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 bone and of the tumor. 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 hip, the knee, the femur and the tibia bone regions in regard to Bodycad’s 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.

GENERAL SCANNING PROCEDURE

Patient preparation for CT or MRI scanning
- Any non-fixed metallic objects worn by the patient must be removed.
- Patient must stay stationary. If movement occurs, the scanning must be restarted.
- Make the patient as comfortable as possible.
- Support may be installed in order to prevent motion or rotation of the body part to be scanned during the whole scanning.
- Put a pillow between the two feet in order to create a space of about 10 cm.
GENERAL CT SCANNING REQUIREMENTS

CT scanning instructions
- Acquire only primary axial slices.
- No edge enhancement.
- No oblique reconstruction.
- No gantry tilt.
- Provide reformatted coronal and sagittal slices.
- The images must be provided in standard DICOM format only. Lossy compression is prohibited.

Field of view
- Position the table so that the area to be scanned is centered in the field of view.
- Do not change the field of view, the table height nor the reconstruction center during the scanning.
- Choose the smallest field of view possible that includes the whole bones of interest and partial skin and soft tissue.

SPECIFIC CT SCANNING REQUIREMENTS FOR THE HIP

Patient position
- The patient must be in a supine position with feet first (FFS) into the gantry.
- The legs are fully straight, without rotation.
- Ensure that there is no rotation of the pelvis.
- The arms are folded upward to the head.
- Support may be used in order to maintain the required patient position. As an example, put a small pillow under the knee.

Region of interest
- Images must be acquired about 5 cm above the most superior point of the ilium to about 5 cm below the most inferior point at the ischium (Figure 1).
- Partial skin and soft tissue must be captured with the bone regions.
SPECIFIC CT SCANNING REQUIREMENTS FOR THE KNEE

Patient position
- The patient must be in a supine position with feet first (FFS) into the gantry.
- The legs are extended, without rotation.
- Support may be used in order to maintain the required patient position.

Region of interest
- Images must be acquired 1/3 distal of the femur to about 1/3 proximal of the tibia and must include the patella (Figure 2).
- Partial skin and soft tissue must be captured with the bone regions (Figure 3).

Figure 2: Sample of Axial Image
Figure 3: 3D model
SPECIFIC CT SCANNING REQUIREMENTS FOR THE FEMUR OR THE TIBIA

Patient position

- The patient must be in a supine position with feet first (FFS) into the gantry.
- 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 4 and Figure 5 for this patient position.
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 (Figure 7).
- Partial skin and soft tissue must be captured with the bone regions.

Figure 6: Sample of Axial Image

Figure 7
## CT Scanning Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slice thickness</td>
<td>1 mm or smaller (0.6 mm is desirable)</td>
</tr>
<tr>
<td>Field of view</td>
<td>Choose the smallest possible FOV that permits the capture of the bones of interest and partial skin and soft tissue</td>
</tr>
<tr>
<td>Matrix</td>
<td>512 x 512</td>
</tr>
<tr>
<td>KVP</td>
<td>120 to 140 kVp</td>
</tr>
</tbody>
</table>
| 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                   |
GENERAL MRI SCANNING REQUIREMENTS

In addition to the patient CT images, MR images of the tumor may be required so as to get precise delineation of the tumor with respect to the surrounding bone and soft tissue region.

MRI scanning instructions

- No oblique reconstruction.
- The images must be provided in standard DICOM format only. Lossy compression is prohibited.
- Use appropriate coil for scanned body part; for example, use the knee coil for the knee.

Patient position

- The patient must be in a supine position with feet first (FFS) into the gantry.
- The legs are fully straight, without rotation.
- Ensure that there is no rotation of the body part to be scanned.
- Support may be used in order to maintain the required patient position and to ensure patient comfort.
REGION OF INTEREST
Images must be acquired inside a bounding box of 5 to 10 cm from either side of the tumor, along the acquisition axis (Figure 8).

MRI SCANNING PARAMETERS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slice thickness</td>
<td>1 mm or smaller</td>
</tr>
<tr>
<td>Acquisition type</td>
<td>3D with isotropic spatial resolution</td>
</tr>
<tr>
<td>Field of view</td>
<td>Choose the smallest possible FOV that permits to capture appropriately the tumor and the surrounding bones and soft tissue</td>
</tr>
<tr>
<td>Matrix</td>
<td>512 x 512</td>
</tr>
</tbody>
</table>
| Protocol name           | • The physician has the responsibility to define the appropriate MRI protocols so as to get the maximum precision about the tumor  
                          | • Questions may be addressed to Bodycad if additional information or validation about the MR imaging protocol is required |
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.
- Label the CD or the DVD.

Mail
- The labeled CD or DVD of the images can be sent by mail to the following address:

  OnCall Imaging  
  Bodycad Laboratories Inc.  
  2035 rue du Haut-Bord  
  Québec, Qc, Canada  
  G1N 4R7  
  Tel.: 418 527-1388

Shipping
- Please contact oncall@bodycad or call 418 527-1388  
  ask for Bodycad OnCall department for shipping account numbers.

Important note
- Ensure that the CD or DVD is packaged appropriately in order to avoid breakage during transport.

Questions and Information
- Please contact oncall@bodycad.com or call 418 527-1388. Ask for the OnCall department.