WHITE PAPER

Formlabs Guide to SLA Quality Control Management for Healthcare Innovators

This guide outlines the steps that healthcare professionals, life science researchers, and medical device developers can take to maintain, track and improve the quality of 3D printed SLA parts. It aims to provide guidance in the areas of standard workflow checks, quality checks and cadence, ensuring dimensional accuracy, what to do post-failure, and additional best practices to help healthcare users achieve the highest level of safety and efficacy for their printed parts.

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formlabs

Contents

NOTICE

This is a living document intended to be updated over time. Feedback is welcomed and can be directed to healthcare@formlabs.com.

DOCUMENT REVISIONS

Date	Version
3/17/2023	REV 00
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Introduction

From patient-specific anatomical models, to surgical guides, boluses, orthotic devices and more, the adoption of 3D printing in healthcare is on the rise. As the role of 3D printing in medicine rapidly expands, it is more important than ever that the quality of 3D printed parts meets the same quality standards as traditional manufacturing methods across applications. While it is the device manufacturer's responsibility to validate the safety and efficacy of all products it produces, Formlabs aims to ease that process by providing guidance on quality control management for SLA parts, and confidence that technical expectations are being met. Here we discuss standard workflow checks, quality checks and preventative maintenance cadences, ensuring dimensional accuracy, what to do post-failure, and other best practices to help you meet regulatory requirements for end-use SLA parts.

WARNING!
Always wear chemically-resistant gloves like nitrile or neoprene (not latex) when handling liquid resin, printer components, or printed parts. During post-processing, wear eye protection to protect eyes from loose debris, and point tools away from yourself.

Methods

STANDARD WORKFLOW CHECKS

Prior to printing, the following checks should occur at each step of the workflow.

Establishing Expectations

When printing for medical applications, it is essential that the requirements and expectations for the printed part are clearly established between the requestor and the person or team doing the printing (Bastawrous et al., 2021). This information will help you to develop quality checks and standards for 3D printing. While each design will be unique, here are some considerations for establishing your own quality standards:

- What risk is associated with this part? Does it need to be dimensionally accurate or is it just a visual guide?
- What mechanical properties and regulatory clearances are needed for your application? Does the chosen material meet those requirements?
- What critical structures need to be captured? Is the printer technology and/or material capable of producing the necessary features of your design? This could include color, texture, biocompatibility, sterilization capabilities, dimensional accuracy, tolerances, specific geometric features of interest, etc.

The answers to these questions and overall expectations for the final printed part should be documented for later reference and can be used to create a checklist to guide the part review. Ideally, this conversation is ongoing between the requestors and printers as the STL is being iterated, a material is being decided upon, and the printer settings can be determined. If implemented inside a QMS, keeping records of these interactions and a final approval by the requestor before manufacturing is suggested.

Regardless of your manufacturing process, you will need to make some favorable design choices for the chosen technology. This is commonly called “Designing for Manufacturing.” The same holds true for 3D printing, where it is called “Design for Additive Manufacturing”. You will have the most success when you design your part for the 3D printing technology you’ve chosen.

Scanning

Scanning is most-often the limiting factor in print resolution (Bastawrous et al., 2021). If patient scanning is part of your workflow, all precautions should be taken to obtain the highest quality scans and segmentations. IQ/OQ/PQ evaluations should be completed for any scanning software or equipment used.

Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and 3D Ultrasound (3DUS)

According to guidelines on Establishing Quality and Safety in Hospital-based 3D Printing Programs by the University of Washington School of Medicine, good imaging quality is crucial to producing dimensionally accurate printed parts (Bastawrous et al., 2021). The spatial resolution of medical imaging modalities can vary significantly depending on the acquisition protocol.

Consider these scanning modalities and slice thickness recommendations from Boston Children’s Hospital, as well as these considerations from the Radiology Society of North America (RSNA) Special Interest Group for 3D Printing. Users are encouraged to check with their segmentation software provider for more specific recommendations. Prior to imaging, it should be confirmed that the scanner and imaging personnel both have up-to-date accreditations, and that images have been acquired within a reasonable amount of time as to still accurately represent the patient’s anatomy and pathology.

Surface Scanners

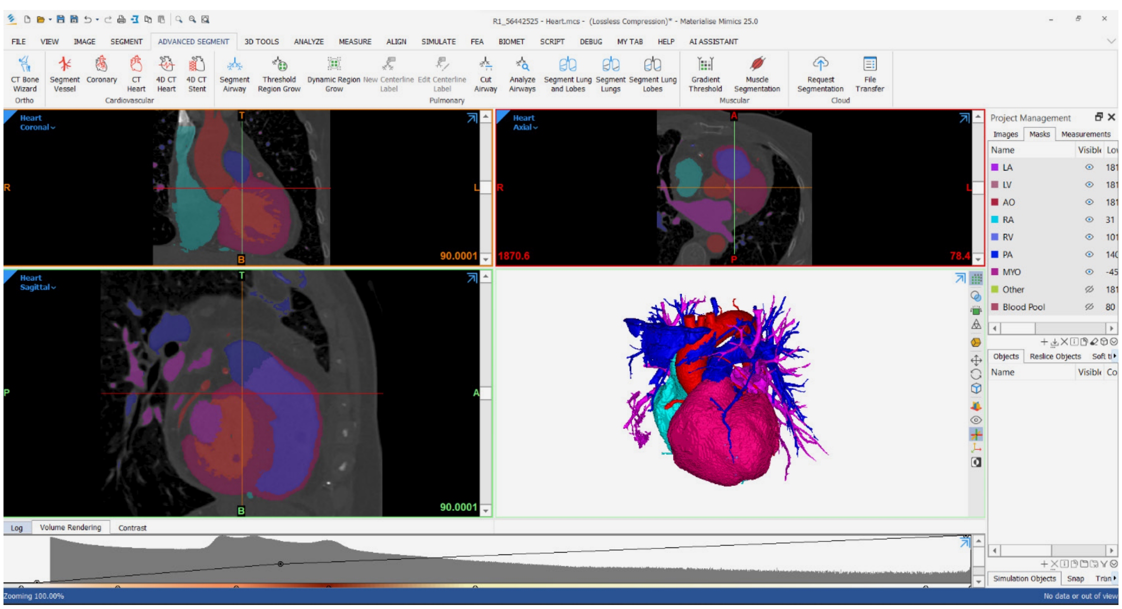
Surface scanners are a highly-efficient way of referencing the exterior surface of the human body. This guide is a great place to start when trying to figure out what type of surface scanner is best for your application. Some specific considerations need to be taken into account when choosing a scanner specifically for healthcare applications, such as whether the subject is able to keep perfectly still, or if the scanner will need to be pointed towards the eyes. Surface scanners are most commonly limited by mesh density, so when aiming to create the highest quality prints from a surface scan, it is important to aim for the highest resolution possible. Additionally, a scanner with an accuracy range of 0.1mm or better is recommended for use in conjunction with Formlabs printers because our printers produce parts of similar accuracy (Ravi et al., 2021). Users may contact Formlabs or check in with their scanner manufacturers for more specific guidelines and best practices based on their chosen device.

Segmentation & VSP

Accuracy errors are most likely to be introduced during the medical image segmentation phase of the printing process (Ravi et al., 2021). If segmentation is part of your workflow, extra precautions need to be taken to ensure that you are reconstructing anatomy with the highest accuracy possible and meeting the clinical requirements defined by the physician. The healthcare professional responsible for segmenting should be aware of any potential artifacts that may warp the image, and should account for those during the image post-processing (Leng et al., 2017). Any segmentation completed using automated algorithms should be closely reviewed, and segmentations should be double-checked by a radiologist when possible. When reconstructing a 3D surface mesh from segmented images, attention should be given to the reconstruction algorithm to ensure the proper settings are used. The 3D model accuracy should then be verified by overlaying the surface contours on top of the source medical images, especially for the critical anatomic structures.

Software packages used for segmentation should be validated for conformity with internal QMS and regulatory compliance. IQ/OQ/PQ evaluations should be completed for any segmentation software used. Information on some of Formlabs' preferred segmentation partners can be found here and a white paper on the topic is also available.

In some point-of-care settings, a virtual surgical planning (VSP) session may be advisable. A VSP is a meeting between the physician and the team involved in the segmentation, design, and printing of the device. In this meeting the model is analyzed, the intended use and expectations for the model are confirmed, and modifications to the model (drill holes, cuts, etc.) are reviewed and adjusted as necessary. During this meeting, models can be signed off on by the physician, radiologist, or other knowledgeable team member for accuracy approvals and traceability. Any parts that have been manipulated as part of the VSP process should be labeled as such, along with the patient identifier.



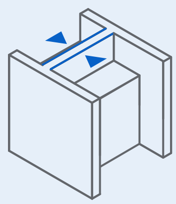
Example segmentation done using Formlabs' partner Materialise.

CAD

Just like any other manufacturing technique, there are certain considerations that need to be made when designing a part to optimize it for 3D printing. Some recommended dimensions for common geometries are listed in the table below, and more details on those recommendations can be found here. These recommendations are based on the use of Clear resin printed with a 100 micron layer height and may need to be exaggerated slightly when printing with less rigid materials, for durability, or engraving/embossing visibility.

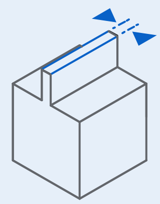
Additional features to consider when designing your part are its size relative to your build platform, the intended printing orientation and how that might affect mechanical properties (you might want to reinforce certain features with fillets or chamfers), avoiding unsupported minima, and introducing drain holes to prevent cups and hollow features from filling with resin while printing.

SUPPORTED WALL THICKNESS



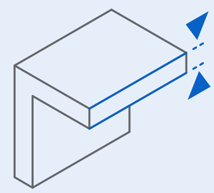
Minimum 0.4 mm

UNSUPPORTED WALL THICKNESS



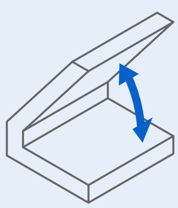
Minimum 0.6 mm

UNSUPPORTED OVERHANG LENGTH



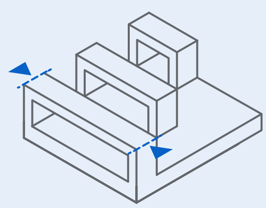
Maximum 1.0 mm

UNSUPPORTED OVERHEAD ANGLE



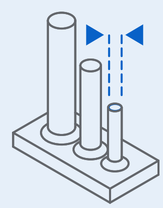
Minimum 19° from level (35 mm long × 10 mm wide × 3 mm thick)

HORIZONTAL SUPPORT SPAN/BRIDGE



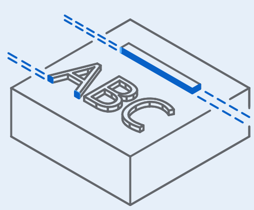
Maximum 21 mm
(5 mm width × 3 mm thick)

VERTICAL-WIRE DIAMETER



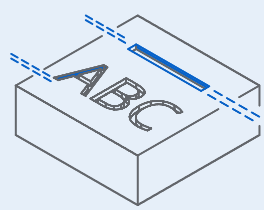
Minimum 0.3 mm
(7 mm tall) to 1.5 mm (30 mm tall)

EMBOSSED DETAIL



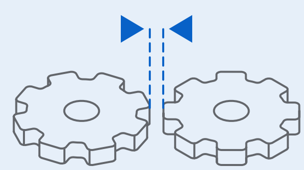
Minimum 0.1 mm

ENGRAVED DETAIL



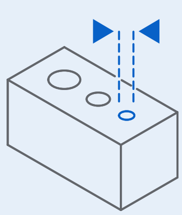
Minimum 0.4mm

TWO-PART CLEARANCE



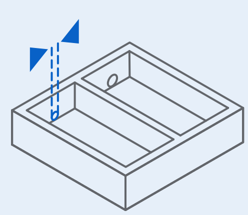
Minimum 0.5mm

HOLE DIAMETER



Minimum 0.5mm

DRAIN HOLE DIAMETER



Minimum 3.5 mm

Recommended dimensional tolerances for common geometry.

File Format

PreForm's native file format is .FORM which saves all of the settings for a specific print job. It is recommended that you save all of your print jobs in .FORM until the print has completed successfully. This will allow you to return to the saved print job in case of a print failure and troubleshoot the source of the failure. In addition, PreForm can accept both STL, OBJ and 3MF formats, which are common formats for migrating between different CAD platforms. Each format has its own pros and cons so it's important to understand which is best suited for your application.

STL

STL is the most commonly used format in the 3D printing industry, so this is the format most people will be accustomed to. It was designed by 3D Systems specifically for 3D printing and produces a smaller file size than other formats. When a model is exported to STL format, the geometry is triangulated so the resulting 3D object can be difficult to modify later. In some cases, this may be desirable to help protect the object from being modified later.

STLs have one significant flaw that may affect your CAD design. That is that STL format does not allow triangles to share vertices. Each triangle is assigned three unique vertices that are not joined with adjacent vertices or triangles. When an STL is imported into another 3D program, including PreForm, each of those vertices must be welded together again using a proximity threshold. In 3D design, it is a common practice to have multiple sub-meshes within one 3D object that are not joined together, often resulting in intersecting geometry. When two sub-meshes within a single 3D object share coincident or overlapping vertices, there is a risk that those vertices will be unintentionally welded together on import, resulting in a broken or non-manifold mesh and producing errors in your 3D print. For this reason, we do not recommend using the STL format for 3D objects that contain multiple sub-meshes and/or that have dense vertex counts.

OBJ

OBJ is a less commonly used format for 3D printing and some CAD software may not support it, however, this format does not result in triangulation and it does allow adjacent polygons to share vertices. This means that there is no risk of coincident or overlapping vertices being welded together on import and corrupting your model. One common objection to the OBJ format is that it does not preserve scale data, however, this is also true of the STL format. Both formats retain the world coordinates of the CAD program they were originally exported from and so it is necessary to know what scale units they were created in (metric or imperial). You can choose the correct Model Units within PreForm in the **Edit** menu.

3MF

In comparison to STL and OBJ, 3MF can support more complex geometric features, including curves, textures, and assemblies, as well as printing parameters. Using 3MF may allow for the production of more accurate and detailed parts. Despite this finer level of detail, 3MF also tends to have smaller file sizes than STL or OBJ. 3MF is not as common as STL or OBJ, and not as widely supported across CAD softwares.

PreForm

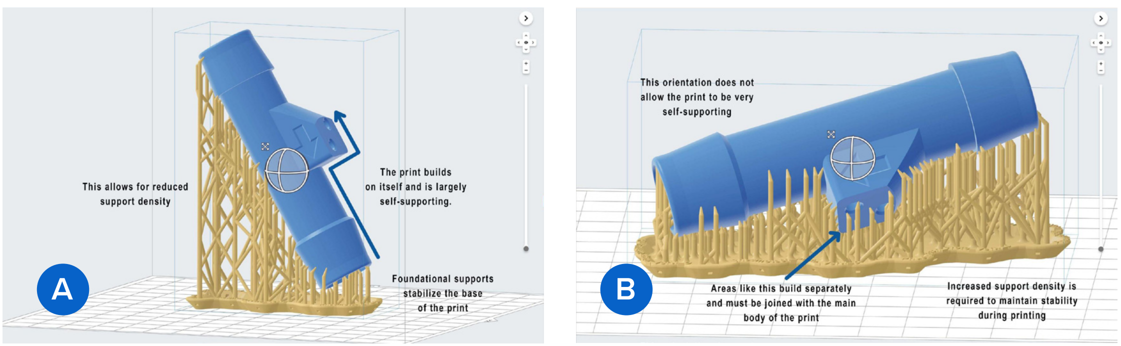
Check Scale

Select the part in PreForm, then click **Size**- the part's scale will be displayed. Confirm that the part is scaled properly.

Check Orientation

To avoid warping and maximize mechanical properties, parts should be oriented manually. Below are some orientation considerations to make when manually orienting, deviating from these practices increases the risk of print failure. More details on part orientation can be found here.

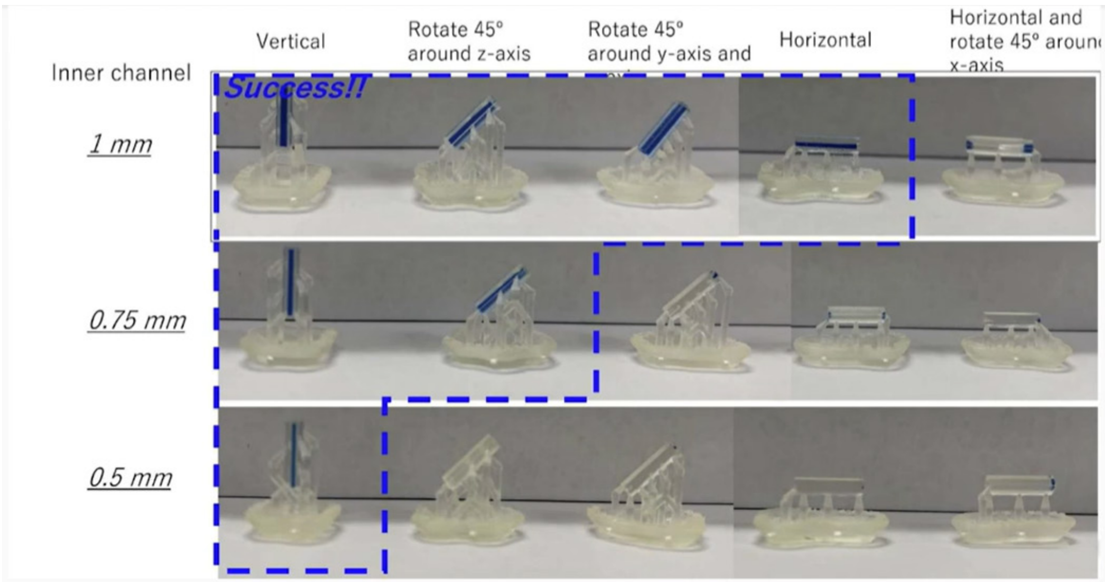
- Orient the part so that it is smaller at the base and then builds on itself. This decreases the likelihood that the print will break away from the supports during printing and increases stability. In these scenarios, support density and touchpoint size can be reduced further from the build platform (grid in PreForm).



Preferable (A) and less preferable (B) part orientation.

- Minimize the number of unsupported minima whenever possible.
- Aim cups away from the build platform (the grid in PreForm) to avoid filling with liquid resin while printing.
- Orient the thinnest part of the object away from the build platform (grid in PreForm) to decrease peel forces and lower failure rate.
- Channels should be oriented as vertically as possible. Below is a chart representing the success associated with channel prints of different sizes at different orientation angles.
- Flat surfaces should be oriented on a slight angle: This study conducted at the Mercer University School of Engineering suggests that a 60° angle is ideal for maintaining dimensional accuracy. Parts should be angled on more than one axis.
- If there is one side where supports are more acceptable than another, or where surface texture/fine details are less important, this side should be oriented towards the build platform (the grid in PreForm). Areas where supports are undesirable, such as a specific region of interest or surfaces intended to interface with patient anatomy, should be oriented facing away from the build platform to avoid having supports here.
- Aim to point junctions between two surfaces down towards the build platform (the grid in PreForm) to preserve dimensional integrity at intersections.

- Thoughtful orientation can sometimes be used to fit a large part, or multiple parts, onto one print. Choosing an orientation that reduces the size of the print in the x and y axis may allow you to fit more parts onto one build platform. Space-saving orientations are not based on maximizing print success, and thus increase risk of failure. Ensure proper support placement to compensate.
- Consider the mechanical stresses that your final part will be experiencing when orienting. [SLA parts are isotropic] (equally-strong in all directions), so this doesn't have to be a particularly strong consideration when printing with resin. It does, however, make a large difference when printing using SLS. When printing with powder, parts tend to be weaker in the z-direction.



Demonstration of success associated with channel prints of different sizes at different orientations.

Evaluate Supports

Once the size and orientation are set, supports can be added. For best results, supports should be placed manually. Less complex parts can be supported using the **Auto-Generate** function in PreForm, but all supports generated automatically should be reviewed thoroughly before printing. To evaluate supports, drag the slicer tool from bottom to top to view the build process. Check that all transitions from supports to part appear secure and have an even distribution. Look especially for unsupported protrusions, unsupported islands, unnecessary clusters of supports, and any visible layer stepping. Also check that any internal support material will be able to be removed after printing if necessary and that it is not located in hard-to-reach slots, holes, or channels. Less-rigid materials will likely require higher support density than more-rigid materials.

Confirm Proper Layer Thickness

Choose layer thickness by clicking on **Job Type** and scrolling down. For highest quality, ensure that the thickness chosen is the smallest possible relative to the amount of time allotted for printing (smaller layers will take longer to print).

Add Patient Identifiers

Patient identifiers should be determined using an internal case number or naming scheme. They can be added to the part's raft by double clicking the name of the part in the bottom right corner of the PreForm window and typing in the patient identifier as the part name. Make sure that **Raft Label** box is checked off under **Supports**. This patient identifier will then be printed on the part's removable raft, and be saved as the parts name in the online Dashboard. In some scenarios, it may be desirable to have the patient identifier embossed or etched into the printed part itself. In this case, the text must be added to the part in the CAD stage of the workflow. More information on best practices associated with patient identifiers can be found in the Resources and Additional Considerations section of this document.

Printing Environment

The printer should be kept on a level work surface, away from any potential source of dust or sparks. Optimal printing occurs within the ambient temperature range of 64–82 °F (18–28 °C). It should also be connected to an uninterrupted power source providing 100–240 V, 2.5 A, 50/60 Hz, 220 W. The printing and post-processing workspace and tools should be kept clean of debris and resin residue to ensure clean finished parts.

In almost all cases, the orange cover is sufficient for eliminating ambient UV light from the printing space. If you are printing small channels and are concerned about ambient light inadvertently curing resin within these channels, you may consider covering your printer with an opaque cloth.

Build Platform

The build platform should be inspected for the presence of any liquid or cured resin on the print surface. If liquid resin is found on the build platform, it should be removed using isopropyl alcohol and a paper towel. Cured resin should be removed using a paint scraper. It is common for the build platform to develop scratches over time. This is generally acceptable and can even improve adhesion to the print, however any obvious burs or sharp edges should be lightly sanded and removed. Lightly resurfacing the build platform with sandpaper is also acceptable but can have an impact on adhesion. Use of the Build Platform 2 can help ease part removal. For biocompatible applications, a single build platform must be dedicated to the biocompatible material in order to maintain biocompatibility standards. For non-biocompatible prints, it is safe to switch the build platform between materials as long as it is free of any liquid or cured resin.

Cartridge

Check for Leaks

Prior to using the cartridge, check the cartridge for any signs of leakage. If present, leakage can usually be noticed around the bottom edge or rubber bite valve.

Shake Cartridge

While not in use, shake resin cartridges every 1-2 weeks to ensure that resin remains thoroughly mixed and has not separated. Prior to printing, shake the cartridge for 1-2 minutes. Some resins contain pigments that can settle to the bottom and may need to be mixed for longer periods of time.

Check Bite Valve

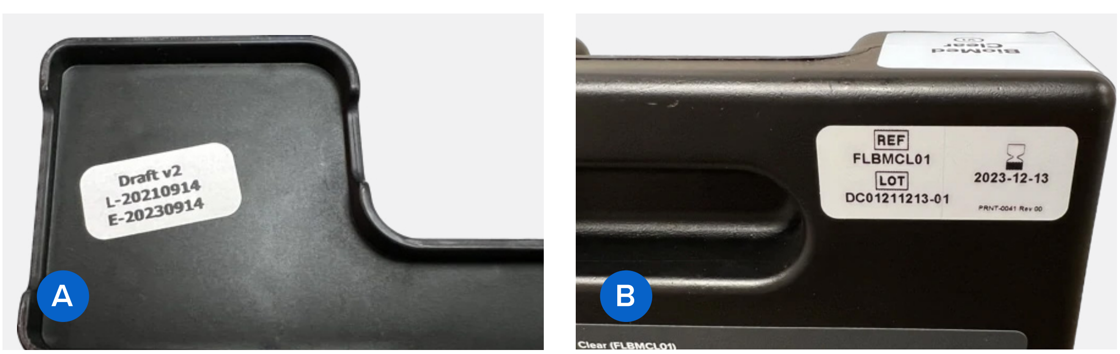
Ensure that the resin cartridge vent cap is closed and turn the cartridge over. On the underside of the cartridge, locate the black rubber bite valve on the bottom of the cartridge. Squeeze the bite valve several times against the hard shell of the cartridge until it appears unsealed and fully opened. If you are unable to manually open the bite valve, do not continue to use the cartridge without contacting Formlabs Services.

Location of the bite valve on the underside of the resin cartridge (A, B), and the bite valve being opened by hand(C).

Be Aware of Expiration Date

For general purpose resins, the production date is located on a white sticker on the bottom of the cartridge, and for BioMed resins, the production date is located on the upper right corner of the cartridge. Some third-party dental resins may have production dates located in different places, but in all cases the production date will be located on a white, rectangular sticker. The production date is the same as the lot number, which can be located in Dashboard by going to **Materials**, clicking on the cartridge that you are interested in, and looking under the manufacturing date.

Most resin has a shelf life of approximately 12 to 24 months. Using resin past its expiration date can result in compromised quality of printed parts and/or restricted resin flow which will cause the printer to throw a dispense error. Information on how to dispose of expired resin can be found here. High-volume users may consider dedicated post-processing equipment for disposal, such as devices from Onulis.



Location of the production date/lot number on a general purpose resin (A) and BioMed resin (B).

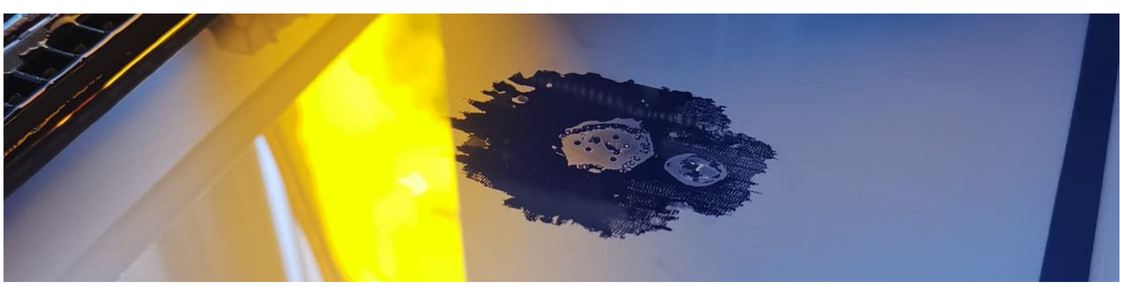
Tank

Check for Debris and Leaks

When installing a new tank for the first time, it is important to remove the foam inserts from all four corners. These inserts protect the tank during shipping, but can damage the printer if left on after the tank is in service. Once in use, the inside of the resin tank should be regularly checked for leaks using the tank tool or a plastic scraper to gently inspect the tank for cured resin adhered to the bottom or loosely mixed into the liquid resin. Do not use a metal scraper as that can damage the resin tank. If cured resin is found, the plastic scraper can be used to gently dislodge the cured resin from the bottom of the resin tank. A cleaning mesh can be printed for certain resins, see the section on Using a Cleaning Mesh under What to do Post-Failure. If many resin chunks are mixed in with the liquid resin and cannot be removed manually, then the resin may need to be filtered (more information on resin filtration available here).

Tank tool and plastic scraper. Do not use a metal scraper in your resin tank.

The inside bottom of the resin tank should be visually inspected for signs of damage, pitting, transparency (also known as “optical coupling”), spotting, or ripples, which can also compromise print quality. Transparency is normal on the Form 2 tank, but not on a Form 3 or Form 3L. If transparency or transparent patches are identified in a Form 3 tank, the tank should be discarded immediately. You can gain a better view of the inside bottom of the resin tank by using the plastic scraper to sweep liquid resin to the side.



Example image of optical coupling in a Form 3 tank.

The bottom of the tank should also be visually inspected from the outside for signs of contamination, fingerprints, smudges, or other signs of wear on the transparent layer. On a Form 3 tank, the film should appear uniformly cloudy. On a Form 2 tank, uniformly clear. Puckering and stretching at the edges of the plastic film is normal and a natural result of tensioning the film over time. If fingerprints or smudges are identified, the underside of the bottom layer can be gently cleaned using photographic wipes (PEC-PADs) and Isopropyl Alcohol. Place the wipe flat on the transparent layer and wipe slowly from one side to the other in a straight line. Repeat in overlapping straight lines until the entire transparent panel is free of streaks or other optical contamination. Getting help from another person can help to avoid resin spills. If a spill has occurred, this process should be followed to clean the printer.

Cleaning the bottom of the tank using photographic wipes (PEC-PADs) and Isopropyl Alcohol.

To increase tank life, it is recommended that you store resin in a separate, opaque container, instead of storing in the tank. We recommend wide-mouth opaque HDPE or polypropylene bottles; containers made of other materials may leak. It is not recommended that the same tank be cleaned for use between multiple materials as this is likely to lead to contamination and print failures. It is best to limit each tank to one type of resin. For biocompatible applications, a single tank and set of tools must be dedicated to the biocompatible material in order to maintain biocompatibility standards.

Filling the Tank Manually

The viscosity of some materials may cause a timeout error due to the long fill time required. If this occurs, the user can partially fill the tank manually using a second cartridge of resin to speed up fill time. After the tank is placed inside the printer, use gloves to unscrew the cap on the top of the resin cartridge and pour directly into the tank. Depressing the bite valve while pouring will allow it to pour smoothly.

Be Aware of Expiration Date

Pay attention to printer warning notifications that your tank may be approaching or exceeding its intended lifetime. A tank that has exceeded its intended lifetime is likely to leak into the printer, affecting the quality of current and future prints. To check the remaining lifetime of a resin tank, insert the tank into your printer and tap the printer icon on the printer's touchscreen. The printer's current status will appear. Tap the section of the touchscreen labeled with the tank type to go to the Tank Details screen. Here you will see a report of the resin tank's remaining lifetime. Resin can be transferred from an old tank to a new one.

Post-Processing

Support Removal

Supports can be removed before the the cure step. Removing supports after curing is more difficult, but can help avoid warping if warping while curing is a concern. Most supports can be removed by hand, but pliers, tweezers, flush cutters, and sandpaper can be used to ease the process and produce a smoother surface. The Formlabs Finishing Kit has tools to aid this process. Remember to wear eye protection and aim tools away from yourself while removing support material.

Wash and Cure

Parts must be completely dry of IPA before curing. This can be done by allowing the IPA on the surface of the part time to evaporate, or manually drying using compressed air or paper towels. If parts are not dry before the start of the curing process, warping is likely to occur. If IPA remains in parts intended for sterilization, additional damage is likely to be done to the model during sterilization. If parts that are intended for sterilization have small features that are likely to hold IPA, a low-temperature dehydration may be added to the workflow between the wash and cure stages to ensure that any remaining IPA is removed.

Before curing, you should also make sure that any small holes or channels are free of residual resin. In some cases, a syringe, pump, or squeeze-bottle may be used to force air or IPA through the channel to clear it. In cases where warping during curing is a particular concern, you should consider creating a jig, clamp, or brace to support your part during the curing process. You may also use a two-part curing process (first cure for 15-30 min without heat, then use recommended settings).

Caution should be taken not to overwash, underwash, overcure, or undercure printed parts, as too much or too little time post-processing can lead to compromised material properties or warping. Recommended post-processing guidelines are material-specific and can be found here. The post-processing instructions in the instructions for use (IFU) manufacturing guide for BioMed/Dental resins should also be followed to maintain biological safety. The IFU library can be found under **User Manuals** here.

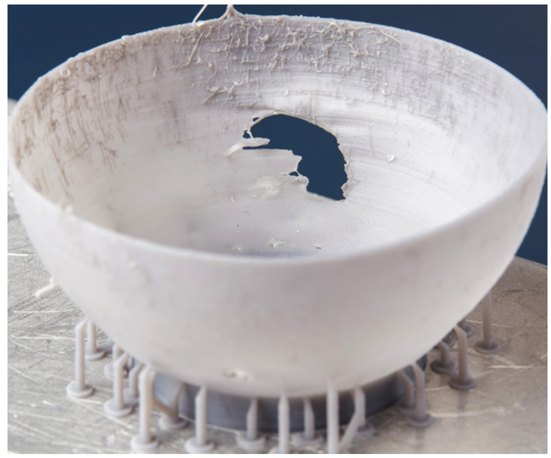
Part Review

After washing and curing, all parts should be visually inspected for signs of non-adherence to the build platform, delamination, cupping blowout, undeveloped features, pinholes, cuts, overcompression, poor surface quality, incomplete or uneven curing, or resin left on the surface or in channels or small features. More information on these issues and others can be found here.

Parts should also be reviewed with the original parameters established by the clinical team in mind. Ideally, these parameters should be turned into a checklist that the reviewing personnel can use to guide their inspection. This checklist can also include other good practices, such as checking for the presence of patient identifiers, or dimensional accuracy. In point-of-care settings, finalized parts should ideally be signed off by an individual with the most applicable knowledge to judge part quality.

QUALITY CHECKS & CADENCE

Printers can be kept in good working order by doing proactive inspection, regular calibration, and scheduled maintenance. In addition to the daily Standard Workflow Checks mentioned above, weekly and quarterly scheduled maintenance and calibration should also occur. More information on scheduled maintenance is available here. Our Medical Service Plan can also support your quality checks by reviewing your equipment diagnostics automatically every six months.



Print failure example.

IQ/PQ/OQ

Forms designed to help track IQ/OQ/PQ (installation qualification, operational qualification, performance qualification) for the Form 3B/3BL, Form Wash and Form Cure are available for Form 3B/3BL users upon request. These editable forms are meant to serve as guidelines for general calibration documentation, but should be modified to fit the specific verification needs of your lab.

Weekly

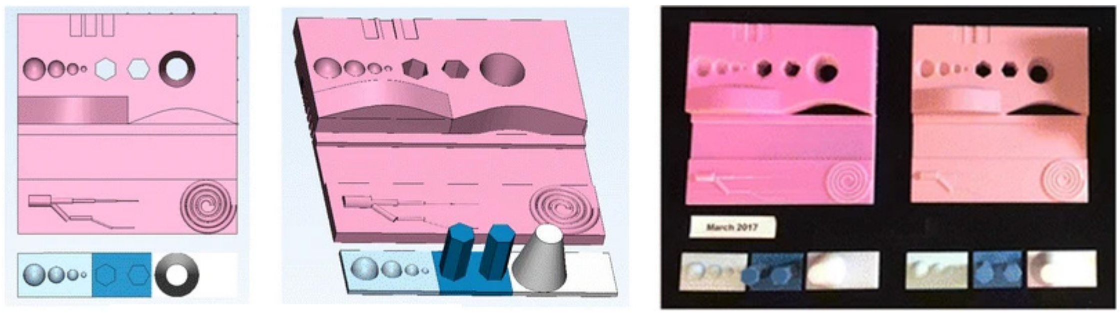
Form 3 Optics Test

The Form 3 optics test is part of scheduled maintenance and should be run weekly, if not daily, to anticipate printing errors before they arise. We encourage running this test with standard resins whenever possible. Some users find it valuable to keep a cartridge of standard resin on hand just for this purpose, but it can still provide valuable information regarding your printer's function when run using some non-standard resins as well. Details on anticipated results from the Form 3 optics test for standard resins can be found here, please note that results for non-standard resins are likely to vary.

This test takes approximately 1-2 hours to run and is designed to test areas all across the build platform with unsupported geometry. To run the Form 3 optics test, first download the optics test FORM file. This test is designed to be printed directly on the build platform at a layer thickness of 100 microns, so ignore all printability warnings and do not modify or add supports. Print, then wash with parts still attached to the build platform. After the build platform is washed, parts should be inspected for shadowing, non-adherence, delamination, cupping blowout, undeveloped features, pinholes, cuts, overcompression, or poor surface quality.

The results of all tests should be documented for future reference. If any of the errors listed above are identified during the optics test, we suggest that you submit a support request for the failed print and be aware that, until remedied, that printer is unlikely to produce top-quality parts.

In many cases, users may prefer to custom design their own coupon that better represents common geometries specific to their printing application, or better demonstrates the function of their non-standard resins. A great example of a custom coupon is this QA phantom created by Mayo Clinic. The quality of each printed coupon should be documented to gain a long-term understanding of the printer's performance. Some features to have in mind when designing a custom phantom are; time required to print the part (or 5 of the part, if you're looking to investigate accuracy across the build platform), materials frequently used, supports required/not required, arches and curvatures, positive and negative features, holes and channels, tapers, fine details, surface finish, specific geometry for common applications, and more.



QA Phantom designed by the Mayo Clinic.

Quarterly

Optical Window

Inspect the optical window for contamination, including dust, resin, spots, streaks, clouding, finger prints, or other signs of wear on the optical glass. To inspect the optical window, remove the build platform, resin tank, and cartridge from the printer. Go to the printer's settings menu (the wrench symbol) and touch **maintenance** > **motor moves**, then hold left until the LPU housing is centered in the printer cavity. Once the LPU housing has been moved, use a flashlight to inspect the optical window for any signs of contamination. If contamination is identified, clean the glass surface with dry photographic wipes (PEC-PADs) and a rubber bulb air blower. Lay the wipe flat against the glass and wipe in a straight line from one side to the other slowly. Repeat in overlapping wipes until the surface is clean. If dry wipes are not sufficient, you may apply small amounts of IPA to the photographic wipe to help loosen up surface contaminants, but be aware that too-frequent use of IPA can degrade the optical window over time.

Optical window being inspected with flashlight.

PreForm

Check that you are using the latest version of PreForm by following **Help** > **About PreForm** in the menu bar. Update if necessary. Prior to updating, we recommend checking out the release notes on this support page to gain an understanding of what the update entails, decide whether or not it is necessary for your applications, and document any changes made. Some of the new features associated with updates may require changes to your SOPs, IQ/OQ/PQ, and other standardized procedures. Before the release of any new software that affects the printing process, Formlabs internally validates all changes by testing for consistent reliability and accuracy, but some changes may call for revalidation within your institution as well.

Form Wash

The resin concentration of the IPA in your Form Wash should be checked periodically- the necessary frequency will depend on how often your unit is used. If the printed parts feel tacky after washing and curing, this is a good indication that the resin concentration is too high and the IPA should be replaced. To check the resin concentration in your IPA, use the hydrometer that came with the Form Wash, or the solvent monitor in the Form Wash L. Detailed instructions on using the hydrometer and solvent monitor can be found here.

To extend the life of your IPA, you may consider using a 2-part wash system; a pre-wash using old IPA, and a post-wash using new IPA. To create a pre-wash using old IPA, let the old IPA sit overnight to separate. Cleaner IPA will rise to the top and concentrated IPA will settle to the bottom. Using the siphon that comes with the Form Wash, move the top layer or IPA into a separate, sealable container. This will become your pre-wash. The bottom layer can be disposed of. By rinsing your parts in a pre-wash bath, an initial portion of residual resin will be removed and the life of the clean IPA will be extended.

Firmware

Confirm that the printer firmware is up to date. You can do this in PreForm by clicking < on the right panel to open it, then clicking on the **Printer Type** box to view all of your devices. In the upper right corner of your devices list, click on **Manage Devices**, and then the device you are looking into. Click **Update** in the upper right corner to see if your printer is outfitted with the latest firmware, and consider updating it if it is not. Like PreForm, we recommend checking out the release notes on this support page prior to updating to confirm that none of the new features associated with the update require changes to your SOPs, IQ/OQ/PQ, or standard operating procedures, and decide if the update is necessary for your applications. These notes can be used to document changes to the firmware over time, and determine if revalidation is necessary.

ENSURING PRINT ACCURACY AND DIMENSIONS

The following are steps that we recommend taking to ensure the best accuracy and dimensions for your printed parts. The concepts presented in this section may also benefit SLS workflows on the Fuse 1+, as well as other methods of additive manufacturing. We suggest picking and choosing what methods may work best for your purposes, as not all of these methods are applicable to all settings and applications.

Test Cube

The purpose of the test cube is to serve as a safety check that can be incorporated into every print. It is not meant to replace scheduled maintenance.

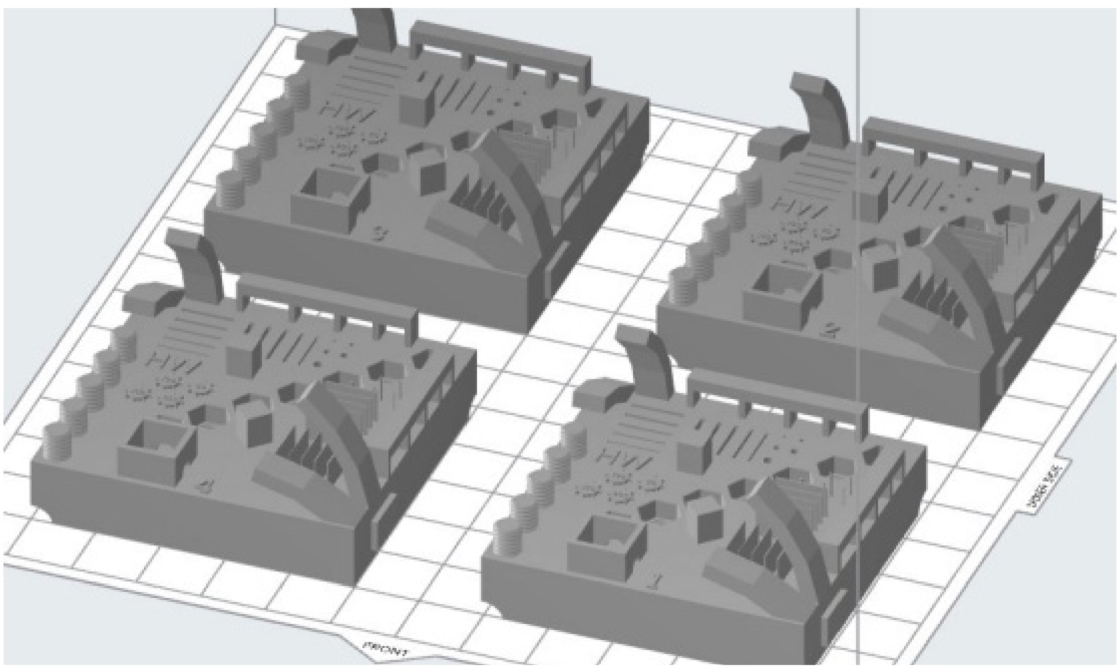
Prior to printing, a solid cube of known, standard dimensions can be added to the build next to the part in PreForm. The test cube should be printed directly on the build platform with no tilt or support material. It is advisable to vary the location of this calibration cube with each print to check for variability in different areas of the build platform. This test cube can be measured with digital calipers after printing and post-processing to confirm that its dimensions haven't changed throughout printing or post-processing. It can be assumed that if the test cube is significantly warped or otherwise not matching dimensional expectations, then the more complex part is erroneous as well. Steps should be taken to investigate the cause of the error and the part should be reprinted with an unaltered test cube before use.

Test cubes can vary in size and should be selected to reflect the geometry of the more-complex part, but we generally recommend dimensions close to 15mm x 15mm x 15mm. The University of Cincinnati had success conducting this study with a slightly larger test cube. This size allows for easy measurement with calipers without significantly adding to the print time. We also recommend labeling the X, Y, and Z planes on the test cube for troubleshooting purposes if an error occurs.

The amount of acceptable error may vary per application. Higher-risk applications call for greater dimensional accuracy than lower-risk applications; parts like surgical guides likely need to be more accurate than anatomical models used for diagnostic purposes (Ravi et al., 2021).The amount of risk associated with the application and the acceptable dimensional accuracy should be determined at the beginning of the workflow. Below is a table of anticipated dimensional inaccuracies for BioMed Black and BioMed White materials as determined by the Formlabs settings optimization team. This data was collected using the test feature pictured below. Each test contains two features for each 1 mm, 4 mm, 9 mm, 27 mm, and 50 mm dimension, measured in the XY direction. The table displays the average deviation from the ideal, or perfect, print for each intended feature size. It should be noted that some minor variability may occur in the z-direction due to over-compression of the first few print layers. This is normal to ensure proper adhesion with the build platform, but can slightly affect parts printed directly on the build platform.

INTENDED SIZE (MM)	AVERAGE DEVIATION	STANDARD DEVIATION
BIOMED WHITE, 50 MICRONS		
1	0.02	0.05
4	0.01	0.05
9	0.01	0.06
27	-0.03	0.05
50	0.05	0.08
BIOMED WHITE, 100 MICRONS		
1	-0.03	0.03
4	-0.03	0.05
9	-0.03	0.03

INTENDED SIZE (MM)	AVERAGE DEVIATION	STANDARD DEVIATION
27	-0.09	0.05
50	0.1	0.08
BIOMED BLACK, 50 MICRONS		
1	0.01	0.04
4	0.01	0.04
9	0.05	0.04
27	0	0.04
50	0.2	0.04
BIOMED BLACK, 100 MICRONS		
1	0.08	0.02
4	0.08	0.02
9	0.1	0
27	0.01	0.02
50	0.05	0.02



Test fine used to determine BioMed Black and White accuracy.

Measurement with Digital Calipers

For parts that use minimal organic shapes or have strong reference geometry, digital calipers can be used to measure key features and compare back to the measurements of the original STL/OBJ/3MF. In some cases, it may be acceptable to insert reference geometry artificially to mark the start and end points of measurements in the STL/OBJ/3MF and on the printed model. For specific geometries that digital calipers are not suited for (i.e. perimeters), a string or wire and a ruler can be used. Be aware that these methods are likely to introduce some additional error.

Parts should have measurements taken in three orthogonal planes. Knowing that an error has been isolated to a specific plane can assist with troubleshooting.

Measuring Complex Organic Shapes

Measuring complex organic shapes can be a little more challenging. One method to address the accuracy of a printed part's organic shapes is to use photogrammetry. In this study by Odeh et al. at the University of Central Florida, digital photos of the printed parts were taken with a small ruler in the frame and uploaded into an image analysis software (we recommend ImageJ). Within the software, measurements of organic shapes can be measured 2-dimensionally using a pixel/distance ratio, and the exact location of these measurements can be recorded using screenshots of the measurement. These screenshots can then be imported into another 3D graphic program that allows vertex-to-vertex measurement of the original STL/OBJ/3MF By overlaying the measurement screenshot and the STL/OBJ/3MF, you are able to see the exact points on the organic shape where the printed part had been measured and recreate the same measurement on the original STL/OBJ/3MF for comparison.

CT scanning and MRI can be used to assess accuracy of printed parts, and is preferable if the part contains internal structures. These methods often require a custom stand to hold the printed part in the desired orientation during the scan. Once a part has been scanned, the resulting DICOM images can be compared to the original DICOM images to ensure accuracy of the printed part. Users without access to an in-house CT may consider more accessible options such as Lumafield.

Similarly, if an external scan was used to create a part, the printed part can be scanned and imported into the viewing software with the original scan for visual comparison.

Another method for checking the dimensional accuracy of frequently-printed organic shapes is a positive/negative fit test. If the same complex geometry needs to be measured often, time can be saved by printing a solid block with the complex geometry removed and left as negative space. Measurements of that negative space should be taken to ensure that those dimensions are accurate, ideally by CT scan or MRI. Once that negative-space has been confirmed to be accurate, that negative-space block can be fit over future prints and assessed for gaps or tightness to quickly confirm if the positive print is properly sized. One final method is to add opposing measurement planes to your organic model. These flat planes provide a position for placing your digital calipers with a known length that can be verified in your CAD software. In practice, these will look like small cubes positioned or merged on each side of the model where you wish to check the scale.

Checking Accuracy Against Scans/DICOM Images

Finalized STL/OBJ/3MFs may be imported back into the original segmenting or viewing software for a final visual check that STL/OBJ/3MF parts match the original anatomical imaging, especially if an automatic segmenter was used. Once imported, the STL/OBJ/3MF should be reviewed by a radiologist in the axial, coronal and sagittal planes. Knowing which plane an error has occurred in can assist with troubleshooting.

If the STL/OBJ/3MF was created based off of an external scan, the printed part could be scanned and uploaded to the original viewing software for visual comparison. If the external scan was produced based on a plaster cast (a method sometimes used in cases of pediatric orthopedic fittings), the printed part should be visually inspected in comparison to the original cast digital caliper measurements should be taken from both.

Mechanical Property Accuracy

A summary of all of Formlabs' materials and their mechanical properties can be found here. It can be assumed that these properties will be achieved if all workflow suggestions provided by Formlabs are followed exactly. Most importantly, completed prints should not be left on the printer for excessive amounts of time. The wash and cure time and temperature suggested per material should not be exceeded or shorted, and sterilizable materials should only be sterilized with modalities and cycles tested and validated by the device manufacturer while considering sterilization compatibility test reports from Formlabs. Resin also must be used within its expiration date and shaken before use.

WHAT TO DO POST-FAILURE

A print failure can often leave partially-cured debris behind on the build platform or tank. The following steps should be taken to prevent this post-print failure.

Build Platform

After a print failure, the build platform should be inspected for the presence of any liquid or cured resin on the print surface. If liquid resin is found on the build platform, it should be removed using isopropyl alcohol and a paper towel. Cured resin should be removed using a paint scraper.

Tank

Cleaning the tank of partially-cured resin can be done manually, or using a cleaning mesh. More details on cleaning the tank post-print failure can be found here.

Manually

Cleaning of the tank manually requires use of the plastic tank tool, found in the Form 3 Finishing Kit. Avoid using sharp or metal tools to clean the tank as they can damage the film located in the bottom of the tank and compromise print quality.

Remove the tank and set it aside on a clean surface. Use the bottom half of the tank tool to skim the tank film's surface and feel for debris stuck to the film. If debris is found, pry from multiple angles with moderate pressure until the material is unstuck. While prying, be careful not to apply direct pressure to the film. Once debris is free, lift it out of the tank using the blade of the tank tool. If the debris is too big to balance on the blade of the tank tool, use the other half of the tank tool to sandwich the piece of debris and squeeze the debris between the tank tool's two ends.

Using a Cleaning Mesh

The cleaning mesh feature is available for most resins and can be used to bind together small resin debris that is hard to pick up with the tank tool. It takes 20 minutes to run. To start printing a cleaning mesh, make sure that your printer is in an idle state, and that the resin cartridge that was in use when the print failed is currently inserted. On your printer, go to **Settings > Maintenance > Cleaning Mesh > Clean**. The build platform will not lower into the tank while the cleaning mesh is printing. Once the cleaning mesh is done being printed, remove it manually using the tank tool by following the steps listed above. More details on the cleaning mesh, as well as the list of resins capable of printing the cleaning mesh, can be found here.

If the debris left in the tank is too fine to be removed manually or with a cleaning mesh, you can filter the resin using a paint or oil filter. More on that process here.

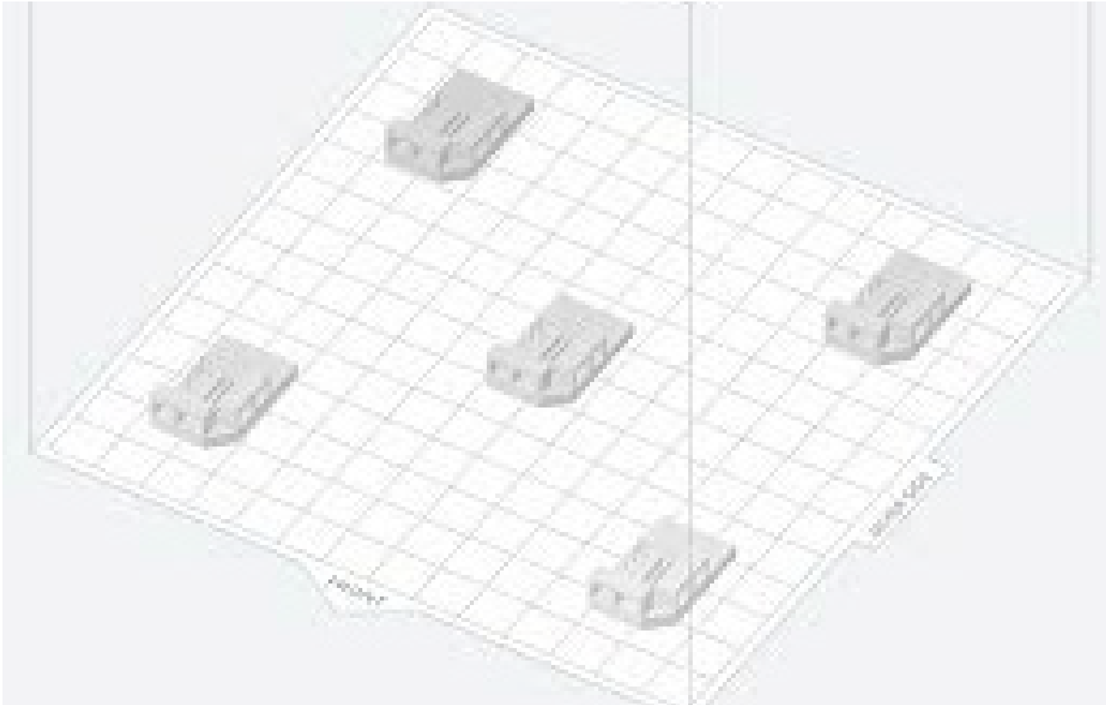
Cleaning mesh and tank tool being used to remove resin debris from the tank.

The tank's mixer may decouple as a result of a print failure. If it appears that the mixer has decoupled, it can be manually reseated by orienting it with the arms facing up and towards the right, then placing it flat in the tank and pushing it all the way to the right side until the magnets engage.

After a print failure, the tank should be inspected for leaks or spills that may have caused, or resulted from, the failure. If a spill has occurred, this process should be followed to clean the printer.

Form 3 Optics Test

A Form 3 optics test should be run, ideally using a standard resin, after a print failure to check that the issue causing the failure has been corrected. Instructions for running this test can be found above in the Quality Checks & Cadence section of this document, and in greater detail here. The results of Form 3 optics tests should be documented for future reference.



Form 3 optics test.

Submitting a Support Request

If you cannot determine the reason for your failed print using the steps above, we recommend getting expedited support by contacting our medical services personnel via our Medical Support Plan. Our medical services team is ready to help with urgent questions via email or phone, and initiate expedited printer replacements when necessary. If you are not currently enrolled in the Medical Support Plan, you can get assistance by submitting a support request to our Formlabs support team. This request should include your machine's serial name, original order number, and photos of your print defects as long as they do not violate patient confidentiality.

Documenting a Failure

When a print failure occurs, it is important to document the details surrounding that failure for long-term troubleshooting. This documentation should include the printer's serial name, material used (including lot number), photos of the defect, as well as any other details that may be valuable for troubleshooting in the future. This documentation should ideally be kept with the IQ/OQ/PQ forms mentioned above. Valuable data regarding print failures can be found in the Dashboard by going to **Prints**, then **Export Data** in the upper right hand corner. This will create a CSV file of your print history, including successes and failures.

RESOURCES AND ADDITIONAL CONSIDERATIONS

Management Software

For large-throughput users, we recommend organizing print production with a 3D print-management software designed specifically for use in point-of-care settings. Using a devoted print-management software may be able to help with securing and anonymizing sensitive information, archiving past prints, submitting and receiving part orders, case management, setting roles and permissions, workflow management, scheduling, print optimization, delivery tracking, and quality assurance.

Exporting to CSV

Valuable data on print success and failure rates and lot numbers can be found in the Dashboard. Some users may prefer to download this information as a CSV for long-term tracking. This information can be downloaded as a CSV by going to **Prints**, then **Export Data** in the upper right hand corner. Those with software capabilities may request access to our Dashboard API by contacting Formlabs Healthcare team via email (healthcare@formlabs.com). More information on how to download print information as a CSV is available here.

SOPs

All high-throughput Formlabs users are encouraged to create standard operating procedures (SOPs) that are specific to their workplace and Formlabs usage. SOPs should include an outline of the repeatable steps required to successfully complete the workflow, and may include additional information such as purpose, PPE or required personnel. SOPs may also be used for the printing process generally, but can also be specified for often-repeated applications or materials. Having and following SOPs can result in more consistent print results and help troubleshoot errors when they occur.

Greenlight Guru

High-throughput medical users are also encouraged to create a system for documenting IQ/OQ/PQ and account for other regulatory affairs in their quality control systems. We highly recommend that these users turn to this ebook by Greenlight Guru and Formlabs for guidance on best practices regarding QA & RA in Medical Device 3D Printing. Greenlight Guru also offers SOPs for Formlabs equipment, tracking of internal training procedures for use of our technology, and organization of approvals and sterilizations in a format that is digestible for FDA compliance.

Part Summary Report

In a very comprehensive article titled Establishing Quality and Safety in Hospital-based 3D Printing Programs: A Patient-Focused Approach by the University of Washington School of Medicine, the team highlights the value of part summary report. This report contains any identification associated with the part, the ordering provider's name, and identifiers associated with the patient, and other details on the part's intended use and key features. This report is signed off by the final inspector and delivered to the provider with the part.

Electronic Health Records

For traceability purposes, STL/OBJs for patient-specific parts should be saved in the patient's electronic health record, as well as the original scan, segmentation, a photo of the part, and the associated PreForm file (including basic information on the part's material and printer).

Patient identifiers & HIPAA

For patient-specific parts, patient identifiers should be added to the raft or body of the part to eliminate any potential confusion and increase traceability. There are many ways to generate a patient identifier based on patient information, or randomly generated. Some current users base theirs on MRN (medical record number) or scan ascension number. Patient identifiers created using MRN must exclude PIH (protected health information). No matter the naming scheme, HIPAA (Health Insurance Portability and Accountability Act) requirements must be followed and patient confidentiality must be maintained. Formlabs cannot provide guidance with respect to HIPAA compliance. In some scenarios, it may also be useful to notate the location of the parts intended use (left side, right side, etc.) in the patient identifier as well.

Patient identifiers can be added to the part's raft by double clicking the name of the part in the bottom right corner of the PreForm window and typing in the patient identifier as the part name. Make sure that **Raft Label** box is checked off under **Supports**. This patient identifier will appear as the part name in the online Dashboard. Patient identifiers can also be engraved or embossed on the body of the part using CAD during the design phase.

Sterilization & Biocompatibility

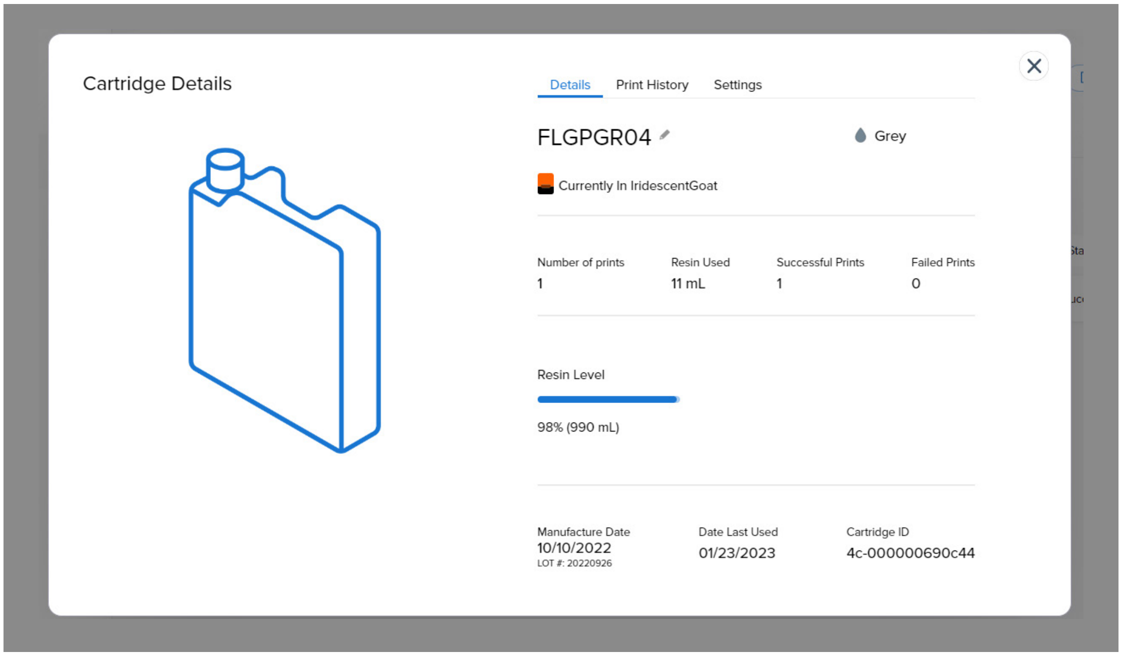
All biocompatibility and sterilizability claims should be re-verified in-house. For biocompatible applications, separate accessories (dedicated resin tank, build platform, and finishing equipment) must be maintained to comply with biocompatibility standards.

Parts that required sterilization should be sterilized in exact accordance with the material's sterilization instruction. Sterilizing materials that are not meant to be sterilized, or sterilizing sterilizable materials by other methods may lead to compromised material and mechanical properties. This study by the College of Surgery at Imam Abdulrahman Bin Faisal University suggests that steam sterilization has no effect on the dimensional accuracy of surgical guides made with Formlabs material. Sterilization reports for all of our BioMed resins can be found here.

Material Development & Resin Lot Tracking

Prior to the release of a new material, full validation testing occurs internally. This includes reliability testing (50 prints on 40 printers), in-depth print quality testing (12 test prints evaluating positive feature, negative feature, structural, functional, and accuracy/precision performance), medical specific testing, and application testing by external customers. Once a material's formulation has been locked, each batch produced is assigned a resin lot number. While the Optics test mentioned above should be sufficient for most customers' needs, details on the internal Formlabs material validation process can be found here.

Resin lot numbers should be documented for all resin purchased and used for traceability purposes. Each cartridge's lot number can be found on a sticker located either on the underside of the resin cartridge, or the upper right corner. The lot number is also available on the Dashboard. To find your resin lot number on the Dashboard, go to **Materials** on the left side of the screen, click on the cartridge that you are interested in, and look at the small number under the manufacturing date in the pop-up window. Additionally, a certificate of analysis and certificate of compliance for all materials are available upon request. More details on the quality system standards for our materials can be found here.



Screenshot of the Dashboard screen where the resin lot number can be found.

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