Click2Correct™
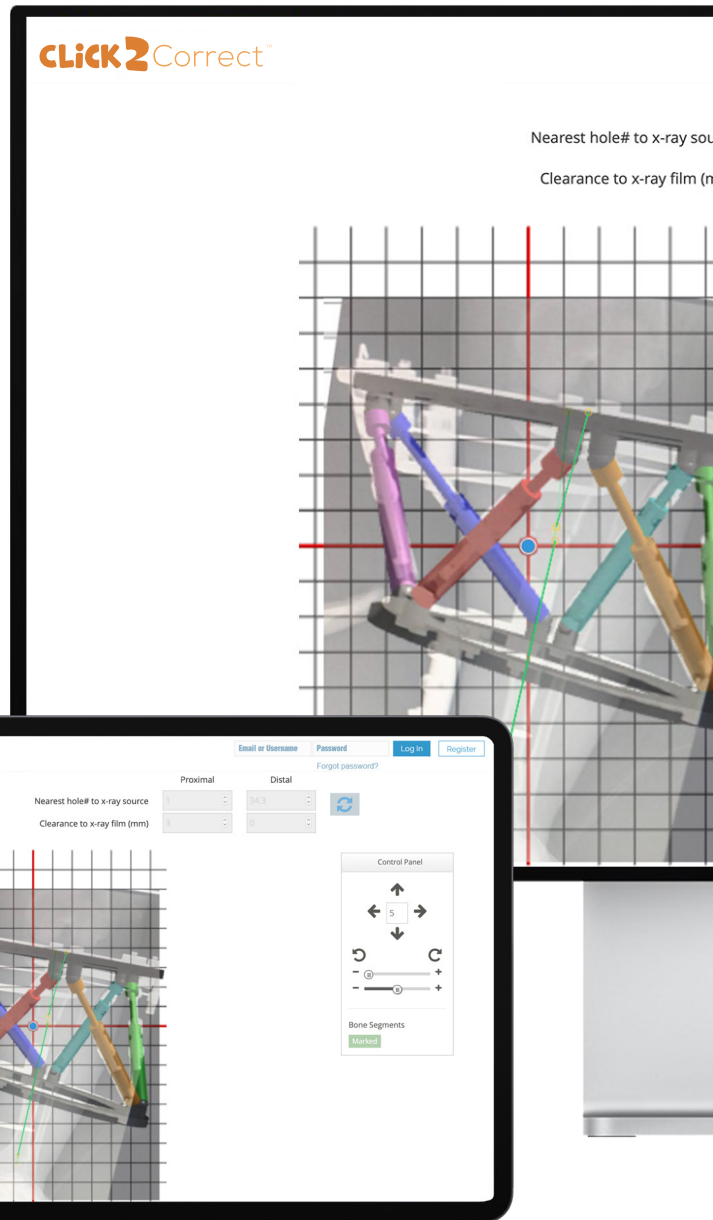
Software User Guide

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.

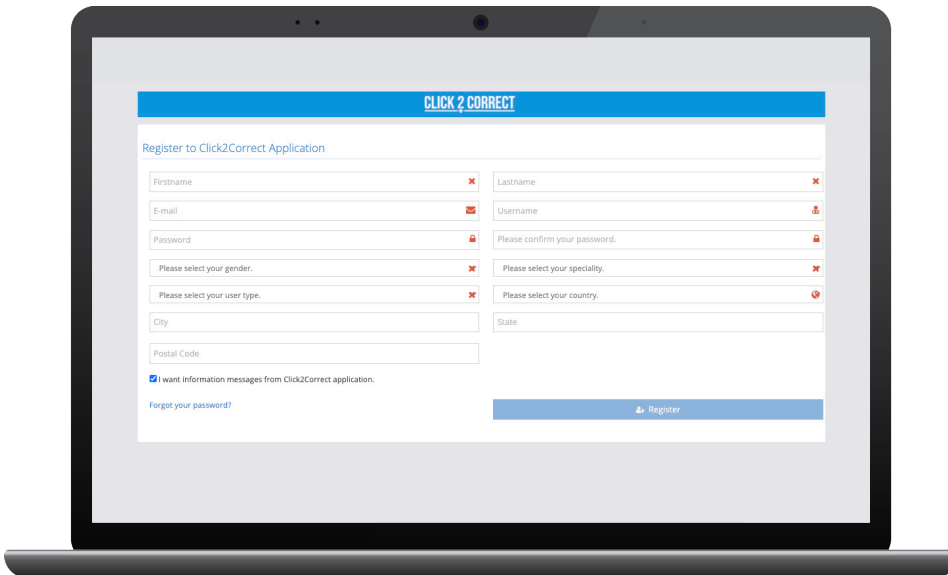To register a new account, select the *Register* button in the top-right corner.

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 Click2CorrectTM 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.

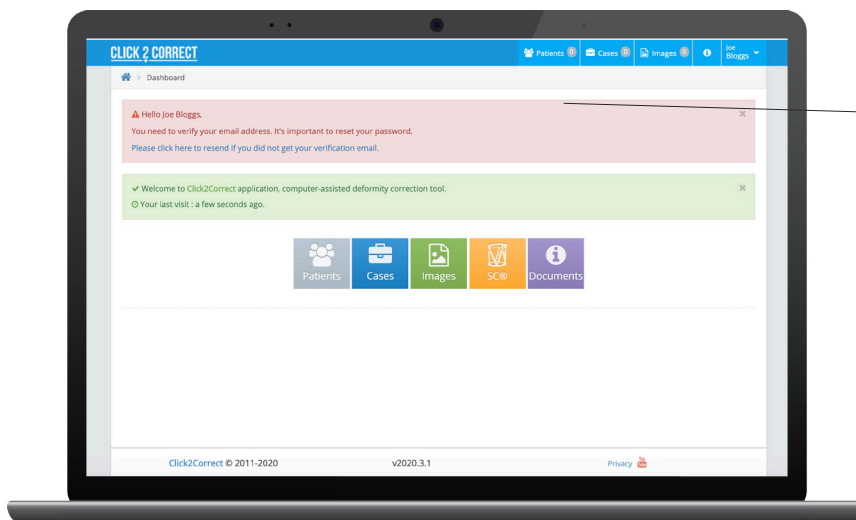After verifying user information, select *Register* to complete registration.

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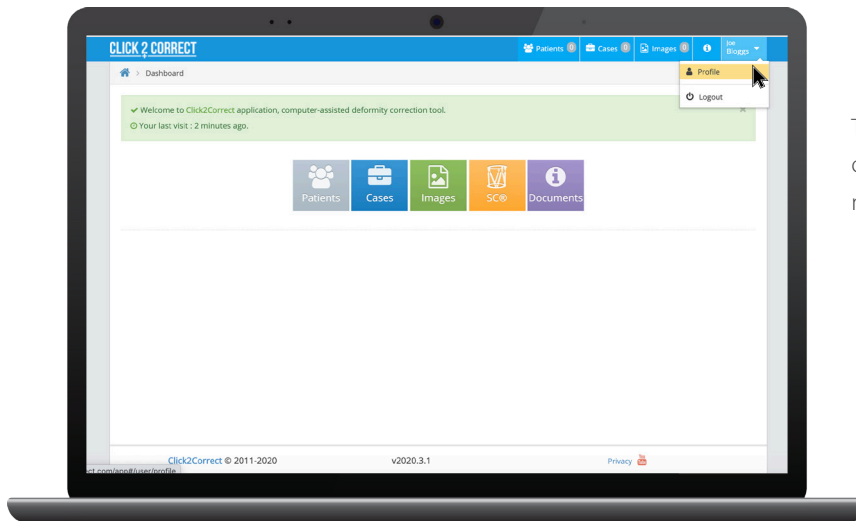
To change/update account information, click on your name, then from the drop-down menu, select *Profile*.

Click2Correct™ Dashboard

Upon logging in, you will be presented with a main dashboard displaying all of the current modules:

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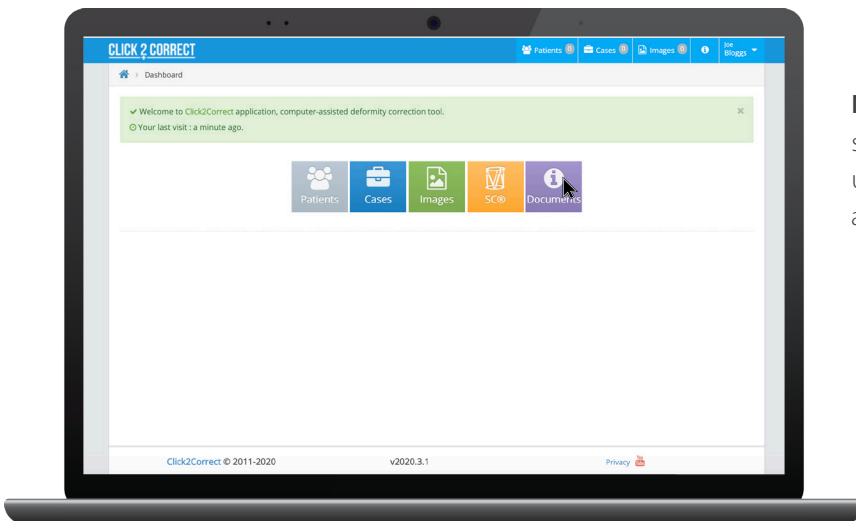
Note: For account issues, customer support contact information is located under the *Documents* page which can be accessed via the purple '**i**' button.

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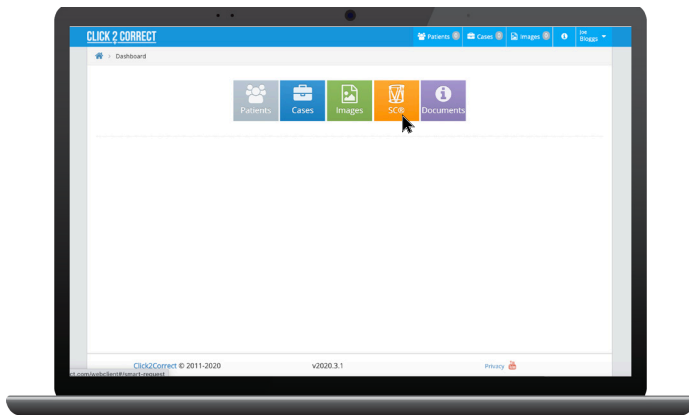
To request full access to the Smart Correction software, select the orange **SC®** button to begin the application.

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.
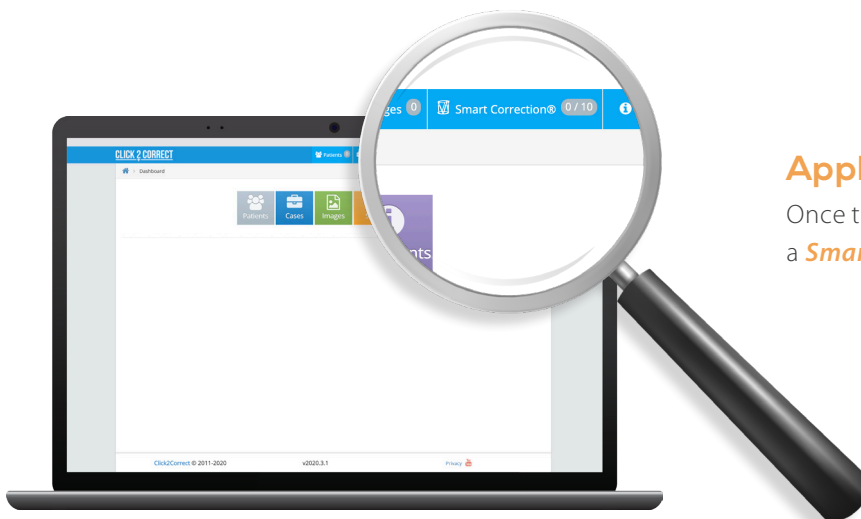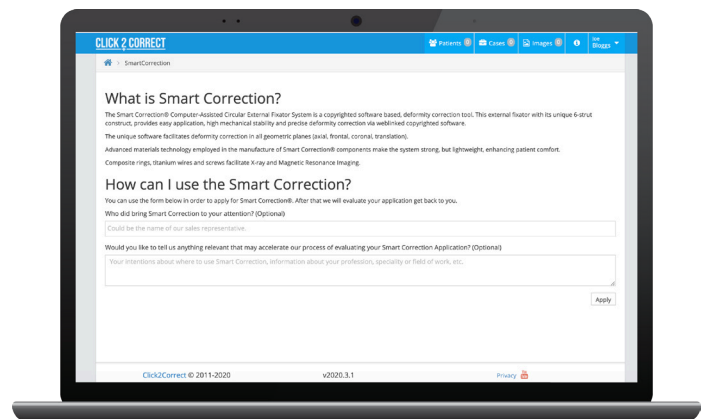
Application Approval

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.
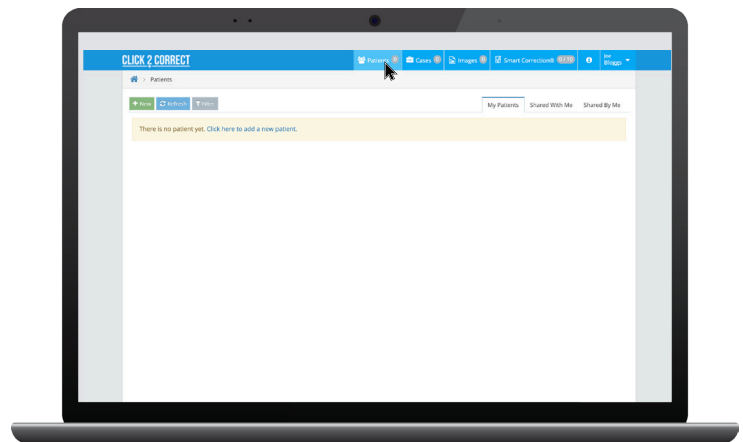
After clicking the *New* button or the *Click here to add a new patient* link (for the first patient record), the following form will appear.

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:
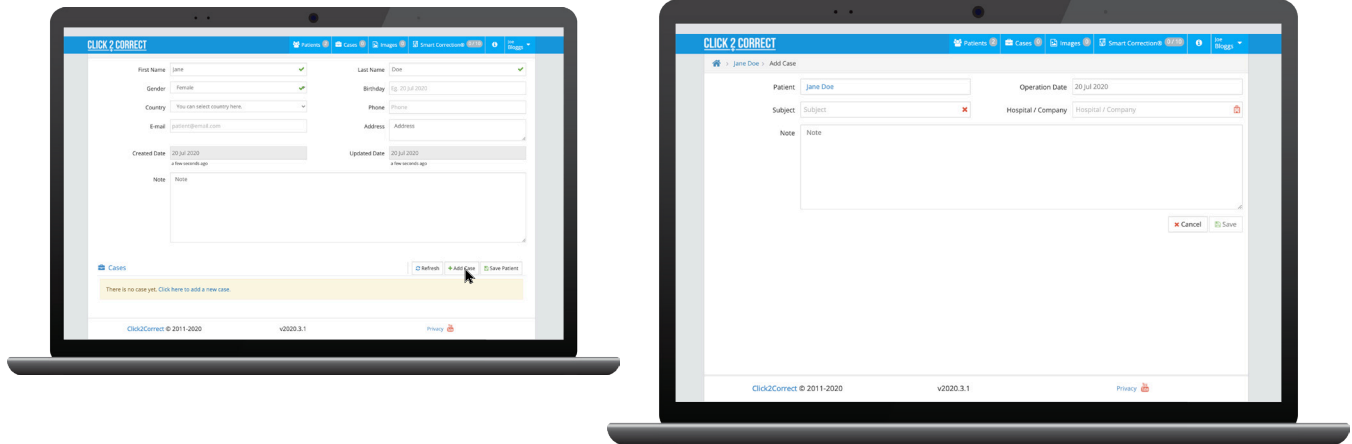
Once the mandatory fields (Subject and Hospital/Company) are filled in and saved, add pictures.
The Smart Correction calculation will then be available.
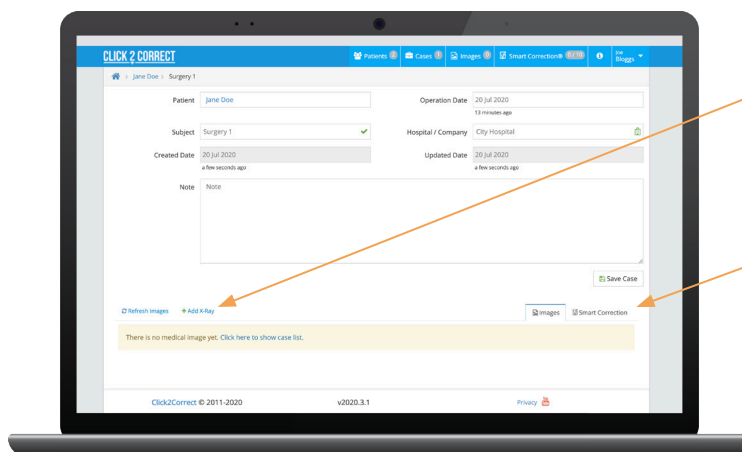
After the case is saved, X-ray images should be stored for preoperative planning and/or Smart Correction calculation through the link.

The Smart Correction calculation will start through the link.

Compatible file formats: JPEG, PNG or DICOM

Scenario #1

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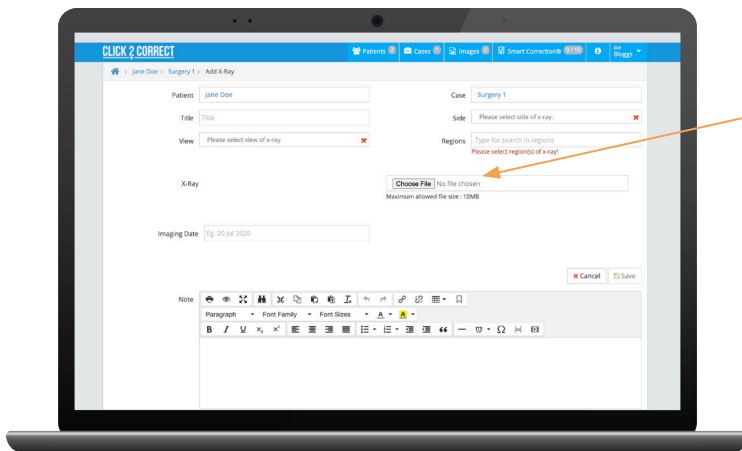
Note: X-ray images should be uploaded through the link.

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.
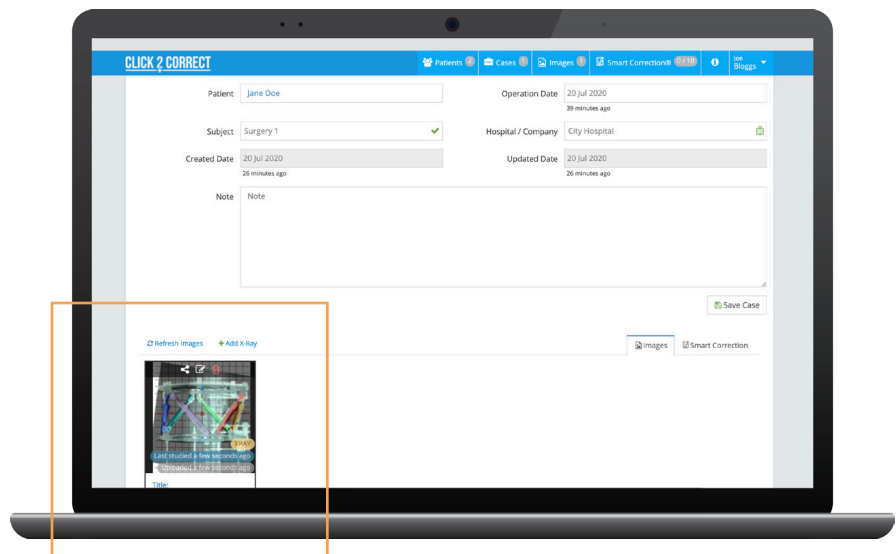
SOFTWARE USER GUIDE, (CONT)

Scenario #2

Start Calculation
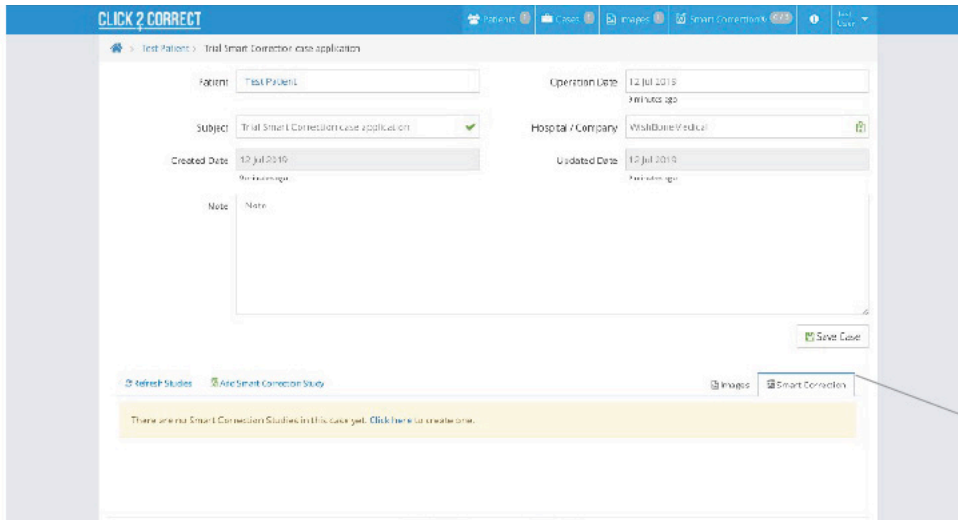
Click on the *Smart Correction* tab to start correction calculation.
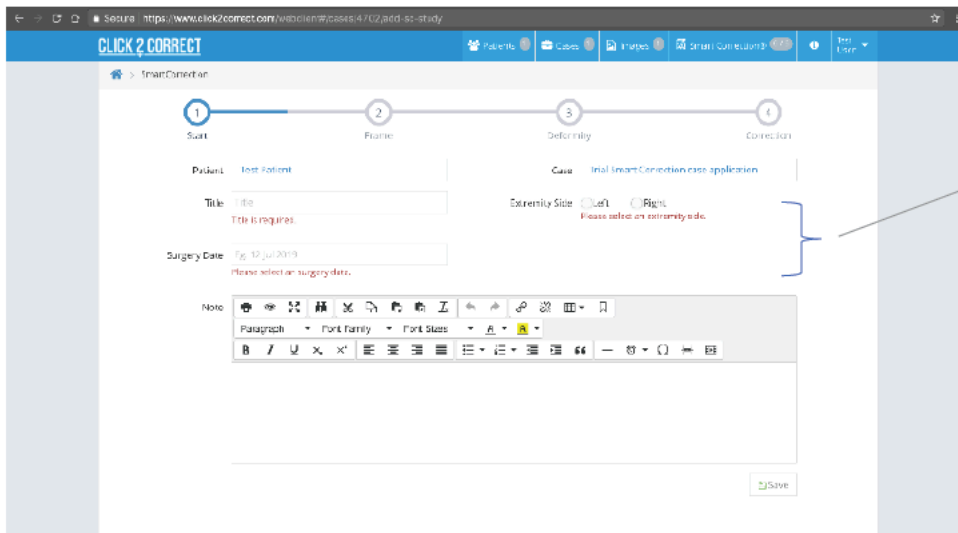
Title is to identify the case.
Extremity side must be selected to correctly apply internal/external rotation.
Surgery date will be part of the prescription date.

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)

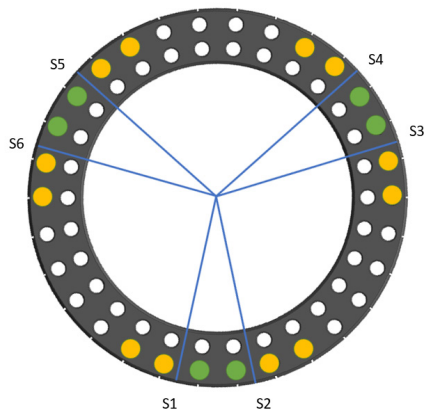| Proximal Ring Size	S1 & S2	S3 & S4	S5 & S6	Acceptable Tolerance
105 mm	1 & 2	10 & 11	19 & 20	± 2 holes
120 mm	1 & 2	11 & 12	21 & 22	± 2 holes
135 mm	1 & 2	12 & 13	23 & 24	± 2 holes
150 mm	1 & 2	13 & 14	25 & 26	± 2 holes
165 mm	1 & 2	14 & 15	27 & 28	± 3 holes
180 mm	1 & 2	15 & 16	29 & 30	± 3 holes
195 mm	1 & 2	16 & 17	31 & 32	± 4 holes
210 mm	1 & 2	17 & 18	33 & 34	± 4 holes
225 mm	1 & 2	18 & 19	35 & 36	± 4 holes
240 mm	1 & 2	19 & 20	38 & 39	± 4 holes
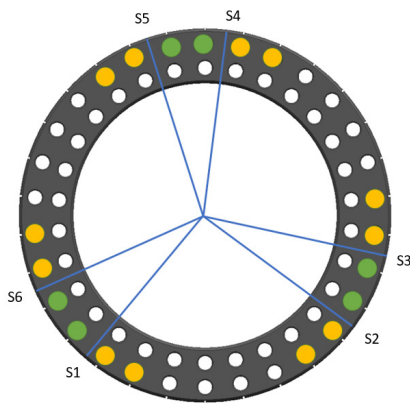
Distal
(120mm shown)

Distal Ring Size	S2 & S3	S4 & S5	S6 & S1	Acceptable Tolerance
105 mm	25 & 6	7 & 15	16 & 24	± 2 holes
120 mm	6 & 7	16 & 17	26 & 27	± 2 holes
135 mm	6 & 7	17 & 18	28 & 29	± 2 holes
150 mm	7 & 8	19 & 20	31 & 32	± 2 holes
165 mm	7 & 8	20 & 21	32 & 33	± 3 holes
180 mm	8 & 9	22 & 23	36 & 37	± 3 holes
195 mm	9 & 10	24 & 25	39 & 40	± 4 holes
210 mm	9 & 10	25 & 26	41 & 42	± 4 holes
225 mm	10 & 11	27 & 28	44 & 45	± 4 holes
240 mm	8 & 9	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
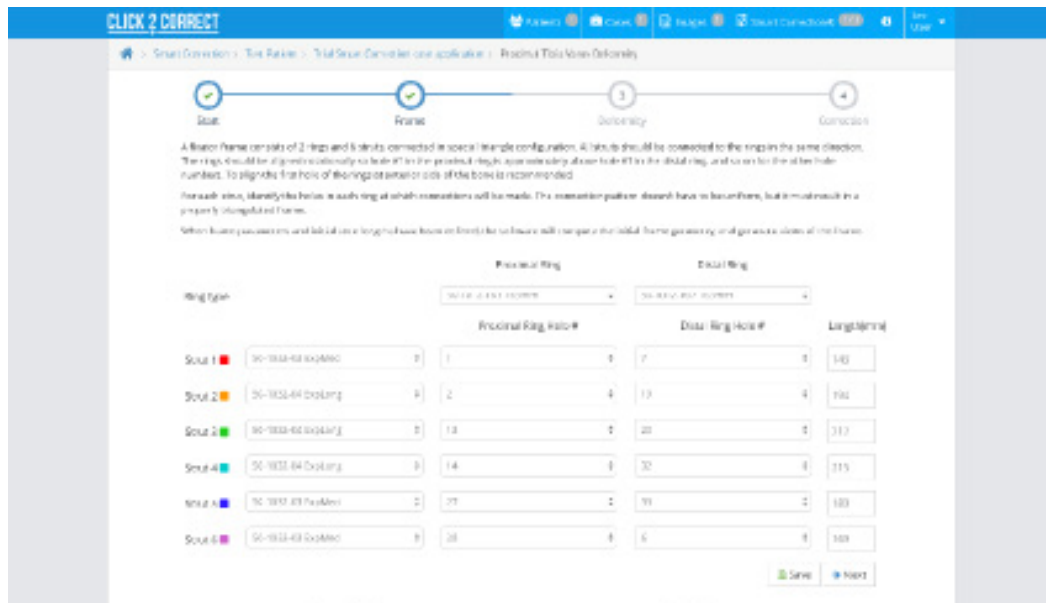
After all the components (rings and struts) are selected and all the fixation holes are entered, the **Save** button should be clicked. The software will generate AP and lateral views of the fixator model for visual confirmation.

SOFTWARE USER GUIDE, (CONT)
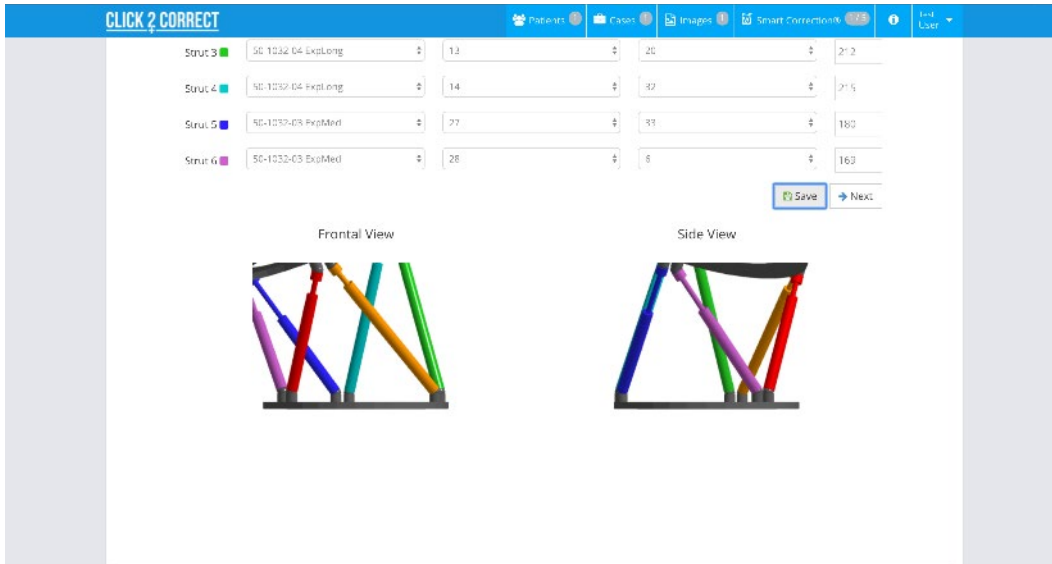
After the frame views are visually confirmed, the **Next** button should be clicked.

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.
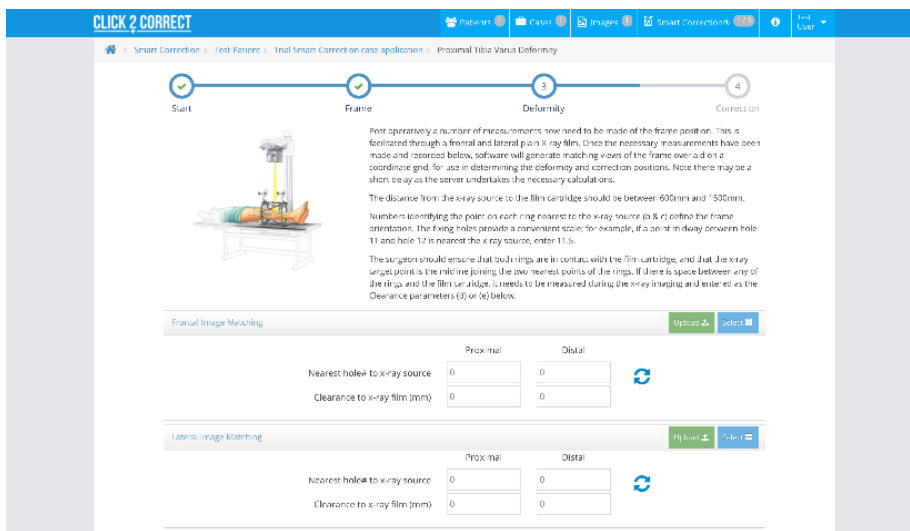
Three seconds after changing any of the field, the software calculates the template automatically.
After the template is correctly built, an X-ray image should be selected or uploaded.
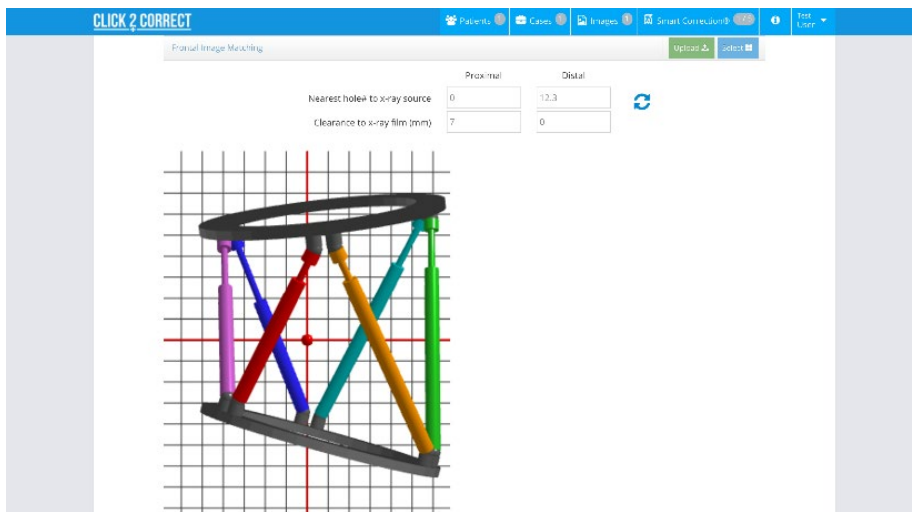
SOFTWARE USER GUIDE, (CONT)
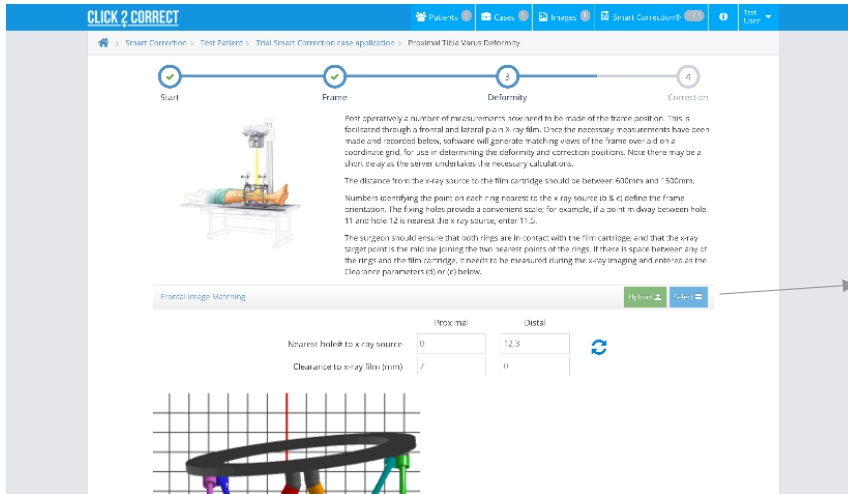
X-ray image should be selected from the pictures. To upload a new X-ray image, select the **Upload** button.
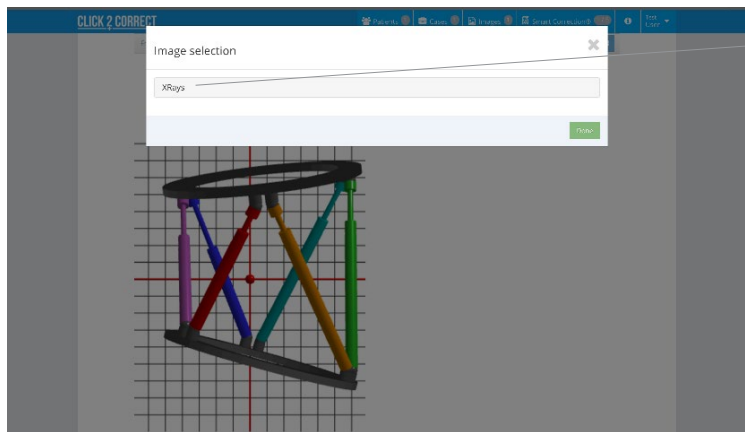
If the **Select** button is clicked, a pop-up window will appear.
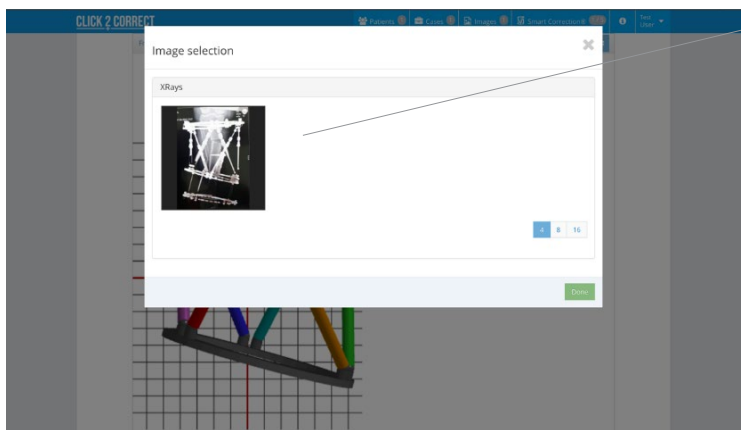
Select the correct image for calculation, followed by the **Done** button.
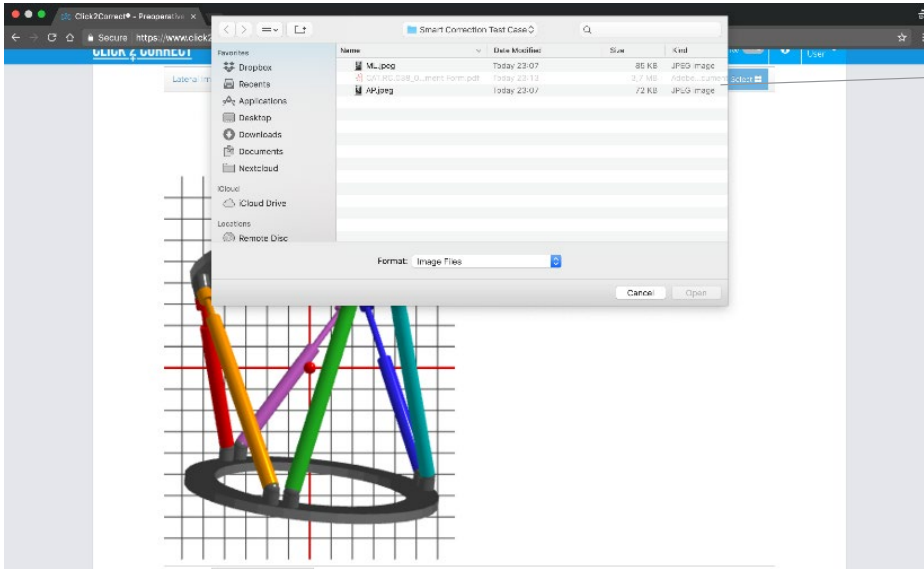
A new X-ray image should be uploaded from the computer through this window.
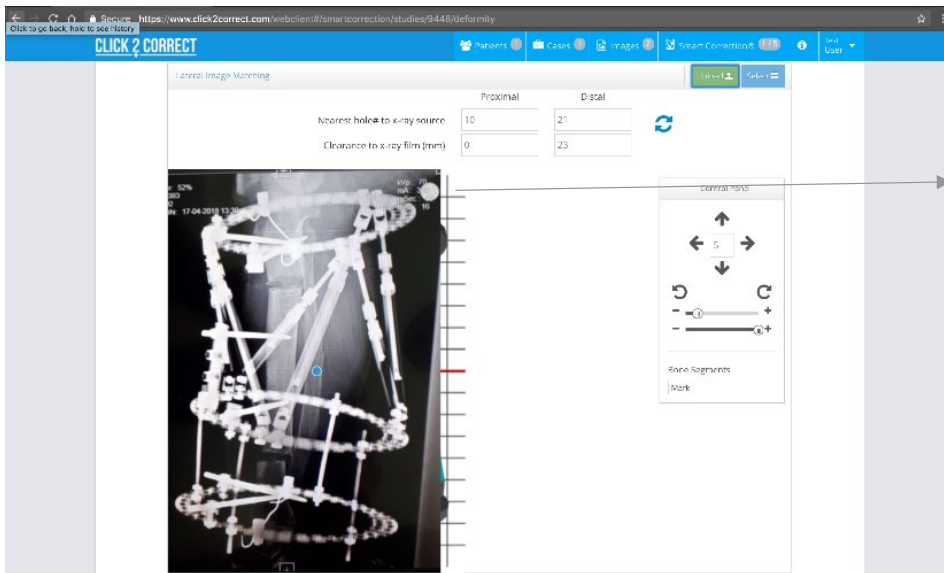
When the X-ray image appears, it should be overlayed onto the Click2Correct™ template.

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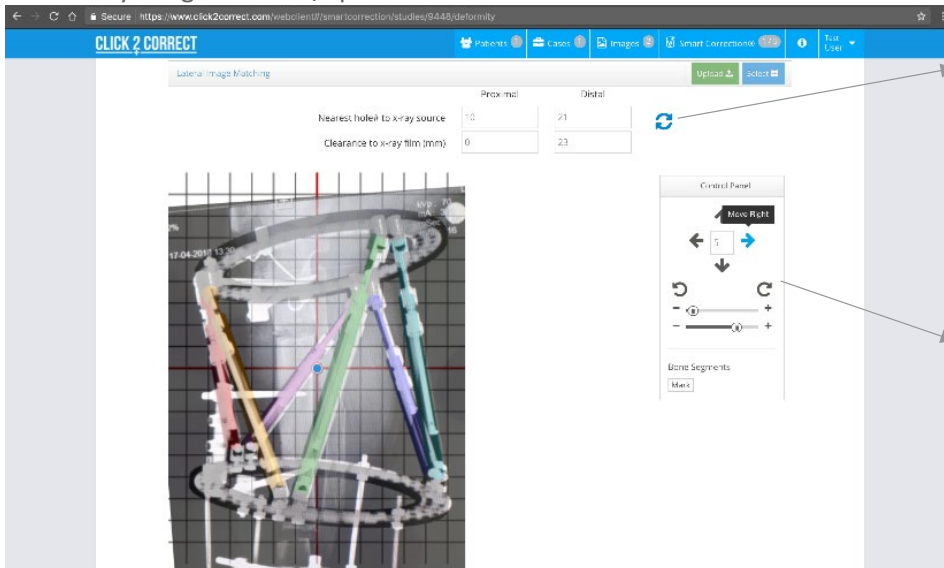
If the X-ray image does not fit on the template, the highest point and clearance values can be adjusted slightly.

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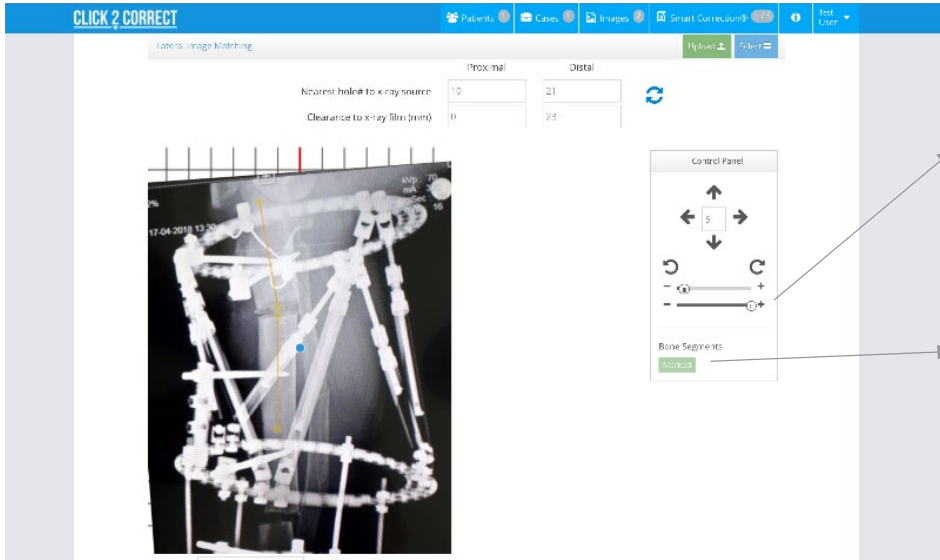
After overlaying is successfully completed, change the transparency to full image view.

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.
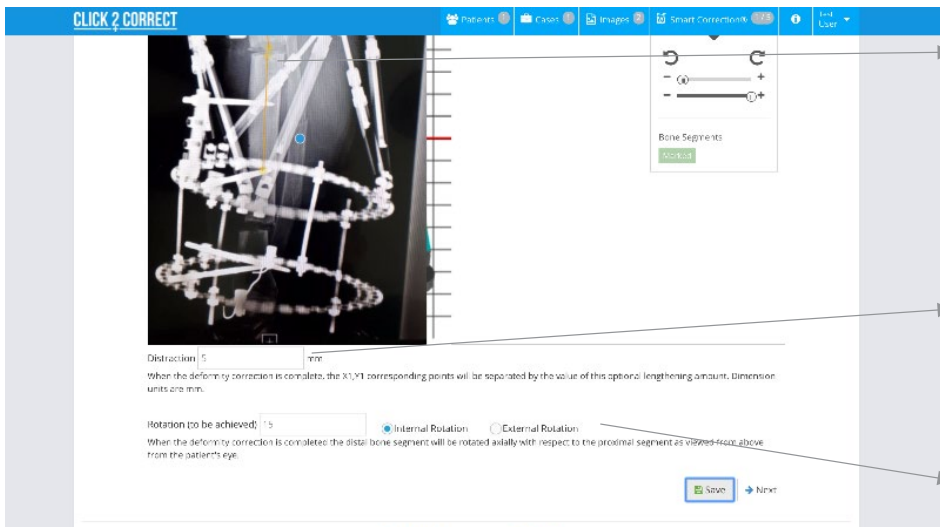
The bone segment axes should be positioned as mid-diaphyseal lines if there is no virtual deformity correction requirement.

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.

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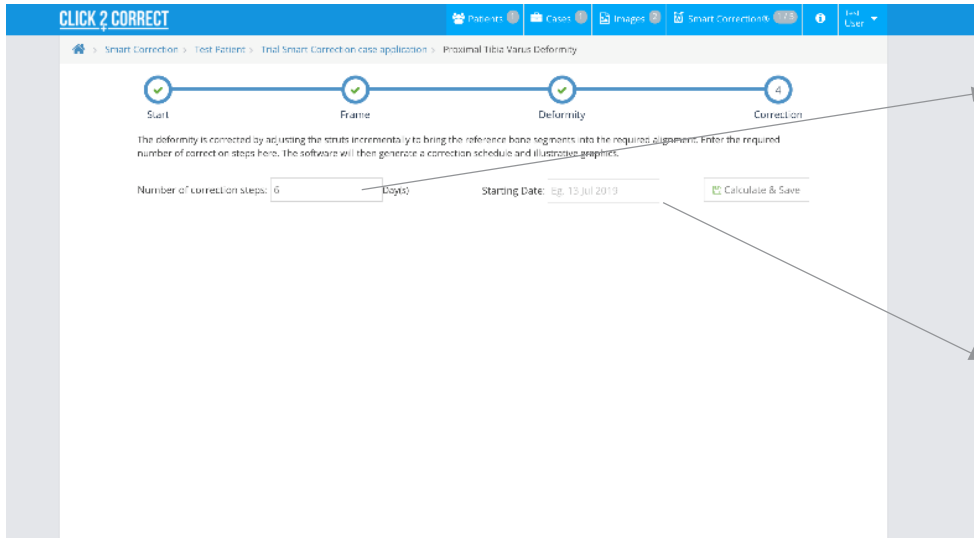
The software calculates a recommended day number for 1mm and/ or 1° per day. It can be changed according to user planning.

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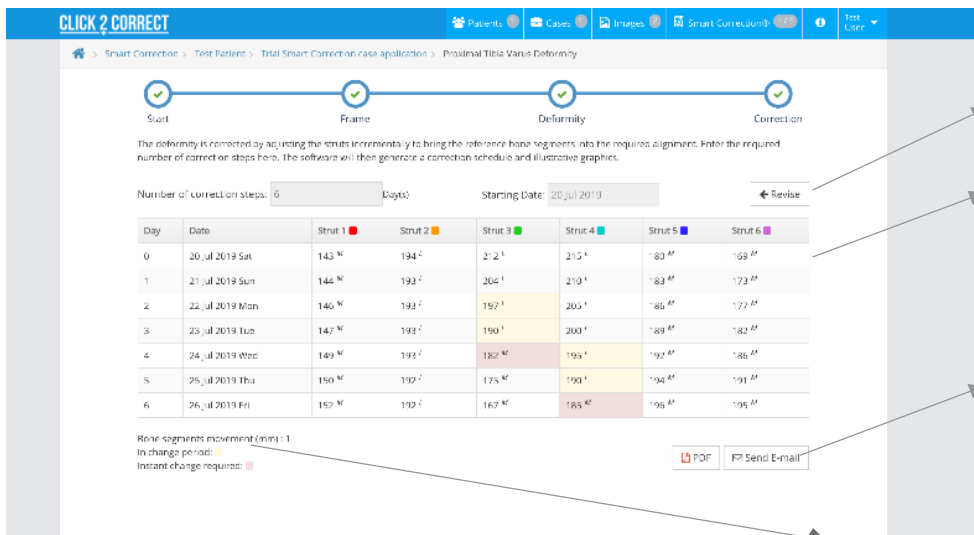
Click the **Revise** button to revise/ correct any parameters and/or to re-calculate the prescription.

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
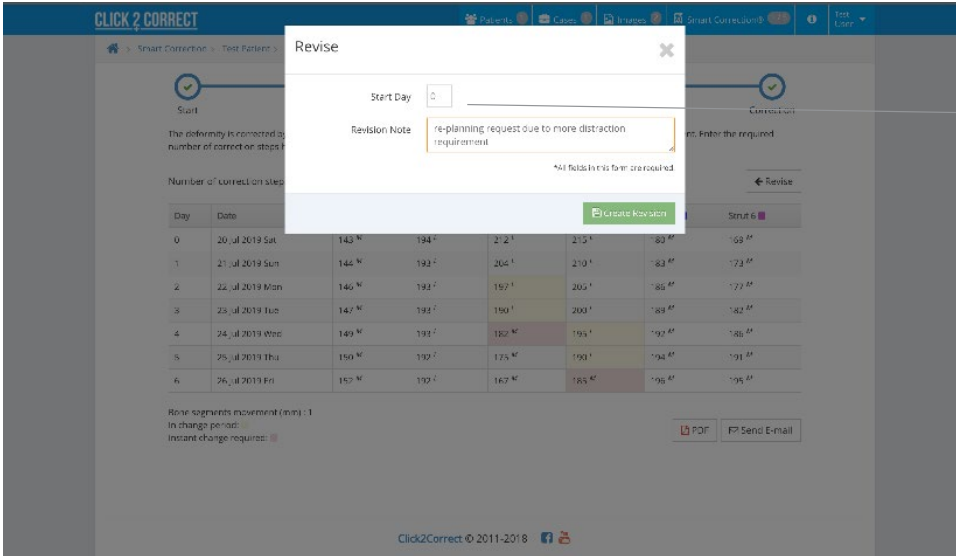
Enter the start day number of revisions to be created.
All strut length parameters will be updated with the values of the day of revision.

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.
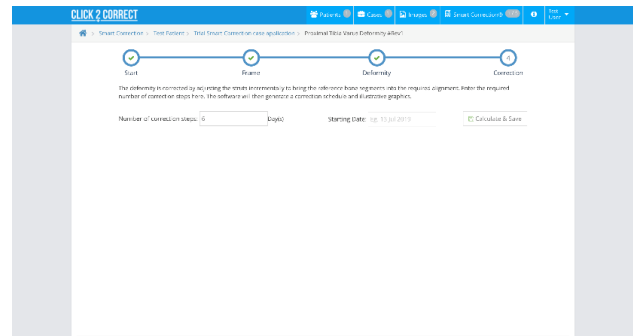
Revise Calculation

Scenario #2: During the correction
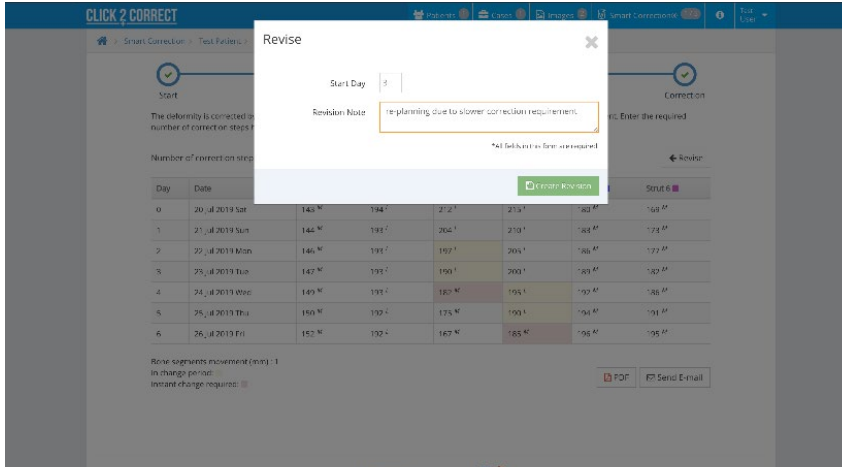
If any revision day (except for '0') is chosen, X-ray images will not be available for this calculation and must be updated.
If a revision occurs during the correction, bone positions will be altered and X-ray images should be refreshed for re-calculation. The *Deformity* tab will be "unchecked" and the case will present like a new case, except for the frame parameters.
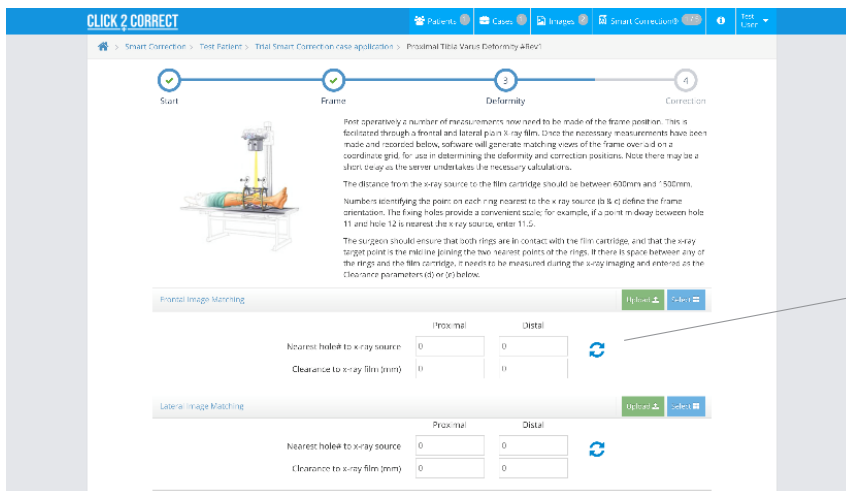
Note: Parameters within the *Deformity* tab will reset to "0" due to revision requested during the correction.

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.
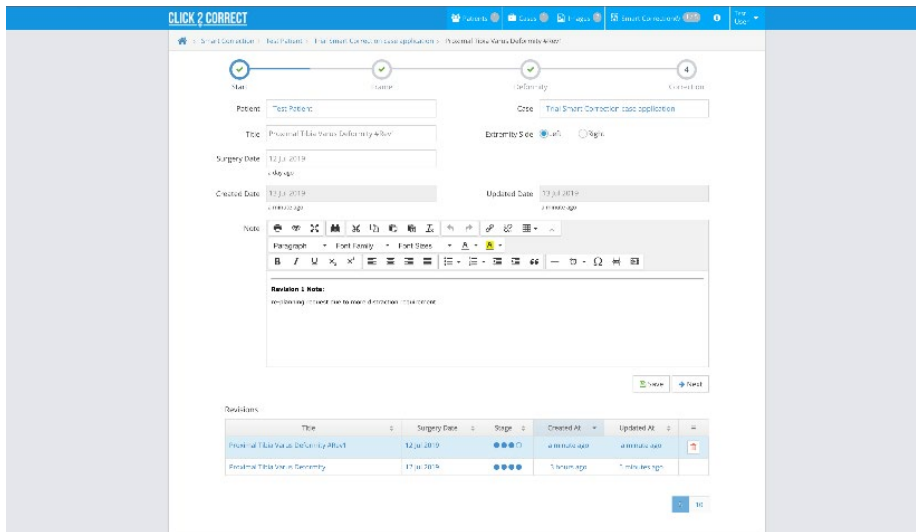
Patient Transfer

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.
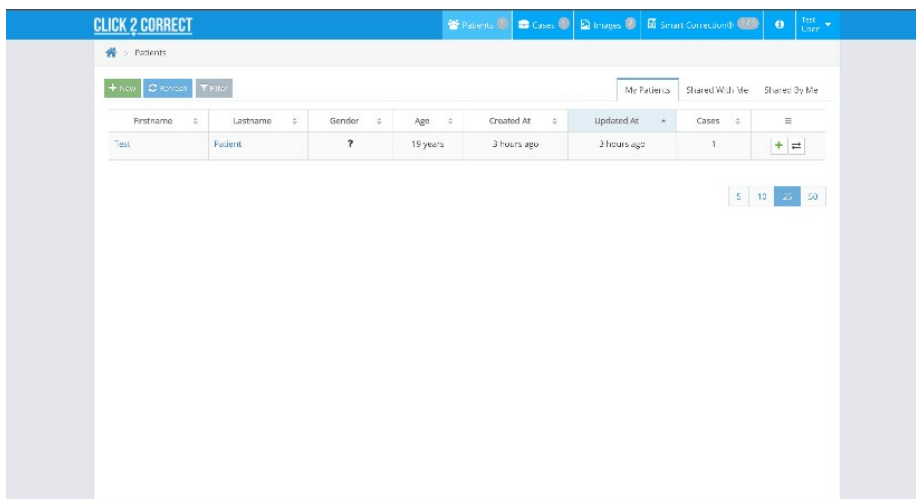
Consultation

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.
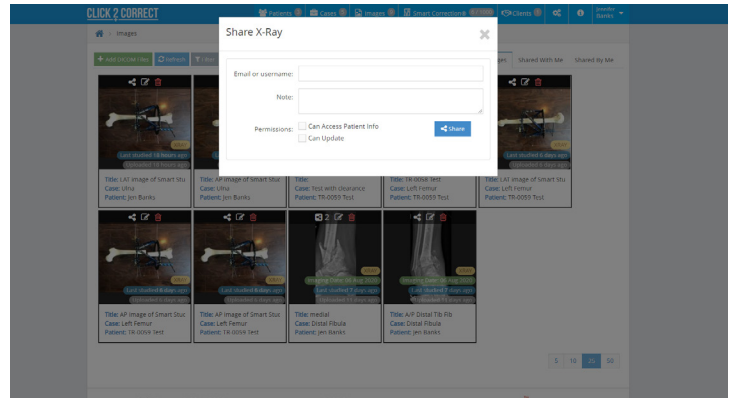
Preoperative Planning Interface Instructions
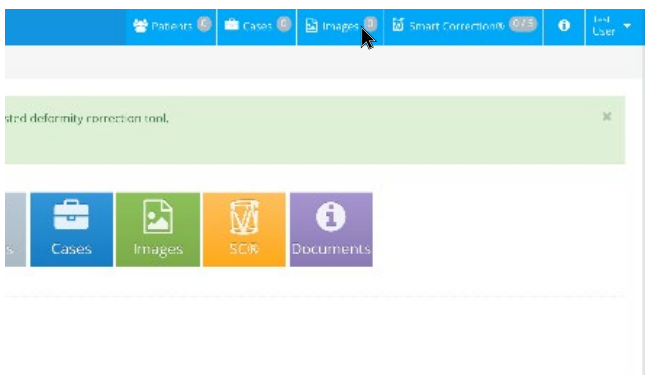
To access instructions for the Preoperative Planning Interface online, simply click on the **Images** tab.

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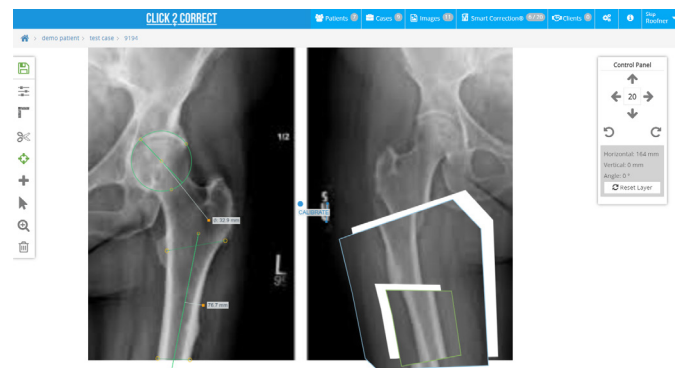
X-RAY POSITIONING

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)**
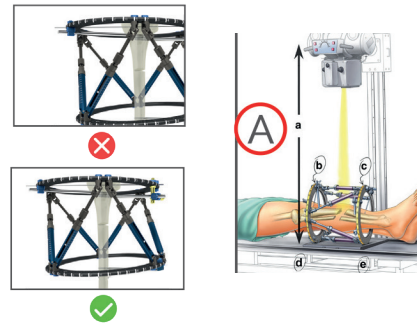
❶ Anterior X-Ray Measurements

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)**.

e.g.
D=20mm

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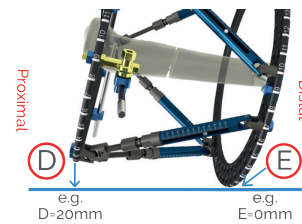
❸ Lateral X-Ray Measurements

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)**.

e.g.
H=35mm

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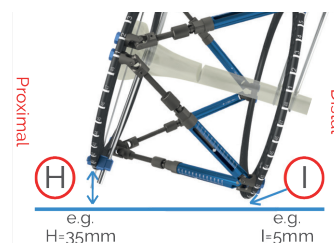
The Smart Correction® Frame Information Form (LIT-FIF-SCEF) is available for frame configuration and X-ray measurement documentation. Access the document online at www.WishBoneMedical.com/product/SC.

SOFTWARE LICENSE AGREEMENT

1. GRANT OF LICENSE

Subject to the payment of the applicable license fees and all the terms and conditions of this End User License Agreement ("EULA"), Response Ortho, LLC ("Response Ortho"), a subsidiary of WishBone Medical, Inc., grants to you a limited, non-exclusive, revocable, non-transferable, non-sublicensable license to use, in binary executable form, the Response Ortho product ("Smart Correction") that accompanies this EULA. If Click2Correct and all associated applications are licensed as a suite or bundled with more than one specified Click2Correct, this license applies to all such specified Products, subject to any restrictions or usage terms specified on the applicable Purchase Order that apply to any of such Products individually. Notwithstanding the foregoing, to the extent Software Templates (or "Libraries") are included with the Products and subject to the payment of the applicable license fees and all the terms and conditions of this EULA, specifically but not limited to Section 8, Response Ortho grants to you a limited, term-based, non-exclusive, revocable, non- transferable, non-sublicensable subscription license to install and use the Libraries.

2. PRECAUTIONS AND PERMITTED USES

Click2Correct and all associated applications may be used only for the intended uses specified in the user manual of Click2Correct. Click2Correct and all associated applications may be used only by trained personnel, who are qualified, licensed and experienced in conducting the relevant medical procedures. Click2Correct and all associated applications may be used only after thorough review of, and strictly in accordance with, the user manual. All results provided by the Click2Correct and all associated applications must be clinically verified and checked before patient treatment. Click2Correct and all associated applications are evaluation tools, intended to provide aid and support to trained personnel, and should not be used as a decision-making tool.

3. LIFE SUPPORT PROCEDURES AND HIGH-RISK ACTIVITIES

You acknowledge that the Click2Correct and all associated applications are not fault tolerant and should not be used in direct life support procedures or other activities requiring fail-safe performance in which the failure Click2Correct could lead directly to death, and you agree not to use or allow the use of the Click2Correct and all associated applications for, or in connection with, any such procedure or activity.

4. OWNERSHIP; COPYRIGHT PROTECTION

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6. TERM AND TERMINATION

This EULA shall continue until terminated as set forth in this section. You may terminate this EULA at any time by cancelling the user registration of Click2Correct and all associated applications and Click2Correct documentation. Response Ortho may terminate this EULA immediately if you violate any provision of this EULA. Any termination of this EULA shall also terminate the licenses granted hereunder. Upon termination of this EULA for any reason, you agree Response Ortho to destroy all of your records on Click2Correct and all associated applications.

7. REPORTS

You agree to prepare and submit to Response Ortho full and accurate reports, immediately upon becoming aware of any adverse effect occurring during procedures in which results of Click2Correct and all associated applications were used or during any other use of the Click2Correct.

8. INDEMNITY

You agree that Response Ortho shall have no liability whatsoever for any use you or any third party makes of Click2Correct and all associated applications. You hereby agree to defend, indemnify, and hold harmless Response Ortho from any and all damages, liability, costs, and expenses (including attorney's fees) arising from claims related to your use, and your personnel's use, of the Click2Correct and all associated applications.

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11. MISCELLANEOUS

This EULA represents the complete agreement concerning the license between you and Response Ortho and supersedes all prior agreements and representations between you and Response Ortho. It may be amended only by a writing executed by you and Response Ortho. If any provision of the EULA is held to be unenforceable for any reason, such provision shall be reformed only to the extent necessary to make it enforceable. The failure of Response Ortho to act with respect to a breach of this EULA by you or others does not constitute a waiver and shall not limit the rights of Response Ortho with respect to such breach or any subsequent breaches. This EULA is personal to you and may not be assigned or transferred for any reason whatsoever without the consent of Response Ortho and any action or conduct in violation of the foregoing shall be void and without effect. Response Ortho expressly reserves the right to assign this EULA and to delegate any of its obligations hereunder. This EULA is governed by and construed under the laws of United States. Should you have any questions concerning this EULA, or if you desire to contact Response Ortho for any reason, please contact your distributor or contact Response Ortho, as appropriate, directly at: info@responseortho.com, or by calling +90 216 314 1104.

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