

MANUFACTURING GUIDE

BioMed Durable Resin

V1 / V1.1

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BioMed Durable Resin is a USP Class VI certified, light-curable polymer based material designed for the additive manufacturing of medical grade, biocompatible, clear, durable, and semi-rigid parts for long term surface contact (more than 30 days) as well as externally communicating short-term bone & dentin contact (less than 24 hours). Users should independently verify the suitability of the printed materials for their particular application and intended purpose. This Manufacturing Guide will give equipment, printing and post-processing recommendations and requirements to ensure the correct and safe usage of this material.

Specific Manufacturing Considerations

BioMed Durable Resin specifications have been validated using the hardware and parameters indicated below. For biocompatibility compliance, validation used a dedicated resin tank and mixer, build platform, wash unit and post-processing equipment that were not mixed with any other resins.

1. Hardware:

a. Formlabs 3D Printer:

- BioMed Durable Resin V1
 - Form 3B/3B+, Form 3BL
- BioMed Durable Resin V1.1
 - Form 4B, Form 4BL

This resin version is incompatible with Form 3 generation printers.

b. Print Accessories: Formlabs Build Platforms, Formlabs Standard Resin Tanks

2. Software:

a. Formlabs Preform

3. Printing Parameters:

a. Layer Thickness: 100 µm

4. Recommended Post-Processing Equipment and Accessories:

- a. Formlabs Processing Accessories: Form Auto, Resin Pumping System
- b. Formlabs Validated Wash Unit: Form Wash, Form Wash V2, Form Wash L, Form Wash L V2, Ultrasonic Wash Unit
- c. Formlabs Validated Cure Unit: Form Cure, Form Cure L, Fast Cure, Form Cure V2, Form Cure L V2

A. PRINTING

1. **Shake cartridge:** Shake the cartridge before every print job. Color deviations and print failures may occur if the cartridge is shaken insufficiently.
2. **Set up:** Insert resin cartridge into a compatible Formlabs 3D printer. Insert resin tank and attach mixer to the tank.
3. **Printing:**
 - a. Prepare a print job using PreForm software. Import desired part file.
 - b. Orient and generate supports.
 - c. Send the print job to the printer.
 - d. Begin print by selecting a print job from the print menu. Follow any prompts or dialogs shown on the printer screen. Printer will automatically complete the print.

B. PART REMOVAL

Remove the build platform from the printer. To remove parts from the build platform, wedge the part removal tool under the printed part raft, and rotate the tool. Formlabs Build Platform 2 or Build Platform 2L may be used for easy, tool free removal. For detailed techniques visit support.formlabs.com.

C. WASHING

Wash printed parts using either a Formlabs-validated wash unit or an ultrasonic wash unit.

Formlabs-validated Wash Unit:

Place the printed parts in a Formlabs-validated wash unit with 99% Isopropyl Alcohol.

1. Form Wash, Form Wash V2 - High speed*, Form Wash L, or Form Wash L V2:
 - a. Wash for 10 minutes or until clean.
 - b. If parts do not appear clean after washing, consider replacing used Isopropyl Alcohol in the

wash unit with fresh solvent.

*For Form Wash V2, High speed settings are validated for use.

2. Ultrasonic Wash Unit:

NOTE: Using Isopropyl Alcohol in an ultrasonic bath presents a risk of fire or explosion. When using an ultrasonic wash read and follow all safety recommendations from the ultrasonic wash manufacturer.

- a. Use clean 99% Isopropyl Alcohol for each wash.
- b. Place parts in a secondary disposable plastic container or plastic resealable bag then fill with 99% Isopropyl Alcohol, ensuring parts are fully submerged.
- c. Place the secondary container in the ultrasonic unit water bath and sonicate for 2 minutes or until clean.*

*Washing efficacy depends on the ultrasonic unit size and power. Formlabs testing was conducted with ultrasonic units at 36 W/L or higher.

D. DRYING

1. Remove parts from Isopropyl Alcohol and leave to air dry at room temperature for at least 30 minutes. **NOTE:** Dry times can vary depending on the design of parts and ambient conditions. Do not let parts sit in Isopropyl Alcohol for longer than needed.
2. Inspect printed parts to ensure that parts are clean and dry. No residual solvent, excess liquid resin or residue particles should remain on the surface before proceeding to subsequent steps.
3. If the residual solvent is still present, dry parts longer. If resin residue is still visible, rewash parts until clean and dry.

E. POST-CURING

Place the printed parts in a Formlabs-validated post-curing unit and cure for the required time.

1. Form Cure or Form Cure L:
 - a. Cure for 20 minutes at 60 °C
 - b. Allow the cure unit to cool down to room temperature between cure cycles.
2. Fast Cure:
 - a. Cure for 5 minutes at Light Intensity 9
 - b. Allow the Fast Cure unit to cool for at least 10 minutes between cure cycles.
3. Form Cure V2 or Form Cure L V2:
 - a. Cure for 7 minutes at 60°C.
 - b. Allow the cure unit to cool down to room temperature between cure cycles.

F. SUPPORT REMOVAL & POLISHING

1. Remove supports using a cutting disk and handpiece, cutting plier, or other appropriate finishing tools.
2. If needed, polish the printed parts using typical polishing methods. Make sure to verify the suitability of the polished printed material for the intended purpose.
3. Inspect the parts for any cracks. Discard if any damage or cracks are detected.

G. CLEANING & DISINFECTION

1. The parts may be cleaned, disinfected, and sterilized according to facility protocols. The manufacturer is responsible for validation of part performance depending on the application requirements post disinfection and/or sterilization. **NOTE:** If alcohol-based disinfectants are used, do not leave parts in alcohol solution for an extended time.
2. After cleaning and disinfection inspect the part for damage or cracks to ensure that the integrity of the designed part meets performance requirements. Discard if any damage or cracks are detected.

H. HAZARDS, STORAGE & DISPOSAL

1. Cured resin is non-hazardous and may be disposed of as regular waste.
2. See SDS for more information at support.formlabs.com