



**PtoleMedic System**

**Instructions for Use - Template Design  
Approval (Surgeon)**

**Software Release Version 1.3.x**

**Document ID: LB-72-01-003**

**Model: Release C**

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**Date: 11/2/2020**

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**Date: 11/2/2020**

These instructions are intended to guide the surgeon in the surgical planning and template design, review and approval stage for an order of the PtoleMedic System guides. Approval is provided online through the Lento Medical Innovation web portal ([www.lentomedical.net](http://www.lentomedical.net)).



**Manufacturer's Contact Address:**

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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**



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Schiffgraben 41  
30175 Hannover, Germany  
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## Introduction

PtoleMedic System *web-based software* offers a simplified Total Knee Replacement (TKR) surgery planning interface. Surgical planning software is widely available but is generally PC or local server based. The use of such programs tends to be time consuming, expensive and requires frequent updating and/or IT maintenance. The PtoleMedic System offers “**log-on-and-use**” surgical planning tools and custom made cutting guide 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 education, training and experience of the practitioner.
- Surgical planning software only provides and documents useful alignment and orientation information based on specific individual anatomic data obtained from current MRI/CT image sources.
- The software does not provide an absolute or only solution plan for joint replacement surgery, 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.
- These are patient specific, single use, disposable instruments.
- Do not attempt to reuse, recondition or re-sterilize.
- Do not alter the instruments in any way.
- PtoleMedic System guides are to be used by a surgeon trained in the use of personalized instrument surgery (custom guides).

- Be aware that these patient specific instruments have been manufactured based of MRI scans of the patient. If the patient’s anatomy has changed significantly since the time of the MRI scan, the instruments should not be used.
- The instruments should be properly cleaned before sterilization. Do not use if the instruments are broken, cracked, or when loose powder is present.
- The instruments in the package are provided non-sterile.
- The instruments in the package must be sterilized prior to use.
- 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. Accuracy of planning and guide fit will diminish with evolving or changing disease processes.



**Precautions:**

- Use only MRI data of recent origin obtained per established PtoleMedic System designated MRI protocols.
- Care should be taken to minimize excessive heat buildup due to friction between the PSI instruments and other instrumentation, such as drills. Excessive heat buildup can lead to deformation of the PSI instrument.
- Do not place heavy instruments on top of the cutting guides instruments during sterilization.



**Limitations**

- Metallic implants in or near the affected joint are known to interfere with the MRI images.
- Provides estimate of implant sizing only. Optimal implant size can only be determined during surgery and may differ from sizes projected during planning. Most estimated implant sizes will typically fall within one size of estimation.
- The software is not for use in planning revision/replacement surgery in persons already having implants in the affected joints.
- DICOM to JPEG file creation – The use of planning images based on the JPEG image format limits some file attributes encoded with the original DICOM images. For instance, some information contained in the DICOM header including image manipulation functions like pan, zoom, full gray scale control, contrast adjustment and pixel resizing are limited or unavailable.
- Digital x-ray data is not acceptable for planning purposes; the files must be MRI images.



**Contra-indications**

- Do not use in patients with active infection of the knee joint area.

**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, touch pad 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)

## **Indication for Use**

The PtoleMedic System is a software interface and image manipulation system used to transfer DICOM images from a Magnetic Resonance Imaging (MRI) system.

The PtoleMedic System creates a surgical plan and produces a **custom surgical instrument** intended to assist the surgeon in the orientation and placement of Total Knee Replacement (TKR) components intra-operatively by guiding the marking of bone or tissue before cutting.

**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 your browser or operating system your screen may look slightly different depending on the software environment. This may include available fonts, spacing between graphical user interface (GUI) components, and some other minor appearance items.

**NOTICE:** The PtoleMedic System Web software does not interact directly with DICOM generating equipment (PACS devices). The image files needed by the PtoleMedic System Web software originate from the MRI/CT 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:  
United States and Canada during normal operating hours +1 (510) 413-3230.

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

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

## 1. Log In

Lento Medical Admin or Sales personnel will assist the surgeon with registering an account for the Lento Medical Innovation web portal. Once a username and password is created, the surgeon will use the information to log in.

- a. Enter Username
- b. Enter Password
- c. Click “Login” button



PtoleMedic Surgical Planning Software Ver. 1.3.1

Please login to see this page.

Enter Username

Enter Password

[New User / Reset Password](#)

 \* Not available for sale in the U.S.A.

## 2. Surgeon Landing Page

The surgeon landing page will appear listing basic information provided by the Surgeon. To see active cases, press the “Current Orders” button.

Surgeon:	Seidel, Markus	<input type="button" value="NEW ORDER"/>
Office Name:	Dr. Markus Seidel	<input type="button" value="CURRENT ORDERS"/>
Office Address:	Kastanienallee 2 Berlin 10435, DE	<input type="button" value="COMPLETED ORDERS"/>
Email Address:	u@lento-medical.com	<input type="button" value="VIEW PREFERENCES"/>
Phone Number:	49304483568	
Fax Number:		

The status of a case that requires surgeon approval will show “Surgeon Approval Ready”

Case #	Patient Name	Order Date	Surgery Date	Surgery Type	Surgery Side	Status
K16g2R	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 will appear.  
From the patient case detail page, surgeon can view case information.

Case ID: K4bgt2R  
Status: Surgeon Approval Ready COMPLETE

Patient

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

[EXPAND](#)  
[SURGEON APPROVAL -](#)

Press “EXPANAD” button to view preference details shown below.

Case ID: K4bgt2R  
Status: Surgeon Approval Ready COMPLETE

Patient

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

<b>Surgeon</b> Name Seidel, Markus Office Name Dr. Markus Seidel Address Kastelenallee 2 Email Address @lentomedical.com Office Number 49304433568 Mobile Number 49304433568 Fax	<b>Distributor</b> Company Name Fedex express Contact Person Express, Fedex Address Jahn-von-Trott-Straße 1 Email Address @lentomedical.com Company Number 491886930003 Mobile Number 491886930003 Fax	<b>Hospital</b> Hospital Name Charité universitätsmedizin Contact Person Berlin, Hospital Address Charitébld. 1 Email Address @lentomedical.com Hospital Number 493043950 Mobile Number 493043950 Fax	<b>MRI Center</b> Center Name IBT-Dentrum Contact Person IBT, Berlin Address Hedder Str. 23 Email Address @lentomedical.com Center Number 4930293607390 Mobile Number 4930293607390 Fax
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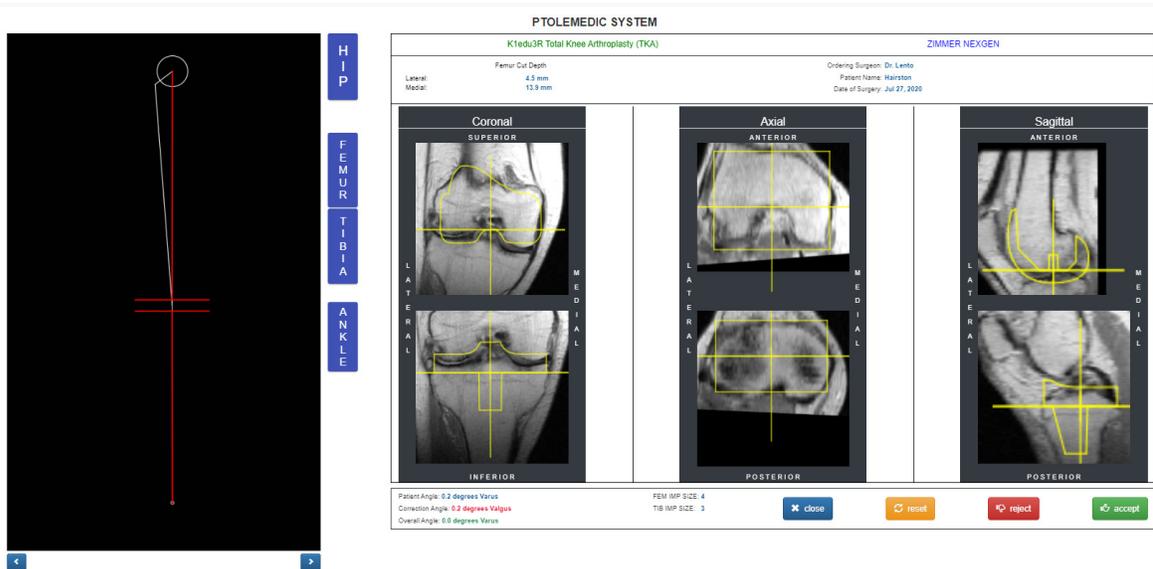
[COLLAPSE](#)  
[SURGEON APPROVAL -](#)

Press “COLLAPSE” to hide the preference.

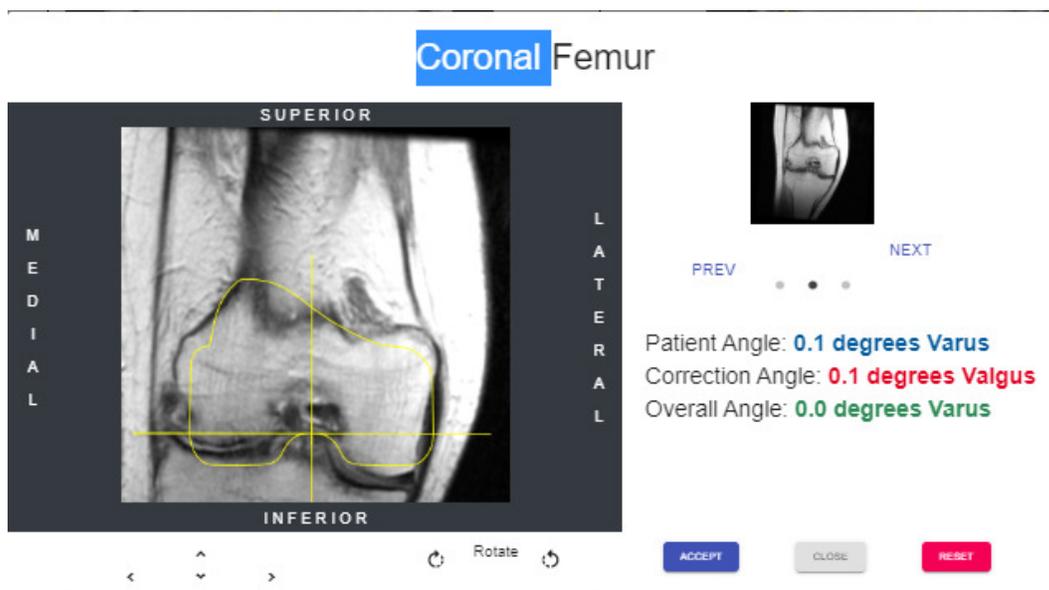
Press the “Surgeon Approve” button and the Surgeon will be directed to the “Surgeon Template Design Approval” Page

#### 4. Surgeon Template Design Approval Page

On this page, surgeon will have the option to view each coronal, sagittal, and axial view of the MRI surgical planning results.

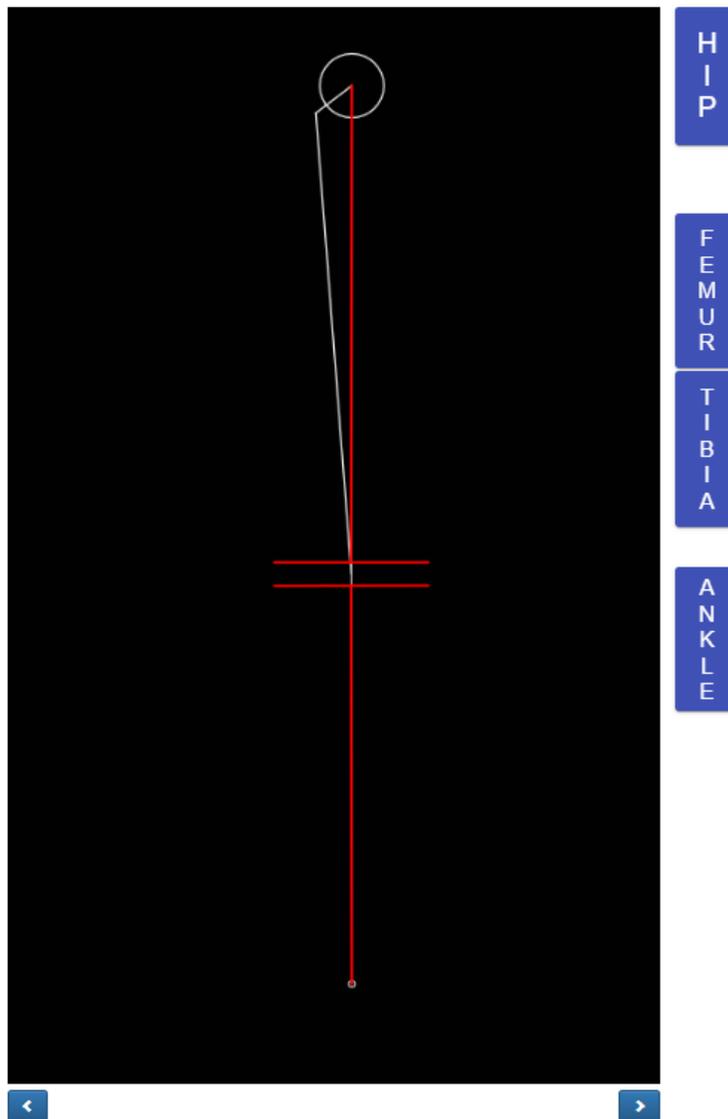


Each Coronal, Axial, and Sagittal view will be enlarged by double clicking the corresponding MRI image, shown as below.



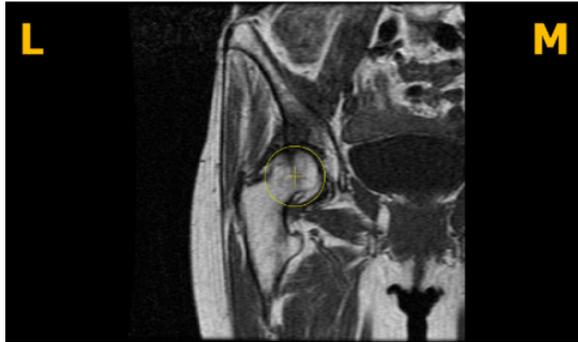
Each arrow button will move the implant positioning (left, right, up, and down)  
The rotate icon/button will rotate the implant by 3 degrees.

The overall limb alignment may be adjusted by clicking the right or left arrow on either side of the knee graphic image. The circle at the top of the graphic represents the center of the femoral head and the brackets at the bottom represent the center of the ankle joint. Each right or left arrow click adjusts the varus/valgus angle of the knee 0.5 degree 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 median of the ankle. The resection lines of the rectangular resection box remain parallel to the floor.



Hip button will display Femoral Head Center in pop up.

Femoral Head Center



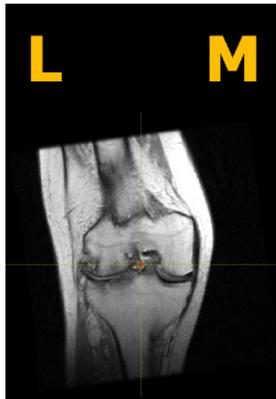
Femur button will display Distal Femur Center in pop up.

Distal Femur Center



Tibia button will display Proximal Tibia Center in pop up.

Proximal Tibia Center



Ankle button will display Ankle Center in pop up.



After the surgeon has finished reviewing the planning data, at the bottom there will be four action buttons displayed. A button labeled reset, a button labeled reject, button labeled accept, and a button labeled close.



If the user presses the close button, system shall discard any saved changes and restore the original values and close the surgeon template approval page. The page will be redirected to the case detail page.

If the user presses the reset button, all the values will revert back to the original values from the beginning prior to any adjustments made by the surgeon user.

If the user presses the reject button, the system shall reject the entire plan. The surgeon will need to submit a reason for rejecting the plan as 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

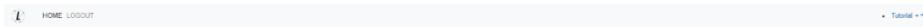
OK Cancel

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.

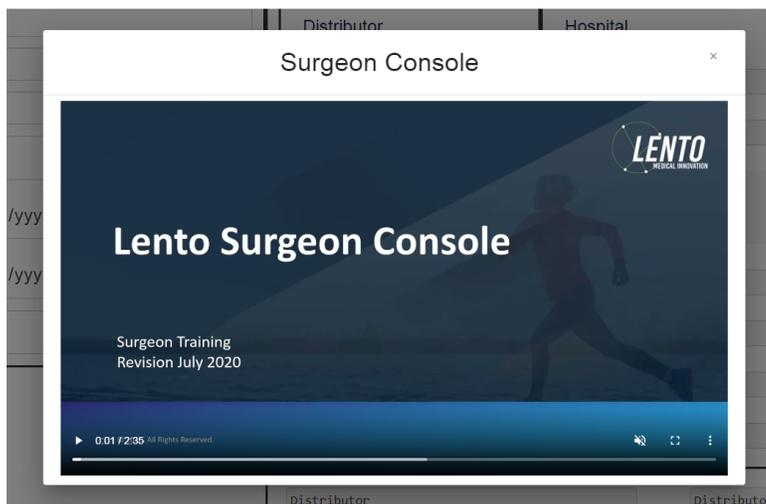
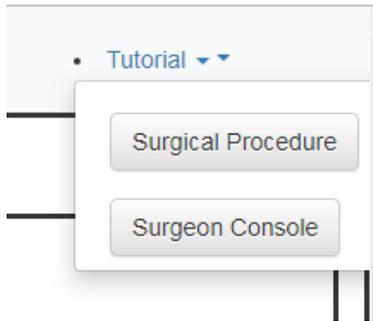
## 5. Tutorial Video

- 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.



Surgeon:	Tuesday, Monday
Office Name:	Monday Office
Office Address:	1254 Humble Berlin, 10719, DE
Email Address:	won1@lenlomedical.com
Phone Number:	4902485800
Fax Number:	1

- NEW ORDER
- CURRENT ORDERS
- COMPLETED ORDERS
- VIEW PREFERENCES



**6. Logout**

If the surgeon user is finished with their session, they can logout by going to the top menu and click logout. The user will be redirected to the login page.

