Image Acquisition Protocol

SM04690 Knee OA Phase 3
STRIDES-X-ray Study (OA-11)
(587)

SM04690-OA-11

medicalmetrics INC.

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X-Ray Acquisition Protocol

Instructions begin on the following page.

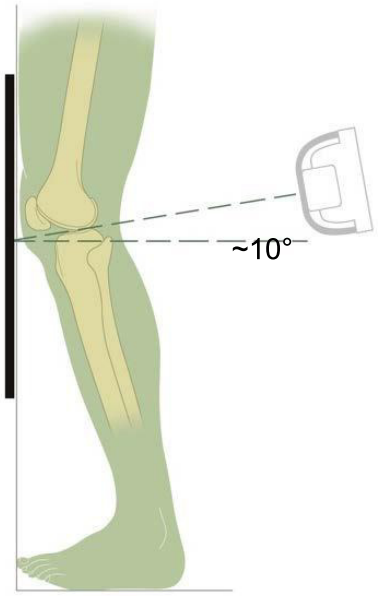
PA Fixed Flexion View of the Knee (Bilateral)

EQUIPMENT SETUP

- ❑ Set up the X-ray system according to your standard protocol for **weight-bearing PA views**.
- ❑ Position the film cassette vertically in landscape orientation such that it is flush with the thighs and knee.
- ❑ The cassette should be coplanar with the tips of the great toes, resulting in fixed knee angulation of approximately 20° flexion, hence “fixed flexion”.
- ❑ Use a cassette loaded with a 14’’ x 17” (35 cm x 43 cm) film.
  - Set the mAs and kVp for an AP/PA Knee X-ray based on your technique chart (**70 kVp, 5 mAs** is typical).
  - A 48 inch (100 cm) source-to-image (SID) distance is recommended.
- ❑ The X-Ray beam should be centered in between the knees at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa, and angled caudally about 10°. The subject should not rotate their legs, the toes should be pointing straight forward.
  - The X-Ray beam angulation may need to be adjusted depending on the subject's specific anatomy in order for the joint space to be open. If an angle other than 10° is used, it should be noted in the subject's file and used for the remainder of the study.

SUBJECT PREPARATION

- ❑ The X-ray must be collected as a **Weight-Bearing View**.
- ❑ Have subject remove shoes (socks are OK).
- ❑ Place a lead shield over the subject to protect the gonads, as required by your imaging facility.
- ❑ Ensure the subject's legs are perpendicular to the floor, with the feet underneath the knee. External support may be provided if subject feels unstable in the imaging position.
- ❑ Feet should be pointed straight forward, with no internal or external rotation.
- ❑ Toes should be in line with the receptor, with the thigh touching the top half of the receptor.
- ❑ Use the Knee-QuAP positioning guide. Directions for using the device are included in the following pages.



EXPOSURE

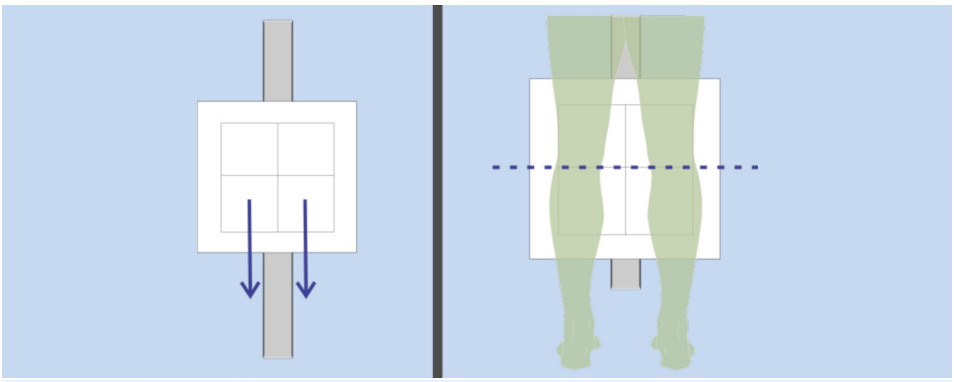
- ❑ Use a **Right** OR **Left** marker to identify the treated knee, as appropriate.
- ❑ Center and collimate further, if necessary.
- ❑ Expose the radiograph.

IMAGE CRITERIA

- ❑ The knee joints should be centered vertically in the FOV with no out-of-plane rotation.
- ❑ Acceptable radiographic alignment of the joint may be verified by ensuring the virtual superimposition of the anterior and posterior margins at the center of medial tibial plateau (MTP). The separation between the two margins of the MTP should ideally be ≤ 1.5 mm.
- ❑ If a beam angle other than 10° is used, annotate the image with the angle and submit to MMI.
- ❑ The joint space should be open, with no overlapping of the femoral condyles over the tibial plateau. If there is overlap, the subject and/or x-ray beam should be adjusted appropriately and the image re-acquired.
- ❑ The Knee QuAP™ should be centered between the knees, with one ball bearing above the joint line and one below.
- ❑ Refer to the following imaging atlases to confirm acceptable imaging quality before the subject leaves the room.

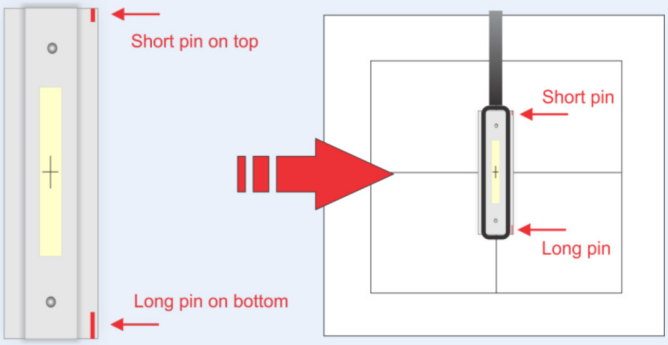
How to use the Knee Positioning Guide

1. Lower the receptor such that the center horizontal line is at the level of the subject's knee joint line

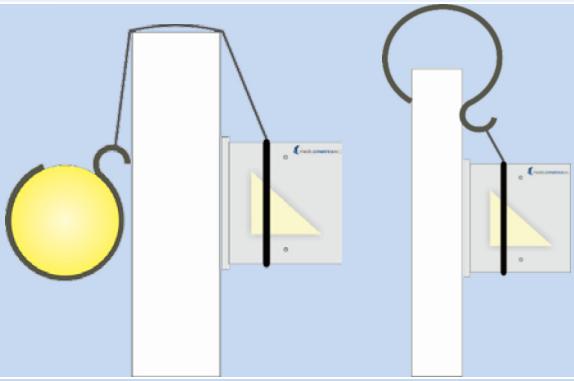


2. Hang the calibration device in the center of the image receptor with the base flush against the bucky

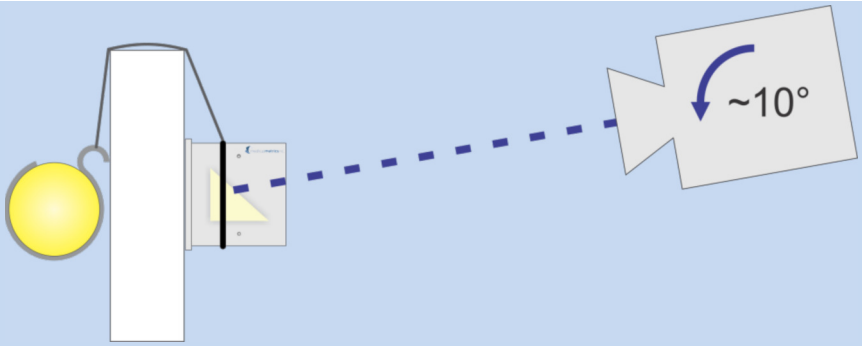
   Note proper orientation of the short and long pins within the flange of the device. The pins will always be on the subject's right side



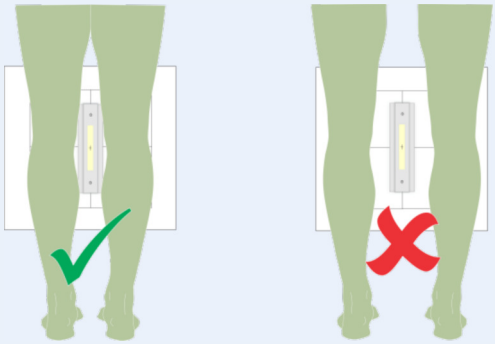
3. Two ways to hold it in place:
   - Use yellow ball and clip as counterweight
   - Remove yellow ball and use white S as a clip



4. Set X-ray beam angle:
   - Start with 10° caudal tilt.
   - Adjust for proper joint profile if needed.
   - Record final angle in subject file for reference at follow-up



5. Subject's knees in contact with device



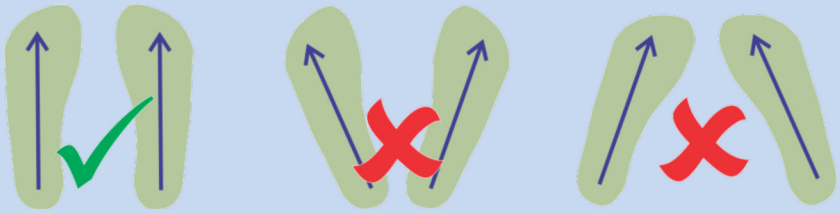
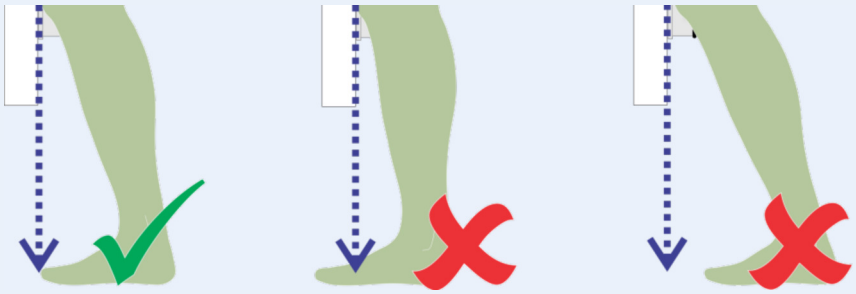
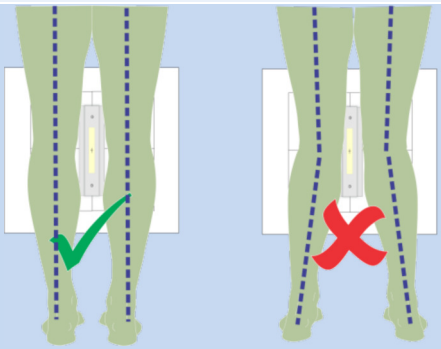
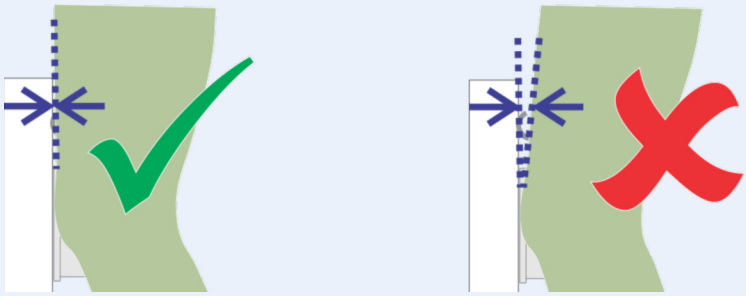
6. Feet pointed straight. • No internal or external rotation!	
7. Toes in line with the receptor	
8. Subject's feet should be under the knees • Do not stand knock-kneed! • Support may be provided if the subject feels unstable while in the imaging position	
9. Subject's thighs touching the image receptor.	

Image Quality Review of Bilateral PA Fixed Flexion Images

All imaging received at MMI will be graded based on the image quality and compliance to this Image Acquisition Protocol.

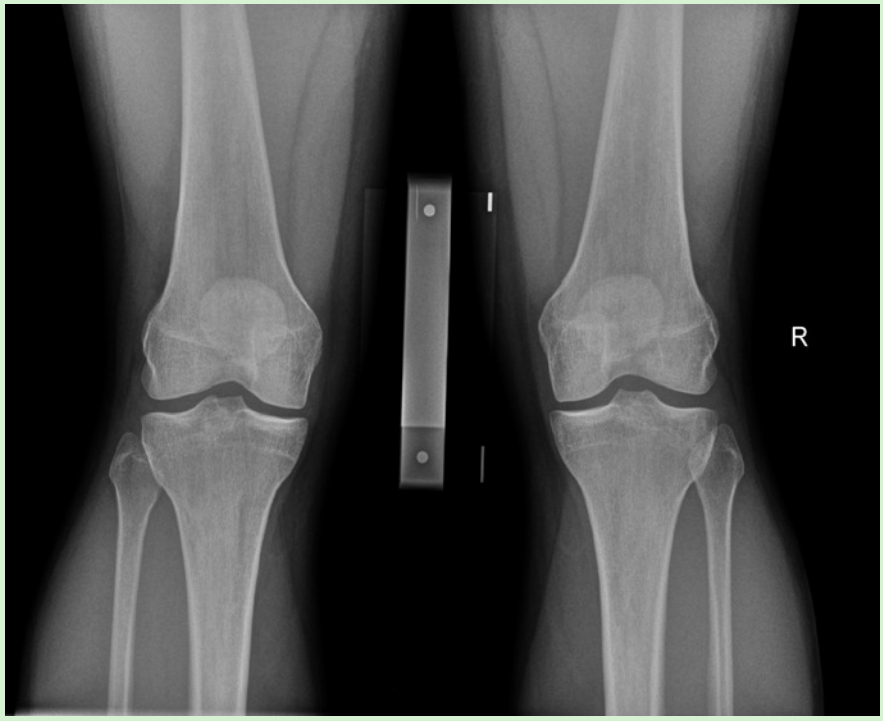
The instructions herein are intended to guide the user in the collection and submission of PA Fixed Flexion radiographs that are suitable for the types of analysis intended for this study.

Each image is assigned a grade:

- **ACCEPTABLE**
- **UNACCEPTABLE**

ACCEPTABLE Imaging demonstrates:

- Open tibiofemoral joint space;
- No overlapping of the femoral condyles over the tibial plateau;
- Superposition of the anterior and posterior margins of the tibial plateau;
- Knees are centered vertically in the field of view;
- The calibration device is centered between the knees;
- There is no out-of-plane rotation of the knees;
- Knees in contact with calibration device;
- Diagnostic quality image resolution and contrast.
- Left / right orientation marker visible

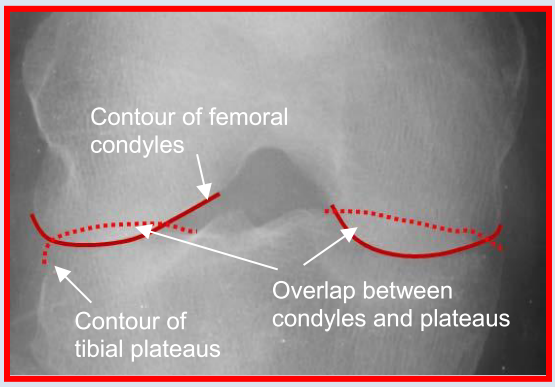
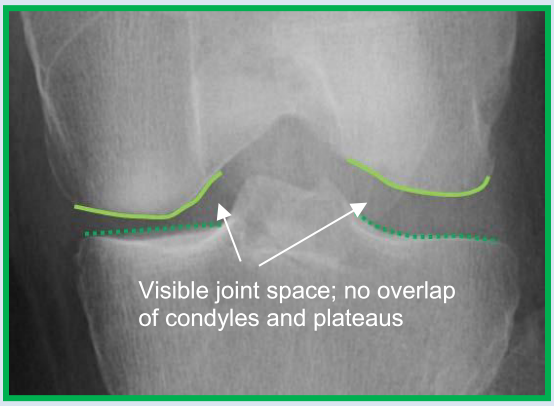
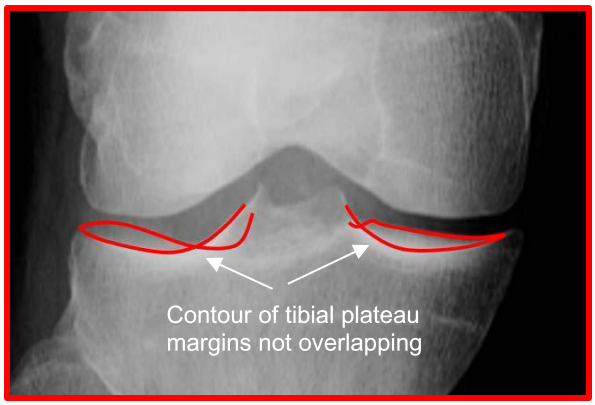
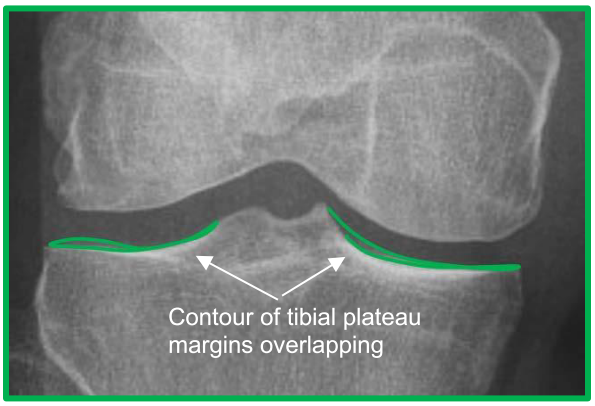
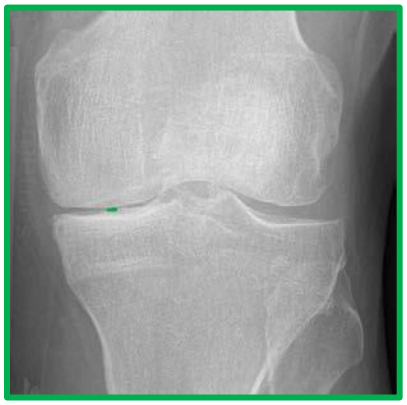


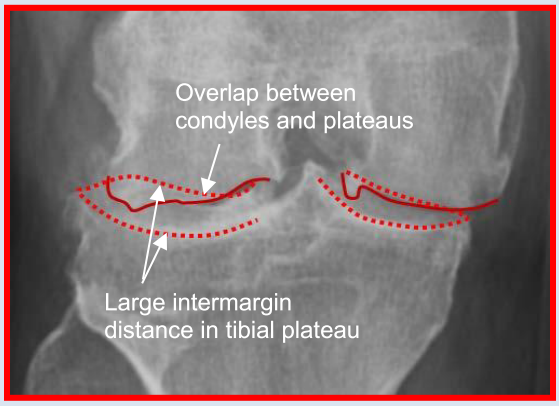
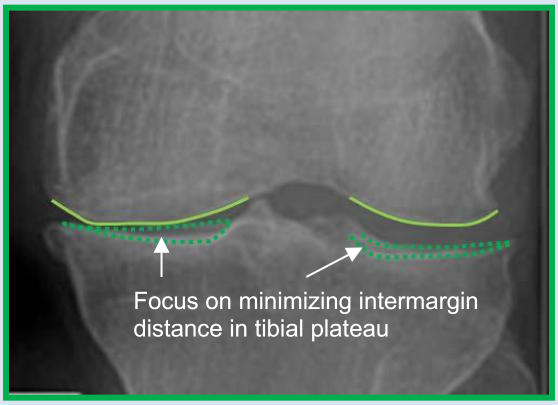
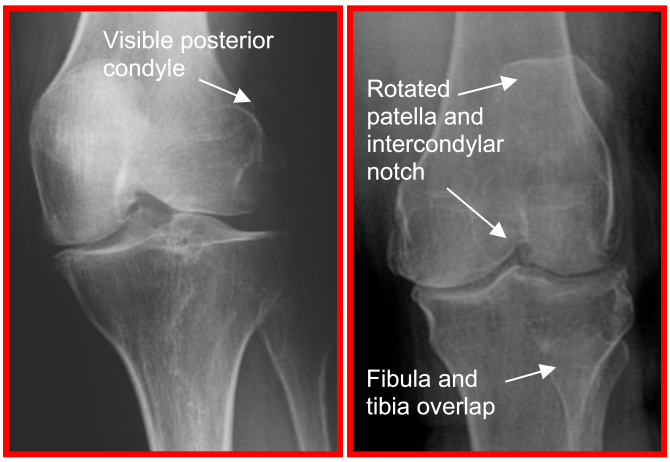
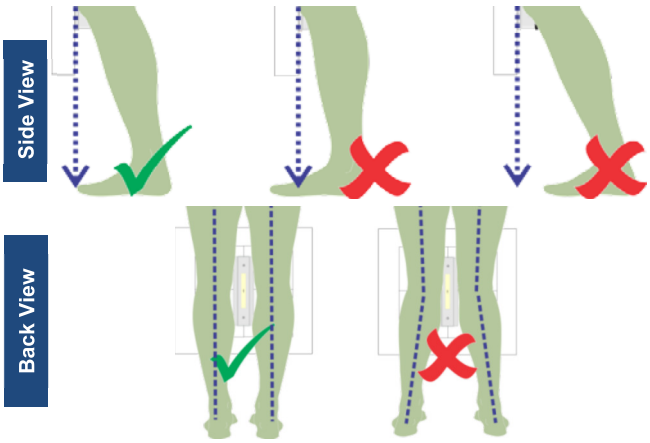
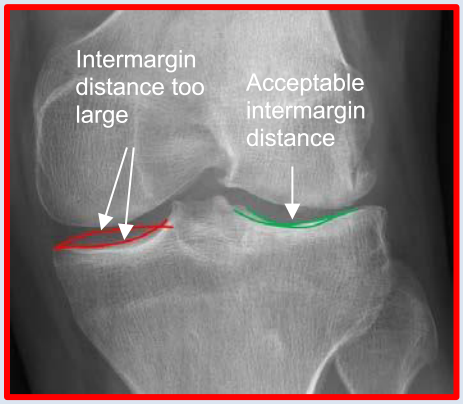
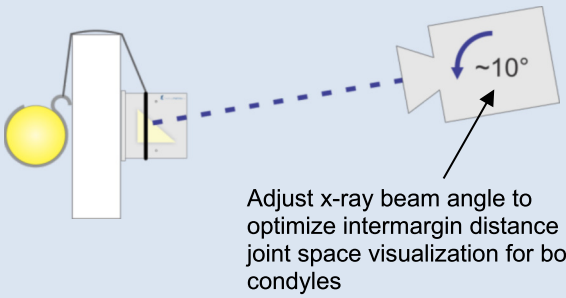
UNACCEPTABLE Images

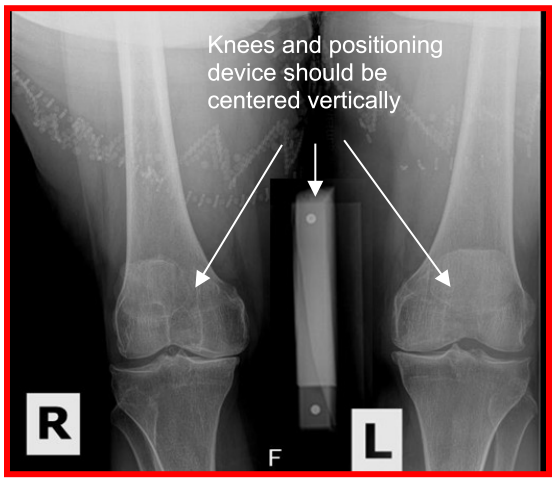
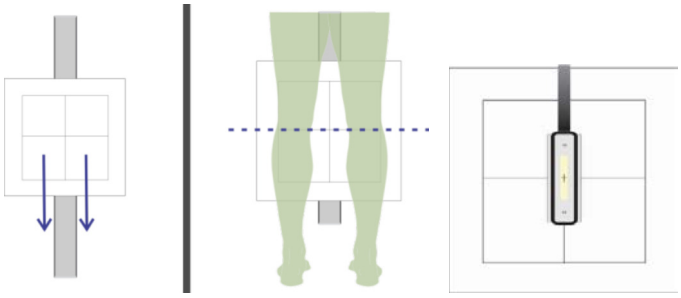
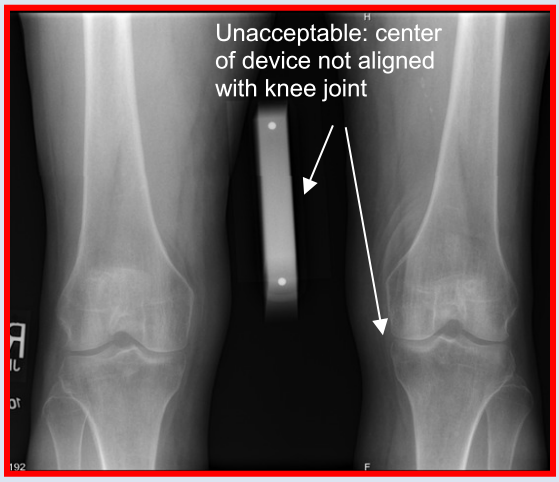
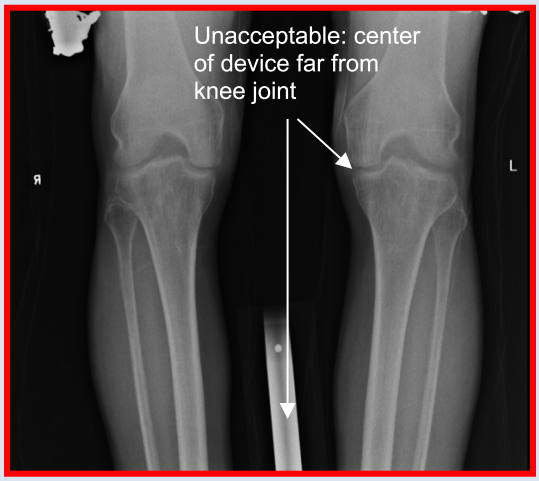
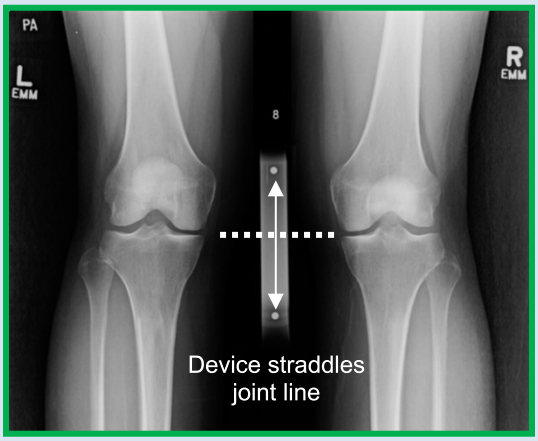
- Unsuitable for analysis
- Call subject back for re-imaging. Implement necessary changes for retake visit

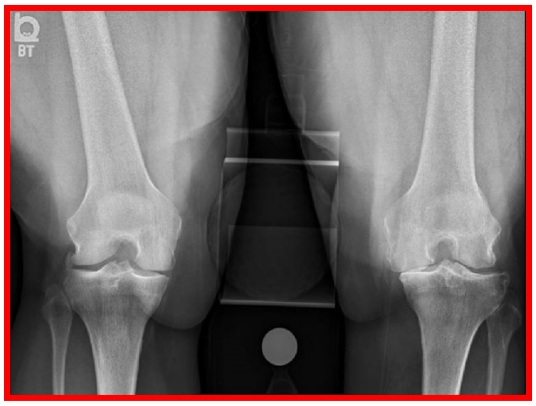
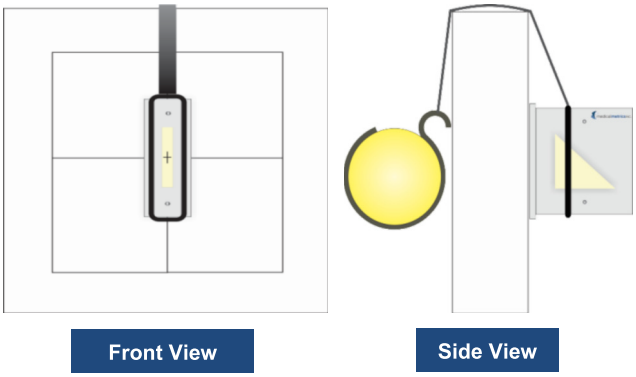
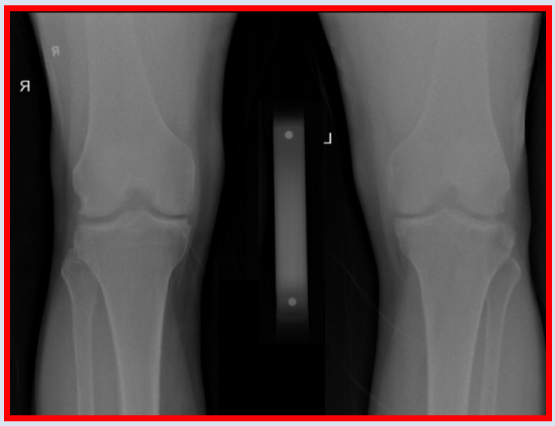
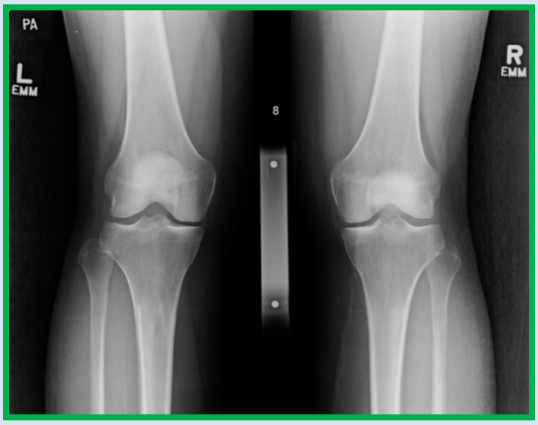
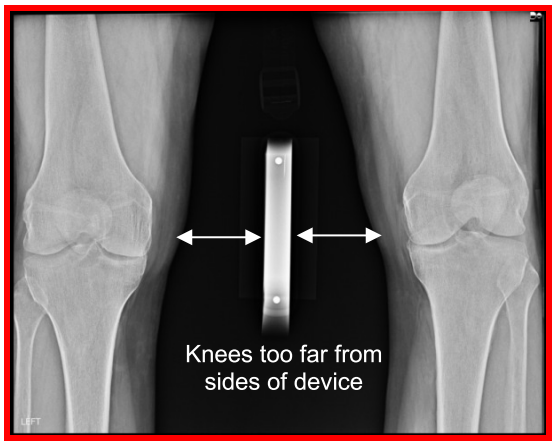
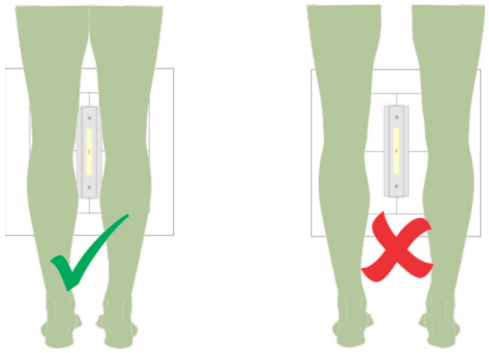
Troubleshooting Unacceptable Images

If you receive a discrepancy notification from MMI indicating that the submitted image was graded **UNACCEPTABLE**, review the image carefully and adjust the acquisition technique as needed to improve the imaging. Some of the more common image quality concerns are shown below.

Issue	Resolution
Overlapping femoral condyle & tibial plateau. (Joint space cannot be visualized) 	Check that the knees are flexed 20° and adjust the x-ray beam angulation to ensure it is parallel to the tibial plateau. Record angulation for later use. 
Anterior and posterior margins of the tibial plateau are not superimposed.  	Check that the knees are flexed 20° and adjust the x-ray beam angulation to ensure it is parallel to the tibial plateau.  

Issue	Resolution
Advanced degeneration makes profiling the joint space difficult. 	Check that the knees are flexed 20° and adjust the x-ray beam angulation to ensure it is parallel to the tibial plateau. Record angulation for later use. 
Knees are rotated out-of-plane. (Either externally or internally) 	Ensure the subjects' toes are perpendicular to the plane of the receptor. The feet should be under the knees so the subject is not standing knock-kneed. Patella should be centered on condyles. 
Lateral joint space is in profile, but medial joint space is not. 	Sometimes the tibial plateau slope is variable from medial to lateral. Increase x-ray beam angle and re-acquire image. 

Issue	Resolution
Knees not centered vertically in the field of view. 	Adjust the x-ray beam such that the knees are centered in the exposure area. 
Calibration device placed too high or too low in the image.  	Ensure the calibration device is centered on the images receptor, and between the knees. 

Issue	Resolution
Calibration device oriented inappropriately in the image. 	Ensure the calibration device is placed in accordance with the instructions in the acquisition protocol. 
Poor image resolution and/or contrast. (Under- or overexposed) 	Adjust kVp and mAs such that bone and soft tissues are well visualized. 
Subject stance too wide  	Remind subject to stand with their knees touching the sides of the device. 

Frequently Asked Questions

Q *Why is the SID listed in the Image Acquisition Protocol preferred? Can a shorter or longer SID be used instead?*

A The specified SID in the acquisition protocols are expected to produce images with minimal to no parallax artifact, which equates to better image quality. Alternative SIDs can be used if the knee cannot be adequately visualized at the specified SID, or if a fixed-arm system prevents an alternative SID from being used.

Q *The Acquisition Protocol references films and cassettes. Can a digital system be used?*

A Yes, absolutely.

Q *Why is a PA Fixed Flexion view being requested instead of a standard AP view?*

A It has been shown that the PA Fixed Flexion view is more reliable than the standard AP view for determining the extent of joint space narrowing.

Q *The subject says they feel unstable while holding the PA Fixed Flexion position. What can I do?*

A You are welcome to provide any support that subject requires to ensure stability, as long as it would not interfere with the acquisition of the image.

Q *Why must the X-ray beam be tilted 10°?*

A The X-ray beam should be angled to the same plane as the tibial plateau, which is around 10° in the PA Fixed Flexion view.

Q *What is the Knee-QuAP and how do I use it?*

A The Knee-QuAP is a positioning device intended to standardize the distance between the knees across subjects, reducing out-of-plane effects and improving the quality of the resultant images. The device may also contain a plug of plastic with a known density which can be used to determine the bone density of the subject.

The device should be secured in place either with the provided clip, or held in place by the subject such that it is between the knees and centered at the knee joint line.

Q *Will a calibration marker be used?*

A The Knee-QuAP has an integrated calibration marker. A second marker will not be used.

Q *Our facility's standard-of-care includes other views. Do you want us to submit those as well?*

A You are welcome to submit any views acquired on the subject, however only the PA Fixed Flexion view is required for this study.

Knee Imaging *PA Fixed Flexion X-Ray View*

Equipment Set-Up

- Use 14” x 17” (35 cm x 43 cm) cassette. Position cassette horizontally such that it is against the thighs and knee.
- The cassette should be coplanar with the tips of the great toes.
- Set the mAs and kVp based on your technique chart and size of the subject.
- 40” (100 cm) SID preferred.
- The X-ray beam should be centered between the knees at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.
- Note any deviations in the subject record.

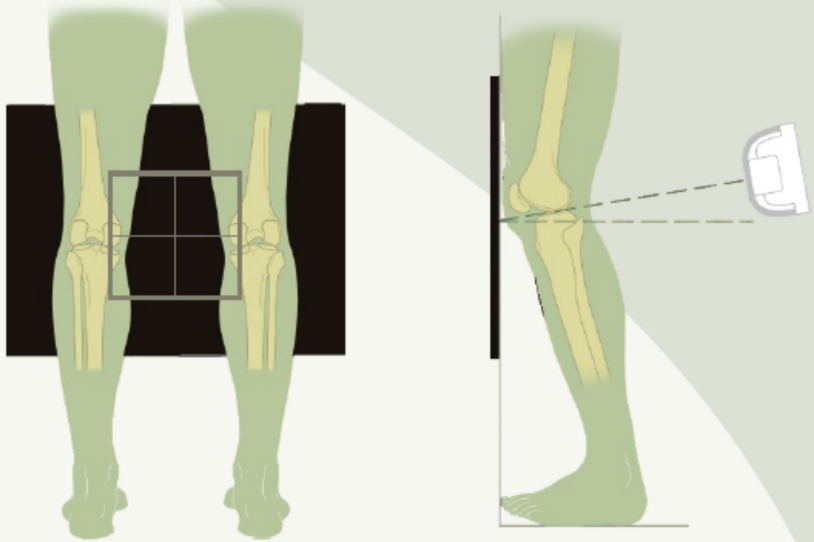
Subject Preparation

- The X-ray must be collected as a **Weight-Bearing** view.
- Place a lead shield over the subject to protect the gonads, as required by the facility.
- Ensure that the X-ray beam angle is fixed at 10° caudally.
- Use a **Right** or **Left** marker, as appropriate.

Quality

X-ray should demonstrate:

- Good alignment of the joint may be verified by ensuring the virtual superposition of the anterior and posterior margins at the center of the medial tibial plateau.



Knee Imaging *Using the Knee Positioning Device*

Placing the Device

- Mark the floor underneath the receptor (bucky or digital panel) with tape to indicate where the subject's toes will be placed.
- Hang the positioning device from the top of the image receptor with the wide plastic base touching the image receptor and with the beam centering marker on the calibration device positioned at the center of the image receptor.
- Adjust the height of the image receptor so the beam centering marker on the device is the same distance from the floor as the crease in the backside of the subject's knees.
- Use the S-clip to attach the device to the top of the receptor, or drape over the top of the receptor with the ball inside the clip as a counterweight.
- Adjust the X-ray tube so that it is angled 10° down from the horizontal and so that the central X-ray beam hits the beam centering marker on the device.
- Have the subject approach the receptor and position the legs on either side of the device, with their feet facing straight0ahead toward the image receptor.
- Have the subject slowly bring both knees together to where the medial side of each knee is just touching the device, being careful that they do not move the device. The subject should NOT try the squeeze the device between their knees.
- If the subject cannot get the knees to touch the device, have the subject place the knees as close together as they are comfortable with.
- Have the subject adjust the position of the feet so that their toes line-up with the front of the receptor.
- The feet should be a comfortable distance apart, oriented perpendicular to the plane of imaging. The thighs should be touching the image receptor.