Kinomatic CT Protocol

Proprietary & Confidential - Page 1 of 9 - Uncontrolled if Printed

1. Introduction

This document describes the guidelines that radiological centers should follow when performing CT-Tech Only scans required by Kinomatic LLC to use the Kinomatic software.

The directives in this document are intended to improve the quality of the resulting CT scans. Radiologic Technologists are, in general, required to follow the instructions outlined in this document; variations to the settings and potential modifications to the protocol are to be discussed with and approved by Kinomatic LLC in advance.

Kinomatic LLC reserves the right to refuse scans performed with settings different from the required ones.

For more information, please do not hesitate to contact Kinomatic LLC at the following email address: radiology@kinomatic.com.

1.1 Warnings and Precautions

The CT scanner being used must be properly maintained and calibrated in accordance with the manufacturer's specifications to obtain the most accurate implant templating.

2. Preparing the Patient

Use the following instructions to prepare the patient for the CT scan:

1. Gather the following items:
    a. CT motion rod
    b. Small Velcro straps
2. Ensure all metal items are removed from the patient.
3. Position the patient supine on the cradle pad feet-first.
4. Extend the patient's legs. Flexion is discouraged, as it may interfere with the alignment of the Kinomatic model. *However, if it is impossible for the patient to achieve straight legs due to pain, extend the legs as much as possible while ensuring that the patient remains comfortable and relaxed.* For comfort, place a pillow or a rolled sheet under the knees.
5. Set the CT motion rod on the lateral side of the patient, as close as possible to the operative bony anatomy to pass from just proximal of Hip Center to distal of Ankle Center.
6. Secure the motion rod with small Velcro straps, as shown in Figures 1 and 2.

Figure 1: Motion rod positioning.

Figure 2: Motion rod positioning from lateral view.

a. The total circumference of the CT motion rod must appear in every slice along the operative leg.
b. The CT motion rod must extend over the entire length of the operative leg, from the femoral head beyond the talus of the ankle.
c. To avoid rod motion due to patient breathing, do not place the CT motion rod on the patient's abdomen.
d. Do not allow the CT motion rod to contact the CT table.

7. Verify that the CT motion rod is secured to the leg so that it will not slip during the scan.
8. It is critical that the patient remains motionless during the entirety of the scan. If the patient has a difficult time remaining still, the feet may be taped to the table in the proper position. Proper feet position is perpendicular to the table with toes pointing straight up as shown in Figure 3.

Figure 3: Proper feet position.

9. Instruct the patient to relax and remain motionless for the entire scan. **Verify that the patient fully understands the importance of a motionless scan.**
10. Position the patient inside the CT scanner, feet first into the gantry.

3. Image Acquisition

The acquisition consists of three (3) separate short spiral axial scans:

1. Both hips
2. Both knees
3. Both ankles

Scans must be the SAME FOV SIZE.

Please note that scans of the hips, knees, and ankles are required to ensure an appropriate alignment of the leg. All three scans must be in the same coordinate system (frame of reference).

3.1 Required Regions/Fields of View

Each acquisition must be centered and collimated accurately to ensure the FOV maximizes the region of interest. Attention must be paid so that the outer bounds of the regions of interest are included in the FOV.

The whole of the required bone regions must be captured. Figures 4 and 5 depict the field of view required in the scan:

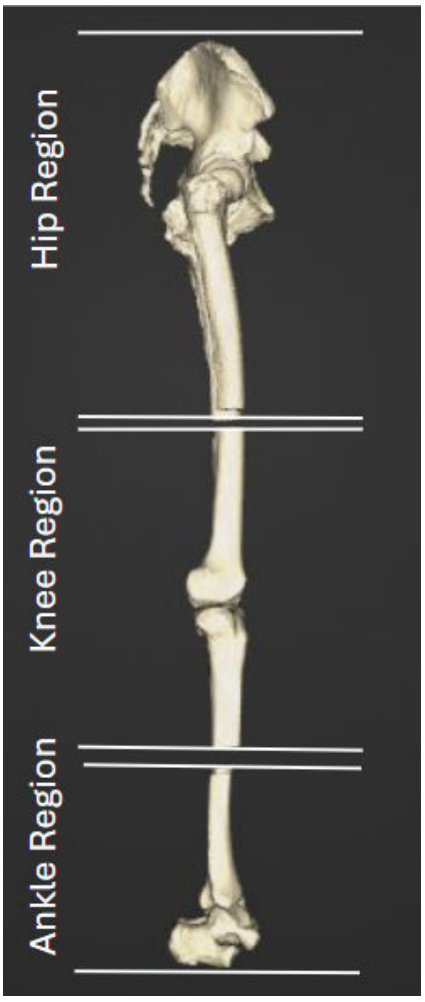

Figure 4. Lateral view of FOV.

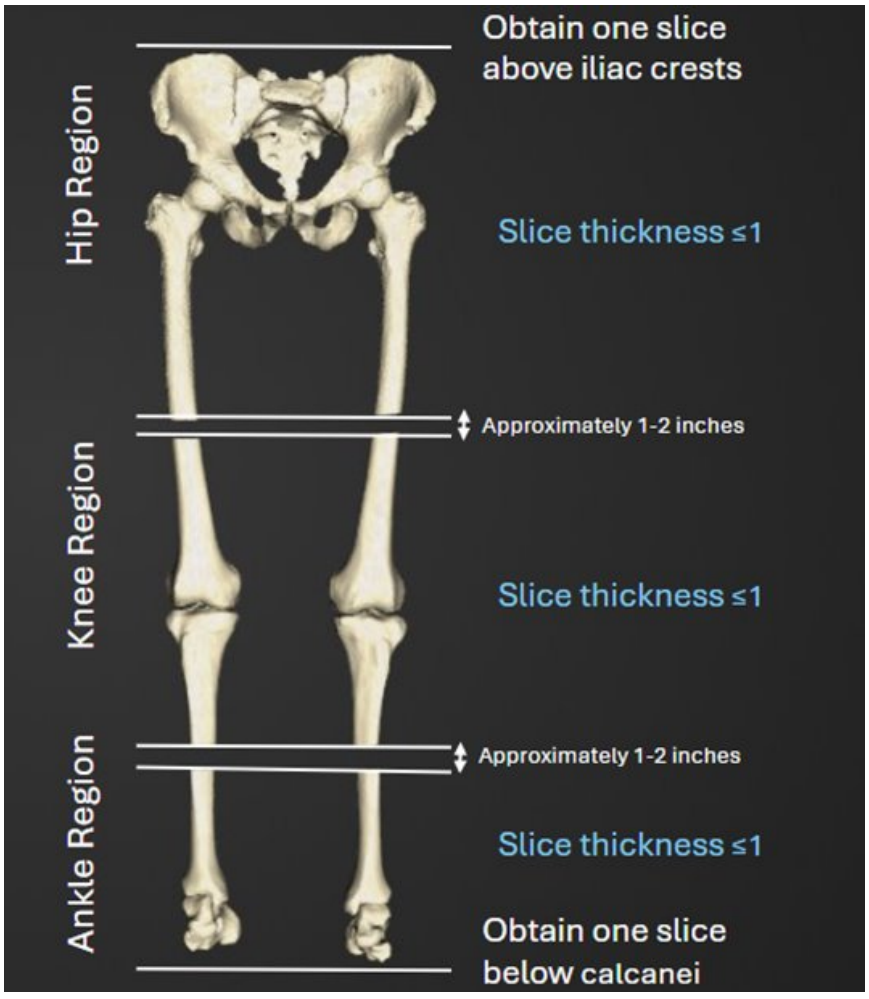

Figure 5. Coronal view of FOV.

3.2 Required Study Header Information

Please enter the following in the scan header:

Header Fields / DICOM Tags	DICOM Tag	Format
Patient Full Name	(0010,0010)	Last, First
Patient Date of Birth (DOB)	(0010,0030)	YYYY-MM-DD
Study Description*	(0008,1030)	Patient Name, <TKA or THA>
Series Description	(0008,103E)	Based on scan region (Hip, Knee, or Ankle)

* Procedure type necessitating scan: Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA)

3.3 Required Scan Protocol (All Regions)

The following settings are intended to maximize the quality of the images. If different values are required on your machine, please inform Kinomatic LLC before proceeding with the acquisition.

Please use the following scan parameters to set up a Kinomatic Scan Protocol:

Parameter	Protocol for All Scan Regions
Scan Type	Helical
Table Motion	Out of gantry
Scout	AP Lateral
Table Tilt / Gantry Angle (°)	0.0
Pitch	<1
Patient Position	Feet-First Supine (FFS), Immobile with Motion Rod strapped to operative leg (see Section 2)
Strength (kV)	120 or higher
X-Ray Tube Current (mA)	120 or higher
Field of View (FOV)	Min 350 mm/ Max 500 mm
Raw Data Save	Temporarily save raw data for reconstruction

CT scanner settings vary based on the manufacturer, operating mode, default configurations, and facility preferences. If your scanner lacks the exact setting mentioned, choose the closest option that provides a higher resolution than the specified one.

3.4 Required Reconstruction Parameters (All Regions)

Parameter	Parameters for All Scan Regions
Reconstruction Slice Thickness (mm)	≤ 1.0 mm
Slice Interval	50% overlap
Filter / Convolution Kernel	Standard or Bone
Field of View (FOV)	Include both operative and non-operative leg; Include entire circumference of Motion Rod. See Section 3.1.
Image Resolution / Matrix Size	512 x 512
Metal Artifact Reduction (MAR)	If option available and metal artifact is present, please apply.
Transfer Syntax	LittleEndianExplicit

3.5 Image Inspection and Export

1. Inspect the scan for evidence of patient motion.
2. Inspect the first and last slices of the scan to ensure that the whole circumference of the motion rod can be seen.
3. The three required scans of the hips, knees and ankles must be exported as original scans. In particular, derived (re-sampled) series will be rejected.
4. Check that the reconstructed study provided contains only the series of interest to minimize confusion and likelihood of error.
5. If multiple series are saved for the different joint regions, name the series accordingly (e.g. Hip, Knee, or Ankle).
6. Both the Study Description and Series Description(s) should be named according to Section 3.2.
7. In general, any localizers automatically produced by the machine should be excluded from the media. If this is not possible, please clearly distinguish between localizers and actual scan series. DO NOT include localizers within the series.
8. DO NOT anonymize or deidentify. Retain all patient identification DICOM Tags.

4. Image Delivery

The DICOM dataset of a Kinomatic CT case can be uploaded to an online medical imaging transfer software. Kinomatic currently supports the following transfer partners:

- Ambra
- SimonMed
- Nuance

Alternatively, the DICOM dataset can be stored on a CD or DVD. A label must be applied including:

- Patient Full Name
- Affected/Operative Side
- Acquisition Date
- If applicable, Surgery Date

Mail CD or DVD to:

Kinomatic LLC

136 W. Branch St.

Arroyo Grande, CA 93420

Do not hesitate to contact Kinomatic LLC for further assistance at: radiology@kinomatic.com.

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Approved By:

(CO-2) CT Protocol & THINK Edits

Description

Purpose: Initial release of CT Protocol and CT Editing Instructions for THINK Surgical Scope: Manufacturing and Operations Doc IDs: MFG-WI-01 and PDPROJ1-1-LBL-001

Justification

Initial release in Greenlight Guru

Assigned To:	Initiated By:	Priority:	Impact:
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