Indications - pre surgical evaluation prior to ankle joint replacement.

Bill under CT LE w/o Contrast charge. Do not include separate knee and ankle charges.

GENERAL SCAN NOTES

Remove any metal from the imaging field of view.

Patient positioning (see images at bottom of page):

Have opposite leg bent at knee with ankle/foot out of way of ankle of interest.

Foot must be dorsiflexed with foot perpendicular to tibia (90 degrees).

Do not allow patient movement between or during the scans.

Topogram - from above knee through bottom of foot.

Craniocaudal scan coverage (see images at bottom of page):

Knee - 5 cm superior to and 5 cm inferior to joint.

Ankle - 10 cm superior to ankle joint through bottom of foot (including all toes).

FOV of 280 mm preferred (must be <400 mm) using a 512 x 512 matrix squared.

Okay if soft tissue from contralateral extremity is included.

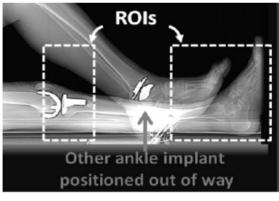
IV Contrast: 100 mL Omnipaque-300, inject at 2.5 mL/sec, 60 secs scan delay.

For <u>GE scanners</u>, it is essential for the 1st recon thickness on the scanner to match the 1st recon thickness in this protocol book for the prescribed Noise Index to be valid. The 1st recon should generally be the thickest recon in the protocol.

Prepare an uncompressed DICOM disc including the AP and lateral topograms, axial images of the knee and axial thin images of the ankle. This CD will need to go with the patient after the exam.









Craniocaudal Scan Coverage

Ankle Positioning

SIEMENS PARAMETERS & RECONS

For **Knee** and **Ankle** scans:

	Scan Mode	kV	mAs	Care Dose	Care kV & Lvl	Pitch	Acq	Coll	Rot Time
Sensation 16	spiral	120	140	on	NA	0.55	16	0.75	1.0
Go Up 32	spiral	Sn 110	366	on	on 75	0.40	32	0.7	1.0
Sensation 64	spiral	120	140	on	NA	0.90	64	0.6	1.0
Definition 64	spiral	120	100	on	off	0.80	64	0.6	1.0
Go Top 64	spiral	Sn 110	898	on	on	0.40	64	0.6	1.0
Drive 128	spiral	120	70	on	off	0.80	128	0.6	1.0
Force 192	spiral	120	70	on	off	0.80	192	0.6	1.0

KNEE RECONS

Name of Series	Thick	Interval	Kernel	Window	IR Lvl	Recon Direction
AX KNEE BONE	3.0	3.0	Br59 / B60	bone/osteo	3	head/feet
COR KNEE BONE	3.0	3.0	Br59 / B60	bone/osteo	3	front/back
SAG KNEE BONE	3.0	3.0	Br59 / B60	bone/osteo	3	left/right

Prophecy specific recon.

ANKLE RECONS

AX ANKLE BONE	2.0	2.0	Br59 / B60	bone/osteo	3	head/feet
COR ANKLE BONE	2.0	2.0	Br59 / B60	bone/osteo	3	front/back
SAG ANKLE BONE	2.0	2.0	Br59 / B60	bone/osteo	3	left/right
AX ANKLE THINS	1.0	1.0	Br59 / B60	bone/osteo	3	head/feet

Prophecy specific recon.

GE PARAMETERS & RECONS

For **Knee** and **Ankle** scans:

	Scan Type	SFOV	kV	mA Range	Noise Index	Smart mA	Slice Thick	Beam Coll	Pitch	Speed	Rot Time	Dose Red	ASIR
LS 16	helical	large	120	100-440	12.50	on	2.5	10	0.938	9.37	0.5	NA	NA
Opt 540	helical	large	120	100-440	12.50	on	2.5	10	0.938	9.37	0.5	NA	NA
LS VCT 64	helical	large body	120	100-450	16.00	on	2.5	40	0.984	39.37	0.5	20	20
Disc VCT 64	helical	large body	120	100-450	16.00	on	2.5	40	0.984	39.37	0.5	20	20

KNEE RECONS

Name of Series	Thickness	Interval	Recon Algorithm/Mode	Window Width/Level	Recon Direction
AX KNEE BONE	2.5	2.5	bone full	2500/480	head/feet
COR KNEE BONE	2.5	2.5	bone full	2500/480	front/back
SAG KNEE BONE	2.5	2.5	bone full	2500/480	left/right

Must be first recon.

Prophecy specific recon.

ANKLE RECONS

AX ANKLE BONE	2.5	2.5	bone full	2500/480	head/feet
COR ANKLE BONE	2.5	2.5	bone full	2500/480	front/back
SAG ANKLE BONE	2.5	2.5	bone full	2500/480	left/right
AX ANKLE THINS	0.625	0.625	bone plus full	2500/480	head/feet

Must be first recon.

Prophecy specific recon.

PHILIPS PARAMETERS & RECONS

For **Knee** and **Ankle** scans:

	Scan Mode	kV		Dose Index		Pitch	Detect	Colli	Rot Time
Incisive 128	helical	120	85	32	on	0.80	64	0.625	1.00

KNEE RECONS

Name of Series	Thick	Interval	Filter	Window	iDose	Recon Direction
AX KNEE BONE	3.0	3.0	YC	bone	3	head/feet
COR KNEE BONE	3.0	3.0	YC	bone	3	front/back
SAG KNEE BONE	3.0	3.0	YC	bone	3	left/right

Prophecy specific recon.

ANKLE RECONS

AX ANKLE BONE	2.0	2.0	YC	bone	3	head/feet
COR ANKLE BONE	2.0	2.0	YC	bone	3	front/back
SAG ANKLE BONE	2.0	2.0	YC	bone	3	left/right
AX ANKLE THINS	1.0	1.0	YC	bone	3	head/feet

Prophecy specific recon.





FIGURE 1 Examples of neutral ankle positioning devices (not provided). Any radiolucent object can be used to prop the bottom of the foot at 90°, such as a box.

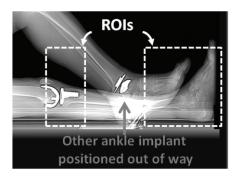


FIGURE 2 Bending the other limb to position the other ankle implant away from the ankle of interest. This minimizes image artifact in the ankle Region Of Interest.

PROPHECY Ankle CT Scan Protocol

PROPHECY INBONE", INFINITY" and INVISION" Preoperative Navigation Reports and Guides are patient-specific tools for total ankle replacement surgery. Adherence to this lower extremity CT protocol of the ankle, with knee, is critical for success. In every case, please follow these instructions:

Patient Position

- ☐ The foot of interest should be positioned in neutral (90°) to the leg. FIGURE 1

 NOTE: If this is not possible due to a patient's condition, such as severe contracture, ensure the CT scan contains slices through the ball of the foot (see bottom of next page).
- ☐ If a contra-lateral implant is present, bend the contra-lateral limb out of the field of view of the ankle to be scanned. FIGURE 2
- Do not allow patient movement between or during scans.

Scanning Instructions

Helical, axial, and cone beam CT modes are acceptable.

Bone or Standard algorithms are acceptable.

No contrast agent is to be used.

- ☐ All scan groups' edges should stay aligned. See dashed lines, next page.
 - Maintain a single coordinate system for both the knee and foot scan.
 - Maintain a consistent field of view and pixel size for both the knee and foot scan.
 - Adjusting the width of both knee and foot groups together to span the required anatomy of both groups is appropriate.
 - One single scan from the bottom of the foot through the knee is also acceptable.
- ☐ 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.
- ☐ Include full knee-to-foot scout images (coronal and sagittal) when submitting CT files to Wright.

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.

NOTE: It is highly recommended that additional x-ray studies be submitted to Wright for analysis for PROPHECY pre-op navigation. Useful additional studies include:

- Weight-bearing lateral x-ray
- Stress x-rays/Talar tilt x-rays of the medial deltoid and/or lateral ligaments.

PROPHECY Ankle CT Scan Protocol

This "ankle" protocol involves a section at the knee.

REQUIRED:

- Provide full Knee-to-Foot CT "scout" images (coronal & sagittal).
- ☐ Scan both the Foot-&-Ankle AND Knee sections at the same time.
- Refer to additional requirements on previous page.

10cm

- 8 - 7

6

5

. 3

. 2

☐ Refer to typical errors and FAQs on next pages.

Sagittal Scout Maintain alignment of edges of scan groups.

REQUIRED:

- Scan 5cm proximal, and 5cm distal to the knee joint line.
- Slice increment: 5mm (or smaller).
- Field Of View: Typical: ~28cm. Max: 40cm.

REQUIRED:

- Ankle and foot scan slice increment: 1.25mm (or smaller).
- ☐ Scan >10cm above the joint line Measure this, see note below.
- Scan <u>past</u> the ball of the foot, and get the toes.

"Joint Line"

Position the foot at 90° with a positioning device or heavy box.

FIGURE 3

NOTE:

☐ Measure (or calculate) to get >10cm above the joint line. Examples: 80 slices @ 1.25mm or 100 slices @ 1.0mm or 160 slices @ 0.625mm above the joint line.

NOTE:

It's better to "airball" the last slices than to not get enough.

Common Scan Protocol Errors

The most common protocol errors resulting in failed scans are shown below:



Region missing from scan.

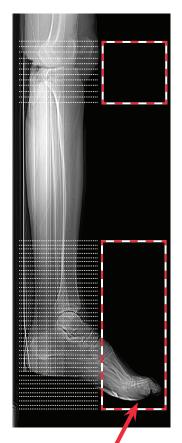


FIGURE 4

Example Failure to scan the entire foot.

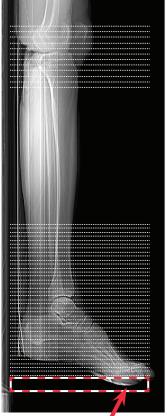


FIGURE 5

X Failure to scan the entire foot.

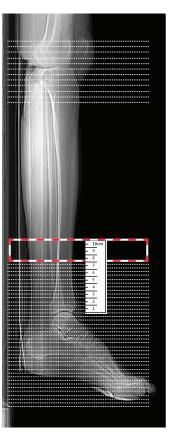


FIGURE 6

Failure to scan at least

10cm above the ankle joint.

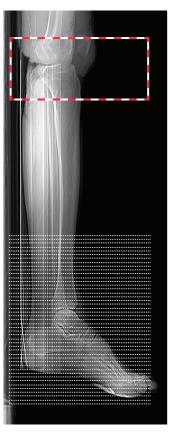
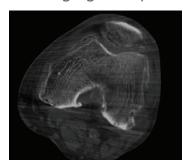
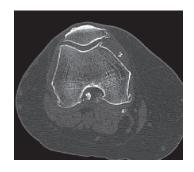


FIGURE 7

Scan of the knee was not performed simultaneously with the ankle.

CT Imaging Examples





Satisfactory CT Imaging

✓ Clear, sharp, distinct boundaries between bone and soft tissue.

Frequently Asked Questions

Q. "I can't put in a 1.25mm slice. I can only do a 1mm increment. Is that ok?"

A. Slices thinner than our specified slice thickness are acceptable; however, using larger slices will result in the scan being rejected for PROPHECY processing.

Q. "What type of CT acquisition can be used?"

A. Axial, helical, and cone beam CT modes are acceptable.

Q. "Is it really necessary to scan 10cm above the ankle joint?"

A. Yes. At least 10cm of the tibia shaft, measured from the ankle joint line, is required.

Q. "Do I need to scan the knee for an ankle surgery?"

A. Yes. The knee scan is required to obtain the complete axis of the lower extremity. Information based on the entire tibia is used to plan the ankle procedure.

Q. "How should the patient be positioned?"

A. Patients are typically supine for the scan, but it does not matter as long as the patient's ankle is in neutral dorsiflexion.

Submitting the Scan

Rapid Electronic Scan Transfer

Preoperative CT may be sent to the PROPHECY engineering team through our secure, rapid electronic transfer system: https://prophecyscans.wmt.com

Please follow these steps to request an account and transfer scans:

- 1. E-mail prophecy@wright.com with the e-mail address of the person who needs access to the system (No other information is needed)
- 2. Within a few hours, an invitation message will be sent to that address with instructions to complete registration on the scan transfer site.

Scan submission is typically done by first putting the DICOM files from the CT Scanner computer onto a CD, then putting the CD into a typical office computer for uploading. Therefore, ensure the CD contains the Axial CT slices and full-length scout images.

FAQ: Can I mail the CD of the CT scan?

A. This method is not preferred.

If uploading the scans directly from the scanning facility is not possible, please contact the local Wright Medical sales rep to do so. If the sales rep contact information is not known, call the number below.

Contact for Assistance

PROPHECY Operations at Wright Medical Technology Phone: 901.290.5884 Fax: 901.867.4791 email: prophecy@wright.com

The Centers for Medicare & Medicaid Services (CMS) established a National Coverage Determination (NCD) for CT Scans. It states, in part, the following, "Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient." CTs performed prior to total joint replacement procedures for diagnostic purposes may be considered medically necessary. In which case, the procedure should be billed using the CPT codes that accurately describe the imaging procedure furnished to the patient. These same images from the diagnostic CT scan may, in turn, be further utilized for developing the personalized cutting or navigation guides that are used in orthopaedic procedures. However, if providers perform CT scans solely for the purpose of developing personalized cutting instruments or guides, providers should contact the payer for billing and coverage guidance and/or the American College of Radiology with billing questions.

^{**} upload times may vary based on connection speed.