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# Health Guidelines for 3D Printing Medical Devices and Personal Protective Equipment During COVID-19 Response

**N95 Working Group Report**

*The COVID-19 Healthcare Coalition is a collaborative private-industry response to novel coronavirus. Our mission is to save lives by providing real-time learning to preserve healthcare delivery and protect populations.* (https://c19hcc.org)

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# Health Guidelines for 3D Printing Medical Devices and Personal Protective Equipment During COVID-19 Response

## Summary

***Note***: *The guidelines in this paper are targeted to the Maker Community. We will shortly publish a companion piece that is directed at the users of 3D printed equipment to help them determine how to make the best use of the equipment and assess its effectiveness.*

We know that medical equipment is in high demand for healthcare providers on the front lines of the COVID-19 response. The Maker community has already mobilized to design and produce functional prototypes to fill the gap for equipment such as re-useable masks, face shields, and other items that Makers 3D print from plastics. The goal is to get protection it those who need it as quickly as possible.

*A face shield with a 3D printed headband and brow shield, made by a Maker in Massachusetts*

*Design and Photo: Lilia Chan*

3D printing has gained traction within the Maker community as this manufacturing method enables rapid prototyping for viable solutions. It may be difficult to scale 3D printing production, but with supply chains overwhelmed, 3D printing is a practical, temporary workaround for multi-use, disposable items.

These 3D printed items **are not** surrogates for vetted Food and Drug Administration (FDA)-approved medical supplies. They should only be used when FDA-approved supplies become unavailable. They should not be considered permanent replacements for traditional personal protective equipment (PPE) and should be exchanged as soon as FDA-approved PPE becomes available again.

The guidelines presented in this paper are directed to engaged Makers. The goal is to give you the information you need to produce viable equipment while staying healthy. These guidelines cover the following areas for fused deposition modeling (FDM), also known as fused filament fabrication (FFF), and stereolithography (SLA), which are two of the most accessible 3D printing methods:

- Printing methods, materials, cleaning, and potential health concerns
- Sanitization during manufacture and delivery of a 3D printed part

## Printing Methods, Materials, Cleaning, and Potential Health Concerns

As you select materials, you will need to consider the biocompatibility, heat resistance, and chemical resistance of the polymers and the printing process. Why? The equipment you create for the COVID-19 response (e.g., a mask) may come in prolonged, direct contact with a person's skin, mouth, and nose. These objects will likely require routine disinfection. Repetitive cleaning stresses materials, so build them to withstand heat and disinfection without degradation.

### Fused Deposition Modeling

Fused deposition modeling is the most commonly available 3D printing process. Below is a brief overview of the materials with which FDM Makers typically work, information on their biocompatibility and heat resistance, as well as health considerations for you as you work.

**Materials and method:** Polymer filament is extruded through a heated nozzle onto a build platform to build a part, layer by layer. Typical FDM polymers include polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), glycol-modified polyethylene terephthalate (PETG), thermoplastic elastomer (TPE), and thermoplastic polyurethane (TPU), which is a subset of TPE [1].

3D printer filaments contain additives such as plasticizers, modifiers, ultra-violet light stabilizers, and dyes, in addition to the primary material [2]. These additives vary in presence and concentration across manufacturers. Therefore, while the primary filament material might be food safe or even used in some medical applications [3], the 3D printer filament version is typically neither.

**Biocompatibility:** Certified biocompatible filaments are preferable but not readily available. Ideally, try to use a biocompatible filament for any part that will be in contact with human skin, mouths, and noses, or in-line with the respiratory system (e.g., a mask). If a certified biocompatible filament is not available, consult the filament manufacturer's safety data sheet (SDS) to understand the risks and then follow the guidelines below. Inform the end user of the material type in case the user has any sensitivities.

- Does a **biocompatible version** of your chosen filament material (e.g., ABS, PLA) exist? If a biocompatible version does not exist, that material may, fundamentally, not be biocompatible.

- Do not use filament with **filler particles,** such as carbon fiber or metal, because they can easily separate from part surfaces. Some filaments contain metal particles that are certified for skin contact and are an exception to this guidance [4].
- Some filaments are considered biocompatible only when they are not dyed and retain their natural color [5]. Use **undyed filament** if there are dye-specific biocompatibility concerns.
- Use a known **biocompatible layer,** such as moleskin tape, on surfaces with direct skin contact when you are aware of skin irritation issues [6].
- Printers with soft **nozzle material** such as brass can shed trace metal elements into the print. We thus recommend printing with a stainless steel or other hard nozzle material [7].

**Heat resistance:** The thermal properties of 3D printing materials are important when printing for the COVID-19 response as many cleaning and disinfection techniques involve heating the printed parts. Two material properties used for assessing the thermal performance of 3D printed parts are the glass transition temperature and the heat deflection temperature (HDT).

The *glass transition temperature* refers to the temperature at which a material softens such that gravity and internal stresses cause deformation, and the material will likely not return to its original shape [8]. The *heat deflection temperature* is measured by applying a specific pressure to a standard part and heating it until it displaces a set amount [9]. Standard HDT testing specifications are ASTM D 648 and ISO 75 [9]. Table 1 summarizes thermal and other properties and concerns for each of these materials. Note that filament properties can vary across manufacturers, so always consult the SDS provided by the filament manufacturer.

**Table 1. Overview of FDM Materials**

| Material | Glass Transition Temperature (ºC) | Heat Deflection Temperature at 0.46 MPa (ºC) | Typical Extrusion Temperature (ºC) | Notes |
|---|---|---|---|---|
| PLA [8] | 60-65 | 56 | 205 | PLA is derived from feedstock such as corn and sugarcane. It is rigid but does not tolerate heat well. PLA on its own is considered a biocompatible material [3], but PLA filament may contain non-biocompatible additives. |
| ABS [8] | 105 | 98 | 230 | ABS is tougher than PLA but typically much more difficult to print well. Also, ABS may have odors[1] that could be uncomfortable or irritating for users. Some ABS filament features non-biocompatible additives, though purpose-made biocompatible ABS filament exists [10]. |
| PETG [11] | 80 | 65 | 230-250 | PETG is more temperature resistant than PLA but is easier to print than ABS and does not carry the same odors as ABS. Some PETG filament features non-biocompatible additives, though purpose-made biocompatible PETG filament exists [5]. |
| TPE/TPU [12] | -35 | 44 | 216 | TPE and TPU filaments allow the printing of flexible parts, but they are very vulnerable to heat. TPU filaments vary in terms of biocompatibility [13]. |

[1] It is unclear whether odors indicate harmful chemical emissions at high enough levels to cause health concerns.

**Health factors:** Well-ventilated areas are required during the 3D printing process to protect the health of individuals in the vicinity of the machines [14], [15]. Take additional considerations into account when 3D printing for medical applications, including the wearing of appropriate PPE:

- Equip your printer with a **build area enclosure**, preferably temperature-controlled, to reduce contaminants that might enter the build area, introduce foreign materials into the print, and decrease the quality and integrity of the 3D printed part. If you cannot build an enclosure, ensure that the printer is in an isolated location. Do not place the printer near fans or vents as temperature changes reduce the quality and consistency of unenclosed prints.
- **Insufficient filament flow** will make a part much more porous than the same part printed with a greater flow rate [16]. Note: there is insufficient data to make firm conclusions about the efficacy of an FDM part as a barrier to droplets of liquid containing the COVID-19 virus in direct contact with the surface of the part.

## Stereolithography

Stereolithography is another commonly available 3D printing method for fabricating PPE and other medical devices. For Maker communities using SLA during this pandemic, here is a brief overview of materials, methods, biocompatibility, heat resistance, and health factors.

**Materials and method:** SLA printers can produce significantly smoother surfaces with layer thicknesses in the range of 0.015-0.050 mm, compared to 0.127-0.5 mm for FDM printers [17]. Therefore, 3D printed parts made with SLA printers have high surface smoothness and consistency, both of which make them easier to clean than FDM-printed parts. However, depending on the resin from which they are made, some SLA parts have limitations when exposed to ultraviolet light and isopropyl alcohol. Similar to FDM printing, SLA 3D printing materials are not generally considered either medical or food safe [2]. However, a few resins are certified as biocompatible for medical and dental applications and have been used in orthopedic applications [18], [19]. Be sure to consult the SDS to understand the risks associated with a particular resin.

SLA 3D printing methods use thermoset resins cured through photopolymerization with an ultraviolet light source. Harmful gases may be generated during the process from uncured resin in the 3D printer’s resin tank and excess resin on the part in-process. Once the part has been fabricated, there should be little concern regarding harmful gas emission from the 3D printed parts when they are used at room temperature.

**Biocompatibility:** Consider using biocompatible materials if the part will come in close contact with users’ skin, mouth, and nose. Most large manufacturers of SLA 3D printing materials have biocompatible materials available for purchase. However, you must be aware of all aspects of the printing process to ensure that the final, post-processed part is safe to use. In contrast to an FDM-printed part, SLA-printed parts are more likely to be exposed to hazardous substances (e.g., chemicals and contaminants) [2]. An FDM-printed part is nearly ready for use after printing, generally only needing support structure removal. However, if you are producing a part from an SLA 3D printer, consider the following to maximize the cleanliness of parts:

- Between prints, cover the **resin tank** with a cover or, if you don’t have one, close the printer chassis to minimize exposure of the resin to ambient air.

- Depending on the 3D printer model, the **build platform** may submerge into the resin tank prior to the first layer of printing. To minimize contamination to the resin, thoroughly clean all parts of the build platform (with isopropyl alcohol when possible) before every new print job.
- All SLA printed parts require cleaning, and most will require curing. Ensure that your **post-processing and handling** result in a part that is free from debris and uncured resin, and that it is dry. This step will ensure that any disinfection processes after post-processing are effective.

**Heat resistance:** Unlike FDM 3D printing, for which filament materials are fairly consistent across manufacturers and brands, SLA resin compositions tend to be proprietary to a specific printer brand or developed by specialty materials manufacturers for a specific application. Therefore, properties such as heat resistance can vary, and we recommend that you refer to the material datasheet for specific values of heat deflection temperature. Ensure that the thermal properties are compatible with disinfection techniques that involve heat when you select a resin for printing medical equipment or PPE.

**Health factors:** Similar to FDM 3D printing, the SLA process requires ventilation for two reasons: the vapors from isopropyl alcohol and the likelihood of a buildup of fumes from uncured resin. Additional considerations to take into account when it comes to 3D printing for medical applications include:

- To handle cured SLA parts, designate a “clean” area that is free from any uncured resin as the residue can cause severe skin irritation. Ensure that this area is properly distanced from the printer and use new gloves to avoid cross-contamination with uncured resin.
- If sanding is required to post-process parts, wear a dust mask to prevent inhalation of resin dust, which is toxic. Consider wet sanding with mineral oil or water to reduce dust accumulation and exposure. After sanding, thoroughly clean the parts to remove the dust and prevent others from being unintentionally exposed.
- Thoroughly clean and cure parts according to the manufacturer’s specifications after printing to ensure the user is not exposed to uncured resins or harmful gases.

**General Considerations for 3D-Printed Parts**

- The **temperature** stability of 3D printed parts depends on which filament or resin material you use. Consult Table 1 for glass transition temperatures of commonly used FDM 3D printing materials so that you know which items and disinfection treatments are appropriate.
- The FDA, Centers for Disease Control and Prevention (CDC), and various research groups have released reports on using liquid solutions, heating, ultraviolet light, and other methods to disinfect PPE and medical devices during the COVID-19 pandemic. The U.S. Environmental Protection Agency (EPA) also maintains a list of cleaning products for use against the virus [20]. Makers are attempting many of these methods for **disinfecting** 3D printed parts. The finish of a 3D printed part using an FDM printing process is naturally rough, with layer thicknesses on the order of 0.2 mm [21]. This may

allow microbes to flourish inside the rough surface features and small crevices characteristic of FDM-printed material. SLA parts typically have thinner layers, resulting in smoother parts that are easier to clean [2]. Always follow cleaning and disinfection procedures verified to work with 3D printed materials before and after each use of a 3D-printed part.

Prusa Research has shared best practices for cleaning an FDM 3D printed face shield through their website. Their tests were limited to only one design printed in PETG, and their website reports the conclusions, though they do not include the full lab results from the testing organizations [22]. However, it may be possible to generalize these results to additional 3D printed materials. Their tests show that submersion in 75% to 99% isopropyl alcohol (depending on the chosen cleaning standard) for at least 5 minutes is an effective option [22]. Hobbyist-level testing has shown that prolonged submersion in isopropyl alcohol reduces the strength of a PETG part by 7% to 13%, depending on the type of load on the part. This reduction in strength is observed to be even greater with other materials [23].

Prusa Research also recommends heating the part using a hot air dryer at 65 ºC for 60 minutes, but they caution that it should only be done with materials that can withstand those temperatures [22]. Although ultraviolet disinfection was also shown to be effective on their test part [22], the effect of a high dosage of ultraviolet light, such as those used in ultraviolet germicidal irradiation (UVGI) disinfection treatments, is not known for all 3D printable materials. Part geometry is critical to consider when using UVGI. Any area that is not in line-of-sight with the ultraviolet source will experience “shadowing” and have reduced ultraviolet exposure or no exposure, which makes the disinfection process ineffective [24]. SLA resins are very sensitive to ultraviolet light [25]; always confirm that your chosen material can withstand those cleaning processes. Consider using a sealant over an SLA-printed part to improve the part’s durability against ultraviolet and chemical exposure.

- 3D printed FDM parts are naturally and unpredictably porous due to layer inconsistencies and the mechanical printing process [26]. **Porosity** contributes to the risk of infectious material permeating 3D printed PPE. FDM parts generated either as solid or, with increased infill, can reduce this property to a certain degree. Chemical or vapor smoothing, filling and painting, solvent dipping of finished parts, or applying a finish can also reduce part porosity [2]. Airtightness is difficult to ensure using these methods, and success can vary depending on the quality of the application [27]. Another common method is applying an epoxy coat, which is more likely to achieve an airtight seal [27], [28].

  Many of these processes are inherently hazardous, so only attempt them if you have experience with them. In the case of epoxy, consider the matter of biocompatibility if the part will be in extended contact with the skin, mouth, and nose. Biocompatible epoxies are available but are generally prohibitively expensive. You can mitigate this risk by using a biocompatible layer between the 3D printed part and the skin, such as moleskin tape [6]. Though SLA parts have a smoother finish than FDM parts, apply some sort of coating to ensure there is no transfer of compounds in the SLA resin to whatever the part touches [2].

- 3D printed equipment, especially PPE, may rely on additional materials like weather stripping, moleskin tape, elastic, and glues. Research the biocompatibility and chemical resistance of any **seals, coverings, and adhesives** you choose to use. Weather stripping or other materials used to create an airtight seal may decrease in structural integrity after repeated exposure to harsh chemicals, and heat may weaken or destroy a glue seal. Remove fragile materials before disinfecting parts and replace them with fresh material after the main part is disinfected.

  Despite the above considerations and risks associated with adapting 3D printed parts for use as medical equipment, in situations where there is a lack of FDA- or National Institute for Occupational Safety and Health (NIOSH)-approved equipment and PPE, **3D printing offers a reasonable, temporary alternative**.

  *Worth repeating: Do not use 3D printed parts as permanent replacements for FDA-approved medical equipment; pay attention to the susceptibility of materials to chemical exposure, heat, and ultraviolet light; and ensure that coatings applied post-print are compatible with selected disinfection or sanitization processes.*

## Sanitization During Manufacture and Delivery of a 3D Printed Part

To protect yourself and what you produce, please take extra time to ensure that 3D printed items are as close to sterile as possible. Acknowledging that most Maker labs do not conform to FDA-approved levels for sterility in producing medical-grade items, follow the steps below to sanitize yourself and your environment prior to supporting the COVID-19 response. Refer to the EPA's "List N: Disinfectants for Use Against SARS-CoV-2" for a list of cleaning products you can use to augment the following sanitization actions [20]:

- **Sanitize the area:** If you or anyone sharing the space in which you are 3D printing has been exposed to COVID-19 within the past 14 days, do not produce parts for the COVID-19 response. Clean all areas associated with the Making process, to include material storage and preparation areas and areas for packaging for onward transportation of finished parts. Ensure they are free from dirt and debris. Before engaging in Making activities, and at least once a day while actively producing parts, wipe down each of these areas with an approved cleaning product.

- **Sanitize the machine:** Take special care to sanitize the machine using an approved cleaning product prior to plugging in or turning on the printer. Ensure the printer is completely dry before plugging it in and turning on the power to avoid the risk of electric shock or damage to the printer or Maker.

- **Sanitize the material:** The high heat associated with extruding 3D printed material of any kind results in a sort of pasteurization process for FDM printers [29]. With a sanitized build area, fresh prints should be clean enough to use for COVID-19 response [29], [30].

- **Sanitize the Maker:** Adopt principles of general cleanliness associated with commercial food preparation. Wear a face mask and fresh disposable gloves to reduce the possibility of transferring microbes to the part during the printing process and any post-processing or assembly steps [31].

- **Sanitize delivery packaging:** Sanitize the insides of containers used to transport 3D printed items using an approved cleaning product. Keep shipping materials under a sealed protective covering unless you are actively using them in a sanitized preparation area. Store parts immediately in a sealable bag [31].

  Seek guidance from the recipients of your donations regarding delivery procedures. Directly delivering finished parts to a hospital can increase exposure risks for everyone involved, leading some organizations to use off-site donation collection locations to better manage this risk [32]. One mitigation strategy is to package completed parts and let them sit for several days before you deliver or use them [31]. *Note: this strategy is not a substitute for proper handling procedures as other pathogens remain viable on surfaces for much longer* [33].

## Other Considerations

3D printed PPE and other parts are not equivalent to FDA-approved PPE and medical devices [34]. To help the end users of 3D printed parts make informed decisions regarding use of these products:

- Partner with healthcare providers to determine effective designs and materials for the COVID-19 response
- Rule out materials that are toxic or harmful in the finished product
- Document and share the processes and materials used to make each piece of equipment [32] so end users can make informed decisions about the equipment

This information paper represents best practices aggregated from a number of sources. Currently, there are no open-source 3D printed PPE that has been FDA- or NIOSH-approved for protecting wearers against COVID-19. However, NIH has launched an initiative to review 3D printed PPE designs: https://3dprint.nih.gov/collections/covid-19-response. Using standards from the FDA, CDC, and NIOSH, designs are subjected to testing and evaluation for use in clinical settings by clinical and partner organizations. Once reviewed, the designs can earn "Clinically Reviewed" and for "Community Use" designations. As we learn more about current practice, the N95 Working Group will disseminate updates.

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