![ci3d Customplants logo]

CUSTOMIMPLANTS®

CT SHOULDER

PROTOCOL FOR COMPUTED TOMOGRAPHY

![materialise logo — innovators you can count on]

CUSTOMIMPLANTS®

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note

CT scan quality can directly affect the design of guides and implants. 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 unnecessary scan.

PRELIMINARY

CT images made with this protocol are used to provide the orthopedic surgeon with a detailed 3D anatomical reconstruction of the patient's scapula and proximal humerus. This virtual 3D model is intended for the creation of a personalized pre-surgical plan, design of personalized instrumentation and/or a personalized implant for shoulder replacement surgery.

This CT protocol consists of a localizer and a detailed axial scan of shoulder. 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 the surgery. When using this protocol apply dose reduction techniques and optimize scan parameters within the provided ranges to limit dose delivered to the patient.

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: head first, supine.

▷ Center the shoulder of interest in the isocenter of the gantry. Arms at sides of the body.

▷ The palm of the surgical side should be rotated so it is facing up (supine). Place a small weight to stabilize the arm in this position, if tolerated.

▷ If the patient cannot rotate the arm comfortably, place the shoulder in neutral rotation with palms facing the body sides, thumbs pointing to the front of the body.

▷ Use a marker indicating that does not hinder the CT scan, indicating the side right or left.

note

Patient position in the case of metal implants:

▷ If an implant is present in the contralateral shoulder, raise the contralateral arm above the head to mitigate artifacts.

▷ If this metal implant includes a glenoid component on the surgical side, do not scan the patient. Please contact CUSTOMIMPLANTS® Customer Service (except for personalized implants selected for 2-stage approach).

Recommendations for data collection

TABLE POSITION

Set table height so that the region to be scanned is centered in the scan field.

FIELD OF VIEW (FOV)

Include the complete scapula and proximal humerus until the distal end of the scapula. Only the bony region are of interest.
Scan the entire scapula and proximal humerus, from just above the acromioclavicular joint to just below the inferior angle of the scapula, on the surgical side.
Soft tissue is unnecessary.

BILATERAL IMAGES

If bilateral shoulder are ordered, reconstruct them separately. Acquire at 500mm FOV and reconstruct individual shoulders at 250mm FOV.

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.

note
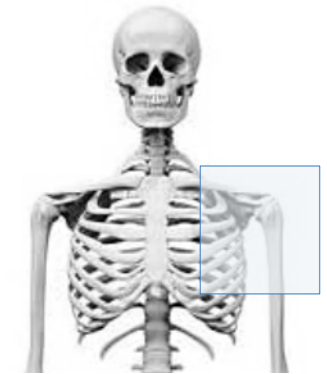
Check whether strategies of optimizing scan parameters to reduce metal artifacts seem beneficial, such as using thin slice collimation and reconstructing to slices of 1.25mm, lowering pitch, and increasing kVp. Use a Metal Artifact Reducing algorithm/filter, if available.

Submit this along with the standard scan.

Increase the HU scan range by using a 16 bit or extended CT scale, if available.

Scanning parameters

Scanner type	Multi-detector row TC with number of detector rows >16[1]
Scan mode	Helical
kVp	100-140 (automatic voltaje selection, if available)
mA(s)	Automatic tuve current modulation
Pitch	<1
Configuration detector	Single collimation < slice thickness
Slice thickness	1.25mm or smaller. Do not acquire a thicker slices and retrospectively reconstruct to noted thickness.
Slice increment	50% overlap
Matrix	512x512
Field of Vision	250mm or smaller
Reconstruction algorithm	Use the following reconstruction algorithms and provide axial: Reconstruction should be obtained from one single acquisition.
HU Scale	If metal implants are present, use a HU scale of 16-bit.

¹ *Scanners with >64 detector rows are sometimes referred to as Volume-CT and can be used in helical scan mode. DO NOT use cone-beam CT.*

note

Apply dose reduction techniques suchs as automatic tuve current modulation and automatic voltage selection whenever possible and applicable (e.g. only apply automatic tuve current modulation when your system can apply it correctly in the presence of metal in the scan region).

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).

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.

note

We recommend building a "CUSTOMIMPLANTS® shoulder 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.
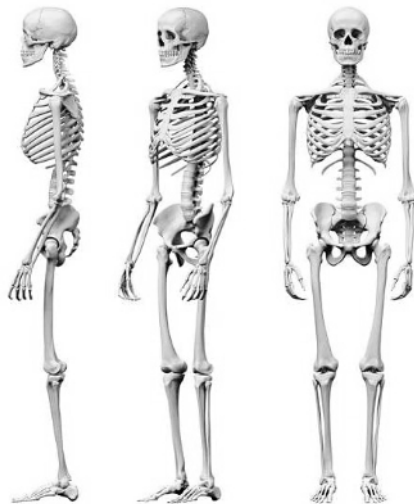
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