METHODS FOR DISINFECTION OF MOUTH-NOSE MASKS IN CASE OF IMPENDING SHORTAGES DURING A PANDEMIC

I. Introduction

The outbreak of SARS-CoV-2, has led to a scarcity of mouth-nose masks. This type of mask is actually made for single use and reuse is not desired. However, if a method of reuse were to be available that would lead to adequate protection, that method could be used in the event of an emergency.

RIVM (National Institute for Public Health and the Environment) conducted a pilot study showing that once and twice sterilization with a short process with hydrogen peroxide ensures that FFP2 mouth masks retain their shape and, in a quick test, proved sufficiently capable of holding back particles. (https://www.rivm.nl/documenten/hergebruik-ffp2-mondmaskers)

The RIVM advice has been studied in the Spaarne Gasthuis by the Clinical Physicist and Clinical Physicist in training, DSMH, Infection Prevention Experts and physician-microbiologist. This showed that the advice of the RIVM for the SG was not applicable. Two alternatives that may be applicable in the SG have been further explored:

- The " TU Delft variant": 121^0C steam sterilization for one-time reuse
- Variant UV-C of UV Smart

J. Kalpoe, Doctor-Microbiologist StreeklabHaarlem

II. 121°C SINGLE-USE STEAM STERILIZATION

Research

An alternative sterilization method of the mouth masks is using steam. In week 12, delft (TU-Delft) looked at the filter operation of the FFP2 mask after the 121°C sterilization process. These tests show that the filter operation remains within specifications after sterilising five times with steam at 121°C. The dates of Delft's measurements are shown below. In the Renier de Graaf Hospital, another sterility check is carried out by the medical microbiological laboratory. These results are expected at any moment. Based on these findings, an autoclave was set up and validated in Hoofddorp on Monday 23 March for the 121° process.

Results Delft

Filter efficiency measurements

The filtration efficiencies of both sterilized and non-sterilized masks were evaluated with use of a Lighthouse Solair 3200 airborne particle counter (Lighthouse Benelux, www.lighthousetest.com). The Solair is intended for clean room validation and enables the measurement of filter integrity for particle sizes between 0.3 and 25 µm. The system has an internal closed-loop controlled vacuum pump for generating a constant inlet flow of 2.0 cfm.

Protocol

The number of free-floating airborne particles of sizes 0.3, 0.5 and 5.0 µm were measured in an enclosed room for 1 minute at a flow of 2.0 cfm as baseline measurement. Next, mask samples were firmly attached on a funnel (diameter 50mm) directly placed at the inlet tube of the Solair. Subsequent measurements reveal a reduction of particles counted by the Solair due to the filtering of the environmental air that enters the inlet tube. Filtering efficiency was expressed as the percentage particle reduction relative to the baseline measurement.

Mask samples

The mask samples (type 3M FFP2 1862+ and 3M FFP1 xxx) consisted of new and reprocessed masks that were previously used and worn according to the intended use in a hospital setting (Sint Franciscus Gasthuis, Rotterdam, The Netherlands). Sterilization was performed at Van Straten Medical (De Meern, Netherlands) at 121 degrees Celsius xxprogrammaxx. For subsets of masks the entire sterilization cycle was repeated 1, 3 or 5 times.

Results

Airborne particles in the environmental air were measured intermittingly between efficiency measurements of the sample masks.

	Particle count (1min, 2.0 cfm)			Filter efficiency (%)		
Size(µm)	0.3 µm	0.5 µm	5.0 µm	0.3 µm	0.5 µm	5.0 µm
Air	10103944	3641821	53445			

New FFP2	28922	9181	1836	99,7	99,7	99,7
1x 121						
FFP2 (No.2)	317204	72677	2569	96,9	98,0	95,2
FFP1 (No.4)	887969	138349	2078	91,2	96,2	96,1
3x 121						
FFP2 (No.4)	258567	57937	2392	97,4	98,4	95,5
5x121						
FFP2 (No.2)	326386	46694	3028	96,8	98,7	94,3
FFP1 (No.1)	1352604	19774	1589	86,6	99,5	97,0

III. UV-C DESINFETIE MET D25 VAN UVSMART

Literature research

During the H1N1 pandemic in 2009, there was a shortage of protective mouth-nose masks, creating the need for practically applicable methods for disinfection of mouth-nose masks so that they can be reused. The American Institute of Medicine identified three criteria to meet decontamination methods for protective disposable face masks (*BurkeDS, BrosseauLM, CohenHJ, GallagherEJ, GensheimberKF ,et al. Reusability of Facemasks During an Influenza Pandemic. Washington (DC): Institute of Medicine, National Academies Press; 2006:*

1. The method must be harmless to the user
2. The method must not compromise the integrity of the parts of the mask.
3. The methods should inactivate the pandemic-causing pathogen

The literature describes several studies that have examined different disinfection methods on one or more of these 3 criteria. Below is a summary of the most recent and relevant studies.

User safety and mask

In a 2009 study, five methods were evaluated for disinfecting different types of mouth nose masks *(Ann. Occup. Hyg., Vol. 53, No. 8, pp. 815–827, 2009)*:

- UVC (15 minutes exposure to 0.18 to 0.20 mW cm^{-2})
- Etyleen Oxide (EtO, 100% EtO gas), 1 hour exposure and 4 hours of venting
- Hydrogen peroxide gas (Sterrad 100S), 55 minutes
- Magnetron (250 MHz, 1100W), 2 minutes exposure
- Chlorine (Bleached, 0.6% watery solution of sodium hypochlorite) after dipping overnight drying to air.

The research focused on two aspects of these 5 methods: safety/discomfort for the user (criterion 1), and the effect on the functioning and material of the masks (criterion 2). The conclusions of the study are summarized below by disinfection method:

Chlorine:

Chlorine had no effect on the aerosol filtering effect and airflow resistance of the masks. The metal parts (such as those of the nose strap) were slightly affected after disinfection and some parts of mask were discolored. Down sire; drying overnight takes a lot of time.

All kinds of masks kept smelling of chlorine. Residual bleach residues have adverse effects on users' health: corrosive and irritation of eyes, skin and mucous membranes of airways. Pale can cause respiratory symptoms in asthmatic people in low concentration. If the chlorinated masks were moistened (to simulate the effect of breathing), the smell of chlorine became stronger (off-gassing). Given the potential health risks, chlorine disinfection was not recommended by the authors.

Ethylene oxide

Had no effect on the aerosol filtering effect, airflow resistance and physical appearance of the masks. The 5-hour processing time (1 hour of exposure and 4 hours of venting) was considered a possible limiting factor. EtO residues were not considered a health risk: 4 hours of venting is more than enough time to get rid of all the remaining EtO gas.

Hydrogen peroxide gas

Had a non-significant effect on the aerosol filtering effect and airflow resistance of the masks. The only visible physical abnormalities was a slight deterioration of the metal parts. The researchers used a relatively short disinfection cycle of 55 minutes. No health risks were identified.

Microwave irradiation (dry heat)

Had a non-significant effect on the aerosol filtering effect and airflow resistance of the masks. However, in some models of masks, the material was found to have partially melted after disinfection. Disinfection cycle is short (2 minutes) and there were no health risks when used according to prescription.

UVC

Had no effect on the aerosol filtering effect, airflow resistance and physical appearance of the masks. Relatively short disinfection cycle (30 minutes). No health risks when used according to prescription.

In summary: the infection in a microwave and with bleach proved to be the least desirable of the five methods examined. UVC, EtO and hydrogen peroxide gas were found to be promising decontamination methods. However, the long duration of the disinfection process in EtO and hydrogen peroxide can be inconvenient in practice.

Inactivating capacity of pathogens

- (myco)bacteria, fungi and yeasts.

In 2019, validation studies were carried out at the Streeklab Haarlem to investigate the microbiological effect of UVC disinfection with the UV Smart D25. These studies showed the(myco)bactericides (at least 6-log reduction) and fungicide (at least 5-log reduction) claims of D25 (see Annex 1).

Viruses

Since the pandemic in 2009 involved the H1N1 Influenzavirus, a study was carried out in 2018 on the effect of UVC radiation on influenza-contaminated N95 masks (AmericanJournal of*Infection Control 46 (2018) e49-e55).* This study showed a 3-log reduction by irradiating with 1 J/m 2 for 60 – 70 seconds.[2] The 3-log reduction was range::

- On both the plastic material of the headband and on the filter parts of the masks.
- Although the masks were soiled with artificial skin oil and mucine buffer (the masks were not cleaned first prior to disinfection).

The 3-log reduction was considered complete disinfection as a previous study showed that oral masks are infected in practice with up to much less than log-3 influenza particles (*Fisher EM, Noti JD, Lindsley WG, Blachere FM, Shaffer RE. Validation and application of models to predict facemask influenza contamination in healthcare settings. Risk Anal 2014;34:1423-34)* .

Corona viruses

The SARSCoV2, like influenza viruses, is a positive single-stranded RNA virus and is genetically 80% similar to the SARS-CoV1. A 2004 journal of *(Virological Methods 121 (2004) 85–91)* studied various methods of inactivating SARS-CoV1. Using UVC, after 6 minutes of irradiation with an intensity of 4016 uW/cm/cm^{2,} a 400-fold decrease in the number of virus particles was able to be achieved (by comparison, UVSmart: 6872 uW/cm/cm^2 in 25 seconds).

The *Ultraviolet Germicidal Irridation Handbook* has a list of measured D90 values in Appendix B (the UVC dose in which 90% of the pathogen is inactivated) for different types of viruses. For Corona viruses, the D90 varies between3 J/m^2 and 3046 J/m^{2,}depending on the research on which the D90 values are based,, and the medium in which it was tested (Air or water).

Summary of literature research:

Based on *(*the documented data in the Ultraviolet *Germicidal Irridation Handbook* and the 2014 journal of *Virological Methods 121 (2004) 85–91)* it can be concluded that sarscov2 with UVC can be inactivated.

UVC seems capable of meeting all three criteria: when correctly applied it is harmless to the user, it does not affect the materials and the operation of the masks and it is very plausible that UVC can inactivate the SARSCoV2.

RESEARCH IN SPAARNEGASTHUIS (SG)

Bart Titulaer (Clinical Physicist), Lisette Tas (Clinical Physicist in training), John van den Dobbelsteen (Associate Professor TU-Delft)

Based on the desire to disinfection and reuse of mouth-nose masks, we have within the SG, among other things, the possibility of UV-C disinfection with a D25 prototype of UV Smart. Below we describe our own tests conducted with FFP2 masks and the D25.

UV-smart disinfection

There is much less data available on the sterilizing effect of the UV light for mouth masks. Problem of sterilisation is the penetrating power of the UV radiation. The advantage of this method of cleaning is to prevent the addition of moisture to the filter materials. Moisture can affect the reliability and durability of the filter operation.

Testing uses UV test strips (type UV dosimeters, intellego technologies), discoloration from yellow to even pink indicates complete destruction of C. difficile. For our purposes we have assumed full discoloration to pink as sufficient for the intended application (sterilization mouth masks for reuse).

Although we could distinguish more from the color coding, the application opted for a binary successful/unsuccessful (1 and X) score.

Figure 1. UV detection strips with color coding. Yellow for exposure, discoloration after detection to pink

We examined the sterilizing effect in 3 different ways:

1. Control at different depths in an open-cut mask
2. Control duration of exposure with multiple sensors along the main axis (light duration determination)
3. Check on a number of different positions of the mask during the intended cleaning process

Ad 1 control at different depths in mouth masks

Figure 2. Schematic representation of the different filter layers of the mouth mask and the 3 measurement positions. Figures 3 and 4 show the inlay in a cut mouth mask again.

Measurement position	UV measurement dose quality (2x50s)
1	Sufficient
2	Unsufficient
3	Sufficient

Table 1. Exposure quality at 3 different depths in the filter at a 2x25s exposure. The cleaning internally in the deepest filter is insufficient based on the UV intensity.

Ad 2. Control duration of exposure with multiple sensors along the main axis (light duration determination)

Sensors are placed along the main axis (from nose to chin) in the three different mouth mask surfaces. From the image of the UV operation it is known that a double exposure (once normal, once inside out) is necessary for the correct achievement of all the material. It has been shown that a process of 2x50s is required for a complete sterilization.

Figure 5. 3 measuring points along the main axis in the mouth mask.

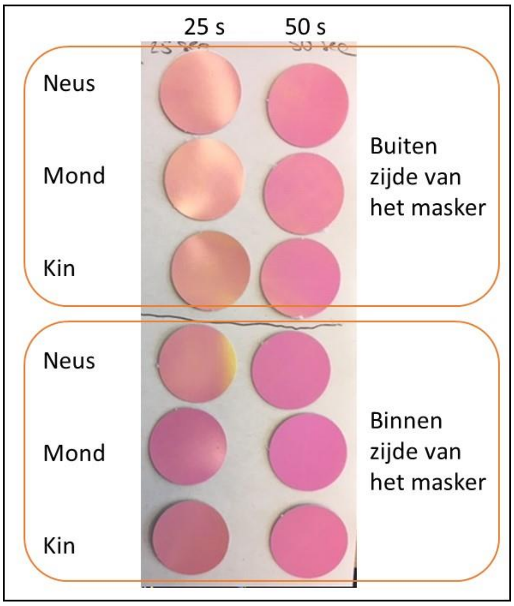

Figure 6. Measurement results of 2x 25s and 2x 50s UV-C exposure.

Ad 3. Check on a number of different positions of the mask during the intended cleaning process

Then on the side on the inside and outside a total of 12 measuring points made and at the intended 2x 50s exposure (once normal, once inside out) the UV-C exposure measured.

Figure 7. 12 measuring points all around on the inside and outside.

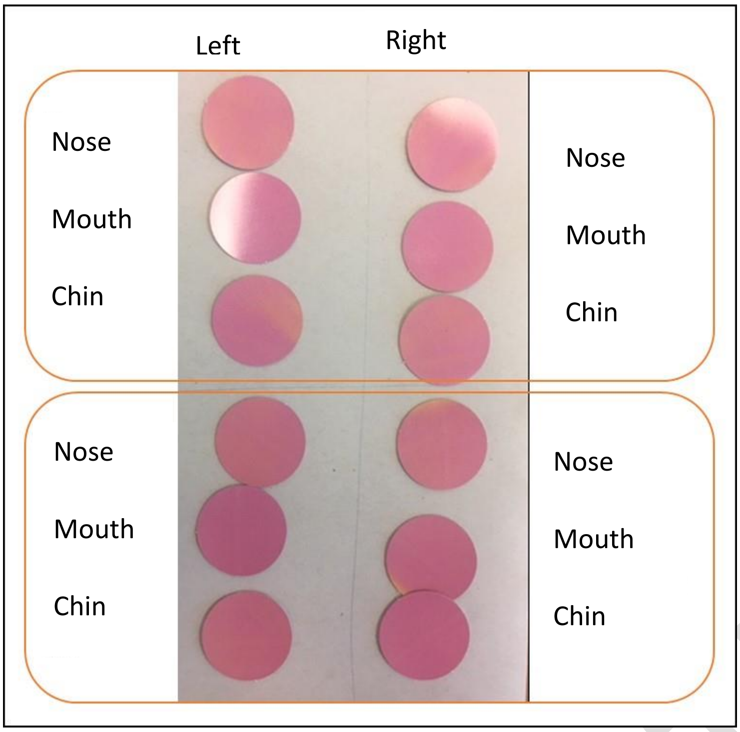

figure 8. Measurement results of the exposure with 2x 50s, inside and outside

Sometimes the color is even less pink depending on where the elastic or the nose rubber has been. Based on it, a 2x50s seems to give a sufficient exposure on all surfaces.

Filter effect after UV-C exposure

The filter effect had previously been measured in Delft (Table 2)) where the exposure used was morethan the exposure times resulting from these measurements. After that, the filter control was carried out with mouth masks of the Spaarnegasthuis after longer and higher intensity UV exposure. This showed that there is no influence of UV exposure on the filter capacity of the different masks, even with 800 sec (8x full disinfection processes) UV exposure does not decrease the filtering capacity. The results of this measurement are shown in the excel "FiltrationMeasurement Mask after UV 2020-03-23"(see Annex 2).).

	% to baseline	% to baseline2	% to baseline3
Airborone Particles	0,30	0.5	5.0
UV Smart 1x 50sec	99,82	99,83	98,46
UV Smart 2x 50sec	99,58	99,62	94,84
UV Smart 3x 50sec	99,69	99,66	93,99
Average %	**99,70**	**99,70**	**95,76**

Table 2. Filter quality after UV-C exposure. Measurements made at TU-Delft by John van den Dobbelsteen.

Overview annex 1. Filtration Measurement Mask After UV 2020-03-23

	Achtergrond			Meting				percentage filtering		
	0.3 micro	0.5 micro	5.0 micro	0.3 micro	0.5 micro	5.0 micro		0.3 micro	0.5 micro	5.0 micro
mean	11420830	1755851	80807	78677	7517	194		99,3	99,6	99,8
	11561056	1725015	62153							
	11696957	1722508	72130							
	11832247	1704851	61076							
3m ffp2+ schoon 1	11734072	1780759	78239	259933	31659	794		97,8	98,2	99,0
3m ffp2+ schoon 2	11734072	1780759	78239	248774	28092	264		97,9	98,4	99,7
3m ffp2+ schoon 3	11734072	1780759	78239	247185	27315	211		97,9	98,5	99,7
3m ffp2+ schoon gemiddeld							gemiddeld	97,9	98,4	99,5
3m ffp2+ schoon 1	11442956	1748605	74037	86044	6833	423		99,2	99,6	99,4
3m ffp2+ schoon 2	11442956	1748605	74037	73984	3743	0		99,4	99,8	100,0
3m ffp2+ schoon 3	11442956	1748605	74037	74920	4379	0		99,3	99,7	100,0
3m ffp2+ schoon gemiddeld							gemiddeld	99,3	99,7	99,8
3m ffp2+ UV 100sec 1	11454115	1720283	66744	55973	6533	370		99,5	99,6	99,4
3m ffp2+ UV 100sec 2	11454115	1720283	66744	41971	2895	17		99,6	99,8	100,0
3m ffp2+ UV 100sec 3	11454115	1720283	66744	41194	3107	17		99,6	99,8	100,0
3m ffp2+ UV 100sec gemiddeld							gemiddeld	99,6	99,8	99,8
3m ffp2+ UV 100sec 1	11420973	1763808	81788	64113	8652	512		99,4	99,5	99,4
3m ffp2+ UV 100sec 2	11420973	1763808	81788	42377	3407	0		99,6	99,8	100,0
3m ffp2+ UV 100sec 3	11420973	1763808	81788	41883	3743	88		99,6	99,8	99,9
3m ffp2+ UV 100sec gemiddeld							gemiddeld	99,6	99,7	99,8
3m ffp2+ UV 200sec 1	11227872	1749153	82000	62242	7398	1465		99,4	99,6	98,2
3m ffp2+ UV 200sec 2	11227872	1749153	82000	40099	1748	17		99,6	99,9	100,0
3m ffp2+ UV 200sec 3	11227872	1749153	82000	40594	2277	17		99,6	99,9	100,0
3m ffp2+ UV 200sec gemiddeld							gemiddeld	99,6	99,8	99,4
3m ffp2+ UV 200sec 1	11284128	1800006	99269	144260	15873	423		98,7	99,1	99,6
3m ffp2+ UV 200sec 2	11284128	1800006	99269	131794	13684	229		98,8	99,2	99,8
3m ffp2+ UV 200sec 3	11284128	1800006	99269	139669	13719	70		98,8	99,2	99,9
3m ffp2+ UV 200sec gemiddeld							gemiddeld	98,8	99,2	99,8
3m ffp2+ UV 400sec 1	11153270	1719948	86520	55691	5597	211		99,5	99,7	99,8
3m ffp2+ UV 400sec 2	11153270	1719948	86520	32348	1730	35		99,7	99,9	100,0
3m ffp2+ UV 400sec 3	11153270	1719948	86520	31200	1871	17		99,7	99,9	100,0
3m ffp2+ UV 400sec gemiddeld							gemiddeld	99,6	99,8	99,9
3m ffp2+ UV 400sec 1	11325199	1783955	93972	46933	5120	123		99,6	99,7	99,9
3m ffp2+ UV 400sec 2	11325199	1783955	93972	24949	1447	17		99,8	99,9	100,0
3m ffp2+ UV 400sec 3	11325199	1783955	93972	24649	1836	35		99,8	99,9	100,0
3m ffp2+ UV 400sec gemiddeld							gemiddeld	99,7	99,8	99,9
3m ffp2+ UV 800sec 1	11473715	1779382	82865	47127	5155	158		99,6	99,7	99,8
3m ffp2+ UV 800sec 2	11473715	1779382	82865	28057	1253	0		99,8	99,9	100,0
3m ffp2+ UV 800sec 3	11473715	1779382	82865	26909	1077	0		99,8	99,9	100,0
3m ffp2+ UV 800sec gemiddeld							gemiddeld	99,7	99,9	99,9
3m ffp2+ UV 800sec 1	11416082	1751007	78327	86097	8652	264		99,2	99,5	99,7
3m ffp2+ UV 800sec 2	11416082	1751007	78327	60405	3460	53		99,5	99,8	99,9
3m ffp2+ UV 800sec 3	11416082	1751007	78327	58922	3266	0		99,5	99,8	100,0
3m ffp2+ UV 800sec gemiddeld							gemiddeld	99,4	99,7	99,9

J. Kalpoe, Doctor-Microbiologist StreeklabHaarlem

IV. Conclusion

Sterilization with steam at 121°C

Based on research in the Spaarne Gasthuis in collaboration with the TU-delft, it can be concluded that one-off sterilization of the mouth-nose masks by autoclave at 121°C does not affect the filter function of the masks. This microbiological effective and validated sterilization procedure is present the in the Spaarne Gasthuis. This procedure can be used as a centrally executable method for the one-time sterilisation of large quantities of mouth masks. An internal document of the Spaarne Gasthuis, written by Erwin van Lent (head of CSD), describes a central disinfection design for these materials by sterilisation at 121°C and is very suitable for entire hospitals or large departments.

UVC-disinfection with D25 of UVSmart

Based on literature research, it appears that Coronaviruses can be effectively killed by UV-C. At the Spaarne Gasthuis, research was carried out on UVC radiation treatment of FFP-2 masks, using UVC indicators to measure how much light ends up in different places in the masks. This shows that the device generates enough UVC energy om to disinfect both the different outside of the mask and the different layers of filters in the mask. This method can be well applied to the nursing wards for disinfection of personal small medical devices (such as telephone, stethoscopes, goggles) and mouth-nose masks. The implementation of these methods is being conducted.

An internal document from the Spaarne Gasthuis, written by the Department of Clinical Physics, describes the disinfection process, including the instructions for users. This process is based on individual care providers in the intensive care units and the corona departments.

J. Kalpoe, Doctor-Microbiologist StreeklabHaarlem