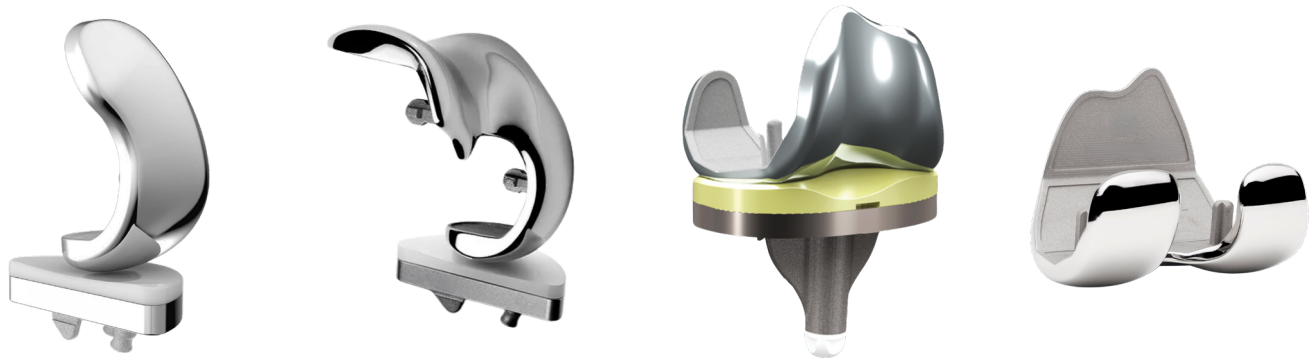


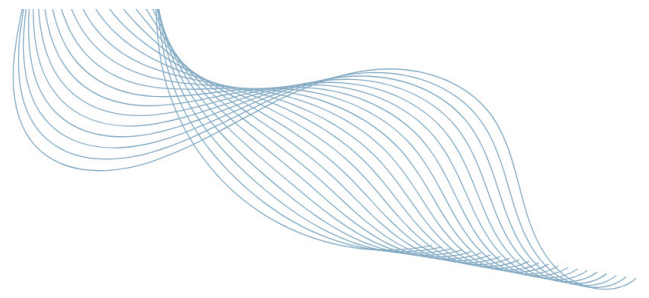


restor3d

CT Lower Extremity Protocol Reference Guide



*For the restor3d Family of
Knee Replacement Implants*



Introduction:

Patients who present with an order for a CT Scan of the lower extremity following restor3d protocol are being considered as a candidate for one of the restor3d knee implants. These are customized implants designed from CT scans.

TABLE OF CONTENTS

1.0	PATIENT POSITION	PAGE 3
2.0	IMAGE ACQUISITION	PAGE 4
	-Protocol Chart	PAGE 5
3.0	IMAGE ARCHIVING	PAGE 8
4.0	IMAGE DATA TRANSFER	PAGE 8

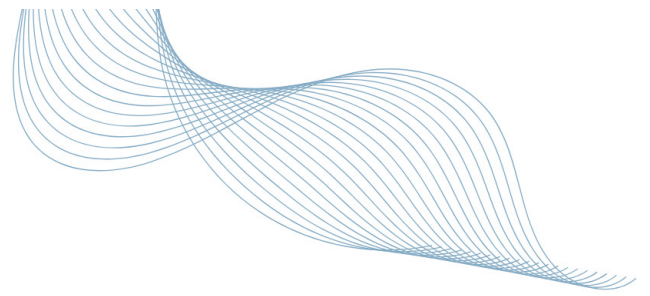
All questions regarding this protocol reference guide should be addressed to:

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 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 orientation. Immobilize the legs and toes to prevent motion. The use of positioning aids is encouraged. It is the 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.

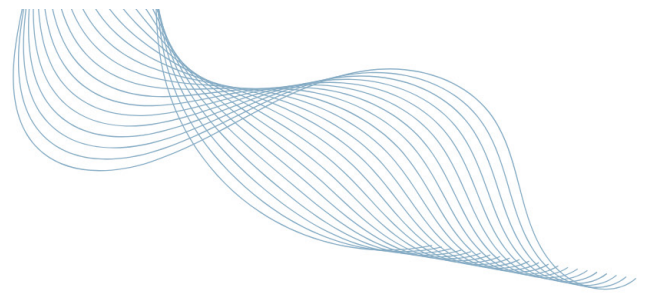
IMMOBILIZATION IS ESSENTIAL



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.

******* 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 you 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 restor3d strongly suggests scanning them as a single series to help reduce the chance of patient motion. For GE scanners use add group feature to build protocol with 3 ranges. For Siemens scanners used fixed axial option only. 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.

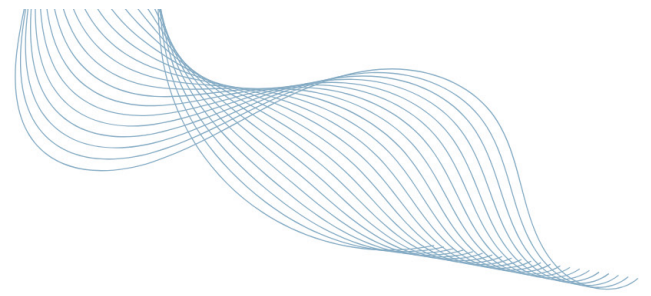
Protocol Build, We recommend building a restor3d protocol in your CT scanner(s) with all of the appropriate ranges.

KV/MaS Settings should be set at your standard setting for each of the anatomic ranges to be scanned. restor3d 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. See *example on last page*.

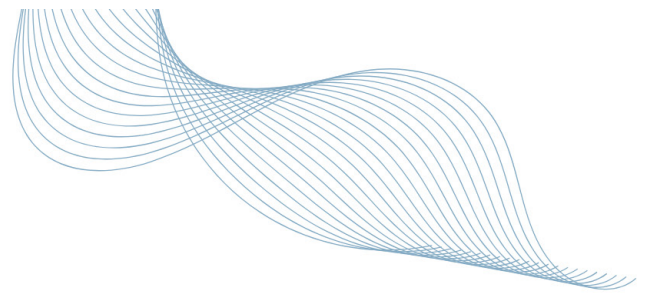
*****Before the patient leaves the scan table, please review all images to ensure that there is no motion and that the patient did not change position during the scan.**

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



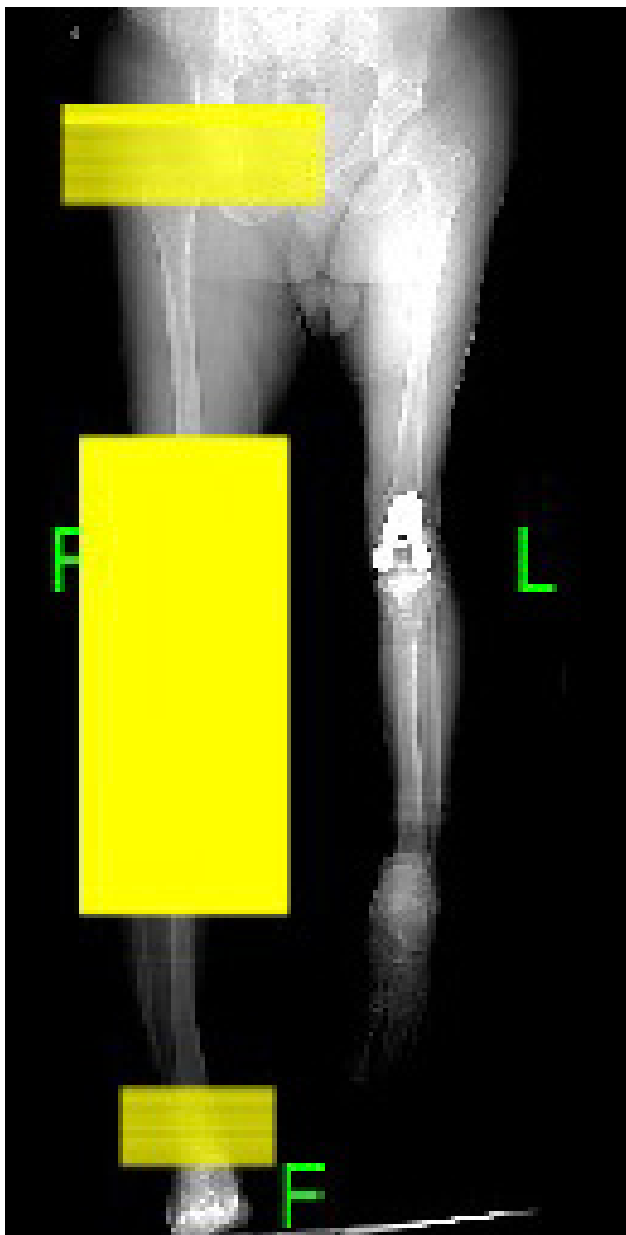
restor3d Protocol for CT of the Lower Extremity

Series	<p><i>**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.**</i></p>			
1	Scout	FULL LEG, Hip through Ankle		
		Kernal / 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 <i>(should include the entire patella through midpoint of the lower leg)</i>	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

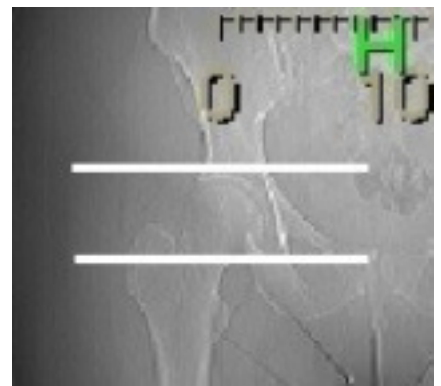


Note: The imaging protocol described in this manual is only for the purpose of providing information needed by restor3d to generate the personalized implant design. It might differ from knee imaging protocols routinely used by your institution for diagnostic purposes and might not provide the same information. 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

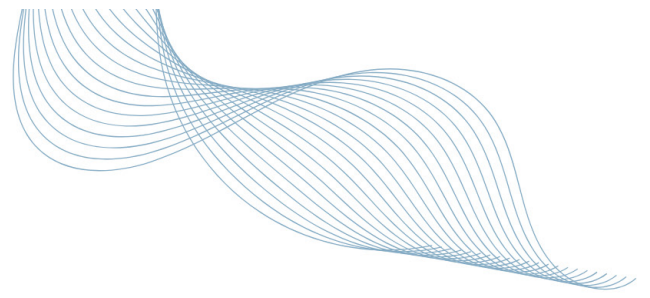


Knee Range



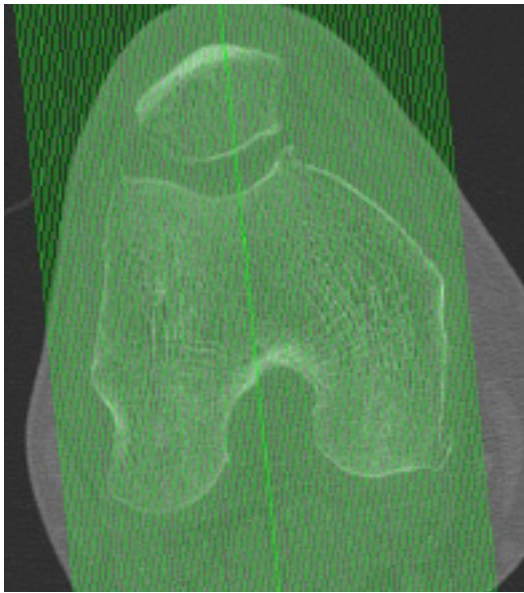
Ankle Range



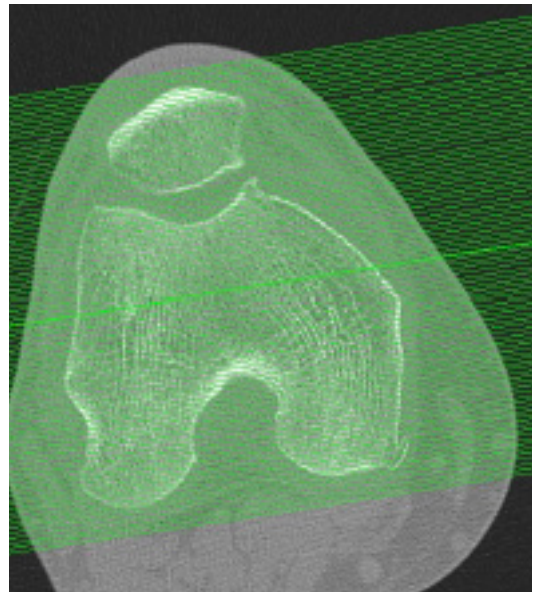


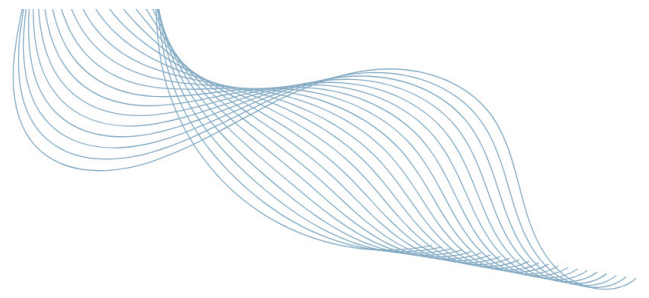
Knee MPR: Sagittal and Coronal Can use DMPR to make reformats

Sagittal MPR



Coronal MPR





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 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 aquired 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 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 restor3d Image Support at 781-345-9170 to discuss establishing a connection. We are a Nuance PowerShare Hub and can be found under Conformis Inc. Just send an invite.

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 labels. To obtain a supply please email imaging-support@restor3d.com

Example of bilateral scan below. If scanner will not allow you to manipulate the raw data to produce a right and left leg with the smaller FOV's you will need to scan each leg separately.

