Qualitative Fit Testing Instructions

for Kimberly-Clark* Tecnol* PFR95* N95 Particulate Filter Respirators and Surgical Masks

Kimberly-Clark

Protection. For life.

OSHA requires fit testing for all employees who are required to wear tight-fitting facepiece respirators. To ensure that KIMBERLY-CLARK* TECNOL* PFR95* N95 Particulate Filter Respirators and Surgical Masks provide the intended level of protection, every wearer should receive training. This includes demonstrations and practice time on how to properly don the respirator and to determine if it fits correctly.

Directions for *Proper Donning:*

Proper donning of a PFR95* N95 Particulate Filter Respirator and Surgical Mask may feel a little awkward at first, but it will become easier with repeated applications. The following instructions should be followed when donning this product (see below and enclosed poster for clarification):

1. Separate the edges of the respirator to fully open it.
2. Slightly bend the nose wire to form a gentle curve.
3. Hold the respirator upside down to expose the two headbands.
4. Using your index fingers and thumbs, separate the two headbands.
5. While holding the headbands with your index fingers and thumbs, cup the respirator under your chin.
6. Pull the headbands up over your head.
7. Release the lower headband from your thumbs and position it at the base of your neck.
8. Position the remaining headband on the crown of your head.
9. Conform the nosepiece across the bridge of your nose by firmly pressing down with your fingers.
10. Continue to adjust the respirator and secure the edges until you feel you have achieved a good facial fit. Now, perform a User Seal Check.

Directions for *User Seal Checking:*

To ensure PFR95* N95 Particulate Filter Respirators and Surgical Masks are providing the intended level of protection, a User Seal Check must be conducted each and every time they are worn.

To User Seal Check a respirator, the wearer should forcefully inhale and exhale several times. The respirator should collapse slightly upon inhaling and expand upon exhaling. The wearer should not feel any air leaking between his/her face and the respirator. This is the sign of a good facial fit and a successful User Seal Check.

If the respirator does not collapse and expand OR if air is leaking out between the wearer's face and the respirator, then this is NOT a good facial fit. The wearer should adjust the respirator until the leakage is corrected and he/she is able to successfully User Seal Check the respirator.

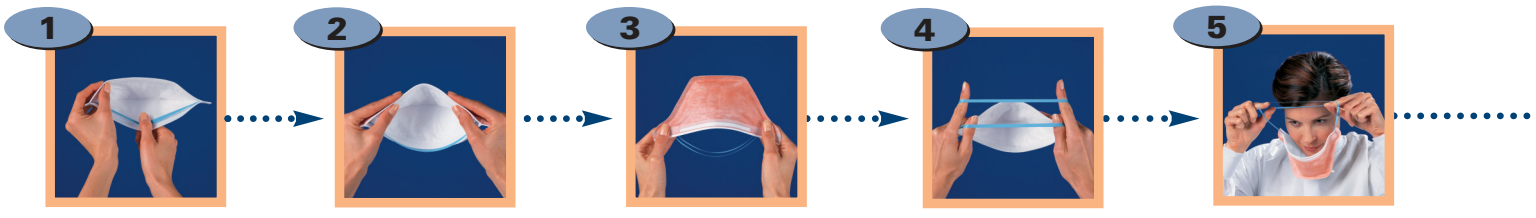
Note: User Seal Checking is NOT a substitute for Fit Testing. User Seal Checking is a simple procedure intended to help the wearer verify that he/she has properly donned the respirator. Fit Testing is designed to determine the appropriate size respirator for each wearer. Fit Testing should be conducted at least annually as required by OSHA. Your facility's respiratory protection program may require more frequent Fit Testing.

Tips for Achieving a Good Fit:
If the wearer is having a problem successfully user seal checking the respirator, he/she should try the following tips:

1. Use a mirror while adjusting the respirator.
2. Ask someone to look for hair or earrings that might be caught in the seal.
3. Make sure the headbands are positioned properly. It is especially important that the top headband is on the crown of your head, as it is designed to hold the bottom of the respirator snug against your chin.

Note: It is important to stress to the wearer that:

- The respirator must be User Seal Checked each and every time it is donned, and
- He/she should not proceed with activities until a successful User Seal Check has been completed.



Qualitative Fit *Testing Protocol:*

The qualitative Fit Testing protocol consists of two parts: a Threshold Check and a Fit Test. The Threshold Check determines the subject's ability to taste a weak solution of the challenge agent. The Fit Test uses the full strength solution to verify that the wearer can achieve an acceptable facial fit with the respirator. A medical evaluation to assess the ability to wear a respirator should be conducted prior to fit testing or respirator use.

The following items are not included in this Kit but should be available to assist in Fit Testing:

- Covered pitcher or container of water and drinking cups (or a nearby water fountain)
- Disposable towels / napkins or baby wipes
- Stop watch or wrist watch with a second hand
- Adequate supply of the respirator style your facility will be using
- Training files or other record-keeping system your facility will be using

Note: This Kit contains saccharin-based Threshold Check and Fit Test solutions. The same protocol, however, can be followed using BITREX® (extremely bitter taste) as the challenge agent. Both saccharin and BITREX® are OSHA-accepted challenge agents. Supplies of both saccharin and BITREX® are available at a nominal charge by calling your local distributor.

Preparation:

1. Pour the contents of Threshold Check Solution into the Threshold Check nebulizer. Prepare the Fit Test nebulizer with the Fit Test Solution in the same manner.
2. Assemble the hood by pressing the VELCRO® strips together and fitting the bouffant cap over the top, securing the seam of the cap under the tabs on the hood.
3. The Fit Test protocol should be explained to the test subject prior to testing. The test subject should not eat, chew gum, or drink anything but water for at least 15 minutes prior to the test.
4. Record the name of the test subject, type of respirator (N95), brand and size of respirator, and date of the test.

Threshold Check Procedure:

1. Have the test subject put on the hood without a respirator.
2. Instruct the subject to breathe through his/her mouth with tongue extended.
3. Instruct the subject to immediately report when the challenge agent is tasted.
4. Insert the nozzle of the Threshold Check nebulizer into the hole at the front of the hood and squeeze the bulb firmly ten times. The nozzle should be directed away from the nose and mouth of the person. (If the person reports a taste during this process, stop squeezing. Record "10" as the number of squeezes required, regardless of when the person reported the taste.)
5. If the subject has not tasted the solution, administer another 10 squeezes. (If the person reports a taste during this process, stop squeezing. Record "20" as the number of squeezes required, regardless of when the person reported the taste.)
6. If the subject has not tasted the solution, administer another 10 squeezes and ask again if they have tasted the solution. (If the person reports a taste during this process, stop squeezing. Record "30" as the number of squeezes required, regardless of when the person reported the taste.)
7. If no taste has been detected, and if saccharin is being used, then the subject should be tested with the alternative BITREX® solution using these same procedures. If the subject is unable to taste either saccharin or BITREX®, then the subject cannot be tested using this protocol. Instead, quantitative Fit Testing is suggested.

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Qualitative Fit Testing Protocol: (cont'd)

Threshold Check Procedure: *(cont'd)*

8. Remove the hood and allow the subject to rinse his/her mouth with water and wipe his/her face. The subject should not proceed to the Fit Test until the taste of the challenge agent has been allowed to clear, which usually takes several minutes.

Fit Test Procedure:

1. Have the subject put on the respirator and perform a Fit Check. The subject should be allowed to wear the respirator for at least five minutes, adjusting it as needed.
2. Place the hood on the subject, making sure that there is sufficient room for the subject to move his/her head from side to side and up and down without the mask touching the sides of the hood.
3. Instruct the subject to breathe through his/her mouth with tongue extended for the duration of the test and to report if the taste of the solution is detected at any time during the test.
4. Insert the nozzle of the Fit Test nebulizer into the hole at the front of the hood and spray 10, 20, or 30 squeezes into the hood, depending on which number was recorded from the Threshold Check.
5. Maintain the aerosol concentration in the hood throughout the test by squeezing one half the initial number of squeezes every 30 seconds into the hood.
6. Instruct the subject to perform the series of exercises below for 60 seconds each:
   I. Normal Breathing
   II. Deep Breathing
   III. Turning head from side to side (pausing for a breath when head is to side)
   IV. Moving head up and down slowly (pausing for a breath while head is up)
   V. Talking (reading the enclosed "Rainbow Passage," reciting the alphabet, etc.)
   VI. Jogging in Place
   VII. Normal Breathing
7. If the exercises are completed without the subject tasting the aerosolized solution, then an acceptable fit has been demonstrated and the subject has passed the test.
8. If the subject reported tasting the aerosolized solution during the test, then the subject has failed to achieve an acceptable fit. The test subject should be allowed to re-test with the same model respirator or with another model respirator of his/her choice. Wait at least 15 minutes before re-testing and begin by repeating the Threshold Check.

Cleaning-Up:

1. Rinse the nebulizers with warm water to prevent clogging. If clogging is found at the end of the test, clean the nebulizer and retest. The nebulizers should be thoroughly rinsed and refilled at least every four hours during testing.
2. Wipe out the inside of the hood with a damp cloth or paper towel to remove any solution residue. A disinfectant, such as isopropyl alcohol, may be used for cleaning to reduce potential contamination.

Additional Resources:

OSHA Websites:

Tuberculosis Information
http://www.osha-slc.gov/SLTC/tuberculosis/index.html

OSHA Standard 1910.134 Respiratory Protection
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=12716

Health Care Information
http://www.osha-slc.gov/SLTC/healthcarefacilities/index.html

CDC NIOSH Websites:

Tuberculosis Information
http://www.cdc.gov/niosh/topics/tb/

Respirators: Your TB Defense
http://www.cdc.gov/niosh/docs/video/tb.html

TB Respiratory Protection Program in Health Care Facilities Administrator's Guide
http://www.cdc.gov/niosh/99-143.html

Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities, 1994
http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00035909.html

Core Curriculum on Tuberculosis, What the Clinician Should Know
http://www.cdc.gov/nchstp/tb/pubs/corecurr/default.htm

Questions & Answers:

Q: Is fit testing mandatory?

A: When respiratory protection is required and respirators are issued to employees, OSHA requires fit testing be conducted as part of that respiratory protection program.

If a respirator is used voluntarily in a situation where respiratory protection is not mandated, then fit testing is not required. This includes visitors, who should be given a respirator and general instructions on its use.

Q: How often should fit testing be conducted?

A: OSHA requires that fit testing be conducted prior to initial use of the respirator and annually, thereafter. In addition, fit testing should be conducted whenever a different respirator facepiece is used and whenever the wearer undergoes changes that could alter facial structure or size, such as facial surgery or a significant change in body weight.

Q: What is the difference between qualitative and quantitative fit tests?

A: Qualitative tests, such as those using a protocol that employs saccharin or BITREX® are pass/fail tests based on the subject's detection of a challenge agent. Quantitative tests objectively measure the number of particles leaking around a mask, providing a numerical measurement of the facial fit expressed as a "fit factor". For a given respirator type, a minimum fit factor must be achieved to pass the test. The minimum fit factor for N95 respirators is 100.

Q: What protocols can be used to fit test PFR95* masks?

A: PFR95* masks are most often fit tested by following the Qualitative Fit Test protocol outlined in this manual and employing saccharin or BITREX® as the challenge agent. The respirators can also be fit tested by following a Quantitative Fit Test protocol which utilizes the TSI PortaCount® Plus Respirator Fit Tester with N95-Companion* (available from TSI Incorporated, #800-926-8378). Protocols which utilize banana oil or irritant smoke are not recommended for use with PFR95* masks.

Q: What if many people are failing using the TSI PortaCount® Plus Respirator Fit Tester procedure?

A: First, verify that the fit test is being conducted with the TSI N95-Companion™ "in an enclosed area." "A medium-sized room [approximately 10' x 16'] is normally a suitable location. The particle generator does not function efficiently in an open area or a very large room." Refer to the TSI manual for the N95-Companion™ to the PortaCount® Plus for these and further instructions for proper equipment use. TSI, Inc., may be contacted at 1-800-926-8378. The address is TSI, Inc., Health and Safety Instruments, 500 Cardigan Rd., P.O. Box 64394, St. Paul, MN 55164. Or, visit their website at www.tsi.com.

Q: Can people with beards be fit tested?

A: OSHA does not permit the use of respirators with tight-fitting facepieces to be worn by individuals with facial hair. Facial hair between the skin and sealing surface of the respirator will interfere with the seal of the respirator. Individuals with mustaches and short goatees that do not interfere with the seal of the respirator can be fit tested and wear a respirator.

Q: Can a person wear glasses while wearing a respirator?

A: Yes, but if an employee wears glasses or protective eyewear they must be worn in a manner that does not interfere with the seal of the facepiece to their face.

Q: Is it safe to fit test a pregnant woman?

A: The potential user should consult with her personal healthcare provider on this issue.

Q: What if the user has asthma?

A: A medical opinion is required to ensure that the health and breathing capability of the user is sufficient to overcome the differential pressure of breathing with a respirator.

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Questions & Answers: (cont'd)

Q: Must those people conducting fit tests be certified?

A: Although no certification is required, the NIOSH *TB Respiratory Protection Program In Health Care Facilities: Administrator's Guide, September 1999* requires "persons administering a qualitative fit test" to be "able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order." Program administrators should also have knowledge of the latest OSHA regulations regarding their situation.

Q: Why are the respirators worn for 5 minutes before fit testing?

A: The fit testing procedure in the NIOSH TB Respiratory Protection Program In Health Care Facilities: Administrator's Guide (September 1999) states, "The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test."

Q: What is the difference between a respirator and a standard face mask?

A: Respirators are designed for higher filtration efficiency and better facial fit than standard face masks. Respirators must be approved by NIOSH and all NIOSH-approved respirators must be marked as such. Look for the NIOSH approval label and on product dispensers and the NIOSH assigned approval code on each respirator if you are unsure if a product is a respirator or a standard face mask.

Q: Is a medical exam required for respirator wearers?

A: A medical evaluation by a physician or other licensed health care professional is required to determine whether any health conditions exist that could affect the employee's ability to wear a respirator.

Q: Does the Respiratory Protection Standard (29 CFR 1910.134) apply to healthcare settings and protection from tuberculosis?

A: As of December 31, 2003, OSHA withdrew the proposed TB standard and revoked the standard Respiratory Protection for M. Tuberculosis (29 CFR 1910.139). At that time OSHA began applying the Respiratory Protection Standard (29 CFR 1910.134) for respiratory protection against TB. This standard does apply to healthcare settings as well as general industry.

Q: When should a respirator be worn?

A: The CDC recommends that health care workers protect themselves from any disease spread through airborne transmission (e.g. tuberculosis, rubeola, varicella, SARS) by wearing a respirator. Further, OSHA and CDC recommend that respirators be worn when entering an isolation room, performing cough-inducing or aerosol-generating procedures, or when transporting an individual with suspected or confirmed infectious tuberculosis in an enclosed vehicle. In general, any time an employee is expected to attend to or come in contact with an unmasked, active tuberculosis patient, that employee should use respiratory protection. Respirators should also be worn during maintenance of air systems which may contain aerosolized tuberculosis. Visitors should be given respirators and instructed in their use before entering isolation rooms.

Q: Are visitors of patients with tuberculosis required to wear respirators and undergo fit-testing?

A: According to OSHA's 1996 Directives CPL 2.106 - Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis, "All persons entering an isolation room should wear respiratory protection. The patient's visitors should be given respirators to wear while in the isolation room, and they should be given general instructions on how to use their respirators." Visitors should be instructed on the proper way to don respirators and to perform a simple user fit check.

Q: How long can a PFR95* mask be worn?

A: A single respirator may be worn over the course of a normal shift, provided it has not become damaged or contaminated. According to the EPA, there is no recommended time limitation for use of an N-series respirator. The exact amount of time for which a respirator is used is not limited since the filtration efficiency is not degraded by use in normal room air. However, donning and removing the respirator several times creates the potential for damage. The user should inspect the respirator for damage and check the fit each time it is donned.

Contamination of a respirator can be difficult to assess. Infection control concerns should be addressed in the formation of the respiratory protection program. Storage and reuse of potentially contaminated respirators is not recommended. Physical damage and contamination should determine when a respirator is discarded. Replacement respirators should be readily available for employees who determine or suspect that their respirators are damaged or contaminated.

Q: Do tuberculosis patients need to wear respirators?

A: Tuberculosis patients do not have to wear respirators, but the CDC does recommend that they wear standard face masks whenever they are outside isolation rooms. Tuberculosis patients may be given a respirator but the patient's pulmonary function and other factors should be considered as respirators offer increased breathing resistance when compared to standard face masks.

Q: Should a respirator be used for other contagious diseases?

A: The CDC is an excellent resource for advice on the appropriate infection control procedures required to prevent transmission of specific diseases. The CDC phone numbers are (404) 639-3534 and (800) 311-3435. Their address is Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333.

Q: Are HEPA filters required for respirators used for protection against tuberculosis?

A: No, OSHA requires an N95 (or better) respirator as approved by NIOSH. A HEPA filter has an even higher filtration level (such as an N100, R100, or P100).

Q: Are Kimberly-Clark* respirators recommended for use with cytotoxic drugs?

A: When cytotoxic drugs are being prepared, the worker should use a biological safety cabinet as described in the OSHA Technical Manual (Section VI: Chapter 2: Controlling Occupational Exposure to Hazardous Drugs).

When cytotoxic drugs are being administered as an aerosol, Kimberly-Clark* respirators are not sufficient protection; only powered air-purifying respirators are appropriate.

Q: Are Kimberly-Clark* respirators recommended for use with laser plume?

A: Both the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommend the use of N95 or N100 respirators to minimize exposure to laser plume in settings were surgical lasers are used.

Q: Must a user re-fit test when changing between a Kimberly-Clark* FluidShield* PFR95* N95 respirator and a Kimberly-Clark* PFR95* N95 respirator?

A: No, a person does not need to be fit tested again when changing between a Kimberly-Clark* PFR95* FluidShield* N95 respirator and a regular Kimberly-Clark* PFR95* N95 respirator.

Q: Must a user re-fit test when changing between a Kimberly-Clark* PFR95* respirator with safety seal film and a Kimberly-Clark* PFR95* respirator or vice versa?

A: Yes, whenever changing between a respirator with safety seal film and one without safety seal film or vice versa, additional fit testing is required.

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