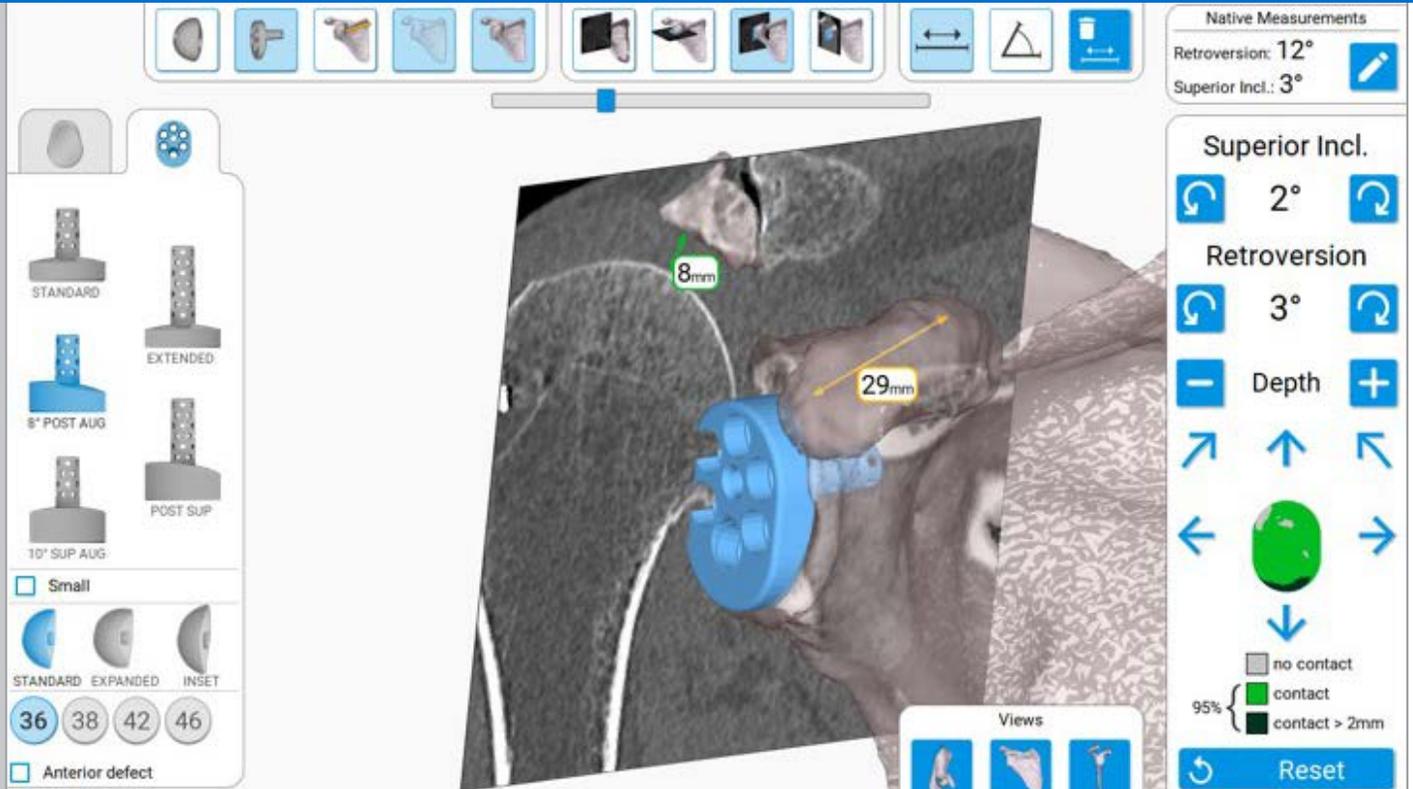


# EXACTECH | EXTREMITIES

Operative Technique



# equinox<sup>®</sup>

Planning App 1.7

## TABLE OF CONTENTS

<b>SETTING UP &amp; GETTING STARTED</b> .....	<b>3</b>
DOWNLOADING SOFTWARE .....	3
LOGGING IN.....	4
CASE MENU.....	5
Editing Case Information.....	5
Statuses.....	6
<b>CREATING A CASE</b> .....	<b>7</b>
REQUIRED CT PROTOCOL .....	7
UPLOADING A CASE FOR EXACTECHGPS NAVIGATION .....	9
IMMEDIATE RECONSTRUCTION INSTRUCTIONS .....	11
<b>PRE-PLANNING WITH THE EQUINOXE PLANNING APP</b> .....	<b>15</b>
IMPLANT SELECTION .....	15
IMPLANT MANIPULATION .....	16
VIEWS.....	17
ADJUSTING NATIVE MEASUREMENTS.....	18
USING THE MEASUREMENT TOOL.....	19
SHORTCUTS .....	20
EXPORTING A CASE FOR NAVIGATION .....	21
<b>INDICATIONS FOR USE/CONTRAINDICATIONS</b> .....	<b>22</b>

The Equinox® Planning App allows surgeons to complete preoperative planning instantly. With a 3D view that helps surgeons understand their patients' anatomy, surgeons can choose implants and placement prior to surgery. Available for MAC and PC.  

### Planning software minimum requirements:

- MacOS X approved versions are "Sierra" (10.12), "High Sierra" (10.13) or "Mojave" (10.14). Minimal version is Sierra.
- Screen resolution should be at least 1280 x 1080.
- It is recommended to have 8GB or more of RAM.
- It is recommended to have at least 10Gb free space on disk.
- It is mandatory to have the **Administrator** privileges during software installation.
- If network security measures are implemented (e.g. Web filtering, firewall, proxy) it may be necessary to ask the surgeon's 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.

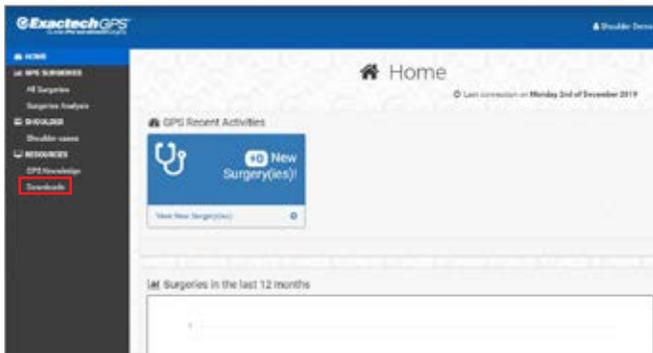


Figure 1a

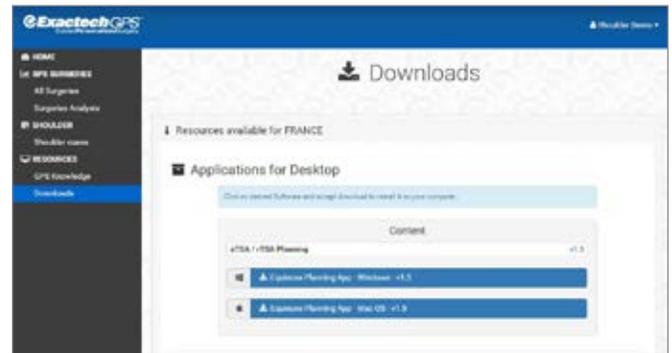


Figure 1b

### DOWNLOADING SOFTWARE

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

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 1b). 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 2

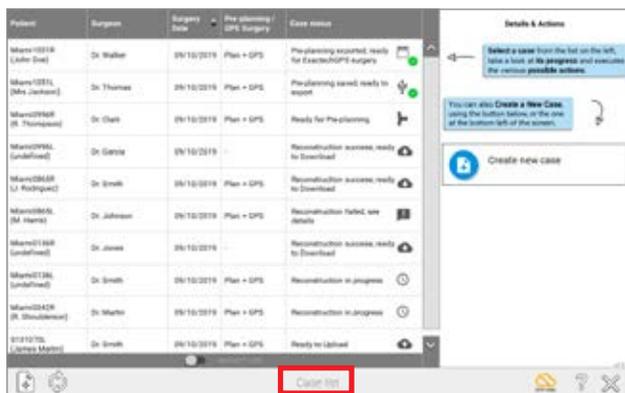


Figure 3



Figure 4

## LOGGING IN

The surgeon must have a GPS Web account to access the Equinox® Planning App and the ExactechGPS Shoulder Application. Upon launching the preoperative planning software, a Login Screen will appear and prompt for login credentials (Figure 2).

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

The Case List Menu screen will appear, showing all surgeon's pending and past cases (Figure 3).

**Note:** Clicking on the  button displays information about the software, including the version. (Figures 4).

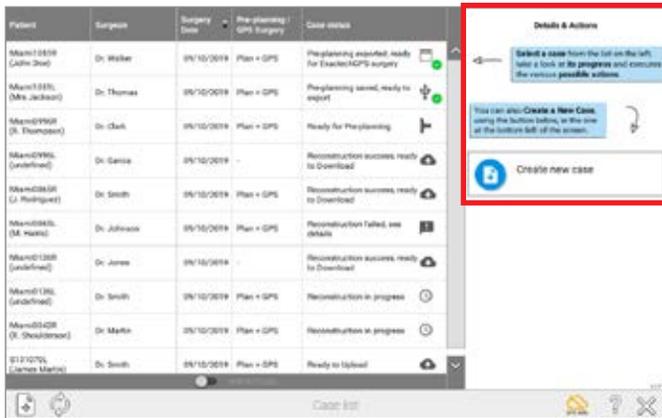


Figure 5

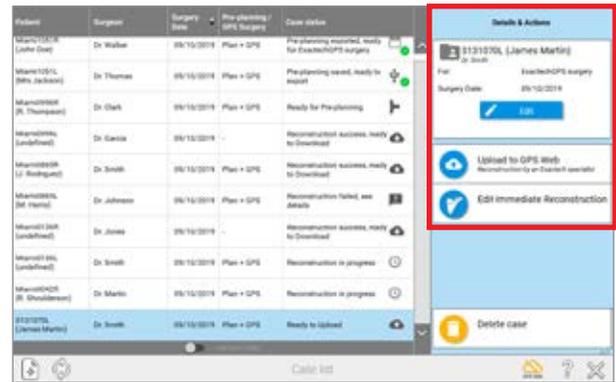


Figure 6

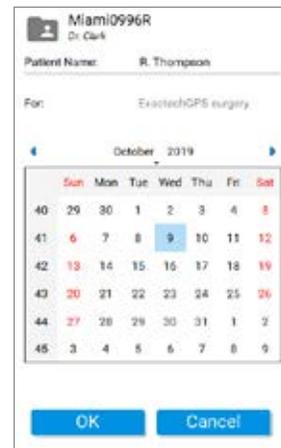


Figure 7

CASE MENU

Cases can have different statuses (Figures 8 and 9). 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 Equinox 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 "Pre-Planning and ExactechGPS surgery" or for "Pre-Planning only". Each type has different possible statuses that change throughout the process (Figure 5).

**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 6).

Click on Edit to modify:

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

**Note:** If switching from pre-planning only to pre-planning and ExactechGPS, 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 7).

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

Case Status	Visual Indicator	Actions
Import CT scans and create a new case		
Refresh Case List to check latest status		
Connected to GPS Web		
Not connected to GPS Web		
Planning synchronized		
Planning not synchronized		Upload to GPS Web
Ready to upload		Upload to GPS Web
Reconstruction in progress		--
Reconstruction failed, see details or Reconstruction success, ready to download	 	-- Download from GPS Web
Ready for pre-planning		Edit pre-planning
Pre-planning saved, ready to export		Edit pre-planning Export to USB media
Pre-planning exported, ready for ExactechGPS surgery		Edit pre-planning Export to USB media

Figure 8

Case Status	Visual Indicator	Actions
Ready for immediate reconstruction		Edit immediate reconstruction
Ready for pre-planning <i>then</i> pre-planning saved		Edit pre-planning

Figure 9

### Statuses

Status and available actions for a case created for “Pre-Planning and ExactechGPS surgery” (Figure 8). These icons can be reviewed within the Equinox Planning App by pressing the question mark button on the bottom right of the screen.

For cases created for “Pre-planning only,” status and actions appear as follows (Figure 9).

In Equinox Planning App 1.7, 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.

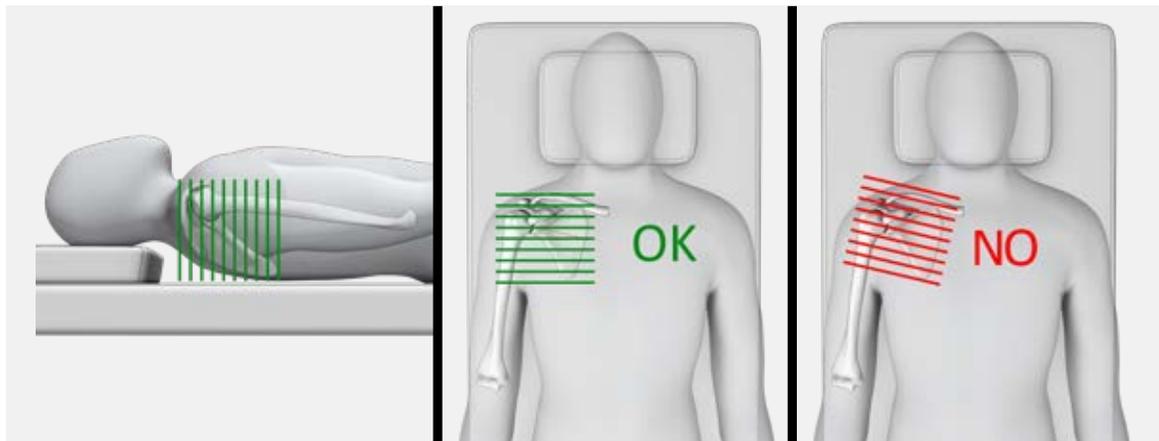


Figure 10

### Prerequisites for the CT Scan Examination

#### Date

It is recommended that the CT exam be performed **less than 6 months** prior to the surgery.

#### 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*)

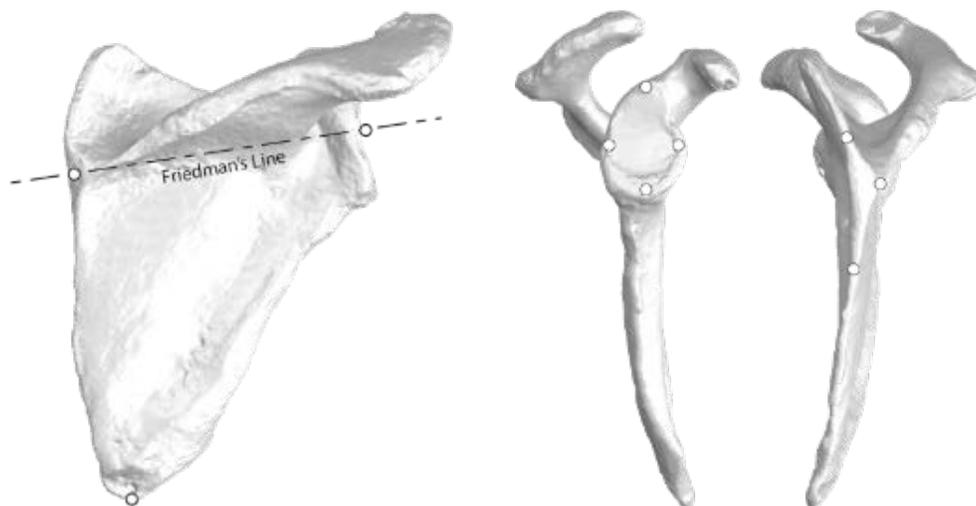
#### Resolution

- Pixels are square and constant for all the images.

- » The minimal resolution for an image is 0.3 x 0.3mm/pixel (i.e. 512 pixels represent at least 15cm/6in)
- » The maximum resolution for an image is 1.25 x 1.25mm/pixel (i.e. 512 pixels represent no more than 50cm/20in)
- Keep both the slice thickness and spacing equal and constant for the entire exam, with no overlap.
  - » Minimum distance: 0.3mm
  - » Maximum distance: 1.25mm
  - » **The recommended distance is 0.625mm**
- The CT-scan series should only contain **axial** slices (gantry tilt = 0°, image orientation 1/0/0/0/1/0.) as shown below.
- Please do not include any sagittal or coronal series when exporting images.
- The pitch should be < = 1.

## 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.

#### 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)  $\geq 120$ .
- Recommended mA: 240mA or higher
- Recommended filters/reconstruction kernels:
  - » GE: Bone
  - » Toshiba: FC30
  - » Siemens: B41
  - » 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.

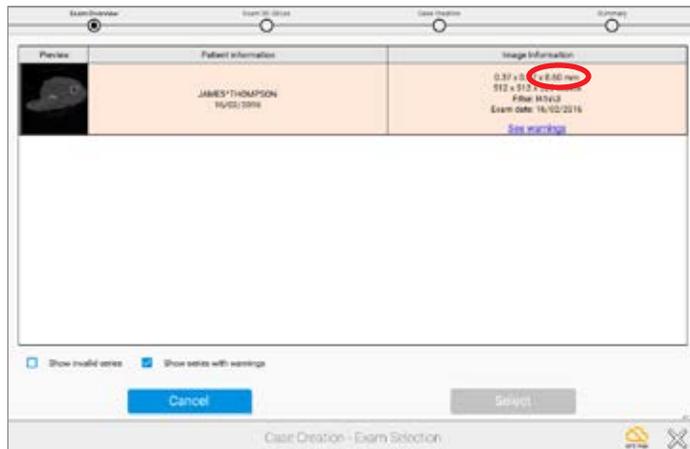


Figure 12



Figure 13

### UPLOADING A CASE FOR EXACTECHGPS 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:** Users MUST follow the CT protocol in the user manual. CT scans must be sent to Exactech 7-10 business days prior to surgery.

## CREATING A CASE

### UPLOADING A CASE FOR EXACTTECHGPS NAVIGATION

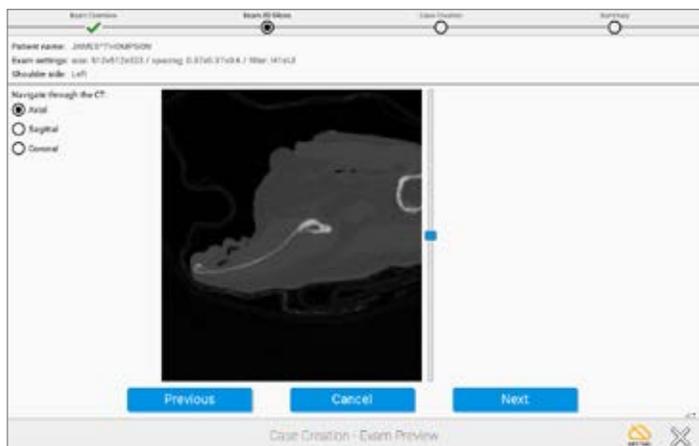


Figure 14



Figure 15

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 15). Then, the Patient ID entered here will be used to de-identify the information transferred for 3D reconstruction.

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

Click on "Pre-planning + Exactech GPS surgery" if submitting for navigation. If pre-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.



Figure 16



Figure 17

### IMMEDIATE RECONSTRUCTION INSTRUCTIONS

Once the case is created, if the case was created for “Pre-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.

The result will be a 3D model of the patient anatomy **for planning and ExactechGPS 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 “Pre-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 pre-planning purposes only.**

The surgeon will not be able to export the pre-planning for ExactechGPS surgery purposes.

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

# IMMEDIATE RECONSTRUCTION INSTRUCTIONS

## USING IMMEDIATE RECONSTRUCTION



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).

## IMMEDIATE RECONSTRUCTION INSTRUCTIONS USING IMMEDIATE RECONSTRUCTION

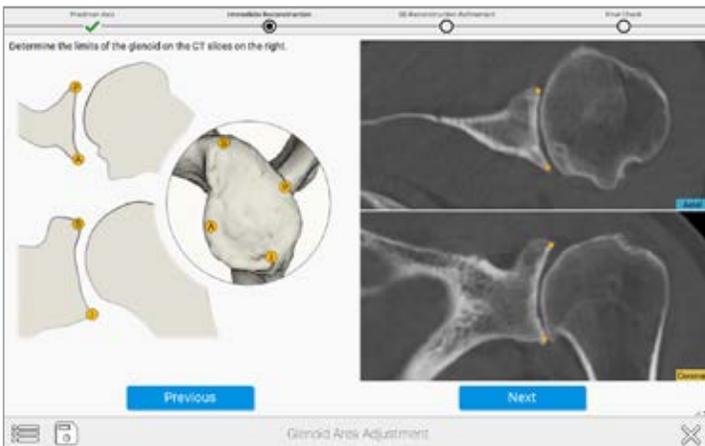


Figure 20

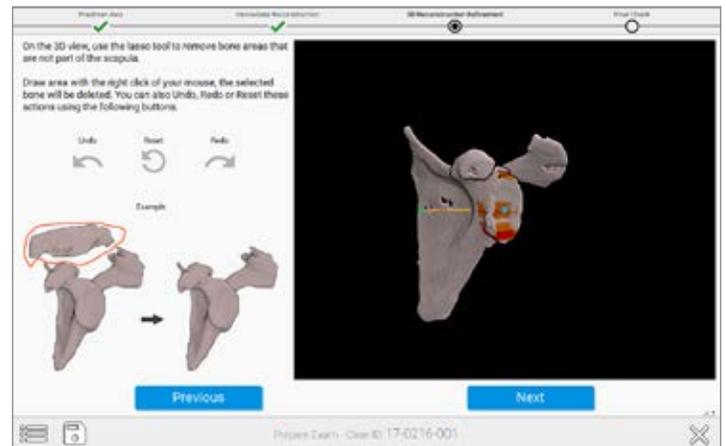


Figure 21

**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).

# IMMEDIATE RECONSTRUCTION INSTRUCTIONS

## CREATING A CASE

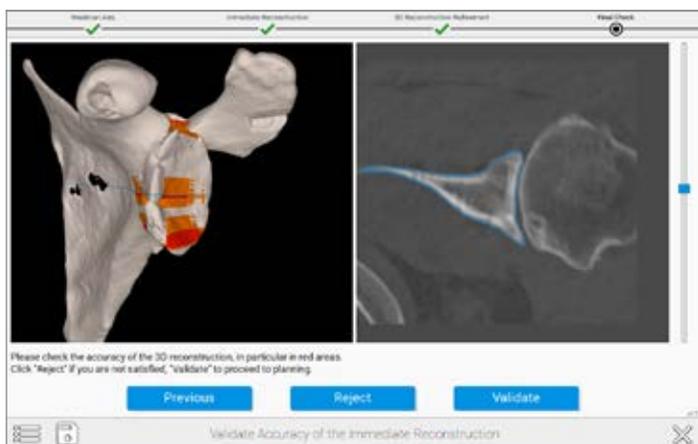


Figure 22

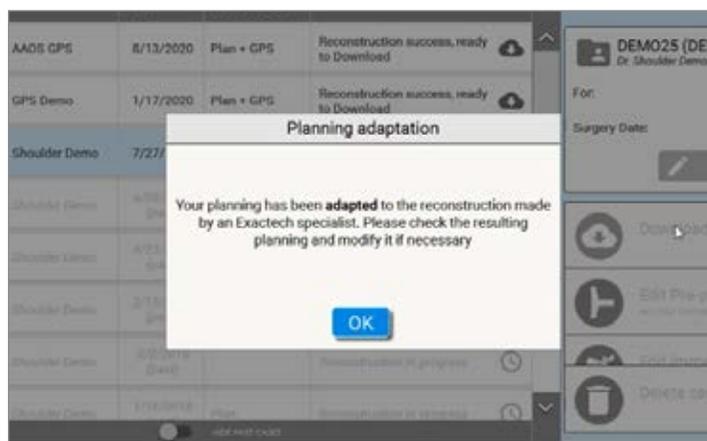


Figure 23

### 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 , the Equinox Planning App preoperative planning tool will open the selected case, with the patient's scapula shown in the viewing window.

**Note:** *If using ExactechGPS 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 (#718-09-30) for detailed surgical technique.

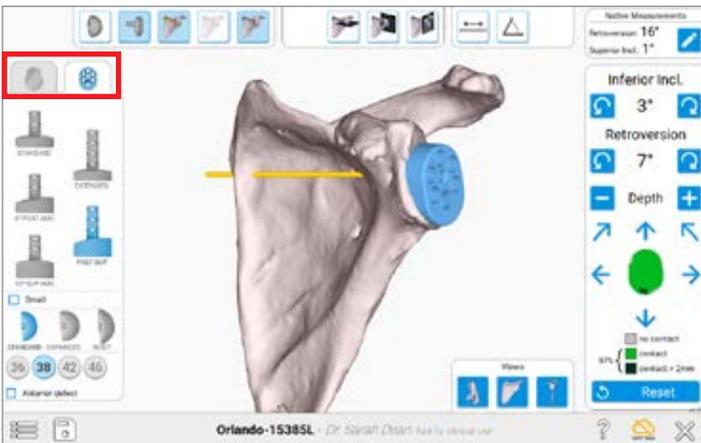


Figure 24

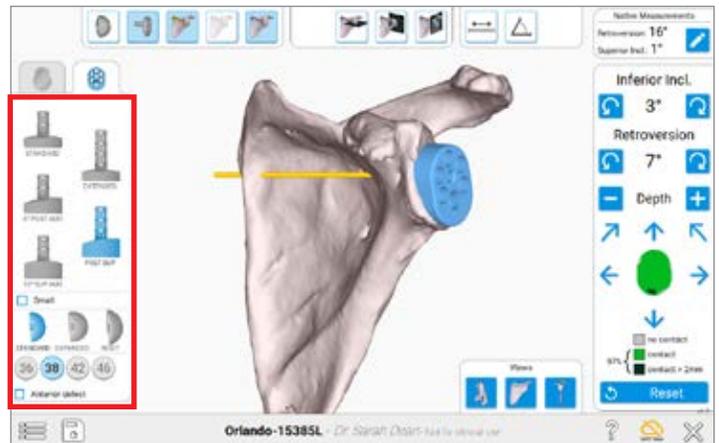


Figure 25

When planning the case, 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 either Anatomical or Reverse on the left side of the screen (Figure 24).

Please note that it is possible to save a plan for both an anatomic and reverse case, and both cases will export accordingly to the ExactechGPS station.

**IMPLANT SELECTION**

After selecting the type of procedure, the surgeon can also activate different implants from the menu on the left side of the screen (Figure 25).

Note that there are additional boxes to enable the ability to plan for the small baseplate implants, as well as anterior augments.

# PRE-PLANNING WITH THE EQUINOXE PLANNING APP

## IMPLANT MANIPULATION

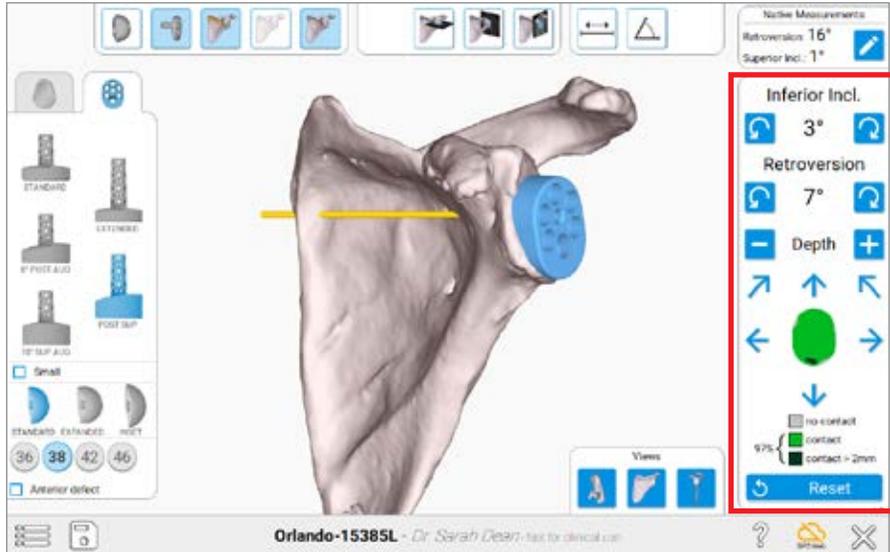


Figure 26

## IMPLANT MANIPULATION

The implant may be manipulated on the bone using the menu on the right side of the screen (Figure 26). 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 coverage. 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 degree of movement.

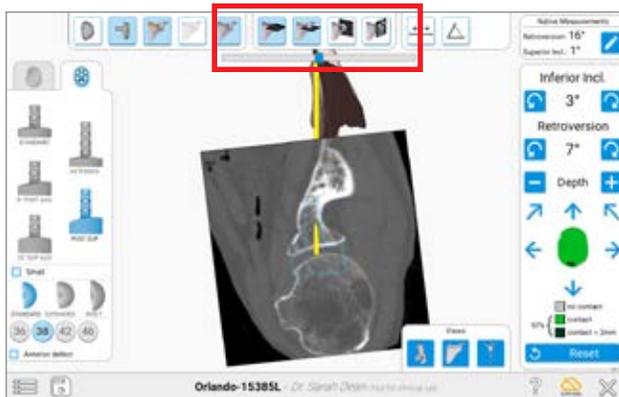


Figure 27

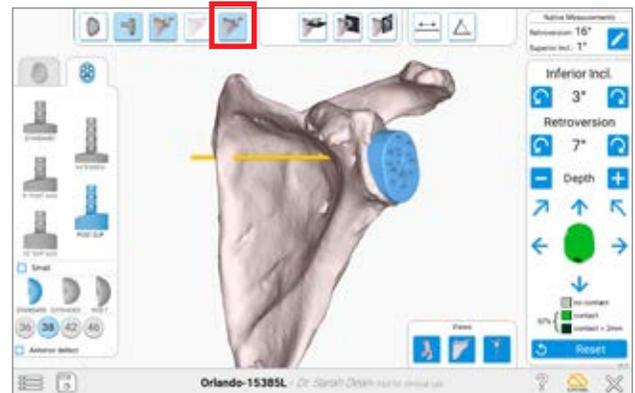


Figure 29

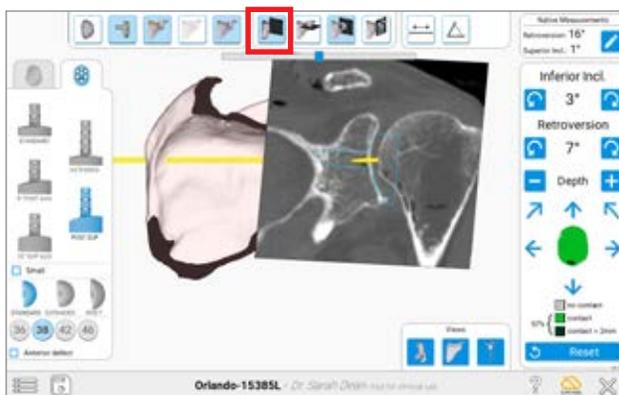


Figure 28

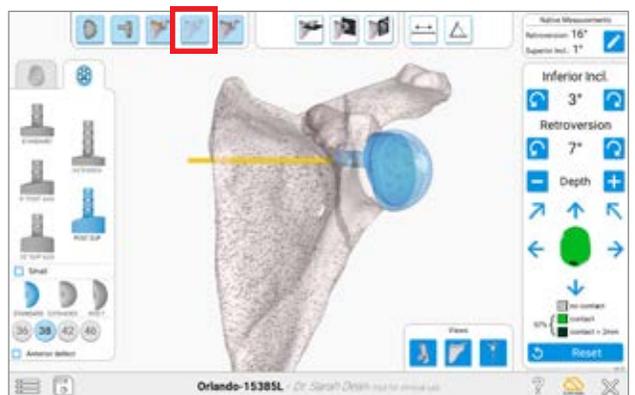


Figure 30

## VIEWS

This view incorporates the CT slices to estimate where the cortices will be relative to the bone (Figure 27). The slide bar can be used to look through all the CT slices in a particular view.

When looking at the CT views, the bone may be sliced at the section of the CT view by selecting the Cut Bone feature (Figure 28).

There are different ways to visualize the bone. These may be toggled using the menu across the top.

**Solid 3D Body** – 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 30).

At any point, the implants may be toggled on or off using the buttons in the upper left of the screen.

**Note:** When planning for the first cases, be mindful of the estimated reaming depth. Most surgeons will plan for 100% backside implant seating, but in surgery would not normally ream this aggressively. The surgeon can stop short of the planned reaming depth in surgery using ExactechGPS.

Once complete, the surgeon can save the plan by selecting the disk in the lower left.

# EQUINOXE PLANNING APP

## ADJUSTING NATIVE MEASUREMENTS

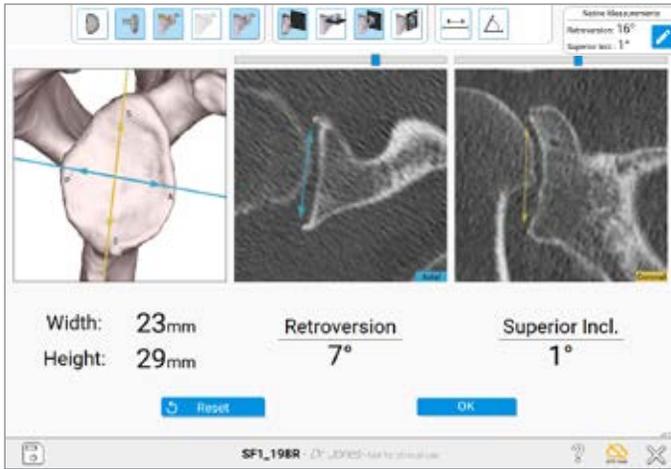


Figure 31

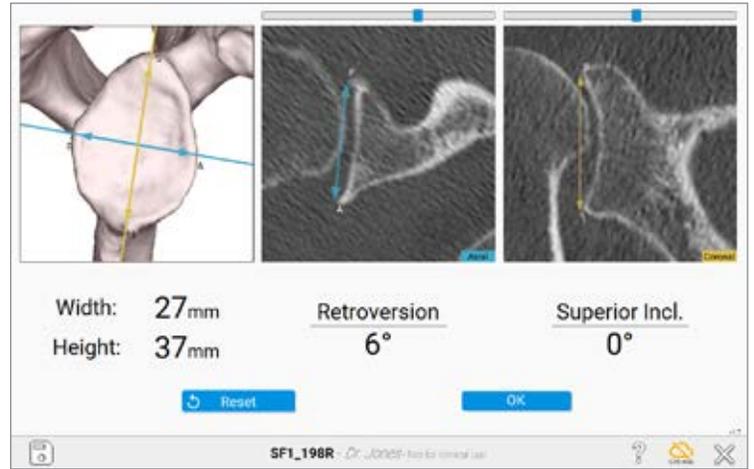


Figure 32

### ADJUSTING NATIVE MEASUREMENTS

The Equinox 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 that these measurements do not affect what the plan shows, as the plan references the auto-selected Friedman's axis (Figure 32).

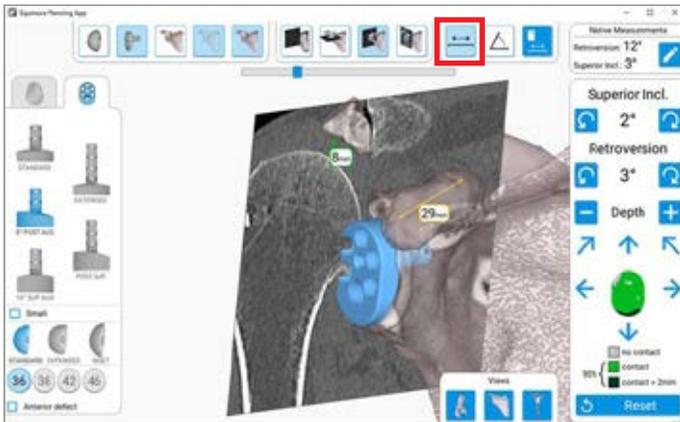


Figure 33

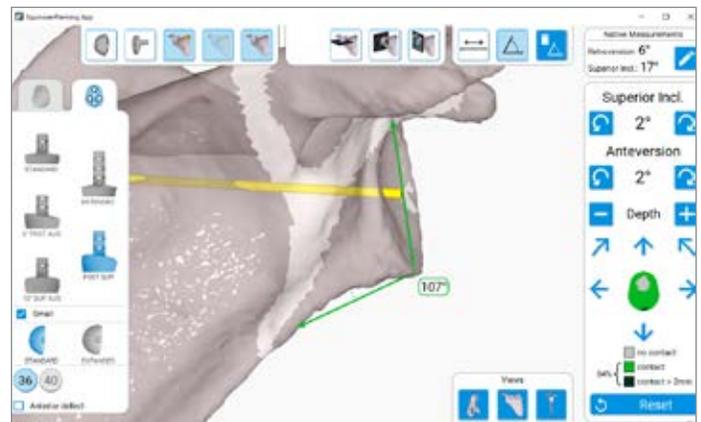


Figure 34

### USING THE MEASUREMENT TOOL

If trying to measure distance between two points, select the left-most image from the measurements tools (show red box around the line icon). 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 and a line will automatically form once the software recognizes the point selected (Figure 33).

To utilize the angle-measurement tool, select three points using the right-click on the mouse. First, select the originating point (the most out-ward point of one of the ends of the desired angle). Then select the second point, which should be the middle/center of the angle. Then select the final and third point which should then automatically create a colored series of line with a bubble that lists the angle of the lines created (Figure 34).

# EQUINOXE PLANNING APP

## SHORTCUTS

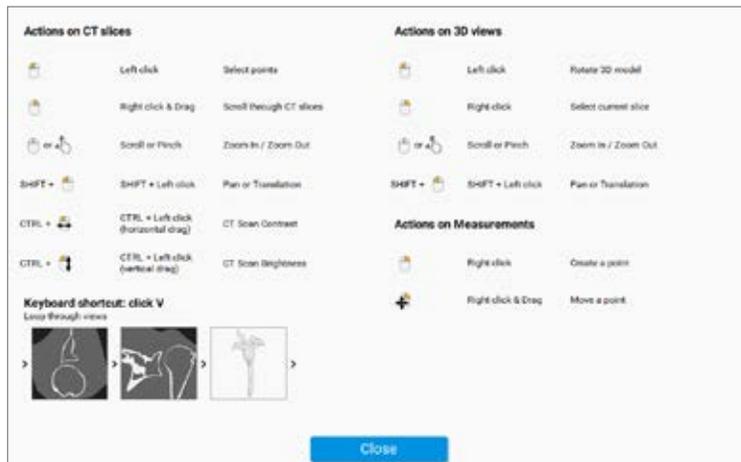
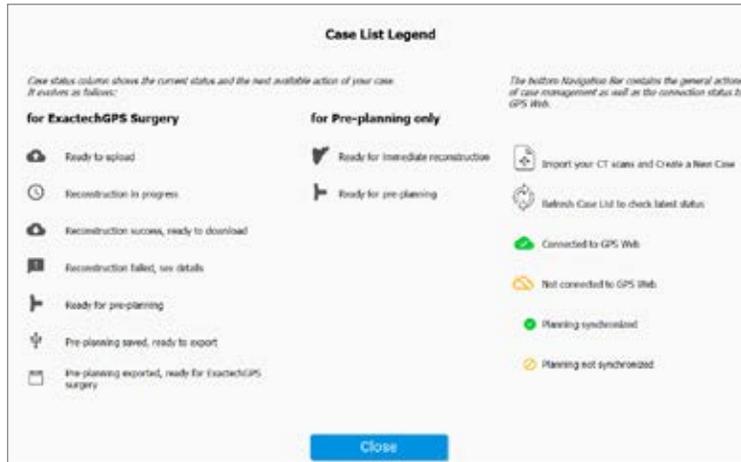


Figure 35

## 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 35).

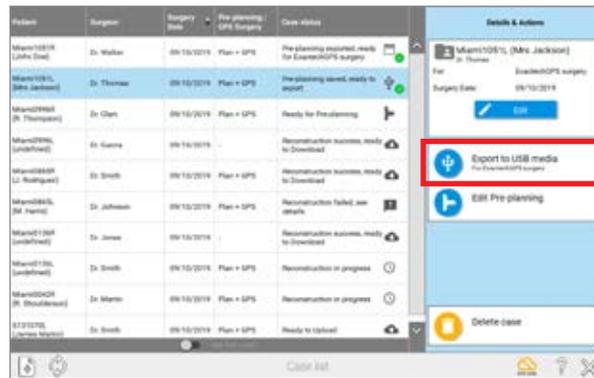


Figure 36

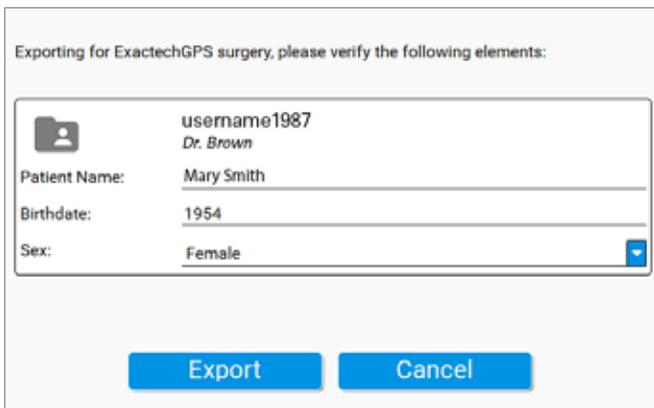


Figure 37

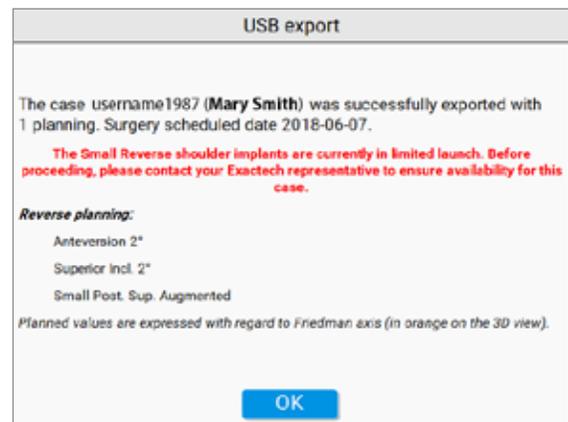


Figure 38

**EXPORTING A CASE**

To export the case to the GPS unit, go to the Case List menu and select the Case on the left to export. The user should then see this button  on the right side of the screen (Figure 36).

Once selected, the software will prompt the user to enter some identifying information (Figure 37). 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 38).

**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 de-encrypted with the ExactechGPS station.

**Note:** The USB starter key is no longer in every disposable kit (A10012), so it is important for the user to have his/her own, beyond just the passkey.

## INDICATIONS FOR USE/CONTRAINDICATIONS

### INDICATIONS FOR USE

The ExactechGPS is intended for use during preoperative planning and during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

The ExactechGPS Shoulder Application is specifically indicated for Total and Reverse Shoulder Arthroplasty using the Equinox system to aid the surgeon in locating anatomical structures and aligning the glenoid component with the anatomical structures.

### CONTRAINDICATIONS

The ExactechGPS Shoulder Application is designed to function only with the Equinox Shoulder System Implants. All indications and contraindications for those implants should be followed when using the ExactechGPS Total Shoulder Application.

The use of the ExactechGPS Shoulder Application is also contraindicated in patients who have inadequate coracoid bone for tracker fixation.

The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not.

A pathological condition against the use of this system could be in some cases:

- Advanced osteoporosis,
- Crack or break of coracoid process.

The system requires a computed tomography (CT) scan of the patient's scapula for planning and registration purposes and is contraindicated if the imported scan does not contain the required bony anatomy.

The ExactechGPS Shoulder Application as well as the Equinox Shoulder System are available for prescription use only.



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

For additional device information, refer to the manufacturer's Instructions for Use for 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.

Exactech, as the distributor of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These 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 comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

The products discussed herein may be available under different trademarks in different countries. All trademarks used herein are registered or common law trademarks of Blue Ortho or Exactech, Inc. This material is intended for the sole use and benefit of the Exactech sales force and physicians. It should not be redistributed, duplicated or disclosed without the express written consent of Exactech, Inc. Copyright in all aspects of these materials is owned by Blue Ortho and/or Exactech, Inc., ©2020. 718-09-31 Rev. A 0420



CE Mark is not valid unless there is a CE Mark on the product label.

Exactech is proud to have offices and distributors around the globe.  
For more information about Exactech products available in your country, please visit [www.exac.com](http://www.exac.com)



**GLOBAL HEADQUARTERS**  
2320 NW 66TH COURT  
GAINESVILLE, FL 32653 USA

+1 352.377.1140  
+1 800.EXACTECH  
+1 352.378.2617  
[www.exac.com](http://www.exac.com)