Decontamination of 3M Filtering Facepiece Respirators: Global Considerations (Archived)

NOTE: This is an Archived 3M Technical Bulletin for historical reference purposes only. 3M does not recommend the practice of decontamination of filtering facepiece respirators (FFRs). Earlier in the COVID-19 pandemic, several governmental agencies had provided guidance concerning the use of decontamination as part of a crisis capacity reuse approach to optimize the use of available FFRs. As the pandemic has progressed, the supply of FFRs has increased and most governmental agencies and public health authorities no longer recommend decontamination of FFRs.

Introduction

NOTE: Please revisit this document often for frequent updates.

The purpose of this document is to communicate information related to the impact of decontamination methods on certain 3M Filtering Facepiece Respirator (FFR) models – the purpose is not to recommend the practice of decontamination or to comment on the efficacy of the decontamination method on the virus that causes COVID-19 or the safety of the decontamination methods for FFR wearers.

During this COVID-19 pandemic, several governmental agencies have provided guidance concerning the use of decontamination as part of a reuse approach to optimize the use of available FFRs. 3M does not recommend decontamination of FFRs, because FFRs are not designed to be decontaminated, and doing so may void the regulatory approval. However, since certain decontamination methods have been indicated by the World Health Organization (WHO) and several countries’ governmental agencies (see Appendix 1), 3M has evaluated the impact of select decontamination methods on certain 3M FFR models, and 3M is publishing this information to help customers who choose to implement decontamination do so in such a way that they are less likely to damage FFRs, as such damage may result in the FFRs not providing the indicated level of exposure reduction, such as N95, FFP2, KN95, etc. Customers who choose to implement decontamination should only do so in accordance with the governmental agency guidance (e.g. FDA Emergency User Authorization) for the specific method implemented including following all guidance on the maximum number of cycles allowed. It’s important to note that the number of decontamination cycles that a particular respirator can withstand will depend on how many times it has been donned, how it has been stored and the duration and conditions of use. Wearers should inspect respirators before every use and perform a user seal check each time the respirator is donned to ensure an effective seal is achieved.

It should be noted that most governmental agencies’ statements regarding decontamination of FFRs identify the practice as a last resort, only to be considered after many other strategies to reduce and extend the use of FFRs have been undertaken. Each employer organization that is considering decontaminating FFRs must understand and follow all applicable local regulations. (See Appendix 1.) Agency guidance concerning the use of decontamination is subject to change. Facilities should always consult the latest guidance. For example, as of April 2021, the US Food and Drug Administration (FDA) is recommending that US health care facilities transition away from crisis capacity strategies such as decontamination or bioburden reduction. In addition the US Centers for Disease Control and Prevention (CDC) has removed decontamination from its Strategies for Optimizing the Supply of N95 Respirators. According to a FDA letter to US Health Care Personnel and
The FDA and CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems.

For additional strategies to reduce and extend the use of FFRs, consider consulting the following resources:

- Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19) (WHO)
- Strategies for Optimizing the Supply of N95 Respirators (U.S. CDC)

Evaluating Decontamination Methods for Filtering Facepiece Respirators

3M has been studying ways to decontaminate FFRs for years and collaborated with several decontamination equipment manufacturers and institutions around the world which are investigating ways for hospitals to safely decontaminate 3M’s N95, FFP2 and similar FFRs, in line with guidance from various health authorities (see Appendix 1). There are at least four key aspects of successful decontamination reprocessing of respirators. Many published studies do not take all four into consideration. The method must:

- inactivate the target organism, such as the virus that causes COVID-19;
- not damage the respirator’s filtration performance;
- not affect the respirator’s fit; and
- be safe for the person wearing the respirator.

If, as a result of decontaminating a respirator, the filtration is damaged or the respirator does not fit, it will not help reduce exposure to airborne particles at the level indicated, such as N95, FFP2, etc. In 3M’s work with external manufacturers of decontamination equipment, 3M relies upon the method developer to confirm the germicidal efficacy of the decontamination method and to provide information on potential hazards to the respirator user. 3M evaluates the effect of the method on filtration efficiency and integrity of our respiratory protection products.

Note that this document does not address sterilization of FFRs. Sterilization is not considered here because of the aggressive nature of treatments that can achieve sterilization, which is variously defined as the destruction and/or removal of all microorganisms.

3M has tested certain 3M FFRs that have been treated by certain companies and institutions who have developed decontamination methods for FFRs. Methods included those FFR decontamination methods that have been identified by regulatory agencies as the most likely to be compatible, efficacious, and safe: Vaporized Hydrogen Peroxide, UV, and Low Temperature Moist Heat, amongst others.

It is important to note that there are both similarities and differences in regions and countries around the world as it relates to:

- available 3M FFRs
- available decontamination equipment
- regulatory framework to allow decontamination of FFRs to occur (See Appendix 1.)

Evaluation of additional 3M FFR models and decontamination methods is ongoing; additional information will be made available in this bulletin as this work is completed and reviewed with applicable regulatory agencies. 3M remains committed to providing data to the healthcare community as soon as possible.

Note these 3M recommendations:

1. Note that 3M has established a firm exclusion of ethylene oxide and formaldehyde decontamination methods for use with 3M FFRs, because ethylene oxide and formaldehyde are inhalation-route carcinogens, and any potential off-gassed residuals could be directly inhaled by the wearer.
**Current Findings on Decontamination Methods**

Current information supports the following conclusions for all 3M filtering facepiece particulate respirators:

- **3M does not** recommend the use of Ethylene Oxide or Formaldehyde for respirator decontamination due to the potential for repeat inhalation exposure to residual ethylene oxide or formaldehyde, known human airborne respiratory carcinogens. Ethylene oxide is an accepted sterilant for many device types, but given that the respirator is directly in line with a person’s breathing zone, it is not recommended for respirator decontamination.
- **3M does not** recommend the use of Ionizing Radiation due to degradation in filter performance.
- **3M does not** recommend the use of Microwave due to melting of the respirator near metal components resulting in compromise of fit.
- **3M does not** recommend the use of High Temperatures above 75°C, such as Autoclave or Steam, unless specifically listed in the tables below due to significant filter degradation and fit degradation.
- **3M does not** recommend the use of Ethanol, Isopropanol, Quat solutions, Soaps, or Detergents due to degradation in filter performance.
- **3M does not** recommend the use of Ozone due to degradation of headband and nosefoam materials.

Table 1 below shows the status of ongoing and completed filtration and fit tests conducted by 3M for decontamination methods which have been issued emergency use authorizations (EUAs) by the U.S. Food and Drug Administration (FDA). EUAs offer static, detailed procedural guidance on how to implement precisely the decontamination method that was performed on the treated respirator samples evaluated by 3M. As previously noted, as of April 2021 the US FDA is recommending US health care facilities transition away from crisis capacity strategies such as decontamination or bioburden reduction, however, at this time they are not revoking the EUAs for these systems. According to an FDA letter to US Health Care Personnel and Facilities “health care personnel may continue to use currently-authorized decontamination and bioburden reduction systems, though such reuse of respirators should be limited to when no other respirators are available, including reusable respirators such as elastomeric respirators or PAPRs.” Please note that for information on efficacy of decontamination, please refer to the decontamination equipment manufacturers. Additional information about decontamination of FFRs can be found in the 3M Technical Bulletin Decontamination of FFRs — Frequently Asked Questions.

Considering the many variables involved in the processes, decontamination of FFRs should precisely follow details provided in the EUA issued for each specific decontamination system. If organizations choose to attempt to decontaminate filtering facepiece respirators using any of the methods described within this document or any other methods, then such organization should understand that doing so may impact the filtration performance and/or the respirator materials in such a way that may reduce the respirator’s ability to seal to the wearer’s face and provide the expected protection.

Note that respirators should be thoroughly inspected each time they are put on, according to the model-specific User Instructions. Filtering facepiece respirators that are reused should be assessed for any signs of damage or fatigue, including such points as headband elasticity, nosefoam compression, pinholes near the staples, or deformation. User seal checks should also be performed. If the wearer cannot achieve an effective seal, the respirator should be discarded.

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1. These conclusions apply to all 3M filtering facepiece respirators including those approved in countries and regions other than the United States.
2. The filter degradation caused by isopropanol would also be seen from a method which combines an alcohol with other physical or chemical treatments, such as an ethanol-vacuum method.
Table 1: Effect on Certain 3M Filtering Facepiece Particulate Respirators following decontamination methods which have received EUAs (3M does not recommend decontaminating FFRs.)

*Note: Effective June 30, 2021, the US FDA revoked the EUAs for respirator decontamination systems.

<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M FFR Models&lt;br&gt; a</th>
<th>Cycle b</th>
<th>Number of Decontamination Cycles Allowed by EUA&lt;sup&gt;f&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Tested&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Filtration Efficiency&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Fit Related Evaluation</th>
<th>*Revoked&lt;br&gt;U.S. FDA EUA Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>VHP – ASP, STERRAD®</td>
<td>1860, 1860S, 8110S, 8210</td>
<td>100S-Short NX-Standard, 100NX-Express</td>
<td>2</td>
<td>2</td>
<td>Pass</td>
<td>Pass</td>
<td>EUA&lt;br&gt;Facility Instructions&lt;br&gt;HC Personnel Instructions</td>
</tr>
</tbody>
</table>
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*Note: Effective June 30, 2021, the US FDA revoked the EUAs for respirator decontamination systems. (Continued) (Sheet 2 of 4)

<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M FFR Models&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Cycle&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Allowed by EUA&lt;sup&gt;f&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Tested&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Filtration Efficiency&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Fit Related Evaluation</th>
<th>*Revoked U.S. FDA EUA Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>VHP - Sterilucent</td>
<td>1860, 1860S, 1870+, 8110S, 8210, 9205+, 9210+</td>
<td>Sterilucent™ HC 80TT - Flexible Cycle</td>
<td>4</td>
<td>10</td>
<td>Pass</td>
<td>Pass</td>
<td>EUA Facility Instructions HC Personnel Instructions</td>
</tr>
<tr>
<td></td>
<td>Models not covered by EUA: 1804, 1804S, 1805, 1805S, 8210V, 8511, 9105, 9105S, 9211+</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaporized Hydrogen Peroxide Environmental Decontamination Systems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VHP- Battelle</td>
<td>1860, 1860S, 1870+, 8110S, 8210, 9205+, 9210+</td>
<td>Battelle CCDS</td>
<td>4</td>
<td>20</td>
<td>Pass</td>
<td>Pass</td>
<td>EUA granted but subsequently revoked Facility Instructions (subsequently revoked) HC Personnel Instructions (subsequently revoked)</td>
</tr>
</tbody>
</table>
Table 1: Effect on Certain 3M Filtering Facepiece Particulate Respirators following decontamination methods which have received EUAs (3M does not recommend decontaminating FFRs.)

*Note: Effective June 30, 2021, the US FDA revoked the EUAs for respirator decontamination systems.

(Continued) (Sheet 3 of 4)

<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M FFR Models&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Cycle&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Allowed by EUA&lt;sup&gt;f&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Tested&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Filtration Efficiency&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Fit Related Evaluation</th>
<th>*Revoked U.S. FDA EUA Information</th>
</tr>
</thead>
</table>

Heat

Steris - AMSCO Medium Steam Sterilizers

1804, 1804S, 1805, 1805S, 1860, 1860S, 8210, 9105S

Steris Steam Decon Cycle (Temperature = 65°C, Pressure = 21 inHg, time = 30 min.)

4 | 10 | Pass | Pass |

Heat- 70°C, 60 min

1804, 1804S, 1805, 1805S, 1860, 1860S, 1870+, 8110S, 8210, 9105, 9105S, 9205+, 9210+

Temperature = 70°C

Humidity = 0 to 90 RH

Time = 60 min

5 | 10 | Pass | Pass |

Other
Table 1: Effect on Certain 3M Filtering Facepiece Particulate Respirators following decontamination methods which have received EUAs (3M does not recommend decontaminating FFRs.)

*Note: Effective June 30, 2021, the US FDA revoked the EUAs for respirator decontamination systems.

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<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M FFR Models&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Cycle&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Allowed by EUA&lt;sup&gt;f&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Tested&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Filtration Efficiency&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Fit Related Evaluation</th>
<th>*Revoked U.S. FDA EUA Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>NovaSterilis – NovaClean 2200</td>
<td>Not recommended for any models. Tested: 1804, 1860, 8210</td>
<td>-</td>
<td>-</td>
<td>Fail – degraded filtration efficiency</td>
<td>-</td>
<td>EUA granted, but subsequently revoked; not recommended since filtration efficiency is degraded.</td>
<td></td>
</tr>
</tbody>
</table>

a. Bold font indicates respirator models that were tested. Other listed respirator models are included based on similarity to the tested models. Models that have been evaluated by 3M but are not authorized for decontamination by the U.S. FDA – such as models that contain cellulose, exhalation valves, or KN95 – are listed as “Models not covered by EUA.”

b. Cycle parameters are determined by the equipment manufacturer. Further details need to be provided by the decontamination equipment manufacturer.

c. This column represents the number of cycles tested on unworn respirators. The number of cycles that a particular respirator will withstand will depend on how many times it has been donned, stored and duration and conditions of use. Always follow the most current EUA for the specific method as information may change. Wearers should perform a user seal check each time the respirator is donned to ensure an effective seal is achieved.

d. Tested per applicable regulatory respirator performance standards.

e. Per manufacturers of VHP equipment, most VHP methods are not to be used with cellulose-based materials. See the 3M Technical Bulletin - Cellulose Certification - Filtering Facepiece Respirators for information about which 3M respirators contain cellulose.

f. This column represents the maximum number of cycles that should be attempted. Always consult the most current EUA for the specific method as information may change. The number of cycles that a particular respirator will withstand will depend on how many times it has been donned, how it has been stored and the duration and conditions of use. Wearers should perform a user seal check each time the respirator is donned to ensure an effective seal is achieved.

g. Review FDA enforcement policy for additional information. The number of cycles that a particular respirator will withstand will depend on how many times it has been donned, how it has been stored and the duration and conditions of use. Wearers should perform a user seal check each time the respirator is donned to ensure an effective seal is achieved.

Table 2 below shows the status of ongoing and completed filtration and fit tests conducted by 3M for crisis strategy decontamination methods which have been recommended by CDC and are identified in OSHA’s enforcement memorandum as methods that may be acceptable for use with filtering facepiece respirators BUT which have NOT been issued EUAs. As such, there may be limited government authority and oversight over how these methods should be implemented to ensure efficacy and safety.

The table below provides certain key details regarding the methods that were used to treat the samples 3M evaluated. However, unlike the methods that have EUAs, there may not be static, detailed implementation procedures published for these methods. Considering the many variables involved in the processes, it may be difficult to implement these decontamination methods exactly as they were performed to treat the samples that 3M evaluated for compatibility with the respirator models listed below. Contact the manufacturer of the equipment used in each method for information about procedures, efficacy, and safety.
Table 2: Effect on certain 3M Filtering Facepiece Particulate Respirators following decontamination methods which DO NOT have EUAs (3M does not recommend decontaminating FFRs.) (Sheet 1 of 3)

<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M FFR Models&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Cycle&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Tested&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Filtration Efficiency&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Fit Related Evaluation</th>
<th>Regulatory Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaporized Hydrogen Peroxide (VHP) Systems for Decontamination</strong>&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VHP - Canon</td>
<td>1860, 1860S, 1870+, 8110S, 8210, 8210J, 9205+, 9210+</td>
<td>ES-1400/Short cycle ES-700i/Short cycle ES-700/Short cycle</td>
<td>10</td>
<td>Pass</td>
<td>Pass</td>
<td>No</td>
</tr>
<tr>
<td>VHP – CISA SPS</td>
<td>1862+, 1870+, 9205+, 9210+, 9320+</td>
<td>P2 (in a single Tyvek pouch)</td>
<td>5</td>
<td>Pass</td>
<td>Pass</td>
<td>No</td>
</tr>
<tr>
<td>VHP – Matachana 130HPO-1®</td>
<td>1862+, 1863+, 1870+, 9205+, 9210+, 9320+, 9330+</td>
<td>RAPID (single pouched)</td>
<td>10</td>
<td>Pass</td>
<td>Pass</td>
<td>No</td>
</tr>
<tr>
<td><strong>Vaporized Hydrogen Peroxide Environmental Decontamination Systems</strong>&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VHP – Steris - Victory™, 1000 ED, ARD, and M100 Biodecontamination Unit</td>
<td>1860, 1860S, 1870+, 8110S, 8210, 9205+, 9210+</td>
<td>STERIS Atmospheric VHP Process</td>
<td>20</td>
<td>Pass</td>
<td>Pass</td>
<td>No</td>
</tr>
<tr>
<td>VHP – Certek Mobile Decontamination Chamber</td>
<td>1860, 1860S, 8110S, 8210</td>
<td>STERIS Atmospheric VHP Process using M100 High Capacity Biodecontamination System</td>
<td>3</td>
<td>Pass</td>
<td>Pass</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ultraviolet Light Environmental Decontamination Systems</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UV-C (254 nm)</td>
<td>1804, 1804S, 1805, 1805S, 1860, 1860S, 8110S, 8210, 9105, 9105S</td>
<td>Refer to CDC guidance or UV OEM</td>
<td>Maximum 100 J/cm² cumulative lifetime exposure</td>
<td>Pass</td>
<td>Pass</td>
<td>No</td>
</tr>
</tbody>
</table>
Table 2: Effect on certain 3M Filtering Facepiece Particulate Respirators following decontamination methods which DO NOT have EUAs (3M does not recommend decontaminating FFRs.) (Continued)

<table>
<thead>
<tr>
<th>Decontamination Method</th>
<th>3M FFR Models&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Number of Decontamination Cycles Tested&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Filtration Efficiency&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Fit Related Evaluation</th>
<th>Regulatory Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xenex Lightstrike™ System</td>
<td>1804, 1804S, 1805, 1805S, 1860, 1860S, 1870+, 8110S, 8210, 9105, 9105S, 9205+, 9210+</td>
<td>Pulsed xenon, 200 – 280 nm for 5 minutes on each side</td>
<td>10 Pass Pass No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UVDI (UV-C, 254 nm)</td>
<td>1804, 1804S, 1805, 1805S, 1860, 1860S, 8110S, 8210, 9105, 9105S</td>
<td>1 J/cm² on each side</td>
<td>10 (cumulative exposure of 10 J/cm² on each side) Pass Pass No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surfacide Helios System</td>
<td>1860, 1860S, 8110S, 8210</td>
<td>15 min exposure of ≥ 1 J/cm² on each side.</td>
<td>5 Pass Pass No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AquiSense Technologies PearlSurface™ (UV-C LED, 280nm)</td>
<td>1804, 1804S, 1805, 1805S, 1860, 1860S, 8110S, 8210, 8511, 9105, 9105S</td>
<td>Maximum 2 J/cm², dual sided treatment with N95 insert</td>
<td>20 Pass Pass No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heat</td>
<td>1804, 1804S, 1805, 1805S, 1860, 1860S, 1870+, 8110S, 8210, 9105, 9105S, 9205+, 9210+</td>
<td>In High Temperature Self-Seal Pouches (1 FFR per pouch) Temperature = 65±5°C, Humidity = 50-80% RH, 30 min</td>
<td>10 Pass Pass No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belimed – Medical Steam Sterilizers MST-H, MST-V</td>
<td>1804, 1804S, 1805, 1805S, 1862+, 1863+, 1870+, 9205+, 9210+, 9320+, 9330+</td>
<td>US: Mask 250 Cycle Global: Prevac 121° cycle (Temperature = 121°C, time = 20 min.)</td>
<td>1 Pass Pass No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Hybrid Systems
During the public health emergency associated with the COVID-19 pandemic, many healthcare institutions are experiencing shortages of N95, FFP2 or similar filtering facepiece respirators (FFR). Different organizations and agencies around the world have issued recommendations around strategies to optimize the supply of respirators.

**Guidance – World Health Organization**

The World Health Organization (WHO) within *Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages* states that "last-resort temporary measures in crisis situations to be adopted only when there is an anticipated PPE shortage that will adversely affect health worker safety and care delivery or in areas where access to the global supply chain of PPE remains limited" which include extended use, reprocessing followed by re-use and use of other types of respirator.

In terms of reprocessing and re-use, the WHO states that "when considering decontamination or reprocessing of single use PPE, manufacturer’s instructions for reprocessing and local regulatory approval processes (including, where applicable, emergency use authorizations) should be followed."

**Guidance and Regulatory Considerations – USA & Canada**

The U.S. Centers for Disease Control and Prevention (CDC) has issued *Strategies for Optimizing the Supply of N95 Respirators*. In this document the CDC recommends conventional capacity strategies, contingency capacity strategies (during expected shortages) and crisis strategies (during known shortages). These strategies are meant to be considered and implemented sequentially. Contingency and crisis strategies include use of N95s past their shelf life, extended use of N95s,
use of other types of respirators, use of respirators from other countries, and re-use of respirators. As of April 2021, the US CDC has removed decontamination or bioburden reduction as a recommended crisis strategy for optimizing the supply of N95 respirators stating, "Decontamination or bioburden reduction of NIOSH-approved N95 respirators is no longer a strategy to conserve supplies as the availability to NIOSH-approved respirators has significantly increased." CDC recommends that healthcare facilities promptly resume conventional practices once FFR availability returns to normal.

The US FDA is also recommending US health care facilities transition away from crisis capacity strategies such as decontamination or bioburden reduction, however, at this time they are not revoking the EUAs for these systems. According to an FDA letter to US Health Care Personnel and Facilities "health care personnel may continue to use currently-authorized decontamination and bioburden reduction systems, though such reuse of respirators should be limited to when no other respirators are available, including reusable respirators such as elastomeric respirators or PAPRs."

According to the U.S. Occupational Safety and Health Administration (OSHA), decontaminating FFRs voids the respirators' NIOSH approval. However, OSHA has published an enforcement memorandum indicating that during the COVID-19 pandemic, U.S. employers may consider using certain decontaminating methods in their procedures for reusing N95s. This dispensation stands only if employers have exhausted many other options – such as the strategies recommended by the CDC – to reduce the need for respiratory protection and/or manage the use of respirators to try to ensure adequate supply. OSHA emphasizes that employers should look to respirator manufacturers for guidance regarding which decontamination methods are compatible with specific respirator models.

The CDC continues to suggest reuse and extended use of N95s as a crisis strategy. CDC suggests a wait and reuse approach can be used as a part of a limited re-use crisis strategy approach.

Excerpt from CDC guidelines on optimizing the supply of N95 respirators: "One potentially effective strategy to mitigate the contact transfer of pathogens from the respirator to the wearer could be to issue each HCP who may be exposed to patients with SARS-CoV-2 infection a minimum of five respirators. Each respirator will be used on a particular day and stored in a breathable paper bag until the next week. This will result in each worker requiring a minimum of five N95 respirators if they put on, take off, care for them, and store them properly each day. This amount of time in between uses should exceed the 72 hour expected survival time for SARS-CoV-2 (the virus that causes COVID-19)."

For additional information on crisis strategies consider consulting the following resources:

- Strategies for Optimizing the Supply of N95 Respirators

Health Canada has published considerations for decontamination of N95 respirators during the COVID-19 response and is similarly authorizing decontamination systems under an Interim Order.

**Guidance and Regulatory Considerations - Europe**

Guidance and recommendations are issued by each European Union member state; there is no single guidance document nor regulation that is directly applicable to optimization or reuse of respiratory protective equipment (RPE) for COVID-19 across the EU. However, the European Centre for Disease Control and Prevention (ECDC) has updated guidance titled Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic. In this document the ECDC discusses conservation and reuse of respirators before using decontamination. A number of decontamination methods are compared as to the effect upon the mask or respirator. The ECDC describes all methods are "only considered as extraordinary last-resort methods due to shortage of FFP supplies.... Each of the methods described in this report have caveats that need to be taken into account before deciding which one is the most suitable in each particular setting. The effects of each of these methods depend also on the specific conditions applied and on the model of FFP."

The Dutch National Institute for Public Health and the Environment (RIVM) has published the results of a limited study on the reprocessing of FFRs using steam sterilisation and hydrogen peroxide gas. RIVM conclude that in times of scarcity, some FFR models can be reused on a limited basis following the decontamination process. While 3M does not recommend decontamination, facilities considering decontamination should review the results and conclusions published by RIVM.
together with the data shown in Tables 1 and 2 in this 3M technical bulletin. The number of cycles specified in the table should be considered a maximum number of times an FFR can be decontaminated for each method. Similar to the key recommendation from CDC guidance, in times of urgent shortages, RIVM recommend reuse of FFR following dry storage for at least 7 days.

A paper by The Munster University School of Health (Fachbereich Gesundheit - Wiederverwendung von FFP2-Masken - FH Münster (fh-muenster.de)) discusses the possible reuse of Filtering Facepiece Respirators (Specifically FFP2) by the general public. They state that the exposure to SARS-CoV-2 is likely to be much lower in these use scenarios, than it would be for health care professionals. They discuss two “methods of decontamination”:

1) “7 days drying in indoor air”. This method states that a Filtering Facepiece Respirator is purchased for each day of the week – for example, a respirator for Monday, a different respirator for Tuesday, etc. After use, the respirator is hung to air dry for 7 days at room temperature, away from humidity. A hook system is suggested. The paper suggests that each respirator can be “hung up to dry” for a maximum of 5 cycles. This system may be suitable for domestic use, where respirators are worn daily, but only for limited period each day. Conduct pre-use inspection and user seal checks of the respirator before reuse.

2) “Dry Heat of 80°C for 60 minutes”. Hang up the respirator to dry in a method similar to the method above until the next day, after which apply dry heat of 80°C for 60 minutes. Conduct pre-use inspection and user seal checks of the respirator before reuse. The authors acknowledge that controlling a domestic oven to such an exact temperature is difficult, due to the accuracy of most domestic devices. Please note:
   - **3M does not** recommend the use of High Temperatures above 75°C unless specifically listed in the tables above due to significant filter degradation and fit degradation.
   - **3M does not** recommend the use of home appliances, such as home ovens and pressure cookers, due to the lack of accuracy and precision of temperature control.
   - The authors specifically state that dry heat should not be used with certain types of filtering facepiece respirators, including respirators with exhalation valves and cup-shaped respirators.
   - The US FDA Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the COVID-19 Public Health Emergency specifically states that dry heat should not be used with certain types of filtering facepiece respirators, including respirators with exhalation valves and certain other respirator styles. The US FDA policy also specifies parameters including that “the system has highly controlled convective heat transfer (e.g., laboratory oven, industrial convection oven) to avoid the risk of localized over-temperature.” In addition, the system must not be a household appliance (e.g., home ovens, pressure cookers, multi-cookers) due to the lack of accuracy and precision in temperature control and the risks of cross-contamination from mixed use.

**Guidance and Regulatory Considerations – Asia**

There is no single guidance document nor regulation that is directly applicable to decontamination of RPE for COVID-19 across Asia. Guidance and recommendations are issued by some countries in Asia. The decontamination guidance is interim and last resort during the COVID-19 pandemic outbreak. The Japan Ministry of Health, Labor and Welfare has issued an office memorandum, broadly aligned with the U.S. CDC. JMHLW recommends reuse and extended use, wait and reuse approach, decontamination of N95 respirators by hydrogen peroxide, use of respirators beyond the recommended shelf life, and use of approved respirators from other countries like KN95 respirators.

In Australia, the Therapeutic Goods Administration (TGA) states that individuals or organizations contemplating reprocessing single-use respirators will need to meet all the responsibilities of a manufacturer under the therapeutic goods legislation and regulations. These responsibilities include ensuring the effectiveness of the method, as well as the materials and performance of the respirators.

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The Indonesia Ministry of Health (MOH) has issued technical PPE guidance, broadly aligned with the U.S. CDC and WHO, while guiding how to optimize supply and how to decontaminate FFRs.
Several organizations in Thailand – namely the Department of Medical Services under MOPH, Department of Disease Control under MOPH, Infectious Disease Association of Thailand, Nosocomial Infection control Group of Thailand, Nursing Association for Prevention & Control of Thailand FDA under MOPH, Healthcare Accreditation Institute and Thoracic Society of Thailand under Royal Patronage – have issued general recommendation for decontamination of respirator using UVC, Dry Heat and VHP, broadly aligned with the U.S. CDC. While Infectious Disease Association of Thailand recommends extended use, and reuse aligned with the U.S. CDC.

**Guidance and Regulatory Considerations – Latin America**

In Latin America, most countries have not authorized the use of decontamination procedures. To date, only Chile and Brazil have offered guidance.

Chile’s Ministry of Health authorized hospitals to adopt decontamination of N95 respirators based on the U.S. FDA- EUAs for Steris and Sterrad.

Brazilian Regulatory agency (ANVISA) issued a Technical Note: Manifestação sobre o processamento (reprocessamento) de Equipamentos de Proteção Individual (EPIs) currently states there is no consistent scientific evidence to ensure the efficacy and safety of the reuse of PPE, classified as "PROHIBITED REPROCESSING" or "THE MANUFACTURER RECOMMENDS THE SINGLE USE." ANVISA does not recommended Decontamination/Reprocessing of PPE but does not forbid decontamination. ANVISA clearly states that the validation protocols, as well as the evaluations, work processes, and operational procedures must be conducted and duly documented by the processing company and the health service.