

 TraumaCad Mobile

2.0 User Guide

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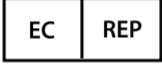


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SYMBOL GLOSSARY

Symbol	Standard Title	FDA Standard Designation Number	Symbol Title	Symbol Reference Number	Explanatory Text
	ISO 15223-1	5-90	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1	5-90	Authorized representative in the European Community	5.1.2	Indicates the Authorized representative in the European Community.
	ISO 15223-1	5-90	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.
			Medical Device		Indicates that the product is a medical device, as defined in Medical Devices Regulation 2017/745/EU.

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

This guide is intended for healthcare professionals who want to perform orthopedic pre-operative planning and evaluate images.

SAFETY 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.

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 templates. 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.

SYSTEM REQUIREMENTS

General

Standard computer or iPad 3, 4 or 5 (Air) with internet connection

Software

Operating System

The following versions:

- Windows 7, 8, 10
 - Mac OS X
 - iOS 8 or later
-

Browser

The following versions or higher:

- Internet Explorer 11, Edge
 - FireFox 26
 - Chrome 30
 - Safari 5 (MAC) or 8 (iPad)
-

Hardware

- 2 GB RAM recommended for PC or MAC
- 1 GB RAM recommended for iPad 3, 4 or 5 (Air)
- Screen resolution: 1024x768 or higher

Network

- Internet connection with at least 2Mbit/sec
- Firewall with open outbound port 80/443 (http and https)
- iPad requires Wi-Fi or Wi-Fi + 3G (Running iOS 7 or above)



TraumaCad Mobile should only be used on computers and iPads that are already qualified for wireless use in a clinical setting.

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.

United States, Canada, Central and South America:

+ 1 (800) 597 5911

us.support@brainlab.com

Europe, Africa, Asia and Australia:

+ 49 89 991568 44

support@brainlab.com

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

For a printed copy of the User Guide, contact Support by email to support@brainlab.com.

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

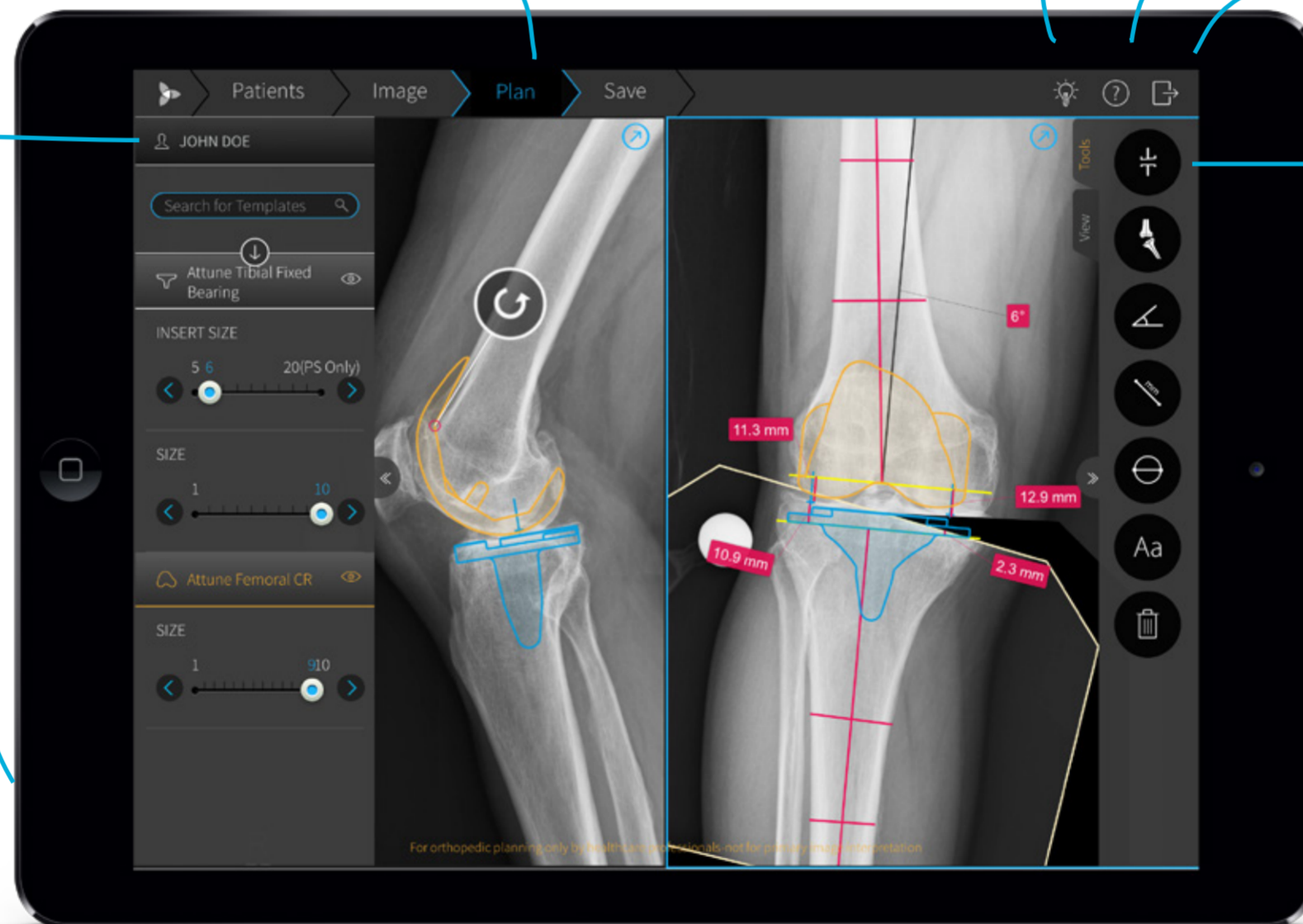
Logout

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

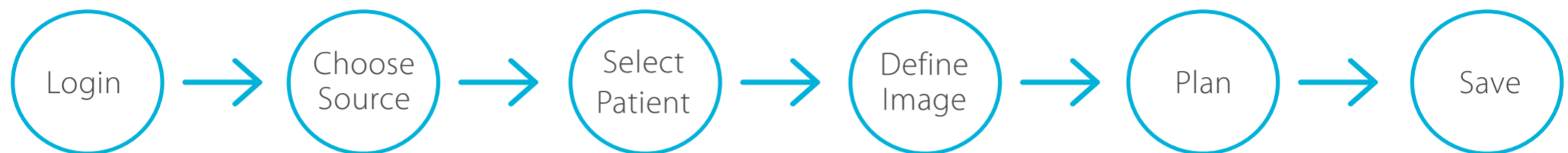
- * Measurement tools
- * Image view tools

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.

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

GETTING A QUENTRY ACCOUNT

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

If you do not have an account, you may register for a free basic account at www.qentry.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.

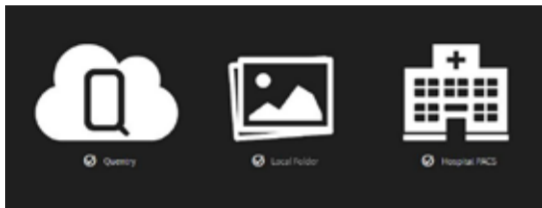


The application can be downloaded from the App Store free of charge; however it has to be provisioned with a license in order to ensure it is used by healthcare professionals.

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 DICOM images, the patient information is imported automatically from the image data.

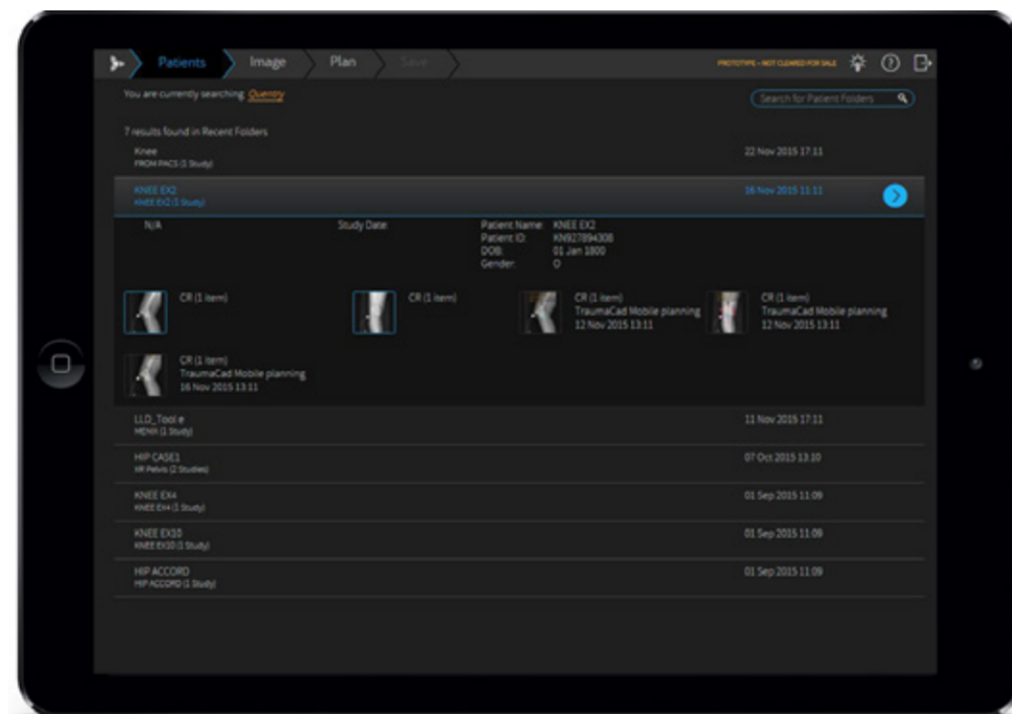
When importing JPG, PNG, BMP and GIF files, the patient information must be entered, in order to later identify the image.

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 icon 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:

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).

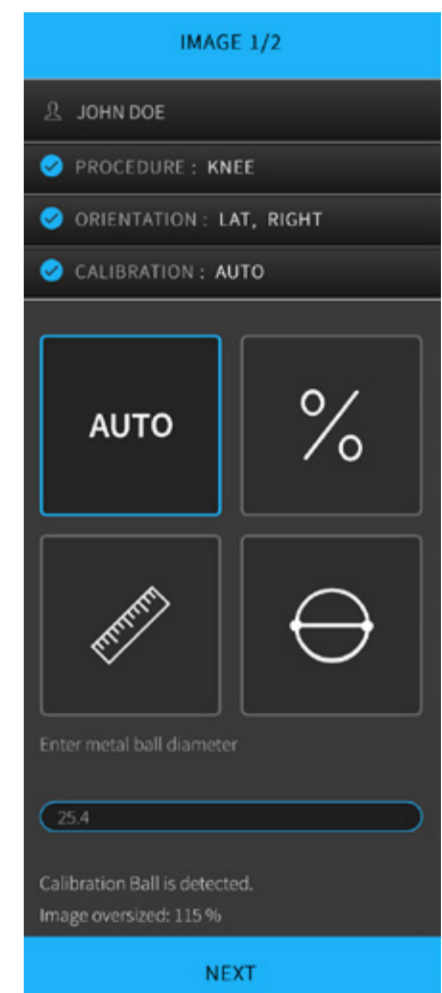
Select one of the following **calibration** methods:

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). To change the default size, use the circle calibration method.

% 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. The size of the line is displayed on the image and changes as you draw and resize the line.

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. The diameter of the circle is displayed on the image and changes as you resize the circle. Set the size of the circle to exactly cover the marker’s image, by dragging the circle onto the outer rim of the marker’s image.



X-ray images can display with incorrect bone measurements due to taking the wrong angle of the bone during X-ray acquisition. Be sure to take X-rays with the bone at the correct angle.

Once the calibration is defined, the oversize value is displayed in the left panel under the calibration methods. If you chose two images, repeat the above procedure to choose orientation and calibration for the second image.



The problems related to accurate calibration are a known issue in digital imaging. A calibration marker placed at the level of interest must be used 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.

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 template is placed on both images. Changes to the template 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 template using the  icon in the template title on the left panel.



When working with Post-operative images, automatic template placement may not occur. Place the template manually on the image 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.



Circle - Measures a diameter of a round object. Drag any of the two points to adjust the size of the circle.



Text Annotation - Adds a text annotation to the image. Point 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 ± 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.

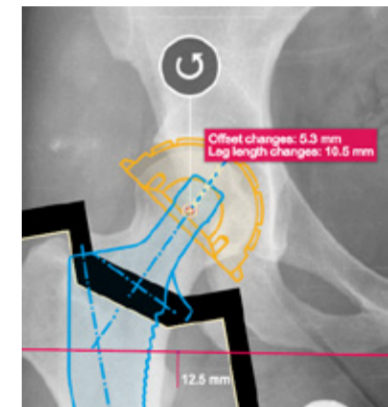
HIP TOOLS

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.

In case a head, linear, or other additional templates are placed on the image, they will be automatically attached to the relevant template.



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 toward identical anatomical landmarks on each proximal femur. Using the pink markers, adjust the tool to the reference points. The label indicates the discrepancy between the right and left legs.



KNEE TOOLS

Auto Knee 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 the implant sizing and position is determined for both AP and LAT images. Finally, a fragment is automatically created to allow visualizing of the expected knee alignment.

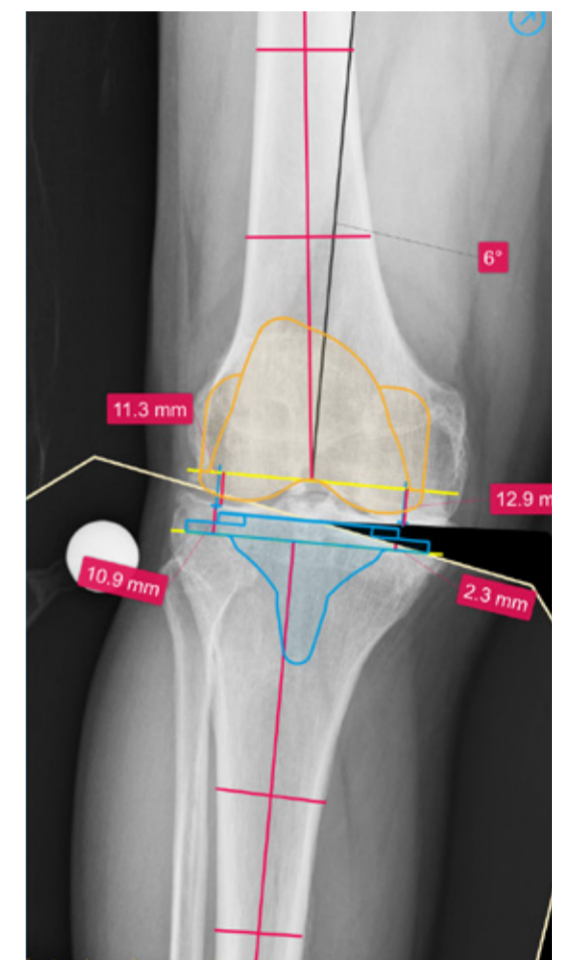
The template size for the femoral component size is evaluated according to the LAT image, while the tibial component size is evaluated according to the AP image. In case one of the images is missing, automatic sizing is not applied for the relevant template.



Auto Alignment - Visualizes alignment correction, available once the resection line and tibial and femoral components are placed on the image. 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 the tool.









Resection Line - Assists in planning the desired femoral distal cut and proximal tibial cut. The tool measures the size of the medial and lateral bone cuts. The tool marks the femoral anatomical and mechanical axis and the tibial axis. The femoral mechanical axis is assumed 6° to the anatomical axis and appears as a dotted line. The angle can be changed by dragging the line anchor. The resection line is located at 90° to the mechanical axis.



The Knee Auto Alignment and Resection Line tools are available for the coronal view only - make sure the AP image is selected to enable these tools.

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** - Fits the image to the screen width.

When viewing 2 images, use the  on the top right corner of the image to view one image only, and  to go back to 2 images mode. On a touch device, you can swipe with 2 fingers to switch between the images.



When working with a computer, 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, you 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 / Photo Gallery can be saved locally or to Qentry.

The image is saved in a JPEG format. Information burned on the image includes: Patient Name, Patient ID, Study Date, Planning Date , Implant Information (implant name, part number and implant properties) and more.

SAVE AND PRINT IMAGES

1. Save to PACS, Qentry or Photo Gallery.

If Qentry is selected, the user can add additional information, that will be added to the report, such as comments, surgery institution and surgery date. The planned images are saved including the planning information, burned on the image. To view the planned and saved images, go to the source where the image was saved.

A Save in Process notification appears, whether the image was successfully saved or not.

2. Select Print to print the image/s.

3. Continue to your next step:

- Keep Planning – Returns to the Plan tab to continue planning the same image.
- Start a 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.

REPORTS

Reports are accessed via the Reports tab in quentry.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!

