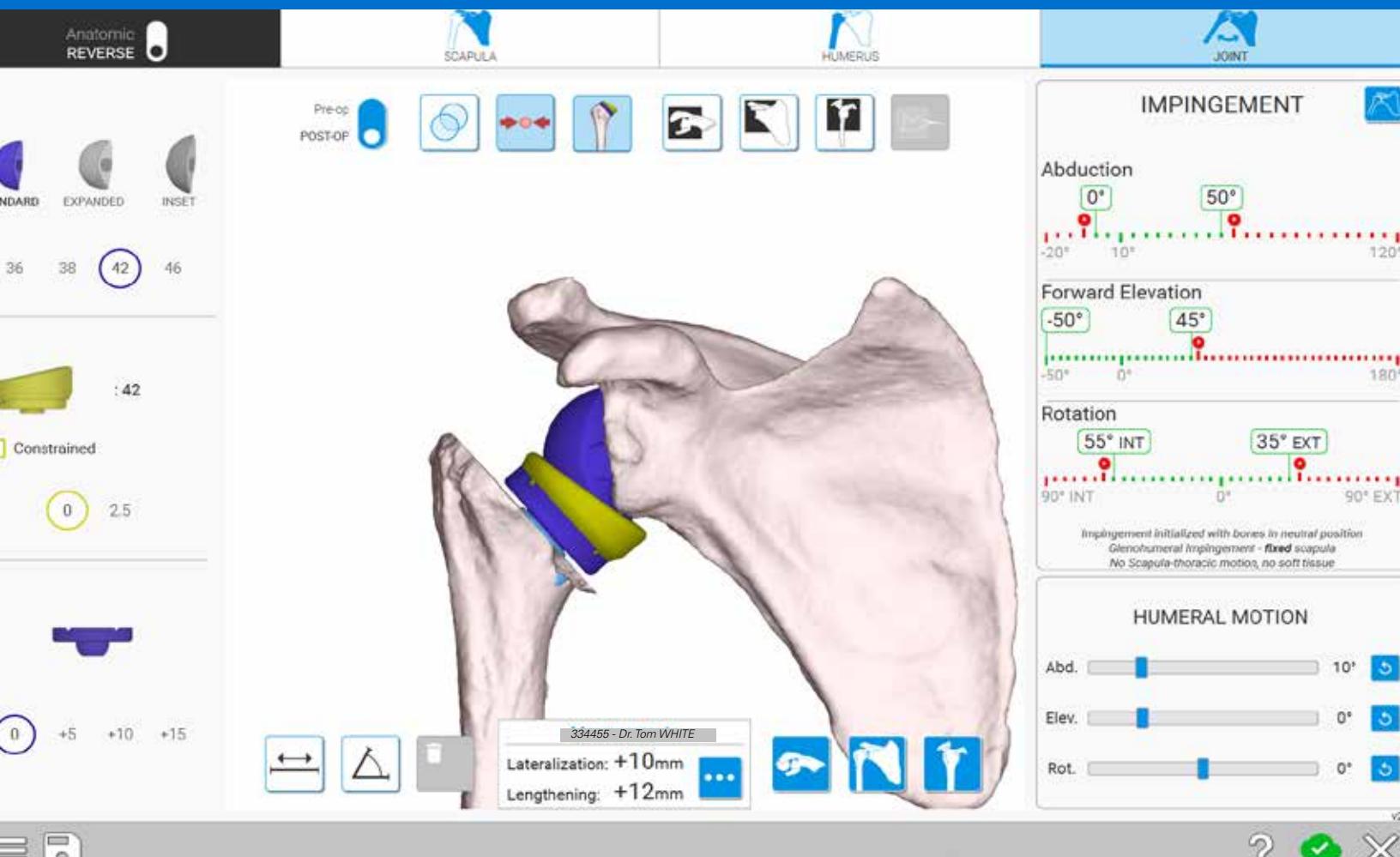


EXACTECH|SHOULDER

Software Guide



equinoxe[®]
with Active Intelligence.[®]

Planning
App 2.2

TABLE OF CONTENTS

SETTING UP & GETTING STARTED	3
DOWNLOADING SOFTWARE	3
LOGGING IN.....	4
CASE MENU.....	5
Editing Case Information.....	5
Statuses.....	6
CREATING A CASE.....	7
REQUIRED CT PROTOCOL	7
UPLOADING A CASE FOR GPS NAVIGATION	9
IMMEDIATE RECONSTRUCTION INSTRUCTIONS	11
PLANNING WITH THE EQUINOXE PLANNING APP	15
SCAPULA PLANNING	15
HUMERUS PLANNING.....	19
JOINT PLANNING.....	21
SHORTCUTS	24
EXPORTING A CASE FOR NAVIGATION.....	25

The Equinoxe® Planning App is available for MAC and PC.  

Planning software minimum requirements:

- Equinoxe Planning App is qualified for Windows 10 environment as well as Mac OS 12 (Monterey) and Mac OS 13 (Ventura).
- It is recommended to have 8GB or more of RAM, and a screen resolution of a least 1280x800 pixels.
- It is recommended to have at least 10Gb free space on disk.
- It is mandatory to have Administrator rights during software installation.
- If network security measures are implemented (Web filtering, firewall, proxy) it may be necessary to ask the IT department to ensure communication (https, port 443) is possible.
- Graphical hardware must support at least OpenGL v3.3. Graphics cards and chipsets made after 2010, with up-to-date drivers, should satisfy this condition.

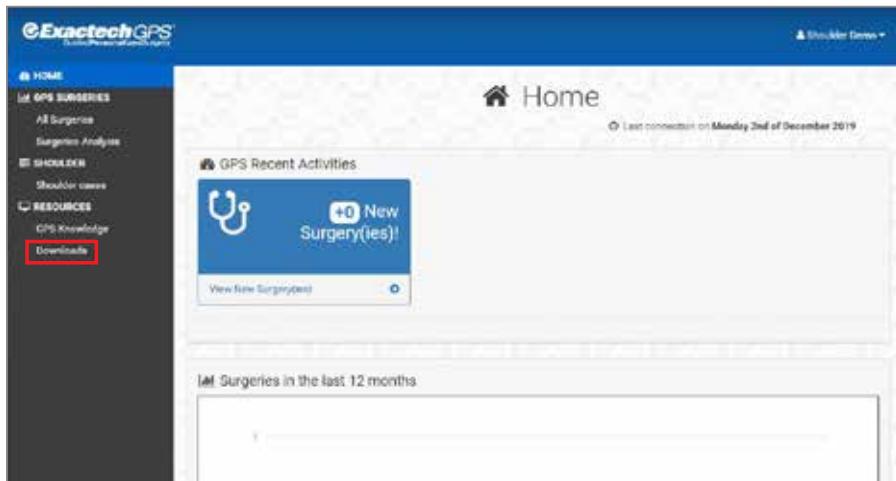


Figure 1

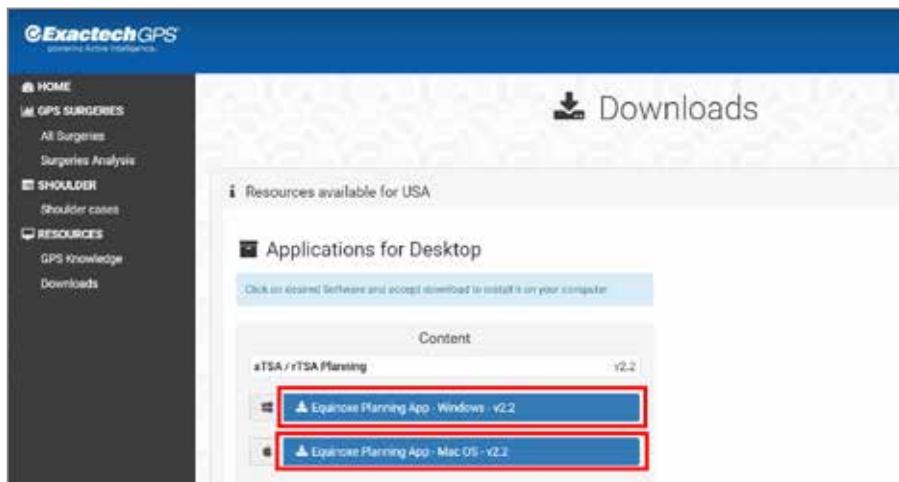


Figure 2

DOWNLOADING SOFTWARE

Using a web browser (i.e. Chrome, Edge, Safari) navigate to ExactechGPSWeb.com and log in using the surgeon's GPSWEB credentials. Then proceed to click the downloads tab on the left (Figure 1).

Once selecting the downloads tab, click on the blue Equinoxe Planning App software download that matches the computer's operating system (Mac or Windows), found under the "Applications for Desktop" section (Figure 2). The installation process will now begin.

The download process should now begin. Double-click the downloaded file once complete, select "run" on a PC, and accept any prompts that appear on the screen to complete the installation. If using a Mac, be sure to drag and drop the Equinoxe Planning App application tile into the "Applications" folder on the Mac.

SETTING UP AND GETTING STARTED

LOGGING IN

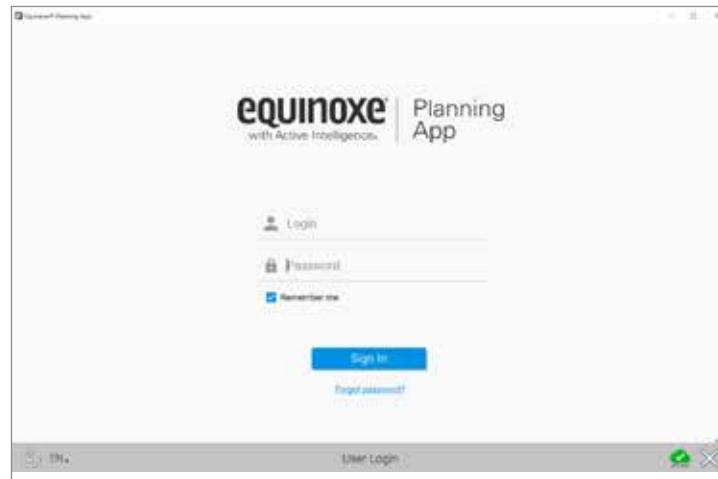


Figure 3

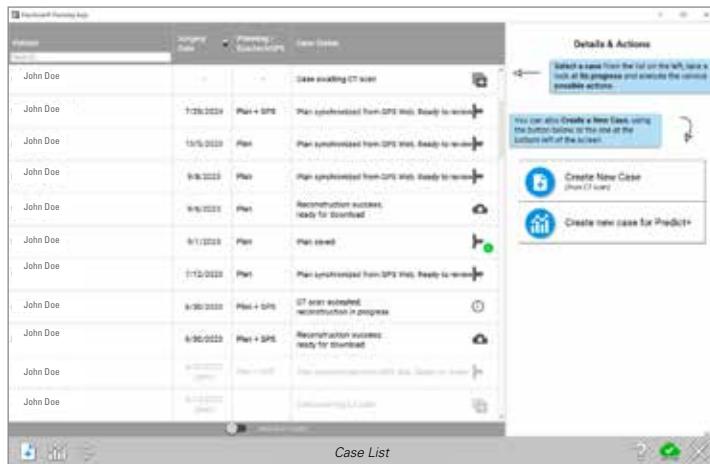


Figure 4

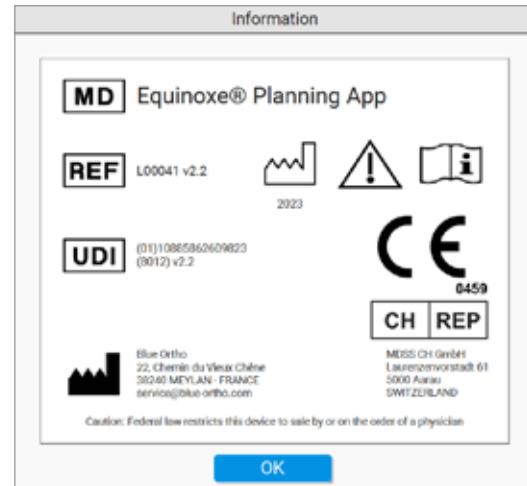


Figure 5

LOGGING IN

The surgeon must have a GPS Web account to access the Equinoxe® Planning App and the GPS Shoulder Application. Upon launching the preoperative planning software, a Login Screen will appear and prompt for login credentials (Figure 3).

Note: For surgeons, the login credentials are the same as their Chime and GPS Web accounts.

The Case List Menu screen will appear, showing all surgeon's pending and past cases (Figure 4).

Note: Clicking on the  button displays information about the software, including the version. (Figure 3 & 5).

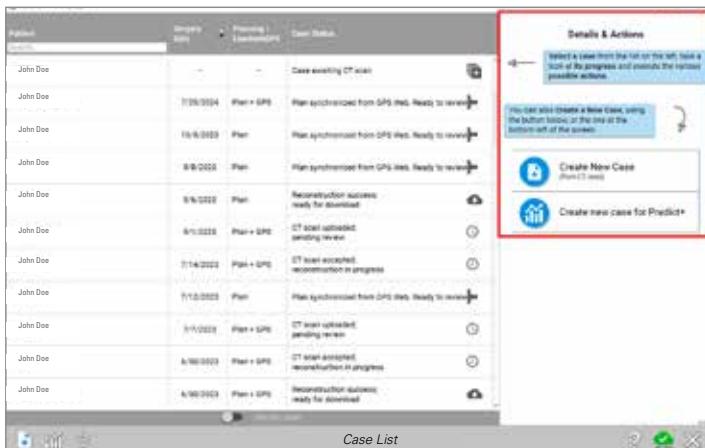


Figure 6

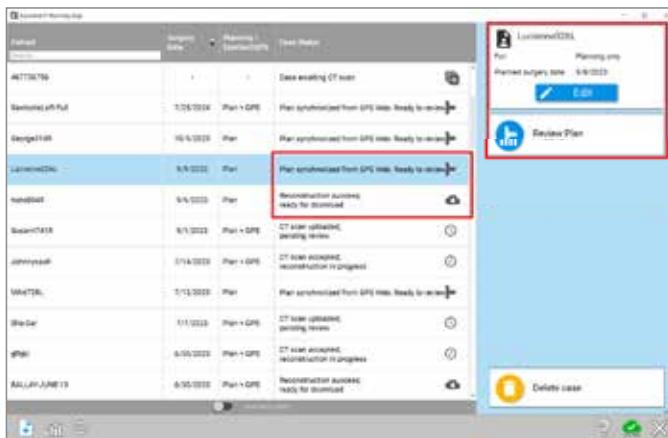


Figure 7



Figure 8

CASE MENU

Cases can have different statuses. Statuses are associated with a list of available actions (upload to GPS Web, download the prepared case, edit planning, etc.). Clicking on the header of the columns will sort the list of cases according to the column. If the GPS Web icon on the bottom right of the screen is green, the application is connected to the internet and the statuses are up to date; if the icon is orange, the surgeon can still utilize the Equinoxe Planning App and the Immediate Reconstruction feature, but the statuses may be out of date, and uploaded cases will not be sent to ExactechGPS Web for reconstruction.

A case can be created either for "Planning and GPS Shoulder surgery" or for "Planning only". Each type has different possible statuses that change throughout the process (Figure 6).

Note: If a case is created and planned using Immediate Reconstruction, the plan will not be synced on GPS Web for use on other computers.

Editing Case Information

To edit case information, click anywhere on its row within the Case List. The right part of the screen changes and presents the details of the action and the possible actions (Figure 7).

Click on to modify:

- The patient's name
- The surgery date
- The purpose of the case ('Planning only', or 'Planning and GPS surgery').

Note: If switching from planning only to planning and GPS Shoulder make sure to press the Upload to GPS Web button.

Note: Patients' private information is not transmitted to GPS Web. It is stored encrypted on the computer to preserve patient confidentiality (Figure 8).

When patient information is exported to a USB drive for navigation, the software adds two layers of encryption to the data and can only be opened on an ExactechGPS station.

SETTING UP AND GETTING STARTED

CASE MENU

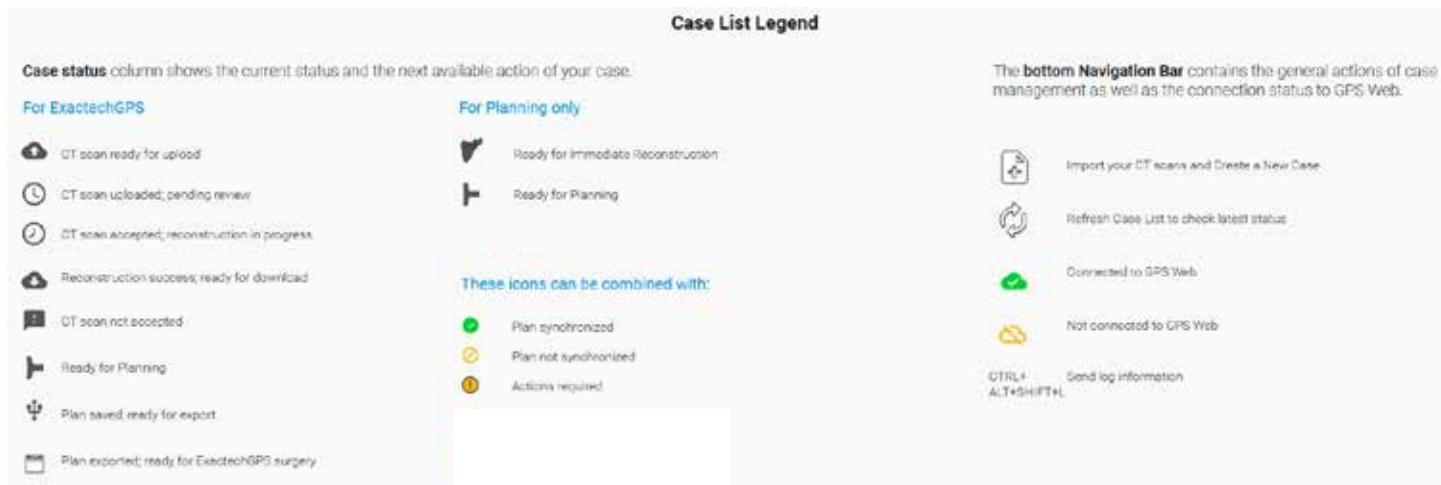


Figure 9

Statuses

Status and available actions for a case created for "Planning and GPS Shoulder surgery" (Figure 9). These icons can be reviewed within the Equinoxe Planning App by pressing the question mark button on the bottom right of the screen.

Similarly, for cases created for "Planning only," status and actions appear above (Figure 9).

In Equinoxe Planning App 2.2, plans for navigation are synced with GPS Web. When a case is saved on one computer and connected to the internet, when opening up the software on another computer connected to the internet, the latest plan will be shown. In reviewing the statuses as shown earlier, when a green check box appears, the latest plan has been saved on GPS Web. If an orange circle with a line through it is displayed, the plan hasn't been able to sync with GPS Web, and it is important to confirm that the plan being exported is the surgeon's latest plan.

Note: Plans utilizing **Immediate Reconstruction ONLY** are not saved or synced with GPS Web as they haven't been shared to the GPS Web server.

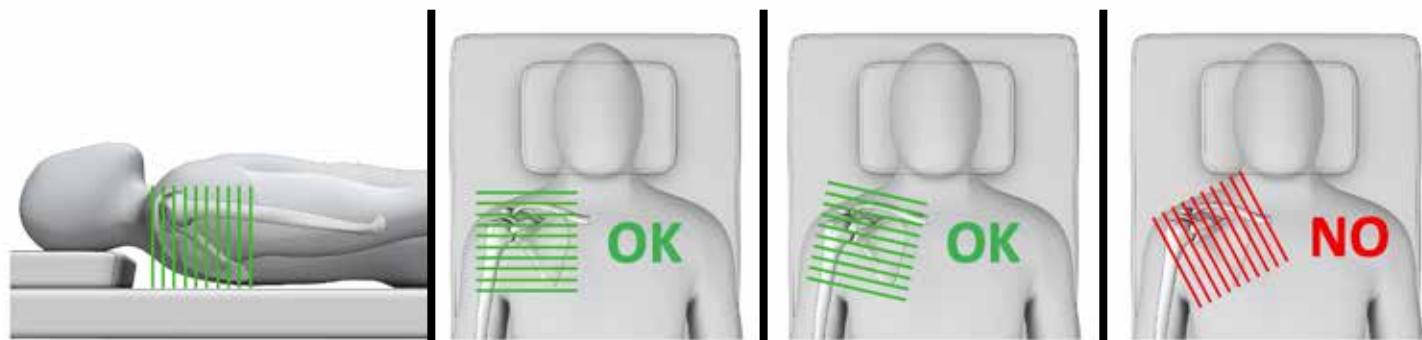


Figure 10

Prerequisites for the CT Scan Examination Date

It is recommended that the CT exam be performed **less than 6 months** prior to the surgery and must be representative of patient anatomy (ex: no fracture, no surgery between the CT examination and the GPS surgery).

Format

- DICOM Format
- Modality = 'CT'
- Hounsfield encoding
- Uncompressed images
- Non-encrypted and non-anonymized images (*an arbitrary identifier can be used in place of the birth date and gender, but the fields cannot be left blank*)

Resolution

- Pixels are square and constant for all the images.
- » The minimal resolution for an image is 0.3×0.3 mm/pixel
(i.e. 512 pixels represent at least 15 cm/6in)

» The maximum resolution for an image is 1.0×1.0 mm/pixel
(i.e. 512 pixels represent no more than 50 cm/20in)

- Keep both the slice thickness and spacing equal and constant for the entire exam, with no overlap.
 - » Minimum distance: 0.3 mm
 - » Maximum distance: 1.25 mm
 - » **The recommended distance is 0.625 mm**
- The CT-scan series should only contain **axial** series as shown in *Figure 10*.
- Please do not include any sagittal or coronal series when exporting images. Please do not include 3D reconstructions.
- The pitch should be $<= 1$.

Note: Please refer to CT Scan Acquisition Protocol v2.1 or later for guidance when referring patients to imaging centers.

CREATING A CASE

REQUIRED CT PROTOCOL

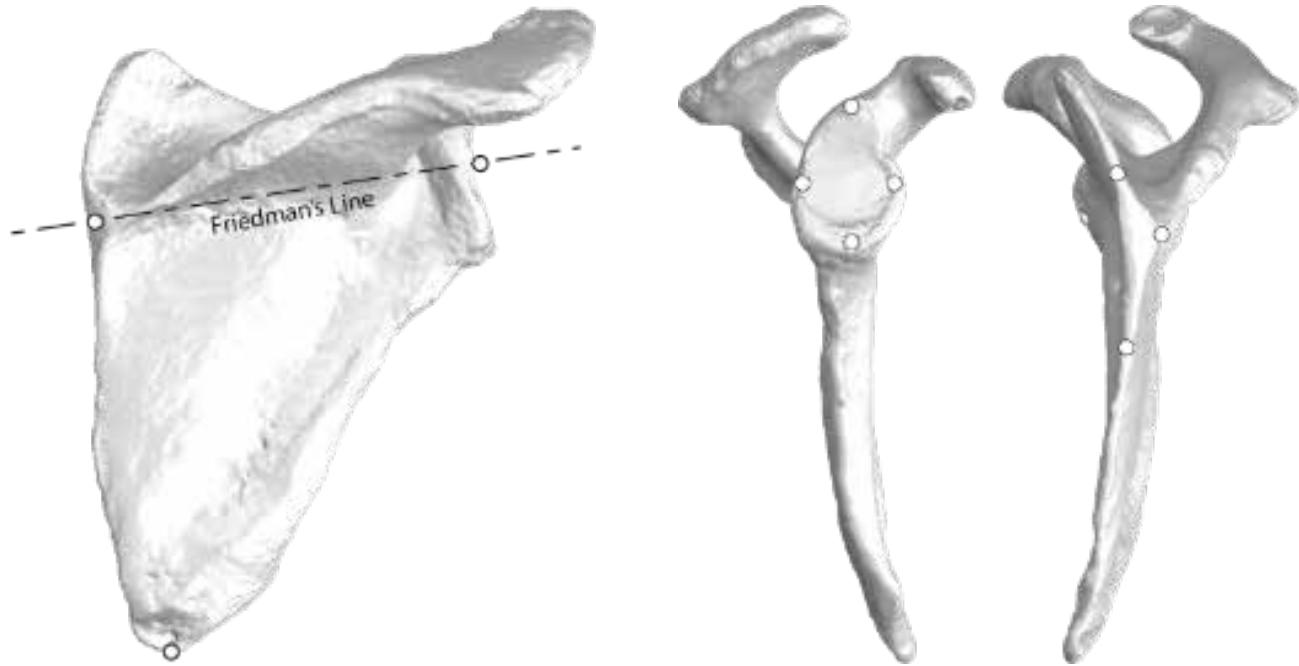


Figure 11

Display field of view should be approximately
25-30cm for a matrix size 512 x 512.

Dimension

The examination includes the entire scapula, complete to medial border and distal tip (Figure 11).

Recommendations

- The CT-scan will typically contain between 200 and 450 images.
- The patient must not move during the exam.
- **Injectable contrast must not be used**, as it can occlude imaging and reconstruction of the CT scan.
- Recommendation for machine settings: kilo volt peak (KVP) $>= 120$.

- Recommended mA: 240mA or higher
- Recommended filters/reconstruction kernels:
 - » GE: Bone
 - » Siemens: B41
 - » Toshiba: FC30
 - » Philips: L
- Scans can be rejected if the image quality is altered. This can be caused by:
 - » Patient motion during examination
 - » Metallic artifacts
 - » Improper image format
- The series should not include scout images, duplicate images and radiology reports or dosage reports.

CREATING A CASE

UPLOADING A CASE FOR EXACTECHGPS NAVIGATION



Figure 12



Figure 13

UPLOADING A CASE FOR GPS NAVIGATION

From the case menu screen, press the  on the bottom left of the screen to create a case. It is not necessary to select the exact folder containing the series; the software will check all subfolders and propose all adequate series. Once the folder containing the DICOM images has been located, press select, the software will automatically select the AXIAL series and won't show the other series that do not comply with our protocol (Figure 12).

Note: Surgeons may be able to upload scans that are outside the CT protocol. It's important to review the Image Information column to ensure the upload meets protocol for navigation, specifically paying attention to the last of the three numbers in the top row (which identifies the distance between slices).

Once the series is selected, the next screen will display a preview of the scan. Confirm that the entire scapula is in view. Select the appropriate side, identifying the shoulder as LEFT or RIGHT shoulder. (Figure 13).

Note: Patient CT scans **MUST** follow the CT protocol in the user manual prior to surgery for GPS Shoulder cases.

CREATING A CASE

UPLOADING A CASE FOR EXACTECHGPS NAVIGATION

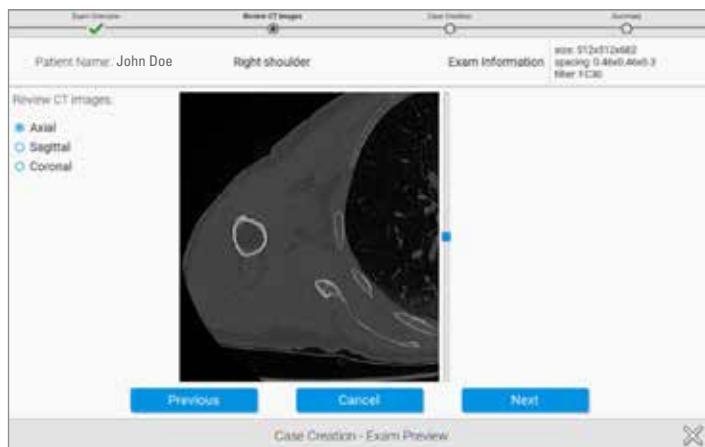


Figure 14

Figure 15a

Figure 15b

It is then possible to visualize the full exam in the axial, sagittal, and coronal planes. (Figure 14).

Press Next to advance to the next step.

The surgeon will be asked to enter information regarding the patient's case (Figure 15a). Then, the Patient ID entered here will be used to de-identify the information transferred for 3D reconstruction.

GPS Sales Rep and Partner accounts will see an additional row of information on this page (Figure 15b). The "For surgeon:" text-boxes will appear and feature a drop-down menu of GPS Surgeon accounts that have been associated through GPS Web's account manager. In the event that a surgeon does not have a GPS account already, there is an

option to select "Other Surgeon" and manually add the surgeon's name. Utilizing this workflow will push GPS cases from the Sales Rep or Partner accounts into the Surgeon's account for review once segmentation is complete.

Create an identifying name that will be recognized once the 3D reconstruction displays on the list of cases.

Click on "Planning + Exactech GPS surgery" if submitting for navigation. If planning only, continue creating the case and utilize the Immediate Reconstruction feature to immediately start planning.

Note: This unique identifier (field "Patient ID") is transmitted to the GPS Web server and must **not** contain patient private information such as patient name or birth date.

CREATING A CASE

IMMEDIATE RECONSTRUCTION INSTRUCTIONS

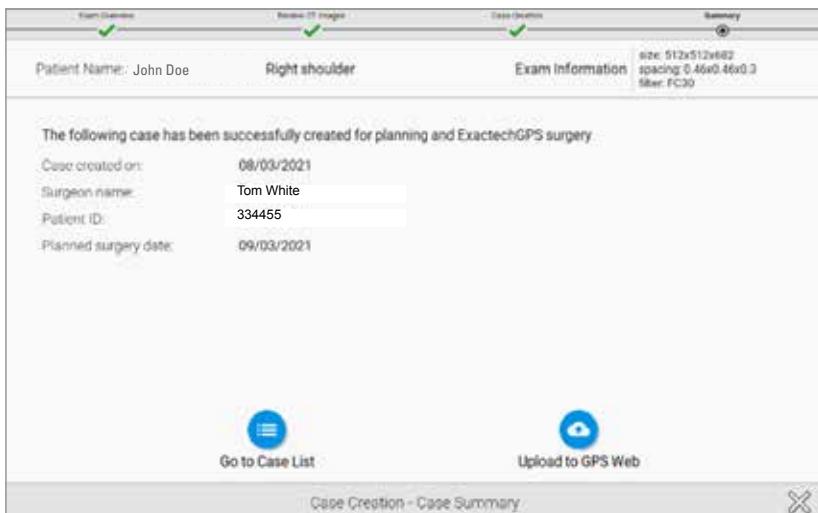


Figure 16

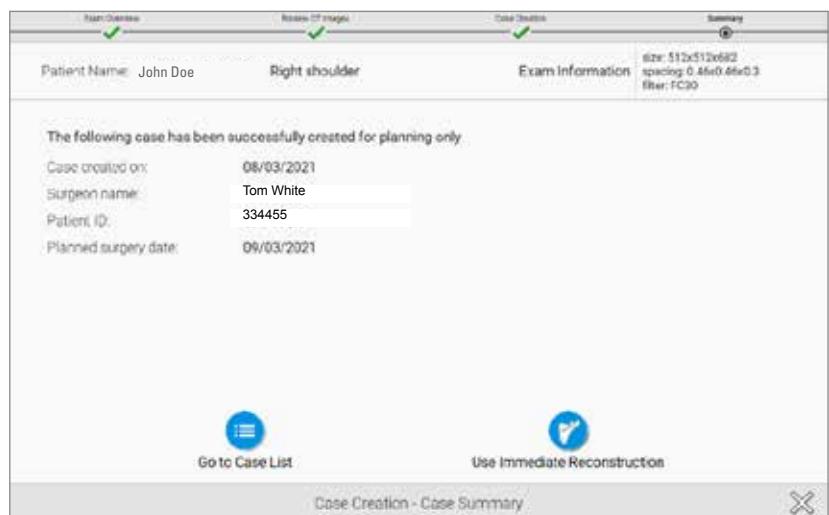


Figure 17

IMMEDIATE RECONSTRUCTION INSTRUCTIONS

Once the case is created, if the case was created for "Planning and ExactechGPS surgery," the surgeon can:

- Click on "**Upload to GPS Web**" to upload the case to GPS Web server for preparation by technicians. While awaiting a manual segmentation, the surgeon can perform an Immediate Reconstruction, as shared in the following pages.

The result will be a 3D model of the patient anatomy **for planning and GPS Shoulder surgery purposes, which is delivered within a few days.**

Once the surgeon receives the 3D model, he/she will be able to perform the planning of the implant and then export the planning for navigation purpose.

- Click on "**Go to Case List**" if the surgeon doesn't want to upload the case right away (Figure 16).

For a case created for "Planning only," the surgeon can:

- Click on "**Edit 3D Reconstruction**" to start the immediate reconstruction process. The surgeon will be guided through four steps to reconstruct the 3D model of the patient anatomy, **for planning purposes only.**

The surgeon will not be able to export the planning for GPS Shoulder surgery purposes.

- Click on "**Go to Case List**" if the surgeon doesn't want to reconstruct the case right away (Figure 17).

CREATING A CASE

IMMEDIATE RECONSTRUCTION INSTRUCTIONS

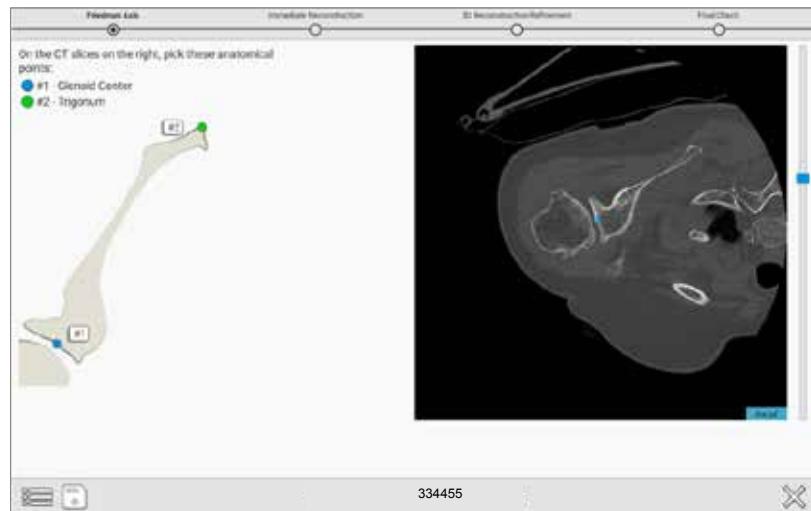


Figure 18

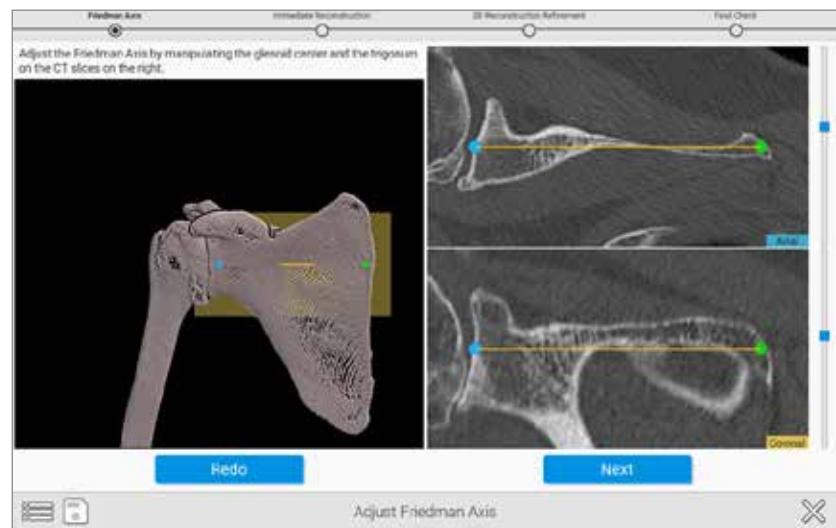


Figure 19

A) Pick and adjust Friedman's axis:

The first step is to pre-position the glenoid center and the trigonum (Figure 18).

Then the surgeon can adjust Friedman's axis on 2D views, with a 3D view presenting the axis for verification purposes (Figure 19).

CREATING A CASE IMMEDIATE RECONSTRUCTION INSTRUCTIONS

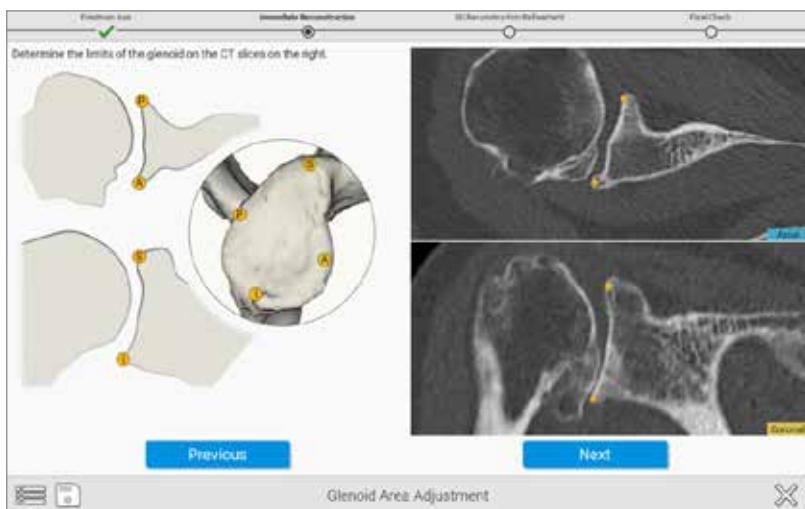


Figure 20

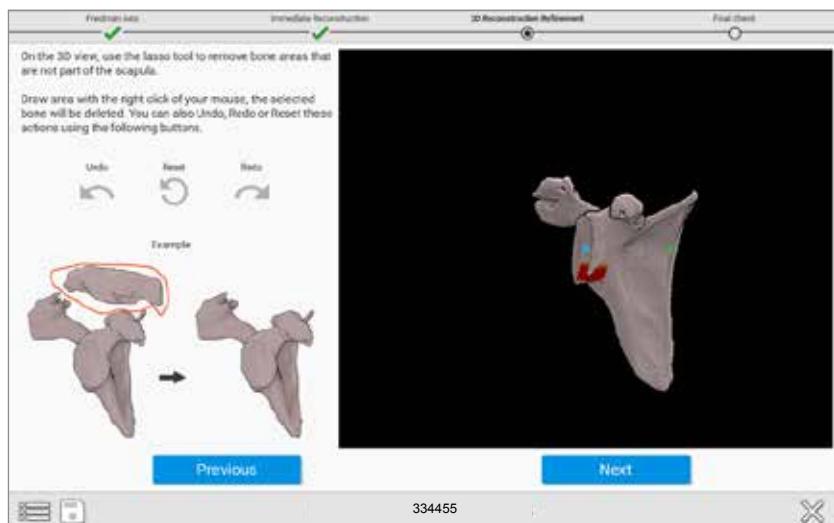


Figure 21

B) Pick four peripheral quadrant points on the glenoid surface On the image in the upper right of the screen (Figure 20), select the points that correspond with the orange dots on the image on the left side of the screen.

C) Review the preliminary reconstruction and remove unwanted portions of the reconstruction. The surgeon can remove unwanted portions of the reconstruction with the “Lasso Tool.” To utilize this, hold down the right click button while drawing a lasso around the area to exclude from the reconstruction (Figure 21).

CREATING A CASE

IMMEDIATE RECONSTRUCTION INSTRUCTIONS



Figure 22

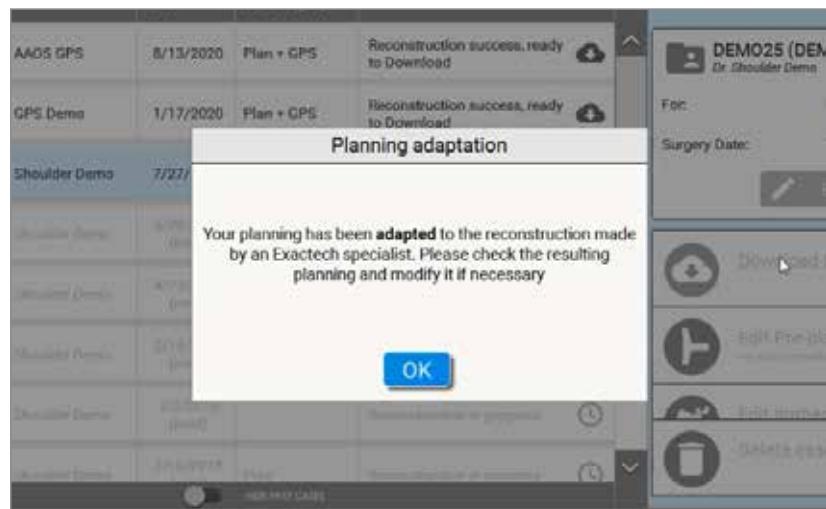


Figure 23

D) Validate the accuracy of the reconstruction:

Red/Orange areas should be checked for accuracy as the software wants to ensure a proper reconstruction. This is done by using the blue slider bar toggle on the right-hand side to sweep through the individual CT images in the right window pane on the screen. The red areas on the left window pane correlate to sections where the blue outline of the algorithmic model does not correlate with the outline of bone in the CT images. This can be caused by low bone density, cysts, or humeral head impaction, which affects the distinction between the articulating surface of the humerus and surface of the glenoid. Complicated or fused anatomy can lead to errors in this step (Figure 22).

After selecting a case and pressing the  button, the Equinoxe Planning App preoperative planning tool will open the selected case, with the patient's scapula shown in the viewing window.

Note: If using GPS Shoulder software for active navigation, the surgeon must accept the manual reconstruction that has been completed by an Exactech specialist and then verify implant placement before uploading the case to a USB drive for use on the ExactechGPS system (Figure 23).

Refer to the ExactechGPS Shoulder Application Operative Technique (#OPTECH-000037) for detailed surgical technique.

PLANNING WITH THE EQUINOXE PLANNING APP

SCAPULA PLANNING



Figure 24

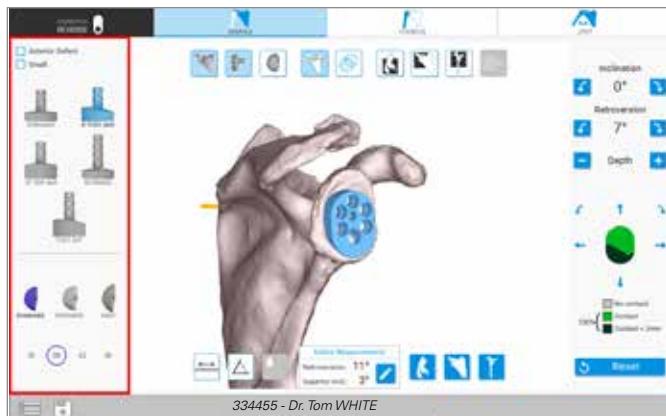


Figure 25

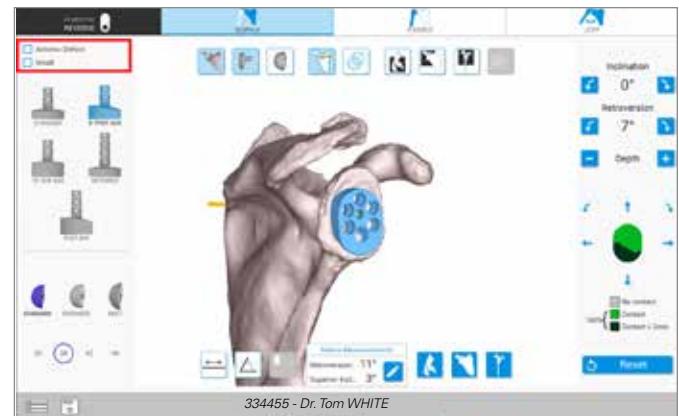


Figure 26

PLANNING WITH THE EQUINOXE PLANNING APP

SCAPULA PLANNING

1) Implant Selection

- When planning the glenoid, there are a variety of options to choose from. First, the surgeon should choose if this will be an anatomic reconstruction or a reverse shoulder reconstruction by selecting the toggle-button in the top-left corner of the screen (Figure 24).
- After selecting the type of procedure, by toggling the anatomic/reverse button in the top-left corner of this screen, the surgeon can also activate different implants from the menu on the left side of the screen (Figure 25).

- Please note that it is possible to save a plan for both an anatomic and reverse case, and both cases will export to the GPS Station.

Note: Checking the Small Baseplate or Anterior Defect boxes (Figure 26) will not change the position of the implant relative to Friedman's Axis. You may toggle back and forth to test without losing your original position selection. Backside contact may adjust depending on the implant selected.

PLANNING WITH THE EQUINOXE PLANNING APP

SCAPULA PLANNING

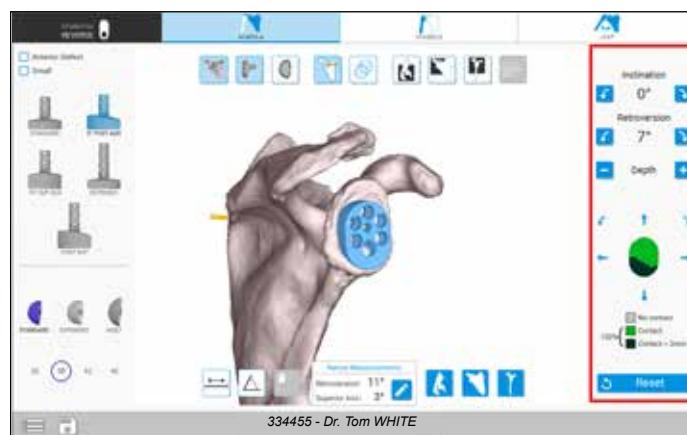


Figure 27



Figure 28

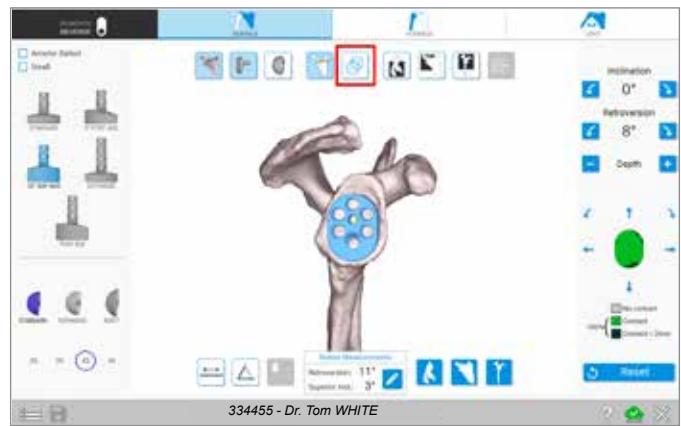


Figure 29

2) Implant Manipulation

- The implant position may be manipulated by using the menu on the right-side of the screen (Figure 27). Keep in mind when the implant is first selected, the component is centered on Friedman's Axis by default. The green coverage on the implant signifies implant % backside contact. Grey means no contact with bone, green means under <.5mm of contact with bone, and dark green means the plan calls for more than 2mm of glenoid bone reaming.

Note: Each click is 1mm or 1° of movement.

When planning for an augmented glenoid component, after planning the implant's rotation, it's important to consider reviewing the implant's % backside contact again.

3) Views

- Show/Hide** (Figure 28) – Used to show or hide objects within the Equinoxe Planning App scapular planning screen.
- Solid 3D Body** – Selected by default when planning. Helps identify perforation of the component outside the cortices (Figure 29).
- Transparent 3D Body** – Helps visualize the placement of the central fixation or peripheral pegs inside the bone as well as backside coverage of the implant (Figure 29).

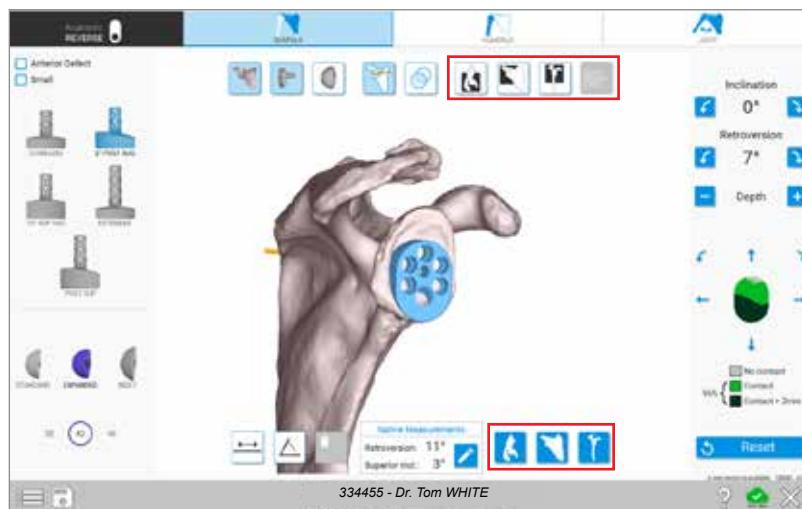


Figure 30

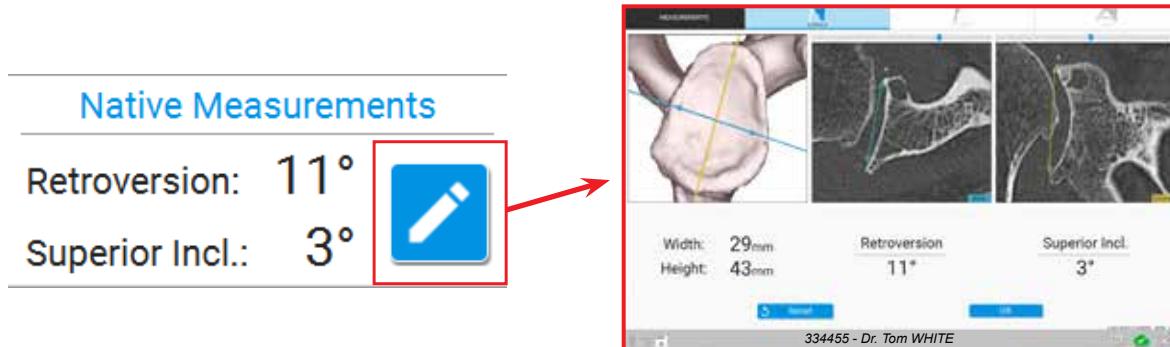


Figure 31

- **CT Views**

(Figure 30) – CT Views are used to overlay a CT image onto corresponding 3D scapula slice. Users of the Planning App can sweep through the CT images by dragging the blue slider-bar left or right.

- **Quick Position**

(Figure 30) – Quick Position options are used to quickly reposition the entire 3D scapula.

Note: Clicking the "V" key on the keyboard is an effective shortcut to seeing a combined CT & Quick Position view to reference current implant positioning.

4) Adjusting Native Measurements

- The Planning App now showcases native anatomy of the scapula. This allows surgeons to understand the specific patient's anatomy as it relates to native version and inclination. Selecting the guides the user to a screen to more closely look at the glenoid's native width, height, version and inclination (Figure 31).

Note: These measurements do not affect the angularity the plan shows, as the plan references the auto-selected Friedman's axis.

PLANNING WITH THE EQUINOXE PLANNING APP

SCAPULA PLANNING

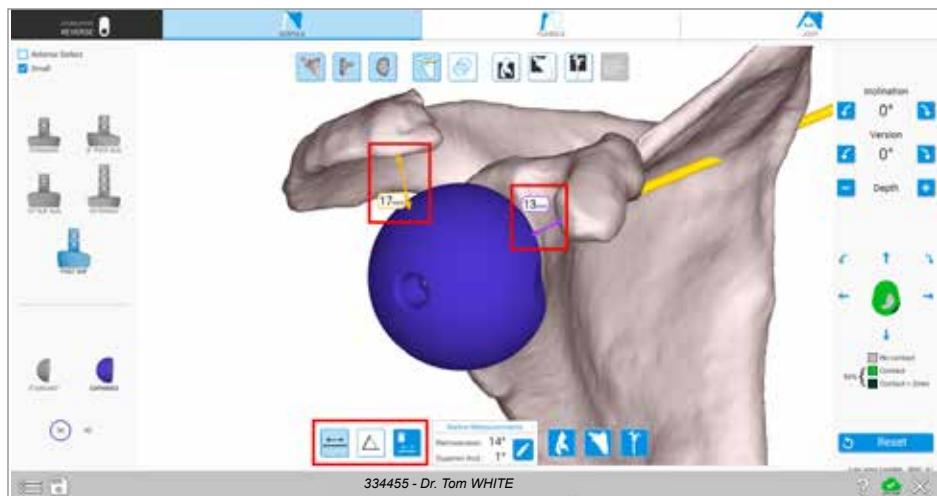


Figure 32

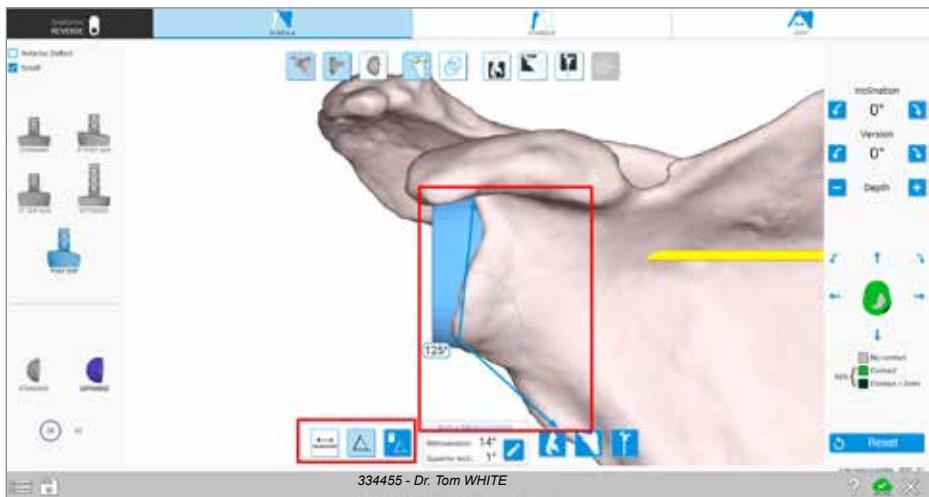


Figure 33

5) Using the Measurement Tool

- To measure distance between two points, select the left-most image from the measurement tools (Figure 32). To select the first point, use the mouse and right-click a point. A small colored triangle will appear. To select the second point, use the same method. A line will automatically span the distance between the two points.

To utilize the angle-measurement tool, select three points by using the mouse right-click (Figure 33). First, select the originating point (the mouse outward point of one of the ends of the desired angle). Then select the second point, which should be the middle of the angle. Then, select the final and third point which will automatically create a colored angular line between the three points with a bubble listing the angle created.

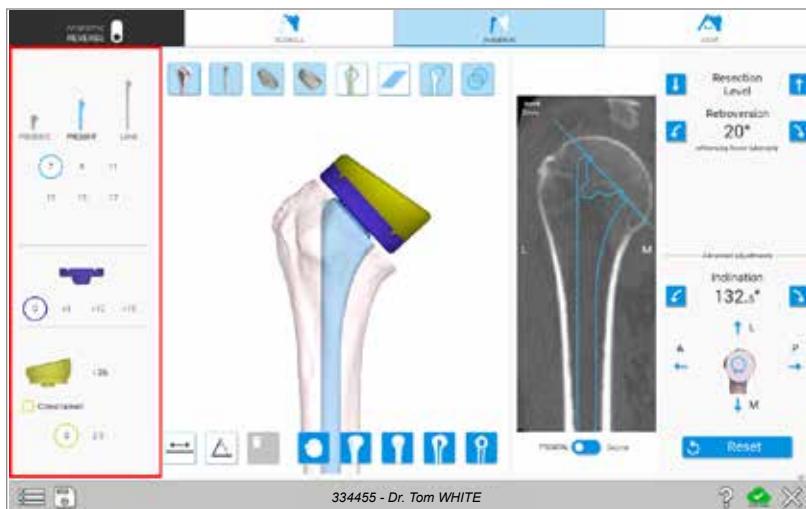


Figure 34

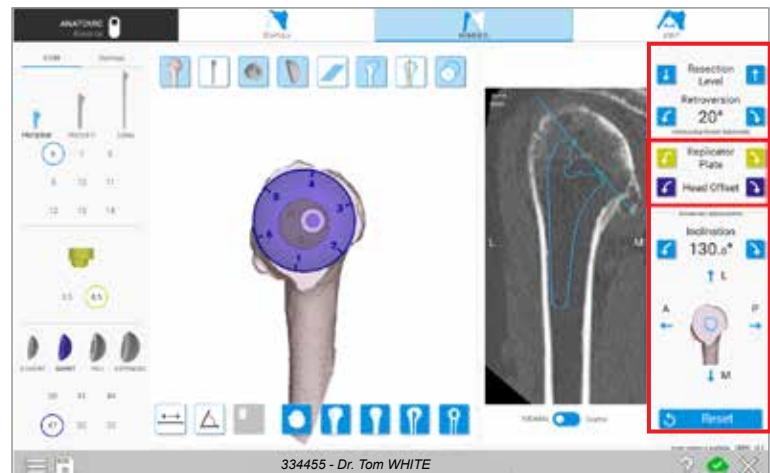


Figure 35

HUMERUS PLANNING

1) Implant Selection

- When planning the humerus, there are a variety of options to choose from. First, the surgeon should choose the stem type. Further selections such as stem size, humeral tray (reverse) or replicator plate (anatomic) size, hemisphere or liner size may also be selected from this menu-section (Figure 34).

Note: The Equinoxe Stemless Humerus options appear by clicking the "Stemless" tab visible at the top of this section when anatomic plan is selected.

2) Implant Manipulation

- Like the scapula planning section, the right-hand side of the Planning App screen (Figure 35) will display buttons that allow for the manipulation of the implant within the humerus.
- For Anatomic Reconstruction Plans, the replicator plate and hemisphere offset toggles will appear within this section. Selecting these buttons will adjust the 3D model to impose the hemisphere onto the replicator plate (Figure 35).

NOTE: The implant is centered in the humeral canal by default. If adjusting the inclination and implant's location within the canal, the resection level buttons will move aligned with the stem axis.

PLANNING WITH THE EQUINOXE PLANNING APP

HUMERUS PLANNING

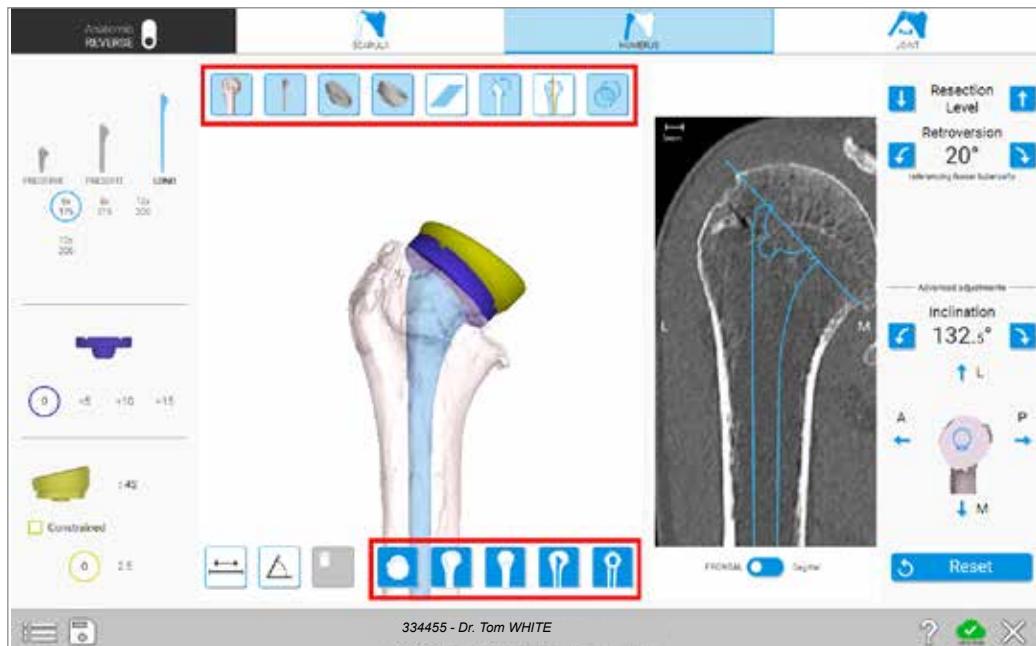


Figure 36

3) Views (Figure 36)

- **Show/Hide** – Used to show or hide objects displayed during the humerus planning step.
- **Transparent 3D Body** – Helps to identify perforation of the stem outside of the cortices.
- **Cutting View(s)** – Used to display a larger cut-slice area or add/remove the humeral head on the planning model.

- **CT Panel** – Used with a Frontal or Sagittal toggle to see the position of the stem within the humeral canal.
- **Quick Position** – Like the glenoid planning section, at the bottom of the planning window there are five Quick Position buttons used to move the entire viewing position of the humeral model shown on the bottom of Figure 36.

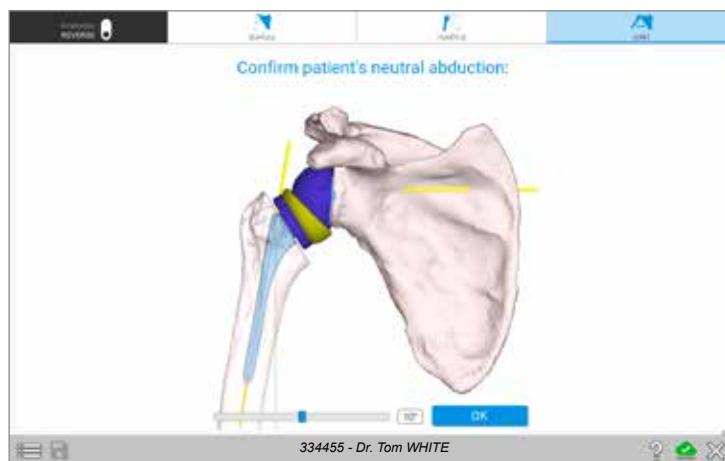


Figure 37

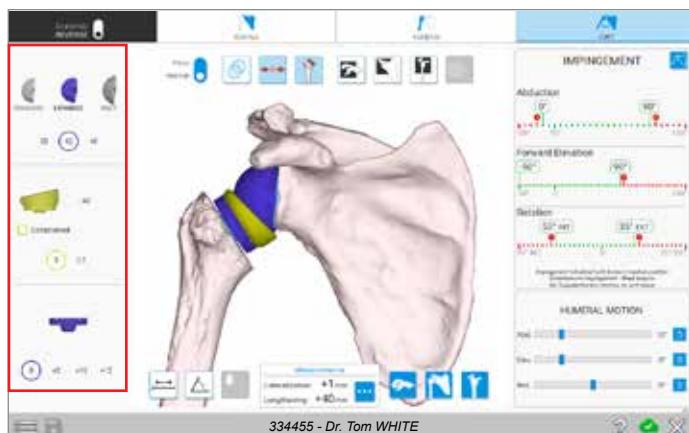


Figure 38

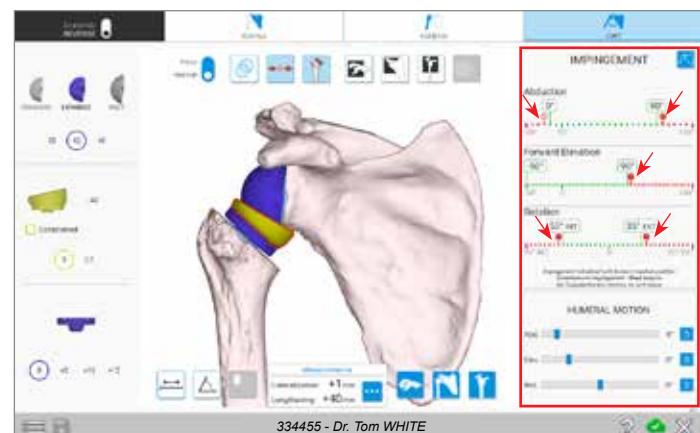


Figure 39

JOINT PLANNING

1) Setting Neutral Position (Figure 37)

- Patient neutral position must be confirmed prior to moving into the impingement planning page. Patient BMI does affect neutral position and should be taken into consideration.
- Clicking and dragging the lower slider bar changes the neutral position. Position can be changed again after this page, from within the joint planning page.

2) Implant Selection (Figure 38)

- The left side of the screen will continue to display some implant selections based on the plan (anatomic/reverse) that can still be adjusted. Adjustments in the software will affect impingement numbers displayed on the right-side.
- At any point, it is possible to return to the scapula or

humerus planning pages to change the planning and then revisit the projected values on the impingement page.

3) Impingement Reference and Humeral Motion (Figure 39)

- The top portion of the right-hand section displays impingement ranges. These simulated ranges are affected by osteophytes and care should be taken to understand how impingement is occurring. Impingement points can be quickly viewed by selecting the red arrow buttons on the border of the unobstructed and obstructed ranges. Clicking these will quickly place the humerus and scapula into points of impingement, adjusting the humeral motion sliders at the bottom of this screen.
- To view dynamic motion, up to and through points of impingement, the slider bars on the bottom right section of this screen can be used to adjust the position of the humerus.

PLANNING WITH THE EQUINOXE PLANNING APP

JOINT PLANNING

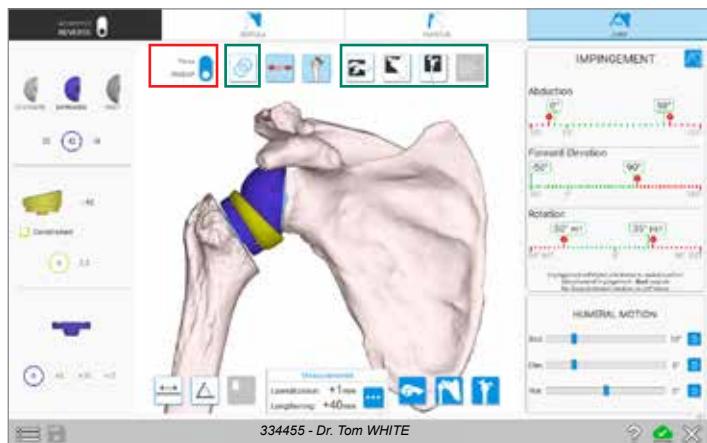


Figure 40

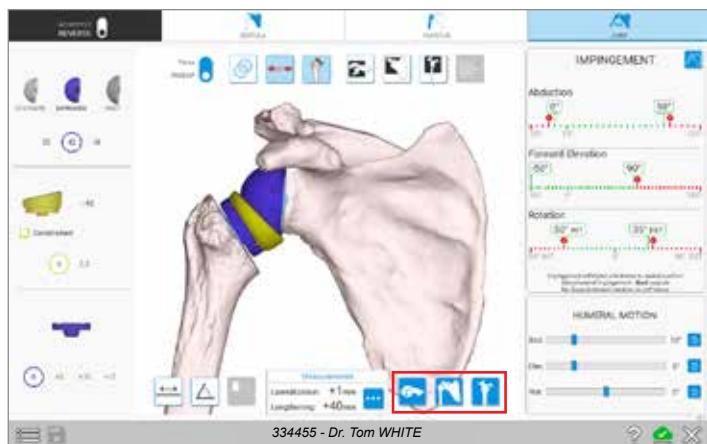


Figure 41

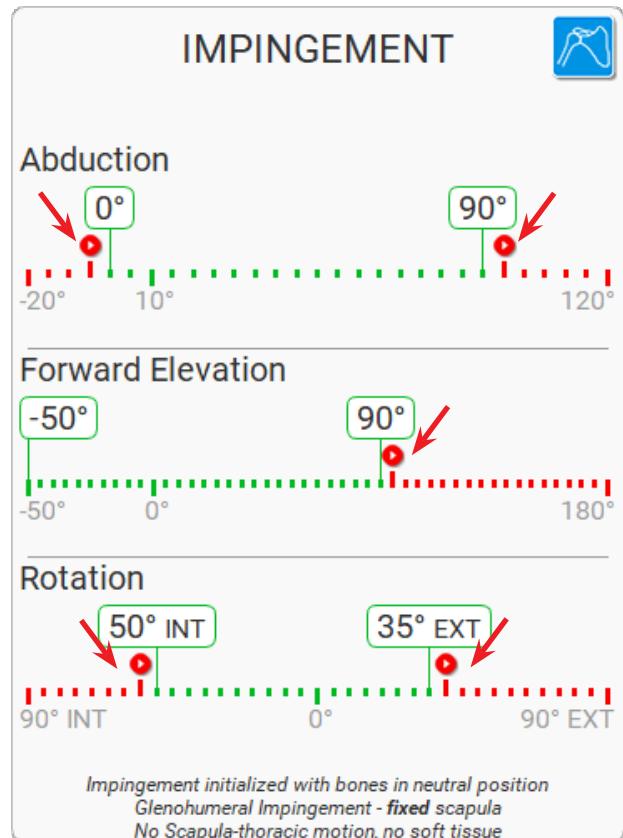


Figure 42

4) Views

- **Pre-Op View, Post-Op View** – Two selections in the top portion of the planning window display the shoulder anatomy before and after a case has been planned out (Figure 40, shown in red box).

- **Transparent 3D Body, Cut View(s)** – Like the glenoid and humerus planning step, a Transparent 3D Body button allows views within the bony anatomy to review implant positioning. The Cut View(s) can be used to sweep through the bony anatomy while viewing the original CT imagery overlaid onto the 3D shoulder anatomy from various planes (Figure 40, shown in green box).
- **Quick Position** – Buttons to quickly position both the humerus and scapula (Figure 41).
- **Impingement Points** – An option to display the point where impingement occurs can be selected and used while moving the humerus using the ROM controls (Figure 42).

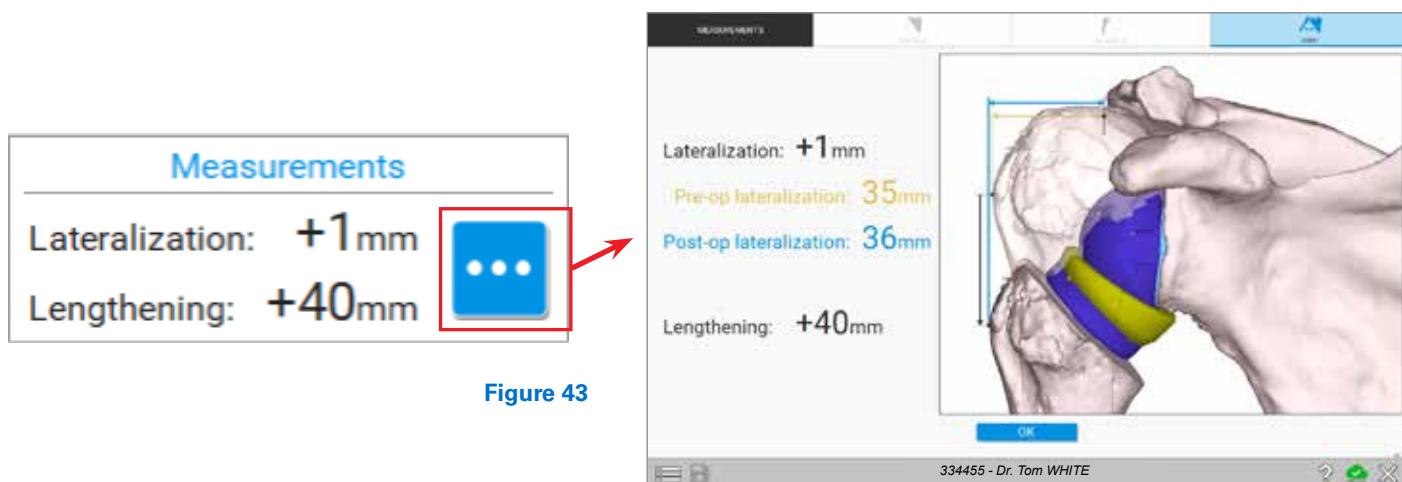


Figure 43

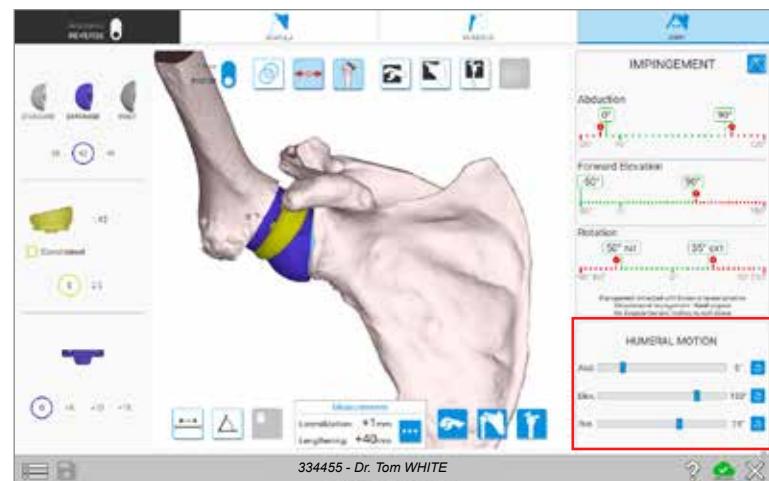


Figure 44

5) Positional Measurements

- Measurements (Figure 43) – Lateralization and lengthening, compared to original anatomical position, are referenced. These measurements change based on implant selection.
- Controls (Figure 44) – Slider-bar controls can be used to simulate humeral range of motion.

- Where there is impingement the humerus or implants will outline in red and show red dots where impingement occurs.

Note: These slider bar controls are not constrained by impinging positions and do not indicate a patient's true range of motion.

PLANNING WITH THE EQUINOXE PLANNING APP

SHORTCUTS

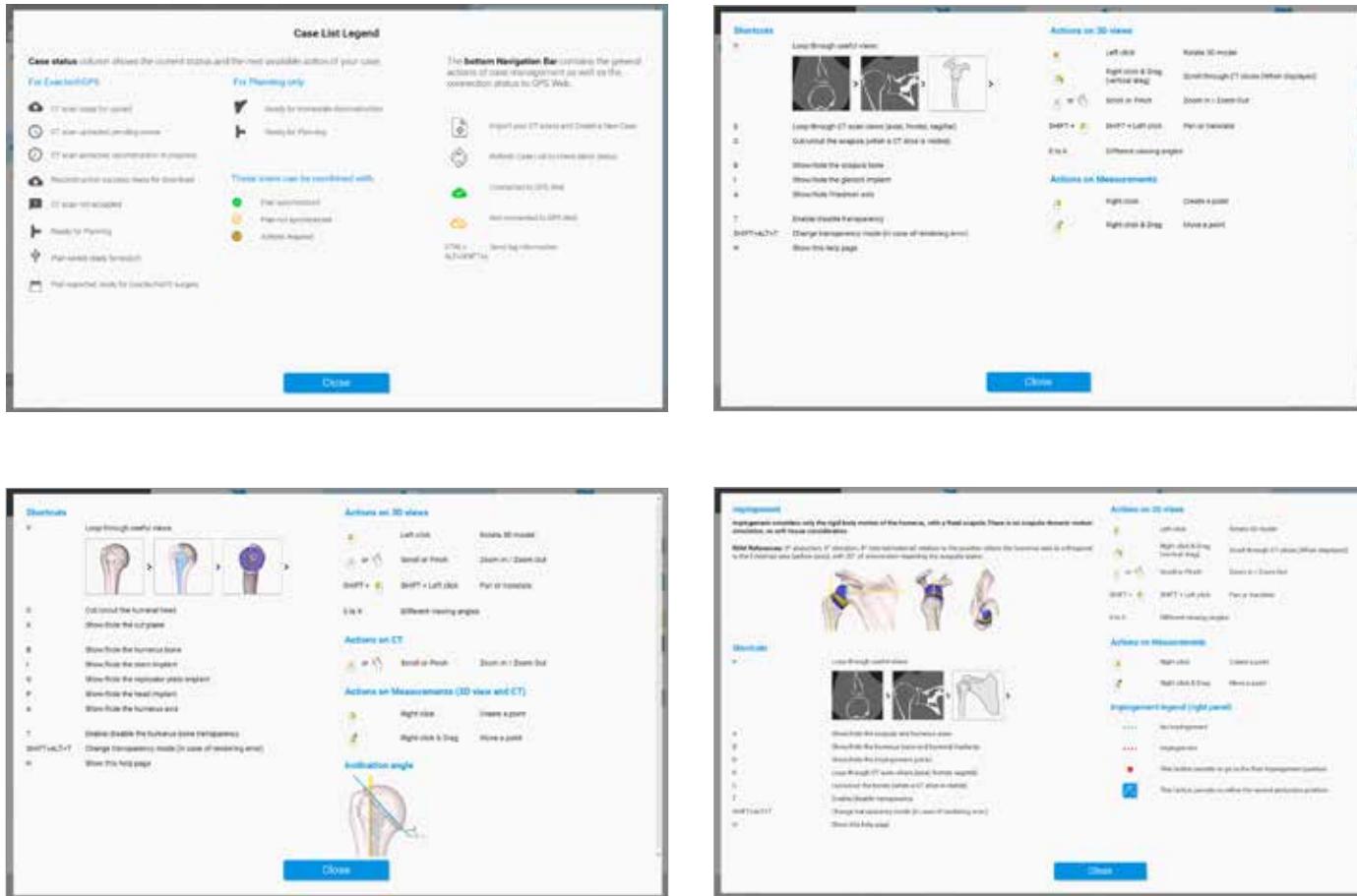


Figure 45

SHORTCUTS

There are many shortcuts built into the software to ensure efficient use of the Equinoxe Planning App.

Clicking the question mark icon when planning a case will open up many of the options for shortcuts as seen above (Figure 45).

PLANNING WITH THE EQUINOXE PLANNING APP

EXPORTING A CASE FOR NAVIGATION

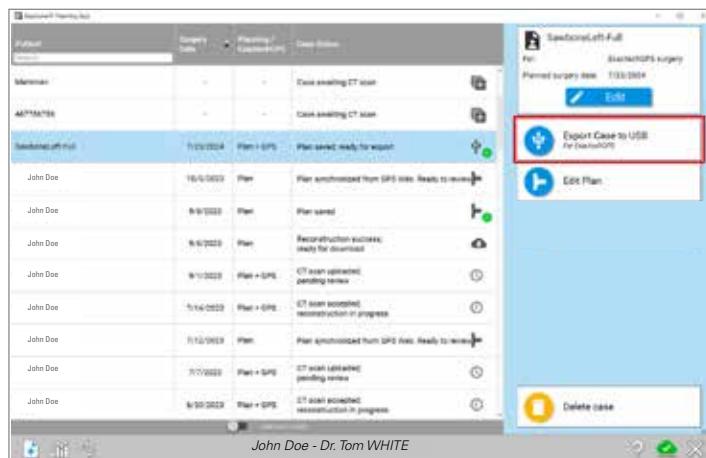


Figure 46

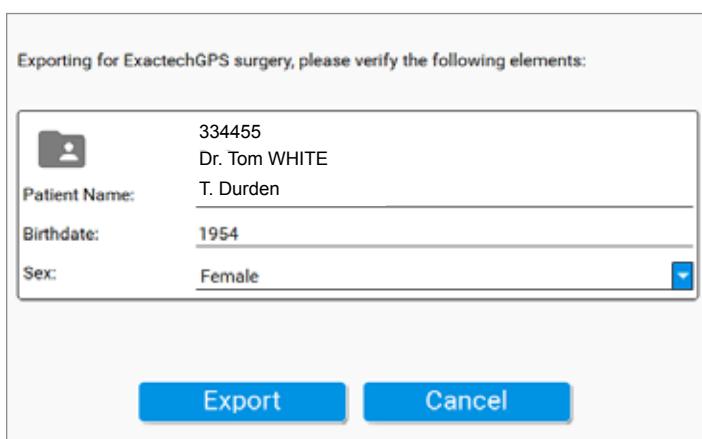


Figure 47

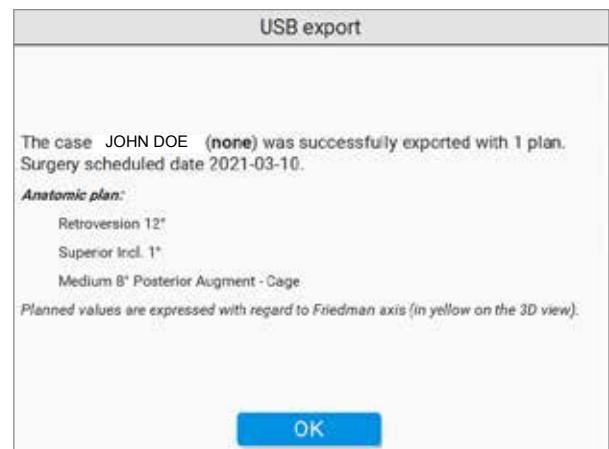


Figure 48

EXPORTING A CASE FOR NAVIGATION

To export the case to the GPS Station, go to the Case List menu and select the Case on the left you want to export. The user should then see this button  on the right side of the screen (Figure 46).

Once selected, the software will prompt the user to enter some identifying information (Figure 47). Once complete, press the Export button. Once the plan has been fully exported to the USB drive, a notification will pop up confirming the successful exportation with some annotations about the plan (Figure 48).

Note: GPS Sales representatives may also transfer cases wirelessly with the Exactech AUGI app.

USB REQUIREMENTS

When exporting cases for navigation, it is important to utilize a non-encrypted USB drive. The software will automatically add two layers of encryption for the plan when exporting to a USB drive. The data on the file/USB drive can only be read and decrypted with the GPS station.

The Equinoxe® Planning App is manufactured by Blue Ortho and distributed by Exactech, Inc.

For additional device information about Exactech shoulder implants, refer to the Exactech Shoulder System—Instructions for Use for information including, but not limited to, a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Blue Ortho, as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for information including, but not limited to, comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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