



Image Acquisition Protocol for X-PSI Knee System

803.305 rev E



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1. Overview

1.1. Image Acquisition protocol for X-PSI Knee System

The X-PSI Knee system is comprised of surgical planning software used pre-operatively, and surgical instrument components that include patient specific guides to precisely align and position the implant components intra-operatively relative to patient's anatomical features per the surgical plan. In X-PSI Knee workflow, the patient X-Ray imaging is used to construct 3-D models of patient's knee joint bony structures and articular surfaces. The constructed model is then used to plan the location and orientation of the knee replacement implant components. The surgical planner software allows the surgeon to review, edit and approved the surgical placement of the implant components relative to the anatomical landmarks. The PSI Knee Planner User Guide (803.307) provides instructions for the use of the Zimmer PSI Knee Planner software application for X-PSI Knee System. The patient specific guides are finally fabricated to fit each patient's anatomy with features that set the relative placement of the implant components per the approved plan.

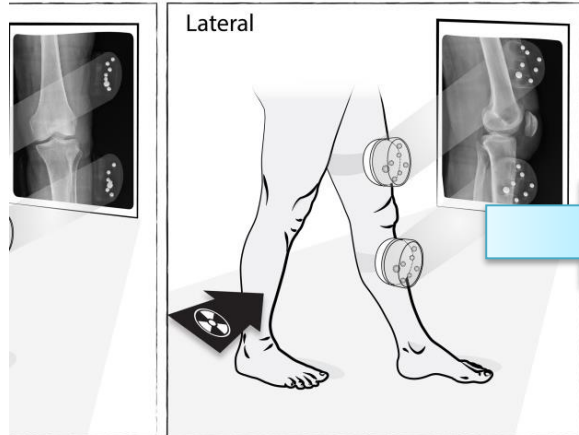
This protocol/guide has to be used with X-PSI Knee System product. It describes the procedure for a full leg X-Ray image set acquisition in Antero-Posterior (AP) and Lateral (LAT). These two full leg image sets are used for creation of patient-specific guides. This protocol is intended for systems with automatic or manual source-tilting. If the full leg images acquisition is done by acquiring several separated images, an adequate overlap between the images is required for an accurate stitching. The stitching of the acquired images (in AP and LAT) by the scan center is optional but it is only acceptable with automatic image stitching. The separated acquired images can be sent to Zimmer Biomet for stitching and image processing. This protocol is not intended for acquisition with source translation and/or manual stitching method.

Consult the PSI Knee Planner User Guide for instructions on utilizing the Zimmer PSI Knee Planner Software for the X-PSI Knee System. For more information on how the system is used in the OR, refer to the X-PSI Knee System Surgical Technique.



1.2. X-PSI Knee 3D Bone Reconstruction Flow

Recreate Acquisition Scene



A 3D scene representing the position of the patient relative to the source and image detector during X-ray scanning is created.

Define patient specific landmarks



The patient's specific bony landmarks are defined on the AP (Antero-Posterior) and lateral images.

Define Patient's Specific Bone contours



The patient's femoral and tibial bone contours are outlined on the A/P and lateral images which captures unique feature of patient's bone anatomy.

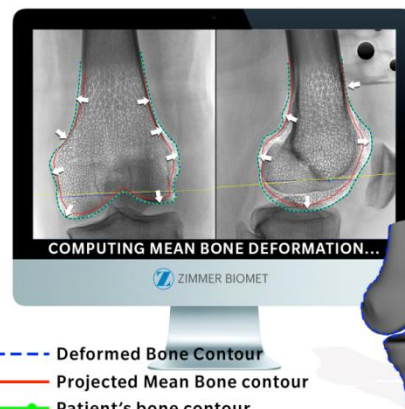
Adding Cartilage



--- Deformed Bone Contour
--- Added Cartilage

Finally, an estimated cartilage thickness is calculated and added for the femur and tibia bones.

Mean Bone Deformation



--- Deformed Bone Contour
--- Projected Mean Bone contour
--- Patient's bone contour

An automatic bone deformation is performed to match the 3D Mean Bone Model to the patient specific contours to fit with the patient anatomy.

Mean Bone Positioning

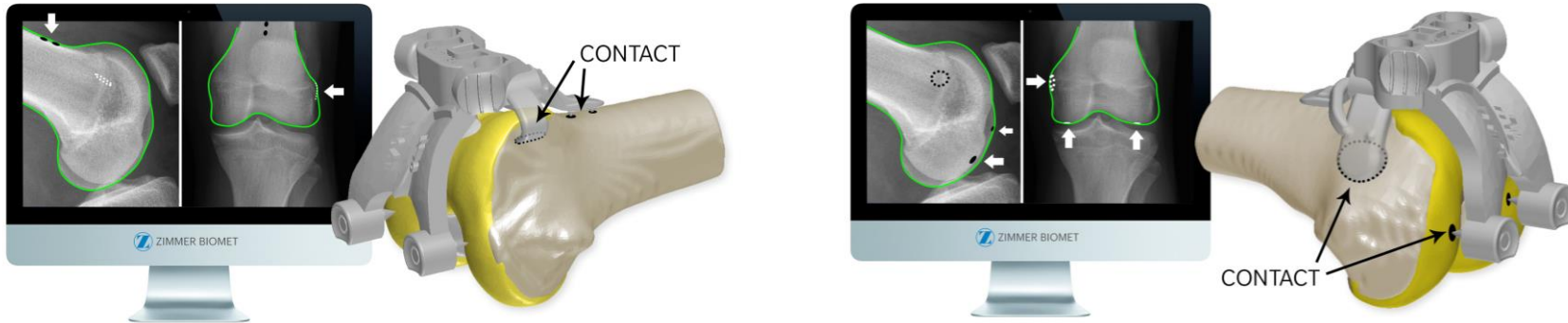


--- Projected Mean Bone contour
--- Patient's bone contour

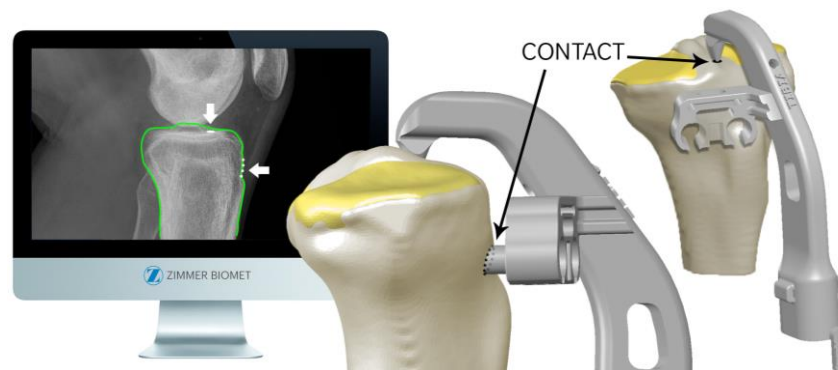
A Mean Bone Model for the femur and tibia is positioned and scaled in the 3D scene inside the patient specific contours.



1.3. X-PSI Knee Patient Specific Guides



The X-PSI Knee instrument guides (jigs) are designed to have a unique fit to the patient's bones using cortical bone contact points and surfaces. The X-PSI Knee Guide's contact surfaces are restricted to the areas which are accurately reconstructed from the A/P and Lateral X-ray images. Details on use of X-PSI Guides are in the "Intraoperative Guide" section in X-PSI System Surgical Technique.





2. Materials



X-Ray Marker 3D X-PSI
(Part Number: 20-8017-020-00)
Quantity: 2



X-Ray Calibration Strap
(Two lengths available)
(Part Number: 20-8017-022-00
and 20-8017-023-00)
Quantity: 2

The X-Ray Marker 3D X-PSI includes seven radio-opaque spheres of different dimensions in a solid plastic housing. It is used to define the distance between the Knee and X-ray source. The Marker has a curvature on one side with the hook component for a hook-and-loop fibrous connection (e.g. Velcro®). This curvature imitates the curvature on the leg. This device needs to be positioned correctly on the **X-Ray Calibration Strap** before X-ray acquisition. The X-Ray Calibration Straps are available in two different lengths (short and long).

The X-Ray Marker 3D X-PSI and the X-ray calibration straps are cleanable and reusable. Refer to the X-PSI Knee System Instruction for use for more details on cleaning method.



3. Patient preparation

3.1. Positioning of the X-Ray Calibration Strap

The X-Ray calibration Strap can be placed by the patient or the scan technician:

- Wrap one band firmly around the thigh and attach it with the hook end. The band should be at least four (4) inches (10 cm) from the knee joint line.
- Wrap one band firmly around the calf and attach it with the hook end. The band should be at least four (4) inches (10 cm) from the knee joint line.



Figure 1: Positioning of X-Ray Calibration Straps



3.2. Positioning of the X-ray Marker 3D X-PSI by the Scan Technician

The X-Ray Marker 3D X-PSI (x2) should be positioned by the scan technician as per following instructions:

- Before positioning the X-Ray Marker 3D X-PSI, make sure both X-Ray Calibration Straps are stable on the patient's leg.
- Install each X-Ray Marker 3D X-PSI, by sticking the curved side of the marker (with the hook face) to the strap. Press firmly the marker onto the strap. Both X-Ray Marker 3D X-PSI should be placed at about 45 degrees related to the patient's body lateral plane (Figure 2). The following visual reference cues must be respected:
 - ✓ The Zimmer Biomet Logo must be legible horizontally
 - ✓ The curvature of the device must match that of the leg

Make sure that each X-Ray Marker 3D X-PSI is stable on both X-Ray Calibration Straps. The markers need to stay in place during the imaging process and while changing patient's position from frontal to lateral.

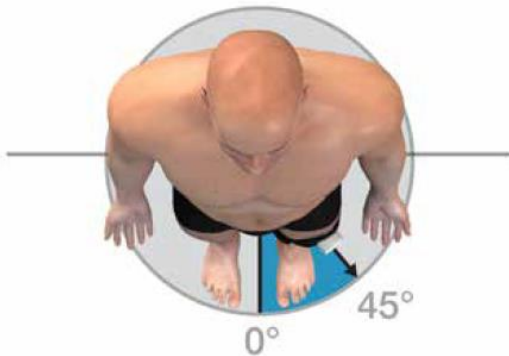


Figure 2: X-Ray Marker 3D X-PSI at 45° relative to body lateral plane



Figure 3: Zimmer Biomet Logo legible horizontally

4. Machine parameters

SID (source to image distance)	A distance of 72 inches, or 180 cm is recommended. Set to the fixed value to capture the full leg with automatic source-tilting. It is recommended to use the same standard fixed value for every patient. Make sure this value is included correctly in the image information or engraved on the images.
Imager spacing	Value less than 0.25mm is recommended. Make sure this value is included correctly in the image information



5. Imaging procedure

- Position the patient in standing position with leg in extension. The imaging needs to be done only in stable standing position, weight-bearing on both legs.
- Minimize the distance between patient and the X-ray detector.
- Select an adequate SID value to cover the entire leg from above the femoral head to below the ankle joint. The knee joint and all bony landmarks (Femoral head contour and ankle) should be visible on the final A/P and Lateral stitched images. **The SID value should be fixed during the entire study. DO NOT alter this distance between different images.**

5.1. A/P Exposure

Place the patient in frontal position with both legs towards X-ray source. The imaging needs to cover the entire leg from above the femoral head to below the ankle joint.

5.2. LAT Exposure

Place the patient in lateral position and offset the leg as recommended. The surgical leg should be towards the X-ray detector. The imaging needs to cover the entire leg from above the femoral head to below the ankle joint.

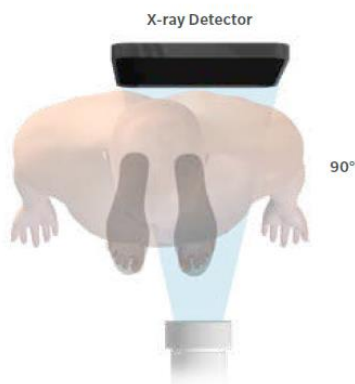


Figure 4: Patient Position for AP Exposure

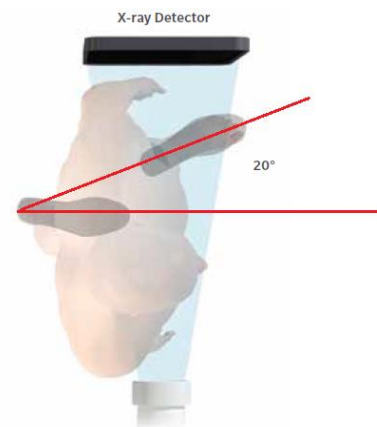


Figure 5: Patient Position for LAT Exposure

Note:

- **No patient movement** between any of the sequential images in A/P or LAT exposure is allowed.
- The **Femoral head contour and ankle** must be clearly discernable on both images.
- **The entire X-Ray Marker 3D X-PSI should be visible** on the final A/P and Lateral stitched images.
- The **X-Ray Marker 3D X-PSI should stay in place** during the image process and while changing from frontal to lateral position. **No repositioning of any of the Marker** is permitted during the procedure.



5.3. Stitching requirement



Figure 6: Example of Stitched images AP and LAT

The stitching can be done automatically on **A/P and LAT** images by available software at the scan center if possible. All acquired images (full leg image (if any) and separate leg regions image acquisition in AP and Lateral) should be sent to Zimmer Biomet.

An adequate overlap between images should exist to make an accurate stitching possible. It is recommended that images are not stitched/overlapped in the knee joint area.

The Scan Technician should check the following on full A/P and LAT images, before image transfer:

- **Visibility of all required anatomy:**

- ✓ Femoral head contour
- ✓ Ankle
- ✓ Entire knee joint

ideally images should not stitch/overlap at these areas

- **Visibility of entire X-Ray Marker 3D X-PSI on AP and LAT,**

- **Following machine parameters as well as patient parameters are recorded correctly and are the same for all images:**

- ✓ SID
- ✓ Pixel spacing
- ✓ Patient gender (male/female)
- ✓ Laterality (left/right)
- ✓ Surgeon name



- ✓ First letter of patient first name and 2 first letters of patient last name OR/ PSI Case ID

Example of acceptable images:

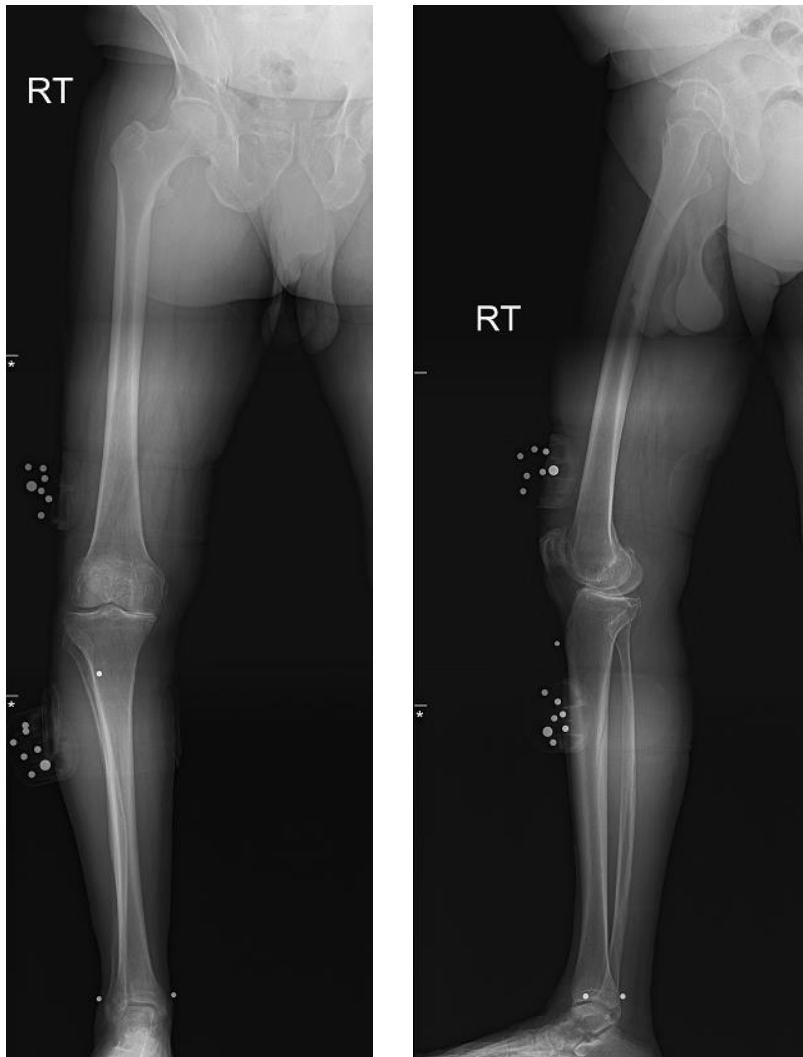


Figure 7: Example of Good Image Quality and Stitching in AP and LAT

The femoral-tibial junctions and bone contours are clearly visible. Both X-Ray Marker 3D X-PSI are entirely visible on images and stitching points are outside of the knee joint region. For an example of acceptable images, please refer to Figure 7.



5.4. Image acquisition requirements in DICOM Header:

Make sure that the following patient reduced information and image acquisition details are included in the DICOM images. If not, create and send an email by using the following template:

To: personalizedsolutions@zimmerbiomet.com

Subject: PSI X-ray patient acquisition details

This email is to send the image acquisition details for the patient, uniquely recognized according to the following reduced information:

- Surgeon name
- Image center name
- Patient operating side (Left/Right)
- Patient Gender (Male/Female)
- First letter of patient first name
- 2 first letters of patient last name
- Source to Image Distance (SID) in mm
- Image pixel spacing in mm

Sender name and contact information

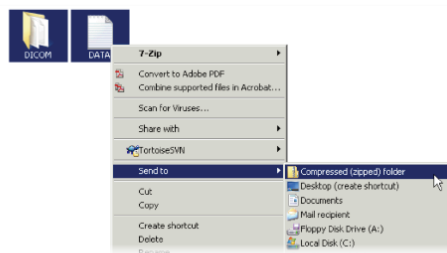


6. Image transfer

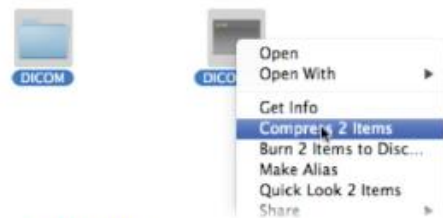
Image Transfer through SMS (www.zimmersms.com)

Note: Reduced identification is NOT required

1. **Acquire** the images according to the protocol in section 4. All acquired images (full leg image (if any) and/or separate leg regions image acquisition in AP and Lateral) should be sent to Zimmer Biomet.
2. **Save** the scan in the DICOM file format.
3. **Compress** the DICOM all together using a Zip (compressed) file format.
First, copy the folder containing all DICOM images on your Desktop. Then, right click on this folder and select compress.



Compressing the DICOM files on a PC ...



... and on a Mac.

4. **Rename** the ZIP (compressed) file with PSI X-ray case ID provided by Zimmer Biomet corresponding to the patient.



5. **Upload** the images on Zimmer SMS:

Transfer the images by clicking on “UPLOAD SCANS” in the corresponding case which will bring you to the upload page.

Case #1571550	PENDING
Details	
Site: 01 T0000 LOS ANGELES, CA	
Sales Associate / Team: CAS SALES REP	
Account: GENERAL SURGERY CENTER (00004)	
Surgeon: JANE DOE	
Patient: JOHN SMITH (Male / Age 89, 01-01-1925)	
Coverage:	
Surgery: Sep 11, 2014 7:00 AM (Sep 11, 2014 4:00 AM)	
Pickup: Sep 11, 2014	
Surgery Information (Show All)	
Description:	
Procedure: Knee - Total (2002)	
Body Side: LEFT	
Zimmer PSI (Show All)	
CAS PSI Case: Yes	
Warnings: Left: Delay Approval, Delay Scan (View)	
Scan Center: GENERAL SCAN CTR (0003)	
Scan Date: Aug 26, 2014	
Left Body Side	
Case ID: TNO411L25J514US	Click
Scan Images:	UPLOAD SCANS
Status: Case Created/Awaiting Images	



Image Transfer through other transfer methods

(CD, DVD, USB, FTP, other transfer methods such as www.wetransfer.com, www.hightail.com¹)

Notes: Reduced identification is ALWAYS required.

Do NOT use “ALTE” (DICOM export via PACS) to save the images. “AGFA” or preferably CD should be used.

If you are located in Europe Middle-East & Africa (EMEA), refer to 806 001 - PSI Logistics Guide EMEA.

The imaging center will be responsible to reduce the patient identification of the DICOM image set. The reduced identification shall remove any element permitting to identify the patient. This includes but is not be limited to:

- Patient Name
- Date Of Birth
- Social Insurance Number
- Phone Number(s)

Follow the steps below for the transfer of images:

1. **Acquire** the images according to the protocol in section 4. All acquired images (full leg image (if any) and/or separate leg regions image acquisition in AP and Lateral) should be sent to Zimmer Biomet.
2. **Save** the scan in the DICOM file format
3. **Reduced identification** the DICOM images as shown in [Table 1](#):

Table 1 | Reduced identification Parameters

DICOM Field	PATIENT Different values for every case; provided by the Zimmer Sales associate
	Value
PatientName	XXX1111R (Zimmer Case ID provided by Zimmer CAS) Can be 8 or 15 characters
PatientID (optional)	XXXX11111 (Hospital Patient ID)
PatientBirthDate	1900/01/01 (If date can't be deleted, put this actual value)

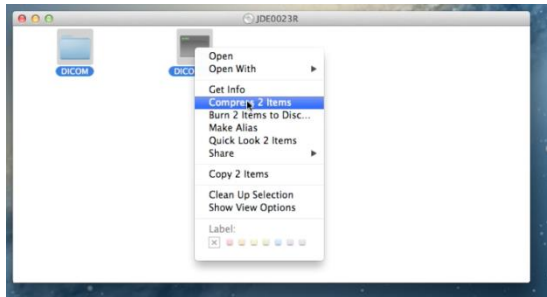
¹ Zimmer does not endorse or recommend any particular transfer method. It is the responsibility of the transferring party to ensure that the transfer method complies with applicable privacy and security laws and regulations.



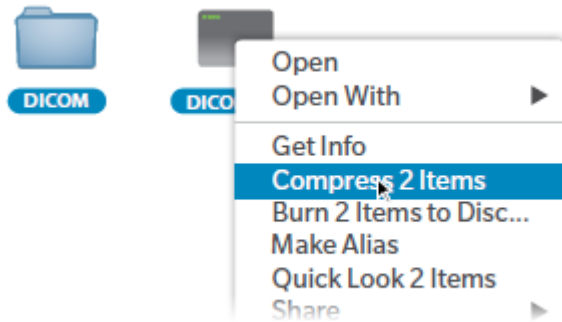
4. **Compress** the DICOM all together using a Zip (compressed) file format.

First, copy the folder containing all DICOM images on your desktop. Then, right click on this folder and select Compress:

On a PC:



On a MAC:



5. **Rename** the ZIP (compressed) file according to Table 1 first row:



6. **Transfer** the zip file to Zimmer per chosen method (CD, DVD, USB, FTP, www.wetransfer.com)

Note: when using www.wetransfer.com www.hightail.com or any other web transfer service, send images to psi-xray@zimmercas.com



7. Contact information

Legal Manufacturer

Zimmer CAS

75, Queen Street, Suite 3300
Montreal (Quebec) H3C 2N6
CANADA

Tel: 1 (514) 861-4074

Fax: 1 (514) 878-3801

Web site: www.zimmerbiomet.com

Email: personalizedsolutions@zimmerbiomet.com

Customer Support

Tel: 1 (866) 336-7846

European Community (EC) Representative

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