

# Samumed SM04690-OA-06

## Quick Reference Guide for Image Acquisition and Data Handling

### QCT of QKP Phantom

Quality Assurance Phantoms need to be scanned at the beginning of the study and once a week when subjects are scanned but at least once a month

#### Acquisition Parameters for QKP phantom

<b>Table Height</b>	
mAs	220
Dose reduction	No
kV	120
Slice collimation	
Pitch	
Scan FOV	

#### (fill in yellow fields) Reconstruction Parameters

Slice thickness	
Reconstruction Increment	
Kernel	
# of slices	Cover complete QKP
Reconstructed FOV	200

### QCT of Knee

#### Visit Schedule

QCT	Screening Visit 2	Week 12	Week 24	Week 36	Week 52 EOS/ET
Knee	X	X	X	X	X

The BDC In-Scan Calibration Phantom for knee must be placed below the target knee.

Scan length: 10 cm above the femorotibial articular space to 10 cm below femorotibial articular space

#### Technical Parameters (fill in yellow fields)

		Target Knee		Contralateral Knee	
<b>Acquisition</b>	mAs	220			
	Automated Exposure Control	Off			
	kV	120			
	Slice Collimation				
	Pitch				
	Gantry Angle	0			
	Table Height				
	Coverage	10 cm above the femorotibial articular space to 10 cm below femorotibial articular space			
	Scan FOV				
<b>Reconstruction</b>		Target Knee		Contralateral Knee	
		Large FoV	Small FoV	Small FoV	
	Reconstructed FOV	200	130	130	
	Slice Thickness				
	Reconstruction Increment				
	Reconstruction Kernel				

Please keep raw data until you have received quality assessment report from Bioclinica.

# Samumed SM04690-OA-06

## Quick Reference Guide for Image Acquisition and Data Handling

### Electronic Data Transfer Using Bioclinica Portal

The Bioclinica Portal (SMART Submit) is the preferred method of data submission. It is a web-based portal that allows sites to submit images via secure file transfer protocol (FTP). It eliminates delays and expenses associated with shipping images via courier. The Transmittal Form (TF) is completed and submitted electronically as well.

**IN ORDER TO ENSURE SUBJECT CONFIDENTIALITY, PLEASE ENTER THE FOLLOWING INFORMATION INTO THE ELECTRONIC CT HEADER:**

- ▶ "Patient Name" enter: [3 digit Site ID, "6", and 3 digit Subject ID number] EXAMPLE: Patient Name: 1236456
- ▶ "Date of Birth" enter: As required per scanner use 01-JAN-YYYY (e.g. 01-JAN-1947) format on all written documents
- ▶ "Comment field" enter: [Visit] EXAMPLE: Screening, Week 12, Week 24, Week 36, Week 52/ET/EOS, Unscheduled

### Labeling CD Media

- ▶ Please do not affix self-adhesive labels directly to the CD. This may harm the disk drives and cause read errors.
- ▶ Please use an indelible marker to write study and subject specific details on the CD.

These are:

- ▶ Protocol Number SM04690-OA-06
- ▶ 3 digit Site ID, "6", 3 digit Subject ID (e.g. 1226555)
- ▶ DOB 01-JAN-YYYY
- ▶ Visit Name
- ▶ Exam Date

### Data Shipping

The data to be sent from the imaging site should contain both the imaging study and the transmittal form. There are two options for sending data to Bioclinica:

- SMART Submit - the preferred method of submission
- Postal mail/courier service.

#### Sending Data Using Courier Service

- The complete package should contain a CD with imaging data and the completed TF
- Export the data to the CD in uncompressed DICOM 3 format.
- Use an indelible marker to label directly on the CD (See Labeling CD Media above for required information)

#### SMART Submit: <https://smartssubmit.bioclinica.com/>

- SMART Submit is Bioclinica's web-based system for clinical trial uploads. Using SMART Submit sites can fill in required case details as per transmittal form, upload images, authorize, and submit trial cases to Bioclinica. Please refer to the SMART Submit User Guide.

#### Sending a Package to Bioclinica

- Complete the sender sections of the air waybill, keeping a copy for tracking purposes.
- Place the white and yellow copies of the TF and the CD for each patient into a shipping envelope. Please keep pink copy at site.
- Call courier to schedule package pick-up

#### Ship data to:

Bioclinica

**Samumed SM04690-OA-06 (10005841) Team**

7707 Gateway Blvd., 3rd Floor

Newark, CA 94560, USA

Please contact the Samumed SM04690-OA-06 Study Team if you have any questions. To order additional supplies, please fax a completed copy of the Supply Reorder Form found in the QCT Procedure Manual.

Phone: +1 (415) 817 8900

Fax: +1 (415) 817 8999

Email: [#MI\\_DEP\\_MSK.Team.SM04690-OA-06@bioclinica.com](mailto:#MI_DEP_MSK.Team.SM04690-OA-06@bioclinica.com)