CT Protocol Reference Guide

For the ConforMIS Family of
Knee Resurfacing Implants

iUni® iDuo® iTotal®

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

ConforMIS Imaging Support
Tel.: 781/345-9170
Fax: 781/345-0104
Email: imaging-support@conformisConforMIS.com
Hours: 8.00 am – 5.00 pm (Eastern Time)

1.0 Patient Position:

The patient should be at isocenter in the gantry and must be supine with extremity of interest fully extended.
It is critical that the foot be perpendicular to the table with toes pointing straight up and secured to prevent motion. Do not place a sponge or pillow beneath the knee or ankle. This will limit our ability to accurately assess for and correct for malalignment of the knee.

2.0 Image Acquisition:

The protocol consists of a series of three (3) separate short spiral scans. One scan each through the hip, affected knee and ankle are required. Although the knee is of primary interest, limited images of the hip and ankle are required to ensure appropriate alignment of the leg with the personalized implant. The axial reconstruction parameters are to be followed as closely as possible as permitted by your specific CT system's capabilities.

Field Of View (FOV) on all series should be limited to only the affected side. Approximate FOV ranges for the hip are 25-30, knee 20-25, and ankle 15-20.

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

GE users tip, if you do not have a pre-defined protocol built: Between scan ranges select "Repeat series" to scan the next range. Do Not select "Add a group".

Toshiba users tip: Between scan ranges select "Quit series" and use original scout to scan the next range.

KV/MaS Settings should be set at your standard setting for each of the anatomic ranges to be scanned.

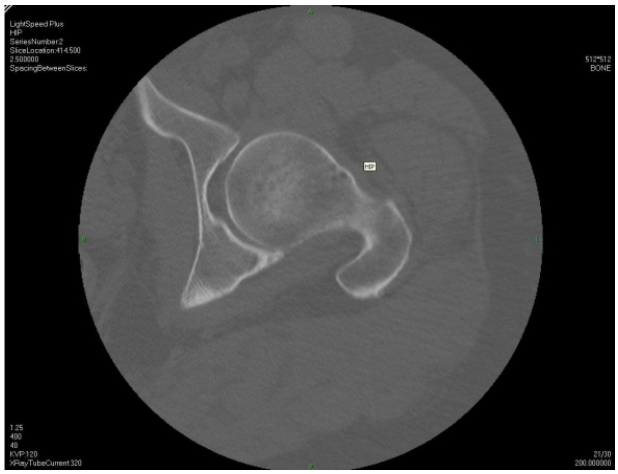
Bilateral Imaging can be accomplished with a single acquisition with reconstructions of each leg independently.

Scan	Area of Interest	Kernel / Algorithm	Axial Reconstruction Thickness X Increment	Multi Planar Reformat MPR
1	Scout – Hip through Ankle			
2	Hip – Femoral head only	Bone	2 - 2.5 X 2 - 2.5	N/A
3	Knee – Top of patella to 3cm below the tibial plateau	Bone	1 - 1.5 X .5 - .625	1mm X 1mm Sagittal and Coronal
4	Ankle – Malleoli through Talus	Bone	2 – 2.5 X 2 – 2.5	N/A

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.

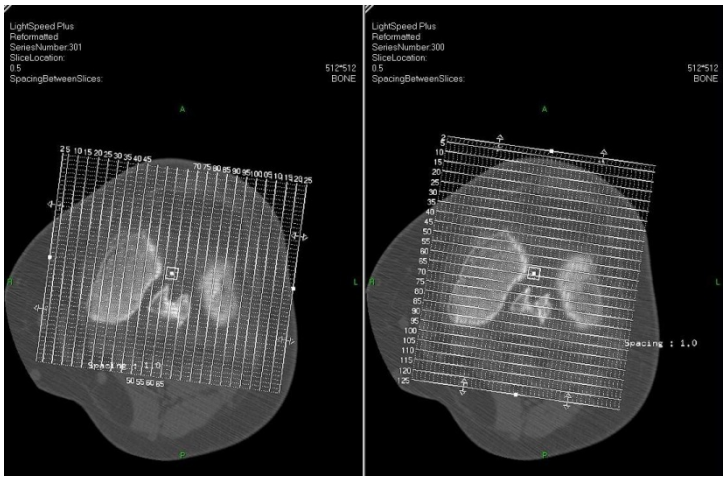
2.1 Scout Representing Appropriate Scan Ranges:

2.2 Hip Image Representing Center of Hip Series:

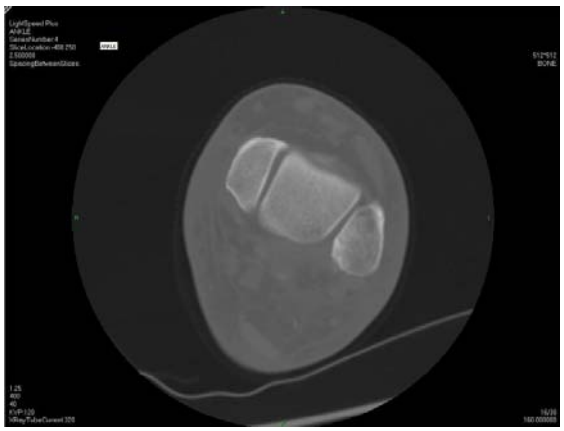


2.3 Knee MPR:

Sagittal and Coronal reformats should be limited to the side of interest and cover bone to bone only. It is preferred for Coronal MPR to be parallel to femoral condyles, and Sagittal MPR to be perpendicular to femoral condyles.



2.4 Ankle Image Representing Center of Ankle Series:



3.0 Optional CT Arthrography Protocol:

This CT imaging option is most often used to assist in the diagnostic evaluation of the patellofemoral cartilage and the cartilage in the other tibiofemoral compartment. It can also be used for evaluating menisci and cruciate ligaments.

3.1 Routine Arthrography:

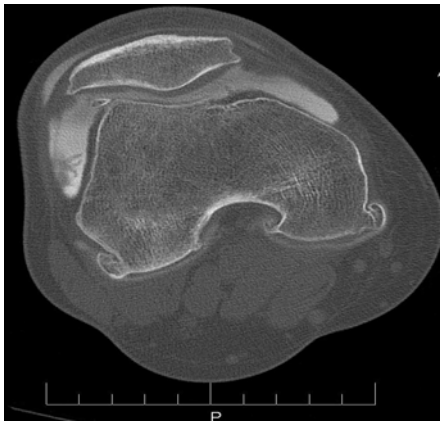
A routine knee arthrogram should be performed using a contrast agent concentration of approximately 150 mg of iodine per milliliter. The dilution is important for the visualization of the bone and soft tissue structures in the joint space.

Example 1: If Omnipaque 300 is used, dilute with 50% saline.
(DO NOT USE FULL STRENGTH 300)

Example 2: If Omnipaque 180 is used, no dilution is necessary.

3.2 Post Arthrogram CT Imaging:

As prescribed in sections 1.0 and 2.0 of the ConforMIS CT Protocol and preferably within 60 minutes of contrast injection.



4.0 Image Archive

Important: Your site **must** keep a permanent archive (PACS) copy of the knee CT exams.

5.0 Image Data Transfer:

There are several methods of image transfer available for ConforMIS protocol exams.

5.1 Image Mailing:

ConforMIS knee exams that have been saved in uncompressed DICOM format on a disk (CD or DVD) can be mailed to ConforMIS. We can provide CD sleeves and self addressed stampedenvelopes. Please email imaging-support@ConforMIS.com or visit http://www.ConforMIS.com/Imaging-Professionals/Request-CD-Mailers to obtain a supply.

Print name of patient and CT center on the disk. Ship disks to:

Imaging Services
ConforMIS, Inc.
11 North Ave.
Burlington, MA 01803-9979 USA
Phone: 781/345-9170
Fax: 781/345-0104

5.2 Image Transmission - Secure Web Upload:

ConforMIS knee exams can be uploaded from a CD, DVD, or a web enabled PACS to our secure website. Go to http://www.ConforMIS.com/Imaging-Professionals/Upload-a-Scan to upload a scan through our secure .ftp site.

5.3 Secure Electronic Image Transport:

ConforMIS partners with AG Mednet to provide a HIPAA compliant, highly secure and simple to use electronic image transport network. This software solution is established on an existing PC on your network and utilizes a direct network connection with your modality to automatically transport images to ConforMIS. To take advantage of this solution please contact ConforMIS Imaging Support at 781-345-9170 or via e-mail at imaging-support@ConforMIS.com.

CE registration only for iUni and iDuo

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