

CLiCK²Correct[™]

Software User Guide

FOR THE SMART CORRECTION EXTERNAL FIXATOR SYSTEM



We WORK so they can PLAY."

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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.



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™** Login Page.

Note: All aspects of Click2Correct[™] 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.

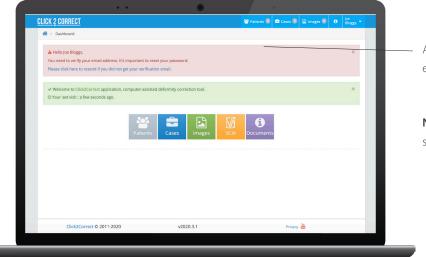
Register to Click2Correct Application			
Firstname	×	Lastname	×
E-mail		Username	*
Password	-	Please confirm your password.	a
Please select your gender.	×	Please select your speciality.	×
Please select your user type.	×	Please select your country.	٥
City		State	
Postal Code			
☑ I want information messages from Click2Correct application.			
Forgot your password?		🕹 Register	

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.

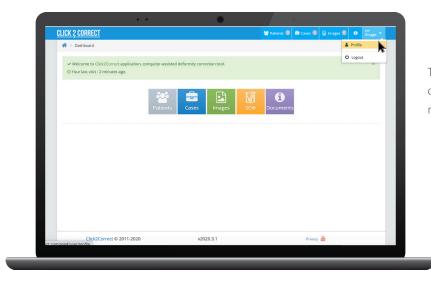


Alert will no longer appear once email is verified.

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

User Profile

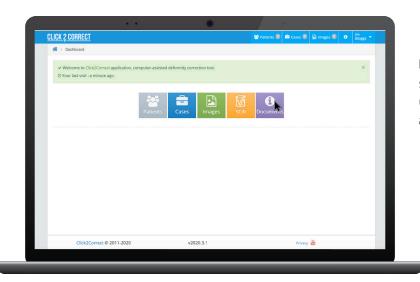
Once the account is registered, a profile link is created through the username.



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

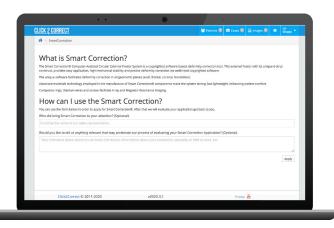
Note: For account issues, customer support contact information is located under the *Documents* page which can be accessed via the purple '**i**' button.

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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.



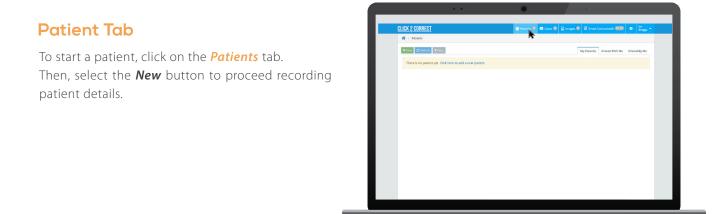


Data Entry Guidelines

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.



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.

CLICK 2 CORRECT		😁 Patient	s 📴 🛱 Cases 📴 🔛 Ima	ges 🔍 📓 Smart Correction® 🔍	4 Bioggs	·
😭 > Patients > Add						
First Name	First Name	×	Last Name	Last Name	1	×
Gender	Please select gender.	×	Birthday	Eg. 17 Jul 2020		
Country	You can select country here.	~	Phone	Phone		
E-mail	patient@email.com		Address	Address		
Note	Note					
					× Cancel 🖄 Save	
					* Cancel 🖄 Save	
					× Cancel 🗈 Save	
					X Cancel D Save	
					X Cancel Save	
					X Cancel Di Seve	

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:

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CLICK 2 CORRECT		🔮 Patients 🚳 🛛	🖥 Casas 🔕 🗟 Imag	is 🕘 📓 Smart Correction® 🕮 🛛 🛗 🛗 🐻	CLICK 2 CORRE	ECT		🔮 Patients 🔞	🖴 Cases 🚳 🖻 In	uges 🔘 📓 Smart Con	rection® 💷 0 🔤 🕬	
First Name	Jane	~	Last Name	loe 🗸	🍘 🗧 jane Doe 🤉	Add Case						
Gender	Ferrale	-	Birthday	(g. 20.) už 2020		Patient	Jane Doe		Operation Date	20 Jul 2020		
Country	You can select country here.	~	Phone	hone		Subject		×	Hospital / Company	Hospital / Company	8	
E-mail	patientijemal.com		Address	Address		Note						
						Note	Note					
Created Date	20 Jul 2020 a few seconds ago		Updated Date	10 jul 2020 fev secands ago								
Cases				D latroch + Add Care IS Save Patient							× Cancel ® Save	
There is no case yet. Click	here to add a new case.											
Click2Correct C	2011-2020	v2020.3.1		Privacy 🚵								
			_		Clid	k2Correct ©	2011-2020 v2	020.3.1		Privacy	à	

Once the mandatory fields (Subject and Hospital/Company) are filled in and saved, add pictures. The Smart Correction calculation will then be available.

<u>CLICK 2 CORRECT</u>		Patients	Cases U 🛛 🖬 🗠	nges 🙆 📓 Smart Correction® 💷	Bioggs *	
👘 > Jane Doe > Surgery 1						
Patient	Jane Doe		Operation Date	20 Jul 2020		
				13 minutes ago		
Subject	Surgery 1	~	Hospital / Company	City Hospital	0	
Created Date	20 Jul 2020		Updated Date	20 Jul 2020		
	a few seconds ago			a few seconds ago		
ØRefresh images + Add	XRg			Spirmages II	Save Case	
	X-lay ge yet. Click here to show case list.			Qimages U		-

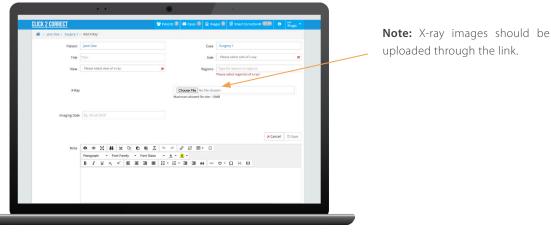
Compatible file formats: JPEG, PNG or DICOM

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.

Scenario #1

Add X-rays first: Fill the data fields and upload the X-ray image for preoperative planning and/or Smart Correction[®] calculation.



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.

<u>CLICK 2 CORRECT</u>		😁 Patients 🙆 🚔 Cases 🕚 🚦	🗟 Images 🚺 📓 Sma	rt Correction® 0210	0 loe Bloggs -
Patient	Jane Doe	Operation	Date 20 Jul 2020		
			39 minutes ago		
Subject	Surgery 1	 Hospital / Complexity 	City Hospital		۵
	20 Jul 2020	Updated	Date 20 Jul 2020		
Note	26 minutes ago Note		26 minutes ago		
2) Refresh Images + Add	×say			🗟 images 📓 Sm.	Save Case
< 2 8					
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Scenario #2

Start Calculation

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🕋 > Test Patient > Trial Sn	rart Correction case application					
Fatient	Test Patient		Operation Date	12 Jul 2015		
				9 minutes ego		
Subject	Trial Smart Correction case application	*	Hospital / Company	WishBoneVedical	121	
Created Date	12 jul 2019		Updated Date	12 Jul 2019		
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Note	Nate					
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					🖺 Save Case	
3 Refresh Studies 5 Adv	- Smark Correction Study			ៀ hogss 🗐 ទី៣	nart Correction	
There are no Smart Cor	nection Studies in this case yet. Click here to cre	ate one.				Click on the Smart Correction tab to
						start correction calculation.

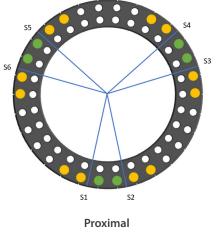
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<u>CLICK 2 CORRECT</u>		🔮 Papents 🕘 📾 Cases 🌖 🖹 1	nages 🌒 🖾 Smart Conlection® 🥨		
☆ SmartCorrection					
1 Sart	2 Frame	3 Deformity	Correction		
Patient	Test Patient	Case Irial Sm	art Correction case application		Title is to identify the case.
Title	Title Title Is requires.	Extremity Side CLeft Please rele	Offigit. et an extramity ade.		Extremity side must be selected to
	Fg. 12 Jul 2019 Heave select an surgery date.		_		correctly apply internal/external rotation.
Note	● ● 光 Ă X Ph 色 む Z Patarsh * Portfamy * Portizes B Z U X X 臣 王 〓	• <u>A</u> • <mark>A</mark> •	to • Ω ⊭ B		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.

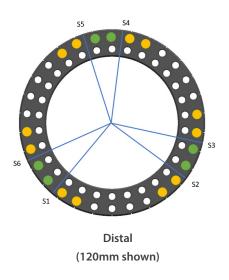
Next, select the appropriate strut type.

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.



(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

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The rings do numbers. To Annuals eite	add ter all presidential and you have a align the first hole of the rings of se	et inn inne y Register pick	e admit height approximately a Follow borne is recommended	ione toole t	fracialities connected to the rings in the set of the deside ring, and second in the other are diseased basis to basis from, but it must	er Foder
		have been	n er freet, die selmare nill ow	pice the la	idal harne passen og er sliger sekan sleve	al che l'hanno-
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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.

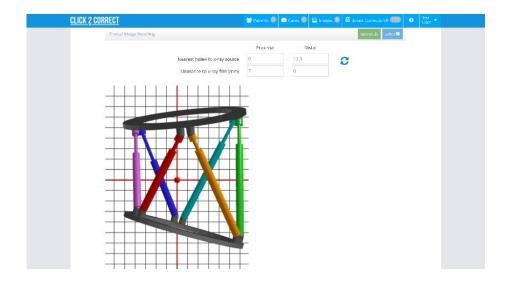
<u>CLICK 2 CORRECT</u>			😤 Patients 🔘 🚔 Case	s 🕕 🖻 Images 🕻	🗴 Smart Correctio	unte 🎯 🛛 🖯	Lest +	
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Strut 4 🔳	50-1032-04 Explore \$	14	\$	32	÷	215		
Strut 5	50-1032-03 ExpMed \$	27	\$	33	\$	180		
Strut 6 📕	50-1032-03 ExpMed +	28	\$	6	\$	169		
					🔁 Save	→ Next		
	Frontal View			Side Vie	w			
					X			

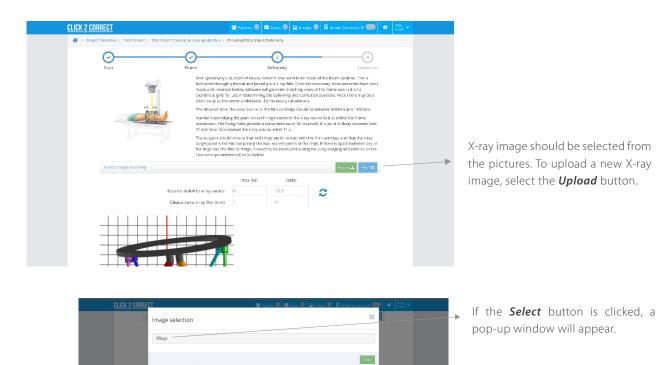
After the frame views are visually confirmed, the *Next* button should be clicked.

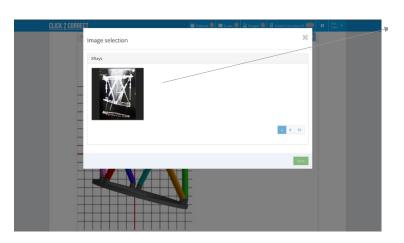
The surgeon should ensure that both rings are in contact with the film cartridge, and that the X-ray target point is the midline joining the two nearest points of the rings. If there is space between any of the rings and the film cartridge, it needs to be measured during the X-ray imaging and entered as the clearance parameters (d) or (e). All the numbers should be entered into each field on the screen below.

📓 Smart Correctionច 📲	🕯 Cases 🔍 🖹 Images 🔍	😁 Patients 🕘 📫		CORRECT
	leformity	Proximal Tibia Varus De	art Correction case application > - P	Smart Correction > Test Patient > 1
4	-0			0
Correc	Deformity	D	Frame	Start
tessary measurements have i the frame overlaid on a positions. Note there may be etween 600mm and 1500mm	ents now need to be made of plain X-ray film. Drice the need (generate matching views of I) the deformity and correction give necessary calculations, le film cartridge should be betting nearest to the x-ray source	a frontal and lateral ple d below, software will g r use in determining the server undertakes the r the x-ray source to the	facilitated through made and records coordinate grid, fo short belay as the s The distance from	
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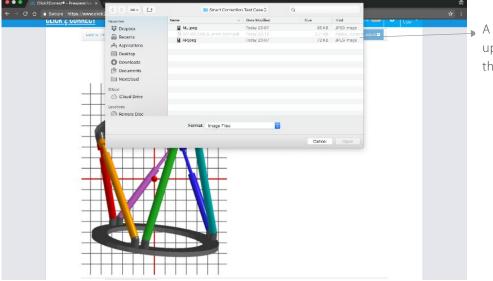
Three seconds after changing any of the field, the software calculates the template automatically. After the template is correctly built, an X-ray image should be selected or uploaded.



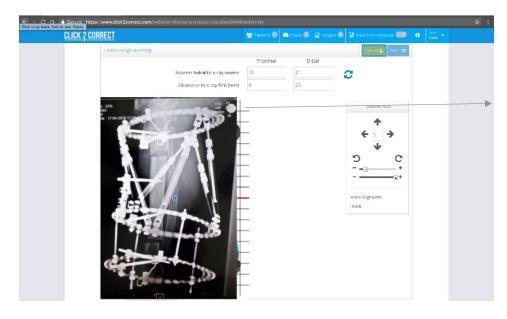




Select the correct image for calculation, followed by the **Done** button.

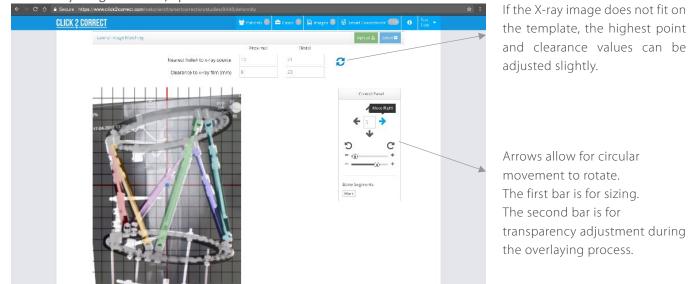


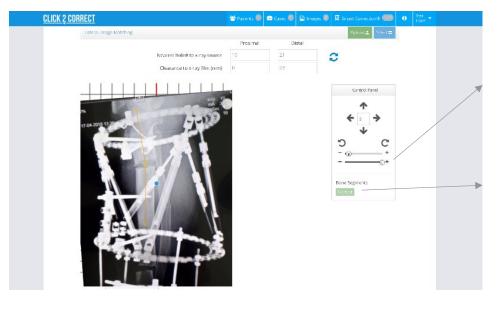
A new X-ray image should be uploaded from the computer through this window.



When the X-ray image appears, it should be overlayed onto the Click2Correct[™] template.

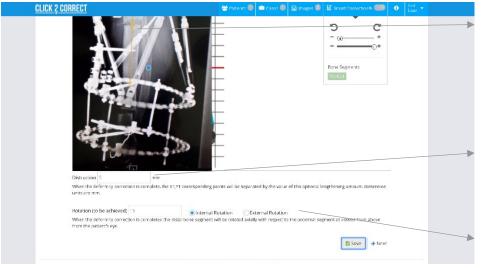
After X-ray image selected/uploaded





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.

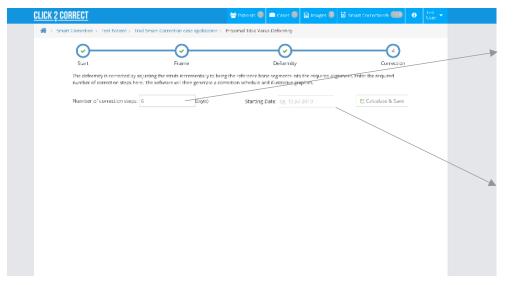


The bone segment axes should be positioned as mid-diaphyseal lines if there is no virtual deformity correction requirement.

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.

	rmity is corrected by adjust of correct on steps here. Th			e reference bone seg		juired alignment. Fr	Correction nter the required	re-calculate	
Number	of correction steps: 6		Day(s)	Starting Date:	20 Jul 2019		€ Revise	The prescrip	otion s
Day	Date	Strut 1 📕	Strut 2 <mark>–</mark>	Strut 3	Strut 4	Strut 5	Strut 6	strut length	chang
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2	22.jul 2019 Mon	146 ^w	193 ²	197 ¹	205 *	185 ^M	177 #		
з	23 jul 2019 Tue	147 ^W	193 /	190 1	200 '	189 ^M	182 #		
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shows the daily bone move distance per day in millimeters.

Revise Calculation

Scenario #1: At the beginning of the correction

Start The defe	rmity is corrected by	Start Da Revision No		nning request due	to more distractio	0	Correction		Enter the start day nu
	of correct on stops F		requir	rement					revisions to be create
Number	of correct on step				*All fields in this fo	m creiroquired	← Revise		All strut length param
Day	Date				E) crea	ate Revision	Strut 6 🔳		will be updated with
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Rone say	ments movement (mm) : a penad:	1							
	hange required: 🗐					10	20F F7 Send E-mail		

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.

Instruction to a functional content or real equations - Protocol Distance and Distance a	CLICK 2 CORRECT		😤 Pateria 🔍 📾 Casa 🔍 🗋 Iruga 🖉	🕽 🕅 Smart Correction D 🏧 🗿 🛛 Loss
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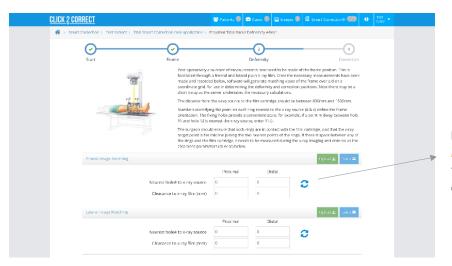
Revise Calculation

Scenario #2: During the correction

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in d	: segments movement (ange period: Int change requires:	mmj : 1					0 POF	F⊠ Send E-mail	

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.

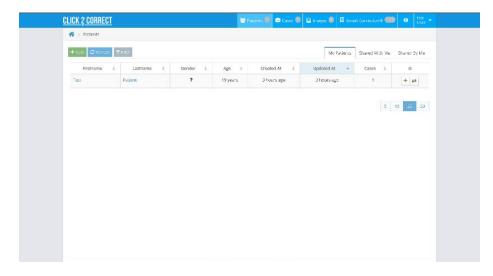
Revision History

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.

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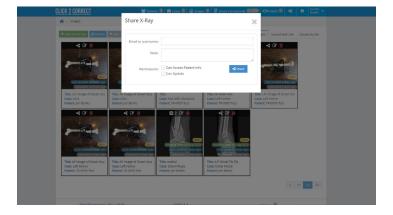
Patient Transfer

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.

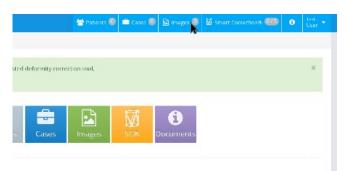


Consultation

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.

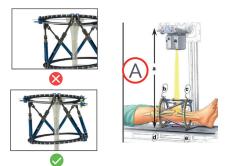
Images that have already been uploaded to the users profile can be viewed, calibrated, measured, and edited.



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.

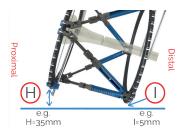
650mm-1500mm distance (A)











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.

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**).

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

Output State And A State A

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**).

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



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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.

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



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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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