Contingency Reprocessing of Single-Use Personal Protective Equipment (PPE)

White Paper
Belimed AG, Zug, Switzerland
Issue 2, May 2020

Contents

PREFACE FOR ISSUE NO 2 3
SUMMARY 4
DISCLAIMER 4
1. BACKGROUND 5
2. RESPIRATORY FFP2/N95 MASK REPROCESSING (AUSTRIA, GERMANY, NL) 6
3. DRY HEAT DISINFECTION OF RESPIRATORY MASKS IN GERMANY 16
4. STEAM STERILISATION OF SINGLE-USE OR GOWNS IN FRANCE AND THE NL 21
5. STEAM STERILISATION OF FACE MASKS FROM STERILISATION WRAP IN FRANCE 23
6. AUTOMATED CLEANING & DISINFECTION OF REUSABLE PPE EQUIPMENT 26
7. STEAM DISINFECTION 105°C/221°F AS BACKUP OPTION FOR FFP2 MASKS 28
8. CONCLUSION 30

Preface for Issue No 2

After the first issue of this document in Mid-April 2020 some changes in the regulatory context occurred and new potentially helpful applied research about the topic of PPE emergency reprocessing was performed. Since it is important to us to share correct and up-to-date information we prepared this updated issue No 2.

Changes / additions relative to issue 1 are:

- Chapter 2:
  - Various research institutes have published information on which respirator models may have sufficient compatibility with steam sterilisation processes
  - A summary table of the results of 6 different applied research institutes was added
    Thanks go to Dr Alexander Blacky from KAV Vienna study group, Dr Holger Hoche from TU Darmstadt, Mr Dirk Diedrich and Mr Daniel Triphaus from Hybeta and Mr Firas Zabaneh (MBA) from Houston Methodist for sharing information beyond the published data.
  - A workflow diagram for application of steam sterilisation for FFP2 masks was added
  - Reference to a recent research by paper Rutala et al 2020 concerning the reliability of different sterilisation processes under dirty conditions was added

- Chapter 3:
  - The German ministry has taken back the official recommendation of 30 min 70°C dry heat reprocessing of FFP2 masks. The chapter is changed accordingly.
  - The description of the Helios two-step heat disinfection decontamination process is kept in the document for information as a highly developed implementation of the dry heat approach to illustrate its possible strengths and weaknesses

- Chapter 4:
  - A reference was added highlighting that the practice of emergency reprocessing of surgical gowns was also officially approved by the Ministry of Public Health of the Netherlands.
    Thanks to Harry Oussoren for pointing that out.

- Chapter 7
  - A German independent validation company published data on filter efficacy of certain FFP2 masks after a 105° steam disinfection process.
    Thanks to Dirk Diedrich and Daniel Triphaus from Hybeta, Germany for sharing insights beyond the published information.
  - A summary table of the results was added

Belimed supports emergency applications as contingency measures to manage the shortage of PPE single use items. All initiatives described have been made in close cooperation with our customers and local national and regional authorities.

Summary

This document is intended to give an overview to interested stakeholders, to foster efficient international knowledge exchange and support informed decision processes. This white paper provides details of medical device reprocessing and contingency measures which have recently been implemented in various countries.

The contingency measures described, include references to the emergency regulation and / or the scientific risk management rationale behind each solution. These references and rationales may not be exhaustive, due to the short time available to prepare this document and the fast changing topic, however it should be a good starting point for anyone who wants to further explore these contingency measures.

The information contained in this document may be helpful to accelerate decision processes of healthcare facilities, regulatory authorities and users. This is especially important where time plays a critical role in ensuring the availability of potentially life-saving Personal Protective Equipment (PPE), in an acceptable quality for healthcare workers around the globe.

Preparing this document we were in exchange with representatives of **WFHSS, SF2S, VDSMH, DGSV, ÖGSV, IAHCSMM.** We are very grateful for their valuable input and feedback. Special thanks to go to Harry Oussoren, expert in sterile medical devices from Amsterdam University Hospital and Dr Tim Horeman-Franse from the TU Delft for sharing detailed insight on the status of research and its practical implementation in the Netherlands. We also thank Karl Heinrich de Roi from Helios Hospital Group in Germany for his outstanding cooperation and for sharing data from their development process.

Whilst all efforts were made to align and validate all shared information with these expert organisations, it was not possible to align 100% of the content in all cases. This was due to the dynamic and complex nature of the COVID-19 topic in the current supply crisis.

Any feedback or proposals for improvement are highly welcome and will be integrated in an updated version of this document.

Disclaimer

Belimed does not recommend using reprocessing methods that are not compliant with their local regulations. This document is an information sharing of processes which have been tested and approved by local health authorities in countries known for high standards in infection control practices. We strongly emphasize that any measures not in compliance with local standard regulations, should only be used WITH APPROVAL from the respective healthcare regulation or authority.

Belimed does NOT recommend the reprocessing of medical equipment classified as a single-use product by its manufacturer, except in **MEASURES OF LAST RESORT** such as the COVID-19 pandemic, where the availability of critical supplies cannot be ensured.

1. Background

As a global supplier for healthcare disinfection and sterilisation solutions, Belimed has received many customer requests to provide **contingency reprocessing measures, to ensure availability of single-use PPE items**, and other single use products during the COVID-19 healthcare crisis.

While Belimed generally discourages the reprocessing of single use devices, we understand that in a crisis situation such as the current COVID-19 pandemic, a reprocessed single-use product - while being associated with a higher risk or uncertainty than a new product – may still have a higher clinical utility (e.g. to significantly reduce infection risk of healthcare workers) compared to a situation of not having this product at all.

Certain PPE equipment (e.g. FFP2 / N95 masks) have become scarce due to the **globally increased demand associated with the pandemic.** At the same time, healthcare providers (as employers) are generally mandated by law to offer sufficient protection to their employees – including gloves, gowns, face shields, FFP2 / N95 respirator masks etc. when they are working directly with COVID-19 patients.

In this difficult situation, healthcare providers are asking reprocessing equipment manufacturers and suppliers of PPE for help. Equipment manufacturers cannot offer fully-validated reprocessing methods for lack of time, resources and because single-use products such as masks, were never designed for reprocessing. While it seems logical that a reprocessed PPE with small or virtually no change in perceivable properties, is better than having no PPE equipment at all, it is still difficult for hospitals and manufacturers to take responsibility to reprocess items that were designed for single-use.

As neither PPE suppliers nor manufacturers of sterilisation equipment can easily recommend reprocessing solutions without exposing themselves to possible liability risks, this can lead to a stalemate situation. **Promising and plausible approaches may exist today, but no one dares to implement them**, out of fear of the possible legal consequences of using a practice that is not fully validated and approved by manufacturers and health authorities.

Hospitals are therefore starting to ask for support from health authorities to offer solutions / give guidance how to act in this extreme situation:

a. Finding ways to **source** additional single-use items
b. Finding smart and safe ways to rationalize the use of existing supplies (e.g. extended use)
c. Emergency regulations defining how the single-use items can be **reprocessed**.

For the reprocessing option, **Belimed is actively working with customers and regulatory bodies** in various countries offering our knowledge of infection control, reprocessing processes and workflows to support the definition of contingency measures based on scientific risk assessment.

For every contingency measure approved by regional healthcare authorities to manage the shortage of PPE items, Belimed supported hospitals with an immediate implementation and testing to maximise availability.

This document describes **six contingency measures** implemented with approval of healthcare authorities in Austria, Germany, the Netherlands and France, namely:

1. Respiratory FFP2 / N95 Mask reprocessing (Austria, Germany and the Netherlands)
2. Dry Heat Disinfection of FFP2 respiratory masks (Germany)
3. Steam Sterilisation of Single Use OR gowns (France)
4. Steam Sterilisation of Surgical Masks made from sterilisation wrap (France)
5. Automated Cleaning & Disinfection of reusable PPE equipment
6. Steam Disinfection 105°C as a backup option for FFP2 respiratory Masks

2. Respiratory FFP2/N95 Mask Reprocessing (Austria, Germany, NL)

Context:
FFP2 / N95 masks have become very scarce in many markets around the world during this crisis.

Various methods for their reprocessing have been proposed by different stakeholders such as hospitals, universities, governmental agencies, non-profit organizations, PPE manufacturers or sterilisation companies to alleviate the shortage. Some health authorities have already officially approved certain methods, or declared that they would give more liberty to hospitals and companies to implement crisis measures than under normal circumstances, as long as the basics of infection control, biomedical engineering and risk management is considered.

Measures proposed include (non-conclusive list):

1. Gamma sterilisation
2. UV light disinfection
3. Low temperature sterilisation with H2O2
4. Low temperatures sterilisation with ETO
5. **Thermal disinfection with dry heat 65-75°C / 150°-160°F**
6. Thermal disinfection with moist heat at 60-80°C
7. **Thermal disinfection with moist heat at 105°C**
8. **Steam Sterilisation with a pre-vacuum 121°C / 250°F 15-20 min cycle**

Each method has advantages and disadvantages, this paper provides information about points 5, 7 and 8.

In the case of steam sterilisation at **121°C / 250°F** advantages include:

- Broad availability in hospitals,
- Can be implemented in a relatively smooth quality assured workflow with existing infrastructure
- Not much additional human labour required
- High throughput
- Cost advantage versus low temperature processes and low dependency on supply chains as only standard steam pouches are needed
- High sterilisation safety against all infectious microbes also under conditions where residual soil might be present (see Rutala et al 2020) - which will typically be the case for respirator masks
- No risk from potentially harmful process residues within the masks (as opposed to chemical low temperature sterilisation processes such as H2O2 or EtO).
- Cleaning effect due to “steam extraction” for all kinds of soils that are soluble in hot water / steam

Disadvantages include:

- Certain types of respirators (e.g. most cup shaped) are clearly not compatible
- Independent research suggests that some commonly used models have sufficiently good compatibility for an emergency measure. This, however, was not yet confirmed by respirator manufacturers.
- limited published data on material compatibility in terms of filtration efficacy and in terms of fit

The method of reprocessing certain respirator masks by standard steam sterilisation with a pre-vacuum 121° / 250°F for 15 or 20 minutes cycle has been proposed by research teams in Austria, Germany and in the Netherlands.

This has led to an edict from the **Austrian Ministry for Health** to reprocess suitable FFP2 masks with 121° C / 250°F steam sterilisation and reuse them once. The **Dutch Ministry of Public Health** has published test results showing that a specific FFP2 mask type can be re-sterilised at least twice without significant change in its filtration or fitting properties.

The **German Society of Sterile Supply (DGSV)** has also expressed their preference for the steam sterilisation approach, citing arguments of workflow, safety and quality assurance with existing infrastructure. However the official healthcare authorities have taken a different position to date, by recommending dry-air decontamination (see chapter 3). Before the health authority recommendation was issued, many German hospitals implemented the steam sterilisation process and are currently evaluating both options.

Important Notes:

- It is important to emphasize that not all FFP2 / N95 masks can be reprocessed this way. Information about which masks have been suggested as suitable can be found in the section "Which types of masks can be steam sterilised?" later in this document.
- There is no suitable non-detrimental cleaning process for FFP2 / N95 masks. One important principle in sterilisation sciences is "… *what is not clean cannot be sterilised*". The reprocessing of single-use masks therefore **cannot** be considered a "sterilisation process" but should rather be called a "***decontamination process***" - using a standard sterilisation process.
- Microbicidal efficacy of steam sterilisation is much more robust to the presence of residual soil than chemical sterilisation processes (H_2O_2, ethylene oxide, formaldehyde etc.).

  This was recently confirmed in a **publication by Rutala et al. (2020)** where a research group tested the efficacy of various sterilisation processes in the presence of salt and serum to simulate residual soil from inadequate cleaning. The group found that H_2O_2 based processes and EtO at high bioburden combined with salt & organic residues yielded **sterilisation failures** (from 1.9% for HPGP or EtO and 76.3% for VHP of sterilised samples living bacteria could be isolated) while **steam sterilisation** (4 min at 132°) had a **100% sterilisation success rate**. The authors concluded that "*Steam sterilisation is the most robust sterilisation process and the least affected by protein, salt, and lubricants*."

  This is especially noteworthy in the context of respiratory masks because they – as described in the former bullet point – cannot be cleaned and will therefore generally have some level of organic and inorganic contamination when entering into a sterilization process.

Implementation in Austria, Germany and the Netherlands:

Based on the described legal and scientific background in those three countries, **Belimed has installed sterilisation programs for the purpose of FFP2/N95 mask reprocessing with medical steam sterilisers**. In addition, Belimed has validated and tested the sterilisation conditions on-site in various hospitals in countries where authorities have officially recommended this practice - so far, in Austria, Germany and the Netherlands.

The steam sterilisation process found most suitable for this purpose, is a **fractionated pre-vacuum process with 121°C/250°F.** This process generally needs to be installed and tested in specific hospitals interested in this contingency measure.

Before the reprocessing of masks is implemented, it is crucial to determine **whether the specific masks used within the hospital are suitable for reprocessing**. Please refer to the published data in references (e.g. TU Delft, Austrian Army Research).

Note: If the available mask type is classified as "*emergency steam sterilisable*" it is still necessary to run test batches on site, to verify that no deformation of the mask takes place. The process should be tested on new masks and on masks that were actually used by healthcare workers (HCW).

3M Respirator NR 8822
Cup-Shaped and Valved Model

- Emergency reprocessing options:
  - Low-Temp in H2O2 (two times)

3M Aura Respirator NR 1862+
Flat-Folded & Non-Valved Model

- Emergency reprocessing options:
  - **Steam sterilisation 121°** (two times)
    or
  - Low-Temp in H2O2 (two times)

Picture 1: Example of FFP2 mask types with recommendations for reprocessing, according to the recommendation of the Dutch Ministry of Public Health (see reference).

The total workflow depends to some extent upon the country and the responsible person for infection control, as well as the on the available infrastructure. The number of reuses of FFP2 / N95 masks varies currently from one (Austria) to two (Netherlands). Each country is continuing their testing to determine if more reuse cycles are acceptable.

Workflow Examples

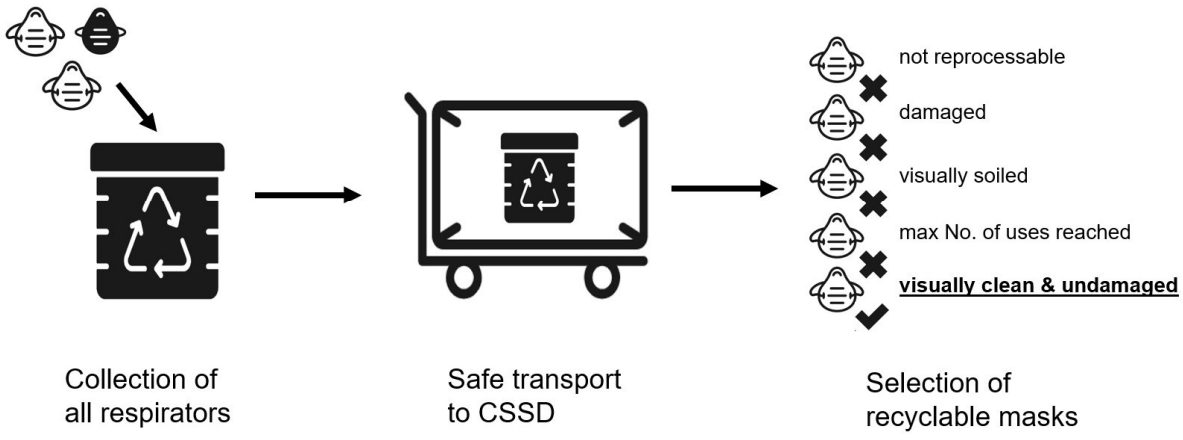
In terms of equipment, some hospitals are sterilising masks in **separate batches** or as a temporary measure **dedicating a steriliser** specifically for this purpose.

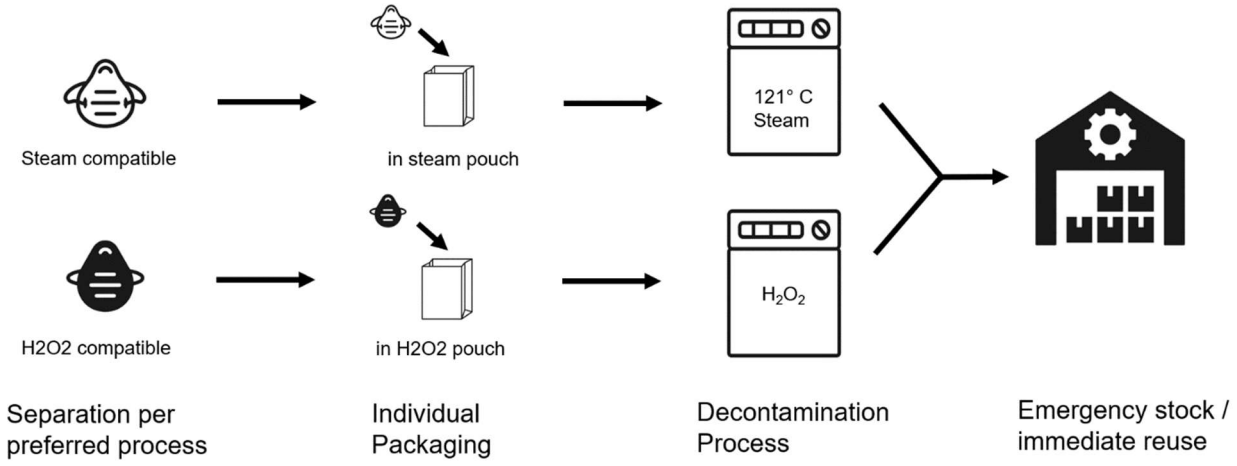
Other sites with an existing 121°C / 250°F sterilisation program in place for other goods, have decided to sterilise **mixed loads in the same cycle**, where it is deemed advantageous for the CSSD workflow. From a regulatory perspective, there are no clear rules in place, however as long as the masks are packed correctly there should be no concerns for cross-contamination (see Picture 2).

Example for reprocessing of FFP respirator masks

- Collection of used masks in a container in the ward
- Transport to the CSSD
- Inspection of masks by trained and PPE-protected sterilisation technician. Masks that are dirty, damaged or have already been reprocessed the maximum number of times are disposed
- Mark of the mask with an “X” with a suitable pen, for every reprocessing cycle
- Packaging in pouches for sterilisation
    - Individually
    - In packs of four (4) or five (5) units

  (Individual packing is preferred since it allows that every HCW received a previously untouched mask)
- Where the hospital has decided to reprocess different categories of mask, then each type must be packed into a suitable sterilisation pouch:
    - Masks suitable for steam sterilisation
    - Masks that are only suitable for H2O2 sterilisation
- Sterilisation at 121°C / 250°F with 15-20 minutes holding time
- Delivery of the reprocessed masks in their closed packaging to the respective point of use
- Healthcare workers control the fitting of their mask (as with a new mask). Where the HCW notices a compromised fit, the mask is thrown away





Workflow Diagram: Illustration of respirator decontamination workflow including two different decontamination processes depending on compatibility of FFP respirator masks as implemented in a hospital in the Netherlands.

Some minor physical changes of the reprocessed mask were reported by HCWs, but they also stated that new masks do not always have a perfect fit for all faces. HCWs are generally free to ask for a new mask if they are uncomfortable with the feel or fit of the decontaminated mask.

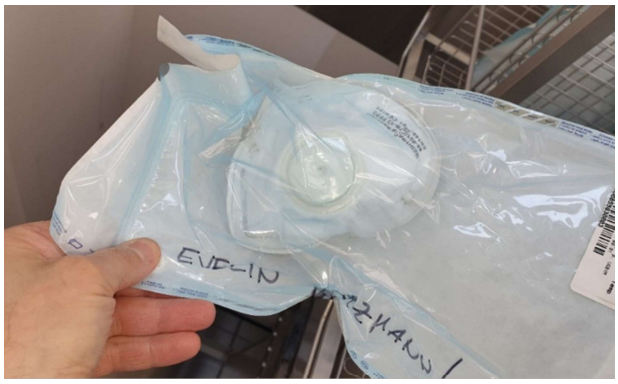
Some small hospitals have personalised this one-time reuse procedure:

- Every second day a HCW is instructed to place his/her mask into a sterilisation pouch at the end of the working day, and to write their name on it.
- On the following day, the HCW can recollect the mask from the previous day, having been sterilised (in the pouch).

In larger hospitals or when the logistics are difficult, HCWs can also receive reprocessed masks without any personalisation.

Picture 2: Steriliser batch with FFP2 masks for decontamination together with other loads suitable for this sterilisation process

Picture 3: Tray pouch packed with FFP2 masks



Picture 4: Individually packed FFP2 mask with name of the HCW written on it for individualised reuse.

Picture 5: Individually packed FFP2 in the Netherlands for non-individualised reuse

Additional Stock

Many hospitals have decided to install the steam sterilisation process for reprocessing FFP2 masks as a risk-reduction procedure (for potential out of stock situations within the next 4-6 weeks). The reprocessed masks are kept on stock in the event that no new masks are available.

Some hospitals (NL) have tested the filtration capacities of newly sourced masks (lower quality) and found that some new masks actually had worse filtration properties than steam sterilised high quality masks. This has resulted in the decision to first issue reprocessed (high quality) masks to employees before giving newly sourced (lower quality) masks.

What information is available about possible compatibility of respirators to steam sterilization?

While being the safest method in terms of excluding infection risk steam sterilisation has the important restriction that so far no respirator manufacturer made an official statement indicating which mask models or types may be suitable concerning the material compatibility for contingency decontamination using steam sterilization processes. Thus the process is not officially recommended by the manufacturer which has strong legal implications in some countries and makes it difficult for anyone to implement this method..
Other countries however have decided that the advantages of steam sterilisation (biological safety, workflow and availability) and the available compatibility data justifies a recommendation – limited to the respirator mask types that were judged to have acceptable compatibility by independent tests labs in those countries.

When looking at material compatibility two categories must be separated.

- Stability of the filtration efficacy (no destruction of the filter structure or electrostatic properties)
- Integrity of the fit (no critical amount of air leakage)

Apart from the University of Delft group, all research groups have systematically investigated only one of both mentioned material compatibility aspects The test methods used were generally not the exact methods as described in the respective technical standards The reason for that is that for these methods specific technical infrastructure is necessary that was generally is not available on the short term.

The goal of these research groups was to provide as fast as possible an as good as possible data base for an informed decision process on which methods can be considered as crisis contingency methods to fight the

pressing shortage of respirator masks considering the total risk (risk from infectious agents surviving the decontamination process and risk of respirators having a potentially reduced grade of protection).
One important finding was e.g. that flat folded respirators generally have better compatibility than cup shaped.

In that sense the respirator masks suggested as compatible with steam cannot be understood as a list where strict compatibility was shown according to all relevant standard, but rather as the result of pragmatic orientation testing with the infrastructure and knowledge available in each of the institutes.

However, some institutes like the University of Delft have achieved a rather high level of technical evaluation quality testing particle filtration rate with four different sizes (0.3, 0.5, 1.0 and 5.0 micrometres) and performing systematic fit tests with real test persons.

In the below table is summarising the test results of **six different institutes** that have tested respirator masks after treatment with different prevacuum steam sterilisation processes. The respective institutes – with all the limitation in applied methodology - did not find strong reduction in fit and / or filtration properties of these respirator types. Therefore, anybody interested in this process might find the table useful as a starting point to determine which respirators could be **potentially acceptable for contingency decontamination in steam sterilisation** provided that the practice is in line with local regulation.

Mask Name	Type	Valve	Manufacturer	Class	Steam Process	No. of cycles	Filter test	Fit test	Source
3M 8322	cup	yes	3M	FFP2	121°C, 20 min	1	x	-	Hybeta[2]
3M 9210	folded	no	3M	N95	121°C, 15 min	10	-	x	Univ of Manitoba[6]
3M 9501+	folded	no	3M	FFP2	121°C, 20 min	1	x	-	TU Darmstadt[3]
3M Aura 1862+	folded	no	3M	FFP2	121°C, 15 min	3	x	x	TU-Delft[1]
3M Aura 1862+	folded	no	3M	FFP2	121°C, 20 min	1	x	-	KAV Vienna[4]
3M Aura 1863+	folded	no	3M	FFP2	121°C, 20 min	1	x	-	KAV Vienna[4]
3M Aura 1863+	folded	no	3M	FFP2	121°C, 20 min	1	x	-	Hybeta[2]
3M Aura 1863+	folded	no	3M	FFP2	134°C, 5 min	1	x	-	Hybeta[2]
3M Aura 1870	folded	no	3M	N95	132°C, 4 min	2	-	x	Houston Methodist [5]
3M Aura 1870	folded	no	3M	N95	121°C, 15 min	10	-	x	Univ of Manitoba[6]
3M Aura 1870+	folded	no	3M	N95	132°C, 4 min	2	-	x	Houston Methodist [5]
3M Aura 9322+	folded	yes	3M	FFP2	121°C, 15 min	1	x	x	TU-Delft[1]
3M VFlex 1804	folded	no	3M	N95	121°C, 15 min	10	-	x	Univ of Manitoba[6]
AO Safety 1054S	folded	no	Aearo	N95	121°C, 15 min	10	-	x	Univ of Manitoba[6]
BARRIER NR 42904	folded	no	Mölnlycke	FFP2	121°C, 20 min	1	x	-	TU Darmstadt[3]
DACH Comfort 243	folded	yes	DACH	FFP3	121°C, 20 min	1	x	-	Hybeta[2]
DACH ecoComfort 245	folded	no	DACH	FFP2	121°C, 20 min	1	x	-	KAV Vienna[4]
DACH ecoComfort 245	folded	no	DACH	FFP2	121°C, 20 min	1	x	-	TU Darmstadt[3]
Dräger X-plore 1920	folded	yes	Dräger	FFP2	121°C, 20 min	1	x	-	KAV Vienna[4]
HG Typ KN95-A/MS-1	folded	no	Dongguan HuaGang	KN95	121°C, 20 min	10	x	-	TU Darmstadt[3]
MED-Comfort P-3900	folded	yes	AMPri	FFP3	134°C, 5 min	1	x	-	Hybeta[2]
Nobaprotect 672062	folded	no	Nobamed	FFP2	121°C, 20 min	1	x	-	KAV Vienna[4]
Nobaprotect 672062	folded	no	Nobamed	FFP2	121°C, 20 min	1	x	-	Hybeta[2]
Oany MS-KN 95-01	folded	no	Meisu In.	KN95	121°C, 20 min	10	x	-	TU Darmstadt[3]
Reis easy flow MAS	folded	no	Reis	FFP2	121°C, 20 min	1	x	-	Hybeta[2]
San Huei 2920V	folded	yes	San Huei	FFP2	121°C, 15 min	1	x	x	TU-Delft[1]
Uniair SH 3200	folded	no	San Hue United	FFP2	134°C, 3 min	1	x	-	Hybeta[2]

[1] projectMask of TU Delft, Netherlands - website - see reference

[2] Hybeta, Germany website - see references

[3] TU Darmstadt, Germany - direct Info received per email from Dr Holger Hoche

[4] KAV Vienna Study Group, Austria - direct Info received per email from Dr Alexander Blacky

[5] Houston Methodist, USA - published data - see references

[6] University of Manitoba, Canada - published data - see references

References:

ECDC - TECHNICAL REPORT Cloth masks and mask sterilisation as options in case of shortage of surgical masks and respirators 26 March 2020
https://www.ecdc.europa.eu/en/publications-data/cloth-masks-sterilisation-options-shortage-surgical-masks-respirators

CDC -Decontamination and Reuse of Filtering Facepiece Respirators (April 9th 2020)
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

A scientific consortium for data-driven study of N95 filtering facepiece respirator decontamination
https://www.n95decon.org/

Website of ProjectMask from the Technical University Delft, including test protocols and test data on specific masks and including an illustrative video (Dutch language with English subtitles)
https://projectmask.nl/

TU Delft website article about the “projectmask” including illustrative video
https://www.tudelft.nl/en/stories/articles/recycling-mouth-masks/

TU Delft Internal publication of the “projectmask” research team
Steam sterilisation of used disposable face masks with respect to COVID-19 shortages
https://pure.tudelft.nl/portal/en/publications/steam-sterilisation-of-used-disposable-face-masks-with-respect-to-covid19-shortages(078a3733-84d6-4d4a-81e6-74210c7fed78).html

TU Delft Internal publication of the “projectmask” research team -
Sterilisation of disposable face masks by means of standardized dry and steam sterilisation processes: an alternative in the fight against mask shortages due to COVID-19
https://pure.tudelft.nl/portal/en/publications/sterilisation-of-disposable-face-masks-by-means-of-standardized-dry-and-steam-sterilisation-processes(f048c853-7e1d-4715-b73d-3b506b274a30).html

van Straten, B., de Man, P., van den Dobbelsteen, J., Koeleman, H., van der Eijk, A., & Horeman, T. (2020). Sterilisation of disposable face masks by means of standardized dry and steam sterilisation processes; an alternative in the fight against mask shortages due to COVID-19. *Journal of Hospital Infection*.
https://www.ncbi.nlm.nih.gov/pubmed/32277964

van den Dobbelsteen, J. J., van Straten, B. J., & Horeman, T. (2020). A Comparison of Particle Filter Efficiency Measurements for Protective Masks using Particle Counters with Different Flow Rates.
https://repository.tudelft.nl/islandora/object/uuid%3A604ed9c2-c218-45e8-8c62-7d669865056c

van Straten, B. J., van den Dobbelsteen, J. J., & Horeman, T. (2020). Steam sterilisation of used disposable face masks with respect to COVID-19 shortages.
https://repository.tudelft.nl/islandora/object/uuid%3A078a3733-84d6-4d4a-81e6-74210c7fed78

van Straten, B. J., van den Dobbelsteen, J. J., & Horeman, T. (2020). Steam sterilisation of used disposable face masks with respect to COVID-19 shortages.
https://repository.tudelft.nl/islandora/object/uuid%3Af048c853-7e1d-4715-b73d-3b506b274a30

Khoukh, K., Dumas, C., El Hssaini, R., Bertin, S., & Bruno, F. (2020). Pandémie COVID-19 et réutilisation des masques: revue bibliographique des méthodes de décontamination. (in French)
https://pharmaciedelpech.fr/Src/Pharmacie/Assets/Download/Revue_biblio_sterilisation_masques.pdf

Social Media post of TU Delft assistant professor Dr. Ir. Tim Horeman about the research
https://www.linkedin.com/posts/timhoreman_rivm-rdgg-lumc-activity-6647000197740142592-L_rT
https://www.linkedin.com/posts/timhoreman_coronacrisis-covid19-activity-6651709076730322944-PzNL/
https://www.linkedin.com/pulse/onderzoekers-tu-delft-hergebruiken-mondkapjes-na-goede-van-vliet/

Example of Dutch hospitals publicly announcing the introduction of steam sterilisation for N95 masks in NL
https://www.linkedin.com/posts/marieke-min-kwantes-0bba46141_samensterker-staysafe-corona-activity-6653919991026581504-imcQ

Statement Dutch Ministry of Public Health for reuse of FFP masks and single use protection clothing (in Dutch)
https://www.rivm.nl/documenten/hergebruik-mondmaskers-isolatiekleding

Research update Dutch Ministry of Public health. Reprocessing tests 3M mask 8822 & Aura 1862+ (in Dutch)
https://www.rivm.nl/sites/default/files/2020-03/Update%20herverwerking%20mondmaskers%20RIVM%2030032020_0.pdf

Edict of the Austrian Ministry for health allowing steam sterilisation of certain FFP masks (in German):
https://oegsv.com/wp/wp-content/uploads/Erlass_BMAFJ_-Wiederaufbereitung_von_Schutzmasken_24.03.2020.pdf

Research of the Austrian Army including a list of masks deemed suitable and unsuitable for reprocessing, independent of the reprocessing method (in German):
http://www.bundesheer.at/organisation/beitraege/arwt/atemschutzmasken/wamch.shtml#downloads

Statement of the Austrian Society for Sterile Supply (ÖGSV) (in German):
https://oegsv.com/wp/wp-content/uploads/Stellungnahme-Aufbereitung-von-Einmalmasken_5.pdf

Statement of the German Society of Sterile Supply (DGSV) (in German):
https://www.dgsv-ev.de/wp-content/uploads/2020/04/Stellungnahme-DGSV-Dekontamination-FFP-Masken-3.pdf

Additional References Edition 2

Rutala, W., Gergen, M., Sickbert-Bennett, E., & Weber, D. (2020). Comparative evaluation of the microbicidal activity of low-temperature sterilization technologies to steam sterilization. Infection Control & Hospital Epidemiology, 41(4), 391-395. doi:10.1017/ice.2020.2
https://doi.org/10.1017/ice.2020.2

TU Delft current test data with list of test data per mask type
https://data.4tu.nl/repository/uuid:95914e2a-c0be-4f5b-8415-b24e5710e5e4

Website Dutch Ministry of Public health concerning reprocessing of FFP masks mentioning their close cooperation with the TU Delft research group (in Dutch)
https://www.rivm.nl/coronavirus-covid-19/professionals/binnen-ziekenhuis/mondmaskers

Document “Reuse of FFP2 masks” by the Dutch Ministry of Public health on reprocessing tests performed with 3M mask 8822 (in English)
https://www.rivm.nl/documenten/hergebruik-ffp2-mondmaskers-eng

Website of Hybeta (Germany) with background about their FFP mask tests
https://www.hybeta.com/

Hybeta summary of current tests results with traffic light system per mask type
https://www.hybeta.com/fileadmin/content/Pruefungsergebnisse_technische_Sicherheit

Irene Carrillo, Anna Floyd, Christian Valverde, Travis Tingle and Firas Zabaneh, Immediate Use Steam Sterilization (IUSS) Sterilizes N95 Masks Without Mask Damage, Published online by Cambridge University Press: 17 April 2020
https://doi.org/10.1017/ice.2020.145

Anand Kumar, Samantha B. Kasloff, Anders Leung, Todd Cutts, James E. Strong, Kevin Hills, Gloria Vazquez-Grande, Sylvain Lother, Ryan Zarychanski and Jay Krishnan; N95 Mask Decontamination using Standard Hospital Sterilization Technologies, Preliminary manuscript APRIL 2, 202
https://news.umanitoba.ca/n95-mask-decontamination-using-standard-hospital-sterilization-technologies/

Press Release of Technical University TU Darmstadt from April 29th: Multiple use of respirator masks is safe for healthcare workers.(German Language)
https://www.tu-darmstadt.de/universitaet/aktuelles_meldungen/einzelansicht_259072.de.jsp

3. Dry Heat Disinfection of Respiratory Masks in Germany

Context:

Decontamination of respiratory masks with dry heat was identified by various experts as a promising approach especially in terms of material compatibility. As mentioned in the introduction mask manufacturers generally cannot give their guarantee that mask properties remain within the minimum specifications as defined by relevant technical standards (e.g. in terms of filter capacity or in terms of fit) after a certain decontamination procedure. In that aspect hot air disinfection may be seen as an exception at least for masks sold in Europe. The reason is that to obtain a CE mark respiratory masks have to comply with the technical standard EN 149 which requires that a mask can maintain its full functionality after a treatment of 24 hours at 70°C dry heat.

At the same time there is published scientific evidence (e.g. Kampf et al 2020) that SARS-CoV-2 virus and SARS-CoV-1 virus infectivity is reduced by at least 4 $\log_{10}$ under conditions of 60°C / 140°F for 30 minutes, 65°C / 149°F for 15 minutes or 80°C / 176°F for 1 minute respectively. A limiting factor is that most of the underlying data was produced with virus in suspension (i.e. moist heat) versus in hot air (dry heat). Kampf et al. argue that for the case of the SARS-CoV-2 it appears unlikely that there is a major difference between dry heat and moist heat in terms of inactivation efficacy. When making this assumption it is important to emphasise that the masks need to be already completely dry at the beginning of the treatment time. As long as there is residual water present there will be a cooling effect by the evaporating water and thus no thermal equilibrium between the heating medium (air) and the object to be heated (masks). The inactivation mechanism was reported to be thermal aggregation of SARS-CoV membrane protein which was shown to completely denaturate at about 55°C for 10 minutes.

If these two factors (dry heat stability of masks and heat sensitivity of the virus) are combined it should be possible to design a dry heat decontamination protocol that at least inactivates SARS-CoV-2 with a sufficient level of safety while having good material compatibility.

The responsible German authorities **Federal Ministry of Labour and Social Affairs and Federal Ministry for Health** issued a document on March 31st recommending the **dry heat disinfection of FFP2 masks** at temperatures of 65°-70°C / 150°-160°F for 30 minutes, to overcome shortage situations. The letter recommended masks to be reused by the same person (“individualised reuse”) in line with the described fact that the decontamination method while assumed to be effective against SARS-CoV-2 viruses, does not provide sufficient safety against other pathogens.

However, the **German Society of Sterile Supply (DGSV)** issued a statement a few days afterwards, questioning the dry heat disinfection approach for various reasons. These included lack of availability of suitable equipment, limited microbicidal efficacy, logistic challenges of individualised reuse and difficulty to implement dry heat disinfection as a quality assured process. The DGSV statement went on to suggest the **steam sterilisation approach at 121°C / 250°F as potentially preferable option** (as implemented in Austria and the Netherlands).

After the adequacy of the dry heat process was questioned also in public media the **Federal Ministry of Labour and Social Affairs and Federal Ministry for Health** stated on their website on April 29th that the **recommendation of** 30 minutes of 65°-70°C / 150°-160°F **dry heat decontamination protocol is taken back** until further notice. The ministry continued that the protocol is currently under validation and left open if it might be reintroduced with possible modifications.

After the recommendation had been taken back by the ministry German hospitals that had started to implement the dry heat disinfection switched to steam sterilisation as contingency method instead or considered a longer dry heat process with much higher microbicidal impact as described in the following.

Implementation in Germany:

During the time the recommendation was in force various German customers requested Belimed to implement the dry heat process within a Belimed WD 290 Washer Disinfector by using only a drying cycle.

This was seen as beneficial for a relatively smooth implementation and decontamination workflow as many CSSDs in Germany do not have access to drying cabinets. In addition, all CSSDs have workflow and quality assurance for this process (ensuring that all items passing are actually processed in a clearly defined way).

It is important to note that after the discontinuation of the recommendation of the German ministry **the 30 min dry heat process alone cannot be considered as sufficient** – but it may be used as a first step in a longer decontamination protocol as described in the next section.

Under normal circumstances Belimed would have refused to implement such a solution because it is **outside the intended use of a washer disinfector to disinfect only with dry heat.** However, it must be remembered that this is generally also outside of the intended use of a drying cabinet or an oven. The emergency regulation in force gave the regulatory permission implement new processes (that may normally be considered off-label use) for a limited time during the crisis and to solve the problems of PPE shortages.

Because the intended use of a WD does not include **dry heat disinfection** a concern was raised for potential infection risk for CSSD staff, because potentially infectious masks are first treated with cold air before the heating temperature is reached. It was argued that cold air with airborne virus particles, could be exhausted from the WD into the immediate working environment of CSSD.

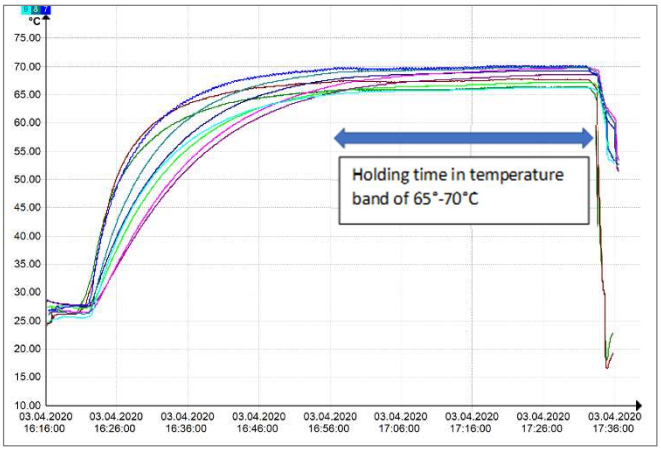
This argument was discussed between hospital infection control teams and washer disinfector manufacturers and they came to the following conclusion which was also accepted by the DGSV÷

This should not be considered a critical risk, as long as the washer disinfector type used is connected to an active exhaust ventilation system and is not discharging drying air into the room (e.g. as small washer disinfectors do). If aerosols going into the exhaust system would be a problem, then the same concern would be there for all process stages in a washer disinfector before thermal disinfection, since during all these stages aerosols of non-disinfected and potentially highly infectious medical devices can exit from the washer into the hospital exhaust system.

Therefore, with an active exhaust ventilation system, the process in WDs is considered safe in terms of aerosol spread and the question is only the technical feasibility of implementing the required decontamination conditions in a reliable and repeatable manner.

On the request of the **German Hospital Group Helios**, Belimed performed tests proving that it is possible to generate the conditions defined by the German ministry recommendation (65-70°C / 150°-160°F for 30 minutes) in a Belimed WD 290 washer disinfector, by implementing a carefully designed drying program.

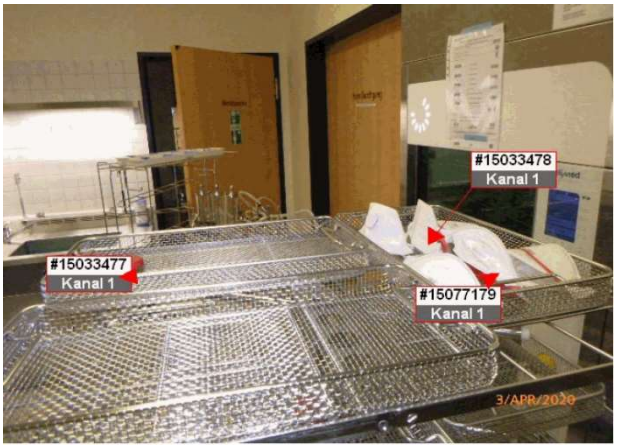
The temperature band of the masks was verified on all levels of a four level instrument rack, similar to the way temperature bands of cleaning and thermal disinfection stages are verified during yearly on site qualification with temperature loggers. The loggers used had a significant thermal mass and temperature sensors placed inside the logger housing for additional safety. This method reflects possible delayed heating kinetics (due to the less efficient heat transfer of air compared to water).



Picture 6: Temperature curve of the dry heat disinfection cycle in the WD 290 measured with loggers that have a delayed response to heating with air due to their thermic mass

Picture 7: Four level rack with FFP2 masks and temperature logger placed within the mask.

Picture 8: Four level rack with FFP2 masks and temperature loggers on various levels



Picture 9: Top level of four level rack with FFP2 masks in front of Belimed WD 290 Washer Disinfector

The Helios Process – Two Steps of Hot Air Treatment with Extensive Quality Control

The Helios Group, currently operating 42 CSSDs in Germany, had researched dry-air disinfection and other methods already before the Ministry had published their recommendations. They had set themselves the challenging goal of implementing a process with highest possible safety standards to ensure uncompromised health protection of their employees - while maintaining a work-flow that:

a) Is manageable on a large scale
b) Can be transferred to different Helios hospital sites

With this ambitious goal, Helios dedicated an interdisciplinary team to work on the challenge of FFP2 mask contingency reprocessing. Their solution was in line with the temporary emergency recommendation by the ministry, while highly increasing the microbicidal efficacy and thus overcoming limitations of individualised reuse, greatly simplifying logistics and process complexity. The Helios process is based on a **two-step thermal decontamination with dry heat**.

The first thermal disinfection step takes place in the normal CSSD inside the washer disinfector at **65-70° for 35 minutes** (as described in this chapter). Here it is made sure that the drying phase before the “dry heat

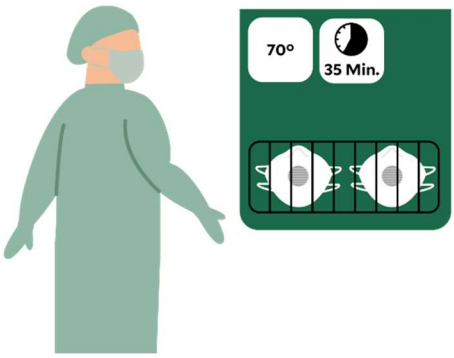
decontamination plateau" is long enough to for the masks to be completely dry. Subsequent to this first treatment step the masks are packed into sterilisation wrap for transport to a specialised CSSD with additional infrastructure for further dry heat decontamination (convection ovens).

There the masks undergo another treatment of **9 hours dry heat at 70°C / 160°F**, resulting in a total thermal disinfection dose that mathematically corresponds to A_0 3000 but with dry heat and not with moist heat as described in the ISO 15883 WD standard. In this way, according to the infection control specialists that were involved into the process design and its quality control a level of disinfection is reached that can be expected to provide safety from SARS-CoV-2 and other pathogens that may present a risk during mask reuse

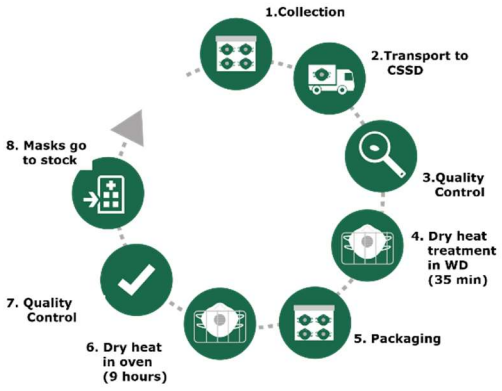
With this method, **Helios can decontaminate any type of CE marked mask**, the only limiting factor for reuse would be potential wear or damage due to repeated use by HCWs. Helios has implemented a stringent quality management system in this decontamination process including microbiological and technical quality control of samples of every batch of reprocessed masks. Helios report a capacity of 8,000 masks per day in the 36 CSSDs where this process was introduced. Due to the fact that enough new masks could be sourced Helios - similar to most hospitals who have tested or introduced steam sterilization for FFP masks - is collecting the reprocessed masks in a separate stock for the time being and will only use them when no other options are available.

Similar as described for steam sterilisation in the Netherlands, there are considerations made that reuse of decontaminated high quality masks could actually be safer for HCWs than use of new low quality masks due to better filtration properties. .

Helios has an extensive press release on their process and will make all relevant data available to healthcare providers, to benefit from their experience and to provide full transparency to stakeholders.



Picture 10: Symbolic depiction of the first thermal decontamination step in the washer disinfector (Graphics from Helios)



Picture 11: Depiction of the 8 step workflow as developed by Helios Group Germany (Graphics from Helios, translated)

References:

Kampf G, Voss A, Scheithauer S, 2020 Inactivation of coronaviruses by heat, Journal of Hospital Infection, Journal Pre-proof. Accepted date March 23rd
https://doi.org/10.1016/j.jhin.2020.03.025.

van Doremalen, N., et al., Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. J New England Journal of Medicine, 2020.
https://www.nejm.org/doi/full/10.1056/NEJMc2004973

Rabenau, HF et al., Stability and inactivation of SARS coronavirus, Medical Microbiology and Immunology, issue 1-2/2005
https://www.springermedizin.de/stability-and-inactivation-of-sars-coronavirus/8504160

Joint Statement of the German Federal Ministry of Labour and Social Affairs and Federal Ministry for Health offered to the crisis management division of the German government concerning dry heat reprocessing of respirator masks from March 31st (later taken back on April 29th – see reference further down):
https://www.bmas.de/SharedDocs/Downloads/DE/Thema-Arbeitsschutz/einsatz-schutzmasken-einrichtungen-gesundheitswesen.pdf?__blob=publicationFile

Website of German Federal Institute of Safety at Work and Occupational Medicine (BAUA) - Questions and answers about use of respirational masks.
https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Biostoffe/FAQ-PSA/FAQ_node.html

Online Newspaper Article: The Guy Who Helped Invent the N95 Mask Thinks He's Found a Way to Clean and Reuse Them, VICE April 1st 2020
https://www.vice.com/en_us/article/g5x9z7/the-guy-who-helped-invent-the-n95-mask-thinks-hes-found-a-way-to-clean-and-reuse-them

Press Release of Helios Hospital Group about their 2-step heat decontamination process for FFP masks (German, English and Spanish language)
https://www.helios-gesundheit.de/unternehmen/aktuelles/pressemitteilungen/detail/news/helios-entwickelt-verfahren-zur-wiederaufbereitung-von-ffp-masken/

Additional References Edition 2

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Press Release of the German Federal Ministry of Labour and Social Affairs concerning the discontinuation of the recommendation of dry heat decontamination process for FFP masks (April 29th)
https://www.bmas.de/DE/Presse/Pressemitteilungen/2020/versorgungssicherheit-bei-atemschutzmasken-sichern.html

4. Steam Sterilisation of Single-Use OR Gowns in France and the NL

Context:
Since OR gowns are frequently used as PPE for HCWs in contact with potential or confirmed COVID-19 patients, a much higher number of these gowns is needed than usual. The French Association for hospital infection Control (SF2H) has published a statement concerning the exceptional-case reprocessing (cleaning & sterilisation) reuse of surgical gowns. Also in the Netherlands a statement with a similar recommendation was published by the Dutch Ministry of Public Health.

Recommended process by the SF2H:

- Cleaning and Disinfection process in a laundry machine at 60°C (140°F) for 30 minutes
- Drying process (attention: some gowns materials can take fire when dried at too high temperatures
- Sterilisation with steam sterilisation at 125°C (257°F) and 20 minutes holding time

Implementation in France:

In close cooperation with the French Society of Sterilisation Sciences (SF2S), **Belimed has defined the standard parameters** following the recommendation by the SF2S (fractionated pre-vacuum steam sterilisation process with a plateau at 125°C / 257°F for 20 minutes) and implemented this process for various interested hospitals. Whenever possible, the pre-phase of the steam sterilisation process should be kept identical to existing validated programs so that the daily Bowie-Dick test results are valid for this special program as well.

Picture 12: Single use surgical gown before packing

Picture 13: Single use surgical gown in sterilisation pouch before steam sterilisation

Picture 14: Single use surgical gown in sterilisation pouch after steam sterilisation

References:

Statement of the French Society of Hospital Infection Control (SF2H) about reuse of surgical gowns:
https://www.sf2h.net/avis-a-la-reutilisation-de-sur-blouses-dans-un-contexte-de-penurie-nationale
https://www.sf2h.net/wp-content/uploads/2020/04/Avis-r%C3%A9vis%C3%A9-SF2H-Re-utilisation-surblouse-05.04.2020-.pdf

Additional References Edition 2

Statement Dutch Ministry of Public Health for reuse of FFP masks and single use protection clothing (in Dutch)
https://www.rivm.nl/documenten/hergebruik-mondmaskers-isolatiekleding

5. Steam Sterilisation of Face Masks from Sterilisation Wrap in France

Context:
During the COVID-19 pandemic many countries encouraged more extensive use of medical face masks (often referred to as “surgical masks”) in healthcare and also in everyday life. As a consequence, a massive increase in consumption of single-use medical face masks has depleted stocks in many countries. In the absence of appropriate masks or lack of knowledge, HCWs and others also may misuse and overconsume FFP / N95 respirator masks when medical face masks (type 1/2/3) would be appropriate, thereby further increasing the scarcity of FFP / N95 masks.

A simple workaround method to overcome out of stock situations for medical face masks is therefore highly beneficial for safety and public health.

Both France and China have started systematic approaches to manufacturing medical face masks from sterilisation wrap (similar to type 1 EN 14683) in CSSDs. Sterilisation wrap materials (SMS or SMMS) that comply with the standards ISO11607 and EN 868 have a proven impermeable for airborne infectious particles and can therefore be considered as **appropriate material for the purpose of medical face masks** for contingency use.

The resulting manufactured masks do not strictly comply with EN 14683, but can have very similar properties as type I masks as defined in this standard. Because of the lack of strict compliance with the standard, the French Society of Sterilisation Sciences (SF2S) recommends not to use these masks for healthcare workers with direct patient contact, but for **administrative and logistic hospital staff** as well as for COVID-19 patients in public environments.

Although the masks do not replace medical face masks according to EN 14683 Type I in all cases they can significantly support the shortage of medical face masks.

Implementation in France:

The SF2S has published an instruction on how to manufacture medical face masks out of sterilisation wrap in times of shortage. It is important to emphasize the indications for use (see chapter context, above). These masks are to be manufactured according to the templates and instructions linked in the reference section. This can take place in the sterile processing department, in other units of the hospital or even at home.

It is not strictly necessary to sterilise masks if they have been manufactured in a hygienically safe environment, however a final sterilisation stage and delivery to the end user in sterilised pouches, will ensure the hygienic safety of the masks.

Note. This was reported to contribute to the *acceptance* of the mask by end users.

Masks can be packed individually or e.g. in packs of ten (10) and sterilised in standard steam sterilisation processes. In the French context, Belimed has supported customers to successfully implement this process with existing French standard sterilisation programs (pre-vacuum, 134°C / 273°F for 18 minutes).

Picture 15: Mask in individually packed in sterilisation pouch

Picture 16: Mask unpacked from sterilisation pouch

Picture 17: Side view of HCW wearing mask

Picture 18: Side view of HCW wearing mask

References:

SF2S-Website - Link to respective section about medical face masks from sterilisation wrap:
https://www.sf2s-sterilisation.fr/infos/avis-conjoint-sf2ssf2h-sur-les-materiaux-utilisables-pour-la-confection-de-masques-de-protection-type-i/#more-3257

SF2S Information about medical face masks from sterilisation wrap:
https://www.sf2s-sterilisation.fr/wp-content/uploads/2020/03/Avis-conjoint-SF2S-SF2H_Confection-Masques_23.03.2020_10h03.pdf

SF2S table of filtering properties of various commercially available sterilisation wrap materials:
https://www.sf2s-sterilisation.fr/wp-content/uploads/2020/03/Tableau-des-BFE-par-fournisseur.pdf

SF2S Building instruction for medical face masks from sterilisation wrap:
https://www.sf2s-sterilisation.fr/wp-content/uploads/2020/03/Masque-de-type-I_-CHMS-Chambery-VD.pdf

SF2S YouTube video showing the production step by step in English, French, Spanish and Italian:
https://www.youtube.com/watch?v=4FQkniz7nhU
https://www.youtube.com/watch?v=QkEWqKntdSc&feature=youtu.be
https://www.youtube.com/watch?v=6GBVzHCHtIw&t=3s
https://www.youtube.com/watch?v=QkEWqKntdSc&t=9s

EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT:69675&cs=1956C06A1BAF887FF462DD56057D34F29

ISO 11607-1:2019 Packaging for terminally sterilised medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
https://www.iso.org/standard/70799.html

EN 868-2:2017 Packaging for terminally sterilised medical devices - Part 2: Sterilisation wrap – Requirements and test method
https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:41743,6085&cs=18D2CEEA7946403872257B254C6C19393

6. Automated Cleaning & Disinfection of Reusable PPE Equipment

Context:
Reusable PPE as goggles and face shields, under normal circumstances are typically cleaned and disinfected manually (e.g. by using a disinfectant wipe in the department of their use).

Face shields and goggles may be recommended to use in combination with FFP2 / N95 respirators to reduce the contamination of these respirators especially when their extended use is being implemented as a measure to manage supply shortages. Goggles can to reduce the risk of airborne infection entering via the eyes of HCWs when working with infectious COVID-19 patients.

In the context of the current pandemic, some hospitals have expressed interest in automated cleaning and disinfection processes, to ensure a more stringent decontamination and quality assured method as opposed to a manual approach. This should increase safety for both the next user of the equipment and the person responsible for manual cleaning. These items typically do not need require additional sterilisation and can be reused after cleaning, disinfection and drying according to their Spaulding classification.

According to Kampf et al (2020), a one (1) minute thermal disinfection at 80°C / 176°F is enough to disinfect SARS-CoV-2 with at least a 4 log reduction factor. Moreover, since SARS-CoV-2 is an enveloped virus, also the cleaning step involving surfactants at elevated temperatures around 50°C / 122°F will bring a significant reduction of infectivity. To be on the safe side, Belimed recommends to use a thermal disinfection step of A_0 600 whenever material compatibility allows to do that in an acceptable cycle time.

Implementation

When implementing automated cleaning & disinfection processes for these items there are a few things to consider:

- High safety of decontamination of SARS-CoV-2 virus and other potentially harmful infectious agents on the whole surface of the item
- Satisfactory cleaning efficacy
- The PPE equipment must have sufficient material compatibility to allow for an acceptable number of reuses. Material damage can typically arise from high temperatures and cleaning chemicals that are not compatible with the materials used, especially if they are not rinsed off sufficiently
- These PPE products are typically not passed through automated washer disinfectors, so there are no dedicated load carriers (washer disinfector racks) available. However, it is generally possible to find a convenient way to position and fix these items such that all surfaces are cleaned by the water jets (even if the capacity utilization might not be optimised)
- Plastics are more difficult to dry than steel, therefore dedicated washer disinfector cycles may need an extended drying time (at moderate temperatures) or a manual drying step added after the wash cycle is completed.

It is highly recommended that customers perform durability tests of the items to be reprocessed at each site (typically 5 or 10 consecutive cycles with visual evaluation of material changes).

Wash cycles will typically use neutral enzymatic cleaning agents at moderate temperatures (rather than alkaline agents and higher temperatures) in the cleaning phase. After that they may feature long/repeated rinse phases to ensure sufficient removal of the cleaning chemicals which could otherwise potentially harm the plastic materials.

Whenever possible, thermal disinfection is recommended because of its generally higher reliability. The wash program ends with a thermal disinfection step of A_0 600 with moderate maximum temperatures of 80°C / 176°F or less, depending on the heat stability of the products.

If 70°C / 158°F is seen to cause material damage, then chemical disinfection instead of thermal disinfection could be considered.

Picture 19: Example for reusable medical goggles (3M)

Picture 20: Example for reusable medical face shield (Westlab)

References:

Kampf G, Voss A, Scheithauer S, 2020 Inactivation of coronaviruses by heat, Journal of Hospital Infection, Journal Pre-proof. Accepted date March 23rd
https://doi.org/10.1016/j.jhin.2020.03.025.

7. Steam Disinfection 105°C/221°F as Backup Option for FFP2 Masks

Context:
The Austrian society for sterile supply (ÖGSV) as proposed a 105°C steam disinfection with 5 minutes holding time as an alternative to the 121°C / 250°F steam sterilisation cycle for decontamination of suitable FFP2 masks. This option was also mentioned as a viable option by the German society for sterile supply (DGSV) in their last statement (April 5th 2020).

Rationale for this practice is again that SARS-CoV-2 virus is relatively easily inactivated by dry and moist heat. A 105°C / 221°F steam disinfection was common for thermal mattress disinfection and is still available in a number of hospitals in Central Europe. Moreover, this process can also be implemented in many standard medical sterilisers and can therefore easily be implemented into the workflow of a CSSD department.

105°C / 221°F thermal disinfection can be seen as an intermediate between the 121°C / 250°F steam sterilisation and the 65°C / 150°F dry heat disinfection approach, in terms of microbicidal efficacy as well as expected material compatibility.

Implementation as backup option in Austria and Germany:

The 105°C moist heat disinfection method was implemented in standard medical steam sterilisers in some hospital sites in Austria and Germany as an option for the future.

Currently, those sites are still preferring to decontaminate suitable FFP2 masks in 105°C / 221°F sterilisation programs because this method is currently preferred by the responsible Austrian ministry. However, testing is continued and if it turns out that the 105°C / 221°F program has clear advantages in terms of material compatibility, it can be expected that the health authorities will give a green light for the broader application of this program for FFP2 masks or other items.

The below table shows a list of masks that were suggested as **potentially acceptable for emergency reprocessing** by of a **German independent validation lab** that has tested the change in filtration efficacy of new versus treated masks. The masks were sent to them by various interested users who were evaluating the 105°C steam disinfection process with different holding times as options for contingency reprocessing.
This table can be seen as addition to the table in Chapter 2 since masks that are assumed compatible with 121°C steam sterilisation processes can also be assumed compatible with 105°C steam disinfection.

Mask Name	Type	Valve	Manufacturer	Class	Steam Disinf.	No. of cycles	Filter test	Fit test	Source
3M 8322	rigid	yes	3M	FFP2	105°, 7 min	1	x	-	Hybeta[2]
3M Aura 1862+	flat	no	3M	FFP2	105°, 5 min	1	x	-	Hybeta[2]
3M Aura 1872V+	flat	yes	3M	FFP2	105°, 5 min	1	x	-	Hybeta[2]
3M Aura 9320+	flat	no	3M	FFP2	105°, 5 min	1	x	-	Hybeta[2]
DACH Comfort 243	flat	yes	DACH	FFP3	105°, 7 min	1	x	-	Hybeta[2]
DACH Neolution 235V	flat	yes	3M	FFP2	105°, 7 min	1	x	-	Hybeta[2]
Dräger X-Plore 1920	flat	yes	Dräger	FFP2	105°, (? min)	1	x	-	Hybeta[2]
Kanglv	flat	no	Guangzhou Kanglv	FFP2	105°, (? min)	1	x	-	Hybeta[2]
Moldex 2405+	rigid	yes	Moldex	FFP2	105°, (? min)	1	x	-	Hybeta[2]
Nobaprotect 672062	flat	no	Nobamed	FFP2	105°, 7 min	1	x	-	Hybeta[2]
Uniair SH 3200	flat	no	San Hue United	FFP2	105°, (? min)	1	x	-	Hybeta[2]
Uniair SH4120V	flat	yes	San Hue United	FFP2	105°, (? min)	1	x	-	Hybeta[2]

[2] Hybeta, Germany website - see references

References:

Kampf G, Voss A, Scheithauer S, 2020 Inactivation of coronaviruses by heat, Journal of Hospital Infection, Journal Pre-proof. Accepted date March 23rd
https://doi.org/10.1016/j.jhin.2020.03.025.

Statement of the Austrian Society for Sterile Supply:
https://oegsv.com/wp/wp-content/uploads/Stellungnahme-Aufbereitung-von-Einmalmasken_5.pdf

Statement of the German Society of Sterile Supply (DGSV) (in German):
https://www.dgsv-ev.de/wp-content/uploads/2020/04/Stellungnahme-DGSV-Dekontamination-FFP-Masken-3.pdf

Additional References Edition 2

Website of Hybeta (Germany) with background about their FFP mask tests
https://www.hybeta.com/

Hybeta summary of current tests results with traffic light system per mask type
https://www.hybeta.com/fileadmin/content/Pruefungsergebnisse_technische_Sicherheit

8. Conclusion

In this document we have described a number of contingency reprocessing methods for single-use or reusable personal protective equipment (PPE). The paper outlines their legal and technical rationale as a measure of last resort, during the current supply shortage due to the global COVID-19 pandemic.

We hope that readers find the shared information useful, if you require more information or your feel that any of these solutions would be of interest to your facility, please contact your local Belimed organisation or partner.

We encourage any interested stakeholder to get into contact with Belimed Scientific Affairs department, to improve this document by expanding the information, removing discrepancies or adding experiences of contingency reprocessing methods or additional examples that would be worth sharing.

For further information of feedback please contact:
scientific_affairs@belimed.com

- END -