Background
Fit testing is a required component of any respiratory protection program in which workers are required to wear tight-fitting respirators. Qualitative fit testing is an acceptable method in many cases. (See the section titled “Fit Test Regulatory Requirements” for more information about when qualitative fit testing is acceptable.) 3M’s three qualitative fit test kits meet OSHA’s performance criteria for fit testing respirators under 29 CFR 1910.134, Appendix A. Two of these kits, FT-10 and FT-20, contain the solutions specified by the Saccharin Solution Aerosol Protocol; the other, FT-30, contains the solutions specified by the Denatonium Benzoate Solution Aerosol Qualitative Fit Test Protocol.

This document contains answers to questions that many of our customers ask.

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Q: How many fit tests can be conducted with one 3M qualitative fit test kit?
Approximately 150 fit tests can be conducted before you need to re-order fit test kit solutions. Note, however: the number of people you can fit test with one set of bottles varies depending on how many people you fit test in each session and what their sensitivity thresholds are (10, 20, or 30). When you first fill the nebulizers, you should use 1 tsp of solution. You might only need to fill the sensitivity nebulizer once per fit test session. If you fit test more than 20 people in each fit test session, you will need to fill your fit test nebulizer multiple times and will run out of fit test solution earlier than you run out of sensitivity solution. The nebulizers should be emptied, rinsed, and refilled at least once every 4 hours, per OSHA 29 CFR 1910.134.

Q: Can we fit test non-3M respirators with a 3M fit test kit?
Yes, you can use 3M fit test kits to fit test non-3M respirators. The qualitative fit test protocol is specified by OSHA in 29 CFR 1910.134 Appendix A. 3M’s fit test kit components meet the requirements of that standard. Therefore, it can be used to fit test any NIOSH-approved tight-fitting facepiece. You can also use non-3M fit test kits to fit test 3M respirators, as long as these fit test kits meet the specifications in OSHA’s fit test standard.

3M Fit Test and Sensitivity Solutions

Q: What is in the fit test kit solutions?
All 3M qualitative fit test solutions are prepared according to OSHA 29 CFR 1910.134 Appendix A, which specifies the solutes and concentrations that are required for compliance. The sweet solutions in the FT-10 and FT-20 kits contain sodium saccharin.
Sodium saccharin is commonly used as an artificial sweetener in many commercially available beverages and foods. The bitter solutions in the FT-30 kit contain denatonium benzoate, which is often marketed under the brand name Bitrex™. Denatonium benzoate is used as a taste aversion agent to prevent children from ingesting certain household products and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers.

**Q: Do the fit test and sensitivity solutions expire?**

There is no published shelf life for the solutions. Any solution left in the nebulizers at the end of your fit test session should not be poured back into the bottles but rather should be discarded to avoid contamination of the solution remaining in the bottle.

**Q: There is a white powdery solid around the cap of the solution. Should I be concerned?**

White crystals will form around the cap if it is not sealed tightly to the bottle. This is true for both the sweet solutions and the bitter solutions. It occurs because the solutions are very concentrated, and if drops of the solutions leak out of loose lids, the water evaporates, leaving crystals of the sweet or bitter solute. It is not cause for concern and can simply be wiped away for appearance and convenience.

**Q: What is in the fit test kit solutions?**

All 3M qualitative fit test solutions are prepared according to OSHA 29 CFR 1910.134 Appendix A, which specifies the solutes and concentrations that are required for compliance. The sweet solutions in the FT-10 and FT-20 kits contain sodium saccharin. Sodium saccharin is commonly used as an artificial sweetener in many commercially available beverages and foods. The bitter solutions in the FT-30 kit contain denatonium benzoate, which is often marketed under the brand name Bitrex™. Denatonium benzoate is used as a taste aversion agent to prevent children from ingesting certain household products and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers.

**Bitter Solutions**

**Q: How can you help subjects remove the bitter taste from their mouths after the fit test?**

The taste of denatonium benzoate can be countered with chocolate. Many fit testers offer chocolate to subjects, but this should be done only after the entire fit test protocol is complete.

**Saccharin Solutions**

**Q: There are solids at the bottom of the bottle of sweet solution. Should I be concerned?**

The fit test solution is a highly saturated solution per the concentration specified in OSHA 29 CFR 1910.134, Appendix A, Saccharin Solution Aerosol Protocol. The FT-12 may crystallize under certain storage conditions, such as if the temperature is lowered. Per the instructions included with the 3M FT-10 Qualitative Fit Test Apparatus, if crystals are present, hold the closed bottle under a warm stream of water and shake vigorously to dissolve back into solution.

**Q: During the sensitivity test, no subjects are able to taste the sweet solution. What should I do?**

Check to make sure your nebulizers are generating aerosol when squeezed. Hold them against a solid dark background so you can see if a cloud of aerosol appears when you squeeze the nebulizer. If no white aerosol cloud appears, perform the following steps:
1. Make sure both white plugs are removed from the nebulizer openings (Fig. A).
2. Make sure the question-mark-shaped insert is present in the nebulizer reservoir (Fig. B) and is pushed down as far as possible on the stem.
3. Verify that the black O-ring is present in the reservoir (Fig. A).
4. The sweet solutions can crystallize on certain parts of the nebulizer, causing it to not function properly. Even if you wash your nebulizers frequently, crystals can remain in the two narrow tubes in the nebulizer (Fig. B). Your fit test kit came with a curl of small-gauge wire that should be used to ensure those narrow tubes are clear of crystals. If you no longer have your wire, contact 3M for a replacement.

See steps 1 – 4 in the answer to the question on Pg. 2 about sensitivity testing with saccharin.

**Q:** *I lost the small plastic question-mark-shaped insert that affixes to the nebulizer reservoir. Can I order a replacement?*

The inserts are non-orderable components. If you need replacements, please call the US Technical Service Helpline at 1-800-243-4630.

**Q:** *I lost the black O-ring for my nebulizer. Can I order a replacement?*

The O-rings are non-orderable components. If you need replacements, please call the US Technical Service Helpline at 1-800-243-4630.

**Q:** *How should I clean my fit test kit components?*

Nebulizers should be rinsed in fresh water after every session or at least every four hours, or if the nebulizer becomes clogged. If you use the sweet solutions, we recommend periodically using the curl of small-gauge wire that came with your fit test kit to remove any crystals that might have formed in the two narrow passageways indicated in Fig. B. Always discard any unused solution.
Hoods and Collars

**Q: Should I worry about the oxygen levels inside the hood during the fit test?**

Oxygen deficiency immediately dangerous to life or health is defined as oxygen content below 19.5% at sea level. We have performed a limited amount of testing on the oxygen levels inside the fit test hood. It is not abnormal to see the oxygen level in the hood temporarily decrease during the exhalation phase of breathing. However, based on our experience, the oxygen levels during the inhalation phase do not pose any significant threat to healthy individuals.

**Q: How should I clean the hoods and collars?**

After each session, the hood and collar should be wiped with a damp cloth or paper towel to remove any deposited fit test solution. If desired, the hood and collar can be wiped with 3M™ Respirator Cleaning Wipes 504 between individuals or between fit test sessions. If non-disposable respirators are used to fit test multiple subjects, the respirators should be cleaned with 3M™ Respirator Cleaning Wipes 504 between each individual.

**Qualitative Fit Test Protocol**

**Q: What is the difference between a qualitative and a quantitative fit test?**

OSHA specifies approved procedures for both qualitative fit testing (QLFT) and quantitative fit testing (QNFT). There are several methods of QNFT – some involve measuring the concentration of an aerosol challenge both inside and outside the facepiece; others involve measuring the seal of the respirator by creating a vacuum inside the facepiece. All four OSHA-approved QNFT methods yield a numerical value called a Fit Factor, which represents the ratio of the concentration outside the facepiece to the concentration inside the facepiece – i.e., the reduction in the airborne concentration.

**Table 1.** Some 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>Pass/fail criteria</strong></td>
<td>Pass if subject does not taste challenge.</td>
</tr>
<tr>
<td><strong>Subject participation</strong></td>
<td>Tester must verify that subject can detect the challenge (sensitivity test). Subject must perform 7 exercises. Subject must indicate if he/she tastes challenge during the fit test.</td>
</tr>
<tr>
<td><strong>Acceptable challenges</strong></td>
<td>- Aerosol: Denatonium benzoate (bitter), sodium saccharin (sweet), stannic chloride (irritant smoke); OR</td>
</tr>
<tr>
<td></td>
<td>- Vapor: isoamyl acetate (banana oil)</td>
</tr>
<tr>
<td><strong>Time requirement</strong></td>
<td>Can fit test up to 5 individuals at once.</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><strong>Probed facepiece or adapter required</strong></td>
<td>No</td>
</tr>
</tbody>
</table>

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concentration of the contaminant. QLFT, on the other hand, yields either a pass/fail result, depending on whether the subject reports detecting the challenge during the fit test. Regulatorily, either QNFT or QLFT can be used for most classes of respirator, including disposable filtering facepieces; however, quantitative fit testing is required for full facepieces used in negative-pressure configurations if the assigned protection factor (APF) of 50 is required (i.e., if airborne concentrations of contaminants exceed 50 times the occupational exposure limit). Table 1 summarizes some of the differences between QLFT and QNFT.

**Q: How many people can I fit test at once?**

In most cases, up to 5 people can be fit tested simultaneously by one fit tester. If all your subjects have a sensitivity threshold of 10 (they taste the sensitivity solution during the first 10 squeezes), you will begin the fit test by inserting 10 squeezes into each person’s hood. This must be accomplished within the first 30 seconds of the fit test so you can administer the next round of squeezes (5 apiece in this scenario) at the 30-second mark, to meet the requirements of the OSHA QLFT protocol. It takes approximately 6 seconds to perform 10 full squeezes. Therefore you can fit test a maximum of 5 individuals at one time (5 people x 6 seconds = 30 seconds). If any subjects have a higher sensitivity threshold than 10, you will probably need to decrease the number of subjects, as more total squeezes will be required.

**Q: How long does each exercise last? How long does a fit test last?**

Each exercise lasts 60 seconds. There are 7 exercises in the fit test, so a properly administered fit test lasts a minimum of 7 minutes. Keep in mind that the entire qualitative fit test procedure includes the sensitivity test, donning, and performing user seal checks – in addition to the fit test itself – so the entire event will require at least 15 minutes of each subject’s time.

**Q: What if an individual doesn’t taste the sensitivity solution after the first 10 squeezes?**

Per the OSHA fit test protocol, administer 10 more squeezes, for a total of 20. If the subject still does not taste the solution, administer 10 more squeezes, for a total of 30. If they still don’t taste it, they are deemed insensitive to that challenge, and you must try an alternative. (If the challenge is the bitter solution, you may switch to the sweet solution, and vice versa.)

**Q: Why must I continue to inject the fit test aerosol into the hood every 30 seconds throughout the fit test exercises?**

As the subject breathes the aerosol-laden air through the respirator filter, they effectively clean the air. After 30 seconds, more aerosol must be injected in order to restore the airborne concentration to its original level. This OSHA-approved protocol was validated to maintain an acceptable concentration of aerosol inside the hood throughout the fit test.

**Q: What should I do if someone tastes the challenge during the fit test?**

Stop the fit test for that person. Ask them to remove the hood and the respirator. (If you are fit testing more than one person simultaneously, finish the fit test for the rest of the subjects.) Work with the person to determine why they failed – examine their donning technique, fit, the respirator, etc. Ask them to re-don the respirator or try a different model or size. Since they may have tasted a high concentration of the fit test solution, encourage them to get a drink of water. When they are ready to be tested again, you must begin the entire procedure again, starting with the sensitivity test and then completing an entire fit test.
Fit Test Regulatory Requirements

**Q: When is qualitative fit testing an acceptable fit test method? When is quantitative fit testing required?**

According to 29 CFR 1910.134, qualitative fit testing is an acceptable method for tight-fitting facepieces used in negative-pressure and positive-pressure configurations, with a few exceptions:

- The assigned protection factor of 50 is needed while using a full facepiece in negative-pressure air-purifying mode.
- A supplied-air respirator (SAR) or self-contained breathing apparatus (SCBA) is used in demand mode (currently very uncommon and distinct from pressure-demand mode).
- Facepieces used in SCBAs for structural firefighting must be quantitatively fit tested, per the National Fire Protection Association.

**Q: Are there any respirators that don’t require fit testing?**

Loose-fitting facepieces, hoods and helmets, which are all used in positive-pressure configurations, do not depend on a tight seal with the face to provide protection and therefore do not need to be fit tested. Furthermore, per OSHA, disposable filtering facepiece respirators that are used in voluntary use situations do not need to be fit tested. Refer to Regulations Update #21 for information on OSHA’s requirements when respirators are worn voluntarily.

**Q: Who can conduct medical evaluations related to fit testing?**

The evaluation must be performed by a physician or other licensed health care professional (PLHCP), per OSHA 29 CFR 1910.134. This may include a variety of health care professionals, depending on the scope of practice permitted by each state’s licensure.

**Q: What is a medical evaluation?**

OSHA requires that employees be determined to be medically able to use a respirator before being fit tested, both in mandatory and voluntary use situations. The employer must supply the medical evaluation at no cost to the employee. Many occupational health clinics offer this service. The evaluation must be performed by a PLHCP, as stated above. During the evaluation, the PLHCP must collect certain information from the employee, which is specified in 29 CFR 1910.134 Appendix C. Additionally, the employer must provide certain information regarding the employee’s work conditions to the PLHCP, which is specified in 29 CFR 1910.134(e)(5)(i). If deemed necessary by the PLHCP, a follow-up exam may be scheduled.

**Q: Do I have to be certified to conduct fit testing?**

No, OSHA does not require any specific certification for fit testers. In 29 CFR 1910.134 Appendix A, OSHA says, “The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.”

**Q: Does the fit test subject need to be clean-shaven?**

Per OSHA, employees wearing respirators must be clean-shaven, including during the fit test. No facial hair may be present that interferes with the respirator seal. Many companies and fit testers create policies regarding shaving for fit tests. For example, in order to hold a position where respirator use is required, an employee must come to work clean-shaven. Or if the work is predictable, the
employee must be clean-shaven any day when a respirator will need to be worn – including fit testing. 3M employees will not fit test someone who is not clean-shaven.

**Q: How should I document my fit testing?**

A. OSHA requires that the employer keep records that include the name or employee number; the type of fit test performed; the make, model, and size of the respirator; the date of the test; and pass/fail results for QLFT or numerical results for QNFT. This information needs to be retained until the date of the next fit test administered to that individual. 3M offers downloadable forms that can be completed and kept on file to meet these requirements. The forms can be found on the 3M website, along with other fit testing resources, including a downloadable wallet card. Although OSHA does not require a wallet card, employees must know which respirator make, model, and size they should be wearing. Wallet cards are one way to help ensure employees will always have quick access to that information.

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For more information, please contact:

**3M Personal Safety Division (PSD)**

In the U.S., contact:

- **Customer Service**
  1-800-328-1667
- **Technical Assistance**
  1-800-243-4630
- **Internet**
  www.3M.com/PPESafety
- **For other 3M products**
  1-800-3M HELPS

In Canada, contact:

- **3M Canada Company, PSD**
  P.O. Box 5757
  London, Ontario N6A 4T1
- **Customer Service**
  1-800-265-1840
- **Technical Assistance (Canada only)**
  1-800-267-4414
- **Internet**
  www.3M.com/PPESafety

**Technical Assistance In Mexico**

- **01-800-712-0646**
- **5270-2255, 5270-2119 (Mexico City only)**

**Technical Assistance In Brazil**

- **0800-132333**