HEX-ray

Software User's Guide
A module of the TL-HEX software version 2.1

ORTHOFIX®

HEX-ray Software User's Guide: A module of the TL-HEX software version 2.1

The applicable End User License Agreement can be found at: http://tlhex.com/policies/Eulapolicy.html

The applicable privacy policy can be found at: http://tlhex.com/policies/privacypolicy.html

Security Precautions:

User is advised to clear the browser history (temporary internet files, cookies, etc.) after logging out of the TL-HEX application.

Computer System Requirements

Display Settings:

Screen resolution of 1280 x 768 pixels or higher.

Supported Browsers:

Microsoft Internet Explorer® Version 11

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Safari® 10

> *Safari is trademark of Apple Inc., registered in the U.S. and other countries. HomeKit is a trademark of Apple Inc.*

Google Browser Chrome™ 56 or higher

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NOTE: for an optimal navigation experience, the Annex A provides instruction on how to configure the browser.

Internet Connection:

Minimum required internet connectivity speed is of 512kbps.

Recommended internet connectivity speed is of 3mbps or higher.

My Username: _____

My Password: _____

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Getting Started with HEX-ray module

The HEX-ray module adds an optional support for the acquisition of the required TL-HEX deformity / fracture and mounting parameters using patient's x-rays.
TL-HEX software maintains the ability to directly input the required parameter values. Users may also access the HEX-ray module that supports the acquisition of parameter values from patient images already calibrated into the system and fill the values in the related parameters fields of the TL-HEX software. The user may switch from TL-HEX to the HEX-ray module way of working freely during any stage of planning or treatment.

Using either the inherent deformity or fracture displacement as a starting point, the TL-HEX software will calculate a comprehensive treatment plan for the operating surgeon's approval. Elements of the plan will include the frequency, direction and extent of adjustment for each strut.

> **NOTE:** Although possible to mix HEX-ray and TL-HEX data, keeping a consistent singular input flow is recommended.

The formulation of the treatment plan is independent of the method of parameter input. The software is equally capable regardless of values being manually inputted or acquired automatically by the analysis of radiographs using HEX-ray.

The HEX-ray module introduces following features:

- Support of **Deformity** and **Fracture cases**
- Support of both **preoperativ**e and **postoperative** mounting stages
- It is optimized to work with the **bone anatomical axis** and **TL-HEX hardware**
- In both deformity and fracture cases, the **translation values are automatically calculated** relative to either the osteotomy level or fracture site
- To perform radiographic assessments of lower limb deformities, tools such as **Line** and the **Goniometer** are provided

- *X-ray images uploaded and processed*
  Upload of x-ray images, and application of **basic image processing** (flip, rotation, brightness, contrast and crop), to **calibrate** the images

- *Deformity Analysis*
  Deformity or trauma assessment and the acquisition of the related parameter values to be used for the TL-HEX treatment plan calculation

- *Correction definition*
  Desired **End Of Correction definition** and the acquisition of the related parameter values to be used for the TL-HEX treatment plan calculation

- *Preplanning with TL-HEX hardware*
  TL-HEX frame preplanning, closely to real surgical application, in order to provide initial recommended struts data set

- *Mounting assessment of TL-HEX hardware*
  Acquisition of the TL-HEX mounting parameter values to be used for TL-HEX treatment plan calculation.

Work Flow Overview

The following flow chart provides a sequential overview of the **7 case management steps** within HEX-ray software.

> ⓘ **NOTE:** It is recommended to follow sequentially the flow even if it is possible to go back and forth.

 # see IMAGE TOOLS

1 – Press on HEX-ray icon → HEX-ray

The HEX-ray icon is on the top of the TL-HEX Deformity Parameters page.
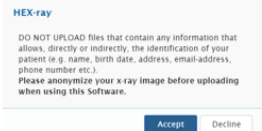
Step 1 – HEX-ray computer system requirements

Supported Desktop Browsers: Microsoft Internet Explorer® 11, Safari® 10, Google Chrome™ Browser 56 or higher

Display Settings: creen resolution of 1280 x 768 pixels or higher.

NOTE: Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to HEX-ray.

NOTE: For an optimal navigation experience, the Annex A provides instruction on how to configure the browser.

2 – Accept the disclaimer and select the Preoperative or Postoperative stage

HEX-ray
DO NOT UPLOAD files that contain any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.)
Please anonymize your x-ray image before uploading when using this Software.
Accept   Decline

3 – Upload and check / modify orientation of the two x-ray images

Load

Image Editing Tools
↻ ⛶ ⛶ ⛶

The supported the x-ray image formats are JPG and PNG, with maximum file size of 5MB.

Steps 2 and 3 – X-ray image requirements

For the HEX-ray module to be effective:

• The Reference Segment in the x-ray image must be perpendicular to the beam, in both views

• Orthogonal (90°) x-ray images are required

• Two x-ray images are required to be uploaded and calibrated in order to activate the working flows.

X-ray images must not contain any information that allows, directly or indirectly, the identification of a patient (e.g. name, birth date, address, email-address, phone number etc.). Refer to local image tools to ensure radiographs are appropriately stripped of patient identifiable data.

NOTE: It is the surgeon's responsibility to ensure that all the above requirements are met with equal consideration given to data protection as X-ray images must be anonymized before uploading in HEX-ray.

4 – Calibrate the x-ray images

Calibration Tools
Line   Circle
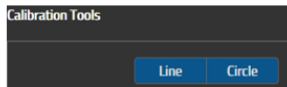
When both x-ray images are calibrated, the arrow appears permitting to continue. ❯

Step 4 – X-ray image calibration

The calibration step is critical. The precision of HEX-ray measurements is highly effected by the accuracy of the calibration.

To improve measurement accuracy it is recommended to use a marker and to accurately use the HEX-ray calibration tool.

5 – Evaluate the Deformity / Fracture

- Position the axis tools
- Set the Reference Points or Fracture Levels position
- Lock the Locks and the arrow appears permitting to continue.

Reference Points

Step 5 – Deformity or Fracture analysis

Deformity cases

For Deformity cases the **APEX** represents the point from which translations are calculated and corrections (angular and translational) applied.

The Reference Points positioning is critical because in Correction tab the Osteotomy line positioning is coordinated between the views; then the Reference Points should be at the same level on both views to permit consistent coordination. In this step, insert the clinical evaluation results of the Axial Rotation and Translation.

Fracture cases

For Fracture cases **the central point of the ending dashed line on the Reference axis** is the point from which translations are measured and corrections (angular and translational) applied. Select the reference value for the Axial Translation and insert the clinical evaluation result of the Axial Rotation.

6 – Define the End Of Correction

- Position the Osteotomy Line (Deformity Case)
- Define the Moving segment final position (EOC)
- Review and lock the Bone Lenght; the arrow appears permitting to continue.

Bone Length (mm)   3   ○ Shortening   ○ Lengthening
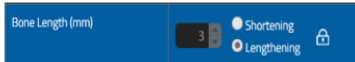
Step 6 – End of Correction analysis

Deformity cases

The **Osteotomy line** should be positioned as desired, paying attention to match the bone cortexes, permitting HEX-ray to suggest the axial bone length to avoid segments impingement during treatment. Any alteration of the Osteotomy position in one view will result in a coordinated move in the orthogonal plane in accordance with the Reference Points set in the Deformity Analysis tab (step 5).

The axial bone length suggested by HEX-ray to avoid segments impingement during treatment considers the following:

• Angular Deformity

• Osteotomy length, inclination angle, distance from the APEX

• Default EoC position

The suggested bone length value is calculated based on both AP/Dorsal and Lateral views and the highest value is shown.

If the Osteotomy is not perfectly perpendicular to the bone axis, this value might be overestimated.

It is recommended to review the value with the End of Correction analysis before continuing.

7 – Position the TL-HEX ring(s)

- Select the TL-HEX supports
- Preoperative: position the selected supports
- Postoperative: match the ring model to the Reference Ring on the x-ray images
- Save & Import all the data to the TL-HEX to complete the treatment planning.

Step 7 – TL-HEX rings positioning

Postoperative assessment

Since the Reference Ring movements are coordinated between the views, the task is to **match the HEX-ray 3D ring model to the Reference Ring on the x-ray images simultaneously in both the views.**

In case the HEX-ray 3D model will not match perfectly the actual x-ray image on both views it is possible to overcome this situation allowing for independent movement of the Reference Rings models between both views.

Others

HEX-rays supports both Preoperative and Postoperative stages. Along the Postoperative Assessment the work done in the Preoperative Planning, if present, will be presented permitting a review and adjustment, if needed, of the tools positioning.

To simplify the HEX-ray user interaction only enabled tools provide visible and selectable handles, according with the working step.
In addition, relevant user actions and selections are highlighted with a blue background.

TL-HEX and HEX-ray integration

The diagram demonstrates the interaction between HEX-ray module and the TL-HEX software in acquiring anatomical, correction and mounting parameters from patient x-rays; the green represents the path for preoperative planning and yellow the path for postoperative assessment.

The software provides the flexibility to access the HEX-ray module at any point within the TL-HEX Deformity or Mounting tabs, depending on the x-ray images uploaded.

When accessing HEX-ray, the user is asked to indicate the x-ray image type as either preoperative or postoperative. This information opens the appropriate HEX-ray Mounting tools and logic for struts within the TL-HEX.

Along the case life cycle the user can upload both preoperative and postoperative x-ray images. However, TL-HEX permits only one working dataset, therefore, the last activity performed in HEX-ray will overwrite any prior TL-HEX Deformity and Mounting parameters value.

Any updated value on TL-HEX or HEX-ray may be saved before continuing. In TL-HEX it possible to save modifications by pressing on the Save & Update button and in HEX-ray with or icons.
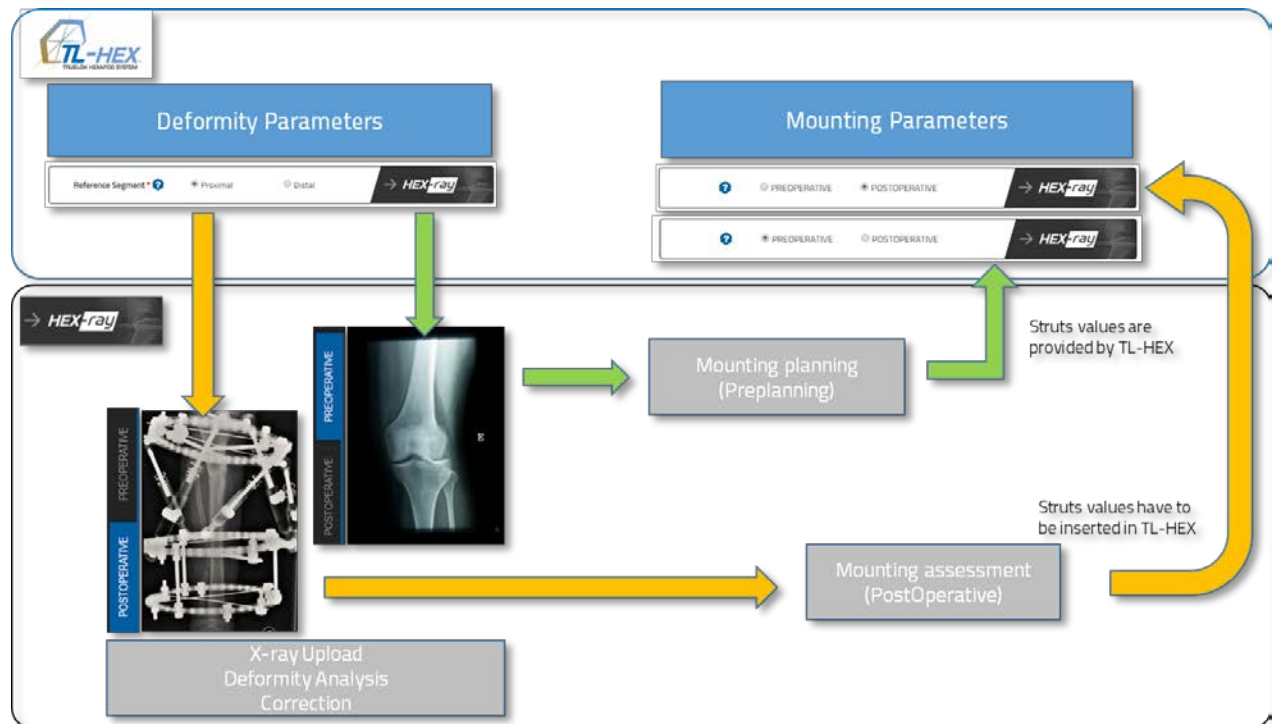
The table below describes the integration between TL-HEX and HEX-ray during a case management:

The TL-HEX Case Data tab has been updated by introducing additional options.

Case Type: *Deformity or Fracture*
The Case Type selection permits access to the appropriate HEX-ray tools and calculation options; it also eases cases organization.
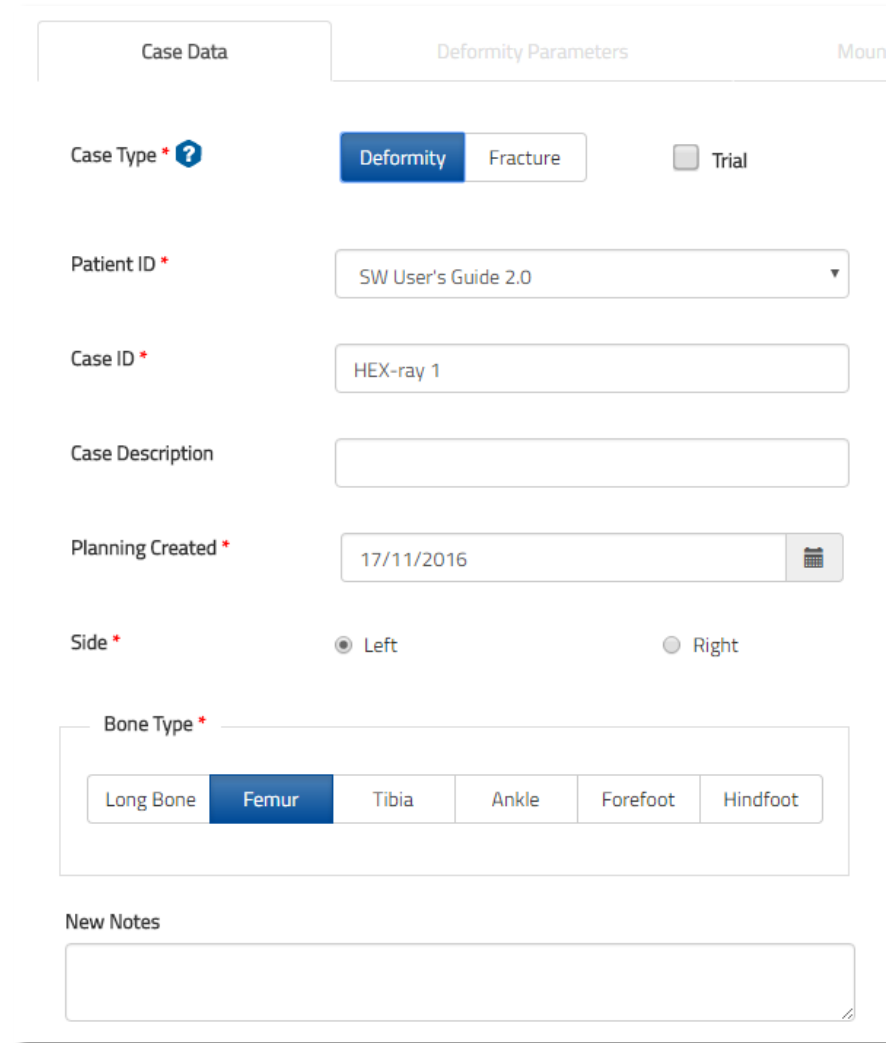
Trial:
It is a flag to identify if the case is with an applied frame to a patient or it is only for practice.

Bone Type:
The appropriate selection of the bone type setup the HEX-ray tools accordingly.

Case Data	Deformity Parameters	Moun

Case Type * ❓   **Deformity**   Fracture   ☐ Trial

Patient ID *   SW User's Guide 2.0 ▾

Case ID *   HEX-ray 1

Case Description

Planning Created *   17/11/2016

Side *   ◉ Left   ○ Right

Bone Type *   Long Bone   **Femur**   Tibia   Ankle   Forefoot   Hindfoot

New Notes

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After selection of the Reference Segment, the Deformity Parameters page is refreshed with images and the HEX-ray icon is enabled.

After returning to TL-HEX from HEX-ray, the parameters will be transferred and locked to avoid undesired modification.

You can unlock and make the TL-HEX parameters editable by clicking on them.

> ⚠ **NOTE:** Keeping a consistent singular input flow is recommended.

Although possible to mix data flows, the surgeon must be aware that any alteration in TL-HEX will have a potentially conflicting result in HEX-ray.

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HEX-ray DESKTOP

The picture below shows the HEX-ray desktop:
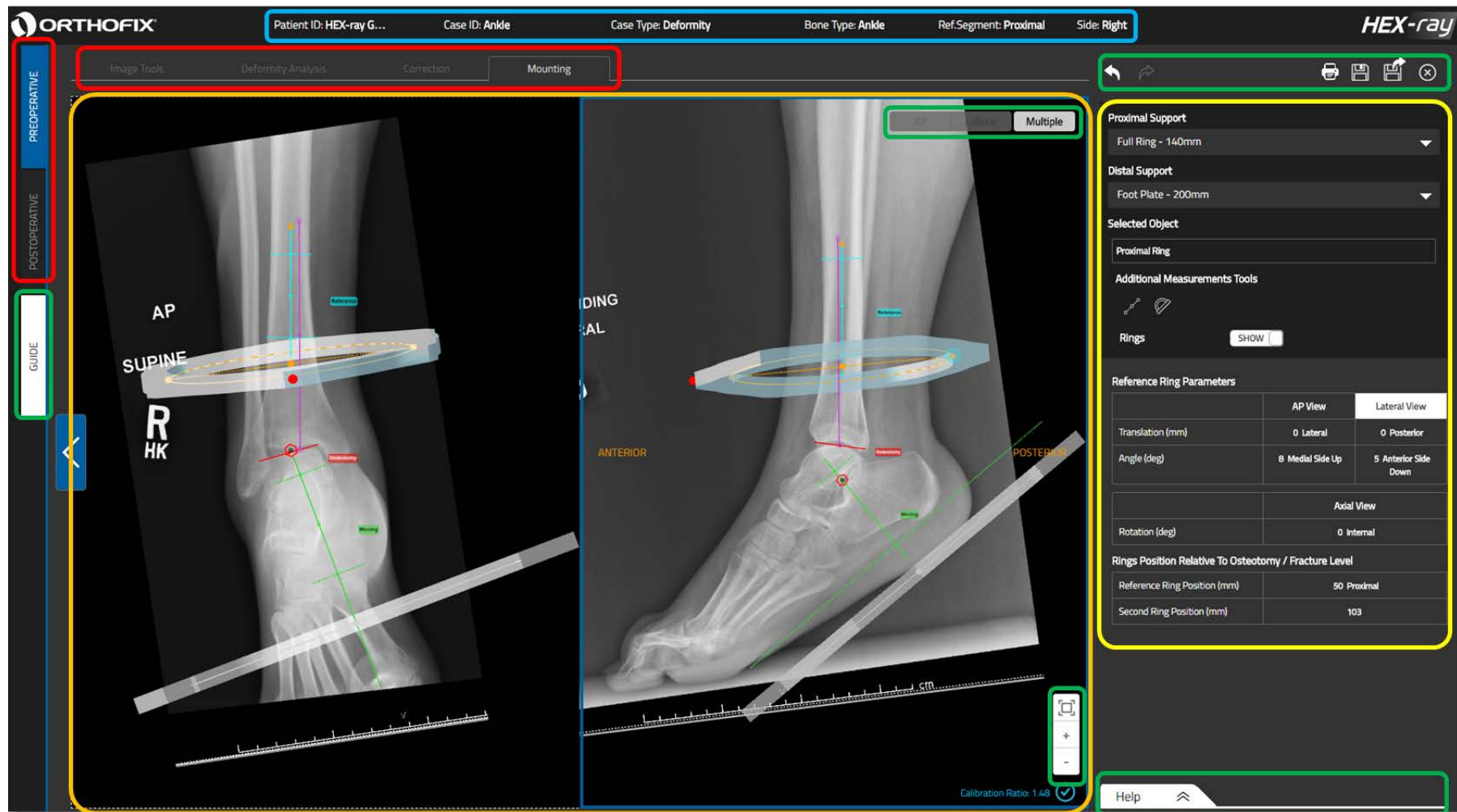
The HEX-ray tabs to manage the work flows

Work area, with the x-ray images and tools

Work area tools and calculation results

Common functions available in each tab

Relevant Case information

Work Flow tabs

HEX-ray is organized into 4 main tabs (red areas):

Image Tools	Deformity Analysis	Correction	Mounting
In this tab the user may upload x-ray images (preoperative and/or postoperative), apply basic image processing (flip, rotation, brightness, contrast and crop) and calibrate the images.	In this tab the user may assess the deformity or fracture characteristics and acquire the related parameter values to be used for the TL-HEX treatment plan calculations.	In this tab, the user may define the desired End Of Correction and acquire the related parameter values to be used for TL-HEX treatment plan calculations.	In this tab the user is provided with different options in relation to the treatment stage: Preoperative planning with TL-HEX hardware • The user may pre-plan surgery with the TL-HEX frame at a time, close to real surgical application Postoperative assessment with TL-HEX hardware • The user may acquire the TL-HEX mounting parameter values to be used for the TL-HEX Treatment plan calculations.

In accordance with the correction or trauma stage and the type of x-ray images uploaded, the tabs in the picture above permit the user to switch between Preoperative and Postoperative flow.

Below is a list of the tools that are available to use in the main working area (orange area):

Tool type / Name	Color	On screen label	On screen values
Calibration Line	Blue		
Calibration Circle	Blue		
Reference segment	Light Blue	Reference	Anatomical or user angles
Moving segment	Light Green	Moving	Anatomical or user angles
Osteotomy line	Red	Osteotomy	
Fracture line	Red	Fracture Level	
Free Line	Purple		Length value
Goniometer	Purple		Length and angle values
Crop area	Orange		

Common functions

Here below a description of the common navigation icons in the green area:

SAVE & CLOSE HEX-ray
User can save the work completed so far and return to TL-HEX.
All HEX-ray data are imported into TL-HEX.

SAVE
User can save the work completed so far.

UNDO
User can undo actions performed after data was last saved.

REDO
User can redo actions performed after data was last saved.

PRINT
User can print all data and the views of the tab.
NOTE: To prevent your summary from being cut off when you print it, print it in landscape format. See Annex B for more instructions.

CLOSE HEX-ray
User can exit from HEX-ray without saving the work.

ZOOM IN/OUT
X-ray image and tools are zoomed in or out.

FIT TO VIEW
X-ray image and tools are zoomed to fit the view.

GUIDE
Contextual guide where the user can find instructions related to the tab and case type.
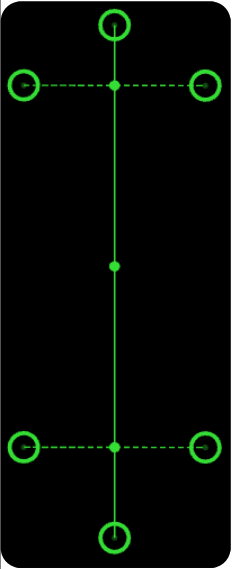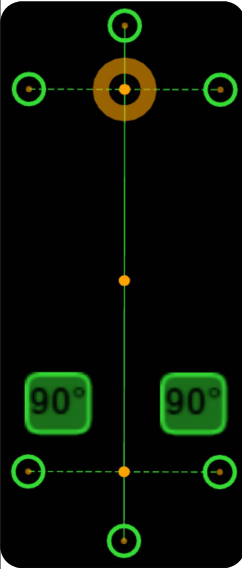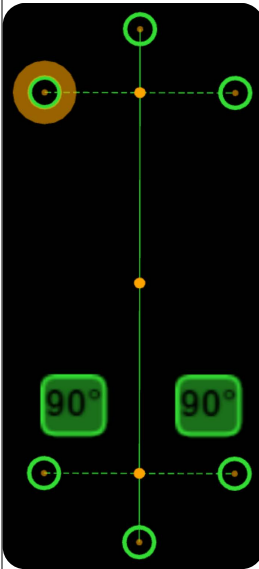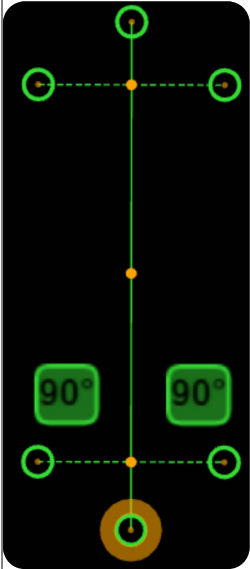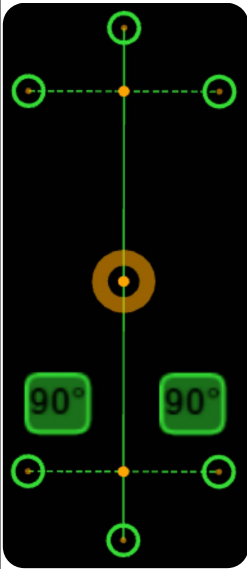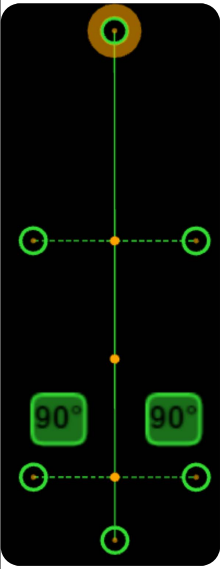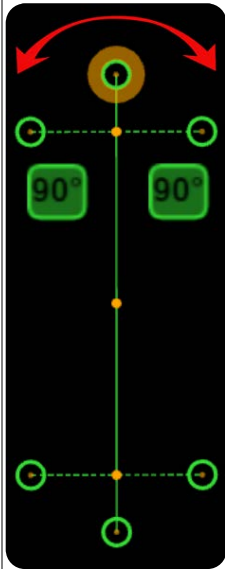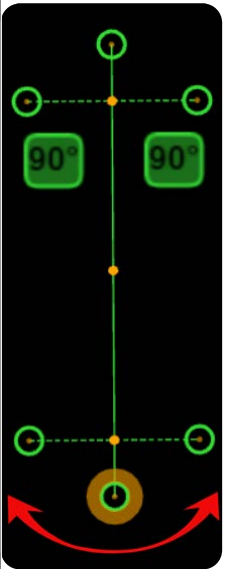
HELP
User is provided with information related to the tab and bone type being working on.

Tools interaction

The images below demonstrate tool status and how to interact with a tool. The described interaction is applicable to all available desktop tools:

Tool Not selected	Tool Selected	Tool Handle selected		Translation	Shortening / Lengthening	Rotation
The tool is visible but not selected	Clicking on the tool the handle points become orange	Hovering the mouse will highlight the handle points with an orange circle. Click on the highlighted orange area to move the handle point and the tool accordingly		The central handle translates the whole tool inside the view	The top and bottom handles change the length of the tool	The top and bottom handles rotate the tool to the opposite end

Mouse actions

Left button	Scroll button	Right button
• Click to Select a view or a tool handle • Hold to Move the tools in the view	• Rotate to Zoom In and Out 	• Click and hold to Move the image and the tools in the view

Coordinated actions

| CRTL key with mouse Left button actions

When in the Deformity Analysis tab, by holding the CRTL key and the Left mouse button, it is possible to rotate or translate simultaneously both the Axes tools, according to the selected axes tools handle. | When selecting one of the axes tools extremities handles, the tools rotate on the opposite extreme handle.
 | When selecting any handle apart from the axes tools extremities handles, the tools translate in any direction.
 |
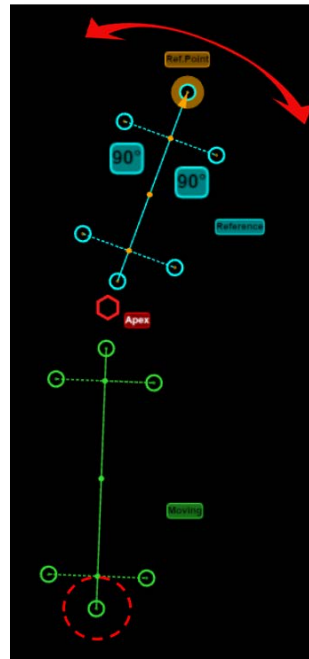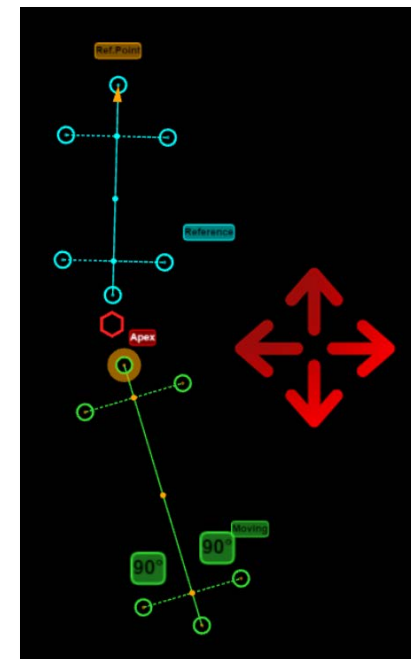
IMAGE TOOLS

Within Image Tools the HEX-ray module will enable the user to:

- Upload x-ray image
- Calibrate the uploaded image
- Apply basic processing like image crop, brightness and contrast fine tuning
- Review image orientation
- Delete or substitute an uploaded image

Image Tools:

Image loaded   **IMAGE LOADED**

User can see the uploaded image file name for reference

BROWSE FOLDER

User can browse folders to identify the x-ray image to be uploaded

DELETE IMAGE

User can delete the image in the active view

ROTATE

User can rotate the image in the active view in a desired orientation

CROP

User can crop the image in the active view for the desired size

FLIP IMAGE HORIZONTALLY

User can horizontally flip the image in the active view

FLIP IMAGE VERTICALLY

User can vertically flip the image in the active view

BRIGHTNESS

User can fine tune the brightness of the image in the active view
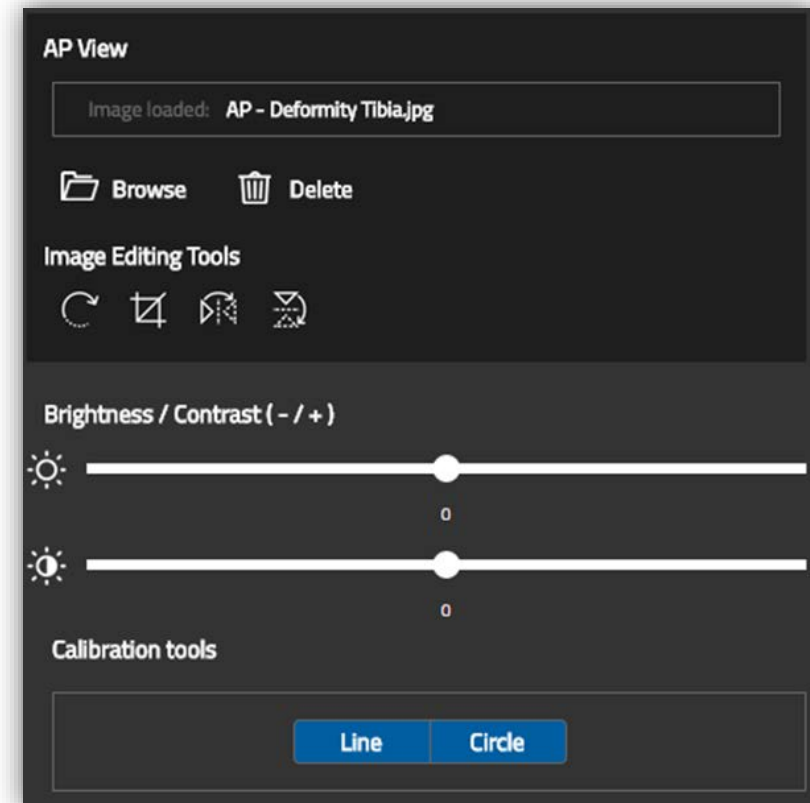
CONTRAST

User can fine tune the contrast of the image in the active view

LINE CALIBRATION

User can calibrate the image in the active view with a linear calibration tool

CIRCLE CALIBRATION

User can calibrate the image in the active view with a circular calibration tool.

Image Upload

The supported x-ray image formats are **JPG** and **PNG**, with <u>maximum file size of **5MB**</u>.
For the HEX-ray module to be effective:

- **The Reference Segment in the x-ray image must be perpendicular to the beam, in both views**
- **Orthogonal (90°) x-ray images are required**
- **Two x-ray images are required** to be uploaded and calibrated in order to activate the working flows.

X-ray images **must** <u>not contain any information that allows, directly or indirectly, the identification of a patient</u> (e.g. name, birth date, address, email-address, phone number etc.). X-ray images must be anonymized before uploading in HEX-ray.

> **❗ NOTE:** At this stage the surgeon is reminded to ensure that no patient identifiable data is uploaded by use of local anonymization tools.

When HEX-ray has been loaded in the browser, press on the [Load] button to start the image upload flow.

User is asked to confirm the x-ray image doesn't contain any personal information of the patient

HEX-ray

DO NOT UPLOAD files that contain any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.).
Please anonymize your x-ray image before uploading when using this Software.

[Accept] [Decline]
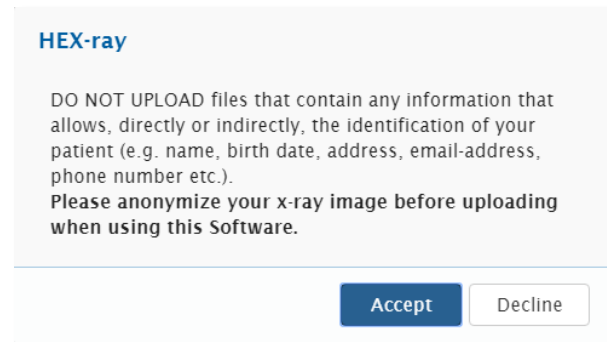
When the disclaimer had accepted, the user may declare the x-ray images treatment stage either Preoperative or Postoperative.

HEX-ray

Do you want to upload Preoperative or Postoperative x-ray images?

[Preoperative] [Postoperative]

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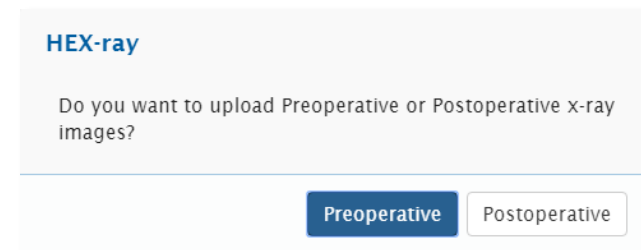
AP/Dorsal x-ray image upload

When the upload of the AP/Dorsal image has completed, the image is visible on the desktop and the **relevant anatomical labels** are shown to support the correct image orientation. In addition, the user is asked to review the proposed **orientation**.
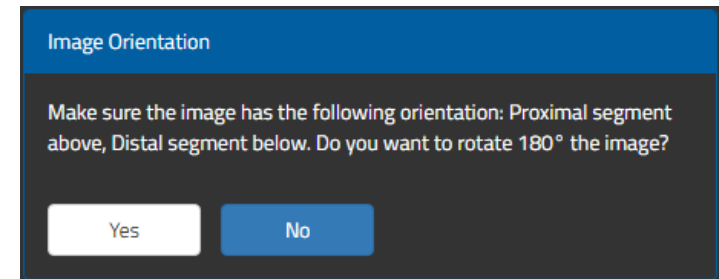
Lateral x-ray image upload

When the upload of the Lateral image has completed, the image is visible on the desktop and the relevant anatomical labels are shown to support the correct image orientation.

In addition, the user is asked to review the proposed orientation.

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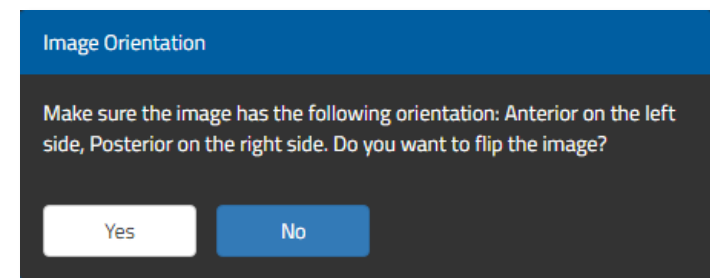
Image Orientation and Processing

It is possible to review the image orientation and characteristics any time; it is recommended anyhow to review and confirm the image orientation just after the upload because following modifications could impact the work completed in the following HEX-ray steps.

Image Orientation

Image Rotation and **Horizontal and Vertical Flip** are applicable in order to correctly orientate the image, according with Reference Segment position and on-screen desktop labels.

Horizontal and Vertical Flip buttons work directly on the image in the view, while the Rotation button starts a workflow permitting the user to review the image rotation and confirming it to complete the flow.
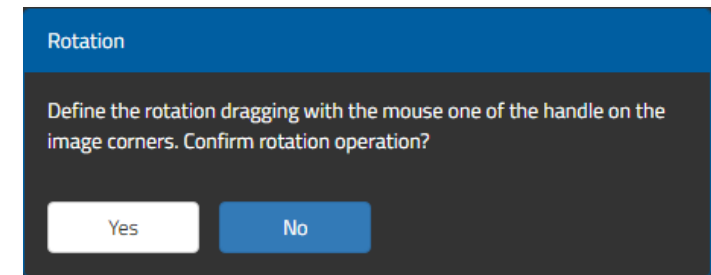
Image Processing

Image Crop and **Brightness / Contrast** review are applicable.

Brightness and Contrast controls work directly on the image in the view, while the Crop button starts a workflow permitting the user to review the image dimension and confirming it to complete the flow.
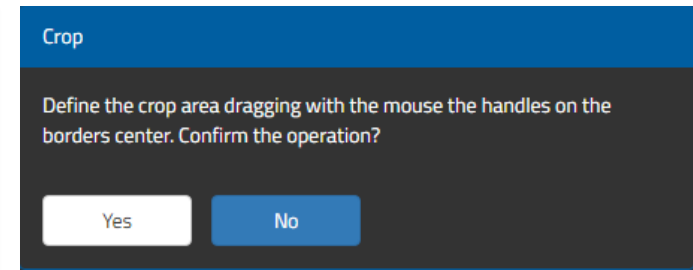
Image Calibration

X-ray image **calibration** can be performed with one of the two available tools: *line* or *circle.*
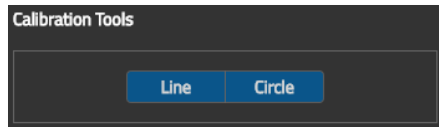
Select the preferred tool and it will appear inside the selected view

1. Position it on a object or scale marker of known dimension.

   > ⚠ **NOTE:** To improve measurement precision it is recommended to use a marker and to accurately use the calibration tool.

2. Insert the dimension value (mm) in the Insert Marker Size box
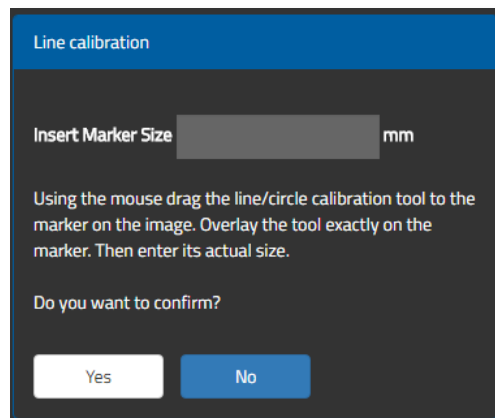
3. Confirm by pressing *Yes* when completed for calibration.

After this confirmation, all measurements will be scaled accordingly to the marker and value provided.
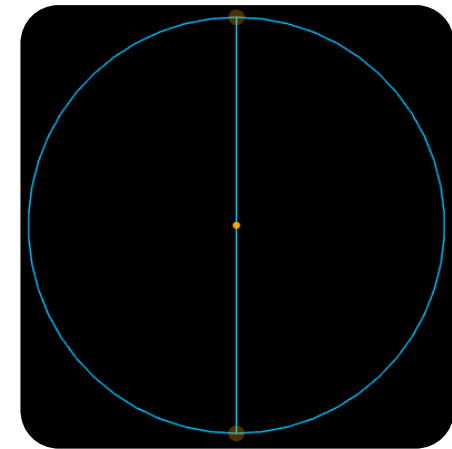
A reminder that calibration has been performed and the calibration ratio will be seen in the bottom-right corner of the view.
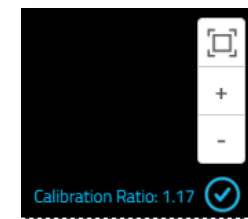
DEFORMITY ANALYSIS

There are two sets of tools depending on the Case Type selection present in the TL-HEX Case Data tab: **Deformity** or **Fracture**.
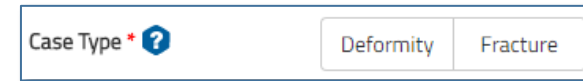
Deformity case

Within Deformity Analysis the HEX-ray module will enable the user to:

- **Position the axes tools** according to the deformity, on both views
  - ➢ The HEX-ray identifies the **Deformity APEX** in the AP/Dorsal and Lateral views and provides numerical Angular Deformity values in the table on the right
- **Insert clinical evaluation** results of the **Axial Rotation** and **Translation**
- **Define the Reference Points position** permitting consistent Osteotomy line coordination between the views in the Correction tab that follows
- Having set the reference points, **declare completion of the deformity analysis** and data entry secondary to clinical evaluation.

> ❗ **NOTE:** Any translation values inserted into TL-HEX prior to the setting of an osteotomy site will be recalculated by HEX-ray once the osteotomy site has been positioned in the Correction tab.

When considering Deformity cases HEX-ray will automatically calculate the secondary translation values resulting from the deformity apex and the osteotomy site.
HEX-ray will not provide a graphical reference of translation. On return to TL-HEX the translation values will be recorded together with a pure graphic representation of the deformity.

Deformity Analysis tools and values areas for Deformity cases:

Selected Object

Angular Deformity

Rotation

Translation

SELECTED OBJECT
When a tool in a view is selected, the Selected Object area reports the tool type

DELETE SELECTED OBJECT
When a Line or Goniometer is selected, Delete icon appears permitting to cancel the object from the active view

BONE SEGMENT AXES SHOW / HIDE
User can hide or show the axes tools anytime

LINE
A Line tool the user may use to evaluate lengths of interest. It is possible to use up to 7 tools at the same time

GONIOMETER
A Goniometer tool the user may use to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time

ANGULAR DEFORMITY
AP/Dorsal and Lateral Angular Deformity (degrees) are automatically provided by HEX-ray when the axis tools have been set in the views

REFERENCE POINT LOCKED / UNLOCKED
Locking the Reference Point declares completion of the deformity analysis and data entry secondary to clinical evaluation.

When both reference points are locked the user can access the Correction tab

AXIAL ROTATION
Axial Rotation (degree) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The rotation value is obtained by the surgeon secondary to clinical evaluation

AXIAL TRANSLATION
Axial Translation (mm) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The translation value is obtained by the surgeon secondary to clinical evaluation.

Axis tool description

The table below provides additional information about the Axis tool:

Axis Tool	The Axis tool has **9 handle points** for manipulation as described in the section Tools interaction. The *light blue* is the **Reference axis** tool to be placed on the Reference Segment and the *green* is the **Moving axis** tool to be placed on the Moving Segment. A label identifies the axis tool type (Reference or Moving). For **Femur** and **Tibia** bone types, the Axis tool is set with the typical anatomical angles of the axis with the corresponding joint line in AP and Lateral views (e.g. in the images Left Tibia Lateral anatomical angles are shown). The Axis tools may be **positioned** either by moving the solid central line or by adjusting the dashed lines to correspond with the relevant outer cortex. ⬤ **NOTE:** by pressing the CRTL key it is possible to translate or rotate simultaneously both the Axes tools	
Dashed line behaviour	Any of the six handles along the dashed lines can be selected and dragged in all directions. **Handles at the ends of the dashed lines extend or reduce the length of related dashed segment**. When placed on the cortex the angle between Axis tools will modify accordingly. The axis line automatically moves to always be in the center of the related dashed segments **Central Handle in the dashed line** translates the dashed line along the axis line.	

APEX of the Deformity	The intersection point of the bone segments axis is highlighted with a RED hexagon and the APEX label. **The APEX represents the point from which translations are calculated and corrections (angular and translational) applied**.	
Reference Point	In Correction tab the Osteotomy Line positioning is coordinated between the views. **The Reference Points should be at the same level on both views to permit consistent coordination.** The Reference Point always corresponds to the respective referencing selected at the beginning of the work flow. When completed, press on the Lock icon of the related view and the icon will change to .	**Reference Segment – Proximal** Reference Point is the TOP handle of Reference Axis tool (highlighted with the orange arrow and label in the picture)

Third column of the Reference Point row:

Reference Segment – Distal
Reference Point is the BOTTOM handle of the Reference Axis tool (highlighted with the orange arrow and label in the picture)

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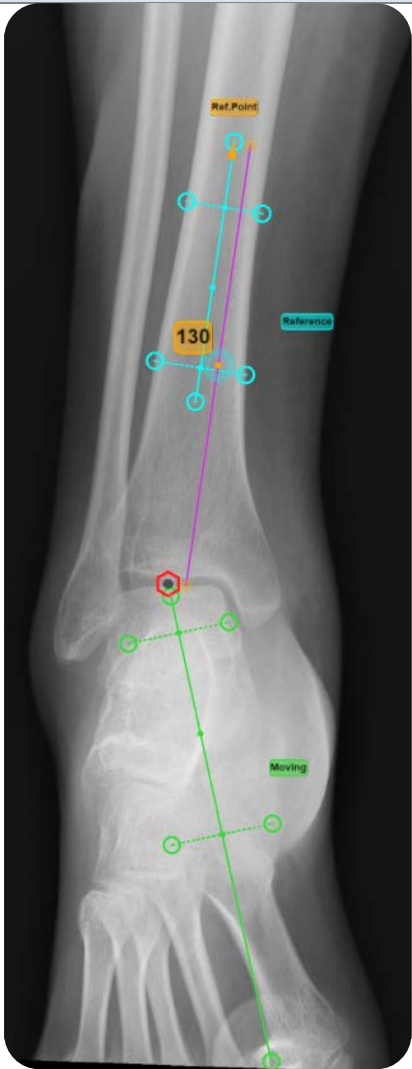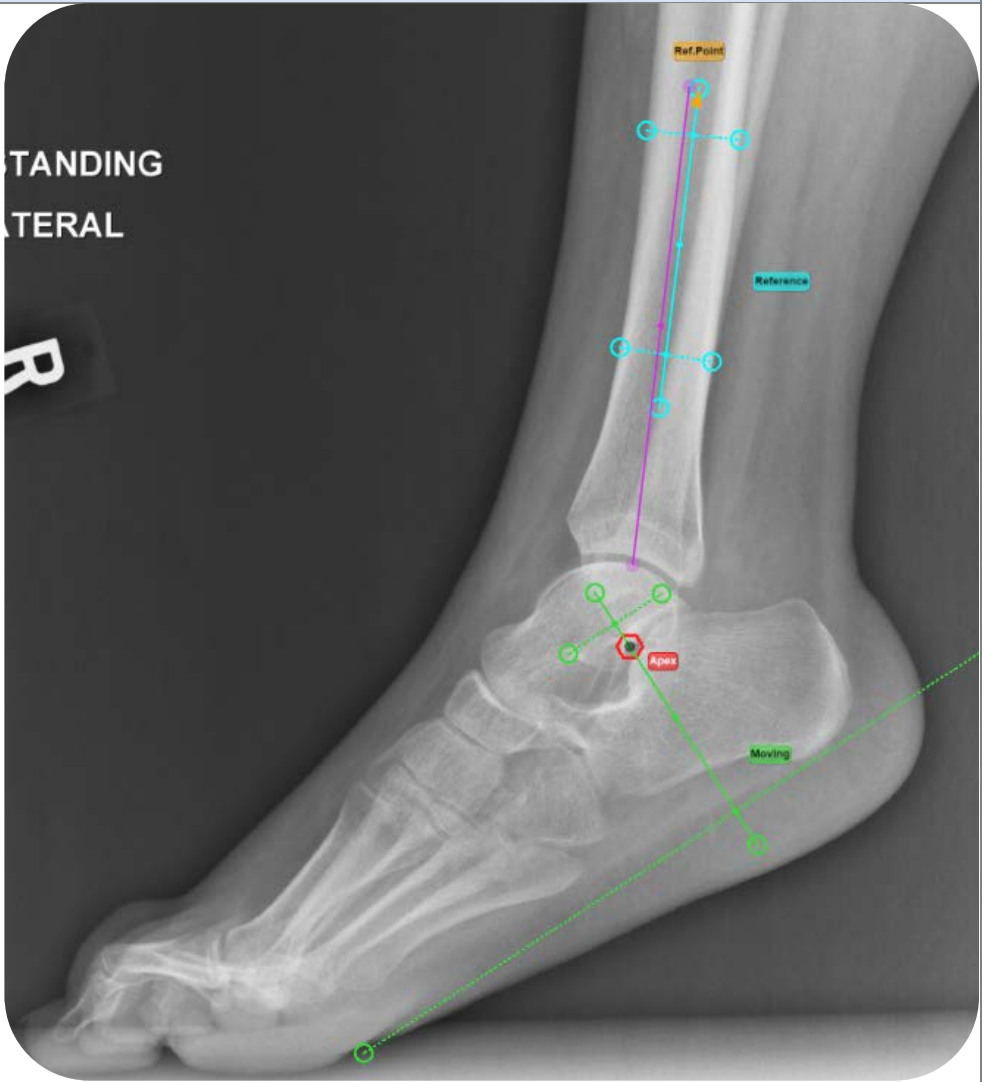
Axis tool interaction

Long Bone – Femur - Tibia
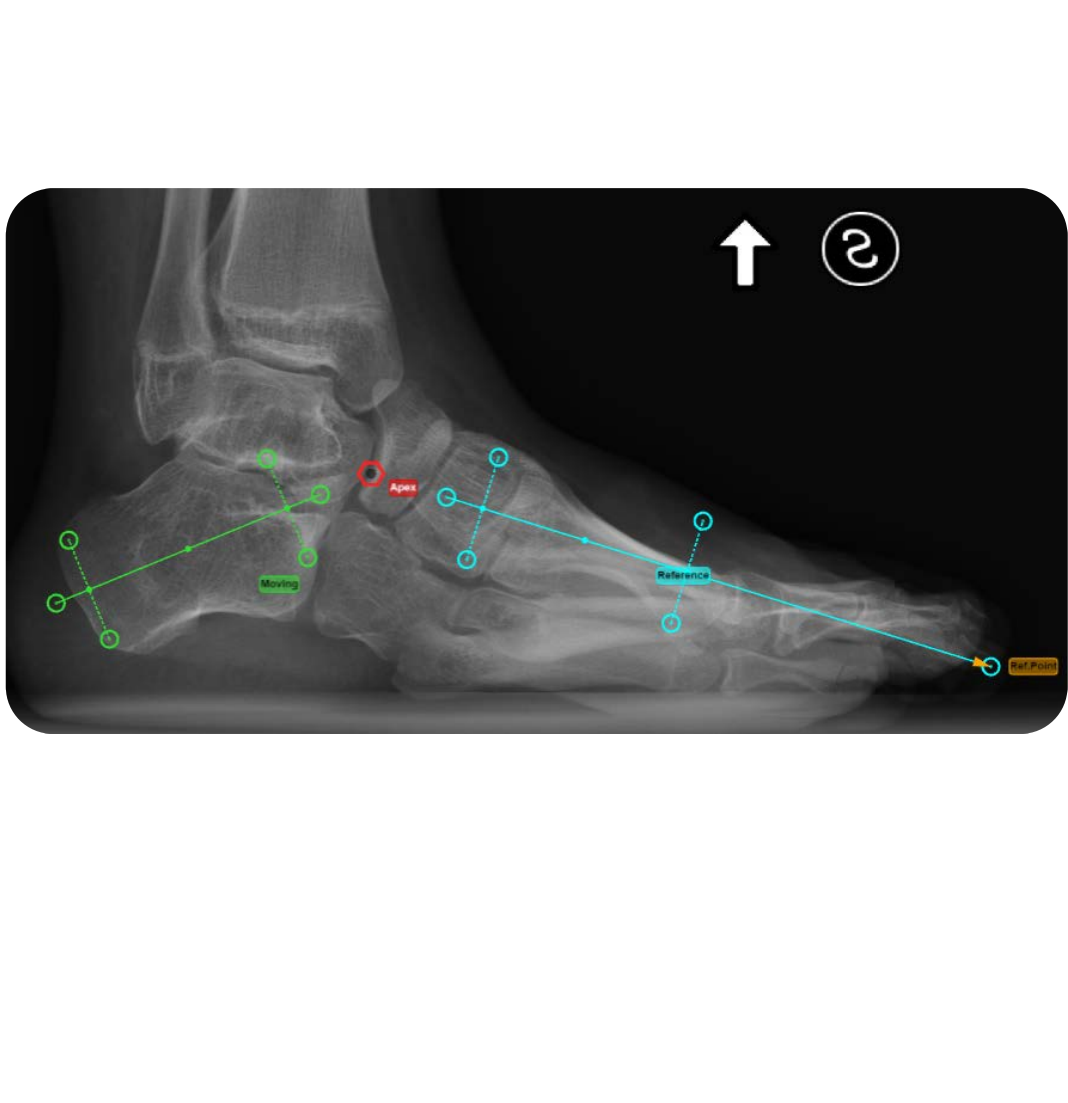
		AP View	Lateral View
Long Bone - Metaphyseal deformity	In metaphyseal deformities the Axis tool will assess the relevant joint orientation angles for the: ▪ Knee joint ▪ Ankle joint ▪ Proximal femur – mechanic and anatomic axis. In cases of metaphyseal and juxta-articular deformities, a mid-diaphyseal line can be drawn on the diaphyseal side of the APEX but not always on the articular side. Joint line referencing maybe helpful in this case. The dashed line should be placed across the relevant joint line. For Femur and Tibia bone types, the Axis tool is set with the typical Anatomical angles of the anatomical axis with the corresponding joint line to support Axis tool positioning (e.g. in the images Right Tibia Anatomical angles are shown). See images: The corresponding AP and Lateral views demonstrate how the proximal dashed line of the proximal Axis tool is placed across the tibial plateau. In this case, the axis line of the juxta-articular segment is referenced from the tibial plateau. The distal Axis tool (green) has been positioned with the extremities of the dashed lines aligned with the bone cortices.		

	AP View	Lateral View
Long Bone - Diaphyseal deformity	The Diaphyseal deformity is identified by the anatomic axes intersection. In cases of diaphyseal deformity, the anatomic axes are defined by drawing mid-diaphyseal lines with the Axis tools as shown in HEX-ray views. Please observe in the images the positioning of matched reference points on the tibial plateau in orthogonal views.	

Ankle

	AP View	Lateral View
Ankle	For Ankle cases the suggested Axis tools are described in the image. A suggested method for proximal referencing is the use of a fixed AP and lateral marker of a set length in both views from the midpoint of the articular surface of the talus proximally. It should be in line with the reference Axis tool and is represented in the adjacent diagrams in purple.		

Foot

	DORSAL View	Lateral View
Foot	For Foot cases the suggested Axis tools are described in the image. Please observe in the images the positioning of matched reference points in orthogonal views.		

Fracture case

Within Deformity Analysis the HEX-ray module will enable the user to:

- **Position the axes tools** according to the bone fragments on both views
  - ➤ The HEX-ray provides numerical Angular Deformity and Translation values in the table on the right
- **Insert clinical evaluation** result of the **Axial Rotation**
- **Declare completion of the fracture analysis** and data entry secondary to clinical evaluation.

Deformity Analysis tools and values areas for Fracture cases:

DELETE SELECTED OBJECT

When a Line or Goniometer is selected, a Delete icon appears permitting the user to cancel the object from the active view

BONE SEGMENT AXES SHOW / HIDE

User can hide or show the axes tools anytime

AXES DOWELS SHOW / HIDE

User can show or hide representation of the TL-HEX sticks overlapped on the bone segments axes

LINE

The Line tool allows the user to evaluate lengths of interest. It is possible to use up to 7 tools at the same time

GONIOMETER

The Goniometer tool allows the user to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time

Angular Deformity

ANGULAR DEFORMITY

AP/Dorsal and Lateral Angular Deformity (degrees) are automatically provided by HEX-ray when the axis tools have been set in the views

AP/DORSAL AND LATERAL TRANSLATION

Translation

AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the axis tools have been set in the views

FRACTURE LEVELS LOCKED / UNLOCKED

Locking the Fracture Levels declares completion of the fracture analysis and data entry secondary to clinical evaluation. When both fracture levels are locked and the Reference Measure selected the user can access the Correction tab

AXIAL ROTATION

Rotation

Axial Rotation (degree) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The rotation value is obtained by the surgeon secondary to clinical evaluation.

AXIAL TRANSLATION

Axial Translation

AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the axis tools have been set in the views.
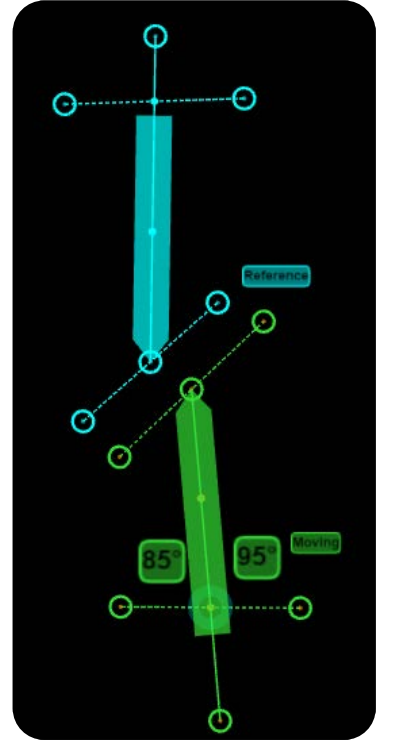
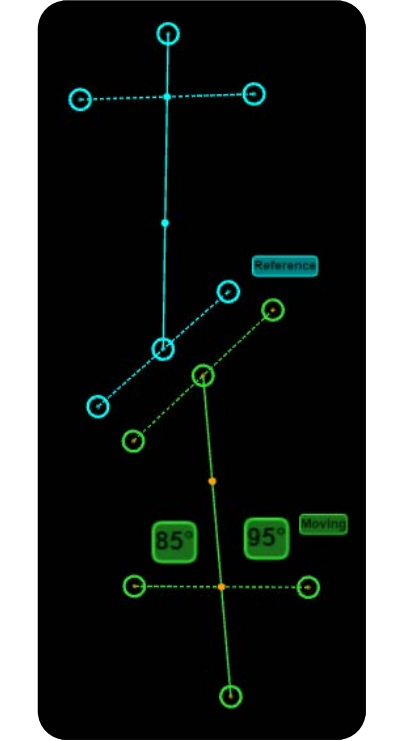### REFERENCE MEASURE FOR AXIAL TRANSLATION
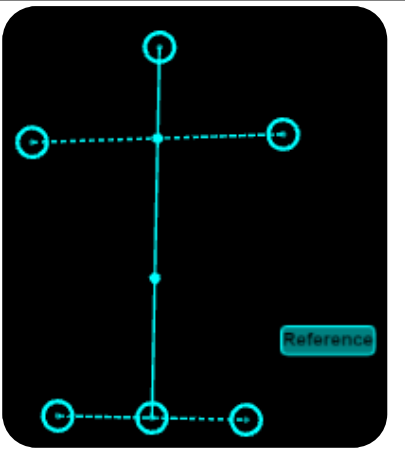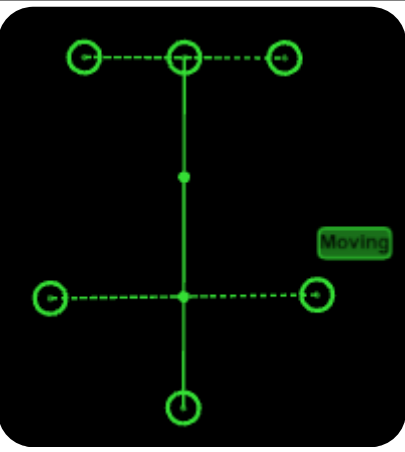
Reference Measure

User must select the reference measure/view for Axial Translation value to be considered

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Axis tool description

Fracture Axis tool	For a Fracture case the axis tools have been modified in order to permit using the **bottom (for proximal) and top (for distal) by the use of dashed lines to mimic the ends of the bone segments.** The Fracture Axis tool has **8 handle points to manage** and are fully described in the section Tools interaction.		
Axis tools Dowels	The Dowels control overlaps to each axis the related dowel describing bone fragments representation as in the TL-HEX software. **The ending point of the Dowel on the Reference axis is the point from which translations are measured and corrections (angular and translational) applied.**		

Axis tool interaction

	AP View	Lateral View
Fracture		

By positioning a dashed line across corresponding fracture ends the axis line will automatically centralize the Axis tool. With the positioning of the second dashed line at either end of the cortex as described above, HEX-ray will then calculate all the angulation and translation parameters values.

The anatomic axis is defined by drawing mid-diaphyseal lines.

In reference to the supplied screen grab, the top dashed line of the Reference axis tool mimics the distal part of the fracture, where the bottom dashed line of the Moving axis tool mimics the proximal part of the fracture.

Line and Goniometer tools

Within the Deformity Analysis, Correction and Mounting tabs the Line and Goniometer tools are available.

The **Line** provides the length (mm) measurement while the **Goniometer** provides both angle (degrees) and length (mm) measurements.
These tools can be used freely and as required in each view.

> 🛈 **NOTE:** Use of the tools will not affect the definitive case analyses performed on HEX-ray.

The Line and Goniometer tools have three handles to translate, rotate and shrink/enlarge the tool.
It is possible to insert multiple (up to a maximum of seven) lines and goniometers.

To **delete a line or goniometer** select the tool and press on the Delete icon
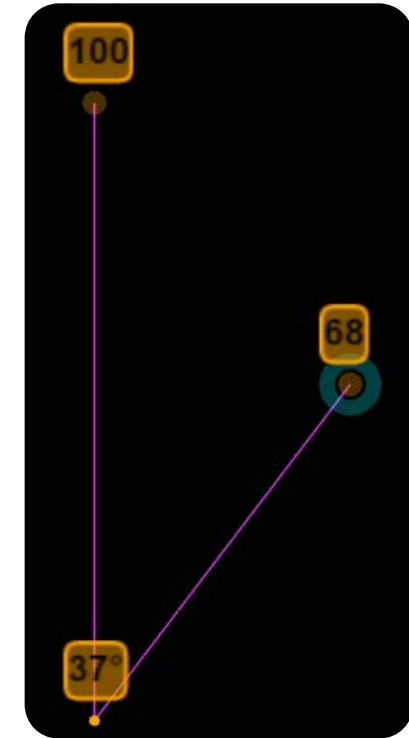
CORRECTION

Deformity Case

Within Correction analysis the HEX-ray module will enable the user to:

- **Position the Osteotomy line** on both views
  - ➢ When considering Deformity cases HEX-ray **will automatically calculate the secondary translation values resulting from the deformity apex and the osteotomy site.**
- **Insert the Axial Rotation** after clinical evaluation
- **Apply the Suggested Bone Length** calculated to avoid bone fragments impingement
- **Fine tune the Bone Length** to the desired value
- **Review and fine tune** the proposed Correction to **the desired End Of Correction**
- **Declare completion** of the correction analysis and data entry secondary to clinical evaluation.

Fracture Case

Within Correction analysis the HEX-ray module will enable the user to:

- **Insert the Axial Rotation** after clinical evaluation
- **Fine tune the Bone Length** to the desired value
- **Review and fine tune** the proposed Correction to **the desired End Of Correction**
- **Declare completion** of the correction analysis and data entry secondary to clinical evaluation.
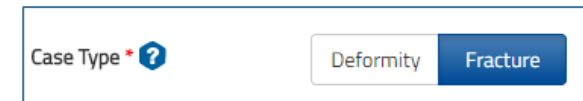
Correction Analysis tools and values areas:

DELETE SELECTED OBJECT

When a Line or Goniometer is selected, Delete icon appears permitting to cancel the object from the active view

OSTEOTOMY LINE SHOW / HIDE

User can hide or show the osteotomy line anytime. Available only for Deformity cases.

AXES DOWELS SHOW / HIDE

User can show or hide representation of the TL-HEX sticks overlapped on the bone segments axes

LINE

A Line tool the user may use to evaluate lengths of interest. It is possible to use up to 7 tools at the same time.

GONIOMETER

A Goniometer tool the user may use to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time.

CORRECTION ANALYSIS ON / OFF

User can assess and fine tune the desired End of Correction.

RESET CORRECTION

User can reset the moving area position to the last saved values

Angular Deformity

ANGULAR DEFORMITY

AP/Dorsal and Lateral Angular Deformity (degrees) are provided by HEX-ray in the Deformity Analysis and reported here for reference.

AP/DORSAL AND LATERAL TRANSLATION

Deformity Case: AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the Osteotomy tool has been positioned in the views.

Translation

Fracture Case: AP/Dorsal and Lateral Translation (mm) are provided by HEX-ray in the Deformity Analysis and reported here for reference.

AXIAL ROTATION

Rotation   Axial Rotation (degree) is defined in the Deformity Analysis and reported here for reference.

AXIAL TRANSLATION

Translation   Axial Translation (mm) is defined in the Deformity Analysis and reported here for reference.

Selected Object

Line_7	🗑 Delete
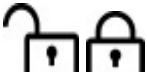
Dowels	HIDE
Osteotomy Line	SHOW

Additional Measurements Tools

Deformity Parameters

	AP View	Lateral View
Angular Deformity (deg)	21 Varus	40 Equinus
Translation (mm)	1 Lateral	20 Anterior

	Axial View
Rotation (deg)	0 External
Translation (mm)	0 Short

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Over Angulation

OVER ANGULATION

AP/Dorsal and Lateral Over Angular (degrees) are 0 by default (Lateral is 37° for Foot cases) and are automatically provided by HEX-ray when the desired End of Correction has been fine-tuned

Over Translation

OVER TRANSLATION

AP/Dorsal and Lateral Over Translation (mm) are 0 by default and are automatically provided by HEX-ray when the desired End of Correction has been fine-tuned

Rotation

AXIAL ROTATION

Axial Rotation (degree) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The rotation value is obtained by the surgeon secondary to clinical evaluation

Suggested Bone Length

SUGGESTED BONE LENGTH (Deformity Cases only)

After the Osteotomy line has been positioned, the suggested Bone Length is automatically provided by HEX-ray to avoid bone segment impingement during treatment

SUGGESTED BONE LENGTH COPY (Deformity Cases only)

The automatically provided Suggested Bone Length value may be copied by the user into the Bone Length field

Bone Length

BONE LENGTH

Bone Length to be used in the TL-HEX treatment calculation

BONE LENGTH LOCKED / UNLOCKED

Locking the Bone Length declares completion of the correction analysis. After locking the user will gain access to the Mounting tab.

End of Correction Parameters		
	AP View	**Lateral View**
Over Angulation (deg)	0 Varus	0 Equinus
Over Translation (mm)	0 Lateral	0 Posterior

	Axial View
Rotation (deg)	0 ● External ● Internal
Suggested Bone Length (mm)	7 Lengthening
Bone Length (mm)	10 ● Shortening ● Lengthening

Deformity case interaction

The Osteotomy line should be positioned as desired, paying attention to match the bone cortexes, permitting HEX-ray to suggest the axial bone length to avoid segments impingement during treatment.

Any alteration of the Osteotomy position in one view will result in a coordinated move in the orthogonal plane in accordance with the Reference Points set in the Deformity Analysis tab.

The **axial bone length suggested by HEX-ray** to avoid segments impingement during treatment considers the following:

- Angular Deformity
- Osteotomy length, inclination angle, distance from the APEX
- Default EoC position

The suggested bone length value is calculated based on both AP/Dorsal and Lateral views and the highest value is shown.
If the Osteotomy is not perfectly perpendicular to the bone axis, this value might be overestimated.

> **NOTE:** It is recommended to review the value with the End of Correction analysis before continuing.

When the Osteotomy line has been positioned as desired in both views, it is possible to *copy the Suggested Bone Length* value found inside the Bone Length field any time by clicking on the icon. The Bone Length may be manually fine-tuned.

If the Correction Analysis has been completed (see Correction Analysis) and Axial Rotation has been clinically evaluated and entered, clicking on the icon will declare activity completion and permit HEX-ray to move forward in the flow (blue arrow).
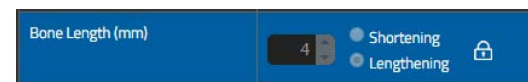
Fracture case interaction
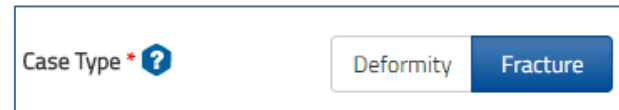
The **Fracture Level line (red)** is positioned on the Moving Axis tool as shown in the screen grab.

If the Correction Analysis has been completed (see Correction Analysis) and Axial Rotation has been clinically evaluated and entered, clicking on the icon will declare activity completion and permit HEX-ray to move forward in the flow (blue arrow).
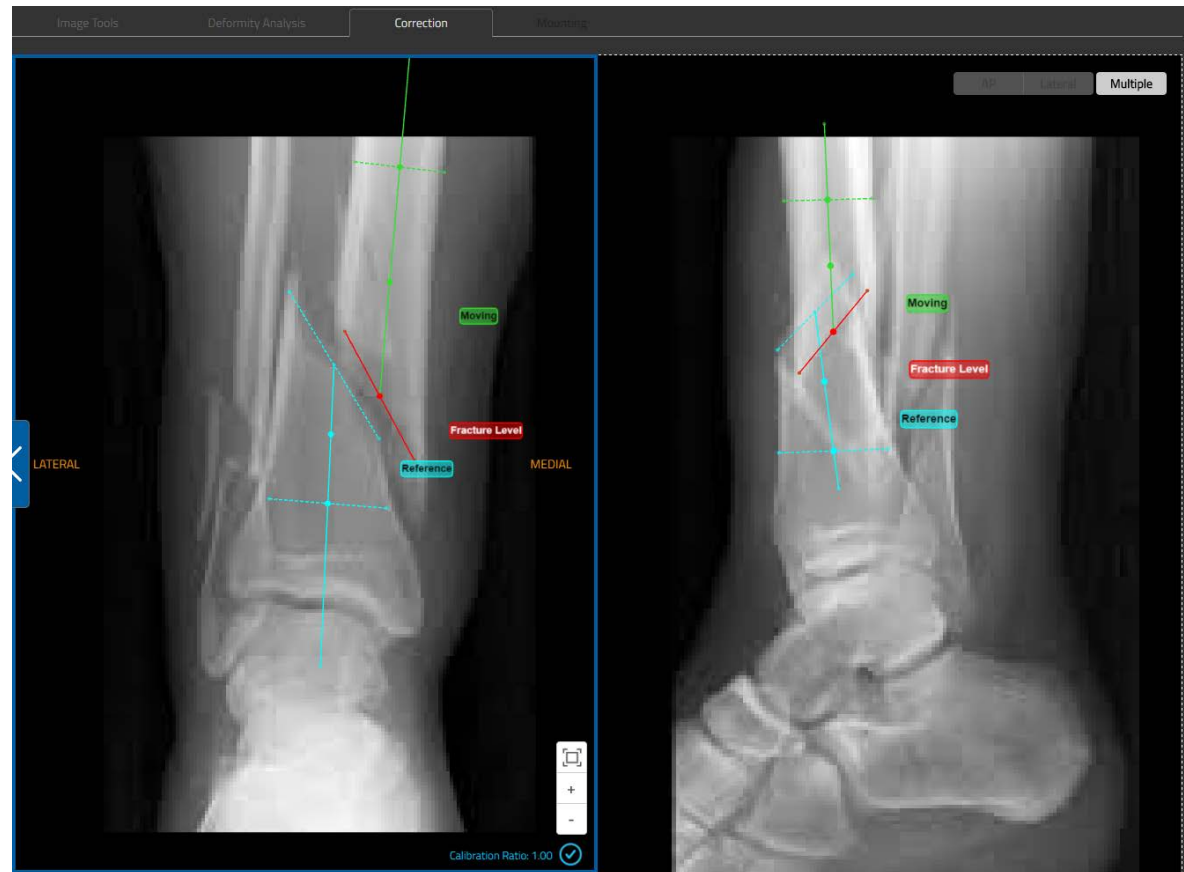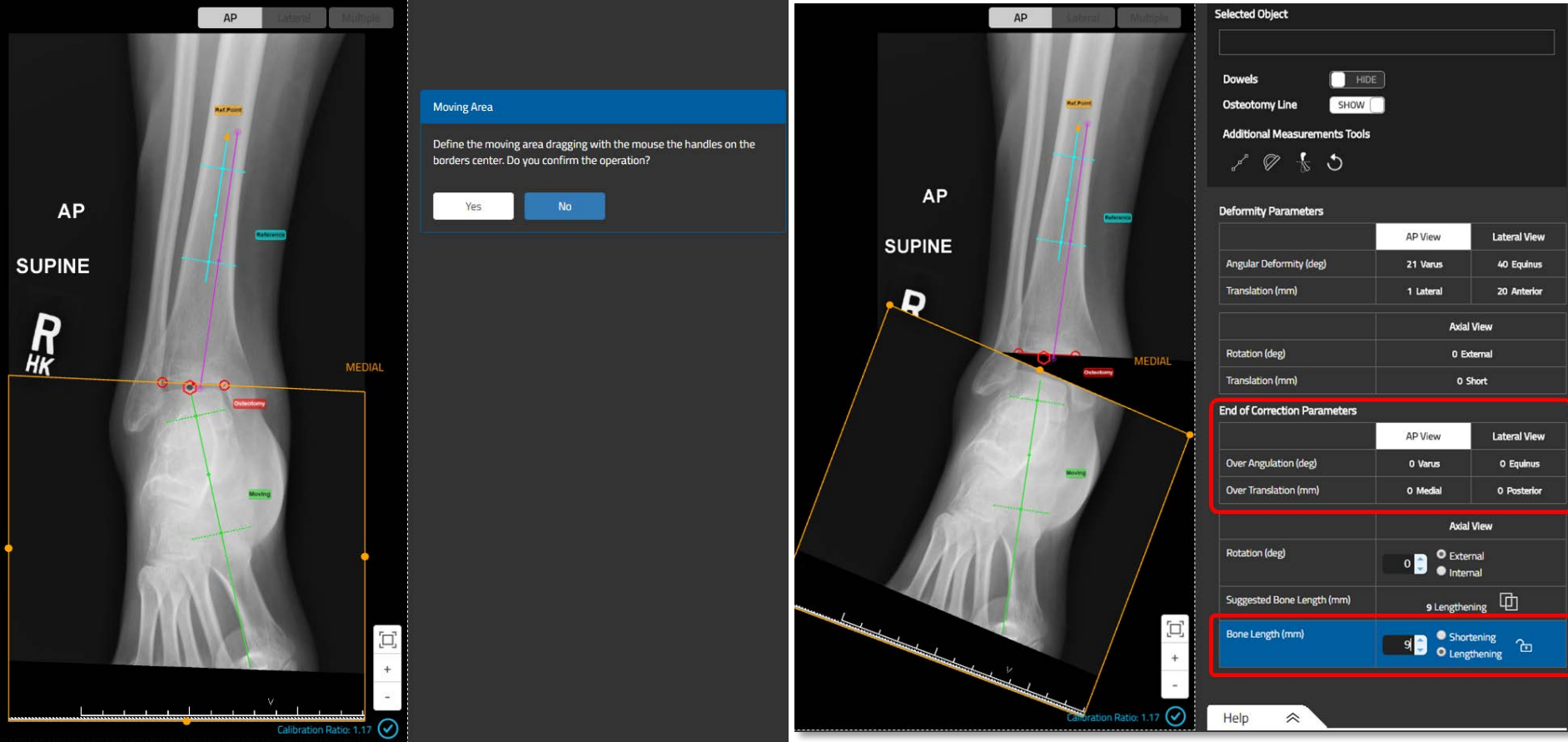
Correction Analysis

Hex-ray provides **the option to visualize and review the End Of Correction** in each view by pressing on [icon] ; it is possible to work also in Multiple views.

The first step is to <u>define the moving area</u> of the x-ray image. HEX-ray proposes an area with one border parallel to the Osteotomy line and the remaining borders coincident with those of the x-ray image. <u>Confirm the moving area</u> by clicking Yes on the related button.
<u>After confirmation, HEX-ray will automatically apply in the selected view the translation and angulation required to achieve the End of Correction and Bone Length</u> (parameters in the red boxes in the image below).

Using the handles of the moving area closest to the osteotomy site (yellow border), it is possible to manually adjust the End Of Correction. The **corresponding angulation and translations values are updated accordingly** in the related fields (red highlighted fields).
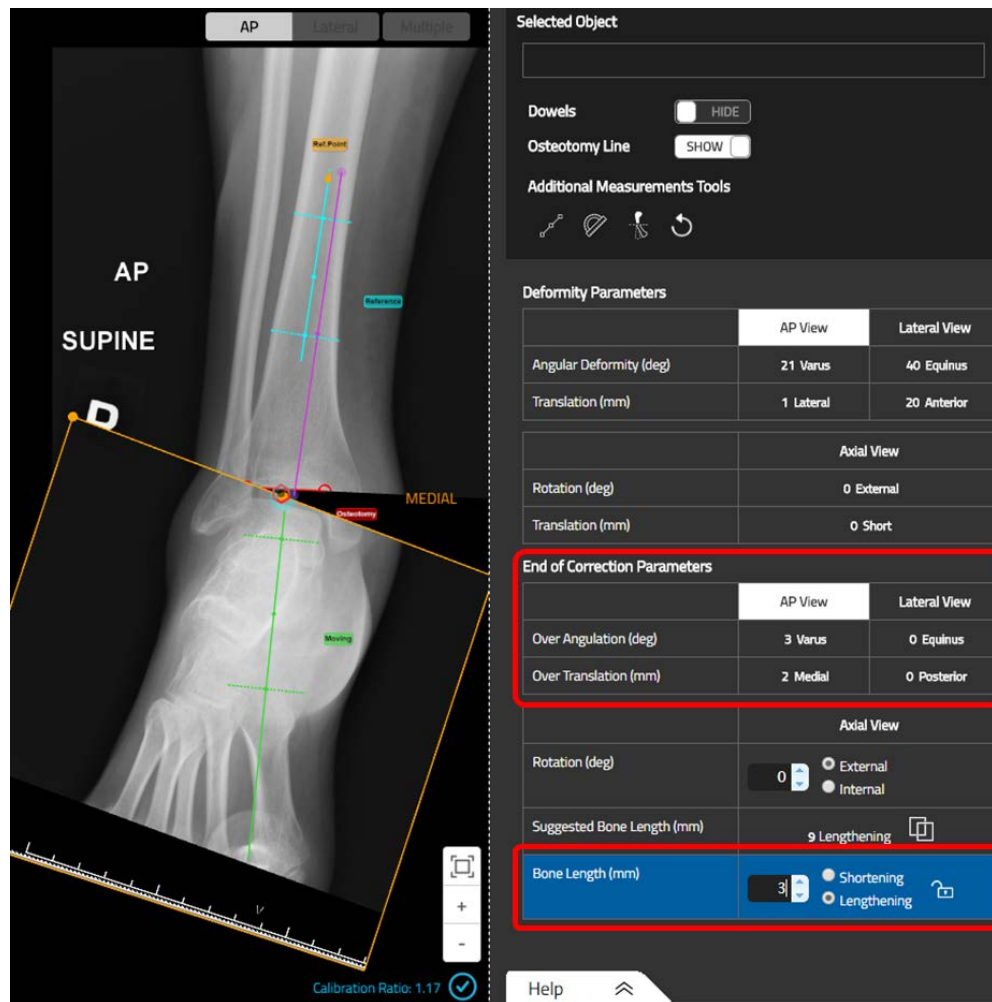
When the desired End of Correction has been set in both views, click on the icon to declare activity completion and permit HEX-ray to move forward in the flow (blue arrow).
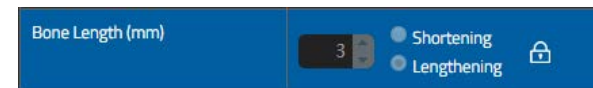
> **NOTE:** The End Of Correction analysis is active only when the lock icon is unlocked ( ).

Correction review reset

Any time during the End Of Correction review, pressing the icon, will **reset the moving area position to the last saved values**.

MOUNTING

Preoperative Planning

Within Mounting in Preoperative Planning the HEX-ray module will enable the user to:

- **Select Proximal and Distal supports**
- **Position the** Proximal and Distal **supports** along the relative axis
  - ➢ The HEX-ray provides the appropriate support position relative to the Osteotomy / Fracture Level
- **Angulate and / or Translate the Reference Ring** (blue) at the desired value
  - ➢ The HEX-ray provides the support Angle and/or Translation values relative to the Reference axis.

Mounting tools and value areas for Preoperative Planning:

Selected Object

SELECTED OBJECT

When a tool in a view is selected, the Selected Object area reports the tool type

DELETE SELECTED OBJECT

When a Line or Goniometer is selected, Delete icon appears permitting to cancel the object from the active view

Proximal and Distal Support

PROXIMAL AND DISTAL SUPPORT

User can select the TL-HEX proximal and distal supports as required

RINGS SHOW / HIDE

User can hide or show the supports 3D model at anytime

LINE

A Line tool the user may use to evaluate lengths of interest. It is possible to use up to 7 tools at the same time

GONIOMETER

A Goniometer tool the user may use to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time

Translation

REFERENCE RING TRANSLATION

Reference Ring Translation (mm) is automatically provided by HEX-ray relative to the Reference axis

Angle

REFERENCE RING ANGLE

Reference Ring Angle (deg) is automatically provided by HEX-ray relative to the Reference axis

Rotation

REFERENCE RING ROTATION

Reference Ring Rotation (deg) is automatically provided by HEX-ray relative to the selected supports

Reference Ring Position

REFERENCE RING POSITION

Reference Ring position is automatically provided by HEX-ray relative to the Osteotomy / Fracture Level

Second Ring Position

SECOND RING POSITION

Second Ring position is automatically provided by HEX-ray relative to the Osteotomy / Fracture Level

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Postoperative Assessment

Within Mounting Postoperative Assessment the HEX-ray module will enable the user to:

- **Select Proximal and Distal supports**
- **Position the Reference Ring (blue)** along the relative axis
  - ➢ The HEX-ray identifies the appropriate support position relative to the Osteotomy / Fracture Level
- **Angulate and / or translate the Reference Ring (blue)** at the desired value
  - ➢ The HEX-ray identifies the support Angle and/or Translation values relative to the Reference axis
- **Rotate the Reference Ring (blue)** at the desired value
- **Manipulate Position and Rotation of the Reference Ring with uncoordinated views** (in situations where there is a mismatch between the ring model and acquired xrays secondary that do not match the xray requirements)
  - ➢ The HEX-ray uses the value from the selected view.

Mounting tools and value areas for Postoperative Assessment:

|	
Proximal Support	**PROXIMAL SUPPORT** User can select the TL-HEX proximal support
Distal Support	**DISTAL SUPPORT** User can select the TL-HEX distal support
SHOW / HIDE	**RINGS SHOW / HIDE** User can hide or show the 3D model supports at anytime
ON / OFF	**SYNC RINGS ON / OFF** User can un-sync or re-sync the Reference Ring and its coordinated values at anytime
Translation	**REFERENCE RING TRANSLATION** Reference Ring Translation (mm) is automatically provided by HEX-ray relative to the Reference axis
Angle	**REFERENCE RING ANGLE** Reference Ring Angle (deg) is automatically provided by HEX-ray relative to the Reference axis

REFERENCE RING ROTATION

Rotation — Reference Ring Rotation (deg) is automatically provided by HEX-ray relative to the selected supports and the user may manually fine-tune

REFERENCE RING POSITION

Reference Ring Position — Reference Ring position is automatically provided by HEX-ray relative to the Osteotomy / Fracture Level

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General interaction

Any movement of The Reference Ring is coordinated across all views. For example, fine tuning the position or angulation of a support is automatically represented with a coordinated change in other view.

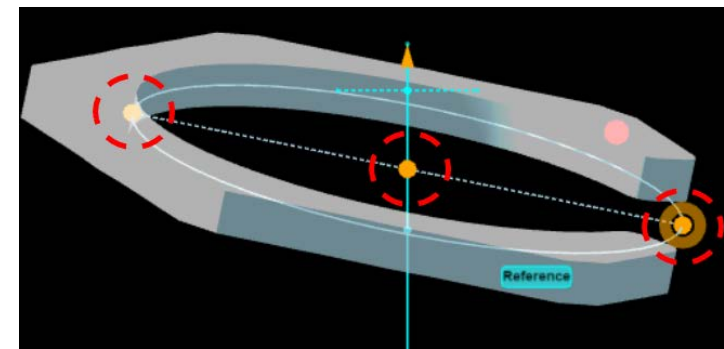HEX-ray provides a consistent frame mounting representation with TL-HEX. In particular:

1. For **Long Bone / Femur / Tibia and Ankle bone types** the Reference Segments are placed parallel to each other in both the views

2. For **Forefoot and Hindfoot** the Reference Segment is placed orthogonal to each other.
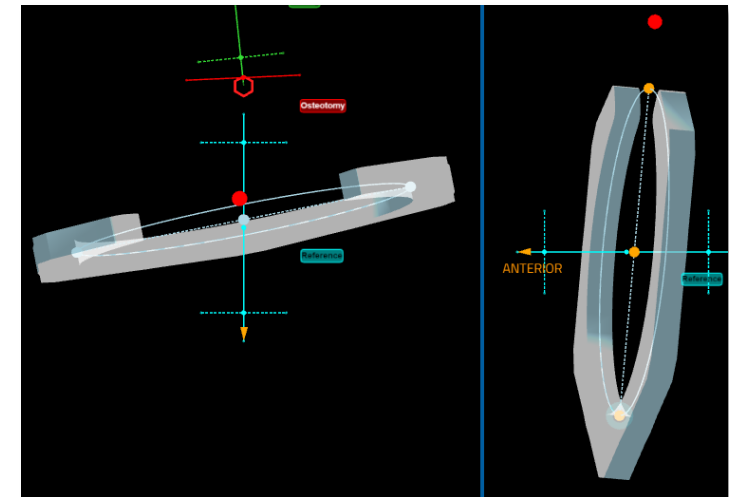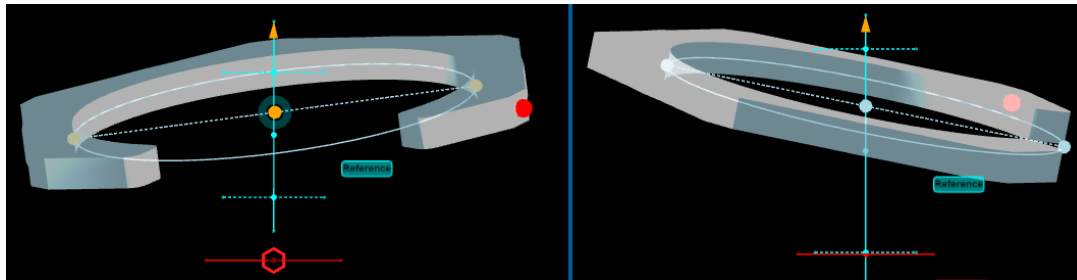
The support 3D model handles are identified by orange dots.

The image shows the handle location (red dashed circles) and the Ring Orientation Tab (red dot). The supports angulation, translation and position may be changed interacting with the support model handles on the selected view.

The Ring Orientation Tab position depends on the supports configuration selected.

Preoperative Planning

HEX-ray provides a consistent frame mounting representation and rules with TL-HEX.

In addition to the General Interaction information, during the Preplanning stage both selected supports are visible, however, only the Reference Ring may be angulated and translated. In consdering any modifications to the Second Ring, only its position relative to the Osteotomy / Fracture level may be fine tuned.

Postoperative Assessment

HEX-ray provides a consistent frame mounting representation and rules with TL-HEX.

In addition to the General Interaction information, during the Postoperative stage only the selected Reference Ring is visible in the views and may be angulated, translated and rotated. The Rotation is fine tuned using the spinner on the side table (or manually inserting a value in the input field).

Since the Reference Ring movements are coordinated between the views, the task is to match the ring model to the Reference Ring on the x-ray images simultaneously in both the views.

HEX-ray provides the angulation and translations values in relation to the Reference Segment to be used for the TL-HEX treatment calculation.

When Postoperative assessment has been completed, click the icon to save and import the data in the TL-HEX software.
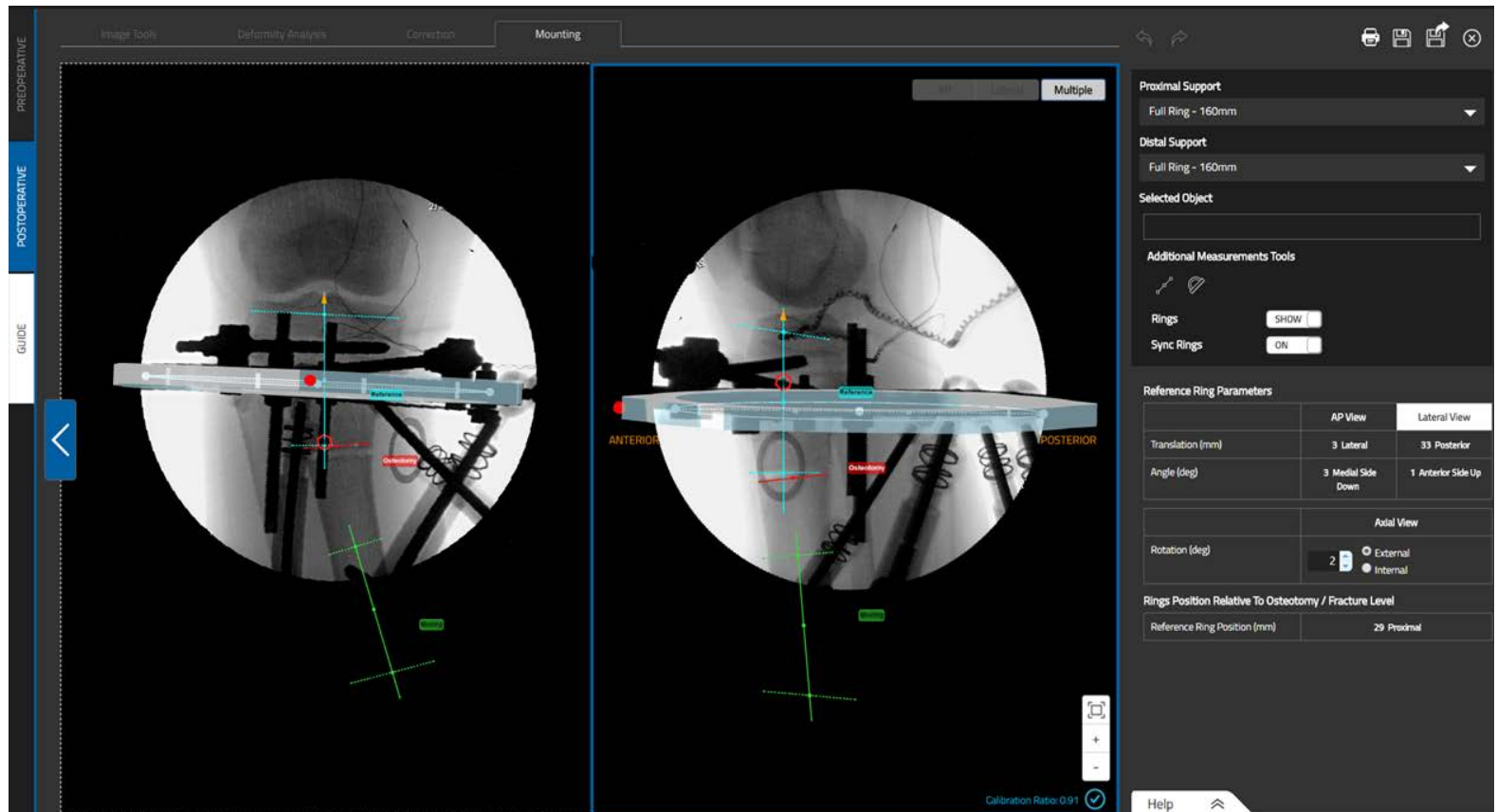
Reference Ring model not matching perfectly the actual x-ray images

X-ray images should be taken in accordance with the following instructions:

- **The Reference Segment in the x-ray image must be perpendicular to the beam, in both views**
- **Orthogonal (90°) x-ray images are required**

In case these instructions are not followed the HEX-ray Reference Ring model will not match perfectly the actual x-ray image on both views.

To overcome this situation HEX-ray allows for independent movement of the Reference Rings models between both views.

To activate this feature, **switch OFF the Sync Rings** option permitting the user to alter the desired Reference Ring position to match the actual x-ray image in either view independently.

With the icons it is possible to tilt the Reference Ring 3D model on the Coronal (Frontal) and Sagittal planes independently to better match the x-ray images.

When Reference Ring matching is completed, select from which view the Rotation and Reference Ring Position has to be taken and imported by the TL-HEX software for completion of the treatment calculation.

When Postoperative assessment has been completed, click the icon to save and import the data in the TL-HEX software.
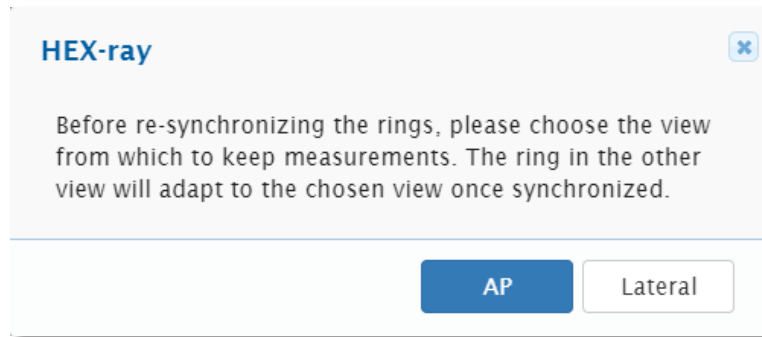

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Re-Sync the Reference Rings models

In case of uncoordinated Reference rings models, it is possible to **make them coordinated again moving the Sync Rings control to ON.** The user is asked to choose the reference view to refresh the side table accordingly. After the reference view selection, HEX-ray works as described before.

Now complete the TL-HEX Mounting Parameters by inserting the struts values

and press button.

After data saving, HEX-ray becomes available in the TL-HEX Mounting tab.
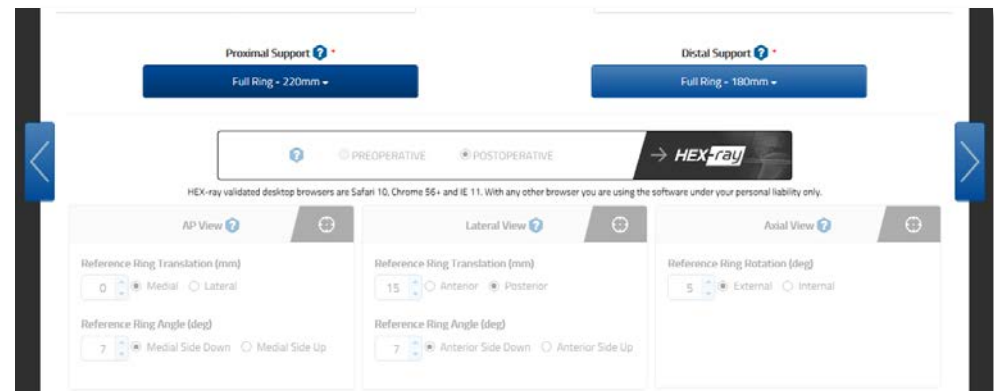
Annex A - HARDWARE ACCELERATION ON BROWSERS
SUMMARY

Hardware acceleration is a feature that lets the Browser move all graphics and text rendering from the CPU to the Graphics Processing Unit (GPU).
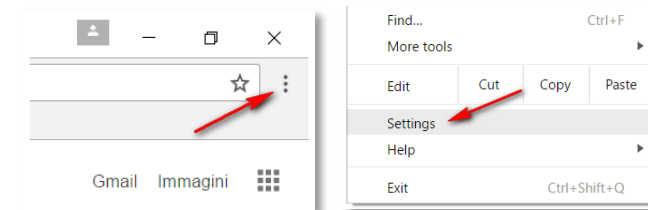
For the HEX-ray enabling the hardware acceleration will allow some functions to perform more efficiently.

CHROME® VERSION 56 - HOW TO TURN ON / OFF GPU HARDWARE ACCELERATION
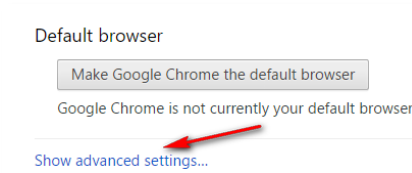
STEP 1. OPEN GOOGLE CHROME

Click the three horizontal lines icon to the far right of the address bar.
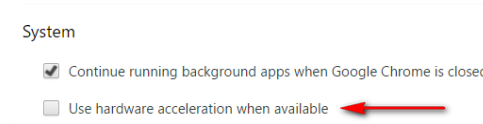
Now choose settings.

STEP 2. AT THE BOTTOM OF THE PAGE CLICK ON 'SHOW ADVANCED SETTINGS…'
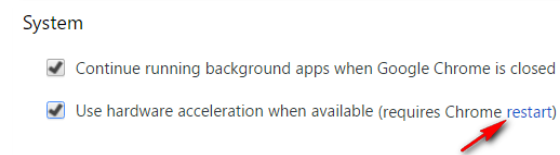
STEP 3. SCROLL DOWN THE PAGE UNTIL YOU FIND THE SYSTEM HEADING, BELOW WHICH IS AN OPTION TO 'USE HARDWARE ACCELERATION WHEN AVAILABLE'

Tick the box to turn on hardware acceleration (or remove the tick to turn it off).
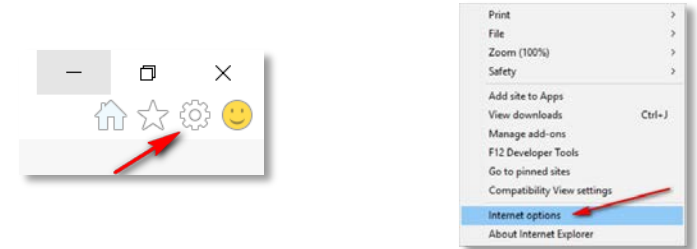
STEP 4. TAP 'RESTART' ON THE LINK TO RESTART CHROME WITH OR WITHOUT HARDWARE ACCELERATION
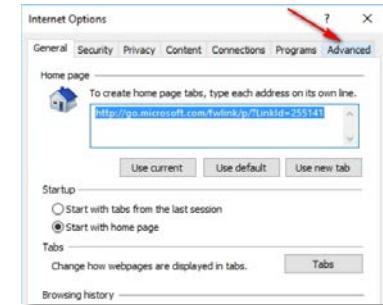
INTERNET EXPLORER® VERSION 11 - HOW TO TURN ON / OFF GPU HARDWARE ACCELERATION

STEP 1. OPEN INTERNET EXPLORER

Click on the gear icon at the top right corner of the window. And then select Internet options.
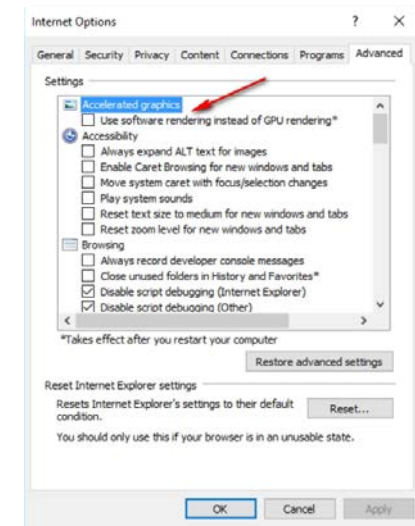
STEP 2. ON THE INTERNET OPTIONS WINDOW CLICK THE 'ADVANCED' TAB

STEP 3. SCROLL DOWN THE SETTINGS MENU UNTIL THE 'ACCELERATED GRAPHICS' HEADING, WHICH IS AN OPTION TO 'USER SOFTWARE RENDERING INSTEAD OF GPU'

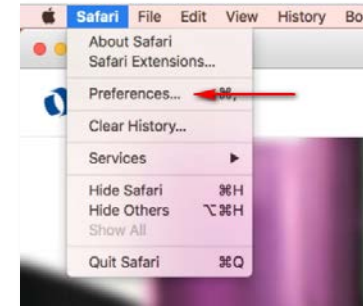Tick the box to turn off hardware acceleration (or remove the tick to turn it on).

STEP 4. CLICK OK AND RESTART YOUR COMPUTER TO HAVE INTERNET EXPLORER WITH OR WITHOUT HARDWARE ACCELERATION ACCORDING TO YOUR CHOICE
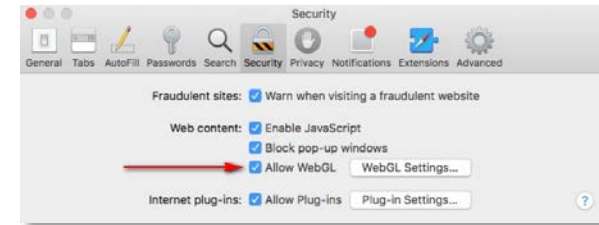
SAFARI® VERSION 10 - HOW TO TURN ON / OFF GPU HARDWARE ACCELERATION

STEP 1. OPEN SAFARI

Bring up Safari's Preferences window.

STEP 2. SELECT THE 'SECURITY' TAB AND ENABLE THE 'ALLOW WEBGL' SETTINGS

STEP 3. CLICK 'WEBGL SETTINGS…' TO SEE WHICH WEBSITES IN YOUR HISTORY USE WEBGL AND SET POLICIES FOR WEBGL

- *Ask*: When you visit the website, Safari displays a dialog asking whether you want to trust the website's use of WebGL. See If a website has WebGL graphics.
- *Block*: When you visit the website, Safari tells the website WebGL isn't supported.
- *Allow*: Safari lets the website use WebGL, unless WebGL presents a security risk on your computer.
- *Allow Always*: Safari lets the website use WebGL, even if WebGL presents a critical security risk on your computer. Choosing Allow Always may present a security risk, so only select this option for websites you trust.
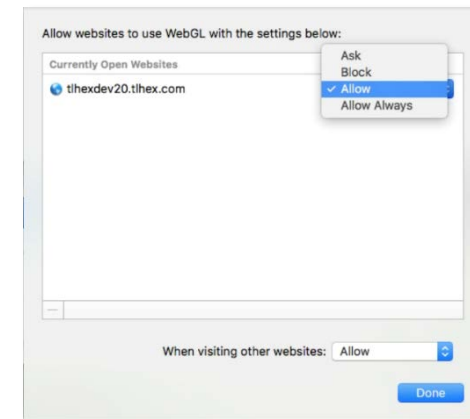
Select the *Allow* option for the HEX-Ray website, if not already done.

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MORE INFORMATION

If your current video card or video driver does not support GPU hardware acceleration, download the latest video driver that supports hardware acceleration.

To do this, you can look for a driver on the manufacturer's website. You can usually find driver updates in the support section of the website.

If you find an updated driver, follow the installation instructions on the website; most drivers are self-installing.

Annex B – LANDSCAPE PRINTING CONFIGURATION

Different printers may yield different results, and the printing dialog box may contain different options, depending upon the specific printer and browser you are using, but generally you should follow these steps:

PC Users

Internet Explorer 11
1. Click the **Gear** icon in the upper right-hand corner of the browser.
2. Click **Print > Page Setup**.
3. Under Paper Options, select "Landscape".
4. Place a check next to the "Enable Shrink-to-Fit" option.
5. Click **OK**.
6. Print your case summary

Chrome 56+ for Windows

1. Open the page, image, or file you want to print.
2. At the top right, click **More** ⋮ › **Print**… or use a keyboard shortcut: **Ctrl + p**.
3. In the window that appears, select the destination printer and change **Layout** print settings: "Horizontal".
4. When ready, click **Print**.

MAC Users

Safari
1. Click **File** > **Print**.
2. Click **Show Details**.
3. Next to Orientation, click on the second icon of a man standing sideways.
4. Click on **Print**.

Chrome 56+ for MAC

1. Open the page, image, or file you want to print.
2. At the top right, click **More** ⋮ › **Print**… or use a keyboard shortcut: ⌘ + p
3. In the window that appears, select the destination printer and change **Layout** print settings: "Horizontal".
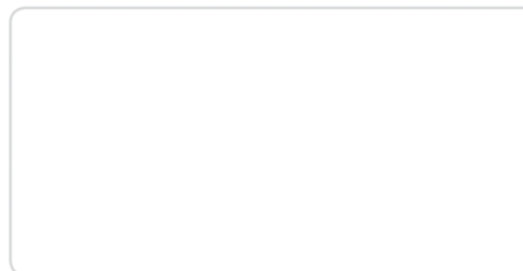4. When ready, click **Print**.

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Instructions for Use: See actual package insert for Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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