

# Procedures for reprocessing FFP masks in the event of shortages in Switzerland as of 28.04.2020

Situation as of 28.04.2020

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## 1 GLOSSARY

Word	Description
<b>FFP Masks</b>	<p><b>FFP Masks, particle Filtering FacePiece, or personal protection facemasks are masks meeting the criteria of the norm EN 149 (e.g. FFP1, FFP2, FFP3, N95, or equivalent)</b></p> <p>FFP masks are personal protective equipments and have to comply with the EU directive (EU/2016/425, SR 930.115 – Verordnung über die Sicherheit von persönlichen Schutzausrüstungen (PSA-Verordnung)). They have to be tested according to the norm EN 149 and must be certified by an independent certification body. FFP masks are classified into FFP1, FFP2 and FFP3 depending on their filtration capacity.</p> <p>In the current situation of limited supply, FFP masks are to be strictly reserved for healthcare professionals directly exposed to aerosols by performing aerosol generating procedures (e.g. bronchoscopy, resuscitation, open suctioning, non-invasive ventilation) on individuals with laboratory-confirmed or clinically suspected COVID-19.</p>
<b>Surgical Masks</b>	<p><b>Surgical Masks (preferred name in Switzerland), 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)</b></p> <p>Surgical masks have to comply with the regulation on medical products</p>

(EU/2017/745, SR 812.213 Medizinprodukteverordnung – MepV). They have to be tested according to the norm EN 14683 and certified. Surgical masks are classified into Type I, Type II and Type IIR. Only Type IIR protects against splashes.

### **Community masks**

**“Community” mask is not an official term, but is been 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. Community masks is a wide concept that does not refer to any established standard. Still, research is presently being conducted to identify the best mask designs and to establish performance criteria on masks sufficiently blocking droplets while being comfortable to wear and allowing reprocessing at home. Not all mask designs and materials are suitable for barrier masks.(1)

### **Sterilization**

Validated process used to render product free from viable microorganisms.(2)

### **Disinfection**

Disinfection is a process that is designed to kill actively growing and vegetative microbial microorganisms to a certain level, and it does not, unless the disinfectant is classified as a sterilant, apply to bacterial endospores.(3)

### **Bio-decontamination**

Removal and/or reduction of biological contaminants to an acceptable level. (2)

## **2 AUTHORSHIP**

### **2.1 ReMask**

This consortium, named “ReMask”, has representatives from the cantonal hospital of Winterthur (KSW), the Geneva University Hospitals (HUG), Indema AG, Labor Spiez, Schutz & Rettung Zürich, Rettungsdienst Regio 144 AG (Zürichsee, Oberland, Linth), the Swiss Armed Forces - Armed Forces Staff - Medical Directorate, the Swiss Federal Institute of Technology in Lausanne (EPFL), the Swiss Federal Institute of Technology in Zurich (ETH Zurich), Swiss Federal Laboratories for Materials Science and Technology (EMPA), the Swiss society of hospital sterilization SGSV/SSSH/SSSO, the University of Bern (UNIBE), Unisanté, the University Hospital of Basel (USB), the University Hospital of Zürich (USZ), the Valais Hospital (HVS), and the Industry. It aims at providing help in the form of testing, together with evidence-based recommendations, to the healthcare and the authorities regarding mask use, mask sterilization, alternative mask designs and to support the industry in its effort to manufacture masks or authorities when receiving mask deliveries from abroad.

### **2.2 Authors**

For ReMask and the Swiss Armed Forces, the following authors contributed to this document to the best of their knowledge: Hervé Ney, HUG, SSSO, Walter Zingg, HUG, Jean-Romain Delaloye, KSW, Damien

de Courten, Indema AG, Jing Wang, ETH, EMPA, and Staff Warrant Officer Christophe Grange - Armed Forces Staff - Medical Directorate.

### 3 INTRODUCTION:

Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, a global increased demand of personal protective equipment, and particularly of FFP2 or equivalent masks becomes a bottleneck in managing the COVID-19 crisis in hospitals. The National COVID-19 Science Task Force (NCS-TF) recommends that, for the duration of the pandemic, used personal FFP2 or equivalent masks should be decontaminated before a possible reuse in the event of a complete shortage.

Decontamination and subsequent reuse of FFRs should only be practiced as a crisis capacity strategy. In the absence of serious shortage, these masks will be destroyed.

#### 3.1 Effective decontamination should:

- Reduce the pathogen burden
- Maintain the filtration capacity and physical properties of the mask
- present no residual chemical hazard

#### 3.2 General considerations

To ensure the efficacy of the sterilization process, all material should be washed first. However, based on our current knowledge, washing of masks interferes too much with the filtering properties, and thus, is not feasible. Manufacturers of single-use masks do not provide validated cleaning instructions.

No current data exist supporting the effectiveness of decontamination methods specifically against SARS-CoV-2 on an FFR. Other pathogens may also be present on FFRs. Therefore, even after removal of SARS-CoV-2, these FFRs should not be distributed to a different person after reprocessing.

#### 3.3 Disclaimer

The content is provided 'as is' and must not be used to make a clinical diagnosis or replace or overrule a licensed health care professional's judgment or the recommendation of the federal authorities. Before reusing mask after sterilization or decontamination, the process should be validated and the approval of the competent authorities (Swissmedic for Surgical masks, Swissmedic AND Suva for FFP Masks) should be obtained, with the proposal made in coordination with them and ReMask.

Art. 20a Amendment: good practices of reprocessing of medical devices Switzerland November 2016 SSSH/SSHH/Swissmedic

Any person who modifies or orders to be modified or who refurbishes or orders to be refurbished a medical device in a manner which does not conform to its intended purpose or in such a way as to change its performance must comply with the requirements governing the first placing on the market.

The reprocessing of products intended by their manufacturer for single use involves use not in accordance with the intended purpose, falls under Art. 20a and therefore requires compliance with the requirements for placing on the market (cf. Section 2 of the MDDO).

#### 3.4 Requirements:

- Each mask is collected individually, identified and returned to its owner after reprocessing.

- All masks must be free of damage and visual soiling/contamination (e.g. blood, dried sputum, makeup, body fluids). Masks that are visually soiled or damaged should not be collected for decontamination and should be discarded by healthcare providers.
- Masks should be discarded after a defined number of decontamination cycles, which depends on the reprocessing method (cf table 3)
- Masks whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
- Institutions that perform reprocessing of the masks are legally responsible for the quality and integrity of the masks:
  - Proof that essential prerequisites are met
  - Procedures for correct mask collection and reprocessing are available
  - Validation of the decontamination or sterilization processes according to national standards and to the sterilizer manufacturer's instructions

#### 4 STERILIZATION AND DECONTAMINATION PROCESSES FOR FFP MASKS

Table 1: Summary of the decontamination process and effect on filtering facepiece respirators performance (filtration, fitting)

Method	CDC (4)	N95Decon (5)	ReMask: Tests	ReMask: Review of literature	Comments
Hydogen Peroxide	+	+	+	+	Low capacity
UV	+	+	+	NA	Shadowing
Ethylene oxyde	Evaluation	NA	+	+	
Humid heat (60°, 80% RH)	+	+	NA	NA	Uncertainty of decontamination efficacy for various pathogens
Dry heat	NA	NA	NA	-	
Microwave	-	NA	-	NA	Incompatible with metal
Autoclave with vapor <sup>1</sup>	-	NA	-	-	
Steam	+	NA	+	NA	
Ozone	NA	NA	+	+	
Hot water	NA	NA	-	+/-	Material dependent

Method	CDC (4)	N95Decon (5)	ReMask: Tests	ReMask: Review of literature	Comments
Bleach	-	-	-	-	
Alcohol	-	-	+/-	NA	
Soap	-	-	NA	NA	
Drying in ambient air	NA	NA	NA	NA	SARS-CoV-2 remains active on surfaces
Ionizing radiation	NA	NA	NA	+/-	Material dependent

<sup>1</sup> Autoclave with vapor: CDC process not specified; ReMask tests 121° for 20' and 105° for 5'; ReMask review of literature, 121° for 40'.

#### 4.1 Promising Methods for FFP masks

All methods included preserve the performance of the mask while demonstrating a ≥99.9% antimicrobial efficiency

Table 1: List of promising methods

Method	Comments
Hydrogen Peroxide	Recommended by the FDA Not compatible with cellulose Low capacity (table3) Maximal number of cycles according to the instruction of the sterilization company
Ethylene Oxide	Ethylene Oxide is carcinogenic, teratogenic and chronic inhalation has been linked to neurologic dysfunction. However, tests currently performed in HUG on 4 types of masks demonstrated no residual ethylene oxide after 48 hours desorption. High capacity (industrial process) Logistic and mask collecting should be organized
UV	Shadowing blocks UV-C rays, residual contamination Pending issues: adequate dose, penetration of rays

Table 2: Sterilization by diffusion of hydrogen peroxide vapours (Values expressed as number)

Manufacturer / Process	Cycle type	Masks/cycle	Reprocessing procedures/mask	Total mask uses
Sterrad 100 NX/ All Clear	Standard	10	2	3
Steris VPro Max / Max 2	Non Lumen	10	10	11
Matachana HPO 130 / HPO 50	Rapid	20/10	2	3

#### 4.2 Discouraged Methods for FFP masks

Table 3: Discouraged methods

Methods	Comments
Autoclave, Soap, alcohol, bleach	Results of our tests and those published in literature demonstrated an impairment of filtering facepiece respirators performance

## 5 CONCLUSION

Based on literature and research performed by the members of the ReMask taskforce and in collaboration with the Swiss Armed Forces - Armed Forces Staff (AFS) – Medical affairs, Hydrogen peroxide can be recommended to be used in hospitals for reprocessing FFP2 masks or equivalent during the COVID-19 pandemic.

UV and Ethylene oxide were promising, but further results are needed before they can be recommended.

## 6 REFERENCES:

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