

# Filtering Facepiece Respirators with an Exhalation Valve: Measurements of Filtration Efficiency to Evaluate Their Potential for Source Control

## Introduction

Filtering facepiece respirators (FFRs) are used extensively by healthcare personnel (HCP) during a pandemic. FFRs are primarily reserved for those personnel who have a greater risk and longer duration of exposure compared with other workers and the general public. Some FFR models contain an exhalation valve, which is a device that closes to allow inhaled breath to be pulled through the filter media and opens to allow exhaled breath to be expelled from the respirator through the exhalation valve as well as the filter media. These FFR models provide the wearer with a level of protection like that of an FFR without an exhalation valve, and they are thought to increase the wearer's comfort at high work rates and be suitable for longer periods of use. However, respiratory secretions expelled by wearers may exit along with air through the exhalation valve. A concern with FFRs with an exhalation valve is that individuals may spread disease if unfiltered, virus-laden aerosols pass through the valve.

During the COVID-19 pandemic, guidance from the Centers for Disease Control and Prevention (CDC) did not recommend using an FFR with an exhalation valve for source control (i.e., to filter respiratory secretions to prevent disease transmission to others) and advised that if only this option is available and source control was needed, then the valve should be covered with a surgical mask, procedure mask, or a cloth face covering that does not interfere with the respirator fit. The CDC requested research to provide improved science-based recommendations on the use of exhalation valves.

This study had three aims: (1) to measure the filtration efficiency provided by FFRs with an exhalation valve under conditions of inward airflow (i.e., in the direction of inhalation) and outward airflow (i.e., in the direction of exhalation); (2) to evaluate how particle penetration in FFRs with an exhalation valve compares to particle penetration in surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts; and (3) to determine the filtration efficiency of three modifications to the exhalation valve in FFRs with the goal of mitigating the emission of unfiltered particles. To accomplish these three aims, thirteen FFR models were each tested in two positions: inward position, which is used by the NIOSH Respirator Approval Program when testing N-type respirators, and outward position, which was used experimentally to channel airflow in the direction of exhalation. For the inward position, three mitigation strategies were used:

- (1) covering the valve on the interior of the FFR with commonly available surgical tape,
- (2) covering the valve on the interior of the FFR with an electrocardiogram (ECG) pad; and
- (3) stretching a surgical mask over the exterior of the FFR.

The purpose of these three strategies was to measure the varying filtration efficiencies to determine their contribution toward source control. Both positions and all mitigation strategies were tested at three airflow rates: 25, 55, and 85 lpm (liters per minute). In addition to the FFR evaluations, researchers evaluated a selection of surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts using the outward position and flowrates described previously.

## Methods Collection

Respirators

A convenience sample of models taken from available excess NPPTL stock of FFRs with exhalation valves that had four or more specimens with some beyond their “use-by” date and/or taken from an open box.

- N95® Filtering Facepiece Respirators
  - o Dräger Safety AG & Company KGaA X-plore 1750
  - o 3M Company 9211 and 8511CN
  - o Visca Safety Comercial Limitada Visca 2740V
  - o AirGas Inc., Radnor 65059520A
  - o Willson Dalloz Safety Products NBW95V
  - o Makrite Industries, Inc. 710VOV and 9800V
  - o ATEM Company, Ltd. 4030
  - o Uline S-10479
  - o Makrite Industries, Inc. 2201V
- N99® Filtering Facepiece Respirator
  - o Moldex-Metric, Inc. 2310
- Non-NIOSH Approved® Respirator meeting NIOSH testing requirements
  - o Jinhua Meixin Protective Equipment Factory 2001V

#### Non-FFR Protective Devices

- Masks intended for medical purposes
  - o Four surgical masks
  - o Seven procedure masks
- Unregulated barrier face coverings
  - o Six models of cloth face coverings
    - Two with filter inserts
    - Three with exhalation valves
  - o Two types of fabric from cotton t-shirts
- Sample size too small to represent the population of these devices

#### Filtration Efficiency Testing

- Evaluated using a TSI 8130 filtration efficiency tester with a sodium chloride (NaCl) 2% solution in distilled water.
  - o Sodium chloride (NaCl) aerosol statistics
    - Count median diameter (CMD) –  $75 \pm 20$  nanometer (nm)
    - Geometric standard deviation (GSD) –  $\leq 1.86$ .
    - Density – 2.13
    - Mass median aerodynamic diameter (MMAD) –  $0.347 \mu\text{m}$
- Six replicates were tested for each model, except for the following due to unavailability of six samples:
  - o 3M 9211 (Five replicates)
  - o ATEM Company Ltd. 4030 (4 replicates)
- Respirator pressure drop (an indicator of breathing resistance) measured by the TSI 8130.
- Flowrates
  - o 85 Lpm – used for approval testing corresponding to a moderate exercise breathing rate
  - o 55 Lpm
  - o 25 Lpm
- Efficiency determined with two flow directions (devices sealed to mannequin)
  - o Inward – test flow in direction of inhalation
    - FFRs only with no mitigation (Used during approval testing)

- Outward – test flow in direction of exhalation
  - No mitigation (exhalation valve uncovered) – FFRs and non-FFR protective devices
  - Mitigated (exhalation valve covered)
    - FFRs only
    - Evaluate source control capability
- Three mitigations to cover exhalation valve
  - Tape – 2" x 2" swatch of Nexcare Tape (3M Micropore surgical tape) gently pressed onto the interior of the FFR.
  - Covered – ECG pad (3M Red Dot) pressed into interior
  - Masked-over – surgical mask stretched over the exterior of the respirator to simulate a realistic, snug fit.
  - Mitigation Strategy Selection
    - Tape and ECG pads
      - Available in a hospital
      - Nontoxic
      - Provide good adherence to moist surfaces
    - Masked-over mitigation
      - Aligns with the current CDC recommendation if source control is needed and only an FFR with an exhalation valve is available
- Total of 1,125 tests conducted – (13 models × [2 positions + 3 mitigations] × 3 flowrates × 6 replicates) – ([2 positions + 3 mitigations] × 3 flowrates × 3 replicates)

### **Attribution**

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#### **Disclaimer**

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