

THE COVID-19 PANDEMIC AND RESPIRATORY PROTECTION

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INTRODUCTION

The protection of health workers is one of the priorities for the response to COVID-19 outbreaks. Occupational health services in health care facilities have an important role for protecting health workers and ensuring the continuity of care in all healthcare facilities.¹

In most instances, coronaviruses are believed to be transmitted through large respiratory droplets from person to person, through inhalation or deposition on mucosal surfaces. Other routes implicated in transmission of coronaviruses include inhalation of aerosols.²

Although airborne transmission is not considered the principal transmission route, ECDC recommends a cautious approach because of possible transmission through aerosols.^{3,4}

On their website, ECDC recommends that Healthcare workers performing aerosol-generating procedures such as for instance swabbing should wear an FFP2 or FFP3 respiratory protective device together with gloves, and goggles.²

Looking at what healthcare workers and also the 'general public' is currently wearing, to protect themselves or their environment from possible airborne transmission of COVID-19, we need to distinguish two types of masks;

- A Surgical Mask (also known as a procedure mask, medical mask or simply as a face mask)
- A Respiratory Protective Device also called a "Respirator"

Although in very different ways, both masks can play a role in containment and mitigation of the COVID-19 pandemic.

Over the past weeks, respiratory protective devices and other masks are discussed in all known (social) media. These stories were rarely complete or correct and thus contributed to an increasing confusion amongst the general public as well as amongst healthcare workers.

In this white paper I would like to:

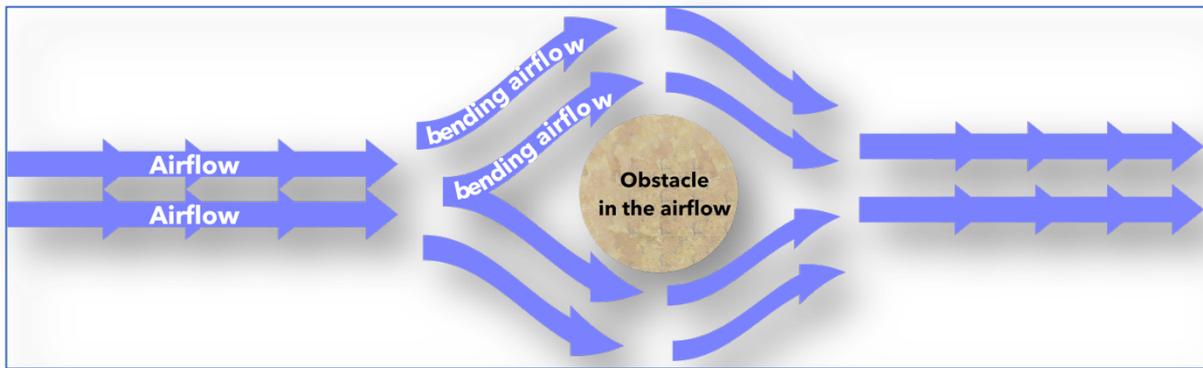
- Explain some basic principles of air filtration
- Explain the differences between a surgical mask and a respiratory protective device and
- Identify the roles of both products in the pandemic containment / mitigation actions
- Explain some differences between N95 and EN149 tested respirators
- Reduce and if possible, eliminate confusion about appropriate respiratory protection amongst healthcare workers
- Explain why it is a bad idea to re-use Respiratory Protective Devices

BASIC PRINCIPLES OF FILTRATION

First of all, we must realize that pathogens (such as viruses and bacteria) do not move in the air as so-called "naked" microorganisms. When brought in air, pathogens will always attach to a bigger particle. These bigger particles can be sputum or other secretions.

If we aim to filter pathogens out of air, we therefore focus on these bigger particles rather than on the viruses or bacteria. Because of the focus on particles, it is a misconception to believe that viruses are harder to filter out of air than bacteria just because of the fact that viruses are smaller than bacteria.

In order to understand air filtration, we first need to understand how air moves if we bring an obstacle as for instance a fibre of a filter in the airstream.



If we bring an obstacle (fibre of a filter) in an airstream, we see that the stream of air will bend (deflect) as soon as it meets the obstacle.

Filtration works when particles in an air stream come into contact (collide) with a fibre of the filter. So, filtration of air is nothing more than bringing particles which are transported in an airstream in contact with the fibers of a filter.

Another misconception is the thought that filters work as sieves, whereby the particles which are retained are larger than the pores in the filter medium.^{6,7,8}

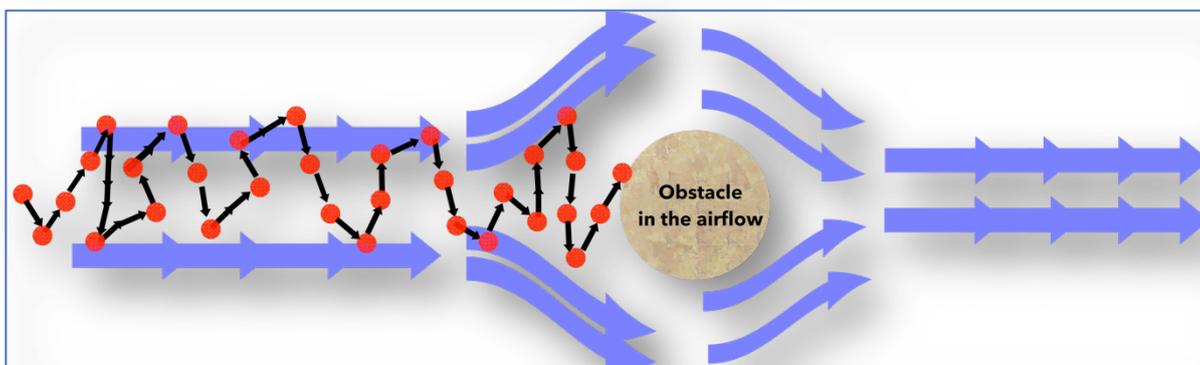
The process of air filtration is characterized by different filter-mechanisms which are responsible for filtration of 3 different "size-ranges" of particles.

Talking about air filtration, we distinguish the following particle sizes:

- Particles < 0,1 micron
- Particles in the range of 0,1 - 1 micron
- Particles which are bigger than 1 micron in diameter

Particles < 0,1 micron (sub-micron size particles)

The smallest particles will continuously collide with air molecules when they are in an airstream. Due to these collisions, they not only constantly change speed, but also change direction. The relatively large movements they make, are known in literature as "Brownian movements" and they ensure that the particles cannot escape the fibers of the filter. For these particles in the sub-micron size, this is so called the "Diffusion-mechanism" is very effective.⁸

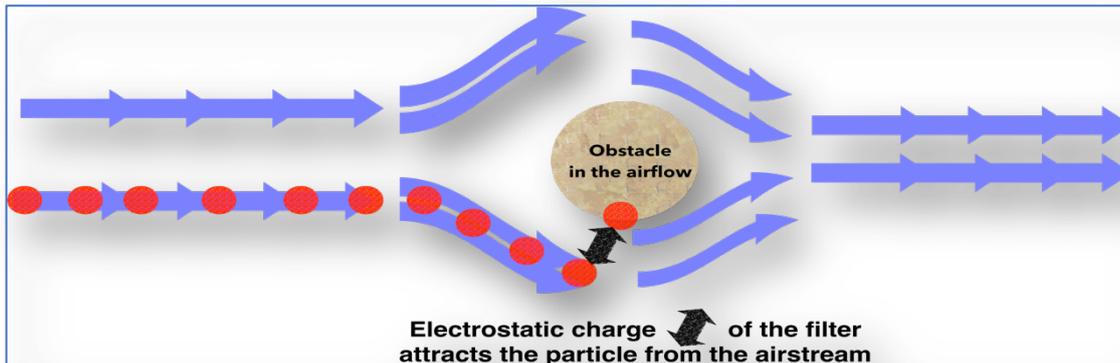


Particles in the range from 0,1 – 1 micron

Particles with a diameter between 0.1 - 1 micron are in principle the particles that are most difficult to filter out from an airstream because they follow the airstream (when it deflects when hitting a fibre of the filter) more or less exactly and therefore they do not easily come into contact with the fibres of a filter.

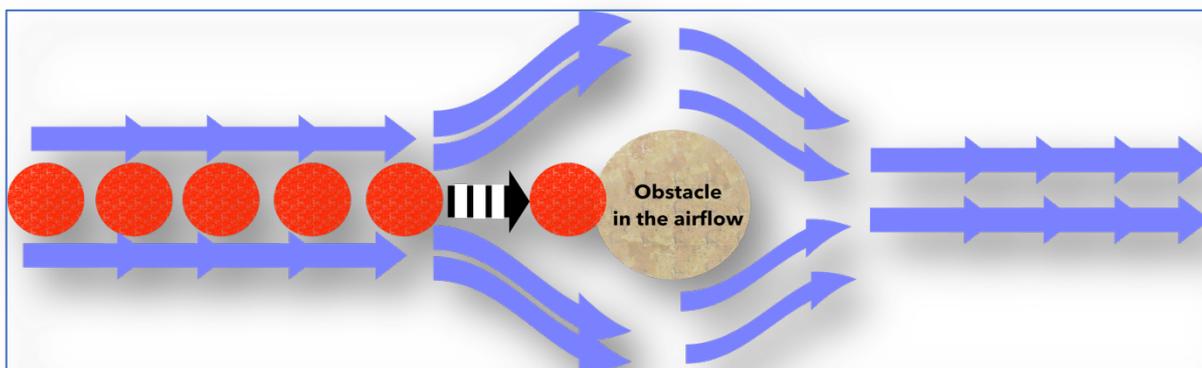
To improve filtration efficiency in this particle size range, the fibres of many disposable filtering facepieces are electrostatic charge. This electrostatic charge will attract these particles with the result that they “pulled-out” of the airstream.

In literature, this is known as the “Interception-mechanism”.⁸ The electrostatic charge will disappear over time as well as when the masks becomes wet and is the reason for the fact that a mask has an **expiration date** and that it can be worn for a limited time.



Particles > 1 micron

Particles with a diameter of >1 micron, will when they are in an airflow that deflects upon encountering an obstacle react slower than the deflecting airflow due to their mass, their velocity and their original direction. Therefore, they continue for a moment in the original direction and thus come into contact with the fibres of the filter. In literature, this is known as the “Inertial Impaction Mechanism”.⁸



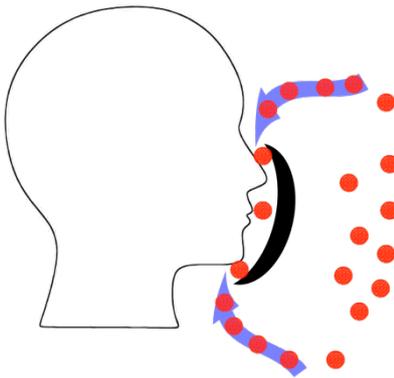
If the size of a particle approaches 10 microns (a droplet), the so called gravitational mechanism (meaning that the particle literally falls out of the breathing zone) becomes effective.

DIFFERENCES BETWEEN A SURGICAL MASK AND A RESPIRATORY PROTECTIVE DEVICE

The surgical mask

The first surgical mask was developed and used by Jan Mikulicz-Radecki. ⁹

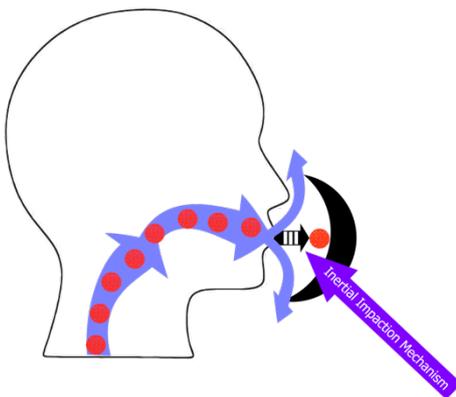
A surgical mask, also known as a procedure mask, medical mask or simply as a face mask was from the very beginning intended to be worn by health professionals during surgery and during nursing to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose. Also, according to the European Personal Protective Equipment Directive, surgical masks do NOT **protect the wearer from inhaling airborne bacteria or viruses**.¹⁰



When a person wearing a surgical mask inhales, a negative pressure is created between the mask and the wearer's face (e.g. the inside of the mask).

This negative pressure draws in air (containing potentially contaminated particles) to the inside of the mask.

Because of the fact that there is a poor or actually no sealing between the surgical mask and the face of the wearer, inhaled air (with contaminated particles) will not pass through the filter but will enter the inside of the mask by passing along the edges of the mask.



The reason why a surgical mask is effective in filtering out potentially contaminated particles from the exhalation air of the wearer of the mask is that the particles in exhaled air are normally between 4 and 8 microns in diameter. With particles in that size-range the inertial impaction mechanism is effective. Exhaled air comes into contact with the (inside) of the mask, after which the air deflects. The relatively big particles in that airflow react more slowly than the airstream, continue in the original direction and are "caught" by the fibers of the filter.

So, particles filtered out from the exhalation air are no longer in the air leaving the mask either through the material, or through the leakage paths at the top, bottom or at the lateral sides of the mask. It is evident that the contamination risk for COVID-19 is proportional to the number of contaminated particles per cubic meter air in the breathing zone. More particles mean higher risk of contamination, due to the fact that a surgical mask is able to potentially help to reduce the number of contaminated particles in the wearer's exhaled air, the transmission risk for COVID-19 may potentially decrease if potentially infected individuals wore a surgical mask.

Test standard EN 14683:2019+AC:2019 for Medical face masks (surgical masks);

In Europe, the requirements and test methods for surgical masks are specified in the above-mentioned standard. In the introduction part of this standard it says: *"The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations."*¹¹

In accordance with the standard, surgical masks have to be tested for their:

- Bacterial filtration efficiency (BFE) which is tested in vitro
- Breathability
- Splash Resistance (optional)
- Microbial Cleanliness
- Biocompatibility

Based on the result of the BFE tests, masks are divided into two types.

- Type I masks have a minimum bacterial filtration efficiency of 95%,
- the so-called Type II masks need to have a minimum bacterial filtration efficiency of 98%.

In the standard, it is also mentioned that Type I surgical masks should only be used for patients and other persons to reduce the risk of spread of infection particularly in epidemic or pandemic situations. Type I masks are according to the standard **NOT** intended to be used by healthcare professionals in operating rooms or medical settings with similar requirements, but instead are for use by patients and other persons to reduce the spread of infection.

According to the standard, Type II masks (e.g. masks with a minimum BFE of 98%) can be tested and classified as splash resistant. Splash Resistance is indicated with the capital "R". This means that Type IIR surgical masks are Splash Resistant masks with a minimum BFE of 98%.

The eventual Splash Resistant feature of a surgical mask should NOT be confused with "aerosol protection". The "R" just indicates that the mask has a (limited) ability to withstand penetration of synthetic blood projected at the mask at a given pressure. Important is to note that no class of surgical mask is considered Personal Protective Equipment.

The Respiratory Protective Device (respirator)

The primary intended use of a Respiratory Protective Device (RPD) is to protect the wearer against microbiological agents (viruses and bacteria) that may be present in the air.

In Europe, RPDs are tested in accordance with the test standard EN 149: 2001+A1:2009.

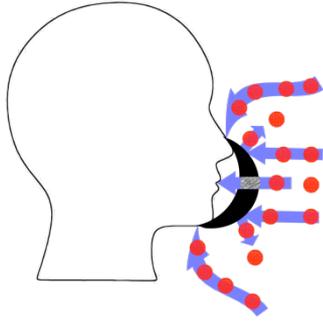
When respiratory protective devices are tested in accordance with EN 149, the so called "Total Inward Leakage" (TIL) of the device is measured. TIL is defined as the sum of: ¹²

- the filter efficiency,
- the efficiency of the seal between the mask and the skin of the face of the wearer (facial seal)
- the performance of an existing exhalation valve (if fitted).

Based on the test results, respirators are divided into 3 categories; FFP1, FFP2 or FFP3. (FFP stands for Filtering Face Piece). The minimum performance criteria for TIL are:¹²

- FFP1 respirators must have a TIL not greater than 22%
- FFP2 respirators must have a TIL not greater than 8%
- FFP3 respirators must have a TIL not greater than 2%

Note that the filtration efficiency test for in EN149 and in EN14683 are very different and it is not possible to compare the two performance tests.



A Respiratory Protective Device (respirator) will protect against breathing in potentially contagious particles in the air because of the good seal between the face and the mask and the high-performance filtration of the filter media. It is important to know that an RPD will only be effective if the wearer of the device is clean-shaven and the facial fit is not compromised by stubbles, beards or sideburns.

Note: In some countries an assessment of fit (a Fit Test) is mandated.

Some RPD's are tested and certified to be able to protect both the wearer of the device as well as the patient or the environment. These devices are referred to as 'healthcare respirators or medical respirators' and are typically certified under both the Personal Protective Equipment Regulations and the Medical Devices Directive. Respiratory protective device equipped with an exhalation valve (unless shrouded) can NOT be used in situations in which a patient or an (aseptic) environment have to be protected against potentially contaminated particles in the exhaled air of the wearer.

Different from surgical masks which are tested in vitro and in accordance with EN14683, respiratory protective devices are tested on a panel of 10 clean-shaven persons. ¹²

Differences between Surgical Masks and Respirators in summary;

- Surgical masks are NOT intended and developed to protect the wearer of the mask against airborne biological hazards in the air. Respiratory Protective Devices are intended to protect the wearer against airborne and respirable biological hazards
- Surgical masks can protect a patient or the environment from exhaled potentially contagious particles.
- A filter which has lost the electrostatic charge will be less efficient against filtering out certain particles from the air.
- Microbial cleanliness (bioburden), breathability and BFE are important requirements for surgical masks
- TYPE IIR surgical masks do NOT offer respiratory protection
- TYPE I surgical masks according to EN14683 are meant to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
- Based on Total Inward Leakage and filtration efficiency, Respiratory Protective Devices are classified in FFP1, FFP2 and FFP3

DIFFERENCES BETWEEN EN149 AND N95

The most important test protocols and classification systems for Respiratory Protective devices are the (European) EN149 test standard and the (USA) N95 test protocol. In the previous paragraph we have already discussed the

EN149 test standard as well as the FFP1, FFP2 and FFP3 classification.

Respiratory Protective Devices which are sold on the European market need to bear a CE mark. The CE-mark for a Respiratory Protective Device actually exists out of 4 components which need to be printed on every individual product as well as on the packaging of the product.

The 4 components are:

1. The CE-mark
2. The test standard (EN149)
3. The FFP class (FFP1, 2 or 3)
4. The 4-digit identification number of the Notified Body



The N95 standard

The National Institute for Occupational Safety and Health (NIOSH) is the US organization responsible for testing and certifying Filtering Facepiece Respirators (FFRs). Depending on the test results, they classify Respiratory Protective Devices in 9 categories. Which are: ¹⁴

- N95, N99, N100
- P95, P99, P100
- R95, R99, R100

The numbers in the NIOSH classification indicate the minimum filter efficiency

N stands for **Not** resistant to oil (suitable for use in healthcare settings)

R for **Resistant** to oil.

P for oil **Proof**.

Next to the different categories there are three more important differences between the N95 test standard and the EN149 test standard.

1. As mentioned before, the EN149 test standard evaluates the efficiency of the filter, the efficiency of the seal between the wearers face and the mask as well as the efficiency of an eventual exhalation valve. The N95 test standard does only test filter efficiency ¹³
2. The EN149 test standard uses an aerosol with a particle size distribution from 0,02 - 2 micron and a mass median diameter of 0,6 micron. NIOSH uses an aerosol with particles with a median of 0,3 micron. Earlier in this article we have already seen that the size of a particle can influence the filter efficiency.
3. In the EN149 test standard a panel of ten clean-shaven persons (without beards or sideburns) are selected for testing the respirators and the Total Inward Leakage is measured. The N95 test standard is an in vitro test in which only filter efficiency is tested ¹³

Due to these three important differences it is difficult or maybe even impossible to compare the classification of EN149 with the classification of NIOSH. In literature however the N95 and FFP2 are often considered equivalent.

WHAT IF THERE IS A SHORTAGE OF RESPIRATORY PROTECTIVE DEVICES?

The worldwide demand for personal protective equipment, including the demand for Respiratory Protective Devices, has risen to unprecedented levels (and is still increasing) due to the rapid spread (pandemic) of COVID-19. China is the world's largest producer of Respiratory Protective devices, with a reported daily capacity of 20 million pieces, but by the estimate of its manufacturers domestic demand alone is around 50 to 60 million per day. ¹⁵

The message is, that shortage of Respiratory Protective Devices cannot be avoided.

The European Center for Disease Prevention and Control published in their "Technical Report March 2020" some guidance on how to deal with a potential shortage of PPE. ²

On page 2 of that report we can read:

- The use of PPE for the different procedures to be performed should be considered on a case-by-case risk assessment

Based on the current knowledge on the transmission of COVID-19, in which respiratory droplets seem to play a major role (although airborne transmission cannot be ruled out at this stage), and taking into consideration the possible shortage of PPE in healthcare settings due to the increasing number of COVID-19 patients, the suggested set of PPE for droplet, contact and airborne transmission (gloves, goggles, gown and FFP2/FFP3 respirator) can be adapted for the clinical assessment of suspected COVID-19 cases as below:

- Healthcare workers performing the first assessment without direct contact; **the patient should wear a surgical mask and keep a distance of at least 1 meter.**
If possible, a physical barrier such as glass or a plastic teller window can be used to avoid direct contact and keep the distance; **in such case no PPE is necessary.**

- If available, provide a surgical mask for patients with respiratory symptoms (e.g. cough)
- Healthcare workers performing aerosol-generating procedures (AGP), such as swabbing, should wear the suggested PPE set for droplet, contact and airborne transmission (gloves, goggles, gown and FFP2/FFP3 respirator)
- If there is a shortage of FFP2/FFP3 respirators, healthcare workers performing procedures in direct contact with a suspected or confirmed case (but not at risk for generating aerosol) can consider wearing a mask with the highest available filter level, such as a surgical mask, in addition to gloves, goggles and gown.
- In order to maximize the use of PPE if there is an insufficient access to stocks of PPE materials, staff should be assigned to carry out procedures, or a procedure, in designated areas. For example, assign staff to swabbing procedures in a dedicated swabbing area.
- While swabbing patients, healthcare personnel can use the same respirator for several patients for a maximum of 4 hours without having to remove the respirator, as long as it is not damaged or soiled, unless the manufacturer explicitly advises against this.

REPROCESSING RESPIRATORY PROTECTIVE DEVICES TO PREPARE THEM FOR RE-USE

Imagine the true horror-scenario of being in an accelerating pandemic and at the same time facing a shortage of necessary Respiratory Protective Devices.

In a scenario like that it is understandable that people start thinking about possibilities to re-use Respiratory Protective Devices which are intended not to be re-used.

It is true, that "Challenging times are asking sometimes for unconventional measures".

It is the humble opinion of the author, that unconventional measures should not become **irresponsible** measures and that reprocessing of single use, disposable Personal Protective Devices should be avoided.

The publication of RIVM: ¹⁶

- The Dutch National Institute for Public Health and the Environment did a pilot study on which they concluded that reprocessing used Respiratory Protective Devices using hydrogen peroxide sterilization would lead to an acceptable quality of reprocessed face masks. However, in their communication they also state that only limited research was done on the retention of particles by the reprocessed masks.
- In their study a "fit-test" was used as a surrogate for measuring real "Total Inward Leakage". In EN149, a test aerosol is used with particles in a range from 0,02– 2 micron and a mean diameter of 0,6 micron. The particle size of the fit test is unknown.
- In their study they evaluated only Respiratory Protective Devices which were unused, there was no microbiological challenge of the tested Respirators involved. Furthermore, they evaluated a sterilization method known to inactivate coronaviruses in normal conditions, it is unknown if the method will also inactivate viruses if they are captured by a filter. It was not measured if the sterilizing medium did penetrate into the filter.
- RIVM based their conclusion on testing very few masks, in total only 10 masks were tested of which even less masks were used for their fit testing
- In sterilization, it is a very well-known principle that it is possible to clean without sterilization, but that sterilization without cleaning is not possible. The RIVM test showed that cleaning of Respiratory Protective Devices was not possible. In their communication the RIVM makes a remark that only unsoiled masks were used and that soiling could negatively affect the sterilization process.
- The fact that the elastic head bands of the sterilized Respiratory Protective Devices were intact after the sterilization process does not mean that they were still doing the job they are meant to do.
- No biological safety tests were carried out and, in their communication, they also mention that no studies have been conducted to determine if reprocessed masks still meet requirements of FFP2

In this COVID-19 crisis, it is all about protecting the people who are working at the front-line of the pandemic. They need and deserve to be protected in the best possible way and it is again the humble opinion of the author that offering them a false sense of safety as will be done with offering them re-processed Respiratory Protective Devices is the wrong thing to do.

With regards to the microwave technology:

Also, in Social Media I have seen people who believe that Respiratory Protective Devices can be made ready for re-use by placing them in a microwave. If we would want to do that, we would however need to remove all the metals from the device, this would mean that the metal nose-bar and the staples which are used to attach the headbands to the device would need to be removed prior to reprocessing. Removing those items would definitely destroy the device.

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