

 TraumaCad Mobile

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2.0 User Guide

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# SYMBOL GLOSSARY

Symbol	Standard Title	FDA Standard Designation Number	Symbol Title	Symbol Reference Number	Explanatory Text
	ISO 15223-1	5-134	Unique Device Identifier	5.7.10	Indicates a carrier that contains unique device identifier information
	ISO 15223-1	5-134	Manufacturer	5.1.1	Indicates the medical device manufacturer
	ISO 15223-1	5-134	Importer	5.1.8	Indicates the entity importing the medical device into the locale
	ISO 15223-1	5-134	Authorized representative in the European Community	5.1.2	Indicates the Authorized representative in the European Community.
			Swiss Authorized Representative		Indicates the Authorized representative in Switzerland
	ISO 15223-1	5-134	Consult instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use.
RX only			Prescription Use only		Caution: USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1	5-134	Medical Device	5.7.7	Indicates that the product is a medical device

## SYMBOLS

The following symbols are used throughout the documentation. Please pay particular attention when one of the following messages appears.



**A WARNING!** denotes a hazard. It calls attention to a procedure that, if not correctly performed or adhered to, could result in injury or loss of life. Do not proceed beyond a warning note until the indicated conditions are fully understood and met.



**Notes** provide pertinent information to help obtain optimum performance from the application.



**Tips** provide useful suggestions and information.

# INTRODUCTION

## WHAT IS TRAUMACAD® MOBILE?

TraumaCad Mobile is a web application assisting healthcare professionals in pre-operative planning of orthopedic surgery. The application allows surgeons to easily load and view orthopedic digital images while performing pre-operative planning. TraumaCad Mobile features full PACS integration and an extensive regularly updated library of digital templates from leading manufacturers.

TraumaCad Mobile is integrated with Qentry®, a web-based environment where the medical staff can upload and store their patient folders in a highly secured location. Doctors can manage patient folders including images, attachments and any other files into a private account and share them with their colleagues online.

TraumaCad Mobile can be accessed as an iPad® app, or via web browser on your computer (PC or Mac). The web application runs on multiple platforms and does not require installing any software. The iPad version of TraumaCad Mobile can be downloaded from the Apple App Store®.

Select the help icon within the application to view the user guide or contact TraumaCad support for any question or information.

Use of TraumaCad Mobile for planning on a tablet is not to replace planning on a workstation. Use on a tablet is only for situations when a workstation is not available.

## AUDIENCE

Intended use: The TraumaCad Mobile program is indicated for assisting healthcare professionals in pre-operative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.



Rx Only - Caution: USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Intended users: This product is intended for healthcare professionals who want to perform pre-operative surgical planning and evaluate medical images.

Intended patient population: Adult patient group.

Clinical benefits: The software helps healthcare professionals prepare in advance for orthopedic procedures, by evaluating the patient's anatomy, by considering potential outcomes, and by choosing the appropriate implants.



# SYSTEM REQUIREMENTS

## General

TraumaCad Mobile is a web application. For more information on system requirements [click here](#).

## Security Measures

TraumaCad Mobile does not store any data. All planning data is saved back to the user's selected destination. IT security measures, including protection against unauthorized access, are taken to run the software as intended:

- Login - Authentication with unique user credentials and license verification.
- Audit logs - Key actions in the system are logged.
- Data access - Authorization according to granted permissions from the selected image data source.
- Encryption - All data is encrypted.
- Save to Quentry - All user-generated data is stored on Amazon servers located in secured facilities with 24/7/365 surveillance. Quentry utilizes data centers which are ISO 27001, SOC 1/SSAE 16/ISAE 3402 (formerly SAS70), and FISMA certified and accredited.



TraumaCad Mobile can be used on internet connected computers and iPads only.

## Combination with Other Devices

TraumaCad Mobile can be used in combination with Brainlab Quentry cloud service and various PACS systems.

## SUPPORT AND CONTACT INFORMATION

If you need help using TraumaCad Mobile, please contact our technical support team. Technical support is available by live online chat, email and phone.

**Americas excl. Brazil:**

+ 1 866 717 0272

[traumacad.support@brainlab.com](mailto:traumacad.support@brainlab.com)

**Brazil:**

(0800) 892 1217

[brazil.support@brainlab.com](mailto:brazil.support@brainlab.com)

**Europe, Africa, Asia and Australia:**

+49 89 991568 1044

[traumacad.support@brainlab.com](mailto:traumacad.support@brainlab.com)

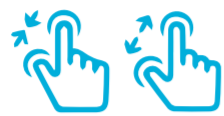
Visit [traumacad.com](http://traumacad.com) for more details or connect with a support representative online at [traumacad.com/chat](http://traumacad.com/chat) (during normal business hours).

During your support session, you may be asked to provide information about your copy of TraumaCad Mobile.

The Help menu displays the software version and access to support contact information.

For a printed copy of the User Guide, contact Support by email to [traumacad.support@brainlab.com](mailto:traumacad.support@brainlab.com).

## TOUCH SCREEN FUNCTIONALITY



Pinch and spread to zoom in or out



Drag your finger on the image to pan



Swipe up or down to scroll



Double tap to fit the image to the screen



Select an object and drag to move it around the image



Swipe 2 fingers to switch between two images



A virtual keyboard opens automatically when text typing is required

# APPLICATION AT A GLANCE

## Top Menu

Guides you through the planning process.

Note! Stepping back from Plan mode to Define Image / Patients mode will erase your planning

Show/hide hints

Help - About

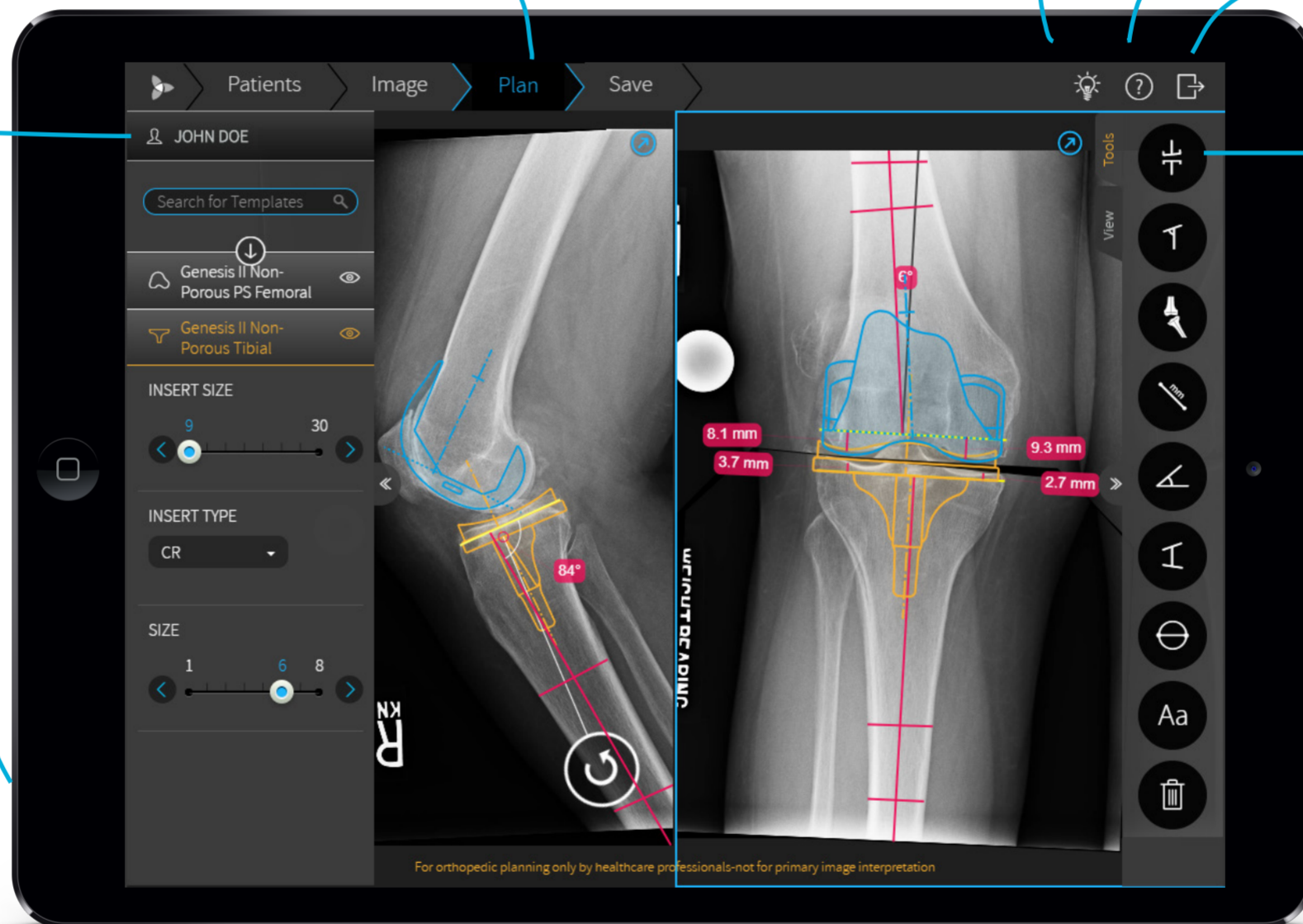
Logout

## Patient Information

Displays Patient name, ID, date of birth, gender, and study date.

## Templates Panel

Find templates, place them on the image, and adjust their properties.



## Toolbar

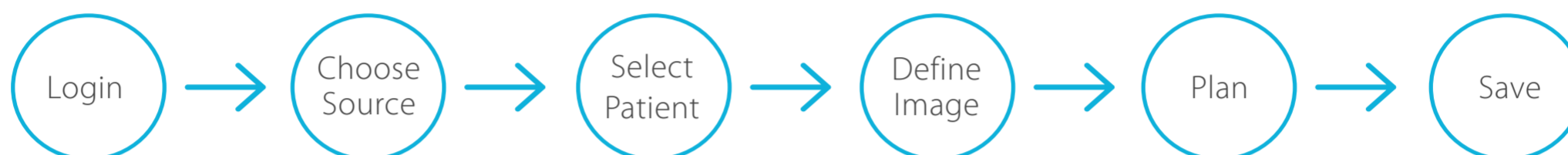
\* Measurement tools  
\* Image view tools

## Image Area

Plan the surgery, including measurements and templates

# GETTING STARTED

## TRAUMACAD MOBILE WORKFLOW



- **LOGIN** to TraumaCad Mobile using your Qentry credentials.
- **CHOOSE THE SOURCE** of your patient images: Qentry, hospital PACS, or from your device.
- **SELECT PATIENT** by searching for patient images. Select up to two images.
- **DEFINE** the images by determining the surgery procedure, treated body side, image orientation, and calibration.
- **PLAN** the surgery, insert templates and apply measurements.
- **SAVE** the planning back to your preferred destination (Qentry , PACS, iPad's Photo Gallery or a local folder) and print the planning when required.



Be sure to save the patient's case in order not to lose patient data.

## GETTING A QUENTRY ACCOUNT

To get started, login to Quentry web service is required.

If you do not have an account, you may register for a free basic account at [www.quentry.com](http://www.quentry.com).

### **To login to TraumaCad Mobile:**

Download the application from the App Store and launch it from the TraumaCad Mobile icon.

Or

if you are using the web application, go directly to the web application [URL](#).

Enter your Brainlab ID and password and click the arrow button.

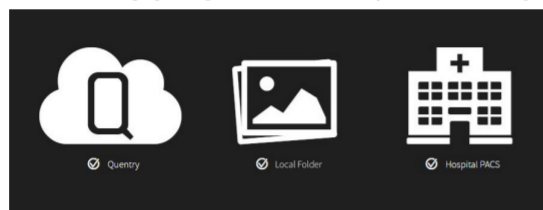


The application can be downloaded from the App Store free of charge; however it has to be provisioned with a license in order to ensure it is used by healthcare professionals.

# IMPORT IMAGES

TraumaCad Mobile is transparently integrated with the PACS and Qentry, and also allows importing images from your device, either from your iPad Photo Gallery or a local folder on the computer. To integrate with your PACS, contact your system administrator.

After logging in, select your image source.



You can always change the images source by clicking on “Back to image source” on the top left.

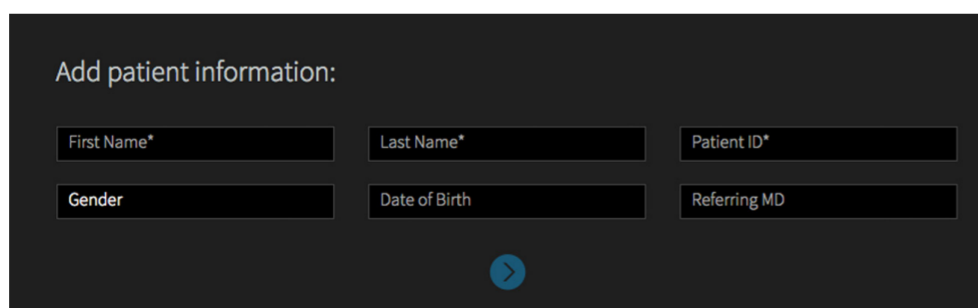
[Back to image source](#)

## UPLOAD IMAGES FROM YOUR DEVICE

To upload images from your device:



- o iPad - select one or two images from the Photo Gallery
- o PC or Mac - browse and select the images

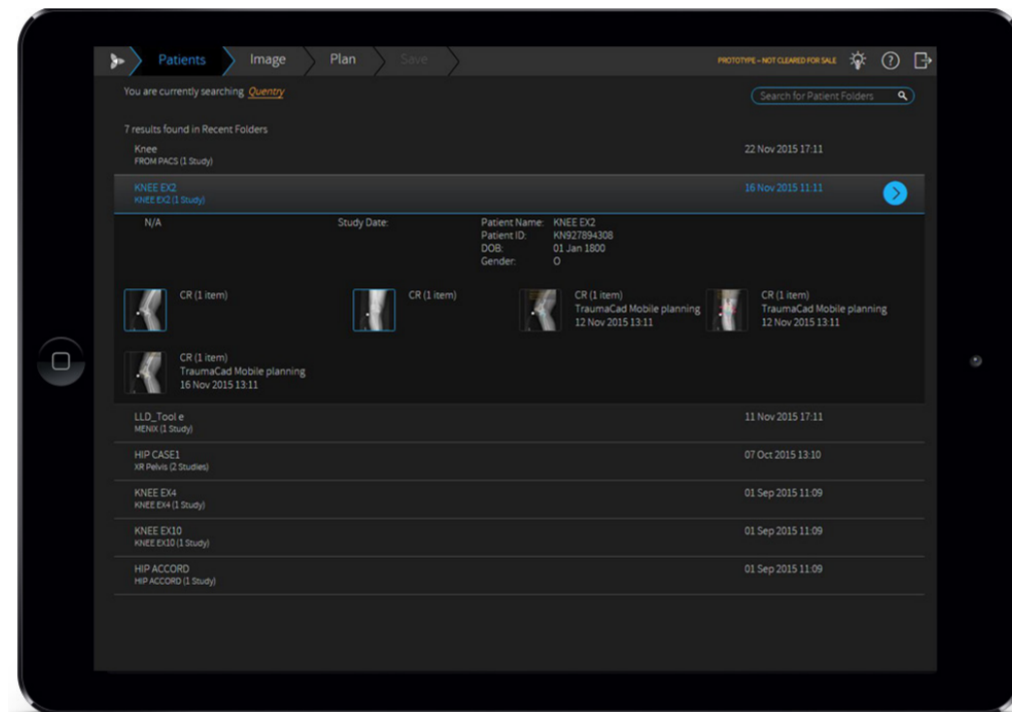
When importing images from a local folder, patient information must be filled in order to later identify the image. In case of DICOM images the patient information will be taken from the image data.

A screenshot of a dark-themed form titled 'Add patient information:'. It contains six input fields arranged in two rows. The first row has 'First Name\*', 'Last Name\*', and 'Patient ID\*'. The second row has 'Gender', 'Date of Birth', and 'Referring MD'. A blue arrow button is centered below the fields.

## SEARCH IMAGES IN QUENTRY AND PACS

In the Patients tab, you can search for images in patient folders:

1. In the **Search for Patient Folders** box, type in all or part of the Patient Name, Patient ID, or Study Description.
2. Click the search icon  to run the search.
3. The search results show the patient details such as Patient Name, Patient ID, Folder Title (for Quentry only), etc.
4. Select the requested patient study or folder to display more information and image thumbnails.
5. Select up to 2 images in the study / folder you are interested in and click the  button to open.



When selecting Quentry as the image source, a list of recently viewed images, as well as new patient folders, is displayed by default.



When importing an image from the PACS system, make sure that you import data from the correct patient and use the relevant image.



# DEFINE IMAGES

In order to perform accurate planning, image definition is mandatory.

The software attempts to automatically detect the procedure and image orientation.

Review the pre-populated fields, fill in the missing fields, and confirm all selections:

1. Select the surgery **procedure**.
2. For each image, specify image **orientation** (AP or LAT) and body side to treat (Right or Left).
3. Calibrate each image by determining the magnification factor in the X-ray. The magnification factor can be determined by including an object of known size in the plane of interest or by specifying a magnification (oversize) value (available for DICOM images only).

Select one of the following **calibration** methods:

**AUTO** Automatically attempts to find a marking device in the image. The marking device is then used to calibrate the image. Recommended devices are KingMark and VoyantMark.

When a metal ball marking device is detected, the message “Calibration ball detected” is displayed in the left panel and a circle appears on the image, indicating where the marker was found. By default, the ball size is 25.4 mm (1 inch). This size can be changed by setting a new size in the text box area.

**%** In the Oversize value field, specify a magnification ratio to scale the image from its original size.

**RULER** The Ruler method enables you to measure a known marker that appears on the image. Draw a line across the image. Drag any of the two dots to adjust the size of the ruler. Specify the length of the line in the left panel.

**CIRCLE** The Circle method enables you to measure a known marker that appears on the image. Click the image to draw a circle. Drag any of the two dots to adjust the size of the circle. Specify the diameter of the circle in the left panel.



In order to ensure correct length and angle measurements, the anatomical structures of interest need to be aligned parallel to the x-ray detector during image acquisition. Make sure to only use x-ray images which have been acquired accordingly.

IMAGE 1/2

JOHN DOE

PROCEDURE : KNEE

ORIENTATION : LAT, RIGHT

CALIBRATION : AUTO

AUTO %

RULER CIRCLE

Enter metal ball diameter

25.4

Calibration Ball is detected.  
Image oversized: 115 %

NEXT

If you chose two images, repeat the above procedure to choose orientation and calibration for the second image.



A calibration marker should be used and placed according to instructions of use during x-ray image acquisition.

4. Click **NEXT** to start planning your surgery.



# PLAN SURGERY



In the Plan tab, you can start planning your surgery: Insert templates, determine sizing, perform measurements, and visualize surgery results.

TraumaCad Mobile offers some automatic features for THR and TKR planning, where the application attempts to automatically detect the anatomical regions in the image, evaluate measurements, position templates, and create fragmentations for image manipulation such as hip reduction and knee alignment.

In case the image is not automatically detected, you can always continue planning manually.

For shoulder and foot & ankle procedures, planning can be done manually using the general measurement tools and relevant templates".


## INSERT TEMPLATES

1. Type the name of the template in the **Search for Templates** field, and click .
2. Select a template from the list. Once the template is inserted, adjust its location, position, and properties.
  - Use the  icon to rotate the template as required.
  - Select a template to view and modify its properties in the left panel.
  - If both AP and LAT images are available, the implant is placed on both images. Changes to the implant size are reflected in both images.

3. To select a second template, return to the left panel and search for the additional template.

Note that all of your selected templates are automatically added to your list of **Recently Used**, which appears by default in the templates list in left panel.

Even though the application automatically places the template, it is recommended to fine-tune its position, rotation, size and additional properties.

At any point you can hide or show the templates using the  icon on the left panel in the template title.









When working on images containing implants, the automatic image detection may not occur. You may continue planning manually instead.

## PLANNING TOOLS

On the right toolbar you can find 2 tabs with **Measurement Tools** and **Image View Tools**. Select the appropriate tab to choose the desired tool you want to work with.

### BASIC TOOLS

Select a measurement tool from the toolbar and point to the location on the image, where you wish to position it.

-  **Ruler** - Measures the distance between two points. Drag any of the two points to adjust the ruler.
-  **Angle** - Measures an angle between two lines. Drag any of the three points to adjust the angle.
-  **Interline Angle** - Measures the angle between two lines. Drag any of the four points to adjust the angle.
-  **Circle** - Measures a diameter of a round object. Drag any of the two points to adjust the size of the circle.
-  **Text Annotation** - Adds/edit a text annotation to the image. Point to the area on the image and start typing in the desired location on the image.
-  **Delete** – Select any object and click delete to remove the object. In case no object is selected, all planning on the image will be deleted.



The accuracy of the Angle tool is  $\pm 0.8^\circ$ .

The accuracy of the Ruler and Circle measurements tools is  $\pm 0.25$  mm.

Accuracy is also affected by the calibration of the image.

According to the calibration method chosen, the accuracy of the measurement tools can vary.

## HIP TOOLS

With Auto-Hip planning, templates are automatically positioned on the specified body side. The cup is positioned in the area of the acetabulum and the stem is placed in the femur canal.

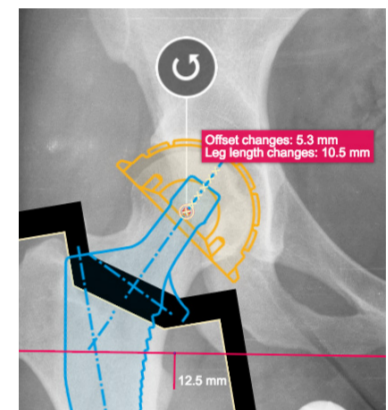
In addition, a leg length discrepancy measurement tool is positioned, and a fragment is created according to the suggested femur head osteotomy line. This allows to later visualize the resulting leg length and offset change.

The cup inclination angle (where available) is presented in relation to the measured LLD reference line. In case a head, liner, or other additional templates are placed on the image, they will be automatically attached to the relevant template.

The Offset and Leg length changes appear automatically on the image.



**Attach to Cup** - Visualizes hip reduction. Automatically groups the stem and fragment and attaches them to the cup, so that their attachment points are locked together. The default attachment point can be changed in the template properties. When the cup and stem are positioned automatically, the fragment moves according to the stem. To change the fragment, drag its anchors to the desired location. Once attached, the cup, stem, and fragment all move together.



The Attach to Cup button is enabled once two implant components (cup and stem) are placed on the image. Both components should have attachment points.



### Leg Length Discrepancy (LLD)

Draws a tangent line on the image by marking two points at the most inferior points on the ischial tuberosities. From this reference line, two vertical lines are drawn towards the lesser trochanters. Using the pink markers, adjust the tool to the reference points. The label indicates the discrepancy between the right and left legs.

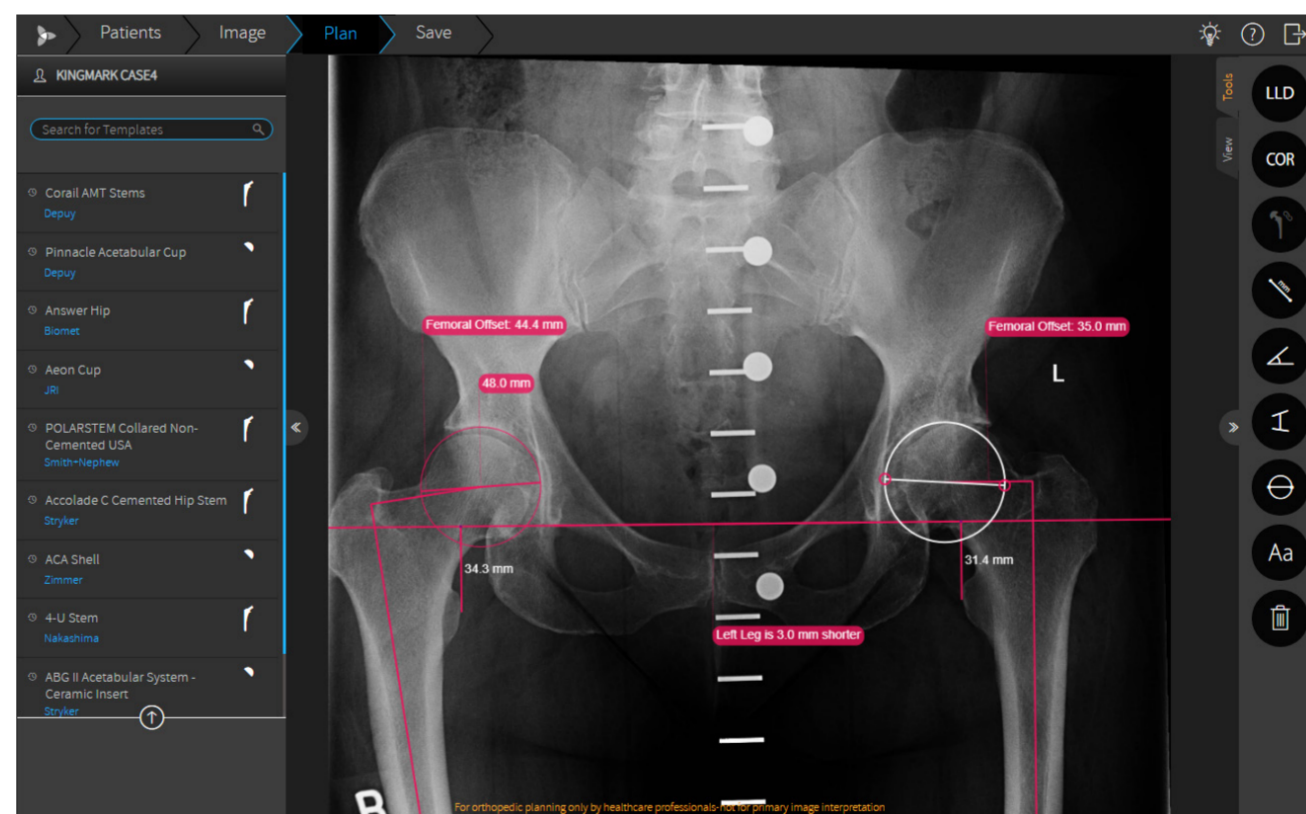


**COR** **Center of Rotation (COR)** - Helps to find the approximate center of rotation on the treated side by locating the center of rotation on contralateral side.

The tool combines several anatomical measurements:

- The teardrop locations establish a horizontal reference line for the COR tool.
- The lesser trochanter locations are used to calculate the leg-length discrepancy with respect to the horizontal reference line.
- The center line finder on the femur is used to determine its mechanical axis and to calculate the total offset of the femur with respect to the closest teardrop.
- The circle on the contralateral femoral head is used to accurately measure its center of rotation and diameter. This circle measurement is reflected over to the treated side using the perpendicular bisector of the teardrops as an axis of reflection.

Using the pink markers, adjust the tool to the reference points.



Note: When using the COR tool, the cup size is determined based on the diameter measurement of the femoral head.

## KNEE TOOLS

Auto Knee functionality provides a quick method to perform Total Knee Replacement planning for AP and LAT images. With this functionality, the application attempts to automatically detect the anatomical regions in the image, a resection line is added to the AP image, and implant sizing and position is determined both for AP and LAT images. Finally, a fragment is automatically created to allow visualizing the expected knee alignment.

In the automatic Total Knee Replacement planning, the femoral template component size is evaluated according to the lateral image, while the tibial component size is according to the AP image. In case one of the images is missing, then automatic sizing is not applied for the relevant template.



**Resection Line** - Assists in planning the desired femoral distal cut and proximal tibial cut on AP view. The tool measures the size of the medial and lateral resection levels.

The tool displays the anatomical and mechanical axes of the femur as well as the tibial anatomical axis. The femoral mechanical axis is initially assumed to be at  $6^\circ$  with respect to the anatomical axis and appears as a dotted line. The angle can be changed by dragging the anchor on the mechanical axis line.

The resection line is located at  $90^\circ$  to the mechanical axis, thus providing Mechanical Knee Alignment. Toggle the Resection Line button to show/hide the tool.



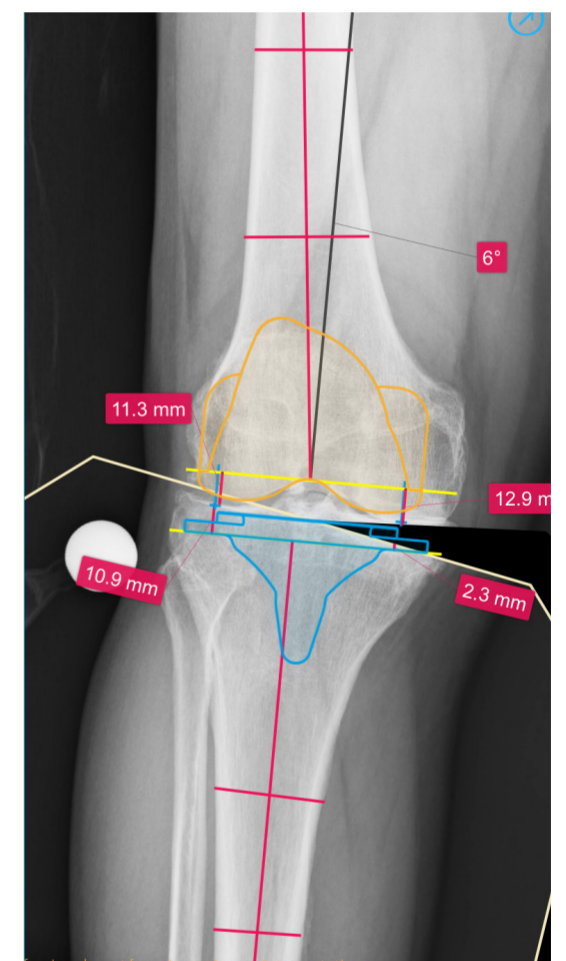
**Tibial Slope** - Measures the angle between the tibial plateau line and the tibial anatomical axis, in sagittal view. Using the pink markers, drag the joint line and anatomical line to adjust the measurements.







**Auto Alignment** - Visualizes alignment correction. Once the femoral and tibial components and the resection lines are placed in the image, auto alignment functionality is available. This tool creates a tibial fragment and re-positions it together with the tibial component and resection line until they are located in parallel to the femoral component. Toggle the Auto Alignment button to apply/remove Auto Alignment.



The Knee Auto Alignment is available for the coronal view only - make sure the AP image is selected to enable the tool.



## IMAGE VIEW TOOLS

-  **Windowing Level** – Sets image contrast and brightness (for DICOM images only).
-  **Reset Windowing** – Sets image contrast and brightness back to default.
-  **Zoom** - Zooms in (enlarges) or zooms out (reduces) the image view.
-  **Fit to Screen** - Adjust the zoom such that the entire image is visible.

When viewing two images, use the arrows on the top right corner of each image to view one image only, to toggle between the two images, and to go back to side-by-side images mode.

On a touch device, you can swipe with 2 fingers to toggle between the images.



When working on a computer, you can also **Zoom in** by using Ctrl+up arrow and **Zoom out** by using Ctrl+down arrow.

## USING THE SOFTWARE IN DIFFERENT LIGHTING ENVIRONMENTS:

The software has a “**Windowing**” feature which enhances the visible distinction between contrasting tissue regions, by changing the brightness and contrast levels of an image. As a result, the user can adjust the image to different lighting environments.



TraumaCad Mobile may not be appropriate for use in all lighting environments, such as direct bright sunlight, which can affect the ability to use the software on iPad devices. You must ensure that surgical planning can still be performed in the lighting environment that you choose to work in.



# — SAVE, PRINT AND REPORTS —

In the Save tab, you can save the planned images, print them and generate reports via Qentry. You can choose to save the image depending on the original image source:

- Images retrieved from the PACS can be saved back to the PACS, uploaded to Qentry or saved locally.
- Images retrieved from Qentry can be saved back to Qentry or saved locally.
- Images retrieved from the local drive / camera roll can be saved locally or to Qentry.

The planned case is saved including the templated image and a descriptive PDF report. Planned cases saved to PACS or Qentry are stored in DICOM format and can be re-opened for plan editing. Planned cases saved locally are stored in JPG format and cannot be edited.

## SAVE AND PRINT IMAGES

Information burnt on the image includes: Patient Information, Study Date, Planning Date, Implant Information (implant name, part number, and implant properties) and more.

### 1. Save to PACS, Qentry or Photo Gallery.

If Qentry is selected, specify the recipient - my account, a CareTeam or another user..

Additional information can be added to the Qentry Report: Comment – free text, Surgery Institution, and Surgery Date.

### 2. Select Print to print the image/s.

### 3. Continue to your next step:

- Back to Plan – Returns to the Plan tab to continue planning the same image.
- New Case – Returns to the image source selection to start a new case.



Be sure to save the patient's case in order to not lose patient data. In case you receive notification of low battery or other general failure notifications from your device, it is your responsibility to immediately save your work.

## QUENTRY REPORTS

TraumaCad Mobile reports are accessed via the Reports tab in [qentry.com](https://qentry.com).

In the report, you can see your planning data such as the Surgery Institution, Surgery Date, Patient Name, Procedure, etc. and the Implant data such as the Implant Name, Manufacturer, etc.

Reports can be exported to CSV format.



All information received from the software as output must be clinically reviewed regarding its plausibility before patient treatment!

