



Galapagos/Servier CL2-201086-002/GLPG1972-CL-201

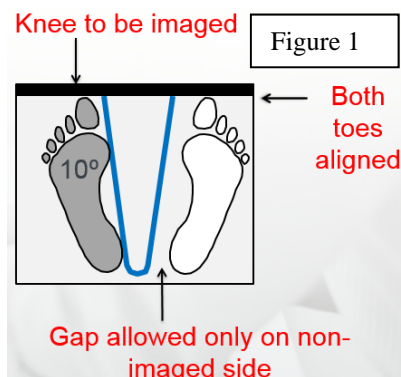
Quick Reference Guide for X-Ray Image Acquisition of the Knee

For a full description of devices and procedures, please refer to the study imaging guidelines

POSITIONING – Unilateral PA Knee weight-bearing Radiograph

Proper foot positioning (unilateral knee imaging):

- The V-shaped foot support (Fig1, shown in blue) on the base of the SynaFlexer will be used to align the patient’s foot. This standardizes knee rotation in the medial-lateral plane for the knee to be imaged.
- The SynaFlexer positioning device frame will be placed off-center to the Bucky’s vertical center line relative to the knee being imaged. (Fig 4)
- The great toes of both feet (or the longest toes) will touch the anterior wall of the SynaFlexer
- The other foot does not need to have the heel touching the V-shaped foot support. Ensure both feet remain on the base of the SynaFlexer. This will help the patient feel more stable in positioning



Proper PA Knee Positioning:

Knee radiographs will be obtained in the PA projection using the weight-bearing, semi-flexed position (modified Lyon Schuss) at ASSE visit

- The patient must be barefoot and in either a gown or shorts to have the knees exposed
- The patient is gently guided forward into position by the technologist with the hand in the small of the back
- The knees and thighs must be pressed directly against the anterior wall of the SynaFlexer device and erect Bucky frame (Fig 2 & 3)
- The patella of both knees should make firm contact with the anterior wall of the SynaFlexer
- Both knees are at a fixed angle flexion of ~20 degrees
- The patient’s body weight needs to be equally distributed between both legs and both feet fixed and flat on the SynaFlexer base
- To ensure proper centering of the patella being imaged, subject should be facing forward with hips and shoulders squared to avoid rotation (Fig 4)
- Start with 10 degree caudal angle. Review* and continue with additional angles (either 8,12, etc.) as necessary to obtain an IMD (inter-margin distance) of 0 mm (Perfect Alignment) or ≤ 1.5 mm (Fig 7)
- Ensure laterality marker of the knee to be imaged is clearly visualized (Fig 5)
- Both columns of beads on Positioning Frame (SynaFlexer™) should be visible on the image (Fig 5).

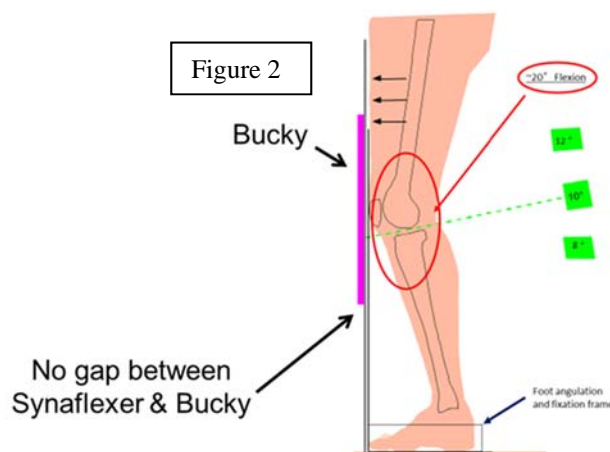


Figure 3



Figure 4



TECHNICAL REQUIREMENTS – PA Knee weight-bearing Radiograph

The mAs and kVp can be adjusted to penetrate the knee adequately

- A small increase in knee size from “average” would best be imaged with an increase in kVp
- A large increase in knee size from “average” would best be imaged with an increase in both mAs and kVp

Focal Spot

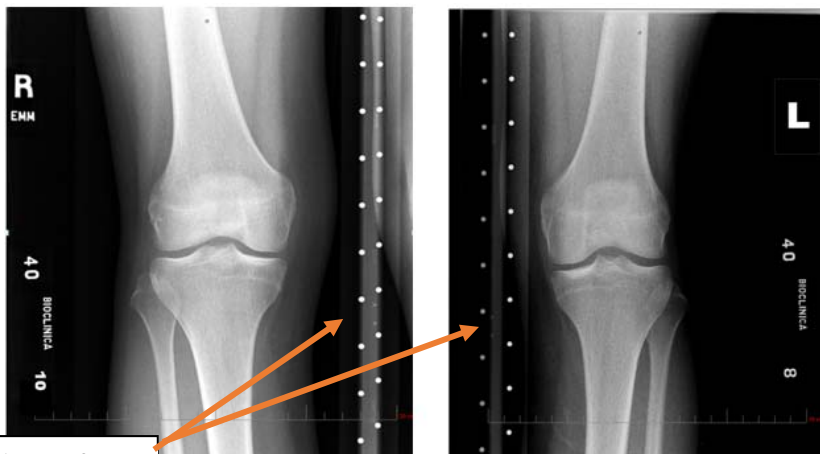
- Small focal spot required

Film/Cassette (IR)

- If a 10x12 inch (24 cm x 30 cm) film/cassette(IR) cannot capture the knee fully with both bead columns, a larger film/image size can be used.
- Ensure there is adequate collimation on all images

FFD/SID

X-ray tube should be positioned 40 inches (100 cm) from the film or image receptor, however the distance may be increased to 47 inches (120 cm) if necessary. X-ray technique factors (mAs, kVp) should be adjusted accordingly. Please note: **Use same FFD/SID for all visits.**

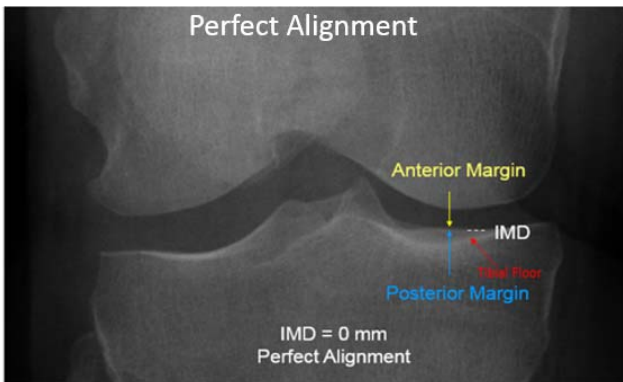
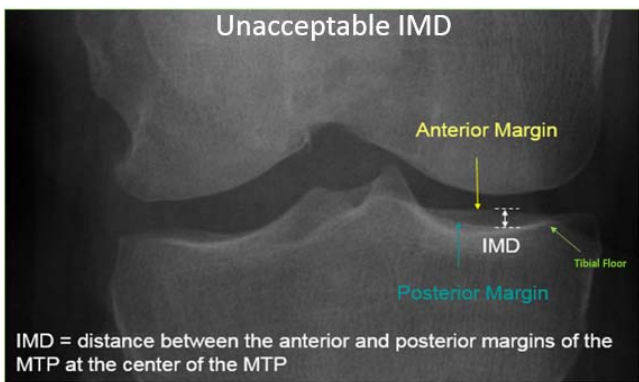


Both Column of beads clearly visible

Figure 5

Figure 6

Figure 7



X-Ray Quick Reference Guide

Galapagos/Sevier Study Protocol CL2-201086-002 / GLPG-1972-CL-201

Entering Subject Data in Electronic Header

In order to ensure patient confidentiality, please enter the following information into the electronic header:

- **“Patient Information”** enter 4 digit Site Number and 5 digit Subject Number.

Example:

- **“Date of Birth”** enter **01-JAN-YYYY*** The day and month for each subject should be entered as 01-Jan followed by the true birth year of a patient.

Example:

- **“Patient History”** enter: **Visit Name (Visit and Laterality if applicable)**

Example:

The possible entries for Visit identification:

ASSE
W052
Premature Withdrawal(WD)

X-Ray Quick Reference Guide

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DATA SHIPMENT TO BIOCLINICA

The data to be sent from the imaging site should include both the imaging study and the transmittal form. Submitting data electronically via the secure FTP website: <https://smart.bioclinica.com/> is the required method of submission for this protocol. If your site cannot submit data electronically after attempts have been made to submit a test image, courier services can be utilized.

Electronic Data Transfer Using SMART submit

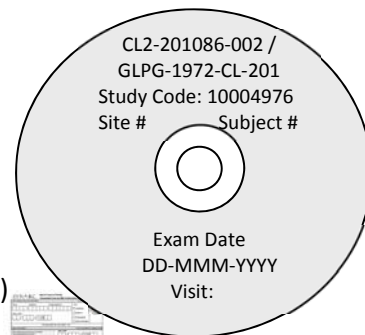
SMART submit is a web-based portal that allows sites to submit images via secure file transfer protocol (FTP). It eliminates delays and expenses associated with shipping images via courier. The Transmittal Form (TF) is completed and submitted electronically as well. Access to SMART submit or technical support may be requested by emailing the study team at 10004976Support@Bioclinica.com

Sending Data Using Courier Service – Digital

The complete package should contain a CD with imaging data and the completed TF.

Export the data to the CD in **uncompressed DICOM** format. Use an indelible marker to label directly on the CD with:

- Study Protocol Number: CL2-201086-002/GLGP-1972-CL-201 (10004976)
- Subject Identifiers (Site Number and Subject Number)
- Exam Date (DD-MMM-YYYY) Visit Name



Sending Data Using Courier Service – Film

Send original radiographic films to BioClinica.

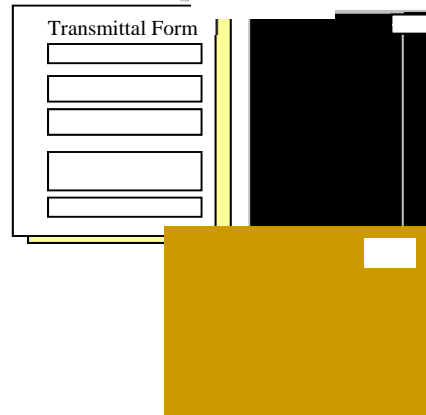
Affix a properly completed radiograph identification label to each radiograph (on front of film, right side – top or bottom) and complete the required information.

Do not wrap the label around the edge of the film.

Do not attach any other labels to the films.

Do not mark on the films. If you must, do not use grease or wax pens.

A Radiograph Transmittal Form must be filled out completely to accompany the radiograph (white and yellow pages).



Sending a Package to BioClinica

1. Complete the sender sections of the air waybill, keeping a copy for tracking purposes.
2. Place the white and yellow copies of the TF and the CD or Film for each patient into a shipping envelope.
Retain the pink copy of the TF at the imaging center.
3. Call courier to schedule package pick-up.

Ship data to: Galapagos and Sevier CL2-201086-002/GLGP-1972-CL-201 Study Team

BioClinica, Inc.
7707 Gateway Blvd., Third Floor
Newark, CA 94560 USA
10004976Support@bioclinica.com
Office: +1-415-817-8900

For additional assistance, contact the Help Desk:

Toll Free from the US and Canada: 1-888-ASK-BIO2 (1-888-275-2462)
International: +1-484-928-6076
Email: helpdesk@Bioclinica.com