Introduction

Fit testing of tight-fitting respirators is now required in a number of countries around the world. In the US, the Occupational Safety and Health Administration (OSHA) specifies when and how fit testing is to be done. This includes fit-testing filtering facepieces, reusable respirators with cartridges and filters, and tight-fitting facepieces that are used with powered or supplied air systems. Loose-fitting respirators (e.g. hoods, helmets and loose-fitting facepieces used with powered or supplied air respirators) are not required to be fit tested.

There are different types of fit test methods. Qualitative fit test (QLFT) methods rely on a taste, smell or irritation from the test agent. These include isoamyl acetate, saccharin solution aerosol, Bitrex™ (Denatonium Benzoate) solution aerosol, and irritant smoke (stannic chloride).

Quantitative fit test (QNFT) methods generate a numerical assessment of respirator fit. These include ambient aerosol condensation nuclei counter (e.g., PortaCount® Respirator Fit Tester) and controlled negative pressure (CNP). A third method, the generated aerosol method, is mainly used in certain laboratories, and not as much by respirator users. In contrast, the PortaCount® and CNP methods are more widely used. The purpose of this technical data bulletin is to clarify when QNFT is required, highlight the differences between QNFT and QLFT and discuss various types of QNFT technologies available.

When is Quantitative Fit Testing Required?

Either QLFT or QNFT may be used for most classes of tight-fitting respirators, including disposable filtering facepieces. Tight-fitting facepieces used with powered or supplied air systems, must be converted to a negative-pressure respirator with the appropriate cartridge or filter for the specific fit test method. There are a few exceptions when QNFT is required:

• If an assigned protection factor (APF) of 50 is needed while using a full facepiece in negative-pressure air-purifying mode (i.e., used with cartridges or filters). APF is expected level of protection when used in an effective respirator program that meets all of the relevant OSHA requirements (e.g., reduces inhalation exposure by a factor of 50).
• If a supplied-air respirator (SAR) or self-contained breathing apparatus (SCBA) is used in demand mode (uncommon and distinct from continuous flow or pressure-demand mode).
• If facepieces are used in SCBAs for structural firefighting, per the National Fire Protection Association.
What are Some of the Differences Between Qualitative and Quantitative Fit Testing?

<table>
<thead>
<tr>
<th>Qualitative Fit Testing (QLFT)</th>
<th>Quantitative Fit Testing (QNFT)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Exercises</strong></td>
<td>One minute each: normal breathing, deep breathing, turning head side to side, moving head up and down, talking, bending over (or jogging) and normal breathing.</td>
</tr>
<tr>
<td></td>
<td>Same as QLFT, plus grimace. An alternate shortened exercise regimen “Redon” is allowed for Controlled Negative Pressure (CNP).</td>
</tr>
<tr>
<td></td>
<td>There are alternative shortened exercise regimens for both CNC and CNP (&quot;Modified Ambient Aerosol&quot; protocol for CNC; “Redon” for CNP).</td>
</tr>
<tr>
<td><strong>Subject Participation</strong></td>
<td>Tester must verify that subject can detect challenge agent (sensitivity test). Subject must indicate if he/she detects challenge during the fit test.</td>
</tr>
<tr>
<td></td>
<td>Machine calculates result. CNP: subject or administrator pushes button for 8 seconds while measurement taken.</td>
</tr>
<tr>
<td><strong>Pass/Fail Criteria</strong></td>
<td>Pass if subject does not detect challenge agent.</td>
</tr>
<tr>
<td></td>
<td>Minimum fit factor of 100 for half facepieces and 500 for full facepieces.</td>
</tr>
<tr>
<td><strong>Acceptable Challenges</strong></td>
<td>Aerosol: Denatonium benzoate (bitter), sodium saccharin (sweet), stannic chloride (irritant smoke); OR Vapor: isoamyl acetate (banana oil).</td>
</tr>
<tr>
<td></td>
<td>Aerosol: Sodium chloride, corn oil, etc. OR CNP (air).</td>
</tr>
<tr>
<td><strong>Number of Simultaneous Tests</strong></td>
<td>Potential to fit test up to 5 individuals at once.</td>
</tr>
<tr>
<td></td>
<td>Must fit test one person at a time per machine.</td>
</tr>
<tr>
<td><strong>Type of Respirator or Filter Required</strong></td>
<td>Particulate respirator or filters are required for methods using aerosol challenges; organic vapor respirators or cartridges are required for the isoamyl acetate method.</td>
</tr>
<tr>
<td></td>
<td>Particulate respirator or filters are required for aerosol challenges; adapters (no filters) are required for CNP.</td>
</tr>
<tr>
<td><strong>Probed Facepiece or Adapter Required</strong></td>
<td>No.</td>
</tr>
<tr>
<td></td>
<td>Yes.</td>
</tr>
</tbody>
</table>

Quantitative Fit Testing Devices

QNFT with Ambient Aerosol Condensation Nuclei Counter (PortaCount®)

The manufacturer of PortaCount® currently offers several different quantitative fit test devices. The PortaCount® Respirator Fit Tester Models 8030 and 8040 are used with 99 or 100 level (or European P3) particulate respirators, but is not for 95 level (or European P1 or P2) particulate respirators. The PortaCount® Respirator Fit Tester Models 8038 and 8048 are for use with all types of particulate respirators (These instruments must be operated in N95 mode when fit testing <99% efficient respirators). The PortaCount® instruments measure particles inside and outside the respirator in order to calculate a fit factor. Please see the User Instructions for more information.

Respirators must be probed in order to draw a sample from inside the facepiece. The 3M™ Quantitative Fit Test Adapter 601 is used with 3M™ Facepieces 6000, 6500, 7500, 7800, and FF- 400 Series. The 601 adaptor is attached to one side of the facepiece, and a small tube is connected from the inside to the 601 adaptor to the inside of the facepiece. The end of the tube is affixed with a small suction cup against the inside of the facepiece so that it rests midway between the mouth and nose. For
full facepieces, the tube must pass all the way into the nosecup. On the outside of the 601 adapter, a separate longer tube connects to the PortaCount®. Please read User Instructions for further detail, or contact 3M Technical Service with any questions.

Appropriate particle filters (depending on the PortaCount® model) must be attached to the facepiece prior to fit testing. For disposable respirators, TSI Model 8025-N95 Probe Kit includes disposable probes and insertion tool, and TSI Model 8025-N95R Probe Refill Kit includes additional probes.

In addition to the standard quantitative fit testing protocol for CNC, OSHA allows for a "Modified ambient aerosol condensation nuclei counter" protocol that shortens the time required for fit testing. This shortened protocol includes the following exercises for elastomeric respirators:

- The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom.
- The test subject shall jog in place comfortably for 30 seconds.
- The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme.
- The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme.

And the following exercises for filtering facepiece respirators:

- The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom.
- The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds.
- The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme.
- The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme.

QNFT with Controlled Negative Pressure (CNP)

Another quantitative fit test device is the Quantifit® made by Occupational Health Dynamics. In order to use the Quantifit, model-specific adapters must be attached to reusable respirator facepieces (filtering facepieces cannot be tested using this method). Adapters are listed on the OHD website (www.ohdusa.com). No particle filters or cartridges are required, but the facepiece inhalation valves must be either removed or propped open.

While the subject remains still and holds their breath, the Quantifit pulls air from the facepiece to create a specified negative pressure, which may be similar to breathing resistance during inhalation. The air flowing out of the respirator is noted as the leak rate. Then the fit factor is determined by dividing a predetermined inhalation flow rate by the leak rate. Please see the Quantifit User Instructions for more information.

An optional shortened test method “Redon” involves the following exercises:

- Stand and breathe normally for 30 seconds, then hold breath 10 seconds for measurement.
- Bend at the waist with face parallel to the floor for 30 seconds, then hold breath 10 seconds for measurement.
- Stand upright, shake head back and forth vigorously for about 3 seconds while shouting, then hold breath 10 seconds for measurement.
- Remove the facepiece, loosen all facepiece straps, and then redon the facepiece. Hold breath 10 seconds for measurement.
- Remove the facepiece again, loosen all facepiece straps, and then redon the facepiece again. Hold breath 10 seconds for measurement.
The manufacturer of the Quantifit device claims that the Redon protocol may be done in 3 minutes or less. However, time to redon the respirator twice may depend on the test subject’s physical dexterity and how familiar they are with the facepiece.

**Is Quantitative Fit Testing Better than Qualitative Fit Testing?**

US OSHA accepts both QLFT and QNFT. Studies have been published regarding the advantages and disadvantages of QNFT.\(^2\)\(^-\)\(^5\) It should be noted that little to no correlation was found between quantitative fit factors and respirator performance unless poor-fitting respirators were included in the analysis.\(^3\)\(^-\)\(^6\) In other words, those subjects who failed a quantitative fit test also showed lower respirator performance. But higher fit factors above the minimum requirement did not necessarily translate to higher respirator performance. Rather, wearers who pass either a qualitative or quantitative fit test and are part of complete respirator program that meets all local regulatory requirements can expect their respirator to reduce inhalation exposure according to the assigned protection factor (e.g., by a factor of 10 for half facepiece respirators).\(^7\)

**References**


**WARNING:** Respirators help reduce exposures to certain airborne contaminants. Before use, the wearer must read and understand the User Instructions provided as a part of the product packaging. Follow all local regulations. In the U.S., a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134, including training, fit testing and medical evaluation. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Misuse may result in sickness or death. For correct use, consult supervisor and the User Instructions, or call 3M Technical Service in USA at 1-800-243-4630 and in Canada at 1-800-267-4414.