

ASTM F3407 – 20: Respirator Fit Capability Standard for Negative- Pressure Half-Facepiece Particulate Respirators



Application Note RFT-036 (US)

Purpose of this Application Note

This application note is to help respirator manufacturers using CNC-based quantitative fit testers (such as the PortaCount® Fit Tester) to understand how the quantitative fit test is applied to Respirator Fit Capability (RFC) Test for new respirator design, development and performance, to better fit a general worker population per the ASTM F3407 Fit Capability Standard.

The quantitative respirator test criteria for the ASTM F3407 Fit Capability Standard can also be applied for the ASTM F3502 Barrier Face Covering (BFC) Standard, where quantitative analysis of Total Inward Leakage (ratio) is conducted as part of barrier face covering mask design, analysis and performance as part of the BFC certification.

Significance of the Standard and its Use

This fit capability standard was developed to so that respirator manufacturers would have a process to follow to design and develop new respirator designs that better fit a general worker population based on the NIOSH Bivariate Panel.

The ASTM F3407 standard introduces new processes to follow and the instrumentation to be utilized to meet the standard RFC testing criteria.

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Selected Excerpts from F3407

The below sections are selected excerpts from the F3407 – 20 Standard Test Method for Respirator Fit Capability for Negative-Pressure Half- Facepiece Particulate Respirators.

Within the Standard's text below, relevant **"You Should Know How TSI® Can Help"** notes are included to inform readers and connect them with relevant resources.

Scope of the ASTM F3407 – 20 Standard

1.1 This standard provides detailed instructions for performing a respirator fit capability test to determine the fit of air-purifying, half-facepiece respirators, which will include both filtering facepiece respirators and elastomeric respirators equipped with any type of particulate filter. The purpose is to increase the probability that available respirators fit a general worker population.

The standard provides increased assurance to respirator purchasers and users that respirators that meet the requirement of this standard can be expected to effectively fit persons with various lengths and widths of faces, such as long and narrow or short and wide, when fit tested in the workplace as part of a complete respiratory protection program in accordance with 29 CFR 1910.134.

Definition of a Fit Test

3.1.1 Fit Test - The use of a protocol to qualitatively or quantitatively evaluate the fit of a particular respirator on an individual.

Definition of "Respirator Fit Capability"

3.1.4 Respirator fit capability (RFC) test: An assessment of a respirator model's ability to achieve passing face seal performance on either the complete NIOSH Bivariate Panel or a specified subset of the panel representing the population of respirator wearers when the wearers are properly trained and fit tested in compliance with the manufacturer's user instructions and Practice F3387 and the Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134.

Significance and Use

5.3 This standard can be used to evaluate all particulate removing respirators on a population of wearers. A respirator model meeting the fit capability requirement will be capable of fitting the facial sizes and shapes for which it was designed. To achieve this goal, it is necessary for the method to reject poor-fitting respirators, while still passing well-fitting respirators meeting the pass/fail criteria established in this standard. It is thought that this standard will increase the likelihood that respirators meeting this requirement will fit a wide variety of their prospective wearers when properly fit tested, donned, and used.

Apparatus

7.1 Condensation nuclei counter with particle classifier technology (for example, a differential mobility analyzer). The particle classifier technology shall only allow nominal 55 nm negatively charged particles to pass through to the condensation nuclei counter for counting while eliminating the zero-charge and positive-charge particles from the sample.

You Should Know How TSI® Can Help: The PortaCount® Respirator Fit Tester (models 8030, 8038, 8040 and 8048) are all Condensation Nuclei Counter-based (CNC) quantitative fit testing instruments with differential mobility analyzers (DMA) in the 8038 and 8048 models. N95-Companion™ Technology (i.e., DMA = particle classifier technology) only allows nominal 55 nm negatively charged particles to pass through to the condensation nuclei counter during testing in N95 Mode, while also eliminating the zero-charge and positive-charge particles from the ambient and mask samples.

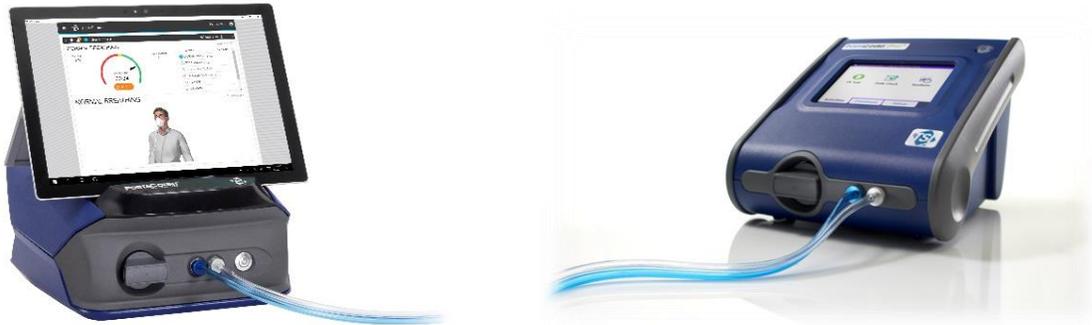


Figure 1: The PortaCount® Respirator Fit Testers. **Left:** PortaCount® Models 8040/8048. **Right:** PortaCount Models 8030/8038.

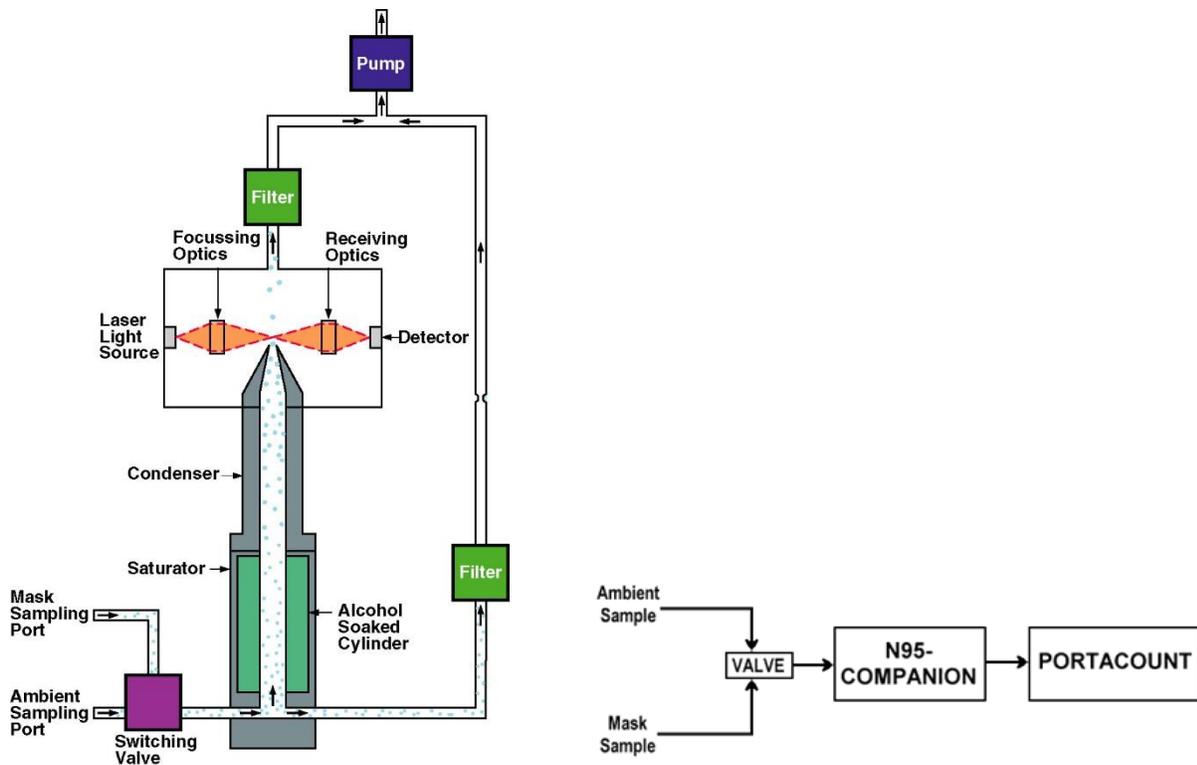
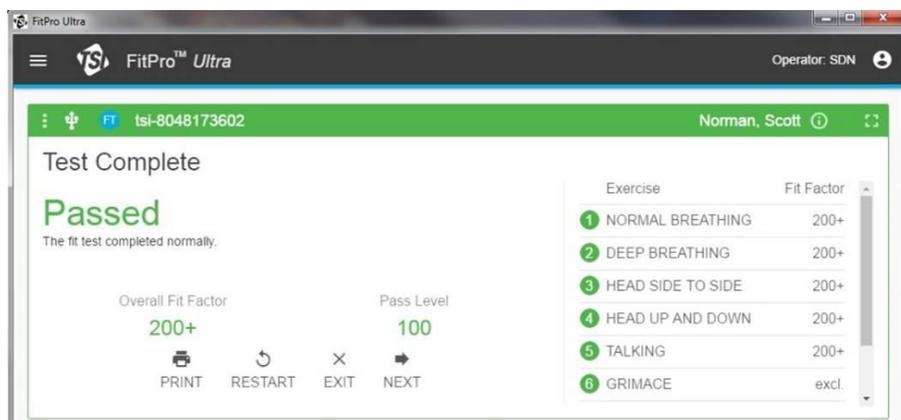


Figure 2: **Left:** Schematic of the internal components of the PortaCount fit tester. **Right:** a schematic of the N95-Companion™ Technology with the PortaCount fit tester.

7.2 Software to control the condensation nuclei counter.

You Should Know How TSI® Can Help: PortaCount® Fit Tester instruments include fit test software. FitPro™+ Fit Test Software is included with PortaCount® Model 8030 and 8038 instruments and FitPro™ Ultra Fit Test Software is included with PortaCount Model 8040 and 8048 instruments to conduct RFC testing, recordkeeping and data management.



PortaCount® Fit Tester instruments conduct all required RFC Test Preparation checks defined in Sections [11.1](#) and [11.2](#):

- **Automate ASTM RFC testing and recordkeeping using TSI FitPro™ Ultra or FitPro™+ Fit Test Software**
 - o ASTM RFC defined fit test protocols are pre-loaded on the instrument
 - o Customize tests and control parameters
 - o View real-time data to monitor the progression of tests
 - o Analyze completed RFC Test Panel test result data
 - o Generate custom reports (i.e., Fit Test Record RFC Test Panel Summary Reports)
- **Ensure test accuracy by conducting automated instrument daily (diagnostic) checks:**
 - o Minimum Ambient Particle Concentration Check
 - o Classifier Check
 - o Zero Check
 - o Maximum Fit Factor Check
- **Utilize the PortaCount instrument's Real-Time FitCheck™ Mode to Conduct Chamber Particle Concentration Checks and ensure the RFC Test Chamber ambient concentration conditions are being met**

7.3 High-efficiency particulate (HEPA) filter for diagnostic checks recommended by the instrument manufacturer.

7.4 Test Chamber:

7.4.1 Size—Large enough to permit each of the test subjects conducting an RFC test to freely perform all required exercises without disturbing the positioning of the facepiece or the measurement apparatus, or interfering with the movements of any other test subjects in the chamber.

7.4.4 Aerosol Concentration—The aerosol concentration shall be well mixed (that is, uniformly distributed) throughout the chamber ($\pm 10\%$) where the test subject(s) will be performing the test. The concentration shall

be stable (that is, $\pm 10\%$ of the initial concentration of between 2000 and 8000 particles/cm³) for the duration of the test.

7.4.5 Particle Size—The particles in the chamber should be between 0.02 μm and 1 μm with a geometric standard deviation ≤ 2.2 .

7.5 Particle Generator—An aerosol generator capable of producing the sodium chloride concentration specified in [7.4.4](#).

You Should Know How TSI Can Help: [The Particle Generator Model 8026](#) is an instrument that supplements the ambient particle concentration. The RFC test must be conducted in a test chamber and the Model 8026 Particle Generator may be used to generate the sodium chloride ambient challenge aerosol allowing the PortaCount® Respirator Fit Tester to be used in either N99 mode or N95 mode for RFC testing.



7.6 In-Facepiece Sampling Apparatus—For filtering facepiece respirators, a flush-mounted probe equipped with a push nut specifically designed to be attached to this type of respirator. For elastomeric respirators, a fit test adapter placed between the facepiece and the filter can be used. The flush mounted filtering facepiece probe (N95 probe) shall not be used for elastomeric respirators.

You Should Know How TSI® Can Help: The PortaCount® Respirator Fit Tester (models 8038 and 8048) includes an accessory kit for probing filtering facepieces. Additionally, fit test adapter kits are available for all types of full- and half-facepiece elastomeric respirators. These fit test adapter kits include everything needed to conduct a RFC test. See our [Fit Test Adaptor informational guide](#) for more information.

7.6.1 The probe should be placed on the midline between the nose and the mouth, whenever possible. If a different position is necessary, every effort should be made to avoid contact with the face, placement on a seam, or interference with other features of the respirator. The sampling apparatus should be supported in a way that it does not affect or interfere with the fit of the respirator (that is, the respirator with the sampling apparatus connected must fit the test subject in the same manner as it would without the sampling apparatus).

Annex A2 contains more information on probe location.

You Should Know How TSI® Can Help: The TSI® PortaPunch™ Probe Insertion Tool allows users to easily probe filtering facepiece respirators for fit testing. Proper setup and use of the TSI® PortaPunch™ Probe Insertion Tool is shown in a video on our YouTube page titled: [TSI PortaPunch™ Probe Insertion Tool Training Video](#)

Preparation of Apparatus

11.1 Several diagnostic checks shall be performed at least daily. These shall include:

- 11.1.1 Chamber Particle Concentration Check—To ensure the chamber concentration is within the range specified in [7.4.4](#).
- 11.1.2 Particle classifier check.
- 11.1.3 Zero Check—To provide assurance that there are no leaks in the system.
- 11.1.4 Maximum Fit Factor Check—To ensure the condensation nuclei counter is capable of measuring high fit factors.

11.2 Follow the condensation nuclei counter and particle classifier manufacturer's instructions for performing these checks.

You Should Know How TSI® Can Help: Daily Checks are easy to complete on the PortaCount® Fit Tester. Simply follow the on-screen instructions and prompts. This simple process is shown in a video on our YouTube page titled: [PortaCount® Respirator Fit Tester 8040/8048: How to perform Daily Checks for fit testing](#).

Calibration and Standardization

12.1 At a minimum, all measuring equipment utilized for this testing must have been calibrated by the manufacturer within the timeframe specified in the equipment's operation manual. The calibration shall use methods traceable to National Institute of Standards and Technology (NIST) standards.

12.2 Equipment calibration records shall be available for examination at each testing facility.

12.3 Prior to beginning any testing, a statement that all test equipment is within calibration shall be attested by the lab technician, laboratory manager, or other designated person on each test report.

Procedures and Misc. (14.2.5 subject RFC test procedures).

You Should Know How TSI® Can Help: The PortaCount® Fit Tester is a CNC-based instrument that satisfies the requirements of these sections in ASTM F3407 that pertain to using a PortaCount® Respirator Fit Tester.

In order to comply with this section of the Fit Capability Standard, your PortaCount® CNC-based instrument must have a current annual calibration certificate on-file at your facility. Only TSI® provides factory OEM-authorized calibration, repair and services for PortaCount® Respirator Fit Testers.

To schedule calibration and service for your PortaCount Respirator Fit Tester, see [our website](#). To learn more about how calibration and service is done, see our YouTube video titled: [Get an inside look at TSI service – PortaCount® Fit Testers](#).

Subject RFC Testing Procedure

See Section 14 of the ASTM F3407 – 20 standard for the full text.

You Should Know How TSI® Can Help: The Respirator Fit Capability (RFC) test is outlined in section 14.2.7 and uses the same 8-exercise Ambient Aerosol (AA) Condensation Nuclei Counter (CNC) Quantitative Fit Test (QNFT) Protocol as used and defined by US OSHA in 29CFR1910.134, Appendix A; Respiratory Protection Regulation. The 8-exercise fit test protocol uses 1-minute exercise times, except for the Grimace exercise, which is 15-second in duration and is not used in the calculation of the Overall Fit Factor for a quantitative respirator fit test. All RFC testing will occur in a test chamber with design dimensions that will allow for all of the fit test exercises to be performed.

As referenced in ASTM F3407, the TSI PortaCount® Respirator Fit Tester Models 8040/8048/8030/8038 are CNC-base quantitative fit testers. Depending upon the type of respirator being fit tested you can use N99 Mode with particle concentration range of 2,000 – 8,000 pt/cm³ in the test chamber for respirators utilizing ≥99% efficient filter media or N95 Mode with particle concentration range of 200 – 800 pt/cm³ in the test chamber for respirators utilizing <99% efficient filter media. PortaCount Models 8048 and 8038 are equipped with N95-Companion Technology that allows QNFT for respirator designs using <99% efficient filter media.

The PortaCount Respirator Fit Tester modes of operation:

<i>PortaCount Models</i>	<i>N99 Mode of Operation</i>	<i>N95 Mode of Operation</i>
PortaCount Model 8040	Yes	No
PortaCount Model 8048	Yes	Yes
PortaCount Model 8030	Yes	No
PortaCount Model 8038	Yes	Yes

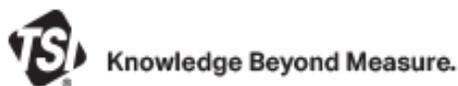
Calculation or Interpretation of Results

See Section 15 of the ASTM F3407 – 20 standard for the full text.

You Should Know How TSI® Can Help: The RFC Test result is calculated by taking the fit factor result for each fit test exercise and calculating the Overall Fit Factor as a Harmonic Mean (weighted average), just the same as for the AA CNC QNFT Protocol as used and defined by US OSHA in 29CFR1910.134, Appendix A; Respiratory Protection Regulation. The Grimace exercise is not included in the calculation.

You Should Know How TSI® Can Help: Below is a comprehensive list where the PortaCount Fit Tester complies with relevant sections of the ASTM F3407 Respirator Fit Capability Standard. Not all sections in the table are detailed in the text above. Take note of the additional compliance with sections 4, 8 and 16 within the below table.

ASTM F3407 Respirator Fit Capability Standard Sections that the PortaCount Respirator Fit Tester complies with	<i>See specific sections in ASTM F3407 Respirator Fit Capability Standard for details.</i>
Section 1. Scope	1.1
Section 3. Terminology	3.1.1 (fit test); 3.1.2 (HEPA filter); 3.1.1 (individual exercise RFC result); 3.1.4 (respirator fit capability (FRC) test); 3.1.6 (subject RFC result); 3.1.7 (subject RFC test)
Section 4. Summary of Test Method	4.1
Section 5. Significance and Use	5.2; 5.3
Section 7. Apparatus	7.1; 7.2; 7.3; 7.4; 7.4.4; 7.4.5; 7.5; 7.6; 7.6.1
Section 8. Reagents and Materials	8.1 (Sodium chloride solution); 8.2 (Isopropyl alcohol)
Section 11. Preparation of Apparatus	11.1 (Diagnostic checks); 11.1.1 (Chamber Particle Concentration Check); 11.1.2 (Particle classifier check/N95-Companion™ Technology Check); 11.1.3 (Zero Check); 11.1.4 (Maximum Fit Factor Check); 11.2
Section 12. Calibration and Standardization	12.1; 12.2; 12.3
Section 14. Procedure	14.2.5 (Subject RFC Testing Procedure); 14.2.5.1; 14.2.6; 14.2.7 (A subject RFC test consists of following exercises): 14.2.7.1 (Normal breathing); 14.2.7.2 (Deep breathing); 14.2.7.3 (Turning head side to side); 14.2.7.4 (Moving head up and down); 14.2.7.5 (Talking); 14.2.7.8 (Grimace); 14.2.7.9 (Bending over); 14.2.7.10 (Normal breathing); 14.2.8
Section 15. Calculation or Interpretation of Results	15.1; 15.2 (For Unique One-Size Models): 15.2.1; 15.2.2; 15.2.3; 15.2.4; 15.3 (For Multiple Size Models): 15.3.1; 15.3.2; 15.3.3; 15.3.4; 15.3.5; 15.4
Section 16. Report	16.1



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