CT Conformis Knee

Indications - pre surgical evaluation prior to knee joint replacement.

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

GENERAL SCAN NOTES

Remove any metal from the imaging field of view.

Patient positioning:

    Patient in supine position feet first with knees extended and toes pointing straight up.

    Elevate contralateral leg if prosthesis present to minimize streak artifact.

    Do not allow patient movement between or during the scans.

Topogram - iliac crests through feet.

Craniocaudal scan coverage (see images below):

    Hip - acetabulum through bottom of femoral head. FOV 250-300 mm.

    Knee - distal third of femur through proximal half of tibia. FOV 200-250 mm.

   Ankle - 2 cm above to 2 cm below ankle joint. FOV 150-200 mm.

IV Contrast: not given for this protocol.

For **GE scanners**, 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 containing all images.

Knee CC Coverage
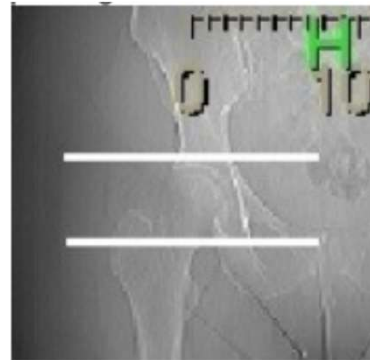
Hip CC Coverage

Ankle CC Coverage

CT Conformis Knee

SIEMENS PARAMETERS & RECONS

For **Hip** scan:

	Scan Mode	kV	mAs	Care Dose	Care kV & Lvl	Pitch	Acq	Coll	Rot Time
Sensation 16	spiral	120	200	on	NA	0.80	16	0.75	0.5
Go Up 32	spiral	130	109	on	on 170	0.80	32	0.7	1.0
Sensation 64	spiral	120	200	on	NA	0.90	64	0.6	0.5
Definition 64	spiral	120	190	on	on	0.80	64	0.6	1.0
Go Top 64	spiral	120	131	on	on 170	0.80	64	0.6	1.0
Drive 128	spiral	120	133	on	on	0.80	128	0.6	1.0
Force 192	spiral	120	133	on	on	0.80	192	0.6	1.0

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

HIP RECONS

Name of Series	Thick	Interval	Kernel	Window	IR Lvl	Recon Direction
AX HIP BONE	2.0	2.0	Br59 / B60	bone/osteo	3	head/feet

KNEE RECONS

AX KNEE BONE	1.0	0.5	Br59 / B60	bone/osteo	3	head/feet
COR KNEE BONE	1.0	1.0	Br59 / B60	bone/osteo	3	front/back
SAG KNEE BONE	1.0	1.0	Br59 / B60	bone/osteo	3	left/right

ANKLE RECONS

AX ANKLE BONE	2.0	2.0	Br59 / B60	bone/osteo	3	head/feet

CT Conformis Knee

GE PARAMETERS & RECONS

For **Hip** 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

For **Knee** scan:

	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	17.68	on	1.25	10	0.938	9.37	0.5	NA	NA
Opt 540	helical	large	120	100-440	17.68	on	1.25	10	0.938	9.37	0.5	NA	NA
LS VCT 64	helical	large body	120	100-450	22.63	on	1.25	40	0.984	39.37	0.5	20	20
Disc VCT 64	helical	large body	120	100-450	22.63	on	1.25	40	0.984	39.37	0.5	20	20

HIP RECONS

Name of Series	Thickness	Interval	Recon Algorithm/Mode	Window Width/Level	Recon Direction	
AX HIP BONE	**2.5**	**2.5**	**bone full**	**2500/480**	**head/feet**	**Must be first recon.**

KNEE RECONS

Name of Series	Thickness	Interval	Recon Algorithm/Mode	Window Width/Level	Recon Direction	
AX KNEE BONE	**1.25**	**0.625**	**bone full**	**2500/480**	**head/feet**	**Must be first recon.**
COR KNEE BONE	0.625	0.625	bone plus full	2500/480	front/back	
SAG KNEE BONE	0.625	0.625	bone plus full	2500/480	left/right	

ANKLE RECONS

Name of Series	Thickness	Interval	Recon Algorithm/Mode	Window Width/Level	Recon Direction	
AX ANKLE BONE	**2.5**	**2.5**	**bone full**	**2500/480**	**head/feet**	**Must be first recon.**

CT Conformis Knee

PHILIPS PARAMETERS & RECONS

For **Hip**, **Knee** and **Ankle** scans:

	Scan Mode	kV	Avg mAs	Dose Index	3D Dose	Pitch	Detect	Colli	Rot Time
Incisive 128	helical	120	103	20	on	0.80	64	0.625	0.75

HIP RECONS

Name of Series	Thick	Interval	Filter	Window	iDose	Recon Direction
AX HIP BONE	2.0	2.0	YC	bone	3	head/feet

KNEE RECONS

AX KNEE BONE	1.0	0.5	YC	bone	3	head/feet
COR KNEE BONE	1.0	1.0	YC	bone	3	front/back
SAG KNEE BONE	1.0	1.0	YC	bone	3	left/right

ANKLE RECONS

AX ANKLE BONE	2.0	2.0	YC	bone	3	head/feet

Introduction:

Patients who present with an order for a CT Scan of the lower extremity following Conformis protocol are being considered as a candidate for one of the Conformis Inc. knee implants. These are customized implants designed from CT scans.

TABLE OF CONTENTS

All questions regarding this protocol reference guide should be addressed to:

Conformis Imaging Support
600 Technology Park Drive
Billerica, MA 01821
Tel: 781-345-9170
Email: imaging-support@conformis.com

Conformis Imaging Support is available:
Monday-Friday
8:00 am – 6:00 pm (Eastern Time)

Medical Device Safety Service, GMBH
Schiffgraben 41
30175 Hannover, Germany
Tel: +49(511)6262-8630

CE 0086

1.0   Patient Position:

To ensure our ability to correct for malalignment position the extremity of interest with the foot perpendicular to the table and with the toes pointing straight up. While some patients may not be able to be placed exactly as described please position them as closely as possible to the desired orientation. Immobilize the legs and toes to prevent motion. The use of positioning aids is encouraged. It is best not to place a sponge or pillow beneath the knee or ankle of interest. Instruct the patient to hold very still during the scan acquisition. Ensure that no foreign objects are in the scan field.

The use of a solid, firm positioning aid (as depicted by the black board in the images on this page) is recommended to help immobilize the feet and legs to prevent motion during the scan. There are many common objects that can be used for this purpose.

IMMOBILIZATION IS ESSENTIAL

*** *When an implant or other device is present in the opposite knee, please make every effort to position that knee flexed and out of the FOV to reduce the artifacts in the affected knee joint. Please do so before acquiring any of the study images. If available please use a metal artifact reduction technique.* ***
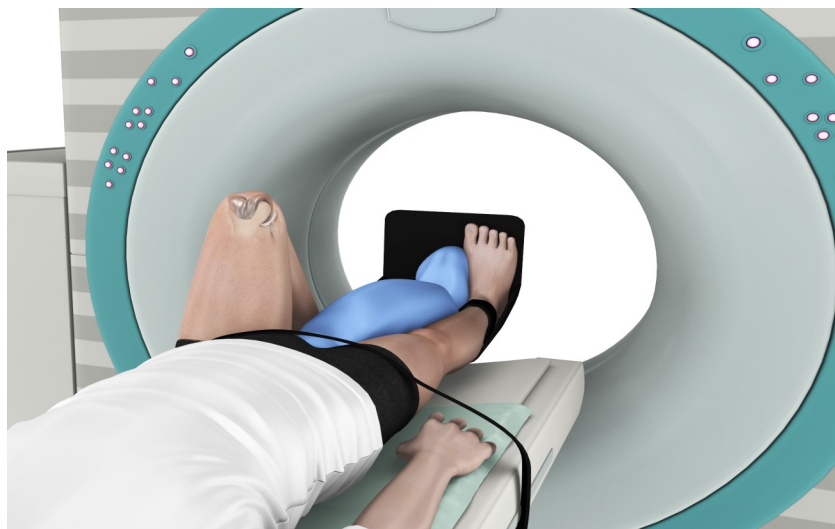
2.0   Image Acquisition:

**The patient's first and last name data in the DICOM header
MUST reflect the patient's legal name associated with supporting documentation
(ex: license or insurance card)**

From the full leg scout scan the hip, knee and ankle images in a single acquisition following the protocol outlined in the graph on page 4.

Series 1: Full leg scout from the hip through the ankle
Series 2: Hip, Knee, Ankle
Series 3: Coronal MPR Knee
Series 4: Sagittal MPR Knee

Please note: It is acceptable to scan the Hip, Knee and Ankle in separate series but Conformis strongly suggests scanning them as a single series to help reduce the chance of patient motion.

Although the knee is of primary interest, limited images of the hip and ankle are required to ensure appropriate alignment of the personalized implant. The axial reconstruction parameters are to be followed as closely as possible as permitted by your specific CT system's capabilities.

Displayed Field Of View (DFOV) on all series should be limited to only the affected side. Approximate FOV ranges for the hip are 25-30cm, knee 20-25cm, and ankle 15-20cm. Check the images to make sure that all the anatomy is included. If necessary please reconstruct any series with appropriate centering to recover missing anatomy.

Protocol Build, We recommend building a Conformis protocol in your CT scanner(s) with all of the appropriate ranges.

KV/MaS Settings should be set at your standard setting for each of the anatomic ranges to be scanned. Conformis suggests employing dose reduction techniques whenever possible.

Bilateral Imaging—To reduce radiation exposure bilateral imaging should be accomplished in a single acquisition with separate reconstructions of each leg.

***Before the patient leaves the scan table, please review all images to ensure that there is no motion and that the patient did not change position during the scan.

If motion and/or positional changes are detected, all series (hip, knee and ankle) should be reacquired.***

# Conformis Protocol for CT of the Lower Extremity

Series	**All scans should be acquired in the helical/spiral mode, pitch as close to 1:1 as possible, using the body filter (50 cm SFOV). From the full leg scout the hip, knee and ankle images can be acquired in a single scan acquisition. Then provide reconstructed series in the coronal and sagittal planes of the knee. Send all images that are acquired including the scout and dose page.**			
1	*Scout*	*FULL LEG, Hip through Ankle*		
		Kernel / Algorithm	Reconstruction Thickness X Increment (table increment should not exceed slice thickness)	Projection
2	**Hip** – Femoral head only (acetabulum only)	Bone	2mm X 2mm or 2.5mm X 2.5mm	Axial
2	**Knee** – distal 1/3 of the femur through proximal 1/2 of tibia *(should include the entire patella through midpoint of the lower leg)*	Bone	1mm X .5mm or 1.25mm X .625mm	Axial
2	**Ankle** – center at tibiotalar joint space scan 2cm above the joint to 2cm below	Bone	2mm X 2mm or 2.5mm X 2.5mm	Axial
3	**Multi Planar Reformat**– knee only	Bone	1mm X 1mm	Coronal
4	**Multi Planar Reformat**– knee only	Bone	1mm X 1mm	Sagittal

Note: The imaging protocol described in this manual is only for the purpose of providing information needed by Conformis to generate the personalized implant design. It might differ from knee imaging protocols routinely used by your institution for diagnostic purposes and might not provide the same information. The responsible radiologist should decide whether additional scans from your routine diagnostic protocol should be added to the exam to provide any additional information.

Scout

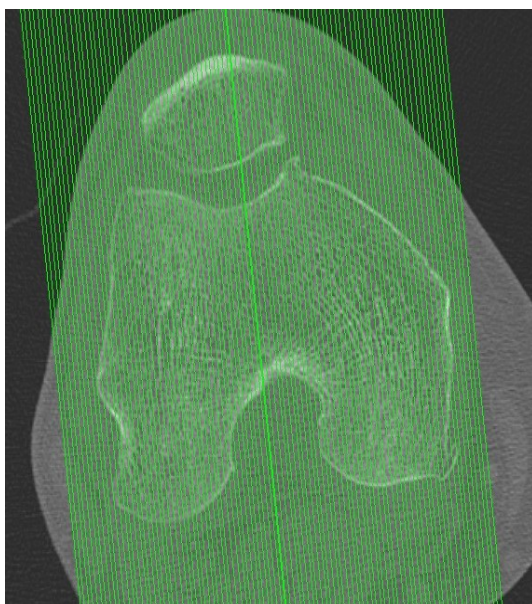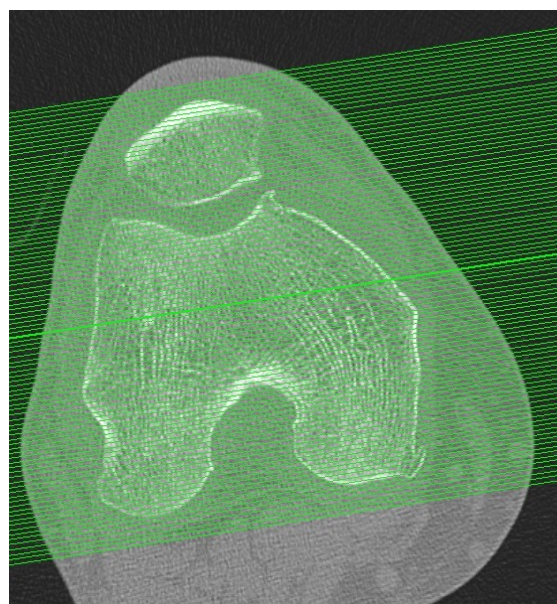
Hip Range
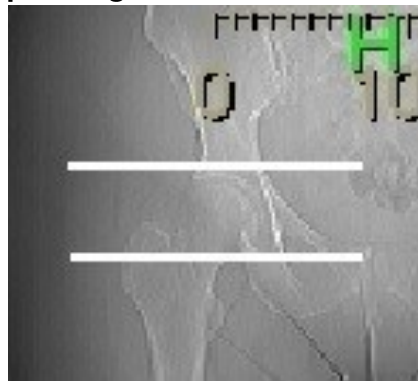
Knee Range

Ankle Range

Knee MPR: Sagittal and Coronal

Sagittal MPR
Perpendicular to femoral condyles

Coronal MPR
Parallel to femoral condyles

3.0   Image Archive

Important: Your site **must** keep a permanent archive (PACS) copy of the CT exams. We also encourage you to protect the the raw data for as long as possible.

4.0   Image Data Transfer:

It is critical that Conformis protocol scans are <u>sent immediately</u> upon completion of the exam via electronic upload whenever possible to ensure the best possible care for the patient.

There are several methods of image transfer available for Conformis protocol scans. Prior to transmitting, ensure that your DICOM data file is complete, containing the scout, the dose page and all images and series aquired for the patient.

4.1 Secure Web Upload:
Conformis scans can be uploaded from a CD, DVD, or a web enabled PACS to our secure website. Go to https://www.conformis.info/scanupload/details.faces to upload a scan through our secure .ftp site.
** Requires the use of Java which is not supported by Google Chrome**

4.2 Secure DICOM transfer via Cloud Sharing Networks:
Conformis is able to retrieve images from cloud based image sharing sites. If you are currently using one of these types of applications or are interested in establishing a secure cloud connection please contact Conformis Image Support at 781-345-9170 to discuss establishing a connection.

4.3 Priority Shipping:
To ensure that the patient's images are received and reviewed as quickly as possible we strongly recommend the use of an electronic method of DICOM data transfer for Conformis protocol scans. However if you are unable to send studies electronically Conformis scans that have been saved in uncompressed or loss–less compression DICOM format on a disk (CD or DVD) can be shipped to Conformis. We provide pre-paid envelopes. To obtain a supply please email   imaging-support@Conformis.com or visit http://www.Conformis.com/Imaging-Professionals/Request-CD-Mailers