TECH IN MOTION™

*By **MODJAW®***

THE 4TH DIMENSION LIVE AT THE CHAIR

USER MANUAL EN

Summary

1 General product information

1.1 Exclusions of warranties and limitations of liability

1.1.1 Copyright

1.1.2 Guarantee

If the user installs additional hardware or third-party software, this will be the only responsibility of the operator and the manufacturer's warranty will no longer be applied.
Modjaw® is not responsible for damages or functional errors caused by improper use of the software or the use of inappropriate computer equipment.
Warranty of the device is 3 years from the date of delivery. This includes the parts contained in the patient kit.

1.2 Manufacturer information

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

Trademark
Modjaw® is a Registered Mark

CE Marking
Tech In Motion™ is a Class I medical device according to Directive 93/42/EEC and CE marked by auto certification.

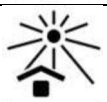
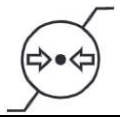
1.3 Structure of the user manual

This document is a guide for users of the Tech In Motion™ device. The manual contains instructions for installation, pre-use verification, use and storage of the device.
It also includes technical data as well as safety, hygiene, and maintenance instructions.
This document is intended to be read by anyone who is supposed to 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.

1.4 Use of labelling symbols

RM-074

CE	CE logo which indicates that the medical device meets the requirements of European Directive 93/42 / EEC of 14 June 1993.
	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
	Name and address of the manufacturer
	To identify the country of manufacture of products
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste
	Indicates the date after which the medical device is not to be used
	Indicates a medical device that is intended for one single use only
	Indicates a medical device that needs protection from light sources
	Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the range of humidity to which the medical device can be safely exposed
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
UDI	Indicates a carrier that contains unique device identifier information : (01) Device Identifier (10) Batch number (11) Manufacturing date (17) Expiration date (21) Serial Number
MD	Indicates the item is a medical device
	Indicates the need for the user to consult the instructions for use
	Indicates the need to refer to instructions for use.

1.5 Modifications

Modjaw® has taken care to write this document as a guideline for using the TECH IN MOTION™ device.
The information provided in this document is subject to change without notice. We have made every effort to ensure the correctness of the information provided in this document.
In the event of an error identified by the user when reading this manual, please contact Modjaw® before using the device.

Last reviewed: 13/09/2022

2 Usage environment and safety

2.1 Intended use

Tech in Motion® is an active medical device intended to record and analyze mandibular kinematic to help diagnosis, characterization and therapeutic planning of occlusion patterns.

2.2 Indication

Tech in Motion® 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 patient must have a morphology compatible with the port of the trackers (wearing the frontal tracker and setting the mandibular marker support in the mouth).
The use of the Tech in Motion® device is contraindicated to 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.

RM-070

2.4 Environmental conditions

The user agrees to install and use the device in a location that meets the environmental conditions specified below. The Tech in Motion ™ device is intended for use in dental offices only. The system is suitable for use in dry interior rooms, as can be seen in hospitals and medical practices.

RM-073

The optimal environmental conditions for using this device are as follows:

- Temperature: 15°C to 25°C
- Atmospheric pressure: 80 kPa to 106 kPa
- Humidity level: 30% to 75%
- Altitude under 2000 m

The device is not intended to be used:

- In areas where there is a risk of explosion or in a flammable atmosphere (enriched with oxygen)
- Near high frequency surgical equipment
- Near a strong source of heat or light at the risk of corrupting the proper functioning of the device (total cessation of use or malfunction leading to distorted data)
- Near magnetic fields (distorted data or data generation impossible)
- In a dirty environment (risk of contamination of the device)

2.4.1 Obligations of the user

Values provided by the Tech in Motion 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 Tech in Motion device.

MODJAW cannot be held accountable for the exploitation of data provided by the Tech in Motion device

The use of the device is reserved to qualified and trained dentists, or under their control (students in dental surgery) or to dental technicians.
The device should not be used by unqualified and untrained persons.

RM-175/ RM-202

Under no circumstances should the device be used for invasive measurement or invasive surgery, putting the patient at risk based on measurement results.
The user must ensure that all operating instructions provided on the system are accessible to all users at all times and that they are kept near the device.

The elements of the device are not designed for use with any other system than Modjaw®'s.
Any inappropriate use is prohibited:

- Do not attempt to prepare or maintain the device in any way other than those described in this manual
- Do not modify the device and its instruments, if the device is changed without the permission of Modjaw®, the device warranty will no longer be valid
- Never attempt to introduce any inappropriate object that is not part of the device into the device.

The user must not connect any device not provided by Modjaw.

RM-105

2.5 Incident reporting

If the user/patient had a serious incident, please report it to MODJAW support (for contact details, see section 8), and the competent authority of the Member State in which the user/patient is established.

3 Product description

3.1 List of components

Modjaw®'s Tech In Motion™ feature consists of:

Quantity	Name of the components	Picture
1	Operational Cart including camera and panel PC	
1	Modjaw® Software	
1	Pen Tracker	
1	frontal tracker	
2	Rear band	
1	Reflective markers (x36)	
1	Mandibular marker support (x20)	 
1	Mandibular Tracker	

3.2 Labelling

The following components of the system have their own individual labelling:

- Tech In Motion System
- Cart
- Modjaw® software
- Patient Kit that contains Frontal tracker, Rear band, Pen tracker, Mandibular tracker, Mandibular marker support, Reflective markers

3.3 TECH IN MOTION™ hardware description

3.3.1 Operational cart

The operational cart is composed of several elements:

- A bracket that carries the Panel PC (inside this bracket transit several cables: RJ 45, PC power ...)
- An articulated arm that carries the camera and allows the camera to be positioned approximately 0.8 to 1m from the patient's face
- A bracket that carries the PC panel
- A base on which are attached 4 wheels with brakes allowing its movement
- A box of the base under which the power supply and the isolation transformer are installed
- The connection cable to a dental office wall socket (the cable can be wound for less space)

The cover of the cart must not be removed and none of the electrical elements inside this cover must be removed and / or replaced.

The arm locks at 90 ° on the right or left side. There is therefore a possible total movement of 180 ° from below. The cart is delivered already assembled and ready to use (camera and PC panel are fixed on the cart).
The camera is attached to the carriage and delivered in right or left-handed configuration, depending on the user's preference.

The cart is mounted on wheels; the user must make sure to lock the wheels before each use.

3.3.1.1 Camera

RM-034

The camera is an optical location system specifically designed to detect and track reflective sensors in real time.
The camera is delivered mounted on the cart. The camera is fixed on the arm of the cart in right-handed or left-handed configuration, according to the choice of the user. The following sections detail the characteristics of the equipment.

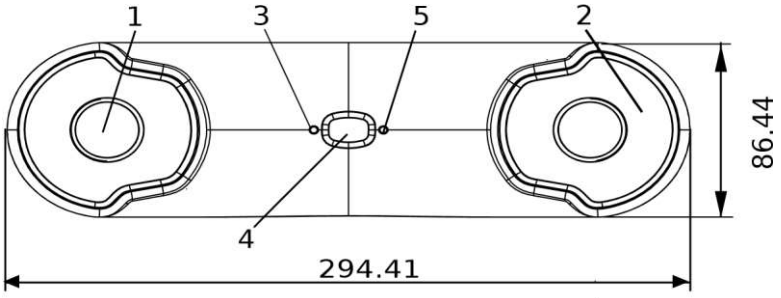
Specifications of the camera

The camera specifications are shown in the table below:

Characteristics	Data
Dimensions (L × W × H)	294mm × 86mm × 99mm
Weight	1.28kg
Infrared	~ 850nm
Power requirements	Power over Ethernet (*PoE*+ IEEE 802.3at-2009) 48V 0.6A

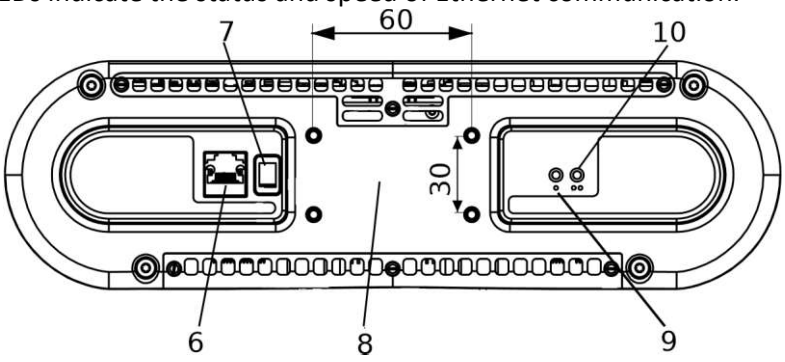
Description of the camera

1. The figure below shows the front view of the camera. It should be noted that “Left” and “Right” always refer to the vision of the camera.



Front view of the camera, showing: (1) camera sensor; (2) IR LEDs sound; (3) User status LED; (4) IR receiver; (5) Device status LED.

2. The rear plane of the camera is shown in the following figure. The Ethernet interface provides both communication and power. The device is switched on / off using the power switch. Finally, both LEDs indicate the status and speed of Ethernet communication.



Description of the rear plane of the camera, showing: (6) the RJ-45 connector, provides power and data transmission between the camera and the computer; (7) Power switch, turn on or off the unit; (8) Permissible surface for mounting on 4 × M4 screws; (9) LED Ethernet RX (10) LED Ethernet TX.
The LEDs on the front of the camera can have multiple states indicating normal operation or not of the camera. The different states are described in the table below.

LED indicating the status of the camera	green	Intermittent	The camera is heating, initialization course
	green	Continuous	The camera is ready to use
	red	Intermittent	Critical error, please contact Modjaw®

Description of indications provided by the LEDs on the front of the camera

Principle of operation of the camera

Below , a simple description of how the camera works:

1. The camera emits infrared light (IR)
2. Infrared light is reflected by reflective markers
3. The camera detects reflected (or emitted) infrared light and transmits the information to the host computer with status information
4. The computer, equipped with the software, extracts the position of each detected point, calculates the 3D position of each detected source, then attempts to match the geometries of known markers.

The camera should not be used covered: this would change the operating temperature of the device and could change the optical path, which would cause a change in the calibration parameters, resulting in a degradation of the precision of the device.

RM-177

Be careful not to obstruct the ventilation ducts of the camera and the PC panel.

RM-178

The camera should be turned on at least every month for minimum 2 hours.
In any case, the camera device should be recharged for 24 h, if the camera has not been used for 6 months.

3.3.1.2 Panel PC

The cart is delivered with the PC panel attached to the cart. The connectors are already installed and the user must not modify the connections in place. The attachment allows the PC panel to be oriented to adjust the screen to the user's position. The PC panel must however be handled with care in order to avoid any deterioration.
When delivered or in storage position, the PC panel can be rotated and placed in a vertical position (see picture below of the storage position of the cart) to minimize the size of the device. The user must ensure that the cables connecting the computer to the cart remain free at all times to prevent premature wear.

Illustration of the two possible storage positions of the PC Panel

The PC panel mounted on the device is an all-in-one computer. To enable optimal operation, the PC panel must have the minimum configuration as shown below:

RM-032/RM-157

Components	Characteristics
Operating system	Microsoft Windows 10 Pro
Processor	Intel Core i7
RAM	32 GB
Hard disk	512 GB
Screen Resolution	1920 x 1080 pixels
Other	Touchscreen

To ensure proper data protection, the user must ensure that **an updated antivirus and firewall are properly installed, updated and maintained on the computer** as soon as the TECH IN MOTION™ device is brought into service.

RM-121

Connecting the PC to the internet exposes the system to the risk of data piracy. The user must ensure that appropriate protection and cyber security measures are in place and functional on the PC (antimalware installation).

RM-122

The device is not intended to be used in a network. If the user decides on a network installation, they are required to check, analyse and evaluate all associated risks.
The update of the operating system of its Panel PC is under the responsibility of the user. The user is required to have their own Windows account installed and configured on the PC.
The procedure for installing and using the PC panel is detailed in section 4.1.

RM-123

The user must use a PC that meets Modjaw®'s specifications and minimum requirements.

RM-032

The user must check the PC panel at commissioning.

3.3.2 Patient kit

The technology of the camera is based on the emission and detection of an infrared (IR) signal. Detection of reflected IR is enabled by the use of reflective trackers placed in the dedicated slots on the TALLY pen tracker, the SMIL'IT mandibular marker and the TIARA headset. The frontal and mandibular trackers, placed on the patient's head, allow the capture of the mandibular movements following a calibration and the acquisition of the characteristic points previously identified on the 3D models using the TALLY pen tracker provided for this purpose.

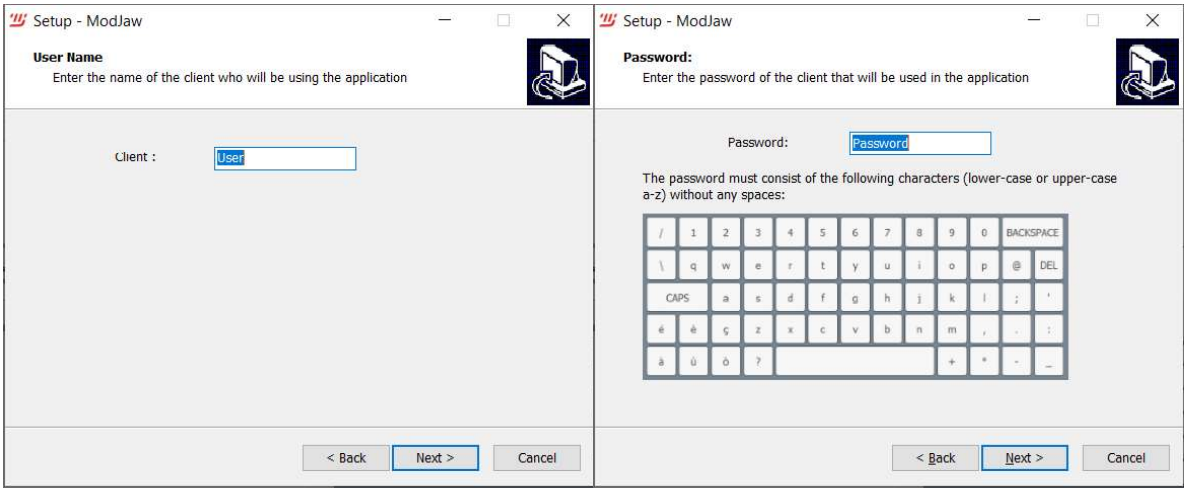
3.4 Install and update software

To use the software on the PC panel of the system, directly go to step 3.4.3.

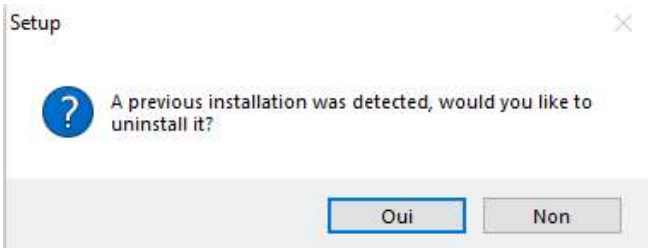
3.4.1 First installation of the software

Click on the link provided by Modjaw® to access the software download webpage and follow the instructions:

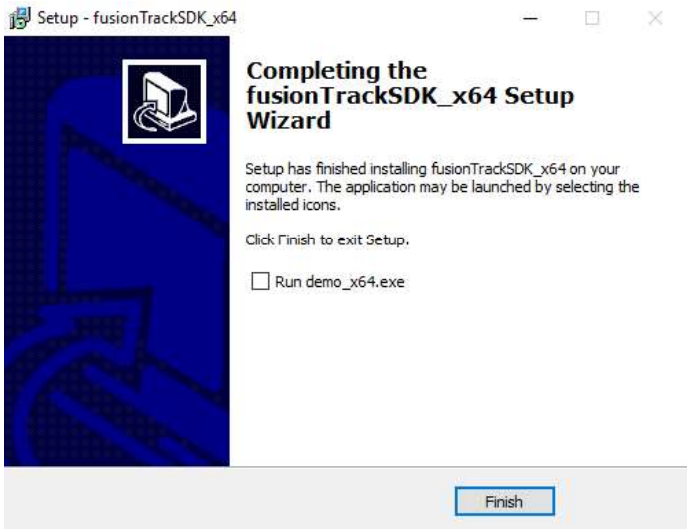
1/ Download the installer (left button) as well as the license file (right button).
2/ Launch the installer to install the software and follow the instructions.
Choose a username and a password for the application:



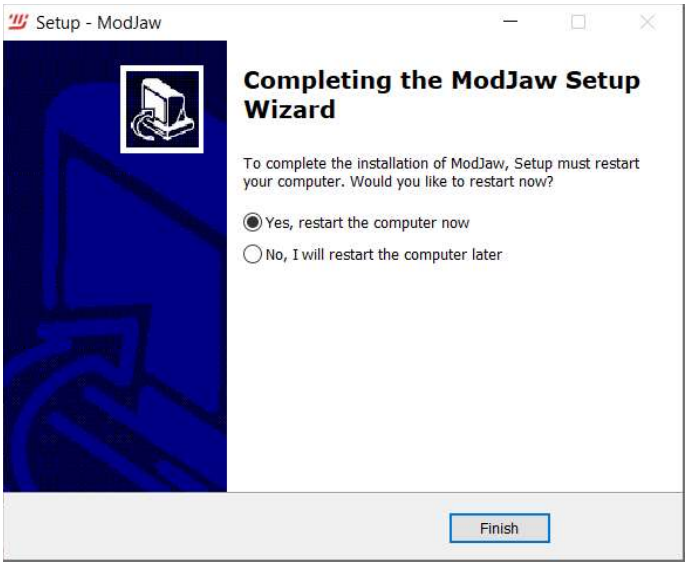
The password will be required when launching the software.
If a previous version of the software was already installed, the following window appears:



Click on “Oui” and follow the instructions.
At the end of the installation, uncheck **“Run demo.exe”** then click on **“Finish”**.



Modjaw® will then be installed automatically, wait while it is being installed.
Installing Modjaw® requires restarting the computer, check **“Yes, restart the computer now”** then click on **“Finish”**.



The installation is complete. The computer will restart.
3/ Once the computer has restarted, launch the software. The license activation page appears.

3.4.2 Activate the license

Launch the software. If no license has been activated, the license activation page appears.

Click on the “Browse” button and browse to the license file downloaded in step 1/ of 3.4.1 then click on the “Activate license” button.
The activation of the license requires an Internet access.
The license is regularly checked online. As such, the Modjaw® system must be connected to the Internet at least once a month.
The software can now be used.

3.4.3 Update the software

When updating the software, a link to download the new version is sent to the user.
Follow the instructions in 3.4.1 and 3.4.2 to update the software.

4 Preparation of the exam

4.1 Setting up the cart

- Unfold the articulated arm of the cart so that it makes a 90 ° angle with the stem

The user must not manipulate the arm while passing through the top.

RM-111

The camera has to be placed horizontal. An orientation other than horizontal (e.g. vertical) can detoriate precision due to thermal gradients inside the device..

RM-180

- Place the cart along the dental chair between the knees and the patient's pelvis,
- Engage the brakes on each wheel of the cart,

Block the cart wheels before each use.

RM-007

- Connect the cart to the mains (to a wall socket of the dental office) containing a grounding connection.

Do not make unplanned connections (network connection, keyboard with non-waterproof wire, mouse with wire ...).
Do not remove the capping accessories on the back of the computer.

The cart is not liquid proof.
Do not use liquid near the truck.
In case of fluid penetration:

- Immediately switch off the device,
- Stop any use in progress,
- Notify Modjaw®'s technical service.

- Make sure the cart is stabilized, and the wheels are locked.
- Check that the cart is connected to the mains.
- Make sure the camera and the computer are securely attached to the carriage.
- Turn on the camera and let it warm up for about 20 minutes, until the LED indicating the status of the camera is green.

Note: the camera is only operational after a warm-up time. Do not attempt to use it until the end of the warm-up period.

The camera should not be used if a hot air outlet is present between the camera and the markers. This could affects the camera acquisition.

RM-181

- Make sure the camera turns on properly and is properly connected to its RJ45 cable.

The user must ensure that the camera is never placed within 20 cm of the patient's skin or eyes.

RM-150

- Check that the camera is on (LED on),
- Check that the PC panel is connected to its power cable and to the RJ 45 cable,
- Turn on the Panel PC. The operating system starts automatically.

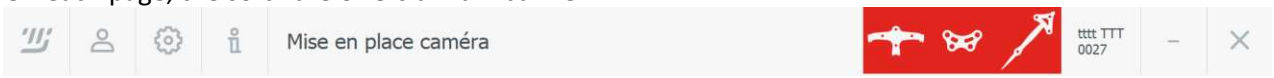
4.2 Starting the software and preparing the patient file

RM-033

4.2.1 Starting the software

Turn on the PC panel and launch the application, if it has not been configured to automatically launch on computer start. The homepage of the software is accessible.
Enter the password, then press the "Start" button to start the use.

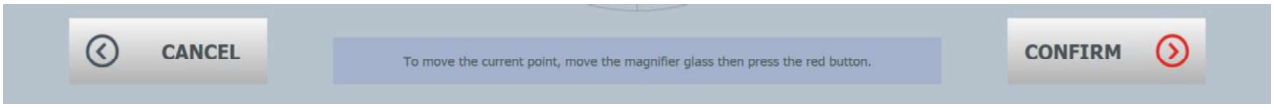
The software is organized into pages that correspond to the different stages of the analysis protocol.
On each page, the software offers a main banner:



1 2 3 4 5 6 7 8 9

From left to right, this banner allows you to:
- Go back to home page (1)
- Go back to the Patient Record page (2)
- Return to key steps of the protocol and access advanced functionalities (3)
- Get additional information, export logs to support, or visualise tutorials (4)
- Identify the title of the current step (5)
- View the visibility status of the instruments. When the pictogram of the instrument is displayed on a red background, the instrument is not visible by the camera (6)
- View the selected patient and their identifier (7)
- Minimise the application in the task bar (8)
- Quit the application (9)

In the lower part of each page, the user finds the following information:



1 2 3

- A button to go back in the protocol (1)
- Contextual help (2)
- A button to advance in the steps of the protocol (3)

4.2.2 Help and tutorials

Modjaw® tutorials are available. To access them, click on the button of the banner (4) then click on the Tutorials button.

The list of available tutorials appears, the user can select the one they wish to visualise.

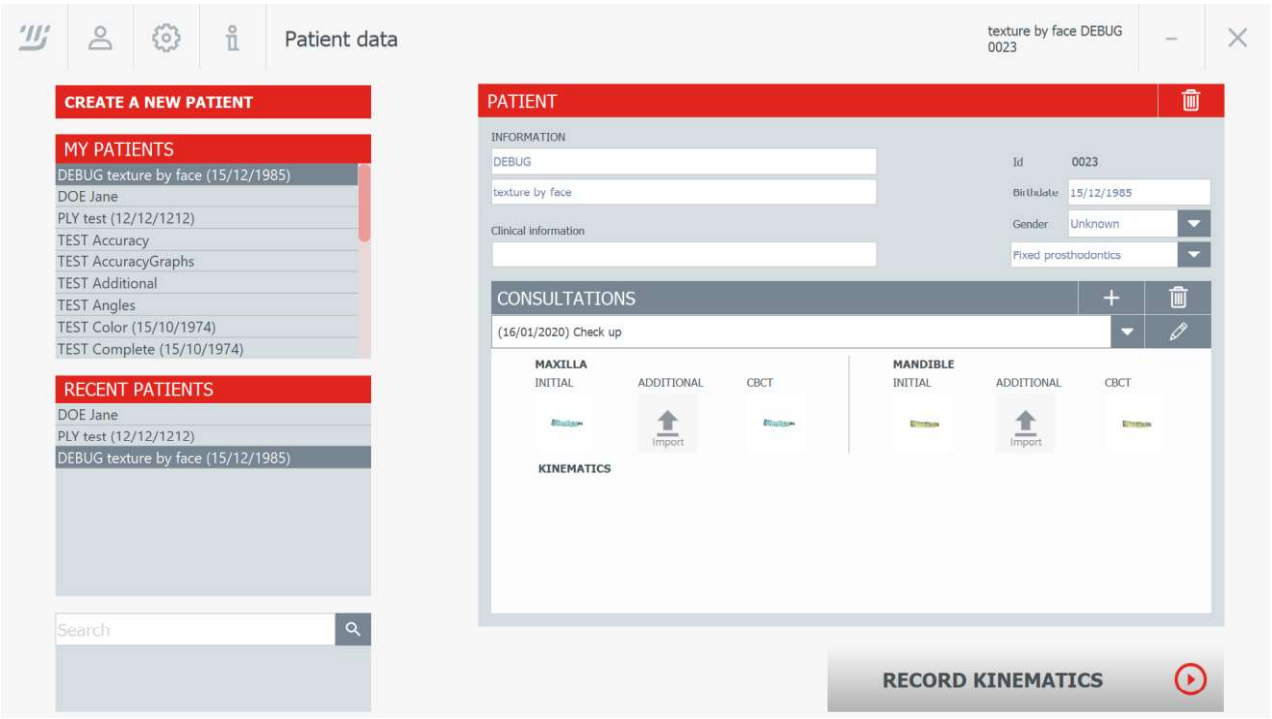
If viewing the tutorials does not work (blank page), install the video codecs (for example by installing https://www.codecguide.com/download_kl.htm).

4.2.3 Creation and management of the patient file

The Patient Data page allows you to:

- Create a new patient record
- Access the file of an existing patient
- Search an existing patient record
- Enter patient information

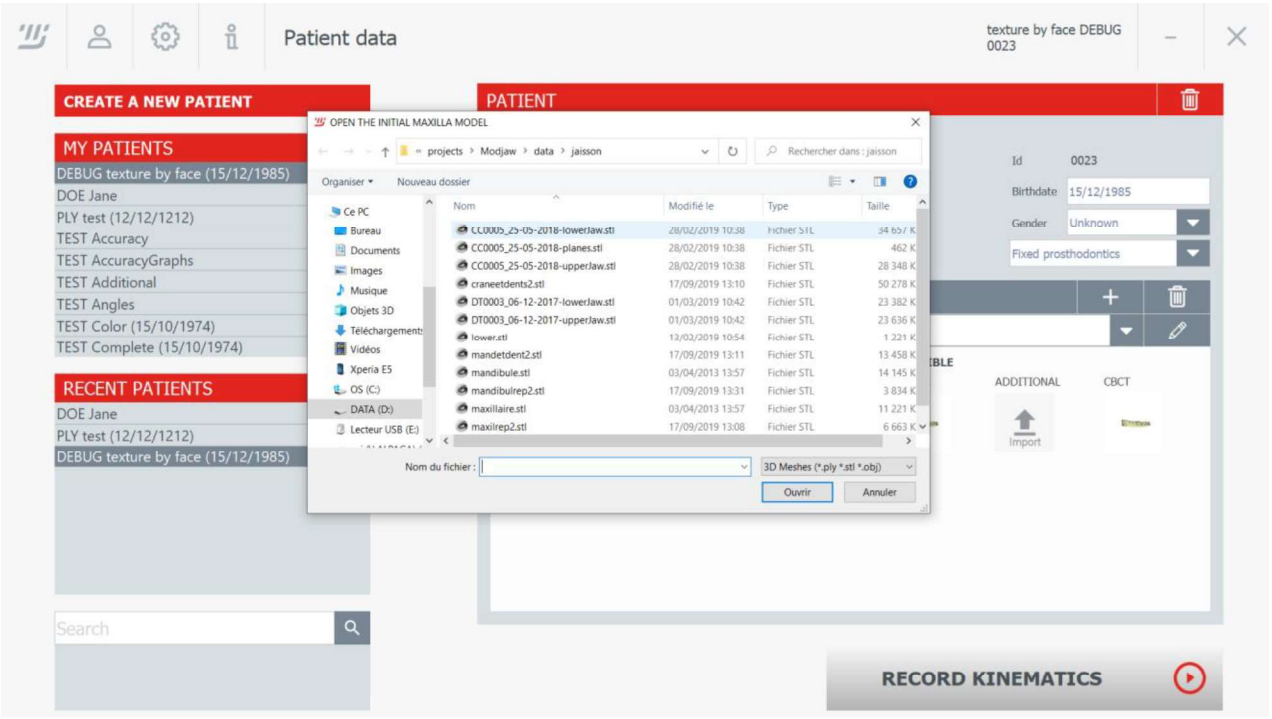
- Add and manage different patient consultations
- Import a consultation shared by another user (click on CREATE A NEW PATIENT then on the  button)



4.2.4 Importing the initial 3D models

RM-108

Once the patient and the consultation are selected, the practitioner can import the 3D models of the patient's dental arches. To do this, they click on the "Import" button corresponding to the desired model, then select the appropriate file.



Prerequisites of 3D models:

- Mesh type models
    - 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 colour per vertex data.
    - In OBJ format
- Mesh at 1:1:1 scale, expressed in mm

RM-129

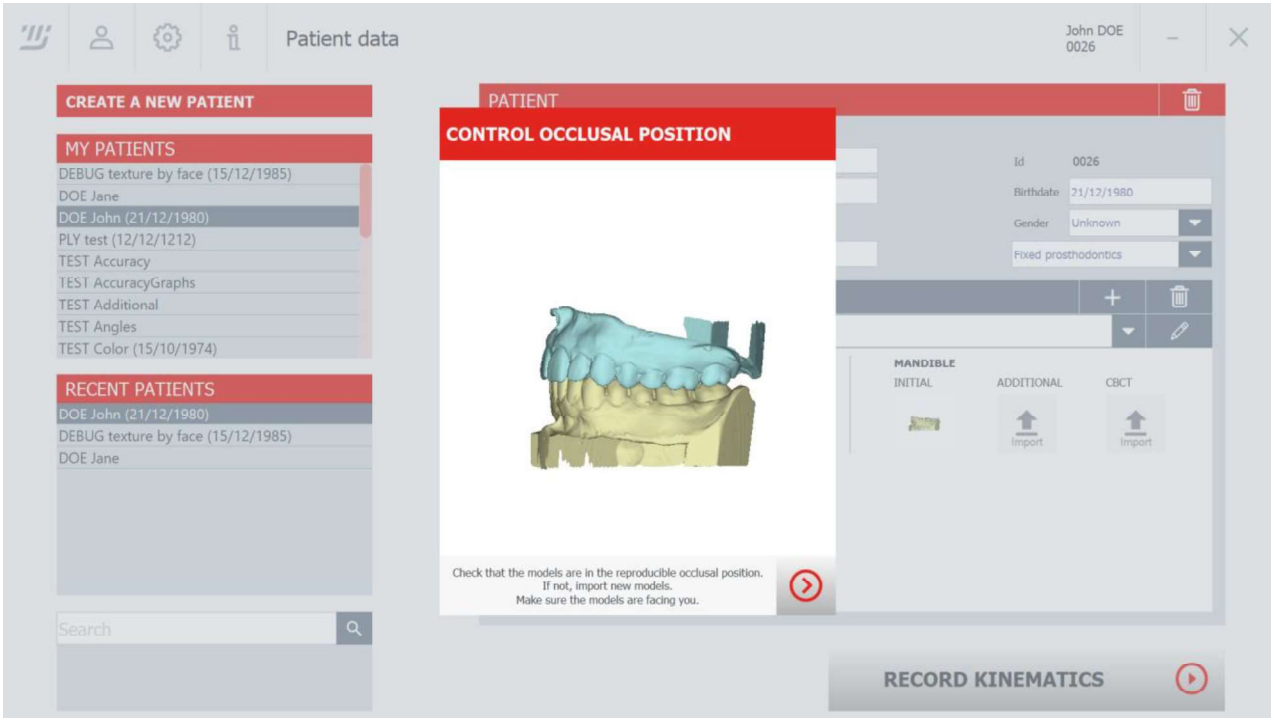
- The Maxillary model and the mandible model are imported in the patient's reproducible occlusion position. They are expressed in the same frame of reference.

Recommendations on 3D models:

- Minimum mesh precision: 200 µm
- Homogeneous and regular mesh, 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 precision of the system. It is the user's responsibility to select models that conform to the above prerequisites and recommendations, as well as their intended use.

When importing models, the user must visually check that the models are imported and that they correspond to their current patient. They must also visually ensure that the models are in the reproducible occlusion position.



The user is responsible for importing mandibular and maxillary models generated in the patient's reproducible occlusion position, and visually checking that is the case when importing the models into the software. Any relative positioning defect of the models has an impact on the precision of the software.

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

4.2.5 Import CBCT models

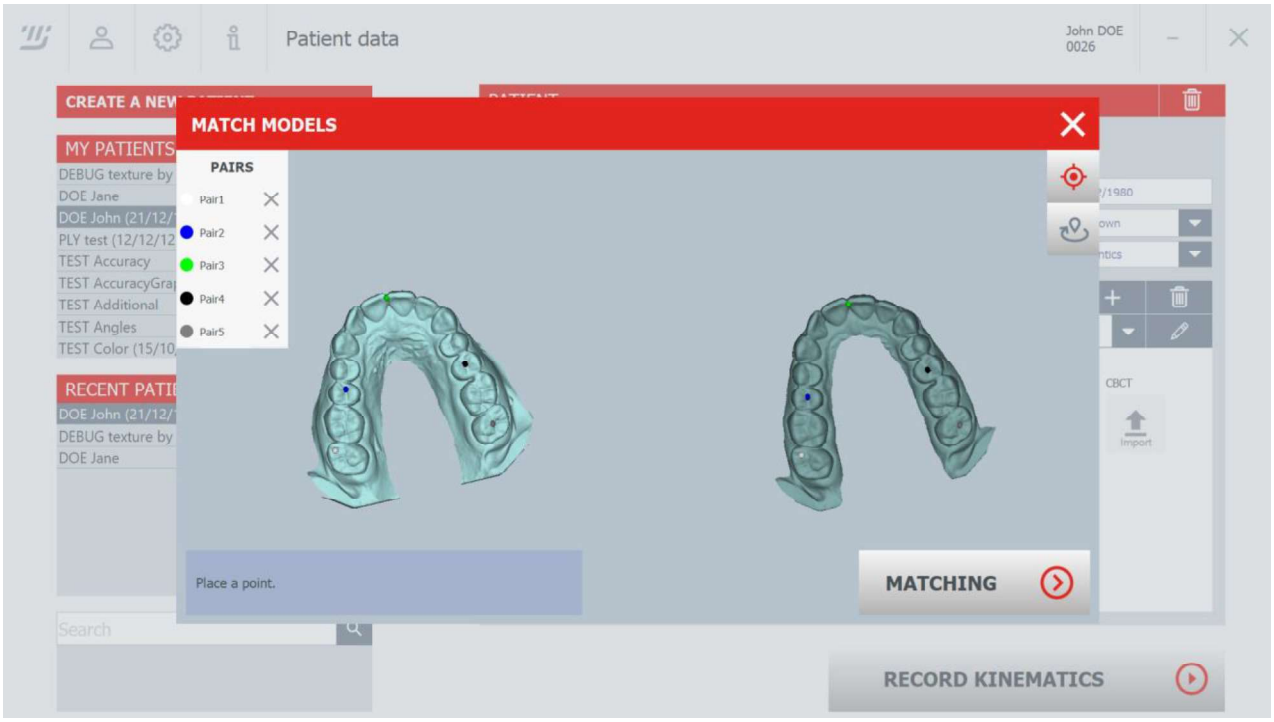
Once the initial models have been loaded, the user can import the CBCT models of their patient. These models must be matched to initial imported 3D models beforehand.

The quality and precision of 3D CBCT models imported into the application have a direct impact on the precision of the system. It is the user's responsibility to select models that conform to the above prerequisites and recommendations, as well as their intended use.

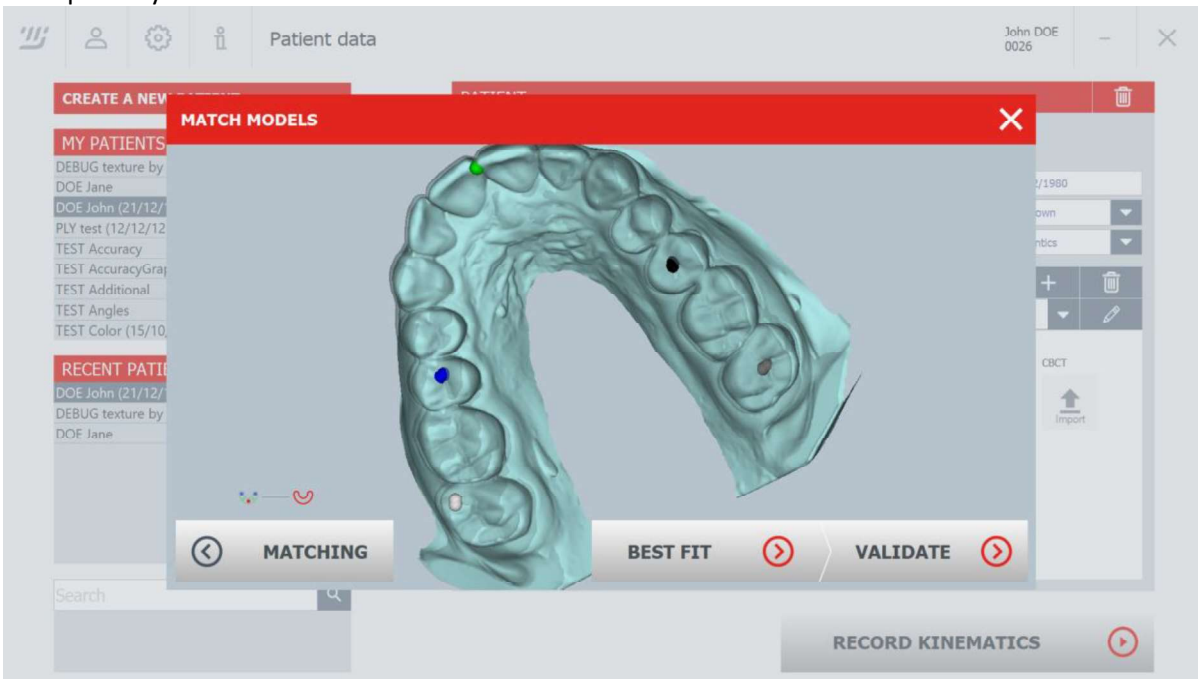
The user is responsible for importing the CBCT models corresponding to their patient and segmented and registered on the initial models with sufficient precision.

4.2.6 The import and the matching of additional 3D models.

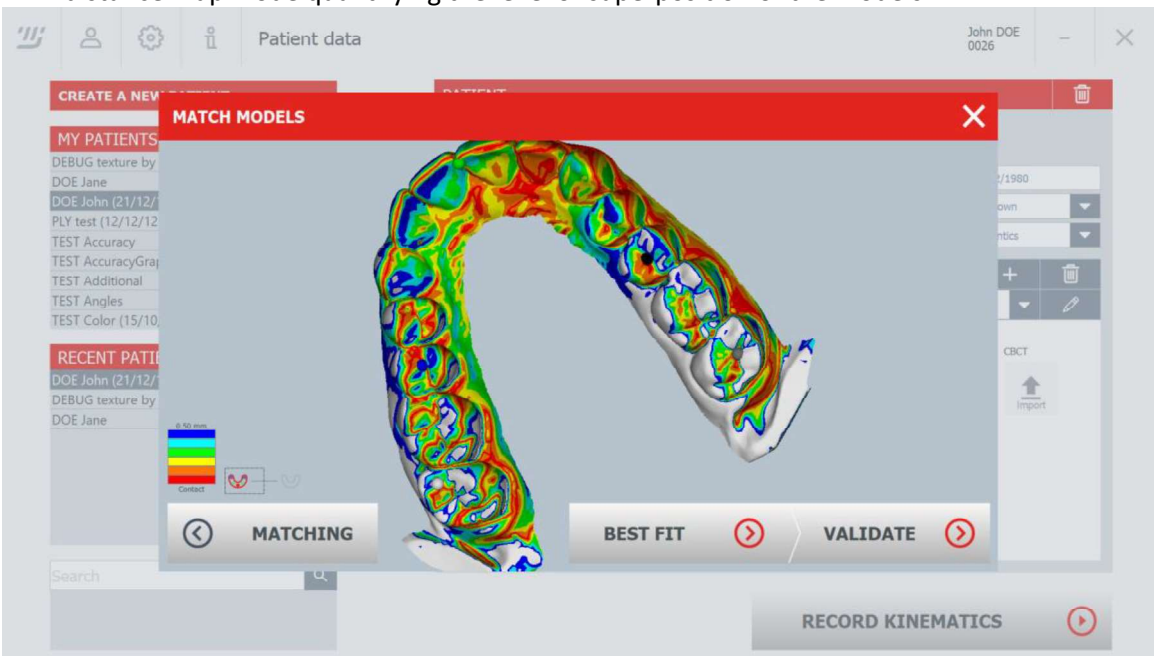
Once the initial models have been loaded, the user can also import additional models of their patient, for example modified models. These models are then matched compared to the initial models. For this, the user defines on each model 5 pairs of common anatomical points.



The user then validates the quality of the matching, by visually verifying the superposition of the models.
Two modes of representation are available:
- A transparency mode



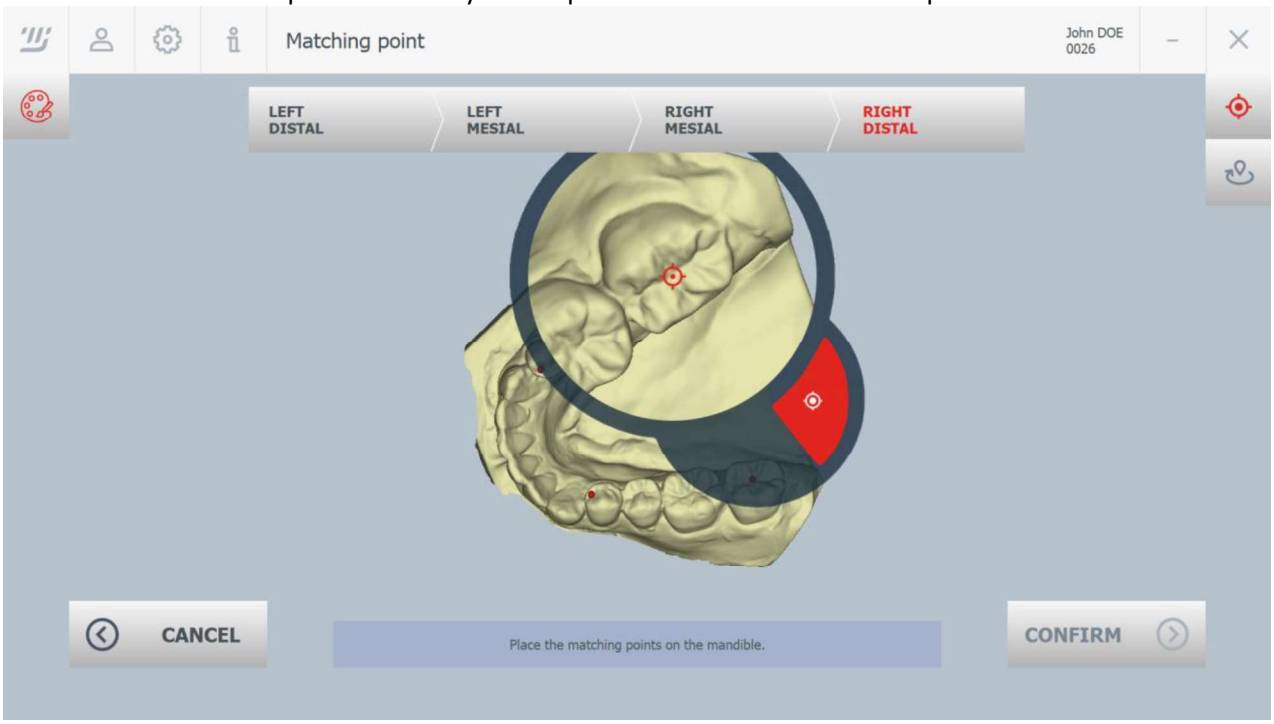
- A distance map mode quantifying the level of superposition of the models



If the quality of the matching is insufficient, the user can return to the matching step ("matching" button) to modify the positioning of the points, or click on the "Adjustment" button so that the software refines the registration automatically.
When the matching is satisfactory, the user clicks on the "Validation" button.

4.2.7 Identification of the matching points

In order to be able to register the 3D models of the patient, the user identifies on the 3D model of the mandible 4 remarkable points that they will acquire in the mouth later in the protocol.



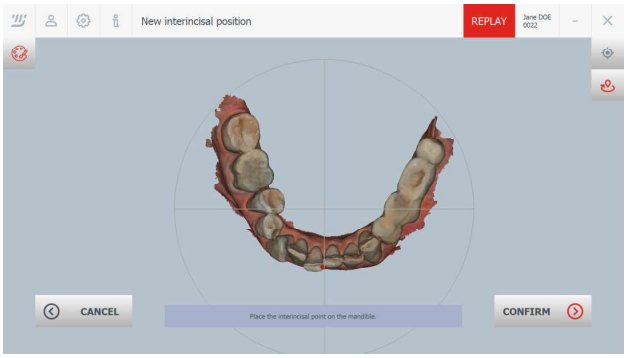
For this, they can zoom the 3D model or rotate it, then switch to the “point selection” mode to position each of the 4 points. A previously positioned point can be readjusted.

2 modes of interaction with the model are proposed:

 - the model can be rotated and zoomed. Points cannot be selected

 - points can be selected. The orientation and zoom of the model cannot be modified.

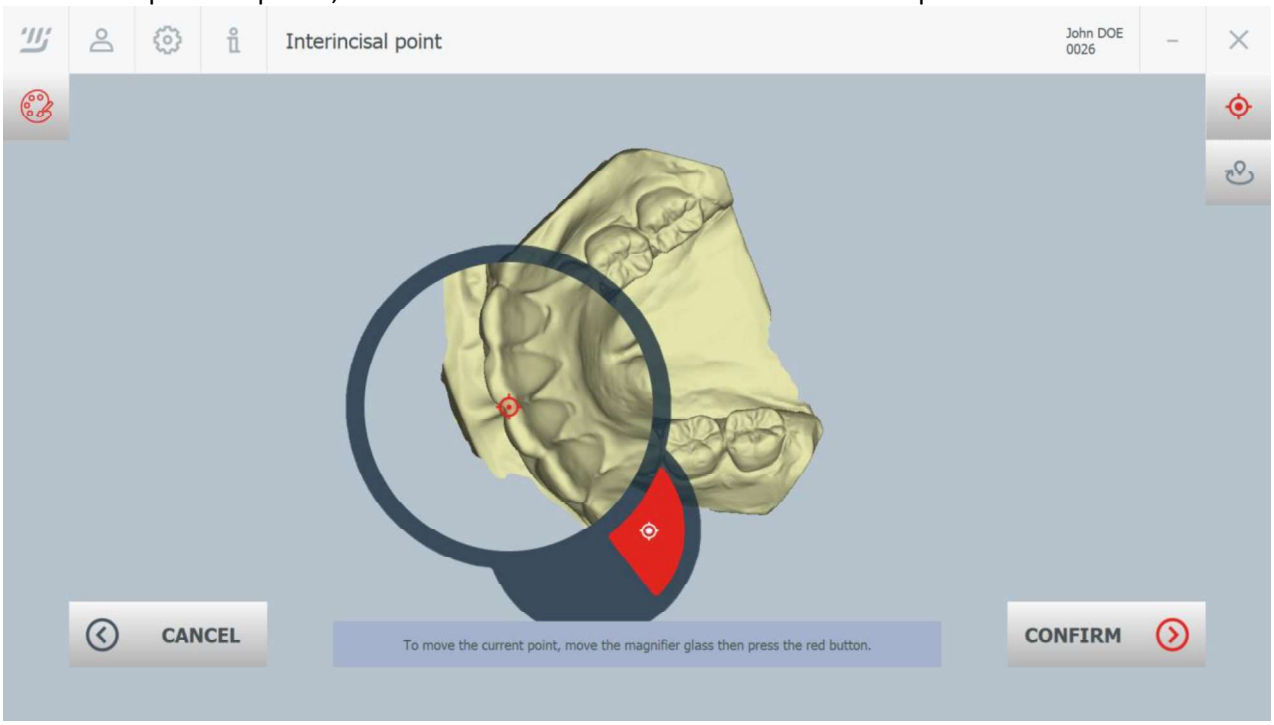
The button activates or deactivates realistic colours on the model:



The choice of points is free. However, to ensure an accurate matching, it is recommended to position the points in the dental dimples and distribute these points over the entire occlusal surface. In addition, these points should be easily accessible in the mouth with the tip of the Tally pen tracker.

4.2.8 The identification of interincisal point

As for the 4 previous points, the user identifies on the model the interincisal point of the mandible:



4.2.9 Analyze previous consultations

The user can reread the data from an earlier consultation in which kinematics were recorded. For this, they select a previous consultation and click on "Replay the kinematics". They do not need the presence of the patient or the instruments. It goes directly to the kinematics step in "Replay" mode.
The user can also add modified models or CBCT models as described above, in order to apply to the previously recorded kinematics.

4.3 Preparing the instruments

4.3.1 Some recommendations before you begin

Before use, instruments should be cleaned following the procedures described in section 6.3 of this document. All reflective markers must be removed from instruments before cleaning.

The stylus is not delivered sterile. **The user must sterilize the stylus before the first use** and before each new use by following the protocol described in chapter 6.3. Sterilization should take place immediately after cleaning.

RM-026

In summary, prior to use, SMIL'IT mandibular trackers and TIARA frontal trackers were cleaned and disinfected by soaking in Enzyme Anios solution (see section 6.3 for detailed protocol or refer to the manufacturer's instructions) then dried and stored in the storage case. The TALLY pen tracker has been similarly cleaned and autoclaved to prevent cross-contamination.

Clean instrumentation should be unpacked on a clean surface to prevent contamination.

The user must check the condition of the instruments before use. The instruments must not be deformed or damaged, as this may alter the information provided by the system or injure the patient.

The integrity and proper functioning of all instruments (frontal tracker, reflective sensors, mandibular holder, mandibular tracker and pen tracker) must be checked before use in accordance with the instructions below.

Check before each use that the instruments positioned on the patient are secure.

RM-025

4.3.2 The assembly of reflective markers

reflective markers are for single use only. They are in a bag in the patient kit box (see section 3.1 of this manual). In preparation for each examination, reflective marker must be assembled on previously cleaned instruments.
On each instrument are housings to set-up the reflective markers. The reflective side of the reflective marker should be positioned towards the front of the trackers (pen tracker, frontal tracker and mandibular tracker). A simple thumb press can clip the reflective marker.
Each reflective marker must be locked at the bottom of its housing and its edges must be in contact with the bottom of the housing (see the following illustration)

Illustration of the positioning of fiducials in the housings provided on the frontal tracker

for more details about the installation of the reflective markers, refer to annex 1.

The user must verify that the instruments are equipped with clean and new reflective marker before starting the instrument placement. The use of deteriorated, deformed reflective marker can affect the precision of the system

RM-025

Check for proper clipping of reflective marker. Any poorly clipped reflective marker can alter the precision of the system.

The user must wear gloves to assemble the reflective marker to avoid contaminating clean parts.

Once the instruments are ready, the user can continue with the calibration of the tip of the TALLY pen.

4.3.3 Calibrating the TALLY picking head

The tip of the Tally Pen must be calibrated before each use.

RM-091

This calibration step is performed by following the corresponding instructions on the software interface. For this, the user clicks on the "Calibration of the Tally" button.

Then, the user positions the TIARA frontal tracker held in hand facing the camera, at a distance of about 80 cm. They make sure not to hide the reflective markers with their fingers, then position the tip of the TALLY pen in the calibration slot, small cone located at the top of the TIARA frontal tracker, as shown on the screen (see illustration below).
When the two instruments are visible by the camera, they start the calibration by clicking on the screen on the "Launch" button. The start is delayed a few seconds.
The user then makes circular pivot movements, wide and slow, with the stylus, while maintaining the tip at the bottom of the cone during the calibration period. If the calibration is successful, the software automatically goes to the next step.

Any fall of an instrument before or during use can degrade the precision of the system. If the instrument falls between calibration and acquisition, it is recommended to recalibrate the stylus or to change the stylus and redo the calibration

RM-080

4.4 Instructions to give to the patient before starting

It must be ensured that the patient is able to do the examination. They must be able to understand the instructions and execute them.

The user must inform the patient that they must try not to move during the acquisition.
The patient should not touch the device (cart, panel PC, camera).

RM-100

The patient should be in a semi-sitting position with the head slightly tilted back, facing the camera.

The user must warn the patient that they should not look directly at the camera front.

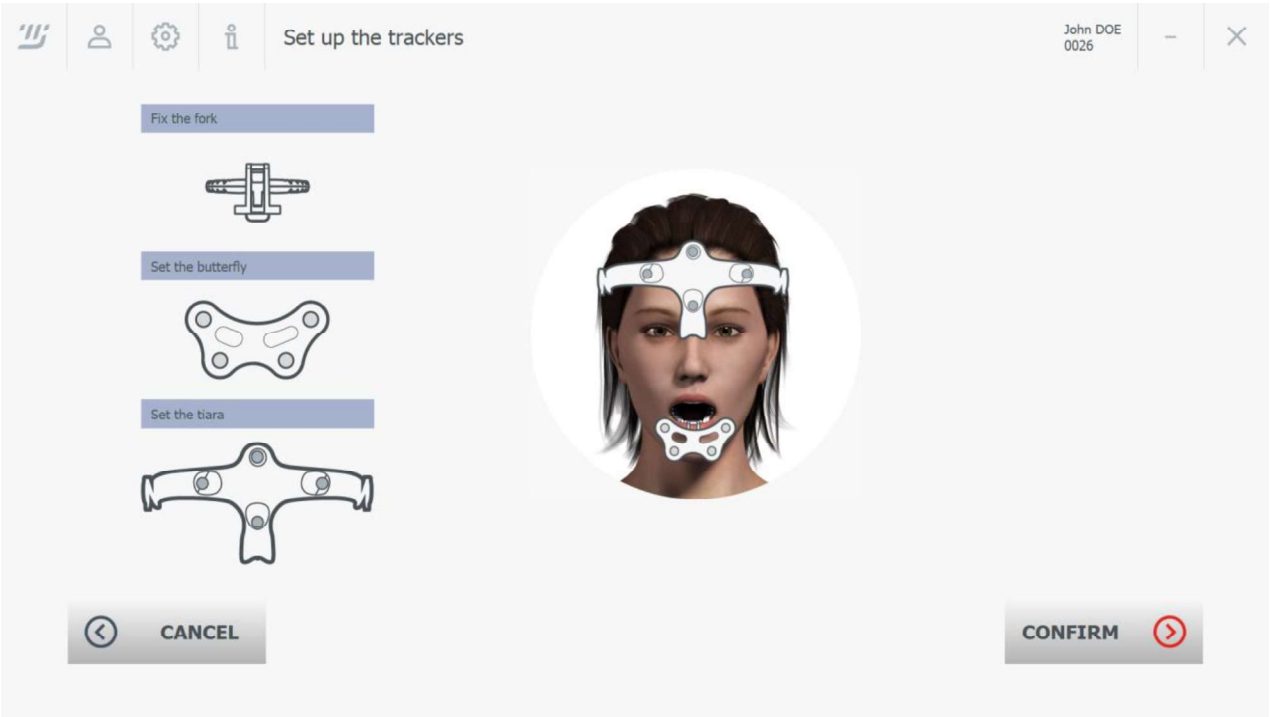
To ensure the proper functioning of the camera, the markers must be in the camera's working field throughout the acquisition process. The camera must be positioned facing the patient.
Reflective surfaces and polluting lights (sunlight, lamps with a high IR component of around 850 nm, etc.) should be avoided. During acquisition, potential sources of sunlight (or equivalent) should be removed.

4.5 Setting up the instruments on the patient

The software interface guides the user in setting up markers. As shown below, this step allows to position the frontal markers (TIARA headset) and mandibular markers (SMIL'IT).

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



4.5.1 Mandibular marker placement - SMIL'IT Mandibular Marker

In order to prepare the patient for the examination, the user must position the SMIL'IT mandibular tracker. This mandibular tracker is held in front of the mandible of the patient with a support. These supports for mandibular marker are single-use pieces that can be found in the patient kit box.

Supports for the placement of mandibular markers are delivered clean. They must be handled with medical gloves.

The positioning of the mandibular marker is therefore done in two steps:

- Fixing the support in the mouth
- Clip SMIL'IT mandibular tracker on the support

These two steps are described below:

Step 1: Fixing the support in the mouth:

RM-055

Before insertion, the mandibular tracker support can be adjusted in length if necessary. For this, just break the ends.

The user should be careful not to injure the patient with the ends of the mandibular marker holder, especially after adjustment. Check before introduction into the mouth that no roughness remains, likely to injure the patient.

RM-093

The support is glued to the surface of the teeth of the mandible using a self-hardening resin (Structur types, VOCO company) following the protocol indicated by the resin manufacturer. Part of the support remains positioned outside the mouth to allow clipping of the SMIL'IT

It is recommended to use a self-hardening resin model among those recommended by Modjaw®. The user must follow the application protocol specified by the resin manufacturer.

After the setting time indicated by the manufacturer of the resin, the user verifies the proper fixation of the support on the teeth of the patient. The support must be positioned in such a way it should not disturb the patient mastication, the movements of the jaw must be possible and natural.

Step 2: Clip mandibular tracker

The mandibular tracker, equipped with reflective markers is then added to the support. For this, place the male part located on the mandibular marker SMIL'IT in the female part located on the outer part of the support. The patient must close the mouth during this operation to facilitate posing the marker and avoid any pain. The addition of SMIL'IT Mandibular tracker should not interfere with the patient when moving the lower jaw.

Illustration of the support clip on the mandibular marker

4.5.2 Installation of frontal markers - TIARA Headset

The TIARA headset should then be positioned on the patient's head. The positioning is correct if the red rubbers located on the posterior face of the front piece are placed on the forehead and the top of the patient's nose.
The white band is positioned high above the ears and is positioned above the patient's neck. Finally, the tightening is adjusted using the knobs on each side.
The TIARA headset must be fixed and move as little as possible to minimize inaccuracies during the acquisition.

Illustration of the position of the headset on the patient.

5 Completing the acquisition

RM-033

Once the patient is equipped and the Operational cart is in place, some checks should be made to ensure optimal operation of the TECH IN MOTION™ device.
The user must check the device is in general good conditions (good connection cables, power supply, power outlets ...) to ensure the protection of their patients, third parties, other operators and assistants.

The user must not use defective products (stripped, worn cables ...). In the event that the hardware condition is incorrect, any use of the device must be stopped.

The user must not disconnect the cables from the system during operation as it may damage the system and make it non-functional.

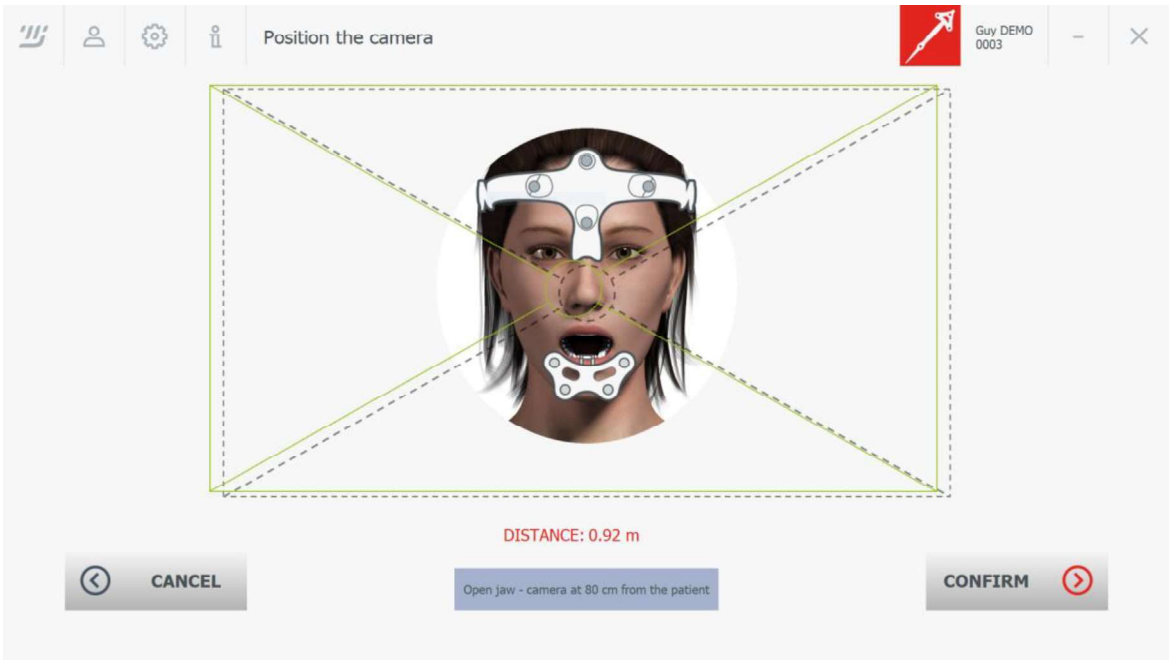
RM-113

5.1 Step 1: Setting up the camera

The camera should be positioned facing the patient's face at about 80 cm.
In the Camera Setup page, the user orients the camera so that the distance to the patient and the rectangle representing the work volume turn green.

The user must ensure that the patient does not remove the markers from the camera's field.

RM-008



They then check that the TIARA headset and the SMIL'IT mandibular tracker are clearly visible by the camera, patient in occlusion and patient mouth wide open.

Throughout the protocol, if a required instrument is not visible by the camera, a pictogram on a red background appears in the upper banner:

- TIARA helmet not visible by the camera
- Mandibular tracker SMIL'IT not visible by the camera
- Pen tracker TALLY not visible by the camera

If an instrument is not visible, the user can:

- Reorient the instrument, facing the camera, the reflective markers facing the camera.
- Adjust the orientation and the position of the camera in front of the patient's face so that the instrument is in the field of view of the camera.
- Clear the line of sight between the instruments and the camera.
- Check the condition of the reflective markers and their correct clipping.

To redo the acquisitions, the user can click on the button in the top banner, then on the "redo acquisitions" option.

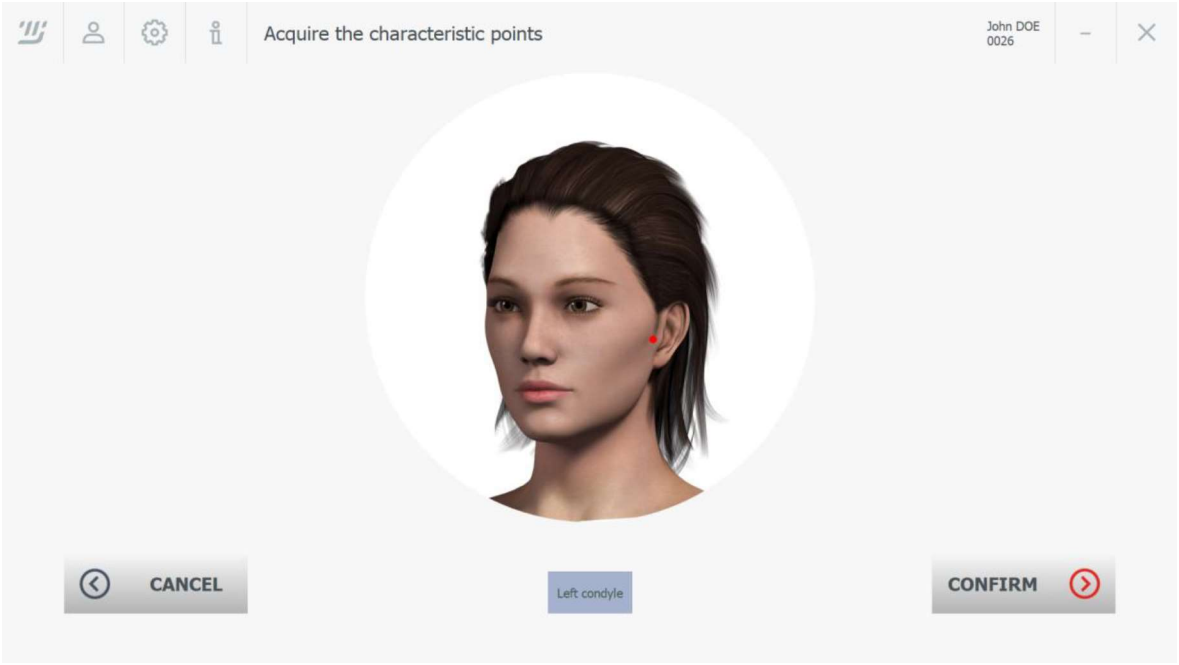
5.2 Step 2: Acquisition of anatomical reference points

Prior to being able to record the kinematics of the patient's dental arches, the user must perform various anatomical acquisitions on the patient.

5.2.1 Anatomical reference points on the patient's face

The following anatomical points are recorded following the instructions given by the software:

- Left condyle
- Sub nasal point
- Right condyle



The user positions the tip of the TALLY stylus on the anatomical point indicated on the patient's face. They check visibility of the instruments and then presses the "Validate" button. The stylus must not move during the acquisition.

The user must be careful not to bend the pen tip with excessive pressure. If bent, the precision of the system may be impaired and the patient may be injured.

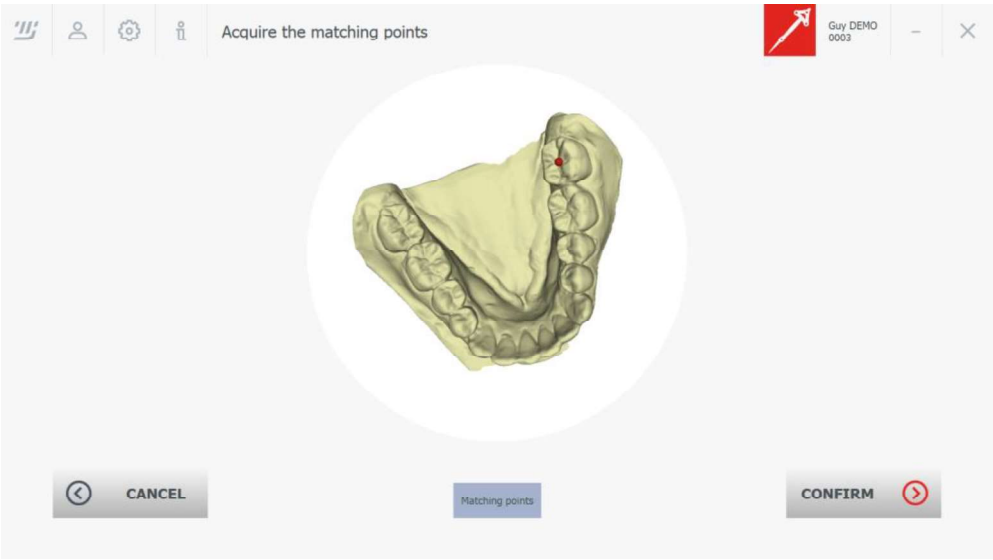
RM-083

The user should be careful not to injure the patient with the tip of the stylus, especially when placing the stylus near the eyes.

RM-077

5.2.2 Registration points in the mouth

In order to position the models of the patient in space, the user acquires in the mouth the 4 noticeable points defined above on the mandible 3D model.
For this, they position the tip of the stylus TALLY in the mouth on the remarkable point indicated on the screen. They check the visibility of the instruments and then press the "Validate" button. The stylus must not move during the acquisition and the reflective markers must be seen by the camera.



In order to avoid cross-contamination between the patient's skin and the mouth, it is recommended to clean the tip of the stylus with a disinfectant wipe between acquiring points on the face and in the mouth.

5.2.3 Reproducible occlusion position

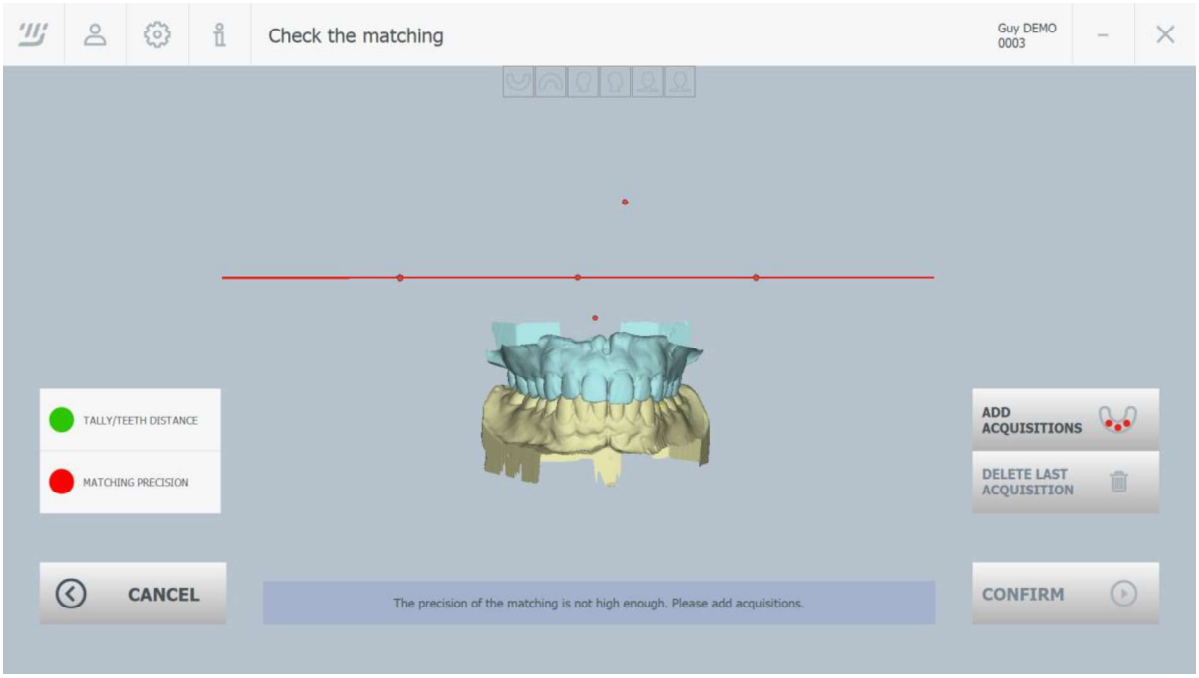
RM-148

In order to match patient's models, the user records the reproducible occlusion position. For this, they position their patient in the reproducible occlusion position, check the visibility of the instruments and press "Validate".

The user must make sure that the actual occlusion position of the patient exactly matches that of the imported 3D models. Otherwise, the precision of the system may be altered

5.2.4 Registration check

In order to guarantee the precision of the system, the user checks the registration of the 3D models of the patient.



For this, the user must check the Matching precision indicator*:* 

If the indicator is Green, the registration has good overall precision.
If the indicator is Orange, the registration is of average overall precision. The precision of the system may be impaired. It is recommended to improve the registration.

Then, the user must check the local precision of the registration. For this, they position the tip of the Tally pen in contact with the teeth on the mandible and the maxillary, in different areas of interest of the occlusal surface and check the indicator 

.

If the indicator is green, the registration is accurate at the controlled position.
If the indicator is orange, the registration is moderately accurate at the controlled position.
If the indicator is red, the registration is inaccurate at the controlled position.

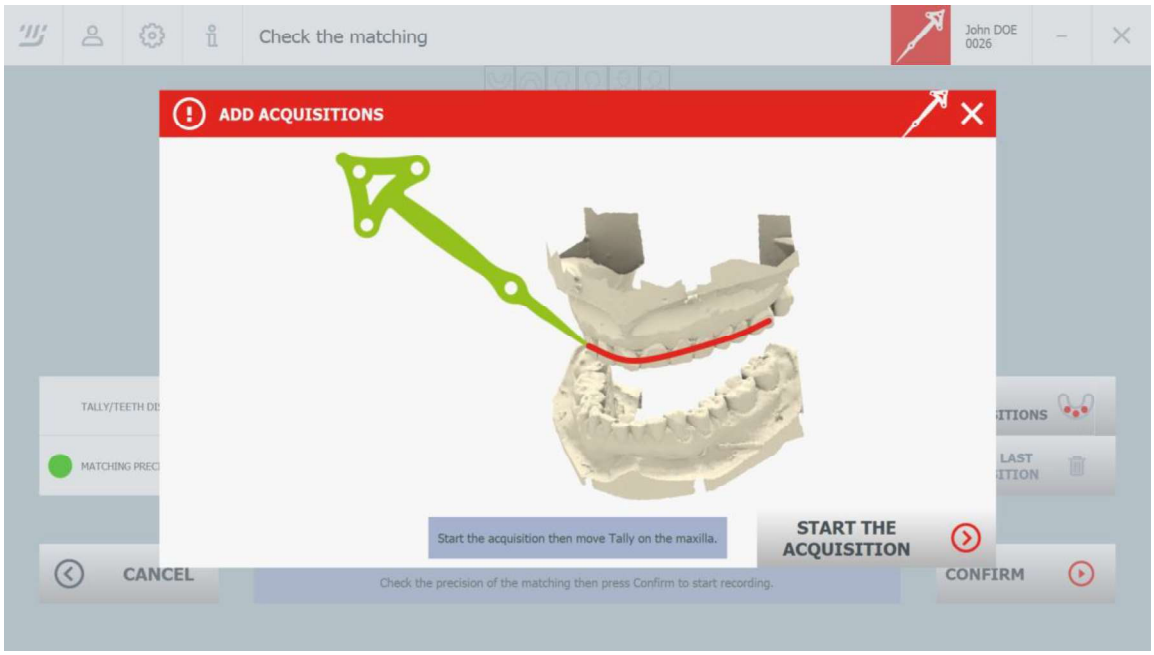
If different areas of interest have a moderately accurate or inaccurate registration, the precision of the system may be altered. It is recommended to improve the registration.

The user must check their registration precision

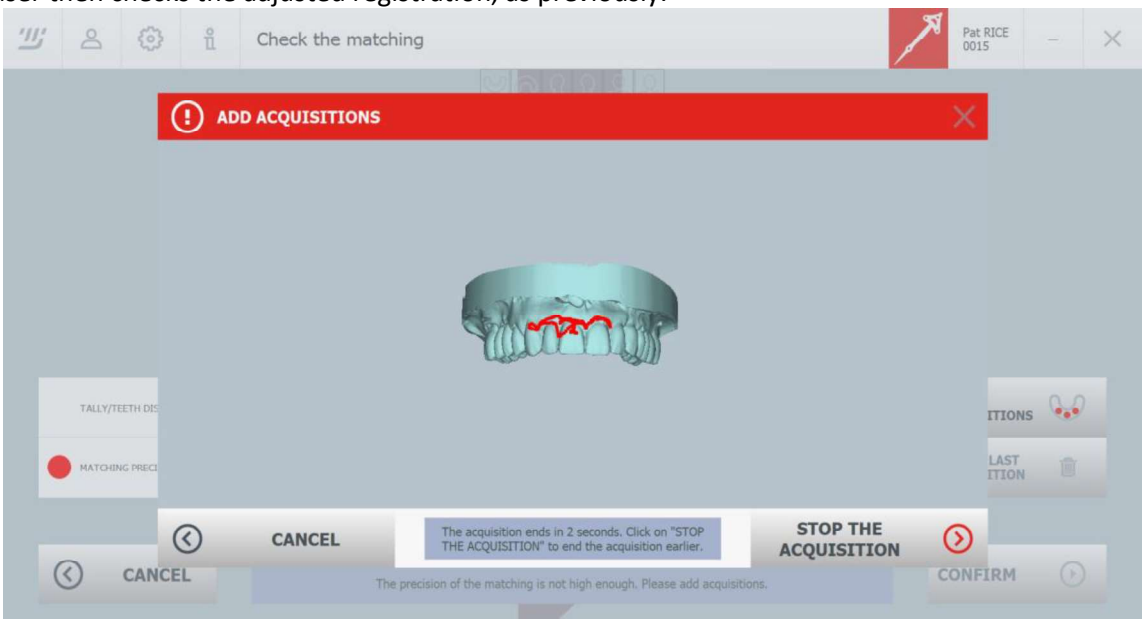
RM-143

5.2.5 Improving the registration

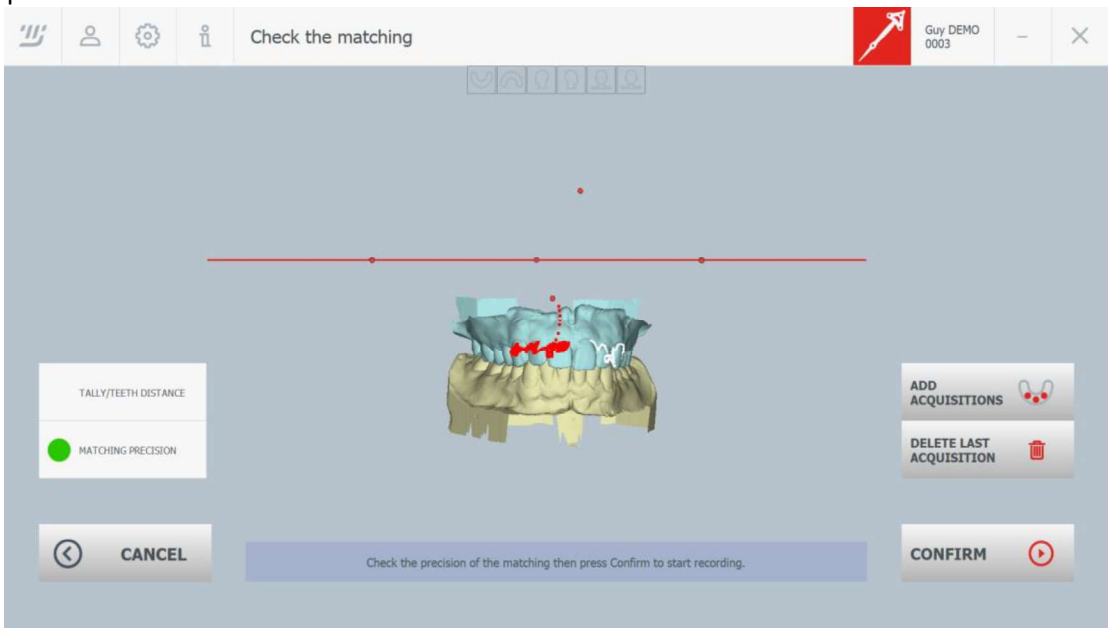
To improve the registration, the user can add or delete acquisitions by clicking respectively on "Add acquisitions" and “Delete last acquisition”.



The tip of the pen tracker is placed on the teeth of the maxilla of the patient. The user starts the acquisition and moves the tip on the teeth, while making sure to maintain contact throughout the acquisition.
The user then checks the adjusted registration, as previously.

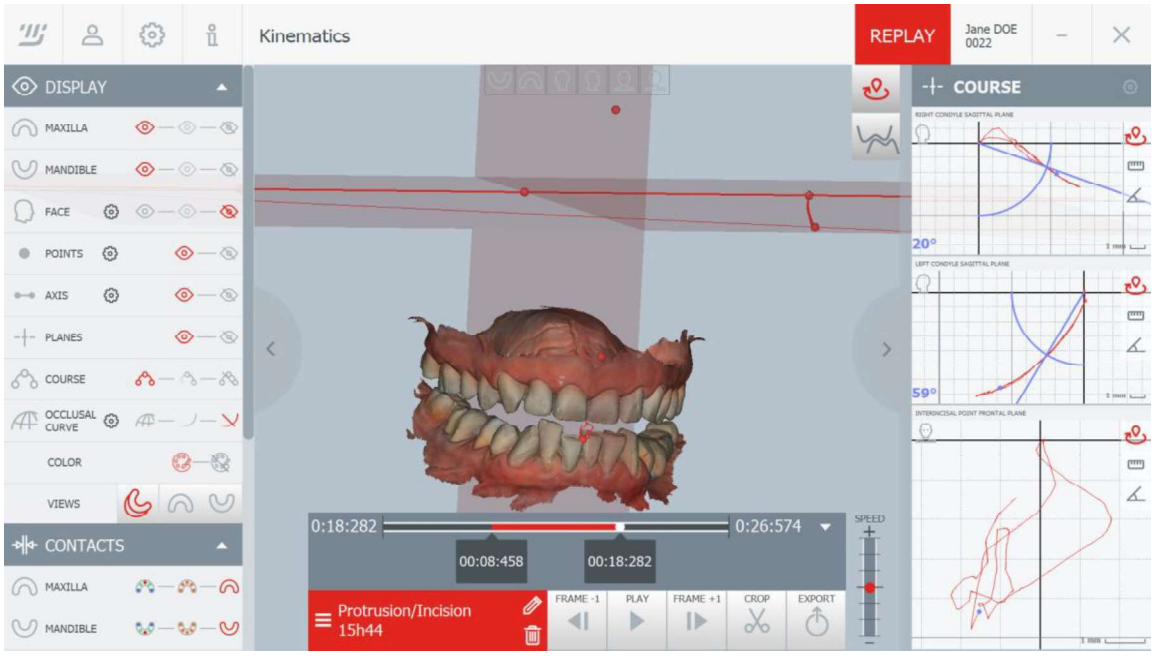


Several sets of acquisitions can be added to improve precision, and it is possible to iteratively delete the last acquisition of the list.



5.3 Step 3: Recording kinematics

Once the acquisitions made and the registration validated, the recording of kinematics can be performed.



This *Kinematics* stage, there are 3 different modes, displayed in the main banner:

LIVE - LIVE mode: The patient's current movements are displayed live. They are not recorded. This is the default mode after acquisitions.

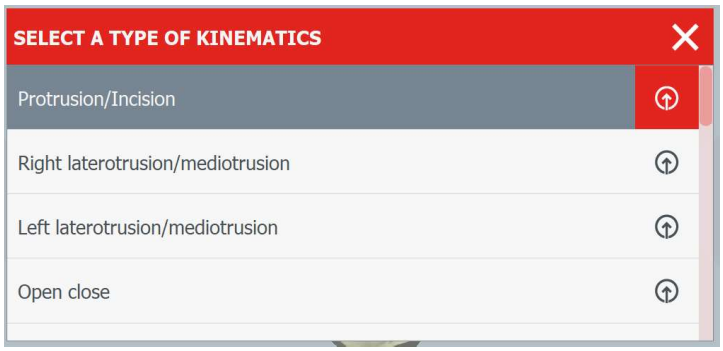
RECORD - RECORD mode: The patient's current movements are recorded. This mode is triggered from LIVE mode by clicking the kinematics recording button and quit by stopping the recording.

REPLAY - REPLAY mode: The previously saved movements of the patient are replayed. This mode is accessible directly after recording a kinematic or when the user analyses a previous consultation, without the presence of the patient.

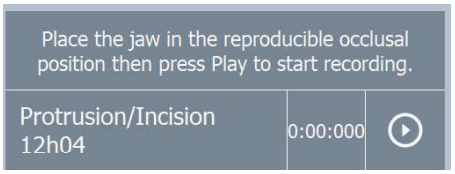
5.3.1 Record a first kinematic

The *Kinematics* stage starts by a step to preview the dental arches motion in LIVE mode. From this step, the user can launch the first recording by clicking on the Play button in the bottom central panel. To record the first kinematics:

- The user selects the type of trajectory to perform:



- In LIVE mode, the patient must be placed in a reproducible occlusion position before recording
- Then the user can start recording from the bottom centre panel (see below)



- The patient performs the movement
- The user stops recording once the movement is made from the lower centre panel

The user must visually check the consistency between the virtual movements and the actual movements displayed. If the movements are inconsistent, abandon the use of the system, or redo the acquisitions.

RM-082

5.3.2 Record of an additional kinematics

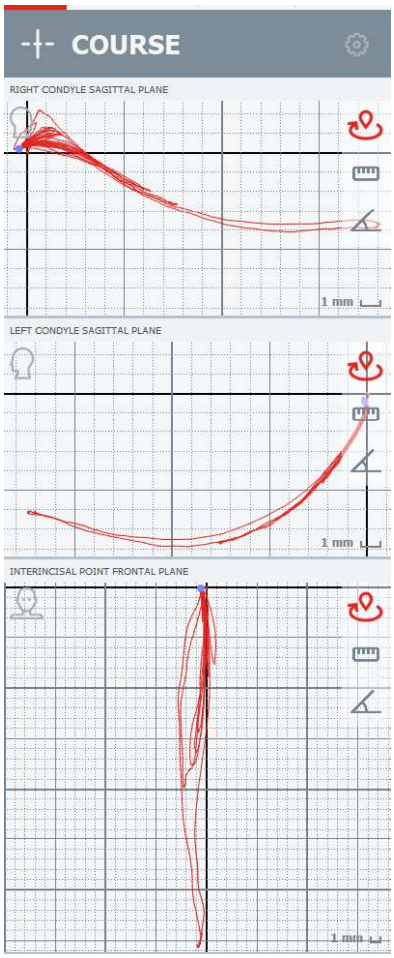
- In REPLAY mode, the user clicks on the lower centre panel button , then selects "Record another kinematics"
- Then they repeat the previous steps.

5.3.3 Replay a kinematic

- In REPLAY mode, the user clicks on the lower centre panel button , then selects the name of the kinematics they want to re-read
- They interact with the lower centre panel to:
  - Change the name of the kinematics
  - Remove kinematics
  - Play the kinematics (continuous play / pause / step by step)
  - Crop the trajectory
  - Adjust the playing speed of the trajectory

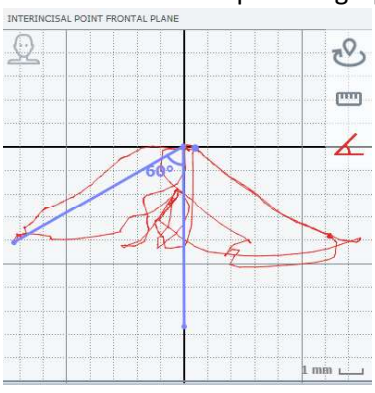
5.3.4 Visualise course graphs

In the right-side panel, the trajectory of the anatomical points is represented on a graph to generate data. The displayed trajectory corresponds to the projection of the anatomically selected anatomical point on the selected anatomical plane.



The user can modify the default selection by clicking on the button  .

Distances and angles can be evaluated on the graphs, by clicking respectively on the  and  buttons of the graph. The button  is used to return in default mode: zoom and pan the graph.

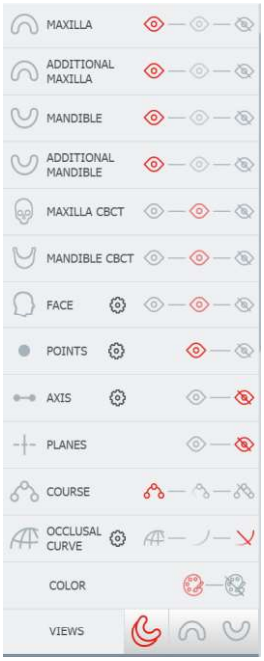


Distance display unit in all graphs is the millimeter (mm).
Angle display unit in all graphs is the degree (°).

RM-088

5.3.5 Display configuration

From the left side panel, the user can adapt the displayed elements in the 3D view.



Maxilla: maxilla model display (opaque / transparent / hidden)

Additional maxilla: additional maxilla model display (opaque / transparent / hidden)

Mandible: display of mandible model (opaque / transparent / hidden)

Additional mandible: additional mandible model display (opaque / transparent / hidden)

Maxilla CBCT: display of the CBCT model (opaque / transparent / hidden)

Mandible CBCT: display of the CBCT model (opaque / transparent / hidden)

Face: display of the face scan (opaque / transparent / hidden)Points: displaying anatomical points (displayed / hidden)

Axis: display of the condylar axis (displayed / hidden)

Planes: display of anatomical planes (displayed / hidden)

Course: displaying the 3D trajectory of the anatomical points (whole / disappearing / hidden)

Occlusal curve: Sphere / spherical cap / hidden

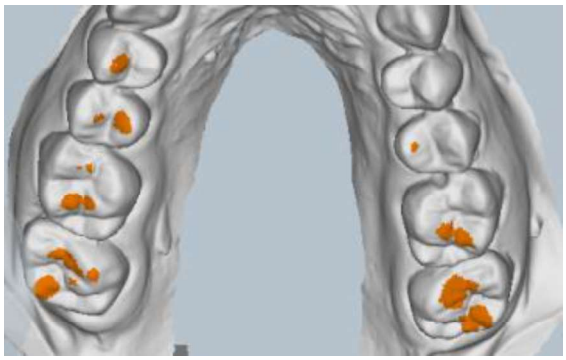
Colors: Display the models with realistic / generic colours

Views: 3D models view (normal view / exploded view)

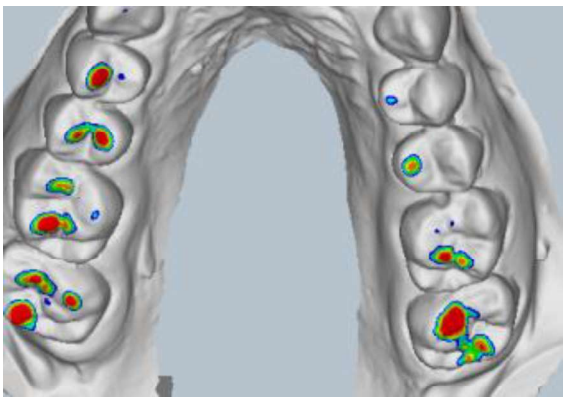
5.3.6 View and configure arches contacts

The software displays the contacts between the 3D models of the arches.
2 types of contacts are available:

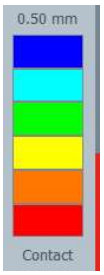

: Presence of contacts: the areas of contact between the teeth are identified by orange traces.
A contact is identified if both models of the arches are less than 300 µm apart. This type of representation is available in all modes, and allows to visualize the teeth in contact, without quantifying the contact.




: Proximity maps of the arches: the zones of strong proximity or contacts between the teeth of the 2 arches are mapped by colour according to the distance between the models. This type of representation is only available in REPLAY mode, and allows a quantitative analysis of contacts and proximity between teeth



Colour mapping of the contacts:



Blue: the models are distant from 500 µm (+/-50 µm)
Cyan: the models are distant from 400 µm (+/-50 µm)
Green: the models are distant from 300 µm (+/-50 µm)
Yellow: the models are distant from 200 µm (+/-50 µm)
Orange: the models are distant from 100 µm (+/-50 µm)
Red: Models are in contact (+/-50 µm)

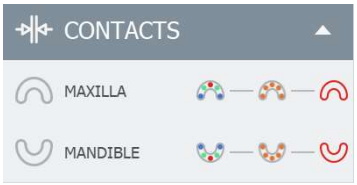
RM-164

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

Acquisitions are sampled and there is a risk of missing the most significant contacts.

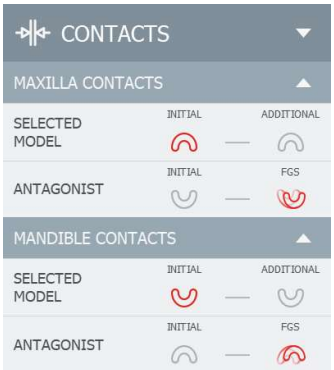
RM-173

The left side panel can change the type of display of the contacts between the dental arches:



Maxillary: display of contacts (proximity map / presence of contacts / no contacts)
Mandible: display of contacts (proximity map / presence of contacts / no contacts)

The user can select which models are used to calculate the contacts, from the left side panel, "Maxillary Contacts" and "Maxillary Contacts" sections:

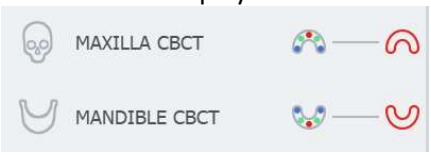


Calculation of maxillary contacts from a maxillary model and an antagonistic mandible
Selected model: initial or additional maxillary model
Antagonist: selected antagonist mandibular model or FGS

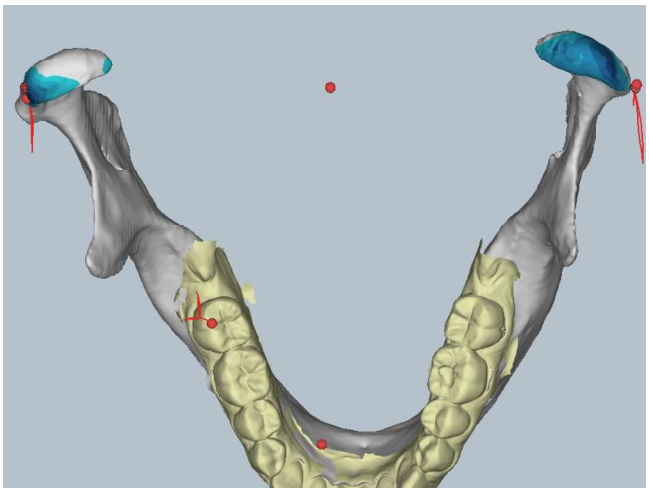
Calculation of the mandibular contacts from a mandible and maxillary model antagonist
Selected model: initial or additional mandible model
Antagonist: selected antagonist maxillary model or FGS

5.3.7 View and configure CBCT contacts

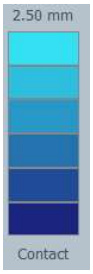
The software displays the contacts between the 3D CBCT models in the temporomandibular joint region.



 : Proximity maps of the arches: the zones of strong proximity or contacts between the 2 CBCT models are mapped by colour according to the distance between the models. This type of representation is only available in REPLAY mode, and allows a quantitative analysis of contacts and proximity between in the temporomandibular joit region



Colour mapping of the contacts:

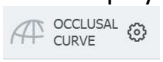


Cyan: the models are distant from 2.5 mm (+/-0.25 mm)
Very light blue: the models are distant from 2.0 mm (+/-0.25 mm)
Light blue: the models are distant from 1.5 mm (+/-0.25 mm)
Blue: the models are distant from 1.0 mm (+/-0.25 mm)
Dark blue: the models are distant from 0.5 mm (+/-0.25 mm)
Very dark blue: Models are in contact (+/-0.25 mm)

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

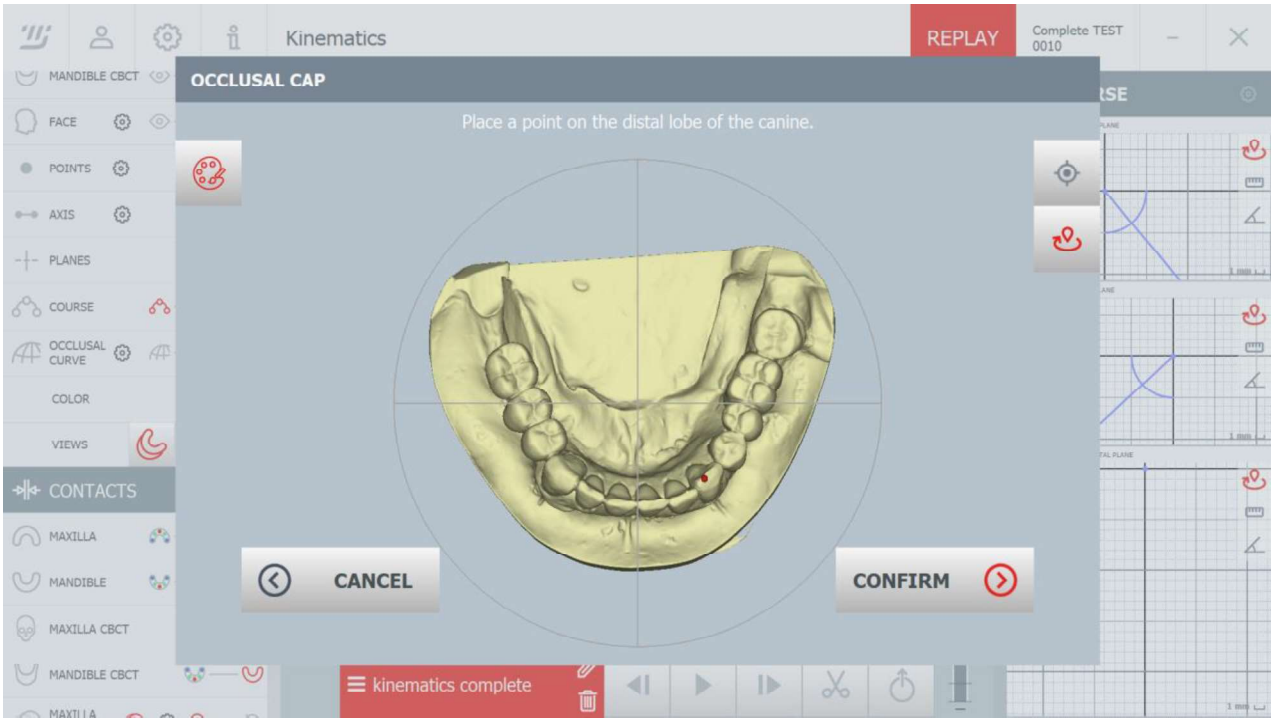
Acquisitions are sampled and there is a risk of missing the most significant contacts.

5.3.8 Calculation of the Occlusal Reference Sphere

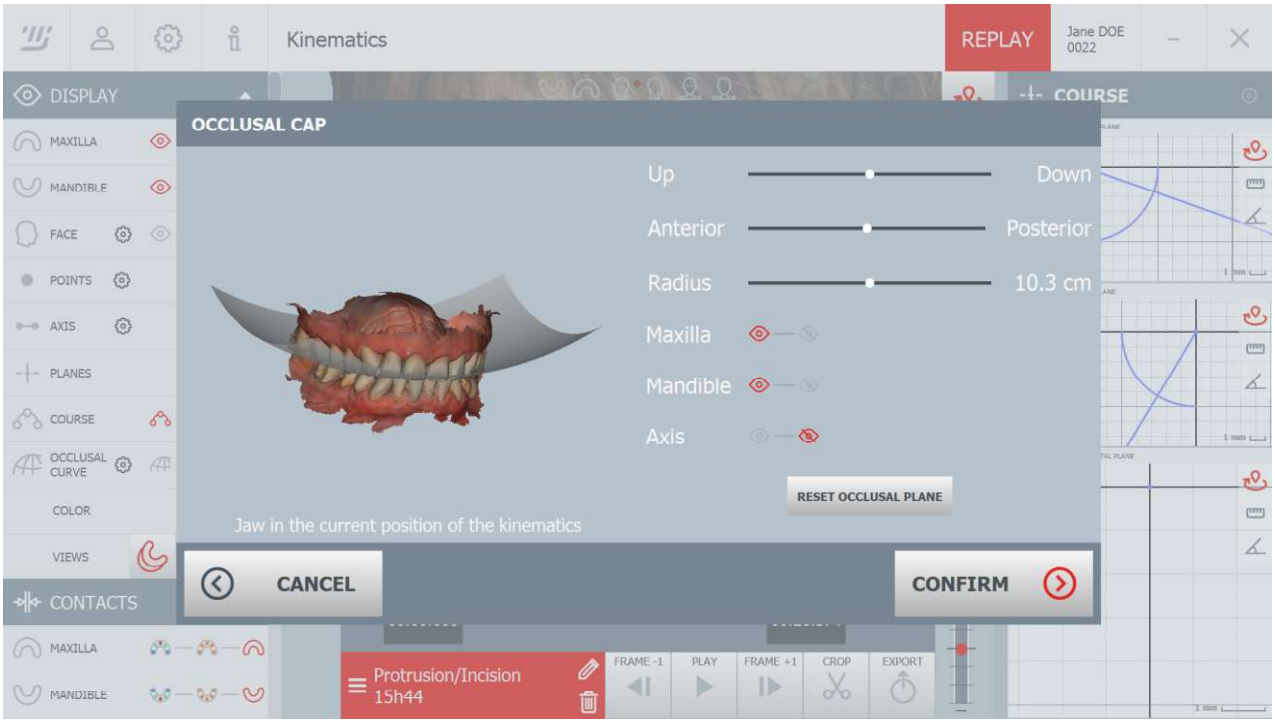
At the replay stage, the occlusal reference sphere can be calculated. For this, the user must press the button 

in the Displays panel. The distal lobe point is placed by the user on the model of the mandible, then the sphere is automatically calculated and positioned.

RM-166



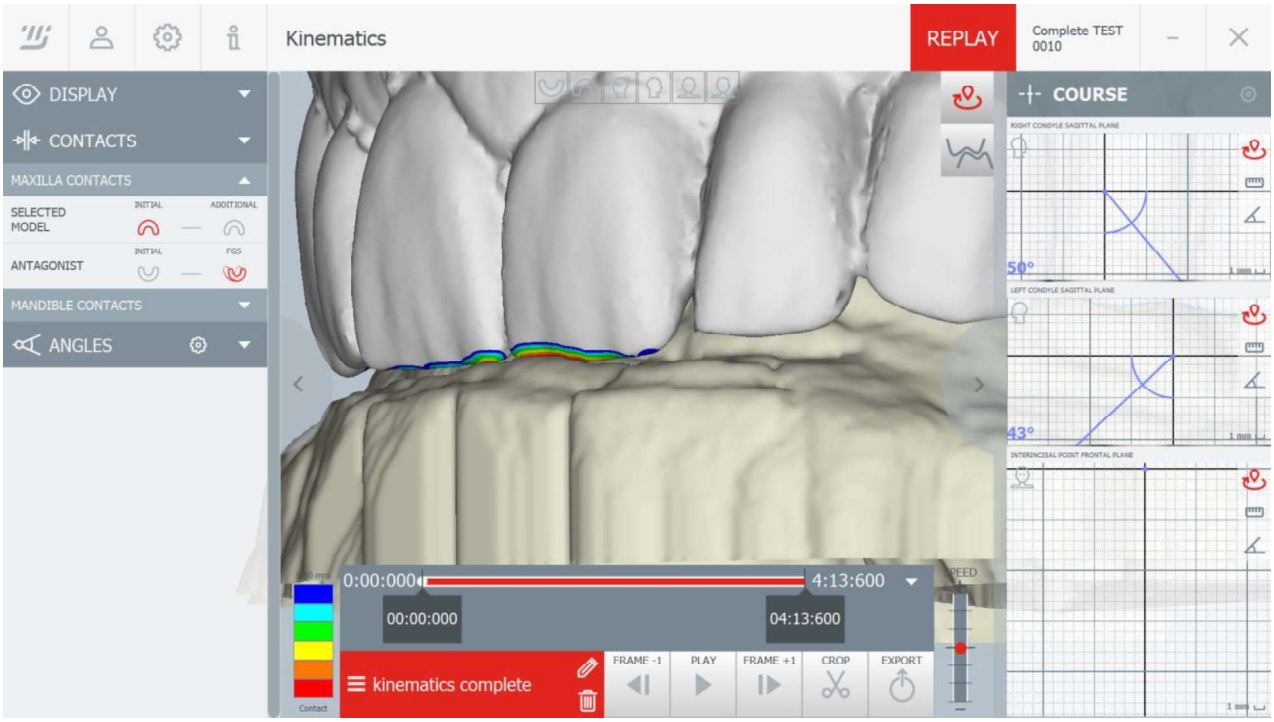
The user can then manually adjust the centre of the sphere and its radius or relaunch the computation (button “Reset occlusal plane”).



5.3.9 FGS (functionally generated surface) calculation

Whilst at the replay stage, models of the Maxillary or Mandibular FGS can be calculated. For this, the user must press one of the following buttons: 

The FGS model can then be used for calculating and displaying contacts.

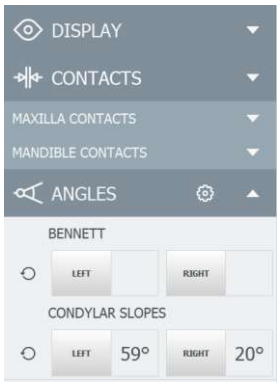


Note: The FGS model is calculated only on the selected subsequence of the current trajectory. If the subsequence or kinematics is changed, the user must manually restart the calculation of the FGS by pressing the button above. The calculation time depends on the duration of the subsequence.

The user can then manually adjust the position, orientation and size of the volume in which the FGS is computed, by clicking on the now red dental arch button that has been activated by computing the FGS.

5.3.10 Calculation of Bennett's Angle and Condylar Slope

The software automatically calculates the Bennett angle and the condylar slope of the current trajectory. Click on one of the following buttons to launch the corresponding calculation:



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

Note: The calculation is performed on the subsequence of the selected trajectory. The user must manually restart the calculations in the event of a change of trajectory or modification of the subsequence. The user is responsible for launching calculations on trajectories relevant for this type of calculation.

The little gear next to the ANGLES title is used to select the radius of the condylar slope, either 3 or 5 mm.

5.3.11 Data Export

From the Kinematic screen, the user can export their analysis data by clicking the button:

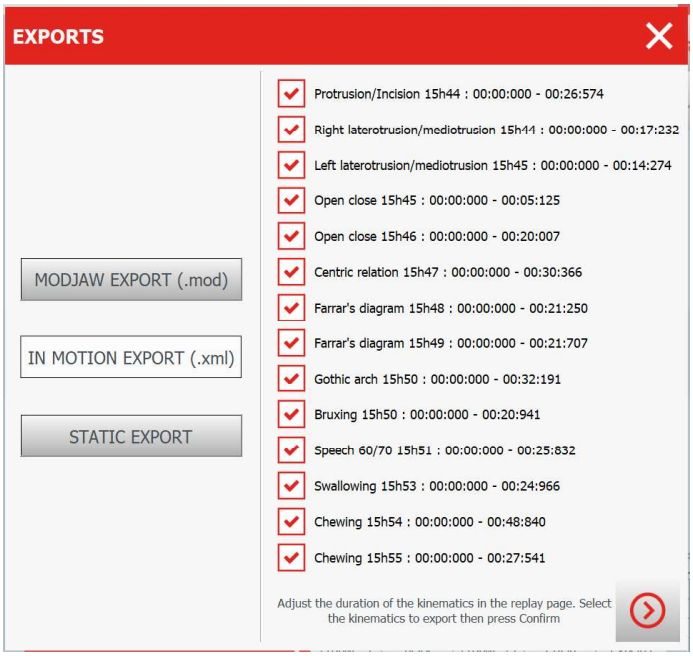
Then select which type of export to perform:

5.3.11.1 Share with another Modjaw® user

If the user wants to export a consultation in order to share it with another user, they click on “MODJAW® EXPORT (.mod)”.
They then select the kinematics to include and export the .mod file that can later be imported in the software.

5.3.11.2 Export of the kinematics of a consultation

If the user wants to export the kinematics of a consultation, they click on “IN MOTION EXPORT (.xml)”.
They then select which kinematics of the consultation are to be exported:



Only the sub-parts of the kinematics selected in the main screen are exported.
The exported data is anonymised and saved in STL format for the mandible and maxilla models and in XML format for the kinematics data.
A file in PDF format sums up the Bennett angles and condylar slopes computed in the consultation.

5.3.11.3 Export of a specific position

If the user wants to export a specific position, they click on “STATIC EXPORT”.
They then choose whether they export the data in the reproducible occlusal position or in the current position of the sequence, as displayed on the screen:

The exported data is anonymised and saved in STL format, in order to be exploitable with third party software. All exported models are expressed in a common reference frame.
A file in PDF format sums up the Bennett angles and condylar slopes computed in the consultation.

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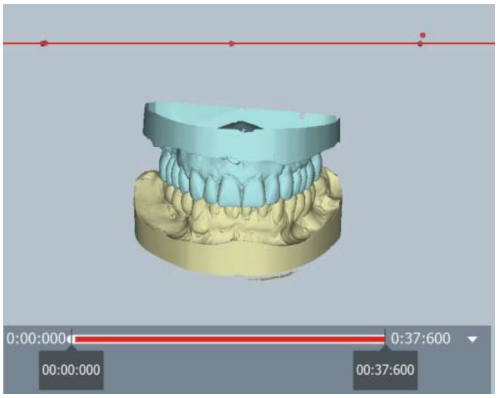
5.3.12 Define a new inter-maxilla relation

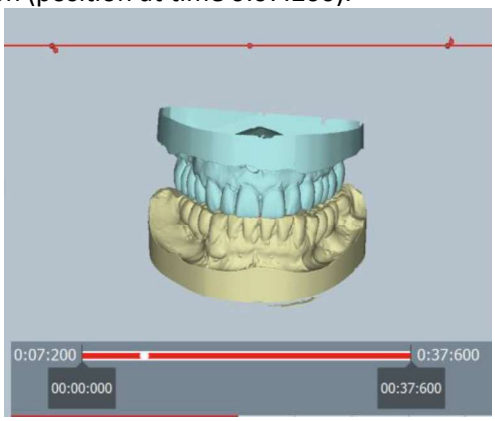
From the Kinematics screen, the user can define a new inter-maxilla relation (IMR). They can define as new intermaxillary relation either a position recorded with the system or a simulated position.

5.3.12.1 Select a recorded position

To select a recorded position as new intermaxillary relation, the user selects the position they wish to use as new inter-maxilla relation in the recorded sequence.
Initial position of occlusal reference (position at time 0:00:000):



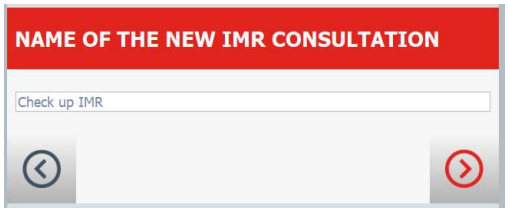
Desired new inter-maxilla relation (position at time 0:07:200):



Once on the desired position, the user clicks on the button:  in the options.

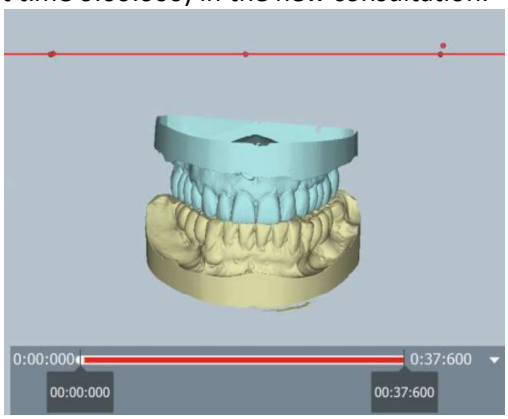
They then select “CURRENT POSITION”:

They then select a name for the new consultation about to be created:



Once confirmed, a new consultation is created for the patient. In this consultation, the kinematics have been transferred to the new inter-maxilla relation.

Position of occlusal reference (at time 0:00:000) in the new consultation:



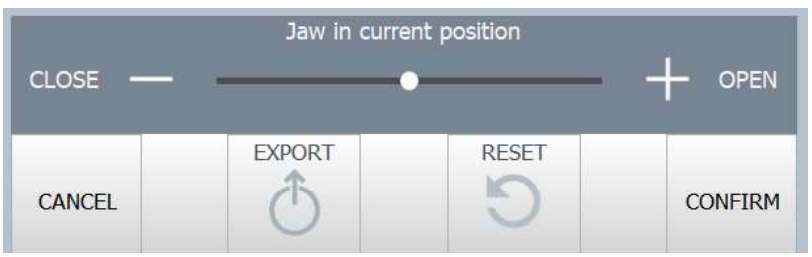
*5.3.12.2 **Simulate a position***

To simulate a position to use as new intermaxillary relation, the user can rotate the mandible about the hinge axis starting from a recorded position.

Once on the desired starting position, the user clicks on:  in the options.

They then select “SIMULATED POSITION”:

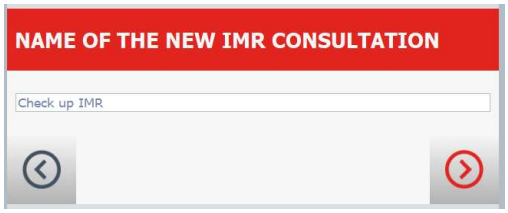
They can then apply a rotation to the mandible to get the desired new intermaxillary relation by using the following slider:



The user can:

- Go back to the replayed kinematics by clicking on “CANCEL”
- Export the current simulated position by clicking on “EXPORT”
- Go back to the starting position by clicking on “RESET”
- Validate the selected position by clicking on “CONFIRM”.

Once they have validated, the user selects a name for the new consultation about to be created:



Once confirmed, a new consultation is created for the patient. In this consultation, the kinematics have been transferred to the new inter-maxilla relation.

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

5.3.13 Add a face scan

From the Kinematics screen, the user can add a face scan to the current consultation by clicking on 

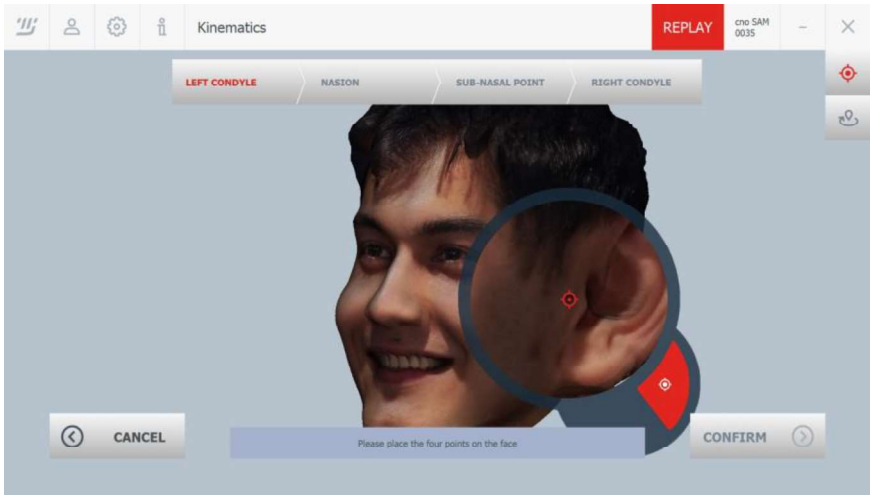
in the options.

A file browser appears, allowing the user to select a face model.

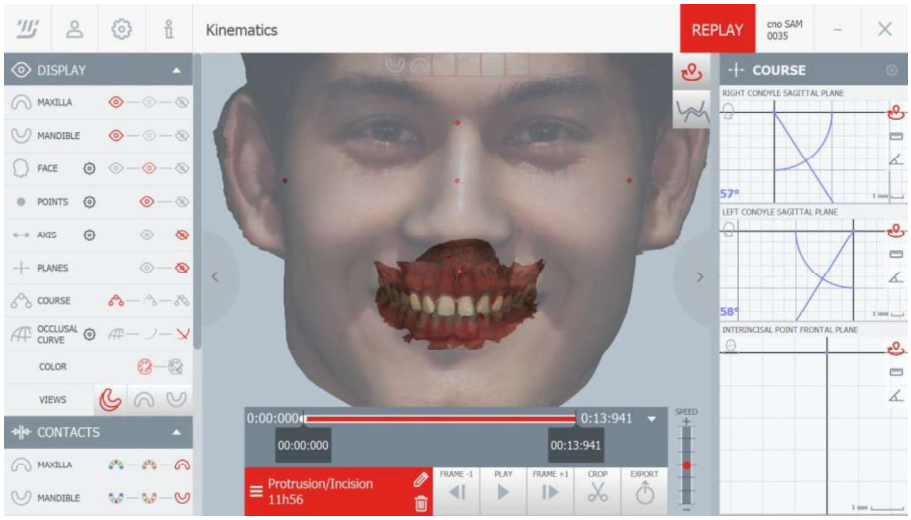
A pop-up to preview the model appears.

To import the model, click on the red arrow at the bottom right of the pop-up.

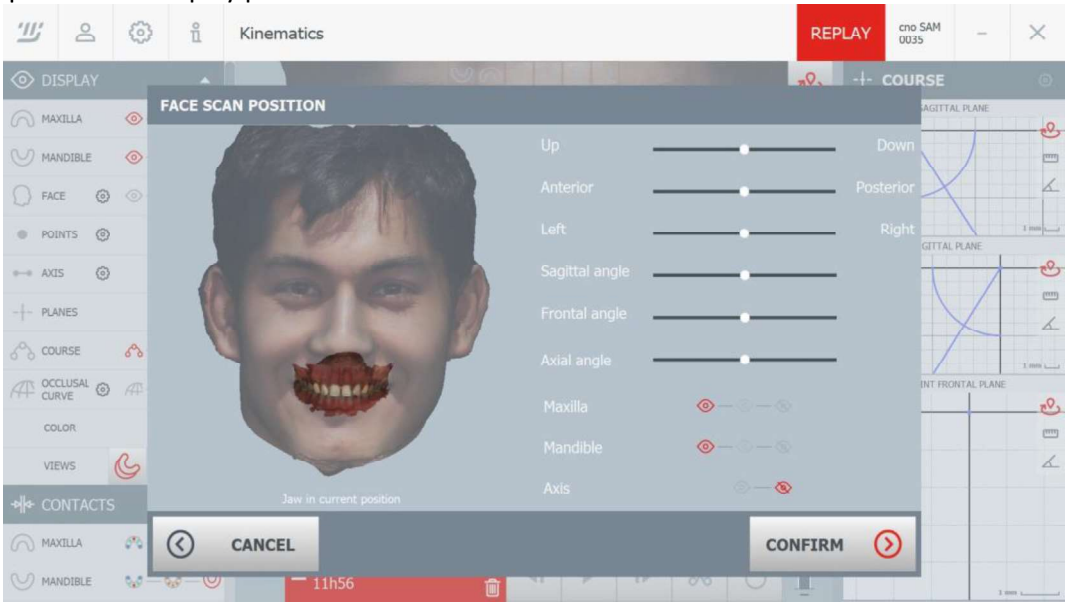
The user must then locate four anatomical points (left and right condyles, sub-nasal point and nasion) on the face and validate to match the face model on the dental arches.



The matched face model is then displayed in the 3D view and the option “FACE” appears in the display panel.



The user can manually adjust the position and orientation of the face model by clicking on the gear in the “FACE” option of the display panel.

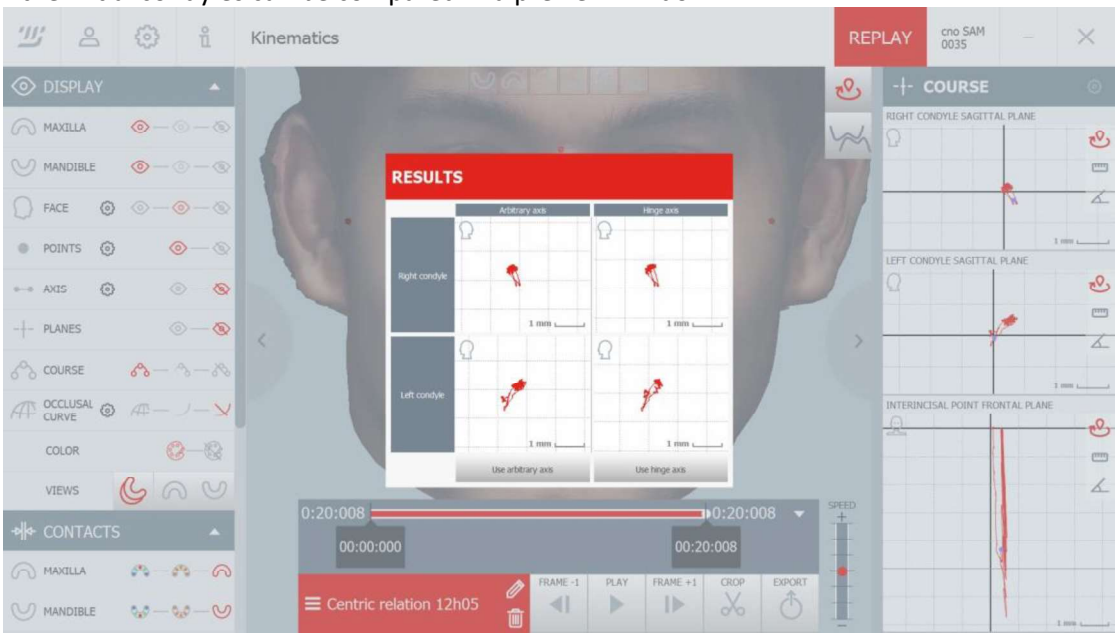


5.3.14 Automatically compute the hinge axis

It is possible to automatically compute the rotation axis of the jaw and position the left and right condyles (as well as the bicondylar axis) on this axis.
To do so, the user must first select part of the appropriate kinematics i.e. with a pure rotation motion (for example a centric relation).

Then, click on the gear of the “AXIS” option in the display panel. 

The axis of rotation is then 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.



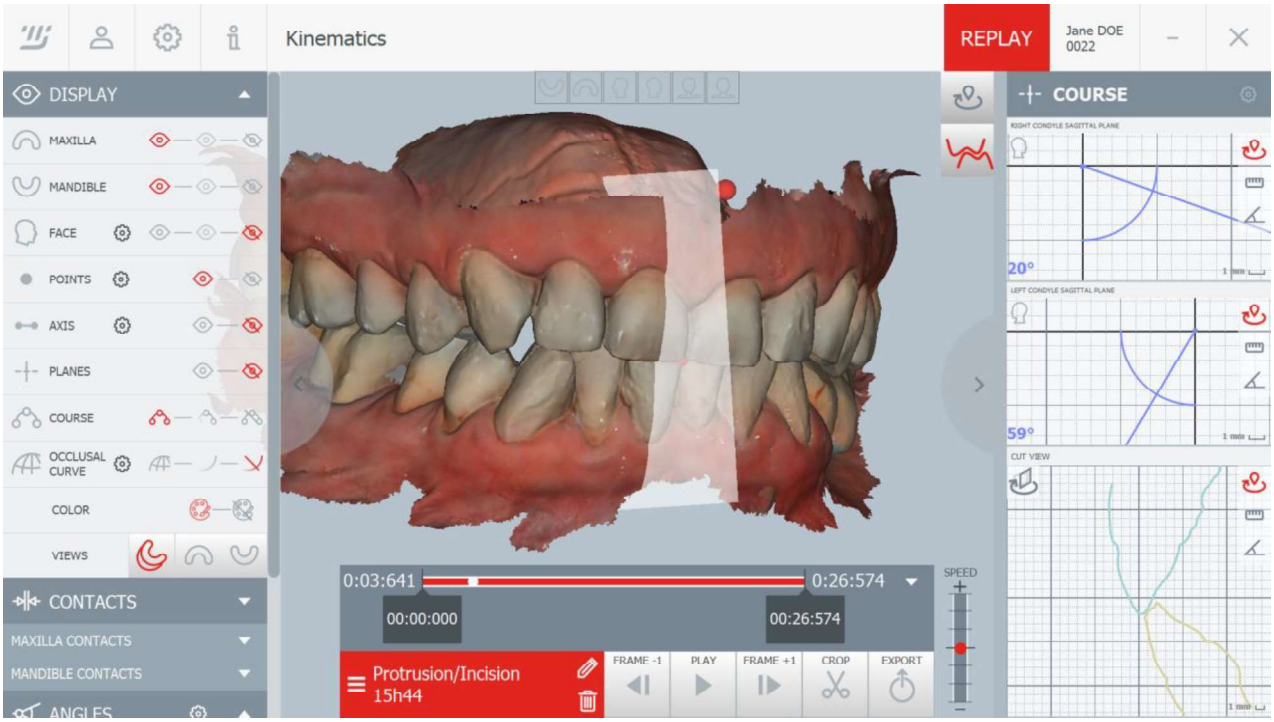
The user can then either keep the condyle positions recorded with TALLY by clicking “Use arbitrary axis” or use the condyles on the computed hinge axis by clicking “Use hinge axis”.

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.

5.3.15 Display a cut view of the models

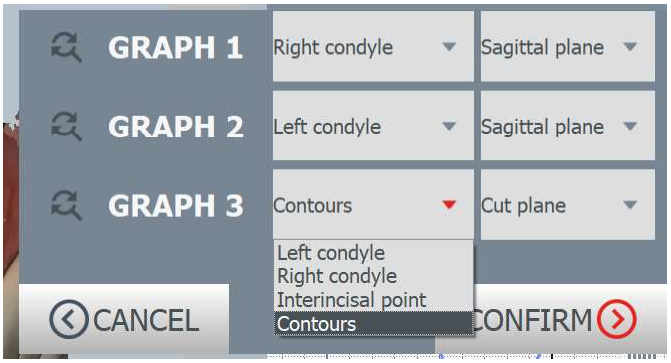
5.3.15.1 Display the cut view

A cut view of the currently displayed models can be viewed by cling on the button  .
A cut plane then appears in the 3D view and the intersecting contours between the visible models and the cut plane are displayed in the bottom graph. The user can move the cut plane by clicking on the point of interest of the models in the 3D view. The cut plane is automatically rotated, but its orientation can be adjusted by clicking on the button  in the cut view, which gives access to the buttons to adjust the plane orientation  .



To go back to manipulate the 3D view (zoom, pan, rotate), click on the button  .

To show or hide the cut view, click the gear button of the graph panels and select the desired options for the bottom graph.



5.3.15.2 Distances and angles on cut view

Distances and angles can be displayed on cut view, by clicking respectively on the  and  buttons of the graph. The button  is used to return in default mode: zoom and pan the graph.

5.3.16 Modify the position of the inter-incisal point

The position of the inter-incisal point can be modified once kinematics have been recorded. To do so, click on the gear in the “POINTS” option in the display panel:

The page to locate the inter-incisal point appears, and it is possible to move the point. Click on CONFIRM to confirm the modifications, or on CANCEL to cancel the modifications.

5.3.17 Screenshot the current configuration

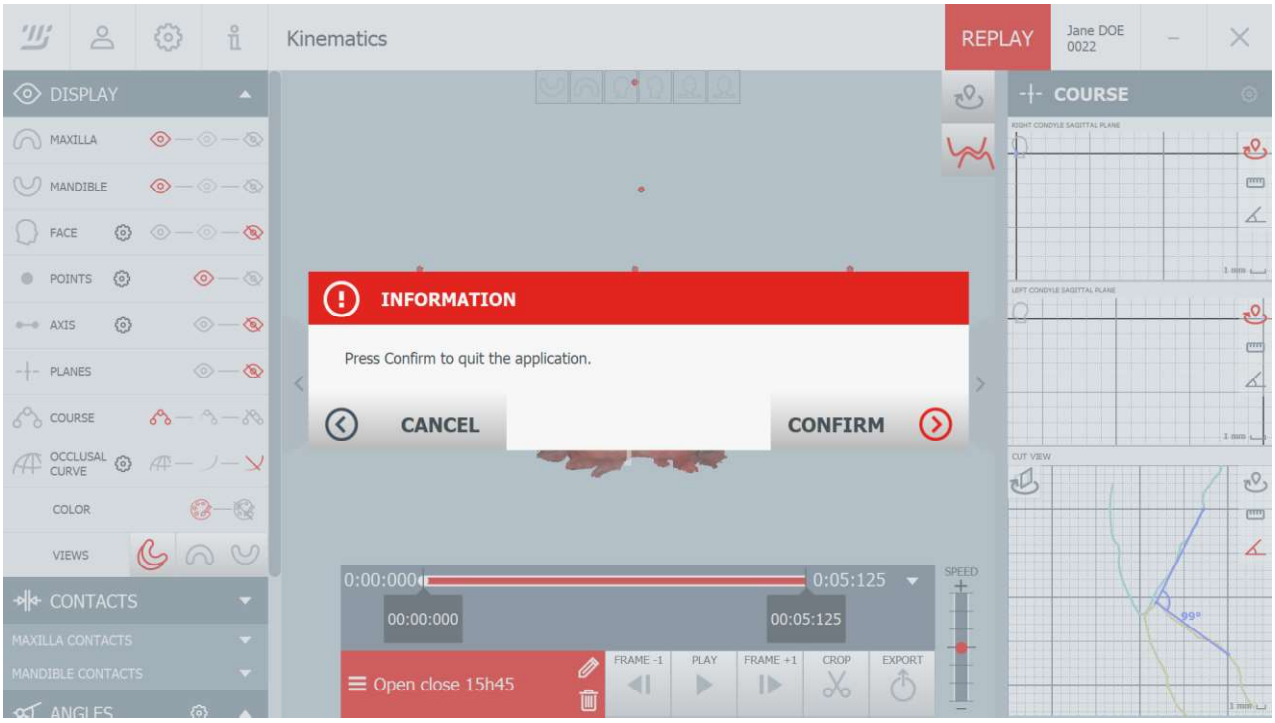
The user can do a screen grab of the 3D view and the graphs by clicking on the button 

in the options.

A file browser then appears, opened on the folder in which the screen grab has been saved as an image.

5.4 End of Acquisition

The software can be closed using : 
Data are automatically saved.



The TIARA headset is removed from the patient's head, the SMIL'IT marker is removed from the support still in the mouth. SMIL'IT marker support can then be removed from the patient's mouth. Be careful not to injure the patient by removing the support.
All instruments must be cleaned according to the protocol indicated in this user manual (see section 6.3) between 2 uses.

The PC and camera are turned off and the carriage is put in the storage position until the next use (see section 7 of this manual).

6 Hygiene and Cleanliness

6.1 Cleaning of the cart

RM-017

Once the cart has been cleaned, the articulated arm must be placed along the stem. The cart should be cleaned with Anios Dentaspet SH wipes.

Do not spray cleaner on the cart to clean it, liquid could come into contact with the protected components, damage them or create an electrical hazard.

6.2 Cleaning the camera

RM-017

The camera can be disinfected with hospital disinfectant detergent type Anios Dentaspet SH wipes. Optical parts should be cleaned only with lens cleaning solutions. Eyeglass wipes should not be used as they may scratch the lens. Other surfaces should be dried with a clean, dry cloth.

The appliance must be switched off and unplugged before cleaning. Disinfectant detergent must not be spilled directly onto the device or any of its components.

Spraying cleaning agent directly on the equipment is prohibited. It must be ensured that no fluid enters the camera. This can damage electrical components by causing short circuits and corroding the material.

Only non-corrosive and non-acidic detergents, whose interactions with materials are known, can be used.

Consequences of multiple clean up

The optics of the camera may be scratched, or the transparency of the window may be changed, resulting in poor image quality and therefore poor tracking precision.

6.3 Cleaning the instruments

RM-017

All reusable instruments (headset, mandibular marker) must be disinfected and cleaned before re-use in accordance with the described process.

RM-051/RM-107

<u>Instrument cleaning procedure:</u>

Remove the reflective sensors from the instruments and clean the instruments by soaking with any Anyos Dentaspet enzymatic detergent following the protocol recommended by the manufacturer.

As an indication, the washing steps are as follows (refer to the manufacturer's instructions before starting cleaning):

1. Dilute the detergent to 1% (for example, 20mL for 2L of water)
2. Immerse the instruments completely in the solution, cover and soak for a recommended contact time of 15 minutes to achieve microbiological efficacy.

3. Remove the instruments from the solution and check for visible debris. If necessary, brush them.
4. Rinse under running water or by immersion.
5. Dry the instruments

Particular case of the stylus: After each use of the stylus, since the latter comes into contact with the patient's oral mucosa, it must be cleaned according to the procedure indicated above and then sterilized before being used on a new patient.

The stylus is not delivered sterile. The user must sterilize the stylus before first use and before each new use by following the protocol described in this chapter. Sterilization must take place immediately after cleaning and must be carried out in accordance with good practice.

RM-092 /RM-106

The recommended sterilization cycle is 134 ° C for 18 min.
The stylus is designed to withstand at least 25 cycles of autoclaving according to the protocol outlined above. After this number of cycles, the precision of the stylus and its robustness are not guaranteed by Modjaw®.

Single use devices:

RM-043

Supports for mandibular markers and reflective markers are single use devices and are discarded at the end of the exam.

The user must discard the mandibular markers support as well as the reflective markers (disposable instrument) after each use and never reuse it for another patient.

Transportation and storage :

In order not to compromise the performance of the device, it is essential that the various components of the device are protected from falls, shocks, vibrations, inappropriate environmental conditions and possible contamination.

The storage and transport conditions to respect in order not to risk damaging the device are as follows:
- Temperature: -25 ° C to 50 ° C
- Atmospheric pressure: 80kPa to 106kPa
- Humidity level: 30% to 75%

As indicated on the packaging and protections, it is necessary to take the following precautions to not compromise the performance of the device:
- The device must not be sheltered from the sun's rays,
- The device must be protected from hot or cold temperatures,
- The device must be protected from fluids.

Between two acquisitions, the device must be in storage position, the articulated arm of the carriage folded in storage mode along the stem.

7 Device malfunctions

RM-176

In case of malfunction:

- stop using the device immediately,
- Try to identify or eliminate the cause of the malfunction by referring to this document
- If it is not possible to identify or eliminate the cause with this document, turn off the power and call Modjaw® customer service (see the manufacturer section at the beginning of the document for detailled contact information)

In the event that the user is obliged to contact Modjaw® customer service, please provide the following information to the customer service:

- Serial number of the device (it is on a cart),
- The software version of the device,
- The operating system version of the Panel PC,
- Screenshot of the bug or problem,
- Log exports, available with button “Export to support” in the “i” button of the Modjaw® banner,
- Export the consultation on which the problem occurred,
- A description as accurate as possible of the process that led to the error message

In the event of malfunctions of the device and / or defects suspected and / or noted, several actions must be taken:

- The user must remove the device from use,
- The device must be labelled as "Out of Service",
- The device must be secure and isolated to prevent its use.

The user may only use the device again after the repair or replacement of the defective parts.

The user must warn Modjaw® of malfunctions so that the latter can carry out an inspection.

Immediate maintenance actions should be taken in the following cases:

- Penetration of liquids into the device,
- Damaged covers and cases,
- Damaged power cables,
- Malfunction of the cart wheels,
- Erased or detached labels,
- Other defect(s) suspected or verified.

In case of malfunction or difficulty using the device, contact the Modjaw® team at the coordinates listed at the beginning of this document.

8 Maintenance and monitoring

Contact Maintenance and monitoring:

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

9 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Special precautions should be taken with electromedical devices regarding electromagnetic compatibility, their installation and commissioning must be carried out in accordance with the electromagnetic compatibility information provided in this document.
This statement currently applies to the entire TECH IN MOTION™ system
This device complies with the requirements of EN 60601-1-2 which describes the conditions of electromagnetic compatibility (EMC) for medical devices. MODJAW® TECH IN MOTION™ requires precautions against EMC. MODJAW® TECH IN MOTION™ must be installed and commissioned in accordance with the recommendations of this manual.
Conformity of the EMC standards does not mean that a device is entirely immune from interferences. MODJAW® TECH IN MOTION™ can be affected by portable or mobile RF communication equipment. MODJAW® TECH IN MOTION™ should not be used next to other devices or stacked with them. If it is not possible to do otherwise, MODJAW® TECH IN MOTION™ should be monitored to check the normal operating conditions in the configuration in which it will be used.

Interference Hazards: The use of accessories, sensors and cables other than those specified, except sensors and cables sold by the manufacturer as spare or replacement parts could induce an increase in emission levels or a decrease in MODJAW® TECH IN MOTION™ immunity levels.

10 Recycling

The cart, the camera and the PC panel must be recycled according to the WEEE directive. These components should not be thrown away with household waste but via suitable sorting channels.
Single-use items are discarded as healthcare waste.

11 Other versions

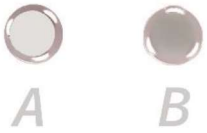
The instructions for use are available in different languages on the MODJAW website: https://modjaw.com/fr/usermanuals
Users can get a paper version of the instructions for use at no extra cost and in less than 7 days following receipt of their request.

RM-200/ RM-205/RM-207

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

12 Annex 1 : patient kit assembly

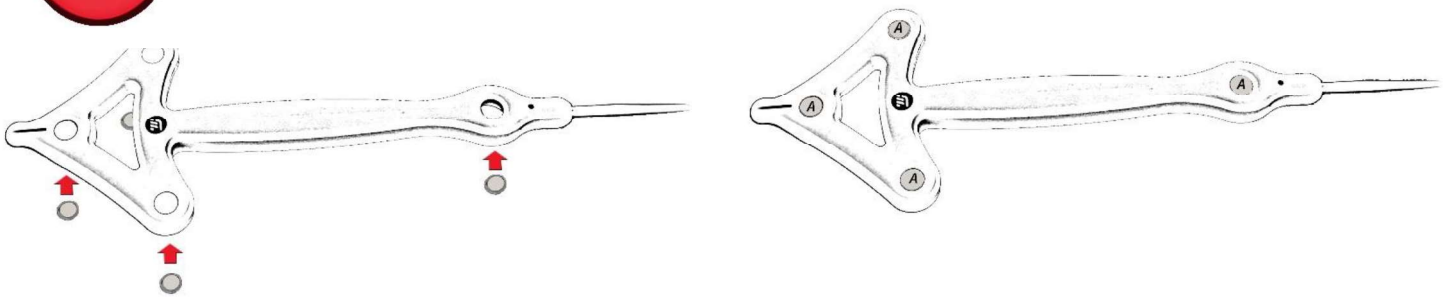
1



Navex reflective side A, non-reflective side B

2

Insert the Navex reflective side (Face A) into the stylus...

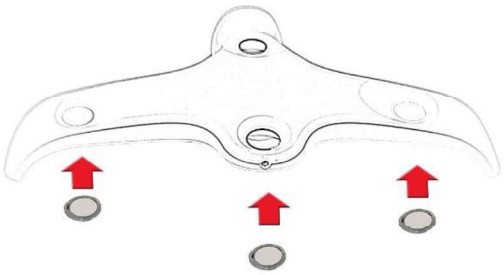


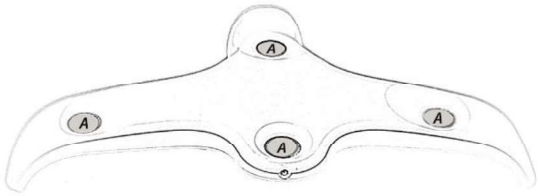
3

In the SMIL'IT...

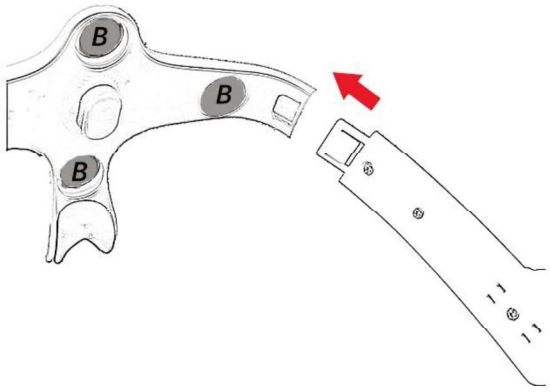
4

And on the TIARA Helmet

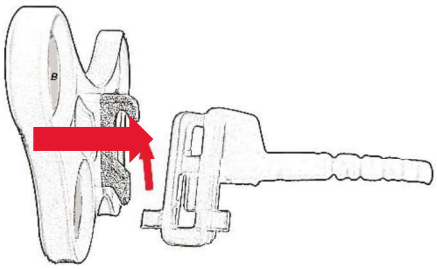


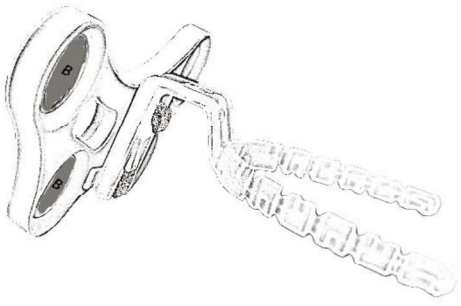


5 *Clip the back of the headband*



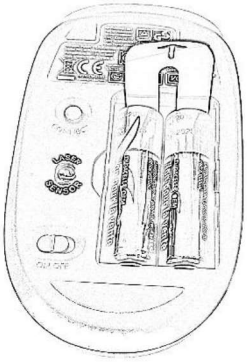
6 *Insert the fork on the SMIL'IT*



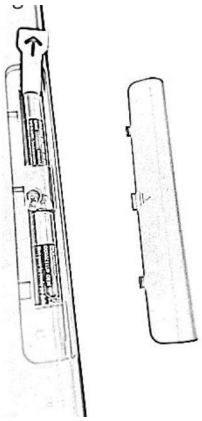


13 Annex 2: setting the mouse / keyboard

1 *Remove the mouse tab before use*



2 *Remove the keyboard tab before use*



3 *Insert the dongle on the back of the computer*