QIH AXIAL3D DIGITAL MODEL

INSTRUCTIONS FOR USE

Document ID: IFU-OPS-002, Version 2

Symbols & Manufacturer Information

LOT	Product reference Number	**MD**	Medical Device
Desc.	Product Description		Consult Instructions for Use
	Manufacturer		Cautions and Warnings
	Date of Manufacture		Device is "fragile" and should be handled with care
	Axial3D Alexander House 17a Ormeau Avenue Belfast, BT2 8HD	**R Only**	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

Introduction and Intended Use

INTENDED USE

Axial3D Insight is intended for use as a cloud-based service and image segmentation framework for the transfer of DICOM imaging information from a medical scanner to an output file.

The Axial3D Insight output file can be used for the fabrication of physical replicas of the output file using additive manufacturing methods. The output file or physical replica can be used for treatment planning.

The output file or the physical replica can be used for diagnostic purposes in the field of trauma, orthopedic, maxillofacial and cardiovascular applications.

Axial3D Insight should be used in conjunction with other diagnostic tools and expert clinical judgment.

CONTRAINDICATIONS

Axial3D Insight is not intended for use with Ultrasound and X-Ray imaging.

CAUTIONS AND WARNINGS

Axial3D Insight is intended for use by trained medical professionals for surgical planning in the following applications: trauma, orthopedics, maxillofacial, and cardiovascular.

The physical 3D printed model or digital file should be used in conjunction with expert clinical judgment and alongside the original DICOM images. Changes in patient anatomy may occur between the time of imaging and surgery, this may impact the performance of the 3D printed physical model, the patient should be assessed for changes in anatomical structures prior to the procedure.

The 3D printed physical models are not intended for sterilization or for use within a sterile field.

Fragments present in orthopedic models below 5 mm shall be removed from the digital file to be printed, this is to reduce the risk of these fragments breaking away from the model during post-processing practices

Users intending to 3D print digital files provided by Axial Medical Printing Limited must be able to follow post-processing and inspection guidelines provided by Axial Medical Printing Limited to ensure the diagnostic quality of the anatomical model. If these processes are not followed, the diagnostic quality of the final 3D printed physical model cannot be guaranteed.

Axial3D defines trauma as orthopedic trauma and craniomaxillofacial trauma including complex fractures in which the 3D images and associated physical models would be used for surgical planning. Fragments present in orthopedic trauma and craniomaxillofacial trauma models below 5mm shall be removed from the digital file to be printed, this is to reduce the risk of these fragments breaking away from the model during post-processing practices.

Please ensure that you are using the latest version of the supported browsers, and you have antivirus protection installed on your end user device. To access the service, all communication is via HTTPS, and only port 443 is required to be open. Any issues with the service will be communicated to you via your registered email address.

Technical Information

As Axial3D Insight is a web-based application, it is accessible via the listed compatible browsers, and operating systems capable of running those versions.

Safari, Microsoft Edge, and Google Chrome are available at a URL https://orders.axial3d.com

Conditions for Printing

3D printed physical models must be printed in line with the manufacturer's guidelines for the orientation, meeting the following requirements for each printing technology.

Anatomical models printed on Formlabs Form 3B, Form 3L and Form3BL printers must be printed in the following orientation for optimal print orientation layout.

- 3D model is angled at a 20 - 60 degree angle to decrease the amount of surface area in contact with the resin tank which in turn reduces the amount of force on the 3D printed physical models as the build platform raises with each layer as per Axial3D recommended Procedures *ref: WI-OPS-062 Preform Setup for Form3, 3B and 3L - Customer instructions*
- Orient the model to stand with the merging feature facing toward the build platform to create a shared base for branching features to grow from so that instead of layers coming together at a joint, the layers separate into individual paths
- Overhanging features are oriented to be self-supporting during the printing process
- The largest region of the model is elevated to be printed towards the mixer side to reduce print time for the final layers of the model.
- Post-print processes should be followed as per Axial3D recommended Procedures *ref: WI-OPS-063 Formlabs Post-processing - Customer instructions*

3D printed physical models printed on all Stratasys Polyjet printer:

- Insert STL file in the default position (File→ Add models)
- Arrange the model in the tray with an auto arrangement set.
- Assign material and send to printer recommended procedures *ref: WI-OPS-059 - Polyjet GrabCAD Print Scene Generation - Customer Instructions*
- Post-print processes should be followed as per Stratasys recommended procedures *ref: WI-OPS-061 - J5 Post-processing - Customer Instructions; WI-OPS-060 - J850 Post-processing - Customer Instructions*
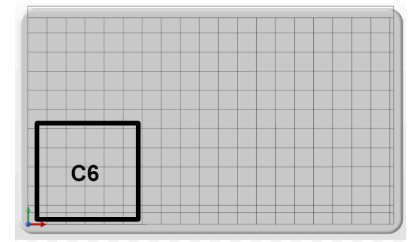
3D printed physical models printed on Stratasys DLP printer:

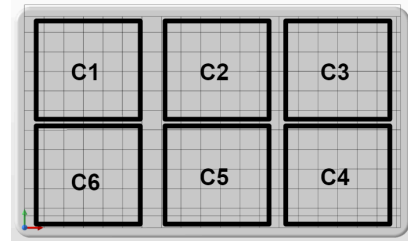| LOCTITE 3D 3172 printed models		
Best printing orientation	20 degrees (Y-axis)	
Best printing build plate position	Front Left hand side and back center	

ORIGIN DM100 by BASF printed models		
Best printing orientation	0 degrees (XYZ-axis), 90 degrees (Y-axis)	
Best printing build plate position	All locations on build plate	

ORIGIN DM200 by BASF printed models		
Best printing orientation	90 degrees (X-axis)	
Best printing build plate position	All locations on build plate	
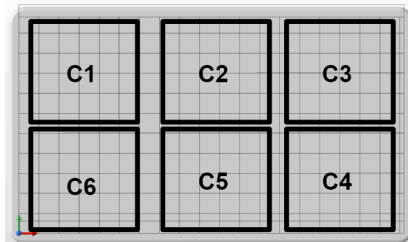
LOCTITE 3D 3843 printed models		
Best printing orientation	0 degrees (XYZ-axis) (Flat to the build plate)	
Best printing build plate position	Back left	
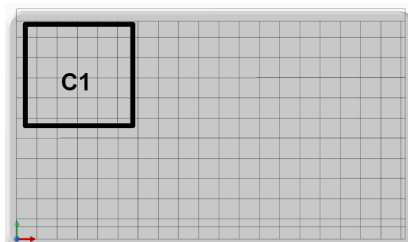
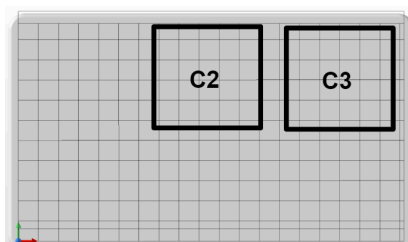| LOCTITE 3D IND405 printed models		
Best printing orientation	20 degrees (Y-axis) / 0 degrees (XYZ-axis)	
Best printing build plate position	Back center and right	

- *3D model is angled between 0 - 90 degrees depending on material type, to decrease the amount of surface area in contact with the resin tank which in turn reduces the amount of force on the 3D printed physical models as the build platform raises with each layer*
- *Orient the model to stand with the merging feature facing toward the build platform to create a shared base for branching features to grow from. Instead of layers coming together at a joint, the layers separate into individual paths*
- *Overhanging features are oriented to self-support during the printing process*
- *The model is to be elevated 5mm from the build plate*
- *Post-print processes should be followed in line with Axial3D recommended Procedures*

Post-processing DLP model
- Remove the build plate with the model from the printer.
- Detach the 3D printed model from the build plate.
- Remove printed supports from the model by hand or with Snips.
- Clean the parts by soaking them in a solution of IPA in an Ultrasonic bath, place the part in a container of IPA solution and place in Ultrasonic bath for 2 minutes.
- Remove the part from the IPA solution and place into a second container of IPA solution, place in the ultrasonic bath for a further 2 minutes.
- Wipe clean the model and air dry for 2-3 hours depending on the size of the part
- Place the part in the Dymax ECE5000 UV Cure
- Press the curing button and cure the model for:
  o Small models: 2 minutes turning every 30 seconds.
  o Large models: 6- 8 minutes turning every 30 seconds.
- The part will need to be rotated during the cure process to ensure all sides are fully cured.
- Sand down any support bumps using 600 grit sandpaper.

3D printed physical models printed on HP printers

When parts are added to the printer, the application automatically checks that the parts satisfy various conditions:

- Inbounds: ensuring parts are positioned within the build volume
- Closed mesh:
- Correctly oriented: orient each part by placing its critical features on the horizontal XY-plane as this will provide the highest resolution.
- Orientation: Place small features such as pins, holes, and thin walls upside-down on the XY plane to improve their look, feel, and strength. This also applies to raised texts, which should be printed on the XY-plane for maximum resolution
- Topologically valid: Are the parts printable? Parts beyond the boundaries of the build volume are considered out-of-bounds.
  Out-of-bounds parts can usually be fixed by clicking Auto-pack, or by manually moving the out-of-bounds part into the build volume. Parts with holes, troublesome orientations, and topologically invalid parts can be fixed by clicking Auto-Pack

- Remove the build unit from the printer after printing the parts
- Allow models to cool for the recommended time based on volume

| Build chamber | Printing time | | Safety cooling time | Natural cooling time | | Fast cooling time * |
	Fast print mode	Default/Strength print mode		Normal	Minimum *	(in systems with fast cooling integrated)
100% full	10 h	16 h 20 min	20–30 min	46 h	31 h	10 h
75% full	7 h 30 min	12 h 15 min	20–30 min	35 h	23 h	8 h

| Build chamber | Printing time | | Safety cooling time | Natural cooling time | | Fast cooling time * |
	Fast print mode	Default/Strength print mode		Normal	Minimum *	(in systems with fast cooling integrated)
50% full	5 h	8 h 10 min	20–30 min	23 h	16 h	6.5 h
25% full	2 h 30 min	4 h	20–30 min	12 h	8 h	5 h

- Once models have been cooled you must clean the parts to remove the thin layer of material attached to the surface.
- To do this, you need a bead-blasting machine. HP recommends a bead-blasting machine with the following specifications:
- Manual or automatic operation; Air pressure in the range of 2–5 bar (29–72.5 psi); Glass beads of 70–110 μm diameter (0.00276–0.00433 in)
- This process consists of shooting an abrasive media, usually a bead (size and type results in different surface finishes), at high pressure at a printed part with compressed air, thereby knocking loose unfused powder while also smoothing the finish of the part.

If these recommended guidelines cannot be met, models will not be within the quality parameters.