User Manual

# brAIn™ Shoulder Positioning

## Shoulder Surgery Planning


**Manufacturer Name:** Avatar Medical SAS
**Software Name:** brAIn™ Shoulder Positioning
**Software Version:** CE.1.0.0
**Document Number:** BSP_CE_UM_EN
**Document Version:** 1

# Table of Contents

# Introduction

## Software information

**Name of device:** brAIn™ Shoulder Positioning

**Basic UDI-DI:** 3770026095BSP001WU

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) 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 Europe: 2025/03

Last revision date of user manual: 2024/08

Software release date (version CE.1.0.0): 2024/08

## brAIn™ Shoulder Positioning Directions for Use

### Description

The brAIn™ Shoulder Positioning software is a cloud-based application intended for shoulder surgeons. It is used to plan 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 are used for planning, which includes an interactive 3D viewer that allows for soft tissue visualization. Implants for the glenoid and humerus are positioned using this same 3D interface through 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 planning multimodal 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 Purpose

The brAIn™ Shoulder Positioning software is a cloud-based application intended for shoulder surgeons. It is used to plan primary anatomic and reverse total shoulder replacement surgeries using FX Shoulder Solutions implants.

### Intended User

Intended users are trained 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.

### Expected Benefit

The clinical benefit for patients is indirect and consists of additional/useful information for the intended user.

This benefit is induced by the technical performance which is to review CT-scan in software interface to plan primary anatomic and reverse total shoulder replacement surgeries.

### Device Lifetime

The lifetime of the brAIn™ Shoulder Positioning software is 2 years. This lifetime may be reduced according to the evolution of the technologies used by the software and substantial modifications following the users' feedback.

### Location of Use

No specific location.

### Device performance

The performance of brAIn™ Shoulder Positioning's automatic segmentation of bone anatomy algorithm has been thoroughly validated and achieved a Dice score greater than 0.95 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 pre-positioning of shoulder landmarks (refer to section Shoulder landmarks) has been validated and achieved an accuracy less than or equal to 3 millimeters.

## Symbols

| Pictogram | Description |
|---|---|
|  | European Conformity |
|  | Medical Device |
|  | 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 |
|---|---|
| Component or Part | A specific part or element of a medical implant |
| 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.

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 10 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<br>- 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 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. |
| Deleting a plan | Plan deletion cannot be undone! All plan information will be lost. |
| Patient Information Panel | If a scrollbar is visible on the right side of the Patient Information Panel, the user can use it or the mouse wheel to view all the information. |
| Shoulder landmark, measurement 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. |
| 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

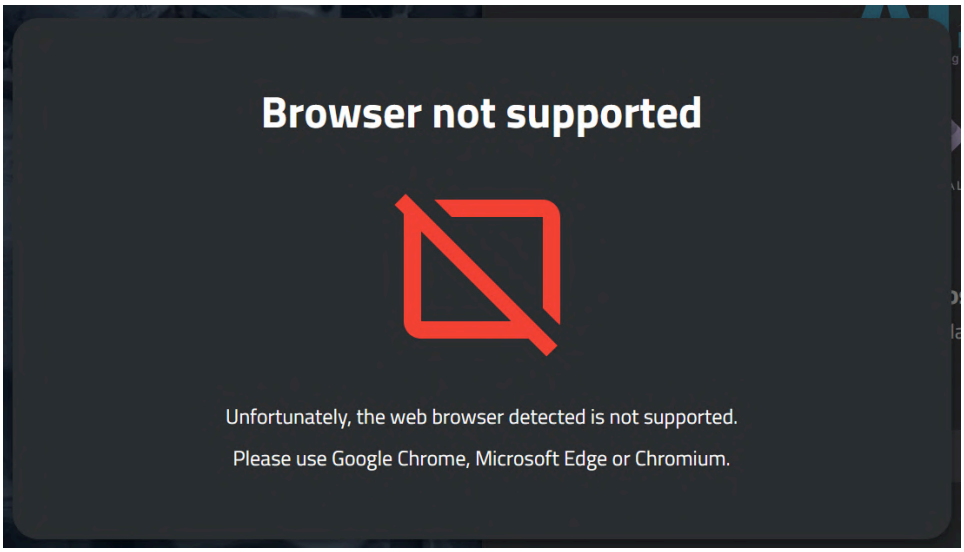
The brAIn™ Shoulder Positioning software is a full-web application deployed on a cloud platform and available at the following link: https://bsp.fx-eu.avatarmedical.cloud.

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 - Administrator 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

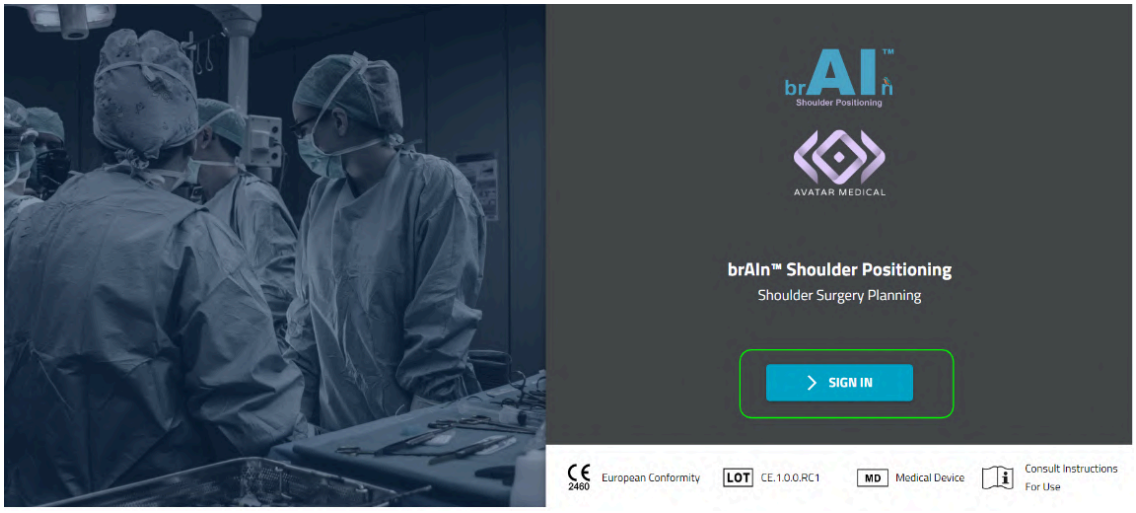
A user account can only be deleted by a Manager-profile or Organization-profile user. If a user with a User profile wishes to delete their account, they must contact customer support (see Troubleshooting & Contact Information).

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

## Authentication

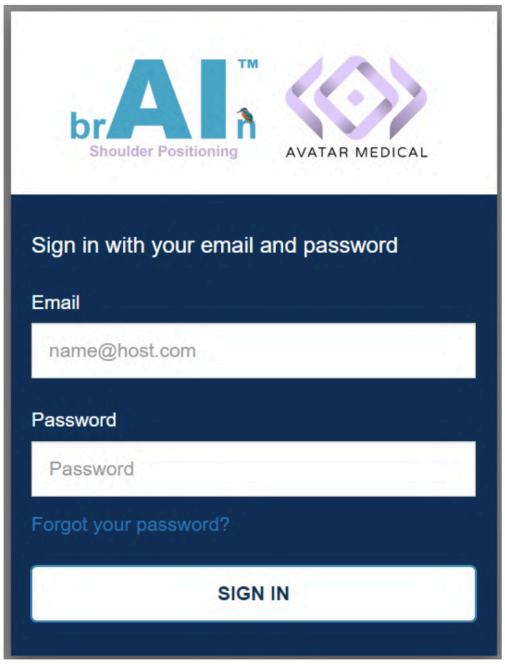
### Connect Interface

The **Connect Interface** is the homepage of the brAIn™ Shoulder Positioning application. It is accessible without being authenticated with a user account. 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.

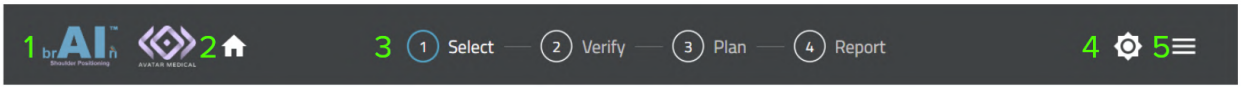
## Navigation bar

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 and company logos
2. A Home icon
3. A 4-step progress bar to help users track their progress in the shoulder surgical planning workflow
4. A dark/light theme toggle shaped like a sun, transitioning smoothly between a bright sun in light mode and a crescent moon in dark mode
5. A dropdown menu with the following options:
    - Access to logout

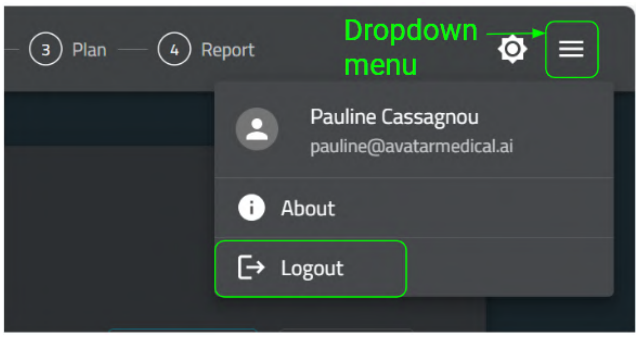
- Access to the About popup
- Name and email of the currently logged-in user




Both the Home icon and the logos 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 the 'Logout' link:




The user will also be automatically logged out after **10 minutes of inactivity**. However, the segmentation process that occurs during plan creation may take longer than 10 minutes and is not considered inactivity.

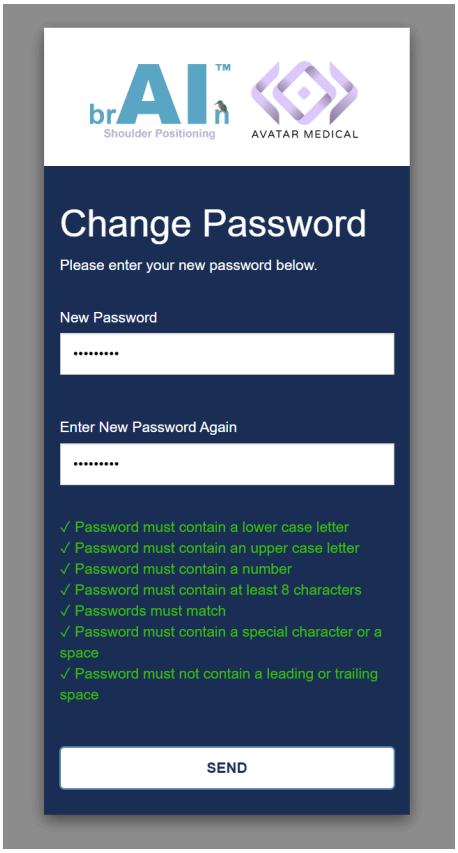
⚠ Closing the web browser tab or exiting the browser will close the software, but it will not terminate the current user session. The user must manually log out using the method described above, or their session will remain active for 10 minutes before automatically ending due to inactivity.

## 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:

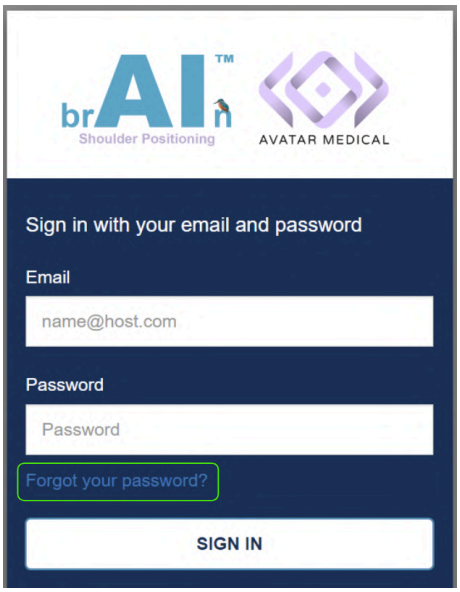


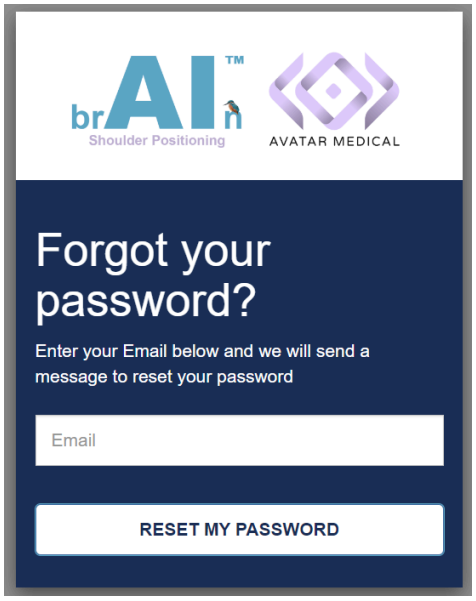

If all the password validation rules are met, clicking “SEND” will redirect the user to the **Select Interface**. The chosen password will then be used for all subsequent connections.

⚠ 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:

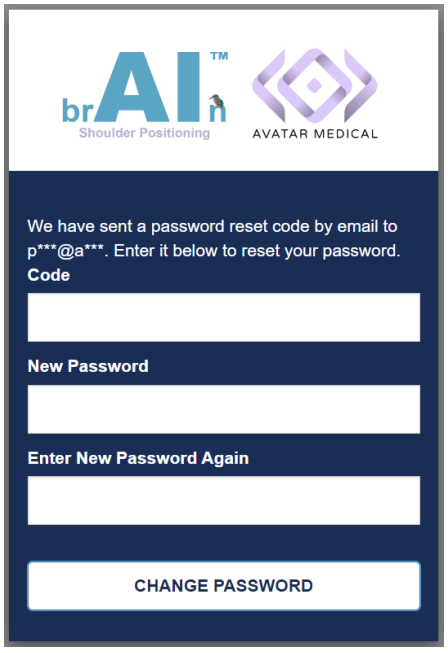



If the email submitted in the form corresponds to a valid user account, an email containing a password reset code will be sent to the email address.

⚠ 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:

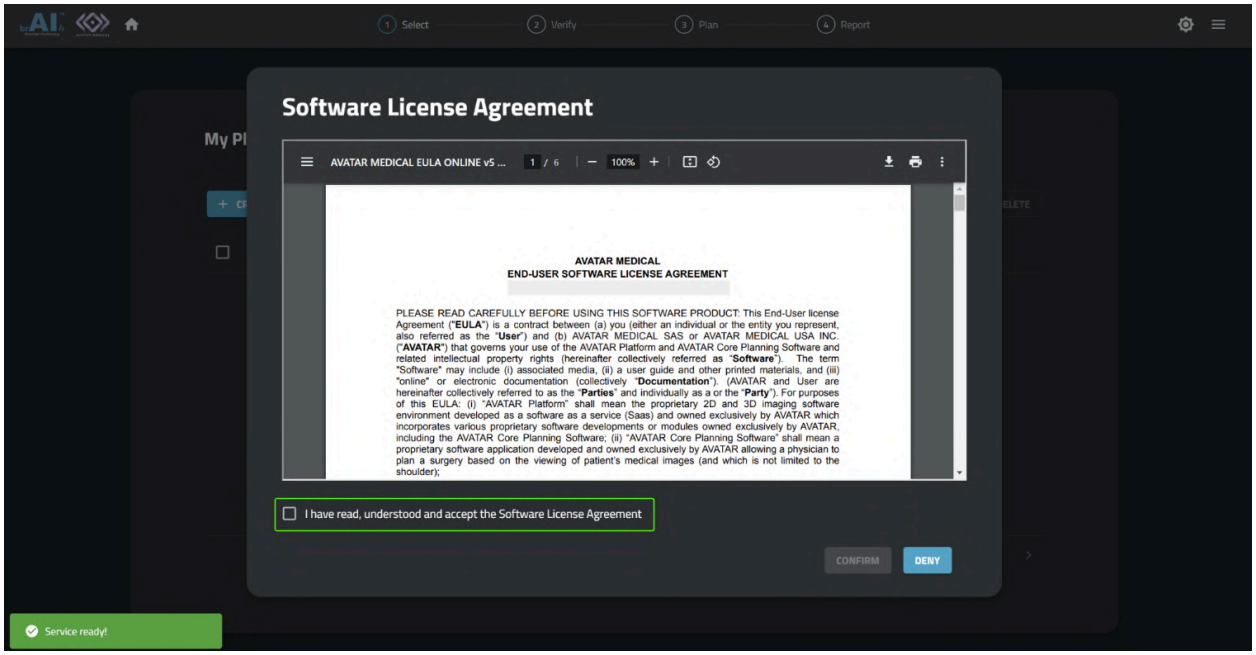


💡 If the password reset code is not used (for example, if the user has remembered their password in the meantime), the old password remains valid. It is not mandatory to update it.

⚠ 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)

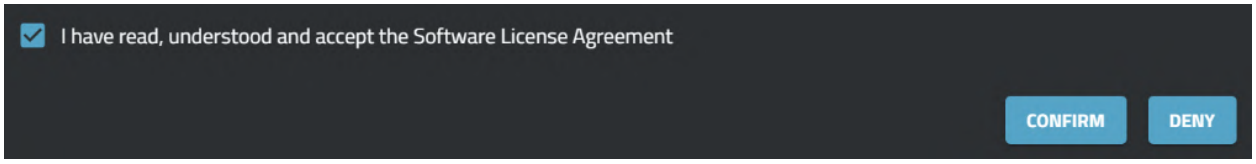
## End-User License Agreement

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
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. European Conformity
9. Medical Device
10. Avatar Medical logo, address and contact information
11. FX Shoulder Solutions logo, address and contact information
12. Copyright information


À propos
1 brAIn™ Shoulder Positioning
Planification chirurgicale de l'épaule
2 LOT CE.1.0.0.RC2
3 REF BSP001
4 Consulter les instructions d'utilisation
5 AVATAR MEDICAL SAS
Dispositif médical classe IIa
6 2024/08/13
7 UDI UDI-DI: 3770026095034
UDI-PI: (01)BSP001(10)CE.1.0.0.RC2(11)20240813
8 CE 2460 Conformité Européenne
9 MD Dispositif médical
10 AVATAR MEDICAL
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fxshouldersolutions.com
12 Copyright © 2024 AVATAR MEDICAL SAS et FX SHOULDER USA Inc.
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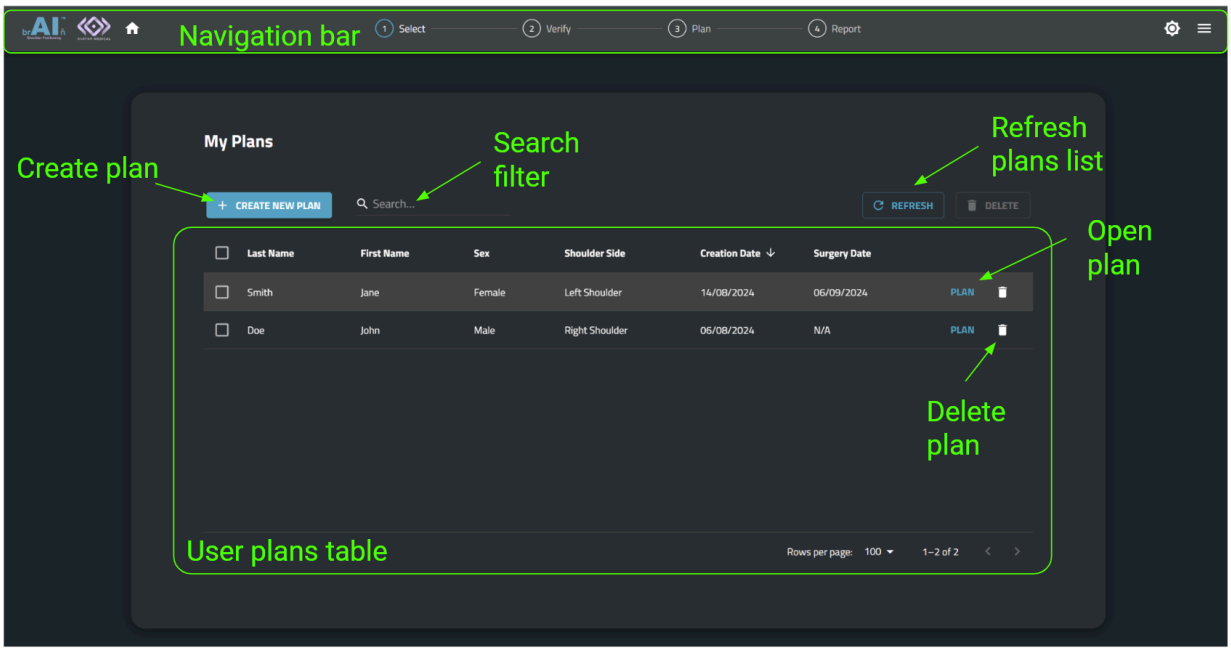
# Plan Management

## 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

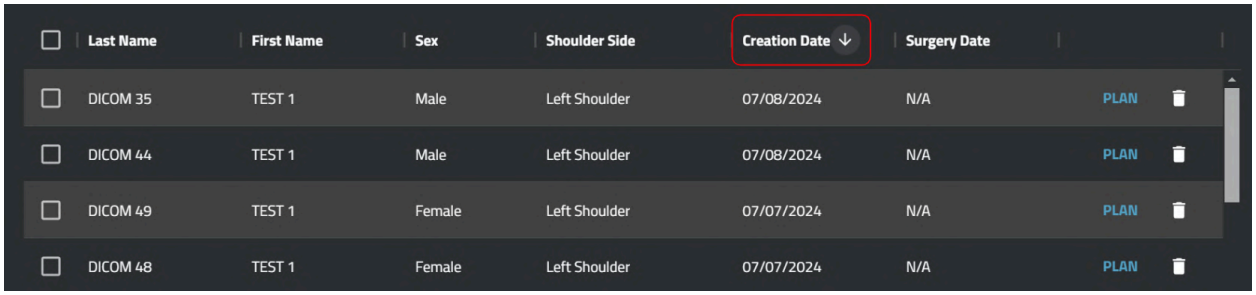
### Plans table

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:

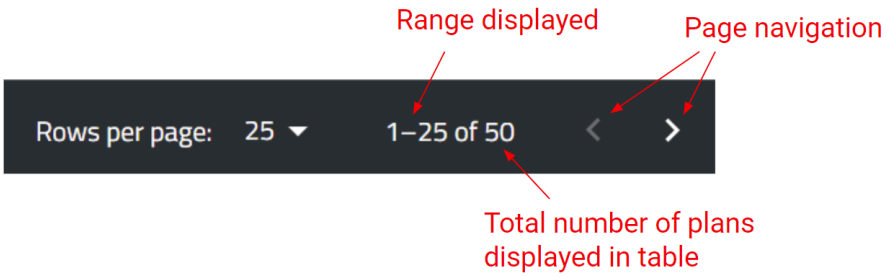
- A checkbox to select the corresponding plan

- 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).

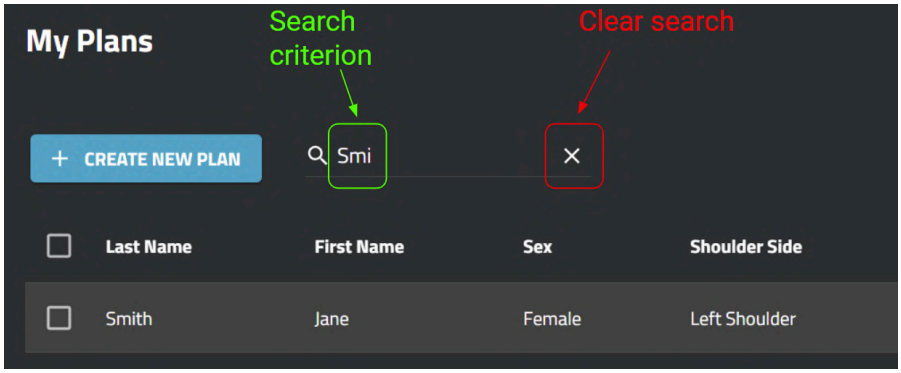



At the bottom of the table, the user can find pagination controls which are useful if there are many plans to be displayed:




### 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):

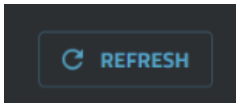



Only plans that match this criterion will be shown. The search filter looks for case-insensitive matches on ‘Last Name’, ‘First Name’, ‘Sex’, ‘Shoulder Side’, ‘Creation Date’ and ‘Surgery Date’. If at least one of the columns contains the search criterion, the plan will be displayed.

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:

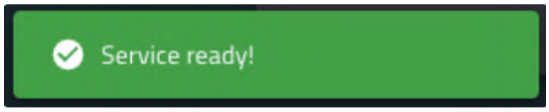



## Planning service availability

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.

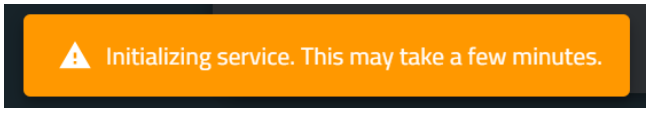
The results of this verification are displayed in a message that appears temporarily in the bottom-left corner of the screen and fades away after a few seconds:

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



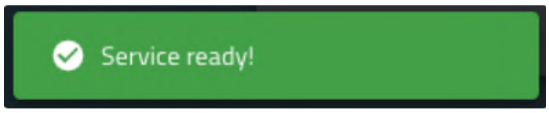

“PLAN” buttons are enabled and become clickable in the “My Plans” table.

- If no resources are available at the time, the following message is displayed:



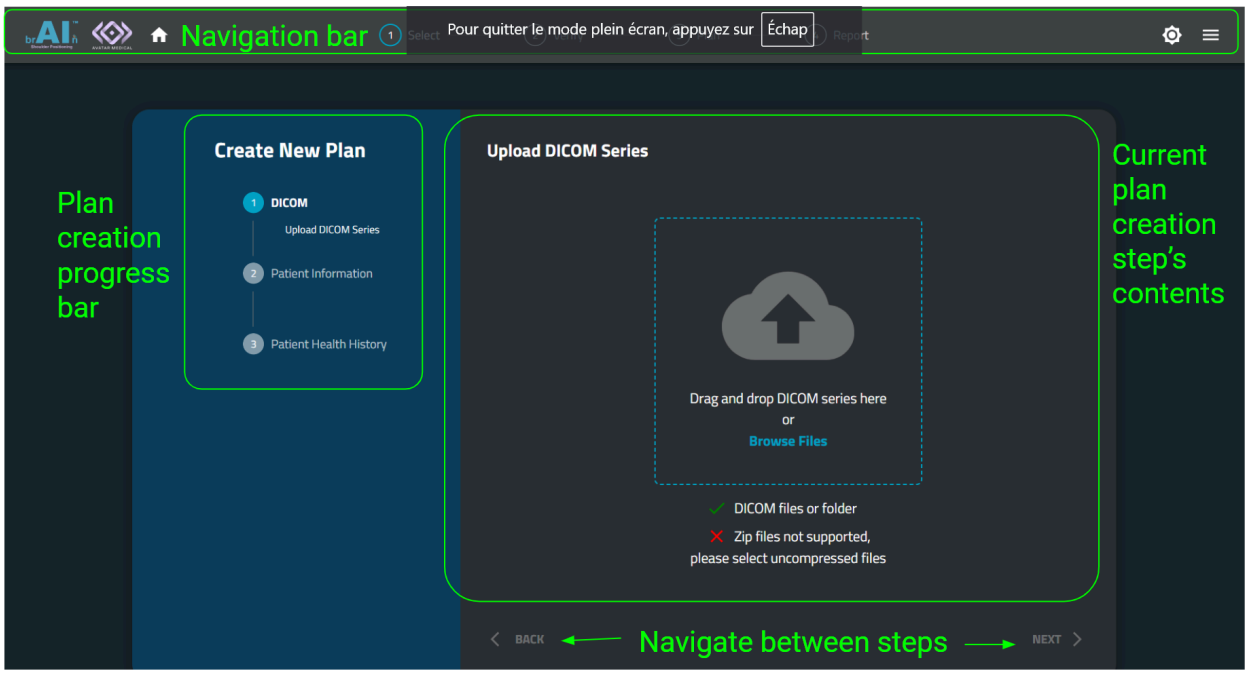

The “PLAN” buttons remain disabled so the user cannot open any plan.

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.

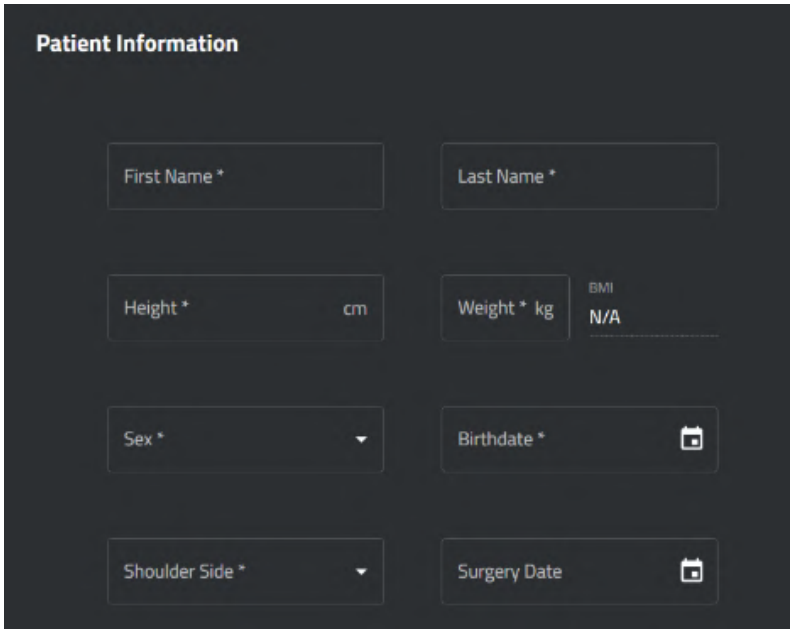
⚠ Zip files are not supported, only uncompressed files must be selected.

💡 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.

**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.

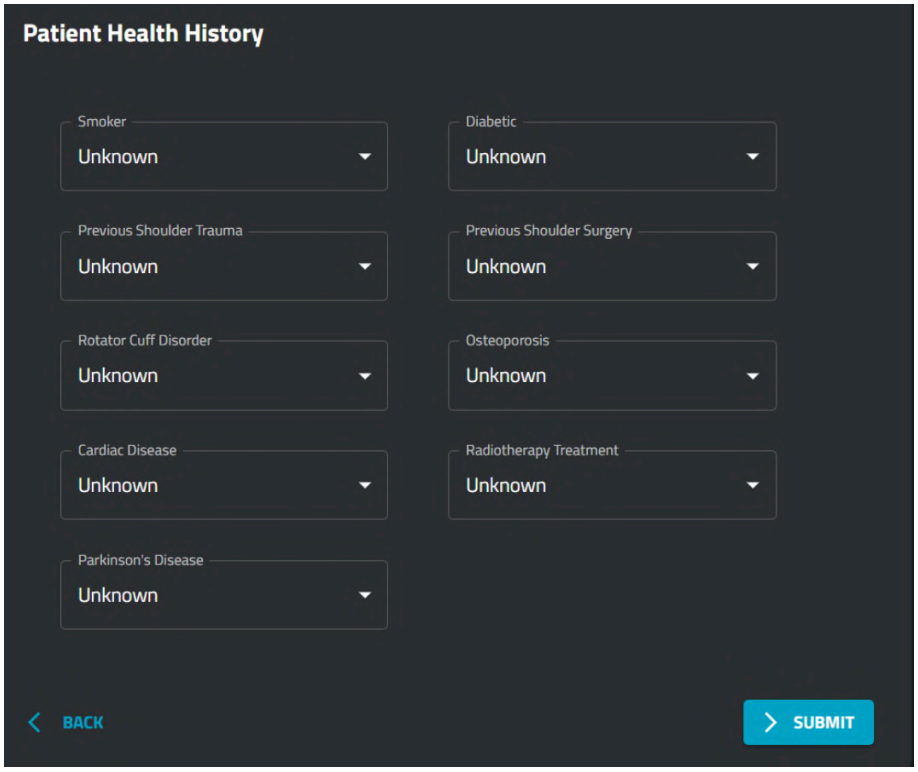



The user must click on the “NEXT” button in the bottom-right corner of the screen to access the third and final step. If any required patient information is missing, the user will not be able to access the next step. Missing or invalid fields will be highlighted in red to help the user fill out missing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

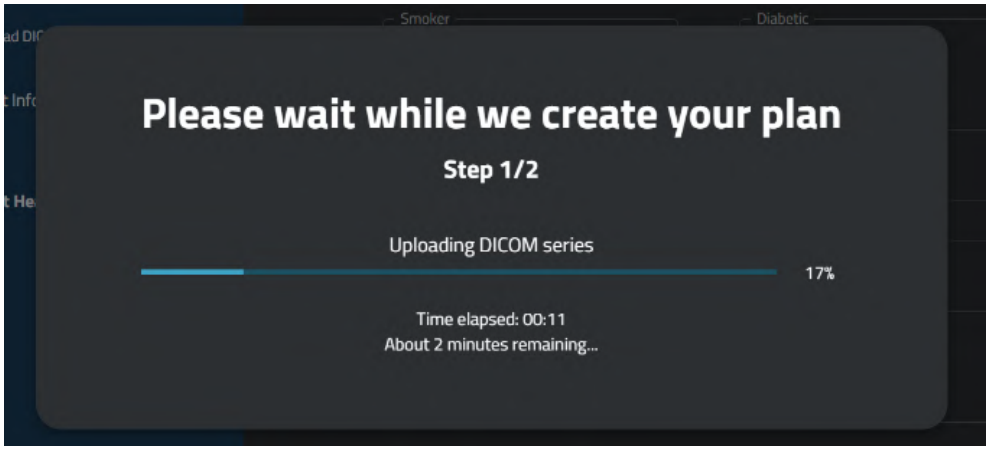
After reviewing their input, the user can click on the “SUBMIT” button to finalize the creation of the plan.

⚠ 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.

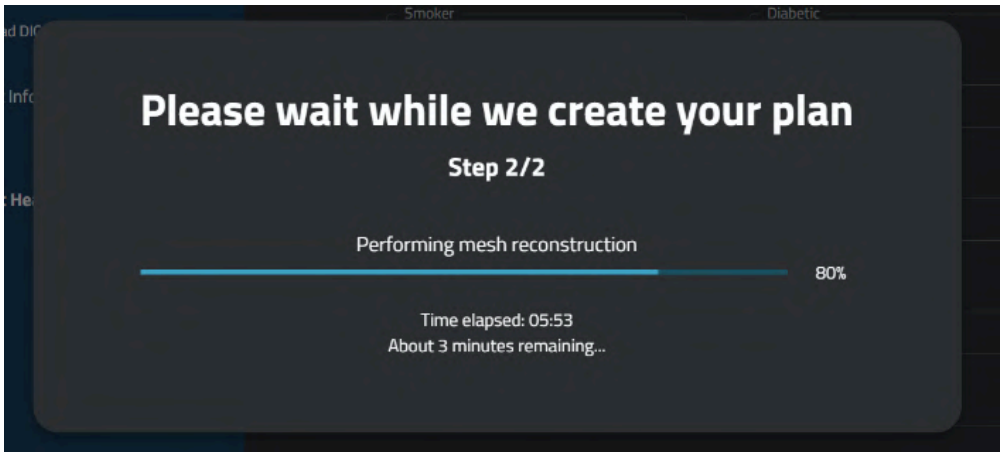
A loading screen popup will appear with an animated progress bar detailing 2 steps:

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. Its speed will depend on the user’s Internet connection’s upload capacity. The files are scanned by an antivirus, checked for DICOM compatibility and anonymized before being sent to the application’s

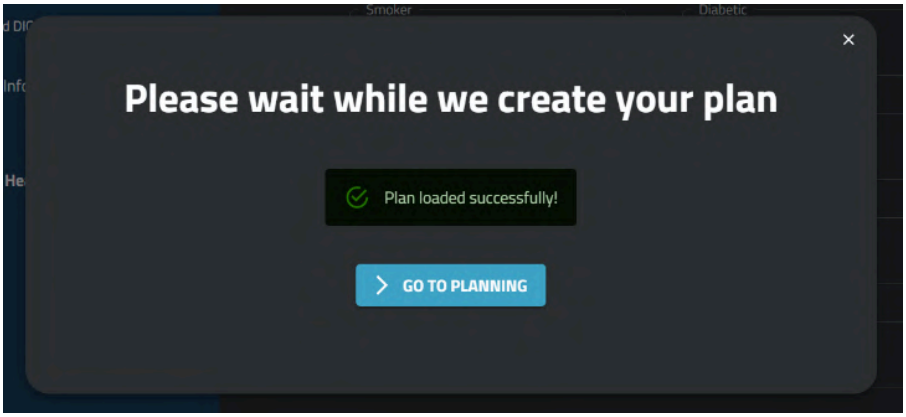
storage.



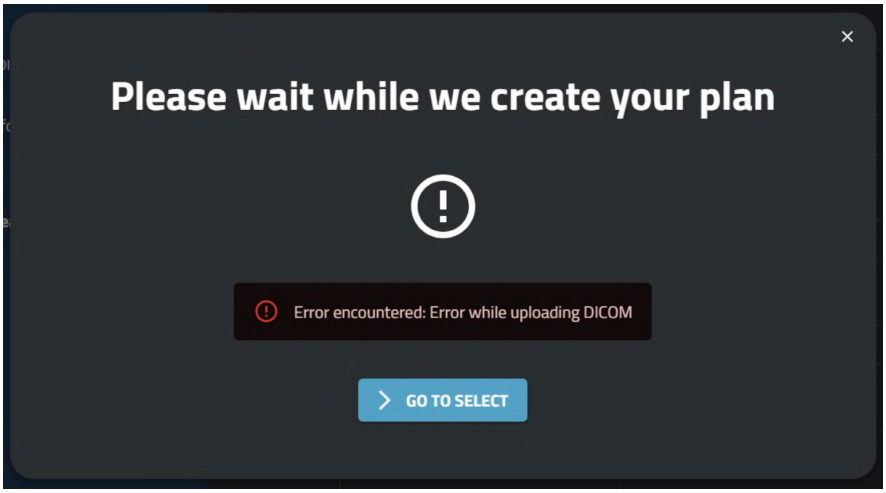

2. **Plan creation:** this step, labeled ‘Step 2/2’, corresponds to the processing of the DICOM images now available on the platform. It is the lengthy part of the plan creation process and can take up to 10-15 minutes. The progress bar indicates to the user the time elapsed since plan creation started, 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
    - **Performing morphology analysis:** this is where the software detects the position of shoulder landmarks (refer to section Shoulder landmarks for more information)

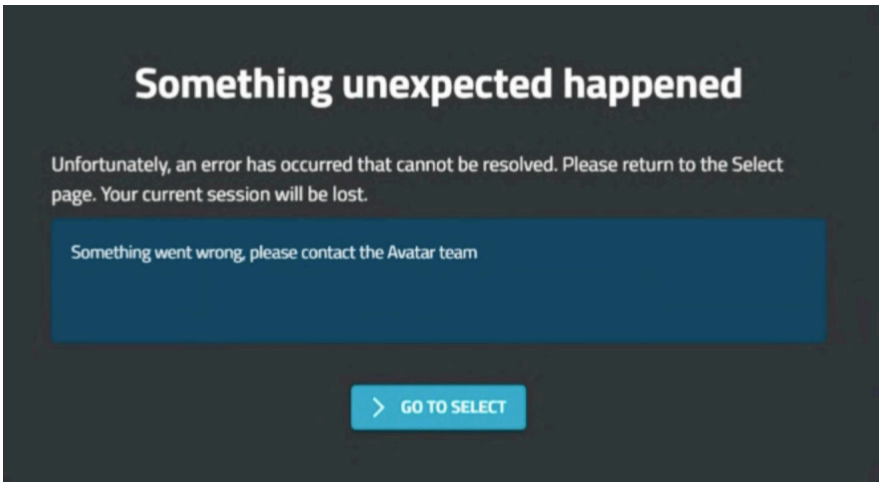



When the plan creation is finished, the progress bar is replaced by a “Plan loaded successfully!” message. The user must click on the “GO TO PLANNING” button to access the Planning Interface (see Pre-Operative Planning):




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

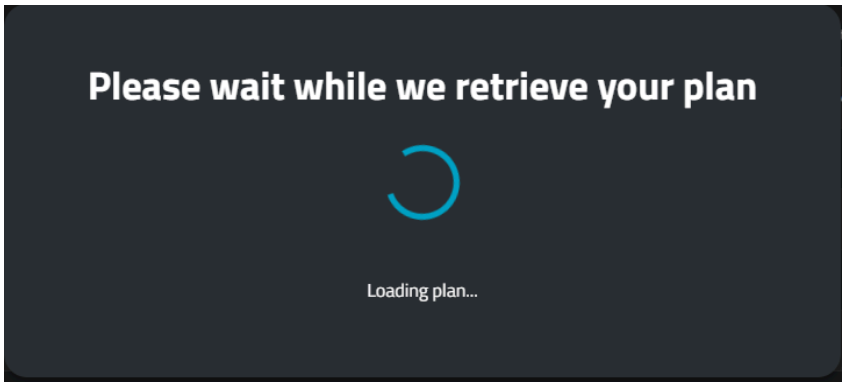


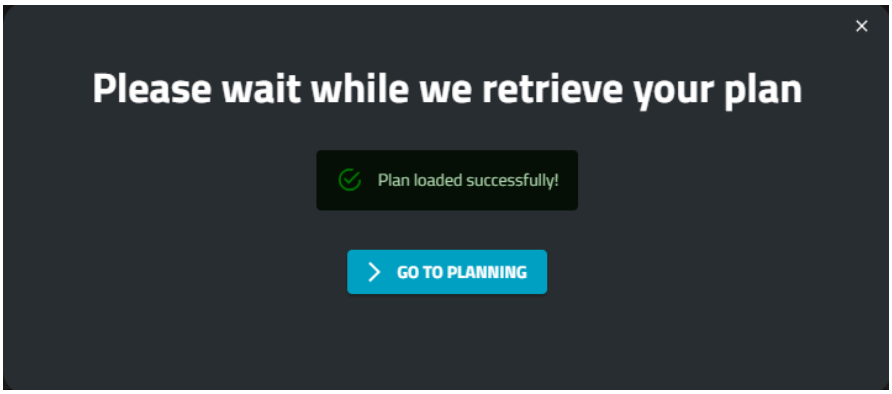
## Opening a plan

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:



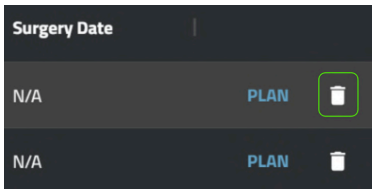

When the plan is loaded, the user must click on the “GO TO PLANNING” button to access the Planning Interface (see Pre-Operative Planning):



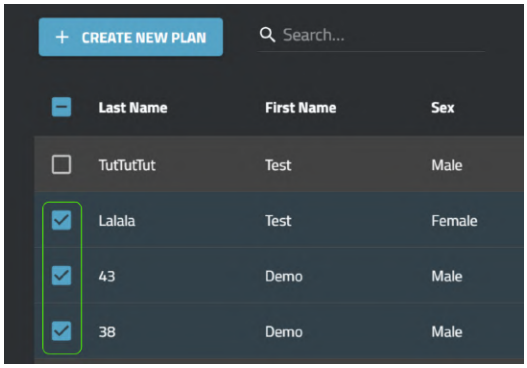
## Deleting a plan

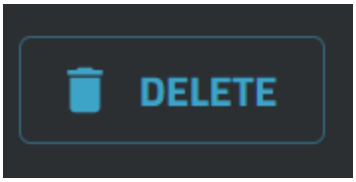
The user can delete a plan from the Select Interface. A plan can be deleted in 2 ways:

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



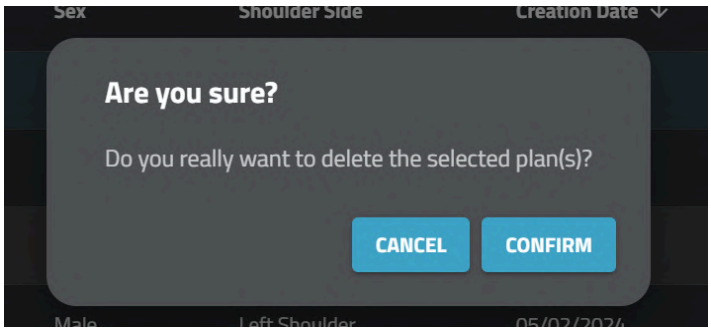

2. Selecting one or several checkboxes at the beginning of the plan row in the My Plans table and clicking the “DELETE” button in the top right corner of the table:




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

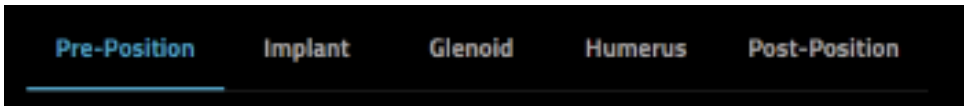
This section describes the common tools and user interface components available across the various pre-operative planning interfaces in brAIn™ Shoulder Positioning.

### 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):

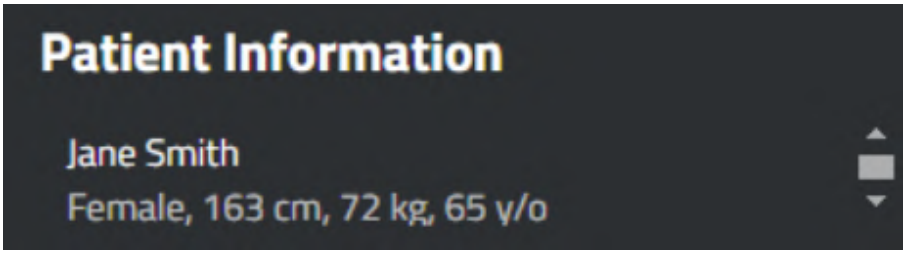

Then, after the user has selected an implant in the Implant tab, the remaining tabs become accessible (white text, tab header clickable). The tab currently selected is the one whose header text is in blue color with a blue underline:

💡 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).

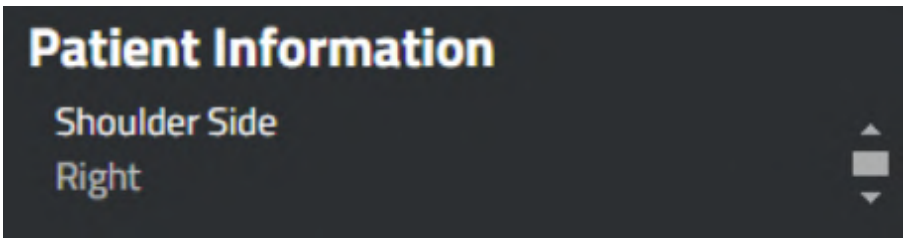
### Patient Information Panel

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:

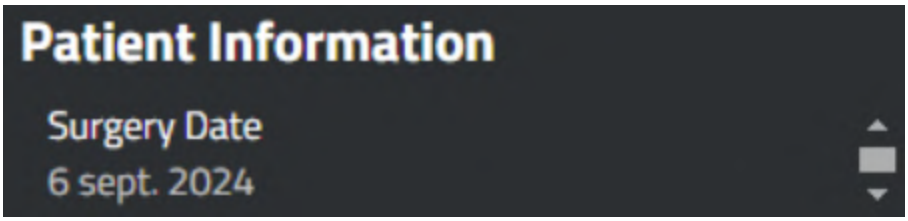
- Patient First Name and Last Name
    - Sex, Height, Weight and Age




- ‘Shoulder Side’ label
    - ‘Left’ or ‘Right’



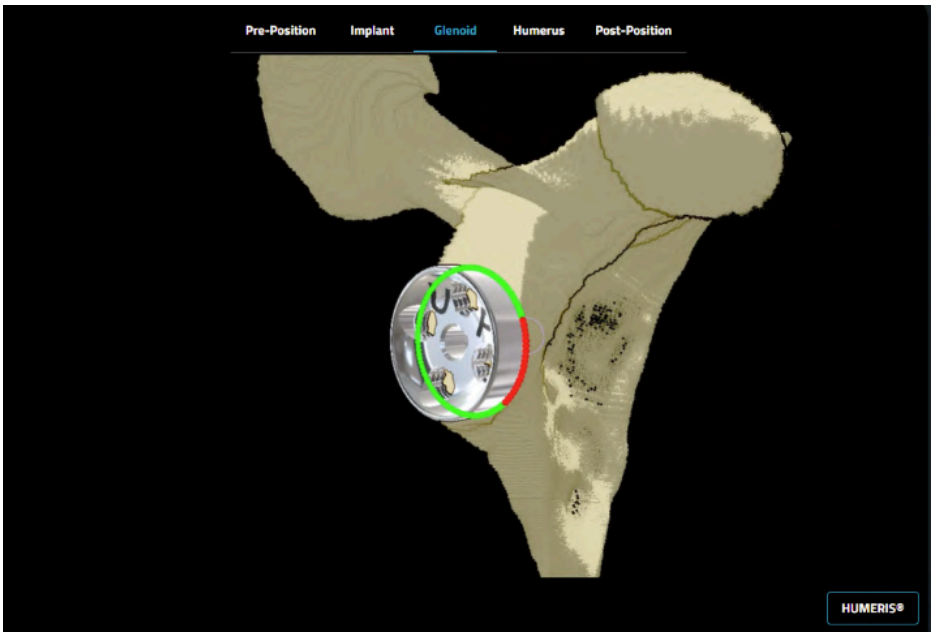

- ‘Surgery Date’ label
    - Date if entered at the time of plan creation, otherwise ‘N/A’ will be displayed




⚠ If a scrollbar is visible on the right side of the Patient Information Panel, the user can use it or the mouse wheel to view all the information.

## 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:




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

- **Zoom:** the user can zoom in or out using the mouse wheel
- **Rotation:** the user can click and hold the left mouse button and move the mouse to rotate the 3D visualization

## 3D Viewer Settings

Below the 3D Viewer is a settings panel to customize the 3D visualization:

- Display toggles:
    - Humerus and Scapula toggles: will hide/show the corresponding anatomy
    - K-Wire toggle: when enabled, will hide any selected implant components and display the K-Wire instead
    - Reaming: will hide/show the visual effect of glenoid reaming
- 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.

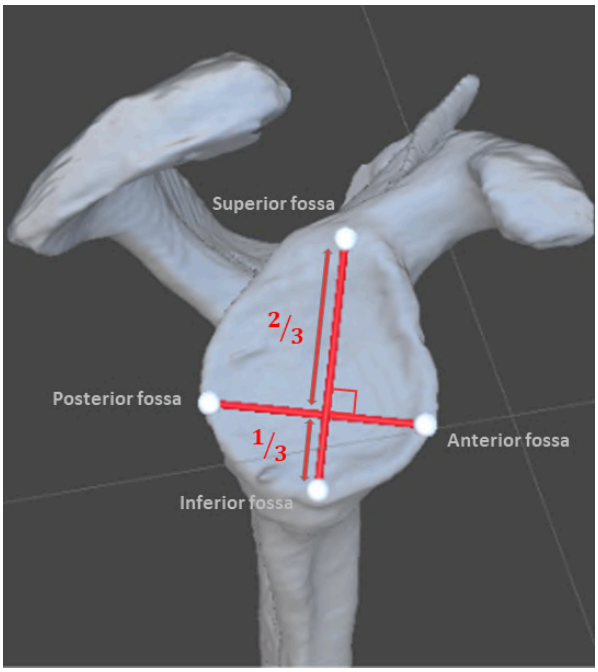
💡 We recommend that users first adjust the Window Center slider to select the anatomy of interest. Once the desired tissues are highlighted, they can fine-tune the appearance by adjusting the Color Offset.

### 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 |

| | | |
|---|---|---|
| Posterior Fossa | Scapula | Dr. Gauci in his thesis[1] (see illustration below) |
| 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 |




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 Shoulder measurements section below) and to pre-position certain implant components.

[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

### Measurements Panel

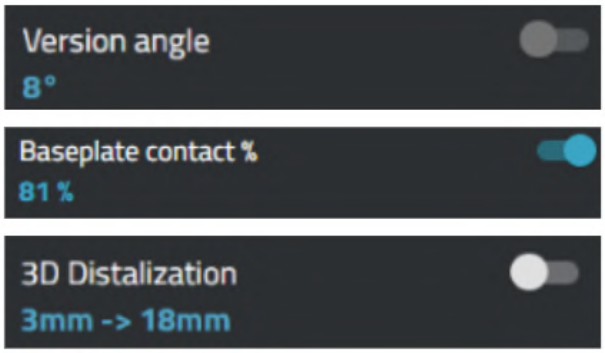
The Measurements Panel, located in the bottom left corner of all Planning tabs, displays a list of all measurements calculated by the application, organized in the following order:

- Version angle
- 3D Subluxation
- Baseplate contact %
- Glenoid reaming depth
- 3D Distalization
- 3D Lateralization
- 3D TSA angle
- 3D RSA angle

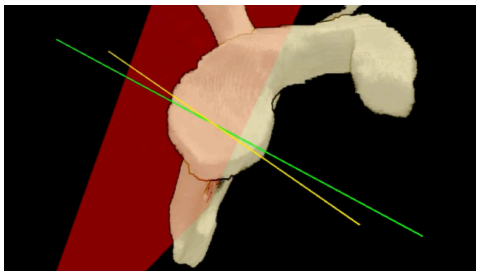
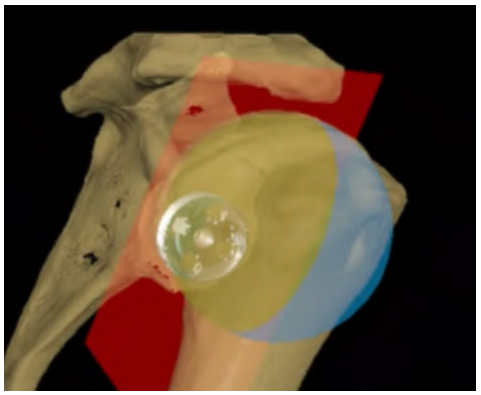
Detailed explanations of how these measurements are calculated can be found in the annex Annex 2: Shoulder measurements definitions.

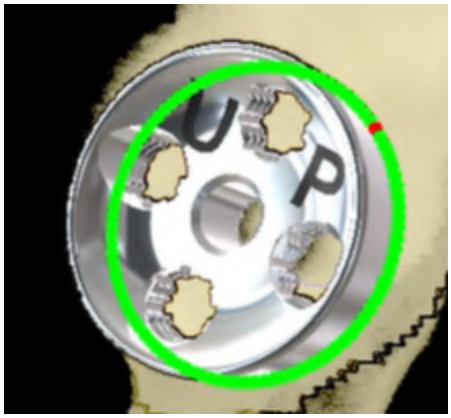
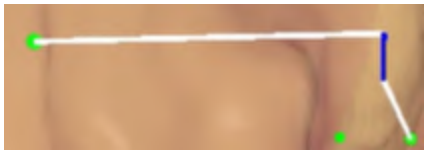
Each measurement is displayed in the following format:

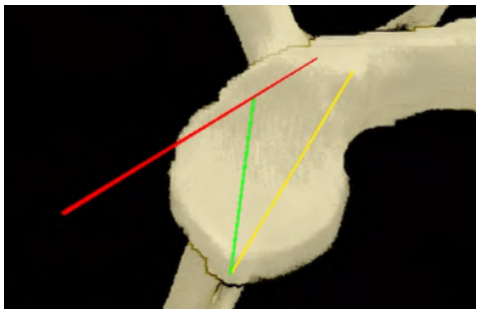
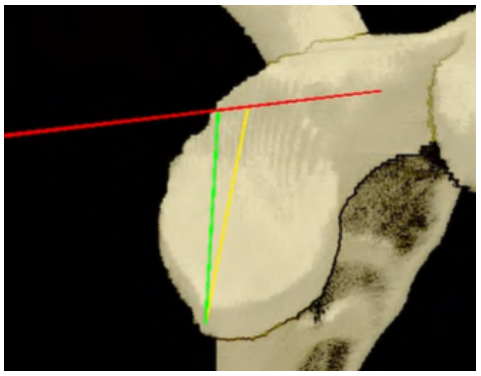
- Measurement name in white text.
- Measurement value(s) in blue text:
    - If the measurement has only a pre-position value (e.g., Version angle) or a post-position value (e.g., Baseplate contact %), this single value will be displayed along with the measurement unit.
    - If the measurement includes both a pre-position value and a post-position value (e.g. 3D Distalization), both values will be shown along with the measurement unit with a right-facing arrow between them.
- Measurement toggle button on the right to enable the visual representation in the 3D Viewer (see Shoulder landmark, measurement and implant component toggles)



The following table provides details for each measurement, including the measurement unit, measurement precision, whether there is a Pre-Position and a Post-Position value, as well as the visual representation for each measurement.

| Measurement Name | Measurement Unit / Precision | Pre-Position Value | Post-Position Value | Visual Representation |
|---|---|---|---|---|
| Version angle | Degree / 1° | Yes | No | Red: scapular plane<br>Green: neutral version line<br>Yellow: glenoid surface line<br>  |
| 3D Subluxation | Percentage / 1% | Yes | Yes | Red: scapular plane<br>Green: posterior portion of the humeral head<br>Blue: anterior portion of the humeral head<br>  |

| | | | | |
|---|---|---|---|---|
| Baseplate contact % | Percentage / 1% | No | Yes | Rim of the baseplate with the points in contact in green and the points not in contact in red   |
| Glenoid reaming depth | Millimeter / 1mm | No | Yes | None, because the average depth is too small to be visualized accurately as a line segment in the 3D Viewer. |
| 3D Distalization | Millimeter / 1mm | Yes | Yes | The three components of the vector between the Glenoid Center and the center of the Humeral Head Sphere are visible. The 3D Distalization (z-axis component) is displayed in blue, while the other two components are shown in white.  |
| 3D Lateralization | Millimeter / 1mm | Yes | Yes | The three components of the vector between the Glenoid Center and the center of the Humeral Head Sphere are visible. The 3D Lateralization (x-axis component) is displayed in blue, while the other two components are shown in white.  |

| | | | | |
|---|---|---|---|---|
| 3D TSA angle | Degree / 1° | Yes | No | Red: Supraspinatus Fossa Line<br>Yellow: Inferior-Superior Fossa axis<br>Green: line segment orthogonal to the Supraspinatus Fossa Line passing through the Inferior Fossa landmark<br>  |
| 3D RSA angle | Degree / 1° | Yes | No | Red: Supraspinatus Fossa Line<br>Yellow: Inferior Fossa to exit point of the Supraspinatus Fossa Line on the glenoid surface axis<br>Green: line segment orthogonal to the Supraspinatus Fossa Line passing through the Inferior Fossa landmark<br>  |

### Implant components

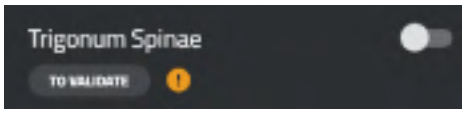
An implant consists of several implant components (baseplate, glenosphere, humeral stem, etc). These components can be selected from dropdown lists available in the Glenoid and Humerus tabs. Mandatory components are indicated with an asterisk (*).

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.

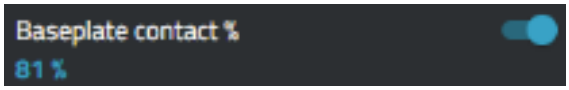
### Shoulder landmark, measurement and implant component toggles

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:

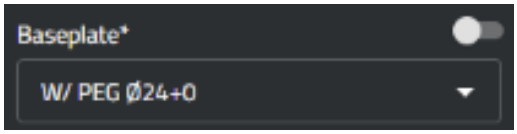
- Shoulder landmark (for manipulation and review)




- Shoulder measurement (for review only)




- 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 'Baseplate contact %' measurement toggle when an anatomical implant is selected).

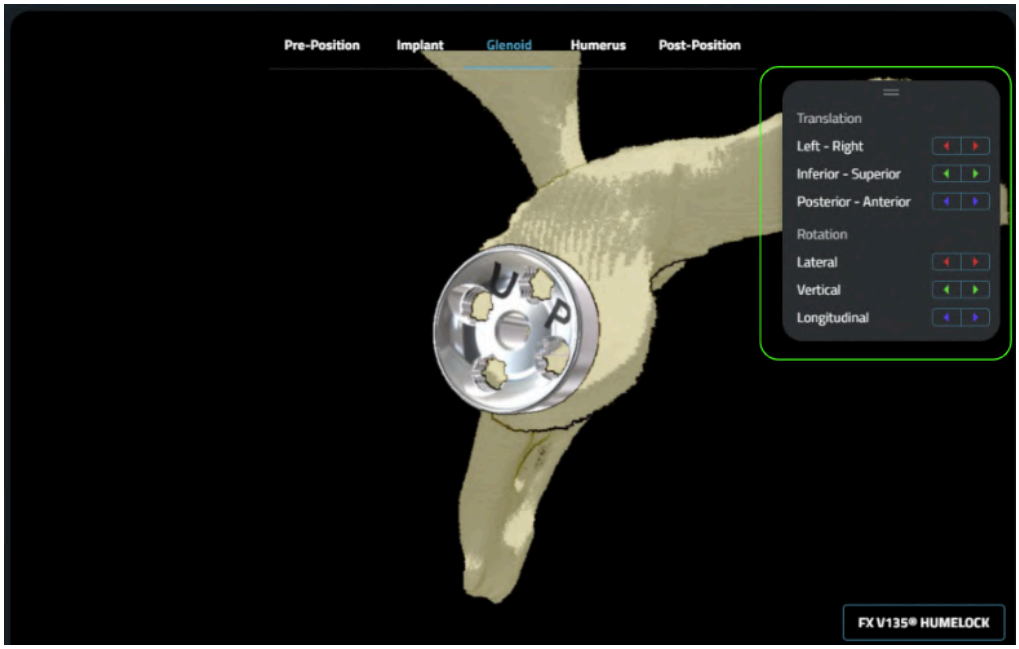
The following table describes, for an active toggle, the effect of toggling ON or OFF depending on the type of item:

| 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 blue. The toggle for the bone anatomy the landmark belongs to (humerus or scapula) is switched on. The Manipulation Panel appears for the selected landmark. |

| | | |
|---|---|---|
| Shoulder measurement | Measurement value can be read in the Measurements box. | Measurement value can be read in the Measurements box. A visual representation of the measurement is displayed in the 3D Viewer except for the Glenoid reaming depth (too small to be displayed). |
| 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 except for the one selected become transparent. The Manipulation Panel appears for the selected component. |

### Manipulation Panel

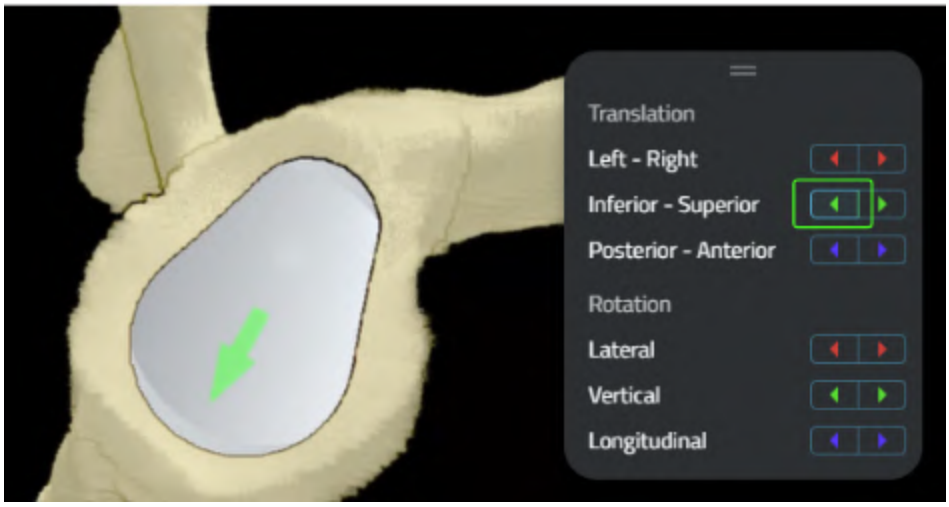
Both shoulder landmarks and implant components can be positioned in the 3D space using brAIn™ Shoulder Positioning's Manipulation Panel:




It appears only when a shoulder landmark or implant component is selected (see Shoulder landmark & 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.

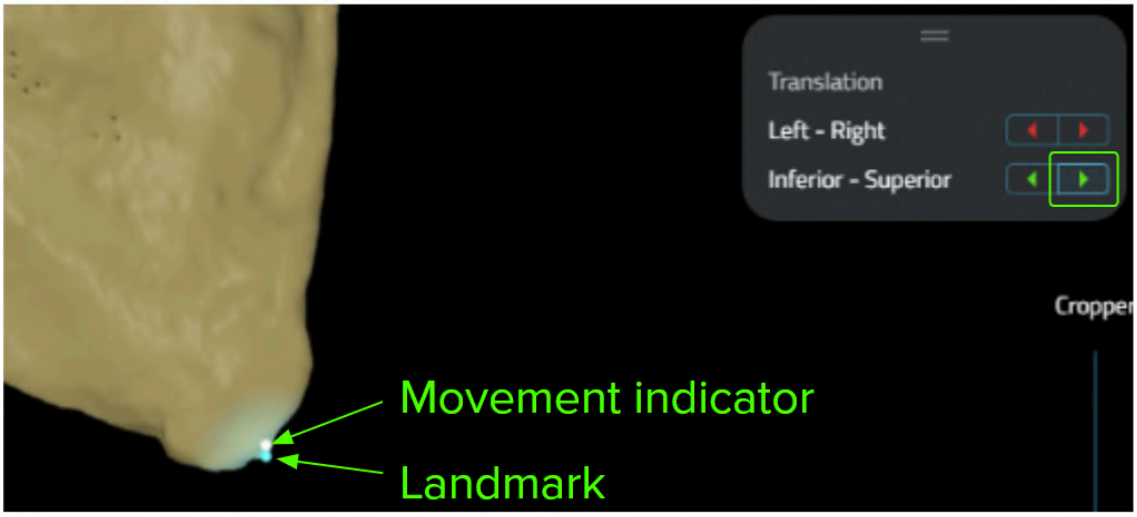
It contains all the degrees of freedom for moving the shoulder landmark or implant component which can be adjusted with left and right arrows. An animation in the 3D Viewer provides a preview of the movement direction:

- 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, for example 'Left - Right' refers to the Left-Right axis of the component.

- 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.

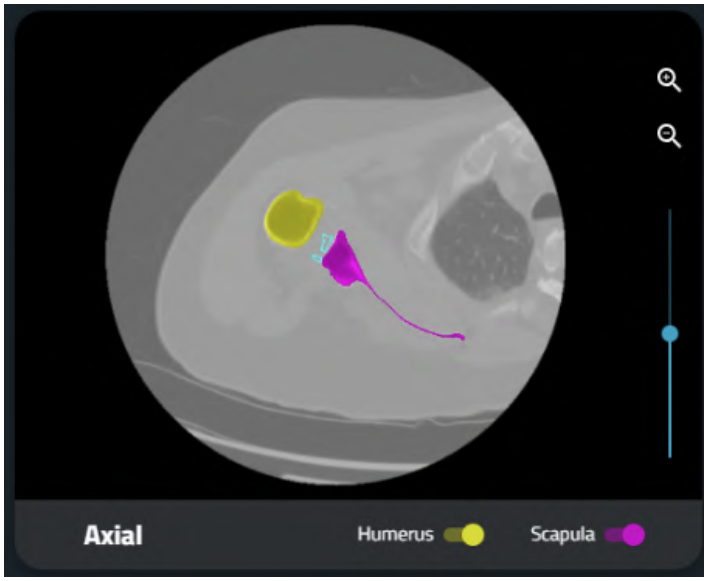
💡 Rotation will be adjusted by ±1 degree for each arrow click.
Size will be adjusted by ±1 millimeter for each arrow click.
For implant components, each arrow click adjusts the translation by ±1 millimeter.
For shoulder landmarks, translation also shifts by ±1 millimeter, followed by projecting the landmark 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 scapular 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-pink mask

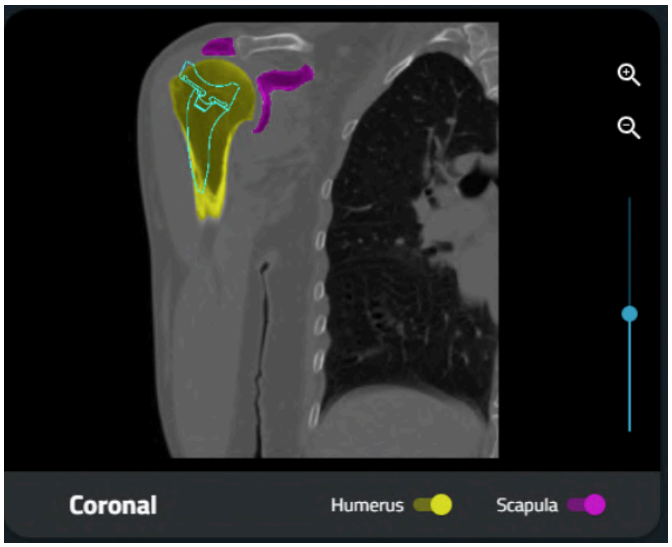


💡 Implant components cannot be positioned in the 2D DICOM Viewer, implant placement is done only via the Manipulation Panel in the 3D Viewer.

### 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-pink 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.

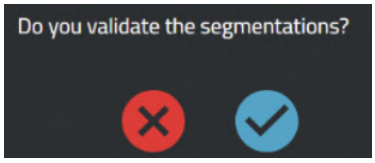
## Segmentation validation

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.

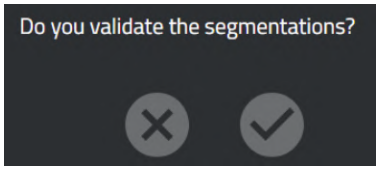
### Shoulder Side Inconsistency Check

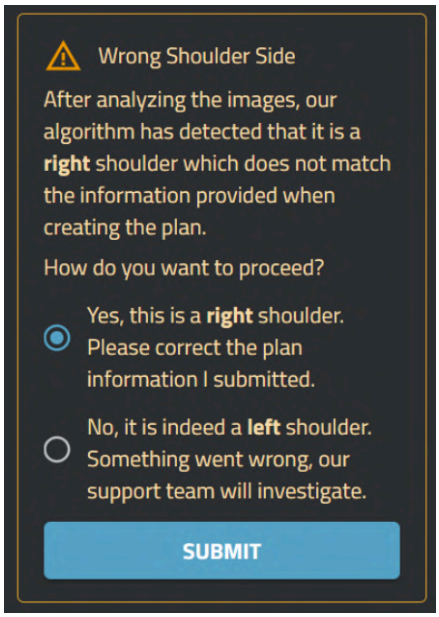
When the user enters the segmentation validation screen, the software has already automatically identified the relevant anatomical shoulder landmarks. These landmarks enable the brAIn™ Shoulder Positioning application to determine the shoulder side (right or left) and compare it with the information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

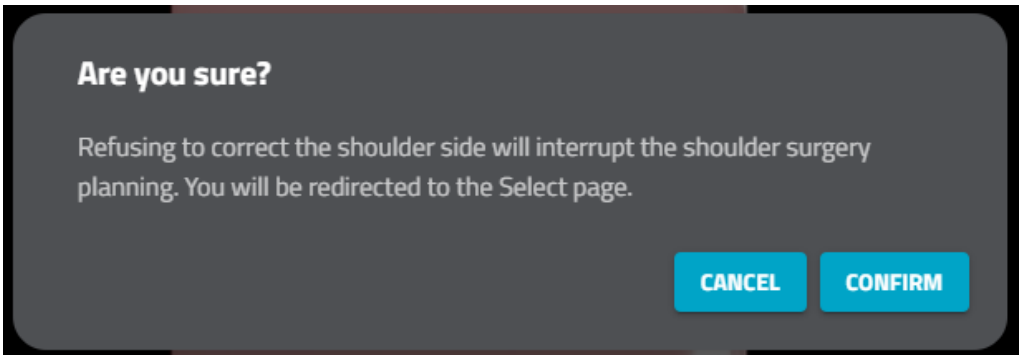





The user must choose between the following two options and click the SUBMIT button to confirm their choice:

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.



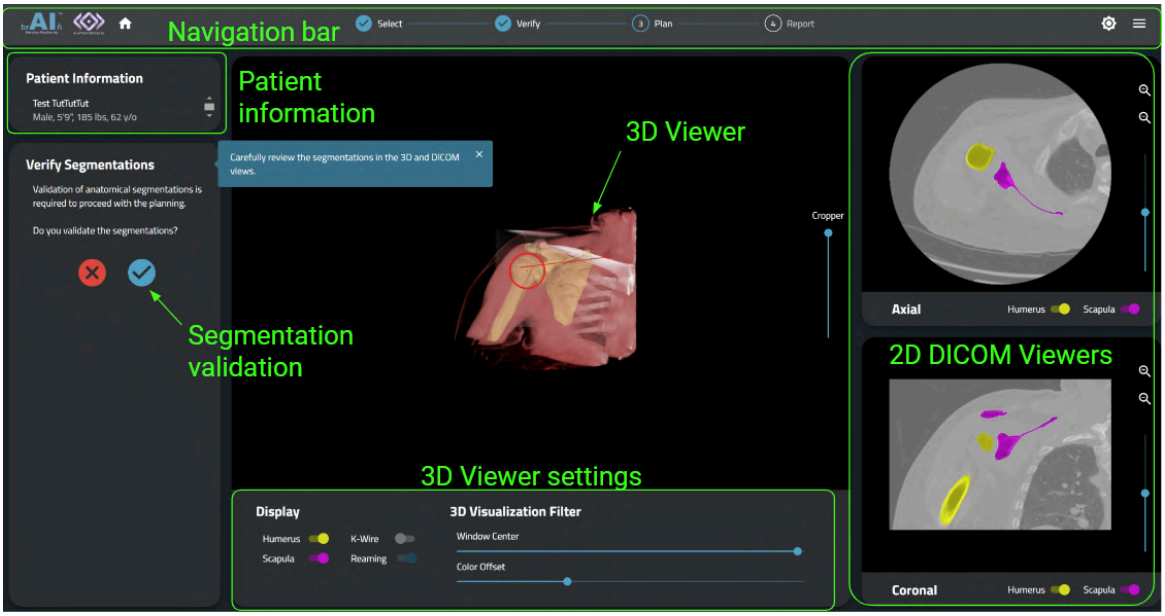

⚠ If a shoulder side inconsistency arises that is not caused by user error in entering patient information, the user must select option b. For further assistance, we recommend contacting customer support (see Troubleshooting & Contact Information).

### 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).

## 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.

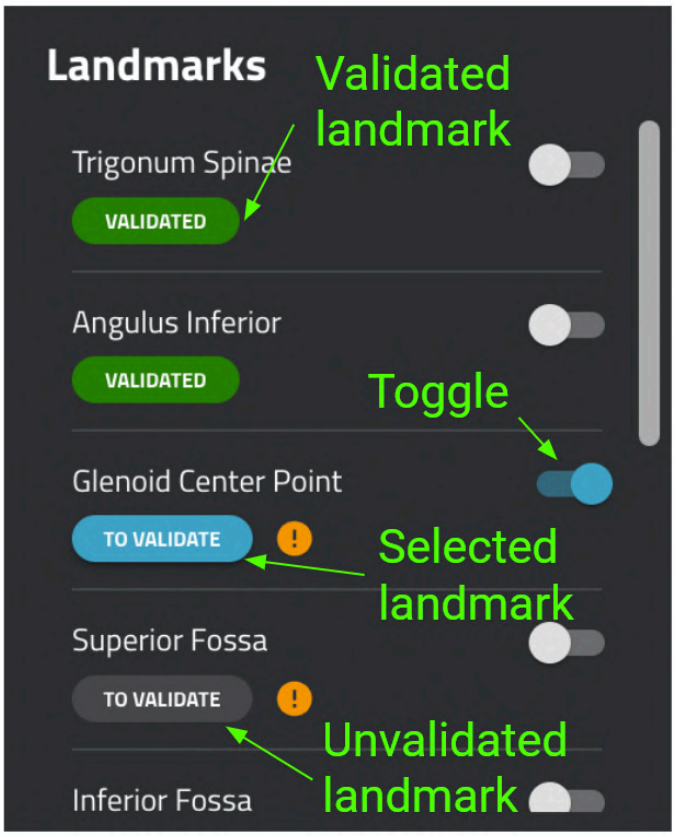

### Shoulder landmarks verification

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

To select a landmark for validation, the user must click on its toggle button. This will automatically rotate the 3D Viewer in the landmark's direction. The user can then:

1. Click on the 'TO 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 'TO VALIDATE' button

An unvalidated landmark displays a 'TO VALIDATE' button with a gray background, which turns blue when the toggle is enabled, as well as an orange warning icon. A validated landmark displays a 'VALIDATED' button with a green background:

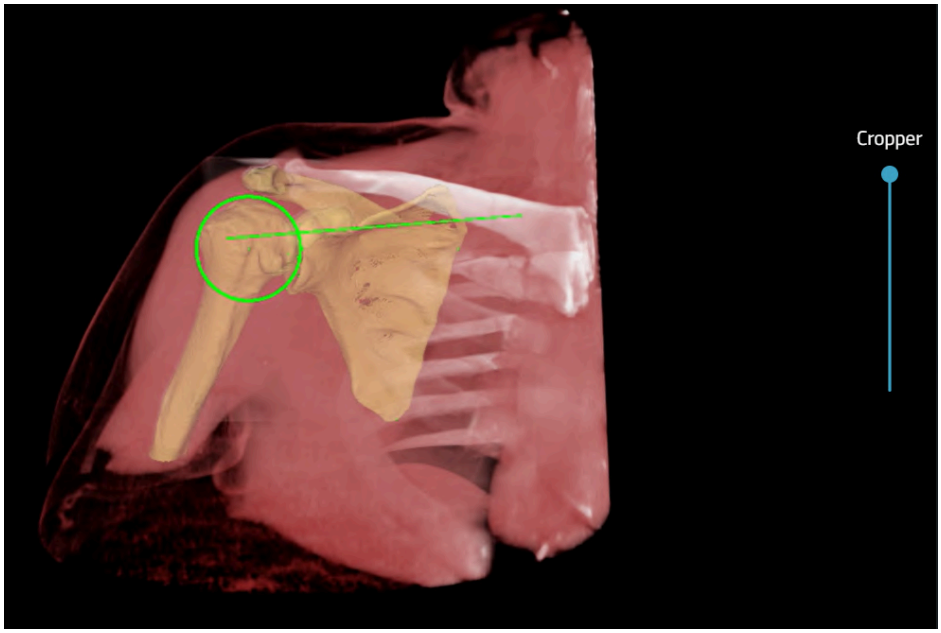



Selecting a landmark that's already been validated will automatically invalidate it.

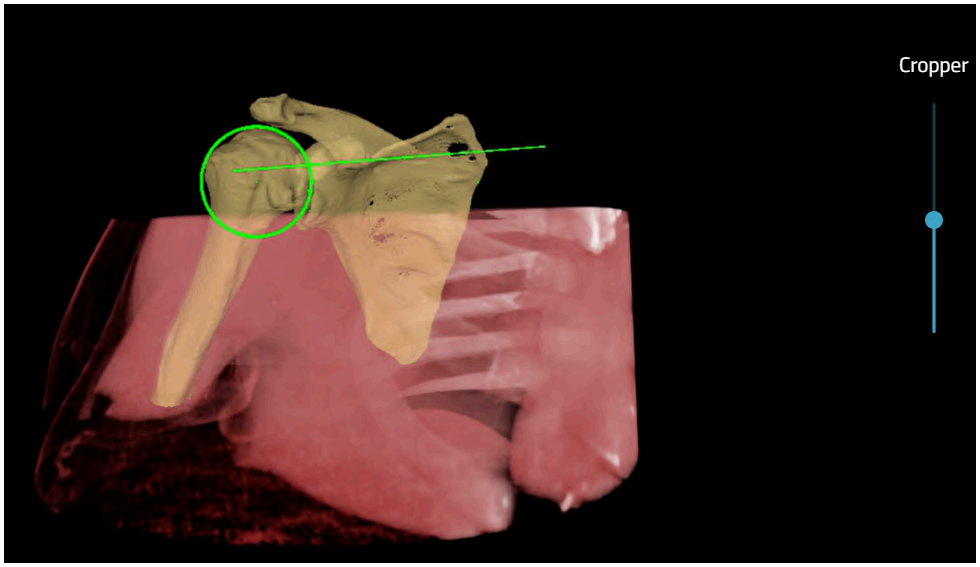
Once all landmarks have been validated, a dialog box will appear, prompting the user to proceed to the next tab, 'Implant', where implant selection is performed.

### 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. As the slider is adjusted, the soft tissues above the slider's position are hidden, leaving only the bone segmentations and shoulder landmarks visible:



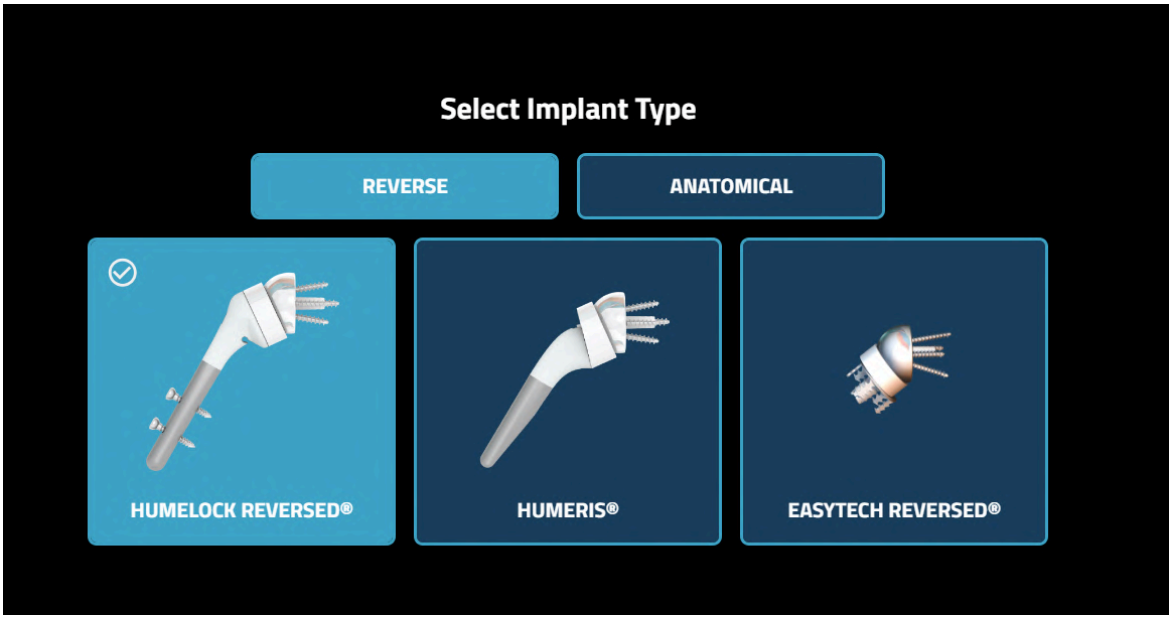
## Implant tab

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

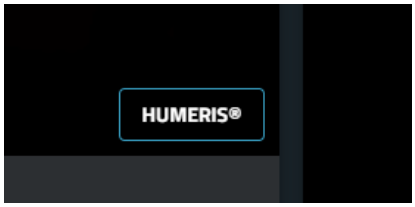
- Reverse:
    - HUMELOCK REVERSED®
    - HUMERIS®
    - EASYTECH REVERSED®
- Anatomical:
    - HUMERIS®
    - EASYTECH®

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

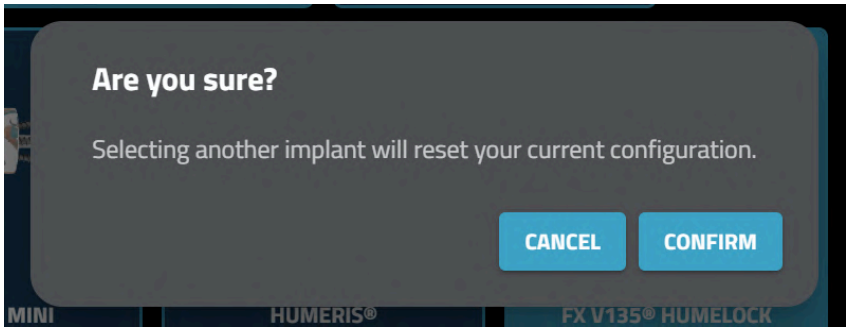

The user can then choose between the different available implants by clicking on the corresponding tile:




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:



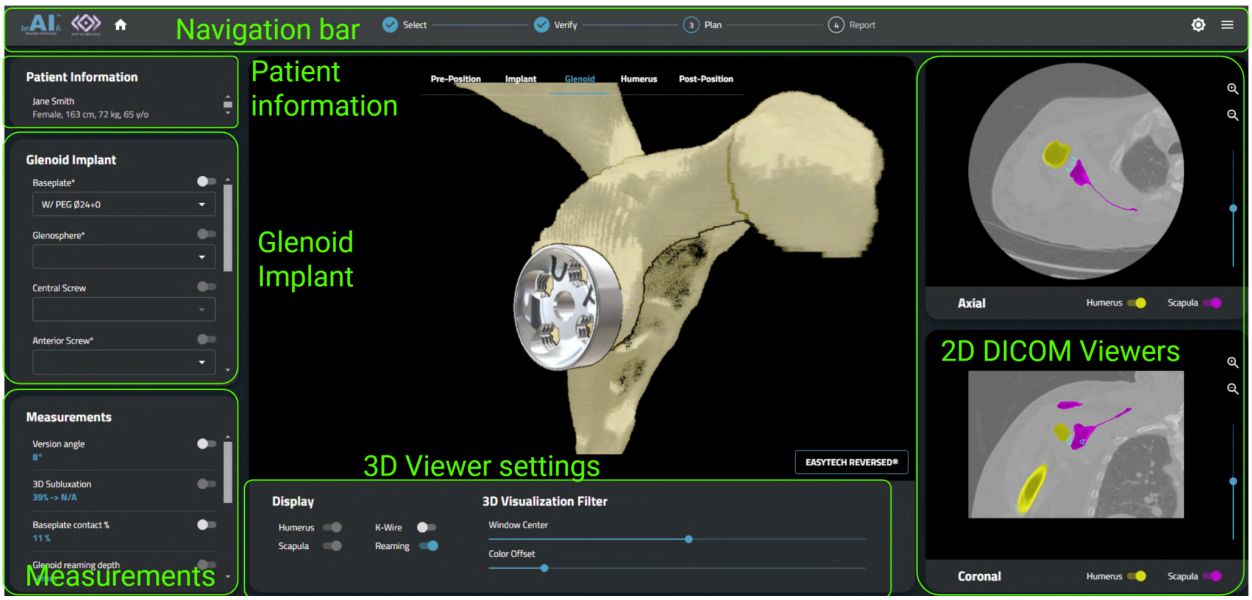

If the user decides to change the selected implant, a warning message will be displayed to inform them that the current implant configuration will be lost:



## 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.

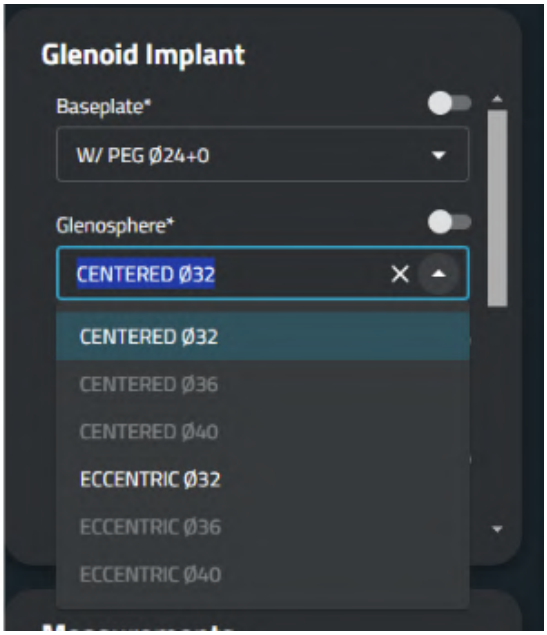



On the left side of the screen, the Glenoid Implant panel displays all the components available for selection for the implant chosen by the user. Mandatory components are indicated with an asterisk (*).

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

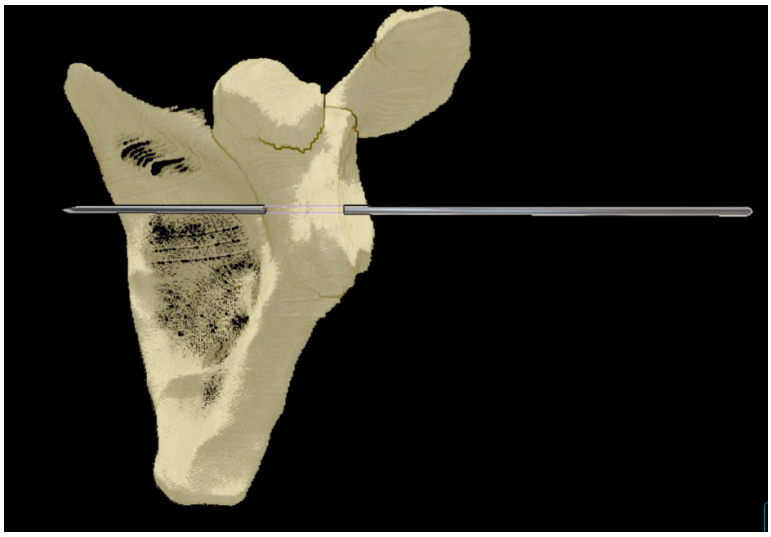
Selecting an option from the dropdown list for a given component will automatically enable its toggle button and display the Manipulation Panel, allowing the user to position the component as desired (see Shoulder landmark, measurement and implant component toggles).

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 effect in the 3D visualization. In the 3D Viewer Settings, the Reaming toggle (enabled by default) can be turned off to hide the reaming effect and display the native glenoid surface.

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.



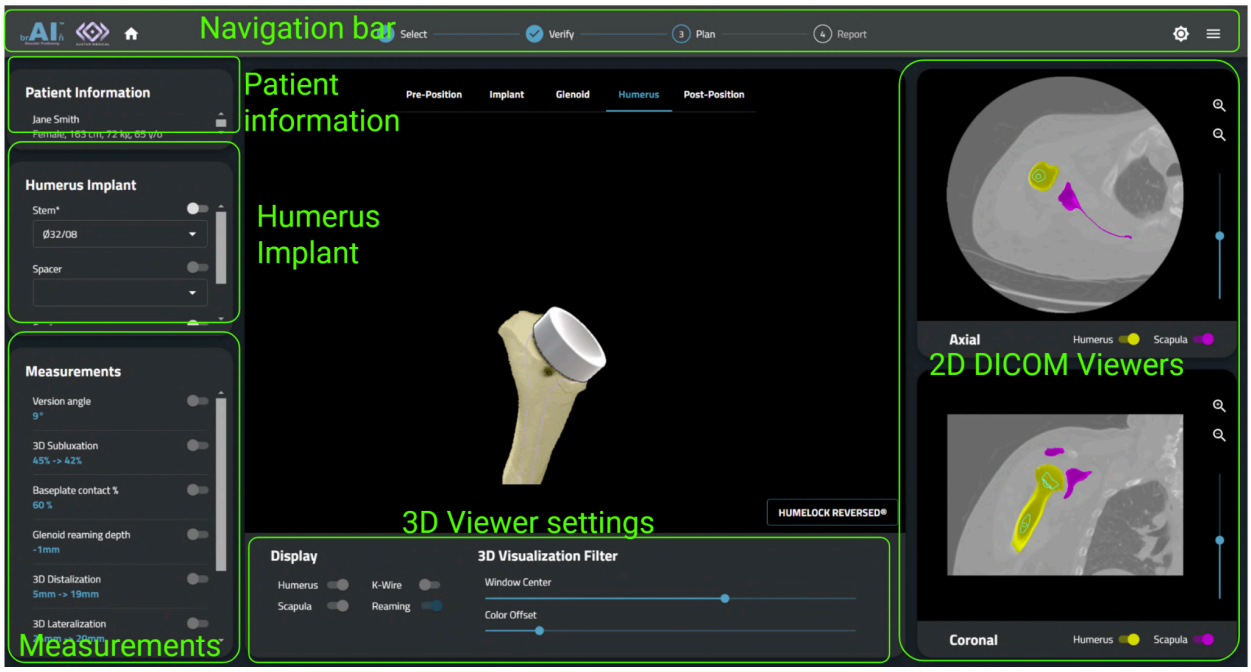
The K-Wire has its own Manipulation Panel and can be positioned just like any implant component. Its position is intrinsically linked to that of the baseplate (or glenoid peg for anatomical implants). Moving one will automatically move the other.

💡 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.

## 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.

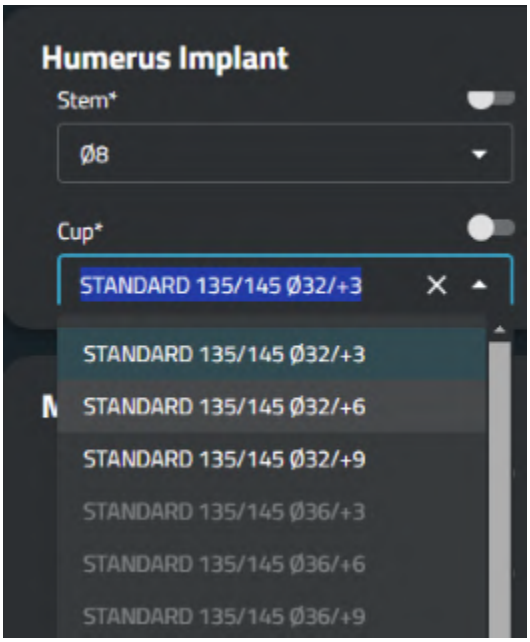



On the left side of the screen, the Humerus Implant panel displays all the components available for selection for the implant chosen by the user. Mandatory components are indicated with an asterisk (*).

⚠ 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, measurement 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.

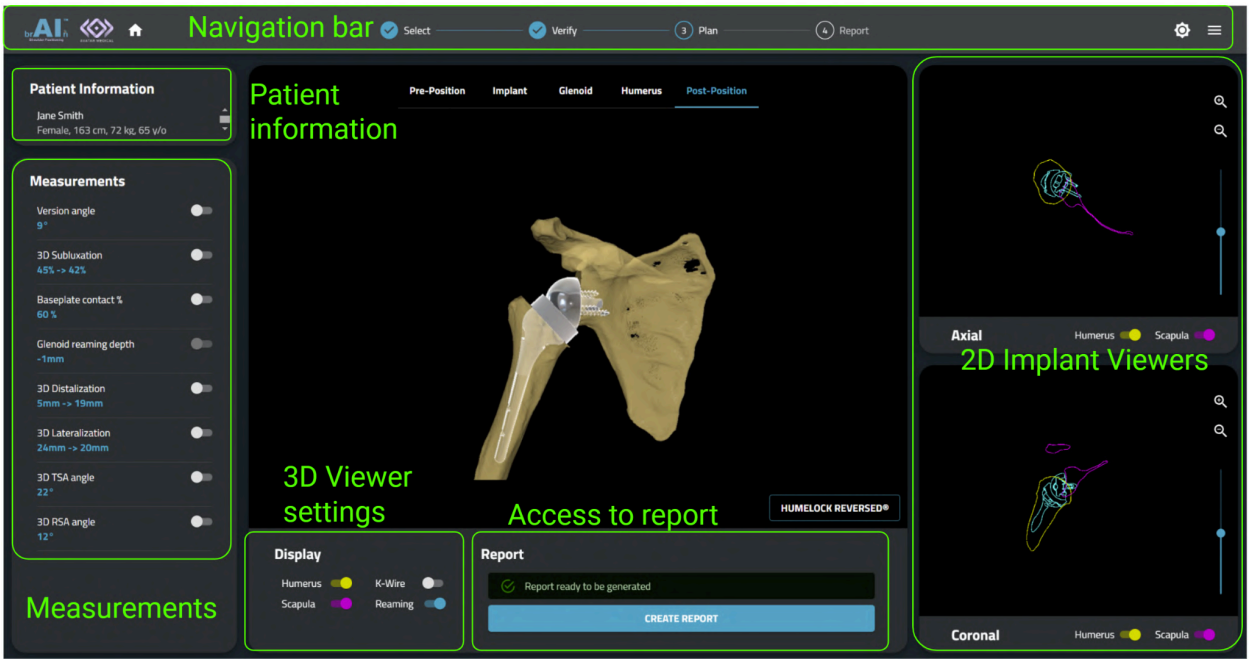
💡 Since the software cannot automatically detect when the user has finished positioning the implant, the user must manually click on the Post-Position tab to continue with the planning.

## Post-Position tab

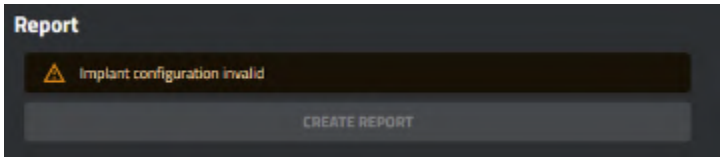
The Post-Position tab allows the user to visualize the glenoid and humeral implants displayed and aligned together. The humerus is translated to create a 'ball and socket' joint with the scapula.

⚠ 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.



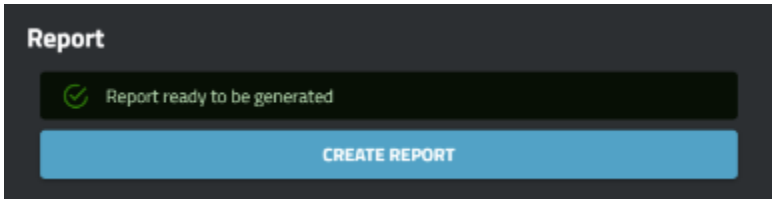

If all mandatory parts of the implant have been selected by the user, a “CREATE REPORT” button will appear at the bottom of the screen. Clicking this button will allow access to the Surgical Planning Report. If not all mandatory parts have been selected, an error message will be displayed and the button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

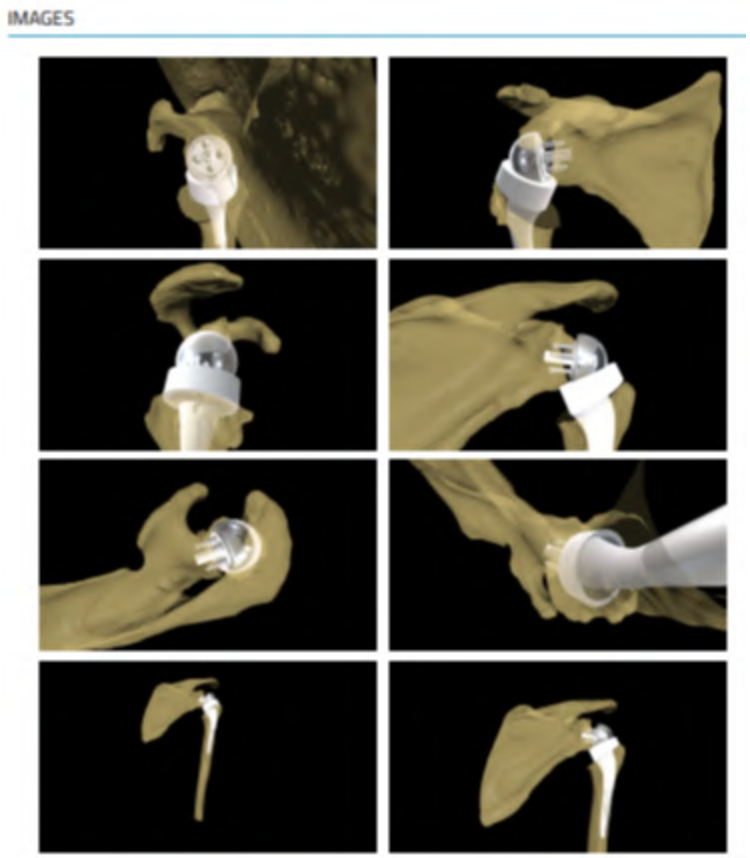
## Surgical Planning Report

If all mandatory parts of the implant have been selected by the user, they can click the “CREATE REPORT” button at the bottom of the Post-Position interface:




This will generate a PDF report, which will be displayed in an embedded PDF viewer. This Surgical Planning Report is 3-pages long and contains:

- 8 images showcasing the implant from different camera angles (shoulder measurements and K-Wire are automatically hidden)




- 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

IMPLANT

Implant: HUMELOCK REVERSED®

Scapula

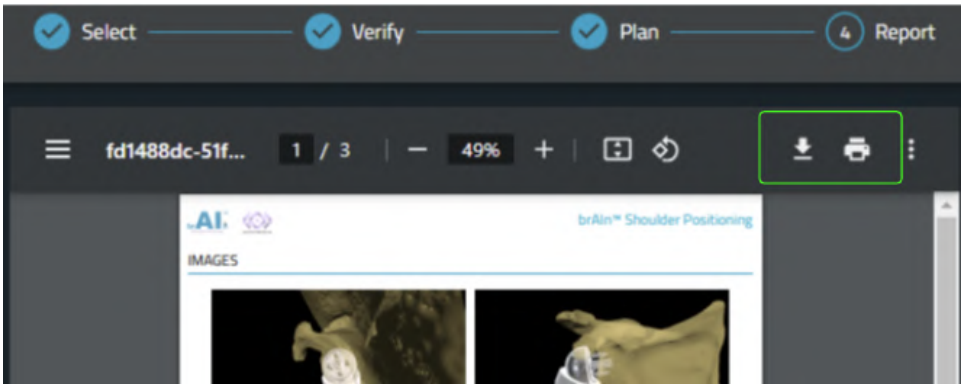
| Part Type | Id | Name |
|---|---|---|
| BASEPLATE | 105-0024 | W/ PEG Ø24+0 |
| GLENOSPHERE | 105-3610 | CENTERED Ø36 |
| ANTERIOR SCREW | 109-4515 | STANDARD 15mm |
| POSTERIOR SCREW | 109-4515 | STANDARD 15mm |
| SUPERIOR SCREW | 109-4515 | STANDARD 15mm |
| INFERIOR SCREW | 109-4525 | STANDARD 25mm |

Humerus

| Part Type | Id | Name |
|---|---|---|
| STEM | 317-3208 | Ø32/08 |
| CUP | 103-0803 | STANDARD Ø36/+3 |

- 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

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 |
|---|---|---|
| bsp.fx-eu.avatarmedical.cloud | HTTPS | 443 |
| console.fx-eu.avatarmedical.cloud | HTTPS | 443 |
| api.fx-eu.avatarmedical.cloud | HTTPS | 443 |
| turnserver.fx-eu.avatarmedical.cloud | TURNS (TCP/UDP) | 443 |

| | | |
|---|---|---|
| ws.fx-eu.avatarmedical.cloud | WSS (HTTPS 1.1) | 443 |

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, Paris, France, 75015

**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

# 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:<br>● Ensure that the patient is not wearing any metal object that could generate artifacts;<br>● 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);<br>● Inform the patient that they must remain motionless throughout the acquisition phase.<br><br>**If there is a prosthesis or other orthopedic material on the shoulder not examined:**<br>● Raise the unexamined arm above the patient's head. |
| **Acquisition protocol** | ● Orientation of the patient during the acquisition: Use only the parameter below:<br>○ HFS - Head First Supine<br>● Do not change the position of the patient and/or the table during the acquisition<br>● Do not change the coordinate system, and/or the field of view between images<br>● Do not tilt the gantry or take oblique images<br>● Provide only axial images; Do not include sagittal/coronal or 3D reconstructions. |

| | |
|---|---|
| | • **Arthroscanners are not accepted**<br><br>**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<br>**Kernel/Algorithm**: Soft, Soft Tissue or Moderate reconstruction algorithms (avoid using Bone or Hard algorithms)<br>**kVP**: 120 or 140<br>**Milli Amperage (mA)**: Auto<br>**Pitch**: 1 mm or less<br>**Slice thickness:** ≤ 2 mm ( ≤ 1.5 mm preferred)<br>**Reconstruction slice increment:** 0.625 mm maximum<br>**Resolution**: Reconstruction matrix size = 512*512 (or other square dimension)<br>**DFOV**: 320 mm maximum<br><br>**ROI: Entire scapula and proximal humerus of the specified side.** Include the acromioclavicular joint and the inferior angle of the scapula in the acquisition. |

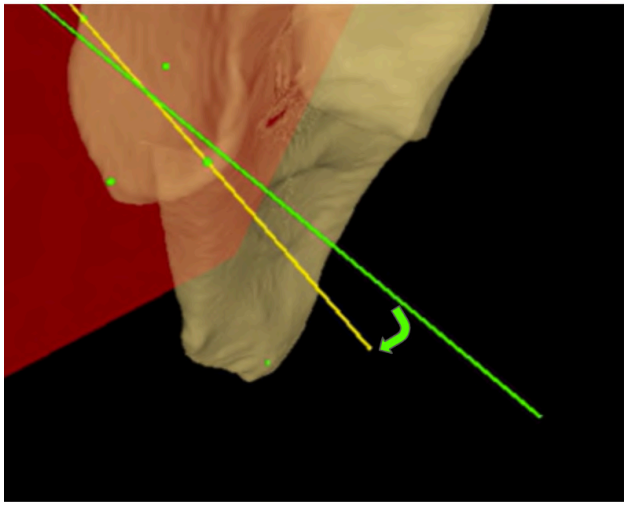
# Annex 2: Shoulder measurements definitions

This annex outlines the calculation method 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 plane*, which is the plane defined by the Trigonum Spinae, Angulus Inferior and Glenoid Center Point landmarks.

**Version angle**

To calculate the Version angle, the software:

- draws a *Glenoid Surface Line* between the Glenoid Anterior Fossa landmark and the Glenoid Posterior Fossa landmark
- the *Glenoid Surface Line* intersects the scapular plane at a point from which the *Neutral Version Line* is drawn, orthogonal to the scapular plane

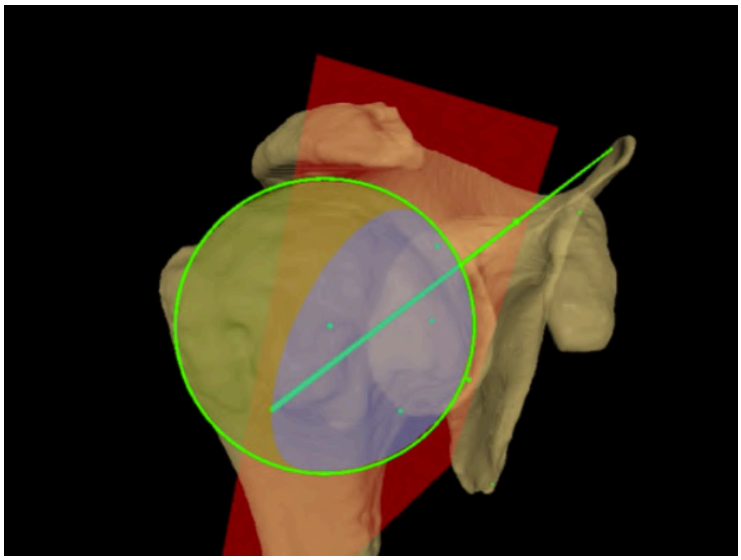


The Version angle is the signed angle between the *Neutral Version Line* (green line above) and the *Glenoid Surface Line* (yellow line above).

**3D Subluxation**

For our 3D Subluxation measurement, we use the best-fit sphere of the humeral head as reference and we display how the scapular 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.

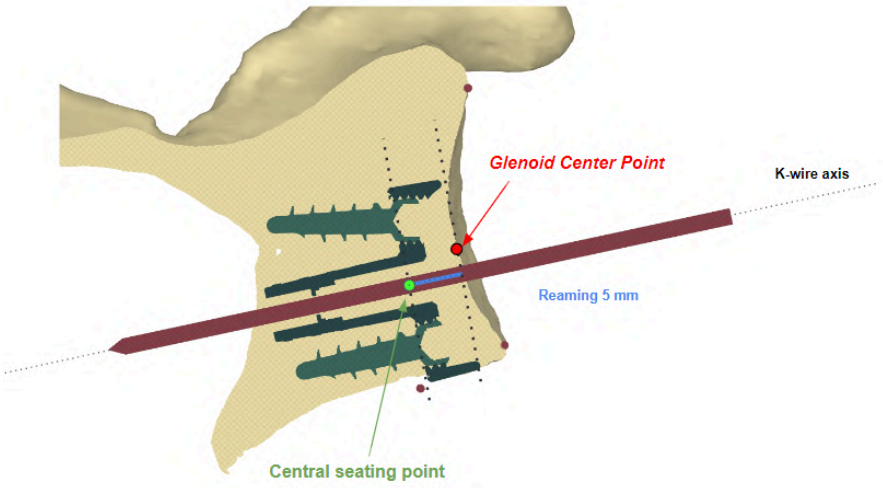


**Baseplate contact %**

The baseplate contact surface is approximated using a set of 100 points distributed along the edge of the baseplate where it contacts the glenoid. The seating or baseplate contact percentage 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 our reaming depth measurement, we use the orthogonal projection of the Glenoid Center Point on the K-wire axis and the baseplate/glenoid peg central seating point as reference points.




### 3D Distalization

3D Distalization is the vertical component of the distance between the Glenoid Center Point and the Humeral Best-Fit Sphere Center Point. Please note that the Glenoid Center Point is detected on the scapular mesh and therefore on the morbid anatomy of the patient.

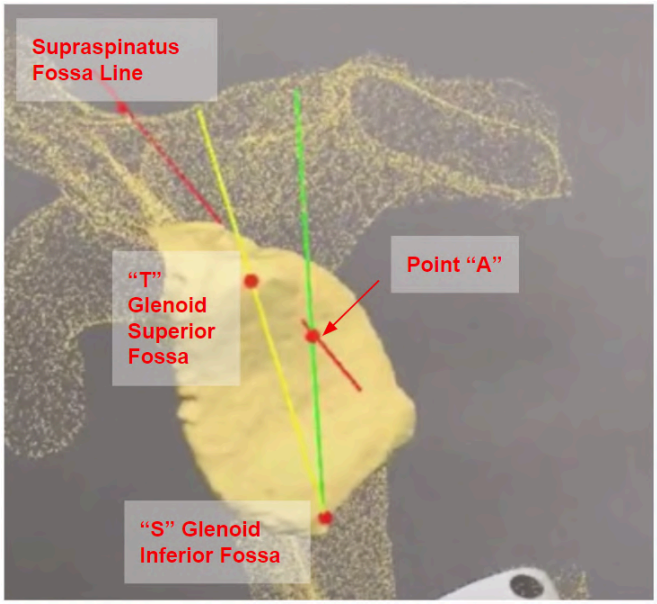
### 3D Lateralization

3D Lateralization is the horizontal component of the distance between the Glenoid Center Point and the Humeral Best-Fit Sphere Center Point. Please note that the Glenoid Center Point is detected on the scapular mesh and therefore on the morbid anatomy of the patient.

### 3D TSA angle

On 2D images, the TSA angle typically refers to the angle between the plane of the glenoid and the axis of the scapula. To calculate its equivalent in 3D, we have utilized the following landmarks for our 3D TSA angle:

- Point “T” is our Glenoid Superior Fossa landmark
- Point “S” is our Glenoid Inferior Fossa landmark
- Point "A" is the vertex of the right triangle created by the Supraspinatus Fossa Line and a perpendicular line passing through point “S”




**3D RSA angle**

On 2D images, the RSA angle typically refers to the angle between the inferior plane of the glenoid and the axis of the scapula. To calculate its equivalent in 3D, we have utilized the following landmarks for our 3D RSA angle:

- Point "R" is the intersection between the Supraspinatus Fossa Line and the glenoid surface
- Point "S" is our Glenoid Inferior Fossa landmark
- Point "A" is the vertex of the right triangle created by the Supraspinatus Fossa Line and a perpendicular line passing through point "S"