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Reuse of medical face masks in domestic and community settings without sacrificing safety: Ecological and economical lessons from the Covid-19 pandemic

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1 Reuse of medical face masks in domestic and community settings without
2 sacrificing safety: ecological and economical lessons from the Covid-19
3 pandemic

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43 **Abstract:**

44 The need for personal protective equipment increased exponentially in response to the Covid-19
45 pandemic. To cope with the mask shortage during springtime 2020, a French consortium was created
46 to find ways to reuse medical and respiratory masks in healthcare departments. The consortium
47 addressed the complex context of the balance between cleaning medical masks in a way that
48 maintains their safety and functionality for reuse, with the environmental advantage to manage
49 medical disposable waste despite the current mask designation as single-use by the regulatory
50 frameworks. We report a Workflow that provides a quantitative basis to determine the safety and
51 efficacy of a medical mask that is decontaminated for reuse. The type IIR polypropylene medical

52 masks can be washed up to 10 times, washed 5 times and autoclaved 5 times, or washed then
53 sterilized with radiations or ethylene oxide, without any degradation of their filtration or
54 breathability properties. There is loss of the anti-projection properties. The Workflow rendered the
55 medical masks to comply to the AFNOR S76-001 standard as “type 1 non-sanitary usage masks”. This
56 qualification gives a legal status to the Workflow-treated masks and allows recommendation for the
57 reuse of washed medical masks by the general population, with the significant public health
58 advantage of providing better protection than cloth-tissue masks. Additionally, such a legal status
59 provides a basis to perform a clinical trial to test the masks in real conditions, with full compliance
60 with EN 14683 norm, for collective reuse. The rational reuse of medical mask and their end-of-life
61 management is critical, particularly in pandemic periods when decisive turns can be taken. The reuse
62 of masks in the general population, in industries, or in hospitals (but not for surgery) has significant
63 advantages for the management of waste without degrading the safety of individuals wearing reused
64 masks.

65

66 **Keywords:** mask, reuse, Covid-19, waste management, filtration, polypropylene

67

1. Introduction

The healthcare sector has a high utilisation of single-use disposables and thus generates a large amount of waste, albeit that 20 to 25% of which is recyclable plastic material (Campion 2015, Byeong Kyu 2002, Kane 2018). Medical masks are medical-use disposables and have become essential for usage by the general community due to the need to control the Covid-19 pandemic. Governments around the world quickly mandated that wearing a mask was compulsory in public spaces. This rapidly increased the demand for respiratory and surgical masks, leading to mask shortages that forced authorities to change their policies and restrict initially the use of surgical masks to healthcare workers (HCW). At the beginning of the pandemic, one or two mask per day per person were distributed instead of following the normal practice of changing the mask for each person between each medical procedure. The consequences for that pattern of usage led to a reduced breathability in the masks and the possibility for germs to translocate. Indeed, sub-optimal recycling procedures consisted of disinfection without any cleaning step (Liao, 2020, Ibáñez-Cervantes 2020, Cai 2020, Cheng 2020, Bernard 2020).

Concurrent with the enhanced needs for HCW, the general community was mandated to have face coverings to combat the spread of Covid-19. Since the use of medical masks was reserved initially for HCW, cloth-tissue mask face coverings were developed as a last-resort interim solution for the general community. However, their level of protection is at least 5 times less than medical masks, simply due to the structure and material used for manufacturing and the light-touch regulatory environment (SI-0).

The Covid-19 pandemic is caused by the community transmission of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) virus. The 60-140 nm virus (Zhu 2020) travels in micron-size water droplets (Tang 2021, Wei 2021) and can also be infectious in the form of aerosols. However, the larger amount of virus is found in large particles (Wei 2021).

The Type IIR medical masks are disposable medical devices following standards: NF EN 14683:2019 in Europe, ASTM F2100-19 level 1,2,3 in USA, and YY/T 0969-2013 and YY 0469-2011 in

27 China (SI-0). Type IIR medical masks are made from at least 3 layers of non-woven polypropylene,
28 with 2 layers (inward-facing and outward-facing) spun bond (S) polypropylene, between which a melt
29 blown (M) higher filtration layer of polypropylene is disposed. Those 3 “SMS” layers provide an
30 efficient network for filtration. They are certified to prevent the projection of secretions from the
31 airways of the wearer as they filter more than 98% of 3µm droplets from inside to outside. They are
32 certified to protect others from the wearer’s respiratory emissions. Nevertheless, they are used to
33 protect the wearer from the respiratory emissions of others.

34 Despite the health-care value of Type IIR masks, such disposable masks create an environmental
35 hazard since the complete biodegradation of polypropylene is a very slow process that requires
36 hundreds of years (Fotopoulou 2017, Dharmarai 2021). Moreover, the term “disposable”, or indeed
37 descriptions such as “paper masks”, reinforces the accumulation of these masks as litter in the
38 environment. Such inappropriate community disposal of contaminated masks raises health
39 questions, not the least of which is the high cost due to environmental damage. Indeed, if good-
40 practices for waste management or recycling have not been established then the disposal of the
41 increased number of polypropylene masks becomes a major, and increasing, environmental
42 pollutant. Recent publications on the subject reveal an overload of the plastic waste used during the
43 pandemic, as occurred in Wuhan’s hospital, producing 200 tonnes of medical waste in one day,
44 which has to be incinerated by mobile treatment facilities (Saadat 2020, Silva 2020, Singh 2020,
45 Arduzzo 2020). The number of medical masks is roughly estimated between 1 and 1.3 billion per
46 month in Italy and UK, corresponding to 66,000 tonnes/year of waste (Allison 2020, Prata 2020).
47 Furthermore, during the first pandemic episode in Europe, the price of medical masks was multiplied
48 by at least a factor 10, including the price increase of the raw material and the transport cost.

49 Here we take a systematic and experimental approach to the question of whether Type IIR masks
50 can be reused. There is a complex context for this question that includes the balance between
51 cleaning medical masks in a way that maintains their safety and functionality for reuse, with the
52 environmental advantage to manage medical disposable waste despite the current mask designation

53 as single-use by the regulatory frameworks. Our approach is to design a Workflow for cleaning masks
54 that is based on elements from existing Standards to ensure the safety and function of reused
55 medical masks. Our Workflow provides data upon which to base a possible revision of the regulatory
56 framework for Type IIR masks. Such an evidence-based Workflow, designed to maintain the efficacy
57 of medical masks, then provides a rational basis to respond to the needs for community protection
58 and prevention in the face of the emergence of highly transmissible SARS-CoV-2 mutants or indeed
59 the next virus pandemic. It also provides the basis for a possible revision of the regulations for the
60 reuse of medical masks to address the significant broader issue of improving the sustainability of
61 medical disposables.

62

63 **2. Materials and Methods**

64 We designed a 8-stage Workflow to assure the safety and functionality of medical masks for reuse
65 derived from existing Standards publications. The Workflow was applied to both unused (new) masks
66 taken directly from the original packaging, and used masks collected from hospitals in Grenoble and
67 Nancy. We anticipated the outcomes from this Workflow can provide quantifiable ways to determine
68 and trace the reusability of medical masks.

69 2.1. Unused (new) masks

70 All the new masks used in this study are type II medical face masks following the European
71 standard “*EN 14683+AC august 2019 Medical face masks - Requirements and test methods*”,
72 corresponding to ASTM F2100-19 (USA) and YY/T 0969-2013 (China). The properties of type IIR masks
73 as defined by *EN 14683+AC august 2019* are as follows:

- 74 (i) the microbial cleanliness should be less than 30CFU/g of mask.
- 75 (ii) the label “II” refers to class II masks featuring a 98% bacterial filtration efficiency (BFE) with
76 $3\pm 0.3\mu\text{m}$ mean particle size. This FE is measured in the direction of its normal usage, i.e. from
77 the wearer to the environment,
- 78 (iii) the breathability refers to the differential pressure and should be lower than $40\text{Pa}/\text{cm}^2$,

79 (iv) the label “R” refers to a splash resistance layer protection ($\geq 16\text{kPa}$) against body fluid spills.

80 The new unused 3 ply IIR-type masks (ref. CA 1960) were provided by CA diffusion to Grenoble
81 and Nancy hospitals for all the 7 stages of the workflow (Figure 1). The masks comprise non-woven
82 fabric SMS (Spunbond, Meltblown, Spunbond). They contain a low amount of phenolic antioxidant
83 (butylated hydroxytoluene, Irganox 1076). The mask fits snugly with the help of a nasal bar (pliable
84 nose piece) and with ear loop elastic bands (containing elastane + polypropylene) or with 2 flat
85 polypropylene ties.

86



87

88 Figure 1: Description of the type IIR new mask used in this study: a) Outside face of the mask b) Nasal bar out of the mask
89 and its non-covered metallic extremity c) The 3 layers of a polypropylene mask.

89 In addition, ten different unused brands of masks have been tested in Nancy Hospital as a control
90 for the washing cycles: CA diffusion 1931 (II), 2015-30 Medicom (IIR), MPB-CH1 Paul Boyé (IIR),
91 PLM.01R Aerokyn (IIR), Earloop LyncMed 302089 (II), Sunrise Nursing (not known), TD Professional
92 45455 (II), The Lite One Kimberly Clark (IIR), LiangYa DGTMY (I), Saudel 85002 (II).

93 2.2. Used masks

94 A protocol was established in different departments of Grenoble Alpes University Hospital
95 (CHUGA) for collection of masks between 03/17/2020 and 06/04/2020, and for collection in different
96 departments of Nancy University Hospital between 04/24/2020 and 08/06/2020.

97 The protocol required that containers and bags dedicated to collection were placed in the
98 different departments where HCW left their used masks at the end of their working day. The used
99 masks were collected within specifically labelled double packaging, transported and stored in an
100 appropriate place. Particular attention was paid to the protection conditions of the collection
101 personnel (wearing of gowns, masks and strict hand hygiene). A wide range of brands was used in
102 the hospital during this period and up to 9 different references of type IIR medical masks have been
103 collected and tested, comprising the trademarks CA diffusion, Kolmi, Valmy, Euronda, Medicom, LCH
104 Medical product, LyncMed and Paul Boyé. Masks with ties have been excluded.

105 2.3. Workflow Stage 1: Sorting and washing of the used masks

106 After collection, the reusable masks have been rapidly selected under a laminar flow cabinet.
107 When the guidelines were properly applied, this step was no more necessary and the masks were
108 then transferred directly to the Hospital's laundry and washed according to the recommendations of
109 the cleaning product manufacturer. The washing step followed the existing classical closed-circuit of
110 the hospital. The 2 procedures are summarized in the washing step procedure in SI-1 section and
111 consist in a 60°C washing with detergents and disinfectants solutions.

112 2.4. Workflow Stage 2: Sterilization

113 (a) by autoclave

114 The Sterility Assurance Level (SAL) of 10^{-6} is the probability of 1-in-1-million to find a remaining
115 living bacteria. It is frequently used for the last step of sterilization of implantable devices. Steam
116 sterilization is the reference method for sterilizing items at the hospital and in all biology science
117 departments. It follows the European regulation ISO 17665-1.

118 Before autoclaving, the masks were unfolded, bundled in lots of 10 masks, and packed in peelable
119 see-through pouches with steam and EtO indicators BOP®. After sealing, the pouches were placed in

120 the autoclave Advantage class B or for a treatment at 121°C during 20min. The pouches were dried at
121 70°C during 20min after this treatment to remove the condensed water inside the pouches.

122 (b) by cold sterilizations

123 Three types of cold sterilizations were conducted. The first two were beta and gamma irradiations
124 from 20kGy to 40kGy. The third one was an EO treatment consisting in an exposition of the masks to
125 850mg/L EO gas during 12h at 40°C and 65% relative humidity (SI-2a and -2b).

126 2.5. Workflow Stage 3: Analysis of microbial cleanliness

127 The microbial cleanliness was verified according appendix D of *EN 14683+AC august 2019* and
128 described in SI-3a. Briefly, 5 washed masks per batch were tested. Each mask was weighed,
129 incubated in a 300mL volume extraction buffer (0,1% peptone, 0,2% Tween 20, 0,5% NaCl) for 5min
130 at 25°C with stirring at 250rpm. Then a volume of 100mL of the extraction buffer was filtered on a
131 0.45µm filter fitted into a filtration apparatus. Rinsing of the filtration apparatus was performed with
132 an additional 5mL of sterile extraction buffer. Then, the 0.45µm filter was removed and placed on
133 trypticase soja agar plate. Bacterial colony counting was performed after 3 days of incubation at
134 30°C. The operation was repeated with another 100mL of the extraction buffer for yeast and fungus
135 counting. The new filter from this second filtration was placed on Sabouraud + chloramphenicol (BD
136 France) plates that were incubated for 7 days at room temperature before counting.

137 2.6. Workflow Stage 4: Sporicidal claim check after washing and autoclave treatment

138 10^6 *Geobacillus stearothermophilus* spores were inoculated on masks under dirty soiling
139 conditions (SI-4a) according to norms NF T72-230/231, NF EN 14347 and NF EN 13704. The spot of
140 inoculation was marked using a permanent marker. The masks were left on the bench for 24h00 and
141 then washed according to the Workflow Stage 1 protocol, and autoclaved (212°C-20min) using the
142 Workflow Stage 2 protocol. Colony counting was carried out after treatment (washing or
143 washing/autoclaving) versus untreated samples. The marked spot was cut out (3 to 4cm²) then
144 transferred to a 15mL tube containing 5mL of 2M NaCl. The tubes were placed under vigorous
145 stirring (250rpm) for 5min at 25°C before being filtered through a 0.45µm filter placed on a filtration

146 apparatus. Rinsing of the device was performed with an additional 5mL of sterile water. The
147 membrane was then transferred to a trypticase soja plate and incubated at 65°C for 24h before
148 colony counting.

149 2.7. Workflow Stage 5: Particle filtration efficiency (PFE)

150 BFE is the existing standard method to evaluate the resistance of a face mask to the penetration
151 of a bioaerosol of *Staphylococcus aureus*. However, we have chosen to confirm and supplement the
152 BFE measurements with spectral PFE measurements for an inert di-ethyl-hexyl-sebacate (DEHS)
153 liquid aerosol. The BFE and PFE techniques are comparable since the respective particle sizes are
154 around 3µm and their capture by a filter is the result of physical mechanisms that depend mainly in
155 inertial impact ([Brosseau 1994](#), [Wake 1997](#), [Gonzales 2016](#)). The main difference is that BFE test was
156 expressed from the number of 1µm viable bacteria contained in 3µm droplets passing through the
157 medical face mask, whereas the PFE test was calculated from the fractional number concentration of
158 3µm vectors measured upstream and downstream of the mask. However, the PFE provides a more
159 robust quantification of the spectral efficiency of the filter in capturing the inert DEHS particles since
160 it based on optical or aerodynamic particle sizer techniques to count particles both upstream and
161 downstream of the filter. The PFE measurements provide more reliable quantification of spectral
162 efficiency of the filtering capability of the masks compared with microbial particle counting using
163 culture-based methods (BFE).

164 (a) according to NF EN 14683

165 The assessment of BFE was performed according to the EN 14683:2019 standard for the
166 performance of medical masks and using a published procedure ([Pourchez 2021](#)). Test specimens
167 with a minimum size of 100mm by 100mm were cut from complete masks so that the test specimen
168 included all layers of the mask. The test specimen of the mask material was clamped between a six-
169 stage viable Andersen cascade impactor and an aerosol chamber (glass, 445mm long and 60mm in
170 external diameter). Each test specimen was conditioned in air at 21±5°C and 85±5% relative humidity
171 for a period of at least 4h to allow equilibration with that atmosphere prior to testing. An aerosol of

172 3.0±0.3µm droplets was formed from a suspension of 3mL at 2,000CFU/mL of *S. aureus* (ATCC 6538)
173 using an E-Flow® mesh nebulizer (Pari GmbH, Starnberg, Germany) to maintain a bacterial challenge
174 2,200±500CFU per test with a 1min nebulization. The aerosol of *S. aureus* was introduced into the
175 aerosol chamber and drawn through the mask material and the impactor under vacuum. The testing
176 was performed with the inside of the medical face mask in contact with the airborne bacterial
177 challenge. The FE of the mask is given by the number of colony forming units (CFU) passing through
178 the medical face mask material expressed as a percentage of the number of CFU present in the
179 challenge aerosol. The positive control reference was obtained by omitting the test specimen from
180 the measurement chamber. Then, the BFE score for the mask, as a percentage, was calculated using
181 the following formula: $BFE=(C-T)/C \times 100$, where C is the mean of the total plate counts for the two
182 positive control runs, and T is the total plate count for the test specimen. The testing procedure was
183 repeated for at least 5 specimens of the mask.

184 (b) Inert particle filtration using PFE

185 The spectral PFE of the tested masks was evaluated using separate devices from two different
186 French laboratories, the GEPEA Lab in Nantes (Génie des Procédés Environnement – Agroalimentaire,
187 UMR 6144) and the LRGP Lab in Nancy (Laboratoire Réactions et Génie des Procédés, UMR 7274).
188 Depending on the device that was utilised, the sample of medical face mask was placed in a filter
189 holder with a filtration surface area of either 168cm² (GEPEA Lab) or 28.3cm² (LRGP Lab). A
190 polydisperse DEHS aerosol was produced with a MAG300 Palas® generator diluted with filtered air
191 for the device with the surface are of section 168cm², and with an AGK 2000 Palas® generator diluted
192 with compressed air for the device of section 28.3cm². The polydispersed liquid aerosol of DEHS
193 generated in both experimental devices produced droplets between 1µm and 3µm to provide a
194 comparison with the 3.0µm droplets generated by the aerosol chamber of the BFE tests. Filtration
195 velocity was adjusted at 9.6cm/s corresponding to the one used in the NF EN 14683+AC. After
196 dilution, the fractional number concentration was measured upstream and downstream of the mask

197 with respectively an optical counter (Welas Palas®) and an Aerodynamic Particle Sizer (Model 3321
198 TSI®).

199 The fractional efficiency, efficiency for a given particle size, is calculated as follows:

$$200 \quad E_N(d_p) = 1 - \frac{C_{N,down}(d_p)}{C_{N,up}(d_p)}$$

201 where $C_{N,up}$ and $C_{N,down}$ are respectively the particle number concentration upstream and
202 downstream of the filter for a given DEHS droplet size (d_p).

203 The efficiency measurement was achieved from a series of 7 counts conducted successively
204 upstream and downstream of the filter. Before each measurement, a sampling of 30 seconds is
205 performed in order to purge and stabilize the concentration of particles in the sampling lines. These 7
206 counts give three efficiency results for the same mask sample (repeatability test). Efficiency
207 measurements are conducted on three or four samples cut in one or two medical face masks
208 (reproducibility test).

209 2.8. Workflow Stage 6: Breathability

210 In accordance with the Standard NF EN 14683, the pressure drop of the mask was determined at a
211 filtration velocity of 27.2cm/s. This differential pressure should be divided by the standard filtration
212 area of 4.9cm² before being compared with the normative values of <40Pa/cm² for type I and II, and
213 <60Pa/cm² for type IIR.

214 2.9. Workflow Stage 7: Projection resistance

215 For these measurement the masks, the experimental set-ups proposed by ISO 22609:2004
216 standard were adapted to the materials and equipment available in the labs. The experimental
217 devices were validated by monitoring the corresponding injection pressure and injection duration
218 with reference to those given by the ISO norm table. The projection resistance tests were performed
219 under the conditions described by the ISO Standard, at a blood ejection rate of 550cm/s
220 corresponding to a blood pressure of 16kPa. The tests were repeated once for each type of mask
221 under the same conditions. To be fully compliant with ISO 22609, nearly 30 tests should be

222 performed for each type of mask, which is obviously not possible in the current context (SI-5a and -
223 5b).

224 2.10. Workflow Stage 8: Chemical and structural characterizations

225 Fourier Transform Infrared (FTIR) spectroscopy and Scanning Electron Microscopy (SEM)
226 experiments were conducted to complete the workflow. Each protocol is described in SI-8a and -8b.

227

228 **3. Results**

229 3.1. Cleanliness after Workflow: Macroscopic inspection of the washed masks

230 For this stage of the Workflow an initial mask sorting step was performed before the washing
231 step. Some masks were excluded from the washing because they were too dirty, mostly due to make-
232 up smears (around 3-4% of the total collection). Masks with low quantity of makeup were well
233 cleaned. We've noticed during this study, that around 1% of the collected masks were repaired with
234 a staple, which highlighted the shortage of masks during the collection periods. Up to 10
235 washing/drying cycles did not modify the appearance of the mask.

236 The visual inspection of the new CA diffusion 1960 masks after washing did not show any
237 significant structural defect, apart from broken elastic ear-loops (5-7% of the masks) that always at
238 the welding spot between the mask and the elastic band. Minor rust spots are appearing on 25% of
239 the mask at the two ends of the nasal bar after 2 washing cycles. Those rust spots do not have any
240 adverse effect on the face mask fitting.

241 Similar results were found with the 9 used collected different brands in Grenoble and 10 different
242 brands in Nancy. All the masks look clean, without any dimensional change, 5% of the mask had a
243 broken elastic ear-loop, rust spots were observed on 1/3 of the masks (Figure 2a). We have noted
244 that for 50% of the Euronada masks the nasal bar was able to dislodge from the sheath on the mask.

245 3.2. Cleanliness after Workflow: Microbial inspection of used masks

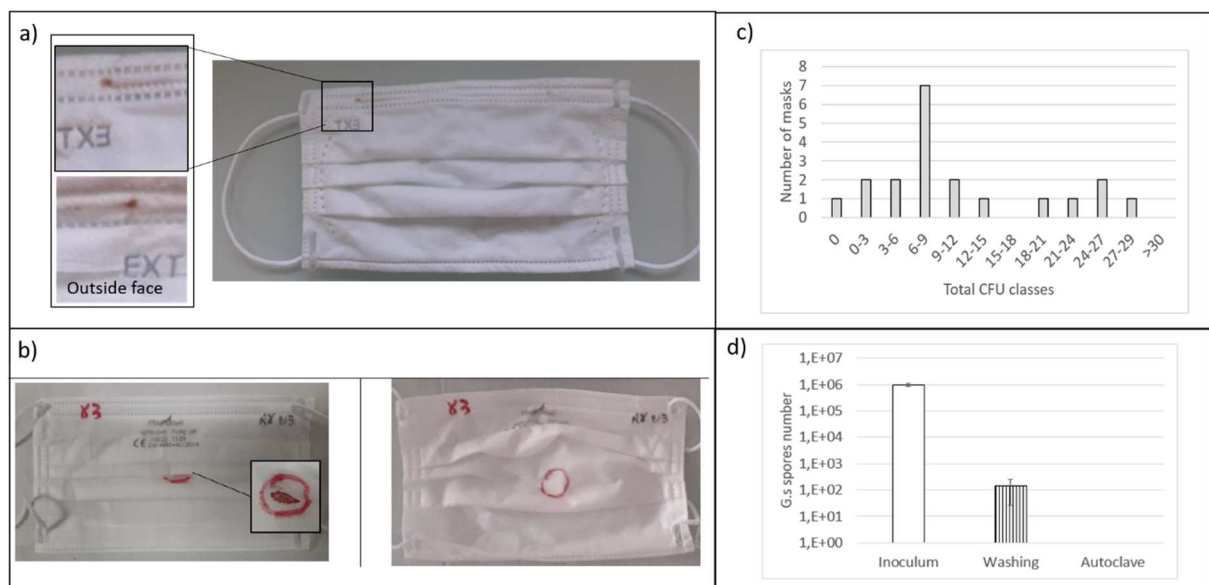
246 We applied to our washed masks the same tests applied for new fabricated masks in accordance
247 with NF EN 14683. For this, we extracted randomly 5 masks from 4 different washing batches and

248 measured the number of bacterial and fungal CFU present on each mask. The results (SI-3b) met
 249 expectations as the total measured CFU is 5 times less than the limit described in the norm
 250 ($\leq 30\text{CFU/g}$). Nonetheless, the variability from one mask to another is large (Figure 2c) with 1/3 of
 251 the mask containing between 6 and 9CFU/g and 1 mask containing 29CFU, which corresponds to the
 252 maximum allowed by the norm.

253 3.3. Cleanliness after Workflow: Masks washed in dirty conditions

254 Washing tests performed with 40 new masks in the dirty conditions recommended by the norms
 255 (SI-4a). Each new mask was soiled with 100 μL inoculum of the "dirty suspension" and then dried
 256 before the treatment (Figure 2b). The blood stain was completely cleaned by the washing step. It
 257 may be noted that the permanent marker used to mark the spot is still present. Thus, the permanent
 258 marking of a used mask ensures easily a good traceability during all processes, and particularly during
 259 the tread life of a recycled mask.

260 We have also conducted an experiment to consider the worst possible case of spotting 10⁶ spores
 261 of *G. stearothermophilus* in dirty conditions onto 5 new masks. A 4 log₁₀-fold reduction of spores was
 262 observed after washing. Spores are considered as the most resistant living organisms and are a good
 263 standard for a quality control. The SAL of 10⁻⁶ was largely achieved with a following sterilization step,
 264 for example by autoclaving the masks 20min at 121°C (Figure 2d and SI-4b).



265

Figure 2: a) Rust spots at the extremity of the nasal bar of a mask b) Mask (before/after) washed in dirty conditions c) Microbial distribution after a washing step d) *Geobacillus stearothermophilus* count after treatment in dirty conditions

266

267 3.4. FE after Workflow

268 The results of BFE (mean and spectral) and spectral PFE are presented in Table 1 and SI-6a,b,c for
269 the treatments of new masks “CA diffusion 1960”. Several batches comprising at least 5 masks were
270 first treated, in particular washing cycles, washing cycles followed by autoclaving cycles and
271 washing/alternative sterilizing cycles. The first line of the table (L201, L203, L204, and L327)
272 corresponds to the untreated masks. Regardless of the treatment used, the filtration properties were
273 preserved as quantified by the mean BFE greater than $99,6\% \pm 0.3$ according to the NF EN 14683
274 standard (SI-0). These results indicate that those treated face masks passed the standard thresholds
275 for filtration efficiencies, despite the possibility that the 3 layers of the masks could have separated
276 during washing.

277 The spectral filtration efficiencies obtained by CFU counting for the BFE and by optical counting
278 for PFE (Table 1) comply with the approved standards for particle size greater than $1\mu\text{m}$. For $3\mu\text{m}$
279 particles, spectral BFE and PFE are always higher than 99.0% ($\%_{\text{CFU}}$ or $\%_{\text{OPTICAL}}$) indicating that the
280 different treatment processes (until 3 or 10 cycles according to the treatment) do not seem to
281 deteriorate the protective performance of those face masks. Alternative cold sterilization
282 procedures, i.e radiations and EO treatment, are described in SI-2 section and in a preliminary IAEA
283 report (Cortella 2020). No degradation of PP and EO residues were found after treatment. Some
284 minor chemical modifications, were measured mostly due to the presence of anti-oxidants in new
285 masks.

286

Batch number	Mask number	Washing	Sterilisation				Filtration analyses after treatments										
		Washing 60°C 12 min Ultimate (F+M)	Autoclave 121°C 20 min	γ rays 20 kGy	Electron beam 40 kGy	Ethylene Oxide	Bacterial filtration efficiency norm NF EN 14683 AC	Fractional bacterial filtration efficiency norm NF EN 14683 AC				Fractional particle filtration efficiency					
								3.3-4.7µm	2.1-3.3µm	1.1-2.1µm	0.65-1.1µm	3µm	2µm	1.6µm	1µm	0.67µm	0.3µm
L201,L203, L204,L327	20	-	-	-	-	-	99.98 ± 0.03%	100.00%	100.00%	99.93%	100.00%	99.99% 99.95%*	99.96%	99.90%	98.26%	80.06%	40.17%
L202,L205, L206	15	1	-	-	-	-	99.9 +/- 0.08%	100.00%	99.96%	99.52%	90.77%	99.99% 98.44%*	99.88%	99.71%	98.48%	88.85%	35.25%
L209	10	3 cycles	-	-	-	3 cycles	99.89 ± 0.05%	100.00%	100.00%	99.19%	91.58%	100%	99.9%	99.8%	91.8%	64.75%	40.0%
L212	10	3 cycles	-	-	-	3 cycles	99.61 ± 0.37%	99.81%	99.50%	99.84%	60.00%	99.2%*	98.0%*	94.0%*	-	-	-
L215	10	3 cycles	-	3 cycles	-	-		-	-	-	-	100%	99.85%	99.7%	93.7%	60.33%	30.37%
L216	10	1	1	-	-	-	99.8 +/- 0.11%	100.00%	100.00%	98.99%	Und--	100%	99.88%	99.0%	96.9%		
L252	10	-	10 cycles	-	-	-	99.73 ± 0.33%	99.95%	99.94%	98.69%	77.60%	-	-	-	-	-	-
L221	10	10 cycles	-	-	-	-	99.79 ± 0.09%	100.00%	100.00%	99.16%	93.78%	98.97%*	-	-	-	-	-
L316	10	-	-	-	-	3 cycles	99.93 ± 0.10%	100.00%	100.00%	99.88%	76.00%	99.99%	99.99%	99.8%	-	-	-

Table 1: Filtration efficiency after new masks treatments. The mean BFE corresponding to the NF EN 14683 AC norm is in bold format. The values under 98% are written in red. * FPE results from LRGP Nancy for intercomparison with IMT Nantes. Und-: Undertermined

Batch number	Mask number	Mask brand	Bacterial filtration efficiency norm NF EN 14683 AC	fractional bacterial filtration efficiency norm NF EN 14683 AC				Fractional particle filtration efficiency					
				3.3-4.7µm	2.1-3.3µm	1.1-2.1µm	0.65-1.1 µm	3µm	2µm	1.6µm	1µm	0.67µm	0.3µm
L271, L107	20	Used Paul Boyé MPB-CH1	99.89 ± 0.11% 99.82 ± 0.12%	100.00%	100.00%	99.57%	73.33%	99.88%	98.91%	98.6%	94.89%	68.72%	39.54%
L272	10	Used CA diffusion unknown ref	98.18 ± 1.06%	100.00%	99.65%	84.74%	20.00%	91.90%*	63.20%*	44.6%*	-	-	-
L103	10	Unknown 1 (Blue 1)	98.91 ± 1.22%	99.92%	100.00%	93.92%	46.67%	99.99%	98.9%	97.5%	82.41%	45.92%	28.3%
L104	10	Used Kolmi Op'R M36101	99.19 ± 0.26%	99.93%	99.87%	95.30%	18.00%	99.39%	97.22%	93.45%	71.47%	37.69%	25.85%
L105	10	Used CA diffusion	99.09 ± 0.27%	100.00%	99.91%	95.54%	3.16%	99.99%	97.78%	94.98%	74.10%	40.11%	24.63%
L106	10	Used Valmy	99.82 ± 0.07%	100.00%	100.00%	98.63%	88.00%	88.38%	87.48%	86.32%	72.99%	37.51%	24.01%
L108	10	Used unknown 2 (Blue 2)	99.62 ± 0.20%	100.00%	99.97%	98.22%	20.00%	98.30%	98.62%	97.24%	80.29%	42.38%	25.74%
L109	10	Used unknown 3 (white light)	99.75 ± 0.08%	100.00%	100.00%	98.19%	42.86%	98.25%	93.40%	92.09%	75.16%	36.00%	17.81%
L110	10	Used Euronda	99.80 ± 0.12%	100.00%	100.00%	98.75%	73.33%	99.99%	99.91%	99.66%	94.23%	61.40%	33.14%
L111	10	Used CA diffusion 1960	99.80 ± 0.09%	100.00%	99.96%	99.20%	91.25%	99.99%	99.96%	99.94%	96.14%	66.22%	36.53%

Table 2: Filtration efficiency of used mask after 5 washing steps followed by 5 autoclaving steps. The mean BFE corresponding to the NF EN 14683 AC norm is in bold format. The values under 98% are written in red. * FPE results from LRGP Nancy for intercomparison with IMT Nantes.

287 The differences between the two sets of spectral PFE measurement can be explained by the use
288 of two different experimental devices inducing differences in (i) the filtration section which a ratio of
289 6 (168 and 28.3cm²), (ii) distribution, and concentration of the liquid particle size of the DEHS
290 generated by the two systems, (iii) the particle counting systems, which are based on two different
291 principles of particle size measurements (optical counter based on light diffraction and aerodynamic
292 sizer based on time of flight).

293 For submicron-sized particles (impaction plate collecting size fraction between 1.1 to 0.65µm for
294 BFE, and particle size of 1, 0.67 and 0.3µm for PFE), the BFE and PFE values are different but show
295 the same tendency for FE to decrease with particle size and the influence of the treatment processes,
296 which altered the efficiency for those fine particles but without degrading the mean BFE values. We
297 have noticed that this loss of efficiency for submicron-sized particles is effective after the first wash
298 and stabilized at the same level after several washes, regardless of the washing process (SI-6b). At
299 submicron-size, the filtration involves other mechanisms than inertial impact that can particularly
300 include electrostatic mechanisms. This electret effect (Lin 2017, Hossain 2020) of the polypropylene
301 fibres is permanently destroyed during the first wash because the washing agents bind to the surface
302 and cannot be removed. This effect can be mimicked by the rinsing of a new mask in isopropanol (SI-
303 6c). Results show that the discharging of a mask leads to the same spectral collection efficiencies
304 than those of a washed mask, confirming the loss of electret effect as a result of the first washing
305 cycles.

306 Used medical masks come from hospital departments and consist of 9 different reference brands
307 (Table 2). They have undergone 5 washing cycles followed by 5 autoclave cycles. After sterilization
308 and washing, the filtration properties were conserved for all the samples, with a minimum mean BFE
309 of 98.2%±1.2 for the sample with the lowest filtration performance, which is above the NF EN 14683
310 standard threshold. The comparison of spectral BFE and spectral PFE (Table 2 and SI-6d) confirms the
311 good protection performances of the used masks after 5 decontamination procedures for particle
312 sizes higher than 2µm (BFE>99.6%_{CFU} and PFE>97.2%_{OPTICAL}). Even if some differences can be observed

313 between these 9 reference brands, results show a preservation of the spectral BFE and PFE for
314 particle size higher than $2\mu\text{m}$ whatever the mask. A significant decrease of spectral efficiencies (both
315 BFE and PFE) is observed for particle size smaller than $2\mu\text{m}$, even though the BFE shows a good
316 filtration performance of greater than 91.2% for submicron particle sizes in the range $0.65\mu\text{m}$ to
317 $1.1\mu\text{m}$.

318 To check the influence of a hole or a notch that can occur accidentally in the mask during the
319 recycling process, we deliberately damaged a series of mask after one use/washing/autoclave cycle
320 and tested their FE. Holes were created in the center of the masks in two ways. The first was to
321 pierce the mask material with a blunt cylindrical tool such as a Phillips screwdriver to create holes
322 from 1 to 5mm. The second was to use a razor blade to make cuts of 7 and 10mm. Those techniques
323 punctured the mask material and created a rough-sided hole from 1 to 5mm or a clean side cut of 7
324 and 10mm without explicit removal of the material within the confines of the punctured hole.
325 Indeed, an accidental explicit removal of material with a hole puncher is highly unlikely compared to
326 a tear (as we have simulated with the razor blade cuts). The figure SI-6e shows results of PFE
327 measurements performed on a medical mask (L101) and on the same mask with holes of different
328 sizes on the center part of the mask face (L102 with hole of respectively 1, 2, 3, 4, 5mm and cuts of 7
329 and 10mm size). Due to the multi layer media constituting the mask, even in the case of big holes
330 ($>3\text{mm}$) no significant influence is observed for spectral efficiency for particle diameter higher than
331 $1\mu\text{m}$ (apart for the test performed with a hole of 2mm for which a slight decrease of PFE is
332 observed). For particle sizes lower than $1\mu\text{m}$, the presence of holes in the mask can contribute to a
333 slight decrease of the spectral efficiency compared with the mask without any hole.

334 3.5. Breathability after Workflow

335 The breathability performances (resistance to air flow) were not significantly affected regardless
336 of the particular decontamination process. When compared with untreated masks, breathability
337 values remained within the variability range of measurements made on the untreated masks
338 (variation due to the intrinsic local heterogeneity of the fibrous structure composing the masks) and

339 were always under normative values, i.e. of 40Pa/cm² for a type I or II and 60Pa/cm² for a type IIR.
340 The Mann-Whitney U test (Murray 2008), a non-parametric statistical test applied to data, confirmed
341 that the breathability of treated masks (regardless of the type of treatment) is not significantly
342 different from that of the untreated masks. Thus, we can conclude that the sterilization and washing
343 cycles do not alter the structure of the non-woven media.

344 3.6. Projection resistance after Workflow

345 The projection resistance (“R” function) was tested on an experimental set-up aiming to
346 reproduce the test conditions recommended by ISO 22609:2004 Standard. This set-up was
347 developed, validated and implemented on new or washed masks with a synthetic blood formulation.
348 The “R” function was lost after a few washing steps, regardless of the particular brand of type IIR
349 mask. It appears that washing changes the surface properties of the outer layer of a washed mask
350 which leads to the loss of the protective function (SI-5c). The projection resistance is not maintained
351 after recycling, which means that medical team working in an operating room should not wear
352 washed IIR masks.

353 3.7. Chemical and structural characterizations

354 The two broad ranges from 2835 to 2952 cm⁻¹ and from 1165 to 1452 cm⁻¹ of FTIR spectrum are
355 characteristics of polypropylene. The FTIR analysis does not reveal significant oxidation processes
356 after cleaning (SI-8a).

357 SEM images of treated masks are presented in SI-8b. No significant morphological modifications
358 were noticed, except for MPB-CH1 melt-blown layer containing thinner fibres (SI-8b). However, these
359 modifications do not impact the filtration that remains very high (Table 2).

360

361 4. Discussion

362 4.1. Cleanliness, filtration and breathability of Type II medical masks remain compatible with
363 EN14683 after up to ten cycles of washing cycles at 60°C with detergent

364 Reuse must ensure the conservation of the paramount properties of the mask. We have proven
365 that the process of washing/sterilizing the masks retains their cleanliness, their filtration capabilities
366 and their breathability. However, the R function is lost in the cleaning process. This does not detract
367 from the function of the masks in a domestic usage, but requires a modified usage of reused masks in
368 the hospital environment. Although reused masks can no longer be used appropriately where blood
369 or bodily fluid splashing can occur, such as in operating rooms, the reused masks can be used
370 appropriately in other areas of the hospital. It is important to note that in any case type IIR masks are
371 already dedicated to operating rooms.

372 The cleanliness of the masks is obtained by washing. This washing step is mandatory to respect
373 good hygiene practice before any other treatment and acceptability for the user. The aim of the
374 washing step is to eliminate all traces of biological contamination (secretions, mucus) and to lower
375 the level of initial contamination (due to the 12min contact with disinfectant). Moreover, it tackles a
376 large part of the problem of wearing a mask that is not your own. Indeed, even if a mask is sterilized,
377 it is difficult to wear a used dirty mask that has not been washed. The SARS-CoV-2 is a virus sensitive
378 to the combined action of detergents, mechanical movements and heat which occur in a washing
379 machine. The commonly accepted recommendation for cloth-tissue mask is a washing step at 60°C,
380 or even lower ([FNAM 2020](#)). As recommended for community use of masks, a sterilization step
381 described in SI-2c is not recommended.

382 The results of excellent FE remaining after even 10 cycles of washing has very positive sanitary
383 consequences on the wearing of used/washed masks in the domestic environment, especially in the
384 context of severe constraints on mask shortage or indeed the reduction of discarded single-usage
385 masks on the environment.

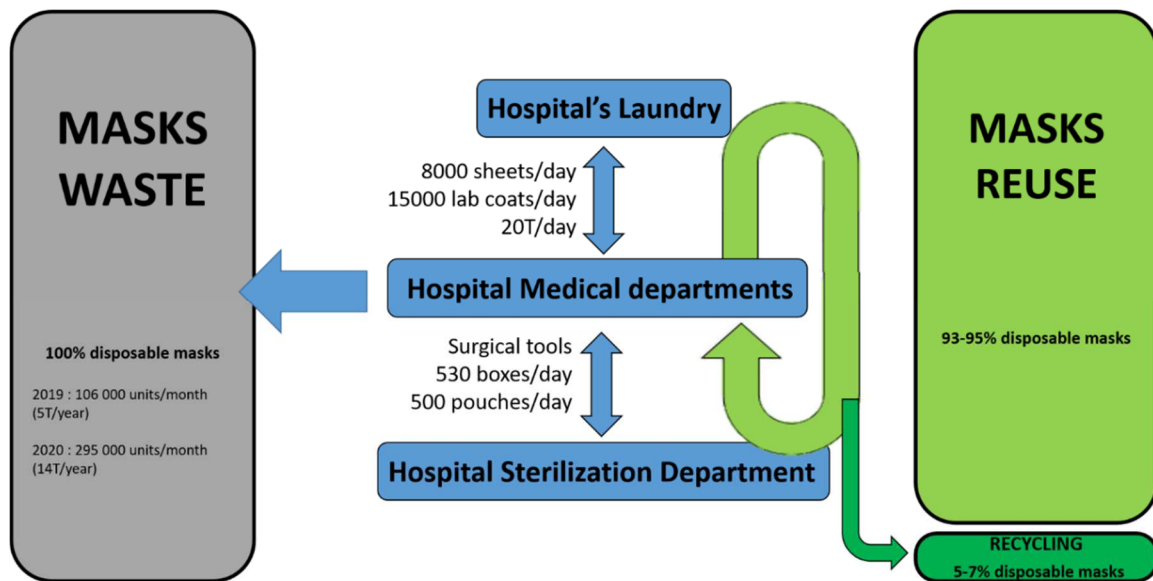
386 4.2. Collective treatment of the masks needs a sterilization step

387 Mask reuse in a collective reprocessing generates more complexity, taking into account good
388 hygiene practice and healthcare waste management. Although [Kane et al, 2018](#), describe that
389 “introducing circular economy principles into design for healthcare is challenging”, it is nonetheless

390 an important point to address. It is critically important to consider the bacterial and fungal
391 cleanliness of the recycled masks used in a healthcare environment. It is indeed required to eliminate
392 all potential risks of bacterial or fungal cross-contamination of masks potentially exposed to
393 microbiological agents of the wearer or of its environment.

394 The 4 log₁₀ spores reduction obtained with washing is in accordance with an experiment
395 performed in Bangkok's hospital ([Luksamijarulkul 2014](#)), which evaluates the bacterial and fungal
396 contamination on used medical masks worn by the HCW. The authors collected 230 used masks from
397 214 HCW and found that the maximal bioburden was less than 10³CFU/mL/piece on the outside area
398 of the masks and less than 10²CFU/mL/piece in the inside area of the masks ($p < 0.001$). In principle,
399 this first washing step should be sufficient to eliminate the microorganisms that are present on the
400 masks. Nonetheless, in the special case of a pandemic, especially for a virus pandemic, it is important
401 to reduce the contamination risk to ensure a health and safety state ([Bernard 2020](#)). Moreover, the
402 analysis of the variability of the cleanliness of washed masks suggest that a safety state is not
403 achieved by a washing step procedure using masks coming from the hospital. The issue can also
404 come from organisms that can be found in an hospital: Hepatitis B Virus or *Mycobacterium*
405 *tuberculosis* are also thermoresistant up to 80-100°C ([Doig 2002](#), [König 2019](#)). Thus, other methods
406 have to be applied after the washing process to ensure a perfect recycling quality.

407 The reuse of cleaned mask is somehow not sufficient to provide enough safety for HCW and a
408 sterilization step is mandatory, not to have a sterile status of the device but to minimize this risk of
409 cross-contamination of resistant germs like spores or mycobacteria. The existing circuits of
410 sterilization process of autoclavable tools and dirty laundry transfer circuit (Figure 3) greatly
411 facilitated the operating procedure in a healthcare environment.



412

413 Figure 3: Waste management. Existing circuit (blue and grey), Masks Reuse and Recycling circuit (green)

414 The industrial sector can also consider a collective recycling. Some companies have already shown
 415 a willingness to make progress in the ecological consequences of polypropylene recycling by creating
 416 specific recycling branches dedicated to medical masks. Despite those good intentions, those small
 417 number of companies do not have sufficient financial resources to expand those recycling activities.
 418 Nonetheless, those examples add value to the global waste management, because before the masks
 419 are either discarded or recycled they are first reused. The risk of cross contamination in the industrial
 420 sector is often less present than in hospitals and the washing step is probably enough to guarantee
 421 the safety. This risk can be evaluated on a case-by-case base. However, the possibility of sterilizing is
 422 still possible with access to different technology platforms described in table 3.

<u>Methods</u>	<u>Washing</u>	<u>Autoclave</u>	<u>β Radiations</u>	<u>γ Radiations</u>	<u>Ethylene oxide</u>
Location	<u>Hospital</u>	<u>Hospital</u>	IONISOS	CEA/IONISOS	IONISOS
Number of treated masks/cycle	5000	1200	170 000	> 1 million	up to 1 million
Conditions	<u>Detergent</u> <u>+disinfectant</u> <u>+60°C/12 min</u>	121°C/20 min.	25 <u>kGy vacuum</u>	25 <u>kGy vacuum</u>	850 mg/L-40°C-65% RH/12h
<u>Treatment duration</u>	2h	7h	<1h	12h	60h
Estimated global recycling time (including transport)	<u>1 day</u>		<u>3 days</u>	<u>3 days</u>	<u>6 days</u>

423

Table 3: Comparison of different treatments capacity and duration for medical mask reuse in collective settings.

424

425 The presence of autoclaves in sterilizing unit facilitates this process but the major drawback is the
426 number of units that can be treated at the same time. The β and γ technologies have some
427 differences in the process. Gamma ray technologies make it possible to deliver the dose to a large
428 volume of masks but slowly, while electron beam technologies, on the other hand, make it possible
429 to achieve the same dose in a fraction of a second, but in a smaller volume. The net result is that β
430 and γ technologies are comparable in processing capacity. Density is also a relevant factor that
431 influences on the penetration of radiation, and thus on the processing capacity. At this stage of the
432 study, there will be no noticeable difference between β and γ radiation because the number of
433 masks was small. They were wrapped into vacuum bag to reduce the thickness of each bag (more
434 than one half-volume reduction), allowing the handling and the cleanliness of the masks until their
435 reuse. A performance qualification study will have to be carried out in each case when the process
436 will be industrialised.

437 EO treatment and irradiation treatments β and γ are cold sterilisation alternative techniques to
438 autoclave treatment. Despite the fact that the logistics have to be created unlike the
439 washing/autoclave circuit, they are useful tools to process a huge quantity of masks at the same time
440 in a single run.

441 4.3. Biocompatibility preliminary data

442 The results of FTIR and SEM analyses performed on the treated masks are very reassuring: they
443 tend to indicate that the treatment yields no major modification of the physico-chemical
444 components of the masks. Besides, most of the reusable cloth-tissue masks contain as much
445 polypropylene as medical masks, and are certified for reuse after between 10 and 50 washing cycles.
446 No adverse event related to wearing washed cloth-tissue masks was reported, although millions of
447 such masks were washed and reused all over the world. Therefore, demonstrating biocompatibility
448 will be necessary only for manufacturers wishing to demonstrate full consistence to EN 14683 of
449 washed masks.

450 4.4. The conformity with the French Standardization Association (AFNOR) SPEC S76-001: 2020
451 allows not only to issue recommendations for the public, but also to perform a clinical trial in
452 real conditions

453 The washing conditions for reusable cloth-tissue masks are described in similar rules for each
454 country ([FNAMHPS 2020](#) for France). Our washing conditions were more demanding (60°C instead of
455 40° C). The conformity according to the French AFNOR SPEC S76-001: 2020 for cloth-tissue masks of 3
456 brands of medical masks washed up to 10 times under these conditions has been checked with
457 success by independent certified actors (SI-7). This conformity, in accordance with European CWA
458 17553:2020 and US F2299/F2299M-03 regulations, allows to recommend the reuse of washed
459 medical masks instead of cloth-tissue masks to guarantee a higher level of filtration. Indeed, the
460 quantity of 3µm particles emitted towards the entourage of a person in 6minutes without any face
461 protection is equivalent to the quantity emitted in 1hour with a 90% filtering cloth-tissue mask or in
462 5hours with a medical face mask filtering at 98% (SI-0).

463 The loss of the CE marking led to the loss of legal status for the treated masks (which are non-
464 reusable Medical Devices). A legal status is recovered by the AFNOR certification that will allow to
465 test wearing/treatment cycles in a future clinical trial. The main objective of this clinical trial will be
466 to demonstrate that at least 10 cycles of use/washing and at least 5 cycles of

467 use/washing/sterilization can be done in real conditions with full compatibility with EN14683 norm
468 (including complete test of biocompatibility, which as previously discussed was not completely tested
469 in the present work).

470 4.5. Mask end of life

471 The major issue is the limit of cycles that can be done. We arbitrarily stopped after 10 cycles of
472 washing, which preserves the filtration properties of the masks. The number of cycle treatments will
473 depend on wearing, washing and storing conditions. How to know when the mask is no more usable?
474 The answer is probably “when it does not fit well to the face”. This answer is due to several reasons.
475 First of all, the structure of the mask: each layer is a non-woven material. When a cut in the fibres
476 occurs, the thread is not uncoiled. Holes or notches in a cloth-tissue mask, which are woven or
477 knitted, will have a devastating effect on the filtration. Secondly, the 3 layers of material can slide
478 one on the other and this phenomenon plugs cracks or holes so that the filtration capability is
479 maintained, as shown in figure 3b. Finally, the most fragile parts of the mask are actually the nasal
480 bar, the ear loop elastic band and especially their welding spot on the corners of the mask. The
481 accumulation of lint can be observed after several washes at home with short cut fibres going out of
482 the mask outside layers. This pilling leads to uncomfortable wear and can define the end of life of the
483 mask even if filtration properties remain efficient.

484 4.6. Economic perspective

485 The reuse of medical mask opens new perspectives. The mask reuse has also a significant
486 economical effect on households: The price of a tissue mask, with a guarantee of 50 washes, can
487 reach up to 50 times the price of a medical mask. Thus, a medical mask washed 10 times is 10 times
488 cheaper. The cost of washing is zero has the masks are washed with the washing of domestic clothes.

489 In collective treatment, the recycling price has to be evaluated according to the number of masks
490 used per day, the presence of a recycling process or the strategic partnership with appropriate
491 companies.

492 4.7. Ecologic perspectives

493 Covid-19 pandemic has led to a widespread of environmental contamination of plastics,
494 comprising the polypropylene medical masks. At a large scale or in highly specific environment, the
495 low cost of disposable masks compared to the cost of recycling its polypropylene is probably not a
496 viable economical target, because of the low weight/volume of each mask, its infectious risk and the
497 lack of existing recycling circuit. However, the ecological cost will more expensive at the end-of-
498 mask-life. The rational reuse of medical mask and their end-of-live management is critical,
499 particularly in pandemic periods when decisive turns can be taken. The reuse is the first step of a
500 recycling process.

501 The use of disposable masks in the general population gives rise to their larger consumption to
502 help fight high transmissible mutants but their reuse up to 10 times will compensate or will even
503 reduce their environmental impact. For lower scale uses, the possibility to safely recycle medical
504 masks is cost-effective, and an eco-friendly gesture.

505 Ecological consequences must be taken into account: a non-woven mask is easily recycled as it is
506 only composed of pure polypropylene when the nasal bar and the elastic bands are removed. This is
507 not the case for woven masks that often uses a mix of synthetic fibres and has to follow a specific
508 recycling. However, the recycling of domestic usage of medical masks has not been yet envisaged.

509

510 **5. Conclusion**

511 We have proven that the lifetime of type II medical face masks can be extended by reusing them
512 after washing and decontaminating treatments. Those treatments consist in washing steps and/or
513 washing sterilizing cycles. The use of a detergent and a disinfectant during the washing step allows
514 not only to clean the device but also to reduce the presence of germs. The masks retain their
515 breathability and their filtration capability up to 10 cycles of washing or 5 washing cycles followed by
516 5 autoclaving cycles without major structural and chemical modifications. Cold sterilizations, like
517 radiations or EO treatment have also been tested with success. These experiments prove that those
518 “disposable” masks remain reusable, with the exception of the anti-projection resistance that is not

519 conserved, so that the masks cannot be reused in operating rooms. As washed medical masks
520 remains more efficient in terms of filtration than cloth-tissue masks, we can recommend their reuse
521 according to the cloth-tissue mask regulations. A clinical trial in real conditions with full compliance
522 with EN 14683 norm will allow the manufacturers to claim that type II medical face masks can be
523 considered as Medical Devices after washing (followed or not by a sterilization process). This will
524 require modifications of laws and regulations in countries like France, where legal prohibitions
525 prevent any reuse of a “single-use” Medical Device. However, we have demonstrated here that type
526 II medical face masks are compliant with the regulations applicable for reusable cloth-tissue masks.
527 This may have a tremendous impact in terms of public health and ecology. In terms of public health,
528 wearing a type II medical face mask provides a much better protection than a cloth-tissue mask. In
529 terms of ecology, reusing 10 times a type II medical face mask would reduce the burden associated
530 with the waste management and the consumption of polypropylene.

531

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543

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