



Total Ankle Replacement

CT Scan Protocol

restor3d

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Total Ankle Replacement

If available, include weight bearing x-rays in the Anterior, Lateral, and Mortise View of the full or partial limb.

CT Scan Protocol

The following CT Scan protocol is used to ensure uniformity between scans at multiple centers. The following CT Scan protocol may be used for the Axiom PSR System.

1 Patient Position

- A. The foot of interest should be positioned in neutral (90°) to the leg with a positioning device or heavy box. If neutral is not possible, a $\pm 25^\circ$ deviation is acceptable.
- B. The entire foot is to be scanned through the ball of the foot and tip of toes.
- C. If a contra-lateral 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.
- E. Provide full Knee-to-Foot images (coronal and sagittal).
- F. Scan both the Foot and Ankle AND Knee Sections at the same time.

2 Knee Scan Protocol Requirements

- A. Scan **5cm** proximal and **5cm** distal to the knee joint line with a **2.5mm** (or smaller) Slice Increment.
- B. Typical Field of View **28cm** (Maximum **40cm**).
- C. In-plane pixel size (resolution) must be less than **0.8mm**.

3 Foot and Ankle Scan Protocol Requirements

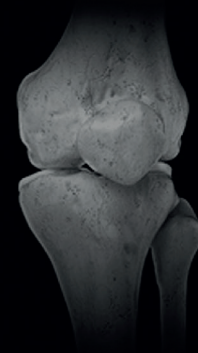
- A. Scan at least **10cm** above the ankle joint line.
- B. Scan the **entire foot**. Scan past the ball of the foot and toe tips to ensure the entire foot is captured.
- C. Slice increment **1.0mm** (or smaller).
- D. Measure or calculate to achieve **>10cm** above the ankle joint line.

Examples: 100 slices at 1.00mm or 160 slices at 0.625mm

4 Scanning Instructions

- A. Helical, axial, and cone beam CT modes are acceptable.
- B. Bone or Standard algorithms are acceptable.
- C. No contrast agent is to be used.
- D. All scan groups' edges should stay aligned.
- E. Maintain a single coordinate system for both the knee and foot scan.
- F. Maintain a consistent field of view and pixel size for both the knee and foot scan.

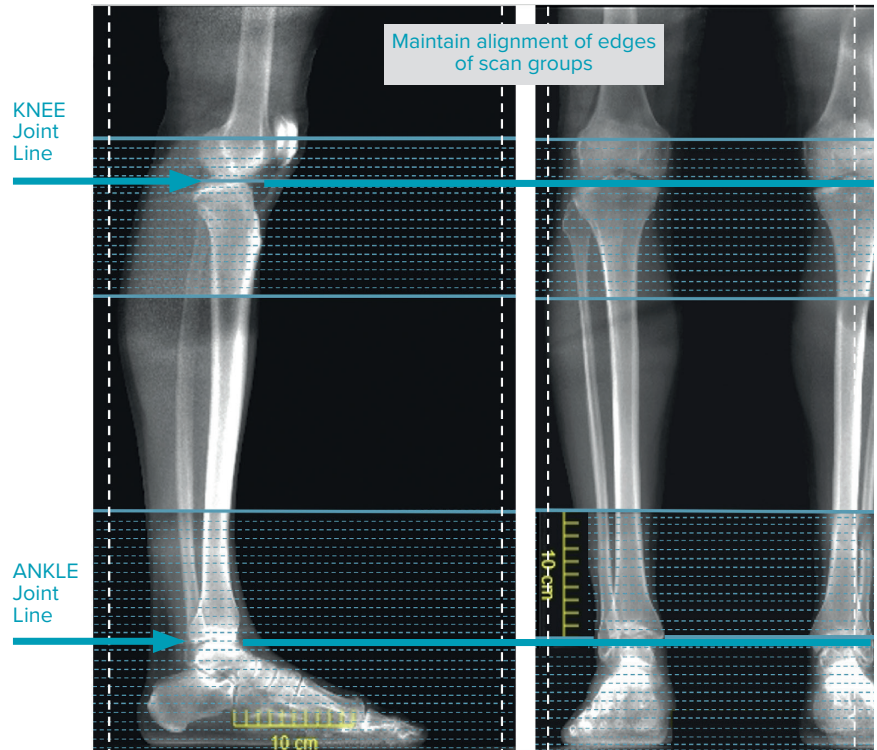
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SCAN PARAMETERS

Pixel Spacing	$R \leq 0.8\text{mm}$
Slice Thickness	$R \leq 1.00\text{mm}$
kVp	120
mA	Determined by software scanner
File Type	Uncompressed DICOM

- G.** Adjusting the width of both knee and foot groups together to span the required anatomy of both groups is appropriate.
- H.** One single scan from the bottom of the foot through the knee is also acceptable.
- I.** In-plane pixel size (resolution) must be less than 0.8mm.
Example: A Field of View of ~28 cm is ideal for a 512x512 matrix in order to keep the pixel size small. The Field of View must be less than 40 cm.
- J.** Include full knee-to-foot images (coronal and sagittal) when submitting CT files.
- K.** Other:
 - Do not scan at higher slice spacing and reconstruct to smaller increments.
 - Only the raw axial images are needed; coronal and sagittal reconstructions are not necessary.
 - Images must be provided in uncompressed DICOM format.
 - If the ankle of interest has existing hardware it can be scanned with the same parameters as listed here.



5 Submitting a Scan / Image Data Transfer



Login to r3id.restor3d.com

An account may be requested via the login screen by clicking the "request access to r3id."



Create a case

Required case information includes physician information, affected anatomy, laterality, surgical procedure or device, and patient information.



Upload CT scan

Only DICOM files will be accepted.

Visit <https://www.restor3d.com/imaging/> or contact patientspecific@restor3d.com for other patient scan sharing options

restor3d Imaging Help

Phone: (781) 345-9170

E-mail: imaging-support@restor3d.com

Imaging support is available Monday–Friday 8:00am–4:00pm ET



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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:

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CAUTION: Federal law restricts this device to sale by or on the order of a physician. Prior to use of a restor3d device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use.