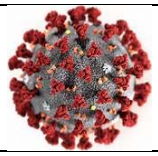
National COVID-19 Science Task Force (NCS-TF)



Type of document: Recommendation for hospitals	
In response to request from:	**Date of request:** 28.04.2020
Expert groups involved: Infection prevention and control-Task Force ReMask 2020	**Date of response:**

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Comment on planned updates :

Recommendation for healthcare facilities in Switzerland for sterilizing protection FFP masks following the norm EN149 (FFP1-3, N95, or equivalent) with vapor hydrogen peroxyde

Summary of request/problem

A global increased demand of personal protective equipment, and particularly of FFP2 (Filtering Facepiece Particles of category 2) 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 FFP masks should be in a first phase sterilized with vapor hydrogen peroxyde by healthcare facilities in the event of a complete shortage. Recommandations for the implementation of a coordinated, state of the art procedure are required.

Executive summary:

The National COVID-19 Science Task Force (NCS-TF) recommends that the Federal Office of Public Health (FOPH) issues healthcare facilites sterilizing in a first phase their used FFP masks meeting the criteria of the norm EN 149 (e.g. FFP1, FFP2, FFP3, N95) and applying the following recommendations for sterilization with vapor hydrogen peroxyde (VH_2O_2) in the event of a complete shortage with the following processes from the manufacturer Steris (VPRO Max and VPRO Max II cycle Non Lumen, Sterrad 100 NX and All Clear cycle Standard, and Matachana HPO 130 et HPO 50 cycle Rapid and validated according to the SN EN ISO 14937.

In short, we recommend collecting and storing FFP2 masks or equivalent individually according to our previous recommendation. Additionally the mask user is asked to add a visible mark with a utility marker (see material) each time before using his mask. Each mask with 2 (Sterrad and Matachana) or 10 (Steris) marks wil be descarded after use. Before reuse and before sterilization, mask will be visually inspected respectively by the sterilization co-worker and the mask user. FFP masks in individualized bags will then be sterilized with vapor hydrogen peroxide. To do so, the usual process is followed according to the manufacturer instructed cycle Steris, Sterrad, and Matachana.

For hygienic reasons, Re-sterilized bag will be returned to their designated user only only in the event of a complete shortage.

When: immediately until the end of the COVID-19 emergency situation.

Who: all healthcare facilities using FFP2 or equivalent masks in Switzerland.

Main text

Glossary

FFP2 Masks, filtering facepiece particles facemasks of category 2 (exceptionally, FFP3 masks may be used), or personal protection facemasks are masks meeting the criteria of the norm EN 149 (or equivalent – N95, KN95)

The user, the user means the healthcare professional who wears a FFP2 mask and is asked to start the storage procedure.

General consideration

All healthcare professionals, including the user, involved in handling such masks before final storage, should be instructed according to these recommendations. Used FFP2 or equivalent masks should not be stored in the wards unprotected for reuse, but put in sterilization pouches which are transported to a dedicated drying room at least once a day.

The user should avoid wearing cosmetics, makeup, or lipstick because such products soil the inner part of the mask and make reprocessing impossible.

Longer exposure to UV-light / sunlight has to be avoided to prevent degradation of the polypropylene material.

Specimens of each type and brand of FFP2 masks (or N95/KN95 masks) used in the hospital should be sterilized in due time. Brands that show signs of degradation after sterilization must not be reprocessed.

Re-sterilized masks should only be used by their designated mask user, according to the individualized bag, only in the event of a complete shortage.

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).

Estimated process capacity and costs

We estimate that the capacities of the VH2O2 process is to sterilize about 9000 used FFP masks in Swizerland for a cost of about 15.- CHF per mask

Recommended process

1. Before putting the mask to storage, the user will discard masks that have been used 2 (Sterrad and Matachana) or 10 (Steris) times, according to the number of marks on the mask.

2. The used FFP masks to be sterilized are packed individually in individualized sterilization pouches and stored according to our recommendation on storing masks.

3. Used masks are brought out of the long-term storage for steriliazion

4. The sterilization personal in charge visually inspects the mask bedore processing it to identify parts or areas that are damaged, deformed or soiled – if present, the mask must be thrown away.

5. The usual VH2O2 process according to manufacturer (Steris, Sterrad, and Matachana) indications and validated according to norm SN EN ISO 14937 is followed.

6. The sterilization personal in charge visually inspects the mask after processing it to identify parts or areas that are damaged, deformed or soiled – if present, the mask must be thrown away he user visually inspects the mask after use to identify parts or areas that are damaged, deformed or soiled – if present, the mask must be thrown away.

7. For longterm storage, before reuse, the sealed sterilized masks are placed in air-tight (ideally stackable) boxes (or in plastic bags within boxes), with 30 g silica gel per 10 masks to keep the masks dry.

8. The boxes are stored in a dry place, separately from the used masks. Correct marking is to be observed

9. For testing and quality insurance purposes a randomly selected sample of healthcare facilities will be asked to provide with preserved masks stored and sterilized according to the present procedure.

10. In the event of a complete shortage, the stored used, re-sterilized mask will be brought to its designated user.

11. Before manipulating the mask, the user performs hand hygiene (using alcohol-based handrub).

12. The user visually inspects the mask before re-use to identify parts or areas that are damaged, deformed or soiled – if present, the mask must be thrown away.

13. Before wearing the mask according to the hospital instruction, the user will add a mark with a utility marker (see material)

Required ressources

Material

- Used FFP masks in individualized sterilization pouches
- Sterilization environment utility marker

Contact

2 persons of contact with a primary contact; Hervé Ney.

Unresolved issues

1. A higher capacity sterilization process will be proposed at a future date.
2. Contacts person for coordinating the implementation and answering questions should be defined

References

1. Recommendation for healthcare facilities in Switzerland for storing protection FFP masks following the norm EN149 (FFP1-3, N95, or equivalent), NCS-TF.
2. Technical Report for H2O2-Based N95 Reuse Risk Management, N95decon, Version 1.2, 4/2/2020.
3. Decontamination Methods for 3M N95 Respirators, 3M Technical Bulletin, April, 2020 Revision 4.
4. nstructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators Using the STERIS Sterilization Systems, Steris Healthcare, April 9, 2020.
5. FACT SHEET FOR HEALTHCARE PERSONNEL - STERIS Sterilization Systems for Decontaminating Compatible N95 Respirators, Steris Healthcare.
6. Instructions for Use for Reprocessing N95 Masks in STERRAD® Sterilization Systems during the COVID-19 Public Health Emergency, Advanced Sterilization Product ASP, 2020.
7. Reuse of FFP2 masks - Onderzoek RIVM naar h ergebruik FFP2 mondmaskers, National Institute for Public Health and the Environment - Ministry of Health, Welfare and Sport 16.04.2020.
8. https://www.steris.com/healthcare/steris-decontamination-solutions-for-compatible-n95-or-n95-equivalent-respirators
9. https://www.n95decon.org/publications
10. Schwartz, A., Stiegel, M., Greeson, N., Vogel, A., Thomann, W., Brown, M., ... & Wolfe, C. (2020). Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor to Address Worldwide Personal Protective Equipment Shortages During the SARS-CoV-2 (COVID-19) Pandemic.
11. Sterilization Process of FFP2 Masks. Unpublished results 07.04.2020
12. Analysis of residual H2O2 on filtering facepiece respirators FFP2 after reprocessing with Vpro Max. Ney H., BREHIER C., university hospital of Geneva. Unpublished results 09.04.2020

Appendices

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