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CT SCAN PROTOCOL

Lower Extremity

Purpose and Summary

CT images made with this protocol are used to provide the orthopedic surgeon with a detailed 3D anatomical reconstruction of the patient's anatomy (femur, tibia, fibula, pelvis). This virtual 3D model is intended for the creation of an anatomical model, a personalized pre-surgical plan or the design of personalized instrumentation for a lower extremity osteotomy surgery.

This CT scanning protocol consists of a localizer and a detailed axial scan of the anatomy (full leg; 3 regions: hip, knee, ankle; fibula or pelvis). A clear visualization of bone structures is needed. Image quality should reach a level required for radiological evaluations of the bone. Deviations from this protocol may result in an unusable scan and delay of surgery.

When using this protocol, apply dose reduction techniques and optimize scan parameters within the provided ranges to limit the dose delivered to the patient.

Read the following instructions carefully before scanning. Please contact Materialise Customer Support if you require further clarification: ortho@materialise.be.ortho@materialise.be

NOTE

CT scan quality is critical to the production of accurate personalized surgical instruments. Please ensure that all protocol steps are followed for optimum scan quality. If there is a recent CT scan (< 4 months old) available, check whether this scan matches the requirements outlined below to avoid an unnecessary scan.

IMPORTANT

This 3-region protocol cannot be used for the planning or design of guides and models for proximal femur or distal tibia cases.

This CT scan protocol has been designed to provide scan centers' personnel with easy-to-use instructions to obtain correct images with optimal quality that will be further used in the process of surgical planning and design of personalized surgical instruments that support on bone. Materialise cannot be held liable for other possible subsequent uses (i.e. diagnostic uses).

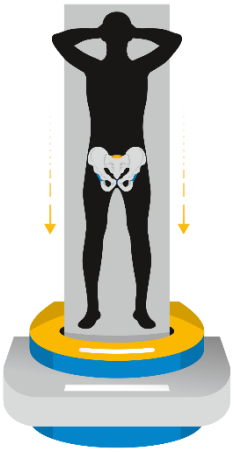
Note that it is required to perform the surgery within 6 months of the CT scan date to ensure anatomic changes are minimized. If the patient's anatomy has changed significantly since the time of the CT scan, the personalized models and instruments should not be used, even if the time period of 6 months has not expired.

Materialise identified a safe period for use of the guides for pediatric cases (3 weeks from the date of performing the CT scans).

SCAN PREPARATIONS

Patient Preparation

- Discuss the procedure with the patient. Make the patient comfortable and instruct him/her not to move during the procedure. Patient movement will prevent the accurate reproduction of the anatomical model.
- Remove any non-fixed metal prosthesis, jewelry, zippers that might interfere with the region to be scanned.
- Prepare the patient for bilateral scanning – left and right anatomies are requested.
- Positioning of the patient:
    - Patient laying supine with legs extended
    - Aim to position the legs in natural alignment with neutral rotation
    - Aim to no un-natural tilt or lift of the pelvis
    - Arms folded upward away



Scan Requirements

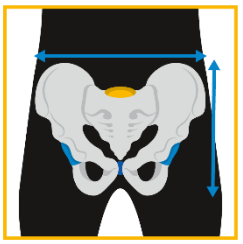
Table position	- Set the table height so that the area to be scanned is centered in the scan field. - **DO NOT** alter the X or Y centering between scans. Center points must be identical. - **DO NOT** change the table position between images so that all images create one unified volume
Side indication	Always place a marker indicating the side. Use a marker that does not hinder the quality of the CT scan.
Gantry Tilt	**NO** gantry tilt
Bilateral imaging	Bilateral imaging is requested. Reconstruct them separately.
Reconstruction	- Use true axial slices. - **NO** oblique slices - **NO** reformatted images. - **NO** secondary reconstructions. Images must be scanned at the given parameters or stricter. - **NO** reformations in coronal or sagittal plane - **NO** MPR's. - **NO** 3D reconstructions. - **NO** lossy compression.
Region of interest	Only the bony regions are of interest. Capturing the surrounding soft tissue is not necessary.
Algorithm	Moderate / soft tissue, with no edge enhancement

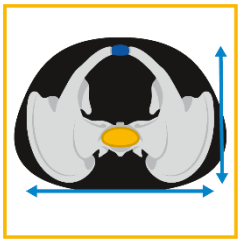
NOTE

We recommend building a "Materialise anatomy" in your CT scanner with the appropriate ranges and parameters.

Scan Parameters Pelvis

Region of interest	**Hip (pelvis):** The complete pelvis needs to be scanned from above the most superior point of the ilium down to below most inferior point at the ischium
Collimation	Slice thickness: 1– 1.5 mm (preferred value; acceptable value: ≤3 mm)
	Slice increment: 0.5 – 0.75 (50% overlap)
kVp	100-140
mAs	As given by the automatic system
Pitch	Use **1** or smaller
Field of View (FOV)	FOV ≤ 40 cm (smallest FOV that includes the complete bony pelvis)
Matrix	Use a 512 x 512 matrix





Scan Parameters Full Leg

Region of interest	**Femur/Tibia:** From below the talus to above the femoral head **Fibula:** From below the talus to above the knee joint
Collimation	Slice thickness: Maximum 1 mm for contiguous and ≤1.5 for overlapping
	Slice increment: 0.625mm – 0.75mm (50% overlap)
kVp	120
mAs	As given by the automatic system
Pitch	Use **1** or smaller
Field of View (FOV)	- Use a FOV for the left and a second FOV for the right anatomy in the same bilateral scan. Although scanning the patient once, two high resolution datasets are obtained. - ≤ 25 cm x 25 cm (32 cm x32 cm for bilateral). Use smallest FOV that includes the complete bony anatomy of interest. - Scan all slices with the same FOV, reconstruction center AND table height (coordinate system).
Matrix	Use a 512 x 512 matrix
Algorithm	Moderate / soft tissue, with no edge enhancement

Scan Parameters – 3 regions scan: for osteotomies around the knee only

Region of interest	**Hip region**: from below to above the femoral head
Collimation	Slice thickness: 1.25mm – 1.50mm
	Slice increment: 1.25mm - 1.50mm (contiguous slices)
kVp	90 (120 for obese patients or metal hardware in hip region)
mAs	As given by the automatic system
Pitch	Use **2** or smaller
Field of View (FOV)	Use a FOV for the left and a second FOV for the right anatomy in the same bilateral scan. Although scanning the patient once, two high resolution datasets are obtained. ≤ 25 cm x 25 cm (32 cm x32 cm for bilateral). Use smallest FOV that includes the complete bony anatomy of interest. Scan all slices with the same FOV, reconstruction center AND table height (coordinate system).
Matrix	Use a 512 x 512 matrix
Algorithm	Moderate / soft tissue, with no edge enhancement

Region of interest	**Knee** – 25cm above and below
Collimation	Slice thickness: 1.25mm - 1.50mm
	Slice increment: 0.625mm – 0.7mm (50% overlap)
kVp	120
mAs	As given by the automatic system
Pitch	Use **1** or smaller
Field of View (FOV)	Use a FOV for the left and a second FOV for the right anatomy in the same bilateral scan. Although scanning the patient once, two high resolution datasets are obtained. ≤ 25 cm x 25 cm (32 cm x32 cm for bilateral). Use smallest FOV that includes the complete bony anatomy of interest. Scan all slices with the same FOV, reconstruction center AND table height (coordinate system).
Matrix	Use a 512 x 512 matrix
Algorithm	Moderate / soft tissue, with no edge enhancement

Region of interest	**Ankle region:** a few cm's below and above the ankle joint
Collimation	Slice thickness: 1.25mm - 1.50mm
	Slice increment: 1.25mm - 1.50mm (contiguous slices)
kVp	120
mAs	As given by the automatic system

Pitch	Use **2** or smaller
Field of View (FOV)	Use a FOV for the left and a second FOV for the right anatomy in the same bilateral scan. Although scanning the patient once, two high resolution datasets are obtained. ≤ 25 cm x 25 cm (32 cm x32 cm for bilateral). Use smallest FOV that includes the complete bony anatomy of interest. Scan all slices with the same FOV, reconstruction center AND table height (coordinate system).
Matrix	Use a 512 x 512 matrix
Algorithm	Moderate / soft tissue, with no edge enhancement

Scan parameter optimization

Scan parameters can be optimized **within the given ranges** according to best practices in CT imaging. Adapt the scan parameters taking image quality, patient-specific factors, presence of metal, scanner specific factors, and dose considerations into account

IN THE PRESENCE OF METAL:
Check whether strategies of optimizing scan parameters to reduce metal artifacts seem beneficial, such as using thin slice collimation, lowering pitch, and increasing kVp.

WITH REGARD TO DOSE OPTIMIZATION:

- Adjust parameters depending on patient body habitus (e.g. kVp, mAs).
- Dose information displayed at your scanner (such as $CTDI_{vol}$) can be used to optimize scan parameters.
- Apply dose reduction techniques such as automatic tube current modulation and automatic voltage selection whenever possible and applicable (e.g. only apply automatic tube current modulation when your system can apply it correctly in the presence of metal in the scan region).
- For patients of standard body size without metal implants it is often possible to use a low-dose protocol for bone imaging and 3D applications.
- Tip: On some scanners, prospective selection of thin reconstructed slice thickness (e.g. 1mm) can lead to higher doses. Consider a retrospective reconstruction from thin acquisitions according to scan protocol parameters (Image Type needs to be ORIGINAL).
- Consult www.imagewisely.org and www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115317.htm
- for additional information about radiation safety.

PROVIDING SCAN DATA

File Format

Submit DICOM format only. No *.jpg images or other formats are acceptable. Do not submit other types of reconstructed or reformatted images. **Uncompressed DICOM data** is necessary for processing.
Lossy and other forms of compression (ISO 10918-1, ISO 14495-1, ISO 15444-1 or ISO 13818-1) **are NOT allowed.**

The scanner should be set to DICOM format “raw image”, with no compression. If loading from PACS, import and export the scan as DICOM files with the uncompressed option.
The complete data set of primary DICOM images must be provided

IMPORTANT

Retain an archive (PACS) copy of the CT exams in uncompressed DICOM format and the original scan parameters

Patient Information

- Do not erase patient name and ID.
- Data will be anonymized by Materialise on receipt of the data, after cross-check with prescription of the surgeon to ensure the images of the right patient are provided.
- Ensure necessary rights are obtained for transfer of data to Materialise.

Data Transfer

Instructions for image submission can be found in the SurgiCase Online User Manual for Uploading Images:
https://mat1euce1oosdoc.s3.amazonaws.com/surgicase/SurgiCase%20Online%20User%20Guide%20for%20Uploading%20Images_L-30442.pdf

Only send following images:
- The requested CT images at the given parameters
- The accompanying scout view

First time users can contact Materialise Customer Service to obtain a SurgiCase account and instructions.

QUESTIONS?

Please contact Materialise Customer Service:

ortho@materialise.be