Axial3D Insight Operator Manual - QIH

IFU-OPS-006

Version 1

AXIAL3D

Table of contents

1. Description of Axial3D Insight

Axial3D Insight is a secure, highly available cloud-based image processing, segmentation and 3D modeling framework for the transfer of imaging information to either a digital file or as a 3D printed physical model.

Axial3D Insight is made up of a number of component parts, which allow the production of patient-specific 1:1 scale replica models, either as a digital file or as a 3D printed physical model.

2. Indications for 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 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.

3. Contraindications

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

4. 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.

5. Validation of 3D printed models

The validation of the physical printed models was completed by CT scanning the physical 3D printed model with a 0.67 mm slice spacing on the Philips Brilliance iCT 256 CT Scanner and compared with the original DICOM data. The Philips machine used in the validation testing is the following FDA cleared device:

Name: System, X-Ray, Tomography, Computed
Product Code: JAK
Regulation No: 21 CFR 892.1750
Class: 11 Panel: Radiology

6. Instructions for use

6.1. How to Register an Account on Axial3D Insight

- Visit **https://orders.axial3d.com/login**
- Click on Register an account today (at bottom of page)

- Enter all information requested on page:
    - **Title**
    - **First Name**
    - **Last Name**
    - **Telephone Number**
    - **Email**
- **Password** (Requires at least 8 characters with at least 1 letter, 1 number, and 1 special character)
- **Confirm Password** (must match previous Password Entry)
- Click the Box to **Accept Axial3D Terms of Use and Privacy Policy** (Click on Terms of Use and Privacy Policy to read)
- Click to **Sign up** for exclusive offers and 3D printing advice (Optional)
- Click **Submit** on bottom right of page to complete registration.
- The next page will provide the following message:

Email Confirmation

Thank you for signing up.

Please check your email and click on the Account Confirmation link sent to yourname@email.com This link will expire in 24 hours.

Once you have confirmed your account, you can start to use our 3D printing platform.

*If you need help verifying your account, contact us at support@axial3d.com or call us on **+1 857 412 7244 (US) / +44 (0) 28 9018 3590 (UK/EU)***

You must confirm your email via the link you will receive from Axial3D in your Inbox. This step must be completed to gain access to the Axial3D Platform.

6.2. How to Request a model - Uploading DICOM images Now

- Visit **https://orders.axial3d.com/login**
- Enter **Email** and **Password**
- Click **Login** at the bottom of the screen
- Click **Create Order** at top left of the main menu to enter the order catalog

- **Choose a speciality** in the upper left of your screen by clicking on the **Down Arrow** ⌄ for the drop down menu to navigate to your area of expertise
    - Navigation of the Catalog is easy, move between menus to see the options Axial3D provides
- Once you have found your solution, simply click on the **Item** to begin the ordering process
- Choose **Order Type** (hovering over the question mark of each type will provide an explanation of each option)
    - **3D Visual**
    - **3D Print-Ready File –** will include a 3D Visual
    - **3D Mesh –** will include a 3D Visual
    - **3D Print –** will include a 3D Visual
- Provide **Patient Birth Year** (this will help you identify your order)
- Provide **Patient Gender** (this will help you identify your order)
- Provide **Date Required** (this is the date you need the finished product to be delivered)
    - **3D Print** will have a longer completion time due to the printing (based on model complexity) and shipping of the model
- Provide **Details** of Surgery/Pathology/Case
    - Describe the surgery, clinical pathology, or use case of model
    - The more detail provided the quicker the Axial3D team can start producing the model
- Provide **Details of 3D Model** Customization
    - Provide as much detail as possible specific to your request
    - Any specific areas to focus, any color requirement, any cuts needed, any areas to not include, type of resin needed (for physical prints), how you plan on using the model, will you be cutting or drilling into the model
- Enter the complete **Shipping Address** the model should be delivered to (or choose from any previous address if you have previously ordered)
- When finished, click **Continue** at bottom left of screen

  - This will create your order and on the next page in the upper left you will see your order number and catalog item selected

- If you have your Images to Upload, click on **Yes, Upload Local Files**
- Open the folder on your computer (or disk) where the files are located
- **Highlight all DICOM images** (.dcm)
  - Do not include the DICOM viewer
  - We also accept compressed ZIP format folders of .dcm files
- Drag the files onto the Screen in the area marked **Drag and Drop to Upload Files**
  - You can confirm the number of files matches at the right of your screen in the summary
- Click **Start Upload** (once you confirm you have the correct number and type of files)
- It is important to keep the next page up open and not navigate away from this in your browser while the files upload
  - The upload screen will provide you the progress of the upload
  - When completed, the Upload Progress will be 100% and a Pop-up will display saying you have successfully uploaded for order number (RC)PXXXXX
- Click **View Order**
  - You will be taken to the summary page of the order just created
  - Navigate back to My Orders table by using the back arrow  top left of the page
- Your order will now also be accessible from the table accessed at My Orders from the main menu

6.3. How to Request a model - Uploading DICOM images Later

- Visit https://orders.axial3d.com/login
- Enter **Email** and **Password**

- Click **Login** at the bottom of the screen
- Click **Create Order** at top left of the main menu to enter the order catalog
- **Choose a speciality** in the upper left of your screen by clicking on the **Down Arrow** ⌄ for the drop down menu to navigate to your area of expertise
    - Navigation of the Catalog is easy, move between menus to see the options Axial3D provides
    - If you don't see what you are looking for, you can select **Alternative Pathology** and we will work with you to create a custom solution to meet your needs
- Once you have found your solution, simply click on the **Item** to begin the ordering process
- Choose **Order Type** (hovering over the question mark of each type will provide an explanation of each option)
    - **3D Visual**
    - **3D Print-Ready File** – will include a 3D Visual
    - **3D Mesh** – will include a 3D Visual
    - **3D Print** – will include a 3D Visual
- Provide **Patient Birth Year** (this will help you identify your order)
- Provide **Patient Gender** (this will help you identify your order)
- Provide **Date Required** (this is the date you need the finished product to be delivered)
    - **3D Print** will have a longer completion time due to the printing (based on model complexity) and shipping of the model
- Provide **Details** of Surgery/Pathology/Case
    - Describe the surgery, clinical pathology, or use case of model
    - The more detail provided the quicker the Axial3D team can start completing the model
- Provide **Details of 3D Mode**l Customization
    - Provide as much detail as possible specific to your request
    - Any specific areas to focus, any color requirement, any cuts needed, any areas to not include, type of resin needed (for physical prints), how you plan on using the model, will you be cutting or drilling into the model

- Enter the complete **Shipping address** the model should be delivered to (or choose from any previous address if you have previously ordered)
- When finished, click **Continue** at bottom left of screen
    - This will create your order and on the next page in the upper left you will see your order number and catalog item selected
- If you don't have your Images to Upload, click on the **Axial3D Logo** ⌄ in the upper left of the screen to return to the main menu, and choose **My Orders** to view your latest order

When you do gain access to your Images

- Click on the **Down Arrow** ⌄ next to the order number (RC)PXXXXX
- Click on the 3 Vertical Dots ⋮
- Choose **Add DICOMs**
- Open the folder on your computer (or disk) where the files are located
- **Highlight all DICOM images** (.dcm)
    - Do not include the DICOM viewer
    - We also accept compressed ZIP format folders of .dcm files
- Drag the files onto the Screen in the Box stating Drag and **Drop to Upload Files**
    - You can confirm whether the number of files matches t the right of your screen in the summary
- Click **Start Upload** (once you confirm you have the correct number and type of files)
- Keep the next Page up while the files upload
    - The upload screen will provide you the progress of the upload
    - When completed, the Upload Progress will be 100% and a Pop-up will display saying you have successfully uploaded for order number (RC)PXXXXX
- Click **View Order**
    - You will be taken to the summary page of the order just created
    - Navigate back to My Orders table by using the back arrow ‹ top left of the page or select **My Orders**

- Your order will also now be accessible from the table accessed at My Orders from main menu

6.4. How to order - For PACs Integration

- Visit **https://orders.axial3d.com/login**
- Enter **Email** and **Password**
- Click **Login** at the bottom of the screen
- Click **Create Order** at top left of the main menu to enter the order catalog
- **Choose a speciality** in the upper left of your screen by clicking on the **Down Arrow** ⌄ for the drop down menu to navigate to your area of expertise
    - Navigation of the Catalog is easy, move between menus to see the options Axial3D provides
    - If you don't see what you are looking for, you can select Alternative Pathology and we will work with you to create a custom solution to meet your needs
- Once you have found your solution, simply click on the **Item** to begin the ordering process
- Choose **Order Type** (hovering over the question mark of each type will provide an explanation of each option)
    - 3D Visual
    - 3D Print-Ready File – will include a 3D Visual
    - 3D Mesh – will include a 3D Visual
    - 3D Print – will include a 3D Visual
- Provide **Patient Birth Year** (this will help you identify your order)
- Provide **Patient Gender** (this will help you identify your order)
- Provide **Date Required** (this is the date you need the finished product to be delivered)
    - **3D Print** will have a longer completion time due to the printing (based on model complexity) and shipping of the model
- Provide **Details** of Surgery/Pathology/Case
    - Describe the surgery, clinical pathology, or use case of model

    - The more detail provided the quicker the Axial3D team can start completing the model
- Provide **Details of 3D Model** Customization
    - Provide as much detail as possible specific to your request
    - Any specific areas to focus, any color requirement, any cuts needed, any areas to not include, type of resin needed (for physical prints), how you plan on using the model, will you be cutting or drilling into the model
- Enter the complete **Shipping Address** the model should be delivered to (or choose from any previous address if you have previously ordered).
- When finished, click **Continue** at bottom left of screen
    - This will create your order and on the next page in the upper left you will see your order number and catalog item selected
- If you have a PACs integration click **No, refer to PACS Dept**
- Enter the approved **PACS Email**
- Select if you wish to receive a copy of this PACS Request to your email address
- Provide the **Patients Healthcare ID**
- Enter the **Types of Scans** you are requesting be uploaded
- Enter the **Date of the Scans** you are requesting be uploaded
- Enter any **Scan Notes** that will help the Imaging Department with your request
    - If you have multiple scans for the request, click **+ Add Another Scan to this Request** (do this as many times as needed to get all images requested for your order)
- Click **Submit**
    - A Pop-Up will appear confirming the request has been submitted to your Imaging Department
    - You will be taken to the summary page of the order just created
    - Navigate back to **My Orders** table by using the back arrow  top left of the page or select My Orders
- The request will be sent to your imaging department to Upload the images
- If you opted to receive a copy of the PACS Request, you should also receive a copy of the same email.

- Your order will now be accessible from the table on the main page of the dashboard

6.5. PACS Image Uploading

- Click on the **Transfer Files** button in your email request you received from orders.axial3d.com
    - Link expires 72 hours following request
- Your Web Browser will open up to an **Axial3D page** to upload images
- Open the folder on your computer (or disk) where the files are located
- **Highlight all DICOM images** (.dcm)
    - Do not include the DICOM viewer
- Drag the files onto the Screen in the Box stating Drag and Drop to **Upload Files**
    - You can confirm whether the number of files matches at the right of your screen in the summary
- Click **Start Upload** (once you confirm you have the correct number and type of files)
- It is important to keep the next page open and not navigate away from this in your browser while the files upload
    - The upload screen will provide you the progress of the upload
    - When completed, the Upload Progress will be 100% and a Pop-up will display saying you have successfully uploaded for order number (RC)PXXXXX
- If you wish to upload more DICOMs, select **Upload More DICOMs** and repeat from step 3

6.6. List of validated printers

The following printers and materials have been validated for 3D printing anatomical models.
NOTE: Using other printers or materials will require additional validation and testing.

Printer Manufacturer	Technology	Model	Material	Applications
Formlabs	Vat Polymerization	Form 3B Form 3L Form 3BL	Standard White V4 FLGPWH04	Orthopedics Cardiovascular Maxillofacial
			Standard Draft V2 FLDRGR02	Orthopedics Maxillofacial Cardiovascular
			Standard Clear V4 FLGPCL04	Cardiovascular
			Flexible 80A V1 FLFL8001	Cardiovascular
			Standard Clear V4.1	Cardiovascular
			Biomed White Resin	Orthopedics Cardiovascular Maxillofacial
			Biomed Clear Resin	Cardiovascular
Note: BioMed White and BioMed Clear material can only be printed on Form 3B and Form 3BL				

Printer Manufacturer	Technology	Model	Material	Applications
Stratasys	Polyjet	J750 	Agilus, VeroBlackPlus, VeroClear, VeroCyan, VeroGrey, VeroMagenta, VeroPureWhite, VeroYellow	Orthopedics Cardiovascular Maxillofacial
	Polyjet	J5 MediJet 	VeroVividTM Cyan, VeroVividTM Magenta, VeroVividTM Yellow, DraftWhite, MED610, MED615RGD, VeroUltraClearTM , ElasticoTM Clear	Orthopedics Cardiovascular Maxillofacial
	Polyjet	J850 	VeroVividTM Cyan, VeroVividTM Magenta, VeroVividTM Yellow, VeroPureWhite BoneMatrixTM GelMatrixTM TissueMatrixTM RadioMatrixTM Agilus30 VeroClear VeroMagenta BlackPlus	Orthopedics Cardiovascular Maxillofacial

	DLP	Origin One 	LOCTITE 3D 3172 ORIGIN DM100 by BASF ORIGIN DM200 by BASFLOCTITE 3D 3843 LOCTITE 3D IND405	Orthopedics Cardiovascular Maxillofacial

Note: Anatomical 3D printed models have not been validated for printing in a combination of materials with differing physical properties

Printer Manufacturer	Technology	Model	Material	Applications
HP	Multi-jet Fusion	HP580 	Nylon PA12	Orthopedics Cardiovascular Maxillofacial
	Multi-jet Fusion	**HP540** 	Nylon PA12	Orthopedics Cardiovascular Maxillofacial

7. Account Management

7.1. Searching for an order on Axial3D Insight

- Visit **https://orders.axial3d.com/login**

- Enter **Email** and **Password**
- Click **Login** at the bottom of the screen
- Click **My Orders**
- Enter (RC)PXXXXX in **Search Order** Field (this will bring up your order)
- Provide **Date Required** (this is the date you need the finished product to be delivered)

7.2. Changing accounts details

- Visit **https://orders.axial3d.com/login**
- Enter **Email** and **Password**
- Click **Login** at the bottom of the screen
- Click **Account**
- Click **Change Password**
- Enter **Current Password**
- Enter **New Password**
- Click **Submit**
- Confirm your new password via the email link you will receive from Axial3D in your Inbox

7.3. Forgotten password

- Visit **https://orders.axial3d.com/login**
- Click **Forgot password**
- Enter **Email Address**
- Click **Continue**
- Select **Reset password** via the email link you will receive from Axial3D in your Inbox
- Enter **New Password**
- Confirm **New Password**, click **submit**

- Confirm your new password via the email link you will receive from Axial3D in your Inbox

7.4. Accessing Axial3D contact details

- Visit **https://orders.axial3d.com/login**
- Enter **Email** and **Password**
- Click **Login** at the bottom of the screen
- Click **Account**
- Click **Contact details**

7.5. Log Out of platform

- Click 
- Select **Sign Out**

8. End User - receiving a 3D printed model from Axial3D

On completion of the End users order request, Axial3D user will process the DICOM images to produce a digital file for printing. Axial3D user will 3D print the anatomical model on their validated printers. The completed 3D model will be delivered to the delivery address provided by the End user.

9. End users receiving a Digital File

On completion of Axial3D user processing an order to produce a digital file, an email will be sent to the end user to advise that the digital file is ready to be downloaded. The End user can retrieve the digital by following the steps outlined below

- Visit **https://orders.axial3d.com/login**
- Enter **Email** and **Password**
- Click **Login** at the bottom of the screen

- Select **My Orders**
- Click on the 3 Vertical Dots  to the far right of the order number (RC)PXXXXX
- Select **Download 3D Product Files**
- A zip file will download containing the digital file(s)

10. End users - Printing a digital file

Axial Medical printing has validated the printing of digital files on the list of 3D printers identified in section 6.6 List of validated printers. An end-user that receives a digital file can upload the digital file to the validated 3D printer to the manufacturer's print file generation software to produce a physical 3D printed anatomical model. The end-user must be trained by the printer manufacturer or a qualified 3D printer technician within their facility on the process for 3D printing models.
The end-user intending to 3D print digital files provided by Axial Medical Printing Limited must be able to follow the below guidelines on uploading a digital file to the printer, 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.
The end-user can upload the digital file to the 3D printer manufacturer's print file generation software. Below is the recommended software.

Printer Manufacturer	Printer Model	Software
Formlabs	Form 2, Form 3B, Form 3L, Form 3BL	PreForm
Stratasys	J750, J5, J850	GrabCAD
Stratasys	Origin One	Netfabb and GrabCAD
HP	HP580, HP540	HP SmartStream 3D Build Manager

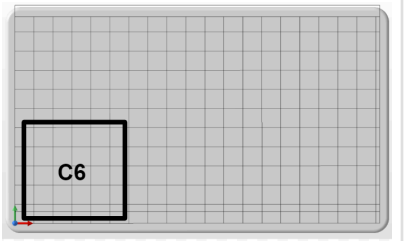
Anatomical models printed on Formlabs Form 3B, Form 3L and Form3BL printers must be printed in the following orientation for optimal print orientation layou, End user must follow Axial Medical printing validated print file orientation instructions if these processes are not followed the diagnostic quality of the final 3D printed physical model cannot be guaranteed.

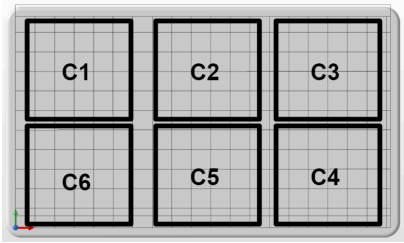
- 3D model is angled at a 20 - 60 degree angle to decrease the amount of surface area in contact with the resin tank which in turn reduces the amount of force on the 3D printed physical models as the build platform raises with each layer recommended procedures ref: *WI-OPS-062 Preform Setup for Form3, 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. 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 region of the model is elevated to be printed towards the mixer side to reduce the print time for the final layers of the model.
- Post-print processes should be followed in line with Axial3D recommended Procedures *ref: WI-OPS-063 Formlabs Post-processing - Customer instructions*

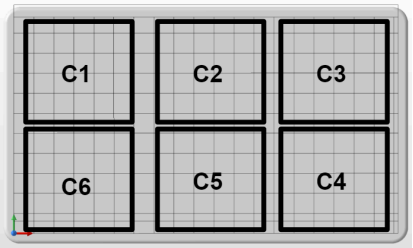
Anatomical models printed on Stratasys Polyjet printer:

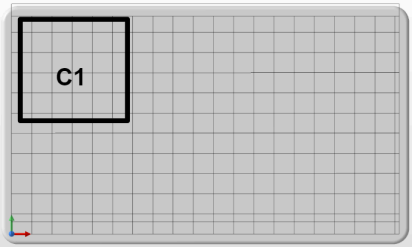
- Insert STL file in the default position (File-> Add models)
- Arrange the model in the tray with an auto arrangement set.
- Assign material and send to printer - recommended procedures *ref: WI-OPS-059 - Polyjet GrabCAD Print Scene Generation - Customer Instructions*
- Post-print processes should be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

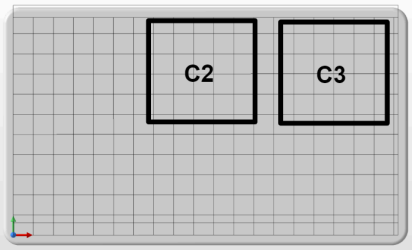
Anatomical models printed on Stratasys Origin One printer:

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*	

- The 3D model is angled between 0 - 90 degrees depending on material and geometry. Altering the angle will 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. The optimal orientation will also limit the amount of support structures required during printing.
- Orient the model to stand with the merging feature of the geometry 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. The optimal orientation from a branching point will also limit the amount of support structures required during printing.
- Overhanging features should be oriented to self-support during the printing process, where possible. This will in turn reduce post-processing times through less supports.
- All models to be printed in DLP need to be elevated 5mm from the build plate to ensure print success.
- Once the model is orientated at the optimal angle and elevated 5mm from the build plate the support generation function is ran.
- After support generation the supports are merged to the model and the print file is generated.

- The print file is then imported in to the printing software and the resin type is selected. The job is then uploaded to the Origin One printer and started.
- Post-print processes should be followed in line with Axial3D recommended procedures.

Anatomical models printed on HP printers

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

- In bounds, 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.
- 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

	Printing time		Safety cooling time	Natural cooling time		Fast cooling time *
Build chamber	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

	Printing time		Safety cooling time	Natural cooling time		Fast cooling time *
Build chamber	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 specifcations:
- Manual or automatic operation; Air pressure in the range 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, knocking loose unfused powder while also smoothing the finish of the part.

10.1. Post-print visual check and reprinting or failed prints

On completion of the 3D printing process at the End users facility a visual check of the printed model should be carried out to confirm that there are no defects to the printed model.
If a defect is identified the model should be reprinted. Before reprinting the End User should inspect and clean the 3D printer after a print failure, in line with the printer manufacturers guidelines.

10.1.1. Formlabs Printer cleaning after failed print

A failed print can result in small partially cured resin floating within the tank or stuck to the film at the bottom of the tank. Before a new print can be started the resin tank should be cleaned by the end user. It is advised that after each print the tank should be inspected to ensure it is clear of small resin particles or debris. To clean the tank the End user should follow the recommended guidelines provided by Formlabs on cleaning resin tanks. Once the resin tank has been cleaned the print can be restarted.

10.1.2. HP Printer cleaning after failed print

If a defect is detected on completion of the 3D print on the HP machine. It is recommended to clear the build chamber before a new print can be started, the End user should follow HP guidelines on cleaning and maintenance of HP printer. Once the printer has been inspected and cleaned the model can be reprinted.

10.1.3. Stratasys Polyjet Printer cleaning after failed print

If a defect is detected on completion of the 3D print on the Stratasys Polyjet machine. It is recommended to clear the build chamber before a new print can be started, the End user should follow Stratasys guidelines on cleaning and maintenance of the printer. Once the printer has been inspected and cleaned the model can be reprinted.

If additional support is required the End user should contact support@axial3D,com or call us on **+1 857 412 7244 (US) / +44 (0) 28 9018 3590 (UK/EU)**

10.1.4. Stratasys Origin One Printer cleaning after failed print

A failed print can result in small partially cured resin floating within the tank or stuck to the film at the bottom of the tank. Before a new print can be started the resin tank should be cleaned by the end user. It is advised that after each print the tank should be inspected to ensure it is clear of small resin particles or debris. To clean the tank the End user should follow the recommended guidelines provided by Stratasys on cleaning Origin One resin tanks. Once the resin tank has been cleaned the print can be restarted.

If additional support is required, the End user should contact support@axial3D.com or call us on +1 857 412 7244 (US) / +44 (0) 28 9018 3590 (UK/EU)

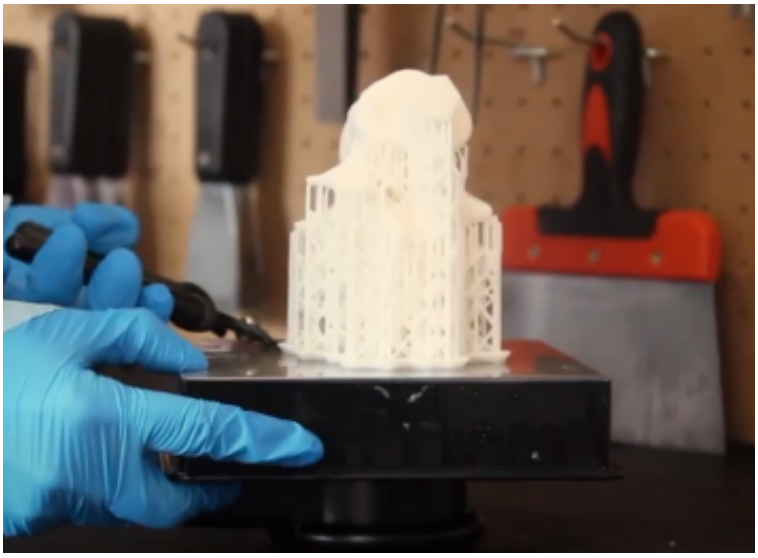
10.2. Post-processing 3D printed models

3D printed anatomical models printed on the end users premises on their printing technology must be post-processed in line with the printer manufacturers guidelines. If these guidelines are not followed Axial3D cannot ensure the diagnostic quality of the final 3D printed model.

10.2.1. Formlabs post-processing of 3D models - **Removing parts from the build platform**

To remove the model from the build plate, ensure the snips are flat to the build plate. Snip around the base of the model. Once complete, using a rounded edge scraper,

slide under the edges previously released by snips. This should allow the model to gently detach from the build plate.



Carefully do this over a table to avoid the model dropping from a height. Using a round edged scraper to scrape off any excess left behind on the build plate. Scrape away from yourself.

Using some IPA and paper towels, wipe down the top surfaces as well as the edges of the build plate until all surfaces are free of resin.

NOTE: It is important to keep the printer and build plate clean so as to avoid any faulty prints in future. Always check the printer and build plates for cleanliness after every print. This can be done using clean IPA and paper towels.

Drying parts

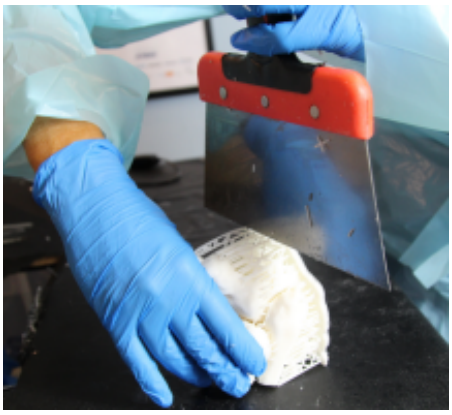
Always let prints fully dry before placing them in the Form Cure to avoid the models becoming tacky. Microfiber cloths can be used to dry the excess IPA on the model. Allow parts to dry for at least 30 minutes after washing to allow the solvent to fully evaporate from part surfaces. Ensure the area is highly ventilated while the solvent evaporates.

Removing support structures

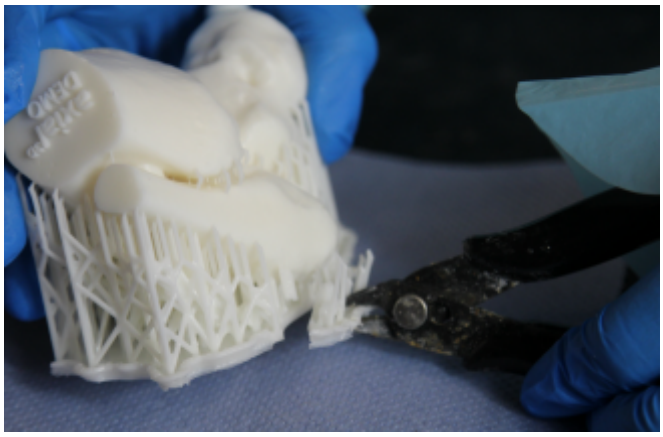
Using wire snips, cut around the base to break the raft into smaller sections.

Using a large sharp-edged scraper and cutting through the support next to the base to fully remove the raft.

Ensure to take great care using the large scraper to remove the raft from the model.

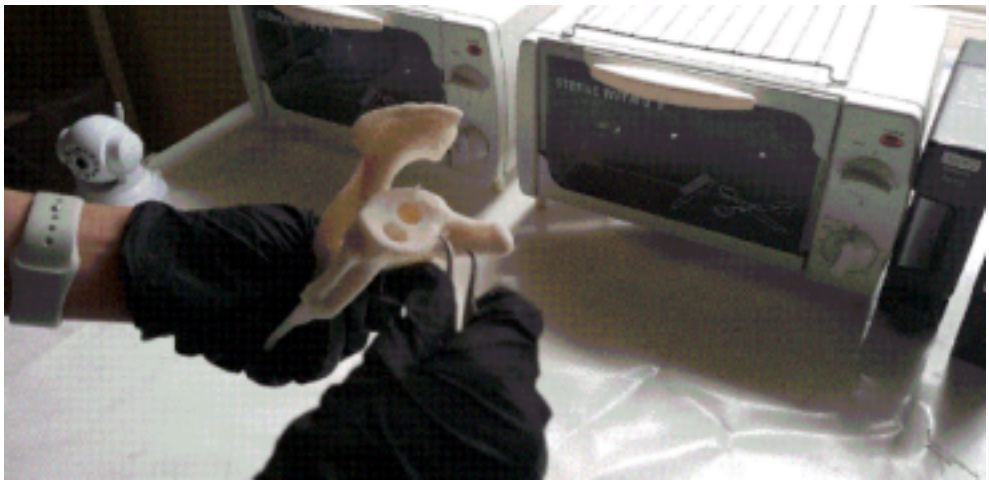


Use the wire snips to slowly release the supports from the model, breaking off small sections until complete.



Carefully remove supports from delicate areas, use light pressure when snipping. Cut from the bottom of the support moving closer to the surface to avoid breaking off small features.

Small hand files and tweezers can be used for highly detailed parts. If parts still feel too fragile to remove supports, place into FormCure for recommended curing time and remove supports after this stage. Peel the supports from the model by hand for larger areas which are easy to access. To remove supports from tight areas within the model it is best to use forceps or tweezers.



When all supports have been successfully removed, wipe over the model with a microfiber cloth and IPA to remove any excess tackiness.

An air compressor may also be used to remove debris when required.

Post curing prints using a Form Cure

Post-curing enables parts to reach the highest possible strength and become more stable. Post-curing is particularly important for Formlabs' range of functional resins: Castable, Flexible and Tough. After printing, optimizing the strength of parts depends on light and heat. Post-curing at higher temperatures results in a shorter time to fully cure. Additionally, higher temperatures lead to higher mechanical properties.

Optimal post-curing settings depend on equipment and the geometry of the part.

Ensure the parts to be cured are fully dry and have no solvent trapped on surfaces or interior of the part. Curing parts that contain solvent can dissolve resin inside the part and prevent parts from strengthening to their material properties.

Open the FormCure hood and distribute parts to be cured onto the round turntable. Close hood to allow part to begin curing.

Turn knob to navigate the display menu and set the material type and version to see the recommended Form Cure time and temperature settings. This will automatically adjunct the Time and Temperature values automatically.

These times are updated regularly so please check your resin's recommended post-cure time and temperature before beginning a post-cure cycle at www.formlabs.com.

You can manually adjust the time and temperature by selecting the Material value to Custom if required.

Form Cure material settings:

Resin	Form Printer	Cure Time (min)	Temperature Notes (degrees)
White	3 / 3B / 3L / 3BL	30	60 Use these settings for standard opaque resins including Black, Grey, Color, and Model, which have equivalent mechanical properties.
Grey	3 / 3B / 3L / 3BL	30	60 Use these settings for standard opaque resins including Black, White, Color, and Model, which have equivalent mechanical properties.

Clear	3 / 3B / 3L / 3BL	15	60
Flexible 80a	3 / 3B / 3L / 3BL	10	60 There is only one recommended post-curing time for Flexible 80A V1.
Clear v4.1	3 / 3B / 3L / 3BL	15	60 - Optimal for clarity and strength - too much curing may lead to yellowing
Biomed White	3B / 3BL	30	60 - Cycle ensures parts meet mechanical strength requirements
Biomed Clear	3B / 3BL	30	60 - Cycle ensures parts meet mechanical strength requirements

Removing Support Bumps from 3D Models

If supports are still visible in certain internal areas, use the snips or tweezers to remove them. Use hand files to remove support marks. A dremel can also be carefully used to remove support bumps.

Sandpaper should be used to give a smooth finish.

NOTE: Gradually move from lower grade up to high grade as required. Metal filing tools

can also be used in this step.

NOTE: only remove the support bumps to ensure all landmarks are as close to exact as possible

Once the model has been completely filed, wash the model under tap water. Use a toothbrush to remove any trapped dust. Dry the model with a microfiber cloth and leave the model to dry further in a ventilated area.

Removing support touchpoints sometimes leaves raised marks and divots on the parts surface. To reduce these marks, begin by using metal hand files to remove larger support marks. Dremel's can also be used. Then use sandpaper to give a smooth finish. Begin by using the lowest grit sandpaper and gradually work to a higher sequence. Using a sequence of 240, 320, 1000 grit sandpaper.

NOTE: When sanding clear models, this procedure must be repeated until the clear model has a glass finish. Wet sanding paper to reduce dust and create a finer surface finish. Wet the surface of the model and sand down.

Use a squirt bottle to rinse the part with IPA or water and use a toothbrush to remove dust caused by sanding. Leave to dry before proceeding with the stage of post-production.

10.2.2. HP post-processing of 3D printed models

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

	Printing time		Safety cooling time	Natural cooling time		Fast cooling time *
Build chamber	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

	Printing time		Safety cooling time	Natural cooling time		Fast cooling time *
Build chamber	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 specification:
For PA materials:

- Manual or automatic operation
- Air pressure in the range 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, knocking loose unfused powder while also smoothing the finish of the part.

10.2.3. Stratasys post-processing of 3D printed models on Polyjet technology

Remove the model from the build chamber.

Cleaning the Model

Using the WaterJet, remove the support material from the model as thoroughly as possible.

Immerse the model in the sodium hydroxide solution for up to two hours, depending on the model size and type.

Caution do not let sodium hydroxide come in contact with your eyes or skin. It may cause chemical burns, scarring and blindness. Use protective goggles and nitrile gloves when handling sodium hydroxide and models soaked in it. In case of direct contact with sodium hydroxide, clean the affected area immediately with running water and then seek medical attention. Mixing sodium hydroxide with water generates heat that could ignite other materials.

Remove the model from the solution and immediately rinse the model under running tap water.

Using the WaterJet, remove any remaining support material from the model.

Wipe down the model with a disposable paper towel and wait until the model is completely dry. (For faster drying, immerse the model in isopropyl for a few seconds and let the model dry for at least half an hour)

10.2.4. Stratasys post-processing of 3D printed models on DLP technology

- 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 an 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:
    - Small models: 2 minutes turning every 30 seconds.
    - 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.

10.3. Final inspection of the 3D printed model.

All digital files provided by Axial3D have a calibration token applied to the anatomical model. This calibration token measures 10 mm x 10 mm. On completion of post-processing the 3D printed anatomical model the end user should carry out a calibration inspection using calibrated digital vernier calipers.
Overall visual inspection shall be carried out to confirm the finish quality of the 3D printed model.

11. Symbols glossary

Symbol	Title	Standard Designation Number	Description of Symbol
	Batch code	ISO 15223-1:2016 (new draft in review) (Symbol 5.1.5) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Medical Device	ISO 15223-1:2019 (new draft in review includes this symbol) (Symbol 5.7.4) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the item is a medical device
	Product description	N/A	N/A
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1:2016 (new draft in review) (Symbol 5.4.3) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the need for the user to consult the instructions for use. NOTE 1 Synonym for “Consult instructions for use” is “Consult operating instructions”.
	Manufacturer	ISO 15223-1:2016 (new draft in review) (Symbol 5.1.1) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the medical device manufacturer. Can be used with ISO 8601 date of manufacturer, YYYY-MM-DD
	Caution	ISO 15223-1:2016 (new draft in review) (Symbol 5.4.4) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or

			operator action in order to avoid undesirable consequences.
	Date of manufacture	ISO 15223-1:2016 (new draft in review) (Symbol 5.1.3) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the date when the medical device was manufactured. To be used with ISO 8601 date of manufacturer, YYYY-MM-DD
	Fragile, handle with care	SO, 15223-1:2016 (new draft in review) (Symbol 5.3.1) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that can be broken or damaged if not handled carefully.
	Prescription Only	CFR 21 801.15(c)(1)(i)(F) (US FDA) Labelling - Medical device: Prominence of required label statements CFR 21 801.109 (US FDA) Labelling - Prescription Devices	Requires a prescription in the United States of America Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

12. Manufacturer details

Axial Medical Printing Limited
17A Alexander House Ormeau Avenue
Belfast, BT2 8HD
+44 (0)2890 183590 (UK)
+1 857 412 7244 (US)

13. Reporting to adverse events to the FDA

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help the FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA
Use one of the methods below to submit voluntary adverse event reports to the FDA:
Report Online at:
www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at
www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf
Call FDA at 1-800-FDA-1088 to report by telephone.
Reporting Form FDA 3500 commonly used by health professionals. The form is available at
www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

14. Glossary

Terminology/ Abbreviations/ Acronyms/ Definitions	Meaning
Bead-Blasting	The operation of propelling, typically with compressed air, a stream of abrasive material against a surface to affect the surface finish.
Build Platform/Build Plate	The plate will hold the 3D print and move layer by layer as the model is made
CAD	Computer Aided Design
Calibration Token	A small additional part of known dimensions added as part of the QA process to ensure accurate printing.
Cardiovascular	relating to the heart and blood vessels.
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
Digital Vernier Calipers	A precision instrument that can be used to measure internal and external distances extremely accurately
DLP	DLP (Digital Light Processing) is a 3D printing technology used to rapidly produce photopolymer parts.
Form Cure	Used to post-cure 3D printed models
Form Wash	Used to wash 3D printed models in IPA after printing
In-Situ	In the natural or original position or place
IPA	Isopropyl alcohol
NM	Nuclear Medicine
OBJ	It is a file format used for a three-dimensional object containing 3D coordinates (polygon lines and points), texture maps, and other object information
Ortho	Orthopaedic

PACS	Picture archiving and communication system
Pathology	The structural and functional deviations from the normal that constitute disease or characterize a particular disease
Post-Processing	The process of removing a printed model from a printer and applying finishes to create the final product
PPE	Personal Protective Equipment
Pre-Processing	The process of making a 3D file ready for printing through addition of dowels and branding
Raft	A horizontal latticework of filament that is located underneath your part, to support the 3D print process
Resin	UV curing liquid used as the substrate for printing
Segmentation	The process of labelling 2D images
STL	Describe only the surface geometry of a three-dimensional object without any representation of color, texture or other common CAD model attributes
Support Bumps	Small, raised areas on the print surface caused by the removal of supports
Supports	Disposable thin lattice structures automatically added to assist in supporting a 3D printed model
Surfaces	3D models of the 2D labels that can be exported
Surface view	The function used to view the generated surface as a 3D model for export
Tank	A resin tank with a transparent base and non-stick surface, which serves as a substrate for the liquid resin to cure against, allowing for the gentle detachment of newly formed layers
Topology	The anatomical structure of a specific area or part of the body

UV	Ultra-violet
WaterJet	A stream of water forced out through a small aperture
3D mesh	Is a collection of vertices, edges and groups to produce a 3D model
3MF	3D manufacturing format file type

15. Appendix Axial3D Insight Release Notes v1.46.0

15.1. Known Software Anomalies

The Axial3D Insight Release Notes v1.46.0 provided alongside this Operator Manual can be referenced to inform the end user of any known issues or anomalies.
Any issues or anomalies present a negligible risk to the end user and this appendix details any actions that should be taken by the end user upon encountering such an anomaly.