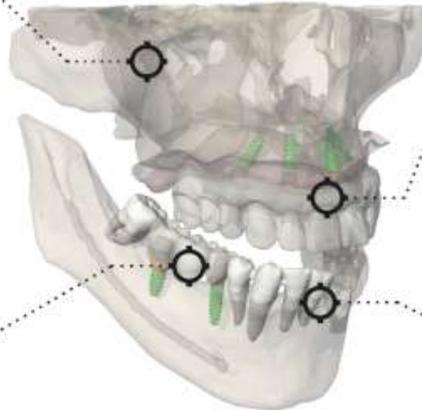


USER GUIDE



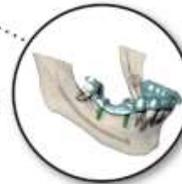
3D DIAGNOSIS

IMPLANTS PLANNING &
IMMEDIATE LOADING
PROSTHESIS DESIGN



CROWNS & BRIDGES
MODELLING

SURGICAL GUIDE
DESIGN



CE
0051



 **RealGUIDE™**
UNIVERSAL OPEN SYSTEM

 **3DIEMME®**
BIOMAGING TECHNOLOGIES

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Disclaimer

A paper copy of this document can be request at the contact details given below. Shipping shall be carried out within 7 working days at no additional cost to the user.

The user of RealGUIDE™ is responsible for determining whether or not any product or treatment is suitable for a particular patient and circumstances. The user of RealGUIDE™ is solely responsible for the correctness, completeness and adequacy of all data entered into RealGUIDE™ software. The user has to check the correctness and accuracy of planning with RealGUIDE™ software and to assess each individual case.

Correct dimensioning of the surgical guide and the usage of validated workflows lie within the sole responsibility of the user.

RealGUIDE™ is marketed standalone. The user is responsible for the necessary hardware to run it. Refer to chapter Hardware requirements (page 15) for further details.

Terms and conditions of use of RealGUIDE™ are given in the Licence agreement, accessible from the software and available on the website.

1. Introduction and overview

1.1. General Information

Manufacturer: 3DIEMME Srl

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

Manufacturing site: Via delle Baraggette 10, 22060 Figino Serenza (CO), ITALY

P +39 031 7073353 - F +39 031 710284

Product Name: RealGUIDE™

Software release: 5.4

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

Website: www.3diemme.it

In cases where the RealGUIDE™ licence is downloaded/purchased from a Distributor and not directly from 3Diemme, the Distributor must be contacted instead. Contact details are available in the digital label of the software (Settings>Info).

1.2.General Product Description

RealGUIDE™ Software is a fully-featured 3D imaging application in medicine, meant to be a multiplatform application, running on PC, Mac and mobile devices (not provided by 3DIEMME).

RealGUIDE™ is available in a series of variants, sharing the same core functions, but differing in the graphic user interface colours and commercial name. More information can be requested at 3Diemme’s contact details above.

RealGUIDE™ is an open software that contains 3rd party libraries, necessary for dental surgery planning and surgical guide design, for which correctness solely the manufacturer is responsible of.

Version	UDI-DI
RealGUIDE APP	08050038830003
RealGUIDE PRO	08050038830010
RealGUIDE DESIGN	08050038830027
RealGUIDE START	08050038830034
RealGUIDE CAD	08050038830041
RealGUIDE CAD+	08050038830058

The software is marketed through a licensing system. For further information, refer to the commercial brochure or request more information to the contact details above/local distributor.

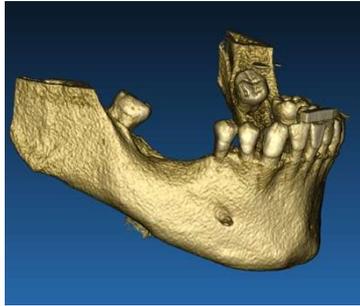
RealGUIDE™ is for multiple patient multiple use.

1.3.Intended Use and Indications for use

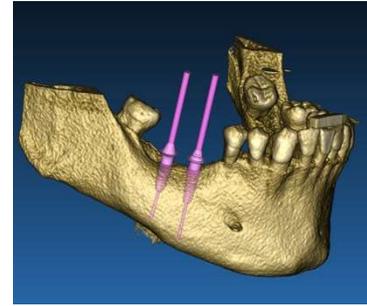
The device is a software to be used in the dental field by trained professionals to support diagnosis, to plan virtual implants and surgeries on 2D/3D reconstructions, to design surgical guides and prosthetic modelling, and manage the endodontic, orthodontic and orthognathic treatments connected to the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

The RealGUIDE™ software is indicated 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.



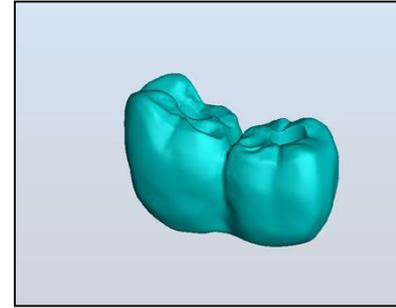
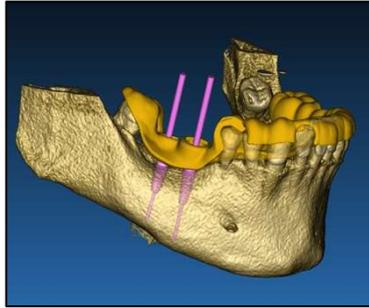
3D reconstruction from DICOM example



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”

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

1.4. Software Description

The RealGUIDE™ software can display oral/maxillofacial radiology. The user is then able to navigate through different views, segmented analysis, and 3D perspective. In addition, the user can 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.

The RealGUIDE™ Software 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 orthognathic 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

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.
- The performance of RealGUIDE™ depends on the quality and accuracy of the images and data that have been imported in the software. Only the user is responsible to ensure that the quality of the data imported in the software is sufficient for proper performance of RealGUIDE™.

The software can be interconnected with other digital planning design software models of RealGUIDE™ only, through TCP/IP protocol.

The data interface:

The software transmission protocol includes HTTPs, DICOM3.0

The storage format of the software includes: ORP, STL, MPR2.

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

1.5. Compatibility information

The projects created with versions of RealGUIDE, previous to 5.1 (e.g. 4.2) are not supported by the current software.

RealGUIDE™ software does not support cross compatibility between the other series of variants of the software.

1.6.Accuracy and precision

The measuring function of the software has an accuracy depending on several aspects, among which:

- if positioning of the endpoints or vertices is less precise
- for angle or polygon measuring, because there are more degrees of freedom
- if the displayed image is shrunken compared to its acquisition size, because the zoom factor will be less than 1. Thus 1 pixel difference on the screen means multiple pixels on the image.

There may be differences between the exact and measured values for the following reasons:

- Inexact positioning of the pixel on the screen. In the best case, the mouse cursor may be positioned exactly on the specific pixel.
- In the worst case, there may be a variation of about 3 pixels per degree of freedom (number of applicable ends or vertices * number of coordinates).
- Rounding errors.

1.7.Computer and hardware requirements

The choice of the computer on which RealGUIDE™ will be used must be made by the user. 3Diemme accepts no liability for incorrect choice due to non-compliance with requirements.

Connection to the network for the computer-based version must happen via LAN. WiFi connection may be slow and not guarantee optimal data transfer speed.

RealGUIDE™ can recall webpages to access content, thus if the user wishes to open the content, they need to have a web browser installed on the computer.

RealGUIDE™ is capable of exporting .pdf files locally, thus if the user wishes to read the file, they need to have installed on the computer a .pdf file reader.

If an antivirus, firewall or Internet security tool is installed on the workstation, check the following details:

- All RealGUIDE™ processes must be excluded from the restriction list
- All ports used by RealGUIDE™ must be open in the firewall

PC INSTALLATION (Windows based):

Processor: Intel I5 or I7 (for laptops). Quad Core recommended (for Workstations)

RAM: minimum 4 GB, for big datasets 8 GB are suggested

Hard disk: Minimum 300 – 500 GB (for patients storage)

Graphics card: With vRAM of at least 3GB

Screen resolution: 1920 x 1080 for optimal visualization

OS: Windows 10, Windows 11

MAC INSTALLATION

MacBook PRO or iMac series

RAM: minimum 4 GB, for big datasets 8 GB are suggested

Hard disk: Minimum 300 – 500 GB (for patients storage)

Graphics card: With vRAM of at least 3GB

Screen resolution: 1920 x 1080 for optimal visualization

OS: macOS (12 Monterey, 13 Ventura)

IOS INSTALLATION

iPad Pro

iOS 16

1.8. Patient Population

The device is not intended for a specific patient population. Any patient requiring endodontic, orthodontic and orthognathic treatments connected to the oral and maxilla-facial rehabilitations can be processed with the RealGUIDE™ software.

1.9. User Profile

The device is for professional use and must be used by dental professionals who have appropriate knowledge in the field of application.

The user must have basic skills about x-ray diagnostics, basic competences to use personal computers (PC) and the relevant programs.

1.10. Use environment

The device is intended to be used in any working or unprofessional environment. This can be the dentist's cabinets, hospital, clinics, medical offices etc.

RealGUIDE™ software does not have accessories and does not require other components to run, apart from the hardware mentioned in this document (page 15). The STL output files that are generated from the software, can be used with 3D printers compatible with the file format.

1.11. Operating principle

Given the device's intended use, the software uses a proprietary algorithm to elaborate and show the diagnostic images. Diagnosis is then demanded to the operator only.

The software algorithm then guides the user through implant planning, surgical guide design and prosthesis design upon the diagnostic images previously imported.

1.12. Contra-indications

None known.

1.13. Warnings

Effectiveness of diagnostic support is not guaranteed if uncontrolled hardware is used, and image source of uncontrolled quality are imported.

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 image's 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.

Surgical guides for dental implant placement, designed with RealGUIDE™, are considered by many regulatory systems to be a medical device. Manufacturing and appropriate device marking is the sole responsibility of the relative Manufacturer.

Any serious incident that has occurred in relation to the device, should be reported to the 3Diemme and the competent authority of the Member State in which the user and/or patient is established.

Software updates are issued only by 3Diemme, prior notice to the user. When available, the new version of RealGUIDE™ will be available only if the user is logged in and network connection is available. It is strongly advised to accept any update that is sent.

RealGUIDE™ has the option to save user access credentials. If activated, the user should make sure that access to his/her computer is possible only with proper authentication.

PC/Mac or iOS device password should be set following common good practices (e.g. minimum length, periodically changed, complexity, non-linkable to personal and retrievable information).

Upon device disposal (uninstallation), system folders only are removed. Database folder must be removed manually during uninstallation.

DICOM data may contain personal data of the patient. RealGUIDE™ software has the option to share privatized patient projects. Sharing files with patient data to other users is responsibility of the user only. National and EU regulations must be considered.

Content sharing / cloud uploading should be done when connected to trusted networks only.

Password reset is advised every 6 months. Password should contain at least one capital letter, one number and be at least 8 characters long.

1.14. Cybersecurity

RealGUIDE™ manages health related data (special personal data) that is related to the patient. RealGUIDE™ creates files to run the software with this data, having a proprietary format.

Secure operation guidelines are detailed as in the following:

Windows:

1. Account Monitoring and Control:

- Regularly review system accounts. Disable ones not associated with a business process or owner.
- Revoke system access immediately for terminated employees or contractors.
- Store login credentials securely using the [Windows Security API](#).

- Periodically review accounts for anomalies like locked-out accounts, disabled accounts, or accounts with passwords that exceed the maximum password age.
 - Automatically lock access or log off users after 15 minutes of inactivity.
 - Monitor attempts to access deactivated accounts through audit logging.
2. **Data Recovery Capability:**
- Ensure automatic data backup on the cloud server using services like Amazon backup and on the local machine.
 - Use Windows' built-in backup system and schedule. This is independent from the software's backup system.
3. **Data Loss Prevention:**
- Always encrypt data at rest using Microsoft BitLocker. You can learn more about it [here](#).
 - Use secure and authenticated mechanisms to move data to and from the cloud server.
4. **Password Policies:**
- Use robust passwords of at least 8 characters, including letters, numbers, and special characters. Change these passwords annually, and don't reuse old passwords.
5. **Regular Updates:**
- Alongside operating system updates, it is essential to ensure that the latest BIOS (Basic Input/Output System) version is installed.
 - Additionally, keeping firmware for various hardware components, such as the motherboard, graphics card, and network adapter, up to date is crucial. These updates often provide critical security patches, compatibility improvements, and performance optimizations.
 - Moreover, regularly updating drivers for hardware components from reputable manufacturers is essential to address potential vulnerabilities and ensure optimal functionality.

6. Security Software:

- It is advised to install and regularly update a reputable antivirus solution, such as the latest version of Microsoft Defender, McAfee, Norton, or Avast.

macOS:

1. Account Monitoring and Control:

- Regularly review system accounts. Disable ones not associated with a business process or owner.
- Revoke system access immediately for terminated employees or contractors.
- Store login credentials securely using the [macOS Security API](#).
- Periodically review accounts for anomalies like locked-out accounts, disabled accounts, or accounts with passwords that exceed the maximum password age.
- Automatically lock access or log off users after 15 minutes of inactivity.
- Monitor attempts to access deactivated accounts through audit logging.

2. Data Recovery Capability:

- Ensure automatic data backup on the cloud server and on the local machine.
- Use macOS's built-in backup system and schedule. This is independent from the software's backup system.

3. Data Loss Prevention:

- Always encrypt data at rest using Apple FileVault. You can learn more about it [here](#).
- Use secure and authenticated mechanisms to move data to and from the cloud server.

4. Password Policies:

- Use robust passwords of at least 8 characters, including letters, numbers, and special characters. Change these passwords annually, and don't reuse old passwords.
- 5. **Regular Updates:**
 - Keep your operating system, drivers, and firmware updated to the latest versions.
- 6. **Security Software:**
 - Always have updated antivirus and firewall programs to protect against malicious software.

Adhering to these cybersecurity guidelines significantly enhances the security posture of the medical device. Staying up to date with the latest operating system versions, security patches, BIOS updates, firmware updates, and hardware drivers helps mitigate potential risks, protect against emerging threats, and ensure optimal performance and compatibility. Additionally, utilizing reputable antivirus and firewall software adds an extra layer of defense.

1.15. Installation

Installation of RealGUIDE can be carried out by the user, without requiring intervention of the manufacturer or authorised person.

In case of any questions or if you need further assistance during installation, contact 3Diemme or the local distributor.

1.15.1. Steps to install RealGUIDE™ (Microsoft Windows version)

1. Check that your hardware and software meet the specifications (page 15).
2. Download the software setup file from 3Diemme's/distributor's website.
3. Start the program manually by executing the setup.exe file from the selected download folder.
4. Follow the installation wizard on the screen.

5. A successful installation windows will inform the user at the end of the process.

1.15.2. Steps to install RealGUIDE™ (macOS version)

1. Check that your hardware and software meet the specifications (page 15).
2. Download the software setup file from 3Diemme's/distributor's website.
3. In the Downloads folder, double-click the disk image or package file (looks like an open box). If the provided installer doesn't open automatically, open it, then follow the onscreen instructions.
4. Follow the installation wizard on the screen.
5. A successful installation windows will inform the user at the end of the process.

1.15.3. Steps to install RealGUIDE™ (iOS version)

1. Check that your hardware and software meet the specifications (page 15).
2. Open the App Store app and tap the "Search" tab to type "RealGUIDE"
3. Tap "Get" to download the app. Installation will begin automatically and RealGUIDE

1.16. Start-up

To start using the software, launch the application by searching "RealGUIDE".

Tap/click on the RealGUIDE app. The software will open.

Upon opening the software will prompt login. If the user has already registered, insert username and password as chosen. If registration has been carried out, create a new user by clicking on the appropriate button and login.

The software is ready for use.

First-time registrations will be given a 30 day free PRO version. Upon expiry, the software licence will be automatically downgraded to the START version. Subscription features will be made available only after login.

1.17. Shutdown

To close the software, save the project if necessary before exiting.

Click on the exit button within the software or the close button of the RealGUIDE window. The patient list section will be reopened and the exit button or close button of the window must be clicked again.

1.18. Uninstallation

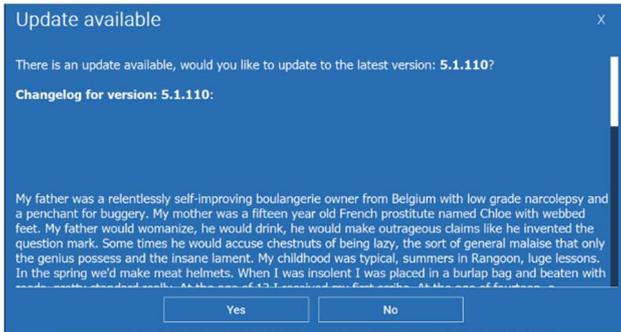
To uninstall RealGUIDE from the machine follow the operating system specific procedure.

Refer to Microsoft Windows, macOS or iOS specific instructions.

1.19. Update

Updates are made available from the Manufacturer only.

Upon starting the program, a notification will be displayed, informing the user about the update. This function is enabled by default (Settings → check for updates ).



Example update notification

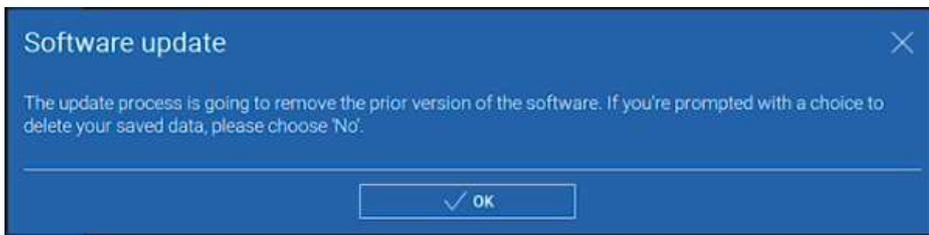
The user has the option to install the update, by clicking “yes”, or decline it, by clicking “no”.

If the update is accepted, the software will start the download, and progress will be displayed.



In case the user needs to interrupt the download, “cancel” button is available.

Upon completion, the software will notify the user of completion and will automatically install the new version of the software.

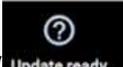


During the process, RealGUIDE is unavailable for use. With only the following being showed, while the update is running in the background:



Once finished, the software will automatically be closed and the new version will automatically start. The updated version of RealGUIDE is ready for use.

If the user declines the update, the initial notification will be closed, and the user can continue using the software normally.

If the user has enabled the “check for updates” setting, an icon will be displayed in the TOP bar () notifying the presence of a software update, even if the user has chosen not to install it. To install the new version of RealGUIDE that is available, the user will have to click on the “Update ready” icon and follow the update installation instruction above.

If the user has disabled the “check for updates” setting, the software will not display update availability, until a new RealGUIDE version is released by 3Diemme.

2. Getting started

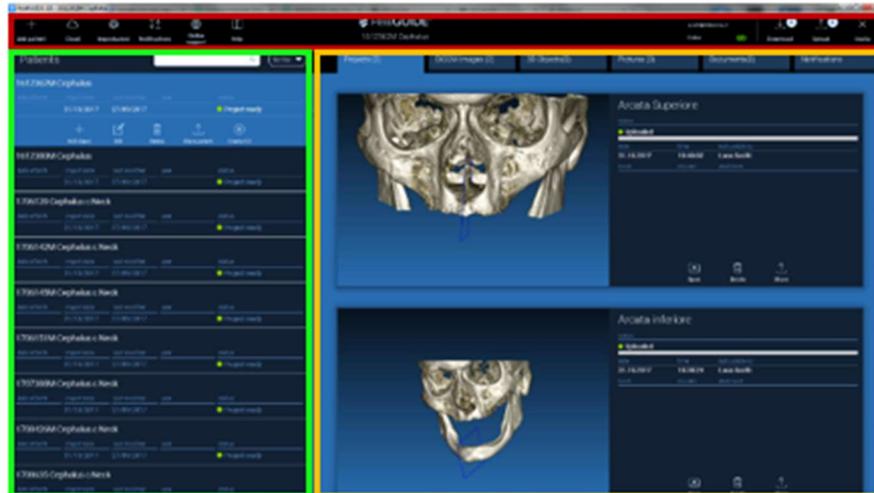
2.1.Home_page

TOOLBAR

PATIENT DATABASE

PATIENT TOOLBAR:

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

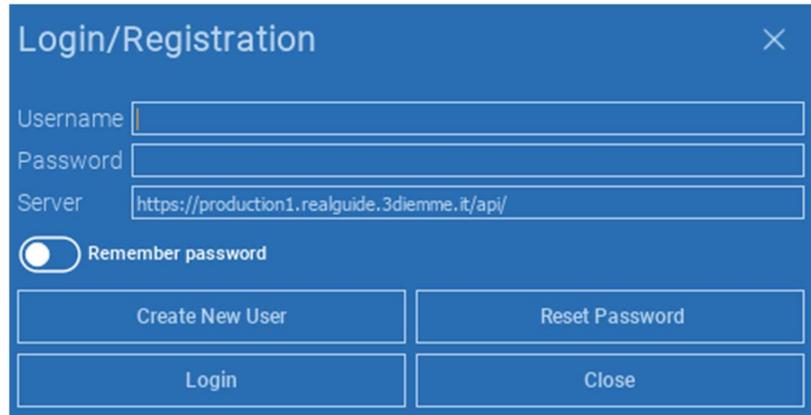
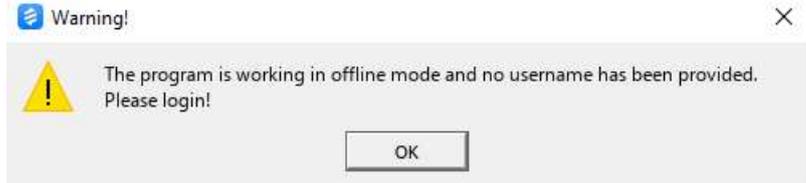


2.2. Login

When the software is opened for the first time, it works in offline mode. It is mandatory to start the registration process. Click OK to start the registration process.

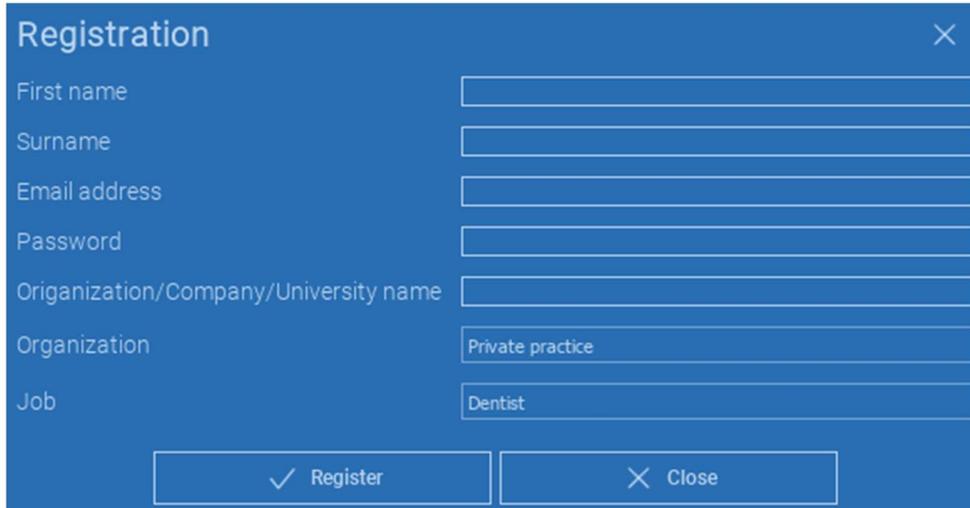
If you already have an account, enter your username (e-mail address) and password. Then click on LOGIN.

If you want to create a new account, click CREATE NEW USER.

A blue-themed "Login/Registration" form. It contains three input fields: "Username", "Password", and "Server" (with the value "https://production1.realguide.3diemme.it/api/"). Below the fields is a "Remember password" toggle switch. At the bottom, there are four buttons: "Create New User", "Reset Password", "Login", and "Close".

Fill in all fields of the new window with all data. Then click on REGISTER.

An automated email will be sent to your email address confirming the correct profile creation. Click on the link displayed in the email to complete the registration process.

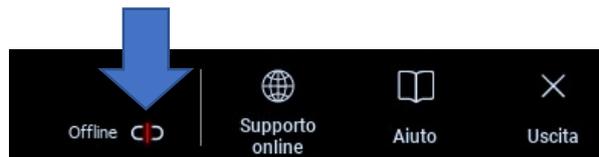


The image shows a registration form window with a blue background. The title bar at the top left says "Registration" and there is a close button (X) at the top right. The form contains the following fields:

- First name:
- Surname:
- Email address:
- Password:
- Organization/Company/University name:
- Organization:
- Job:

At the bottom of the window, there are two buttons: "Register" (with a checkmark icon) and "Close" (with an X icon).

After the process has been completed, go to the TOOLBAR and click on the icon shown in the figure.



Enter your username and password.
Click on SAVE PASSWORD to automatically log in to your account.

Then click on LOGIN.

A screenshot of a 'Login/Registration' dialog box with a blue background and a close button in the top right corner. It contains the following fields and controls:

- Username:
- Password:
- Server:
- A 'Remember password' toggle switch, which is currently turned on (green).
- Four buttons at the bottom: 'Create New User', 'Reset Password', 'Login', and 'Close'.

2.3.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**

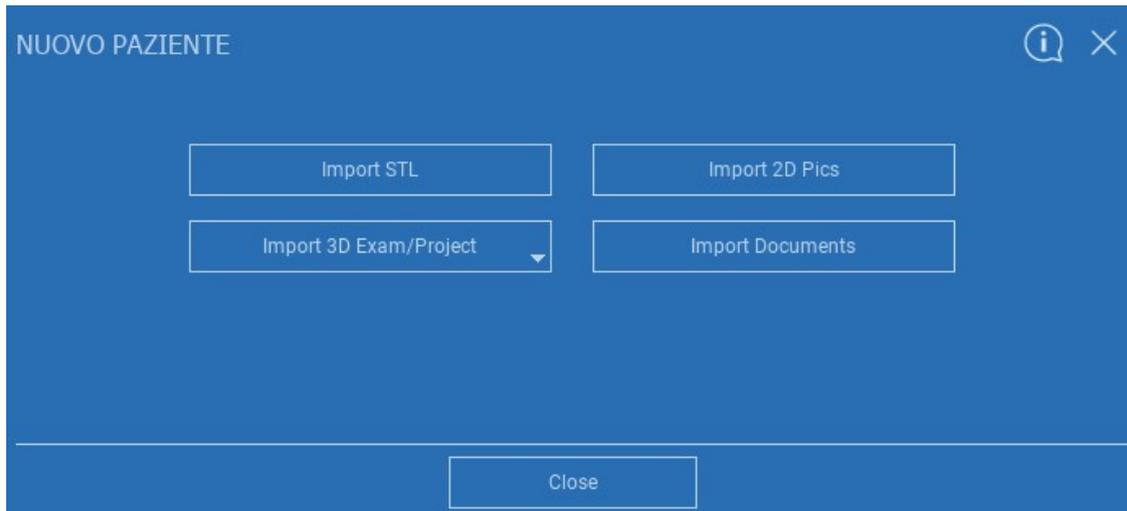
IF THE DICOM DATASET IS ALREADY AVAILABLE, YOU CAN CLICK ON **OK** WITHOUT COMPILING ALL THE FIELDS. THE PATIENT DATA WILL BE AUTOMATICALLY READ FROM DICOM FILES.

A blue dialog box titled "NEW PATIENT" with a close button (X) and an information icon (i) in the top right corner. It contains three input fields: "Name:" with an empty text box, "Surname:" with an empty text box, and "Date of birth (DD/MM/YYYY):" with a text box containing two slashes. Below these is a "Notes:" label and a large empty text area. At the bottom are two buttons: "OK" and "Cancel".

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

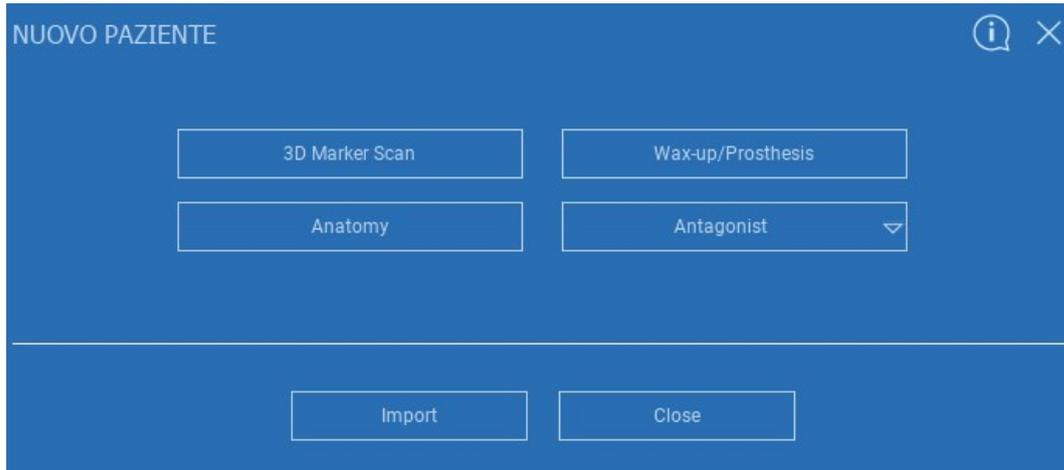
- ➔ **IMPORT STL** (*Anatomy, Wax-up, Evobite and other STL files*)
- ➔ **IMPORT 2D PICS** (*Patient Pics or panorex JPG/PNG/BMP format*)
- ➔ **IMPORT 3D EXAM/PROJECT** (*DICOM images or RealGUIDE™ projects*)
- ➔ **IMPORT DOCUMENTS** (*Pdf prescriptions, notes, reports, etc*)

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



2.3.1. 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.



2.3.2. IMPORT STL FILES

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

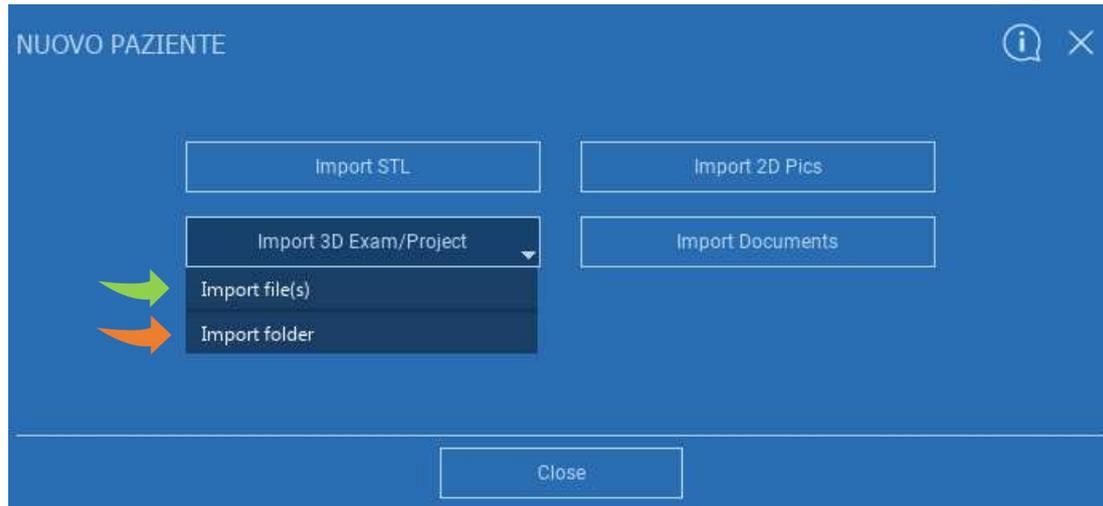


Pay attention! During this step you are only connecting STL files to the patient they belong to. If you are interested in the matching procedure go to Paragraph 2.6.

2.3.3. 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™ 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.

2.3.4. IMPORT 3D EXAM/PROJECT

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

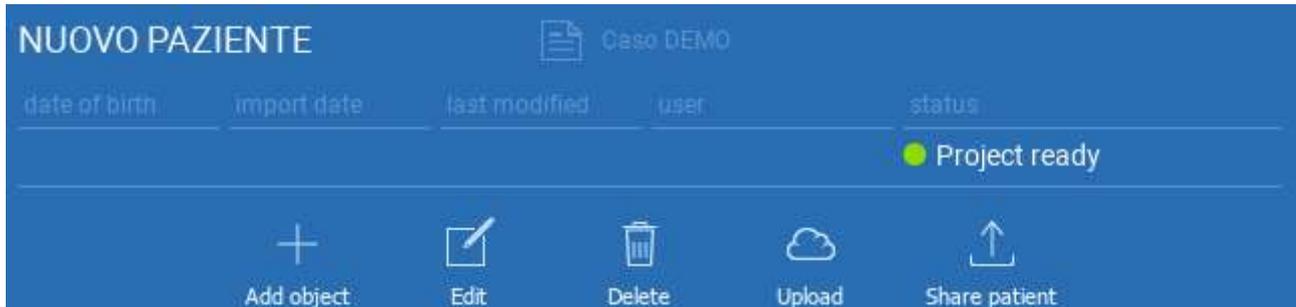


Click on **OPEN** to open the DICOM dataset visualization and diagnosis.

Click on **LOCATION** to open the local folder DICOM files path.

Click on **CANCEL** to delete the DICOM series from your patient folder.

2.3.5. 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.

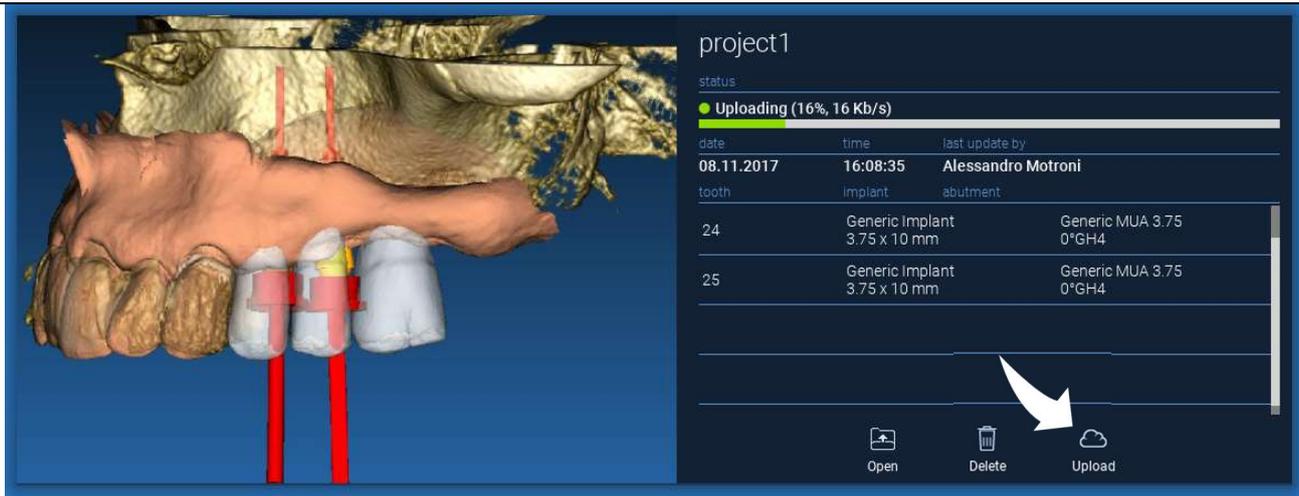


Click on **EDIT** to modify the patient data (Name, Surname, Date of birth, etc).



2.4. 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 set of teeth with two implants and abutments highlighted in red. The panel, titled "project1", shows the upload status as "Uploading (16%, 16 Kb/s)" with a progress bar. Below this is a table with columns for "date", "time", and "last update by".

date	time	last update by
08.11.2017	16:08:35	Alessandro Motroni

Below the table is another table with columns for "tooth", "implant", and "abutment".

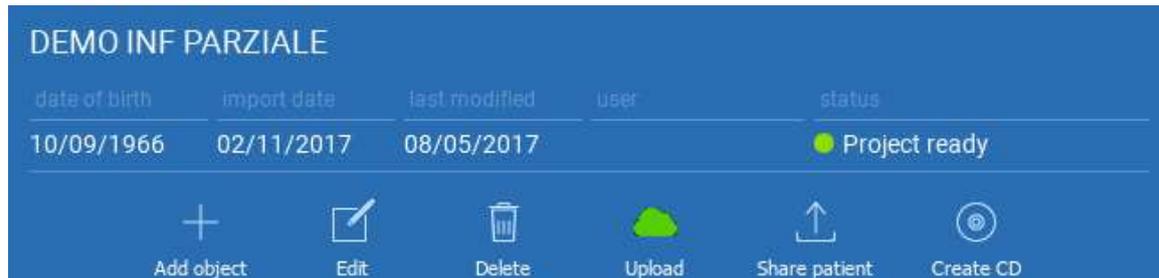
tooth	implant	abutment
24	Generic Implant 3.75 x 10 mm	Generic MUA 3.75 0°GH4
25	Generic Implant 3.75 x 10 mm	Generic MUA 3.75 0°GH4

At the bottom of the panel are three icons: "Open" (a folder icon), "Delete" (a trash can icon), and "Upload" (a cloud icon). A white arrow points to the "Upload" icon.



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.

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

Below the table, a toolbar contains the following actions:

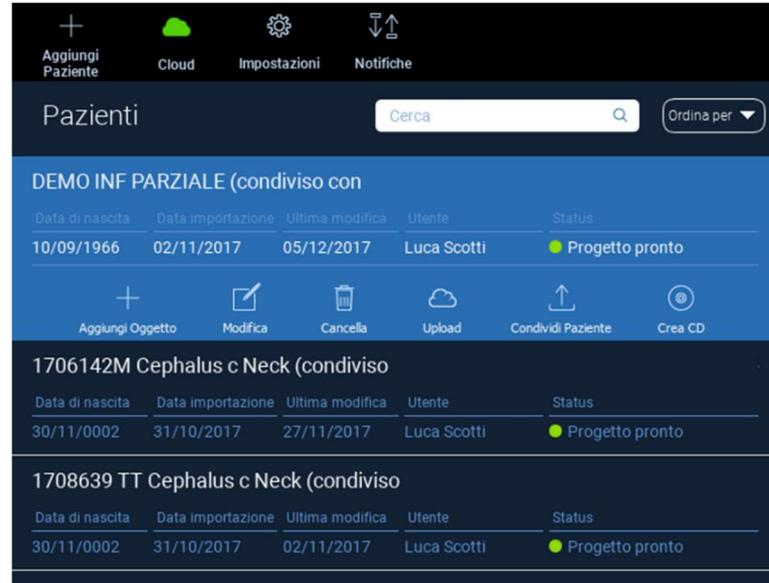
- Add object
- Edit
- Delete
- Upload
- Share patient
- Create CD



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

2.5. 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.



2.6. 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.

The screenshot shows the 'Progetto INF' interface. At the top, it says 'Status' and 'Uploaded'. Below that is a table with columns for 'Data', 'Ora', and 'Ultima modifica di'. The table contains two rows of data:

Data	Ora	Ultima modifica di
15.11.2017	12:47:44	Luca Scotti

Below the table is another table with columns for 'Elemento', 'Implanto', and 'Abutment':

Elemento	Implanto	Abutment
46	Generic Implant 3.75 x 10 mm	Generic MUA 3.75 0°GH2
47	Generic Implant 3.75 x 9.5 mm	Generic MUA 3.75 17°GH2

At the bottom of the interface are three icons: 'Apri', 'Cancella', and 'Condividi'. A white arrow points to the 'Condividi' icon.

Below the main interface is a 'Share' dialog box. It has two radio buttons: 'Share with another user' (selected) and 'Send to production center'. The 'Share with another user' option has a text field for 'Enter the email of the user you want to share the project with:'. The 'Send to production center' option has two checkboxes: 'Anonymize patient' (unchecked) and 'Editable' (checked). At the bottom of the dialog box are 'OK' and 'Cancel' buttons.

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.

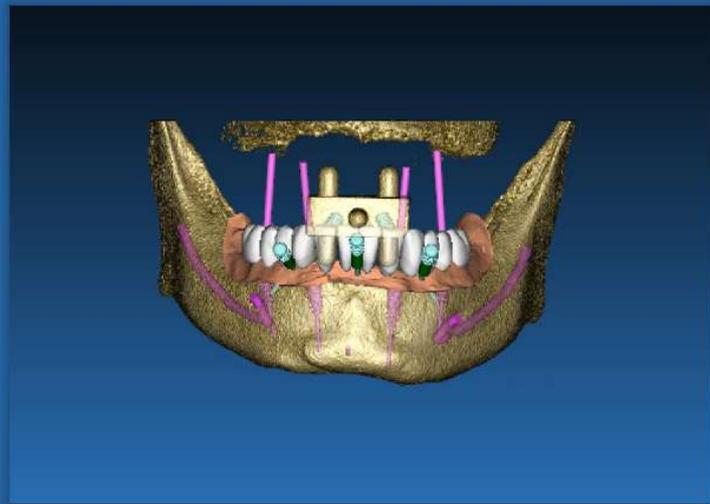
DEMO INF PARZIALE (shared with Alessandro Motroni, Angelo Tocchetti,

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

+ Add object Edit Delete Upload Share patient Create CD

2.7. 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

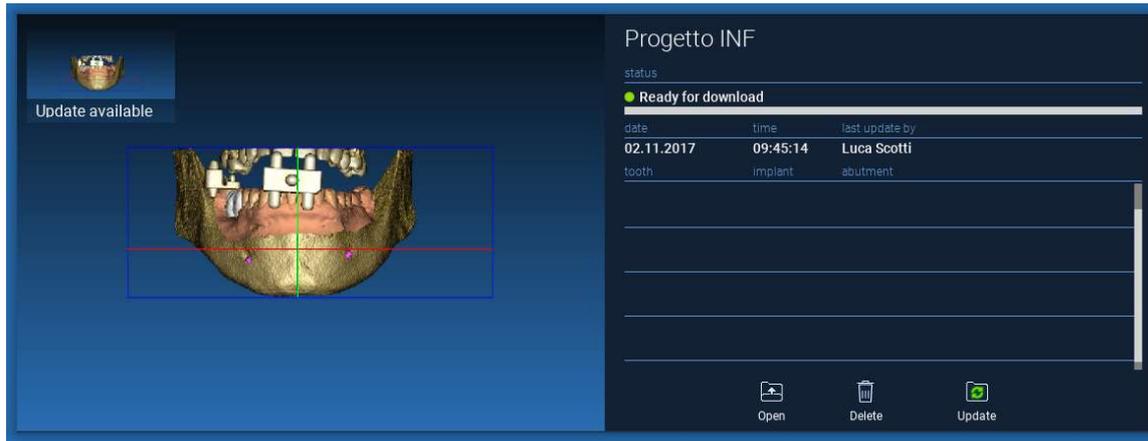
● Ready for download

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

2.8. 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.

3. Top toolbar common functions

3.1. 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 contrast 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.

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

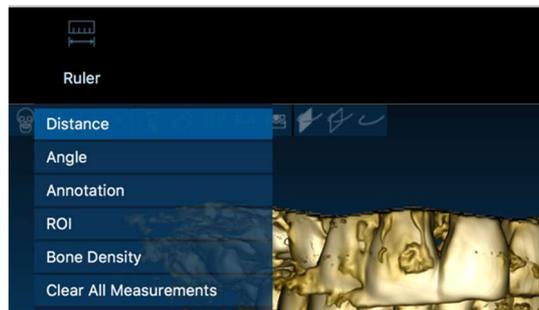
ANGLE: click with the LMB on 3 points on MPR views to see the angle

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.

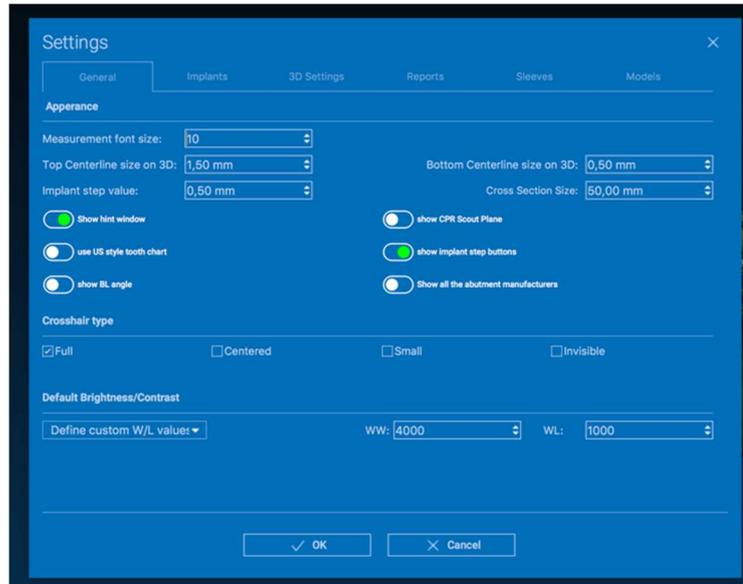
BONE DENSITY: If an implant has been positions, clicking on this button will show the bone density (HU values) around the implant.

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.



3.2. 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.



3.3. 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.



4. Implant planning



4.1. Basic Commands

VOI Setting

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

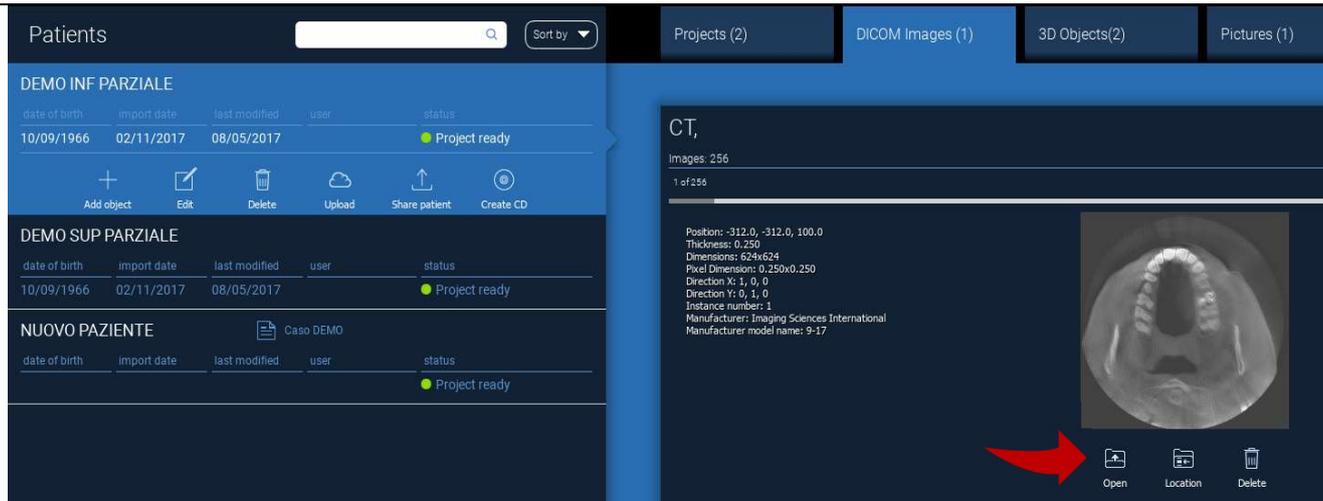
STANDARD 3D VIEWS

- Superiore
- Inferiore
- Sinistra
- Destra
- Frontale
- Posteriore

Modifica gli oggetti in 3D trascinandoli

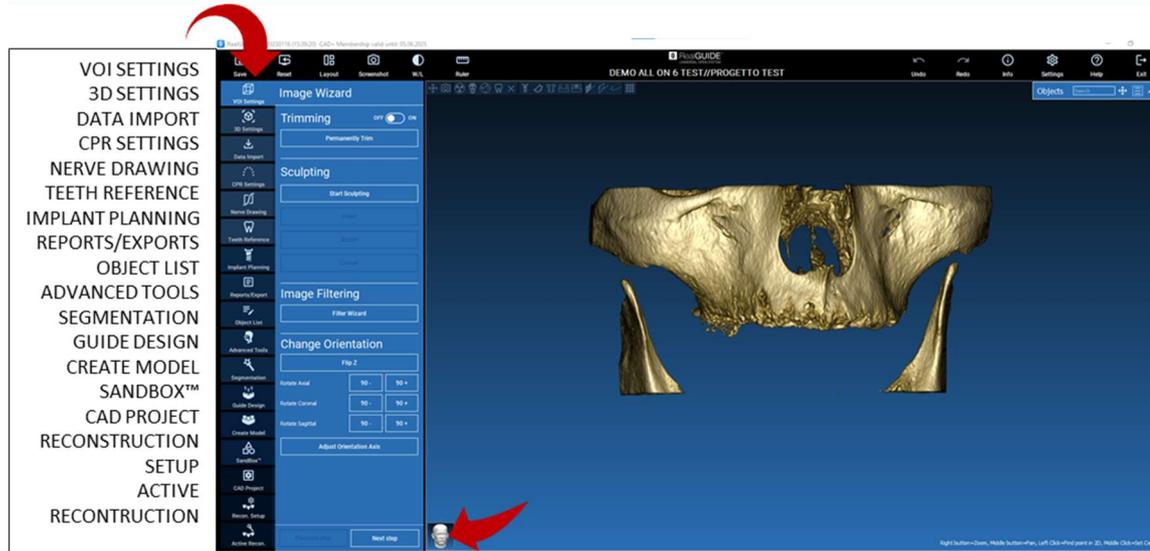
4.2. 3D View Opening

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.



4.3. 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.

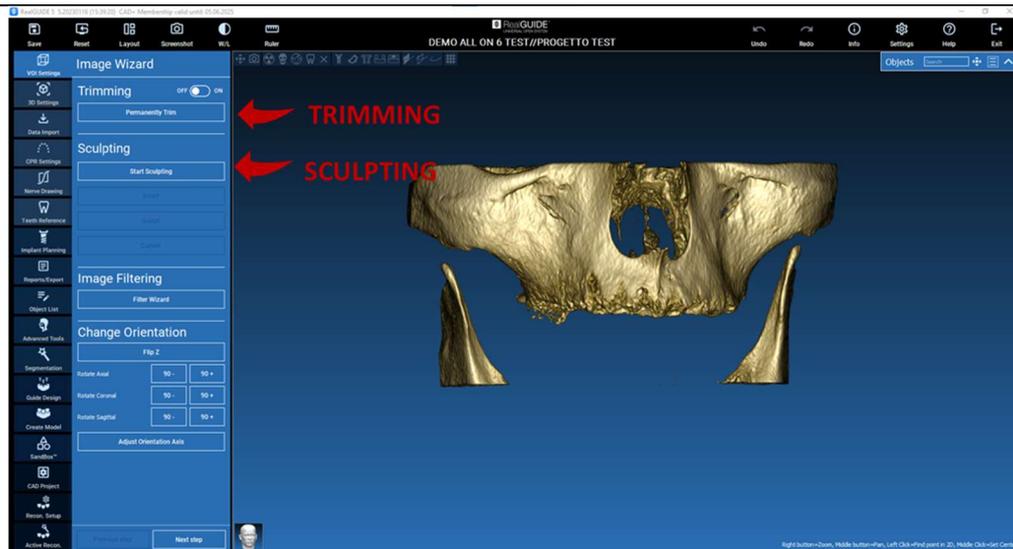




4.4. VOI Settings

VOI Setting

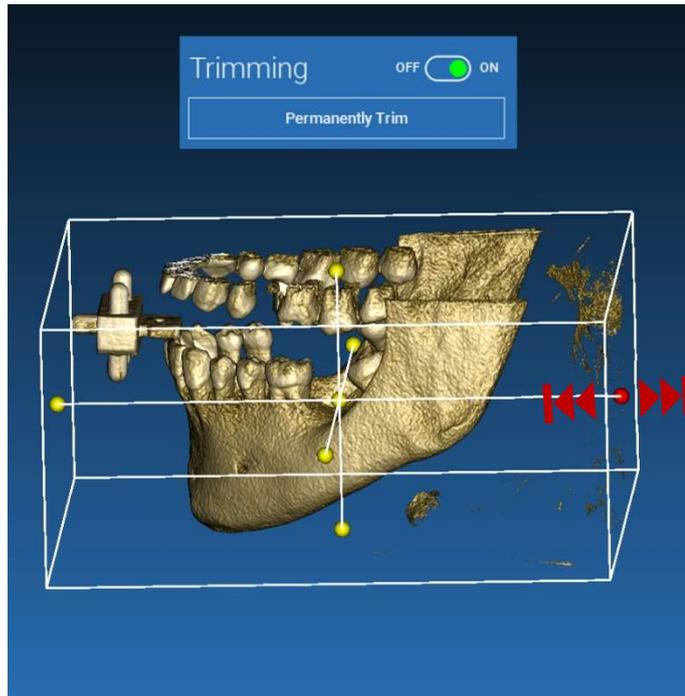
First of all you can modify the reconstructed 3D volume using two different cropping and volume editing tools:
TRIMMING: 3D volume reduction along the 3 main anatomical planes
SCULPTING: custom volume sculpting.





4.4.1. TRIMMING

VOI Setting



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

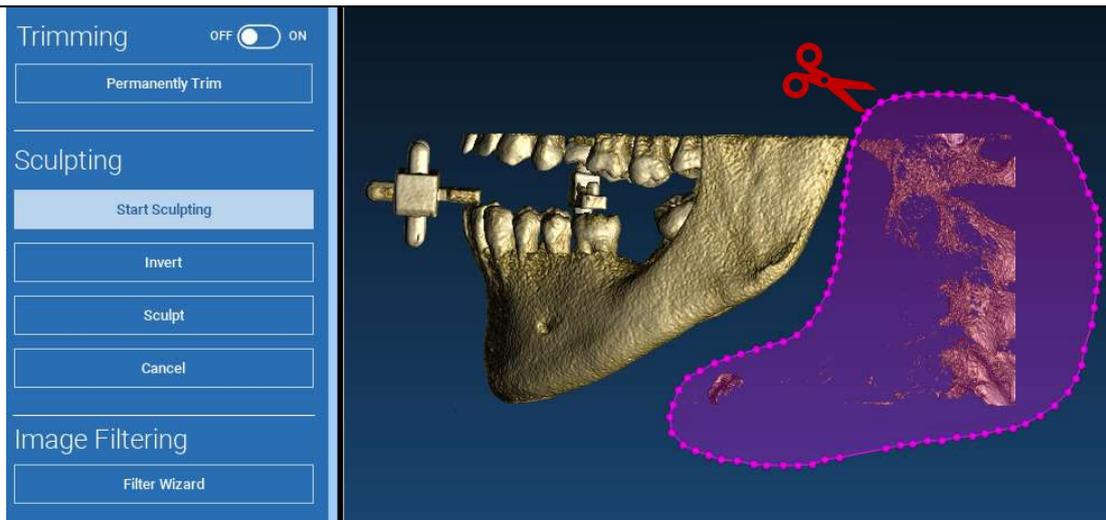
Click on the yellow spheres and move the mouse to restrict/expand the reconstruction volume. Click on **PERMANENTLY TRIM** to confirm.



4.4.2. SCULPTING

VOI Setting

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**.





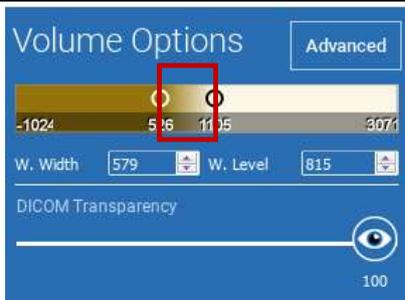
4.5. 3D Settings

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.

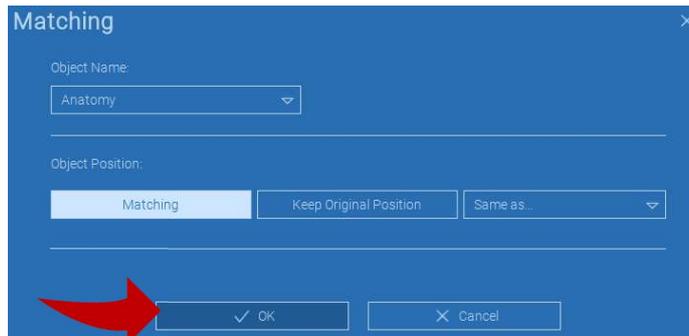
4.6. Data import



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

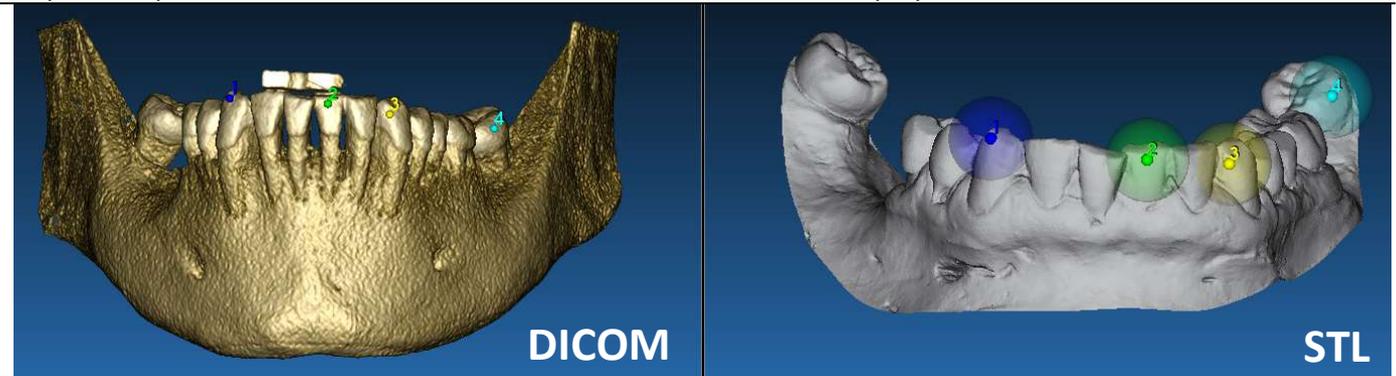
Select the file you want to align, then click on **MATCHING**.

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.



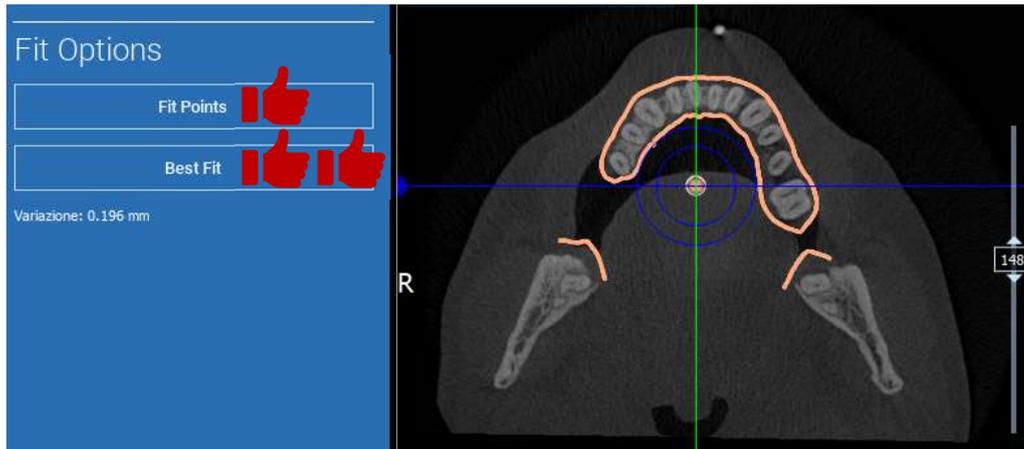
4.7. Matching

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.

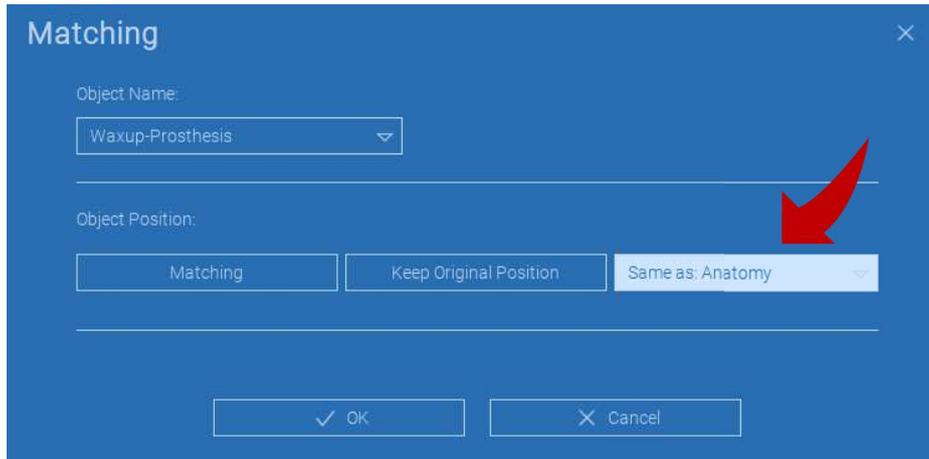


It's very important to choose easily identifiable areas on both 3D objects. Consider for example the evobite 3D marker surfaces, as well as the stable teeth surfaces (if no metal structure is present). Don't take into account areas with high scattering level, being less reliable.

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.



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.

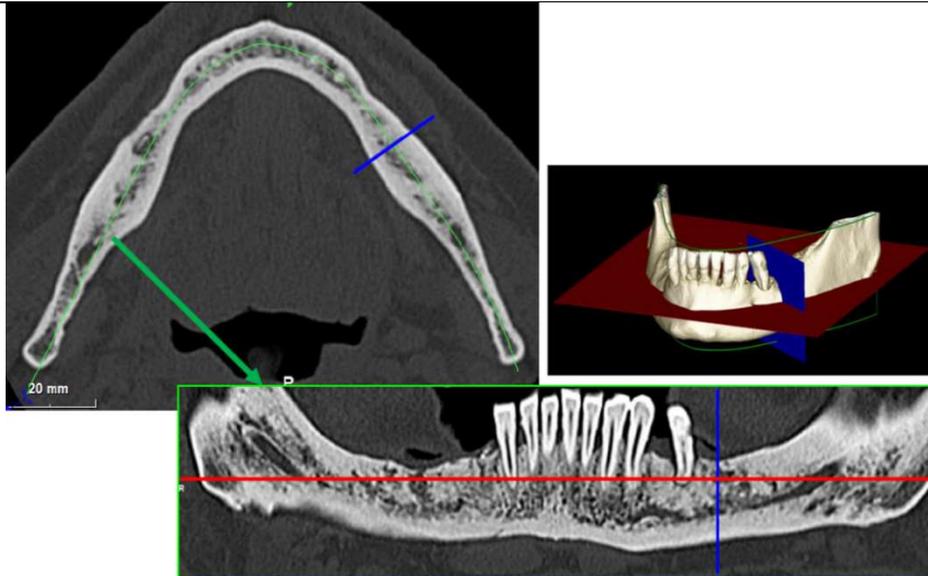


The most important requirement for the lab is to scan and keep all the STL files in the same reference system!

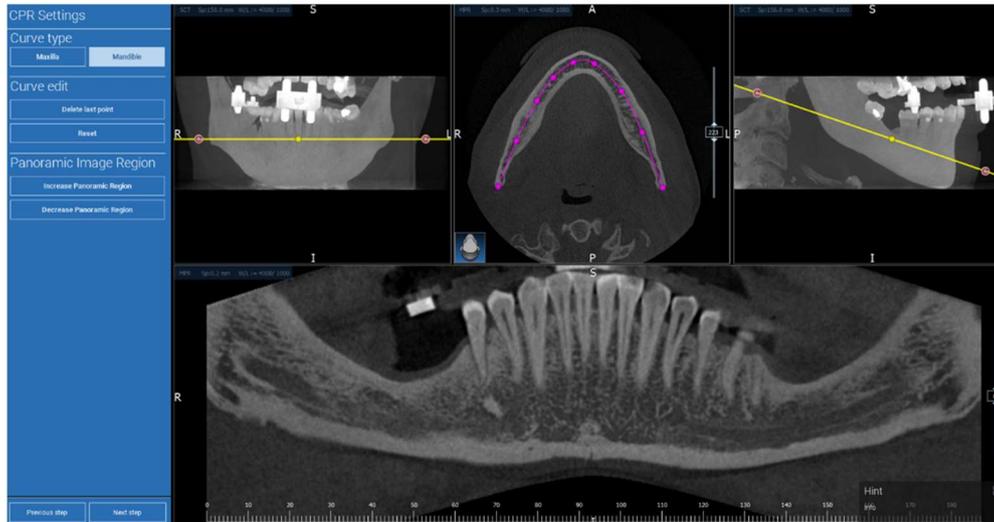


4.8. CPR Settings

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.



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.

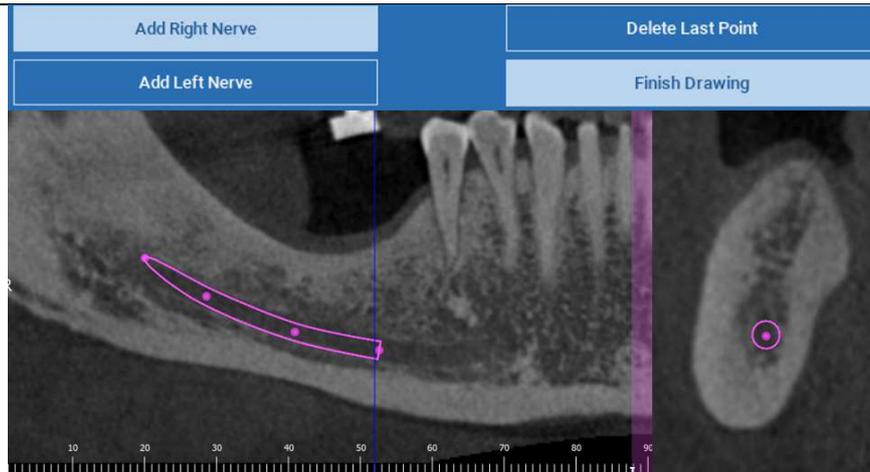




4.9. Nerve Drawing

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.





4.10. Teeth Setup

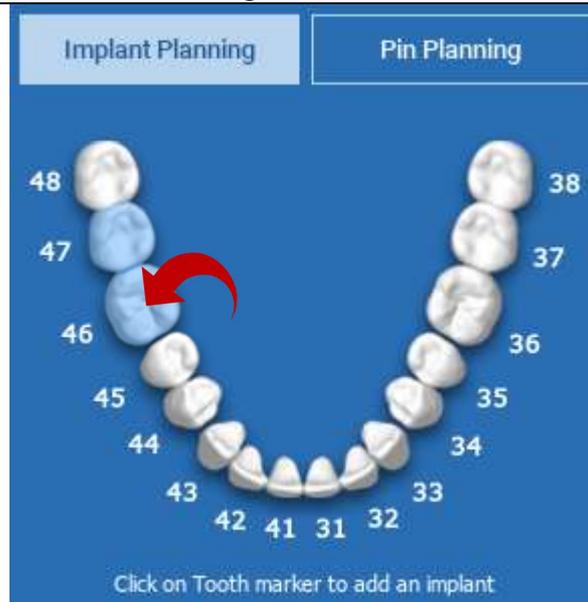
Teeth setup

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.



4.11. Implant positioning

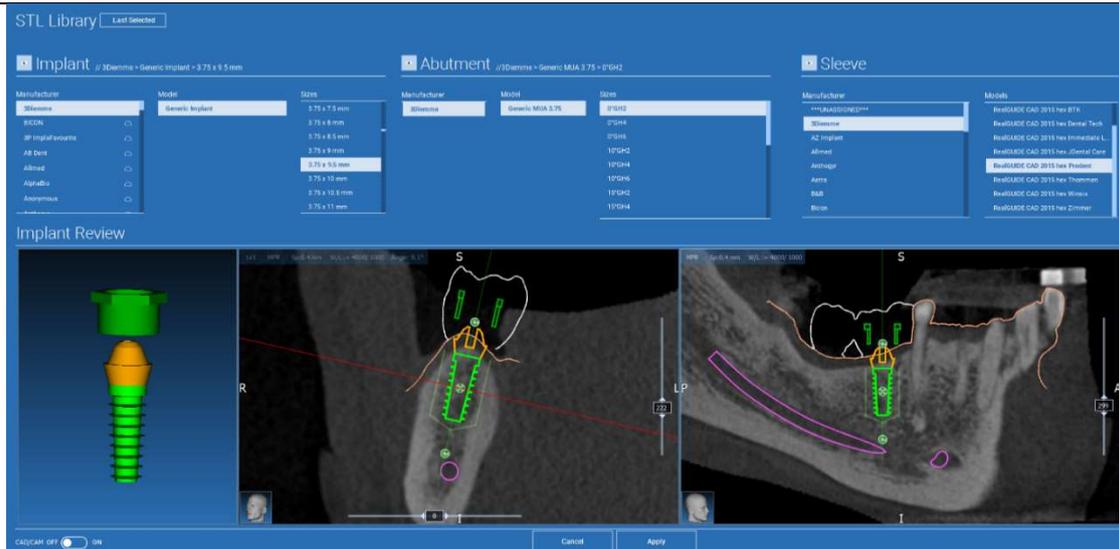
All the elements previously selected are marked in light blue colour. Click on them to open implant library window.





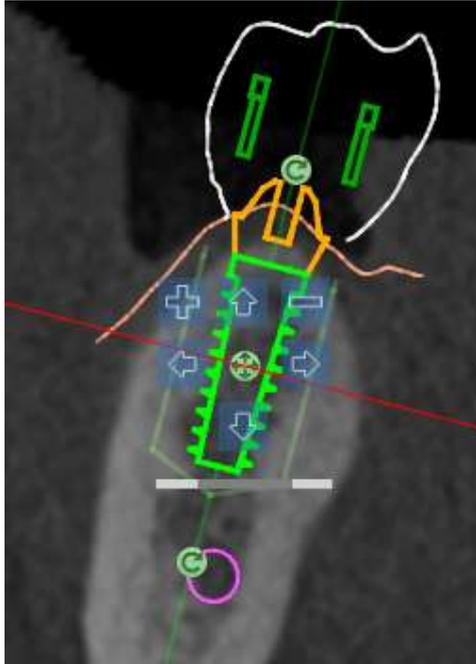
4.11.1. IMPLANT LIBRARY

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.





4.11.2. 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.



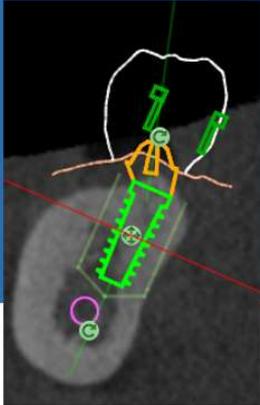
You can pan the implant by clicking on the button positioned in the center of the object.

4.11.3. 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.

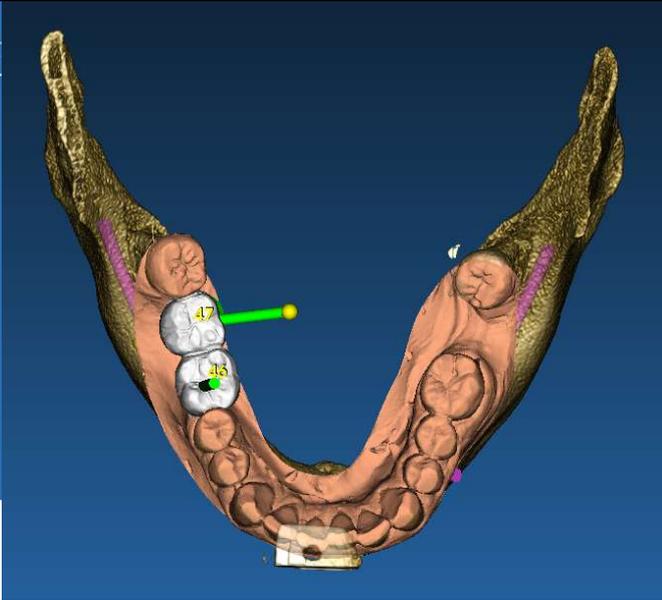
Abutment //3Diemme > Generic MUA 3.75

Manufacturer	Model
3Diemme	Generic MUA 3.75



Sizes

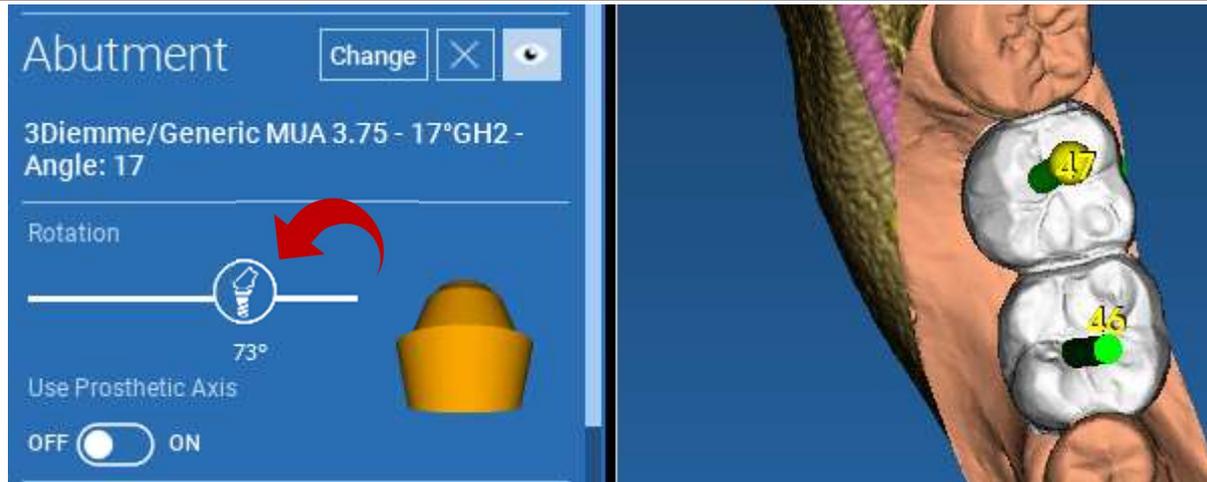
- 17°GH2
- 17°GH4
- 17°GH6
- 20°GH2
- 20°GH4
- 20°GH6
- 25°GH2
- 25°GH4





4.11.4. 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.

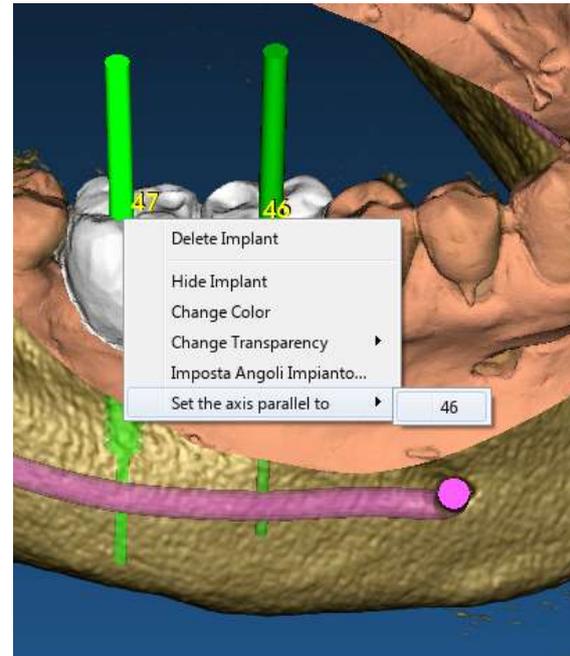


4.11.5. PROSTHETIC AXES PARALLELISM

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.

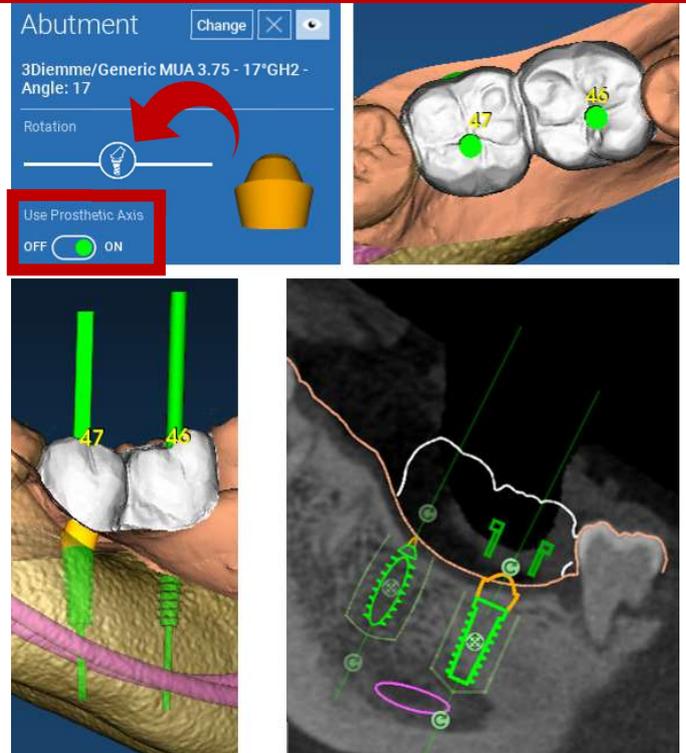


The prosthetic axis will be automatically updated and set parallel to the reference implant.



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.

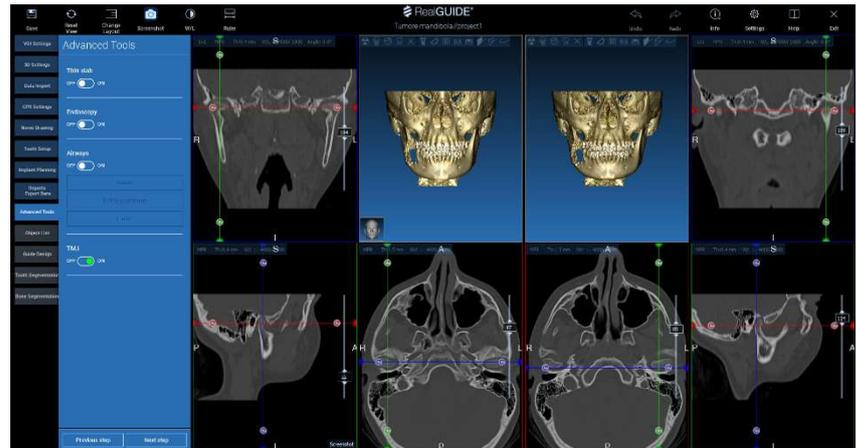


5. Advanced tools

5.1. 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. Surgical Guide design



6.1. Process start

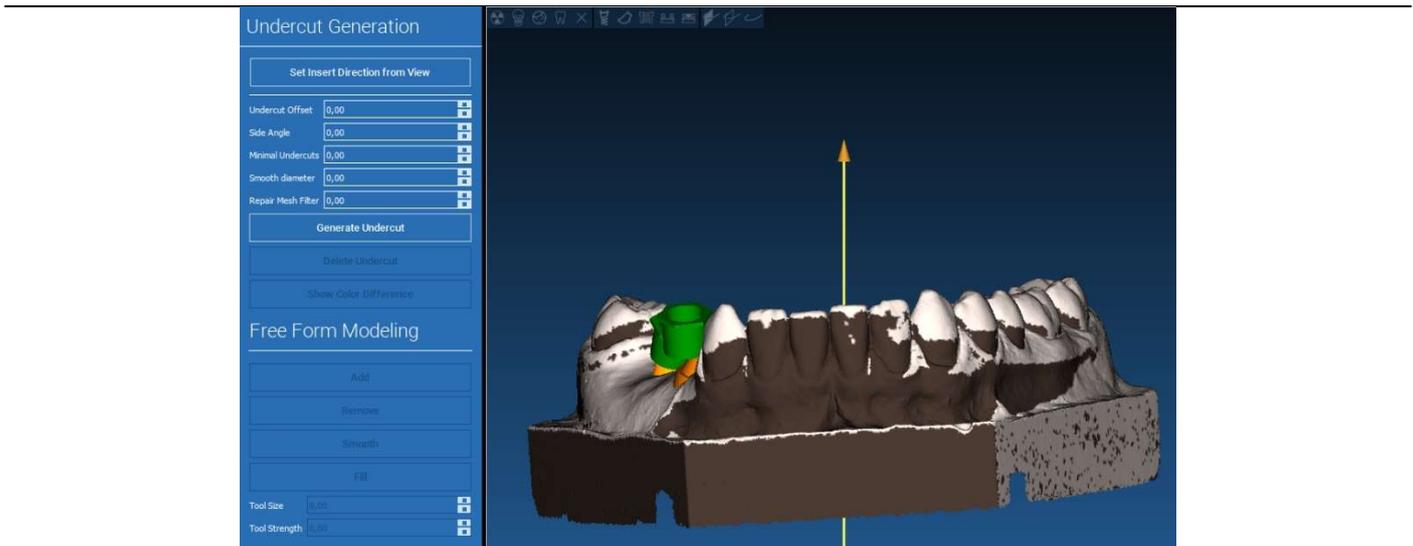
Once the implant planning has been completed, it's possible to proceed to the surgical guide design by clicking on the Guide Design tab on left side menu panel. A guided procedure will be activated, giving the user the chance to setup the construction parameters.





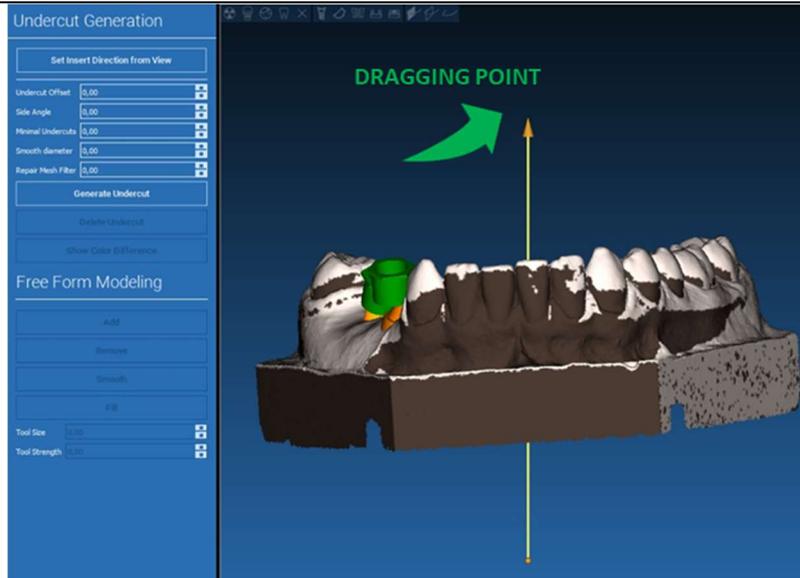
6.2. Undercut blockout setup

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.



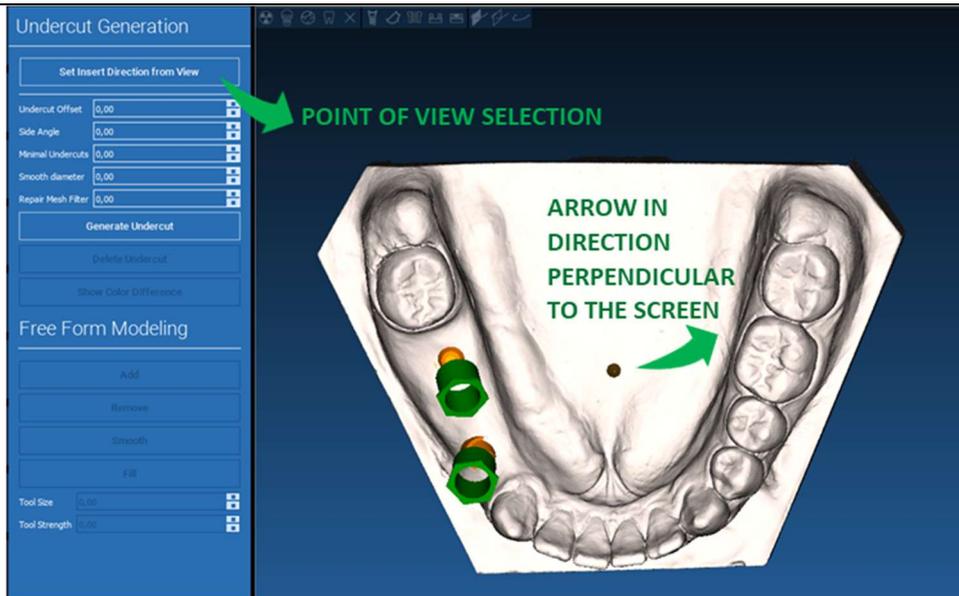
6.2.1. INSERTION DIRECTION – CONTROL ARROW

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.



6.2.2. INSERTION DIRECTION – VIEW DIRECTION

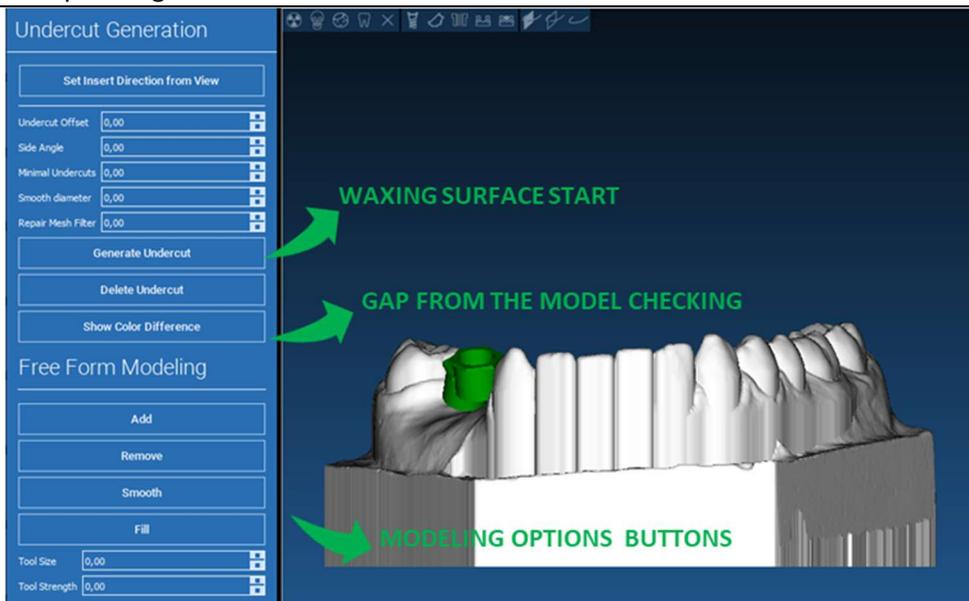
It's possible to define the insertion axis direction also moving the model in a desired point of view. By clicking on **SET DIRECTION FROM VIEW** button, the arrow axis direction will be positioned perpendicular to the screen surface.





6.2.3. 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.





6.2.4. Tracing and construction parameters

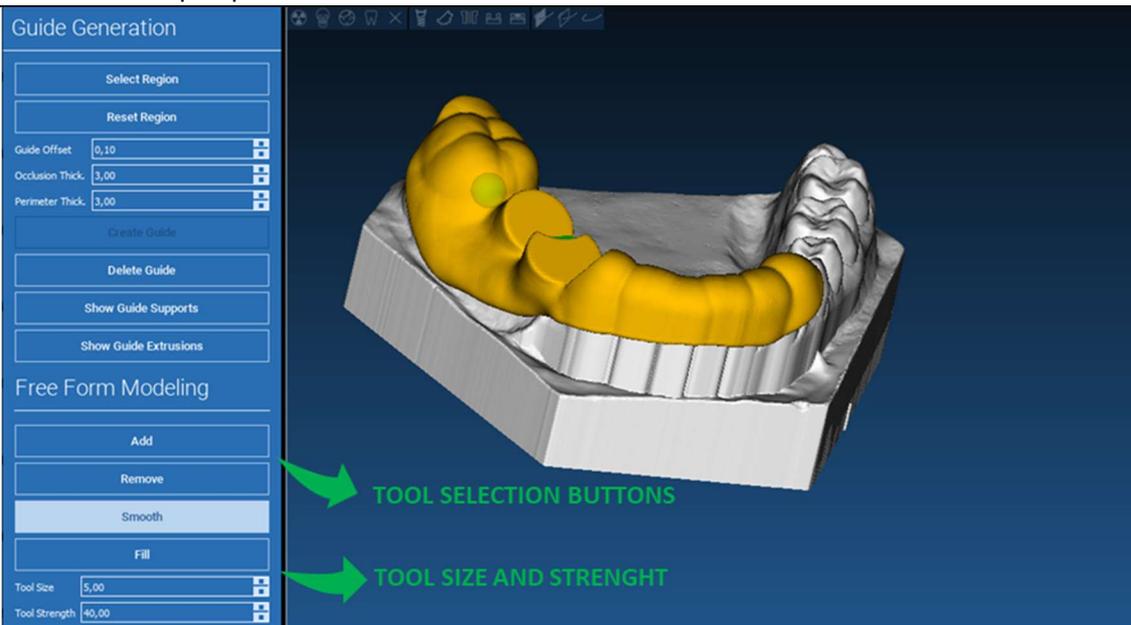
Trace the outer guide margin surrounding an area on the model: the command is active by default. A control point is added with any mouse click. It's not necessary to close the area loop, it's enough to position the last point close to the first one. Then check and define the fitting tolerance, the occlusal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





6.3. Modeling tools

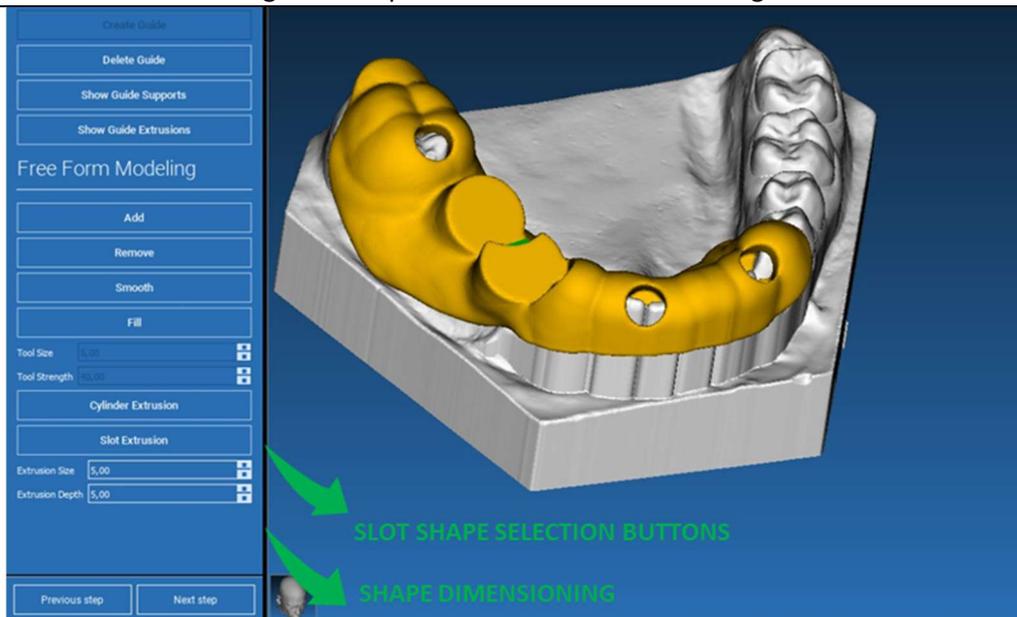
Once the guide volume has been created, the modeling tools become active. They permit to add/remove material, to smooth the surface and to fill in the depressions. Normally they are used to smooth the borders and to reinforce areas with deep depressions.





6.4. Inspection and anaesthetic readadministration windows

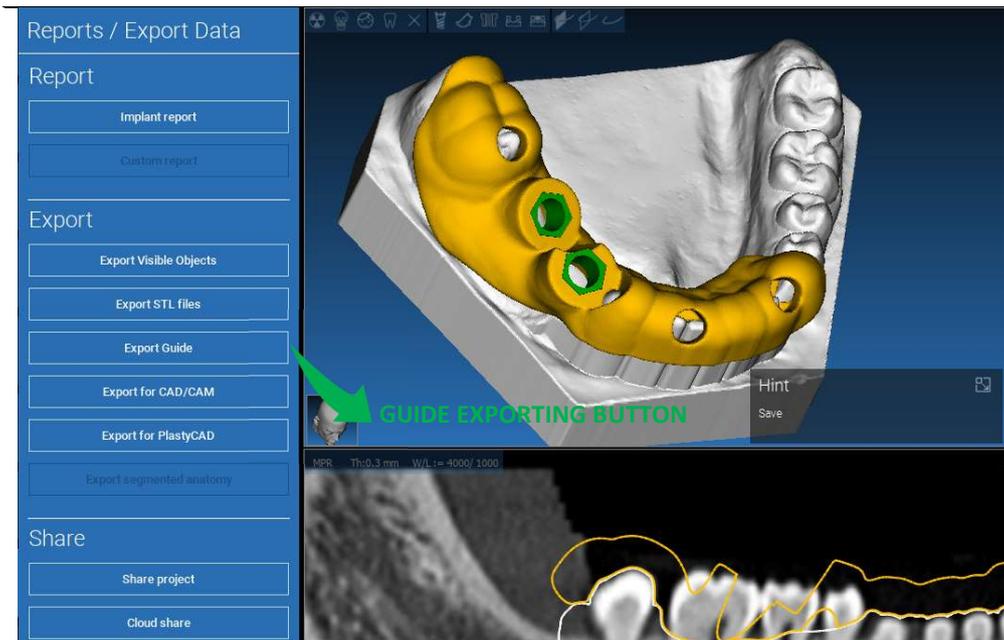
Under the modeling tools are located the commands to generate cylindrical holes and rectangular slots with their depth and size dimension parameters. By clicking on the guide surface in the desired position, the selected geometry with its axis oriented along the user point of view direction will be generated.





6.5. Finalization

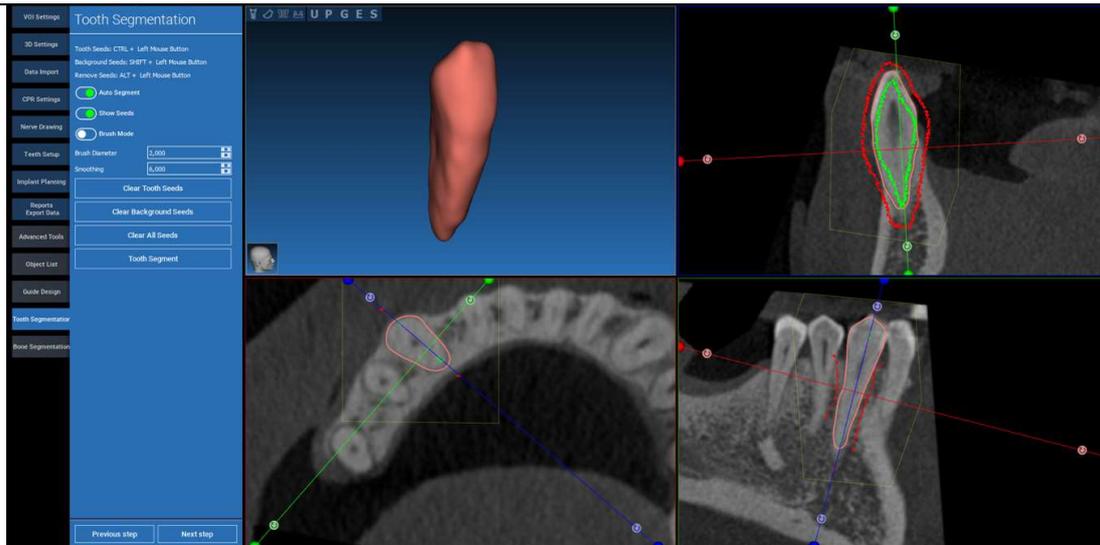
By clicking on **NEXT STEP** button the guide generation will be finalized by the sleeve seats construction. On the side menu the **REPORTS / EXPORT DATA** tab will appear, allowing the STL file export operations.



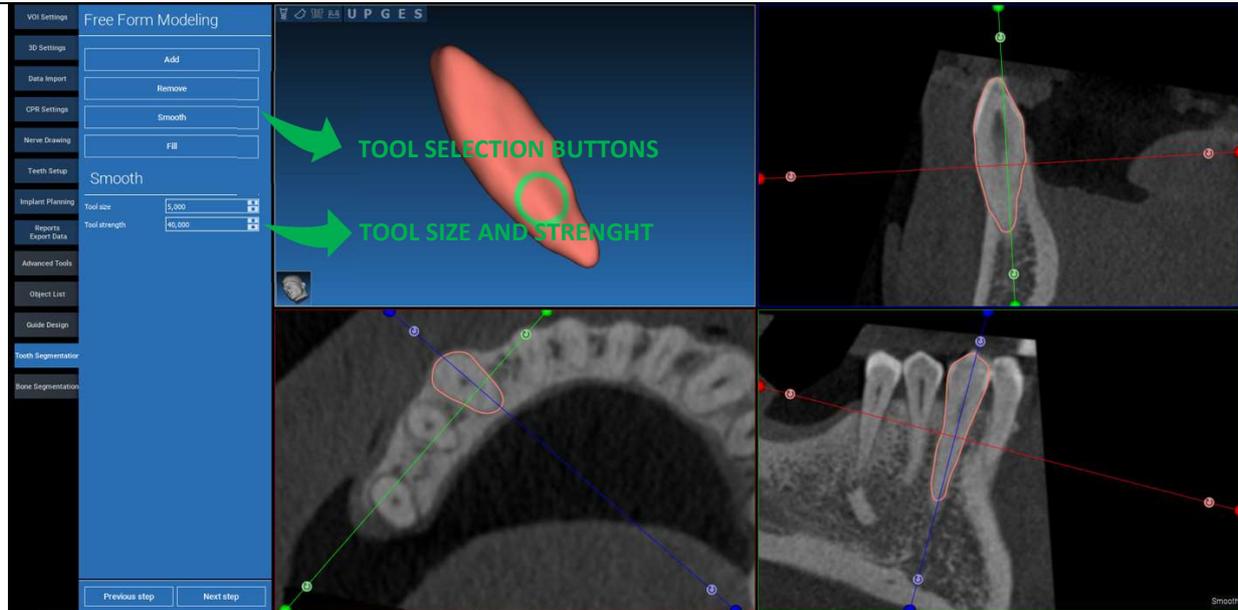
7. Segmentation

7.1. 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)

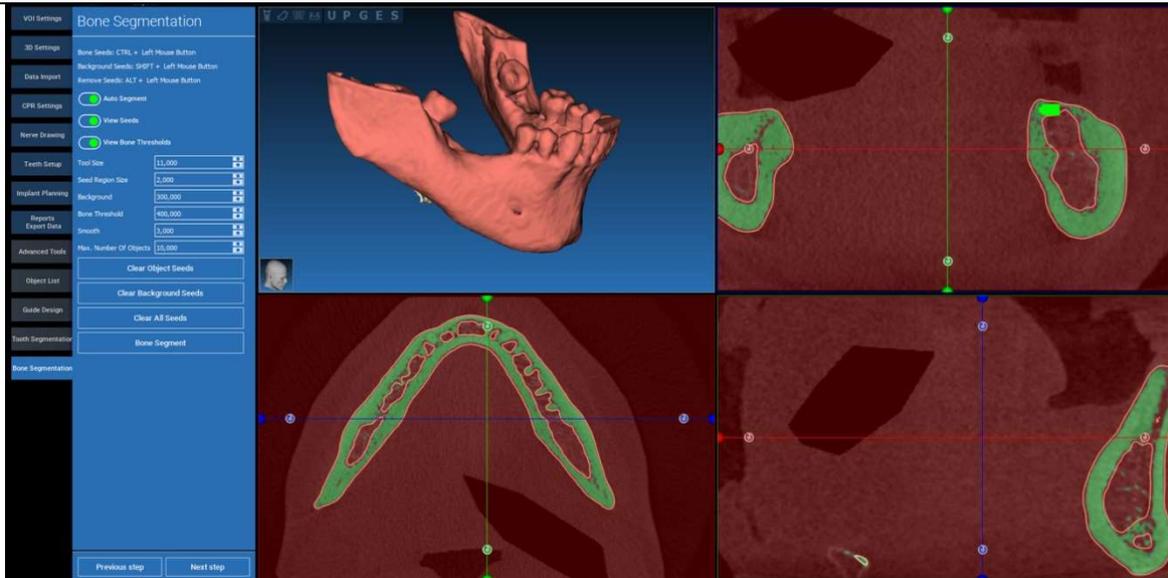


Use the FREEFORM modelling tools to further refine the tooth surface

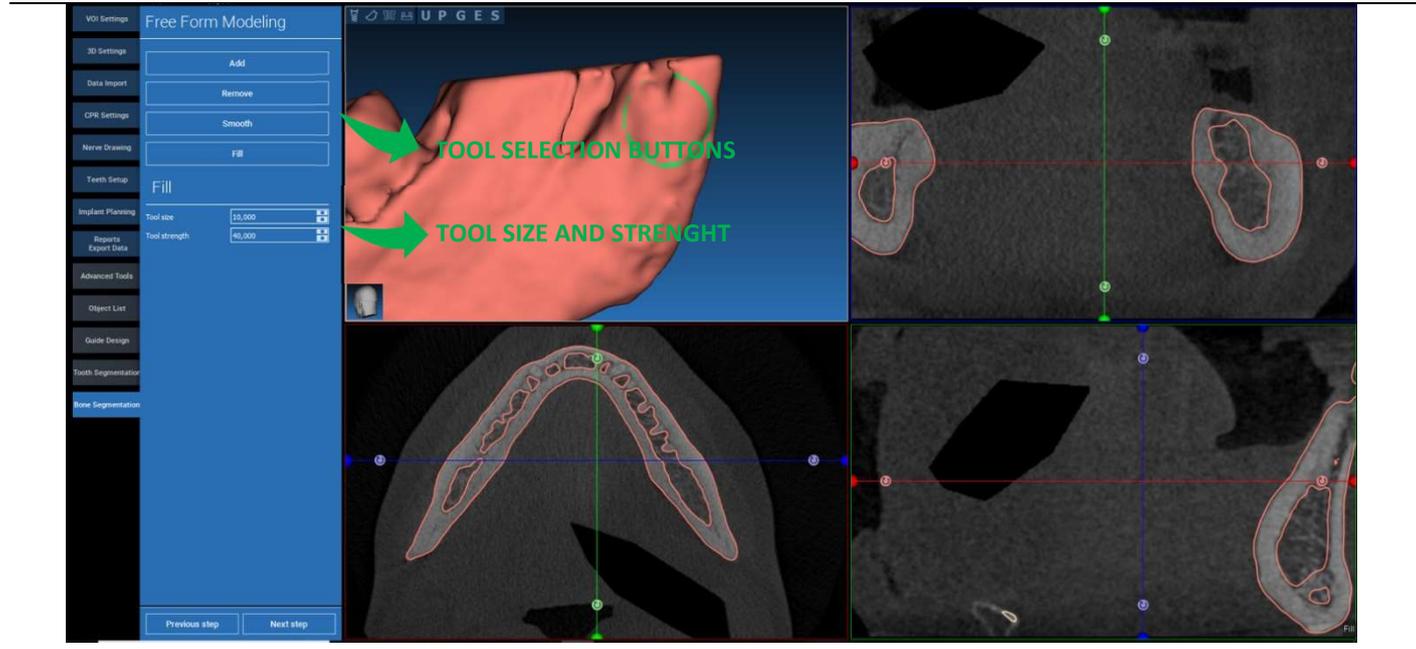


7.2. Bone segmentation

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)

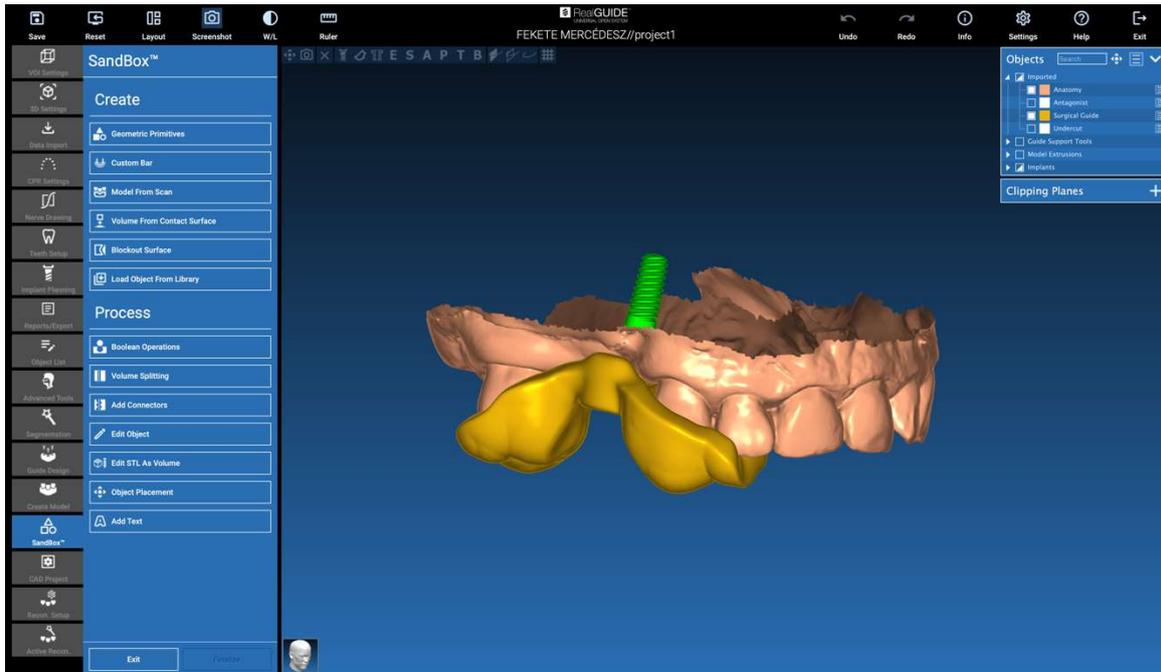


Use the FREEFORM modelling tools to further refine the bone surface



8. Sandbox

Click on the SandBox icon to access the dedicated tools:



The SandBox environment is split in 2 parts:

CREATE: it creates new objects inside the project. It's composed by the following functions:

- **Geometric primitives:** parametric geometric primitives generation and positioning in the 3D space
- **Custom bar:** tubular shape geometry generation, with custom section and free positioning in the 3D space
- **Model from scan:** conversion of a scan into a shell or closed model
- **Volume from contact surface:** it allows the generation of a custom volume starting from a surface selection, useful for the creation of bone grafts, grids, surgical guides parts
- **Blockout surface:** generation of a surface with no undercuts, according to the user settings
- **Load Object from Library:** it allows the insertion of previously saved objects from the Library into the 3D space

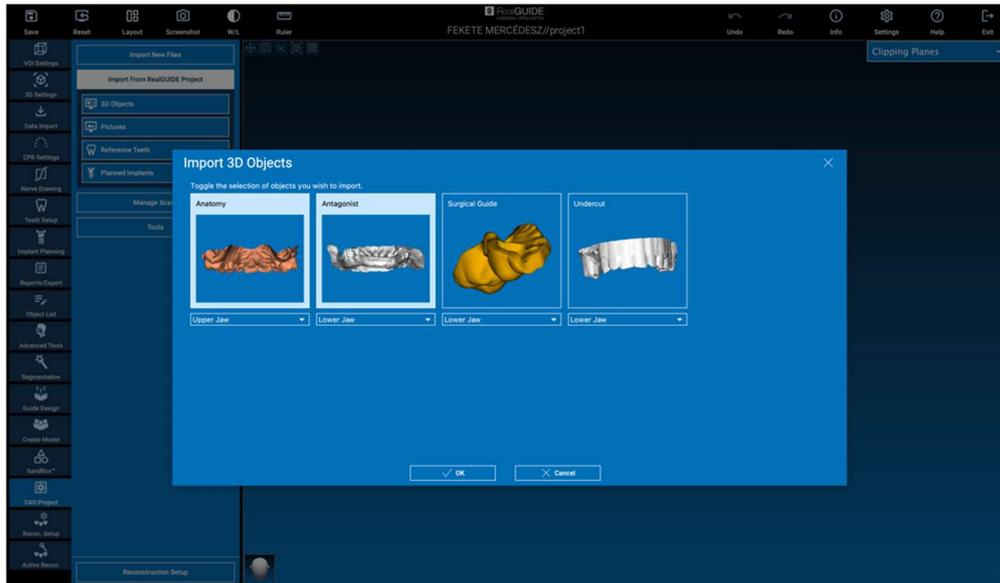
PROCESS: it allows the processing of all the objects create inside or outside SandBox:

- **Boolean operations:** perform any Boolean operation between user selected objects
- **Volume splitting:** create a custom slot to perform a volume splitting
- **Add connectors:** connect split parts with user defined connectors for a correct assembly
- **Edit object:** STL file processing tools
- **Edit STL as Volume:** convert a closed surface into a volume for faster freeform modelling
- **Object placement:** reposition the 3D objects in the 3D space
- **Add Text:** add a text on the objects surfaces

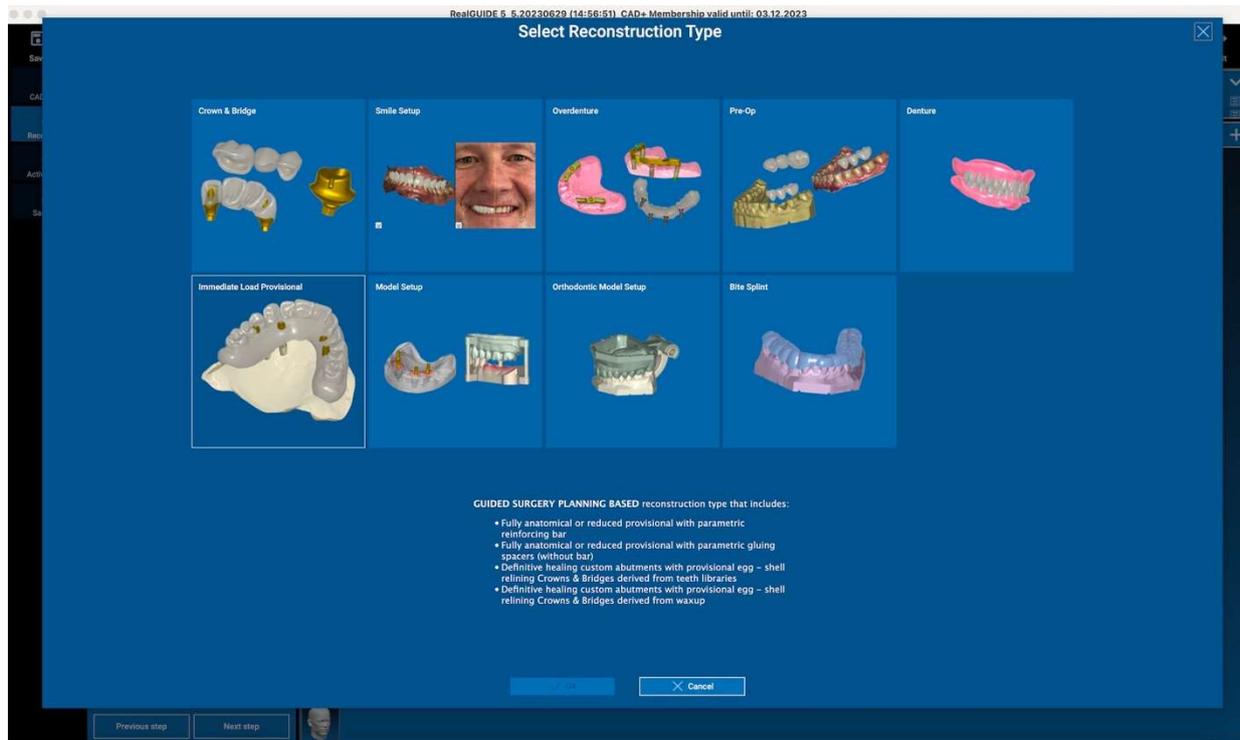
9. CAD

The CAD environment enables the dental prosthesis modelling by importing the following data:

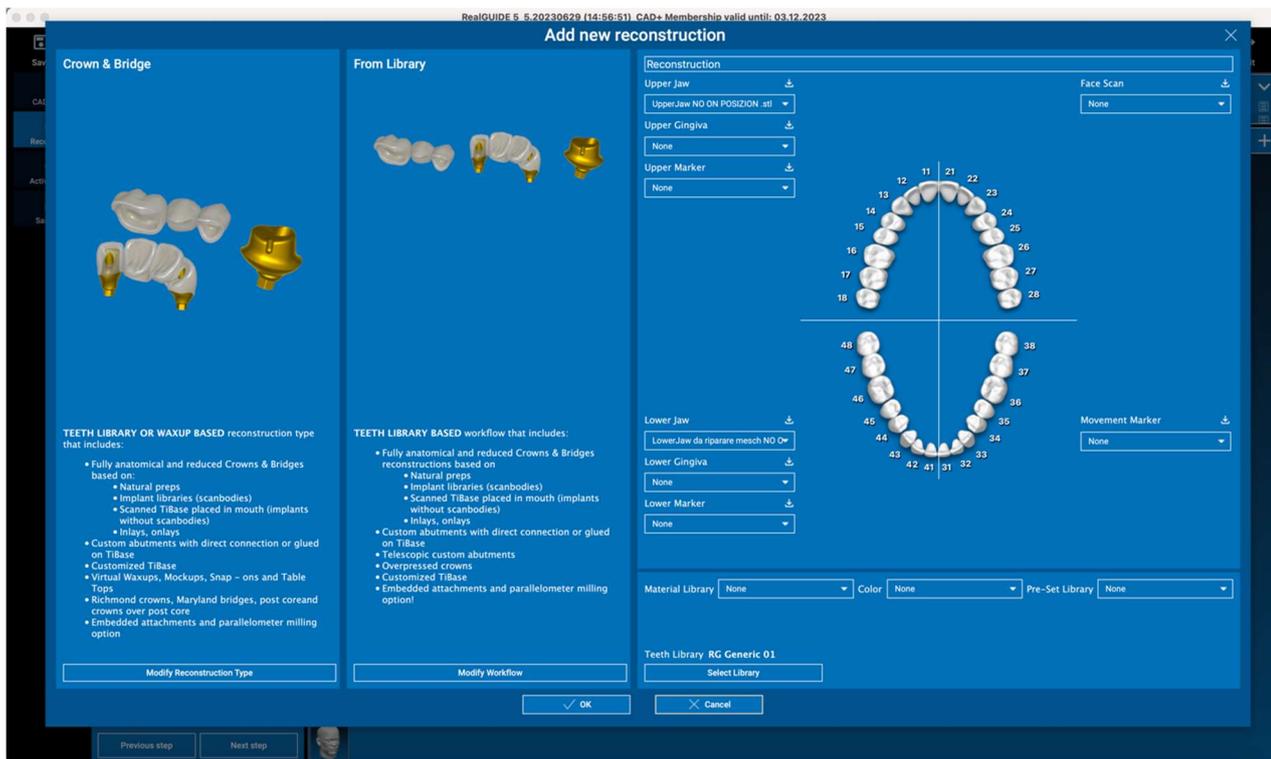
- **Import New Files** (optical scans or 2D pictures)
- **Import from RealGUIDE™ project** (3D objects, 2D pictures, reference teeth, planned implants)



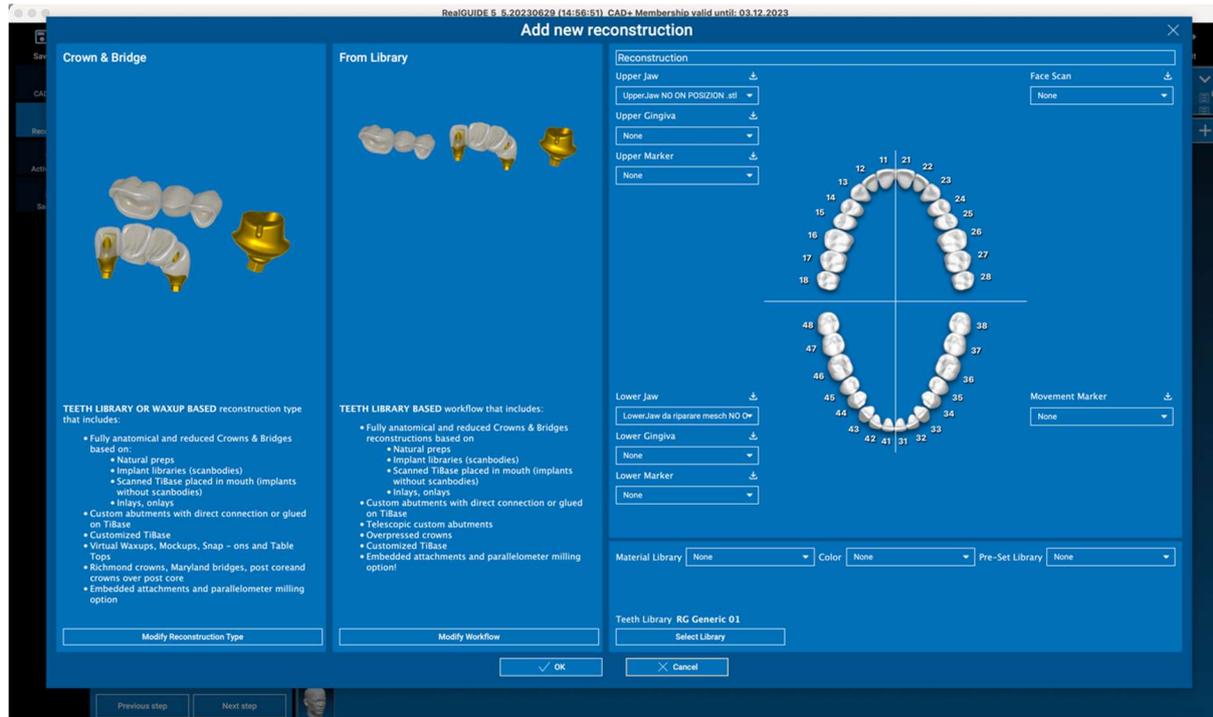
After importing the files it's possible to click on RECONSTRUCTION SETUP to design the desired prosthesis, following a step by step process, which starts from selecting the **RECONSTRUCTION TYPE**:



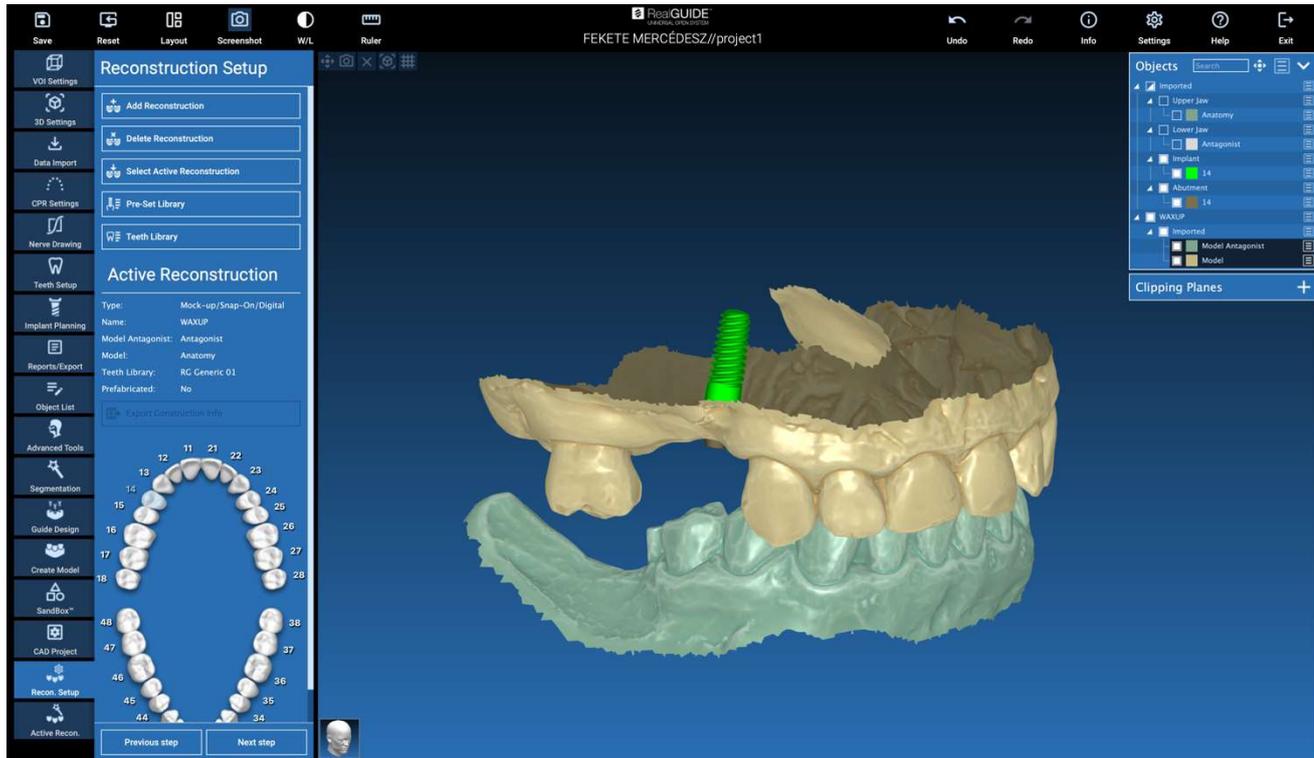
The reconstruction type identifies the macro-area of the rehabilitation; after selecting a reconstruction, a **WORKFLOW** selection window appears, identifying the specific procedure to be used to model the prosthesis:



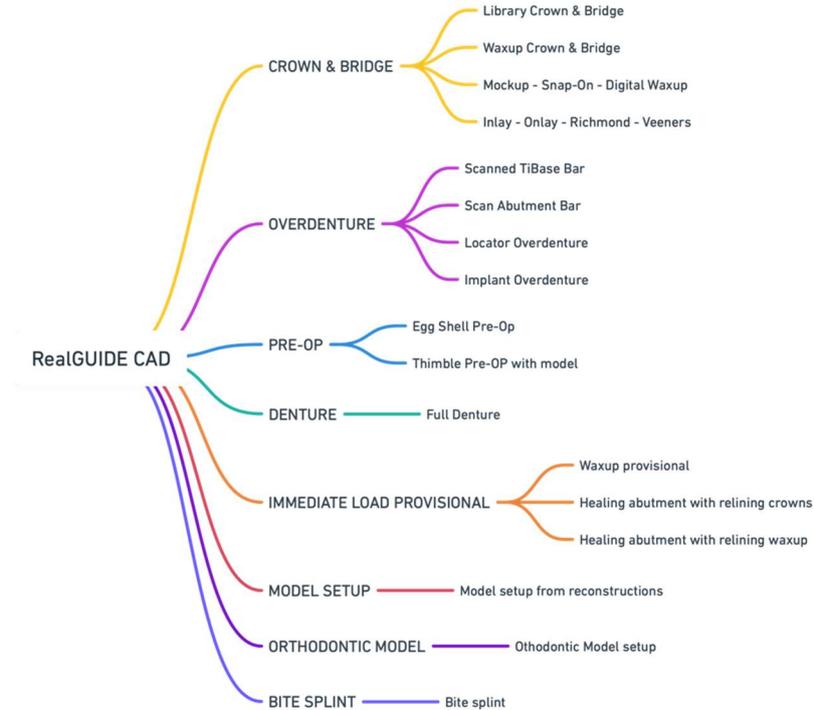
After selecting the workflow, it's necessary to identify the correct files to use (anatomy, antagonist,...), a teeth library and eventually the materials to be used to manufacture the prosthesis, according to the specific library shared by the Production Center:



Click on OK to confirm the selections and see a resume page. If everything's fine clicking on NEXT STEP will start the wizard that guides all the steps for the prosthesis modelling according to the selected reconstruction/workflow:



In the following scheme are reported all the reconstructions and connected workflows available in RealGUIDE:



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)
	Distributed by
	Swiss Authorised Representative

Further information on how to use RealGUIDE™ is available at (video tutorials) [video-tutorial.3diemme](#) and (FAQs) [helpdesk.3diemme](#).