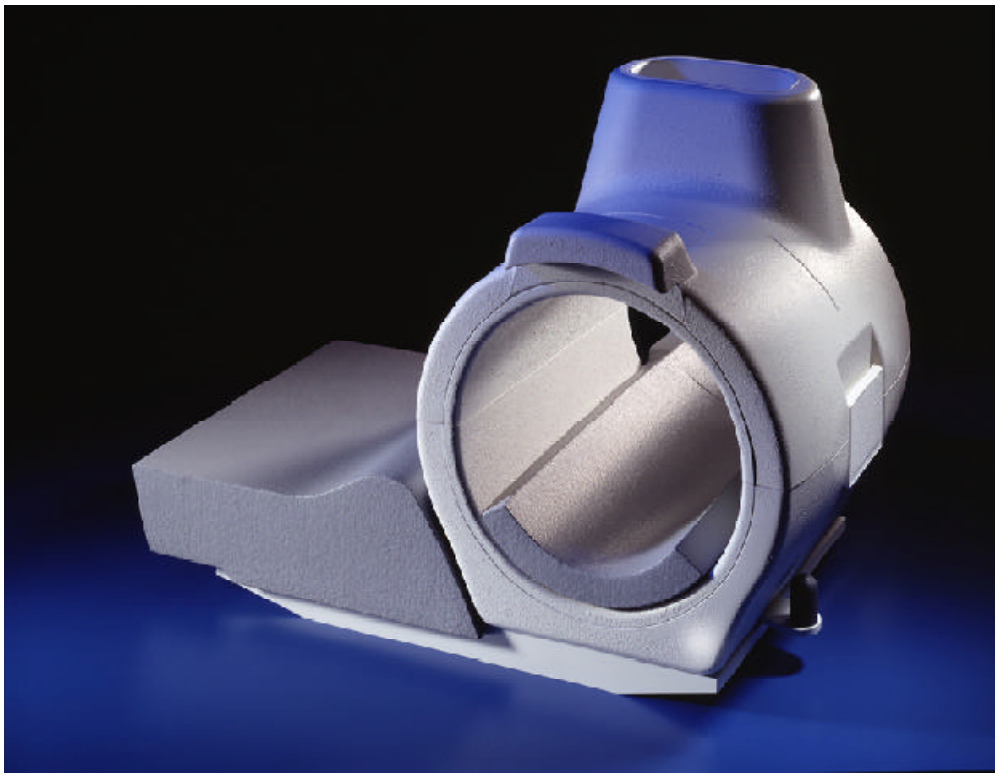
Operator's Manual
Model KFA-63

Knee, Foot and Ankle Array for GE Signa 1.5T MRI System



Manufactured by:

MRI Devices Corporation
1515 Paramount Drive, Suite A
Waukesha, Wisconsin 53186 USA

Distributed by:

GE Medical Systems

First Edition
May 2002

Licenses and Trademarks
The MRI Devices Logo is a registered trademark of MRI Devices Corporation.
Signa System is a registered trademark of the General Electric Company.

Proper performance of this coil is guaranteed only while the coil is being used on the MR system (hardware/software level) specified at the time of purchase. Upgrades or other modifications to the system software and/or hardware may affect compatibility. Prior to upgrading your MR system, please contact your GE Medical Systems representative to discuss coil compatibility issues. Failure to do so may void your warranty.

Medical Device Directive
These products conform with the requirements of council directive 93/42/EEC concerning medical devices, when they bear the following CE Mark of Conformity:

CE 0413

Attention, Consult Accompanying Documents

Type BF Equipment

Class II Equipment

NOTICE:

TRANSPORT AND STORE THIS PRODUCT UNDER THE FOLLOWING ENVIRONMENTAL CONDITIONS ONLY, FOR A PERIOD NOT EXCEEDING 4 WEEKS:

AMBIENT TEMPERATURE OF -40°C to +60°C
RELATIVE HUMIDITY OF 10% TO 100% (Non-Condensing)

ATMOSPHERIC PRESSURE ON 765 hPa TO 1011 hPa

Caution:
Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

Introduction

This manual describes the safety precautions, features, use and care of the MRI Devices Model KFA-63 Knee and Foot Array, compatible with the GE Signa 1.5T MRI System. Please review this manual thoroughly before using the device.

If you have any questions or comments on this manual, or need any assistance with the use of the product, please contact your GE Medical Systems representative at:

1-800-GE CARES

Distributed by:

GE Medical Systems

Manufactured by:

MRI Devices Corporation
1515 Paramount Drive, Suite A
Waukesha, Wisconsin 53186 USA

Model KFA-63 Knee Foot and Ankle Array

The Model KFA-63 Knee and Foot Array Coil Package consists of the following parts.

Please inspect upon receipt to make sure all parts have arrived and are in good order.

Use this guide to refer to part names throughout this manual.

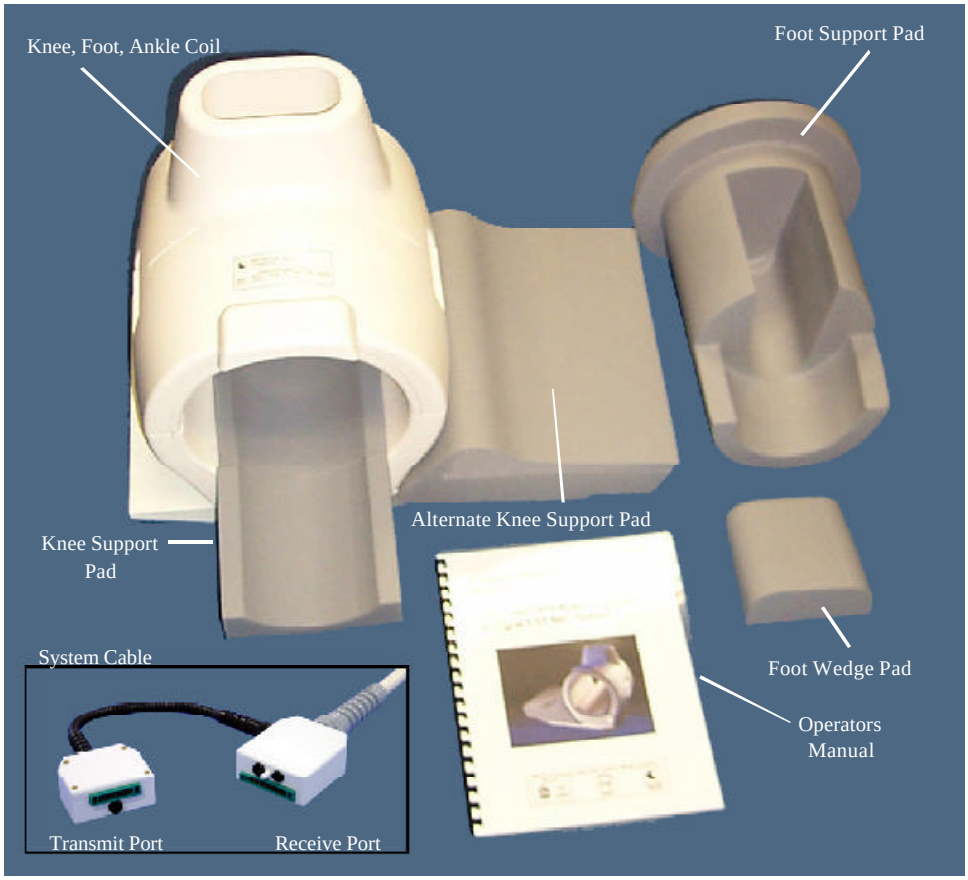


Table of Contents

Chapter 1 - Patient Safety

Training

This manual contains detailed information on the set-up, positioning and use of your MRI Devices Corporation coil. The instructions should be read carefully and thoroughly before attempting to scan patients with the coil.

Quality Assurance

The procedure described in the Quality Assurance Section of this manual should be performed upon receipt of the coil to establish a baseline of coil performance. The procedure should be repeated at regular intervals.

Indications

The coil is indicated for use, on the order of a physician, in conjunction with an MR scanner, as an accessory to produce images of the knee, foot and ankle.

Contra-indications

The operator should be aware of the following contraindications for use related to the strong magnetic field of the MR system:

- Scanning is contraindicated for patients who have electrically, magnetically or mechanically activated implants (for example, cardiac pacemakers). The magnetic and electromagnetic fields produced by the MR System and coil may interfere with the operations of these devices.
- Scanning patients with intracranial aneurysm clips is contraindicated.

Precautions

Precautions should be taken when scanning patients with the following conditions:

- Greater than normal potential for cardiac arrest.
- An increased likelihood for developing seizures or claustrophobia
- Unconscious, heavily sedated, or confused patients
- Patients with whom reliable communications cannot can be maintained.

Cautions

The following general warning statements apply to scanning with a magnetic resonance system. For further details, review the warnings in your MR system Operators Manual.

- **!** Cables should not be looped or crossed. Arcing and patient burns could result.
- **!** If a patient complains of burning, tingling, stinging, or other similar 'burn"-type sensations, promptly stop the scan procedure, examine the patient, and contact the responsible physician before continuing the procedure. Pay special attention to very young, sedated, or other compromised patients who may not be able to communicate effectively.
- **!** Route the cables out of the magnet so that they do not touch the patient.
- **!** Patients with ferromagnetic metal should not be scanned because the magnetic field may interact with implanted surgical clips or other ferromagnetic materials.
- **!** Persons with cardiac pacemakers or other implanted electronic devices should not enter the magnetic field zone delineated by the MR system manufacturer.
- **!** There is a risk to scanning feverish or decompensated cardiac patients.
- **!** Facial makeup should be removed before scanning because it may contain metal flakes which can cause skin and eye irritation. Permanent eyeliner tattoos may cause eye irritation due to ferromagnetic particles.
- **!** Patients who work in environments in which there is a risk of having embedded metallic fragments in or near the eye should be carefully screened before undergoing an MR exam.
- **!** Visually inspect the cable insulator jackets, strain reliefs and connector boxes before each use. If the insulation is broken, or if the cable is frayed, immediately discontinue use of the device.

Emergency Procedures

In the unlikely event that a coil creates smoke, sparks or makes an unusually loud noise, or if the patient requires emergency assistance:

1. Stop the scan if one is in progress.
2. Remove the patient from the scan room if medical treatment is needed.

Chapter 2 - Quality Assurance

SNR Protocol

This section contains the Coil Imaging Performance Verification procedure and the SNR Data Sheet from the GE SIGNA 1.5T T/R Knee and Foot Array Coil Service Manual. The information is duplicated complete with Service Manual section subheadings and numbering.

3-2 Coil Imaging Performance Verification

3-2-1 Tools Required

TOOLS REQUIRED – TABLE 3-2-1

Description	GE Part #	MRIDC #	Qty
Phantom	2293674-3	101448	1
Phantom Positioner	2293674-5	101450	1

3-2-2 Explanation of Procedure

The 1.5T T/R Knee and Foot Array Coil can be used in 2 modes of operation and has 3 coil names for software versions 8.3 and earlier: **TRKneePA, TRFootPA** and **TRKneePA-SHIM**. SNR measurements should be made for the **TRFootPA** mode of operation, requiring 4 sets of signal and noise scans. For software versions 8.5 and later, the 1.5T T/R Knee and Foot Array Coil can be used in 2 modes of operation and has 2 coil names: **TRKneePA** and **TRFootPA**. SNR measurements should be made for **TRFootPA** mode requiring 4 sets of signal and noise scans. Refer to the Data Sheet in Appendix 7-1 to understand the data required to calculate the individual element SNR for each mode of operation. All ROI measurements are made on the individual element images, **not** on the composite image.

The image quality check uses two different protocols for signal and noise image acquisition. The signal scan is an **FSE** sequence used to minimize susceptibility and B_0 inhomogeneity effects. The noise scan is a **GRE** sequence that has a Control Variable (do_noise) to eliminate the transmit RF completely during the scan. The signal scan **must** be run prior to the noise scan as the R1, R2, and TG values from the signal scan are used for the noise scan.

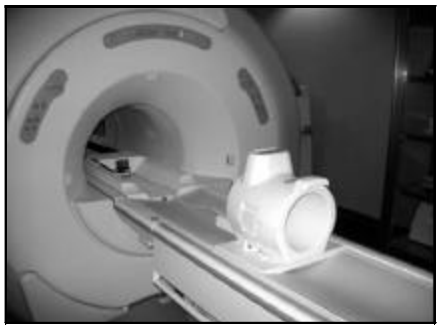
3-2-3 Signal Scan

The following procedure is specific to the LX platform but can be easily adapted for 5.x systems.

1. From the Scan Desktop, start new scan by selecting [**New Pt**]; set **Patient ID** to "*geservice*" and **Patient Weight** to "*111*" pounds. Click [**Patient Position**] to open protocols window.
2. Remove any other surface coils from the cradle. Position the 1.5T T/R Knee and Foot Array Coil on the cradle with the coil cable extending into the magnet [Figure 1]. The coil may be shifted left or right on its baseplate, and is intended for use with the patient entering the magnet feet first [Figure 2]. The coil is landmarked at isocenter [Figure 3].
3. At the magnet, press "**Alignment Light**" button to turn on the light. Move the cradle to align the coil to the alignment lights as shown in figure 3. Press "**Landmark**" button to landmark the alignment.
4. Move the coil to scan position by pushing the "**Move to Scan**" button, ensuring cable does not get snagged.
5. At the console, set the protocols per the Signal section from Table 3-2-4: Signal and Noise Protocols.
6. Click [**Save Series**] to download the protocols, then click [**Prepare to Scan**].

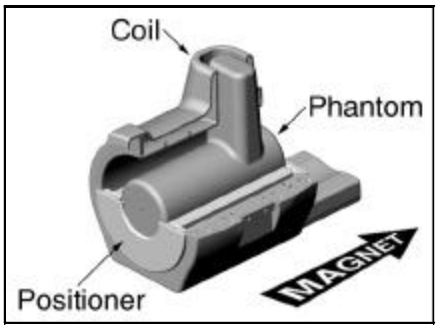
7. Open [**Display CVs**] menu under [**Research Operations**] (click right mouse button). Set the "**saveinter"** CV to "*1*" (saves the intermediate images so ROI measurements can be performed).
8. Run [**Auto Prescan**]. Record the R1, R2 and TG values on the SNR Data Sheet (found at the end of this manual).
9. Run [**Scan**].

Figure 1



Coil Positioning

Figure 2



Coil Orientation

Figure 3

Coil Landmark at Isocenter

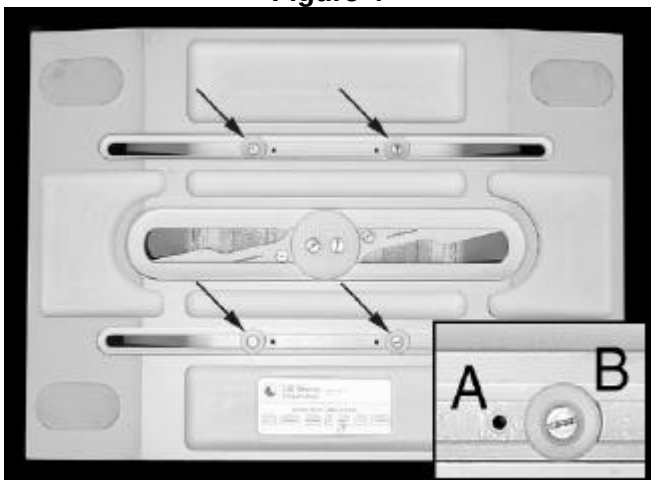
3-2-4 Noise Scan

A signal scan must be run **prior** to the noise scan as the same R1, R2 and TG values must be used for both the signal and noise scans. Do **not** run an Auto Prescan prior to the noise scan as the values will be changed.

1. Copy the signal scan series. Use [**Copy Series**] (highlight signal series and click right mouse button) and [**Paste Series**] in **RX Manager**.
2. Click [**View Edit**] and set the protocols per the Noise section from Table 3-2-4: Signal and Noise Protocols.
3. Click [**Save Series**] and click [**Prepare to Scan**].
4. Open [**Display CVs**] menu under [**Research Operations**]. Set the "**saveinter**", "**rhformat**", and "**do_noise**" CVs to "*1*".
5. Run [**Manual Prescan**], do **not** make any changes, and click [**Done**].
6. Run [**Scan**].

N O T E :

Figure 4



55cm Bore Slider Adjustment

The 1.5T T/R Knee and Foot Array may be adjusted to fit either the standard 60 cm bore or the 55 cm bore, as seen in Figure 4. The arrows detail the location of 4 sliders upon which the coil moves for right or left positioning. Each plastic slider is attached with a screw [inset-B]. Next to each slider is an empty threaded hole [inset-A].

1.5T coils are shipped in the 60 cm configuration. To change the positioning to 55 cm, as seen in Figure 4, use a flat blade screwdriver to remove the 4 slider screws, then move the sliders to the outboard position. This change will limit left-right movement of the coil for smaller bores.

SIGNAL AND NOISE PROTOCOLS – TABLE 3-2-4-1

Protocol	Signal	Noise
Patient/Exam Information		
Patient ID	geservice	geservice
Patient Name	TR foot PA test	TR foot PA
Patient Weight	111 lbs. (50 kg)	111 lbs. (50 kg)
Patient Position		
Patient Position	Supine	Supine
Patient Entry	Feet First	Feet First
Coil	TRfootPA	TRfootPA
Series Description	Signal	Noise
Imaging Parameters		
Plane	Sagittal	Sagittal
Mode	2D	2D
Pulse Seq	FSE	GRE
Imaging Options	Fast	None
PSD Name	*leave blank*	*leave blank*
Protocol	*leave blank*	*leave blank*
Scan Timing		
# of Echoes	1	1
TE	17	minfull
TR	500	34
Echo Train Length/Flip Angle	4	1
Bandwidth	N/A	15.63
Additional Parameters		
no entries required in this area		
Acquisition Timing		
Freq	256	256
Phase	256	256
NEX	1	1
Phase FOV	1	1
Freq DIR	S/I	S/I
Auto Center Freq	Peak	Peak
Autoshim	On	On
Phase Correct	On	N/A
Contrast	Off	Off
# of Reps B4 Pause	0	N/A
Scanning Range		
FOV	30	30
Slice Thickness	3.0	3.0
Spacing	1.5	1.5
Start R/L	0	0
End R/L	0	0
Slices	1	1
P/A Center	A80	A80
I/S Center	0	0
Table Delta	0.00	0.00

CV PARAMETERS – Table 3-2-4-2

Protocol	Signal	Noise
saveinter	1	1
rhformat	0	1
do noise	N/A	1

3-2-5 SNR Image Analysis

SNR Measurement

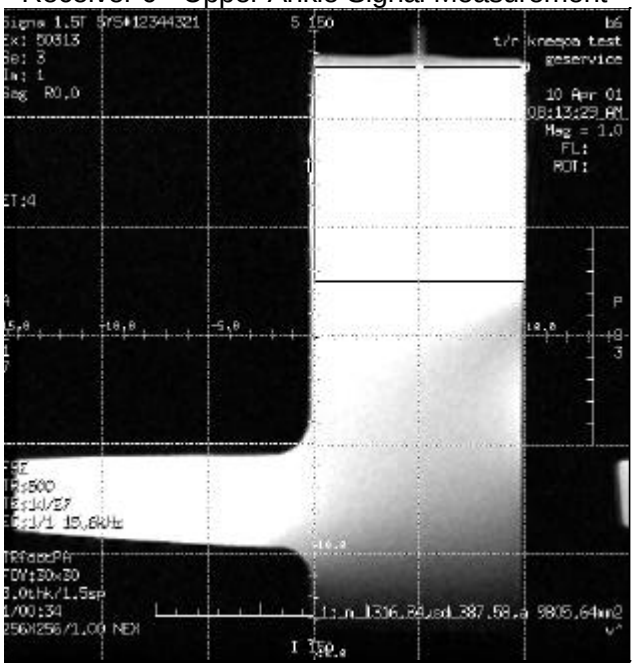
For the signal measurement, choose a rectangular ROI covering the appropriate section of the phantom for the receiver channel being scanned. ROI areas are unique for the anatomy scanned (foot, ankle, or knee), but for each anatomy the same ROI should be measured for each receiver channel utilized. The ROIs are shown in Figures 3-2-5-1 through 3-2-5-4, and the Noise Measurement is shown in Figure 3-2-5-5.

The SNR shall be calculated using the signal to noise ratios of the individual receiver channels. Individual receiver SNR is defined as the mean of data within the signal ROI divided by the standard deviation of data within the noise ROI:

$$SNR_i = \frac{\text{mean of signal within ROI}}{\text{standard deviation of noise within ROI}}$$

SNRi is the individual receiver SNR.

FIGURE 3-2-5-1
Receiver 0 - Upper Ankle Signal Measurement

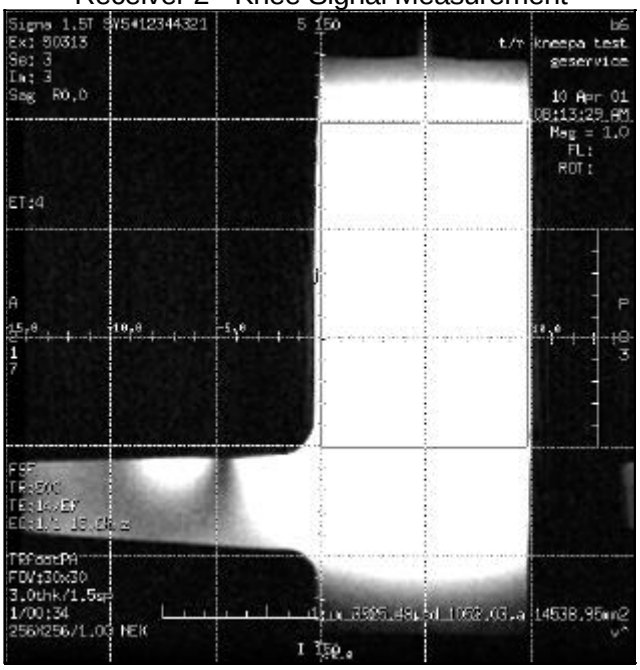


ROI ≈ 9800 mm^2 10 cm A-P 10 cm S-I

FIGURE 3-2-5-2
Receiver 1 - Lower Ankle Signal Measurement

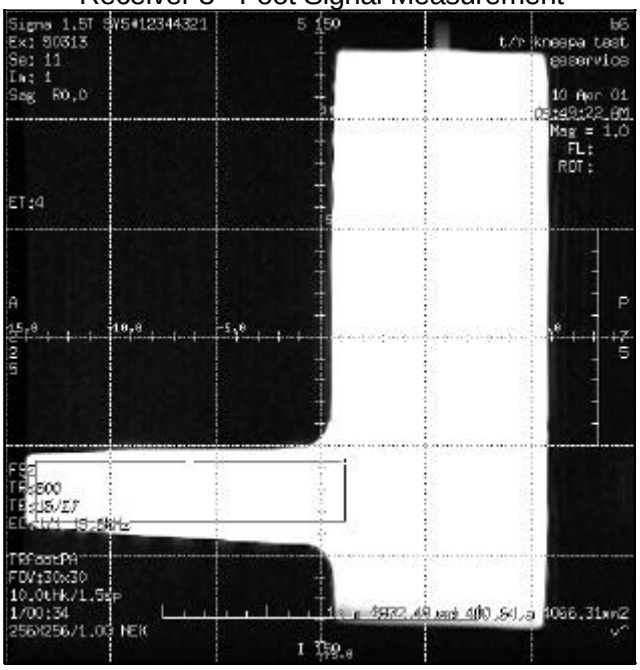
ROI ≈ 9800 mm^2 10 cm A-P 10 cm S-I

FIGURE 3-2-5-3
Receiver 2 - Knee Signal Measurement



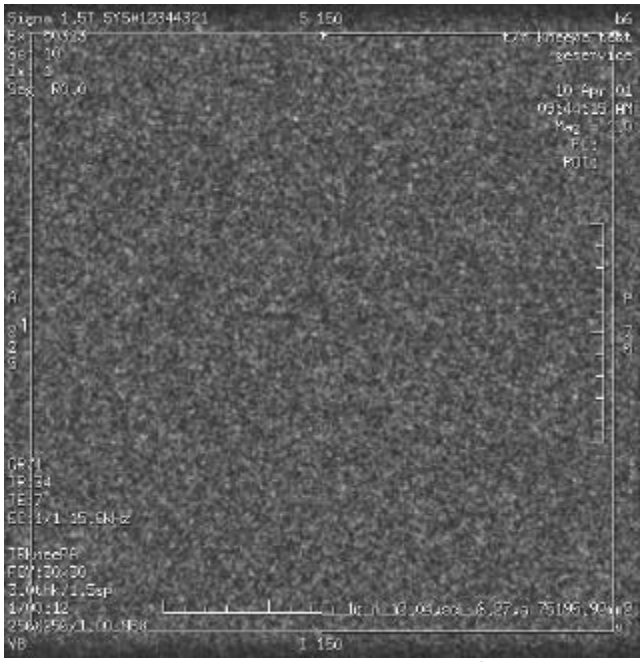
ROI ≈ 14700 mm^2 10 cm A-P 15 cm S-I

FIGURE 3-2-5-4
Receiver 3 - Foot Signal Measurement



ROI ≈ 4200 mm^2 14.8 cm A-P 2.8 cm S-I

FIGURE 3-2-5-5
Noise Measurement



NOISE ROI ≈ 75000 mm^2

Note: The SNR calculation uses the **MEAN** of the signal image and **STANDARD DEVIATION** of the noise image. SNR is measured for each **element**, not on the composite image.

Individual Element Performance

Regions of interest in both signal and noise images can be measured directly in the image browser. Click the user interface button Measure, select the circular or rectangular shape, and adjust its size and orientation when the shape is displayed in the selected image. Mean, standard deviation, and area of the ROI will appear in the lower right corner of the image. Examples of typical Receiver Images are shown in Figures 3-2-5-6 through 3-2-5-10 below. These images look very similar for the foot/ankle and knee configurations.

FIGURE 3-2-5-6: Receiver 0

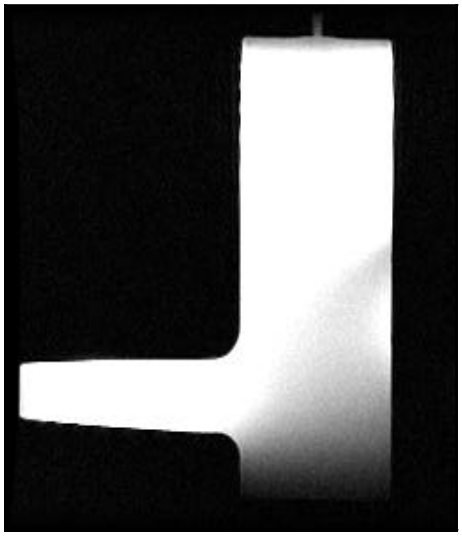


FIGURE 3-2-5-7: Receiver 1

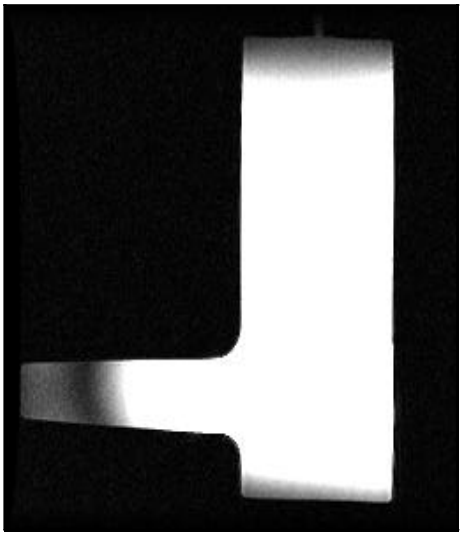


FIGURE 3-2-5-8: Receiver 2

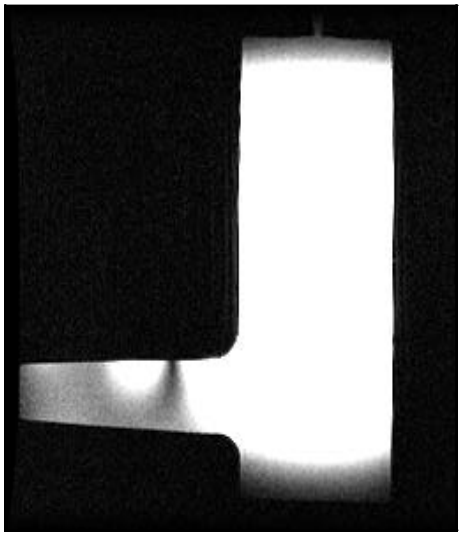


FIGURE 3-2-5-9: Receiver 3

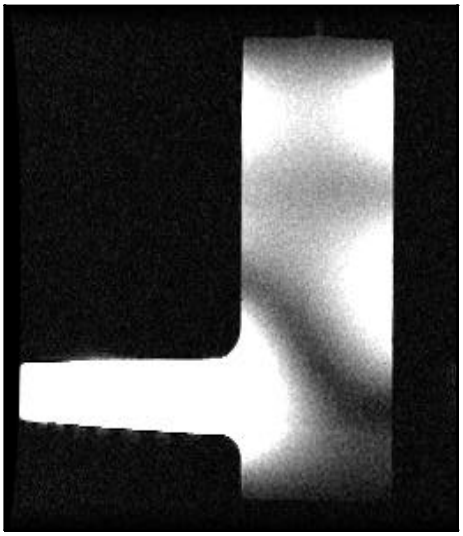
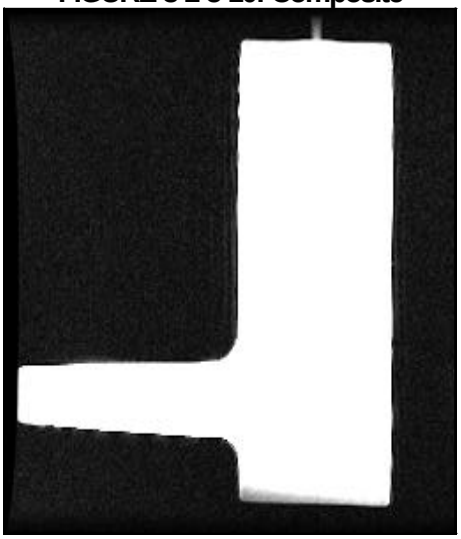


FIGURE 3-2-5-10: Composite



SNR Specification

The SNR measurements must be greater than or equal to the following specificatications:

SNR SPECIFICATIONS – TABLE 3-2-5

Channel	SNR
CH0	242
CH1	164
CH2	289
CH3	205

SNR Data Sheet

Use the table provided below to record the calculated signal to noise ratio (SNR) data obtained from the Functional Checks section.

Date	Comments							
Mode	R1	R2	TG	Element	Signal Mean	Noise Std Dev	SNR	Spec Limit
TRFootPA				0				242
				1				164
				2				289
				3				205

Date	Comments							
Mode	R1	R2	TG	Element	Signal Mean	Noise Std Dev	SNR	Spec Limit
TRFootPA				0				242
				1				164
				2				289
				3				205

Date	Comments							
Mode	R1	R2	TG	Element	Signal Mean	Noise Std Dev	SNR	Spec Limit
TRFootPA				0				242
				1				164
				2				289
				3				205

Date	Comments							
Mode	R1	R2	TG	Element	Signal Mean	Noise Std Dev	SNR	Spec Limit
TRFootPA				0				242
				1				164
				2				289
				3				205

Chapter 3 - Using the Knee Array Coil

Positioning the Base Tray

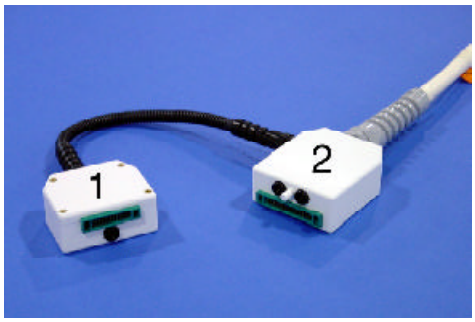
The knee and foot array coil is equipped with a base tray to support the coil. The base tray is designed to rest directly on the patient cradle for stability.

For knee exams, position the base tray about 1/3 down the patient table.

For foot/ankle exams, position the base tray at the magnet end of the patient table.

Shown is the Knee, Foot and Ankle array coil in position for a knee exam.

System Cable



The Transmit Port [1] and Phased Array Receive Port [2] connector boxes are integrated into one system cable.

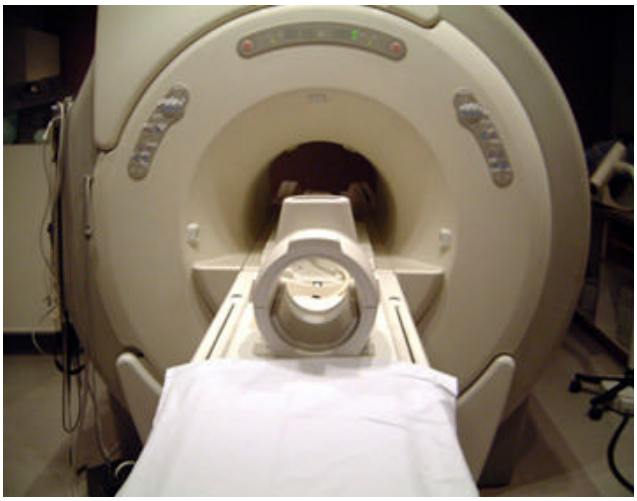
Connecting Cable to the System

The KFA-63 utilizes both the Phased Array Receive Port and the Transmit Port available on the 1.5T Signa system. Connect each of the cable connector boxes to its corresponding system port.

Offset Coil Positioning

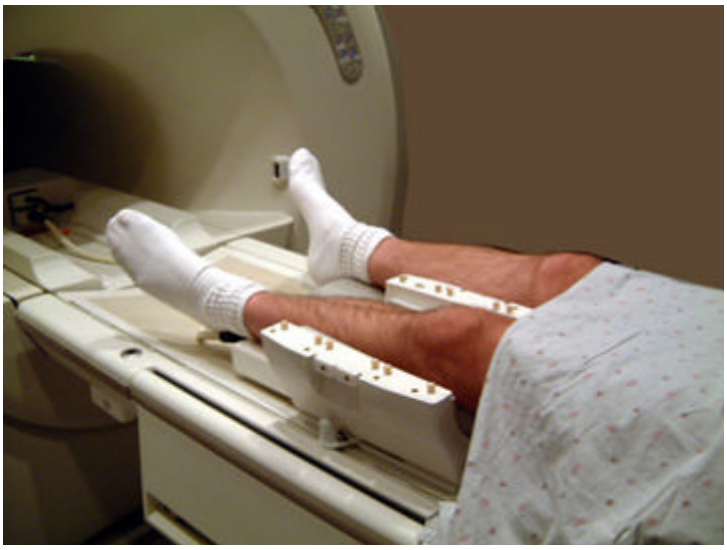
The bottom coil housing is permanently attached to the base tray. The coil may be slid left or right on the tray. Release the locking lever to move the coil into position to scan the desired knee. Place the knee insert pad in the coil when the size of the leg permits.

Using Alternate Knee Pad



Use the Alternate Knee Pad to keep the unaffected knee away from the coil and provide patient comfort.

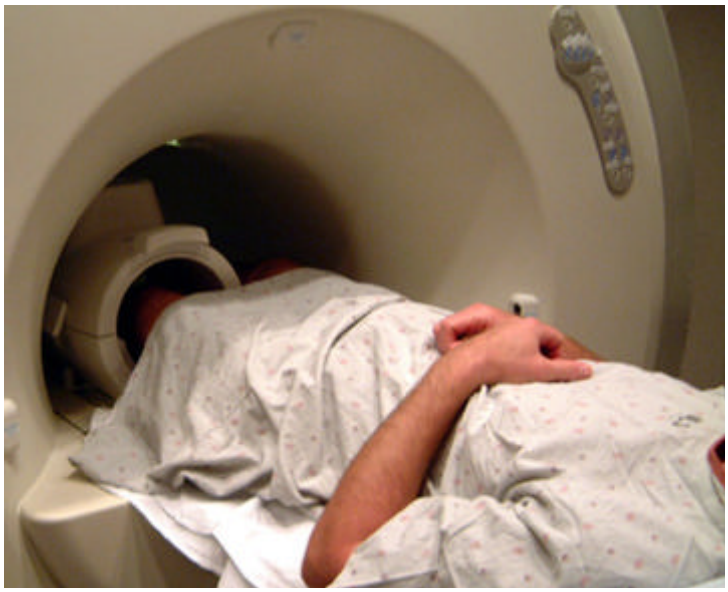
Positioning the Coil for Knee Exam



With the patient lying on the cradle, place the patient's knee into the bottom coil housing. Center the knee in the coil. Place the unaffected leg on the support pad.

Secure the top housing to the bottom housing using the two latches.
NOTE: The scanner will not operate if the top housing is not in place.

Coil Landmark



Turn the scanner alignment lights on and landmark on the mark on the coil housing. Press Advance to Scan.

Fat Saturation Techniques

For best Fat Saturation results, position the patient with the coil as close to isocenter as possible.

When scanning a knee, it is recommended to use Receiver 3 for optimizing center frequency. When scanning a foot and ankle, it is recommended to use Receiver 2 for optimizing center frequency. If scanning a foot, check receiver 4 also.

Positioning the Coil for Foot or Ankle Exam

Position the Knee, Foot and Ankle coil with base at the head end of the patient cradle. Use the foot support pad to center the foot and ankle.

Latch the top housing in place using the two latches. The coil may be slid left or right on the tray for patient comfort.

Foot Immobilization

Place the wedge pad against the superior aspect of the forefoot, to immobilize the ankle and toes.

Chapter 4 - Scanning

DO NOT localize with the GE Signa body coil

You may **NOT** scan using the body coil at any time.

Using the body coil may damage the knee array, requiring the coil to be returned to the factory for service.

Field of view and coverage

The Knee and Foot Array Coil has an internal diameter of 21 cm., and therefore has a maximum inherent field of view (FOV) of 21 centimeters. You may use a smaller or larger FOV if desired.

For high resolution imaging, 12 cm. FOV scans can easily be performed.
See Chapter 5 for suggested scan protocols.

Scanning on a System with Software Prior to ASP2 Release

Knee Scanning

1. Select the TRKneePA coil name and acquire a 3-plane localizer with a 20-24cm FOV. This should be done with Autoshim turned OFF.
2. Graphically prescribe your first clinical series. For this initial series, prescribe using the TRKneePA-SHIM coil name with Autoshim turned ON.
3. Save and prepare this series.
4. Select Manual Prescan, then select Done.
5. Run Auto Prescan, but do NOT scan.
6. Copy and paste the current series. Edit the pasted series to select the TRKneePA coil name and turn Autoshim OFF.
7. Save and prepare this series.
8. Run the scan

Any subsequent series should be performed using the TRKneePA coil name with Autoshim OFF.

For **Fat Saturation**, use **Receiver 3** for optimizing center frequency.

Foot and Ankle Scanning

1. Select the TRFootPA coil name and acquire a 3-plane localizer with a 20-24cm FOV. This should be done with Autoshim turned OFF.
2. Graphically prescribe your first clinical series using a smaller FOV. For this initial series, prescribe using the TRKneePA-SHIM coil name with Autoshim turned ON.
3. Save and prepare this series
4. Select Manual Prescan, then select Done.
5. Run Auto Prescan, but do NOT scan.
6. Copy and paste the current series. Edit the pasted series to select the TRFootPA coil name and turn Autoshim OFF.
7. Save and prepare this series.
8. Run the scan

Any subsequent series should be performed using the TRFootPA coil name with Autoshim OFF.

For **Fat Saturation**, use **Receiver 2** for optimizing center frequency. If scanning a foot, check **Receiver 4** also.

Scanning on a System with Software ASP2 Release and Greater

Knee Scanning

1. Select the TRKneePA coil name
2. Turn Autoshim ON
3. Run Auto Prescan
4. Run the Scan

For **Fat Saturation**, use **Receiver 3** for optimizing center frequency.

Foot and Ankle Scanning

1. Select the TRFootPA coil name
2. Turn Autoshim ON
3. Run Auto Prescan
4. Run the Scan

For **Fat Saturation**, use **Receiver 2** for optimizing center frequency. If scanning a foot, check **Receiver 4** also.

Chapter 5 - Suggested Scan Protocols

Suggested Scan Protocols for Knee or Foot Imaging

The following scan protocols have yielded good results when used with the Knee Array Coil on the Signa 1.5T MRI System.

PLANE: S/C
PSD: 2D SE
TR: 2000
TE: Min.
FREQ. S/I

3.0thk / 1.5 sp
512x256/ 1 NEX
BW: 16
FOV: 16-18 cm.
SAT(SI)

PLANE: S/C
PSD: 2D SE
TR: 2300
TE: 36
FREQ. S/I

4.0thk / 0.5 sp
512x256/ 1 NEX
BW: 16
FOV: 16-18 cm.
SAT(SI), Fat

PLANE: S/C
PSD: 2D SE
TR: 500
TE: 16
FREQ. S/I

4.0thk / 1.0 sp
256x256/ 1 NEX
BW: 16
FOV: 16-18 cm.
SAT(SI)

PLANE: S/C
PSD: FMPIR
TR: 4800
TE: 23, 100/90 TI
FREQ. Default

4.0thk / 1.0 sp
256x192/ 2 NEX
BW: 16
FOV: 12-16 cm.
SAT(SI)

TIP!

For Knee Imaging

Use the leg support pad so that the unaffected leg is not excited by the coil and will not appear in the image. This will allow you to turn off the *No Phase Wrap* option.

Frequency at S/I is suggested for sagittal and coronal planes.

Chapter 6 - Installation and Maintenance

Installation Configuration

Coil installation and configuration requires the services of your GE Service Representative.

Please refer to the Service Manual for coil installation and configuration information.

Cleaning

The KFA-63 Array Coil and patient comfort pads **must** be cleaned and stored using the following procedures:

- Wipe with a cloth that has been dampened in a solution of 10% bleach and 90% tap water, or 30% isopropyl alcohol and 70% tap water.
- **Do not pour any cleaning solution directly on the coil!**
- Let the coil housing and pads dry before use.
- Store the coil in an air-conditioned scan room or equipment room.
- **Under no circumstances should the coil be placed into any type of sterilizer.**

Storage

Store the coil in an air-conditioned scan room or equipment room.

To store the coil, a storage space of 38.1 cm/15.0 in (width) x 46.0 cm/18.1 in (depth) x 35.6 cm/14.0 in (height) is required.

Replaceable Accessories

The following table lists coil accessories that may be purchased for replacement:

Description	GE Part #	MRIDC #
Knee Support Pad	E8801NJ	101144
Alternate Knee Support Pad	E8801NK	101145
Forefoot Wedge Pad	E8801NH	101142
Foot Support Pad	E8801NG	101141

For additional information, contact:

GE Medical Systems Americas
USA 800-558-5102
Canada 800-668-0732

GE Medical Systems Asia
China 86-21-62192228
Taiwan 886-2-2505-7900
Singapore 65-291-8528
Australia 61-2-9975-5501
Japan 81-120-48-2630
Korea 82-31-740-6119
India 91-80-845-2923

GE Medical Systems Europe
(33) 1-41-19-76-76

GE Medical Systems Web Site
www.gemedicalsystems.com

MRI Devices, Corporation
800-524-1476
262-524-1402

MRI Devices Web Site
www.mridevices.com

Distributed by:

GE Medical Systems

Manufactured by:

MRI Devices Corporation
1515 Paramount Drive, Suite A
Waukesha, Wisconsin 53186 USA