AccuStride™ Sytem CT Scan Protocol

This protocol describes the guidelines for a CT scan for ordering the following products and services specific to the anatomical regions listed in the Instructions for Use:

- **ACCUSTRIDE™ Patient-Specific Products and Services**

Thank you for taking a moment to read this protocol. The quality of the CT scan is the most important aspect of creating patient-specific anatomical models and devices. Your observation of the recommendations made in this protocol will have a significant impact on the accuracy of the final model. We understand concerns about keeping the radiation dose to your patients as low as reasonably achievable, therefore, please apply these guidelines as appropriate to your patients. For questions, please contact us at **(214) 453-8864.**

Scan considerations

- **Please use a 3D scanning routine that provides high resolution images** as would be suitable for image guided surgery, stereotactic planning or other 3D applications. It may be useful to consult with your CT vendor's Application Specialist for advice on optimal parameters for your machine that provide the best scan with acceptable radiation dose levels.
- **Acquire scans at a high spatial resolution.** Series should be acquired with thin, contiguous image slices (equivalent thickness and spacing of 1.0 mm or less) and as small a field of view (FOV) as possible while still including the patient's anatomy of interest.
- **Please provide images in the original scanning plane.** If software post-processing is performed to reorient or reformat the scan volume, then a series of thin slice images in the original acquisition plane MUST be included.
- **Do not use gantry tilt during image acquisition.** If series is acquired with a gantry tilt and corrected to 0° with post-processing software, the images will not be accepted. Images must be captured at 0° gantry tilt.
- **Archive the entire study in uncompressed DICOM format** on CD-R or DVD for shipping.
- **Helical (spiral) scanning mode preferred** for CT image acquisition with a minimum number of detector rows of 16, 32, 64 or 128

Patient preparation

- **Please take steps to minimize artifact from the presence of metal** (such as non-fixed metal prosthesis or jewelry). Image artifact caused by metallic implants can obscure anatomy of interest. It is useful to postion any metallic implants parallel to the image plane. This can help to limit artifacting.
- **Patient must remain completely still through the entire scan** to ensure that scans are free from motion artifact. Normal breathing is acceptable, but patient motion can severely distort imaging and compromise the accuracy of a model. If patient motion occurs, the scan must be restarted. Do not deform soft tissue.

Other considerations

- The CT scan date must be within 4 months of surgery date to ensure accurate representation of patient anatomy. Therefore, the device should be used within 4 months of the scan date.
- Changes in the patient anatomy occuring after the CT as well as the use of the device after such changes, may result in a suboptimal fit of the device or implant.
- Automatic Exposure Control AEC is contraindicated for anatomies with metal implants/other similarly highly attenuating objects (prosthesis, orthopedic devices)
- Adjust parameters according to patient body habitus.
- To reduce radiation dosages to as low as reasonably achievable (ALARA) and limit the need for additional scans, MedCAD recommends the following:
  - Check if any existing scans meet the requirements for MedCAD device design.
  - Limit radiation dosage and the area to be scanned to only the amount clinically necessary.
  - Follow the parameters given in the MedCAD Scan Protocol.
  - Save raw data for at least 14 days after scan in case of error in uploaded data.
  - Exposure to ionizing radiation is of particular concern in pediatric patients. For pediatric use, MedCAD also recommends using reduced dose and child-sized protocols where appropriate.

Please use the following scan parameters or closest approximation:

Recommended protocol for CT scanners	
Matrix	512 x 512
Scan spacing	≤ 0.625mm
Gantry tilt	0°
Archive Media	CD or DVD, then Upload via MedCAD.net
File Type	DICOM (uncompressed)
Series	Original/primary/axial (no recon, reformat or post process data)
Slice Increment	≤ 0.625mm
mAs	As suggested by the automatic system
Reconstructed Algorithm	GE: standard (Siemens: H30s, Toshiba: FC20, Philips: B)
KVp	100-120
Approx. Radiation Dose	0.07 - 0.10 msv
Pitch	1.00
Pixel Size	0.3-0.5 mm

For Digital Transfer
of DICOM images,
visit MedCAD.com/upload

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Please provide either a Weight Bearing or Non-Weight Bearing CT. A foot holder or support mechanism is recommended to be used during CT scanning.

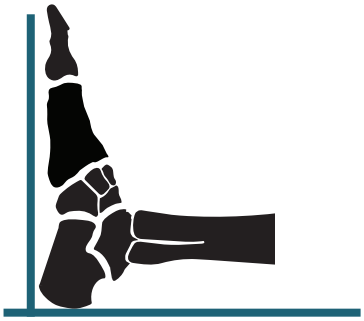
Weight Bearing

- Patient Position – Standing
- Affected Foot Position – Neutral (90deg to the leg)

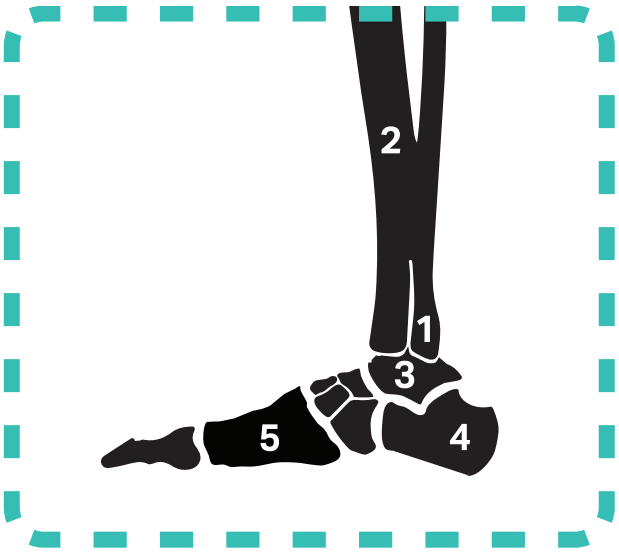
Weight Bearing

Non-Weight Bearing

- Patient Position – Supine
- Affected Foot Position – Neutral (90deg to the leg)



Non- Weight Bearing



Field of View Reference

Scan the entire tibia and fibula, and the entire foot from the ankle joint to past the ball of the foot and toe tips. Ensure the entire foot and ankle are captured.

Patient Data Required:

1. Lower 1/3 of Fibula
2. Lower 1/3 of Tibia
3. Ankle Joint
4. Heel
5. Foot (Tarsals, Metatarsals, Phalanges)

Note:

This reference shows the minimum anatomical landmarks required in a CT scan. Always include all of relevant patient defect.

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