

Bodycad Unicompartmental Knee System

Imaging Guide





IMPORTANT NOTE

This procedure provides only the information necessary for **Bodycad** to design and manufacture personalized restorations. The procedure described in this document can differ from the procedure used for diagnostic purposes. It is the responsibility of the physician to determine if further tests are required for diagnostic purposes. In this document, CT stands for Computed Tomography or Computerized Axial Tomography and MRI for Magnetic Resonance Imaging.

Introduction and purpose

Through its mission, The Pursuit of Orthopaedic Perfection™, Bodycad aims to bring to the market personalized restorations which are designed from a personalized virtual 3D model of the knee joint. The 3D model of the bone is produced by Bodycad Imager software which includes 3D image segmentation from the patients CT and MR images. More specifically, the present protocol provides scanning requirements information to healthcare professionals for capturing the patient CT and MR images of the knee, femur and tibia bone regions, in regards to these algorithms.

It is important to follow this protocol as this will produce a more accurate 3D model and will increase the precision of the personalized restoration. A high quality image will give the best results for a high level of accuracy. A PREP Tech stands ready to assist with any questions you may have or additional information you may need.

MRI Procedure

for the Bodycad Unicompartmental Knee System

Magnetic Resonance Imaging (MRI)

Position of the Patient

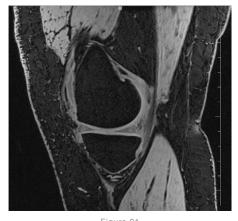
The patient position must be optimized to improve image quality.

Images Acquisition

The magnetic resonance images must be taken using a coil that offers the best fit with patient anatomy. It is recommended to use specific coil as a first choice or a flex coil as an alternate choice.

Sequence Description

Instrument 1.5 / 3.0 tesla	
Type	Isometric
Size	512 x 512
Axis	Sagittal

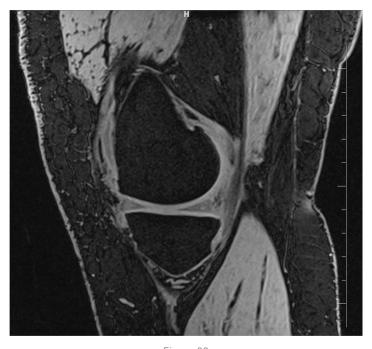


Example of a Magnetic Resonance Image (MRI)

Bone Imaging

The sequence of the magnetic resonance image must produce the most uniform black bone surface. Figure 01 shows an example of the expected image quality

Instrument	Item	Value
Siemens Verio 3T	Name of the Sequence	T1 VIBE WE (Water Excitation) ISO (Isometric)
	Repetition Time (TR)	10.1 msec
	Echo Time (TE)	4.9 msec
	Thickness of the Cut	0.6 mm
	Matrix	256 x 256
	Field of View (FOV)	150 mm
	Flip Angle	10 degrees
	Number of Cuts	160 cuts



- **Figure 02** -Image Example

Instrument	Item	Value
	Name of the Sequence	T1 VIBE WE (Water Selective Cartilage)
	Repetition Time (TR)	14.2 msec
	Echo Time (TE)	6.2 msec
Siemens	Thickness of the Cut	0.6 mm
Avanto 1.5T	Matrix	256 x 238
	Field of View (FOV)	150 mm
	Flip Angle	10 degrees
	Number of Cuts	160 cuts



Image Example with Siemens Avanto 1.5T instrument

Instrument	Item	Value
Philips Achiva 3T	Name of the Sequence	T1 3D WATS (Water Selective Cartilage)
	Repetition Time (TR)	20 msec
	Echo Time (TE)	4.5 msec
	Thickness of the Cut	0.7 mm
	Matrix	300 X 300
	Field of View (FOV)	150 mm
	Flip Angle	15 degrees



Image Example with Philips Archiva 3T instrument

Instrument	Item	Value
GE 1.5T	Name of the Sequence	3D SPGR
	Repetition Time (TR)	42 msec
	Echo Time (TE)	7 msec
	Thickness of the Cut	1 mm
	Matrix	512 x 512
	Flip Angle	20 degrees
	Interpolation	Using ZIP (Zero Interpolation Filling)



Image Example with *GE 1.5T* instrument

X-Rays Scanning procedure

for the Bodycad Unicompartmental Knee System

Position of the Patient

- Any non fixed metallic objects wore by the patient must be removed.
- The patient should be in a standing and weight-bearing position.
- The x-ray must include at least the anterior inferior iliac spine to the talus. The knees are in full extension, without rotation.
- The legs should be as parallel as possible without rotation.
- The knees are in full extension, without rotation.
- The patient's feet are placed straight ahead with weight evenly distributed on both feet.
- The arms are folded upward to the head.
- Patient must not move during the whole scanning period. If this occurs, the scanning must be restarted.
 Support handles may be required for some patients.



— Figure 13 — Example of Image

- Place a marker in order to indicate left or right of the patient.

Exposure

- Use enough density to demonstrate the superimposed bones and to get well defined cortical outlines.
- The soft tissues must be shown.

CT Procedure

for the Bodycad Unicompartmental Knee System

Computed tomography (CT) or Compurterized axial tomography (CT)

Position of the Patient

The patient position must be optimized to improve image quality.

Images Acquisition

Image acquisition must cover region of interest of the joint and enough margins around the region to to obtain the bone shape in order to sit the cutting guide. The margins around the region of interest must be around 3 to 4 cm.

Reconstruction Axis

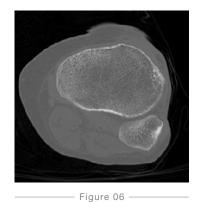
The images should be reconstructed for axial, sagittal, and coronal axis.

Image Renconstruction

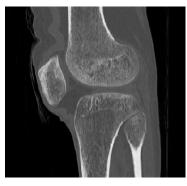
Image resolution should be as high as possible in respect of patient dose. At a minimum, the slice thickness in the axial view should be 1 mm. However, a lower value (e.g. 0.6 mm) is even more desirable if possible.

CT Scanning Parameters

Slice Thickness	1 mm or smaller (0.6 mm is desirable)
Field of View	Choose the smallest possible FOV that permits to capture the bones of interest and partial skin and soft tissue.
Matrix	512 x 512
KVP	120 to 140 kVp
Algorithm / Kernel	 Bone or Boneplus (GE) Ultra High Resolution, at least U40 and higher (Siemens) At least B60f and higher (Siemens) Other kernels that give as much high bone contrast as possible with respect to the surrounding tissue. Ensure that there is no edge enhancement
MAs	150 mm







— Figure 07 — CT - Sagittal View



CT - Coronal View

CT Scaning Procedure for the full legs

for the Bodycad Unicompartmental Knee System

*This is an optional step. Bodycad does not need this data for the design of the personalized restoration. These images are for surgeons who want to further assess the mechanical axis of the patient in 3D.

Position of the Patient

- The patient must be in a supine position with feet first (FFS) into the gantry.
 Patient must stay stationary.
- If movement occurs, the scanning must be restarted.
- The legs should be as parallel as possible to the table horizontally, without rotation.
- The knees are in full extension, without rotation.
- The patient's feet are arranged as perpendicular as possible relative to the table, the toes pointing straight up.
- The arms are folded upward to the head.
- Support may be used in order to maintain the required patient position.
 As an example, provide ankle support in order to stabilize the leg;
 put a lumbar support to prevent from back pain.
- Refer to Figure 09 and Figure 10 for this patient position.



Figure 09

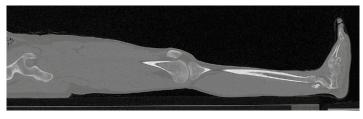
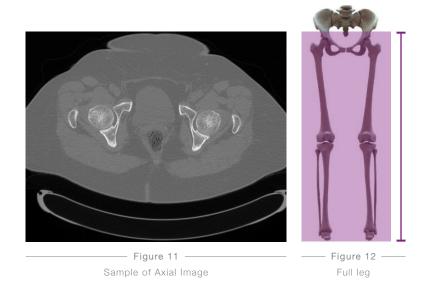


Figure 10

Region of interest

- Images must be acquired from the anterior inferior iliac spine to the ankle and should include at least the talus. The entire foot can be included (see Figure 12).
- Partial skin and soft tissue must be captured with the bone regions.



CT Scanning Parameters

Slice Thickness	1 mm
Field of View	Choose the smallest possible FOV that permits to capture the bones of interest and partial skin and soft tissue.
Matrix	512 x 512
KVP	120 to 140 kVp
Algorithm / Kernel	- Bone or Boneplus (GE)
	- Ultra High Resolution, at least U40 and higher (Siemens)
	- At least B60f and higher (Siemens)
	- Other kernels that give as much high bone contrast as possible with respect to the surrounding tissue.
	- Ensure that there is no edge enhancement
MAs	Automatic value from the machine

Data Anonymization and privacy

- Be sure that the required rights for transmitting data to Bodycad are respected.
- The patient name and ID must be kept in the transmitted data.
- The transmitted data will be anonymized by Bodycad before the whole process of personalized restoration begins. This anonymization follows the established Bodycad quality procedure and patient privacy guidelines.

Transmission of images

File format and instructions:

- Use only DICOM format, without lossy compression.
- Provide the images with the parameters, the scout view, additional images, notes or additional information.

Send the labelled CD or DVD to the following adress:

Bodycad Imaging,
Bodycad Laboratories Inc.
2035 rue du Haut-Bord, Québec (Qc)
Canada G1N 4R7

Use our online tool to send data:

Imager

https://imager.bodycad.com

- Please contact your preptech for shipping instructions and/or account numbers.
- Ensure that the CD or DVD is packaged appropriately in order to avoid breakage during transport.



Please direct all questions to preptech@bodycad.com or call +1 418 527-1388 and ask for a PrepTech.



The Pursuit of Orthopaedic Perfection™



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BC-000026-V03-EN-W-2018-01-25