



CT SCAN PROTOCOL

Shoulder

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 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 protocol consists of a localizer and a detailed axial scan of the 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 unusable images for our medical device. When using this protocol, apply dose reduction techniques and optimize scan parameters within the provided ranges to limit the dose delivered to the patient.

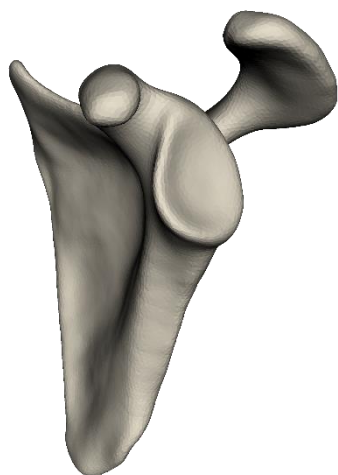
Read the following instructions carefully before scanning. Please contact Materialise's support team if you require further clarification.

NOTE

CT scan quality can directly affect the design of instruments 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 an unnecessary scan.

For questions, please contact Materialise Customer Services:



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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 and implants that support on bone. Materialise cannot be held liable for other possible subsequent uses (i.e. diagnostic uses.)

Note that it is highly recommended 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, instruments, and implants should not be used, even if the time period of 6 months has not expired.

SCAN PREPARATIONS

Patient Preparation

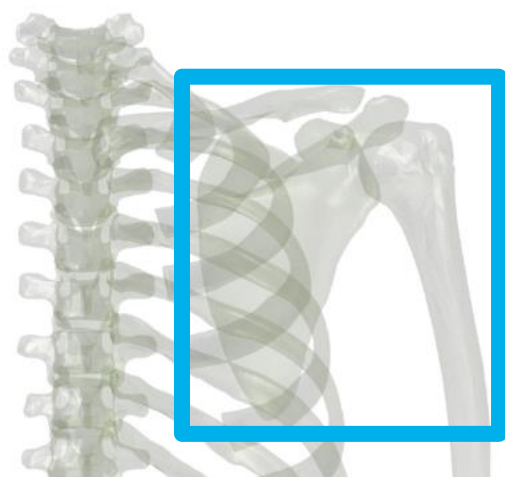
- Discuss the procedure with the patient and instruct not to move during scanning. Patient movement will prevent the accurate production of the anatomical model.
- Remove any non-fixed metal prosthesis, jewelry, or zippers that might interfere with the region to be scanned.
- Position the patient head 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 externally rotate the arm comfortably, place the shoulder in neutral rotation with palms facing the body sides, thumbs pointing to the front of the body.
- Indicate the body side scanned (right or left), for example in the Series description.

Patient positioning 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 Materialise Customer Services (except for personalized implants selected for 2-stage approach).

Scan Requirements

- Use true axial slices. Oblique slices are not accepted. No reformatted images.
- Gantry tilt is not accepted.
- **Region of interest**: Include the complete scapula and proximal humerus until the distal end of the scapula. Only the bony regions are of interest. Capturing the surrounding soft tissue is not necessary.
- **Scan range**: 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.
- If bilateral shoulders are ordered, reconstruct them separately. Acquire at 500 mm FOV and reconstruct individual shoulders at 250 mm FOV.



SCAN PARAMETERS

Scanner type	Multi-detector row CT with number of detector rows $\geq 16^1$
Scan mode	Helical
kVp	100 – 140 (automatic voltage selection, if available)
mA(s)	Automatic tube current modulation
Pitch	≤ 1
Detector Configuration	Single collimation \leq slice thickness
Slice Thickness	1.25 mm or smaller (Do not acquire a thicker slice and retrospectively reconstruct to noted thickness)
Slice Increment	50% overlap
Matrix	512 x 512
Field of View	250 mm or smaller (use smallest FOV that includes the complete bony anatomy of interest)
Reconstruction algorithm	Use the following reconstruction algorithms and provide axial images:
	1) Use a standard or soft tissue algorithm without edge enhancement. <u>Always provide this reconstruction.</u>
	2) When scanning for personalized implants provide an additional reconstruction with a bone algorithm.
	3) If metal is present, provide additional reconstruction(s) with metal artifact reduction applied if available. (Always provide a reconstruction without metal artifact reduction applied.)
	Reconstructions 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.

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.²

IN THE PRESENCE OF METAL

- Check whether strategies of optimizing scan parameters to reduce metal artifacts seem beneficial; such as using thin slice collimation and reconstructing to slices of 1.25 mm, 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.

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.

² These are recommendations. Please also take your institution's guidelines into account when optimizing scan parameters. In case of questions, contact Materialise Customer Service.

DATA TRANSMISSION

File format

- Submit DICOM format only.
- Uncompressed DICOM data is necessary for processing. Lossy and other forms of compression are NOT allowed (ISO_10918_1, ISO_14495_1, ISO_15444_1 or ISO_13818_1).
- 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.

Data anonymization

- Do not erase patient name and ID. Patient date of birth and name need to be included.
- Ensure necessary rights are obtained for transfer of data to Materialise.
- 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.

Transfer scan data to Materialise

Instructions for image submission can be found in the [SurgiCase Online User Manual for Uploading Images](#).

Only send the following images:

- The requested CT images at the given parameters
- The accompanying scout view
- An accompanying 3D reconstruction (if available) in case of metal implants.

IMPORTANT

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

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