User Manual

brAIn™ Shoulder Positioning

Shoulder Surgery Planning Tool

Manufacturer Name: Avatar Medical SAS
Software Name: brAIn™ Shoulder Positioning
Software Version: FDA.1.1.0
Document Number: BSP_FDA_UM_EN
Document Version: 4

Table of Contents

Introduction

Software information

Name of device: brAIn™ Shoulder Positioning

Unique Device Identifier: 03770026095034

The user manual can be consulted in the following formats:

- PDF format. The PDF can be opened by web browsers (Microsoft Edge version 120.0.2210.133 or above, Google Chrome version 120.0.6099.217 or above, Mozilla Firefox version 121.0.1 or above, Chromium 8.0.552.0 or above) and with Adobe Acrobat Reader version 2023.008.20458 or above.
- In paper form upon request within 7 days and free of charge.

For additional information please contact customer support (see Troubleshooting & Contact Information).

Software label

The software label is available in the About popup, accessible from the dropdown menu at the top right of the Navigation Bar.

Date of first marketing in the US: 2025/03

Last revision date of user manual: 2025/08

Software release date (version FDA.1.1.0): 2025/08

brAIn™ Shoulder Positioning Directions for Use

Description

The brAIn™ Shoulder Positioning software is a cloud-based application intended for shoulder surgeons. The software does not perform surgical planning but provides tools to assist the surgeon with planning primary anatomic and reverse total shoulder replacement surgeries using FX Shoulder Solutions implants. The software is accessible via a web-based interface, where the user is prompted to upload their patient's shoulder CT-scan (DICOM series) accompanied with their information in a dedicated interface. The software automatically segments (using machine learning) and performs measurements on the scapula and humerus anatomy contained in the DICOM series. These segmentations serve as a foundation for the surgeon's manual planning, which is performed using an interactive 3D viewer that allows for soft tissue visualization. The surgeon positions the glenoid and humerus implants manually within this same 3D interface using a dedicated manipulation panel. The changes in shoulder anatomy resultant from the implants are relayed in a post-position interface that displays information related to distalization and lateralization. The software outputs a multimodal planning summary that includes textual information (patient information, pre- and post-op measurements) and visual information (screen captures of the shoulder pre- and post-implantation).

Intended Use

brAIn™ Shoulder Positioning is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

Intended User

Intended users are medical professionals, including imaging technicians, clinicians and surgeons.

Intended Patient Population

Indicated for patients with primary anatomic and reverse total shoulder replacement surgeries using FX Shoulder Solutions implants.

Contraindications

Using this medical device is contraindicated in the following cases:

- When used for a joint other than a shoulder joint
- When used for implants other than commercially available FX Shoulder Solutions implants
- Any medical examination other than a CT scan

- A medical arthroscan examination
- When used on images showing both shoulders

Undesirable Side-Effects / Residual Risk

The risk assessment indicates that no significant residual risks remain due to the manufacturer's risk management actions on brAIn™ Shoulder Positioning to ensure safety for patients and users. All remaining risks are considered acceptable.

Location of Use

The software is designed for use in no specific location, in hospital settings.

Device performance

The performance of brAIn™ Shoulder Positioning's automatic segmentation of bone anatomy algorithm has been thoroughly validated and achieved an average Dice score of 0.95 or greater on its testing materials. A Dice score is a way to measure how well the segmentations computed by software like brAIn™ Shoulder Positioning and ground truth segmentations created manually by medical professionals match up, with a score of 1 meaning they match perfectly and a score of 0 meaning they don't overlap at all.

The performance of brAIn™ Shoulder Positioning's shoulder side detection has been validated with a 100% agreement between the identification made by clinical specialists and by the software on the side of the shoulder (left or right).

The performance of brAIn™ Shoulder Positioning's pre-positioning of shoulder landmarks (refer to section Shoulder landmarks) has been validated and achieved an accuracy less than or equal to 3 millimeters.

The performance of brAIn™ Shoulder Positioning's shoulder measurements has been validated and achieved an accuracy of 1° for angle measurement, 1 mm for distance measurement and 1% for 3D subluxation when updating the position of landmarks/implants.

The streaming stability performance of brAIn™ Shoulder Positioning has been validated for a 30-minute usage period and achieved an average FPS over a strictly above 24 FPS (standard frame rate for television and cinema), with an average packet loss under 1% and an average jitter under 30 ms (acceptable threshold for real-time video communication).

Symbols

Pictogram	Description
RX Only	Federal law restricts this device to sale by or on the order of a physician
	Consult Instructions For Use
	Caution
	Unique Device Identifier
	Reference number
	Batch number
	Manufacturer
	Date of Manufacture

These symbols can be found on the Homepage and in the About popup of the brAIn™ Shoulder Positioning application.

Glossary of terms

Term	Definition
Bio-RSA	Bony Increased Offset-Reversed Shoulder Arthroplasty (surgical method used to achieve glenoid lateralization by placing a bone graft on the glenoid)
Component or Part	A specific part or element of a medical implant
Mesh	A network of interconnected triangles or polygons that forms the surface of a 3D anatomical model for visualization and surgical planning
Planning Interface	All brAIn™ Shoulder Positioning screens related to Pre-Operative Planning: Pre-Position tab, Implant tab, Glenoid tab, Humerus tab, Post-Position tab.
Shoulder landmark	A specific anatomical point or feature on the shoulder that is used for identification, measurement, or orientation of the implant.
Software Bill Of Materials (SBOM)	Detailed inventory of all the software components that make up a particular software application or system

Recommendations related to the application

Please carefully review the application description before use.

Please thoroughly review the recommended CT Scan protocol.

The software requires an Internet connection for access. To prevent 3D visualization streaming artifacts, we recommend using a wired connection or a stable WiFi connection. Please thoroughly review the Network requirements.

It also requires a compatible device (see Minimum hardware recommendations and Web browser compatibility). It is the responsibility of the user to ensure that the selected location meets the

necessary requirements for privacy, security, and a professional environment, especially when handling sensitive or protected information

In this user manual, useful information and tips that do not impact patient safety or device performance are highlighted using the following style:

💡 Helpful information example

General warnings related to the application

In this user manual, warnings and information that may impact device performance are highlighted using the following style:

⚠ Warning example

They are listed in the table below, organized by section:

Section	Warning
Workflow Description	This software is designed to assist in surgical planning and support the surgeon's decision-making process. However, the final decisions regarding surgical planning and execution are solely the responsibility of the operating surgeon. While the software offers guidance based on available data and technology, it does not replace the surgeon's expertise and judgment. The ultimate responsibility for all surgical decisions and actions lies with the surgeon.
Account deletion	This action is irreversible. All user-related information, including account details and plans, will be permanently deleted.
Logout	Closing the web browser tab or exiting the browser will close the software, but it will not terminate the current user session. The user must manually log out using the method described above, or their session will remain active for 30 minutes before automatically ending due to inactivity.

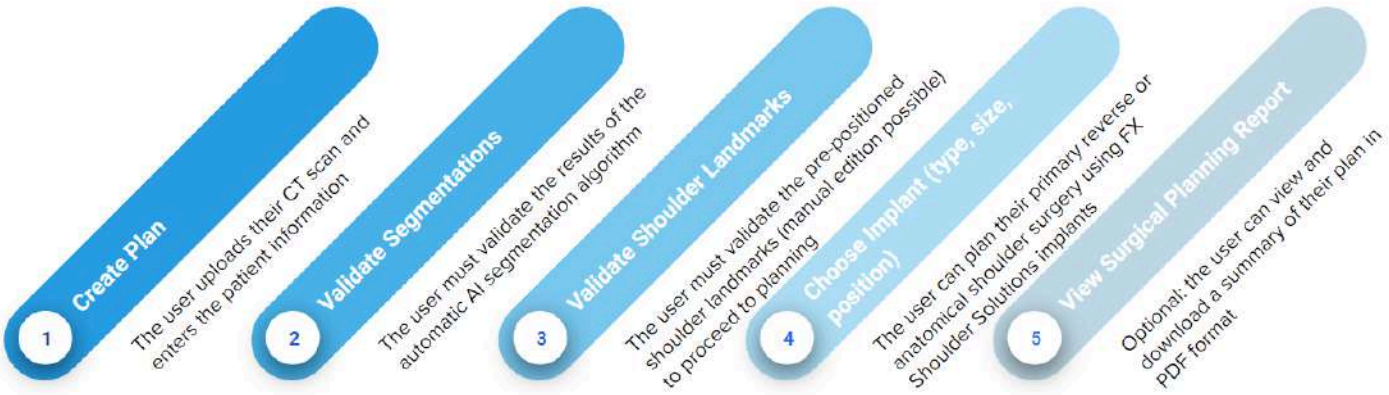
First connection	If the user doesn't receive the welcome email, they should check their spam folder. If it's not there, they should contact customer support (see Troubleshooting & Contact Information).
	This password is temporary and must be used within 72 hours of account creation. After this period, the user should contact customer support (see Troubleshooting & Contact Information).
Password forgotten	This reset code is temporary and must be entered within 8 minutes.
	If the user receives a password reset email without initiating the request, we recommend the following actions: - Secure the account: the user should update their password immediately to ensure the account's security - Contact support if the user has any concerns or notices suspicious activity on their account (see Troubleshooting & Contact Information)
Creating a plan	Zip files are not supported, only uncompressed files must be selected.
	brAIn™ Shoulder Positioning does not support loading multiple CT series in a single plan. If the user wishes to use 2 separate CT DICOM series for their pre-operative planning, they must create 2 plans.
	brAIn™ Shoulder Positioning only supports axial CT series. If the user attempts to load multiple CT series, brAIn™ Shoulder Positioning will choose the axial CT series with the highest number of frames.
	brAIn™ Shoulder Positioning will not compare the patient information entered by the user in this step with the metadata of the DICOM files selected in step 1: users must be extremely careful about submitting information that corresponds to the DICOM files they have selected for upload.

	brAIn™ Shoulder Positioning does not support modifying the patient information and patient health history entered in steps 2 and 3 once the plan creation has been submitted. Users should review carefully before finalizing their input.
	The displayed remaining time is an **estimate** and may not be exact. Please allow for a margin of error.
Deleting a plan	Plan deletion cannot be undone! All plan information will be lost.
Shoulder landmark and implant component toggles	Only one toggle can be switched ON at a time.
Shoulder Side Inconsistency Check	If a shoulder side inconsistency arises that is not caused by user error in entering patient information, the user must select option b. For further assistance, we recommend contacting customer support (see Troubleshooting & Contact Information).
Segmentation approval	brAIn™ Shoulder Positioning does not support manually correcting the segmentations. If the user is not satisfied with the segmentations, they must refuse the segmentations and will not be able to use brAIn™ Shoulder Positioning to plan this particular CT series. We recommend contacting customer support (see Troubleshooting & Contact Information).
Glenoid tab	The software does not automatically select implant components; users must choose them manually.
	The software will not provide any warnings or visual indicators if an implant component perforates the glenoid bone structure. Users must review their plan carefully.
	For baseplates, the glenoid reaming visual effect is achieved using a cylindrical cropping method that conceals elements within the cylinder. However, depending on the patient

	anatomy, some fossa fragments may remain visible after reaming.
	For glenoid pegs, the glenoid reaming visual effect is achieved using a spherical cone cropping method that conceals elements within the cone. However, depending on the patient anatomy, some fossa fragments may remain visible after reaming.
Humerus tab	The software does not automatically select implant components; users must choose them manually.
	The software will not provide any warnings or visual indicators if an implant component perforates the humeral bone structure. Users must review their plan carefully.
Post-Position tab	The software does not offer warnings or visual indicators for bony impingement or implant contact in the Post-Position configuration. Users are responsible for thoroughly reviewing their plan.

Workflow Description

The diagram below illustrates the primary use case of the brAIn™ Shoulder Positioning application following user login (refer to the Application Access section for details):



Step 1 is described in the Plan Management section of this document.

Steps 2, 3 and 4 are described in the Pre-Operative Planning section.

Step 5 is described in the Surgical Planning Report section.

⚠ This software is designed to assist in surgical planning and support the surgeon's decision-making process. However, the final decisions regarding surgical planning and execution are solely the responsibility of the operating surgeon. While the software offers guidance based on available data and technology, it does not replace the surgeon's expertise and judgment. The ultimate responsibility for all surgical decisions and actions lies with the surgeon.

Application Access

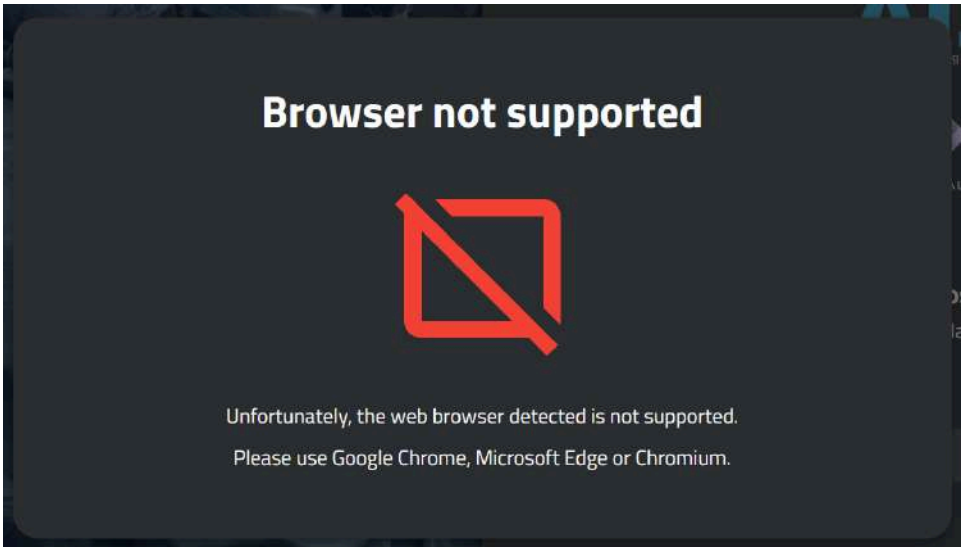
Web platform

The brAIn™ Shoulder Positioning software is a full-web application deployed on a cloud platform and available at the following link: https://bsp.fx.avatarmedical.cloud.

To access the application, the user will need to use a compatible web browser:

- Google Chrome
- Microsoft Edge
- Chromium

If the user attempts to access the software using a web browser not listed above, a warning message will appear, preventing access to the login form:



Access to the brAIn™ Shoulder Positioning software is limited to authorized users only: a user account is required to proceed beyond the homepage of the application.

User account

Definition

A brAIn™ Shoulder Positioning user account is an individual's personalized gateway to access, manage, and interact with the features and services offered by the application.

This user account is unique to them and provides a secure way to use the software, ensuring that their data and settings are kept private and accessible only by the user.

It contains the following information:

- First name
- Last name
- Email address which is used as the username to log in to the application
- Password to log in to the application
- Profile: User/Manager/Organization (see User Profiles)
- Version of the End-User License Agreement validated by the user, if any (see End-User License Agreement)

User Profiles

The brAIn™ Shoulder Positioning software offers 3 levels of User Profiles:

- **User**:
  - Access to all shoulder surgery planning features (plan creation, implant selection, report, etc)
- **Manager**:
  - Access to all shoulder surgery planning features (plan creation, implant selection, report, etc)
  - User account management (creation and deletion of user accounts)
- **Organization**:
  - Access to all shoulder surgery planning features (plan creation, implant selection, report, etc)
  - User account management (creation and deletion of user accounts)
  - Cloud platform management

Surgeons shall be granted User accounts, this User Manual focuses on the features available to User-profile accounts. The features available to Manager and Organization accounts only are described in the *brAIn™ Shoulder Positioning - Manager Guide*.

Account creation

User accounts are created by Manager-profile or Organization-profile users. If a surgeon wishes to be granted access to the brAIn™ Shoulder Positioning application, they must contact customer support (see Troubleshooting & Contact Information).

The following information is mandatory to create a new user account:

- Email address: will be used as username to log in to the software. It must be a valid email address since the first-time connection password will be sent to that email (see First connection).
- First name of the user to be created
- Last name of the user to be created

The email address must be unique among all existing user accounts.

💡 If a user wants to have 2 separate user accounts (for example, if the surgeon works at two different institutions and wants to keep their plans separate), 2 different email addresses must be used to create 2 user accounts for that surgeon.

Account deletion

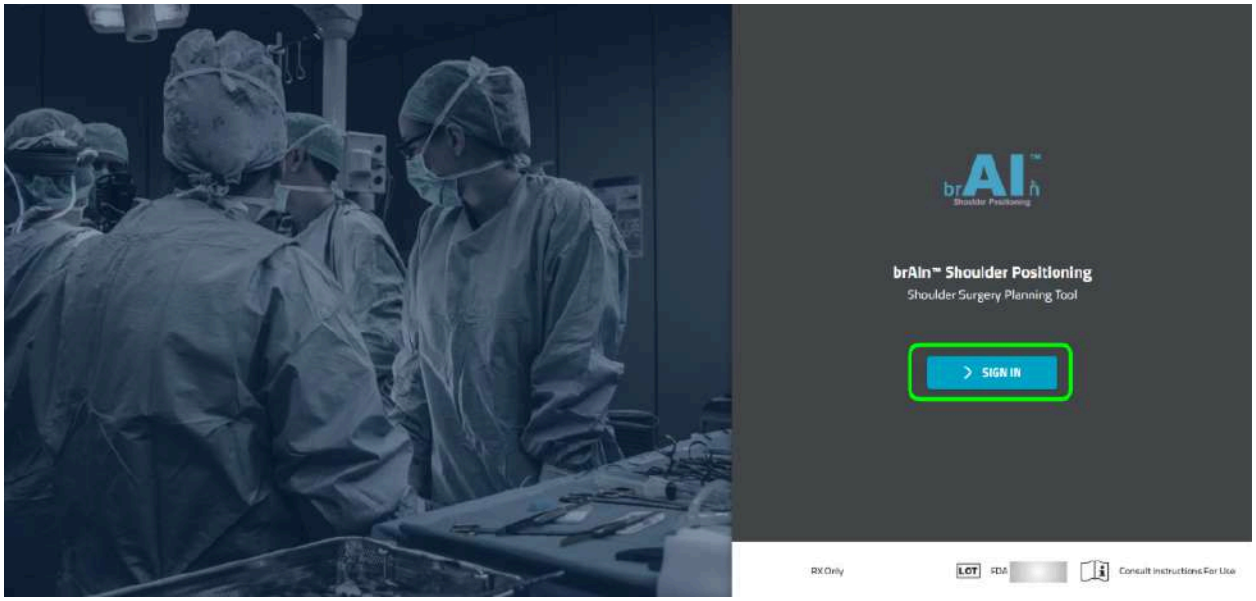
A user account can only be deleted by a Manager-profile or Organization-profile user. If a user with a User profile wishes to delete their account, they must contact customer support (see Troubleshooting & Contact Information).

⚠ This action is irreversible. All user-related information, including account details and plans, will be permanently deleted.

Authentication

Homepage

The Homepage is the landing page of the brAIn™ Shoulder Positioning application. The page is accessible without being authenticated with a user account. By clicking the “SIGN IN” button, the user will be redirected to the Connect Interface to log in to the application.

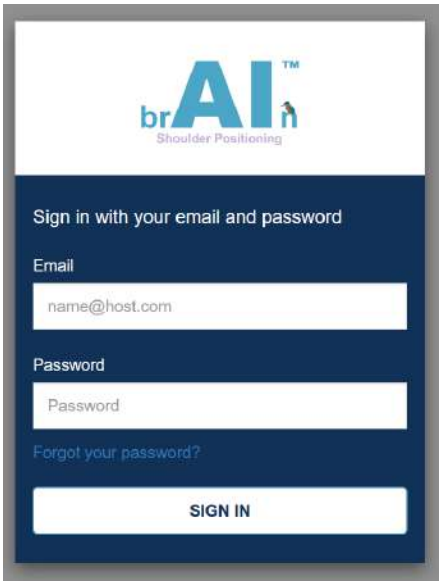


Connect Interface

The **Connect Interface** is the login page of the brAIn™ Shoulder Positioning application. To proceed any further, the user must click the “SIGN IN” button to log in.

Login

To log in to the brAIn™ Shoulder Positioning software, the user must enter their email and password and click the “SIGN IN” button:



If their email and password are correct, the user will be redirected to the Select Interface.

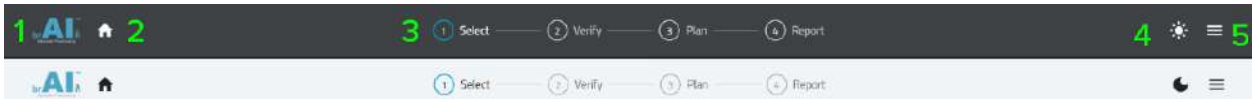
Navigation bar

Once the user has successfully logged in, a navigation bar will appear at the top of the screen. This navigation bar will be present across all interfaces of the application.

It contains the following elements:

1. Application logo
2. A Home icon
3. A 4-step progress bar to help users track their progress in the shoulder surgical planning workflow

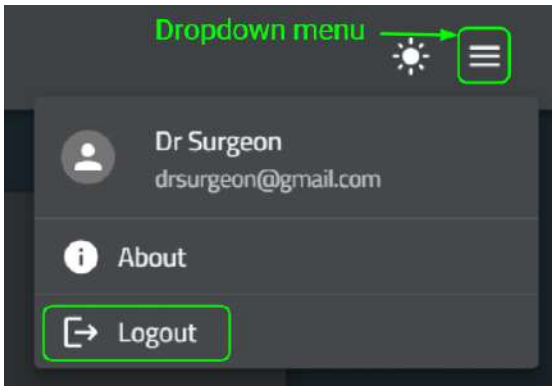
4. Dark and light mode buttons: click the sun icon to switch to light mode, or click the moon icon to switch to dark mode.
5. A dropdown menu with the following options:
    - Access to logout
    - Access to the About popup
    - Name and email of the currently logged-in user



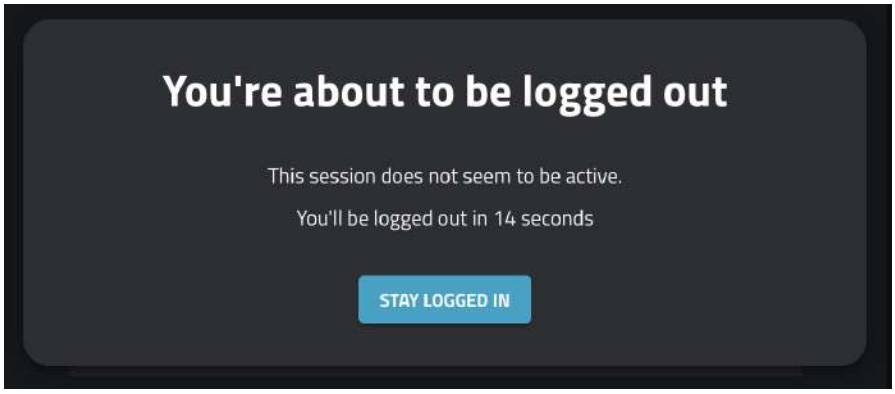
Both the Home icon and the logo will redirect the user to the Select Interface.

Logout

To log out of the brAIn™ Shoulder Positioning software, the user must open the dropdown menu in the top-right corner of the webpage and click on 'Logout':



The user will also be automatically logged out after **30 minutes of inactivity**. A pop-up window (as shown below) will appear 1 minute before the automatic logout to warn the user. Clicking “STAY LOGGED IN” will maintain the current session and keep the user on their present page. Please note that the segmentation process during plan creation, which may take longer than 10 minutes, is not considered inactivity.



⚠ Closing the web browser tab or exiting the browser will close the software, but it will not terminate the current user session. The user must manually log out using the method described above, or their session will remain active for 30 minutes before automatically ending due to inactivity.

First connection

Within a few minutes after account creation, the user will receive a welcome email with a first-time connection password.

⚠ If the user doesn't receive the welcome email, they should check their spam folder. If it's not there, they should contact customer support (see Troubleshooting & Contact Information).

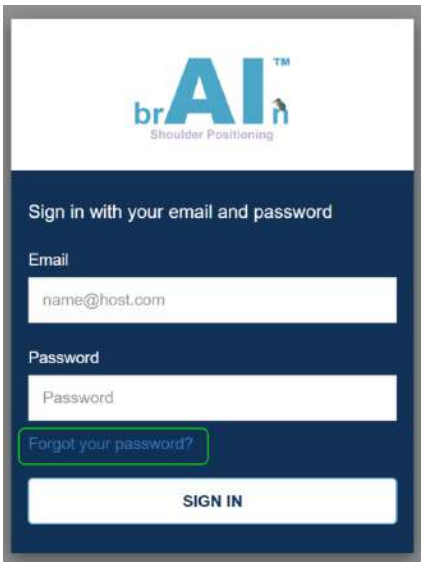
The user must log in with their email and first-time connection password. If the credentials are correct the user will be redirected to a form to configure their connection password:

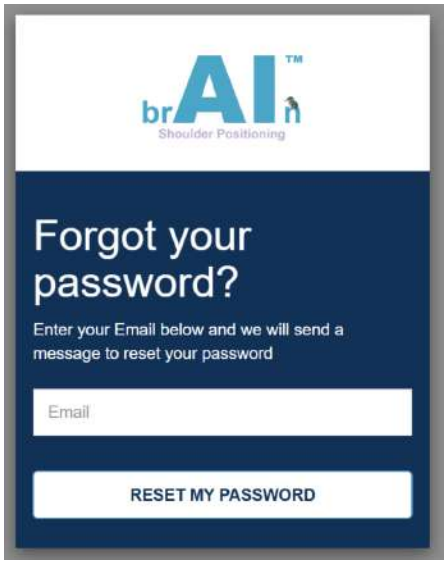
If all the password validation rules are met, clicking “SEND” will redirect the user to the **Select Interface**. The chosen password will then be used for all subsequent connections.

⚠ This password is temporary and must be used within **72 hours** of account creation. After this period, the user should contact customer support (see Troubleshooting & Contact Information).

Password forgotten

If the user has forgotten their password, they can click on the “Forgot your password?” hyperlink on the **Connect Interface** and they will be redirected to the following form:

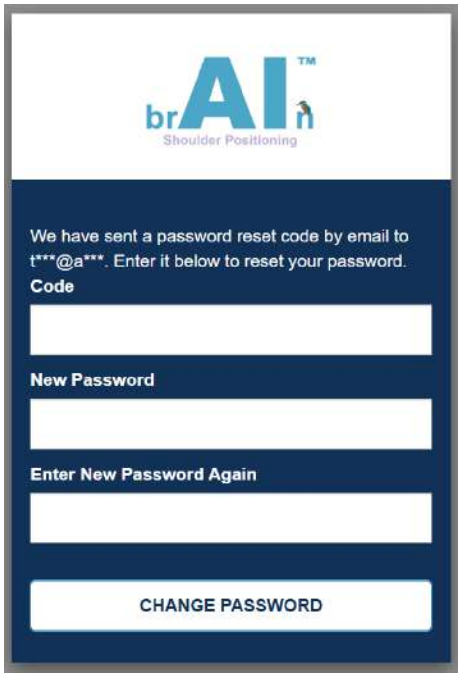




If the email submitted in the form corresponds to a valid user account, an email containing a password reset code will be sent to the email address.

⚠ This reset code is temporary and must be entered within **8 minutes**.

The reset code must be submitted in the password update form along with the user's new choice of password and its confirmation:

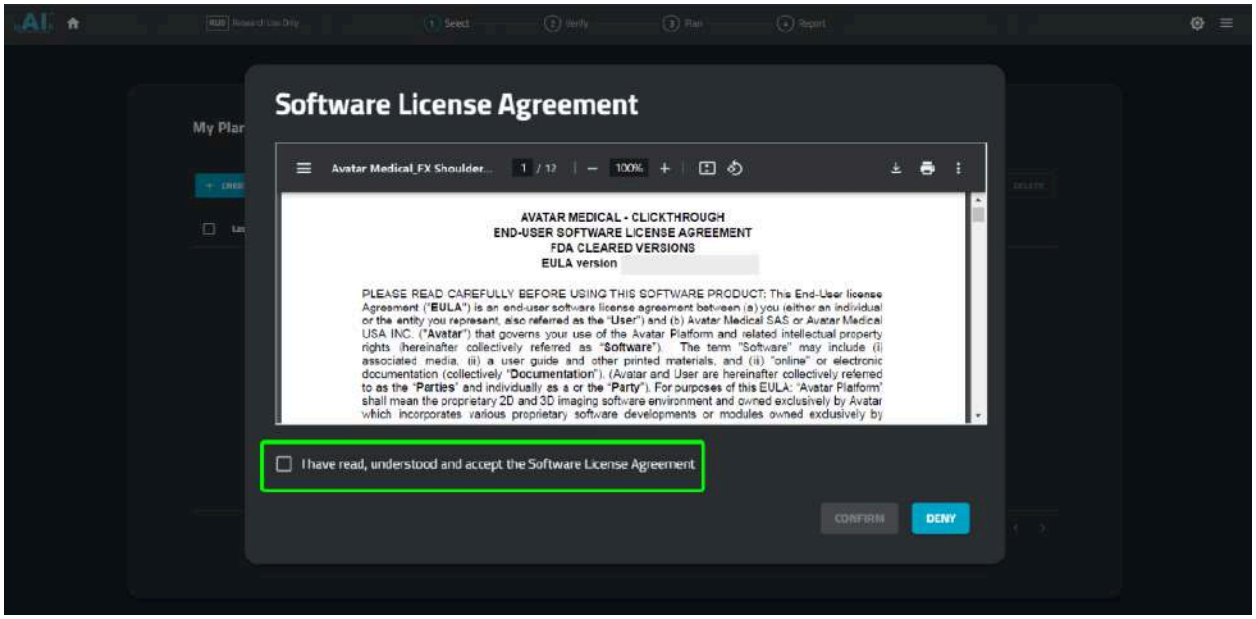


💡 If the password reset code is not used (for example, if the user has remembered their password in the meantime), the old password remains valid. It is not mandatory to update it.

⚠ If the user receives a password reset email without initiating the request, we recommend the following actions:
- Secure the account: the user should update their password immediately to ensure the account's security
- Contact support if the user has any concerns or notices suspicious activity on their account (see Troubleshooting & Contact Information)

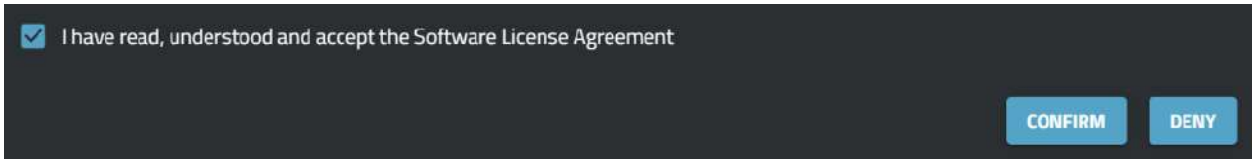
End-User License Agreement

Once authenticated, the user must validate the current version of the End-User License Agreement (EULA) if they wish to continue and use the features of the brAIn™ Shoulder Positioning software. If this validation has not yet been performed by the user, the EULA document will be displayed in PDF format in a dialog:



The user can download or print the EULA using the dedicated icons in the embedded PDF viewer if they wish to save it.

The "CONFIRM" button will only become clickable when the "I have read, understood and accept the Software License Agreement" has been checked:



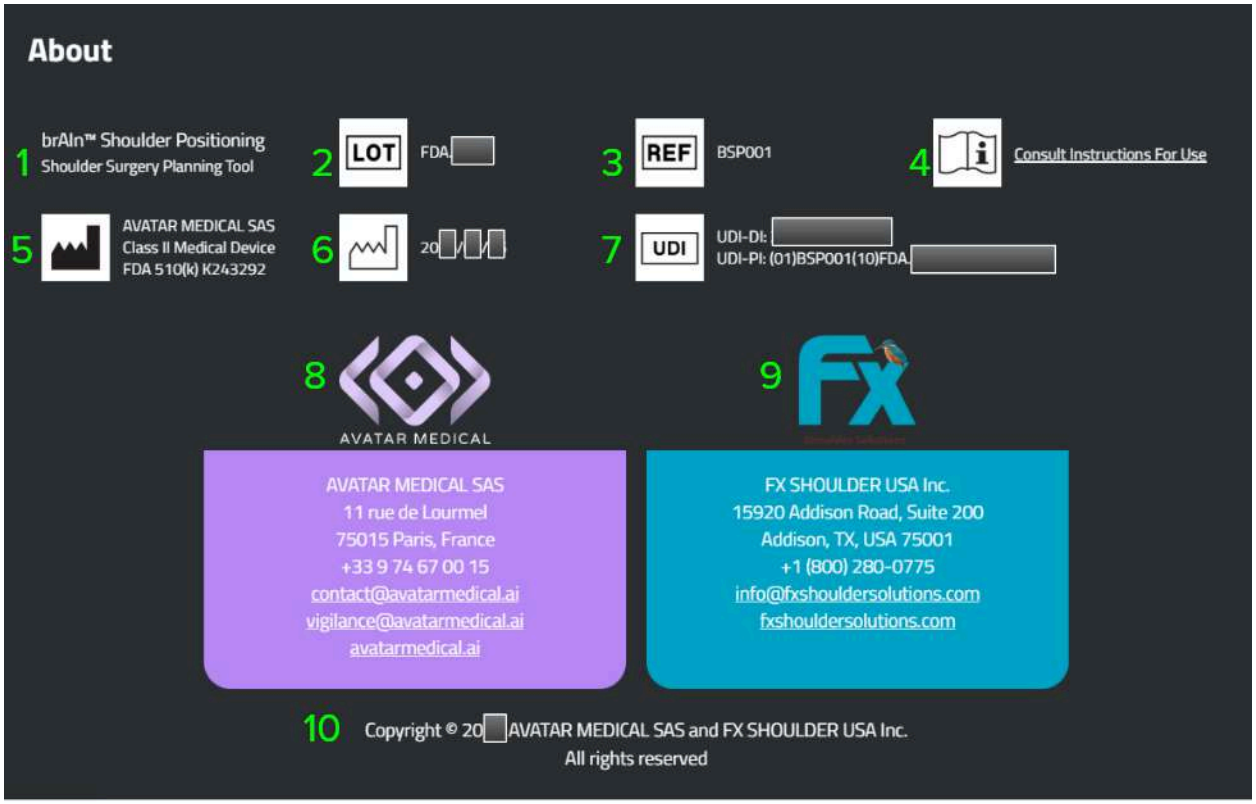
Clicking “DENY” will automatically log off the user, redirecting them to the homepage. It will be possible for the user to log in again, the EULA validation dialog will be displayed once more. The only way the **Select Interface** can be accessed by the user is if the End-User License Agreement is validated by them.

💡 The End-User License Agreement may change over time. If updated, the user must validate the new version to retain access to the software. For any questions or disagreements, the user can contact customer support (see Troubleshooting & Contact Information).

About popup

The About popup is available from the Navigation Bar’s dropdown menu. It contains the following elements:

1. Software name and marketing product description
2. Version number
3. Software reference
4. A link to access the Electronic User Manual in PDF format
5. Manufacturer
6. Manufacture date
7. UDI-DI and UDI-PI
8. Avatar Medical logo, address and contact information
9. FX Shoulder Solutions logo, address and contact information
10. Copyright information

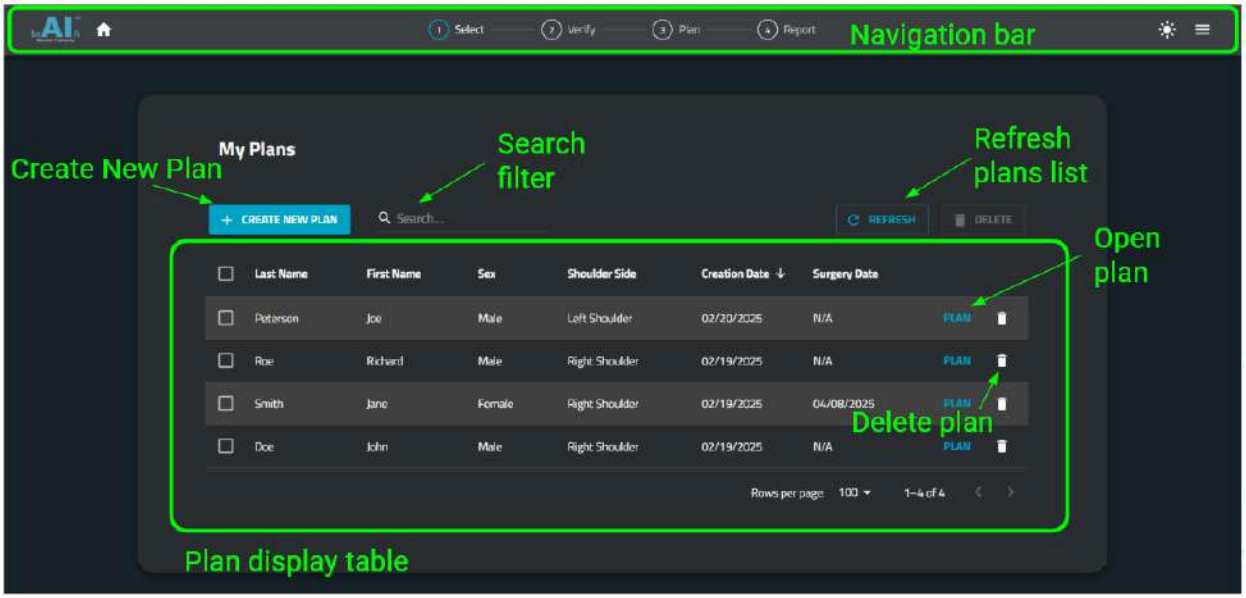


Plan Management

Select Interface

The Select Interface is the webpage the user is redirected to after a successful login. It displays the following elements:

- A table displaying a list of all plans created by the user, featuring buttons to either open or delete each plan
- A “CREATE NEW PLAN” button: clicking this button will start a new plan creation process
- A search filter
- A button to manually refresh the plans list



My Plans

Plans table

The My Plans table contains the list of all the plans created by the user connected to the application. The following graphical components are available for each plan in the table:

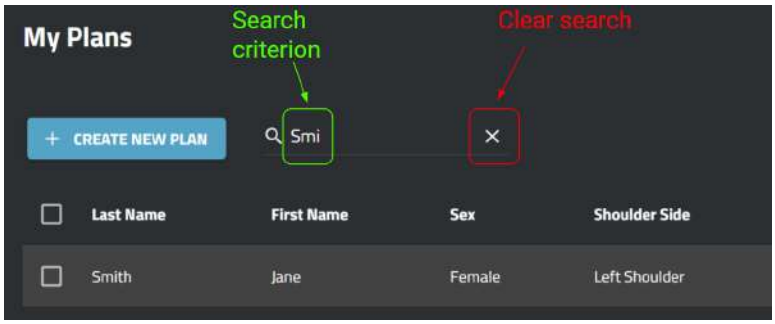
- A checkbox to select the corresponding plan
- Last Name
- First Name
- Sex
- Shoulder Side (left or right shoulder)
- Creation Date (date on which the plan was created by user)
- Surgery Date if entered by the user at the time of plan creation (if not, ‘N/A’ will be displayed)
- A “PLAN” button to open the corresponding plan
- A trash icon button to delete the corresponding plan

The following columns can be sorted by clicking on the arrow icon that appears when the user hovers over the column header: Last Name, First Name, Sex, Shoulder Side, Creation Date and Surgery Date. The default sorting is by descending Creation Date (most recently created plans at the top of the list).

At the bottom of the table, the user can find pagination controls which are useful if there are many plans to be displayed:

Search filter

The user can narrow down the list of plans displayed in the table by entering a search criterion (at least one letter or digit):

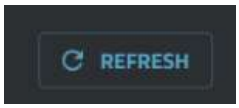


Only plans that match this criterion will be shown. The search filter looks for case-insensitive matches on ‘Last Name’, ‘First Name’, ‘Sex’, ‘Shoulder Side’, ‘Creation Date’ and ‘Surgery Date’. If at least one of the columns contains the search criterion, the plan will be displayed.

The search filter can be cleared by manually deleting the criterion or clicking on the ‘X’ icon.

Refresh button

The plans list is automatically refreshed each time the Select Interface is displayed and when a plan is deleted by the user. A manual refresh can also be performed by clicking on the Refresh button:

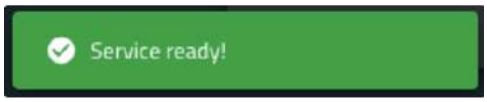


Planning service availability

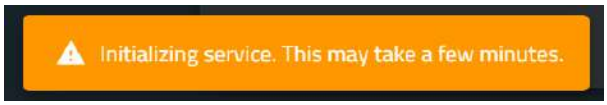
When the user logs in to the brAIn™ Shoulder Positioning application, the software checks whether cloud resources are available to create a plan or to load an existing one. While this check is being performed, the “PLAN” buttons in the “My Plans” table are disabled and cannot be clicked.

The results of this verification are displayed in a message that appears temporarily in the bottom-left corner of the screen and fades away after a few seconds:

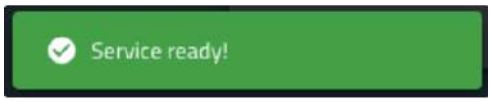
- If resources are available, the following message is displayed:

  “PLAN” buttons are enabled and become clickable in the “My Plans” table.
- If no resources are available at the time, the following message is displayed:

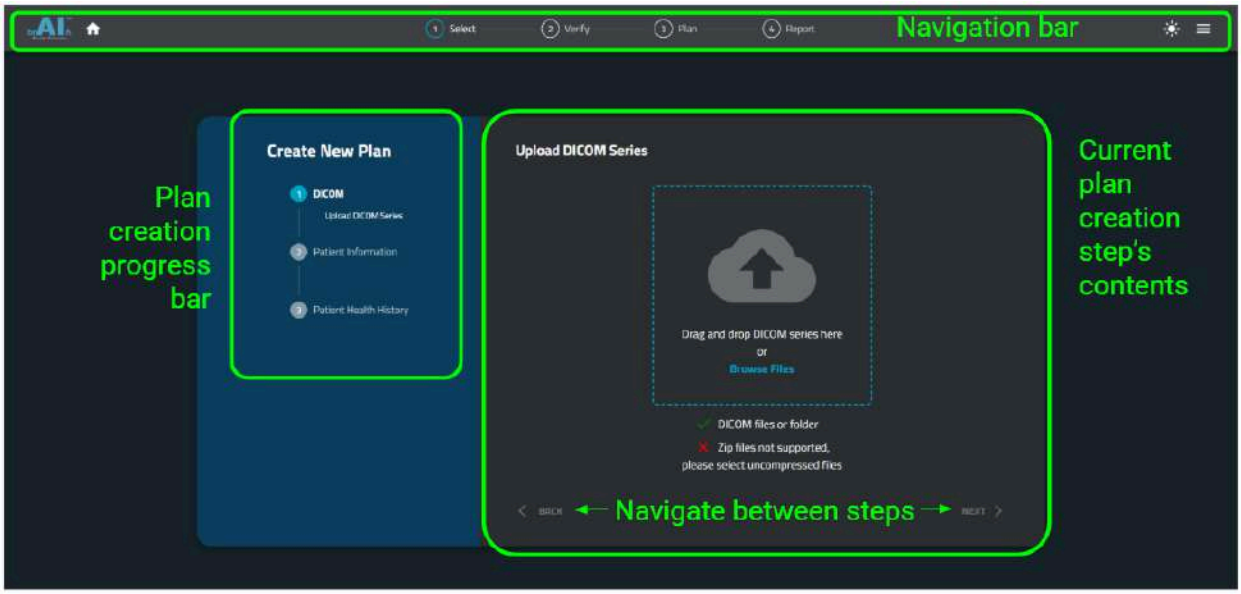
  

  The “PLAN” buttons remain disabled so the user cannot open any plan.
  The software will keep checking regularly for available resources, once they become available the “Service ready!” message will be displayed (no need to refresh the webpage or log in again):

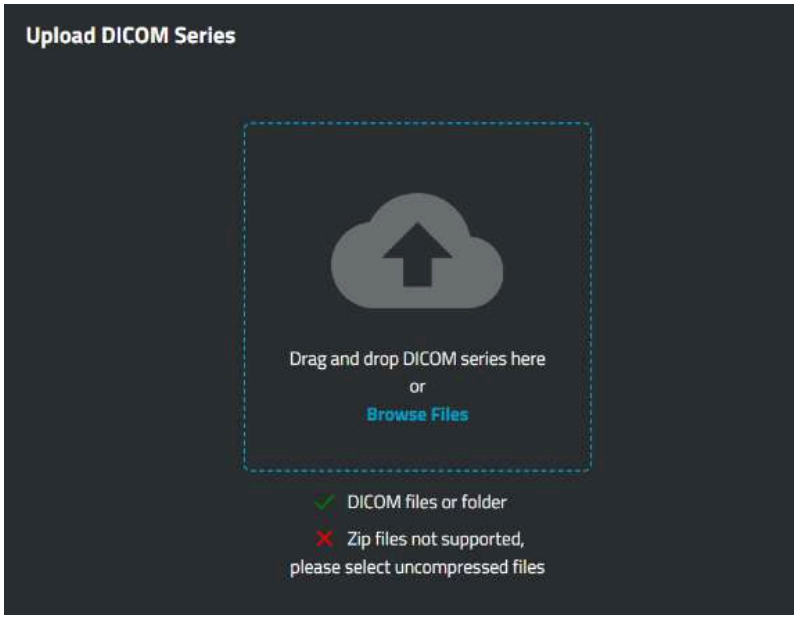
Creating a plan

To create a plan, the user must click the “CREATE NEW PLAN” button. It will start a 3-step process whose progress can be tracked in a vertical progress bar in the left part of the screen:



Step 1: Upload DICOM Series

The user must select the DICOM files corresponding to the CT series that they wish to base their shoulder surgery planning on. To do this, they can either drag and drop the files in the designated area (blue dash-dotted line) or click on “Browse Files” and select the files in their native file browser.



When the selection is complete, the user must click on the “NEXT” button in the bottom-right corner of the screen.

⚠ Zip files are not supported, only uncompressed files must be selected.

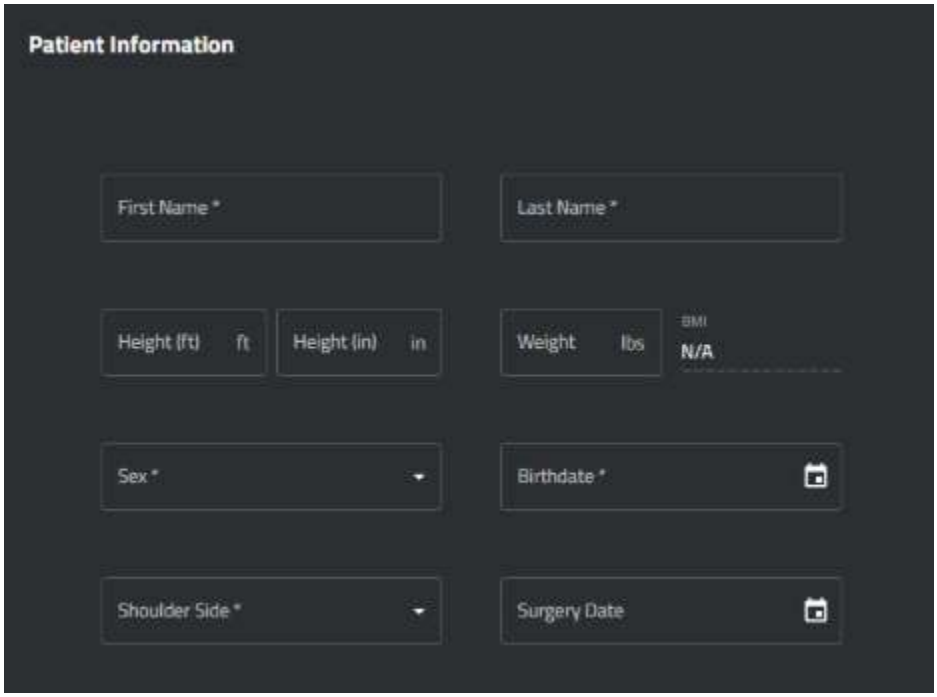
💡 Users can select either multiple files or a single folder containing all the CT series’ DICOM files.

⚠ brAIn™ Shoulder Positioning does not support loading multiple CT series in a single plan. If the user wishes to use 2 separate CT DICOM series for their pre-operative planning, they must create 2 plans.

⚠ brAIn™ Shoulder Positioning only supports **axial** CT series. If the user attempts to load multiple CT series, brAIn™ Shoulder Positioning will choose the axial CT series with the highest number of frames.

Step 2: Patient Information

The user must then enter the patient information associated with the CT series selected in the previous step. Mandatory information is indicated with an asterisk.

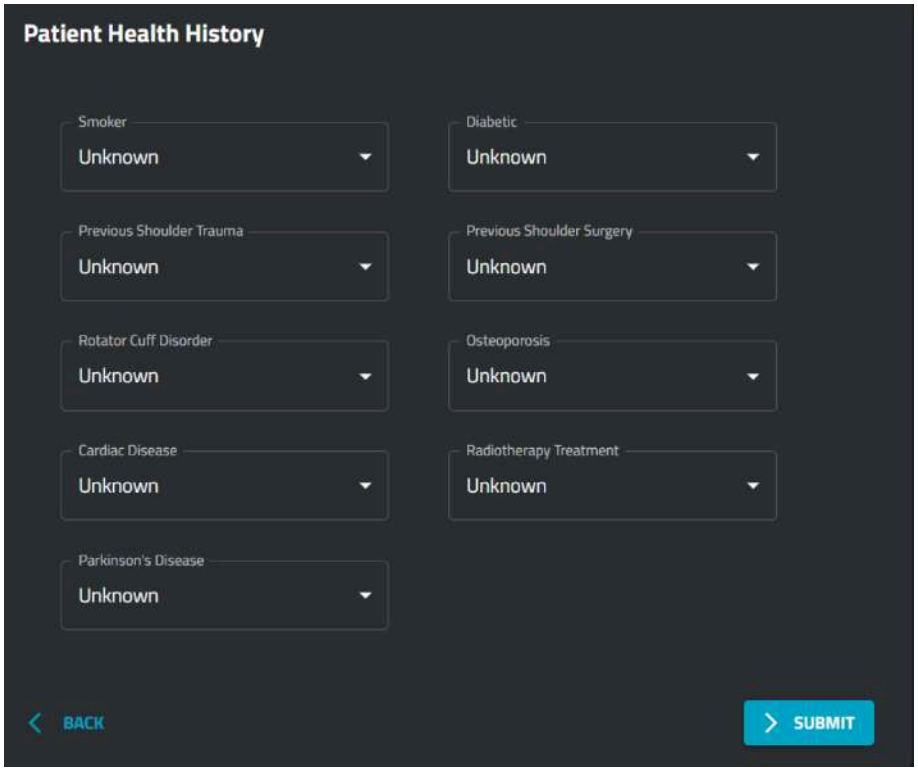


The user must click on the “NEXT” button in the bottom-right corner of the screen to access the third and final step. If any required patient information is missing, the user will not be able to access the next step. Missing or invalid fields will be highlighted in red to help the user fill out missing information.

⚠ brAIn™ Shoulder Positioning will not compare the patient information entered by the user in this step with the metadata of the DICOM files selected in step 1: users must be extremely careful about submitting information that corresponds to the DICOM files they have selected for upload.

Step 3: Patient Health History

The user can choose to enter details regarding the patient’s medical history in this third and final step. All fields are optional:



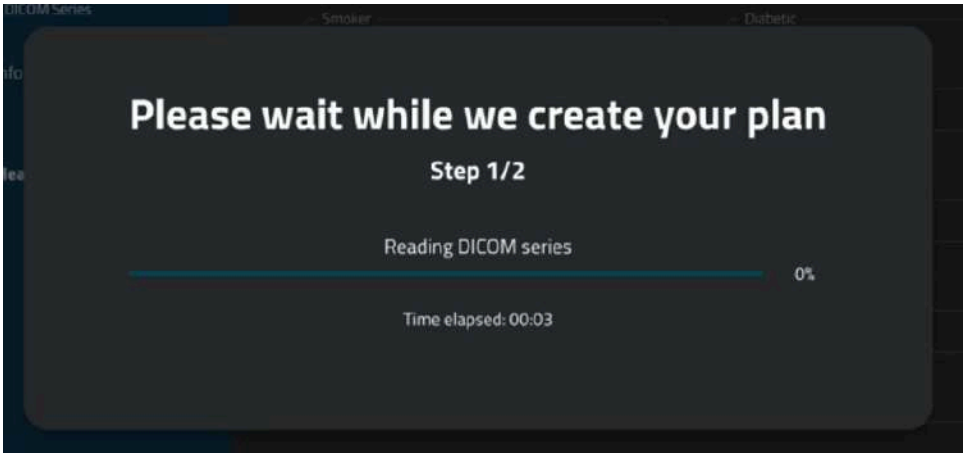
This information will not be displayed in the Select Interface or Plan Interface, it will only be visible in the Surgical Planning Report.

After reviewing their input, the user can click on the “SUBMIT” button to finalize the creation of the plan.

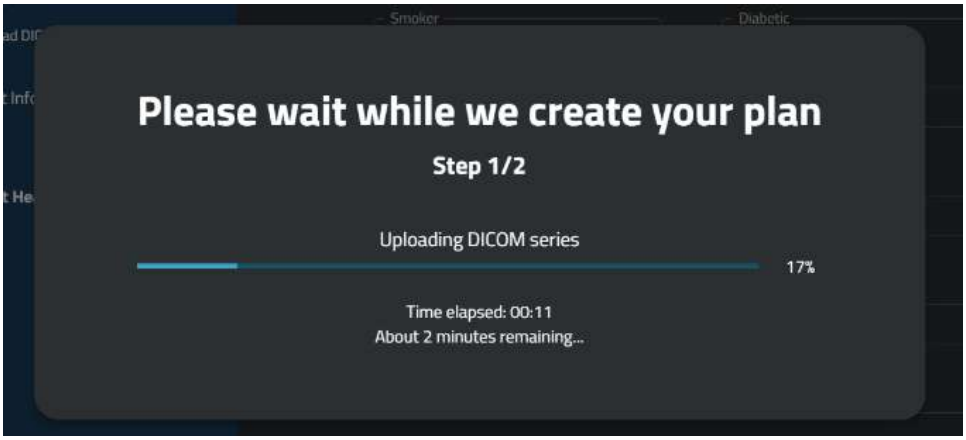
⚠ brAIn™ Shoulder Positioning does not support modifying the patient information and patient health history entered in steps 2 and 3 once the plan creation has been submitted. Users should review carefully before finalizing their input.

A loading screen popup will appear with an animated progress bar detailing 2 steps:

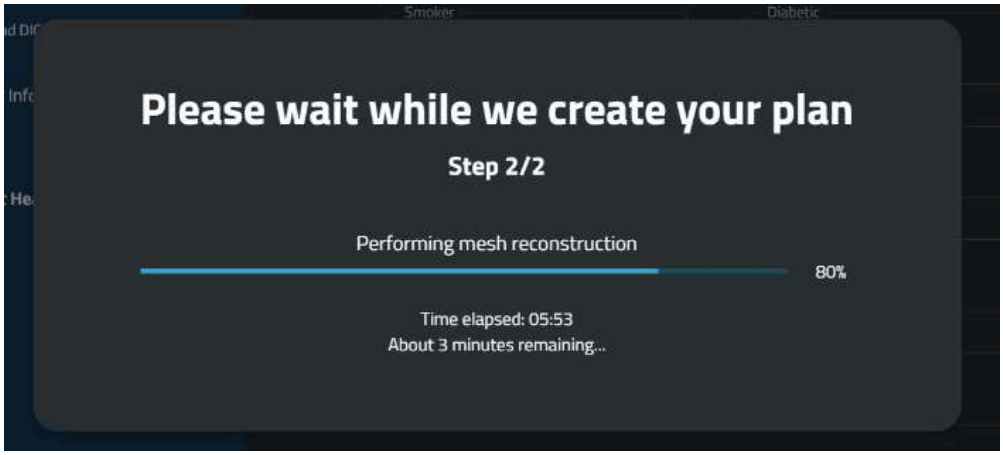
1. **File upload:** this step, labeled ‘Step 1/2’, corresponds to the files selected by the user being uploaded to brAIn™ Shoulder Positioning’s cloud platform. The upload speed will depend on the user’s Internet connection. The progress bar shows the user how much time has passed since the plan creation started, along with an estimated time remaining (once the file upload begins). It also displays a clear label indicating which process the software is currently performing:
    - **Reading DICOM series:** Before the transfer actually begins, the computer quickly prepares the selected files in the background. This preparation step can take a little longer if the files are stored on a slower device, such as a CD drive.



- **Uploading DICOM series:** The files are uploaded to the cloud platform, scanned by an antivirus, checked for DICOM compatibility and anonymized before being sent to the application's storage.

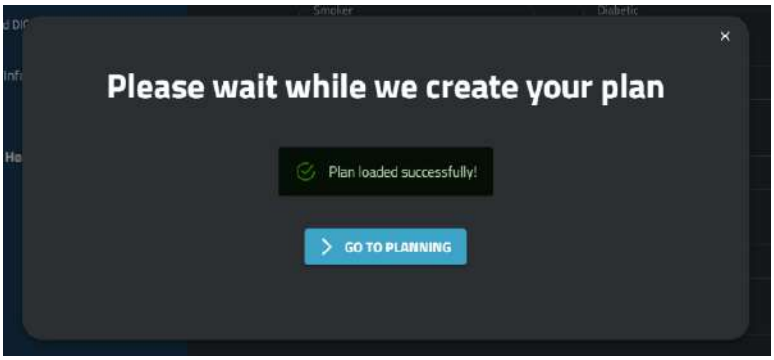


2. **Plan creation:** this step, labeled 'Step 2/2', corresponds to the processing of the DICOM images now available on the platform. It is the lengthy part of the plan creation process and can take up to 10-15 minutes. The progress bar indicates to the user the time elapsed since plan creation started, an estimation of the time remaining and a label to specify what is being done by the software:
    - **Retrieving DICOM:** CT images are loaded into memory
    - **Performing anatomy detection:** this is where the software's AI algorithm automatically segments the scapula and humerus bones in the CT data
    - **Performing mesh reconstruction:** this is where the software converts the results of the segmentation algorithm into 3D objects (meshes)
    - **Performing morphology analysis:** this is where the software detects the position of shoulder landmarks (refer to section Shoulder landmarks for more information)

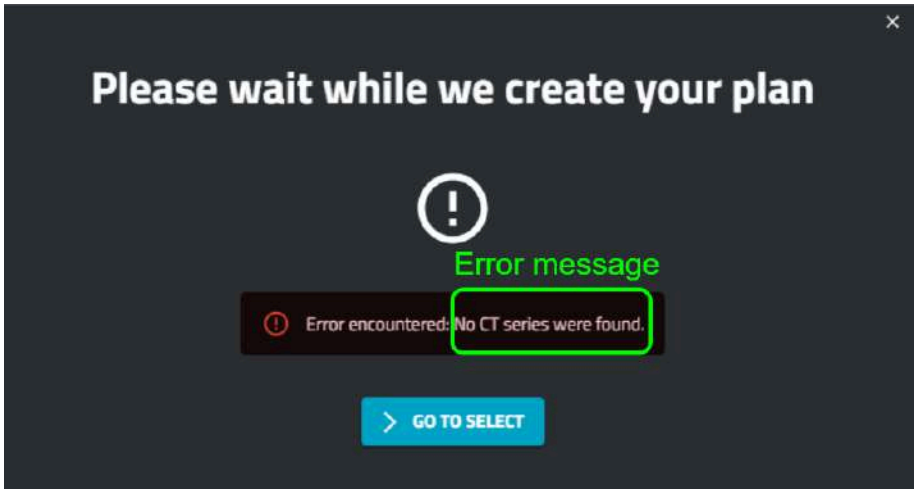


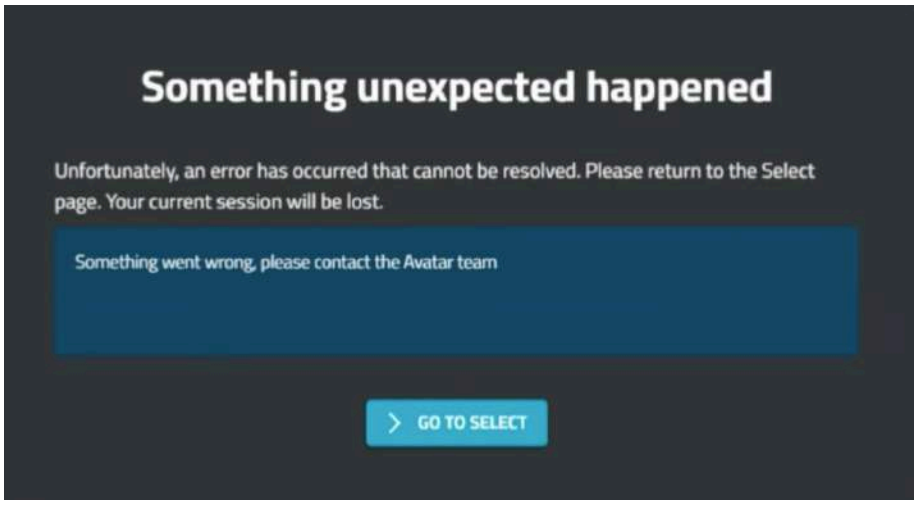
⚠ The displayed remaining time is an **estimate** and may not be exact. Please allow for a margin of error.

When the plan creation is finished, the progress bar is replaced by a “Plan loaded successfully!” message. The user must click on the “GO TO PLANNING” button to access the Planning Interface (see Pre-Operative Planning):



If any problem occurs during plan creation, an error message will be displayed, prompting the user to return to the Select Interface:





The complete list of error messages is described in the table below:

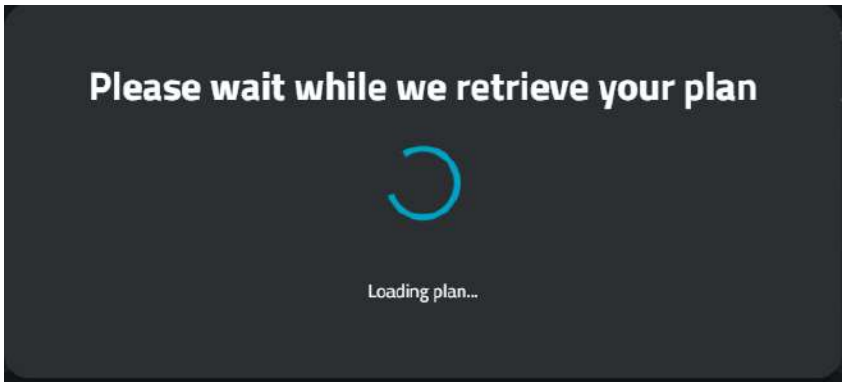
Reference	Error message	Explanation and trouble-shooting
E1	*Error while uploading DICOM*	This error may occur if one of the uploaded files is blocked by the user's antivirus software or if there is a network issue. Please check and verify the files, and ensure the connection is stable before uploading again.
E2	*Failed to retrieve plan information.*	Internal system error. This error cannot be resolved by the user. Please try reloading the plan and contact customer support if the issue persists.
E3	*Failed to convert DICOM files.*	Internal system error. This error cannot be resolved by the user. Please try another CT

		series if available and contact customer support if the issue persists.
E4	*No valid DICOM series were found.*	Please verify your file selection to include a CT series matching our recommended CT Scan protocol.
E5	*No series with an axial, non-oblique orientation were found.*	Please verify your file selection to include a CT series matching our recommended CT Scan protocol (axial series).
E6	*No CT series were found.*	Please verify your file selection to include a CT series matching our recommended CT Scan protocol.
E7	*Failed to retrieve DICOM files.*	No valid DICOM files were recognized and do not meet any of the error conditions E4, E5 or E6.
E8	*The selected DICOM series exceeds the supported size (maximum {N_{Slices}} slices for size {N_{Row}}*{N_{Column}})*	Please try to adjust the number of files uploaded for the CT series or select another series matching our recommended CT Scan protocol.
E9	*Shoulder bone anatomies could not be segmented.*	Please review our Contraindications and recommended CT Scan protocol. If the selected files meet both criteria, please contact our customer support team.
E10	The segmentation could not be converted into a 3D surface.	This error cannot be resolved by the user. Please contact customer support.
E11	Shoulder landmarks could not be detected.	This error cannot be resolved by the user. Please contact customer support.
E12	Failed to update the plan.	Internal system error. Some plan modifications may not have been automatically saved successfully. Please try reloading the plan, verify plan information and contact customer support if the issue persists.

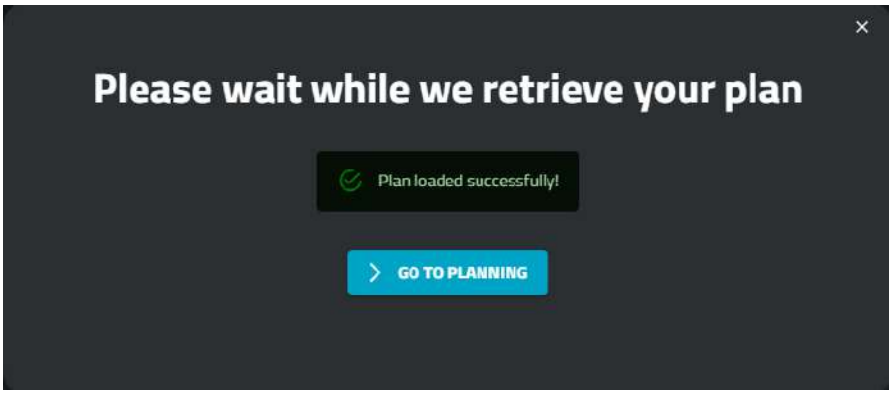
Opening a plan

To open a plan already created from the Select Interface (for example if the user did not have the time to complete the planning at the time of plan creation and wants to resume it), the user must click on the “PLAN” button of the plan they wish to open in the “My Plans” list.

A loading screen popup will appear with an animated loading icon:



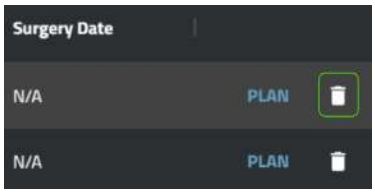
When the plan is loaded, the user must click on the “GO TO PLANNING” button to access the Planning Interface (see Pre-Operative Planning):



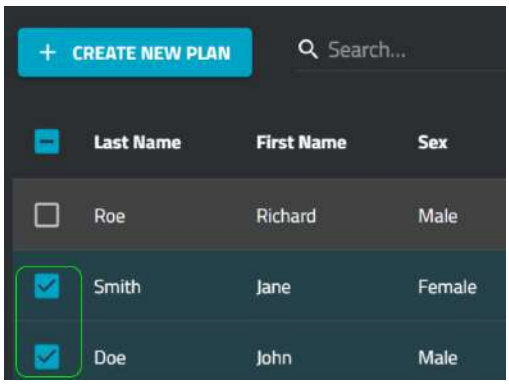
Deleting a plan

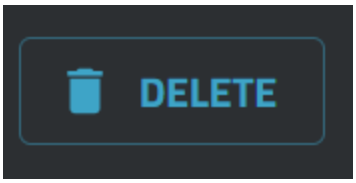
The user can delete a plan from the Select Interface. A plan can be deleted in 2 ways:

1. By clicking on the trash icon at the end of the plan row in the My Plans table:



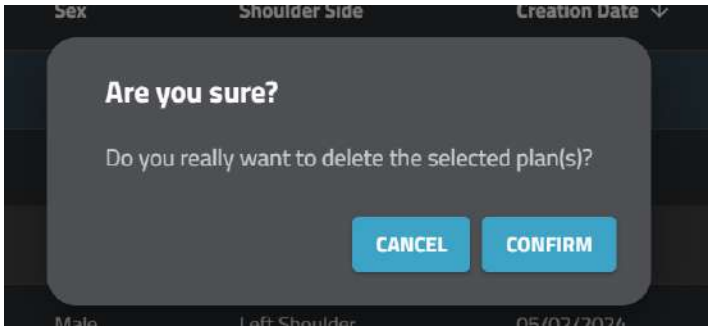
2. Selecting one or several checkboxes at the beginning of the plan row in the My Plans table and clicking the “DELETE” button in the top right corner of the table:





The number of rows selected for deletion is displayed at the bottom of the table.

In both cases, a confirmation dialog will be displayed to the user:



⚠ Plan deletion cannot be undone! All plan information will be lost.

Pre-Operative Planning

Planning tools

This section describes the common tools and user interface components available across the various pre-operative planning interfaces in brAIn™ Shoulder Positioning.

Planning tabs

There are 5 tabs to navigate between the different steps of implant planning:

1. **Pre-Position:** validation of the shoulder landmarks and soft tissue visualization
2. **Implant:** selection of the FX Shoulder Solutions implant
3. **Glenoid:** selection and placement of the glenoid components of the implant
4. **Humerus:** selection and placement of the humeral components of the implant
5. **Post-Position**: glenoid and humeral implants are displayed and aligned together, access to the Surgical Planning Report

Initially, only the Pre-Position tab is accessible to the user and the other tabs are disabled (gray text, tab header not clickable):

Once all the shoulder landmarks have been validated by the user, the Implant tab becomes accessible (the Glenoid, Humerus and Post-Position tabs remain disabled):

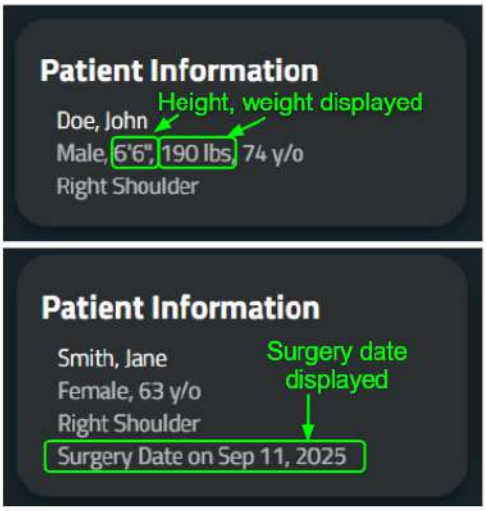
Then, after the user has selected an implant in the Implant tab, the remaining tabs become accessible (white text, tab header clickable). The tab currently selected is the one whose header text is in blue color with a blue underline:

💡 The user is free to navigate between all enabled tabs (e.g. it is possible to go back to the Pre-Position tab at any time).

Patient Information Panel

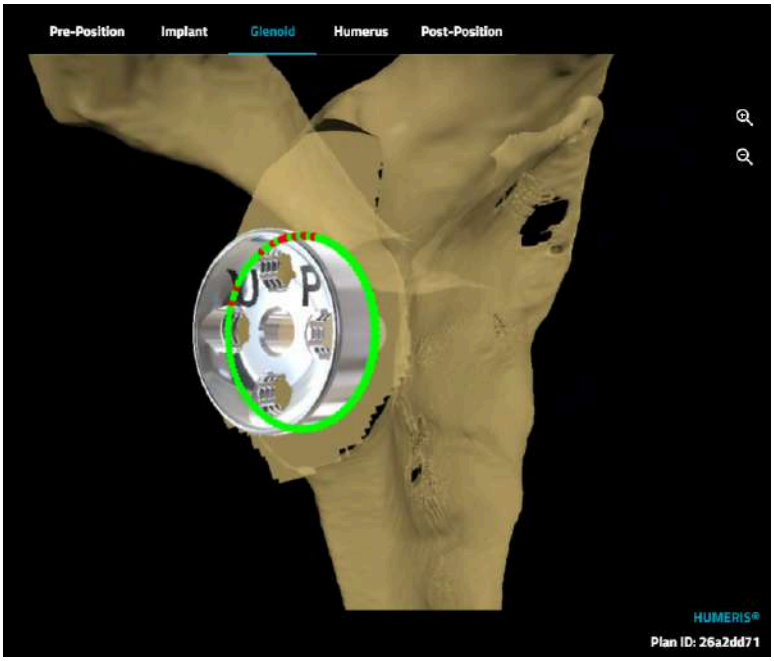
A Patient Information Panel is located in the top left corner of all Planning tabs, helping to minimize the risk of patient identity mistakes. It contains the following information:

- Patient Name displayed in “Last Name, First Name” format
- Sex, Height (if the field was filled), Weight (if the field was filled) and Age
- ‘Right Shoulder’ or ‘Left Shoulder’ label
- ‘Surgery on’ label with the date of surgery if entered at the time of plan creation, otherwise nothing will be displayed



3D Viewer

The Pre-Position, Glenoid, Humerus and Post-Position tabs give the user access to a 3D Viewer that can display a 3D visualization of the humerus and/or scapula, the implant components selected by the user as well as shoulder measurements. The ‘Plan ID’, an 8-character identifier, is also shown in the 3D Viewer.



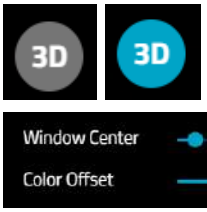
Users can interact with the 3D Viewer in 2 ways:

- **Zoom:** the user can zoom in or out using the mouse wheel or by clicking the zoom control icons located on the right side for precise adjustments.
- **Rotation:** the user can click and hold the left mouse button and move the mouse to rotate the 3D visualization

3D Viewer Toolbox

A toolbox containing context-specific buttons allows customization of the 3D visualization; the available buttons vary based on the selected planning tab:

Icon	Icon button name	Description
	Humerus	Will hide/show the humerus anatomy
	Scapula	Will hide/show the scapula anatomy

	K-Wire	When enabled, will hide any selected implant components and display the K-Wire instead
	Reaming	Will hide/show the visual effect of glenoid reaming
	Full Opacity	When enabled, the shoulder meshes become fully opaque. By default, the 3D rendering of the Humerus and Scapula is partially transparent.
	3D Visualization Filter	**Window Center:** this slider allows the filter's window center to move along the intensity grayscale of the original CT scan image. By adjusting the slider to the left, where lower intensity values are displayed, soft tissues become more visible. Moving the slider to the right, towards higher intensity values, makes bones more prominent, reflecting the typical intensity ranges of different tissues in a CT scan. **Color Offset:** will affect the color filter applied to the 3D image. Moving the slider to the left will apply lighter shades to the viewing window, while moving it to the right will apply darker shades.

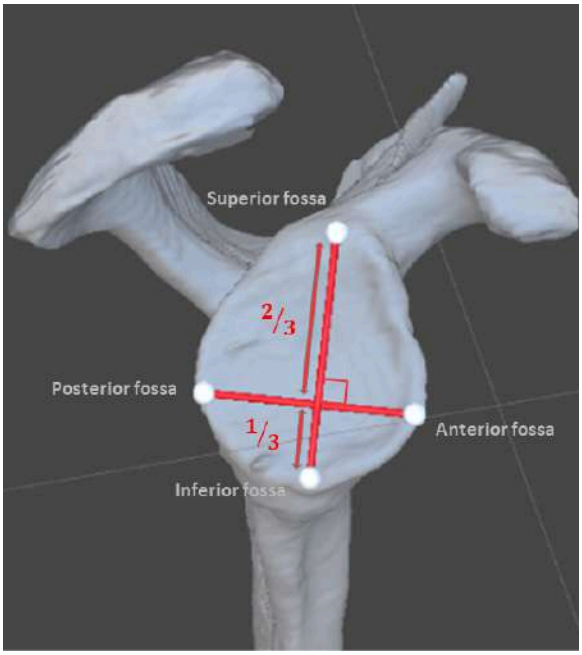
💡 We recommend that users first adjust the Window Center slider to select the anatomy of interest. Once the desired tissues are highlighted, they can fine-tune the appearance by adjusting the Color Offset.

Shoulder landmarks

The brAIn™ Shoulder Positioning software automatically determines the position of the following shoulder landmarks based on the segmented bone anatomies:

Landmark Name	Landmark Bone Anatomy	Description

Trigonum Spinae	Scapula	Most medial point of the scapula
Angulus Inferior	Scapula	Most inferior point of the scapula
Glenoid Center Point	Scapula	Anatomic center of the glenoid fossa
Superior Fossa	Scapula	Extremities of the greatest infero-superior distance on the glenoid perimeter (see illustration below)
Inferior Fossa	Scapula	
Anterior Fossa	Scapula	Extremities of the orthogonal to the Inferior Fossa-Superior Fossa axis positioned at the inferior third, as described by Dr. Gauci in his thesis[1] (see illustration below)
Posterior Fossa	Scapula	
Humeral Head Sphere	Humerus	Best-fit sphere to the articular surface as defined by Jacxsens[2]
Supraspinatus Fossa Line	Scapula	Best-fit line to points positioned at the bottom of the supraspinatus fossa



[1] Gauci (2019) - 3D Description and Classification of Arthritic Glenes for 3D Computer-Aided Preoperative Planning - Doctoral thesis of Marc-Olivier GAUCI - December 2019

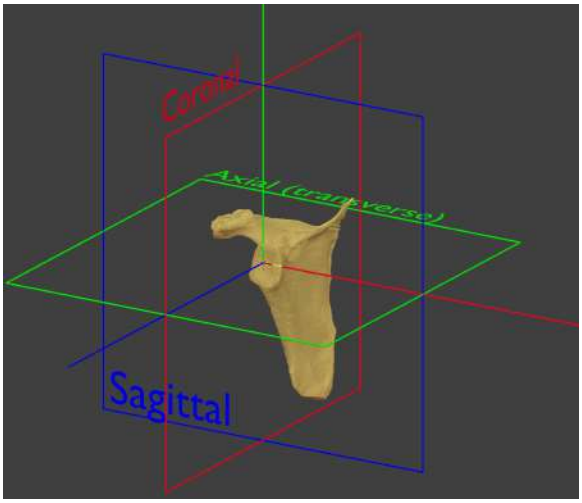
[2] Jacxsens et al. (2016) - A three-dimensional comparative study on the scapulohumeral relationship in normal and osteoarthritic shoulders - Jacxsens M, Van Tongel A, Henninger HB, De Coninck B, Mueller AM, De Wilde L. - J Shoulder Elbow Surg. 2016 Oct

These shoulder landmarks are automatically pre-positioned by the application and can be manually adjusted by the user during the mandatory Shoulder landmarks verification step of the planning workflow. brAIn™ Shoulder Positioning uses these shoulder landmarks to calculate measurements (see the Measurements Panel section below) and to pre-position certain implant components.

Scapular frame of reference

The software makes use of a **scapular frame of reference**, shown in the figure below, to ensure accurate, consistent, and reproducible measurements and implant positioning. Using this frame of reference helps eliminate variability in measurements and part manipulation caused by patient positioning during imaging (DICOM acquisition). It is defined by three orthogonal planes:

- The **Coronal Plane** is defined by 3 points: the *Glenoid Center Point*, the *Angulus Inferior* and the *Trigonum Spinae*
- The normal to the **Sagittal Plane** is the *Supraspinatus Fossa Line* projected onto the Coronal Plane
- The normal to the **Transverse Plane** is perpendicular to the Coronal and Sagittal Plane normals



Measurements Panel

The Measurements Panel, located below the 3D Viewer, displays a list of all measurements calculated by the application:

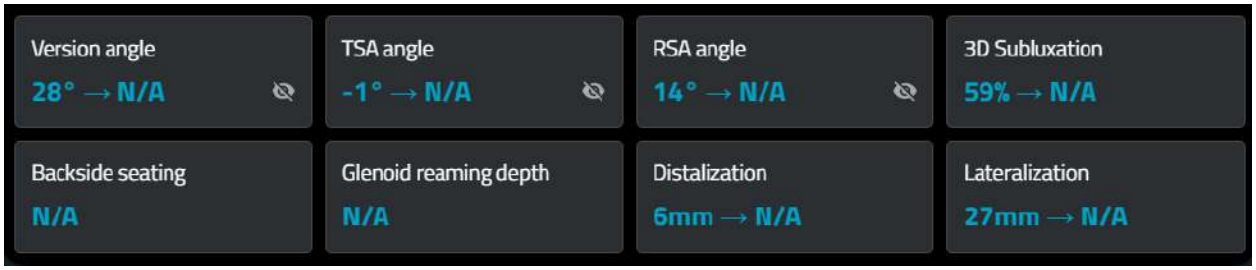
- Version angle

- TSA angle
- RSA angle
- 3D Subluxation
- Backside seating
- Glenoid reaming depth
- Distalization
- Lateralization

Detailed explanations of how these measurements are calculated can be found in the annex Annex 2: Shoulder measurements definitions.

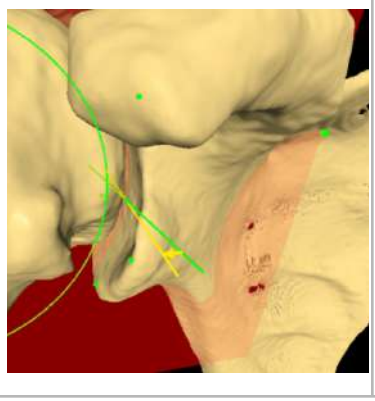
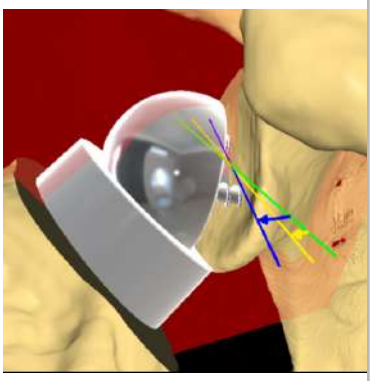
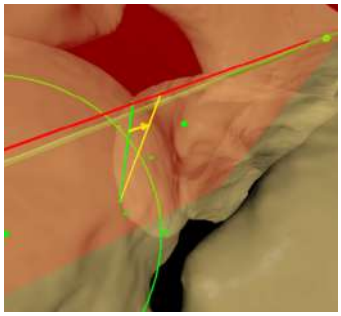
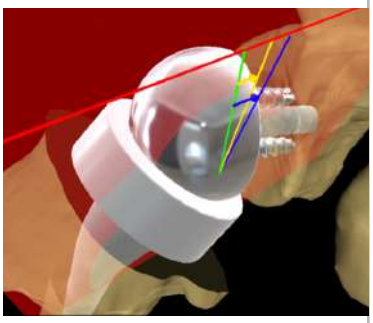
Each measurement is displayed in the following format:

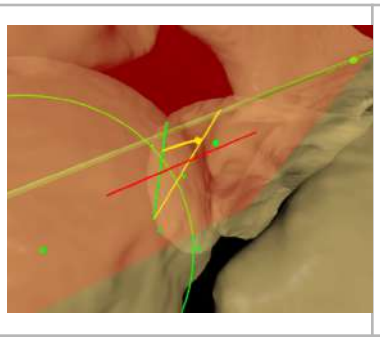
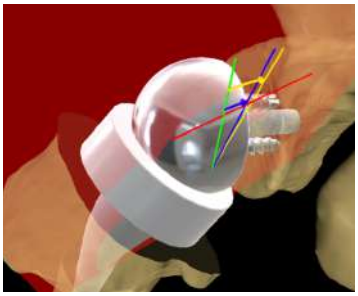
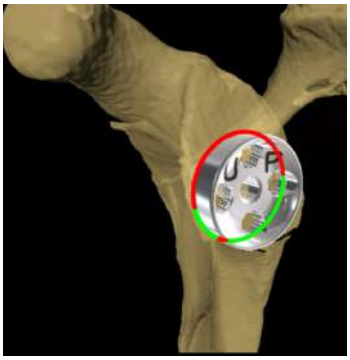
- Measurement name in white text.
- Measurement value(s) in blue text:
    - If the measurement has only a post-position value (e.g., Backside seating), this single value will be displayed along with the measurement unit.
    - If the measurement includes both a pre-position value and a post-position value (e.g. Distalization), both values will be shown along with the measurement unit with a right-facing arrow between them.
- Clicking on a measurement enables its visual representation in the 3D Viewer (see Shoulder landmark and implant component toggles). For each tab, only measurements marked with a slashed eye icon (👁) can be selected. When a measurement is displayed, the icon changes to an open eye, indicating that it is visible in the 3D viewer.

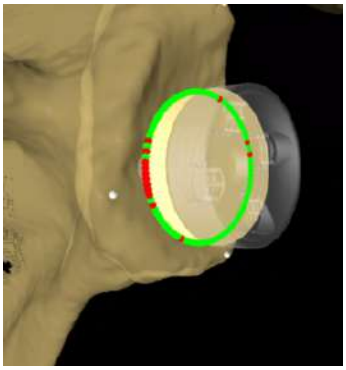
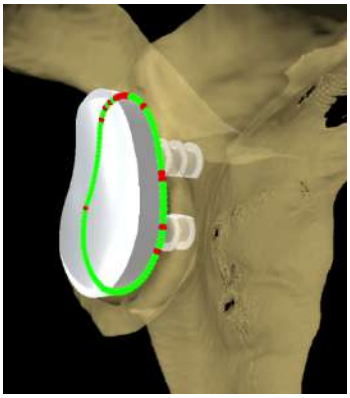


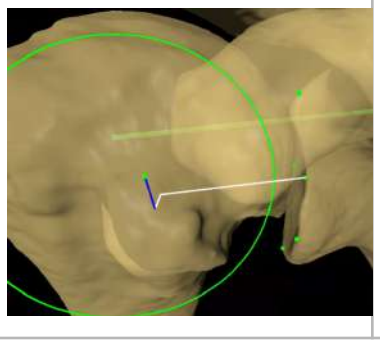
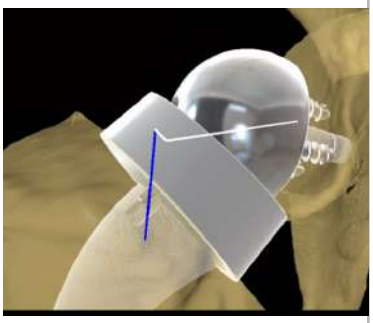
Backside seating and Glenoid reaming depth are the only two measurements that do not have a Pre-Position value because they depend on the presence of an implant. All measurements have Post-Position values.

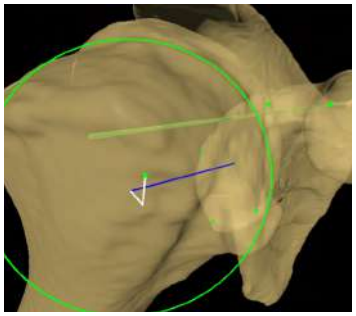
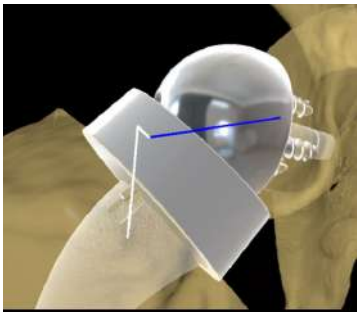
The following table provides details for each measurement, including the measurement unit, measurement precision, as well as the visual representation for each measurement and the determination of the sign of the measurement.

<table>
<tr><th>Measurement Name (Unit / Precision)</th><th>Visual Representation in Pre-Position</th><th>Visual Representation in Post-Position</th><th>Sign of the measurement</th></tr>
<tr><td rowspan="2">Version angle
(Degree / 1°)</td><td>  </td><td>  </td><td rowspan="2">• Positive value: anteversion
• Zero value: neutral version
• Negative value: retroversion</td></tr>
<tr><td colspan="2">Legend:
• Green: reference line (neutral version)
• Semi-transparent red = Coronal Plane
• Yellow: Pre-Position angle
• Blue: Post-Position angle</td></tr>
<tr><td rowspan="2">TSA angle
(Degree / 1°)</td><td>  </td><td>  </td><td rowspan="2">• Positive values: superior inclination of the fossa/baseplate
• Negative values: inferior inclination</td></tr>
<tr><td colspan="2">Legend:
• Green: reference line (neutral inclination)
• Yellow: Pre-Position angle
• Blue: Post-Position angle
• Semi-transparent red: Coronal Plane</td></tr>
</table>

<table>
<tr><td rowspan="2">RSA angle
(Degree / 1°)</td><td>  </td><td>  </td><td rowspan="2">• Positive values: superior inclination of the fossa/baseplate
• Negative values: inferior inclination</td></tr>
<tr><td colspan="2">Legend:
• Green: reference line (neutral inclination)
• Yellow: Pre-Position angle
• Blue: Post-Position angle
• Semi-transparent red: Coronal Plane</td></tr>
<tr><td rowspan="2">3D Subluxation
(Percentage / 1%)</td><td>  </td><td>  </td><td rowspan="2">Always positive or zero (by design)</td></tr>
<tr><td colspan="2">Legend:
• Yellow sphere section = Posterior to the Coronal Plane
• Blue sphere section = Anterior to the Coronal Plane
• Semi-transparent red = Coronal Plane</td></tr>
<tr><td>Backside seating
(Percentage / 1%)</td><td>Not applicable</td><td>  </td><td>Always positive or zero (by design)</td></tr>
</table>

		  Legend: ● Green: Rim of the baseplate/Bio-RSA/glenoid peg with the points in contact ● Red: Points not in contact	
Glenoid reaming depth (Millimeter / 1 mm)	Not applicable	No visual representation, because the average depth is too small to be visualized accurately as a line segment in the 3D Viewer.	● Positive value: bone removed at the *Glenoid Inferior Fossa* level and at the *Glenoid Center Point* level for reverse and anatomical implants, respectively. ● Zero value: no bone removed at the *Glenoid Inferior Fossa* level and at the *Glenoid Center Point* level for

			reverse and anatomical implants, respectively. ● Negative value: implant not in contact with the *Glenoid Inferior Fossa* level and at the *Glenoid Center Point* level for reverse and anatomical implants, respectively; yet, “No reaming” label displayed
Distalization (Millimeter / 1 mm)	 The three components of the vector between the *Glenoid Center Point* and the center of the *Humeral Head Sphere* are visible. Legend: ● Blue: Distalization distance (vertical component, along the normal to the Transverse plane) ● White: the two other components of the Glenoid Center to center of the Humeral Head Sphere vector		The Distalization distance is negative when the center of the *Humeral Head Sphere* is superior to the *Glenoid Center Point*. The delta in Distalization distance is positive when the shoulder joint is shifted inferior compared to the Pre-Position, negative otherwise.

Lateralization (Millimeter / 1 mm)			The Lateralization distance is positive when the center of the *Humeral Head Sphere* is lateral to the *Glenoid Center Point*, negative otherwise. The delta in Lateralization distance is positive when the shoulder joint is shifted lateral compared to the Pre-position, negative otherwise.
	The three components of the vector between the *Glenoid Center Point* and the center of the *Humeral Head Sphere* are visible. Legend: ● Blue: Lateralization distance (horizontal component, along the normal to the Sagittal plane) ● White: the two other components of the *Glenoid Center Point* to center of the *Humeral Head Sphere* vector		

Implant components

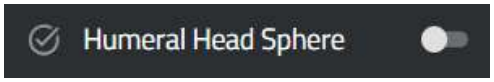
An implant consists of several implant components (baseplate, Bio-RSA, glenosphere, humeral stem, etc). These components can be selected from dropdown lists available in the Glenoid and Humerus tabs. Mandatory components are indicated with an asterisk (*).

Some components are connected through a parent-child relationship, meaning that the movement of the child component will follow the movement of the parent component.

Shoulder landmark and implant component toggles

In addition to the 3D Viewer Settings described above, the brAIn™ Shoulder Positioning software also allows users to select the following items for further manipulation or review using a toggle button:

- Shoulder landmark (for manipulation and review)



- Implant component (for manipulation and review)

⚠ Only one toggle can be switched ON at a time.

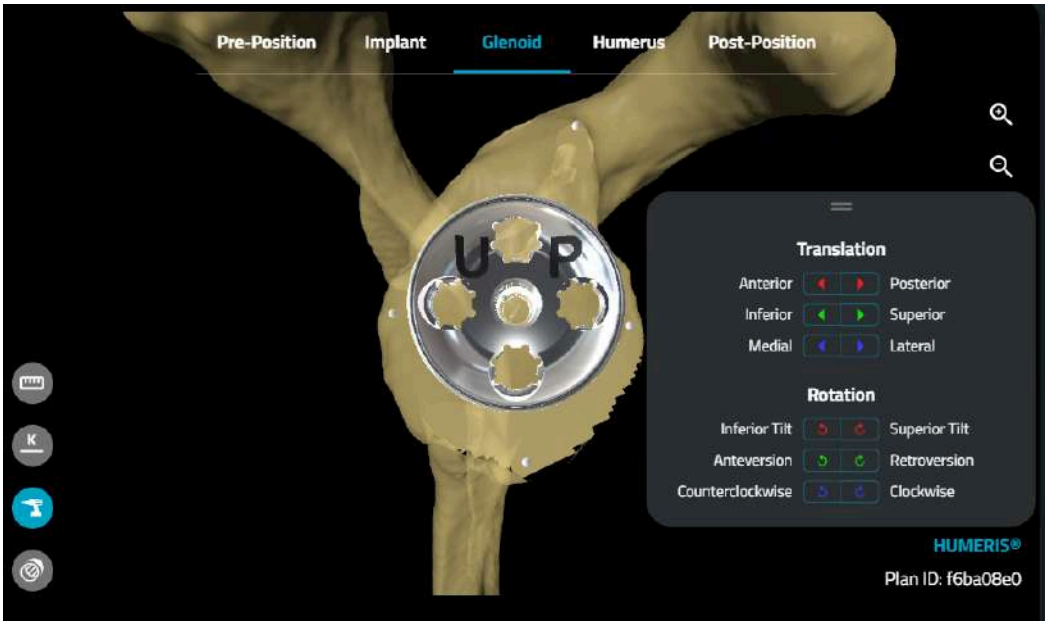
Toggles may be disabled by the application when they are not applicable in the Planning tab currently selected (e.g. the toggle for the “Central Screw” implant part when a peg baseplate is selected).

The following table describes, for an active toggle, the effect of toggling ON or OFF depending on the type of item:

Item	Toggle OFF	Toggle ON
Shoulder landmark	Landmark is visible in the 3D Viewer and displayed either in red or green depending on its validation status.	The 3D Viewer focuses on the selected landmark, which turns the checkbox icon from grey to white. The bone anatomy button the landmark belongs to (humerus or scapula) is activated by default and cannot be disabled. The Manipulation Panel appears for the selected landmark.
Implant component	If a component is selected, its 3D model is displayed in the 3D Viewer (along with any other component selected).	All implant components become transparent except the selected one—unless a Bio-RSA is selected with its baseplate toggled on, in which case the entire Bio-RSA remains opaque. The Manipulation Panel appears for the selected component.

Manipulation Panel

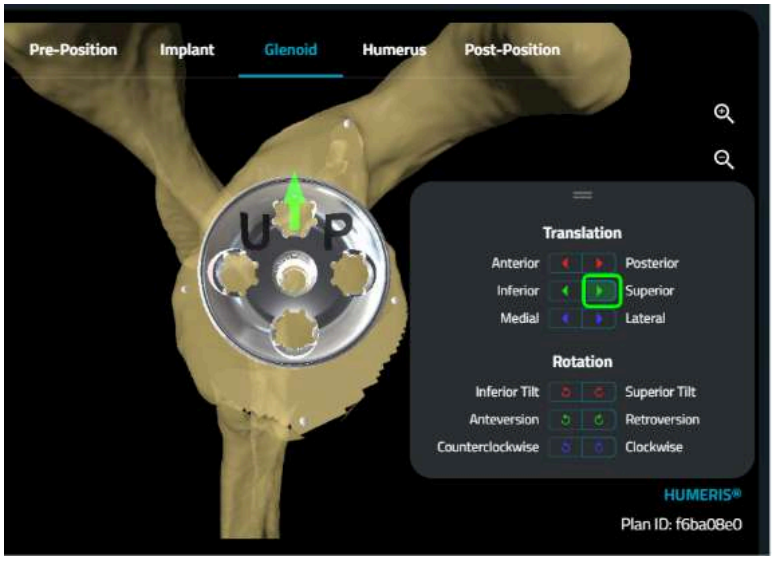
Both shoulder landmarks and implant components can be positioned in the 3D space using brAIn™ Shoulder Positioning’s Manipulation Panel:



It appears only when a shoulder landmark or implant component is selected (see Shoulder landmark and implant component toggles). By default, the Manipulation Panel will be located in the right part of the 3D Viewer, but it can be moved to any location on the webpage.

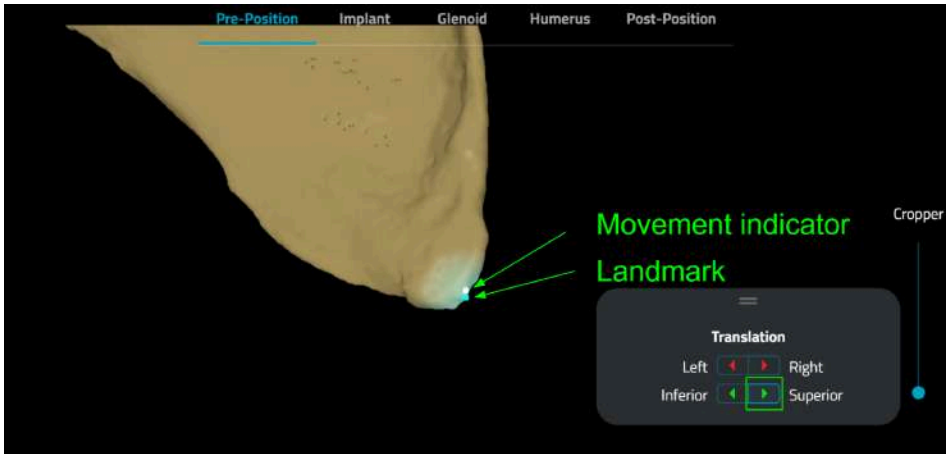
It contains all the degrees of freedom for moving the shoulder landmark or implant component which can be adjusted with left and right arrows. An animation in the 3D Viewer provides a preview of the movement direction:

- For implant components, the animation features an arrow indicating the direction of movement that will occur when the Manipulation Panel button is clicked:



The frame of reference for movement direction is based on the component itself or some axis defined by the shoulder geometry. Directions take the shoulder side into account.

- For shoulder landmarks, the animation is a white dot indicating the direction of movement that will occur when the Manipulation Panel button is clicked:



The frame of reference for movement direction is based on the user's perspective, for example 'Left - Right' corresponds to the Left-Right directions on the 3D Viewer as viewed by the user.

💡 Rotation adjusts by ±1° per arrow click, except for 'Antevert/Retrovert' and 'Superior Tilt/Inferior Tilt' rotations for baseplates, glenoid pegs and the K-Wire, which modify the Version angle and TSA/RSA angle by ±1°.
For Bio-RSA, the rotation adjusts by ±1° per arrow click and ±10° per double-arrow click, allowing faster adjustments when large rotations are needed.
Size will be adjusted by ±1 millimeter for each arrow click.
For implant components, each arrow click adjusts the translation by ±1 millimeter.
For shoulder landmarks, translation also shifts by ±1 millimeter, followed by projecting the landmark to the surface of the bone segmentation.

2D DICOM Viewer

The 2D DICOM Viewer allows the user to visualize in a single plane the CT images they have selected for the plan in the native DICOM orientation (no reorientation in the Coronal Plane). The brAIn™ Shoulder Positioning software displays both an axial and a coronal 2D DICOM Viewer.

Users can interact with the 2D DICOM Viewer in the following ways:

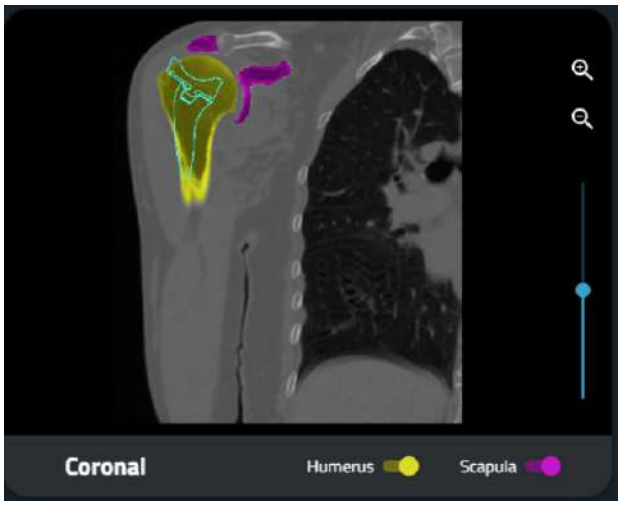
- **Scroll:** the user can scroll through the slices using either the mouse wheel or the vertical blue slider on the right side of the 2D DICOM Viewer
- **Zoom:** the user can zoom in using the “+” magnifying glass icon. They can then zoom out using the “-” magnifying glass icon (it is not possible to have a zoom factor less than 1x)
- **Pan:** the user can click and hold the left mouse button and move the mouse to pan the image
- **Humerus/Scapula toggles:** will hide/show the corresponding segmentation. The humerus segmentation will be overlaid on the CT image as a yellow mask, the scapula one as a fuchsia mask

💡 Implant components cannot be positioned in the 2D DICOM Viewer, implant placement is done only via the Manipulation Panel in the 3D Viewer.

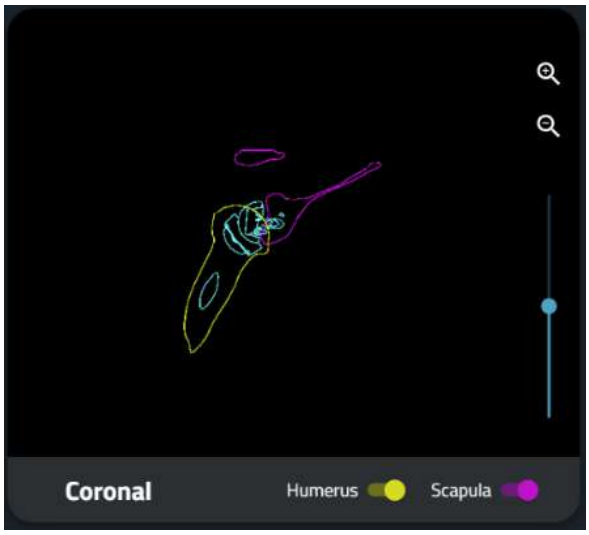
2D Implant Viewer

brAIn™ Shoulder Positioning allows the user to check the positioning of the implant components in 2D in two ways:

1. On the 2D DICOM Viewer, the outline of any implant component selected by the user will be overlaid on the CT image in cyan color:



2. In the Post-Position tab, a dedicated 2D Implant Viewer allows the user to visualize in a single plane the positioning of all implant components relative to the humerus and scapula segmentations:



Users can interact with the 2D Implant Viewer in the following ways:

- **Scroll:** the user can scroll through the slices using either the mouse wheel or the vertical blue slider on the right side of the 2D Implant Viewer
- **Zoom:** the user can zoom in using the “+” magnifying glass icon. They can then zoom out using the “-” magnifying glass icon (it is not possible to have a zoom factor less than 1x)
- **Pan:** the user can click and hold the left mouse button and move the mouse to pan the image

- **Humerus/Scapula toggles:** will hide/show the corresponding segmentation. The humerus segmentation will be overlaid on the CT image as a yellow outline, the scapula one as a fuchsia outline

💡 Implant components cannot be positioned in the 2D DICOM Viewer, implant placement is done only via the Manipulation Panel in the 3D Viewer.

Plan automatic saving

brAIn™ Shoulder Positioning does not have a 'SAVE PLAN' button because the plan is saved automatically. Each time an implant component is selected, positioned, or a tab is accessed, the software will remember these settings the next time the plan is opened.

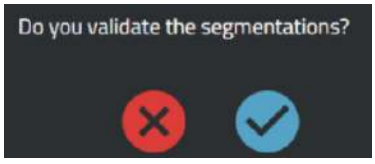
Segmentation validation

For a newly created plan, the first step before choosing the implant is to verify the segmentations (humerus and scapula) automatically computed by brAIn™ Shoulder Positioning's AI algorithm. The brAIn™ Shoulder Positioning software is considered a non-high-risk device under the AI Act since it doesn't directly control life-sustaining functions or make autonomous medical decisions that could pose significant risks to patient safety.

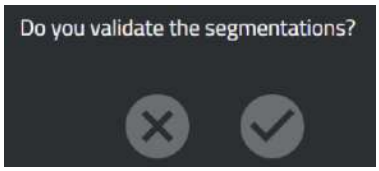
Shoulder Side Inconsistency Check

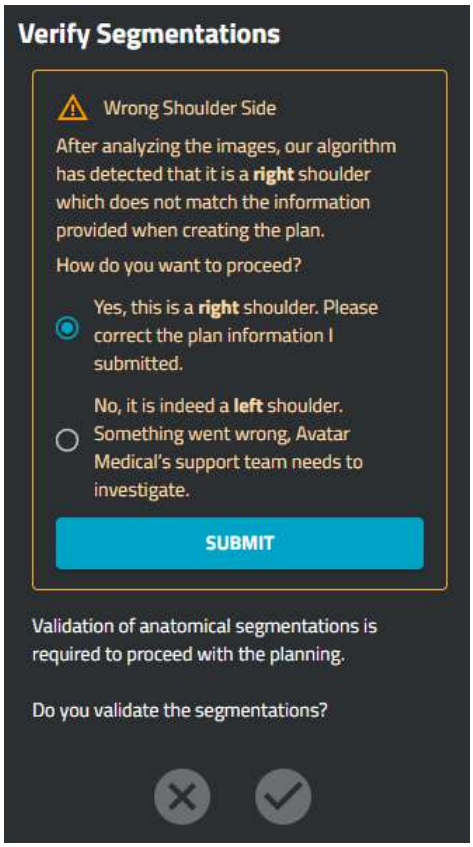
When the user enters the segmentation validation screen, the software has already automatically identified the relevant anatomical shoulder landmarks. These landmarks enable the brAIn™ Shoulder Positioning application to determine the shoulder side (right or left) and compare it with the information provided by the user in the patient information form:

1. If the two shoulder sides - the one automatically detected by the software and the one entered by the user - match, no specific message is displayed and the segmentation validation buttons are accessible to the user.



2. If the two shoulder sides do **not** match, the segmentation validation buttons will not be accessible, and a warning message will be displayed (see the example below where the software detected a right shoulder, but the user entered 'Left' as the shoulder side).

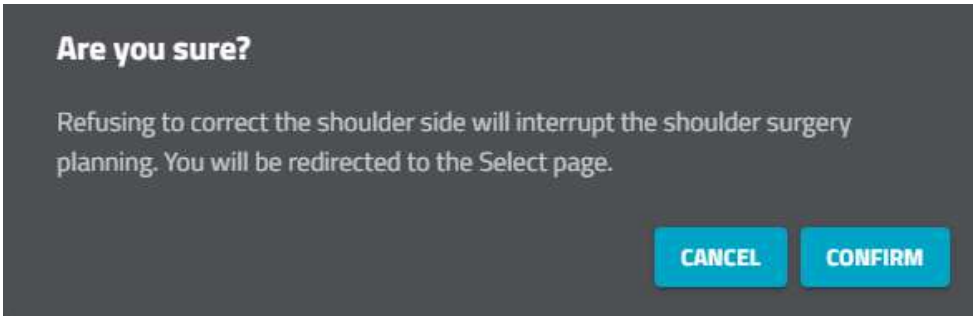




The user must choose between the following two options and click the SUBMIT button to confirm their choice:

a. **Correct the submitted information:** The shoulder side information displayed in the software from now on will be the one automatically detected by the software. The segmentation validation buttons become accessible.
b. **Confirm that the submitted information is correct, indicating that the software's automatic detection has failed:** The user will not be able to proceed with planning and will be redirected to the Select Interface, where this plan will no

longer be visible.



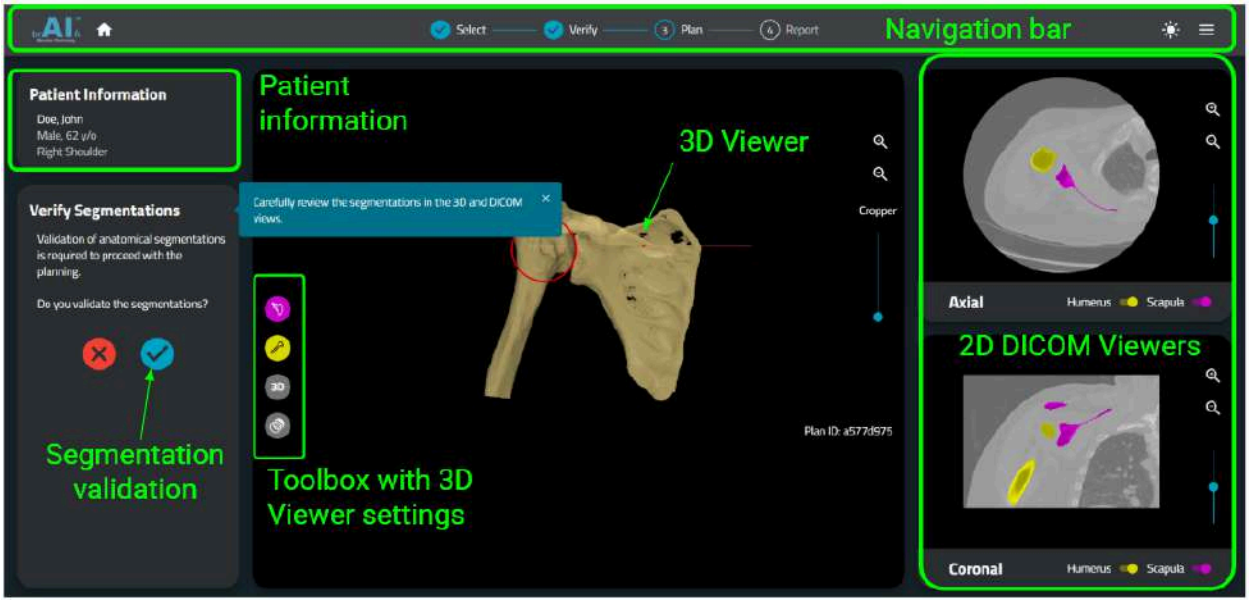
⚠ If a shoulder side inconsistency arises that is not caused by user error in entering patient information, the user must select option b. For further assistance, we recommend contacting customer support (see Troubleshooting & Contact Information).

Segmentation approval

A dedicated page is displayed where the user can check the quality of the segmentation both in the 3D Viewer interface and in the Axial and Coronal 2D DICOM Viewers.

The user is asked to validate the segmentations:

- If the user clicks on the red cross icon to refuse the segmentations, their refusal will be saved by the application: the user will be redirected to the Select Interface where the plan will no longer be visible.
- If the user clicks on the blue checkmark icon to validate the segmentations, their validation will be saved by the application: the user will be redirected to the Pre-Position tab to start planning

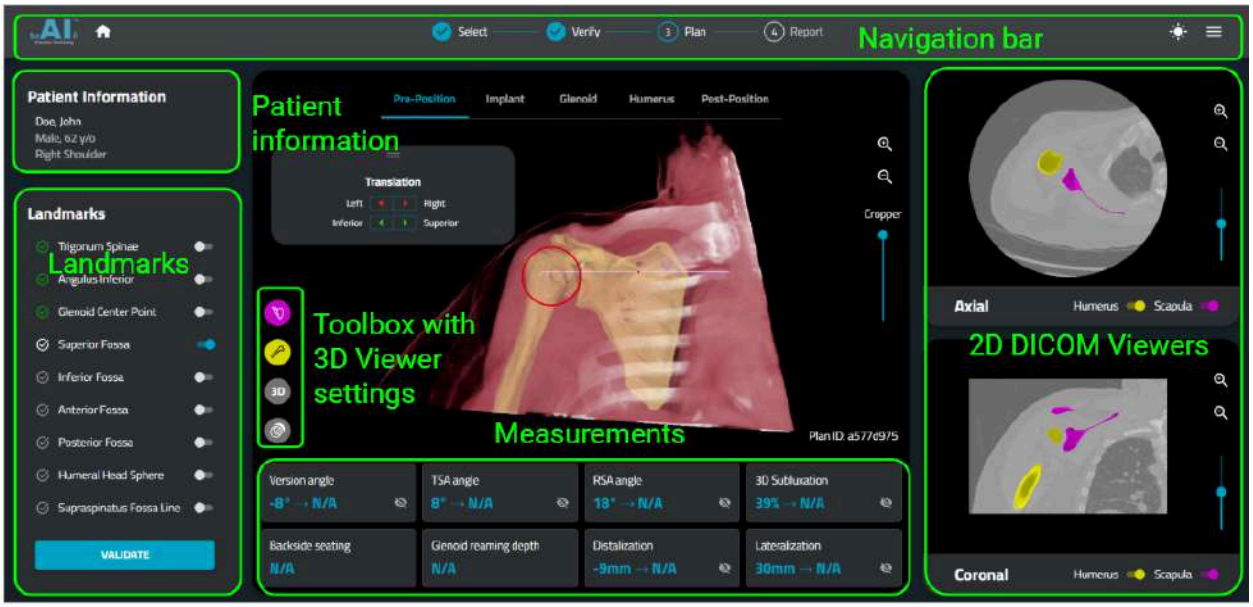


⚠ brAIn™ Shoulder Positioning does not support manually correcting the segmentations. If the user is not satisfied with the segmentations, they must refuse the segmentations and will not be able to use brAIn™ Shoulder Positioning to plan this particular CT series. We recommend contacting customer support (see Troubleshooting & Contact Information).

💡 If the segmentation results are accepted for planning but the user identifies any concerns or imperfections in segmentation quality, they are encouraged to contact customer support to report the issue for quality monitoring purposes (see Troubleshooting & Contact Information).

Pre-Position tab

The Pre-Position tab serves two key purposes: it enables the user to visualize the shoulder anatomy before implantation and provides the essential step of validating shoulder landmarks, which is mandatory before proceeding with the planning process.



Shoulder landmarks verification

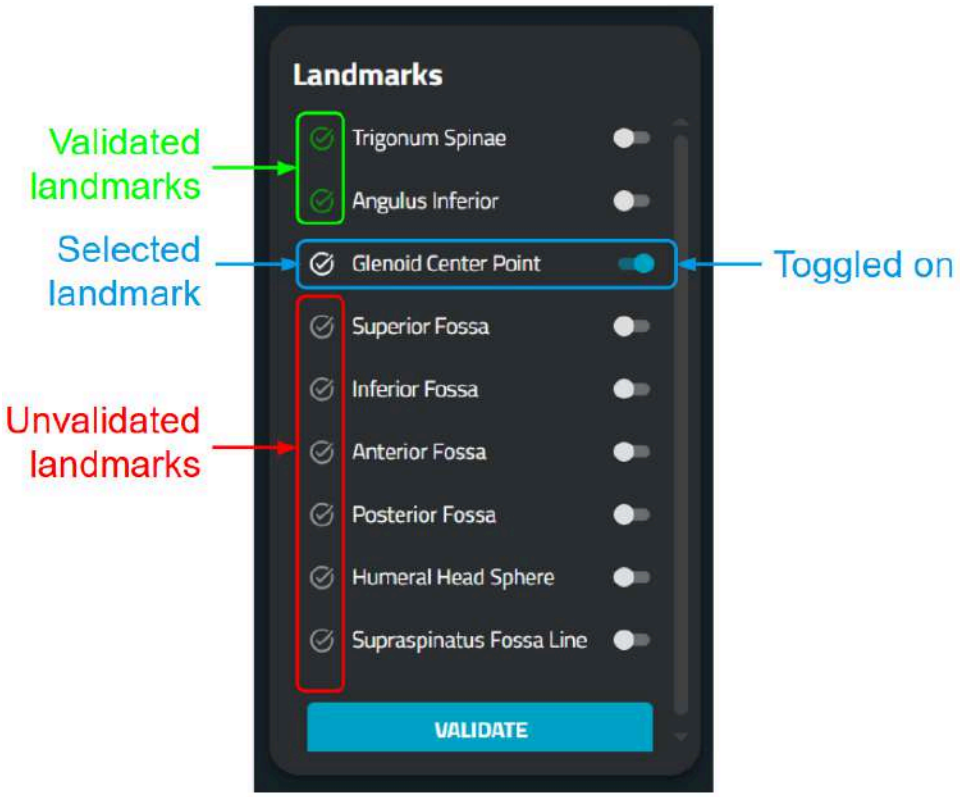
All shoulder landmarks (refer to the section Shoulder landmarks for more details) must be validated by the user before proceeding with case planning.

When the user arrives on the Pre-Position tab, the first landmark is automatically toggled on and this will automatically rotate the 3D Viewer in the landmark's direction. The user can then:

1. Click on the 'VALIDATE' button if they are satisfied with the landmark's current position
2. Adjust the landmark position using the Manipulation Panel until they reach the position the user deems accurate and then click on the 'VALIDATE' button

Upon validation, the next landmark will be automatically toggled on and the 3D Viewer automatically rotated. Steps 1 and 2 will repeat until all landmarks are validated. Once all landmarks have been validated, a dialog box will appear, prompting the user to proceed to the next tab, 'Implant', where they can select the appropriate implant.

An unvalidated landmark displays a grey checkbox icon in front of the landmark name, which turns white when the toggle is enabled. A validated landmark displays a green checkbox icon:

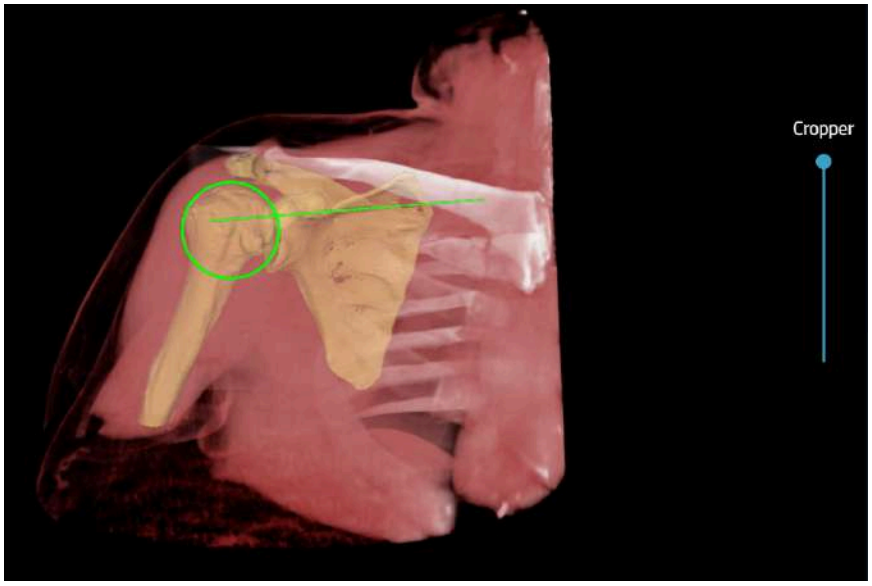


Selecting a landmark that's already been validated will automatically invalidate it.

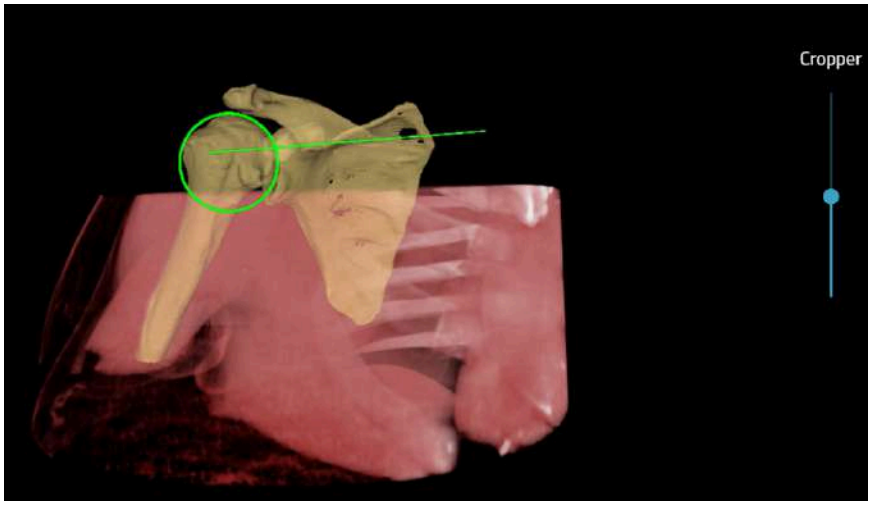
💡 If significant manual corrections were required to adjust the initial landmark positions determined by the software, users are encouraged to contact customer support to report the issue for quality monitoring and continuous improvement purposes (see Troubleshooting & Contact Information).

Soft tissue visualization

The Pre-Position tab's 3D Viewer allows users to visualize soft tissues by adjusting the 3D Viewer Settings:



On the right side of the 3D Viewer, a vertical slider enables the user to crop the 3D visualization. Cropping is performed parallel to the axial plane of the original DICOM dataset. As the slider is adjusted, the soft tissues above the slider's position are hidden, leaving only the bone segmentations and shoulder landmarks visible:

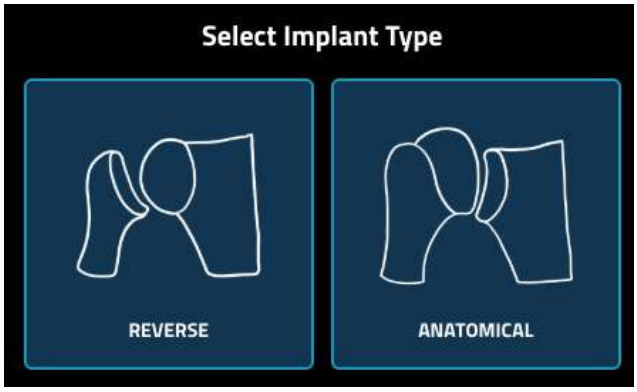


Implant tab

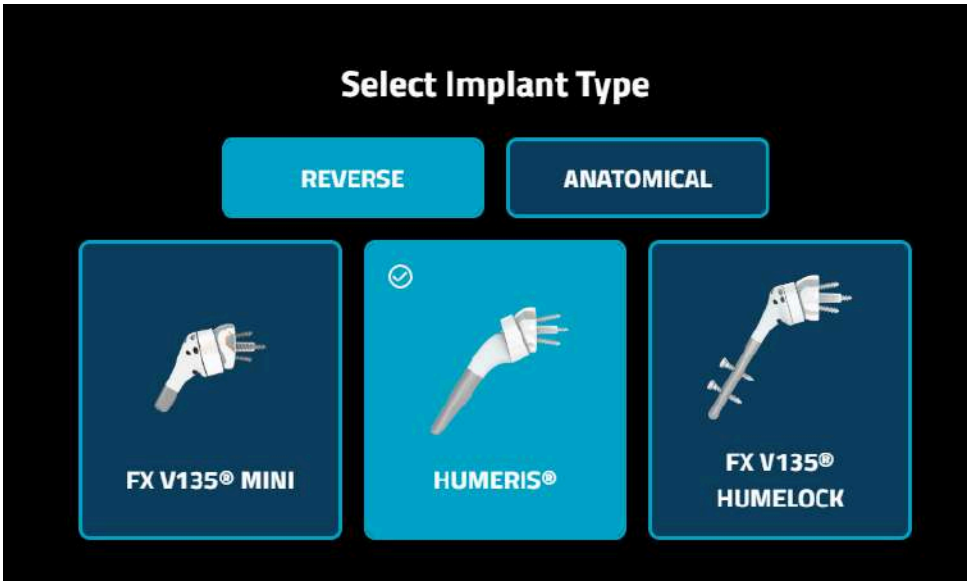
The Implant tab allows the user to select an implant from the FX Shoulder Solutions implants that have received FDA clearance:

- Reverse:
    - FX V135® MINI
    - HUMERIS®
    - FX V135® HUMELOCK
- Anatomical:
    - FX V135® MINI
    - HUMERIS®
    - EASYTECH®

First, the user must select the implant type (reverse or anatomical):

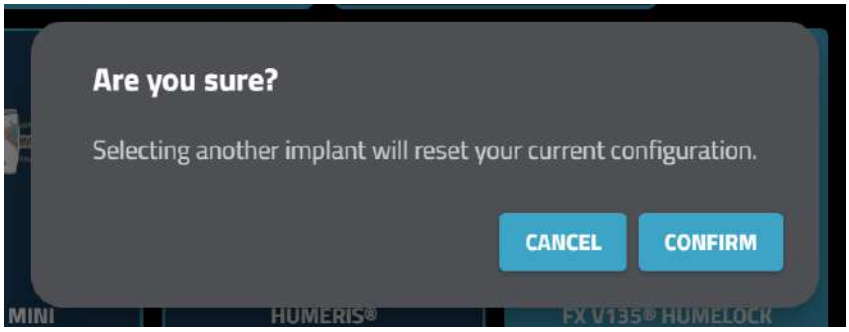


The user can then choose between the different available implants by clicking on the corresponding tile:



In the Implant tab, the implant selected is highlighted in light blue and has a checkmark icon. In the Glenoid, Humerus and Post-Position tabs, the name of the selected implant is displayed in the bottom right corner of the 3D Viewer, above the Plan ID:

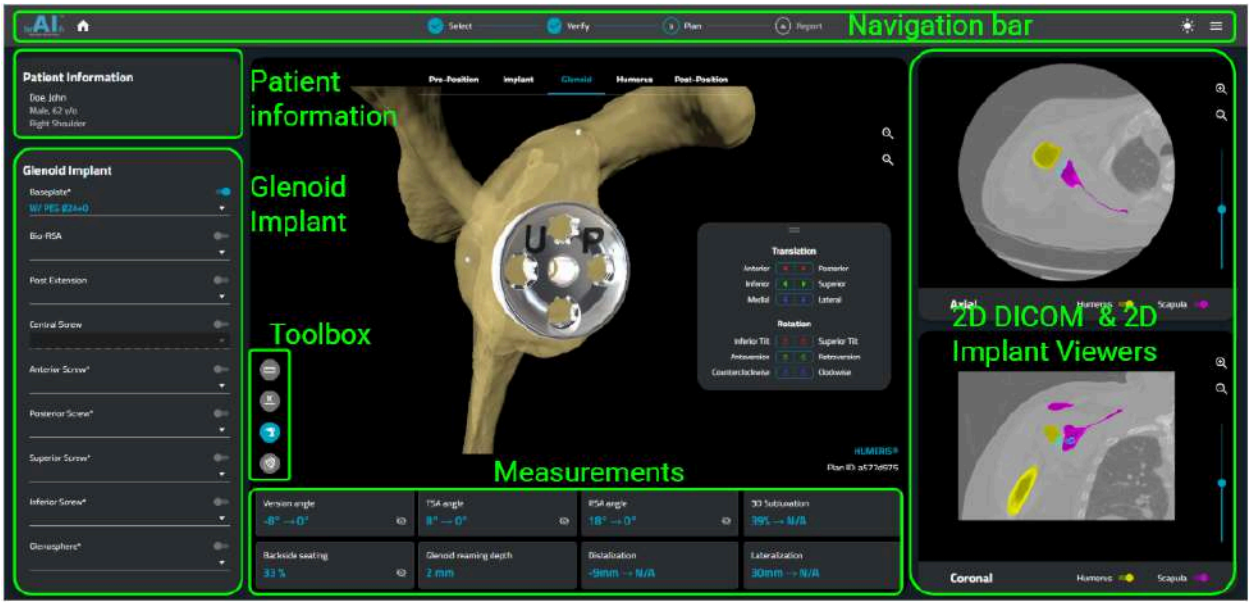
If the user decides to change the selected implant, a warning message will be displayed to inform them that the current implant configuration will be lost:



Glenoid tab

The Glenoid tab allows the user to plan the implant on the scapular side of the shoulder joint.

⚠ The software does not automatically select implant components; users must choose them manually.

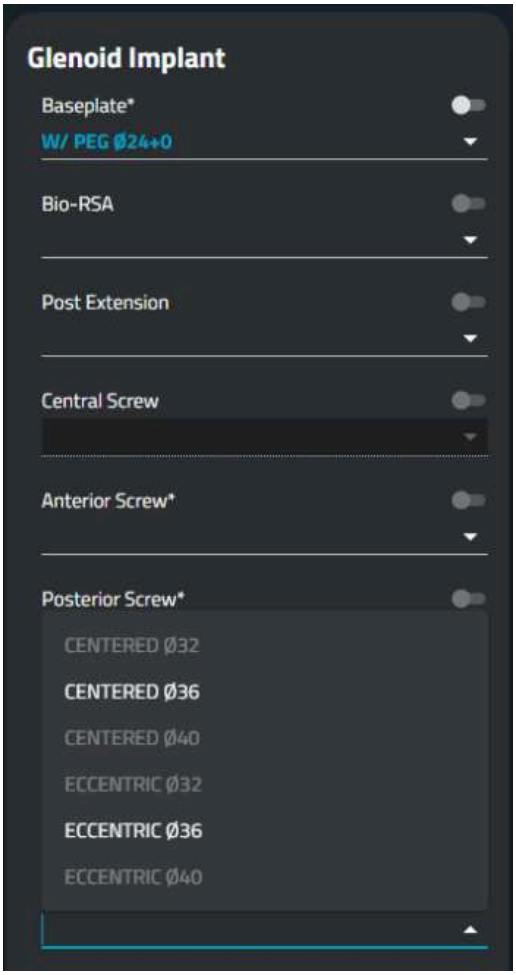


On the left side of the screen, the Glenoid Implant panel displays all available components for the user's selected implant. Mandatory components are indicated with an asterisk (*).

⚠ The software will not provide any warnings or visual indicators if an implant component perforates the glenoid bone structure. Users must review their plan carefully.

Selecting an option from the dropdown list for a given component will automatically enable its toggle button and display the Manipulation Panel, allowing the user to position the component as desired (see Shoulder landmark and implant component toggles).

The software will verify that all components are compatible with each other; incompatible options will be grayed out in the dropdown lists:



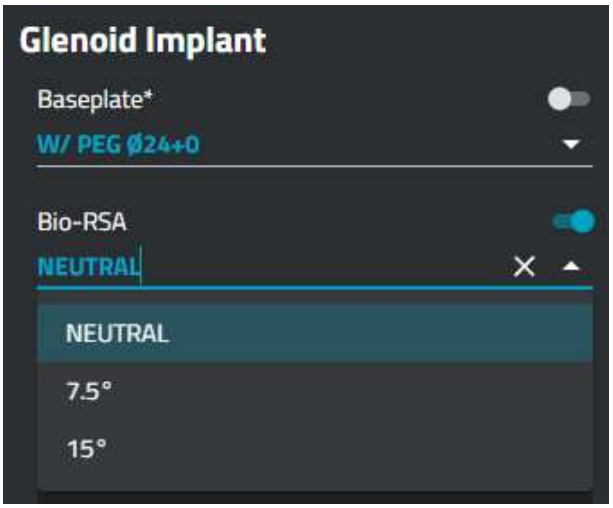
When a baseplate or glenoid peg component is selected, the software automatically applies a reaming visual effect in the 3D visualization. In the 3D Viewer Settings, the Reaming button (enabled by default) can be turned off to hide the reaming visual effect and display the native glenoid surface.

⚠ For baseplates, the glenoid reaming visual effect is achieved using a cylindrical cropping method that conceals elements within the cylinder. However, depending on the patient anatomy, some fossa fragments may remain visible after reaming.

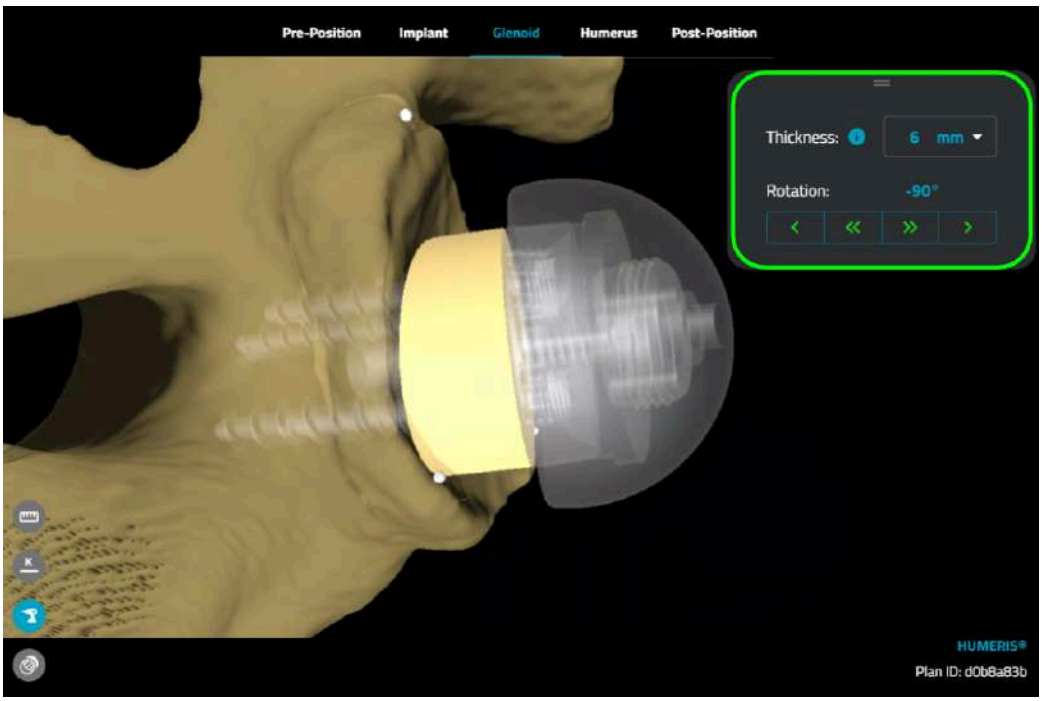
⚠ For glenoid pegs, the glenoid reaming visual effect is achieved using a spherical cone cropping method that conceals elements within the cone. However, depending on the patient anatomy, some fossa fragments may remain visible after reaming.

Bio-RSA

For reverse implants, **neutral** baseplates can be lateralized using an optional Bio-RSA component. Three different shapes are available and can be selected from the Bio-RSA box, as seen on the image below:

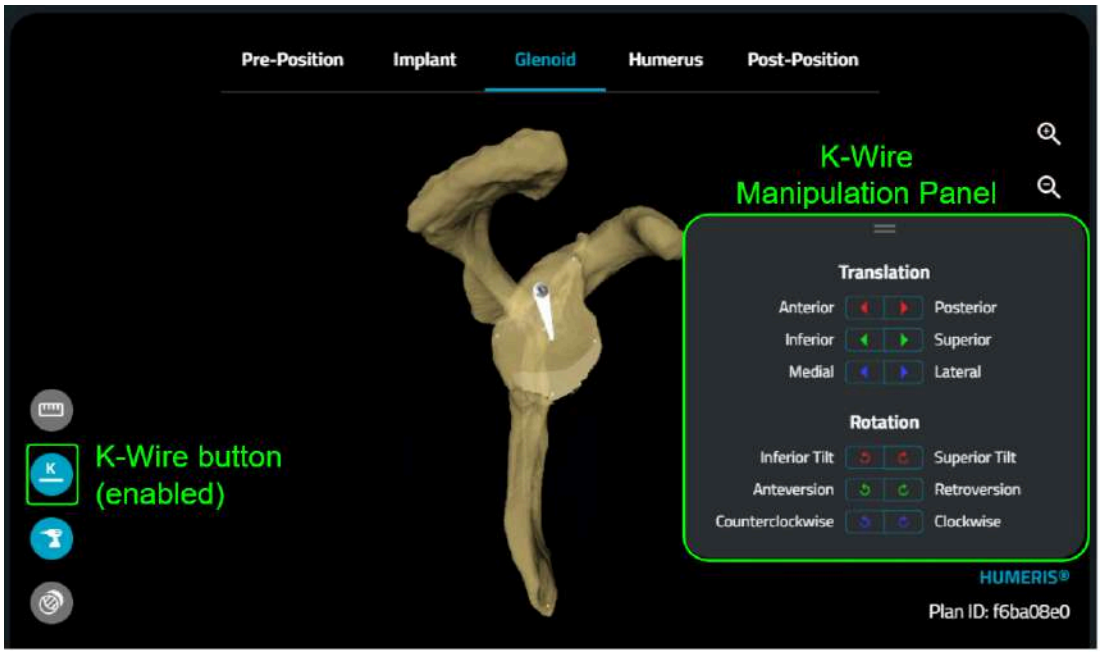


The thickness of the Bio-RSA can be chosen on its Manipulation panel and varies from 2 mm to 10 mm in 2-millimeter increments. For 7.5° and 15° Bio-RSA, their rotation can be modified using the double arrows (±10°) or the single arrows (±1°).



K-Wire

The brAIn™ Shoulder Positioning software also enables the user to visualize the placement of the K-Wire that would be inserted into the bone during surgery to indicate the intended position of the glenoid component.



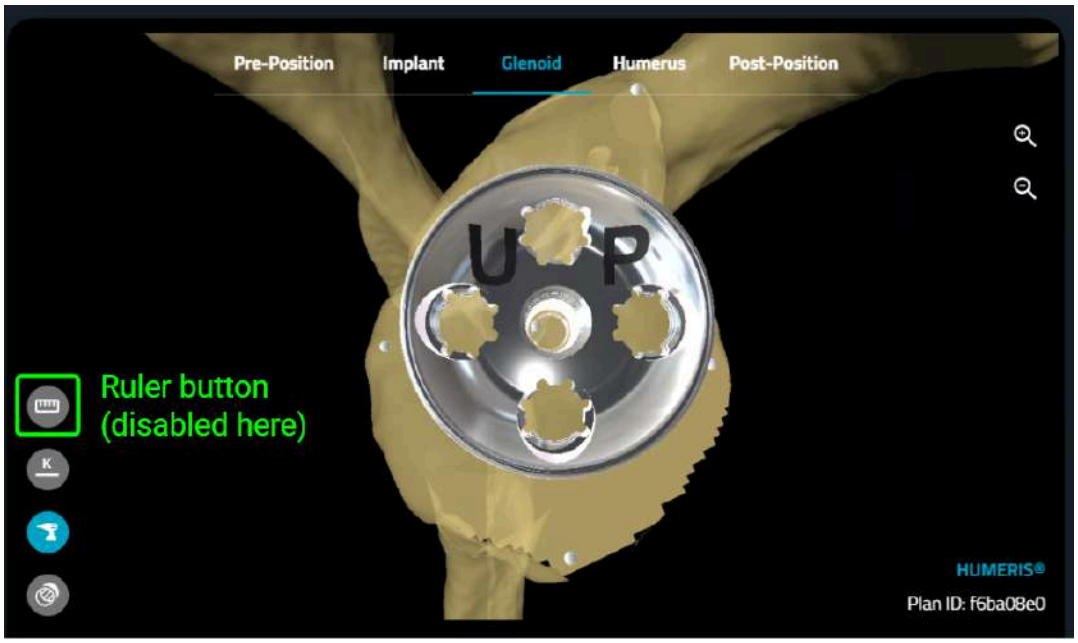
The K-Wire has its own Manipulation Panel and can be positioned just like any implant component. Its position is intrinsically linked to that of the baseplate (or glenoid peg for anatomical implants). Moving one will automatically move the other.

💡 Since the software cannot automatically detect when the user has finished positioning the implant, the user must manually click on the Humerus tab to continue with the planning.

Ruler Tool

The brAIn™ Shoulder Positioning software provides a Ruler tool that allows users to calculate the linear (Euclidean) distance between two user-defined points on the unreamed 3D scapula mesh. This tool supports precise spatial measurements directly within the 3D environment and is available only in the Glenoid tab.

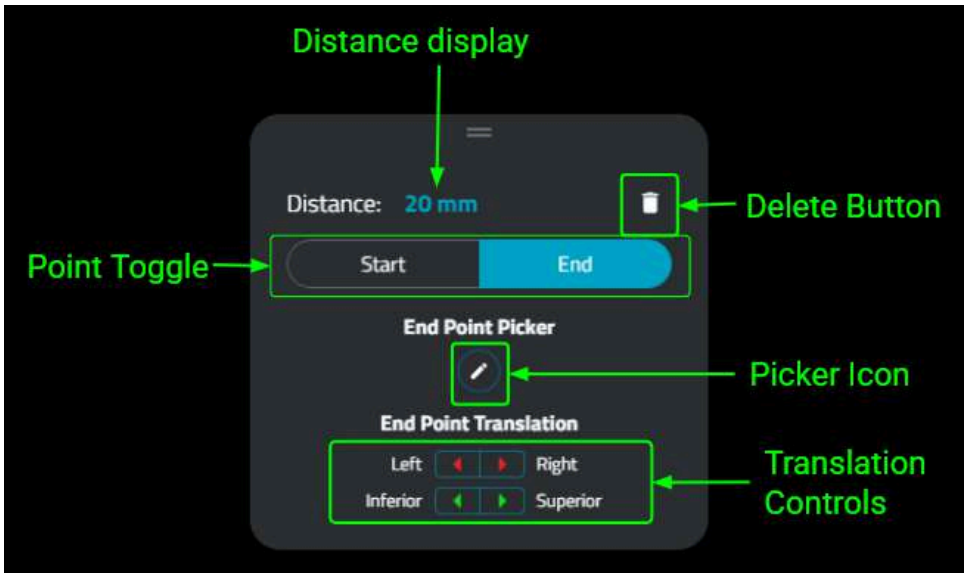
To activate the tool, click the **Ruler button** in the Toolbox:



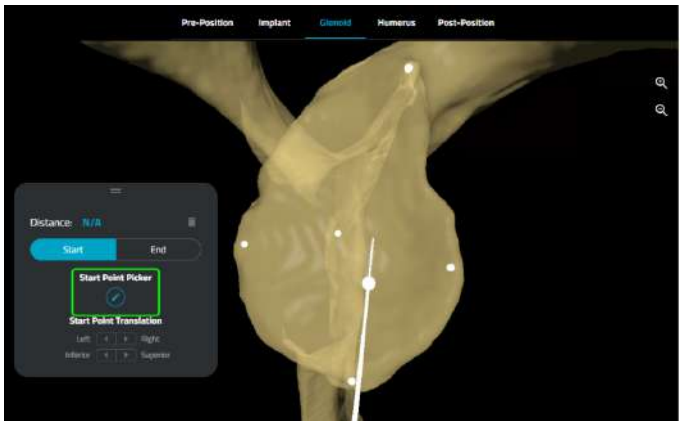
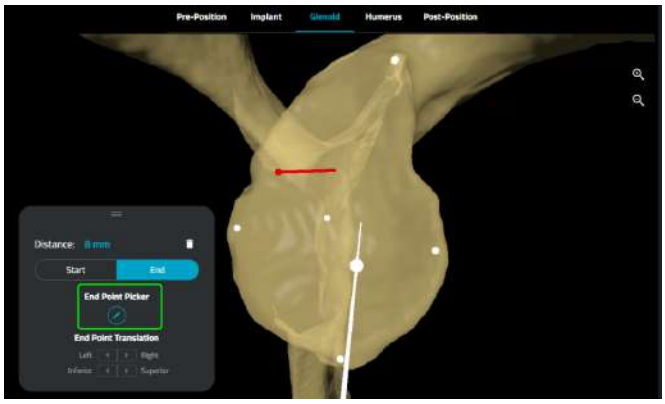
Activating the Ruler tool **disables all other tool buttons** except for the **Full Opacity button**, which remains functional during measurement.

Clicking on the Ruler tool activates a Ruler Tool Interface, which includes the following elements, as shown on the image below:

Component	Description
Distance Display	Shows the computed distance in millimeters with a precision of one millimeter, once at least one point is defined.
Delete Button	Clears the current measurement (bin/trash icon).
Point Toggle	Allows the user to switch between modifying the start or end point.
Picker Icon	Enables point selection within the 3D viewer using mouse input.
Translation Controls	Allows fine adjustment of point positions along the X, Y, and Z axes.



Below is a description of how to use the Ruler tool:

When the Ruler tool is first activated and if a baseplate has already been selected, the K-Wire and its entry point (indicated on the Glenoid Fossa by a white sphere larger than the Glenoid Fossa landmarks) are shown in white. The **start point** is automatically selected, and the **Picker** is enabled. The user defines the start point by clicking directly on the 3D scapula mesh.	
The tool then switches to **end point selection**, with the Picker remaining active. A line segment is displayed between the selected start point and the current mouse hover position, providing a visual preview of the measurement.	

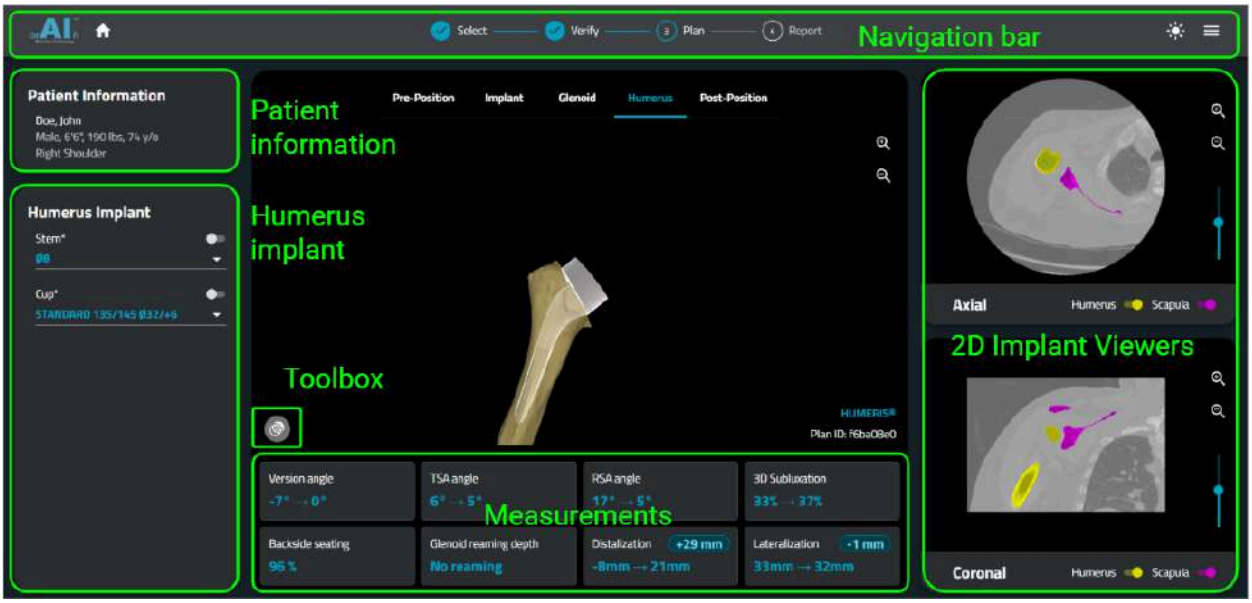
The distance is updated in real time as the user moves the cursor over the mesh.	
Once both points are defined, the measurement is finalized and displayed in the panel, rounded up to the nearest millimeter	

💡 While the Picker tool is active, the scapula mesh cannot be rotated. To adjust the scapula's position, please deactivate the Picker tool first.

Humerus tab

The Humerus tab allows the user to plan the implant on the humeral side of the shoulder joint.

⚠ The software does not automatically select implant components; users must choose them manually.

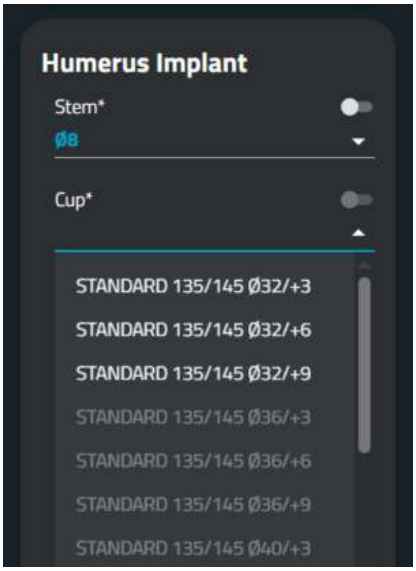


On the left side of the screen, the Humerus Implant panel displays all the components available for selection for the implant chosen by the user. Mandatory components are indicated with an asterisk (*).

⚠ The software will not provide any warnings or visual indicators if an implant component perforates the humeral bone structure. Users must review their plan carefully.

Selecting an option from the dropdown list for a given component will automatically enable its toggle button and display the Manipulation Panel, allowing the user to position the component as desired (see Shoulder landmark and implant component toggles).

The software will verify that all components are compatible with each other; incompatible options will be grayed out in the dropdown lists:



When a stem component is selected, the software automatically applies a resection effect in the 3D visualization to simulate humeral preparation during surgery.

💡 brAIn™ Shoulder Positioning does not automatically remove osteophytes nor provide an option for the user to manually remove them from the 3D visualization.

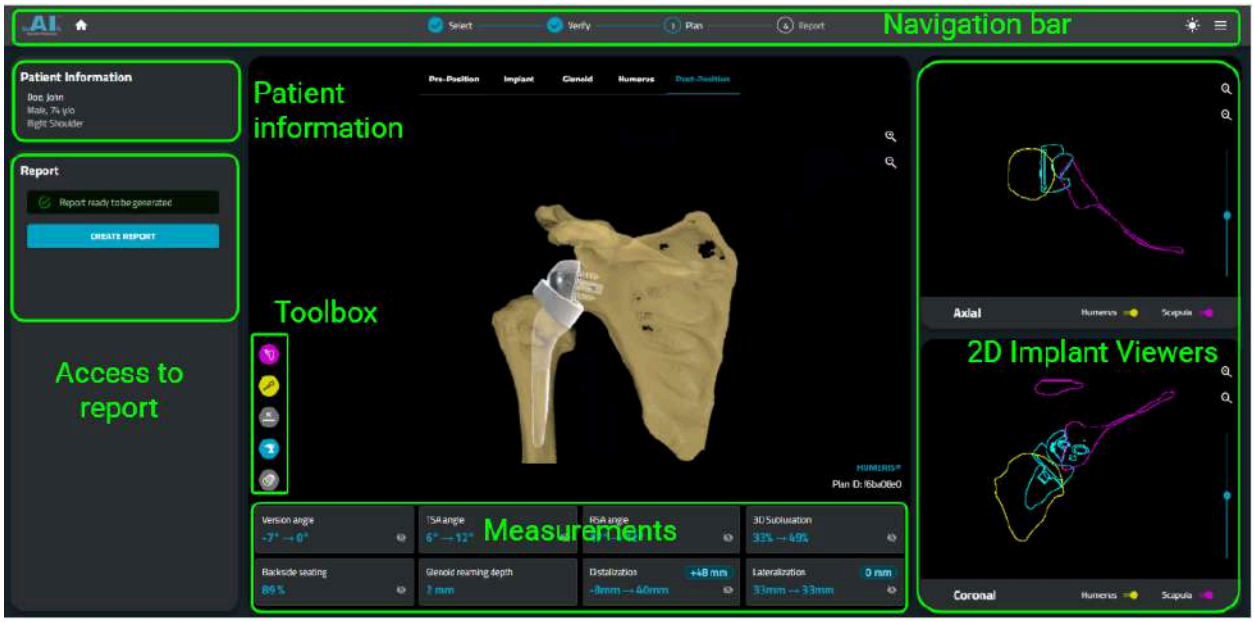
💡 Since the software cannot automatically detect when the user has finished positioning the implant, the user must manually click on the Post-Position tab to continue with the planning.

Post-Position tab

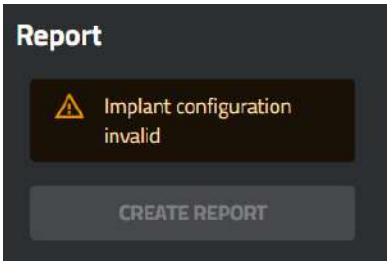
The Post-Position tab allows the user to visualize the glenoid and humeral implants displayed and aligned together. The humerus is translated to create a 'ball and socket' joint with the scapula.

⚠ The software does not offer warnings or visual indicators for bony impingement or implant contact in the Post-Position configuration. Users are responsible for thoroughly reviewing their plan.

Due to this translation, the original CT DICOM data cannot be displayed. Instead, Axial and Coronal 2D Implant Viewers are shown for a comprehensive verification of the implant configuration.



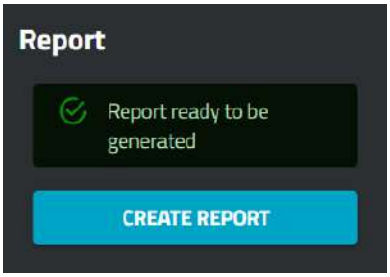
If all mandatory parts of the implant have been selected by the user, a “CREATE REPORT” button will appear in the left panel. Clicking this button will allow access to the Surgical Planning Report. If not all mandatory parts have been selected, an error message will be displayed and the button will be disabled:



💡 If the user does not wish to edit a report, they can either log out or return to the Select Interface by clicking the Home button in the Navigation bar.

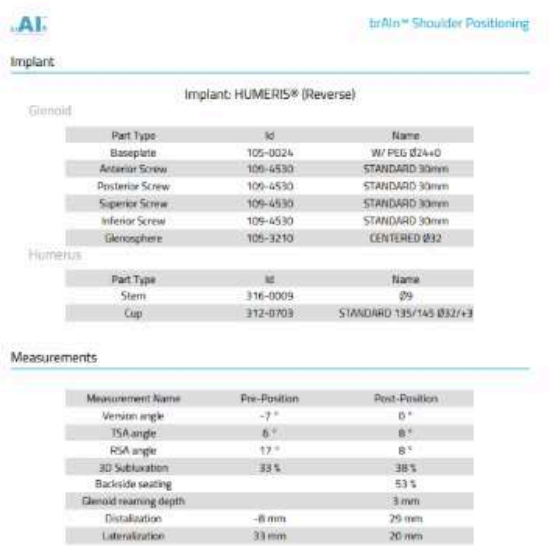
Surgical Planning Report

If all mandatory parts of the implant have been selected by the user, they can click the “CREATE REPORT” button in the left panel:

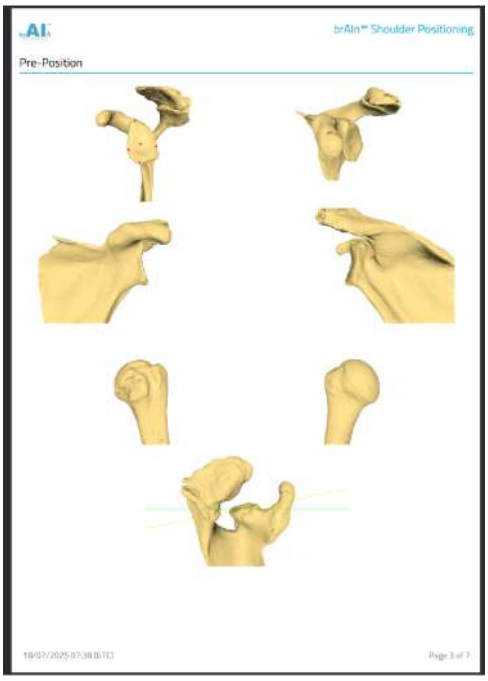


This will generate a PDF report, which will be displayed in an embedded PDF viewer. This 7-page Surgical Planning Report includes the following:

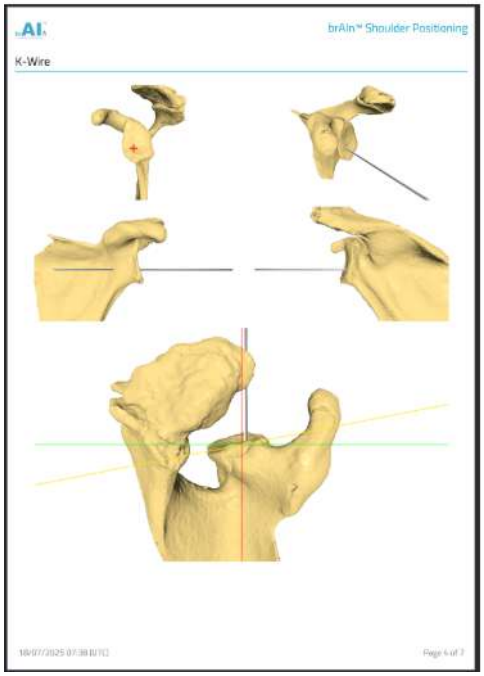
- On pages 1 and 2:
    - A section for the patient information, including the patient's health history entered by the user at the time of plan creation
    - A section for the implant containing the name of the selected implant and two tables listing all the chosen implant components: one for the glenoid and one for the humerus. Each table includes details such as component type, manufacturer reference, and component name.
    - A section for the shoulder measurements containing the measurement name, its value in Pre-Position (if applicable) and its value in Post-Position (if applicable), i.e. with the planned implant.



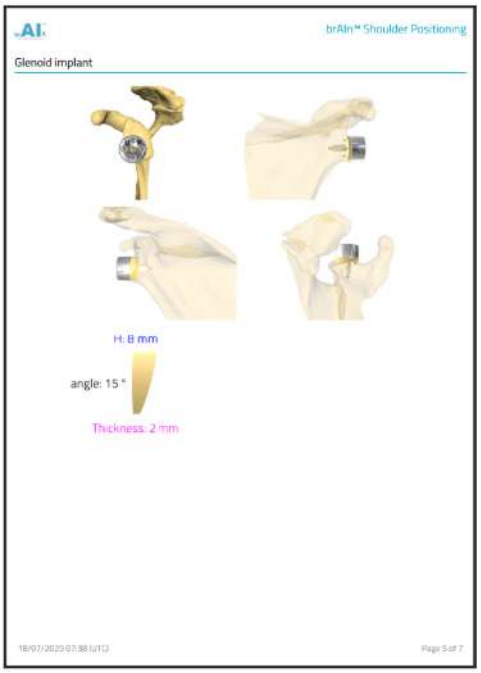
- On page 3: Screenshots of the scapula and humerus in Pre-Position with the Glenoid Fossa landmarks displayed. The neutral version line (green) and the projection of the fossa line in the Transverse plane (yellow) are also displayed on the last screenshot.



- On page 4: Screenshots illustrating the placement of the K-Wire with its entry point marked with a red cross. The neutral version line (green), the projection of the fossa line in the Transverse plane (yellow) and the Supraspinatus Fossa Line (red) are also displayed on the last screenshot.

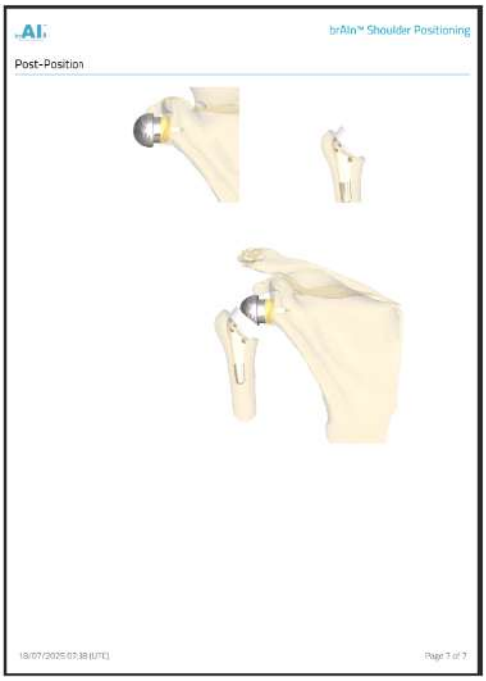


- On page 5: Screenshots illustrating the implants parts on the Glenoid side, taken from different camera angles and with different bone opacity, with the K-Wire hidden. If the planning contains a Bio-RSA, its angle, height and thickness are indicated.

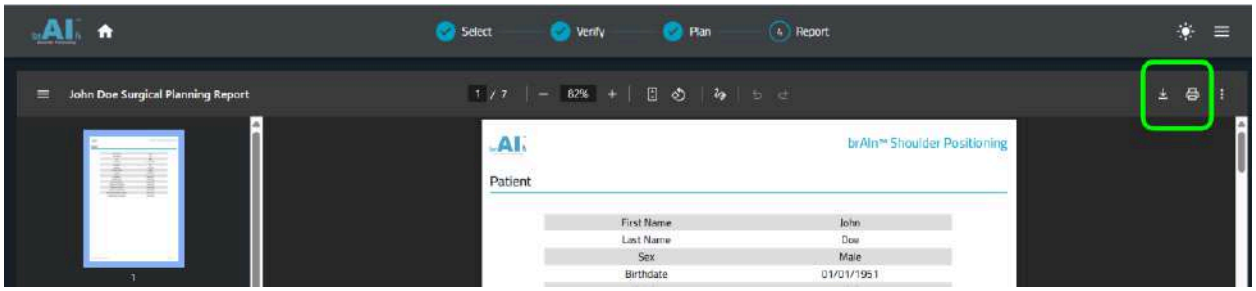


- On page 6: Screenshots illustrating the implants on the humerus side, taken from different camera angles.

- On page 7: Screenshots illustrating the complete implant in its final position.



The user can download or print the PDF using the dedicated icons in the embedded PDF viewer:



The planning workflow is complete! The user can either return to the Select Interface (using the Home button on the Navigation bar, for example) or log out if they are finished using the brAIn™ Shoulder Positioning application.

System and data protection recommendations

Minimum hardware recommendations

The client computer used to access the brAIn™ Shoulder Positioning software must be a desktop or laptop computer with the following minimal hardware configuration requirements:

- Intel(R) Celeron(TM), Apple M or equivalent
- 4 GB of system memory (RAM)
- Intel UHD Graphics or equivalent
- 1 GB of video RAM (VRAM)
- 1 GB of available HDD space or more
- Full HD screen resolution (1920 x 1080 pixels)

Web browser compatibility

brAIn™ Shoulder Positioning supports only the following web browsers:

- Google Chrome
- Microsoft Edge

- Chromium

Network requirements

Internet access is required to use the software. The following network rules must be allowed on the firewall:

Hostname	Protocol	Port	Description
bsp.fx.avatarmedical.cloud	HTTPS	443	Homepage, Connect & Plan Interfaces access
console.fx.avatarmedical.cloud	HTTPS	443	Admin Console Interface access
fx-prod.auth.us-east-1.amazoncognito.com	HTTPS	443	Connect Interface (Amazon Cognito)
api.fx.avatarmedical.cloud	HTTPS	443	API access
turnserver.fx.avatarmedical.cloud	TURNS (TCP/UDP)	443	Web streaming
ws.fx.avatarmedical.cloud	WSS (HTTPS1.1)	443	Web streaming
otel.infra.avatarmedical.cloud	HTTPS	443	Logging

To prevent 3D visualization streaming artifacts, we recommend using a wired connection or a stable WiFi connection as well as the following bandwidth requirements:

- Download: 10 Mbps minimum
- Upload: 3 Mbps minimum

System logs

The brAIn™ Shoulder Positioning software captures detailed records of user activities, system events, and application errors. These logs are aggregated and stored in a centralized, secure location to enable analysis and historical auditing by authorized Avatar Medical personnel only. This helps in identifying potential issues, tracking system performance, and complying with regulatory requirements.

System architecture

In order to maintain the highest level of security, detailed system architecture diagrams are not provided in this manual. Sharing such information could expose sensitive aspects of the system, increasing the risk of unauthorized access or exploitation. However, if you require these diagrams for specific purposes, they can be requested by contacting our customer support team (see Troubleshooting & Contact Information).

Software Bill of Materials

In order to maintain the highest level of security, the Software Bill of Materials (SBOM) is not provided in this manual. Sharing such information could expose sensitive aspects of the system, increasing the risk of unauthorized access or exploitation. However, if you require the SBOM for specific purposes, it can be requested by contacting our customer support team (see Troubleshooting & Contact Information).

Data protection recommendations

The following cybersecurity measures are recommended by Avatar Medical for its users:

- Ensure that the computer used to access the brAIn™ Shoulder Positioning software meets the Network requirements and that at least one of the web browsers listed in Web browser compatibility is installed.
- The brAIn™ Shoulder Positioning user account is unique and strictly personal; the user's email and password must not be shared with colleagues or other individuals.
- IT managers of the healthcare facility that owns the computer running the brAIn™ Shoulder Positioning software are responsible for maintaining an adequate level of cybersecurity.
- Ensure that the computer used to access the brAIn™ Shoulder Positioning software is protected by the latest versions of antivirus and anti-malware software.

Troubleshooting & Contact Information

For any plan-specific questions that arise during the review or to report software anomalies, contact Avatar Medical Customer Support to ensure prompt resolution and maintain optimal software performance:

Avatar Medical SAS - Customer Support

Address: 11 rue de Lourmel, 75015 Paris, France

Email: contact@avatarmedical.ai

Phone Number: +33 9 74 67 00 15

Website: https://avatarmedical.ai

In case of detection of a cybersecurity event, please contact using the email address provided below.

Any serious incident related to the device should be reported to Avatar Medical using the email address provided below and to the competent authority of the Member State.

Vigilance Contact: vigilance@avatarmedical.ai

Release notes

FDA.1.1.0 (2025/08)

Summary

The FDA.1.1.0 software version is an evolution from version FDA.1.0.2 of the brAIn™ Shoulder Positioning application. It contains new features and improvements, SOUP/OTS updates and bug fixes.

New/Improved features

- **Replacement of ray casting rendering with mesh rendering of the shoulder anatomy segmentations in the Glenoid and Humerus Interfaces**, decrease of the transparency of unselected implant parts in the Glenoid and Humerus Interfaces

- **Addition of a ‘Full Opacity’ tool** to control the transparency of the scapula and humerus meshes
- **Addition of a Ruler tool** allowing the placement of 2 points on the unreamed scapula and the live calculation of the distance (in millimeters) between them
- Seating points for Glenoid pegs have been introduced and are now used to compute a **'Backside Seating' percentage**, consistent with the functionality previously available for reverse implants. The label 'Baseplate Contact Percentage' has been renamed to 'Backside Seating'
- **A new Bio-RSA feature is now available when a neutral baseplate is selected.** Once the Bio-RSA component is enabled, the backside seating and glenoid reaming depth values are automatically calculated based on it
- **Now using Scapular frame of reference for Version, RSA, TSA, Distalization and Lateralization measurements calculations**
- **Modification of angle measurements: former 3D angles projected back to 2D**
- Modification of angle measurements labels: “3D” deleted in front of “TSA”, “RSA”, “Distalization”, “Lateralization”
- **RSA and TSA angles now using signed values**, allowing for negative measurements
- Updated visual representation of signed angle measurements by adding an arc with an arrow to improve user comprehension
- **Addition of post-position values for TSA, RSA, and Version angle measurements**
- Initial and final Pre-Position measurements values are now saved in the Plans database
- **Initial positioning of *reverse* implants: initial Post-Position Version and RSA values are set to 0°**
- **Initial positioning of *anatomic* implants: initial Post-Position Version and TSA values set to Pre-Position values**
- **New reference frame and wording for Manipulation Panel:** for Translation (Anterior/Posterior, Inferior/Superior, Medial/Lateral) and Rotation (Inferior Tilt/Superior Tilt, Anteversion/Retroversion, Counterclockwise/Clockwise for Glenoid parts, Valgus/Varus, Anteversion/Retroversion, Extension/Flexion for stems)
- Computation and display in the Measurements Panel of the delta between Pre-Position and Post-Position values for Distalization and Lateralization (humeral shift)
- Indication of “No reaming” instead of negative values for Glenoid Reaming Depth measurement
- Glenoid reaming depth: for reverse implants, the Inferior Fossa point is now used instead of the Glenoid Center Point as the reference point for the glenoid cavity
- Now using two reaming cylinders for reverse implants, providing a more accurate fit for implant geometry and enabling support for asymmetric reaming scenarios such as augmented baseplates and non-flat Bio-RSA

- The spherical cone used for the glenoid reaming visual effect in anatomical implants now matches the size of the glenoid peg
- **All Planning Interfaces have been redesigned** to enhance measurement readability and minimize the use of scrollbars
- Verify Segmentations: soft tissues hidden by default
- **Verify Landmarks: new UI design, streamlined verification workflow**
- Patient weight and height information are now optional fields when creating a plan
- Plan creation: segmentation results are now stored before the user reaches the Verify Segmentations Interface so that the user can resume the plan creation process at any stage
- Automatic subseries selection has been improved: **the software now keeps only axial CT series. If multiple axial CT series are present, the one with the most slices is selected**
- Show plan creation popup as soon as plan creation button has been clicked
- A more detailed error message is now displayed to the user when the draft plan creation process fails
- 3D Viewer: improvement of camera settings for clipping and transparent material management
- The zoom functionality in the 3D Viewer has been improved for a smoother experience, and **dedicated zoom-in and zoom-out buttons have been added** for more precise control
- Pre-Position Interface: initial zoom of the 3D Viewer optimized, improved readability of 3D Viewer settings labels
- Post-Position Interface and Glenoid Interface: **scapula landmarks are displayed on the scapular mesh** (except for the Supraspinatus Fossa Line)
- Glenoid Interface: implant components for reverse implants have been reordered (glenosphere now listed last), improvement of the 3D Viewer's default camera orientation
- Glenoid Interface and Humerus Interface: the 3D Viewer now centers on the bone anatomy, keeping it fixed while the implant is being manipulated
- Post-Position: for reverse implants, the humerus is now reoriented to achieve 0° valgus/varus and extension/flexion
- Report Interface: Improvement of screenshots and overall design of the Surgical Planning Report, Bio-RSA information added, procedure type (reverse or anatomical) information added
- **Automatic session timeout increased from 10 to 30 minutes** on the Planning Interface
- A warning popup is displayed one minute ahead of the automatic logout
- Compatibility rules between humeral heads and glenoid pegs have been revised to ensure full cross-compatibility (anatomical implant)

- **Stem initial positioning: preservation of the position of the center of the stem when changing stem part**
- **Creation of a 'plan ID',** created from the 8 first characters of the full plan unique identifier. The plan ID is visible in the Plans tab of the Admin Console and in the bottom-right corner of the 3D Viewer
- Logging: Plan Id added to some application logs, renderer usage metric created, Improved application logging with monitoring
- Admin Console improvement: 'Number of plans' column added to the Users tab
- Removal of "File Tests" section and "Plan download" button in the Admin Console
- Renamed "File Name" column to "Patient Name" in the Admin Console
- Now redirecting to Login Interface when a 401 status error code is returned to web client
- Shoulder side consistency check's warning message reworded
- The FDA 510(k) number has been added in the About window, replacing the previous "XXX"
- EULA document version updated
- Marketing name updated to "Shoulder Surgery Planning Tool"
- Avatar Medical logo removed from Homepage, Connect Interface, Navigation Bar Interface and Surgical Planning Report
- Implemented a User Acceptance Testing (UAT) mode in Beta versions to collect user feedback. This mode is disabled in release versions.
- Deployment: Kubernetes update, database encryption at rest
- Frontend and backend package updates

Bug Fixes

- Vulnerabilities fixes (Node Package Manager, DICOM Manager) and AvatarMedicalCloud vulnerabilities fixes (MessagePack Nuget, System.Text.Json Package update in the API and Renderer)
- Make sure that plan creation button can only be clicked once
- Set plan status to error when an issue arises while uploading the DICOM files
- Plan reloading fix: some implant components were sometimes not displayed on the first try
- Fixed issue where patient weight value could be altered during pound to kilogram conversions
- Fixed issue where incorrect surgery date could be displayed depending on user's browser timezone

- Files that contain tag *Directory Record Sequence* (present in DICOMDIR files) are now ignored during plan creation
- Fixed issue where, in K-wire display mode, the K-Wire Manipulation Panel disappeared after removing an implant part
- Camera focus behaviour inconsistency fix, when selecting some specific stem parts (error in bounding box configuration in Unity)
- 2D DICOM Viewer Zoom fix: excessive zooming for last zoom level
- Floating point precision update in the ImageOrientationPatient tag of the DicomManager
- Measurements fix: measurements were not recomputed and refreshed upon K-Wire rotation or translation
- Retroversion angle values now have negative values
- Fixed issue where distalization and lateralization post-values were not resetting after changing the implant
- Fixed issue of discrepancy between the SSFL behaviour and its manipulation panel. The SSFL line now respects z-ordering when displayed
- A “0” has been added in front of the current UDI Number on the About window
- Fixed issue where the Admin Console Interface menu could not be accessed if the window is not in full screen
- Removal of “Delete all plans” feature from the Admin Console
- User deletion fix: all plans (and other associated data) created by the deleted user are automatically deleted
- Patient name field in Plans database is now empty

FDA.1.0.2 (2025/01)

Documentation updates only. This release does not include any changes to the software functionality or codebase, except for labeling updates where applicable.

FDA.1.0.1 (2024/09)

Summary

This release includes a hotfix for an issue that was preventing users from accessing the service.

Bug fixes

- Fixed a regression that was preventing renderer machines from registering as available.

Annex 1: Recommended CT Scan protocol

This annex describes the recommended steps to follow to achieve a CT Scan acquisition of the shoulder joint suitable for shoulder surgery planning with the brAIn™ Shoulder Positioning software.

Patient preparation and positioning	To ensure that acquisitions are made in good conditions, the instructions below concerning the patient must be respected: ● Ensure that the patient is not wearing any metal object that could generate artifacts; ● Make sure that the patient is lying on the table, in supination, the examined arm stretched out, shoulder and cervical spine in a neutral position (without rotation); ● Inform the patient that they must remain motionless throughout the acquisition phase. **If there is a prosthesis or other orthopedic material on the shoulder not examined:** ● Raise the unexamined arm above the patient's head.
Acquisition protocol	● Orientation of the patient during the acquisition: Use only the parameter below: ○ HFS - Head First Supine ● Do not change the position of the patient and/or the table during the acquisition ● Do not change the coordinate system, and/or the field of view between images ● **Do not tilt the gantry or take oblique images** ● **Provide only axial, non oblique images;** Do not include sagittal/coronal or 3D reconstructions.

	• **Arthroscanners are not accepted** **In the presence of metal:** provide reconstructions using a metal artifact reduction filter in addition to the standard axial images.
Scanner parameters	**Modality:** Contrastless Shoulder CT scan **Kernel/Algorithm**: Soft, Soft Tissue or Moderate reconstruction algorithms (avoid using Bone or Hard algorithms) **kVP**: 120 or 140 **Milli Amperage (mA)**: Auto **Pitch**: 1 mm or less **Slice thickness:** ≤ 2 mm (≤ 1.5 mm preferred) **Reconstruction slice increment:** 0.625 mm maximum **Resolution**: Reconstruction matrix size = 512*512 (or other square dimension) **DFOV**: 320 mm maximum **ROI: Entire scapula and proximal humerus of the specified side.** Include the acromioclavicular joint and the inferior angle of the scapula in the acquisition.

Annex 2: Shoulder measurements definitions

This annex outlines the calculation methods used for shoulder measurements in the brAIn™ Shoulder Positioning software. It references the shoulder landmarks defined in section Shoulder landmarks as well as the Scapular reference frame.

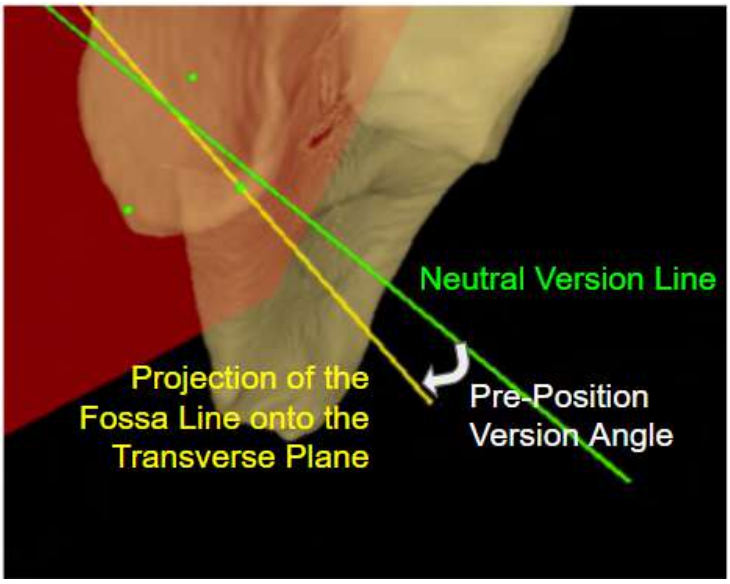
Version angle

Pre-Position value

To calculate the Version angle on the morbid anatomy, the software:

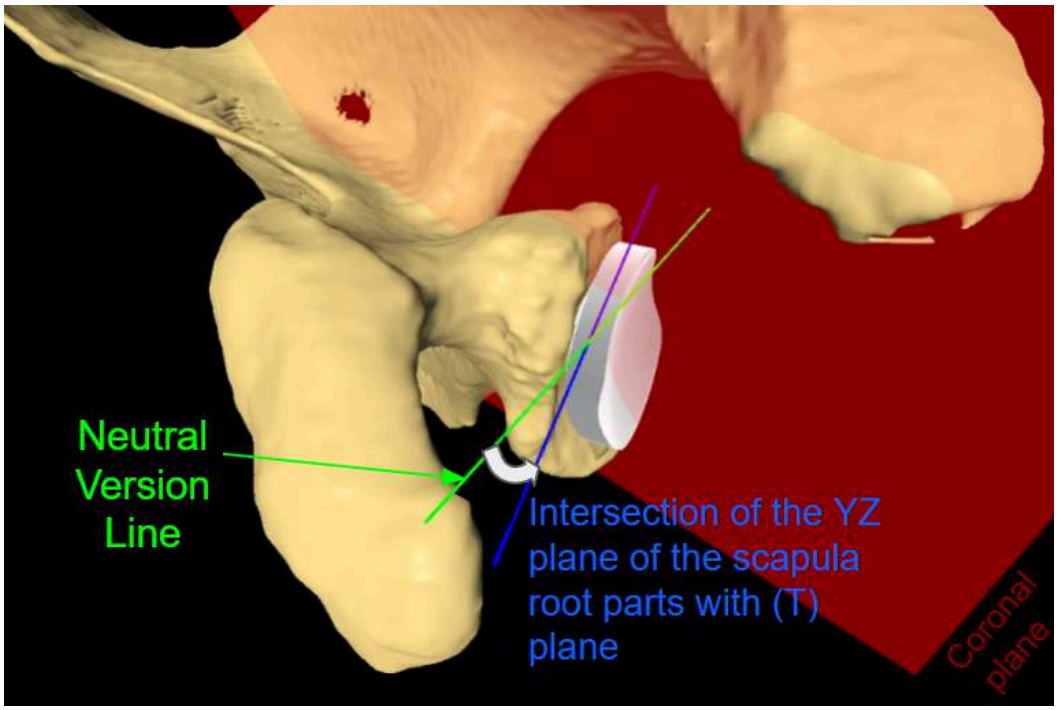
- Draws the *Neutral Version Line* (green line on the figure below) as the orthogonal line to the Coronal Plane
- Projects the *Fossa Line* (yellow line below), extending from the *Glenoid Posterior Fossa* point to the *Glenoid Anterior Fossa* point, onto the Transverse Plane

The Pre-Position Version angle (in white) corresponds to the signed angle between these two lines.



Post-Position value

To calculate the Version angle after implant selection, the software computes the signed angle between the *Neutral Version Line* (green line below, same as in Pre-Position) and the intersection of the local YZ plane of the Baseplate/Glenoid Peg on the Transverse Plane (blue line below).



TSA angle

On 2D images, the TSA angle typically refers to the angle between the plane of the glenoid and the scapular axis.

Pre-Position value

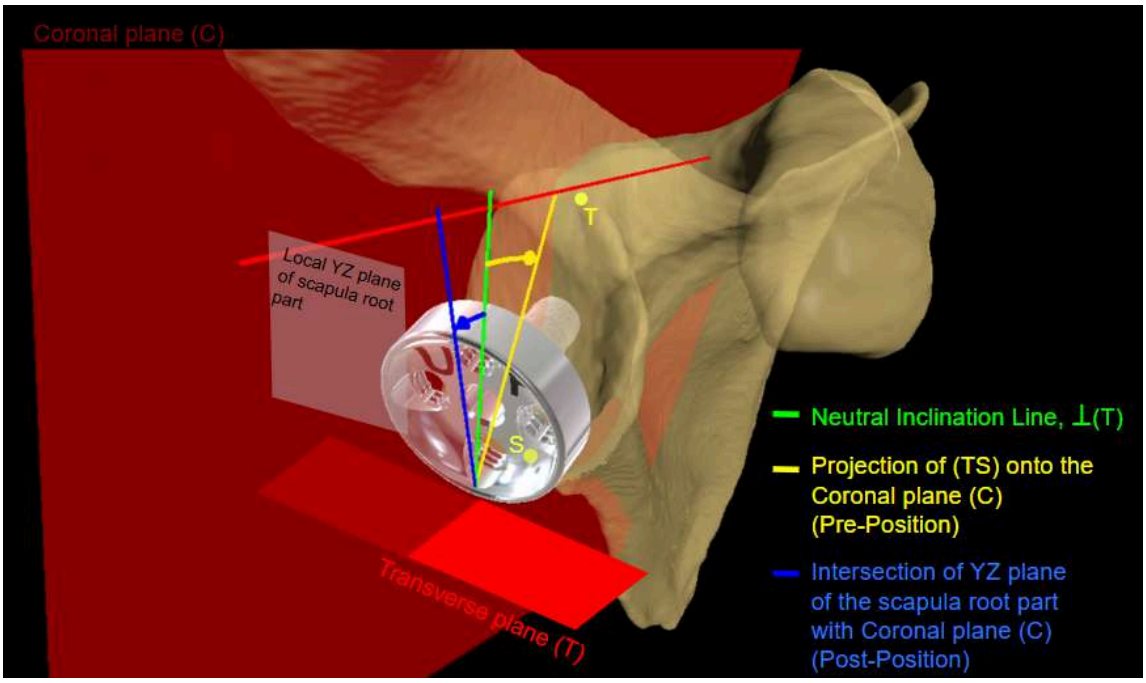
To calculate the TSA angle on the morbid anatomy, the software:

- Draws the *Neutral Inclination Line* (green line on the figure below) as the orthogonal line to the Transverse Plane
- Projects the *Fossa Inclination Line* (yellow line below), extending from the *Glenoid Superior Fossa* (Point T) to the *Glenoid Inferior Fossa* (Point S), onto the Coronal Plane

The Pre-Position TSA angle (represented by the **yellow** arc segment with a capped cone in the figure below) corresponds to the signed angle between these two lines.

Post-Position value

To calculate the TSA angle after implant selection, the software computes the signed angle (represented by the **blue** arc segment with a capped cone) between the *Neutral Inclination Line* and the intersection of the local YZ plane of the Baseplate/Glenoid Peg with the Coronal Plane (shown as the blue Post-Position line in the figure below).



RSA angle

On 2D images, the RSA angle typically refers to the angle between the inferior plane of the glenoid and the scapular axis.

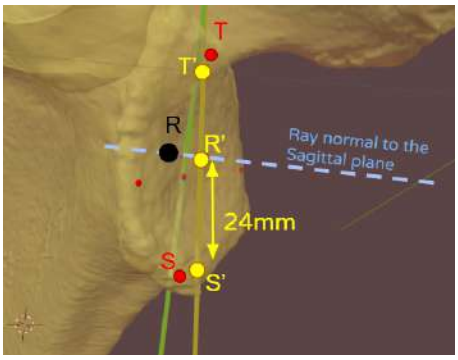
Pre-Position value

To calculate the RSA angle on the morbid anatomy, the software:

- Draws the *Neutral Inclination Line* (green line on the figure below) as the orthogonal line to the Transverse Plane
- Defines Point R by:
    a. projecting Point S (*Glenoid Inferior Fossa* landmark) onto the Coronal Plane — this defines Point S'

b. translating it by the baseplate diameter (24 mm) toward T', the projection of point T (*Glenoid Superior Fossa* landmark) onto the Coronal Plane — this defines Point R'

c. Identifying the intersection of a ray, normal to the Sagittal Plane and passing through R', with the fossa — this intersection is Point R



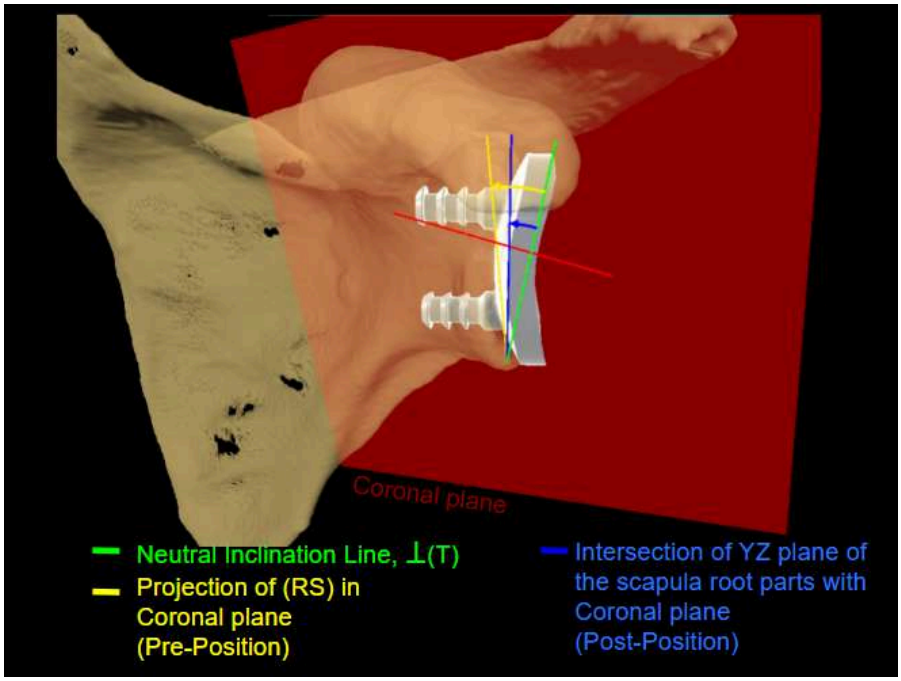
- Projects the *Inferior Fossa Inclination Line* (yellow line below), extending from Point R to the *Glenoid Inferior Fossa* (Point S), onto the Coronal Plane

The Pre-Position RSA angle (represented by the **yellow** arc segment with a capped cone in the figure below) corresponds to the signed angle between these two lines.

Post-Position value

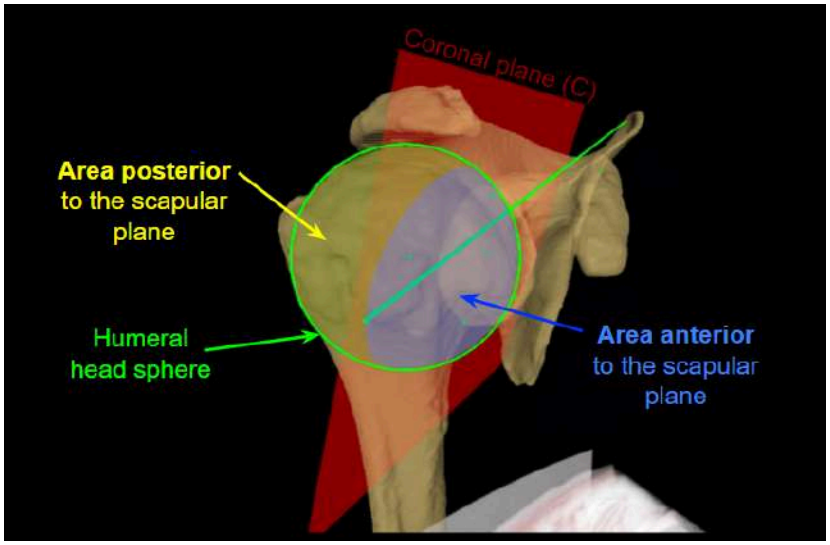
To calculate the RSA angle after implant selection, the software computes the signed angle (represented by the **blue** arc segment with a capped cone) between the *Neutral Inclination Line* and the intersection of the local YZ plane of the Baseplate/Glenoid Peg with the Coronal Plane (shown as the blue Post-Position line in the figure below).

💡 The Post-Position TSA and RSA angles are coplanar and identical in value.



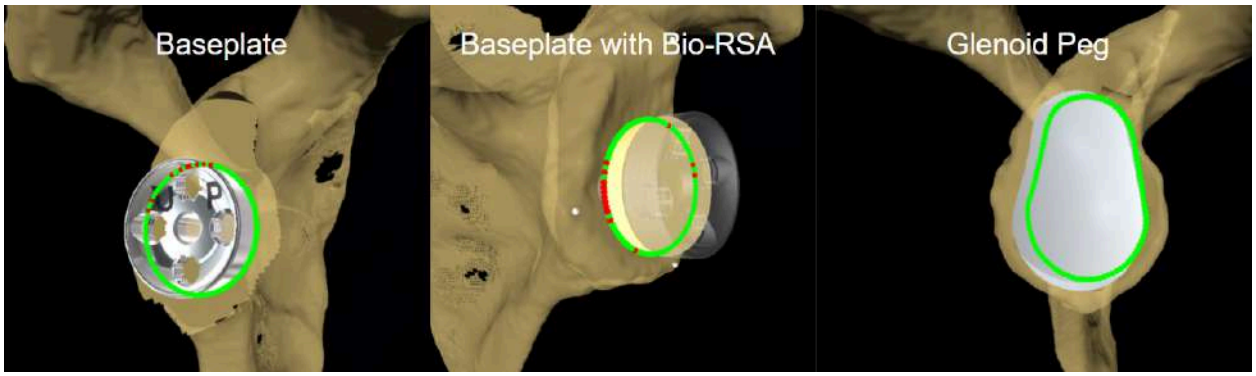
3D Subluxation

For our 3D Subluxation measurement, we use the best-fit sphere of the humeral head as reference and we display how the Coronal Plane intersects with the sphere. The 3D Subluxation is the percentage of the volume of the posterior part of the sphere relative to the total volume of the sphere.



Backside seating

The backside seating surface is approximated using a set of 100 points distributed along the edge of the baseplate, the Bio-RSA or the glenoid peg where it contacts the glenoid. The backside seating is determined by the number of these points that fall within the scapula segmentation geometry and are therefore “in contact”.

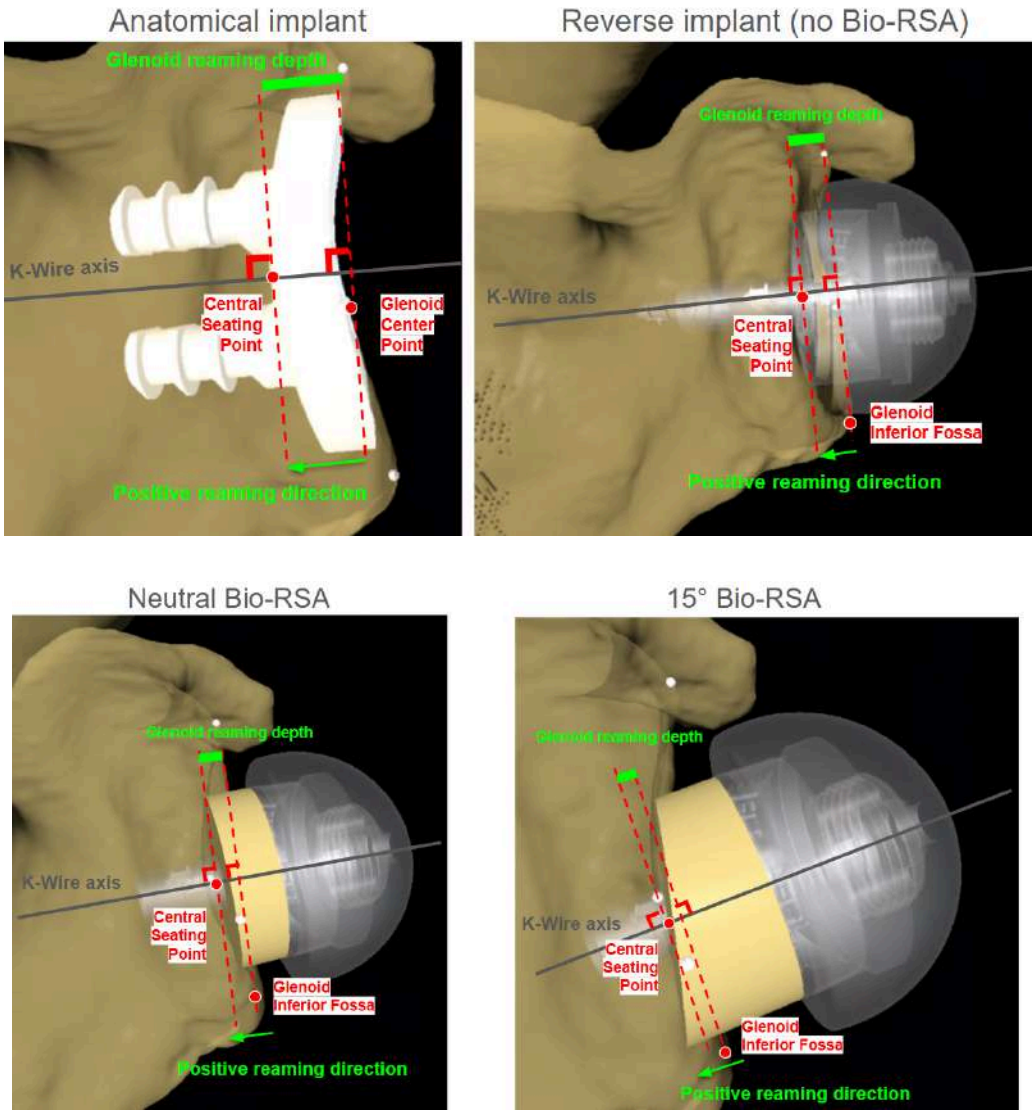


Glenoid reaming depth

Glenoid reaming depth refers to the amount of bone removed from the surface of the glenoid cavity. For the reaming depth measurement, we measure the signed distance (in millimeters) between two orthogonal projections on the K-Wire axis:

- The projection of the *Glenoid Inferior Fossa* for reverse implants (with or without Bio-RSA), and the projection of the *Glenoid Center Point* for anatomical implants
- and the projection of the baseplate/glenoid peg/Bio-RSA’s Central Seating Point.

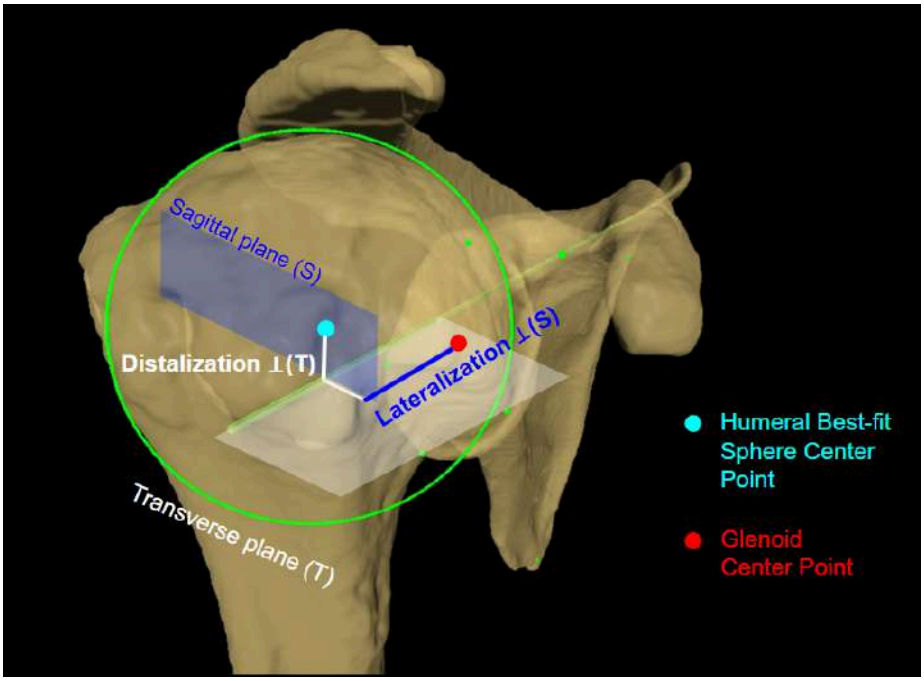
If the distance is positive or zero, the software displays its value rounded to the nearest millimeter. If the distance is negative, the software instead displays the text "No reaming".



Distalization

Distalization is defined as the vertical component of the distance between the *Glenoid Center Point* (red point below) and the *Humeral Best-Fit Sphere Center Point* (turquoise point below). This measurement is taken along the normal to the Transverse Plane, which is represented in semi-transparent white in the figure below. Please note that the *Glenoid Center Point* is detected on the scapular mesh and therefore on the morbid anatomy of the patient.

In Pre-Position, Distalization represents the vertical distance between the native bone anatomies. In Post-Position, it reflects the distance between the bone anatomies with the planned implant.



Lateralization

Lateralization is defined as the sagittal component of the distance between the *Glenoid Center Point* (red point above) and the *Humeral Best-Fit Sphere Center Point* (turquoise point above). This measurement is taken along the normal to the Sagittal plane, which is represented in semi-transparent blue in the figure above. Please note that the Glenoid Center Point is detected on the scapular mesh and therefore on the morbid anatomy of the patient.

In Pre-Position, Lateralization represents the sagittal distance between the native bone anatomies. In Post-Position, it reflects the distance between the bone anatomies with the planned implant.