3DIEMME
BIOIMAGING TECHNOLOGIES
RealGUIDE®
UNIVERSAL OPEN SYSTEM
v. 5.0
USER GUIDE
CE
0051
www.3diemme.it

General Information

Manufacturer: 3DIEMME Srl

Address: Via Risorgimento 9, 22063 Cantù (CO), ITALY

P +39 031 7073353 - F +39 031 710284

Product Name: RealGUIDE

Software release: 5.0

General Product Description

RealGUIDE Graphic Station is a fully-featured 3D imaging application in medicine. Its unique open architecture and modular framework make customization and integration options trivial. On demand, 3DIEMME will create a fully customized 3D medical imaging solution.

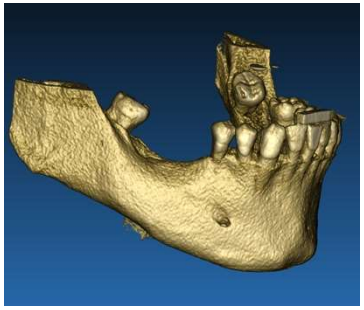
RealGUIDE Graphic Station is meant to be a multiplatform application, running on PC, MAC and mobile devices (not provided by 3DIEMME).

Intended Use

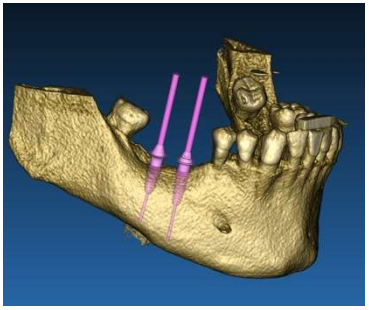
The device is a software to be used in the dental field by trained professionals to support diagnosis, to plan virtual implants and surgeries on 2D/3D reconstructions, to design surgical guides and prosthetic modelling, and manage the endodontic, orthodontic and orthognathic treatments connected to the oral and maxilla-facial rehabilitations.

The RealGUIDE software is intended for the following uses:

1. *Support to the diagnosis for trained professionals*. The input DICOM files acquired by a CT/MRI scanner are not modified in any way but they are showed to the doctor through the classical imaging and volume rendering techniques. It is a stand-alone product. No information of the patient is modified, all the parameters used for the image processing are read from the DICOM file itself. Neither automatic diagnosis is made, nor automatic disease detection is performed. This software is not connected to any medical instrumentation and it doesn't control any medical or energy supplying device. The user imports DICOM data coming from any CT/CBCT/MR imaging device and the software enables him to view the Patient exam in different multi-planar 2D images and easily reconstruct the 3D volume for an immediate visualization of bone structures and surrounding tissues.



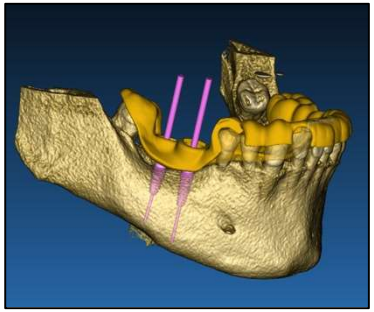
3D reconstruction from DICOM example

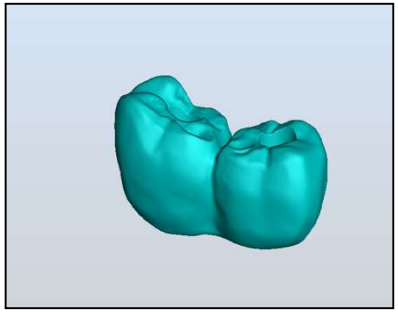


Virtual implants plan

2. *Virtual surgery planning*. Doctors can plan virtual implants and surgeries on 2D/3D reconstructions and export the projects in open or proprietary format for further processing. The user can choose different implant models (for example dental implants models) from a library provided by the Manufacturers and simulate the positioning in the Patient reconstructed volume (this operation is called “virtual plan”

3. *Surgical guides and prosthetic modelling*. The virtual plan is used to design a surgical guide that is used by the doctor to drive the surgery drills according to the planned implants direction and depth. This surgical guide can be manufactured by any 3D printer working from STL files. The user can also design the patient prosthesis (typically a denture) with the surface and volume free-form tools implemented in the software. The result is exported in STL format for 3D printing or CAD/CAM technologies.





Surgical guide designed to correctly drive the surgical drills and modelled teeth prosthesis

Software Description

The RealGUIDE Graphic Station supports all the common 3D medical imaging functionalities used by professional doctors to support their diagnosis. It includes various Volume and IsoSurface rendering, segmentation tools, masking and sculpting, MPR, 2D and 3D measurement and analysis tools. Since 2D imaging is still an important feature, it is possible to switch with a single click to a 2D view, use an even more sophisticated MPR view or switch back to the 3D view.

RealGUIDE software is characterized by its intuitive user interface, 2D, MPR and 3D imaging, prime image quality and extensive visualization options, fast image rendering, measurement and analysis tools, and easy integrated reporting. The software is integrating all the surface and volume modelling tools necessary to integrate the diagnostic and virtual planning functions to any CAD/CAM and rapid prototyping system for further processing and manufacturing.

The output format of the software is a STL file, mainly focused on dental, maxillofacial and orthognatic surgery. A list of the possible devices that can be modelled with the software is reported below:

- Surgical guides for dental implants and surgical screws planning
- Bone cutting and bone reduction guides for maxillofacial surgery
- Bone graft models for mandible/maxilla regenerative procedures
- Dental and maxillofacial prosthesis

Hardware requirements

PC INSTALLATION:

Processor: Intel I5 or I7
RAM: minimum 4 GB, for big datasets 8 GB are suggested
Hard disk: 300 ‑ 500 GB (for Patients storage)
Graphics card: Nvidia Geforce line (€150-200 price range). For higher performances Nvidia GTX o QUADRO line
Screen resolution: 1920 x 1080 for optimal visualization
OS: Windows 7 (64 bit), Windows 8 (64 bit), Windows 10

For professional use we suggest the Dell XPS 15 (9560) notebook lineups.

MAC INSTALLATION

Macbook PRO 15"
iMac
OS: OS X (starting from Yosemite, to activate hardware rendering)

IOS INSTALLATION

iPad PRO
iPhone 7 Plus

Patient Population

The device is intended for the following patient population

SEX	Male Female
AGE	Newborns (<6 months) Babies (>6 months to 2 years) Children (>2 to 18 years) Adults (19-64 years) Elderly (>64 years)

User Profile

The device is for professional use and, in particular, must be used by certified and trained dentists or oral surgeons.

The professional must have basic skills about:

- X-ray emissions;
- Biological and physical dangers due to excessive exposure to x-rays;
- Method to reduce risks of x-ray excessive exposure;

The operator must have basic competences to use personal computers (PC) and the relevant programs.

The operator is trained by the manufacturer before use.

Contra-indications

None known.

Warnings

The RealGUIDE software is capable of displaying oral/maxillofacial radiology. The user is then able to navigate through different views, segmented analysis and 3D perspective. In addition, the user is able to simulate various objects within the radiograph for the purpose of treatment planning.

Once treatment planning and visual simulation is complete, users can generate reports and simulated images for the purpose of evaluation and diagnosis, as well as perform a surgical guide and prosthesis modelling, to be exported in STL format for the manufacturing with any RP or CAD/CAM machine.

This product is certified as CE "class c" medical device and therefore could be used for diagnostic purposes with the proper hardware and resolution settings. Due to different local regulations, use of uncontrolled hardware, and uncontrolled source image quality, 3DIEMME Srl does not guarantees the diagnostic quality of the images.

RealGUIDE must be used by trained professionals only who accept the full responsibility of their own diagnostic judgment. The software does not perform any automatic diagnosis nor can substitute the interpretation of a specialized doctor. Under no circumstances 3DIEMME is responsible for errors in the patient treatment nor in any damage caused by the images wrong interpretation.

RealGUIDE cannot within itself create, effect, or control the progression, sequence, or procedure of any surgical operations, that in any case must be performed by a certified and trained dentist or oral surgeon.

Further notes:

- STL files can be exported to various 3rd party software not controlled or as an accessory to RealGUIDE software
- Original scan data files are never modified or edited but always superimposed to preserve accuracy of radiology data.
- RealGUIDE algorithms have been tested on CT/CBCT DICOM datasets only, thus the filters implemented are not optimized for MRI, although the DICOM images coming from MR datasets could be read by the software.

Surgical guides for dental implant placement are considered by many regulatory systems to be a medical device, which have regulatory requirements such as registration and listing, validation of manufacturing equipment/processes and quality system regulation. Please ensure your manufacturing process is compliant with the local regulations.

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

The software, duly maintained in accordance to the instructions of the manufacturer, has an expected life of 5 years.

Cybersecurity

The RealGUIDE software cybersecurity controls are listed and numbered below. The numeric references are later used for traceability matrix:

- *Account Monitoring and Control*: this keeps attackers from impersonating legitimate users or use old/disabled accounts for cyber-attacks.
    - Review all system accounts and disable any that are not associated with a business process and owner. Immediately revoke system access for terminated employees or contractors. Disable dormant accounts and encrypt and isolate any files associated with such accounts.
    - Use robust passwords. All non-administrator accounts are required to have a minimum length of 8 characters, contain letters, numbers, and special characters, be changed at least annually, and not be allowed to use previous passwords.
    - Login credentials are stored using OS specific security API
        a) Windows Security API: https://docs.microsoft.com/en-us/windows/desktop/api/_security/
        b) MacOS Security API: https://developer.apple.com/documentation/security/keychain_services
        c) iOS built in encryption
    - Periodically review all system accounts and disable any account that cannot be associated with a business process and owner.
    - Regularly review for locked-out accounts, disabled accounts, accounts with passwords that exceed the maximum password age, and accounts with passwords that never expire.

- Establish and follow a process for revoking system access by disabling accounts immediately upon termination of an employee or contractor.
- Automatically lock access or log off users after 15 minutes of inactivity.
- Monitor attempts to access deactivated accounts through audit logging.

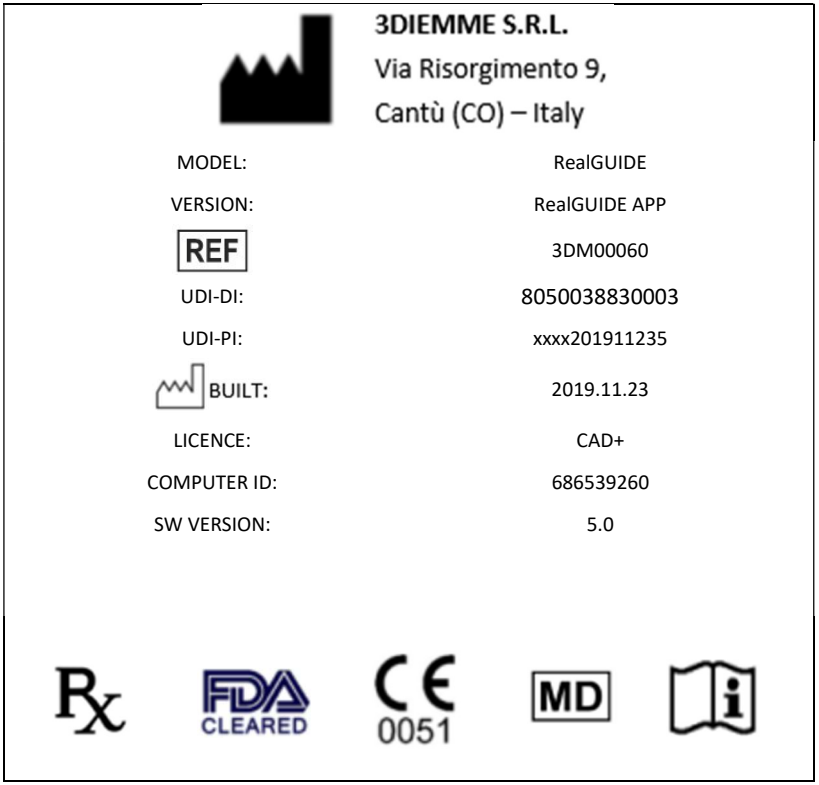
- *Data Recovery Capability*: assured Data Back-Up on the Cloud server as well as on the local computer: data backup is imperative for any software.
  - Data is automatically backed up on the cloud server using Amazon backup services and storage.
  - Local Database is backed up using software's own backup system and schedule. This backup system is independent from the computer backup system, that is still required to be in place.
- *Data Loss Prevention:*
  - Data is always encrypted at rest using industry standard strong encryption technologies:
    a) Microsoft BitLocker on Windows: https://docs.microsoft.com/en-us/windows/security/information-protection/bitlocker/bitlocker-overview
    b) Apple FileVault on MAC computers: https://support.apple.com/en-us/HT204837
    c) Apple mobile devices uses encryption built into the hardware and firmware of its iPads and iPhones.
  - Software uses Amazon's secure, authenticated, and encrypted mechanisms to move data to and from the Amazon AWS cloud server: https://aws.amazon.com/security/
  - Patient data does not contain crucial patient information (for example social security number or credit card data)
- *Secure protocol for receiving patient dataset sources*: patient data can be received only from valid and secure sources

  - Only original and validated patient CD-s can be imported into the database. Homemade patient CDs should not be accepted. The same rule applies to USB sticks.
  - Patient data can be downloaded only from trusted sources/hospital systems.
  - All received patient data needs to go through antivirus scan before importing.
  - RealGUIDE software reads and imports only the valid and dicom compliant patient data. RealGUIDE software does not run any application that might be contained in the patient data.
- *Maintenance and Analysis of complete security logs on the server:* server is logging every user access and action, so logs are also used for fraud detection. System administrators run reports weekly that identify, review and document anomalies in the logs.
- *Continuous Vulnerability Assessment and Remediation*: 3DIEMME proactively identifies and repairs software vulnerabilities reported by security researchers or vendors. 3DIEMME developers are especially in contact with Amazon whose server and communication architecture is used by the RealGUIDE software.
- *Incident Response Capability*:
  - There are written incident response procedures that include a definition of personnel roles for handling incidents.
  - Job titles and duties are assigned for handling computer and network incidents to specific individuals.
  - Management personnel is defined who will support the incident handling process by acting in key decision-making roles.

Labeling

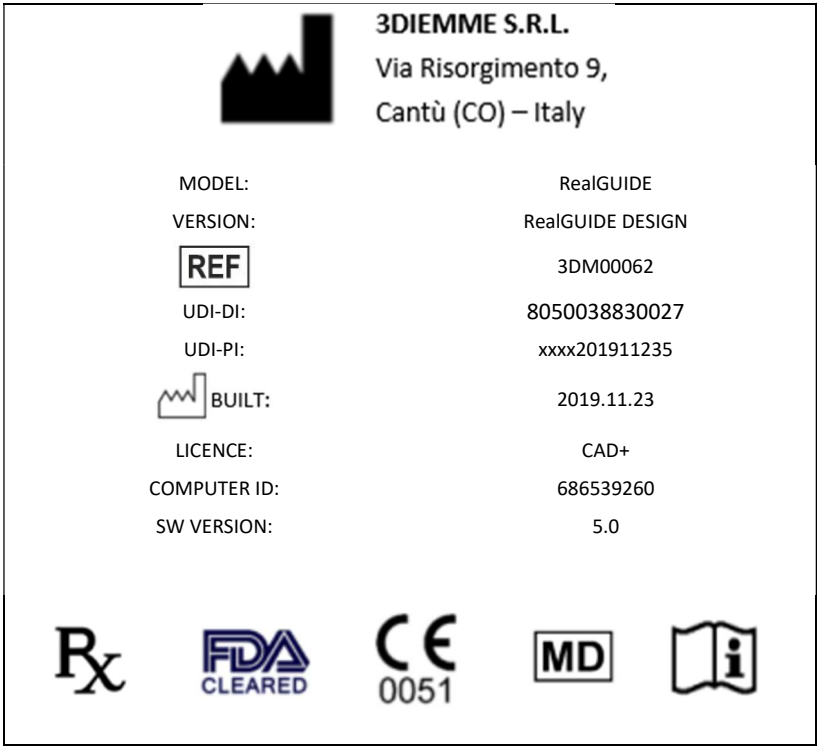
Below are the INFO panels visible within the software, SETTINGS button.

RealGUIDE APP

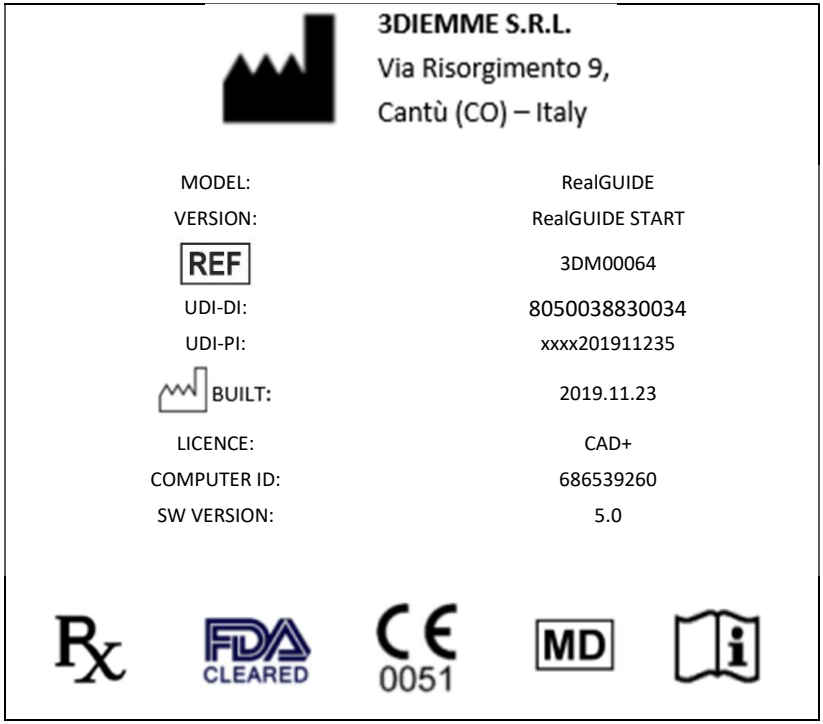


RealGUIDE PRO:

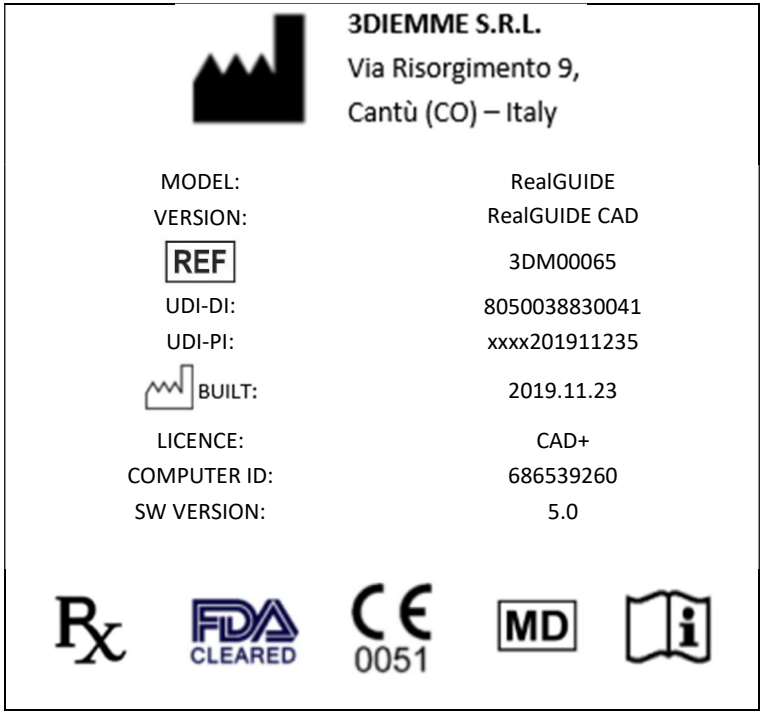
RealGUIDE DESIGN:



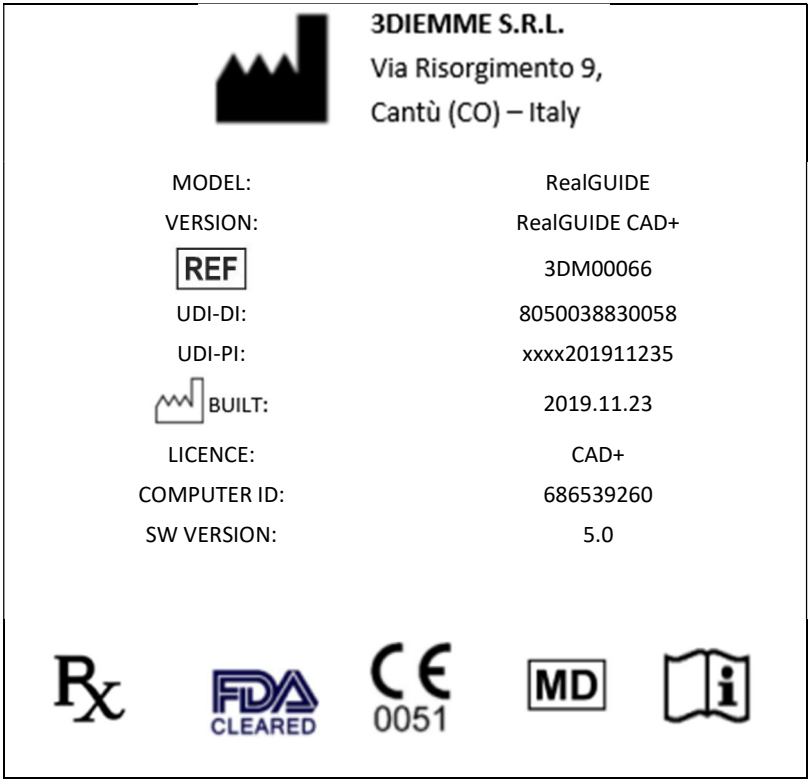
RealGUIDE START:



RealGUIDE CAD:



RealGUIDE CAD+:



Symbol glossary definition

Symbol	Description
	Manufacturer
	Catalogue number
	Date of manufacture
	Consult instructions for use
	Medical device
	Compliant to MDR (UE) 2017/745
	Caution: Federal law restricts this device to sale by or on the order of a dentist

1. GETTING STARTED

1.1 Home page
1.2 Login
1.3 New Patient Folder
Import STL files
Import 3D Exam/Project
Import new objects
1.4 Uploading on CLOUD
1.5 CLOUD Patient Storage
1.6 Sharing
1.7 Project download
1.8 Modified project download

2. IMPLANT PLANNING

Basic Commands

2.1 3D View Opening

2.2 Main layout

2.3 VOI Settings

Trimming

Sculpting

2.4 3D Settings

2.5 Data import

2.6 Matching

2.7 CPR Settings

2.8 Nerve Drawing

2.9 Teeth Setup

2.10 Implant Positioning

Implant Library

Implant setup position

Prosthetic abutments choice

Axis rotation

Prosthetic axes parallelism

3. SURGICAL GUIDE DESIGN

3.1 Start Operation

3.2 Undercut blockout setup

Insertion direction – control arrow

Insertion direction – view direction

Waxing Surface Generation

3.3 Surgical Guide Design

Tracing and construction parameters

Modeling tools

Inspection and anesthetic reinforcing slots

Finalization

4. SEGMENTATION

4.1 Tooth segmentation

4.2 Bone segmentation

5. ADVANCED TOOLS
5.1 Thin slab
5.2 Endoscopy
5.3 Airways
5.4 TMJ

6. TOP TOOLBAR COMMON FUNCTIONS
6.1 Top toolbar functions
6.2 Settings
6.3 HELP

1. GETTING STARTED

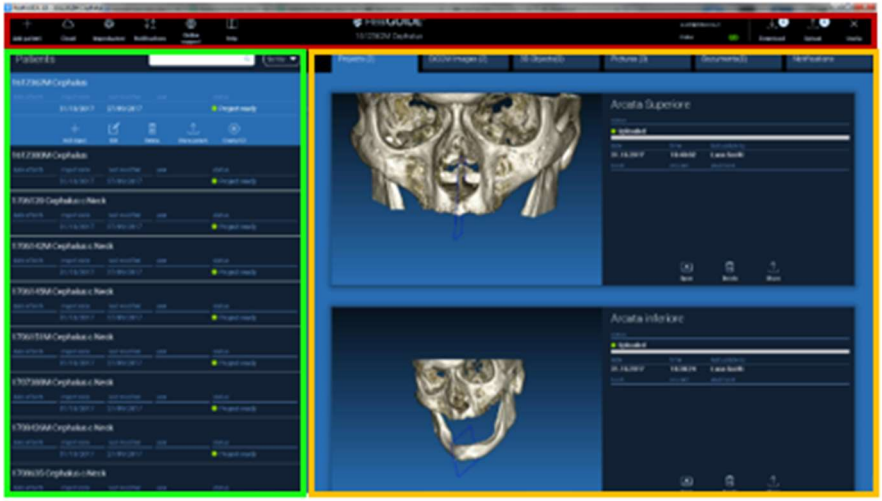
1.1. Home page

TOOLBAR

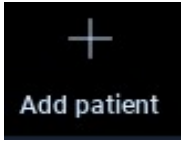
PATIENT DATABASE

PATIENT TOOLBAR:

- Project
- DICOM Dataset
- STL files/3D Object
- Pictures
- Documents
- Notification



Click on the icon **ADD PATIENT** on the **TOOLBAR**

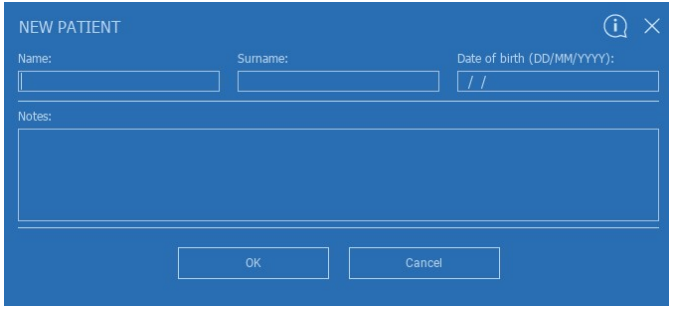


Complete the form with all the patient data: Name, Surname, Date of birth and optional notes.

Then click on **OK**

Delete the entries by clicking on **CANCEL**

IF THE DICOM DATASET IS ALREADY AVAILABLE, YOU CAN CLICK ON **OK** WITHOUT COMPILING ALL THE FIELDS. THE PATIENT DATA WILL BE AUTOMATICALLY READ FROM DICOM FILES.



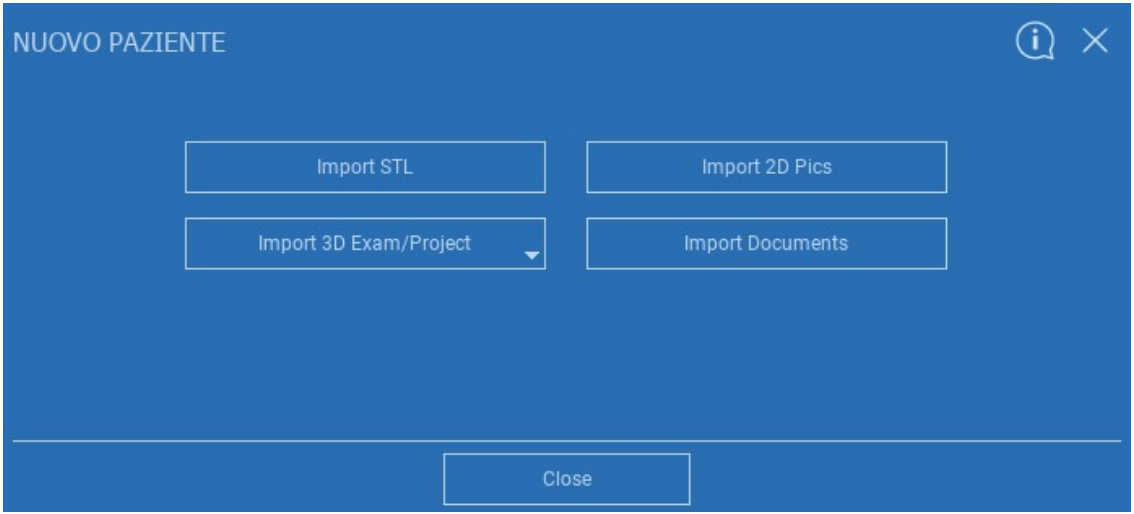
1. GETTING STARTED

1.3 New Patient Folder

Depending on the object you want to import, click on one of the following buttons:

- **IMPORT STL** (Anatomy, Wax-up, E*vobite and other STL files)*
- **IMPORT 2D PICS** (*Patient Pics or panorex JPG/PNG/BMP format)*
- **IMPORT 3D EXAM/PROJECT** (*DICOM images or RealGUIDE 5.0 projects)*
- **IMPORT DOCUMENTS** (*Pdf prescriptions, notes, reports, etc*)

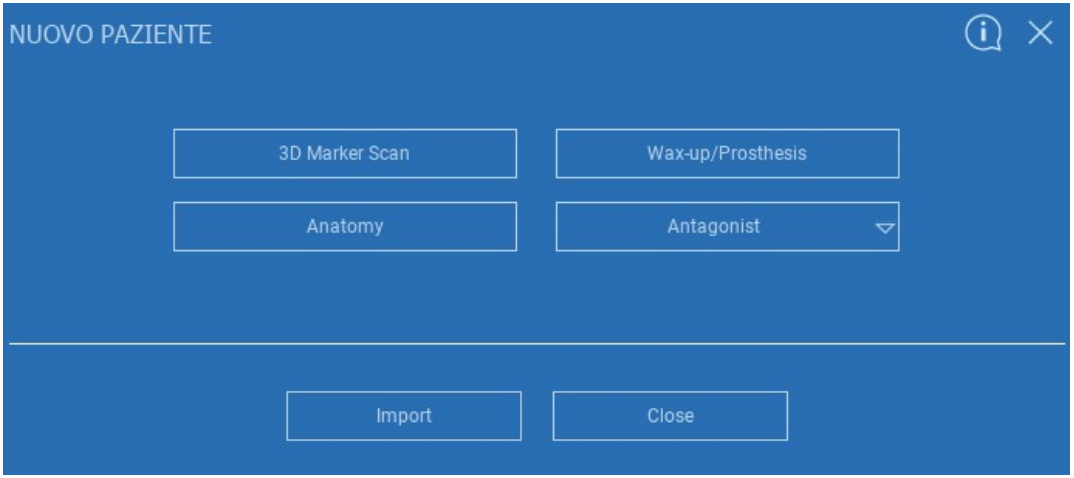
Click on **CLOSE** to go back to the home page.



1.3 New Patient Folder

1.3.1 IMPORT STL FILES

Select the type of STL file you want to import; then click on **IMPORT.**
The Windows Explorer/Finder will automatically open. Search and select the file you need; then click on Import.



1.3 New Patient Folder

1.3.1 IMPORT STL FILES

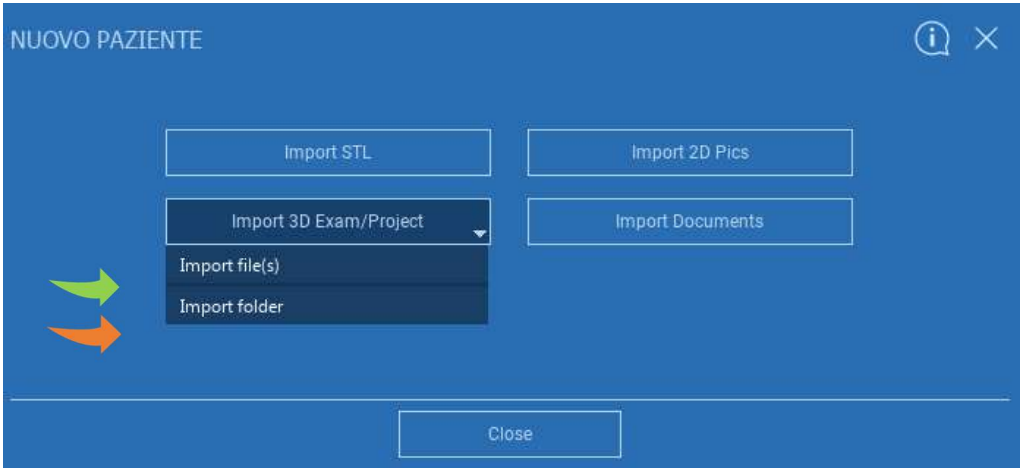
Click on **3D Objects** on the **PATIENT TOOLBAR** to see all imported STL files.

Pay attention! During this step you are only connecting STL files to the patient they belong to. If you are interested in the matching procedure go to Paragraph 2.6.

1.3 New Patient Folder

1.3.2 IMPORT 3D EXAM/PROJECT

Click on **IMPORT FILE(S)** to import DICOM files (single or multiframe) or Projects included in ZIP folder	Click on **IMPORT FOLDER** to import DICOM files or Projects included in open, decompressed folder or CD

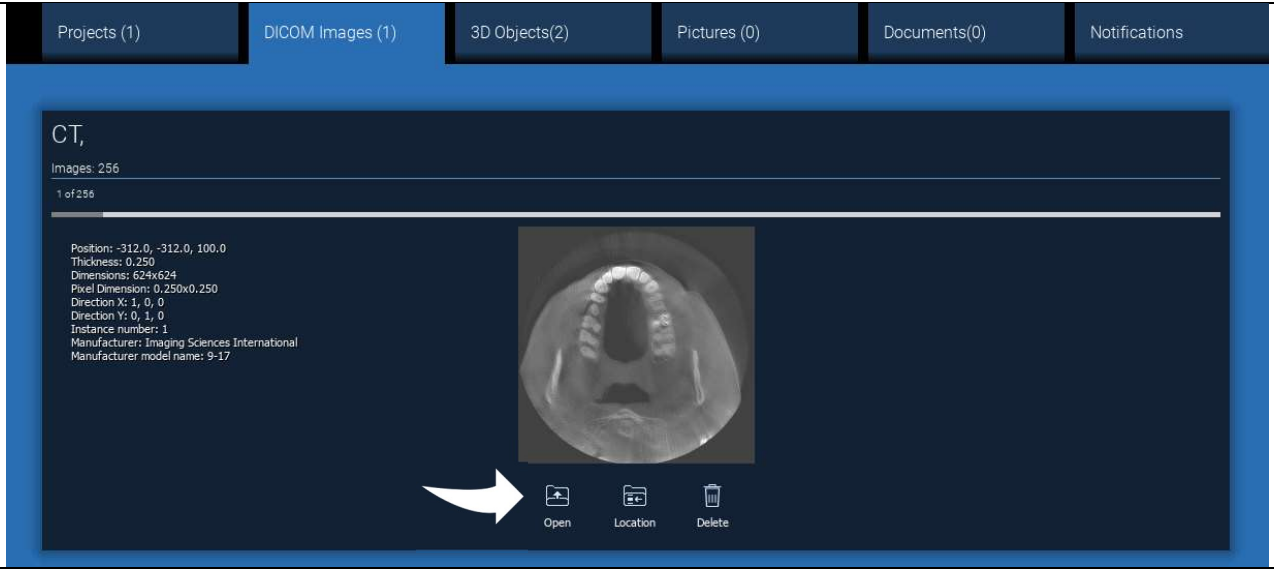


RealGUIDE 5.0® imports STANDARD DICOM images only, ie images acquired through standard CT or CBCT scanners, without any post-processing. Contact your CT/CBCT manufacturer for the correct DICOM stack export options. It is suggested to import just the AXIAL IMAGES, the only orientation managed by the software.

1.3 New Patient Folder

1.3.2 IMPORT 3D EXAM/PROJECT

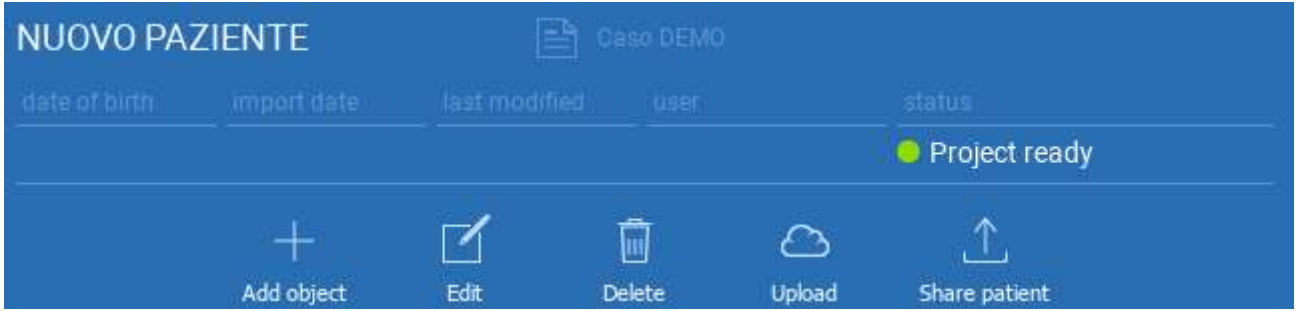
All DICOM series can be found on the **PATIENT TOOLBAR** by clicking on DICOM Images.



Click on **OPEN** to open the DICOM dataset visualization and diagnosis.
Click on **LOCATION** to open the local folder DICOM files path.
Click on **CANCEL** to delete the DICOM series from your patient folder.

1.3 New Patient Folder

1.3.3 IMPORT NEW OBJECTS



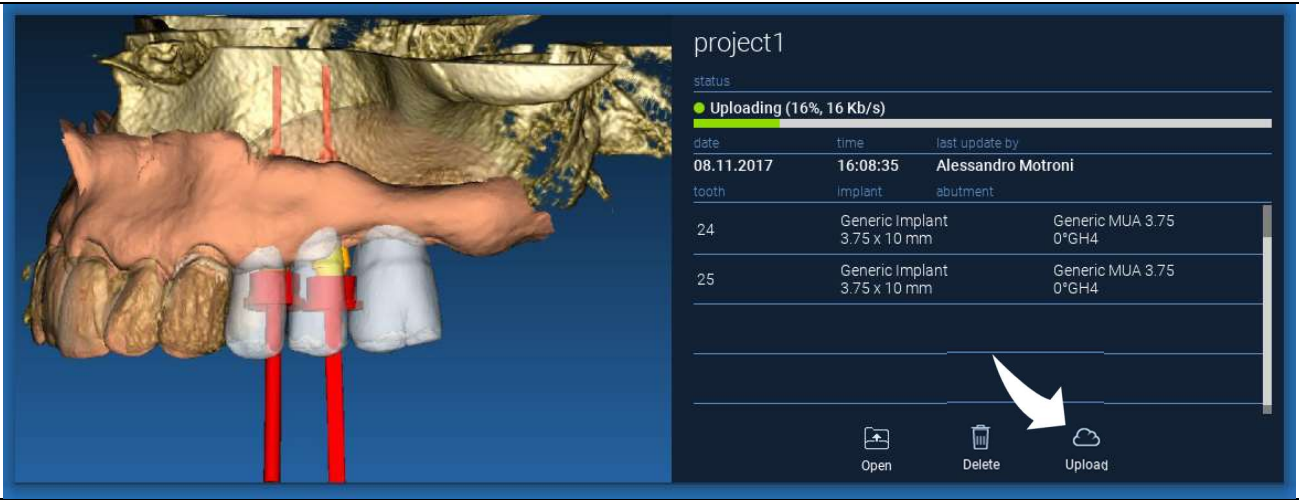
New objects can be added to the patient folder by clicking on **ADD OBJECT**.
The same window of pag. 11 will appear.

Click on **EDIT** to modify the patient data (Name, Surname, Date of birth, etc).

1. GETTING STARTED

1.4 Uploading on CLOUD

All the projects, STL files, images and documents can be individually uploaded on the CLOUD in order to be shared with other users and downloaded also on mobile devices. Click on **UPLOAD** to store the file you want on the CLOUD. Follow the upload process on the progress bar. At the end of the process you will see a status change in “Uploaded”.

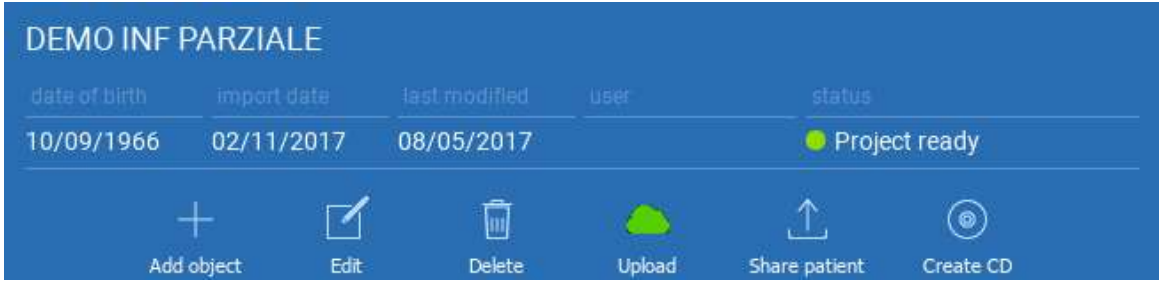


Due to security policy, DICOM images can be only shared in the form of PROJECT. Open DICOM series you want to share and then click on **SAVE** on the top left of the new window. A new project will be ready to be uploaded.

1. GETTING STARTED

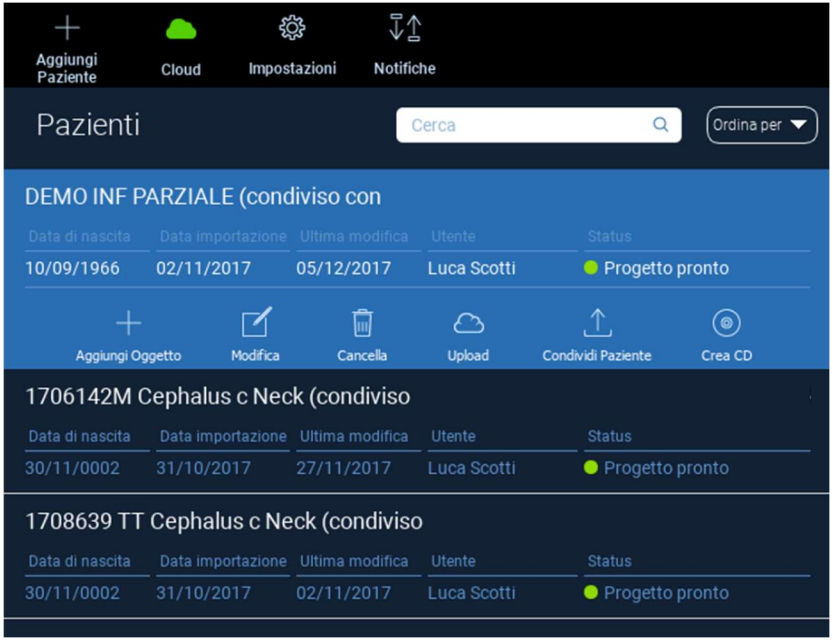
1.4 Uploading on CLOUD

If you want to upload the entire Patient Folder, select the correct patient and click on **UPLOAD** as shown in the figure. All the projects, STL files, images and documents will be sequentially uploaded on the CLOUD.



All the CLOUD operations are tracked in a list of notifications on the **PATIENT TOOLBAR** (NOTIFICATIONS section). Pay attention! A project uploaded is stored on the CLOUD but not shared yet. If you want to share it with the 3Diemme Production Centre or another user see the SHARING section

Click on **CLOUD** icon on the **TOOLBAR** in order to see all the projects, STL files, etc stored in the CLOUD. The icon will automatically become green and you will see the entire CLOUD Patient Storage.



1. GETTING STARTED

1.6 Sharing

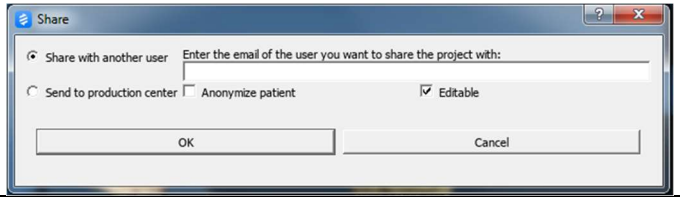
On the CLOUD Patient Storage it is possible to select the files to share by clicking on **SHARE**.

Click on **SEND TO PRODUCTION CENTER** if you want to share the files with the 3Diemme Production Center.

Click on **SHARE WITH ANOTHER USER** if you want to share the project with other partners equipped with a RealGUIDE software and a related user. In this case you only need to insert the proper user e-mail.

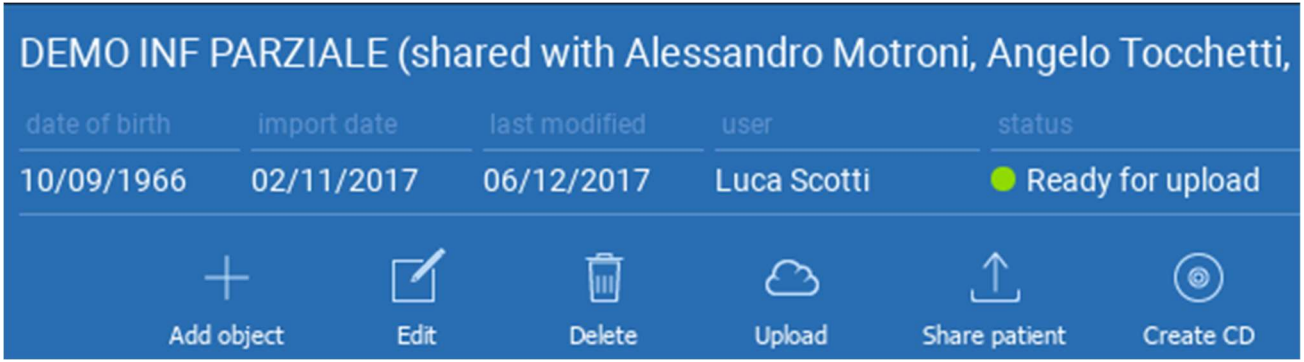
Enable the **EDITABLE** flag if you want to share a project in write mode and give to another user the possibility to modify what you have planned. Instead you will share it in read mode only.

Click on **OK** to complete the process and close the window.



If you want to share the entire Patient folder with other users it is possible to click on **SHARE PATIENT** as shown in the figure below.

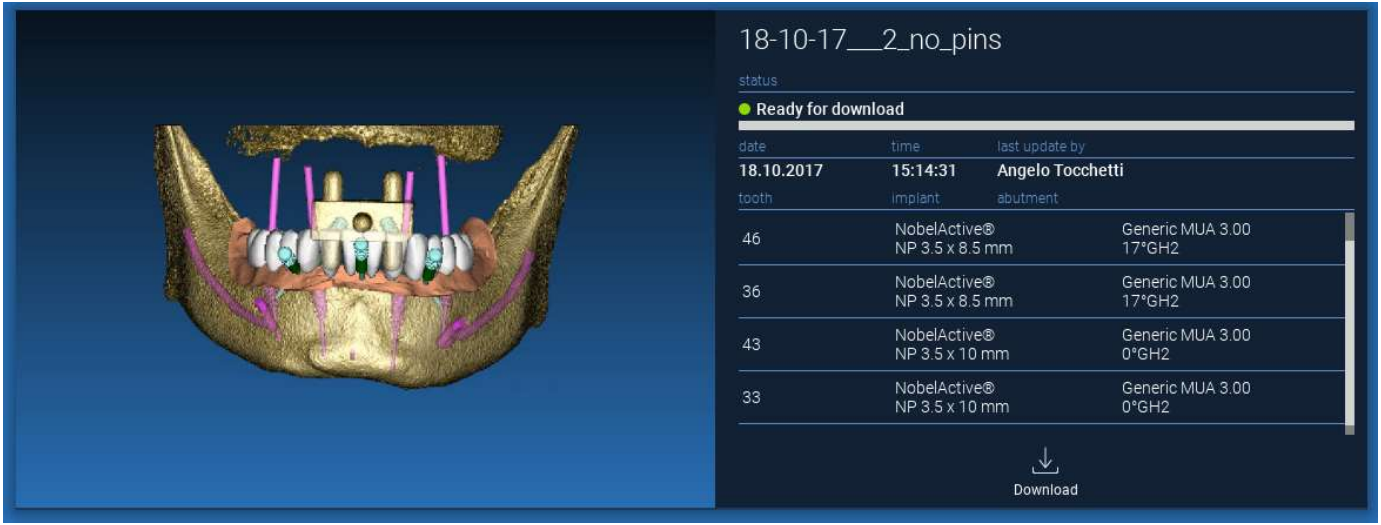
The same window of the previous page will appear. All the files linked with the patient will be shared, including all subsequent updates.



1. GETTING STARTED

1.7 Project Download

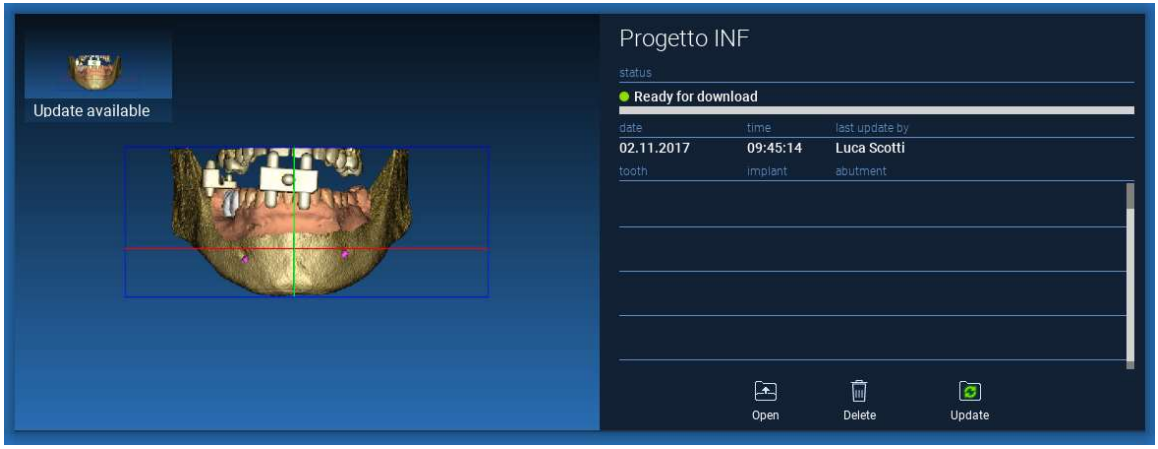
The Patient files on the CLOUD and not yet downloaded in the local database show the DOWNLOAD icon below the files to download



1. GETTING STARTED

1.8 Modified Project Download

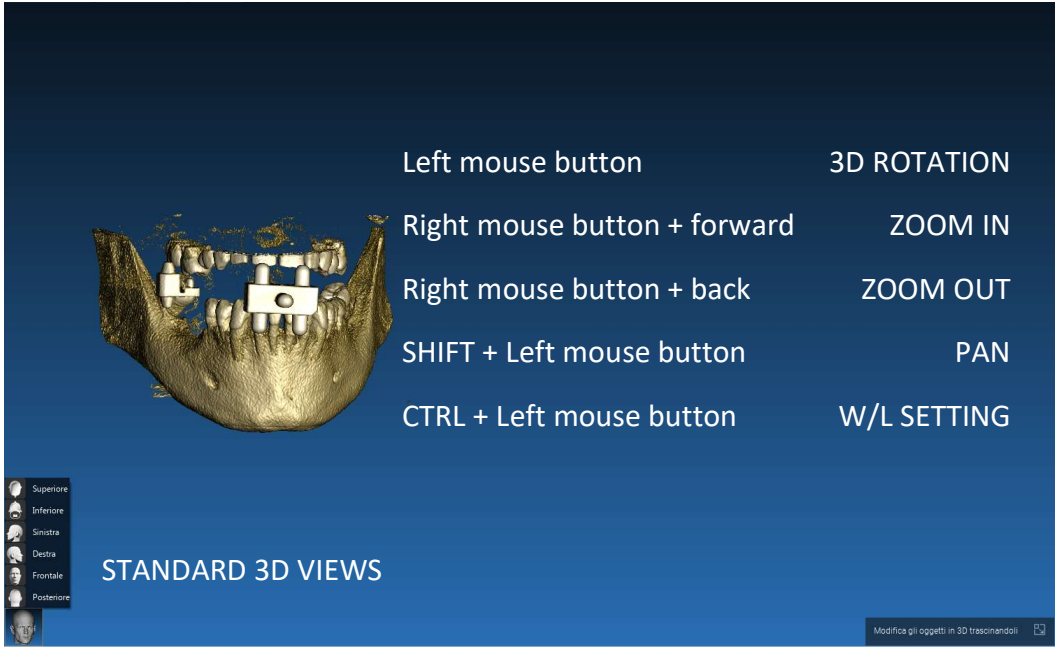
The Patient files on the CLOUD that have been modified in respect of the same project in the local database show a notification icon (UPDATE) in the correspondent window, and a preview image on the top left corner of the actual local project image preview



ALWAYS CONSIDER THE PROJECT LAST UPDATE DATE AND THE CORRESPONDENT USER NAME THAT MODIFIED THE PROJECT BEFORE SHARING IT WITH OTHER USERS OR THE PRODUCTION CENTER.

2. IMPLANT PLANNING

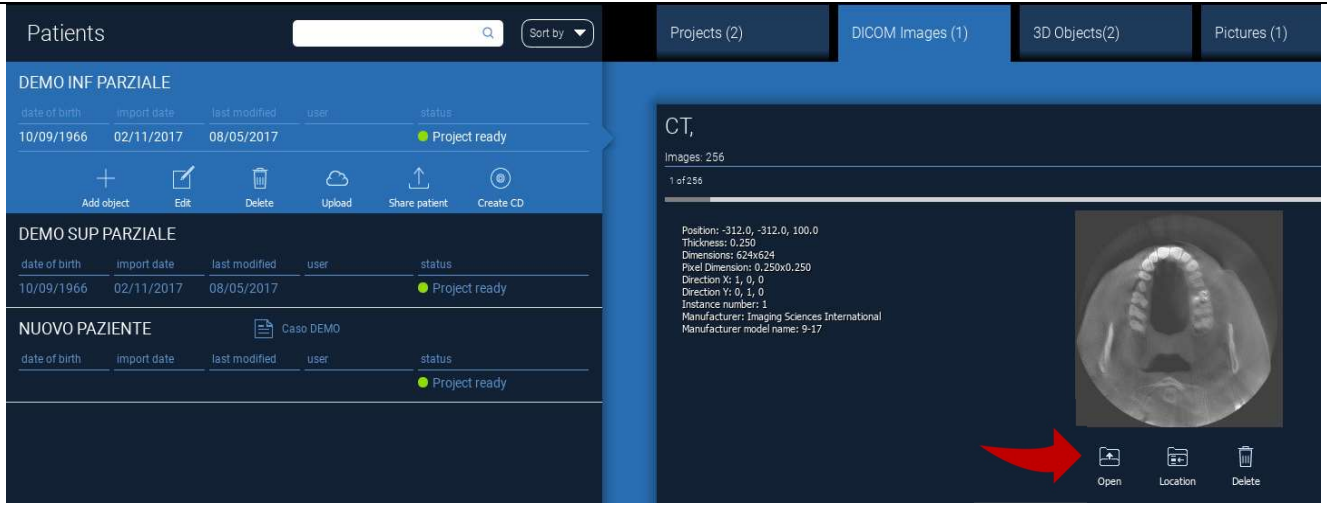
Basic Commands



2. IMPLANT PLANNING

2.1 3D View Opening

The first thing to do to start the implants planning is to open the DICOM dataset.
Select the Patient folder you want from **PATIENT DATABASE**. Then click on the DICOM series on **PATIENT TOOLBAR** and click on **OPEN** as shown in the figure.



2. IMPLANT PLANNING

2.2 Main Layout

The entire planning process, starting from the selection of the proper 3D volume up to the surgical guide design, is managed in a unique window with an easy and guided Wizard bar. All the steps are shown on the left. It is essential to follow them in order not to forget any passage. Press on **NEXT STEP** to advance or click directly on the desired step in the left vertical bar.

VOI SETTINGS

3D SETTINGS

DATA IMPORT

CPR SETTINGS

NERVE DRAWING

TEETH SETUP

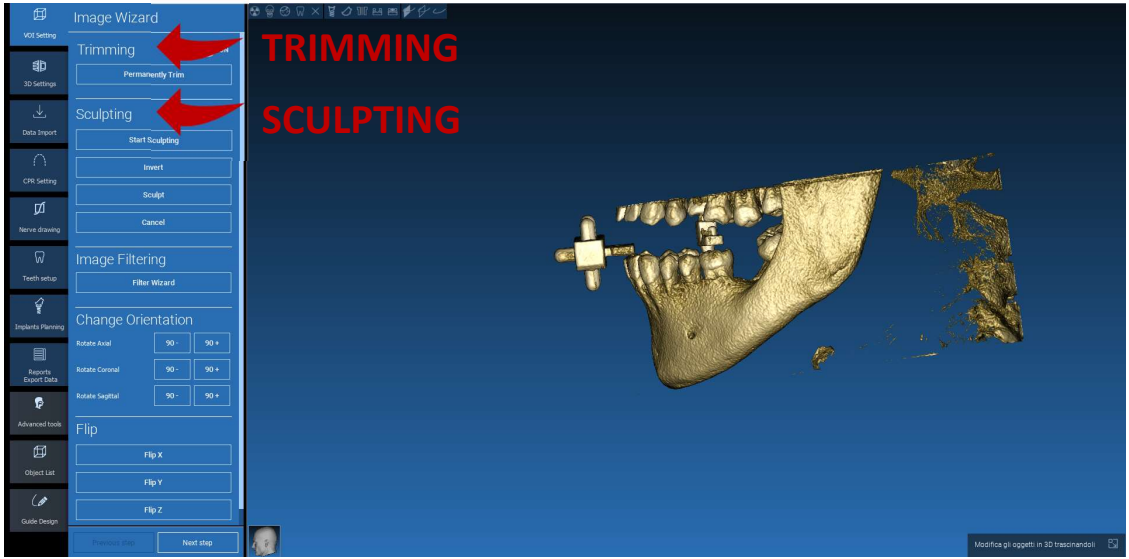
IMPLANT PLANNING

EXPORT DATA

2. IMPLANT PLANNING

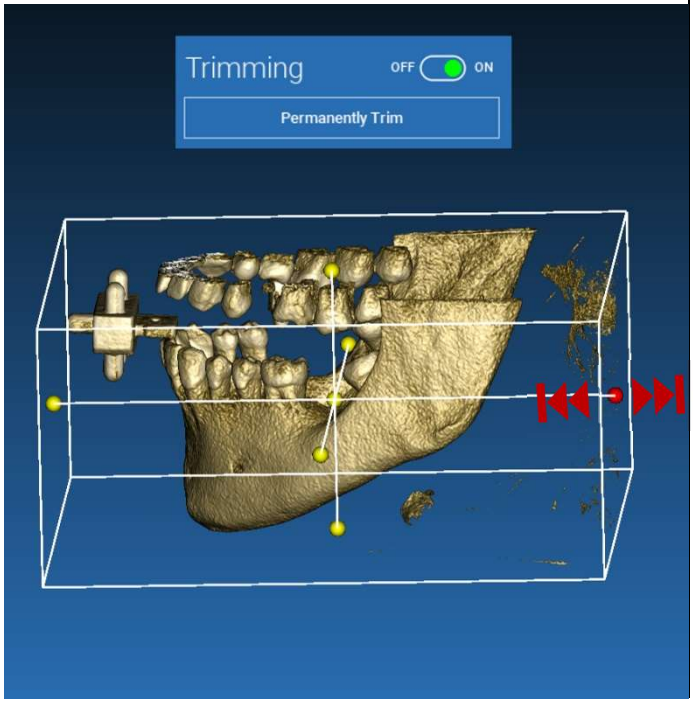
2.3 VOI Settings

First of all you can modify the reconstructed 3D volume using two different cropping and volume editing tools:
TRIMMING: 3D volume reduction along the 3 main anatomical planes
SCULPTING: custom volume sculpting.



2.3 VOI Settings

2.3.1 TRIMMING



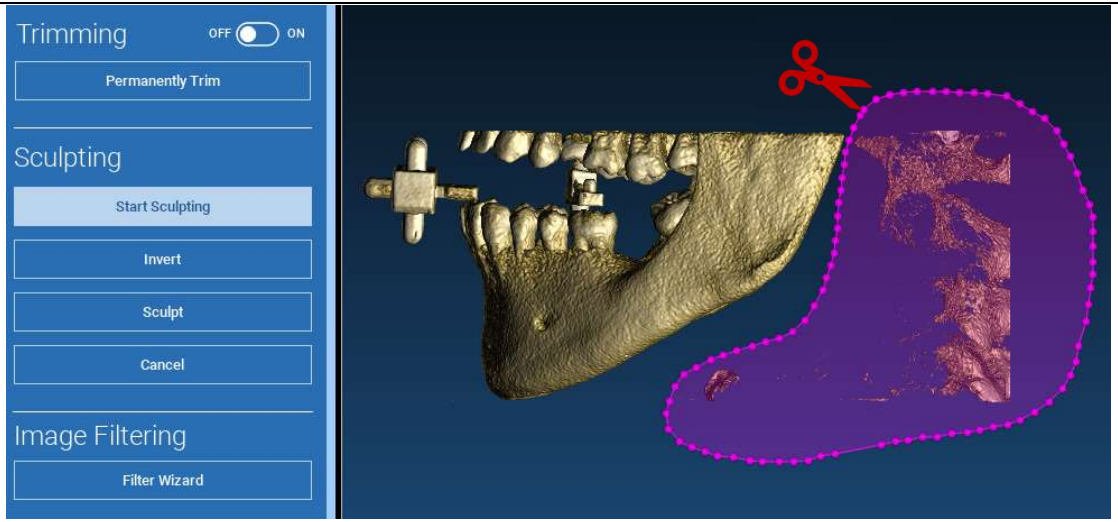
Click on **ON/OFF** button to activate the tool.
The three anatomical planes will automatically appear around the 3D object.

Click on the yellow spheres and move the mouse to restrict/expand the reconstruction volume. Click on **PERMANENTLY TRIM** to confirm.

2.3 VOI Settings

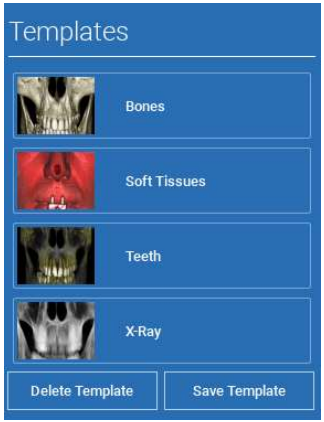
2.3.2 SCULPTING

Click on **START SCULPTING**, to start selecting the specific area to remove. Click with the left mouse button point by point around the region to cut, then press on the **SCULPT** button to confirm the sculpting area.
Click on **INVERT** to mantain the area selected and remove the rest. If you want to ignore the selection click on **CANCEL**.



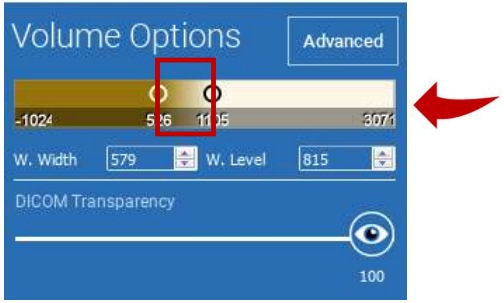
2. IMPLANT PLANNING

2.4 3D Settings



In this second step you can change 3D visualization settings by selecting the desired 3D template from the list showing all the available templates.

Each template represents a pre-defined (or user-defined) tissue according to the volume rendering settings shown in **VOLUME OPTIONS**.



When selecting the template, the volume settings will automatically be updated and ready for fine tuning.

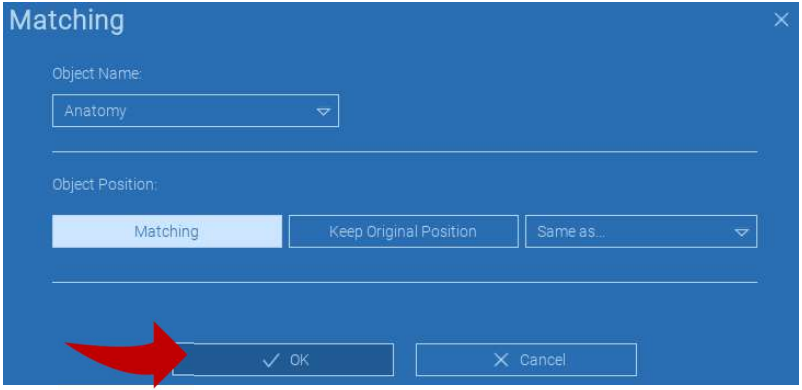
2. IMPLANT PLANNING

2.5 Data import

In this step the original STL files, previously imported without modification, are aligned to DICOM images.

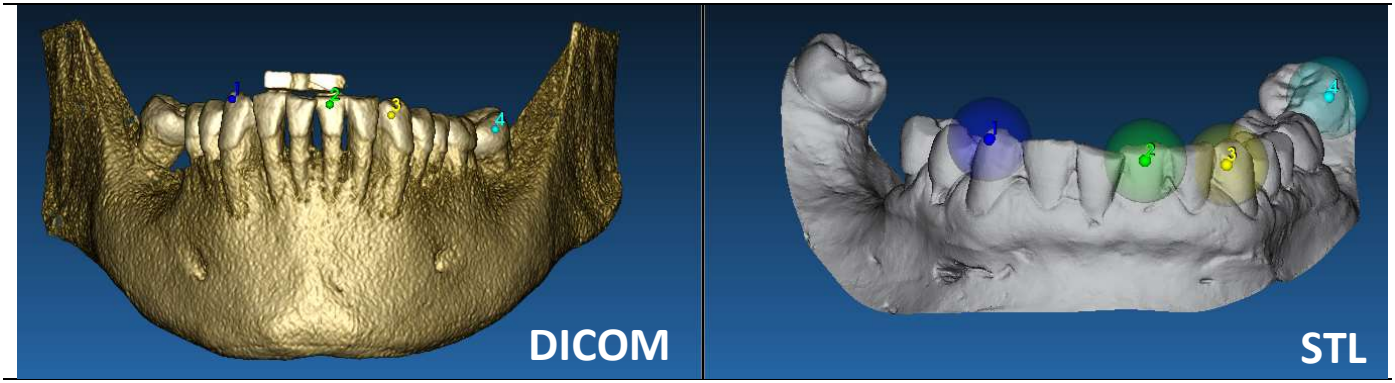
Select the file you want to align, then click on **MATCHING**.

In the new popup window (see below), check if the MATCHING button is highlighted and set the correct object name of the file to be aligned; then click on **OK** to start the procedure.



2. IMPLANT PLANNING
2.6 Matching

A new window appears with two different 3D views: the 3D DICOM reconstruction on the left and the STL file (to be aligned) on the right. These two files have different reference systems (RS), respectively the CBCT and the scanner one. Left click on the two files to select at least three correspondent reference points. For each selection a sphere of points around it will be taken into account for the best fit superposition.

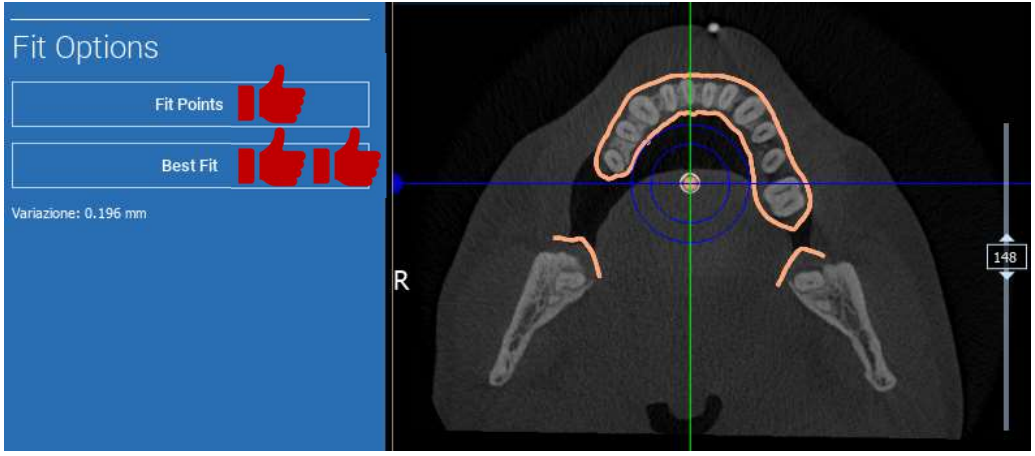


It's very important to choose easily identifiable areas on both 3D objects. Consider for example the evobite 3D marker surfaces, as well as the stable teeth surfaces (if no metal structure is present). Don't take into account areas with high scattering level, being less reliable.

2. IMPLANT PLANNING

2.6 Matching

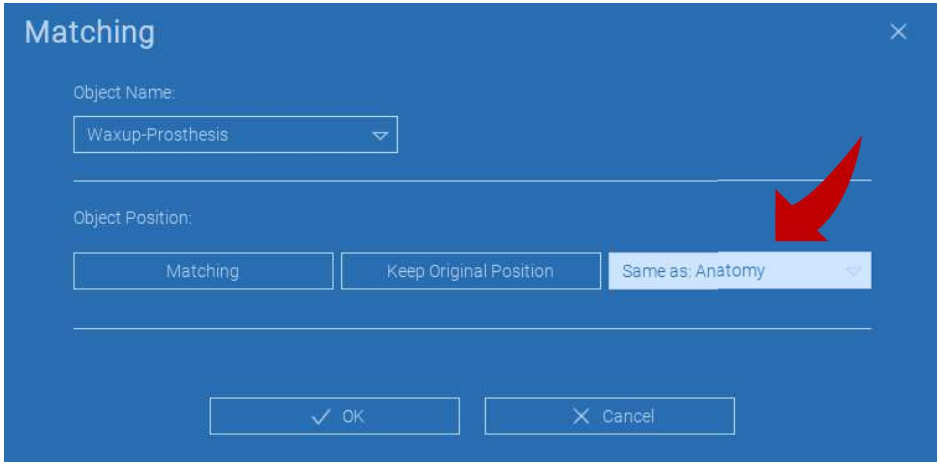
After selecting the reference points click on **FIT POINTS**. The software will perform a basic, rigid STL file positiong based on the selected common points. In order to improve the superposition precision click on **BEST FIT**. Thanks to a proprietary best fitting algorithm the software minimizes the distance between the surfaces included in the spheres set around the reference points, increasing the superposition precision between the STL and DICOM files. A mean error value appears below the BEST FIT button, indicating the mean distance between the surfaces. Check the STL files profiles on the different multiplanar (MPR) views, eventually fine tuning the final position through the object widget positioned in the middle of the images.



2. IMPLANT PLANNING

2.6 Matching

You can apply the first STL transformation to all the other files. Select the STL file you want to align then click on **MATCHING** as previously shown. Select the option: **SAME AS: [ANATOMY]** and click on **OK**.
The software will automatically move this new file in the correct position, based on the previous transformation.

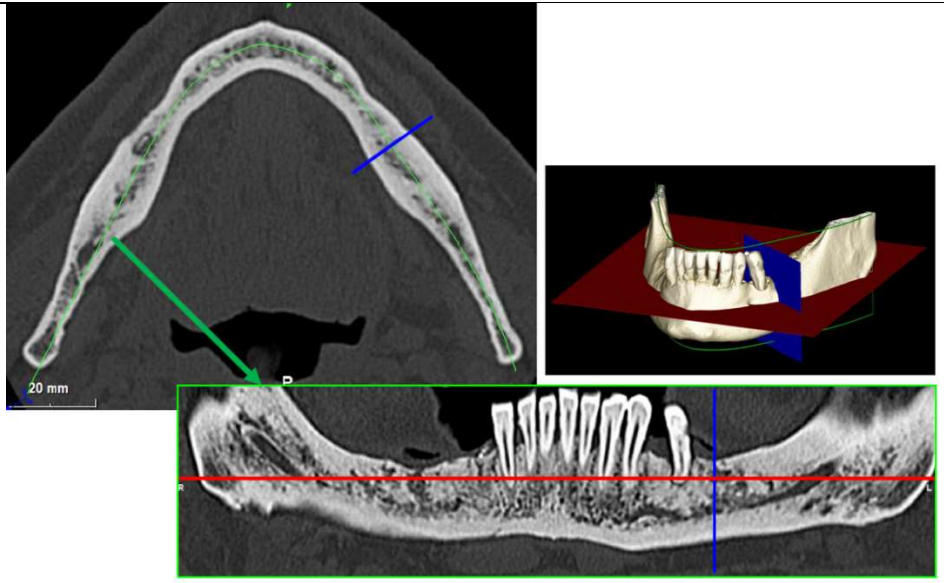


The most important requirement for the lab is to scan and keep all the STL files in the same reference system!

2. IMPLANT PLANNING

2.7 CPR Settings

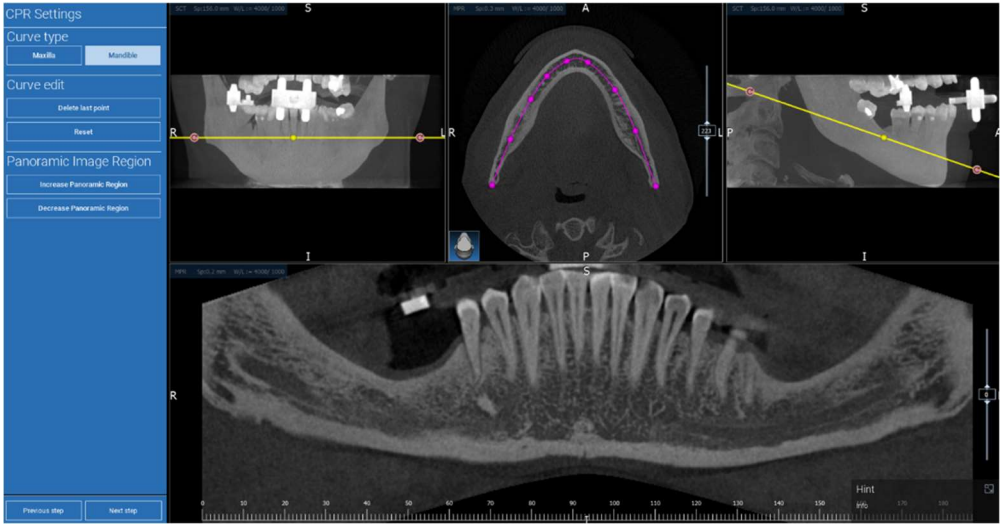
Clicking on the CPR icon it's possible to draw the CPR curve, indicating the reconstruction plane along a line useful to reconstruct the panoramic image. The CPR view (or reconstructed panoramic image) is calculated by projecting on a single 2D view all the voxels values visible on a plane perpendicular to the selected axial image and intersecting the CPR curve. The resulting surface is then adjusted on a plane to obtain the standard panoramic view.



2. IMPLANT PLANNING

2.7 CPR Settings

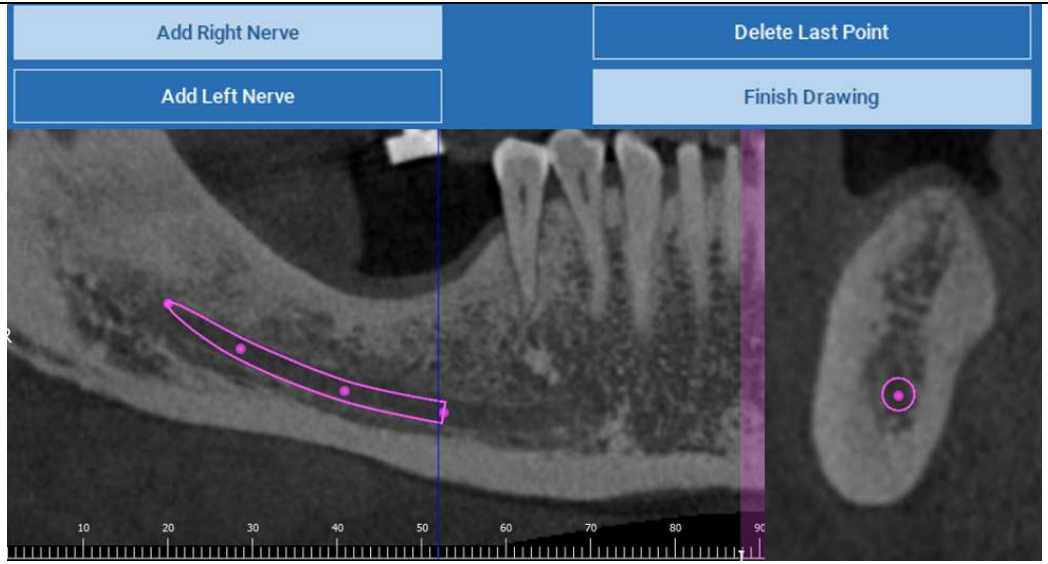
Before starting tracing the CPR curve, select on which arch you want to work. Select the axial image where tracing the CPR curve and, if necessary, modify the plane inclination according to the acquisition plane and patient anatomy. To modify the plane inclination click on the rotation pointers at the end of the yellow line on the scout view with the LMB, keep it pressed and drag the mouse in the desired direction.



2. IMPLANT PLANNING

2.8 Nerve Drawing

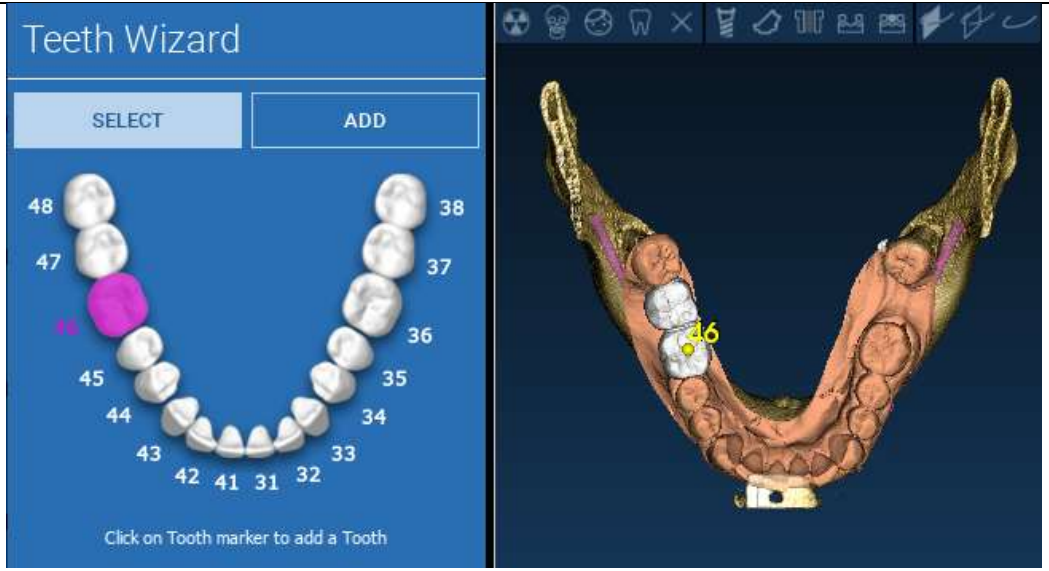
Along the new CPR curve it is possible to track the right and left nerves in the mandibular arch. Start to draw right nerve on the CPR view by clicking the points with the left mouse button. The points can be also adjusted on the cross section view. Click on **RESET** to restart drawing. Scroll the mouse wheel to change the panoramic image and follow the nerve position on different planes. Click on **FINISH DRAWING** to complete the object. Then click on **ADD LEFT NERVE** to start with the left mandibular side.



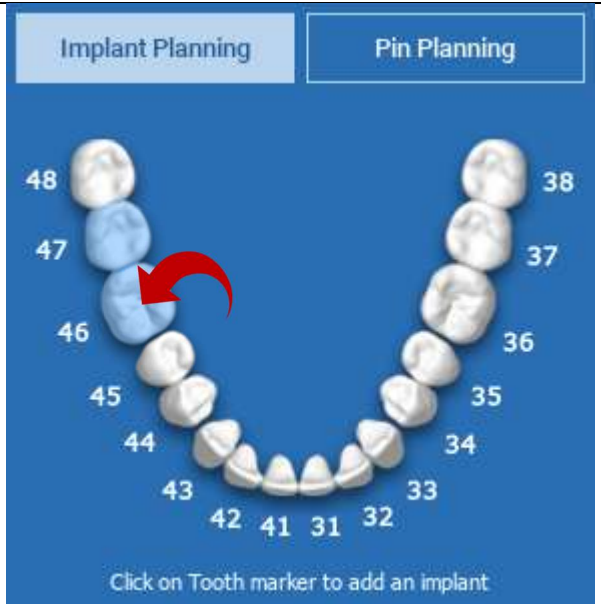
2. IMPLANT PLANNING

2.9 Teeth Setup

Before positioning the implants it is necessary to identify all the elements to rehabilitate. Click on the desired element then select the correspondent area (digital wax-up or edentulous areas) on the 3D reconstruction. You can also insert a virtual wax-up by clicking on **ADD** and adjust its volume and position directly on the 3D or MPR views. Once completed all the operations click on **NEXT STEP** to go on**.**



All the elements previously selected are marked in light blue colour. Click on them to open implant library window.



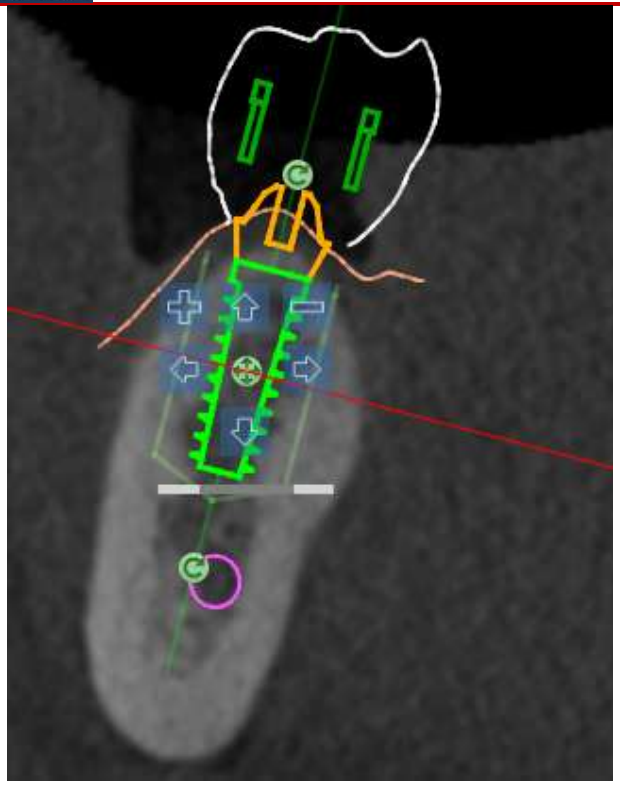
2.10 Implant positioning

2.10.1 IMPLANT LIBRARY

In the new window a standard implant is already positioned inside the bone in the area previously selected. It is possible to download the desired implant library from the CLOUD and then choose the most suitable prosthetic component. Click on **APPLY** to confirm and return to the implant planning window.

2.10 Implant positioning

2.10.2 IMPLANT POSITION SET UP



A list of buttons allows you to modify the implant position in all the 2D views:

Implant angle change: rotate the implant top keeping the apex fixed.

Increase/Decrease the implant dimension

Implant pan (0.5 mm for each left mouse click in the selected direction). It is possible also to move the implant along its axis using the arrow keys (UP and DOWN)

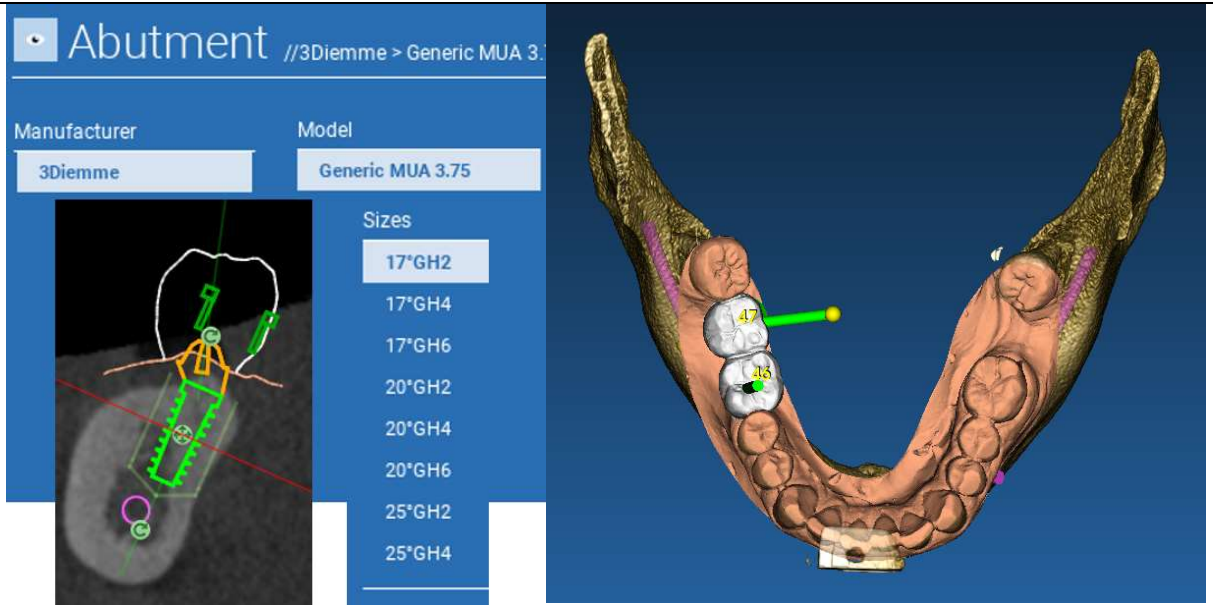
Implant tilt change: rotate the implant apex keeping the top fixed.

You can pan the implant by clicking on the button positioned in the center of the object.

2.10 Implant positioning

2.10.3 PROSTHETIC ABUTMENTS CHOICE

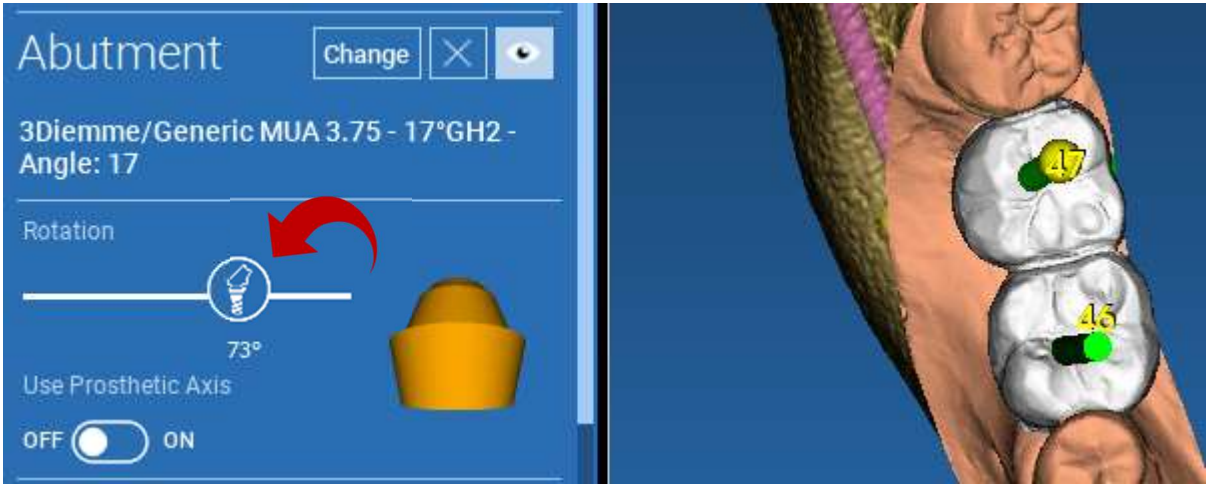
Once the implant has been positioned in the correct site it is possible to choose/modify its abutment and adjust the prosthetic axis.



2.10 Implant positioning

2.9.4 AXIS ROTATION

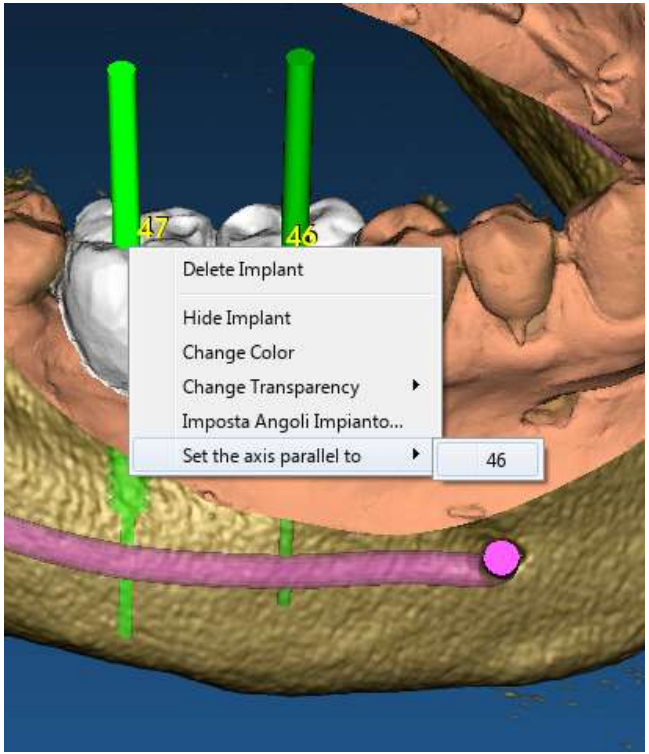
You can change the abutment axis orientation (keeping the implant axis fixed) moving along the slider the button pointed out in the figure below. Control it also on the occlusal 3D view to be more accurate.



The new release allows you to control the prosthetic axis parallelism in two simple steps:

Right click on the prosthetic axis you want to modify;

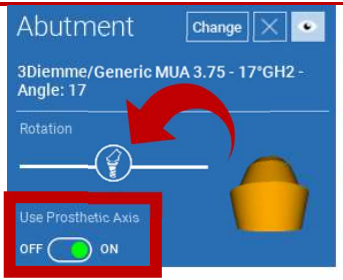
Then choose the option **SET THE AXIS PARALLEL TO** and select the element you want to align with.

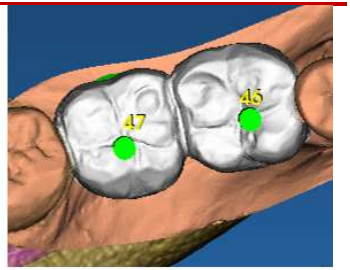


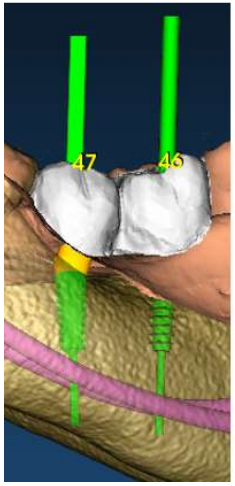
The prosthetic axis will be automatically updated and set parallel to the reference implant.

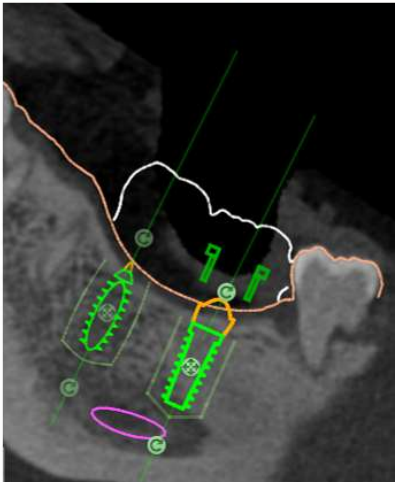
Now that you have reached the prosthetic axes parallelism be sure that all the implants are in a safe position yet.

If you want to make some adjustments activate the option **USE PROSTHETIC AXIS** as shown in the figure. Only in this case you will be able to change the implant axis by rotating the implant around the prosthetic axis, keeping the prosthetic one fixed in the correct position.





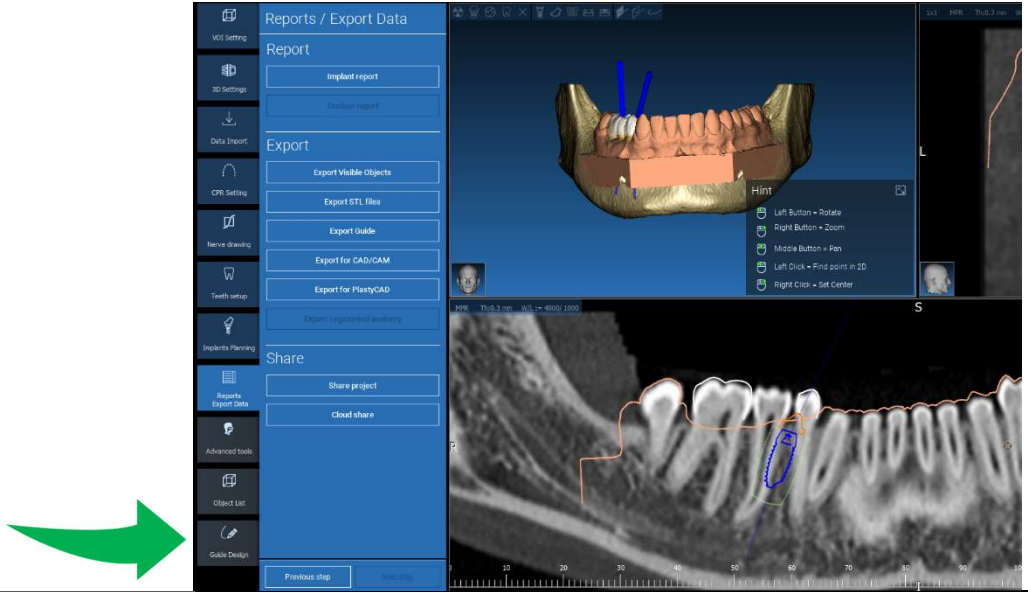




3. SURGICAL GUIDE DESIGN

3.1 Process start

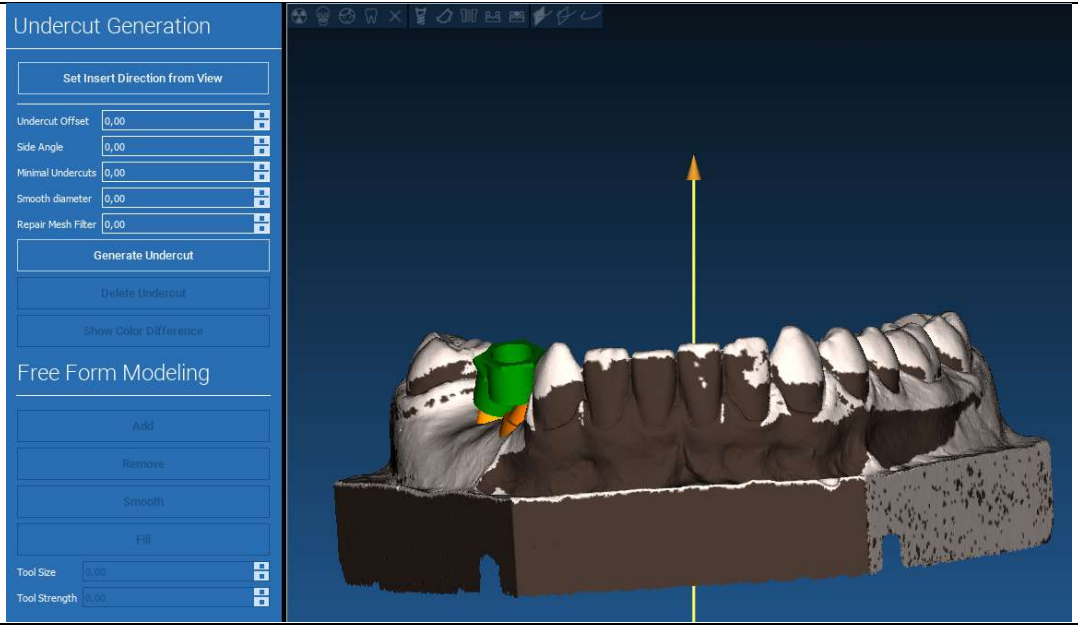
Once the implant planning has been completed, it's possible to proceed to the surgical guide design by clicking on the Guide Design tab on left side menu panel. A guided procedure will be activated, giving the user the chance to setup the construction parameters.



3. SURGICAL GUIDE DESIGN

3.2 Undercut blockout setup

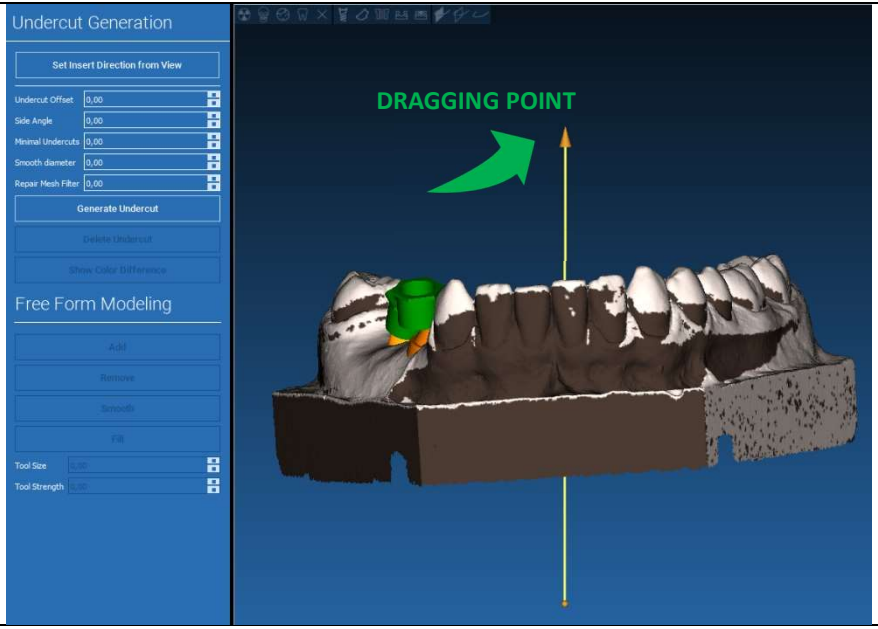
The side menu reports the commands that regulate the model undercut block out, just like a preliminary waxing. It will be possible to define the thickness, the angle of block out, the grip grade and the smoothness of the virtual waxing.



3.2 Undercut blockout setup

3.2.1 INSERTION DIRECTION – CONTROL ARROW

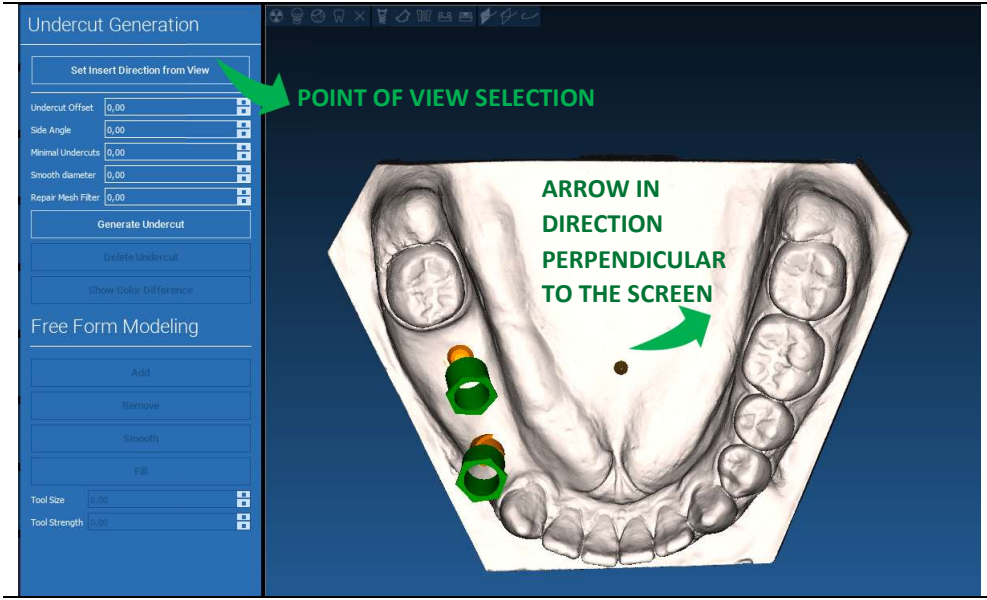
The arrow visualized at model center defines an insertion axis direction calculated automatically in relation to the model shape. To modify this insertion direction and the generated shadow areas (brown color) drag the arrow point in the desired direction.



3.2 Undercut blockout setup

3.2.2 INSERTION DIRECTION – VIEW DIRECTION

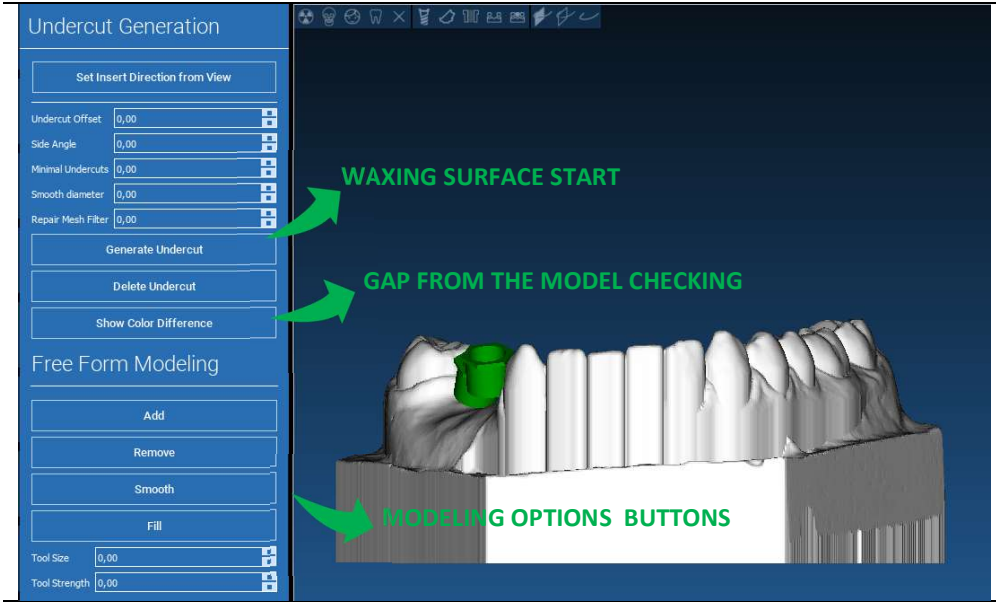
It’s possible to define the insertion axis direction also moving the model in a desired point of view. By clicking on **SET DIRECTION FROM VIEW** button, the arrow axis direction will be positioned perpendicular to the screen surface.



3.2 Undercut blockout setup

3.2.3 WAXING SURFACE GENERATION

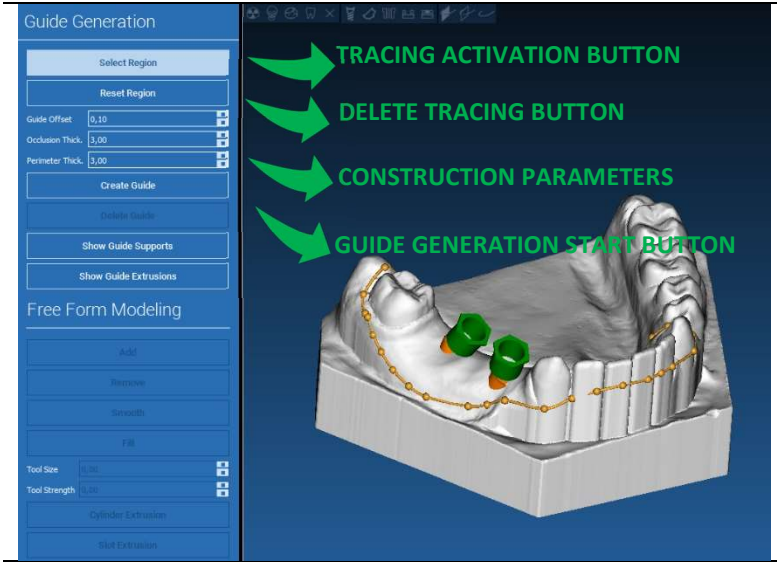
Once the insertion axis direction has been defined, clicking on **GENERATE UNDERCUT** starts the waxing surface generation. It's also possible to locally modify this surface, checking the distance from the model, activating the modeling functions and the gap visualizing buttons located on the right side menu. By clicking on **NEXT STEP** menu button starts the last part of guide construction.



3. SURGICAL GUIDE DESIGN

3.2.1 Tracing and construction parameters

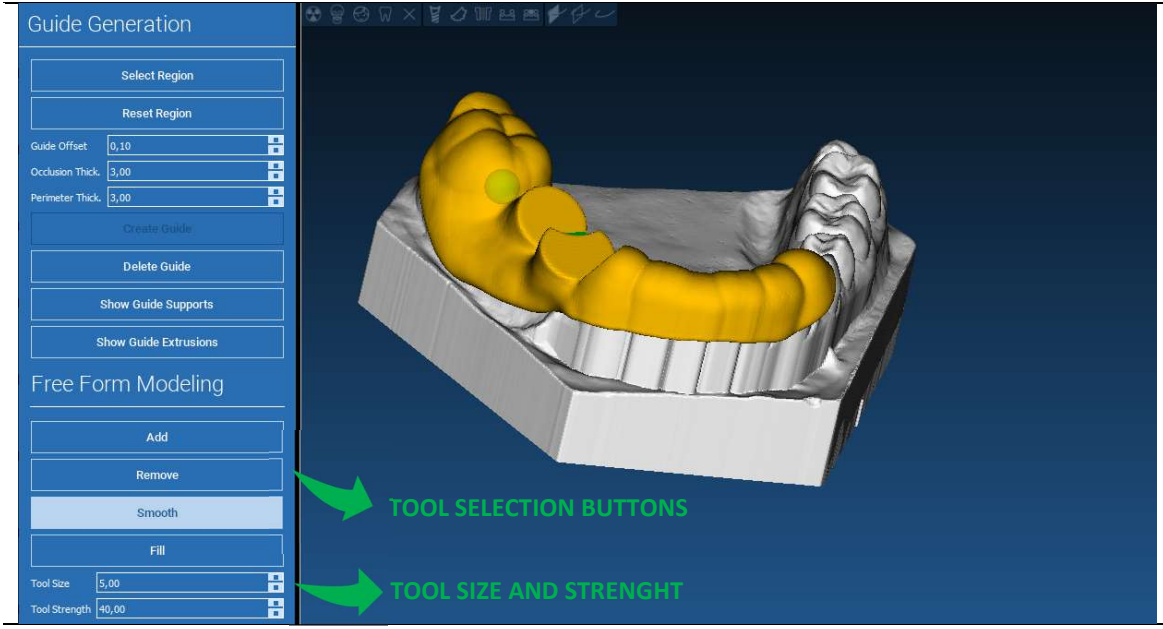
Trace the outer guide margin surrounding an area on the model: the command is active by default. A control point is added with any mouse click. It's not necessary to close the area loop, it's enough to position the last point close to the first one. Then check and define the fitting tolerance, the occlusal and lateral thickness values. To modify, eventually, the defined margin click and drag any point in the desired position, click on **CREATE GUIDE** to confirm and to proceed to the volume construction.



3. SURGICAL GUIDE DESIGN

3.2.2 Modeling tools

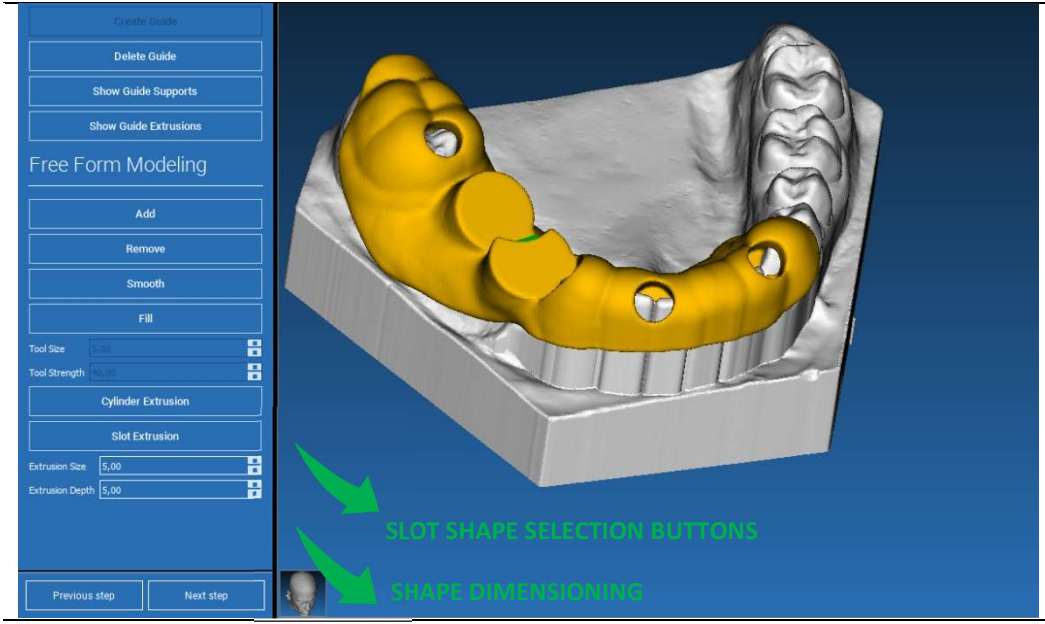
Once the guide volume has been created, the modeling tools become active. They permit to add/remove material, to smooth the surface and to fill in the depressions. Normally they are used to smooth the borders and to reinforce areas with deep depressions.



3. SURGICAL GUIDE DESIGN

3.2.3 Inspection and anesthetic reinforcing slots

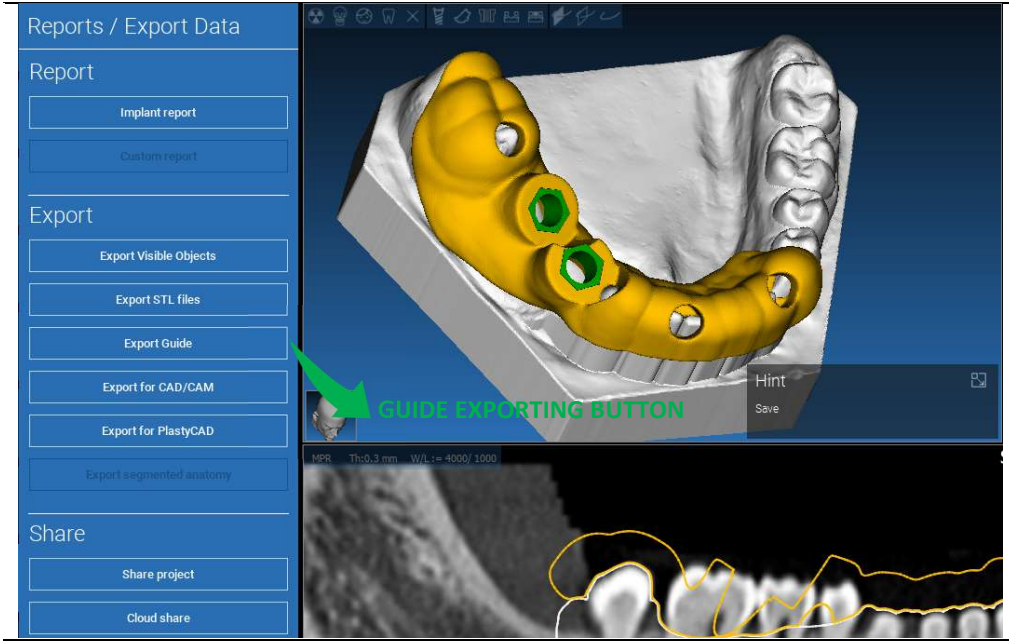
Under the modeling tools are located the commands to generate cylindrical holes and rectangular slots with their depth and size dimension parameters. By clicking on the guide surface in the desired position, the selected geometry with its axis oriented along the user point of view direction will be generated.



3. SURGICAL GUIDE DESIGN

3.2.4 Finalization

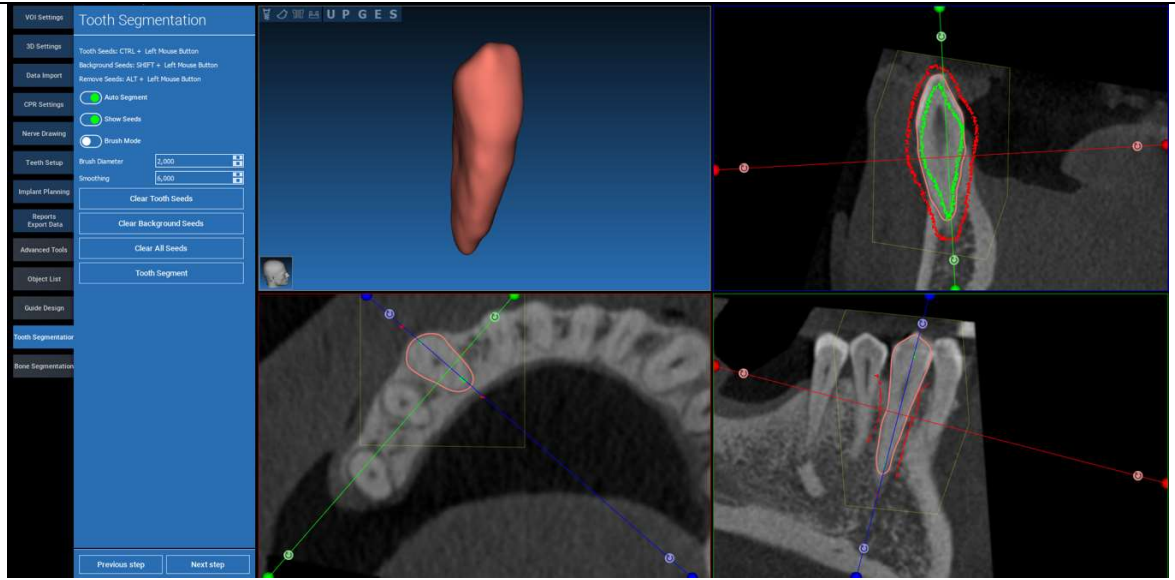
By clicking on **NEXT STEP** button the guide generation will be finalized by the sleeve seats construction. On the side menu the REPORTS / EXPORT DATA tab will appear, allowing the STL file export operations.



4. SEGMENTATION

4.1 Tooth segmentation

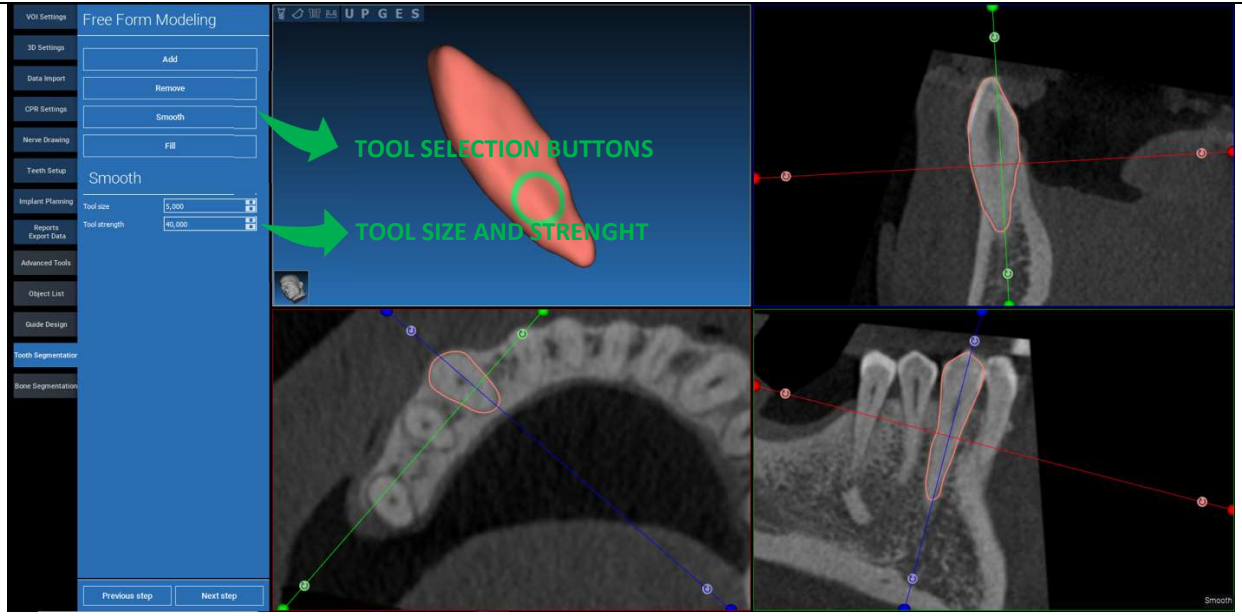
Activate BRUSH mode and manually trace the desired tooth contour keeping the LMB pressed. If AUTO SEGMENT is ON the tooth is extracted as soon as the LMB is released, otherwise click on TOOTH SEGMENT button. Edit the seeds to refine the tooth shape (CTRL+LMB to add seeds, SHIFT+LMB to add background seeds)



4. SEGMENTATION

4.1 Tooth segmentation

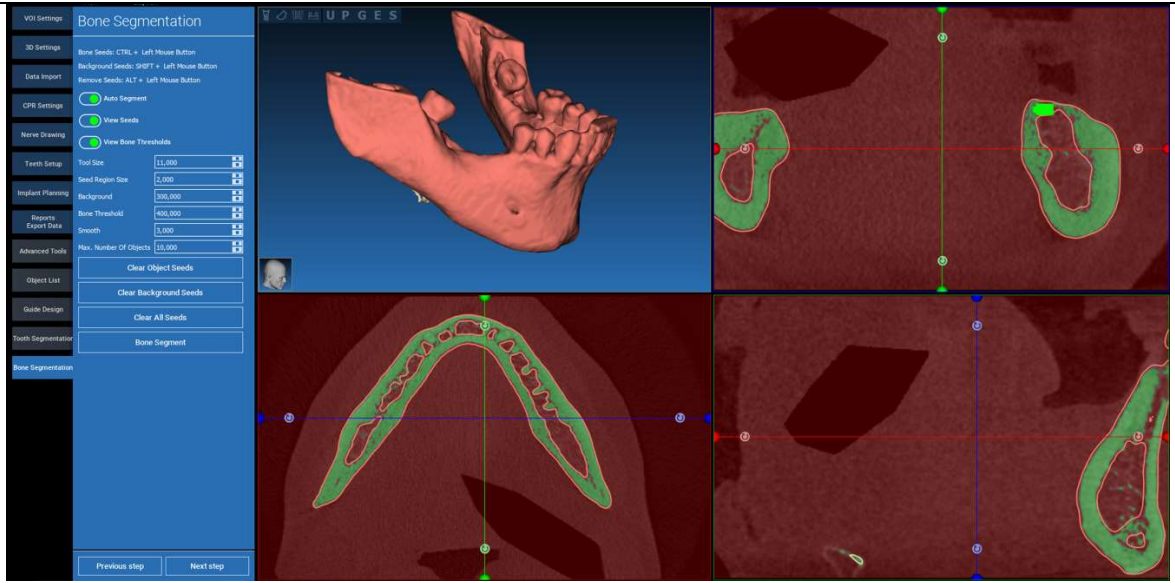
Use the FREEFORM modelling tools to further refine the tooth surface



4. SEGMENTATION

4.2 Bone segmentation

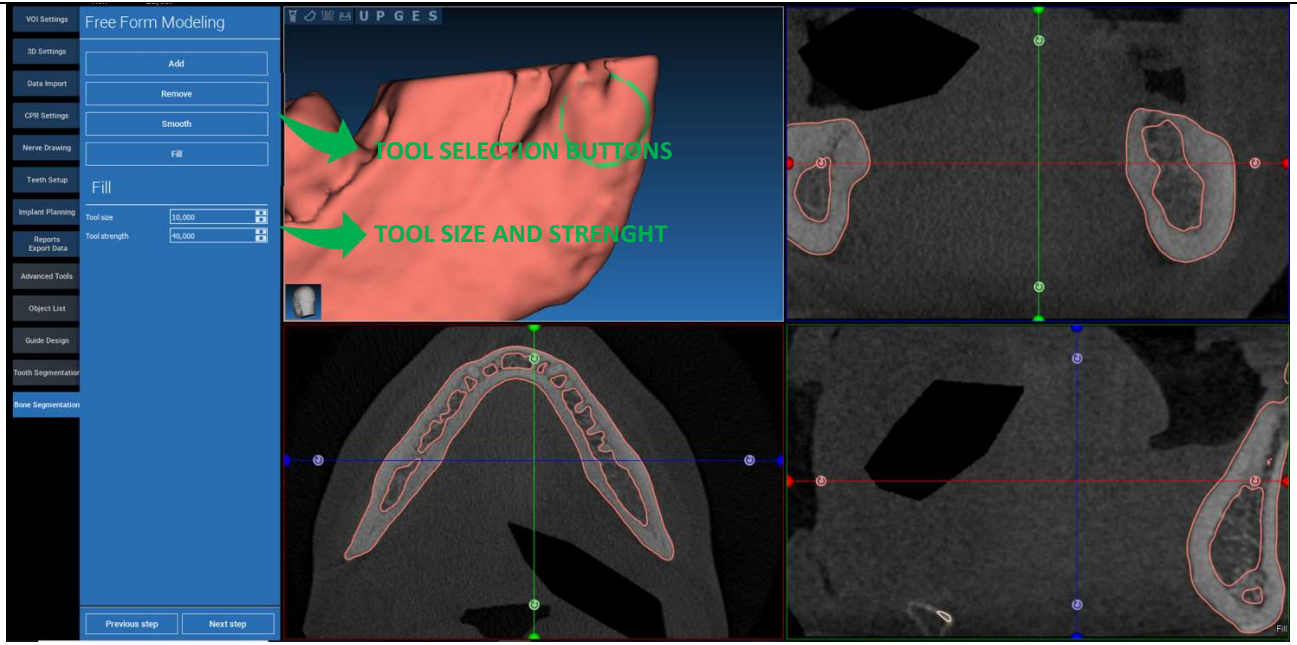
Set the bone and background thresholds. If AUTO SEGMENT is ON, the bone is extracted as soon as the LMB is released, otherwise click on BONE SEGMENT button. Edit the seeds to refine the bone shape (CTRL+LMB to add seeds, SHIFT+LMB to add background seeds)



4. SEGMENTATION

4.2 Bone segmentation

Use the FREEFORM modelling tools to further refine the bone surface



5. ADVANCED TOOLS

5.1 Thin slab

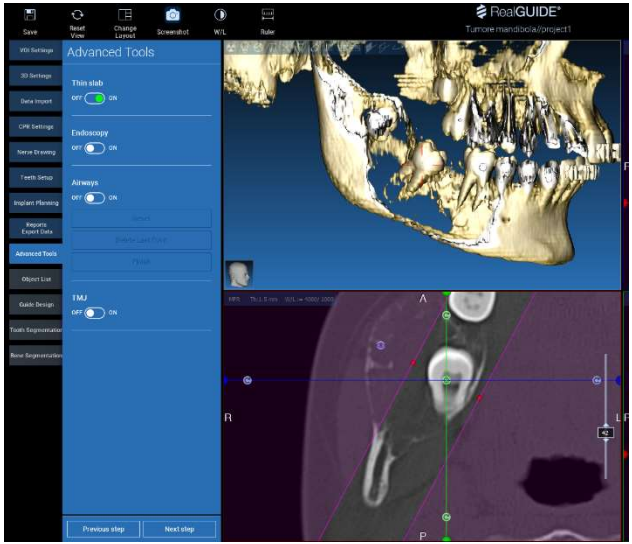
Switch on the THIN SLAB button, the parallel cutting planes appear and everything outside the plane is hidden to the 3D view. This feature is useful to isolate a ROI and to rotate the views around the ROI, like a wisdom tooth.

- Move the crosshair cursor to move the thin slab

- Drag the red points on the thin slab planes to increase/decrease the slab thickness

- Rotate the camera on 3D view to analyze the ROI

- Switch back the THIN SLAB button to go back to the previous visualization mode



5. ADVANCED TOOLS

5.2 Endoscopy

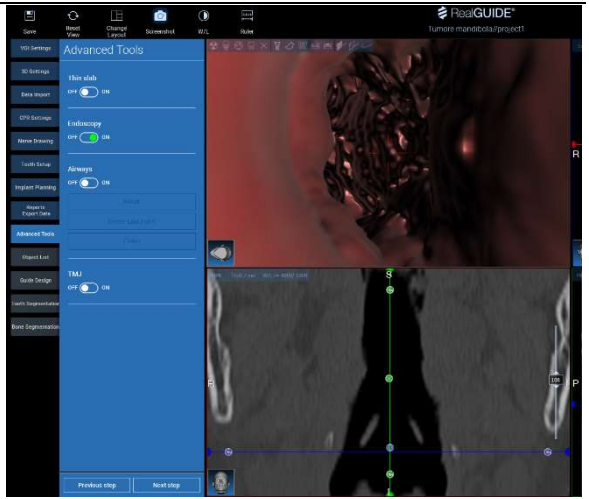
Switch on the ENDOSCOPY button, the perspective camera mode is activated, attached to the actual cursor position. The perspective mode simulates the visualization mode of a real camera and is useful to qualitatively explore cavities, like the maxillary sinus and the airways

- Use the LMB to move the camera forward

- Use the RMB to move the camera backward

- Use both the LMB and RMB and move the mouse to explore the area around the camera

- Switch back the ENDOSCOPY button to go back to the previous visualization mode



5. ADVANCED TOOLS

5.3 Airways

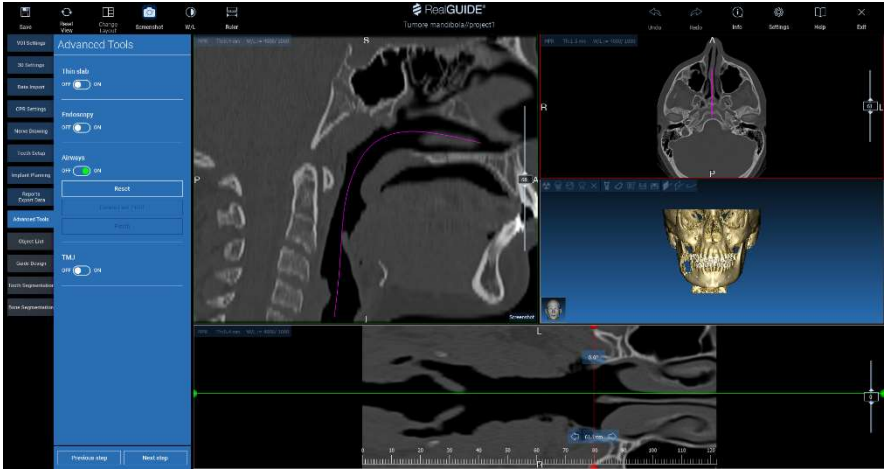
Switch on the AIRWAYS button, the windows layout is turned to AIRWAYS mode, where the coronal image should be manually centered along the airways, in order to correctly manually click with the LMB to draw the camera trajectory

- Use the LMB to click inside the airways and trace a line on the coronal view

- Click FINISH to exit the drawing mode

- Switch on the ENDOSCOPY button to active the perspective view and attach the camera to the line

- Switch back the AIRWAYS button to go back to the previous visualization mode



5. ADVANCED TOOLS
5.4 TMJ

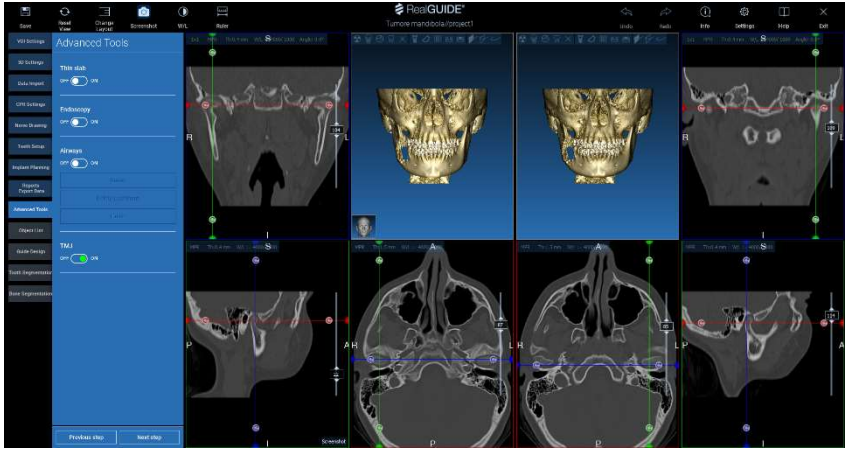
Switch on the TMJ button, the windows layout is turned to TMJ mode, where the MPR images are split in 2 parts in order to analyze the TMJs separately but at the same time

- Use the LMB to position the cursors on the left/right TMJ

- Click on THIN SLAB button to better analyze the condyle without the maxillary fossa interference (interactive mode)

- Switch back the THIN SLAB button to go back to the previous visualization mode

- Switch back the TMJ button to go back to the previous visualization mode



6. TOP TOOLBAR COMMON FUNCTIONS

6.1 Top toolbar common functions

The software TOP TOOLBAR contains the functions that are common to all the wizard pages. Below the icons a self-explanatory description of the action is reported. All the functions available are listed below:

SAVE: save the current project and store it in the Patients List

RESET VIEW: reset the 2D MPR cursor angle and fit the views to the screen (reset the zooming factor everywhere)

CHANGE LAYOUT: open a pop-up window to change the screen appearance. The layouts proposal may be different for each wizard page, according to the actions available in the current wizard page

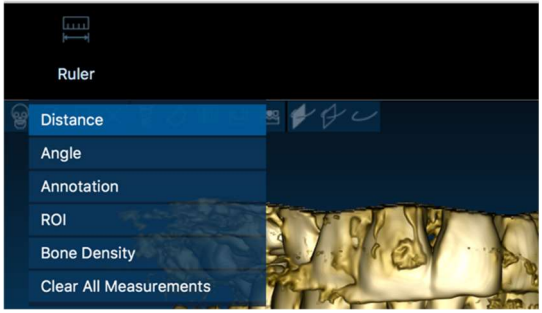
SCREENSHOT: save the current view as an image file

W/L: activate the contract setting cursor. Moving the mouse vertically changes the window width, moving it horizontally changes the window level, interactively modifying the image brightness/contrast. The same command works on the 3D window as well. Click back on the icon to return back to the MPR cursor.

6. TOP TOOLBAR COMMON FUNCTIONS

6.1 Top toolbar common functions

Clicking on the **RULER** icon shows the drop-down menu with the available measurement tools:



DISTANCE: click with the LMB on 2 points on MPR views to see the distance. Click with the RMB to show the HU profile along the line

ANGLE: click with the LMB on 3 points on MPR views to see the angle

ANNOTATION: click with the LMB on MPR views and drag the mouse in the desired arrow direction. Releasing the mouse button pops up an annotation window, where it's possible to add a text. Clicking on OK will add the annotation to the current MPR view

ROI: click with the LMB around the desired area, then click on FINISH POLYGON button to end drawing. The surrounded area data will be extracted (area, perimeter, mean, max, min, std. dev. HU values). Keep SHIFT button (on PC) or CMD button (on Mac) pressed while drawing to design a freeform area.

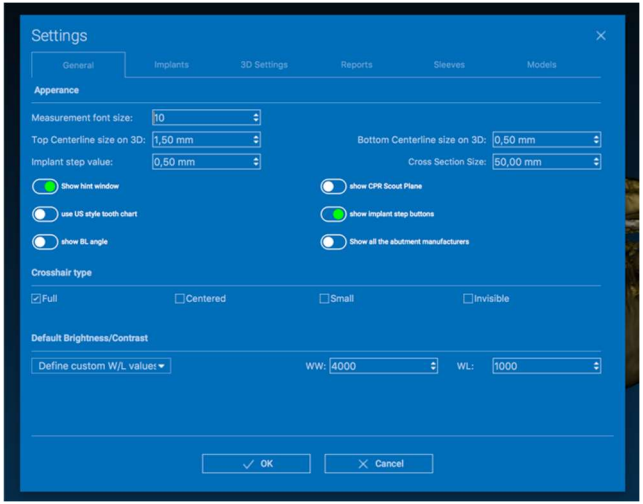
BONE DENSITY: If an implant has been positions, clicking on this button will show the bone density (HU values) around the implant.

CLEAR ALL MEASUREMENTS: deletes all the measurements. To delete just one measure, simply click on the measure value to delete with the RMB and select DELETE OBJECT from the pop-up menu.

6. TOP TOOLBAR COMMON FUNCTIONS

6.2 Settings

Clicking on the SETTINGS icon a pop-up window appears giving the user the possibility to customize the basic GUI features (fonts, colors,…). The commands are self-explanatory.



6. TOP TOOLBAR COMMON FUNCTIONS

6.3 HELP

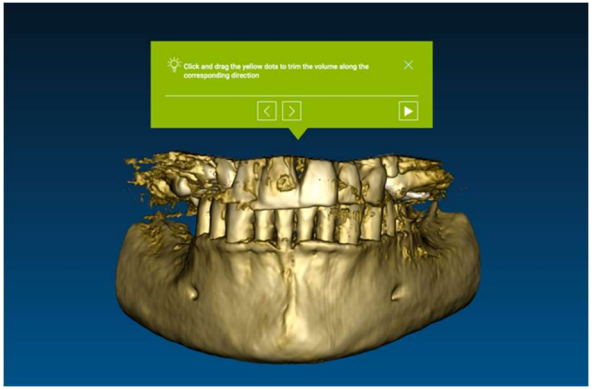
Clicking on the HELP button a step by step interactive guide appears, suggesting the user the most common functions use

- Click on the **PLAY** button to open a video, showing the user how the suggested function works

- Click on **NEXT** button to move to the next hint

- Click on **PREVIOUS** button to go back to the previous hint

- Click on **CLOSE** button to close the HELP system



Following the HINTS will open the next suggested function HINT window.