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Technical Bulletin

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Revision 5

Reusable Respirator FAQ: Healthcare

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), he Food and Drug Administration (FDA) 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 is not FDA cleared for fluid resistance. Can it be used in healthcare?

Respirators - including standard N95 FFRs, elastomeric respirators, and PAPRs - have been used in healthcare since the multi-drug resistant tuberculosis outbreak in the early 1990s. Elastomeric respirators are appropriate for healthcare settings, however they are not cleared by the FDA for resistance to high velocity splashes or sprays of blood or body fluids. If fluid resistance is required while wearing an elastomeric respirator the CDC recommends the use of a faceshield.

While elastomeric respirators are not cleared by FDA for fluid resistance, based on their NIOSH approval, they provide at least equivalent protection to N95 FFRs. They are available as alternatives to disposable half mask filtering facepiece respirators (FFRs), such as N95 FFRs, for augmenting the total supply of respirators available for use by HCP*.

*https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/

My reusable elastomeric respirator has an exhalation valve. Can I use an elastomeric (reusable) respirator as source control?

The CDC says, "Until more is understood on exhalation valves, elastomeric respirators with unfiltered exhalation valves should not be used as source control in surgical and other healthcare settings due to concerns that air coming out of the exhalation valve may contaminate the sterile field. The NIOSH Certified Equipment List identifies the elastomeric respirators without exhalation valves or with filtered exhalation valves that may be used in surgical settings."

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

Note: See page 6 of this document for FAQs on the 3M™ Exhalation Valve Filter 604, an optional accessory to the 3M™ Half Facepiece 6000 Series, used to filter the wearer's exhaled breathe when source control is required.

According to the NIOSH Science Blog, "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 each facility determine where respirators with exhalation valves are appropriate for use.

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

3M particulate filters are constructed with non-woven fibers to help capture 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, filter retainer 501 and 604 Exhalation Valve Filter. 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

3M™ 6000 Half Facepiece Reusable Respirators Implementation Guide for Healthcare: https://multimedia.3m.com/mws/media/1953527O/3m-6000-series-half-facepiece-reusable-respirator.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 formaldehyde
- 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?

The frequency of Cleaning and Disinfection of the respirator facepiece and its components, is determined by wearer use and per facility guidelines. A thorough wipe down of the assembled respirator can be considered between uses during the work shift.

- Filters (except for unprotected disc type, i.e., pancake style) may be used for an extended period, and 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
2. https://multimedia.3m.com/mws/media/1840112O/reusable-respirators-cleaning-guide-wipe-down-quick-start-guide.pdf

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/147751O/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	36 g	21 g

Does my elastomeric respirator contain latex?

The following 3M respirator facepieces are not made with natural rubber latex:

- 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)

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.
- **6092X Series Cartridge 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.
- **604 EVF:** 5-year shelf life when stored in original packaging and within recommended storage conditions.

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?

When respirator use is required, the OSHA Respiratory Protection standard 29 CFR 1910.134, requires that all employee use of respirators be done within the context of a comprehensive and effective respiratory protection program. 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.

The NIOSH approved accessory 3M™ Exhalation Valve Filter 604 works with 3M™ 6000 Series Half Facepiece Reusable Respirators with the 3M™ Particulate Filter 7093, the 3M™ Particulate Filter 5N11 combination, and the 3M™ Particulate Filter 2091 to help filter the wearer's exhaled breath and provide source control when needed allowing for use in many areas of healthcare. Current CDC guidance indicates that elastomeric respirators with filtered exhalation valves (such as the 3M™ 6000 Series Half Facepiece when used with approved filters and the EVF) may be used in surgical settings.

FAQs on the 3M™ Exhalation Valve Filter (EVF) 604

General Use

Does the 3M™ Exhalation Valve Filter 604 provide source control?

Yes, the 6000 Series half facepiece can be used with the EVF when source control is required.

How does the EVF provide source control?

The EVF mounts on the outside of the 3M 6000 Series half facepiece and filters the exhaled air coming out of the exhalation valve.

When used with the EVF, can the 6000 Series half facepiece be used in surgical settings?

Current CDC guidance states that elastomeric respirators with filtered exhalation valves may be used in surgical settings. 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.

How is the EVF installed onto the 3M 6000 Series half facepiece?

Refer to the EVF User Instructions and follow the steps for installation. The EVF can be easily installed and removed from the 6000 Series facepiece, as needed.

EVF User Instructions: https://multimedia.3m.com/mws/media/1945363O/3m-604-reusable-respirator-exhalation-valve-filter-user-instructions.pdf

Can I perform a positive and negative pressure seal check with the EVF in place?

Yes, both a positive and negative pressure seal check is possible while using the EVF. The negative pressure seal check is unchanged when the EVF is in place. The positive pressure seal check is conducted by covering the opening in the EVF instead of the opening in the valve cover. See the EVF User Instructions for seal check steps.

Do I need to complete another Fit Test if I use the EVF on my 6000 Series half facepiece?

No, another fit test is not required if the wearer has already passed a fit test on the same size 6000 Series half facepiece.

Can I replace the filter pad inside the EVF?

The filter media inside the housing of the 604 Exhalation Valve Filter is not designed to be replaced. Users should discard the entire unit.

How often does the EVF need to be replaced?

Changeout/replacement guidance for the EVF will be the same as the guidance for 3M N95 and P100 particulate filters – replace when the filter is dirty, damaged, difficult to breathe through or per facility's infection control policy. Given the same changeout guidance, healthcare facilities may elect to set the same changeout schedule for the EVF as for their particulate filters. Healthcare facilities have shared particulate filter changeout schedules ranging from every three months to "as needed" with limited need for replacement.

How can I clean the EVF?

The hard-plastic case of the EVF can be wiped down for cleaning and disinfection and set aside for reuse.

If gross contamination is present, consider a cleaning wipe step before disinfection. To disinfect, refer to the EPA label for the selected disinfectant to determine contact time for the disinfecting solution. use a water wipe down to remove residual disinfectant and air dry or hand dry before next use.

Do not allow the cleaning or disinfecting solution to reach the internal filter media, and do not submerge the EVF in any liquid. Utilize the same cleaning and disinfection solutions as recommended for 3M Half Facepiece Respirator 6000 Series. Refer to 3M Technical Bulletin "Cleaning and Disinfecting 3M Reusable Elastomeric Half and Full Facepiece Respirators Following Potential Exposure to Coronaviruses" for expected disinfectant compatibility information.

Breathability

What is the impact of the EVF on breathing resistance?

The EVF is designed to maintain the use of the exhalation valve for the user's breathing comfort and meets the NIOSH requirements for breathing resistance. Compared to not having the EVF attached to the 6000 series facepiece, the EVF will add some breathing resistance for the wearer.

Why not block off the exhalation valve instead of using the EVF?

We know comfort and breathability is important when workers must wear a respirator for extended periods. Leaving the exhalation valve in place allows exhaled breath to exit the facepiece more easily.

Filtration Performance

What type of filter material is used in the EVF?

The filter media used in the EVF is charged non-woven polypropylene. Charged filter media is utilized to improve filtration efficiency.

What level of filtration efficiency does the EVF provide?

EVF filter media meets 99% Bacterial Filtration Efficiency (BFE) based on testing conducted per ASTM F2101 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials. The EVF is not FDA cleared as a medical device.

Does the 6000 Series with an EVF provide N95 level filtration performance?

The EVF filter media meets 99% Bacterial Filtration Efficiency (BFE) based on testing conducted per ASTM F2101.* N95 or P100 level filters provide at least 95% or 99.97% filtration efficiency, according to NIOSH filtration efficiency testing. NIOSH filtration efficiency testing and BFE are two different test methods so these results should not be compared directly.

*Not FDA cleared as a medical device.

Refer to this link to learn more about the differences between the requirements for respirators and surgical masks.

https://multimedia.3m.com/mws/media/957730O/respirators-and-surgical-masks-contrast-technical-bulletin.pdf

Fluid Resistance

Is the EVF Fluid Resistant?

The EVF meets Level 3 for fluid resistance based on testing conducted per ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood. The EVF is not FDA cleared as a medical device.

Regulatory

Is the EVF NIOSH approved?

The EVF is NIOSH approved as an accessory on the 6000 Series half facepiece and can only be used when the following 3M filters are installed on the facepiece: 7093, 5N11/603/501, or 2091.

Product Number	Photo
3M™ Half Facepiece Reusable Respirator 6000 Series	
3M™ Particulate Filter 7093	
3M™ Filter/Adapter/Retainer Kit 6N01, which includes:	
3M™ Particulate Filter 5N11, N95,	
3M™ Filter Adapter 603,	
3M™ Filter Retainer 501	
3M™ Particulate Filter 2091, P100	

The NIOSH approval letter can be found here:

https://multimedia.3m.com/mws/media/1960247O/evf-niosh-approval-letter.pdf

Why are only certain filters approved for use with the EVF?

To expedite the NIOSH approval process, only the three most common 3M filters utilized in healthcare were submitted for approval. No gas & vapor cartridges are approved for use with the EVF.

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3M PSD products are occupational use only.

In United States of America
Technical Service: 1-800-243-4630
Customer Service: 1-800-328-1667
3M.com/workersafety
In Canada
Technical Service: 1-800-267-4414
Customer Service: 1-800-364-3577
3M.ca/Safety