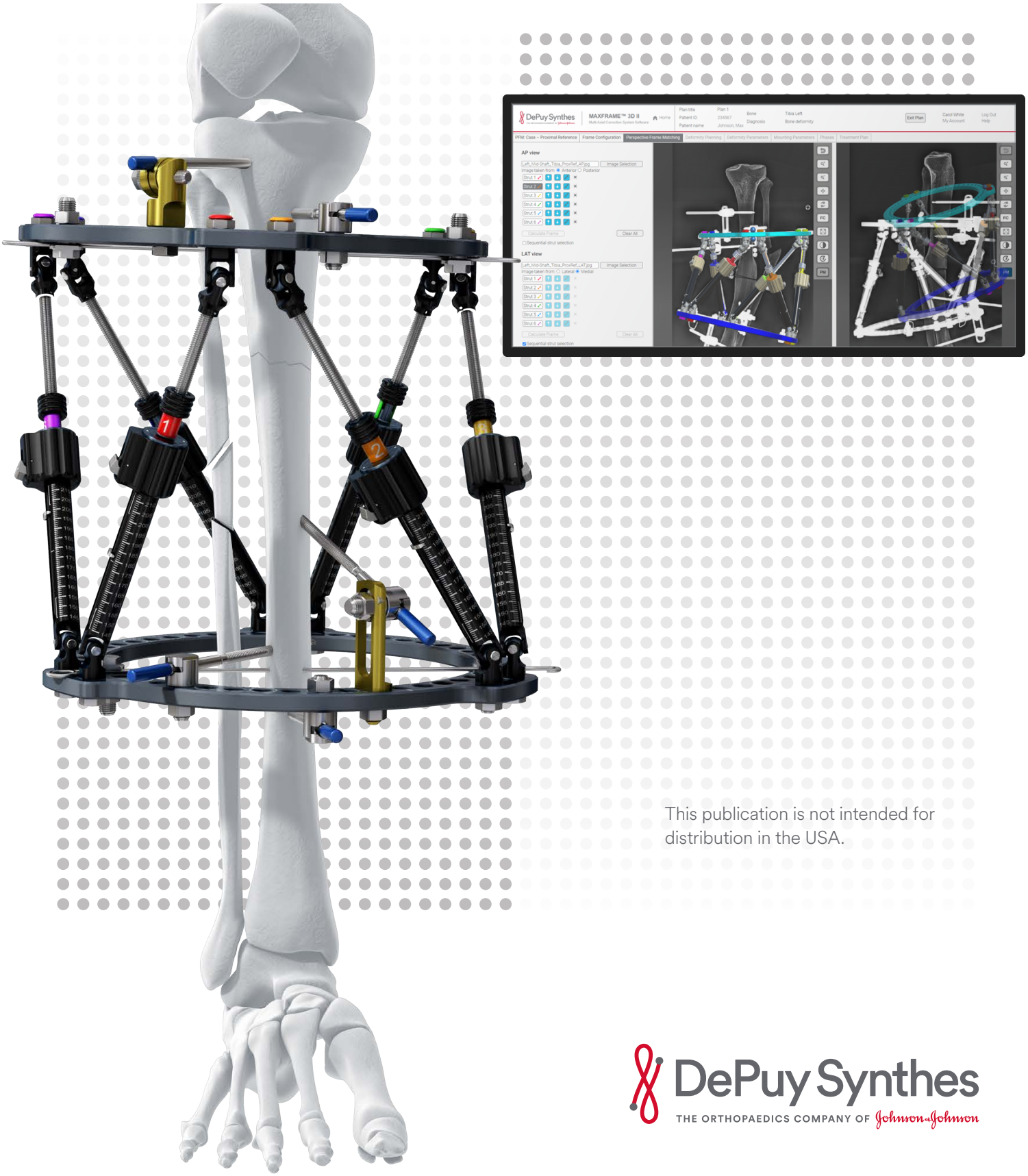
MAXFRAME™

Multi-Axial Correction System

MAXFRAME 3D II Software User's Manual

Software Release 2021.01



This publication is not intended for distribution in the USA.

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

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1 Welcome

1.1 About This Manual

This User's Manual familiarizes you with the functionality of the *MAXFRAME™ 3D II Software* by providing you a step-by-step procedure for all important tasks, starting with the first steps, continuing with the treatment planning, and leading up to the management of treatment plans, patients, and images.

Furthermore, this manual serves as a reference guide for the *MAXFRAME 3D II Software*, providing in-depth information on the software's user interface, functions, and options.

1.2 Typographic Conventions Used in This Manual

This manual uses a simple notation with several type styles for presenting information. The following list explains the meaning of the typographic conventions used in this manual:

Style	Example
Menu commands and buttons in the user interface are printed in **bold** type.	Click on **Accept**.
Names of elements in the user interface are set in *italic* type.	Switch to the *Patient* view.
Values are set in quotation marks.	If the value is zero, enter "0".
Important text is emphasized with a **bold type in gray**.	You **cannot** undo this action.
Terms described in the Glossary of Terms are set in *italic type in blue*. The terms are clickable. Click on a term to jump to its entry in the Glossary of Terms.	Enter the *coronal angulation value* here.
Product names are set in *italic* type.	*MAXFRAME 3D II Software*

Table 1.1 – Typographic conventions with examples.

1.3 Safety & Security

All passwords, patient details, and their Personal Health Information will be encrypted.

1.3.1 Warning, Attention, Important, and Note Statements

Warning, Attention, and Important statements are used throughout this manual to emphasize critical information. You must read these statements to ensure safety, prevent potential harm to the patient, and allow for effective use of the device. Note statements provide additional information, hints, or tips about the system and/or software. The statements are defined below.

Warning: A warning indicates that the personal safety of the patient may be compromised. Disregarding the warning may result in serious injury.

Attention: Statements to indicate where any special care must be exercised by the user for the effective use of the device, for example, in the case of a loss of data.

Important: Statements that provide important information to the user. In cases when there is potential risk, the user is blocked from continuing.

Note: Additional information, hints, or tips about the system and/or software that is not related to risk.

1.3.2 Residual Risk Documentation

DePuy Synthes has undertaken the necessary steps to ensure that residual risks associated with using in-scope devices are reduced as far as possible by applying the available state-of-the-art techniques in designing and manufacturing the medical devices to ensure safe usage. Identified residual risks are documented as the following:

Warning: If the software shows a warning which requires your confirmation, please make sure you understand the warning and the consequences. Continuation in the process might cause harm to the patient.

Warning: If the radiographic markers are not used properly as described in the *MAXFRAME System Technique Guide*, the software could potentially use incorrect parameters resulting in harm to the patient.

1.3.3 Product Safety & Risk Management

Warning: The user should not install browser extensions with auto complete feature.

2 Product Overview

This chapter provides you with information on the following topics:

- Features and functions of the *MAXFRAME System* (section 2.1 below).
- The intended use and purpose of the *MAXFRAME System* (section 2.2).
- The software requirements for the *MAXFRAME 3D II Software* (section 2.3 on page 8).
- An overview of software maintenance (section 2.4 on page 9).
- Cybersecurity considerations (section 2.5 on page 10).
- An overview of the hardware components of the *MAXFRAME System* (section 2.6 on page 10).
- Contact details of the customer support teams (section 2.7 on page 16).

2.1 Features and Functions

The *MAXFRAME™ 3D II Software* is a treatment planning software and part of the DePuy Synthes *MAXFRAME™ Multi-Axial Correction System*.

The *MAXFRAME 3D II Software* provides a surgeon with several features and functions, including:

- Planning methods.
- Treatment plan simulation.
- Calculation and review of strut adjustment plans.
- Review of strut swap dates.
- Treatment plan sharing with other users.
- Transfer patients to other users.
- Re-planning of treatment plans.
- Fully documented approval of treatment plans.
- Patient and case management.

DePuy Synthes offers the *MAXFRAME 3D II Software* as a web application.

Note: All measurements will be expressed in SI units (mm, degrees) as specified by ISO 80000.

2.2 Intended Use and Purpose

The DePuy Synthes *MAXFRAME Multi-Axial Correction System* is intended for external fixation of fractured long bones and bones of the foot, limb lengthening, and deformity correction in adult, children[1] (3–12), and adolescent[1] (12–21) patient populations. The DePuy Synthes *MAXFRAME Multi-Axial Correction System* utilizes software for assisting surgeons in treatment planning.

[1] in which the growth plates have fused or will not be crossed.

2.2.1 Indications

The DePuy Synthes *MAXFRAME Multi-Axial Correction System* is indicated for external fixation of fractures, arthrodeses, and deformity corrections.

2.2.2 Contraindications

MAXFRAME is not intended for use in the spine.

2.2.3 Software User Profile

The use of the software is limited to technical specialists for data input and health care professionals for patient treatment. Patients will not use the software.

2.2.4 General Warnings

Warning: The *MAXFRAME 3D II Software* must only be used with the *MAXFRAME System* hardware.

Warning: The *MAXFRAME 3D II Software* is not to be used for diagnosis.

2.2.5 Restrictions

- The *MAXFRAME 3D II Software* is designed to be used outside the sterile field.
- The *MAXFRAME 3D II Software* does not directly modify the *MAXFRAME System* hardware.
- The *MAXFRAME 3D II Software* will not offer or show surgical components (wires, nails, plates, scalpel) other than the *MAXFRAME System* device components (struts, rings).

2.3 Software Requirements

This section provides the supported operating systems, web browsers and computer hardware for the *MAXFRAME 3D II Software*.

Important: You will be blocked from logging into *MAXFRAME 3D II Software* if you have an unsupported combination of operating system and web browser.

Notes

- A PDF viewer application will be required (e.g., *Adobe Reader* or *Apple Preview*).
- The most recent information regarding supported operating systems and web browsers can be found on the ***MAXFRAME* product information page** [http://www.maxframesystem.com].
- The accurate setting of the date and time on your computer is important for the proper functioning of the application.

Operating System

The *MAXFRAME 3D II Software* can be used with the following operating systems:

- *Windows (Microsoft)* – Minimum *Windows 10*
- *macOS (Apple)* – Minimum *Catalina* (10.15)
- Please check the ***MAXFRAME* product information page** [http://www.maxframesystem.com] for status of operating system compatibility above the minimum. Not all newer versions may be compatible.

Web Browser

The *MAXFRAME 3D II Software* can be used with the following web browsers:

- *Google Chrome* (*Windows* and *macOS*)
- *Microsoft Edge* (*Windows*)
- *Firefox* (*Windows*)

Note: You can find the most up to date web browser information on the ***MAXFRAME* product information page** [http://www.maxframesystem.com].

Computer Hardware

To use *MAXFRAME 3D II Software*, your computer must meet the following minimum hardware requirements:

- **CPU:** SSE2 instructions set support (*Pentium 4* or *Athlon 64* with minimum 1.3 Ghz or newer)
- **RAM:** 4 GB or more
- **Video:** Graphics card with *DX10* (shader model 4.0) capabilities
- **Screen display:** 1280 x 768 pixels or more

2.4 Software Maintenance

The *MAXFRAME 3D II Software* is deployed as a medical web application and not as a product specific software on your local computer.

Prior to updating the operating system or web browser on your local computer, always please check to ensure that the combination of operating system and web browser is supported by the *MAXFRAME 3D II Software*. The most recent information regarding the supported operating systems and web browsers can be found on the ***MAXFRAME* product information page** [http://www.maxframesystem.com].

Important: You will be blocked from logging into *MAXFRAME 3D II Software* if you have an unsupported combination of operating system and web browser.

Note: Browser extensions and plugins are not supported, and the user is prohibited from opening the *MAXFRAME 3D II Software* application using extensions and plugins.

2.5 Cybersecurity Considerations

The *MAXFRAME 3D II Software* is deployed as a web application; hence it is important that the local computer is secure from web application threats. To promote cybersecurity the, *MAXFRAME 3D II Software* application implements the following requirements:

- Password must satisfy a minimum strength requirement.
- Passwords expire every 90 days and cannot be reused withing one year.
- Software will be locked for 15 minutes after 5 unsuccessful login attempts.
- User session will automatically logout after 15 minutes of inactivity.
- Accounts with extended inactivity will be automatically deactivated.

Important: You can activate your deactivated account by contacting support.

Note: Some additional security recommendations for the user are:

- Access to the *MAXFRAME 3D II Software* is managed by the account request and approval process.
- Choose passwords that are complex.
- Do not use easy guess words or phrases as a password.
- Always protect your password.
- Never share your password information.
- Maintain your local computer security by regular updates/patching for the OS and applications and implement anti-malware solution.
- Log in from kiosks or other public computers is prohibited.
- If you suspect your *MAXFRAME* account has been compromised, or you suspect any type of cybersecurity incident related to *MAXFRAME* please contact support to report the issue.

2.6 Hardware

The *MAXFRAME System* is a multi-axial frame correction system and includes the following hardware components.

The hardware is validated for use with the *MAXFRAME 3D II Software* and only current DePuy Synthes hardware is available for selection.

Refer to the *MAXFRAME System Technique Guide* for hardware requirements and proper use.

Note: The *MAXFRAME 3D II Software* must be used only with the hardware listed in the software database and with no other external frame system.

2.6.1 Frame

A *MAXFRAME System* basic frame consists of 2 rings and 6 struts (cf. figure 1)

Figure 1 – Hardware – Frame.

2.6.2 Rings

The *MAXFRAME System* contains 3 types of rings:

- Full rings (cf. figure 2)
- 5/8 rings (cf. figure 3) with the bridging plate as an accessory (cf. figure 4)
- Foot plates (cf. figure 5)

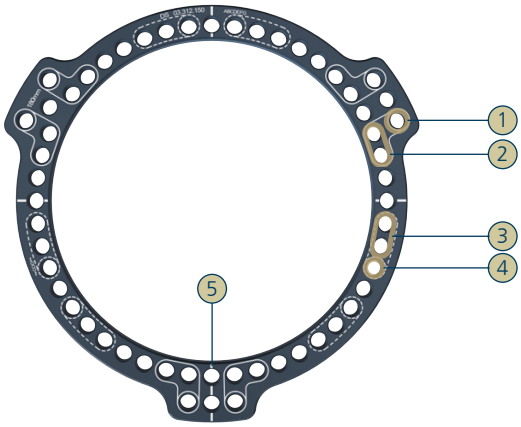


Figure 2 – Hardware – Full ring (and mounting points).

1. Tab mount default hole
2. Tab mount non-default holes
3. Ring mount non-default holes
4. Ring mount default hole
5. Ring center line

Figure 3 – Hardware – 5/8 ring.

Figure 4 – Hardware – Bridging plate.

Figure 5 – Hardware – Foot plate.

2.6.3 Struts

The *MAXFRAME System* contains 2 types of struts compatible with the *MAXFRAME 3D II Software*:

Standard struts

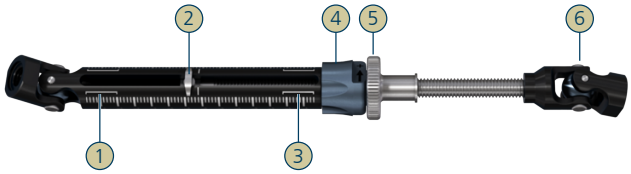


Figure 6 – Hardware – Standard strut.

1. Strut swap overlap line (bottom)
2. Length indicator
3. Strut swap overlap line (top)
4. Adjustment knob
5. Locking collar
6. Spherical hinge

Strut Size	Length
XX-Short	65–82 mm
X-Short	81–103 mm
Short	97–135 mm
Medium	126–193 mm
Long	184–309 mm

Table 2.1 – List of Standard strut sizes and their length range.

Quick Adjust struts

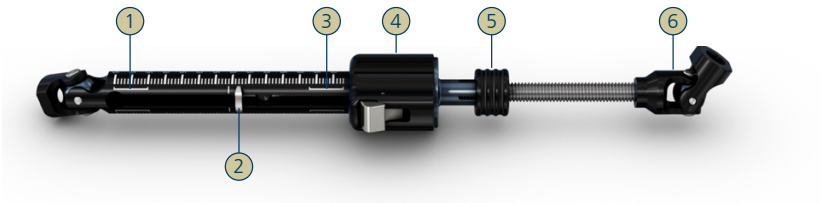


Figure 7 – Hardware – Quick Adjust strut.

1. Strut swap overlap line (bottom)
2. Length indicator
3. Strut swap overlap line (top)
4. Quick Adjust locking collar
5. Adjustment knob
6. Spherical hinge

Strut Size	Length
X-Short	101–126 mm
Short	116–155 mm
Medium	145–213 mm
Long	203–329 mm

Table 2.2 – List of QA strut sizes and their length range.

2.6.4 Accessories

The *MAXFRAME System* contains the following accessories:

- ID bands (cf. figure 8)
- ID plugs (cf. figure 9)
- Radiographic markers

Figure 8 – Hardware – ID bands.

Figure 9 – Hardware – ID plugs.

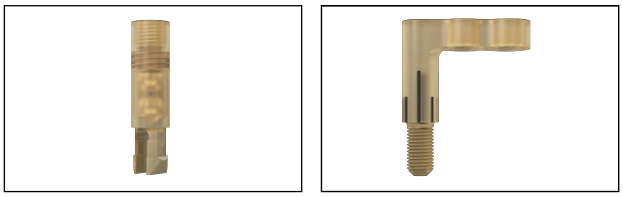


Figure 10 – Hardware – Radiographic markers.

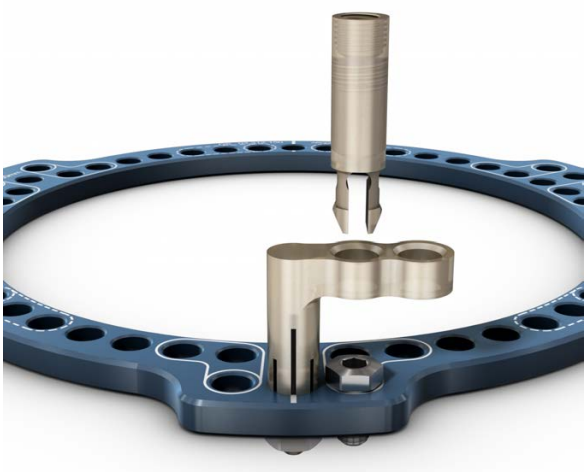


Figure 11 – Hardware – Installation of radiographic markers.

2.7 Customer Support Contact

Phone
+1 (800) 227-6633

Email
HCSGOSYNOPCSCOORD@its.jnj.com

Address

1302 E. Wrights Lane
West Chester, PA
19380
USA

3 First steps with the *MAXFRAME 3D II Software*

This chapter describes how to get started with the *MAXFRAME 3D II Software*:

- Obtaining Your User Account (section 3.1 on page 17).
- Authentication (section 3.2 on page 19).
- Software Security Information & Features (section 3.2 on page 19).
- Software Maintenance and Planned Downtime (section 3.2 on page 19).
- Initial Login (section 3.5 on page 21).

Section 3.6 on page 22 explains how to reset your password, if needed.

Section 3.7 on page 22 explains how to change your email address, if needed.

3.1 Obtaining Your User Account

1. Open the ***MAXFRAME 3D II Software* web page** [http://www.maxframe3dii.com] in your web browser.

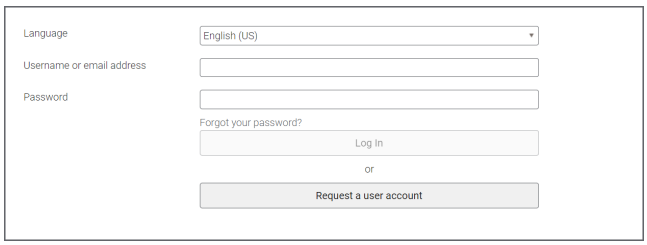


Figure 12 – Log In screen.

2. a. Select your preferred language if desired.

   Note: The language will be set to English by default.

   b. Click **Request a user account**.

3. Read the *Privacy Collection Notice*.

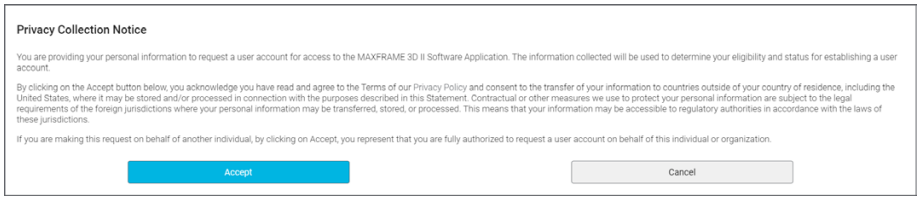


Figure 13 – The Privacy Collection Notice.

If you agree, click **Accept**.

Note: If you select **Cancel** you are prevented from proceeding further with the account request process.

4. Enter your *Last name*, your *First name*, your *Email address*, *Confirm email address*, *Password*, *Confirm password*, and your *Sales consultant or manager name*. Select your *Country of employment* from the drop-down list.

   The password requirements are as provided in the dialogue box.

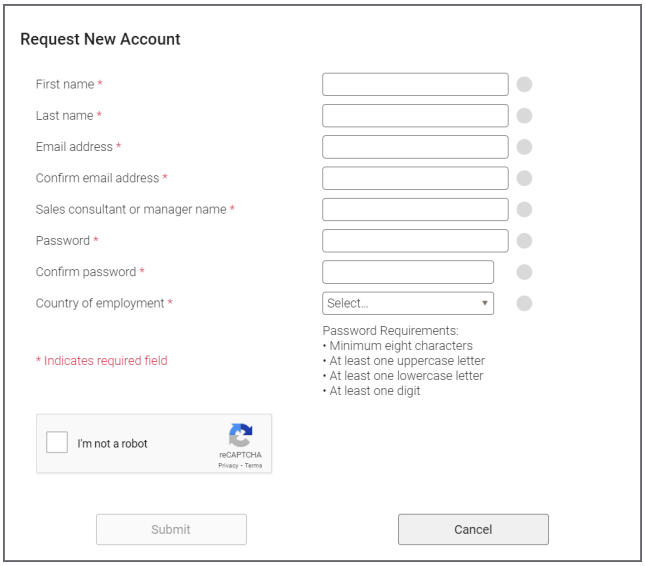


Figure 14 – The Request a user account dialog.

5. Click **Submit** to send your account request. A message confirms that the system submitted your account request successfully:

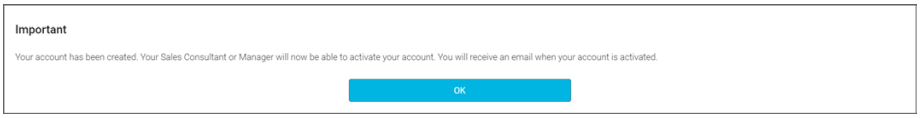


Figure 15 – Account request successfully transmitted.

   Close this message with **OK**.

6. Check your email for the approval of your account request. You should expect a response from our support team within 24–48 hours.

   Note: You will receive an email if your account request has been declined. Please contact support for more information.

7. Go to the *MAXFRAME 3D II Software* login page to complete the account setup. Login using your email address and password. The *Edit User Account* dialog appears. Enter a *Username*. All the other fields are optional.

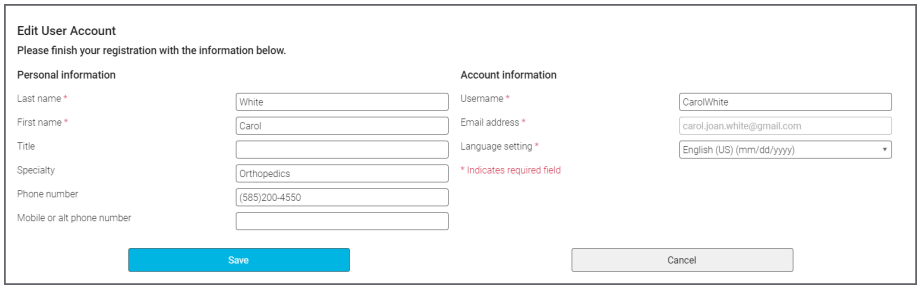


Figure 16 – The Edit User Account dialog for personal and account information.

8. Read the *End user license agreement*.

   If you agree, click **Accept**.

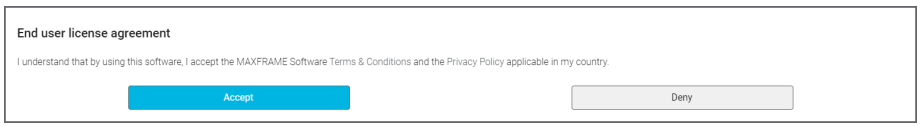


Figure 17 – The End user license agreement dialog.

   Note: The account setup cannot be completed if you do not accept the *End user license agreement* and select the **Deny** button.

9. A success message appears, stating that you've successfully created your account:

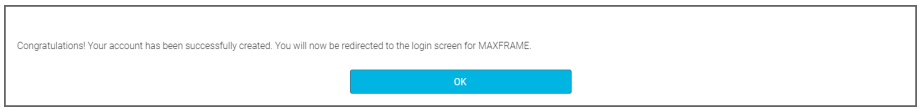


Figure 18 – Success message for creating your user account.

   Close this message with **OK**.

3.2 Authentication

To avoid unauthorized access, the *MAXFRAME 3D II Software* requires user authentication comprising of the following information:

Combination of username and password. You have selected your username and your password during the account request process. Each time you log in, the software asks for your username and password. The access will be locked after 5 unsuccessful logins within 15 minutes.

Important: The password is case-sensitive.

Note: The user is obliged to protect login credentials from unauthorized access as per the information in **protection against unauthorized access and prohibition of shared accounts**.

3.3 Software Security Information & Features

The login page is provided with a *WARNING NOTICE* (as a footer text) indicating that:

- The *MAXFRAME 3D II Software* application is a private website restricted only to authorized users.
- Access to this application via a shared account or from an untrusted workstation, including, but not limited to, cyber cafes and public kiosks, is prohibited.
- Sharing details of user account information is prohibited.

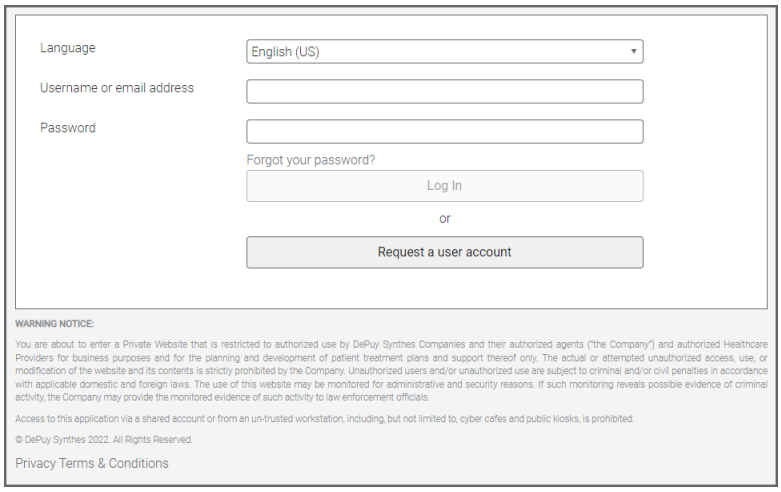


Figure 19 – Warning Notice: Footer Text.

You will receive a confirmation email for password change:

- As a security feature
- Indicating that your password has been modified
- To confirm if you have made these changes
- Instruction to contact support if password was not modified by you

Attention: To help ensure protection of the data, an inactivity period of 15 minutes results in a session expiration and an automatic logout. A countdown of the inactivity period's final few seconds is displayed and provides you the option to stay logged in and continue the session or logout.

Note: Unsaved data will be lost upon automatic logout.

Figure 20 – Session expiration message.

Attention: As an added security feature, the system only allows one active session per user account at any time. Do not start a second session, as this will close the initial login session and may result in the loss of data.

3.4 Software Maintenance and Planned Downtime

The software periodically undergoes planned downtime for maintenance and upgrades. Users cannot access the software during these times.

Users receive notification of planned downtime:

- As information posted on the *MAXFRAME 3D II Software* application login page
- Via email in advance of planned downtime

Notes:

1. Scheduled maintenance is typically performed monthly for a period of a few hours on a weekend.
2. Software upgrades are planned as needed to release new features and/or bug fixes.

3.5 Initial Login

For logging in the first time, proceed as follows:

1. Open the ***MAXFRAME 3D II Software* web page** [http://www.maxframe3dii.com] in your web browser. The login page appears.

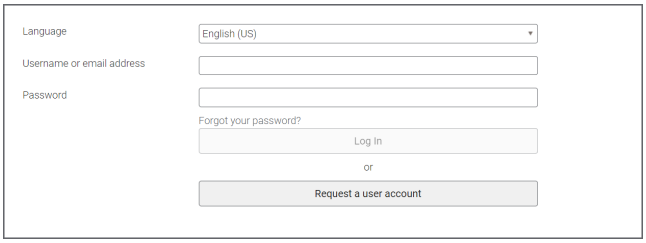


Figure 21 – Login page.

2. Enter your *Username/Email address* and *Password*.
3. Click **Log In**. The *Home* view opens:

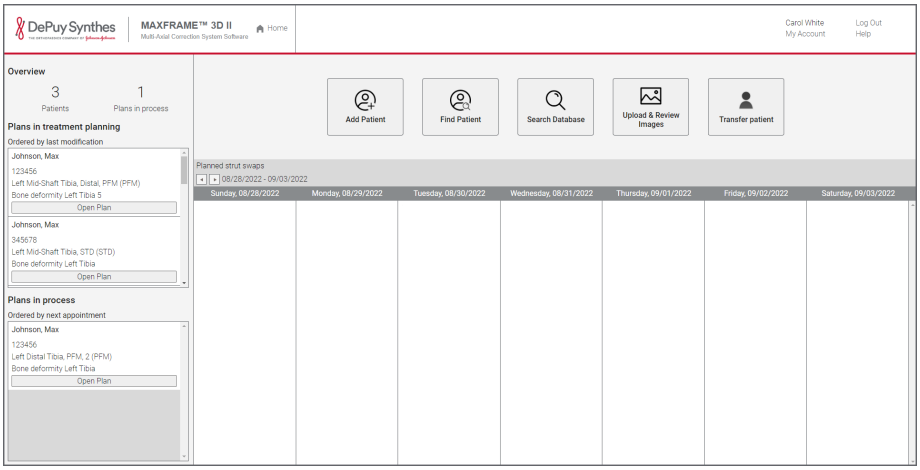


Figure 22 – Home view.

3.6 Password Reset

If you forgot your password, request a password reset as follows:

1. Open the ***MAXFRAME 3D II Software* web page** [http://www.maxframe3dii.com] in your web browser. The login dialog appears (cf. figure 21 on page 21).

2. Click *Forgot your password*. The *Reset Password* dialog appears:

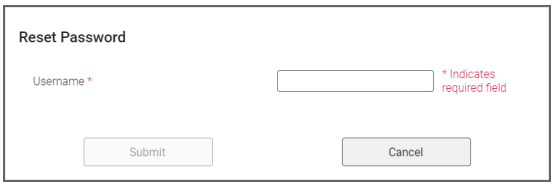


Figure 23 – Reset Password dialog.

3. Enter your *Username/Email address*.

4. Click **Submit**. A message will be displayed indicating that an email will be sent to the registered email address.

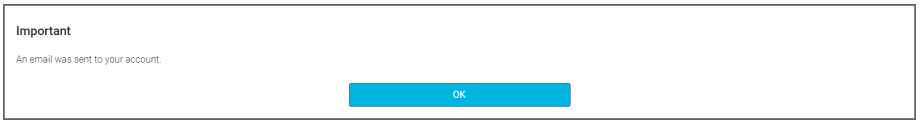


Figure 24 – Email sent message.

5. An email with a link to reset password will be sent to the user registered email address.

   Note: The email link to edit password expires within 24 hours

Select the link in the email to open the *MAXFRAME 3D II Software* application and set the new password.

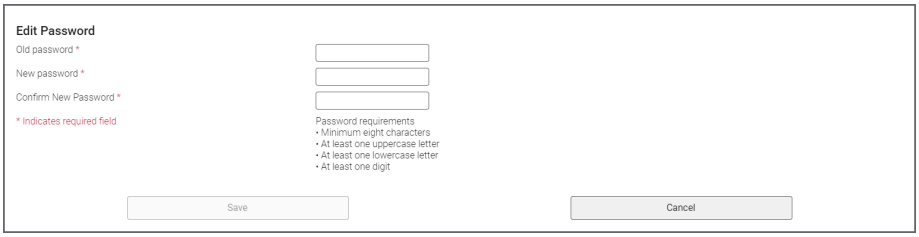


Figure 25 – Edit Password dialog.

Note: The password is case-sensitive.

6. Click *Save*. The login dialog appears (cf. figure 12 on page 17).
7. Enter your *Username/Email address* and your new *Password*.
8. Click **Log In**.

3.7 Edit Email Address

If you change your email address under *Edit Information*, the change process is as follows:

1. Open *Edit Information* and edit the email address.

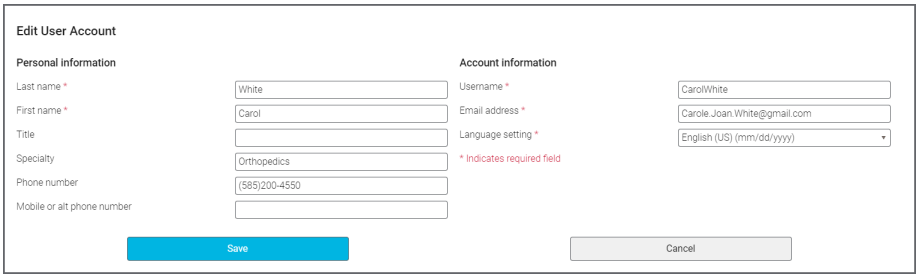


Figure 26 – Edit Email.

2. Select **Save**. A message will be displayed indicating that the email address must be verified.

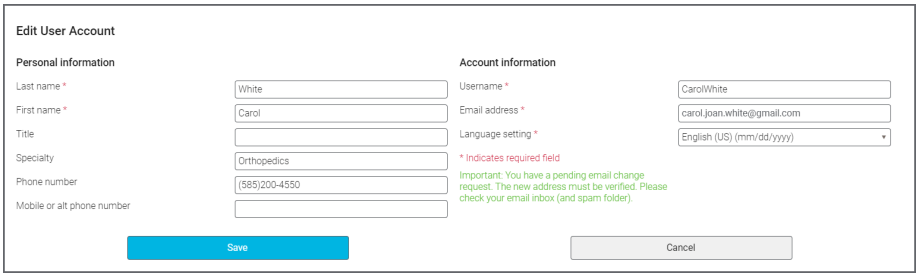


Figure 27 – Pending email change request.

3. Select **OK** to close the message. A message is displayed on the *Edit User Account* window indicating that an email change request is pending.

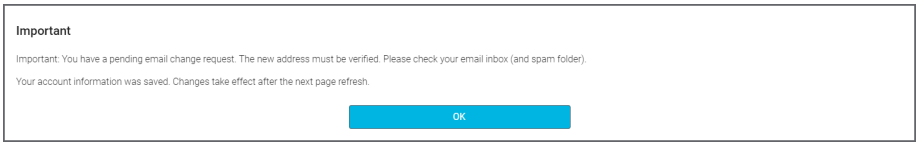


Figure 28 – Confirm email change request.

4. An email with a link to confirm the email address will be sent to the user registered email address.

   Note: The email link to verify the email address expires within 24 hours.

5. Select the link in the email to open the *MAXFRAME 3D II Software* application and confirm your new email address. A message will be displayed indicating that the email address has been verified and will be modified upon next login.

4 User Interface

The user interface of the *MAXFRAME 3D II Software* is designed to provide you flexibility with planning and creating your cases. This chapter describes the general structure and the elements of the different views of the *MAXFRAME 3D II Software*.

Warning: Do not use your web browser to zoom the software user interface as doing so may distort the controls on the screen. A zoom function is provided in the software application for the rendering area, the frame matching view, and the deformity planning view.

Note: To refresh your web browser, use **Ctrl**+**F5** for web browsers on *Microsoft Windows* and **Command**+**R** for web browsers on *Apple OS X*.

There are two types of views in the *MAXFRAME 3D II Software*:

- **Dashboard views:** Provide you with a good overview as well as a quick access to functions and options, which you might want to use in the current context (refer to section 4.1 below).
- **Detail views:** Are used for entering and managing clinical data (refer to section 4.2 on page 30).

4.1 Dashboard Views

After logging into *MAXFRAME 3D II Software*, you're landing on the *Home* view. The *Home* view is a Dashboard type of view.

The *Home* view contains the following areas and elements:

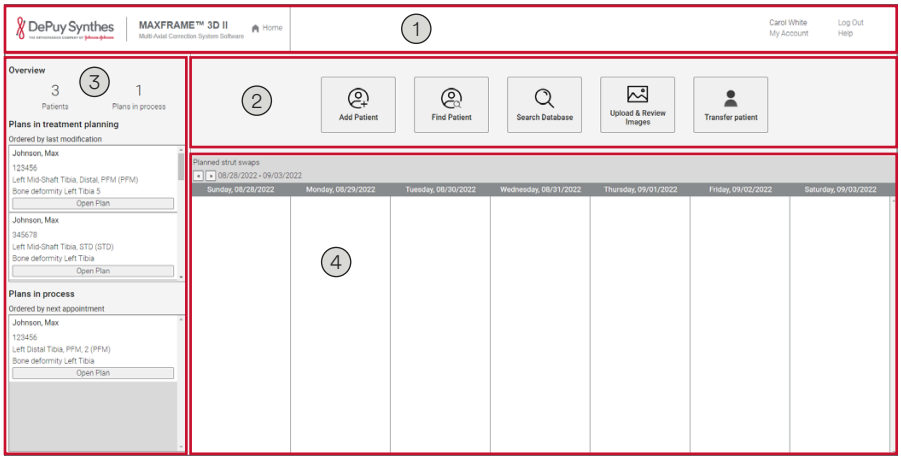


Figure 29 – The Home view.

1. Header area
2. Menu buttons
3. Quick selection lists
4. Calendar of planned strut swaps

4.1.1 Header Area

The Header area is shown in all views of the *MAXFRAME 3D II Software*. It contains different elements, depending on the situation and its context.

Figure 30 – The Home view – Header Area.

The header area of the *Home* view contains the following elements:

1. *Home icon* – the quickest and easiest way to get back to the *Home* view.
2. *Your username* – for your reference.
3. *Log Out* link – logout and exit the *MAXFRAME 3D II Software*.
4. *My Account* menu – provides options for managing your user account. For details, refer to section 4.1.1.1 below.
5. *Help* menu – provides different sources of help and assistance for the *MAXFRAME 3D II Software*. For details, refer to section 4.1.1.2 on page 27.

4.1.1.1 My Account Menu

The *My Account* menu contains the following options:

Edit Information

Edit and save your user account information. User Account fields include first and last names, title, specialty, e-mail address, phone number, mobile or alternate phone number, and an option to select the desired preferred language and date format of the user interface.

Edit Preferences

Edit and save preferences for Header fields displayed, including patient name, surgery date, diagnosis, and bone undergoing treatment.

The patient name is defaulted to be displayed to assist you in assuring the correctness of the patient during planning.

Edit Password

Replace your old password with a new one.

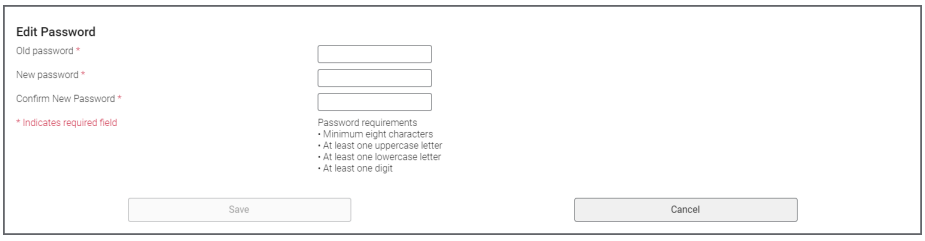


Figure 31 – Edit Password on Home page.

Important: To prevent unauthorized access and ensure data protection, passwords expire every 90 days. You can change your password with **Edit Information** ▸ **Edit Password** at any time before it expires.

4.1.1.2 Help Menu

The *Help* menu contains the following options:

About
The *About* box displays information about the *MAXFRAME 3D II Software* as well as the support contact phone number and email address.

Documents
Documents provides links to Privacy Policy, Terms and Conditions, *MAXFRAME* Product Page, Software User's Manual – US version, and Software User's Manual – Outside the US Version.

Generate Issue Report
Generates an issue report file that can be shared with the support team in case of usage issue.

4.1.2 Menu Buttons

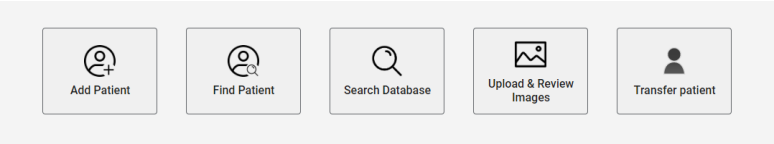


Figure 32 – The Home view – Menu area.

The menu buttons of the *Home* view provide the following functions:

Add Patient
Add a patient by entering the patient's general information and contact details.

Find Patient
Find a patient by searching for the patient's first name, last name, or ID. To assist in selecting the correct patient, you can see the patient's details by clicking on the patient name in the search results.

Search Database
Search the system's database for your treatment plans.

Upload & Review Images
Select a patient and upload x-ray or clinical images into the patient record.

Transfer patient
Transfer a patient and all relevant treatment plans to another MAXFRAME 3D II Software user.

4.1.3 Overview and Quick Selection Lists

On the left side of the *Home* view, you find overviews of patients and plans as well as two quick selection lists, which allow you to open recently accessed treatment plans.

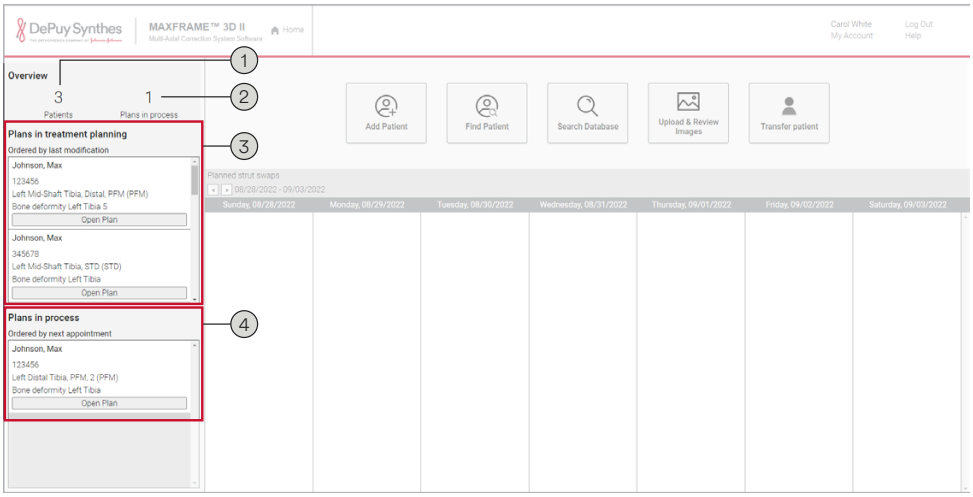


Figure 33 – The Home view – Overview and quick selection lists.

1. The number of patients that are defined in your user account.
2. The number of treatment plans that are planned, approved, and in process – that is, the patient is actively adjusting the daily strut settings on the frame.
3. *Plans in treatment planning*. Quick selection list of recently accessed treatment plans that are created but not yet approved. The most recently edited plan will be listed first. Click the **Open Plan** button provided below each plan to open the Case Dashboard (refer to section 10.2 on page 101).
4. *Plans in process*. Quick selection list of recently accessed treatment plans that are completely planned, approved, and in process – that is, the patient is actively adjusting the daily strut settings on the frame. The list is ordered based on the suggested strut swaps and planned appointments. Click the **Open Plan** button provided below each plan to open the Case Dashboard (refer to section 10.2 on page 101).

4.1.4 Planned Strut Swaps Calendar

The Planned Strut Swaps Calendar in the *Home* view provides you with a weekly overview of all the scheduled strut swaps of your patients.

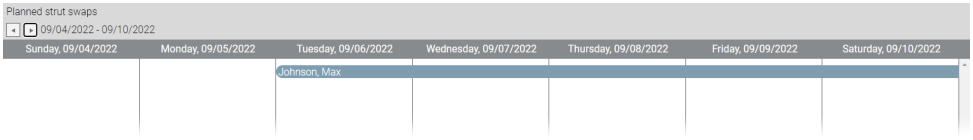


Figure 34 – The Home view – Planned Strut Swaps Calendar.

The calendar displays the patient name indicating all appointments and/or planned strut swaps in the current week for treatment plans in process. You can switch to the preceding or the following weeks by clicking on the corresponding arrow icon left to the start and end dates of the displayed week on top of the calendar.

Suggested strut swap entries and planned appointments in the calendar display the patient first name and last name. Selecting the patient in the landing page calendar opens a pop-up window with all the suggested strut swaps (for all the cases associated to the selected patient) for the patient during the week displayed.

Figure 35 – Patient Strut Swaps Calendar overview.

If a day for the swap appointment has been set in the treatment plan swap calendar, that day is indicated on the *Home* view calendar and labeled as a swap appointment. If a day for the swap appointment has not been set in the treatment plan swap calendar, all the potential strut swap days for the displayed week are indicated on the *Home* view calendar for the swap.

Selecting the appointment will open the treatment plan strut swap calendar.

4.1.5 Other Dashboard views

Other Dashboard views are:

- The **Case Dashboard** view (refer to section 10.2 “Review Treatment Plan” on page 101).
- The **Patient Dashboard** view (refer to section 11.2 on page 109).

4.2 Detail Views

To enter, manage, and review treatment plan parameters, the application uses Detail views. Detail views are opened whenever you create or review a treatment plan.

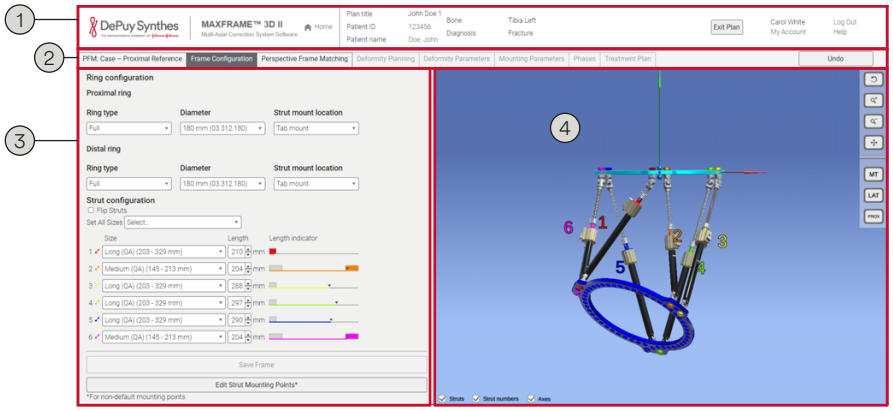


Figure 36 – Detail view – the Frame Configuration view as an example.

All Detail views contain the following four essential elements:

1. Header area
2. Tab selectors
3. Data area
4. Preview area

4.2.1 Header area

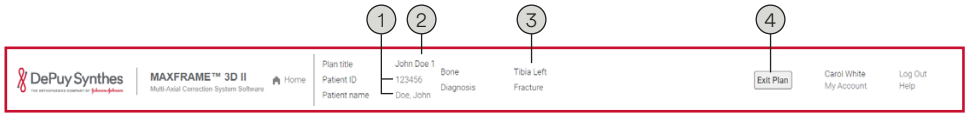


Figure 37 – The Detail view – Header Area.

The header area of the Detail view contains the following additional elements:

1. *Patient ID* and *Patient name* – the patient's ID (and patient) to which the treatment plan belongs. *Patient ID*/*Patient name* act as links to the Patient Dashboard. Click the *Patient ID*/*Patient name* to jump to the Patient Dashboard view.
2. *Plan title* – the title of the current treatment plan.
3. *Additional Information* – you can define in your user account preferences the fields which shall be displayed here (cf. section 4.1.1.1 "My Account Menu" on page 26).
4. *Exit Plan* – to exit the current plan and return to the Patient Dashboard view.
5. *Manage Images* – open the Image Manager to upload images directly into the current patient record, to manage patient's images and to assign patient's images to treatment plans.

4.2.2 Tab selectors

The tabs represent the navigation structure which guide you through the creation, planning, and approval of the treatment plan. The displayed tabs are ordered specifically according to the selected treatment planning method.

Click on the title of a specific tab selector to switch to this tab.

You need to enter and save the information in your current tab before you can proceed to the next one or switch to a preceding one. When all the required information is complete on your current tab, the next tab will be enabled.

Attention: Using web browser functions to change to another web page or reload it (**Back**, **Forward**, **Home**, **Refresh**), can lead to unintended termination of your session and loss of unsaved data on the current page. In these cases, your web browser will prompt you a warning message. You can either confirm this warning message and lose the unsaved data, or you can cancel and remain on the current web page.

4.2.3 Data area

The Data area contains all the text and selection fields of a tab. You specify or confirm all treatment plan parameters in the Data area. The contents of the Data area in the different tabs depend on the selected treatment planning method. Required data fields will be indicated.

Note: Data fields have the following restrictions:

1. All text fields are limited. A character counter will show the number of remaining characters once you are close to the limit.
2. Some data fields are limited to numerical characters only (e.g., deformity parameters)
3. All numerical data input fields have upper and/or lower limits. Limits will be shown with a mouse over. Limits cannot be exceeded when using the up/down arrow keys (however it is possible to exceed the defined limits by manual data entry, but the option to save the data will not be available if the value is out of the defined range).
4. Numerical data is validated if it fulfills the requirements for completeness and correctness. A checkmark next to the input fields indicates data validation.
5. Moving on to the next step in the workflow is possible only if all input data has been properly defined and successfully validated.

For detailed information on the contents of the different tabs, refer to chapter 6 “Perspective Frame Matching (PFM)” on page 48, chapter 7 “Standard Planning Method” on page 75, and chapter 8 “Acute Intentional Deformation (AID)” on page 85.

4.2.4 Preview Area

The preview area displays the applicable model of the frame and the sticks and/or bones depending on the step in the workflow and the parameters entered.

Below the model view, you can select specific elements in the preview to be displayed or hidden (e.g., labels or bone models). The offered elements depend on the current Detail view.

4.2.4.1 Direction Reference Bone

The direction reference bone is a bone model of the case's bone, which rotates synchronously with the rendered image in the preview area. The purpose of the direction reference bone is to provide you with an orientation of the rendered image with respect to the bone.

The direction reference bone (cf. figure 38) is displayed in the lower left corner of the preview area.

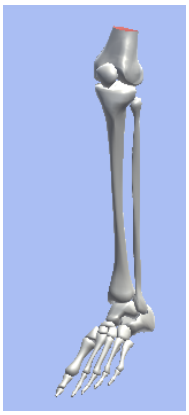


Figure 38 – The Detail view – Direction Reference Bone.

The direction reference bone is only displayed when the system is certain about the orientation of the rendered image with respect to the bone. Therefore, the direction reference bone is provided only in specific detail views of the Standard and the Perspective Frame Matching (PFM) planning methods:

- *Deformity Parameters*
- *Mounting Parameters*
- *Treatment plan*

4.2.4.2 Controlling the Preview

To change the detail and perspective of the preview area, use either the mouse functions or the corresponding control buttons to the right in the preview area. The following two subsections provide more detail about these two ways to control the preview area.

4.2.4.2.1 Mouse control

- **Rotate** – click into the preview area and move the mouse using the **left click** to rotate the model.
- **Zoom** – move the mouse over the preview area and use the **scroll wheel** to zoom in or out.
- **Pan** – click into the preview area and move the mouse using the **right click** to pan the model.

4.2.4.2.2 Control buttons next to the preview area

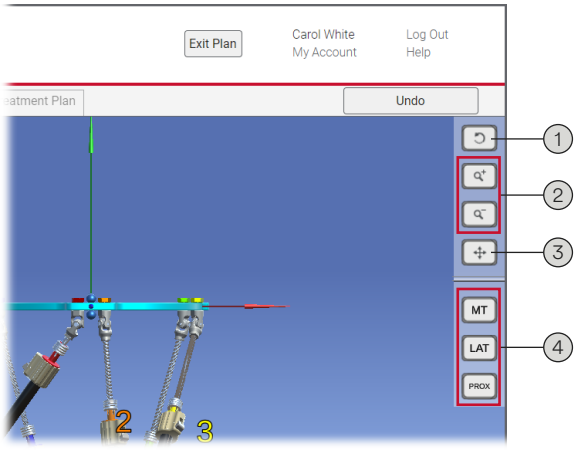


Figure 39 – The Detail view – Control buttons for the preview area.

1. Rotate.
2. Zoom in, zoom out.
3. Pan.
4. View: Frontal (**AP**), lateral (**LAT**), proximal (**PROX**). The available control buttons vary in the different views.

5 Create Treatment Plan

This chapter provides an overview and a general introduction into the treatment plan creation process. First, section 5.1 “Patients, Cases and Treatment Plans” gives you an overview of patients, cases and treatment plans and shows the relationship between the three.

The following sections show the treatment planning process, which is common for the three treatment planning methods: Perspective Frame Matching (PFM), Standard, and Acute Intentional Deformation (AID).

The treatment planning process consists of four higher level steps:

1. Add a New Patient or Select an Existing Patient (section 5.2 on page 35).
2. Define Case and Select Treatment Planning Method (section 5.3 on page 35).
3. Enter Planning Parameters (section 5.4 on page 39).
4. Define, Review and Approve Treatment Plan (section 5.5 on page 40).

5.1 Patients, Cases and Treatment Plans

A treatment plan contains one strut adjustment plan and all parameters that are necessary to calculate this strut adjustment plan. Each treatment plan is part of a case. Each case is assigned to a patient.

Between patients, cases, and treatment plans, the following relationship rules apply:

- A patient can have multiple cases.
- Each case can have multiple treatment plans.
- Each case can have not more than one active treatment plan with a status of “in planning” or “in process” (refer to section 10.1 “Treatment Plan Life Cycle and Statuses” on page 100 for details).

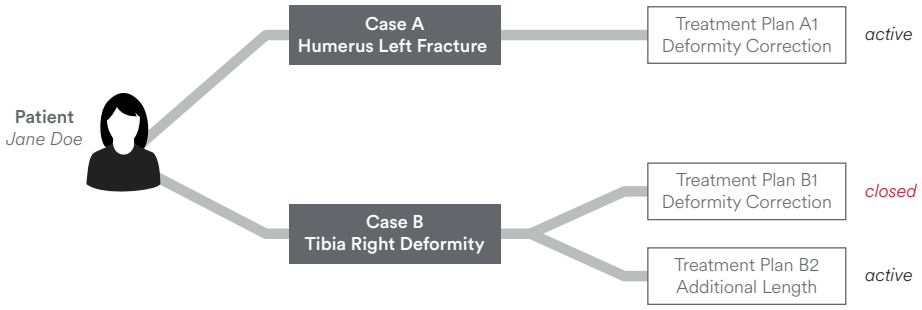


Figure 40 – Relationship between patients, cases, and treatment plans.

5.2 Add a New Patient or Select an Existing Patient

The first step in creating a treatment plan is to add a new patient or select an existing one. Please proceed as follows:

5.2.1 Add new patient

1. In the *Home* view, click **Add Patient**.
2. Enter whether you acknowledge the receipt of patient consent (refer to section 11.1.1 on page 107).
3. Enter a *Patient ID*, *First name*, and *Last name*.
4. Select the desired language for the patient's strut adjustment instructions in the *Strut adjustment instructions* field.
5. If desired, enter optional *Patient information*, *Contact information* and *Legal guardian information*.
6. Click **Save**.

For more details on adding a patient refer to section 11.1 on page 107.

5.2.2 Select existing patient

1. In the *Home* view, click **Find Patient**.
2. Search and select a patient. You can search by patient first name, last name, or patient ID (refer to section 13.1.2 "Search for Patients" on page 122).
3. Click **Select Patient**. The Patient Dashboard view is displayed (refer to section 11.2 "The Patient Dashboard" on page 109).

For more details on searching patients refer to section 13.1.2 on page 122.

5.3 Define Case and Select Treatment Planning Method

A treatment plan is part of a patient's case. When you create a new treatment plan, you choose whether the plan is part of a new case or part of an existing case (refer to section 5.1 "Patients, Cases and Treatment Plans" on page 34 for details).

Note: When the system creates a new case, it automatically sets a case title based on the case diagnosis, the bone undergoing treatment, and the body side.

5.3.1 Define Case

In the Patient Dashboard view, click **Start New Treatment Plan**. From that moment on, the system guides you step by step throughout the rest of the treatment plan creation process.

In the *Create New Treatment Plan* view, you select the treatment planning method, specify the case parameters, and set a title for the new treatment plan. The case definition parameters are not defaulted and require you to enter or select these parameters.

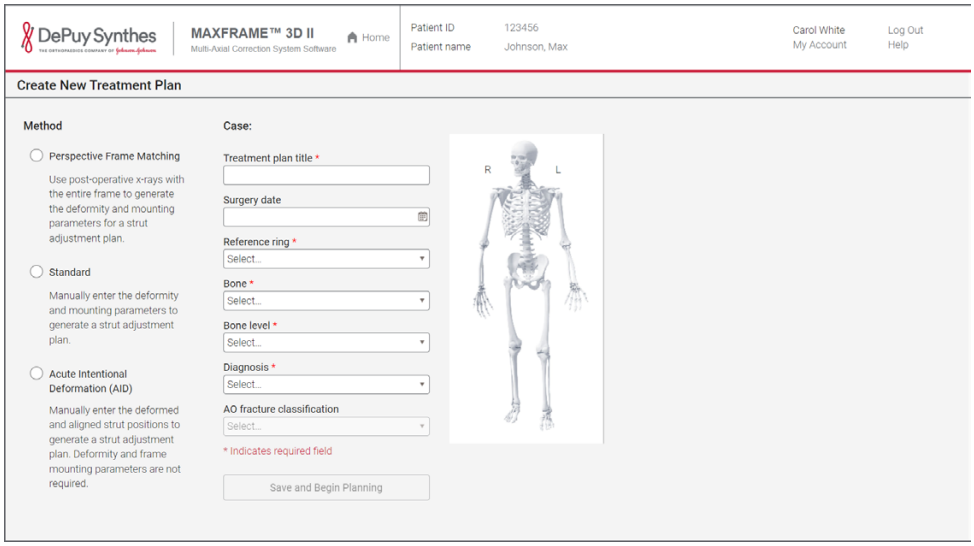


Figure 41 – Create New Treatment Plan view.

5.3.2 Select Treatment Planning Method

In the left pane titled *Method*, select the treatment planning method. The *MAXFRAME 3D II Software* offers the following three methods to plan a treatment plan.

Perspective Frame Matching

The Perspective Frame Matching (PFM) method uses post-operative x-ray images with the entire frame to generate the deformity and mounting parameters for a strut adjustment plan (refer to chapter 6 starting on page 48).

Standard

The Standard planning method allows you to manually enter the deformity and mounting parameters to generate a strut adjustment plan (refer to chapter 7 starting on page 75).

Acute Intentional Deformation (AID)

The Acute Intentional Deformation (AID) method allows you to manually enter the initial and final strut positions to generate a strut adjustment plan. Deformity and frame mounting parameters are not required in this method (refer to chapter 8 starting on page 85).

Important: It is highly recommended to decide the treatment planning method as part of your pre-surgery planning. To facilitate the treatment planning process, you should select the treatment planning method before starting the surgery.

In the middle pane labeled *Case*, select whether you want to create a new case (default setting) or to add the new treatment plan into an existing (closed) case. If you choose to create a new case, the system asks all the parameters required, including bone undergoing treatment, diagnosis, and the selection of the reference ring.

Enter the following parameters:

Treatment plan title
Enter a title for the treatment plan. This title should be specific enough for you to identify the treatment plan within a patient's case easily.

The software requires that a treatment plan title is unique at the patient level.

Surgery date
Enter the date of the surgery manually or click the calendar icon on the right side of the date field to display a calendar and select the date in it. The surgery date is optional and just for your own information and reference.

Reference ring
Select whether the proximal or the distal ring is the reference ring.

Warning: The correct selection of the reference ring (*Proximal* or *Distal*) is important for the measurement of the frame mounting and thus the calculation of the strut adjustment plan.

Bone
Select the bone undergoing treatment from the drop-down list or click the desired bone in the skeleton figure.

Warning: The body side selection is critical to the treatment planning and outcome.

Bone level
Select the location of the osteotomy or fracture as bone level from the drop-down list or click the desired level in the bone figure. The bone figure is displayed to the right of the skeleton after you have selected the bone undergoing treatment.

Note: The bone level value is used only for the treatment plan simulation. The bone level value has no impact on the calculation of the strut adjustment plan.

Bone level is disabled if the selected planning method is AID.

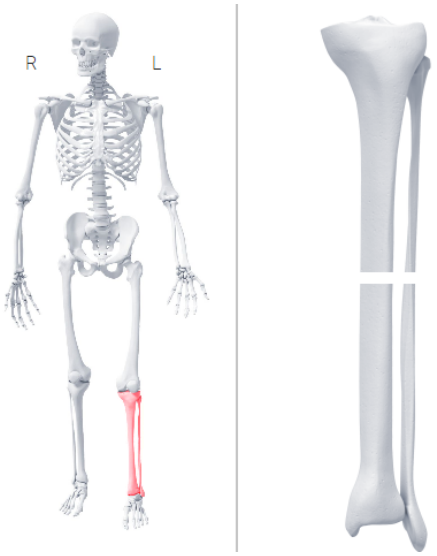


Figure 42 – The Bone Level.

Diagnosis

Select the diagnosis from the drop-down list. The following diagnoses are available:

- Bone deformity
- Joint deformity (Contracture)
- Bone defect
- Leg length discrepancy
- Fracture

Note: The *diagnosis* is used for data purposes only. The selected diagnosis has no further impact (i.e., neither on the workflow nor on the strut adjustment plan calculation).

AO fracture classification

If the diagnosis is *Fracture* you may specify the related *AO Fracture Classification* by selecting it from the drop-down list. The *AO Fracture Classification* is optional and has no impact on the calculation of the strut adjustment plan.

To save the parameters and proceed, click the **Save and Begin Planning** button. The **Save and Begin Planning** button will be enabled once all required fields have been completed.

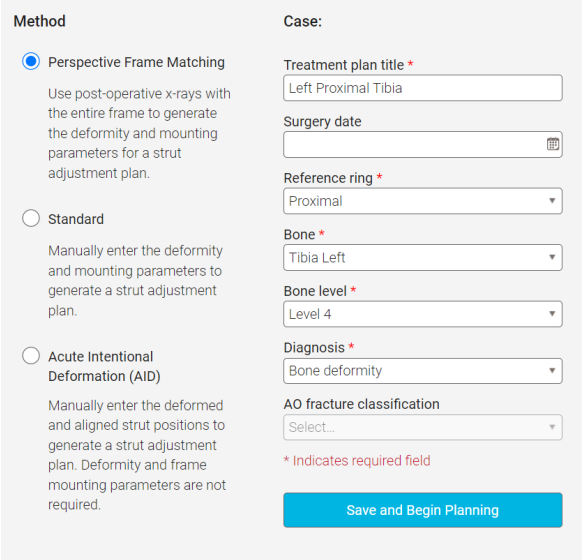


Figure 43 – Save and Begin Planning.

5.4 Enter Planning Parameters

The required steps to specify the necessary treatment plan parameters depend on the selected treatment planning method:

Perspective Frame Matching (PFM)

Figure 44 – Steps – PFM.

For detailed information on the PFM planning method, refer to chapter 6 starting on page 48.

Standard

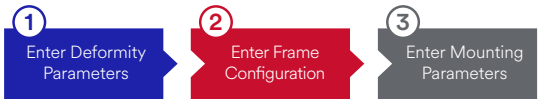


Figure 45 – Steps – Standard planning method.

For detailed information on the Standard planning method, refer to chapter 7 starting on page 75.

Acute Intentional Deformation (AID)

You enter the frame configuration including the initial and final strut settings.

Figure 46 – Steps – AID planning method.

For detailed information on the AID planning method, refer to chapter 8 starting on page 85.

5.5 Define, Review and Approve Treatment Plan

For the final phase of the treatment plan creation process, the software provides functions and options to perform the following substeps:

1. Define Treatment Plan Parameters (section 5.5.1 below).
2. Simulate Treatment Plan (section 5.5.2 on page 41).
3. Configure and Review Strut Adjustment Plan (section 5.5.3 on page 42).
4. Review and Adjust Strut Swap Dates (section 5.5.4 on page 44).
5. Treatment Plan Result – Exceptions (section 5.5.5 on page 44).
6. Approve Treatment Plan (section 5.5.6 on page 46).
7. Strut Adjustment Instructions (section 5.5.7 on page 47).

5.5.1 Define Treatment Plan Parameters

In the *Treatment plan* tab, you define the calculation parameters for the treatment plan and select the calculation method (when using AID, you also define the value for the calculation method).

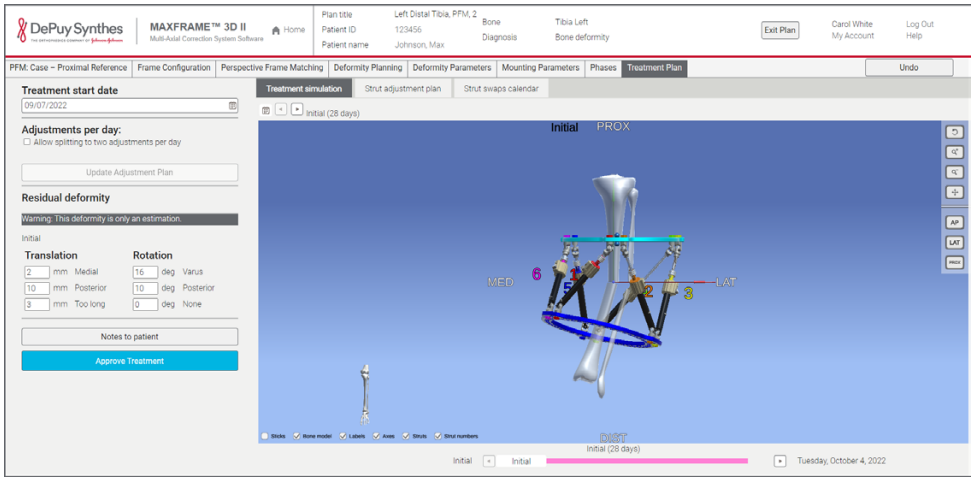


Figure 47 – Treatment plan tab.

Treatment start date

Enter the treatment start date manually or click the calendar icon on the right side of the date field to display a calendar and select the date in it.

Allow splitting to two adjustments per day

Check *Allow splitting to two adjustments per day* to allow the patient to split the strut adjustments into two times per day. By selecting this option, the number of allowed adjustments per day (1 or 2) can be adjusted later in the resulting strut adjustment plan either for specific days or for all days. For more information on splitting strut adjustments, refer to section 5.5.3 “Configure and Review Strut Adjustment Plan” on page 42).

Notes to patient

Click **Notes to patient** to enter individual notes which are included on the strut adjustment instructions provided to the patient.

When you have selected and entered all necessary parameters, click **Update Adjustment Plan** to calculate the strut adjustment plan.

5.5.2 Simulate Treatment Plan

The *Treatment plan* tab has on its right side three subtabs: *Treatment simulation*, *Strut adjustment plan*, and *Strut swaps calendar*.

In the *Treatment simulation* subtab, you can simulate the calculated treatment plan. The simulation provides you an opportunity to visualize the estimated movement of the fragments for the current plan to confirm its correctness.

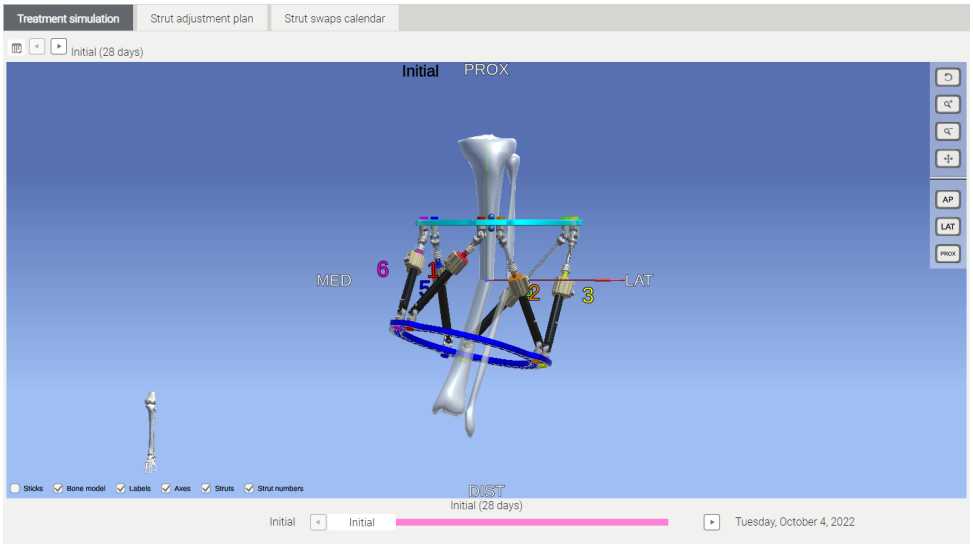


Figure 48 – Treatment Plan Simulation.

There are two ways of simulating the treatment plan:

1. Use the calendar navigation on top of the preview to navigate through the days of the treatment or to select a specific day.

2. Use the slider or slider arrows below the preview to move the plan forward or backward.

Note: The color of the slider changes as per the number of treatment phases defined in the *Phases* tab (refer to section 6.9 “Define Phases” on page 70). Treatment plan result simulation for each individual phase is indicated using a color defining the specific phase.

The preview updates the model automatically, whenever you switch the treatment day to be simulated. The remaining translational and rotational deformity parameters as of the simulated day are displayed to the left of the preview. As with all the preview area models, the simulation model can be zoomed, panned, and rotated for additional visualization.

You can display or hide *Sticks*, *Bone model*, *Labels*, *Axes*, *Struts*, and *Strut numbers* in the preview. Check or uncheck the corresponding check boxes below the model. By default, only *Sticks*, *Labels*, and *Axes*, *Struts*, and *Strut numbers* are active and displayed in the preview.

Warning: Bone models are only intended to be used for simulation purposes only. Bone models do not need to correspond to the clinical situation. The deformity is only an estimation (as always displayed as a warning in the left pane of the *Treatment simulation* subtab under *Residual deformity*, cf. figure 49).

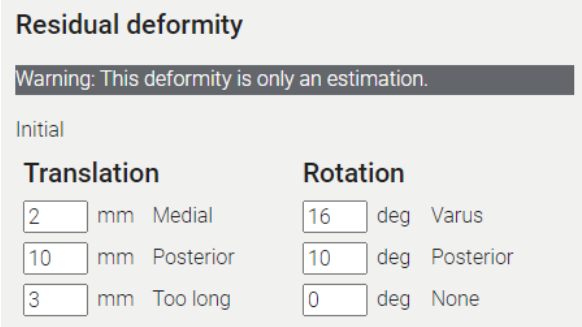


Figure 49 – Warning that the deformity is only an estimation.

5.5.3 Configure and Review Strut Adjustment Plan

To configure and review the strut adjustment plan, click on the *Strut adjustment plan* subtab within the *Treatment plan* tab.

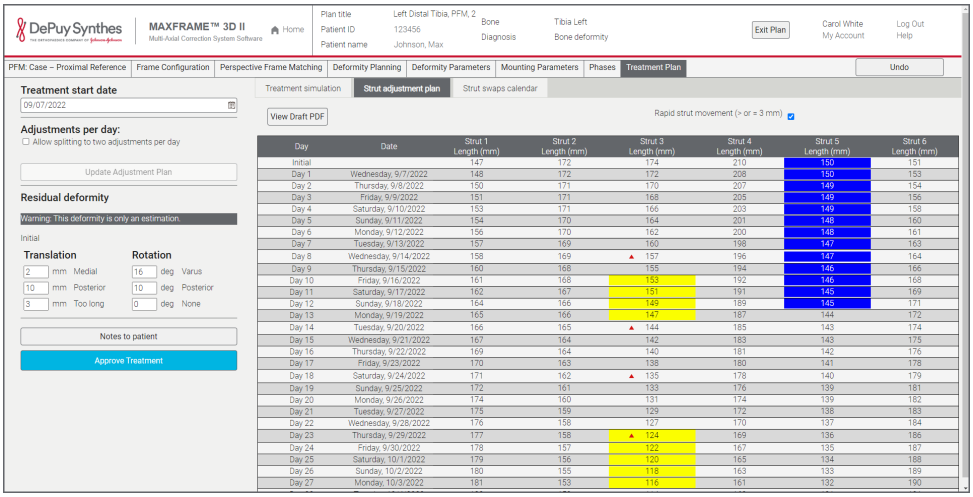
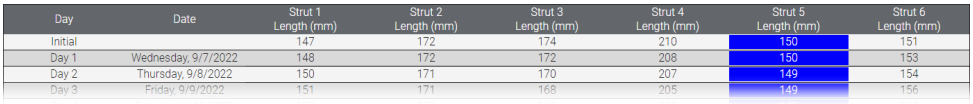


Figure 50 – Strut Adjustment Plan.

Each row of the strut adjustment plan represents the calculated daily setting for each of the struts. The initial frame setting is displayed.

Each treatment phase duration is indicated by highlighting the treatment days for each individual phase with a different color.

The color used matches the color of the slider in the treatment simulation and the color corresponding to the individual phases in the *Phases* tab.



Day	Date	Strut 1 Length (mm)	Strut 2 Length (mm)	Strut 3 Length (mm)	Strut 4 Length (mm)	Strut 5 Length (mm)	Strut 6 Length (mm)
Initial		147	172	174	210	150	151
Day 1	Wednesday, 9/7/2022	148	172	172	208	150	153
Day 2	Thursday, 9/8/2022	150	171	170	207	149	154
Day 3	Friday, 9/9/2022	151	171	168	205	149	156

Figure 51 – Initial settings and the calculated daily settings for the first treatment day.

View Draft PDF

Click on the **View Draft PDF** button to create and display a draft of the strut adjustment plan as PDF file.

Rapid strut movement (> or = 3 mm)

Activate this option to tag all strut movements in the plan, which are greater than or equal to 3 mm/day. This option is defaulted to indicate the rapid strut movements by red triangle markers (▲).

Allow splitting to two adjustments per day

Check *Allow splitting to two adjustments per day* to allow the patient to split the strut adjustments into two times per day to avoid a large movement between two steps. To split a specific day into two adjustments, check the corresponding check box in the *Split* column.

Click on **Split All** on top of table to split all days of the plan. Click on **Unsplit All** to remove all split check marks in the plan.

5.5.4 Review and Adjust Strut Swap Dates

To review and adjust the strut swap dates, click on the *Strut swaps calendar* subtab within the *Treatment plan* tab.

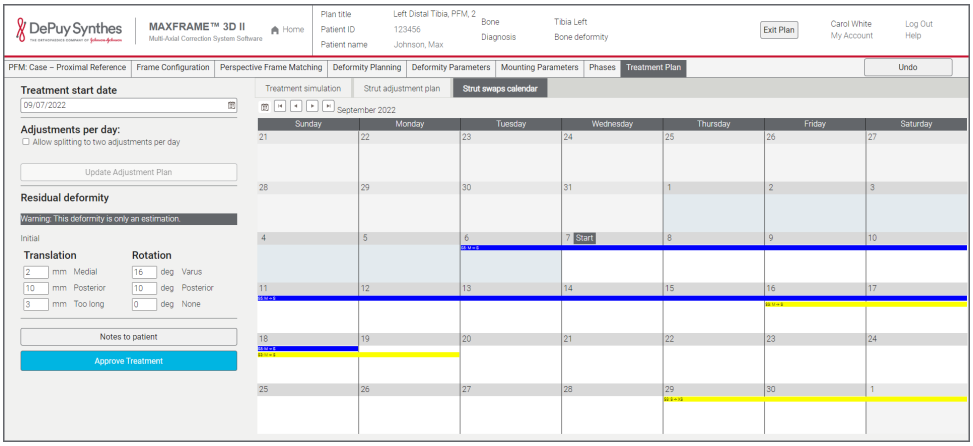


Figure 52 – Strut Swaps Calendar.

The calendar provides a view to the recommended date ranges for the necessary strut swaps during the treatment. The date ranges indicated on the calendar match the color of the strut that requires a swap and list from and to sizes of the strut.

The date ranges of the strut swaps in the calendar view assists you in planning for follow up office visits. Select a specific date in the range as an appointment for the patient by clicking the header of the desired day.

If necessary or preferred, you could set a different Treatment Start Date or edit the calculation parameters to adjust resulting strut swap date ranges. Click **Update Adjustment Plan** to re-calculate the adjustment plan and the strut swaps calendar.

5.5.5 Treatment Plan Result – Exceptions

The calculated treatment plan results in an error in some exceptional cases as mentioned below. In these cases, the **View Draft PDF** button and **Approve Treatment** are deactivated. An error message is displayed as a text message in the *Treatment simulation* subtab indicating the error.

1. When the suggested strut swap is before the first day (or treatment start) of the treatment plan. The message indicates re-planning by increasing the treatment duration or slowing down the plan.

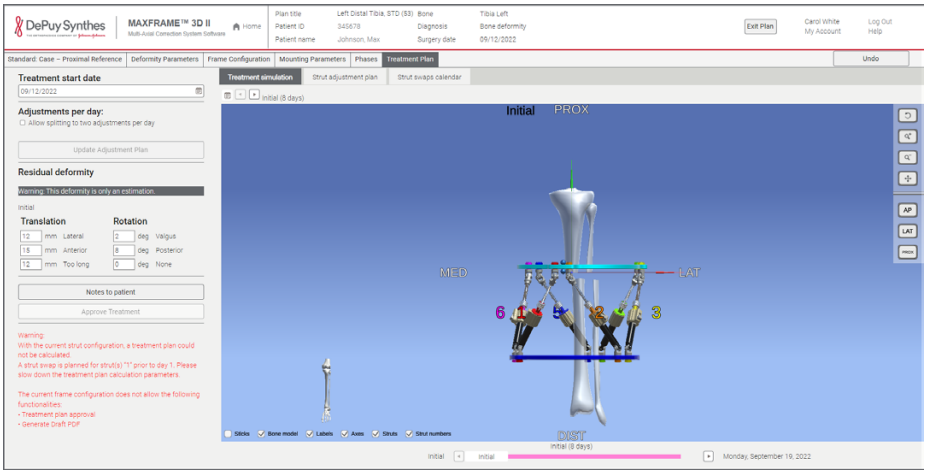


Figure 53 – Treatment plan results exception: Strut length exceeds limits.

Note: An additional phase can be added to the plan (as defined in section 6.9 “Define Phases” on page 70) with no strut movement.

2. When the strut swap duration is not available. The message indicates re-planning by increasing the treatment duration or slowing down the plan.

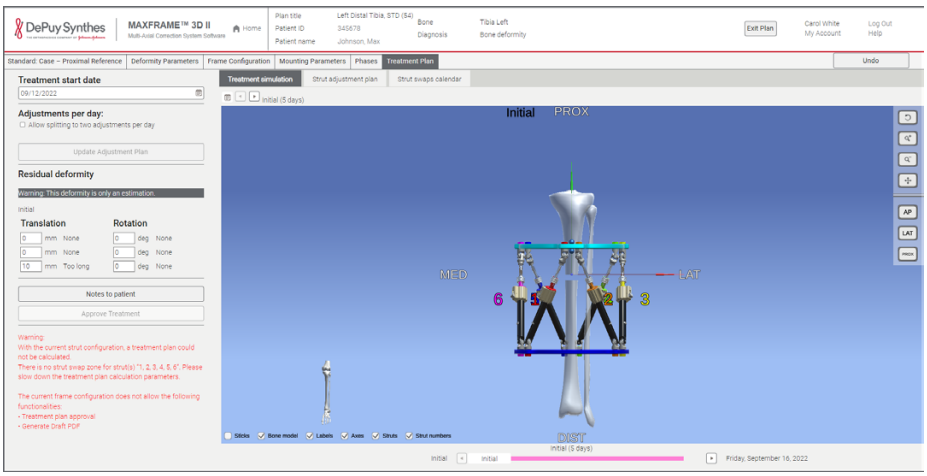


Figure 54 – Treatment plan results exception: Swap duration not available.

3. When the suggested strut length is not available in the database. The message indicates a re-plan.

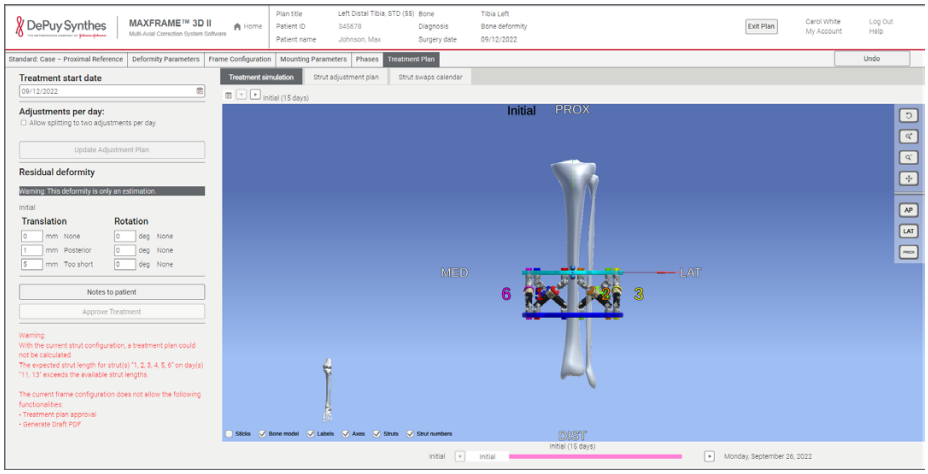


Figure 55 – Mounting parameter limits.

Note: The Treatment Simulation displays 2D dotted lines to visualize the struts that are not available in the list.

5.5.6 Approve Treatment Plan

To approve the current treatment plan, proceed as follows:

1. Click on **Approve Treatment** in the upper right side of the view to approve this treatment plan. The *Electronic signature* pop-up window appears (figure 56). The electronic signature requires that you review and approve the treatment plan and the patient selected for correctness.

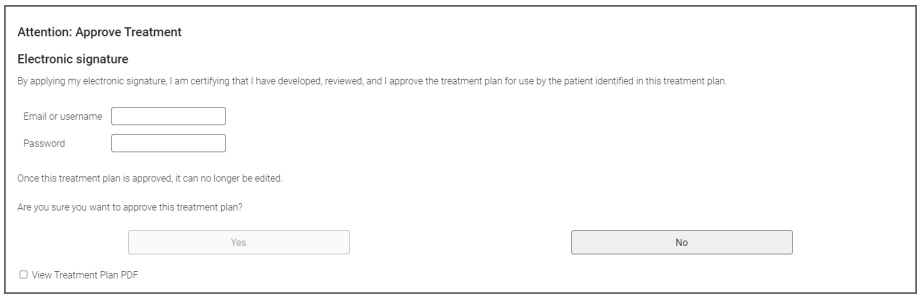


Figure 56 – Electronic signature pop-up window.

2. Enter your *Username* and *Password*.
3. If you want to view the generated treatment plan PDF file, check the option *View Treatment Plan PDF*.
4. Click **Yes** to approve the current treatment plan and complete it.

   Note: Once a treatment plan is approved, it can no longer be edited.

   Click **No** to cancel the approval process and return to the *Treatment plan* tab.

Warning: We recommend periodic checks between the planned correction and strut settings and the actual strut settings of the frame on the patient. Follow-up visits and x-rays can be used to compare the planned with the actual. If needed, the treatment plan in planning can be completed and re-planned (refer to section 10.4 “Re-plan a Treatment Plan” on page 104 for more information).

5.5.7 Strut Adjustment Instructions

The strut adjustment instructions are the approved strut adjustment plan provided as a PDF file to the patient. The strut adjustment instructions are intended to be used and followed by the patient during the treatment.

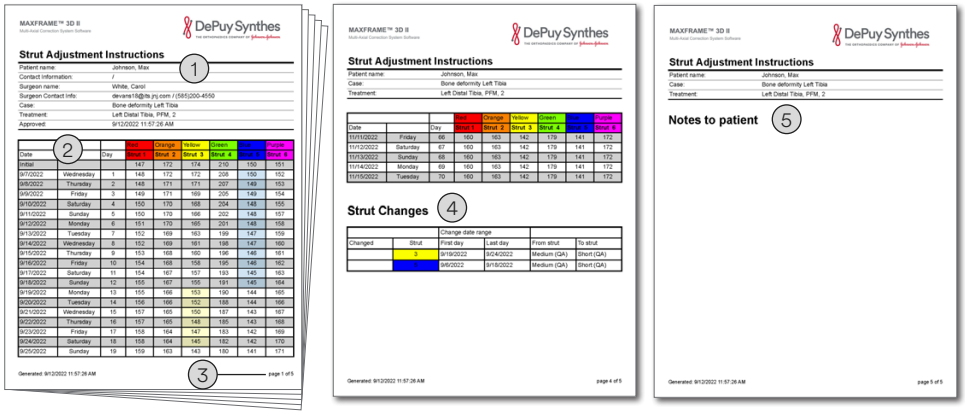


Figure 57 – Strut Adjustment Instructions.

Strut adjustment instructions contain the following information:

1. Information about patient, surgeon, case and treatment plan, and plan status.
2. Daily settings for each strut with a header that is color-coded by strut.
3. Each page of the instructions displays the current page number and the total number of pages.
4. Recommended or confirmed strut swap duration.
5. Notes to the patient.

Warning: You should review the strut adjustment instructions for correctness, completeness, correct version of the plan and print quality prior to providing the instructions to the patient.

Note: Notes to patient can be included by clicking **Notes to patient** and should also contain information regarding all the precautions to be taken.

6 Perspective Frame Matching (PFM)

Use post-operative x-rays with the entire frame mounted to the bone to generate the deformity and mounting parameters for a strut adjustment plan.

Note: At this point in the manual, it is assumed that you have selected the patient and defined the case. For details refer to chapter 5 starting on page 34.

6.1 Check Prerequisites

To create the strut adjustment instructions using the PFM planning method, the following prerequisites must be met:

1. The AP and LAT x-rays with frame mounted on patient that include the full frame must be available as digital images. For detailed requirements refer to section 12.1 “Supported Images” on page 115.
2. The Clinical Rotational Deformity parameter must be known.
3. The frame configuration parameters (rings, struts, and strut mounting points) of the actual frame mounted on the patient in surgery must be known.

Important:

- A Surgeon Planning Worksheet is available and can be utilized to record required data parameters.
- Refer to the *MAXFRAME System Technique Guide* for hardware requirements and proper use, as needed.

6.2 Steps

Figure 58 – Steps – PFM planning method.

6.3 Enter Frame Configuration

In the *Frame Configuration* tab, you describe the case’s frame configuration – namely, all rings and struts, including ring and strut size and length installed.

Note: A frame must not use rings that are more than 2 sizes apart.

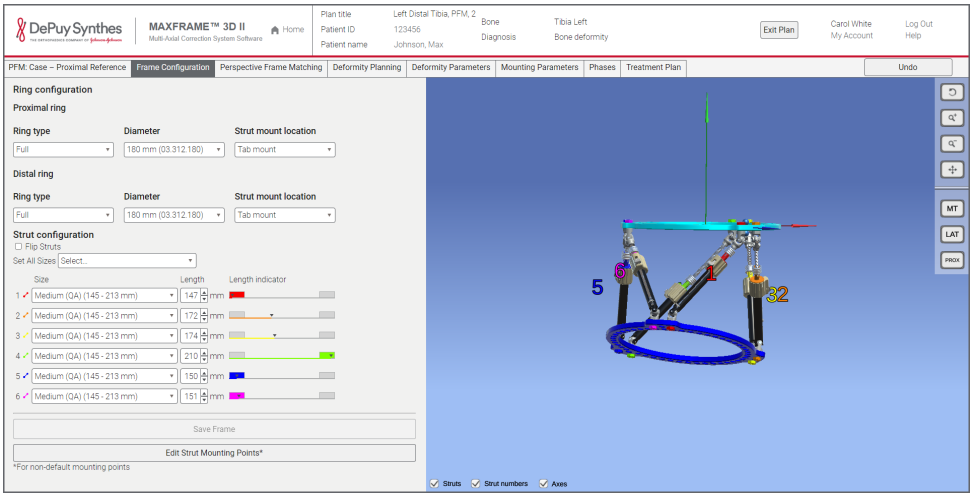


Figure 59 – PFM – Frame Configuration.

Ring Configuration – Proximal Ring

The ring configuration of the proximal ring might consist of up to three parameters (depending on the selected ring type):

- *Ring type*: *Full*, *5/8*, or *Foot Plate*.

  Note: If a 5/8 ring is used with a bridging plate, select *Full* with the same diameter.

- *Diameter*: Select the ring by its diameter in millimeters (mm) and in case of a foot plate additionally its type (“Short” or “Long”) from the drop-down list. Each entry in this list contains only DePuy Synthes validated parts to ensure proper selection. For the full list of available ring sizes, refer to section 2.6 “Hardware” on page 10.

- *Strut mount location*: If you have selected *Full* as the ring type, then specify whether the struts are mounted on the ring or the tab mount location.

  Warning: When frames are constructed in a ring mount to ring mount configuration, struts located in the default hole position maximizes stability. If a strut is required to move to a non-default hole, please check the stability of the frame.

- *Opening (5/8 Ring)*: If you have selected *5/8* as the ring type, then specify where the opening of the ring is located (between *Strut 1 & 2*, *Strut 3 & 4*, or *Strut 5 & 6*).

Ring Configuration – Distal Ring

The ring configuration of the distal ring is similar to the ring configuration of the proximal ring, might consist of up to three parameters (depending on the selected ring type):

- *Ring type*: *Full*, *5/8*, or *Foot Plate*.

- *Diameter*: Select the ring by its diameter in millimeters (mm) and in case of a foot plate additionally its type (“Short” or “Long”) from the drop-down list. Each entry in this list contains only DePuy Synthes validated parts to ensure proper selection.

- *Strut mount location*: If you have selected *Full* as the ring type, then specify whether the struts are mounted on the ring or the tab mount location.

  Warning: When frames are constructed in a ring mount to ring mount configuration, struts located in the default hole position maximizes stability. If a strut is required to move to a non-default hole, please check the stability of the frame.

- *Opening (5/8 Ring)*: If you have selected *5/8* as the ring type, then specify where the opening of the ring is located (between *Strut 1 & 2*, *Strut 3 & 4*, or *Strut 5 & 6*).

Strut configuration

After the frame is mounted, the strut identification numbers and colors are assigned by adding plugs or clips to the struts according to the following rule: Start on the *master tab* where struts 1 and 2 come together, with strut 1 on the left side, then continue counterclockwise.

The strut numbers and colors are defined as follows:

- Strut 1 is Red.
- Strut 2 is Orange.
- Strut 3 is Yellow.
- Strut 4 is Green.
- Strut 5 is Blue.
- Strut 6 is Purple.

For more details on strut numbers and colors refer to the *MAXFRAME System Technique Guide*.

For each of the six struts, select the strut type (“Quick Adjust”/“QA” or “Standard”/“Std.”) and the strut size from the corresponding drop-down list.

Use the drop-down list labeled *Set All Sizes* on top of the individual strut configuration settings to select the same type and size for all six struts at one time. For example, if you select strut type and size “Long (QA) (203–329 mm)”, the type and size for each of the six struts will be updated to “Long (QA) (203–329 mm)”.

Enter each strut’s measured length in millimeters (mm) in its corresponding *Length* field. The unit of measure (mm) is indicated with each of the strut length input fields.

If you enter a strut length that is not within the strut size range the strut length indicator will not be displayed.

The colored *Length Indicators* display for each strut is its entered length value in relation to the selected strut size. The strut length indicators also indicate where overlaps with adjacent strut sizes exist (see figure 92 on page 80).

The **Save Frame** button will be enabled only when all the ring parameters and strut lengths have been set. Strut length must be within the defined selected strut type range.

Notes

1. If the defined strut length lies within the range of any other strut size, all the strut sizes that support the defined strut length are highlighted in the drop-down list.

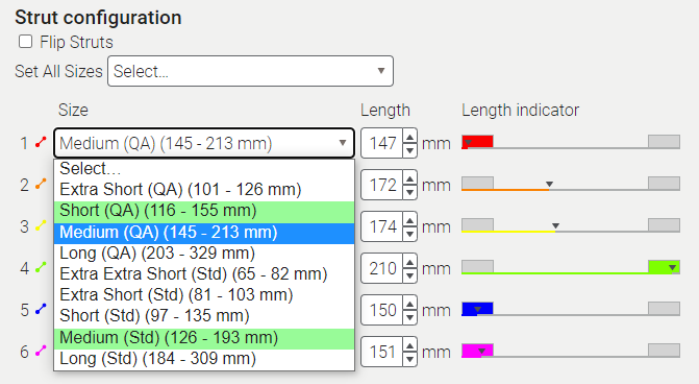


Figure 60 – PFM – Strut size options for the defined strut length.

2. If the defined strut length is in the overlap region of the preceding or succeeding strut, the strut size can be changed by clicking the overlap region in the length indicator.

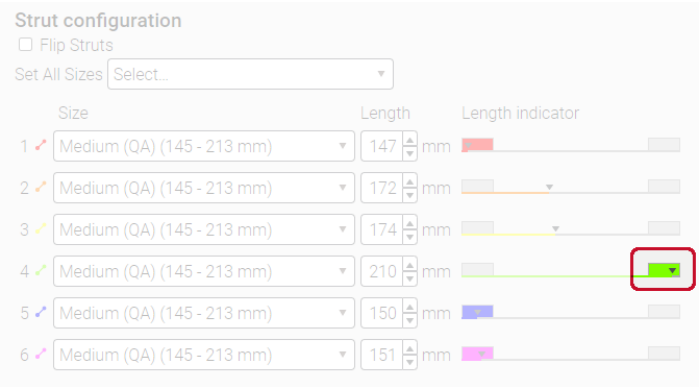


Figure 61 – PFM – Strut length indicator overlap.

3. **Note:** Selecting the *Flip Struts* option allows to change the direction of all the struts opposite to the current direction. This helps to visualize the strut direction in the software as in the real-life scenario, to understand better the strut movement during treatment.

Strut Mounting Points

For detailed information on editing the default strut mounting points, refer to section 9.1 on page 91.

To save your entered data and update the preview, click **Save Frame**.

If you want to hide *Struts*, *Strut numbers*, or *Axes* in the preview, uncheck their corresponding check boxes below the model. By default, all three options are active and displayed in the preview.

Important: In the preview area, the strut number labels are always facing you, even when rotating the rendered image.

Click the tab title **Perspective Frame Matching** to proceed to the *Perspective Frame Matching* tab.

6.4 Perform the Frame Matching

In the *Perspective Frame Matching* tab, you describe the frame's position on the two x-ray images in a visual way by matching the struts and hinges of the model with the case's AP and LAT x-ray images.

The initial *Perspective Frame Matching* view looks as follows:

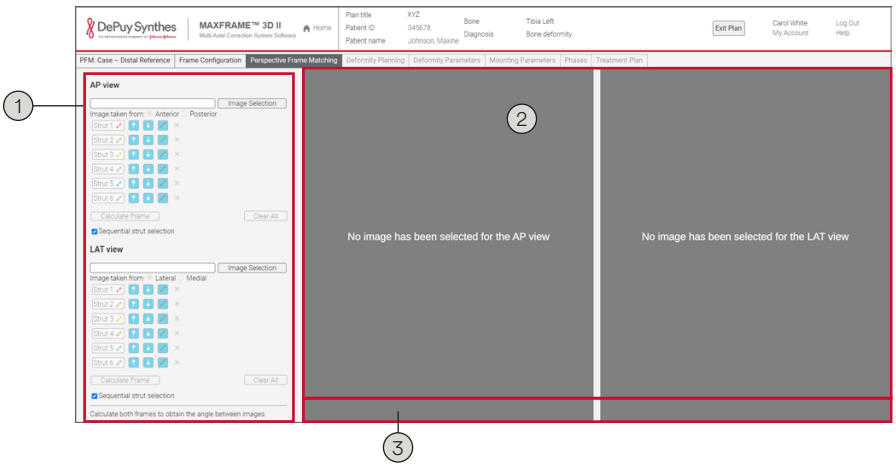


Figure 62 – PFM – Overview.

The *Perspective Frame Matching* consists of the following components and areas:

1. Selection buttons for strut and hinges and image selectors for AP and LAT.
2. Matching views for AP and LAT.
3. Options for AP and LAT view (these controls are available when the images are uploaded).

First, select the AP and LAT x-ray images.

6.4.1 Load and Select Images

To select the AP and LAT x-ray images for the Perspective Frame Matching, proceed as follows:

1. Click on the **Image Selection** for AP view. The following dialog opens:

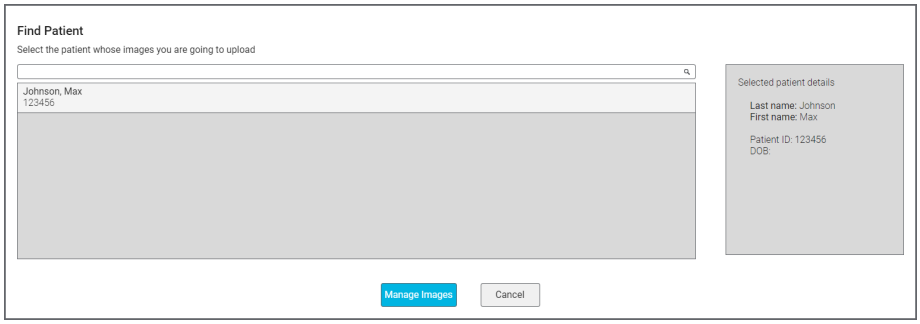


Figure 63 – PFM – Select image – Initial Dialog.

Note: If you have already loaded images into the current case, these images will be listed in the *Select AP Images* dialog.

2. To load x-ray images, click **Manage Images**. The Image Manager opens:

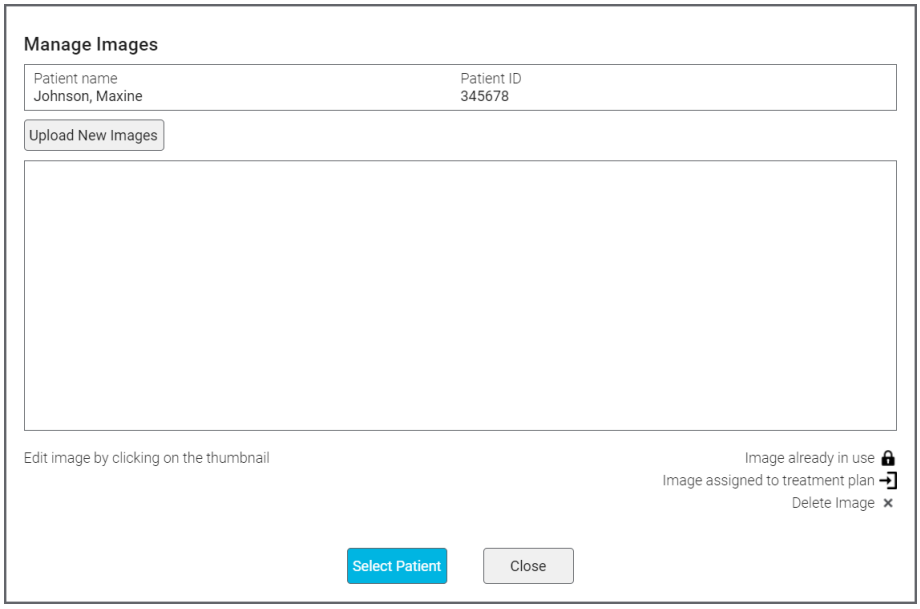


Figure 64 – PFM – Select image – Manage Images.

Note: For a full description on uploading and reviewing images using the Image Manager, refer to chapter 12 starting on page 115.

3. Click **Upload New Images** and select the AP and LAT x-ray image files to be uploaded (cf. section 12.4 on page 117).

4. Set the date taken and the image type.

   Note: Both tags are optional. The image type tag is helpful (*AP/LAT*) as it then allows the Image Manager to filter the list of images for selection by view.

   Other Image Type is set to *Other* by default.

   When you've uploaded the x-ray images and set the image tags, the Image Manager looks as follows:

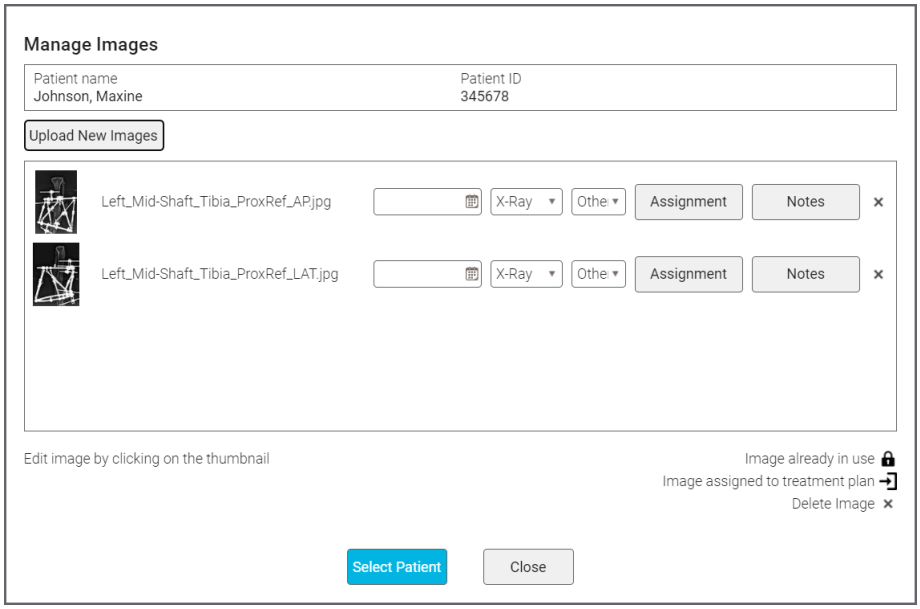


Figure 65 – PFM – Select image – Image Manager with uploaded x-ray images.

5. (Optional) Flip or rotate x-ray images:

   Click on the thumbnail of the image you would like to mirror/rotate.

   You have the option to rotate the image in 15° increments. You can mirror the image by selecting the *Mirrored* check box (cf. figure 66).

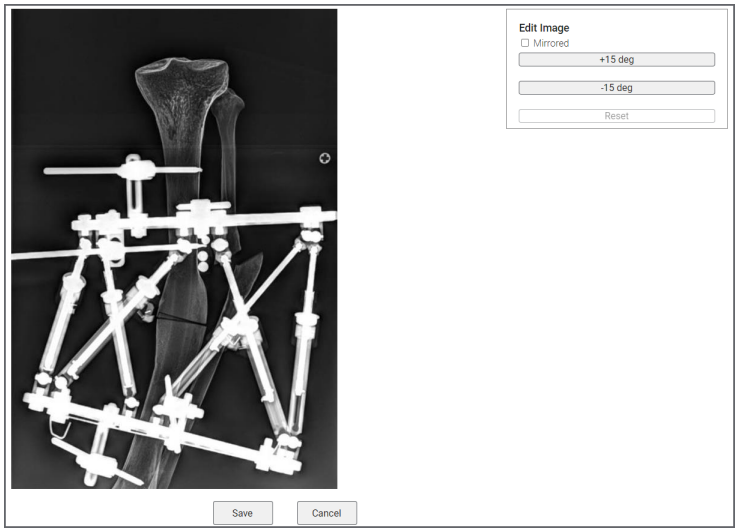


Figure 66 – PFM – Mirror/rotate images window.

   The original image is retained without any manipulation. The processed image appears as a child image linked to the original parent image. The processed image is given a default name by the software.

   Click on the **Save** button and the edited image is automatically named and saved into the Patient Image Database (cf. figure 67).

Note: Results of all image edits (flip/rotate) can be visualized immediately in the rendering area (cf. figure 67).

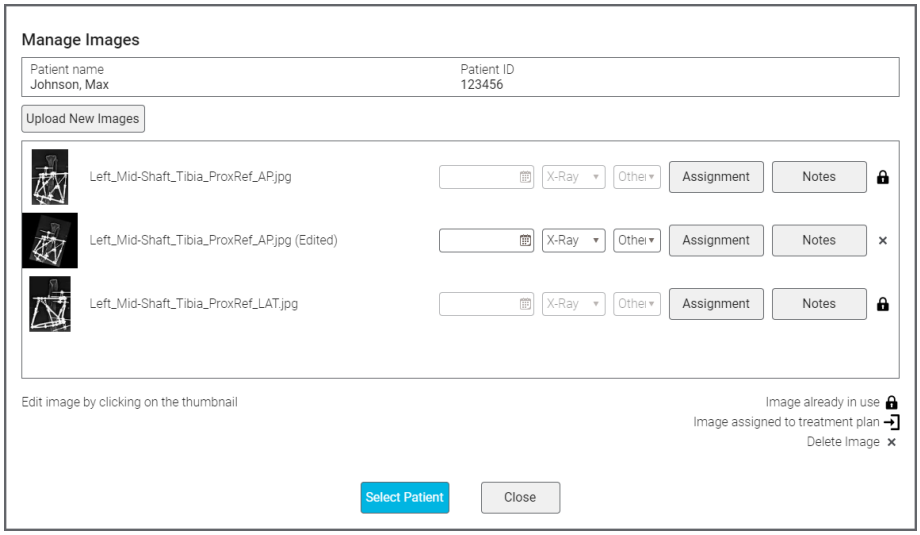


Figure 67 – PFM – Review images window.

6. Click **Image Selection**. The *Select AP Images* dialog opens, containing the AP x-ray image (or image type defined as *Other*):

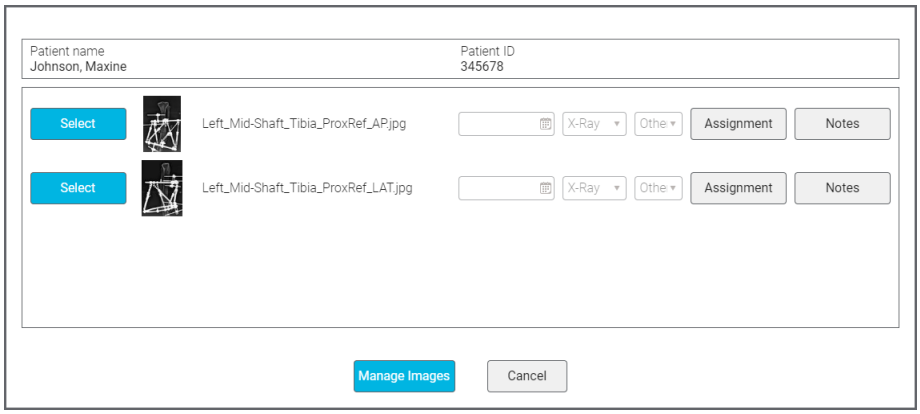


Figure 68 – PFM – Select image – Select AP images.

7. Click the **Select** button of the desired AP image. The *Select AP Images* dialog closes and the selected AP x-ray image is displayed in the AP view. The image file name is displayed to provide confirmation that your selected image is correct. The strut and hinges selection buttons (cf. figure 69) for the AP view are enabled.

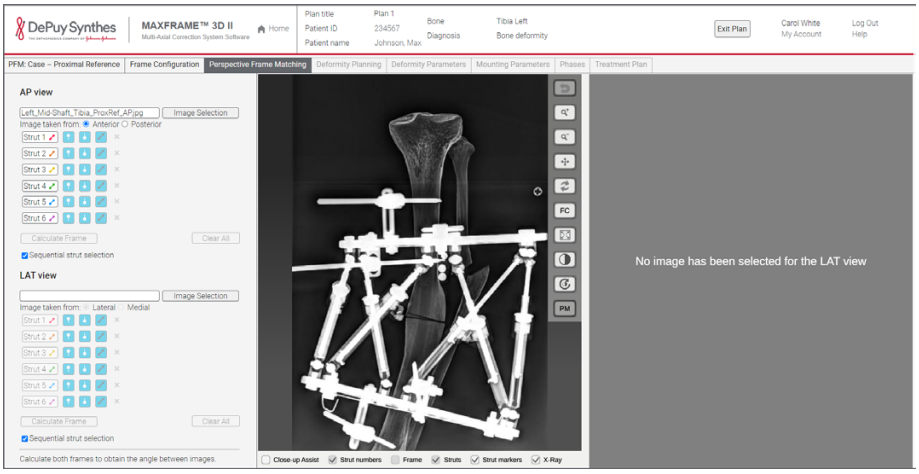


Figure 69 – PFM – Perspective Frame Matching with loaded AP and image file name displayed.

8. Select the AP image's *Image taken from* orientation. The orientation is defaulted to *Anterior*.

9. Adjust the AP image's brightness and contrast if needed.

10. Select the LAT view image by clicking *Image Selection* button for LAT view on the right side and selecting the x-ray image in the *Select LAT Images* dialog.

11. Select the LAT image's *Image taken from* orientation. The orientation is defaulted to *Lateral*.

12. Adjust the LAT image's brightness and contrast if needed.

6.4.2 Mark Struts and Hinges on Images

To mark the six struts and their hinges on the AP and LAT images, proceed as follows:

1. Click the corresponding strut selection button on the left side of the view (cf. [A] in figure 70). The button changes color to dark blue to indicate it has been selected.

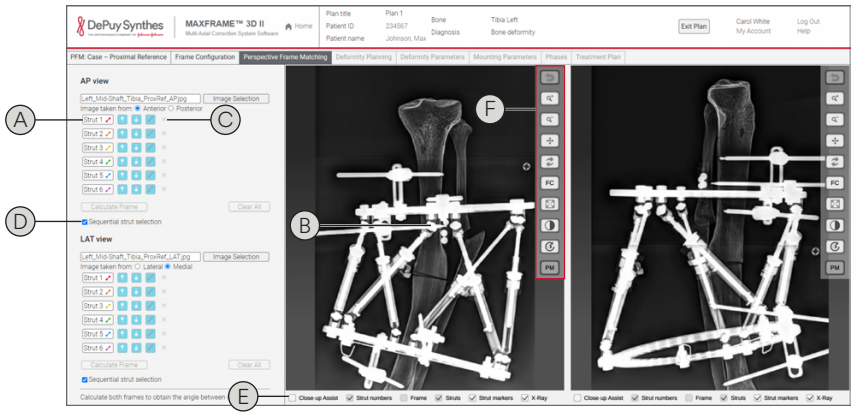


Figure 70 – PFM – Strut selection.

2. Locate the corresponding strut's proximal or distal hinge's position in the AP x-ray and click on it. The selected position is marked with its associated hinge indicator.

   Note: To help differentiate between struts, check and compare the size of the strut hinges to one another. The strut closer to you will appear slightly larger.

3. Drag the mouse to the opposite hinge's position in the AP x-ray and click it. The selected position is marked with its associated hinge indicator (cf. [B] in figure 70).

   Note: You can deselect any of the hinge and/or strut direction icons based on your visual results (cf. section 6.4.2.1 on page 57).

4. Click a hinge and move to adjust its position. Click the strut line and move to adjust the position of the whole strut.

5. Draw the other five struts in the same way as the first into the AP view.

   Notes

   - To select the struts in sequence automatically, activate the *Sequential strut selection* option (cf. section 6.4.2.3 "Sequential Strut Selection").
   - The struts can be selected in any order and started in either direction (i.e., proximal to distal or distal to proximal).

6. Click **Calculate Frame** to calculate the frame model and show it on the actual x-ray image.

   Note: Calculate Frame to calculate the frame model will be activated when at least 6 hinges or strut lines have been marked.

7. Repeat the whole procedure for the LAT view.

   Note: You can select **PM** to match the frame in one of the views if the frame has been calculated in the corresponding view to help identify struts. Pre-match is explained in section 6.4.2.6 "Pre-Match" on page 59.

6.4.2.1 Selecting Struts and Hinges for Calculation

Next to each strut selection button (cf. [A] in figure 70 on page 56), you find the following options to include or exclude specific components in the frame matching calculation:

Icon	Option
	If activated, the position of the corresponding proximal hinge is included in the frame matching calculation. Activated by default.
	If activated, the position of the corresponding distal hinge is included in the frame matching calculation. Activated by default.
	If activated, the direction of the corresponding strut is included in the frame matching calculation. De-activated by default.

Table 6.1 – Icons in Perspective Frame Matching User Interface.

Note: If all three icons are selected for a strut, only the hinge point positions will be included in the frame matching calculation. If you want the strut direction to be included in the calculation, you must deselect one of the hinge points for that strut.

6.4.2.2 Delete Strut Markers

To delete a single strut marker, click the **Delete** icon (✕) right to the corresponding strut selection button (cf. [C] in figure 70 on page 56).

To delete all strut markers in a view, click **Clear All** below the strut selection buttons of the corresponding view. Click **Yes**/**No** in the message box that appears when selecting to delete all strut markers.

6.4.2.3 Sequential Strut Selection

Select the option *Sequential strut selection* (cf. [D] in figure 70 on page 56) to automatically select the next strut not yet drawn for the selected view (AP or LAT) after finishing drawing a strut.

6.4.2.4 Close-up Assist

The *Close-up Assist* (cf. [E] in figure 70 on page 56) aids you with adjusting the positions of the hinges. When selected, zoomed views of the proximal and the distal hinges of the selected strut are displayed below the regular view. You can adjust the position of the hinges directly in the close-up views.

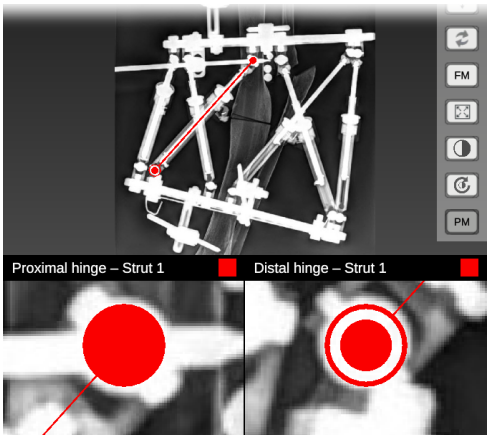


Figure 71 – PFM – Close-up Assist.

To display a strut's hinges in the zoomed views, click the corresponding strut selection button on the left side of the view (cf. [A] in figure 70 on page 56). Only the activated strut can be manipulated in the close-up assist windows.

Note: If you have selected the *Sequential strut selection* option (cf. section 6.4.2.3 on page 58) and activate the *Close-up Assist* mode, the *Sequential strut selection* option is automatically turned off. When *Close-up Assist* is selected, it is possible to reselect the *Sequential strut selection* option along with the *Close-up Assist* mode.

Note: If you see more than one hinge in the *Close-up Assist*, only the selected hinge can be moved. This protects against moving the other hinges by accident.

The marker diameter can be enlarged or reduced using the mouse wheel.

6.4.2.5 View Tools

The AP view and the LAT view offer the following functions in their toolbars (cf. [F] in figure 70 on page 56):

Icon	Function
	Reverses the last edit to a strut in the corresponding view.
	Zooms the image in.
	Zooms the image out.
	Pans the image in the direction of mouse movement.
	Resets the zoom and pan settings of the view to their defaults.
	Displays the current frame configuration model in the respective other planning view (cf. section 6.4.2.7 “Display Frame Configuration Model”).
	Expands the view to double width.
	Adjust image brightness and contrast.
	Resets the image brightness and contrast to their defaults.
	Provides an option to support strut marking (cf. section 6.4.2.6 “Pre-Match”).

Table 6.2 – Icons in Perspective Frame Matching User Interface.

Note: The **Pan** button will automatically be turned off (if already selected), when drawing the strut lines.

6.4.2.6 Pre-Match

Pre-match (cf. figure 72) provides an option to support strut marking. Pre-match can be used in the corresponding view only when the x-ray image in the other view has been matched. Select the **PM** button in the view where the frame must be matched. The pre-match 3D frame is displayed in the appropriate view in the respective rendering area.

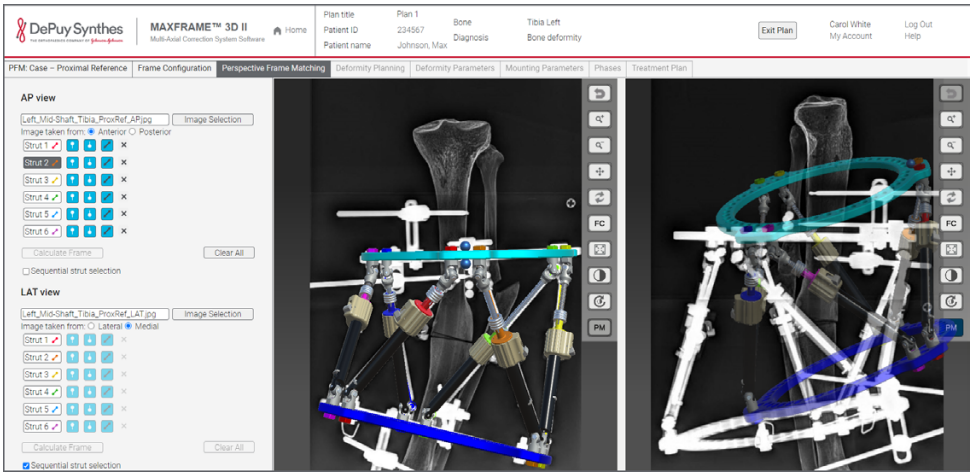


Figure 72 – PFM – Pre-match image shown in LAT view.

Using Tools, move and scale the x-ray image. Adjust the image contrast and brightness to clearly display the matched frame in the selected view. Draw the struts and adjust the hinge positions for the x-ray image using the pre-matched image as the reference before calculating the frame.

Note: To support pre-matching:

1. X-ray image Rotation:
   a. 3 button mouse: Hold **Ctrl** key on keyboard + right mouse button while moving the mouse.
   b. *Macbook Trackpad*: Hold **Control** key + use 2 fingers to click/hold, then move one finger relative to the other to rotate image.
2. X-ray image Pan:
   a. 3 button mouse: Hold right mouse button while moving the mouse.
   b. *Macbook Trackpad*: Use 2 fingers to click/hold while moving both fingers around together.
3. X-ray image Zoom:
   a. 3 button mouse: Use scroll wheel.
   b. *Macbook Trackpad*: Use 2 fingers with a light touch (no click).
4. X-ray image can be hidden using the check box at the bottom of the screen.

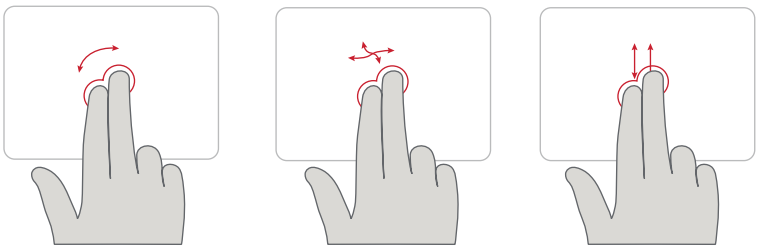


Figure 73 – PFM – Trackpad gestures left to right: Rotation, Pan, Zoom.

Warning: Strut matching must be done using x-ray images to avoid any errors with frame matching.

6.4.2.7 Display Frame Configuration Model

You can display the current frame configuration model in the corresponding planning view to get a better idea of the orientation of the frame in the x-ray images. To display the current frame configuration model of the active view, click the *FC* (“Frame Configuration”) button in the toolbar of *AP view* or *LAT view*.

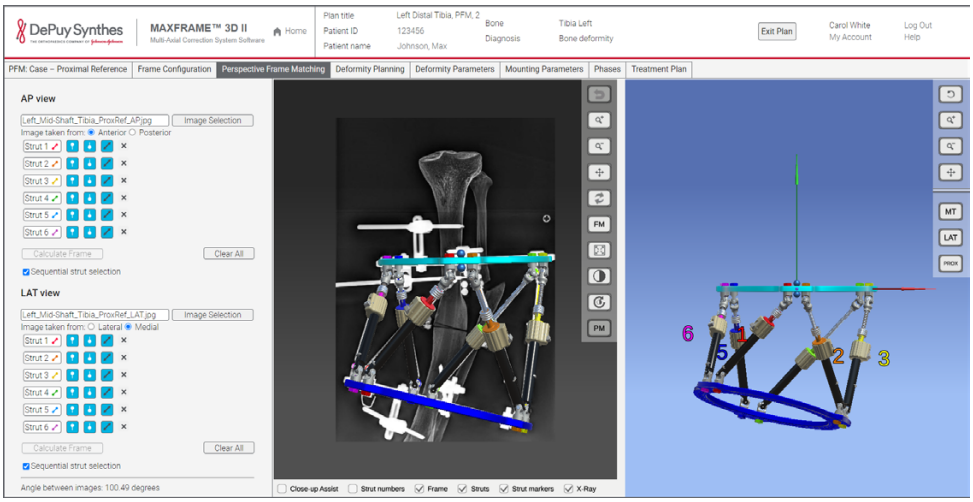


Figure 74 – PFM – Display the Frame Configuration Model.

You can rotate, zoom, and pan the frame model the same way as in the preview area (cf. section 4.2.4.2 “Controlling the Preview” on page 32).

The *FC* button will change to *FM* (“Frame Matching”). Click the **FM** button to hide the frame configuration model and to display the regular planning view content for the other x-ray image.

6.4.3 View Options

You can display or hide *Strut numbers*, *Frame*, *Strut markers*, *X-Ray*, and *Struts* in each view. Check or uncheck the corresponding check boxes below the model.

6.5 Save and Proceed

When you finished the matching and calculated the model in both views, the angle between the AP and the LAT x-ray images is being displayed below the view options (cf. figure 75).

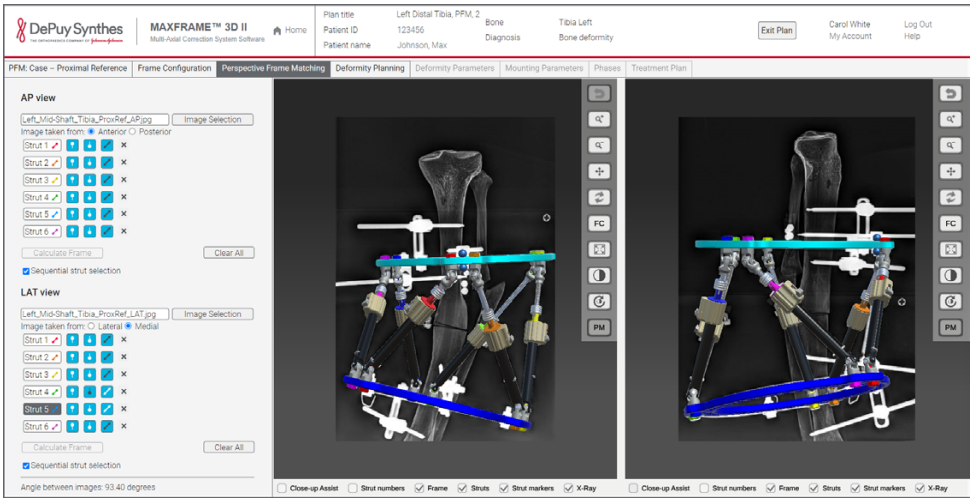


Figure 75 – PFM – Finalized matching with frames and angle between images displayed.

A calculation and match of the AP and LAT images is required to move forward in the current plan.

Click the tab title **Deformity Planning** to save your PFM data and proceed to the *Deformity Planning* tab.

6.6 Perform Deformity Planning

In the *Deformity Planning* tab, you fully describe the case's deformity in a visual way by identifying the deformity elements in the AP and LAT x-ray images.

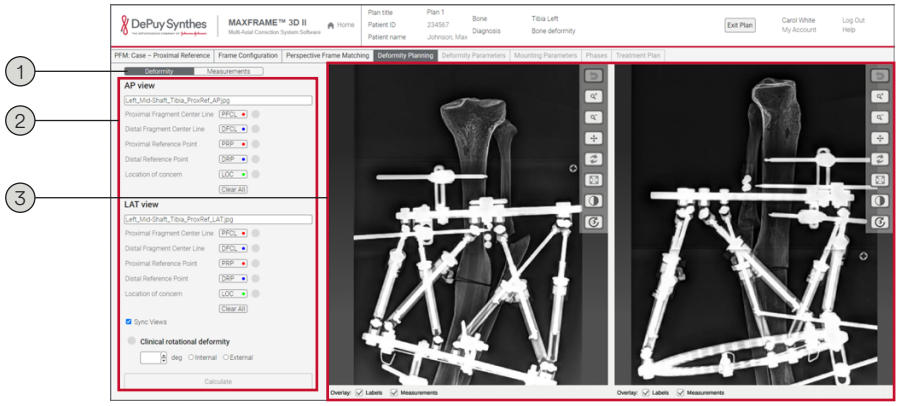


Figure 76 – PFM – Perform Deformity Planning.

The *Deformity Planning* consists of the following components and areas:

1. Marking type selector (**Deformity** or **Measurements**).
2. *Deformity elements* and *measurement tools*.
3. AP and LAT views (like the AP and LAT views in the *Perspective Frame Matching* tab). The image file name is displayed to provide confirmation that your selected image is correct.

6.6.1 Define the Deformity Planning Parameters

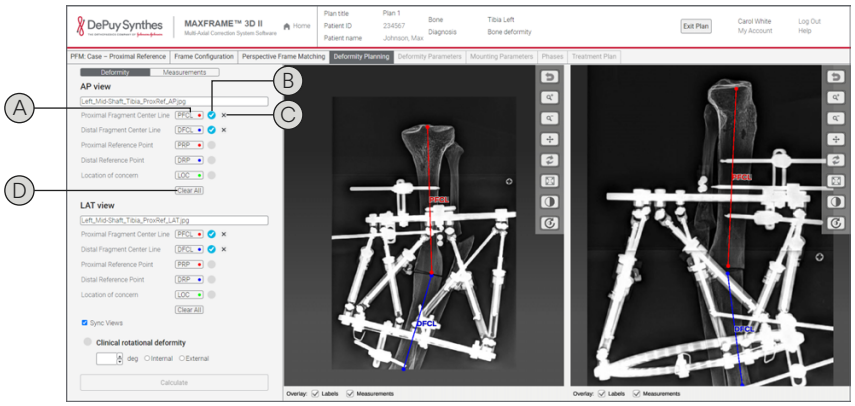


Figure 77 – PFM – Deformity Parameters.

Select the following deformity parameters from the left pane (cf. [A] in figure 77) and identify their position in the AP and the LAT views:

Button	Parameter	Procedure
PFCL	*Proximal Fragment Center Line.*	Click a central point on one end of the proximal fragment, keep the mouse button pressed, drag the mouse to the opposite end of the proximal fragment, and release the mouse button on a central point there. The green guidelines assist you locating the bone's central axis.
DFCL	*Distal Fragment Center Line.*	Click a central point on one end of the distal fragment, keep the mouse button pressed, drag the mouse to the opposite end of the distal fragment, and release the mouse button on a central point there. The green guidelines assist you locating the bone's central axis.
PRP	*Proximal Reference Point.*	Mark the Proximal Reference Point.
DRP	*Distal Reference Point.*	Mark the Distal Reference Point.
LOC	*Location of concern (LOC).*	Mark the central position of the *location of concern* (optional).

Table 6.3 – Deformity Planning Parameters.

When the Proximal Reference Point (*PRP*), the distal reference point (*DRP*), or the location of concern (LOC) is selected in the AP or LAT view, a dashed guideline representing the potential location of that element will be displayed in the other view. This guideline is an estimation to assist you in placing the element in the other view.

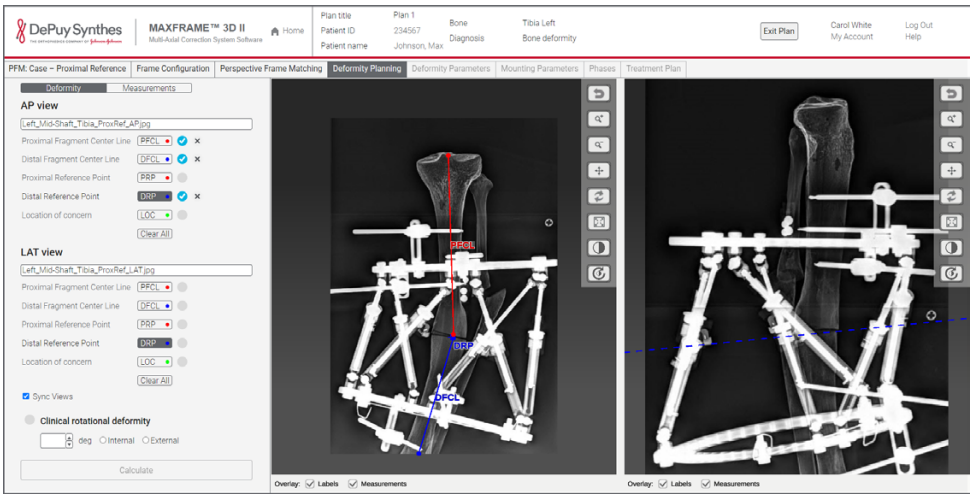


Figure 78 – PFM – dashed location guideline in the LAT view for the Proximal Reference Point (selected in the AP view).

When a deformity parameter has been set, its corresponding *OK* icon is displayed (✓, cf. [B] in figure 77).

To modify a deformity parameter, select it and drag it to its new position.

To delete a deformity parameter, click the **Delete** icon (✕, cf. [C] in figure 77) of the corresponding deformity element.

To delete all deformity parameters in a view, click the **Clear All** button of the corresponding view (cf. [D] in figure 77).

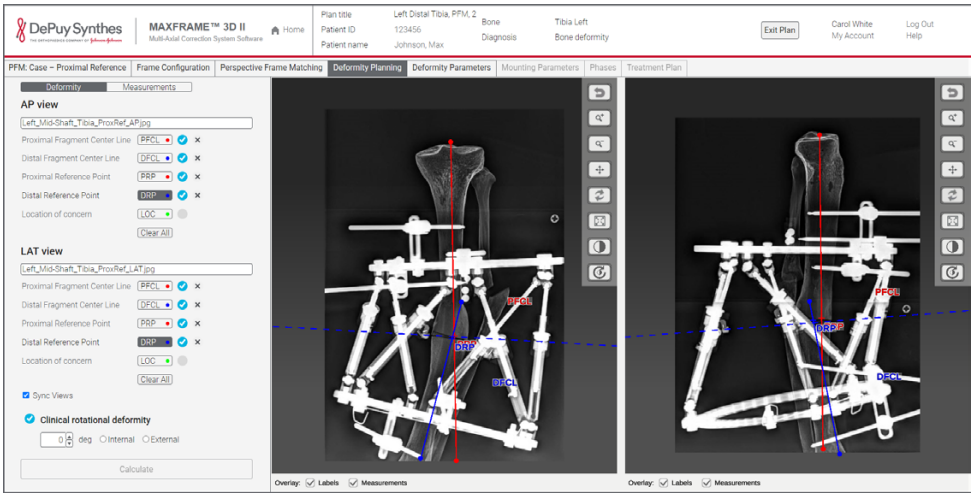


Figure 79 – PFM – deformity parameters set.

If the *Sync Views* is checked *on* the guided lines in both views correspond to the last selected deformity parameter, independent of the image in view. Uncheck the *Sync Views* to display the guided lines independently in each view, AP and LAT respectively.

Note: *Sync Views* is checked by default.

6.6.1.1 Clinical Rotational Deformity

Under the *Deformity* view, you can define the *Clinical rotational deformity*. Enter the *Clinical rotational deformity* value in degrees and specify the direction (internal or external). The translation parameter accepts values of 0 to 89 degrees. If the value is zero, the direction setting will be deactivated.

To save your entered data and update the preview, click **Calculate**.

6.6.2 Additional Measurement Tools

In the *Additional Measurements* view, you can add angulation measurements (**Angle**) and intersecting lines (**Four Point**), and segmented straight line (*Segmented Line Element*).

Note:

1. The additional measurements made with the measurement tools are not used for the calculation of the strut adjustment plan. The additional measurements are only used for reference or validation purposes.
2. The number of segments in the *Segmented Line Element* defaults to two segments, but can be changed from a minimum of one segment to a maximum of five segments.

Click on **Measurements** to switch to the *Additional Measurements* view.

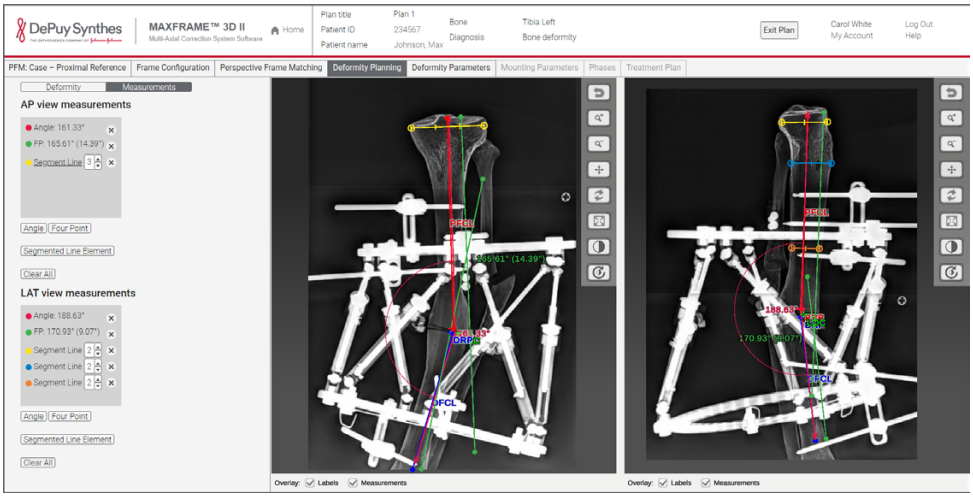


Figure 80 – PFM – Additional Measurements.

For detailed information on performing additional measurements, refer to section 9.3 “Additional Measurement Tools for Deformity Planning” on page 95.

Click the tab title **Deformity Planning** to proceed to the *Deformity Planning* tab.

6.7 Review Deformity Parameters

In the *Deformity Parameters* tab, you review and adjust the deformity. The view shows the five calculated skeletal deformity parameters and the *Clinical rotational deformity*, which is defined manually in the *Deformity Planning* tab. The deformity parameters describe the translation and angulation between the Proximal Reference Point on the proximal fragment and the Distal Reference Point on the distal fragment.

Important: Sticks do **not** represent bones but rather represent reference points and axes.

The *PFM* icon (PFM) indicates the values which have been calculated by frame matching and deformity planning. If you change a value, the corresponding *PFM* icon is removed.

Click **Refresh Perspective Frame Matching Data** to discard the manually entered values for the calculated parameters and restore their calculated values.

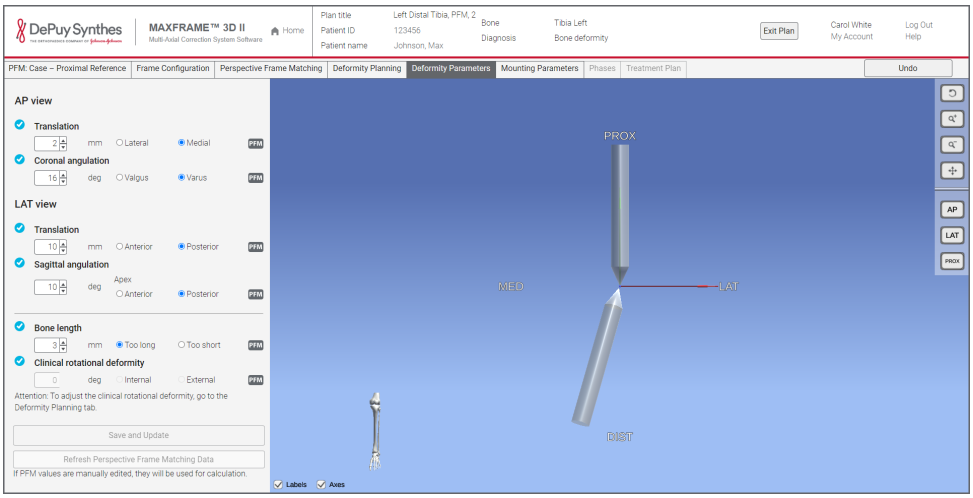


Figure 81 – PFM – Calculated Deformity Parameters.

If you select to refresh, a message will be displayed that all the values will be over-written.

AP view – Translation

Review (and edit if necessary) the *anteroposterior translation value* in millimeters (mm) and including the respective direction (lateral or medial).

AP view – Coronal angulation

Review (and edit if necessary) the *coronal angulation value* in degrees and including the respective direction (valgus or varus).

LAT view – Translation
Review (and edit if necessary) the *lateral translation value* in millimeters (mm) and including the respective direction (anterior or posterior).

LAT view – Sagittal angulation
Review (and edit if necessary) the *sagittal angulation value* in degrees and including the respective direction (anterior or posterior).

Bone length
Review (and edit if necessary) the discrepancy of the *bone length* between Distal Reference Point and the Proximal Reference Point in millimeters (mm) including the respective direction, whether the bone is too short or too long.

Clinical rotational deformity
Clinical rotational deformity value in degrees and the specified direction (internal or external) is automatically filled in as defined in Deformity Planning tab (cf. section 6.6.1.1 "Clinical Rotational Deformity" on page 65) and can only be viewed in the *Deformity Parameters* screen. The value field cannot be edited or deleted here. Clinical Rotational Deformity can be added/deleted/modified only in the *Deformity Planning* tab.

Notes

1. The directional field radio buttons are disabled when the corresponding field value (PFM calculated or manually defined) is 0 mm, 0°, or 180°.
2. The limit for each parameter is as indicated in the table below. Exceeding this limit will deactivate the **Save and Update** button (this limit can be exceeded only by manual entry, not when using the **up**/**down** arrow keys).

Deformity Parameter	Lower Limit	Upper Limit	Unit
AP view – Translation	0	100	mm
AP view – Coronal angulation	0	89	degrees
LAT view – Translation	0	100	mm
LAT view – Sagittal angulation	0	89	degrees
Bone length	0	260	mm
Clinical rotational deformity	0	89	degrees

Table 6.4 – Deformity parameter value limits and units.

To save the parameters and proceed, click the **Save and Update** button. The rendering area will be updated only when all the mandatory parameters have been defined.

After clicking **Save and Update**, the system renders a model of the deformity.

Note: The rendered model will disappear if you change one or more parameters. Click **Save and Update** again to render the model for the changed parameters.

If you want to display labels and axes in the model, you can do so by checking their respective check boxes in the rendering area. To rotate the model, zoom, or pan, use the mouse (cf. section 4.2.4.2.1 “Mouse control” on page 33), or click on the respective buttons at the right side of preview area (cf. section 4.2.4.2.2 “Control buttons next to the preview area” on page 33).

The preview area displays the body direction of the bone model of the selected bone in its lower left corner to provide a clear reference (cf. section 4.2.4.1 on page 32.

Click the tab title **Mounting Parameters** to proceed to the *Mounting Parameters* tab.

6.8 Review Mounting Parameters

In the *Mounting Parameters* tab, you describe the position of the frame with respect to the Proximal Reference Point. The view shows the six PFM calculated mounting parameters. The mounting parameters describe the offset and angulation between the Proximal Reference Point on the reference ring.

Note: This section covers mounting parameters for proximal reference cases. If your case requires a distal reference ring or a foot plate, refer to section 9.4 “Using a Distal Reference Ring or Foot plate” on page 97 for more information.

The *PFM* icon (PFM) indicates values which have been calculated by frame matching. If you change a value, the corresponding *PFM* icon is removed.

Click **Refresh Perspective Frame Matching Data** to discard the manually entered values for the calculated parameters and restore their calculated values.

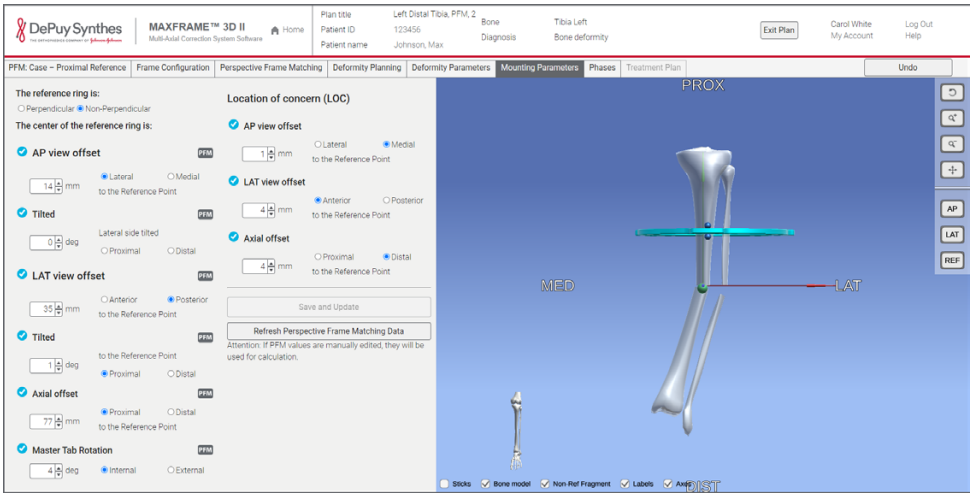


Figure 82 – PFM – Calculated Mounting Parameters.

If you select to refresh, a message will be displayed that all the values will be over-written.

Review and, if desired, adjust the following parameters:

AP view offset

Review (and edit if necessary) the *anteroposterior offset value* of the center of the reference ring with respect to the Proximal Reference Point in millimeters (mm), including the respective direction (lateral or medial).

AP view offset – Tilted

Review (and edit if necessary) the *tilt of the lateral side* in degrees, including the respective direction (proximal or distal).

LAT view offset

Review (and edit if necessary) the *lateral offset value* in millimeters (mm), including the respective direction (anterior or posterior).

LAT view offset – Tilted

Review (and edit if necessary) the *tilt of the anterior side* in degrees, including the respective direction (proximal or distal).

LAT view offset – Axial offset

Review (and edit if necessary) the *axial offset value* in millimeters (mm), including the respective direction (proximal or distal).

LAT view offset – Master Tab Rotation

Review (and edit if necessary) the *rotation of the sagittal plane* of the reference ring in degrees, including the respective direction (internal or external).

Input/Edit Location of Concern

Refer to section 9.2 “Input or Edit a Location of Concern (LOC)” on page 92 for more information regarding *Input/Edit Location of Concern*.

Notes

1. The directional field radio buttons are disabled when the corresponding field value (PFM calculated or manually defined) is 0 mm, 0°, or 180°.
2. When the master tab rotation field is either 0 degrees or 180 degrees, the direction setting will be deactivated.
3. The limit for each parameter is as indicated in the table below. Exceeding this limit will deactivate the **Save and Update** button (this limit can be exceeded only by manual entry, not when using the **up**/**down** arrow keys).

Mounting Parameter	Lower Limit	Upper Limit	Unit
AP view offset	0	½ the reference ring diameter	mm
AP view offset – Tilted	0	45	degrees
LAT view offset	0	½ the reference ring diameter	mm
LAT view offset – Tilted	0	45	degrees
Axial offset	0	400	mm
Master Tab Rotation	0	180	degrees

Table 6.5 – Mounting parameter value limits and units.

To save entered data and update the preview, click **Save and Update**. You can display or hide *Sticks*, *Bone model*, *Labels*, *Axes*, and the *Non-Ref Fragment* in the preview. Check or uncheck the corresponding check boxes below the model.

Click the tab title **Phases** to proceed to the *Phases* tab.

6.9 Define Phases

In the *Phases* tab, you describe the different phases of the treatment plan, depending on how you want to approach the deformity correction.

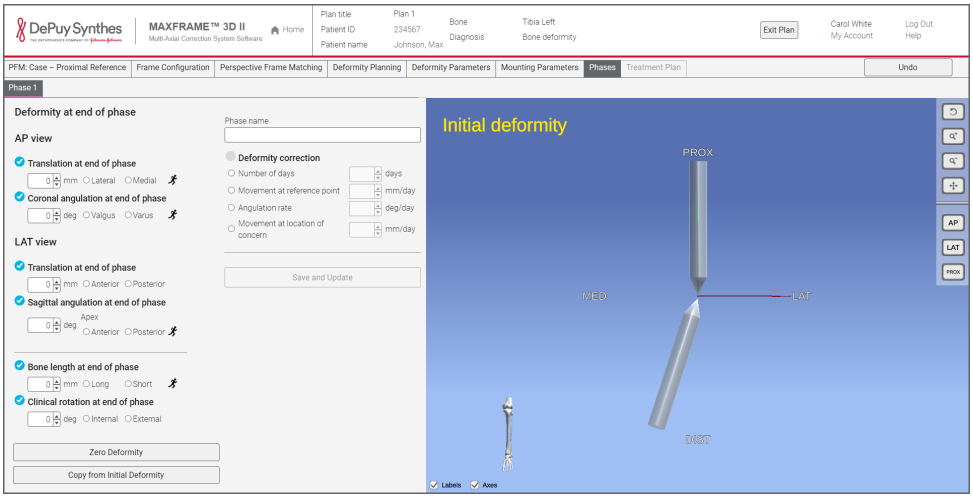


Figure 83 – Phases.

Note: You can plan a treatment with a single phase or multiple phases.

6.9.1 Enter Phase Parameters

AP view – Translation at end of phase

Enter the desired *anteroposterior translation value* in millimeters (mm) and specify the direction (lateral or medial). This is the translation you desire to achieve at the end of the phase.

AP view – Coronal angulation at end of phase

Enter the *coronal angulation value* in degrees and specify the direction (valgus or varus). This is the angulation you desire to achieve at the end of the phase.

LAT view – Translation at end of phase

Enter the *lateral translation value* in millimeters (mm) and specify the direction (anterior or posterior). This is the translation you desire to achieve at the end of the phase.

LAT view – Sagittal angulation at end of phase

Enter the *sagittal angulation value* in degrees and specify the direction (anterior or posterior). This the angulation you desire to achieve at the end of the phase.

Bone length at end of phase

Enter the desired *bone length* between Distal Reference Point and the Proximal Reference Point in millimeters (mm). This is the length you desire to achieve at the end of the phase. Specify whether the final bone is short (in compression) or long (if a gap is desired).

Clinical rotation at end of phase

Enter the *clinical rotational deformity* in degrees and specify the direction (internal or external). This the value you desire to achieve at the end of the phase.

Notes

1. The directional field radio buttons are disabled when the corresponding field value (PFM calculated or manually defined) is 0 mm, 0°, or 180°.
2. When the values copied from the initial deformity or from the previous phase are edited a symbol (🏃) is displayed indicating movement.

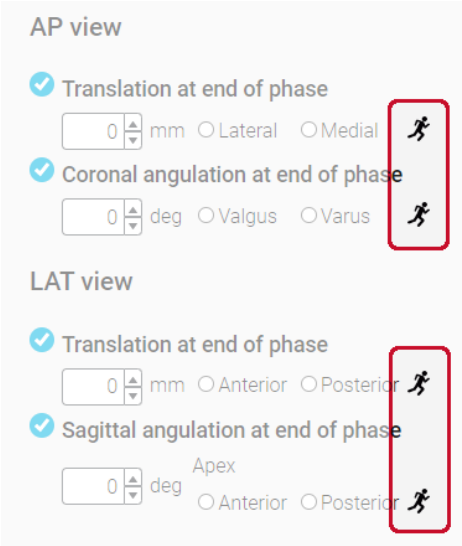


Figure 84 – PFM – Symbol indicating movement in the phase.

Zero Deformity

You can select the **Zero Deformity** button if you want to set all the above values to zero as the final expected result.

Note: The target parameters for phase one only will be initially set to zero by default. They can however be modified as per user definition.

Copy from Initial Deformity

You can select the **Copy from Initial Deformity** button if you want to copy the deformity values initially from the *Deformity Parameters* tab or the values defined in the preceding phase.

These values can be edited before saving and updating the data. All edited values will display a symbol (🏃) indicating movement.

Note: If the target deformity is the same as the initial deformity (the target deformity of the previous phase, the treatment plan can be calculated only when the selected *Deformity correction* is *Number of days*.

A message will be displayed indicating no frame movement in the selected phase.

Phase name

Enter the *Phase name*. This is an optional field.

If you do not define the *Phase name* it is given a default name “Phase n”, where “n” defined the phase number in the order of planning.

Note: The *Phase* tab requires a minimum of 1 phase.

Deformity correction

The deformity plan can be defined by specifying one of the following: number of days, movement at reference point, or angulation rate.

- *Number of days*: Select this option to define the number of treatment days for the movement.

  Warning: If the treatment duration exceeds 300 days, you cannot proceed with treatment planning.

- *Movement at reference point*: Select this option to define the movement at reference point. This option is the default method with a movement rate of 1.00 mm/day.

  Warning: When generating a treatment plan, a warning will be displayed if the movement at reference point is below 0.50 mm or greater than 1.00 mm per day. This warning is for informational purposes only and is not a contraindication. It is at the surgeon’s discretion to define the optimal treatment plan including the movement at reference point (cf. figure 85).

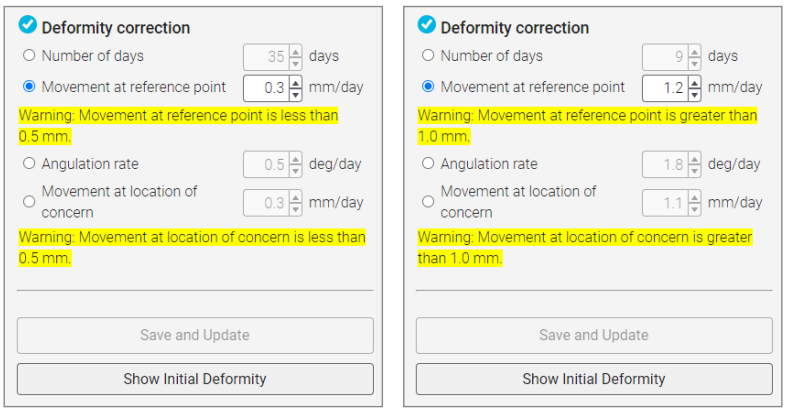


Figure 85 – PFM – Warning that the movement at reference point is less than 0.5 mm/day (left) or more than 1.0 mm/day (right).

Warning: A warning message is displayed if the treatment plan cannot be calculated with a movement at reference point rate of ±0.20 mm/day from the given nominal value. (Example: Treatment plans are always limited to an integer number of days. If you enter a movement rate, a plan is calculated internally with e.g., 11.5 days. This is then rounded to 12 days and the movement rate is then recalculated for 12 days. If the new movement rate value deviates more than 0.2 mm/day from the given value, the plan is rejected and must be calculated using the number of days.)

- *Angulation rate*: Select this option to define the angulation rate for the angular correction applied to the largest angular change in the phase. Selecting this option defaults the value to 1.0°/day.
- *Movement at Location of Concern*: If you have defined a location of concern (LOC), you can select this option to define the movement rate at this location.

  Warning: A warning message is displayed if the entered rate is lower than 0.50 mm/day or greater than 1.00 mm/day (cf. figure 86).

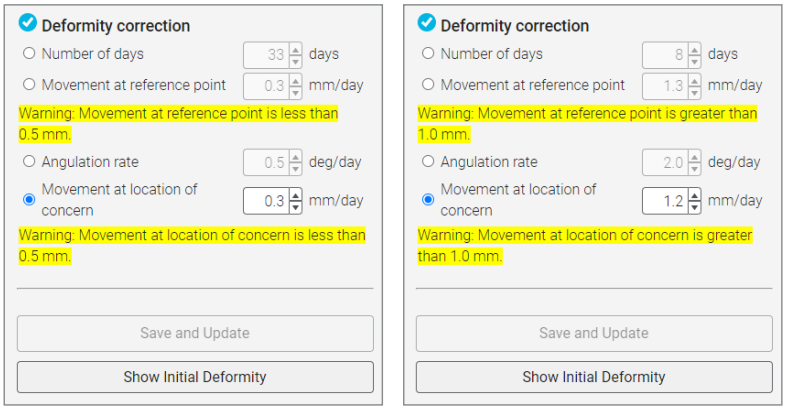


Figure 86 – PFM – Warning that the rate of movement at the LOC is less than 0.5 mm/day (left) or more than 1.0 mm/day (right).

To save the parameters and proceed, click the **Save and Update** button. The rendering area will be updated only when all the mandatory parameters have been defined.

After clicking **Save and Update**, the system renders a model of the corrected deformity.

Note: The rendered model will disappear if you change one or more parameters. Click **Save and Update** again to render the model for the changed parameters.

If you want to display labels and axes in the model, you can do so by checking their respective check boxes in the rendering area. To rotate the model, zoom, or pan, use the mouse (cf. section 4.2.4.2.1 “Mouse control” on page 33), or click on the respective buttons at the right side of preview area (cf. section 4.2.4.2.2 “Control buttons next to the preview area” on page 33).

The preview area displays the body direction of the bone model of the selected bone in its lower left corner to provide a clear reference (cf. section 4.2.4.1 on page 32.

Click the tab title **Treatment plan** to proceed to the *Treatment plan* tab (cf. section 5.5 “Define, Review and Approve Treatment Plan” on page 40).

6.9.2 Add or Remove a Phase

Add Phase

You can add a new phase by selecting the **+** button next to the current phase on the top left.

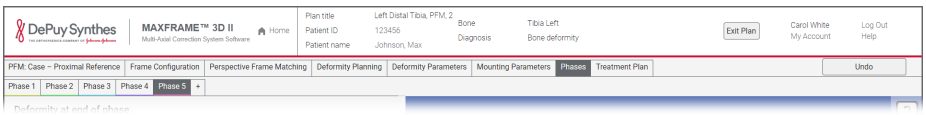


Figure 87 – PFM – Add new phase option.

Remove Phase

To remove a defined phase, select **Remove Phase** to delete the selected phase.

Show Previous Phase Deformity/Show Current Phase Deformity

To visualize the deformity and how it changes from one phase to the next in the rendering area, select the button that switches between **Show Previous Phase Deformity**/**Show Current Phase Deformity** to display the previous/current deformity.

Click the tab title **Treatment plan** to proceed to the *Treatment plan* tab (cf. section 5.5 “Define, Review and Approve Treatment Plan” on page 40).

7 Standard Planning Method

This chapter describes the treatment planning process for the Standard planning method. Using the Standard planning method, you enter the deformity and mounting parameters manually.

Note: At this point in the manual, it is assumed that you have selected the patient and defined the case. For details refer to chapter 5 starting on page 34.

7.1 Check Prerequisites

To create the strut adjustment plan using the Standard planning method, the following prerequisites must be met:

1. The deformity parameters must be available.
2. The mounting parameters must be known, taken after the frame has been mounted on the patient.
3. The frame configuration parameters of the actual frame mounted on the patient in surgery must be known.

Note: The AP and LAT x-ray images should be taken orthogonally (90 degrees) with the reference ring on edge.

Important:

- A Surgeon Planning Worksheet is available and can be utilized to record required data parameters.
- Refer to the *MAXFRAME System Technique Guide* for hardware requirements and proper use, as needed.

7.2 Steps

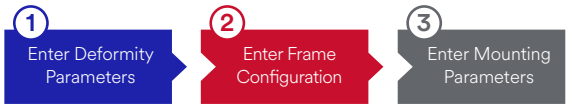


Figure 88 – Steps – Standard planning method.

7.3 Enter Deformity Parameters

In the *Deformity Parameters* tab, you specify the deformity by entering six measured skeletal deformity parameters. The deformity parameters describe the translation, angulation, and rotation between the proximal fragment and the distal fragment.

Note: The convention for the deformity parameters and frame mounting parameters are the **same** for both proximal and distal referencing.

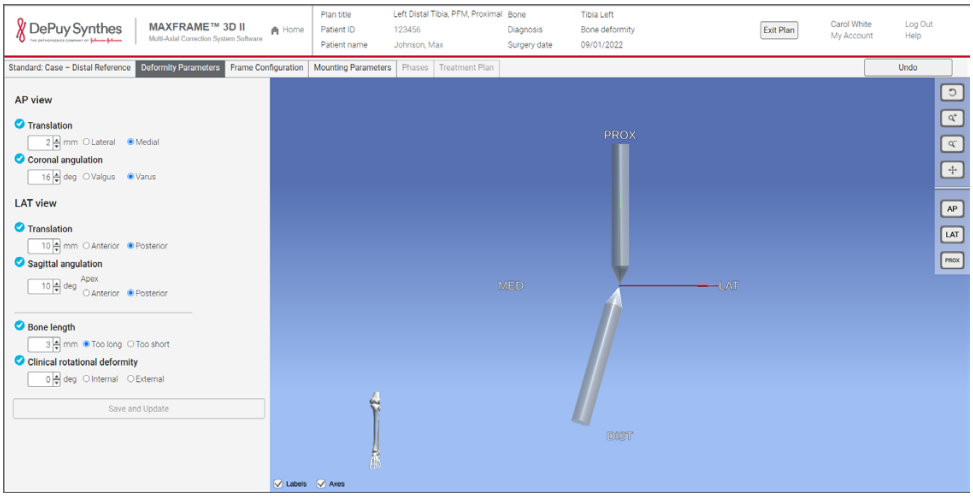


Figure 89 – Deformity Parameters.

Important: Sticks do **not** represent bones but rather represent reference points and axes.

AP view – Translation

Enter the *anteroposterior translation value* in millimeters (mm) and specify the direction (lateral or medial).

AP view – Coronal angulation

Enter the *coronal angulation value* in degrees and specify the direction (valgus or varus).

LAT view – Translation

Enter the *lateral translation value* in millimeters (mm) and specify the direction (anterior or posterior).

LAT view – Sagittal angulation

Enter the *sagittal angulation value* in degrees and specify the direction (anterior or posterior).

Bone length

Enter the discrepancy of the *bone length* between Distal Reference Point and the Proximal Reference Point in millimeters (mm). Specify whether the bone is too short or too long.

Clinical rotational deformity

Enter the *clinical rotational deformity* value in degrees and specify the direction (internal or external).

Notes

1. If the value of any of the above parameters is zero (0 mm or 0°), the direction setting will be deactivated.
2. The directional field radio buttons are disabled when the corresponding field value is 0 mm, 0°, or 180°.
3. The limit for each parameter is as indicated in the table below. Exceeding this limit will deactivate the **Save and Update** button (this limit can be exceeded only by manual entry, not when using the **up**/**down** arrow keys).

Deformity Parameter	Lower Limit	Upper Limit	Unit
AP view – Translation	0	100	mm
AP view – Coronal angulation	0	89	degrees
LAT view – Translation	0	100	mm
LAT view – Sagittal angulation	0	89	degrees
Bone length	0	260	mm
Clinical rotational deformity	0	89	degrees

Table 7.1 – Deformity parameter value limits and units.

To save the parameters and proceed, click the **Save and Update** button. The rendering area will be updated only when all the mandatory parameters have been defined.

After clicking **Save and Update**, the system renders a model of the deformity.

Note: The rendered model will disappear if you change one or more parameters. Click **Save and Update** again to render the model for the changed parameters.

If you want to display labels and axes in the model, you can do so by checking their respective check boxes in the rendering area. To rotate the model, zoom, or pan, use the mouse (cf. section 4.2.4.2.1 “Mouse control” on page 33), or click on the respective buttons at the right side of preview area (cf. section 4.2.4.2.2 “Control buttons next to the preview area” on page 33).

The preview area displays the body direction of the bone model of the selected bone in its lower left corner to provide a clear reference (cf. section 4.2.4.1 on page 32.

Click the tab title **Frame Configuration** to proceed to the *Frame Configuration* tab.

7.4 Enter Frame Configuration

In the *Frame Configuration* tab, you describe the case’s frame configuration – namely, all rings and struts, and strut mounting location including ring type, ring diameter, strut size and length installed.

The *Frame Configuration* tab is similar to the PFM method (cf. section 6.3 “Enter Frame Configuration” on page 48).

Note: A frame must not use rings that are more than 2 sizes apart.

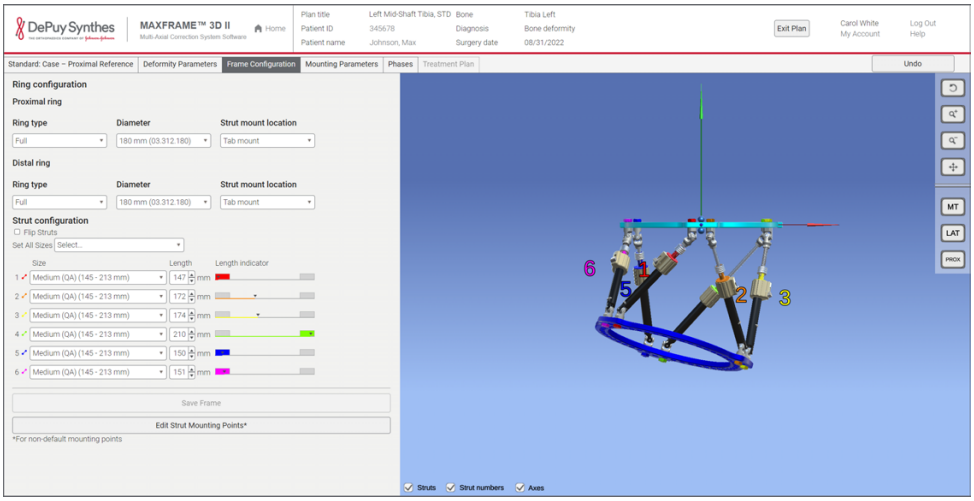


Figure 90 – Frame Configuration.

Ring Configuration – Proximal Ring

The ring configuration of the proximal ring might consist of up to three parameters (depending on the selected ring type):

- *Ring type*: *Full*, *5/8*, or *Foot Plate*.

  Note: If a 5/8 ring is used with a bridging plate, select *Full* of the same diameter.

- *Diameter*: Select the ring by its diameter in millimeters (mm) and in case of a foot plate additionally its type (“Short” or “Long”) from the drop-down list. Each entry in this list contains only DePuy Synthes validated parts to ensure proper selection. For the full list of available ring sizes, refer to section 2.6 “Hardware” on page 10.

- *Strut mount location*: If you have selected *Full* as the ring type, then specify whether the struts are mounted on the ring or the tab mount location.

  Warning: When frames are constructed in a ring mount to ring mount configuration, struts located in the default hole position maximizes stability. If a strut is required to move to a non-default hole, please check the stability of the frame.

- *Opening (5/8 Ring)*: If you have selected *5/8* as the ring type, then specify where the opening of the ring is located (between *Strut 2 & 3*, *Strut 4 & 5*, or *Strut 6 & 1*).

Ring Configuration – Distal Ring

The ring configuration of the distal ring is similar to the ring configuration of the proximal ring, might consist of up to three parameters (depending on the selected ring type):

- *Ring type*: *Full*, *5/8*, or *Foot Plate*.

- *Diameter*: Select the ring by its diameter in millimeters (mm) and in case of a foot plate additionally its type (“Short” or “Long”) from the drop-down list. Each entry in this list contains only DePuy Synthes validated parts to ensure proper selection.

- *Strut mount location*: If you have selected *Full* as the ring type, then specify whether the struts are mounted on the ring or the tab mount location.

  Warning: When frames are constructed in a ring mount to ring mount configuration, struts located in the default hole position maximizes stability. If a strut is required to move to a non-default hole, please check the stability of the frame.

- *Opening (5/8 Ring)*: If you have selected *5/8* as the ring type, then specify where the opening of the ring is located (between *Strut 1 & 2*, *Strut 3 & 4*, or *Strut 5 & 6*).

Strut configuration

After the frame is mounted, the strut identification numbers and colors are assigned by adding plugs or clips to the struts according to the following rule: Start on the *master tab* where struts 1 and 2 come together, with strut 1 on the left side, then continue counterclockwise.

The strut numbers and colors are defined as follows:

- Strut 1 is Red.
- Strut 2 is Orange.
- Strut 3 is Yellow.
- Strut 4 is Green.
- Strut 5 is Blue.
- Strut 6 is Purple.

For more details on strut numbers and colors refer to the *MAXFRAME System Technique Guide*.

For each of the six struts, select the strut type (“Quick Adjust”/“QA” or “Standard”/“Std.”) and the strut size from the corresponding drop-down list.

Use the drop-down list labeled *Set All Sizes* on top of the individual strut configuration settings to select the same type and size for all six struts at one time. For example, if you select strut type and size “Long (QA) (203–329 mm)”, the type and size for each of the six struts will be updated to “Long (QA) (203–329 mm)”.

Enter each strut’s measured length in millimeters (mm) in its corresponding *Length* field. The unit of measure (mm) is indicated with each of the strut length input fields.

If you enter a strut length that is not within the strut size range the strut length indicator will not be displayed.

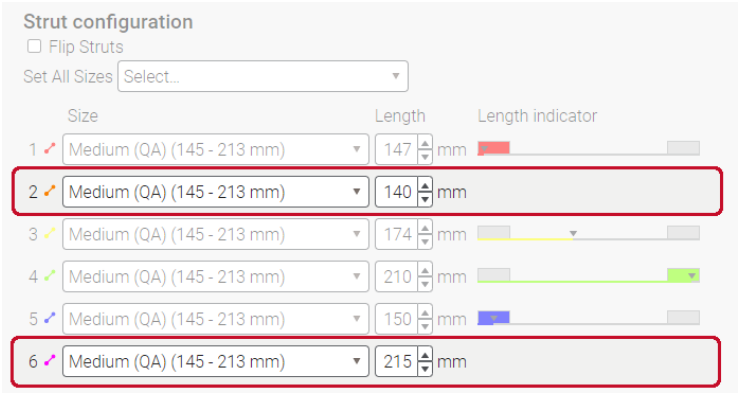


Figure 91 – Frame Configuration – Missing Strut length indicators.

The colored *Length Indicators* display for each strut is its entered length value in relation to the selected strut size. The strut length indicators also indicate where overlaps with adjacent strut sizes exist (see figure 92).

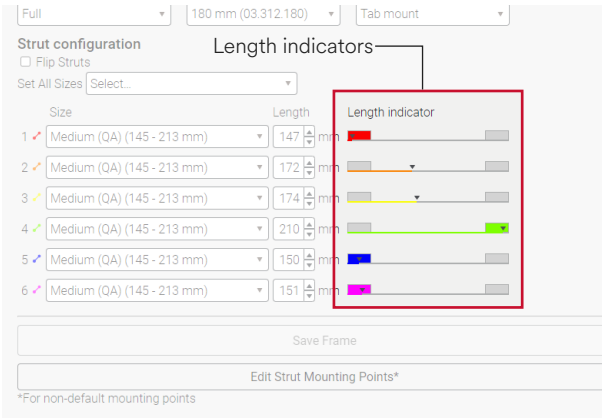


Figure 92 – Frame Configuration – Strut length indicators.

Note: Selecting the *Flip Struts* option allows to change the direction of all the struts opposite to the current direction. This helps to visualize the strut direction in the software as in the real-life scenario, to understand better the strut movement during treatment.

The **Save Frame** button will be enabled only when all the ring parameters and strut lengths have been set. Strut length must be within the defined selected strut type range.

Notes

1. If the defined strut length lies within the range of any other strut size, all the strut sizes that support the defined strut length are highlighted in the drop-down list.

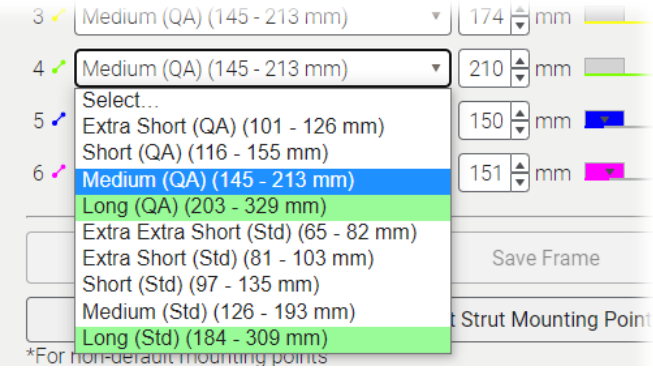


Figure 93 – Frame Configuration – Highlighted Strut List.

2. If the defined strut length is in the overlap region of the preceding or succeeding strut, the strut size can be changed by clicking the overlap region in the length indicator.

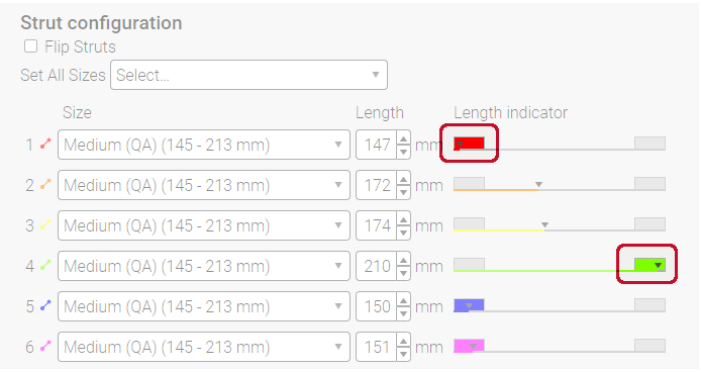


Figure 94 – Frame Configuration – Strut length indicator overlap.

Strut Mounting Points

For detailed information on editing the default strut mounting points, refer to section 9.1 on page 91.

To save your entered data and update the preview, click **Save Frame**.

If you want to hide *Struts*, *Strut numbers*, or *Axes* in the preview, uncheck their corresponding check boxes below the model. By default, all three options are active and displayed in the preview.

Important: In the preview area, the strut number labels are always facing you, even when rotating the rendered image.

Click the tab title **Mounting Parameters** to proceed to the *Mounting Parameters* tab.

7.5 Enter Mounting Parameters

In the *Mounting Parameters* tab, you describe the position of the frame with respect to the Proximal Reference Point.

Note: This section covers mounting parameters for proximal reference cases. If your case requires a distal reference ring or a foot plate, refer to section 9.4 “Using a Distal Reference Ring or Foot plate” on page 97 for more information.

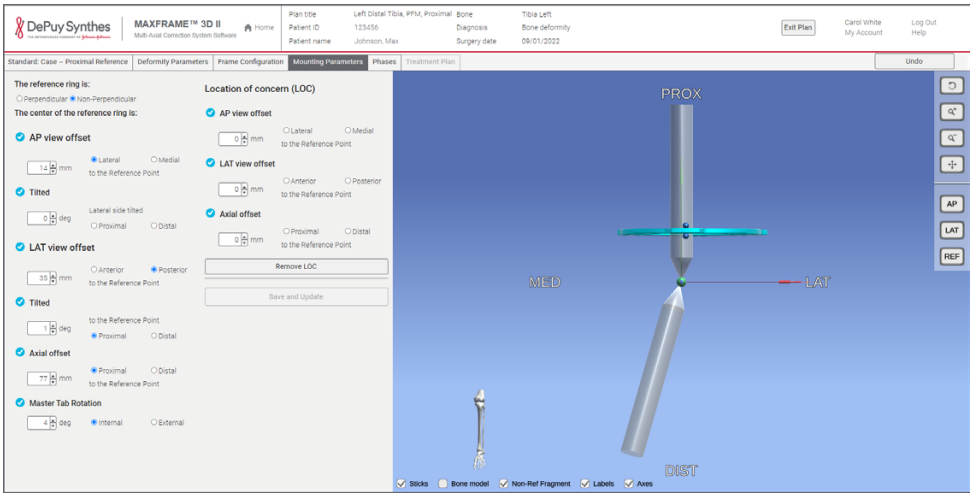


Figure 95 – Mounting Parameters.

Note: The directional field radio buttons are disabled when the corresponding field value is zero or 180° for the angulation fields.

Perpendicularity of the Reference Ring

Specify if the *reference ring is fully perpendicular* (AP and LAT) to the bone axis of the reference fragment. The reference ring is defaulted to *Perpendicular* in the software. Select *Non-Perpendicular*, if needed, to display and enter the axial tilt values.

Note: Reconfiguring the reference ring to *Perpendicular* from *Non-Perpendicular* retains the previously defined offset tilt values in the database. These values can be called back at any point but will not be used for treatment plan calculation until specified.

AP view offset

Enter the *anteroposterior offset value* of the center of the reference ring with respect to the Proximal Reference Point in millimeters (mm) and specify the direction (lateral or medial).

AP view offset – Tilted

If you have selected that the reference ring is non-perpendicular to the bone axis, enter the *tilt of the lateral side* in degrees and specify the direction (proximal or distal).

LAT view offset

Enter the *lateral offset value* in millimeters (mm) and specify the direction (anterior or posterior).

LAT view offset – Tilted

If you have selected that the reference ring is non-perpendicular to the bone axis, enter the *tilt of the anterior side* in degrees and specify the direction (proximal or distal).

LAT view offset – Axial offset

Enter the *axial offset value* in millimeters (mm) and specify the direction (proximal or distal).

LAT view offset – Master Tab Rotation

Enter the *rotation of the sagittal plane* of the reference ring in degrees and specify the direction (internal or external).

Input/Edit Location of Concern

If you need to input a *Location of Concern*, refer to section 9.2 “Input or Edit a Location of Concern (LOC)” on page 92.

Notes

1. If the value of any of the above parameters is zero (0 mm or 0°), the direction setting will be deactivated.
2. When the master tab rotation field is 180 degrees, the direction setting will be deactivated.
3. The limit for each parameter is as indicated in the table below. Exceeding this limit will deactivate the **Save and Update** button (this limit can be exceeded only by manual entry, not when using the **up**/**down** arrow keys).

Mounting Parameter	Lower Limit	Upper Limit	Unit
AP view offset	0	½ the reference ring diameter	mm
AP view offset – Tilted	0	45	degrees
LAT view offset	0	½ the reference ring diameter	mm
LAT view offset – Tilted	0	45	degrees
Axial offset	0	400	mm
Master Tab Rotation	0	180	degrees

Table 7.2 – Mounting parameter value limits and units.

To save your entered data and update the preview, click **Save and Update**.

You can display or hide *Sticks*, *Bone model*, *Labels*, *Axes*, and the *Non-Ref Fragment* in the preview. Check or uncheck the corresponding check boxes below the model. Only *Sticks*, *Labels*, and *Axes* are displayed by default in the preview.

Click the tab title **Phases** to proceed to the *Phases* tab.

7.6 Define Phases

In the *Phases* tab, you describe the different phases of the treatment plan, depending on how you want to approach the deformity correction. This process is identical to that defined in the PFM method (cf. section 6.9 “Define Phases” on page 70)

Click the tab title **Treatment plan** to proceed to the *Treatment plan* tab (cf. section 5.5 “Define, Review and Approve Treatment Plan” on page 40).

8 Acute Intentional Deformation (AID)

Manually enter the frame configuration, the initial and the final strut positions to generate a strut adjustment plan. Deformity and frame mounting parameters are not required.

Note: At this point in the manual, it is assumed that you have selected the patient and defined the case. For details refer to chapter 5 starting on page 34.

8.1 Check Prerequisites

To create the strut adjustment plan using the AID planning method, the following prerequisites must be met:

1. The frame configuration must be known. For AID, reference ring and ring sizes are essential only for the rendering of the frame in the software.
2. The deformed (initial) strut sizes, lengths, and positions must be known.
3. The aligned (final) strut sizes, lengths, and positions must be known.

Important:

- A Surgeon Planning Worksheet is available and can be utilized to record required data parameters.
- Refer to the *MAXFRAME System Technique Guide* for hardware requirements and proper use, as needed.

8.2 Steps

Figure 96 – Steps – AID planning method.

8.3 Enter Ring Configuration

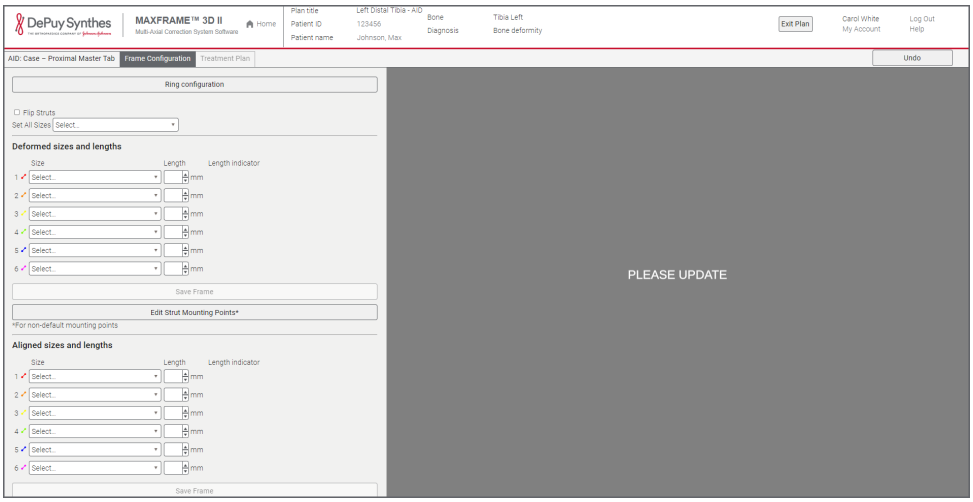


Figure 97 – AID – Frame Configuration.

In the *Frame Configuration* view (figure 97), click on **Ring configuration**. The *Ring configuration* pop-up window opens (figure 98).

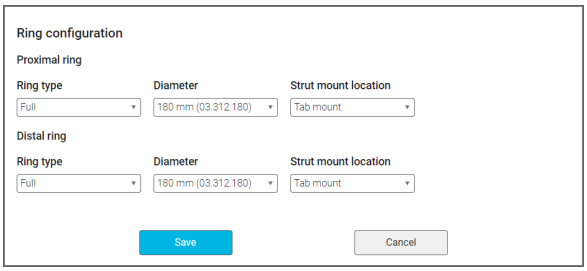


Figure 98 – AID – Ring Configuration pop-up window.

Ring Configuration – Proximal Ring

The ring configuration of the proximal ring might consist of up to three parameters (depending on the selected ring type):

- *Ring type*: *Full*, *5/8*, or *Foot Plate*.

  Note: If a 5/8 ring is used with a bridging plate, select *Full* with the same diameter.

- *Diameter*: Select the ring by its diameter in millimeters (mm) and in case of a foot plate additionally its type (“Short” or “Long”) from the drop-down list. Each entry in this list contains only DePuy Synthes validated parts to ensure proper selection. For the full list of available ring sizes, refer to section 2.6 “Hardware” on page 10.

- *Strut mount location*: If you have selected *Full* as the ring type, then specify whether the struts are mounted on the ring or the tab mount location.

Warning: When frames are constructed in a ring mount to ring mount configuration, struts located in the default hole position maximizes stability. If a strut is required to move to a non-default hole, please check the stability of the frame.

- *Opening (5/8 Ring)*: If you have selected *5/8* as the ring type, then specify where the opening of the ring is located (between *Strut 2 & 3*, *Strut 4 & 5*, or *Strut 6 & 1*).

Ring Configuration – Distal Ring

The ring configuration of the distal ring might consist of up to three parameters (depending on the selected ring type):

- *Ring type*: *Full*, *5/8*, or *Foot Plate*.
- *Diameter*: Select the ring by its diameter in millimeters (mm) and in case of a foot plate additionally its type (“Short” or “Long”) from the drop-down list. Each entry in this list contains only DePuy Synthes validated parts to ensure proper selection.
- *Strut mount location*: If you have selected *Full* as the ring type, then specify whether the struts are mounted on the ring or the tab mount location.

  Warning: When frames are constructed in a ring mount to ring mount configuration, struts located in the default hole position maximizes stability. If a strut is required to move to a non-default hole, please check the stability of the frame.

- *Opening (5/8 Ring)*: If you have selected *5/8* as the ring type, then specify where the opening of the ring is located (between *Strut 1 & 2*, *Strut 3 & 4*, or *Strut 6 & 1*).

Click on **Save** to save the data and close the *Ring configuration* pop-up window.

8.4 Enter Strut Sizes and Lengths

Using the AID planning method, you enter twelve strut configuration settings in total: six deformed (initial) and six aligned (final) strut configuration settings.

After the frame is mounted, the strut identification numbers and colors are assigned by adding plugs or clips to the struts according to the following rule: Start on the *master tab* where struts 1 and 2 come together, with strut 1 on the left side, then continue counterclockwise.

The strut numbers and colors are defined as follows:

- Strut 1 is Red.
- Strut 2 is Orange.
- Strut 3 is Yellow.
- Strut 4 is Green.
- Strut 5 is Blue.
- Strut 6 is Purple.

For more details on strut numbers and colors refer to the *MAXFRAME System Technique Guide*.

To enter the strut sizes and lengths for the deformed and the aligned frame configurations, proceed as follows:

1. Use the drop-down list labeled *Set All Sizes* below the **Ring configuration** button to select the same type and size for all twelve strut configuration settings at one time. For example, if you select strut type and size “Long (QA) (203–329 mm)”, the type and size for each of the twelve strut configuration settings will be updated to “Long (QA) (203–329 mm)”.

2. Enter the six deformed (initial) strut configuration settings in the area labeled *Deformed sizes and lengths* as follows:

    a. For each of the six struts, select the strut type (“Quick Adjust”/“QA” or “Standard”/“Std.”) and the strut size from the corresponding drop-down list.

    b. Enter each strut’s measured length in millimeters (mm) in its corresponding *Length* field.

    The colored *Length Indicators* display for each strut is its entered length value in relation to the selected strut size. The strut length indicators also indicate where overlaps with adjacent strut sizes exist (see figure 99).

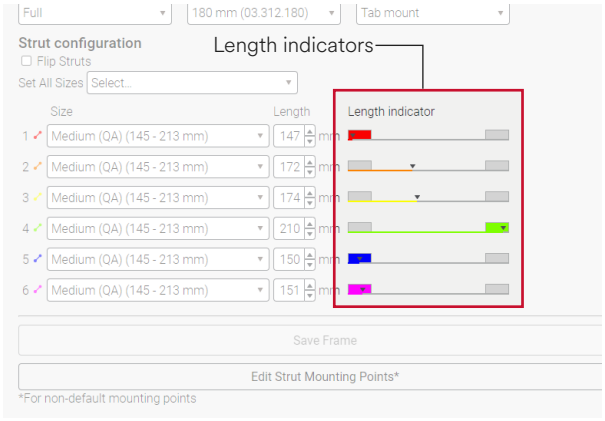


Figure 99 – AID – Frame Configuration – Strut length indicators.

3. Click **Edit Strut Mounting Points*** if you need to use non-default mounting points. For detailed information on editing the default strut mounting points, refer to section 9.1.

4. To save your entered data and show the model of the deformed frame setting in the preview, click the upper **Save Frame** button.

5. Enter the six aligned (final) strut configuration settings in the area labeled *Aligned sizes and lengths* the same way you did for the deformed (initial) strut configuration settings.

6. To save your entered data and show the model of the aligned frame setting in the preview, click the lower **Save Frame** button.

The **Save Frame** button will be enabled only when all the ring parameters and strut lengths have been set. Strut length must be within the defined selected strut type range.

Notes

1. If the defined strut length lies within the range of any other strut size, all the strut sizes that support the defined strut length are highlighted in the drop-down list.

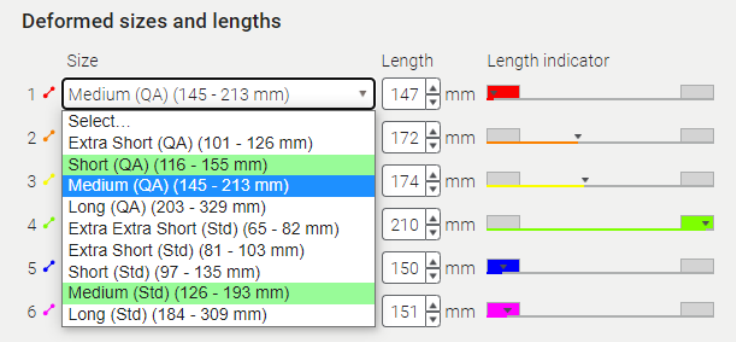


Figure 100 – AID – Strut size options for the defined strut length.

2. If the defined strut length is in the overlap region of the preceding or succeeding strut, the strut size can be changed by clicking the overlap region in the length indicator.

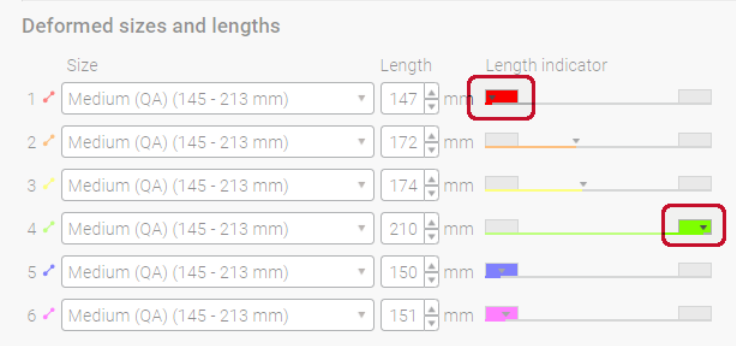


Figure 101 – AID – Strut length indicator overlap.

3. **Note:** Selecting the *Flip Struts* option allows to change the direction of all the struts opposite to the current direction. This helps to visualize the strut direction in the software as in the real-life scenario, to understand better the strut movement during treatment.

   The *Flip Struts* option is applicable for both deformed and aligned struts.

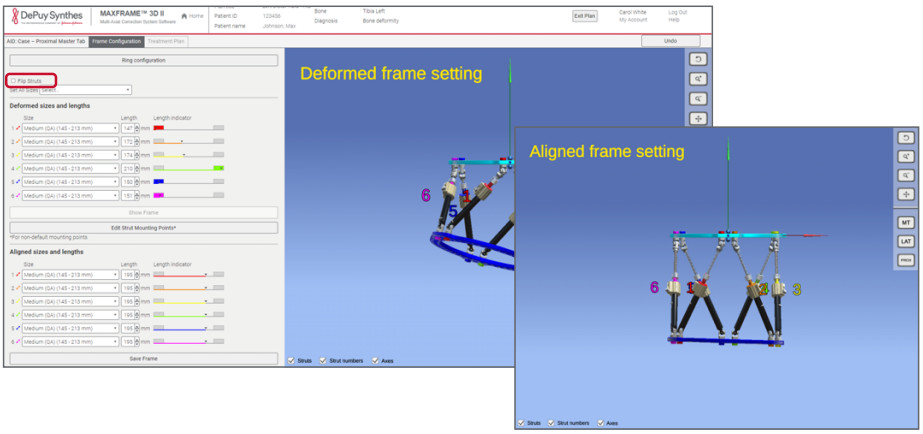


Figure 102 – AID – Flip Struts option.

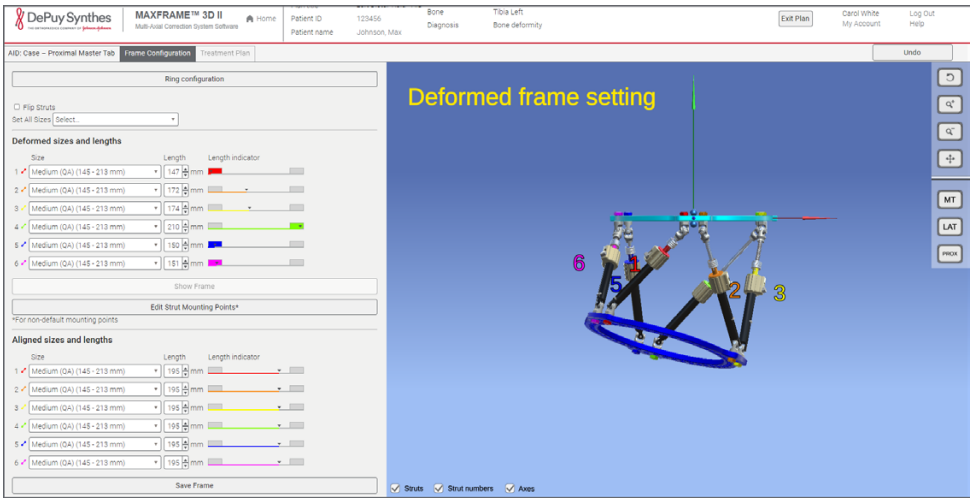


Figure 103 – AID – Final frame configuration.

To switch the preview between the model of the deformed frame setting and the model of the aligned frame setting, click the corresponding **Show Frame** button.

You can display or hide *Struts*, *Strut numbers*, and *Axes* in the preview. Check or uncheck the corresponding check boxes below the model. By default, all options are active and displayed in the preview.

Important: In the preview area, the strut number labels are always facing you, even when rotating the rendered image.

Click the tab title **Treatment plan** to proceed to the *Treatment plan* tab (cf. section 5.5 “Define, Review and Approve Treatment Plan” on page 40).

9 Alternate Options

This chapter covers certain alternate options that are used in special cases and situations.

9.1 Edit Strut Mounting Points

The system applies default strut mounting points according to the ring types and sizes selected. For editing the default strut mounting points, click **Edit Strut Mounting Points*** in the *Frame Configuration* tab (Standard, PFM, or AID).

Warning: No more than 2 non-default mounting points shall be used per ring/footplate for 90 mm and 120 mm rings/footplates.

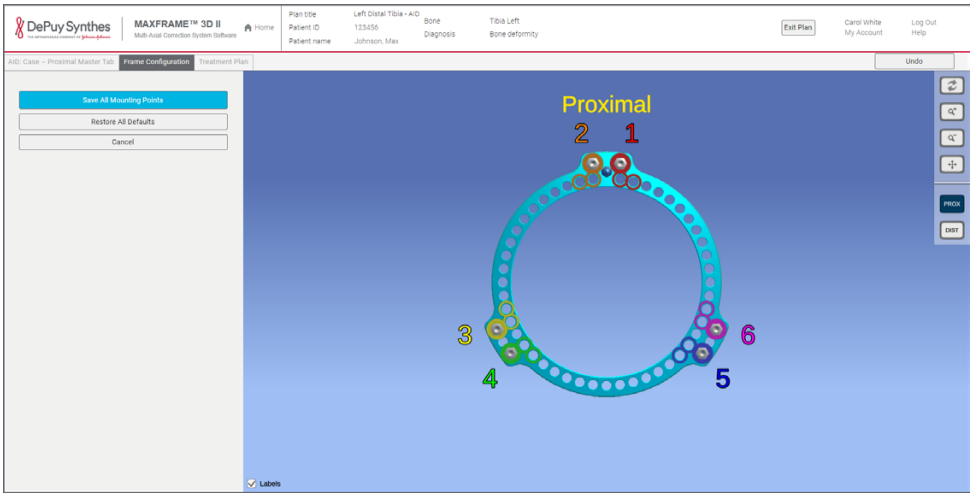


Figure 104 – Edit Strut Mounting Points view.*

The preview area will open defaulted to the proximal view. You can now change each strut's mounting position directly in the model in the preview area. For changing a strut's mounting position, proceed as follows:

1. Switch the view to the desired ring (proximal or distal) by clicking the corresponding perspective button (**PROX** or the **DST**, located to the right of the model). The reference ring is lighter in color.

2. Click on the desired strut's mounting point in the model and hold down the mouse button. While you keep a strut's mounting point clicked, the system displays all valid non-default mounting positions for this specific mounting point (refer to figure 105).

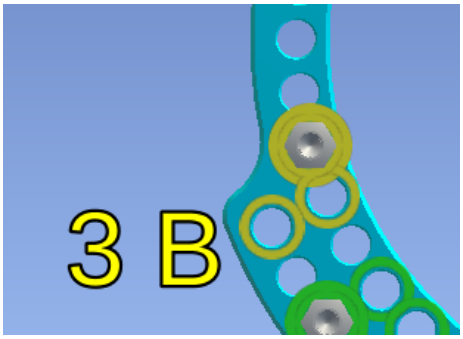


Figure 105 – Non-default mounting positions for strut 3.

3. Move (“drag”) the selected mounting point to the desired new mounting position.

4. Release the mouse button (“drop”) on top of the desired new mounting position. The preview updates immediately as a mounting point is positioned to a new mounting position.

Click **Restore All Defaults** to discard any modifications of mounting points and to restore the default positions for all mounting points.

Click **Save All Mounting Points** to save all modifications and to finish editing the mounting points.

Click **Cancel** to cancel all changes and exit.

Note: Mounting points can be modified once the ring has been configured, even before strut configuration.

9.2 Input or Edit a Location of Concern (LOC)

The following procedure describes, how to define or edit a *location of concern* using the PFM and Standard planning methods.

Note: With PFM, you define and edit the location of concern graphically on the *Deformity Planning* tab (cf. section 6.6.1 “Define the Deformity Planning Parameters”), but edit it both on the *Deformity Planning* and *Mounting Parameters* tab. The translated values for the LOC marked in the *Deformity Planning* tab is displayed in the *Mounting Parameters* tab.

9.2.1 For PFM planning method

1. Open the *Mounting Parameters* tab and review the *Location of concern* parameter values.

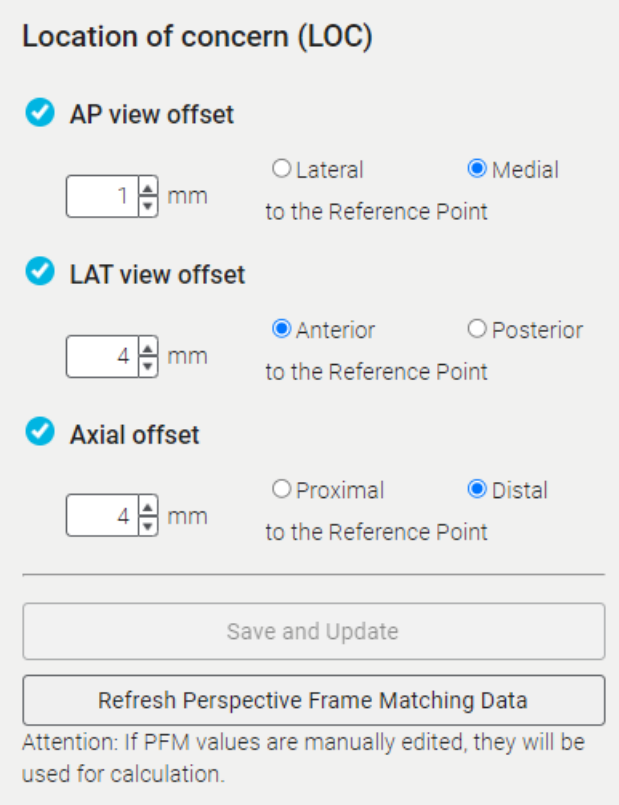


Figure 106 – PFM Mounting Parameters – Enter a location of concern.

2. Review (and edit if necessary) the *AP view offset* value of the location of concern with respect to the Reference Point in millimeters (mm) and the respective direction setting (lateral or medial).

3. Review (and edit if necessary) the *LAT view* value of the location of concern with respect to the Reference Point in millimeters (mm) and the respective direction (anterior or posterior).

4. Review (and edit if necessary) the *Axial offset* value of the location of concern with respect to the Reference Point in millimeters (mm) and the respective direction (proximal or distal).

5. Click **Save and Update** for saving and applying any changes. The preview indicates the entered location of concern as a green point in the model.

Notes

1. The directional field radio buttons are disabled when the corresponding field value is 0 mm.
2. The limit for each parameter is as indicated in the table below. Exceeding this limit will deactivate the **Save and Update** button (this limit can be exceeded only by manual entry, not when using the **up**/**down** arrow keys).

Location of Concern Parameter	Lower Limit	Upper Limit	Unit
AP view offset	0	½ the reference ring diameter	mm
LAT view offset	0	½ the reference ring diameter	mm
Axial offset	0	400	mm

Table 9.1 – LOC parameter value limits and units for PFM.

9.2.2 For Standard planning method

1. Open the *Mounting Parameters* tab and click on **Add LOC** to define the *Location of concern* parameter values.

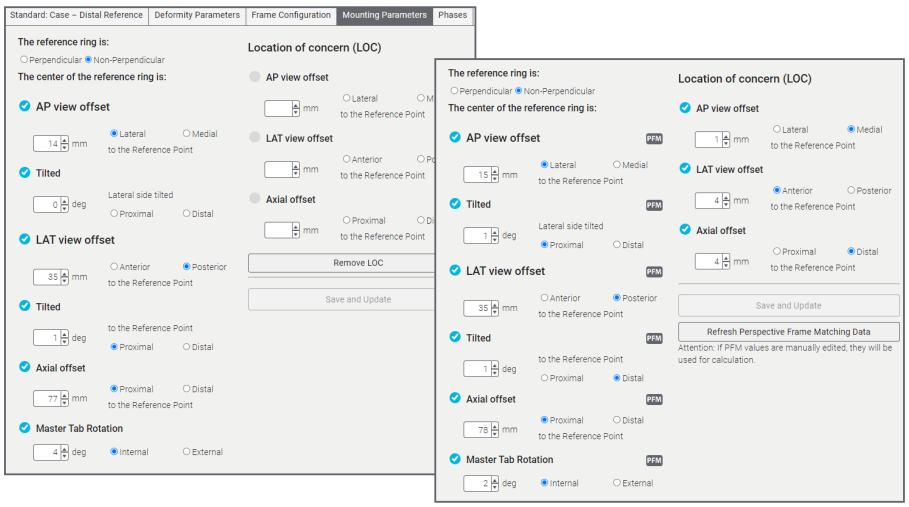


Figure 107 – Standard Mounting Parameters – Enter a location of concern.

2. Enter the *AP view offset* value of the location of concern with respect to the Reference Point in millimeters (mm) and the respective direction setting (lateral or medial).

3. Enter the *LAT view* value of the location of concern with respect to the Reference Point in millimeters (mm) and the respective direction (anterior or posterior).

4. Enter the *Axial offset* value of the location of concern with respect to the Reference Point in millimeters (mm) and the respective direction (proximal or distal).

5. Click **Save** for saving and applying your entered values. The preview indicates the entered location of concern as a green point in the model.

6. Click **Remove LOC** for removing the entered location of concern.

Notes

1. The directional field radio buttons are disabled when the corresponding field value is 0 mm.

2. The limit for each parameter is as indicated in the table below. Exceeding this limit will deactivate the **Save and Update** button (this limit can be exceeded only by manual entry, not when using the **up**/**down** arrow keys).

Location of Concern Parameter	Lower Limit	Upper Limit	Unit
AP view offset	0	½ the reference ring diameter	mm
LAT view offset	0	½ the reference ring diameter	mm
Axial offset	0	400	mm

Table 9.2 – LOC parameter value limits and units for Standard.

9.3 Additional Measurement Tools for Deformity Planning

This section describes the additional measurement tools on the *Deformity Planning* tab (PFM).

Note: The additional measurements are not used for the calculation of the strut adjustment plan. The additional measurements are only used for reference or validation purposes.

Open the *Deformity Planning* tab and click on **Measurements**. The *Measurements* view appears:

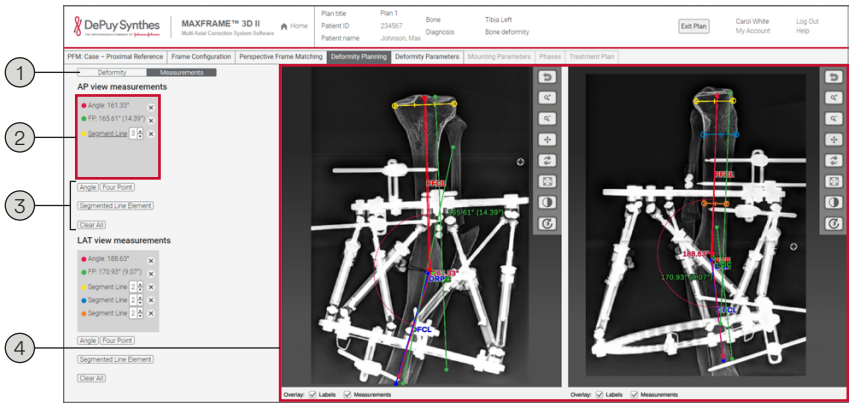


Figure 108 – PFM – Measurements.

The *Measurements* view consists of the following components and areas:

1. Marking type selector (**Deformity** or **Measurements**).
2. Lists of measurements added for AP and LAT view.
3. Measurement tool selector and **Clear All** button:
   - **Angle** – draws two intersecting sides and displays the angle of them.
   - **Four Point** – draws two lines. If the lines intersect, the system displays the angle between them. The four point tool provides angular locking at 90 degrees and proportional scaling of the lines.

- **Segmented Line Element** (SLE) – draws a straight line with segments of equal length. The total number of segments in the line can be increased or decreased using the **up**/**down** arrow keys. The minimum number of segments in the line is one and the maximum number of segments are five. The number of segments in the line always defaults to two.
- **Clear All** – deletes all the added measurements in AP and LAT view.

4. AP and LAT views (like the AP and LAT views in the *Deformity Planning* tab).

9.3.1 Add Measurements

1. Select the measurement tool (**Angle**, **Four Point**, or **Segmented Line Element** cf. [2] in figure 108).

2. Draw a measurement in the AP view or the LAT view as follows:

   - **Angle:**

     a. Click a position as the endpoint of the first side.

     b. Click the position of the vertex.

     c. Click a position as the endpoint of the second side.

     d. To change positions, click and move the endpoints or the vertex.

   - **Four Point:**

     a. Click sequentially the four endpoints of the two lines. If the two lines intersect, the system displays the angle between them.

     b. To change positions of endpoints, click and move them. Endpoint moves are restricted in two ways:

        - Angular locking: The smaller angles lock at a maximum of 90.0 degrees.
        - Proportional scaling: When you move an endpoint, the opposite endpoint moves synchronously. This function keeps the length relations of the two-line segments unchanged.

     c. Drag either line to move the whole construct.

   - **Segmented Line Element (SLE):**

     a. Click a position as the start point.

     b. Extend to the desired length.

     c. Click a position as the endpoint.

     d. To change the number of segments in the line, click and press the **up**/**down** arrow keys.

Each added measurement is displayed in the selected view and is assigned a unique color to differentiate the measurement.

9.3.2 Modify Measurements

1. To modify a measurement, click its entry in the list of measurements (cf. [3] in figure 108 on page 95).
2. Click and move endpoints of the selected measurement to change their positions.
3. To move a complete Four Point measurement, drag either of its lines.

9.3.3 Delete Measurements

To delete a single measurement, click its **Delete** icon (✕) in the measurement list (cf. [2] in figure 108 on page 95).

To delete all the added measurements in AP and LAT view, click **Clear All** in AP or LAT respectively (cf. [3] in figure 108 on page 95).

9.4 Using a Distal Reference Ring or Foot plate

This section describes what needs to be observed when using a distal reference ring or a distal reference foot plate.

In regards of the position of the master tab (i.e., the tab where struts 1 and 2 meet), there are two differences between a frame with proximal reference ring and a frame with distal reference ring or distal reference foot plate:

- The master tab of a frame with **proximal reference ring** is positioned on the proximal ring **anterior**.
- The master tab of a frame with **distal reference ring** is positioned on the distal ring **anterior**.
- The master tab of a frame with **distal reference foot plate** is positioned on the foot plate **posterior**.

9.4.1 Master Tab View

In the *Frame Configuration* tab, you can select the frame to be displayed in the Master Tab perspective (**MT** button). The Master Tab perspective displays the frame with the master tab in front. Foot plates are the exception to the master tab perspective and display the master tab in back.

Summarized, the three frame types are displayed in the Master Tab perspective as follows:

- Proximal reference ring: anterior
- Distal reference ring: anterior
- Foot plate: posterior

The following figure 109 shows on its left side the Master Tab view of a frame with proximal reference ring and on its right side the otherwise identical frame configured with distal reference ring:

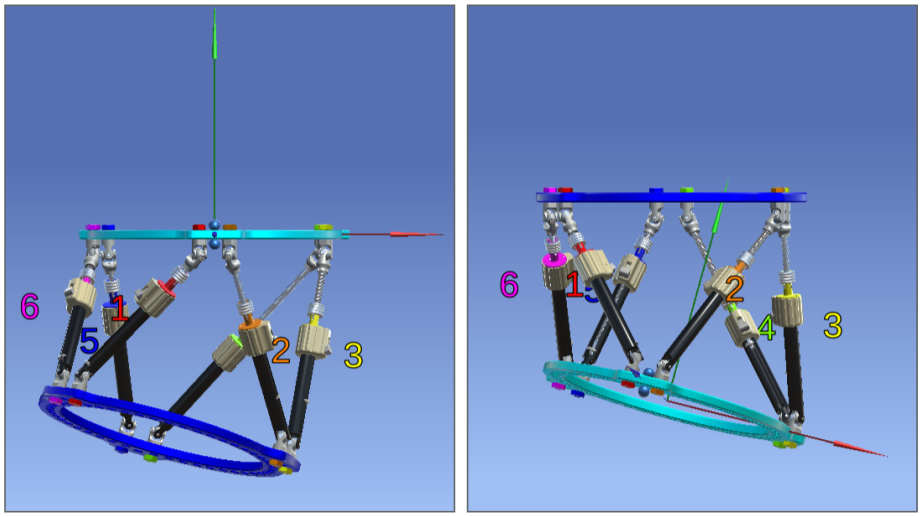


Figure 109 – Master Tab views of the same frame in proximal (left) and distal (right) configuration.

The following figure 110 shows the Master Tab view of a frame with a distal reference foot plate:

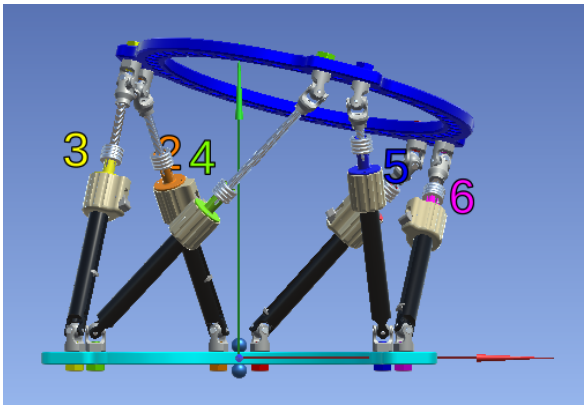


Figure 110 – Master Tab view of a distal reference foot plate.

9.4.2 Mounting Parameters

The position of the reference ring (proximal, distal) has two implications on the mounting parameters of the frame:

Axial offset

The Axial Offset is proximal when using a proximal reference ring and distal when using a distal reference ring or distal reference foot plate.

Master Tab Rotation for Proximal and Distal Reference Ring

Master Tab Rotation for proximal and distal reference ring does not differ. The master tab is anterior for 0 degrees in both cases and the ring rotates internal or external for any values larger than zero, depending on the direction setting.

Note: When the *Master Tab Rotation* field is 0 degrees, a direction setting cannot be selected.

Master Tab Rotation Distal Reference Foot plate

In order to bring the master tab posterior for a foot plate, the software initially applies a master tab rotation of 180 degrees to the frame. This value is also shown in the input field and is the basis for the setting of the actual rotation of the foot plate.

If the frontal part of the foot plate is rotated **internally** by X degrees, the master tab is rotated **externally** by 180–X degrees.

If the frontal part of the foot plate is rotated **externally** by X degrees, the master tab is rotated **internally** by 180–X degrees.

See figure 110 for an illustration.

Note: When the master tab rotation field is 180 degrees, a direction setting cannot be selected.

10 Treatment Plan Management

The Treatment Plan Management allows you to review a treatment plan, share a treatment plan with other users and re-plan a treatment plan.

10.1 Treatment Plan Life Cycle and Statuses

This section provides an overview of the life cycle of treatment plans in the *MAXFRAME 3D II Software*.

10.1.1 The four statuses

During its life cycle, a treatment plan carries at any time exactly one of the following four statuses:

Figure 111 – The four statuses during the life cycle of a treatment plan.

In Planning
The treatment plan has been started but not been approved nor completed yet. During its “In Planning” phase, you can fully edit the treatment plan.

In Process
The treatment plan has been approved, the treatment is in process and the patient adjusts the struts according to the Strut Adjustment Plan. During this treatment phase, you cannot edit the treatment plan parameters. To adjust parameters of a treatment plan in process, you can re-plan it. The re-planning function closes the active treatment plan and creates a new one within the same case information. The system takes over the treatment plan parameters up to a specific treatment day.

Complete
The treatment plan has been tagged as “Complete” but not been closed yet. A treatment plan is switched to the status “Complete” by clicking **Archive and Lock (Complete Plan)** in the Case Dashboard area (cf. section 10.2 on page 101). You can complete a treatment plan which is in planning or in process. A completed treatment plan is not editable except for its case notes.

Closed
A closed treatment plan is made inactive and read-only except for its case notes.

10.1.2 Active and non-active treatment plans

Treatment plans in the following statuses are considered “active”:

- In Planning

- In Process
- Complete

Closed treatment plans are considered “non-active”.

Figure 112 – Active and non-active treatment plans.

Each case can include not more than one active treatment plan at a time. If a case already includes an active treatment plan, it’s not possible to select this specific case for the option **Use existing** when creating a new treatment plan.

10.2 Review Treatment Plan

The *MAXFRAME 3D II Software* provides the option to review all parameters of a treatment plan if the treatment plan status is in process, complete, or closed. The parameters of a treatment plan with a status of in process, complete, or closed are not editable.

To review a treatment plan, open the corresponding Case Dashboard view by one of the following methods:

- Select and click a treatment plan in the *Plans in treatment planning* list or the *Plans in process* list. Both lists are located on the left side of the *Home* view.
- Search the treatment plan by using the **Search Database** function in the *Home* view. Open the desired treatment plan from the search results list.
- Open the patient of the desired treatment plan by using the **Find Patient** function in the *Home* view. In the Patient view, click **Review Treatment Plans**.

The Case Dashboard view opens.

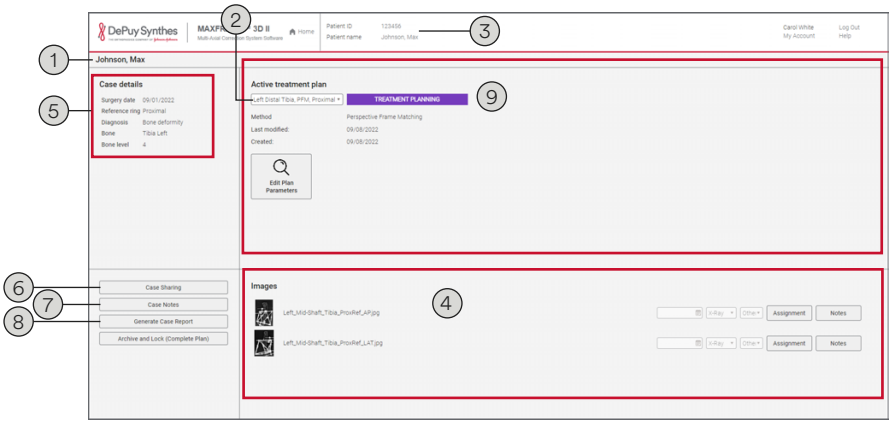


Figure 113 – The Case Dashboard view.

The Case Dashboard view contains the following specific areas and elements:

1. Patient's last name and first name. To edit the patient's data directly, click on the *Patient ID* in the header area.
2. Case selection filter. To switch to another case of this patient, click on the case selection field and select the desired case from the list.
3. **Patient Dashboard** button. Click to switch to the Patient Dashboard view.
4. *Images* – list of all images which are assigned to treatment plans of the displayed case.
5. *Case details* (read-only).
6. **Case Sharing** – allows you to share the case with other users.
7. *Case Notes* – opens the *Case Notes* window, in which you can create and manage notes for this case.
8. *Generate Case Report* – generates the report of the displayed case. Once the system has completed generating the report, your web browser shows an *Open* dialog, asking if you want to open the Case report PDF file in a viewer application or save it to disk.

   Note: Depending on your installed web browser and its settings, the web browser might open the PDF file directly within a browser window. In this case, use the **Save as** function of your web browser to save the displayed PDF file to disk. For more information, refer to the help function of your web browser.
9. *Active treatment plan* area. Overview of the active treatment plan in this case (if available). For more details on the *Active treatment plan* area, refer to the next section.

10.2.1 The Active treatment plan area

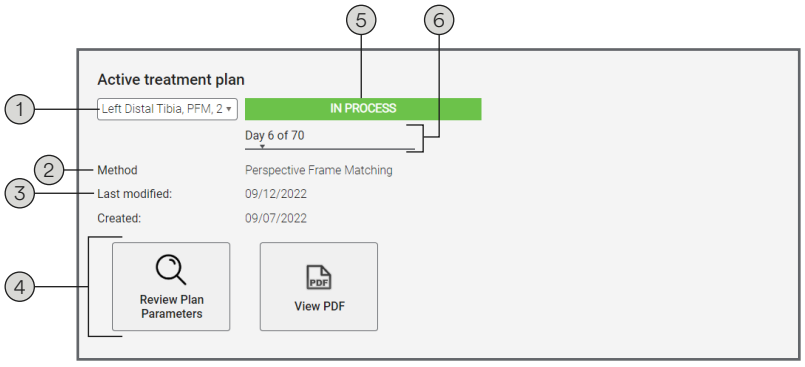


Figure 114 – The Active treatment plan area.

The *Active treatment plan* area contains the following elements:

1. Title of the active treatment plan.

2. Used treatment planning method.
3. Dates of last modification and creation.
4. Available functions for the treatment plan. The offered functions depend on the status the treatment plan is currently in.
5. Current status.
6. If the treatment plan is “In Process”, the current treatment day and a progress indicator are displayed.

10.2.2 Open a treatment plan for review

The way you open a treatment plan in review mode depends on the treatment plan’s status:

- “In Planning”: Click **Edit Plan Parameters** in the *Active treatment plan* area.
- “In Process” or “Complete”: Click **Review Plan Parameters** in the *Active treatment plan* area.
- “Closed”: Click the **Review Plan Parameters** button in the corresponding line of the desired treatment plan in the list of closed treatment plans.

The treatment plan opens in a Detail view.

For more details of the single Detail view tabs, refer to the Treatment Plan creation description for the corresponding planning method:

- Perspective Frame Matching (PFM) – Chapter 6.
- Standard – Chapter 7.
- Acute Intentional Deformation (AID) – Chapter 8.

10.2.3 Rules for reviewing treatment plans

While reviewing a treatment plan, the following rules apply:

- When a treatment plan is approved (“In Process”, “Complete”, or “Closed”), all its parameters are read-only, except the case notes.
- You can rotate, zoom in, zoom out, and pan the model preview.
- You can switch the view of the model preview between **AP**, **LAT**, **PROX**, **MT**, and **REF** (available options are specific to the Detail view tab).
- In the preview, you can show/hide labels, axes, struts, strut numbers, sticks, bone model, non-ref fragment, frame, and measurements (available options are specific to the Detail view tab).
- In the strut adjustment plan, you can show/hide the rapid strut movement indication.

10.3 Share a Treatment Plan

To share a treatment plan with another user, proceed as follows:

1. Open an active treatment plan in the Case Dashboard view.
2. Click the **Case Sharing** button. A pop-up window opens.

Figure 115 – Treatment Plan Management – Share a treatment plan view.

3. Enter the email address/username of the person with whom you want to share the treatment plan in the *Email or username* field.
4. If you want to have the sharing link expired at a certain date, specify the desired expiry date manually or click the calendar icon and select the date.
5. Enter a message that you want to convey to the recipient under **Optional message to the user**. This message is optional.
6. Click **Share**. The case is shared and an email is also sent to the recipient.

For sharing treatment plans, the following rules apply:

- You can only share a treatment plan with a registered user.
- If you try sharing a treatment plan with a non-registered user, you will receive a prompt indicating “You are not able to share the case with a non-registered user”.
- The patient’s health information or PHI will be masked for the recipient of the shared case.
- You can identify a shared treatment plan with a unique ID registered with the case.

Any plans shared with you can be found by clicking the **Search Database** button on the *Home* view and selecting the *Plans shared with me* tab.

Note: You cannot generate case reports for treatment plans shared with you.

10.4 Re-plan a Treatment Plan

This section describes how to re-plan a treatment plan. Re-planning is suitable to adjust parameters of a treatment plan in process.

The re-planning function works as follows:

1. The re-planning function closes the treatment plan in process and creates a new one within the same case.

   Note: You can only re-plan treatment plans which are in process.

2. The system copies over most of the parameters from the closed plan to the new plan using a specific user-selected date in the old plan.
3. The selected date will be the Initial Day for the new plan.

To re-plan a treatment plan, proceed as follows:

1. Open a treatment plan in process in the Case Dashboard view (e.g., from the *Plans in process* list located on the left side of the *Home* view).

2. Click **Review Plan Parameters** in the *Active treatment plan* area of the Case Dashboard view.

3. Select the **Treatment plan** tab.

4. Select the **Strut adjustment plan** tab.

5. To re-plan a treatment plan, click **Re-Plan** for the day from which you want to re-plan the treatment plan.

Notes

- The first set of strut settings as of the selected re-planning day are used as the initial settings for the new treatment plan.
- If a strut swap date range ends earlier than the date selected for re-planning, the strut sizes in the initial frame configuration of the new treatment plan already reflect the strut swap.
- If the date selected for re-planning is within a specific strut swap date range, the strut sizes in the initial frame configuration of the new treatment plan will not reflect the strut swap.

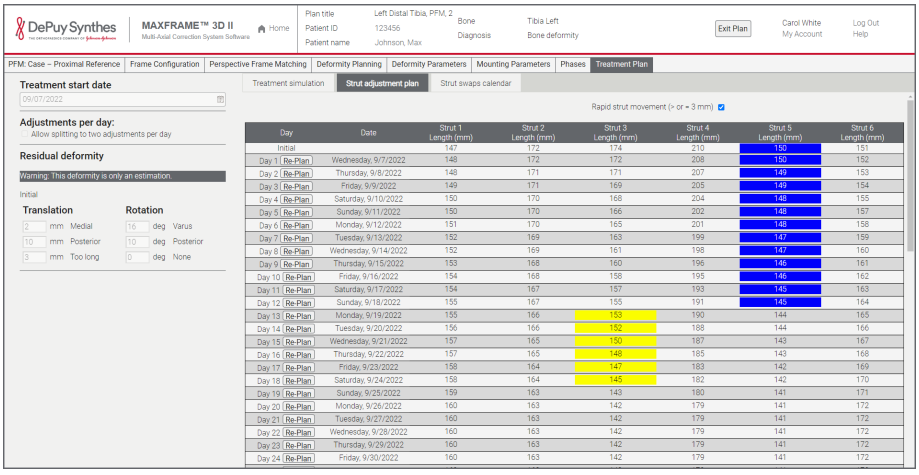


Figure 116 – Treatment Plan Management – Re-plan a treatment plan view.

The following parameters will automatically be copied from the original treatment plan to the new treatment plan:

- Treatment planning method. You can change the planning method. If the planning method is changed from AID to PFM or Standard, the bone level will become editable.

- Case information (the new treatment plan is created within the same case as the original treatment plan). You cannot edit the re-planned case information. The new treatment plan title will be the name of the original treatment plan added by a postfix indicating the number of runs (starting at “2” and increment each time it is re-planned). You can edit the proposed treatment plan title.
- Mounting parameters.

  Note: If PFM is being used in the re-planning, the mounting parameters are re-calculated based upon the new PFM data.
- Frame configuration.

  Note: Includes ring types, ring diameters, mounting points, and **openings** if applicable, and strut sizes and lengths as of the specified re-planning day.

6. Verify the frame configuration of the new treatment plan when you enter its frame configuration the first time. The system will prompt you then to verify the frame configuration. The message requires your confirmation before you can proceed to updating the frame configuration.

11 Patient Data

This chapter covers the management of patient data, namely:

- Adding a new patient.
- Editing patient data.
- Revocation of Patient Consent.
- Transferring a patient to another user.

11.1 Add Patient

This section provides a step-by-step instruction for adding a patient to the system. Preparing the creation of a new patient's electronic record, the following subsection deals with important regulatory aspects, namely the Patient Consents.

11.1.1 Patient Consents

Before adding the details of a new patient to the patient database, you need to acknowledge whether or not you have received the *Patient Consent for the Collection, Storage and Transfer of Patient's personal data* and *Patient Consent for use by the Manufacturer of Patient's radiographic images and aggregate data*.

If you do not acknowledge receipt of the *Patient Consent for the Collection, Storage and Transfer of Patient's personal data*, the patient can still be added and the patient de-identified data will not be included in any reports.

The acknowledgement status for the *Patient Consent for use by the Manufacturer of Patient's radiographic images and aggregate data* can be edited when needed. If the patient revokes consent, you will need to open the *Edit Patient* dialog and edit the consent selection(s) to *No*.

11.1.2 Procedure to Add a Patient

To add a patient, proceed as follows:

1. Click **Add Patient** in the *Home* view. The application displays the *Choose Patient Consent Status* dialog:

Figure 117 – Choose Patient Consent Status dialog.

2. Select *Yes* to continue and acknowledge the receipt of *Patient Consent for the Collection, Storage and Transfer of Patient's personal data*.If you select *No*, you can continue with patient addition and the patient de-identified data will not be included in any reports.

3. Select whether you acknowledge the receipt of *Patient Consent for use by the Manufacturer of Patient's radiographic images and aggregate data*.

4. Click **Continue**. The *Create New Patient* dialog opens.

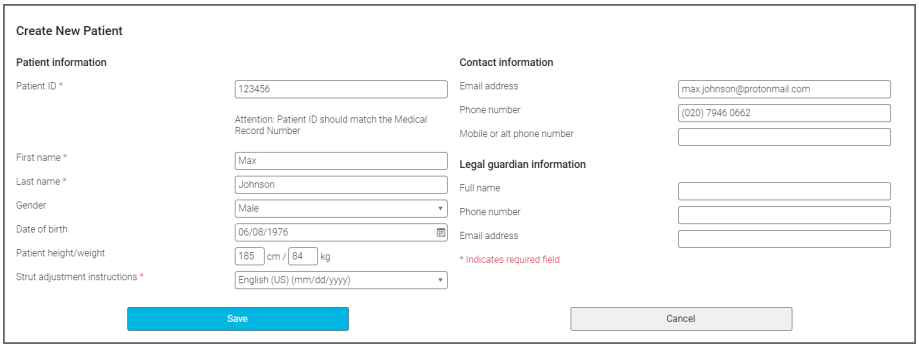


Figure 118 – Create New Patient dialog.

5. Select the desired language and date format for the strut adjustment instructions.

6. Enter an ID in the *Patient ID* field. The *Patient ID* is an alpha-numeric open text data field. The *Patient ID* needs to be unique for all your patients. If desired, the entered ID may be the same as your medical record number.

   Important: To successfully create a patient record, the *Patient ID*, *First name*, and *Last name* will be required to ensure patient safety. Adding additional patient information is recommended. Having more patient information helps to identify and confirm you are working with the correct patient record.

7. If desired, enter the following data under *Patient information*:

   - The patient's gender in the *Gender* field.
   - The patient's date of birth in the *Date of birth* field. You can specify the date manually or by clicking the calendar icon and selecting the date from the calendar.
   - The patient's height and weight in the *Patient height/weight* fields. Enter the height in centimeters (cm) and the weight in kilograms (kg).
   - The patient's preferred language for the strut adjustment instructions in the *Strut adjustment instructions* field can be edited.

8. If desired, enter the following data under *Contact information*:

   - The patient's email address in the *Email address* field.
   - The patient's phone number in the *Phone number* field.
   - A patient's mobile number or any other alternate phone number in the *Mobile or alt phone number* field.

9. If necessary, enter the following data under *Legal guardian information*:

- The guardian's first name and the last name in the *Full name* field.
- The guardian's phone number in the *Phone number* field.
- The guardian's email address in the *Email address* field.

10. Click **Save** to finish the creation of the new patient record and close the *Create New Patient* dialog.

11.2 The Patient Dashboard

This section deals with the Patient Dashboard view:

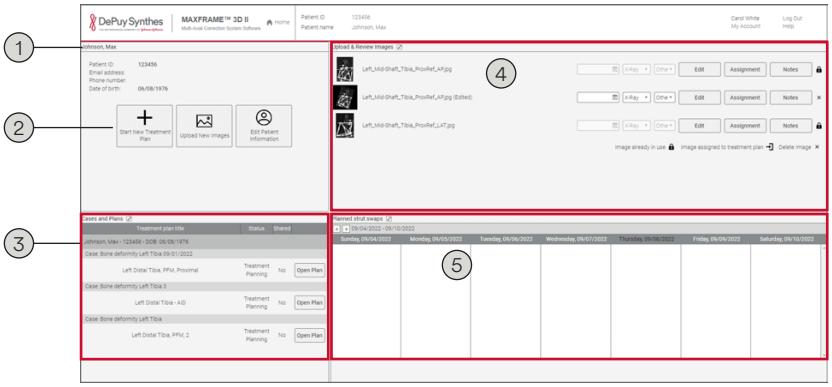


Figure 119 – The Patient Dashboard view.

The Patient Dashboard view contains the following specific elements:

1. Patient's last name and first name.

2. Menu buttons which provide access to the following functions for the selected patient:
   - **Start New Treatment Plan** – for creating a new treatment plan.
   - **Upload & Review Images** – for uploading new images or reviewing existing images.
   - **Edit Patient** – for editing the data of the selected patient.

3. Cases and Plans list for the selected patient. This list displays all the plans, respective plan status and indicates information regarding case share status. You can open any plan from this list. Selecting to open a plan leads to the selected Case Dashboard view.

4. The option **Upload & Review Images** for the selected patient is provided here. The list of all images uploaded for the patient is displayed.

5. Strut Swap Calendar for the selected patient is displayed. Selecting the suggested strut swap or appointment shall open the treatment plan strut swap calendar.

Use one of the following methods to open the Patient Dashboard view for a specific patient:

- Use the **Find Patient** function in the *Home* view (refer to section 13.1.2 "Search for Patients" on page 122 for more details).

- Click on the *Patient ID* or *Patient name* located in the header area.

11.3 Edit Patient Data

To edit a patient data, proceed as follows:

1. Open the *Edit Patient Information* dialog for a specific patient:
   - Open the Patient Dashboard view (refer to section 11.2 on page 109 for more details). Click on **Edit Patient**.
   - If the header area shows a *Patient ID* link, click it.

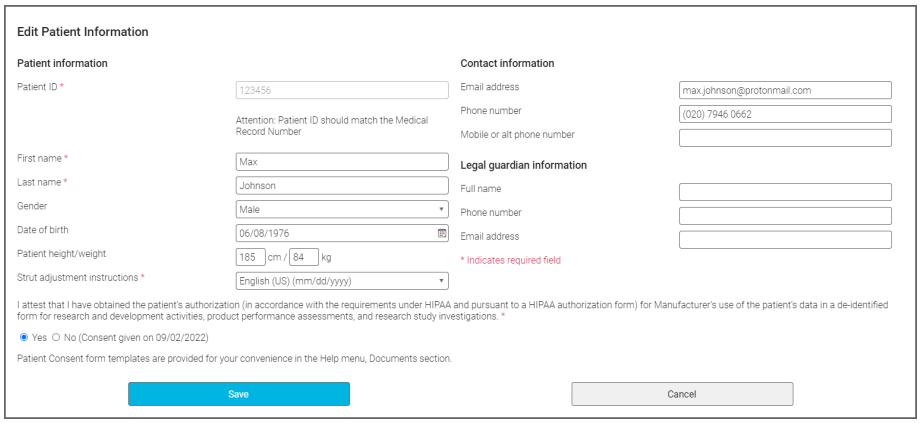


Figure 120 – The Edit Patient Information dialog.

2. Edit the patient data in the following sections of the dialog as needed:
   - *Patient information*
   - *Contact information*
   - *Legal guardian information*

   Note: The patient ID can only be edited when the treatment plan is “In Planning”. Once a treatment plan is approved and the patient strut adjustment instructions are generated, the patient ID can no longer be edited for any future treatment plans for this patient. Therefore, the patient ID cannot be edited for treatment plans that are “In Process” or “Complete”.

3. If required, modify the patient consent settings.

4. If you have modified any information, click **Save** to save the updates and close the *Edit Patient Information* dialog.

11.4 Revocation of Patient Consent

If a patient revokes their *Patient Consent for use by the Manufacturer of Patient’s radiographic images and aggregate data*, open the *Edit Patient Information* dialog (cf. section 11.3 “Edit Patient Data” on page 110):

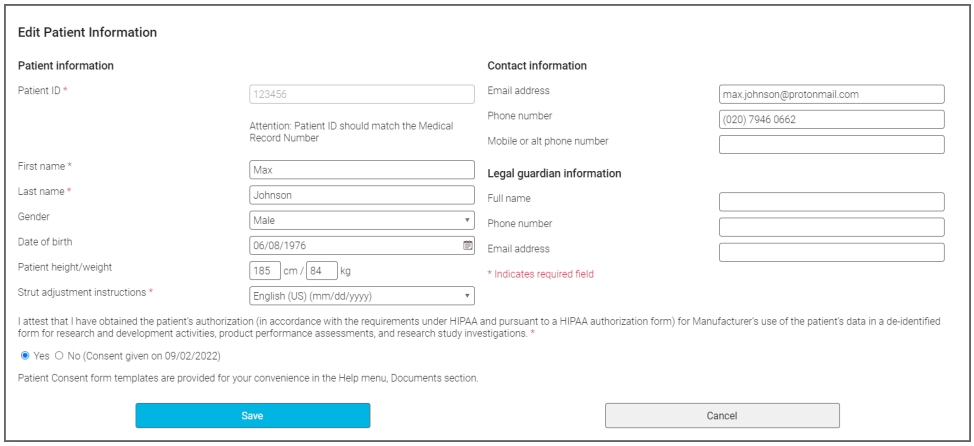


Figure 121 – The Edit Patient Information dialog.

1. Select *No* for “I acknowledge receipt of Patient Consent for Use by the Manufacturer of Patient’s radiographic images and aggregate data”.

2. Click **Save**. The following message appears:

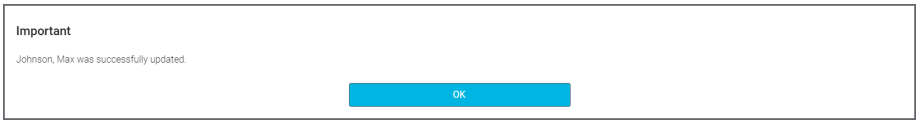


Figure 122 – Patient Consent for use by the Manufacturer of Patient’s radiographic images and aggregate data.

3. Click **OK** to finish.

The *MAXFRAME 3D II Software* stores the new status to the patient’s account.

11.5 Transfer a Patient to another User

To transfer a patient to another user, proceed as follows:

1. Click the *Transfer patient* button in the home view.

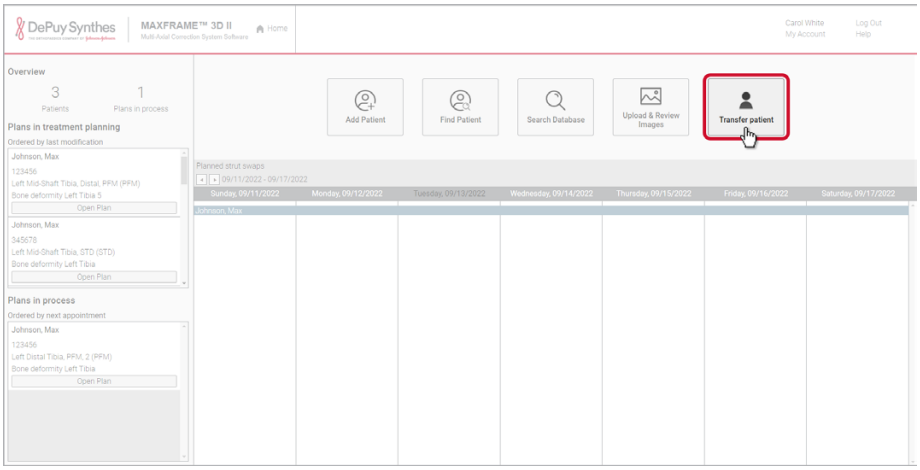


Figure 123 – Transfer patient button located on the home screen.

The *Transfer patient* Dashboard view opens (cf. figure 124 on page 113).

2. Select the patient in the top left that you wish to transfer to another user.

3. Enter the email address/username of the person with whom you want to transfer the patient to in the email or username field.

   Note: You can only transfer a patient to a registered user with the correct privileges.

4. Enter a message that you want to convey to the recipient under *Optional message to the user*.

5. Click **Transfer**.

   a. A message confirming that you want to transfer the patient to the recipient and that you have all the necessary authorization and consents to do so appears. Select **OK** or **Cancel** accordingly.

   b. If there is no treatment plan that has been calculated, a message appears stating: “No treatment plan has been calculated yet, are you sure you want to transfer this patient?” Select **Yes** or **No** accordingly.

6. The patient is transferred and an email is sent to the recipient. The recipient will also receive a pop-up message indicating that a patient has been transferred to them when they login to the *MAXFRAME 3D II Software*. They can **Accept** or **Reject** the patient transfer.

   Note: Prior to the recipient accepting the patient transfer, the sender can revoke the transfer by clicking the **x** next to the name of the patient.

The Patient Transfer Dashboard view contains the following specific areas and elements:

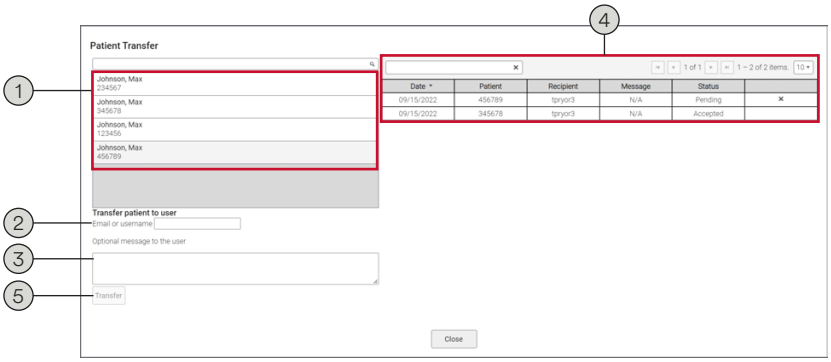


Figure 124 – Transfer patient Dashboard view.

1. List of patients available to transfer.

2. *Email or username* – Enter the email or username of the user you wish to transfer the patient to.

3. *Optional message to the user* – Enter an optional message to the user that will appear when the patient is transferred.

4. Patient Transfer Dashboard – Dashboard view of patients that have been transferred from your account. The status can be one of the following:

    - *Pending*: The patient transfer is waiting for the recipient to accept. Prior to the recipient accepting the patient transfer, the sender can revoke the transfer by clicking the “x” next to the name of the patient.

    - *Canceled*: The patient transfer was cancelled prior to the recipient accepting the transfer.

    - *Accepted*: The recipient has accepted the patient transfer and it will now be available in their *MAXFRAME 3D II Software* account.

    - *Rejected*: The recipient has rejected the patient transfer. The patient will still be available in the sender’s *MAXFRAME 3D II Software* account.

5. *Transfer* – Completes the patient transfer action.

To receive a patient transfer from another surgeon:

1. If a patient was transferred to your account from another user, you will receive a pop-up notification the next time you login to your *MAXFRAME 3D II Software* account.
2. To accept the patient, review the information and click **Accept**.
3. Any patients transferred to you will appear in your patient database once accepted. Click **Find Patient** to search for the patient.

12 Upload & Review Images

This chapter describes the Image Manager function of the *MAXFRAME 3D II Software*. The Image Manager provides the following functions:

- Upload images (cf. section 12.4 on page 117)
- Set image attributes (cf. section 12.5 on page 117)
- Add notes (cf. section 12.6 on page 118)
- Assign and unassign images to or from treatment plans (cf. section 12.7 on page 118)
- Remove images (cf. section 12.8 on page 119)

12.1 Supported Images

The *MAXFRAME 3D II Software* supports image files with the following characteristics:

- Images need to be in JPEG format.
- Images can be up to 20 MB in file size.
- The supported x-ray image resolution is between 512x512 and 4096x4096 pixels. The recommended x-ray image resolution is 1024x1024 pixels.
- Refer to the *MAXFRAME System Technique Guide* for hardware requirements and proper use, as needed.

12.2 Open the Image Manager

The Image Manager can be opened in two different contexts:

12.2.1 For a Patient Record

New images are added to the selected patient record. All the images of the selected patient are listed and can be managed.

To open the Image Manager for a specific patient, proceed as follows:

1. Click **Upload & Review Images** in the *Home* view.

   The *Search Patients* window opens where you can search and select a patient.

2. Enter a search text in the search box. The search text is not case-sensitive.

3. Click the search icon on the right side of the search box or press the **Enter** key to execute the search. The result list displays all patients which contain the search text.

4. Select the patient from the result list and click **Manage Images**.

12.2.2 From Within a Treatment Plan

Any new images added from within a treatment plan will automatically be assigned to the treatment plan and the patient. You will not need to search and select the patient. All the images of the treatment plan's patient are listed and can be managed.

To open the Image Manager for a specific treatment plan, open the Detail view of the desired treatment plan (refer to section 10.2.2 "Open a treatment plan for review" on page 103).

12.3 Overview of the Image Manager

Figure 125 – The Image Manager.

The Image Manager contains the following elements:

1. Patient's last name, first name, and the patient ID.
2. **Upload New Images** – to upload additional images into the patient record (cf. section 12.4 on page 117). If you have opened the Image Manager from within an opened treatment plan, the uploaded images selected for PFM will be assigned automatically.
3. List of images in the patient record.
4. Image attributes (cf. section 12.5 on page 117):
   - Date taken.
   - Image type (*X-Ray* or *Clinical*).
   - Image view (*LAT*, *AP*, *Other*).

   Note: By tagging the image view, the images will be filtered by view type when selecting images from the *Frame Matching* view.
5. **Assignment** – click to assign the image to a treatment plan, to review the current assignment or to modify the current assignment (cf. section 12.7 on page 118).
6. **Notes** – add notes to an image or edit existing notes (cf. section 12.6 on page 118).

7. Status and function icon. The image shows one of the following icons:

Icon	Description
	The image is assigned to a treatment plan – namely, being selected in frame matching.
	The image is being used in a treatment plan – namely, selected in frame matching. The image cannot be deleted if it is being used in a treatment plan.
	The image is neither assigned to a treatment plan nor is it being used in a treatment plan for frame matching. To delete the image from the patient record, click this icon.

8. **Image Selection** – disabled if you have opened the Image Manager from within a treatment plan.

12.4 Upload Images

To upload an image into a patient record, proceed as follows:

1. Open the Image Manager for the desired patient or treatment plan (refer to section 12.2 on page 115).

2. Click **Upload New Images**.

   The web browser opens a file selection window. Select the image files you want to upload.

   Note: Use the **Shift** or **Ctrl** keys to select multiple image files at once for uploading.

3. Click **Open** to finish the image file selection.

   A progress bar indicates the progress of image uploading. If desired, you can cancel the upload of an image.

4. When the upload is complete, click **Close** to close the Image Manager.

Attention:

- If the image file being uploaded exceeds the size limit of 20 MB, a message will be displayed and the image will not be uploaded.
- When attempting to upload an image while the network connection is lost, a message is being displayed and the image upload will not be completed.

Important: If the image file being uploaded is outside the recommended resolution, a message will be displayed but the image can still be used.

12.5 Set Image Attributes

For each image, you can set the following attributes in the Image Manager:

- Date taken – specify the date the image was taken either manually or click the calendar icon to select the date from the calendar.
- Image type – select *X-Ray* or *Clinical* from the selection list.
- Image view – select *LAT*, *AP*, or *Other* from the selection list.

  Note: By tagging the image view, the images will be filtered by view type when selecting images from the *Frame Matching* view.

Note: These three image attributes are read-only if the image is assigned to a treatment plan in process, complete, or closed.

12.6 Add Notes

For each image, you can add a free text note. Proceed as follows:

1. In the Image Manager, click the **Notes** button of the image you want to add a note for.
2. Enter the note in the *Image notes* pop-up window.
3. Click **Close** to close the *Image notes* pop-up window.

To edit a note, proceed the same way.

12.7 Assign and Unassign Images

To assign an image to a treatment plan or unassign an image from a treatment plan, proceed as follows:

1. In the Image Manager, click the **Assignment** button of the image you wish to assign to a treatment plan or unassign from a treatment plan.

Figure 126 – Change assignment of image.

Note: You can unassign an image from a treatment plan only if the treatment plan is in planning.

The *Treatment Plan Assignment* window opens.

2. Select or unselect the desired treatment plan from the image list.

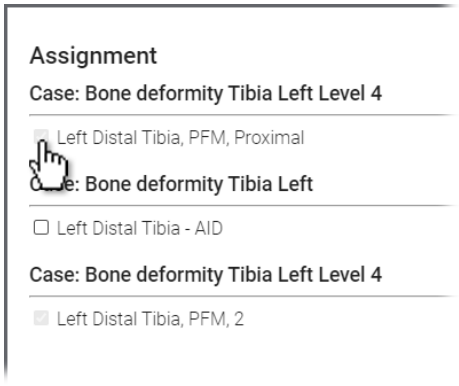


Figure 127 – Select treatment plan.

3. Click **Close** to close the *Treatment Plan Assignment* window.

12.8 Remove Images

To remove an image from a patient record, proceed as follows:

1. In the Image Manager, click the *Delete* icon of the image you wish to remove.

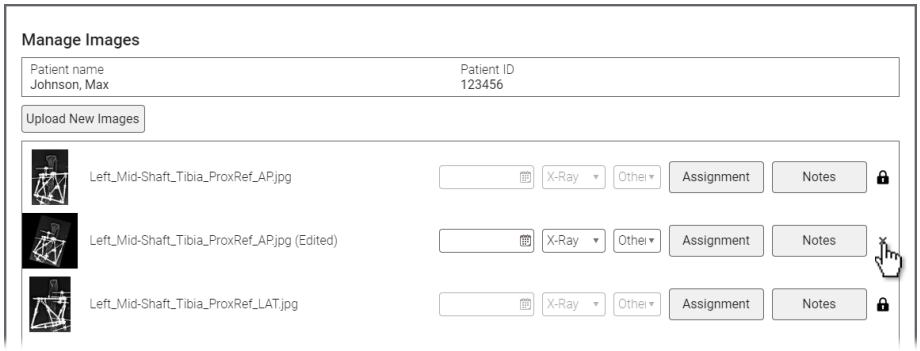


Figure 128 – Remove image from Image Manager.

Note: You can remove an image from the patient record only if the image is not assigned to a treatment plan or not being used in a treatment plan (for frame matching).

2. Click **Yes** in the confirmation message.

Figure 129 – Confirm image removal.

Attention:

- When attempting to remove an image, a message is displayed to confirm the removal of the image.
- Images that are assigned to a treatment plan cannot be removed.

13 Searching and Reporting

This chapter explains the searching and reporting functions of the *MAXFRAME 3D II Software*.

13.1 Searching

In the *MAXFRAME 3D II Software*, you can search for two categories of data:

- Treatment plans
- Patients

13.1.1 Search for Treatment Plans

Using the function **Search Database** in the *Home* view, you can search for all treatment plans you have access to. To search for a treatment plan, proceed as follows:

- Click **Search Database** in the *Home* view. The *Search Database* result view opens, listing all the treatment plans you have access to.

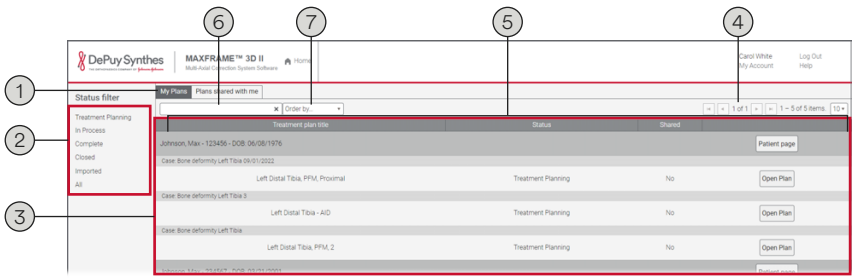


Figure 130 – Search Database result view.

The *Search Database* result view contains the following areas and elements:

1. Tab selectors for the following subtabs:
   - *My Plans* – contains all the treatment plans which you have created by yourself.
   - *Plans shared with me* – contains all the treatment plans which have been created by other users and shared with you.

2. Treatment status filters – click on a specific status (*Treatment Planning* for treatment plans in planning, *In Process*, *Complete*, *Closed*) to limit the result list to treatment plans in the selected status. Click *All* to reset this filter setting.

3. Result list – displays all treatment plans which match the current filter criteria. Click the **Open Plan** button in the result list to open the corresponding treatment plan.

4. Page navigation bar – to switch to a specific page of the result list, click the corresponding page button. To go to the previous or to the next page, click the corresponding page backward/forward button. To go to the first or the last page in the list, click the corresponding first page or last page button.

   On the right side, the page navigation bar displays the number range of the entries displayed on the current page as well as the total number of entries in the result list.

5. Column heads – click a column head to sort the result list by that column. Click the column head again to resort in descending order.

6. Search box – enter a search text in the search box and click the search icon on the right side of the search box (or press the **Enter** key) to restrict the result list to entries which contain the search text. The search text is not case-sensitive and is being applied on the following data:
   - *My Plans* – patient first and last name, patient ID, patient date of birth, treatment plan title, and treatment plan status.
   - *Plans shared with me* – treatment plan title, share case ID, last modified, date received, and treatment plan status.

   Combine any search criteria to narrow down the results.

7. Select the filter in the *Ordered by* box to order the results in the selected option (Title, First Name, Last Name, Patient ID, Date of Birth, Diagnosis, Bone, Surgery Date) in ascending or descending order as selected.

13.1.2 Search for Patients

To search for a patient, proceed as follows:

1. In the *Home* view, click **Find Patient**. The *Find Patient* window opens:

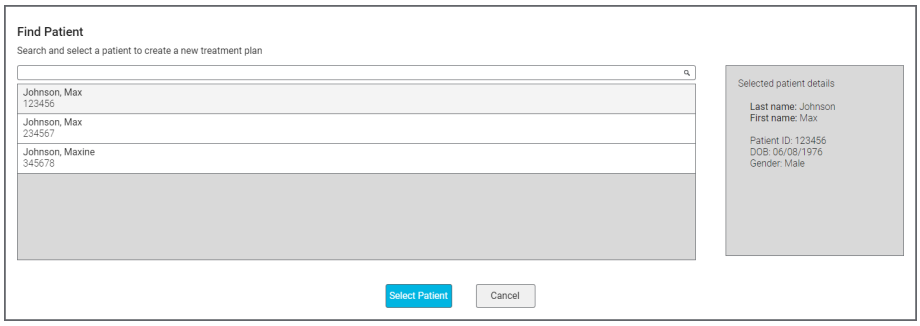


Figure 131 – The Find Patient window.

2. Enter a search text in the search box. You can search for the patient first name, the patient last name, and the patient ID. Combine any search criteria to narrow down the results. The search text is not case-sensitive.

3. Click the search icon on the right side of the search box or press the **Enter** key to execute the search. The result list displays all patients which contain the search text.

4. To display the details of a certain patient, click the corresponding row in the result list. The details are displayed on the right side of the window.

5. Select the desired patient from the result list and click **Select**.

The Patient Dashboard of the selected patient opens.

Warning: If multiple patients have the same name, a message is being displayed to confirm or reject that the intended patient has been selected:

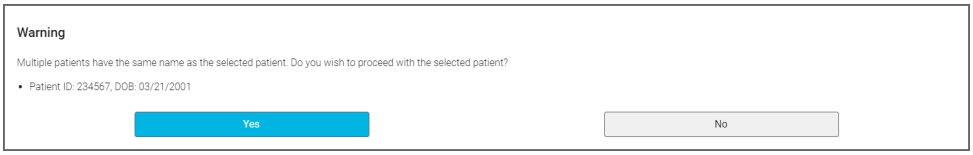


Figure 132 – Duplicate patient warning message

13.2 Generate Case Reports

Case reports are PDF files intended to save and archive all relevant information of a case.

A Case report contains the following information of each of its treatment plans:

- Patient ID, patient name, surgeon name, surgeon phone number, treatment plan title, and case title.
- Bone undergoing treatment.
- Diagnosis.
- Selected planning method (Standard, PFM, or AID).
- Ring types, ring openings, and ring sizes.
- Strut sizes and deformed (initial) strut lengths.
- Aligned strut lengths (only for AID treatment plans).
- Strut mounting point settings, deformity parameters, and mounting parameters.
- Location of concern.
- Treatment start dates, axial movement only phase parameters (number of days, movement at reference point, movement at location of concern), and additional lengthening.
- Deformity correction phase parameters (number of days, movement at reference point, movement at location of concern), daily strut settings of the strut adjustment instructions, and if the strut adjustment plan is split into two adjustments per day or not.
- Split adjustments for the daily strut settings of the strut adjustment instructions, strut swap information for all strut swaps, notes to patient, and treatment plan approved dates.

To generate a case report, proceed as follows:

1. Open a treatment plan. The treatment plan opens in the *Case* view.

2. Click **Generate Case Report**. The web browser shows an *Open* dialog, asking if you want to open the Case report PDF file in a viewer application or to save it to disk.

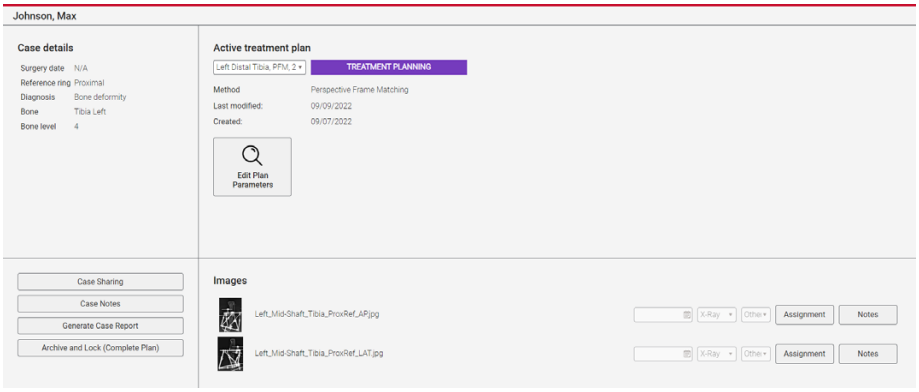


Figure 133 – Open dialog for the Case report.

Note: Depending on your installed web browser and its settings, the web browser might open the PDF file directly within a browser window. In this case, use the **Save as** function of your web browser to save the displayed PDF file to disk. For more information, refer to the help function of your web browser.

3. Select the *Save File* option and confirm with **OK**.

4. The web browser opens a *Save as* dialog asking you for the target folder to save the PDF file to. Specify the target folder and click **Save**.

Appendix

1 Glossary of Terms

The following glossary defines terms, abbreviations and acronyms that are used in this manual.

Acute Intentional Deformation (AID)
: The planning method in the software that includes manually entering the ring configuration and the initial and the final strut positions to generate a strut adjustment plan. Deformity and frame mounting parameters are not required.

AO Fracture Classification
: A classification of specific types of fractures defined by the AO (*Arbeitsgemeinschaft für Osteosynthesefragen* – the Association for the Study of Internal Fixation).

AP View Offset (Mounting Parameter)
: The anteroposterior offset value of the center of the reference ring with respect to the Proximal Reference Point (figure 135).

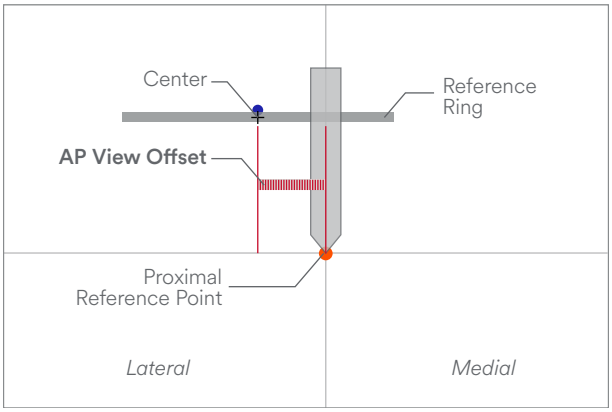


Figure 135 – AP View Offset

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

AP View Offset – Tilted (Mounting Parameter)
: The tilt of the lateral side of a reference ring that is non-perpendicular to the mechanical axis (figure 137).

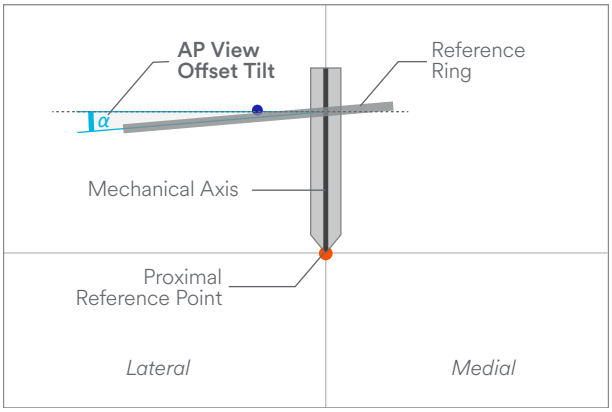


Figure 137 – AP View Offset Tilt

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

AP View – Coronal Angulation (Deformity Parameter)

The coronal angulation value of the Distal Reference Point with respect to the Proximal Reference Point (figure 134).

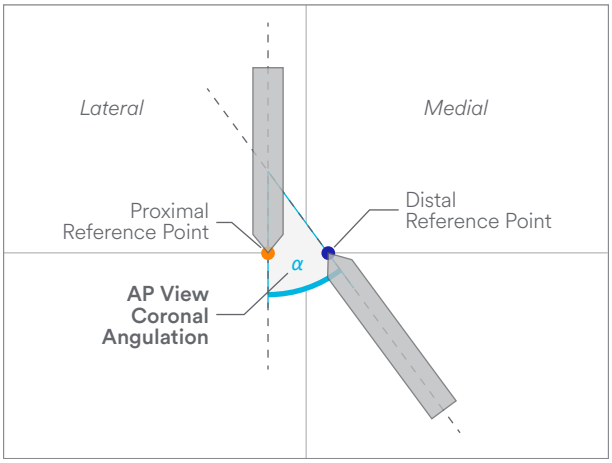


Figure 134 – AP View – Coronal Angulation

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

AP View – Translation (Deformity Parameter)

The anteroposterior translation value of the Distal Reference Point with respect to the Proximal Reference Point (figure 136).

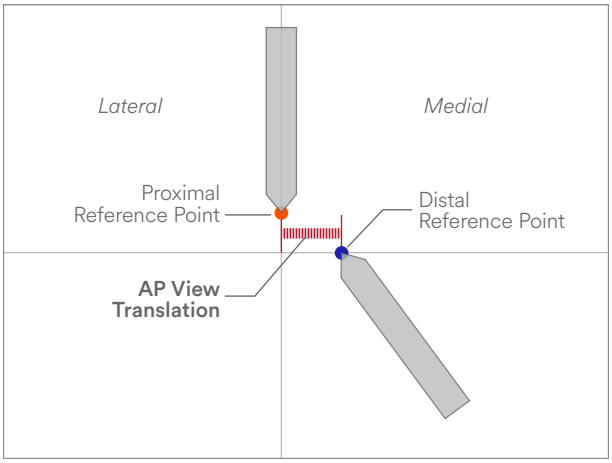


Figure 136 – AP View – Translation

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

Axial Frame Offset (Mounting Parameter)

The axial offset value of the center of the reference ring with respect to the Proximal Reference Point (figure 138).

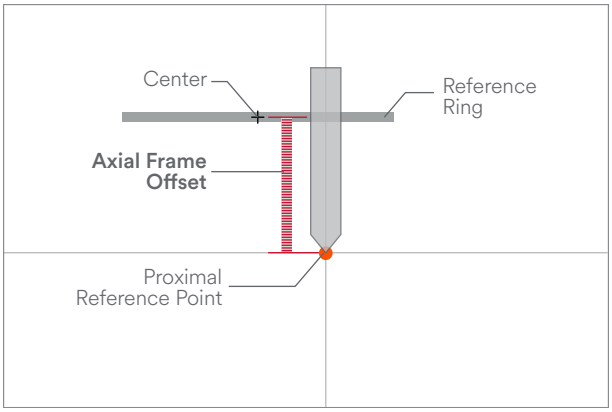


Figure 138 – Axial Frame Offset

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

Bone Length (Deformity Parameter)

The discrepancy of the bone length between Distal Reference Point and the Proximal Reference Point (figure 139).

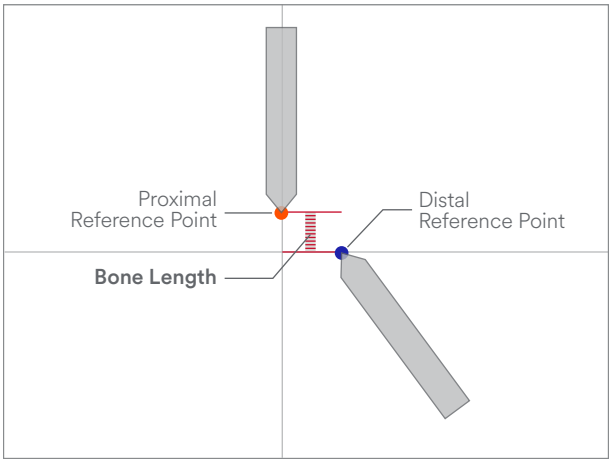


Figure 139 – Bone Length

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

Bone Model

A representation of a bone used only as a reference.

Clinical Rotational Deformity (Deformity Parameter)

The clinical rotational deformity value of the Distal Reference Point with respect to the Proximal Reference Point (figure 140).

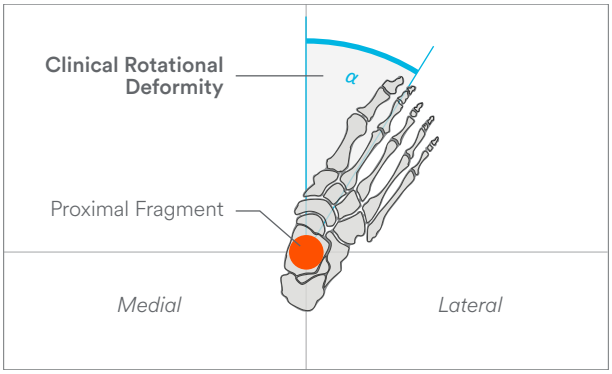


Figure 140 – Clinical Rotational Deformity

For the Standard planning method and PFM, this value is entered.

Note: For PFM, the Clinical Rotational Deformity is not calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

CS

Coordinate System

Deformity Elements

In PFM, the following deformity elements are used to define and calculate the deformity:

- *Proximal Reference Point (PRP)*
- *Distal Reference Point (DRP)*

- Proximal Fragment Center Line (PFCL)
- Distal Fragment Center Line (DFCL)
- *Location of Concern (LOC)*

Deformity Parameters

Anticipated or measured parameters that define how the proximal reference point is positioned with respect to the distal reference point. There are six deformity parameters:

- *AP View – Translation*
- *AP View – Coronal Angulation*
- *LAT View – Translation*
- *LAT View – Sagittal Angulation*
- *Bone Length*
- *Clinical Rotational Deformity*

DFCL

Distal Fragment Center Line

Diagnosis

User Interface (UI) Data selection of the “surgery type” and includes:

- Bone Deformity
- Joint Deformity (Contracture)
- Bone Defect
- Leg Length Discrepancy
- Fracture

Direction Reference Bone

The rendering area visual representation of the bone to identify the viewing direction with respect to the body direction. The direction reference bone rotates with the rendered image.

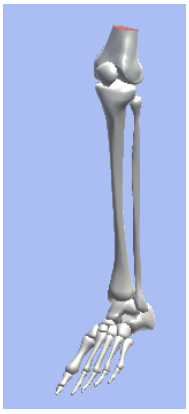


Figure 141 – Direction Reference Bone.

DOB

Date of Birth

GTIN

Global Trade Item Number.

LAT view offset (Mounting Parameter)

The lateral offset value of the center of the reference ring with respect to the Proximal Reference Point (figure 142).

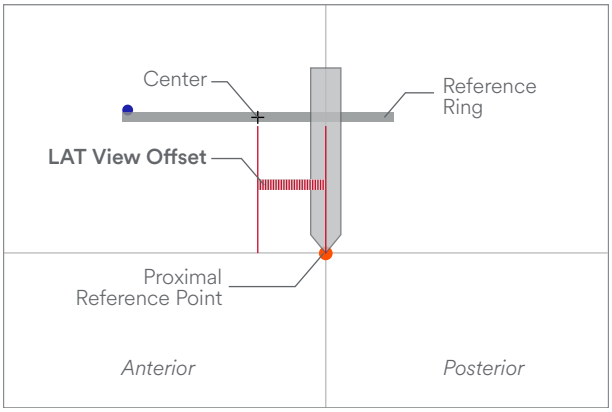


Figure 142 – LAT view offset

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

LAT view offset – Tilted (Mounting Parameter)

The tilt of the anterior side of a reference ring that is non-perpendicular to the mechanical axis (figure 143).

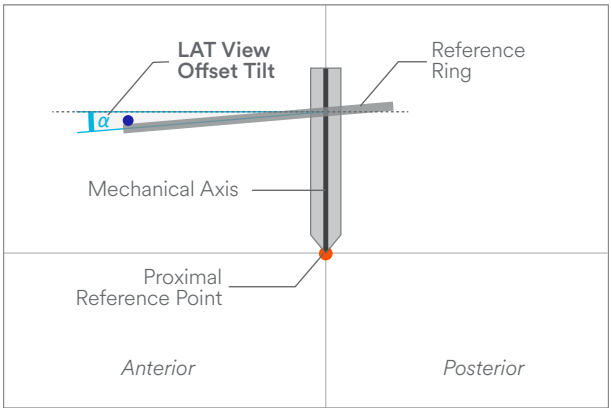


Figure 143 – LAT view offset – Tilted

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

LAT View – Sagittal Angulation (Deformity Parameter)

The sagittal angulation value of the Distal Reference Point with respect to the Proximal Reference Point (figure 144).

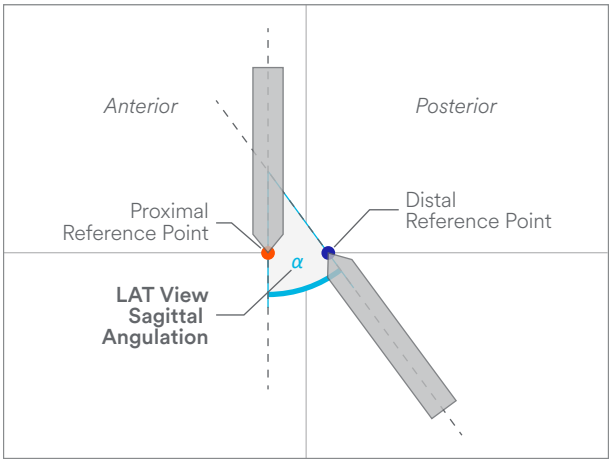


Figure 144 – LAT View – Sagittal Angulation

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

LAT View – Translation (Deformity Parameter)

The lateral translation value of the Distal Reference Point with respect to the Proximal Reference Point (figure 145).

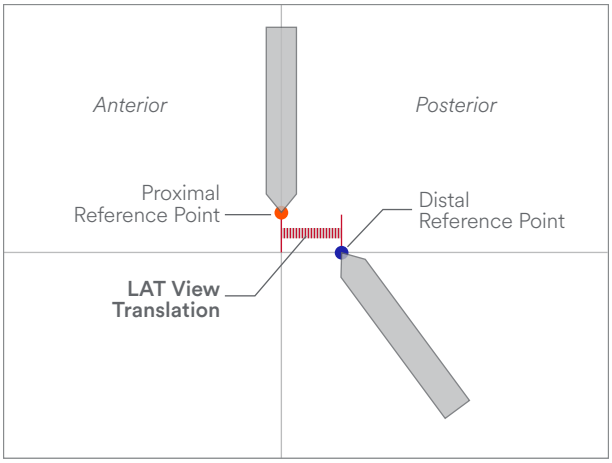


Figure 145 – LAT View – Translation

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

Location of Concern (LOC)

A location of concern represents a location (neurovascular bundle, soft tissue envelope, skin graft, or bone ends of the fracture itself) that may be affected by the correction. You can define a location of concern in the *Mounting Parameters* tab (Standard planning method) or in the *Deformity Planning* tab (PFM).

When a location of concern is defined, you will be given an option to calculate a movement rate at the location of concern in the *Treatment plan* tab.

Master Tab

The tab on the ring that contains struts 1 and 2.

Master Tab Rotation (Mounting Parameter)

The rotation of the sagittal plane of the reference ring with respect to the sagittal plane of the reference fragment (figure 146).

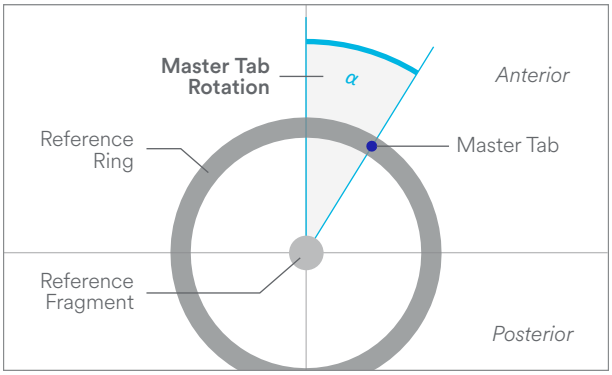


Figure 146 – Master Tab Rotation

For the Standard planning method, this value is entered. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

Note: When the master tab rotation field is 180 degrees, a direction setting cannot be selected.

MAXFRAME System

Refers to the DePuy Synthes *MAXFRAME Multi-Axial Correction System* including "hardware and software" with responsibility being with DePuy Synthes Trauma.

MAXFRAME 3D II Software or "Software"

Refers to the *MAXFRAME 3D II Software*.

Measurement Tools

Aid in determining the *deformity elements* and include the four point and angle tools. These are not included in the calculation of the deformity.

Mounting Parameters

Anticipated or measured parameters that define how the reference ring is positioned with respect to the reference point. These parameters are measured along the reference ring coordinate axes. There are six mounting parameters:

- *AP View Offset*
- *AP View Offset – Tilted*
- *LAT view offset*
- *LAT view offset – Tilted*
- *Axial Frame Offset*
- *Master Tab Rotation*

Mounting Points

Holes on the rings. There are four types of mounting points:

- *Tab Mount Default Holes*
- *Tab Mount Non-Default Holes*
- *Ring Mount Default Holes*
- *Ring Mount Non-Default Holes*

Non-Reference Fragment
The moving fragment. The other fragment is the stationary reference fragment.

Patient Active
In the software, a patient with open cases or no cases.

Patient Inactive
In the software, a patient with only closed case(s).

Perpendicularity of the Reference Ring
Specifies if the reference ring is fully perpendicular (AP and LAT) to the mechanical axis of the reference fragment. For the Standard planning method, a deviation from perpendicularity is entered in the fields *Tilted* for *AP view offset* and *LAT view offset*. For PFM this parameter is calculated from the *Perspective Frame Matching* and *Deformity Planning* tabs.

Perspective Frame Matching (PFM)
The planning method that uses post-operative x-rays with the entire frame to generate the deformity and mounting parameters for a strut adjustment plan.

PFCL
Proximal Fragment Center Line

PHI
Protected Health Information

Planning Method
The process flow selected by the surgeon that he/she will use to perform deformity and fracture correction planning in the software – Standard, PFM, or AID (also referred to as Workflow).

Radiographic Markers
A hardware part that allows identification of AP and ML orientation of hardware within the x-rays and the scaling of the hardware to the x-ray for planning and measuring purposes.

Reference Fragment
The stationary fragment. The other fragment is the moving non-reference fragment.

Reference Point – Distal
A point in space used to coincide with the origin before the deformity occurred.

Reference Point – Proximal
A point defined as the tip of the (stationary) reference fragment. Also defined as Intrinsic origin

Residual Deformity
Calculated deformity remaining at any point in the treatment plan.

Ring Mount Default Holes
Holes identified by a dashed circle on the ring between the tabs.

Ring Mount Non-Default Holes
Holes identified within a dashed line perimeter, one or two holes away from Ring Mount Default.

Safety
Freedom from conditions that can cause death, injury, occupational illness, or damage to or loss of equipment or property.

Standard Planning Method
The planning method that uses manually entered deformity and mounting parameters to generate a strut adjustment plan.

Strut Adjustment Instructions
An approved strut adjustment plan provided by the surgeon to the patient with the instructions for required daily adjustments of struts and recommended dates for strut swaps.

Strut Swap
Replace a mounted strut with a new strut.

Strut Types
Strut types refers to Standard struts and Quick Adjust struts.

Tab (user interface element)
A clickable area within a view designed to look like a tab on a file folder. In the *MAXFRAME 3D II Software* user interface tabs are arranged horizontally and allow to switch between related subviews. In this manual, “tab” refers to subviews within the user interface of the *MAXFRAME 3D II Software*. “Tab” never refers to “tab” elements of other applications like browser tabs, nor to any hardware tabs like tab mount holes and master tab.

Tab Mount Default Holes
Holes identified by a solid circle on the tabs.

Tab Mount Non-Default Holes
Holes identified within a solid line perimeter, one or two holes away from Tab Mount Default.

Treatment Parameters

The fields used to calculate the treatment plan:

- Treatment Start Date
- Axial Movement First
- Final Distance Between Reference Points
- Number of Days
- Movement at Reference Point
- Movement at Location of Concern
- Angulation Rate

Treatment Plan Status
During its life cycle, a treatment plan carries at any time exactly one of the following four statuses:

Figure 147 – The four statuses during the life cycle of a treatment plan.

For detailed information on the four treatment plan statuses, refer to section 10.1.1 “The four statuses” on page 100.

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