PtoleMedic System

USA-Instructions for Use
Clinical MRI Scanning

US-LB-72-01-004 (B)

April 12, 2022

This MRI Scanning instruction is organized as a quick reference guide. The MRI Technologist may use this guide to rapidly set the listed MRI scanning equipment for use with the PtoleMedic System surgery planning software. Detailed MRI scanner instructions are available for patient positioning and orientation for the MRI examination. All MRI guidance documents may be reviewed or printed from the MRI portal online, including detailed instructions to assist with uploading completed images.

WARNING: Please note that MRI scans on patients with metallic implants in or near the involved joint may adversely affect the quality and accuracy of the images obtained. It is recommended that MRI scans not be attempted when metal is present.

WARNING: The use of the PtoleMedic System software in pediatric patients has not been studied, and the value of such use is not known. The use of the planning software in skeletally immature patients should not be attempted.

Manufacturer:
Lento Medical Innovation, Inc.
15110 Northwest Freeway, Suite 150
Houston, TX 77040 USA
+1 (510) 413-3230

CE 2460

The EU Authorized Representative for the PtoleMedic System:

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

A. PATIENT SET-UP

1. The patient should be metal/implant free in the scan volume.
2. Place patient supine, feet first, for lower extremity with the involved limb as close to IsoCenter as possible
3. Consider using small foam wedges to stabilize or support the joint.
4. Use tape, sponges, or Velcro strapping as needed on extremity to maintain anatomic "toes up" position.
5. Remind the patient to remain motionless during the entire scan.
6. Landmark or Zero table
7. Begin scanning at the Distal Tibia (Ankle) for the Coronal T1 Series, move to the Knee series, and complete the study with the Hip series (see Figure 11).
8. Phased array coils (receive only coils) or the "Body Coil" may be used to scan the hip and ankle without removing the knee surface coil. New GEM suite GE systems have built-in phased array coils in the MRI table.

B. SCANNER SET-UP

1. Enter the patient name (Last, Middle, First)
2. Enter patient DOB. (dd/mm/yyyy)
3. Enter scan date (dd/mm/yyyy)
4. Enter left or right joint (Right/Left)
5. Enter patient gender (M/F)
6. Enter the name of Surgeon (Last, Middle, First)
7. Enter the name of the imaging center

C. CORONAL T1 DISTAL/ANKLE MRI PROTOCOL

1. Perform one three-plane (Axial, Coronal, Sagittal) locator scan
2. Perform a Coronal(T1FSE) series using the minimum scan

Parameters:

Slice Plane:	Coronal
Slice thickness (mm):	4
Spacing/Gap (mm):	1
Number of slices:	10
FOV(mm):	240 mm
Matrix:	256 x 160
NEX:	2
NPW/Anti-Aliasing/Fold Over Suppression:	ON
File Series Name:	"Coronal Ankle"

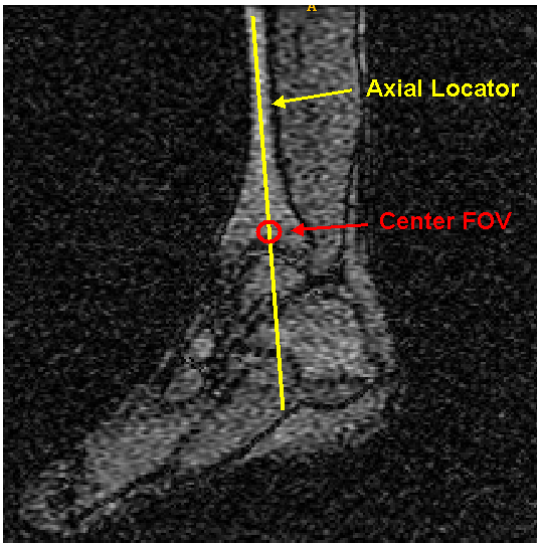


Figure 1
Coronal Slice Placement

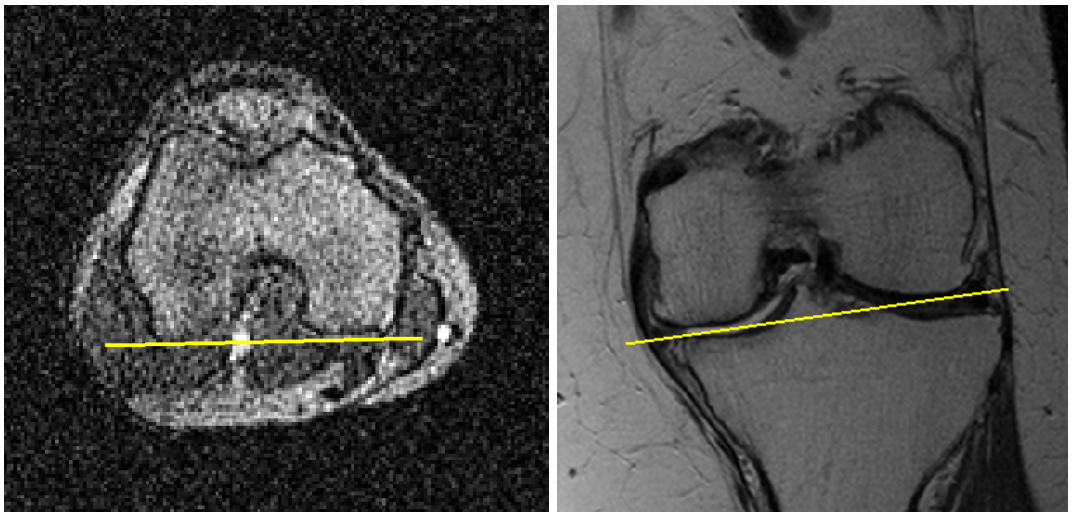
D. CORONAL T1 DISTAL TIBIA/ANKLE SLICE POSITIONING

View the **Sagittal** locator to place the slice Coronally through the long axis of the Tibia. *The Axial locator slices are not used for alignment.* Center the FOV approximately one inch above the Tibial Talar joint space. See Figure 1 for a slice position and FOV centering.

E. CORONAL FSE PD KNEE MRI PROTOCOL

1. Perform one three-plane (Axial, Sagittal, Coronal) locator series.
2. Refer to "PtoleKnee Imaging Reference for 1.5T and 3T Scanners section for the Coronal scan parameters

F. CORONAL FSE PD KNEE SLICE POSITIONING



(a) **(b)**

Figure 2

Slice Positioning through Posterior Reference and Distal Reference Lines

1. Using the best axial and coronal locator images that show in Figure 2 above
    i. Align both posterior lateral and medial condyles, place slice parallel through the posterior reference for correct slice angle
    ii. Align both distal lateral and medial condyles, place slice parallel through the distal reference for correct slice angle.

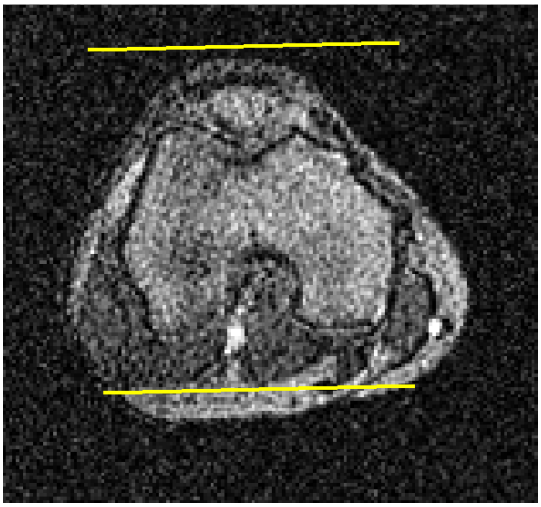


Figure 3
Slice Coverage

2. Slice coverage must include all of the Femur, including the condyles, Tibia and Patella, as shown in Figure 3

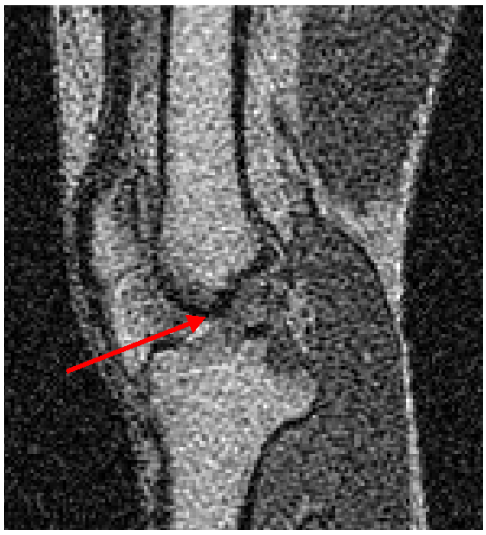


Figure 4
Centering FOV

3. Using the best sagittal locator image that shows Knee's center, adjust the FOV to be centered at the Femur's distal point, as shown in Figure 4.

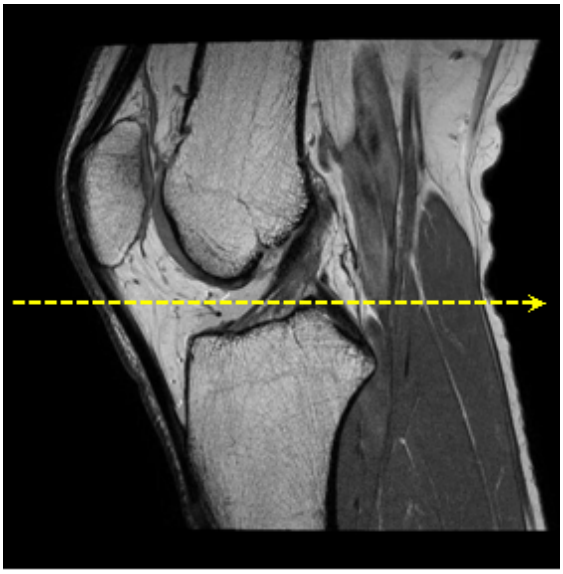


Figure 5
Axial axis of the Knee joint

4. Find the Knee joint's real Axial plane or axis, as shown in Figure 5 by the yellow dash line.

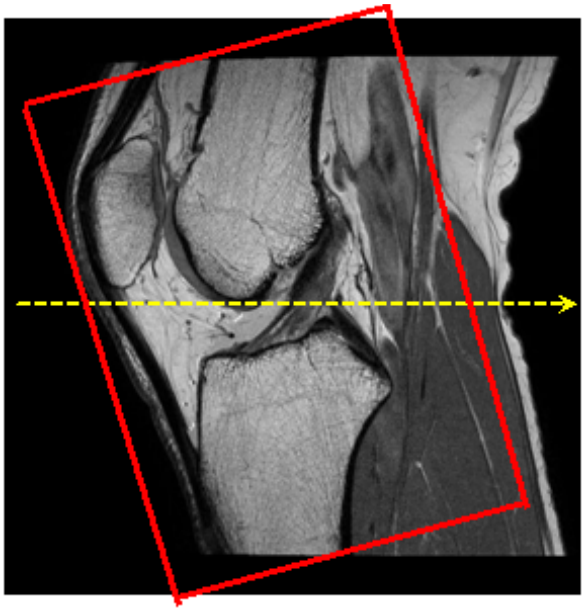


Figure 6
Slice Coverage

5. Enter File Series Name: "Coronal Knee."

PtoleKnee Imaging Reference for 1.5T and 3T MRI Scanners

1. General Electric

3plane Localizer Scan Parameter	GP FLEX (GE Users), 4mm x 1mm Skip 24cm FOV, Matrix 256x192
Coronal Knee: Pulse Sequence	FRFSE-XL CORONAL
Mode	2D
Imaging Option	No Phase Wrap ON, Tailored RF, 3DGR (3D Geometry Correction for software version 23+)
TE (Echo Time)	Min Full
TR (Repetition Time)	Use TR to get series in one acquisition
Flip Angle (deg)	90
Echo Train Length (ETL) **Turbo Spin Factor** (TSF)	7
FOV (Field of View)	18cm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor(mm)	0mm
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	S/I

***Higher resolution than 256 x 256 is allowed, using the software.**

2. Philips

3plane Localizer Scan Parameter	4mm x 1mm Gap, 240mm FOV, Voxel Size to equal 256 x 192
Coronal Knee: Pulse Sequence	TSE CORONAL
Mode	2D
Imaging Option	Fold Over, Suppression ON, 100% Sampling, "Default" Selected for Distortion Correction
TE (Echo Time)	~24 to 35 (28 nominal)
TR (Repetition Time)	Use TR to get the shortest scan time
Flip Angle (deg)	90
Echo Train Length (ETL) **Turbo Spin Factor** (TSF)	8
FOV (Field of View)	180mm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor(mm)	0mm
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	S/I

***Higher resolution than 256 x 256 is allowed, using the software.**

3. Siemens

3plane Localizer Scan Parameter	4mm x 25% Distance Factor, 240mm FOV, Base Resolution 256 x 80% Phase Resolution
Coronal Knee: Pulse Sequence	TSE CORONAL
Mode	2D
Imaging Option	100% Phase Oversampling 3D Distortion Correction Filter ON
TE (Echo Time)	~24 to 35 (28 nominal)
TR (Repetition Time)	Use TR to get the shortest scan time
Flip Angle (deg)	120
Echo Train Length (ETL) **Turbo Spin Factor** (TSF)	7
FOV (Field of View)	180mm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor	0%
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	H/F

***Higher resolution than 256 x 256 is allowed, using the software.**

4. Toshiba

3plane Localizer Scan Parameter	4mm x 1mm Spacing, 24cm FOV, Matrix 256 x 192
Coronal Knee: Pulse Sequence	TSE CORONAL
Mode	2D
Imaging Option	Fold Over Suppression ON, IDC (Intelligent Distortion Correction) Selected
TE (Echo Time)	~24 to 35 (28 nominal)
TR (Repetition Time)	Use TR to get the shortest scan time
Flip Angle (deg)	90, Flop Angle 160
Echo Train Length (ETL) **Turbo Spin Factor** (TSF)	7
FOV (Field of View)	18cm
Slice Thickness(mm)	3mm
Spacing/Skip/Gap/Distance Factor(mm)	0mm
Scan Matrix/Voxel Size (Base Resolution x Phase Resolution)	256 x 256
NEX/NSA/Averages	2
Frequency Direction	S/I

***Higher resolution than 256 x 256 is allowed, using the software.**

G. CORONAL T1 HIP MRI PROTOCOL AND SLICE POSITIONING

1. Perform one three-plane (Axial, Sagittal, Coronal) locator scan.
2. Perform a Coronal (T1 FSE) series using the minimum scan parameters total below:
3. Place Coronal slice plane parallel through the femoral neck's long axis when viewing the axial locator, as shown in Figure 8. Center the 14 slices to cover the Femoral Head, Neck, and Greater Trochanter, as shown in Figure 9.

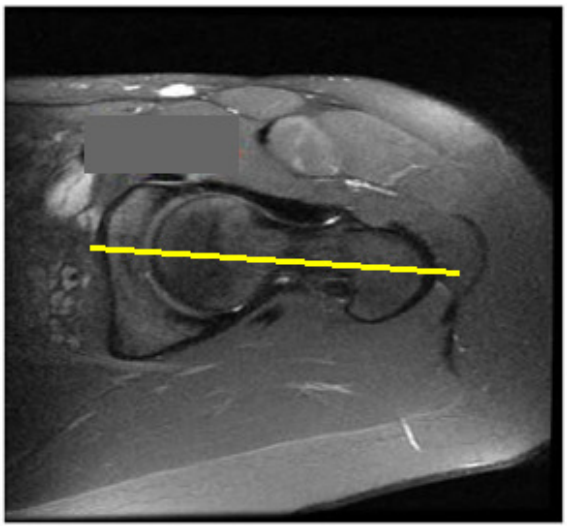


Figure 10
Center Hip FOV

Slice Plane:	Coronal
Slice thickness (mm):	4
Spacing/Gap (mm):	1
Number of slices:	14
FOV(mm):	240 mm
Matrix:	256 x 160
NEX:	2
NPW/Anti-Aliasing/Fold Over Suppression:	ON
File Series Name:	"Coronal Hip"

I. QUALITY CHECK AND METAL ARTIFACT INSTRUCTIONS

a. Coverage: Include 1 or 2 slices of soft tissue on both medial and lateral side of bony knee anatomy.
b. Motion: Make sure the sequential transition of the bone/cartilage outline does not jump or shift back and forth between slices
c. If the patient presents with metal in the affected lower extremity, follow these instructions
    - Metal Hardware Knee – Do **NOT** Scan the patient. Refer them back to the surgeon
    - Metal Hardware near the Hip or Distal Tibia – Use MARS (Metal Artifact Reduction Sequence) series. Keep in mind the FOV, Slice Thickness, and Spacing/Gap/Skip/Distance Factor must be set to our parameters. Do not use FAT SAT at any time.
    - Those facilities not using a MARS series increase the bandwidth and NEX/NAQ/NSA to increase the signal-to-noise ratio.

II. FILE FORMAT & OUTPUT

a. Save all image series in DICOM format
b. Upload the following DICOM files to Lento Medical Innovation's database (www.Lentomedical.net)
    i. Coronal FSE PD Knee Series
    ii. Coronal FSE PD Hip Series
    iii. Coronal FSE PD Ankle Series

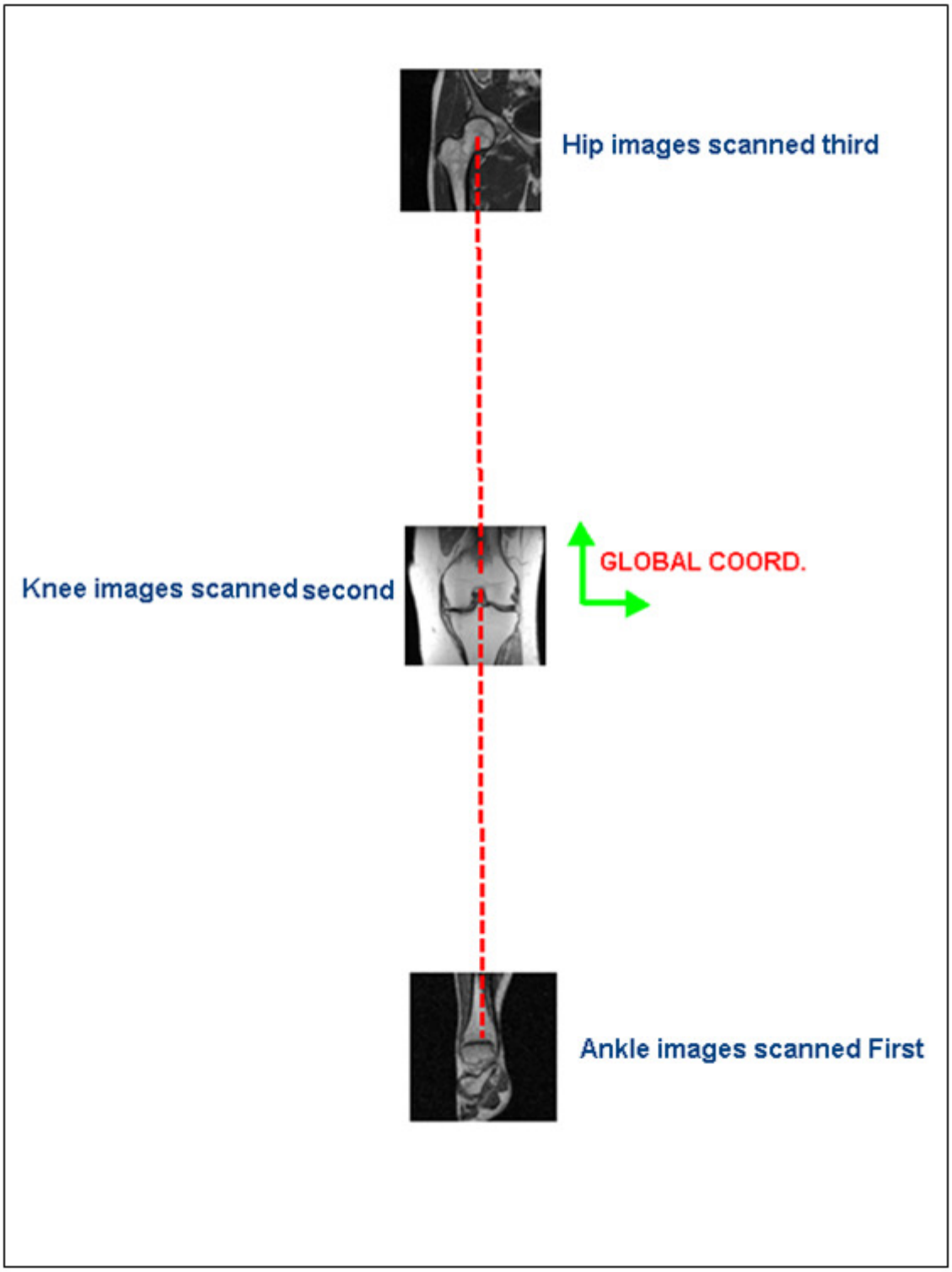
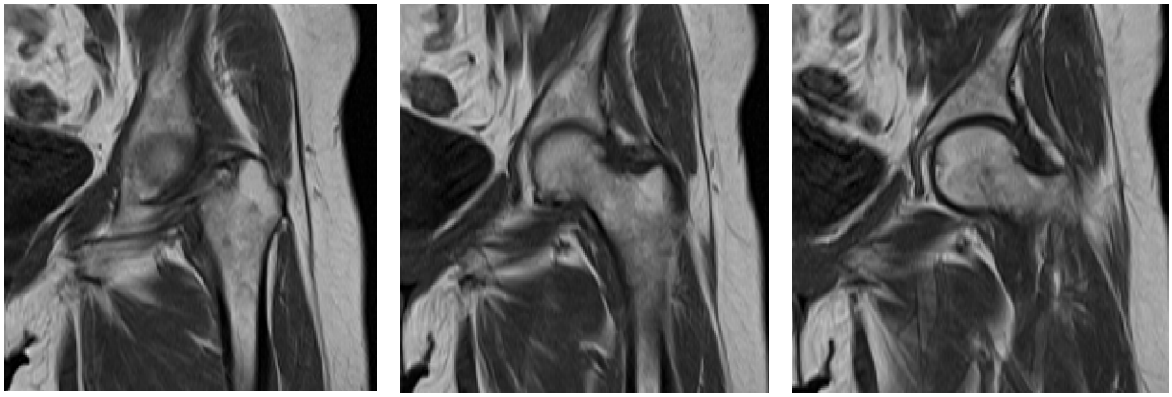


Figure 11
Scanning Order

III. HIP, ANKLE, AND KNEE MRI SAMPLE IMAGES

a. HIP MRI

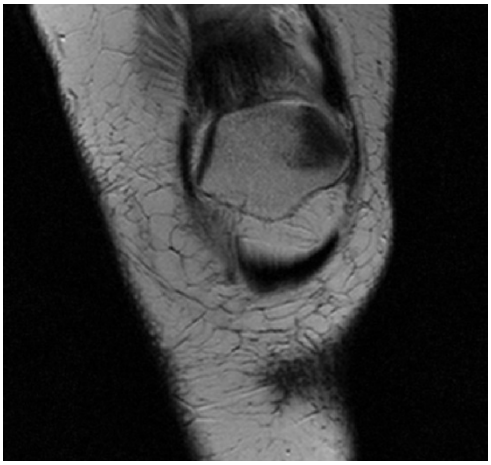


(a) (b) (c)

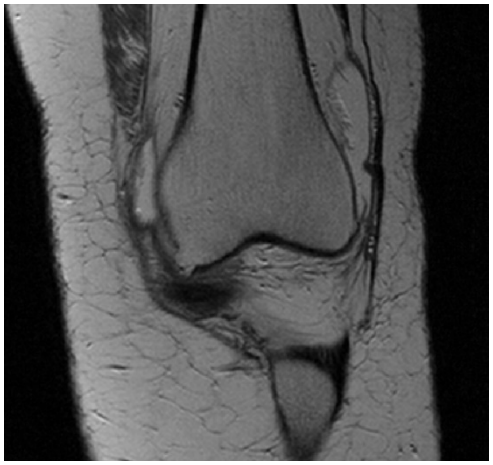
b. ANKLE MRI

(a) (b) (c)

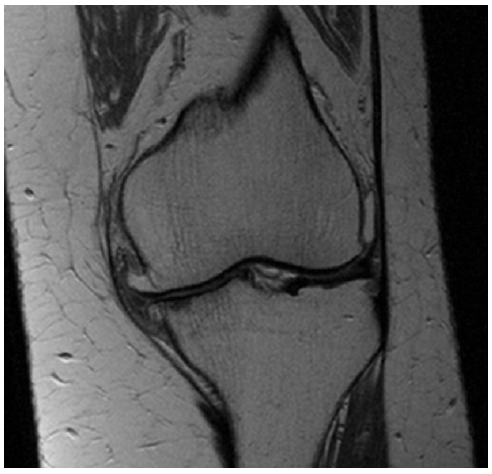
c. KNEE MRI



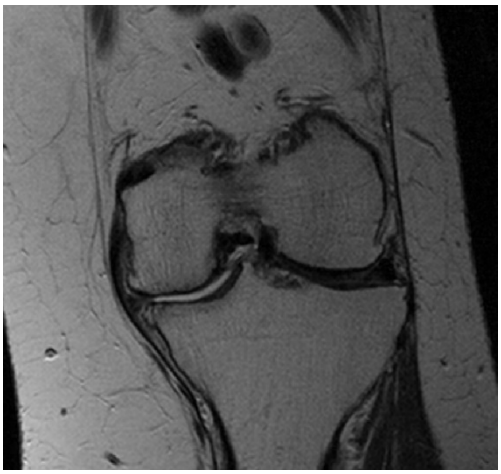
(a)



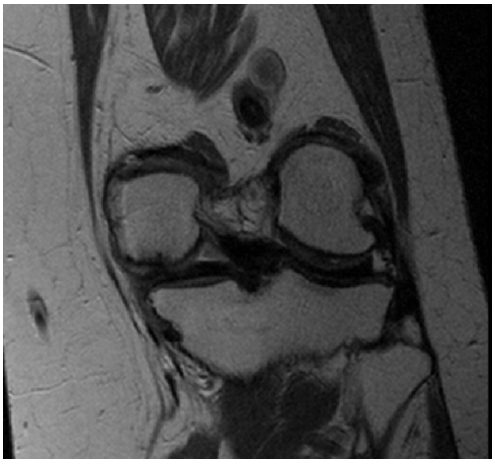
(b)



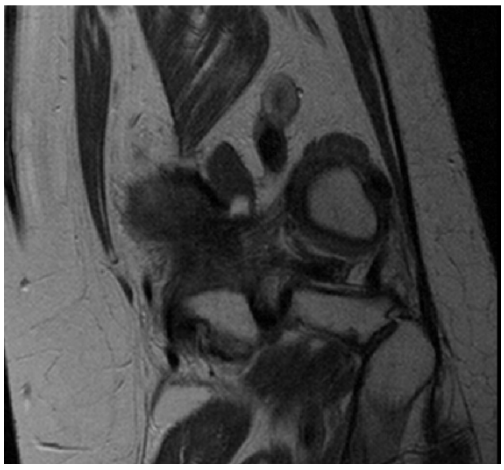
(c)



(d)



(e)



(f)