

CT Scan Protocol

Patient Specific Total Talus

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The following CT Scan protocol is used to ensure uniformity between scans at multiple centers and maintain image quality. The protocol should be optimized to reduce dose, by carefully selecting appropriate technique factors and limiting the volume to be scanned to just the area of interest. The following recommendations can be used to limit radiation exposure; The radiologist or technician can use dose information displayed at the scanner (such as CT Dose Index Volume (CTDIvol)) to optimize scan parameters.

Automatic tube current modulation and automatic voltage selection should be used when appropriate to reduce radiation dosage while maintaining the requisite image quality in alignment with As Low As Reasonably Achievable (ALARA) principles.

1. Recommended Parameters for Foot and Ankle Scan Protocol

Scan Mode	Helical, axial, and cone beam are acceptable.	
Reconstruction Algorithm/Kernel	Soft Tissue Reconstruction if available. Bone or Standard algorithms are acceptable.	
Reconstruction Method	Filtered Back Projection (FBP)/ Feldkamp-David-Kress (FDK)	
Field of View	≤ 28cm (maximum 40cm)	
Matrix	512 x 512 recommended. No smaller matrix should be used.	
Slice Thickness	≤ 1.00 mm	
Slice Increment	≤ slice thickness	
Pixel Size	≤ 0.8mm	
Detector Rows	Minimum 16	
kVP	120 kVP	
Tube Current (mA)	Multidetector CT (MDCT)	Weight-bearing Lower Extremity Cone-Beam CT (CBCT)
	100 to 230 mA	5mA
Exposure (mAs)	50 to 150* mAs	29 to 43* mAs
Pitch	≤1.0 for helical	N/A
Gantry Tilt	0°	
File Format	Uncompressed Digital Imaging and Communications in Medicine (DICOM)	

* Higher than recommended mAs values will be acceptable if existing hardware or additional anatomy is present. A combination of Tube Current, Exposure Time and kVp must be used to provide an acceptable quality of image.

2. CT Scanners used in Device Validation

CT Scanner Type	Manufacturer	Model
MDCT	Siemens	Sensation 64 SOMATOM Definition AS SOMATOM Definition AS+ SOMATOM Definition Edge SOMATOM Force
	Toshiba	Aquilion Aquilion PRIME
	GE Medical Systems	Lightspeed VCT Revolution HD
CBCT	CurveBeam	LineUp PedCat HiRise

3. Patient Position

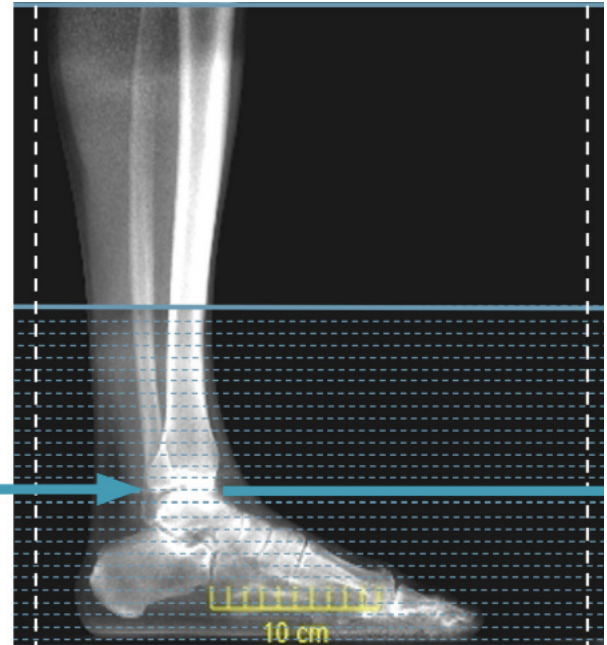
- A. If weight-bearing CT scan is being used,
- patient should place their leg to be imaged in the center of the scan area first. The heel of the imaged leg should be just inside the center circle.
 - The other leg should be brought into the scanner after, offset from the imaged foot. Ensure the entire foot is on the patient platform.
 - Position the patient's knee using the knee positioner. Ensure the patient's knee is within the center circle in the platform.

If weight-bearing CT scan is not used,

- The patient should be lying in supine position and the foot should be extended and positioned neutral (90°) to the leg with a positioning device or heavy box.
- B. The entire foot from the ankle joint line is to be scanned through the ball of the foot and tip of toes. Inclusion of contralateral (non-affected foot/extremity) scan is preferred.
- C. If a contralateral implant is present, bend the contra-lateral limb out of the field of view of the ankle to be scanned.
- D. Do not allow patient movement between or during scans. If patient motion occurs, the scan must be restarted. Image distortion from patient motion can severely compromise the integrity of the model.

4. Scanning Instructions

- A. Scan the entire foot, from the ankle joint to past the ball of the foot and toe tips to ensure the entire foot and ankle are captured. Provide full foot images – one view is acceptable (axial, coronal or sagittal). Two views preferred.
- B. Bilateral scan of the affected foot and contralateral is preferred to minimize artifacts, if any.
- C. No contrast agent is to be used.
- D. Other recommendations:
- Do not scan at higher slice spacing and reconstruct to smaller increments.
 - Provide images in the original scanning plane (axial, coronal, or sagittal images). There should be no secondary reconstructions or reformatting (including but not limited to iterative reconstruction, metal artifact reduction, re-orientation, or re-slicing).
 - If the ankle of interest has existing hardware it can be scanned with the same parameters as listed here.
 - During the post-surgical period (as determined by the physician) weight bearing CT scans should be avoided to protect patient safety.
 - The implant must be used within 6 months from the date of the CT scan. If the patient's anatomy has changed significantly since the time of the CT scan, the implant should not be used, even if the time period of 6 months has not expired.





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This document outlines restor3d's recommended CT scan parameters. restor3d does not practice medicine and is making these recommendations for optimal design of patient-specific implants, instruments, and anatomic models as necessitated by surgeon prescription. Please use these guidelines appropriately for each patient under the guidance of a physician.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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