Corrosion Testing of Materials to Shield a Noninvasive Vital Sign Monitoring Device for Use in Hazardous Environments

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Biomedical Engineering
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Context

- **Standard UL 1203 for Explosion Proof and Dust Ignition Proof Electrical Equipment for use in Hazardous (Classified) Locations:** Standard that dictates testing guidelines for intrinsic safety for electronic equipment.
- **Standard ISO-10993-1: Attachment G Biocompatibility of Certain Devices in Contact with Intact Skin:** Standard that dictates FDA biomaterial selection recommendations.
- **Standard UL 94 V-0 Classification of Flame-Retardant Plastic Materials:** Standard that dictates the thermoplastic flammability guiding the material selection.
- **Standard ASTM D638 Plastics and Polymer Testing:** Standard that guides tensile testing of polymers.

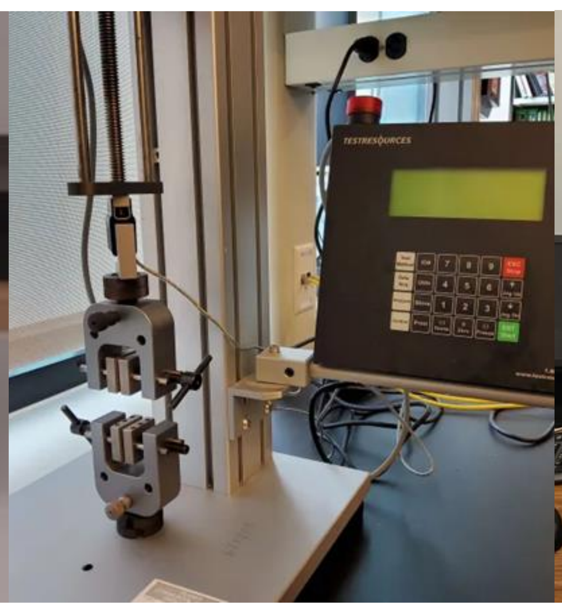
Problem Statement

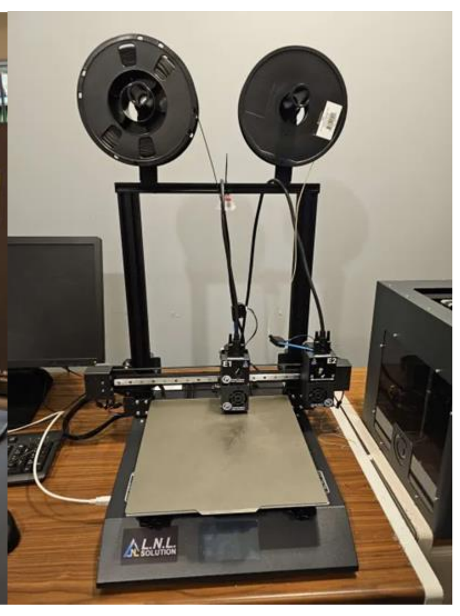
There is an average of 7500 deaths per day due to unsafe working conditions throughout the world and no medical devices are currently designed to allow monitoring under hazardous conditions. VigiLife Inc. is currently exploring the development of intrinsically safe wearable vital sensors to allow the monitoring of an employee's health in real-time while they are in hazardous environments. The current materials used in the shield casing of the product have been found to be insufficient due to the FDA labeling requirements for medical devices. Moreover, whatever material that is chosen needs to be able to withstand the various chemical compound exposures that may be found in medical or industrial work environments.

Technical Approach

Material selection criteria for the corrosion testing process were based upon the client's preferences, FDA-approved materials for intact skin contact biocompatibility per ISO-10993-1, and polymers pre-tested for thermoplastic flammability per UL 94 V-0. Testing of polymers was chosen due to the brittleness of ceramics, the higher cost of polymer-ceramic composites, and the heat conductivity of metals. Chemical selection criteria were based on UL 1203.

ASTM D638 Type V samples for tensile testing were chosen due to limited space constraints. Utilizing an L.N.L. Solutions 3D printer, approximately 50-60 samples of PC, PBT, PETG, and TPU-95A each were printed. All samples were quality tested to verify proper dimensions as per ASTM D638 and any samples that were found to have inclusions such as pitting, cracking, or peeling were excluded. Tensile testing was performed on non-corroded samples in batches of 5 to verify the proper speed of rupture and establish the material's Ultimate Tensile Strength through the use of an actuator.



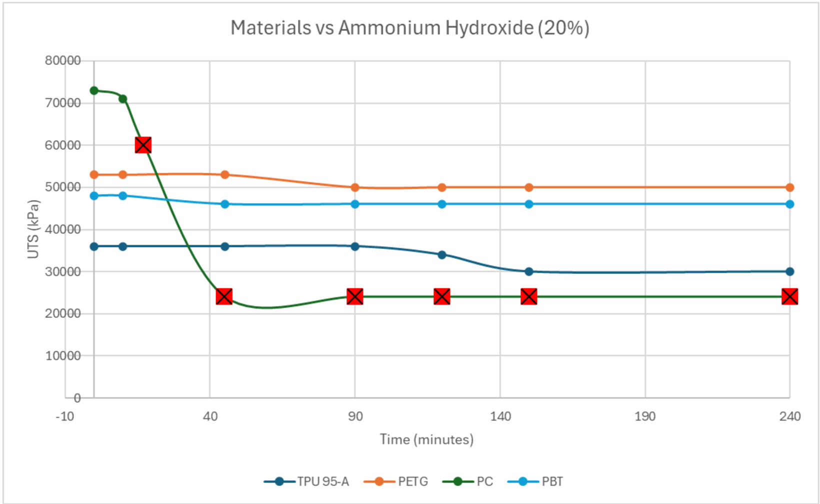


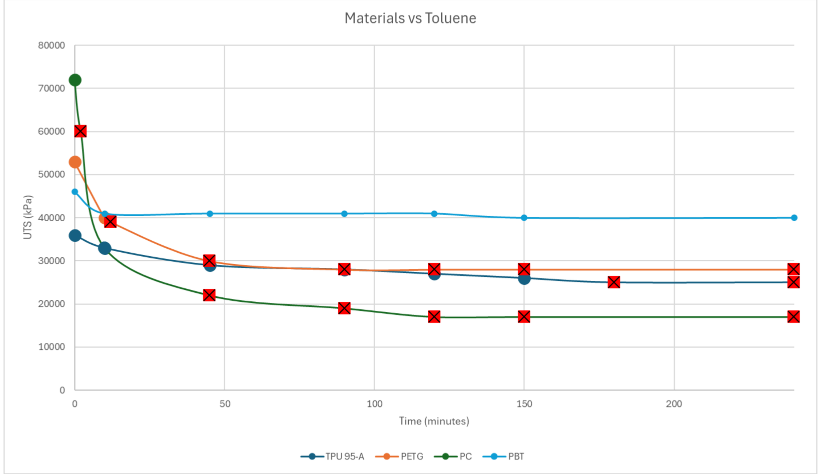
The rest of the samples were then subjected to submersion chemical exposure (against toluene, 20% ammonium hydroxide, and glacial acetic acid) for 10 min, 45 min, and 90 min to aid in determining the point of failure through the utilization of regression analysis. If no failure occurred times were extended to 120 min, 150 min, and 240 min. Failure was established for the material as <85% of the original Ultimate Tensile Strength per UL 1203 and ASTM D638 in batches of 5-10.

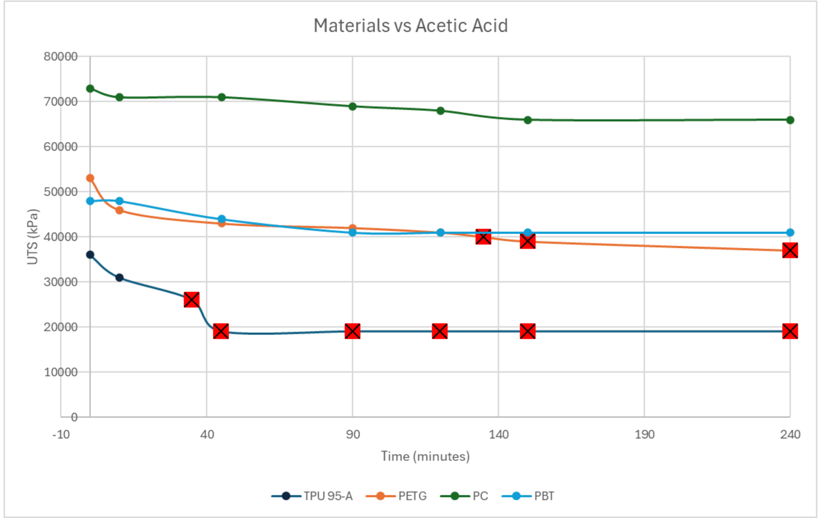
Results

Points of failure indicated by ☒.

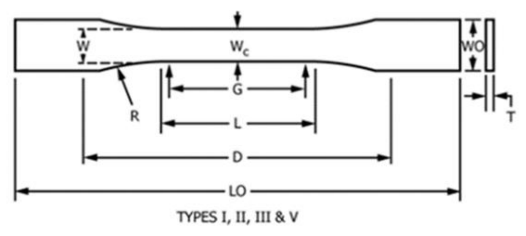
-TPU-95A: Thermoplastic Polyurethane
-PETG: Polyethylene Terephthalate Glycol
-PBT: Polybutylene Terephthalate
-PC: Polycarbonate







A 4.0 grading point system was utilized where a ranking of "A" is 4 points, "B" is 3 points, "C" is 2 points, and "D" is a single point. The rankings were determined primarily through the comparison of failure times. If no failure was determined for multiple polymers within four hours of exposure, the polymers were then ranked through a comparison of the final Ultimate Tensile Strengths calculated at the four-hour benchmark.



MATERIAL		CHEMICAL: Toluene (Solvent)	Acetic Acid (Acid)	Ammonium Hydroxide 20 % (Base)	Total Score
	TPU 95-A (Thermoplastic Polyurethane)	B	D	C	6
	PETG (Polyethylene Terephthalate Glycol)	C	C	A	8
	PC (Polycarbonate)	D	A	D	6
	PBT (Polybutylene Terephthalate)	A	B	B	10

Conclusion

After experimentation was completed, insight into each material's resistance to chemicals was obtained. TPU failed to strongly resist any of the three chemicals, with only a moderate performance against toluene. PETG showed impressive resistance against ammonium hydroxide, but it was subpar against other chemicals. PC performed well against glacial acetic acid but failed against the other chemicals. Finally, PBT was strong against toluene and resistant against glacial acetic acid and ammonium hydroxide, meaning this material had the best overall performance. With the capacity to resist acid, base, and solvent, PBT was the recommended material for shield casing construction due to its versatility in hazardous environments.

Acknowledgments

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