

CUSTOMIMPLANTS®



PROTOCOL FOR COMPUTED TOMOGRAPHY





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The CT scan quality, **with clear bony edges and details,** is critical to the production of accurate patient-specific surgical instruments

PRELIMINARY

This CT protocol consists of a localizer and a detailed axial scan of 3 regions of the lower extremity: ankle, knee andhip. The CT scan quality –with clear bony edges and details- is critical to the production of accurate patient-specific surgical instruments. Deviations from this protocol may result in an unusable scan and delay of the surgery.

Please contact the CUSTOMIMPLANTS® support team if further clarification is required.

Patient Preparation

- ▶ Remove any non-fixed metal prosthesis, jewelry, zippers and/or any other metal piece that may interfere with the region to be scanned.
- ▶ Inform the patient on the procedure.
- ▶ Make him/her comfortable but always minimizing the movement.
- ▶ Patient positioning: supine, feet first (SFF), patellae pointing forward and the knees in maximal extension, toes pointing straight up.
- ▶ Always place a marker on the contralateral knee (for indication left or right). Use a marker that does not hinder the quality of the CT scan.
- ▶ If an implant is present in the contra lateral knee, elevate the contra lateral knee to prevent artifacts appearing in the joint line of interest.

Recommendations for data collection

TABLE POSITION

Set the table height so that the are ato be scanned is centered in the scan field. Do not raise or lower the CT table between slices. Do not alter the X or Y centering between scans. Center points must be identical.

FIELD OF VIEW (FOV)

Use the smallest FOW (25x25 max.) to capture the whole of the required bone regions. This wll require a careful alingment of the leg to obtain femoral head, knee and talus.

Capturing all of the soft tissue is unecessary, only bony regions are of interest.

Scan all slices with same FOV, reconstruction center and table height. (coordinate system).

BILATERAL IMAGES

Bilateral imaging can be obtained with a single acquisition.

GE users: if you do not have a pre-defined protocol, select "repeat series" between scan ranges. Do no select "add a group".

RECONSTRUCTION

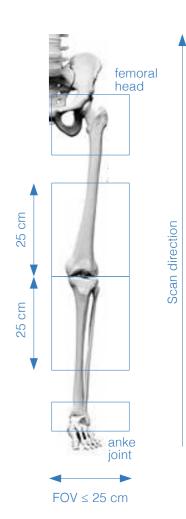
No secondary reconstructions; images must be scanned at the given parameters or more precise.

No reformatting into coronal or sagittal planes. No MRP's. No 3D reconstructions.

No obliqueness; no gantry tilt. No oblique reconstructions.

Scanning parameters

Region of interest Axial 1	Hip region: from below to above the femoral head.
Collimation	Slice Thickness: 3.00 mm Incremento de corte: 3.00mm (en corte contiguo)
kVp	90 (120 for obse patients or metal hardware in hip region)
mAs	As given by the automatic system
Pitch	2 or smaller
Field of View	20 cm or smaller (bilateral: 32 cm max.)
Matrix	512x512
Kernel/algorithm	Moderate/soft tissue (Do not use "bone")
Region of interest Axial 2	Knee: from 5cm below through 25cm above the knee joint.
Collimation	Slice thickness: 1.25mm-1.50mm Slice increment: 1.25mm-1.50 mm(contiguous slices)
kVp	120
mAs	As given by the automatic system
Pitch	1 or smaller
Field of View	25 cm or smaller (bilateral 32 cm max.)
Matrix	512x512
Kernel/algorithm	Moderate/soft tissue (Do not use "bone")
Region of interest Axial 3	Ankle región: a few cm's below and above the ankle joint
Collimation	Slice thickness: 3.0mm Slice increment: 3.0mm (contiguous slices)
kVp	90
mAs	As given by the automatic system
Pitch	2 or smaller
Field of View	25 cm or smaller (bilateral 32 cm max.)
Matrix	512x512
Kernel/algorithm	Moderate/soft tissue (Do not use "bone")



DATA MANAGEMENT

Your site should keep and archive (PACS) copy of the CT exams, in uncompressed DICOM format and the original scanning parameters.

- ▶ Provide 1 localizer + 1 complete data set of images.
- ▷ Only true axial scanning is required.



- ▶ For processing purposes, only uncompressed DICOM is accepted. No .jpg images or other formats are acceptable. Do not submit any other types of reconstructed or reformatted images.
- ▶ Lossy compression is NOT allowed. (ISO_10918_1,ISO_14495_1, ISO_15444_1 o ISO_13818_1).
- ▶ 3D images or similar that may seem beneficial for diagnosis are accepted, if available. Submit them separately.
- Do not erase patient name and ID.
- ▶ Ensure necessary rights are obtained for transfer of data to CUSTOMIMPLANTS®.
- Data will be anonymized by CUSTOMIMPLANTS® on receipt of the data, after cross-check with prescription of the surgeon to ensure images of the right patient are provided.



We recommend building a "CUSTOMIMPLANTS® leg-low dose post-op protocol" in your CT with the appropriate ranges and parameters.

Disclaimer

The information is intended exclusively for healthcare professionals. A healthcare professional should always rely on his or her clinical and professional opinion when deciding which product is most suitable to treat a patient.

Custom Implants SL do not provide medical advice and recommend that healthcare professionals be trained in the use of any particular product before using it in a procedure or in surgery.

Before using any product from Custom Implants SL., the healthcare professional must always read the instructions which are inside the package, the label of the product and/or the instructions for use, included those for cleaning and sterilization, when applicable. The information provided is for the purpose of showing specific products as well as the wide range of Custom Implants products.

It may occur that not every product be available in all markets due to their availability is subject to the medical or regulatory practice.

