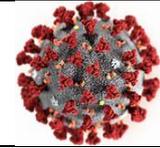


Swiss National COVID-19 Science Task Force (NCS-TF)



Type of document: suggestion and recommendation paper

In response to request from: Lukas Bruhin,
via Matrin Ackermann und Matthias Egger

Date of request: 11/04/2020

Expert groups involved: Sub task IPC; S. Tschudin Sutter,
P. Wick, R. Rossi, A. Mortensen and ReMask Expert group

Date of response: 21/04/2020, finalized 25/04/2020

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Comment on planned updates : none planned as of writing

Title: - Recommendations for minimal specifications for the community masks for Swiss manufacturers

Summary of request/problem

On request of the Swiss governmental Krisenstab, the "ReMask" Expert group has formulated a recommendation for test methods and minimal specifications for community masks. 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 14.4.20. and has received from the Krisenstab (L. Bruhin per 22.04.2020) the permission to be published .

Executive summary:

Recommended specifications for Community masks:

Community masks , mostly aimed at source control, should offer a sufficient protection against liquid droplets of different sizes produced during coughing or sneezing and aerosols (particle size down to 1 micrometer). They should have a sufficient air permeability to minimize breathing hindrance and different fitting sizes for adults and children to guarantee an adequate face coverage.

In brief:

Air permeability < 60 Pa/cm² according to ISO 9237

Splash resistance: no liquid penetration following EN 14683:2019+AC:2019

Mask filtration efficiency FE ≥ 70 % with a particle size of 1 micrometer.

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, FFP2, FFP3, N95, 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 EN 149 and certified. 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 be tested according to EN 14683 and certified. 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 are certified neither by the norm EN 14683 nor by the norm EN 149. The use of non-certified community masks is aimed at the general population, primarily for source control (respiratory etiquette) – thus, for protecting others from exhaled virus-containing droplets or aerosols emitted by the mask bearer. Not all mask designs and materials are suitable for community masks. and research is presently being conducted to identify the best mask designs. The performance criteria defining masks sufficiently blocking to droplets while being comfortable to wear and allowing reprocessing do not correspond to an existing standard **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].

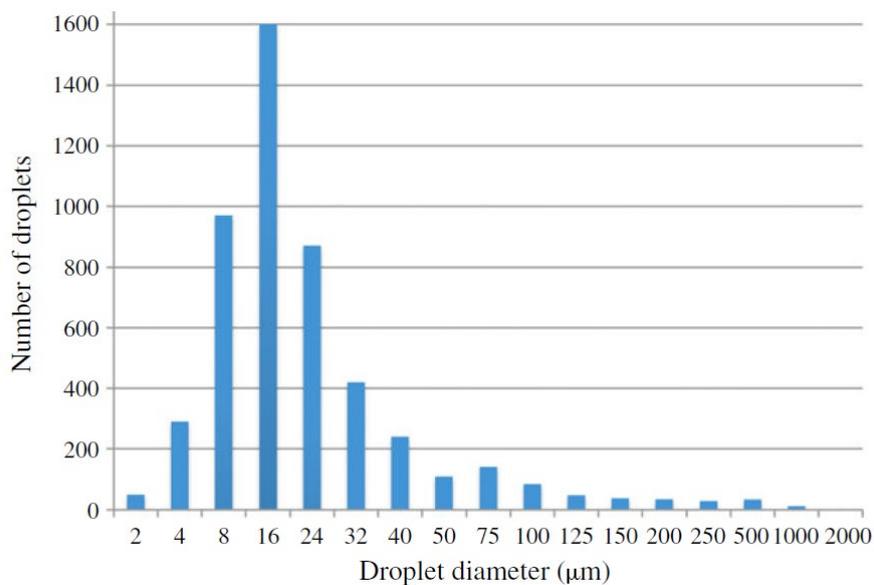


Figure 1: Histogram of droplet size in coughs [4]

In order to simulate coughing more precisely than does a blood jet, a synthetic colored artificial saliva (according to [5]) 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. 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 Pa/cm² 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 cm².

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.

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 the norm DIN EN ISO 6330 without loss of barrier properties or degradation of the elastic material.

The manufacturer should provide an easy method to allow control of the number of washing cycles (e.g. knots in the straps, waterproof marking, etc.).

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) [6] for adults.

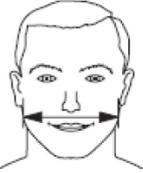
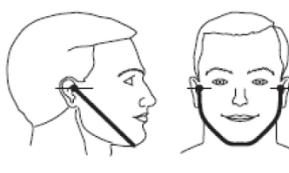
			
Distance bigoniale 132.5 – 144.5 mm	Longueur menton-sellion 123 – 135 mm	Distance interpupillaire 65 – 71 mm	Arc bitragus-gnathion 295 – 315 mm

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

None

References

Definition Standard textile Masks:

[1] <https://www.afnor.org/en/news/protective-masks-faced-with-coronavirus-standard-development-bodies-follow-multiple-leads/>, accessed 11 April 2020.

[2] Rahiminejad, M., Haghighi, A., Dastan, A., Abouali, O., Farid, M., & Ahmadi, G. (2016). Computer simulations of pressure and velocity fields in a human upper airway during sneezing. *Computers in biology and medicine*, 71, 115-127.

[3] Man, William DC, et al. "Cough gastric pressure and maximum expiratory mouth pressure in humans." *American journal of respiratory and critical care medicine* 168.6 (2003): 714-717.

[4] Bourouiba, Lydia, Eline Dehandschoewercker, and John WM Bush. "Violent expiratory events: on coughing and sneezing." *Journal of Fluid Mechanics* 745 (2014): 537-563.

[5] Łysik, Dawid, et al. "Artificial saliva: Challenges and future perspectives for the treatment of xerostomia." *International journal of molecular sciences* 20.13 (2019): 3199.

[6] <https://masques-barrieres.afnor.org/> , accessed 11 April 2020.

Appendices