# Personal Protective Equipment: Respirators and Surgical Masks

The purpose of this section is to provide practical information on the rationale and role of personal protective equipment (PPE) against airborne M*ycobacterium tuberculosis (Mtb)*. Surgical (procedure) masks are traditionally used for keeping the surgical field or environment sterile. They are also used in healthcare settings as personal protection from droplet-borne disease transmission. However, surgical masks offer minimal protection against airborne *Mtb*. Rather, they are best used to reduce the release of infectious aerosols into the room air by persons with infectious TB. To be protected against airborne infectious particles, a person will need to wear a well-fitting respirator (e.g., N95 respirator shown in **Figure 1**). Although masks have often been strongly associated as a symbol of infection prevention and control (or potentially a trigger for stigma or political discord), it is essential to know that respiratory protection is but one component of an integrated program of TB Infection Prevention and Control for protecting healthcare personnel (HCP) from airborne *Mtb*.

FIGURE 1.

**TB healthcare provider wearing an N95 respirator**

Source: CITC

## Why are respirators needed?

TB was the first disease proven to be transmitted by the airborne route, and more recently, viable *Mtb* have been isolated from cough aerosols and exhaled breath aerosols from persons with TB.

- Most of the particles in these aerosols are smaller than 5 micrometers (μm) in diameter, a size that can be inhaled and deposited deep into our lungs where they can establish infection and possibly disease.
- Respirators reduce the risk of inhaling infectious particles and can mitigate the occupational risk for TB transmission to HCP.

Although not all persons with TB are infectious, there currently is not an accurate way to determine which persons are most infectious. The range of infectious aerosol production from persons with TB varies over 1000-fold, suggesting why some persons may be 'super-spreaders' and some not infectious at all. However, an often-quoted statement remains relevant for all settings: the most infectious persons with TB are those not yet on appropriate antitubercular therapy.

# Who should wear respirators?

HCP working with persons undergoing evaluation for active TB disease or with confirmed infectious TB disease should wear respirators, even if they are in an airborne infection isolation room (AIIR), because there may be a higher amount of infectious aerosol close to the person with TB as they breathe and cough. HCP outside the AIIR (e.g., in the adjacent hallway), however, do not need to wear a respirator as long as the ventilation system in the AIIR is functioning correctly. HCP on the frontlines of care (e.g., in emergency rooms or ambulances) should wear respirators when evaluating and caring for persons who are undergoing evaluation for presumptive TB disease, as the most dangerous situation for potential TB transmission is during the care for a person before TB is diagnosed and appropriate treatment started. Anesthesia, surgical, and pathology staff may benefit from PPE if a person with disseminated TB is undergoing a procedure in which there may be a risk of aerosolization (e.g., from the use of bone saws). Laboratorians should also use respirators when manipulating specimens with *Mtb*.

FIGURE 2.

**Surgical mask worn by person with infectious TB during transit through facility**

Source: iStock.com/Sasirin Pamai

Note: The most appropriate use for **surgical masks** (rather than a respirator) is for use on infectious persons with TB when they are outside of an AIIR (e.g., in transit to radiology or during an outpatient clinic visit). See **Figure 2**.

- The use of surgical masks on persons with TB has been shown to decrease transmission to guinea pigs by over 50%.
- Given the increased work of breathing associated with pulmonary TB, it may not be appropriate to ask persons with TB to wear respirators as they have more resistance to breathing than surgical masks.
- There may be circumstances where it may be reasonable to ask a person with TB to temporarily wear a surgical mask inside an AIIR (e.g., if a procedure is being done close to the head of that person). However, due to the benefit of rapid dilution ventilation in the AIIR, constant use of a mask by a patient inside an AIIR is not normally required.

# Where should HCP wear respirators?

Some settings appropriate for respirator use have been mentioned above. PPE should be used in tandem with administrative and environmental controls and **never be used instead of**, or as a substitute for, those control measures. For example, if a resident in a nursing home becomes ill and is considered a presumptive TB case, the HCP caring for that person should wear a respirator in the person's room while transport to another facility with an appropriate AIIR is being arranged. In addition, the person with presumptive TB should wear a surgical mask.

# Which respirators are best for protection against *M. tuberculosis*?

There are four major types of respirators:

- Filtering facepiece respirators (FFR); includes N95 respirators
- Powered air-purifying respirators (PAPR)
- Elastomeric half mask respirators
- Elastomeric full facepiece respirators

For this chapter, we will focus on N95 respirators and briefly discuss powered air-purifying respirators (PAPRs) for the protection of HCP. The use of respirators in healthcare settings is relatively new, having been first implemented in the early 1990s for protection of HCP against multidrug-resistant TB due to multiple outbreaks.

In the United States, the most common respirator recommended for protection against TB is the N95 respirator. See **Figure 3**.

FIGURE 3. **Examples of N95 respirators**


Sources: CDC https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/free-n95-manufacturers.html and jocic/Shutterstock.com

The 'N' designation refers to its approval for use against non-oil aerosols, and the '95' means that the filter material is at least 95% efficient at removing the most penetrating (0.3-micron size) particles, see **Table 1**.

Note: This **does not mean** that the N95 respirator is 95% protective; this is a common misunderstanding. Wearing a properly fitted N95 respirator is estimated to provide a factor of ten reduction in infectious particles in the air that is inhaled by the wearer. Hence, there is a ≥90% reduction in inhaled particles, or one is inhaling <10% of the aerosol concentration in the environment.

TABLE 1. **NIOSH-approved Filtering Facepiece Respirator (FFR) filter classes and efficiencies** (also applies to elastomeric respirator filters).
The N, R, and P designations refer to the filter's oil resistance as described.

| FILTER CLASS | DESCRIPTION |
|---|---|
| **N95, N99, N100** | Filters at least 95%, 99%, 99.97% of airborne particles. Not resistant to oil. |
| **R95, R99, R100** | Filters at least 95%, 99%, 99.97% of airborne particles. Somewhat resistant to oil. |
| **P95, P99, P100** | Filters at least 95%, 99%, 99.97% of airborne particles. Strongly resistant to oil. |
| **HE (High Efficiency) PAPR100-N, PAPR100-P** | Filters at least 99.97% of airborne particles. |

Source: Adapted from CDC/NIOSH National Personal Protective Technology Laboratory: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsourceTypes.html; Accessed November 30, 2022.

Although the N95 is the most common FFP respirator used in the U.S., global colleagues should be aware of similar respirators used and certified by countries other than the U.S.

- These include the FFP2 in Europe, the KN95 in China, the P2 in Australia and New Zealand, the Korea 1st class (or KF94) in South Korea, the DS2 in Japan, and the PFF2 in Brazil.

The filter efficiency in most of these is certified to be ≥ 94%. Although some of these respirators, e.g., KN95, were approved for use during the early phase of the COVID-19 pandemic under an emergency use authorization, this authorization was revoked for imported, non-CDC/NIOSH approved respirators on June 30, 2021.

- HCP can also check the authenticity of their respirator on this CDC/NIOSH website: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html.

Some of the K95 models did not offer adequate protection as marketed during the COVID pandemic and are not authorized for use in the U.S. HCP or administrators should consult their local respiratory protection and public health guidelines in selecting appropriate respirators.

## N95 respirators are classified as FFRs

All types of FFRs are disposable respirators, and although also described as "single-use respirators", CDC/NIOSH respirator regulations (42 CFR 84.2) allow for reuse by an individual wearer and describes conditions under which use should be stopped: "Single-use respirator means a respirator that is entirely discarded after excessive resistance, sorbent exhaustion, or physical damage renders it unsuitable for further use."

- The actual protection provided by a respirator is a function of the filter characteristics, face seal, and, if present, leakage through an exhaust valve.
- OSHA has coined the term "Assigned protection factor (APF)" to account for total inward leakage (i.e., room air potentially containing infectious particles may leak under the respirator with inhalation rather than be filtered through the respirator). OSHA describes APFs for various types of respirators. Note that an N95 respirator has the same APF as an N100 respirator.

A common practice during the COVID-19 pandemic has been to wear a surgical mask over the N95 respirator to prevent contamination of the N95 respirator. In response to the SARS outbreak of 2003, CDC developed interim guidelines that if N95 respirators were being reused, that HCP "consider wearing a loose-fitting barrier that does not interfere with fit or seal (e.g., surgical mask, face shield) over the respirator." In addition, the Institute of Medicine published a report in 2006 that N95 respirator users exposed to influenza can "protect the respirator from external surface contamination when there is a high risk of exposure to influenza (i.e., by placing a medical mask or cleanable face shield over the respirator so as to prevent surface contamination but not compromise the device's fit)" as shown in **Figure 4**. Definitive data supporting this practice is lacking, but there is likely low risk for harm for most HCP. Of note, individuals with medical conditions impacting cardiopulmonary reserve may not, in general, be able to tolerate the additional work of breathing presented by any prolonged respirator use with or without an additional layered mask.

FIGURE 4. **TB healthcare provider wearing a recommended unvalved respirator with surgical mask**

Source: Centers for Disease Control and Prevention

It is critically important that the surgical mask **not be placed under** the respirator (see **Figure 5**) as this will result in a poor fit at the face seal allowing leakage around the respirator as the wearer inhales. The other dangerous practice is providing infectious patients with a respirator with an exhaust valve. While this may provide more comfort to the patient, it will result in the exhalation of infectious aerosol (e.g., *Mtb*, influenza, and SARS-CoV-2) outside of the respirator unless a surgical mask is worn over the N95 respirator.

N95 respirators appear similar to surgical masks used frequently in healthcare, which has likely improved acceptability.

- The major limitation and complaint of HCP is that they are less comfortable than surgical masks because of the tight face seal and increased breathing resistance required to inhale air through the filter material. This provides an important clue. If a particular N95 respirator feels as comfortable as a surgical mask, it is probably **not providing adequate protection.**

FIGURE 5.

**Do not wear a surgical mask under your respirator**

Source: CITC

## Half-mask elastomeric respirators

Some HCP or facilities may wish to use a non-disposable FFR or reusable respirator, such as a **half-mask elastomeric respirator** (see **Figure 6**). These are made of a lightweight flexible material that is a rubber-like polymer of various types.

- They typically have two replaceable cartridges with either N95 (95% efficient) or P100 (>99.97% efficient) filters.
- These may feel more comfortable and secure on the face, but they still require fit testing.
- Even with the more efficient filters, they are not rated as more protective than N95 respirators by OSHA.
- Their major limitations are that they appear more 'industrial', and they may interfere with the ability to communicate clearly while being worn.
- Although they cost more per unit, they can be more cost-effective than disposable N95 respirators depending on the frequency of use of the disposables.

FIGURE 6.

**Half-mask elastomeric respirator**

Source: anmbph/Shutterstock.com

Elastomeric full-facepiece respirators that are generally used in industrial applications (e.g., confined spaces and high dust/vapor/fume workplaces) can offer a little more protection. However, we do not recommend these, largely due to their interference with communication, cost, and appearance that may be frightening to patients.

## Powered air-purifying respirators

**Powered air-purifying respirator** (PAPR; **Figure 7**) hoods offer the best protection for airborne-transmitted diseases and are the only respiratory protection option for situations where individuals cannot wear N95 or other respirators because of the inability to an achieve adequate seal of the respirator to the face (e.g., facial hair, face anthropometrics). Healthcare facilities may have state or local mandates to make PAPRs available for high hazard procedures (e.g., bronchoscopies and other aerosol generating procedures) for individuals who cannot wear N95 respirators or elastomeric respirators.

- PAPRs operate by drawing air through a high-efficiency filter (HE, PAPR100-N, or PAPR100-P) and then blow the clean, filtered air into the hood above the face (and therefore can also be cooler than other respirators).
- One drawback is that the moving air inside the hood can mask noises for the wearer and interfere with communication.
- Other advantages are that they offer face and eye protection, and the face shield allows patients to see the wearer's full face (important if they depend on reading lips or other non-verbal cues).
- Although fit testing is not required, training for safe and effective use of hooded PAPRs, including proper cleaning and disinfection, is needed.
- A major limitation is the dependence on keeping battery packs fully charged and equipment maintenance.

PAPR models that have the motor and filter unit on a belt in the back have the risk of interfering with mobility (e.g., knocking over specimens or materials on trays or countertops). This can be avoided by using a "Controlled Air-Purifying Respirator (CAPR)", a version of PAPR with the air blower and motor unit in the headgear (see **Figure 8**). A drawback for the CAPR is that the disposable headliners and face shields are sometimes difficult to assemble and remove. The APF of a loose-fitting or hooded PAPR is 25 (96 reduction). In healthcare settings, HCPs using PAPRs will generally wear a hood.

Note: The protection provided by a PAPR with a hood, after the battery runs out, approaches zero (i.e., no protection).

FIGURE 7.

### Powered Air-Purifying Respirators (PAPR)

Source: CDC https://phil.cdc.gov/Details.aspx?pid=23209 and 3M

FIGURE 8.

### Controlled Air-Purifying Respirator (CAPR), a special type of Powered Air-Purifying Respirator (PAPR)

Source: CDC, courtesy of MaxAir

# What is and when should I do fit testing?

The major limitation in the protection offered by respirators is the potential degree of air leak between the respirator and the face. Fit testing is required to assure a tight fit of the assigned respirator. This is analogous to making sure that your shoes fit; few of us would buy shoes without trying them on to confirm that they fit.

- Fit testing provides a means to determine which respirator model and size fits the wearer best and to confirm that the wearer can don the respirator properly to achieve a good fit.
- Periodic fit testing of respirators can also serve as an effective, hands-on training tool in conjunction with the infection prevention and control content included in employee training and retraining.

FIGURE 9.

**Qualitative fit-testing**

Source: iStock.com/Pornpak Khunatorn

The frequency of periodic fit testing should be determined based on:

- Risk for transmission of *Mtb* (e.g., HCP in high-TB prevalence or high-risk job settings may benefit from annual fit testing)
- Changes in facial features of the wearer
- Medical conditions that would affect respiratory function
- Changes in the physical characteristics of respirator (despite the same model number)
- Changes in the model or size of the assigned respirator
- Local or national regulations

Fit testing (see **Figure 9**) uses a test agent, either:

- Qualitatively detected by the wearer's sense of taste, smell, or involuntary cough (irritant smoke).
- Quantitatively measured by an instrument (ratio of aerosol concentration outside the respirator to aerosol concentration inside the respirator) to verify the respirator's fit.

CDC/NIOSH researchers reported similar results with fit testing using the qualitative fit test with Bitrex and the TSI PortaCount® with the N95-Companion.

- Additional information on fit testing may be found in the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005, MMWR 2005; 54 (No. RR-17) and the OSHA website (OSHA.gov).
- A video describing both quantitative and qualitive fit testing may be found at https://www.osha.gov/video/respiratory-protection/fit-testing.
- CDC/NIOSH has additional fit testing information at https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3fittest.html.
- In addition, you can verify whether or not a particular respirator model is certified, as well as download a copy of the manufacturer's user instructions for a model at https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html.

Note: A "User Seal Check" (formerly called Fit Check) is not to be confused with a respirator fit test. Absent manufacturer's user seal check instructions, OSHA describes a positive and a negative test. The benefit of a user seal check is controversial. Researchers have shown an absence of good correlation between passing a user seal check and passing a respirator fit test. Emphasis should be made on selecting well-fitting respirators and conducting periodic respirator fit testing. See **Table 2**.

# How to check if a respirator is a CDC/NIOSH-certified respirator?

Helpful steps to check are listed in **Table 2** and **Figure 10**.

TABLE 2. **Steps to verify if a "respirator" is a CDC/NIOSH-certified respirator**

**Step 1:** Does the respirator box and/or insert contain the "approval label" with the following information included in **Figure 10**.

**Step 2:** Does the label (stencil) on respirator contain the following information?

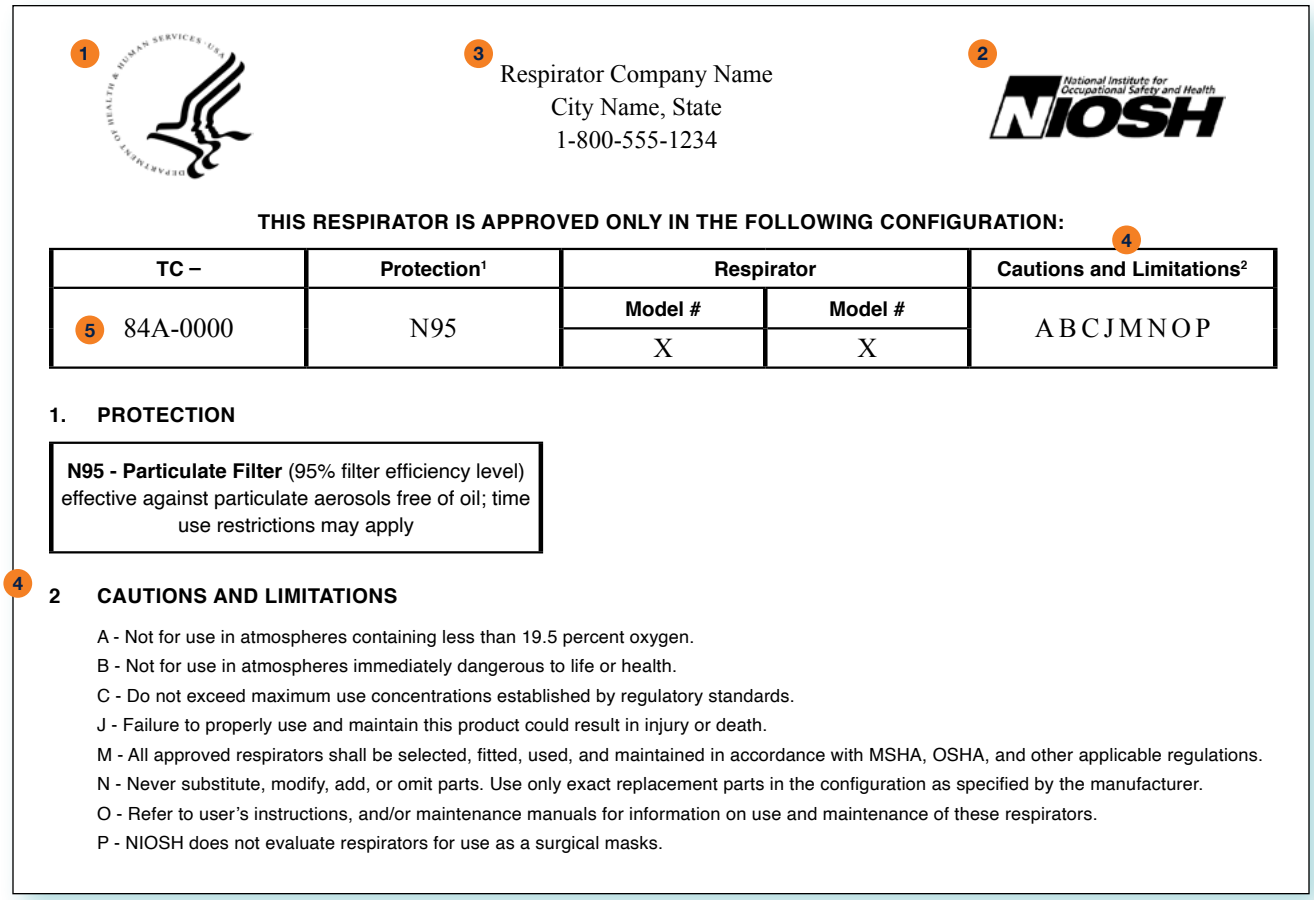
- Name of the applicant/manufacturer.
- Name and letters or numbers by which the respirator or respirator component is designated for trade purposes.
- Lot # (filters and N95 respirators) and/or serial # (elastomeric respirator or PAPR).
- Approximate date of manufacture.

**Step 3:** Is the "respirator" listed on the CDC/NIOSH website?
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

If the answer is **no to any** of the three questions above, **the respirator is not CDC/NIOSH approved.**

If the answer is **yes to all** of the questions above, **the respirator is likely CDC/NIOSH approved.** The respirator under consideration must also pass fit testing.

FIGURE 10. **Sample certification label for a N95 filtering facepiece respirator**
(one model with two sizes)



1

Respirator Company Name
City Name, State
1-800-555-1234

2

**THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:**

| TC – | Protection[1] | Respirator | | Cautions and Limitations[2] |
|---|---|---|---|---|
| | | Model # | Model # | |
| 5 84A-0000 | N95 | X | X | A B C J M N O P |

4

**1. PROTECTION**

**N95 - Particulate Filter** (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply

4 **2 CAUTIONS AND LIMITATIONS**

A - Not for use in atmospheres containing less than 19.5 percent oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
J - Failure to properly use and maintain this product could result in injury or death.
M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O - Refer to user's instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as a surgical masks.

**Six critical elements to check on the label or package insert from a box of respirators:**

1. Seal of the Department of Health and Human Services
2. Emblem of the National Institute for Occupational Safety and Health (NIOSH)
3. Applicant's/Manufacturer's name and address
4. Where appropriate, restrictions or limitations placed upon the use of the respirator by CDC/NIOSH
5. Approval number assigned by CDC/NIOSH, designated by the prefix TC
6. Lot # (filters and N95 respirators) and/or serial # (elastomeric respirator or PAPR)

For more information, see CDC's Counterfeit Respirators/Misrepresentation of NIOSH Approval https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.

## SUMMARY

- Respirators should always be used in concert with administrative and environmental controls.
  - The most important TB infection prevention and control measure is the rapid diagnosis and effective treatment of pulmonary TB (a primary aim of administrative controls).
  - Environmental controls can provide for an environment where infectious aerosols are reduced as much as possible.
- In most settings where active or infectious persons with TB are seen, N95 respirators are appropriate PPE for HCP.
- Some individuals cannot use N95 respirators or elastomeric respirators because of the inability to achieve an adequate seal and will require access to a PAPR for appropriate protection.

# References


- *Approval of Respiratory Protective Devices.* Code of Federal Regulations, Title 42, Part 84. (n.d.). Retrieved from https://www.ecfr.gov/current/title-42/chapter-I/subchapter-G/part-84.
- *Assigned Protection Factors for the Revised Respiratory Protection Standard.* (n.d.). https://www.osha.gov/sites/default/files/publications/3352-APF-respirators.pdf
- Centers for Disease Control and Prevention / National Institute for Occupational Safety & Health. (2021, September 3). *Types of respiratory protection.* Centers for Disease Control and Prevention. Retrieved November 30, 2022, from https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsourceTypes.html.
- Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005;54(No. RR-17).
- Chalikonda S, Waltenbaugh H, Angelilli S, Dumont T, Kvasager C, Sauber T, Servello N, Singh A, Diaz-Garcia R. Implementation of an Elastomeric Mask Program as a Strategy to Eliminate Disposable N95 Mask Use and Resterilization: Results from a Large Academic Medical Center. J Am Coll Surg. 2020 Sep;231(3):333-338. doi: 10.1016/j.jamcollsurg.2020.05.022. Epub 2020 Jun 11. PMID: 32534935; PMCID: PMC7289096.
- Coffey CC, Lawrence RB, Zhuang Z, Campbell DL, Jensen PA, Myers WR (2002). Comparison of Five Methods for Fit-Testing N95 Filtering-Facepiece Respirators, Applied Occupational and Environmental Hygiene, 17(10), 723-730, DOI: 10.1080/10473220290107002.
- Danyluk Q, Hon CY, Neudorf M, Yassi A, Bryce E, Janssen B, Astrakianakis G. Health care workers and respiratory protection: is the user seal check a surrogate for respirator fit-testing? J Occup Environ Hyg. 2011 May;8(5):267-70. doi: 10.1080/15459624.2011.566016. PMID: 21462067.
- Dharmadhikari AS, Mphahlele M, Stoltz A, Venter K, Mathebula R, Masotla T, Lubbe W, Pagano M, First M, Jensen PA, van der Walt M, Nardell EA. Surgical face masks worn by patients with multidrug-resistant tuberculosis: impact on infectivity of air on a hospital ward. Am J Respir Crit Care Med. 2012 May 15;185(10):1104-9. doi: 10.1164/rccm.201107-1190OC. Epub 2012 Feb 9. PMID: 22323300; PMCID: PMC3359891.
- Hines SE, Brown C, Oliver M, Gucer P, Frisch M, Hogan R, Roth T, Chang J, McDiarmid M. User acceptance of reusable respirators in health care. Am J Infect Control. 2019 Jun;47(6):648-655. doi: 10.1016/j.ajic.2018.11.021. Epub 2019 Jan 10. PMID: 30638674; PMCID: PMC7115316.
- Pandemic, Committee on the Development of Reusable Facemasks for Use During an Influenza. Reusability of Facemasks During an Influenza Pandemic: Facing the Flu. United States, National Academies Press, 2006. https://doi.org/10.17226/11637.