Smilecloud Blueprint

Instructions for Use

V1.1
27.05.2026

CE

Table of Content

Overview of Instructions for Use

These instructions for use (IFU) provide comprehensive guidance on the use of the Smilecloud Blueprint software module. It is designed to support dental professionals in understanding, accessing, and operating the product effectively and safely. The IFU include detailed instructions on the system's features, intended use, limitations, and responsibilities related to security and data protection.

IFU Access and Language. The Instructions for Use are available in digital form and can be accessed directly from the Smilecloud platform or via the smilecloud.com website. Users may download a copy for offline reference. A paper copy of the IFU may be requested at no additional cost in accordance with applicable regulatory requirements.

Manufacturer and Device Identification

For technical assistance, product inquiries, or requests for documentation, please contact:

Smilecloud SRL
Address: 8 Calea Aradului, floor 5, Timisoara, Timis, Romania
Email: contact@smilecloud.com
Website: https://www.smilecloud.com

MD Device Name: Smilecloud Blueprint
Software Version: 1.1
UDI-DI: (01)5940805430013

Symbols and Markings Used in the IFU

The following symbols may appear within these IFU, on the Smilecloud interface, or within associated documentation and labeling, where applicable:

Symbol	Meaning
	Manufacturer
	Follow Instructions for Use
	Caution
	Medical Device

Regulatory Information

Compliance Statements

Smilecloud Blueprint is developed and maintained in accordance with national and international regulations and standards such as:

- ISO 13485:2016 – Quality Management System for Medical Devices
- Regulation (EU) 2017/745 (MDR) – as applicable to software classified as a medical device

Compliance documentation and declarations of conformity are available upon request for authorized users and institutions.

Regulatory Classification and Intended Market Regions

Smilecloud Blueprint is intended for use within the European Union and other territories where regulatory approval or exemption permits its use.

EMC and Electrical Safety Considerations

Smilecloud Blueprint is a web-based software service (cloud-hosted) and does not directly interface with electrical medical hardware or require local installation.

Device Information

Intended Purpose

Smilecloud Blueprint is a software-only module for dental professionals to visualize user-provided imaging and design data of the oral-maxillofacial region for communication and illustration. It enables import and alignment of inputs (e.g., portrait images, intraoral scans, CBCT), provides segmentation, and allows interactive adjustment of illustrative 3D

anatomy/design representations. Blueprint does not perform diagnosis, prediction, monitoring, or treatment planning and is not to be relied upon for clinical decisions.

Indications for Use
Use by dental professionals, in professional settings, on patients with mixed or permanent dentition, to create and review illustrative visualizations of potential aesthetic outcomes and anatomical context for communication with patients and interdisciplinary teams. Not for diagnosis, clinical assessment, or treatment planning.

Characterization of User Profile. Smilecloud Blueprint is intended to be used exclusively by dental professionals, including dentists and dental specialists, who are trained in the acquisition, interpretation, and clinical use of dental and maxillofacial imaging.
Users are expected to have:

- Formal education and professional licensure in dentistry or a dental specialty.
- Familiarity with digital imaging systems such as CT, CBCT, and intraoral scanners.
- Competence in interpreting dental imaging and integrating visualization outputs into clinical workflows.

The manufacturer does not provide specific user training before providing access to the software.

Characterization of Patient Population. Smilecloud Blueprint is intended for patients with mixed or permanent dentition of the oral and maxillofacial region. The software is not indicated for patients with only primary teeth.

Contraindications

- Patients without permanent teeth: Contraindicated for use in patients who have only primary teeth and no erupted permanent dentition. Use in patients with mixed or permanent dentition is at the discretion of the dental professional.
- Non-professional use: Contraindicated for use by laypersons or for direct-to-consumer applications. The operation is intended only for dental professionals.
- Sole-basis clinical decisions: Contraindicated for making or confirming diagnoses or treatment decisions based solely on the software's visualizations. Outputs must always be interpreted in the context of other clinical information and professional judgment.

Characterization of Use Environment Including Software / Hardware. Smilecloud Blueprint is a software module of the Smilecloud Platform, intended for use in a professional dental environment such as a dental clinic, academic institution, or outpatient healthcare center.

The software is accessed through a secure internet connection and a compatible device (PC or Mac) and requires a compliant web browser.

The following minimum requirements must be observed:

	Minimum requirements		Recommended requirements	
	Windows	Mac	Windows	Mac
Device		iMac®, Mac® Mini (*), Mac Pro®, MacBook Pro®, MacBook Air® (*). All models released since 2020 are supported. (*) The graphics card of some MacBook Air® and Mac® Mini configurations has restrictions with regard to volume rendering. Consider selecting low-resolution volume rendering.	-	iMac®, Mac® Mini (*), Mac Pro®, MacBook Pro®, MacBook Air® (*). All models released since 2022 are supported. (*) The graphics card of some MacBook Air® and Mac® Mini configurations has restrictions with regard to volume rendering. Consider selecting low-resolution volume rendering.
Operating System (OS)	MS Windows 10 (build 18362+) MS Windows 11 - 64 bit	macOS 11.0 or later	MS Windows 10 (build 18362+) MS Windows 11 - 64 bit	macOS 11.0 or later
Processor (CPU)	Intel Core i5-12500 (e.g.) AMD Ryzen 5 5600X	Apple M1 chip or later	Intel Core i7-13700 (e.g.) AMD Ryzen 7 6800H	Apple M2 Pro chip or later
Memory (RAM)	16 GB	16 GB	32 GB	32 GB
Graphic card model	NVIDIA RTX 2060		NVIDIA RTX 4070	
Graphic card drivers	Update to the latest version available from the manufacturer's website.		Update to the latest version available from the manufacturer's website.	
Internet Browser	Latest Chrome browser			
Monitor	Recommended 1920 / 1080 px			
Internet Connection	Recommended +50Mbit/s			
Disk space	Minimum 5GB free on the drive with the browser			

It is recommended to use Smilecloud Blueprint exclusively in a professional clinical environment, where sufficient data security, confidentiality, and focus are maintained.

Residual Risks and Warnings

Our risk management concludes that the Smilecloud Blueprint is designed in such a way that, when used under the conditions and for the purposes intended, all risks constitute acceptable risks when weighed against the benefits to the patient.

⚠	Smilecloud Blueprint is not intended to detect, measure, or diagnose pathology. It provides illustrative aesthetic and anatomical visualizations of potential dental treatment outcomes for communication purposes. Use only as described in the Intended Use section of these IFU; the software does not provide diagnosis, prediction, measurements, or automated treatment recommendations.
⚠	The fidelity and representativeness of visualizations depend on the quality, completeness, and relevance of input data (e.g., scan accuracy, photographic quality, visibility of anatomical structures). Suboptimal or incomplete inputs may produce less representative visualizations.
⚠	Smilecloud Blueprint must be used in accordance with these IFU and the stated intended purpose. Use outside these instructions may lead to misleading or incorrect visualizations or unexpected behavior.
⚠	Smilecloud Blueprint is not designed for detection tasks and makes no claims of sensitivity or specificity. Visualizations may not depict every anatomical or prosthetic detail; users must verify relevant features against the original clinical data.
⚠	Clinicians must always review original clinical data. All visualizations and mock-ups generated by Smilecloud Blueprint should be reviewed in conjunction with the original scans and images. The software is an adjunct tool and does not replace the role or expertise of the clinician.
⚠	Smilecloud does not guarantee response times or availability of specific services. The software is not intended for use in emergency situations. In the case of a medical emergency, users must seek immediate professional medical assistance.
⚠	Smilecloud Blueprint requires an active internet connection for access, data upload, processing, and storage via the Smilecloud Platform. Connectivity interruptions may affect access, uploads/exports, or saving of work in progress. Ensure reliable connectivity and maintain access to original source data in accordance with your clinic's policies and applicable law.
⚠	Prohibited Conduct: ● Users may not upload, generate, or transmit any content that violates intellectual property rights, privacy rights, or applicable laws. ● The platform may not be used to share or disseminate any illegal, obscene, defamatory, threatening, or otherwise harmful material. ● Use of Smilecloud Blueprint in violation of local, national, or international regulations is strictly prohibited.

Security and Privacy

Smilecloud Blueprint is designed with a strong emphasis on data security, privacy, and regulatory compliance. The device may process sensitive health-related data and operates under a shared responsibility model to ensure that both Smilecloud and its users uphold best practices in data protection.

Data Protection. All processing of personal health information (PHI) is subject to applicable legal standards and internal data protection policies. To learn more, please consult our publicly available Privacy Policy and visit our Legal and Compliance Center for regulatory documentation, data processing addenda, and compliance resources.

Please note, that the actual use of Smilecloud Blueprint is subject to your compliance with our General Terms of Service.

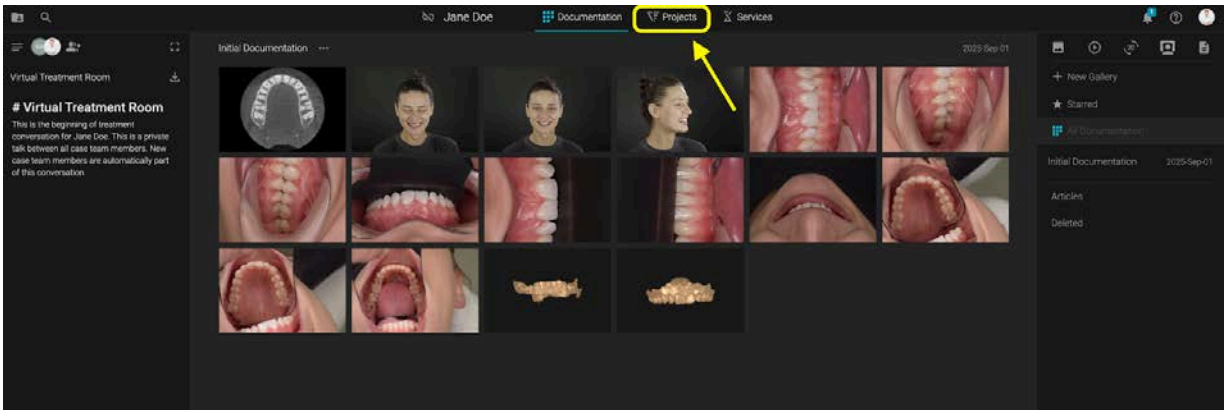
Reporting an Incident

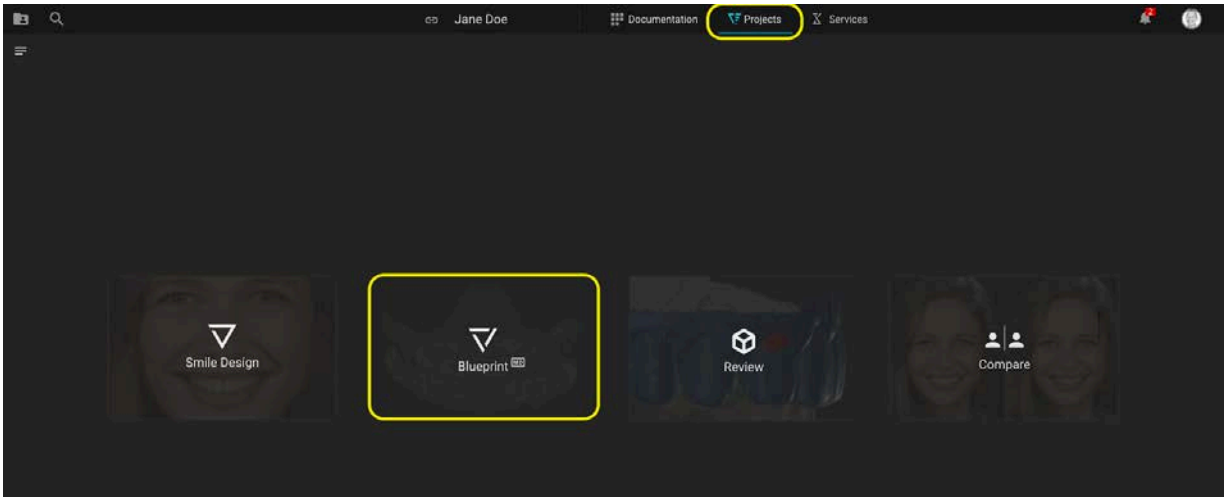
Any serious incident that occurs in relation to this device must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

1. Start a Blueprint

There are 3 options to start a Blueprint:
- From Projects
- From an existing Smile Design
- From + New Project

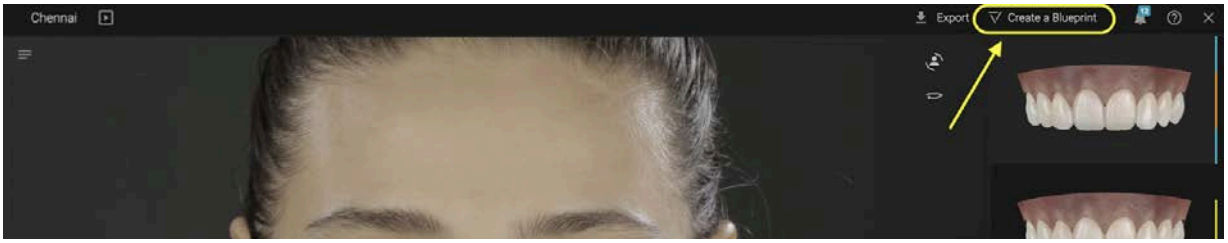
1.1. From Projects:





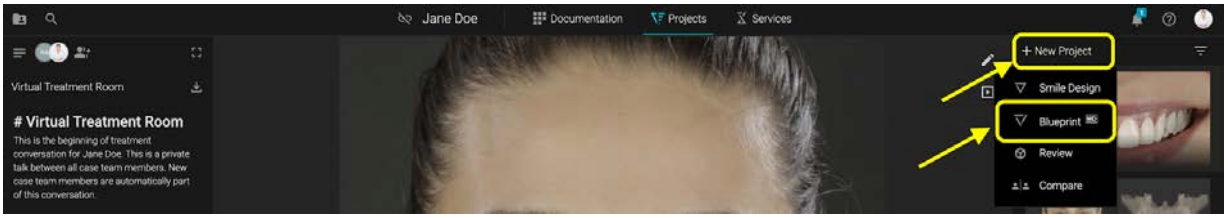
When no other projects are created, click on the Projects tab and then select Blueprint.

1.2. From an existing Smile Design:



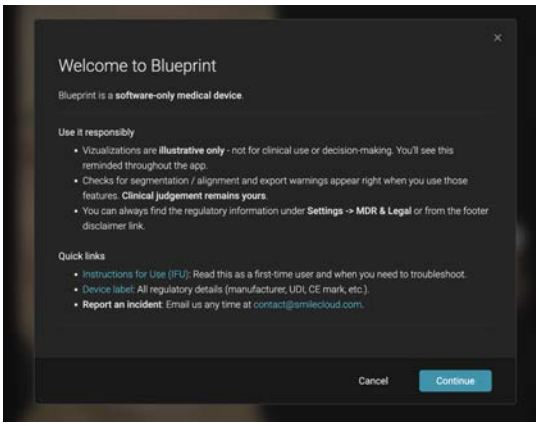
If a Smile Design was previously created, open the Smile Design in edit mode -> click on the direct button to start a Blueprint

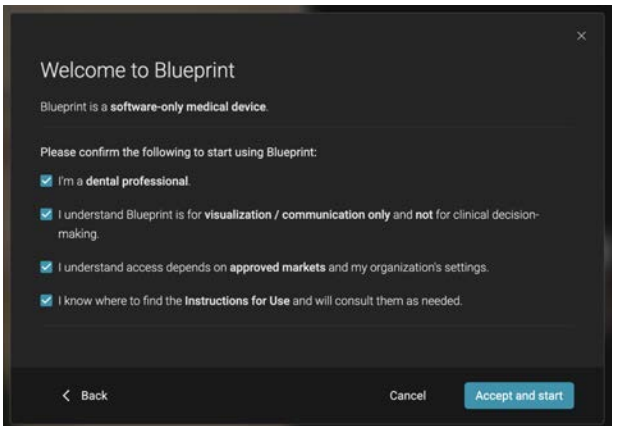
1.3. From +New Project:



On the Projects Tab -> Click +New Project -> Select Blueprint

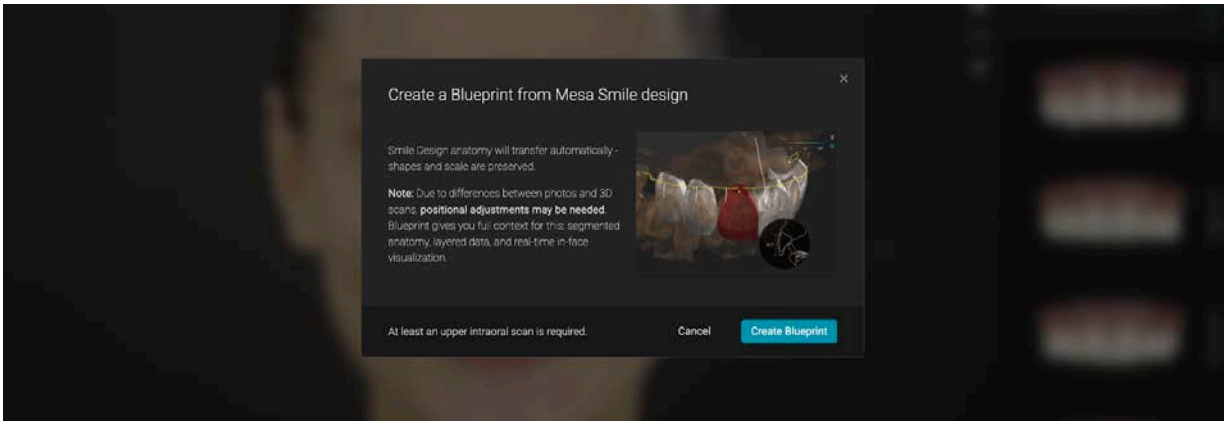
When creating a Blueprint for the first time, read the **Instructions for Use** and confirm the required information.





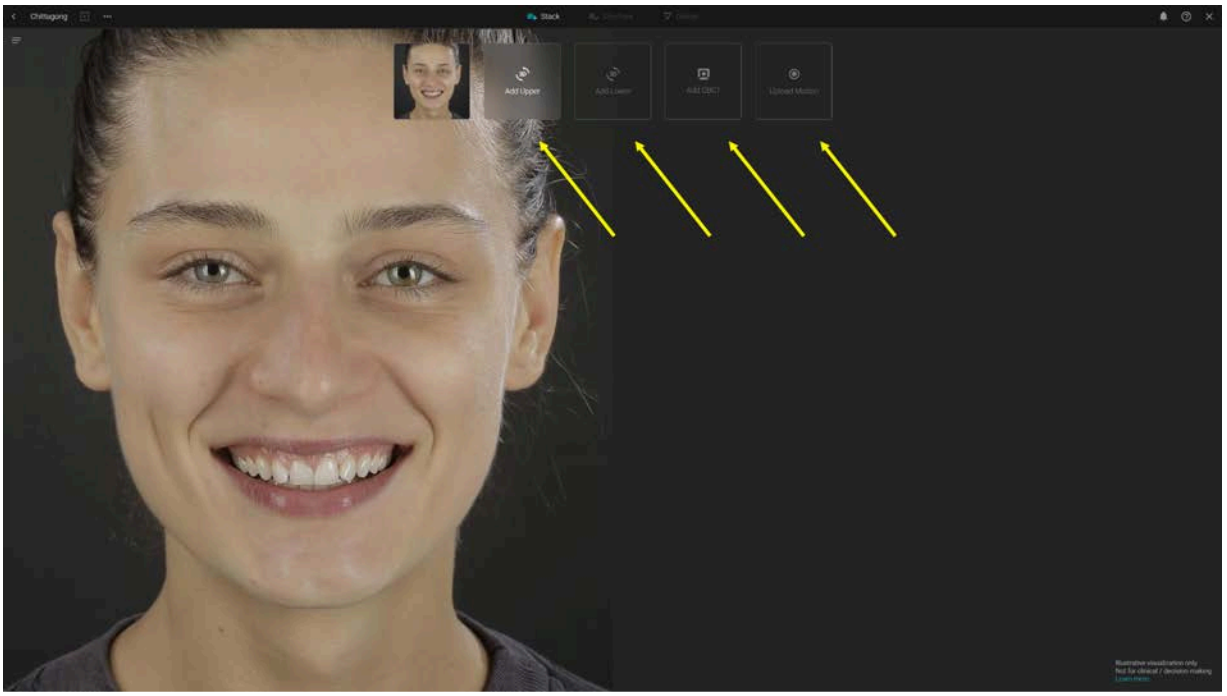
2. Stack

Stack is the first step in Blueprint.

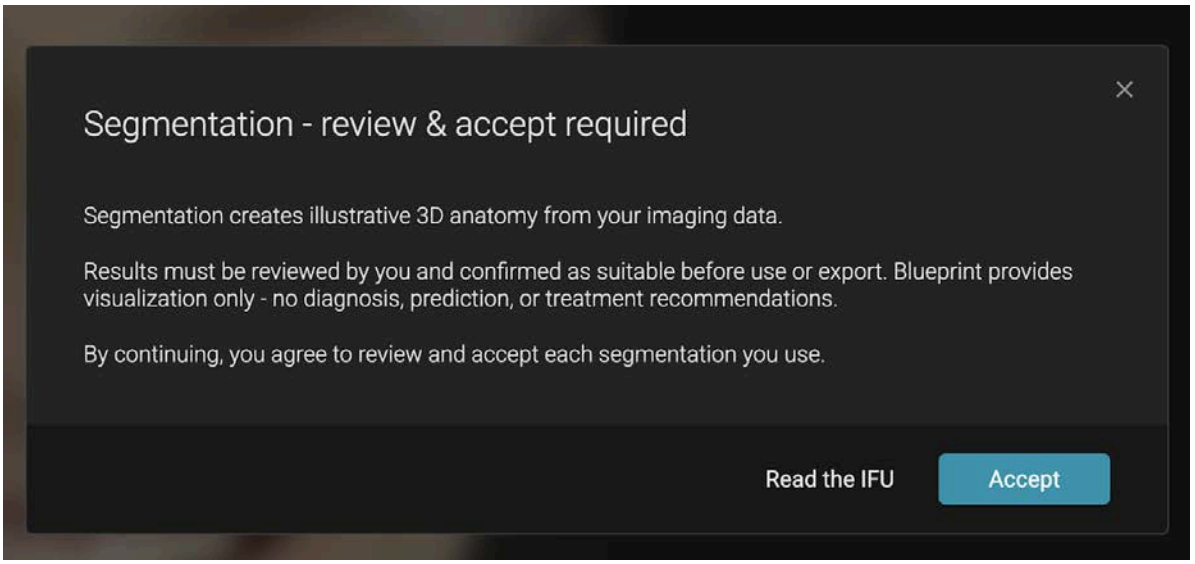


If the Blueprint started from a Smile Design -> the portrait is already present in the stack -> you will be prompted to upload at least an upper intraoral scan.

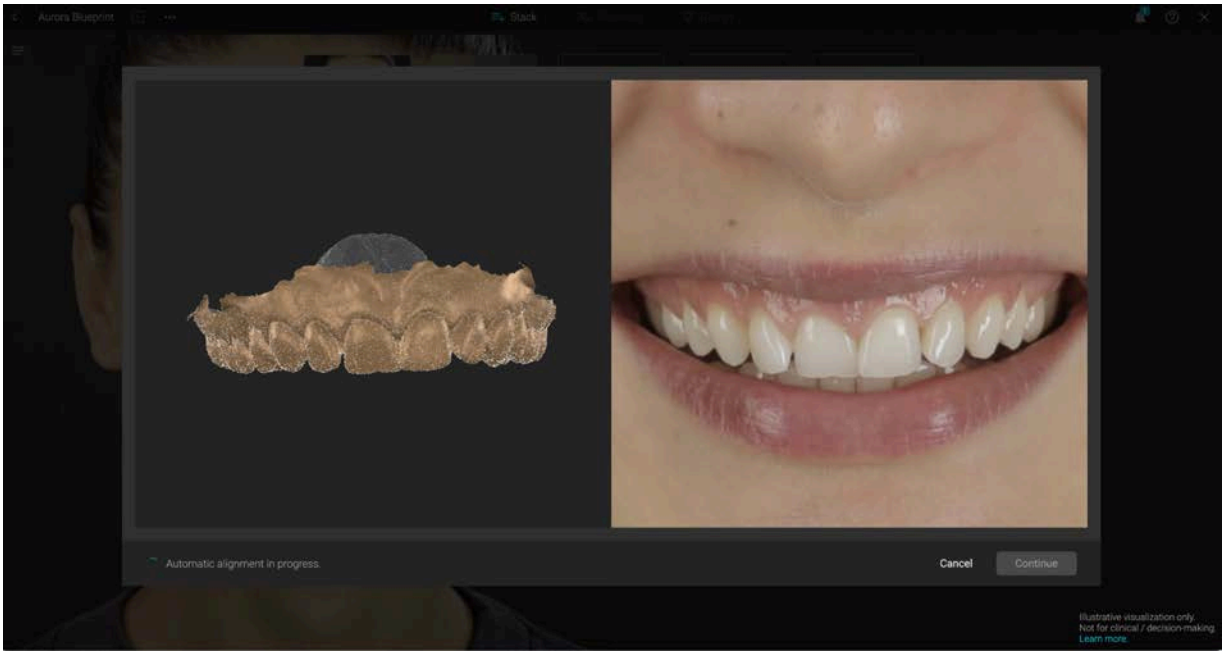
Optionally, you can add:
- Lower scan
- CBCT
- Modjaw Motion File.xml



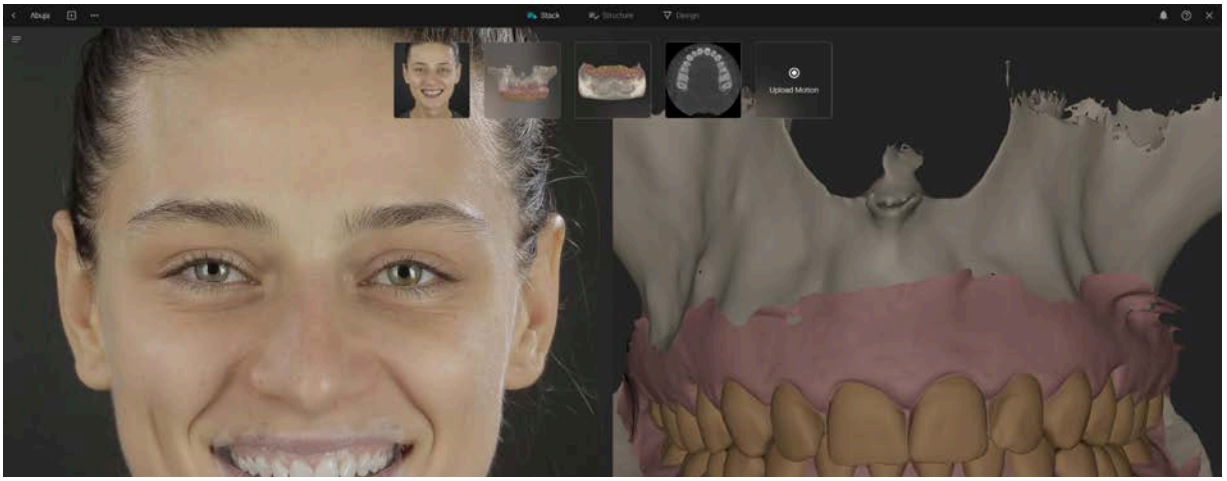
When using segmentation, please remember that results must always be reviewed and confirmed before use or export.



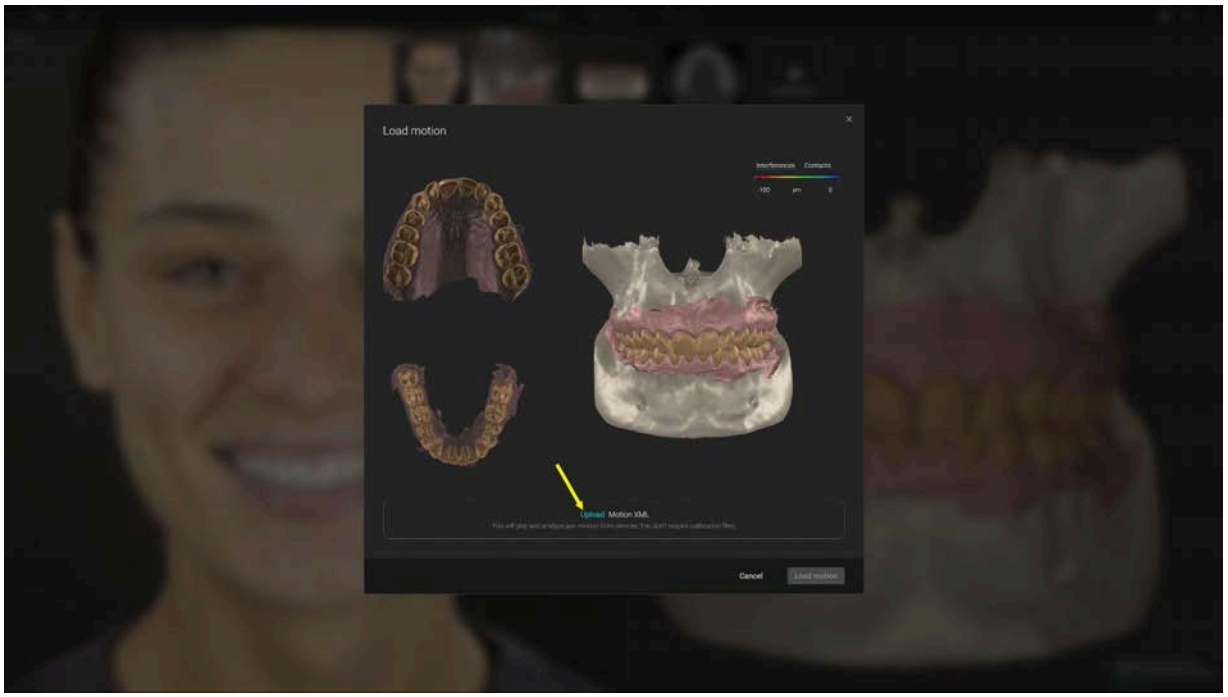
Once accepted, you can select the upper scan, which you will be prompted to align with the portrait image.



Always check that the alignment is suitable for your needs before accepting the results.

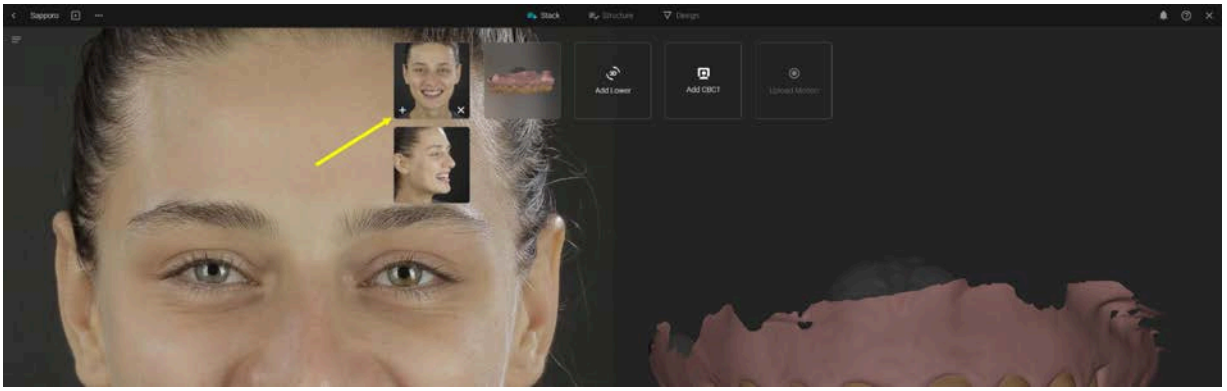


Load Motion:

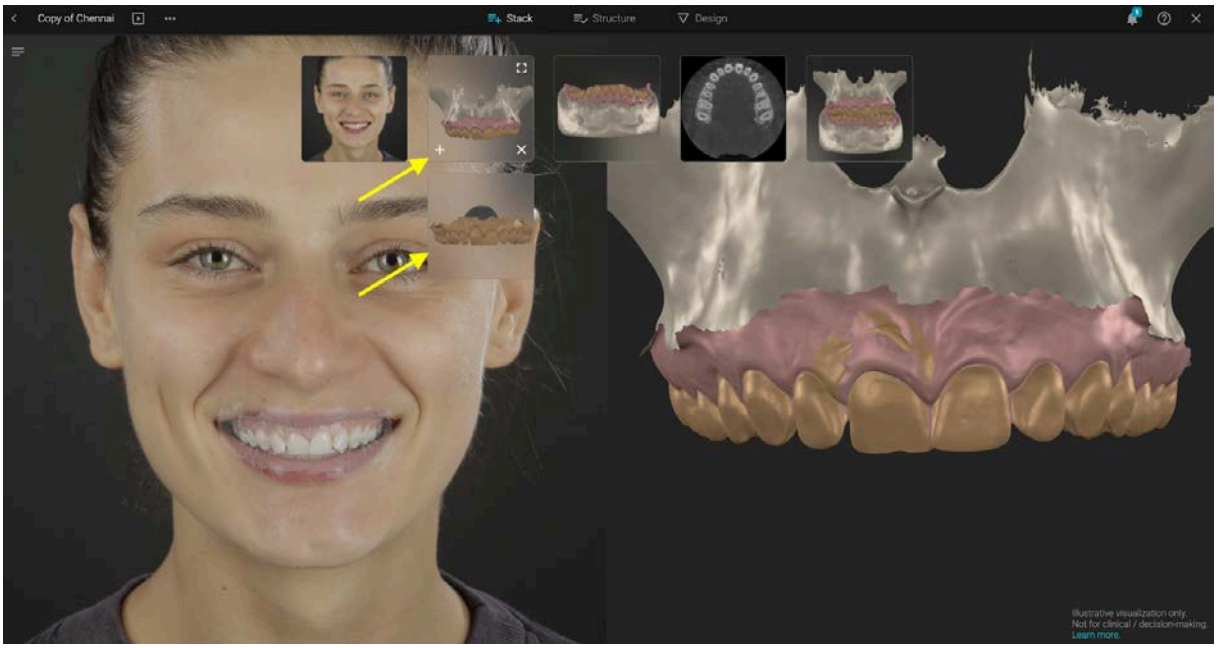


If you start a Blueprint directly from projects, you must also upload a portrait image.

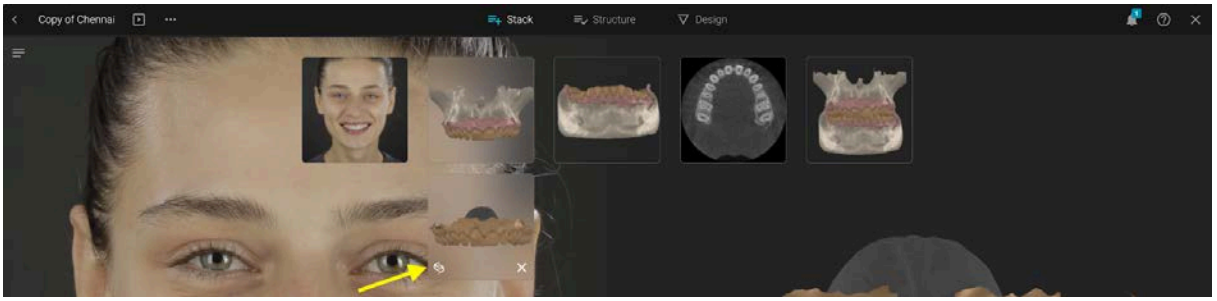
The portrait can be replaced, or, from the + button, you can add additional face pictures from multiple angles:

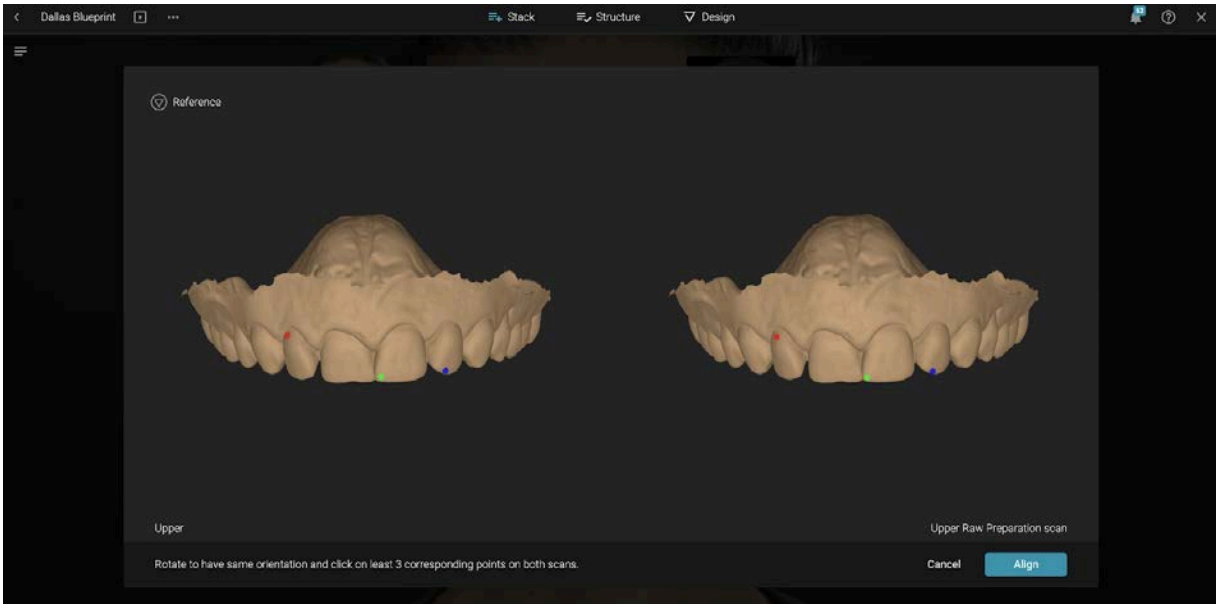


You can also add additional upper scans, lower scans or CBCTs from the + button.



Manual Alignment: When adding additional scans or CBCT, you will use the manual alignment tool. To align two files, place at least 3 corresponding points with mouse clicks.





3. Structure

On the Structure step, you create an order by defining which teeth you plan to change in your Blueprint simulation. Click on a tooth and select from the options:

- Reshape
- Align
- Remove
- Relabel

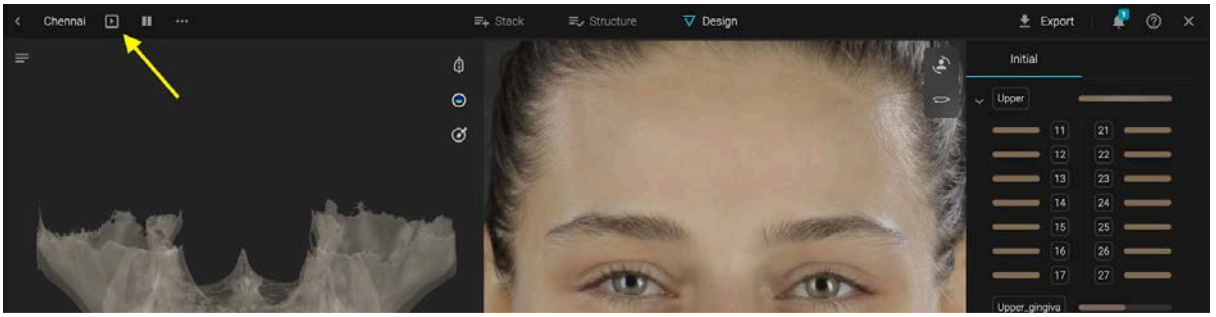
To select multiple teeth, hold COMMAND or CTRL on your keyboard and select with clicks.

You can do these actions on the upper as well as on the lower.

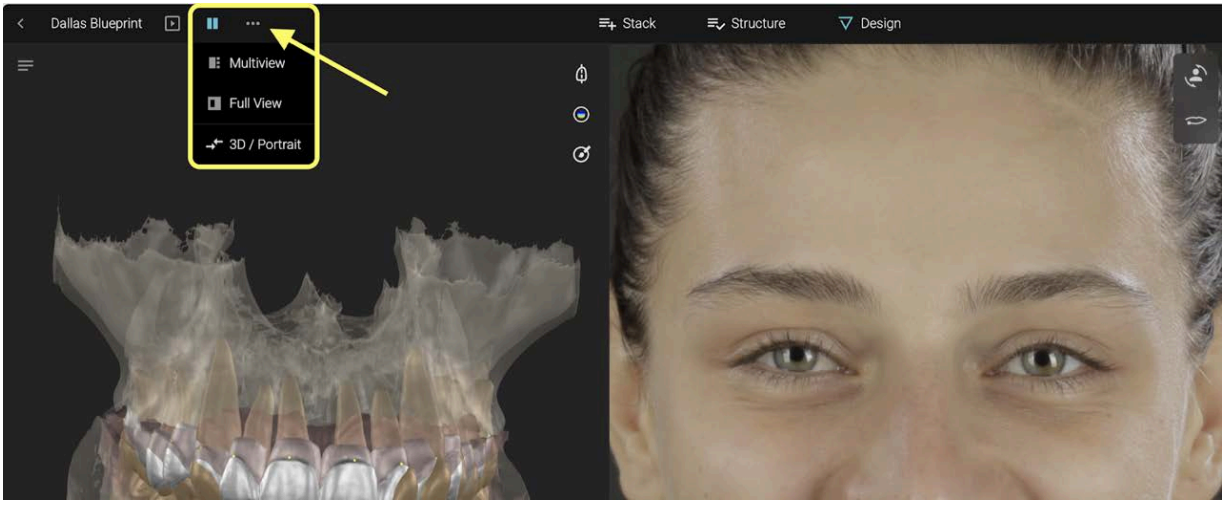
Remember that by proceeding to Design, you represent that you reviewed the segmentation and accept the results.

4. Design

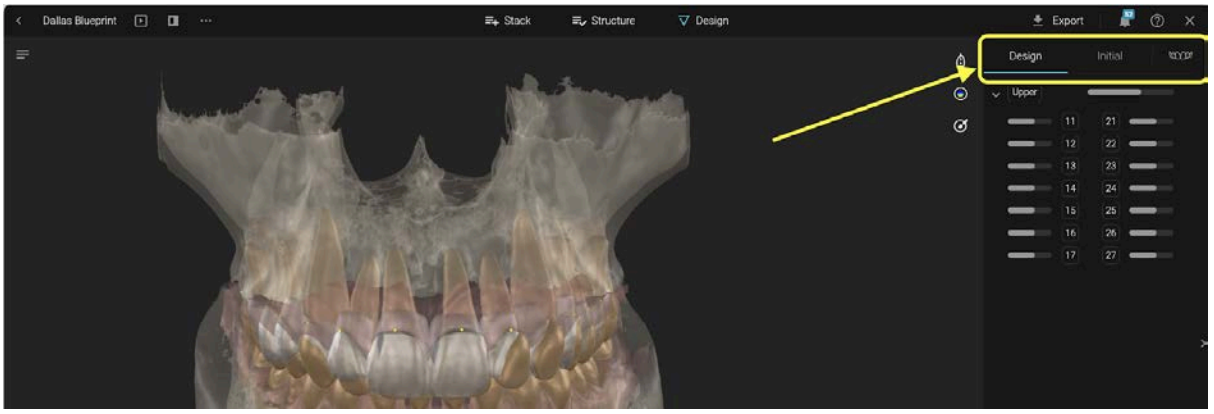
4.1 View Tools



Present mode -> takes you to a before-and-after view of the project on the portrait.
View mode

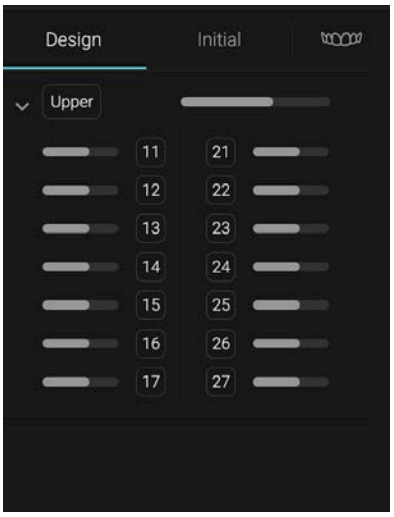


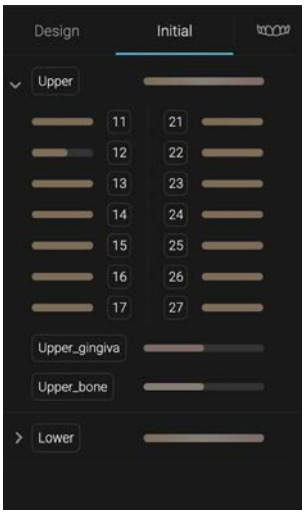
4.2. Layers



Choose to show or hide different objects/structures from the Layers section.

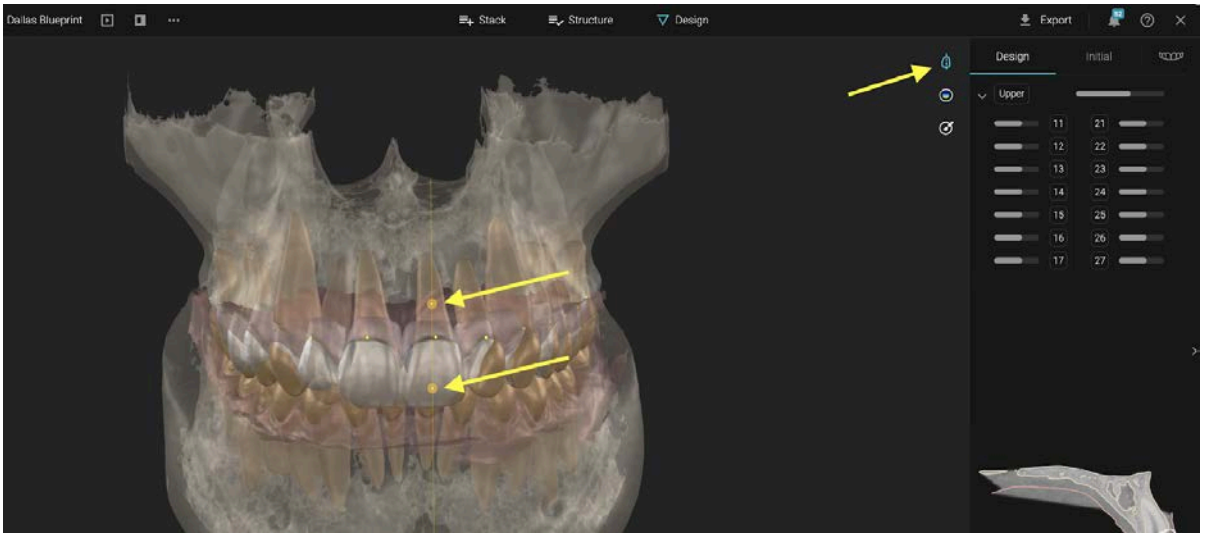
On the Design and Initial Layers: Show / Hide by dragging with the mouse
On the Libraries Layer - browse different morphologies



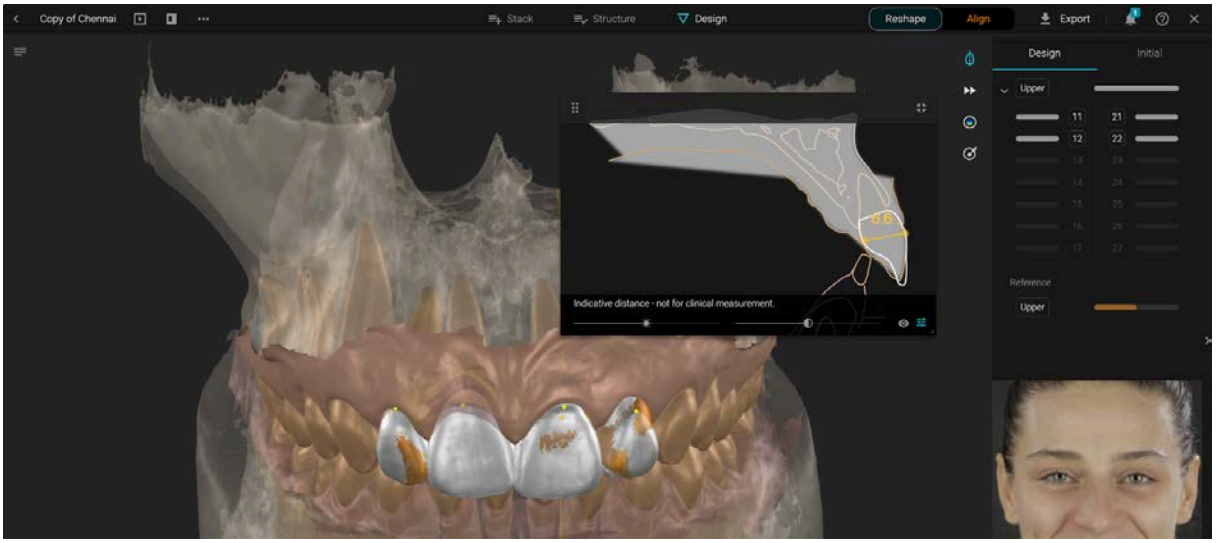


4.3. 3D Control Menu

Cross-section



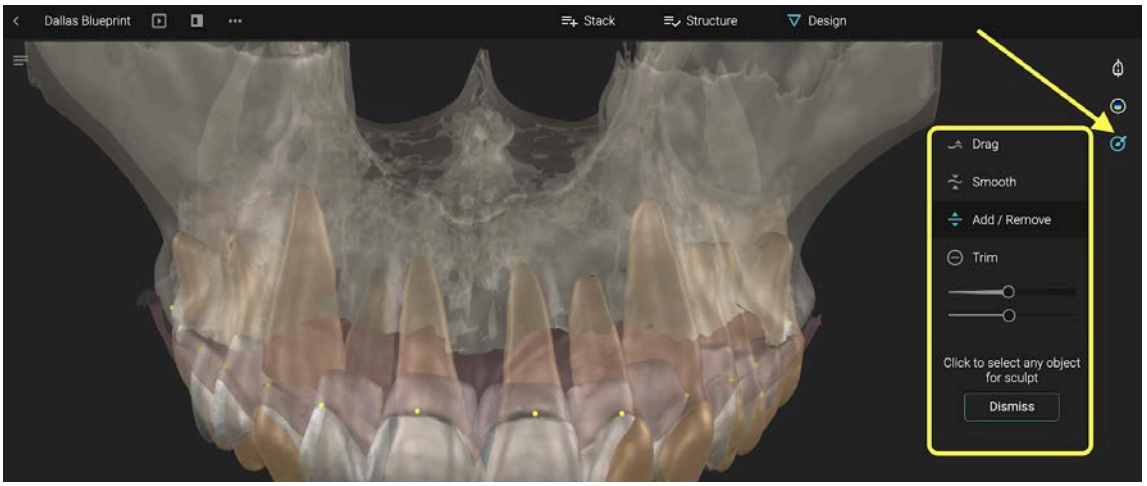
Click on the cross-section button -> then place 2 points to create the section
On the cross-section window, double-click to place points and measure



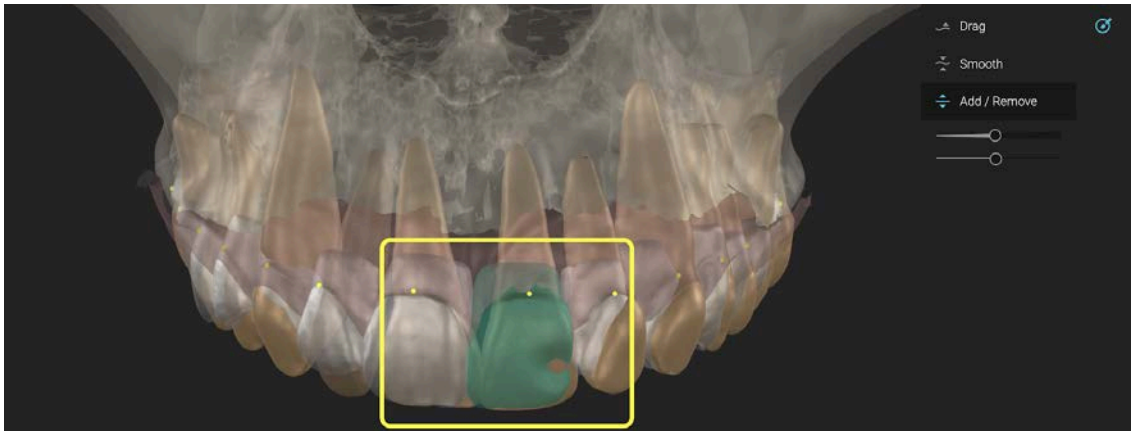
Remember that Blueprint displays indicative distances only - not for clinical measurement.

Heatmap - Activate the heatmap to show contacts or interferences

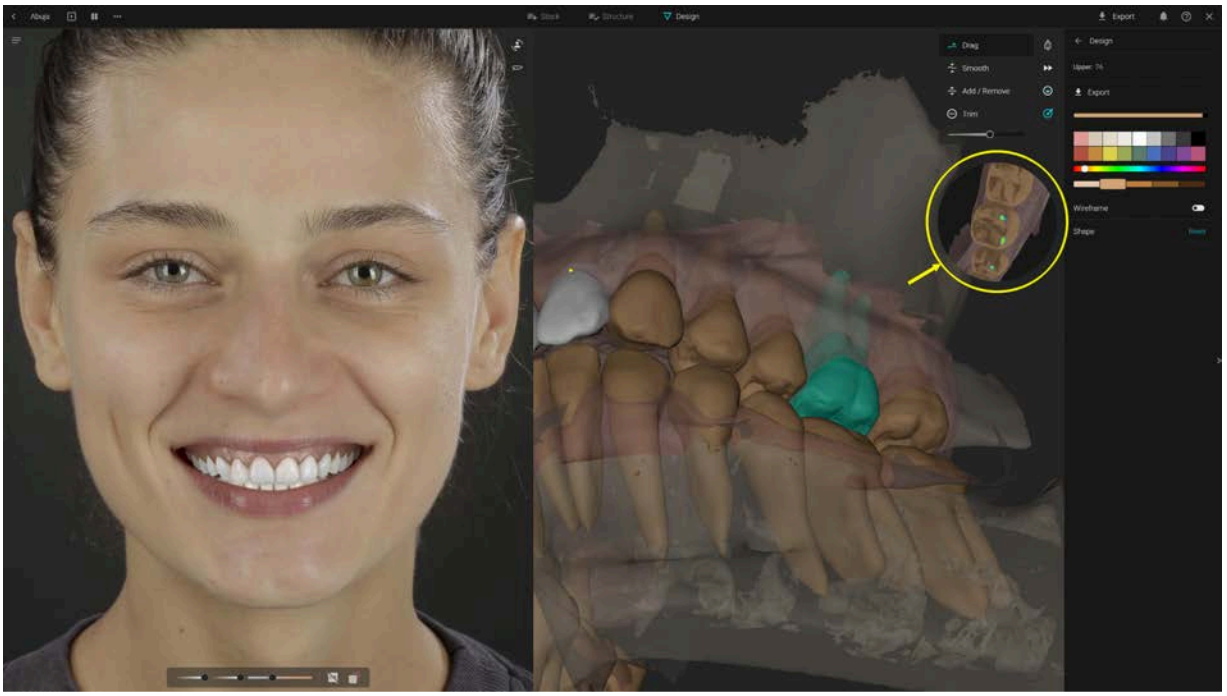
Sculpt tool - Select the type of action, brush size, and brush intensity



Click on a structure and drag with the mouse to sculpt. If using the Drag brush, hold the Y key to limit your action by the antagonist teeth. The action will be stopped at the first contact obtained within your brush area.

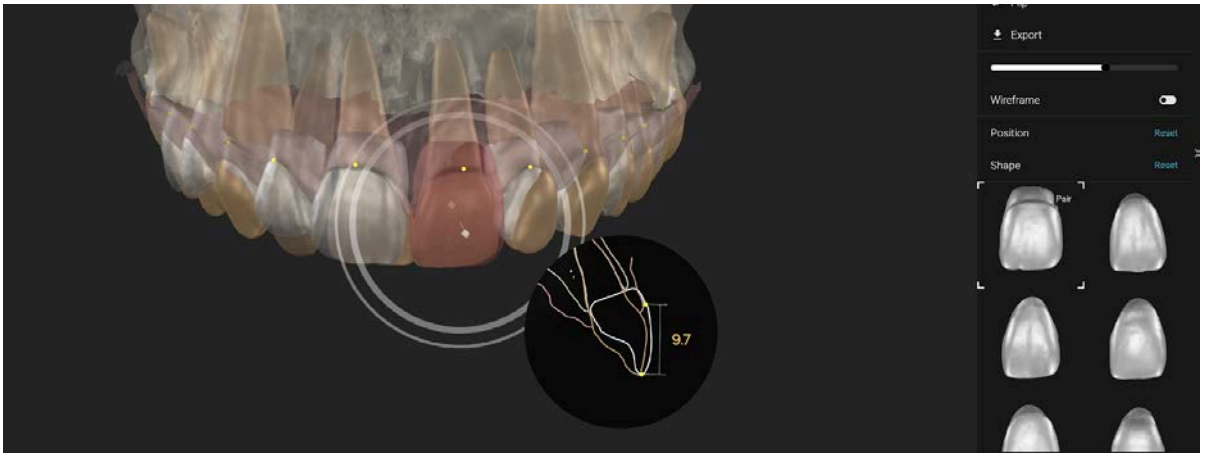


While dragging the brush onto a tooth, a pop-up window called the Companion Window shows up displaying contacts on the antagonist's teeth regardless of the Heatmap tool being active or not.



4.4. Design Controls

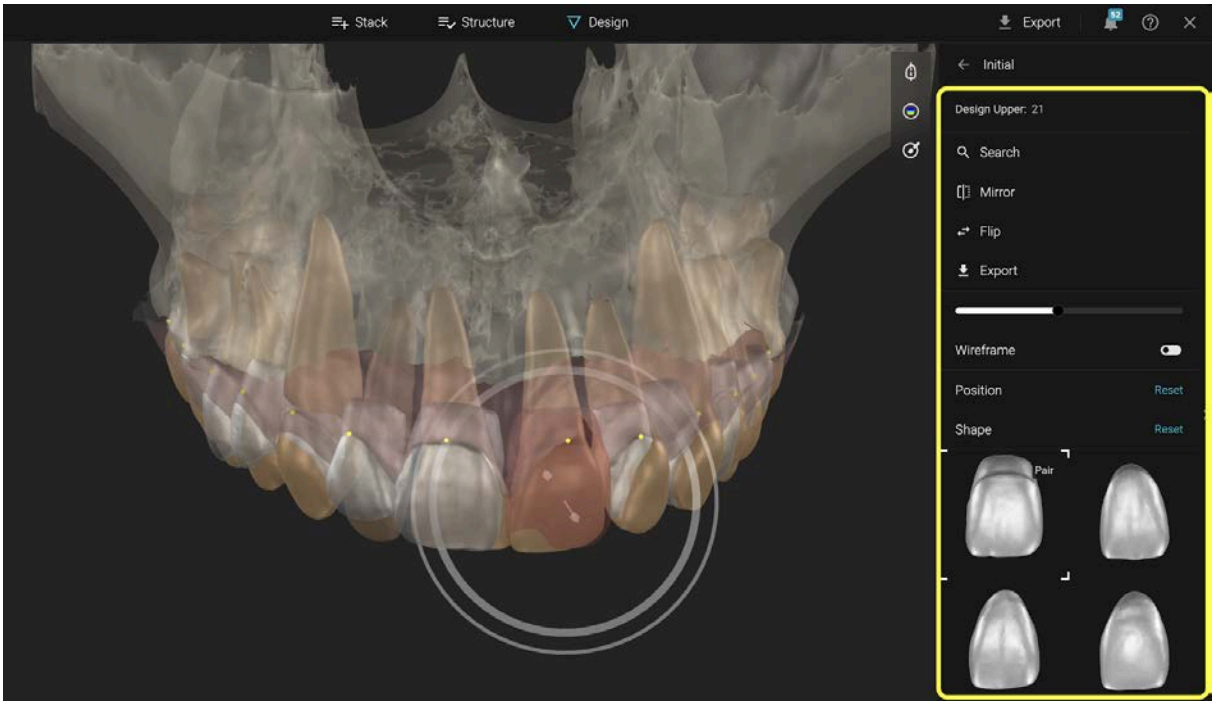
Click on a tooth shape from the design to move with the mouse
Hold COMMAND or CTRL on your keyboard to rotate the tooth on its axis
Drag the outer circle to scale



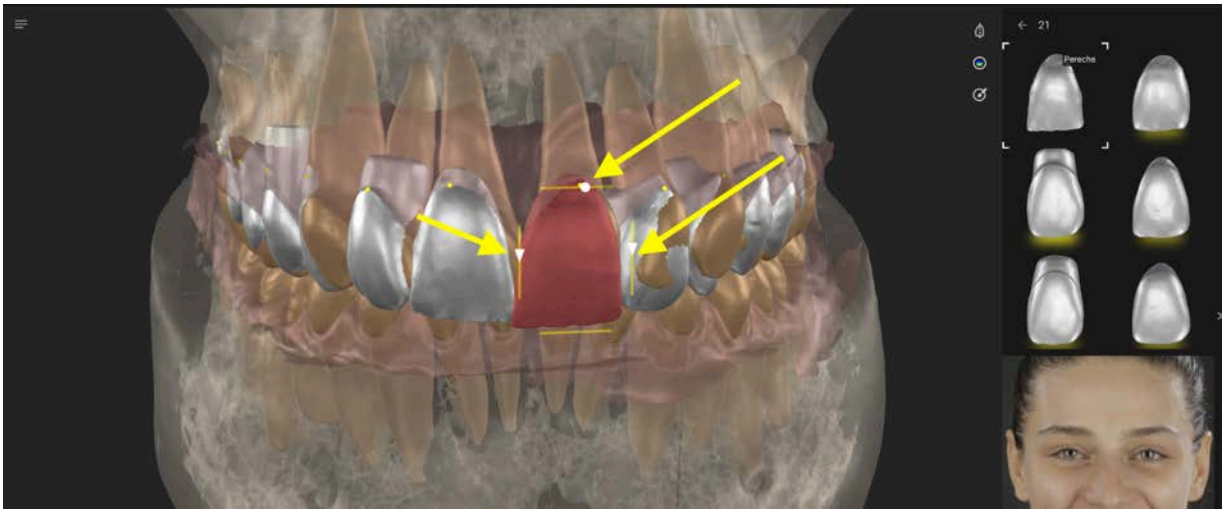
Drag the inner circle to move on the horizontal axis

More tools are available in the design Menu:

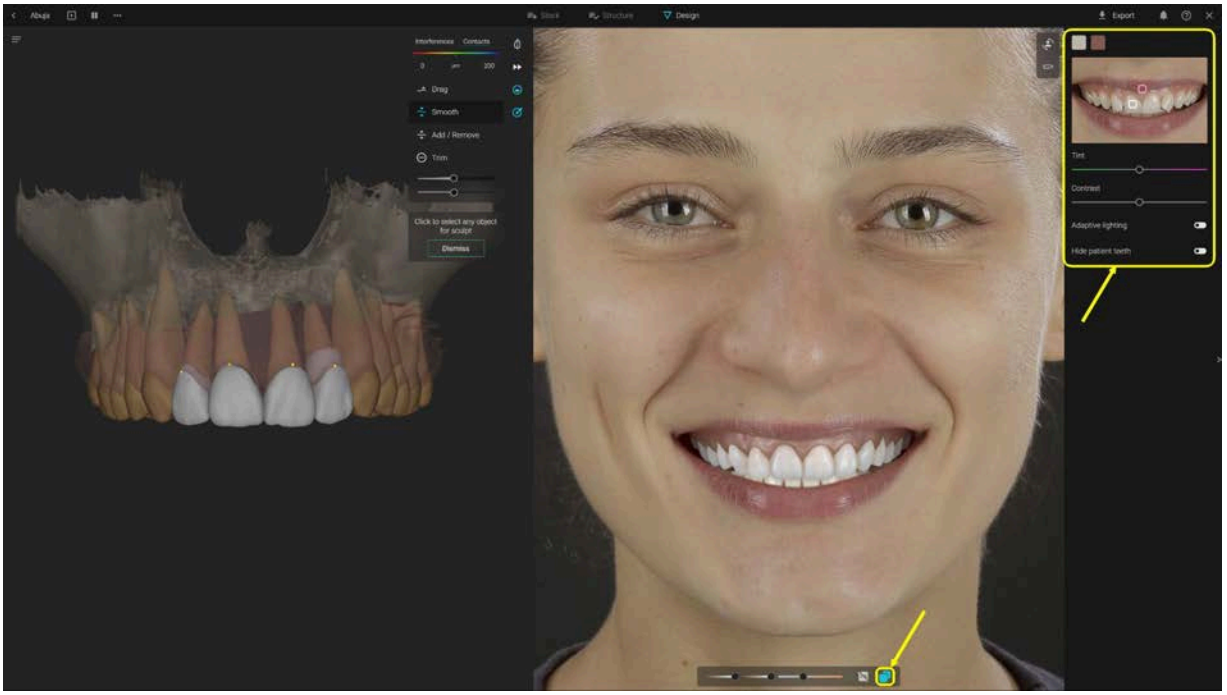
- Search for different shapes
- Mirror the shape
- Flip the shape
- Export
- Show / hide
- Show / hide wireframe
- Reset position changes and Shape changes



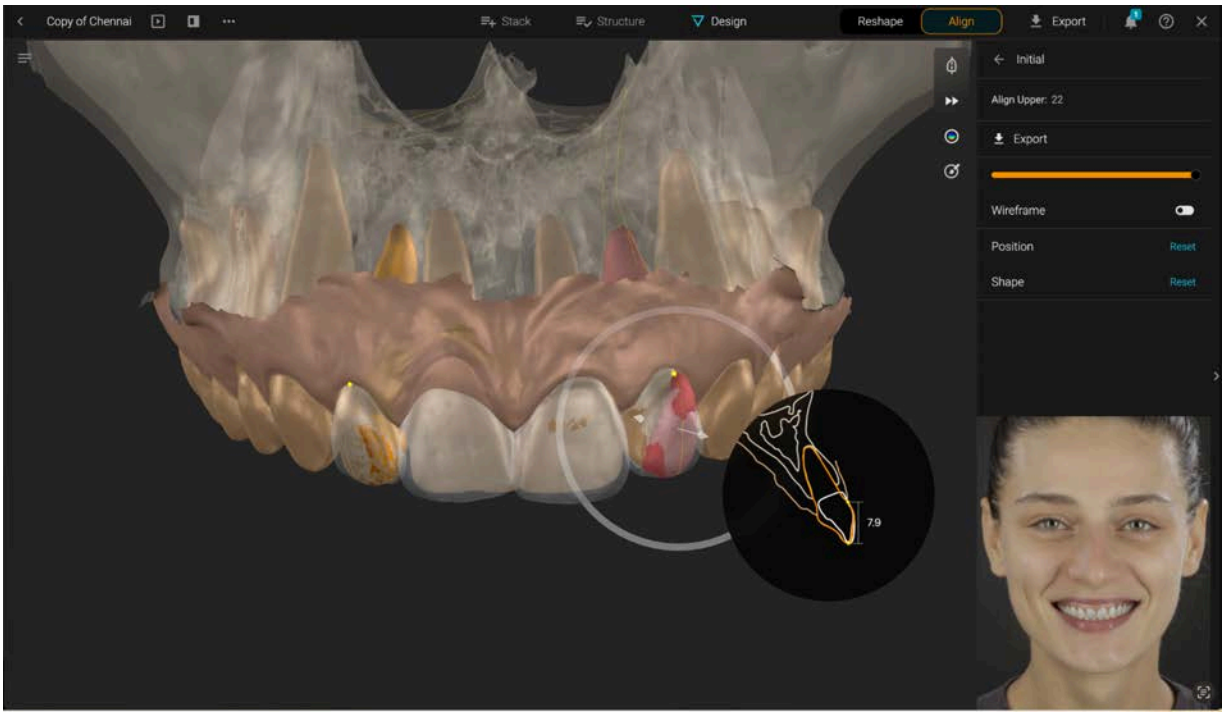
To search shapes for individual teeth - click on the library shape and modify the parameters to get different suggestions.



To adjust color of the simulation on portrait access the color menu



4.5. Align tools

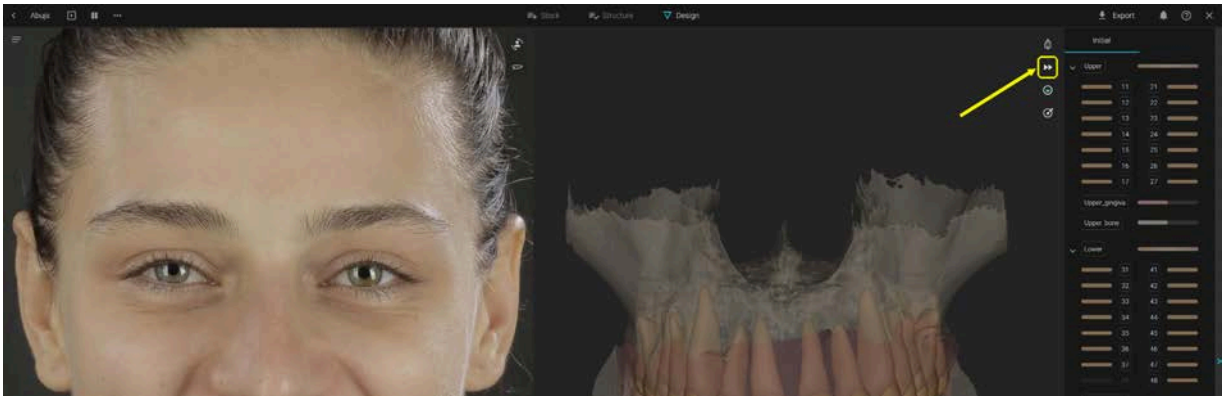


When the align function is selected on Structure, the align tool menu is on the right side. Show or hide the selected teeth from the slider
Align Tooth Controls: Click on a tooth marked for Align to move. Drag from the arrow or the circle.

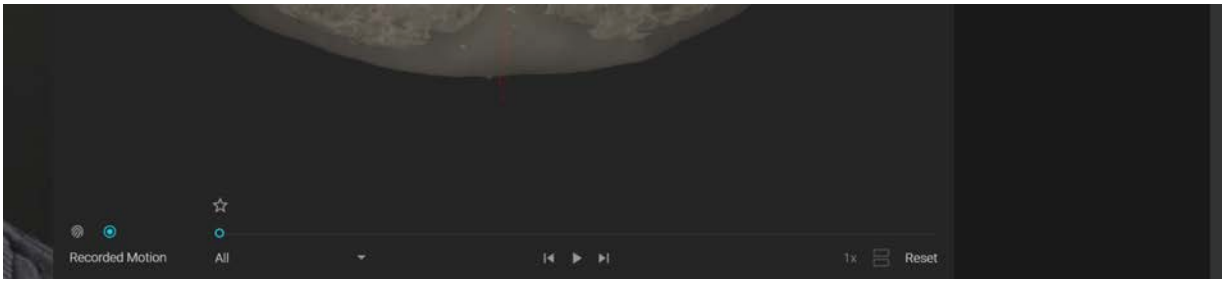
Additional tools are on the right side to reset position, shape and show / hide wireframe.

4.6 Motion Tools

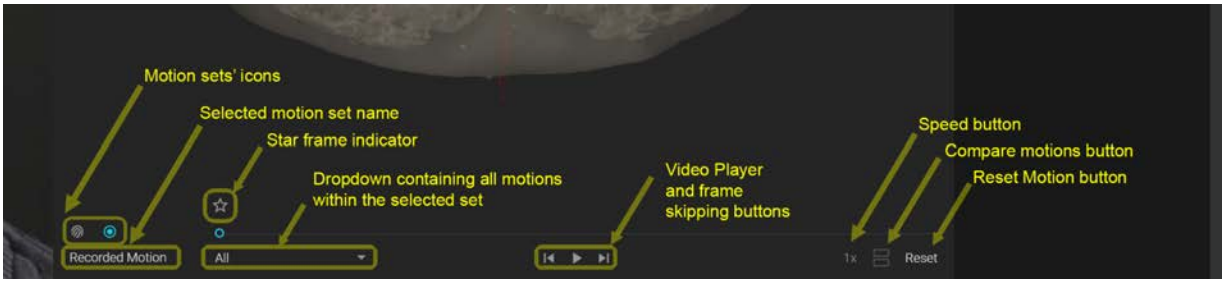
Access to the Motion Tools is given from the Motion button in the top right corner of the 3D viewport. In order to have access to the motion tools, the project must contain both an upper and a lower segmented scan.



Clicking on the Motion tool button opens up the Motion video player at the bottom of the 3D viewport as seen in the image below:



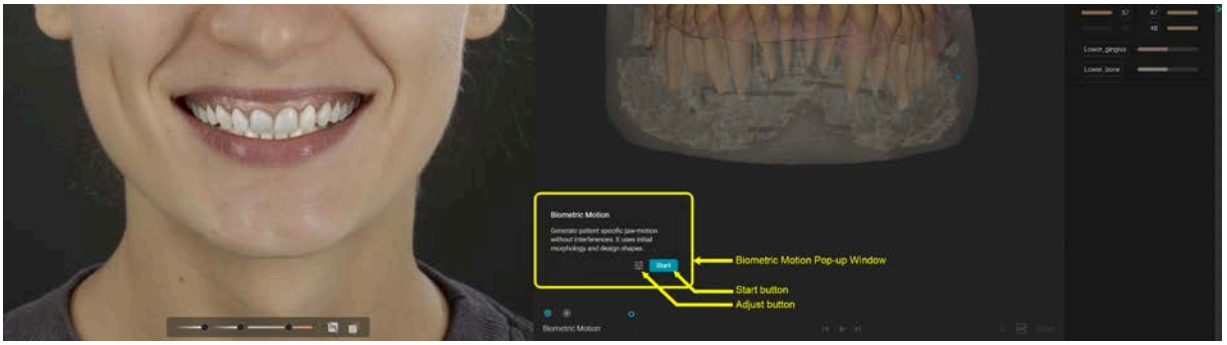
The video player consists of the following elements:



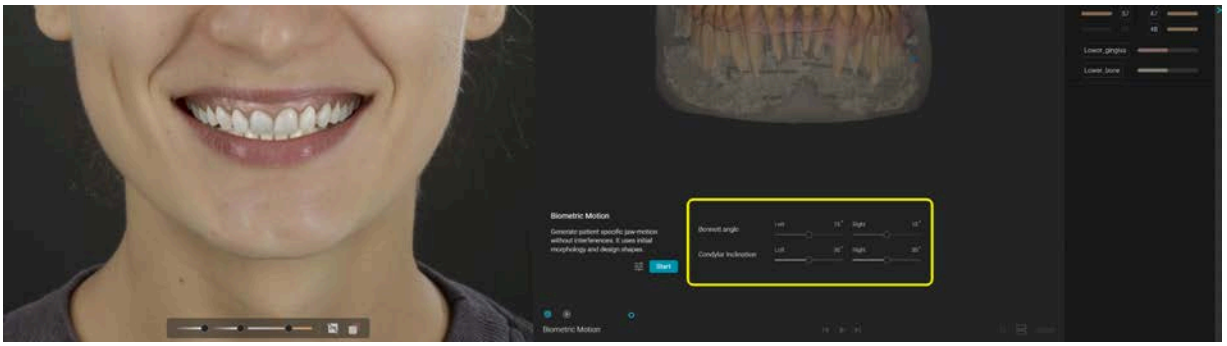
The video player groups animations into two sets that can be played separately.
The sets are: Biometric Motion and Recorded Motion.
These sets are represented by the two buttons in the top left of the Video Player.

If the user has uploaded recorded motion in the Stack Tab and lacks animations in the Biometric Motion set, opening up the motion tool will display the Recorded Motion set by default. Otherwise, it will display the Biometric Motion set.

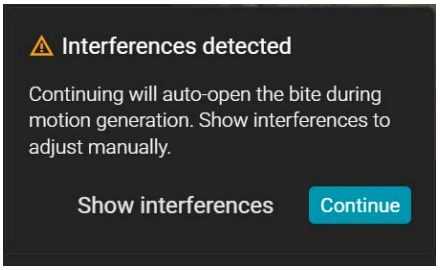
The Biometric Motion set will be empty by default, but clicking on the icon brings up the following pop-up menu consisting of the description of the set with two buttons below: Adjust Button and Start Button.

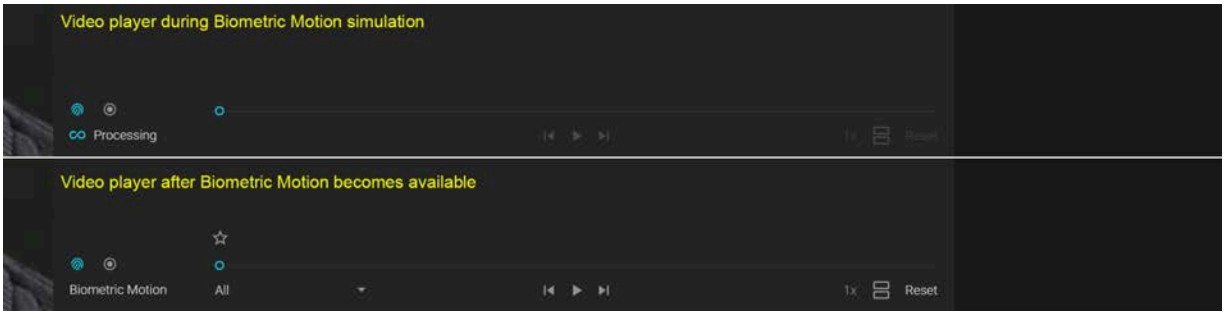


The *Adjust* button allows the user to set custom patient-specific data: Condylar angle, Bennett angle and Condyle positions if the Blueprint contains a CBCT.



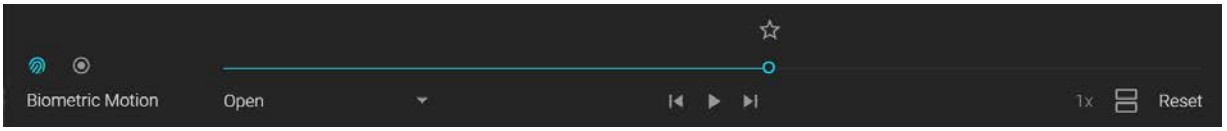
To access the Biometric Motion set the user must press Start. If no custom settings are defined, the Biometric Motion will use the default values of the adjust parameters. If there are interferences between the two scans the user is notified via a message in the Biometric Motion Pop-up Window.



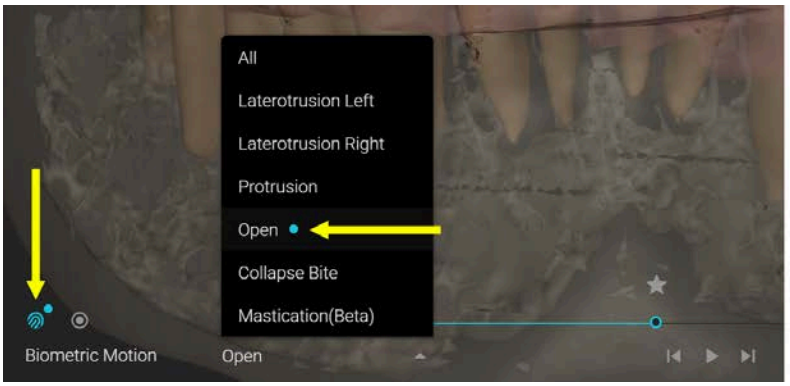


The reset button becomes available.
The first animation of both sets is called “All”, allowing for a fast playthrough of the entire set combined. To select a specific motion and play it solely, the user should click on the dropdown, displaying all animations contained within the set and click on the desired one.

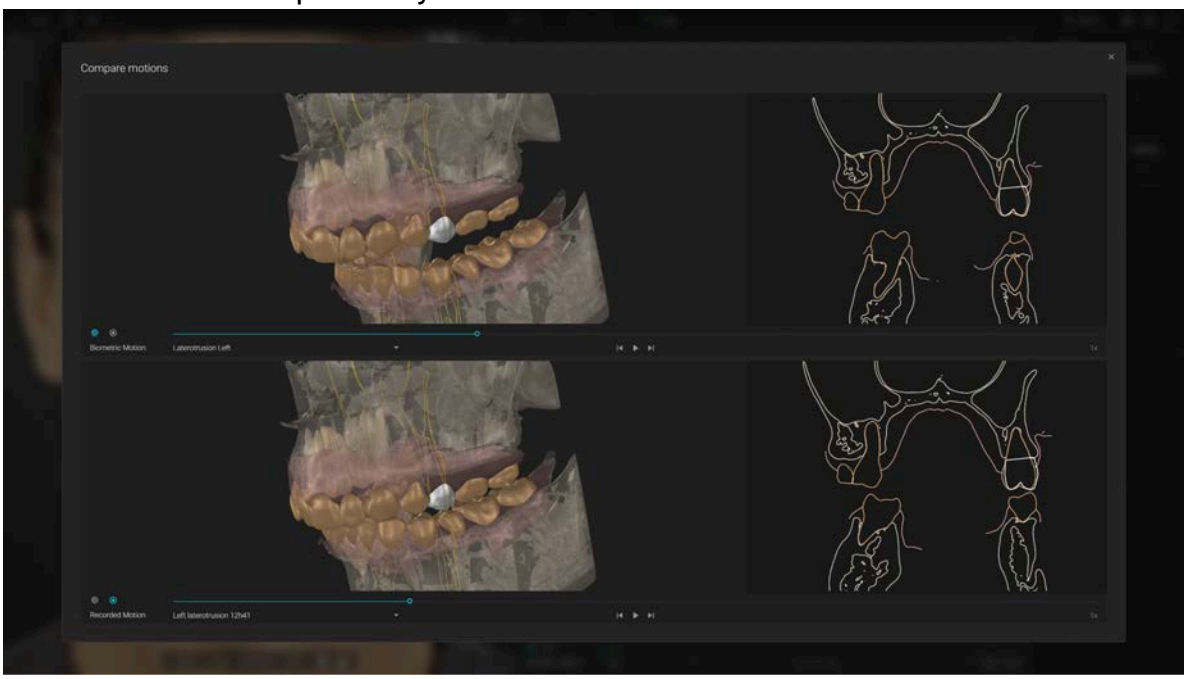
The name of the dropdown switches to the selected animation.



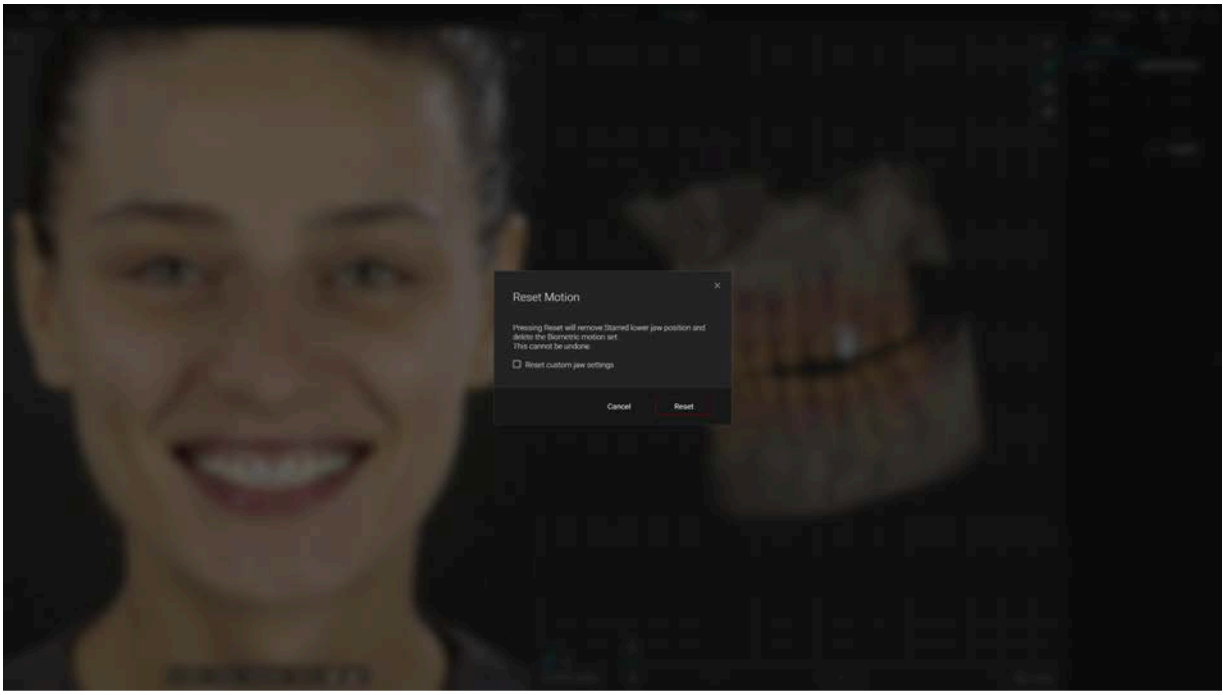
The star icon follows the frame indicator on the seeker bar of each animation. Pressing it adds a filled-up star icon while the outline continues to follow the frame indicator.
Marking a frame with a star maintains the lower jaw position even after closing the motion tool. An indicator of the star frame appears on the motion tools icon, on the motion set icon and on the animation containing the star as a small blue dot.



There can only be one star frame marked at a time. Pressing Start while having a starred frame will resimulate the Biometric Motion set from the starred positions of the two jaws.
The compare button is available only if the user has two sets of motions available in the project. If available and pressed, the Compare Window pops up, allowing the user to view motions comparatively in both 3D and Cross Section.



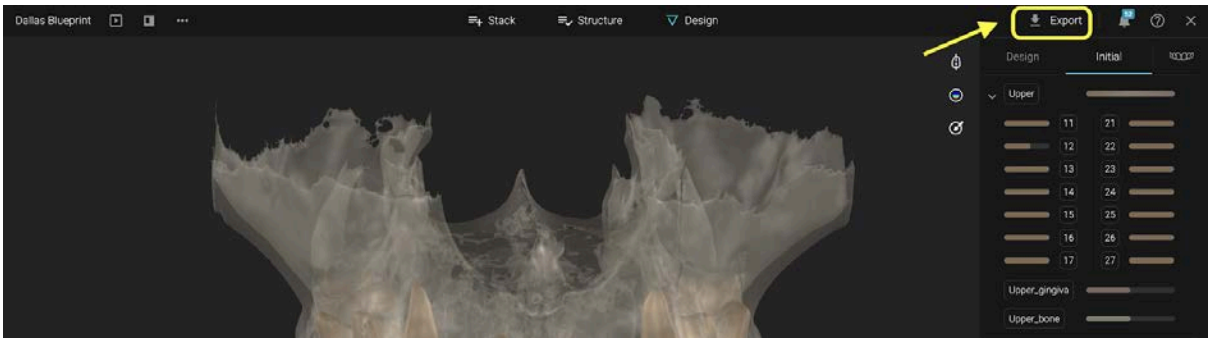
The reset button deletes the Biometric Motion set and optionally resets the custom settings from the Adjust menu. When pressing it, the user gets a pop-up window to confirm the undoable action.

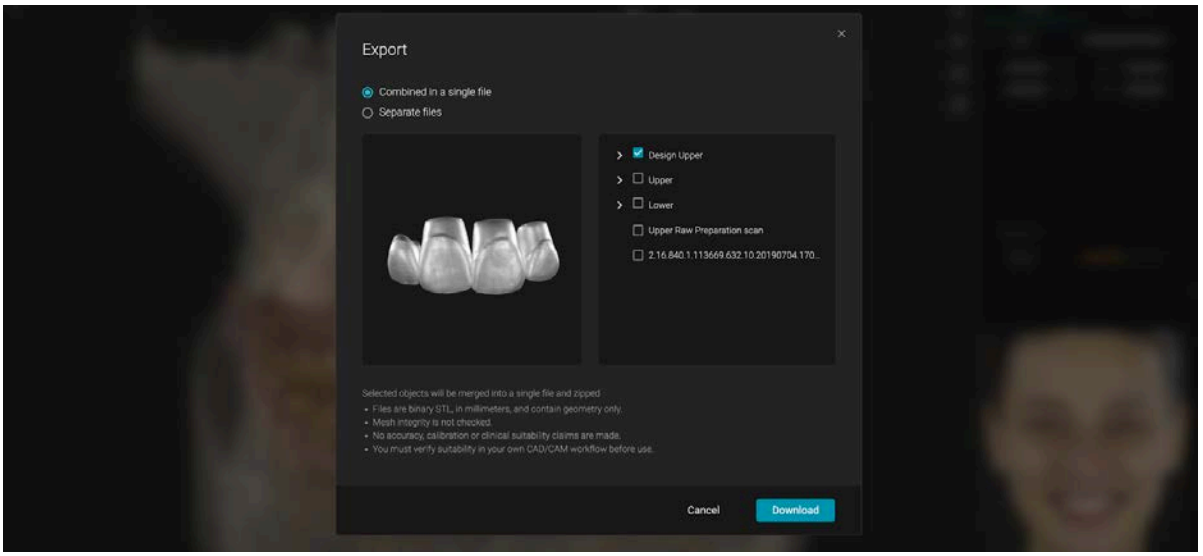


⚠ Remember that the Biometric Motion is a mechanically generated, illustrative animation — not a recording or prediction of the patient's actual jaw movement. It is not a measurement of mandibular function and is not to be used for diagnostic, treatment-planning, or other clinical decisions.

4.7 Export Blueprint as STL to your computer

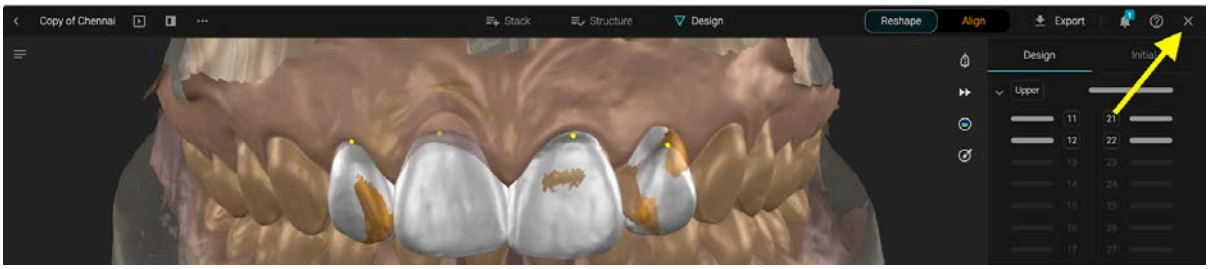
Export as combined or separate files.
Choose which objects you wish to export





4.8 Save Blueprint

Click on the X to save and close the Blueprint



4.8. Blueprint Project Options

From the Project section you have different options for managing the Blueprint:

- Rename
- Share with Patient
- Duplicate (creates a copy)
- Lock (prevents other members to make changes)
- Set as Case Cover
- Delete