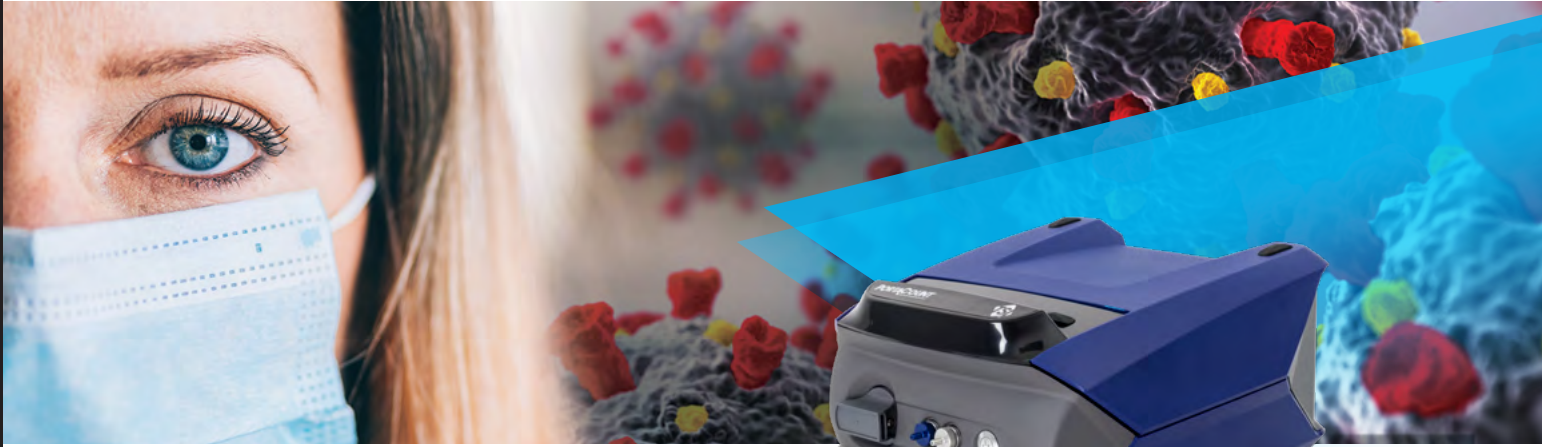


COVID-19 AND RESPIRATOR FIT TESTING

WHAT ARE THE ADVANTAGES OF QUANTITATIVE FIT TESTING AND WHAT SHOULD BE CONSIDERED?



Due to the Coronavirus pandemic, loose-fitting masks and tight-fitting respirators have become commonplace. Respiratory protection has entered the consciousness of many people and terms like community mask, N95 and FFP2 respirators are omnipresent. Not all masks and respirators are equal, nor provide equal protection. And even though a respirator can theoretically protect against infection from the Coronavirus, it must be worn correctly and fit tightly so that the protective function can be fulfilled. To ensure respirators provide the intended level of protection, they must be fit tested.

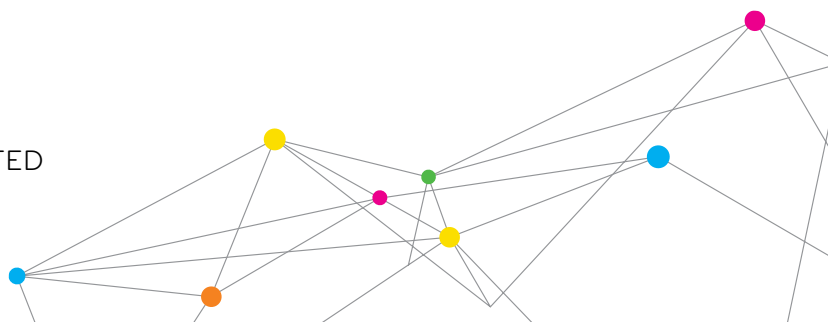
Understanding the Coronavirus

The Coronavirus is not a single virus, but a family of viruses. The virus of the Coronavirus family newly identified at the end of 2019 is called SARS-CoV-2 and can cause COVID-19. A COVID-19 infection can trigger coughing, fever, rhinitis and the loss of the sense of smell or taste. However, other secondary diseases such as pneumonia or diseases of the cardiovascular system are also possible.^{1,2,3}

Coronavirus SARS-CoV-2 can be transmitted via several different routes. The main transmission routes are droplet infections (i.e. the contact of virus-containing droplets with the mucous membranes) and transmission via aerosols, i.e. transmission by particles aerosolized within space such as a room. In order to reduce transmission, it is necessary to use spacing and to wear masks and/or respirators. Other probable transmission paths are smear infection and transmission via surfaces.^{1,4}



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Masks Are Not Equal to Respirators

During the pandemic, masks have become an everyday object used in communities and workplaces to reduce the spread of infection. However, the difference between masks and respirators is sometimes misunderstood. What are the differences between loose-fitting masks and tight-fitting filtering facepieces? The German Federal Institute for Drugs and Medical Devices has prepared the following comparison (excerpt):

	Mouth and Nose Cover	Surgical Masks	Filtering Facepieces
Abbreviation/ Synonym	DIY mask; Community mask	Medical masks	Particle filtering half-face respirators: FFP1, FFP2, FFP3
Purpose of Use	Private	Protection to others	Personal safety/ occupational health and safety
Personal Protective Equipment	No	No	Yes
Protective Effect (when used correctly)	Reduction of the speed of the respiratory flow and saliva/ mucus/droplet ejection and interception of droplets during inhalation	Protection from droplets, low protection from aerosols	Protection from droplets and aerosols

Table 1: Overview of the different mask types⁵

Various standards must be observed in the manufacture of surgical masks and FFP1, FFP2 and FFP3 respirators. However, the major difference is that FFP respirators are personal protective equipment (PPE) and must therefore meet higher standards. According to the official EU agency ECDC (European Centre for Disease Prevention and Control), FFP respirators require a fit test. The tight fit of PPE is one crucial aspect for fulfilling the protective function.^{5,6}

Significance of respirator fit testing

FFP respirators fit differently for each person. However, only properly fitting respirators offer protection. This means that only well-fitting and correctly used respirators provide protection against COVID-19 infection. Proof of this tight fit must be provided by a fit test.⁷

Respirators that do not fit tightly form leaks through which ambient air is inhaled unfiltered. If no filtering takes place, droplets and aerosols containing viruses are also inhaled. It is therefore all the more important to check that respirators fit tightly.

Advantages of quantitative fit testing

Two different methods can be used to perform a fit test:

- **Qualitative fit testing**, in which subjective odours or tastes must be sensed by the person being fit tested. This method can be very tedious and time-consuming if the respirator does not fit.
- + **Quantitative fit testing**, in which an instrument collects objective data and provides a clear measurement of the respirator's fit.

An example of a quantitative instrument is the PortaCount® Respirator Fit Tester. The instrument measures the number of small particles in the ambient air and compares this to a measure of the number of particles inside the respirator, while the PPE wearer performs specific movements. A "fit factor," which is a ratio of the two measurements, is then calculated as a measure of the respirator's fit. If the resulting fit factor is equal to or greater than the required fit factor, the respirator fits tightly and is suitable for use as PPE for the tested person.

The quantitative method has another decisive advantage during the coronavirus pandemic: *it also works in the case of loss of smell and taste, as can be caused by COVID-19 infection.* The Sandwell and Birmingham Hospitals NHS Trust in the UK have had this experience during the pandemic. Due to the great demand for fit testing and the shortage of quantitative fit testing instruments, they have expanded on their existing quantitative fit test program with the PortaCount® Respirator Fit Tester by adding testing using the qualitative method. However, this created situations where many employees had to be tested twice. When they performed qualitative tests, they found that many employees had lost or significantly reduced their sense of smell and taste. These employees then had to be tested once again using the quantitative method. Retesting costs time. A quantitative fit test, for example with the PortaCount® Respirator Fit Tester, can be carried out even if the persons to be tested have a reduced sense of taste or smell, are pregnant or have asthma. For this reason, the Sandwell and Birmingham Hospitals NHS Trust have expanded their equipment of quantitative PortaCount Respirator Fit Testers to enable rapid and safe fit testing in future extreme situations, such as pandemics.

Frequently asked questions about fit testing, PortaCount® Instruments and COVID-19

How can the PortaCount® Respirator Fit Tester be cleaned and disinfected?

TSI® recommends that you always follow your own company's specifications for cleaning/disinfection (e.g. respiratory protection program, COVID-19 hygiene procedures). The surface of the PortaCount® Respirator Fit Tester and the twin tubes can be disinfected with disinfectant that meets the US criteria^{8,9} for use against SARS-CoV-2 viruses. It should be noted, however, that TSI® has not conducted any studies of the effect of disinfectants on the lifetime of the PortaCount Respirator Fit Tester. TSI® cannot guarantee that the lifetime of the PortaCount Respirator Fit Tester will not be affected.

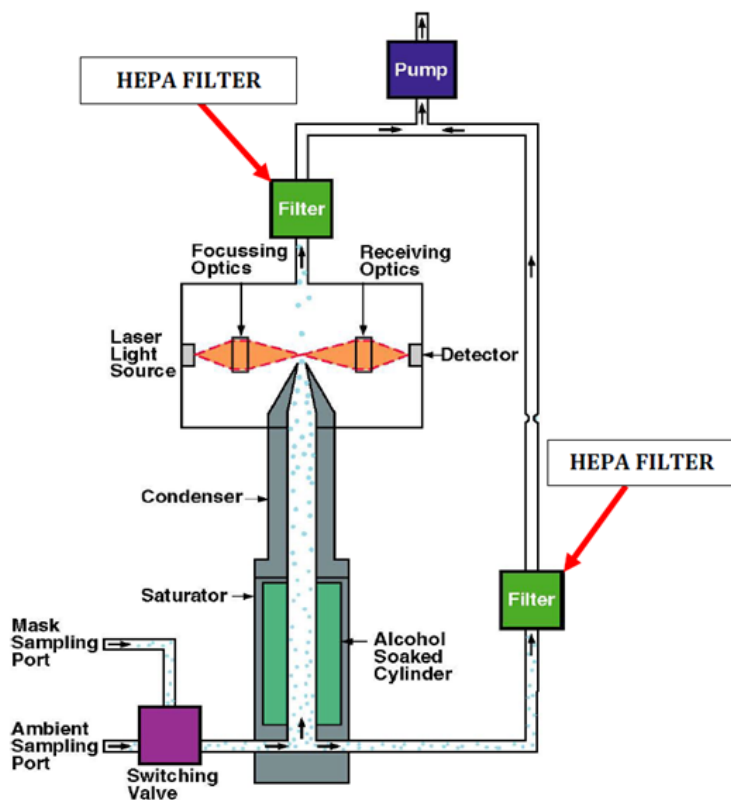
Can the exhaled air of a tested person be hazardous to the next test person?

Can viruses remain in the twin tubes and be inhaled again by the next person?

The twin tubes are under negative pressure or sealed during the operation of the PortaCount Respirator Fit Tester. The air is either flowing into the tube to the PortaCount Respirator Fit Tester or a valve has blocking the air flow in the tube. See TSI Application Note ITI-034 for more information, the conclusion applies to all models of the PortaCount Respirator Fit Tester.

Can the exhaust air from the PortaCount Respirator Fit Tester spread the Coronavirus?

The PortaCount Respirator Fit Tester has two built-in HEPA filters that filter the exhaust air before it leaves the unit. HEPA filters have a 99.95% collection efficiency for particles within a wide range of sizes. This means that corona viruses as well as larger exhaled particles and droplets can be filtered by the HEPA filters from the exhaust air of the PortaCount Respirator Fit Tester.¹⁰



Disclaimer

TSI® does not have expertise in pathogens such as viruses or their transmission. Therefore, we cannot assess the risk(s) of your unique situation and can make few recommendations. For all statements regarding corona virus, COVID-19 infection, or the protective effect of individual masks and respirators, we expressly refer to the sources given in this document.

- ¹ ECDC - European Centre for Disease Prevention and Control (Ed.): "Q & A on COVID-19: Basic facts". See: <https://www.ecdc.europa.eu/en/covid-19/facts/questions-answers-basic-facts>, last viewed on: 30.11.2020. Stockholm, 25.09.2020.
- ² WHO - World Health Organization (Ed.): "Coronavirus disease (COVID-19)". See: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19>, last viewed on: 30.11.2020. Genf, 12.10.2020
- ³ BZgA - Bundeszentrale für gesundheitliche Aufklärung (Ed.): "Infektion mit dem Coronavirus: Symptome und Krankheitsverlauf". See: <https://www.infektionsschutz.de/coronavirus/basisinformationen/symptome-und-krankheitsverlauf.html>, last viewed on: 19.11.2020. Cologne, 02.11.2020.
- ⁴ BMG - Bundesministerium für Gesundheit, Referat L7 "Presse, Internet, Soziale Netzwerke" (Ed.): "Basiswissen zum Coronavirus". See: <https://www.zusammengegencorona.de/informieren/basiswissen-coronavirus>, last viewed on: 19.11.2020. Bonn, Berlin, 2020.
- ⁵ BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte (Ed.): "Empfehlungen des BfArM - Hinweise des BfArM zur Verwendung von Mund-Nasen-Bedeckungen, medizinischen Gesichtsmasken sowie partikelfiltrierenden Halbmasken (FFP1, FFP2 und FFP3) im Zusammenhang mit dem Coronavirus (SARS-CoV-2 / Covid-19)". See: <https://www.bfarm.de/SharedDocs/Risikoinformationen/Medizinprodukte/DE/schutzmasken.html>, last viewed on: 19.11.2020. Bonn, Cologne, 12.11.2020.
- ⁶ ECDC - European Centre for Disease Prevention and Control (Ed.): "Safe use of personal protective equipment in the treatment of infectious diseases of high consequence". Stockholm, 2014. See: <https://www.ecdc.europa.eu/en/publications-data/safe-use-personal-protective-equipment-treatment-infectious-diseases-high>, last viewed on 30.11.2020.
- ⁷ RKI - Robert-Koch-Institut (Ed.): "Antworten auf häufig gestellte Fragen zum Coronavirus SARS-CoV-2 / Krankheit COVID-19". See: <https://www.rki.de/SharedDocs/FAQ/NCOV2019/gesamt.html>, last viewed on: 20.11.2020. Berlin, 18.11.2020.
- ⁸ See: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19>
- ⁹ See: <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/cleaning-disinfection.html>
- ¹⁰ ECDC - European Centre for Disease Prevention and Control (Ed.): "Heating, ventilation and air-conditioning systems in the context of COVID-19". 10 November 2020. Stockholm, 2020. See: <https://www.ecdc.europa.eu/en/publications-data/heating-ventilation-air-conditioning-systems-covid-19>, last viewed on 30.11.2020.



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