



PtoleMedic System

**USA-Instructions for Use
Surgical Plan Creation**

USA Surgeons

Doc. ID: US-LB-72-01-003(B)

April 12, 2022

The PtoleMedic System software Total Knee Replacement (TKR) planning instructions guide the Surgeon in the surgical planning of a knee replacement procedure. The creation, review, and approval process for using the PtoleMedic System surgical software follows this section. Plan approval is provided online through the cyber secure Lento Medical Innovation web portal (www.lentomedical.net).



Caution: Please do not share your Lento login information and keep your password confidential. Please reset your password or contact Lento Medical Administrator (support@lentomedical.com) if you have trouble logging into the system.



Manufacturer's Contact Address:

Lento Medical Innovation, Inc.
15110 Northwest Freeway, Suite 150
Houston, TX 77040 – USA
+1 (510) 413-3230

The following organization is the Authorized Representative for the PtoleMedic System:

C € 2460



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Introduction

PtoleMedic System *web-based software* offers a simplified Total Knee Replacement (TKR) surgery planning interface. Surgical planning software is generally available. However, much of such software is PC or local server-based. Available programs tend to be time-consuming, expensive and require frequent updating and IT maintenance. The PtoleMedic System offers "**log-on-and-use**" surgical planning tools and custom-made femoral and tibial resection model creation. And the system is **low-to-no maintenance** requiring no IT support to install, use, or maintain. The PtoleMedic® System web-based software provides direct, focused assistance on setting angles, rotation, cut plane, offsets, and implant sizing as appropriate to TKR surgery.



Warnings:

- The PtoleMedic System has not been evaluated in a pediatric population; therefore, performance in such cases is unknown and not recommended.
- The PtoleMedic System software is a prescription-only medical device.
- The software is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on the practitioner's education, training, and experience.
- Surgical planning software only provides and documents good alignment and orientation information based on specific individual anatomic data obtained from current MRI image sources.
- The software does not provide a complete or only solution plan for joint replacement surgery, and it only documents one possible approach; no surgical philosophy is recommended.
- The use of the software on mobile platforms, such as Google Android, Apple iPhone, or similar tablet-type devices, has not been validated and is not recommended at any time.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.



Cautions:

- The use of aged (>3 months) MRI image files is not recommended. The accuracy of planning may diminish with evolving or changing disease processes.



Precautions:

- Use only MRI data of recent origin obtained per established PtoleMedic System designated MRI protocols.



Limitations

- Metallic implants in or near the affected joint are known to interfere with the MRI images.
- The PtoleMedic System provides an estimate of implant sizing only. Final implant size can only be determined during surgery and may differ from sizes projected during planning.
- If PtoleMedic System estimated implant sizes vary, it is seldom more than +/- one size.
- The software is not for use in planning revision or replacement surgery.
- Digital x-ray data is not acceptable for planning purposes; the files must be MRI images.



Contra-indications

- Patients with active infection of the knee joint area typically are not appropriate candidates for TKR.

User System Requirements

1. High-speed internet access
2. A color monitor or display with VGA image display capabilities with 1280 x 800 resolution (recommended)
3. A mouse, touchpad, or similar input device to interact with the surgery case
4. A keyboard (virtual or physical) for text input
5. A PC/Workstation w/1GB of RAM or more capable of running Windows or Mac OS
6. A Web Browser (Internet Explorer, Firefox, Google Chrome or Safari)

NOTICE: PtoleMedic System software does not utilize any compression techniques or technology when accepting, storing, or viewing DICOM images.

NOTICE: *Software Anomalies.* The PtoleMedic System software supports the following Web Browsers, Internet Explorer (Ver 9.0) or newer, Firefox (Ver 15.0) or newer, Google Chrome (Ver 25.0), and Safari (Ver 4.0) or newer. Such browsers may be used with various operating systems, including those supporting Windows OS (XP, 7, Vista) or newer or Mac OS X (Ver 10.0) or newer. Depending on the users' browser or operating system, the screen may look slightly different depending on the software environment, including available fonts, the spacing between letters, graphical user interface (GUI) components, and some other minor appearance items.

NOTICE: The PtoleMedic System Web software does not communicate directly with DICOM generating equipment (PACS devices). The image files needed by the PtoleMedic System Web software originate from the MRI center as DICOM files, which are transferred to the company server by Imaging Center personnel using DICOM compliant processes. File transfer protocols or file transfer requests are not generated or provided.

NOTICE: The PtoleMedic System Surgical Planning Software program does not interact with or affect DICOM image source equipment (PACS devices).

Updates: For updates to this document, please contact the Help Desk support team.

Help Desk: If this document does not address your question, please contact Lento Medical Innovation, Inc.

Telephone: The Help Desk and Customer Service support teams can be reached via:
The United States and Canada during regular operating hours +1 (510) 413-3230.

Company URL: <http://www.lentomedical.com>

PtoleMedic System URL: <http://www.lentomedical.net>

Once MRI images are user uploaded to the secure database, the PtoleMedic System software interface allows Lento technologists to transfer DICOM images into the planning modules of the PtoleMedic System.

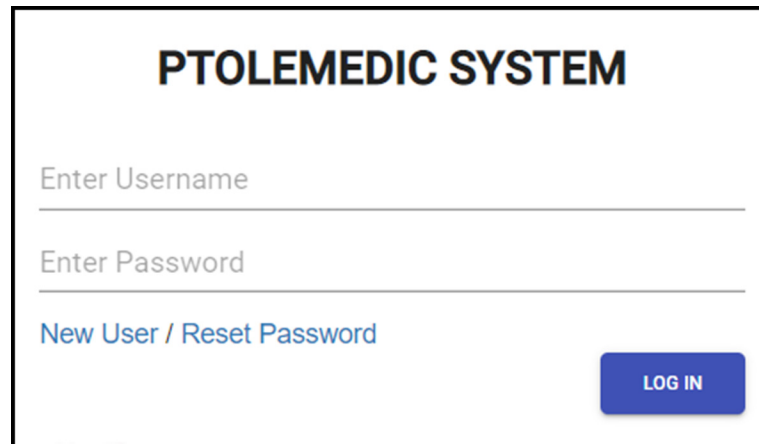
When the MRI file images are uploaded, the images are subjected to verification and quality confirmation. After QC, the PtoleMedic System files must complete stages Planning 1 and Planning 2. Completion of the second planning stage results in an initial surgical plan for presentation to the operating Surgeon. The surgeon review modifies the plan as necessary and authorizes a completed surgical plan. The approved plan provides orientation, placement, and sizing of the TKR components with recommendations for bone or tissue resections before cutting.

Cleared Indications for Use:

The ***PtoleMedic System*** is an online orthopedic surgical planning software system. MRI images supply data sufficient to allow accurate modeling of anatomy for on-line surgical planning before joint replacement surgery. The Surgeon preoperatively plans, reviews, adjusts, and orients generic implant images to select implant size and create an idealized surgical plan for the first bony cuts only.

Using the Software:

Start a computer with internet access. In the browser, type in the PtoleMedic System software secure web address; lentomedical.net. A screen like the one depicted below appears:



The screenshot shows a web interface for the PTOLEMEDIC SYSTEM. At the top, the title "PTOLEMEDIC SYSTEM" is displayed in bold, black, uppercase letters. Below the title, there are two input fields: "Enter Username" and "Enter Password", each followed by a horizontal line for text entry. Under the password field, there is a link that reads "New User / Reset Password" in blue text. In the bottom right corner, there is a blue rectangular button with the text "LOG IN" in white, uppercase letters.

Select "**New User**" and follow the instructions to register initially. Lento staff assists with verification of physician identity and validity of professional status. Log off. A temporary ID & password are provided in a separate communication once the information is verified.

Once verification and acceptance are completed, return to lentomedical.net and follow the steps below.

1. Logging In

Lento Medical Innovation staff are available to assist with qualification, registration, and use of the Lento Medical Innovation web portal. Once a username and password are generated, use the information to log in.

On the initial login screen;

- Enter Username
- Enter Password
- Click the "Login" button



The login screen for the PTOLEMEDIC SYSTEM. It features a title 'PTOLEMEDIC SYSTEM' at the top. Below the title are two input fields: 'Enter Username' and 'Enter Password'. A link 'New User / Reset Password' is located below the password field. A blue 'LOG IN' button is positioned to the right of the password field. At the bottom left, there is a CE mark and the number '2460' with a red asterisk and text '* Not available for sale in the U.S.A.'. The version 'Ver. 1.3.1' is displayed at the bottom right.

2. Surgeon Landing Page

The surgeon landing page appears, listing all user-supplied information provided by the Surgeon.

To see active cases, press the "Current Orders" button.

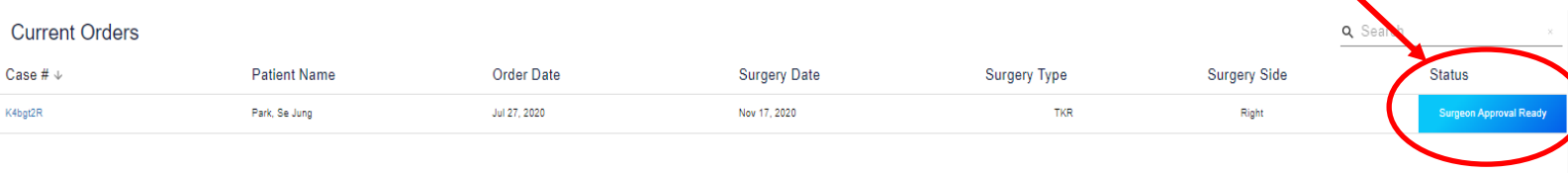


The Surgeon Landing Page displays surgeon information on the left and action buttons on the right. The surgeon's name is Seidel, Markus. The office name is Dr. Markus Seidel, located at Kastanienallee 2, Berlin, 10435, DE. The email address is u@lentomedical.com, the phone number is 49304483568, and the fax number is 49304483568. The action buttons are NEW ORDER, CURRENT ORDERS, COMPLETED ORDERS, and VIEW PREFERENCES.

Surgeon:	Seidel, Markus
Office Name:	Dr. Markus Seidel
Office Address:	Kastanienallee 2 Berlin, 10435, DE
Email Address:	u@lentomedical.com
Phone Number:	49304483568
Fax Number:	49304483568

[NEW ORDER](#)
[CURRENT ORDERS](#)
[COMPLETED ORDERS](#)
[VIEW PREFERENCES](#)

The status of a case that requires surgeon approval shows **"Surgeon Approval Ready."**



The 'Current Orders' table lists surgical cases. The first row shows a case for 'Park, Se Jung' scheduled for 'Jul 27, 2020' with a 'TKR' surgery type on the 'Right' side. The 'Status' column for this case is 'Surgeon Approval Ready', which is highlighted with a red circle and a red arrow pointing from the text above.

Case # ↓	Patient Name	Order Date	Surgery Date	Surgery Type	Surgery Side	Status
K4bg2R	Park, Se Jung	Jul 27, 2020	Nov 17, 2020	TKR	Right	Surgeon Approval Ready

3. View Surgeon Planning Reference

The Surgeon can click the case number, and the patient case detail page appears.

From the patient case detail page, the Surgeon can view case information.

Case ID: K4bgt2R
Status: Surgeon Approval Ready

COMPLETE

Patient

First Name	Middle Name	Last Name	Surgery Type	Surgery Side	Default Alignment	Date of Purchase Order
Se Jung		Park	TKR	Right	Mechanical Alignment	Jul 27, 2020
Date of Birth	Sex	Age	Date of Surgery	Implant Information	Ship To	Bill To
Nov 17, 1959	female	60	Nov 17, 2020	STRYKER TRIATHLON	Charité Universitätsmedizin	Fedex express

EXPAND

SURGEON APPROVAL →

Press the "EXPAND" button to view the preference details shown below.

Case ID: K4bgt2R
Status: Surgeon Approval Ready

COMPLETE

Patient

First Name	Middle Name	Last Name	Surgery Type	Surgery Side	Default Alignment	Date of Purchase Order
Se Jung		Park	TKR	Right	Mechanical Alignment	Jul 27, 2020
Date of Birth	Sex	Age	Date of Surgery	Implant Information	Ship To	Bill To
Nov 17, 1959	female	60	Nov 17, 2020	STRYKER TRIATHLON	Charité Universitätsmedizin	Fedex express

Surgeon Name Seidel, Markus Office Name Dr..Markus Seidel Address Kastanienallee 2 Email Address u@lentomedical.com Office Number 49304483568 Mobile Number 49304483568 Fax	Distributor Company Name Fedex express Contact Person Express, Fedex Address Aden-von-Trott-Straße 1 Email Address v@lentomedical.com Company Number 491806900800 Mobile Number 491806900800 Fax	Hospital Hospital Name Charité Universitätsmedizin Contact Person Berlin, Hospital Address Charitépl. 1 Email Address x@lentomedical.com Hospital Number 493045050 Mobile Number 493045050 Fax	MRI Center Center Name MRT-Zentrum Contact Person Mri, Berlin Address Kadiner Str. 23 Email Address x@lentomedical.com Center Number 4930293697300 Mobile Number 4930293697300 Fax
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COLLAPSE

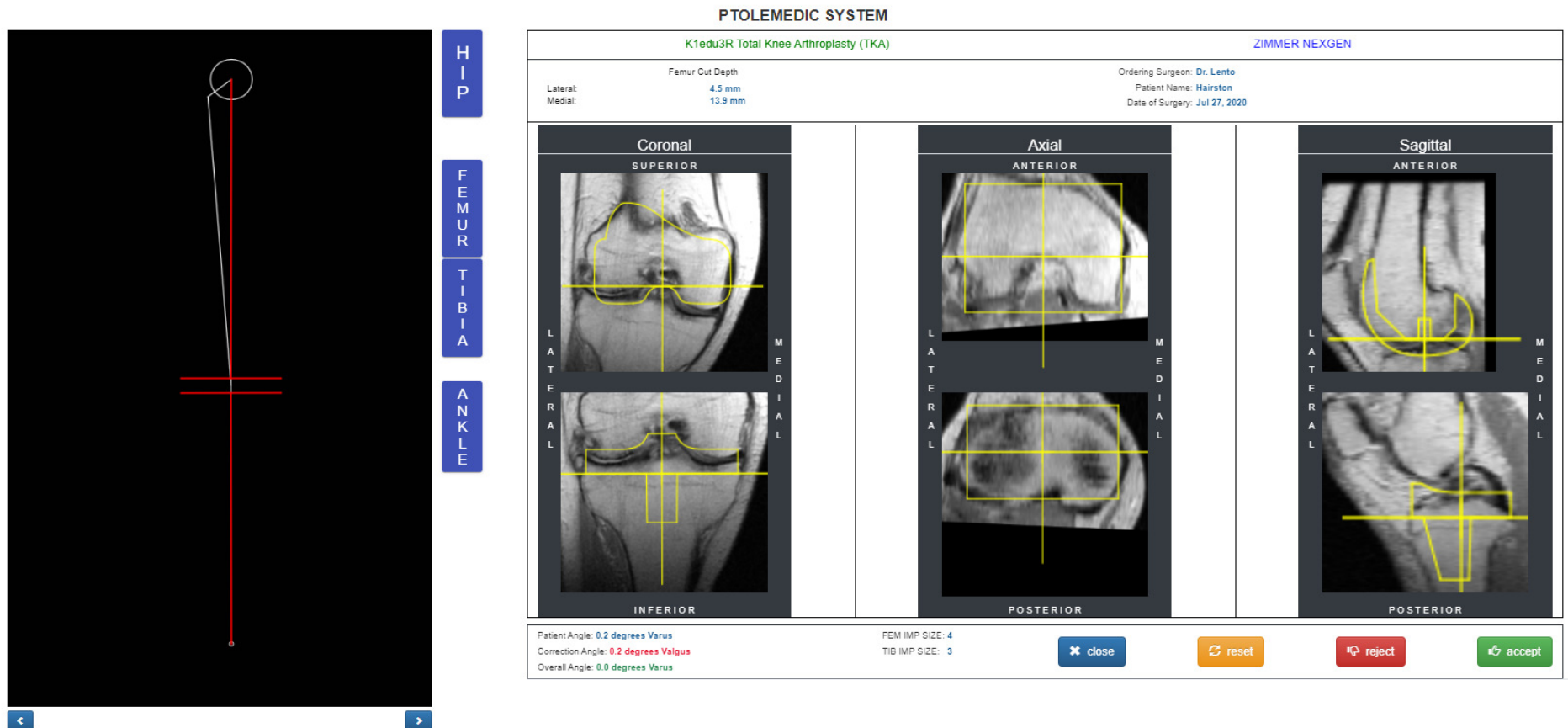
SURGEON APPROVAL →

Press "COLLAPSE" to hide the preference.

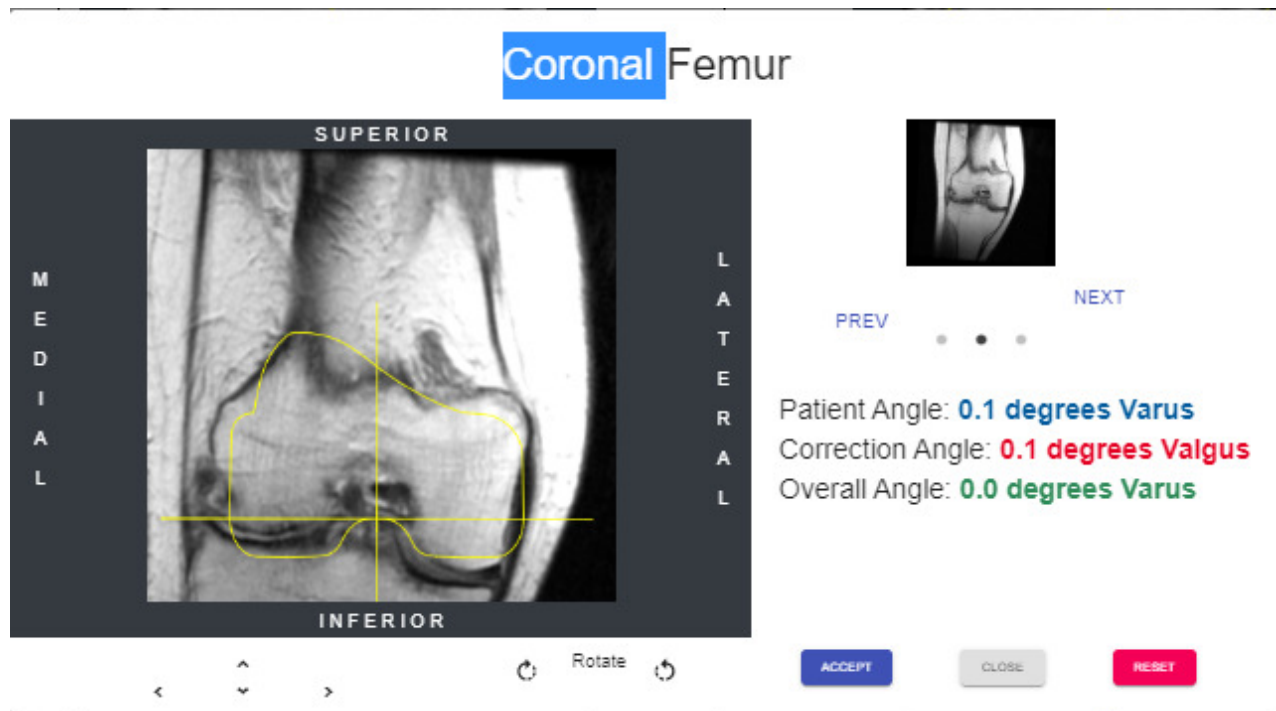
Pressing the "Surgeon Approve" button directs the Surgeon to the "Surgeon Template Design Approval" Page.

4. Using the Surgeon Template Design Approval Page

The Surgeon views each coronal, sagittal, and axial view of the MRI surgical planning results presented, as shown below. The yellow overlays represent an outline of a generic representation of the branded physician-designated implant and are sufficiently accurate for primary cut-plane orientation and sizing estimation purposes. Lento technologists estimate the implant size and position during the previous planning processes (Planning I and Planning II). The reviewing surgeon may accept, adjust, approve or reject any plan presented for their review.

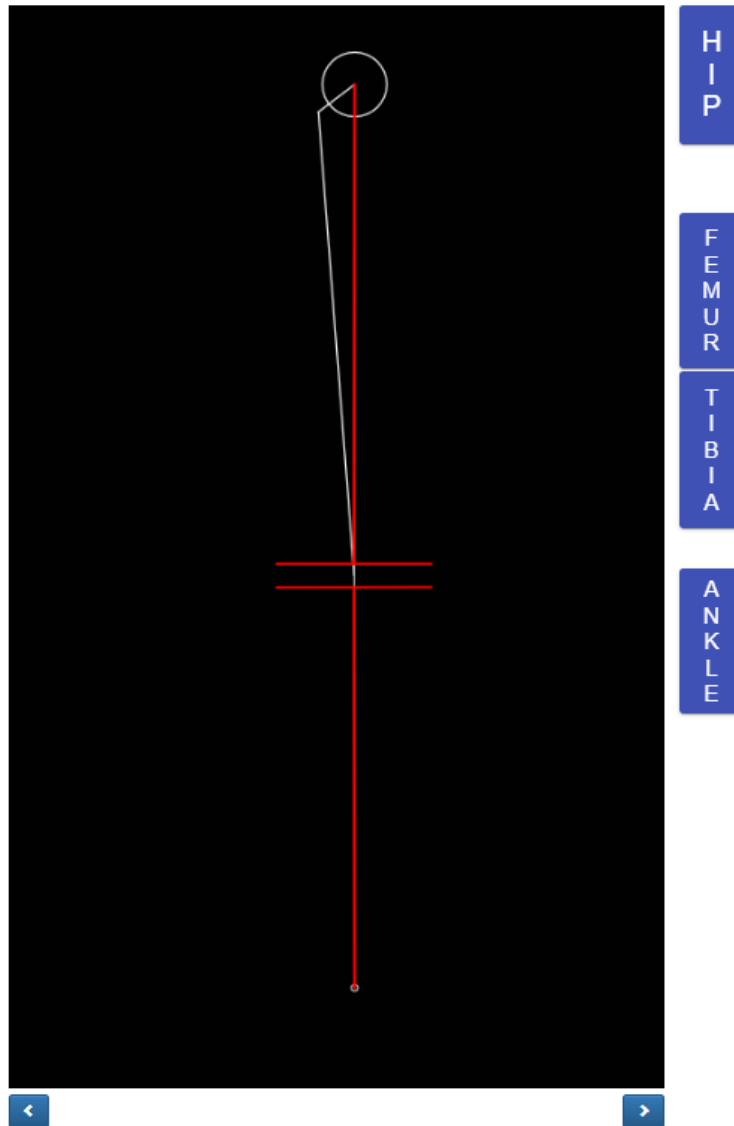


Each Coronal, Axial, and Sagittal view may be enlarged by double-clicking the corresponding MRI image, shown below.



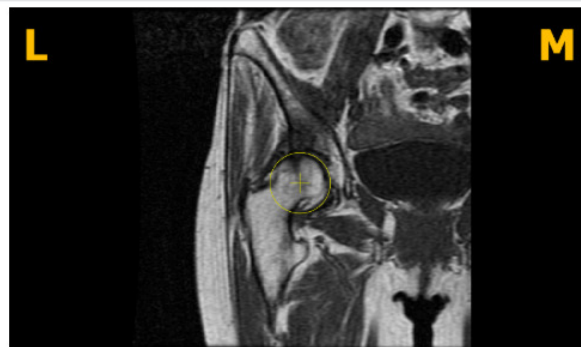
The arrow buttons below the presented image adjust the implant positioning (left, right, up, and down).

Selecting the rotate icon/button rotates the implant outlines by 3 degrees. Overall limb alignment adjusts by clicking the right or left arrow on either side of the knee graphic image. The circle graphic below outlines the femoral head's circumference with the center marked by the two divergent lines' origin. Brackets at the bottom represent the center of the ankle joint. Clicking a right or left arrow adjusts the varus/valgus angle of the knee 0.5 degrees or 0.5mm, max +/- 5 degree or mm. The knee image is moved medially or laterally while maintaining the upper and lower boundary area within the femoral head and the ankle's center. The horizontal lines representing the rectangular resection box remain parallel to the floor. The Blue boxes to the graphic's right are buttons to activate expanded views of the referenced joint level.



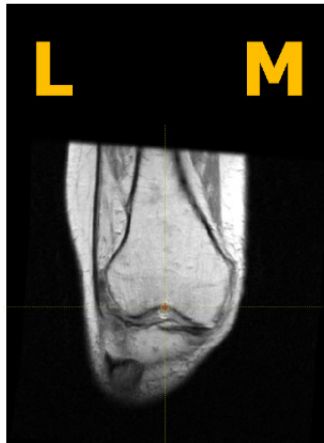
Selecting the hip button displays the Femoral Head Center in the pop-up view. A surgeon can view and confirm the femoral head center position, set from the previous planning process.

Femoral Head Center



Selecting the Femur button displays the Distal Femur Center in the pop-up view. A surgeon can view and confirm the distal femur center position, set from through the previous planning process.

Distal Femur Center



Selecting the Tibia button displays the Proximal Tibia Center in the pop-up view. A surgeon can view and confirm the proximal tibia center position, set from the previous planning process.

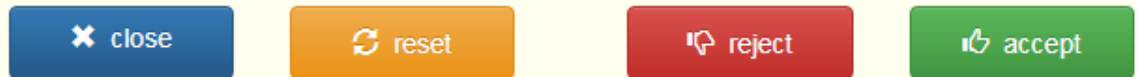
Proximal Tibia Center



Selecting the Ankle button displays the Ankle Center in the pop-up view. A surgeon can view and confirm the ankle center position, set from the previous planning process.



After the Surgeon finishes a review of the planning data and images, four action buttons display below. Buttons labeled CLOSE, RESET, REJECT, and ACCEPT.



Pressing the CLOSE button discards any existing changes restoring the original values closing the template approval page redirecting to the case detail page.

Selecting the RESET button restores the plan values and images, reverting to the original values provided at the beginning of the session but does not close the planning session.

Selecting the REJECT button results in rejection of the entire plan and closes the planning session, and displays a CAUTION screen where the Surgeon is asked to supply a reason for rejecting the entire plan using the screen shown below.

CAUTION!

This is to confirm that you are rejecting the pre-planned adjusted measurements made on the surgeon approval page. Please fill out rejection form below.

☐ Cancelled Surgery

☐ Others

Rejection Form

OK

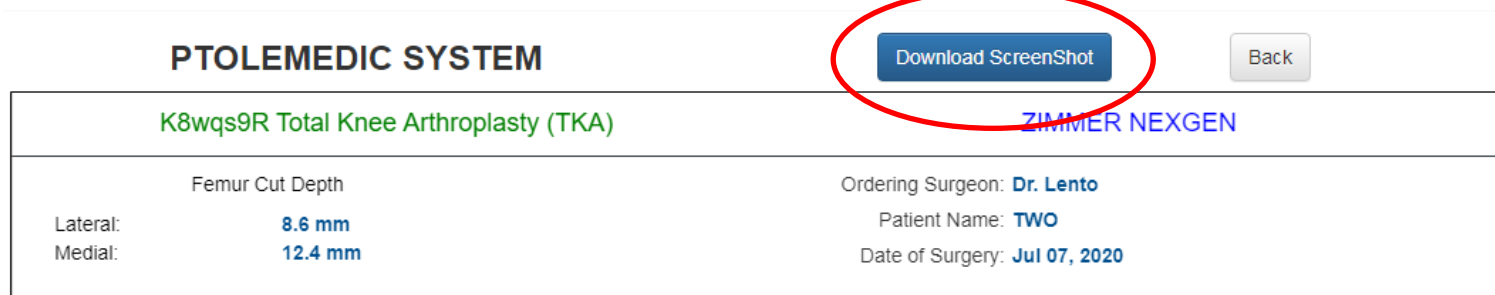
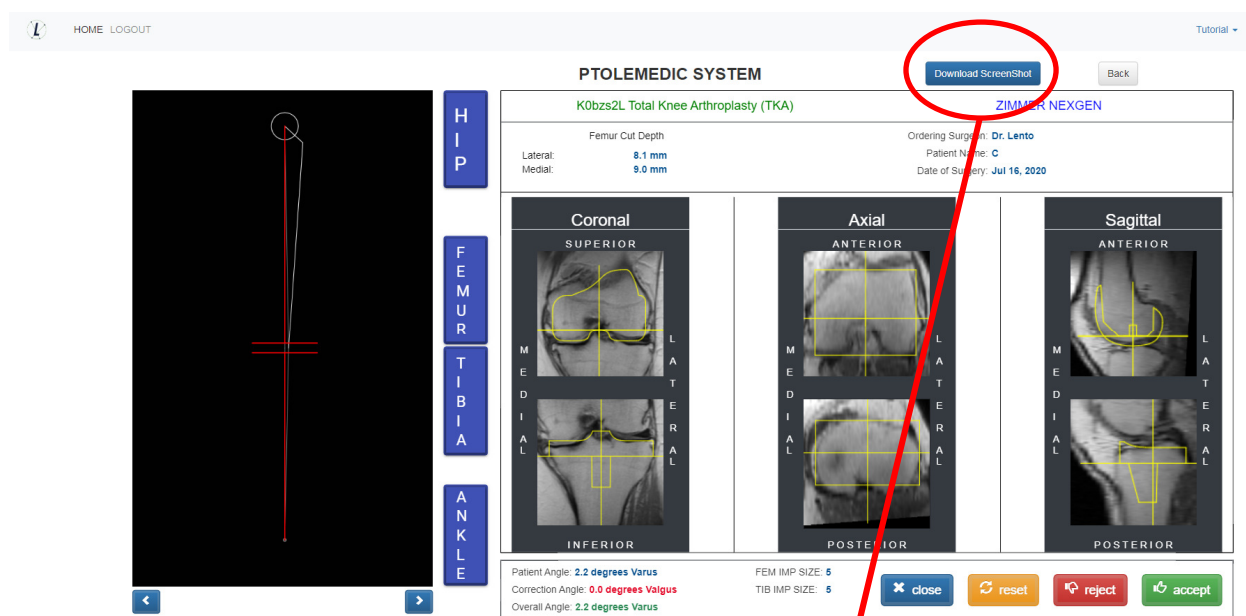
Cancel

Press Ok to submit the reason for rejection.

If the user presses the accept button, the OMM shall accept the current planning values. The user shall not be allowed to change the values after acceptance.

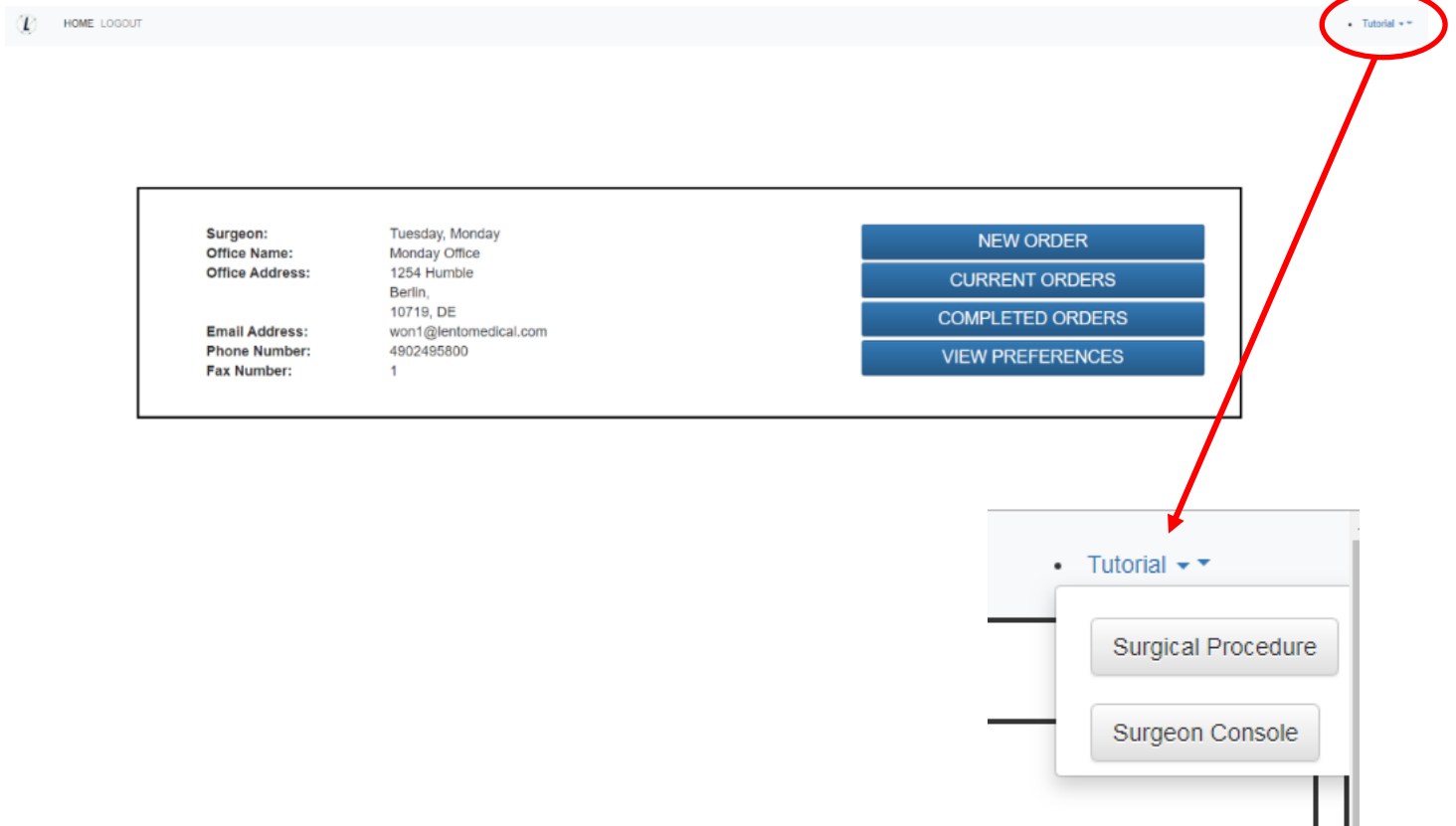
5. Downloading Screenshot of the Approval Page.

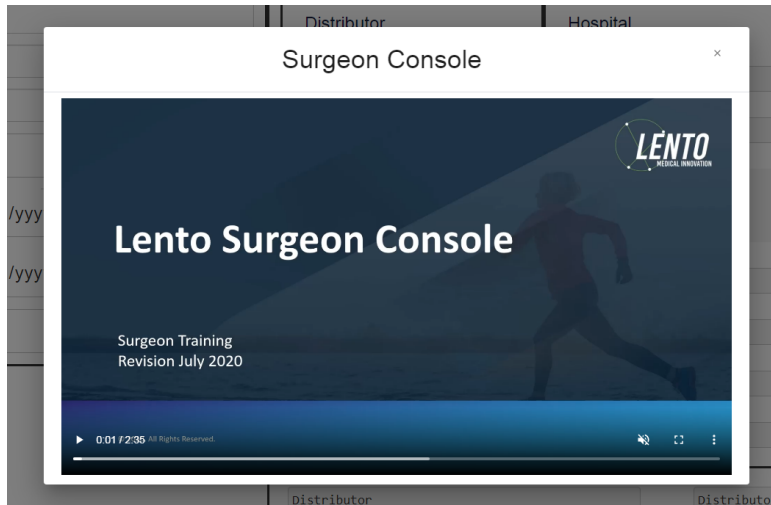
Once the Surgeon has approved the planning data, the surgeon will be able to download a screenshot of the entire approval page containing the numeric information (patient angle, correction angle, overall angle, and implant size).



6. Tutorial Video

- a. You can also access a tutorial video link located at the top-right menu for a visual demonstration on how to approve the Template Design.





7. Logout

If the surgeon user is finished with the planning session, they can log out by going to the top menu and click logout. The user redirects to the login page.

