Lower Extremity CT Protocol Guide for the restor3d® Hip System

Introduction:

Patients who present with an order for a Lower Extremity CT Scan for the restor3d Hip system are being considered as a candidate for one of the restor3d® 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:

restor3d Imaging Support

600 Research Dr.
Wilmington, MA 01887
Tel: 781-345-9170
Email: imaging-support@restor3d.com

Imaging Support is available:
Monday-Friday
8:00am - 4:00pm (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)

This 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. Saggital MPR

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

For Siemens scanners used fixed axial option only
All scans are bilateral no matter which side the surgeon orders

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. restor3d has provided minimum guidelines below for these parameters.

Field of View (FOV) - Appropriate 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 restor3d 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******

restor3d 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 all images that are acquired including the scout and dose page if available***			
1	**Scout**	**LIMITED LEG, Hip through the Tibial Plateau**		
		Kernal / 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**	**1mm X .5mm or 1.25mm X .625mm**	**Axial**
3	**Multi Planar**	Bone	**1mm X 1mm**	**Coronal**
4	**Multi Planar**	Bone	**1mm X 1mm**	**Sagital**

****If your CT system does not allow you to meet the specific requirements of this protocol reference guide please contact restor3d 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 restor3d 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.

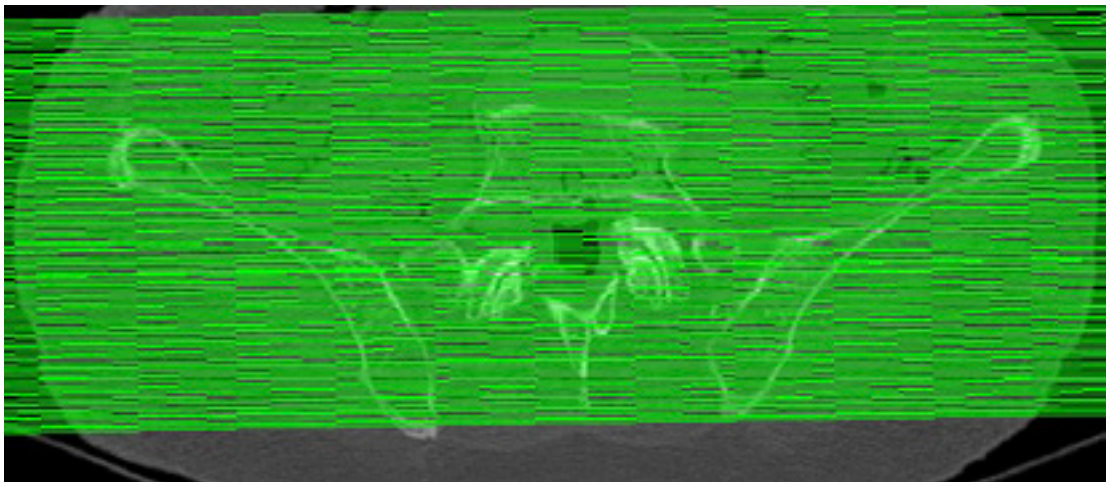
Scout

Scan Range

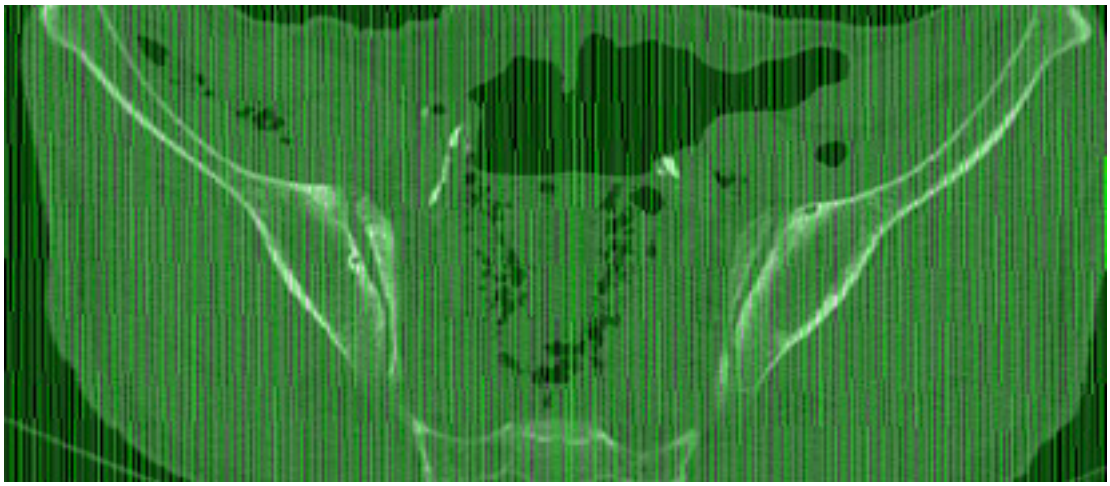
MPR's:

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 raw data for as long as your system will allow.

3.0 Image Data Transfer:

****** It is critical that restor3d 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 restor3d protocol scans. Prior to transmitting, ensure that your DICOM data file is complete, containing the scout, the dose page and all images and series acquired for the patient.

4.1 Secure Web Upload:

restor3d scans can be uploaded from a CD, DVD, or a web enabled PACS to our secure website. Go to https://widgets.nuancepowershare.com/easyupload/Conformis to upload a scan through our secure .ftp site.

4.2 Secure DICOM transfer via Cloud Sharing Networks:

restor3d scans can be uploaded from a CD, DVD, or a web enabled PACS to our secure website. Go to https://widgets.nuancepowershare.com/easyupload/Conformis to upload a scan through our secure .ftp site.

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 restor3d protocol scans. However if you are unable to send studies electronically restor3d scans that have been saved in uncompressed or loss–less compression DICOM format on a disk (CD or DVD) can be shipped to restor3d. We provide pre-paid envelopes. To obtain a supply, please email imaging-support@restor3d.com.