

INNER VISION MRI

Specialized MRI Systems for Medicine, Industry and Research

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FDA 510K Summary

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1. DEVICE NAME: Magnetic Resonance Diagnostic Device

Trade/Proprietary Name: Ortho 8000

2. EQUIVALENT DEVICE : Esaote Biomedica ArtoScan

3. DEVICE DESCRIPTION

A. Device Characteristics

Model Name : Ortho 8000

Isotope : Proton Imaging

Model Characteristics

Magnet Permanent

Static Field strength 0.17 Tesla
Homogeneity +/-20ppm over 16cm DSV

RF Coil Types

- 1 Leg coil
 Transmit/receive coil for knee/foot/ankle/leg/elbow
 15 cm Diameter x 8 cm Length
2. Arm Coil
 Transmit/receive coil for hand/wrist/forearm
 10 cm Diameter x 6 cm Length
- 3 18 cm Loop Coil
 Transmit/receive coil for general purpose use
- 4 12 cm Loop
 Transmit/receive coil for general purpose use

Data Acquisition Modes

Phase and frequency encoding to sample k-space
2D Multiple Slice
2D Multiple Slice, Multiple Echo
3D Multiple Slice

Pulse Sequences

Spin echo
Gradient (Field) echo
Inversion recovery
Dynamic imaging
These sequences can provide
T1 weighted, T2 weighted, T2* weighted images

Reconstruction Techniques

2D Fourier Transform

3D Fourier Transform

Type of Installation

Fixed Site

Slice Selection Methods

Selective excitation in the presence of a field gradient

Phase encoding for 3D

Display Matrix

256 x 256

1 - 4 Simultaneous Images

Acquisition Matrix

64 - 256 in steps of 1 for the phase encoding direction

256 in the frequency encoding direction

Image Acquisition Time

2D - Repeat Time x Number of Excitations x Number of Phase Encoding Steps

3D - Repeat Time x Number of Excitations x Number of Phase Encoding Steps x

Number of Slice Encoding Steps

Image Pre and Post Processing

Magnitude Value

Pixel Value

Horizontal/Vertical Line Profiles

Spatial Filtering - Hamming Filter in Frequency and Phase Directions

Number of Slices, Range and Increment

2D - 1-16 in steps of 1

3D - 16 slice only

Slice Orientation

Transverse (Axial)

Sagittal

Coronal

Oblique

3 Orthogonal Plane Scouts

Interslice Spacing, *minimum, maximum and increment*

0 mm, 10mm, Increment 1 mm

B Safety Parameters

Static Field Strength 0.17 Tesla

Rate of change of magnetic field, maximum < 6 Tesla/Second

Radiofrequency Power Deposition, maximum < 0.4 W/Kg

C. Imaging Performance

Specification Volume

75mm length x 75 mm diameter Cylinder

a. Signal to Noise Ratio (SNR)

- 1 Leg Coil
SNR > 20:1 Transverse, Sagittal, Coronal, Oblique
- 2 Arm Coil
SNR > 40:1 Transverse, Sagittal, Coronal
- 3 18 cm Loop Coil
SNR > 20:1 Transverse, Sagittal, Coronal
- 4 12 cm Loop Coil
SNR > 30:1 Transverse, Sagittal, Coronal

b. Uniformity

- 1 Leg Coil
Non-Uniformity < +/-20% Transverse, Sagittal, Coronal
- 2 Arm Coil
Non-Uniformity < +/-20% Transverse, Sagittal, Coronal
- 3 18 cm Loop Coil
Non-Uniformity < +/-20% Transverse, Sagittal, Coronal
- 4 12 cm Loop Coil
Non-Uniformity < +/-20% Transverse, Sagittal*, Coronal

c. Geometric Distortion

Geometric Distortion < +/- 5% Transverse, Sagittal, Coronal

d.1 Slice Profile

Arm coil

>80% of material within Full Width Half Maximum. See detailed plots. Transverse, Sagittal, Coronal

d.2 Slice Thickness

Arm coil

2-10 mm in 1mm increments - Transverse, Sagittal, Coronal

d.3 Slice Spacing

Arm coil

0 - 10 mm in 1mm increments - Transverse, Sagittal, Coronal

Simultaneous Slices

16 maximum

e Spatial Resolution

Leg Coil

Maximum theoretical pixel resolution = $80/256$ mm = 0.31 mm.

1mm test rods resolved in all 4 quadrants Transverse, Sagittal, Coronal.

Note : Performance parameters measured using the phantom and techniques described in Section 8B below.

4. INTENDED USE

Anatomical region : Extremities
Nuclei excited : H-1
Diagnostic uses : 2D imaging, 3D imaging

5 TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

See Appendix A

6. CLINICAL DATA

Testing of the system was performed at the Middlesex Hospital, London, England during the period February - July 1996. Clinical scans performed included investigation of Du Puytren's contracture of the hand localisation of the calcaneus for steroid injections and scans of the normal anatomy of the toes, feet, ankles, lower leg, knee and upper thigh, fingers, hand, wrist, forearm, elbow and upper arm.

7. CONCLUSIONS FROM TESTING

The measurement methods used are based on calibration using a well characterised physical object and provide direct evidence of the performance characteristics of the scanner.

The signal to noise ratio values were consistently above the target specification values for each of the coils with the parameters measured above.

Non-uniformity was $< \pm 20\%$ for all coil and sequence combinations tested.

Geometric distortion was $< \pm 5\%$ for all coil and sequence combinations tested.

Slice thickness, spacing and gap were all within the quoted specifications using the frequency encoding method. This method relies on accurate calibration of the Field of View using MR imaging. The size of the test object is very accurately known and the measurement method provides a scale with 256 pixels. It is believed that this method gives more reliable results than the slice ramp technique which was also used to confirm the measurements. This is because the method has a much higher signal to noise ratio.

In conclusion, the InnerVision MRI extremity scanner meets the performance specifications claimed.

8. OTHER INFORMATION REQUIRED BY FDA

Appendix A

Equivalency Information

This information has been obtained from a recent report by ECRI.

Model	Esaote/Lunar Artoscan	Innervision/Vision Ortho 8000
Clinical application	Extremities	Extremities
Magnet type	Permanent	Permanent
Field Strength	0.18T	0.17T
5 Gauss Fringe Field m	0.6/0.28	0.3/0.3
Shimming	Passive	Passive/Active
Gradient Subsystem mT/m Risetime to 10mT/m msec	10/0.5	15/0.5
Computer System	PC DX2, 66	2 x PC Pentium 100 MHz
Memory Size (MB)	32	16+16
Array Processor	DSP 25 Mflops	DSP Dalanco Spry Model 500
Storage Media	MOD	MOD, Tape
No. Images Stored	5,000	5,000
Imaging Modes		
Single	Yes	Yes
MultiSlice	Yes	Yes
Volume Study	Yes	Optional
Other	3 Plane Scout View	3 Plane Scout View
Reconstruction time		
Single Slice (sec)	1.5	5
Multi Slice (sec)	1.5	5
Volume Study	1.5	20/slice average
Cardiac Gating	NA	NA
Respiratory Gating	NA	NA
Angiography	NA	NA
Spectroscopy	NA	NA
Pulse Sequences	SE, Multiple SE, GE, IR, STIR, 3D TSE, TME HSE	SE, Multiple SE, GE, IR, STIR, 3D
Repetition Time (msec)	50-5000SE, 40-5000 GE, 260-5000 IR, 100-4000 STIR	50-5000SE, 35-5000 GE, 100-5000 IR
Echo Time (msec)	18-120 SE, 12-34 GE, 18-34 IR, 12-120 TSE	20-100 SE, 5 GE, 20 IR
Inversion Time (msec)	50-800	25-999
Slice Thickness mm	2-10 0.5 incr 2D, 0.8 - 10 0.1 incr 3D	2 - 10, 1 incr 2D, 1-10 1 incr 3D
FOV mm	100 - 200	80 - 200
Displayed FOV	110 max increments of 10	200 max increments of 1
FOV offsets	NA	NA
Scan Orientations	Transverse, coronal, sagittal, oblique, compound oblique	Transverse, coronal, sagittal, oblique
Measuring Matrix	128x128 to 256x256 2D, 128x128x8 to 256x256x128 3D	64x256 to 256x256 2D, 64x256x16 to 256x256x16 3D Incr 1 in phase
Display Matrix	254x238, 510x478	256x256, 512x512
Pixel Intensity	0-4095	0-255
Spatial Resolution	0.4 mm	0.5
Coils	Knee 2 Sizes, Extremity	Arm Coil, Leg Coil, 12 cm Loop, 18 cm Loop
Bore Diameter W x H cm	16 x 33.6	20 x 75
Bore Features	Self centring mechanism, internal RF shield, Leg-locking device	Self centring mechanism
Cooling System	Not required	Air Conditioning Control +/- 1C
Cryogenics	NA	NA
Magnet Weight	1000	500
HxWxD cm	120x73x52	118x51x52
Dicom 3.0	Optional	From 3rd Party
Power Requirements		
Line Voltage	110	110/240
kVA	1.3	<3
AC BTU	4500	<10,000
Siting Requirement ft2	<100	<100
RF shielding	Integral	Modular screened room