CLiCK 2 Correct™
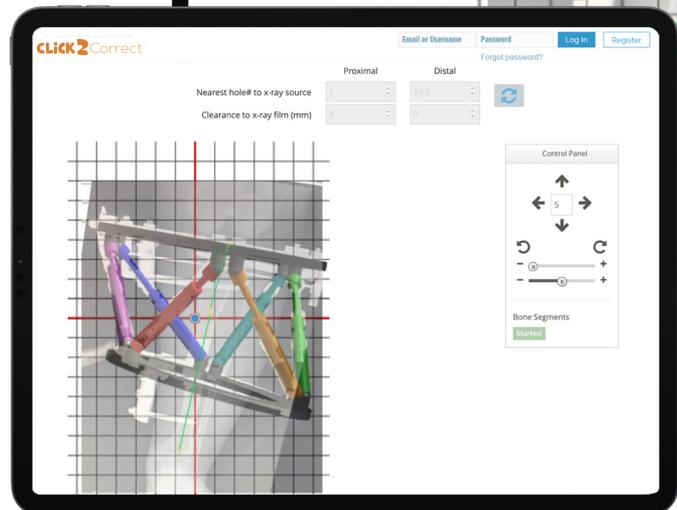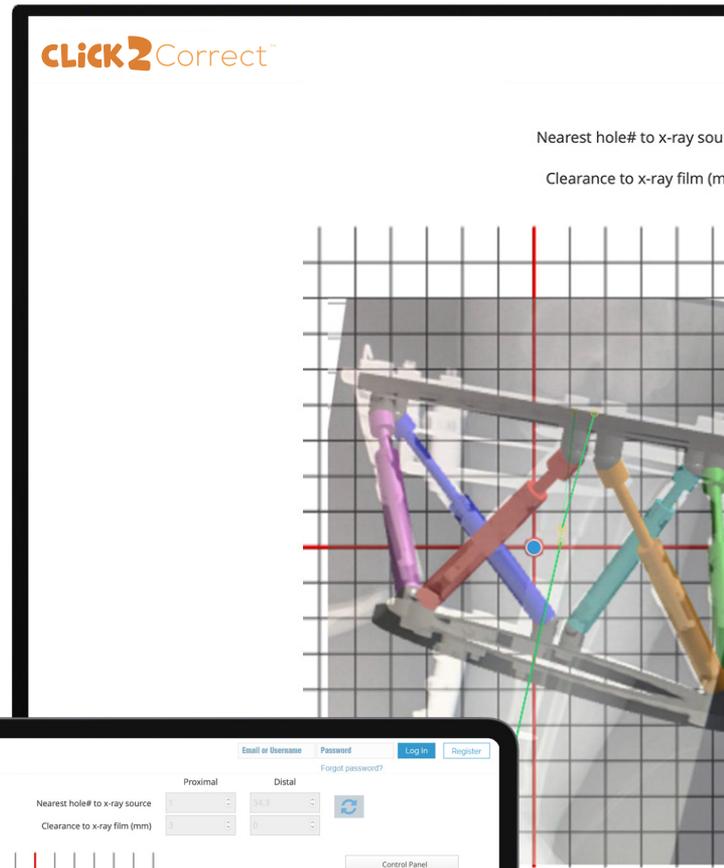
Software User Guide

FOR THE SMART CORRECTION® EXTERNAL FIXATOR SYSTEM

We **WORK** so they can **PLAY**.™

WishBone
MEDICAL

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Software User Guide

SOFTWARE USER GUIDE

Introduction

The Smart Correction® System is a copyrighted software-based, deformity correction tool. This external fixator, with its 6-strut construct, provides easy application, mechanical stability and precise deformity correction via weblinked copyrighted software.

The software facilitates deformity correction in all anatomic planes* (axial, frontal, coronal, translation).

Computer System Requirements

In order to accommodate a large quantity of information, detailed graphical images and proper sequencing of correction methods, each screen of the Smart Correction® Web Application is designed to provide an efficient user interface. To ensure the best possible experience with this site, we recommend the following display and browser settings.

Display Settings
Screen resolution of 1024 x 768 or higher.

Supported Browsers
Any HTML 5 compatible web browser.
(Microsoft Edge, Microsoft Internet Explorer, Mozilla Firefox, Google Chrome and Apple Safari)

Browser Settings
Must support 128-bit SSL encryption. JavaScript enabled. Cookies enabled.

Internet Connection
A high-speed connection is recommended.

Note: In order to use the Smart Correction Software, admin approval must be granted. It is recommended to submit an application prior to the time that software is needed.

Software is not validated for use with foot rings and half rings at this time.

Account Registration

Approved users can access the Smart Correction software using any computer or mobile device connected to the Internet from anywhere in the world. Simply visit **www.Click2Correct.com** to get started.
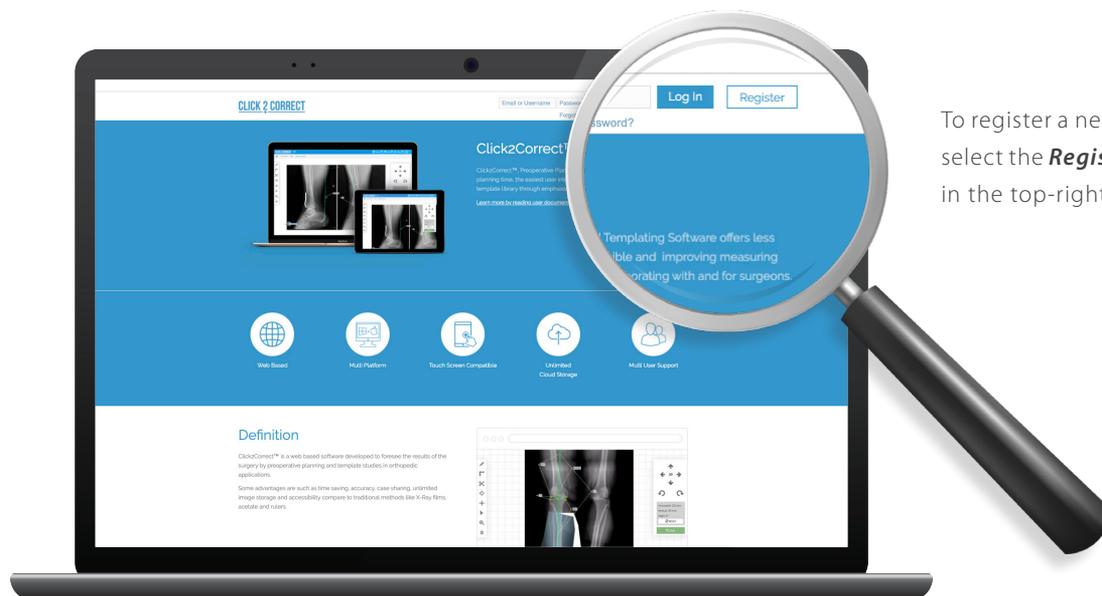
To register a new account, select the *Register* button in the top-right corner.

If a registered user previously opted to 'remember me' on their browser, a *Go to Application* button will display; when selected, users can return to the *Click2Correct*^{TM} Login Page.

Note: All aspects of Click2Correct^{TM} and Smart Correction software are handled electronically, from account registration to resetting passwords. All requests are accessed via the login page at www.Click2Correct.com.

Account Registration (cont.)

Complete the fields shown below. Please carefully review your information prior to submitting.
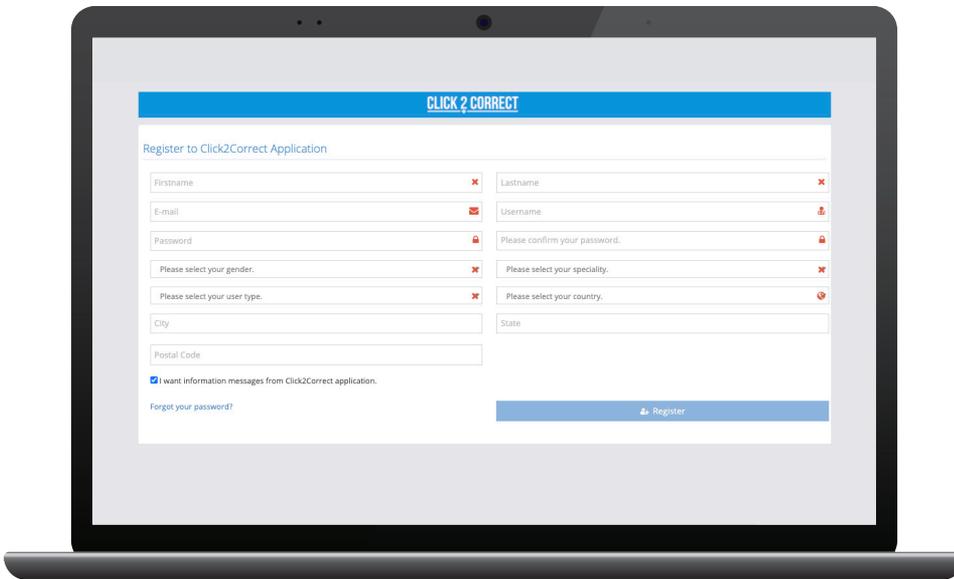

After verifying user information, select *Register* to complete registration.

Warning: In order to protect patient information, do not share your username or password information with others.

Verify Email

Upon registration, you will immediately receive a confirmation email from the system (*noreply@click2correct.com*). Please verify your email address through the link provided in the email.
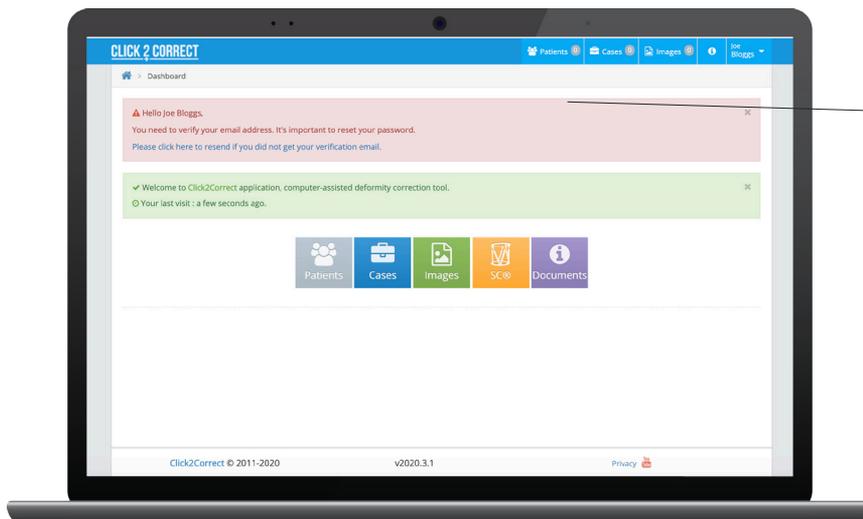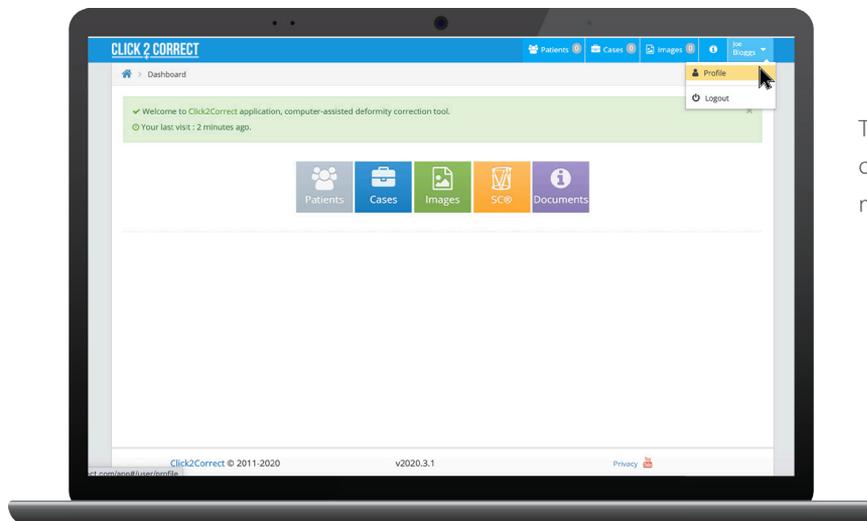

Alert will no longer appear once email is verified.

Note: If the confirmation email does not show in your inbox, check the spam folder.

User Profile

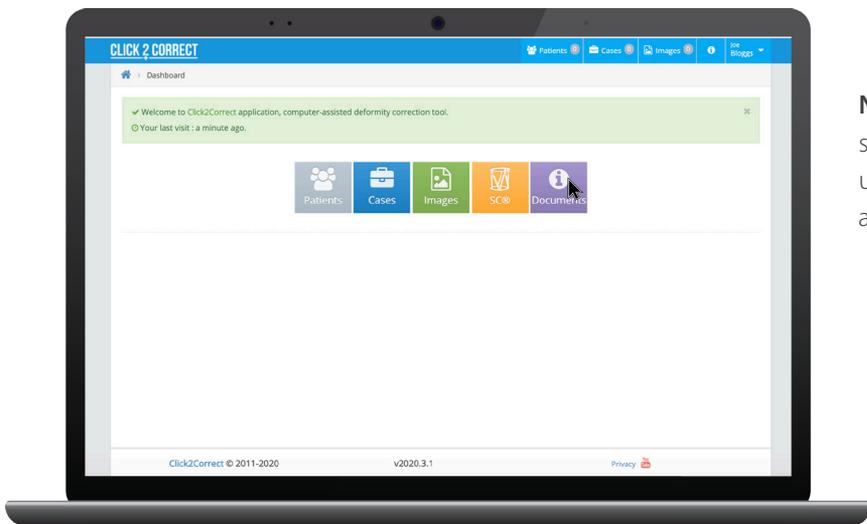Once the account is registered, a profile link is created through the username.

To change/update account information, click on your name, then from the drop-down menu, select *Profile*.

Click2Correct™ Dashboard

Upon logging in, you will be presented with a main dashboard displaying all of the current modules:
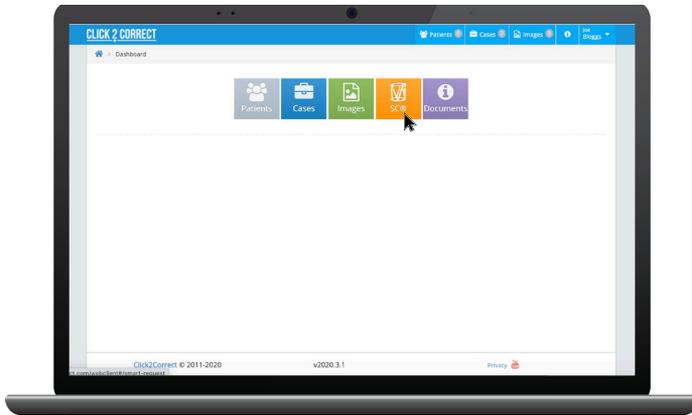
Patients | Cases | Images | SC® | Documents

Note: For account issues, customer support contact information is located under the *Documents* page which can be accessed via the purple '**i**' button.

Smart Correction Authorization

To request full access to the Smart Correction software, select the orange **SC®** button to begin the application.

Fill out the application and submit for review. An administrator will review the application. Once approved for full access, you will be notified via the email previously provided.
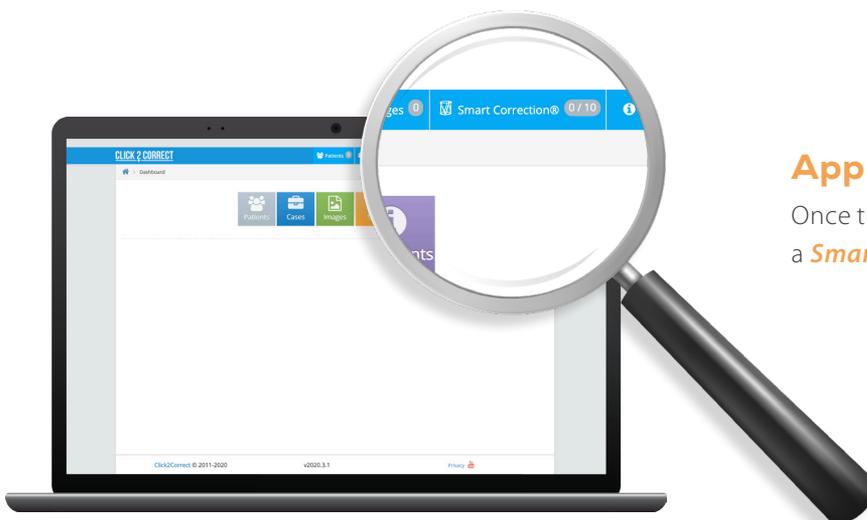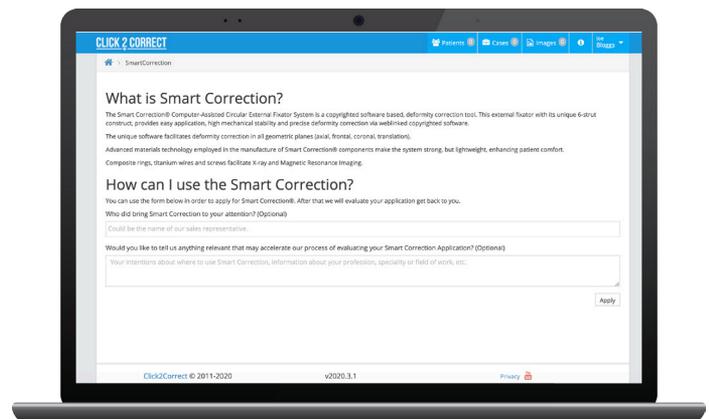
Application Approval

Once the application is approved, you will see a *Smart Correction* tab on the home page.

Data Entry Guidelines

All parameters should be entered with both a magnitude and a direction. Where distance measurements are required, those numbers should be entered in millimeters, not centimeters.
The software will provide a prescription to correct the exact deformity you describe. Therefore, it is important to enter your data as accurately as possible.
You can advance from field to field within a page by using the tab key.
Advance from one page to the next by clicking on the sub tab in sequence or by clicking *Next*.

Patient Tab

To start a patient, click on the *Patients* tab.
Then, select the *New* button to proceed recording patient details.
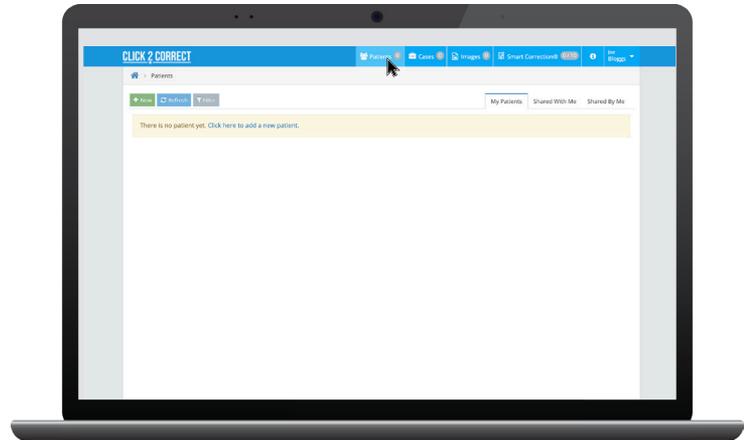
After clicking the *New* button or the *Click here to add a new patient* link (for the first patient record), the following form will appear.
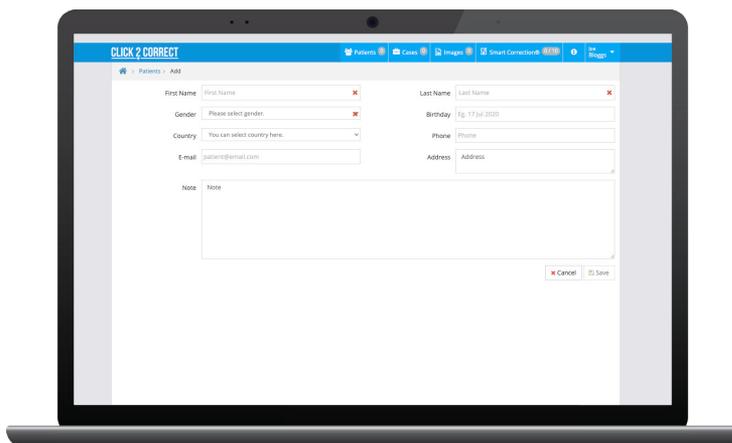
Note: First Name, Last Name and Gender are mandatory fields and must be entered to move to the next step. After the information is entered, the software will activate the *Save* button.

Add Case

After clicking the **Add Case** button or the *Click here to add a new case* link (for new case record), the following form will appear:
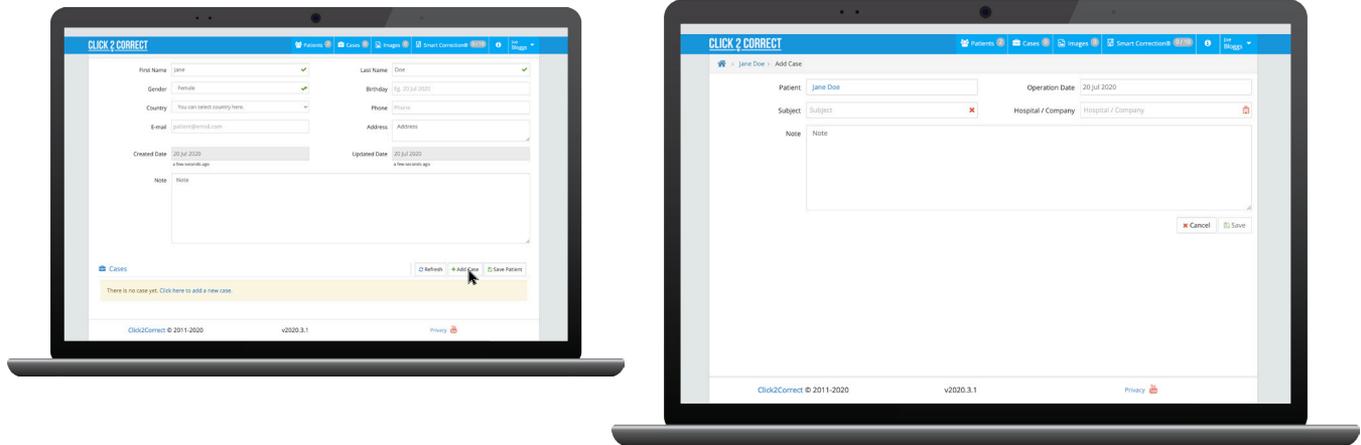
Once the mandatory fields (Subject and Hospital/Company) are filled in and saved, add pictures.
The Smart Correction calculation will then be available.
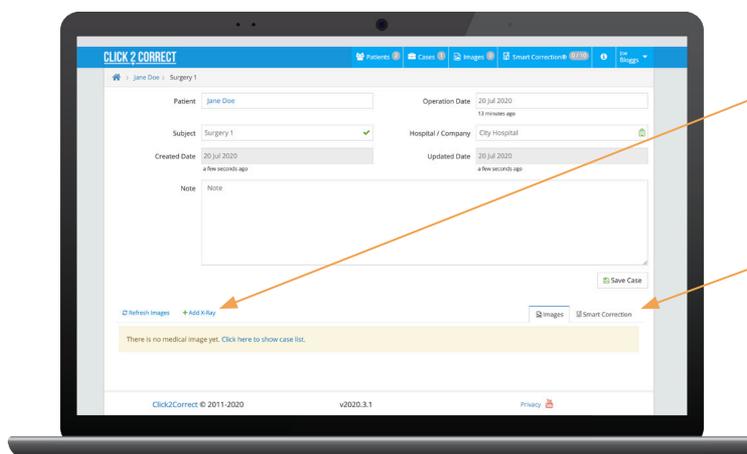
After the case is saved, X-ray images should be stored for preoperative planning and/or Smart Correction calculation through the link.

The Smart Correction calculation will start through the link.

Compatible file formats: JPEG, PNG or DICOM

SOFTWARE USER GUIDE, (CONT)

Scenario #1

Add X-rays first: Fill the data fields and upload the X-ray image for preoperative planning and/or Smart Correction® calculation.
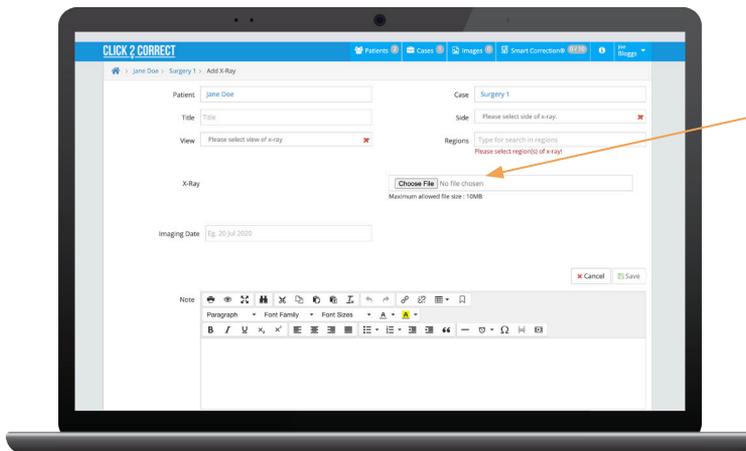
Note: X-ray images should be uploaded through the link.

Compatible file formats: *JPEG, PNG or DICOM*

To take measurements or excecute any preoperative planning works on the X-ray image, click on the image directly to open the preoperative planning interface.
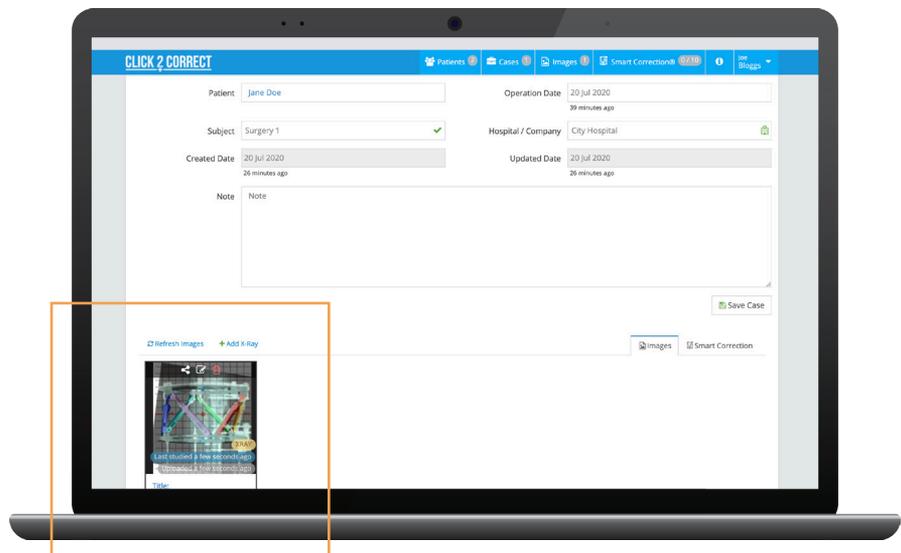
SOFTWARE USER GUIDE, (CONT)

Scenario #2

Start Calculation
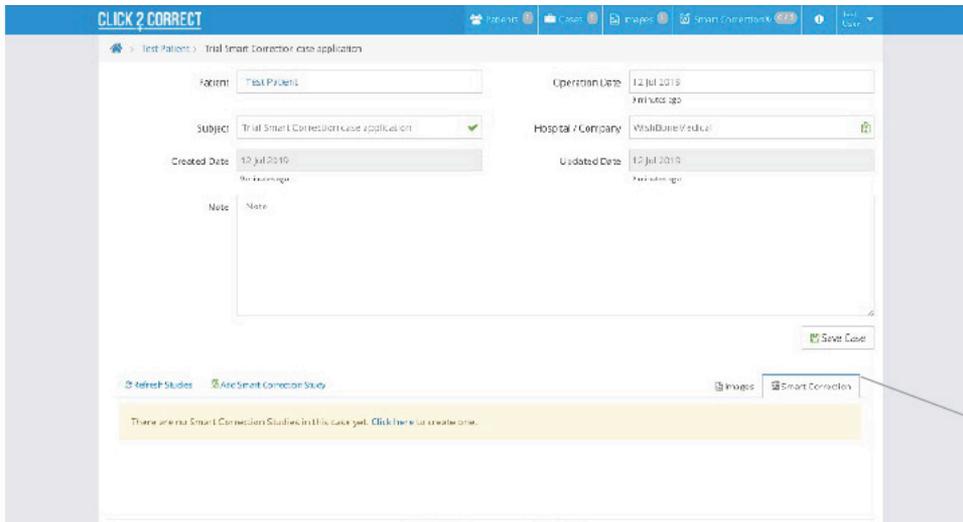
Click on the *Smart Correction* tab to start correction calculation.

Title is to identify the case.
Extremity side must be selected to correctly apply internal/external rotation.
Surgery date will be part of the prescription date.

Frame Parameters

Select the appropriate proximal and distal ring sizes* by clicking the down arrow on the drop down box. After each ring is selected, recommended strut fixation hole numbers appear in a drop-down box for each strut number. Smart Correction frame assembly flexibility allows for fixation hole numbers to be reviewed and corrected as necessary.
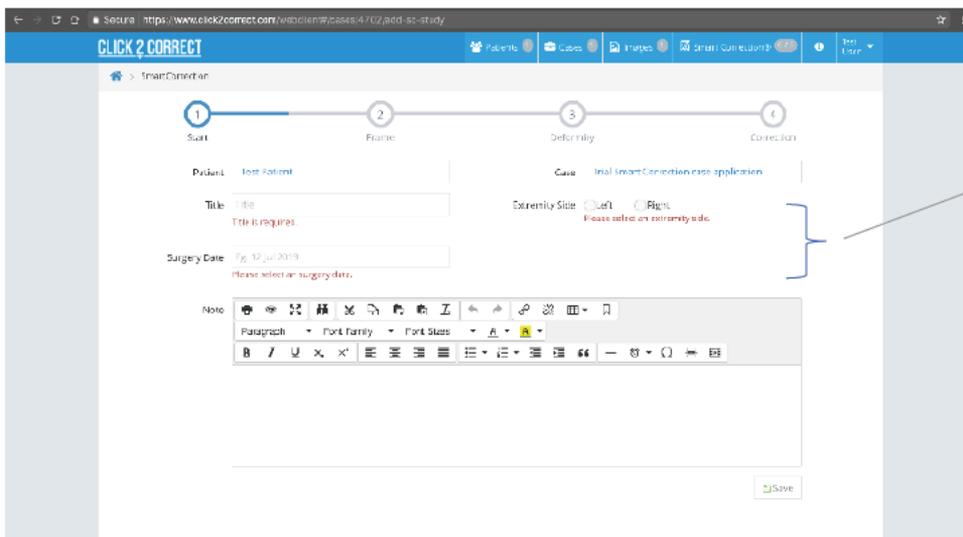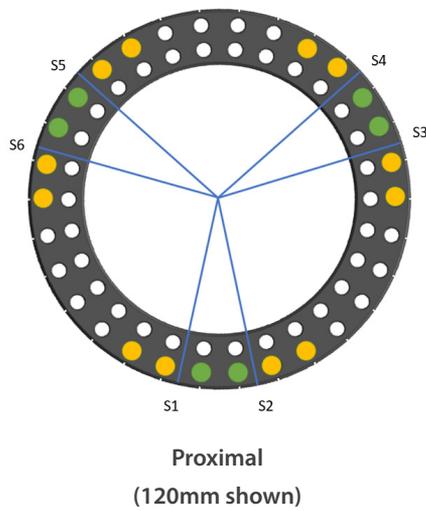
Next, select the appropriate strut type.
Each frame uses six struts. You can use any combination of sizes and strut family *(Express or Standard)* and any combination of ring type and sizes on a frame.

Proximal
(120mm shown)

Proximal Ring Size	S1 & S2	S3 & S4	S5 & S6	Acceptable Tolerance
70mm	1 & 2	7 & 8	14 & 15	± 1 hole
80mm	1 & 2	8 & 9	15 & 16	± 1 hole
90mm	1 & 2	9 & 10	17 & 18	± 1 hole
105mm	1 & 2	10 & 11	19 & 20	± 2 holes
120mm	1 & 2	11 & 12	21 & 22	± 2 holes
135mm	1 & 2	12 & 13	23 & 24	± 2 holes
150mm	1 & 2	13 & 14	25 & 26	± 2 holes
165mm	1 & 2	14 & 15	27 & 28	± 3 holes
180mm	1 & 2	15 & 16	29 & 30	± 3 holes
195mm	1 & 2	16 & 17	31 & 32	± 4 holes
210mm	1 & 2	17 & 18	33 & 34	± 4 holes
225mm	1 & 2	18 & 19	35 & 36	± 4 holes
240mm	1 & 2	19 & 20	37 & 38	± 4 holes
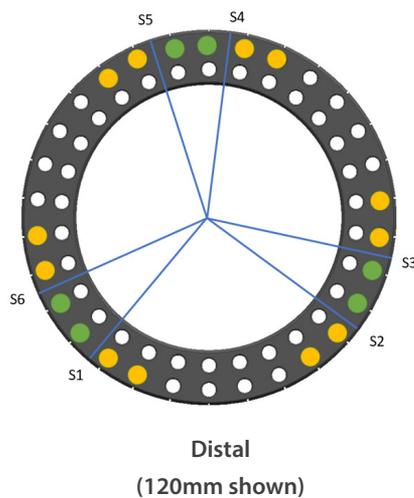
Distal
(120mm shown)

Distal Ring Size	S2 & S3	S4 & S5	S6 & S1	Acceptable Tolerance
70mm	4 & 5	10 & 11	17 & 18	± 1 hole
80mm	5 & 6	12 & 13	19 & 20	± 1 hole
90mm	5 & 6	13 & 14	21 & 22	± 1 hole
105mm	6 & 7	15 & 16	24 & 25	± 2 holes
120mm	6 & 7	16 & 17	26 & 27	± 2 holes
135mm	6 & 7	17 & 18	28 & 29	± 2 holes
150mm	7 & 8	19 & 20	31 & 32	± 2 holes
165mm	7 & 8	20 & 21	33 & 34	± 3 holes
180mm	8 & 9	22 & 23	36 & 37	± 3 holes
195mm	9 & 10	24 & 25	39 & 40	± 4 holes
210mm	9 & 10	25 & 26	41 & 42	± 4 holes
225mm	10 & 11	27 & 28	44 & 45	± 4 holes
240mm	7 & 8	25 & 26	43 & 44	± 4 holes

Software is not validated for use with foot rings and half rings at this time.

Posterior Open

Proximal 2/3 Ring Size	S1 & S2	S3 & S4	S5 & S6
105mm	13 & 14	21 & 22	6 & 7
120mm	15 & 16	24 & 25	7 & 8
135mm	16 & 17	26 & 27	7 & 8
150mm	19 & 20	29 & 30	8 & 9
165mm	20 & 21	31 & 32	8 & 9
180mm	21 & 22	34 & 35	9 & 10
195mm	23 & 24	37 & 38	10 & 11
210mm	24 & 25	39 & 40	10 & 11
225mm	27 & 28	42 & 43	11 & 12
240mm	27 & 28	44 & 45	11 & 12

Anterior Open

Distal 2/3 Ring Size	S2 & S3	S4 & S5	S6 & S1
105mm	6 & 7	13 & 14	21 & 22
120mm	7 & 8	15 & 16	24 & 25
135mm	7 & 8	16 & 17	26 & 27
150mm	8 & 9	19 & 20	29 & 30
165mm	8 & 9	20 & 21	31 & 32
180mm	9 & 10	21 & 22	34 & 35
195mm	10 & 11	23 & 24	37 & 38
210mm	10 & 11	24 & 25	39 & 40
225mm	11 & 12	27 & 28	42 & 43
240mm	11 & 12	27 & 28	44 & 45
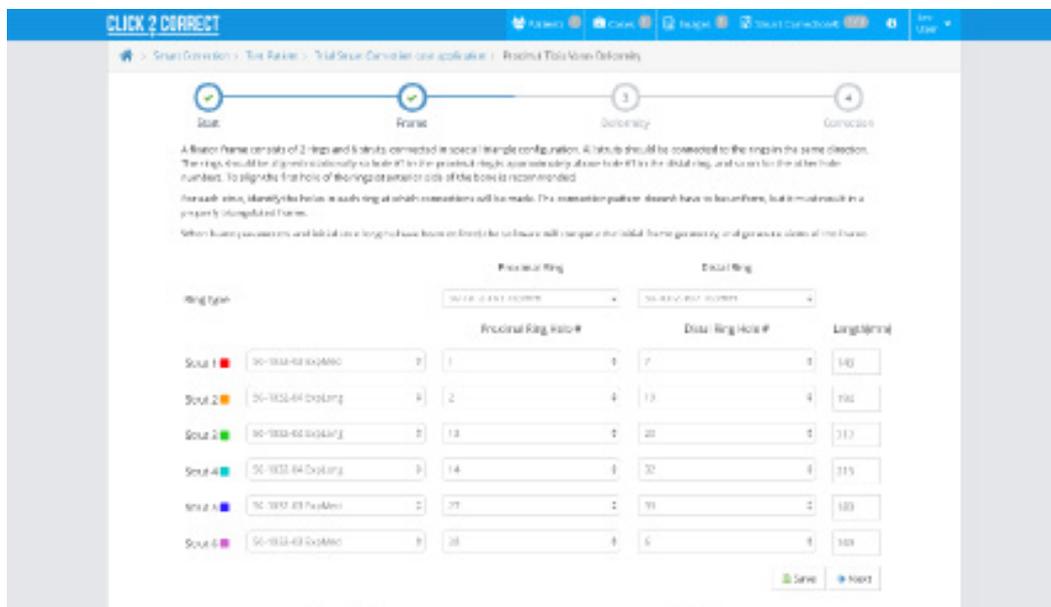
After all the components (rings and struts) are selected and all the fixation holes are entered, the **Save** button should be clicked. The software will generate AP and lateral views of the fixator model for visual confirmation.
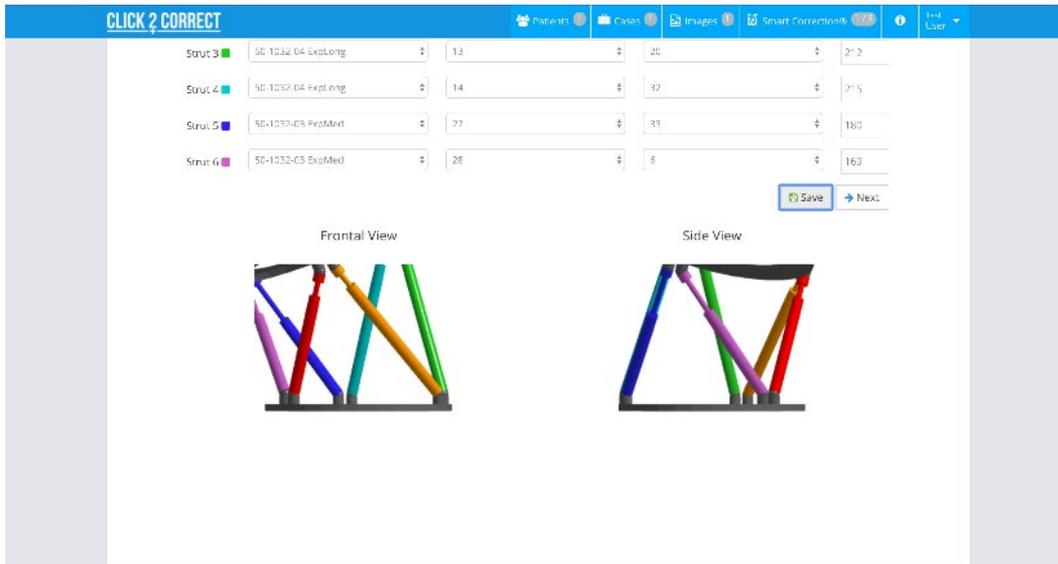
After the frame views are visually confirmed, the **Next** button should be clicked.

The surgeon should ensure that both rings are in contact with the film cartridge, and that the X-ray target point is the midline joining the two nearest points of the rings. If there is space between any of the rings and the film cartridge, it needs to be measured during the X-ray imaging and entered as the clearance parameters (d) or (e). All the numbers should be entered into each field on the screen below.
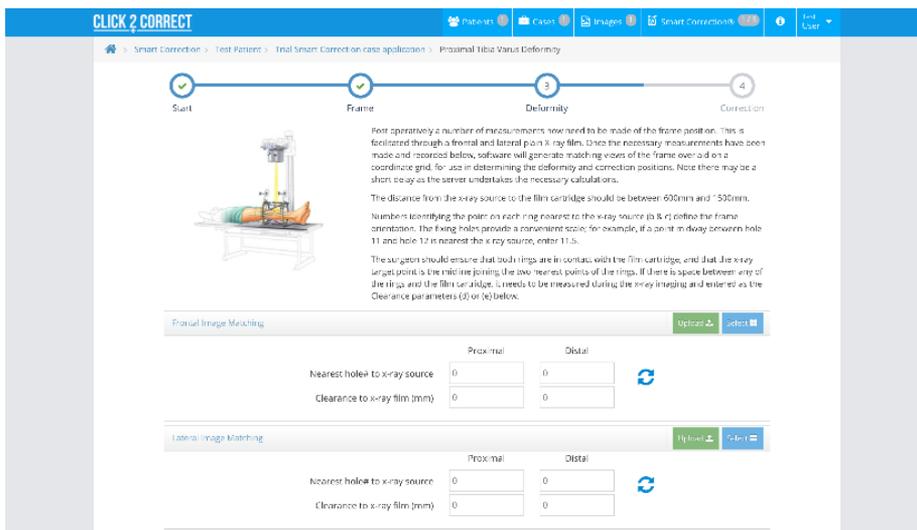
Three seconds after changing any of the field, the software calculates the template automatically.
After the template is correctly built, an X-ray image should be selected or uploaded.
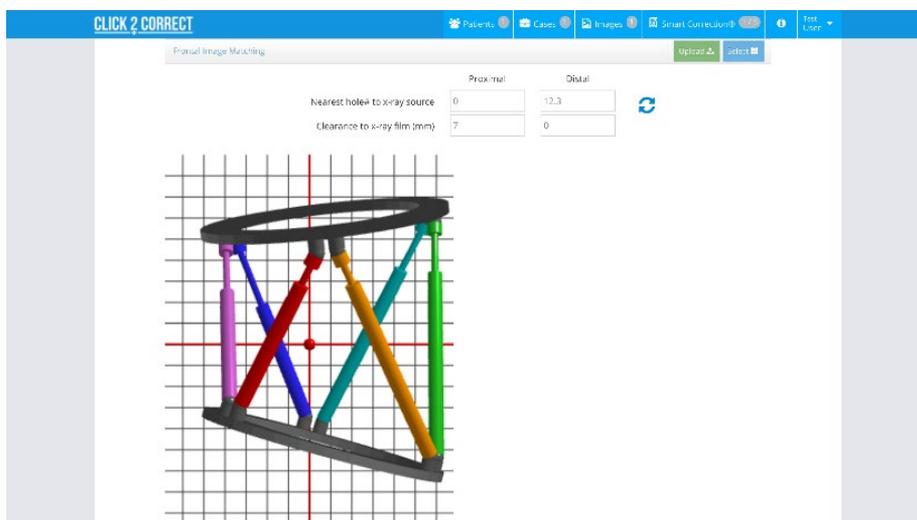
SOFTWARE USER GUIDE, (CONT)
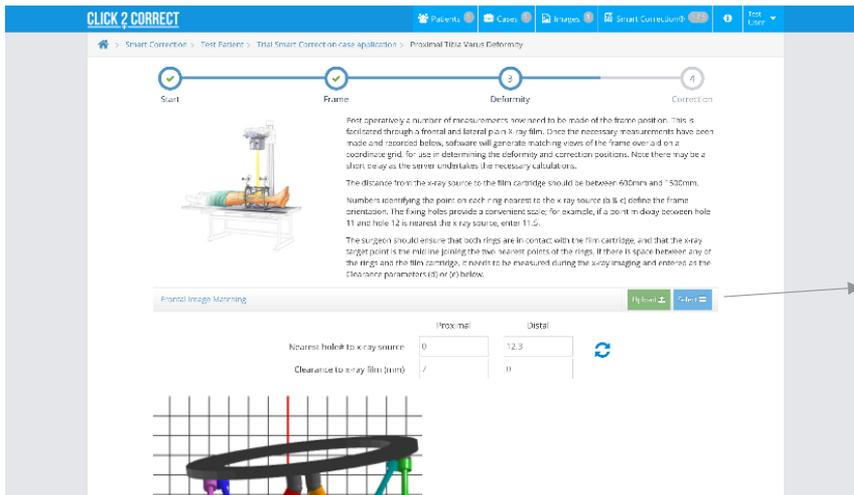
X-ray image should be selected from the pictures. To upload a new X-ray image, select the **Upload** button.
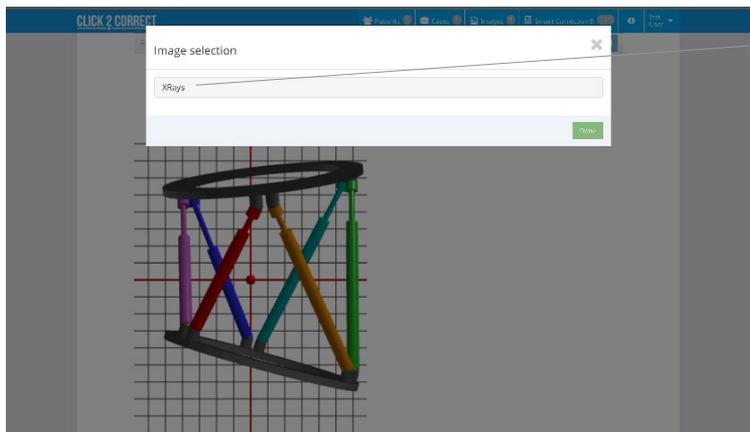
If the **Select** button is clicked, a pop-up window will appear.
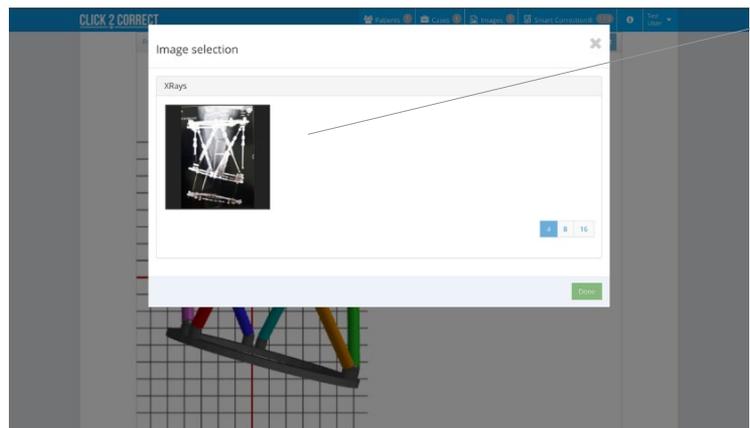
Select the correct image for calculation, followed by the **Done** button.
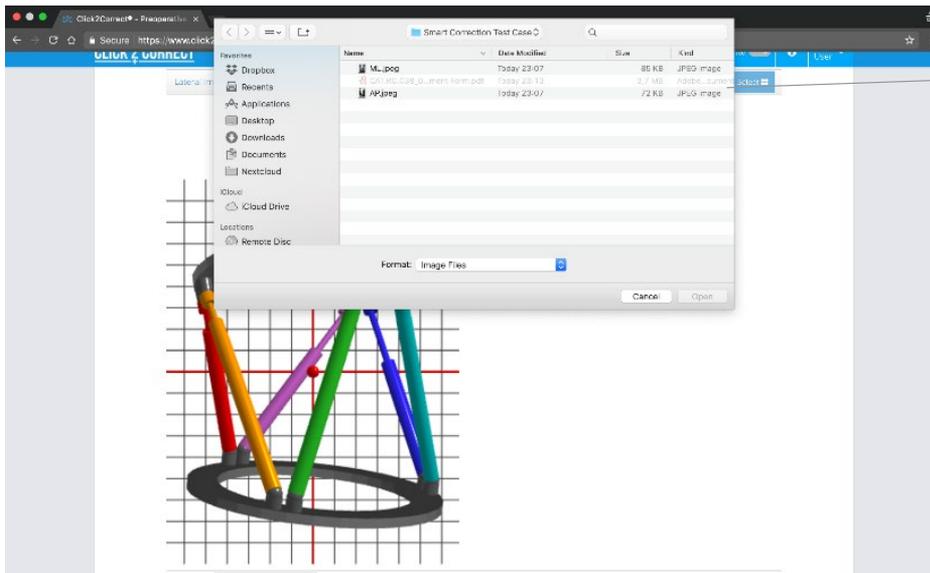
A new X-ray image should be uploaded from the computer through this window.

SOFTWARE USER GUIDE, (CONT)
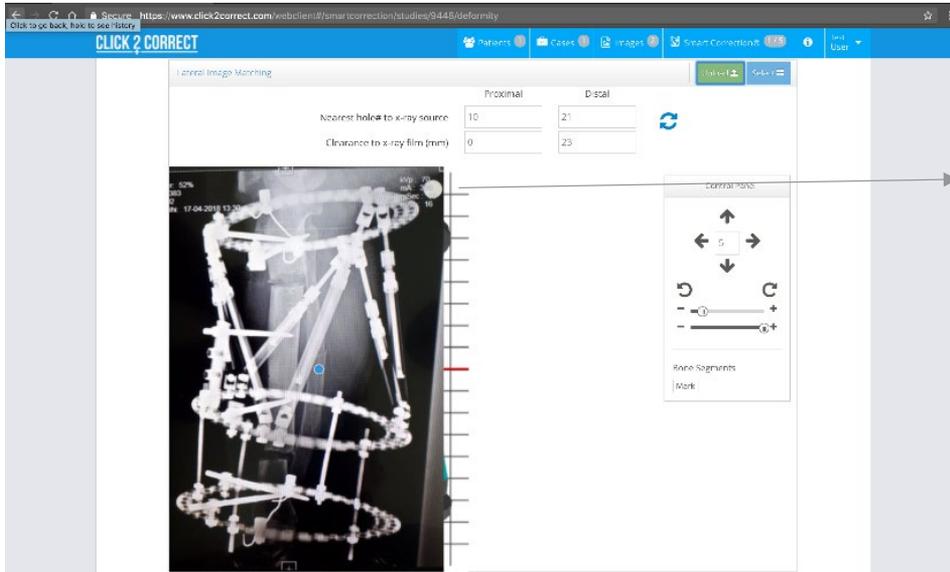
When the X-ray image appears, it should be overlayed onto the Click2Correct™ template.

After X-ray image selected/uploaded
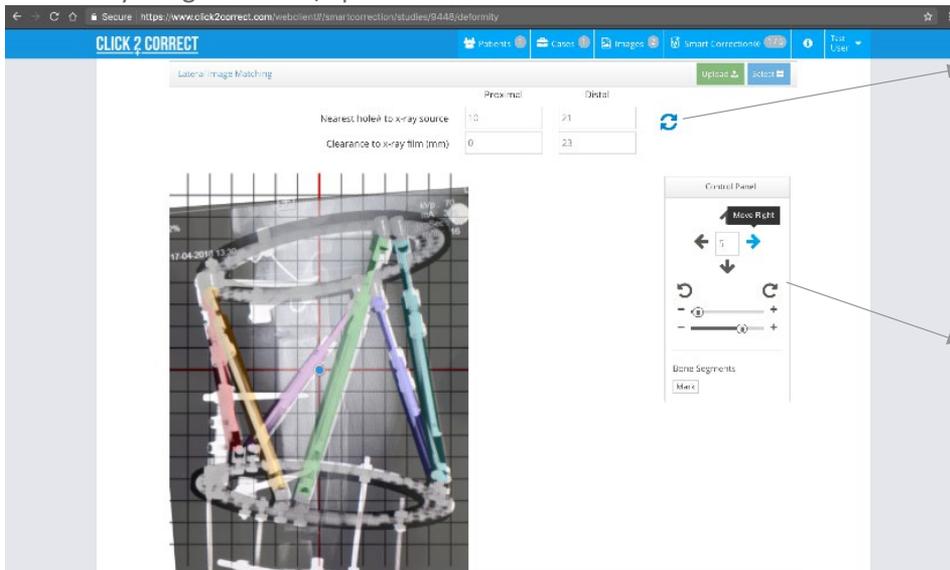
If the X-ray image does not fit on the template, the highest point and clearance values can be adjusted slightly.

Arrows allow for circular movement to rotate.
The first bar is for sizing.
The second bar is for transparency adjustment during the overlaying process.
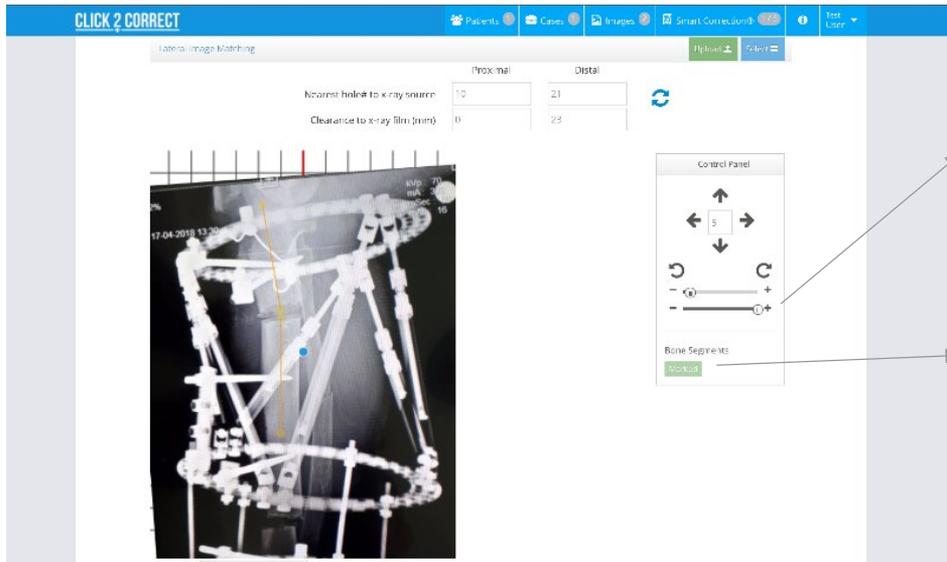
After overlaying is successfully completed, change the transparency to full image view.

Locate and identify the individual bone segment axes to be corrected.
Align the two lines by clicking on the 'Mark' button and bringing the bone segment axes lines into a single axis.
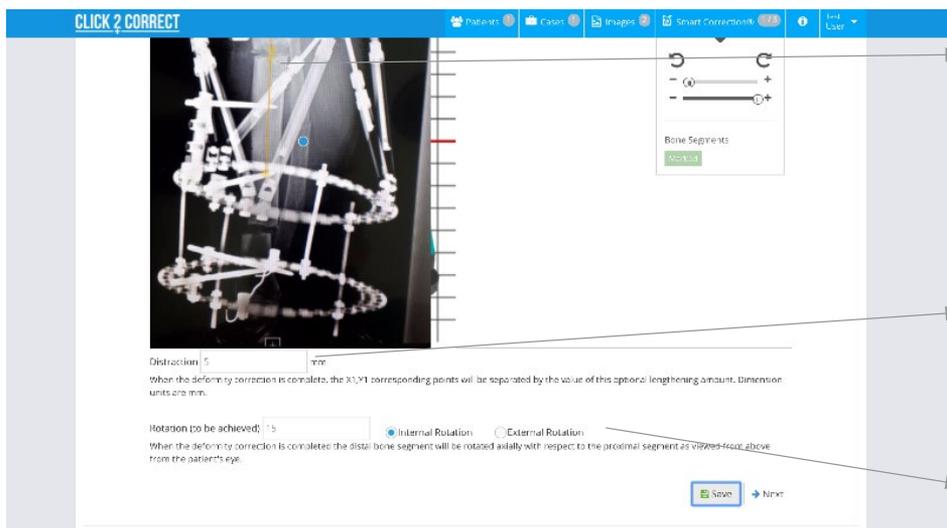
The bone segment axes should be positioned as mid-diaphyseal lines if there is no virtual deformity correction requirement.

Enter the distraction requirement to be achieved at the end of the correction period.

Enter the rotational correction requirement and its direction to be achieved at the end of the correction period.

SOFTWARE USER GUIDE, (CONT)

Correction and Prescription
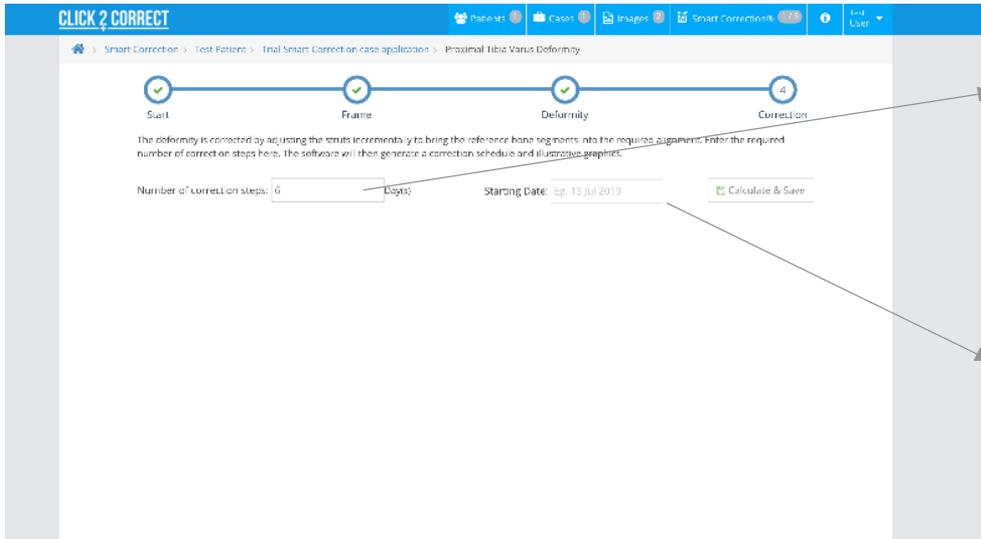
The software calculates a recommended day number for 1mm and/ or 1° per day. It can be changed according to user planning.

A starting day should be selected accordingly.
Click on the **Calculate & Save** button for a prescription and to save the case.
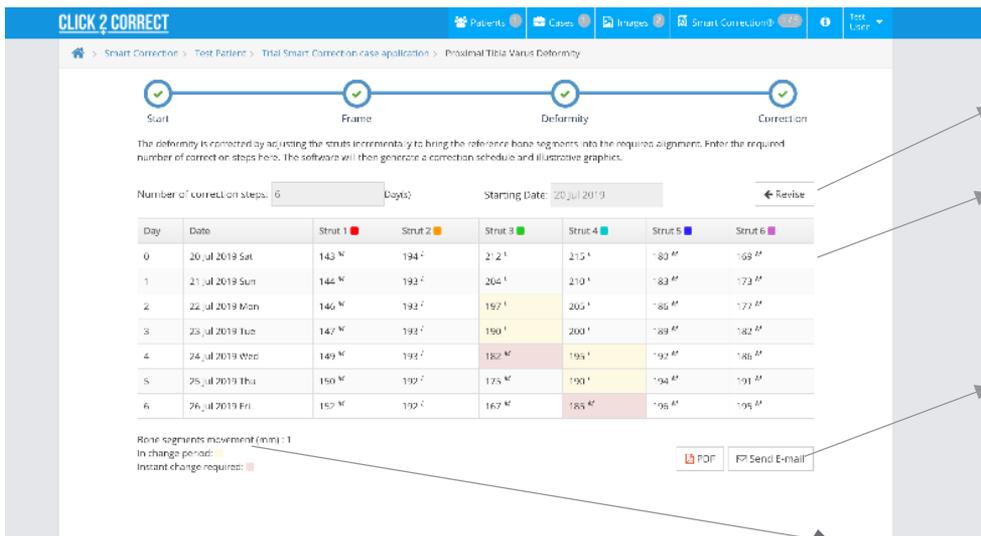
Click the **Revise** button to revise/ correct any parameters and/or to re-calculate the prescription.

The prescription shows the strut length changes and strut type changes.

The prescription can be printed or emailed to the patient.

Bone segment movement shows the daily bone move distance per day in millimeters.

Revise Calculation

Scenario #1: At the beginning of the correction
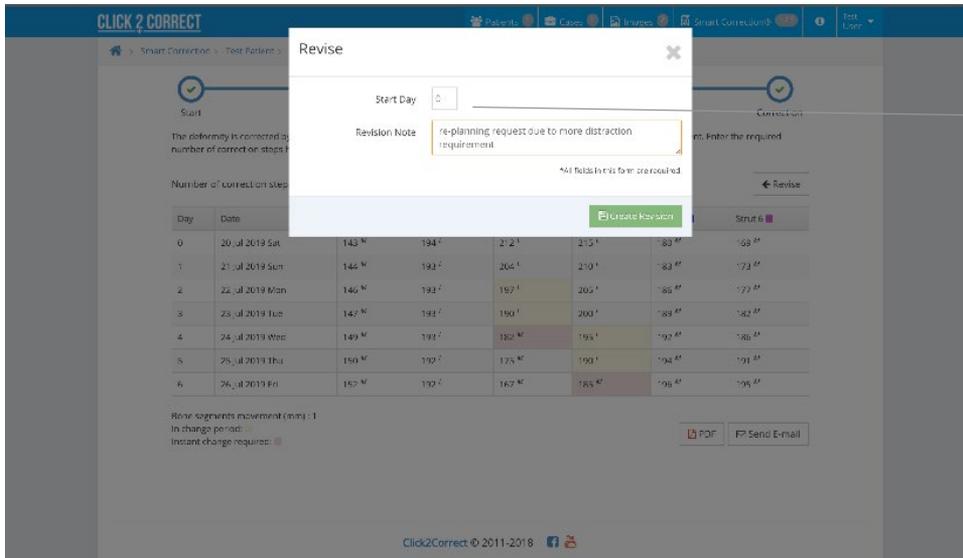
Enter the start day number of revisions to be created.
All strut length parameters will be updated with the values of the day of revision.

Note: Highlighted boxes within the prescription indicate when a strut exchange needs to take place. Red boxes indicate that an immediate exchange is necessary (refer to Strut Exchange section).

If revision day '0' is chosen, X-ray images will be kept for re-calculation and the *Deformity* tab will "checked".
The user may also correct any mistakes with data entry and/or make changes to the correction plan at this time.
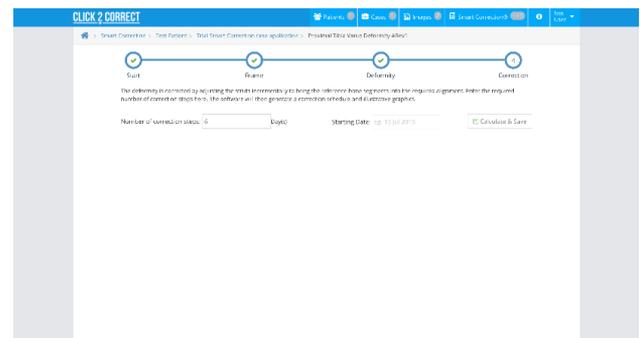
Revise Calculation

Scenario #2: During the correction
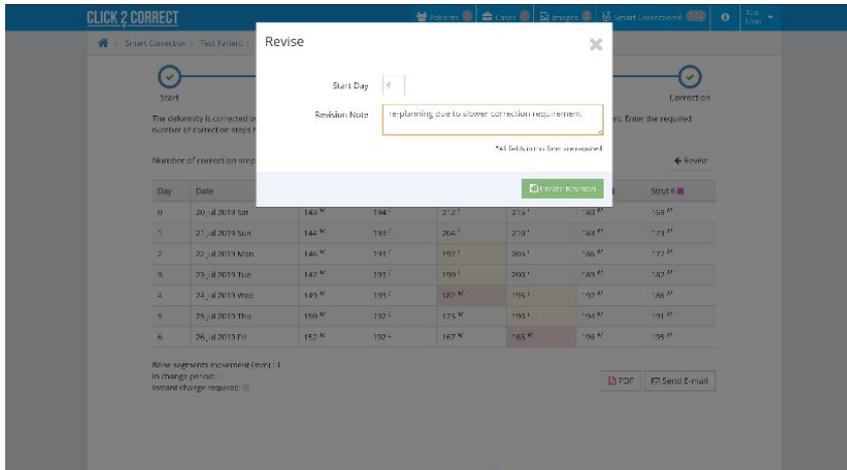
If any revision day (except for '0') is chosen, X-ray images will not be available for this calculation and must be updated.

If a revision occurs during the correction, bone positions will be altered and X-ray images should be refreshed for re-calculation. The *Deformity* tab will be "unchecked" and the case will present like a new case, except for the frame parameters.
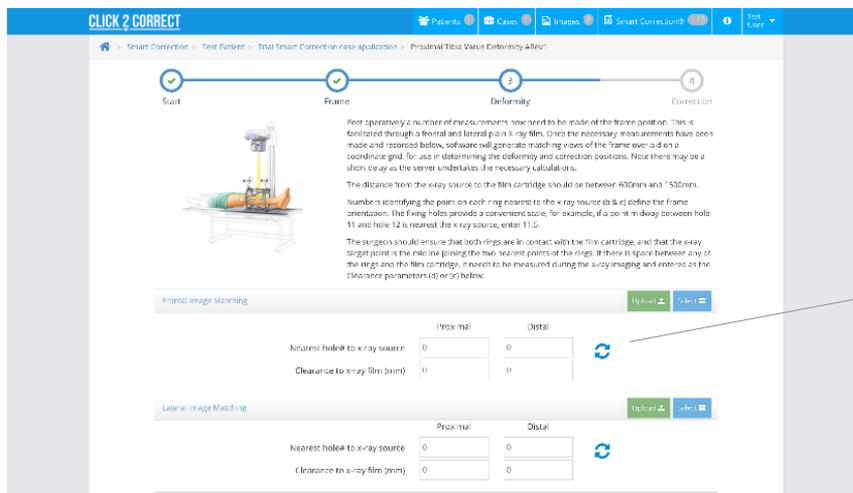
Note: Parameters within the *Deformity* tab will reset to "0" due to revision requested during the correction.

Revision History

All revision records will be saved and the user may view details of the revision(s) in the *Start* tab. The latest revision may be deleted, but the user is not permitted to delete any earlier revisions.
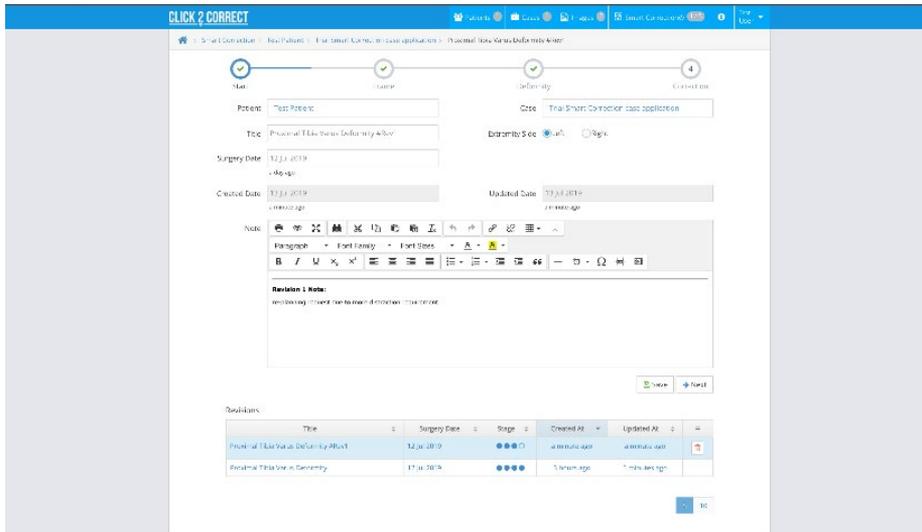
Patient Transfer

To transfer patient records to another user account, open the *Patient* tab and click on the "double arrow" (>>) button. Then, enter the recipient's Smart Correction® username or email address. The recipient will be notified.
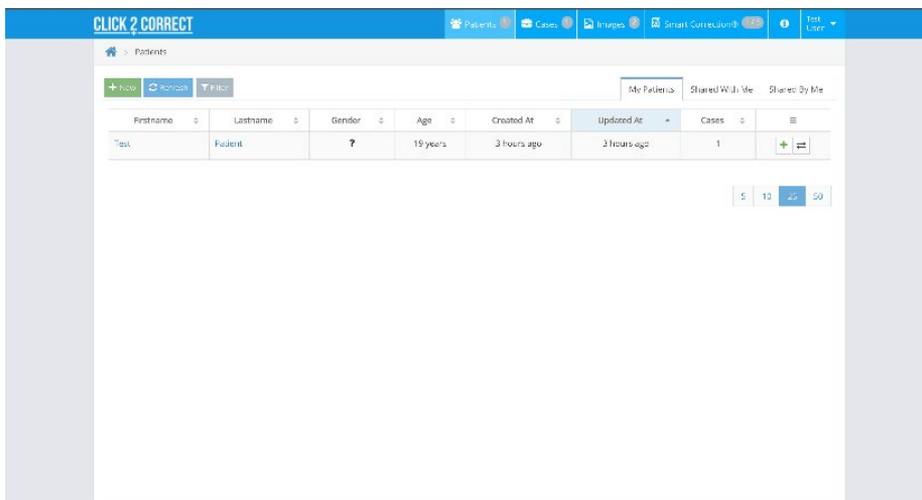
Consultation

To seek consultation from another approved Click2Correct™ user, the case may be shared via the software. From HIPAA law perspective, the case can be shared without patient data attached. It can also be decided if the shared approved user may perform edits to the record.
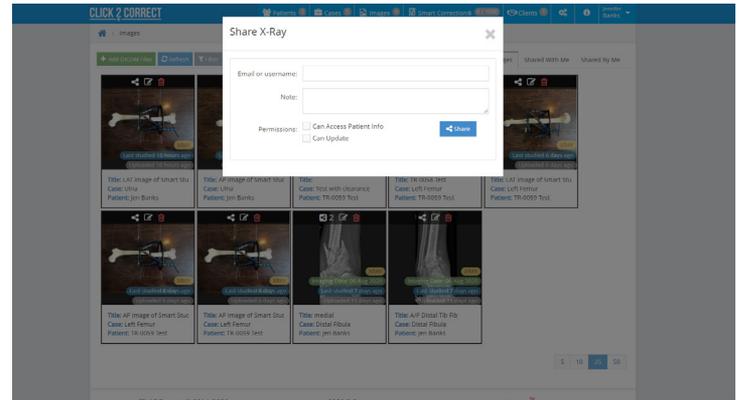
Preoperative Planning Interface Instructions
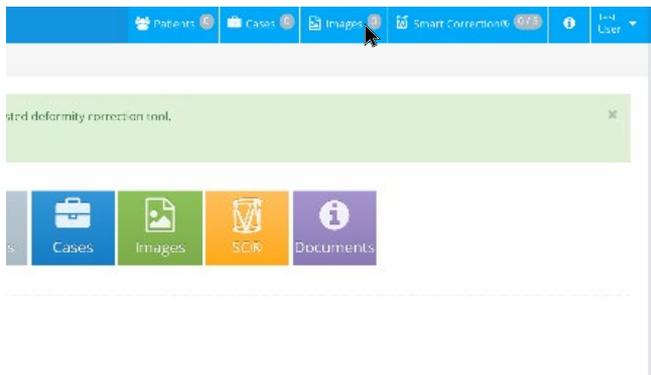
To access instructions for the Preoperative Planning Interface online, simply click on the **Images** tab.

Images that have already been uploaded to the users profile can be viewed, calibrated, measured, and edited.

SOFTWARE USER GUIDE, (CONT)

X-RAY POSITIONING

Position the X-ray source over the center of the frame between the two Rings. It is important that the entire frame can be seen on the X-ray.

650mm-1500mm distance **(A)**
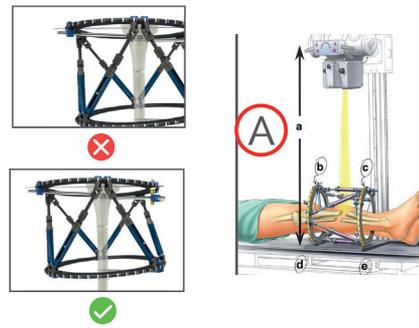
❶ Anterior X-Ray Measurements

Record the number that appears closest to the X-ray source on both the proximal and distal Ring at the time the X-ray is taken **(B & C)**.

e.g.
B=1

e.g.
C=48

❷ Record the distance between the Rings and X-ray cassette **(D & E)**.

Proximal   Distal

e.g.
D=20mm

e.g.
E=0mm
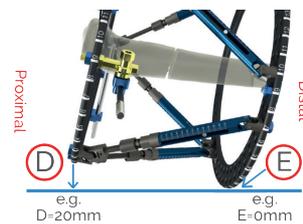
❸ Lateral X-Ray Measurements

Record the number that appears closest to the X-ray source on both the proximal and distal Ring at the time the X-ray is taken **(F & G)**.

e.g.
F=10

e.g.
G=9.5

❹ Record the distance between the Rings and X-ray cassette **(H & I)**.

Proximal   Distal

e.g.
H=35mm

e.g.
I=5mm
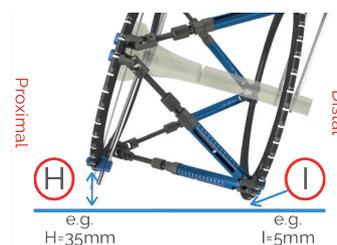
The Smart Correction® Frame Information Form (LIT-FIF-SCEF) is available for frame configuration and X-ray measurement documentation. Access the document online at www.WishBoneMedical.com/product/SC.

SOFTWARE LICENSE AGREEMENT

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Response Ortho, LLC
ITOSB, 10. Cadde, No:1
Tuzla, 34959, Istanbul
TURKEY

WishBone Medical, Inc.
100 Capital Drive
Warsaw, IN 46582
USA

WishBoneMedical.com

100 Capital Drive
Warsaw, IN 46582

+1-574-306-4006

The MR environment presents risks to patients with metal implants. Physicians should consider the risks when recommending MR imaging for patients with metal implants.

The Smart Correction System components have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of the Smart Correction System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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