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Reuse of Filtering Facepiece Respirators in the COVID-19 Era

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Abstract: The current COVID-19 pandemic has resulted in an immense and unforeseen increase in demand for personal protective equipment (PPE) for healthcare workers worldwide. Amongst other products, respirator masks are crucial to protect the users against transmission of the virus. Decontamination and reuse of the existing stock could be a solution to the shortage of new respirators. Based upon existing studies, it was found that (I) a solid quality control method is essential to test product reuse, (II) in-depth evaluation of the different parts of the filtering facepiece respirator (FFR) should be considered, and (III) communication of the reuse cycle is essential to take track of the amount of reuse, as this is limited to ensure quality. The goal of this paper is two-fold. First, we identify the impact of decontamination on the different parts of the FFRs and how the quality control should be performed. Two different types of FFRs are analysed within this paper, resulting in the recommendation of combining quantitative respirator mask fit testing with a thorough sensory evaluation of decontaminated FFRs to qualify them for reuse. Secondly, the possibilities of communication of this reuse to the eventual user are mapped through in-depth reasoning.

Keywords: reuse; respirators; product shortage; quality control; COVID19

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1. Introduction

During the COVID-19 pandemic, a number of personal protection precautions are employed to form a barrier against exchange of body fluids between patients and healthcare workers and as anti-viral respiratory protection for the healthcare workers (through filtration). One of these precautions is the use of masks, which, despite their reported discomfort such as itching [1], are currently seen as an indispensable part of the equipment of healthcare workers. Due to the current COVID-19 pandemic, a worldwide scarcity is occurring, for both surgical face masks and for filtering facepiece respirators (FFRs), endangering healthcare workers [2]. Most of these masks are manufactured only for single-use. However, the reuse of existing masks offers a probable solution. In contrast to other medical products (e.g., gloves), masks are fit for reuse in professional healthcare institutions after sterilisation according to well-known agencies such as the European Centre for Disease Prevention and Control (ECDC) [3] and The National Institute for Occupational Safety and Health (NIOSH) [4] in the United States. Reuse of single-use respirators, after decontamination, should however only be considered during a severe shortage and after implementation of strategies for optimised use of current stock [2,4]. Since these masks are developed for single-use, an additional re-evaluation is necessary to determine the respiratory protection of these masks after sterilisation. The WHO [2] recommends the presence of a solid quality control system to inspect the items before and after every cycle of reprocessing. All the respirators should be checked for visible soil, damage or other failures before qualifying for reuse. In addition to this, the WHO has developed guidance

for institutions that are considering reprocessing respirators, and they must carry out a thorough evaluation of their process and workflow to ensure quality. A distinction is made between situations inside and outside a health service setting, as transport of potentially contaminated respirators has to be handled carefully.

In Belgium, the University Hospital of Antwerp (UZA) forecasted a chronic shortage of masks at the beginning of March 2020. In order to cope with this shortage, an urgent project was initiated at the University of Antwerp, combining expertise to find local alternatives for the particulate filtering facepiece (FFP) respirators, more specific: FFP2 and FFP3 respirators [5]. FFP2 and FFP3 are the European respiratory performance standard which are nominally equivalent to the North American standards of N95 and N99, respectively. To get an idea of the quantities consumed, on average 1000 FFP2/3 respirators are consumed per year in the UZA [6]. However, during the first wave of the COVID-19 pandemic (March–May 2020), the UZA consumed 30,000 FFRs [6]. This means that the hospital needs to acquire more than 10,000 new masks every month. The University Hospital of Leuven had a usage of 1000 FFP2 respirators per day during the first wave of the COVID-19 pandemic [7]. To fulfil the minimal demands of all healthcare workers in Belgium, a total of 2.8 million FFP2 respirators were needed in the month of April 2020 [8]. This demand for new respirators could not be fulfilled, therefore Belgium, on 4 April 2020, published a guidance on the sterilisation of used FFP2 masks as a solution during the crisis. Other European countries faced similar shortages and all responded in a comparable way, for example, The Netherlands created guidance on sterilisation [9] and France created guidance on prolonged use [10].

Furthermore, these used masks end up as waste to be disposed of on a daily basis, for example through incineration, together with all additional personal protective equipment (PPE) such as gowns, coveralls, gloves, hair nets, or shoe/boot covers. In itself, the weight of a mask is relatively low, but all together, they have a significant impact on the waste generated by a hospital. Reuse of the mask would have a substantial impact on both the purchase of new masks and the waste costs. If every mask could be used twice (i.e., once reused), the number of needed masks can be halved.

1.1. Opportunity for Cleaning and Reuse

Typically, design for maintenance and repair should be included during the design phase of new products [11]. Consequently, in this research, reuse of existing products is investigated, so new suggestions regarding design for cleaning or reuse remain valuable for future development. We can, however, start from the guidelines for reuse and maintenance to consider how far they are present in the existing products. Design for lifetime extension, which is the basis or motivation for reuse and cleaning, mainly focusses on avoiding technical and emotional failure [12]. Regarding masks, the need is especially high when it comes to improving physical durability. During the design phase, attention should be paid to several factors: from the robustness of the material, to the opportunities to upgrade and adapt products, to the efficiency in cleaning and maintenance.

In this paper, we will investigate the opportunity for cleaning and reuse by means of existing sterilisation methods for medical products in order to kill viruses and bacteria. Because of the severe shortages of respirators and surgical masks in the COVID-19 pandemic, a number of methods could be considered for the sterilisation of used FFR masks. We will focus on the opportunities to reuse FFP2 and FFP3 or equivalent respirators as they are acknowledged as safe for healthcare workers. Therefore, it is crucial to investigate the functionality and quality of the products after sterilisation by means of thorough quality control.

1.2. Importance of Testing and Quality Control

To find new solutions, it is necessary first to understand and control the desired quality and manner of testing. The functionality of respiratory protective equipment (RPE) is commonly expressed by maximum filter penetration level and maximum total inward

leakage level, complemented with usability and clogging resistance [13,14]. The main performance tests concern breathing resistance, total inward leakage, filter penetration, extended exposure and flammability [14]. The protection level offered by FFRs and face masks is commonly defined by the percentage of ambient particles penetrating inside the protection device. There are two penetration pathways: (I) through face seal leakage, and (II) through the filter medium [15].

To evaluate the total inward leakage, a fit test should be performed. Fit tests are done either qualitatively (by means of using the sense of taste or smell) or quantitatively (by means of a device to measure the actual amount of leakage into the facepiece), the latter being the most effective. One of the most commonly used devices for this purpose is the TSI PortaCount, which is used in many studies evaluating fitting of respirators in a quantitative manner [9,13,16,17]. According to the European standard EN149 + A1:2009: Respiratory protective devices—Filtering half masks to protect against particles—Requirements, testing, marking [18], a fit test should be performed using the following method. (I) Ten subjects perform five test exercises whilst wearing the respirator. (II) The total inward leakage inside the respirator due to face seal leakage, filter penetration and valve leakage (if present) is measured for each subject exercise. (III) The subject mean total inward leakage for 8 out of 10 subjects shall not exceed the determined limits. However, within the context of the first wave of COVID-19, as a response to unprecedented demand for testing or certifying new respirator masks as safe to use for frontline healthcare workers, the European Union PPE working group gave recommendations from the Co-ordination of Notified Bodies (PPE-R/02.075 Version 2) regarding PPE Regulation 2016/425 [19]. This document describes tests that are performed on the COVID Pandemic mask, which is a limited set of tests from the EN149 + A1:2009 standard. Many European accredited testing facilities employed these simplified particle filtering measurements to gain insight quickly into the minimal required filtering performance of a mask, mainly for new masks but also for sterilised, used masks. Due to the severity of this mask scarcity, these tests might be performed on fewer subjects than described in the European standard. For example, the Dutch National Institute for Public Health and the Environment evaluated 50 different sterilised and non-sterilised respirators during the COVID-19 pandemic using 2–4 different test subjects [20]. To exclude the subject as a variable for comparison, Anderegg et al. [21] used a single test subject to validate ten different respirators ranging between 0 and 5 cycles of sterilisation. A preprint article in Medrixiv used one test subject for each of nine heat-treated disposable respirators [22]. A second preprint article evaluated two 3M respirators after UV sterilisation, both fit tested on one volunteering model [23].

To evaluate the filter medium, the recommended method is using a TSI model 8130 automated filter tester or equivalent instrument, as used by the National Institute for Occupational Safety and Health [24] and a vast majority of studies evaluating filtration efficiency [25–28]. The TSI model 8130 measures the filter aerosol penetration during this test. More research is needed to explore the opportunities for setting up emergency testing facilities in times of need. However, for new respirators, quality-controlled filter material is currently often considered to be sufficient. Moreover, the fit test could be considered most crucial; if this test fails, testing of the filter material separately becomes irrelevant as it is already proven that the respirator will not reach the required protection level. The filter material penetration test, in such cases, will only be used to determine the cause of the failure.

Many European countries developed alternative testing procedures to evaluate respirator masks during the COVID-19 pandemic. Due to the scarcity, new and faster procedures were needed. The Belgian government, for example, generated an Alternative Test Protocol where only Penetration of Filter Material and Total Inward Leakage (TIL) is measured [29]. To evaluate both, a PortaCount is being used. To measure the penetration of the filter material, an experimental method is used: the respirator is taped to the face to avoid face seal leakage during a fit test. In the Czech Republic, a special Czech certification CSN EN140:1999 was developed based upon the complete European standard EN140:1999

"Respiratory protective devices—Half masks and quarter masks—Requirements, testing, marking", but only evaluated CO_2 content of inhalation air, breathing resistance and inward leakage [30].

1.3. Aim of the Research

The aim of the research is to investigate if reuse of respirators can reduce the number of respirator masks needed in a hospital during a pandemic. Within the investigation, additional focus is placed on (I) the importance and execution of quality control, and (II) the communication of the number of reuse cycles, and (III) the communication of cleanliness and safety.

Within this research, first the existing state of the art studies on mask reuse are explored, then documented in the next Section to identify the additional needed research.

2. State of the Art

2.1. The Different Sterilisation Techniques and Impact on SARS-CoV-2

Multiple studies have been performed on evaluating decontamination of respirator masks. Selecting the most suitable technique for decontamination is crucial to obtain the best results. Based upon existing research the following list of possible techniques was compiled.

Ultraviolet germicidal irradiation (UVGI) of respirators was studied in [17,25–28]. While using this technique, the limited UV penetration depth must be taken into account while decontaminating respirators [26,27]. According to experiments and models by Huber et al. [23], a UVGI treatment should be able to reduce the presence of SARS-CoV-2 on the surface and interior of respirators. Earlier research was able to inactivate the similar SARS-CoV-1 virus by 15 min of UV at 254 nm [31].

Microwave oven irradiation (or microwave heat irradiation (MHI)) and Microwave oven Generated Steam (MGS)) are two different techniques based on microwave radiation. MHI [26,28] and MGS [17,25,32,33] are both often used in studies analysing decontamination of respirators. MGS was able to inactivate SARS-CoV-2 on N95 respirators, evaluated by using a surrogate virus, MS2 phage [32]. Microwave irradiation has been proven to kill the same airborne MS2 virus effectively in [27] and a more than a 99.99% reduction of the H1N1 influenza virus on respirators was noted in [33]. Both of these viruses show similarities with SARS-CoV-2.

Vaporised hydrogen peroxide (VHP) or hydrogen peroxide vapour (HPV) are different terms to refer to the same technique. VHP is considered one of the most promising techniques to decontaminate filtering facepiece respirators by Viscusi et al. [26]. Multiple studies have verified the use of VHP as a decontamination technique for respirators [25,26,28,34]. Two preprint articles intentionally contaminated respirators, in one case using SARS-Cov-2 and in the other case a surrogate, to evaluate the inactivation of SARS-CoV-2, and after one cycle of decontamination no detection above the infectious dose was found on the respirators [35,36]. A third article measured a 99.999% reduction in SARS-CoV-2 RNA after VHP treatment; in case of influenza this would be below the infectious degree, however, for SARS-CoV-2 more research on this level of residue is needed [34]. A comparable technique called hydrogen peroxide gas plasma (HPGP) is evaluated as a decontamination technique for respirators in [25,28]. No studies could be found on the inactivation of SARS-CoV-2 by HPGP, but the technique has been proven to inactivate other viruses such as human immunodeficiency virus (HIV), hepatitis A virus, respiratory syncytial virus (RSV), herpes simplex virus (HSV) and poliovirus [37].

Ethylene Oxide (EtO) is known to be a human carcinogen, however, it is commonly used to sterilise medical devices [38]. Contact with the skin, for example, can cause irreversible toxic effects [39]. However, EtO as a decontamination method for respirators is verified in several studies [25,26,28]. A study by Salter et al. [40] on FFRs could not find any EtO residue left after sterilisation. However, 3M, as a prominent manufacturer of FFRs, does not recommend the use of EtO. In their opinion, it is not acceptable for a

respirator used in the direct line of a person's breathing zone to be exposed to a proven human airborne respiratory carcinogen [41]. EtO has been found effective in inactivating human viruses before [42,43], but no specific test on SARS-CoV-2 could be found.

Bleach (sodium hypochlorite (solution)) is often used as an easy-to-access decontamination method. Several studies have used bleach for decontamination of respirators [25,26,28]. Off-gassing might be needed due to the potential health risks of residual chlorine gas [26]. A minimum concentration of 0.1% sodium hypochlorite is sufficient to inactivate the coronavirus on surfaces [44].

Dry heat was explored by a multitude of studies as a decontamination method for N95 respirators [27,28,45–48]. Using a static air oven, time and temperature are the two critical variables, and within these variables studies range from minimal 60 °C [47] up to 160 °C [28] and from three minutes [46] up to three hours [47]. Heat treatment for 30 min at 60 °C has been shown to inactivate SARS-CoV-1 [49]. Experiments on SARS-CoV-2 found inactivation of the virus after five minutes at 70 °C [50].

Moist heat or steam is often used to sterilise medical materials because of its excellent penetration capability [47], resulting in a multitude of studies evaluating steam or moist heat as a candidate for decontaminating respirators [17,21,25,27,33,51–53]. Based upon the knowledge of inactivation of similar viruses to SARS-CoV-2, a 15-min steam procedure at 121 °C is adequate to sterilise FFP2 masks [53]. Another study used avian coronavirus (H120), to mimic SARS-CoV-2, which was inactivated after being steamed for five minutes [52].

Gamma irradiation is a method commonly used for the large-scale sterilisation of medical devices and food items. The necessary equipment is not commonly available in hospitals. A few studies validated gamma irradiation as a decontamination technique for respirators [53–55]. A dose of 20 kGy (2 MRad) is recommended as sufficient for the inactivation of coronaviruses [56].

The last commonly used technique to sterilise surfaces and medical equipment is chlorine dioxide gas (ClO_2). This technique is most efficient at low temperatures from 25 °C to 30 °C and is relatively rapid (1.5 h to 3 h) [57]. In contrast to, for example VHP, ClO_2 can be used to sterilise porous and non-porous materials [58]. The scientific consortium N95Decon [59] concludes that the available commercial ClO_2 sterilisation systems are likely to be sufficient for decontamination of N95 FFRs, if combined with adequate aeration after treatment. Based upon the high similarity with SARS-CoV-1, Wang et al. [60] stated that SARS-CoV-2 could be inactivated by ClO_2. The study was performed using SARS-CoV-1 in wastewater and inactivation was reached after a 30-min ClO_2 treatment of 40 mg/L [60,61].

2.2. Understanding of Sterilisation Influences on Mask Parts

Only a limited number of studies investigating the reuse of mouth masks could be found, all of which are still very recent and therefore probably only reflect the first results. It must be noticed that there are many limitations regarding the existing research as they do not include saturation, filtration or functionality. These existing studies were investigated in detail to derive conclusions regarding the different parts of the masks as shown in Figure 1: (I) mask shell, (II) filter material, (III) elastics, (IV) nose clip, and (V) nose comfort cushion.

2.2.1. Impact on the Mask Shell

The shape of the mask is determined by the outer material which is usually a non-woven polypropylene (PP) material. In general, there are two types of mask shapes: preformed and foldable. PP is used because of its hydrophobic characteristics. The added value of PP is that it is often used for plastic products that need to be sterilised such as baby milk bottles.

The Dutch National Institute for Public Health and the Environment (RIVM) [62] analysed steam sterilisation of multiple types of not reusable (NR) respirators that have passed the dolomite clogging test (abbreviated as D).It was found that the selected preformed cup-shaped respirators (3M 8822 FFP2 NR D mask) were deformed and, as such,

not suitable for fit testing after steam sterilisation at 134 °C. In the same study, steam sterilisation at lower temperatures was only performed for foldable masks. For the tested foldable masks (type 3M Aura 1862 + FFP2 NR D mask) no deformation was observed by the RIVM after steam sterilisation at both 121 and 134 °C. The fit test was reported to be successful at 121 °C. Two cycles of steam sterilisation at 134 °C made the masks fail fit testing, one cycle resulting in variable results [62]. The reason for failure is not specified, but could be due to invisible damage to the mask shell or to the filter media. The same institute evaluated hydrogen peroxide for cup-shaped respirators, where deformation was only shown after four cycles of sterilisation [9]. Possible deformation of respirators was shown after sterilisation with a 24 kGy dose of gamma irradiation, decreasing the mask fit to the face and compromising the inner filtering layer [3]. However, an FFP2 flat-folded respirator showed no deformation after gamma irradiation with 25 kGy during a study in the Netherlands, but the fit test after the decontamination process failed [62]. Deformation of cup-shaped respirators is more likely to occur in comparison to flat-folded respirators for all types of decontamination.

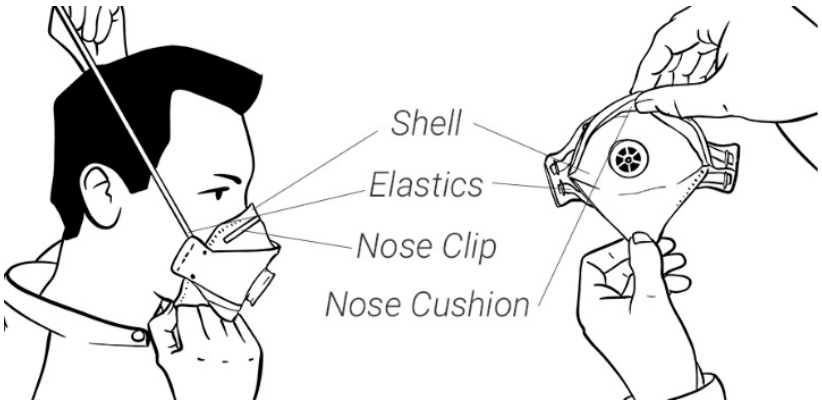

Figure 1. Overview of different mask parts.

The use of dry heat as a decontamination method should be well thought out. As most respirators are made from polypropylene, the used temperature should stay well below the melting point of 165 °C, and the recommended maximum operating temperature is 90–100 °C [28]. One study reported the use of 160 °C and ended with largely melted respirators that are unusable to test or wear [28], whereas studies at 75 °C or 80 °C did not observe visible changes [26,28].

In addition to deformation due to sterilisation, the mask shell might be damaged at the level of the material layers. According to 3M, microwave radiation will melt the material near the metal nose bridge, which will have an impact on the ability to block particles and on the fit of the respirator. The microwaves will result in arcing due to the metal nose bridge, and these arcs will burn holes into the layers of the masks. Consequently, they do not recommend the use of microwave radiation as a suitable sterilisation technique [41]. The research of [26,28] shares the point of view of 3M as they observed in both of their studies melted filter media around the ends of the aluminium nose bridge. Visible holes were observed after microwave irradiation which make the masks no longer eligible to wear. Adding a container of water into the microwave will solve the arcing; in this way microwave generated steam will be the method used, where no damages were observed [25,26,32,33].

UVGI of respirators at high doses will reduce the material strength of the different layers, and depending on the model of respirator this reduction went up to 90% in some cases [63]. A reduction in strength will impact the sealing of respirators, causing a decrease in the fit factor [27]. However, no observable physical changes were found by Viscusi et al. [26], nor signs of deterioration or deformation by Smith et al. [34].

A final problem that could occur is the disappearing of labels/qualifications on the mask or rendering them unreadable. Only one study noticed this as a result of moist heat,

where the labels on two 3M respirators were slightly blurred [21]. These labels are crucial for the wearer to be confident in using the correct respirator.

2.2.2. Impact on Filter Material

To analyse the impact of sterilisation techniques on the filter material, two different approaches are often used. The filter efficiency can be measured by analysing the aerosol penetration grade [26,28,46,54] and the change in structure can be analysed using an electron microscope [27,51]. A degraded filter in respirators will impact their ability to pass the minimum required level of filter aerosol penetration linked to their qualification.

According to Liao et al. [27], UV radiation degrades the polypropylene layers of the masks slowly, and after 20 cycles of sterilisation the filter efficiency of tested N95 masks decayed to 93%. Marking the number of cycles when using UV radiation is therefore crucial. 3M evaluated three different UV decontamination systems; for the two systems where they performed up to 10 cycles, all tested N95 respirators passed filter efficiency and fit testing [41]. This was confirmed in multiple studies where no significant decrease of the filtration efficiency was measured and no significant visible changes were observed after a limited number of decontamination cycles [25,26,28]. Additionally, the filter airflow resistance did not change [26].

Decontamination of respirators by MGS did not affect the filter penetration after three cycles [25], and no changes in fit test performance were found after 1, 5 or even 20 cycles [32]. Dry microwave oven irradiation caused physical damage to different models of respirators in different studies [25,26,28]. Filter aerosol penetration of the material itself was, however, not affected for the majority of the models [26,28].

After bleach decontamination (at 0.5% or 0.6%) the filter material still passed the filter aerosol penetration standard, although for some models there was a decrease [25,26,28]. A fourth study used a higher concentration of bleach (2%) but measured a large decrease in filtration efficiency [27], while no differences in pressure drop were measured. According to Liao et al. and Lin et al. [27,46], this indicates that there was no structural change in the melt-blown filter material, but that its static charge was harmed. Static charges can, however, be restored using proper techniques [27].

A second chemical decontamination technique makes use of Ethylene Oxide (EtO). After EtO decontamination respirators still succeed aerosol penetration level testing according to [25,26,28], and no change in airflow resistance was measured either [25,26].

There is a consensus that dry heat below 100 °C will not increase the filter aerosol penetration level above 5% [26–28,47]. The pressure drop of the respirators will not change at these temperatures implying that there will be no change in structure or morphology of the filter media [27]. With the use of higher temperatures, in some respirators the outer layers will start to melt, making the filter media unsuitable for testing. In one study the three remaining models start to show filter aerosol penetration results >5% at a certain point, respectively at 110 °C for one type and 120 °C for two other types of respirator [28].

A second method of heat decontamination is moist heat or steam. Multiple studies have analysed moist heat decontamination (60–85 °C at 30%–100% relative humidity) where no degradation of aerosol penetration levels above 5% was measured, even after multiple cycles [17,21,25,27]. However, when using steam at 121 °C or higher one study noticed a sharp drop in efficiency after five cycles [27]. After a single cycle the results were dependent on the model being used; some succeeded and some failed penetration testing [27,28,46,53]. In most studies the pressure drop remained constant [27,53], which might indicate a loss of static charge in the filter media [27].

Gamma irradiation increased the filter penetration level for all tested respirators to levels higher than 5% [54]. Gamma irradiation is known to degrade the electret filter media [45], which is a plausible explanation for the failing tests. According to 3M, a leading producer of FFP-respirators, ionizing radiation will degrade the filter performance. This approach is therefore not recommended as a suitable sterilisation technique [41]. The research of [55] confirms this statement in a study with Cobal-60 gamma irradiation.

The sterilised 3M 8210 (cup-shaped), 3M 9105 (flat-folded) and 3M 1805 (flat-folded) all passed a qualitative fit test using saccharin, but a significant decrease in performance was determined using the particulate filtering efficiency test [55].

While using HPGP, four out of the six FFR models had aerosol penetration levels above 5% after three cycles of decontamination [25]. A second study, making use of the same machine, did not measure a significant decrease after a single cycle of HPGP [28]. In other studies using a similar process of VHP, the filter aerosol penetration of the material was not significantly affected after one or three cycles [25,26,28,34].

2.2.3. Impact on Elastics

The impact of sterilisation on elastics is only evaluated in a limited number of studies. In one study executed by the Maastricht University Medical Centre+, the elastics of the specific FFP2 respirators tested could not withstand the high temperature of 121 °C, during the steam sterilisation [64]. It is reported that the blue elastic (material not mentioned) is melted and sticks to the other parts of the respirator [64]. On the other hand the blue elastics of the tested FFP2 masks did pass the plasma sterilisation process [64]. A second study by Bergman et al. [25] noticed melting of the head straps after one cycle of MGS for two of the three samples of one specific type of surgical N95 respirator. For a single decontamination technique, UVGI, it has been shown that the breaking strength of the elastic will decrease after a single cycle [63]. Depending on the dose, the breaking strength decreased between 10% up to 51% [63]. This is a concern and more research is needed. Aged straps may also affect the fit of the respirator [45,54] due to reduced elasticity [21]. Moreover, it should also be considered whether accelerated ageing of the elastics is occurring as an effect of the different decontamination techniques.

Other studies do not report anything regarding the effect of sterilisation on the elastics. It is not clear whether there was no impact noticed or whether there was no attention paid to the state of the elastics after sterilisation. Further tests should be done with multiple masks as different types/materials of elastic are used.

2.2.4. Impact on Nose Clip

Currently no studies report any irregularity regarding the nose clip. It is not clear how it is connected to the base material and what specific materials are used. Regarding connection techniques, using hot glue or other types of heat-sensitive adhesives might have an impact when using heat (moist or dry) sterilisation. However, this should be investigated in detail.

The nose clip of used masks will not be perfectly flat, which will impact the ability to shape the nose clip to the new user's face and assure good fitting. 3M advises reuse of the same respirator for the same person due to this reason [41]; flattening the nose clip in a convenient, repeatable way might be a different solution.

According to [26,28], when using bleach or VHP as a decontamination technique the nosebands were slightly tarnished and visibly not as shiny as before after a single cycle. The study of Bergman et al. [25] evaluated three cycles and observed a similar effect for bleach. This effect might only have an aesthetic influence, and no mechanical evaluation was performed.

2.2.5. Impact on Nose Comfort Cushion

Multiple studies noticed discolouration (yellowing) of the nose comfort cushion on different models of N95 masks while using one or more cycles of bleach decontamination [25,26]. Partial separation of the nose comfort cushion from the respirator itself was noticed for multiple N95 respirators in multiple studies, while using (moist) heat decontamination techniques such as MGS or MHI [17,21,25,33].

Due to wear, permanent compression of the nose comfort cushioning could occur, depending on the material being used. Therefore, research is needed on a variety of worn masks, as compressed nose comfort cushioning might affect the fit to the face.

2.2.6. Conclusions

Based on the executed research activities, we conclude that different sterilisation methods present in hospitals are useful. They all have specific advantages and disadvantages. We recommend the use of moist heat or dry heat at least below 90 °C. A minimum temperature of 60 °C is required to inactivate SARS-CoV-2 [49], but we recommend a temperature of 70 °C [50] to achieve higher throughput. For example 3M is even more strict, whereas they do not, at this time, recommend the use of high temperatures above 75 °C, such as autoclave or steam, due to significant filter degradation [41]. A third valuable option is the use of Ethylene Oxide (EtO), but this technique is linked to concerns about the health of the users. A respirator will be in the breathing zone of the user, which would require high quality off-gassing to avoid exposure to the EtO residue. A technique closely linked to EtO is ClO_2 decontamination. No specific research on the influence of respirator parts could be found, and more data will be useful to evaluate the application of this technique. Further tests are needed to explore the impact of sterilisation methods on each component of various types of mask. If only one specific component does not survive the sterilisation, it should be considered whether the component can be replaced.

It must be noticed that there are numerous types of FFP2 masks currently used within hospitals, each having different materials, different connection techniques, different designs and different performance. Consequently, in fact, each mask type should be tested for appropriateness of sterilisation, by means of a fit test, breathing resistance test, and (if available) filtration test. Currently, there are no reports of tested FFP3 masks that have the additional breathing valve.

Furthermore, the filter of a used mask can be saturated, which can affect the functionality. The saturation of masks is currently not taken into account in the known research. An additional cleaning step might be appropriate to increase the efficiency of the masks. This cleaning has not yet been investigated. However, we know that no detergents or liquid organic solvents (aqueous chlorine solutions or alcohols) can be used as a disinfection method. The liquid organic solvents will remove the static charge in the micro-fibres, reducing filtration efficiency [28,45]. Detergents influence the outer layers of the masks that provide waterproofing of the product. In addition, chlorine also retains gas after decontamination and these fumes may be harmful. Further research is needed to investigate the impact of other cleaning products. At first, visual examination can be used to evaluate the masks in order only to sterilise those masks that do not have any visual indicators of contamination. It is also mentioned that external contamination of the respirator surface can be avoided by placing a medical mask over it, or wearing a face shield that can be cleaned [65].

It is known that sterilisation as well as the usage of the masks will have a significant impact on the product. Each decontamination cycle might lead to deformation or deterioration. Consequently, the masks can be sterilised only a limited number of times. There is no clear indication on how many times this should be, as studies vary between 1–50. Nevertheless, communication on the number of sterilisation cycles is crucial. Nonetheless, even if masks could only be reused once, that would already be a significant reduction of the created waste.

Lastly, there might be a need to flatten the nose clip in order to allow the new user to optimise the fit with their face and achieve a higher fitting and safety level.

3. Materials and Methods

The research reported in this paper is twofold. On the one hand, new technological tests are executed using the existing infrastructure of UZA to further evaluate the possibilities for cleaning and sterilisation of multiple types of masks. These respirators will be further evaluated by assessing the deterioration of any component (mask shape, elastics, nose clip, nose comfort cushion and, if present, breathing valve) and by performing the fit test. Further investigation is done to communicate the number of reuse cycles for each

product, which was found to be essential if any sterilisation is performed in the future. This investigation is done by analysing the technological possibilities, using desk research.

3.1. Sterilisation Tests

To perform these sterilisation tests, a cooperation with two main hospitals in Belgium was established. The Antwerp University Hospital (UZA) provided two types of respirators, which were sterilised by the use of chlorine dioxide, and multiple cycles were performed. The General Hospital Jan Palfijn, Ghent provided six different types of masks, sterilised by the use of steam. An overview of the sterilised masks is shown in Figure 2.

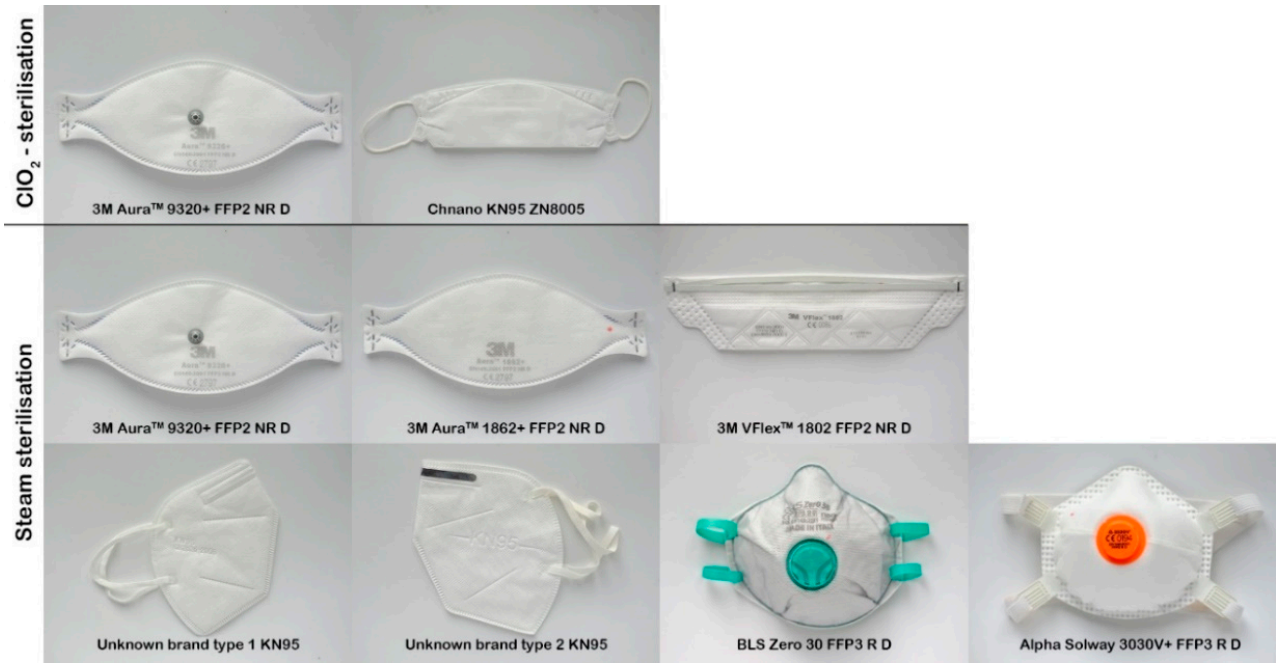

Figure 2. Overview of all types of respirator used in this paper.

The respirators provided by the UZA's sterilisation department were both types of disposable respirators: the regular used 3M Aura 9320 + FFP2 NR D (NR is an abbreviation for Not Reusable), and the Chnano KN95 ZN8005, a Chinese mask recently bought due to lack of availability of the European-certified disposable masks. Both are flat-folded types of respirator. The masks were not worn, and a comparative respirator of the same batch was used as reference material. All the respirators were sterilised using a full cycle of chlorine gas. This was performed by the company Decon-O-Logic using the following four step procedure: (I) the preconditioning phase where the relative humidity (RH) was raised to 65%, (II) the conditioning phase where a hold time of 15 min was used for the 65% RH, (III) the exposure phase using a ClO_2 concentration of 1 mg/L (360 ppm) for two hours to achieve a target dosage of 720 ppm-h and (IV) the aeration phase to reduce the ClO_2 gas from the chamber to a concentration of 0.02 ppm.

The respirators provided by the General Hospital Jan Palfijn, Ghent, were sterilised with the Miele PS5662 vR using a steam sterilisation cycle of 90 min consisting of a peak temperature of 134 °C for 5 min. Six different models were provided, consisting of both FFP2 (or similar) and FFP3-types of respirator. The following flat-folded FFP2 respirators (or similar) were included: 3M Aura NR D 9320+/1862+, 3M VFlex 1802 NR D and two types of unbranded KN95 masks. The following FFP3 respirators were included: BLS Zero 30 R D and Alpha Solway 3030V + R D. Both are marked as reusable and are cup-shaped. In this case, the sterilised respirators were worn by healthcare workers, and a comparative unused and non-sterilised mask was included as a reference.

Evaluation of all masks was done in the university laboratory based on the previously discussed approach. In other words, the verification was done by means of (I) evaluation of visual deformation, (II) fit test to evaluate deformation of the mask shell, (III) visual check of elastics, nose clip, and nose comfort cushion.

To perform the fit test, each respirator was evaluated using the TSI PortaCount Pro+ Respirator Fit Tester 8038 using the Occupational Safety and Health Administration (OSHA) protocol on a trained human model. Respirators were fitted to the face to the best of the test person's ability before starting a test, following the correct donning (abbreviated from "doing on") procedure. To perform a measurement, two modes are available on the PortaCount: N99 or N95, corresponding with the specifications for N99 (US) or FPP3 (EU) respirators and N95 (US), FFP2 (EU) and KN95 (CN) respirators. In our experience, an excellent N95/FFP2 respirator should also succeed for the N99-mode, meaning these respirators out-perform their designated certification (N95/FFP2). The hypothesis is to still perform as expected after long-term wearing, in less ideal conditions, or on users with facial dimensions at the extremities of the normal distribution. However, N95/FFP2 respirators failing in the N99 mode but succeeding in the N95 mode are in compliance with the regulations and should also be considered as valuable masks. All measurements performed with the PortaCount will result in a certain fit factor, and a score of 100 is the pass mark [66]. This means the air inside the mask is 100 times cleaner than the air outside the mask within the determined particle size range [66].

3.2. Reuse Communication

As mentioned above, clear communication in the context of reusing respirators is highly important. The added value here is not only to satisfy the perception of quality (to reassure the users), but is also practical, as the masks have a limited number of reuse cycles. We propose that the required communication, by means of a marking on the masks, is twofold and highly linked to quality control. This could be combined with other activities that should be performed during the sterilisation process (e.g., flattening of the foldable masks). Firstly, a permanent marking should communicate the number of use-and-sterilisation cycles and should therefore be able to withstand any sterilisation process that inactivates the coronavirus. Secondly, a temporary marking should provide the evidence that a mask has indeed been cleaned and sterilised, i.e., it should disappear after the sterilisation process, and be marked again after every use. To generate insights into the possibilities of communicating the number of reuses, desk research was executed, and all opportunities were discussed, by means of reasoning with consequences, by the research team.

4. Results

4.1. Sterilisation Tests

4.1.1. Visual Deformation

The sterilised FFRs provided by the Antwerp University Hospital were non-used FFRs, which guaranteed there was no deformation of the FFR due to previous use. Each type of deformation had to be a result of the sterilisation method. No deformation of the FFRs was observed. Considering ClO_2 gas sterilisation is performed at low temperatures, heat deformation, for example, could not happen in this case.

The FFRs provided by the General Hospital Jan Palfijn Ghent, however, were worn by healthcare workers. This caused minimal visual deformation in the 3M Aura flat-folded respirators. Due to wearing, wrinkles were visible on the inside of the respirators, and the upper and lower flaps became less stiff due to these imperfections, which made it slightly harder to fit the mask to the face as well as a new mask. However, we reason that this deformation is not caused by the sterilisation process but is as a result of the usage before. Due to the steam sterilisation process, the labels were slightly blurred (see Figure 3), making them hard to read.

Figure 3. Left: Label of non-sterilised respirator, Right: Blurred label on 3M Aura 1882+ respirator after 1 cycle of steam sterilisation.

4.1.2. Fit Test

As shown in Figure 4, all the provided non-sterilised masks from 3M, BLS and Alpha Solway passed the 100-score pass level mark making them qualify as good-fitting masks. None of the provided KN95 respirators succeeded the fit test, they were not further fit tested and will no longer be evaluated in the rest of this study. Evaluating a FFR that is not suitable to wear will be irrelevant. All the provided KN95 missed essential design features for establishing a good fit, such as a strong aluminium nose clip, nose comfort cushioning (except for the Chnano) and elastic behind the head of the user.

Brand	Model	Type		Portacount mode	New mask	Steam sterilisation 1 cycle	ClO2 gas sterilisation 1 cycle	ClO2 gas sterilisation 3 cycles	ClO2 gas sterilisation 5 cycles	ClO2 gas sterilisation 6 cycles
3M	Aura 9320+	FFP2	N99	286			520	710	724	
				276						
	Aura 1862+	FFP2	N99		79					
					85					
			N95		200+					
					168					
	Vflex 1802	FFP2	N99	144	64					
					78					
			N95		200+					
					200+					
KN95	Chnano ZN8005	KN95	N99	2		2				
			N95	4		3				
	Unknown brand type 1	KN95	N95	36						
	Unknown brand type 2	KN95	N95	8						
BLS	Zero 30 RD	FFP3	N99	145	182					
Alpha Solway	3030V+ RD	FFP3	N99	5719	3490					

Figure 4. Overview of the fit test results against different sterilisation methods.

Chlorine gas sterilisation did not decrease the fit factor of the 3M masks, and no degradation of the filter was observed. The fit factor increased after multiple cycles of chlorine gas sterilisation. A possible explanation could be that this is caused by clogging of the filter material; in this case breathability testing should be performed before reuse. During the fit test, a residual smell of chlorine was noticeable but was not irritating according to the human model.

Steam sterilisation did affect the filter material, and the masks from 3M failed N99-mode but did pass for N95. They should be considered as valuable respirators, but the

effect of multiple cycles should be verified. A plausible explanation is that the steam affected the static charge of the electret media after multiple cycles due to condensed water droplets formed by saturation of the fibres, as suggested by Liao et al. [27]. For the BLS ZERO FFP3 mask, no significant change was observed. The Alpha Solway fit factor did decrease but still achieved an exceptionally high score.

4.1.3. Visual Check of Elastics

A visual check of the elastics was performed. As chlorine dioxide is known as an effective bleaching agent for coloured compounds [58], this resulted in this case in discolouration of the elastics as shown in Figure 5. The discolouration does not happen homogeneously; instead yellowish spots can be seen on the elastics.

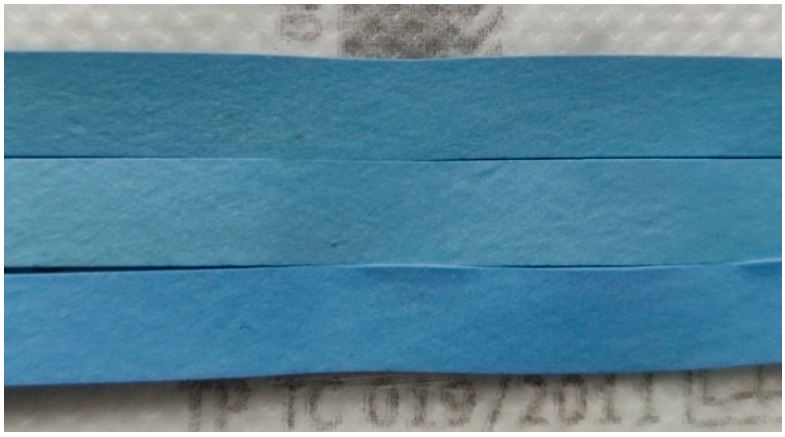

Figure 5. Photo of the elastics showing discolouration after different ClO_2 sterilisation cycles (Bottom: 0 cycles, middle: 3 cycles, upper: 6 cycles).

Steam sterilisation did not seem to have an effect on the elastics. The observed changes could be attributed to the wearing of the mask. The elastics of the 3M Aura masks worn by persons with larger heads were slightly elongated. One of the elastics of the Alpha Solway respirator had make-up stains as shown in Figure 6. These elastic bands were partially made from polyester making permanent stains more likely.

Figure 6. Make-up stains on the polyester elastic from the Alpha Solway respirator.

4.1.4. Visual Check of Nose Clip

After chlorine gas sterilisation, the nose bridge of the non-used respirators was still flat and bonded to the material, and no influence of the sterilisation technique was observed in this case. The respirators which were worn and sterilised by the use of steam were brought back to their neutral position (probably manually flattened), resulting in a wavy pattern instead of a perfect flat nose clip, as seen in Figure 7. This was especially the case for the flat-folded types of mask.

Figure 7. Nose clip after usage showing wavy pattern (Top: unused filtering facepiece respirator (FFR), Bottom: used FFR brought back to neutral position).

4.1.5. Visual Check of Nose Comfort Cushion

A similar discolouration as for the elastics was observed for the nose comfort cushion after chlorine gas sterilisation. However, compared to the elastics, the discolouration was more constant over the cushion and was slightly more yellow-brown, as seen in Figure 8. The discolouration was more noticeable after more sterilisation cycles. After steam sterilisation no changes in the nose comfort cushion were observed. No permanent compression was observed linked to the wearing of the mask. The PVC foam ring from one of the used Alpha Solway masks had make-up stains (shown in Figure 9). This visible remnant of previous usage can be a crucial factor for future users not to trust the safety of the mask. this could result in an increased difference between the perceived safety and the actual safety of the mask in a negative manner and generate an aversion to reuse. Either exploration of mask cleaning should be considered or reuse of personally assigned respirators could be a solution to this problem. Consequently, in addition to the number of reuse cycles, communication must also include appropriate labelling of the masks.

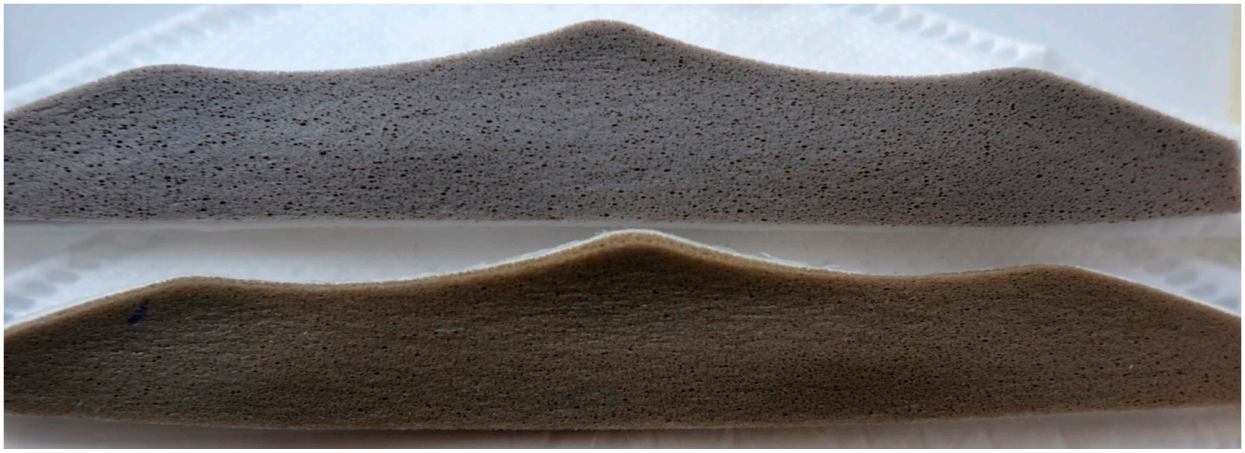

Figure 8. Nose comfort cushion after different ClO_2 sterilisation cycles (Top: 0 cycles, bottom: 6 cycles).

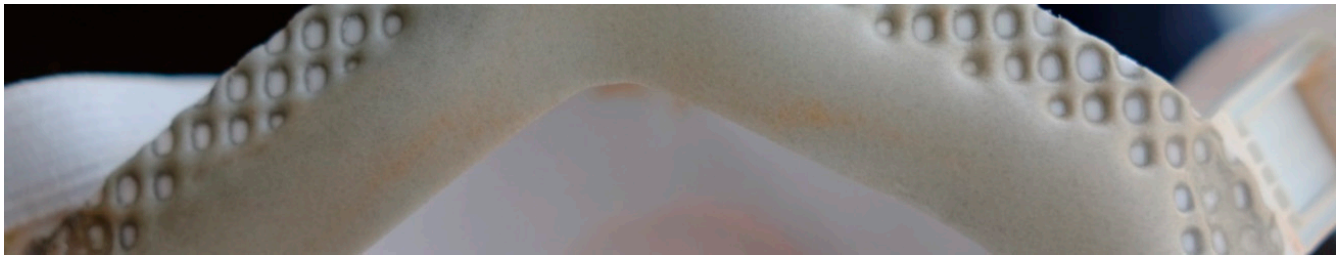

Figure 9. Photo of the nose comfort cushion make-up stain.

4.1.6. Smell Test of Respirator Mask

Not only visual deformations or changes in performance should be verified for a sterilised respirator, but other sensory observations will influence the user perceptions of a respirator. This test was not pre-discussed in the materials and methods section, but during the experiment the research team decided to include it, as smell might influence the future users' perception of sterility. Steam sterilisation did not remove the smell of perfume, which was noticed during the fit test, as a strong perfume smell remained in one of the BLS Zero masks. In addition, chlorine gas sterilisation resulted in a remaining chlorine smell while wearing the mask. A similar smell was noticed in previous studies while using bleach as a decontamination agent [25,26].

4.2. Communication of Reuse Number

As mentioned in the previous section, the focus was on two types of marking: (I) permanent marking to indicate the number of reuse cycles, and (II) temporary marking to prove cleanliness. After the sterilisation test, a third communication was added, namely, to communicate personal use. This latter opportunity gives the first user the possibility to name tag the masks in order to communicate personal usage.

With regard to the permanent marking (number of uses and sterilisation rounds), an easy solution could be the use of dedicated sterilisation markers, such as the ISP® Sterilization Marker from Interster [67], whose ink is waterproof, non-toxic and neutral scented, and the Sterilization Markers of Steriking® [68]. Moreover, the ink is steam, gamma, formaldehyde, plasma and EtO resistant. However, as this is usually applied to medical packaging to mark date and content, compatibility with the non-woven PP material of mouth masks should still be checked. In addition, markings could be made by pressing or indenting a symbol, or perhaps by laser engraving or ultrasonic welding, before or after each sterilisation round. A combination with branding and quality control could also be highlighted, by providing such essential information on the same part of the mask. Besides the use of ink, embossing can be used as a technique to make an imprint in the mask before or after sterilisation, and should be considered if the activity of embossing can be combined with the need to flatten the foldable masks. A new appliance could be designed that combines the "resetting" of the mask to the original form with the identification of the reuse cycle.

With regard to the temporary marking (cleanliness control), this might be done with a normal, non-toxic marker. For textiles, various types of markers exist of which those that are designed for children can often easily be washed out with normal detergent or even with only (cold) water. These markers are mostly made from non-toxic ink to ensure that children do not get poisoned after coming into bodily contact with the marker, for example by eating, licking or skin contact. Another comparison can be made with erasable markers for whiteboards, which are dry erase markers. The erasable ink does not contain the toxic chemical compounds xylene and/or toluene, unlike permanent markers [69]. In contrast to masks, whiteboards have glossy surfaces (mostly metal or glass) and do not absorb anything. However, testing should be done to be sure that these markings effectively are erased in each sterilisation process, even without a cleaning step. Furthermore, the temporary marking could be linked to the cleaning process but only to verify the cleaning

action. In that case, further testing should demonstrate how the masks could be cleaned and consequently which temporary marking could be used. Another option is the use of chemical autoclave indicators such as heat-sensitive tape of which the ink changes colour when the temperature reaches 121 °C (steam sterilisation) [70]. However, the tape only indicates that this temperature is reached (externally), not whether the sterilisation step was actually successful (e.g., materials that are difficult to penetrate may not be able to reach the intended temperature internally). Similar adhesive tape exists for VH_2O_2 sterilisation [71]. After the sterilisation, the tape needs to be taken away and applied again for the next sterilisation. Consequently, this communication of successful sterilisation can unfortunately not be brought to the attention of healthcare workers. Finally, biological indicators such as bacterial spores also exist. Spores of Bacillus and Geobacillus are often used in the context of surface decontamination according to Raguse et al. [72]. However, this might be less suitable for this situation, as additional tests would be required to check whether the bacterial spores are inactivated (or not) to indicate successful sterilisation.

Personalisation of masks should be considered by means of a permanent marking and individual users should be able to add their subsequent markings easily, without impairing the functionality of the filter material, nor exposing users to additional health risks due to toxic chemicals from a marker or other ink. Furthermore, the diversity of information communication is much higher compared to identification of reuse number. In addition, we could reason that this personalisation can be used as an opportunity to allow healthcare workers to recognise each other. As mentioned by the collaborating hospitals, healthcare personnel express the need to use additional signs to recognise each other while wearing protective material such as gown, masks and screens.

5. Discussion and Conclusions

In this research project, an investigation was performed to obtain insights in the reusability of single-use FFRs to avoid any shortage of medical material during the COVID-19 pandemic. Although these products are not designed to be reused, it is essential to ensure the availability of protective material for healthcare workers to take care of COVID-19 patients without risking their own health. Within this research, an overview is given of all previous studies that examined the sterilisation of masks with various techniques. Based upon these studies, it was found that (I) a solid quality control method is essential to test products before reuse, (II) an in-depth evaluation of the different mask parts should be considered, and (III) communication of the reuse cycle is essential to record the reuse count, as this is limited to ensure quality.

Quality control is essential to guarantee that after decontamination a filtering facepiece respirator is still in compliance with the regulations, linked to the specific type. To verify the performance of the decontaminated respirators, the most accessible method will be the use of a qualitative fit tester for total inward leakage such as the PortaCount 8038. To make quick on-site verifications possible, a hospital can train an in-house human model for fit testing and start evaluating random samples of decontaminated respirators.

Regarding the evaluation of the FFR parts, it was noticed that different types of quality control are needed for the different parts of the masks. The first step in the process of qualifying FFRs for reuse should always be a visual check to exclude any deformation or damage. Deformation will decrease the ability to fit the respirator to the user's face whereas damage will increase the number of particles penetrating the respirator. Furthermore, a check for stains should be performed. Only clean respirators will be perceived as safe; to remove stains from the other respirators more research should be performed to evaluate the effect of the cleaning methods.

Lastly, communication is essential in the context of reusing face masks. The need for communication is threefold: (I) permanent marking can indicate the number of reuse cycles, (II) temporary marking can prove the cleanliness after sterilisation, and (III) personal use can be communicated by healthcare workers allowing them also to recognise each other. Based on our reasoning process, sterilisation markers or imprinting offer opportunities for

permanent marking, while ordinary markers or (heat) sensitive tapes can indicate cleanliness and personal use. Further research is needed to test the suggested communication means and the possibility to remove markings through the most appropriate cleaning and sterilisation processes.

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