performed, a fit test adapter will likely need to be purchased for use with the selected quantitative fit testing machine.

The fit test adapter is 3M part number 601- https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Fit-Test-Adapter-601-1-EA-Case/?N=5002385+3294755083&preselect=3293786499&rt=rud

For more details on fit testing, including hygiene considerations during the COVID-19 pandemic, please see these resources-

https://multimedia.3m.com/mws/media/973364O/3m-respirator-fit-testing-frequently-asked-questions-faq.pdf

https://multimedia.3m.com/mws/media/1819154O/fit-test-hygiene-during-covid-19-pandemic.pdf

**In what practice settings are reusable respirators currently being used in the United States?**

We've received feedback that elastomeric reusable respirators are being adopted on Cohort Units, Environmental Services, Emergency Medical Services, Emergency Department, Radiology, Home care and Long Term Acute Care Hospitals. In healthcare organizations, decisions about respirator use and infection prevention should be made on a use- and user-specific basis in consultation with applicable requirements and guidance, including from infection prevention and occupational health and safety teams.

**Are healthcare facilities allowed to use elastomeric reusable respirators?**

In addition to surgical respirators, standard filtering facepiece respirators, elastomeric respirators, and Powered Air Purifying Respirators (PAPRs) have been used in healthcare since the multi-drug resistant tuberculosis outbreak in the early 1990s. Standard filtering facepiece respirators, elastomeric respirators and PAPRs are appropriate for healthcare settings, but per the CDC, there are limitations on where certain products can be used (specifically related to use in surgical settings and sterile fields).

Two respirator selection points:

- OSHA governs respirator selection and use in all U.S. workplaces, including healthcare workplaces. OSHA requires that respirators used by U.S. workers hold NIOSH approval. All N95 respirators, both standard and surgical, meet NIOSH N95 requirements. 3M elastomeric respirators and PAPRs also hold NIOSH approval.
- FDA clears surgical respirators (and surgical masks) to be marketed for use in surgery, based on fluid resistance, filtration efficiency, and flame resistance capabilities. FDA does not have a process or criteria to clear elastomeric respirators or PAPRs for use in surgery.

Healthcare facilities can refer to the joint DHHS/DOL publication from 2015 called "Respiratory Protection Program Toolkit for Hospitals", which includes information on standard (non-surgical) N95s, elastomeric respirators and PAPRs. Hospitals should be using this document as a guide for their respiratory protection program.

Additionally, it's important to note that respirator selection and use, including of elastomeric reusable respirators, should be based on a hazard assessment performed by the healthcare organization – which should involve occupational health and safety professionals, infection control professionals, and healthcare practitioners.

1. Hospital Respiratory Protection Program Toolkit. https://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117.pdf?id=10.26616/NIOSHPUB2015117

**Is my elastomeric reusable respirator fluid resistant?**

3M surgical masks and surgical respirators are cleared for use as medical devices by the U.S. Food and Drug Administration (FDA) and are designed to be worn by healthcare professionals during surgical procedures. Because surgical masks and surgical respirators are meant for use during surgery, one key performance requirement for these products is fluid resistance.

While we haven't evaluated 3M elastomeric reusable respirators to the same fluid resistance test method typically used on surgical masks and surgical respirators (ASTM F 1862), the materials used in many elastomeric respirator components are inherently liquid resistant. Even certain filters, such as the 7093, are encased in plastic and are designed to be used in wet applications.

In environments where high velocity splashes, sprays or splatters of blood or body fluids are expected, a faceshield over the elastomeric respirator assembly should be considered.

For more details on fluid resistance testing performed on 3M surgical masks and surgical respirators, please see this video: https://multimedia.3m.com/mws/media/1824182O/3m-fluid-resistance-testing.mp4

**Valves in Surgery- Can I use my valved respirator in surgical settings?**

3M valved respirators (either elastomeric respirators or valved filtering facepiece respirators) are not currently cleared by the U.S. FDA (or similar government agencies) as surgical masks providing fluid resistance or as medical devices, unlike the multiple 3M N95 surgical respirator and surgical mask models that are. Also, the U.S. CDC indicates use of any respirator (elastomeric or filtering facepiece respirator) with an exhalation valve over a sterile field or in the operating room could expose the patient to the risk of contamination.

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

**Sterile Field-Can I use my valved respirator over a sterile field?**

The U.S. CDC indicates use of any respirator (elastomeric or filtering facepiece respirator) with an exhalation valve over a sterile field could expose the patient to the risk of contamination. The purpose of a respirator's exhalation valve is one or both of the following: to help reduce the breathing resistance during exhalation or to provide a pathway for exhaled air to exit the facepiece. It is important that this valve is recognized, evaluated as part of a risk assessment, and then determined to be appropriate by the facility where these respirators are to be used. It is important to understand how the performance, selection, and use regulations in your location apply to respirators used over sterile fields.

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

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