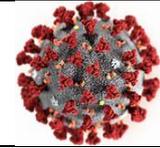


Swiss National COVID-19 Science Task Force (NCS-TF)



Type of document: suggestion and recommendation paper

In response to request from: update on handling and the washing procedure for community masks

Date of request

Expert groups involved: Sub task IPC; S. Tschudin Sutter, P. Wick, R. Rossi, A. Mortensen and ReMask Expert group <https://www.remask.ch/>

Date of response: 24/9/2020

Contact persons: Peter Wick (peter.wick@empa.ch), René Rossi (rene.rossi@empa.ch)

Comment on planned updates : none planned as of writing

Recommendations on minimal specifications for community masks and their use

Summary of request/problem

On request of the Swiss governmental Krisenstab, the "ReMask" Expert group formulated a recommendation for test methods and minimal specifications applicable to community masks. On 22.04.2020 these minimal specifications have been discussed and agreed upon with the Krisenstab and the Task Force VBS.

This document complements the document dated 25.4.20. It now additionally contains recommendations on handling and on the washing procedure applicable to community masks.

Executive summary:

Recommended specifications for community masks:

Community masks, mostly aimed at source control (meaning protection of others from the wearer), should offer a sufficient protection against liquid droplets of different sizes and aerosols (particle size down to 1 micrometer) produced by the wearer, for example while talking, coughing or sneezing. Community masks should have a sufficient air permeability to minimize breathing hindrance and should be available in different fitting sizes appropriate for both adults and children, so as to guarantee an adequate face coverage.

In brief, the following minimal specifications are recommended:

- Air permeability < 60 Pa/cm² according to ISO 9237
- Splash resistance: no liquid penetration as defined in EN 14683:2019+AC:2019
- Mask filtration efficiency FE ≥ 70 % with a particle size of 1 micrometer.
- >5 times washable at 60 degree Celsius with usual detergent

Recommendation on handling and washing frequency of community masks

We recommend washing the community masks once per day if it is worn twice daily (e.g. using it in public transportation in the morning and evening). The community mask should be stored unfolded in a sealed but breathable bag, so as to avoid cross contaminating the mask inner surface or the wearer with the potentially contaminated outer side of the mask. Plastic bags should be avoided due to an increased risk of bacterial or fungal overgrowth in the mask.

This document defines the test methods and minimal specifications recommended by the Science Task Force, "ReMask" Expert group.

Main text

Definition of the Community masks specification and their testing procedure

Mask terminology

FFP Masks	FFP Masks, Filtering Facepiece Particles facemasks, or personal protection facemasks are masks meeting the criteria of the norm EN 149 (e.g. FFP1-3, , N95, KN 95 or equivalent) FFP masks are personal protective equipment and have to comply with the PPE-directive (EU/2016/425, SR 930.115 – Verordnung über die Sicherheit von persönlichen Schutzausrüstungen (PSA-Verordnung)). They have to be tested according to the European Standard EN 149 and certified by an accredited Notify Body (before they can be put on the market). FFP masks are classified into FFP1, FFP2 and FFP3 depending on their filtration efficiency.
Surgical Masks	Surgical Masks, OP-Masks, or Medical masks are masks meeting the criteria of the norm EN 14683 (e.g. Type I, Type II, Type IIR, or equivalent) Surgical masks have to comply with the regulation on medical products (EU/2017/745, SR 812.213 Medizinprodukteverordnung – MepV). They have to meet the requirements of European Standard EN 14683 but do not require third party assessment (before they can be put on the market). There is hence no 'certification' as such and compliance is demonstrated by the manufacturer. Surgical masks are classified into Type I, Type II and Type IIR. Only Type IIR offers a protection against liquid splashes.
Community masks	"Community" mask is not an official term; it is used here for masks that don't need to meet the requirements of European Standard EN 14683 or EN 149. The use of such non-certified community masks is aimed at the general population, primarily for source control (respiratory etiquette) – thus, to protect others from exhaled virus-containing droplets or aerosols emitted by the mask bearer. Not all mask designs or materials are suitable for community masks and research is presently being conducted to identify the best mask designs. Performance criteria defining masks that are sufficiently blocking to droplets while being comfortable to wear and allowing reprocessing by cleaning do not correspond to an existing standard. As a result, this new specification list is defined and justified in the present document and is a recommendation.

Splash/droplet resistance

This test is defined in ISO 22609:2004. It is performed for new masks as well as reprocessed masks after a number of wash-/ decontamination cycles but below the maximum number guaranteed by the manufacturer. The test method is in line with ISO 22609:2004 and it is intended to evaluate the protection of the person wearing the mask from exposure to blood and other body fluids. The test evaluates the resistance of masks to penetration by a fixed volume of synthetic blood applied to the mask by high-velocity liquid contact over a time period between 0 s and 2,5 s. Outcome is based on visual and/or optical inspection of synthetic blood penetration.

In detail, the test method consists of spraying/squirting a volume of liquid horizontally onto the mask at a defined speed, corresponding to human blood pressure (16 kPa in EN 14683), in order to simulate the scenario of a mask being contaminated by a punctured blood vessel. This pressure is higher than what is known to occur during sneezing (7 kPa [2]) and also higher than the maximal static expiratory mouth pressure (13 kPa [3]). After projecting the synthetic blood on the outside,

the internal side of the mask is inspected for penetration of liquid. A swab can be used to test the target area in case of doubt of visual inspection.

The droplet size distribution during coughing is summarised in Figure 1 [4]. The droplet size is determining the resistance time in the air. However the debate is still ongoing and partially addressed in previous Policy Briefs of the National COVID-19 Science Task Force [12,13, 14]

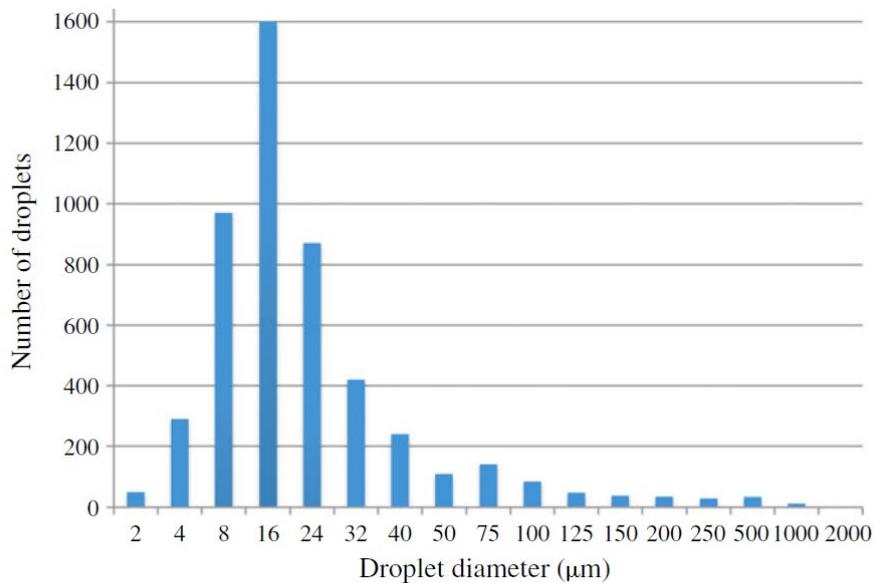


Figure 1: Histogram of droplet size in coughs [4]

In order to simulate coughing more precisely than does a blood jet, a synthetic colored artificial saliva (according to [7]) is used with a pressure of 12 kPa. The saliva mass is 2.04 ± 0.040 g. The masks are preconditioned 4 hours at 21°C and 85% rH.

Minimal requirement: no liquid penetration in 10 specimens

Aerosol filtration efficiency

This test is intended to evaluate the filtration efficiency and thus protection of the person wearing the mask from exposure to aerosols or droplets. Studies on the exhaled breath of influenza infected patients contained about 70% of influenza virus in particles between 300 nm and 500nm [5]. FDA-cleared surgical mask models tested varied between 7.5 – 76.3% filtration efficacy at 85 liters/minute with particles ranging from 40nm-1000nm [6]. Therefore, filtration efficiency is determined by exposing the mask to aerosol particles (particle size: 1 µm) applying laminar flow.

Minimal requirement: Mask filtration efficiency $FE \geq 70\%$ with particle size of 1 µm.

Air permeability

The mask must have sufficient air permeability to allow normal breathing.

Minimal requirement: according to EN 14683, the pressure difference must be $<60 \text{ Pa/cm}^2$ during a test of air permeability, applied according to the norm ISO 9237: 1995 (Textiles - Determination of the permeability of fabrics to air). Measurements should be carried out at a pressure differential of 100 Pa and a test area of 4.9 cm^2 .

Innocuity of the materials

Materials in contact with skin must not be irritative or toxic, e.g. they must comply with ISO 10993-1:2018 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a

risk management process). If chemicals are used (for hydrophobicity, virucidal effect, etc.); masks also must comply with the REACH regulation.

Handling

We recommend washing the community masks once per day if worn twice daily (e.g. using it in public transportation in the morning and evening). In the meanwhile, while not worn, the community mask should be stored in a way that avoids cross contamination (from the potentially contaminated outer surface to the clean inner surface) and avoids damaging the integrity of the mask (in terms of loss of function of the textile and poorer fit):

(i) Storing the mask unfolded within a disposable, breathable bag (e.g. paper envelope, after use to be disposed - or textile bag, to be washed with the mask) so that the outer surface of the mask always faces the same direction within the bag, thus avoiding cross-contamination of the inner mask surface is most favorable. Plastic bags, that will keep humidity, should be avoided due to an increased risk of bacterial or fungal overgrowth in the mask.

(ii) Folding the mask may damage the textile or the metal piece negatively affecting mask performance or the fit of the mask. On the other hand folding of the mask may reduce the risk of cross contamination within a storage bag if the mask is folded so that the outer surface is held inward and against itself to reduce contact with inner surface during storage. For most mask designs a horizontal fold may be less damaging than a vertical fold as the metal piece is not affected by the fold.

(iii) As the outer surface of the mask may have become contaminated by use, hand hygiene should always be performed before and after touching the mask.

Washing procedure and reusability

Masks, including textiles and straps, must tolerate at least 5 washing cycles at 60°C in a domestic washing machine (Washmaschine Type A) with phosphate-free detergents ('Pulvervollwaschmittel') including a dry programme according to European Standard DIN EN ISO 6330 and must do so without loss of barrier properties or degradation of the elastic material.

The manufacturer should provide an easy method to allow one to control of the number of washing cycles (e.g. knots in the straps, waterproof marking, etc.). Masks should be disposed after the maximum number of washing cycles has been achieved.

Washing masks with detergent at 60°C is currently the only officially recommended method. However, alternative methods like 30°C washing [9, 10], heat treatment by a household oven at 70°C for 30 min [11] or ironing have been proposed by other expert groups.

Mask design

The mask must be designed to cover nose, mouth and chin and it should guarantee close fitting on the sides. Different sizes should be produced to allow appropriate and safe use in different populations (children, adults). Anthropometric details can be found in ISO/TS 16976-2:2015 (Respiratory protective devices - Human factors - Part 2: Anthropometrics).

Figure 2 shows the specifications of the French mask task force (AFNOR SPEC S76-001) [8] for adults.

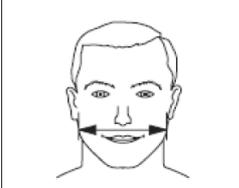
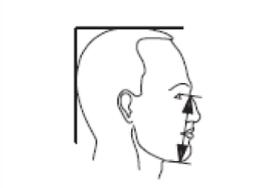
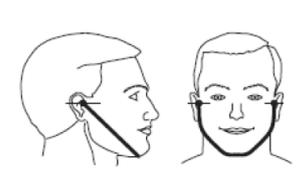
			
Distance bigoniale 132.5 – 144.5 mm	Longueur menton-sellion 123 – 135 mm	Distance interpupillaire 65 – 71 mm	Arc bitragus-gnathion 295 – 315 mm

Figure 2: Relevant dimensions for mask manufacturing according to AFNOR SPEC S76-001

Wear comfort

Straps must allow easy donning and doffing of the mask. They must be strong enough to maintain the mask in place during use, and sufficiently elastic to allow easy fit. They must maintain elasticity after repeated use and particularly after washing.

Unresolved issues

The level of evidence of the mask efficacy worn by the non healthcare professional is not completely solved today. There are some evidence, there are good arguments and we will continue observing the appearance of new evidences which will be acquired with time during the pandemic.

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