stryker

Hoffmann® LRF
web application

Software user's manual

United States:
For web application or Hoffmann LRF Hexapod assistance, please contact the customer support team at: 1-844-393-4933
For non-urgent requests, feel free to contact the Hoffmann LRF helpdesk via email at: fixmyleg_helpdesk@stryker.com

All other regions:
For assistance or customer support please contact your local Stryker Sales Representative

REF 983031

Contents

Introduction

Important information for doctors and operating room staff

This user manual is designed to aid in understanding of the workflow of the Hoffmann LRF web application software and to use its features effectively. This user's manual does not include all of the information necessary for selection and use of a device. For guidance on the application of the Hoffmann LRF Hexapod, please consult Instructions for use (www.ifu.stryker.com) and the corresponding Hoffmann LRF Hexapod operative technique (Content ID: H-ST-34).

Before using any system component or any component compatible with this system, read and understand the instructions. Please see full labeling for all necessary information. Ensure that you are familiar with the intended uses, indications and contraindications, compatibility and correct handling of the system.

The use of these devices provides the surgeon with a means of bone fixation for the management of fracture and reconstructive surgery.

⚠WARNING

These devices are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. If the patient's activity comprises significant impact loads (walking, running, lifting or turning) the resulting forces could lead to failure of the fixation, the system or both. The system will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.

The web based HLRF software is intended to assist the surgeon in the use of the Hoffmann LRF in the correction of limb deformities using hexapod struts. The web application has three basic modes of operation, pre-operative, post-operative, and residual.

As suggested by the title, the pre-op mode is used pre-operatively to define the deformity, ring and strut configuration, and to calculate the deformity correction plan. The corresponding frame may then be pre-built and then surgically attached to the patient.

Surgeons who prefer applying rings initially (i.e., a "rings first" approach), may proceed directly to the post-op mode after surgically applying the frame.

The work flow is the same as the pre-op mode, however, the post-op mode allows the surgeon to fine-tune his or her frame construct to more accurately reflect the surgical outcome using radiographic measurements or directly from post-op or intra-operative radiographs.

Introduction

General warnings and cautions

NOTICE

Per the Health Insurance Portability and Accountability Act of 1996 (HIPAA), no input fields should contain patient's full name or other patient identifiers. The user takes full responsibility for non-compliance.

⚠ CAUTION

The bone models used in the software application can be manipulated to create a graphical representation of the anatomy being treated. This graphical representation is intended to mimic the general anatomy of the deformed bone, and is not meant to include any patient-specific bone characteristics.

⚠ CAUTION

The user shall ensure that the deformity values entered into the software application are in accordance with his / her clinical evaluation.

⚠ CAUTION

For reliable deformity measurements using the deformity measurement tool, the user must ensure that patient X-ray markers and corresponding overlay markers match as closely as possible. Please refer to the applicable sections of this software user's manual for a more detailed explanation of scaling X-ray images and the use of the DMT.

⚠ CAUTION

For reliable measurements of bone offset from the reference ring center using the ring offset measurement tool (OMT), the user must ensure the ring template is accurately placed at the ring edges. Please refer to the applicable sections of this software user's manual for a more detailed explanation of the use of the OMT tool.

⚠ WARNING

The user must ensure reference and moving ring type, size and placement entered into the software application are consistent with the actual frame applied to the patient. This is critical for the software application to generate an accurate correction plan.

⚠ WARNING

The user must ensure type and length of all 6 struts entered into the software application are consistent with the actual frame applied to the patient. This is critical for the software application to generate an accurate correction plan.

⚠ CAUTION

It is recommended that the user define a limiting anatomical structures (LAS) point and calculate a minimum correction time in accordance with the prescribed distraction rate. Use caution when overriding the recommended minimum correction time to avoid an undesirable distraction rate in excess of 1.0mm/day.

System settings before using the software

In order to accommodate the large quantity of information, the detailed graphical images and the proper sequencing of the correction methods, each screen of the Hoffmann LRF web application has been designed to provide an efficient user interface. To ensure the best possible user experience with this site, the following minimum system requirements and browser settings are required.

System requirements

CPU:
Intel or AMD x86 processor, minimum 1GHz

Memory:
Minimum 1GB

Internet connection

Display resolution:
Minimum 1024 x 768

Graphics adapter:
DirectX 9.0 compatible

Keyboard and mouse
(or compatible pointing device)

Software requirements

Windows:
Windows 7 or above

Browser:
Edge 13 or above

Google Chrome latest version

Mozilla Firefox latest version

Browser Plug-in:
WebGL and Java enabled flag set on Browser settings

Mac:
Mac OS version 10.10 or above

iOS:
iOS version 12 or above

Browser:
Safari latest version

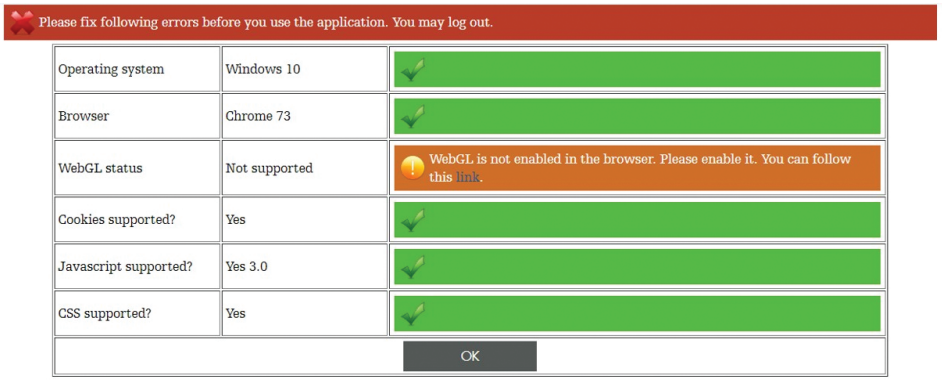
Google Chrome latest version

Browser Plug-in:
WebGL and Java enabled flag set on Browser settings

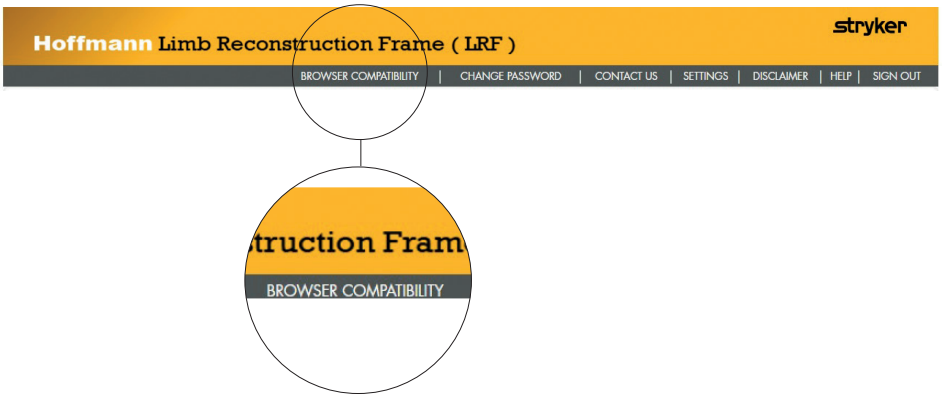
System settings before using the software

When logging in to the Hoffmann LRF Web Application, the application automatically checks that the proper versions of software are installed. If everything is compatible, your login will proceed normally. If not, a screen similar to that shown in the figure to the right will be displayed.

This screen will notify you of the components that need to be upgraded.

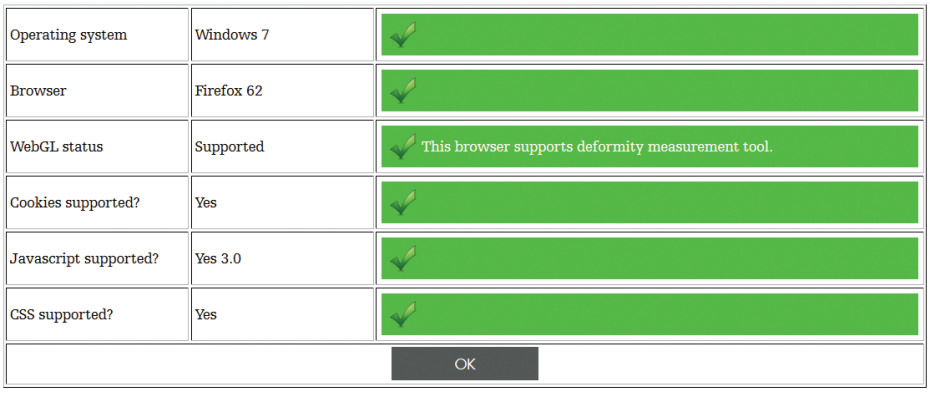


You may check your configuration at any time from within the application by clicking on the **browser compatibility** link at the top of the screen and to the right of your username.



Clicking on the **browser compatibility** link will bring up the compatibility status of your browser components.

This screen shows all required components are installed and up-to-date.



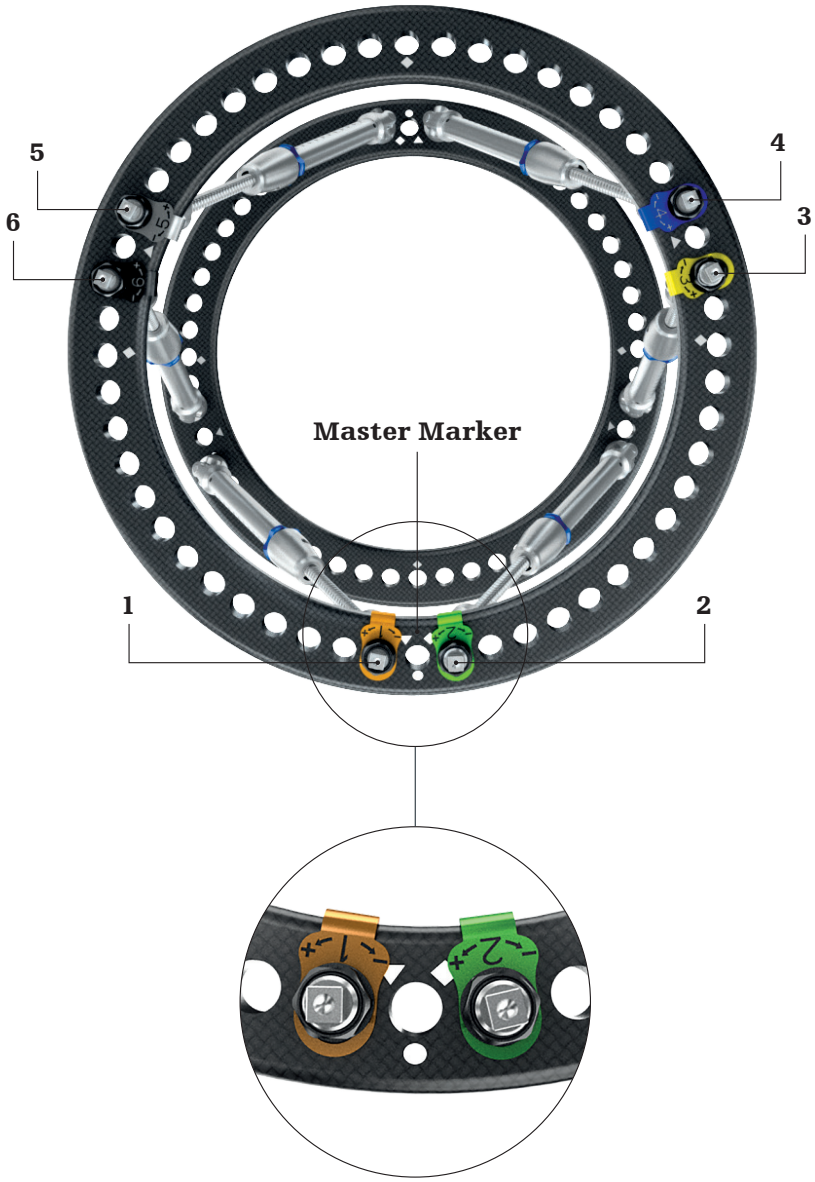
Frame assembly assumptions

⚠ WARNING

For the required safety information and contraindications, please consult Instructions for Use (www.ifu.stryker.com), and the corresponding Hoffmann LRF Hexapod Operative Technique (Content ID: H-ST-34). As with any technical guide, the surgeon should consider the particular condition of the patient and perform the necessary adjustments if required. As always, proceed with caution.

Within the Hoffmann LRF Web Application, the 6 struts are numbered according to the following convention when looking at the frame from the AP view:

1. If the reference ring has been initially rotated or translated during placement to accommodate patient anatomy, then the offset must be entered in the web application.
2. With the reference ring centered on the bone, the master marker refers to the hole position(s) directly anterior to the reference bone fragment.
3. With the master marker of the proximal ring oriented anteriorly, strut 1 (orange) and strut 2 (green) are inserted to the left and right of the strut markers as shown to the right.
4. When looking at the proximal ring, struts 3 (yellow) and 4 (blue) are nominally located at the triangle marker in the counter-clockwise direction from struts 1 and 2.
5. When looking at the proximal ring, struts 5 (gray) and 6 (black) are nominally located at the triangle marker in the counter-clockwise direction from struts 3 and 4.



Nominal strut mounting sites: full ring (Reference Ring)

Frame assembly assumptions

6. The reference fragment refers to the bone fragment used as a reference point during deformity definition and correction.
   The reference fragment can be defined in the web application as either the proximal or distal fragment with respect to the deformity.
7. To aid patient access, the click-lock (adjustable) end of the strut is always inserted from the inferior side of the proximal ring regardless of whether the case is a proximal or distal reference.

Proximal reference

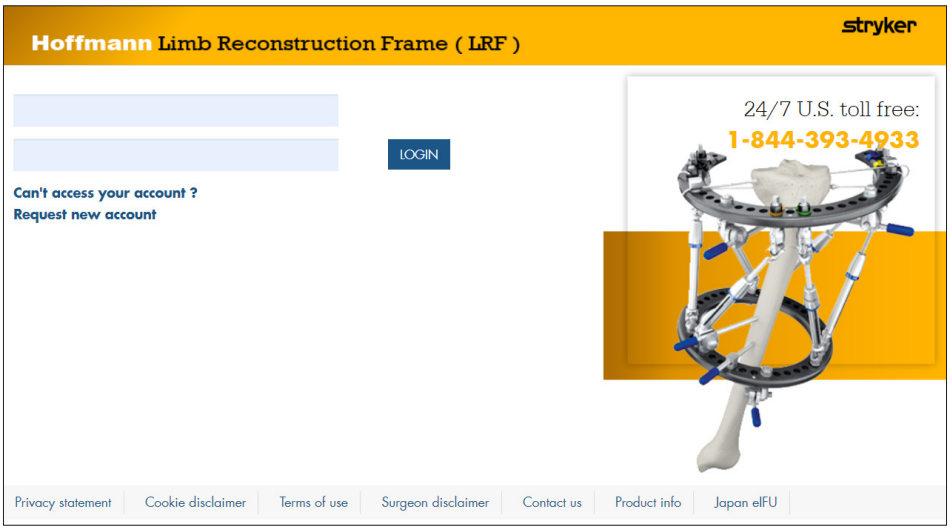
Distal reference

Logging in to the web application

Access the login page at **http://fixmyleg.stryker.com.**

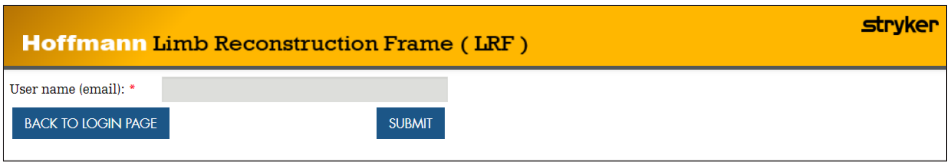
1. Enter your username and password to log into the application.
2. Click **LOGIN** to continue.

If you do not yet have an account, see the section **creating a new user account** below.



Forgotten password

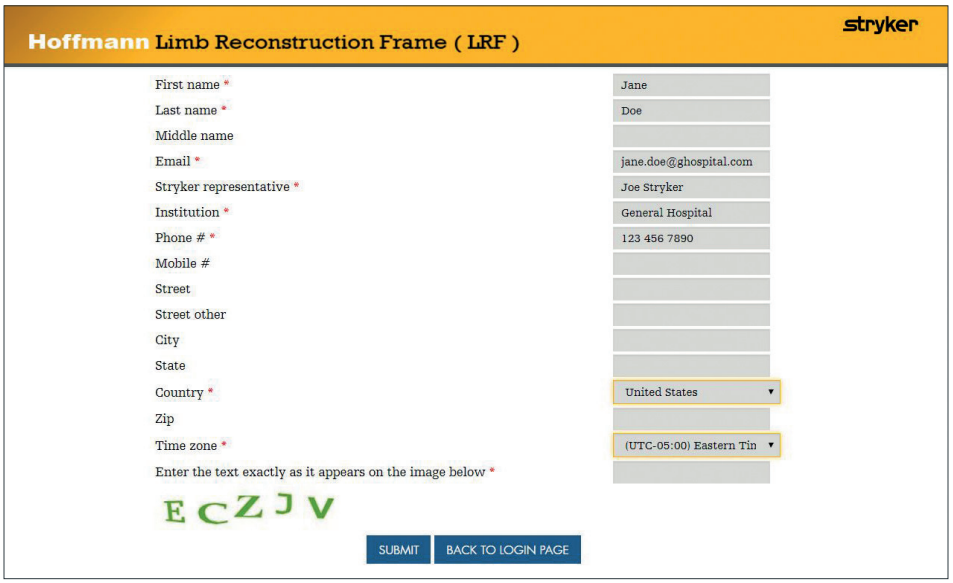
If you cannot access the system, click the **Can't access your account?** link. Enter the email address you originally registered with as shown in the screen to the right, and click on the **SUBMIT** button. You will receive an email containing a one-time password (OTP) and a link to create a new password.



Logging in to the web application

Creating a new user account and obtaining a password

1. Access the login page at **http://fixmyleg.stryker.com**
2. Click the **Request new account** link.
3. Enter the requested information.
4. Mandatory fields are marked with an asterisk (*) and must be filled out.
5. Fields not marked with an asterisk are optional.
6. Click **SUBMIT.** A confirmation email will be sent to the email address you entered into the new account page.
7. The email contains a link to setup your password and account. Click on the link in the email which will redirect you to a separate page where you can set your password. If you have problems while creating your account, contact the Hoffmann LRF helpdesk at: **fixmyleg_helpdesk@stryker.com**
8. Once you have activated your account, you are ready to login and begin using the HLRF web-based software.

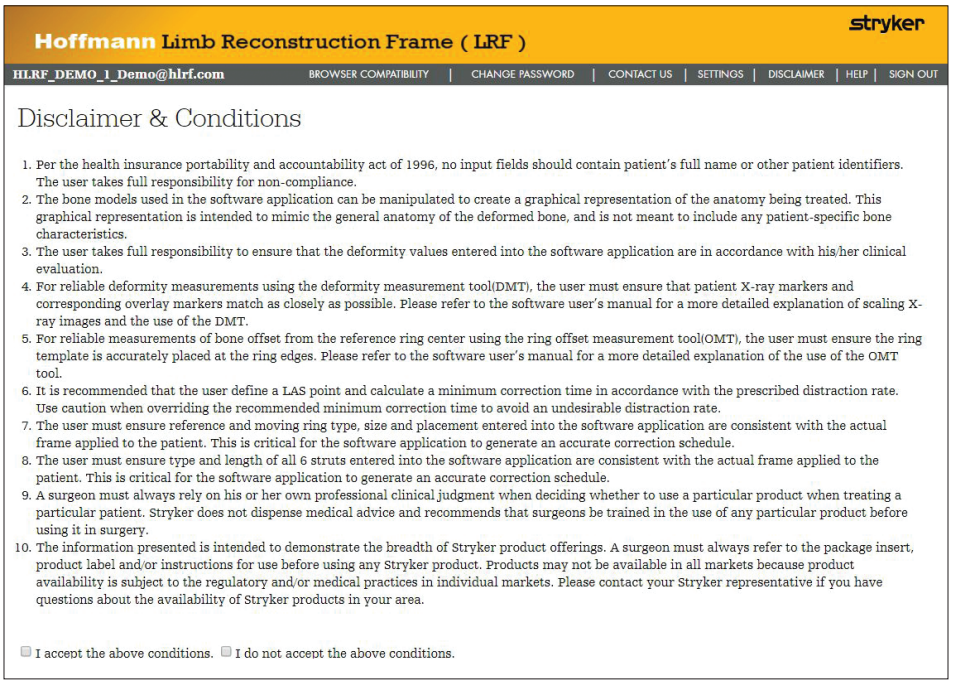


Logging in to the web application

Your first login

After your first login, you will be asked to accept the disclaimers and conditions for using the Hoffmann LRF Web Application. Please read the disclaimers and conditions carefully, and if acceptable, please check the box labelled **I accept the above conditions.**

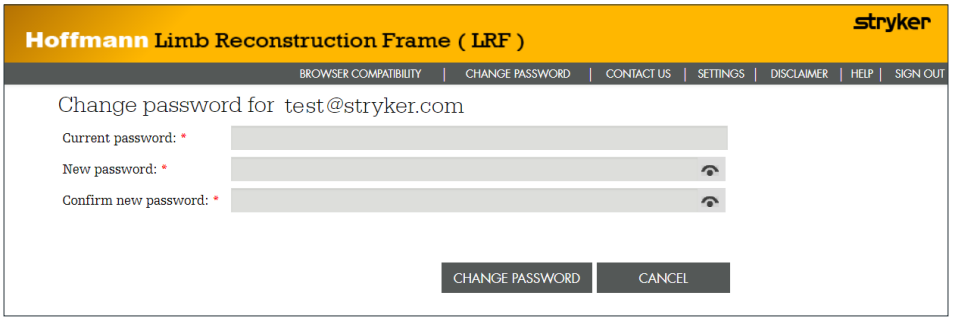
Once checked, the application will proceed to the My Dashboard page.



Changing your password

Directly under the Stryker logo you will find links to change your password, contact us, update settings, access system help, and sign out.

1. Click on the **CHANGE PASSWORD** link.
2. Enter the requested information as shown to the right.
3. Mandatory fields are marked with an asterisk (*) and must be filled out.
4. Passwords must be a minimum of 8 characters in length, must contain at least 1 non alphanumeric character, and may not be the same as the user name. In addition, your new password may not be the same as any of your last 5 passwords. Click **CHANGE PASSWORD**.
   A confirmation screen will be displayed asking you to click on a link which will redirect you to the login screen where you can login with your new password.



Logging in to the web application

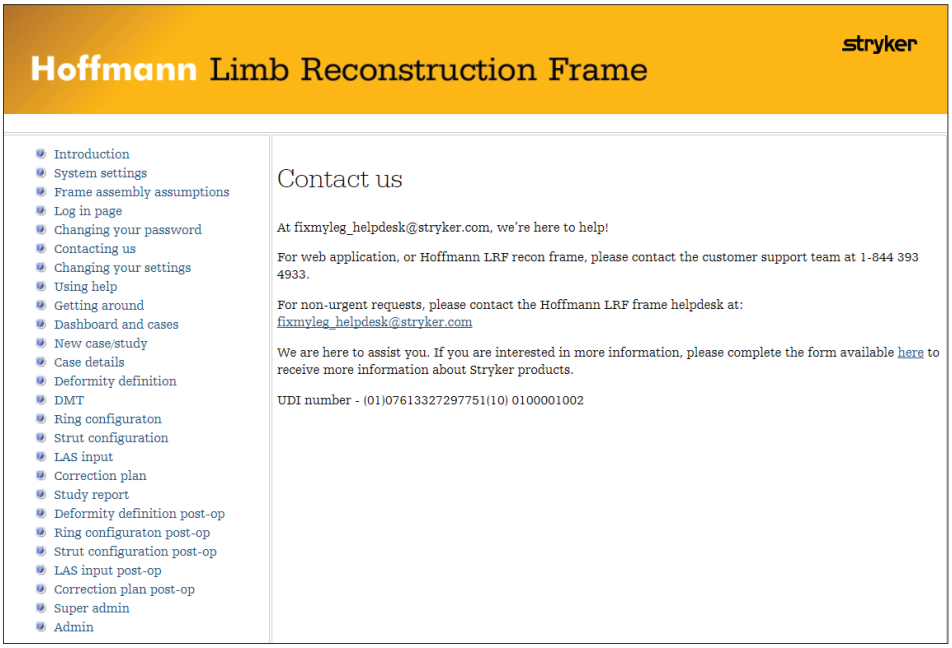
Contacting us

Clicking on the **CONTACT US** link brings up the following page:

For web application assistance, please contact the Stryker customer support team at 1-844-393-4933.

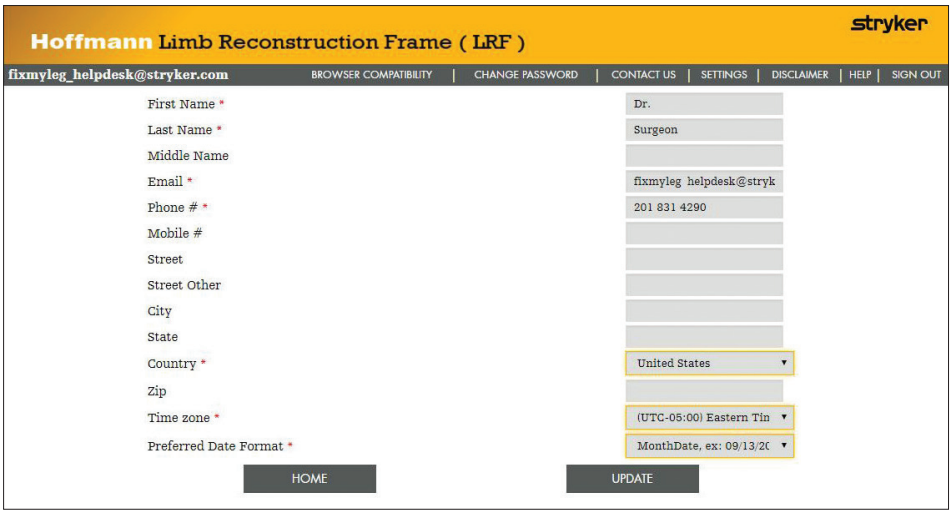
For non-urgent requests, please contact the Hoffmann LRF helpdesk at: **fixmyleg_helpdesk@stryker.com**.

The web application UDI number is also displayed on this page for reference.



Changing your settings

1. Click on the **SETTINGS** link.
2. Enter the requested information.
3. Mandatory fields are marked with an asterisk (*) and must be filled out.
4. When complete, click on the **UPDATE** button as shown to the right.
5. Click **HOME** if you do not wish to change any settings.



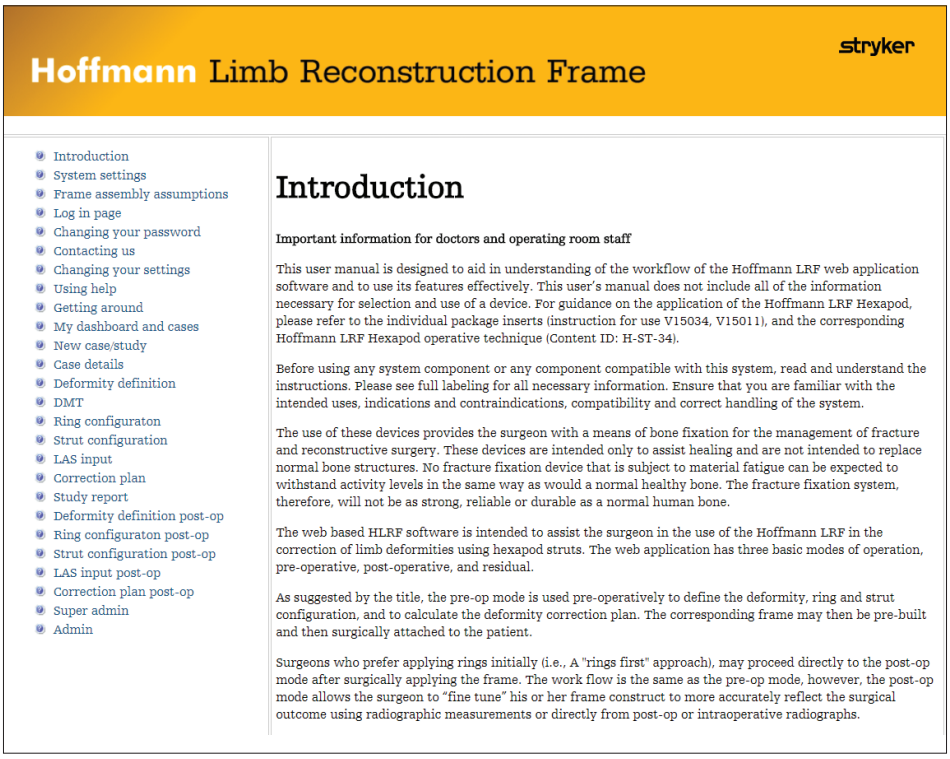
NOTICE

The email field will not be able to be edited as this is your username.

Using help

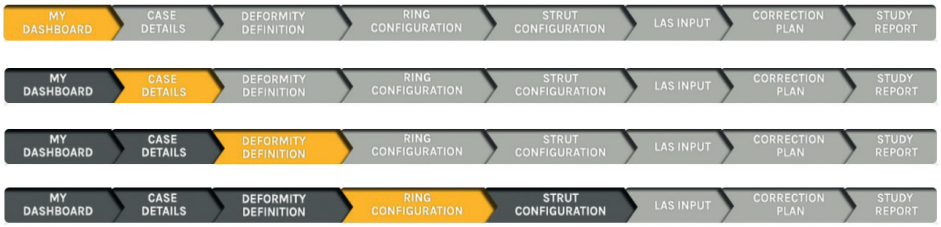
Clicking on the **HELP** link brings up a separate browser window that displays the web application help menu.

Clicking any link in the left hand pane will bring up a help screen for that topic.



Getting around – the Hoffmann LRF Web Application workflow

The progress bar at the top of the page identifies the steps in the web application work flow as a series of chevron shaped tabs. The current step is identified in gold. Steps to be completed are shown in light gray. Steps that have been completed are shown in dark gray. To navigate to a particular section, click on a tab and you will be directed to it immediately. You may always navigate to a section that has already been completed (to go back and change a deformity parameter for example.) However, you can only move forward to steps that have already been completed or to the next page after completing the prerequisite page.



To navigate between screens, click on the related chevron on the progress bar or click the **NEXT** or **PREVIOUS** buttons on the bottom right of each page.

The **SAVE** button allows you to save your work if you expect to leave the application in mid-entry for any length of time, and the **RESET** button restores all parameters on the page to their default values.

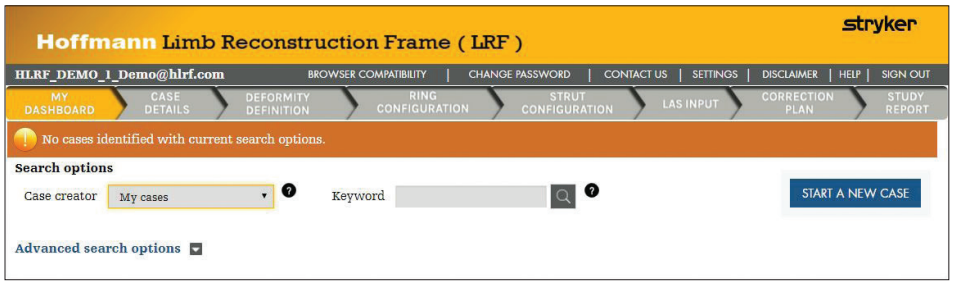
> ***NOTICE***
>
> To avoid losing your work, users should periodically hit the "save" button after inputs have been made.

Deformity and ring parameters may be entered using the sliders, or by direct numerical entry within the value box.

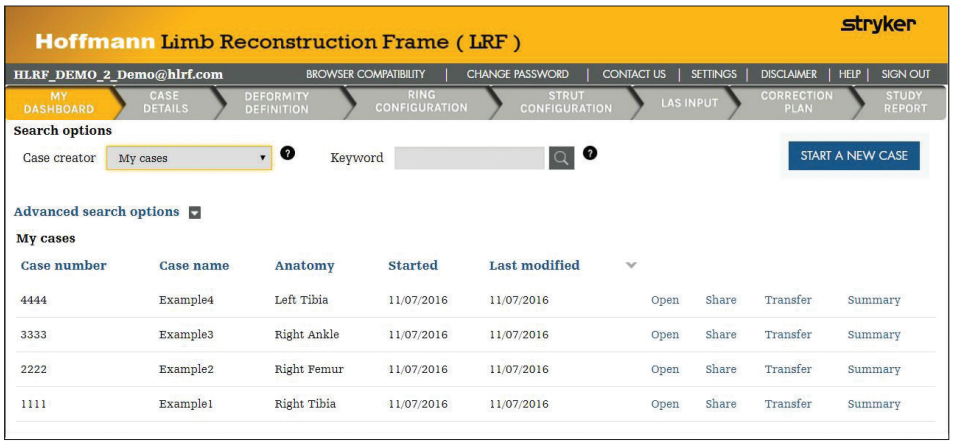
All measurements are in millimeters unless identified otherwise. When the value box is selected, keyboard controls can also be used to incrementally increase and decrease the entered value.

My dashboard and cases

After logging in, the **MY DASHBOARD** page will be displayed. The page shown here to the right will be displayed upon your first login. No cases will be listed in your account.



After working through a number of cases, the **MY DASHBOARD** page will resemble the example page to the right. Once you have entered cases into the system, you can use the search options and advanced search options to perform the following activities:

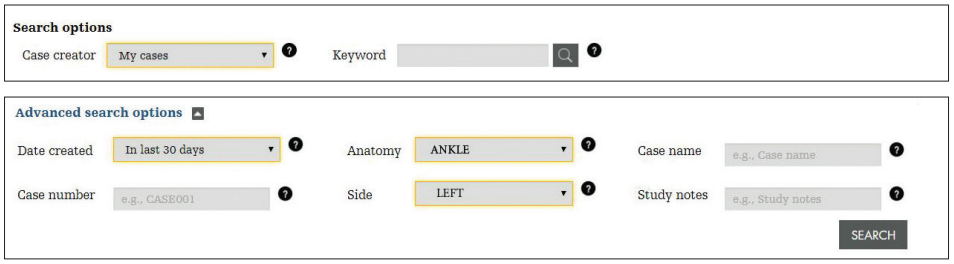


Search options:

Case creator:

- My cases - search for any case created by you
- Cases from others - search for any case that has been shared with you
- Keyword - search for any keywords within a case. The keywords will be searched in the fields case number, case name, anatomy, etc.

After entering your search criteria, click on the magnifying glass icon to start the search.



You can expand the search by using the advanced search options for:

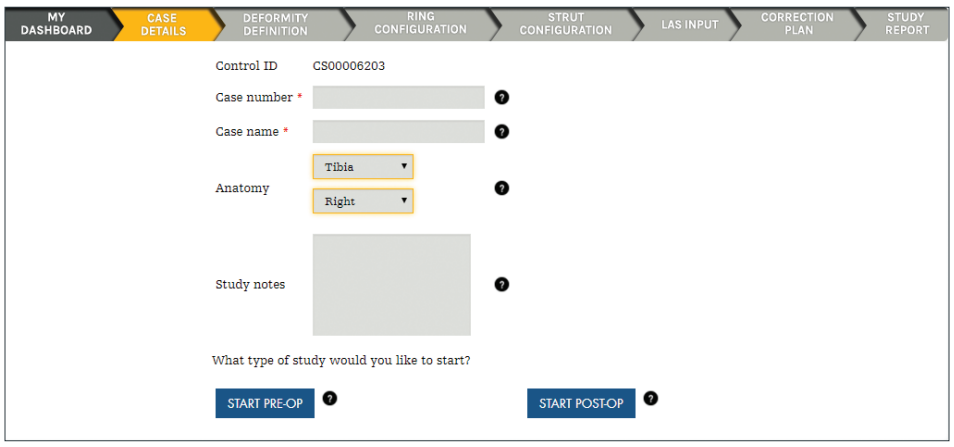
- Date created
- Case number
- Anatomy
- Side
- Case name
- Study notes

After you have entered your search criteria, click the **SEARCH** button to get a list of cases that match.

Starting a new case

Press the **START A NEW CASE** button in the upper right of the screen and the case details screen will be displayed.

The case details screen contains the control ID, which is a unique control number assigned to this case, a user provided case name and case number, dropdowns to select the anatomy to be corrected, and user provided study notes.



NOTICE

Mandatory fields are marked with a red asterisk as shown in the image to the right.

1. Click **START A NEW CASE** on the My Dashboard page.
2. Enter a Case Number.
3. Enter a Case Name.
4. Select the anatomy (bone) and left or right side. Choices are Femur, Tibia, Humerus, Radius, and Ankle, Left or Right.
5. If desired, enter any study notes for this case.
6. Select either **START PRE-OP** or **START POST-OP MODE**.

NOTICE

Do not enter personal health information (PHI) or other personal information in these fields.

See the following explanations of the pre-operative and post-operative mode to determine which mode to use.

Pre-operative mode

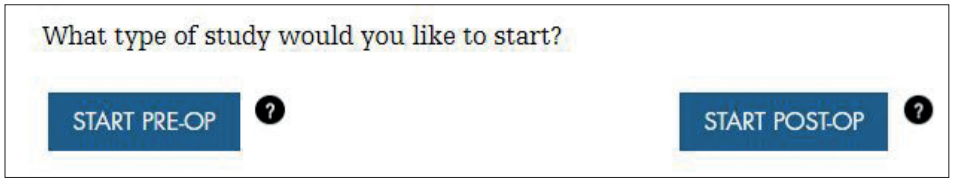
As the title suggests, this mode is used pre-operatively to help plan the possible ways of mounting the frame to correct the deformity.

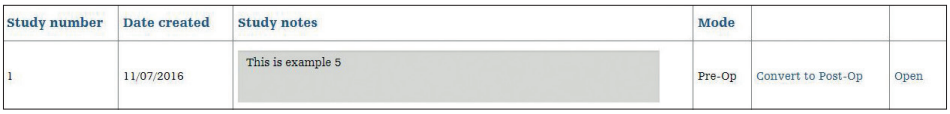
In pre-op mode, you will define the deformity (using the deformity measurement tool or manual input), and then enter type, position, and orientation of the moving and reference rings. The software will then generate various strut combinations to correct the deformity.

In this mode you can experiment with different values for the moving and reference ring parameters and calculate possible strut combinations that can be used. The HLRF algorithm automatically searches for the strut combination that will result in the fewest number of strut change outs, given the chosen deformity and frame configuration. Starting in pre-op mode is recommended to allow proper planning and pre-construction of the frame to minimize OR time.

NOTICE

Use the pre-op mode to plan the building of the frame and mounting of the frame to the patient. After you have mounted the frame to the patient intra-operatively, if adjustments need to be made after you mounted the frame to the patient intra-operatively, you can adjust the deformity and frame configuration software settings in the post-op mode.





Study number	Date created	Study notes	Mode		
1	11/07/2016	This is example 5	Pre-Op	Convert to Post-Op	Open

To change a pre-op case to a post-op case:

1. Navigate back to the **MY DASHBOARD** page.
2. Open the appropriate case.
3. Click the convert to post-op link.
4. A convert to post-op link may also be found at the bottom left of the correction plan page. This mode is used if the frame has already been mounted on the patient. You will define the deformity (using the deformity measurement tool or manual input), and enter type, position, orientation of the moving and reference rings, and strut length values and type (short, medium, etc.).

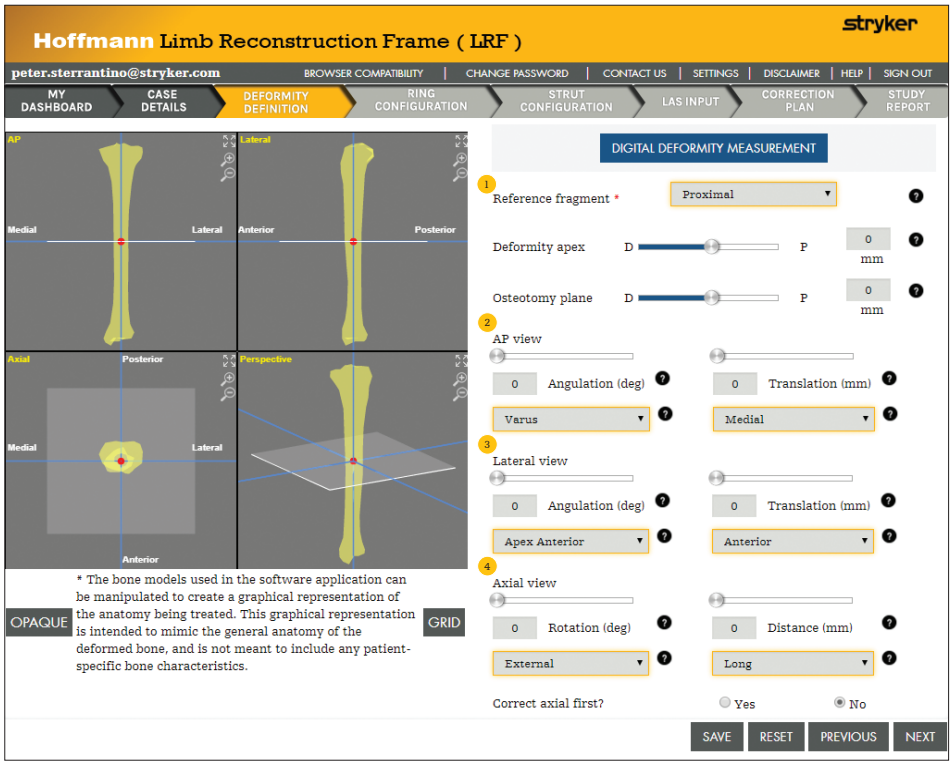
The software will then generate the correction plan based on this frame to correct the deformity.

The primary difference between pre-op and post-op modes is that in pre-op mode, you select the deformity, ring, and strut parameters and the software suggests a range of possible solutions. In post-op mode, you tell the software what has been built and the placement on the patient, and it computes the solution for that case.

If this mode has been entered through the conversion of a pre-op case, the case parameters will all be filled in based on the pre-op values. You may then adjust or correct any parameter to represent the as-built post-operative case (e.g., osteotomy location is different than planned). Post-op mode is discussed in more detail in a later section.

Deformity definition using manual controls (pre-op mode)

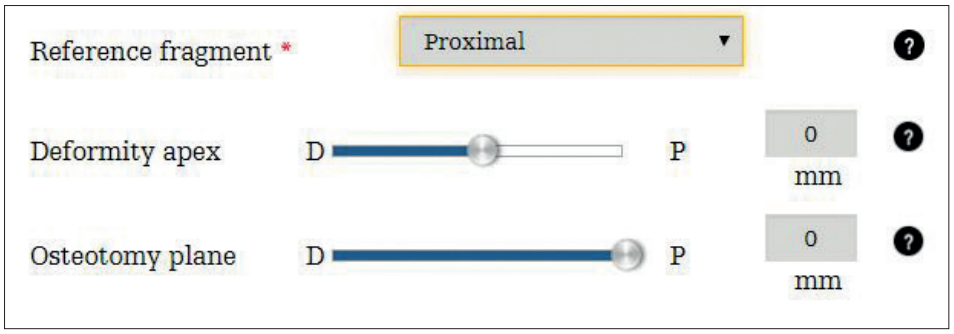
An overview of the deformity definition page is shown to the right. This page allows you to fully define the deformity in the AP, lateral, and axial planes.



The deformity definition page allows you to set the following deformity parameters:

- Reference fragment – use the drop down to select proximal or distal
- Deformity apex – enter the apex of the deformity in mm
- Osteotomy plane – enter the location of the osteotomy on the bone in mm

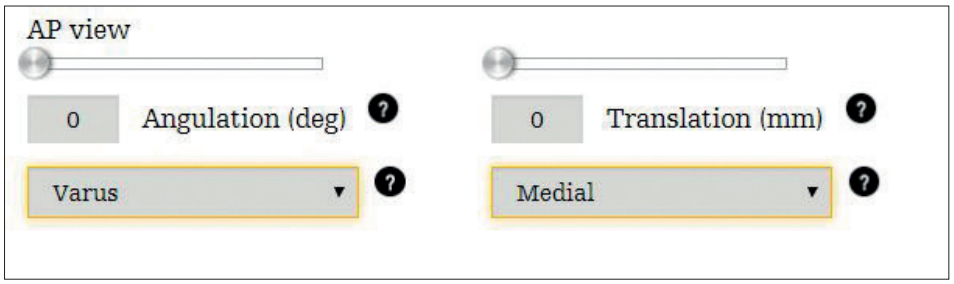
1



In the AP View:

- Angulation – enter a value in degrees to set AP angulation. Varus or valgus may be selected using the drop-down box
- Translation – enter a value in mm to set AP translation. Medial or lateral may be selected using the drop down box

2



Deformity definition using manual controls (pre-op mode)

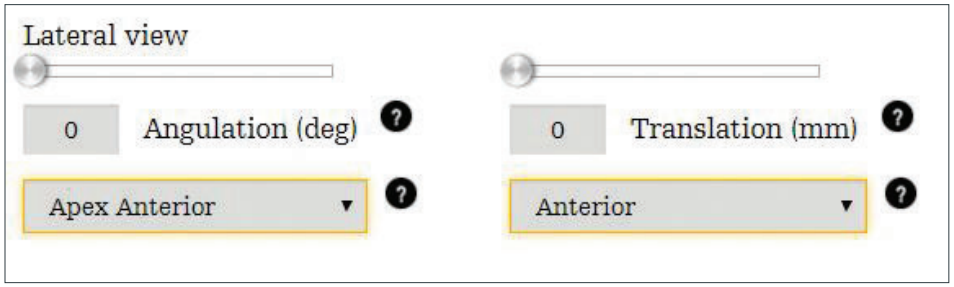
In the lateral view:

- Angulation – enter a value in degree to set lateral angulation. Apex anterior or apex posterior may be selected using the drop down box
- Translation – enter a value in mm to set lateral translation. Anterior or posterior may be selected using the drop down box

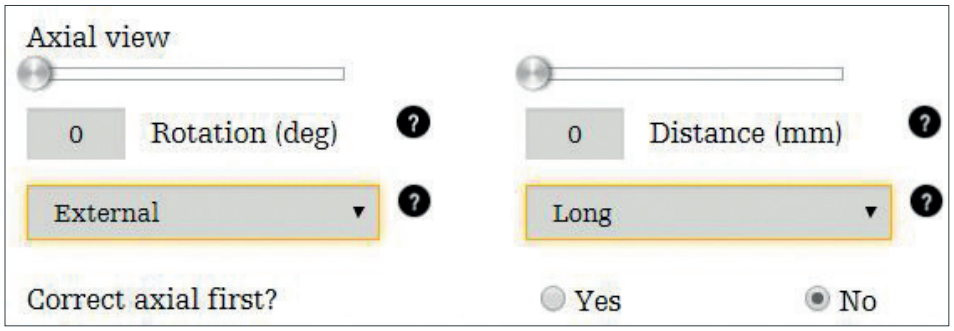
In the axial view:

- Rotation – enter a value in degrees to set axial rotation. External or internal may be selected using the drop down box
- Distance – enter a value in mm to set axial translation. Long or short may be selected using the drop down box
- Correct axial first? – select the yes radio button if you would like the axial portion of the deformity correction plan to be performed **BEFORE** the angulation, translational, and rotational components of the correction. Otherwise, select No

3



4



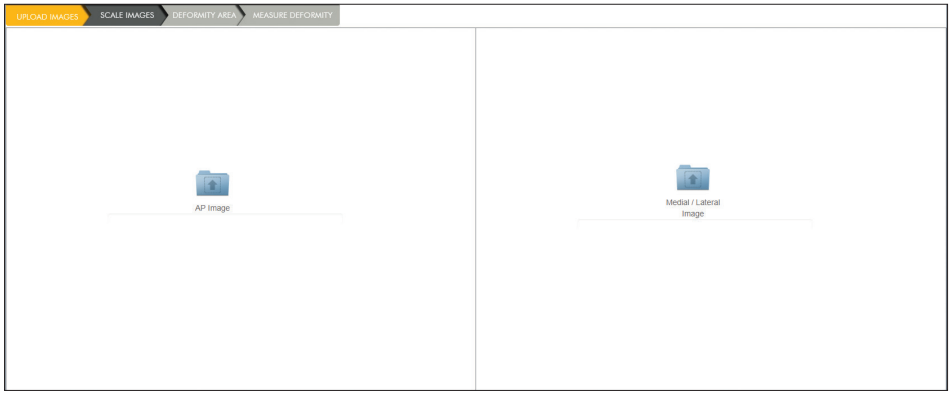
NOTICE

Depending on the type of osteotomy, correcting axially first may avoid impingement at the osteotomy site in certain cases.

Deformity definition using the deformity measurement tool (pre-op mode)

An alternative to entering in the deformity definition manually is to use the deformity measurement tool (DMT). While in pre-op mode, click on the **DIGITAL DEFORMITY MEASUREMENT** button at the top right of the page.

A new browser window will open showing the deformity measurement tool process flow and AP and lateral image panes, on the left and right hand sides of the screen respectively.



The chevron bar at the top of the window shows the DMT process flow.

This process involves four steps:

- Upload both the AP and lateral radiographic (X-ray) images
- Scale the images
- Define (or crop) the deformity area of interest in the image (if necessary)
- Measure the deformity by manipulating the X-ray images and bone model to match the deformity

Deformity definition using the deformity measurement tool (pre-op mode)

Uploading images

NOTICE

The following image file formats can be uploaded to the application: *.png, *.jpg, *.bmp, *.tif, *.tiff and *.dicom.

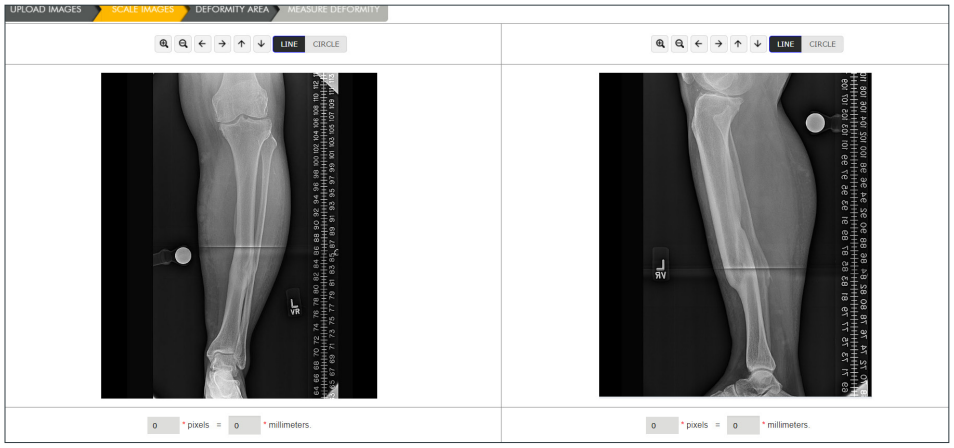
1. Click on the file folder in the AP image field.
2. Browse to search for the X-rays you wish to upload in the AP view image field.
3. To confirm click **OPEN**. The image will load in the AP pane.
4. Repeat steps 2 and 3 for the upload of the lateral view X-ray.
5. Click next to be directed to the scale images screen.

If the loaded image is incorrect, a new image may be loaded by clicking on the file folder icon again.

You may leave the DMT at any time and revert back to manually entering the measured deformity values from the radiographs by pressing the **CANCEL** button.

Scaling Images

The imported radiographic images must be scaled pre-operatively so the measured deformity values are accurate.



A tool bar is provided to assist in scaling the images.

The function of the tools is described in the table to the right.

	**Line/Circle Selection** Selects either a linear (line) or circular (circle) scale marker.
	**Image Movement** Using these arrows, you can move the image up and down, and to the left and right.
	**Zoom in/out** Zoom the image in or out

Deformity definition using the deformity measurement tool (pre-op mode)

1. In the AP pane, select either a linear (line) or circular (circle) marker.
2. Draw a line on the X-ray to identify the length of the marker.

⚠CAUTION

The more accurate the line, the more accurate the deformity measurement. This is critical for the software application to generate an accurate correction plan.

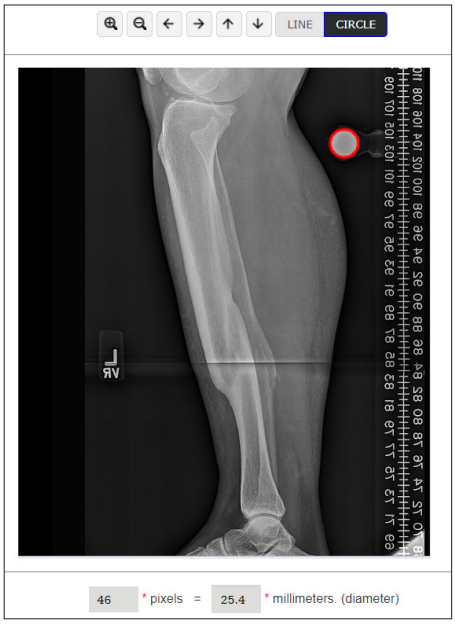
3. If using the circle marker, position the circle so it just surrounds the marker.

⚠CAUTION

The more accurate the circle, the more accurate the deformity measurement. This is critical for the software application to generate an accurate correction plan.

4. Enter the actual length or diameter in millimeters of the marker which is indicated on the X-ray (in the line marker example shown to the right, 100mm = 149 pixels). The system will fill out the pixels field automatically.
5. Perform the scaling process on the lateral X-ray.
6. Click next to continue with the definition of the deformity area.

Example of scaling with line scale marker

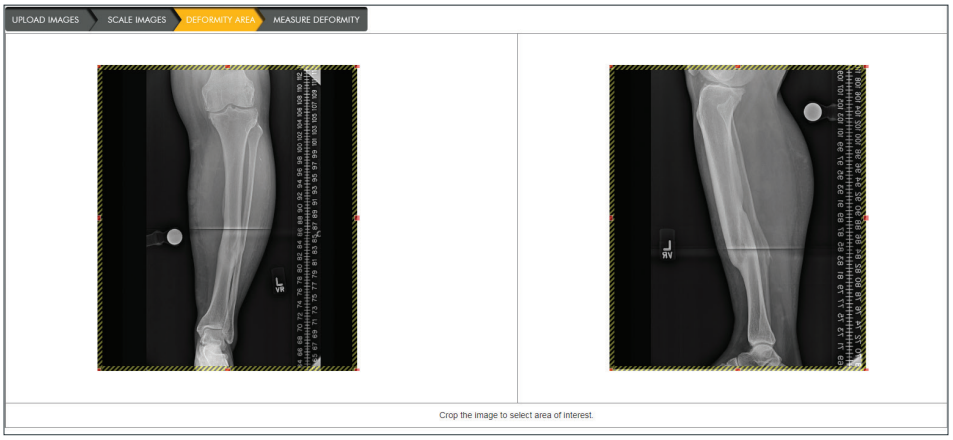


Example of scaling with circle scale marker

Deformity definition using the deformity measurement tool (pre-op mode)

Deformity area

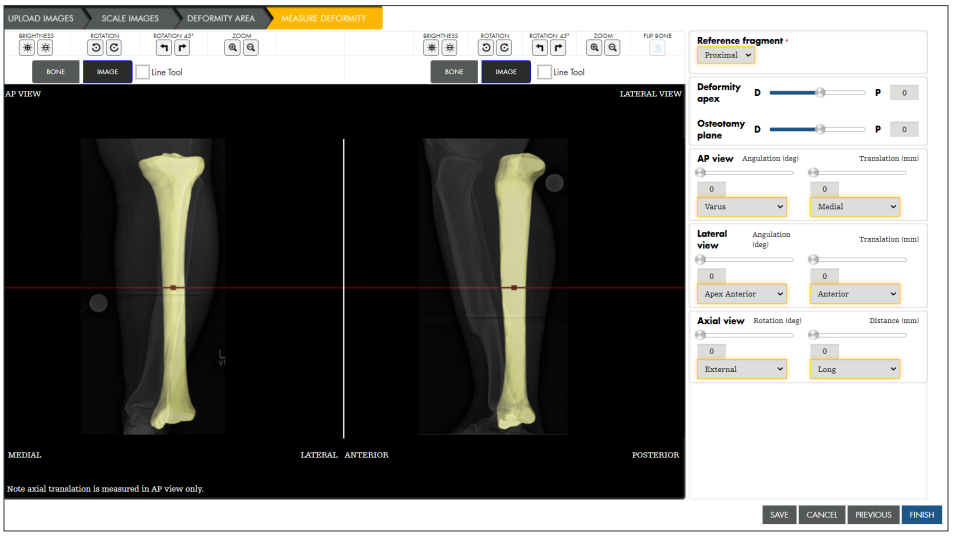
The deformity area of interest can be cropped to remove unwanted information.



1. Pull the red cubes on the edge of the X-ray image to adjust the yellow hashed frame so that the area of interest is shown within the yellow frame. The image to the right shows the AP image area "cropped" to remove the scaling rule.
2. Repeat for the lateral image.
3. Click **NEXT** to continue.

Measure deformity:

The measure deformity screen allows you to manipulate the X-ray images and bone model to match the deformity. This simplifies deformity definition by allowing the user to measure deformity parameters directly from the radiographic image. Angular and translation parameters may also be measured directly off the radiographic images using the Line Tool.



Deformity definition using the deformity measurement tool (pre-op mode)

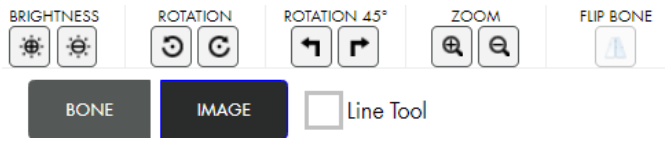
Deformity area (continued)

There is a tool bar to help manipulate the X-ray images and bone model to match. Mouse-over help is available to describe the functions of each control.

The functions of the tools are described in the table to the right.

NOTICE

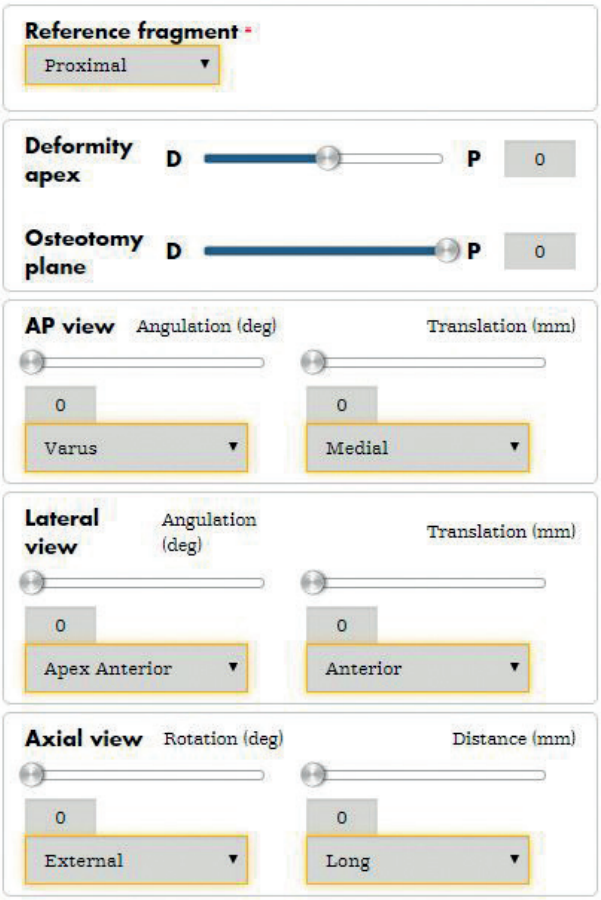
The image or bone model may also be moved using a drag and drop method if desired.



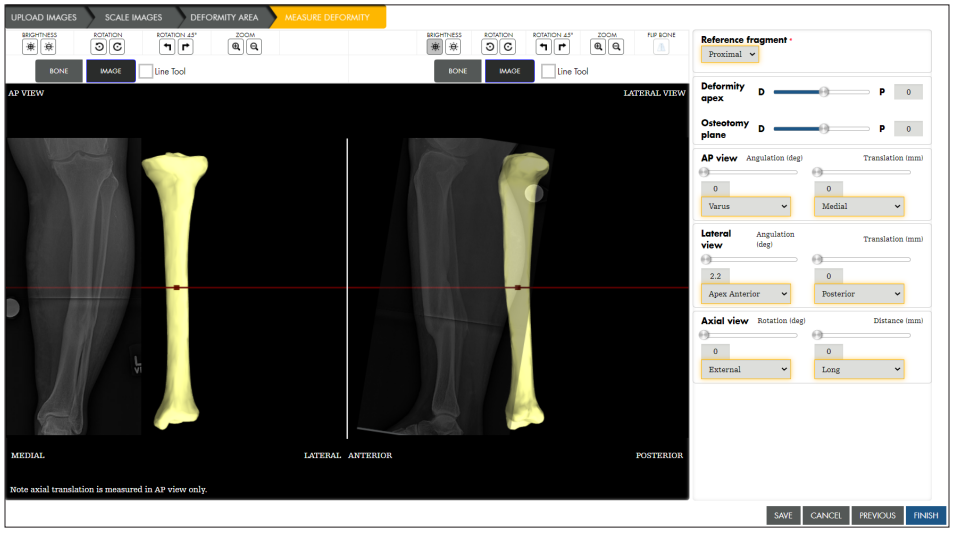
BONE IMAGE	**Bone/Image Selector** Selects whether the controls apply to the bone model or X-ray Image (default is the X-ray Image – white background).
BRIGHTNESS	**Increase/decrease opacity** Controls the opacity of the X-ray image (only available when Image is selected).
ROTATION	**Rotate clockwise/anti-clockwise (fine)** Rotates the X-ray image one degree in the appropriate direction (available when Image is selected).
ROTATION 45°	**Rotate clockwise/anti-clockwise (coarse)** Rotates the X-ray image 45 degrees in the appropriate direction (available when Image is selected).
ZOOM	**Image zoom** Zooms the X-ray image in or out (only available when Image is selected).
FLIP BONE	**Bone Flip** Flips the bone left or right to compensate for the situation where the X-ray image was taken with the wrong Lateral orientation (only available when bone is selected and on the lateral view).
Line Tool	**Line Tool Selector** Checking the Line Tool checkbox turns on a line based angle and offset measurement tool for measuring joint angles, deformity angles, and offset parameters.

Deformity definition using the deformity measurement tool (pre-op mode)

In addition, the same controls as shown in the deformity definition section are available to manipulate the bone model to match the deformity in the X-ray image (as shown to the right).



The goal is to manipulate the yellow bone model into the same size and shape as the deformed bone in the X-ray image. Align the bone model (yellow highlighted in the software) to the X-ray image to get the deformity values. Using the tools and/or drag and drop techniques, line up the X-ray image and the bone model by matching anatomical landmarks (e.g., lateral /medial tibial plateaus, tibial plafond, medial malleolus, tibial shaft, etc.). Use the tools on the toolbar to manipulate the X-ray or the bone model as needed. This shaped bone model will now accurately reflect the deformity measurements.



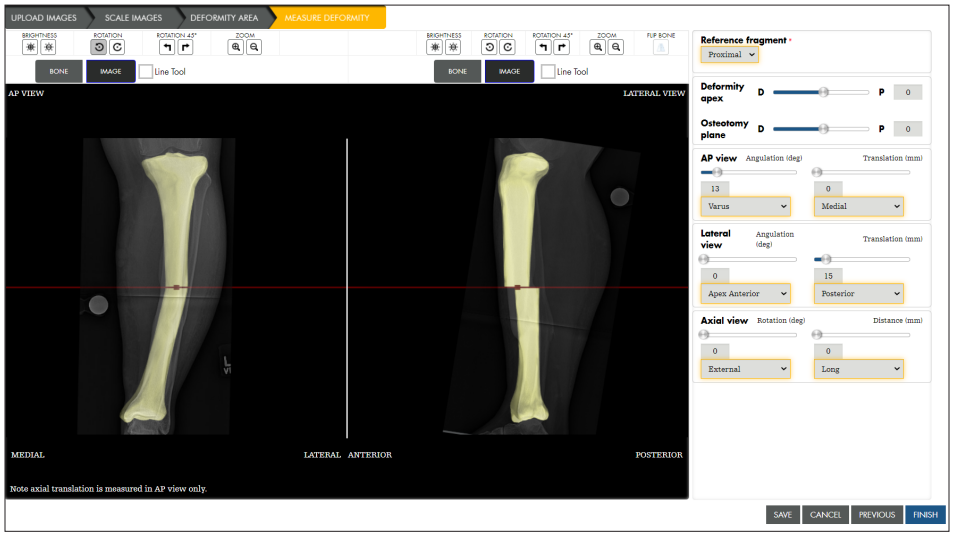
Before alignment

Deformity definition using the deformity measurement tool (pre-op mode)

Follow these steps to measure the deformity using the deformity measurement tool:

1. Select which image you want to manipulate: the bone model or the X-ray image.
2. Adjust the deformity apex (red dot on the bone model) and the osteotomy plane using the corresponding sliders.
3. Adjust the AP view values of angulation and translation.
4. Choose between varus and valgus or medial and lateral in the AP view.
5. Adjust the lateral view values of angulation and translation.
6. Choose between apex anterior and apex posterior or anterior and posterior in the lateral view.
7. Adjust the axial view values of rotation (degrees) and distance (mm).
8. Choose between external and internal or short and long in the axial view.

This auto-populates the deformity values which are now seen on the deformity definition page shown to the right. Click **NEXT** to move on to the ring configuration page.

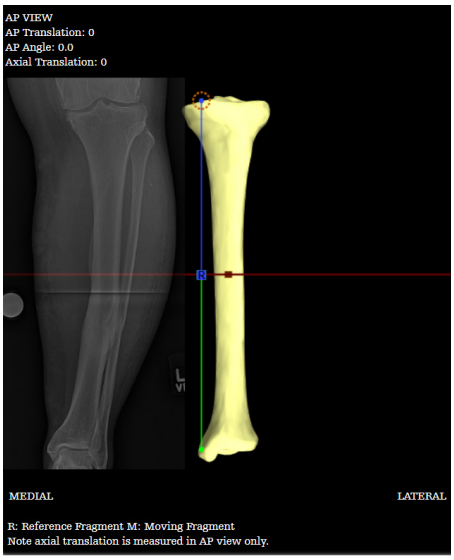


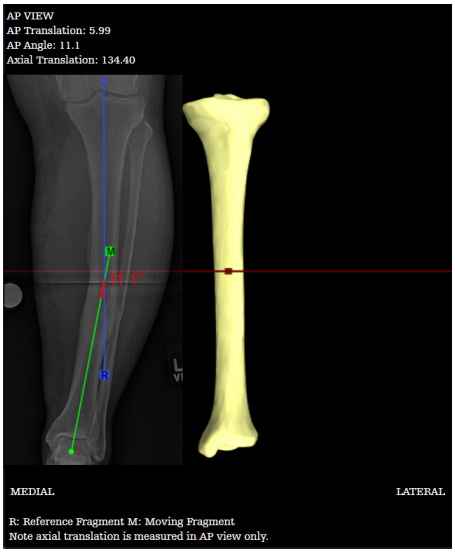
After alignment

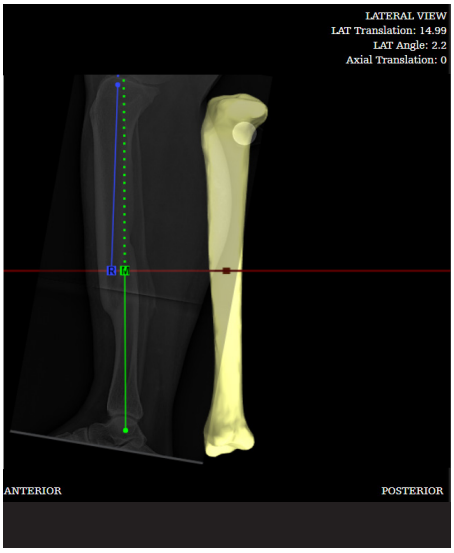
Deformity definition using the line tool (pre-op mode)

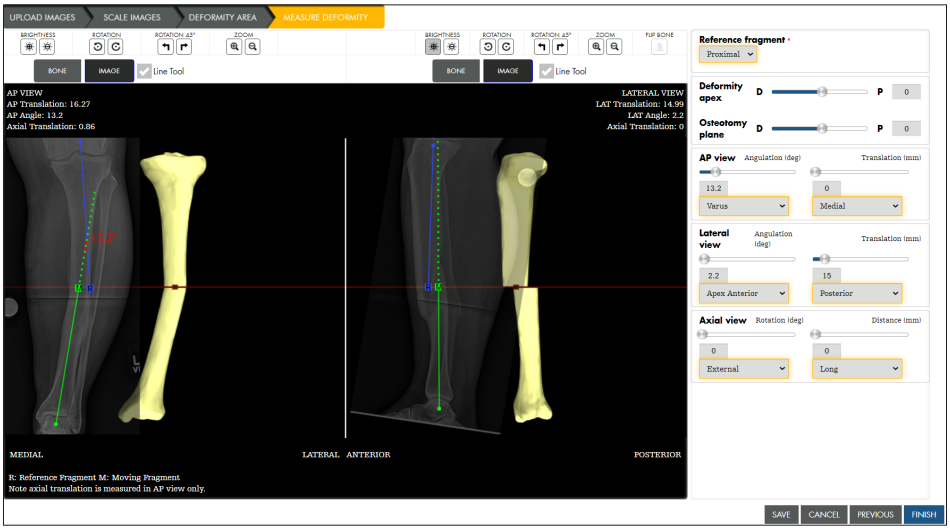
Follow these steps to measure the deformity using the line tool:

1. Check the line tool checkbox.
2. Using your mouse, drag and drop the radiograph image to a place on the AP or Lateral view where it is not obscured by the bone model.
3. Brighten the radiographic image as needed using the brightness controls.
4. Select a line endpoint to move by positioning your cursor over the point. The point will change to a dotted circle as shown to the right.
5. Drag and drop the endpoints of the lines as needed to measure the angle of interest as shown to the right. The angle and translation values are displayed. Note: Translation values represent the distance between the line endpoints (R and M points).
6. The line tool values may be copied and entered on the deformity measurement page or entered in the deformity pane on the right of the deformity measurement window. Entering the deformity values will deform the bone model accordingly as shown to the right.
7. Clicking **FINISH** will auto-populate the deformity values which are now seen on the deformity definition page. Click **NEXT** to move on to the ring configuration page.



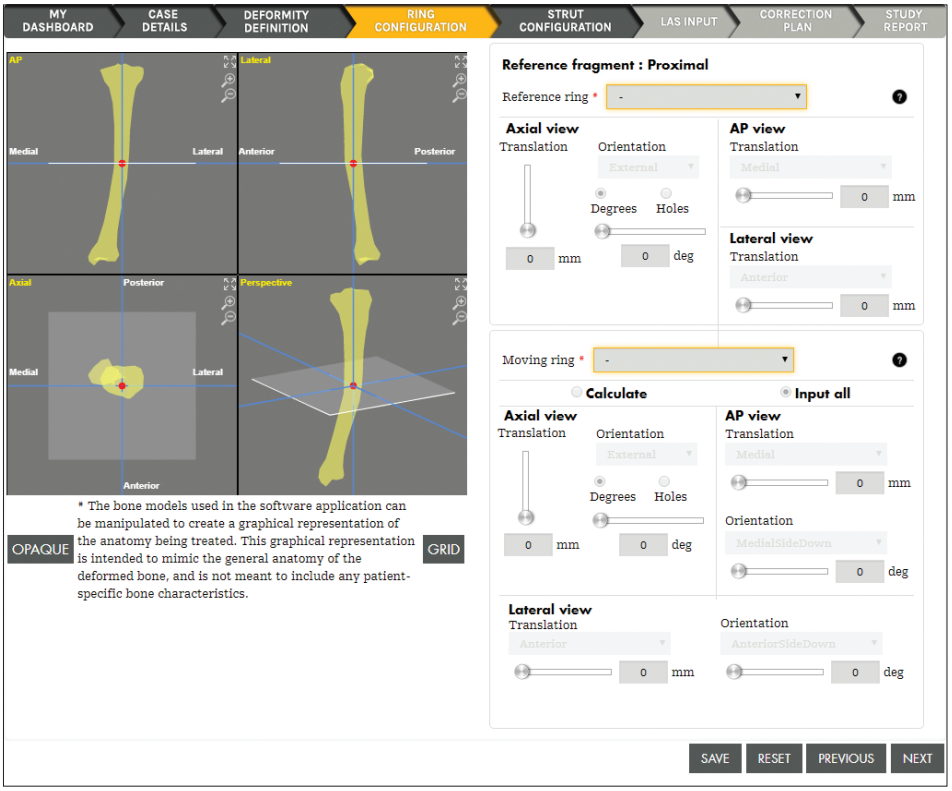






Ring configuration (pre-op mode)

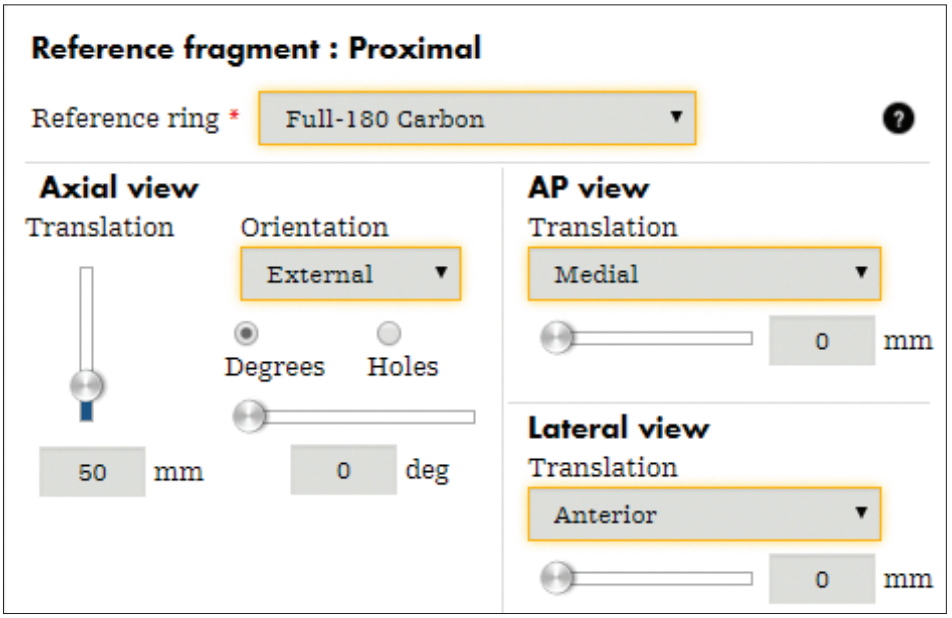
In the ring configuration page, you define the reference and moving ring type and size, and their planned placement on the bone. The ring configuration page shows the multi-planar-view (MPV) on the left side of the screen and control panels for the reference and moving rings on the right.



> **NOTICE**
>
> For detailed information on the operation of the Hoffmann LRF Hexapod (Manual) External Fixation Frame please consult Instructions for Use (www.ifu.stryker.com), and the corresponding Hoffmann LRF Hexapod Operative Technique (Content ID: H-ST-34).

Reference ring:

1. Select the reference ring size and type (full or open and material) from the drop down menu. Once selected, your ring choice will appear on the bone model in the MPV. The default position for this ring is 50 mm above the osteotomy plane.
2. To facilitate your preferences, the reference ring may be moved axially, or translated in the AP or lateral view by using the controls. In addition, the ring orientation may be rotated internally or externally by either degrees or holes depending on the radio button selection.



Ring configuration (pre-op mode)

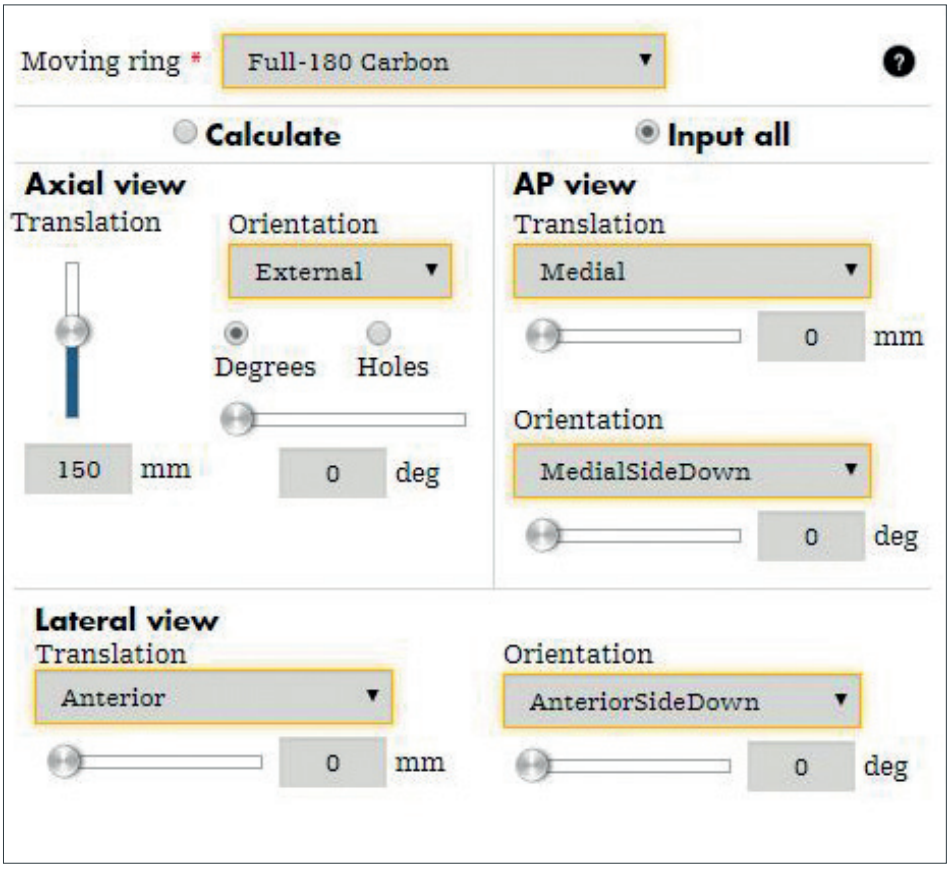
Moving ring:

There are 2 options to input the moving ring position, input all and calculate.

Option 1: Input all

Input all requires you to manually enter the parameters that define the position of the moving ring.

1. Define the position of the moving ring with respect to the osteotomy location.
2. Enter the values for the following parameters which correspond to the position of the center of the moving ring:
   A. Axial view translation (in mm).
   B. Axial view orientation (in deg. or holes).
   C. AP view translation (in mm).
   D. AP view orientation (deg.).
   E. Lateral view translation (in mm).
   F. Lateral view orientation (deg.).
3. You can change the moving ring rotation angle to a different value than the default. Axial View orientation of the moving ring follows the reference ring orientation by default.
4. Click **NEXT** to continue.

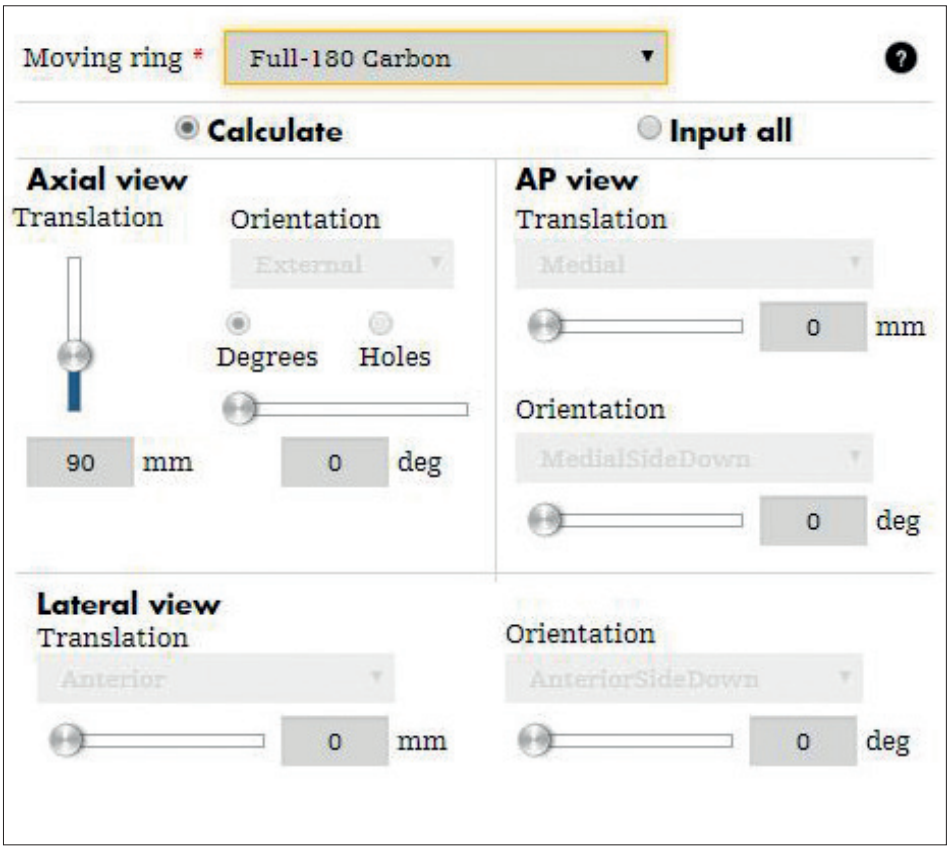


Ring configuration (pre-op mode)

Option 2: Calculate

Calculate will measure and determine the optimal placement of the moving ring based on minimizing strut change-outs during the correction.

1. Enter the reference ring axial translation (if desired) and select the calculate radio button.
2. The optimal moving ring mounting parameters are calculated. The software will suggest the ideal location.
3. The reference ring orientation may change based on the calculation.
4. If any reference ring parameters are changed, the **REFRESH** button will appear in the moving ring window. Pressing the **REFRESH** button will update the moving ring position, based on the new reference ring position.
5. Click **NEXT**.

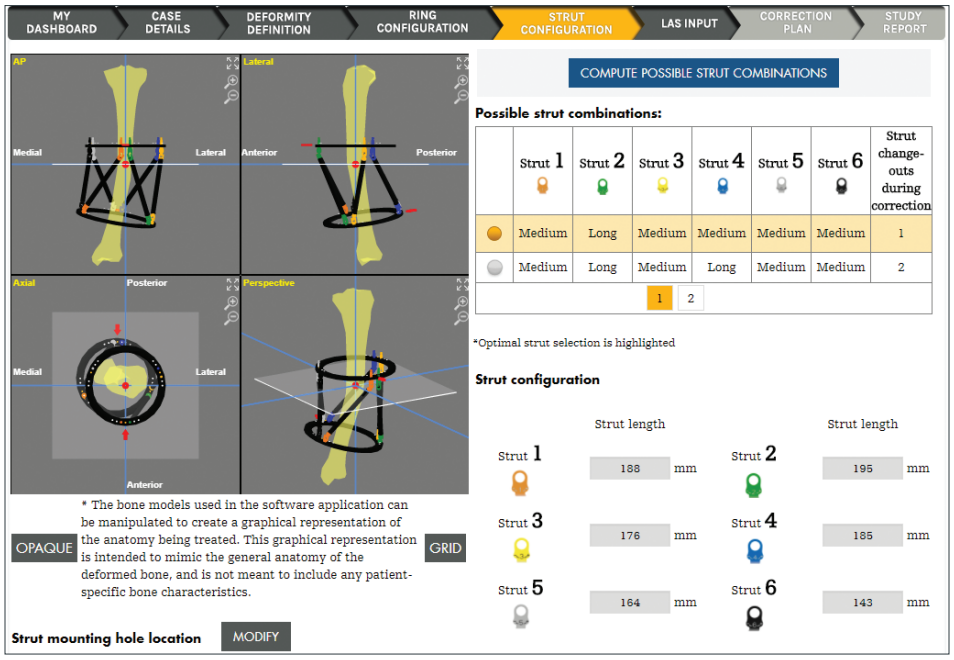


Strut configuration (pre-op mode)

In the pre-op mode **STRUT CONFIGURATION** page, the software computes the optimum strut placement and lengths to minimize strut changes over the course of the correction.

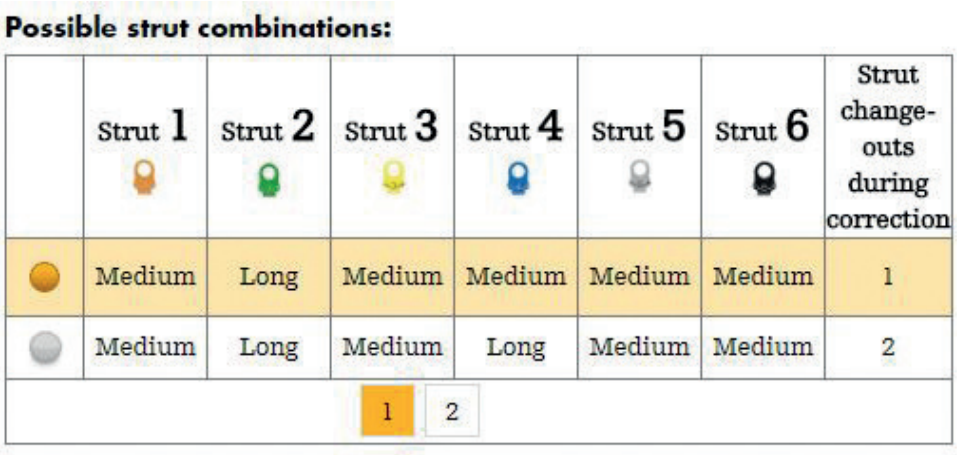
1. Click **COMPUTE POSSIBLE STRUT COMBINATIONS**. This will compute the possible strut combinations to perform the correction.

2. The ideal solution (based on minimum number of strut changes) is selected by default (gold button and highlighted).



3. Should a different combination be desired, click the button on the left side of the row to select the alternate. If more than two choices are available, a page selector will appear below the strut selection window.

4. If the default (nominal) strut position(s) are not acceptable (visibility or access issues), you can adjust the strut mounting hole locations by clicking on the **MODIFY** button beneath the MPV.

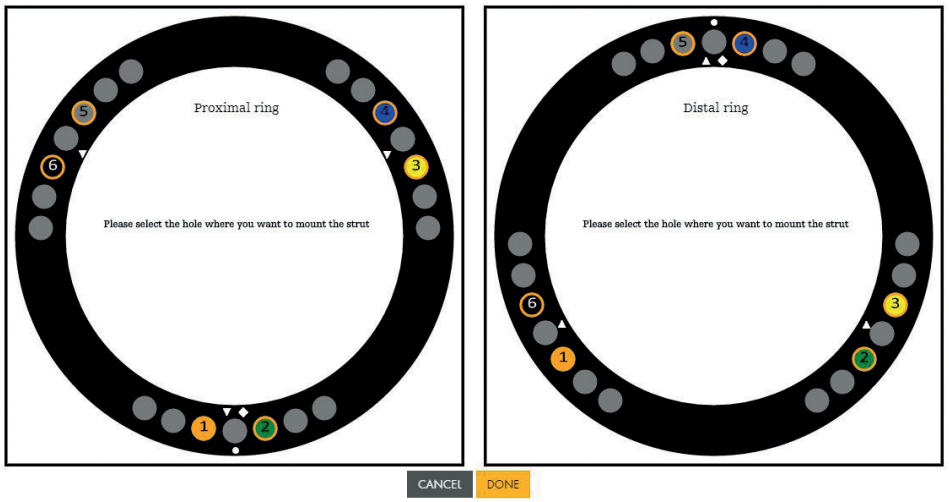


Strut configuration (pre-op mode)

The Modify button brings up a new menu that allows you to offset struts up to two holes from their default (nominal) position. Using the numbered icons in the offset user interface shown to the right you can adjust the struts location by up to two holes in either the clockwise or counter-clockwise direction.

Clicking on the strut you wish to offset will show the optional hole placement "highlighted in green" for strut 1 on the proximal ring as shown to the right.

In the example to the right, strut 2 on the distal ring has been offset two holes in the clockwise direction.

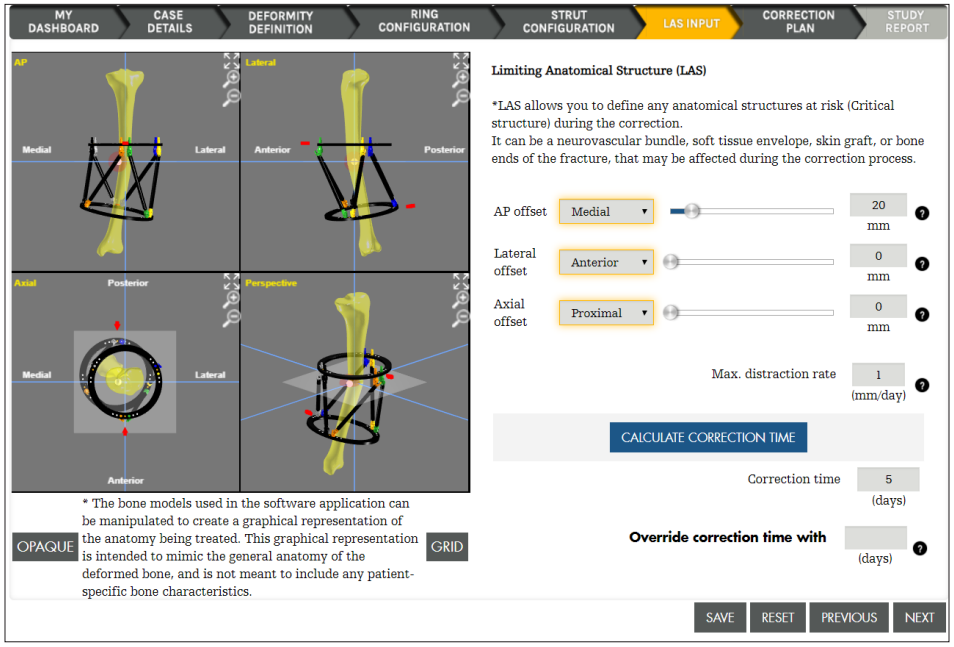


5. When all offsets have been entered, press **DONE** to close the window and save your strut offset choices.
6. If no changes have been made, you can press **CANCEL** to return to the strut configuration page with no changes.
7. Upon returning to the Strut Configuration page, after strut position changes have been made, the system will prompt you to recalculate the strut lengths with the following message to the right:

8. Click **COMPUTE POSSIBLE STRUT COMBINATIONS.** This will compute the new strut combinations to perform the correction.
9. Click **NEXT** to continue.

Limiting anatomical structure (LAS) input (pre-op mode)

The limiting anatomical structure or LAS allows you to define any anatomical structures at risk during the correction. It can be a neurovascular bundle, soft tissue envelope, skin graft, or bone ends of the fracture, that may be affected during the correction process. In this step, you will identify where the LAS is in relation to the deformity apex in the AP, lateral, and axial planes.



1. Using the mouse or pointer, drag and drop the LAS at the desired location (20mm in the example to the right). The AP, Lateral, and Axial offsets will populate automatically. Alternately, you may also enter values in the text boxes directly.
2. You must also enter a maximum distraction rate. 1.0mm/day of correction is generally accepted.
3. Press the **CALCULATE CORRECTION TIME** button and the correction time field will be updated with the calculated correction time.
4. You may override the calculated correction time, with a time (in days) of your choosing by entering a number in the **override correction time** with field, but it may result in a distraction rate that is unacceptable.
5. Click **NEXT** to continue.

NOTICE

For other than pure lengthening cases, at least one non-zero value must be entered.

⚠CAUTION

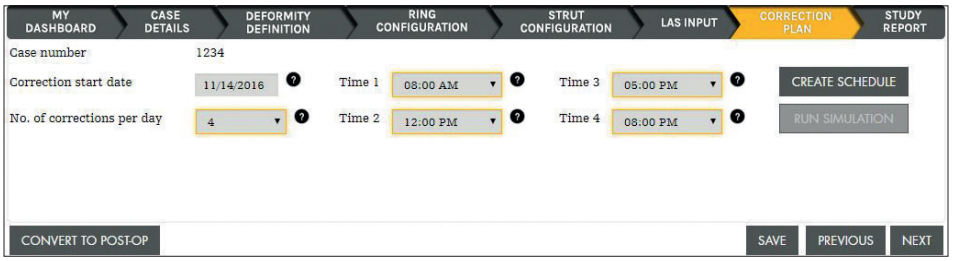
It is recommended that the user define a limiting anatomical structures (LAS) point and calculate a minimum correction time in accordance with the prescribed distraction rate.

⚠CAUTION

Use caution when overriding the recommended minimum correction time to avoid an undesirable distraction rate in excess of 1.0mm / day.

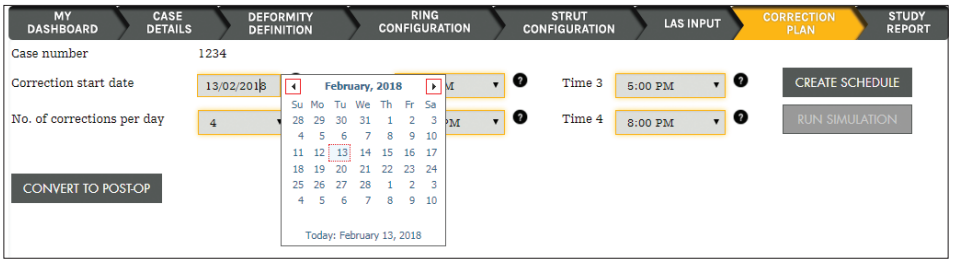
Correction plan (pre-op mode)

The correction plan page allows you to compute a correction plan to correct the defined deformity. The correction plan may be started on any day you select, and you can choose up to 4 corrections per day.



1. Enter the correction start date by clicking on the date field to bring up a calendar and select the date. The date selected may be before the current date. The default date is the current date.
2. Select the number of corrections per day from the drop down box. From 1 to 4 adjustments per day can be selected. The Hoffmann LRF System struts are capable of adjustments as small as 0.25mm with one click.
3. Select the time of day for each correction.
4. Press the **CREATE SCHEDULE** button to generate the correction plan. It will also display any strut change information that may be required during the course of the correction.

   After pressing the button, the correction plan will be generated as shown to the right.
5. Select the whole numbers or decimal radio button to have the correction schedule display digits in whole numbers or decimal format, depending on your preference.



Strut change schedule

Correction range	From	To	Strut ID	Old strut size	New strut size
2 - 4	14/02/2018	16/02/2018	Strut2	Long	Medium

Correction schedule

Strut length in: ○ Whole numbers ◉ Decimal

No.	Date	Time	Strut 1 Orange		Strut 2 Green		Strut 3 Yellow		Strut 4 Blue		Strut 5 Gray		Strut 6 Black	
			clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm
0	Initial position		0	188.25	0	194.75	0	176.50	0	185.00	0	163.50	0	143.00
1	13/02/2018 Tuesday	8:00 AM	5	187.00	11	192.00	10	174.00	2	184.50	14	167.00	15	146.75
2	14/02/2018 Wednesday	8:00 AM	5	185.75	11	189.25	11	171.25	3	183.75	14	170.50	16	150.75
3	15/02/2018 Thursday	8:00 AM	5	184.50	11	186.50	11	168.50	4	182.75	15	174.25	15	154.50
4	16/02/2018 Friday	8:00 AM	5	183.25	12	183.50	11	165.75	4	181.75	14	177.75	15	158.25
5	17/02/2018 Saturday	8:00 AM	6	181.75	12	180.50	11	163.00	4	180.75	16	181.75	15	162.00

Correction plan (pre-op mode)

The correction plan page highlights the strut changes required during the correction period in bright green.

It also displays a Strut change schedule table at the top of the page containing the following information:

1. **Correction range:**
   Day range when the strut change-out can be possible
2. **From:**
   Date the strut change-out phase begins
3. **To:**
   Date the strut change-out phase ends
4. **Strut ID:**
   Strut number that needs to be changed
5. **Old strut size:**
   Old strut size
6. **New strut size:**
   New strut size which replaces the old strut size

Strut change schedule

Correction range	From	To	Strut ID	Old strut size	New strut size
2 - 4	14/02/2018	16/02/2018	Strut2	Long	Medium

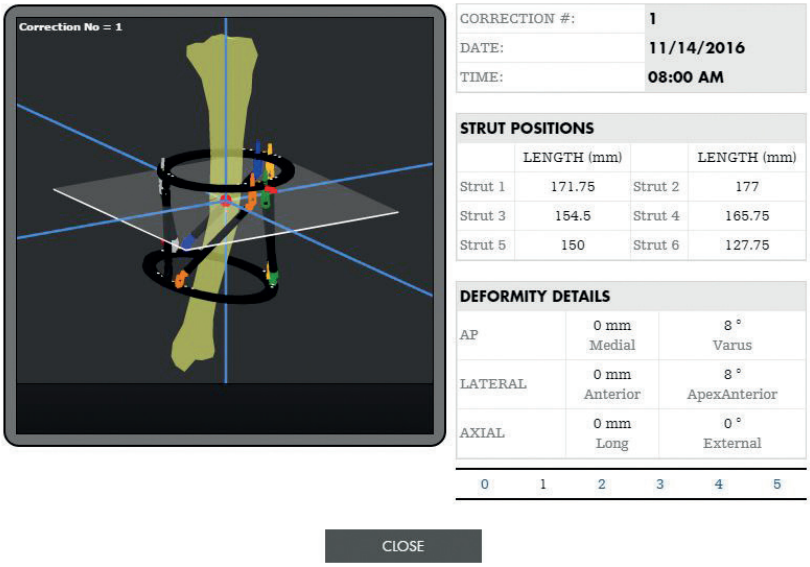
Correction schedule

Strut length in: ○ Whole numbers ◉ Decimal

No.	Date	Time	Strut 1 Orange		Strut 2 Green		Strut 3 Yellow		Strut 4 Blue		Strut 5 Gray		Strut 6 Black	
			clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm
0	Initial position		0	188.25	0	194.75	0	176.50	0	185.00	0	163.50	0	143.00
1	13/02/2018 Tuesday	8:00 AM	5	187.00	11	192.00	10	174.00	2	184.50	14	167.00	15	146.75
2	14/02/2018 Wednesday	8:00 AM	5	185.75	11	189.25	11	171.25	3	183.75	14	170.50	16	150.75
3	15/02/2018 Thursday	8:00 AM	5	184.50	11	186.50	11	168.50	4	182.75	15	174.25	15	154.50
4	16/02/2018 Friday	8:00 AM	5	183.25	12	183.50	11	165.75	4	181.75	14	177.75	15	158.25
5	17/02/2018 Saturday	8:00 AM	6	181.75	12	180.50	11	163.00	4	180.75	16	181.75	15	162.00

Correction plan (pre-op mode)

To display the progress of the limb correction for any day (or an individual adjustment) click on the number in the No. column. Doing so will bring up a status window showing the state of the limb correction at that time.



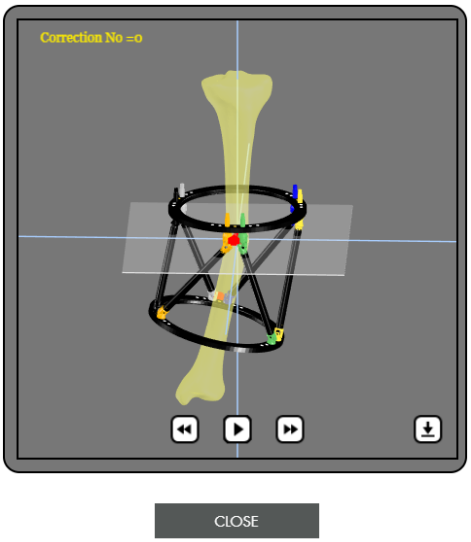
A simulation of the correction plan can be seen by pressing the **run simulation** button. This feature can only be used **after** the correction plan is generated.

Pressing the play button will run the simulation and shows the correction plan run to completion.

Pressing the pause button will pause the simulation.

The forward and rewind step buttons will step the animation one frame forward or backward.

The perspective can be manipulated as desired using mouse controls within the window. Click **CLOSE** to continue.



Study Report (pre-op mode)

The Study Report page provides a complete report of the study including:

- Case details
- Deformity definition
- Reference ring
- Moving ring
- Strut configuration
- Limiting Anatomical Structure
- Correction plan
- Strut change schedule
- Surgeon visit plan (for changing struts)

A partial image of the Study Report page is shown to the right.

The Study Report may be saved in one of two PDF formats for archival and printing. Pressing the **PDF FOR SURGEONS** button will save the full report.

Pressing **PDF FOR PATIENTS** will save a report containing just the case details, the strut change schedule, and the correction plan suitable for printing and giving to your patients. When either button is pressed, the PDF of the chosen Study Report is generated and downloaded to the "downloads" folder on the host PC.

NOTICE

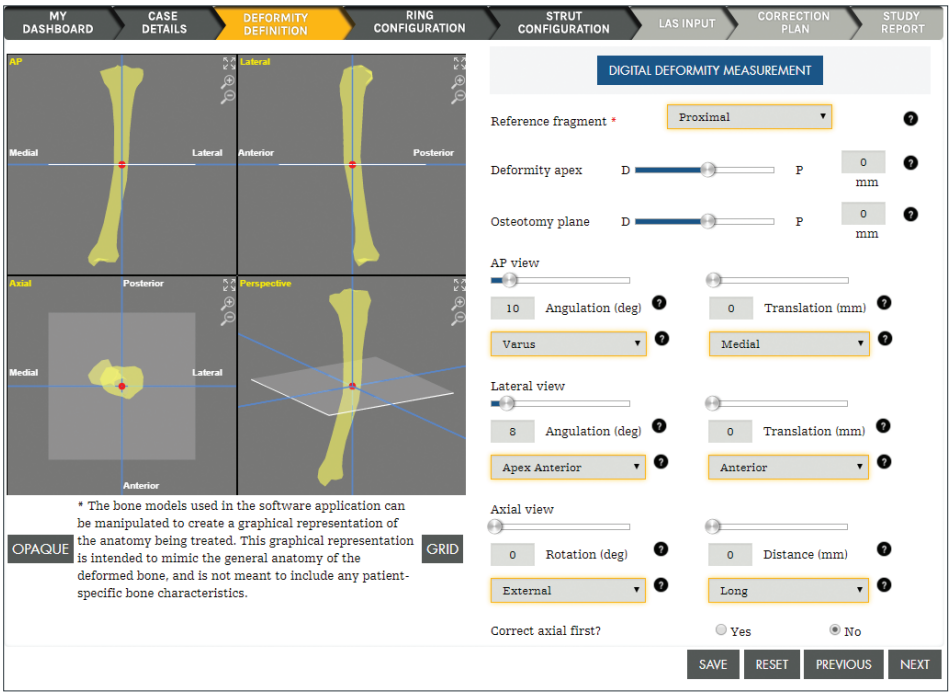
Make sure the frame configuration shown in the multi-planar-view is completely visible before pressing the open in PDF button.

Deformity definition (post-op mode)

The purpose of the post-op deformity definition page is to **fine tune** the deformity parameters based on the outcome of the frame application surgery and to capture the "as built" frame parameters.

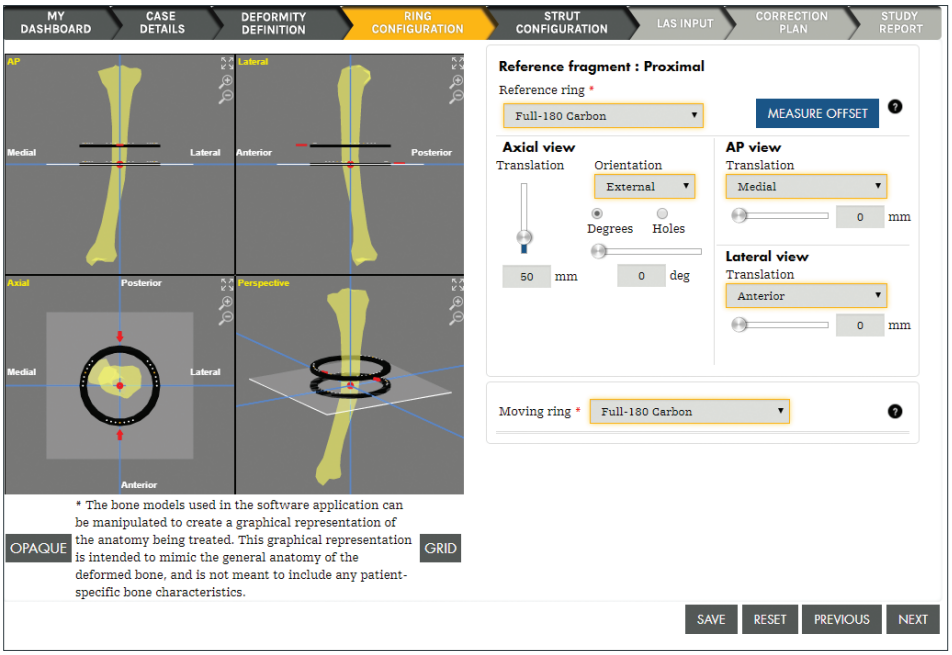
The post-op deformity definition page is identical to the pre-op mode. Post-op X-rays can be used to measure deformity parameters to correct or update the pre-op (planned) values.

As in pre-op mode, this page allows you to fully define the deformity in the AP, lateral, and axial planes using either manual entry of the deformity parameters or the deformity measurement tool (DMT).



Ring configuration (post-op mode)

In the post-op ring configuration page, you define the Reference and Moving Ring type and size, and their post-operative placement on the bone. The Ring Configuration page shows the Multi-Planar-View (MPV) on the left side of the screen and control panels for the reference and moving rings on the right.



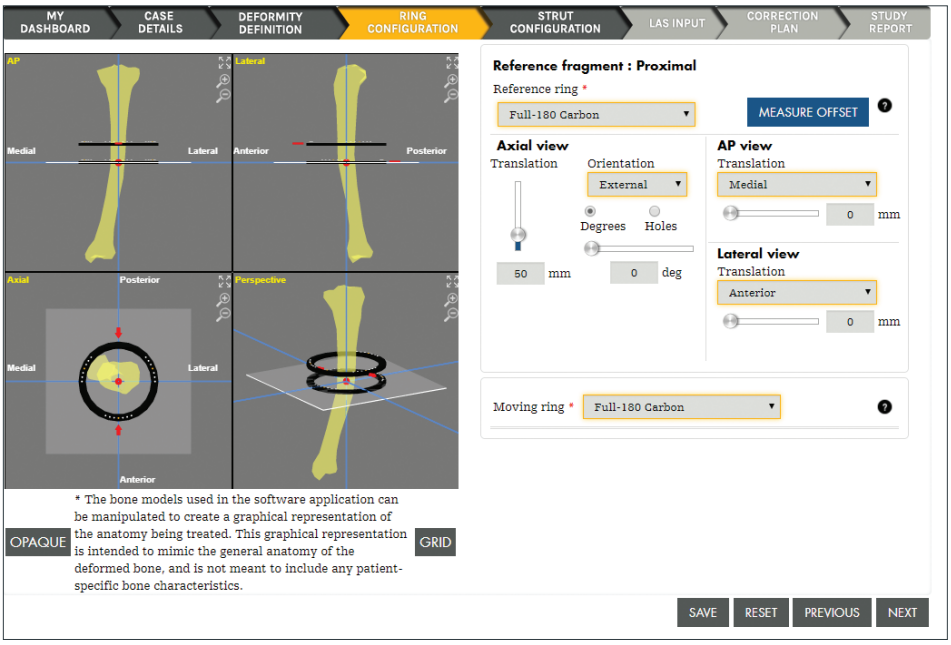
⚠WARNING

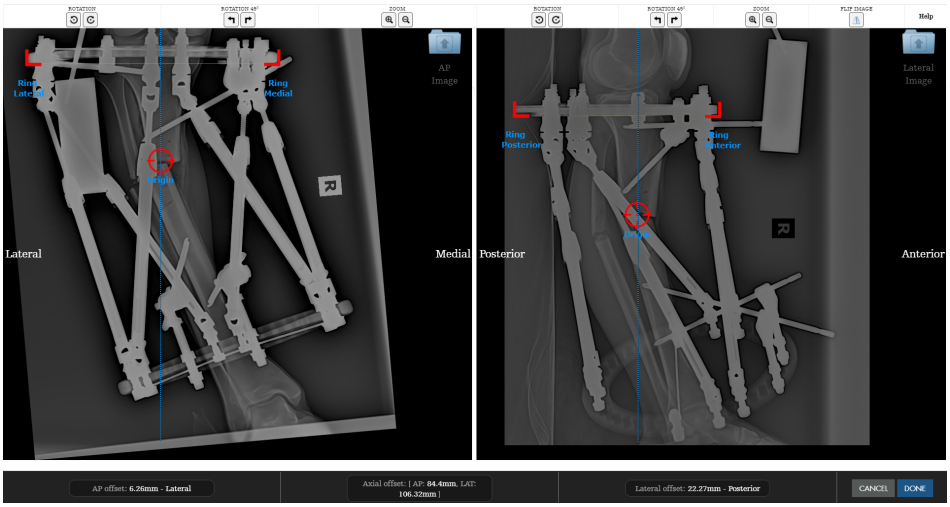
The user must ensure reference and moving ring type, size and placement entered into the software application are consistent with the actual frame applied to the patient. This is critical for the software application to generate an accurate correction plan.

Ring configuration (post-op mode)

Reference ring:

1. If selected in the pre-op mode, the reference ring size will be auto-populated with the ring size previously selected. If using the post-op mode without having done any pre-op planning, select the reference ring size and type (full or open and material) from the drop down menu. Once selected, your ring choice will appear on the bone model in the MPV as shown above. The default position for this ring is 50mm above the osteotomy plane.
2. To facilitate your preferences, the reference ring may be moved axially, or translated in the AP or lateral view by using the controls. In addition, the ring orientation may be rotated internally or externally by either degrees or holes depending on the radio button selection. Ring offsets may be entered manually, or you can use the offset measurement tool.
3. The offset measurement tool (OMT) helps you define the ring offsets with respect to the anatomy by allowing you to directly measure these values off of the post-op radiographs that were loaded in the deformity definition page. Since these images are already scaled, and the application knows the ring size and appropriate dimensions internally, the measurement is done by simply dragging and dropping a set of markers onto the post-op radiographs.

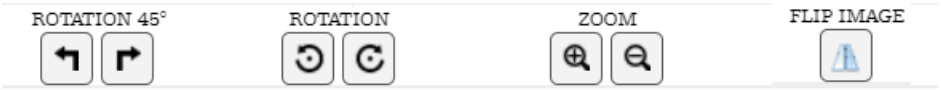


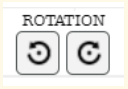


Ring configuration (post-op mode)

There is a tool bar at the top of the page to help manipulate the X-ray images. Mouse-over help is available to describe the functions of each control.

The functions of the tools are described in the table to the right.



	**Flip** Flips the lateral image to the left or right to compensate for when the X-ray image was taken with the wrong lateral orientation (only available on the lateral view).
	**Rotate clockwise/anti-clockwise (fine)** Rotates the X-ray image one degree in the appropriate direction (available when image is selected).
	**Rotate clockwise/anti-clockwise (coarse)** Rotates the X-ray image 45° in the appropriate direction (available when image is selected).
	**Image zoom** Zooms the X-ray image in or out.

NOTICE

The image may also be moved using a drag and drop method if desired.

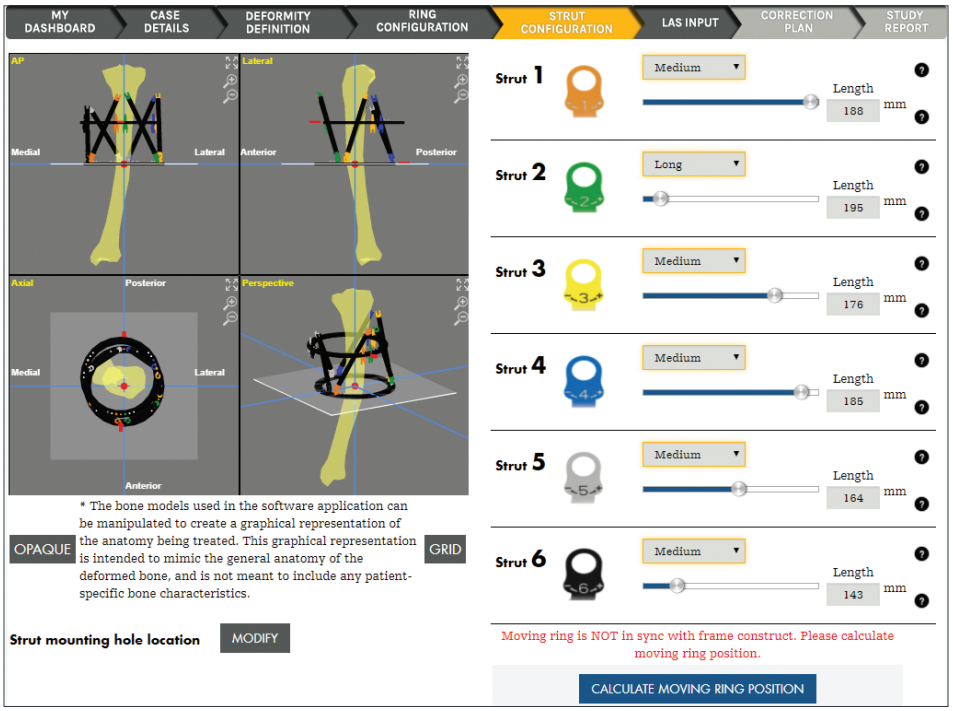
1. In the AP frame, line up the "L" shaped markers with the bottom of the reference ring lateral and ring medial as shown in the example image above. The target circle for the origin is placed at the tip of the deformity.
2. Do the same for the lateral radiograph, aligning the markers on ring posterior and ring anterior, and again at the origin.
3. Clicking **DONE** will capture these values and transfer them automatically to the ring configuration page.

⚠CAUTION

Ensure the markers line up with the bottoms of the ring at the edge of the outer diameter. They are appropriately shaped to assure proper positioning for both proximal and distal cases. Positioning the target circles inaccurately will affect the accuracy of the measurement. Also ensure that anterior / posterior are oriented correctly in the lateral view.

Strut configuration (post-op mode)

In the post-op mode, the strut configuration used on the assembled frame is entered into the web application. If post-op mode was chosen first, initially, the strut sizes and lengths are not populated. If the post-op plan was preceded by a pre-op plan, the strut sizes and lengths are pre-populated with the pre-op values.



⚠ WARNING

The user must ensure type and length of all 6 struts entered into the software application are consistent with the actual frame applied to the patient. This is critical for the software application to generate an accurate correction plan.

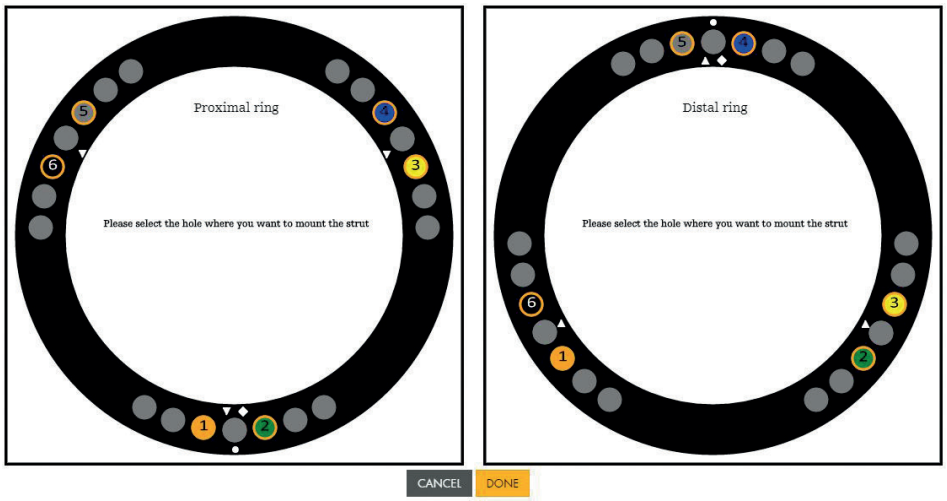
1. Enter strut sizes and lengths from the as-built frame, using the drop down boxes and the slider controls on the right side of the screen. The length values may also be directly entered into the text boxes. The web app will display "moving ring is **NOT** in sync with frame construct. Please calculate moving ring position." This indicates that the moving ring position needs to be recalculated based on the new strut parameters that have been entered.
2. Once the strut parameters have been updated, press the **CALCULATE MOVING RING POSITION** button to update the MPV with the as-built frame construct.
3. If the default (nominal) strut position(s) are not acceptable (visibility or access issues), you can adjust the strut mounting hole locations by clicking on the **MODIFY** button beneath the MPV.

Strut configuration (post-op mode)

The **MODIFY** button brings up a new menu that allows you to offset struts up to two holes from their default (nominal) position. Using the numbered icons in the offset user interface shown below, you can adjust the struts location by up to two holes in either the clockwise or counter-clockwise direction.

Clicking on the strut you wish to offset will show the optional hole placement highlighted in green for strut 1 on the proximal ring as shown to the right.

In the example to the right, strut 2 on the distal ring has been offset two holes in the clockwise direction.

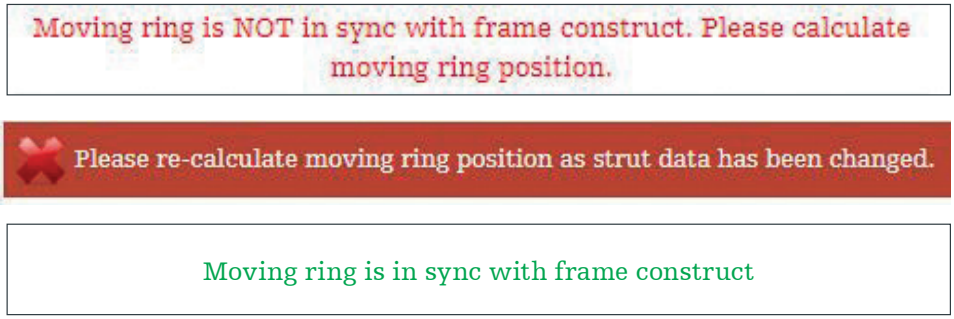


4. When all offsets have been entered, press **DONE** to close the window and save your strut offset choices.

5. If no changes have been made, you can press **CANCEL** to return to the strut configuration page with no changes.

6. Upon returning to the strut configuration page, after strut position changes have been made, the system will prompt you to recalculate the moving ring position with the following message.

   If you press the **NEXT** button without re-calculating the moving ring position, you will receive the following error message.



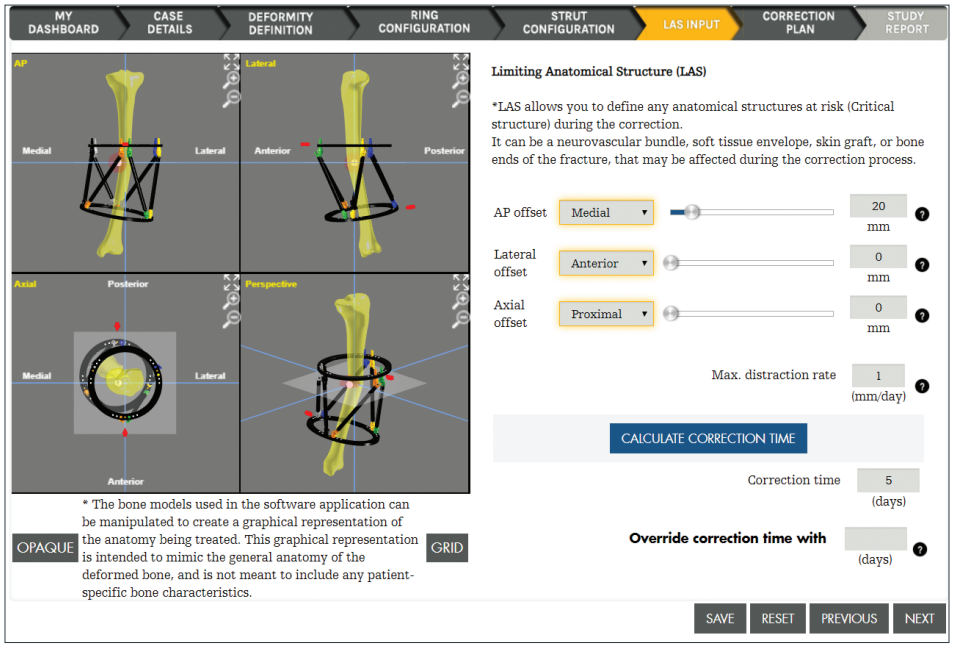
7. Click the **CALCULATE MOVING RING POSITION** button to update the MPV with the new strut positions as in the as-built frame construct. The page will update and display the above:

8. Click **NEXT** to continue.

Limiting anatomical structure (LAS) input (post-op mode)

The limiting anatomical structure or LAS allows you to define any anatomical structures at risk during the correction. It can be a neurovascular bundle, soft tissue envelope, skin graft, or bone ends of the fracture, that may be affected by the correction process. In this step, you will identify where the LAS is in relation to the deformity apex in the AP, lateral and axial planes.

1. Using the mouse or pointer, drag and drop the LAS at the desired location (20mm in the example to the right). The AP, Lateral, and Axial offsets will populate automatically. Alternately, you may also enter values in the text boxes directly.
2. You must also enter a maximum distraction rate. 1.0mm / day of correction is generally accepted.
3. Press the **CALCULATE CORRECTION TIME** button and the correction time field will be updated with the calculated correction time.
4. You may override the calculated correction time, with a time (in days) of your choosing by entering a number in the **override correction time** with field, but it may result in a distraction rate that is unacceptable.
5. Click **NEXT** to continue.



NOTICE

At least one non-zero value must be entered.

⚠CAUTION

It is recommended that the user define a limiting anatomical structures (LAS) point and calculate a minimum correction time in accordance with the prescribed distraction rate.

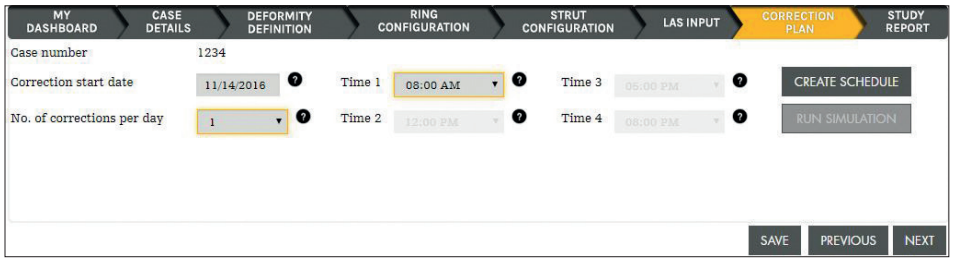
Use caution when overriding the recommended minimum correction time to avoid an undesirable distraction rate in excess of 1.0mm / day.

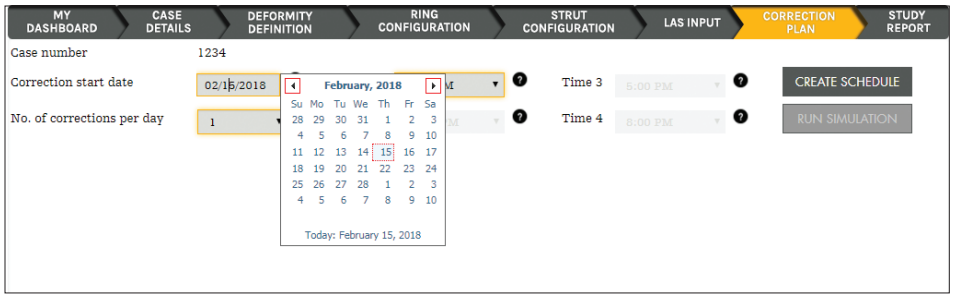
Correction plan (post-op mode)

The correction plan may be started on any day you select, and you can choose up to 4 corrections per day.

1. Enter the correction start date by clicking on the date box. This will bring up a calendar for you to select the correction start date. The date selected may be before the current date. The default date is the current date.
2. Select the No. of corrections per day from the drop down box. 1 to 4 adjustments per day can be selected. The Hoffmann LRF Hexapod struts are capable of adjustments as small as 0.25mm per click.
3. Select the time of day for each correction.
4. Press the **CREATE SCHEDULE** button to generate the correction plan. It will also display any strut change information that may be required during the course of the correction. After pressing the button, the correction plan will be generated as shown to the right.
5. Select the whole numbers or decimal radio button to have the correction schedule display digits in whole numbers or decimal format, depending on your preference.

The correction plan page highlights the strut change-outs required during the correction in bright green. It also displays a strut change schedule table at the top of the page containing the following information:





Strut change schedule

Correction range	From	To	Strut ID	Old strut size	New strut size
2 - 3	02/16/2018	02/17/2018	Strut6	Short	Medium

Correction schedule

Strut length in: (•) Whole numbers ( ) Decimal

No.	Date	Time	Strut 1 Orange		Strut 2 Green		Strut 3 Yellow		Strut 4 Blue		Strut 5 Gray		Strut 6 Black		
			clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm	
0	Initial position		0	173	0	180	0	157	0	164	0	146	0	124	
1	02/15/2018 Thursday	8:00 AM	-4	172	-10	178	-10	154	-1	164	+12	149	+15	128	Revise study
2	02/16/2018 Friday	8:00 AM	-5	171	-11	175	-11	152	-3	163	+14	152	+15	132	Revise study
3	02/17/2018 Saturday	8:00 AM	-4	170	-11	172	-11	149	-3	162	+13	156	+15	135	Revise study
4	02/18/2018 Sunday	8:00 AM	-5	168	-11	169	-11	146	-3	162	+14	159	+15	139	Revise study
5	02/19/2018 Monday	8:00 AM	-5	167	-12	166	-12	143	-4	160	+14	163	+15	143	Revise study

Correction range:
Day range when the strut change-out can be possible

From:
Date the strut change-out phase begins

To:
Date the strut change-out phase ends

Strut ID:
Strut number that needs to be changed

Old strut ID:
Old strut type

New strut ID:
New strut type which replaces the old strut ID

Correction plan (post-op mode)

6. A simulation of the correction plan can be seen by pressing the **RUN SIMULATION** button.

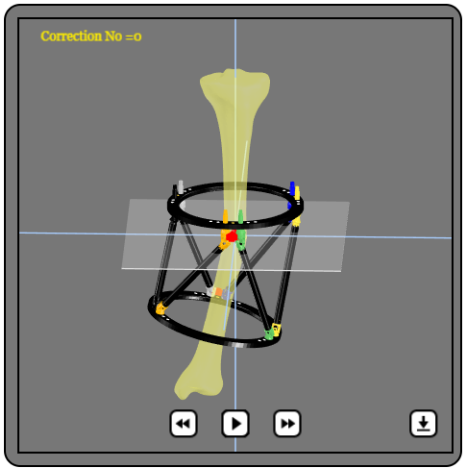
Pressing the **PLAY** button will run the simulation and shows the correction plan run to completion.

Pressing the **PAUSE** button will pause the simulation.

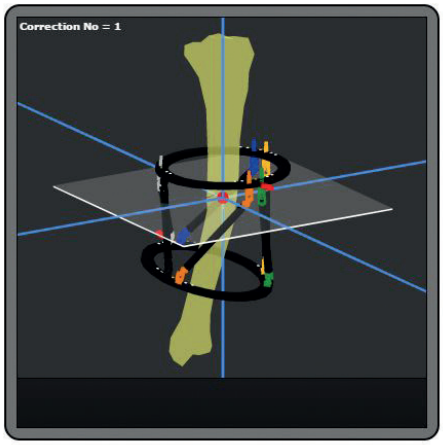
The **FORWARD** and rewind step buttons will step the animation one frame forward or backward.

The perspective can be manipulated as desired using mouse controls within the window. Click **CLOSE** to continue.

To display the progress of the correction for any day (or individual adjustment) click on the number in the No. column. Doing so will bring up a status window showing the state of the correction at that time. This can be used to compare the computed position to the patient's actual position at any time during the correction.



CLOSE



CORRECTION #:	1
DATE:	11/14/2016
TIME:	08:00 AM

STRUT POSITIONS

	LENGTH (mm)		LENGTH (mm)
Strut 1	171.5	Strut 2	176.75
Strut 3	154.5	Strut 4	166
Strut 5	149.25	Strut 6	128

DEFORMITY DETAILS

AP	0 mm Medial	8 ° Varus
LATERAL	0 mm Anterior	8 ° ApexAnterior
AXIAL	0 mm Long	0 ° External

0 1 2 3 4 5

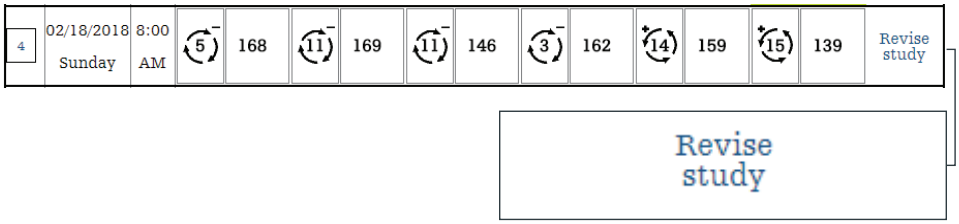
CLOSE

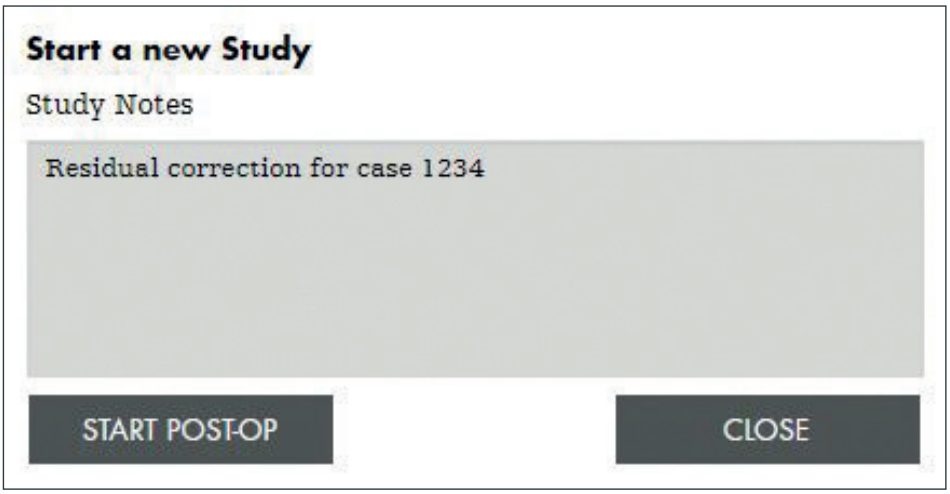
Revisions to the correction plan (post-op mode) or residual corrections

It is possible that after the correction plan has been completed there remains some residual deformity that should be corrected. To do a residual deformity correction, click on the Revise study link at the right side of the correction plan.

A revision to the correction plan may be performed at any time during the correction if the surgeon feels that the correction is not progressing as expected.

1. To revise a study for a specific case, navigate to the correction plan page and click on the revise study link at the right side of the correction plan.
2. A pop-up will be provided to add study notes as shown to the right.
3. Click on the **START POST-OP BUTTON**. This will return you to the deformity definition page which has been pre-populated with the deformity values at the time of the residual correction. For example, revising a study on day 15 of the correction plan will pre-populate the deformity definition page with the deformity values that were computed for day 15 of the original correction. These values can be manually changed if necessary.
4. Treat the residual correction as another post-op correction plan and continue as described in the sections above.





Study Report (post-op mode)

The post-op Study Report page provides a complete report of the post-op study including:

- Case details
- Deformity definition
- Reference ring
- Moving ring
- Strut configuration
- Limiting anatomical structure
- Correction plan
- Strut change schedule
- Surgeon visit plan (for changing struts)

A partial image of the Study Report page is shown to the right.

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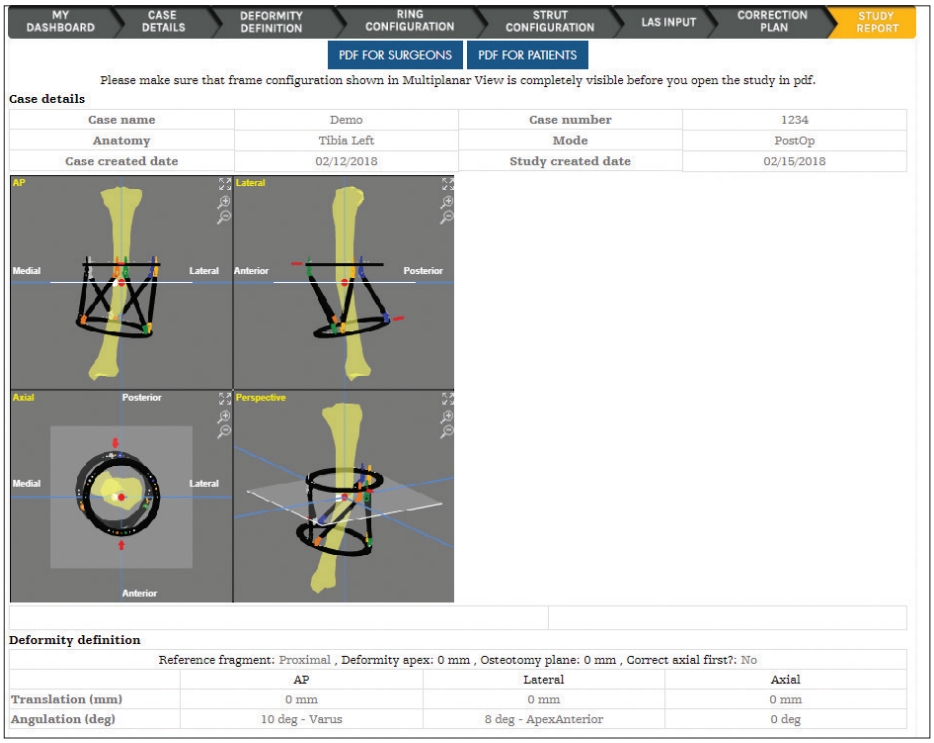

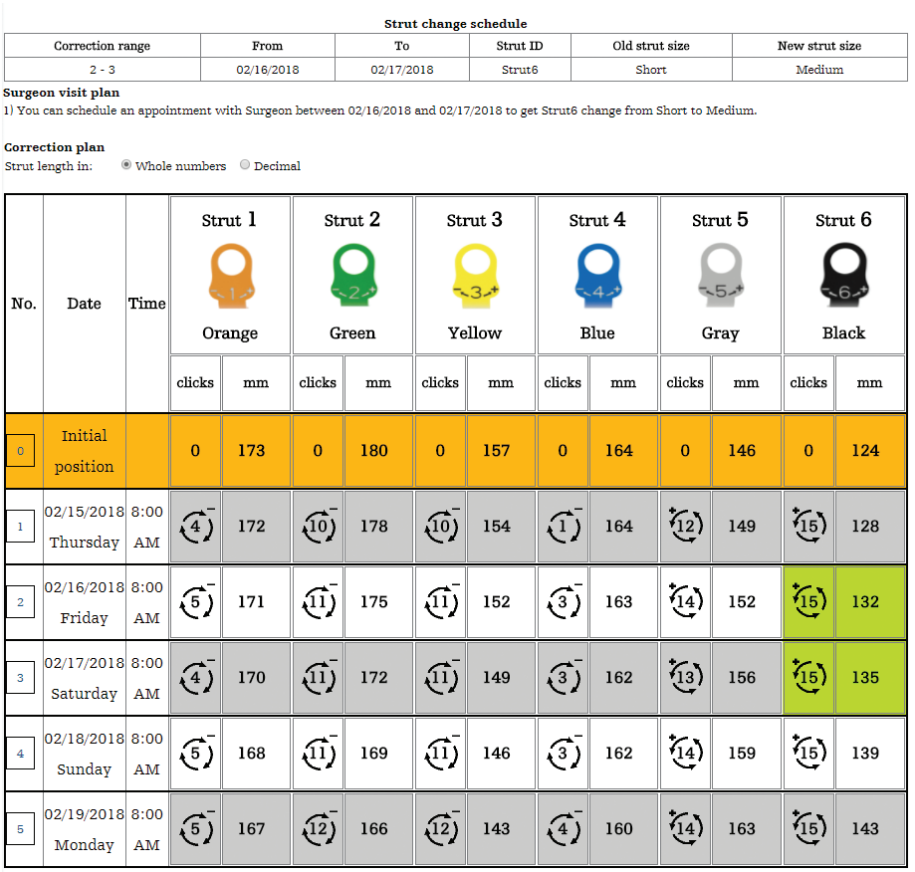

Strut change schedule

Correction range	From	To	Strut ID	Old strut size	New strut size
2 - 3	02/16/2018	02/17/2018	Strut6	Short	Medium

Surgeon visit plan

1) You can schedule an appointment with Surgeon between 02/16/2018 and 02/17/2018 to get Strut6 change from Short to Medium.

Correction plan

Strut length in: (•) Whole numbers ( ) Decimal

No.	Date	Time	Strut 1 Orange		Strut 2 Green		Strut 3 Yellow		Strut 4 Blue		Strut 5 Gray		Strut 6 Black	
			clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm	clicks	mm
0	Initial position		0	173	0	180	0	157	0	164	0	146	0	124
1	02/15/2018 Thursday	8:00 AM	4	172	10	178	10	154	1	164	12	149	15	128
2	02/16/2018 Friday	8:00 AM	5	171	11	175	11	152	3	163	14	152	15	132
3	02/17/2018 Saturday	8:00 AM	4	170	11	172	11	149	3	162	13	156	15	135
4	02/18/2018 Sunday	8:00 AM	5	168	11	169	11	146	3	162	14	159	15	139
5	02/19/2018 Monday	8:00 AM	5	167	12	166	12	143	4	160	14	163	15	143

NOTICE

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