eQUINOXe®

Equinoxe® Planning App

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

Planning software minimum requirements:

- **Equinoxe Planning App** is qualified for Windows 7, Windows 8.1 and Windows 10 environments as well as Mac OSX 10.11 (El Capitan), OSX 10.12 (Sierra) and OSX 10.13 (High Sierra).

- It is recommended to have 8GB or more of RAM, and a screen resolution of a least 1280x800 pixels.

- It is mandatory to have the **Administrator** rights during software installation.

- If network security measures are implemented (e.g. Web filtering, firewall, proxy) it may be necessary to ask your 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.
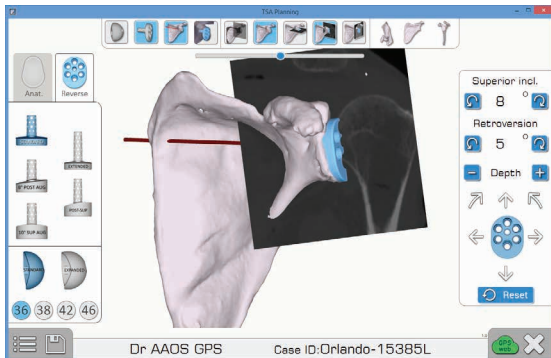
Screen Layout

The Equinoxe Planning App can be used for pre-operative planning either with or without ExactechGPS. Within the software, a decision to do **Pre-planning only** or **Pre-planning and ExactechGPS surgery** is made.

Pre-planning only: Use of the Immediate Reconstruction feature creates, after a few steps and within minutes, an automated 3D reconstructed scapula on which experimentation with implant selection and position can be done. At this point in time, Immediate Reconstruction is not used for the purpose of navigation. If it is desired to navigate the case the other option, **Pre-planning and ExactechGPS surgery should be selected. If Pre-planning only** was selected and completed and then a decision is made to navigate, the CT scan can be sent for a manual 3D reconstruction to be completed at Blue Ortho with the intent to eventually navigate. Normal submission timelines will be maintained from the date it is uploaded to ExactechGPS web/Blue Ortho.
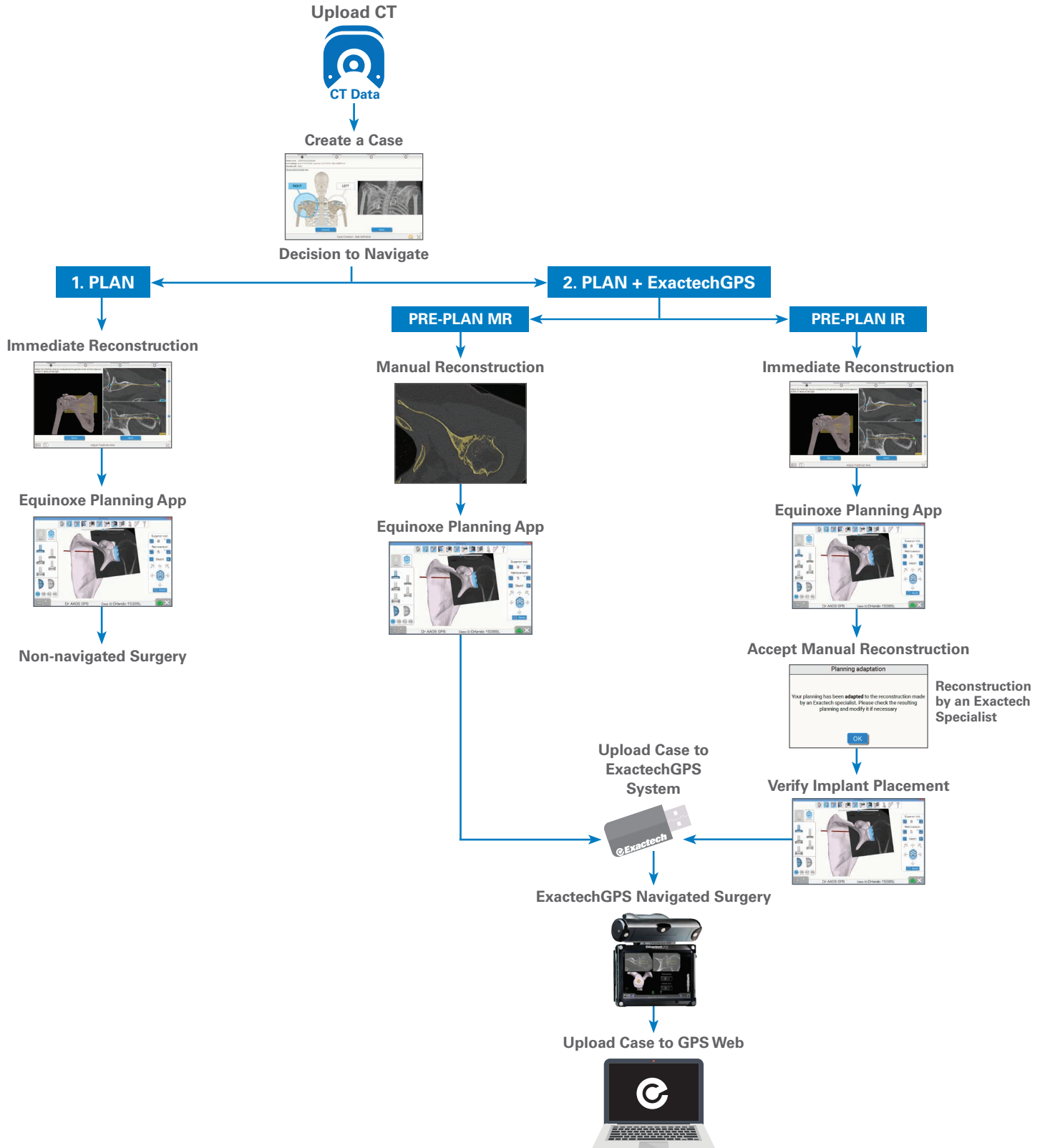
Pre-planning and ExactechGPS surgery: Use of the Immediate Reconstruction feature creates, after a few steps and within minutes, an automated 3D reconstructed scapula on which experimentation with implant selection and position can be done. At this point in time, Immediate Reconstruction is not used for the purpose of navigation. For the sake of navigation, a manual 3D reconstruction will be completed at Blue Ortho and you will be sent the scapula rendering to go forward with planning. Normal submission timelines will be maintained from the date it is uploaded to ExactechGPS web/Blue Ortho. The new plan will be updated according to the Friedman axis of the manual reconstruction and you will have the opportunity to review it before exporting for navigation.

EQUINOXE PLANNING APP

Workflow: Preoperative Planning Only or Preoperative Planning and ExactechGPS Surgery

1. Pre-planning Only *for traditional Non-Navigated Surgery*
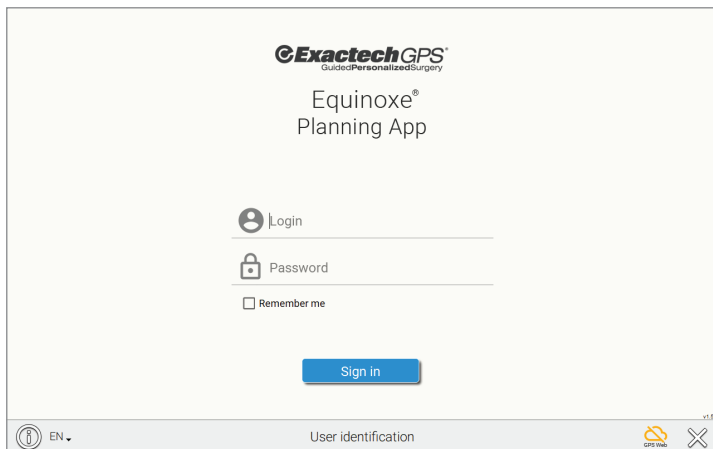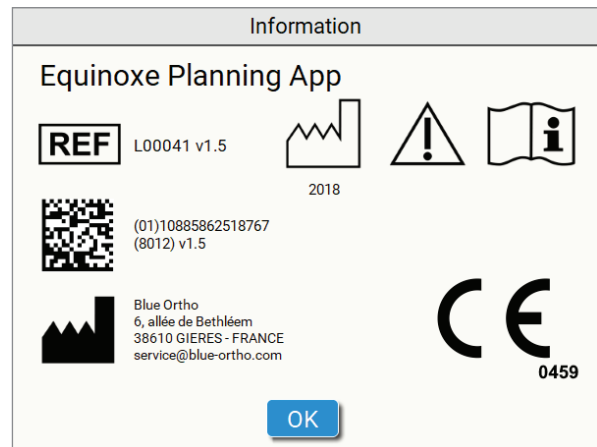2. Pre-planning and ExactechGPS Surgery *for ExactechGPS Navigated Shoulder Surgery*

Upload CT

CT Data

Create a Case

Decision to Navigate

1. PLAN	2. PLAN + ExactechGPS

PRE-PLAN MR   **PRE-PLAN IR**

Immediate Reconstruction   **Manual Reconstruction**   **Immediate Reconstruction**

Equinoxe Planning App   **Equinoxe Planning App**   **Equinoxe Planning App**

Non-navigated Surgery

Accept Manual Reconstruction

Planning adaptation

Your planning has been **adapted** to the reconstruction made by an Exactech specialist. Please check the resulting planning and modify it if necessary

OK

Reconstruction by an Exactech Specialist

Verify Implant Placement

Upload Case to ExactechGPS System

ExactechGPS Navigated Surgery

Upload Case to GPS Web

Figure 1

Figure 2

Note: Clicking on the ⓘ button displays information about the software, including the version. *(Figures 1 and 2).*

Patient	Surgeon	Surgery Date	Pre-planning / GPS Surgery	Case status	
Miami1051R (undefined)	Dr. Walker	07/09/2018	Plan + GPS	Reconstruction success, ready to Download	☁
Miami1051L (undefined)	Dr. Thomas	07/09/2018	Plan + GPS	Reconstruction success, ready to Download	☁
Miami0996R (undefined)	Dr. Clark	07/09/2018	Plan + GPS	Reconstruction success, ready to Download	☁
Miami0996L (undefined)	Dr. Garcia	07/09/2018	-	Reconstruction success, ready to Download	☁
Miami0865R (undefined)	Dr. Smith	07/09/2018	Plan + GPS	Reconstruction success, ready to Download	☁
Miami0865L (undefined)	Dr. Johnson	07/09/2018	Plan + GPS	Reconstruction failed, see details	❗
Miami0136R (undefined)	Dr. Jones	07/09/2018	-	Reconstruction success, ready to Download	☁
Miami0136L (undefined)	Dr. Smith	07/09/2018	Plan + GPS	Reconstruction in progress	🕐
Miami0042R (undefined)	Dr. Martin	07/09/2018	Plan + GPS	Reconstruction in progress	🕐

Details & Actions

Select a case from the list on the left, take a look at **its progress** and executes the various **possible actions**.

You can also **Create a New Case**, using the button below, or the one at the bottom left of the screen.

Create new case

HIDE PAST CASES

Case list

v1.5

GPS Web

Figure 3

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 is green, the application is connected to the internet and the statuses are up to date; if the icon is orange, you 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.

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 3)*.

Case Status	Visual Indicator	Actions
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

| Case Status	Visual Indicator	Actions
Ready for immediate reconstruction		Edit immediate reconstruction
Ready for pre-planning *then* pre-planning saved		Edit pre-planning

Figure 4

Figure 5

Status and available actions for a case created for "Pre-Planning and ExactechGPS surgery" *(Figure 4)*.

For cases created for "Pre-planning only," status and actions appear as follows *(Figure 5)*.

Create or add a case to the case list by pressing the "Create new case" button:
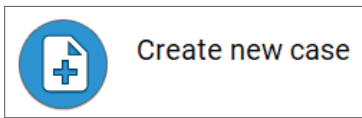
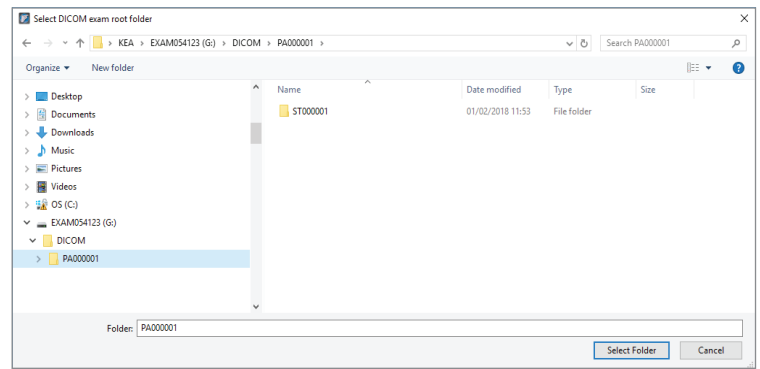Or by pressing the permanent button on the bottom left of the task bar:

Figure 6

Figure 7

CASE CREATION:

It is possible to create a case from the "Case List" page *(Figure 6)*.

The first step is to browse your computer and select the parent folder containing the CT exam *(Figure 7)*.
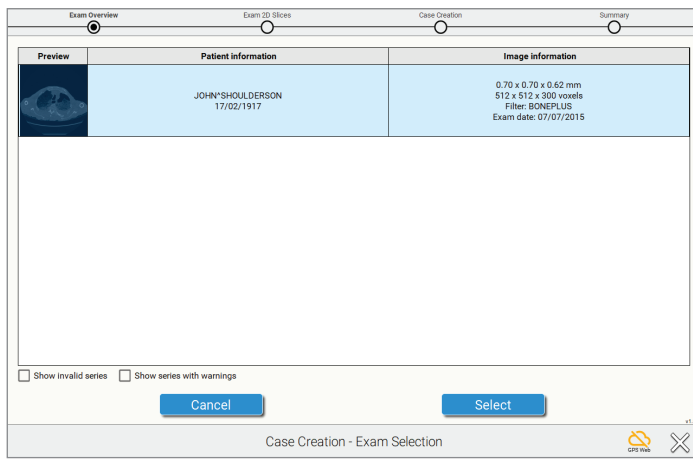
Figure 8

Figure 9

It is not necessary to select the exact folder containing the series; the software will check all subfolders and propose all adequate series. The software will automatically select the AXIAL series and won't show the other series that do not comply with our protocol *(Figure 8)*.
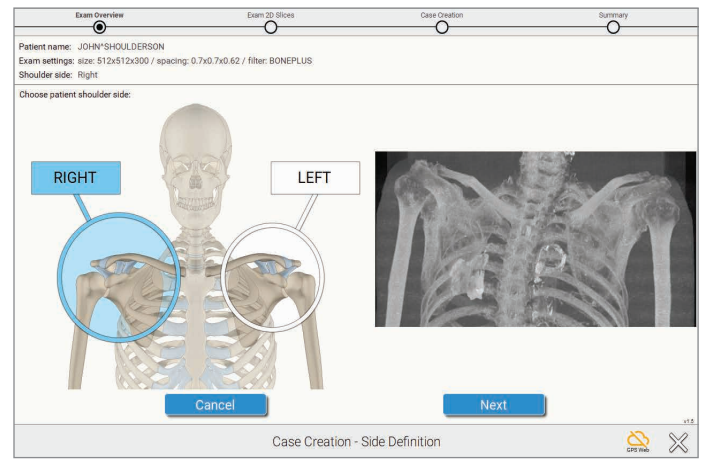
Once the series is selected, a frontal "pseudo X-ray" pre-view is shown. It permits to quickly confirm the side, and check that the entire scapula is present *(Figure 9)*.

Note: *This view is calculated from the axial slices.*
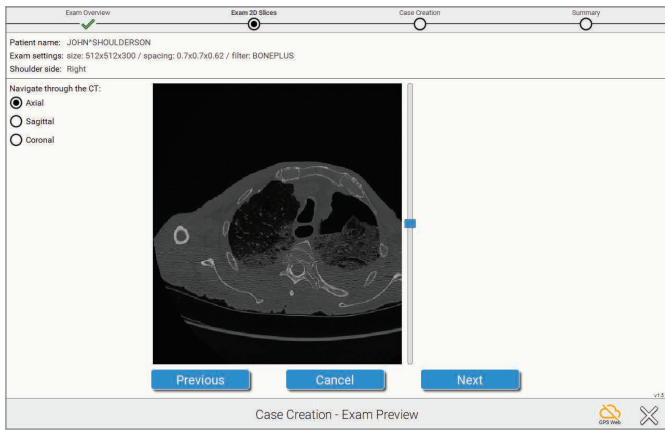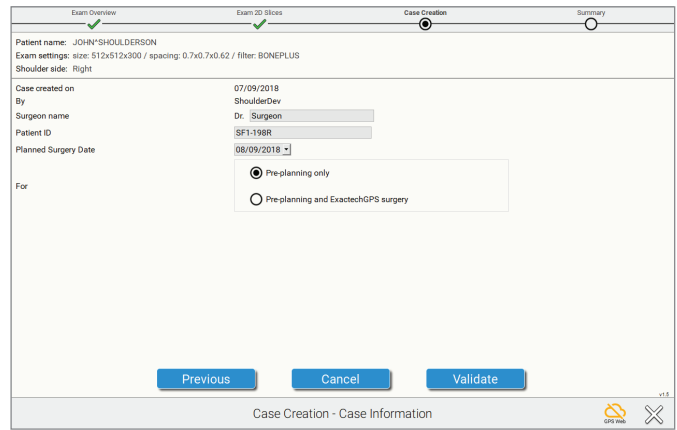
Figure 10

Figure 11

It is then possible to visualize the full exam *(Figure 10)*.

Then assign a unique identifier to that exam *(Figure 11)*.

Note: This unique identifier (field "Patient ID") is transmitted to GPS Web server and must not contain patient private information such as patient name.
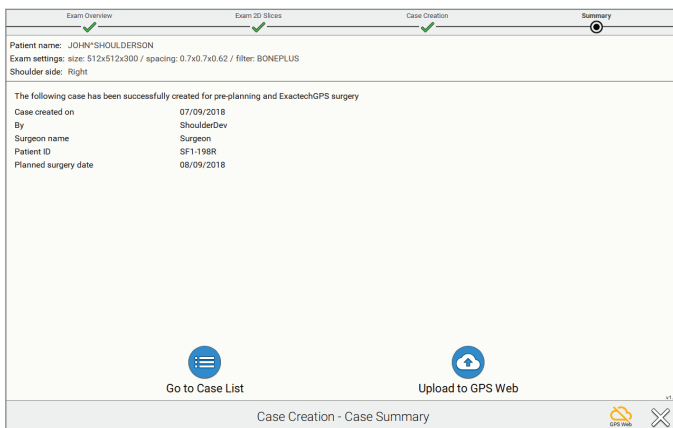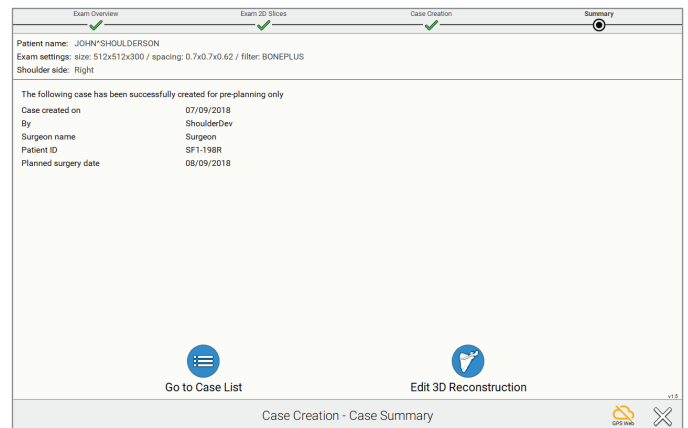
Figure 12

Figure 13

Once the case is created, if the case was created for "Pre-planning and ExactechGPS surgery," you 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.**

Once you receive the 3D model, you will be able to perform the planning of your implant and then export the planning for navigation purpose.

- Click on **"Go to Case List"** if you don't want to upload the case right away *(Figure 12)*.

For a case created for "Pre-Planning only", you can:

- Click on **"Edit 3D Reconstruction"** to start the immediate reconstruction process. You will be guided through 4 steps to reconstruct the 3D model of the patient anatomy, **for pre-planning purposes only.**

You will not be able to export the pre-planning for ExactechGPS surgery purpose.

- Click on **"Go to Case List"** if you don't want to reconstruct the case right away *(Figure 13)*.

Figure 14

Figure 15

EDITING CASES:

To edit a case, first select it, by clicking anywhere on its row, in the Case List. The right part of the screen changes and presents the details of the action and the possible actions.

If you click on [Edit] you can modify:

- The patient's name

- The surgery date

- The purpose of the case ('Pre-Planning only', or 'Pre-Planning and ExactechGPS surgery') *(Figure 14)*.

Note: *If switching from pre-planning only to pre-planning and ExactechGPS, you must press the button that says Upload to GPS Web.*

Note: *Patient's private information is not transmitted to GPS Web. They are stored encrypted on the computer to preserve patient confidentiality (Figure 15).*

When patient information is exported to a USB drive for navigation, the software double-encrypts the data and can only be opened on an ExactechGPS station.
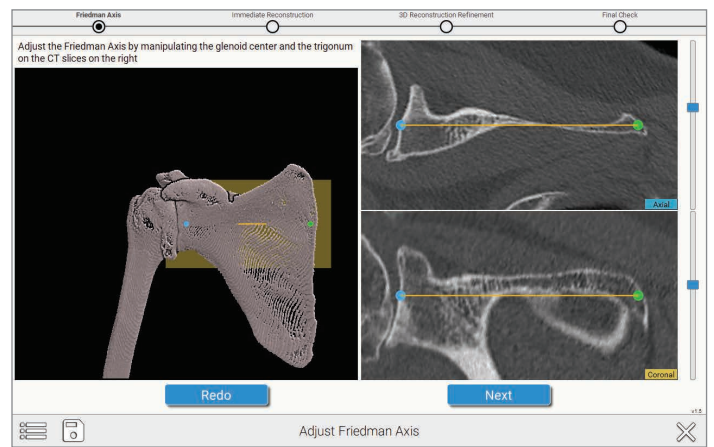
Figure 16

Figure 17

IMMEDIATE RECONSTRUCTION INSTRUCTIONS:

A) Pick and adjust Friedman's axis:

The first step is to pre-position the glenoid center and the trigonum *(Figure 16)*.

Then you can adjust Friedman's axis on 2D views, with a 3D view presenting the axis for verification purposes *(Figure 17)*.
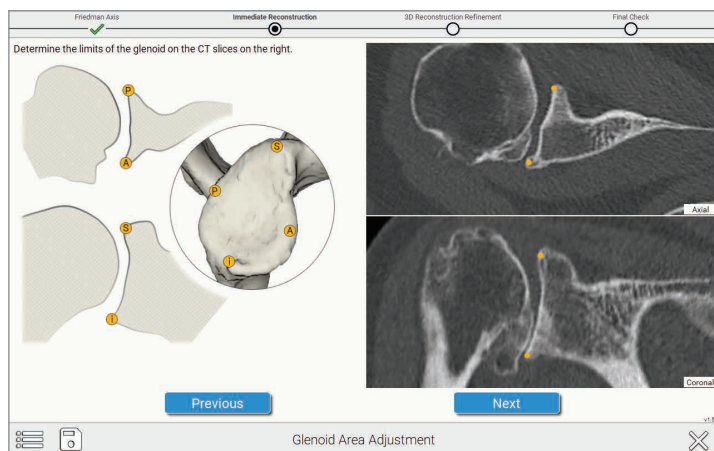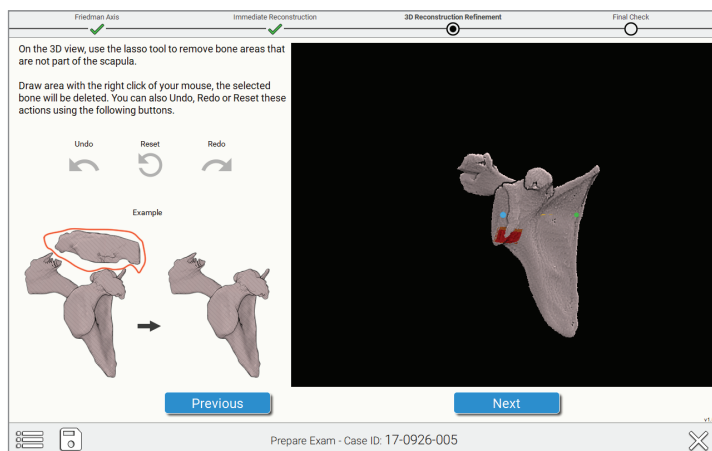
Figure 18

Figure 19

B) Pick four peripheral quadrant points on the glenoid surface On the image in the upper right of the screen *(Figure 18)*, select the points that correspond with the orange dots on the image on the left side of the screen.

C) You can remove unwanted portions of the reconstruction with the "Lasso Tool." To utilize this, hold down the right click button as you draw a lasso around the area you want to exclude from the reconstruction *(Figure 19)*.
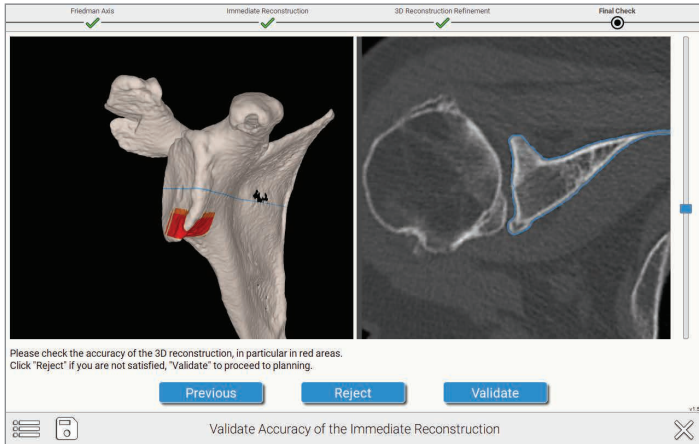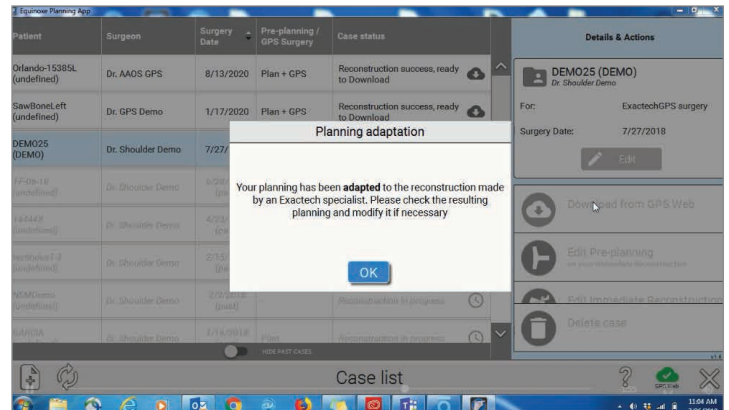
Figure 20

Figure 21

D) Validate the accuracy of the reconstruction:

Red/Orange areas should be checked for accuracy as the software wants to ensure a proper reconstruction. Complicated or fused anatomy can lead to errors in this step. *(Figure 20)*.

Note: *If you are using the ExactechGPS unit in surgery, you 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 21).*

Refer to the ExactechGPS Shoulder Application Operative Technique (#718-09-30) for detailed surgical technique.

Examples of situations where the user must pay attention to validate the accuracy
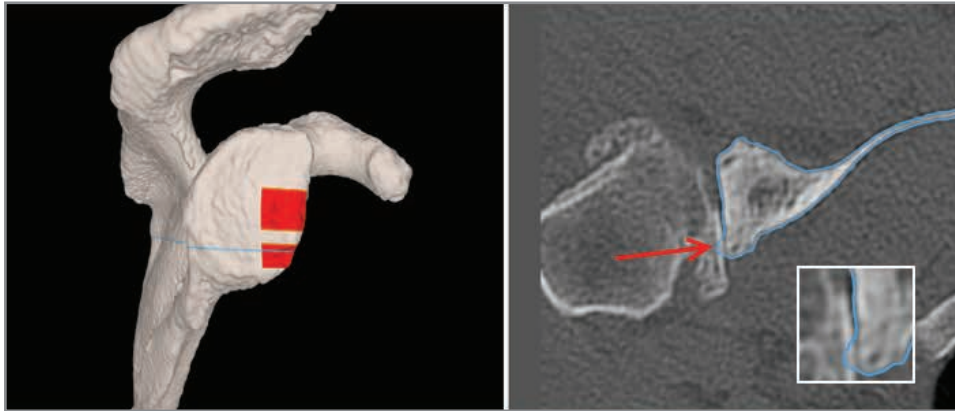
Example 1 – Small spike
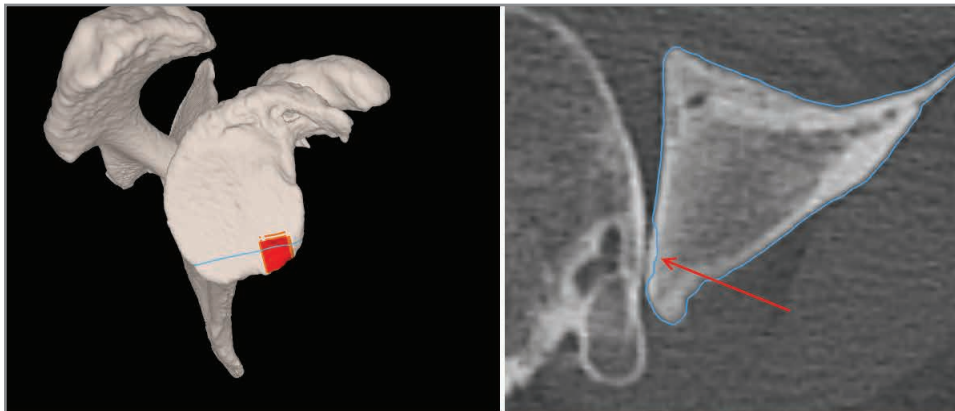
Example 2 – Minor defect
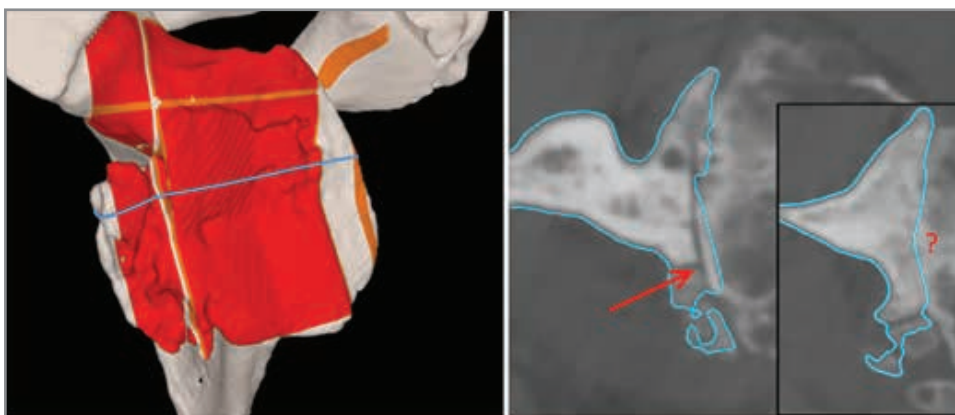
Example 3 – Bigger inaccuracies
In this case, it is recommended to upload the exam for a manual reconstruction

Note: The immediate reconstruction process can be used offline (without being connected to GPS Web) a maximum of 20 cases or for one month.

Note: If a manual reconstruction is submitted but not navigated, your office or agency may incur a charge.

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 Equinoxe 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 Equinoxe 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 Equinoxe Shoulder System are available for prescription use only.

NOTES

NOTES

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

Exactech, Inc. 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.

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.

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