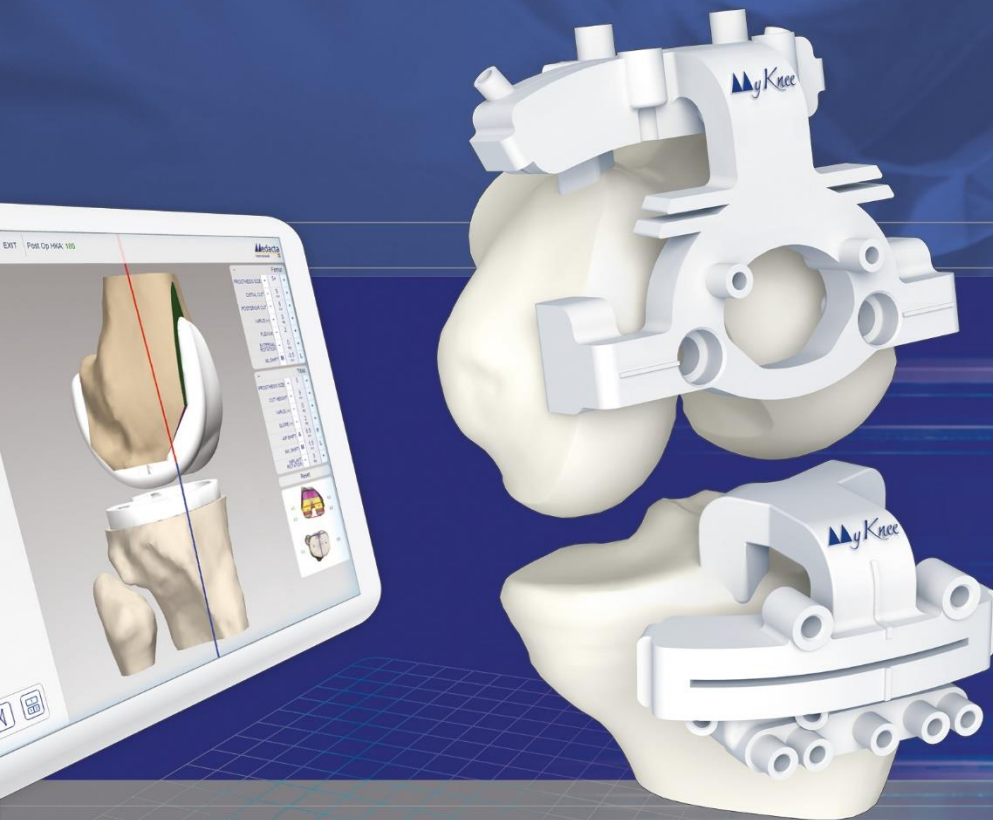




PATIENT MATCHED TECHNOLOGY
IN KNEE REPLACEMENT

DESIGNED FOR YOU BY YOU



CT Protocol

Joint

Spine

Sports Med

REFERENCE GUIDE

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CAUTION: Scans must be performed up to 6 months before the surgery.

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1 Introduction

This document describes the guidelines that radiological centers should follow when performing CT scans required by Medacta International SA to manufacture the MyKnee® cutting blocks. These cutting blocks are prepared for a patient to receive a Medacta knee implant system, and are the direct result of the CT scans.

The directives contained in this document are intended to improve the quality of the resulting CT scans. Radiology technicians are, in general, required to follow the instructions outlined in this document; variations to the settings and potential modifications to the protocol are to be discussed with and approved by Medacta International SA in advance.

Medacta International SA reserves the right to refuse scans performed with settings different from the suggested ones.

For more information, please do not hesitate to contact Medacta International SA at e-mail address radiology@medacta.ch.

2 Patient position

The patient must be in supine position at isocenter in the gantry. The leg of interest must be in complete extension. No sponge or pillow should be placed beneath the knee or ankle.

The critical aspect is the position of the foot, which must be perpendicular to the table with the toe pointing straight up.

Importantly, the position of the foot should be secured to prevent motion and the consequent loss of accuracy to assess and correct any misalignment of the knee.



Where a contralateral knee implant is present in the opposite leg to the affected one, please keep the implanted leg bent during the scan (see picture on left) to avoid 'scattering noise': it increases the image quality of the affected knee.

3 Image acquisition

The acquisition consists of three (3) separate short **spiral axial scans**:

- 1) hip
- 2) affected knee
- 3) ankle

Please note that scans of the hip and ankle are **required** to ensure an appropriate alignment of the leg. All three scans must be in the same coordinate system (frame of reference).

Please note:

Tip for GE users: if you do not have a pre-defined protocol built, between scan ranges select “Repeat series” to scan the next range. **Do not** select “Add a group”.

Tip for Toshiba users: between scan ranges select “Quit series” and use original scout to scan the next range.

3.1 Field of view (FOV)

Each acquisition must be centered and zoomed accurately to ensure the FOV maximizes the region of interest. In particular, only the affected side must be included in the FOV. Attention must be paid so that the outer bounds of the regions of interest are included in the FOV.

The whole of the **required bone regions** must be captured:

- **Hip:** femur head
- **Knee:** femur, fibula and tibia contours
- **Ankle:** medial and lateral malleolus

3.2 Image parameters

Scans should be acquired in slices of minimum 512x512 pixels. The thickness of a single slice should be no more than 4mm for the hip and ankle and 1mm for the knee. The spacing between slices should be no larger than the slice thickness; a slight overlapping is allowed.

The following table summarizes the **recommended** image settings.

	Ankle and Hip	Knee
Rows x Columns	512 x 512 pixels	512 x 512 pixels
Slice thickness	2 - 4mm	0.5 - 1mm
Spacing between slices	2 - 4mm	0.5 - 1mm
FOV	Max 200mm	Max 200mm

The FOV should be as small as possible, as long as the articulation is completely demonstrated. **Ideally** it should be inferior to 200 mm, which brings to a pixel dimension (defined as the ratio between the FOV and the acquisition matrix) inferior to 0.39 mm with a 512 x 512 acquisition matrix.

3.3 Machine settings

The following settings are intended to maximize the quality of the images. If different values are required on your machine, please inform Medacta International SA before proceeding with the acquisition.

KiloVolt Peak (KVP)	120 KV or higher
X-Ray tube current	120 mA or higher

3.4 Scan ranges

The following figure depicts the scans required.



Hip

The whole femoral head and at least 10 centimeters of femur must be included in the hip acquisition.

Knee*

Both the femoral and tibial parts of the knee joint must be included in the knee acquisition. The scan must extend to at least 15 centimeters towards the hip and 10 centimeters towards the ankle, past the beginning of the fibula.

Ankle

The ankle scan must include at least 5 centimeters of tibia and extend past the lateral malleolus.

* Please note, for MyKnee R cases the scan must extend to at least 19 centimeters towards the hip and 18 centimeters towards the ankle, past the beginning of the fibula, in order to correctly allow the evaluation of extension stems positioning.

3.5 Image exportation

The three required scans of the hip, knee and ankle must be **exported as original scans**. In particular, derived (re-sampled) series will be rejected. The DICOM dataset provided should contain only the series of interest to minimize confusion and likelihood of error.

Regarding the Reconstruction Convolution Kernel we suggest to use “bone kernel” for all three scans (hip, knee and ankle).

Both the study and the series should be named according to what they represent. As a rule of thumb, include the patient’s name and affected side in the study description, and the affected side and part in the description of each series, e.g.:

Study: “John Smith, left knee study”

Series 1: “Left hip”

Series 2: “Left knee”

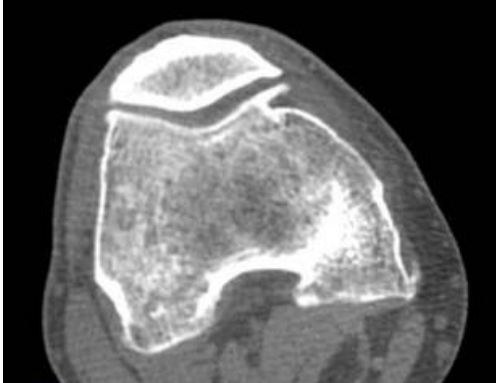
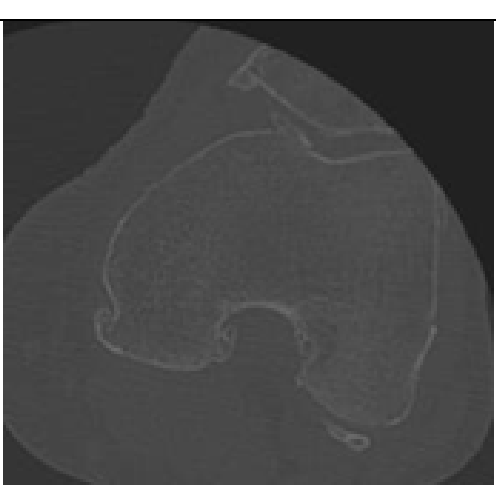
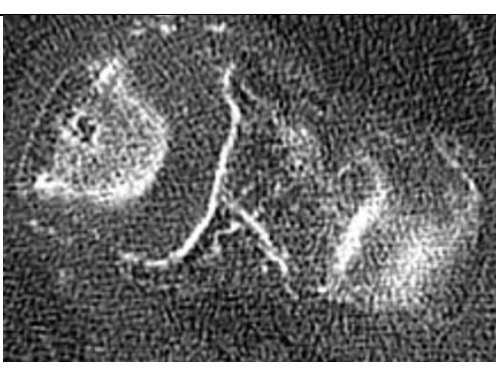
Series 3: “Left ankle”

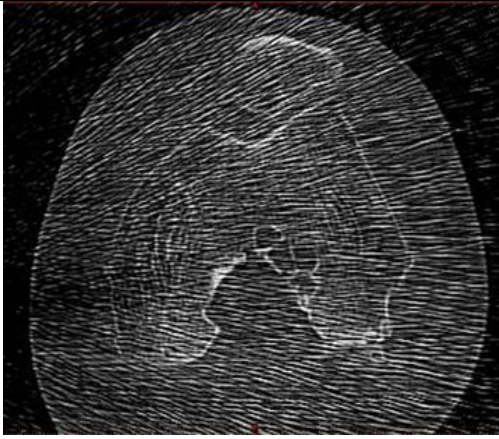
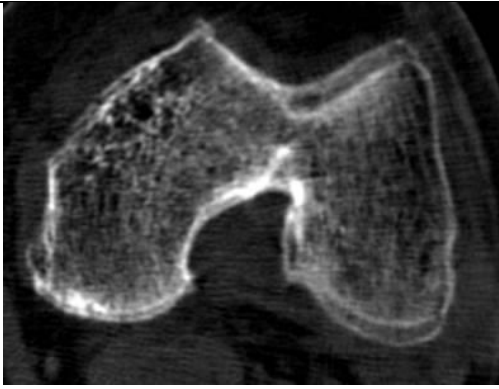
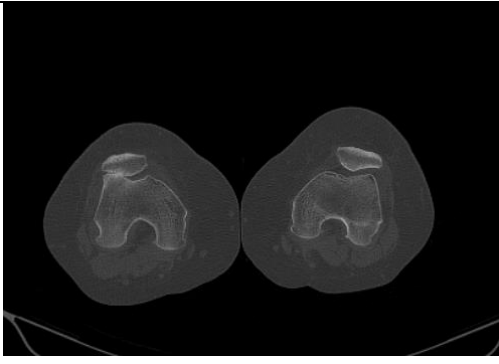
In general, any localizers automatically produced by the machine should be excluded from the media. If this is not possible, please clearly distinguish between localizers and actual scans by providing a series consisting of localizers only. **DO NOT include localizers within the series.**

The image data exported should be in uncompressed RAW format (MONOCHROME2) or compressed using lossless algorithms (i.e. JPEG2000 lossless).

3.6 Examples

The following figures show examples of good and bad CT scans.

	<p>GOOD</p> <p>Good centered image, very good quality: all bone contours are easily recognizable and no noise.</p>
	<p>BAD</p> <p>Image not in the center, cannot see lateral compartment.</p>
	<p>BAD</p> <p>High salt and pepper noise: low mA tube current value</p>

	<p>BAD</p> <p>High scattering noise caused by contralateral implant: in this case the contralateral leg has not been bent.</p>
	<p>BAD</p> <p>Split cortical bone contours caused by patient movement during the scan.</p>
	<p>BAD</p> <p>Bilateral scan, FOV too big, bad image resolution: Medacta requires a single scan of the affected leg only.</p>

4 Image delivery

The DICOM dataset of a MyKnee® case must be uploaded on the MyKnee® WebPortal (<https://myknee.medacta.com/>) by the radiological center or, alternatively, by the surgeon or his surgical scheduler. We suggest uploading dimension DICOM files no greater than 500Mb in order to avoid uploading problems and to reduce uploading time. Please do not upload sagittal or coronal series. NOTE: 300 Mb should (usually) be the standard file dimension for the MyKnee process.

If you want to be sure that your scans conform to our protocol, you can send us DEMO CT scans (real patient images or phantom scans) using the **Demo Upload Section** of our website. We will evaluate the images and send you our feedback.

For detailed instructions, 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 storage media can then 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.