MODJAW
Live in motion

TWIN IN MOTION™

THE 4TH DIMENSION LIVE AT THE CHAIR

Twim™

USER MANUAL EN

Table of Contents

1 General product information

1.1 Copyright

No part of this document may be reproduced, transcribed, transmitted, disseminated, modified, merged, translated into any language, or used in any form - graphic, electronic, or mechanical, including but not limited to computer systems, photocopying, recording or storage and retrieval of information without the prior written consent of MODJAW®. Copies of the software included in this document are illegal.

MODJAW neither warrants nor represents that your use of materials displayed on the software will not infringe rights of third parties not owned by or affiliated with MODJAW®.

1.2 Trademarks

The trademarks, service marks, logos and other distinctive signs (collectively, the "Trademarks") presented on this software are trademarks, registered or common law Trademarks (protected by use), belonging to MODJAW®. Nothing contained on the software should be construed as granting, by implication, estoppel or otherwise, any license or right to use any Trademark displayed on the software without the written permission of the Trademark owner. Any use of the Trademarks or a sign similar to them or of any other content of the software, not expressly authorized by these General Conditions, is strictly prohibited. You are also advised that MODJAW® will enforce its intellectual property rights by all legal means at its disposal, including legal prosecution.

The following signs (non-exhaustive list) are used, filed and/or registered trademarks belonging to MODJAW®:

MODJAW, the black and red logos, the MODJAW Live in Motion logo, the MODJAW Tech in Motion logo, MODJAW Tech in Motion, MODJAW Live in Motion, 4DD, 4D Dentistry, the S Sphere logo, the T Twim logo, the TIM Tech in Motion logo, the TIM Twin in Motion logo, Sphere, Tech in Motion, Twin in Motion, Twim, T Twim, TIM Tech in motion, TIM Twin in Motion, OVD Shift, the OVD Shift logo.

Other brands and product names mentioned on the software belong to their respective owners.

1.3 Patents and models

The designs or products represented on this software may be protected as designs or models in the name of MODJAW, in France and/or internationally. Any reproduction or imitation of these designs or models without the express prior authorization of MODJAW® is prohibited and constitutes an act of infringement of these designs or models.

The products represented on this software may also be protected by patents in the name of MODJAW®, in France and/or internationally. Any reproduction of the technical characteristics of these patents is prohibited and constitutes an act of infringement of these patents.

MODJAW SAS 798 221 859 RCS Lyon.

1.4 Warranty

Warranty of the device is 1 year from the date of delivery.

1.5 Manufacturer information

MODJAW®
11-13 Avenue Albert Einstein
69100 Villeurbanne
France
Telephone: +33 (0)482771111
Email: support@modjaw.com
Website: www.modjaw.com

United Stated of America sponsor name

Emergo Global Representation LLC

United Stated sponsor address

2500 Bee Cave Road
Building I, Suite 300, Austin
Texas 78746
USA

FDA Clearance

Device	Device, Jaw Tracking, For Monitoring Jaw Positions
Regulation Description	Jaw tracking device.
Product Code	NFS
Regulation Number	872.2060
Device Class	1

1.6 Structure of the user manual

This manual is a guide for users of the TWIN IN MOTION device. It contains instructions for installation, preliminary verification and use of the device at all times.

It also includes technical data as well as safety, hygiene, and maintenance instructions.

This document is intended to be read by anyone who might interact with the medical device.

Extensions, new settings, modifications, or repairs are made by MODJAW®. Authorized parties are: MODJAW®, authorized and trained technicians, authorized personnel.

Please read the instructions in this user manual carefully before using the medical device.

1.7 Use of labelling symbols

Symbol	Description
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Indicates the need for the user to consult the instructions for use
	Indicates the medical device manufacturer
	To identify the country of manufacture of products
	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Indicates the item is a medical device
	Indicates a carrier that contains unique device identifier information (01) Device Identifier (10) Version number (11) Manufacturing date

2 Usage environment and security

2.1 Intended purpose

TWIN IN MOTION is a software medical device intended to be used with the Tech In Motion Hardware accessories to record mandibular kinematic to monitor jaw positions.

2.2 Indication

TWIM™ is indicated for edentulous or dentate patients at an age allowing understanding and cooperation during the recording protocol.

There is no gender restriction.

2.3 Contraindication

The use of the TWIN IN MOTION device is contraindicated in patients with pathologies that are incompatible with the correct picking of dental models, or who are unable to follow the necessary instructions for the procedure, or who are unable to maintain a correct posture during the examination.

2.4 Clinical benefits and performances

- Helps to generate functionally relevant restorative and orthodontic treatments
- Minimizes the possibility of occlusal adjustments of the definitive restoration, increasing patient comfort
- Reduces processing time of treatment

2.5 Environmental conditions

The supported operating system is Microsoft Windows 10 or Windows 11.

The user must use a PC that meets the minimum recommended configuration.

If you change your hard disk, please contact our support team at support@modjaw.com.

RM-032 and RM-157

Components	Characteristics
Processor	Intel Core i7 or equivalent
RAM	16 GB
Hard disk	500 GB SSD
Resolution	1GB Video RAM
Graphic card	Preferred configuration : Nvidia GTX or AMD Radeon series dedicated GPU with at least 1 GB graphics memory, OpenGL 4, DirectX 11.1, Shader Model 5 and a graphics driver dated August 2017 or newer.
Network parameters	Please, make sure that your network and security settings allows the TWIM software to contact Modjaw servers with the following parameters: - Ports: 80 HTTP, 443 HTTPS (TLS) - Domains: modjaw-admincenter.com, twimprodst.blob.core.windows.net If you intend to use the 3Shape integration capability, “Please, make sure that your network and security settings allow the TWIM software to contact Modjaw servers with the following parameters:

Components	Characteristics
	- Ports: 80 HTTP, 443 HTTPS (TLS) - Domains: identity.3shape.com, users.3shapecommunicate.com, eumetadata.3shapecommunicate.com, asmetadata.3shapecommunicate.com, ammetadata.3shapecommunicate.com, modjaw.com

In order to avoid the risk of data loss or corruption, the hardware platform executing the TWIM software must be connected to a stable power grid

2.6 Obligations of the user

Values provided by the TWIM device highly depend on:

- Quality of input data (especially imported 3D models)
- The use of the device by the user (quality of calibration, reference points picking, reproducible ICP recording, and recorded kinematics)

The user is therefore responsible for the exploitation of data provided by the TWIM device.

MODJAW cannot be held accountable for the exploitation of data provided by the TWIM device

RM-240

The use of the device is reserved to qualified and trained dentists, or under their supervision (students in dental surgery) or to dental technicians.

The device should not be used by unqualified or untrained persons.

RM-175 and RM-230

All data must be interpreted by a qualified specialist who is able to verify the appropriateness of the latter, while taking into account any medical history.

Any inappropriate use is prohibited:

- Do not attempt to maintain the device in any way other than those described in this manual
- Do not modify the device. If the device is modified without the permission of MODJAW®, the device warranty will no longer be valid.

To ensure proper data protection, the user must ensure that the appropriate information system security policy is applied. The user must at least:

- Ensure that an antivirus and a firewall are installed, updated and maintained on the computer where the TWIM software is used
- Ensure that the proper level of access protection and restriction is applied on the computer where the TWIM software is used (nominative access, password policy, account right restrictions)

- Ensure that the operating system where the TWIM software is used is updated regularly to apply security fixes
- Ensure that common and appropriate cybersecurity best practices, guidelines or measures are followed

RM-123

If TWIM is installed on a portable electronic device such as laptop computers or if EPHI are stored on removable storage media, user shall ensure that EPHI are not accessible by unauthorized persons on these devices, through installing and activating adequate encryption software on such devices, and encrypting any PHI and EPHI stored on such removable media prior to distribution, to render such PHI or EPHI, as the case may be, unusable, unreadable or indecipherable to unauthorized individuals, in compliance with the Department of Health and Human Services Guidance, 74 Fed. Reg. 19006, 19009-10 (April 27, 2009) and consistent with the National Institute of Standards and Technology Special Publication 800-111, Guide to Storage Encryption Technologies for End User Devices.

The license is regularly checked online. As such, the TWIM software must access to the Internet at least once a month.

2.7 Incident reporting

If the user/patient had a serious incident, please report it to MODJAW® support (for contact details, see section 7), and the competent authority of the Member State in which the user/patient is established.

3 Product description

3.1 Module description

The TWIN IN MOTION (version 3) includes 3 modules:

- ACCESS: provides the basic functionalities of MODJAW® such as recording patient motions, replaying patient motions, exporting patient motions out of a 3D scan. Basic analysis features are available, such as contacts display and FGS.
- ADVANCED: provides advanced features such as trajectory analysis (graphs), estimation of articulator parameters, patients bone scans import, patients bone contacts analysis during the motion, hinge axis estimation.

  AESTHETIC: provides aesthetic features such as patient's face scan import, patient's picture import or capture, face proportion verification tools, OVD adjustment, motion transposition with adjusted OVD, split view, Aesthetic plan record and display.

3.2 Install and update software

Please refer to "TWIM installation guide" document.

3.3 Cloud synchronization

According to your license, cloud data synchronization may be available.

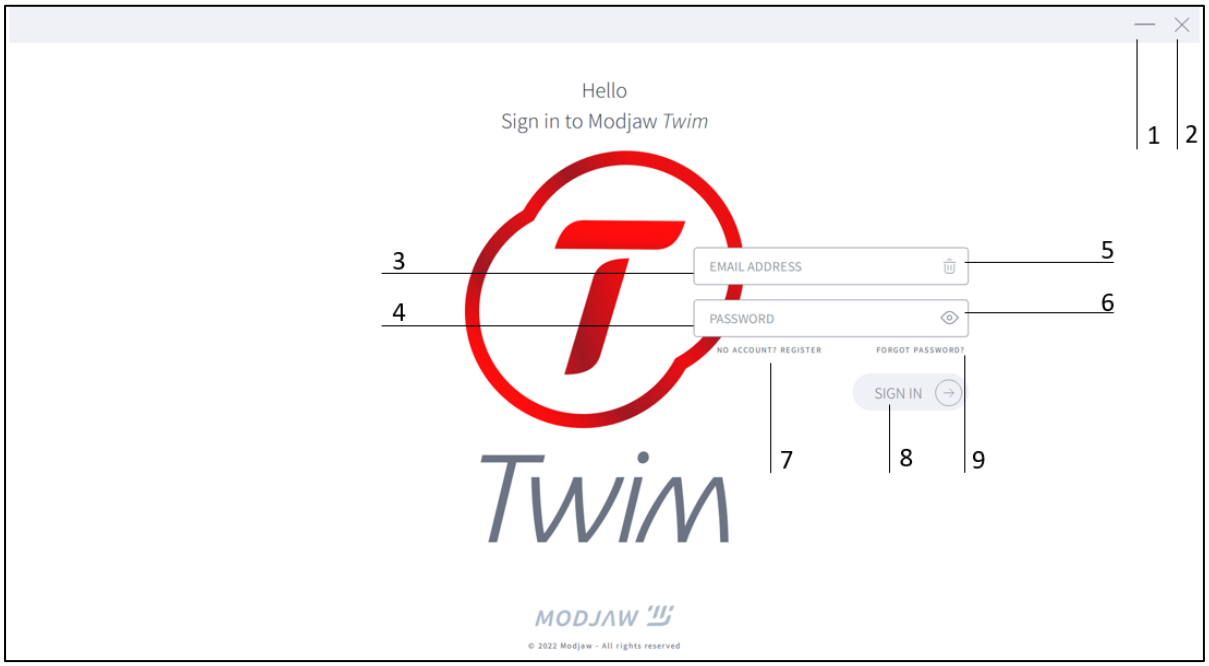
If cloud synchronization is available, you can access to all your synchronized data by logging in to TWIM™ on another machine attached to your customer account.

RM-033

4 Login, patients and consultations

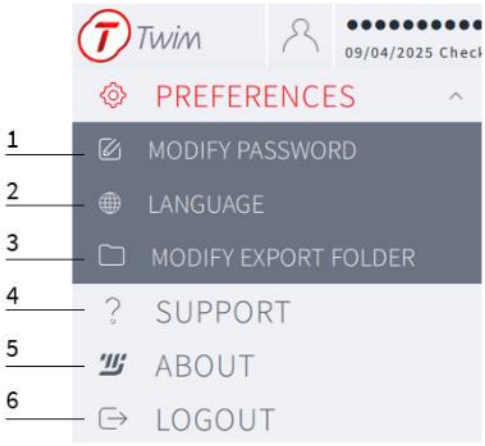
RM-033

4.1 Login



1	Minimise TWIM software window
2	Exit TWIM software
3	Login
4	Password
5	Delete
6	Show password (hold to show)
7	Register
8	Sign in
9	Forgot password

4.1.1 “Preferences” and “About”

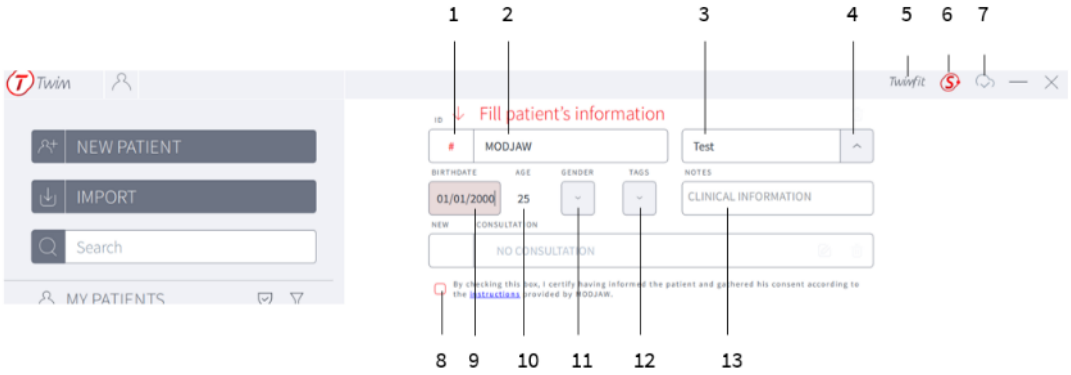


1	Modify password (only available if logged-in)
2	Select language *RM-214*
3	Modify export folder (selection of the folder to store exported files)
4	Display MODJAW support contact details
5	Display TWIM software information (label)
6	Logout (only available if logged-in)

4.2 Patients

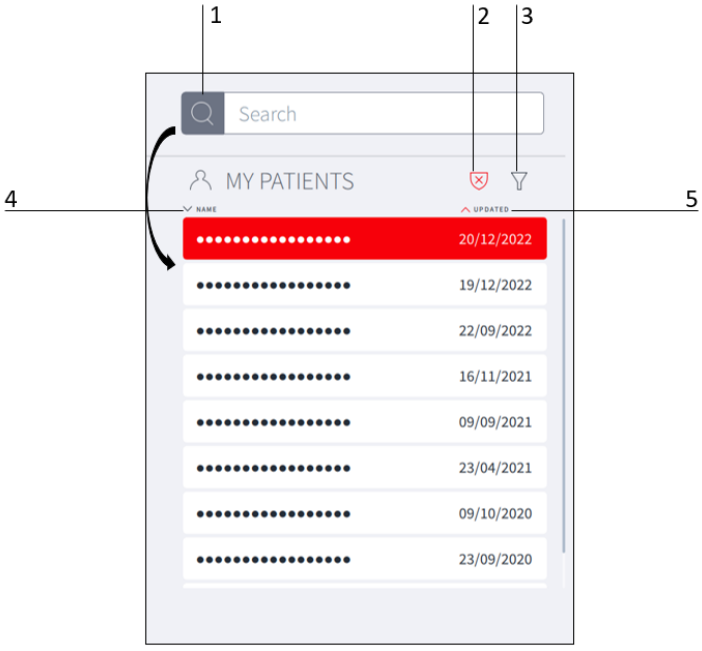
1	Create new patient file
2	Import consultation file (.mod)
3	Search patient

4.2.1 Create patient



1	Patient ID
2	Patient last name
3	Patient first name
4	Hide/show patient detailed information
5	Twimfit analysis information
6	Sphere
7	Cloud connection status
8	Patient's consent
9	Patient's date of birth (dd/mm/yyyy)
10	Patient's age
11	Patient's gender
12	Treatment project tags
13	Notes about the patient

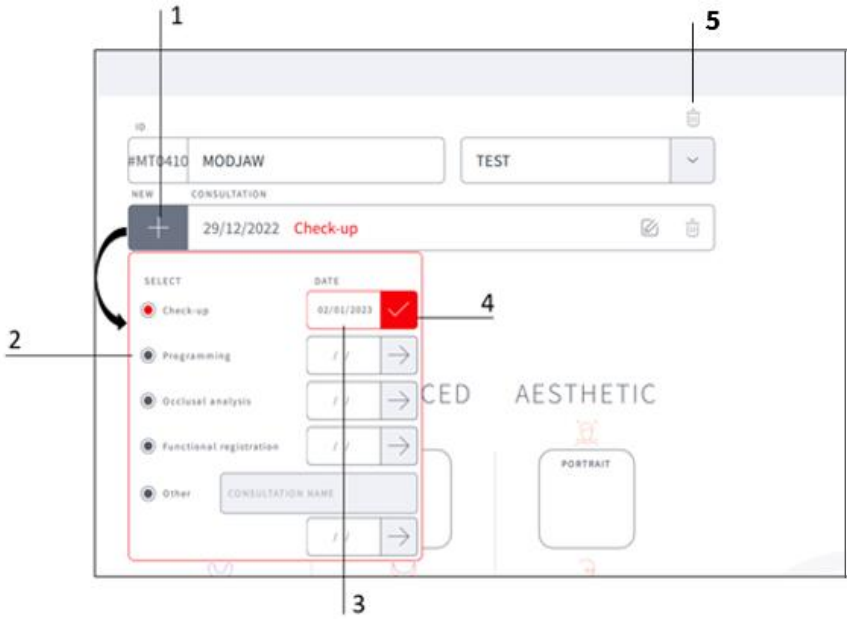
4.2.2 Search patient



1	Select existing patient file
2	Hide/show patient names in list
3	Filters
4	Sort by last Name
5	Sort by Last Updated Date (dd/mm,yyyy)

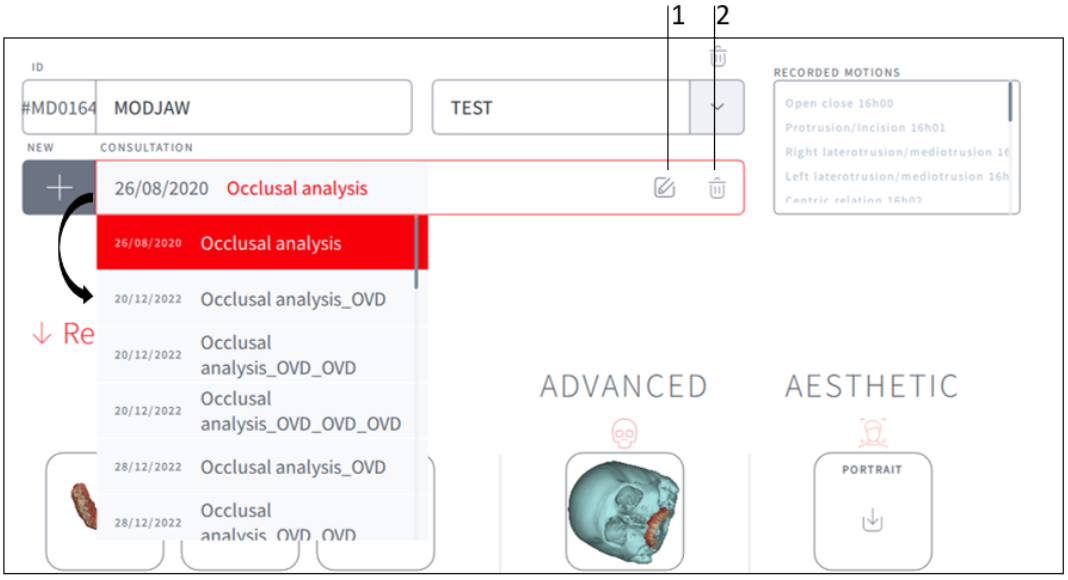
4.3 Consultations

4.3.1 Create consultation



1	Create new consultation
2	Select consultation purpose
3	Enter consultation date (dd/mm/yyyy)
4	Confirm consultation creation
5	Delete consultation

4.3.2 Manage consultation



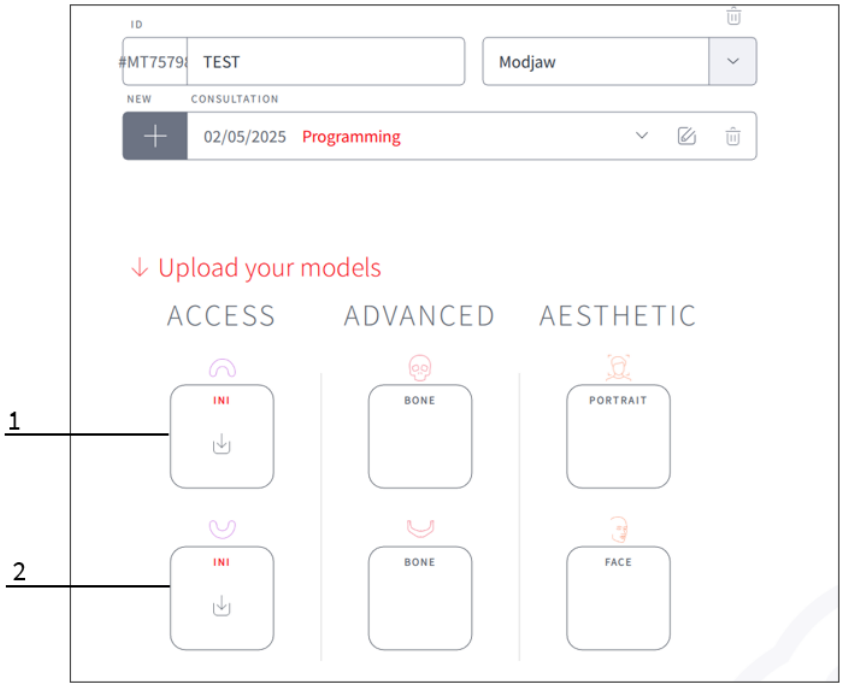
1	Modify selected consultation
2	Delete selected consultation

5 LIVE AND RECORD

RM-033

5.1 Preparation of the exam

5.1.1 Importing the initial 3D models



1	Import maxillary model
2	Import mandibular model

<u>Prerequisites of 3D models:</u>

<u>Mesh models:</u>

- In binary OBJ format
- In binary STL format
- In binary or ASCII PLY format with a unique texture and texture coordinates per vertex, or with texture coordinates per face, or without an associated texture but color per vertex data
- Mesh at 1:1:1 scale, expressed in mm

RM-129

The maxillary model and the mandibular model are imported in the patient's reproducible ICP. They are expressed in the same frame of reference.

<u>Recommendations for the 3D models:</u>

- Minimum mesh size: 200 µm
- Homogeneous and regular meshes, especially in contact areas
- Average edge size: 300 µm
- Maximum resolution: 300 000 vertices

The quality and precision of 3D models of dental arches imported into the application have a direct impact on the information provided by the system. The user must respect the recommendations listed above for the selection of 3D models.

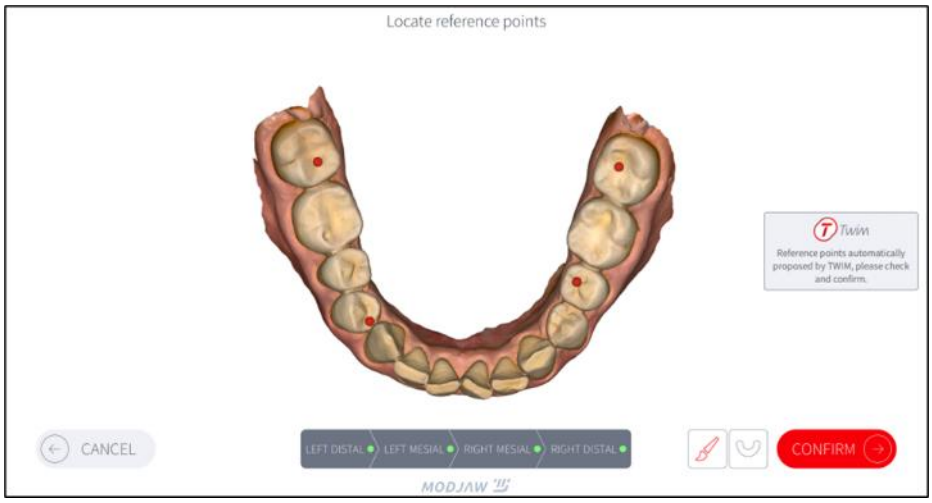
RM-108

The user is responsible for importing mandibular and maxillary models generated in the patient's reproducible ICP, and visually checking that the models have indeed been generated while the patient was in that position. Any relative positioning defect of the models has an impact on the information provided by the software.

The user is responsible for importing the mandibular and maxillary models corresponding to their patient.

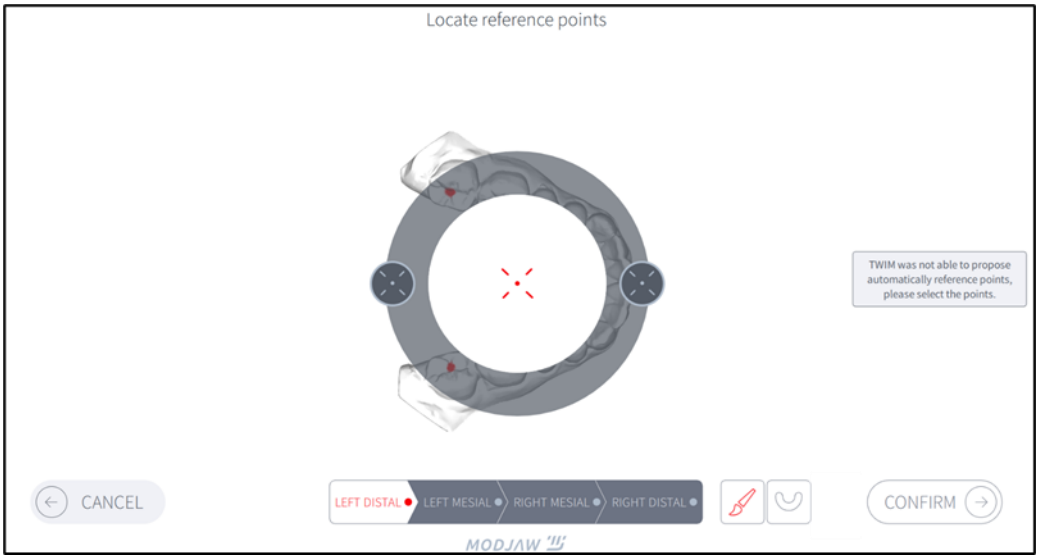
5.1.2 Identification of the reference points

5.1.2.1 Auto selection of the reference points



In mouth picking points are automatically selected by TWIM. Users should check the proposed points and adjust if needed by clicking on the point's name.

In some situations, TWIM may not be able to propose points. If so, the reference points must be selected manually.

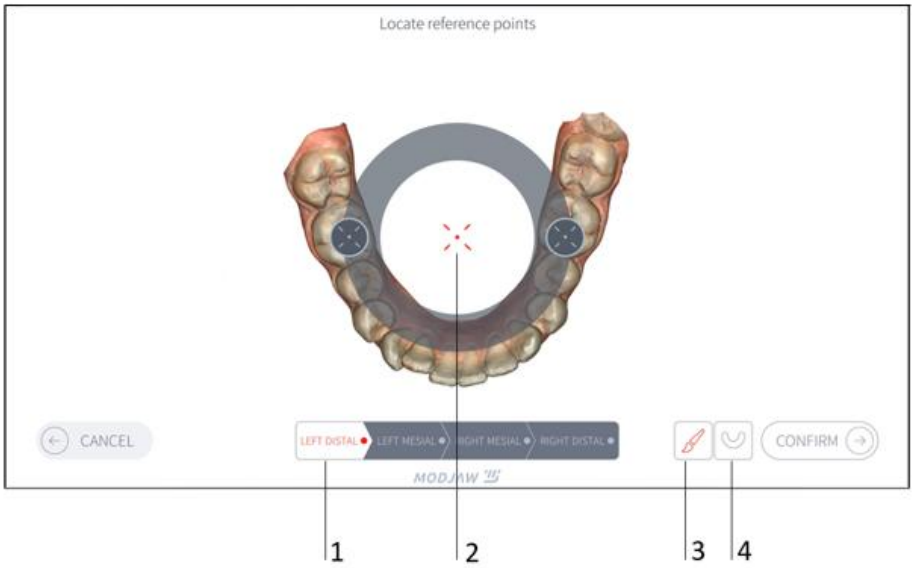


5.1.2.2 Manual selection of the reference points

RM-214

On the 3D model of the mandible or the maxilla, identify 4 points that will be acquired later in the mouth. To ensure accurate matching, it is recommended:

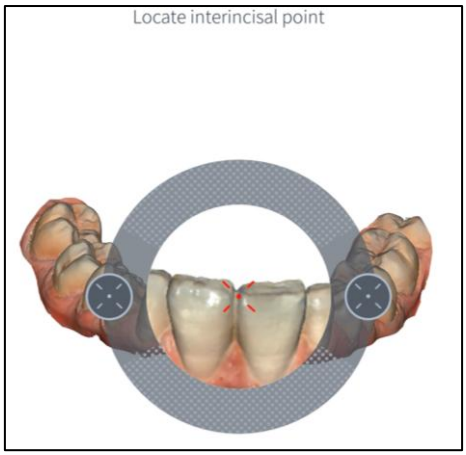
- To define points that will be easily acquired in the patient's mouth with the TALLY
- To distribute these points over the entire occlusal surface



1	Point to locate
2	Point selection tool
3	Activate/Deactivate colours
4	Switch between models (maxilla/mandible)

5.1.3 Identification of the interincisal point

RM-214



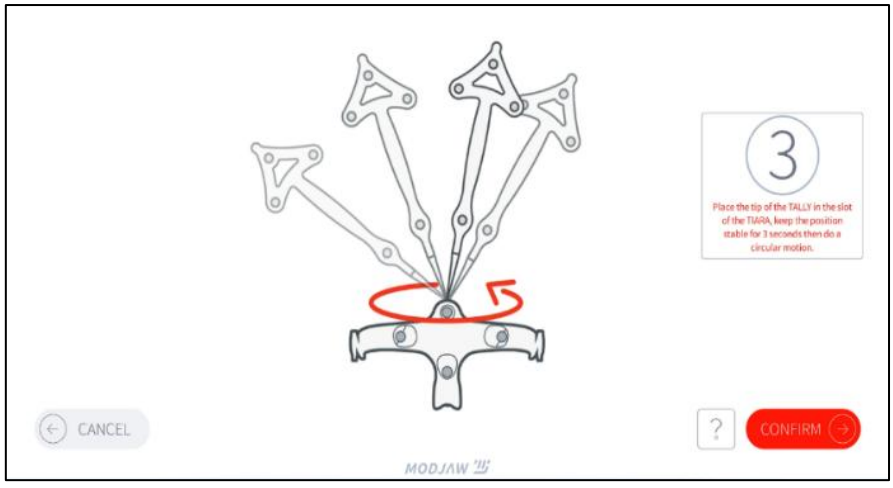
5.2 Calibration

RM-214

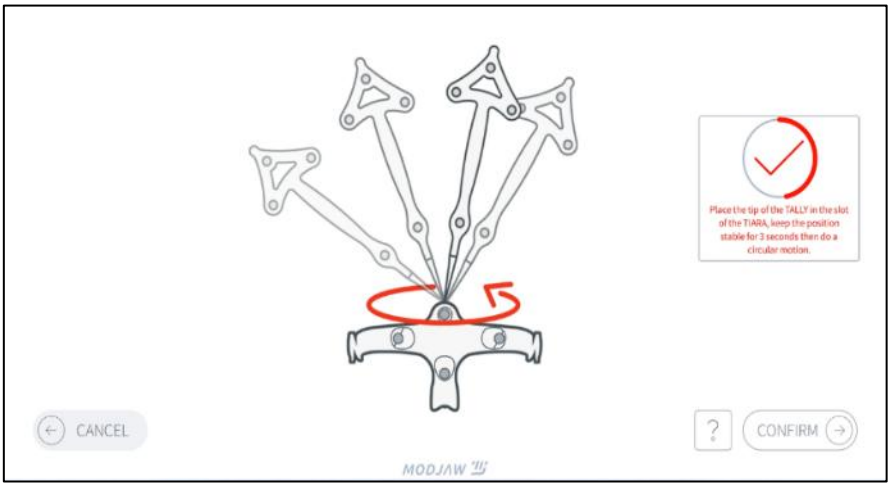
Any fall of an instrument before or during use can alter the information provided by the system. If the instrument falls between calibration and picking, it is recommended to recalibrate or to change the TALLY, before calibrating again.

Calibration is required before each record. During calibration, keep the frontal tracker in front of the camera, about 80 cm away from it and follow the displayed instruction:

- Waiting phase:



- Moving phase:



5.3 Instructions to give to the patient before starting

Ensure that the patient faces the camera, and that the patient is able to:

- Do the examination
- Understand the instructions and execute them

The user must inform the patient that they must not move during the picking.

RM-100

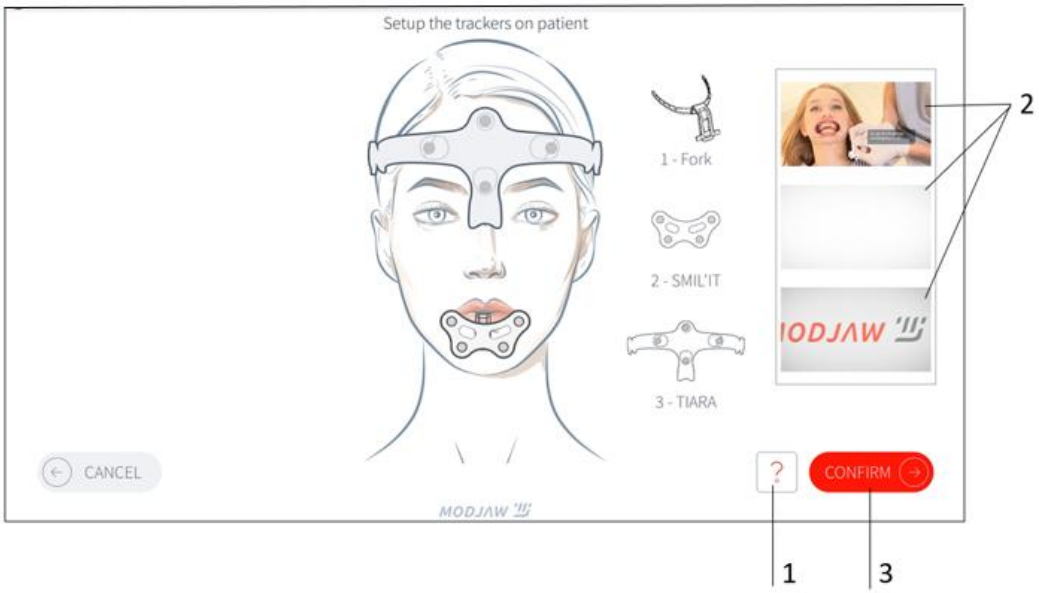
The user must ensure that:

- The trackers are in the camera's field of view throughout the picking process
- The camera faces the patient
- Reflective surfaces and polluting lights (sunlight, lamps with high IR emission around 850 nm, etc.) are avoided

5.4 Setting up the instruments on the patient

It is important to check that the instruments are correctly positioned and that they do not move once in place. Otherwise, the precision of the system will be altered.

RM-101



1	Display tutorial videos
2	Play tutorial videos dedicated to each instrument
3	Confirm the correct position of the instruments

5.5 Setting up the camera

- Position the camera 80 cm away from the patient's face
- Adjust the camera so that the distance to the patient and the rectangle representing the work volume turn green
- Check that the TIARA and the SMIL'IT are clearly visible by the camera and that the patient is in occlusion

Ensure that the markers remain in the camera's field of view.

RM-214/RM-008

If an instrument is **not visible** by the camera, it will be indicated by one of the following symbols:

 TIARA **not visible**	 SMIL'IT **not visible**	 TALLY **not visible**

If so, the user can:

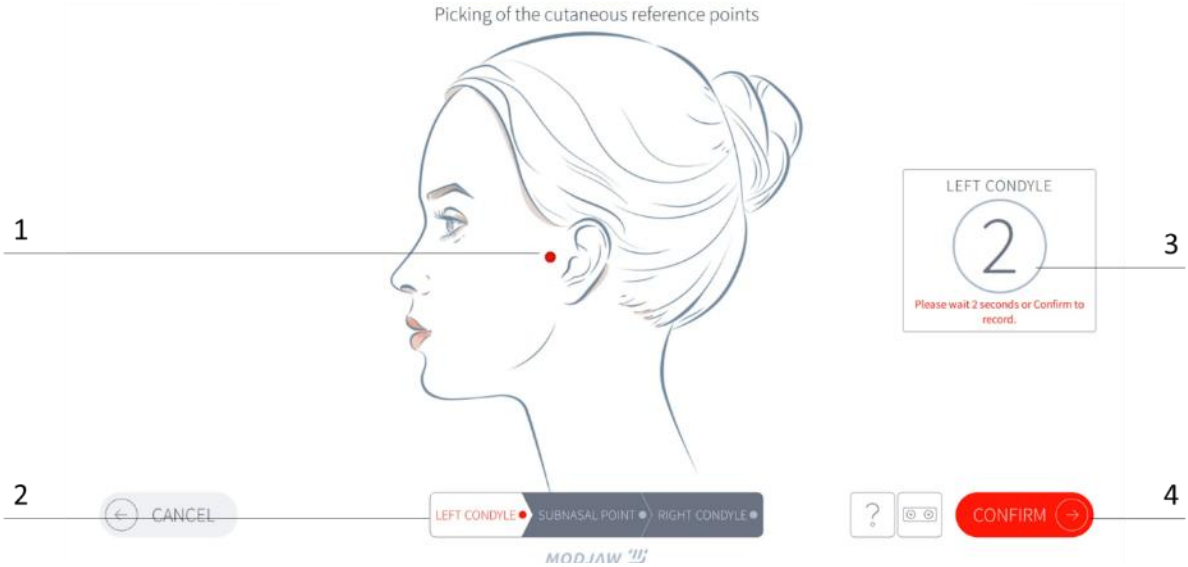
- Adjust the position of the patient
- Adjust the orientation and the position of the camera in front of the patient's face to ensure that the instruments are in the field of view of the camera
- Clear the line of sight between the instruments and the camera
- Check the condition of the fiducial markers (NAVEX) and that they have been correctly clipped in
- Make sure there is no light pollution

1	Light pollution warning
2	When clicking on the warning, an explanation message is displayed

5.6 Picking of reference points

RM-214

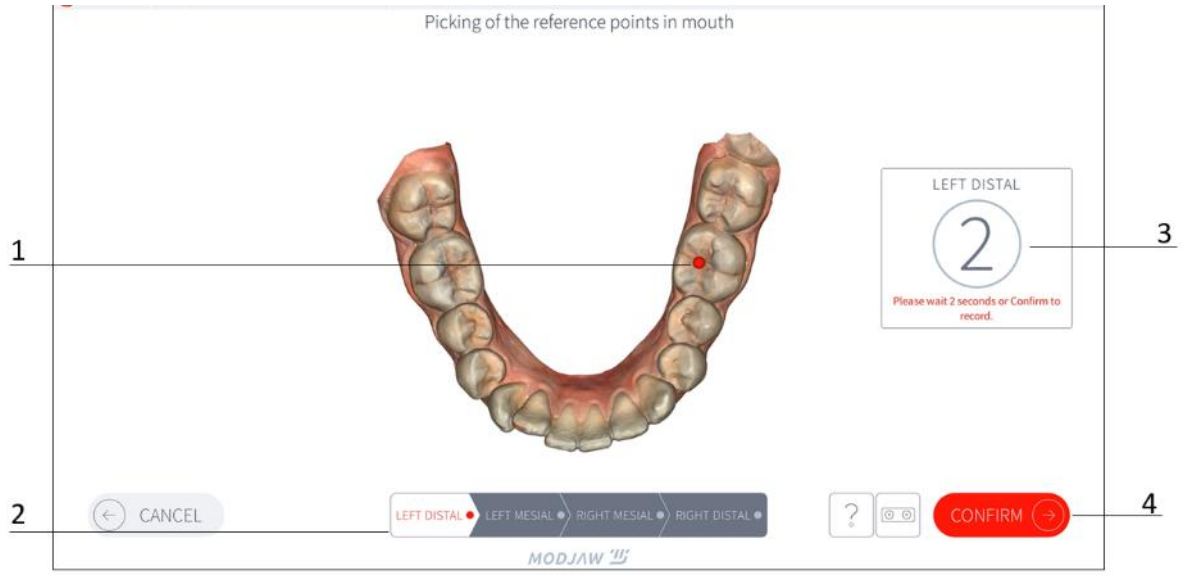
5.6.1 On the face



1	Indication of the anatomical point to pick
2	Order of the points to pick
3	Automatic confirmation of the picking after 2 seconds
4	Manual confirmation

5.6.2 In the mouth

Position the tip of the TALLY in the mouth on the point indicated on the screen.

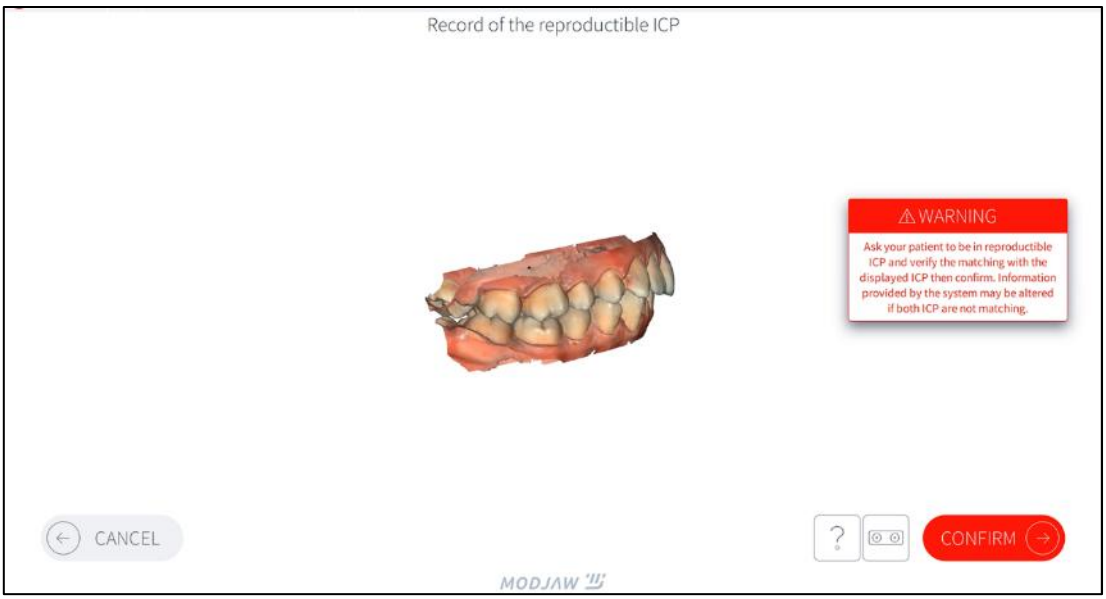


1	Indication of the point to pick
2	Order of the points to pick
3	Automatic confirmation of the picking after 2 seconds
4	Manual confirmation

To avoid cross-contamination between the patient's skin and mouth, it is recommended to clean the tip of the TALLY with a disinfecting wipe between the picking of the cutaneous reference points and the picking of the points in the mouth.

5.7 Recording the reproducible ICP

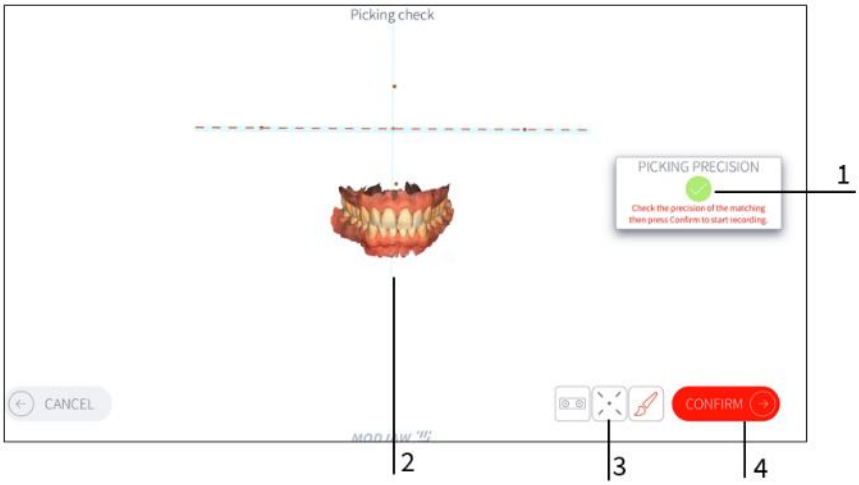
Position the patient in the reproducible ICP, check if the instruments are visible and confirm.



The user must ensure that the current occlusion position of the patient matches that of the imported 3D models. Otherwise, the information provided by the system may be altered.

RM-214

5.8 Picking check



1	Picking precision indicator
2	Displayed planes
3	Add/Remove reference points
4	Confirm picking

Picking precision must be checked

RM-214

5.9 Recording Kinematics

1) To record a kinematic a predefined list of six movements is automatically selected (user can adjust the selection if needed):

– Protrusion,
– Right laterotrusion,
– Left laterotrusion,
– Open close,
– Speech,
– Chewing.

2) Put your patient in a reproducible ICP before each recording

RM-148

3) Start recording and ask the patient to repeat the movement 3 or 4 times
4) The next movement will be displayed as soon as you stop recording the previous one

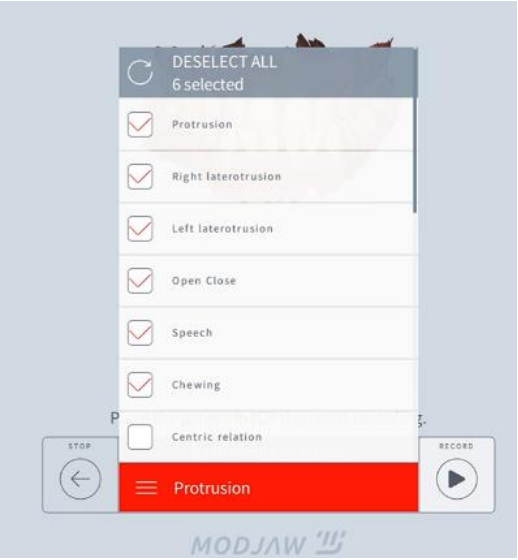
Notes:

The user must ensure:

- That the virtual movements and the patient's current movements are matching,

- That each recorded movement matches with its motion name,

To enable automatic calculations, at least the following motion must be recorded: protrusion, right laterotrusion, left laterotrusion, open close. However, it is recommended to record the preselected movements.

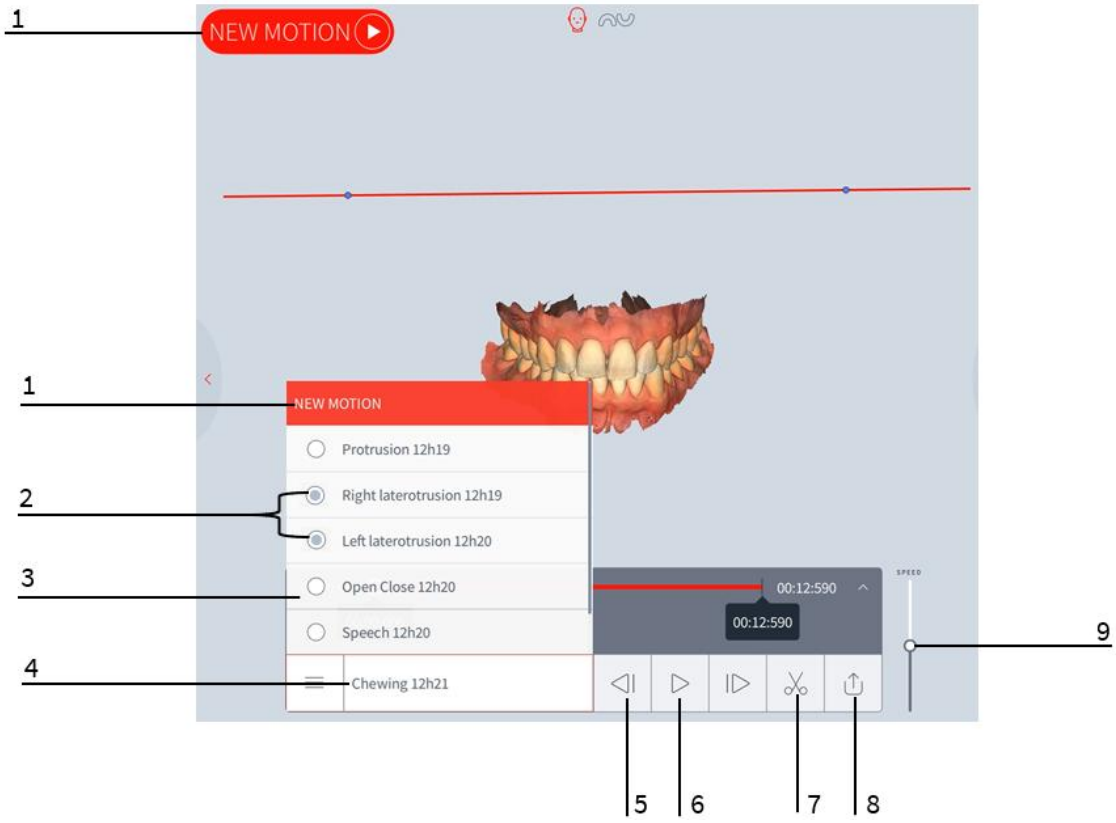


5.10 Manage motions records during recording session

As soon as a first motion set is recorded:

- TWIM tries to automatically compute the following: optimized axis, condylar slopes, Bennett angles and occlucurve,

- Previously recorded motions can be reviewed, managed, or completed by clicking on “New motion” during your ongoing session with the patient.

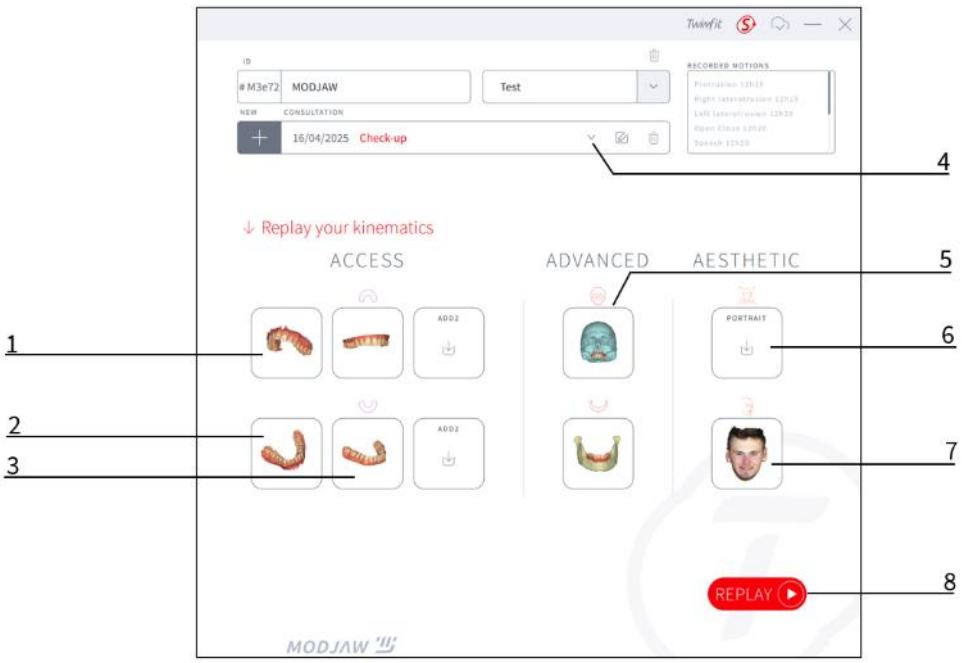


1	Record new motion
2	Selected movements to superimpose on the graph display
3	List of recorded motions
4	Selected record on display
5	Go to the previous frame
6	Play the record
7	Crop the record
8	Export the data
9	Modify the record speed

6 REPLAY

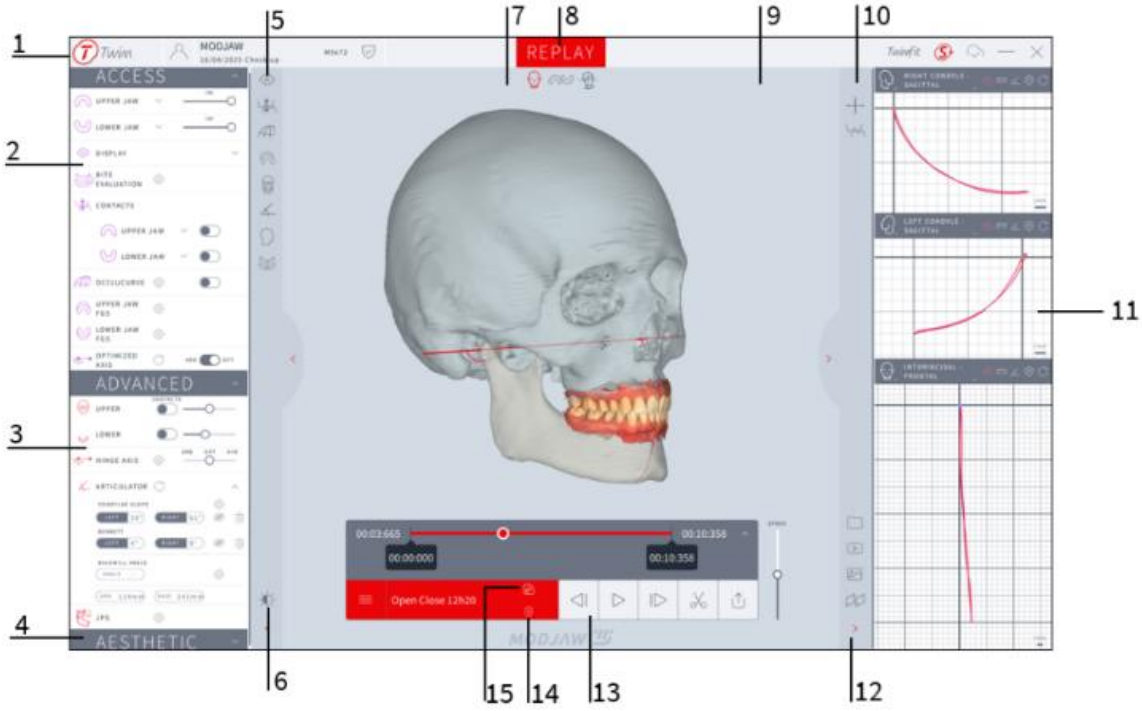
As soon as the consultation recording is over, the user has access to the REPLAY mode of this consultation. This section describes all the tools and functions available in REPLAY mode.

6.1 Manage consultation



1	Import maxilla
2	Import mandible
3	Import additional models (up to 4 additional models)
4	Access to the list of consultations.
5	Import bone models - *optional (ADVANCED)*
6	Add a picture (take a picture or import) - *optional (AESTHETIC)*
7	Import Facescan - *optional (AESTHETIC)*
8	Replay

6.2 Replay overview



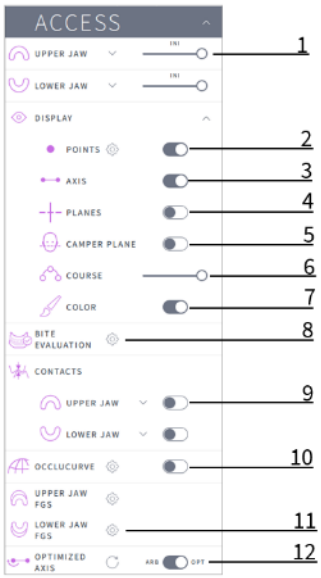
1	Top menu (go back to patient page, consultation name, anonymous toggle)
2	ACCESS module tools
3	ADVANCED module tools
4	AESTHETIC module tools
5	Tools shortcuts
6	Dark/Light mode toggle
7	Predefined 3D views
8	Application mode (LIVE / RECORD / REPLAY / SPLIT)
9	3D view
10	Graph configuration (ADVANCED)
11	Graph display (ADVANCED)
12	Capture tools and split view
13	Motion player
14	Delete the record
15	Rename the record

6.3 ACCESS

ACCESS: provides the basic functionalities of MODJAW® such as recording patient motions, replaying patient motions, exporting patient motions out of a 3D scan. Basic analysis features are available, such as contacts display and FGS.

RM-033

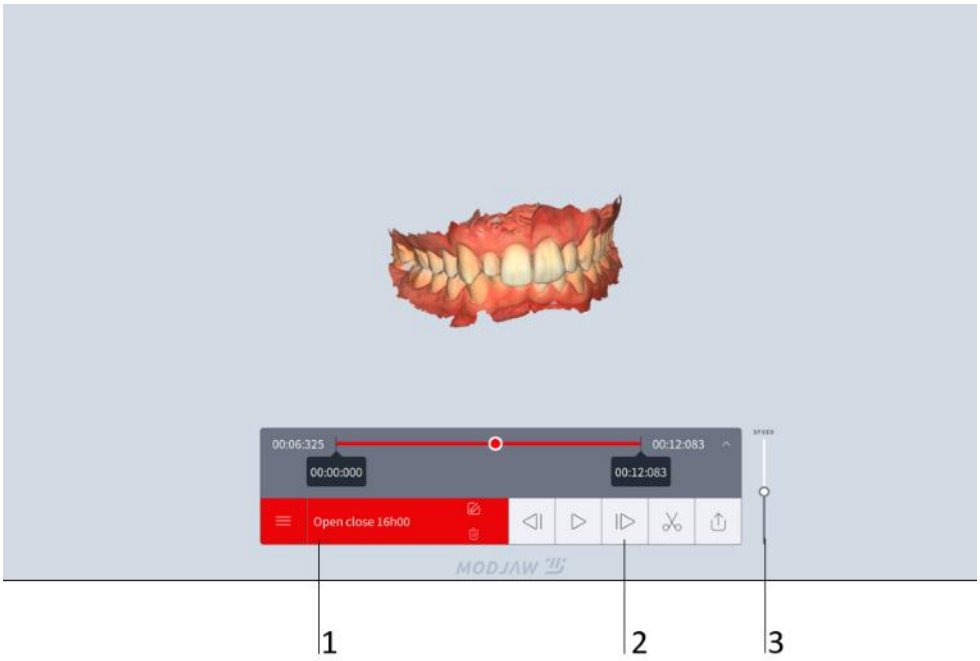
6.3.1 ACCESS toolset



1	Display models (initial and additional)
2	Display points
3	Display axis
4	Display planes
5	Display Camper plane
6	Display motion course
7	Display colours of the 3D models
8	Display Bite Evaluation
9	Display contacts of the initial models
10	Display Occlucurve
11	Compute FGS (Functionally Generated Surface)
12	Arbitrary / Optimized axis selection toggle

6.3.2 Replay a kinematic

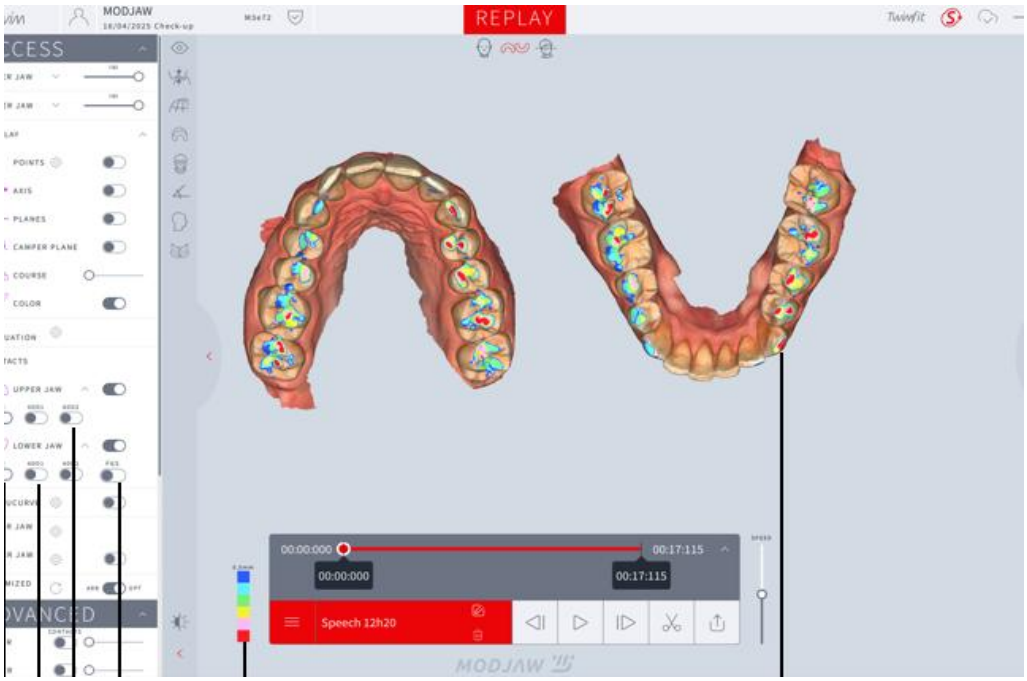
1) Select the record
2) Use the replay control panel (play, pause, frame by frame, crop)



1	Select a record
2	Replay control panel (play, pause, frame by frame, crop, export)
3	Reading speed

6.3.3 Contacts

The software displays contacts between the 3D models of the arches.

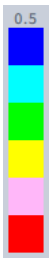


1	Display the contacts of the initial model (upper or lower)
2	Display the contact of the additional models (upper or lower)
3	Display the contacts of the FGS (only if the FGS has been generated)

4	Display the contacts of the FGS (only if the FGS has been generated)
5	Proximity and contact color scale
6	Occlusal proximities and contact between the teeth of the 2 arches.

Proximity and contact zones between the teeth of the 2 arches are mapped by colour according to the distance between the models.

Blue	Approximate distance of 500 µm (+/-50 µm)
Cyan	Approximate distance of 400 µm (+/-50 µm)
Green	Approximate distance of 300 µm (+/-50 µm)
Yellow	Approximate distance of 200 µm (+/-50 µm)
Pink	Approximate distance of 100 µm (+/-50 µm)
Red	The models seem to be in contact (+/-50 µm)



RM-242

Distance, angles and contact precision is directly related to the quality of the imported models, the quality of the picking, and the proper fixation of the instruments on the patient. Distance values provided are not absolute.

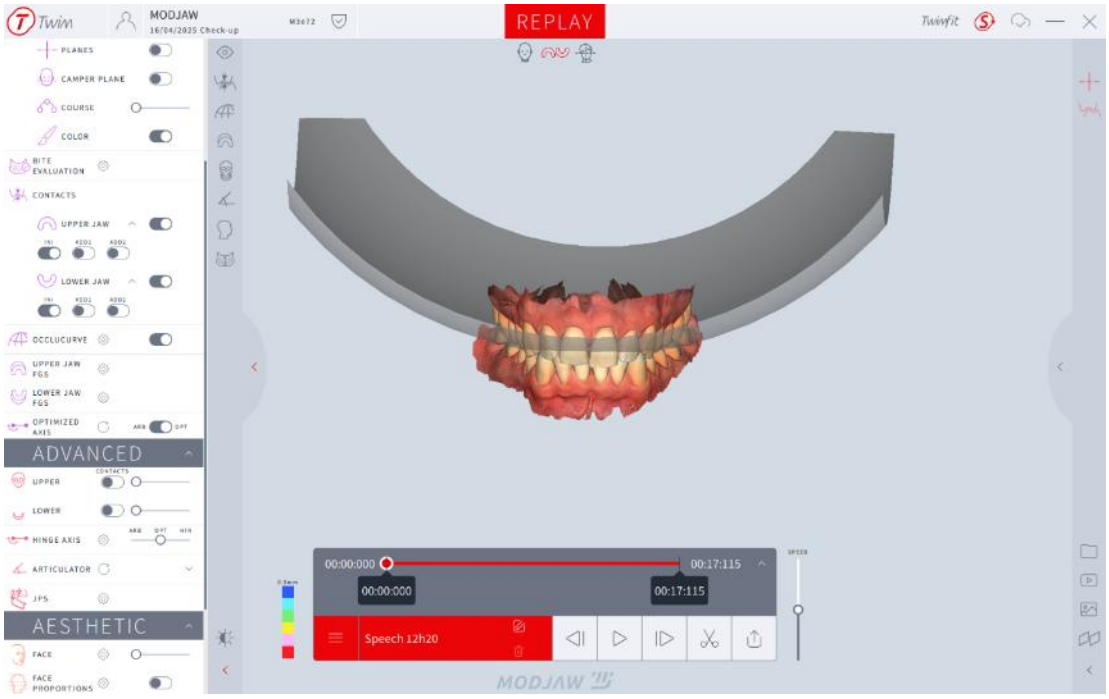
3D models and computations use sampled data. There is a risk of missing contacts.

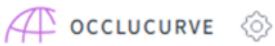
RM-173

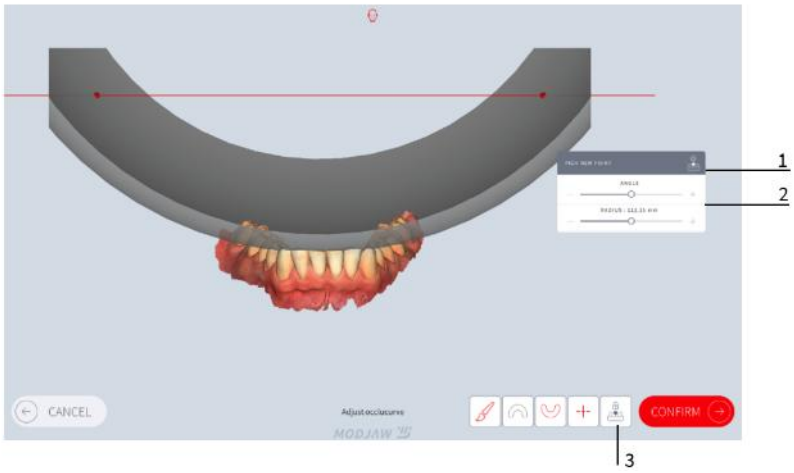
6.3.4 Occlucurve

RM-166 and RM-214

1. The Occlucurve is automatically calculated as soon as a first motion set is recorded.



2. The occlucurve can be manually adjusted or modified 

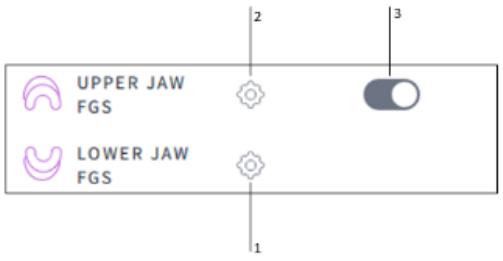


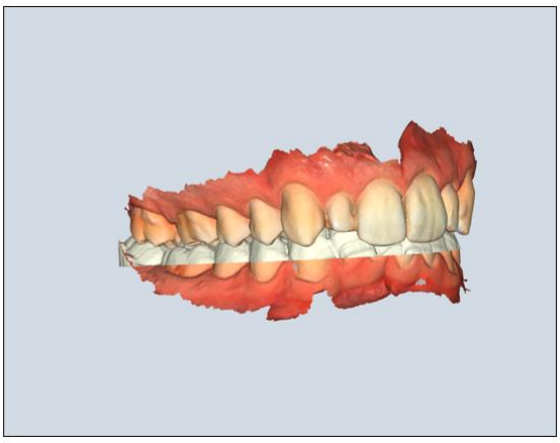
1	Recalculate occlucurve by picking new point
2	Slide bar to adjust occlucurve position
3	Lock the selected point

3. Occlucurve always goes through both condyles (the ones related to the selected axis, Optimized axis by default). Verify the selected axis and recalculate the occlucurve if necessary.

6.3.5 FGS

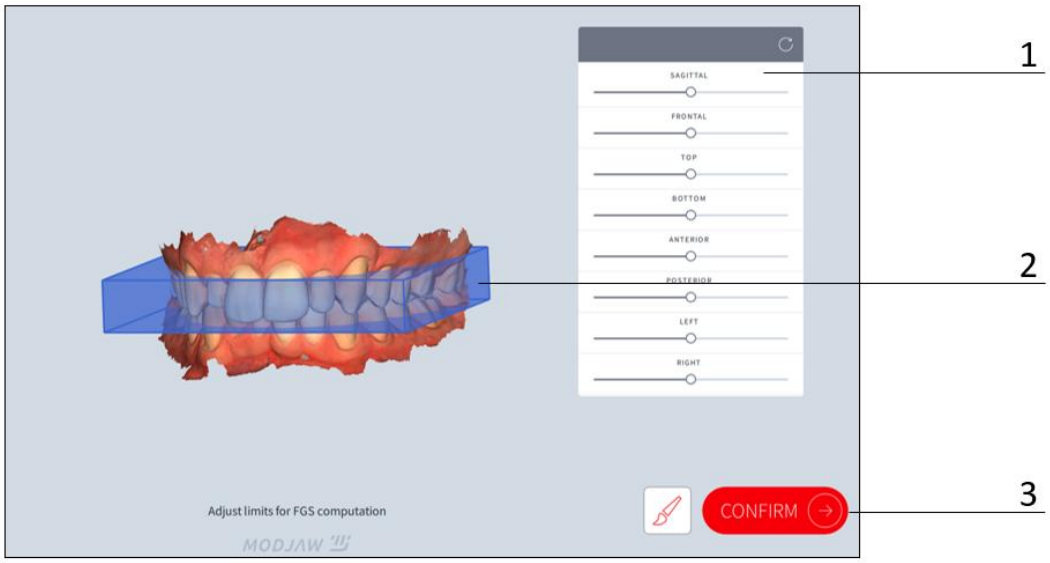
The FGS (Functionally Generated Surface) represents the envelop of function created by dental arches' motion.





1	Computation of the FGS on the current motion (if defined, cropped motion taken into account)
2	Adjust limits for the FGS computation (only accessible if the FGS has been computed, by clicking on it again)
3	Display FGS

You can adjust the limits for the computation of the FGS:



1	Adjustment parameters
2	3D view of the limits
3	Confirm the new limits

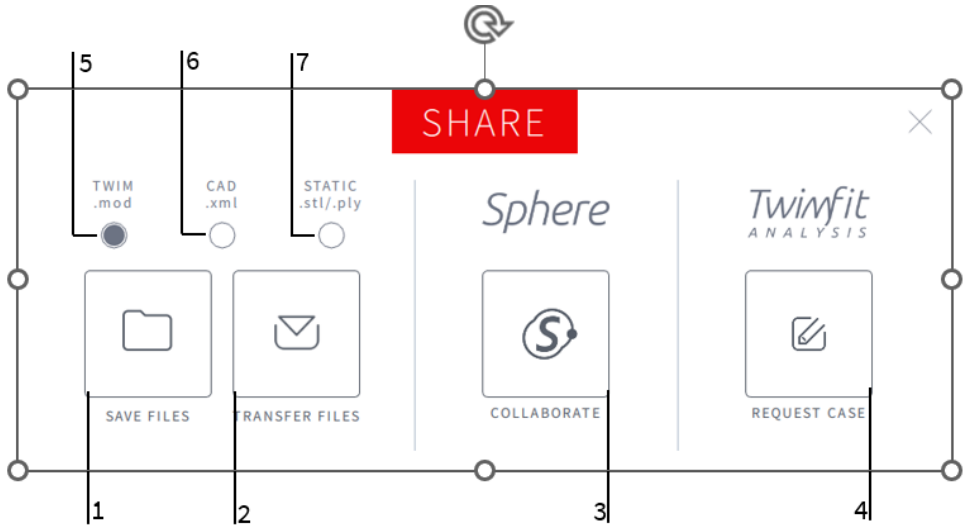
You can adjust the motion subsequence taken into account for the FGS computation. However, there is no automatic recalculation of the FGS on the sub-sequence.

RM-214

6.3.6 Data Export

6.3.6.1 Export of the kinematics of a consultation

You can access the export menu by clicking on the export icon  located in the player controls and then export data.

	Save file : local export on computer
1	
2	Transfer files : file sharing with email and download link
3	Collaborate on Sphere = to add participant to the consultation on Sphere from TWIM

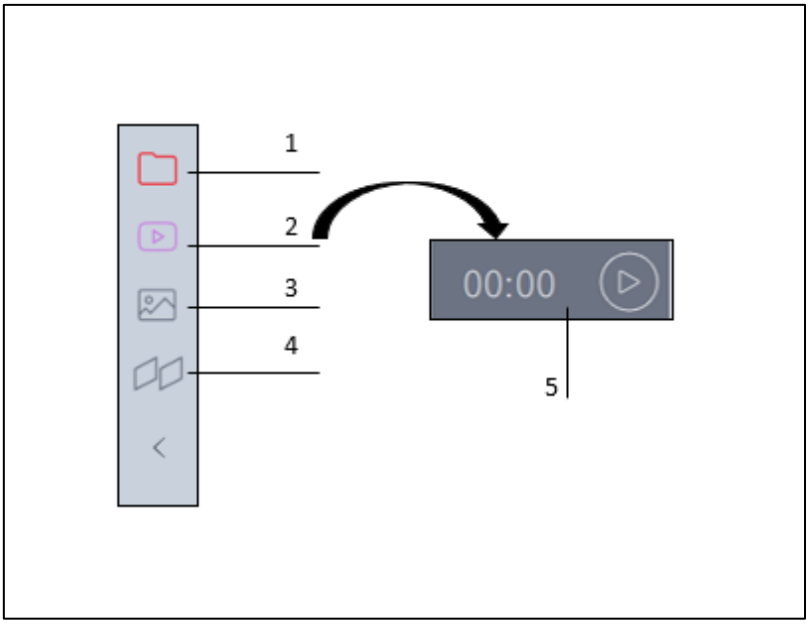
4	TWIMFIT Analysis request
5	MODJAW export .mod (full MODJAW consultation)
6	CAD .xml export . You can select multiple files at once, or just one (only the subparts of the kinematics selected in the main screen are exported)
7	Static export (export of the currently displayed position of models)

Notes:

- Exported data is anonymized and saved in STL or PLY format (mandible and maxilla models) and in XML format (kinematics data)
- A file in PDF format sums up angles and distances computed during the consultation

The user must indicate necessary precautions to be taken by dental technicians regarding the limits of the data exported by MODJAW® for the creation of dental appliances.

6.3.6.2 Capture of the software



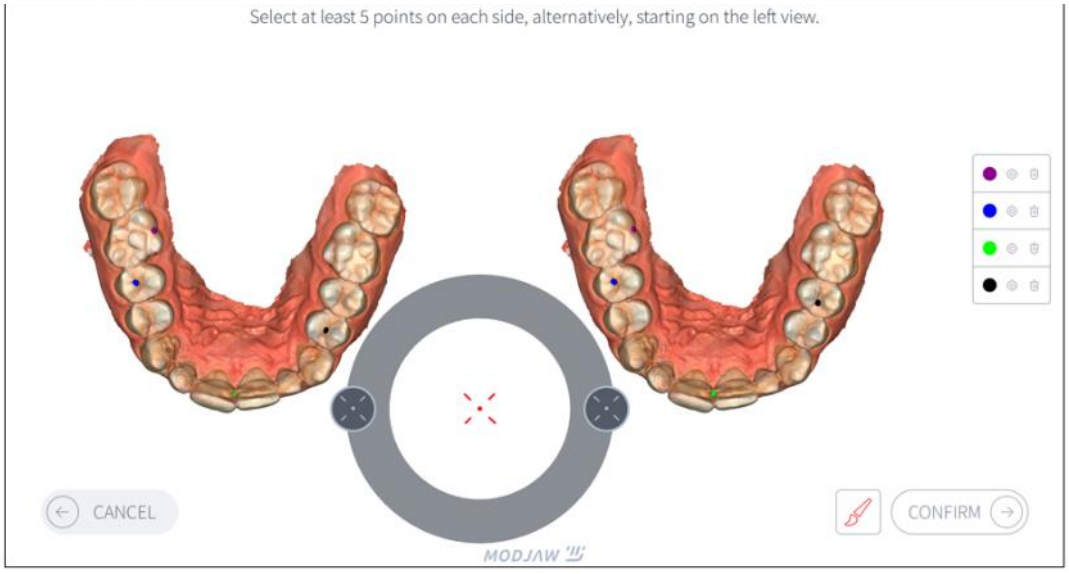
1	Captured files folder
2	Video capture of the 3D view and of the graphs
3	Screenshots
4	Split the view
5	Start to capture

6.3.7 Import and matching of additional or already matched 3D models

RM-214

The user can import additional models of their patient:

1) Define 5 pairs of anatomical points (alternating between left and right) on each model.



2) Validate the quality of the matching by visually verifying the superposition of the models.

1	Show/Hide colours of the models
2	Colour mapping of the distance between models
3	Confirm matching
4	Automatically improve the coarse matching

6.4 ADVANCED

ADVANCED: provides advanced features such as trajectory analysis (graphs), estimation of articulator parameters, patients bone scans import, patients bone contacts analysis during the motion, hinge axis estimation and joint position simulator.

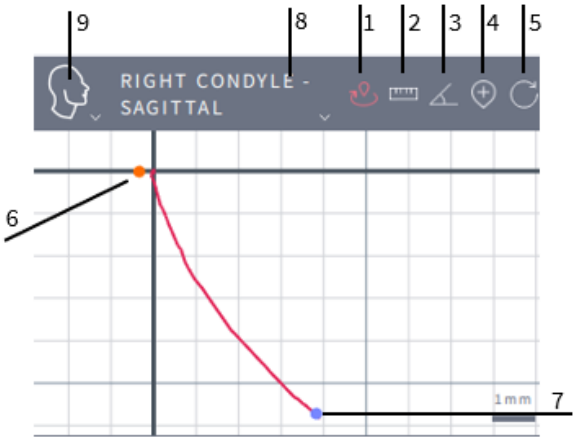
RM-033

6.4.1 Graphs

On the right-side panel, the trajectory of the anatomical points is represented on a graph and generates data. The displayed trajectory corresponds to the projection of the selected point in the selected anatomical plane.

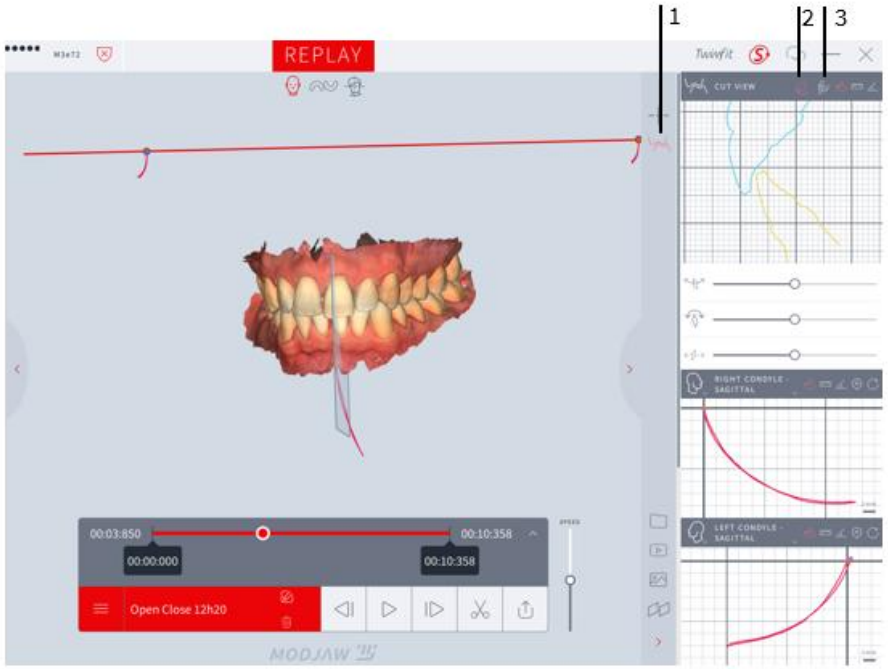
Unit of distance in all graphs is the millimeter (mm).
Angle measurement unit in all graphs is the degree (°).

RM-088



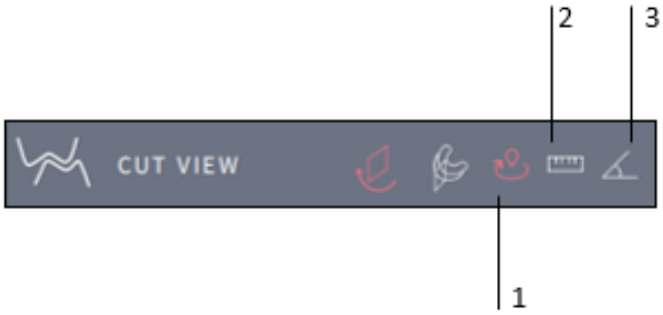
1	Zoom-in and pan the graph view
2	Distance measurement (in mm)
3	Angle measurement (in degree)
4	Select a point on the curve to match record time with the corresponding frame
5	Return to default mode
6	Condylar reference position in occlusion
7	Current condylar position
8	Selection of the reference point
9	Selection of the anatomical plane

6.4.2 Cut view

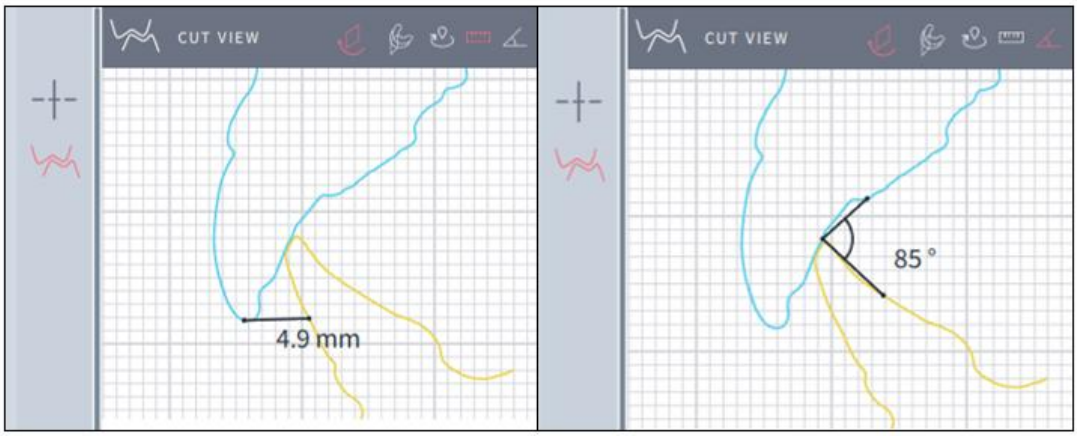


1	Show/Hide the cut view
2	Adjust the position and the orientation of the plane
3	Select a point of interest on the model

Cut view features



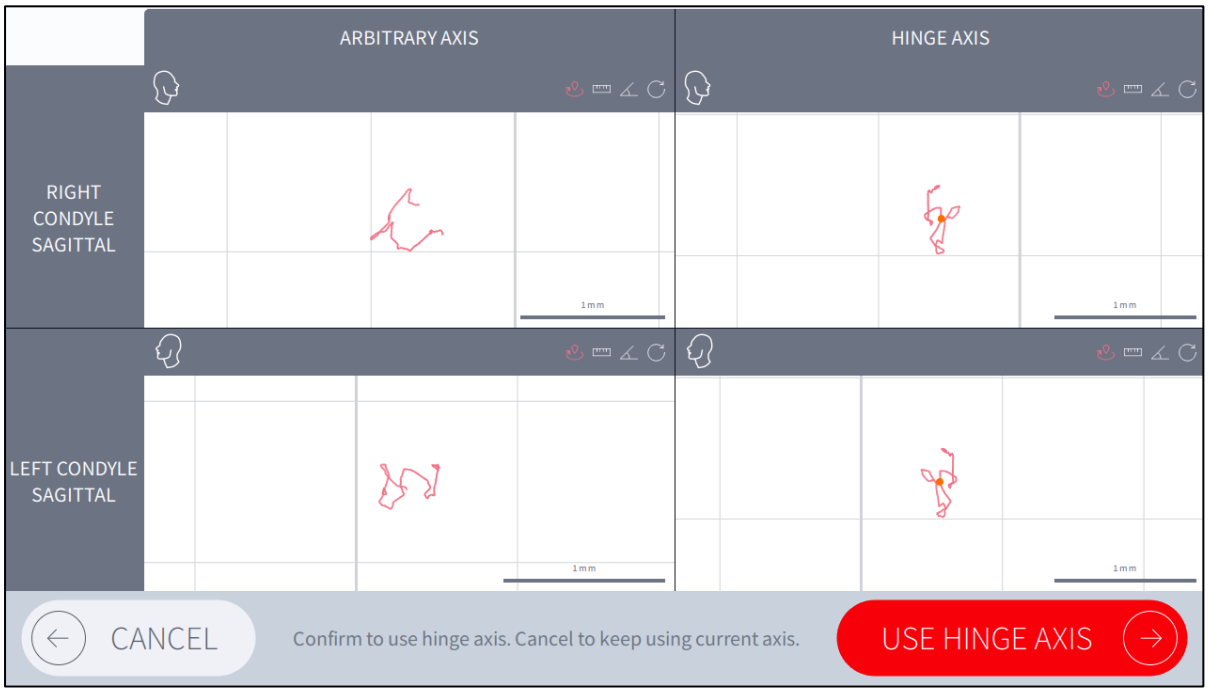
1	Return to default mode: zoom in and pan the graph
2	Distance measurement (in mm)
3	Angle measurement (in degree)



6.4.3 Hinge axis

The user must select an appropriate motion (pure rotation motion, such as a centric relation for example) for the right computation of the Hinge axis.

When the Hinge axis computation is launched (HINGE AXIS), a candidate Hinge axis is automatically computed, and the trajectories of the new condyles as well as the ones of the initial condyles can be compared in a preview window:



If confirmed, a default replay view is displayed, and the newly computed Hinge axis is taken into account (ARB OPT HIN : use this toggle to go back to the arbitrary axis or to the optimized axis.)

6.4.4 Articulator feature

As soon as the first motion set is recorded, if protrusion, right laterotrusion and left laterotrusion have been recorded, condylar slopes and the Bennett angles are automatically calculated based on recorded movements and the selected axis.

When modifying the selected axis, condylar slopes and Bennett angles are automatically re-computed.

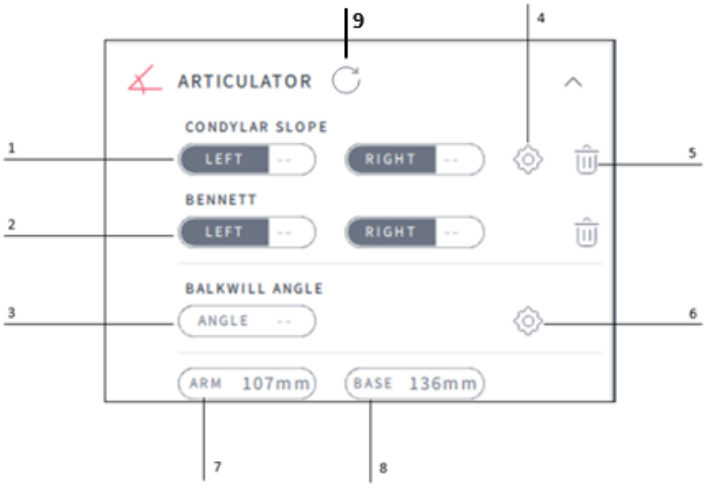
For the condylar slope computation, a protrusion movement must be used.

For the left Bennett angle computation, a right laterotrusion movement must be used.

For the right Bennett angle computation, a left laterotrusion movement must be used.

It is recommended to compute the Hinge axis at least once before using the articulator tool.

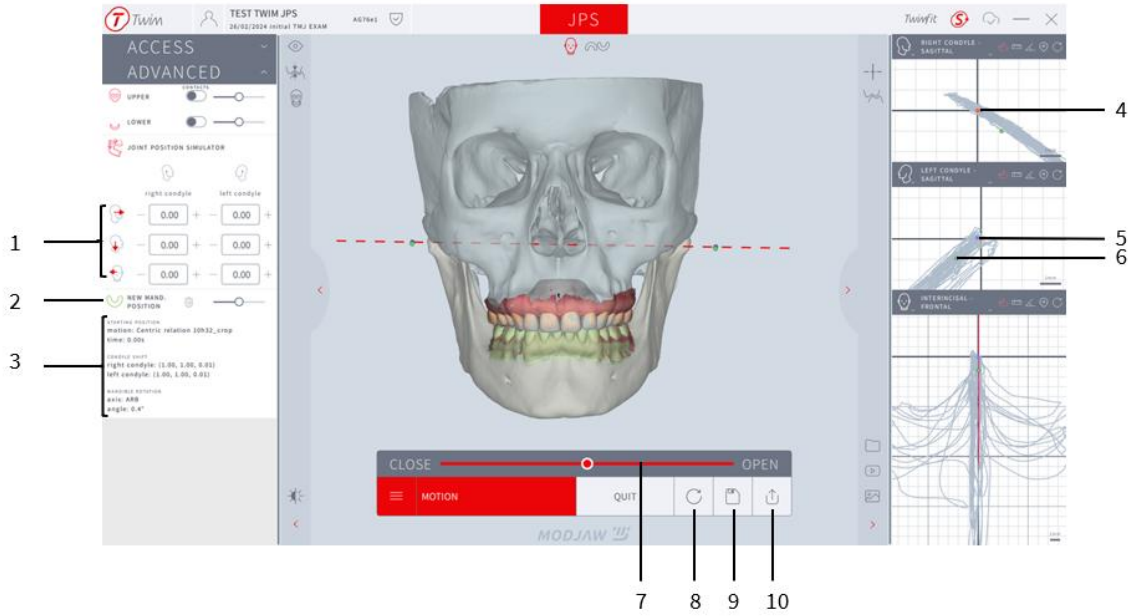
Distance, angle and contact information are directly linked to the quality of the imported models, the quality of the picking, and the proper fixation of the instruments on the patient. Distance values provided are not absolute.



1	Condylar slope
2	Bennet angles
3	Balkwill angle
4	Set the radius of the condylar slope
5	Delete
6	Balkwill angle setting
7	Arm
8	Base
9	Restart the calculation

6.4.5 Joint position simulator

The user can simulate a temporomandibular joint (TMJ) position, JPS



1	Move left or right condyles
2	Delete / Adjust display of the saved new mandible position
3	Information about the saved new mandible position
4	Orange point: reference condyle locations (ICP in ARB/OPT, centric in HIN)
5	Blue point: current condyle location
6	Green point: saved condyle location
7	Close/open: rotate the mandible around the axis that goes through the current condyle locations (blue points)
8	Reset the condyle move (to retrieve the state when opening the feature)
9	Save the new mandible position
10	Export the mandible position

6.4.6 Bones

6.4.6.1 Import bones models

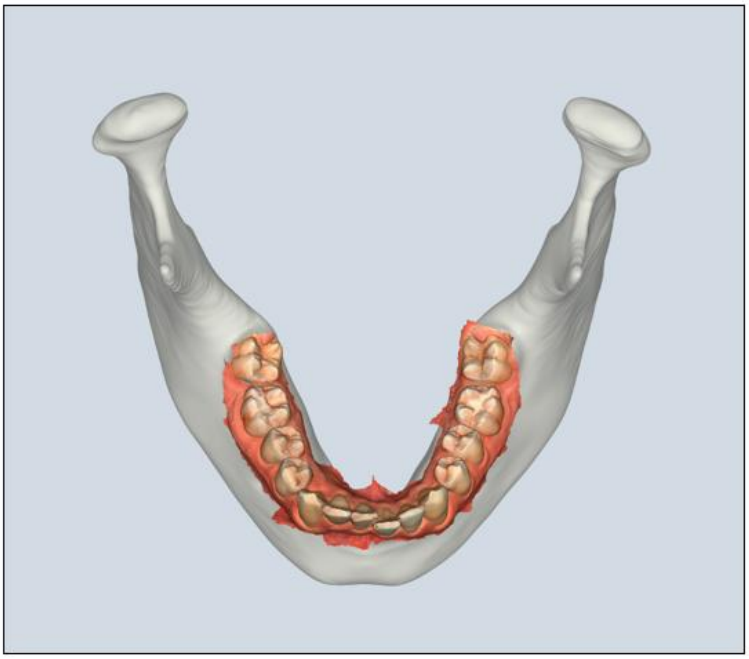
Quality and precision of the 3D CBCT models imported into the application have a direct impact on the information provided by the system. The user must respect recommendations specified for the selection of the 3D models

The user is responsible for the importation of CBCT models corresponding to their patient. These models must be segmented and registered on the initial models with sufficient precision.

RM-214

The user can import 3D models that come from a CT scan or a CBCT scan. DICOM files are not accepted and must be converted into a 3D mesh model in STL format

The imported models must be matched with the previously imported initial models

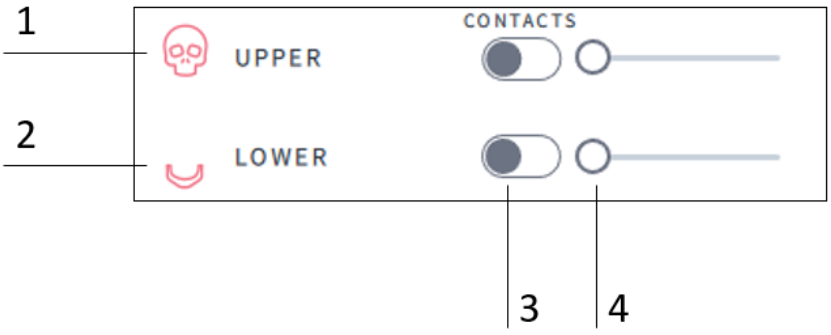


6.4.6.2 Bone contacts

Distance, angle and contact information are directly linked to the quality of the imported models, the quality of the picking, and the proper fixation of the instruments on the patient. Distance values provided are not absolute.

3D models and computations use sampled data. There is a risk of missing contacts.

RM-173



1	Maxilla CBCT
2	Mandible CBCT
3	Contacts
4	Show/hide CBCT

Color mapping of the models distances:

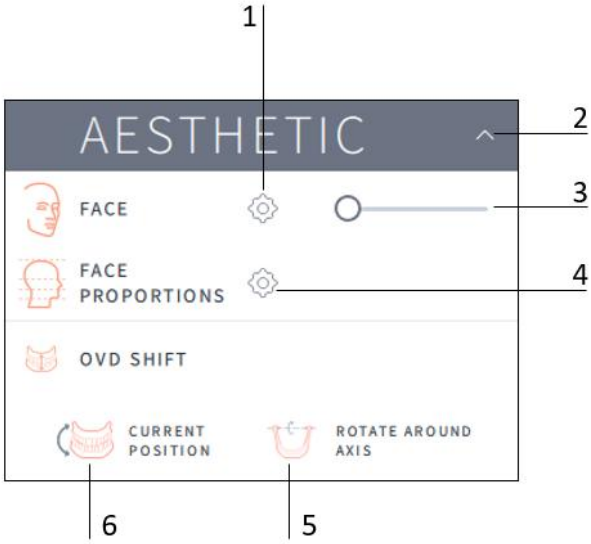
Color	*Distance between models (in mm)*
Cyan	Mildly close (2.5 +/- 0.25)
Very light blue	Relatively close (2.0 +/- 0.25)
Light blue	Very close (1.5 +/- 0.25)
Medium blue	Intensely close (1.0 +/- 0.25)
Blue	Extremely close (0.5 +/- 0.25)
Dark blue	The models seem to be in contact (+/- 0.25)

6.5 AESTHETIC

AESTHETIC: provides aesthetic features such as patient's face scan import, patient's picture import or capture, face proportion verification tools, OVD adjustment, motion transposition with adjusted OVD, split view, Aesthetic plan record and display.

RM-033

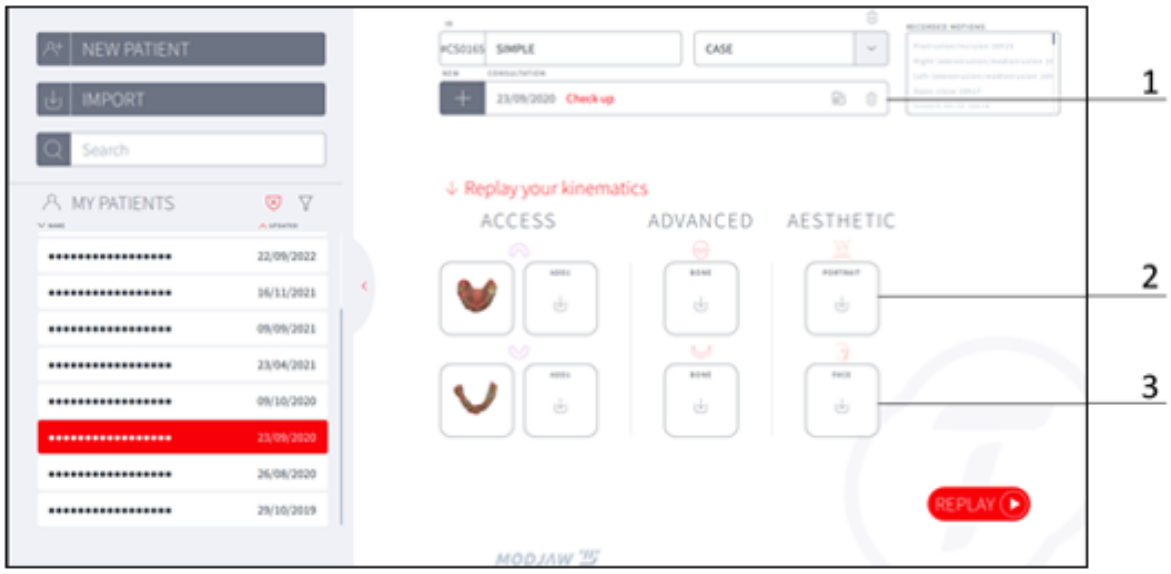
6.5.1 Aesthetic toolset



1	Adjust Facescan
2	Expand/Collapse AESTHETIC tools
3	Adjust Facescan transparency
4	Compute face proportions
5	Rotate around axis (Arbitrary or Hinge axis)
6	OVD Shift on current position

6.5.2 Import aesthetic data

RM-214

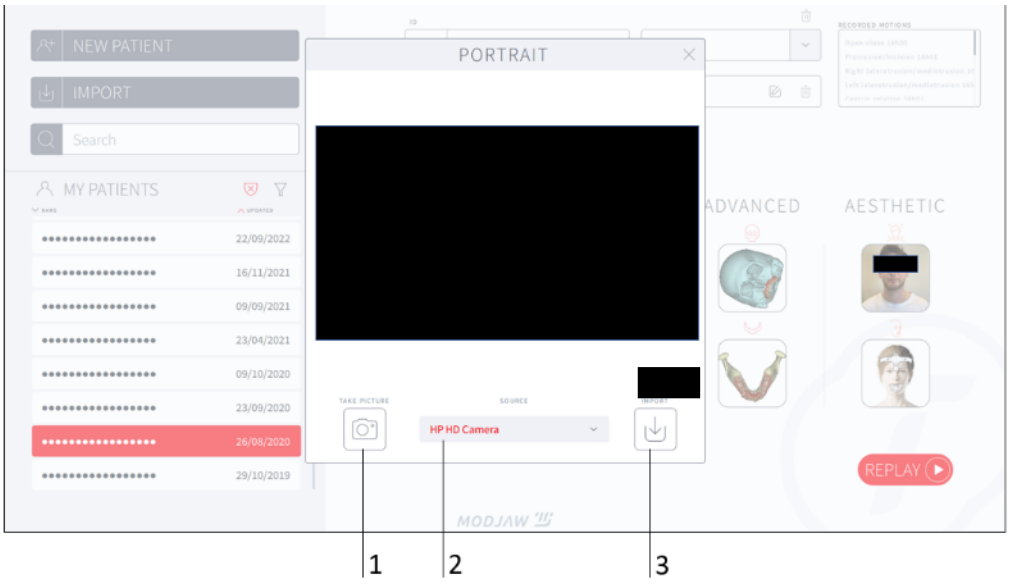


1	Current consultation
2	Select the option “PORTRAIT” to import a picture
3	Select the option “FACE” to import a Facescan

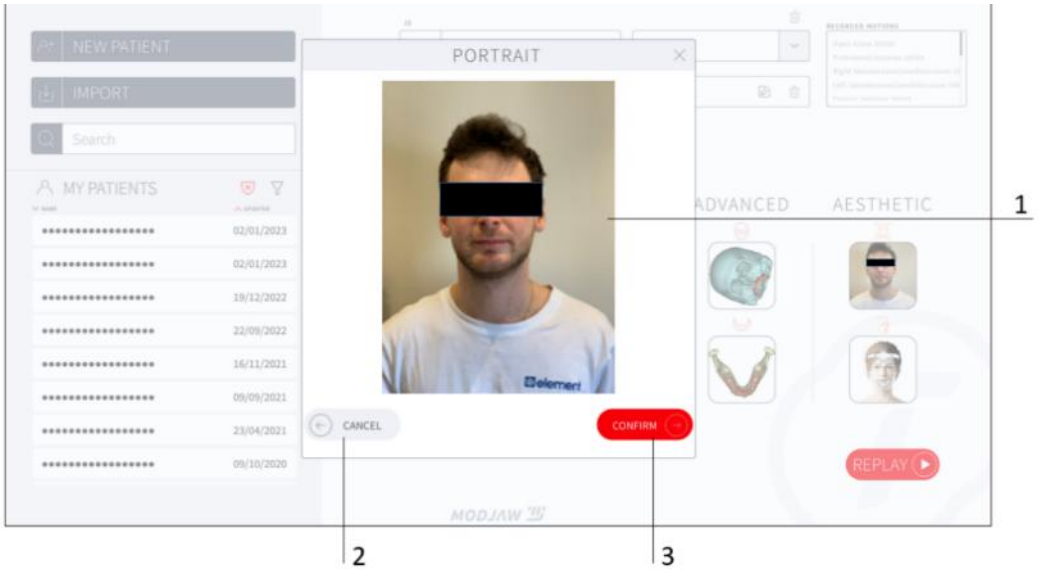
6.5.2.1 Portrait

RM-214

It is also possible to directly take a picture:



1	Picture selected
2	Cancel the selection
3	Confirm the selection



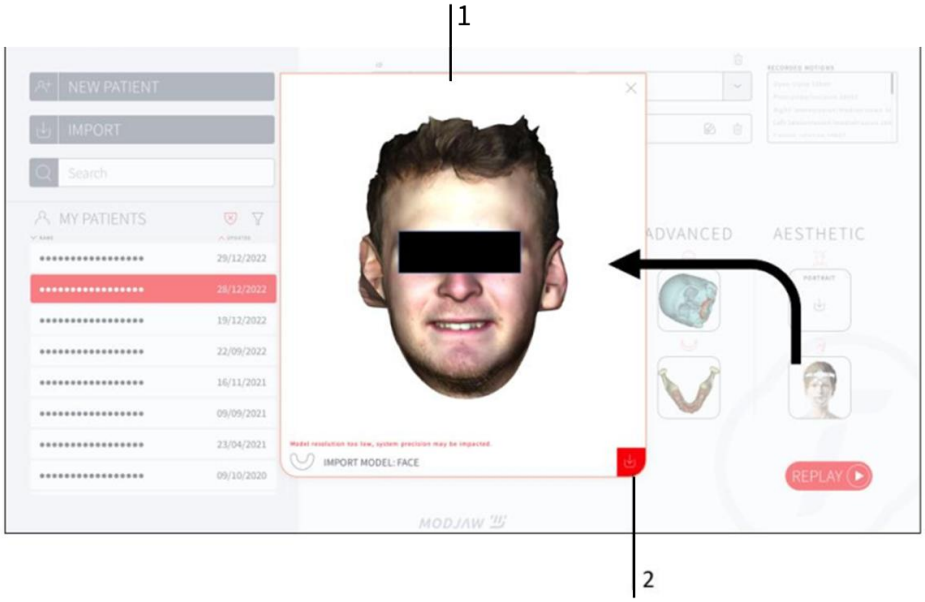
1	Picture selected
2	Cancel the selection
3	Confirm the selection

Picture position and display can then be adjusted:

1	Crop the picture
2	Manually adjust the position, orientation and size of the photo
3	Modify the opacity of the picture, by adjusting the cursor
4	Realign the 3D view with the picture

6.5.2.2 Facescan

Facescan data can be imported:

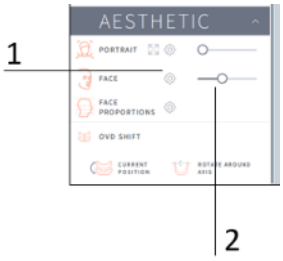


1	Preview of the Facescan
2	Confirm the import

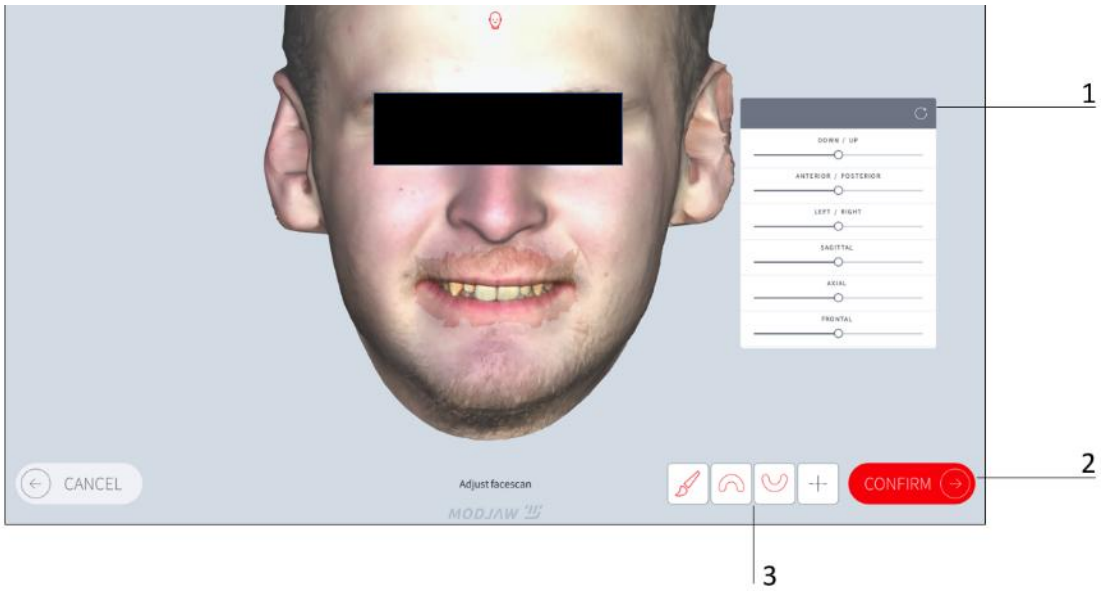
To match the imported Facescan to already imported data, four anatomical points (left and right condyles, subnasal point and nasion) must be located on the face:

1	Point selection tool
2	Indication of the points to locate
3	Confirm the position of the Facescan

The Facescan location and display can be adjusted:



1	Manually adjust the position, orientation, and size of the Facescan
2	Modify the opacity of the Facescan, by adjusting the cursor

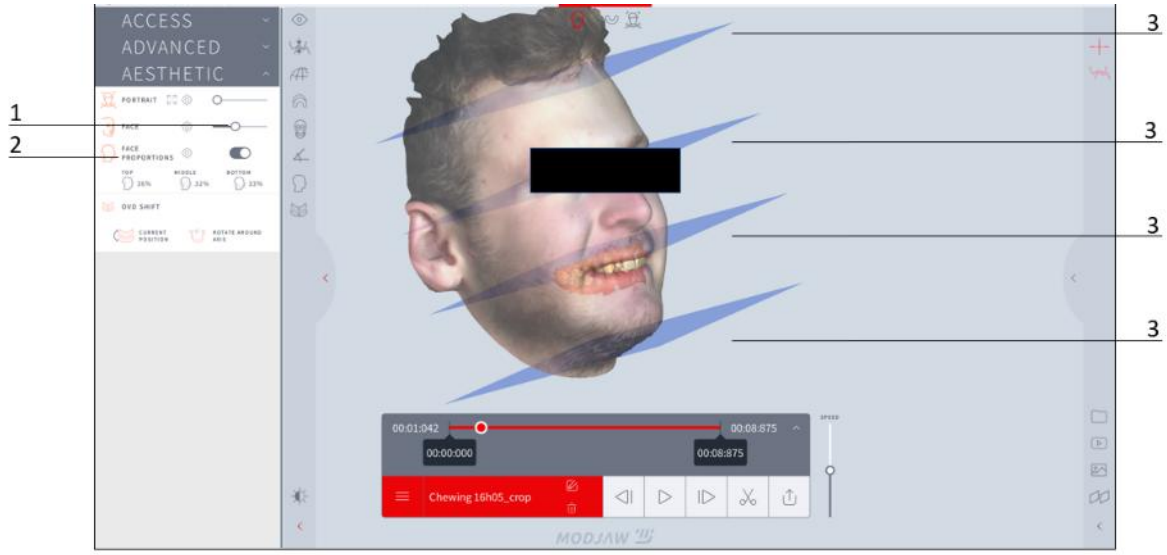


1	Adjustment parameters
2	Confirm the newly adjusted face model
3	Display options

6.5.3 Face proportions

As soon as the face proportions are computed:

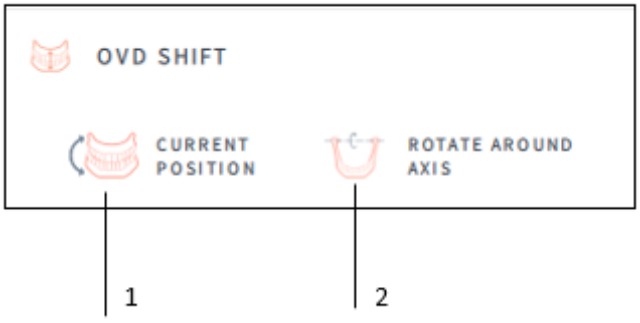
- The four plans are displayed on the 3D view
- Face proportions are displayed



1	Show/hide proportion planes
2	Results of the computation of face proportions
3	Proportion planes

6.5.4 OVD SHIFT™

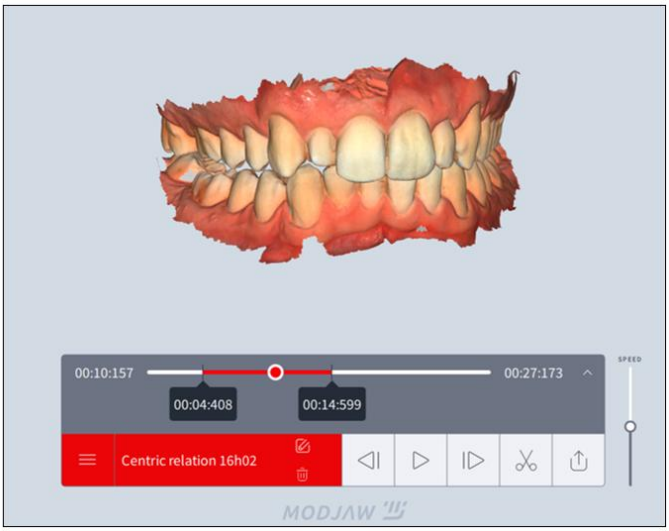
From the Kinematics screen, the user can define a new intermaxillary relation (OVD SHIFT). They can define as a new intermaxillary relation either a recorded position or a simulated position:



1	Current position = Recorded position
2	Rotate around axis = Simulated position

6.5.4.1 Recorded position

If a recorded position must be used, first pause the motion to the desired position:



Once on the desired position, select "CURRENT POSITION" under OVD SHIFT: 

Once confirmed, a new consultation is created, and the kinematics have been transferred to the new intermaxillary relation.

RM-214

6.5.4.2 Simulated position

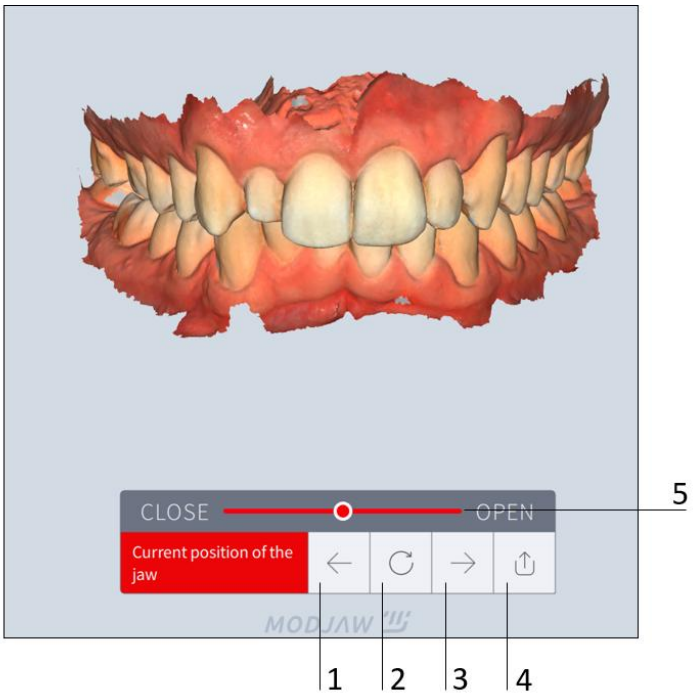
To simulate a position to use as the new intermaxillary relation, the user can rotate the mandible around an axis.

RM-214

First make sure that the desired axis is selected (Arbitrary axis or Hinge axis), then launch the simulated position option: 

Note: The Hinge axis is available only if your license includes the ADVANCED module.

The next view allows you to rotate the mandible around the chosen axis:



1	Go back to the replayed kinematics
2	Go back to the starting position
3	Confirm the selected position
4	Export the current simulated position
5	Rotate the mandible

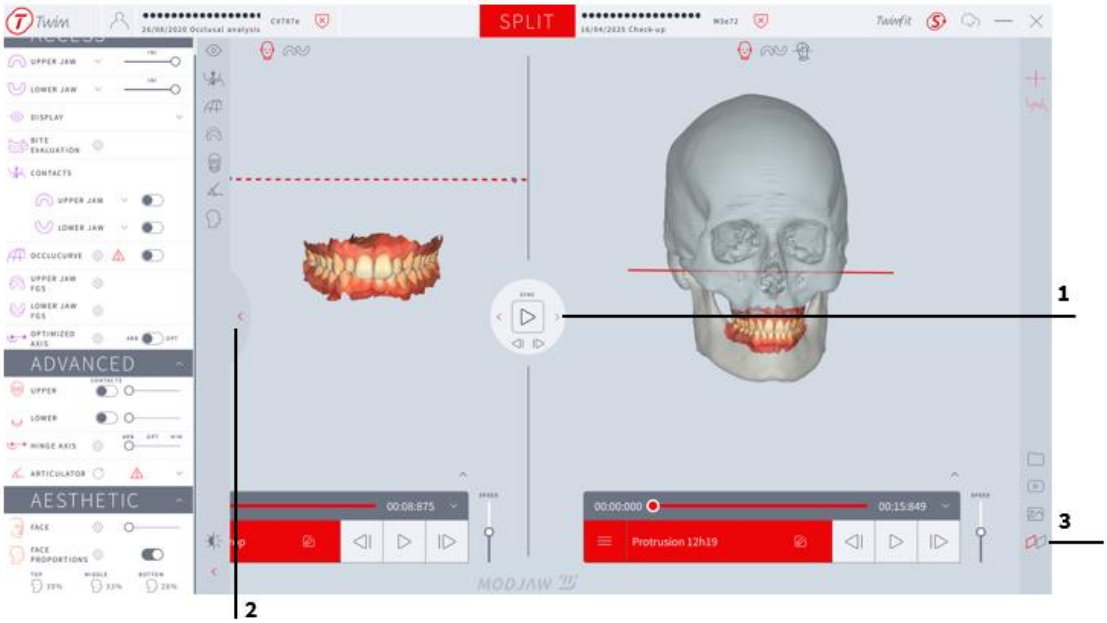
Once confirmed, a new consultation is created for the patient, in which the kinematics have been transferred to the new intermaxillary relation.

The user must ensure to select a new intermaxillary relation that is appropriate for treatment.

6.5.5 Split view

In REPLAY mode, you can display two consultations at a time, side by side, using the split view ( ).

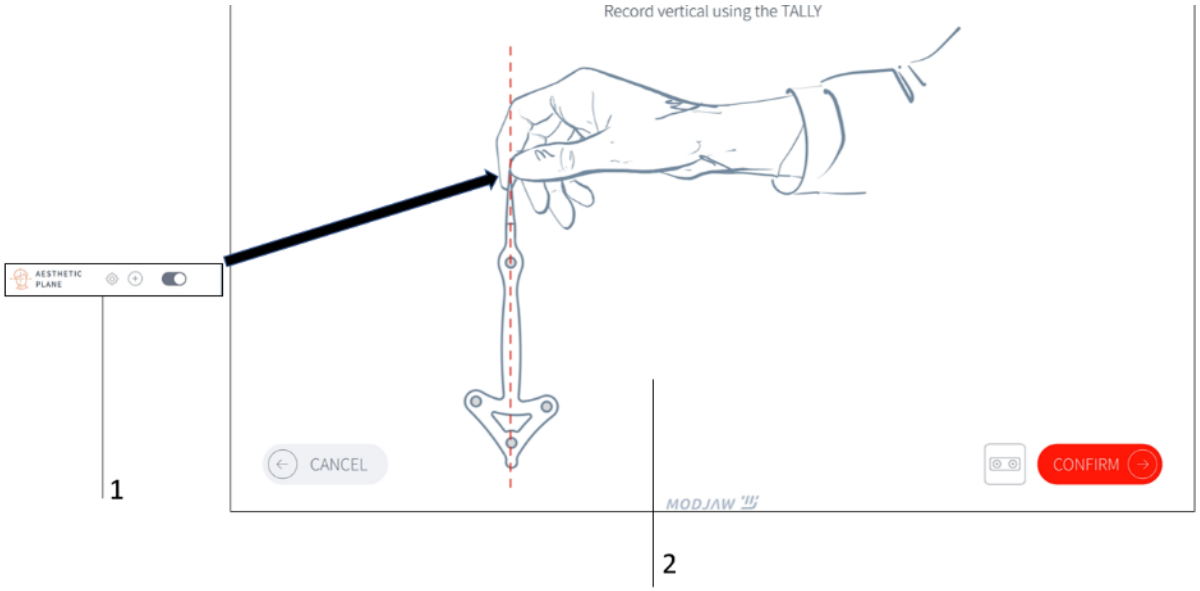
1	Select a second consultation
2	Patient's ID
3	Select Consultation
4	Click on "SPLIT" to confirm



1	Define which consultation is active (red arrow) and inactive (grey arrow)
2	The left panel is only linked to the active consultation
3	Active window indicator (indicated in red). Exit the split view by clicking on it again

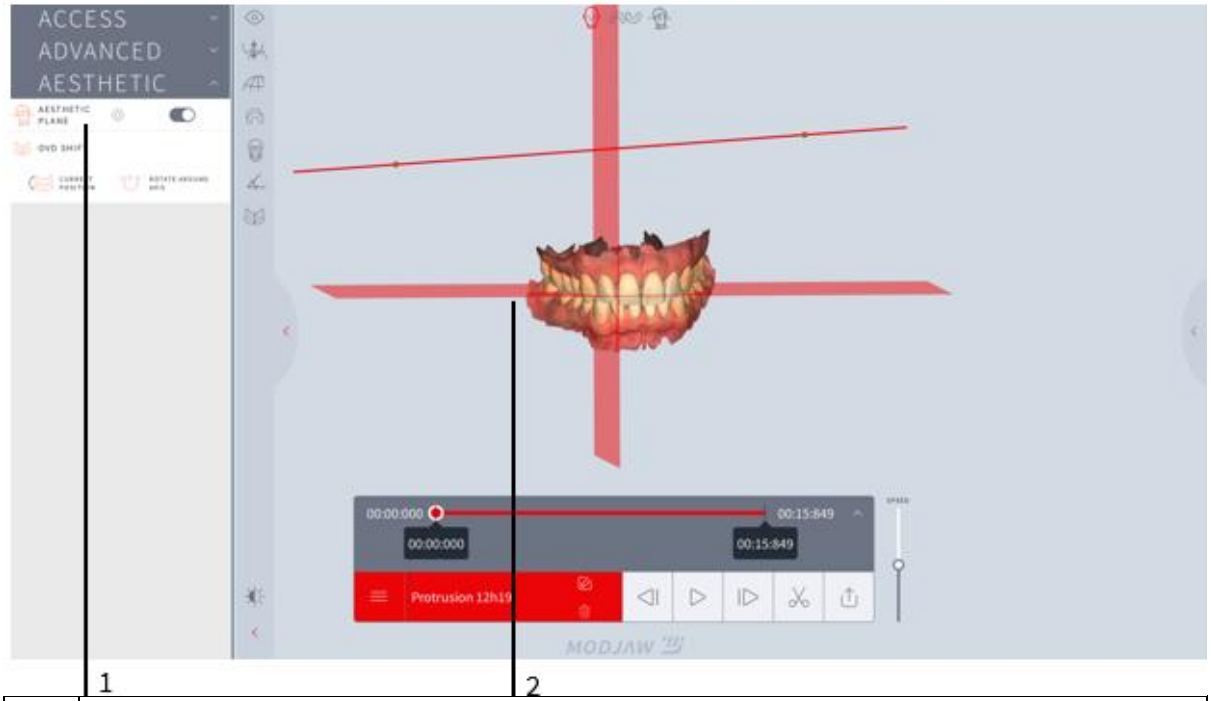
6.5.6 Aesthetic plan record and display

You can measure the patient's Aesthetic plan during the **RECORD** step:



1	Record the Aesthetic plan
2	Hold the TALLY like a plumb line, to represent the gravity

As soon as the Aesthetic plan is recorded, it can be displayed in the replay scene:



1	Display the Aesthetic plan of the patient
2	Aesthetic plan of the patient

7 After-sales service and Monitoring

Contact:

MODJAW
11-13 avenue Albert Einstein
69100 Villeurbanne France
Telephone: +33 (0)482771111
Email: support@modjaw.com
Website: www.modjaw.com

In case of a malfunction or difficulties using the device, contact the MODJAW® team, whose coordinates are listed at the beginning of this document.

RM-176

8 Other versions

The instructions for use are available in different languages on the MODJAW® website: www.modjaw.com/usermanuals

Users can get a paper version of the instructions for use at no extra cost and in less than 7 days following receipt of their request.

RM-209/ RM-231/RM-234/RM-236/RM-239

MODJAW® will notify the user when a new version of this document is released.

9 Acronyms

CBCT: Cone Beam Computed Tomography
FGS: Functionally Generated Surface
ICP: Intercuspal Position
IR: Infrared
OVD: Occlusal Vertical Dimension
TWIM: Twin In Motion
EPHI: Electronic Protected Health Information
JPS: Joint position simulator