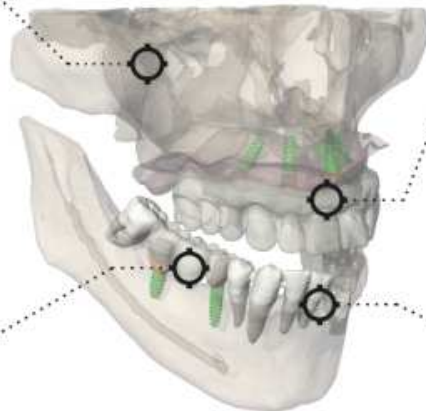


USER GUIDE



3D DIAGNOSIS

IMPLANTS PLANNING &
IMMEDIATE LOADING
PROSTHESIS DESIGN



CROWNS & BRIDGES
MODELLING

SURGICAL GUIDE
DESIGN



Manufactured by



3DIEMME Srl
www.3diemme.it

RG_IFU_EN rev.6 – 03/2022

 **RealGUIDE™**
UNIVERSAL OPEN SYSTEM

CE
0051

Certificate n. 003/MDR



510(k) number: K173041

Owner number: 10059505

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: 5.1

Version: APP, PRO, DESIGN, START, CAD, CAD+

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.

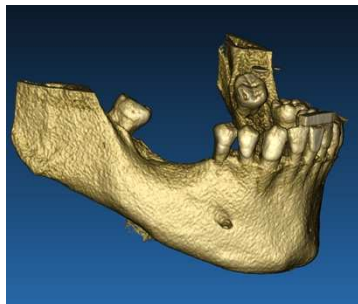
RealGUIDE Graphic Station is meant to be a multiplatform application, running on PC, MAC and mobile devices (not provided by 3DIEMME).

Intended Use

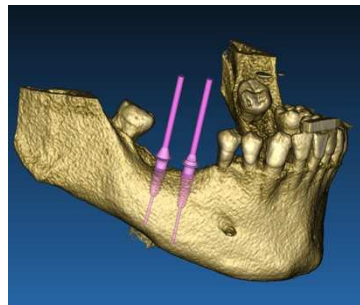
The device is a software to be used in the dental field by trained professionals to support diagnosis, to plan virtual implants and surgeries on 2D/3D reconstructions, to design surgical guides and prosthetic modelling, and manage the endodontic, orthodontic and orthognathic treatments connected to the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

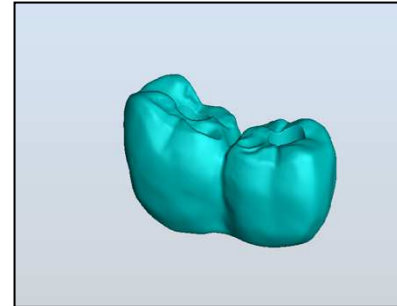
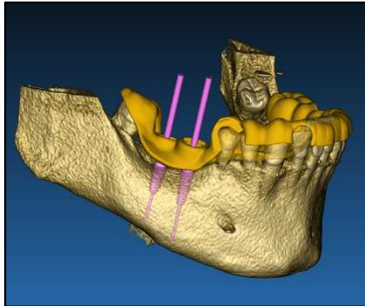


3D reconstruction from DICOM example



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

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: With vRAM of at least 3GB

Screen resolution: 1920 x 1080 for optimal visualization

PC INSTALLATION:

OS: Windows 7 (64 bit), Windows 10

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

MAC INSTALLATION

Macbook PRO 15 ”

iMac

OS: macOS (10.15 Catalina, 11 Big Sur, 12 Monterey)

IOS INSTALLATION

iPhone X 64GB, iPad Pro 12.9” (3rd gen) 64GB

iOS 12

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 B" 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 guarantee 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.

Version identification

The present document applies to the following versions:

Version	UDI-DI
RealGUIDE APP	8050038830003
RealGUIDE PRO	8050038830010
RealGUIDE DESIGN	8050038830027
RealGUIDE START	8050038830034
RealGUIDE CAD	8050038830041
RealGUIDE CAD+	8050038830058

Symbol glossary definition

Symbol	Description
	Manufacturer
 eIFU	Consult instructions for use
	Medical device
	CE Marking of Conformity
	Caution: Federal law restricts this device to sale by or on the order of a dentist (USA market)

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

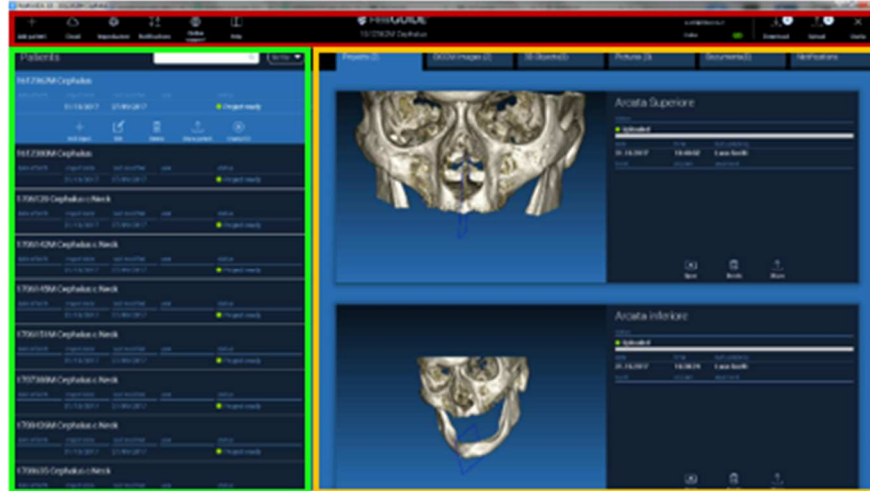
1.1. Home_page

TOOLBAR

PATIENT DATABASE

PATIENT TOOLBAR:

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



1. GETTING STARTED

1.3 New Patient Folder

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.

A screenshot of a "NEW PATIENT" dialog box. The title bar is blue with "NEW PATIENT" and an information icon. The form has three input fields: "Name:" with a white text box, "Surname:" with a white text box, and "Date of birth (DD/MM/YYYY):" with a white text box containing two slashes. Below these is a "Notes:" label and a large white text area. At the bottom are two buttons: "OK" and "Cancel".

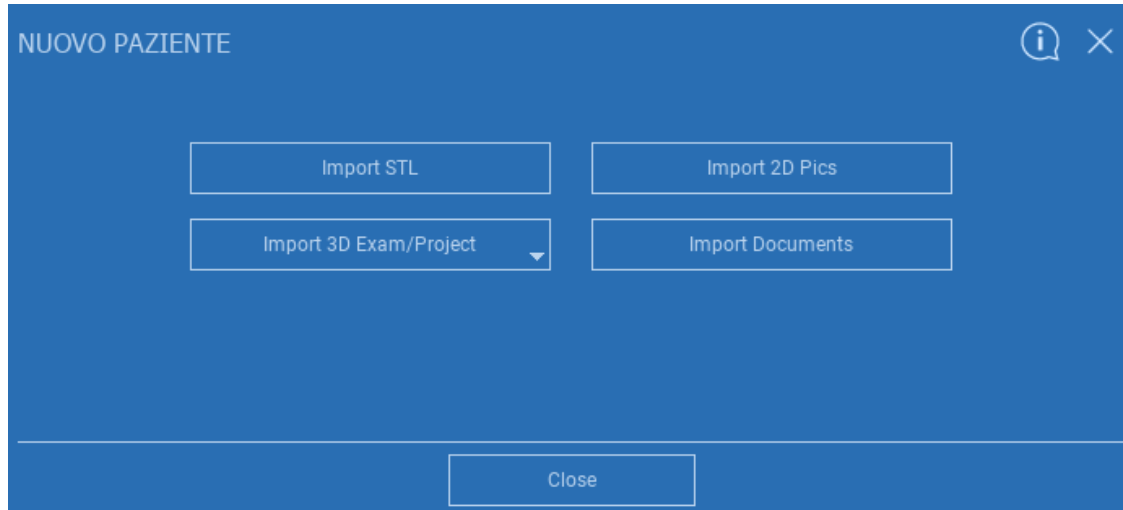
1. GETTING STARTED

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, Evobite 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.

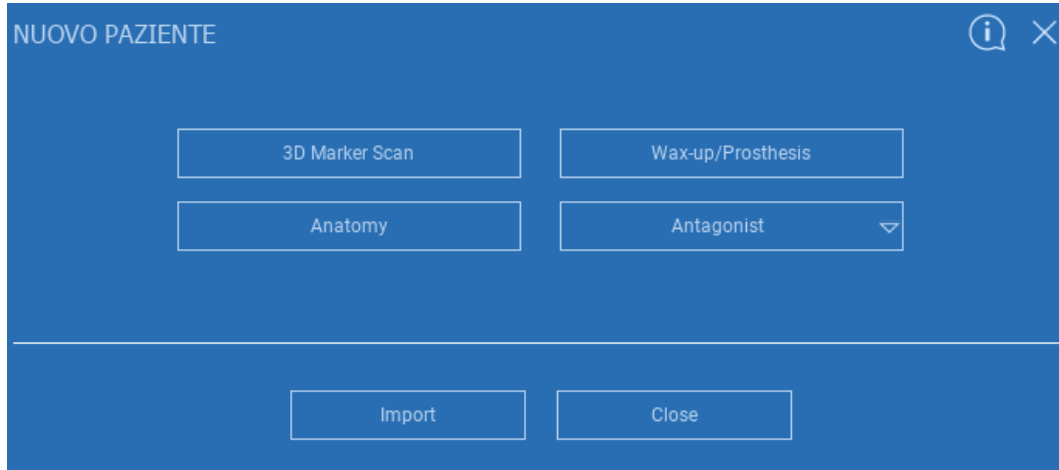


1.3 New Patient Folder

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.



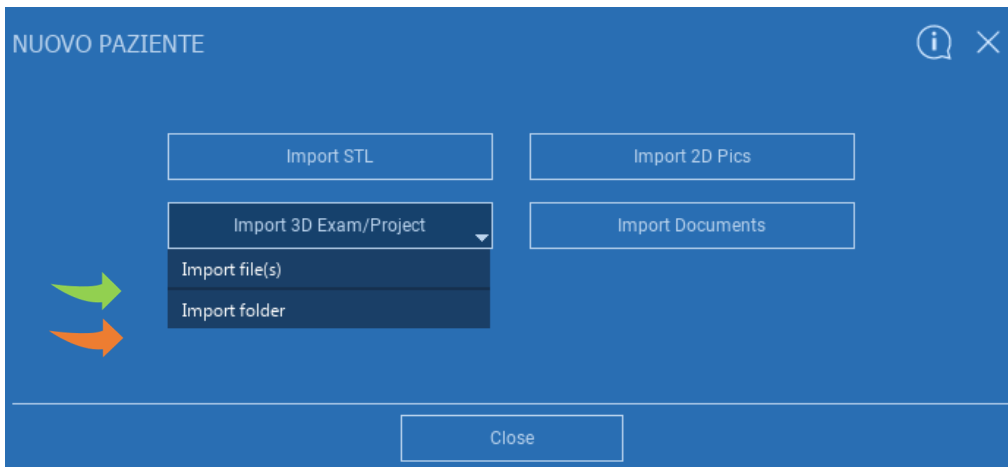
Pay attention! During this step you are only connecting STL files to the patient they belong to. If you are interested in the matching procedure go to Paragraph 2.6.

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.



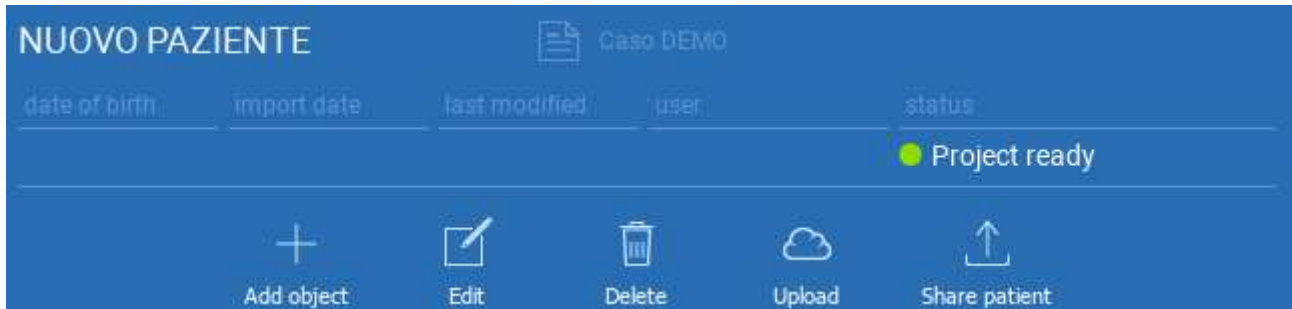
Click on **OPEN** to open the DICOM dataset visualization and diagnosis.

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.



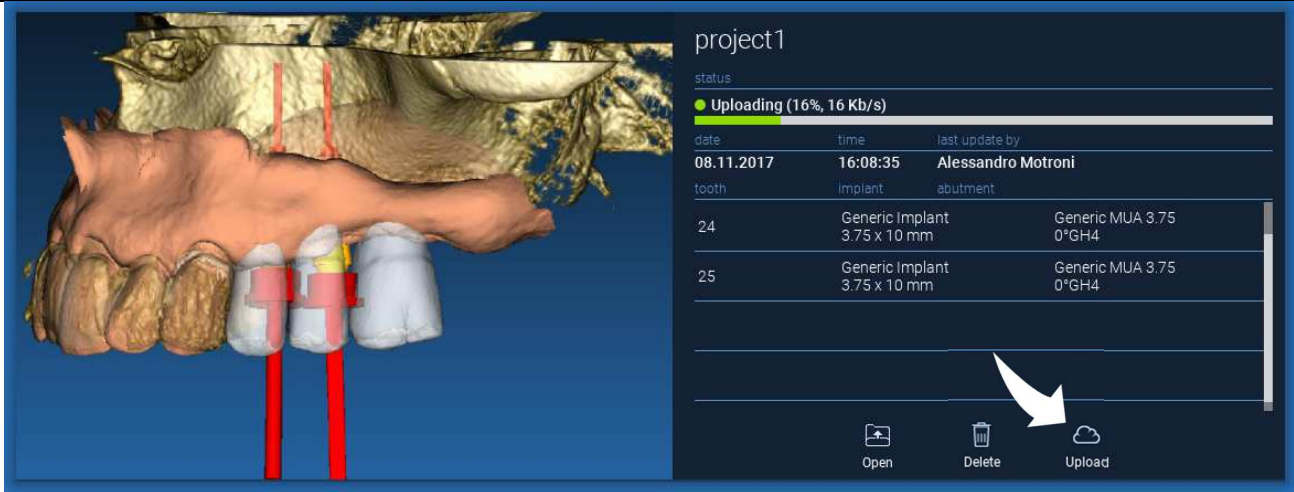
Click on **EDIT** to modify the patient data (Name, Surname, Date of birth, etc).



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".



The screenshot displays a 3D dental model on the left and a project management panel on the right. The model shows a cross-section of a human jaw with several teeth and two dental implants. The implants are connected to a pink abutment structure. The project panel on the right is titled "project1" and shows a progress bar for "Uploading (16%, 16 Kb/s)". Below the progress bar is a table with columns for "date", "time", and "last update by". The table contains two rows of data for teeth 24 and 25. At the bottom of the panel, there are three icons: "Open", "Delete", and "Upload". A white arrow points to the "Upload" icon.

date	time	last update by
08.11.2017	16:08:35	Alessandro Motroni
tooth	Implant	abutment
24	Generic Implant 3.75 x 10 mm	Generic MUA 3.75 0°GH4
25	Generic Implant 3.75 x 10 mm	Generic MUA 3.75 0°GH4

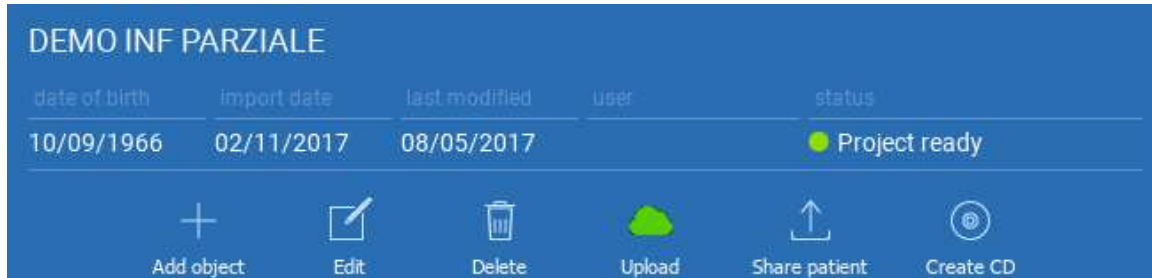


Due to security policy, DICOM images can be only shared in the form of PROJECT. Open DICOM series you want to share and then click on **SAVE** on the top left of the new window. A new project will be ready to be uploaded.

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.



date of birth	import date	last modified	user	status
10/09/1966	02/11/2017	08/05/2017		● Project ready

Toolbar actions:

- Add object
- Edit
- Delete
- Upload
- Share patient
- Create CD



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

1. GETTING STARTED

1.5 CLOUD Patient Storage

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.

The screenshot shows the 'CLOUD' icon in the toolbar highlighted in green. The main interface displays a list of patients under the heading 'Pazienti'. The first patient is 'DEMO INF PARZIALE (condiviso con)'. Below this heading is a table with the following data:

Data di nascita	Data importazione	Ultima modifica	Utente	Status
10/09/1966	02/11/2017	05/12/2017	Luca Scotti	● Progetto pronto

Below the table is a toolbar with the following icons and labels:

- Aggiungi Oggetto
- Modifica
- Cancella
- Upload
- Condividi Paziente
- Crea CD

Two other patients are listed below:

- 1706142M Cephalus c Neck (condiviso)
- 1708639 TT Cephalus c Neck (condiviso)

Each of these patients has a table with the following data:

Data di nascita	Data importazione	Ultima modifica	Utente	Status
30/11/0002	31/10/2017	27/11/2017	Luca Scotti	● Progetto pronto

The second table also has the following data:

Data di nascita	Data importazione	Ultima modifica	Utente	Status
30/11/0002	31/10/2017	02/11/2017	Luca Scotti	● Progetto pronto

1. GETTING STARTED

1.6 Sharing

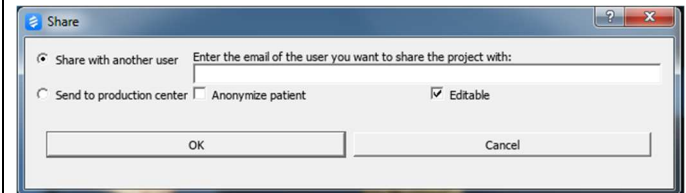
On the CLOUD Patient Storage it is possible to select the files to share by clicking on **SHARE**.

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.



1. GETTING STARTED

1.6 Sharing

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.

The screenshot shows a patient record for "DEMO INF PARZIALE" which is shared with Alessandro Motroni and Angelo Tocchetti. Below the patient name is a table with columns for date of birth, import date, last modified, user, and status. The status is "Ready for upload". At the bottom of the interface is a toolbar with icons for Add object, Edit, Delete, Upload, Share patient, and Create CD.

date of birth	import date	last modified	user	status
10/09/1966	02/11/2017	06/12/2017	Luca Scotti	● Ready for upload

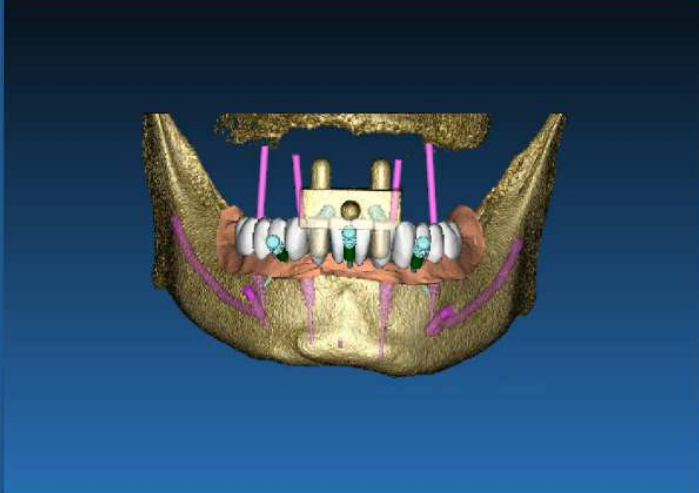
Toolbar actions:

- Add object
- Edit
- Delete
- Upload
- Share patient
- Create CD

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



18-10-17__2_no_pins

status

● Ready for download

date	time	last update by
18.10.2017	15:14:31	Angelo Tocchetti
tooth	implant	abutment
46	NobelActive® NP 3.5 x 8.5 mm	Generic MUA 3.00 17°GH2
36	NobelActive® NP 3.5 x 8.5 mm	Generic MUA 3.00 17°GH2
43	NobelActive® NP 3.5 x 10 mm	Generic MUA 3.00 0°GH2
33	NobelActive® NP 3.5 x 10 mm	Generic MUA 3.00 0°GH2

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

Update available

Progetto INF

status

● Ready for download

date	time	last update by	tooth	implant	abutment
02.11.2017	09:45:14	Luca Scotti			

Open Delete Update

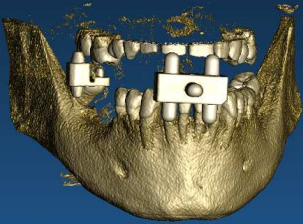


ALWAYS CONSIDER THE PROJECT LAST UPDATE DATE AND THE CORRESPONDENT USER NAME THAT MODIFIED THE PROJECT BEFORE SHARING IT WITH OTHER USERS OR THE PRODUCTION CENTER.



2. IMPLANT PLANNING

Basic Commands



Left mouse button	3D ROTATION
Right mouse button + forward	ZOOM IN
Right mouse button + back	ZOOM OUT
SHIFT + Left mouse button	PAN
CTRL + Left mouse button	W/L SETTING

Superiore
Inferiore
Sinistra
Destra
Frontale
Posteriore

STANDARD 3D VIEWS

Modifica gli oggetti in 3D trascinandoli

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.

The screenshot displays a software interface with a dark blue theme. At the top, there are tabs for 'Patients', 'Projects (2)', 'DICOM Images (1)', '3D Objects(2)', and 'Pictures (1)'. The 'Patients' tab is active, showing a list of patients. The first two patients are labeled 'DEMO INF PARZIALE' and 'DEMO SUP PARZIALE', both with a status of 'Project ready'. Below the list is a toolbar with icons for 'Add object', 'Edit', 'Delete', 'Upload', 'Share patient', and 'Create CD'. The third patient is labeled 'NUOVO PAZIENTE' with a 'Caso DEMO' tag. The right panel shows details for a selected CT scan, including technical parameters like Position, Thickness, Dimensions, Pixel Dimensions, Direction X, Y, and Instance number. A thumbnail image of the CT scan is displayed. At the bottom of the right panel, there are three buttons: 'Open', 'Location', and 'Delete'. A red arrow points to the 'Open' button.

date of birth	import date	last modified	user	status
10/09/1966	02/11/2017	08/05/2017		Project ready
10/09/1966	02/11/2017	08/05/2017		Project ready

CT,
Images: 256
1 of 256

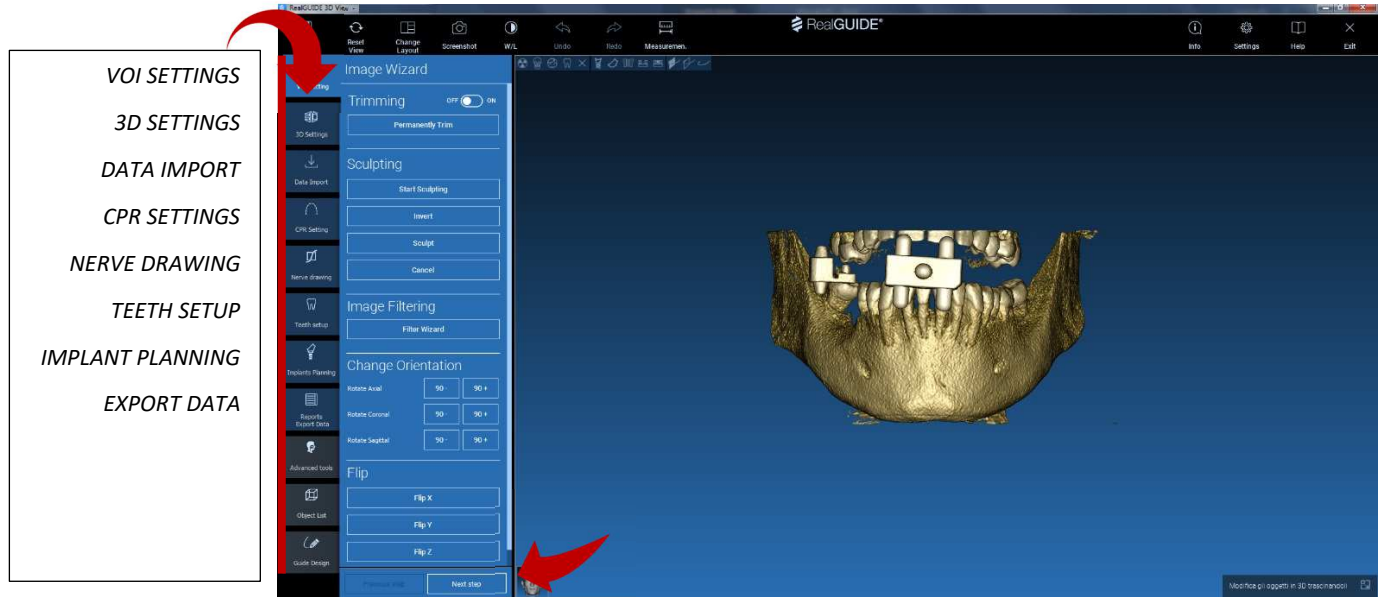
Position: -312.0, -312.0, 100.0
Thickness: 0.250
Dimensions: 624x624
Pixel Dimensions: 0.250x0.250
Direction X: 1, 0, 0
Direction Y: 0, 1, 0
Instance number: 1
Manufacturer: Imaging Sciences International
Manufacturer model name: 9-17

Open Location Delete

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.



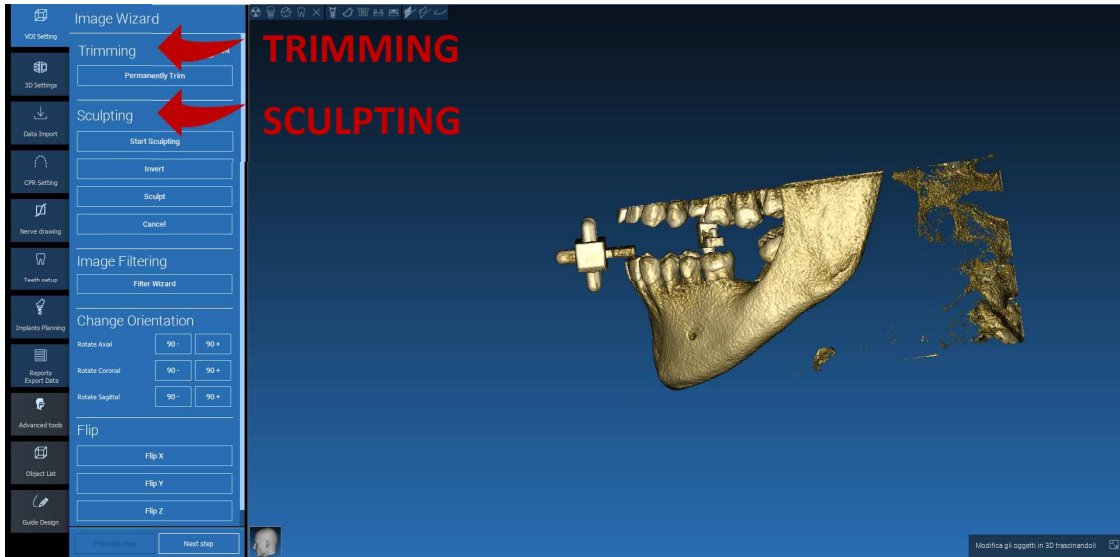
2. IMPLANT PLANNING

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

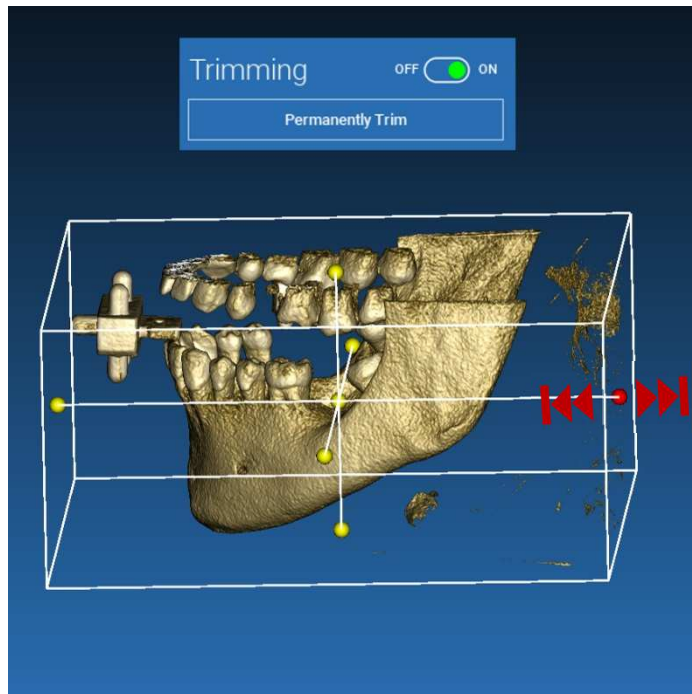
SCULPTING: custom volume sculpting.





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.

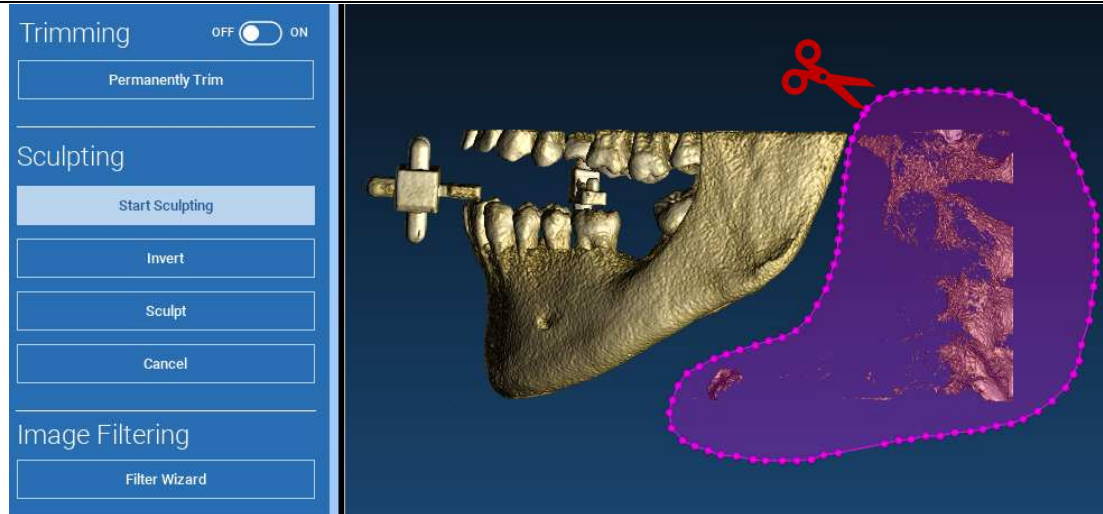
Click on the yellow spheres and move the mouse to restrict/expand the reconstruction volume. Click on **PERMANENTLY TRIM** to confirm.



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 maintain the area selected and remove the rest. If you want to ignore the selection click on **CANCEL**.





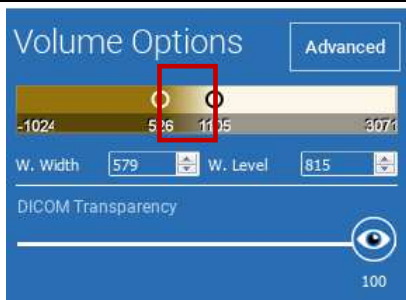
2. IMPLANT PLANNING

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.



Data Import

2. IMPLANT PLANNING

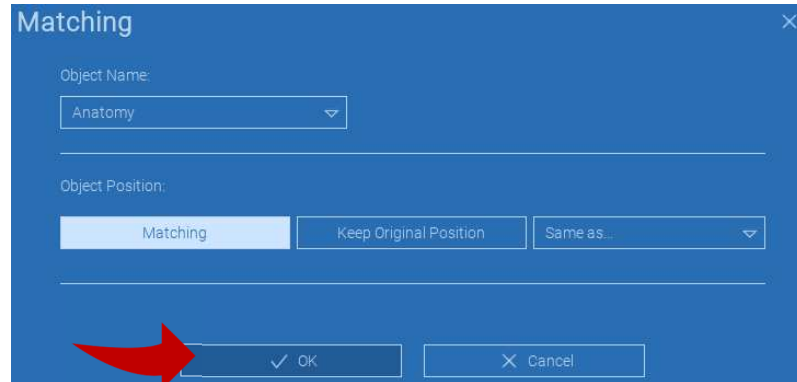
2.5 Data import



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**.

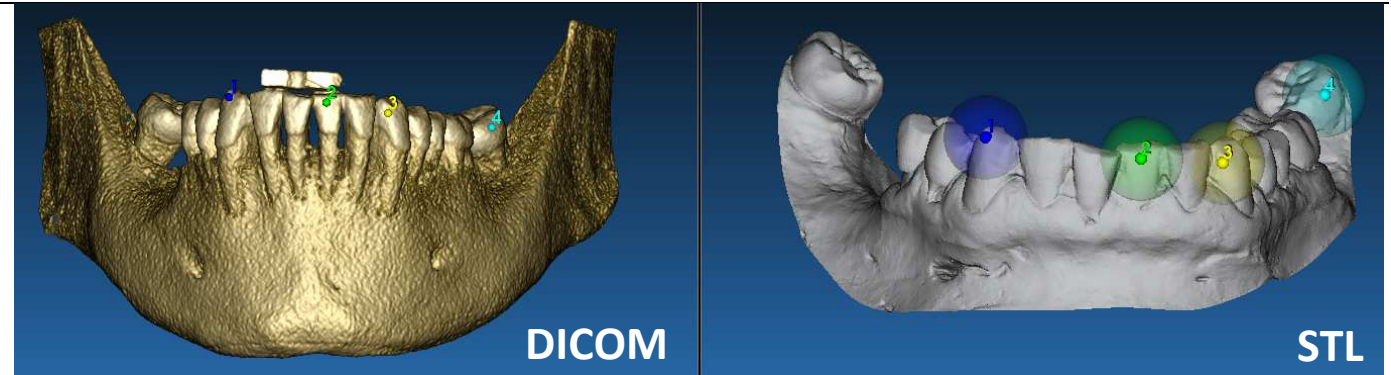
In the new popup window (see below), check if the MATCHING button is highlighted and set the correct object name of the file to be aligned; then click on **OK** to start the procedure.



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.

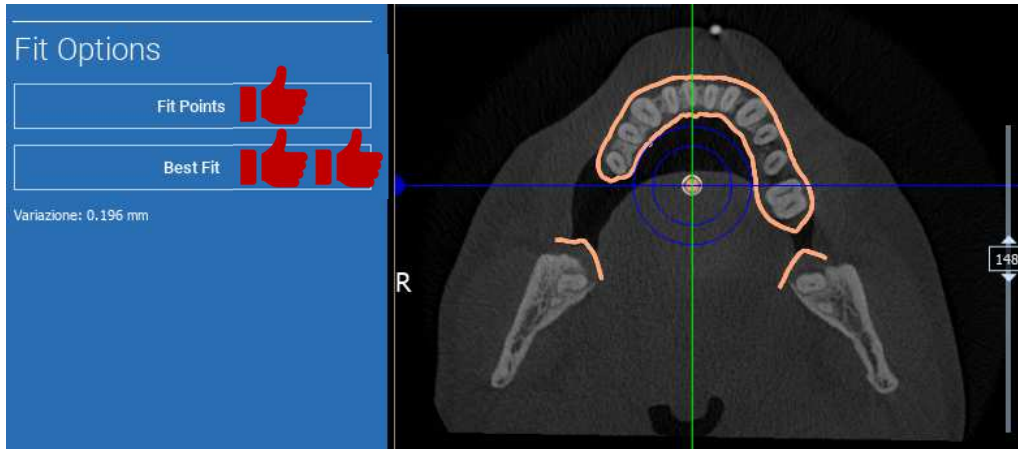


It's very important to choose easily identifiable areas on both 3D objects. Consider for example the evobite 3D marker surfaces, as well as the stable teeth surfaces (if no metal structure is present). Don't take into account areas with high scattering level, being less reliable.

2. IMPLANT PLANNING

2.6 Matching

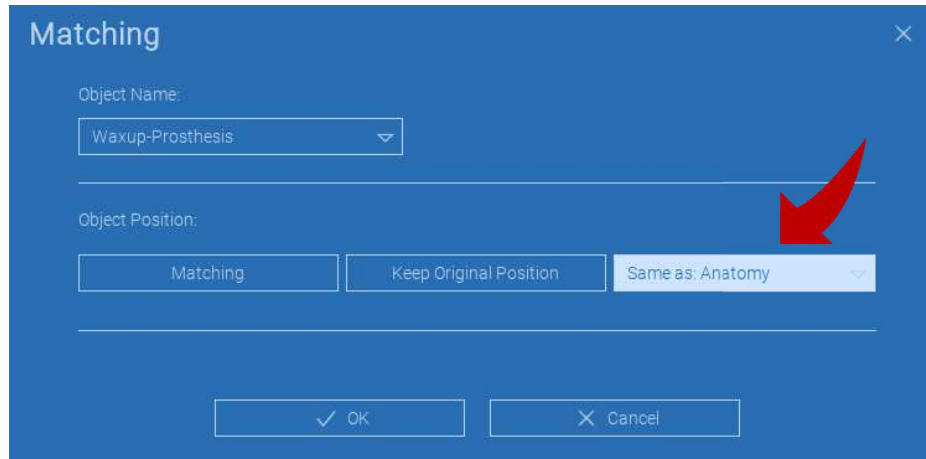
After selecting the reference points click on **FIT POINTS**. The software will perform a basic, rigid STL file positioning based on the selected common points. In order to improve the superposition precision click on **BEST FIT**. Thanks to a proprietary best fitting algorithm the software minimizes 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.

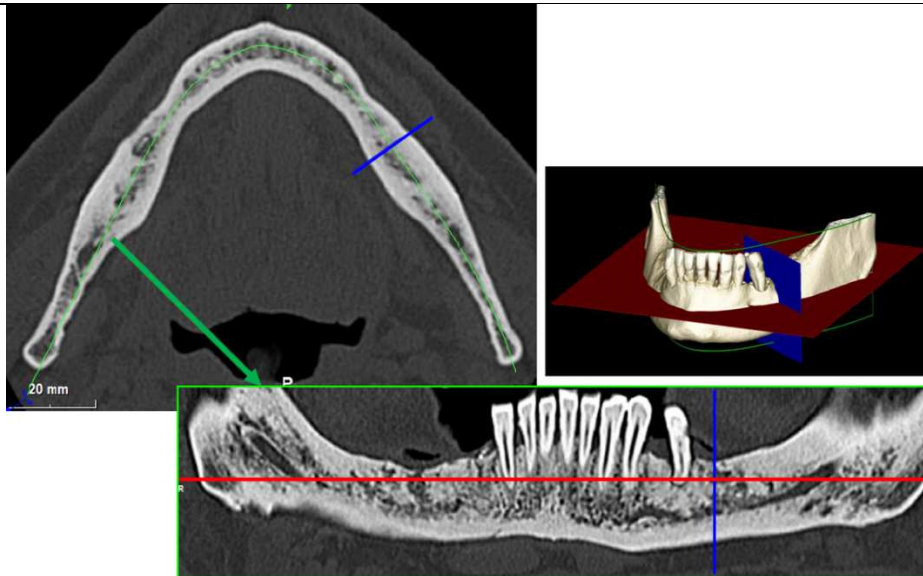


The most important requirement for the lab is to scan and keep all the STL files in the same reference system!

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.

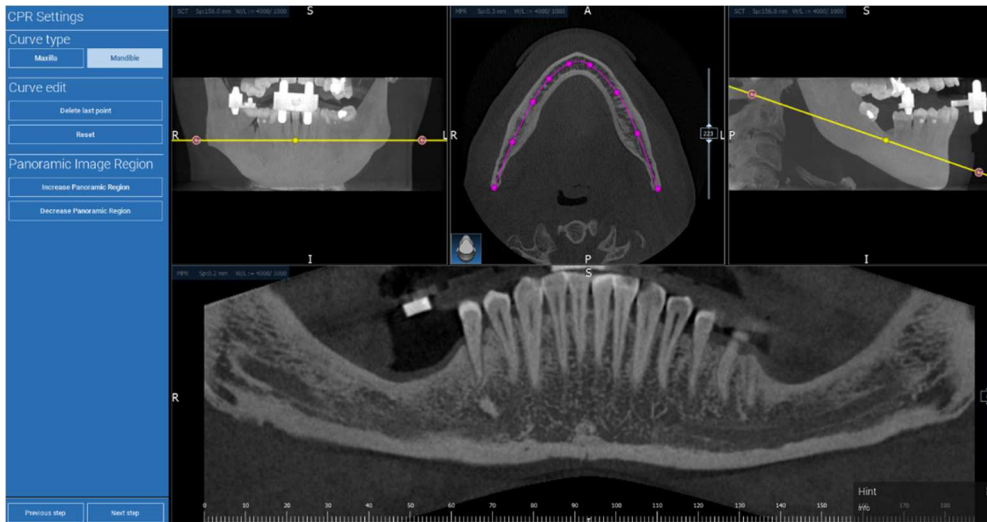




2. IMPLANT PLANNING

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.

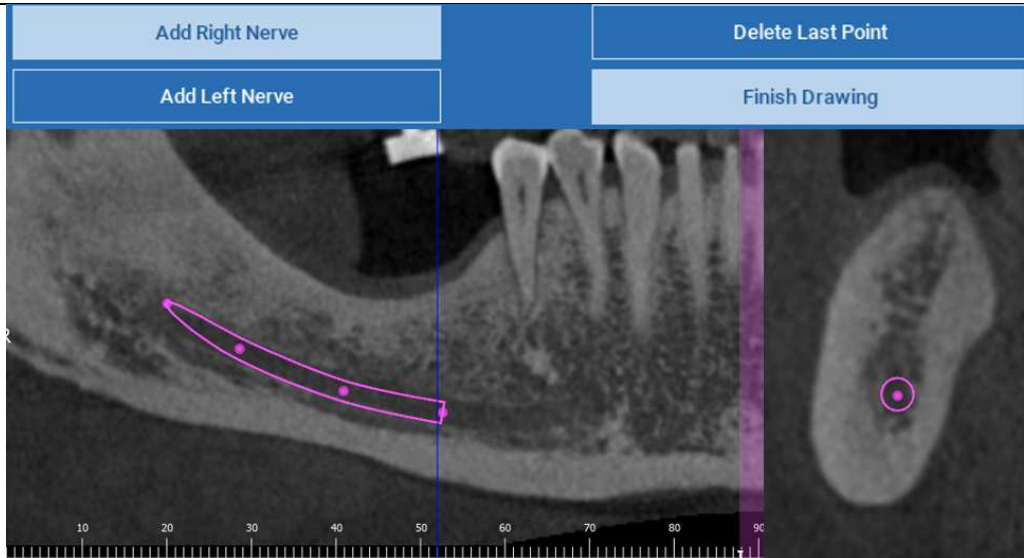


Nerve drawing

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.



Teeth setup

2. IMPLANT PLANNING

2.9 Teeth Setup

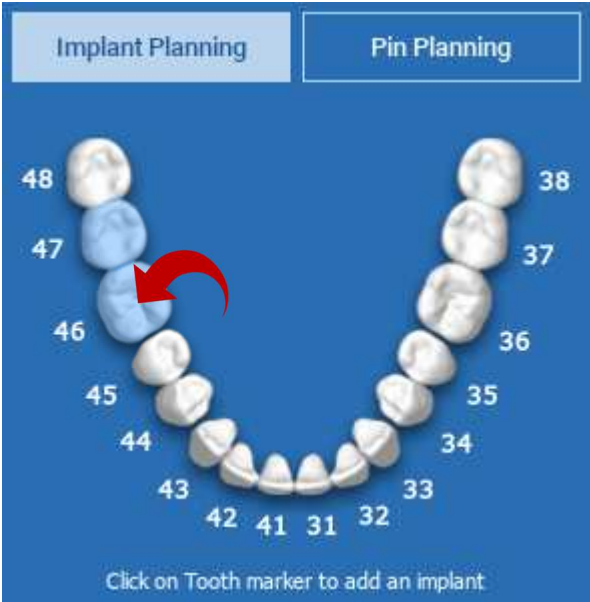
Before positioning the implants it is necessary to identify all the elements to rehabilitate. Click on the desired element then select the correspondent area (digital wax-up or edentulous areas) on the 3D reconstruction. You can also insert a virtual wax-up by clicking on **ADD** and adjust its volume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



2. IMPLANT PLANNING

2.10 Implant positioning

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.

STL Library Last Selected

Implant // 3Diamma • Generic Implant • 3.75 x 9.5 mm

Manufacturer	Model	Size
3DScenex	Generic Implant	3.75 x 7.5 mm
BICON		3.75 x 8 mm
implafavourites		3.75 x 8.5 mm
AS Dent		3.75 x 9 mm
Allmed		3.75 x 9.5 mm
AlphaBio		3.75 x 10 mm
Anonymous		3.75 x 10.5 mm
		3.75 x 11 mm

Abutment // 3Diamma • Generic MIA 3.75 • 0°GH2

Manufacturer	Model	Size
3DScenex	Generic MIA 3.75	0°GH2
		0°GH4
		0°GH6
		10°GH2
		10°GH4
		10°GH6
		15°GH2
		15°GH4

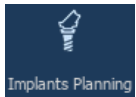
Sleeve

Manufacturer	Model
UNASSIGNED	RealGUIDE CAD 2015 New BTA
3DScenex	RealGUIDE CAD 2015 New Dental Tech
AZ Implant	RealGUIDE CAD 2015 New Immediate L
Allmed	RealGUIDE CAD 2015 New J-Dental Care
Asthopar	RealGUIDE CAD 2015 New Prodent
Attra	RealGUIDE CAD 2015 New Thomsen
B&B	RealGUIDE CAD 2015 New Winax
Bicon	RealGUIDE CAD 2015 New Zimmar

Implant Review

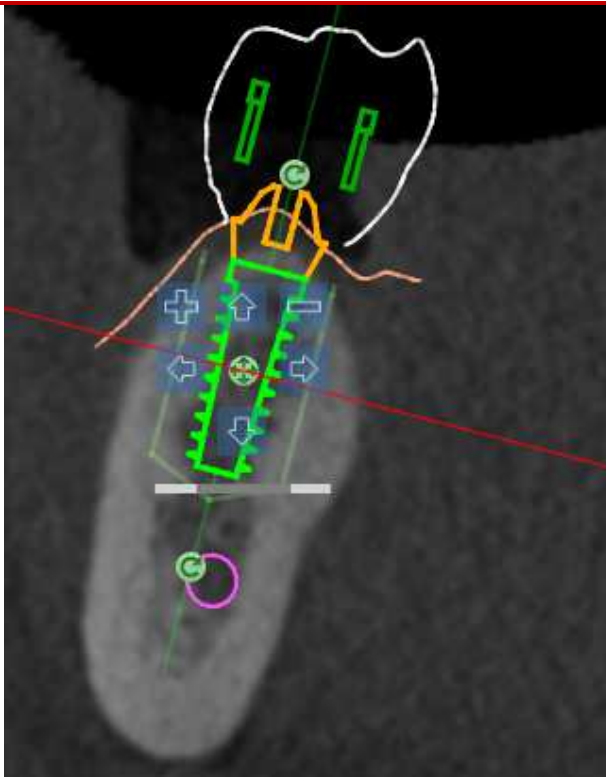
CAD/CAM OFF ON

Cancel Apply





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.

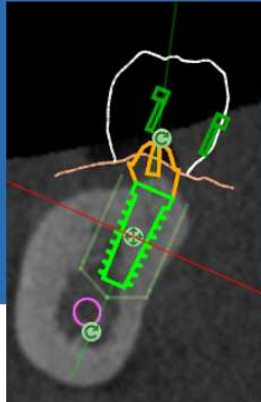
2.10 Implant positioning

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.

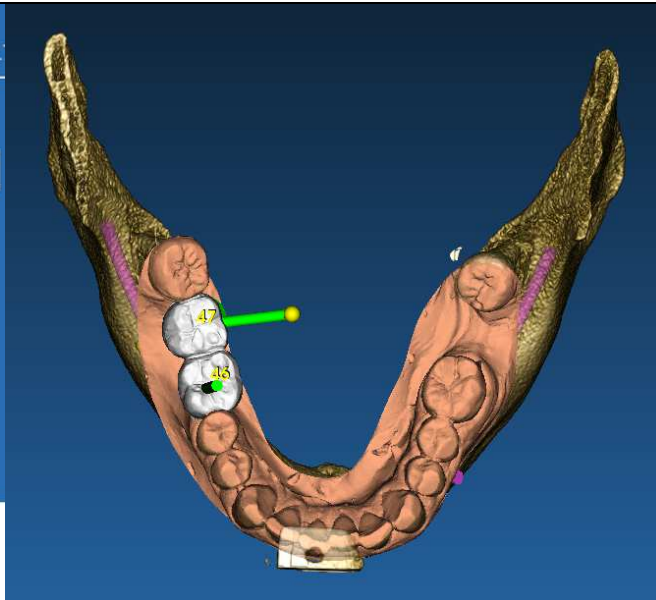
Abutment //3Diemme > Generic MUA 3.75

Manufacturer	Model
3Diemme	Generic MUA 3.75



Sizes

- 17°GH2
- 17°GH4
- 17°GH6
- 20°GH2
- 20°GH4
- 20°GH6
- 25°GH2
- 25°GH4

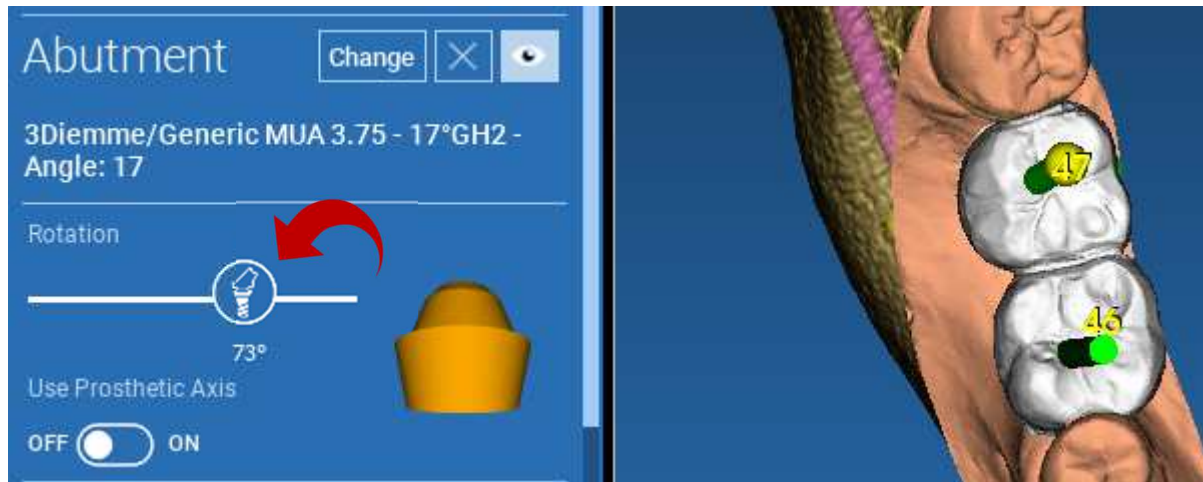




2.10 Implant positioning

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.



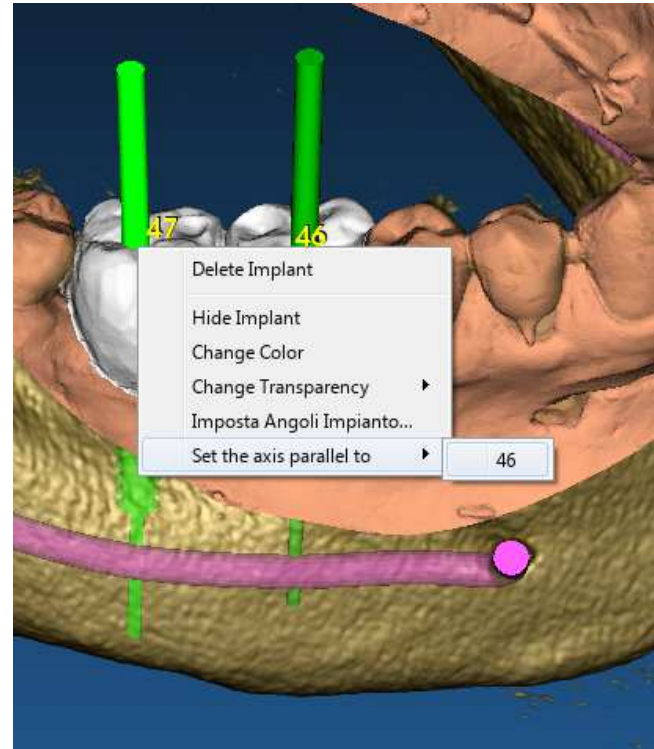
2.10 Implant positioning

2.9.5 PROSTHETIC AXES PARALLELISM

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.



2.10 Implant positioning

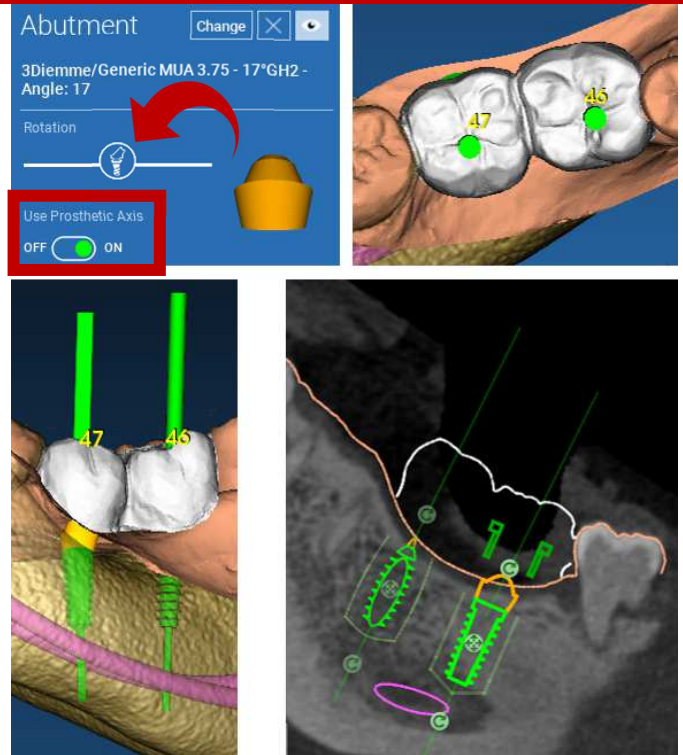
2.9.5 PROSTHETIC AXES PARALLELISM

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.



Reports / Export Data

Report

- Implant report
- Custom report

Export

- Export Visible Objects
- Export STL files
- Export Outline
- Export for CAD/CAM
- Export for PlasticAD
- Export suggested assembly

Share

- Share project
- Cloud share

Previous step

Hint

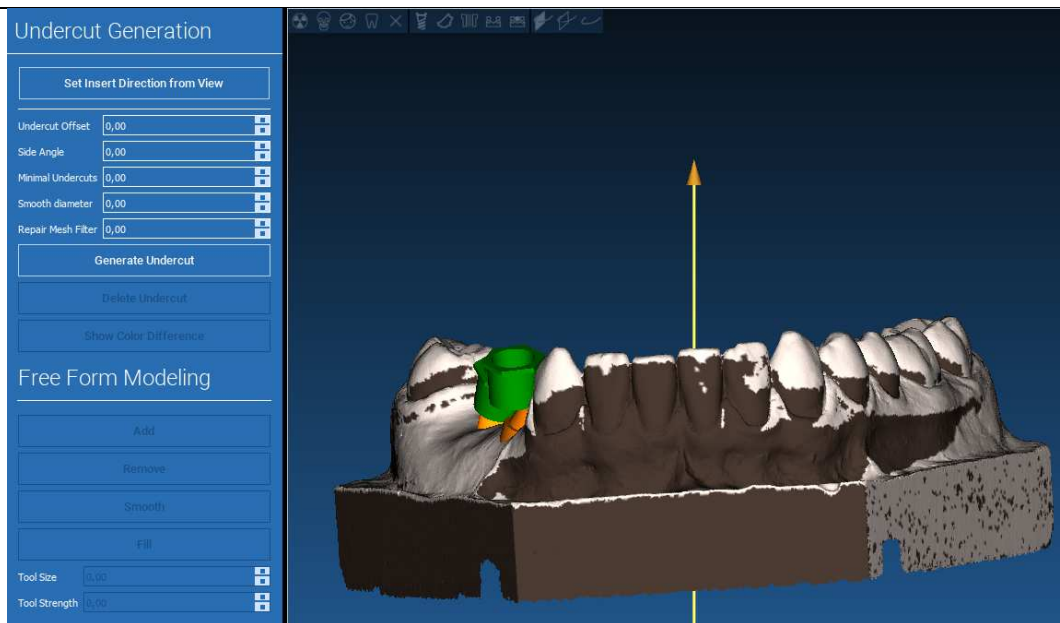
- Left Button = Rotate
- Right Button = Zoom
- Middle Button = Pan
- Left Click = Find point in 2D
- Right Click = Set Center



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.

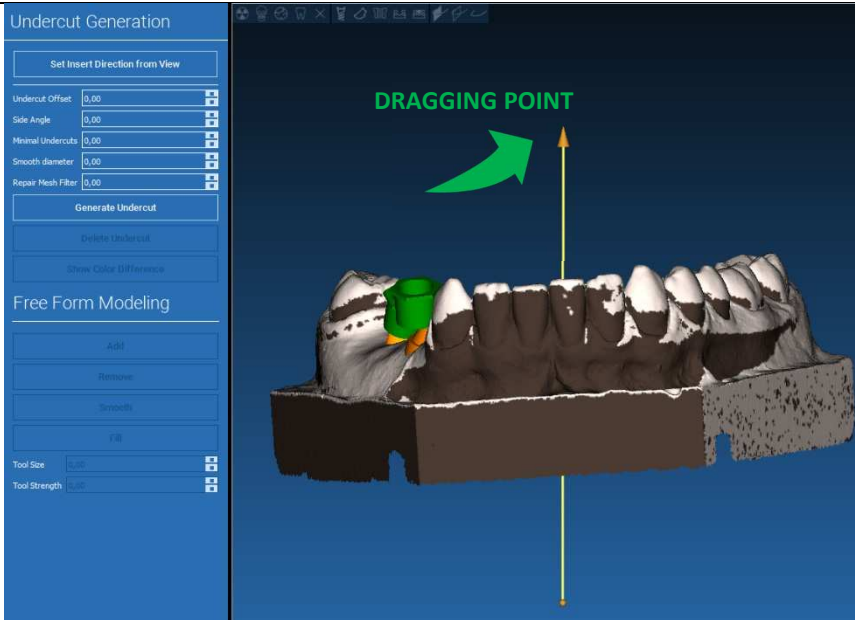




3.2 Undercut blockout setup

3.2.1 INSERTION DIRECTION – CONTROL ARROW

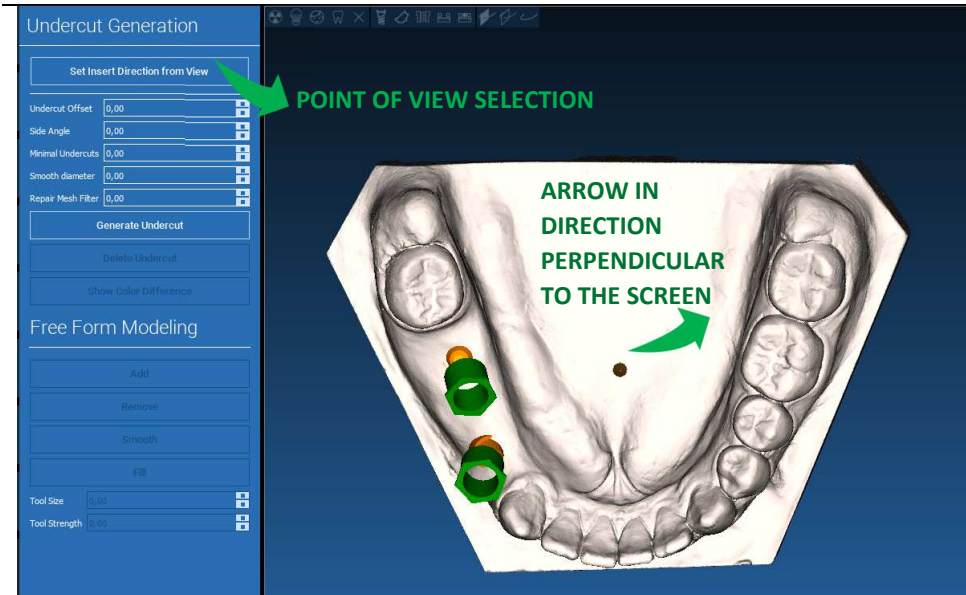
The arrow visualized at model center defines an insertion axis direction calculated automatically in relation to the model shape. To modify this insertion direction and the generated shadow areas (brown color) drag the arrow point in the desired direction.



3.2 Undercut blockout setup

3.2.2 INSERTION DIRECTION – VIEW DIRECTION

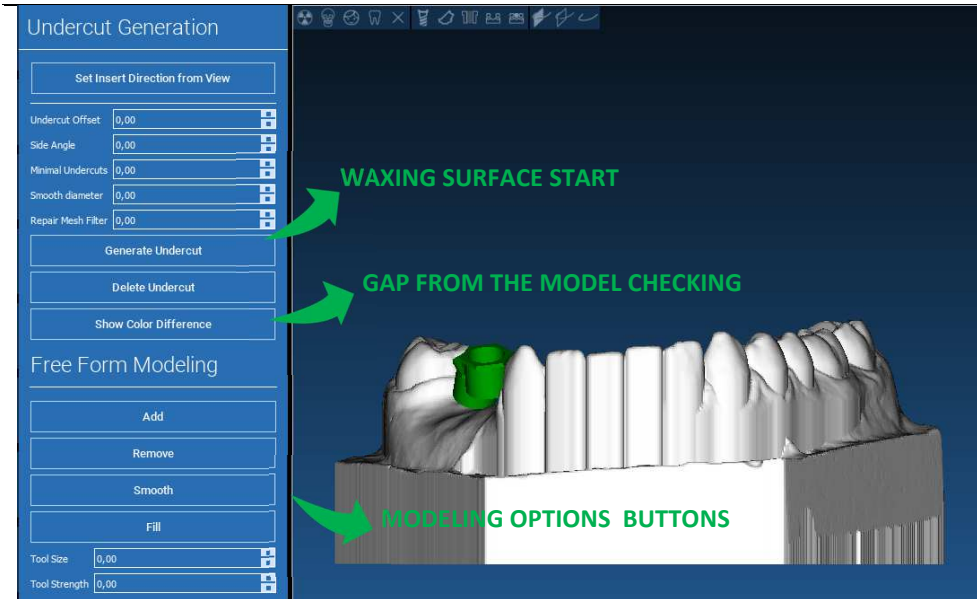
It's possible to define the insertion axis direction also moving the model in a desired point of view. By clicking on **SET DIRECTION FROM VIEW** button, the arrow axis direction will be positioned perpendicular to the screen surface.



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.



Guide Design

3. SURGICAL GUIDE DESIGN

3.2.1 Tracing and construction parameters

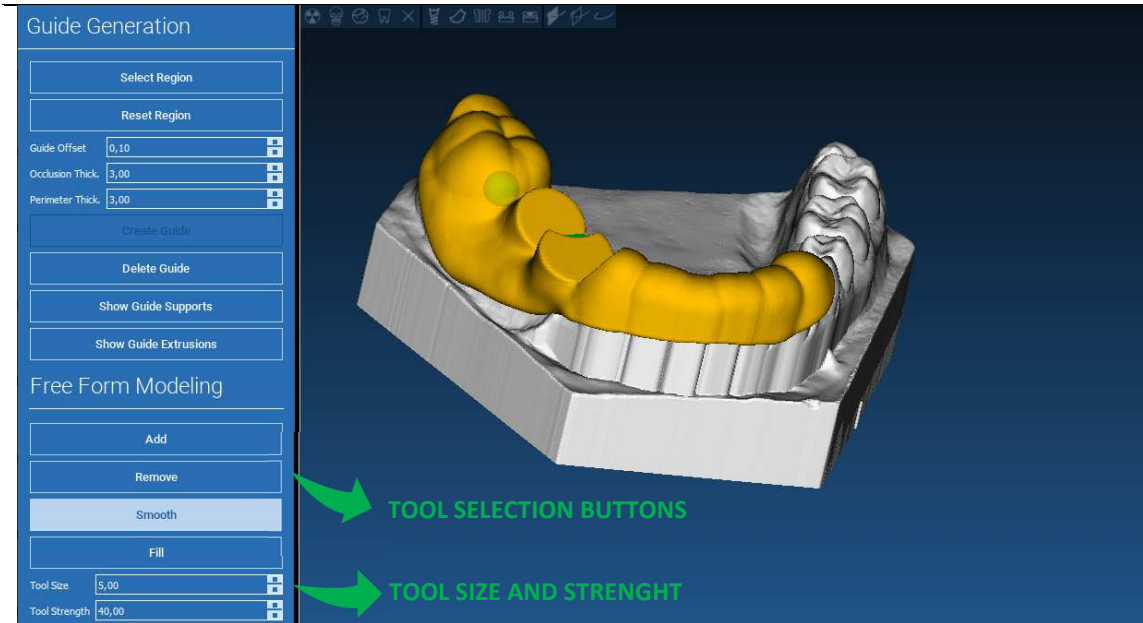
Trace the outer guide margin surrounding an area on the model: the command is active by default. A control point is added with any mouse click. It's not necessary to close the area loop, it's enough to position the last point close to the first one. Then check and define the fitting tolerance, the occlusal 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

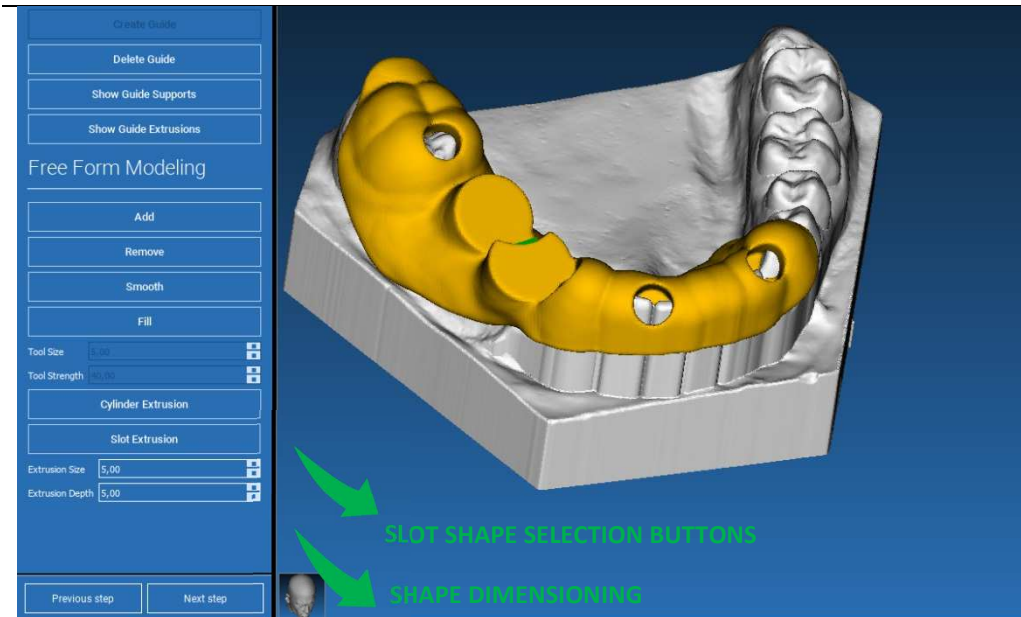
Once the guide volume has been created, the modeling tools become active. They permit to add/remove material, to smooth the surface and to fill in the depressions. Normally they are used to smooth the borders and to reinforce areas with deep depressions.



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.

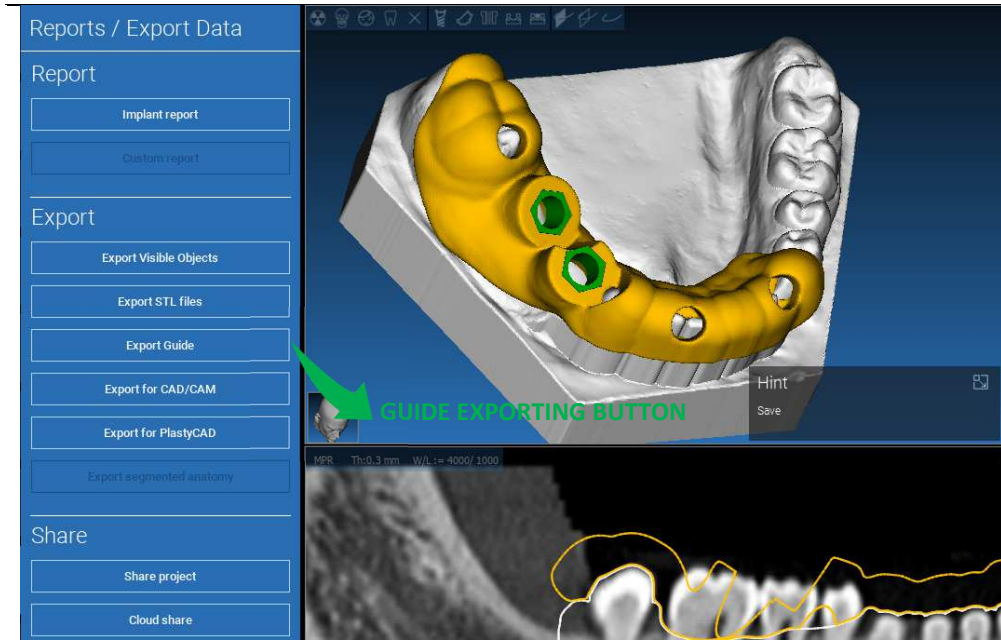


Guide Design

3. SURGICAL GUIDE DESIGN

3.2.4 Finalization

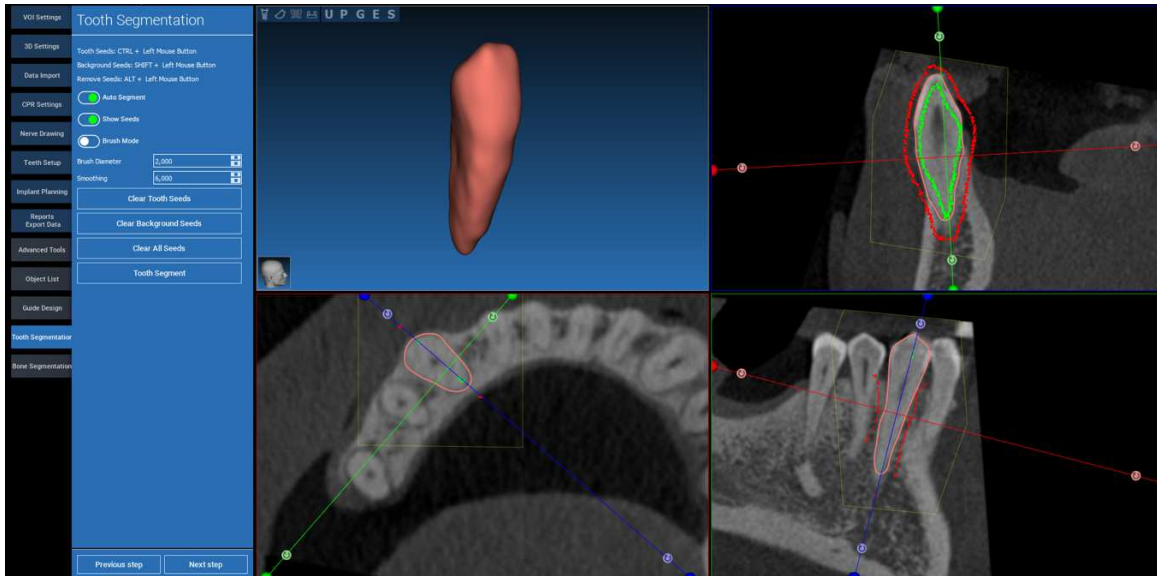
By clicking on **NEXT STEP** button the guide generation will be finalized by the sleeve seats construction. On the side menu the **REPORTS / EXPORT DATA** tab will appear, allowing the STL file export operations.



4. SEGMENTATION

4.1 Tooth segmentation

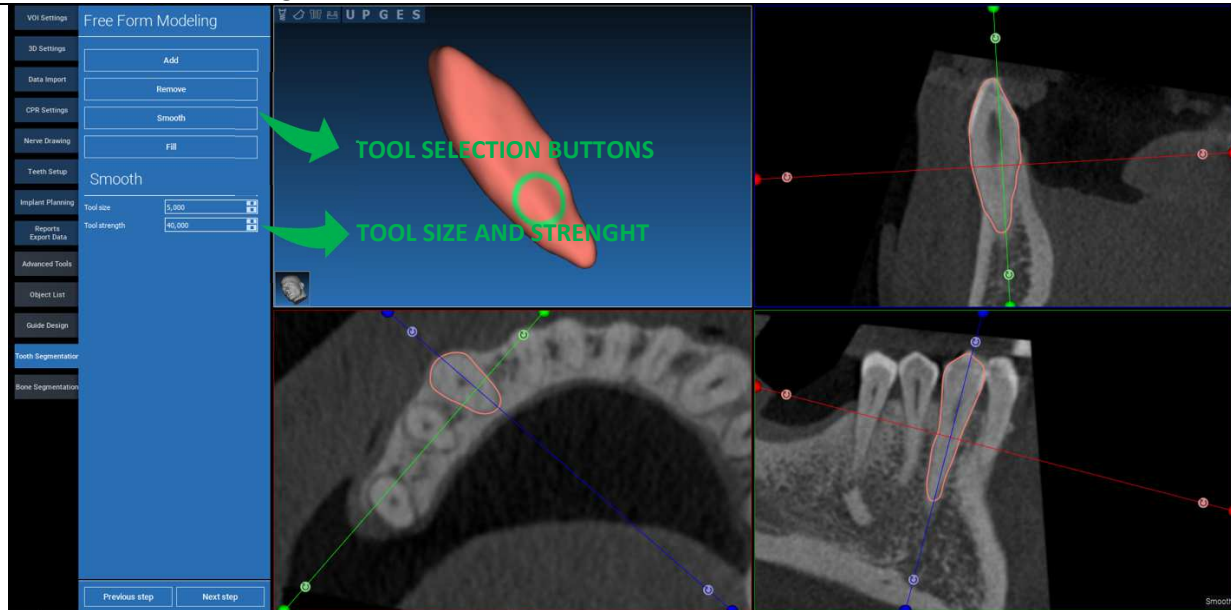
Activate BRUSH mode and manually trace the desired tooth contour keeping the LMB pressed. If AUTO SEGMENT is ON the tooth is extracted as soon as the LMB is released, otherwise click on TOOTH SEGMENT button. Edit the seeds to refine the tooth shape (CTRL+LMB to add seeds, SHIFT+LMB to add background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



4. SEGMENTATION

4.1 Tooth segmentation

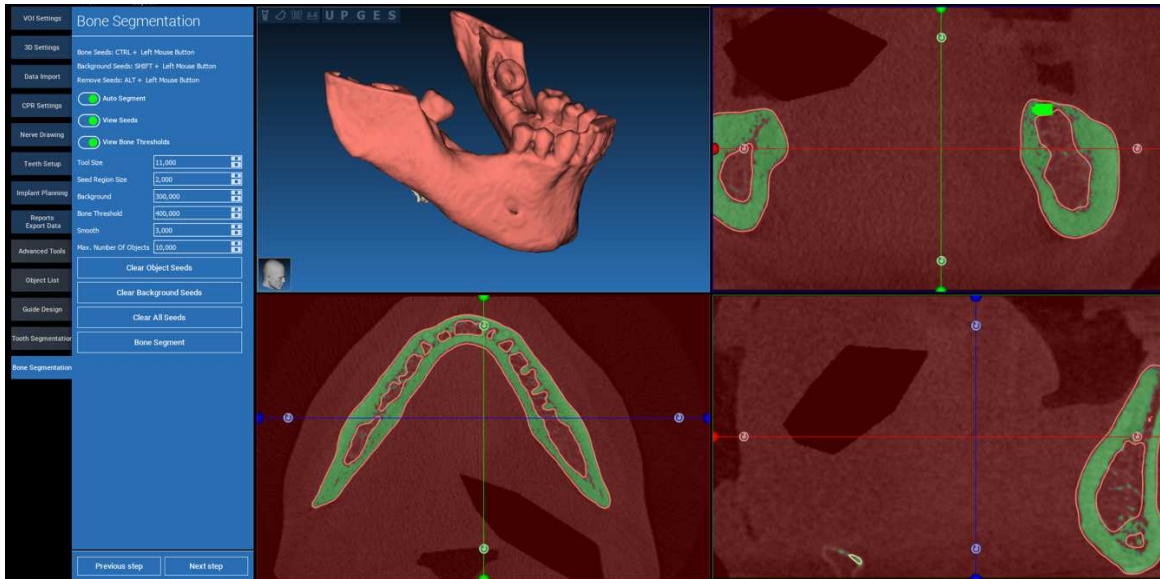
Use the FREEFORM modelling tools to further refine the tooth surface



4. SEGMENTATION

4.2 Bone segmentation

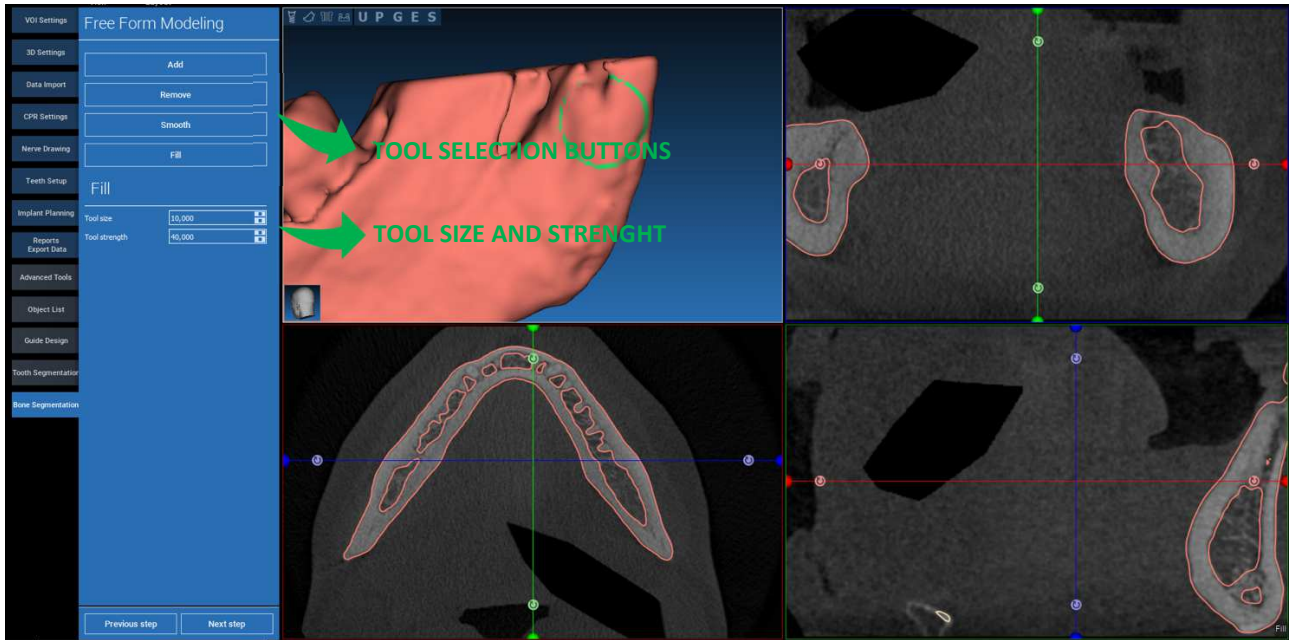
Set the bone and background thresholds. If AUTO SEGMENT is ON, the bone is extracted as soon as the LMB is released, otherwise click on BONE SEGMENT button. Edit the seeds to refine the bone shape (CTRL+LMB to add seeds, SHIFT+LMB to add background seeds)



4. SEGMENTATION

4.2 Bone segmentation

Use the FREEFORM modelling tools to further refine the bone surface

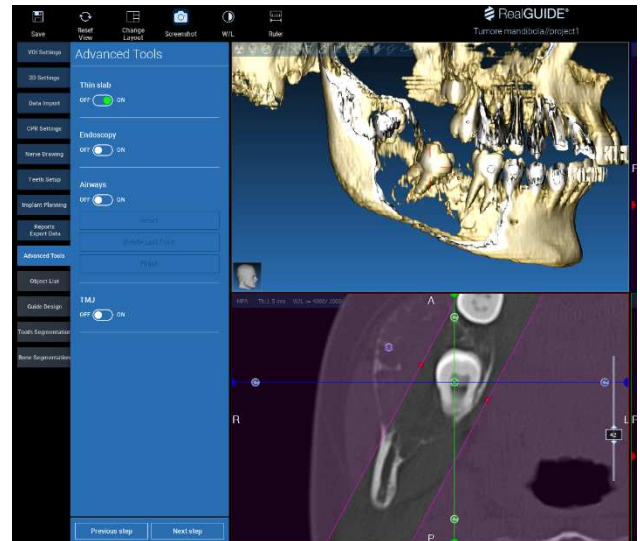


5. ADVANCED TOOLS

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

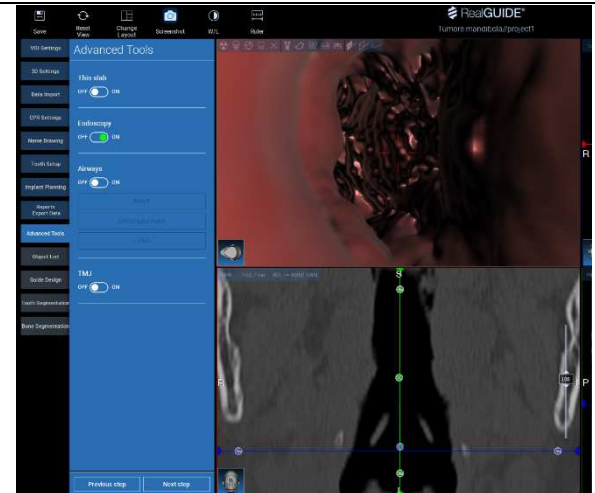


5. ADVANCED TOOLS

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



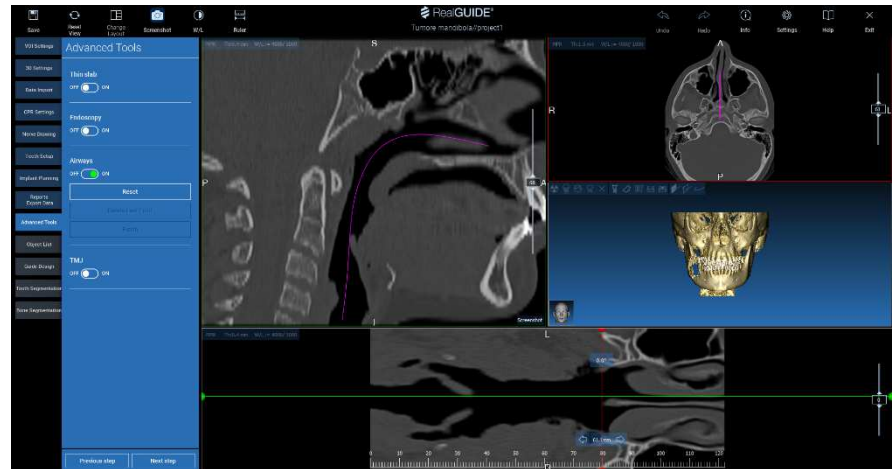


5. ADVANCED TOOLS

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

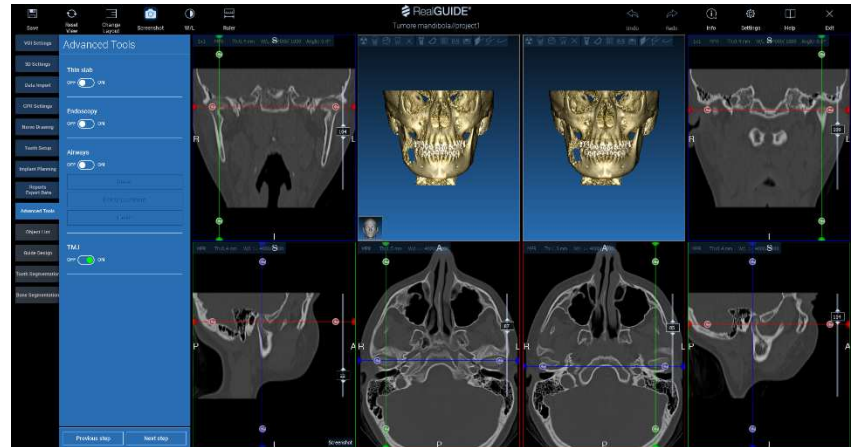


5. ADVANCED TOOLS

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

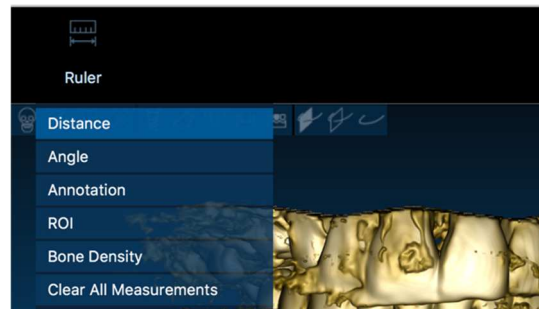
ANGLE: click with the LMB on 3 points on MPR views to see the angle

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.

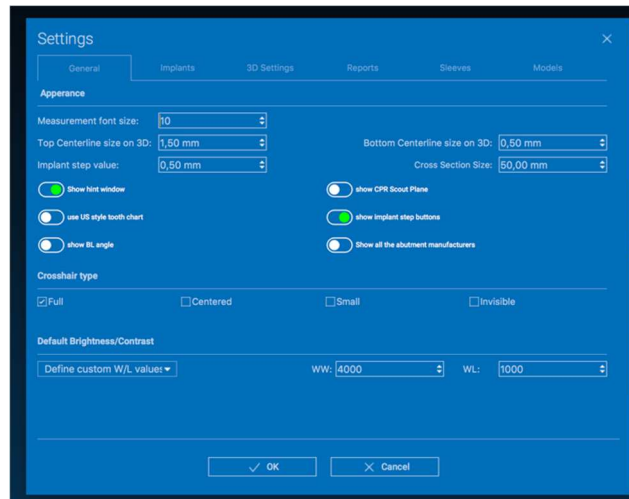
CLEAR ALL MEASUREMENTS: deletes all the measurements. To delete just one measure, simply click on the measure value to delete with the RMB and select DELETE OBJECT from the pop-up menu.



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.

