Yomi Robotic System User Manual

Module II: YomiPlan 2.6 Software



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YomiPlan Version 2.6

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1. General Information For The User

1.1 Important Information

Safety warnings appearing through this User Manual are marked with this symbol.

The Yomi may only be used in accordance with local regulations and by qualified practitioners (user's) who fully observe the operating instructions and have the required technical training.

Federal law restricts this device to sale (or use) by or on the order of a qualified practitioner (user) (Per 21 CFR 801.109 Prescription Devices).

Note: Neocis does not endorse nor accept liability for off label uses of our devices.

1.2 Safety Measures

This manual shall be followed to ensure the protection of the patient.

The safety, reliability and performance of the equipment can be assured only if:

- **Installation, adjustment, maintenance, modification and service are performed by Neocis Inc. personnel, or persons authorized by Neocis Inc.**
- **The electrical installation of the facility where the device is installed meets the appropriate regulatory requirements.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.**
- **The Equipment is used as specified in the User Manual.**
- **Where specified in the User Manual, Neocis supplied spare parts and accessories are used.**

1.3 User Assistance Information

For any inquiries associated with the Yomi, or to report any problems or issues please email support@neocis.com or contact the following customer assistance line: 855-9NEOCIS.

1.4 Cleanning and Disinfection Methods

All external parts of the system such as monitors, laptops and cart should be cleaned by wiping with an EPA registered disinfectant wipe such as Sani-Cloth®AF3 Germicidal Disposable Wipes (EPA# 9480-6). Excess cleaning liquids should be wiped off with a soft cloth.

Cleaning, disinfection, and sterilization methods are described in greater detail in LB-0194 Yomi Robotic System User Manual Module I: Hardware.

Avoid spilling liquids into the surface of the device during cleaning / disinfecting. This may cause damage to the device

1.5 Explanation symbols

I/O	Mains switch ON / OFF
	Safety Warning! Consult the accompanying documents.
	Degree of protection against electric shock - Applied Part Type BF
 2014	Manufacturer / Date of Manufacture
	Consult Instructions for Use
	Refer to Instruction Manual / booklet
	Keep dry
	To ensure that the user is aware of a potential pinch hazard.
	Ensure safe movement of Yomi over a threshold.
	Do not use for more than one patient.
	Catalog Number or Reference Number
	Batch Code or Lot Number
	Serial Number



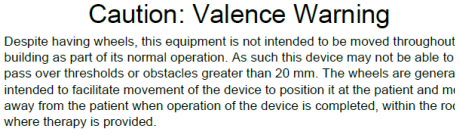
Indicates a medical device that has not been subjected to a sterilization process.



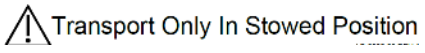
Do not use if package is damaged



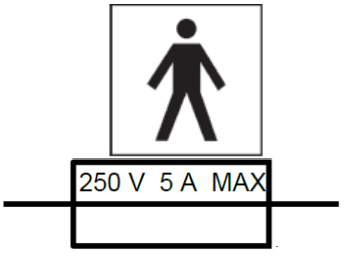
Federal (USA) law restricts this device to sale by or on the order of a physician.



Despite having wheels, this equipment is not intended to be moved throughout a building as part of its normal operation. As such this device may not be able to pass over thresholds or obstacles greater than 20 mm. The wheels are generally intended to facilitate movement of the device to position it at the patient and move away from the patient when operation of the device is completed, within the room where therapy is provided.



Transport Only in the Stowed Position

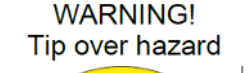


Applied Part

Fuse rating shall not exceed 250 Volts and 5 Amps



Tipping Hazard





Emergency Stop



Do Not Push



Push

2. Connection To Specified Compatible Equipment

The Yomi shall only be coupled with an Aseptico Drill Motor (Model No. AEU-7000LNE-70V), the Aseptico 20:1 Mont Blanc Implant Handpiece (Aseptico Model No. AHP-85MBFO-CX), and the Aseptico 1:1 Slow Speed Dental Surgical Handpiece (Aseptico Model No. AHP-64). Please refer to LB-1007 Yomi Robotic System User Manual Module III: YomiPlan 2.4 Surgical Technique for instructions regarding use of the Aseptico motor with the Yomi. Please refer to Aseptico's website (https://aseptico.com/resources/aseptico-manuals/) for further instructions regarding the cleaning, sterilization, and use of the Aseptico equipment.

For Yomi Robotically Guided Bone Reduction, Yomi is only compatible with the Meisinger HM72GX-060-HP Laboratory Carbide Bur, Medium, Cross Cut, Barrel 6.0MM, HP.

Refer to Aseptico Handpiece Maintenance Instructions AHP_Maint_420254 for the AHP-64 Handpiece and Meisinger Alveoplasty Surgical Kit User Manual for the Meisinger HM72GX-060-HP Laboratory Carbide Bur, Medium, Cross Cut, Barrel 6.0MM, HP for all indications, contraindications, warnings, and precautions associated with these devices.

3. Technical Specifications for PC Installation

The following requirements are the specifications necessary to install and run YomiPlan software on a PC not provided by Neocis. Users require a PC running Windows 10 OS, a minimum of 16 GB of RAM, a NVIDIA GPU (4GB), and an Intel Core i7 processor (8th Gen or newer). The minimum hard drive should be a 500 GB SSD. Connectivity requirements include ethernet or Wi-Fi and USB for DICOM file and plan file transfer.

4. Information For Clinician

4.1 Indications for Use

The Yomi Robotic System (Yomi) is a computerized robotic navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides robotic navigational guidance of the surgical instruments. The system can also be used for planning and performing guided bone reduction (also known as alveoplasty) of the mandible and/or maxilla. Yomi is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

When YomiPlan software is used for preplanning on third party PCs, it is intended to perform the planning (pre-operative) phase of dental implantation surgery. Yomi Plan provides pre-operative planning for dental implantation procedures using the Yomi Robotic System. The output of Yomi Plan is to be used with the Yomi Robotic System.

4.2 Contraindications

- The Yomi is not intended for use with patients that have insufficient bone or teeth to retain a Neocis YomiLink rigidly throughout a surgical procedure (refer to LB-0191 and LB-0253 User Manual Addendums for additional information on the indications, contraindications, warnings, and instructions for the YomiLink's).

- The YomiLink Teeth should not be affixed, to patients that exhibit:
    - Periodontal disease to include loose teeth and inflamed tissue
    - Fixed orthodontic appliances, bridges, and/or dental implants
    - Patients with a history of jaw or TMJ pain
    - Patients with allergies to O-Bite (i.e., Vinyl Polysiloxane bite registration material)
- The YomiLink Bone should not be used in patients with insufficient bone quality for fixation of the YomiLink and patient tracker loading.
- The YomiLink Bone should not be used in patients with a history of jaw or TMJ pain.

4.3 Caution

- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in procedural complications or patient harm.

4.4 Warnings

- Neocis Inc. has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the Yomi in applications other than the preparation of sites for placing dental implants.
- Sufficient teeth and underlying bone are necessary for rigidly maintaining a link in the patient's mouth. Any movement of a link relative to the rest of the mouth may lead to inaccurate preparation of the implant site.
- The Yomi is intended only to be used following installation qualification by a trained Neocis Inc. professional. The device is not to be used in an unqualified manner.
- All users must be properly trained, following approved Neocis Inc. training materials, prior to use.
- All assembly, adjustment, modification, or repairs associated with the Yomi shall only be performed by a trained Neocis Inc. representative.
- Do not touch the patient and other electrical equipment simultaneously when operating the device.
- Preplanning cases with the Yomi requires verification of the plan upon uploading to the Yomi planning station prior to performing the procedure on the patient. Always use best clinical judgement.
- Corrupted or inaccurate plans should be discarded and replanned.
- Only the dental materials listed in the Neocis User Manual Addendums for the selected YomiLink should be used (refer to LB-0191 and LB-0253)
- Dental material may flow into undercuts.
- Refer to the specific Neocis User Manual Addendums for each YomiLink for additional warnings (refer to LB-0191 and LB-0253)



The Yomi is not intended for use in an MR environment and has not been evaluated for use with RF emitting devices such as diathermy, RFID and electromagnetic security systems (metal detectors and EAS systems).

4.5 Precautions

- The Yomi should only be used by qualified practitioners trained in the placement of dental implants at facilities properly equipped for such procedures.
- Prior to using the Yomi to guide drilling, check the integrity of the system by using anatomical landmarks for verification. Touch the drill tip to a distinct anatomical landmark and verify that the visualization on the screen matches.
- The device is intended to be used with a single phase 120VAC 60 Hz Mains power source. Do not attempt to use the device with any other power source.
- The device is not designed to protect against ingress of solid foreign objects, or liquids (IPX0).
- The device is only designed to be used on a hard, flat, stable surface.
- When transporting and stowing the system, use proper handles.
- Ensure that the device is positioned in such a manner that the Device Power Cord is accessible during normal operation.

4.6 Adverse events

The following adverse events are possible:

- Inaccurate implant site preparation, resulting in suboptimal tooth placement or patient harm.
- Injury to user or patient due to uncontrolled or unintended motion of the system.
- Electric shock to user or patient due to electric malfunction.
- Misuse or off label use of the system that leads to manual manipulation of the osteotomy, resulting in patient injury or hazard to the user.

Neocis Inc. risk analysis documents reflect a complete description of potential adverse events. Although the system has been designed to mitigate all reasonably foreseeable risks, there is the possibility that unknown risks exist.

5. Device Description and Workflow

The Yomi Robotic System (Yomi) is a dental stereotaxic instrument and a powered surgical device for bone cutting. The Yomi System is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments. The Yomi System is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implant.

The Yomi System allows the user to plan the surgery virtually in our YomiPlan software, which is installed on the Yomi System Planning Station. Alternatively, Yomi Plan may be installed on a 3rd party PC for pre-planning. The operative plan is based on a cone beam computed tomography (CBCT) scan of the patient, which is used to create a 3-D model of the patient anatomy in our planning software. The plan is used by a guidance system to provide physical, visual, and audible feedback to the surgeon during the implant site preparation. The Yomi System robotic arm holds and guides a standard FDA-cleared third party powered bone cutting instrument.

The patient tracking portion of the Yomi System is used to track patient movement and is comprised of linkages from the patient to the Yomi System, which includes the YomiLink Bone for edentulous patients, the End Effector (EE) and the Patient Tracker (PT). The YomiLink is secured to the patient per the YomiLink Bone User Manual Addendum (LB-0191-00) prior to the presurgical CBCT scan.

A Fiducial Array (FA) with radio-opaque fiducial markers is placed on the YomiLink prior to the CBCT scan so the virtual plan can be related to the physical space of the system using the markers.

Key safety features include:

- Emergency stop
- Safety pause
- Audio and visual queues
- Drill torque limits
- Surgeon control

5.1 Stepwise Process Overview

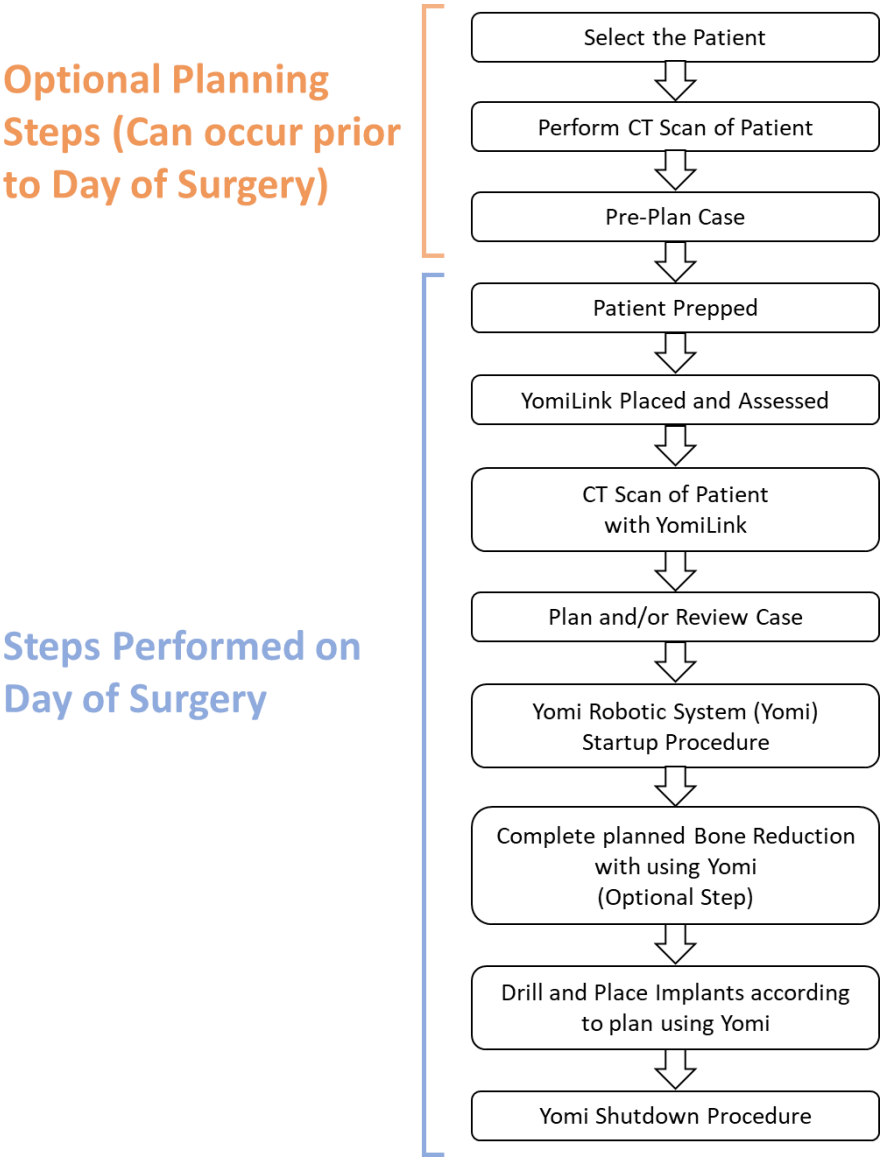


Figure 1: Standard Yomi Workflow

- Patient is examined by a trained qualified practitioner to ensure that the patient is eligible for dental implant surgery. The surgeon then determines if the patient has sufficient anchoring (teeth or bone) to provide a mount for the YomiLink, and if the patient's bone is sufficiently dense to provide rigid fixation for the YomiLink. Select the appropriate YomiLink for the procedures so access to the surgical site is not blocked and the YomiLink is stable and rigid. The procedure may be planned ahead of time using the Yomi planning station laptop.
- The YomiLink is prepared chairside. The surgeon can prepare the YomiLink, using one of the dental materials cleared for use with the selected YomiLink. Apply the YomiLink to a section of the arch away from (or contralateral to) where the surgery is going to be performed prior to acquiring the CBCT scan.
- The YomiLink is mounted on the patient at the proper location on the dental arch and evaluated.
- A Fiducial Array is mounted on the YomiLink and the patient then undergoes a CBCT scan.

- For dual arch, a YomiLink is mounted on each arch at the proper location and a Fiducial Array is mounted to each YomiLink
- The CBCT scan images are loaded into the YomiPlan software. The surgeon uses the anatomical images to plan the surgery.
- The Yomi is started when the surgeon is ready to perform surgery.
- The Yomi guides the surgeon through a series of modes that provide mechanical restriction and assists them in performing the osteotomy.
- Once the surgery is complete, the Patient Tracker is detached from the YomiLink and the YomiLink is unmounted from the patient. The Yomi is then shutdown and returned to its storage location.

5.2 Use of the YomiLink

Based on the clinical situation and the patient's anatomy, the clinician should select the YomiLink that will provide the best stability as indicated per the YomiLink indications. Please refer to LB-0194 Yomi Robotic System User Manual Module I: Hardware for additional information on the YomiLink options.

6. Software Utilization Instructions

All system software is installed and maintained by Neocis. Do no attempt to alter or service the software. Contact your Neocis representative if you need assistance.

6.1 Cybersecurity

YomiPlan 2.4 enables network transmission of CBCT image files over wireless networks using W-Fi for procedural planning. While any networked computer is vulnerable to attack, Neocis has made all practical efforts to ensure that the likelihood of such an event is very low and that the system impacts of such an event are minor or easily recoverable. To ensure the system remains as secure as is reasonably practicable, please observe the following instructions:

- Do not download or install any software applications to the Planning Station PC.
- Do not stream music or videos using the internet browser.
- Do not alter the settings of the OS or any software installed on the Planning Station PC.
- Do not connect any peripheral devices to the Planning Station PC.
- Do not disconnect the Planning Station PC from the system.
- Do not try to bypass or defeat any security measures.
- Do not access email from any provider on the Planning Station PC.
- Neocis retains administrative privileges. Do not attempt to make any changes that require administrative rights.
- The Planning Station PC Auto-Lock feature is set to off. Do not change this setting.
- Windows OS update is purposely disabled. Do not enable it on your own. Neocis will notify you if your system requires an OS update.
- Windows Firewall is enabled. Do not change its settings.
- Windows Defender antivirus/antimalware software is enabled and active. Do not change its settings. Do not install additional security software.
- Do not change the system passwords and ensure that they are kept private.
- If you have any questions or concerns about cybersecurity, please contact Neocis.
- Neocis can access your Planning Station PC using a software application called TeamViewer. It provides a secure end-to-end connection over the network. It allows Neocis to retrieve system files and to provide remote assistance during planning. TeamViewer is restricted to use by trained Neocis personnel only. Do not attempt to alter any TeamViewer settings. If you encounter any issues with TeamViewer, contact Neocis.

Failure to follow these instructions could cause the Planning Station PC to run too slowly, to shut down, or to become infected with a virus or malware that could impair its performance or compromise patient data.

6.2 Software Controls

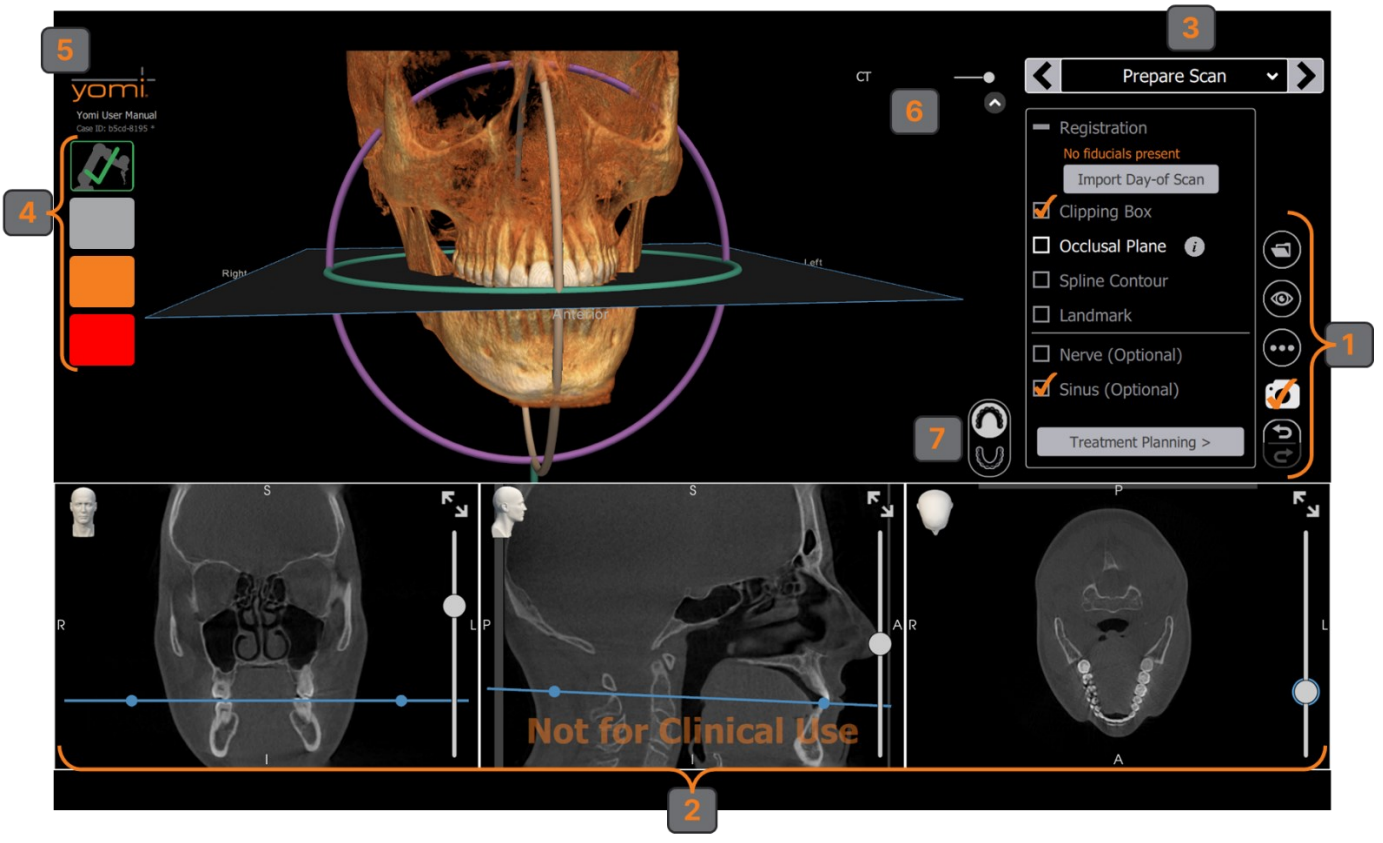


Figure 2: YomiPlan Software User Interface Layout

1. **Menu Bar:** Contains the File, Edit, Layout, Display and Advanced menu options. These options provide the user with the means to save / load data and information, undo / redo operations, optimize desired settings and views, and manipulate registration settings. This area of the YomiPlan Software window is also dedicated to creating, editing and adjusting the planning features.
2. **Visualization Area:** The area of the YomiPlan Software window dedicated to visualizing the patient anatomy and planning features.
3. **Control Panel Tabs:** The Control Panel consists of 7 tabs – PreOp Setup, Prepare Scan, Treatment Planning, IntraOp Setup, Bone Reduction (if planned), Osteotomy, Place Implant, and Complete Case. Surgical pages will be nested under the corresponding jaw grouping. The arrows can be used to change jaw execution order. Clicking on a tab displays the associated controls in the Control Panel area.

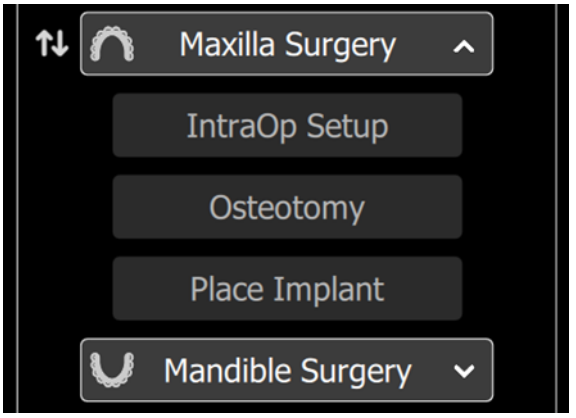


Figure 3: Control Panel Tab Jaw Grouping

4. **Message Box and Communication Status:** Icon boxes are displayed in this area and indicate active Warning and Error messages coming from the system. Colored indicators help the user identify the status of the Robot, the Force Torque (FT) Sensor, the Patient Tracker, the Work Volume and the Landmark. Green indicators represent properly functioning subsystems. Red indicators represent an error with the subsystem. Orange indicators represent the presence of warning conditions, that may require remedial action (troubleshooting) to ensure continued proper operation. Grey / disabled indicators represent the absence of communication between the YomiPlan Software and the subsystem.
5. **Title Bar:** Displays the YomiPlan name and case information (Patient's name, DICOM file name and case name).
6. **Sliders:** Sliders are displayed in this area to control the visibility of each of the layers displayed in the 3D and 2D views. To hide the sliders, click on the upward facing caret at the bottom of the slider list. To show the slider list when closed click on the downward facing caret. The sliders can be used to control the transparency of each one of the available layers. Transparency levels range from 0, completely transparent, to 100, completely opaque. To change the transparency of a specific layer you can either click on the location of the slider for the desired transparency or click and drag the circle available on the slider. The transparency value will be displayed on the slider. Clicking on the label on the left side of the slider will toggle between the layer being completely transparent (0 transparency) and the last selected level of transparency.
7. **Jaw Toggle:** The Jaw Toggle is used to control between upper and lower jaw planning. Clicking the jaw toggle will switch the interface to be aligned with the features on the corresponding jaw and allow to plan both upper and lower features.

   NOTE: The jaw toggle selection will be kept when moving through planning steps. The jaw toggle can be used to plan both jaws for every step in the Prepare Scan Page or it can be switched once, and the steps repeated to plan one jaw at a time.

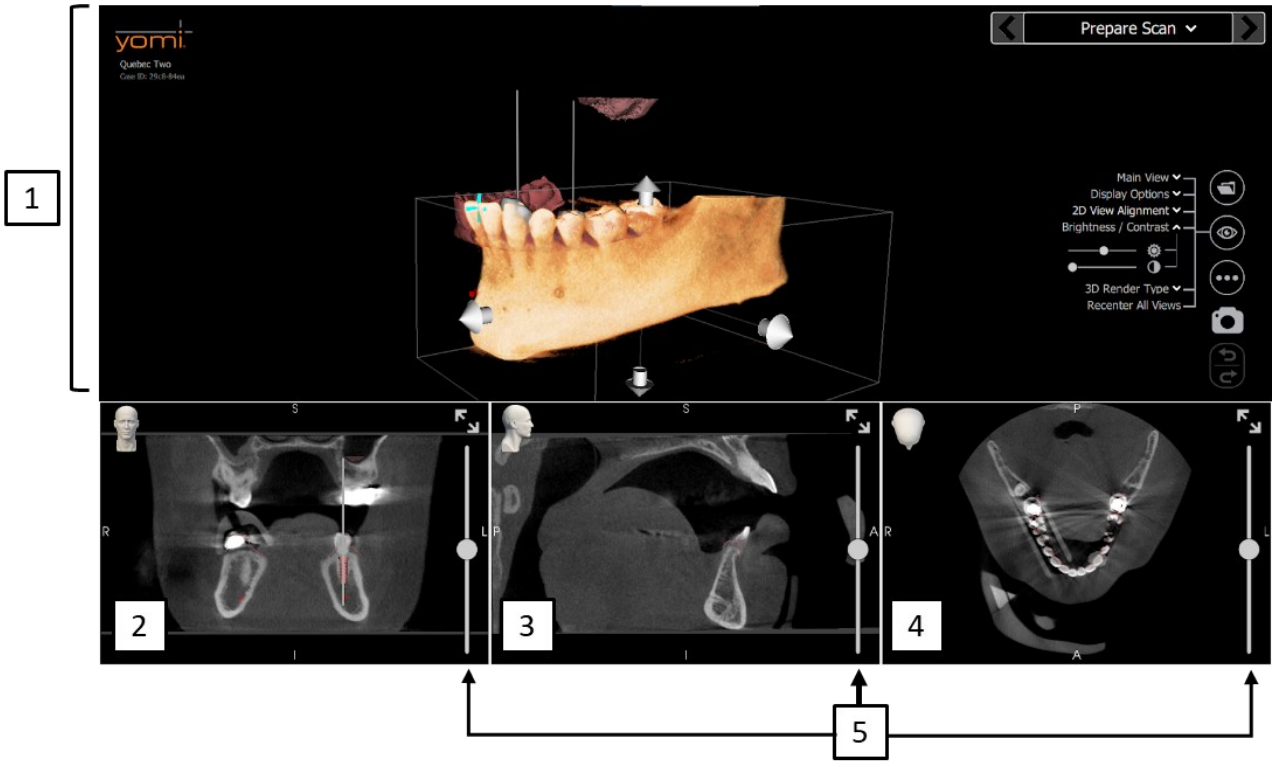


Figure 4: YomiPlan Software 3D Layout

1. **3D View:** Visualizes a 3D representation of the patient anatomy and planning features and allows the user to interact with it to rotate, pan and zoom the image. The CBCT scan coordinate frame is displayed in the lower left-hand corner. During surgery, an icon is displayed in the upper right-hand corner that indicates the system's current behavior mode.
2. **2D Coronal View:** Visualizes a Coronal slice through the 3D representation. Patient anatomy and planning features that intersect with the Coronal slice are displayed in this view.
3. **2D Sagittal View:** Visualizes a Sagittal slice through the 3D representation. Patient anatomy and planning features that intersect with the Sagittal slice are displayed in this view.
4. **2D Transverse View:** Visualizes a Transverse slice through the 3D representation. Patient anatomy and planning features that intersect with the Transverse slice are displayed in this view.
5. **2D Slider:** A slider that enables the user to adjust the 2D slice displayed in the 2D View is available on the right side of each 2D View. Adjusting the slider will show the 2D cross-section's location along the axis in the 3D view to provide visual guidance of the 2D slice's location within the patient's anatomy.

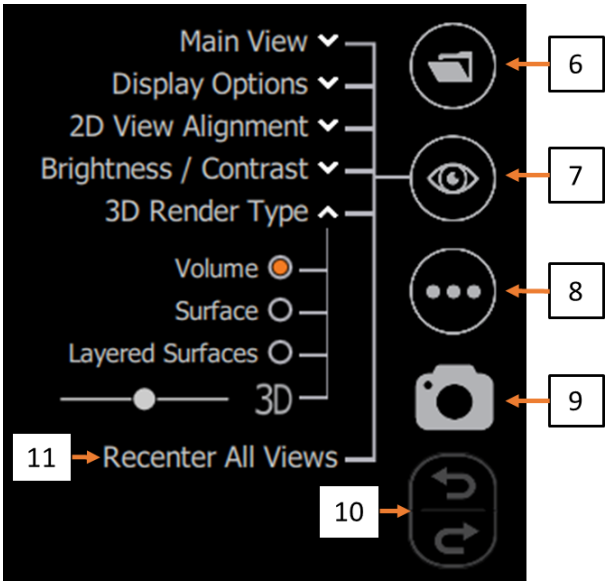


Figure 5: 2D View Adjustment

6. **File Menu:** The "file" icon displays a list of file-handling functions. These functions include Save, Save As, Import Scan, Import STL, Export STL, About, Close Case, and Exit.
7. **View Menu:** The "eye" icon displays a list of submenus with tools that allows the user to adjust the visuals and display options presented. Included in the View Menu is the ability to switch between a Panoramic and 3D visual in the Main View, turn on/off the visualization of 2D and 3D objects and labels, adjust the relative alignment of the 2D views (relative to the occlusal plane, landmark, implant, or drill bit), adjust the brightness and contrast of the DICOM data, adjust the threshold and rendering style of the 3D anatomy, and Recenter All Views.
8. **More Options Menu:** The "..." icon displays a list of submenus and tools that further expand the users experience planning and interacting with the Yomi. Included in the More Options Menu are Implant Planning Tools for length and angular measurement, Osteotomy Tools for dynamic adjustments, Robot Positioning tools to help position the guide arm without returning to IntraOp setup, and Change Jaw which allows the user to switch the selected arch in which to perform the dental implant procedure.
9. **Capture Screenshot:** The "camera" icon is a button that saves an image of the YomiPlan software screen in the Pictures folder on the Planning Laptop.
10. **Undo/Redo Buttons:** The Undo button (top arrow pointing to the left) reverses the previous planning actions taken. The user can reverse multiple actions by continuing to press the Undo button. The Redo button (bottom arrow pointing to the right) restores any action undone. The user can restore multiple actions by continuing to press the Redo button. Hovering over the Undo or Redo buttons will describe what action the button will reverse or restore. Any new action will clear the list of actions that can be restored with the Redo button. Entering the Osteotomy and Place Implant pages will reset the list of actions that can be reversed with the Undo button
11. **Recenter All Views:** A button that resets the position and orientation of the patient anatomy in the 3D View, taking into account the Occlusal Plane. It also adjusts the slice shown in the 2D Views to pass through the center of the selected Implant.

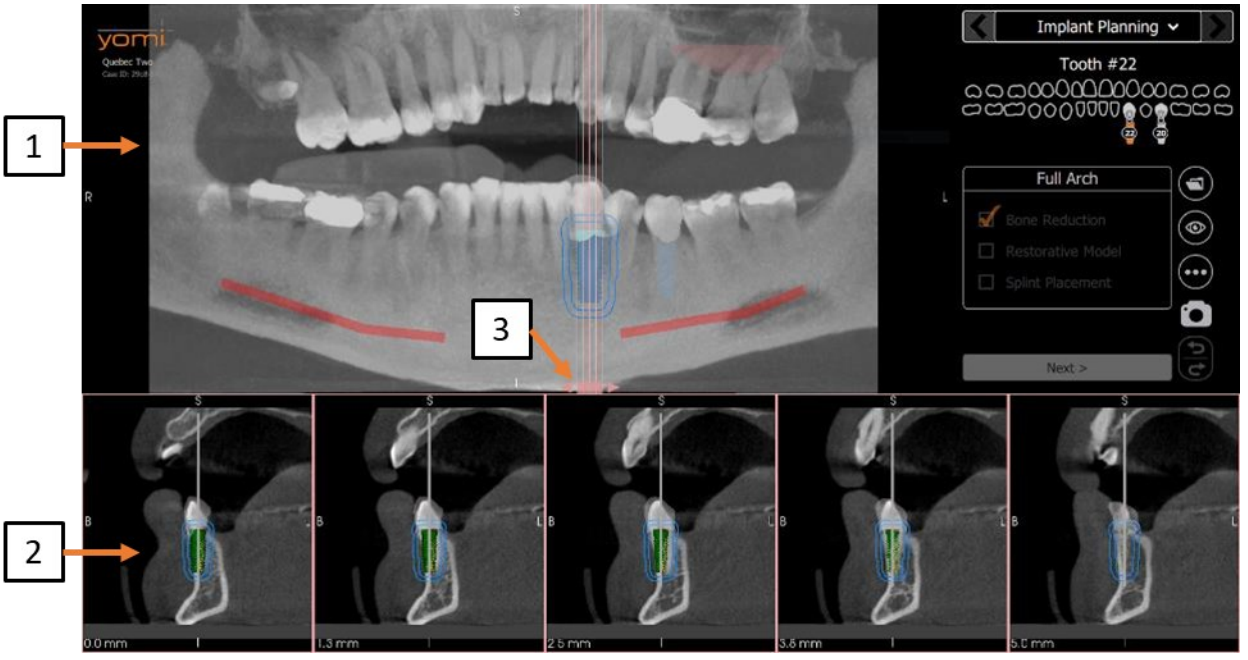


Figure 6: YomiPlan Software Panoramic Layout

1. **Panoramic View:** Visualizes the patient anatomy and the planning features, including Implants and Nerve, as a panoramic image created using the Spline Contour.
2. **2D Oblique Views:** Five 2D Oblique Views visualize the Oblique Planes through the 3D representation. Patient anatomy and planning features that intersect with the Oblique Planes are displayed in this view. The Oblique Planes are represented by the pink vertical lines displayed in the Panoramic View.
3. **Panoramic Slider:** Allows user to adjust the location of the Oblique Planes along the panoramic image. Clicking and dragging the bar translates the planes. Clicking and dragging either arrow located at the ends of the bar will increase/decrease the spacing between the Oblique Planes. Any adjustments made will update the 2D Oblique views in real time.

6.3 Interacting with Views

1. **Panning:** The images in the 3D View and 2D Views can be panned by clicking and holding the middle mouse button within the view. With the middle mouse button still pressed, move the mouse to pan the desired view.
2. **Zooming:** The images in the 3D View and 2D Views can be zoomed by clicking and holding the right mouse button within the view. With the right mouse button still pressed, move the mouse cursor toward the top of the screen to zoom in and toward the bottom of the screen to zoom out. Alternatively, using the scroll wheel while the cursor is over the desired view will also zoom the view in and out.
3. **Rotating:** The image in the 3D View can be rotated by clicking and holding the left mouse button within the view. With the left mouse button pressed, move the mouse to rotate the 3D model to the desired orientation.
4. **Maximizing**: Each 2D View can be maximized for additional visualization. Select the maximize button (two arrows pointing away from each other) in the upper right corner of the view you wish to expand. The restore button (two arrows pointing toward each other in upper right corner of the view) will return the screen to the default layout. Maximizing sub views are disabled when the Guide Arm is moving (Free and Guided Modes).

7. CBCT Scan Process

Refer to LB-0194 Yomi Robotic System User Manual Module I: Hardware for initial preparation of the patient, including the CBCT Scan Protocol.

8. Planning Protocol

8.1 Opening the Software

Start by Opening the software by selecting the YomiPlan 2.4 icon shown in Figure 6.



Figure 7: YomiPlan 2.4 Desktop Icon

8.2 Start Dialog

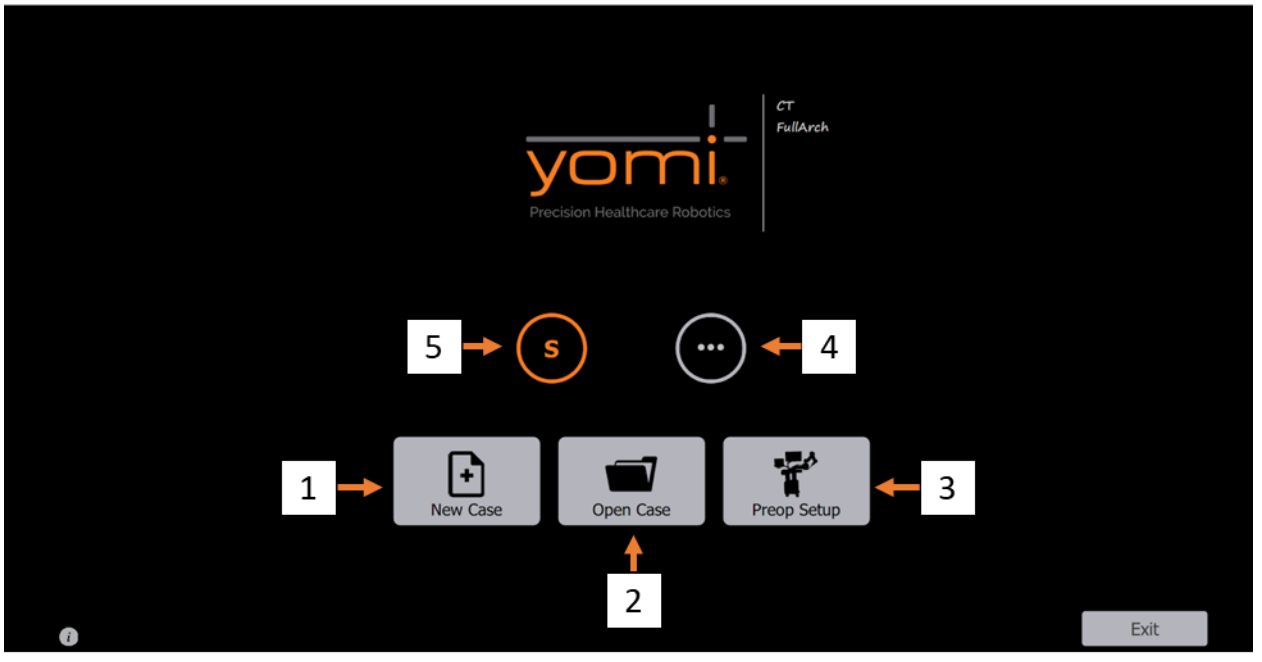


Figure 8: Start Dialog screen

1. **New Case:** Button used to start a new case.
2. **Open Case:** Button used to load an existing patient's case file into the YomiPlan Software in order to resume planning or perform surgery.
3. **Preop Setup:** Button used to launch the Startup Routine to initialize the Yomi prior to opening the YomiPlan.

4. **Surgeon Preferences:** Select the "…" button to add and edit the list of surgeon profiles and their associated surgeon preferences.
5. **Recent Surgeon Profile(s):** Surgeon profiles that have already been created using Surgeon Preferences (maximum of the 3 most recently selected), will be available for selection to the left of the Surgeon Preferences button.



Figure 9: Surgeon List - Clicking plus will add new surgeon and selecting the pencil by surgeon name will open the surgeon's profile to be edited.

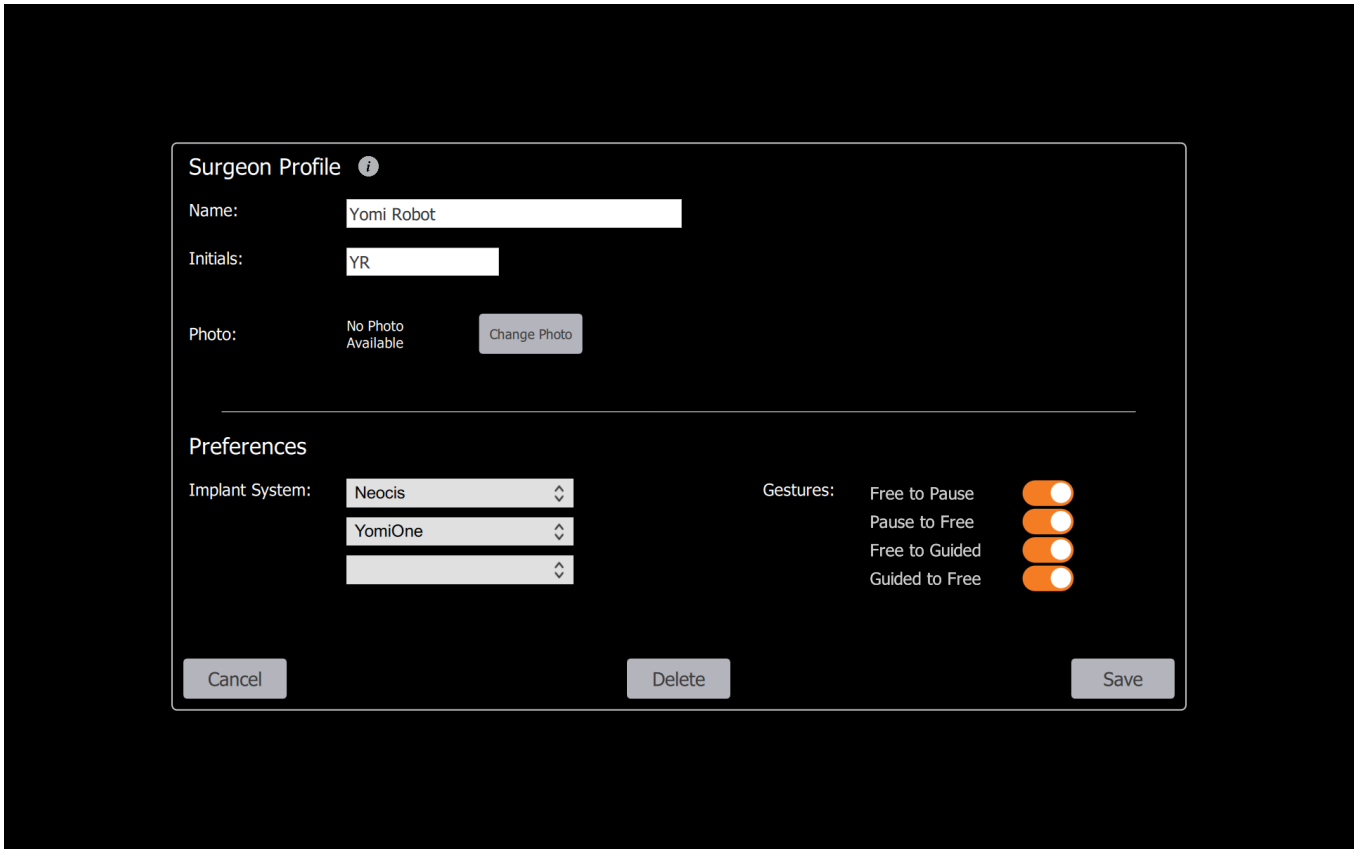


Figure 10: Surgeon Profile Screen

Surgeon Profile Page: Customize surgeon name, picture, default implant system and Gestures controls to be enabled/disabled during surgery.

8.3 Starting New Case and File Transfer

1. After YomiPlan is started and the Start Dialog screen is displayed, click on the "New Case" button.

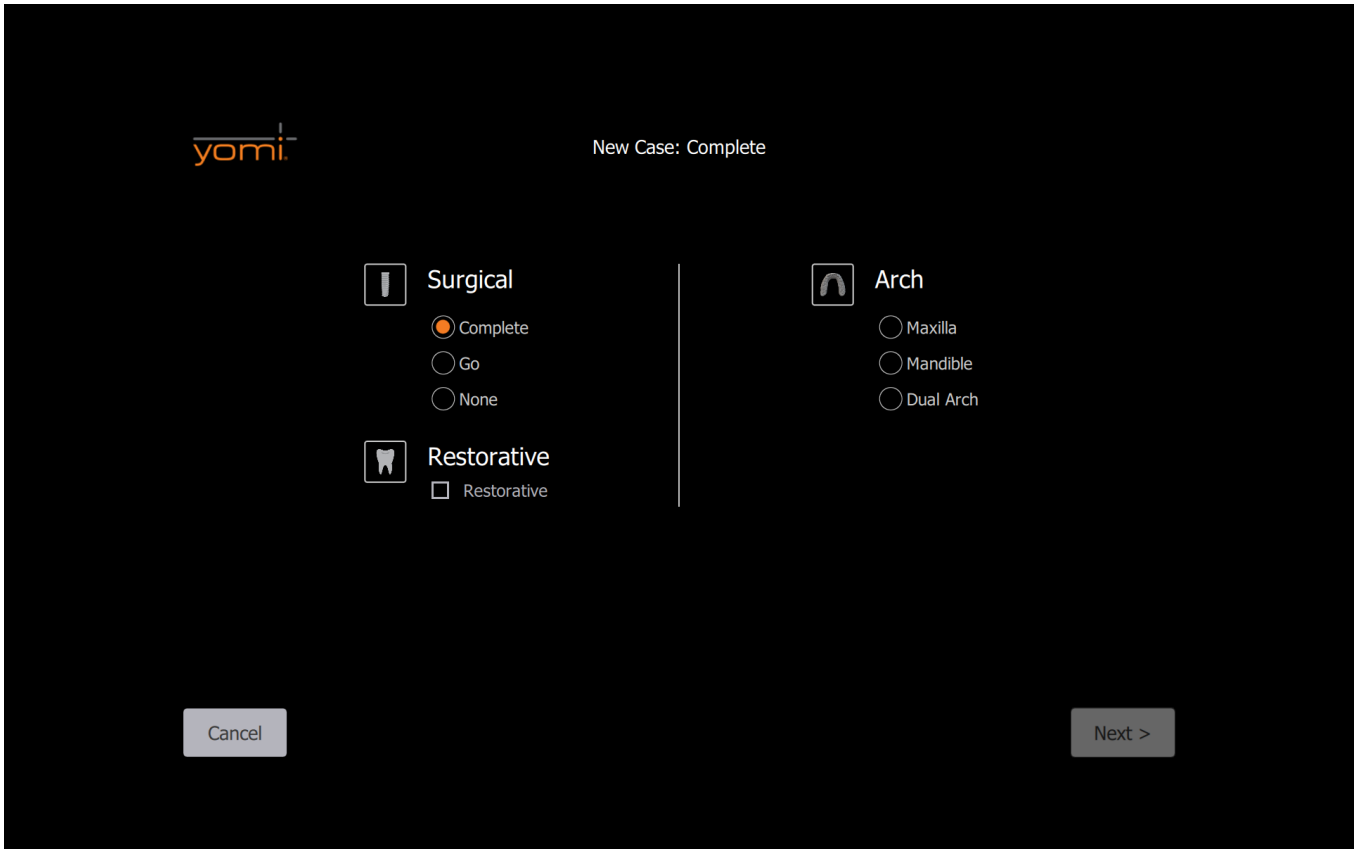


Figure 11: New Case Dialog Box

2. Next, select the desired workflow and arch to work on. Complete is the standard YomiPlan workflow utilizing preoperative planning. YomiPlan Go is a workflow that allows a surgeon to plan and execute an osteotomy using the drill tip to define the starting point and trajectory of the drill path during the osteotomy – all without the need of a CBCT scan. For further instructions on the YomiPlan Go workflow, refer to LB-1001 YomiPlan Go User Manual. None is a restorative only workflow to design crowns, bridges, and arches.

   Note that the Arch Selection can be modified after this step using the Change Workflow option under the File Menu on the right side of the screen as seen in the image below.

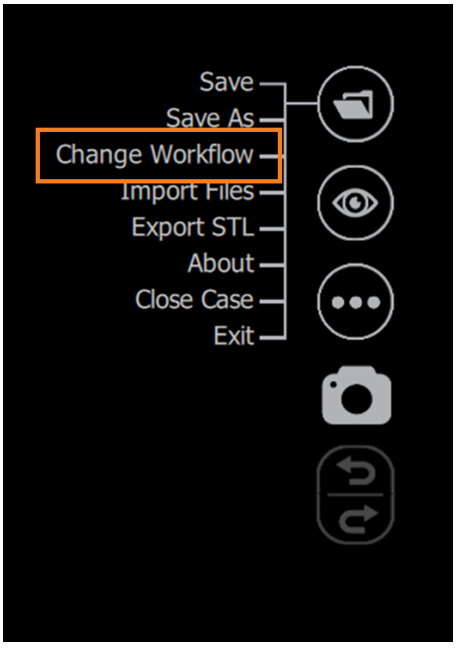


Figure 12: Change Workflow Option

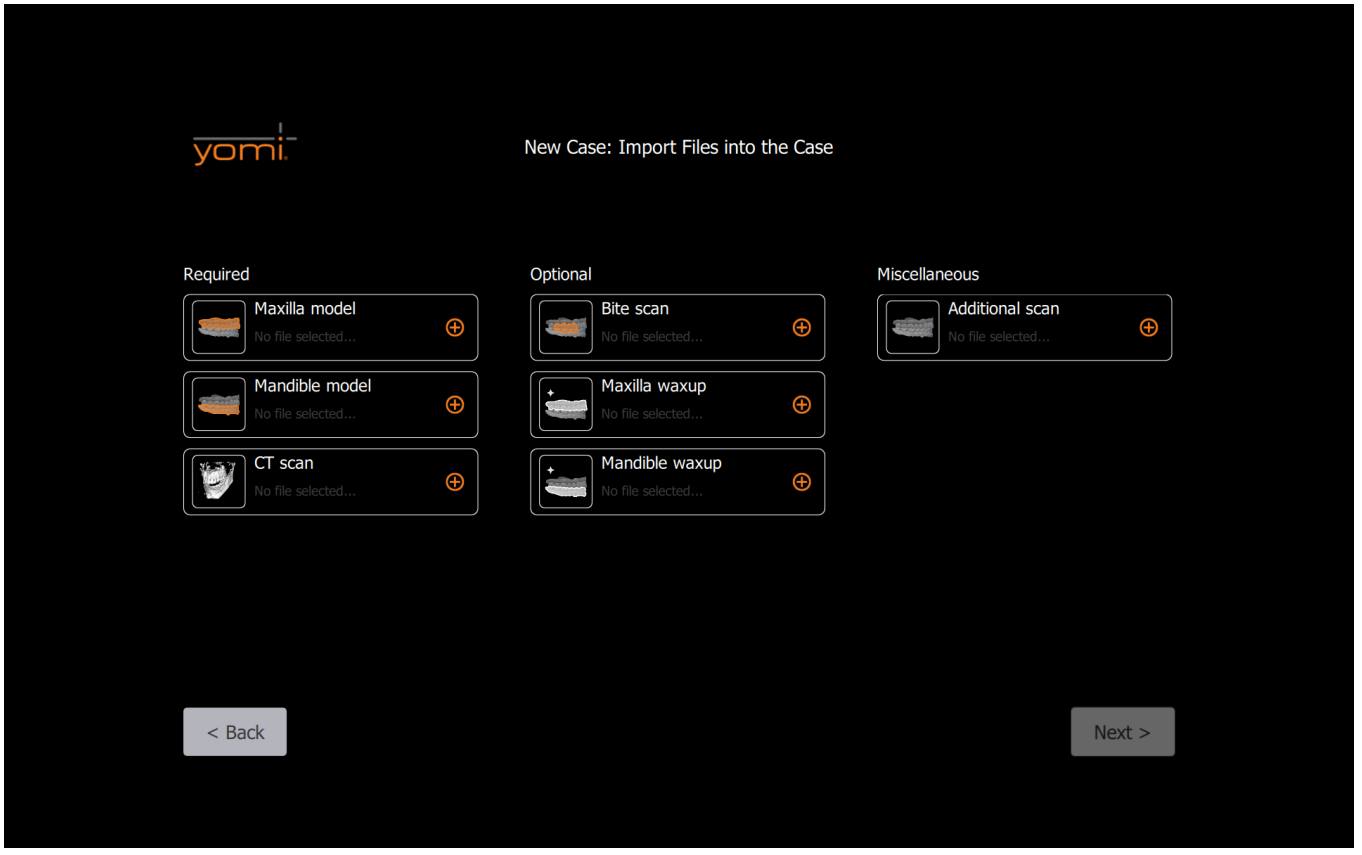


Figure 13: Import Files Dialog

3. Select the  icon next to the desired model or scan to be imported. Navigate to the STL or DICOM file and select Open. Additional scans can be renamed and associated with a jaw during import. The given name will be used for slider display. If no name is given during import, the filename will be used.

   When creating a new case based on a CBCT scan, the software inspects which directory the CBCT scan is in at time of import. If it is on a USB drive, an external hard drive, a network drive, or any drive other than the local “C:” hard drive, the software will first copy the CBCT scan directory to the local "Documents\Neocis\DICOM" directory before reading it in. When saving, the saved case file refers to the local copy of the CBCT scan.

   If a CBCT scan is already on the local “C:” hard drive, then no copy operation is performed, and the scan is read from its existing location.

   To facilitate loading CBCT scans from network servers, and to enable remote access for service and support activities, network connectivity to a local network is possible. The network settings on the planning station laptop should only be changed by a Neocis field service engineer.

4. If at least one intraoral scan model is added during import, the software will require an alignment step between the intraoral and CBCT scans.

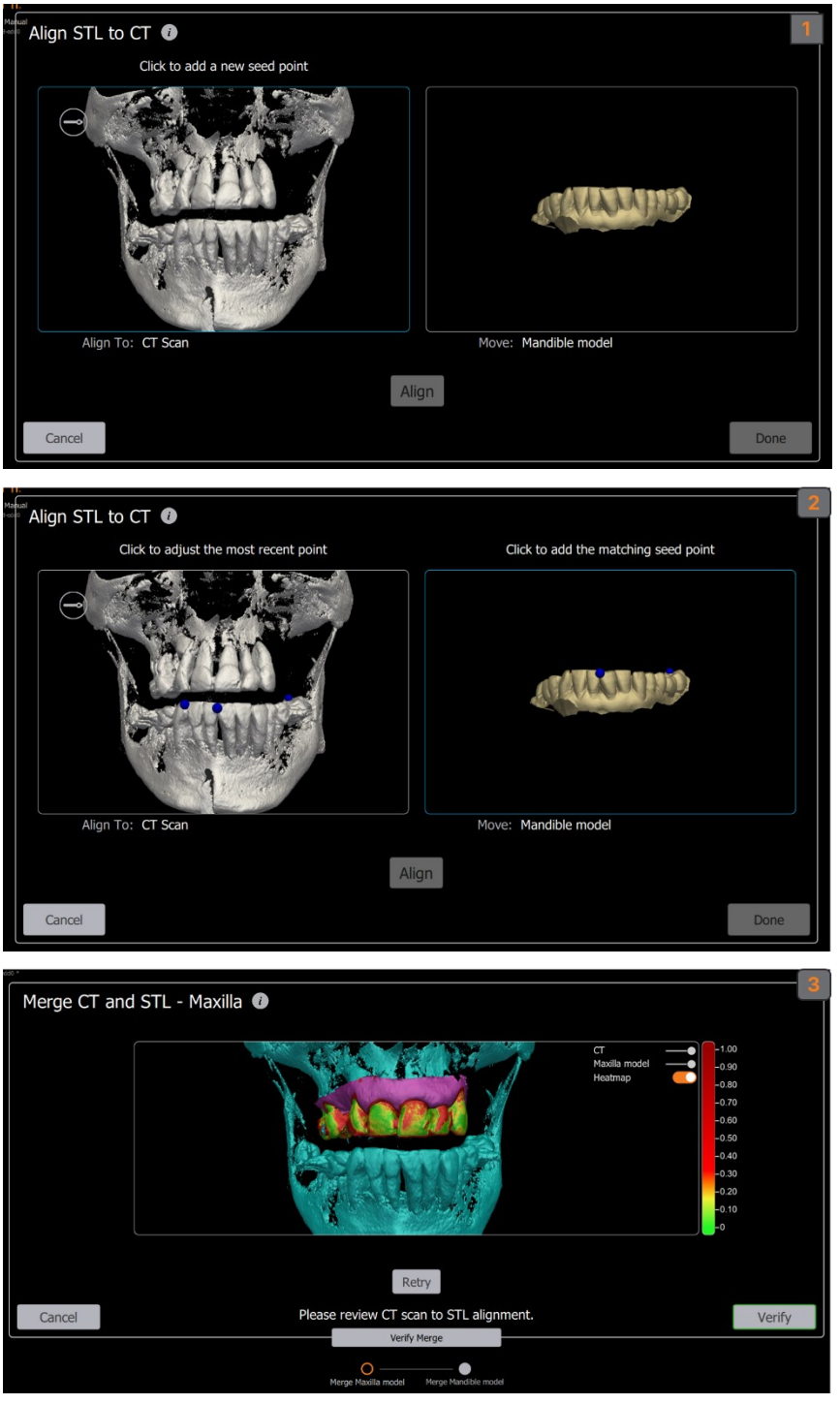


Figure 14: Aligning of an Intraoral Scan - (1) Import Intraoral Scan window in which the left window is the CBCT based 3D patient model and the right window is the patient's Intraoral optical scan. (2) Click 3 distinct points, alternating between the CBCT scan model and the intraoral scan, that match between the two models. The window highlighted in blue indicates the active window that needs to be clicked on next. (3) After clicking Align, confirm proper optimization of the scan has occurred by noting and clicking "Verified".

a. The Import Intraoral STL window will appear. The left side contains the patient's CBCT based 3D model while the right side contains the patient optical Intraoral scan
b. Utilize the Surface Threshold Slider button (only available in the CBCT based 3D model window) to adjust the visualization of the patient's CBCT based 3D model.
c. Starting from the left window, select a distinct point on the anatomy by clicking. Then in the STL window, click the location on the anatomy that corresponds to the previous selection. The point must be on the surgical arch of the patient.
d. Repeat the previous step until at least 3 distinct points have been matched between the two models, alternating between the two as points are selected. The window highlighted in blue indicates the model that must be clicked on next.
e. After at least 3 points are matched between the two models, click the Align button. YomiPlan will optimize the placement of the intraoral scan on the CBCT model.
f. When the optimalization is complete, review and confirm the proper alignment of the intraoral scan. The heatmap display can be turned off, and the CBCT scan or STL transparency can be changed with the sliders on the screen. When satisfied, click "Verified".
g. If the optimization appears to be off, click "RETRY".

5. After the selected scans are loaded into YomiPlan, the software will ask the user to name the file. The default file name is a combination of the date and patient's name obtained from the DICOM metadata. After a file name is entered, select Save. The patient's CBCT data displayed as a 3D model in the 3D View and the cross sections through the CBCT scan are visible in the 2D Views.

8.4 Loading a Saved Case File



Figure 15: Open Case button from Start Dialog screen

1. After YomiPlan is started and the Start Dialog screen is displayed, click on the "Open Case" button. Navigate to and select the patient's Case File.
2. The patient's CBCT scan and planning features are loaded into the application software.

8.5 Prepare Scan Tab

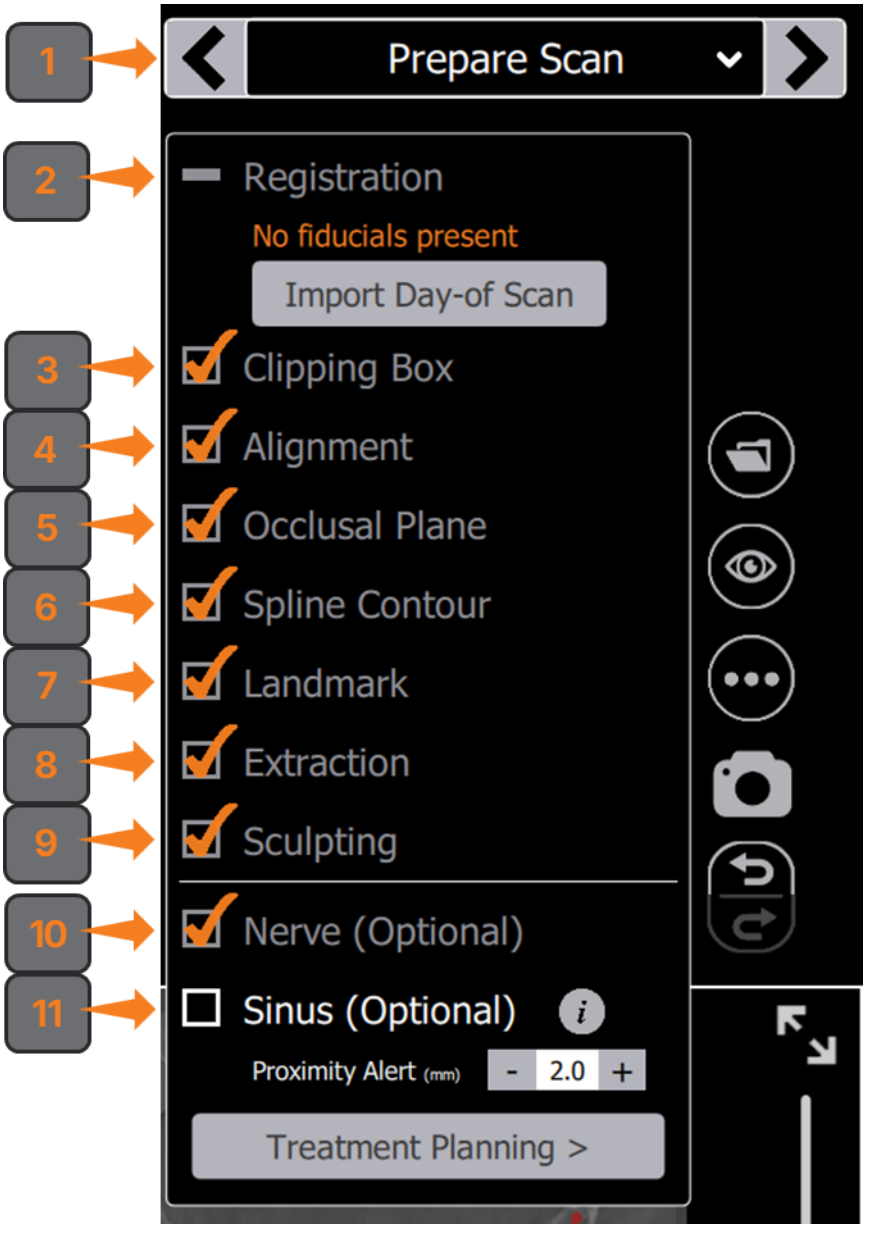


Figure 16: Prepare Scan Tab

1. **Prepare Scan Tab:** Contains all functions necessary to appropriately prepare a patient CBCT for treatment planning and ultimately utilization of the Yomi. When the user clicks on the desired checkbox step, the onscreen controls for that function are displayed.
2. **Registration Checkbox:** Show / hide the Registration tools and the 3D view defaults to surface render. Colored fiducial beads will appear in the 3D and 2D views. Further information on registration is below. Note that the software defaults to the Clipping Box step automatically when registration is successful
3. **Clipping Box Checkbox:** Show / hide the Clipping Box planning tools in the 3D View.
4. **Alignment Checkbox:** Enables intraoral and facial scans alignment mode. While in this step, it is possible to move and adjust alignment between imported files.

5. **Occlusal Plane Checkbox:** Show / hide the Occlusal Plane Adjustment tools in the 3D View.
6. **Spline Contour Checkbox:** Show / hide the Spline Contour tools in the 3D View and the 2D Transverse View.
7. **Landmark Checkbox:** Enables Landmark defining mode. While enabled, the user can click in any of the 3D, 2D or Panoramic Views to define the Landmark point. It is recommended to place initial Landmark in the 3D view and fine tune the location in the 2D views.
8. **Nerve Checkbox:** Enables Nerve defining mode. When enabled, the main view will automatically change to the Panoramic view. The user can click in each of the 2D Oblique Views and in the Panoramic View to attempt to define the Nerve. To delete a selected nerve location, right click on desired point. The user then has the ability to delete a single nerve point or the entire nerve sequence that has been plotted. If the plotted nerve has a larger or smaller radius than the defaulted 2.0mm, the user may adjust the radius using the Nerve Radius slider (which is present when the Nerve defining checkbox is selected).
9. **Sinus Checkbox:** Enables Sinus defining mode. While enabled, the user can click in the 2D or Panoramic Views to define a seed point in the Sinus cavity from which the Sinus will be extrapolated. It is recommended to place the crosshairs near the bottom 1/3 of the sinus cavity for best results. To delete a defined sinus, right-click and select “delete sinus.”

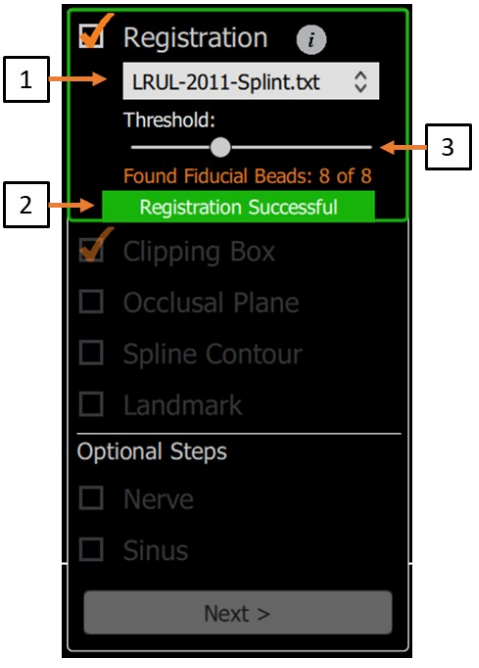


Figure 17: Registration Tab

1. **Fiducial Array Selection Box:** Contains a list of available Fiducial Arrays for the user to choose from. The Fiducial Array file tells the software how many fiducial beads it expects and their precise location in order to perform registration and calculate registration error. When a day-of CBCT scan is loaded into the YomiPlan 2.4 software, automatic fiducial registration is attempted using the fiducial array files loaded into the software which are specific to each Yomi system.
2. **Fiducial Registration Status Indicator:** This box indicates the status of the fiducial registration. The box will indicate the number of fiducials selected and the success or failure of the registration.
3. **Fiducial Threshold Slider:** Adjust the threshold slider to alter 3D render settings. This action can be used to aid in fiducial registration should registration be achieved at less-than-ideal values or when troubleshooting a failed registration.

8.6 Automatic Fiducial Registration

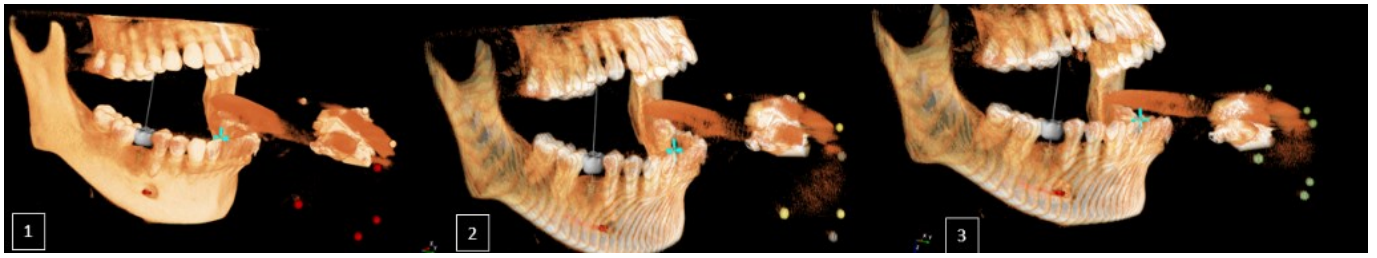


Figure 18: Fiducial Coloring Scheme - (1) Fiducials are colored red if registration was unsuccessful. (2) Fiducials are colored yellow if the registration error is between 0.4 mm and 0.6 mm. (3) Fiducials are colored green if the registration is less than 0.4 mm. (4) Blue if capture, but not registered (not shown).

Upon loading of a DICOM, the system will automatically look for the Fiducial Array and attempt a registration. The user will be notified of the success or failure of the registration as well as the number of Fiducial markers captured.

- If the registration error is greater than 0.6 mm the software treats it as an unsuccessful registration. Captured Fiducials are colored red.
- If the registration error is less than 0.4 mm, the registration is within specifications and captured Fiducials are colored green. If the registration error is between 0.4 mm and 0.6 mm, the registration error is higher than it should be, and the captured Fiducials are colored yellow.
- If the software finds fewer Fiducials than expected, it enables manual Fiducial capturing and allows the user to continue manually. If the software finds more Fiducials than expected, it ignores all found Fiducials, enables manual Fiducial capturing and allows the user to continue manually.

8.7 Manual Fiducial Registration

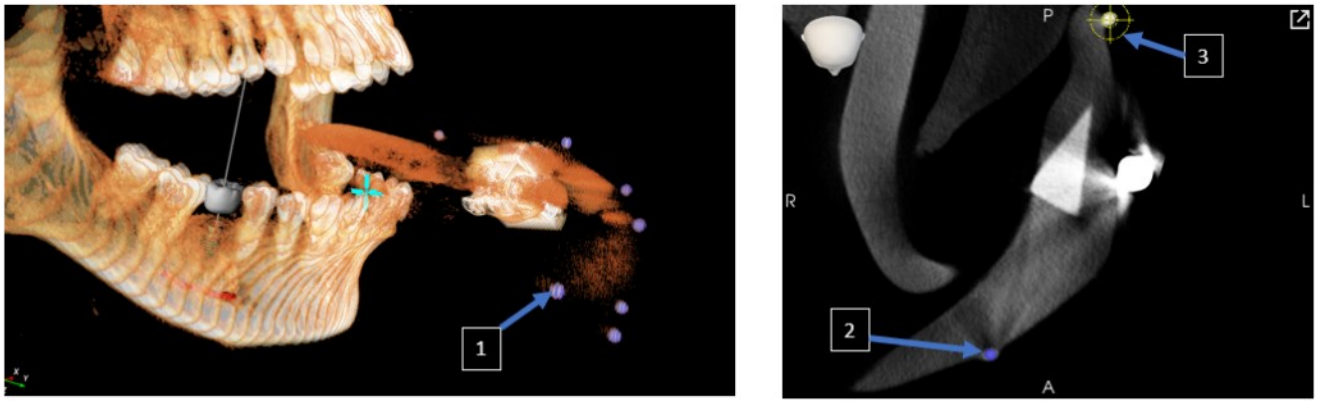


Figure 19: Manual Fiducial Registration - (1) Successfully captured Fiducial in 3D View. (2) Successfully captured Fiducial in 2D Transverse View. (3) Fiducial Marker in 2D Transverse View covered by crosshair cursor

1. Select the Fiducial Array file corresponding to the physical Fiducial Array used while taking the CBCT scan.
2. Adjust the threshold value using the “Fiducial Threshold Slider” until the Fiducial Markers (small spherical beads) are clearly visible. The Fiducial Marker Threshold value should correspond to the Hounsfield value of the Fiducials in the CBCT scan.

3. If more fiducials are required, locate a Fiducial in the 3D View or in the 2D Views and click on it to capture the Fiducial. If the Fiducial was successfully captured, the Fiducial will turn blue (see example in image above). If the Fiducial was not successfully captured, the software will inform the user of the reason.
4. If a Fiducial needs to be deleted, right-click on the Fiducial in any view and select “Delete Fiducial” or select “Delete All Fiducials” if the user wishes to restart the manual registration selection process.
5. When all but two Fiducials have been captured (number of Fiducials for the array is displayed just below the Fiducial Threshold Slider), the software will attempt to calculate the Fiducial Registration Error. The user is then informed of the Fiducial Registration Error.
6. If the registration error is less than 0.4 mm, the registration is within specifications and captured Fiducials are colored green. If the registration error is between 0.4 mm and 0.6 mm, the registration error is higher than it should be, and the captured Fiducials are colored yellow. If the registration error is greater than 0.6 mm, the software treats it as an unsuccessful registration. Captured Fiducials are colored red.
7. If the registration error is yellow or red, select any remaining Fiducial. The software will recalculate the registration after each additional Fiducial. If the registration error is still above 0.6 mm, registration is unsuccessful, and the case cannot proceed.



For Dual Arch workflow, use the Jaw Toggle to register both maxilla and mandible. If a registration is missing, it will not be possible to proceed to the surgical pages for that jaw.

8.8 Clipping CBCT Scan

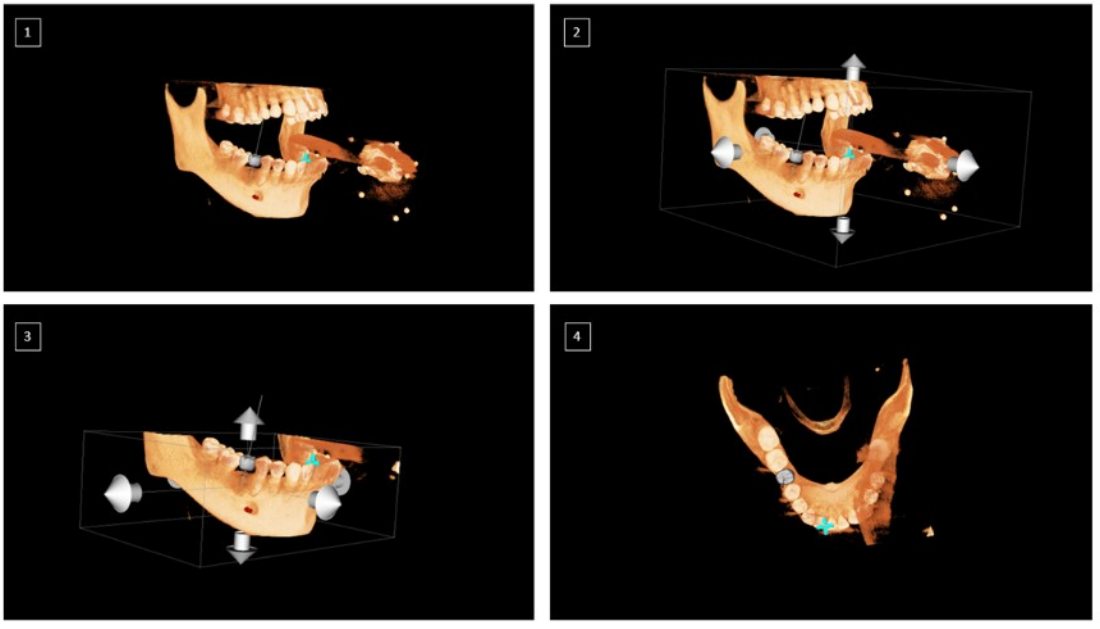


Figure 20: Clipping Box: (1) Original, unclipped 3D patient rendering. (2) Clipping Box can be seen as a wireframe in the 3D View. Clipping Box Handles are shown as white arrows. (3) Adjusting the Clipping Box Handles reduces the 3D rendering displayed to only the volume inside the clipping box. (4) View of clipped image from above.

1. Click the Clipping Box Checkbox to display the Clipping Box in the 3D View.
2. The Clipping Box has six white Handles on the faces of the box. Moving these Handles adjusts the volume of the CBCT scan to be clipped. Adjust the Clipping Box Handles to reduce the displayed 3D volume. It is recommended to reduce the 3D volume to only display the site of surgery in the 3D View.

   Note that clipping the 3D volume has no impact to the CBCT scan data displayed in the 2D views.
3. Select another checkbox to hide the Clipping Box from the 3D View.

8.9 Alignment Step

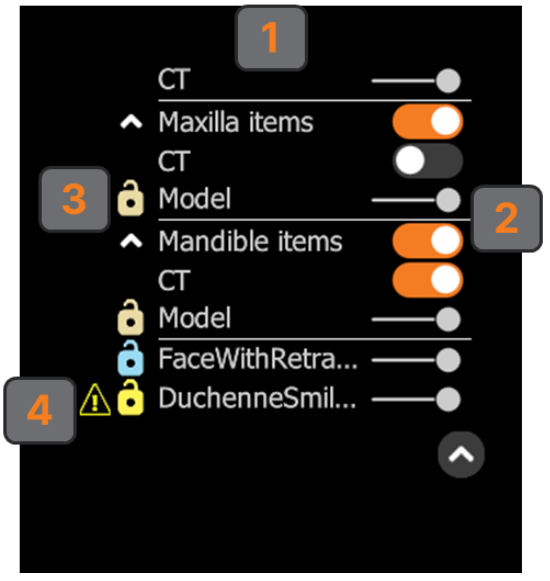


Figure 21: Visualization sliders

The software will try to automatically align imported scans. If the automatic alignment fails to align a scan, a warning icon will be displayed next to the scan. Scan alignments can be modified in the Alignment Step in the Prepare Scan Page.

1. **Slider Title:** Scans are listed based on the assigned name during import and grouped under the corresponding arch. Scans that do not have an associated jaw will be placed below both Maxilla and Mandible Items. Object titles can be right-clicked to expand the alignment options menu.

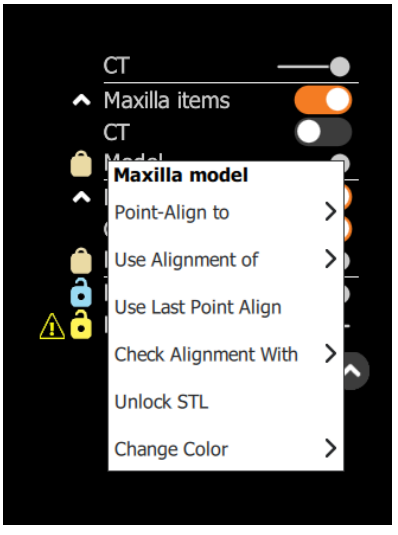


Figure 22: Alignment options menu

- **Point-Align To:** Alignment performed by selecting 3 or more common points on each object. This option will bring up an alignment dialog to select common points followed by an alignment verification step.

- **Use Alignment Of:** This option will move the selected scan based on the alignment of the target scan. This option works well for scans that were created in the same space or exported from the same software. Useful for models and waxups to keep relation with each other and follow the same alignment to the CT Scan. Hovering over this option will temporarily move the scan to display where the alignment would place it.
- **Use Last Point Align:** This option will repeat the last Point-Align movement for the selected scan. This option requires the scans to be in alignment with each other prior to using *Point-Align To* for the first and *Use Last Point-Align* for the remainder of the aligned scans. Hovering over this option will temporarily move the scan to display where the alignment would place it.

2. **Jaw Group:** Items are grouped under Maxilla or Mandible based on arch association. Group visibility can be toggled on/off using the Maxilla/Mandible items toggle. Arch groups can be expanded and collapsed as needed.
3. **Lock/Unlock:** The lock next to the Slider Title indicates the lock state of the object. Clicking the lock toggles between the locked and unlocked state. Unlocked objects can be interacted with and moved in the 2D views and 3D views. Locked objects will not get highlighted when the cursor is hovered-over in the 2D or 3D views.
4. **Alignment Warning:** Objects that were not successfully auto-aligned will display a warning next to the Lock/Unlock indicator. It is recommended to review and verify alignment of these objects. The Alignment Warning can be right-clicked to display alignment verification options. The alignment can only be verified with the CT Scan or other items that do not have an alignment warning associated to them.

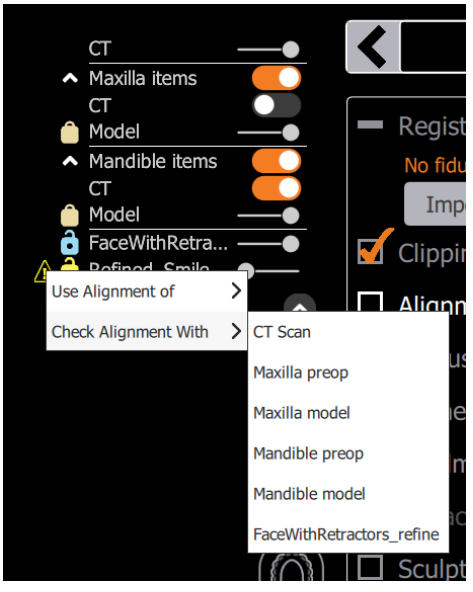


Figure 23: Alignment warning verification menu

For Dual Arch workflow, use the Jaw Toggle to toggle between maxilla and mandible. The occlusal plane will be used to trim the 3D view and hide the opposing arch.

8.10 Defining and Adjusting Occlusal Plane

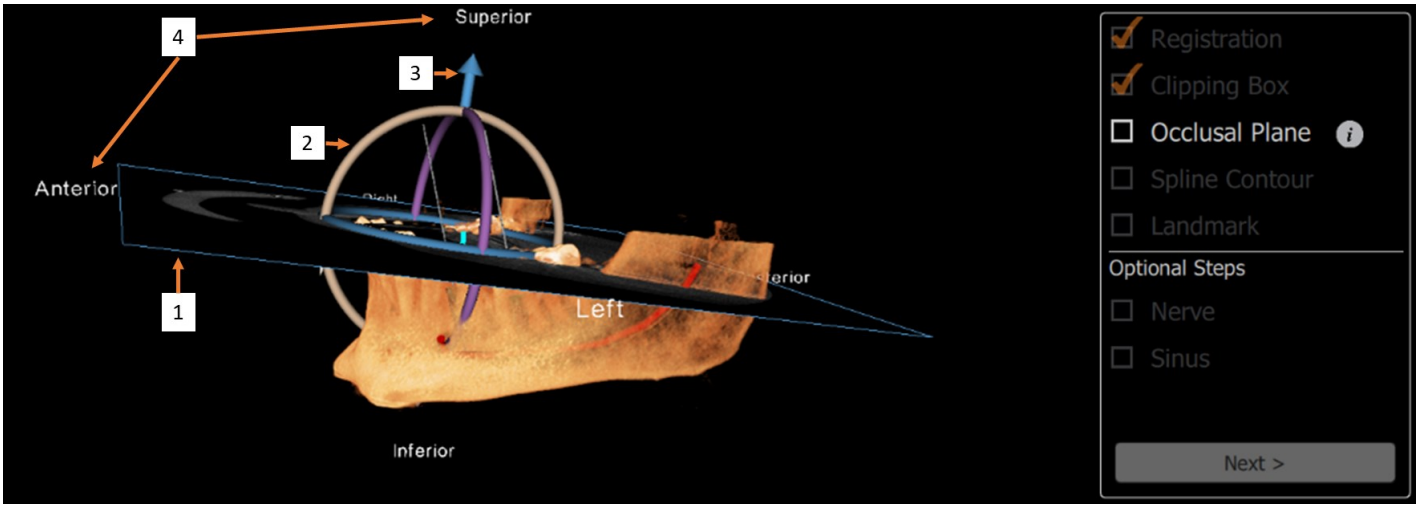


Figure 24: Occlusal Plane Adjustment Tool. (1) The Occlusal Plane. (2) Occlusal Plane Adjustment Tool Rings used to adjust the orientation of the Occlusal Plane. (3) Occlusal Plane Adjustment Tool Arrows used to adjust the Occlusal Plane Position. (4) Anatomical Position Indicator

1. Check the Occlusal Plane Checkbox to show the Occlusal Plane Adjustment Tool in the 3D View.
2. A 2D CBCT slice representing the Occlusal Plane and the Occlusal Plane Adjustment Tool is now shown in the 3D view. The 2D Transverse View will now displays the CBCT cross-section representing the Occlusal Plane.

   The Occlusal Plane Adjustment Tool has three rings to adjust the orientation of the Occlusal Plane about each axis and six arrows to adjust the position of the Occlusal Plane along each axis. Use the rings and arrows to place the Occlusal Plane at an anatomically correct location.
3. When completed, check the Occlusal Plane Checkbox to hide the Occlusal Plane Adjustment Tool from the 3D View and move forward to the next Prepare Scan step.

For Dual Arch workflow, use the Jaw Toggle to toggle between maxilla and mandible, and plan both occlusal planes.

8.11 Defining and Adjusting Spline Contour

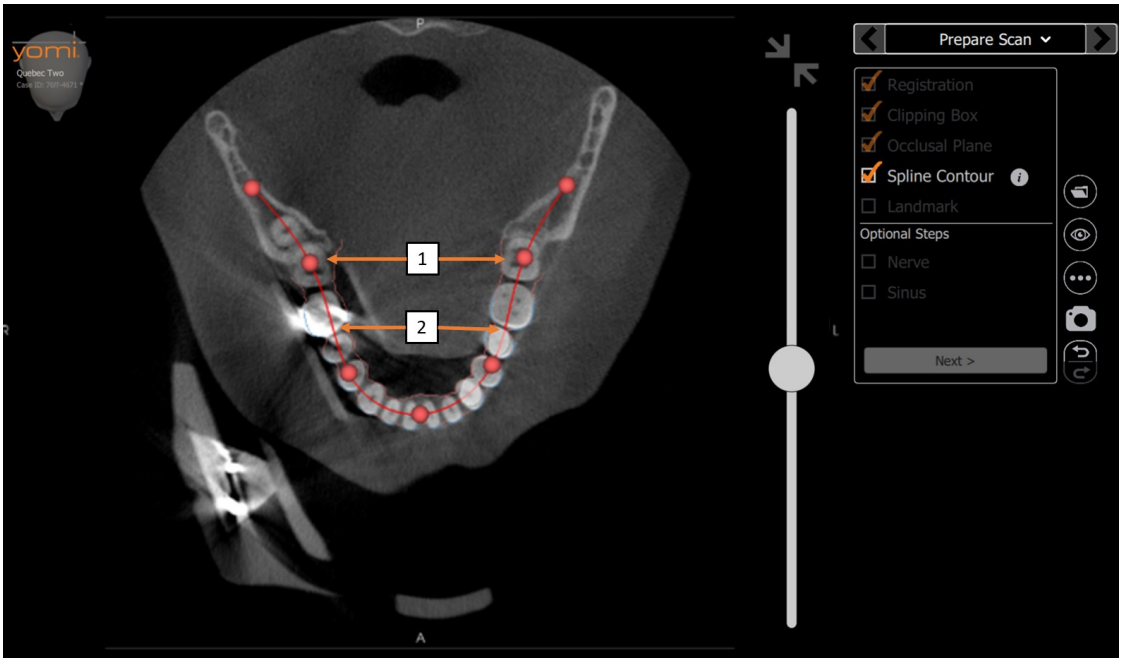


Figure 25: When the Spline Contour Checkbox is selected, then screen displays a Transverse 2D View. (1) Spline Handle in 2D Transverse View. (2) Spline Contour Line in 2D Transverse View.

1. Select the Spline Contour Checkbox to plan the Spline Contour in the 2D Transverse View.
2. The Spline Contour has pink spherical handles that can be adjusted to alter its shape. Adjust the Spline Contour such that it is aligned with the arch. Click and hold the Spline Contour Line to translate the entire Spline Contour as a unit.
3. When the Spline Contour is defined, check the Spline Contour Checkbox to move forward to the next Prepare Scan step.

For Dual Arch workflow, use the Jaw Toggle to toggle between maxilla and mandible, and define both splines.

8.12 Defining a Landmark

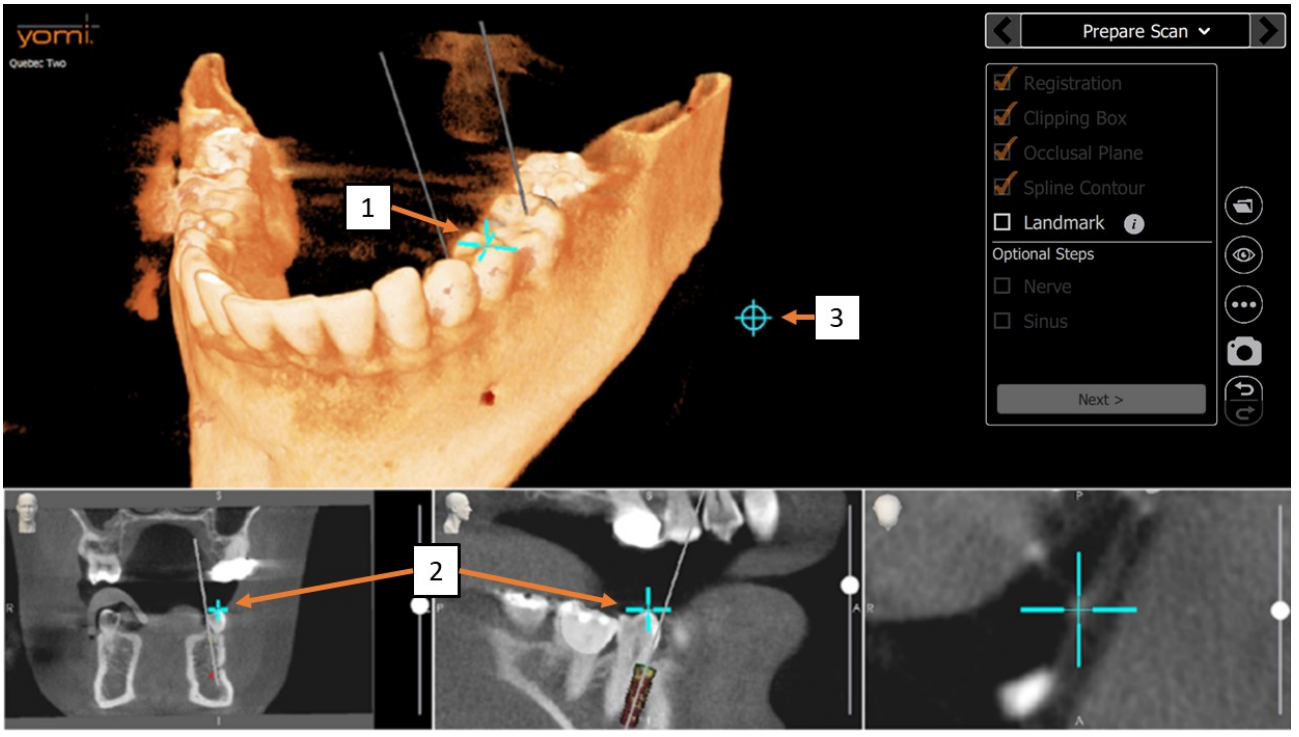


Figure 26: Defining a Landmark in the 3D Layout - (1) Landmark in 3D View, (2) Landmark in the 2D Views, and (3) Mouse cursor as crosshair for Landmark selection

1. Select the Landmark Checkbox to define a Landmark point.
2. In the 3D view, 2D views, or Panoramic view, locate a desired location for the Landmark and left mouse click. The Landmark is placed at the location of the click point.

   It is recommended to place the Landmark in the 3D views and fine tune the placement using the 2D views. This will help ensure accurate placement on patient anatomy.
3. When the Landmark is defined, check the Landmark Checkbox. All required Prepare Scan steps should have been completed and the “Next” button below the Optional Steps will be active.

For Dual Arch workflow, use the Jaw Toggle to toggle between maxilla and mandible, and define both landmarks.

8.13 Extraction Step

Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the extraction step.

8.14 Sculpting Step

Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the sculpting step.

8.15 Defining a Nerve

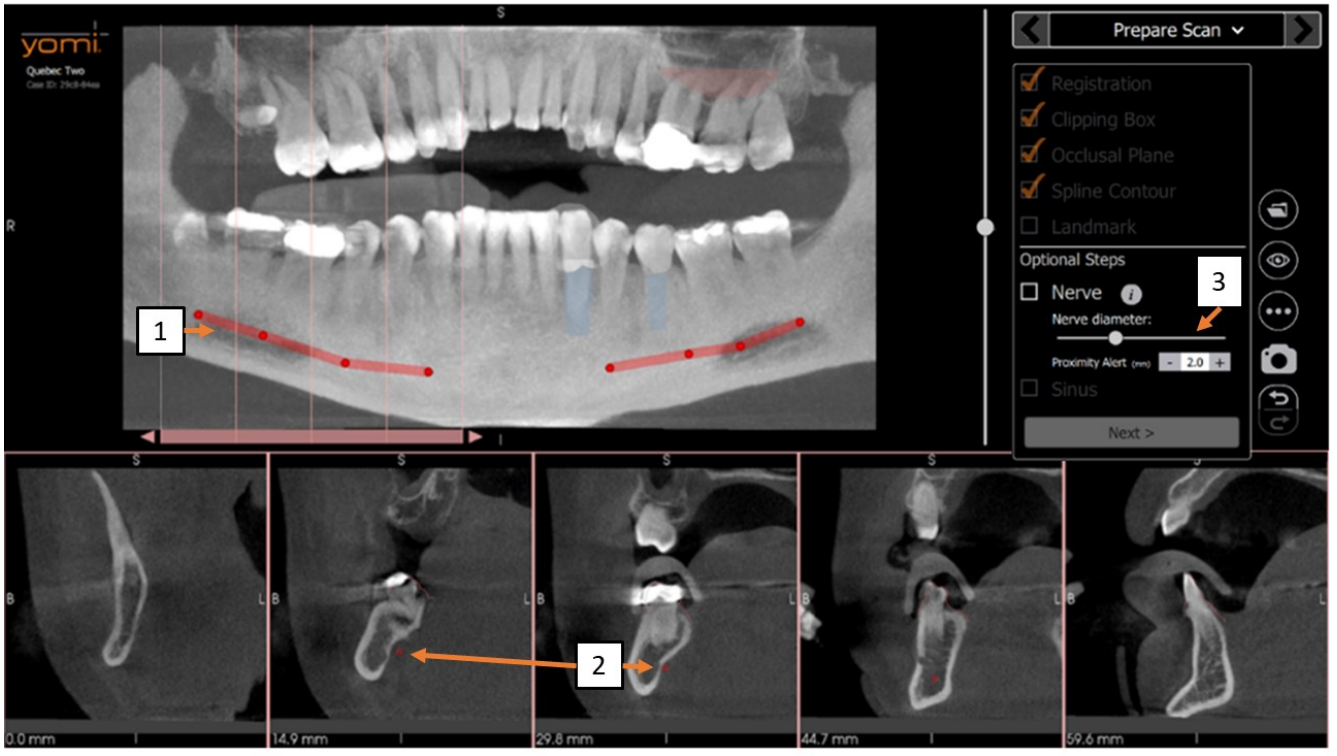


Figure 27: Defining a Nerve in the Panoramic Layout - (1) Nerve in Panoramic View, (2) Nerve point in 2D Oblique Views, (3) Nerve diameter slider and Proximity Alert Menu

1. Select the Nerve Checkbox under Optional Steps to begin planning the nerve(s). When entering Nerve Planning, the main screen will default to the Panoramic View.
2. In any of the five 2D Oblique Views and the Panoramic View, locate a Nerve Point and click on it. A Nerve Point is placed at the click point.

   To better visualize the Nerve, drag the Panoramic Slider left and right to adjust the 2D Oblique views and expose the nerve. As more Nerve points are added, the Nerve displayed in the Panoramic View and 2D Oblique Views is updated. The software will trace the projected nerve position to the mouse as points are added.

   Note that two Nerves can be defined for bilateral surgeries. The nerve will automatically split at the midline of the image into two separate nerves.
3. Adjust the diameter of the Nerve by using the Nerve diameter slider.
4. By default, the software will alert that an implant is within 2.0 mm of a planned Nerve by turning the implant bright red. Adjust this distance using the Proximity Alert menu. A proximity alert warning will be generated if any object, including implants, YomiLink Bone screws and / or the bone reduction plane, is closer to the nerve than the threshold specified in this step. We recommend the proximity alert be set larger than 1mm.
5. To delete a point on the Nerve, right click the desired point and select Delete Nerve Point or to delete the entire Nerve, right click the Nerve and select Delete Nerve.

6. Once the Nerve has been defined, complete the step by clicking on the Never Checkbox to return to the 3D model in the main view.

8.16 Defining a Sinus

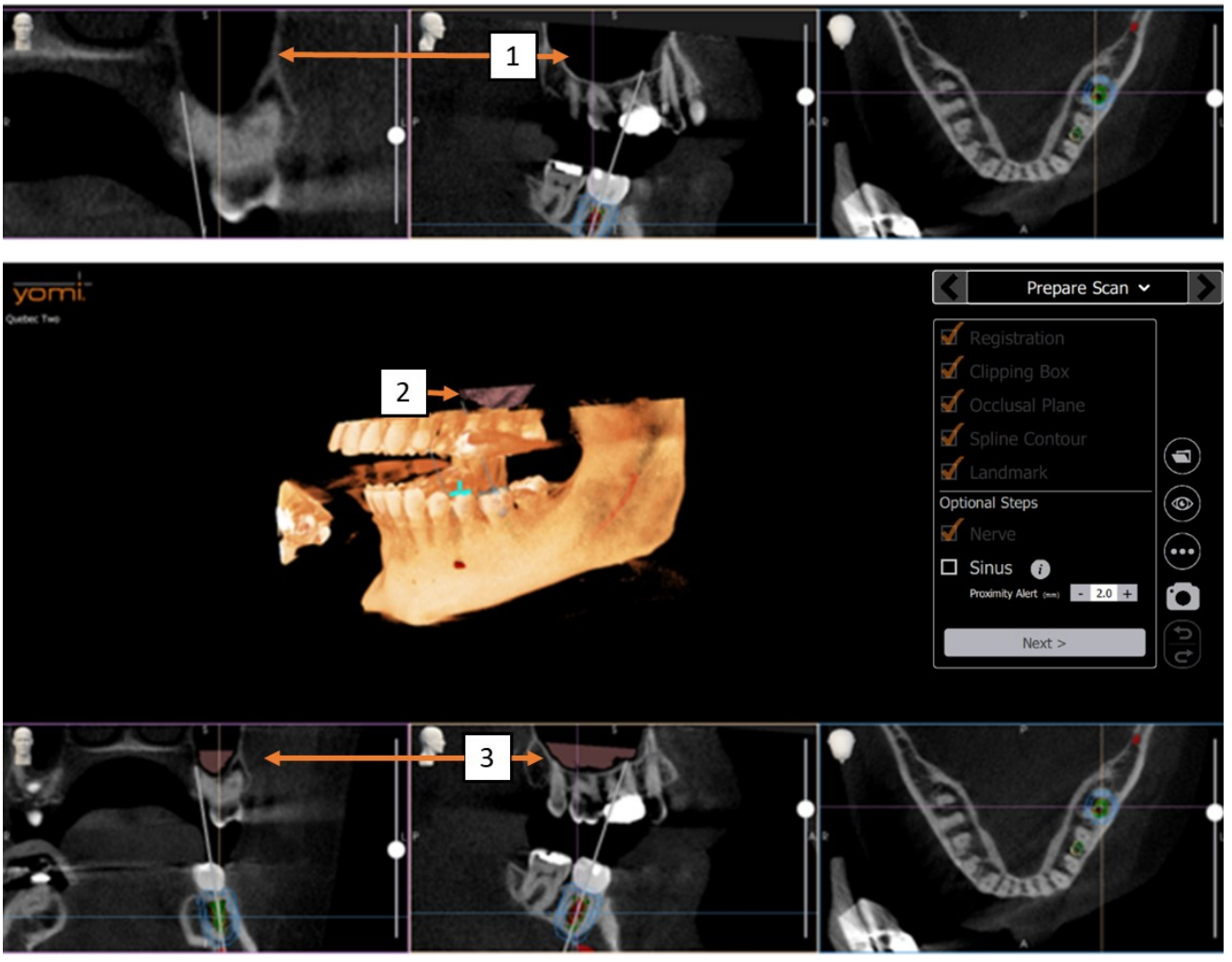


Figure 28: Defining a Sinus - (1) Sinus cavity location in the 2D Views prior to selection, (2) Segmented Sinus in 3D View, (3) Segmented Sinus in 2D Views.

1. Click the Sinus Checkbox under Optional Steps to begin defining a Sinus.
2. In the 2D Views, the cursor will appear as a green crosshair. Scroll through the 2D views to locate the Sinus Cavity. Click within the Sinus Cavity noting that, when possible, click towards the bottom 1/3 of the cavity. The software will try to find and render the Sinus Cavity.
3. Once defined, the Sinus is visible in the 3D and 2D Views. Repeat step 2 to define the other Sinus Cavity. If the user wishes to delete a Sinus segmentation, right-click the segmented Sinus and select “Delete Sinus” to erase it from all views.
7. By default, the software will display an alert when an implant is within 2.0 mm of a planned Sinus by turning the implant bright red. Adjust this distance by increasing or decreasing the “mm” using the Proximity Alert menu. A proximity alert warning will be generated if any object, including implants,

YomiLink Bone screws and / or the bone reduction plane, is closer to the sinus than the threshold specified in this step. We recommend the proximity alert be set larger than 1mm.

4. Once the Sinus Cavities have been defined, complete the step by clicking on the Sinus Checkbox.

8.17 Open Case and Merge Day-of Scan

Users have the option to preplan surgical cases to be used on the day-of surgery. The user will plan the case on a previously obtained CBCT scan, and prior to surgery, will merge that case with the day-of CBCT scan taken with the YomiLink and Fiducial Array. To import a preplanned case:

1. Open the Preplan of the patient. This plan uses a CBCT scan that does not include a Fiducial Array.
2. On the “Prepare Scan” tab of the planned case file, select “Import Day-of Scan” under the Registration Checkbox.



Figure 29: Import Day-of Scan button under Registration section

3. Navigate to and open the folder with the patient’s Day-of CBCT scan. Click on one of the DICOM image files inside the folder and select Open. YomiPlan will launch a window with the Preplan scan in the left-side window and the Day-of Scan on the right-side window.



Figure 30: Import Scan Window - (1) Preplan Scan, (2) Day-of Scan, (3) Surface Threshold Button and Slider, (4) Blue Outline indicating active window, (5) Full Scan toggle, (6) Jaw indicator

4. Adjust the surface threshold for either window (if necessary) by clicking the Surface Threshold Slider button in that window and adjusting the slider.
5. To align the scans, select at least 3 matching points between the two images. To place a point, identify the active window outlined in blue. Select a point on the 3D model of the anatomy that is easily identifiable on the models of both scans. When selected, the blue outline will switch to the other window indicating the active window has changed. Click the matching point in the second scan. Repeat this process until at least 3 matching points are selected.

   Note - When selecting points, it is recommended to place at least one point on either side of the planned implant location(s), and one point on the bony anatomy away from the occlusal surface. All points must be placed on the surgical arch.

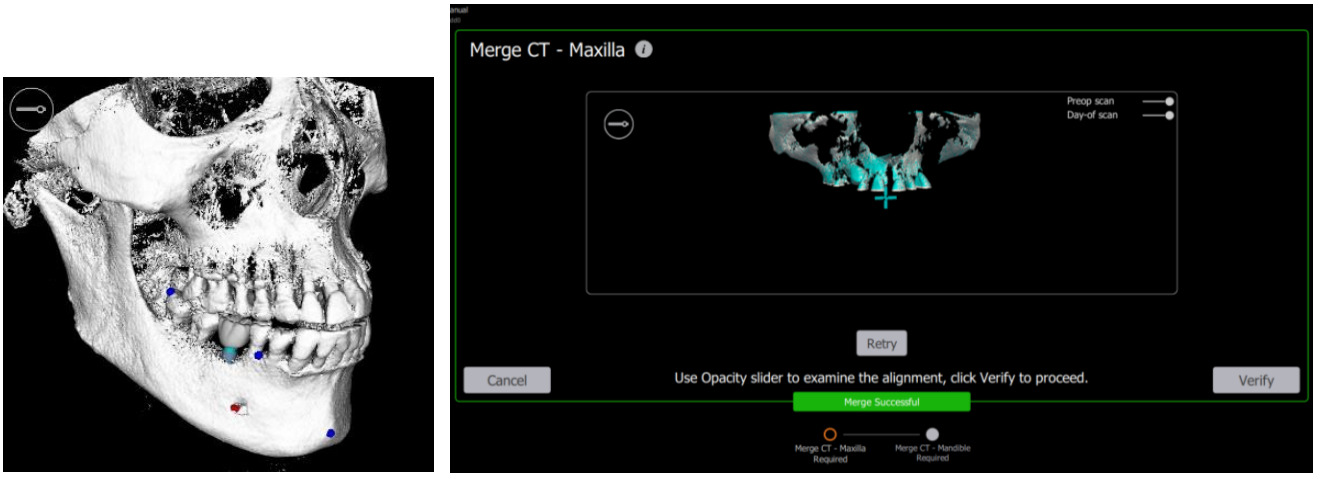


Figure 31: [Left] Points selected on the surgical arch. Note how there are points on either side of the implant, and at least one point on the bony anatomy of the patient. [Right] Successfully aligned scans showing green “Merge Successful” message.

6. When at least 3 matching points have been selected on both models, select “Align.” The software will use the selected points to help align the two scans.
7. If the optimization was successful, a green indicator will appear acknowledging the success. If the green indicator does not appear, inspect the optimized image to ensure the plan matches the imported case accurately. The opacity slider can be adjusted to visualize the alignment of the Preplan and Day-of Scan. If the alignment is not satisfactory, select “Retry” and repeat steps 4-6 with a different set of points.
8. Click “Verify” to import the merged case with the current alignment into YomiPlan. Clicking “Cancel” will abort the import and close the window.

For Dual Arch workflows, a second merge will be required to align both Maxilla and Mandible

8.18 Treatment Planning Tab

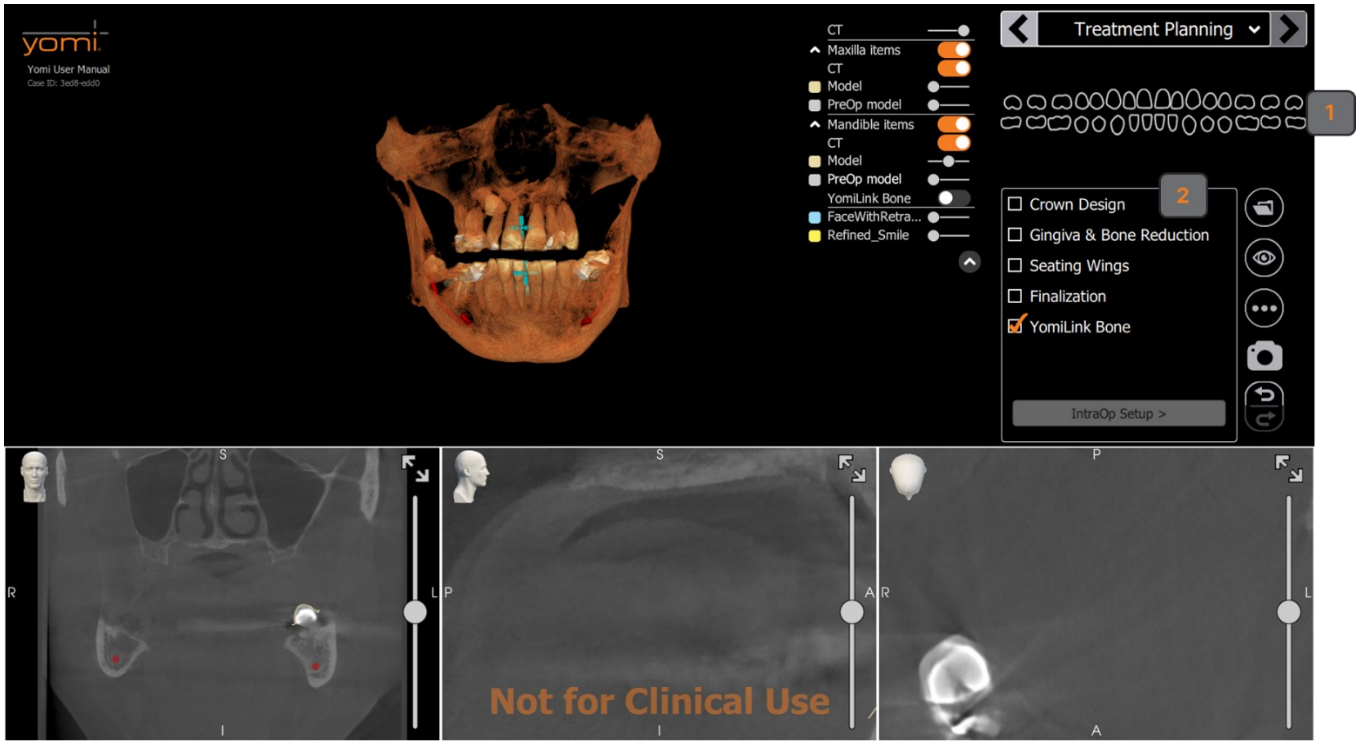


Figure 32: Treatment Planning Tab

1. **Tooth Map:** A visual representation of the upper and lower arches that indicates the location of planned implants and crowns (see image below).

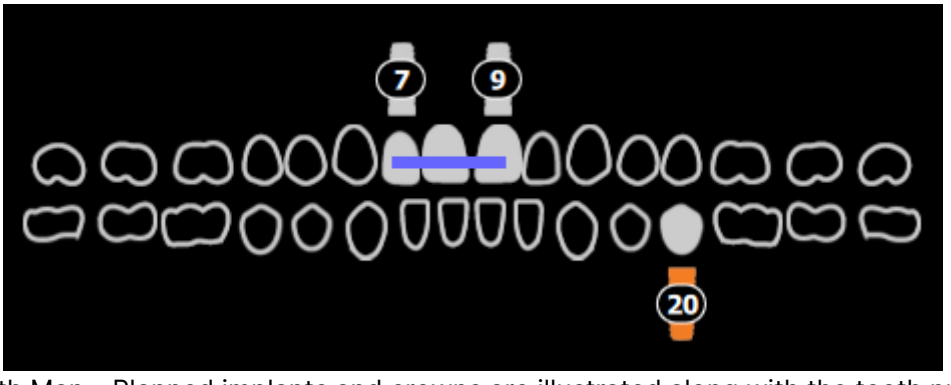


Figure 33: Tooth Map - Planned implants and crowns are illustrated along with the tooth number. Orange highlights indicate the planned implants, crowns, or a combination of the two that are currently “selected” in the planning window. Grey highlights indicate “unselected” planned implants, crowns, or combinations of the two. A blue line across crowns indicates a bridge.

2. **Crown Design:** Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Crown Design step.

3. **Gingiva & Bone Reduction:** Planning step to design bone reduction plane, distal boundary, and lingual boundary. Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Gingiva design step.
4. **Seating Wings:** Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Seating Wings design step.
5. **Finalization:** Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Finalization step.
6. **YomiLink Bone:** Planning step for the YomiLink Bone and bone screws used to fixate the YomiLink Bone.

8.19 Adding an Implant from the Tooth Map

1. In the Tooth Map on the Treatment Planning Tab, hover over the desired tooth location for an implant and/or crown and click on the object to be planned (implant/crown).
2. Once selected, an Implant Library window with Crown, Scan Body, Abutment, and Implant customization parameters will open (see image below) to allow customization by the user. Utilize the implant library to customize implant specifics for ideal planning representation purposes.

   Note that a surgeon's preferred default implant system will be displayed if defined in their surgeon preference.
3. Click Done to create and add the Crown, Scan Body, Abutment and/or Implant. Click Cancel to return to the Treatment Planning Tab.

8.20 Implant Library Dialog

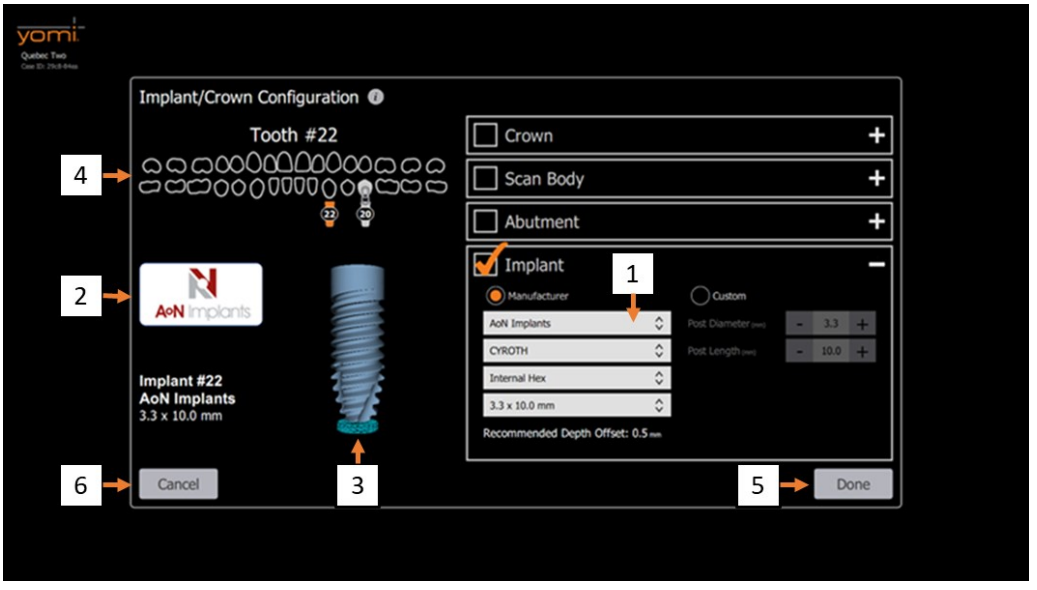


Figure 34: Implant Library Dialog Box

1. **Manufacturer Combo Box:** Contains a list of available Manufacturers. Selecting an item from the lists populates the Category and Prefix Implant System Combo Boxes below. Users can generate a custome Implant by selecting "custom" in the Implant Library Menu.

2. **Logo Picture:** Displays the logo of the selected Manufacturer. If the Generic item is selected a generic icon is displayed.
3. **3D View:** Displays a model of the selected implant and/or crown plus any scan body or abutment associated with the selected implant. Note that some implants have an offset which specifies that the osteotomy will extend beyond the apical tip of the planned implant. These offsets are represented by a blue mesh as shown in the picture above and can be visualized in both the 2D and 3D views.
4. **Tooth Map:** Allows the user to select the tooth that should be associated with the Implant that is being placed/edited. If an impant/crown's planned location and tooth number do not align, the user can click the implant/crown on the Tooth Map and drag and drop it at the correct site.
5. **Done Button:** Clicking the button attempts to apply all changes to the selected Implant. If any field value constraints are violated, the YomiPlan Software displays a message box. All violations must be solved in order to apply changes to the selected Implant.
6. **Cancel Button:** Clicking this button discards any changes made to the Implant dimensions and closes the Implant Library dialog.

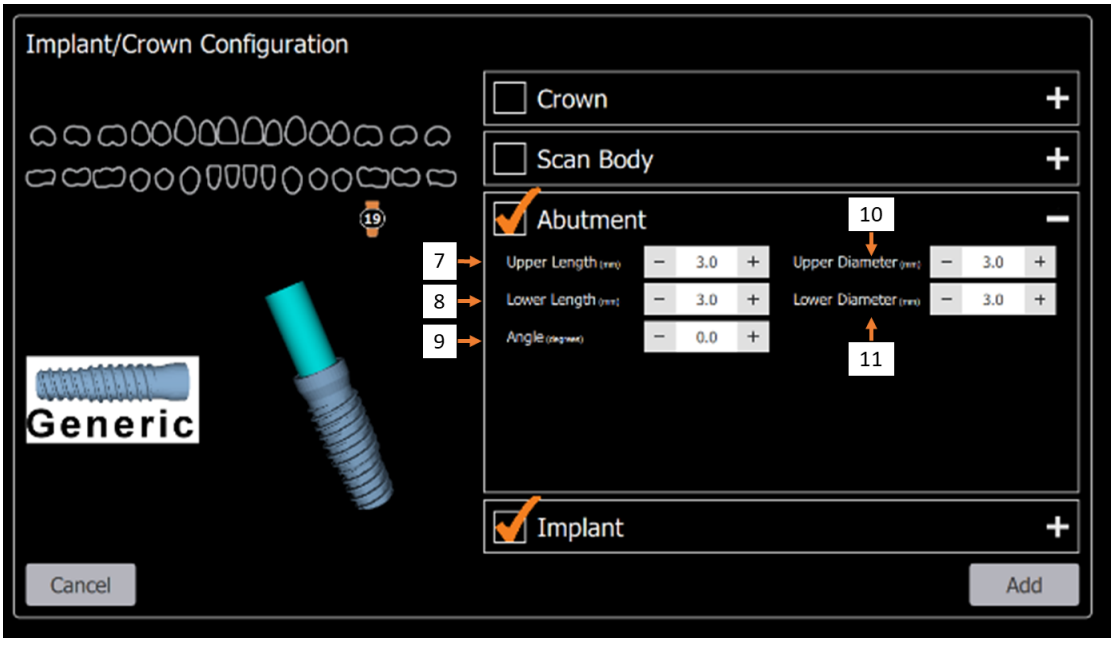


Figure 35: Abutment Parameters

7. **Abutment Upper Length:** A field to specify the Abutment's Upper length in millimeters. Value must be between 0.1 and 100.
8. **Abutment Lower Length:** A field to specify the Abutment's Lower length in millimeters. Value must be between 0.1 and 100.
9. **Abutment Angle:** A field to specify the Abutment's Angle in degrees. Value must be between -90 and 90.
10. **Abutment Upper Diameter:** A field to specify the Abutment's Upper diameter in millimeters. Value must be between 0.1 and 100.
11. **Abutment Lower Diameter :** A field to specify the Abutment's Lower diameter in millimeters. Value must be between 0.1 and 100.

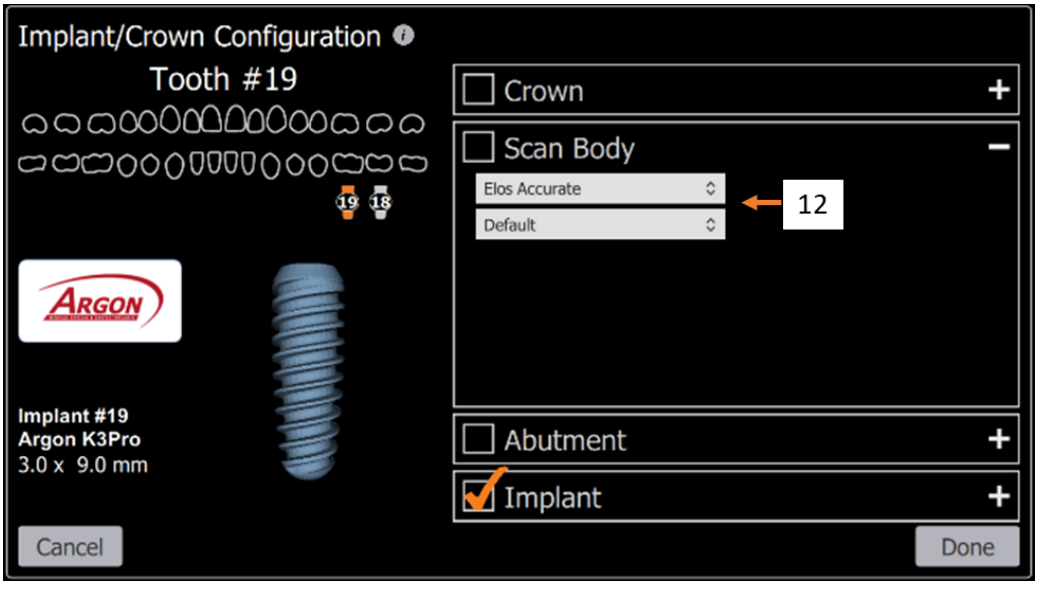


Figure 36: Scan Body Parameters

12. **Scan Body:** Displays the scan body option(s) for the selected implant. The user can select between differing Scan body options.

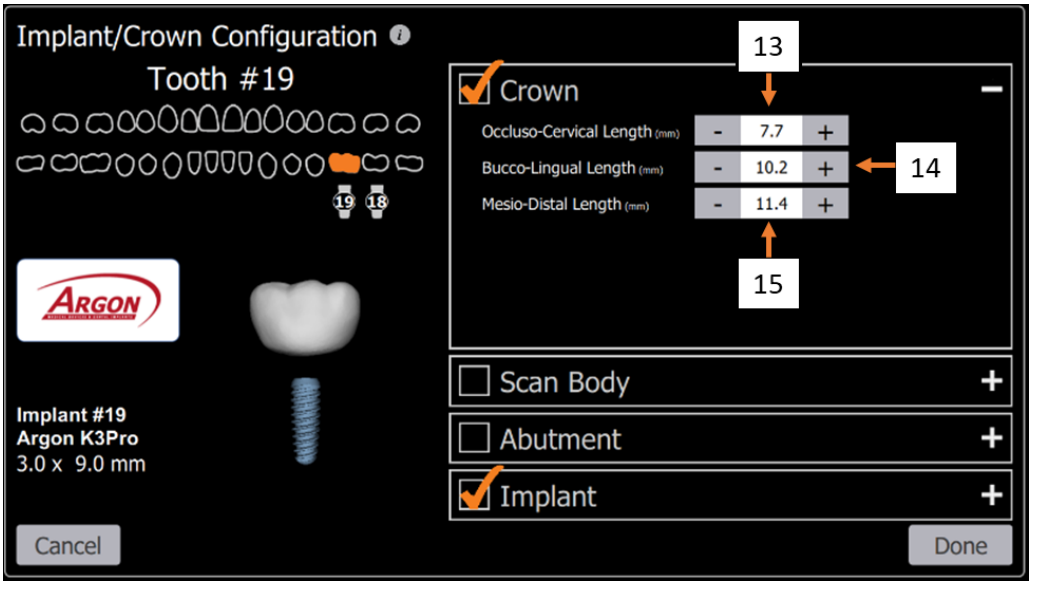


Figure 37: Crown Parameters

13. **Occluso-Cervical Length:** A field to specify the Crown's Occluso-Cervical length in millimeters. Value must be between 0 and 100.
14. **Bucco-Lingual Length:** A field to specify the Crown's Bucco-Lingual length in millimeters. Value must be between 0 and 100.
15. **Mesio-Distal Length:** A field to specify the Crown's Mesio-Distal Length in millimeters. Value must be between 0 and 100.

8.21 Editing Implant

1. Select the Implant to be edited from the by double-clicking the implant on the Tooth Map or right clicking and selecting “Edit Implant”. The Implant Library Dialog Box will appear.
2. Adjust the previously defined Implant using the manufacturing library or by selecting a Custom Implant and editing the Post Diameter and Length in the implant dimension fields. Note that the diameter must be between 2.0 and 10.0 mm and the length must be between 3.0 and 25.0 mm. The software will automatically default to the closest allowable dimension if exceeded.
3. Click the Done button to apply the changes. Click the Cancel button to discard the changes.

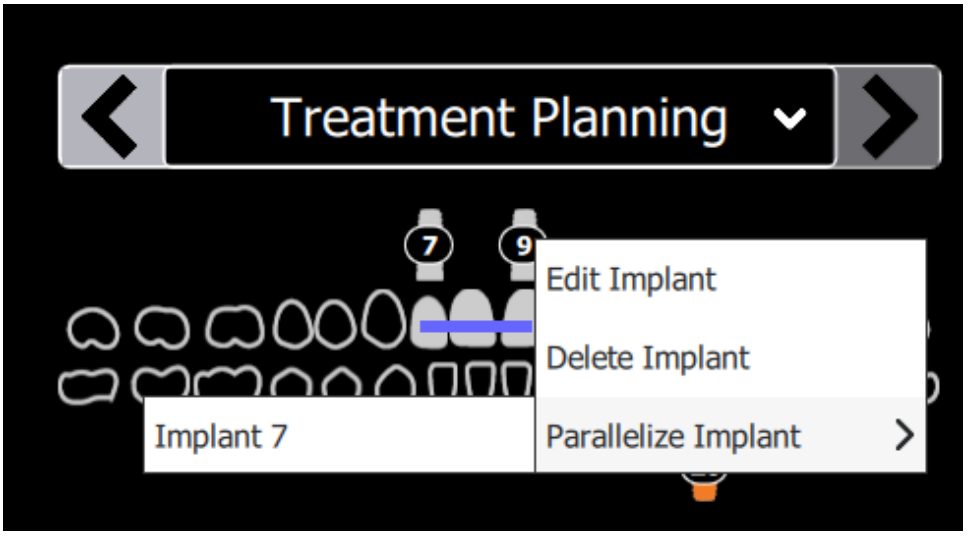


Figure 38: Parallelize Implants Feature

In addition to editing the implant parameters, right-clicking on an implant or crown in the Tooth Map will allow the user to delete an implant/crown, and Parallelize Implants. To make multiple implants parallel, first select the target implant that needs to be parallelized to another implant. Then right click, select “Parallelize Implant” and then select the reference implant to parallelize too.

8.22 Adding/Editing a Crown from the Tooth Map

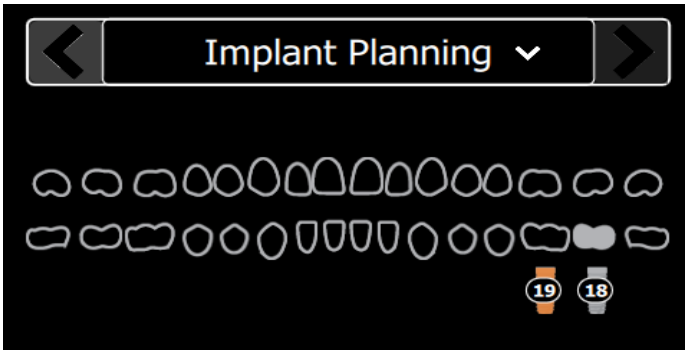


Figure 39: Tooth Map with Crown and Implant at 18 and Implant only at 19.

1. On the Tooth Map in the Treatment Planning Tab, click on the image of the crown of the tooth that should be associated with the Crown. If editing a Crown, double click on the Crown or right-click and select Edit Crown.
2. The Crown dialog box will appear. Customize the Crown's dimensions in the Crown dialog. Click Done to complete the addition/edit. Click the Cancel button to discard the changes.

   If any field value constraints are exceeded, the software will default to the minimum or maximum allowable dimension (whichever is closest to the dimension attempted).

   The Crown selected on the Tooth Map will be highlighted in orange when selected and grey when unselected, but planned. The crown is displayed in the 2D and 3D views in the appropriate location. If an implant already exists on that tooth, the Crown location is determined from the Implant location and its abutment dimensions.

8.23 Adjusting Implant and Crown Locations in 3D

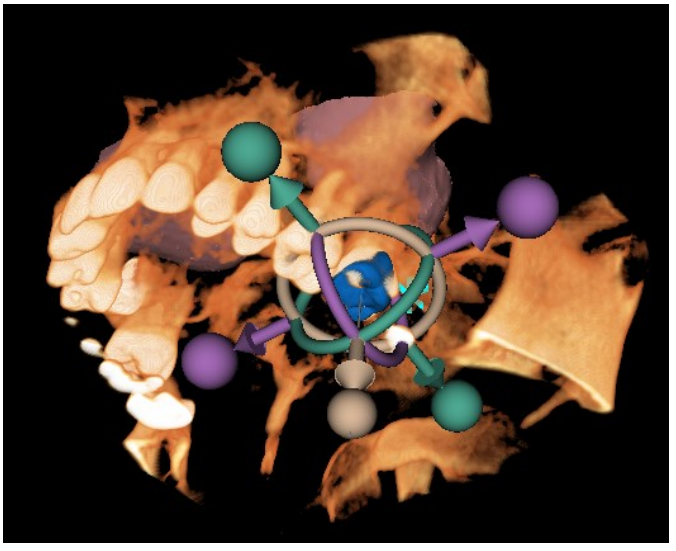


Figure 40: Object Adjustment Tool (3D View) - Rings can be used to adjust rotation. Arrows can be used to adjust translation. Spheres at Arrow Tips can be used to adjust size.

To modify the Implant or Crown position using the 3D Object Adjustment Tool:

1. Click on the Implant or Crown to be adjusted in the 3D View to show the Object Adjustment Tool.
2. The Object Adjustment Tool will appear around the selected object in the 3D View. It has arrows to adjust the position of the Implant or Crown. Click and drag an arrow to translate the selected object. It has rings to adjust the orientation of the Implant or Crown. Click and drag a ring to rotate the selected object about the axis of the ring selected. For Crowns, spheres at the tips of the translation arrows will appear that can resize the selected object. Click and drag a sphere to increase or decrease the size of the selected object in that dimension.
3. Move the cursor away from the selected object in the 3D View. After a brief delay or if the user clicks away from the object, the Object Adjustment Tool disappears.

Alternatively, you can modify the Implant or Crown position by clicking and dragging the Implant or Crown you wish to adjust. The object will follow the mouse position as you drag and will be positioned at the location of the screen where it is located when the mouse button is released.

8.24 Adjusting Implant and Crown Locations in 2D

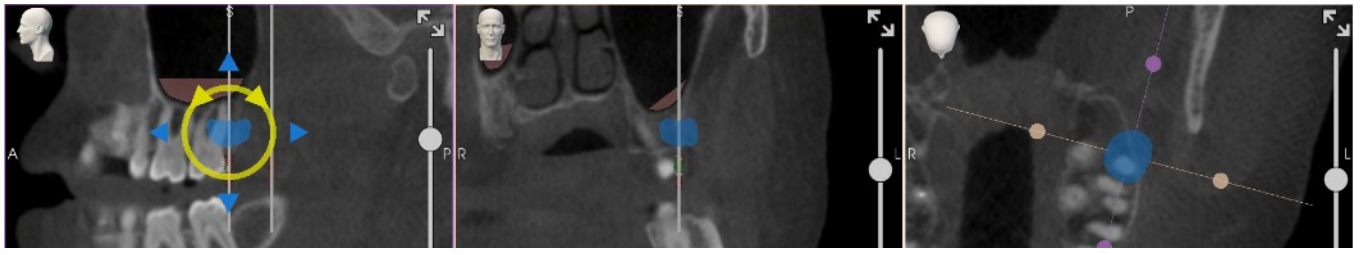


Figure 41: Object Adjustment Tool (2D View) - Rings can be used to adjust rotation.
Arrows can be used to adjust translation.

1. Click on the Implant or Crown to be adjusted in the 2D View to show the Object Adjustment Tool.
2. The Object Adjustment Tool is shown in the 2D View. It has arrows to adjust the position of the selected object. The arrows are aligned with the axis of object in the sagittal and coronal views, and aligned with the selected 2D View Alignment in the transverse view . Click and drag a blue arrow or the object to translate selected object by an arbitrary amount in the direction of the arrow. Click and drag the yellow ring or arrow to rotate the selected object by an arbitrary amount in the direction of the arrow about an axis normal to the 2D View. Use a single click an arrow to translate the selected object by 0.5 mm or rotate by 2 degrees.

   Blue proximity zones will appear around the implant body when selected. The inner proximity zone is 1.5mm from the implant body, while the outer proximity zone is 3mm from the implant body.
3. Move the cursor away from the selected object in the 2D View. After a brief delay or if the user clicks away from the object, the Object Adjustment Tool disappears.

8.25 Crown Design

Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Crown Design step.

8.26 Gingiva & Bone Reduction

Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Gingiva Design step.

The Bone Reduction feature allows the surgeon to set the desired bone reduction plane and other boundaries in which the Yomi System will use to safely confine the Bone Reduction Burr during the guided bone reduction. If planning to use the robotically navigated Bone Reduction feature, it is recommended to plan the Bone Reduction prior to planning implants. When planning implants after the Bone Reduction, the implant shoulder will default to the planned Bone Reduction Plane. The accuracy of the Bone Reduction feature is +/- 2 mm.

1. After clicking on the Bone Reduction Checkbox, the user will enter the Bone Reduction feature. The Main View will default to the Panoramic view with all boundaries and Bone Reduction Plane represented by purple-colored lines. The blue line represents the Occlusal Plane, and the shaded green area represents the volume that will be reduced. A permanent ruler showing the distance between the Occlusal Plane and Bone Reduction Plane is locked at the midsagittal plane. If a Restorative Model(s) has been imported, a colored outline of the model (color selected during import) will appear in all views so the user can reference it to plan the bone reduction.

   Note: The initial volume representing the bone to be reduced may appear red instead of green when entering Bone Reduction planning if the default constraints intersect with critical anatomy or the YomiLink Bone screws.

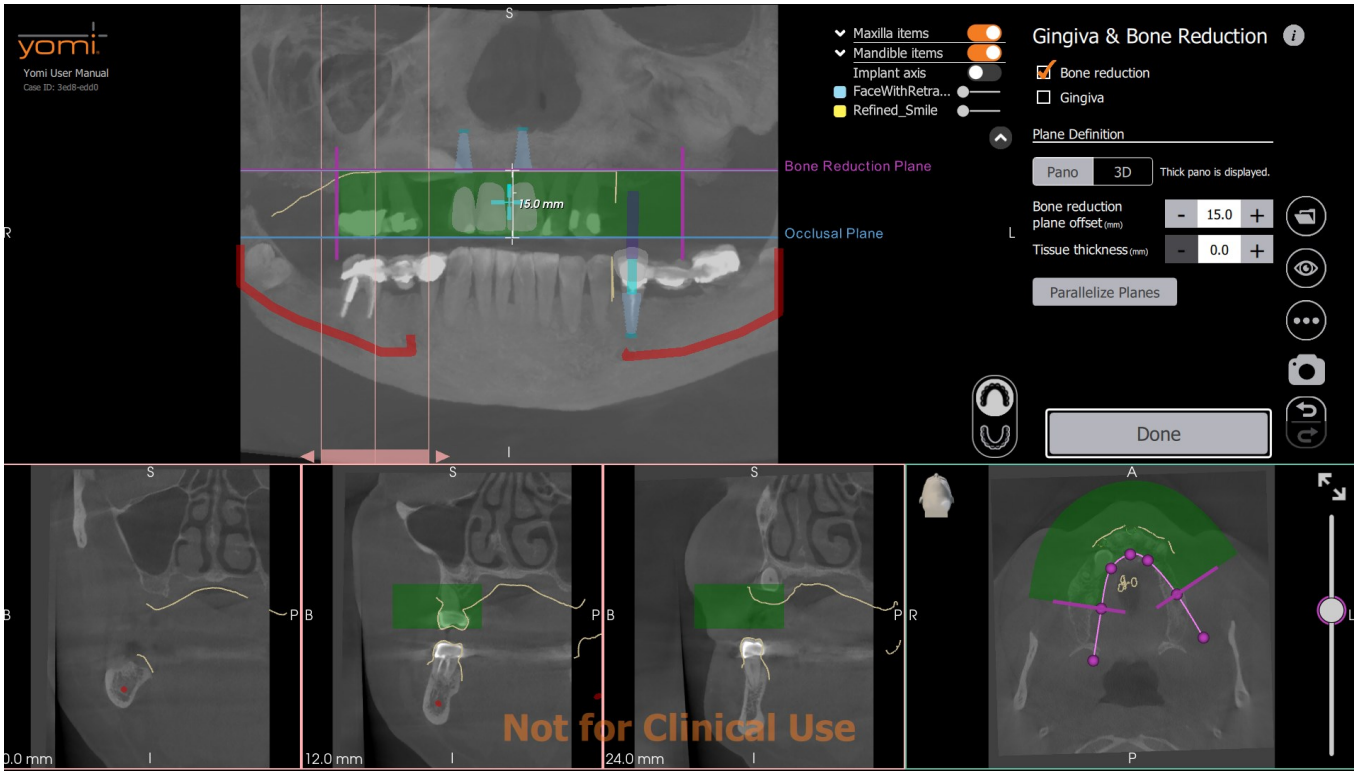


Figure 42: Bone Reduction Feature

2. The default Bone Reduction Plane (shown as the horizontal purple line in the figure below) is set 15 mm offset from the Occlusal Plane for the given jaw (as defined on the checklist on the “Prepare Scan” tab).

   Adjust the Bone Reduction Plane to the desired distance below the Occlusal Plane by either dragging the horizontal purple line within the panoramic image or by defining a plane offset from the Occlusal Plane using the *Bone Reduction Plane Offset* and +/- buttons in the right side of the screen.

   The *Tissue Thickness* textbox and +/- buttons can be used to create an offset on the designed gingiva to account for the thickness of the soft tissue on the patient.

3. The posterior boundaries are represented by the purple vertical boundaries on either side of the green volume in the Panoramic View and the two purple lines normal to the Spline Contour in the transverse view in the lower right corner of the screen. To adjust the posterior boundaries of the bone resection volume, drag the vertical lines in the Panoramic View to the desired location. The posterior boundaries in transverse view will reflect the change once the user completes the drag.

4. The lingual purple boundary is visible in the transverse view as well. By default, the lingual boundary is defined as an offset of the Spline Contour set in the “Prepare Scan” tab. To adjust the lingual boundary of the bone reduction volume, click and drag the purple spheres visible on the lingual boundary (figure below). To translate the whole boundary, click and drag the purple contoured line. If necessary, the users can expand the transverse view by clicking on the opposing arrow above the slider bar in the transverse window shown in the figure above. When the desired lingual boundary is set, the transverse view can be minimized by clicking the convergent arrows above the slider bar at the top of the screen.

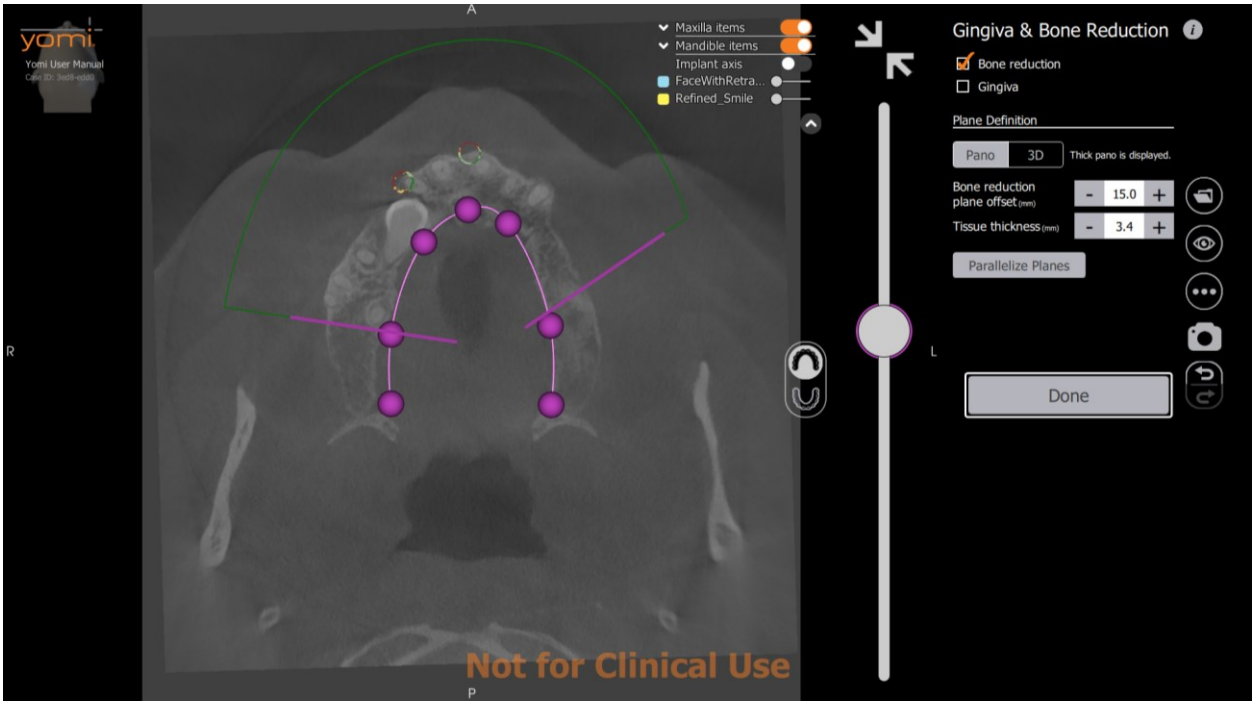


Figure 43: Expanded Transverse View for Lingual Boundary Adjustment

5. If the view is changed from Panoramic to 3D, the Bone Reduction plane can be adjusted further. To change the view, toggle between the *Pano / 3D* using the toggle on the right menu. The plane has three rings to adjust the rotational orientation about each axis and two arrows to adjust the plane along the transverse axis superiorly or inferiorly to the Occlusal Plane. Rotational adjustments to the Bone Reduction Plane can also be achieved by dragging the purple spheres in the sagittal and coronal views below the 3D Main View.

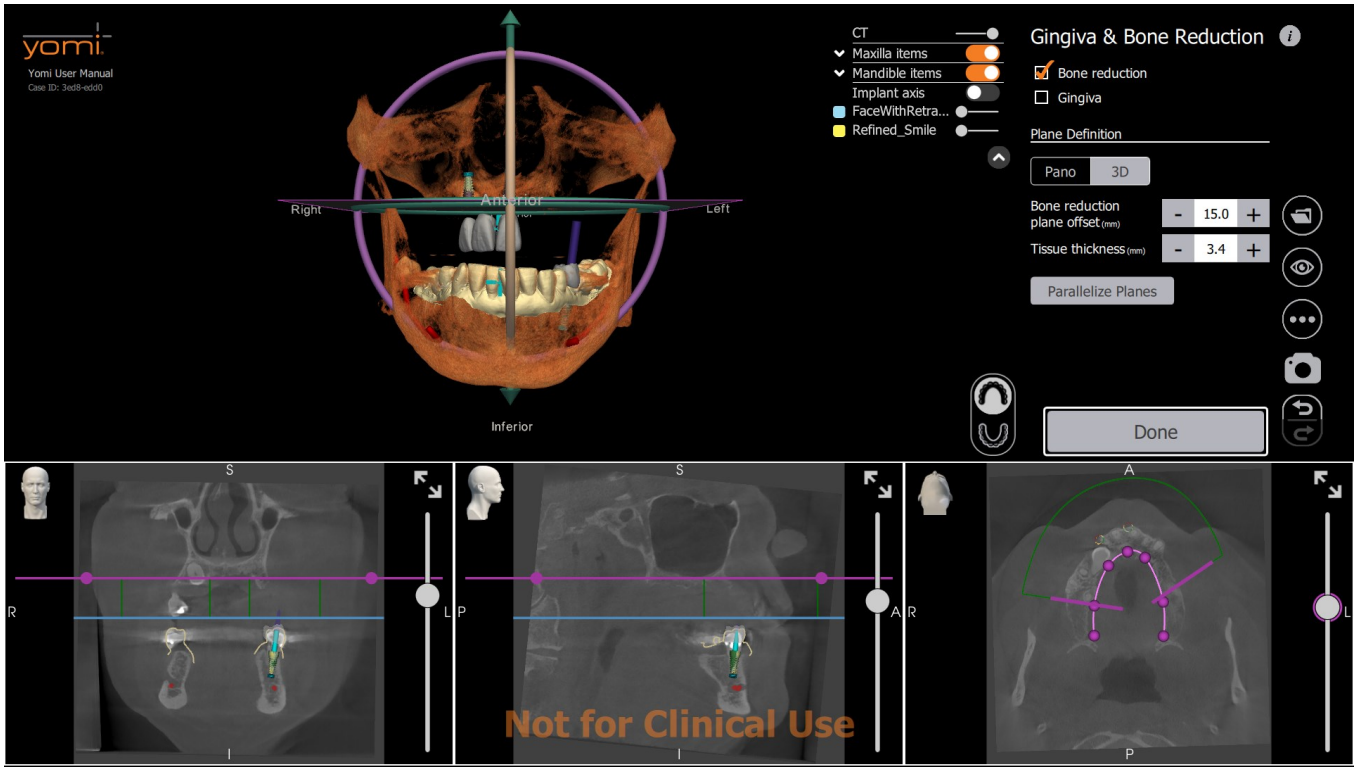


Figure 44: Bone Reduction Feature with 3D Main View

6. Adjustments made to the rotational orientation of the Bone Reduction Plane will result in an arched line in the Panoramic View. If the Bone Reduction Plane is not parallel to the Occlusal Plane, the panoramic view will be presented as a *thin panoramic*. A non-parallel bone reduction plane will be displayed as a curve in the panoramic view. The *Parallelize Planes* button can be used to make the bone reduction plane parallel to the occlusal plane and convert the panoramic view to a *thick panoramic* type.

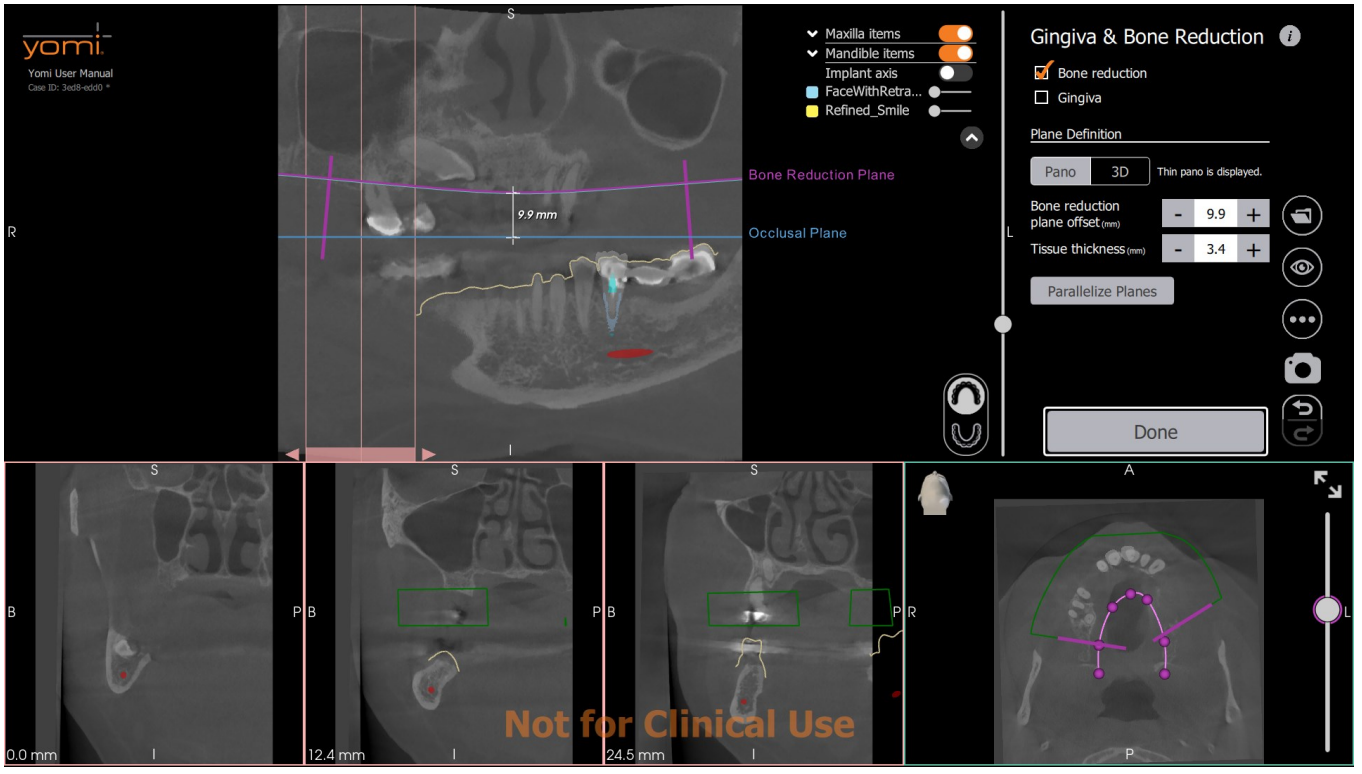


Figure 45: Panoramic View with a posteriorly sloped Bone Reduction

7. Review all boundaries before closing the Bone Reduction feature. Drag the pink bar in the lower section of the Panoramic View to change the location of the three oblique images and confirm the desired bone reduction volume. Drag the slider on the transverse view to visualize the lingual boundary across the superior - inferior dimension of the arch. The purple circle on the slider represents the planned Bone Reduction Plane and the teal-colored line in the Panoramic View represents the location of the transverse slide axially (see figure below). Using the slider bar for the Panoramic View will allow you to adjust the Panoramic View buccal/lingual to the Spline Contour. A transverse cross-section will appear in the upper right corner of the Panoramic View as the slider is adjusted. The red spline represents the Spline Contour, and the green spline represents the spline of the current Panoramic View.

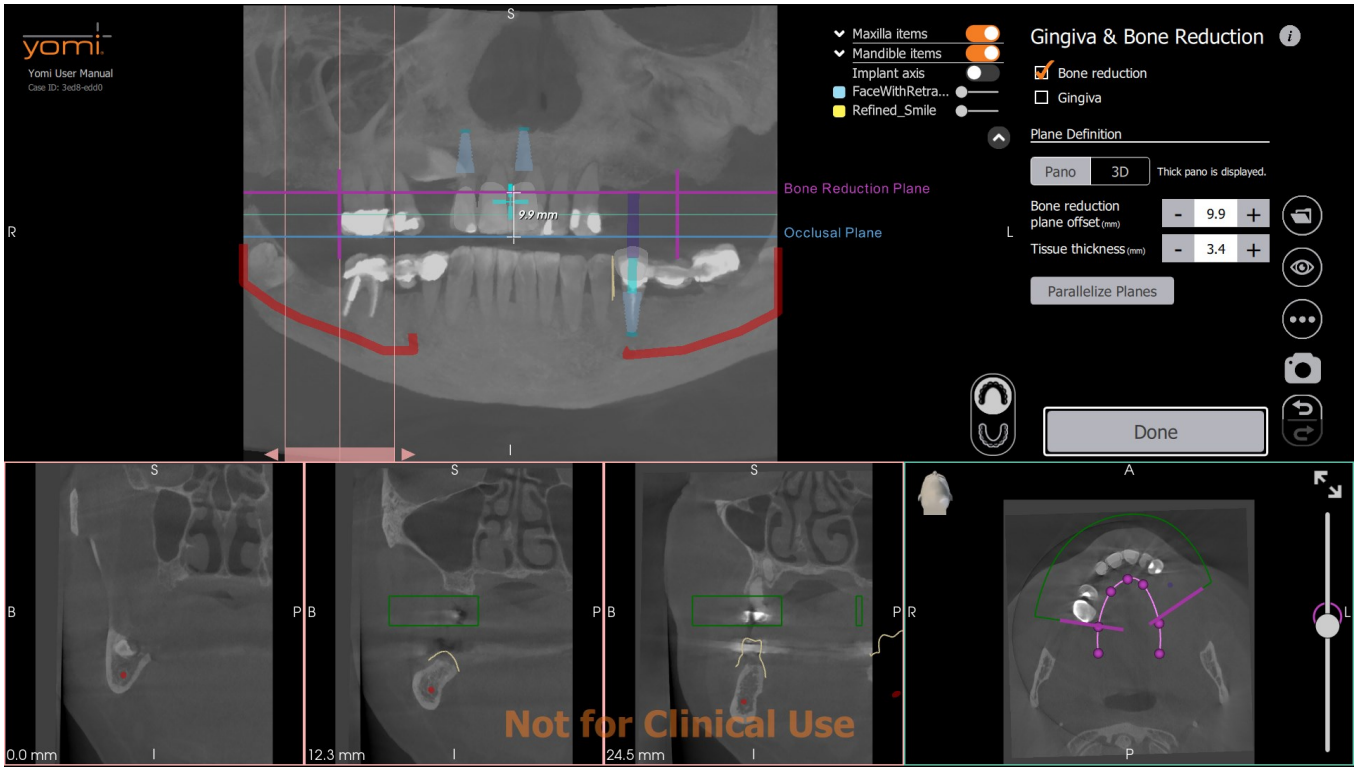


Figure 46: Bone Reduction Volume Review

If the bone reduction volume is within the user defined proximity parameters of the nerve, sinus, or YomiLink Bone screws, the green volume and the purple boundary lines will change to red. In this example the bone reduction volume is intersecting the nerve and several of the YomiLink Bone screws. The user can resolve the warning by dragging the bone reduction boundaries to a location where the bone reduction volume is not intersecting any of the structures mentioned above.

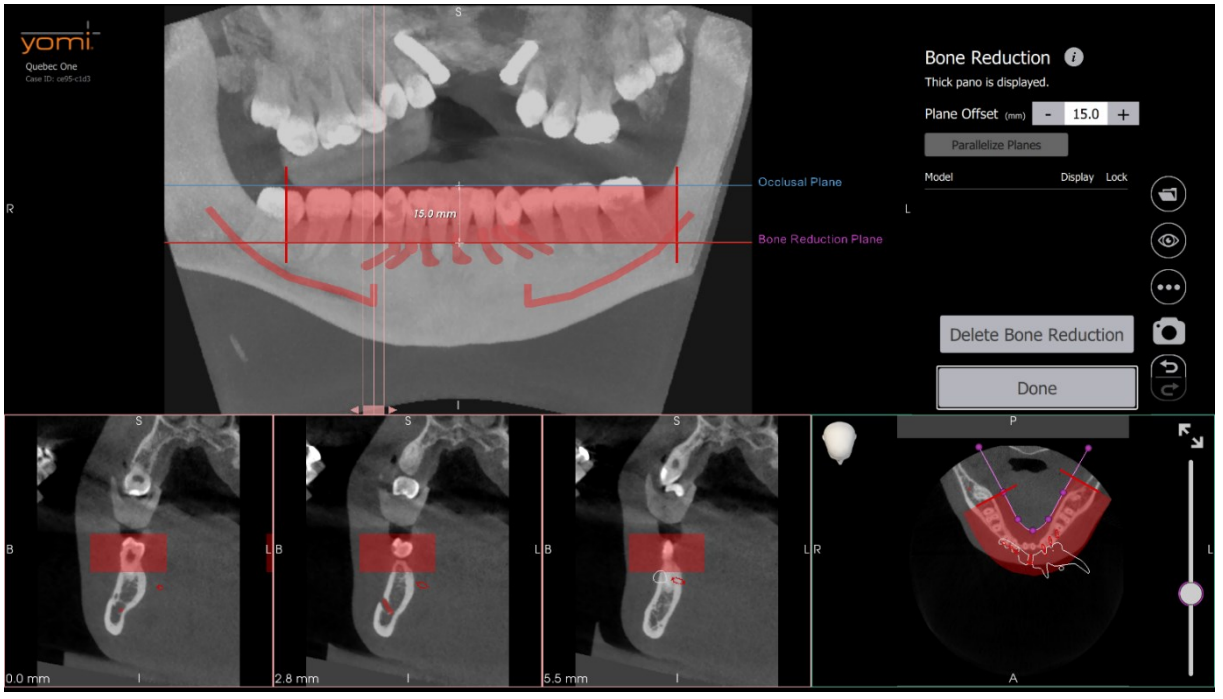


Figure 47: Panoramic View showing Proximity Alert

8. If the user decides to no longer perform a bone reduction, the bone reduction plan can be deleted by unchecking the Bone Reduction checkbox. Deleting the bone reduction will remove the visualization of the bone reduction volume from all screens and will remove all bone reduction steps from the workflow.
9. After the Bone Reduction plan has been reviewed, click “Done” to exit the Bone Reduction Planning feature. If the user proceeds with a plan with a proximity alert warning active, a popup window will appear when entering the Bone Reduction tab. The user will need to resolve the proximity warning or accept the risk to proceed to guided Bone Reduction.

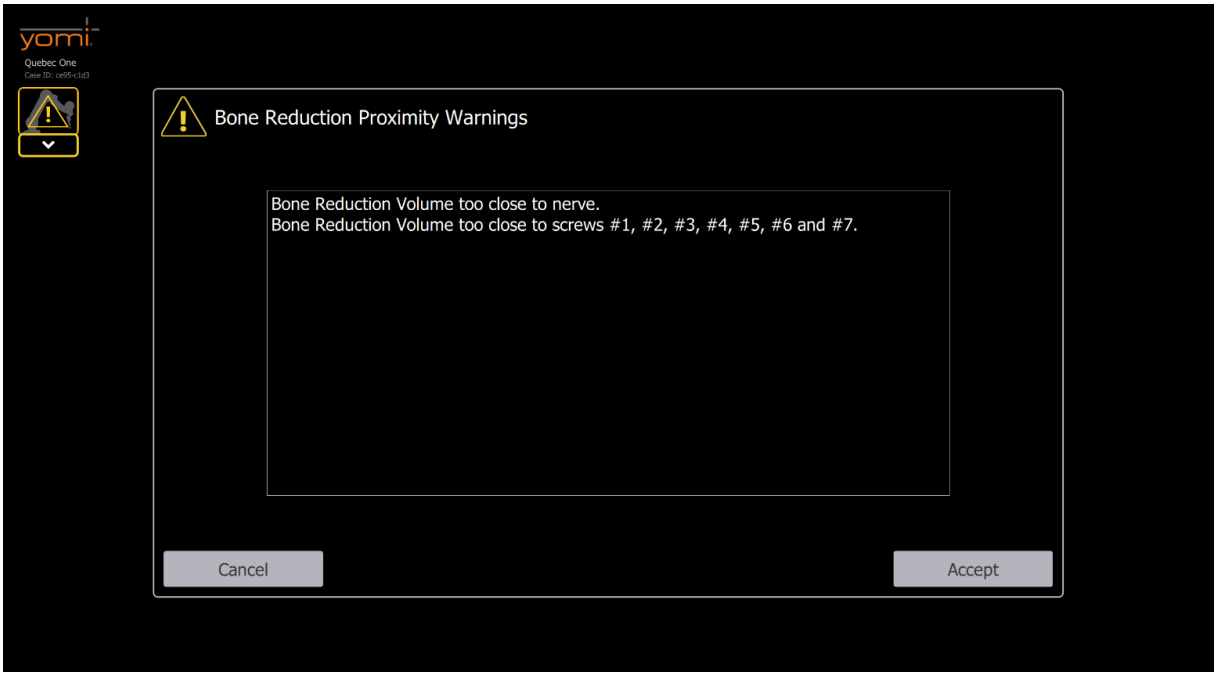


Figure 48: Bone Reduction Proximity Warnings

For Dual Arch workflow, use the Jaw Toggle to toggle between maxilla and mandible Bone Reduction plans.

8.27 Seating Wings

Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Seating Wings step.

8.28 Finalization

Please refer to **LB-1156 Restorative Module User Manual Addendum** for information on the Finalization step.

8.29 YomiLink Bone

On the Treatment Planning page, select the YomiLink Bone planning menu. Upon entering the YomiLink Bone planning page, the 3D render will change to *Surface* render to visualize the alveolar ridge for YomiLink Bone planning and *snapping*. The threshold slider can be used to modify the render intensity and the surface to which the YomiLink Bone will *snap* (refer to *YomiLink Bone Snapping Tool* section below).

From the dropdown select a Link Type (**Figure 49**).

NOTE: The selected type of YomiLink Bone appears on the screen in a default position for further user adjustments to a desired location. The default position is 3 mm apical to the bone reduction plane, if bone reduction is part of the surgical plan, or 15 mm apical to the occlusal plane if bone reduction is not part of the surgical plan.

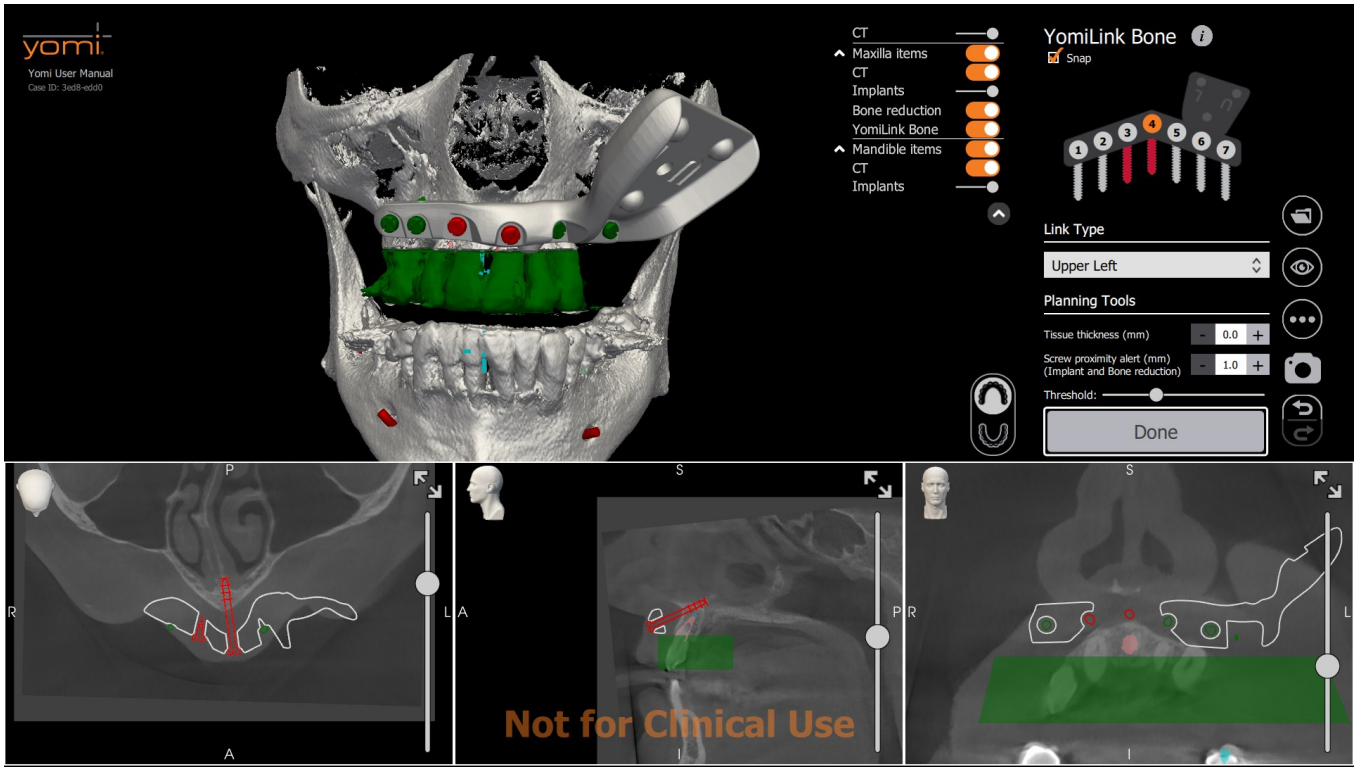


Figure 49: YomiLink Bone Planning Page

Selecting the YomiLink Bone will bring up the widget in the 3D view or the directional arrows in the 2D views. You can use the arrows to move and rotate the YomiLink Bone to desired position. Also, clicking and dragging the YomiLink Bone in the 3D view will move the YomiLink Bone in the plane from the point of view perspective.

Right-click the screws on the screw map to change screw length and diameter, or to delete a screw. The default screw is 2 mm in diameter and 20 mm in length. Multiple selection is possible in the screw map by holding the SHIFT or CTRL keys on the keyboard while clicking on the desired screws. Screws can be created by left-clicking an empty screw space or the head of an empty screw in the Screw Map.

It is recommended to measure how apical the YomiLink Bone can fit the patient on during a consult and to utilize that measurement during YomiLink Bone treatment planning. This measurement allows to determine apical limits based on patient soft tissue elasticity. The measurement can be taken from the incisal edge of teeth #8/9 or #24/25. The YomiLink Bone can be planned to that achievable apical depth using the ruler tool in YomiPlan. Refer to **Figure 50.**

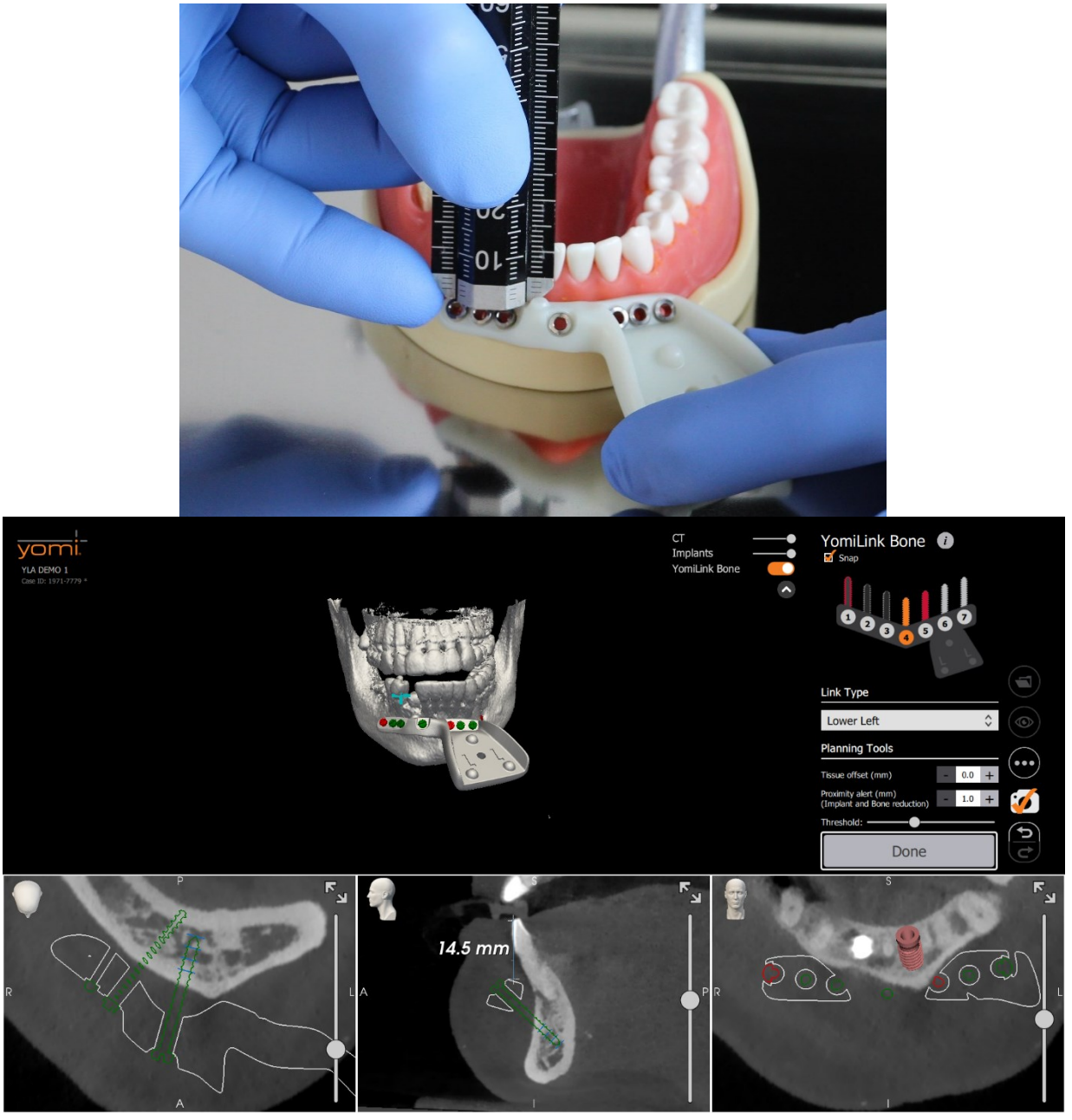


Figure 50: [TOP] YomiLink Bone measurement using provided depth gauge. [BOTTOM] YomiLink Bone treatment planning page with apical measurement from #25 incisal edge.

The screws in the Screw Map and in the YomiLink Bone object will change to red color when a proximity violation is triggered. Screw proximity violations can occur with implants, nerves, sinus, and/or the bone reduction plane. The proximity alert threshold specified for the nerve and sinus in the Prepare Scan section will be used to generate proximity warnings for the nerve and sinus. The proximity alert threshold entered in the YomiLink Bone planning page will be used to generate proximity warnings with implants and the bone reduction plane.

Unreachable screws are shown in gray in the Screw Map. For more information on unreachable screws, refer to **LB-1109-00 YomiLink Arch User Manual Addendum**.

If a screw is both unreachable and has a proximity warning it will be displayed in gray with a red outline.

Hovering the mouse over a screw in the Screw Map will display screw information: dimensions of the screw planned, or unreachability of the screw. Refer to **Figure 51** for different screw states displayed in YomiPlan.

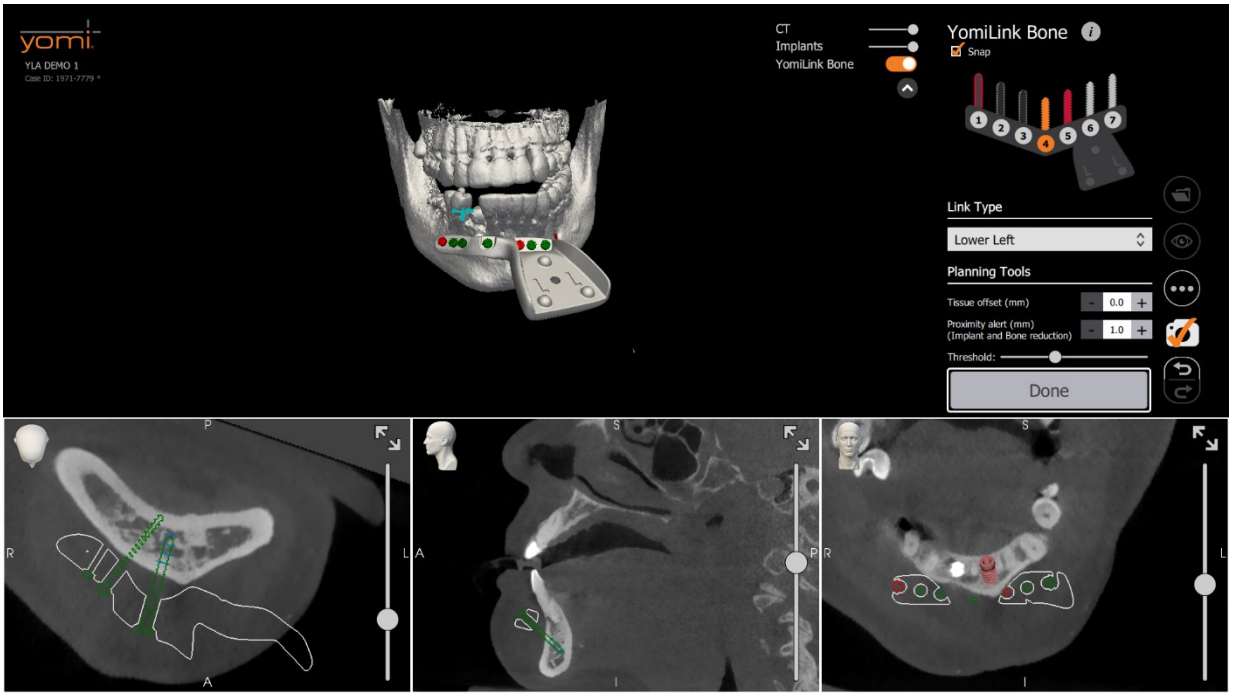


Figure 51: YomiPlan displaying different screw states.

The YomiLink Bone sleeves are oriented apically from the patient's occlusal plane for both mandible and maxilla. Align the YomiLink Bone such that the middle notch of the YomiLink Bone is aligned with the midline of the patient.

The following features are designed to facilitate YomiLink Bone planning:

YomiLink Bone Snapping Tool: The snapping tool places the YomiLink Bone flush with the patient bone according to active jaw alignment. The snapping feature translates and pans the YomiLink Bone to reduce the gap between the back of the YomiLink Bone and the patient anatomy. The rotation of the YomiLink Bone is only in the left/right direction. The feature will not change the pitch up/down of the YomiLink Bone. The Snapping feature can be disabled with the "Snap" Checkbox. Adjusting the threshold slider will change the render intensity to help visualize the bone surface to which the YomiLink Bone will snap to.

If the snap movement of the YLB is the last action in planning YLB placement, the user will be informed and asked to confirm the relevance of the placement. However, the final snap location should always be reviewed for clinical accuracy.

Soft Tissue Offset Tool: This tool accounts for soft tissue thickness entered by the user when planning the YomiLink Bone location. Soft tissue offset tool will compensate by the input number when using YomiLink Bone Snapping. It is set to zero as default.

Screw Aligned View: When clicking on a screw on the YomiLink Bone planning page, the 2D views will be aligned to the screw for easier screw size planning. The 2D views also display ruler markings based on the available screw lengths (14, 16, 18, 20 mm). Refer to **Figure 52** for the YomiPlan Screw Aligned 2D views.

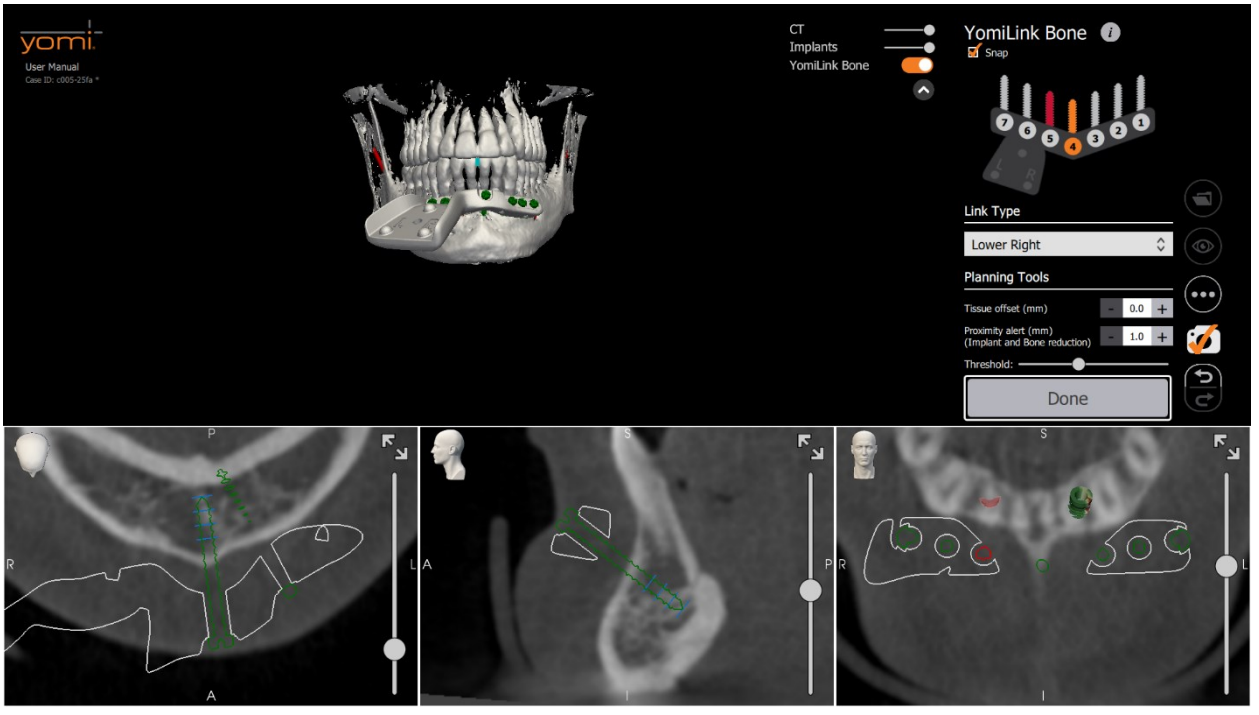


Figure 52: YomiPlan displaying Screw Aligned 2D views. Note ruler markings at 2mm increments based on the available screw lengths (14, 16, 18, 20 mm)

The pitch of the YomiLink Bone can be modified if screws are in collision with implants or anatomical structures instead of translating the YomiLink Bone apically. Translating the YomiLink Bone too apical might result in difficulties placing the YomiLink Bone due to soft tissue elasticity. The threshold slider can be moved to a higher value to better visualize dental roots if needed. Refer to **Figure 53**.

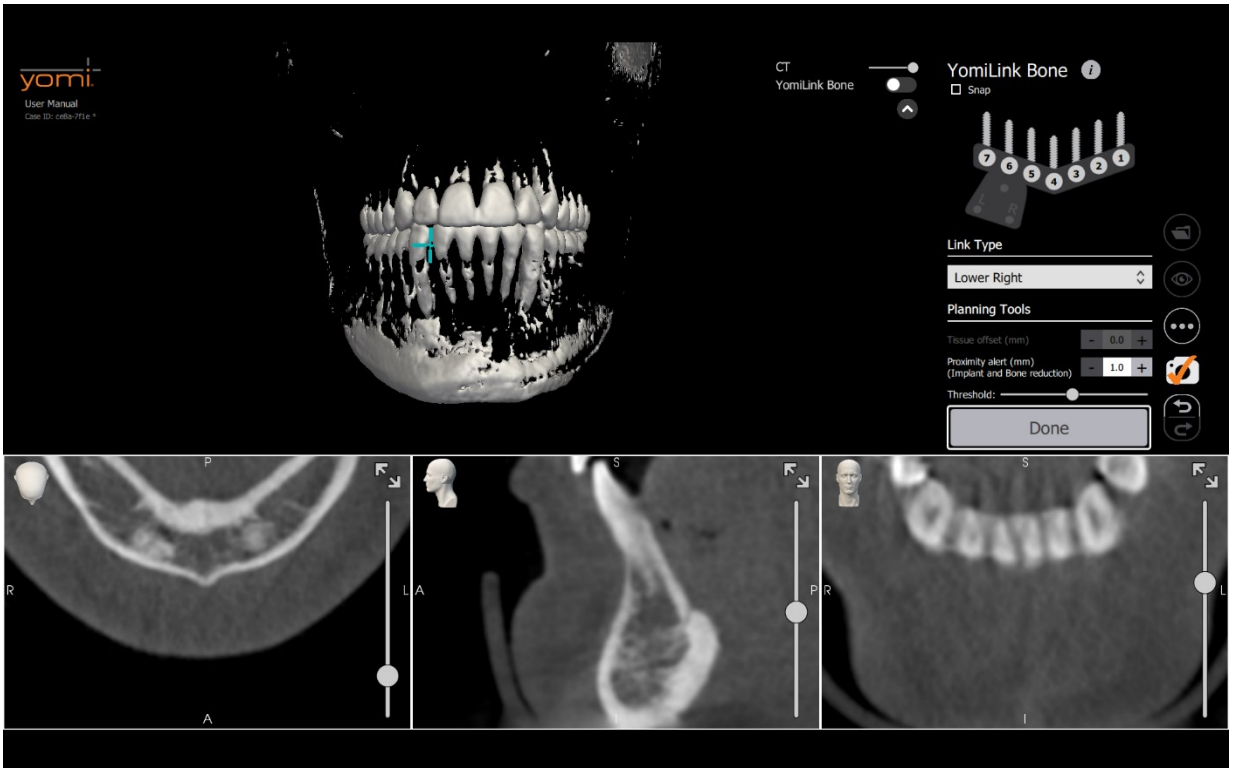


Figure 53: Dental roots displayed at a higher threshold value

For Dual Arch workflow, use the Jaw Toggle to toggle between maxilla and mandible YomiLink Bone.

8.30 Making Linear Measurements

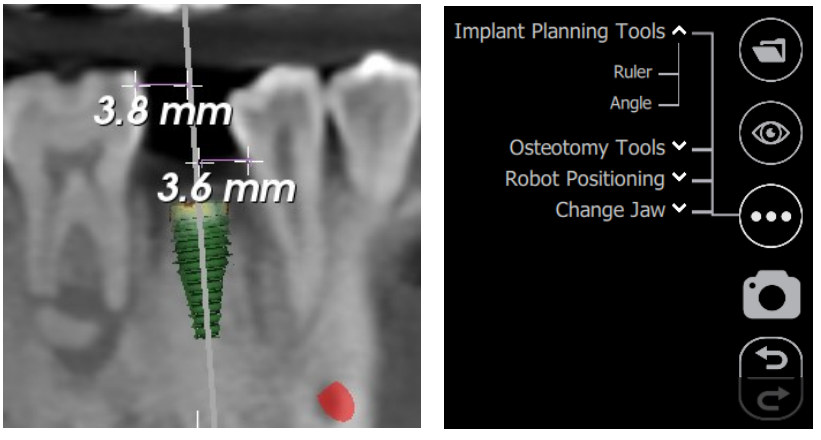


Figure 54: Using the Ruler Measurement Tool to measure the distance between an implant and the adjacent teeth.

1. Identify a 2D View in which to measure a linear distance.

2. Click the “More Options” icon and then select “Ruler” from under the Treatment Planning Tools menu to activate the Ruler. The mouse cursor will now have a ruler next to it when hovering in the 2D views.
3. Click on a desired point in a 2D View where the measurement should start.
4. Click again on a desired point in the same 2D View where the measurement should end.
5. A line with cross “+” at each end will appears in the 2D View. Text next to the line denotes the distance between the start and end points. The measurement or ruler can be adjusted by clicking and dragging the “+” handles of the ruler. The mouse courser will turn into a hand when near the handle.
6. Multiple liner measurements can be made by repeating the steps above. To delete a measurement, right-click on a measurement handle and select “Delete Measurement”.
7. Click the “Stop Ruler” button to turn off the feature.

8.31 Making Angular Measurements

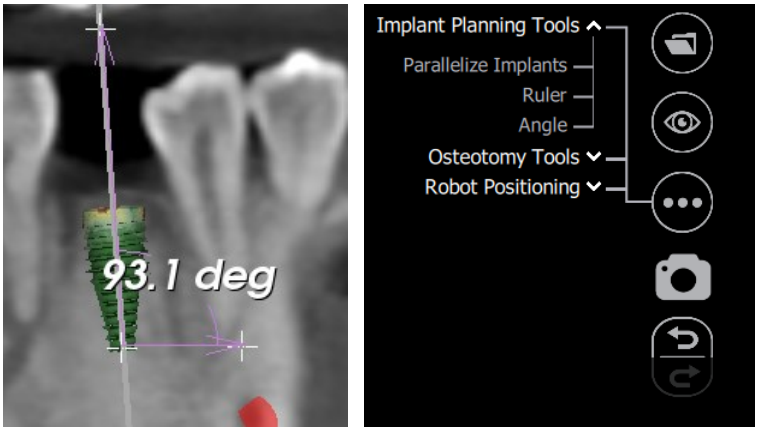


Figure 55: Using the Angle Measurement Tool to measure an angle

1. Identify a 2D View to use to measure an angle.
2. Click the “More Options” Icon then “Angle” button to enable it and to show angle measurements.
3. Click at the point in the 2D View where the measurement should start.
4. Click at the point in the 2D View that corresponds to the common vertex in an angular measurement.
5. Click at the point in the 2D View where the measurement should end.
6. Two lines and the angle between them are shown in the 2D View. The text on the angle denotes the angle between the two lines.
7. The measurement can be adjusted by clicking and dragging the handles of the angle.
8. Click the “Stop Angle” button to disable.
9. To delete a measurement widget; right click on the widget and select “delete measurement”.

8.32 Switching between 3D and Panoramic Views

1. To switch between a 3D main view and Panoramic main view, click on the View Icon (shown in top image below).
2. Then select the desired main view option under the Main View drop-down.

   The 3D and Panoramic main views will appear as radial buttons under the drop-down. The selected option will also update the 2D views shown in the main window. Selecting 3D will show the anatomical 2D cross-sectional views while Panoramic will display five 2D Oblique Views.

8.33 Showing and Hiding 2D Cross-sections

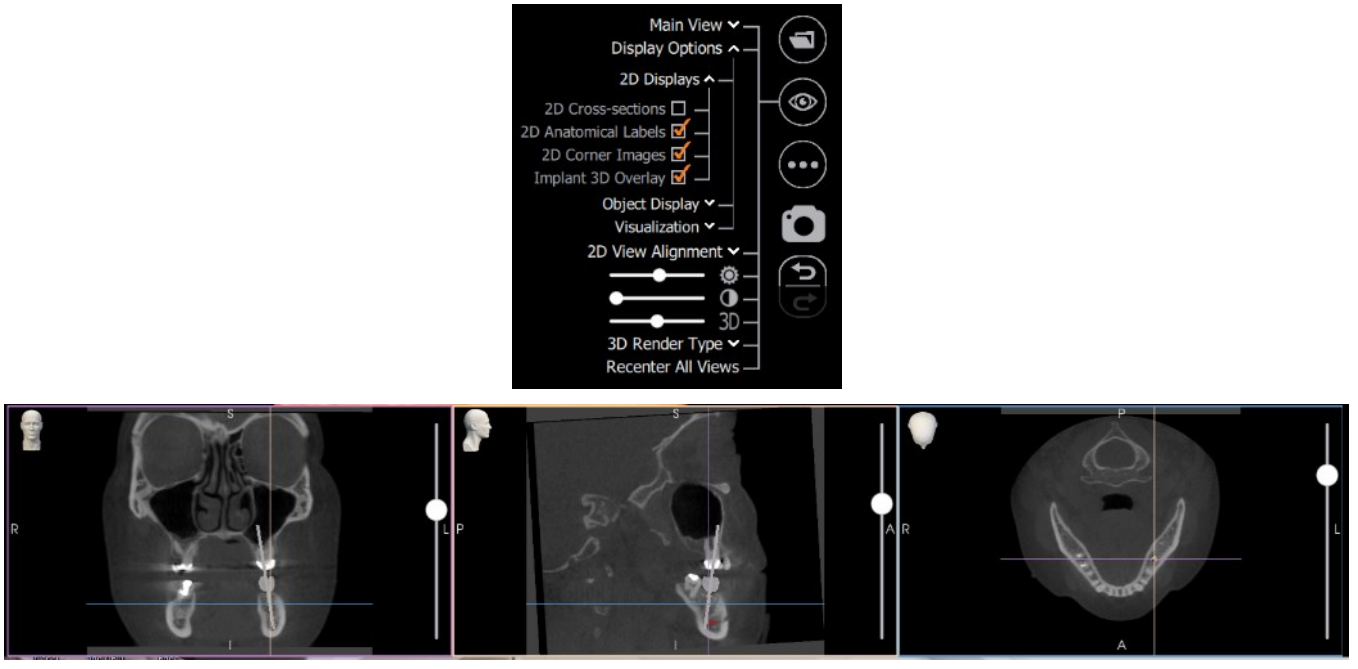


Figure 56: [Top] 2D Displays drop-down with 2D Cross-sections off; [Bottom] Colored Outlines around the 2D Views indicate: Sagittal plane (tan), Coronal plane (purple), and Transverse or Axial plane (blue)

1. Turning on the 2D Cross-sections provides an onscreen visual reference of the other 2D planes in each 2D View. To turn on/off the 2D Cross-sections, first click on the View Icon.
2. Next click on the 2D Cross-Sections checkbox under the 2D Displays drop-down.

   The colored lines in each image represent the corresponding colored Cross-sections for each 2D plane. Adjusting the slider beside a 2D view will adjust the same colored 2D Cross-section in the other two views.

8.34 Showing and Hiding Implant 3D Overlay

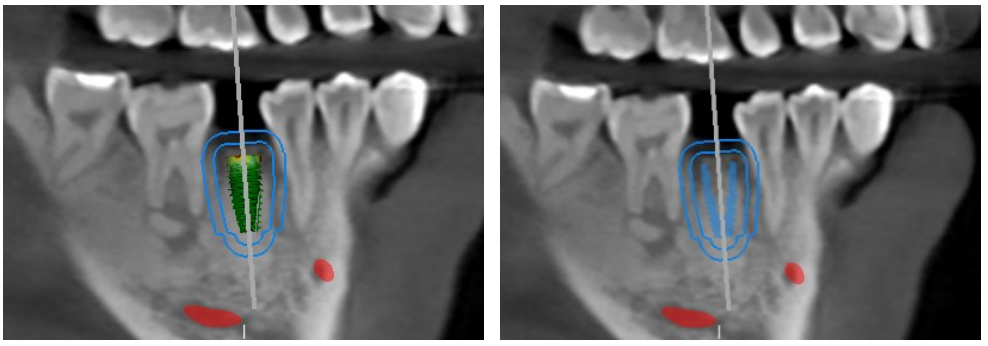


Figure 57: [Left] Implant 3D Overlay displayed; [Right] Implant 3D Overlay hidden

1. Turning on the Implant 3D Overlay superimposes a 3D visual representation of the planned implant based on the cross-sectional position of the 2D View. Turning off the Implant 3D Overlay shows a 2D cross-section of the planned implant in the 2D Views. To turn on/off the Implant 3D Overlay, first click on the View Icon.
2. Next click on the Implant 3D Overlay checkbox under the 2D Displays drop-down. When the checkbox is checked, the Implant 3D Overlay is on.

8.35 Showing and Hiding 2D Anatomical Labels and Corner Images

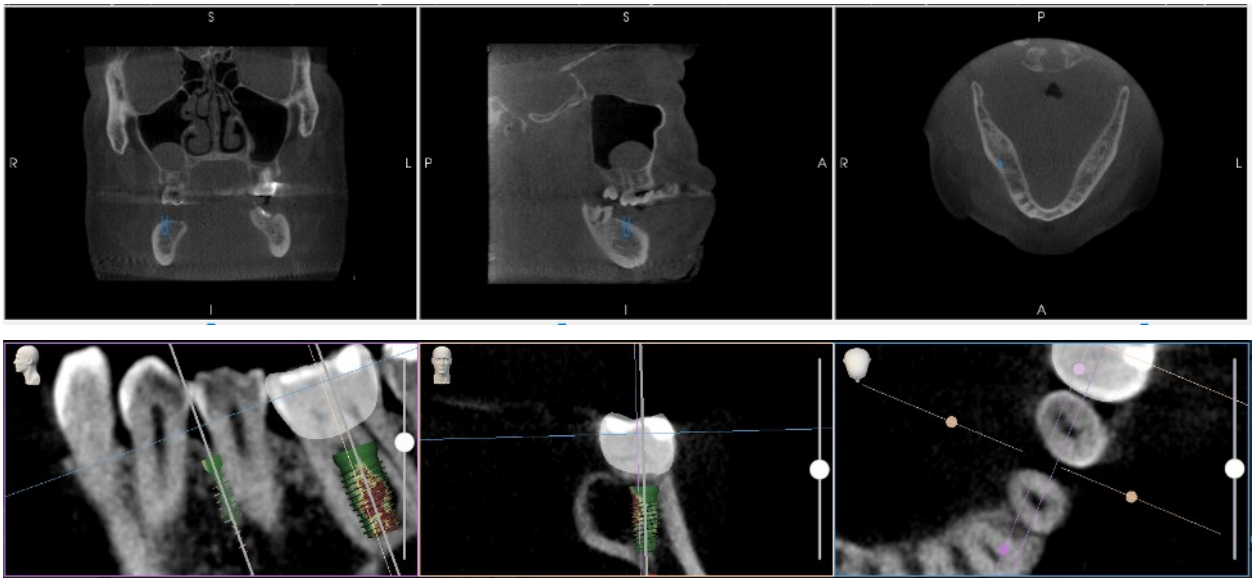


Figure 58: 2D Views with [Top] 2D Anatomical Labels enabled and 2D Corner Images disabled [Bottom] 2D Anatomical Labels disabled and 2D Corner Images enabled

1. The user can turn on/off the 2D Anatomical Labels visible in the 2D, Panoramic, and Oblique Views, and the 2D Corner Images (Head Icon) in the upper left corner of the 2D Views. To turn on/off the 2D Anatomical Lables and Corner Images, first click on the View Icon.
2. Next click on the 2D Anatomical Labels and/or 2D Corner Images checkbox under the 2D Displays drop-down. When the checkbox is checked, the anatomical labels and corner images will appear in the aforementioned views.

Note that when enabled, the 2D Corner Images allow the user to quickly align the 3D model to the represented orientation of the icon (i.e., the Coronal, forward-facing Head Icon will orient the 3D model to the same perspective).

When the 2D Anatomical Labels are enabled, R/L (Right/Left), I/S (Inferior/Superior) and A/P (Anterior/Posterior) labels will appear in the Panoramic and 2D Views. In the 2D Oblique Views, the labels will be I/S (Inferior/Superior) and L/B (Lingual/Buccal).

8.36 Showing and Hiding Implant and Emergence Axis

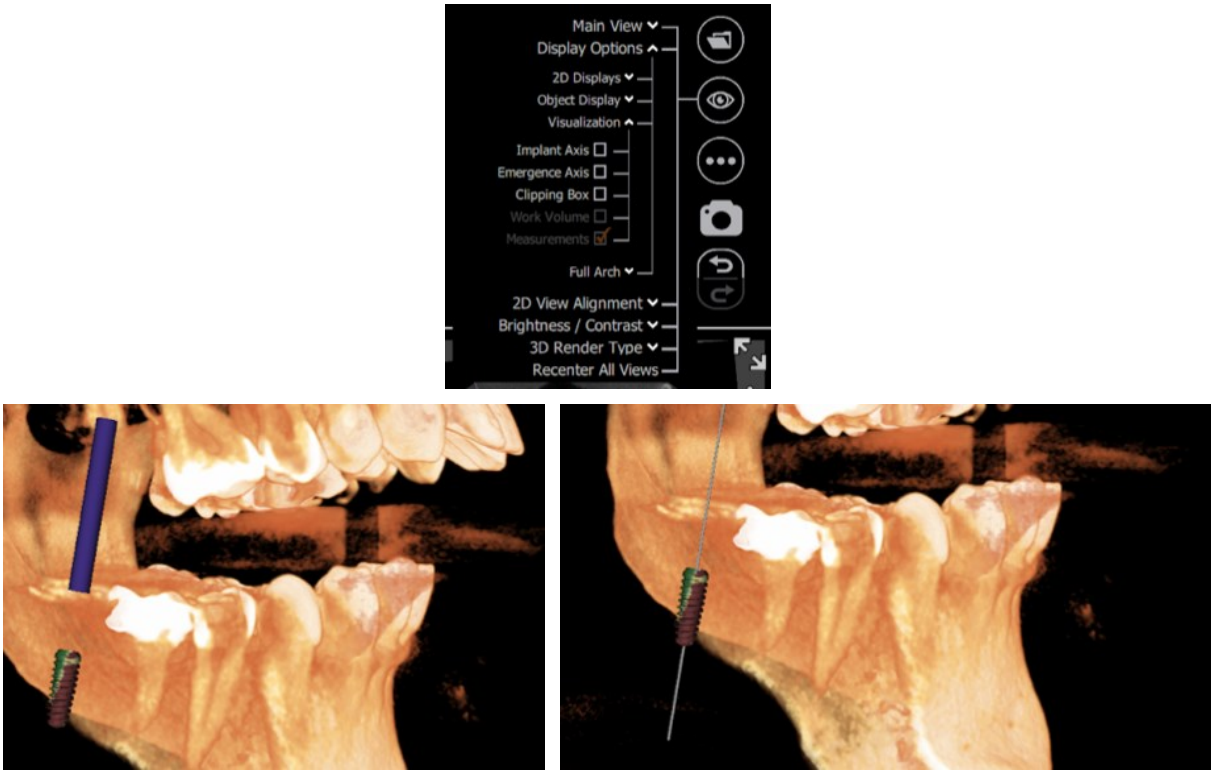


Figure 59: [Top] Images of the Visualization drop-down;
[Bottom Left] Emergence Axis visualization on; [Bottom Right] Implant Axis visualization on

1. Turning on an Implant or Emergence Axis provides an onscreen visual reference on the desired axis for each planned implant in the 3D and 2D Views. To turn on/off an Implant or Emergence Axis, first click on the View Icon.
2. Next click on the Implant Axis and/or Emergence Axis checkbox under the Visualization drop-down.

8.37 Showing and Hiding Fiducials

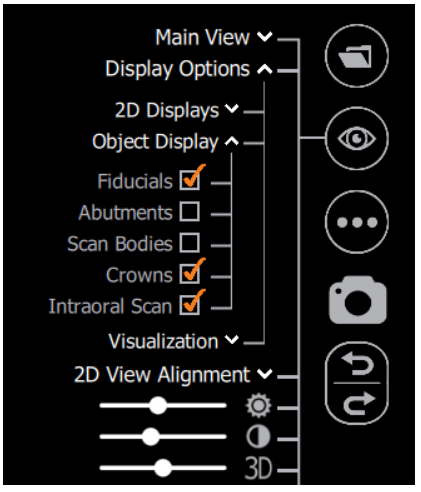


Figure 60: Fiducial Markers and Intraoral Scan On in the 2D and 3D Views

1. Turning on/off the Fiducials provides an onscreen visual reference of the Fiducial Markers and their registration status (green, yellow, red, or blue) in the 3D and 2D Views. To turn on/off the Fiducials, first click on the View Icon.
2. Next click on the Fiducials checkbox under the Object Display drop-down. The Fiducial Markers will be visible when the Fiducials checkbox is checked and will be hidden when unchecked.

8.38 Showing and Hiding the Intraoral Scan

1. Turning on/off the Intraoral Scan determines if the visual reference for an imported intraoral scan is visible in the 3D and 2D Views. To turn on/off the Intraoral Scan, first click on the View Icon.
2. Next click on the Intraoral Scan checkbox under the Object Display drop-down. The imported intraoral scan will be visible when the Intraoral Scan checkbox is checked and will be hidden when unchecked.

8.39 Showing and Hiding Crowns, Abutments, and/or Scan Bodies

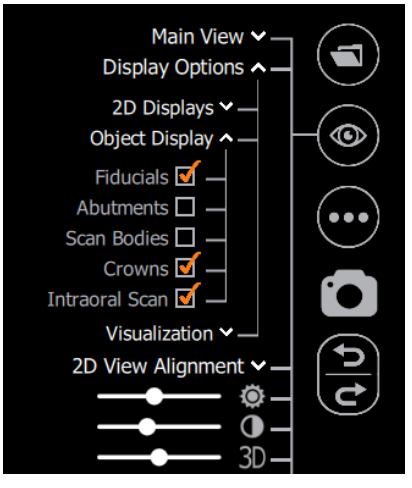


Figure 61: Toggling Implant Crowns and Abutments on/off in 2D and 3D views

1. Turning on/off the the Crowns, Abutments, and Scan Bodies determines if the visual representations of these objects are visible in the 3D and 2D Views. By default, any Crown planned will be displayed. If Scan Bodies or Abutments are turned on using the Implant Library Dialog Box, they will be displayed. To turn on/off, first click on the View Icon.
2. Next click on the checkbox under the Object Display drop-down for the Crown, Abutment, and/or Scan Bodies you wish to display or hide. Checking or unchecking a checkbox will display or hide all objects related to that checkbox.

   Note that using the Abutment and Scan Bodies checkboxes in either the Object Display drop-down or Implant Library Dialogue Box will show/hide these objects for all planned implants.

   When no Crowns have been planned, the Crowns checkbox will be disabled. When no Implants have been planned, the Abutments and Scan Bodies checkboxes will be disabled.

8.40 2D View Alignment Options

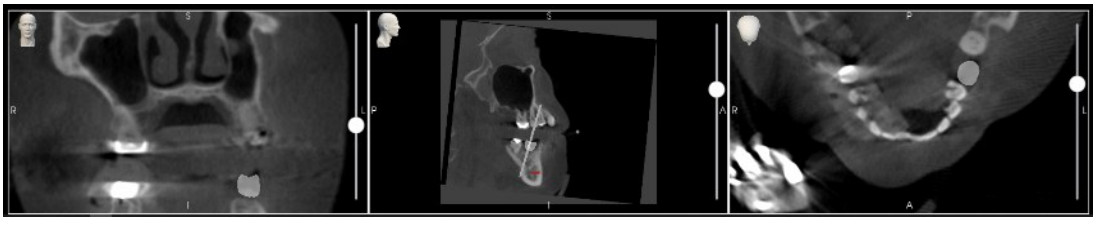


Figure 62: Occlusal Aligned View - 2D Views are aligned with the occlusal plane

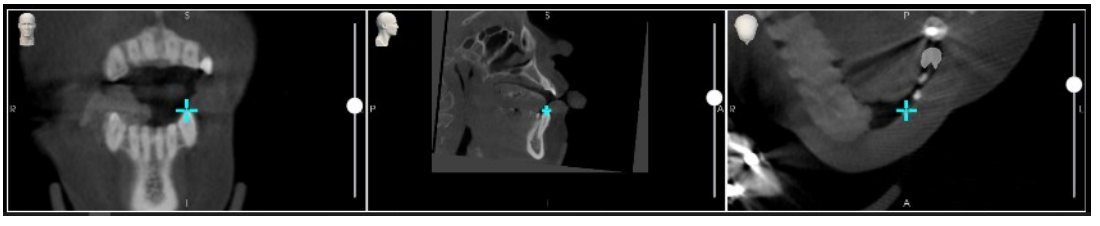


Figure 63: Landmark Aligned View - 2D Views are aligned with the occlusal plane centered on the landmark

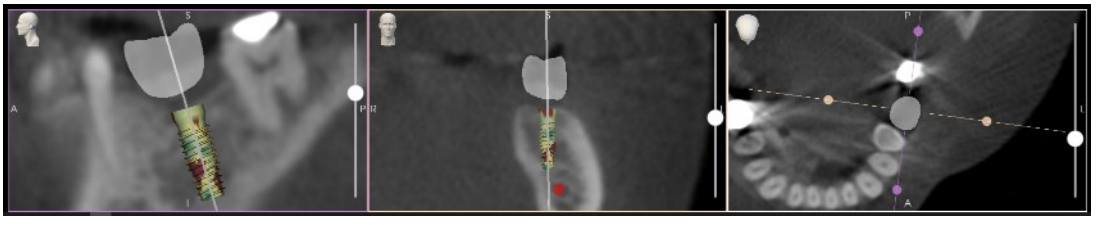


Figure 64: Implant Aligned View - 2D Views are aligned with the implant cross-section

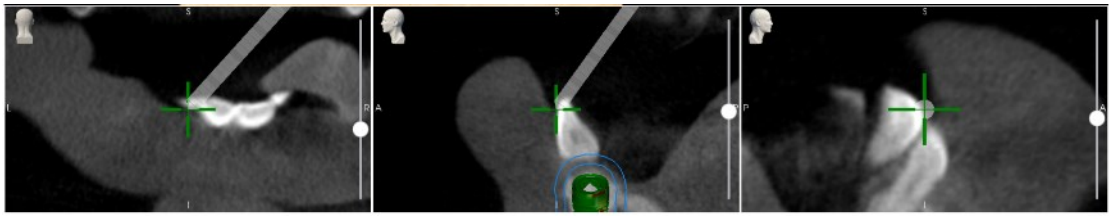


Figure 65: Drill Bit Aligned View - 2D Views are aligned and centered on the drill bit cross-section (only available in “Osteotomy” tab)

1. By default, the planes shown in the 2D Views are aligned with the Implant Aligned 2D View. To view the 2D cross-sectional planes aligned with the world coordinate frame as set by the Occlusal Plane, first click on the View Icon and then select Occlusal Aligned from the 2D View Alignment drop-down.
2. If the 2D Views are aligned to the implant, the 2D View planes can be rotated around the Implant’s axis. To rotate the planes, click and drag one of the tan or purple spheres using the View Adjustment Tool in the 2D Transverse View. As you rotate clockwise or counterclockwise, both the 2D Sagittal View and the 2D Coronal View will update showing slices from the new angle. Manipulating the View Adjustment Tool only modifies the slice angles for the 2D Views, it does not modify the Implant position at all.
3. To switch back to any alignment option, return to the 2D View Alignment drop-down under the View menu and check the radial button for any of the available options (Occlusal Aligned, Landmark Aligned, Implant Aligned, and Drill Bit Aligned). Note some options may be disabled if prerequisite steps have not been completed (e.g., Landmark Aligned is disabled if no Landmark has been placed).

8.41 Changing 3D View Render Settings

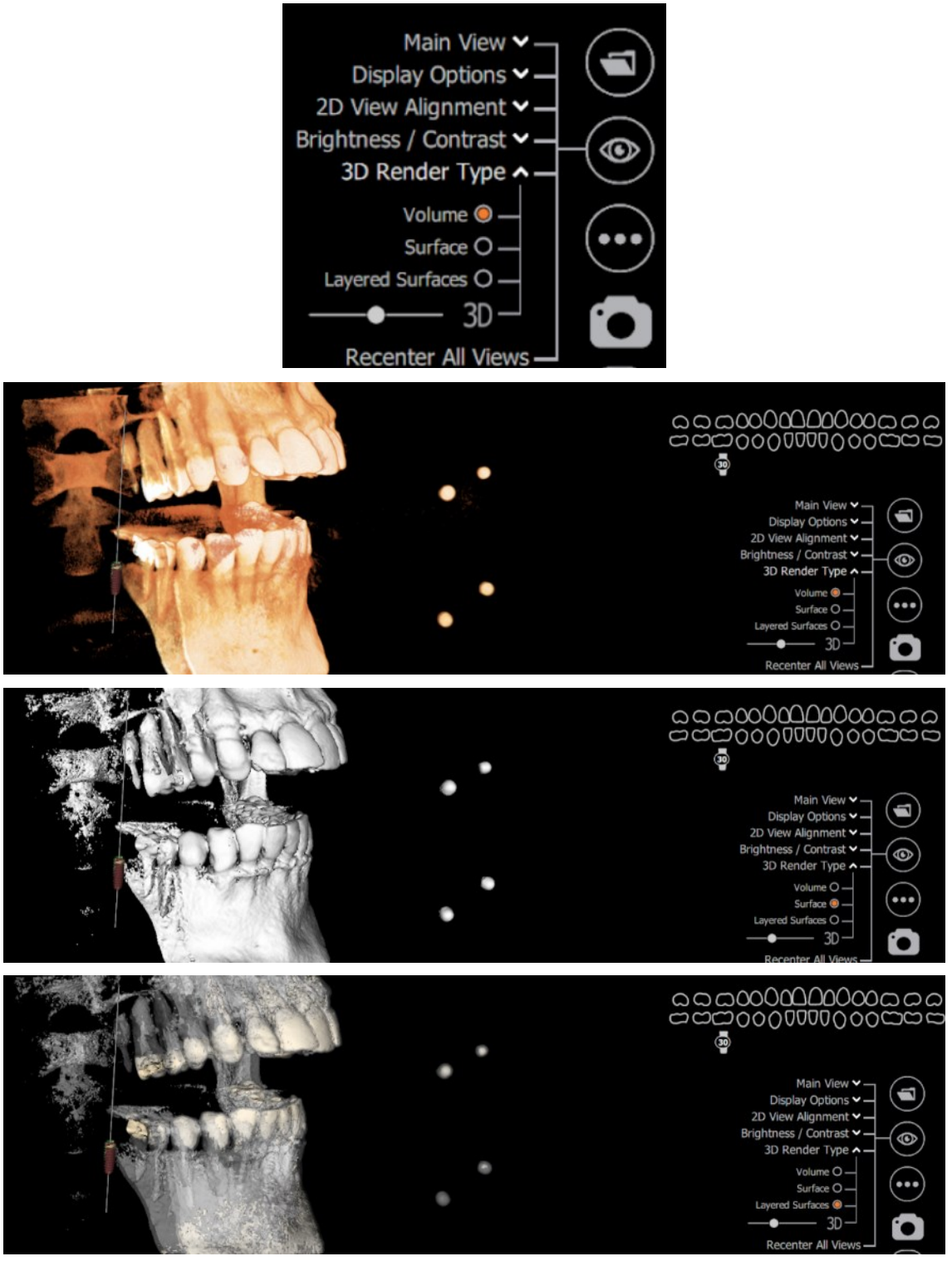


Figure 66: [From top down] 3D Render Settings Menus – (1) Volume Rendering; (2) Surface Rendering; (3) Layered Surface Rendering

1. By default, the 3D View visualizes a full Volume rendering of the CBCT scan (except Registration uses the Surface 3D Renter). To access and change the 3D Render Settings, click the View and select the 3D Render Type drop-down.
2. The user can then select a Volume, Surface or Layered Surface 3D rendering. To switch to a rendering scheme that enhances the teeth, select the Layered Surfaces Volume Rendering option. When a 3D Render Type radial button is selected, the 3D View will update accordingly.
3. Each type of rendering can be adjusted based on the threshold associated with it. To adjust the amount of the model rendered, use the 3D Slider under the Layered Surface radial button to adjust the threshold level used for the currently selected 3D Render Type. The 3D View will update accordingly and interactively as the slider is adjusted.

8.42 Saving a Case

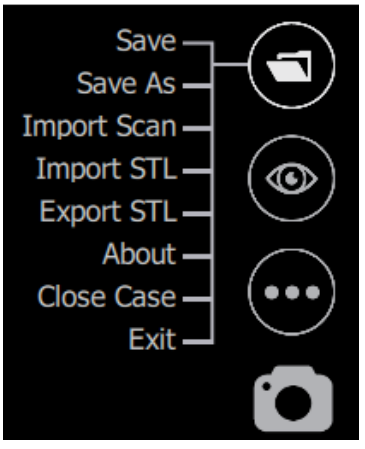


Figure 67: Files Menu

1. The current state of a patient's YomiPlan can be saved as a Case file. Case files can later be loaded into the YomiPlan software to resume planning. To save a Case, click the File Menu icon and select Save or use the keyboard shortcut Ctrl + S.
2. If the Case has been saved previously, changes made to the plan will be saved to the same Case file. If the Case file has not been saved previously, the Save As window will appear. The user can navigate to an appropriate folder and enter a name for the Case file. When they click Save, the Case file will be saved.
3. If the user wishes to save the case as a new file, use Save As under the File Menu to save the Case as a new Case file.

   Note: Cases will Auto Save periodically as the software runs. A small asterisk will appear next to the Case ID at the top of the software when the case has been edited but not saved.

8.43 Export to STL

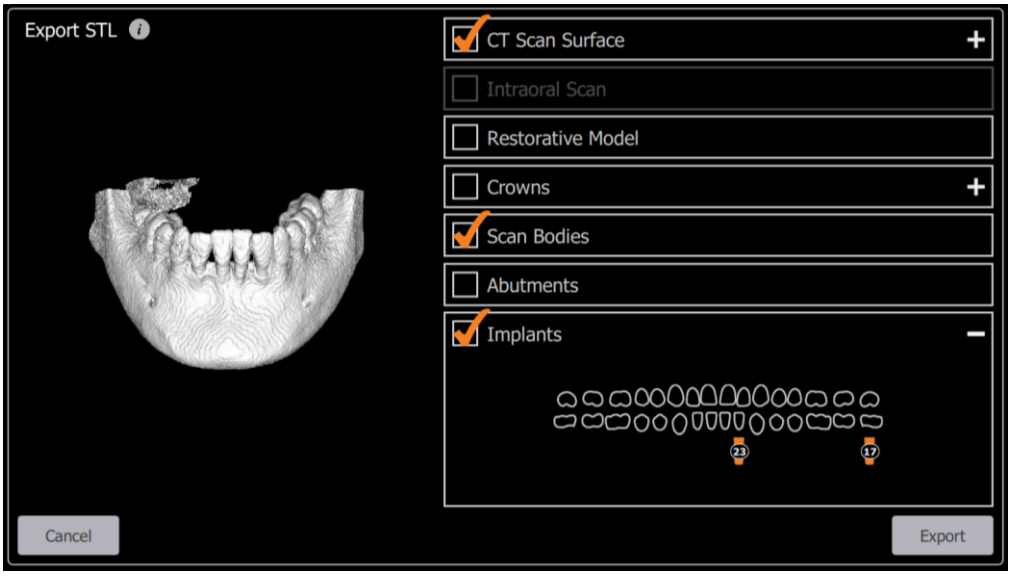


Figure 68: Export STL Dialog Box

1. A user can export STL of objects from a planned case to be used for other purposes outside of the YomiPlan software. To export an STL, first click on the File Menu icon and select Export STL to launch the Export STL Dialog Box.
2. Use the Export STL Dialog Box to select which objects you wish to export an a .STL file. For CT Scan Surface, Crowns, and Implants, additional options are available,
3. For Crowns and Implants, the user can click on the desired implant(s) and crown(s) they wish to export. By default, all Crowns and Implants will be selected when entering the dialog box. To unselect all Crowns and/or Implants, uncheck the checkbox next to the Crowns and/or Implants label respectively. For CT Scan Surface, the user can select where to export the model Clipped, Smoothed, in Low Resolution, and with Small Objects Removed. The user can also adjust the Surface Threshold before export. Adjusting the Surface Threshold slider will update the 3D model shown in the Export STL Dialog Box.

8.44 Closing or Exiting a Case

1. To Close a Case and return to the YomiPlan Start Dialog screen, click the File Menu icon and select Close Case.
2. To Exit YomiPlan, click the File Menu icon and select Exit or use the keyboard shortcut Alt + F4. A confirmation window will appear. Select Confirm to continue with the Exit or Cancel to remain in the YomiPlan software.

8.45 Yomi Centers and Doctors of Excellence



Figure 69: Yomi Center and Doctors of Excellence

After completing a certain number of cases and specific milestones, clinics and surgeons may be eligible for the Yomi Center of Excellence or Doctor of Excellence award. This award has three different levels – gold, diamond, and platinum – each signifying different levels of mastery with the Yomi system.

9. Definitions

Term	Definition
Yomi Robotic System (Yomi)	Previously known as the Neocis Guidance System (NGS). Yomi is defined in the indications for use and device description above.
YomiPlan	Graphical User Interface (GUI) Software that is used for surgical planning and navigation of anatomical features during surgical execution.
Arch	Superior and inferior lines of permanent teeth curved in the row of the upper and lower jaw
Clipping Plane	A plane about which images can be removed.
Control Software	Software intended to interface with the YomiPlan Software, Patient Tracking System, and Guidance System in order to coordinate movement
CBCT Protocol	CBCT scanner settings that are optimal for use with the YomiPlan Software
DICOM	Digital Imaging and Communications in Medicine: A standard object oriented image and patient information file type.
Fiducial Marker	Standard Reference or measurement point accepted as a fixed basis of reference or comparison.
Guidance Arm	Arm used for providing mechanical guidance per surgical plan.
Mains Power	General purpose alternating current (AC) electric power supply for US / North America.
Patient Tracker	System intended to identify the location of the patient, relative to the Guidance Arm and surgical planning.
Spline	A series of points along the circumference of a 1/2 circle that is intended to be manipulated to fit the contour of the patient's arch.
YomiLink	A dental appliance placed on teeth or attached to the boney anatomy, that is made stationary by use of dental material adhesive (YomiLink Teeth) or bone screws

	(YomiLink Bone) and is intended to be a rigid support structure for placement of the Patient Tracker and Fiducial Markers.
Stereotaxic	Surgical method for location of points within a patient anatomy using external, three-dimensional frame of reference usually based on the Cartesian Coordinate System
End Effector	Dental instrument and attachments connected to the Guidance Arm of the Yomi used to perform dental implant procedures

10. Patents And Trademarks

This product and / or its use are covered by one or more of the following United States Patents: US 8,808,000 B2. Other U.S. patents pending. Foreign patents pending.

11. Electromagnetic Compatibility (EMC) Information

The following section provides details regarding the manner in which the Yomi complies with EN 60601-1-2: Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests. The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The essential performance of the system is "maintain guidance during drilling for dental implant surgery."



Medical Electrical Equipment (Yomi) needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.



Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.



Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Yomi. Including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



There are certain RF emitters which are not covered under the Yomi compliance to IEC 60601-1-2 regarding EMC. These include radiofrequency identification (RFID) readers, electronic security systems, near-field communication (NFC) systems, wireless power transfer (WPT) and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment. Do not use these RF emitters in the vicinity of the Yomi as this may result in electromagnetic interference and impact the overall performance of the Yomi. The user might need to take mitigation measures, such as relocating or re-orienting the equipment if this is not possible.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Neocis Guidance System (NGS) is intended for use in the electromagnetic environment specified below. The customer or the user of the Neocis Guidance System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The NGS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The NGS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The NGS is intended for use in the electromagnetic environment specified below. The customer or the user of the NGS should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 500 mS 70 % U_T (30 % dip in U_T) for 100 mS <5 % U_T (>95 % dip in U_T) for 5000 mS	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NGS requires continued operation during power mains interruptions, it is recommended that the NGS be powered from an uninterruptible power supply or a battery. The NGS comes equipped with a UPS internal to the system cart, and should be powered directly from the mains.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The NGS is intended for use in the electromagnetic environment specified below. The customer or the user of the NGS should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the NGS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NGS is used exceeds the applicable RF compliance level above, the NGS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NGS. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the NGS

The NGS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NGS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NGS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.33\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12. Wireless Coexistence

The wireless communication links for the Yomi can coexist with an IEEE 802.11n network as the interfering network operating at maximum throughput and maximum transmit power when a separation distance of 5.6m is maintained between the Yomi and the companion device. Wireless coexistence testing was successfully performed to ANSI C63.27-2017 and AAMI TIR69:2017.

The following section provides details regarding Wireless Coexistence and the wireless technology employed in the Yomi.

- Wireless Technology:
    - 2.4 GHz ISM Band
        - Transmit power < 20dBm
        - Receiver Sensitivity Range for 11n: -74dBm/-94dBm
    - 5 GHz UNII and ISM Bands
        - Transmit power < 23dBm
        - Receiver Sensitivity Range for 11n: -73.5dBm/-94dBm
- Highest Frequency Generated or Used in Yomi
    - 5 GHz
- Lowest Frequency Generated or Used in Yomi
    - 60 Hz
- The Yomi is a Class A Digital Device to be used in commercial, industrial, or business environments
- Power source for the Yomi:
    - AC: Single Phase, 120 V, 60 Hz
- Other wireless products able to connect to Yomi wireless network:

    - Imaging scanners
    - Desktop computers

- Wireless Functions
    - The Yomi wireless function is used to upload CBCT scanned images and surgery plans onto the Yomi planning station. Uploads have no impact on the patient, but they can affect the user experience quality. If the upload is unsuccessful, a new attempt can be made.
- Intended Use Environment with Possible Wireless Devices in Co-channel and Adjacent Band
    - Yomi is to be used in a dental office connected to a local network operating at 2.4 or 5 GHz.
    - Potential interferers include IEEE 802.11b/g/n networks (2.4 GHz and 5 GHz)
- Risk Management / Mitigations
    - A failure in wireless transfer will require the transfer of images from a CBCT scan to the planning station using a tethered connection (e.g., ethernet cable, USB flash drive).
    - Data transfer is performed manually, and a failure has no impact on Yomi functionality. To be able to use the Yomi, however, patient data (e.g., CBCT scan, patient plan) will need to be transferred to the Yomi using a tethered connection.
    - Mitigation techniques when there is interference include moving the device causing the interference away from the Yomi or moving the Yomi away from the offending device.