

Software User's Manual

Software Release 2017.01

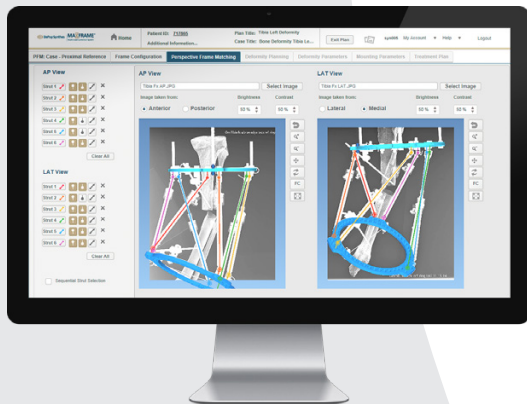


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1 Welcome

1.1 About This Manual

This User's Manual familiarizes you with the functionality of the *MAXFRAME™ 3D Software* by providing you step-by-step procedures 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 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 bold 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 serif type in golden color .	You cannot undo this action.
Terms that are described in the Glossary of Terms are set in <i>italic</i> type. The terms are clickable. Click on a term to jump to its entry in the Glossary of Terms.	Enter the <i>coronal angulation value</i> here.
Product names are set in <i>italic</i> type.	<i>MAXFRAME 3D Software</i>

1.3 Safety & Security

All passwords and Personal Health Information is 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.

2 Product Overview

This chapter provides you with information on the following topics:

- Features and Benefits of the *MAXFRAME 3D Software* (section 2.1 below).
- The intended use and purpose of the *MAXFRAME System* (section 2.2 below).
- The software requirements for the *MAXFRAME 3D Software* (section 2.3 on page 9).
- An overview of the hardware components of the *MAXFRAME System* (section 2.4 on page 10).
- Contact details of the customer support teams (section 2.5 on page 15).

2.1 Features and Benefits

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

- The *MAXFRAME System* is designed to reduce procedure complexity by streamlining the surgical and software workflows.
- A simplified surgical workflow and streamlined set configuration can optimize your time in the operating room.

The *MAXFRAME 3D Software* provides a surgeon with a number of 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.
- Re-planning of treatment plans.
- Fully documented approval of treatment plans.
- Patient and case management.

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

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, children¹ (3–12), and adolescent¹ (12–21) patient populations. The DePuy Synthes *MAXFRAME™ Multi-Axial Correction System* utilizes software for assisting surgeons in treatment planning.

¹in 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 the following treatments in adults, and in both children (3–12) and adolescents (12–21) in which the growth plates have fused or will not be crossed with hardware:

- fracture fixation (open and closed)
- pseudoarthrosis of long bones
- limb lengthening (epiphyseal or metaphyseal distraction)
- joint arthrodesis
- infected fractures or nonunions
- correction of bony or soft tissue deformities
- correction of segmental defects.

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 health care professionals. Patients will not use the software.

2.2.4 General Warnings

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

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

2.2.5 Restrictions

- The *MAXFRAME 3D Software* is designed to be used outside the sterile field.
- The *MAXFRAME 3D Software* does not directly modify the *MAXFRAME System* hardware.
- The *MAXFRAME 3D 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 Software*.

Important: You will be blocked from logging into *MAXFRAME 3D 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 at the *MAXFRAME 3D Software* web page [<http://www.maxframesystem.com>].

Operating System

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

- *Windows (Microsoft)*—Minimum *Windows 7 SP1+*
- *macOS (Apple)*—Minimum *El Capitan (10.11)*

Web Browser

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

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

Computer Hardware

To use *MAXFRAME 3D 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 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 Software* and only current DePuy Synthes hardware is available for selection.

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

2.4.1 Frame

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



Figure 1 – Hardware—Frame.

2.4.2 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)

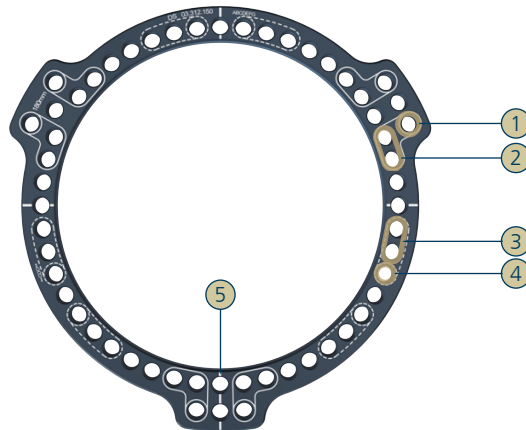


Figure 2 – Hardware—Full ring (and mounting points).

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.

2.4.3 Struts

The *MAXFRAME System* contains 2 types of struts:

Standard struts

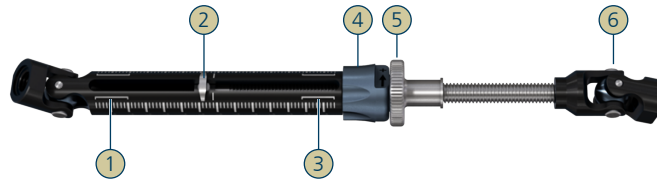


Figure 6 – Hardware—Standard strut.

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

Quick Adjust struts

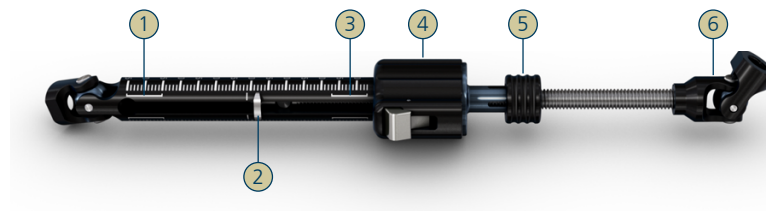


Figure 7 – Hardware—Quick Adjust strut.

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

2.4.4 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.

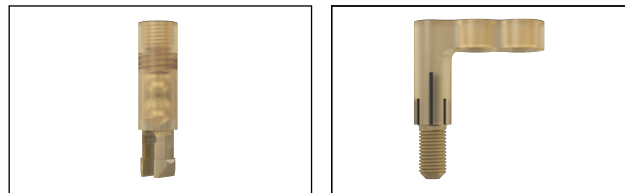


Figure 10 – Hardware—Radiographic markers.



Figure 11 – Hardware—Installation of radiographic markers.

2.5 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 Software

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

1. Obtaining Your User Account (section 3.1 on page 16).
2. Authentication (section 3.2 on page 23).
3. Device Registration (section 3.3 on page 23).
4. Initial Login (section 3.4 on page 24).

Section 3.5 on page 25 explains how to reset your password, if needed.

3.1 Obtaining Your User Account

1. Open the MAXFRAME 3D Software web page [<http://www.maxframesystem.com>] in your web browser.

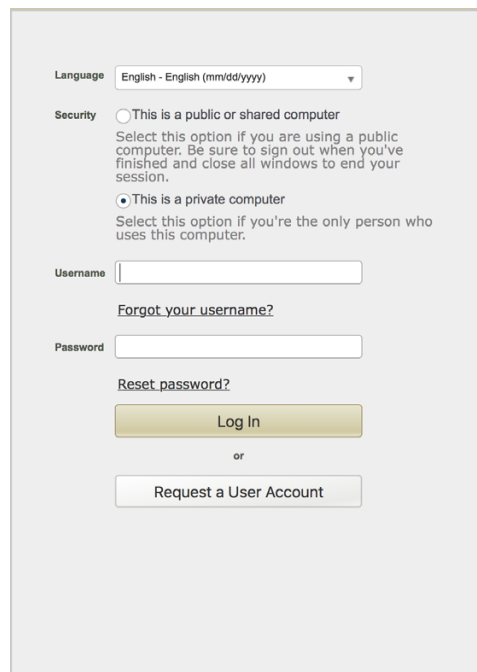


Figure 12 – Login screen.

2. a. Select your preferred language if desired.
- b. Under **Security**, indicate whether your computer is a public/shared computer or a private computer.

- c. Click **Request a User Account**.
3. Read the **Privacy Collection Notice #1**.

Privacy Collection Notice #1

You are providing your personal information to request a User Account for access to the MAXFRAME 3D Software Application. The information collected will be used to determine your eligibility and status for establishing a User Account.

By clicking on the Accept button below, you acknowledge you have read and agree to the Terms of our Privacy Policy and consent to the transfer of your information to countries outside of your country of residence, including the United States, where it may be stored, and/or processed in connection with the purposes described in this Statement. Contractual or other measures we use to protect your personal information are subject to the legal requirements of the foreign jurisdictions where your personal information may be transferred, stored, or processed. This means that your information may be accessible to regulatory authorities in accordance with the laws of these jurisdictions.

If you are making this request on behalf of another individual, by clicking on Accept you represent that you are fully authorized to request a user account on behalf of this individual or organization.

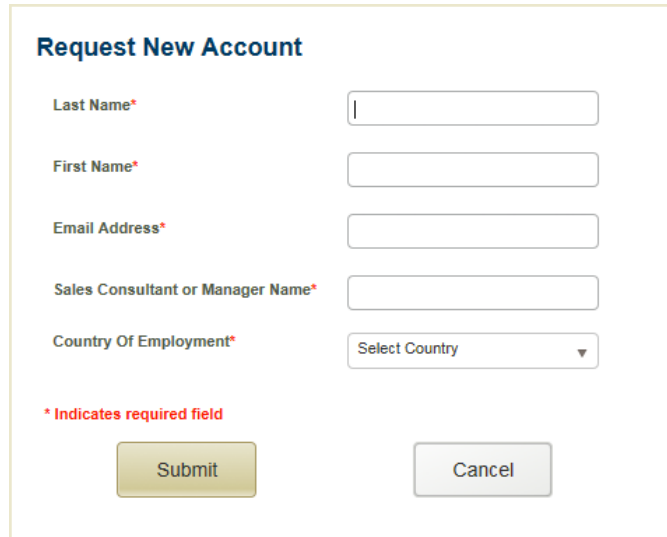
[Privacy Policy](#)

Figure 13 – The **Privacy Collection Notice #1**.

If you agree, click **Accept**.

If you select **Do not Accept** you are prevented from going further in the account request process.

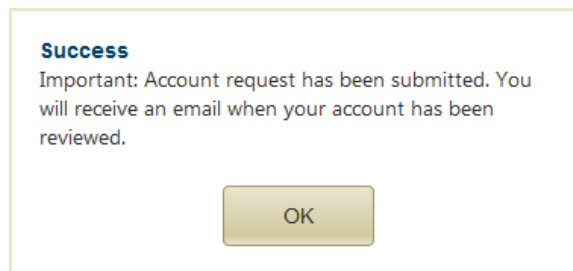
4. Enter your **Last Name**, your **First Name**, your **Email Address**, and your **Sales Consultant or Manager Name**. Select your **Country Of Employment** from the drop-down list.



The dialog box is titled "Request New Account" in bold blue text. It contains five input fields, each with an asterisk indicating it is required: "Last Name*", "First Name*", "Email Address*", "Sales Consultant or Manager Name*", and "Country Of Employment*". The "Country Of Employment*" field is a dropdown menu with "Select Country" and a downward arrow. Below the fields is a red asterisk with the text "* Indicates required field". At the bottom are two buttons: "Submit" (yellow) and "Cancel" (grey).

Figure 14 – The **Request New Account** dialog.

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



The dialog box is titled "Success" in bold blue text. It contains the following text: "Important: Account request has been submitted. You will receive an email when your account has been reviewed." Below the text is a single "OK" button (yellow).

Figure 15 – Account request successfully transmitted.

Close this message with **OK**.

Note: You will also receive an email, which confirms the successful submission of your account request.

6. Check your emails for the approval of your account request. You should expect a response from our Support Team within 24–48 hours.

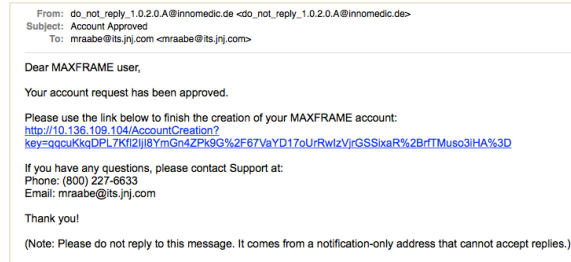


Figure 16 – Approval email for an account request.

The approval email contains a link. Click this link to complete your account request.

7. Read the **Privacy Collection Notice #2**.

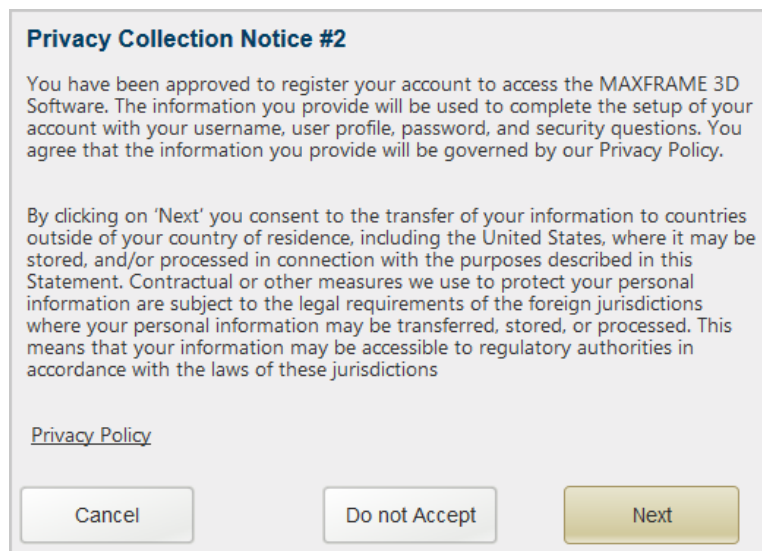


Figure 17 – The **Privacy Collection Notice #2**.

If you agree, click **Next**.

If you select **Do not Accept** you are prevented from going further in the account request process.

8. The **Create New Account** dialog appears, asking for personal and account information.

The screenshot shows a 'Create New Account' dialog with two columns: 'Personal Information' and 'Account Information'. The 'Personal Information' column includes fields for Last Name* (White), First Name* (Carol), Title, Specialty (Orthopedics), Phone Number ((585) 200-4550), and Mobile or Alt Phone Number. The 'Account Information' column includes Username* (CarolWhite), Email Address* (carol.white@mail.com), Password* (masked with dots), Confirm Password* (masked with dots), and Language Setting (English - English (mm/dd/yyyy)). A red asterisk indicates required fields. At the bottom are 'Cancel' and 'Next' buttons.

Figure 18 – The **Create New Account** dialog for personal and account information.

Enter a **Username** and a **Password**. Enter the password a second time in **Confirm Password**. All the other fields are optional. Confirm your entered data with **Next**.

Note: The password is case-sensitive. The password needs to be at least 8 characters and contain at least 1 digit and 1 uppercase letter.

9. Select for each of the six security challenging questions one predefined question from the drop-down list. For each of these six security challenging questions, the system offers 27 predefined questions to choose from. Enter the answers in the corresponding text fields below each question. The answers are case-sensitive.

The screenshot shows the 'Create New Account' dialog for security challenging questions. It features a 'Security Challenge Questions' section with six rows. Each row has a 'Question' dropdown menu and an 'Answer' text field. The questions are labeled Question 1* through Question 6*. A red asterisk indicates required fields. At the bottom are 'Cancel', 'Back', and 'Next' buttons.

Figure 19 – The **Create New Account** dialog for security challenging questions.

Confirm your entered data with **Next**.

10. Select your preferred settings and confirm with **Next** in the **Create New Account** dialog that asks your preferred settings:

Create New Account

Preferences

Display in Case Header

Bone

Diagnosis

Surgery Date

Display throughout Application

Patient Name

Cancel Back Next

Figure 20 – The **Create New Account** dialog for preference settings.

11. Check your account data in the **Create New Account** overview and confirm with **Next**:

Create New Account

Personal Information	Security Challenge Questions	Display Settings
Last Name: White	What is your pet's name?	Bone: No
First Name: Carol	What hospital were you born in?	Diagnosis: No
Title:	What is your favorite movie?	Surgery Date: No
Specialty: Orthopedics	What was your favorite place to visit as a child?	Patient Name: Yes
Phone Number: (585) 200-4550	Who is your favorite actor, musician, or artist?	
Mobile or Alt Phone Number:	What was the first car you owned?	
Account Information		
Email Address: carol.white@mail.com		
Username: CarolWhite		
Password: *****		
Language Setting: English - English (mm/dd/y...		

Cancel Back Next

Figure 21 – The **Create New Account** overview.

12. Read the **Software General Terms**.

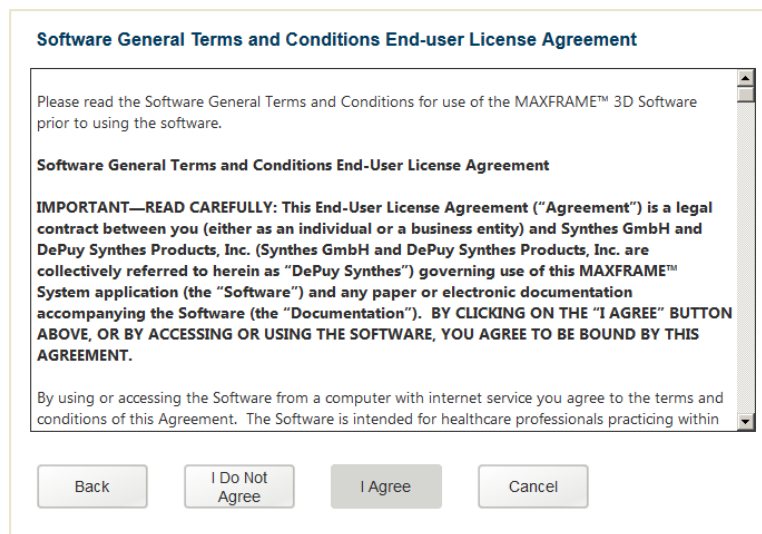


Figure 22 – The **Software General Terms** dialog.

If you agree, click **I Agree** on top of the text.

Note: The **I Agree** button is not active unless you’ve scrolled the text to its bottom.

13. Read the **Privacy Terms & Conditions**:

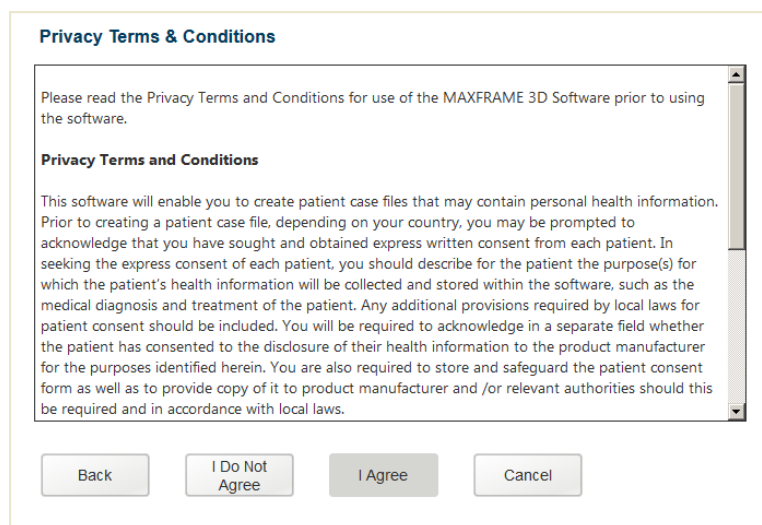


Figure 23 – The **Privacy Terms & Conditions** dialog.

If you agree, click **I Agree** on top of the text.

Note: The **I Agree** button is not active unless you’ve scrolled the text to its bottom.

14. A success message appears, stating that you’ve successfully created your account:

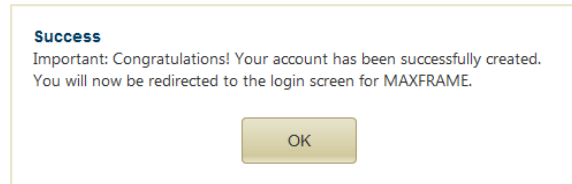


Figure 24 – Success message for creating your user account.

Close this message with **OK**.

3.2 Authentication

To avoid unauthorized access, the *MAXFRAME 3D Software* requires user authentication comprising two components:

- **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.

Note: The password is case-sensitive. The password needs to be at least 8 characters and contain at least 1 digit and 1 uppercase letter.

- **Correct answers to three security challenge questions.** During the account request process, you have answered six security challenge questions (out of 27). When prompted, you are required to answer three security challenge questions correctly, which are randomly selected. If you have indicated your computer as “private”, the three security challenge questions will be prompted only at your first login. The answers are case-sensitive.

3.3 Device Registration

If you have indicated your computer as private, the *MAXFRAME 3D Software* registers this device. This device registration allows you to login just by entering your username and password. On a registered device, the three security challenge questions are needed only for the first login (and for some special functions, e.g., resetting the password). The device registration requires that your “Cookies” are enabled.

If you have indicated your computer as public/shared, the *MAXFRAME 3D Software* does not store any private data on it. That also includes any kind of device registration information. For this reason, on a public/shared computer you need to answer the three security challenge questions on every login.

Attention: To help ensure protection of the data, an inactivity period of 15 minutes with a tolerance of ± 1 minute results in a session expiration and an automatic logout. A countdown of the inactivity period's final 60 seconds is displayed and provides you the option to stay logged in and continue the session:

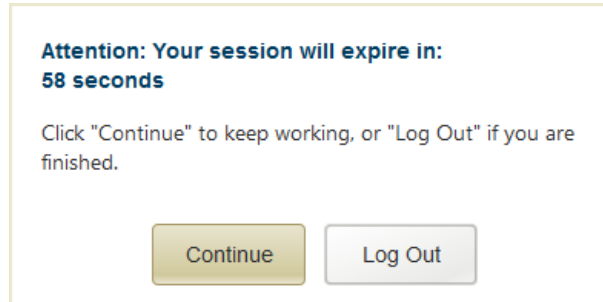


Figure 25 – Session expiration message

Attention: As added security, the system only allows one active session per user account at any time. Do not log in from a second computer as it will expire the initial login session and may result in the loss of data.

3.4 Initial Login

For logging in the first time, proceed as follows:

1. Open the *MAXFRAME 3D Software* web page [<http://www.maxframesystem.com>] in your web browser. The login dialog appears (cf. figure 12 on page 16).
2. Under **Security**, indicate whether your computer is a public/shared computer or a private computer.
3. Enter your **Username** and **Password**.
4. Click **Log In**. The software asks three security challenge questions:

Question 1) What is your favorite movie?

Answer*

Submit

Figure 26 – Dialog asking three security challenge questions.

- Enter your three answers, which are case-sensitive, and click **Submit**. The **Home** view opens:

MAXFRAME 3D Software Home

syn005 My Account Help Logout

Overview
10 Patients 2 Plans In Process

Plans In Treatment Planning

- Johnson, Max
717865
Bone Deformity Tibia Left
- Johnson, Max
717865
Fracture Tibia Left
- Doe, Jane
367723
Bone Deformity Foot Left

Plans In Process

- Green, Lisa
685489
Fracture Tibia Left
- Johnson, Max
717865
Fracture Tibia Left

Planned Strut Swaps
Sunday, January 15, 2017 - Saturday, January 21, 2017

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Johnson, Max Strut 6					
			Green, Lisa Strut 1			
				Green, Lisa Strut 2		

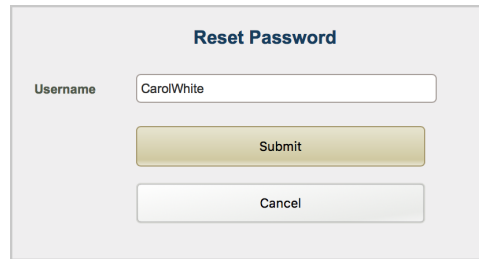
Figure 27 – Home view

3.5 Password Reset

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

- Open the *MAXFRAME 3D Software* web page [<http://www.maxframesystem.com>] in your web browser. The login dialog appears (cf. figure 12 on page 16).

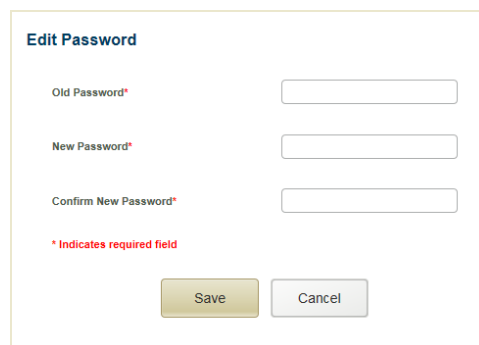
2. Click **Reset password**. The **Reset Password** dialog appears:



The image shows a dialog box titled "Reset Password". It contains a label "Username" followed by a text input field with the text "CarolWhite". Below the input field are two buttons: "Submit" and "Cancel".

Figure 28 – **Reset Password** dialog

3. Enter your **Username**.
4. Click **Submit**. The software asks three security challenge questions (cf. figure 26 on page 25).
5. Enter your three answers and click **Submit**. The **Edit Password** dialog appears:



The image shows a dialog box titled "Edit Password". It contains three text input fields labeled "Old Password*", "New Password*", and "Confirm New Password*". Below the fields is a red asterisk with the text "* Indicates required field". At the bottom are two buttons: "Save" and "Cancel".

Figure 29 – **Edit Password** dialog

6. Enter your **New Password** and confirm it.

Note: The password is case-sensitive. The password needs to be at least 8 characters and contain at least 1 digit and 1 uppercase letter.

7. Click **Reset Password**. The login dialog appears (cf. figure 12 on page 16).
8. Enter your **Username** and your new **Password**.
9. Click **Log In**.

4 User Interface

The user interface of the *MAXFRAME 3D 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 Software*.

Note: 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 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 on page 27).
- **Detail views:** Are used for entering and managing clinical data (refer to section 4.2 on page 32).

4.1 Dashboard Views

After logging into *MAXFRAME 3D 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:

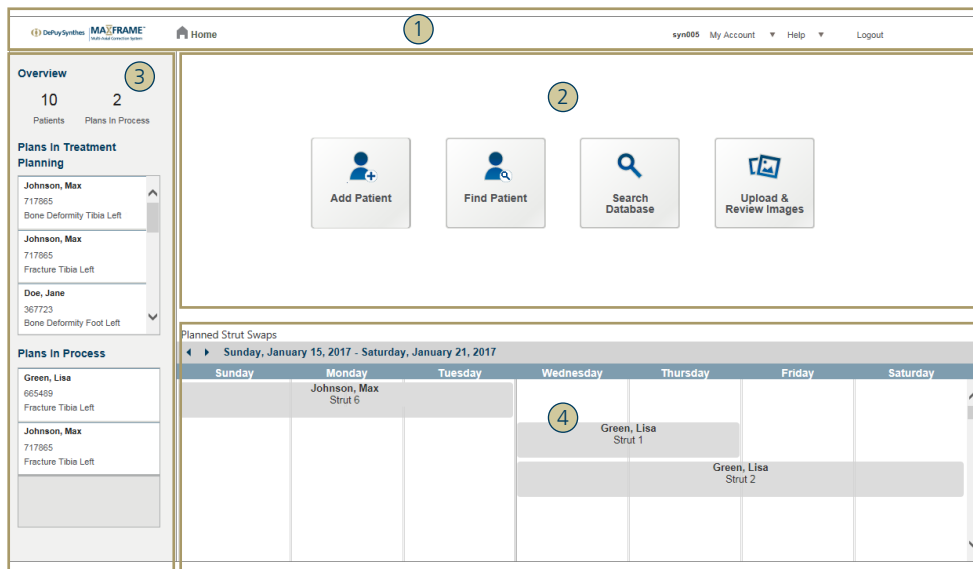


Figure 30 – The **Home** view.

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 Software*. It contains different elements, depending on the situation and its context.



Figure 31 – 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. **My Account** menu—provides options for managing your user account. For details, refer to section 4.1.1.1 below.
4. **Help** menu—provides different sources of help and assistance for the *MAXFRAME 3D Software*. For details, refer to section 4.1.1.2 on page 29.
5. **Logout** link—logout and exit the *MAXFRAME 3D Software*.

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 Security Questions

Edit and save your answers of six different security challenge questions.

The application offers 27 questions to choose from, of which you need to complete 6. When prompted, you will be required to answer 3 questions correctly, which are randomly selected by the application. The answers are case-sensitive.

Edit Preferences

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

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.

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:

User's Manual-US/User's Manual-Outside US

Either directly open the appropriate User's Manual or save the manual on your client computer.

Contact

Displays contact details, including e-mail addresses, phone numbers, and the main contact address.

About

The **About** box displays information about the *MAXFRAME 3D Software*.

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.

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.

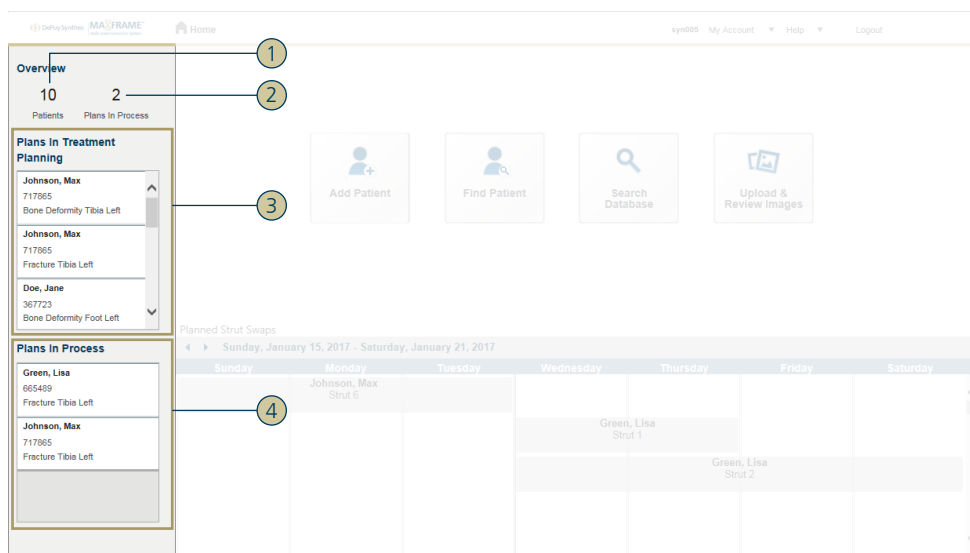


Figure 33 – The **Home** view—Overview and quick selection lists.

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 accessed plan will be listed first.
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 most recently accessed plan will be listed first.

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.

Planned Strut Swaps						
◀ ▶ Sunday, January 15, 2017 - Saturday, January 21, 2017						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Johnson, Max Strut 6					
			Green, Lisa Strut 1			
				Green, Lisa Strut 2		

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

The calendar displays all 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.

Each swap entry in the calendar shows the patient and the strut numbers to be swapped.

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.

4.1.5 Other Dashboard views

Other Dashboard views are:

- The **Case Dashboard** view (refer to section 10.2 “Review Treatment Plan” on page 97).
- The **Patient Page** (refer to section 11.2 on page 107).

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.

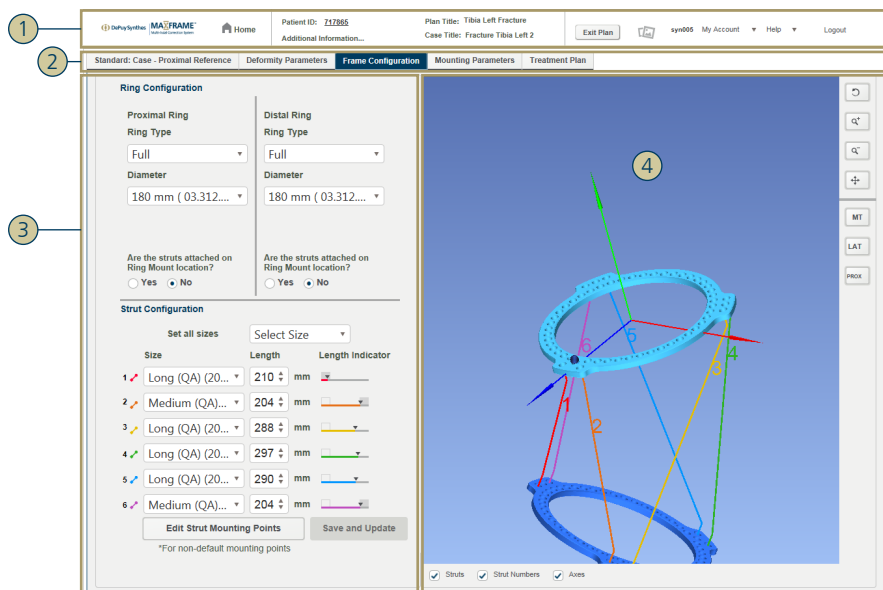


Figure 35 – Detail view—the **Frame Configuration** view as an example.

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 36 – The Detail view—Header Area.

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

1. **Patient ID**—the patient’s ID to which the treatment plan belongs to. Click the ID to edit the patient data directly.
2. **Additional Information**—you can define in your user account preferences the fields which shall be displayed here (cf. section 14.2 “Change Preferences” on page 123).

3. **Plan Title** and **Case Title**—the titles of the current treatment plan and the case it is part of.
4. **Exit Plan**—to exit the current plan and return to the **Active Treatment Plan** view for the patient.
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.

Important: If you switch to a preceding tab and make edits, a warning will be displayed due to potential loss or refreshing of data.

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.

For detailed information on the contents of the different tabs, refer to chapter 6 "Standard Planning Method" on page 52, chapter 7 "Perspective Frame Matching (PFM)" on page 60, and chapter 8 "Acute Intentional Deformation (AID)" on page 82.

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 in respect to the bone.

The direction reference bone (cf. figure 37) is displayed in the lower left corner of the preview area.

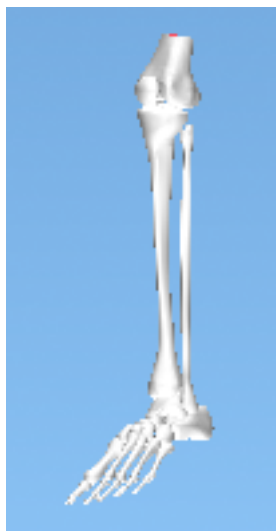


Figure 37 – The Detail view—Direction Reference Bone.

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

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

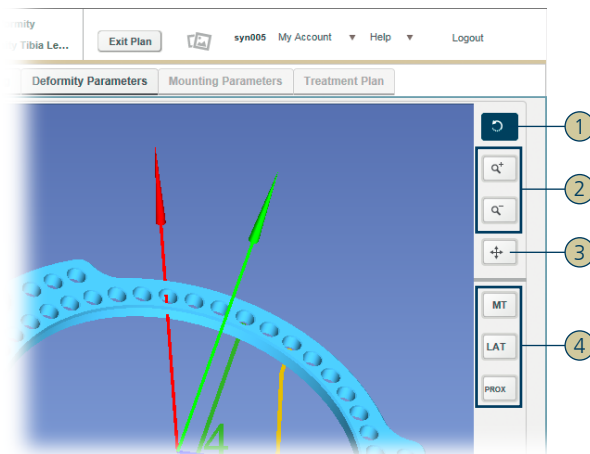


Figure 38 – The Detail view—Control buttons for the preview area.

1. Rotate.
2. Zoom in, zoom out.
3. Pan.
4. View: Master tab (**MT**), 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 relations between the three.

The following sections show the treatment planning process, which is common for the three treatment planning methods Standard, Perspective Frame Matching (PFM), 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 37).
2. Define Case and Select Treatment Planning Method (section 5.3 on page 37).
3. Enter Planning Parameters (section 5.4 on page 40).
4. Define, Review and Approve Treatment Plan (section 5.5 on page 41).

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 96 for details).

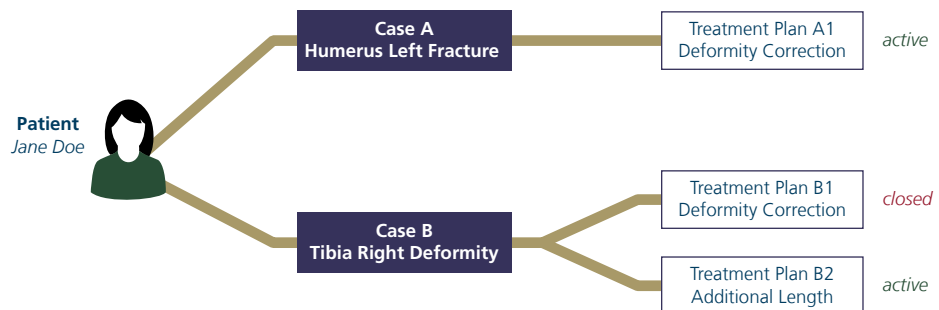


Figure 39 – Relations between patients, cases, and treatment plans.

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 105).
3. Select the desired language for the patient's strut adjustment instructions in the **Strut Adjustment Instructions** field.
4. Click **Continue**.
5. Enter a **Patient ID**, **First Name**, and **Last Name**.
6. If desired, enter optional **Patient Information**, **Contact Information** and **Legal Guardian Information**.
7. Click **Save**.

For more details on adding a patient refer to section 11.1 on page 105.

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 117).
3. Click **Select**. The **Patient Page** view is displayed.

For more details on searching patients refer to section 13.1.2 on page 117.

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 36 for details).

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

5.3.1 Define Case

In the **Patient Page** view, click **Create 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.

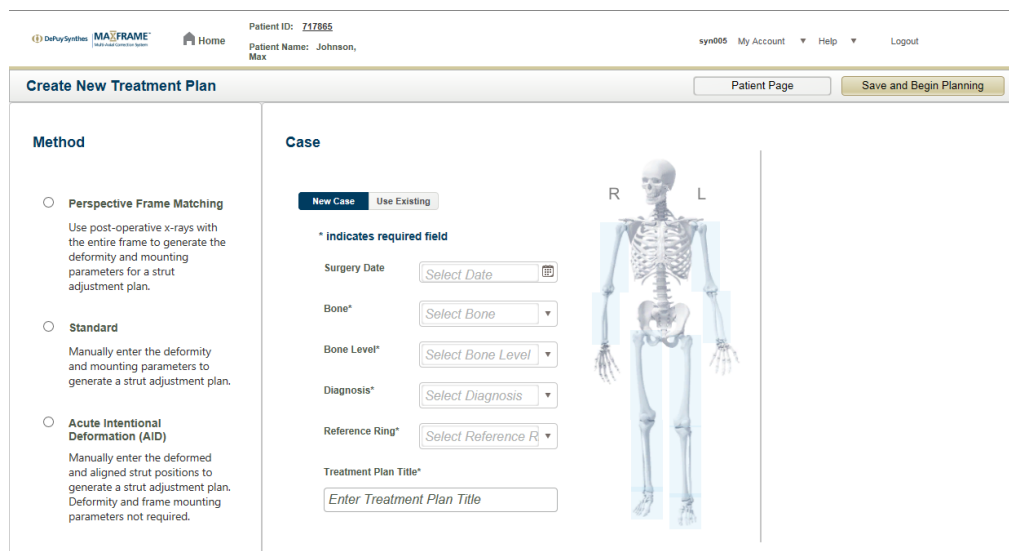


Figure 40 – Create New Treatment Plan view.

5.3.2 Select Treatment Planning Method

In the left pane titled **Method**, select the treatment planning method. The *MAXFRAME 3D 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 7 from page 60).

Standard

The Standard planning method allows you to manually enter the deformity and mounting parameters to generate a strut adjustment plan (refer to chapter 6 from page 52).

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 from page 82).

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 case. If you choose to create a new case, the system asks all the parameters required, including operating bone, diagnosis, and the selection of the reference ring.

Enter the following parameters:

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.

Bone

Select the operating bone 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 operating bone.

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.

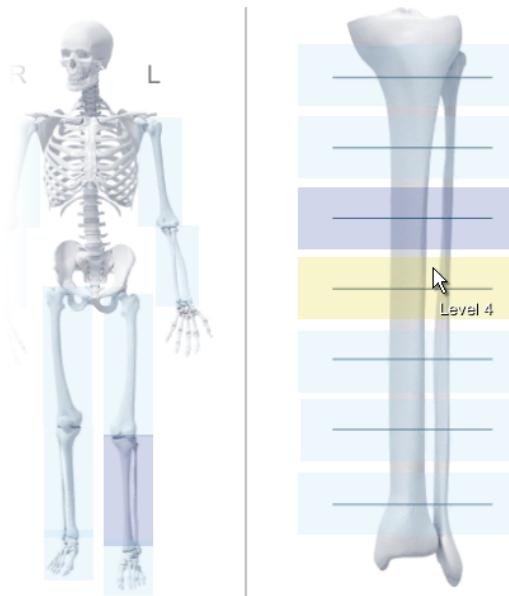


Figure 41 – The Bone Level.

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).

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.

AO Fracture Classification

If the diagnosis is **Fracture** you can 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.

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.

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

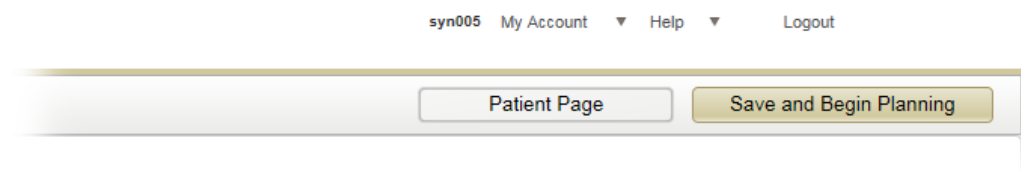


Figure 42 – **Save and Begin Planning**.

5.4 Enter Planning Parameters

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

Standard

Figure 43 – Steps—Standard planning method.

For detailed information on the Standard planning method, refer to chapter 6 from page 52.

Perspective Frame Matching (PFM)

Figure 44 – Steps—PFM.

For detailed information on the PFM planning method, refer to chapter 7 from page 60.

Acute Intentional Deformation (AID)

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



Figure 45 – Steps—AID planning method.

For detailed information on the AID planning method, refer to chapter 8 from page 82.

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 46).
3. Configure and Review Strut Adjustment Plan (section 5.5.3 on page 47).
4. Review and Adjust Strut Swap Dates (section 5.5.4 on page 49).
5. Approve treatment plan (section 5.5.5 on page 50).

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.

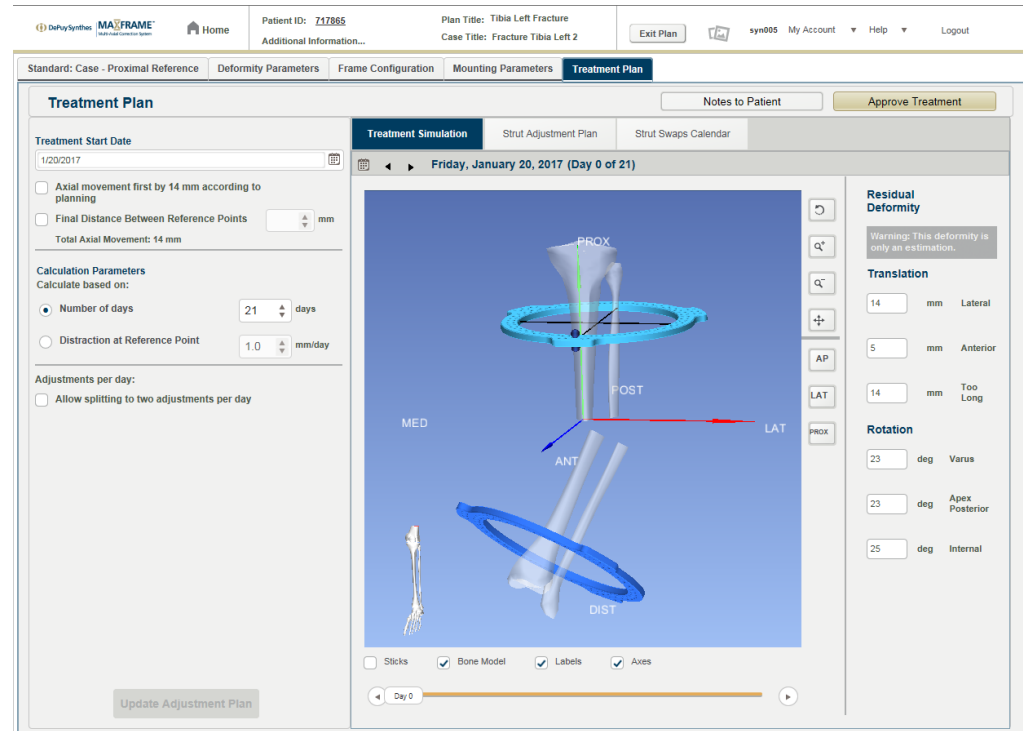


Figure 46 – **Treatment Plan** tab.

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.

Axial Movement Only

Check the option **Axial Movement Only** to split the treatment plan into two phases, where only the axial movement (distracting/lengthening or compressing along the proximal fragment axis) is performed first and the angulation or translation correction of the deformity is performed subsequently.

Final Distance Between Reference Points

Check the option **Final Distance Between Reference Points** to lengthen the bone additionally. Enter the desired additional length in millimeters (mm). The entered additional length is over and above the **Bone Length** value found on the **Deformity Parameters** tab.

Notes:

- The maximum amount of additional lengthening allowed is 30 mm.
- Additional lengthening will not be compensated in the end of the treatment. To compensate additional lengthening, an additional treatment plan is needed.

- The residual deformity (values on the right side of the view) is always calculated with respect to the additional lengthening.

The additional length will be added to the axial movement that's been entered as part of the deformity and displayed as **Total Axial Movement**.

Axial Movement Only

If you have selected the option **Axial Movement Only**, then select in this area the planning method for the first phase of the treatment plan, the axial movement. There are three options:

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

Warning: A warning message is displayed if the number of days is greater than 300 days (cf. figure 47).

Figure 47 – Warning the number of days is greater than 300 days.

Warning: When generating a treatment plan, a warning will be displayed if the distraction rate is below 0.5 mm or greater than 1.0 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 distraction rate.

- **Distraction at Reference Point:** Select this option to define the distraction/compression rate for the axial movement at the reference point. This option is the default method with a distraction/compression rate of 1.0 mm/day.

Warning: A warning message is displayed if the entered rate is lower than 0.5 mm/day (cf. figure 48) or greater than 1.0 mm/day (cf. figure 49).

Figure 48 – Warning that the distraction/compression rate is less than 0.5 mm/day.

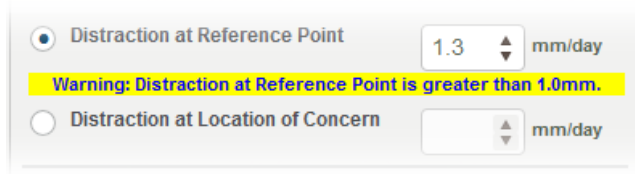


Figure 49 – Warning that the distraction/compression rate is greater than 1.0 mm/day.

Warning: A warning message is displayed if the treatment plan cannot be calculated with a distraction/compression rate of ± 0.2 mm/day from the given nominal value.

- **Distraction at Location of Concern:** If you have defined a *location of concern* (LOC), you can select this option to define the distraction/compression rate for the axial movement at this location of concern.

Warning: A warning message is displayed if the entered rate is lower than 0.5 mm/day (cf. figure 50) or greater than 1.0 mm/day (cf. figure 51).

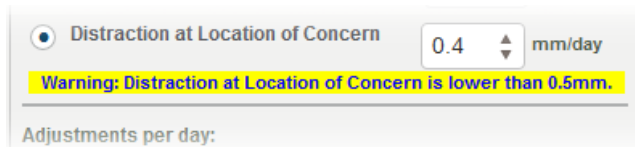


Figure 50 – Warning that the distraction/compression rate at the LOC is less than 0.5 mm/day.

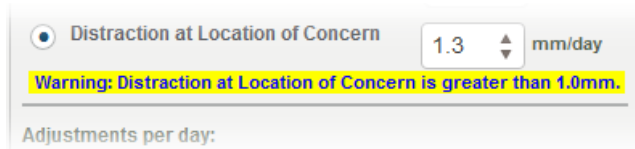


Figure 51 – Warning that the distraction/compression rate at the LOC is greater than 1.0 mm/day.

Deformity Correction

Select the planning method for the deformity correction. There are three options:

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

Warning: A warning message is displayed if the number of days is greater than 300 days (cf. figure 47 on page 43).

Warning: When generating a treatment plan, a warning will be displayed if the distraction rate is below 0.5 mm or greater than 1.0 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 distraction rate.

- **Movement at Reference Point:** Select this option to define the movement rate at the reference point. This option is the default method with a movement rate of 1.0 mm/day.

Warning: When generating a treatment plan, a warning will be displayed if the movement rate is below 0.5 mm or greater than 1.0 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 distraction rate.

The screenshot shows a software interface with two radio button options. The first option, 'Movement at Reference Point', is selected and has a value of 0.4 mm/day. A yellow warning banner is displayed below it, stating 'Warning: Movement at Reference Point is lower than 0.5mm.' The second option, 'Distraction at Location of Concern', is unselected and has a value of 0 mm/day.

Figure 52 – Warning that the movement rate is less than 0.5 mm/day.

The screenshot shows the same software interface. The 'Movement at Reference Point' option is selected with a value of 1.4 mm/day. A yellow warning banner is displayed below it, stating 'Warning: Movement at Reference Point is greater than 1.0mm.' The 'Distraction at Location of Concern' option remains unselected with a value of 0 mm/day.

Figure 53 – Warning that the movement rate is greater than 1.0 mm/day.

Warning: A warning message is displayed if the treatment plan cannot be calculated with a distraction/compression rate of ± 0.2 mm/day from the given nominal value.

- **Distraction at Location of Concern:** If you have defined a *location of concern*, you can select this option to define the distraction/compression rate for the axial movement at this location of concern.

Warning: A warning message is displayed if the entered rate is lower than 0.5 mm/day (cf. figure 50 on page 44) or greater than 1.0 mm/day (cf. figure 51 on page 44).

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 47).

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 **Create 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.

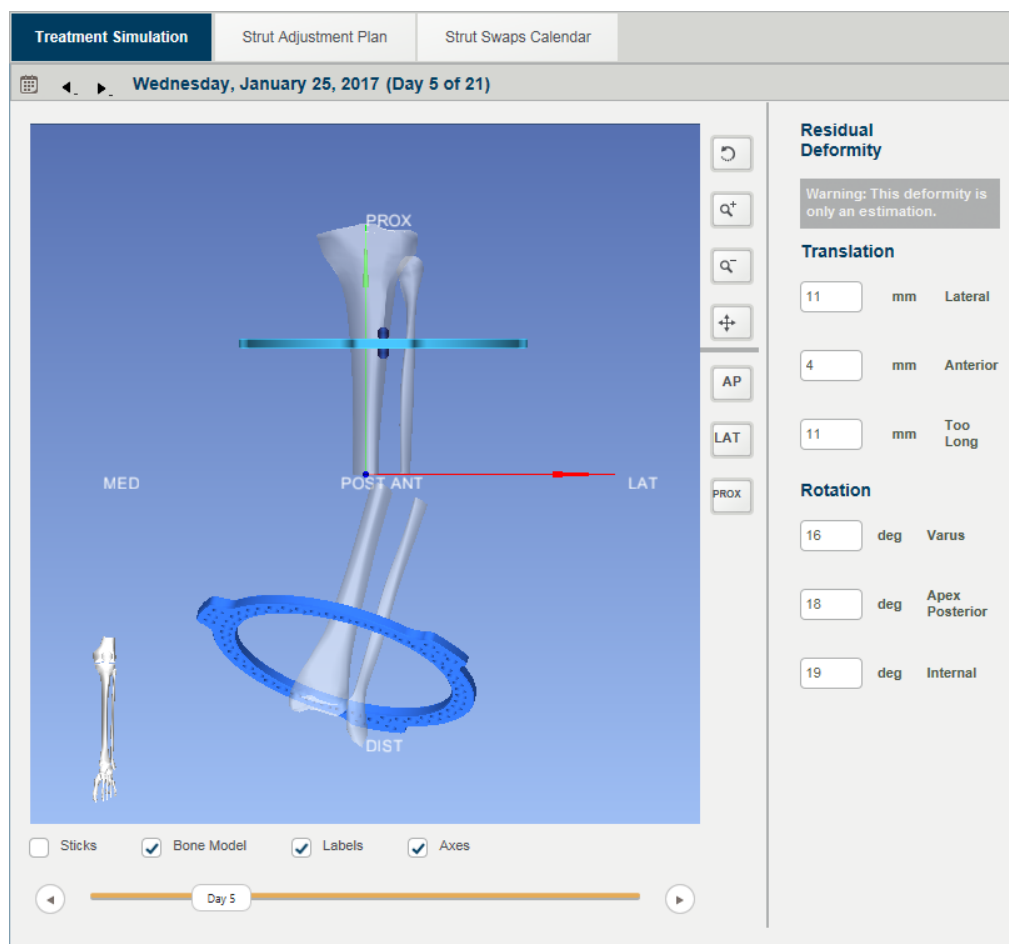


Figure 54 – Treatment Plan Simulation

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.

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 right 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**, and **Axes** in the preview. Check or uncheck the corresponding check boxes below the model. By default, only **Sticks**, **Labels**, and **Axes** are active and displayed in the preview.

Warning: Bone models are only intended to be used for simulation purposes. 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 right pane of the **Treatment Simulation** subtab under **Residual Deformity**, cf. figure 55).



Figure 55 – 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.

Standard: Case - Proximal Reference Deformity Parameters Frame Configuration Mounting Parameters **Treatment Plan**

Treatment Start Date: 1/20/2017

Calculation Parameters: Calculate based on: Number of days (21 days) Distraction at Reference Point (1.0 mm/day)

Adjustments per day: Allow splitting to two adjustments per day

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)
Day 0	Fri 1/20/2017	210	204	288	297	290	204
Day 1	Sat 1/21/2017	211	205	286	▲ 294	288	206
Day 2	Sun 1/22/2017	212	206	284	▲ 291	286	207
Day 3	Mon 1/23/2017	213	207	▲ 281	▲ 289	▲ 283	208
Day 4	Tue 1/24/2017	214	209	▲ 279	▲ 286	▲ 281	211
Day 5	Wed 1/25/2017	214	210	▲ 276	▲ 283	▲ 278	212
Day 6	Thu 1/26/2017	215	211	▲ 274	▲ 280	▲ 276	214
Day 7	Fri 1/27/2017	216	211	▲ 271	▲ 277	▲ 273	215
Day 8	Sat 1/28/2017	217	212	▲ 268	▲ 275	▲ 271	217
Day 9	Sun 1/29/2017	218	213	▲ 265	▲ 272	▲ 268	218
Day 10	Mon 1/30/2017	219	214	▲ 262	▲ 269	▲ 265	219
Day 11	Tue 1/31/2017	220	215	▲ 259	▲ 266	▲ 263	220
Day 12	Wed 2/1/2017	221	216	▲ 256	▲ 264	▲ 260	222
Day 13	Thu 2/2/2017	222	216	▲ 253	▲ 261	▲ 257	223
Day 14	Fri 2/3/2017	223	217	▲ 250	▲ 258	▲ 254	224

Figure 56 – 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 as **Day 0**.

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)
Day 0	Fri 1/20/2017	210	204	288	297	290	204
Day 1	Sat 1/21/2017	211	205	286	▲ 294	288	206
Day 2	Sun 1/22/2017	212	206	284	▲ 291	286	207

Figure 57 – 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 = 3mm)

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 distraction 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.

The screenshot shows the MA3FRAME software interface. At the top, there is a navigation bar with 'Home', 'Patient ID: 717865', 'Plan Title: Tibia Left Fracture', and 'Case Title: Fracture Tibia Left 2'. Below this is a 'Treatment Plan' tab with sub-tabs for 'Treatment Simulation', 'Strut Adjustment Plan', and 'Strut Swaps Calendar'. The 'Strut Swaps Calendar' is active, showing a calendar for January 2017. The calendar has columns for days of the week (Sun to Sat) and rows for dates (8 to 11). Colored bars indicate recommended date ranges for strut swaps: orange for S2: M (QA) → L (QA) and purple for S6: M (QA) → L (QA). A 'Start' button is visible on the 20th, and an 'End' button is on the 10th. The left sidebar contains 'Treatment Start Date' (1/20/2017), 'Axial movement first by 14 mm according to planning', 'Final Distance Between Reference Points' (0 mm), 'Calculation Parameters' (Number of days: 21, Distraction at Reference Point: 1.0 mm/day), and 'Adjustments per day' (Allow splitting to two adjustments per day: unchecked). An 'Update Adjustment Plan' button is at the bottom of the sidebar.

Figure 58 – 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 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 59). The electronic signature requires that you review and approve the treatment plan and the patient selected for correctness.

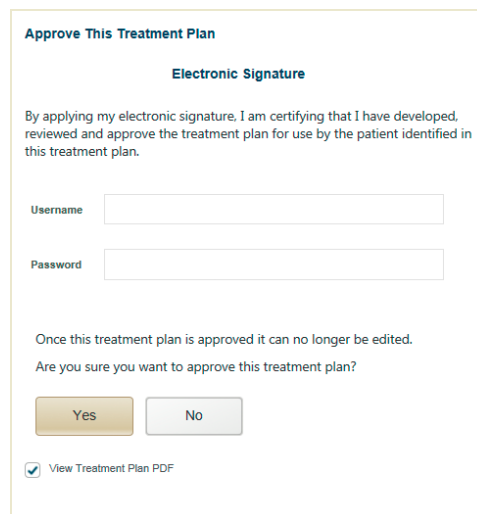


Figure 59 – **Electronic Signature** pop-up window

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 102 for more information).

5.5.6 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.

Strut Adjustment Instructions

DePuySynthes

Patient name: Lisa Green
 Surgeon name: Carol White
 Surgeon's Phone Number: (555) 205-4500
 Case: Fracture Femur Left
 Treatment: Tibia Left Prox
 Approved: Thursday, January 19, 2017 2:29:21 PM

Date	Day	Strut Swap	Strut 1	Strut 2	Strut 3	Strut 4	Strut 5	Strut 6
Initial			210*	204*	208	207	205	204
1/20/2017	1	<input type="checkbox"/>	211	205	208	206	203	205
1/21/2017	2	<input type="checkbox"/>	212	207	207	204	203	205
1/22/2017	3	<input type="checkbox"/>	213	206	207	203	203	205
1/23/2017	4	<input type="checkbox"/>	215	207	206	203	207	207
1/24/2017	5	<input type="checkbox"/>	217	207	205	203	205	208
1/25/2017	6	<input type="checkbox"/>	218	208	205	203	206	208
1/26/2017		<input type="checkbox"/>	219	205	204	203	205	209
1/27/2017		<input type="checkbox"/>	220	206	203	203	204	209
1/28/2017		<input type="checkbox"/>	221	207	203	202	203	210
1/29/2017		<input type="checkbox"/>	222	210	202	200	203	210
1/30/2017		<input type="checkbox"/>	223	210	202	200	202	211

Generated Thursday, January 19, 2017 2:29:21 PM EST page 1 of 5

Strut Adjustment Instructions

DePuySynthes

Patient name: Lisa Green
 Case: Fracture Femur Left
 Treatment: Tibia Left Prox

Strut Changes

Changed	Strut	Change date range	From strut	To strut
	Strut 1	1/19/2017	Medium (GA)	Long (GA)
	Strut 2	1/19/2017	Medium (GA)	Long (GA)

Generated Thursday, January 19, 2017 2:29:21 PM EST page 4 of 5

Strut Adjustment Instructions

DePuySynthes

Patient name: Lisa Green
 Case: Fracture Femur Left
 Treatment: Tibia Left Prox

Notes to Patient

Generated Thursday, January 19, 2017 2:29:21 PM EST page 5 of 5

Figure 60 – Strut Adjustment Instructions

Strut adjustment instructions contain the following information:

1. Information about patient, surgeon, case, and treatment plan.
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 dates.
5. Notes to the patient.

Warning: You should review the strut adjustment instructions for correctness and completeness prior to providing the instructions to the patient.

6 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 from page 36.

6.1 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.

6.2 Steps



Figure 61 – Steps—Standard planning method.

6.3 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.

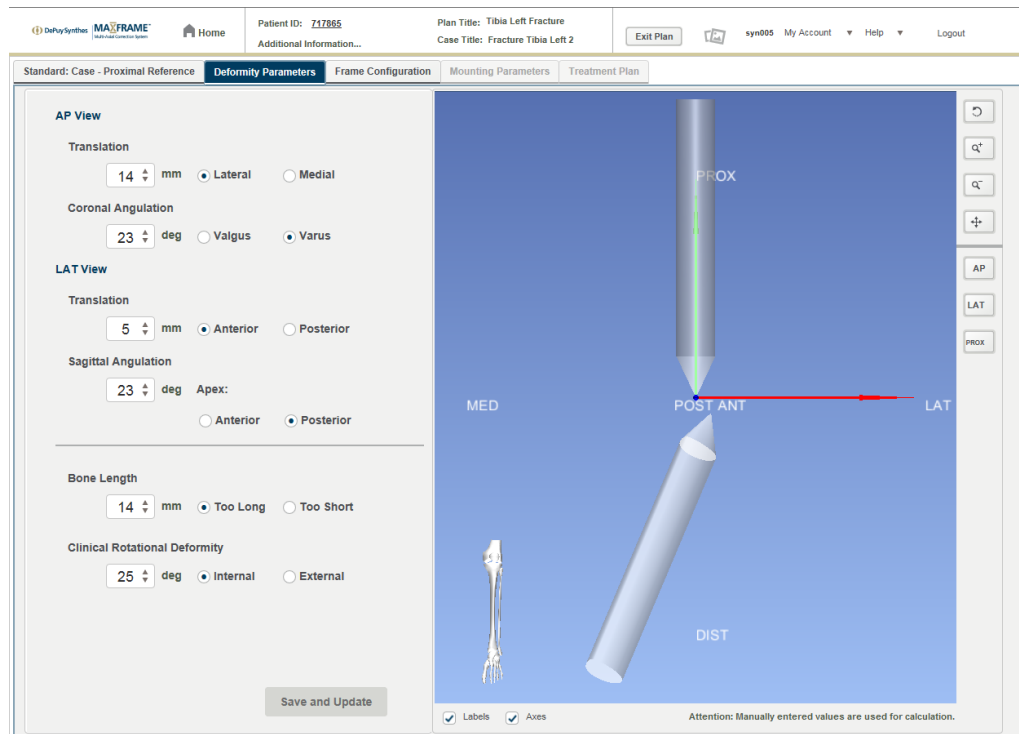


Figure 62 – Deformity Parameters.

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). If the value is zero, enter "0".

AP View—Coronal Angulation

Enter the *coronal angulation* value in degrees and specify the direction (valgus or varus). If the value is zero, enter "0".

LAT View—Translation

Enter the *lateral translation* value in millimeters (mm) and specify the direction (anterior or posterior). If the value is zero, enter "0".

LAT View—Sagittal Angulation

Enter the *sagittal angulation* value in degrees and specify the direction (anterior or posterior). If the value is zero, enter "0".

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. If the value is zero, enter "0".

Clinical Rotational Deformity

Enter the *clinical rotational deformity* value in degrees and specify the direction (internal or external). If the value is zero, enter "0".

Note: The directional field radio buttons are disabled when the corresponding field value is zero.

To save the parameters and proceed, click the **Save and Update** button. The rendering area will only be updated after all required parameters have been completed.

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 below the model. To rotate the model, zoom, or pan, use the mouse (cf. section 4.2.4.2.1 "Mouse control" on page 35) 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 35).

The preview area displays the *direction reference bone* in its lower left corner to provide confirmation (cf. section 4.2.4.1 on page 34).

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

6.4 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.

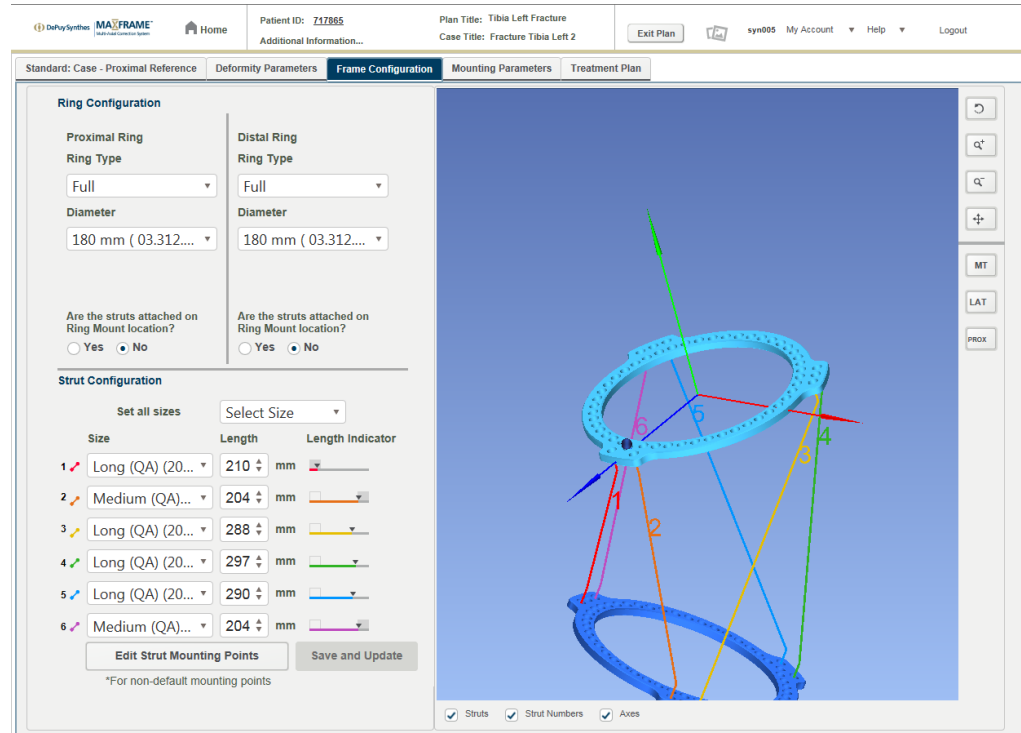


Figure 63 – Frame Configuration.

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* or *5/8*.

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) 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 2.4 “Hardware” on page 10.
- **Are the struts attached on Ring Mount location:** If you have selected **Full** as the ring type, then specify whether the struts are mounted on this ring on inner holes (**Yes**) or not (**No**). Default is **No**.

Note: Only one ring (proximal or distal) per frame shall allow struts mounted on ring mount holes between the tabs.

- **Opening (5/8 Ring):** If you have selected **5/8** as the ring type, then specify additionally 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.
- **Are the struts attached on Ring Mount location:** If you have selected *Full* as the ring type, then specify whether the struts are mounted on this ring on inner holes (**Yes**) or not (**No**). Default is **No**.
- **Opening (5/8 Ring):** If you have selected *5/8* as the ring type, then specify additionally 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, an error message will be displayed and you will not be able to update the preview area.

The colored **Length Indicators** display for each strut 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 64).

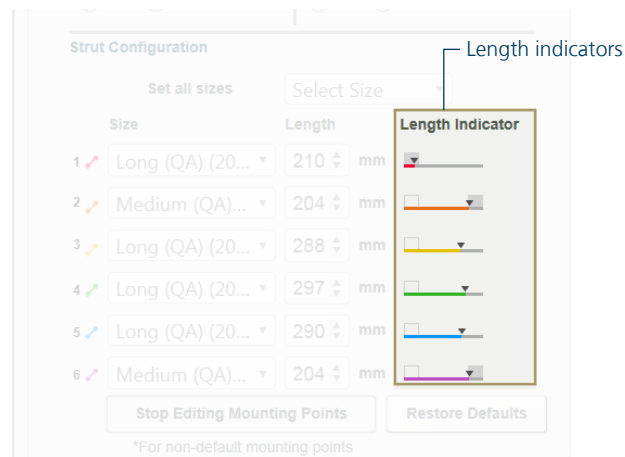


Figure 64 – Frame Configuration—Strut length indicators.

Strut Mounting Points

For detailed information on editing the default strut mounting points, refer to section 9.1 on page 88.

For saving your entered data and updating the preview, click **Save and Update**.

If you want to hide **Struts**, **Strut Numbers**, or **Axes** in the preview, uncheck their corresponding check boxes below the model in the preview area. 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.

6.5 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 92 for more information.

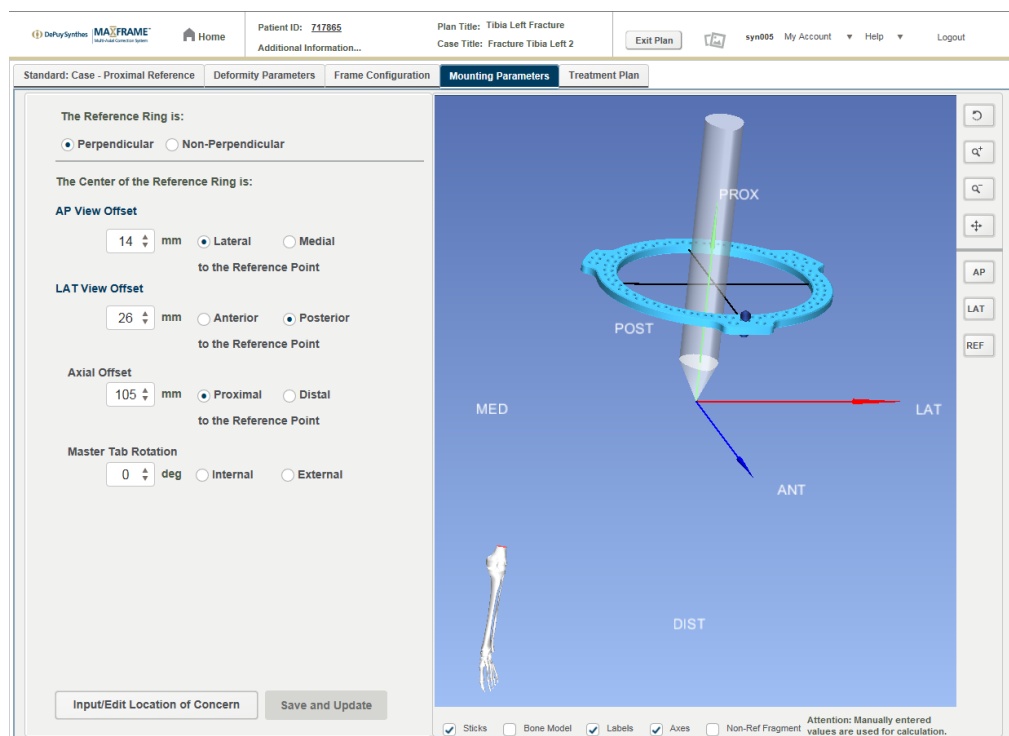


Figure 65 – Mounting Parameters.

Note: The directional field radio buttons are disabled when the corresponding field value is zero.

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.

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). If the value is zero, enter "0".

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). If the value is zero, enter "0".

LAT View Offset

Enter the *lateral offset value* in millimeters (mm) and specify the direction (anterior or posterior). If the value is zero, enter "0".

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). If the value is zero, enter "0".

LAT View Offset—Axial Offset

Enter the *axial offset value* in millimeters (mm) and specify the direction (proximal or distal). If the value is zero, enter “0”.

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). If the value is zero, enter “0”.

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

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 89.

For saving your entered data and updating 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. By default, only **Sticks**, **Labels**, and **Axes** are active and displayed in the preview.

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 41).

7 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 from page 36.

7.1 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 110.
2. The Clinical Rotational Deformity parameter must be known.
3. The frame configuration parameters (rings and struts) 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.

7.2 Steps



Figure 66 – Steps—PFM planning method.

7.3 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.

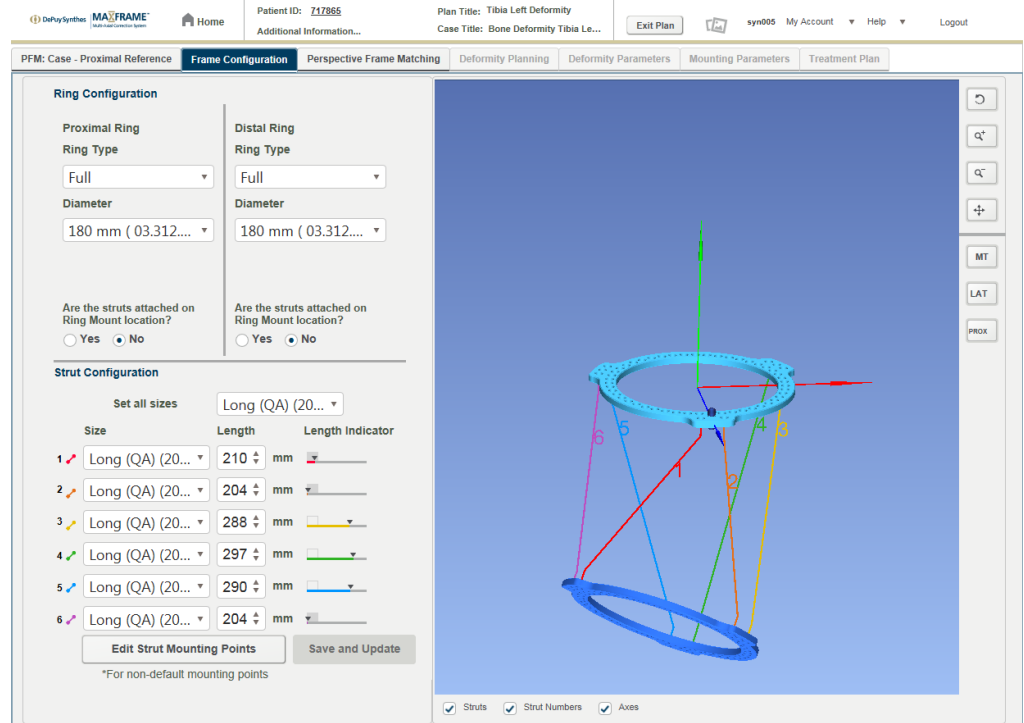


Figure 67 – PFM—Frame Configuration

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* or *5/8*.

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) 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 2.4 “Hardware” on page 10.
- **Are the struts attached on Ring Mount location:** If you have selected *Full* as the ring type, then specify whether the struts are mounted on this ring on inner holes (**Yes**) or not (**No**). Default is **No**.

Note: Only one ring (proximal or distal) per frame shall allow struts mounted on ring mount holes between the tabs.

- **Opening (5/8 Ring):** If you have selected *5/8* as the ring type, then specify additionally 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.
- **Are the struts attached on Ring Mount location:** If you have selected **Full** as the ring type, then specify whether the struts are mounted on this ring on inner holes (**Yes**) or not (**No**). Default is **No**.
- **Opening (5/8 Ring):** If you have selected **5/8** as the ring type, then specify additionally 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* 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, an error message will be displayed and you will not be able to update the preview area.

The colored **Length Indicators** display for each strut 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 64 on page 57).

Strut Mounting Points

For detailed information on editing the default strut mounting points, refer to section 9.1 on page 88.

For saving your entered data and updating the preview, click **Save and Update**.

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.

7.4 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:

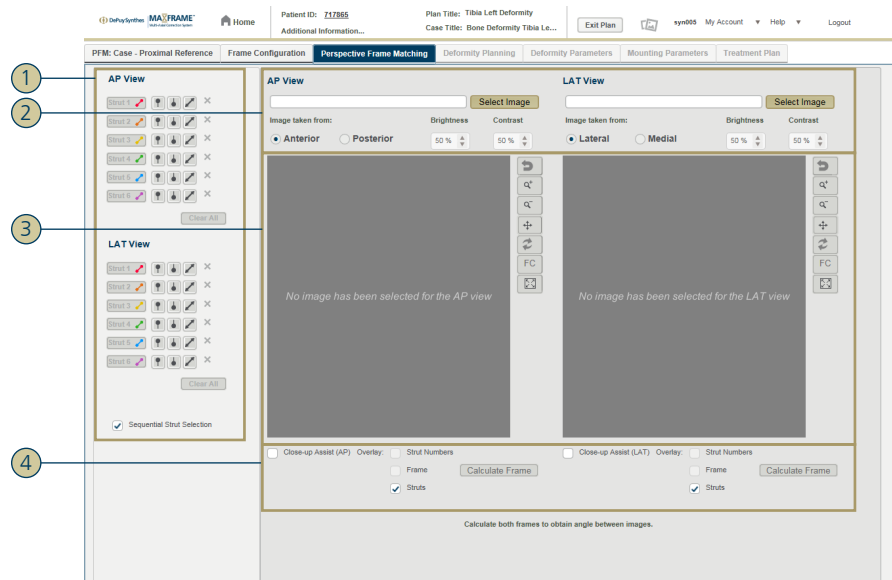


Figure 68 – PFM—Overview

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

1. Strut and hinges selection buttons for AP and LAT.
2. Image selectors and parameters for AP and LAT.
3. Matching views for AP and LAT.
4. Options for AP and LAT view.

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

7.4.1 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 **Select Image** for AP view. The following dialog opens:

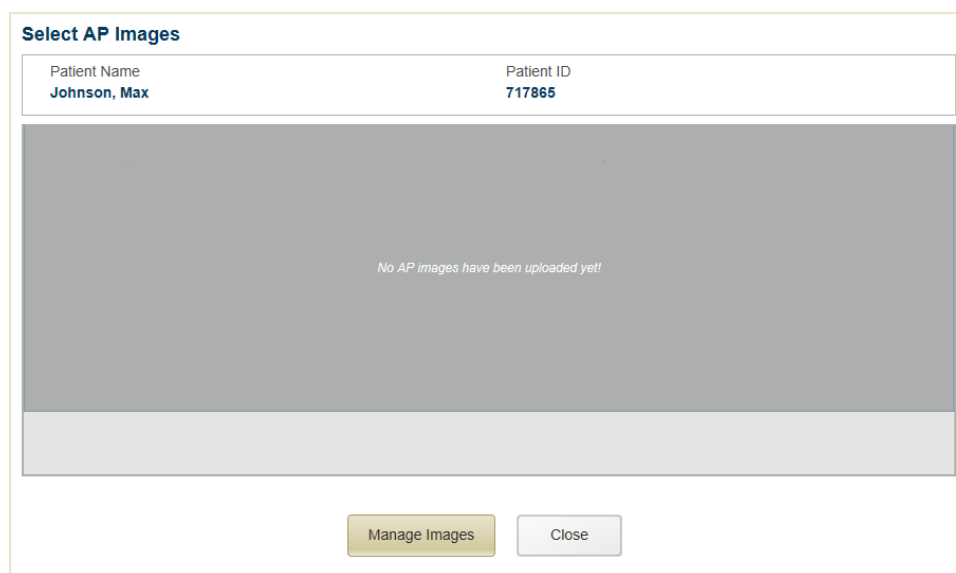


Figure 69 – PFM—Select Image—Initial Dialog

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:

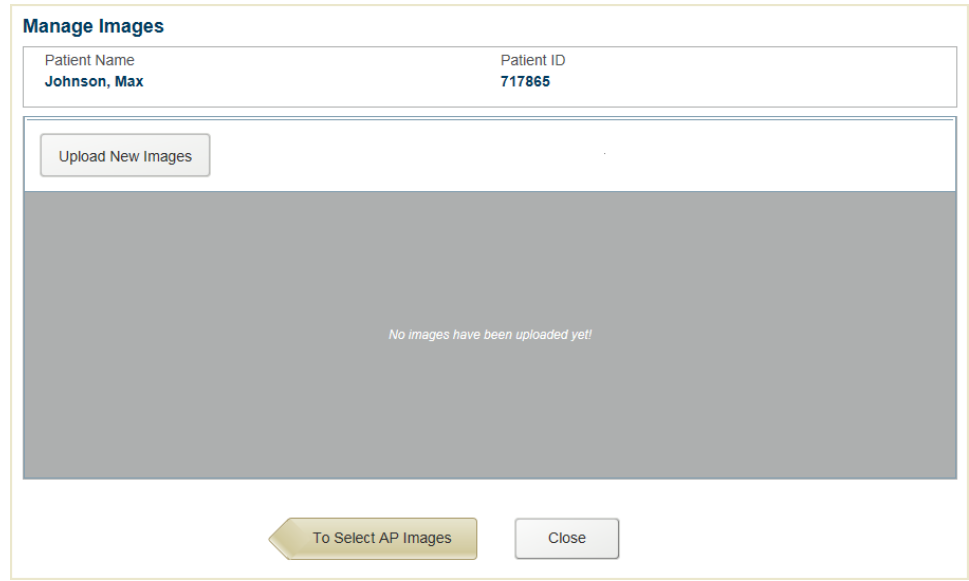


Figure 70 – PFM—Select Image—Image Manager

Note: For a full description on uploading and reviewing images using the **Image Manager**, refer to chapter 12 from page 110.

3. Click **Upload New Images** and select the AP and LAT x-ray image files to be uploaded (cf. section 12.4 on page 112).
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.

When you've uploaded the x-ray images and set the image tags, the **Image Manager** looks similar to the following dialog:

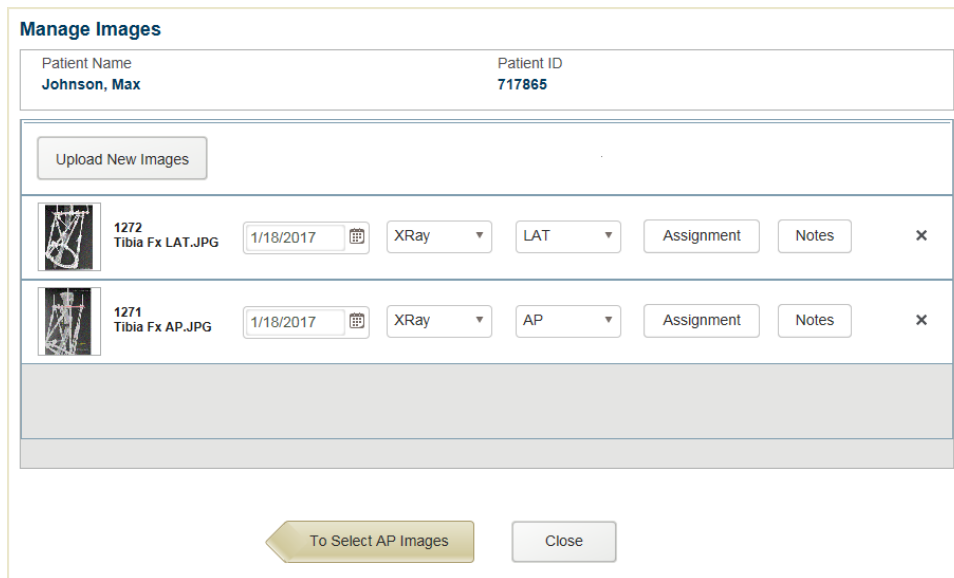


Figure 71 – PFM—Select Image—Image Manager with uploaded x-ray images

5. Click **To Select AP Images**. The **Select AP Images** dialog opens, containing the AP x-ray image:

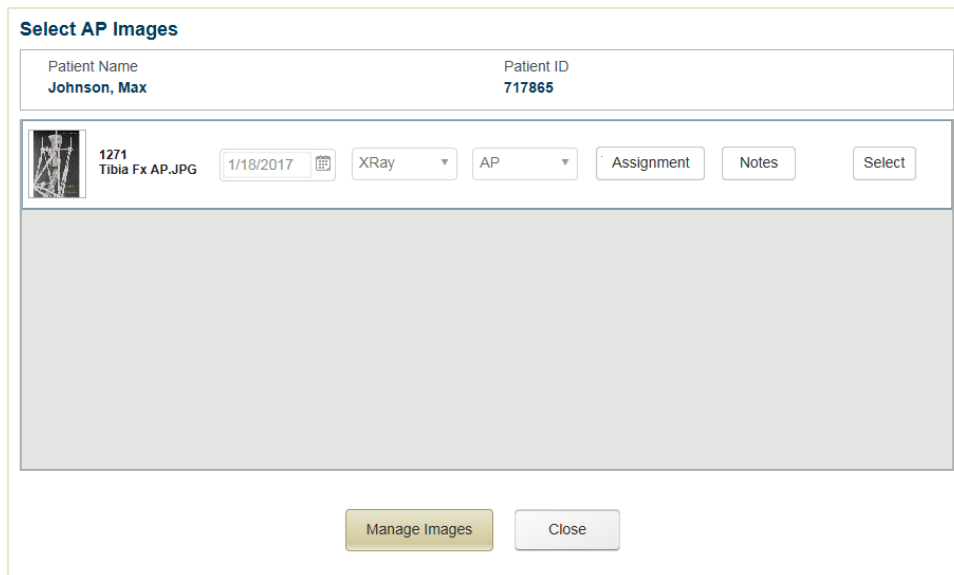


Figure 72 – PFM—Select Image—Select AP Images

6. 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. [1] in figure 68 on page 63 for the AP view) are enabled.

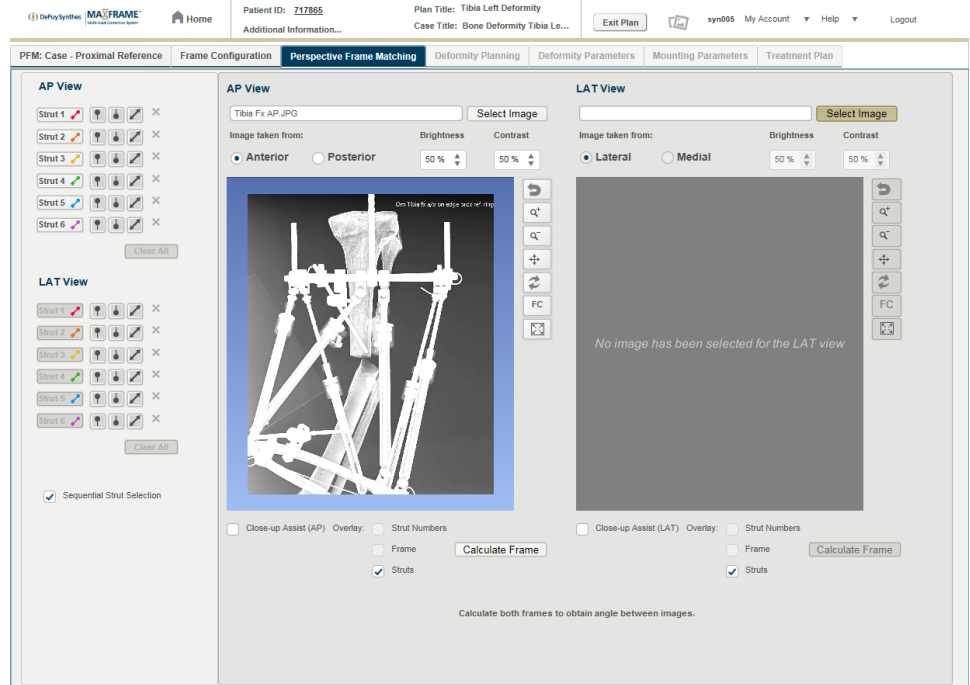


Figure 73 – PFM—**Perspective Frame Matching** with loaded AP and image file name displayed

7. Select the AP image's **Image taken from** orientation. The orientation is defaulted to **Anterior**.
8. Adjust the AP image's **Brightness** and **Contrast** if needed.
9. Select the LAT view image by clicking **Select Image** button on the right side and selecting the x-ray image in the **Select LAT Images** dialog.
10. Select the LAT image's **Image taken from** orientation. The orientation is defaulted to **Lateral**.
11. Adjust the LAT image's **Brightness** and **Contrast** if needed.

7.4.2 Mark Struts and Hinges on Images

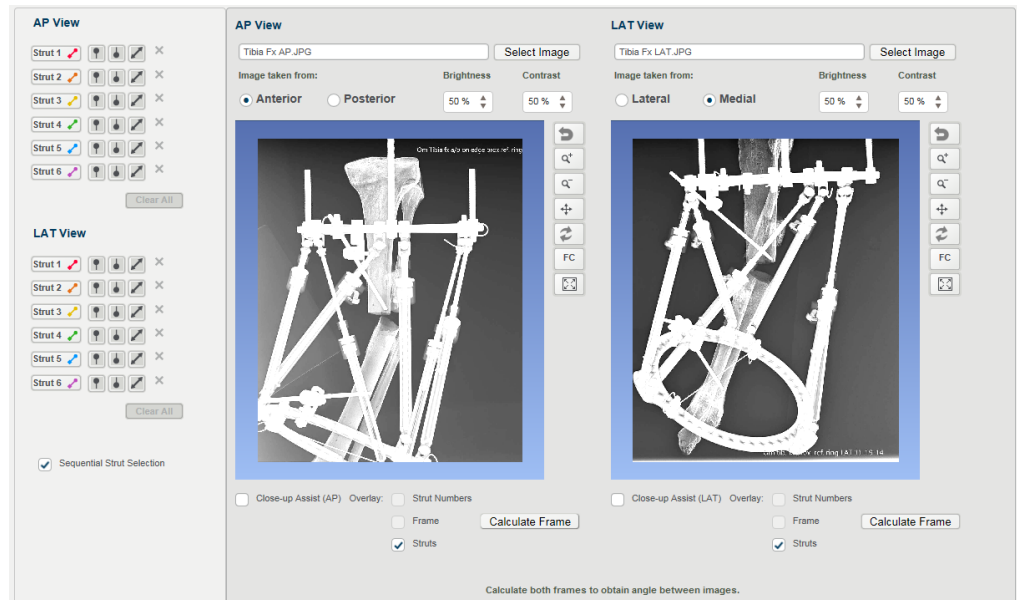


Figure 74 – PFM—AP and LAT images selected

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 75). The mouse cursor indicates the selected strut (cf. [B] in figure 75).

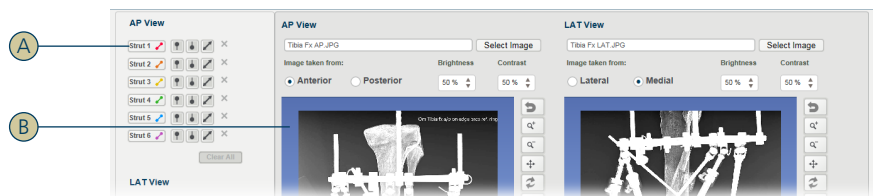


Figure 75 – PFM—Strut selection

2. Locate the proximal or distal hinge's position in the AP x-ray and click it. The selected position is marked with its associated hinge indicator and a red line to the mouse cursor indicates the strut (cf. [C] in figure 76).

Note: 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. [E] in figure 76).

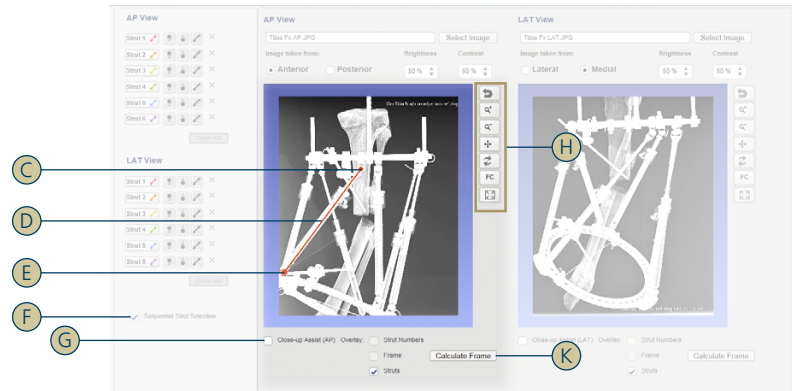


Figure 76 – PFM—Strut drawn

Note: You can deselect any of the hinge and/or strut direction icons based on your visual results (cf. section 7.4.2.1 on page 69).

4. Click a hinge and move to adjust its position. Click the strut line and move to adjust the position of the whole strut (cf. [D] in figure 76).
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 7.4.2.3 “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** (cf. [K] in figure 76) to calculate the frame model and show it on the actual x-ray image.
 7. Repeat the whole procedure for the LAT view.

7.4.2.1 Selecting Struts and Hinges for Calculation

Next to each strut selection button (cf. [A] in figure 75 on page 68), 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.

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.

7.4.2.2 Delete Strut Markers

To delete a single strut marker, click the **Delete** icon (✕) right to the corresponding strut selection button (cf. [C] in figure 76 on page 69).

To delete all strut markers in a view, click **Clear All** below the strut selection buttons of the corresponding view.

7.4.2.3 Sequential Strut Selection

Select the option **Sequential Strut Selection** (cf. [F] in figure 76 on page 69) to automatically select the next strut not yet drawn for the selected view (AP or LAT) after finishing drawing a strut.

7.4.2.4 Close-up Assist

The **Close-up Assist** (cf. [G] in figure 76 on page 69) 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 (cf. figure 77). You can adjust the position of the hinges directly in the close-up views.

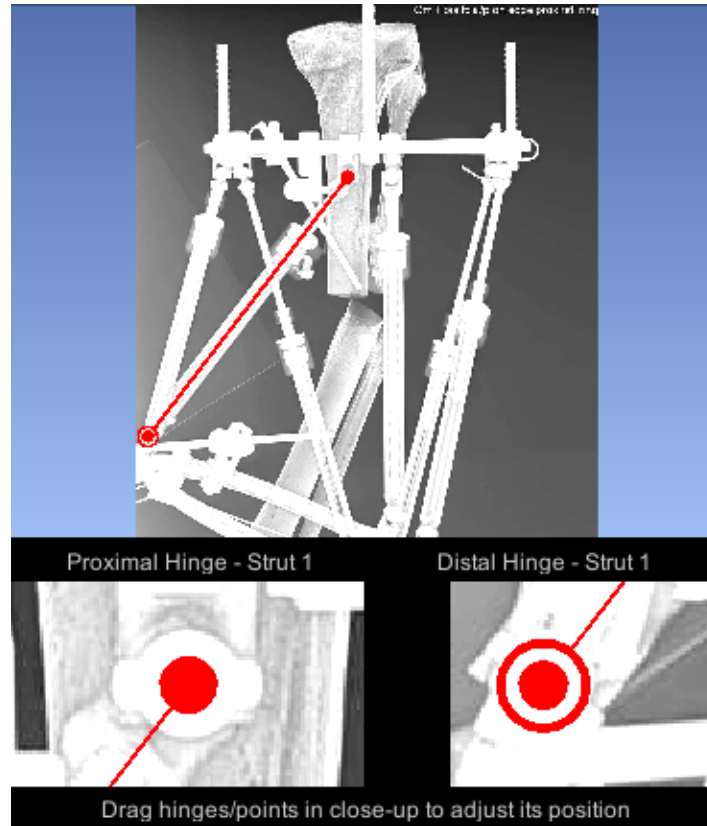


Figure 77 – PFM—Close-up Assist



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 75 on page 68). 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 7.4.2.3 on page 70) and activate the **Close-up Assist** mode, the **Sequential Strut Selection** option is automatically turned off.

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.

7.4.2.5 View Tools

The AP view and the LAT view offer the following functions in their toolbars (cf. [H] in figure 76 on page 69):

Icon	Function
	Reverses the last edit to a strut in the corresponding view.
	Zooms the image in.

Icon	Function
	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 7.4.2.6 "Display Frame Configuration Model").
	Expands the view to double width.

7.4.2.6 Display Frame Configuration Model

You can display the current frame configuration model in the respective other 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**.

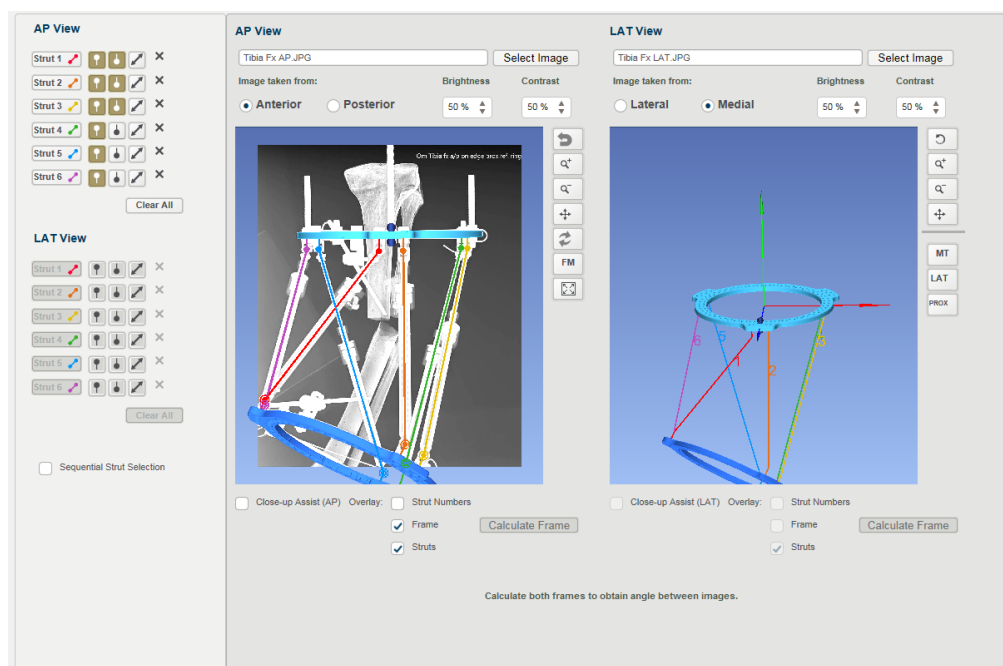


Figure 78 – PFM—Display the Frame Configuration Model.

You can rotate, zoom, and pan the frame model the same way as in the preview area (cf. section 4.2.4 "Preview Area" on page 34).

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.

7.4.3 View Options

You can display or hide **Strut Numbers**, **Frame**, and **Struts** in each view. Check or uncheck the corresponding check boxes below the model. By default, only **Struts** is active and displayed in the preview.

7.5 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 79).

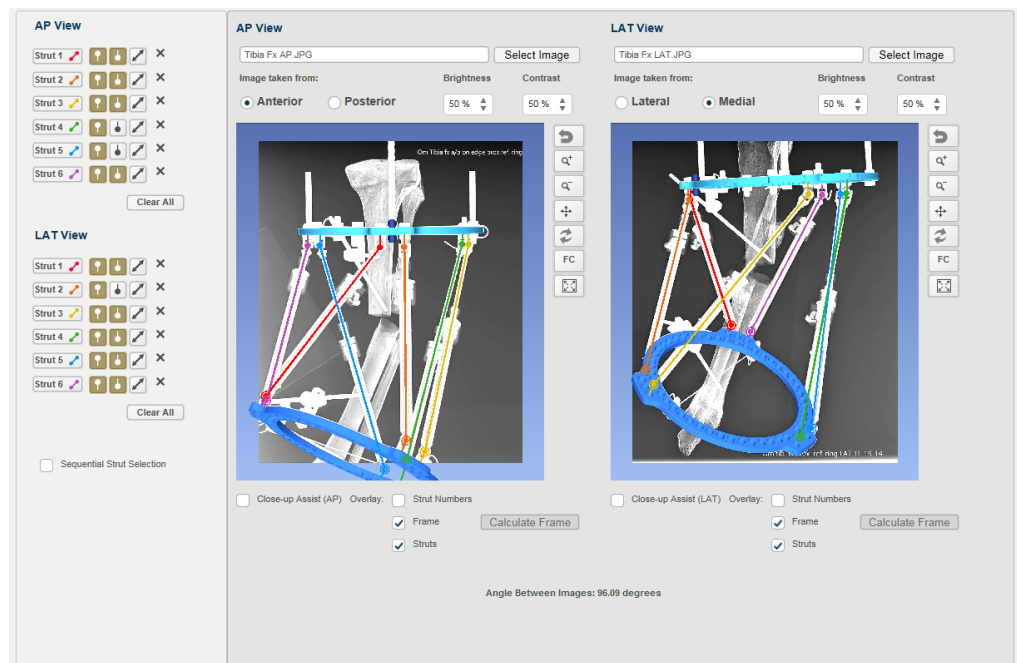


Figure 79 – PFM—Finalized matching with frames and angle between images displayed.

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.

7.6 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.

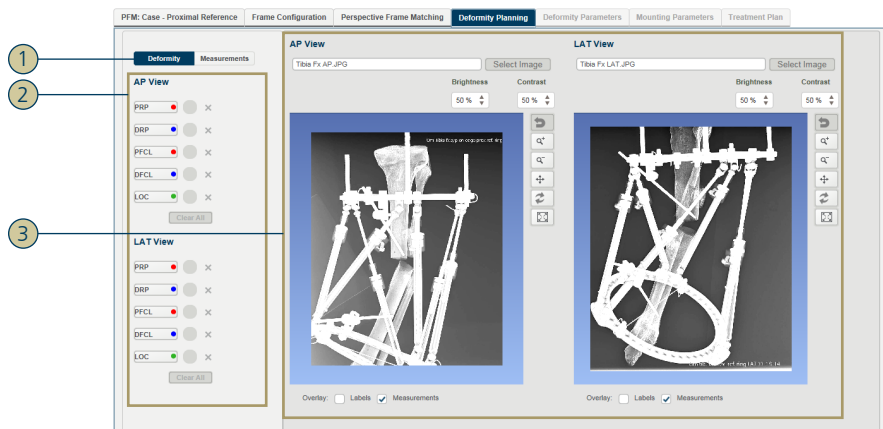


Figure 80 – PFM—Perform Deformity Planning

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

1. Marking type selector (**Deformity** or **Measurements**).
2. *Deformity elements* and *measurement tools*.
3. AP and LAT views (similar to 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.

7.6.1 Define the Deformity Parameters

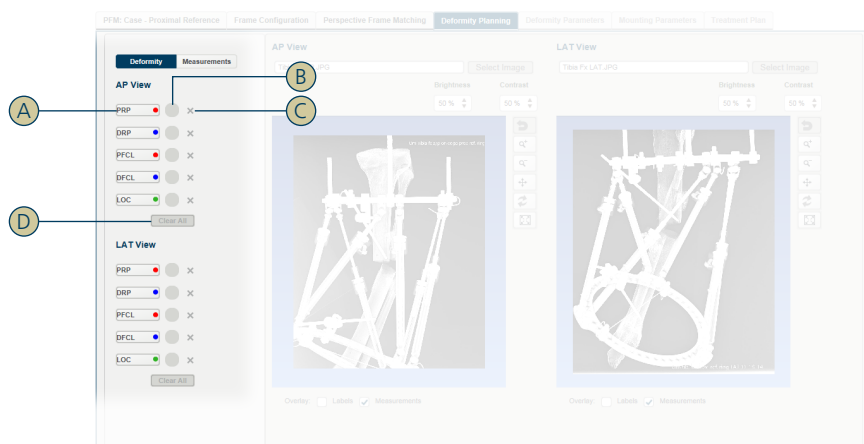


Figure 81 – PFM—Deformity Parameters

Select the following deformity parameters from the left pane (cf. [A] in figure 81) and identify their position in the AP and the LAT views:

Button	Parameter	Procedure
<input type="checkbox"/> PRP <input checked="" type="checkbox"/>	<i>Proximal Reference Point.</i>	Click the proximal reference point.
<input type="checkbox"/> DRP <input checked="" type="checkbox"/>	<i>Distal Reference Point.</i>	Click the distal reference point.
<input type="checkbox"/> PFCL <input checked="" type="checkbox"/>	<i>Proximal Fragment Center Line.</i>	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.
<input type="checkbox"/> DFCL <input checked="" type="checkbox"/>	<i>Distal Fragment Center Line.</i>	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.
<input type="checkbox"/> LOC <input checked="" type="checkbox"/>	<i>Location of Concern (LOC).</i>	Click the central position of the <i>location of concern</i> (optional).

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.

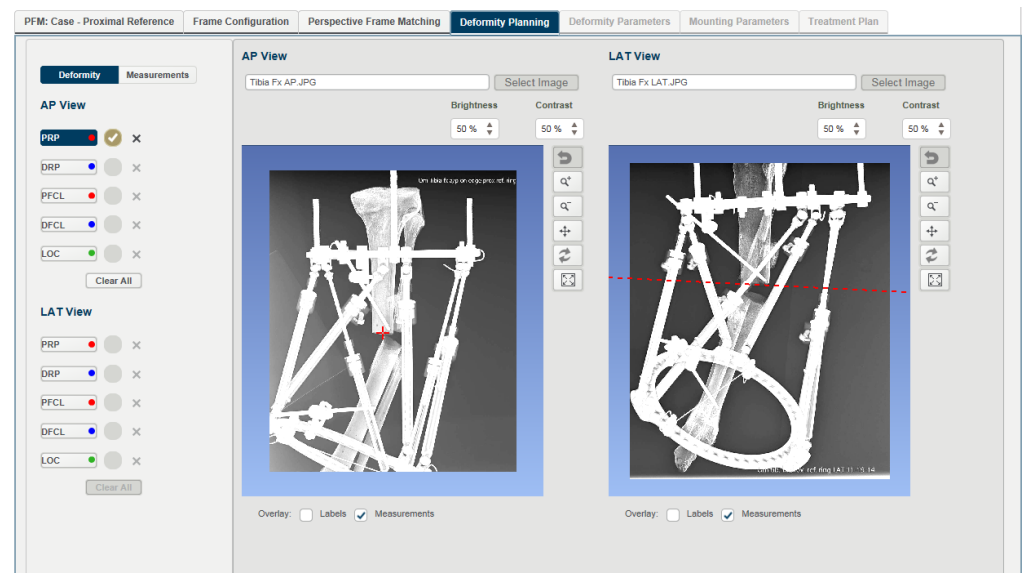


Figure 82 – PFM—dashed location guideline in the LAT view for the proximal reference point (selected in the AP view)

When a deformity parameter has been set, its corresponding **OK** icon is displayed (✓, cf. [B] in figure 81).

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 81) 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 81).

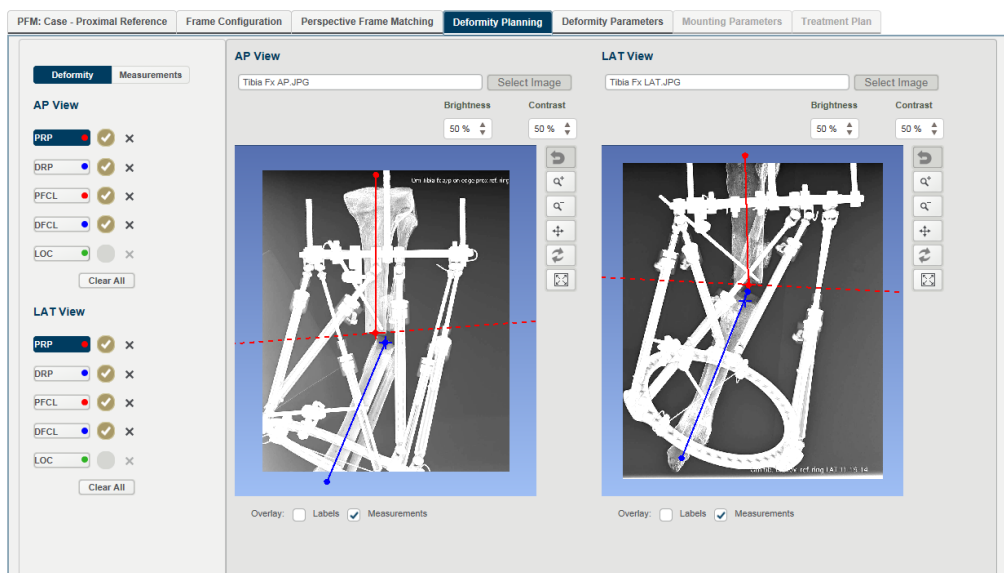


Figure 83 – PFM—deformity parameters set

7.6.2 Additional Measurement Tools

In the **Additional Measurements** view, you can add angulation measurements (**Angle**) and intersecting lines (**Four Point**).

Note: 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.

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

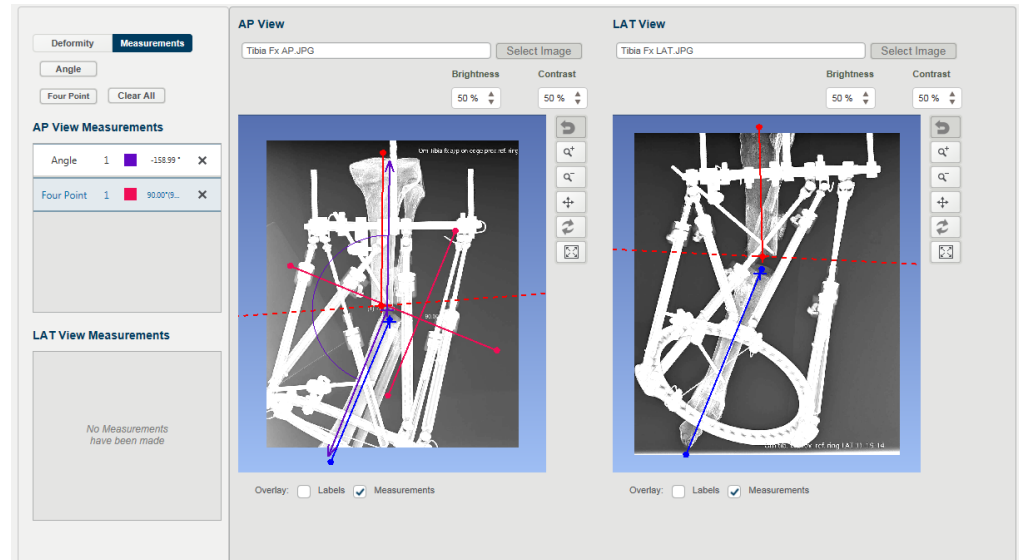


Figure 84 – PFM—Additional Measurements

For detailed information on performing additional measurements, refer to section 9.3 “Additional Measurement Tools for Deformity Planning” on page 90.

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

7.7 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 needs to be entered manually. 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) initially indicates the values, which have been calculated by frame matching and deformity planning. If you change a value, the corresponding **PFM** icon is removed and the background changes from blue to white.

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

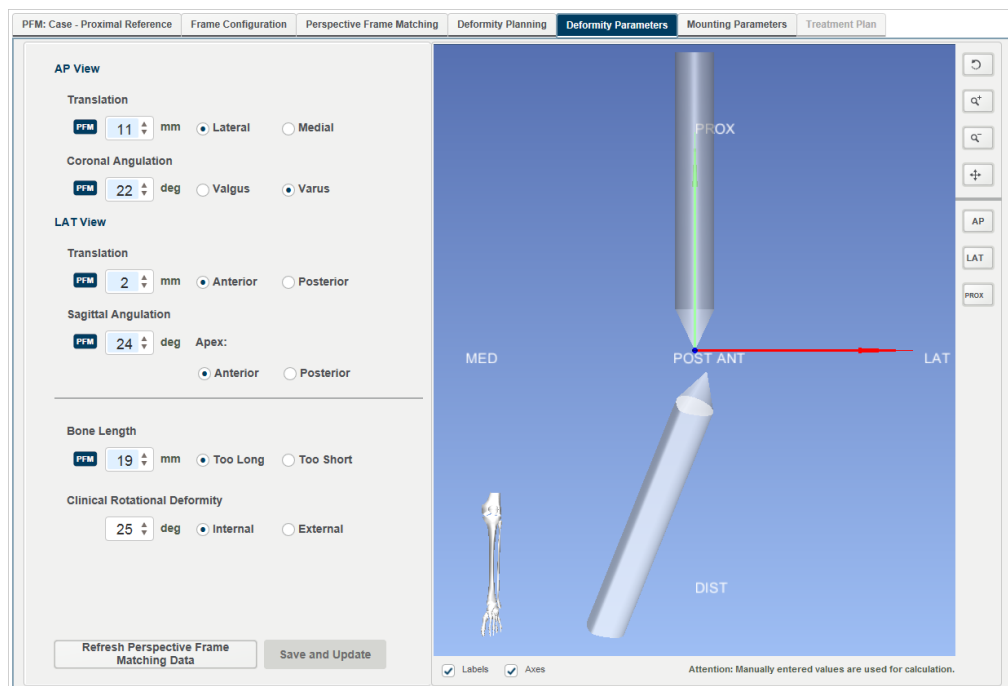


Figure 85 – PFM—Calculated Deformity Parameters.

If you select to refresh, a message will be displayed that all the values will be overwritten. You will be required to re-enter the clinical rotational deformity value.

AP View—Translation

Enter the *anteroposterior translation value* in millimeters (mm) and specify the direction (lateral or medial). If the value is zero, enter "0".

AP View—Coronal Angulation

Enter the *coronal angulation value* in degrees and specify the direction (valgus or varus). If the value is zero, enter "0".

LAT View—Translation

Enter the *lateral translation value* in millimeters (mm) and specify the direction (anterior or posterior). If the value is zero, enter "0".

LAT View—Sagittal Angulation

Enter the *sagittal angulation value* in degrees and specify the direction (anterior or posterior). If the value is zero, enter "0".

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. If the value is zero, enter "0".

Clinical Rotational Deformity

Enter the *clinical rotational deformity value* in degrees and specify the direction (internal or external). If the value is zero, enter "0".

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, a "0" needs to be entered.

Note: The directional field radio buttons are disabled when the corresponding field value is zero ("0").

For saving your entered data and updating the preview, click **Save and Update**.

After clicking **Save and Update**, the system renders a model of the deformity. If you want to display labels and axes in the model, you can do so by checking their respective check boxes below the model. To rotate the model, zoom, or pan, click on the respective buttons at the right side of preview area.


The preview area displays the *reference bone* in its lower left corner.

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

7.8 Review 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 92 for more information.

The **PFM** icon () indicates values which have been calculated by frame matching. If you change a value, the corresponding **PFM** icon is removed and the background changes from blue to white.

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

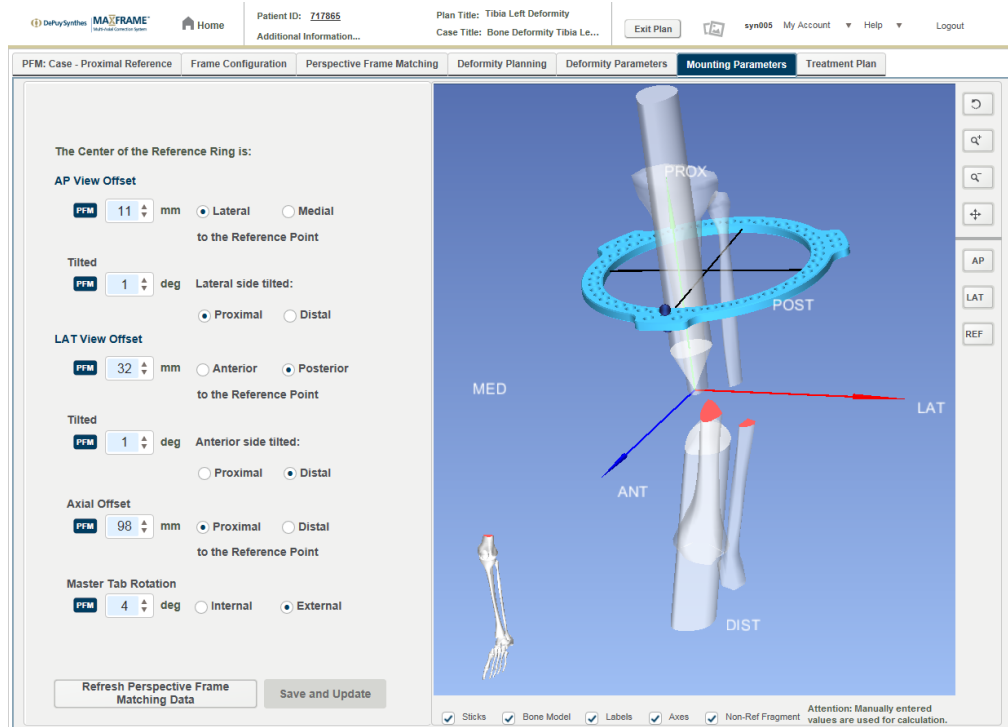


Figure 86 – PFM—Calculated Mounting Parameters.

If you select to refresh, a message will be displayed that all the values will be overwritten. You will be required to re-enter the clinical rotational deformity value.

Review and, if desired, adjust the following parameters:

AP View Offset

The *anteroposterior offset* value of the center of the reference ring with respect to the Proximal Reference Point in millimeters (mm), including the direction (lateral or medial). If the value is zero, a “0” needs to be entered.

AP View Offset—Tilted

If you have selected that the reference ring is non-perpendicular to the bone axis, the *tilt of the lateral side* in degrees, including the direction (proximal or distal). If the value is zero, a “0” needs to be entered.

LAT View Offset

The *lateral offset* value in millimeters (mm), including the direction (anterior or posterior). If the value is zero, a “0” needs to be entered.

LAT View Offset—Tilted

If you have selected that the reference ring is non-perpendicular to the bone axis, the *tilt of the anterior side* in degrees, including the direction (proximal or distal). If the value is zero, a “0” needs to be entered.

LAT View Offset—Axial Offset

The *axial offset value* in millimeters (mm), including the direction (proximal or distal). If the value is zero, a “0” needs to be entered.

LAT View Offset—Master Tab Rotation

The *rotation of the sagittal plane* of the reference ring in degrees, including the direction (internal or external). If the value is zero, a “0” needs to be entered.

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

For saving your entered data and updating 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. By default, only **Sticks**, **Labels**, and **Axes** are active and displayed in the preview.

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 41).

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 from page 36.

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, ring referencing and ring sizes are essential for the rendering of the frame in the software only.
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 87 – Steps—AID planning method.

8.3 Enter Ring Configuration

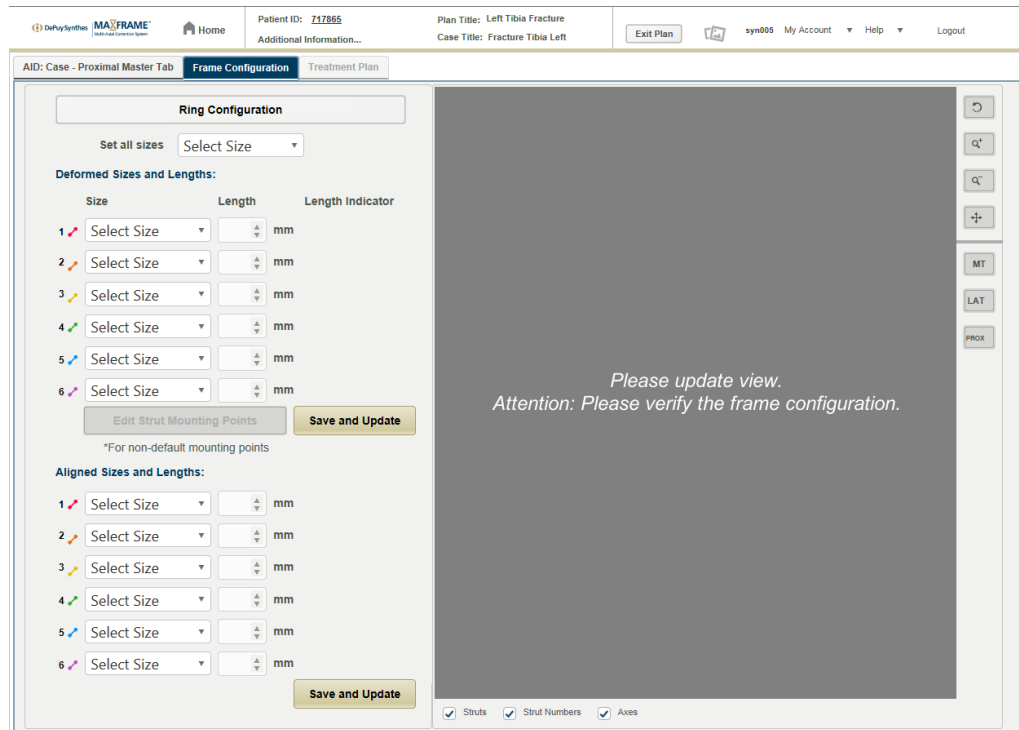


Figure 88 – AID—Frame Configuration

In the **Frame Configuration** view (figure 88), click on **Ring Configuration**. The **Ring Configuration** pop-up window opens (figure 89).

Ring Configuration

<p>Proximal Ring</p> <p>Ring Type</p> <div style="border: 1px solid #ccc; padding: 2px; width: 100%;">Full</div> <p>Diameter</p> <div style="border: 1px solid #ccc; padding: 2px; width: 100%;">180 mm (03.312....</div> <p>Are the struts attached on Ring Mount location?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p>	<p>Distal Ring</p> <p>Ring Type</p> <div style="border: 1px solid #ccc; padding: 2px; width: 100%;">Full</div> <p>Diameter</p> <div style="border: 1px solid #ccc; padding: 2px; width: 100%;">180 mm (03.312....</div> <p>Are the struts attached on Ring Mount location?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p>
---	---

Save

Cancel

Figure 89 – 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* or *5/8*.

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) 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 2.4 “Hardware” on page 10.
- **Are the struts attached on Ring Mount location:** If you have selected **Full** as the ring type, then specify whether the struts are mounted on this ring on inner holes (**Yes**) or not (**No**). Default is **No**.

Note: Only one ring (proximal or distal) per frame shall allow struts mounted on ring mount holes between the tabs.

- **Opening (5/8 Ring):** If you have selected **5/8** as the ring type, then specify additionally 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.
- **Are the struts attached on Ring Mount location:** If you have selected **Full** as the ring type, then specify whether the struts are mounted on this ring on inner holes (**Yes**) or not (**No**). Default is **No**.
- **Opening (5/8 Ring):** If you have selected **5/8** as the ring type, then specify additionally where the opening of the ring is located (between **Strut 1 & 2**, **Strut 3 & 4**, or **Strut 5 & 6**).

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* 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 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 90).

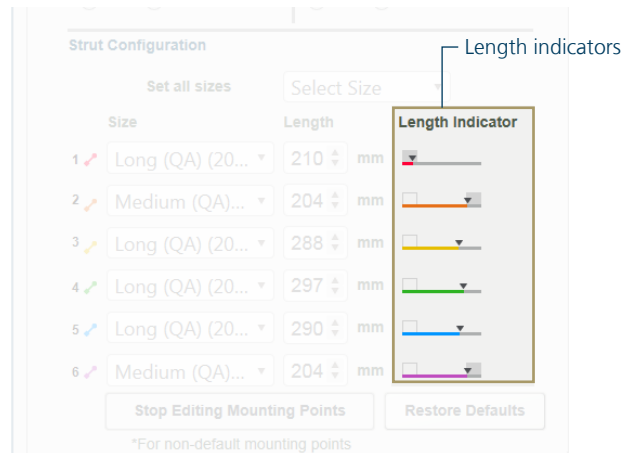


Figure 90 – AID—Frame Configuration—Strut length indicators.

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 on page 88.
4. For saving your entered data and show the model of the deformed frame setting in the preview, click the upper **Save and Update** 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. For saving your entered data and show the model of the aligned frame setting in the preview, click the lower **Save and Update** button.

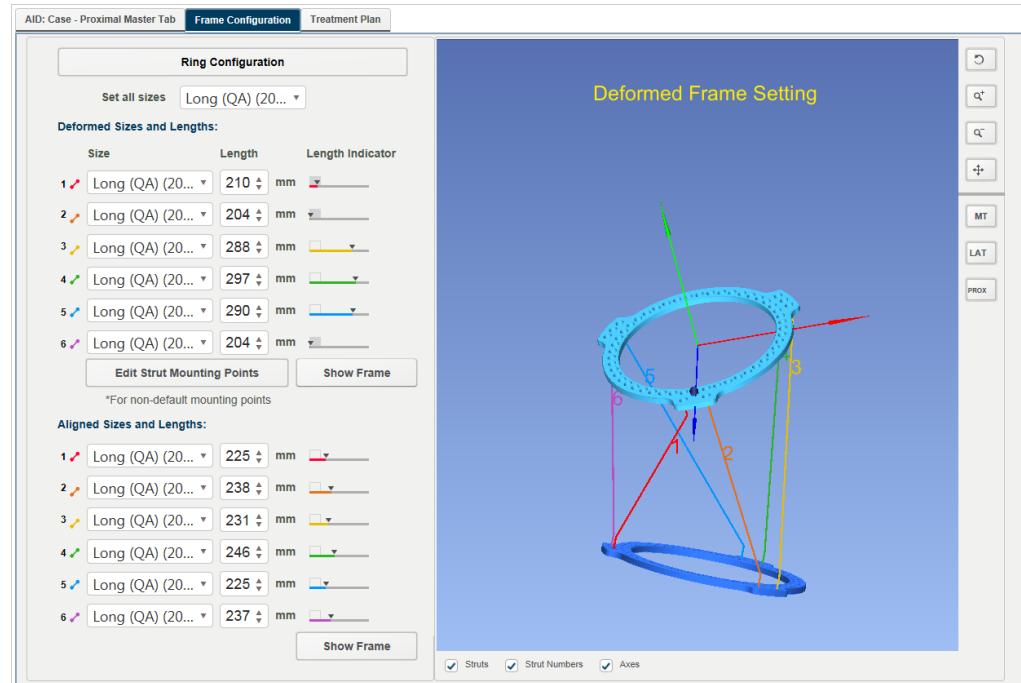


Figure 91 – AID—Final frame configuration.

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.

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 41).

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).

Note: In rare instances, a frame configuration may only be valid with non-default mounting points. Because the system applies default mounting points when initially rendering a frame, such a configuration will result in a geometry error and leave the **Edit Strut Mounting Points** feature unavailable. To enter non-default mounting points in this case, first, create an arbitrary frame that will render. Once the system has rendered the frame, click **Edit Strut Mounting Points** and enter the non-default mounting points used in this unique case. Once the frame is rendered with the updated mounting points, input the correct strut lengths and proceed. If the system is still unable to generate a valid frame, please contact Support.

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

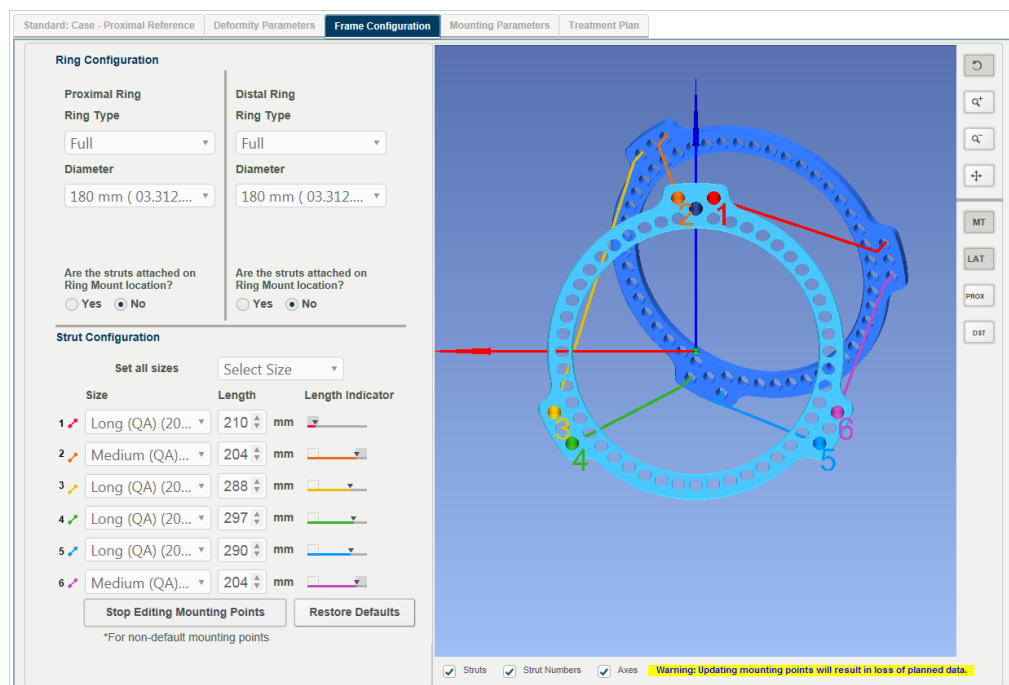


Figure 92 – Edit Strut Mounting Points view.

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 93).

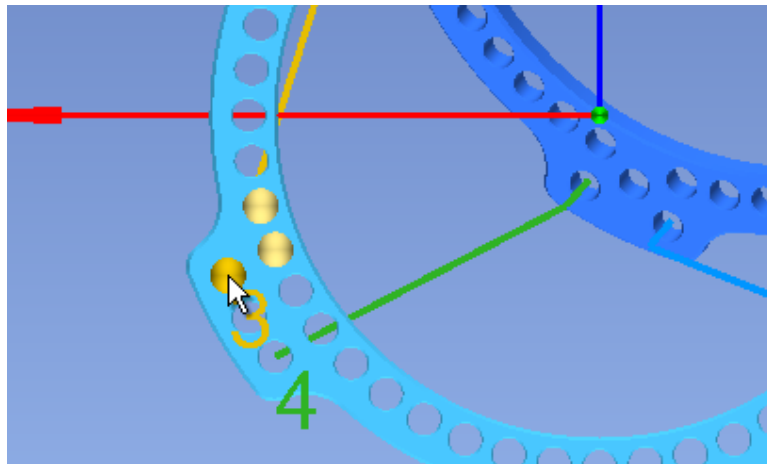


Figure 93 – Non-default mounting positions for strut 3.

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

Click **Stop Editing Mounting Points** to save all modifications and to finish editing the mounting points.

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 Standard planning method.

Note: With PFM, you define and edit the location of concern graphically on the **Deformity Planning** tab (cf. section 7.6.1 “Define the Deformity Parameters”).

1. Open the **Mounting Parameters** tab and click on **Input/Edit Location of Concern**. The following pop-up window appears:

The screenshot shows a dialog box titled "Location of Concern (LOC)". It has three sections for offset values relative to a reference point. The first section, "AP View Offset is:", has a text input field containing "20" followed by "mm" and two radio buttons: "Lateral" (unselected) and "Medial" (selected). Below this is the text "to the Reference Point". The second section, "LAT View Offset is:", has a text input field containing "20" followed by "mm" and two radio buttons: "Anterior" (unselected) and "Posterior" (selected). Below this is the text "to the Reference Point". The third section, "Axial Offset is:", has a text input field containing "20" followed by "mm" and two radio buttons: "Proximal" (unselected) and "Distal" (selected). Below this is the text "to the Reference Point". At the bottom of the dialog are three buttons: "Save" (highlighted in gold), "Remove LOC", and "Cancel".

Figure 94 – 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 specify the direction (**Lateral** or **Medial**). If the value is zero, enter "0".
3. Enter the LAT view value of the location of concern with respect to the Reference Point in millimeters (mm) and specify the direction (**Anterior** or **Posterior**). If the value is zero, enter "0".
4. Enter the axial offset value of the location of concern with respect to the Reference Point in millimeters (mm) and specify the direction (**Proximal** or **Distal**). If the value is zero, enter "0".
5. Click **Save** for saving and applying your entered values and closing the pop-up window. 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 and closing the pop-up window.

Note: The directional field radio buttons are disabled when the corresponding field value is zero ("0").

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:

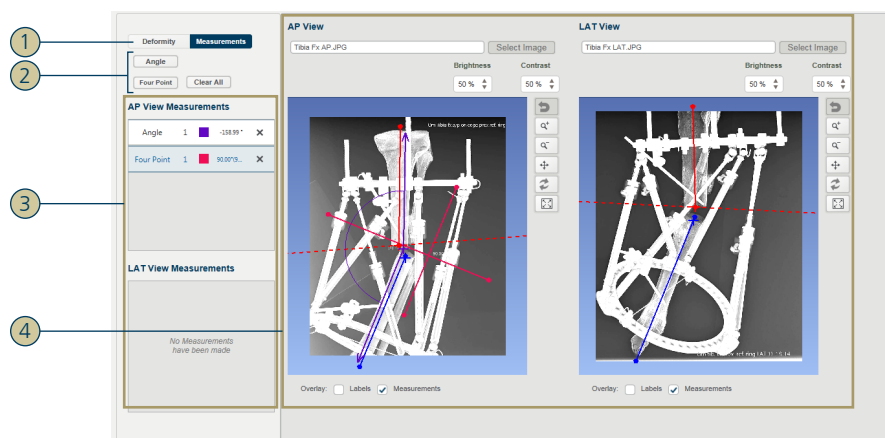


Figure 95 – PFM—Measurements

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

1. Marking type selector (**Deformity** or **Measurements**).
2. 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.
 - **Clear All**—deletes all the added measurements in AP and LAT view.
3. Lists of measurements added for AP and LAT view.
4. AP and LAT views (similar to the AP and LAT views in the **Deformity Planning** tab).

9.3.1 Add Measurements

1. Select the measurement tool (**Angle** or **Four Point**, cf. [2] in figure 95).
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.

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 95 on page 91).
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. [3] in figure 95 on page 91).

To delete all the added measurements in AP and LAT view, click **Clear All** (cf. [2] in figure 95 on page 91).

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 96 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:

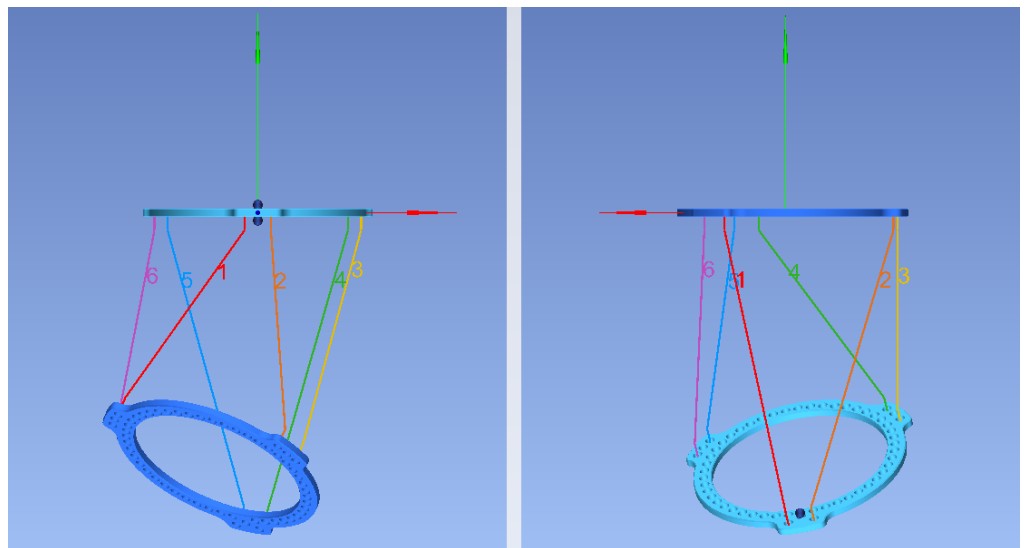


Figure 96 – Master Tab views of the same frame in proximal (left) and distal (right) configuration.

The following figure 97 shows the Master Tab view of a frame with a distal reference foot plate:

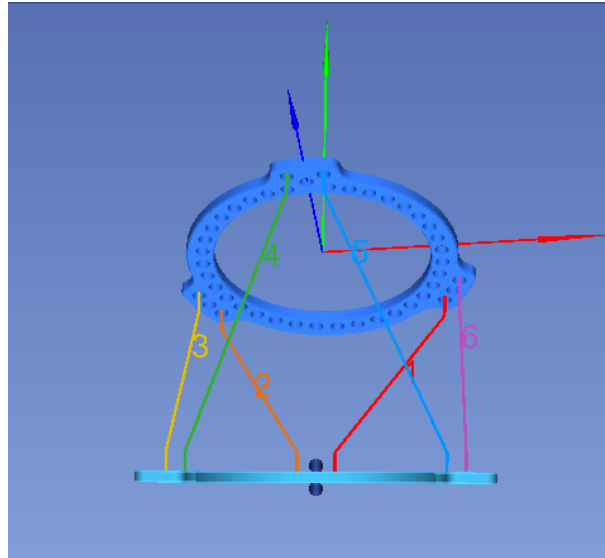


Figure 97 – Master Tab view of a distal reference foot plate.

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 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 97 for an illustration.

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

9.5 Revocation of Patient Consent

If a patient revokes their consent, open the **Edit Patient Information** dialog (cf. section 11.3 "Edit Patient Data" on page 108):

Edit Patient Information

Patient Information

Patient ID* 223442
*Important: Patient ID should match the Medical Record Number

First Name* Alice

Last Name* Johnson

Gender Female

Date of Birth 6/12/2001

Patient Height/Weight 175 cm / 63 kg

Strut Adjustment Instructions English - English (mm/dd/yy...)

Contact Information

Email Address alice.johnson@mail.com

Phone Number (020) 7946 0659

Mobile or Alt Phone Number

Legal Guardian Information

Full Name

Phone Number

Email Address

I acknowledge receipt of Patient Consent for Use by the Manufacturer of Patient's radiographic images and aggregate data.* Yes No

* indicates required field

Save Cancel

Figure 98 – 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:

You have changed the acknowledgement of Patient Consent to indicate you no longer have receipt of Patient Consent for the use by the manufacturer of the Patient's data and/or radiographic images. This change will be effective from the date of change forward and will not impact any data or radiographic images that may have already been accessed by the manufacturer.

OK

Figure 99 – Patient Consent for use by the Manufacturer of Patient's radiographic images and aggregate data.

3. Click **OK** to finish.

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

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 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 100 – 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 accordingly 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. 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 completed treatment plan is still considered “active”. A treatment plan is switched to the status “Complete” by clicking **Archive and Lock (Complete Plan)** in the **Active Treatment Plan** area (cf. section 10.2.1 on page 99). You can complete a treatment plan which is in planning or in process. During its “Complete” phase, a 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 101 – 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 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.

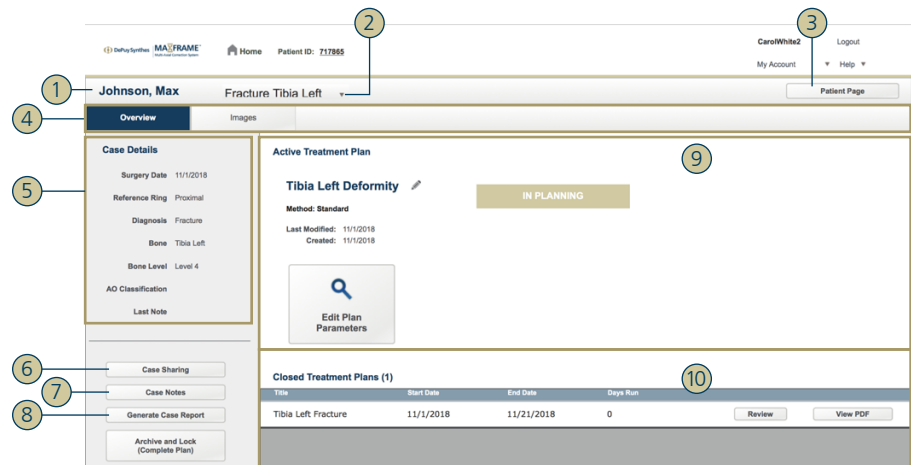


Figure 102 – The Case Dashboard view.

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 field. To switch to another case of this patient, click on the case selection field and select the desired case from the list.
3. **Patient Page** button. Click to switch to the **Patient** Dashboard view.
4. Tab selectors for the following subtabs:
 - **Overview**—contains the case data and lists of its treatment plans.
 - **Images**—list of all images which are assigned to treatment plans of the displayed case.
5. **Case Details** (read-only).
6. **Share Case**—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 to 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. List of **Closed Treatment Plans** (if any).

10.2.1 The Active Treatment Plan area

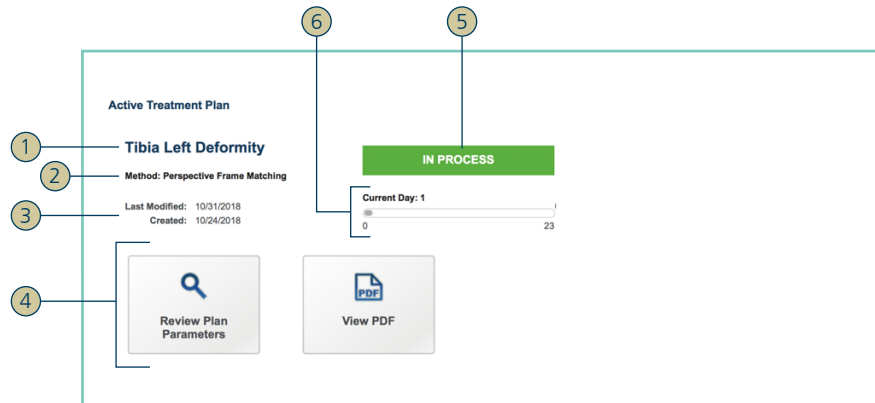


Figure 103 – The **Active Treatment Plan** area.

The **Active Treatment Plan** area contains the following elements:

1. Title of the active treatment plan. If the treatment plan is in status “In Planning”, you can edit the title by clicking on the pencil button. The title is read-only if the treatment plan is “In Process” or “Complete”.
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** 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:

- Standard—Chapter 6.
- Perspective Frame Matching (PFM)—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 up.

Figure 104 – Treatment Plan Management—**Share a treatment plan** view.

3. Enter the email address of the person with whom you want to share the treatment plan in the **Email** field.
4. If you want to have the sharing link expired at a certain date, select the **Set Expiration Date** option.
5. Specify the desired expiry date manually or click the calendar icon and select the date.
6. Enter a message that you want to convey to the recipient under **Optional message to user**. This message is optional.
7. Click **Share**.

Note: The system does not notify the user that a plan has been shared. You should notify the user that you have shared a plan.

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 “Important: 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 should not 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 Day 0 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.

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)
Day 0 (Re-Plan)	Wed 1/18/2017	210	204	288	297	290	204
Day 1 (Re-Plan)	Thu 1/19/2017	212	205	287	▲ 294	289	205
Day 2 (Re-Plan)	Fri 1/20/2017	214	205	285	▲ 291	287	206
Day 3 (Re-Plan)	Sat 1/21/2017	216	206	284	▲ 288	286	207
Day 4 (Re-Plan)	Sun 1/22/2017	218	206	282	▲ 285	285	208
Day 5 (Re-Plan)	Mon 1/23/2017	219	207	280	▲ 281	283	209
Day 6 (Re-Plan)	Tue 1/24/2017	221	207	279	▲ 278	282	209
Day 7 (Re-Plan)	Wed 1/25/2017	223	208	277	▲ 275	280	210

Figure 105 – 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 Standard or PFM, 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 recalculated 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.

Warning: You will be prompted to verify the frame configuration on your first entry to the **Frame Configuration** tab of your re-planned treatment plan (cf. figure 106).

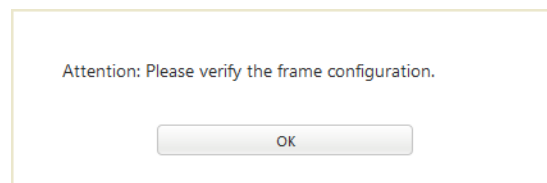


Figure 106 – Warning to verify the frame configuration of a re-planned treatment plan.

Important: The deformity parameters will not be copied.

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.

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 Consent

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 use by the Manufacturer of Patient's radiographic images and aggregate data*.

If you do not acknowledge receipt of the *Patient Consent for use by the Manufacturer of Patient's radiographic images and aggregate data*, the system will:

- Block the access to the patient's radiographic images by the manufacturer.
- Block the patient's data from being included as part of the aggregate reporting.

The acknowledgement status for the Patient Consent 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** (cf. section 9.5 "Revocation of Patient Consent" on page 95).

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 107 – **Choose Patient Consent Status** dialog

2. Select whether you acknowledge the receipt of *Patient Consent for use by the Manufacturer of Patient’s radiographic images and aggregate data*.
3. Select the desired language and date format for the strut adjustment instructions.
4. Click **Continue**. The **Create New Patient** dialog opens.

Figure 108 – **Create New Patient** dialog

5. 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.

6. 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.
7. 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/Alt. Phone Number** field.
 8. 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.
 9. Click **Save** to finish the creation of the new patient record and close the **Create New Patient** dialog.

11.2 The Patient Page

This section deals with the **Patient Page** Dashboard view:

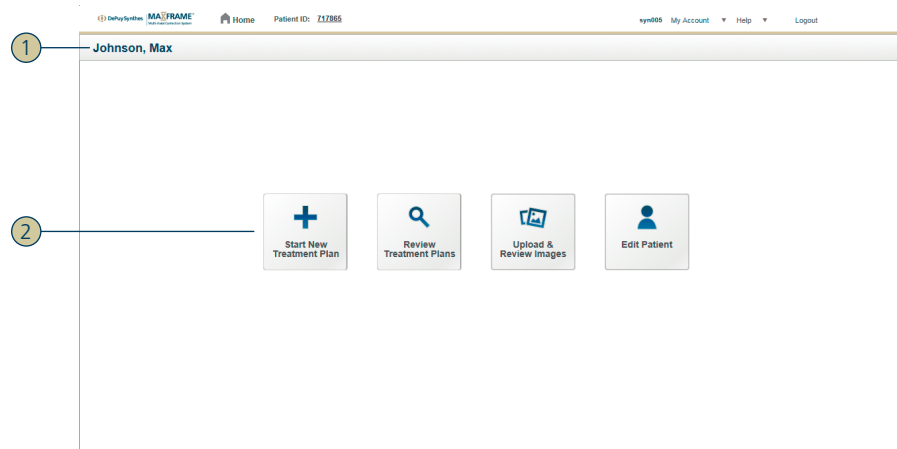


Figure 109 – The **Patient Page** Dashboard view.

The **Patient Page** 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.
 - **Review Treatment Plans**—for reviewing an existing treatment plan.
 - **Upload & Review Images**—for uploading new images or reviewing existing images.
 - **Edit Patient**—for editing the data of the selected patient.

Use one of the following methods to open the **Patient Page** 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 117 for more details).
- In the Case Dashboard view, click on the **Patient Page** button located on the right side below the header area (refer to section 10.2 “Review Treatment Plan” on page 97 for more details).

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 Page** Dashboard view (refer to section 11.2 on page 107 for more details). Click on **Edit Patient**.
 - If the header area shows a **Patient ID** link, click it.

Edit Patient Information

<p>Patient Information</p> <p>Patient ID* <input type="text" value="223442"/> <small>*Important: Patient ID should match the Medical Record Number</small></p> <p>First Name* <input type="text" value="Alice"/></p> <p>Last Name* <input type="text" value="Johnson"/></p> <p>Gender <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text" value="Female"/></p> <p>Date of Birth <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text" value="6/12/2001"/></p> <p>Patient Height/Weight <input style="border: none; border-bottom: 1px solid #ccc; width: 50%;" type="text" value="175"/> cm / <input style="border: none; border-bottom: 1px solid #ccc; width: 50%;" type="text" value="63"/> kg</p> <p>Strut Adjustment Instructions <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text" value="English - English (mm/dd/yy...)"/></p>	<p>Contact Information</p> <p>Email Address <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text" value="alice.johnson@mail.com"/></p> <p>Phone Number <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text" value="(020) 7946 0659"/></p> <p>Mobile or Alt Phone Number <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text"/></p> <p>Legal Guardian Information</p> <p>Full Name <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text"/></p> <p>Phone Number <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text"/></p> <p>Email Address <input style="border: none; border-bottom: 1px solid #ccc; width: 100%;" type="text"/></p>
---	--

I acknowledge receipt of Patient Consent for Use by the Manufacturer of Patient's radiographic images and aggregate data. Yes No

* Indicates required field

Figure 110 – 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. For more information, refer to section 9.5 “Revocation of Patient Consent” on page 95.
4. If you have modified any information, click **Save** to save the updates and close the **Edit Patient Information** dialog.

12 Upload & Review Images

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

- Upload images (cf. section 12.4 on page 112)
- Set image attributes (cf. section 12.5 on page 113)
- Add notes (cf. section 12.6 on page 113)
- Assign and unassign images to or from treatment plans (cf. section 12.7 on page 114)
- Remove images (cf. section 12.8 on page 115)

12.1 Supported Images

The *MAXFRAME 3D 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 recommended x-ray image resolution is between 512x512 and 4096x4096 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, proceed as follows:

1. Open the Detail view of the desired treatment plan (refer to section 10.2.2 "Open a treatment plan for review" on page 99).
2. Click the **Image Manager** icon in the header of the treatment plan.



Figure 111 – Open the Image Manager from within an opened treatment plan.

12.3 Overview of the Image Manager

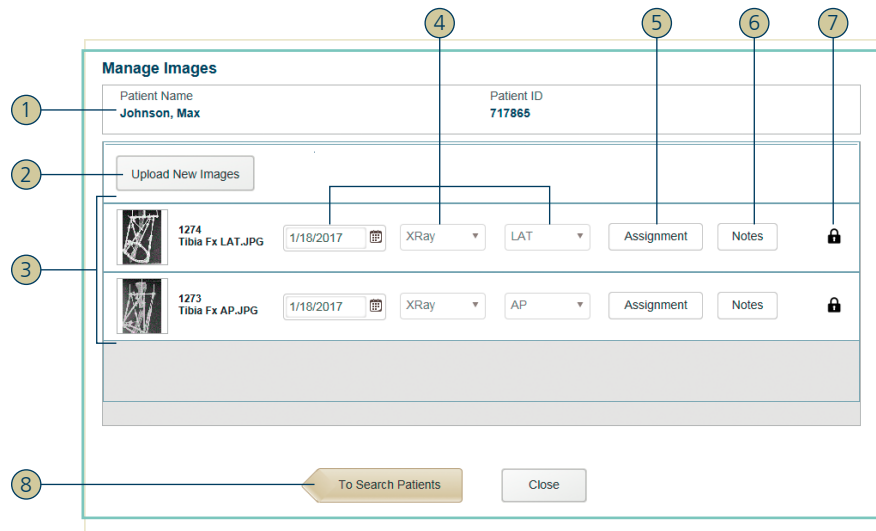





Figure 112 – The Image Manager.

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 112). 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 113):
 - Date taken.
 - Image type (***XR**ay* 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 114).
 6. **Notes**—add notes to an image or edit existing notes (cf. section 12.6 on page 113).
 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 as long as 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. **To Search Patients**—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 110).
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 **XRay** 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.

Note: If a note has been added to an image, a note icon is displayed right to the corresponding **Notes** button.

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.

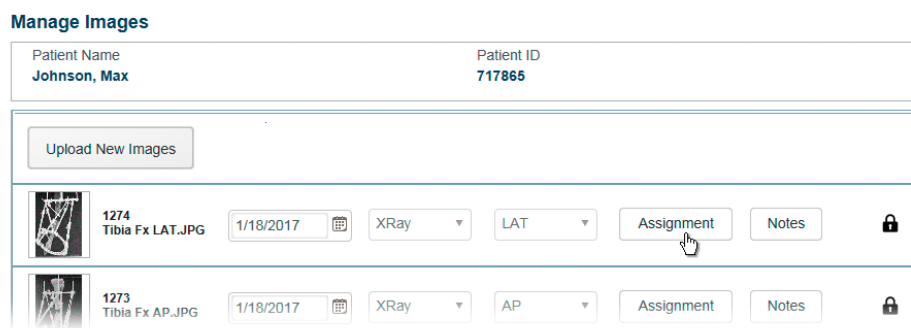


Figure 113 – Change assignment of image.

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.

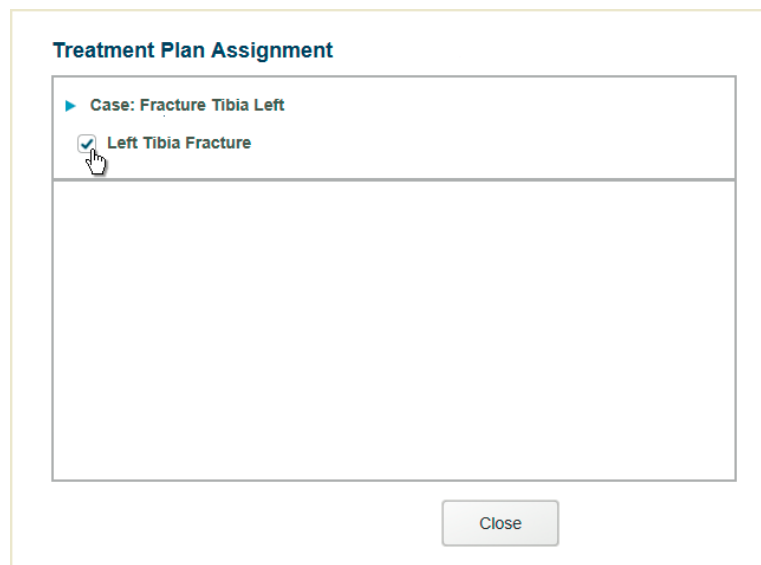


Figure 114 – Select treatment plan.

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.

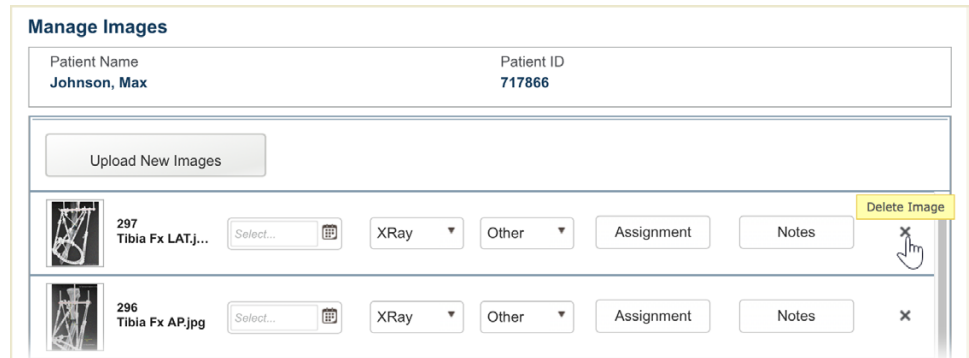


Figure 115 – Remove image from Image Manager.

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

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



Figure 116 – 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 Software*.

13.1 Searching

In the *MAXFRAME 3D 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 for which 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.

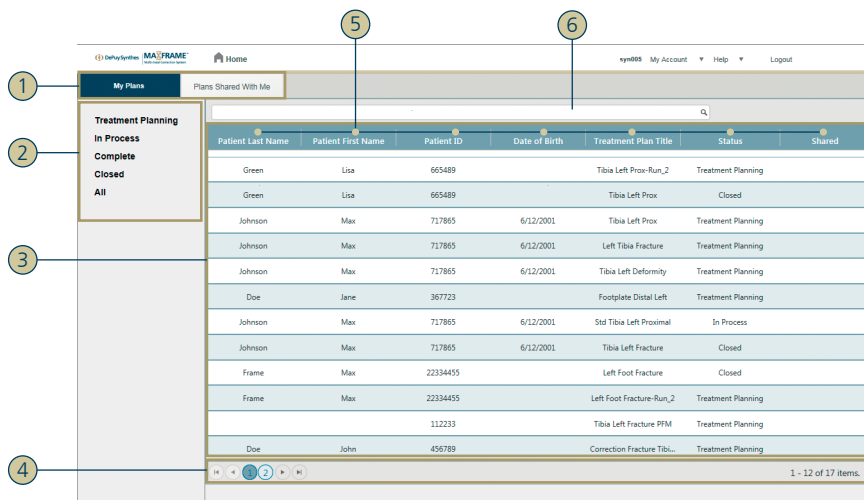


Figure 117 – Search Database result view.

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. Double-click a row 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.

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:

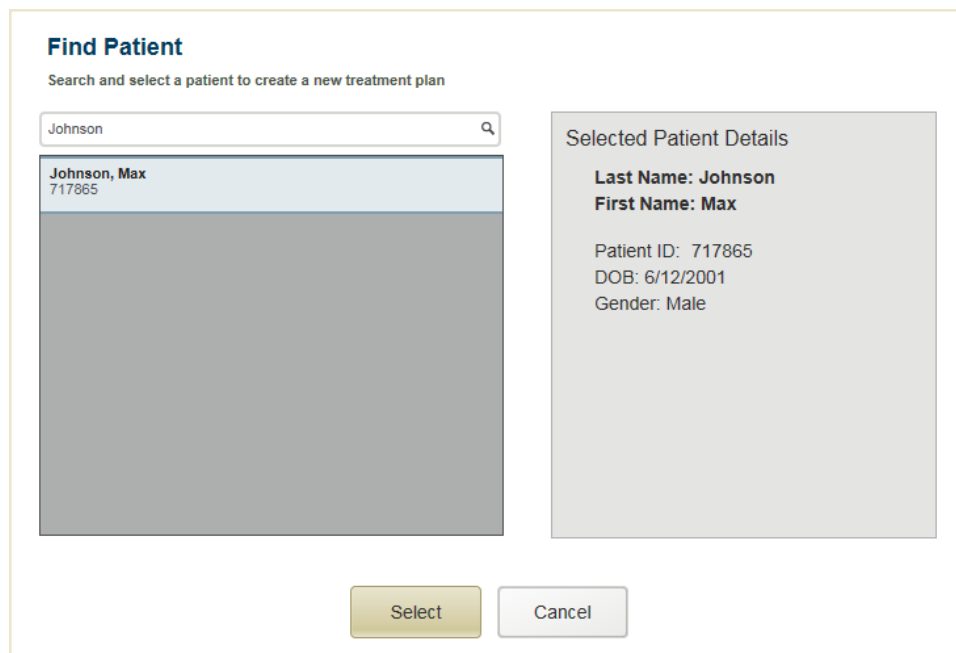


Figure 118 – The **Find Patient** window.

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 Page** 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:

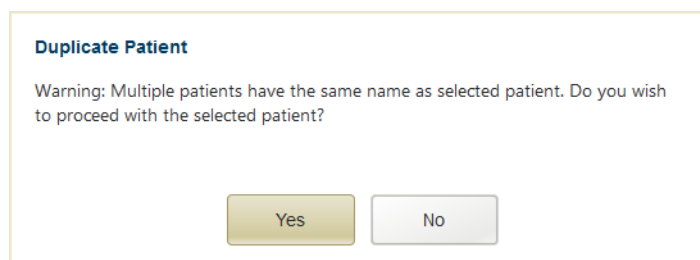


Figure 119 – **Duplicate Patient** warning message

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.
- Operating bone.
- 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, distraction at reference point, distraction at location of concern), and additional lengthening.
- Deformity correction phase parameters (number of days, movement at reference point, distraction 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.

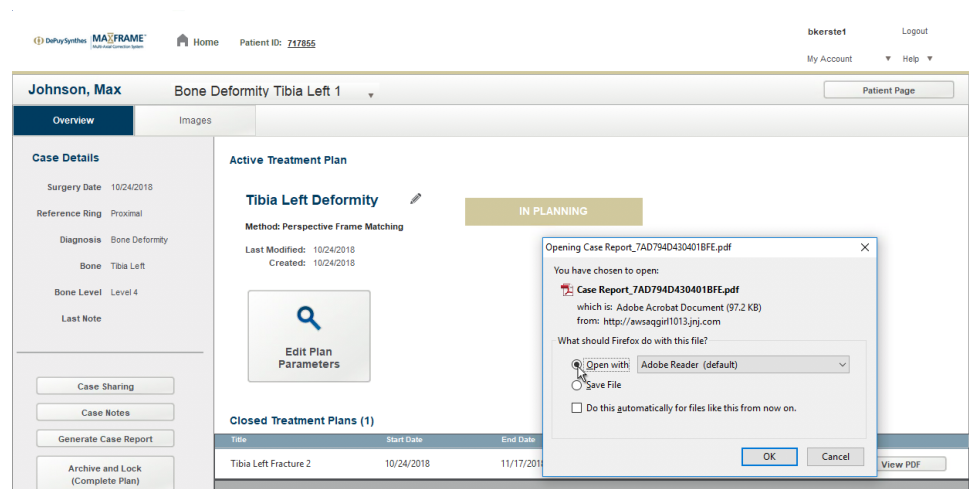


Figure 120 – The web browser's **Open** dialog for the Case report.

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**.

14 Administration

This chapter explains the administration functions of the *MAXFRAME 3D Software*.

14.1 User Account Management

You can view and edit the following information of your user account:

- Personal & Account Information (refer to section 14.1.1).
- Security Challenge Questions (refer to section 14.1.2 on page 122).

14.1.1 View and Edit your Personal Information

1. Click **My Account** ► **Edit Information** in the header (cf. [3] in figure 31 on page 28). The **Personal Information & Account Information** dialog appears:

The screenshot shows a dialog box titled "Edit User Account" with two columns of input fields. The left column is titled "Personal Information" and contains fields for Last Name* (White), First Name* (Carol), Title, Specialty (Orthopedics), Phone Number ((585) 200-4550), and Mobile or Alt Phone Number. The right column is titled "Account Information" and contains fields for Username* (CarolWhite), Email Address* (carol.white@mail.com), and Language Setting (English - English (mm/dd/yyyy)). A red asterisk indicates required fields. At the bottom are "Save" and "Cancel" buttons.

Figure 121 – Edit User Account—Personal Information & Account Information

2. Edit the fields you want to change.
3. Click **Save** to save your changes.
4. A confirmation message appears. Close this message with **OK**.

14.1.2 View and Edit the Security Challenge Questions

1. Click **My Account** ► **Edit Security Questions** in the header (cf. [3] in figure 31 on page 28). The **Security Challenge Questions** dialog appears:

The screenshot shows a web form titled "Edit User Account" with a sub-section "Security Challenge Questions". It contains six pairs of question and answer fields. Each question field is a dropdown menu, and each answer field is a text input. The questions and answers are as follows:

Question	Answer
Question 1*: What is your pet's name?	Charlie
Question 2*: What hospital were you born in?	St. Mary's Hospital
Question 3*: What is your favorite movie?	Lion
Question 4*: What was your favorite place to visit as a ch...	Appletree
Question 5*: Who is your favorite actor, musician, or arti...	Mozart
Question 6*: What was the first car you owned?	Beetle

At the bottom right, there is a red asterisk with the text "* Indicates required field". At the bottom center, there are two buttons: "Save" (highlighted in yellow) and "Cancel".

Figure 122 – Edit User Account—Security Challenge Questions

2. Edit the answers you want to change. The answers are case-sensitive.
3. Click **Save** to save your changes.
4. A confirmation message appears. Close this message with **OK**.

14.2 Change Preferences

Click **My Account** ► **Edit Preferences** in the header (cf. [3] in figure 31 on page 28). The **Preferences** dialog appears:

Edit User Account

Preferences

Display in Case Header

Bone

Diagnosis

Surgery Date

Display throughout Application

Patient Name

Save Cancel

Figure 123 – Edit User Account—Preferences

Display in Case Header (Bone, Diagnosis, Surgery Date)

The case header is being displayed whenever you work in a case. You can add the following values of the open case to the case header:

- **Bone**
- **Diagnosis**
- **Surgery Date**

If you have selected one or more of these values, the *MAXFRAME 3D Software* adds the text **Additional Information** to the case header. To show the values, move the mouse over this text:

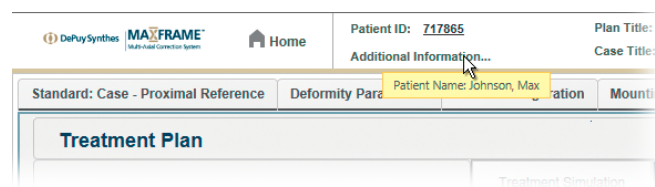


Figure 124 – Display additional information in the case header (as info box on mouse over).

Display throughout Application (Patient Name)

Select **Patient Name** to display the current patient's name. The patient's name is either displayed below the header on the left side or shown as part of the **Additional Information** mouseover box in the case header (cf. figure 124). The patient name is defaulted to be displayed throughout the application.

Note: The displayed patient name in the case header provides a visual confirmation of the patient.

Click **Save** to save your changes. A confirmation message appears. Close this message with **OK**.

14.3 Change Password

1. Click **My Account ▶ Edit Password** in the header (cf. [3] in figure 31 on page 28). The **Edit Password** dialog appears.

2. Enter your **Old Password**.

3. Enter your **New Password**.

Note: The password is case-sensitive.

4. Repeat your new password in the **Confirm New Password** field.

5. Click **Save** to save your new password.

6. A confirmation message appears. Close this message with **OK**.

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 126).

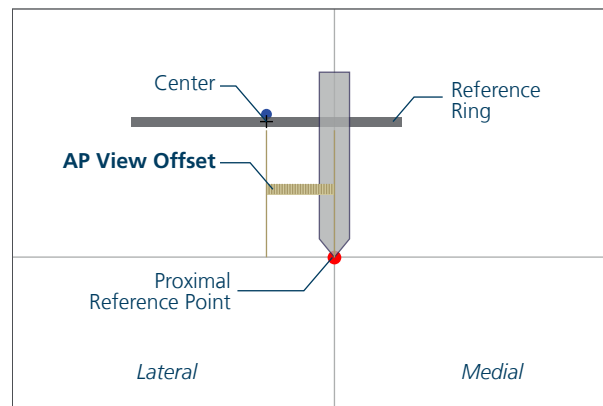


Figure 126 – AP View Offset

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 128).

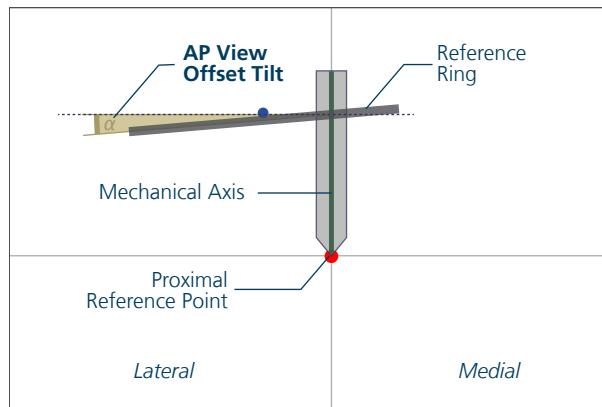


Figure 128 – AP View Offset Tilt

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 125).

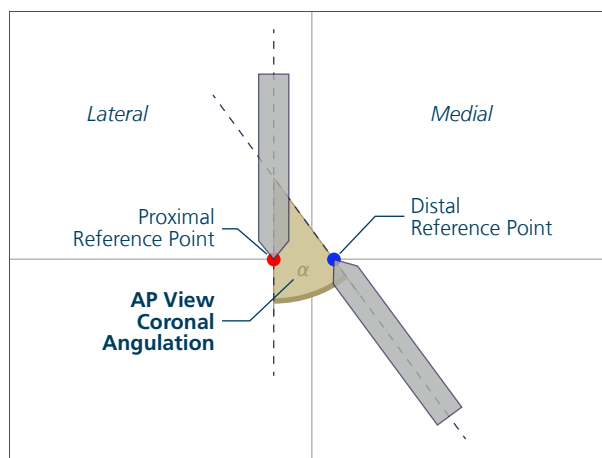


Figure 125 – AP View—Coronal Angulation

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 127).

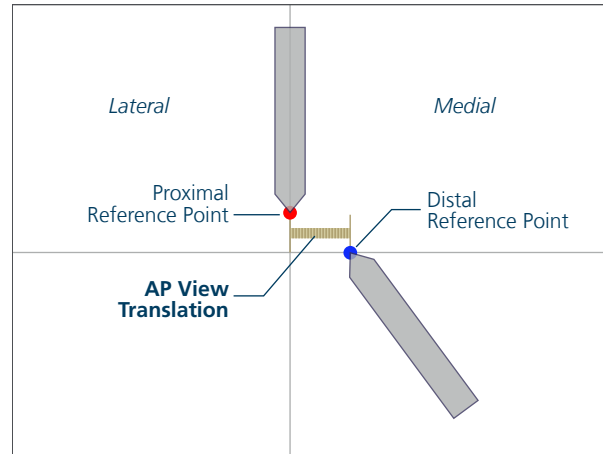


Figure 127 – AP View—Translation

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 129).

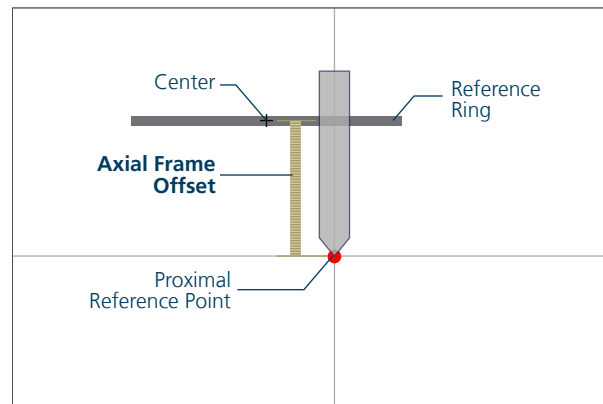


Figure 129 – Axial Frame Offset

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 130).

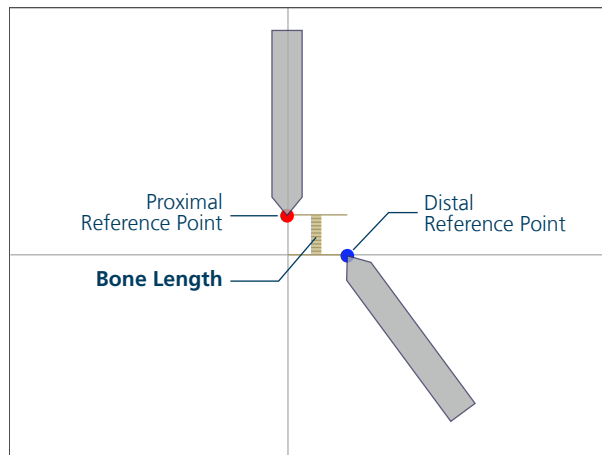


Figure 130 – Bone Length

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 131).

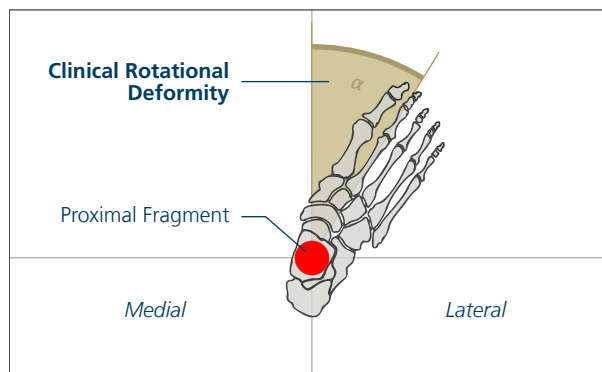


Figure 131 – Clinical Rotational Deformity

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 132 – 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 133).

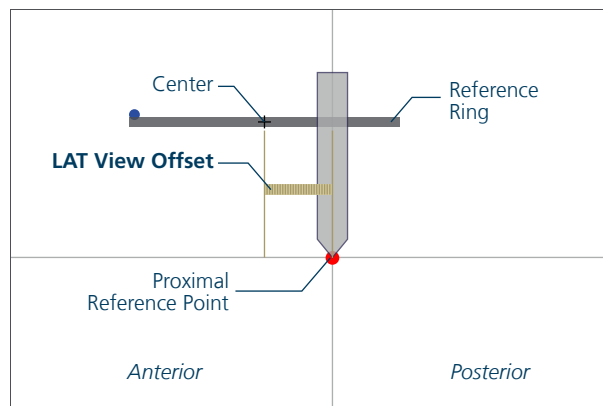


Figure 133 – LAT View Offset

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 134).

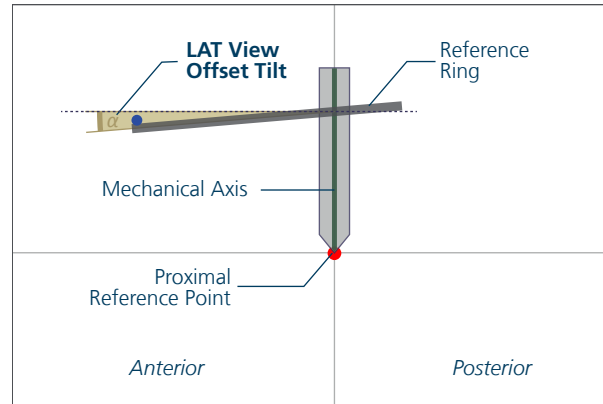


Figure 134 – LAT View Offset—Tilted

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 135).

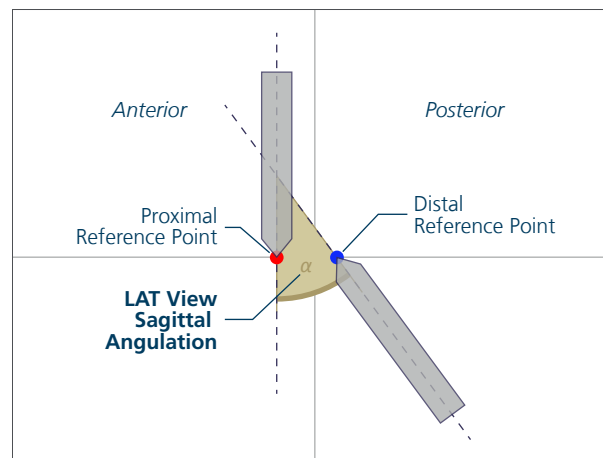


Figure 135 – LAT View—Sagittal Angulation

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 136).

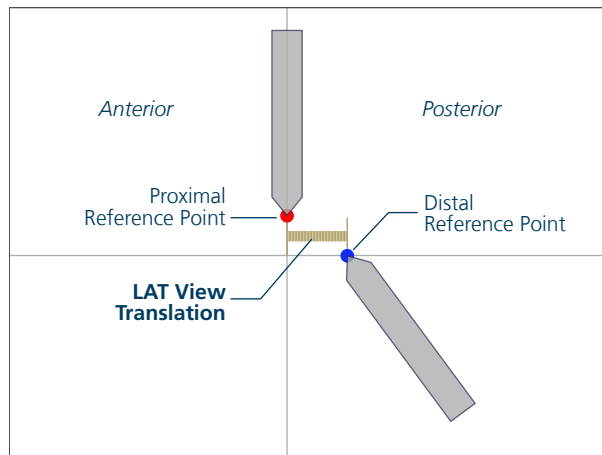


Figure 136 – LAT View—Translation

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 distraction 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 137).

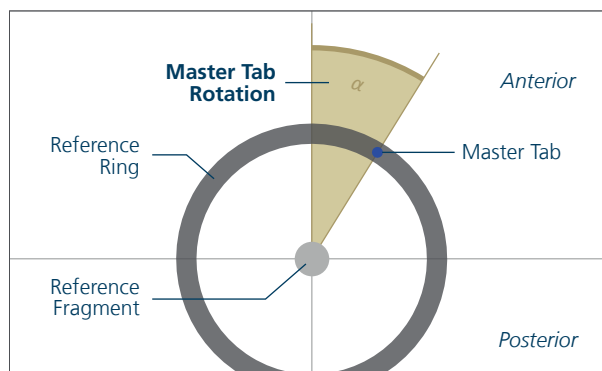


Figure 137 – Master Tab Rotation

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 Software or “Software”

Refers to the *MAXFRAME 3D 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 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 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
- Distraction at Reference Point
- Distraction at Location of Concern
- Movement at Reference Point

Treatment Plan Status

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



Figure 138 – 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 96.

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