EPISEALER® KNEE
MRI PROTOCOL INSTALLATION GUIDE
SIEMENS
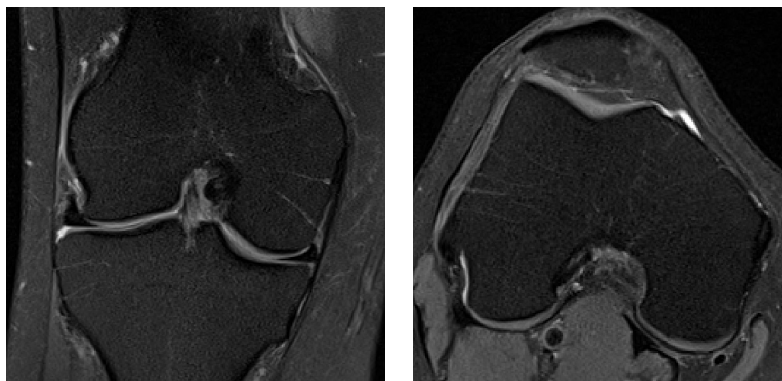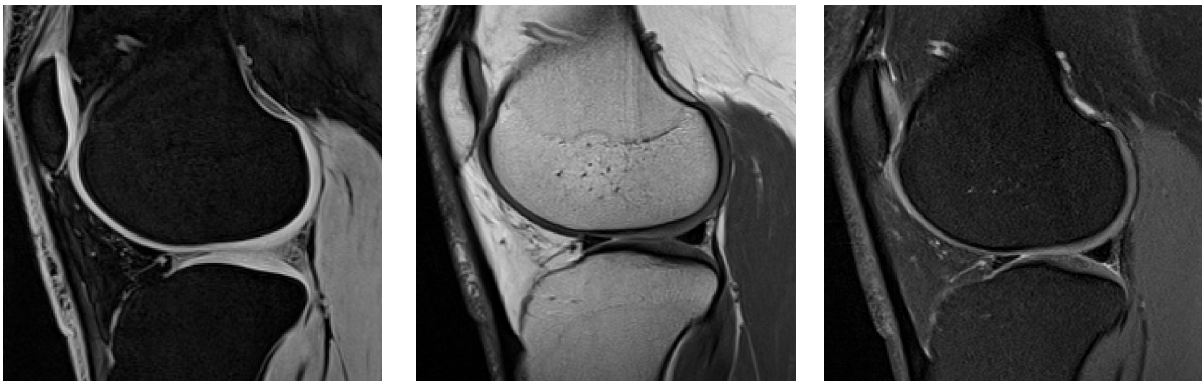
CONTENT

Episurf Medical

Episurf Medical designs and manufactures individualised solutions for focal chondral and osteochondral lesions in the femoral condyles and trochlea of the knee. The design of the Episealer knee implant and associated surgical instrument kit is based on a virtual 3D visualisation of the patient's knee. This visualisation is achieved by segmentation of MR images of the patient's knee using the specific Episurf MRI Knee Protocol, consisting of a 3D sequence and four diagnostic MS sequences. It can be applied to Philips, Siemens and GE MRI scanners with a magnetic field strength of at least 1.5 T and an appropriate knee coil.
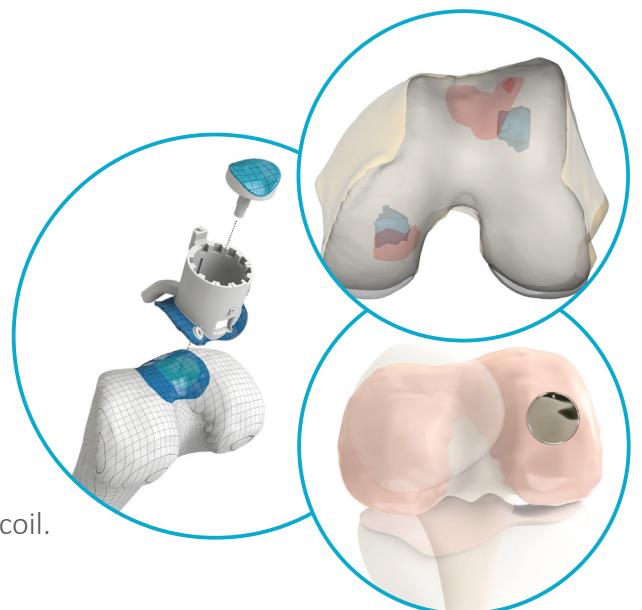
INTRODUCTION

Why a specific protocol?

MRI provides detailed images of the knee anatomy and is used both for visualisation and assessment of e.g. lesions in the cartilage and the underlying bone. Episurf Medical uses an MRI protocol with a tailored 3D sequence as well as conventional diagnostic sequences (2D sequences). This particular combination is essential for the software and the design process in order to make precise, individualised implants and surgical instruments. It is mandatory to adhere to this protocol. An incorrect protocol can entail patient risks and will therefore not be accepted.

3D sequences

An SPGR (Spoiled Gradient Echo) fat-saturated sequence with **1 mm thick** slices with a **resolution of 0.5 x 0.5 mm** is used to reconstruct the joint anatomy. The surgical tools and the individualised implant are designed using the data from the MRI to accurately reconstruct the patient's unique anatomy.

Diagnostic scans

To make a complete damage assessment of the distal femur, four (4) different conventional diagnostic sequences are required. Together with our radiological team, we identify cartilage and bone lesions and suggest individualised implant sizes and positions thereafter.

Episurf MRI Protocol Knee sequences

The Episurf MRI Protocol consists of five (5) MRI sequences; one (1) 3D sequence and four (4) 2D sequences.

Number	Type	Orientation	Pulse sequence	Optional pulse sequence
1	2D	Transversal/Axial	TSE PD FS	
2	2D	Coronal	TSE PD FS	
3	3D	Sagittal	3D T1 WE Vibe	3D T1 FAT SAT FLASH (*3dfl1)
4	2D	Sagittal	TSE PD	TSE Dual Echo PD/T2
5	2D	Sagittal	TSE PD FS	

The settings for these sequences will be described in detail further in this guide.

Setting up the protocol

The MRI protocol is put in place in **3 simple steps**:

1. **Configure the protocol**
   Load the specific settings on your MRI scanner. Your Episurf representative will be available to help you.

2. **Run a test scan**
   Once the MRI protocol has been correctly set up on the MRI scanner, a test scan must be performed and assessed by Episurf. This is to ensure that the MRI data is producing the correct image quality.

3. **Complete the set-up**
   Episurf will inform you when test scan is satisfactory. You are now ready to start scanning patients.

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MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE

Summary of 3D sequence settings

The table below summarises the settings for the 3D sequence. A more comprehensive step-by-step guide on how to adjust the settings follows on pages 5-6. Any parameter not specified in the table below can be adjusted according to user preferences, provided that the image quality is maintained. To improve the image quality and/ or reduce the scan time, see the tips on page 7.

Tab	Setting	Value
Program	Pulse sequence	3D T1 WE Vibe or 3D T1 FAT SAT FLASH (*3dfl1)
Routine	Slabs	1
	Orientation	Sagittal[1]
	Phase enc. dir.	A>>P
	Slices per slab	112 (recommended value; ensure that the bone and cartilage of the distal femur are included)
	FoV read (mm)	128[2]
	FoV phase (%)	100.0 (recommended value - avoid folding artefacts)
	Slice thickness (mm)	1.0
	Averages	Knee coil: min. 1 Flex coil: min. 2
	Concatenations	1
Contrast	TE	Shortest possible
	TR (ms)	20.00
	Flip angle (deg)	25.0
Resolution	Base resolution	256[2]
	Interpolation	OFF
	Slice resolution	Min. 50%
	PAT mode	None *(located in iPAT sub tab)*
	Distortion correction	Enable. Mode: ''3D'' or ''2D + 3D'' (if available, otherwise ''2D'') *(located in Filter Image sub tab)*
Sequence	Bandwidth (Hz/Px)	Max. 130 (for 1.5 T), max. 260 (for 3 T)
	Optimization	Min. TE

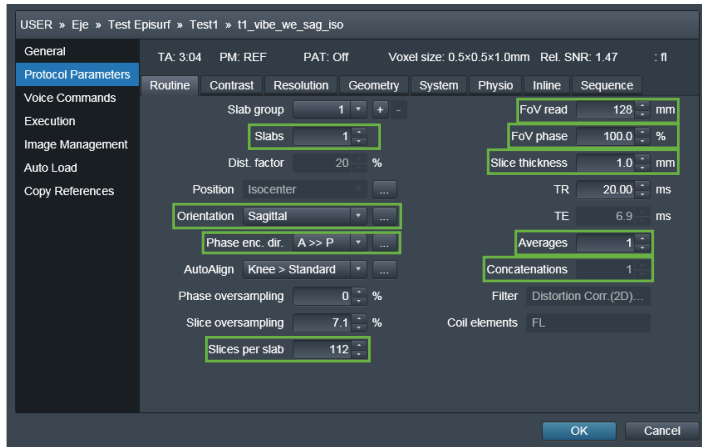[1] Value will be automatically updated to ''S > C -/+ (value)'' once the FoV is set.
[2] For larger knees, use the values as specified in the table on page 14 of this guide.
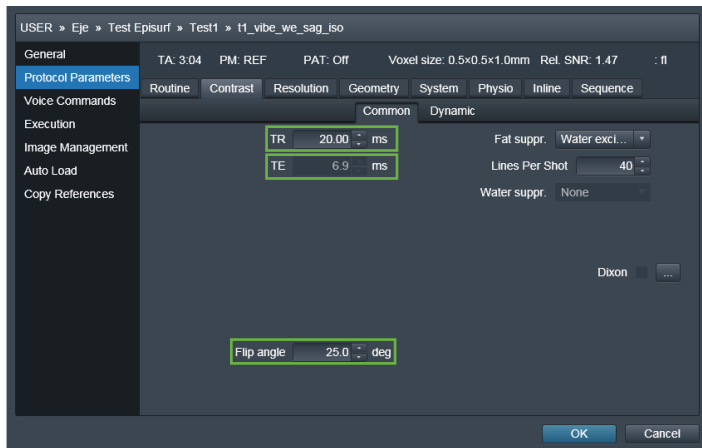
Accepted voxel size		
	Min	**Max**
Acquired voxel size	0.45x0.45x1.0 mm	0.55x0.55x1.0 mm
Reconstructed voxel size	0.45x0.45x1.0 mm	0.55x0.55x1.0 mm

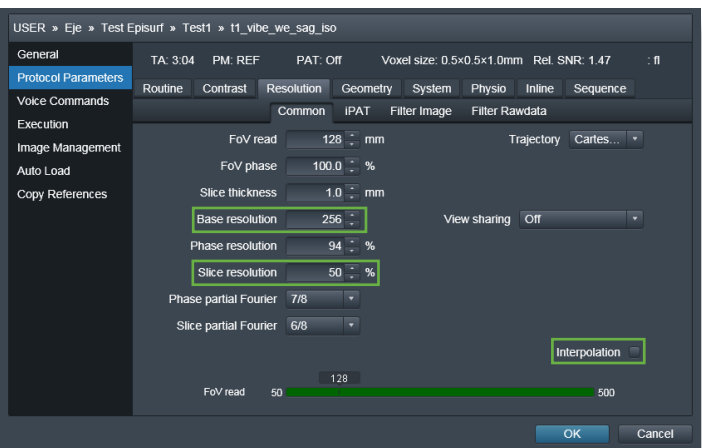# MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE

1. 3D sequence Routine tab

2. 3D sequence Contrast tab - Common sub tab
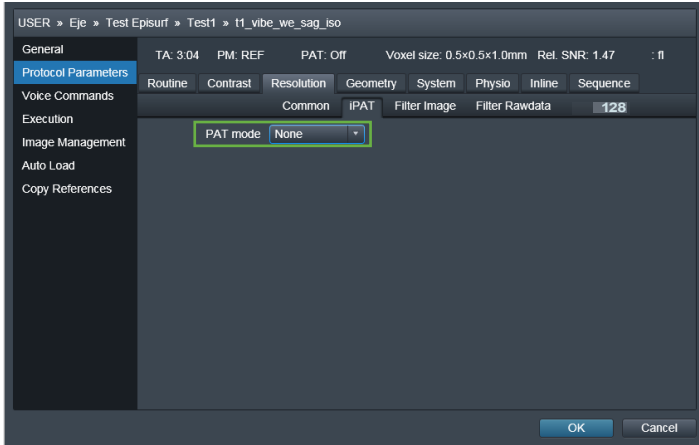

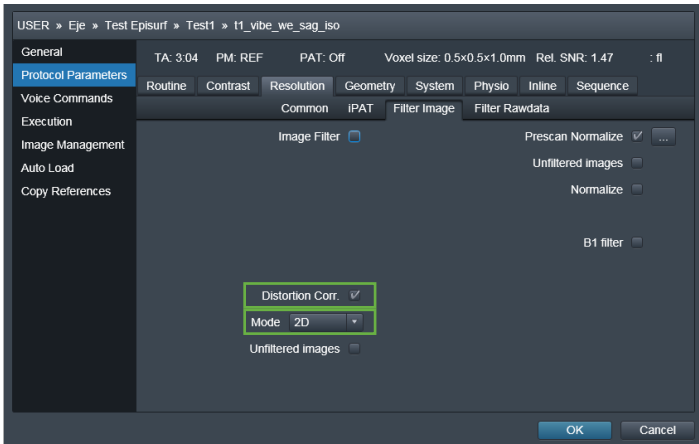## 3. 3D sequence Resolution tab - Common sub tab

Ensure that Interpolation is deselected.

MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE
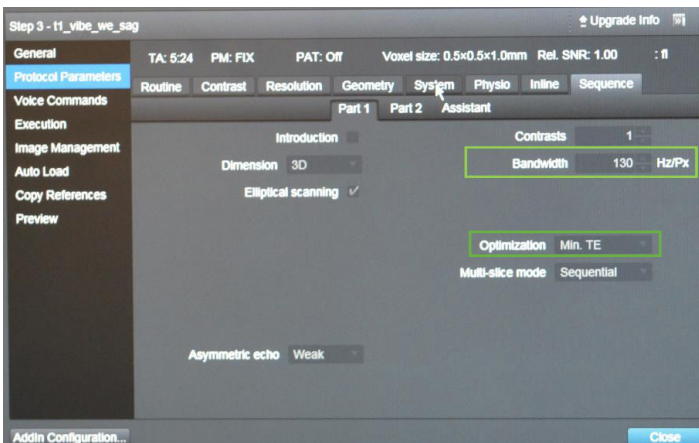
4. 3D sequence Resolution tab - iPAT sub tab

5. 3D sequence Resolution tab - Filter image sub tab

Enable Distortion correction. Set **Mode** = ''3D'' or ''2D + 3D'' if available, otherwise select ''2D''.

6. 3D sequence Sequence tab

Bandwidth (Hz/Px)	
1.5 T	130
3 T	260

MANUAL PROTOCOL INSTALLATION - 3D SEQUENCE

Tips for improving the image quality in the 3D sequence

- Recommended <u>minimum</u> scan time is approximately 5:00 min (1.5 T) and 4:30 min (3T)
- Increase Averages
- Increase Slice Resolution
- Decrease Bandwidth

Tip for reducing the scan time in the 3D sequence

⚠️ **IMPORTANT**
Maintain Image Quality

- Set Phase Oversampling to 0% (in Routine tab) but make sure that folding artefacts do not interfere with the femoral cartilage (see page 14 in this guide)

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MANUAL PROTOCOL INSTALLATION - 2D SEQUENCES

Summary of 2D sequence settings

The table below summarises the settings for the 2D sequences. A more comprehensive step-by-step guide on how to adjust the settings follows on page 9 of this guide. To improve the image quality and/or reduce the scan time, see the tips on page 10. **Make sure to adjust the settings for all four sequences.**

Number	Orientation	Pulse sequence	Optional pulse sequence
1	Transversal/Axial	TSE PD FS	
2	Coronal	TSE PD FS	
3	Sagittal	TSE PD	TSE Dual Echo PD/T2
4	Sagittal	TSE PD FS	

| Tab	Setting	Value
Resolution	FoV read	128[1] (ensure that the bone and cartilage of the distal femur are included)
	Slice thickness	3.0
	Base resolution	Recommended 320-384 (minimal value 256)[1]
	Distortion Corr.	Enable. Mode: 3D *(located in **Filter Image** sub tab)*
Geometry	Slices	33 (recommended value; ensure that the bone and cartilage of the distal femur are included)
	Dist. factor (%)	10

[1] For larger knees, use the values as specified in the table on page 14 of this guide.

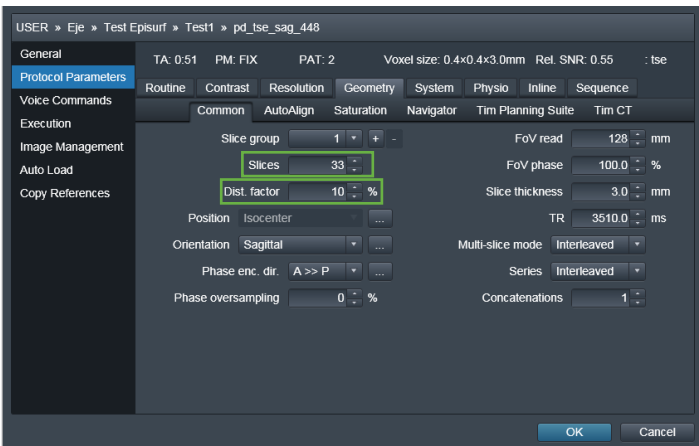## MANUAL PROTOCOL INSTALLATION - 2D SEQUENCES

1. 2D sequence Resolution tab - Common sub tab
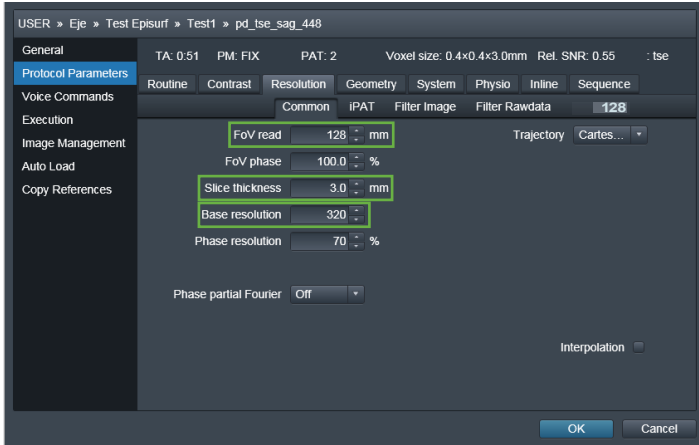
2. 2D sequence Resolution tab - Filter Image sub tab
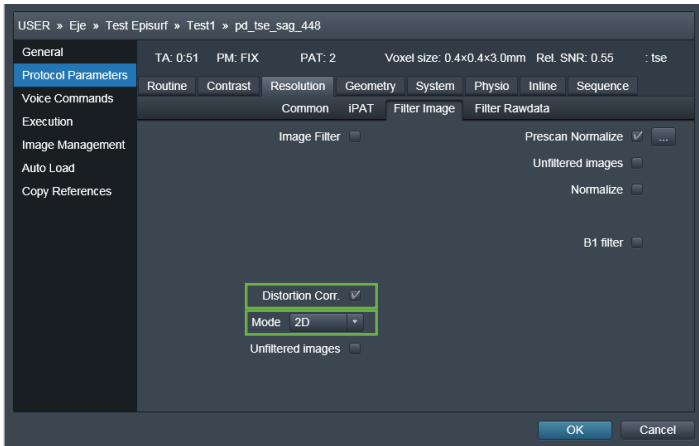
3. 2D sequence Geometry tab

MANUAL PROTOCOL INSTALLATION - 2D SEQUENCES

Tips for improving the image quality in the 2D sequences

- **Recommended <u>minimum</u> scan time is approximately 3:30 min (1.5 T) and 3:00 min (3T)**
- **Increase Averages**
- **Decrease Bandwidth**

Tips for reducing the scan time in the 2D sequences

⚠️ **IMPORTANT**
Maintain Image Quality

- **Choose Phase Encoding Direction as following**
  - **Sag: A>>P**
  - **Cor: R>>L**
  - **Tra: R>>L**
- **Set Phase Oversampling to 0% (in Routine tab) but make sure that folding artefacts do not interfere with the femoral cartilage (see page 14 in this guide)**
- **Use accelerations techniques such as GRAPPA, but make sure that the image quality is maintained**
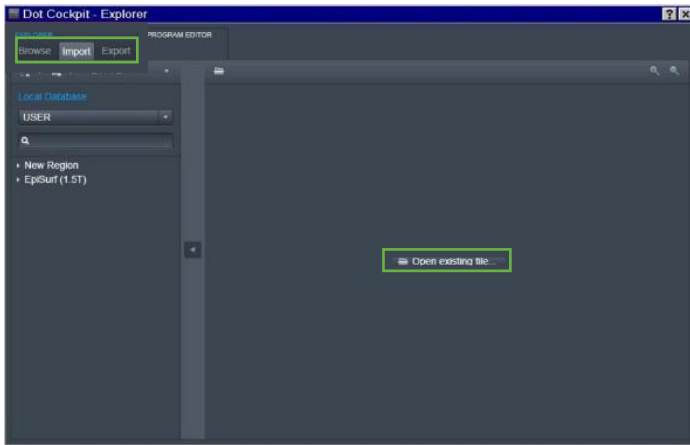
PROTOCOL INSTALLATION VIA USB

Episurf provides two Episurf MRI protocols available on USB sticks for Siemens MRI machines:

Tab	Setting	Software version	Compatible machines
1.5 T	EpiSurf1.5T.exar1	11C	Aera, Avanto Fit
3 T	EpiSurf3T.exar1	11C	Skyra, Prisma

Instructions

1. Insert the USB stick and open Dot Cockpit and choose "Import".
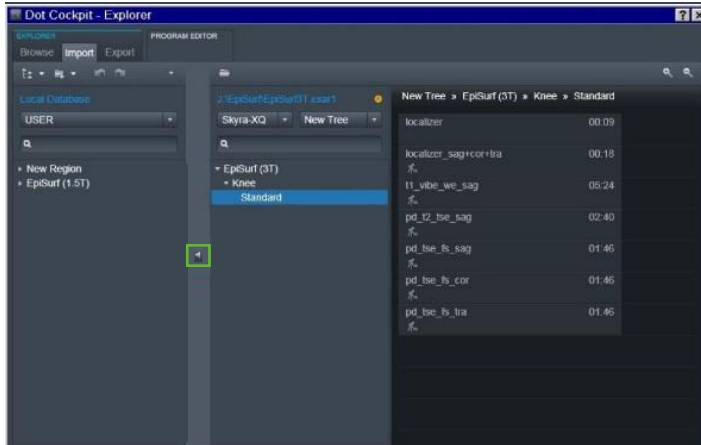   Choose " Open existing file...".

2. Locate the USB stick, select the appropriate Episurf Protocol and press "Open".
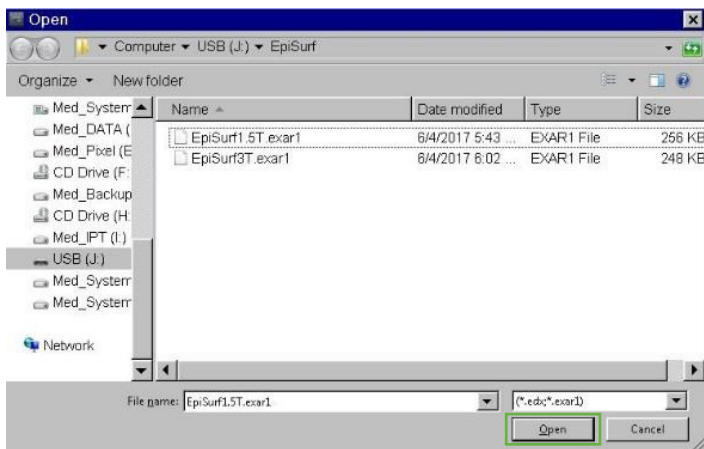
PROTOCOL INSTALLATION VIA USB

3. Select the protocol and press the small arrow button to transfer the protocol to the local database.

Final check

1. Depending on machine configuration, minor changes may occur in the protocol during the USB installation. Once the protocol is installed, check if any changes were made. If necessary, adjust the parameters according to the settings described in the manual protocol installation guide (pages 4-10).

2. Check that all sequences were installed, see the example below.
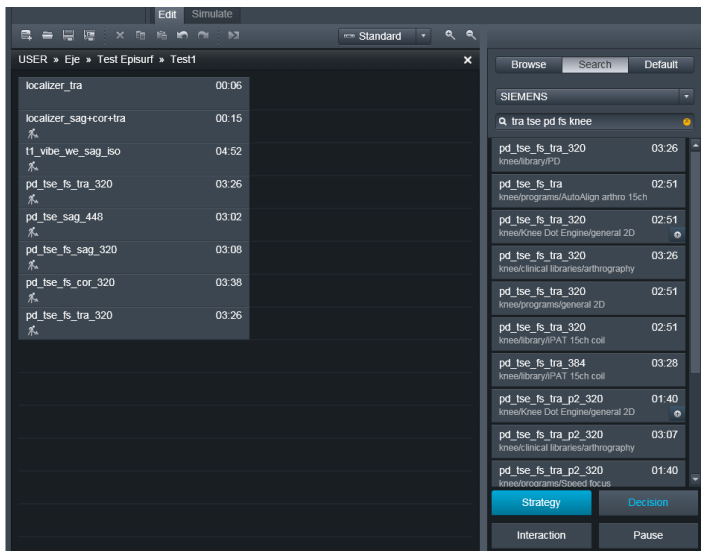
*Example of the installed 1.5 T MRI protocol*

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# IMAGE ACQUISITION

Angulation

To be able to make a correct assessment of the patient's knee, it is of utmost importance that the sagittal scans are acquired with the Episurf angulation. Please follow the steps below when scanning a patient with the Episurf Knee Protocol.
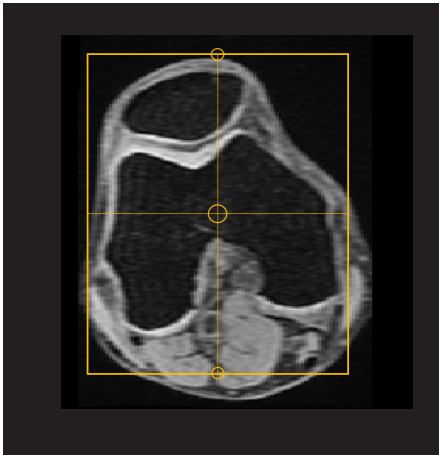
1. Adjust the size of the FoV to fully cover the femoral bone and articular cartilage.
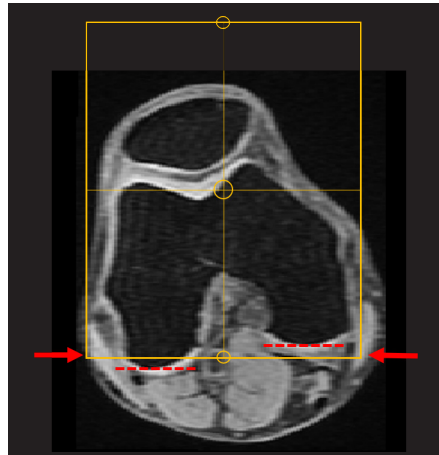

2. Place the FoV box with the bottom border of the box at approximately the same height as the back of the condyles.
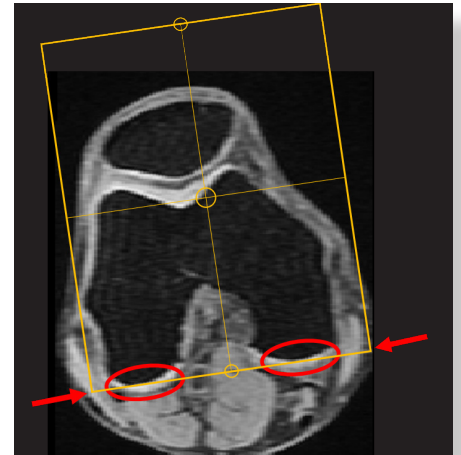
3. Rotate the Fov box so that the bottom border of the box is aligned with and touching the back of both condyles.

4. Adjust the position of the FoV box to fully cover the femoral bone and articular cartilage.

Correct angulation

Sagittal sequence (axial view)

Incorrect angulation

Sagittal sequence (axial view)
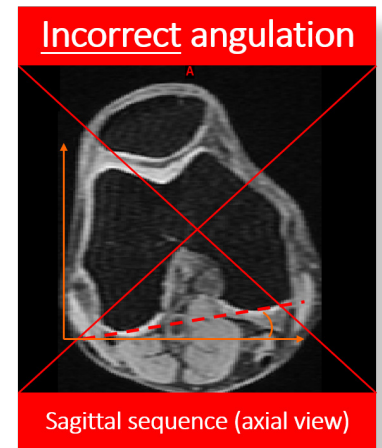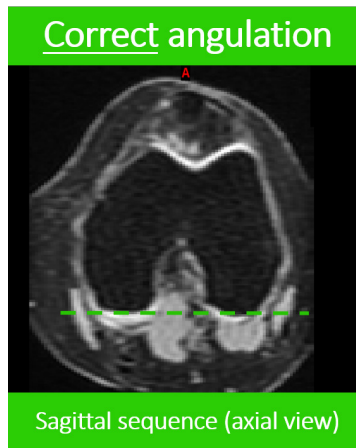
⚠️ **IMPORTANT**
Do not rotate the FoV box in this step!

Tip

To make sure the operator performs the correct alignment when scanning a patient with the Episurf Knee Protocol, name the series including a comment about the angulation. Example: pd_tse_fs_sag_along_back_of_condyles

IMAGE ACQUISITION

When scanning a patient with the Episealer Knee Protocol, please ensure to follow the guidelines below.

- Use a **knee coil** when available. Set **Average = min. 2 when a flex coil** is used.
- Place the knee as close as possible to the **epicentre** of the main coil.
- The protocol consists of one (1) 3D squence and four (4) 2D sequences: **5 sequences** in total.
- All sequences must have a Field of View (FoV) that **covers the whole femoral bone and articular cartilage**.
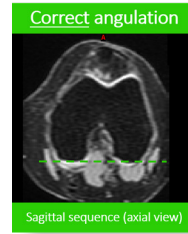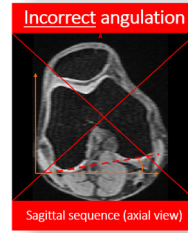
Folding artefacts
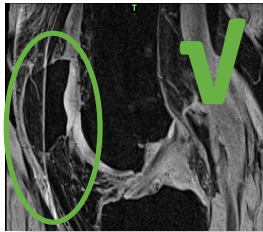
Folding artefacts which are not interfering with the femoral cartilage are **accepted.**

Alignment

For **all sagittal sequences** (3D and 2D), align the bottom line of the FoV box parallell to the back of the condyles.

Do **NOT** align the sagittal sequences along the lateral condyle.

See page 13 for further information.

Field of View (FoV) and Base Resolution

Verify the voxel size by hoovering the mouse pointer over the "Voxel size" label, see image on the right. The reconstructed pixel size is determined by the FoV read and base resolution. Choose **one** of the four options for FoV read and base resolution according to the table below. Make sure that the FoV fully covers the femoral bone and articulate cartilage.

Note: **Pixel sizes other than specified in the table below will not be accepted by Episurf. Do NOT interpolate the 3D image.**

		3D sequence		2D sequences	
Option	**FoV read (mm)**	**Base resolution**	**Pixel size (mm)**	**Base resolution**	**Pixel size (mm)**
Option 1 (standard)	128	256	0.5	Minimum 256 (preferably larger)	Less than 0.5
Option 2 (larger knee)	160	320	0.5	Minimum 320 (preferably larger)	Less than 0.5
Option 3 (larger knee)	192	384	0.5	Minimum 384 (preferably larger)	Less than 0.5
Option 4 (larger knee)	256	512	0.5	Minimum 512 (preferably larger)	Less than 0.5

If you encounter problems related to this protocol, please contact **production@episurf.com.**

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