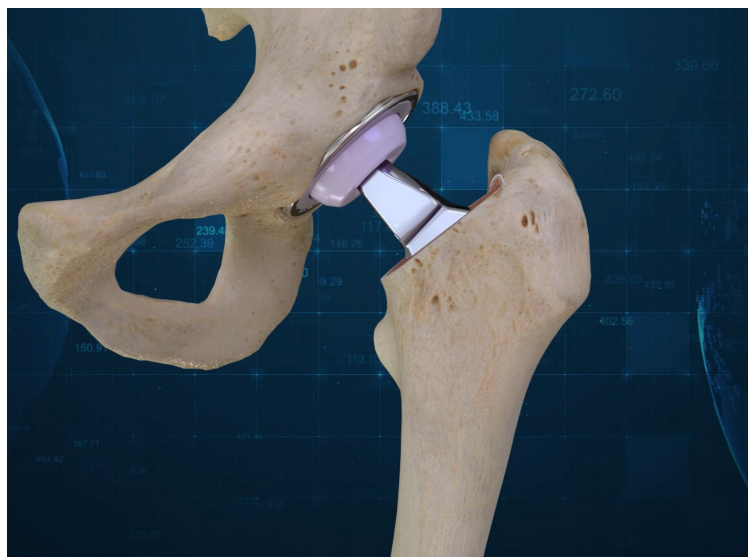


Lower Extremity CT Protocol Guide for the Conformis® Hip System



Introduction:

Patients who present with an order for a Lower Extremity CT for the Conformis Hip System are being considered as a candidate for one of the Conformis, Inc. hip implants. These are customized implants designed from CT scans.

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

Conformis Imaging Support
600 Technology Park Dr.
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)

1.0 Patient Position:

To ensure our ability to correct for malalignment and to overcome anteversion of the femoral neck, position the toes internally rotated 15°. 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 knees or ankles. When necessary, please have the patient change from street clothing and ensure that no foreign objects are in the scan field. Please instruct the patient to hold very still during the scan acquisition.

IMMOBILIZATION IS ESSENTIAL



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

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)

The scan protocol consists of scout and 3 series

1. Scout—Above iliac crest to below tibial plateau
2. Top of Pelvis to mid Knee joint
3. Coronal MPR
4. Sagittal MPR

The scan description should identify whether left or right side is of primary interest as requested on the physician's order.

FOV, kV and mAs necessary to produce acceptable image quality while reducing dose as much as possible will vary according to patient size and your system specifications. Conformis has provided minimum guidelines below for these parameters.

Field Of View (FOV) - Approximate FOV ranges for the scan are 38-45cm kV - 120 mAs - ~100-200

*** When an implant or other device is present in the opposite hip or knee please use metal artifact reduction software or a metal artifact reduction technique increasing KVP by 15% to reduce the artifacts in the affected joint . ***

Protocol Build—We recommend building a Conformis Hip Protocol in your CT scanner(s) with the appropriate range.

*****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 repeat scan.*****

Conformis Protocol for CT of the Lower Extremity

Series	**All scans should be acquired in the helical mode, rotation speed not less than 1 sec, pitch as close to 1:1 as possible, using the body filter. From the limited leg scout acquire images from the top of the pelvis through the knee joints. Send <u>all</u> images that are acquired including the scout and dose page if available**			
1	<i>Scout</i>	<i>LIMITED LEG, Hip through the Tibial Plateau</i>		
		Kernel / Algorithm	Reconstruction Thickness X Increment (table increment should not exceed slice thickness)	Projection
2	Hip – (include full pelvis) – top of the iliac crest to mid knee joint	Bone	1 mm X .5mm or 1.25mm X .625mm	Axial
3	Multi Planar	Bone	1 mm X 1 mm	Coronal
4	Multi Planar	Bone	1 mm X 1 mm	Sagittal

***** If your CT system does not allow you to meet the specific requirements of this protocol reference guide please contact Conformis Imaging Support at 781-345-9170 for assistance *****

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 hip/pelvis 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



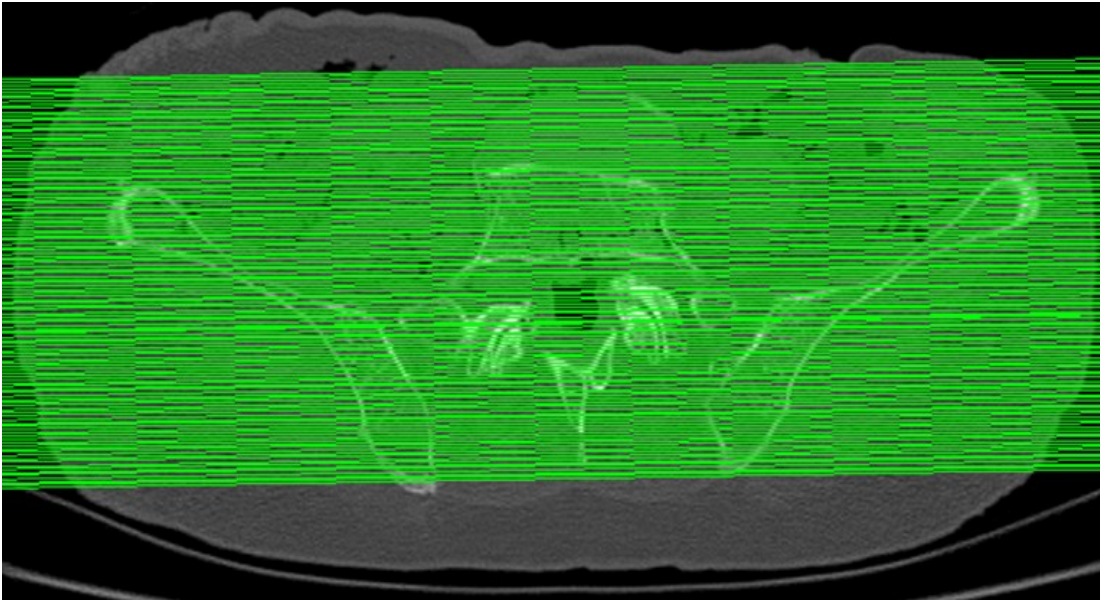
Scan Range



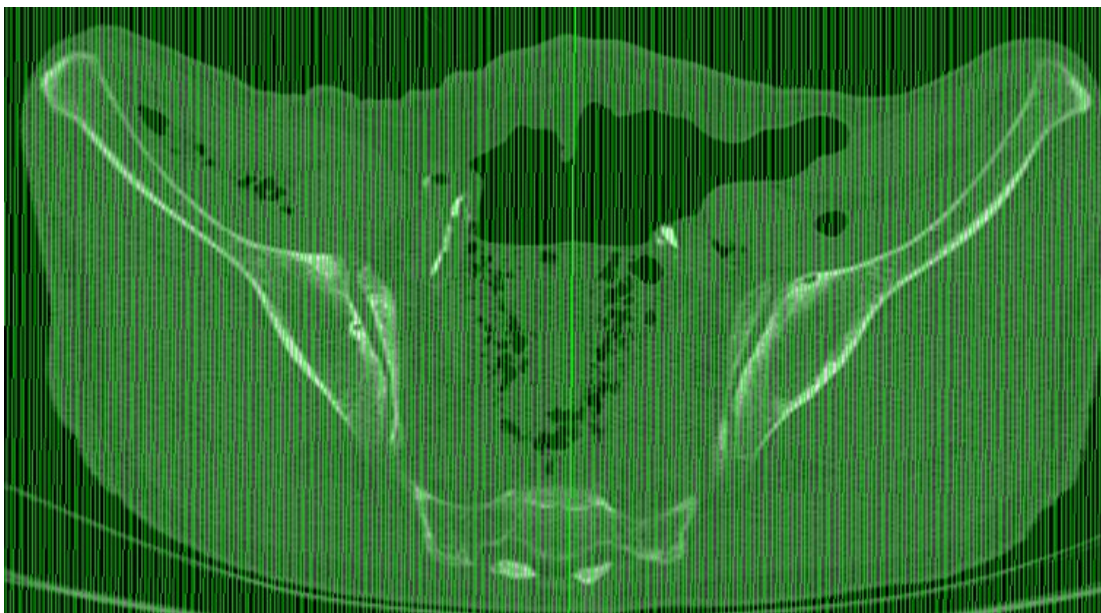
MPR's:

Coronal and Sagittal reformats of the scan are required. The Sagittal reformats should be perpendicular to the Coronal reformats as seen in the images below

CORONAL



SAGITTAL



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 your system will allow

4.0 Image Data Transfer:

******It is critical that Conformis protocol scans are sent immediately 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>