Medacta International

MyKnee®
PATIENT MATCHED INSTRUMENTATION

MYKNEE® MRI PROTOCOL

REFERENCE GUIDE

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1 Introduction

This document describes the guidelines that radiology centers must adhere to when performing MRI scans as required by Medacta International SA so the MyKnee® patient specific cutting blocks can be manufactured. MyKnee patient specific cutting blocks are used to facilitate the implantation of a Medacta total knee prosthesis. The directives outlined in this document are intended to help improve the quality of the submitted MRI scans and reduce imaging failures.

It is the responsibility of the radiology center to manage their MRI machine's specific protocol settings. Medacta International SA highly recommends that before scanning a patient for an official case, the radiology center should perform a DEMO scan to ensure the parameters are correct. For additional information about this procedure, please refer to the *"MyKnee WebPortal - How To Manual"* (ref. 99.MYK.1HT). All modifications made to this protocol are to be discussed with and approved by Medacta International SA in advance.

For more information, please contact Medacta International SA at radiology@medacta.ch.

2 Standard Considerations

Scans must be performed up to 7 months before the surgery. Images will be considered expired if the surgery will take place more than 7 months later the MRI exam.

It is a requirement that a MRI machine have the following features:

1. A magnetic field of 1.5 T or bigger.
2. The ability to use a receive-only knee coil or a flexible receive-only coil for the scan of the knee joint.
3. The ability to have all three series (axial hip, sagittal knee, axial ankle) in the same frame of reference.

Please bear in mind that there is a strong risk of MRI scan rejection in the following cases:

1. patients not able to stand still in supine position during acquisition phase
2. patients having implants or other metallic devices into the hip or ankle of the leg that has to undergo knee replacement.

In such cases, we highly suggest to avoid MRI and switch to a CT scan. **Caution: please, always avoid MRI and switch to a CT scan in case of patients having implants or other metallic devices into the knee being operated**.

If the patient has an implant or any other metallic device in the contralateral limb, the MRI scan can be accepted ONLY if the resulting images of the knee are not affected by metallic artefact. Otherwise, a CT scan has to be performed.

3 Patient position and stabilization

The patient must be in supine position, as close as possible to the isocenter, without running out of space on the body coil.

MRI technicians are recommended to inform the patients about what the exam consists on and what indications the patients are asked to follow during the scan. Well-informed patients generally result in good and conforming images.

3.1 Ankle

Place a small sponge (3-4 cm) under the ankle and use sandbags around the malleoli to secure the ankle into the proper anterior/posterior position. Put tape across the ankle (silk tape is recommended), stretching it from one side of the table to the other side, to secure the placement of the sandbags and ankle. This procedure will limit the patient's ability to move the ankle during the scan.

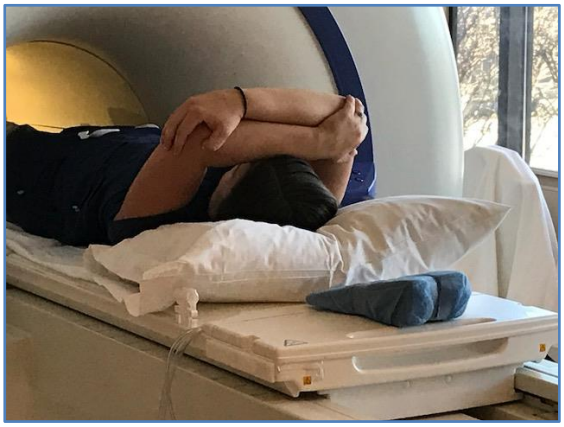
3.2 Knee

First, wrap the diseased knee with the coil. You want to wrap the coil as tight as possible; use tape to secure the coil if necessary. If the knee is too large for the coil to completely wrap around, place the opening on either the medial or lateral side of the knee. You want to ensure the coil has the best coverage anteriorly and posteriorly.

For patient comfort, place two small sponges (3-4 cm) under the patient's knee being scanned. This will be especially helpful for those patients who are externally rotated and getting their knee to lay completely flat is impossible. Place an additional small sponge under the opposite leg for extra comfort. Put tape across the knee, stretching it from one side of the table to the other, to secure the wrapped knee in place. This will limit the patient's ability to move the knee during the scan. The image below show the suggested set-up.

3.3 Hip

Ensure the patient's arms are not near the hip area. The images below show the suggested two possible positions for the patient's arms.



4 Image Requirements

Images of the hip, knee and ankle must include the following:

- **Hip**: The whole femoral head and at least 10 cm of proximal femur must be included.
- **Knee**: The distal femur, proximal tibia and proximal fibula are required. The FOV must be set so that approximately 7 cm of the distal part of the femur and approximately 5 cm of the proximal part of the tibia are clearly demonstrated.
- **Ankle**: Both of the malleoli must be included. The series must cover at least 5 cm of the distal tibia.

5 Scanning Parameters

5.1 Ankle and Hip

It is suggested to use a T1 axial series for both the ankle and hip scans. The 2D slices should be centered on 2 of the 3 planes (coronal and axial).

Please use the table in section 5.3 to reference all parameters needed to perform an MRI scan of the ankle and hip.

5.2 Knee

It is suggested to use a 3D sagittal series for the knee scan. The 3D box should be centered on at least 2 scanograms. On average the axial and coronal scanograms will be selected. The box should maintain a completely straight orientation. Do NOT tilt or move the box out of this orientation. Be sure you are through both the medial and lateral sides of the knee. The lateral side must include the fibula.

Please use the table in section 5.3 to reference all parameters needed to perform an MRI scan of the knee.

5.3 Suggested Parameters for All MRI Machines

The table below summarizes the MRI parameters suggested by Medacta International SA. **If different values are required by your machine, please contact radiology@medacta.ch before setting the protocol.**

	ANKLE	KNEE	HIP
Axis (average patient)	First scan set point is 0	Advance table to H350 on scout of ankle	Advance table to H750 on scout of ankle
FOV (Field Of View)	260 (Phase FOV 100%)	200-220 (Phase FOV 90%)	360 (Phase FOV 100%)
Resolution	256 x 256	256 x 256 **Interpolation must be ON**	256 x 256
Number of slices (average patient)	20	• 112-120 if using a 1.0 mm slice thickness. • More slices may be necessary to clearly capture the knee joint.	20
Slice thickness	4.0 mm	• 1.0 mm is suggested • No bigger than 1.0 mm	4.0 mm
Inter-slices gap	• No bigger than 2.0 mm • 1.0 mm is suggested	• No gaps allowed. • Some inter-slices overlap is acceptable	• Not bigger than 2.0 mm • 1.0 mm is suggested
Coil	Inbuilt body coil	• **Receive only knee coil or flexible receive only coil wrapped around knee.** • **Do not use torso coil.**	Inbuilt body coil
Flip angle	90	25	90
Fat sat **NEX = Number of Excitation** **NSA = Number of Signal Averages / Acquisitions**	1 NEX (or NSA)	• Norm 1 NEX. • **Fat saturation or Water Excitation**	1 NEX (or NSA)
Pulse sequence	2D T1	**Choose the 3D pulse sequence that allows for better visualization of the patient's cartilage** (refer to section 8 of this protocol to see examples of acceptable images) These are some suggested sequences: ▪ Philips: 3D_WATT_c3x, THRIVE ▪ Siemens: 3D-FLASH, VIBE ▪ GE: SPGR, LAVA ▪ Hitachi: RSSG, TIGRE ▪ Toshiba: RF-spoiled FE, QUICK 3D	2D T1
Orientation	• True axial • **No angulation of the slices is permitted**	• True sagittal • **No angulation of the slices is permitted**	• True axial. • **No angulation of the slices is permitted**
Bandwith	Highest possible	Not higher than 130	Highest possible
Image type	Original series ONLY! **Derived series are not acceptable**		
Frame of reference	The frame of reference should be the same for all the three acquired series.		
Extras	If available, use distortion correction or any other filters to improve images	▪ If available, use distortion correction or any other filters to improve images ▪ If necessary to increase the quality of the images, use of superior saturation bands ▪ Phase and slice partial Fourier can be used to reduce acquisition time ▪ Use bands to prevent aliasing	If available, use distortion correction or any other filters to improve images

5.4 Additional Scanning Suggestions

- For bilateral patients, separate right and left scans must be performed.

- When entering the MRI protocol into the machine, use a 3 plane localizer for each scan (knee, hip, and ankle). For the average patient, this is the suggested procedure:

    - Set the first localizer to H350 from the ankle.
    - The second localizer should be used to center all three plans. Ensure the 3D box covers the entire area.
    - Now, it is possible to determine how many slices are needed to clearly capture the knee joint.
    - The third and last localizer should be set to H750 from the ankle.

- For radiology centers with manual tables, this is the suggested procedure for the average patient:

    1. The center point for the ankle should be 0.
    2. After having scanned the ankle, manually bring the table to H350.
        a. At this point it is mandatory to keep the light off.
        b. **Do NOT re-landmark the center point to 0**. Re-landmarking would change the orientation resulting in a failing scan.
    3. After having scanned the knee, manually move the table to H750.
        a. Again, please do not re-landmark the center point to 0.

6 Image Acquisition

6.1 Ankle Imaging

Once the patient has been properly positioned on the table, use a designated location on the patient's body as a landmark. Choose a location which will not be scanned. It is suggested to use a spine coil at the S1 vertebrae. This position now becomes the 0 set point. **Caution: it is NOT possible to change the set point back to 0.** The image below provides an example of how to properly center on a 3 plane scanogram. You should obtain 20 slices which should take approximately 2:40 min.

6.2 Knee Imaging

After scanning the ankle, it is important to tell the patient that the table will be moving. Communicating the movement of the table usually limits and/or stops the patient from moving resulting in good, clear scans.

Advance the patient to H350 from the ankle. H350 from the ankle is the first localizer for the knee. **Caution: You CANNOT change your set point** (which should be at H350 for the knee). There are two possible options to acquire an image of the knee:

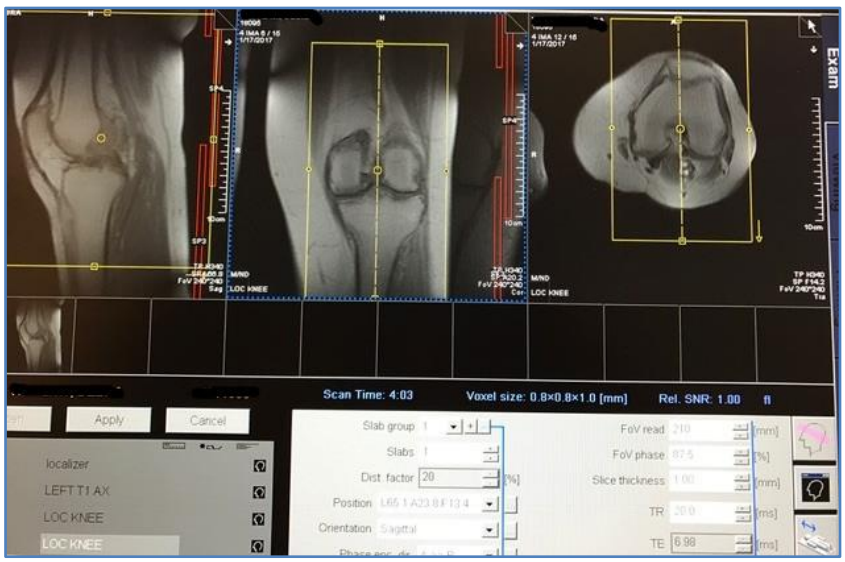
1. First, use only one localizer. The 3D sequence should be set off this localizer
2. Secondly, use a second set of 3 plane localizers. The first plane should be utilized to get the knee centered properly. This does not change anything as far as table movement. Using a 3 plan localizer will allow for clear images. See example below to clarify the concept.

Now it is possible to determine how many slices are needed to clearly capture the knee joint of the patient. On average, 112-120 slices are needed when using a slice thickness of 1.0 mm. Use more slices to capture the knee joint if necessary.

The table position will not change from the first knee scanogram. Position the 3D box over the knee. It should cover a minimum of 2 planes. It is suggested to use the coronal and axial planes. The 3D box must reaming perfectly straight in order to obtain acceptable DICOM images.

- **Caution:** Do NOT rotate the 3D box left or right when making adjustments.
- **Note:** If the knee is tilted more than 20 degrees, the images will NOT be accepted. Put the center of images line exactly down the middle of the knee.

Be sure you have cleared both sides of the bone. The proper position is shown in the image below.



6.3 Hip Imaging

After the knee is scanned, again, it is recommended to tell the patient that the table will be moved. Move the table to H750 from the ankle. Use a 3 plane scanogram capturing a minimum of 2 different planes. It is recommended to use the axial and coronal planes. The proper position is shown in the image below. The time to complete the scan should be approximately 2:40 min.

6.4 Final Check

Once the ankle, knee and hip scans are completed, review each series. Double check that:

- full coverage was achieved for all three scans
- the patient did not move, creating a blurry image.

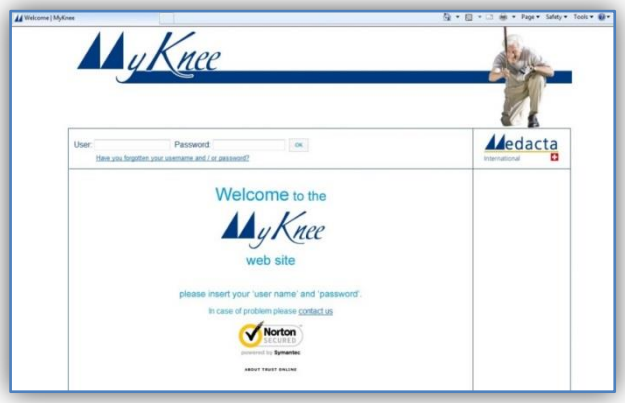
The patient can be removed from the table after a final check of the scans. Then, send the DICOM images to PACS and create a CD with the patient's images.

7 Uploading Images to the MyKnee Website

The DICOM dataset can be uploaded to the MyKnee Website by the radiology center, surgeon, surgical scheduler, or sales agent.

Please bear in mind that the series that have to be uploaded are the original series. **A dataset made by derived series only (series that have the dicom tag (0008, 0008) "IMAGE TYPE" = DERIVED) will be rejected.**

To upload the scans, navigate to the Website (https://myknee.medacta.com/) and log in with your username and password.



After logging in, all cases associated with the surgeon who requested the scan will be visible. It is possible to filter the cases by surgeon or by status flag. These filters are located on the top of the MyCases page.

Click on the patient case code which matches with the scanned patient. The patient case codes can be read as follows: N_SUR_XTK_SN_DDMMYYYY

- N = first letter of patient's given name
- SUR = first three letters of patient's family name
- XTK = side being operated on (left or right):

  - LSK = Left Sphere Knee
  - RSK = Right Sphere Knee
  - LTK = Left GMK Primary Knee (either PS, UC, or CR)
  - RTK = Right GMK Primary Knee (either PS, UC, or CR)
- SN = the first letter of the surgeon's given and family name
- DDMMYYYY = patient's date of birth (DD=day, MM=month, YYYY=year).

The case should be created before the MRI scan is taken. If the case code does not exist for a given patient, please contact the local sales representative to assist. A case code can be created only by a surgeon or a surgical scheduler.

For detailed instructions about how to upload a dataset to the website, please refer to the MyKnee® WebPortal How-to manual (ref. 99.MYK.1HT).

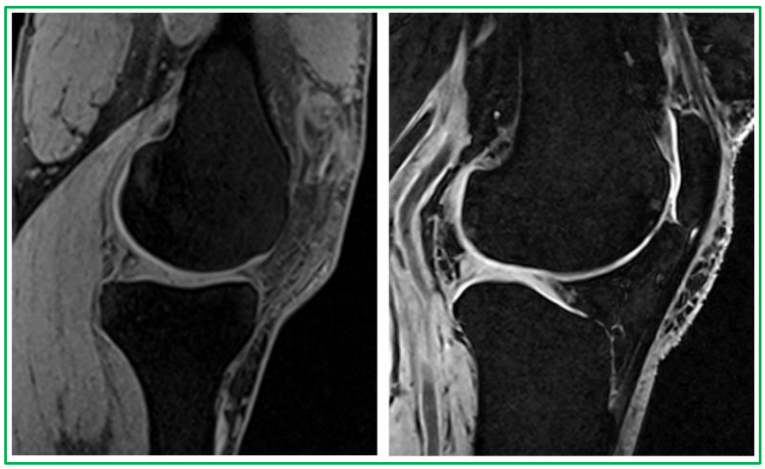
Alternatively, the DICOM dataset can be stored on a CD or DVD. A label must be applied including the patient's name, affected side, acquisition date and, if applicable, planned surgery date. The CD or DVD can be mailed to:

Medacta International SA
Strada Regina
CH-6874 Castel San Pietro
Switzerland

Do not hesitate to contact us for any further assistance at radiology@medacta.ch.

8 Examples of Acceptable MRI Series for the Knee

The following figures are examples of good quality MRI images of the knee.



GOOD - The patient did not move during the scan. The images clearly demonstrate the knee joint, and allows a clear identification of the cartilage. No magnetic lines are visible.

9 Examples of Not Acceptable MRI Series of the Knee

BAD - Fat saturation not selected

BAD - Distorted images with magnetic field lines

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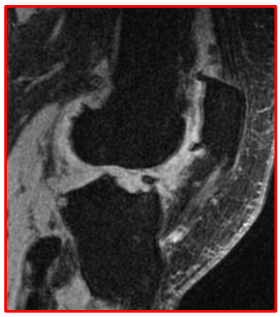
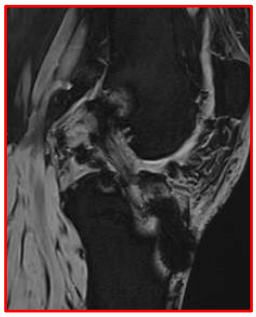
BAD - Poor signal-to-noise ratio



BAD - Patient movement



BAD - In-situ metallic devices in the knee being scanned.

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