Material Guidelines for Ventilator Challenge

The scope of this document is to provide general guidelines in selecting the appropriate materials for your device. Keep in mind that all materials used in the device must be quickly available globally to assure efficient manufacturing. Materials should also be suitable for ventilators, and will be in contact with either air or oxygen. You will have to demonstrate that the material oxidation will not alter functional properties of the device.

Mechanical ventilators used as breathing assistance devices are medical devices and are subjected to regulatory requirements. Please be reassured that the team will be there to assist you during the regulatory requirements phase.

For materials that **will not** be exposed to gas pathways in direct contact with the patient, please consider that any mechanism with constant moving parts or motors will generate heat and thus might melt surrounding parts. Some properties to consider during material selection of parts that could be exposed to heat are the Heat Deflection Temperature (HDT, ASTM D648 or ISO 75) and the Coefficient of Linear Thermal Expansion (CLTE, ASTM E228).

For materials that **will** be exposed to gas pathways in direct contact with the patient, you will have to verify if there are emissions of particulate matters (ISO 18562-2) or volatile organic compounds (ISO 18562-3). You will also need to validate the biocompatibility of the materials (ISO 10993 series). Another aspect to consider is the fact that 3D printing creates intrinsic porosities. A top layer or smoothing technique might be required to seal surfaces and limit leaching of components.

Many suppliers provide medical grade materials. As a general reference, the table below summarizes properties of some FDA approved polymers used in FDM, namely polylactic acid (PLA), polyethylene terephthalate (PET), polyethylene terephthalate glycol (PETG), acrylonitrile butadiene styrene (ABS), nylon, polycarbonate (PC), thermoplastic polyurethane (TPU), thermoplastic elastomer (TPE) and polyetheretherktone (PEEK). To confirm the chemical resistance of thermoplastic polymers used in 3D printing of ventilators please refer to: https://www.plasticsintl.com/chemical-resistance-chart

Material	Bed T (ºC)	Printing T (ºC)	Tg* (ºC)	HDT (ºC)	FDA grade	Elong. (%)	PRO´s	CON´s
PLA	<60º	180º<230º	55	60	yes	4%	Biodegradable Strong and easy to 3D print	Can be brittle depending on the model´s geometry PLA vapors can be toxic.
PETG/PET	90º	235º<250º	80	180	yes	35%	Strong and easy to 3D print	Cannot be glued
ABS	110º	220º<230º	105	98	yes	20%	Strong and pliable Easy to 3D print	Petroleum based, melts with acetone
Nylon	130º	235º<280º	50	160	yes	60%	Strong and pliable Impact resistance High Temp resistance	Difficult to 3D print as parts tend to bend
PC	140º	250º<280º	145	140	yes	35%	Strong	Difficult to 3D print as parts tend to bend
TPU/TPE	50	220º<230º	-35		yes	600%	Flexible but very strong Some are resistant to fungus	Difficult to print, poor bridging characteristics Possibility of blobs and stringing
PEEK	120<150º	370<410º	143	152	yes	45%	Strong	Difficult to 3D print

Simply 3D also built a comparison tool for commodity or high performance materials used in FDM (https://www.simplify3d.com/support/materials-guide/properties-table/), but these materials are not necessarily FDA approved.

Another class of materials are specialty high performance plastics, such as PEEK, polyphenylene sulfide (PPS), polyetherketone (PEK), polyphthalamide (PPA), polyetherketoneketone (PEKK), polysulfone (PSU), polyethersulfone (PES), polyimide (PI), and/or polyetherimide (PEI). These thermoplastic polymer materials possess HDT above 150°C. Adding glass or carbon fibers can also significantly increase HDT above 250°C. These 3D printed parts have to be conditioned using the same parameters as for sterilization for at least 30 minutes and their performance re-evaluated keeping those conditions.

During the course of this challenge, you will have to certify that your device follows regulatory requirements. According to Health Canada ventilators are Class 3 Medical Devices, while they are categorised as class 2 Medical Devices by the US Food and Drug Administration (FDA). The FDA has established a list of recognized consensus standards which you will most certainly have to consult (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MNT). The FDA also published a guidance document for industrials on technical considerations for additive manufactured of medical devices (https://www.fda.gov/media/97633/download).

In the scope of preventing further infection and/or contamination respiratory equipment, such as ventilators, need to be subjected to cleaning and disinfection methods. Steam sterilization is an effective method to sanitise devices, where devices are exposed to high temperatures (above 110C) and pressurized vapor (ISO 11134). Commodity and high performance materials used in polymeric 3D printing are generally not suitable for this technique. The World Health Organization (WHO) established guidelines for cleaning and disinfecting mechanical ventilators as described in 2014 report “Infection Prevention and Control of Epidemic- and Pandemic-Prone Acute Respiratory Infections in Health Care” (Annex I - Cleaning and disinfection of respiratory equipment).

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